Now there's a new approach to permanent birth control

Introducing the Essure™ procedure

essure™

IMPORTANT

- This device is intended for permanent pregnancy prevention
- This device does not protect against either HIV infection or other sexually transmitted diseases
- Before this device can be used for contraception, you must first undergo a test, called a hysterosalpingogram (HSG), which is performed to make sure that both of your tubes are blocked and that the devices are in the correct positions. This test is performed approximately 3 months after the *Essure* micro-insert placement procedure. You must use another form of contraception until you have this test and your doctor tells you that you can rely on *Essure* for contraception
- If at any time you suspect that you are pregnant, you should seek immediate medical attention to rule out the possibility that you have an ectopic pregnancy (pregnancy occurring outside of your uterus)
- After completion of the *Essure* micro-insert placement procedure, you will be given a patient identification card, which you should keep with you at all times and present to other physicians involved in your present or future care

This booklet is designed to provide important information regarding permanent female contraception (sterilization) using the *Essure* Permanent Birth Control System. This device must be prescribed by a doctor. This booklet is not intended to be a substitute for a thorough discussion with your doctor about whether or not this treatment is right for you. It is important that you read this booklet carefully and discuss its contents with your doctor.

Table of Contents

Glossary 3

Introducing Essure™ 4

What are the benefits of Essure? 5

The Essure *procedure: key risks and considerations* 6

Is Essure *right for you?* 8

Risks 14

How is the Essure *procedure performed?* 18

Glossary

Anesthesia—Medically induced partial or complete loss of sensation, in all or part of the body, with or without loss of consciousness. General anesthesia is total loss of consciousness and sensation

Cervix—The passageway that connects the vagina to the uterus

Contraceptive—Any process, device, or method that reduces the likelihood of pregnancy

Delivery Catheter—A long tube-like device that helps the doctor place the *Essure* micro-inserts in the fallopian tubes

Ectopic Pregnancy—The development of a fertilized egg outside of the uterus, but inside the body

Expulsion—Forcing (expelling) something out

Fallopian Tubes—The tubes that carry the eggs from the ovaries to the uterus

Hysterosalpingogram (HSG)—An X ray of the uterus and fallopian tubes after they have been filled with dye (contrast medium)

Hysteroscope—A telescope-like instrument, which is used to view the inside of the uterus

In Vitro Fertilization (IVF)—Fertilization of an egg outside of the body, followed by placement of the fertilized egg into the uterus

Intrauterine Device (IUD)/Intrauterine System (IUS)—A medical device that is put into the uterus to prevent pregnancy

Irreversible—Cannot be changed back to its original state

Local Anesthetic—Medicine that is applied to or injected in a certain spot in the body to cause a loss of sensation in that part of the body

Major Surgery—Surgery that requires general anesthesia and incisions in the body

Micro-insert—A small, flexible, coil-type device that is put into your fallopian tube for permanent pregnancy prevention

Occlusion—A closed or blocked part of a hollow tube

Perforation—A hole in something

Permanent—Not able to change back and forth

Reversible—Able to change back and forth

Tubal Ligation—Permanent female sterilization by means of cutting, tying, burning, or clipping the fallopian tubes

Uterus—The womb in which a developing fetus grows

Vasectomy—Permanent male sterilization by means of cutting or blocking a segment of the vas deferens (the tube that carries the sperm)

Introducing Essure™

A nonincisional approach to permanent birth control

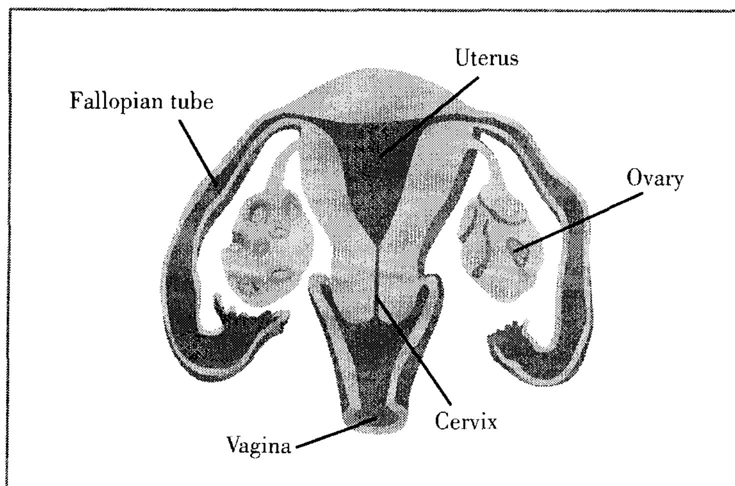
Essure is a new method of permanent birth control developed by Conceptus Incorporated. Because it is intended to permanently prevent pregnancy, it is similar to other permanent birth control procedures, such as vasectomy or tubal ligation ("having your tubes tied"). All of these procedures are intended to prevent pregnancy for the rest of your life.

This brochure will provide you with information about *Essure*, as well as the benefits and risks of this method of birth control; however, this information is not intended to be a substitute for a thorough discussion with your doctor, as all women have individual needs and concerns. Your doctor will advise you whether the *Essure* procedure is appropriate for you with regard to your circumstances and medical history.

How does Essure work?

The *Essure* procedure is a nonincisional surgical procedure that involves placing a small, flexible device called a micro-insert into each of your fallopian tubes (the tubes your eggs travel through from your ovaries to your uterus). The micro-inserts are made from polyester fibers and metals (nickel-titanium and stainless steel), materials that have been studied and used in the heart and other parts of the human body for many years.[1] Once the micro-inserts are in place, body tissue grows into the micro-inserts, blocking the fallopian tubes. Blocking the tubes is intended to prevent sperm from reaching and fertilizing the egg, thereby preventing pregnancy. It is believed that the tissue response to the micro-insert that creates the blockage of your tubes will last for the rest of your reproductive life, but data regarding use of *Essure* beyond 2 years are not available. Studies are ongoing to obtain these data. Your doctor will be able to explain the procedure to you in more detail.

The female reproductive organs



71

What are the benefits of Essure?

Two separate studies of the safety and effectiveness of the *Essure* Permanent Birth Control System have been conducted in women from the United States, Australia, and Europe.[2] The first study involved approximately 200 women, and the second study involved approximately 500 women. The following has been demonstrated in these trials:

No incisions are required[2]

- Unlike the incisional methods of tubal ligation, the *Essure* procedure does not require incisions. It also does not involve cutting, crushing, or burning of the fallopian tubes
- Because there are no incisions, the *Essure* procedure does not cause scars

Can be performed without general anesthesia[2]

- The *Essure* procedure can be performed without general anesthesia. In the clinical trials of *Essure*, general anesthesia was used rarely

Essure *does not contain hormones*[2]

- The *Essure* micro-inserts do not contain or release any hormones

Effective[2]

- In the first study, almost 200 women relied on *Essure* for contraception for 1 year, and more than 180 relied on *Essure* for contraception for 2 years. In the second study, 439 women relied on *Essure* for contraception for 1 year, and over 300 relied on *Essure* for contraception for 18 months. None of the women who relied on *Essure* for contraception during the clinical trials became pregnant over the 1 to 2 years of follow-up. However, no method of contraception is 100% effective, and there is a small chance that you can become pregnant.[3] Additional information regarding the effectiveness of *Essure* and other methods of contraception is found in **Tables 1 and 2.**

Rapid recovery[2]

- Women were typically discharged from the medical facility 45 minutes after the procedure
- Almost all employed women who participated in the second *Essure* study resumed work in 24 hours or less after the day of the procedure. Return to work was not evaluated in the first study
- The majority of women returned to normal activities in 1 to 2 days
- Almost all women rated their comfort as "good" to "excellent" within 1 week of the procedure

High patient satisfaction[2]

- Almost all women rated their satisfaction with *Essure* as "good" to "excellent" at all study visits after the 1-week visit

The Essure™ procedure: key risks and considerations

The procedure should be considered irreversible

There are no data on the safety or effectiveness of surgery to reverse the *Essure* procedure. What is known is that any attempt to surgically reverse the *Essure* procedure will require major surgery and has a poor chance for success. *Essure* is only meant to be used by women who are certain they no longer want to have children. There are also no data on the safety or effectiveness of in vitro fertilization (IVF) after the *Essure* procedure has been performed.

Studies have shown that women under the age of 30 are more likely to **regret their decision to be sterilized.**[4] If you are under 30 years old, this decision should be considered carefully, especially since the *Essure* procedure should not be considered reversible at any age.

Like all methods of birth control, the Essure *procedure should not be considered 100% effective*

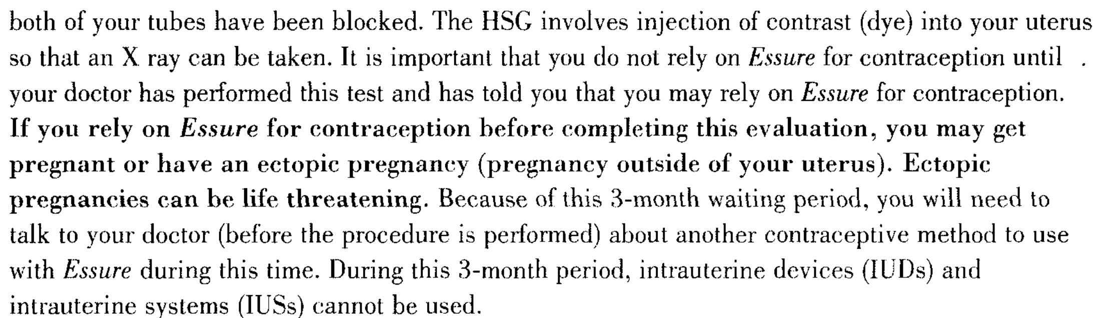
No method of birth control is 100% effective, and there is a small chance you can become pregnant, even many years after you undergo the procedure. The risk of unintended pregnancy, even years after the procedure, also exists for patients who chose incisional tubal ligation or vasectomy.[3] Also, because any type of tubal ligation affects the fallopian tube, where a pregnancy begins before it moves into the uterus, there is an increased risk of a tubal pregnancy (ectopic pregnancy occurring in the fallopian tube), should you become pregnant.[5]

Not all women who undergo the Essure *placement procedure will achieve successful placement of both micro-inserts*

Approximately 1 out of every 7 women in the *Essure* clinical studies did not achieve successful placement of both micro-inserts during the first placement procedure. Some of these women chose to undergo a second placement procedure, achieved successful placement of both micro-inserts during the second procedure, and subsequently were able to rely on *Essure* for contraception.[2]
If you do not receive successful placement of both micro-inserts during the first procedure, you should talk with your doctor about whether to undergo a second placement procedure or to rely on other methods of birth control.

You must use another method of birth control for at least 3 months after the procedure

It takes at least 3 months before your doctor can advise you whether you can begin relying on *Essure* for contraception. You will need to visit your doctor 3 months after your *Essure* procedure to have an evaluation performed. This evaluation is called a hysterosalpingogram (HSG), and it is performed to make sure that both of your *Essure* micro-inserts are in the correct location and that



both of your tubes have been blocked. The HSG involves injection of contrast (dye) into your uterus so that an X ray can be taken. It is important that you do not rely on *Essure* for contraception until your doctor has performed this test and has told you that you may rely on *Essure* for contraception. **If you rely on *Essure* for contraception before completing this evaluation, you may get pregnant or have an ectopic pregnancy (pregnancy outside of your uterus). Ectopic pregnancies can be life threatening.** Because of this 3-month waiting period, you will need to talk to your doctor (before the procedure is performed) about another contraceptive method to use with *Essure* during this time. During this 3-month period, intrauterine devices (IUDs) and intrauterine systems (IUSs) cannot be used.

The Essure *procedure is newer than other procedures*

Essure is one of the newest methods of permanent birth control, so it has not been studied in as many women or for as long as most birth control methods. Over 600 clinical study participants have relied on *Essure* for contraception for 1 year, and approximately 200 of them have relied on *Essure* for 2 years.[2] There are very little data on the safety of or the chance of pregnancy with *Essure* beyond this time frame. Once longer-term data are available, the information on the safety of and chance of getting pregnant while using *Essure* may be different than the data based on 1 or 2 years of use.

Removal of the Essure *micro-inserts requires surgery*

If the *Essure* micro-inserts need to be removed for any reason after they have been placed in your body, major surgery will be required. This surgery will require an abdominal incision and, most likely, general anesthesia.

As with all procedures, there are risks associated with Essure

You should be aware of these risks and discuss them in detail with your doctor before you make your decision. **Some of the risks associated with *Essure* have already been discussed above, but additional risks, such as pain and bleeding following the *Essure* placement procedure as well as risks associated with future medical procedures that you may undergo after your *Essure* placement procedure, are discussed in the *Risks* section at the end of this booklet. Please read the *Risks* section at the end of this booklet carefully.** In addition to the risks previously discussed, other risks and considerations are also discussed. Some of the risks discussed in this booklet were experienced by women in the clinical studies of *Essure*. Some of the risks were not among those reported during the clinical trials, but should still be considered as potential risks of *Essure*. You should talk to your doctor about the likelihood of these risks, particularly in relation to your own situation.

Is Essure™ right for you?

The *Essure* procedure is only appropriate if you are sure you do not want any more children, would like to have permanent birth control, and believe you will not change your mind. If there is any chance you may want to have children in the future, you should choose another form of birth control. You should avoid making this choice during times of stress, such as a divorce or after a miscarriage, and NEVER while under or due to pressure from a partner or others.

YOU SHOULD NOT USE *the* Essure *Permanent Birth Control System if you:*

- Are uncertain about your desire to end fertility
- Are pregnant or suspect that you are pregnant
- Have delivered a baby, had a miscarriage, or had an abortion within 6 weeks before the *Essure* micro-insert placement procedure
- Have an active or recent pelvic infection
- Have an unusual uterine shape (for example, a uterus with only one tube or a divided uterus)
- Have a known allergy to dye (contrast media)
- Have a known hypersensitivity or allergy to nickel as confirmed by skin test
- Are unwilling to use another method of contraception for at least 3 months after the *Essure* micro-insert placement procedure
- Are unwilling to undergo an HSG approximately 3 months after your *Essure* placement procedure to make sure that your tubes are blocked and the devices are in the correct positions
- Have had a prior tubal ligation

Note: If you are currently undergoing immunosuppressive therapy (eg, taking steroid medication such as prednisone, undergoing chemotherapy, etc), you should discuss this in detail with your physician, since the *Essure* micro-inserts may not be effective in patients undergoing immunosuppressive therapy. Also, if you have previously had abdominal or pelvic surgery, please discuss this with your physician prior to undergoing an *Essure* placement procedure.

If you decide you want to have the *Essure* procedure performed, you will undergo a general examination and laboratory tests (for example, a PAP smear) to evaluate whether you are a good candidate for the procedure. It may turn out that the *Essure* procedure is not an option for you.

You should be aware that there are other methods of birth control, both temporary/reversible and permanent. Table 1 on the following page shows pregnancy rates for various birth control methods. This information is being presented to assist you in your choice of contraception during the 3-month waiting period until the HSG is performed after placement of the *Essure* micro-inserts. Table 2 provides information regarding some of the characteristics of the 3 forms of permanent birth control: *Essure*, tubal ligation, and vasectomy. Your doctor will explain these alternative methods to you and advise you whether *Essure* is a suitable option for you. It is your right to decide what method suits you. If, at any time before the start of the *Essure* procedure, you decide not to have it, you should tell your doctor and cancel the procedure. You do not have to provide any explanation or reason for your decision.

Table 1 Pregnancy Rates for Temporary Birth Control Methods[3,6-8,*]

(For 1 Year of Use)

The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for 1 year. These estimates are based on a variety of studies.

Method	Rate of Pregnancy
Hormonal Methods:	
Implant (Norplant® [levonorgestrel implants] and Norplant® 2 [levonorgestrel implants])	0.05%
Hormone Shot (Depo-Provera® [medroxyprogesterone acetate injectable suspension])	0.3%
Combined Pill (Estrogen/Progestin)	5%
Minipill (Progestin only)	5%
NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring)	1.2%
Ortho Evra™ (norelgestromin/ethinyl estradiol transdermal system)	1%
Lunelle™ (medroxyprogesterone acetate and estradiol cypionate injectable suspension)	<1%
Barrier Methods:	
Male Latex Condom[†]	14%
Diaphragm[‡]	17%
Cervical Cap[‡]	17%
Female Condom	21%
Lea's Shield®	15%
Spermicide:	
Gel, Foam, Suppository, Film	26%
Natural Methods:	
Withdrawal	19%
Natural Family Planning (calendar, temperature, cervical mucus)	25%
No Method	85%

*Data adapted from FDA's Uniform Contraceptive Table and modified per FDA input based on new studies.
†Used without spermicide.
‡Used with spermicide.

Please note that information regarding the failure rates with IUDs and IUSs is not presented since these methods of birth control cannot be used during the 3-month waiting period after the *Essure* placement procedure.

Table 2 Permanent Methods of Birth Control[2,3,5,9,10]

The following table provides information about the permanent birth control methods currently available: *Essure*, tubal ligation, and vasectomy.[2,3,5,9,10]

	Essure™
Who undergoes the procedure?	Women
How effective is the procedure?	99.81% at 1 year of follow-up. 99.78% at 2 years of follow-up. Data not available beyond 2 years.
How is the surgical procedure performed?	The devices are routed through the vagina, cervix, and uterus into the fallopian tubes, where the devices are placed. No incisions are required.
How long does the procedure take?	Average procedure time is 35 minutes.
How many visits to the doctor does it require, and what type of follow-up is required?	Three visits. One consultation visit, 1 visit to place the micro-inserts, and 1 follow-up visit at 3 months to check for tubal occlusion and proper micro-insert location.
How is pain or discomfort controlled during the procedure?	Local anesthetic and/or intravenous sedation.
Can I rely on it right away?	**No. There is a 3-month waiting period, during which another form of contraception must be used.** You will need a hysterosalpingogram (HSG [a special kind of X ray]) before you can rely on *Essure*. The purpose of this test is to make sure that both of the tubes are blocked and both of your devices are in the correct position. You must continue to use another form of contraception until your doctor instructs you that you can rely on *Essure* for birth control.

Tubal Ligation	Vasectomy
Women	Men
99.45% at 1 year of follow-up. 99.16% at 2 years of follow-up. 99.15% at 10 years of follow-up.	99.85% at 1 year of follow-up.
The fallopian tubes are either cut, burned (cauterized), or clamped using either: • Laparoscopic tubal ligation (most common method), where 1 to 2 incisions are made in the abdomen to access the fallopian tubes using a telescope-type device. The tubes are then blocked with clips or rings or burned • Open surgery (called a laparotomy or mini-laparotomy), which requires a larger incision (usually 2 to 5 cm) in the abdomen	The 2 tubes (the vas deferens) that carry sperm from the testicles to the penis are cut or blocked. This is achieved by: • Making a small incision in the scrotum. This is the most common method • Making a small puncture in the center of the scrotum
Average procedure time is 30 to 45 minutes for laparoscopic method. May be longer if open surgery.	Average procedure time is 15 to 30 minutes.
Three visits. One consultation visit, 1 visit to perform the tubal ligation, and 1 follow-up visit in 1 to 2 weeks to check the incisions.	Three visits. One consultation visit, 1 visit to perform the vasectomy, and 1 follow-up visit to make sure that the vasectomy is effective (ie, sperm count is 0).
General anesthetic, spinal block, or epidural anesthesia is typically used.	Local or general anesthetic.
Yes. Following your doctor's advice, you may resume intercourse when you have recovered from the procedure, typically about a week after the procedure.	**No. There is a 2 to 3 month waiting period required to flush out any existing sperm.** Sperm counts are taken to demonstrate the success of vasectomy, ie, when the sperm count is 0. You must use another method of contraception until then.

Table 2 Permanent Methods of Birth Control[2,3,5,9,10] (continued)

	Essure™
What should I be doing to help the recovery process after the procedure?	• Rest for 45 minutes following the procedure before going home. Follow your doctor's instructions to report any unusual pain, bleeding, or high fever • Consider having someone drive you home
When can I return to regular activities?	Typically, within 1 to 2 days of the procedure.
What are the typical temporary effects following the procedure?	• Cramps (like menstrual cramps) • Discharge (like a light menstrual flow or spotting) • Mild nausea or vomiting associated with the procedure • Fainting or lightheadedness following the procedure
What are the major risks of the procedure?	• You may become pregnant several years after undergoing the procedure • **Ectopic pregnancy occurs more often in women who have had a sterilization, if they become pregnant** • For a percentage of women (14% in the clinical studies) it may not be possible to place the micro-inserts in the fallopian tubes during the first placement procedure • Despite micro-insert placement, a small percentage of women (3% in the clinical studies) may not be able to rely on the micro-inserts for birth control due to incorrect position of the devices or lack of tubal blockage • Although death and serious injury following hypervolemia were not reported in the *Essure* clinical trials, hypervolemia can lead to serious injury and death

Tubal Ligation	Vasectomy
• Most women are ready to go home 2 to 4 hours after the procedure • Must have someone drive you home • The incision will need to be kept dry for a few days • Follow your doctor's instructions to report any unusual pain, bleeding, or high fever	• Rest for at least 15 minutes following surgery • Consider having someone drive you home • Apply ice packs to the scrotum and wear supportive underwear to minimize bruising/swelling • Follow your doctor's instructions to report any unusual pain, bleeding, or high fever
For laparoscopic tubal ligation, typically within 4 to 6 days. For tubal ligation performed by an open procedure, typically within 9 to 10 days.	Typically, in 2 days.
• Cramps (like menstrual cramps) • Discharge (like a menstrual flow) • Mild nausea or vomiting associated with general anesthesia or the procedure • Pain in the neck or shoulder • Pain in the incision • A scratchy throat if a breathing tube was used • Feeling tired and achy • Swollen abdomen, which resolves as gases are absorbed • Bruising around the incision that fades	• Swelling and bruising. If this occurs, it usually resolves within 2 weeks following the procedure • A dull ache in the testicles that usually fades during the first week
• You may become pregnant several years after undergoing the procedure • **Ectopic pregnancy occurs more often in women who have had a sterilization, if they become pregnant** • Major complications, such as infections, bowel injuries, bleeding, burns, or complications from anesthesia, occur in about 2% of women who have the operation by laparoscopy and in about 6% of women who have the operation by laparotomy (open procedure). Internal bleeding is the most common and may require an open operation to stop the bleeding • Other injuries such as damage to the bladder or burns to the bowel may also require additional surgery • Other risks such as blood clots and death are rare	• Pregnancy may occur several years after undergoing the procedure • Bruising on the scrotum is experienced by 1.6% of men • Infection of the incision/puncture in the scrotum is experienced by 1.5% of men • Painful testicles (epididymitis) is experienced by about 1.4% of men • Sperm may leak into the surrounding tissue (less than 1% leakage rate) forming small lumps (granuloma). This process generally subsides spontaneously, although pain medication may be required

Risks

Failure to place 1 or both of the Essure™ micro-inserts in the correct location or to obtain tubal occlusion by 3 months after the procedure[3]

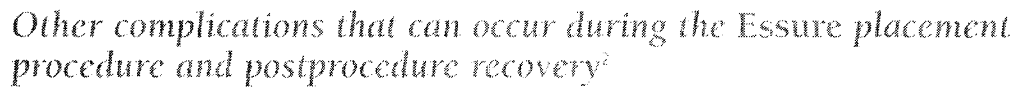
In the clinical studies, approximately 1 out of every 7 women were not able to have the micro-inserts placed in both fallopian tubes during the first placement procedure. At routine 3-month follow-up, 4% of the women who did receive placement in both tubes were found to have micro-inserts in the incorrect position. The types of incorrect positions included:

- The micro-insert(s) was (were) too far or not far enough into the tube
- The micro-insert(s) had been poked through the wall of the fallopian tube or uterus (perforation)
- The micro-insert(s) had come out of the body (expulsion)
- The micro-insert(s) was (were) in the body, but outside the fallopian tube

As a result of the above-listed incorrect positions of the micro-insert(s), these women could not *initially* rely on the *Essure* micro-inserts for birth control. Some of the women whose micro-inserts had come out of their bodies decided to undergo a second placement procedure and were then able to rely on the *Essure* micro-inserts for birth control.

Approximately 3.5% of women did not have occlusion of both fallopian tubes at the HSG performed 3 months after the procedure. All of the women, however, did have occlusion of both fallopian tubes at a second HSG performed approximately 6 months after the procedure.

81



Other complications that can occur during the Essure placement procedure and postprocedure recovery[2]

- **Pain/vaginal bleeding.** Most women in the clinical studies reported mild to moderate pain during the *Essure* micro-insert placement procedure. Many women reported mild to moderate pain and/or cramping and vaginal bleeding for a few days following the procedure

- **Nausea/vomiting/fainting.** Some women in the clinical studies reported nausea and/or vomiting or fainting following the procedure

- **Overabsorption of fluid.** Rarely, women in the clinical studies absorbed too much of the fluid used to expand the uterus during the placement procedure. This can result in shortness of breath or the need for medication to get rid of the excess fluid. If this condition is not treated by your doctor immediately, serious complications can occur, including death

- **Broken *Essure* micro-insert.** Rarely in the clinical studies, a portion of the *Essure* micro-insert was broken off during the placement procedure. This occurrence has not been reported to have caused a problem in preventing pregnancy or to have resulted in pain or other problems

- **Undiagnosed pregnancy at time of *Essure* placement procedure.** Women who undergo the *Essure* placement procedure, or any other sterilization procedure, during the second half of their menstrual cycle (after ovulation) are at an increased risk of unknowingly being pregnant at the time of the placement procedure. Therefore, the micro-insert placement procedure should be scheduled during the first half of the menstrual cycle, before ovulation occurs. On rare occasions during the clinical studies, when the *Essure* procedure was performed in the second half of the menstrual cycle, the women in whom the procedure was performed were unknowingly pregnant at the time of the procedure. The effects of the micro-inserts on you or the developing fetus are not known

- **Anesthesia risks.** There are risks associated with the anesthesia (medicine to control sensation or consciousness) used during the *Essure* placement procedure. You should discuss with your doctor the risks of the particular anesthesia method recommended for you

- **Infection.** You should contact your doctor if you have fever, vaginal discharge or odor, or severe pain following the procedure

Complications that may occur after the Essure™ placement procedure

- **Pregnancy.** No method of birth control is 100% effective, so pregnancy can occur even with a permanent birth control procedure such as *Essure*. *Essure* has been demonstrated in clinical studies to be 99.8% effective at 2 years of follow-up[2]

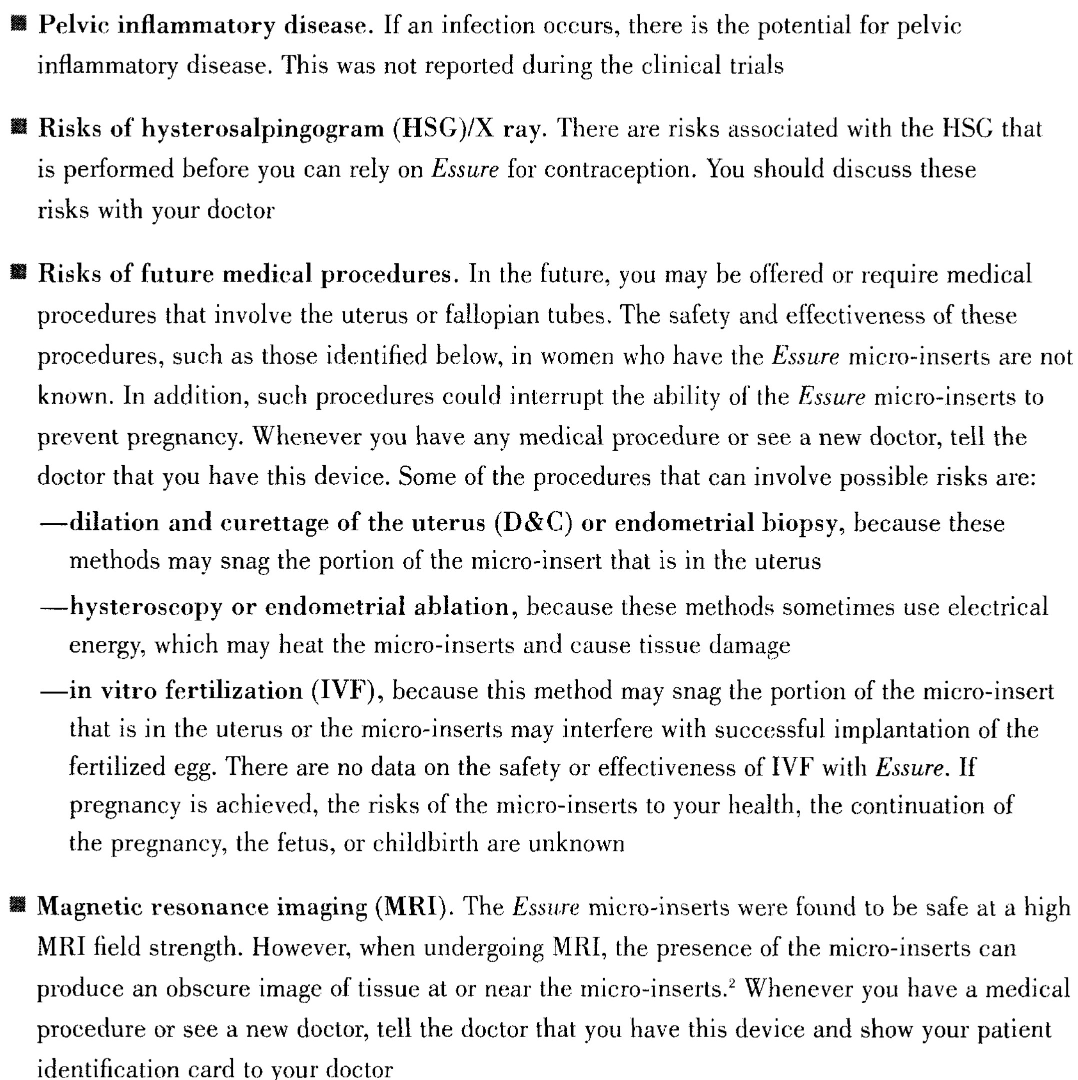
- ***Ectopic* pregnancy.** Ectopic pregnancy is when the pregnancy occurs outside of the uterus (womb), usually in one of the fallopian tubes. While this did not occur in the clinical studies, it is still possible with the *Essure* procedure. Women who undergo sterilization, by *Essure* or incisional tubal ligation, are more likely to have an ectopic pregnancy if they get pregnant. **If your period is more than 5 days late, or you suspect for any reason that you might be pregnant, call your doctor immediately so that you can be tested for pregnancy and monitored for the possibility of ectopic pregnancy. Ectopic pregnancy can be life threatening if not treated**

- **Risks to mother/fetus if you become pregnant.** If you do become pregnant, the risk of the *Essure* micro-inserts to you, the continuation of the pregnancy, the fetus, childbirth, or a pregnancy termination procedure (abortion) are unknown

- **Changes in menstrual cycle (period).** Some women in the clinical studies reported temporary changes in their periods; however, very few women reported permanent changes. These temporary/permanent changes included the following:
  —periods that were heavier or longer than normal
  —bleeding or spotting between periods

- **Pelvic/back/abdominal pain.** Some women in the clinical studies reported 1 or more episodes of pelvic, back, or abdominal pain. Very few women reported persistent pain

- **Regret.** As with any major decision, there is the risk that you will regret your decision to end your fertility. **The risk is much greater for younger women**



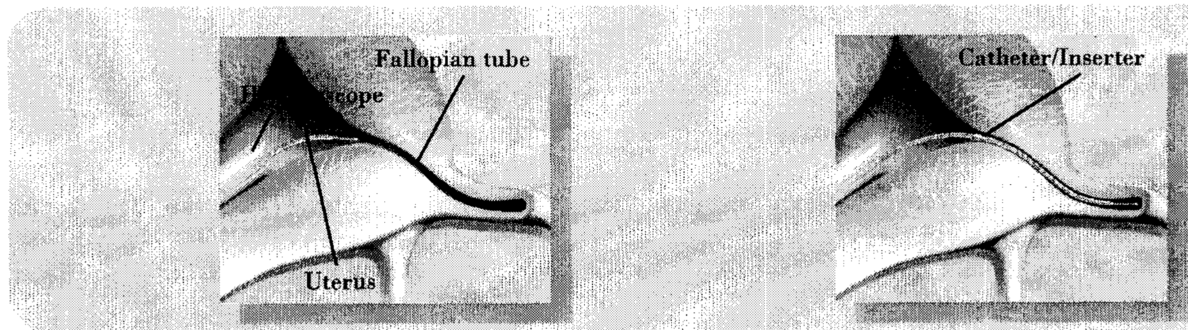
- **Pelvic inflammatory disease.** If an infection occurs, there is the potential for pelvic inflammatory disease. This was not reported during the clinical trials

- **Risks of hysterosalpingogram (HSG)/X ray.** There are risks associated with the HSG that is performed before you can rely on *Essure* for contraception. You should discuss these risks with your doctor

- **Risks of future medical procedures.** In the future, you may be offered or require medical procedures that involve the uterus or fallopian tubes. The safety and effectiveness of these procedures, such as those identified below, in women who have the *Essure* micro-inserts are not known. In addition, such procedures could interrupt the ability of the *Essure* micro-inserts to prevent pregnancy. Whenever you have any medical procedure or see a new doctor, tell the doctor that you have this device. Some of the procedures that can involve possible risks are:
  —**dilation and curettage of the uterus (D&C) or endometrial biopsy**, because these methods may snag the portion of the micro-insert that is in the uterus
  —**hysteroscopy or endometrial ablation**, because these methods sometimes use electrical energy, which may heat the micro-inserts and cause tissue damage
  —**in vitro fertilization (IVF)**, because this method may snag the portion of the micro-insert that is in the uterus or the micro-inserts may interfere with successful implantation of the fertilized egg. There are no data on the safety or effectiveness of IVF with *Essure*. If pregnancy is achieved, the risks of the micro-inserts to your health, the continuation of the pregnancy, the fetus, or childbirth are unknown

- **Magnetic resonance imaging (MRI).** The *Essure* micro-inserts were found to be safe at a high MRI field strength. However, when undergoing MRI, the presence of the micro-inserts can produce an obscure image of tissue at or near the micro-inserts.[2] Whenever you have a medical procedure or see a new doctor, tell the doctor that you have this device and show your patient identification card to your doctor

How is the Essure™ procedure performed?



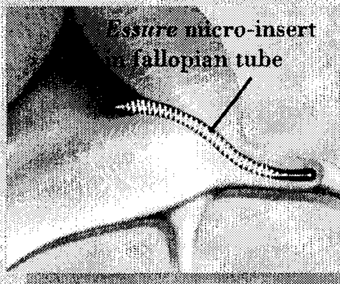
One to 2 hours before the procedure, you are given medication to reduce tubal spasms and uterine cramping during the procedure.

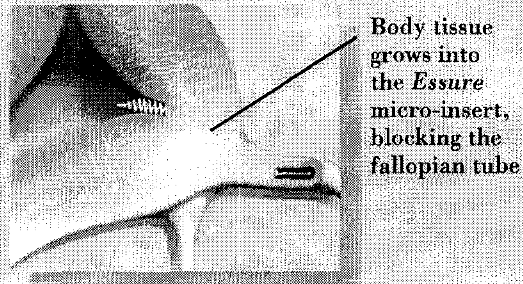
Step 1

After a local anesthetic is injected into or applied to the cervix, the doctor inserts a narrow telescope, called a hysteroscope, through your vagina and cervix (the entrance to the uterus from the vagina) and into the uterus. The doctor may need to gently expand the opening of your cervix and may insert an instrument to do this. The hysteroscope is attached to a video camera and monitor so the doctor is able to see exactly what he or she is doing. Fluid, called normal saline (salt water), flows through the hysteroscope and into your uterus. The fluid is used to expand the uterus so the doctor can see the openings to your fallopian tubes. You might feel cramping from this.

Step 2

A narrow inserter, called a catheter, is passed through the hysteroscope and into your fallopian tube. The micro-insert is attached to the end of the inserter.





Step 3

The micro-insert is placed in the fallopian tube and the inserter is removed. The process is repeated in the other fallopian tube. The entire procedure should take about 35 minutes, with only 15 minutes typically required to place the micro-inserts into the fallopian tubes.

Step 4

During the next 3 months, tissue will begin to grow into the micro-inserts, eventually blocking your fallopian tubes. You will need to use another form of birth control during this period until your doctor confirms that the procedure has worked.

After 3 months, you need to have a test called a hysterosalpingogram (HSG). This test is required before your doctor can tell you whether you may begin relying on *Essure* for contraception. During an HSG, your doctor fills your uterus with dye and then takes an X ray to see if the dye remained in your uterus or traveled down your fallopian tubes. The purpose of this test is to make sure that both of your tubes are blocked and that both of the micro-inserts are in the correct position.

Note: Always call your doctor if you have any unusual pain, bleeding, or other symptoms.