

# essure™

Permanent Birth Control System

## Instructions For Use

### IMPORTANT

- **Caution:** Federal law restricts this device to sale by or on the order of a physician. This device should only be used by physicians who are knowledgeable hysteroscopists, have read and understood the information in this Instructions for Use and in the Physician Training Manual, and have successfully completed the Essure training program. Completion of the Essure Training Program includes preceptoring in Essure placement until competency is established, which is typically expected to be achieved in 5 cases.

### IMPORTANT

- The Essure micro-inserts should NOT be relied on for contraception until the patient has undergone a hysterosalpingogram (HSG) 3 months after micro-insert placement, which demonstrates **both** bilateral tubal occlusion **and** satisfactory location of the micro-inserts.
- If Essure micro-inserts cannot be placed bilaterally, then the patient should not rely on this method of sterilization. Essure has not been proven to be effective when it is placed unilaterally.
- This product is intended to prevent pregnancy. It does not protect against either HIV infection or other sexually transmitted diseases.

**NOTE: A patient ID card is supplied with each Essure System. Please give this to your patient and ask that she carry it with her at all times and show it to other physicians involved in her present or future care.**

## I. OVERVIEW OF ESSURE PROCEDURE AND PRINCIPLES OF OPERATION

Using a transvaginal approach, one **Essure** micro-insert is placed in the proximal portion of each fallopian tube lumen. When the **Essure** micro-insert expands upon release, it acutely anchors itself in the fallopian tube. Subsequently, the **Essure** micro-insert elicits an intended benign, occlusive tissue response, resulting in tissue in-growth into the device that anchors the device and occludes the fallopian tube, resulting in permanent contraception.

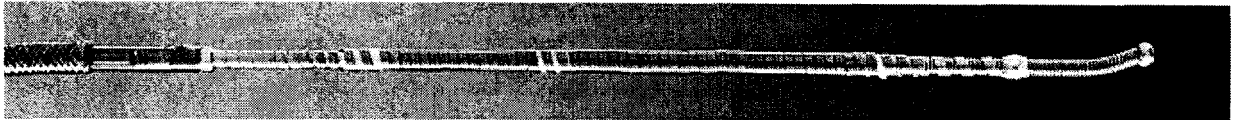
## II. DEVICE DESCRIPTION

The **Essure System** is comprised of the **Essure** micro-insert, a disposable delivery system, and a disposable split introducer.

The **Essure** micro-insert is a dynamically expanding micro-coil that consists of a stainless steel inner coil, a nickel titanium (Nitinol) expanding, superelastic outer coil, and polyethylene terephthalate (PET) fibers. The PET fibers are wound in and around the inner coil. The micro-insert, shown below in its wound-down and expanded configurations (**Figure 1a and Figure 1b, respectively**), is 4 cm in length and 0.8mm in

diameter in its wound down configuration. When released from the delivery system, the outer coil expands to 1.5 to 2.0 mm in diameter to anchor the micro-insert in the varied diameters and shapes of the fallopian tube.

**Figure 1a**  
**Essure Micro-insert:**  
**Shown in its Wound-Down Configuration, Attached to Release Catheter**  
**(NOT TO SCALE)**



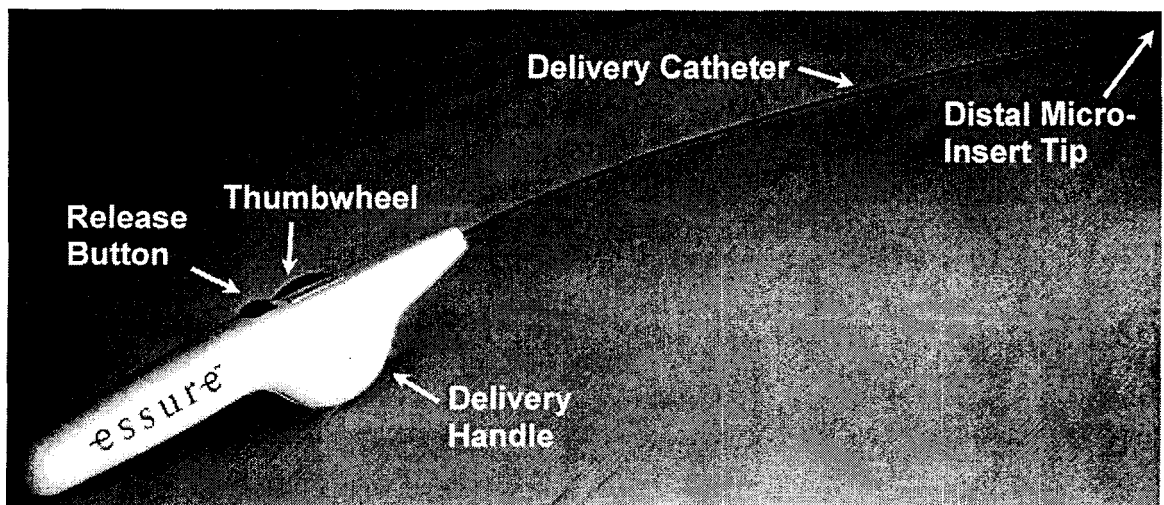
**Figure 1b**  
**Essure Micro-insert:**  
**Shown in its Expanded Configuration**  
**(NOT TO SCALE)**



The disposable delivery system, shown in **Figure 2** below, consists of a delivery wire, a release catheter, a delivery catheter and a delivery handle.

NOTE: The delivery wire and the release catheter are not visible in the figure shown below.

**Figure 2**  
**Essure Delivery System**



The **Essure** micro-insert is provided attached to the delivery wire, in a wound-down configuration. The delivery wire is composed of a nitinol core wire, which is ground at the distal end to result in a flexible, tapered profile. The device is constrained by the release catheter, which is sheathed by a flexible delivery catheter. A black positioning marker on the delivery catheter aids in proper placement of the device in the fallopian tube.

The delivery handle controls the device delivery and release mechanism. The thumbwheel on the delivery handle retracts both the delivery catheter and the release catheter. The button allows the physician to change the function of the thumbwheel from retracting the delivery catheter to retracting the release catheter. The delivery wire is detached from the micro-insert by rotating the system.

The split introducer (**Figure 3** below) is placed into the sealing cap of the working channel of the hysteroscope, and is intended to help protect the **Essure** micro-insert as it is being passed through the sealing cap of the hysteroscope working channel. Please see Section XIV.B., step #7, for a photograph showing how the **Essure** System is introduced through the split introducer.

**Figure 3**  
**Split Introducer**  
**(NOT TO SCALE)**



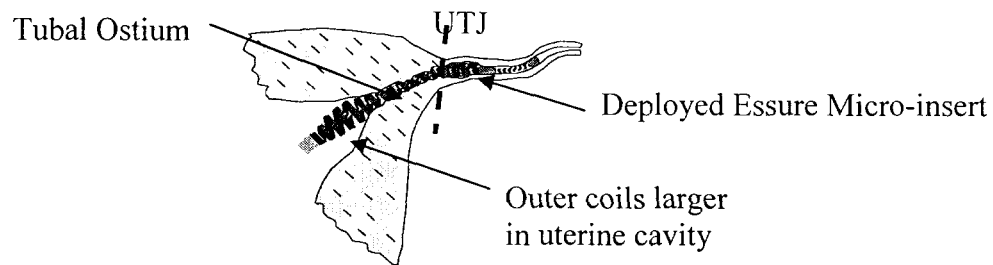
### III. MECHANISM OF ACTION

#### A. Placement at Utero-Tubal Junction (UTJ)

The **Essure** micro-insert is intended for placement into the fallopian tube with the implant portion of the device spanning the utero-tubal junction (UTJ). For purposes of micro-insert placement, the UTJ is defined as the portion of the fallopian tube, just as it exits the uterus (refer to **Diagram III.1** below for graphic representation of UTJ). This specific portion of the anatomy was chosen for the site of implantation so that devices would be placed far enough into the tube to prevent expulsion due to uterine contractions during menses, yet still proximal enough to allow a portion of the device to trail into the uterus (specifically, 3 - 8 coils or approximately 5-10 mm). It is desirable to have a trailing portion in the uterus to aid device anchoring. This anchoring is achieved by the greater outer diameter of the expanded coils that trail into the uterus, as compared to the outer diameter of the expanded coils within the fallopian tube. The outer diameter of the expanded coils trailing in the uterus is expected to be as much as two times the outer diameter of the expanded coils that are compressed by the walls of the fallopian tube at the UTJ (please refer to **Diagram III.1** below). In addition, placement at the UTJ is expected to aid in anchoring since it most consistently represents the narrowest portion of

the fallopian tube. Unacceptable rates of expulsions and failures with transcervical sterilization devices that were placed more proximally, at the ostial section of the fallopian tube, have been noted in the literature. In addition, expulsion of the **Essure** micro-insert has occurred when micro-insert placement was too proximal. Finally, if the device is placed without any trailing portion of the device in the uterus, then direct visualization of device location is not possible.

**Diagram III.1: Ideal Essure Micro-insert Placement**



**B. Dynamic Anchoring micro-insert**

The Essure micro-insert is a dynamic, spring-like device, in that it is inserted into the fallopian tube at a reduced diameter, and then expands once deployed to conform to the fallopian tube. The spring-like mechanism is intended to provide the necessary anchoring forces during the acute phase of device implantation (3 months post-micro-insert placement), during which time the PET fibers are eliciting tissue in-growth into the coils of the Essure micro-insert and around the PET fibers.

**C. Tissue In-Growth**

The effectiveness of the Essure micro-insert in preventing pregnancy is believed to be due to a combination of the space filling design of the device and a local, occlusive, benign tissue response to the PET fibers. The tissue response is the result of a chronic inflammatory and fibrotic response to the PET fibers. It is believed that the tissue in-growth into the device caused by the PET fibers results in both device retention and pregnancy prevention.

The PET fibers were chosen for this application due to their success in causing tissue in-growth into devices used in other medical applications, such as prosthetic arterial grafts, percutaneous catheters, aneurysm coils, and other long-term implants.

**D. Permanency of Tubal Occlusion (and Sterilization)**

The long-term nature of the tissue response to the Essure device is not known. The majority of the clinical data regarding PET in the fallopian tube is based on 12-24 months of implantation, with little data at 36 months. Therefore, beyond 24 months, the nature of the cellular/fibrotic response and the ability of the response and the device to maintain occlusion are not known. Data for up to 5 years of wear will become available as participants in the clinical trials of safety and effectiveness continue to be followed. In addition, women who choose the Essure method of sterilization will be requested to

notify the manufacturer if they have surgery in the future (such as hysterectomy) that will result in explantation of the devices. Also, the published failure rates for the device as a method of contraception will be updated as these patients continue to be followed to account for long-term sterilization failures.

#### IV. INDICATIONS FOR USE

The **Essure System** is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.

#### V. CONTRAINDICATIONS

The **Essure System** should not be used in any patient who is:

- Uncertain about her desire to end fertility.
- Patients in whom only one micro-insert can be placed (including patients with apparent contralateral proximal tubal occlusion and patients with a suspected unicornuate uterus).
- Patients who have previously undergone a tubal ligation.

Or any patient with any of the following conditions:

- Pregnancy or suspected pregnancy.
- Delivery or termination of a pregnancy less than 6 weeks before **Essure** micro-insert placement.
- Active or recent upper or lower pelvic infection.
- Known allergy to contrast media.
- *Known* hypersensitivity to nickel confirmed by skin test (see Warnings section below for patients with suspected hypersensitivity to nickel).

#### VI. WARNINGS

- The patient must use alternative contraception (cannot rely on the **Essure** micro-inserts for contraception) until an HSG performed three months post-micro-insert placement demonstrates satisfactory micro-insert location and tubal occlusion. During this time frame, the patient may be at an increased risk of ectopic pregnancy.
- The **Essure** procedure should be considered irreversible. There are no data on the safety or effectiveness of surgery to reverse the **Essure** procedure. Any attempt at surgical reversal will likely require utero-tubal reimplantation. Pregnancy following such a procedure carries with it the risk of uterine rupture and serious maternal and fetal morbidity and mortality.
- The effectiveness rates established for **Essure** were based on clinical data from women in whom micro-inserts were placed bilaterally. There is very little data on the effectiveness of unilateral **Essure** placement in a unicornuate uterus or unilateral **Essure** placement with presumed or confirmed contralateral proximal tubal occlusion (PTO).
- Micro-insert removal should not be attempted hysteroscopically once the micro-insert has been placed. The only exception is during the actual placement procedure when removal may be attempted if 18 or more coils of the **Essure** micro-insert are trailing into the uterine cavity. Because of device anchoring, however, removal may not be possible even immediately after placement. Attempted removal of a micro-insert

having less than 18 coils trailing into the uterine cavity may result in fallopian tube perforation or other patient injury.

- In order to reduce the risk of hypervolemia, the procedure should be immediately aborted if the fluid deficit of the physiologic saline distension medium exceeds 1500cc. To further reduce the risk of hypervolemia, the hysteroscopic procedure time should not exceed 20 minutes.
- The **Essure** micro-insert will conduct energy if directly or closely contacted by an active electrosurgical device. If this occurs, then there is a risk of patient injury. Therefore, electrosurgery should be avoided in procedures undertaken on the uterine cornua and proximal fallopian tubes without either hysteroscopic visualization of the micro-inserts, or visualization of the proximal portion of the fallopian tube via open surgical procedures or laparoscopy. During LAVH and other procedures in which electrosurgical instruments could contact the serosa of the fallopian tube, instruments should not be placed more proximal than the ampullary portion of the tube.
- Bench studies suggest that endometrial ablation using radio frequency (RF) energy will cause significant damage to surrounding tissue if an active RF instrument comes into direct contact with the **Essure** micro-inserts. Consequently, if using RF energy to perform endometrial ablation, direct contact with the **Essure** micro-inserts should be avoided. Global auto-ablative systems that employ RF energy should not be used in women with the **Essure** micro-inserts in place.
- Bench studies suggest that endometrial ablation of the uterus with thermal (heated fluid) techniques can be done with the **Essure** micro-inserts in place without significant tissue damage, however, there is little clinical data regarding the safety of thermal endometrial ablation in women with the **Essure** micro-inserts.
- There are no data regarding cryo-ablation techniques or the use of laser for endometrial ablation of the uterus with the **Essure** micro-inserts in place.
- There are also no data regarding the use of endometrial ablation devices that operate at microwave frequencies with the **Essure** micro-inserts in place. The use of microwave energy near metallic implants has been shown to pose significant risk of serious injury to patients. Use of microwave endometrial ablation devices near the **Essure** micro-inserts therefore should be avoided.
- Although not reported in the clinical trials of **Essure**, there is a theoretical increased risk of ectopic pregnancy in patients with the **Essure** micro-inserts, should they become pregnant.
- Placement of **Essure** micro-inserts into women who are undergoing immunosuppressive therapy (e.g., systemic corticosteroids or chemotherapy) is discouraged, because the immunosuppressive therapy is expected to negatively affect the tissue response to **Essure** that leads to tubal occlusion.
- To reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilation, e.g. in the case of stenotic cervix.
- When introducing the **Essure** micro-insert into the fallopian tube, never attempt to advance the micro-insert(s) against excessive resistance. Refer to Section XIV. B. #9 (Directions for Use) for guidance on what constitutes “excessive” resistance.
- If tubal or uterine perforation occurs or is suspected, immediately discontinue the **Essure** placement procedure, and work-up the patient for a perforation.

- A very small percentage of women in the Essure clinical trials reported recurrent or persistent pelvic pain, and only one woman requested device removal due to pain; however, if device removal is required for any reason, it will likely require surgery, including an abdominal incision and general anesthesia, and possible hysterectomy.
- Patients with *suspected* hypersensitivity to nickel should undergo a skin test to assess hypersensitivity prior to an Essure placement procedure (see Contraindications section above for patients with known hypersensitivity to nickel).
- Patients may decide, in future years, to undergo *in vitro* fertilization (IVF) to become pregnant. The effects of the **Essure** micro-inserts on the success of IVF are unknown. If pregnancy is achieved, the risks of the Micro-insert to the patient, to the fetus and to the continuation of a pregnancy are also unknown.

## VII. PRECAUTIONS

- Women who undergo sterilization at a relatively young age are at greater risk of regretting their decision to undergo sterilization.
- Micro-insert placement should be performed during the early proliferative phase of the menstrual cycle in order to decrease the potential for micro-insert placement in a patient with an undiagnosed (luteal phase) pregnancy and to enhance visualization of the fallopian tube ostia. In women with menstrual cycles shorter than 28 days, the day of ovulation must be carefully calculated to reduce the potential of a luteal phase pregnancy. Micro-insert placement should NOT be performed during menstruation.
- Do not continue to advance the **Essure** System once the black positioning marker on the catheter has reached the tubal ostium. Advancement beyond this point could result in unsatisfactory micro-insert placement and/or tubal/uterine perforation.
- Diagnostic procedures under direct visualization are optimal with the **Essure** micro-inserts in place. Blind insertion of instruments into the uterus with the micro-inserts in place should be undertaken with caution and care to avoid disruption of the micro-inserts.
- Any intrauterine procedure performed without hysteroscopic visualization following **Essure** implantation could interrupt the ability of the **Essure** micro-inserts to prevent pregnancy. Following such procedures, device retention and location should be verified by hysteroscopy, x-ray, or ultrasound. In addition, the presence of the **Essure** micro-inserts could involve risks associated with intrauterine procedures that, at this time, have not been identified.
- Testing to ensure safety and compatibility with Magnetic Resonance Imaging (MRI) has been conducted using a 1.5 tesla magnet. The **Essure** micro-inserts were found to be MR safe at this field strength. Test results at 1.5 tesla indicate zero magnetic force and radio frequency (RF) heating of 0.6<sup>0</sup> C in a phantom when a whole body specific absorption rate (SAR) of 1.3 W/kg was applied. The presence of the micro-inserts produces an MR artifact, which will obscure imaging of local tissue. The artifact is expected to be larger at higher field strength.
- As with all outpatient or office surgery procedures, appropriate equipment, medications, staff, and training should be in place to handle emergency situations, such as vaso-vagal response.
- Uterine or fallopian tube anomalies may make it difficult to place the **Essure** micro-inserts. Both tubal ostia should be identified and assessed hysteroscopically prior to

proceeding to **Essure** micro-insert placement. No attempt should be made to place a micro-insert in one tubal ostium unless there is a reasonable expectation that the contralateral tube is accessible and patent. If it appears unlikely that successful bilateral micro-insert placement can be achieved, then the procedure should be terminated and potentially rescheduled. See Section XV regarding patient counseling in the event of failed placement.

- Do not advance the **Essure** System if the patient is experiencing extraordinary pain or discomfort. Terminate the procedure and work-up the patient for possible perforation.
- The **Essure** System is for single use only. Never attempt to resterilize an **Essure** micro-insert or delivery system.
- When removing the stylet from the introducer, there is a possibility that saline will be washed back through the operating channel of the hysteroscope. Proper eye and face protection should be utilized.
- The split introducer must be used in order to avoid damage to the device tip.
- The split introducer should be removed after the micro-insert is introduced into the working channel. The working channel stopcock must remain in the open position to avoid damage to the micro-insert or to the introducer.
- Do not place more than one **Essure** micro-insert in a single fallopian tube.
- Do not use the **Essure** System if the sterile package is open or damaged. Do not use if the micro-insert is damaged.
- There are no data on **Essure** placement in nulliparous women.



## VIII. ADVERSE EVENTS

### A. Patient Population

Between November of 1998 and June of 2001, a total of 745 women underwent an Essure placement procedure in two separate clinical investigations to evaluate the safety and effectiveness of the **Essure System** (227 in the Phase II study and 518 women in the Pivotal trial<sup>1</sup>). Some women underwent more than one procedure if successful bilateral placement was not achieved in the initial procedure. Placement of at least one Essure Micro-insert was achieved in 682 women (206 in the Phase II study and 476 in the Pivotal trial).

### B. Observed Adverse Events

**Tables 1 and 2** below present adverse events that prevented reliance on **Essure** for contraception in the Phase II and Pivotal studies, respectively.

**Table 1**  
**Phase II Study**  
**Adverse events that prevented reliance on Essure for contraception**

<b>Event</b>	<b>Number</b>	<b>Percent</b>
Perforation	6/206	2.9%
Expulsion	1/206	0.5%
Other unsatisfactory micro-insert location	1/206	0.5%
<i>Initial</i> tubal patency	7/200	3.5%*

\*Tubal patency was demonstrated in seven women at the 3-month HSG, but all seven women were shown to have tubal occlusion at a repeat HSG performed 6 months after **Essure** placement.

**Table 2**  
**Pivotal Trial**  
**Adverse events that prevented reliance on Essure for contraception**

<b>Event</b>	<b>Number</b>	<b>Percent</b>
Expulsion	14/476	2.9%*
Perforation	5/476	1.1%
Other unsatisfactory micro-insert location	3/476	0.6%
<i>Initial</i> tubal patency	16/456	3.5%**

\*Fourteen women experienced an expulsion, however nine of these 14 women chose to undergo a second micro-insert placement procedure, which was successful in all nine cases.

\*\* Tubal patency was demonstrated in sixteen women at the 3-month HSG, but all sixteen women were shown to have tubal occlusion at a repeat HSG performed 6-7 months after **Essure** placement

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<sup>1</sup> In the Pivotal trial, 657 women initially enrolled in the study. Ninety-nine women subsequently changed their mind about participating. Twenty-three women were subsequently terminated because they did not meet the inclusion criteria, and 17 failed the screening tests. Therefore, 518 underwent the Essure placement procedure. There were a total of 13 women who were lost-to-follow-up in the Pivotal trial.

Other adverse events or side effects reported as a result of the hysteroscopic placement procedure are shown below in **Tables 3 and 4** for the Phase II and Pivotal studies, respectively.

**Table 3**  
**Phase II Study**  
**Adverse events reported on day of placement procedure**  
**(N=233 procedures)**

<b>Event</b>	<b>Number</b>	<b>Percent</b>
Band Detachment	3	1.3%
Vaso-vagal response	2	0.9%
Pain	2	0.9%

**Table 4**  
**Pivotal Trial**  
**Adverse events and side effects reported on day of placement procedure**  
**(N=544 procedures)**

<b>Event</b>	<b>Number</b>	<b>Percent</b>
Cramping	161	29.6%
Pain	70	12.9%
Nausea/vomiting	59	10.8%
Dizziness/light headed	48	8.8%
Bleeding/spotting	37	6.8%
Vaso-vagal response/fainting	7	1.3%
Hypervolemia	2	0.4%
Band Detachment	2	0.4%
Other*	16	2.9%

\*Includes: ache (3), hot/hot flashes (2), shakiness (2), uncomfortable (1), weak (1), profuse perspiration (1), bowel pain (1), sleepy (1), skin itching (1), loss of appetite (1), bloating (1), allergic reaction to saline used for distension (1).

In addition, the majority of women experienced mild to moderate pain during and immediately following the procedure, and the majority of women experienced spotting for an average of 3 days after the procedure. Pain was managed in every case with oral non-steroidal anti-inflammatory drugs (NSAIDs) or oral narcotic pain reliever.

**Table 5** summarizes all adverse events rated by the Investigators to be at least "possibly" related to the **Essure** micro-insert or micro-insert placement procedure during the first year of reliance on **Essure** in the Pivotal trial (approximately 15 months post-device placement). The percentages presented reflect the number of *events* in the numerator and the number of *women in the trial* in the denominator. While a woman reporting numerous episodes of the same event is represented in the numerator as multiple reports of that event, she is only represented in the denominator once. Consequently, in some cases these percentages over-represent the percentage of *women* who have experienced that event.

**Table 5**  
**Pivotal Trial**  
**Adverse Events by Body Systems, First Year of Reliance\***  
**(N=476 patients implanted with at least one device)**

Adverse Events by Body System	Number	Percent
<b>Abdominal:</b>		
Abdominal pain/abdominal cramps	18	3.8%
Gas/bloating	6	1.3%
<b>Musculo-skeletal:</b>		
Back pain/low back pain	43	9.0%
Arm/leg pain	4	0.8%
<b>Nervous/Psychiatric:</b>		
Headache	12	2.5%
Premenstrual Syndrome	4	0.8%
<b>Genitourinary:</b>		
Dysmenorrhea/menstrual cramps (severe)	14	2.9%
Pelvic/lower abdominal pain (severe)	12	2.5%
Persistent increase in menstrual flow	9**	1.9%
Vaginal discharge/vaginal infection	7	1.5%
Abnormal bleeding - timing not specified (severe)	9	1.9%
Menorrhagia/prolonged menses (severe)	5	1.1%
Dyspareunia	17	3.6%
<b>Pain/discomfort - uncharacterized:</b>	14	2.9%

\* Only events occurring in  $\geq 0.5\%$  are reported

\*\* Eight women reported persistent *decrease* in menstrual flow

In the Phase II trial, 12/206 (5.8%) women with at least one micro-insert reported episodes of period pain, ovulatory pain, or changes in menstrual function.

**C. Potential Adverse Events Not Observed in Clinical Studies**

The following adverse events were not experienced by women who participated in clinical studies evaluating the **Essure System** but are still possible:

- Pregnancy and ectopic pregnancy in women relying on **Essure**<sup>2</sup>
- Perforation of internal bodily structures other than the uterus and fallopian tube.
- Adnexal infection/salpingitis.
- Adverse events associated with the hysterosalpingogram or X-rays.
- The effect of future medical procedures that involve the uterus or fallopian tubes on the ability of the **Essure** micro-insert to provide protection against pregnancy.
- Adverse events associated with surgery attempting to reverse the **Essure** procedure, as well as adverse events associated with pregnancy following a reversal procedure or an IVF procedure.
- Adverse events associated with gynecologic surgical procedures (e.g. endometrial ablation).

**D. Adverse Event Reporting**

Any adverse event (clinical incident) involving the **Essure System** should be reported to Conceptus immediately.

**To report an incident, call (877) Essure2 OR (877) 377-8732.**

**IX. CLINICAL STUDIES**

**A. Purpose of the Study, Study Design, Primary Endpoints**

Conceptus has conducted two clinical trials (a Phase II Trial and a Pivotal Trial) to demonstrate the safety and effectiveness of the **Essure System** in providing permanent contraception.

**1. Phase II Study**

The Phase II study was a prospective, multi-center, single-arm, non-randomized, international study of women seeking permanent contraception. The objectives of the study were to evaluate:

- The woman's tolerance of, and recovery from, the Micro-insert placement procedure;
- The safety of the micro-insert placement procedure;
- The woman's tolerance of the implanted Micro-inserts;
- The long-term safety and stability of the implanted Micro-inserts; and
- The effectiveness of the micro-inserts in preventing pregnancy.

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<sup>2</sup> One woman in the Phase II study who received a prior device design that was discontinued in 1998 (the Beta design of the STOP device) became pregnant after nearly two years of reliance on the device for contraception. That pregnancy is not included in the effectiveness rate calculations, since that device design was not subject of the Premarket Approval Application (PMA) that supported approval of the **Essure System**.

## 2. Pivotal Trial

The Pivotal study was a prospective, multi-center, single-arm, non-randomized, international study of women seeking permanent contraception. The study used findings from the U.S. Collaborative Review of Sterilization (CREST study) as a qualitative benchmark. The primary endpoints for the study included:

- Prevention of pregnancy;
- Safety of device placement procedure, and;
- Safety of device wearing.

The secondary endpoints for the study included:

- Participant satisfaction with device placement procedure;
- Participant satisfaction with device wearing;
- Bilateral device placement rate, and;
- Development of a profile for an appropriate candidate for the Essure procedure.

### B. Patients Studied

The study population of the two studies combined consisted of 664 women in whom bilateral device placement was achieved after one or more attempts (200 in the Phase II study and 464 in the Pivotal trial). All study participants were between 21 and 45 years of age and were seeking permanent contraception prior to enrollment in the study. Additionally, all women had at least one live birth, had regular, cyclical menses and were able and willing to use alternative contraception for the first three months following **Essure** micro-insert placement.

### C. Methods

All study participants were screened for eligibility to participate in the clinical study. A complete medical history was obtained. A physical examination, a pelvic examination and required laboratory tests (including a pregnancy test) were conducted.

An **Essure** device placement procedure was attempted on each fallopian tube. In the Pivotal Trial, a pelvic x-ray was performed within 24 hours following device placement to serve as a baseline evaluation of device location. Participants were instructed to use either a barrier contraceptive method or oral contraceptives for the first 3 months following the device placement procedure.

A hysterosalpingogram (HSG) was performed three months post device placement to evaluate device location and fallopian tube occlusion. If both fallopian tubes were occluded and both devices were satisfactorily placed within the fallopian tubes, the participant was instructed to discontinue use of alternative contraception and rely on the **Essure** devices for prevention of pregnancy.

**D. Results**

Of the 632 women enrolled in the clinical trials (with bilateral Micro-insert placement) and who have relied on the **Essure System** for contraception for 12 to 36 months, no (zero) pregnancies have been reported. Of the 632 women, all have been followed for 12 months, 197 have been followed for 24 months, and 34 have been followed for 36 months. Adverse events that were reported in the clinical studies are provided in Section VIII., B above, and events by study are provided below. **Tables 6 and 7** present the principal safety and effectiveness results as of October, 2002, and **Tables 8 and 9** present patient demographic information.

**Table 6**  
**Micro-insert Placement and Reliance Rates**

Outcome	Phase II N=227		Pivotal N=518	
	Number	Percent	Number	Percent
<b>Bilateral Placement*:</b> <i>After one procedure</i>	196/227	86%	446/518**	86%
<b>Bilateral Placement*:</b> <i>After two procedures</i>	200/227	88%	464/518**	90%
<b>Reliance Rate***:</b> <i>Among women with bilateral placement</i>	194/200	97%	449/464	97%

\*The placement rates presented here are based on data from the Essure clinical trials. Data on the placement rates in the commercial setting are being gathered in a post-approval study. As updated data regarding placement rates are included in the product labeling, they will also be posted on the Conceptus website: [www.Essure.com](http://www.Essure.com).

\*\*Of these 518 women, 11 did not undergo attempted micro-insert placement because the tubal ostia could not be visualized. Also, 18 women who did not achieve bilateral placement underwent a follow-up HSG, and 15/18 (83%) were diagnosed with proximal tubal occlusion (PTO).

\*\*\*The reliance rate is the number of women who were able to rely on **Essure** for contraception divided by the number of women with bilateral micro-insert placement.

**Table 7**  
**Effectiveness Results as of October, 2002**

Cumulative Failure Rates	Phase II N=193	Pivotal Trial N=439	Both Trials Combined N=632
<b>One-Year*</b>	0%** (95% CI 0 – 1.53%) (Adj 95% CI 0-2.19%***)	0%** (95% CI 0 – 0.68%) (Adj 95% CI 0 – 0.78%***)	0%** (95% CI 0 – 0.47%) (Adj 95% CI 0 – 0.57%***)
	Phase II N=181	Pivotal Trial N=16	Both Trials Combined N=197
<b>Two-Year*</b>	0%** (95% CI 0 – 1.54%) (Adj 95% CI 0 – 2.36%***)	0%** (95% CI 0 – 0.86%) (Adj 95% CI 0 – 0.93%***)	0%** (95% CI 0 – 0.55%) (Adj 95% CI 0 – 0.67%***)

\* While the one- and two-year effectiveness rates for **Essure** compare quite favorably to the effectiveness rate for other methods of tubal sterilization at these time points, longer-term data on **Essure** are not available and may not compare favorably to other methods once these data are obtained. Follow-up of the women in both the Phase II and Pivotal trials is ongoing, and will continue to 5 years of follow-up. As updated data regarding longer-term failure rates are included in the product labeling, they will also be posted on the Conceptus website: [www.Essure.com](http://www.Essure.com).

\*\*Although the effectiveness rate established in the clinical trials of **Essure** was 100%, no method of contraception is 100% effective, and pregnancies are expected to occur in the commercial setting.

\*\*\*Adjustment using indirect method, adjusted to CREST study population based on three age groups.

**Table 8**  
**Age Distribution**

<b>Study</b>	<b>&lt;28 years old</b>	<b>28-33 years old</b>	<b>≥34 years old</b>
<b>Phase II</b> <b>(Average age: 35)</b>	7%	23%	70%
<b>Pivotal Trial</b> <b>(Average age: 32)</b>	17%	47%	36%

**Table 9**  
**Patient Demographics**

	<b>Phase II</b> <b>N=227</b>	<b>Pivotal Trial</b> <b>N=518</b>
<b>Race</b>	Not collected	
<b>White/Caucasian</b>		428
<b>Latin</b>		31
<b>Black</b>		24
<b>Other</b>		9
<b>Gravidity</b>	Mean=2.6 (0-10.0)	Mean=3.03 (1.0-11.0)
<b>Parity</b>	Mean=2.2 (0-5.0)	Mean=2.26 (1.0-6.0)
<b>Body Mass Index (BMI)</b> <b>(kg/m<sup>2</sup>)</b>	Mean=26 (17-57)	Mean= 27(16-52)

**Table 10** provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.



**Table 10**  
**Pregnancy Rates for Birth Control Methods**  
**(For One Year of Use)**

Method	Typical Use Rate of Pregnancy
<b>Sterilization:</b>	
Male Sterilization	0.15%
Female Sterilization	0.5%
<b>Hormonal Methods:</b>	
Implant ( <i>Norplant</i> ™ and <i>Norplant</i> ™ 2)	0.05%
Hormone Shot ( <i>Depo-Provera</i> ™)	0.3%
Combined Pill ( <i>Estrogen/Progestin</i> )	5%
Minipill ( <i>Progestin only</i> )	5%
Nuva Ring	1.2%
Ortho Evra	1%
Lunelle	<1%
<b>Intrauterine Devices (IUDs):</b>	
Copper T	0.8%
Progesterone T	2%
LNg 20	0.1%
<b>Barrier Methods:</b>	
Male Latex Condom <sup>1</sup>	14%
Diaphragm <sup>2</sup>	17%
Cervical Cap <sup>2</sup>	17%
Female Condom	21%
Lea's Shield	15%
<b>Spermicide:</b> ( <i>gel, foam, suppository, film</i> )	26%
<b>Natural Methods:</b>	
Withdrawal	19%
Natural Family Planning ( <i>calendar, temperature, cervical mucus</i> )	25%
<b>No Method:</b>	85%

<sup>1</sup> Used Without Spermicide

<sup>2</sup> Used With Spermicide

Data adapted from FDA's Uniform Contraceptive Table, and modified per FDA input based on new studies.

## X. INDIVIDUALIZATION OF TREATMENT

The **Essure System** is available in one size only. The risks and benefits previously described in Section VII - CLINICAL STUDIES should be carefully considered for each patient before use of the **Essure System**. Patient selection factors to be assessed should include:

- Patient's certainty about her desire to end fertility,
- Gynecological co-morbidities (e.g., pelvic infection, cervicitis, undiagnosed vaginal bleeding), and

- Reproductive tract anatomical variants and/or pathology, such as a bicornuate uterus or a submucous leiomyoma, that could make a patient unsuitable for transcervical delivery/placement of micro-inserts.

The decision to undergo treatment is at the discretion of the patient, with the advice of her physician.

**A. Use in Specific Populations**

The safety and effectiveness of the **Essure System** has not been established in patients with any of the following characteristics:

- Patients less than 21 years old or greater than 45 years old
- Nulliparous women
- Patients who delivered a baby or terminated a pregnancy less than 6 weeks before **Essure** micro-insert placement.

**XI. PATIENT COUNSELING INFORMATION**

**IMPORTANT: Patients should be counseled that this product is intended to prevent pregnancy. It does not protect against either HIV infection or other sexually transmitted diseases.**

The physician should consider the following points when counseling the patient about this device:

- Details contained in the Patient Information Booklet regarding risks associated with placement and wearing of the **Essure** micro-inserts.
- The procedure is permanent, and irreversible.
- **Instruct the patient to use an alternative form of contraception (except an IUD or IUS) for the first 3 months following the micro-insert placement procedure until she has undergone the 3-month HSG. Ensure that the patient is supplied with, or already has, contraception for this time frame. In addition, the patient should be counseled to use the most effective means of contraception for which she is a candidate. The patient should also be counseled that there is a theoretical increased risk of ectopic pregnancy during this time period, so compliance with her contraception regimen is critical.**
- Like all methods of birth control, the **Essure** procedure should not be considered 100% effective.
- Micro-insert placement may not be successful, resulting in either bilateral placement failure or only unilateral placement. Please refer to Section XIII for directions on how to manage cases of unsuccessful micro-insert placement. Before conducting the **Essure** procedure, you should discuss with the patient a management plan that may be implemented in the event that successful placement is not achieved.
- Data regarding the effectiveness of **Essure** beyond 2 years is currently not available.

Conceptus recommends that the physician disclose to the patient (in written form) all risks associated with the **Essure System**, that the **Essure** procedure is permanent, and irreversible. Please also refer to the Patient Counseling section of the Technical Bulletin

from the American College of Obstetricians and Gynecologists (ACOG) regarding female sterilization (ACOG Technical Bulletin Number 222, April 1996).

**NOTE: A patient ID card is supplied with each Essure System. Please give this to your patient and ask that she carry it with her at all times and show it to other physicians involved in her present or future care.**

## **XII. HOW SUPPLIED**

**CONTENTS:** Two (2) Essure Systems  
Two (2) Split introducers  
One (1) Instructions for Use  
One (1) Patient Identification Card

**STERILE:** Each **Essure System** is sterilized using ethylene oxide and is supplied sterile for single use only. Do not reuse or resterilize. Resterilization may adversely affect proper mechanical function and could result in patient injury. Carefully inspect the sterile package for damage or defects prior to use.

**STORAGE:** Store in a cool, dry place.

## **XIII. PHYSICIAN TRAINING MANUAL**

The **Essure System** Physician Training Manual contains detailed information not included in this Instructions for Use. Refer to the Physician Training Manual for additional information as required.

## **XIV. DIRECTIONS FOR USE**

### **A. Prior to Micro-insert Placement Procedure**

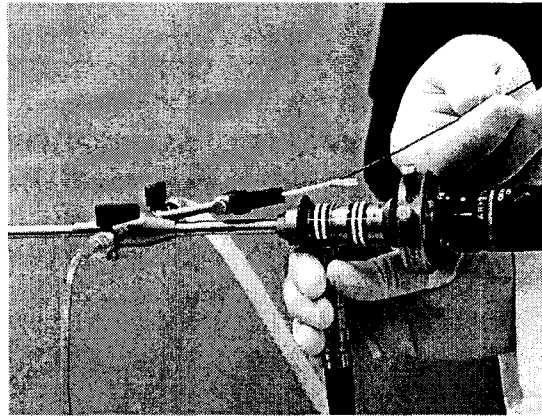
1. Micro-insert placement should be performed during the early proliferative phase of the menstrual cycle, in order to decrease the potential for micro-insert placement in a patient with an undiagnosed (luteal phase) pregnancy and to enhance visualization of the fallopian tube ostia. In women with menstrual cycles shorter than 28 days, the day of ovulation must be carefully calculated to reduce the potential of a luteal phase pregnancy. Micro-insert placement should NOT be performed during menstruation.
2. A pregnancy test administered by the physician or designee, should be conducted within 24 hours prior to the micro-insert placement procedure.
3. Administration of a non-steroidal anti-inflammatory drug (NSAID) is recommended one to two hours before the micro-insert placement procedure. If using only a paracervical block, an anxiolytic agent may also be offered 30 minutes prior to the procedure to reduce anxiety.

## B. Micro-insert Placement Procedure

The **Essure** micro-insert placement procedure can be performed in an outpatient or office surgery setting. As with all outpatient procedures, appropriate equipment, medications, staff, and training should be in place to handle emergency situations, such as vaso-vagal response. Sterile technique should be used during the micro-insert placement procedure following universal precautions. Face and eye protective covering should be worn by the physician. The amount of time required to complete the hysteroscopic portion of the micro-insert placement procedure should not exceed 20 minutes.

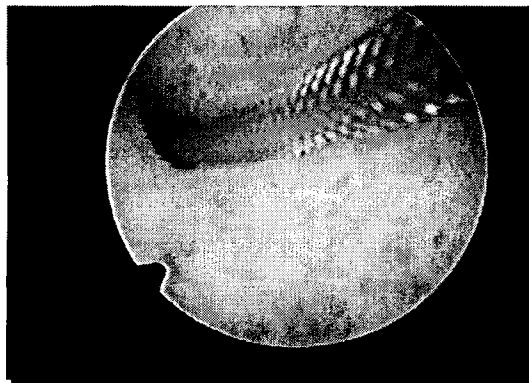
1. Check all necessary equipment to ensure that there is no damage to equipment and that there are no missing parts.
2. Place the patient in the lithotomy position. An under buttocks drape with fluid control pouch is recommended for fluid management.
3. Introduce a speculum into the vagina to allow access to the cervix. Prep the cervix with betadine or other suitable antibacterial solution according to standard practice.
4. Local anesthesia (e.g. paracervical block), with or without IV sedation, is the preferred method for implantation of the micro-inserts, including implantation during preceptored cases conducted as part of the Essure training program.
5. Insert a sterile hysteroscope, with attached camera and operating channel ( $\geq 5$  French), through the cervix into the uterine cavity. Do not perform cervical dilation unless necessary to allow hysteroscope insertion. If dilation is necessary, dilate only as much is required to insert the hysteroscope. In order to prevent uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.
6. Uterine cavity distension should be accomplished with a physiologic saline infusion through the inflow channel of the hysteroscope. It is strongly recommended that the saline solution be pre-warmed to body temperature (but no greater than body temperature) and introduced under gravity feed to minimize spasm of the fallopian tubes and to reduce over-distension of the uterus. Adequate uterine distension must be achieved and maintained throughout the procedure in order to allow identification of and access to the fallopian tube ostia. Standard fluid monitoring procedures should be followed throughout the procedure. In order to reduce the risk of hypervolemia, the procedure should be immediately aborted if the fluid deficit of the physiologic saline distension medium exceeds 1500cc. To further reduce this risk related to hypervolemia, the hysteroscopic procedure time should not exceed 20 minutes.

7. Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** micro-insert placement. No attempt should be made to place a micro-insert in one tubal ostium unless there is a reasonable expectation that the contralateral tube is patent.
8. Once the fallopian tube ostia have been identified, insert the split introducer through the sealing cap on the hysteroscope working channel. Remove the stylet while keeping the Introducer in place in the operating channel. The operating channel stopcock should remain in the open position (the device and/or introducer can be damaged if the stopcock closes on either device). Place the **Essure** delivery system through the introducer and advance through the operating channel of the hysteroscope and remove the introducer.



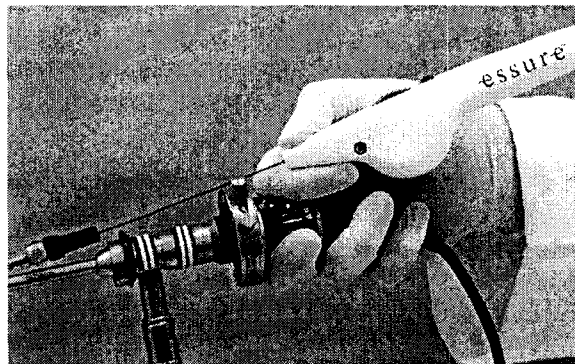
*Insert split introducer and **Essure** micro-insert through sealing cap on hysteroscope working channel*

9. Advance the **Essure** delivery system into the proximal fallopian tube with gentle, constant forward movement to prevent tubal spasm. Advance the delivery system until the black positioning marker on the delivery catheter reaches the fallopian tube ostium. This visual marker indicates that the **Essure** micro-insert is spanning the intramural and the proximal isthmic segments of the fallopian tube, with the outer coil spanning the uterotubal junction. This is the ideal placement for the **Essure** micro-insert.



*Advance until black positioning marker at tubal ostium.  
This is visual indicator for proper position for deployment.*

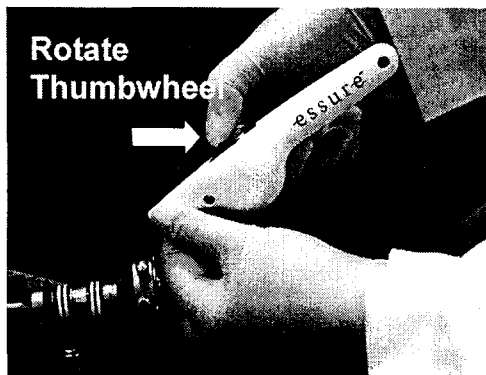
10. Proper concentric alignment of the delivery catheter with the tubal lumen is suggested by the ability to advance the catheter under direct visualization without undue resistance. Resistance to advancement is usually apparent if: 1) the black marker on the outside surface of the catheter is seen not to advance forward towards the tubal ostium, and/or 2) the delivery catheter bends or flexes excessively, thus preventing the physician from applying forward pressure on the catheter assembly. When such resistance to forward advancement of the catheter is observed, no further attempts should be made to place the micro-insert in order to avoid the possibility of uterine perforation or inadvertently placing the micro-insert in the uterine musculature rather than within the tubal lumen. A follow-up HSG should be undertaken to determine tubal patency.
11. If the tube is blocked or the catheter cannot be advanced to the black positioning marker, the case should be terminated. If micro-insert placement is not successful after 20 minutes of hysteroscopic procedure time, the case should be terminated and potentially rescheduled (see Section XV for management of cases with unsuccessful placement).
12. Only after the delivery catheter has been advanced to the black positioning marker should the micro-insert be deployed. To do so, first stabilize the handle of the **Essure** micro-insert against the hysteroscope or camera to prevent inadvertent forward movement of the **Essure** System during retraction of the delivery catheter. Please refer to the Physician Training Manual for specific instructions regarding techniques for stabilizing the handle.



*Stabilize handle against camera head or some  
other fixed object to prevent inadvertent  
forward movement of the **Essure** System*

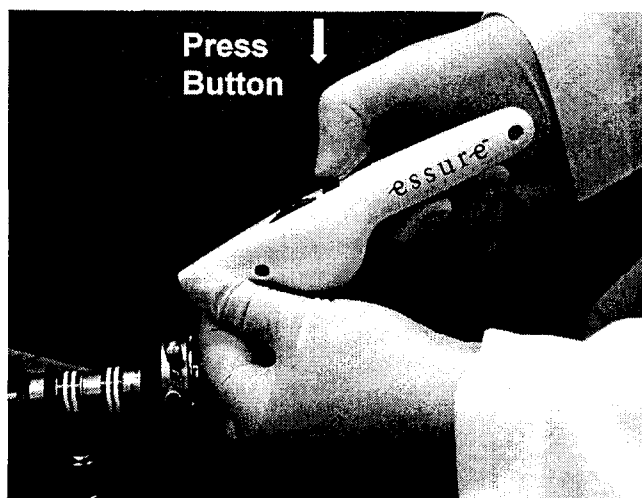
13. Being certain that the black positioning marker is at the fallopian tube ostium, rotate the thumb-wheel on the handle toward you. This should be accomplished no faster than 1 click per second until the wheel no longer

rotates. This facilitates withdrawal of the delivery catheter. The black positioning marker will be seen to move away from the tubal ostium (towards the hysteroscope) and disappear into the operating channel. Withdrawal of the delivery catheter exposes the wound-down **Essure** micro-insert attached to the orange release catheter. Approximately 1cm of the micro-insert (wound-down coils) should appear trailing into the uterus when the delivery catheter is withdrawn. To confirm proper positioning, look for a small notch in the wound-down micro-insert. This notch appears where there is also a slight increase in the diameter of the coils. The notch should be located just outside of the tubal ostium. Visualization of the notch just outside the ostium, as well as visualization of the distal tip of the orange release catheter will confirm proper positioning. If more than 1 cm of the micro-insert is visible in the uterus, then the micro-insert should be repositioned by moving the entire system further into the tube, if possible, before proceeding to step #13.



*Rotate thumbwheel to retract catheter*

14. After retracting the delivery catheter, depress the button on the handle to enable the thumb-wheel to be further rotated.

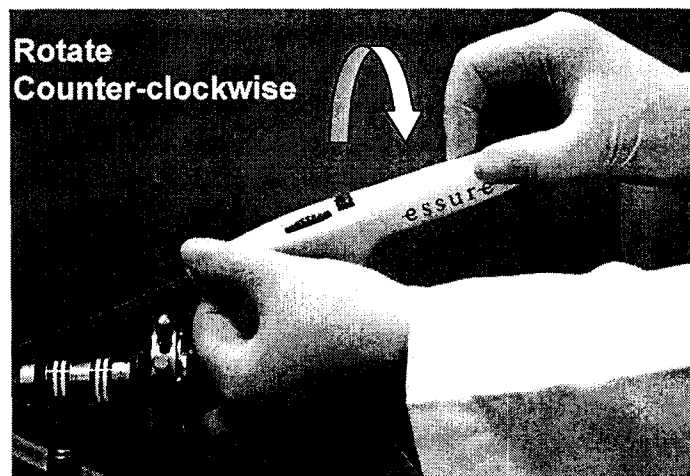


*After complete retraction of catheter,  
press button to enable thumbwheel to rotate again*

Rotate the thumb-wheel toward you to withdraw the orange release catheter. When the thumb-wheel cannot be rotated any further, orange release catheter withdrawal is complete. Withdrawal of the orange release catheter enables the outer coil of the **Essure** micro-insert to expand. The operator should see the outer coils expand. If expansion is not observed, gently move the delivery wire away from the uterine wall to release pressure on the outer coil.

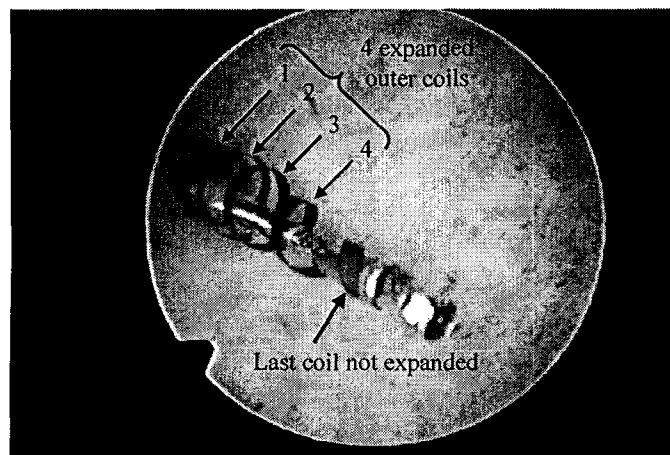
15. **Wait approximately 10 seconds to allow the outer coils to fully expand.**

Once the outer coils are expanded, rotate the entire handle counter-clockwise at least 10 full rotations. Continue to rotate while gently pulling backwards on the handle to release the delivery wire from the **Essure** micro-insert. The delivery system will then be withdrawn through the working channel of the hysteroscope.



*Rotate handle counter-clockwise to detach delivery wire from Micro-insert*

16. Once the delivery system has been withdrawn, the position of the **Essure** Micro-insert should be assessed. There should ideally be 3 to 8 expanded outer coils of the **Essure** micro-insert trailing into the uterus.





*Expanded outer coils of the **Essure** Micro-insert trailing into the uterus indicates ideal placement*

17. Unless the micro-insert has a trailing length that is 18 or more expanded outer coils, the micro-insert should be left in place and evaluated via HSG three months post device placement.

**WARNING: Micro-insert removal should not be attempted hysteroscopically once the micro-insert has been placed. The only exception is during the actual placement procedure when removal may be attempted if 18 or more coils of the Essure micro-insert are trailing into the uterine cavity. Because of device anchoring, however, removal may not be possible even immediately after placement. Attempted removal of a micro-insert having less than 18 coils trailing into the uterine cavity may result in fallopian tube perforation or other patient injury.**

**IMPORTANT:** If the micro-insert was inadvertently deployed in the uterine cavity and not into the tube, then the micro-insert should be removed from the uterus and another attempt made at micro-insert placement in the tube.

18. If there are 18 or more expanded outer coils trailing into the uterus, then the micro-insert should be immediately removed from the uterus (as described in steps 1-5 below) and another attempt made at micro-insert placement in the tube. **Micro-insert removal may not always be possible. Removal of a micro-insert should only be attempted during the same procedure in which the micro-insert was placed.**

- 1 - As necessary, administer analgesia/anesthesia to reduce or prevent patient discomfort.
- 2 - Introduce a grasping instrument through the hysteroscope working channel.
- 3 - Grasp the outer coil of the **Essure** micro-insert. Try to grasp the outer and inner coil of the micro-insert together.
- 4 - Slowly pull back on the grasping instrument and withdraw the hysteroscope at the same time. Since the *expanded* micro-insert is too large to be removed through the operating channel, the entire **Essure** system, together with the hysteroscope, should be removed from the uterus.
- 5 - The outer coil and/or the inner coil of the **Essure** micro-insert may stretch or elongate as micro-insert removal is being attempted.

If complete micro-insert removal is accomplished, an attempt should be made to place another **Essure** micro-insert. If micro-insert removal is not

accomplished, it should be left in place and no attempt should be made to cut the micro-insert. If the physician is not completely satisfied that the entire **Essure** micro-insert has been removed from the fallopian tube, another micro-insert should **NOT** be placed in that tube and a post-placement x-ray should be taken to determine if a micro-insert fragment remains *in vivo*.

19. Record the length of the micro-insert trailing into the uterine cavity, noting any issues with identifying or confirming either tubal ostium or any concern regarding potential perforation. These should be noted in patient records for subsequent reference when reviewing the 3-month hysterosalpingogram (See Section C below). Additionally, the following information should be noted in the patient records:
  - Concern, at the time of device placement, of possible perforation due to excessive force required on the delivery catheter, a sudden loss of resistance, or no visible trailing length in the uterus, as seen hysteroscopically after device placement.
  - The visible trailing length of the micro-insert at the conclusion of device placement, if less than 3 coils or greater than 8 coils. As stated, however, do not remove the micro-insert unless 18 or more coils are trailing into the uterine cavity.
  - Identification of the tubal ostium, at the device placement procedure, was compromised due to poor distension, poor illumination or poor visualization, secondary to endometrial debris.
20. Repeat the **Essure** micro-insert placement procedure in the contralateral fallopian tube.
21. Remind the patient to use an alternative form of contraception (except an IUD or an IUS) for the first 3 months following the micro-insert placement procedure until she has undergone the 3-month HSG. Ensure that the patient is supplied with, or already has, contraception for this time frame. In addition, the patient should be counseled to use the most effective means of contraception for which she is a candidate. The patient should also be counseled that there is a theoretical increased risk of ectopic pregnancy during this time period, so compliance with her contraception regimen is critical.
22. Provide the patient with the Patient ID Card and instruct her to carry it with her at all times and show it to physicians involved in her present and future care.

**C. Patient Follow-up Requirements**

Patients should be scheduled for an HSG 3 months following the **Essure** micro insert placement procedure. The HSG is performed to evaluate micro-insert location and fallopian tube occlusion. If micro-insert location is satisfactory, and there is evidence of bilateral occlusion of the fallopian tubes, the physician will

instruct the patient to discontinue use of alternative contraception and use only the Essure micro-inserts for pregnancy prevention.

## **XV. Management of Cases with Unsuccessful Micro-insert Placement**

In the event of unilateral or bilateral micro-insert placement failure, the patient should be informed that her permanent contraception has not been completed. Patients who experience micro-insert placement failure should be counseled about the opportunity to undergo a second attempt at micro-insert placement, especially in the case of unilateral placement. Of the women in the Pivotal trial who underwent a second procedure following the follow-up HSG, 83% achieved bilateral placement at the second procedure. If the patient chooses to undergo a second placement procedure, she must first undergo an HSG after her next menses to determine tubal patency. If tubal patency is observed, the physician may offer the patient a second attempt at micro-insert placement. If a second attempt at micro-insert placement fails, the patient is unlikely to have success with subsequent attempts. If the patient has one micro-insert left *in vivo* she should be counseled not to rely on the unilateral micro-insert for contraception. If a patient undergoes a follow-up HSG in order to qualify for a second placement procedure, this HSG is NOT considered to be a substitute for the 3-month HSG described in Section XIV.C. of this document.

If the patient chooses laparoscopic sterilization (i.e., clip application or electrical cautery), both fallopian tubes should be clipped or coagulated even if one tube has the **Essure** micro-insert implanted in it. Clipping or coagulation of the tube or tubes should be performed in the ampullary portion of the fallopian tube.

## **XVI. Performing and Evaluating Hysterosalpingograms Three Months Post- Micro-insert Placement**

Three months following the **Essure** micro-insert placement procedure, the patient should be scheduled for an HSG. The HSG is performed to evaluate: 1) micro-insert location; and 2) fallopian tube occlusion. Only if micro-insert location is satisfactory and there is evidence of bilateral occlusion of the fallopian tubes, may the physician instruct the patient to discontinue use of alternative contraception and rely on the **Essure** micro-inserts for pregnancy prevention.

The following steps should be followed for performing and evaluating the HSG.

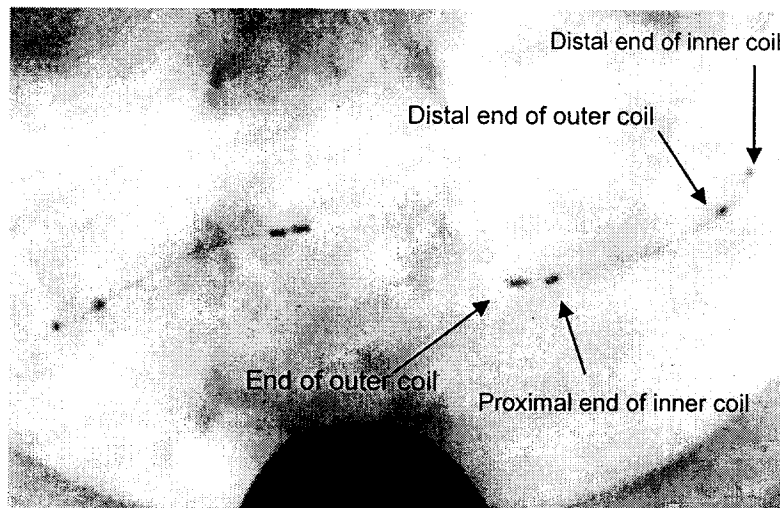
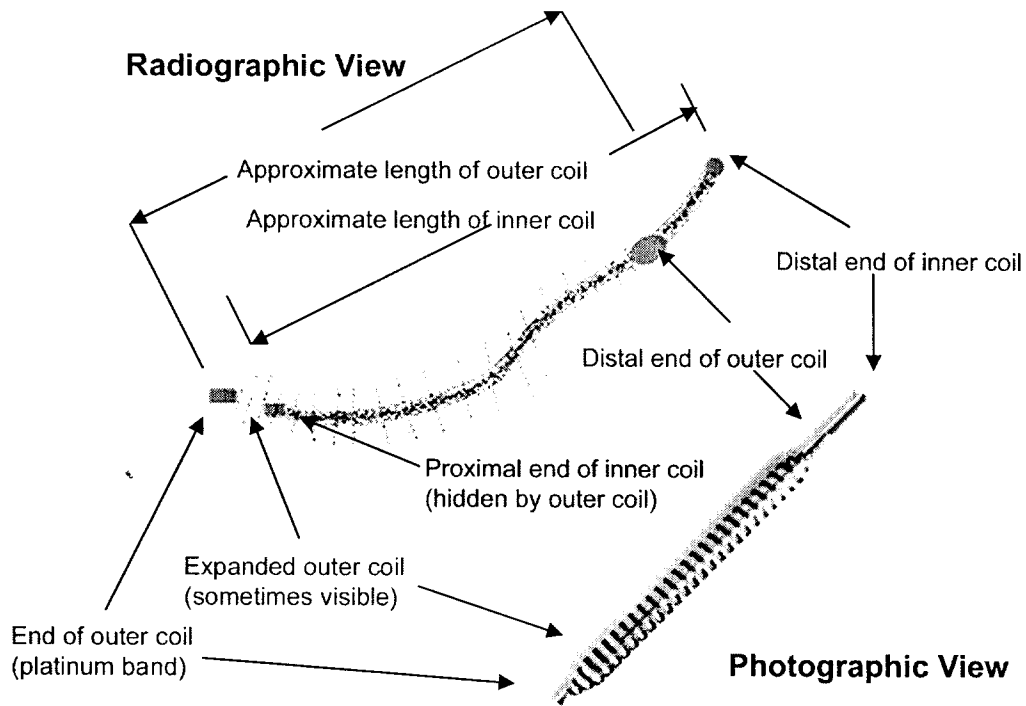
### **A. Performing the HSG**

One objective of the HSG is to evaluate the relationship of the proximal end of the inner coil of the micro-insert to the uterine cornua, thus verifying that the micro-insert spans the UTJ. In order to achieve this, the following guidelines should be adhered to:

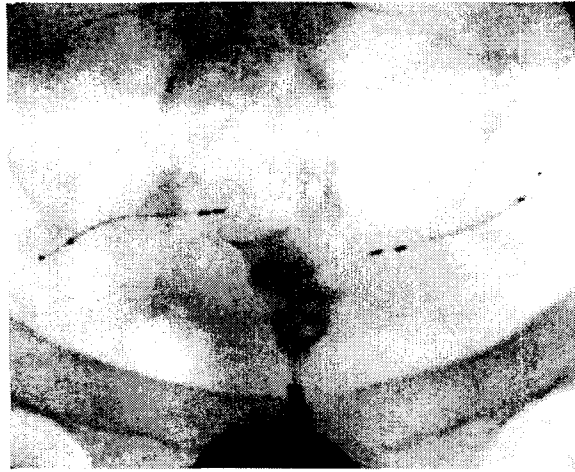
1. The uterine cavity silhouette must be clearly seen with good cornual filling.
2. The fluoroscopy beam with respect to the uterus should be as close to A/P projection as possible.

3. A good cervical seal should be maintained throughout the procedure to ensure good uterine distension. Accordingly, do not dilate unless necessary.
4. Downward traction on the cervical tenaculum may be required in patients having a midpositional uterus, to allow for ideal images of the uterine cavity. The speculum should be removed prior to fluoroscopy in order to assure the best possible visualization of uterine anatomy.
5. A minimum of six still radiographs should be taken to assess micro-insert location and tubal occlusion. A description of each radiograph is provided below with associated pictures.

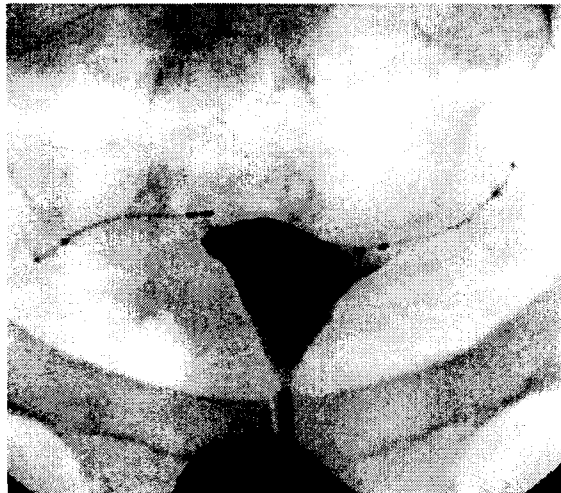
NOTE: Assessment of the location of the micro-inserts on HSG is not the same as noted at hysteroscopy. Therefore, a correctly placed micro-insert may appear to be more distal on HSG than noted at the time of hysteroscopy.



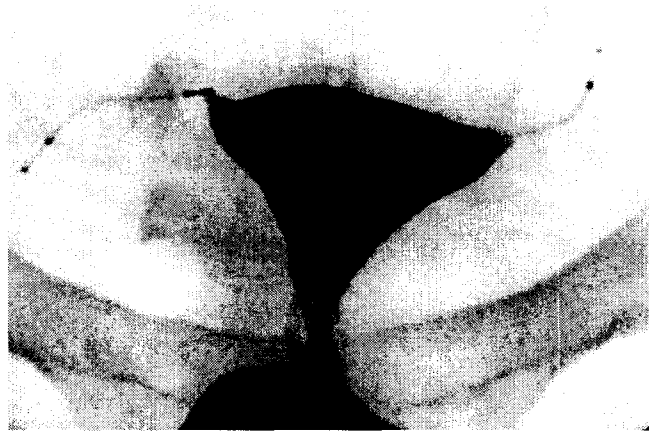
**Radiograph 1 – “Scout Film”:** Capture an image of the uterus immediately prior to infusion of contrast into the uterine cavity. The **Essure** micro-inserts should be clearly seen. The lie and curvature of the micro-inserts should be noted.



**Radiograph 2 – Minimal Fill of the Cavity:** Capture an image of the uterus after a small amount of radio opaque contrast is instilled into the uterine cavity. This image should demonstrate evidence of an adequate seal of the uterine cervix and the beginning of opacification of the uterine cavity. In this radiograph, contrast material is likely not to have reached the uterine cornua. If the uterine cavity silhouette is not seen in a nearly A/P projection, the fluoroscopy beam and/or the patient need to be adjusted.



**Radiograph 3 – Partial Fill of the Cavity:** Capture an image of the uterus when it is nearly full of contrast or opacified. The cornua may not yet have been adequately distended. Proximal (uterine) portions of the **Essure** micro-insert may not yet be obscured by the advancing dye.



**Radiograph 4 – Total Fill of Cavity:** Capture an image of the uterus when the uterine cavity is completely filled to patient tolerance or maximal distension of the cornua has been achieved, whichever comes first. In this image, the advance of contrast (i.e., opacification) is likely to meet or obscure the proximal (uterine) portions of the **Essure** micro-inserts.

**NOTE:** An increase in volume of the intracavitary contrast, with resultant increase in intrauterine pressure, is often needed to allow for a satisfactory image.

**CAUTION:** An increase in intrauterine pressure beyond that needed to produce image #4 serves no purpose and should be avoided, so as to avoid undue patient discomfort and the possibility of resultant vaso-vagal reaction such as profound bradycardia, lightheadedness, sweating and fainting.





**Radiograph 5 & 6- Magnifications of uterine cornua:** Once the uterine cornua are filled to maximum distension, magnified views of both right and left cornua should be obtained, highlighting the position of the micro-insert in reference to the uterine cornua.

### **B. Evaluating HSGs**

When evaluating the HSG, it is important to first confirm that the appropriate radiographs described above are provided, a good A/P image of the uterine silhouette is obtained, and the uterus is maximally distended in at least one view. The HSG will need to be immediately repeated if:

1. The appropriate sequence of radiographs has been captured but one or both uterine cornua are not maximally distended;
2. The projection of the silhouette is fundal rather than A/P;
3. The appropriate sequence of radiographs was not taken, and/or the uterine cornua are not distended or are otherwise obscured making evaluation of micro-insert position impossible or equivocal.

### **C. Micro-insert Location**

In evaluating micro-insert position it is important to note the “markers” for the proximal end of the micro-insert (the end of the inner coil and the platinum band of the outer coil). Micro-insert position is then evaluated according to its relationship to the distended uterine cornua. **Ideal micro-insert location is when the inner coil of the micro-insert crosses the utero-tubal junction.**

The following scale should be used to categorize assessment of micro-insert location (please refer to the Physician Training Manual for sample HSGs that depict these categories):

- 1 - Micro-insert not present, OR more than 50% of the length of the inner coil of the micro-insert is trailing into the uterine cavity.
- 2 - Distal end of the inner coil is within the tube, with <50% of the length of the inner coil trailing into the uterine cavity, OR the proximal end of the inner coil appears to be up to 30 mm into the tube from where contrast fills the uterine cornua.
- 3 - Micro-insert is in the tube but proximal end of the inner coil appears to be more than 30mm distal into the tube from the contrast filling the uterine cornua, OR the micro-insert is within the peritoneal cavity.

**A patient with micro-insert location that is rated to be in categories 1 or 3 should not rely on the Essure micro-inserts for contraception.**

#### **D. Occlusion**

The most critical aspect of evaluating tubal occlusion is determining whether the contrast is visible in the tube beyond the micro-insert. It is also important to note any degree of proximal tubal filling with contrast even if the tube is occluded.

The following scale should be used to categorize assessment of tubal occlusion:

- 1 - Tube is occluded at the cornua.
- 2 - Contrast seen within the tube but not past any portion of the length of the outer coil of the micro-insert (i.e., past the distal end of the outer coil, see Diagram above for Radiograph #1).
- 3 - Contrast seen past the distal end of the micro-insert or in the peritoneal cavity.

If tubal occlusion is rated to be in categories 1 or 2 above, and micro-insert location is satisfactory (category 2 above), then the patient may be instructed to discontinue alternative contraception. If occlusion is rated as a 3 and micro-insert location is satisfactory at the 3 month HSG, then the patient should remain on alternative contraception for 3 more months and have a repeat HSG. **If occlusion is again rated as a 3, then she should be advised to not rely on the Essure micro-inserts for contraception.**

## **XVII. PATIENT INFORMATION BOOKLET AND PATIENT ID CARD**

The Patient Information Booklet contains valuable information for patients considering treatment with the **Essure System**. Please be sure to provide a copy of this brochure to all patients considering treatment with the **Essure System**. Also, a patient ID card is supplied with each Essure System. Please provide one of these cards to any patient who receives implantation of an Essure micro-insert.

## **XVIII. REFERENCES**

1. Peterson HB, Xia Z, Hughes JM, et al. The risk of pregnancy after tubal sterilization: Findings from the U.S. Collaborative Review of Sterilization. *Am J Obstet Gynecol* 1996; 174:1161-1170.

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The Essure system is covered under U.S. Patent No. 6,176,240. Other patents pending.

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For more information on the *Essure*<sup>™</sup> procedure, please speak to your doctor.

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