

essure[®]
permanent birth control



- An Essure Confirmation Test should be performed three months after insert placement to evaluate insert retention and location. The patient must use alternative contraception until an Essure Confirmation Test demonstrates satisfactory results (see section XII 'Essure Confirmation Test').
- There have been reports of perforation of the uterus and/or fallopian tubes, inserts located in the intra-abdominal or pelvic cavity, persistent pain, and allergy or hypersensitivity reactions in some patients. Some of these reported events resulted in insert removal that required abdominal surgery. Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered. This information should be shared with patients considering sterilization with Essure during discussion of the benefits and risks of the device.

IMPORTANT: Device to be used only by physicians who are skilled hysteroscopists; have read and understood the Instructions for Use and Physician training materials; and have successfully completed the Essure training program, including preceptoring in placement until competency is established, typically 5 cases.

INSTRUCTIONS FOR USE

I. Product Description

Overview of Essure Procedure and Principles of Operation

The **Essure (Essure®)** System for Permanent Birth Control Model ESS 305 is designed for permanent contraception by physical occlusion of the fallopian tubes. Using a transvaginal approach, one **Essure** insert is placed in the proximal portion of the fallopian tube lumen. When the insert expands upon release, it conforms to and acutely anchors in the lumen of the fallopian tube. Subsequently, the insert elicits a benign tissue in-growth that permanently occludes the lumen of the fallopian tube, resulting in permanent contraception.

Step 1: Essure insert placement procedure.

NOTE: Patient must remain on alternative contraception until a satisfactory **Essure** Confirmation Test is documented.

Step 2: Essure Confirmation Test must show fallopian tube(s) with either satisfactory insert location (when using a transvaginal ultrasound (TVU) and/or X-ray) or both satisfactory insert location and occlusion (when using a modified hysterosalpingogram (modified HSG)) before the patient can rely on **Essure** for contraception.

Device Description

The **Essure**[®] Permanent Birth Control System is comprised of several components. The **Essure** insert, a dynamically expanding insert, is attached to a delivery wire and a release catheter. The entire assembly is sheathed within a delivery catheter. This system, (shown in Figure 1), is attached to a handle that facilitates insert delivery and deployment. The insert is designed with a 15 degree angle at the tip to facilitate entry into the fallopian tube. A valved **DryFlow**[®] Introducer, (Figure 1d) is also provided with the **Essure** system. It is intended to help protect the **Essure** insert as it is being passed through the rubber port of the hysteroscope working channel.

Figure 1a
Essure Delivery System
Showing detail of placement procedure symbols.
(NOT TO SCALE)

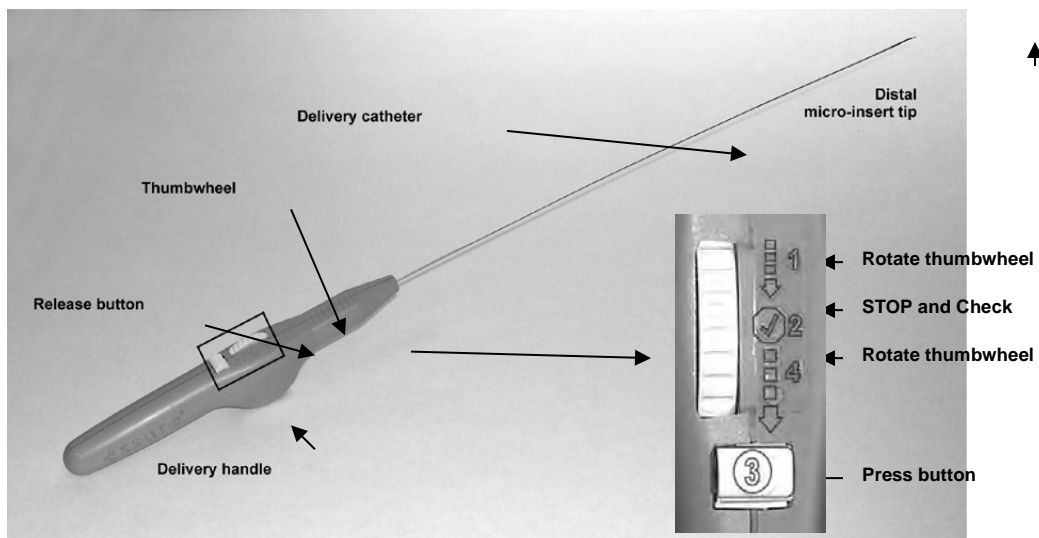


Figure 1b: Essure Insert: Wound-down configuration, attached to the delivery system. The wound-down insert is approximately 4 cm in length and 0.8 mm in diameter. (NOT TO SCALE)

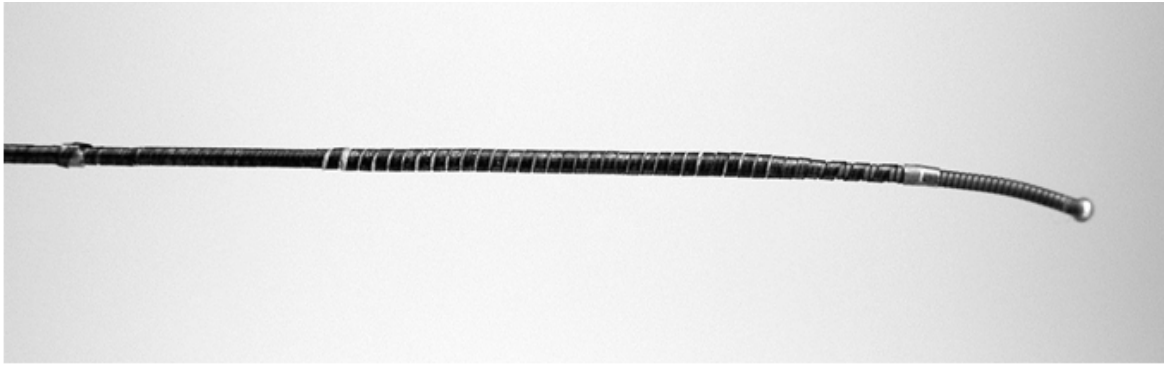


Figure 1c: Essure Insert: Expanded configuration, detached from the delivery system. When released, the outer coil expands up to 2.0 mm in diameter, conforming itself to the varied diameters and shapes of the fallopian tube. **(NOT TO SCALE)**



Each insert consists of a Nitinol (nickel-titanium alloy) outer coil, a 316L stainless steel inner coil wrapped in polyethylene terephthalate (PET) fibers, platinum marker bands (2) and a silver-tin solder.

Figure 1D: DryFlow Introducer
(NOT TO SCALE)



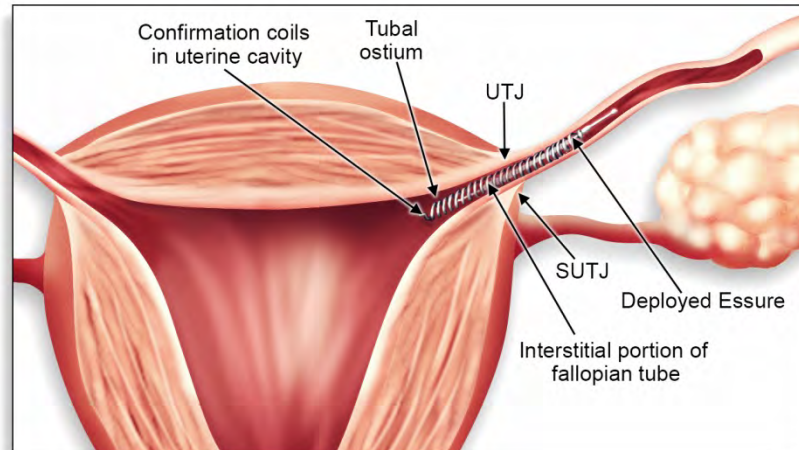
II. Mechanism of Action

Under hysteroscopic visualization, the **Essure** system is delivered by the physician to the proximal section of the fallopian tube utilizing the delivery system.

A. Placement at Utero-Tubal Junction

Optimal placement occurs when the insert spans the serosal utero-tubal junction (SUTJ), as viewed on transvaginal ultrasound (Figure 2) or the utero-tubal junction (UTJ) as visualized on a modified HSG. The serosal utero-tubal junction (SUTJ) refers to the anatomical location where the fallopian tube intersects with the serosal boundary of the uterus. This term is used when imaging is performed by ultrasound. The utero-tubal junction (UTJ) refers to the region identified by HSG where contrast material enters the proximal fallopian tube.

Figure 2: Optimal Essure Insert Placement



B. Dynamic Anchoring

The insert is a dynamic and flexible spring-like device. The outer coil expands upon deployment, conforms to and pushes against the fallopian tube wall, acutely anchoring the insert in the lumen of the fallopian tube.

C. Tubal Occlusion and Tissue In-Growth

Tubal occlusion is attributed to the space filling design of the device and the benign occlusive tissue response. PET fiber causes tissue in-growth into and around the insert, facilitating insert retention, resulting in tubal occlusion and contraception.

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.

III. Indications for Use

The **Essure** system is intended for use as a tubal occlusion insert for purposes of permanent contraception.

IV. Contraindications for Use

- Patient uncertainty about her desire to end fertility.
- Pregnancy or suspected pregnancy.
- Delivery or a termination of a second trimester pregnancy less than 6 weeks before **Essure** insert placement.
- Active upper or lower genital tract infection.
- Unexplained vaginal bleeding.
- Gynecological malignancy (suspected or known).
- Known abnormal uterine cavity that makes visualization of the tubal ostia impossible and/or abnormal tubal anatomy or previous tubal ligation (including failed tubal ligation).
- Allergy to contrast media (a modified HSG may be required for the **Essure** Confirmation Test).

V. Warnings and Precautions

General

WARNINGS

- The **Essure** procedure should be considered irreversible. Safety and effectiveness of insert removal for restoration of tubal patency is unknown.
- Unilateral placement may be performed in patients with confirmed history of salpingectomy or unicornuate uterus. Unilateral tubal occlusion demonstrated by HSG alone is not sufficient evidence to allow for unilateral placement.
- Pain (acute or persistent) of varying intensity and length of time may occur and persist following **Essure** placement. Individuals with a history of pain are more likely to experience both acute and chronic pelvic pain following **Essure** placement. Unsatisfactory device location including perforation, uterine embedment and expulsion may result in pain. Patients should be advised to contact their physician if there is significant pain or if pain persists. Not all pain will be related to the **Essure** insert; therefore, other unrelated gynecological (e.g. endometriosis, adenomyosis) or non-gynecological (e.g., irritable bowel syndrome, interstitial cystitis) conditions that may result in pain should be considered. (see section VII ‘Adverse Effects’, subsection ‘Pain’)
- Surgery including device removal, hysterectomy or other procedures may be required to treat the pain (see section XIV ‘Essure Insert Removal’), (see section VII ‘Adverse Effects’, subsection ‘Pain’).
- Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered.

- Patients with known hypersensitivities to nickel, platinum, titanium, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the **Essure** system (see section I ‘Product Description’) may experience an allergic reaction to the insert. This includes both patients with or without a history of metal allergies; there are no known diagnostic tests that are predictive of allergic reactions to any of the components of **Essure**. In addition, some patients may develop an allergy to nickel or other components of the insert following placement within the fallopian tube. Symptoms reported for this device that may be associated with an allergic reaction include hives, urticaria, rash, angioedema, facial edema and pruritis. Patients should be counseled on the materials contained in the insert prior to the **Essure** procedure.
- Patients on active immunosuppressive therapy (e.g. systemic corticosteroids or chemotherapy) may experience delay or failure of the necessary tissue in-growth needed for tubal occlusion. For these patients, physicians must use the modified HSG as the **Essure** Confirmation Test. TVU or pelvic X-ray should not be utilized for confirmation, as these tests cannot confirm tubal occlusion. Clinical trials were not conducted with patients undergoing immunosuppressive therapy.

PRECAUTIONS

- The **Essure** procedure should only be performed by skilled hysteroscopists who have completed the **Essure** training program (Clinical Pathway), including preceptoring in placement until competency is established, typically 5 cases.
- Women undergoing sterilization at a younger age are at greater risk of regretting their decision.
- Safety and effectiveness of **Essure** is not established in patients under 21 or over 45 years old at the time of placement.
- Do not use the **Essure** system if the package is open or damaged. Do not use if the insert is damaged.
- Never attempt to re-sterilize the **Essure** system as it is single use only. Resterilization may adversely affect device function or cause patient injury.

Pregnancy Risk

WARNINGS

- Pregnancies, including ectopic pregnancies, have been reported among women who have undergone the **Essure** procedure.
- The patient must use alternative contraception until an **Essure** Confirmation Test performed three months post- insert placement demonstrates satisfactory results.
- If the **Essure** inserts are not properly placed or are not in a satisfactory location, then the patient should be advised to not rely on **Essure** and use alternative contraception.

- In the case of unintended pregnancy with **Essure in situ**, **Essure** cannot be relied on for contraception and alternative contraception is required to prevent subsequent unintended pregnancies.
- Physicians must adhere to the **Essure** Confirmation Test protocol (see section XII ‘**Essure** Confirmation Test’). Incorrect execution and/or interpretation of the **Essure** Confirmation Test results have led to unintended pregnancy.
- Effectiveness rates for the **Essure** procedure are based on patients who had bilateral placement. Limited effectiveness data exist for unilateral insert placement in patients with, unicornuate uteri, or contralateral proximal tubal occlusion (PTO) or prior tubal surgery.
- If the patient conceives and chooses to continue an intrauterine pregnancy, she should be informed that there may be risks of an in situ insert to the patient, to the fetus, and to the continuation of the pregnancy. While most pregnancies with **Essure in situ** have been reported as healthy deliveries at term, pregnancy loss, pre-term labor, pre-term rupture of membranes, pre-term delivery, stillbirth, and neonatal complications have also been reported.

Procedure

WARNINGS

- In order to reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.
- Never attempt to advance **Essure** insert against excessive resistance. If a perforation occurs or is suspected, do not continue with **Essure** insert placement attempt and monitor the patient for signs and symptoms of possible complications related to perforation which may include unusual post-operative pain. If unusual post-operative pain occurs, imaging to localize the insert should be performed prior to the 3 month confirmation test. A very small percentage 12/682 (1.8%) of women in **Essure** clinical trials were identified as having device related perforations. Retrieval of perforating inserts, if necessary, will require surgical removal (see section XIV. ‘**Essure** Insert Removal’). A false positive modified HSG and pregnancy have been associated with tubal perforation by the insert in the literature; evaluate **Essure** Confirmation Test for perforation if excessive resistance is experienced during the procedure.
- If **Essure** insert placement attempts are not successful after 10 minutes of attempted cannulation per tube or excessive resistance is encountered, avoid repeated attempts at cannulation, terminate the procedure and potentially reschedule the procedure.
- Terminate the procedure if distention fluid deficit exceeds 1500cc, to reduce the risk of hypervolemia. Excess fluid deficit may signal uterine or tubal perforation. If noted, discontinue procedure and evaluate patient for possible perforation.
- Once the insert has been placed (i.e., detached from the delivery wire), hysteroscopic insert removal (at the time of placement procedure) should not be attempted, unless 18 or more coils of the **Essure** insert are trailing into the uterine cavity indicating proximal placement. Removal of such an insert should be attempted immediately following the placement (see section XIV ‘**Essure** Insert Removal’, subsection ‘At time of Placement

Procedure’). Attempted removal with less than 18 trailing coils may result in a fractured insert, fallopian tube perforation, or other injury.

PRECAUTIONS

- Adequate visualization of the uterine anatomy and tubal ostia is required.
- Timing of the procedure to the early proliferative phase of the menstrual cycle should:
Enhance visualization of the uterine cavity and fallopian tube ostia.
 - Decrease the potential for insert placement in a patient with an undiagnosed pregnancy.
- Pre-treatment of the patient with medications that suppress endometrial proliferation may minimize intra-uterine debris and improve visualization during the procedure.
- Use an introducer to avoid insert tip damage.
- Unusual uterine anatomy may make it difficult to place the **Essure** insert(s).
- Keep the operating channel of the hysteroscope open to avoid damage to insert or introducer.
- All tubal ostia for which occlusion is planned should be identified and assessed hysteroscopically prior to proceeding to **Essure** insert placement. No attempt should be made to place an insert in the tubal ostium unless fallopian tube(s) appear to be accessible.
- When introducing the **Essure** insert into the fallopian tube, never advance the insert(s) against excessive resistance. Do not advance the **Essure** system if the patient is experiencing excessive pain or discomfort.
- Do not continue to advance the **Essure** system once the end of the black positioning marker on the catheter has reached the tubal ostium. Advancement beyond this point could result in unsatisfactory insert placement or tubal/uterine perforation.
- If breakage of any component (e.g., catheter or insert) occurs during placement, all fragments should be removed (see section XIV ‘**Essure** Insert Removal’).
- Do not deploy more than one insert in a single fallopian tube during the same procedure. If a physician suspects that the device has not deployed in the tube (e.g., sees no trailing coils), the physician must ensure that the insert is not in the tube by inspection of the delivery system to verify deployment has not occurred. Refer to Figure 11 which shows delivery system before and after deployment. If needed, imaging (e.g. X-ray or TVU) may be used.

Interactions with Other Procedures

Patients who undergo placement of the **Essure** insert may, in future years, be offered gynecological therapies that may pose additional risk due to the presence of the insert:

WARNINGS

- DO NOT perform the **Essure** procedure concomitantly with endometrial ablation. Ablation causes intrauterine synechiae which can compromise (i.e., prevent the proper interpretation of) the modified HSG, which may be required for the **Essure** Confirmation Test. Women with inadequate confirmation tests cannot rely on **Essure** for contraception.
- Endometrial ablation can result in thermal injury to the gastrointestinal (GI) tract or abscess formation around the inserts. This could cause bowel or bladder injury if there is an unrecognized tubal perforation and part of the insert lies outside of the tubal serosa. Endometrial ablation (if medically appropriate) should only be performed after correct location of the **Essure** insert is confirmed by a satisfactory **Essure** Confirmation Test, in order to minimize the risk of injury to the surrounding tissue (e.g. bowel).
- During endometrial ablation, thermal injury to the proximal portion of the fibrotic ingrowth that causes tubal occlusion may occur. It is unknown whether thermal injury will interfere with tubal occlusion. Bench and clinical studies have been conducted which demonstrate that endometrial ablation of the uterus can be safely performed with **Essure** insert in place after a satisfactory confirmation test has been performed. Contraception rates following NovaSure Endometrial Ablation System with **Essure** inserts in place are under investigation.
- Performing intrauterine procedure such as endometrial ablation, endometrial biopsy, dilation and curettage (D&C) and hysteroscopy (diagnostic or operative) may result in trailing coils of the insert being ensnared in another device. When the device/instrument is withdrawn, the insert may be stretched or removed and tubal patency may be restored.
- Some surgical instruments utilize energy sources such as electrical current, radio frequency, thermal energy, or freezing (e.g., cryotherapy). There is a risk of fragmentation of the insert and/or conduction of energy to surrounding structures if these energy sources are used adjacent to or in contact with the insert. There may be risks associated with such procedures that, at this time, have not been identified. Avoid direct contact between the **Essure** inserts and monopolar radio frequency (RF) when performing endometrial ablation during operative hysteroscopy as this may cause injury to surrounding tissue.
- Endometrial ablation using microwave energy is contraindicated when an **Essure** insert is in place.
- Other surgical instruments such a morcellator, clamp, or scissors can result in fragmentation of the inserts and should therefore be avoided or used with caution in proximity to the insert. If fragmentation occurs, intra-operative imaging to localize the fragments should be performed and the fragments should be removed, as determined by the physician's judgment. Care must be taken to completely remove the insert(s) when performing a hysterectomy when the adnexa are being retained.

PRECAUTIONS

- Use caution and avoid the **Essure** inserts when undertaking blind intrauterine procedures as disturbing the inserts could interrupt their ability to prevent pregnancy. Direct visualization of inserts during intrauterine procedures is optimal. Insert retention and location may need to be verified following intrauterine procedures if there is a concern of entanglement with the insert. Modalities that may be used for this purpose include hysteroscopy, X-ray, HSG, or TVU. There could be risks associated with intrauterine procedures and the presence of inserts not currently identified.
- Performing endometrial ablation following placement of **Essure** inserts may increase the risk of post-ablation tubal sterilization syndrome, a rare condition that has been reported in women with a history of tubal sterilization who undergo endometrial ablation.
- There are limited data related to the effects, including risks, of **Essure** inserts on in vitro fertilization (IVF).

MRI Safety Information

Non-clinical testing has demonstrated the ESS305 insert is MR Conditional. It can be scanned safely under the following conditions:

- o Static magnetic field of 3.0 T or less
- o Maximum spatial gradient field of 720 Gauss/cm (7.2 T/m) or less
- o Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 3 W/kg (First Level Controlled Operating Mode)
- o Using a transmit/receive RF body coil
- o Under the scan conditions defined above, the ESS305 insert is expected to produce a maximum temperature rise of 1.7 °C after 15 minutes of continuous scanning.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the **Essure** insert. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Dimensions: Wound-down and expanded length: 4-cm

Expanded diameter: 1.5 to 2.0-mm

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	173-mm ²	53-mm ²	621-mm ²	277-mm ²

Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular
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Post-procedural management

WARNINGS

- Counsel the patient on the need for the **Essure** Confirmation Test, the options for the confirmation test including their risks and benefits, and the possibility of an increased risk of unintended pregnancy, if the **Essure** Confirmation Test is unsatisfactory. If the **Essure** Confirmation Test is unsatisfactory, the patient must continue using an alternative form of birth control.
- Following **Essure** placement and prior to the confirmation test at three months, the patient must use alternative contraception and should use the most appropriate means of contraception for which she is a candidate during this time.

PRECAUTIONS

- Counsel the patient that **Essure** placement may not be successful and discuss management options in the event of this outcome.

VI. Patient Counseling Information

Important Factors to be discussed with the Patient

- Patient must be certain about her desire to end fertility.
- The procedure is permanent, and irreversible. Safety and effectiveness of insert removal for restoration of tubal patency is unknown.
- It is important that all patients seeking to undergo the **Essure** procedure understand the risks and benefits of **Essure**.
- No contraceptive method is 100% effective. Like all birth control methods, there is a risk of pregnancy; pregnancies have been reported with **Essure**.
- A complete medical and social history should be obtained to determine if the patient has a condition that may make her an unsuitable candidate or place her at increased risk for adverse events. Patients should be encouraged to discuss any history of chronic pain, mental health disorders including a clinical diagnosis of depression during her consultation visit. Results of an evaluation for pelvic infection, undiagnosed vaginal bleeding, anatomical variants and/or uterine pathology may make patient unsuitable for the procedure.
- Patients with known hypersensitivity to nickel, platinum, titanium, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the **Essure** system (see section I ‘Product Description’) may experience an allergic reaction to the insert. This includes both patients with or without a history of metal

allergies; there are no known diagnostic tests that are predictive of allergic reactions to any of the components of Essure. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Typical allergic symptoms reported for this device include hives, urticaria, rash, angioedema, facial edema and pruritis. All patients should be counseled on the materials contained in the insert, as well as potential for allergy/hypersensitivity prior to the **Essure** procedure. Currently, there is no test that reliably predicts who may develop a hypersensitivity reaction to the materials contained in the insert.

- Patient must use alternative contraception for at least three months post-placement procedure, until a satisfactory **Essure** Confirmation Test is documented. Physician must counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all steps of the **Essure** procedure. Ensure patient is supplied with the most effective means of contraception for which she is a candidate during this time frame.
- Discuss the three methods utilized in the **Essure** Confirmation Test (Pelvic X-ray, TVU and modified HSG). Inform patients of the differences between the methods, including benefits and risks.
- The management of adverse events may include surgery and removal of the inserts. Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered. The management of an unsatisfactory confirmation test may include a repeat of the **Essure** procedure or alternative contraception, including laparoscopic tubal sterilization.
- As with any procedure, hysteroscopic placement of **Essure** inserts into the fallopian tubes is NOT without risks. **Essure** placement is an elective procedure, and the patient must be well counseled and understand the risk/benefit relationship. The patient should read the Patient Information Booklet (PIB). While the PIB is not intended to replace appropriate physician counseling, each patient should receive the PIB during their initial visit/consultation to allow her sufficient time prior to the procedure to read and adequately understand the important information on the risks, the need for the confirmation test, and the contraceptive benefit associated with **Essure**. Allow the patient adequate time after reviewing and considering this information before deciding whether to have the **Essure** procedure. The Patient-Doctor Discussion Checklist should be reviewed with the patient, and all of the patient's questions answered.
- Warnings, precautions, important factors to consider including possible adverse events.
- The decision to undergo treatment is at the patient's discretion, following physician counseling and informed consent.
- Following the procedure, the patient should be counseled to inform all of her healthcare providers that she has the inserts prior to any planned gynecological, lower abdominal surgical or imaging procedure.

IMPORTANT: Counsel patients that this product does not protect against either HIV infection or other sexually transmitted infections.

VII. Adverse Effects

ADVERSE EVENTS IN PHASE II/PIVOTAL PREMARKETING STUDIES

A. Patient Population

From November 1998 - June 2001, a total of 745 women underwent the **Essure** procedure in two clinical trials that evaluated safety and effectiveness (227 Phase II; 518 Pivotal¹). Placement of at least one insert was achieved in 682 women (206 Phase II study; 476 Pivotal). If bilateral placement was not initially achieved, some women underwent additional procedure(s).

B. Observed Adverse Events

Adverse events resulting from the **placement procedure** are detailed in **Table 1**.

Table 1

Adverse events reported day of placement procedure in Phase II & Pivotal Trials

Adverse Event/ Side Effect	Phase II Trial		Pivotal Trial	
	Number (N=233 procedures)	Percent	Number (N=544 procedures)	Percent
Cramping	**	**	161	29.6%
Pain	2	0.9%	70	12.9%
Nausea/vomiting	**	**	59	10.8%
Dizziness/light headed	**	**	48	8.8%
Bleeding/spotting	**	**	37	6.8%
Other	**	**	16*	2.9%
Vaso-vagal response	2	0.9%	7	1.3%
Hypervolemia	**	**	2	0.4%
Band Detachment	3	1.3%	2	0.4%

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

**Data not collected

During and immediately following the procedure, the majority of participants experienced mild to moderate pain. The majority of participants experienced spotting for an average of 3 days after the procedure. Pain was managed with oral non-steroidal anti-inflammatory drugs (NSAIDs) or oral narcotic pain reliever.

Table 2 summarizes adverse events rated as "possibly" related to the insert or procedure during the first year of reliance in the Pivotal trial (approximately 15 months post-device placement). Percentages reflect the number of *events* divided by the number of *participants* in the trial.

¹Pivotal trial: 657 women initially enrolled; 518 underwent the procedure; 99 changed their minds about participating; 23 did not meet the inclusion criteria and were terminated from study; 17 failed screening tests.

When numerous episodes of the same event were reported by one participant, each report was counted as a separate event. Therefore, percentages may over-represent the percentage of *women* who have experienced that event.

Table 2
Pivotal Trial
Adverse Events by Body Systems, First Year of Reliance*
(N=476 patients implanted with at least one insert)

Adverse Events by Body System	Number	Percent
Abdominal:		
Abdominal pain/abdominal cramps	18	3.8%
Gas/bloating	6	1.3%
Musculo-skeletal:		
Back pain/low back pain	43	9.0%
Arm/leg pain	4	0.8%
Nervous/Psychiatric:		
Headache	12	2.5%
Premenstrual Syndrome	4	0.8%
Genitourinary:		
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%
Pain/discomfort - uncharacterized:	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 insert reported episodes of period pain, ovulatory pain, or changes in menstrual function.

OBSERVED AND POTENTIAL ADVERSE EVENTS

The following adverse events have occurred (in clinical trials and/or commercial usage) or may potentially occur during the **Essure** placement procedure and with wearing the insert; however, there is the potential that unknown risks exist. Symptoms other than those listed in the sections below have been reported by women implanted with **Essure**, although they were not seen in the clinical trials supporting **Essure** approval. The more common of these symptoms include headache, fatigue, weight changes, hair loss and mood changes such as depression. It is unknown if these symptoms are related to **Essure** or other causes.

Risks Associated with the Insert Placement Procedure

Possible adverse events that have been reported within 24 hours following the **Essure** placement procedure include; nausea/vomiting, dizziness/lightheadedness, vaso-vagal response/syncope, pain, dysmenorrhea, uterine bleeding/spotting, infection, fluid overload, anesthetic complications, detachment difficulties and unsatisfactory insert location.

Anesthesia:

- Local anesthesia, oral analgesia/sedation, regional anesthesia (i.e., spinal, epidural), oral or conscious (intravenous) sedation, or general anesthesia may be administered to the patient to prevent or reduce discomfort. Regardless of the type of anesthesia, patients may not be able to resume normal activities for 12-24 hours following the procedure.
- Serious reactions to anesthesia including general anesthesia and paracervical block have been reported. Risks and benefits associated with the planned anesthesia should be discussed prior to performing the procedure.

Intra-operative and post-operative symptoms:

- Pain, cramping, vaginal bleeding, nausea/vomiting, and dizziness, lightheaded, vasovagal response may occur during and following the insert placement procedure. Typically, these incidents are tolerable, transient and successfully treated with medication.

Device Properties and Deployment:

- Bending of the insert tip or catheter, breakage of the catheter during attempted insertion and difficulty in deployment or detachment can occur, especially in tubal ostia that are more laterally located or in cases of tubal spasm.

Unsatisfactory Insert Location:

- Any insert that is not satisfactorily located within the fallopian tube can NOT be relied on for effective contraception. Unusual pain or uterine bleeding after the placement procedure should prompt investigation of an unsatisfactory insert location.
- There is a risk of perforation or dissection of the fallopian tube or uterine cornua. Bleeding and scarring may result from such a perforation or dissection; however, treatment is typically not required.
- There is a risk of uterine perforation by the hysteroscope, **Essure** system or other instruments used during the procedure with possible injury to the bowel, bladder, and major blood vessels. Surgical intervention at the time of placement or shortly thereafter may be required, but is unlikely for most perforations. To

reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.

- Imaging may be required to identify the location of the insert(s). Removal of an unsatisfactorily located insert (perforation, embedment, migration/expulsion, proximal or distal fallopian tube placement, or within the peritoneal cavity) may require surgery for removal (see section XIV. 'Essure Insert Removal').

Fluid Overload:

- There is a minimal risk of excess fluid absorption of the physiologic saline fluid, used for distention of the uterus, to perform the hysteroscopic procedure.

Infection:

- As with all hysteroscopic procedures, the insert placement procedure can cause an infection. An infection could cause damage to the uterus, fallopian tubes, or pelvic structures which may require antibiotic therapy, or rarely, hospitalization or surgery, including hysterectomy.

Risks Associated with Essure Insert Wearing

Possible adverse events that have been reported (>24 hours) following the **Essure** placement procedure include; uterine bleeding, dysmenorrhea, dyspareunia, vaginal discharge/infection, headache, upper genital tract infection, lower abdominal/pelvic and back pain, abdominal distention/bloating, unsatisfactory insert location, hypersensitivity and allergy including rash and urticaria.

Pregnancy:

- There is a possibility of pregnancy and ectopic pregnancy each of which has risks. Most intrauterine pregnancies in patients with **Essure** that were not electively terminated and progressed beyond the first trimester have resulted in full term births. Premature labor, premature rupture of membranes, preterm delivery, stillbirth, and genetic and developmental abnormalities have been reported in pregnancies with **Essure**. Removal of **Essure** may result in termination of pregnancy and is not recommended in patients who desire continuation of pregnancy.

Pain:

- Pain (acute or persistent) of varying intensity and length of time may occur and persist following **Essure** placement. Individuals with a history of pain are more likely to experience both acute and chronic pelvic pain following **Essure** placement. Unsatisfactory device location including perforation, uterine

embedment and expulsion may result in pain. Patients should be advised to contact their physician if there is significant pain or if pain persists. Not all pain will be related to the **Essure** insert; therefore, other unrelated gynecological (e.g. endometriosis, adenomyosis) or non-gynecological (e.g., irritable bowel syndrome, interstitial cystitis) conditions that may result in pain should be considered.

- Pain and cramping may be a more likely occurrence during the menstrual period, during and after sexual intercourse or with other physical activity.
- Surgery including device removal, hysterectomy or other procedures may be required to treat the pain (see section XIV ‘**Essure** Insert Removal’).
- Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered.

Bleeding:

- Changes in the pattern or amount of menstrual bleeding have been reported. (See Table 2). Changes in menstrual bleeding may occur following discontinuation of hormonal contraception.

Infection:

- Endometritis, and pelvic inflammatory disease, including tubo-ovarian abscesses, have been infrequently reported in individuals with **Essure**. Surgery including hysterectomy may be required for treatment.

Hypersensitivity:

- Hypersensitivity reactions including hives, urticaria, rash, angioedema, facial edema and pruritis have been reported with **Essure** (see section V ‘Warnings And Precautions’). If a patient is experiencing a reaction suspected to be due to materials contained in the insert, removal of the insert should be considered (see section XIV ‘**Essure** Insert Removal’).

Sterilization Regret:

- Sterilization regret can be associated with emotional disturbances including depression. Patients should be properly counseled prior to the **Essure** procedure (see section VI ‘Patient Counseling Information’)

Risks Associated with Follow-up Procedures

- There is the risk of radiation associated with the pelvic X-ray that that may be performed three months following insert placement to evaluate insert location. There are approximately 0.033 rads in the fluoroscopic portion (< 30 seconds) of a hysterosalpingogram procedure. As a point of comparison, radiation exposure from a barium enema is 0.85 rads which is higher than the modified HSG. The amount

of radiation exposure from one pelvic X-ray is about the same as the amount an individual would receive from one year of natural background radiation.

- The following additional risks are associated with the modified HSG: vasovagal response; infection, which may require antibiotic treatment and in rare cases could require hospitalization; intravasation; perforation of the uterus; uterine cramping and/or bleeding; and pain or discomfort.
- The use of contrast media, used to perform a modified HSG which may be required for the **Essure** Confirmation Test has been associated with allergic reaction in some patients. Allergic reaction can result in hives or difficulty breathing. In some individuals, an anaphylactic response may occur which may lead to death.
- Latex exposure may occur during a procedure, and in rare cases can lead to a hypersensitivity reaction.

Risks Associated with Future Procedures

- Patients who undergo placement of the **Essure** insert may, in future years, be offered gynecological therapies that may pose additional risk due to the presence of the insert.
- Some surgical instruments utilize energy sources such as electrical current, radio frequency, thermal energy, or freezing (e.g., cryotherapy). There is a risk of fragmentation of the insert and/or conduction of energy to surrounding structures if these energy sources are used adjacent to or in contact with the insert. There may be risks associated with such procedures that, at this time, have not been identified. Endometrial ablation using microwave energy must not be performed in the presence of the **Essure** insert.
- Other surgical instruments such as a morcellator, clamp, or scissors can result in fragmentation of the inserts and should therefore be avoided or used with caution in proximity to the insert. Care must be taken to completely remove the insert(s) when performing a hysterectomy when the adnexa are being retained (see section XIV ‘**Essure** Insert Removal’).
- Endometrial ablation (if medically appropriate) should only be performed after correct location of the **Essure** insert is confirmed by a satisfactory **Essure** Confirmation Test, in order to minimize injury to the surrounding tissue (e.g. bowel). Bench and clinical studies demonstrated that endometrial ablation of the uterus can be safely and effectively performed with properly located **Essure** inserts.
- Any intrauterine procedure such as endometrial biopsy, D&C, hysteroscopy (diagnostic or operative) including endometrial ablation could interrupt the ability of the inserts to prevent pregnancy. Endometrial ablation can result in thermal injury to the GI tract or abscess formation around the inserts. It may also cause intrauterine synechiae that can compromise conduct and interpretation of a modified HSG which may be needed for the **Essure** Confirmation Test.
- Performing endometrial ablation following placement of **Essure** inserts may increase the risk of post-ablation tubal sterilization syndrome, a rare condition that

has been reported in women with a history of tubal sterilization who undergo endometrial ablation.

- There are limited data related to the effects, including risks of **Essure** inserts on in vitro fertilization (IVF).
- The **Essure** inserts are radiopaque. The **Essure** inserts are MR conditional, except for pelvic imaging, where they may cause some artifacts (see section V ‘Warnings and Precautions’, subsection ‘MRI Safety Information’).

Adverse Event Reporting

For reporting of adverse events, please contact your local **Essure** Representative.

VIII. Clinical Studies

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

Two clinical trials were conducted (Phase II Trial; Pivotal Trial) to demonstrate safety and effectiveness of the **Essure** system in providing permanent contraception prior to marketing. The ESSTVU study was conducted to evaluate the effectiveness of the **Essure** procedure when using the TVU/HSG Confirmation Test Algorithm. All clinical trials prior to ESSTVU study used the modified HSG only as the **Essure** Confirmation Test.

1. Phase II Trial with modified HSG confirmation testing

Phase II was a prospective, multi-center, single-arm, non-randomized, international study which evaluated:

- Participant’s tolerance of, and recovery from, procedure
- Safety of the procedure
- Participant’s tolerance of implanted inserts
- Long-term safety and stability of implanted inserts
- Effectiveness of the inserts in preventing pregnancy

2. Pivotal Trial with modified HSG confirmation testing

The Pivotal trial was a prospective, multi-center, single-arm, non-randomized, international study which used the U.S. Collaborative Review of Sterilization (CREST study) as a qualitative benchmark. The study included the following primary endpoints:

- Prevention of pregnancy
- Safety of insert procedure
- Safety of insert wearing

Secondary endpoints included:

- Participant satisfaction with procedure
- Participant satisfaction with insert wearing
- Bilateral device placement rate
- Profile development for appropriate procedure candidates

3. ESSTVU Study with TVU/HSG Confirmation Testing Algorithm

The ESSTVU Study was a prospective, multi-center, single-arm, non-randomized international study to evaluate the effectiveness of the **Essure** procedure when the TVU/HSG Confirmation Test Algorithm is used for confirmation testing. The study included the following primary endpoints:

- Occurrence of confirmed pregnancy at 1 year among subjects relying on **Essure** inserts for birth control on the basis of the **Essure** (TVU/HSG) Confirmation Test Algorithm.
- Intent-to-treat reliance rate 3 months following **Essure** (TVU/HSG) Confirmation Test Algorithm.

B. Patients Studied

Table 3

Age Distribution (Combined Data from Pivotal Study and Phase II Study); Average age: 33

<28 years old	28-33 years old	≥34 years old
14%	40%	46%

Table 4

Patient Demographics

	Phase II and Pivotal Studies Combined N=745
Race*	
White/Caucasian	428
Latin	31
Black	24
Other	9
Gravidity	Mean=2.91 (0 – 11)
Parity	Mean=2.23 (0 – 6)
Body Mass Index (BMI) (kg/m²)	Mean=27 (16-57)

*Data from Pivotal study only; race not collected in Phase II study.

1. The Phase II and Pivotal trials combined consisted of 664 participants in whom bilateral insert placement was achieved after one or more attempts (200 Phase II study; 464 Pivotal). **Tables 6 and 7** present patient demographic information. Participants were between 21 and 45 years of age and seeking permanent contraception. All participants had at least one live birth, regular menstrual cycles and were willing to use alternative contraception for the three months following the procedure.

2. The study population of the ESSTVU Study consisted of 597 women in whom insert placement was attempted. Subjects were enrolled at 20 sites (12 in the US and 8 outside of the US). All study participants were between 21 and 44 years of age and were seeking permanent contraception prior to enrollment.

C. Methods

All study participants were screened for eligibility. Medical history, physical examination and required laboratory tests were performed.

Insert placement was attempted in each fallopian tube. In the Phase II/Pivotal trial, pelvic X-rays were performed within 24 hours of placement to serve as a baseline evaluation of insert location. Participants used alternative contraception for three months following the procedure.

In the ESSTVU study, TVU, modified HSG, or both were utilized in the **Essure** Confirmation Test algorithm in accordance with the current labeling. For TVU confirmation tests done in this study, endovaginal ultrasound probes with center frequencies from 5.8 to 6.5 MHz were utilized. In all other trials, a modified HSG was performed three months post procedure to evaluate insert location and fallopian tube occlusion. If bilateral placement and occlusion were satisfactory, participants discontinued alternative contraception and relied on the inserts for contraception.

D. Results

As of the final 5-year follow-up data extracts of the Phase II study-(January 6, 2006) and Pivotal Study-(December 5, 2007), 643 trial participants with bilateral placement (194 Phase II; 449 Pivotal) contributed 35,633 months of follow-up time with zero pregnancies reported.

In the most recent clinical study, ESSTVU, 547 trial participants were instructed to rely on **Essure** for contraception. The TVU/HSG Confirmation Test Algorithm was used as the confirmation test. In this study, three pregnancies were reported in the 1 year follow up. All three pregnancies occurred in women who had TVUs to confirm **Essure** placement.

Adverse events reported in the Pivotal and Phase II clinical studies conducted prior to marketing are provided in **Tables 1 and 2** in Section VII B above. **Tables 5A, 5B and 6A and 6B** present principal effectiveness results.

**Table 5A –Insert Placement Rate*
(ESSTVU Trial)**

Placement Status	ESSTVU Study	
	Number	Percent
Procedure Initiated**	597	100%
Insert Placement Attempted***	594/597	99%
Bilateral Placement after first attempt	574/597	96%

Bilateral Placement after first or second attempt	582/597	97%
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* Assessed at time of placement

** Intent-to-treat population in the ESSTVU trial includes all participants who had the **Essure** procedure initiated (i.e. all study subjects who entered the procedure room/operating room with the intent to undergo the procedure).

*** All subjects where the **Essure** system was passed through the working channel of the hysteroscope.

**Table 5B – Insert Reliance Rates
(Pivotal, Phase II and ESSTVU Trials)**

Outcome	Number	Percent
Reliance Rate*: <i>Among women with bilateral placement</i> Phase II & Pivotal Trials Bilateral* Reliance Rate** (N=745)	643/664	97%
ESSTVU Trial Bilateral* Reliance Rate	547/582	94%
ESSTVU Trial Intent-To-Treat Reliance Rate*** (N=622)	547/597	92%

*The reliance rate is the number of women who relied on **Essure** for contraception divided by the number of women with bilateral insert placement.

In the Phase II trial, the following adverse events prevented reliance: Perforation (7/206; 3.4%, including one patient that relied for 31 months before laparotomy and cornual resection due to pain, the other six never relied); Expulsion (1/206; 0.5%); Unsatisfactory insert location (1/206; 0.5%); Initial tubal patency (7/200; 3.5%) was found at the 3-month **Essure Confirmation Test using a modified HSG, however, all had tubal occlusion at a 6-month repeat **Essure** Confirmation Test using a modified HSG. In the Pivotal trial, the following adverse events prevented reliance: Perforation (5/476; 1.1%); Expulsion (14/476; 2.9%, nine out of the fourteen underwent a successful second placement procedure; Unsatisfactory insert location (3/476; 0.6%); Initial tubal patency (16/456; 3.5%) was found at the 3-month **Essure** Confirmation Test using a modified HSG, however, all had tubal occlusion at a 6 or 7-month repeat **Essure** Confirmation Test using a modified HSG.

***In the ESSTVU Trial, the following prevented reliance: Non bilateral placement after 1 or 2 procedures (15/597; 2.5%), incomplete or no confirmation testing (28 /597; 4.7%); unsatisfactory device location/occlusion identified at confirmation testing (perforation, expulsion, distal placement, proximal placement) (7/ 597; 1.2%).

**Table 6A Phase II / Pivotal with Modified HSG Confirmation Testing
Effectiveness Results Among Women Told to Rely
Cumulative Failure Rates**

	One-Year	Two-Year	Three-Year	Four-Year	Five-Year
Phase II and Pivotal Trials Combined N=643^D	0% N=635^C (95% CI 0 – 0.10%) ^{A, B}	0% N=605^C (95% CI 0 – 0.20%) ^{A, B}	0% N=586^C (95% CI 0 – 0.30%) ^{A, B}	0% N=567^C (95% CI 0 – 0.40%) ^{A, B}	0% N=567^C (95% CI 0 – 0.50%) ^{A, B}

^A95% confidence intervals are based on a “constant-hazard” exponential failure-time model, whose parameter is determined by the total number of woman-months accumulated during the trial as well as the observed number of pregnancies (0 in Phase II and Pivotal trials).

^B Combined effectiveness data obtained using Bayesian statistics.

^C The number of women “N” were considered to have completed follow-up at 1 year if patient contact occurred at \geq 11 months, 2 years if contact occurred at \geq 23 months, 3 years if contact occurred at \geq 35 months, 4 years if contact occurred \geq 47 months and 5 years if contact occurred at \geq 59 months.

^D The number of women “N” who were told to rely

No pregnancies were reported in the 5 years of follow up in the Phase II and Pivotal clinical trials based on 2,969 woman-years of follow up.

**Table 6B ESSTVU Trial with TVU/HSG Confirmation Testing Algorithm
Effectiveness Results Among Women Told to Rely
Cumulative Failure Rates**

	One-Year
ESSTVU Trial N=547^A	0.67% N=503 ^B (95% CI 0.16-1.53%)

^A The number of women “N” who were told to rely

^B The number of women “N” who attended follow-up at 1 year

Three pregnancies were reported in the 1 year follow up in the ESSTVU trial based on 518 woman–years of follow up. In all 3 pregnancies, TVU was utilized as the confirmation test, and the insert locations were deemed “optimal” in the initial assessment. In 2 of the 3 pregnancies, perforation not detected by initial TVU assessment was determined to be the cause. In the third pregnancy, insert placement was unsatisfactory, and not detected by initial TVU. One additional pregnancy was reported 16 months after the subject was told to rely. As it occurred after the 1-year follow up, this pregnancy was not included in the 1-year effectiveness rate calculation. No pregnancies were reported in the Phase II and Pivotal clinical trials, however all subjects in the Phase II and Pivotal trials underwent modified HSG prior to being counselled to discontinue alternative contraception and rely on **Essure**.

E. OBSERVATIONAL STUDY

SUCCESII is a single arm, multi-center, 5 year prospective, non-interventional, and observational study assessing patient satisfaction, safety and efficacy of the **Essure** procedure.

The study is currently ongoing and is being conducted in 14 French centers. Patients were enrolled between June 2008 and June 2011; 2575 patients had at least one attempt at placing **Essure**. Bilateral placement was achieved in 95.1% of the patients with two fallopian tubes. Unilateral placement was achieved in 96.9% of the patients with one fallopian tube (2.5% of the cohort).

Based on a satisfactory confirmation test utilizing pelvic X-Ray, TVU, and/or modified HSG, 2185 of the 2257 patients who returned for the confirmation test (96.8%) were able to rely on **Essure** for contraception.

Two pregnancies occurred in women who were told to rely on **Essure** for contraception, resulting in an efficacy rate of 99.9%.

IX. Essure Effectiveness In The Commercial Setting

In the commercial setting, unintended pregnancies have been reported in women who have worn the inserts.

Table 7 summarizes the reasons for pregnancy from reports received by Bayer HealthCare LLC and additional reports from the published scientific literature.

Table 7: Summary of Pregnancies Reported in Commercial Use of Essure*

Potential Contributing Factor	United States		Outside the United States**		Total	
	n	% of US causes	n	% of OUS causes	n	%
Patient Non-compliance (e.g., failure to use alternative contraception or return for Essure Confirmation Test)	213	32%	16	18%	229	31%
Perforation*** /#	91	14%	4	5%	95	13%
Unsatisfactory Placement***	32	5%	13	15%	45	6%
Physician Non-compliance	22	3%	13	15%	35	5%
Pregnant at time of Placement (Luteal)	26	4%	6	7%	32	4%
Inadequate Confirmation Test***	28	4%	0	0%	28	4%
Expulsion***	20	3%	4	5%	24	3%
Tubal Patency***	19	3%	1	1%	20	3%
Insufficient Information to determine	209	32%	31	35%	240	32%
Total	660		88		748****	

*Table includes pregnancy reports received directly by Bayer Healthcare LLC, recorded in the FDA MAUDE database and reported in the scientific literature; data reported to FDA in PMA Annual Reports. Pregnancies in **Essure** patients may be underreported.

Outside of the United States, during this reporting period, the **Essure Confirmation Test may have been an x-ray or transvaginal ultrasound; device location alone, not occlusion, is primarily used to determine whether the patient may rely on **Essure**.

*** Most of these pregnancies are due to misinterpreted **Essure** Confirmation Tests. Please note that many misinterpretations are due to the fact that occlusion is seen on the HSG films even though the insert is not properly located.

****Number of pregnancies reported from worldwide commercial launch in 2001 through end of 2010. 497,306 **Essure** kits sold during this time. Note that an accurate pregnancy rate is difficult to obtain as the number of devices actually implanted is not known.

#The causal association cannot be established between the perforation and the pregnancy. However, perforations have been identified in pregnant women who were relying on **Essure** for contraception.

The majority of unintended pregnancies are preventable. Most unintended pregnancies are related to patient non-compliance and physician misinterpretation of the **Essure** Confirmation Test. In order to ensure maximum contraceptive effectiveness by **Essure**, the physician should ensure that the patient is counseled in accordance with Section VI ‘Patient Counseling Information’.

It is important to evaluate insert location and, in some cases, occlusion carefully before telling the patient that she may rely on **Essure** for contraception.

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Table 8 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 8
Pregnancy Rates for Birth Control Methods
(For One Year of Use)

Method	Typical Use Rate of Pregnancy
Sterilization:	
Male Sterilization	0.15%
Female Sterilization	0.5%
Hormonal Methods:	
Implant (<i>Norplant</i> ™ and <i>Norplant</i> ™ 2)	0.05%
Hormone Shot (<i>Depo-Provera</i> ™)	3%
Combined Pill (<i>Estrogen/Progestin</i>) and Progestin-only Pill	8%
NuvaRing	8%
Ortho Evra	8%

Intrauterine Devices (IUDs):	
Copper T (<i>ParaGard</i>)	0.8%
LNG-IUS (<i>Mirena</i>)	0.2%
Barrier Methods:	
Male Latex Condom ¹	15%
Diaphragm ²	16%
Female Condom	21%
Spermicide: (gel, foam, suppository, film)	29%
Natural Methods:	
Withdrawal	27%
Natural Family Planning (<i>calendar, temperature, cervical mucus</i>)	25%
No Method:	85%

¹ Used Without Spermicide

² Used With Spermicide

Data adapted from Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. *Contraceptive Technology: Nineteenth Revised Edition*. New York NY: Ardent Media, 2007.

X. Directions for Use

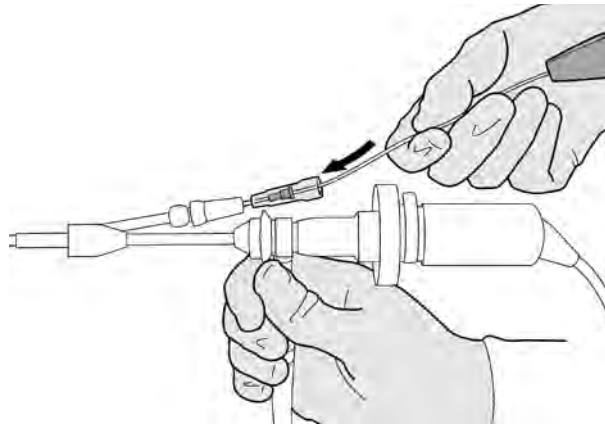
A. Prior to Insert Placement Procedure

1. Adequate visualization of the uterine and proximal tubal anatomy is required. In order to enhance visualization of the fallopian tube ostia and decrease the potential for insert placement in a patient with an undiagnosed pregnancy, insert placement should be performed during the early proliferative phase of the menstrual cycle. Women with menstrual cycles shorter than 28 days should undergo careful ovulation day calculations. Insert placement should not be performed during menstruation. Pretreatment of the patient with medications that suppress endometrial proliferation may enhance visualization and scheduling flexibility.
2. A pregnancy test administered by the physician or designee, should be conducted within 24 hours prior to or immediately preceding the insert placement procedure.
3. Administration of a non-steroidal anti-inflammatory drug (NSAID) should be considered one to two hours before the scheduled insert placement procedure, if appropriate for the patient. Local anesthesia is the preferred method for placement of the inserts. A paracervical block may be administered. Midazolam (IV), or a similar agent, may also be administered to prevent or reduce discomfort if needed (see section VII 'Possible Adverse Effects', subsection 'Risks Associated with the Insert Placement Procedure').

B. Essure Insert Placement Procedure

The **Essure** insert placement procedure can be performed in an ambulatory or day surgery setting. Sterile technique should be used during the insert placement procedure. The amount of time required to complete the insert placement procedure should not exceed 30 minutes.

1. Place the patient in the lithotomy position.
2. Prep the vagina and cervix with betadine or other suitable antibacterial solution according to standard practice. Introduce a speculum into the vagina to allow access to the cervix. Vaginoscopy may also be used to access the uterine cavity.
3. Administer anesthesia as required.
4. Insert a sterile hysteroscope, with camera and operating channel (≥ 5 French), through the cervix into the uterine cavity. Do not perform cervical dilation unless necessary; if necessary, dilate only enough for hysteroscope insertion. In order to prevent uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.
5. Uterine cavity distention should be accomplished with a physiologic saline infusion through the working channel of the hysteroscope. It is strongly recommended that the saline solution be pre-warmed to body temperature and introduced under gravity feed to minimize spasm of the fallopian tubes. Excellent uterine distention must be achieved and maintained throughout the procedure. Standard fluid monitoring procedures should be followed throughout the procedure. The fallopian tube ostia should be identified by hysteroscopic visualization.
6. Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** insert placement except when there is a known unilateral salpingectomy or a unicornuate uterus. For patients with two fallopian tubes, no attempt should be made to place an insert in one tubal ostium unless there is a reasonable expectation that the opposite tube is patent.
7. Once the fallopian tube ostia have been identified, insert the introducer through the sealing cap on the hysteroscope working 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 (see Figure 3). If undamaged from the first insert placement, the valved introducer may remain in the operating channel throughout the **Essure** procedure.

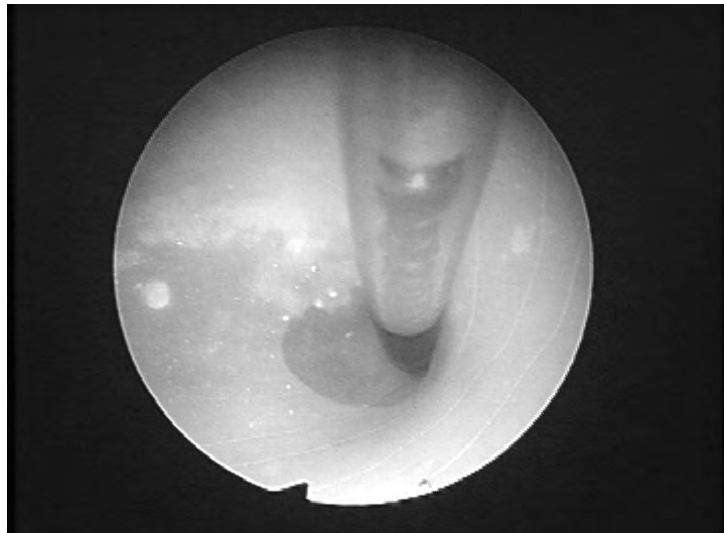


*Figure 3: Insert the introducer through sealing cap on the hysteroscope working channel, then place **Essure** delivery system through the introducer.*

8. Advance the **Essure** delivery system into the proximal fallopian tube with slow, steady movement to prevent tubal spasm. The **Essure** delivery system is designed with a 15 degree angle at the tip to facilitate placement within the fallopian tube. When advancing the catheter, direct the tip laterally following the contour of the fallopian tube. This should facilitate advancement of the catheter under direct visualization without undue resistance. Do not attempt to advance the delivery system if excessive resistance is encountered. If tubal spasm is suspected, move the hysteroscope closer to the tubal ostium. Apply **gentle**, constant forward pressure on the delivery catheter and wait. Repeatedly removing and attempting to re-cannulate may irritate the tube. It may take more than a minute for a spasm to resolve and the catheter to advance. If excessive resistance occurs, i.e., the catheter does not advance toward tubal ostium and/or catheter bends or flexes excessively, or if several minutes have passed, terminate the procedure to avoid perforation or placement into a false passage.

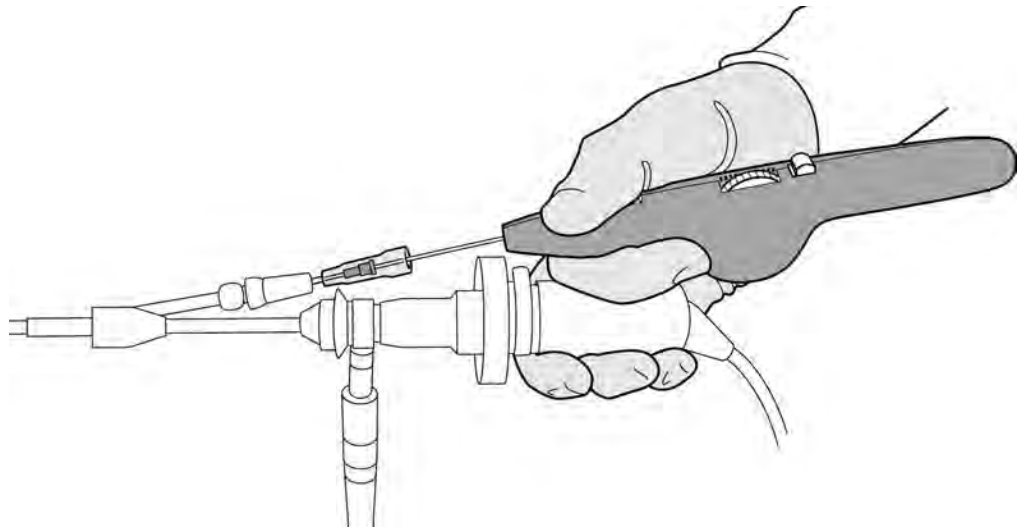
Resistance to advancement is usually apparent in two ways: 1) the black marker on the outside surface of the catheter is seen not to advance forward toward the tubal ostium, and/or 2) the delivery catheter bends or flexes excessively, thus preventing the physician from applying forward pressure on the catheter assembly. When such resistance to forward motion of the catheter is observed, no further attempts should be made to place the insert, in order to avoid the possibility of uterine or tubal perforation or inadvertently placing the insert in the uterine muscle rather than within the tubal lumen.

9. Advance the delivery system until the positioning marker on the delivery catheter reaches the fallopian tube ostium (see Figure 4). This visual marker indicates that the **Essure** insert is spanning the distal intramural to proximal isthmic segments of the fallopian tube, with the outer coil spanning the uterotubal junction. This is the ideal placement for the **Essure** insert.




*Figure 4: Advance until the black positioning marker is at tubal ostium.
This is a visual indicator for proper position for deployment.*

10. If the tube is blocked or the catheter cannot be advanced to the positioning marker, the procedure should be terminated. If insert placement is not successful after 10 minutes of attempted cannulation per tube, the procedure should be terminated.
11. When the delivery catheter has been advanced to the positioning marker, deploy the insert. To do so, first stabilize the handle of the **Essure** insert against the hysteroscope camera or some other fixed object to prevent inadvertent forward movement of the **Essure** system during retraction of the delivery catheter (see Figure 5). Before proceeding with the **Essure** procedure, recall that two distinct operations will take place. The first is retraction of the delivery catheter away from the insert, prior to actual detachment of the insert. Full retraction is accomplished by rotating the thumb wheel to the point where you cannot rotate the thumbwheel any further. Actual detachment is accomplished after retraction by pressing the handle button and then continuing to rotate the thumbwheel. Only after detachment of the insert has occurred can you remove the delivery system.



*Figure 5: Stabilize handle against camera head or some other fixed object to prevent inadvertent forward movement of the **Essure** system*

12. Being certain that the black positioning marker is at the fallopian tube ostium, rotate the thumbwheel on the handle toward you until the wheel no longer rotates (see Figure 6). This operation corresponds to the symbol  on the delivery system handle. This facilitates withdrawal of the delivery catheter. You will see the black positioning marker 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** insert. Approximately 1 cm of the insert (wound-down coils) should appear trailing into the uterus when the delivery catheter is withdrawn.

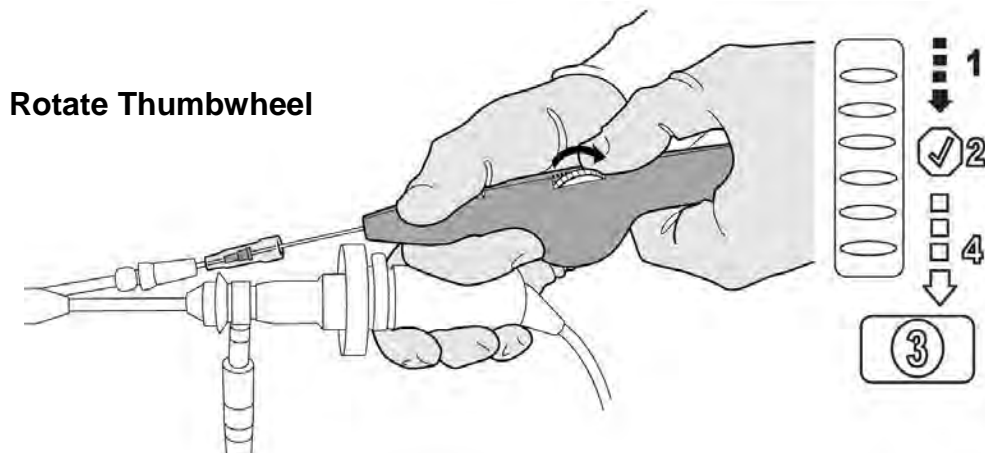



Figure 6: Rotate thumbwheel to retract catheter

13. To confirm proper positioning, place gold marker band just outside the ostium (see Figure 7), which corresponds to the symbol  on the delivery system handle. Visualization of the gold band just outside the ostium, as well as visualization of the distal tip of the green release catheter will confirm proper positioning. It is very important that the gold band is not inside of the tube at time of deployment. If gold band is not visible, do not deploy the device. Move the delivery catheter toward you

until the gold band is visible. If more than 1 cm of the insert is visible in the uterus, then the insert should be repositioned by moving the entire system further into the tube, if possible, before proceeding to the next step.

STOP and Check

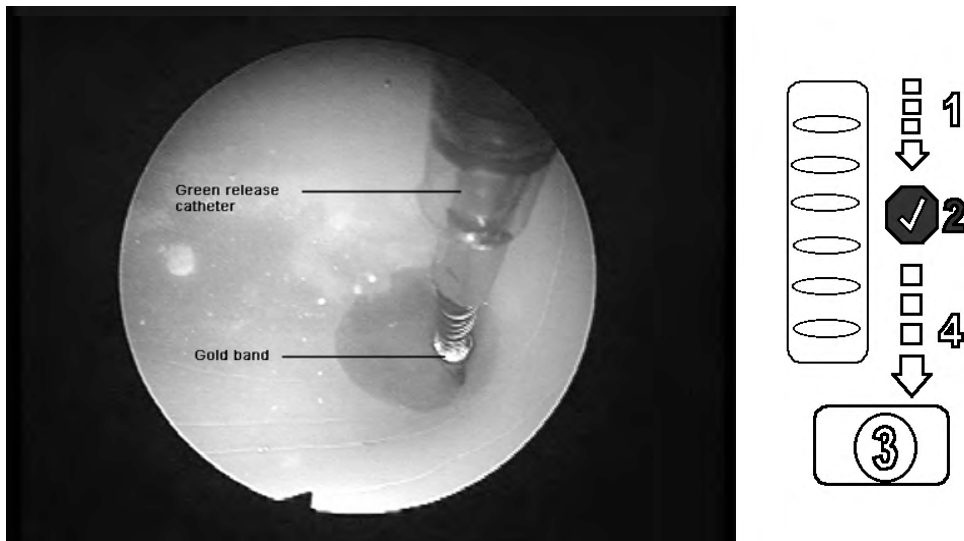


Figure 7: Visualize gold band at ostium

14. Press the button on the delivery handle to enable the thumbwheel to be further rotated which corresponds to the symbol ③ on the handle button (see Figure 8).

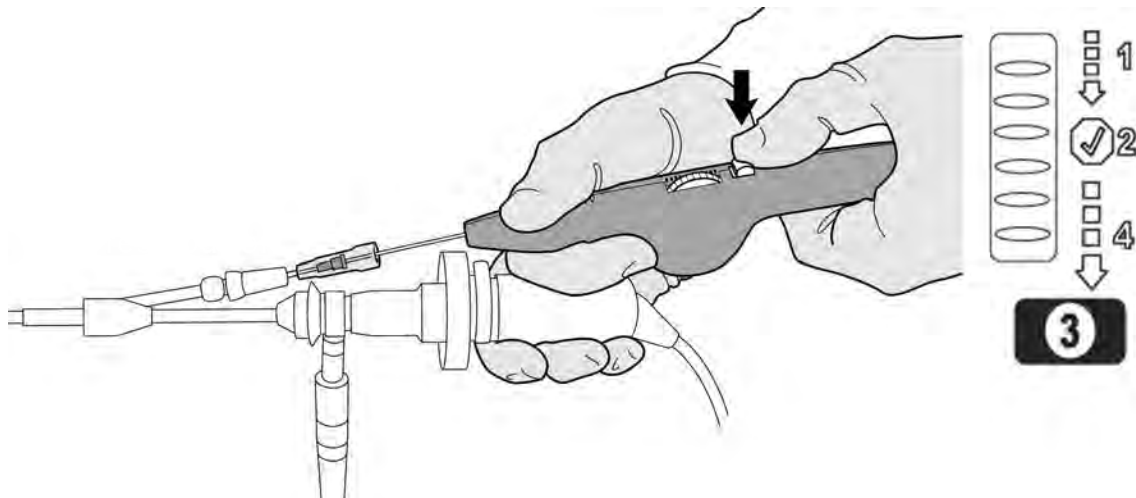


Figure 8: Press button to enable thumbwheel to rotate again.

NOTE: DO NOT PUSH THE BUTTON until the delivery system is in the current position for insert placement.

15. Rotate the thumbwheel toward you to deploy the outer coil of the insert, which corresponds to the symbol ↴⁴ on the delivery system handle (see Figure 9). Continue to rotate the thumbwheel until it stops rotating. When the thumbwheel cannot be rotated any further and the expanded outer coils are visible, withdraw the system.

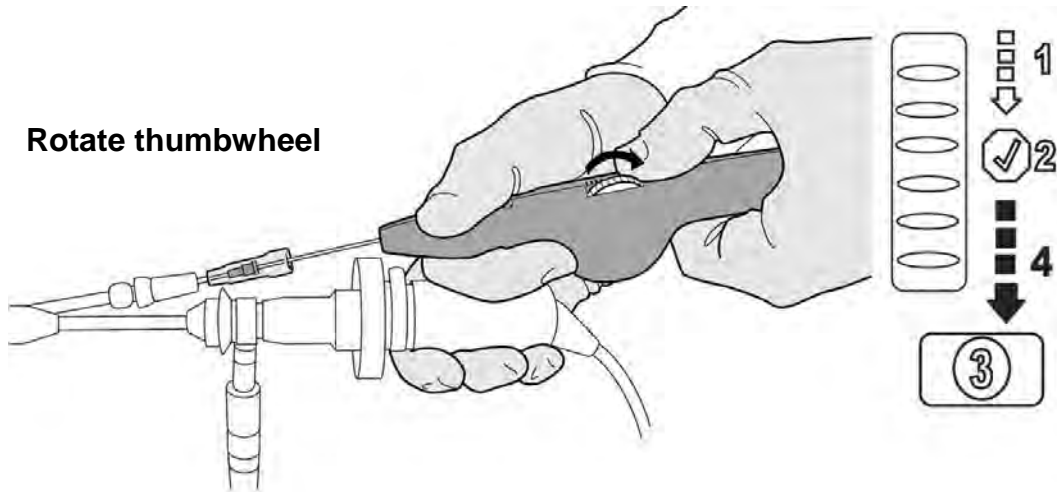


Figure 9: Rotate thumbwheel to deploy the outer coil of the insert

16. The position of the deployed **Essure** insert will be assessed under hysteroscopic visualization. There should ideally be 3 to 8 expanded outer coils of the **Essure** insert trailing into the uterine cavity (see Figure 10); however, 0 to 17 trailing coils is a satisfactory placement.

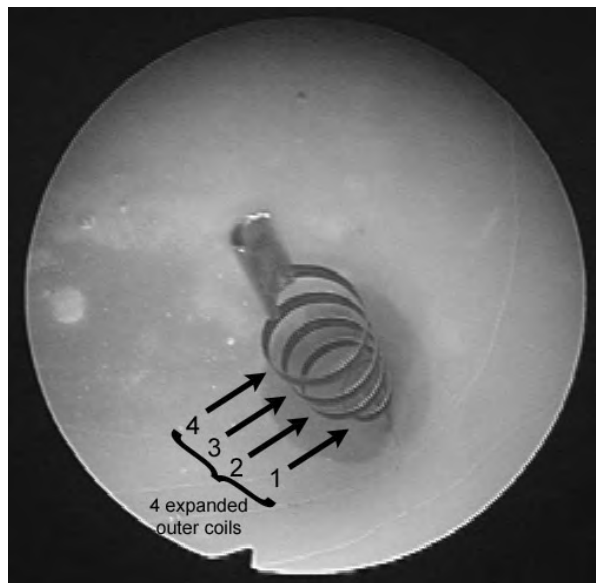


Figure 10: Expanded outer coils of the **Essure** insert trailing into the uterus indicates ideal placement

17. If the physician is dissatisfied with insert placement based on the hysteroscopic view, and there are fewer than 18 trailing coils, the insert(s) should be left in place and assessed during the **Essure** Confirmation Test. In cases of suspected perforation, monitor the patient for signs and symptoms of possible complications related to

perforation which may include unusual post-operative pain. If unusual post-operative pain occurs, imaging to localize the insert should be performed prior to the 3 month confirmation test. If no trailing coils are visible, examine the delivery system upon removal from the hysteroscope. Refer to Figure 11 below to determine if the insert has been deployed from the delivery system. **IMPORTANT:** If insert was inadvertently deployed in the uterine cavity and not in the tube, remove from uterus and attempt another placement.

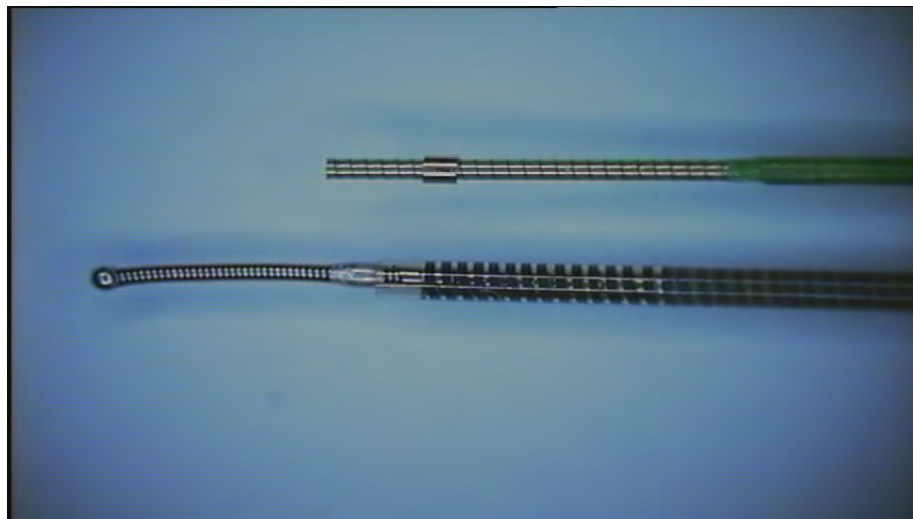


Figure 11: Delivery systems showing absence of insert after deployment (top) and with insert attached (bottom)

WARNING: AFTER THE INSERT HAS BEEN PLACED AND RELEASED INTO THE FALLOPIAN TUBE, DO NOT ATTEMPT TO REMOVE THE INSERT HYSTEROSCOPICALLY UNLESS 18 OR MORE COILS OF THE ESSURE INSERT ARE TRAILING IN THE UTERINE CAVITY. An attempted removal of inserts having fewer than 18 trailing coils may cause insert to fracture or patient injury. If 18 or more coils are trailing into the uterine cavity, removal should be attempted immediately during the placement attempt. However, removal of inserts may not be possible. Please refer to section XIV 'Essure Insert Removal' for additional information. If the insert was inadvertently deployed in the uterine cavity and not into the tube, the insert should be removed from the uterus and another attempt made at insert placement in the tube.

18. If insert removal is indicated, perform removal immediately after failed placement as follows:

- a - As necessary, administer analgesia/anesthesia to reduce or prevent patient discomfort.
- b - Introduce a grasping instrument through hysteroscope operating channel.
- c - Grasp both the outer and inner coils of the insert together.
- d - Withdraw the grasping instrument and hysteroscope simultaneously; the insert may stretch or elongate. Do not pull insert through the operating channel.

19. Repeat the **Essure** insert placement procedure in the contralateral fallopian tube when applicable.
20. Record the length of the insert trailing into the uterine cavity, noting any issues with identifying or confirming either tubal ostium or any concerns regarding potential perforation (see Figure 10). These should be noted in patient records and be provided to the physician performing the **Essure** Confirmation Test (See Section XII – ‘**Essure** Confirmation Test’).
21. Document procedural concerns. Review during **Essure** Confirmation Test. Note possible perforations due to:
 - a. excessive or sudden loss of resistance;
 - b. inability to visualize coils;
 - c. problems with identification of tubal ostium;
 - d. poor distension;
 - e. poor illumination;
 - f. or poor visualization secondary to endometrial debris.
22. **Ensure patient uses alternative contraception until the Essure Confirmation Test.** Counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all steps of the **Essure** procedure.
23. Schedule the patient for an **Essure** Confirmation Test three months following the **Essure** insert placement procedure to evaluate insert retention and location.

XI. Management Of Cases With Unsuccessful Essure Insert Placement During The Initial Procedure

Placement may not be achieved due to conditions such as temporary difficulty with visualization which could be satisfactorily managed prior to a second attempt. The patient should be informed that her permanent contraception has not been completed and should continue to use alternative contraception (see section XIII ‘Management Of Patients Who Are Not Able To Rely’).

Counsel patient on undergoing a second procedure, especially if unilateral placement was achieved. In the Pivotal trial, 83% of those who underwent a second procedure achieved bilateral placement. Before a second placement attempt, determine tubal patency by modified HSG which can be scheduled after patient’s next menses. If patency is documented, a second attempt may be performed. If a second attempt fails, success with subsequent attempts is unlikely.

If the patient chooses laparoscopic sterilization, clip or coagulate both fallopian tubes distal or proximal to the insert. Do not perform clipping or coagulation adjacent to or over the insert.

XII. Essure Confirmation Test

A. An **Essure** Confirmation Test should be performed three months after insert placement to evaluate insert retention and location. The **Essure** Confirmation Tests (transvaginal ultrasound (TVU), pelvic x-ray or hysterosalpingogram (modified HSG) should be performed only by an experienced gynecologist, ultrasonographer and/or radiologist.

B. For the first-line confirmation test, either a pelvic X-ray or a TVU may be performed three months after an insert placement procedure.

1. X-ray and TVU should not be used as the **Essure** Confirmation Test under the following circumstances:

- a) Difficult placement procedure including one or more of the following:
 - (1) Concern at the time of placement of possible perforation due to excessive force required for insert delivery and/or a sudden loss of resistance.
 - (2) Difficulty identifying the tubal ostia during placement due to anatomical variation or technical factors such as poor distention, suboptimal lighting or endometrial debris.
 - (3) Physician is uncertain about placement.
- b) Procedure time > 15 minutes (scope in-scope out).
- c) Placement with zero or > 8 trailing coils
- d) Unusual post-operative pain, transient or persistent, or onset at some later time post procedure, without any other identifiable cause.

2. Patients on active immunosuppressive therapy (e.g. systemic corticosteroids or chemotherapy) may experience delay or failure of the necessary tissue in-growth needed for tubal occlusion. For these patients, physicians must use the modified HSG as the **Essure** Confirmation Test. TVU or pelvic X-ray should not be utilized for confirmation, as these tests cannot confirm tubal occlusion. Clinical trials were not conducted with patients undergoing immunosuppressive therapy.

3. Trans-abdominal ultrasound cannot be substituted for TVU. If X-ray or ultrasound or is not indicated, the patient must proceed to a modified HSG to evaluate insert location and tubal occlusion. If X-ray or ultrasound evaluation is equivocal or unsatisfactory, the patient must proceed to a modified HSG to evaluate insert location and tubal occlusion.

C. Transvaginal Ultrasound

1. A minimum of three images must be obtained and retained for documentation:

- a) A transverse or oblique transverse view demonstrating a portion of each insert in the cornua labeled “scout image”.



Figure 12: Bilateral inserts are identified in this transverse (coronal / oblique coronal) view.

- b) A transverse or oblique transverse image of the linear axis of the left insert including the proximal end crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with the serosal utero tubal junction and labeled “left”.
- c) A transverse or oblique transverse image of the linear axis of the right insert crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with the serosal utero tubal junction and labeled “right.”
- d) All three images should be captured on film and placed in the subject’s medical record to document satisfactory insert retention and location.

2. Classification of Insert Location

- a) **Insert identification:** In a single scout image, a portion of each insert must be visualized in the cornua in the transverse or oblique transverse view to ensure bilateral placement and reduce the risk of duplicate imaging of the same insert. The linear axis of the inserts should appear relatively symmetric.
- b) **Optimal Location**
Insert location is optimal when the proximal end of the insert is in contact with the uterine cavity or endometrium, and the linear axis is within the myometrium in the cornua (interstitial portion of the fallopian tube) and can be visualized at or crossing the serosal utero tubal junction (SUTJ). The portion of the insert located in the fallopian tube may or may not be visualized. The linear axis of the insert must be visualized to confirm it is not coiled or elongated.

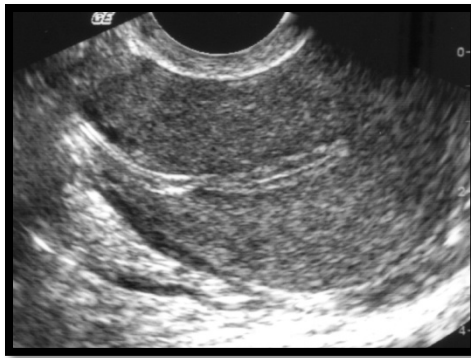


Figure 13: Optimal Location

c) Satisfactory Location

Insert location is satisfactory when the proximal end of the insert is distal to the endometrium, however the linear axis is within the myometrium in the cornua (interstitial portion of the fallopian tube) and can be visualized at or crossing the serosal utero tubal junction (SUTJ). The portion of the insert located in the fallopian tube may or may not be visualized. The linear axis of the insert must be visualized to confirm it is not coiled or elongated.

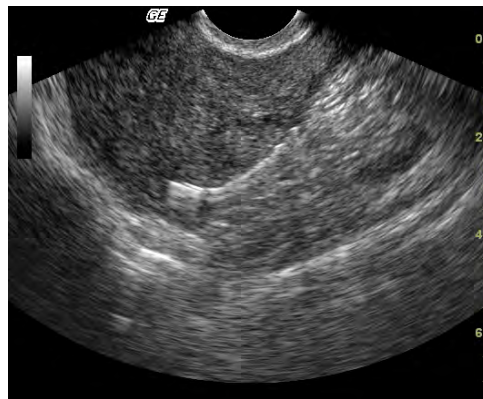


Figure 14: Satisfactory location

d) Unsatisfactory Location

(1) Insert location is unsatisfactory if a portion of each insert cannot be visualized in the cornua in the transverse or oblique transverse view in one scout image.

(2) Expulsion is suspected if one or both inserts are not identified in the cornua in a transverse view in a single scout image.

(3) Distal placement is suspected if the proximal end of the insert is not located in the myometrium in the cornua (interstitial portion of the fallopian tube), and not crossing or in contact with the SUTJ.

(4) Proximal placement is suspected if greater than 50% or the majority of the insert is visualized in the uterine cavity or if the linear axis of the insert(s) is visualized in the midline sagittal view.

(5) Perforation is suspected if the linear axis of one or both inserts are parallel to the endometrial stripe in the sagittal view, or if the linear axis of

an insert is visualized crossing the myometrium in the midline sagittal view.

(6) Unclassified position: If the linear axis of an insert cannot be identified, suggesting it is coiled, bent or elongated, insert location is considered unsatisfactory. If the surrounding soft tissue cannot be clearly defined, position is considered unsatisfactory.

3. Assessing Ability to Rely- Can only be performed when TVU is indicated as per the **Essure** Confirmation Test protocol (see section XII. '**Essure** Confirmation Test', Subsection B).

1) If location of the inserts is rated as either satisfactory or optimal, instruct the patient to discontinue alternative contraception and that she can rely on **Essure** for contraception. The **Essure** Confirmation Test with TVU does not assess tubal occlusion. Both optimal and satisfactory locations of the insert are appropriate to elicit a benign tissue in-growth that permanently occludes the fallopian tube, resulting in contraception.

2) If ultrasound evaluation is equivocal or unsatisfactory, patient must proceed to a modified HSG to evaluate insert location and tubal occlusion. The patient must also be instructed not to discontinue her alternative contraception.

D. Pelvic X-ray

1. Capture an image of the uterus with both **Essure** inserts clearly seen. The lie and curvature of the inserts should be noted.

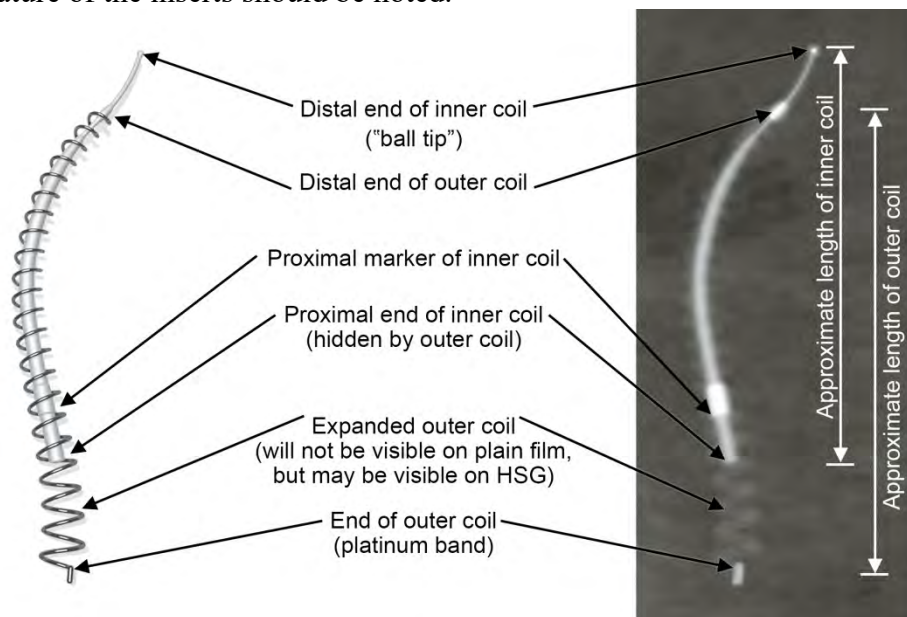


Figure 15: Corresponding radiographic view of the **Essure** insert

2. Evaluate pelvic X-ray as follows:

- a) Satisfactory: Inserts appear to be in the tubal lumen and spanning the SUTJ, and appear relatively symmetrical. Patients whose X-rays are determined to be “satisfactory” may begin to rely on the **Essure** insert for contraception.
- b) Suspicious: One or both of the inserts appear to be distal or proximal to optimal position, or may be partially or completely perforated through the tube, and/or appear relatively asymmetrical.
- c) Unsatisfactory: Obvious intraperitoneal insert location or expulsion.

3. If x-ray evaluation is unsatisfactory; or insert location is suspicious, or a satisfactory location cannot be confirmed, the patient must proceed to a modified HSG to evaluate insert location and tubal occlusion and should be instructed to continue alternative contraception.

E. Performing and Evaluating modified HSGs

A modified HSG is an HSG that is performed by instilling contrast slowly and gently until the uterine cornua are distended. An increase in intrauterine pressure beyond that needed to produce cornual distention serves no purpose and should be avoided.

1. The HSG is performed to evaluate **Essure** insert location and fallopian tube occlusion. Follow the instructions below for performing and evaluating the HSG.

2. Performing the HSG - Guidelines:

- a) Obtain good cornual filling so that the uterine cavity silhouette is clearly seen.
- b) Place fluoroscopy beam as close to A/P projection as possible.
- c) Do not dilate cervix unless necessary; if dilation occurs, maintain a good cervical seal.
- d) Downward traction on cervical tenaculum may be required in for midpositional uterus. Remove speculum prior to fluoroscopy for best visualization of uterine anatomy.
- e) Take a minimum of six radiographs to assess insert location and tubal occlusion.
 - (1) Radiograph 1 – “Scout Film” - Uterus and inserts without contrast. (see Figure 16)
 - (2) Radiograph 2 – Minimal Fill of the Cavity – Uterus and inserts with small amount of contrast.
 - (3) Radiograph 3 – Partial Fill of the Cavity - Uterus and inserts when nearly full of contrast.
 - (4) Radiograph 4 – Total Fill of Cavity - Uterus and inserts when the cornua is distended by contrast. (see Figure 17)
 - (5) Radiographs 5 & 6- Magnifications of uterine cornua – Insert within the fallopian tube with right (5) and left (6) cornua.

CAUTION: Avoid excessive intrauterine pressure beyond Radiograph 4 to avoid undue patient discomfort and vaso-vagal reaction.

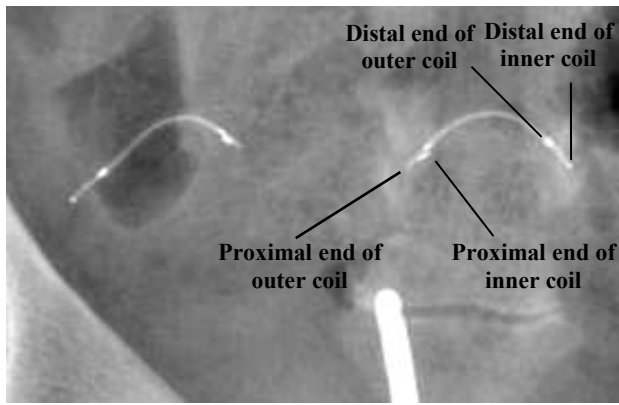


Figure 16: Radiograph 1: Scout Film



Figure 17: Radiograph 4: Total Fill of Cavity

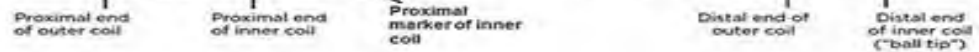
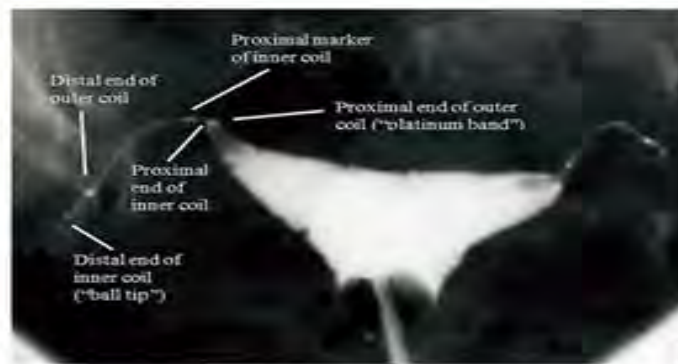


Figure 18: Assessing insert location on a modified HSG. Note: The outer coil may sometimes be visible on a modified HSG, if dye is present in the tube.

3. Assessing Insert Location

During evaluation, note the four “markers” on each insert: two on the inner coil and two on the outer coil. The two distal markers and the proximal marker of the inner coil are fixed in relation to one another, but the proximal markers of the outer coil may move or seem stretched because of the flexibility of the outer coil.

- a) Satisfactory location: Distal end of inner coil is within the tube, with <50% of inner coil trailing into the uterine cavity, or proximal end of inner coil ≤ 30 mm into tube from where contrast fills cornua.
- b) Proximal location (partial expulsion): $\geq 50\%$ of the inner coil is trailing into the uterine cavity;
- c) Distal location: Proximal end of the inner coil is >30 mm distal from where contrast fills cornua.

- d) Peritoneal location: Insert is found within the peritoneal cavity and not located within the tube.
 - e) Expulsion: Insert lies completely in the uterine cavity or insert is not present in the radiographic images.
 - f) Perforation: The insert does not conform to the expected anatomical curvature of the tube (e.g., curves back on itself like a pigtail or has an acute angle to it) or the markers appear reversed).
4. Assessing Tubal Occlusion
 - a) Determine whether the contrast is visible beyond the insert and note any degree of proximal tubal filling even if the tube is occluded.
 - b) Assess tubal occlusion:
 - (1) Satisfactory occlusion: Tube is occluded at the cornua.
 - (2) Satisfactory occlusion: Contrast seen within tube but not past distal end of outer coil.
 - (3) Unsatisfactory occlusion: Contrast seen past the distal end of the insert or in the peritoneal cavity.
 5. Assessing Ability to Rely
 - a) If location and tubal occlusion are both rated satisfactory, instruct patient to discontinue alternative contraception.
 - b) If location is unsatisfactory, instruct patient to not rely on the inserts for contraception.
 - c) If location is satisfactory but occlusion is unsatisfactory, instruct patient to remain on alternative contraception. Repeat the modified HSG in three months. If occlusion is still unsatisfactory, instruct patient to not rely on the inserts for contraception.

XIII. Management of Patients Who Are Not Able To Rely

In the event of unilateral or bilateral insert placement failure, the patient should be informed that her permanent contraception has not been completed. The location of all deployed inserts should be ascertained. Based on the insert location a decision should be made as to whether the insert should be left *in situ* or removed (see section XIV ‘**Essure** Insert Removal’).

For patients who are not able to rely management may include, a second placement attempt, incisional sterilization, or remaining on alternative contraception. The patient should be informed that her permanent contraception has not been successful and she should continue to use alternative contraception.

Second Placement Attempt: If the insert is determined to be in unsatisfactory location (i.e., distal, perforation, and expulsion), tubal patency is seen on modified HSG, and no part of an **Essure** insert is detected within the proximal 30 mm of the fallopian tube, a second attempt to place an insert into the tube may be performed. If a portion of the insert is within the proximal 30 mm of the fallopian tube, counsel the patient on incisional sterilization or to remain on alternative contraception.

If the patient chooses laparoscopic sterilization (i.e., clip application, bipolar cautery, or salpingectomy, or other methodologies), the location of the insert(s) should be clearly identified prior to performing the sterilization procedure. Do not clamp, cut or coagulate directly over the insert to avoid transecting or fracturing the insert. In order to achieve complete ligation of the fallopian tube, insert removal may be required. (see section XIV ‘**Essure** Insert Removal’). Caution must be taken not to leave any perforations proximal to the tubal ligation.

XIV. **Essure Insert Removal**

WARNING: **Essure** inserts are intended to be left in place permanently. Do not remove insert(s) unless the patient is experiencing an adverse event(s) associated with its presence, if removal is clinically indicated (see section XIV ‘**Essure** Insert Removal, subsection ‘Removal of insert located within the within peritoneal cavity’) or if requested by the patient. If insert removal is planned, the patient should be counseled on the risks of surgery. Clinical judgment as to the appropriate procedure must be used. Physicians should be thoroughly familiar with the characteristics and performance of any instrument they select for the removal procedure. Consultation with a physician familiar with removal techniques may be appropriate.

For all surgical removal procedures, care should be taken to avoid transecting the insert during removal. If the entire insert has not been removed, intra-operative imaging to localize the remaining fragments should be performed and the fragments should be removed, if indicated.

At Time of Placement Procedure

Hysteroscopic insert removal should not be attempted at the time of insert placement, unless 18 or more coils of the **Essure** insert are trailing into the uterine cavity indicating placement is too proximal. If 18 or more coils are trailing into the uterine cavity, removal should be attempted immediately during the placement attempt. However, if removal is not achieved with gentle traction, the insert may be left in place; subsequent hysteroscopic removal may be attempted at a later date.

Steps for Hysteroscopic Removal:

1. As necessary, administer analgesia/anesthesia to reduce or prevent patient discomfort.
2. Introduce a grasping instrument through the hysteroscope working channel.
3. Try to grasp the outer and inner coil of the insert together. Grasping both the inner and outer coils together may help prevent excessive stretching of the outer coil, which could result in fragmentation.
4. Gently pull back on the insert with the grasping instrument while extracting the insert in small increments to prevent fragmentation of the insert or excessive stretching of the coils. Once the insert has been removed from the

fallopian tube, pull back on the hysteroscope and the grasping instrument at the same time. Do not attempt to pull the deployed insert through the working channel of the hysteroscope. The hysteroscope along with the grasper containing the deployed insert should be removed from the uterus together.

5. If upon inspection of the removed insert, if the physician is not completely satisfied that the entire **Essure** insert has been removed from the fallopian tube, an X-ray should be taken to determine if an insert fragment remains *in vivo*.
6. If complete insert removal is accomplished, an attempt should be made to place another **Essure** insert.

Subsequent to Placement Procedure

Location of **Essure** inserts should be confirmed through imaging prior to any attempted surgical removal as the appropriate surgical approach will be influenced by the location. Availability of intraoperative fluoroscopy and/or intraoperative x-ray is recommended to identify the location of the insert or fragments of the insert during the removal procedure.

The physician should attempt to remove the entire insert to avoid the potential need for subsequent surgical procedures.

Insert removal may be performed along with, or independent of, an incisional sterilization procedure (e.g., tubal ligation). If following insert removal the patient should be counseled about risk of pregnancy, including ectopic pregnancy.

A. Removal of insert located within the fallopian tube(s):

Hysteroscopic Removal:

Limited case reports describe hysteroscopic insert removal subsequent to the placement procedure. In these cases, the proximal coils were visible within the uterine cavity and were easily removed with gentle traction.

Hysteroscopic removal should only be attempted when the proximal coils are visible within the uterine cavity. Refer to steps for 'Hysteroscopic Removal' (section XIV '**Essure** Insert Removal, subsection 'At time of Placement Procedure').

Combined hysteroscopic/laparoscopic removal:

When planning a laparoscopic removal, consideration should be given to first excising the most proximal part of the outer coil (the "platinum band") hysteroscopically with scissors (see section XII. '**Essure** Confirmation Test', see Figure 15). This may facilitate laparoscopic removal of the insert as the platinum band is the widest portion of the outer coil, which can be the most difficult portion to pass through the cornual region of the fallopian tube.

Laparoscopic removal:

Laparoscopic removal techniques for inserts within the fallopian tubes include salpingotomy, salpingectomy, and cornual resection. Visualization or palpation of the fallopian tube should be performed to confirm the location of the insert.

If electrocautery is employed, it should be used judiciously to avoid injury to adjacent structures or fracturing of the insert.

1. To perform a linear salpingotomy, make a small incision (approximately 2 cm in length) along the antimesenteric border of the fallopian tube, overlying the insert. Use of vasoconstrictive agents is at the discretion of the operating surgeon. The insert needs to be exposed and may need to be freed from the surrounding tissue prior to grasping the coils. During removal, the inner and outer coils should be grasped together. Once the insert is exposed, a grasping instrument may be used to extract the insert using gentle traction along the axis of the fallopian tube. The insert should be gently extracted in small increments to prevent fragmentation of the insert or excessive stretching of the coils. If excessive resistance is encountered, this may be due to the platinum band (largest diameter of the insert) not being able to pass through the cornual region. The platinum band may break off if excessive traction is applied during laparoscopic removal. Hysteroscopic excision of the platinum band may facilitate removal of the entire insert (see section XIV '**Essure** Insert Removal', subsection '*Combined hysteroscopic/laparoscopic removal*').
2. In some cases, a cornual resection of the proximal fallopian tube may be required for insert removal. In these cases patients should be counseled about the risk of hysterectomy in order to achieve hemostasis.

3. Removal via Salpingectomy:

Distally located inserts (all portions of the insert distal to the cornua):

When removing the insert via salpingectomy, the location of the proximal portion of the insert within the fallopian tube should be reconfirmed intra-operatively by palpation, visualization and/or imaging prior to removing the fallopian tube containing the insert to avoid transecting or fracturing the insert.

Insert(s) partially located within the cornual region of the tube:

When the proximal end of the insert is within the cornua, consideration should be given to performing a combined hysteroscopic/laparoscopic procedure (see section XIV '**Essure** Insert Removal, subsection '*Combined hysteroscopic/laparoscopic removal*'). Laparoscopic exposure and visualization of the insert is then necessary. Based on case studies and expert opinion,

techniques include linear salpingotomy and circumferential incision adjacent to the cornua. Clinical judgment as to the appropriate procedure must be used.

To perform circumferential incision, the isthmic portion of the tube is circumscribed near the cornua, thus exposing the insert. Once the insert is exposed by salpingotomy or circumferential incision, it can be grasped with forceps and slowly extracted in small increments to prevent fragmentation of the insert or excessive stretching of the coils. After removal of the proximal portion of the insert from the cornual region, the salpingectomy can be completed.

B. Perforations:

The technique for removal of an insert that has perforated the uterus or tube will depend on the location of the insert. Localization should be assessed with imaging prior to the surgical procedure and confirmed intra-operatively.

Tubal Perforations:

Inserts perforating the fallopian tube but still partially within the tube can be removed by salpingotomy, salpingectomy, cornual resection, or combined hysteroscopic/laparoscopic procedures depending on the location of the insert (refer to ‘Subsequent to Placement Procedure; Laparoscopic removal’).

Uterine Perforations:

Inserts that penetrate the myometrium may be embedded and difficult to remove. For cases in which the insert is primarily within the uterine cavity, hysteroscopic removal should be attempted. For cases in which the insert is partially within the endometrial cavity/uterine wall and partially in the peritoneal cavity, hysteroscopic excision of the platinum band, if visible, should be considered prior to planned laparoscopic removal. Cornual resection may be required for perforations within or adjacent to the cornual region. If the primary removal procedure is not successful then hysterectomy may be required.

C. Removal of Insert located within peritoneal cavity:

The majority of insert(s) located within the peritoneal cavity are asymptomatic and do not require removal. If removal is planned, the technique for removal of an insert within the peritoneal cavity will depend on the location of the insert. As with all removal procedures, localization should be assessed with imaging prior to the surgical procedure and may need to be confirmed intraoperatively. Availability of intraoperative fluoroscopy and/or intraoperative x-ray is recommended to identify the location of the insert or fragments of the insert during the removal procedure.

In rare instances, the outer coil of the insert may stretch across the abdominal/pelvic cavity and create a situation in which the bowel may be entrapped. A stretched insert can be identified on X-ray by the location of the “platinum band” marker being several centimeters away from the remainder of the insert (see Figure 18). In this circumstance, consideration should be given to removing the insert, even if the patient is asymptomatic.

D. Hysterectomy:

While hysterectomy generally is not required to remove the **Essure** inserts, there may be situations when a hysterectomy is indicated. These may include inability to remove the insert using the techniques described above, excessive bleeding, or other concomitant gynecological pathology (e.g. uterine fibroids, uterine prolapse, chronic pain or bleeding) that may be best managed with hysterectomy.

When performing a hysterectomy, it is important that the insert(s) be identified prior to surgery and care used not to transect or cauterize the inserts as this may result in fragmentation. Removal of the insert(s) through one of the techniques outlined in Section XIV '**Essure** Insert Removal', subsection 'Subsequent to Placement Procedure' may be required prior to the completion of the hysterectomy in order to avoid transecting or fracturing the insert.

XV. Patient Identification Card

Each patient who has had **Essure** insert(s) implanted should be given a laminated, wallet-sized card stating that she has **Essure** insert(s) in place. **The card is enclosed in this package.** The card will additionally state that there may be risks associated with the participant undergoing future intrauterine procedures or abdominal surgery.













XVI. How Supplied and Product Handling

STERILE: Each **Essure** system is supplied sterile. Inspect each package and do not use if damaged.

STORAGE: Store in a cool, dry place. Keep away from sunlight.

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.

XVII. Legend of Symbols

	1.1	Sterilized using ethylene oxide	
	1.2	Batch Code	
	1.3	Do Not Reuse	
REF	1.4	Catalog Number	
	1.5	Caution	
	1.6	Use By Date	
1.7		1.8	Keep away from sunlight
1.9		1.10	Do Not Use If Package Is Damaged
1.11		1.12	MR Conditional
1.13		1.14	
	1.15	Authorized Representative in the European Community	
1.16		1.17	Device complies with European Directive 93/42/EC
1.18		1.19	Keep Dry
1.20		1.21	
	1.22	Content	



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