I. OVERVIEW OF ESSURE PROCEDURE AND PRINCIPLES OF OPERATION

Step 1: Essure insert placement procedure ("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 with either bilateral satisfactory insert location and occlusion (when using a modified hysterosalpingogram ("modified HSG")) before the patient can rely on Essure for contraception. The effectiveness of Essure when unilateral insert placement occurs has not been evaluated.

II. DEVICE DESCRIPTION

The Essure system ("system") is comprised of a disposable delivery system and a wound-down insert. A disposable introducer is also provided to facilitate delivery system entry into the hysteroscope operating channel. 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. The wound-down insert is approximately 4 cm in length and 0.8 mm in diameter. The floor-down configuration, detached from the delivery system (NOT TO SCALE). The disposable delivery system, (shown in Figure 2), consists of a delivery wire, a release catheter, a delivery catheter, and a delivery handle.

NOTE: The delivery wire and the release catheter are not visible in Figure 2.

III. MECHANISM OF ACTION

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

A. Placement at Utero-Tubal Junction

Ideal placement occurs when the insert spans the serosal utero-tubal junction (SUTJ) as viewed on TVU or the utero-tubal junction (UTJ) as visualized on modified HSG. The SUTJ refers to the anatomical location where the fallopian tube meets with the serosal boundary of the uterus. The UTJ refers to the region identified by modified HSG where contrast material enters the proximal fallopian tube (Figure 4). This location is distal enough to avoid expulsion, yet proximal enough to visualize trailing coils in the uterine cavity.
VI. INDICATIONS FOR USE
Essure is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.

V. CONTRAINDICATIONS
Essure is contraindicated for patients who:
• Are uncertain about ending fertility.
• Have only one insert placed (including contralateral proximal tubal occlusion or suspected unicornuate uterus).
• Have a known abnormal uterine cavity that makes visualization of the tubal ostia impossible and/or abnormal tubal anatomy or previous tubal ligation (including failed ligation).
• Are pregnant or suspect pregnancy.
• Have delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure.
• Have an active upper or lower genital tract infection.
• Have unexplained vaginal bleeding.
• Have a gynecological malignancy (suspected or known).
• Have a known allergy to contrast media (a modified HSG may be required for the Essure Confirmation Test).

VI. WARNINGS AND PRECAUTIONS

GENERAL WARNINGS
• The Essure procedure should be considered irreversible. Safety and effectiveness of reversal surgery is unknown.
• 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. In addition to pain associated with Essure, unrelated gynecological (e.g., endometriosis, adenomyosis) or non-gynecological (e.g., irritable bowel syndrome, interstitial cystitis) conditions may result in pain and should be considered during evaluation (see section VII. ADVERSE EVENTS, subsection ‘Pain’).
• Surgery including device removal, hysterectomy or other procedures may be required to treat the pain (see section XVII. INSERT REMOVAL), (see section VII. ADVERSE EVENTS, subsection ‘Pain’).
• Patients with known hypersensitivity to nickel, titanium, platinum, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the Essure system (see section II. DEVICE 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. 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 for tubal occlusion. For these patients, physicians must use the modified HSG as the Essure Confirmation Test. TVU should not be used as the Essure Confirmation Test, as TVU cannot confirm tubal occlusion. Clinical trials were not conducted with patients undergoing immunosuppressive therapy.

PREGNANCY RISK
• Pregnancies, including ectopic pregnancies, have been reported among women who have undergone the Essure procedure.
• The patient must use alternative contraception until a satisfactory Essure Confirmation Test is documented.
• 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 to use alternative contraception.
• Clinicians must counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all stages of the Essure procedure.
• In the case of unintended pregnancy that occurs at least 3 months after insertion, Essure cannot be relied on for future contraception, and alternative contraception is required to prevent subsequent unintended pregnancies.
• Physicians must adhere to the Essure Confirmation Test algorithm (see section XV. 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 and a satisfactory Essure Confirmation Test.
• 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 successful pregnancies with healthy deliveries have been reported with Essure devices in place, pregnancy loss, premature labor, premature rupture of membranes, preterm delivery, stillbirth, genetic and developmental abnormalities have been reported in pregnancies with Essure.

PROCEDURE
• In order to reduce risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilation.
• Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or is suspected, discontinue procedure 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 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 XVII. 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 procedure.
PRECAUTIONS

- Have appropriate equipment, medication, staff, and training in place to handle emergency situations such as vaso-vagal response. 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.

- Utilize eye protection as back splash of hysteroscopic distention fluid (saline) into face can occur. Use an introducer to avoid insert tip damage.

- Identify and assess both tubal ostia prior to insert placement. Unusual uterine anatomy may make it difficult to place Essure inserts. Essure placement should not be attempted if uterine abnormalities make visualization of the tubal ostia impossible.

- Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to Essure insert placement. No attempt should be made to place an insert in one tubal ostium unless both tubes are accessible.

- Keep the operating channel of the hysteroscope open to avoid damage to insert or introducer.

- When introducing the Essure insert into the fallopian tube, never advance the insert 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 if possible and appropriate based on physician's judgment. (see section XVII. INSERT REMOVAL). Each fallopian tube should only contain one insert. If a physician suspects that the device has not deployed (e.g., sees no trailing coils), the physician must verify by inspection of the delivery system that deployment has not occurred. Refer to Figure 13 which shows delivery system before and after deployment. If physician suspects or is uncertain that deployment has occurred, imaging (e.g., X-ray, or TVU) may be used to identify presence of an insert in the tube or elsewhere in the body. If physician verifies that the tube does not contain an insert, a second placement attempt may be performed (see section XIII. DIRECTIONS FOR USE).

INTERACTION 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 tract or abscess formation around the insert. 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 injury to the surrounding tissue (e.g., bowel).

- During endometrial ablation, thermal injury to the proximal portion of the fibrotic in-growth 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 inserts 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 procedures, 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 (i.e., 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 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. 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 inserts when performing a hysterecomy when the adnexa are being retained. The Essure insert may conduct energy and cause patient injury if contacted by an active electrosurgical device. Avoid electrosurgery on uterine cornua and proximal fallopian tubes without visualizing inserts. During Laparoscopically Assisted Vaginal Hysterectomy do not place instruments more proximal than the ampullary portion of the tube.

PRECAUTIONS

- Intrauterine procedures such as endometrial biopsy, dilation and curettage (D & C), and hysteroscopy may involve the use of instrumentation that may come into contact with the inserts. If the inserts are displaced or removed by such instrumentation, the patient’s ability to rely may be affected.

- 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 should 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 Essure insert placement 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.

- Patients may decide, in future years, to undergo in vitro fertilization (IVF) to become pregnant. There are limited data related to the effects, including risks, of Essure inserts on in vitro fertilization (IVF).

MRI SAFETY INFORMATION

PRECAUTIONS

- MRI Information. The Essure insert was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005. Non-clinical testing demonstrated that the Essure insert is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:
  - Static magnetic field of 3-Tesla or less
  - Maximum spatial gradient magnetic field of 720-Gauss/cm or less

- MRI-Related Heating
In non-clinical testing, the Essure insert produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla/128-MHz, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change +1.7°C
Therefore, the MRI-related heating experiments for the Essure insert at 3-Tesla using a transmit/receive RF body coil at an MR system measured whole body averaged SAR of 3.0-W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.8-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.7°C.

**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

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>1.73 -mm2</td>
<td>53 -mm2</td>
<td>621-mm2</td>
<td>277-mm2</td>
</tr>
<tr>
<td>Plane Orientation</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

**POST-PROCEDURAL MANAGEMENT**

(Also refer to section X. PATIENT COUNSELING INFORMATION)

**WARNINGS**

- Some Essure patients have reported pelvic pain that may be device related (see section VII. ADVERSE EVENTS). If device removal is indicated, this will require surgery.
- 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 that the Essure Confirmation Test may be 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 the Confirmation Test may indicate that they may not be able to rely on Essure. Discuss management options in the event of either of these outcomes (refer to section XIV. MANAGEMENT OF CASES WITH UNSUCCESSFUL INSERT PLACEMENT DURING THE INITIAL PROCEDURE).

**VII. ADVERSE EVENTS**

**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 Pivotal). 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**

<table>
<thead>
<tr>
<th>Adverse Event/ Side Effect</th>
<th>Phase II Trial</th>
<th>Pivotal Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number (N=233 procedures)</td>
<td>Percent</td>
</tr>
<tr>
<td>Cramping</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Pain</td>
<td>2</td>
<td>0.9%</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Dizziness/light headed</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Bleeding/spotting</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Other</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Vaso-vagal response</td>
<td>2</td>
<td>0.9%</td>
</tr>
<tr>
<td>Hypervolemia</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Band Detachment</td>
<td>3</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

* 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).

** Table 2: Pivotal Trial**

**Adverse Events by Body Systems, First Year of Reliance**

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

* Only events occurring in ≥ 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 to FDA by women implanted with Essure, although they were not seen in the clinical trials supporting Essure approval. The more common symptoms reported 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.

**A. 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. Risks and benefits associated with the planned anesthesia should be discussed prior to performing 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, vaso-vagal response may occur during and following the insert placement procedure. Typically, these incidents are tolerable, transient and successfully treated with medication.

**References**

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. 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.
Device Properties and Deployment:

- Bending of the insert tip or catheter, breakage of the catheter during attempted insertion and difficulty in deployment or detachment may 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 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. Depending on symptomatology, surgical intervention at the time of placement or shortly thereafter may be required, however for asymptomatic perforations, intervention may not be necessary. To reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.

- 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 perforation of internal bodily structures other than the uterus and fallopian tube for inserts located outside the fallopian tube and uterus.

- Additional imaging may be required to identify the location of the inserts. Removal of an unsatisfactorily located insert (perforation, embedment, migration, expulsion, proximal or distal fallopian tube placement, or within the peritoneal cavity) may require surgery (see section XVII. INSERT REMOVAL).

Infection:

- As with all hysteroscopic procedures, insert placement 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.

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.

B. Risks Associated with the 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. While successful pregnancies with healthy deliveries have been reported with Essure devices in place, pregnancy loss, premature labor, premature rupture of membranes, preterm delivery, stillbirth, genetic and developmental abnormalities have been reported in pregnancies with Essure.

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. In addition to pain associated with Essure, 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 during evaluation.

- Pain and cramping may be more likely 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 XVII. INSERT REMOVAL).

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 VI. WARNINGS AND PRECAUTIONS). If a patient is experiencing a reaction suspected to be due to material(s) contained in the insert, removal of the inserts should be considered (see section XVII. INSERT REMOVAL).

Sterilization Regret:

- Sterilization regret can be associated with emotional disturbances including depression. Patients should be counseled prior to the Essure procedure (see section X. PATIENT COUNSELING INFORMATION).

C. Possible Risks Associated with Follow-up Procedures

- 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.

D. Possible Risks Associated with Future Procedures

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

- Some surgical instruments utilize energy sources such as electrosurgical devices, 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 is contraindicated when an Essure insert is in place.

- 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 to taken to completely remove the inserts when performing a hysterectomy when the adenexa are being retained.

- Intrauterine procedures such as endometrial biopsy, dilation and curettage (D & C), and hysteroscopy may involve the use of instrumentation that may come into contact with the inserts. If the inserts are displaced or removed by such instrumentation, the patient’s ability to rely may be affected. Endometrial ablation can result in thermal injury to the GI tract or abcess formation around the inserts. It may also cause intrauterine synchiae that can compromise conduct and interpretation of a modified HSG which may be needed for the Essure Confirmation Test.

- 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 the endometrial ablation systems and the Essure inserts in place (following a satisfactory Essure Confirmation Test performed three months post-insert placement). Endometrial ablation or other intra-uterine procedures may result in stretching or removal of the Essure insert.

- 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 also MR conditional, except for pelvic imaging, where they may cause some artifacts (see section VI. WARNINGS AND PRECAUTIONS, subsection ‘MRI Safety Information’).

E. Adverse Event Reporting

Report any adverse event involving the Essure system to Bayer immediately by calling 888-84 BAYER (888-842-2937).
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

<table>
<thead>
<tr>
<th>Age Distribution</th>
<th>Phase II and Pivotal Studies Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;28 years old</td>
<td>14%</td>
</tr>
<tr>
<td>28-33 years old</td>
<td>40%</td>
</tr>
<tr>
<td>≥34 years old</td>
<td>46%</td>
</tr>
</tbody>
</table>

Table 4: Patient Demographics

<table>
<thead>
<tr>
<th>Race*</th>
<th>Phase II and Pivotal Studies Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>White/Caucasian</td>
<td>N=745</td>
</tr>
<tr>
<td>Latin</td>
<td>428</td>
</tr>
<tr>
<td>Black</td>
<td>31</td>
</tr>
<tr>
<td>Other</td>
<td>24</td>
</tr>
<tr>
<td>Gravidity</td>
<td>Mean=2.91 (0 – 11)</td>
</tr>
<tr>
<td>Parity</td>
<td>Mean=2.3 (0 – 6)</td>
</tr>
<tr>
<td>Body Mass Index (BMI) (kg/m²)</td>
<td>Mean=27 (16-57)</td>
</tr>
</tbody>
</table>

*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
The effectiveness results from the Phase II/Pivotal studies conducted prior to marketing and the ESSTVU study are presented in this section. Insert placement and reliance rates are provided for the ESSTVU study, which utilized the ESS305 system and TVU/HSG Confirmation Test Algorithm. Reliance rates are also provided for the Phase II/Pivotal studies, which utilized the modified HSG confirmation test. One year contraceptive effectiveness results are provided for the ESSTVU study; contraceptive effectiveness results up to five years are presented for the Phase II/Pivotal studies. Safety results from the Phase II and Pivotal clinical studies are provided in the Adverse Event Section (Tables 1 and 2 in Section VII B) above.

In most recent clinical study, ESSTVU, the placement procedure was initiated in 597 women, and the insert placement was attempted in 594/597 (99%) women. Successful bilateral placement, as assessed at the time of placement by the physician, was achieved in 574/597 (96%) women after the first placement attempt, and in 582/597 (97%) women after the first or second placement attempt. Using the TVU/HSG Confirmation Test Algorithm at least 3 months after placement, 547/597 (92%) women who had the Essure procedure initiated, were told to rely. For those women who had successful bilateral placement as assessed by the TVU/HSG Confirmation Test Algorithm, 547/582 (94%) were told to rely, see Table 5. In the Phase II/Pivotal trial (N=745) with modified HSG confirmation testing, the reliance rate in women with successful bilateral placement was 643/664 (97%)(see footnote E of Table 5).
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 to assess reliance. In this study, three pregnancies were reported in the 1-year (518 woman-years) follow-up, see Table 6B. In all 3 pregnancies, TVU was utilized to confirm Essure placement, 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.

### Table 6A:
**Phase II / Pivotal with Modified HSG Confirmation Testing**

<table>
<thead>
<tr>
<th>Trials</th>
<th>Combined</th>
<th>One-Year</th>
<th>Two-Year</th>
<th>Three-Year</th>
<th>Four-Year</th>
<th>Five-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=643C</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>(95% CI 0 – 0.20%)A</td>
<td>(95% CI 0 – 0.30%)A</td>
<td>(95% CI 0 – 0.40%)A</td>
<td>(95% CI 0 – 0.50%)A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A 95% 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). The combined effectiveness data was obtained using Bayesian statistics.

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

C The number of women “N” who were told to rely.

### Table 6B:
**ESSTVU Trial with TVU/HSG Confirmation Testing Algorithm**

<table>
<thead>
<tr>
<th>Trials</th>
<th>N=547A</th>
<th>One-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=503B</td>
<td>(95% CI 0.16-1.53%)</td>
</tr>
</tbody>
</table>

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

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

---

As of the final 5-year follow-up data 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 or 2,969 woman-years of follow-up time with zero pregnancies reported, as presented in Table 6A. All subjects in the Phase II and Pivotal trials underwent modified HSG prior to being counselled to discontinue alternative contraception and rely on Essure.
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*

<table>
<thead>
<tr>
<th>Potential Contributing Factor</th>
<th>United States</th>
<th>Outside the United States**</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% of US causes</td>
<td>n</td>
</tr>
<tr>
<td>Patient Non-compliance (e.g., failure to use alternative contraception or return for Essure Confirmation Test)</td>
<td>213</td>
<td>32%</td>
<td>16</td>
</tr>
<tr>
<td>Perforation***/#</td>
<td>91</td>
<td>14%</td>
<td>4</td>
</tr>
<tr>
<td>Unsatisfactory Placement***</td>
<td>32</td>
<td>5%</td>
<td>13</td>
</tr>
<tr>
<td>Physician Non-compliance</td>
<td>22</td>
<td>3%</td>
<td>13</td>
</tr>
<tr>
<td>Pregnant at time of Placement (Luteal)</td>
<td>26</td>
<td>4%</td>
<td>6</td>
</tr>
<tr>
<td>Inadequate Confirmation Test***</td>
<td>28</td>
<td>4%</td>
<td>0</td>
</tr>
<tr>
<td>Expulsion***</td>
<td>20</td>
<td>3%</td>
<td>4</td>
</tr>
<tr>
<td>Tubal Patency***</td>
<td>19</td>
<td>3%</td>
<td>1</td>
</tr>
<tr>
<td>Insufficient Information to determine</td>
<td>209</td>
<td>32%</td>
<td>31</td>
</tr>
<tr>
<td>Total</td>
<td>660</td>
<td>88</td>
<td></td>
</tr>
</tbody>
</table>

* 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 X. 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.

References

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.
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 two methods utilized in the Essure Confirmation Test (TVU and modified HSG). Inform patients of the differences between the methods, including benefits and risks (including possible increased risk of pregnancy if TVU is the only confirmation method utilized).
- The management of adverse events may include surgery and removal of the inserts. 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 important 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.
- 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.


### X. 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 the 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 upper or lower genital tract infection, undiagnosed vaginal bleeding, anatomical variants and/or uterine pathology may make patient unsuitable for the procedure.
- Patients with known hypersensitivity to nickel, titanium, platinum, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the Essure system (see section II. DEVICE DESCRIPTION) may experience an allergic reaction to the insert. This includes both patients with or without a history of metal allergies. 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. Prior to the Essure procedure all patients should be counseled on the materials contained in the insert, as well as potential for allergy/hypersensitivity to these materials. Currently, there is no test that reliably predicts who may develop a hypersensitivity reaction to the materials contained in the insert.
- Essure may be placed with an IUD in the uterine cavity. In some cases, the IUD may need to be removed to complete the placement procedure and the patient must use alternative contraception until a satisfactory Essure Confirmation Test is documented. While highly unlikely, there is a theoretical risk of dislodgement of an Essure insert at the time of IUD removal.
- Bilateral insert placement may not be successful. Discuss a management plan with the patient in the event that bilateral placement is not achieved.

### XI. HOW SUPPLIED

Each Essure kit contains:

- Two (2) Essure systems
- Two (2) DryFlow Introducers
- One (1) Instructions for Use (IFU)
- One (1) Patient Identification Card

The Essure system is available in one size only.

STERILE: Each Essure system is supplied sterile. Each Essure system is sterilized using ethylene oxide and is supplied sterile for single use only. Do not re-use or re-sterilize. Resterilization may adversely affect proper mechanical function and could result in patient injury. Inspect each package and do not use if damaged.

### XII. PHYSICIAN TRAINING MANUAL

Refer to the Essure Physician Training Manual for detailed information not included in this IFU.

### XIII. 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. Administer a pregnancy test 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. An anxiolytic agent, may also be administered to prevent or reduce discomfort if needed (see section VII. ADVERSE EVENTS, subsection ‘Risks Associated with the Insert Placement Procedure’).
B. Essure Insert Placement Procedure

1. The Essure insert placement procedure can be performed in an outpatient or ambulatory setting. Use universal precautions and sterile technique.
2. Check all equipment for damage; ensure there are no missing parts.
3. Place patient in the lithotomy position.
4. Introduce speculum to allow cervical access. Prep cervix with betadine or other antibacterial solution according to standard practice. Vaginoscopy may also be used to access the uterine cavity.
5. Administer anesthesia as needed.
6. Insert sterile hysteroscope, with camera and operating channel (≥ 5 French), through cervix into 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 dilation.
7. Distend uterus with a physiologic saline solution 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. Maintain uterine distension throughout procedure for optimal visualization. Monitor fluids to reduce the risk of hypervolemia; terminate procedure if fluid deficit exceeds 1500cc or hysteroscopic time exceeds 20 minutes.
8. Identify and assess hysteroscopically both tubal ostia prior to insert placement. Do not attempt placement in one tubal ostium unless both tubes are accessible.
9. Once the fallopian tube ostia have been identified, insert introducer through sealing cap on the operating channel of the hysteroscope. The operating channel stopcock should remain in the open position (the device and/or introducer can be damaged if stopcock closes on either device). Place the Essure delivery system through the introducer and advance through the operating channel of the hysteroscope (see Figure 5).
10. Insert delivery catheter through the introducer; avoid bending the insert tip. Under direct visualization, advance catheter through the proximal fallopian tube with gentle, constant forward 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.

11. Advance the delivery system until the black positioning marker on the delivery catheter reaches the fallopian tube ostium (see Figure 6). 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.

12. 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.
13. Stabilize the delivery system handle against the hysteroscope to prevent inadvertent forward movement. 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 7).

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 thumbwheel 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: Insert the introducer through sealing cap on the hysteroscope operating channel, then place delivery catheter through the introducer.

Figure 6: Advance until black positioning marker at tubal ostium, indicating proper position.

Figure 7: Stabilize handle against camera head or some other fixed object to prevent inadvertent forward movement of the Essure system.

Figure 8: Rotate thumbwheel to retract delivery catheter, exposing wound down insert.
14. 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 8) (corresponds to the symbol on the delivery system handle). The delivery catheter and black positioning marker will move away from the tubal ostium 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.

15. Stop and check proper positioning, which corresponds to the symbol on the delivery system handle. Confirm placement of the gold marker band just outside the ostium (see Figure 9), and confirm visualization of the distal tip of the green release catheter. 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. Move the delivery catheter toward you until 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.

STOP and Check

16. Press the button on the delivery handle which corresponds to the symbol on the handle button (see Figure 10). This enables the thumbwheel to be rotated further for insert deployment.

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

17. Rotate the thumbwheel once more (symbol) until the thumbwheel cannot turn any further (see Figure 11). When the thumbwheel cannot be rotated any further and the expanded outer coils are visible, remove the delivery system.

Note: Hold the valved introducer in place during removal of the delivery system as it may also be inadvertently withdrawn. If the introducer is removed, replace with a new introducer provided in the Essure system packaging.

A. Assessment of Insert After Deployment

1. The position of the deployed Essure insert will be assessed under hysteroscopic visualization. Inserts showing 0-17 trailing coils should be left in place and evaluated via Essure Confirmation Test. Ideally, 3 to 8 expanded outer coils should be trailing into the uterine cavity (see Figure 12).

2. If the physician is dissatisfied with insert placement based on the hysteroscopic view, and there are fewer than 18 trailing coils, the inserts 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 13 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.

3. 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.

WARNING: Do not attempt insert removal hysteroscopically unless 18 or more coils of the Essure insert are trailing into 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 XVII. INSERT REMOVAL for additional information.
4. If insert removal is successful, repeat the Essure® insert placement procedure. If removal is not accomplished, leave insert in place. If insert is not completely removed, do not place additional inserts. Take a diagnostic X-ray to determine if insert fragment remains in the patient. If fragment remains, refer to section XVII. INSERT REMOVAL.

5. 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.

B. Post Procedure Instructions and Patient Follow-up Requirements

1. Ensure patient uses alternative contraception until the Essure® Confirmation Test. Physician should counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all steps of the Essure® procedure.

2. Schedule patient for an Essure® Confirmation Test three months following the procedure to evaluate insert location (TVU), or location and occlusion (modified HSG) of the fallopian tubes.

3. Provide patient with the Patient Identification Card and instruct her to show it to her physicians.

XIV. MANAGEMENT OF CASES WITH UNSUCCESSFUL 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 successful and should continue to use alternative contraception. 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 second attempt fails, success with subsequent attempts is unlikely. If one insert is left in vivo, counsel patient to not rely on the insert for contraception. Do not remove a unplacated insert unless the patient experiences an adverse event(s) due to its presence. 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.

XV. 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) or modified hysterosalpingogram (modified HSG)) should be performed only by an experienced healthcare provider, including gynecologist, ultrasonographer and/or radiologist who knows how to perform the appropriate Essure® Confirmation Test. Training and/or educational materials on the Essure® Confirmation Test are available through Bayer.

When utilizing the TVU/HSG Confirmation Test Algorithm, TVU may be performed as a first-line confirmation test three months after a bilateral insert placement procedure. However, TVU should not be used as the Essure® Confirmation Test under the following circumstances:

1) Difficult placement procedure including one or more of the following:
   a. Concern at the time of placement of possible perforation due to excessive force required for insert delivery and/or a sudden loss of resistance.
   b. Difficulty identifying the tubal ostia during placement due to anatomical variation or technical factors such as poor distention, suboptimal lighting or endometrial debris.
   c. Physician is uncertain about placement.

2) Procedure time > 15 minutes (scope in-scope out).

3) Placement with zero or > 8 trailing coils.

4) Unusual post-operative pain, transient or persistent, or onset at some later time post procedure, without any other identifiable cause.

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 should not be utilized for confirmation, as this test cannot confirm tubal occlusion in these patients. Clinical trials were not conducted with patients undergoing immunosuppressive therapy.

Healthcare providers who utilize the Essure® Confirmation Test with TVU must complete training, which is administered by Bayer and documented by a certificate of completion. Trans-abdominal ultrasound cannot be substituted for TVU. If ultrasound is not indicated, patient must proceed to a modified HSG to evaluate insert location and tubal occlusion. If ultrasound evaluation is equivocal or unsatisfactory, patient must proceed to a modified HSG to evaluate insert location and tubal occlusion.

B. Transvaginal Ultrasound

1) A minimum of three images must be obtained and retained for documentation:
   a. A transverse or oblique transverse view (see Figure 14) demonstrating a portion of each insert in the cornua labeled “scout image”.

   Figure 14: Bilateral inserts are identified in this transverse (transverse / oblique-transverse) view.

   (b) A transverse or oblique transverse image of the linear axis of the left insert, labeled “left” including the proximal end crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with SUTJ (See Figure 4).

   (c) A transverse or oblique transverse image of the linear axis of the right insert, labeled “right” including the proximal end crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with SUTJ (See Figure 4).

   (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 insert 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 SUTJ (see Figure 15). 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.

   (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 SUTJ (see Figure 16). 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.
(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 in patients meeting criteria for Essure Confirmation Test with TVU (see section XV. ESSURE CONFIRMATION TEST, subsection 'A').

- If location of the inserts is classified as either satisfactory or optimal, instruct the patient to discontinue alternative contraception. The Essure Confirmation Test with TVU does not assess tubal occlusion. Satisfactory and optimal placement, as assessed by TVU, has been demonstrated in clinical studies to be an effective measure of the patient’s ability to rely when utilizing the TVU/HSG Confirmation Test Algorithm.

- If ultrasound evaluation is equivocal or unsatisfactory, the 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.

C. 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 modified 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 modified HSG - Guidelines:

   a) Obtain good cornual filling so that 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 for midpositional uteri.

   e) Remove speculum prior to fluoroscopy for best visualization of uterine anatomy.

   f) Take a minimum of 6 radiographs to assess insert location and tubal occlusion.

During evaluation, note four “markers” on each insert: two on the inner coil and two on the outer coil (see Figure 17). The two distal markers and the proximal marker of the inner coil are fixed in relation to one another, but the proximal marker of the outer coil may move or seem stretched because of the flexibility of the outer coil.

(1) Radiograph 1 – “Scout Film” – Uterus and inserts without contrast (see Figure 18).

(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 19).

(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.

A. Assessing Insert Location

Assess insert location:

1. Expulsion or proximal placement: Insert is not present, or ≥ 50% of inner coil trailing into uterine cavity.

2. Satisfactory placement: 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 ≤ 30mm into tube from where contrast fills cornua.

3. Distal placement or perforation: Insert is in tube but proximal end of the inner coil > 30mm distal from where contrast fills cornua or the insert is completely or partially perforated.

4. Peritoneal location: Insert is found within the peritoneal cavity and not located within the tube.
B. 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 outer
         coil or in the peritoneal cavity.

C. Assessing Ability to Rely
   If location and tubal occlusion are both rated satisfactory, instruct patient to
continue alternative contraception.
   If location is unsatisfactory, instruct patient to not rely on the inserts for
contraception.
   If location is satisfactory but occlusion is unsatisfactory, instruct patient to remain
on alternative contraception. Repeat the Essure Confirmation Test (modified HSG)
in three months. If occlusion is still unsatisfactory, instruct patient to not rely on the
inserts for contraception.

XVI. MANAGEMENT OF PATIENTS WHO ARE NOT ABLE TO RELY
For patients who are not able to rely management may include, 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 insert is determined to be perforated or expelled, tubal
patency is seen on modified HSG, and no part of an Essure insert is in the fallopian tube,
a second attempt to place an insert into the tube may be performed. If a portion of the
insert is in the fallopian tube, counsel the patient on incisional sterilization or to remain
on alternative contraception.
Incisional Sterilization or Remain on Alternative Contraception: If insert is in an
unsatisfactory location (distal, perforation, proximal/expulsion) but occlusion is seen on
modified HSG, advise patient of potential for false positive diagnosis of occlusion.
If the patient chooses laparoscopic sterilization (clip application, bipolar cautery,
salpingectomy, or other methodologies), the location of the inserts 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 XVII.
INSERT REMOVAL). Caution must be taken not to leave any perforations proximal to the
lubal ligation.
Peritoneal Location: Location of insert(s) should be evaluated and decision should
be made as to whether the insert should be left in situ or removed (see section XVII.
INSERT REMOVAL).

XVII. INSERT REMOVAL
WARNING: Essure inserts are intended to be left in place permanently. Do not remove
insert(s) unless patient is experiencing an adverse event(s) associated with its presence,
if removal is clinically indicated, (see section XVII. INSERT REMOVAL, subsection
‘Removal of insert located within the peritoneal cavity’) or if requested by the patient.
If insert removal is planned, 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.
For all removal procedures, inspection of the removed insert is essential. 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, as determined
by the physician’s judgment. The following are potential surgical approaches that can
be considered for the removal of Essure.

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
may 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’s working channel.
3. Try to grasp the outer and inner coils 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, 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 may 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). 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 up to seven weeks following
placement. 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’ in section XVII. 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 (refer to Figure 17: Corresponding radiographic view of the Essure
insert). 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 electrosurgical instruments are employed, they should be used judiciously to avoid
injury to adjacent structures or fracturing of the insert.
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 vasocostrictive 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
graped 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 XVII. INSERT REMOVAL, subsection
‘Combined hysteroscopic/laparoscopic removal’). Removal may be
along with, or independent of, an incisional sterilization procedure.
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.
Section XVII. INSERT REMOVAL, subsection 'Subsequent to Placement Procedure'

When removing the insert via salpingectomy, the location of the proximal and distal portions of the insert within the fallopian tube should be confirmed intraoperatively by palpation, visualization and/or imaging prior to transecting the fallopian tube containing the insert to avoid transecting or fracturing the insert. The insert may be exposed and visualized via salpingotomy prior to transection or removal of the fallopian tube.

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 XVII. INSERT REMOVAL, subsection 'Combined hysteroscopic/laparoscopic removal').

When performing a hysterectomy, it is important that the inserts be identified prior to surgery and care used not to transect or cauterize the inserts as this may result in fragmentation. Removal of the inserts through one of the techniques outlined in section XVII. INSERT REMOVAL, subsection 'Subsequent to Placement Procedure' may be required prior to the completion of the hysterectomy, with or without bilateral salpingectomy.

A. Salpingectomy:

Distally located inserts (all portions of the insert distal to the cornua):
When removing the insert via salpingectomy, the location of the proximal and distal portions of the insert within the fallopian tube should be confirmed intraoperatively by palpation, visualization and/or imaging prior to transecting the fallopian tube containing the insert to avoid transecting or fracturing the insert. The insert may be exposed and visualized via salpingotomy prior to transection or removal of the fallopian tube.

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 XVII. 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. Availability of intraoperative fluoroscopy and/or intraoperative x-ray is recommended to identify the location of the insert or fragments of the insert during surgery.

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 section XVII. INSERT REMOVAL, subsection '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 (see section XVII. INSERT REMOVAL, subsection ‘D. Hysterectomy’) may be required.

C. Removal of Insert located within peritoneal cavity:
There have been reports of unsatisfactory device locations, including inserts located in the peritoneal cavity. Removal of inserts in asymptomatic cases may not be necessary. 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 be stretched within 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 17). 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 in the physician’s medical judgment when a hysterectomy is appropriate. 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 inserts be identified prior to surgery and care used not to transect or cauterize the inserts as this may result in fragmentation. Removal of the inserts through one of the techniques outlined in section XVII. INSERT REMOVAL, subsection ‘Subsequent to Placement Procedure’ may be required prior to the completion of the hysterectomy, with or without bilateral salpingectomy, in order to avoid transecting or fracturing the insert.

XVIII. SYMBOL LEGEND

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilized using ethylene oxide</td>
<td>STERILE EO</td>
</tr>
<tr>
<td>Batch Code</td>
<td>LOT</td>
</tr>
<tr>
<td>Do Not Reuse</td>
<td></td>
</tr>
<tr>
<td>Catalog Number</td>
<td>REF</td>
</tr>
<tr>
<td>Attention, See Instructions for Use</td>
<td></td>
</tr>
<tr>
<td>Use By</td>
<td></td>
</tr>
<tr>
<td>Keep away from heat</td>
<td></td>
</tr>
<tr>
<td>MR Conditional</td>
<td></td>
</tr>
<tr>
<td>Do Not Use If Package Is Open Or Damaged</td>
<td></td>
</tr>
<tr>
<td>Do not re-sterilize</td>
<td></td>
</tr>
<tr>
<td>Keep Dry</td>
<td></td>
</tr>
<tr>
<td>Content</td>
<td>CONT</td>
</tr>
</tbody>
</table>

Manufactured for: Bayer Pharma, AG
Müllerstr. 178
D- 13535 Berlin
Germany

Essure® and DryFlow® are trademarks or registered trademarks of Bayer Essure Inc. in the United States and/or other countries. All other trademarks are the property of their respective owners.

Recyclable

Manufactured for:
Bayer Pharma, AG
Müllerstr. 178
D-13535 Berlin
Germany

©2002 Bayer
All Rights Reserved
Printed in USA

6906902M