IMPORTANT SAFETY INFORMATION

WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device.

NOTE: Essure® should be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use and this Physician Training Manual; and have successfully completed the Essure training program, including preceptoring in placement.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3.
Dear Doctor:

Congratulations! You have joined a growing number of physicians who have chosen to provide their patients with the Essure in-office procedure for permanent birth control.

The Essure Clinical Resource is a comprehensive resource that provides clinical instruction and information on the following:

- Selecting appropriate Essure® patients
- Counseling patients on the benefits and risks of Essure
- Performing the Essure permanent birth control procedure
  - Device removal, including device removal instructions
- Conducting and evaluating results of the Essure Confirmation Test with transvaginal ultrasound (TVU) or modified hysterosalpingogram (HSG)

If you have any questions that cannot be answered by this manual or the Instructions for Use, please do not hesitate to contact your Bayer Clinical Sales Specialist or call the Bayer Product Information department at (877) 377-8732.

INDICATION

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

IMPORTANT SAFETY INFORMATION

**WARNING:** Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device.

**Caution:** Federal law restricts this device to sale by or on the order of a physician. Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the instructions for Use and Physician Training Manual; and have successfully completed the Essure training program, including preceptoring in placement until competency is established, typically 5 cases.

**Contraindications**

Essure is contraindicated in patients who are uncertain about ending fertility, can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicorne 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, 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, or have a known allergy to contrast media.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
IMPORTANT SAFETY INFORMATION About Essure® (continued)

General Warnings
• The Essure procedure should be considered irreversible.

• Pain (acute or persistent) of varying intensity and length of time may occur following Essure placement. This is also more likely to occur in individuals with a history of pain. If device removal is indicated, this will require surgery.

• Patients with known hypersensitivity to nickel, titanium, platinum, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the Essure system may experience an allergic reaction to the insert. 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. Currently there is no test that reliably predicts who may develop a hypersensitivity reaction to the materials contained in the insert.

• Patients on immunosuppressive therapy may experience delay or failure of the necessary tissue ingrowth for tubal occlusion. For these patients, physicians must use the modified HSG as the Essure Confirmation Test. Transvaginal ultrasound (TVU) should not be used as the Essure Confirmation Test, as TVU cannot confirm tubal occlusion.

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.

• 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.

• Effectiveness rates for the Essure procedure are based on patients who had bilateral placement and a satisfactory Essure Confirmation Test.

Procedure Warnings
• 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.

• To reduce the risk of hypervolemia, terminate procedure if distension fluid deficit exceeds 1500cc or total hysteroscopic procedure time exceeds 20 minutes. Excess fluid deficit may signal uterine or tubal perforation. If noted, discontinue procedure and evaluate patient for possible perforation.

• Do not attempt hysteroscopic Essure insert removal during the placement procedure unless 18 or more trailing coils are seen inside the uterine cavity due to risk of a fractured insert, fallopian tube perforation, or other injury.

• DO NOT perform the Essure procedure concomitantly with endometrial ablation.

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.

Adverse Events
The most common (≥10%) adverse events resulting from the placement procedure were cramping, pain, and nausea/vomiting. The most common adverse events (≥3%) in the first year of reliance were back pain, abdominal pain, and dyspareunia.

This product does not protect against HIV infection or other sexually transmitted diseases.

Prescription Only
OVERVIEW OF UNINTENDED PREGNANCIES AND USE OF CONTRACEPTION

A SIGNIFICANT NUMBER OF WOMEN ARE DONE HAVING CHILDREN

Analysis of the CDC National Survey of Family Growth (NSFG) 2011-2013 shows that*:  
• 59% of women aged 21-45 years have decided their families are complete (N=49 million)

Among those who are using contraception and have completed childbearing (N=23 million)†:
• 45% are using temporary methods of contraception or nothing at all‡
• 55% were using permanent methods of contraception

UNINTENDED PREGNANCY OCCURS AMONG THOSE DONE HAVING CHILDREN

Even women who report they are finished having children experience unintended pregnancies. In this particular group, unintended pregnancies are more likely to be reported in:

• Women using a less effective method of contraception (eg, barrier methods, rhythm, or withdrawal) or no method at all or have a history of contraceptive discontinuation or incorrect use²

Pregnancies, including ectopic pregnancies, have been reported among women who have undergone the Essure procedure.

*Based on analysis from the 2011-2013 CDC NSFG: a survey sample of women aged 21 to 45 (n=4379) extrapolated to the US population (N).
†Based on analysis from the 2011-2013 CDC NSFG: a survey sample of women aged 21 to 45 who had completed childbearing yet were still at risk of an unintended pregnancy (n=1912) extrapolated to the US population (N).
‡Methods include: pill, injection, vaginal ring, skin patch, condom, implant, and other.

OF THE OVERALL UNINTENDED PREGNANCIES IN WOMEN (AGED 35-45 YEARS), 58% OCCURRED IN THOSE WHO WERE DONE HAVING CHILDREN (N=170,487)¹⁹

Most unintended pregnancies are attributable to nonuse, inconsistent use, or incorrect use of contraceptives.³

IUD=intruterine device.

³Based on an analysis from the 2011-2013 CDC NSFG: survey sample (n) extrapolated to the US population (N). Results include data from 20 US women aged 35 to 45 years who conceived during this time frame and participated in the study.

Other methods grouped in this category include implant, contraceptive ring or patch, withdrawal, and natural family planning.

USE OF STERILIZATION AMONG WOMEN AGED 21-45 WHO HAVE COMPLETED CHILDBEARING

The majority of women (55%) use permanent contraception³

• Female sterilization is the most commonly used method (41%)

[Graph showing contraceptive methods used among women aged 21-45 who have completed childbearing.]

23 million US women

Contraceptive Method

Female sterilization 41%

Male sterilization

Injectable

Pill

IUD

Male condom

Other

None

Unintended Pregnancies

Done having children 58%

Open to having children 42%

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
PRODUCT OVERVIEW

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
PRODUCT OVERVIEW

WHAT IS ESSURE®?
Essure is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes. Essure was designed as an alternative to incisional methods of tubal ligation that require general anesthesia.

Essure is contraindicated for patients who:
- Are uncertain about ending fertility
- Can 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)

ESSURE COMPONENTS
Before you begin the Essure procedure, it’s important to be able to identify the components of the Essure delivery system and understand how they work.

- Essure insert
- Disposable delivery system
- DryFlow™ introducer

A rigid hysteroscope with a ≥5 French working channel, continuous flow, and a 12- or 30-degree angled lens is used to place Essure.

ESSURE INSERT
The Essure insert consists of a stainless steel inner coil, a nitinol, superelastic outer coil, and polyethylene terephthalate (PET) fibers. The PET fibers are wound in and around the inner coil. The insert is 4 cm in length and 0.8 mm in diameter in its wound-down configuration. When released, the outer coil expands to 1.5 to 2.0 mm to anchor the insert in the varied diameters and shapes of the fallopian tube.

Material Composition of Components of Essure Insert

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer coil</td>
<td>Chromium-doped nitinol (nickel-titanium)</td>
<td>56% nickel, 44% titanium, trace chromium</td>
</tr>
<tr>
<td>Inner coil, thread coil</td>
<td>316L stainless steel</td>
<td>~62.5% iron, 17.6% chromium, 14.5% nickel</td>
</tr>
<tr>
<td>Stopper band, platinum band, platinum ring, bump</td>
<td>Platinum-iridium</td>
<td>90% platinum, 10% iridium</td>
</tr>
<tr>
<td>Solder</td>
<td>Silver-tin</td>
<td>95% tin, 5% silver</td>
</tr>
<tr>
<td>Fiber</td>
<td>PET polyester, white</td>
<td>≥92% polyester, &lt;5% titanium dioxide, &lt;3% fiber lubricants</td>
</tr>
</tbody>
</table>
PRODUCT OVERVIEW

ESSURE® INSERT (CONTINUED)

Disposable delivery system

Wound-down insert, attached to the release catheter, 0.8 mm in diameter (not to scale)

Expanded insert (1.5-2.0 mm in diameter), 4 cm in length with white PET fibers on inner coil (not to scale)

DISPOSABLE DELIVERY SYSTEM

The disposable delivery system consists of a single-handed ergonomic handle that contains a delivery wire, release catheter, and delivery catheter. The delivery wire and release catheter are not visible in the figure below (not to scale).

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

The delivery handle controls the delivery and release mechanism. The thumbwheel on the delivery handle retracts the delivery catheter. The button allows the physician to change the function of the thumbwheel from retracting the delivery catheter to deploying the outer coils. The delivery wire is detached from the insert by rolling the thumbwheel to a hard stop.

DryFlow™ INTRODUCER

The DryFlow™ introducer helps facilitate entry and advancement of the Essure insert and protects the insert; it also minimizes fluid splash-back as the Essure insert passes through the sealing cap of the hysteroscope working channel.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
HOW ESSURE® WORKS

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

Placement at the 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.
- This location is distal enough to avoid expulsion, yet proximal enough to visualize trailing coils in the uterine cavity.

For more detailed placement steps, please refer to the Essure placement procedure section or the Instructions for Use.

The Essure insert is a dynamic, spring-like device that expands once deployed to conform to varied diameters and shapes of fallopian tubes:

- The spring-like mechanism is intended to provide the necessary anchoring forces during the acute phase of insert implantation (3 months post-insert placement), during which time the PET fibers within the device are eliciting tissue in-growth into the coils of the insert and around the PET fibers.

The efficacy of Essure is believed to be due to a combination of the space-filling design of the insert and a local, occlusive, benign tissue response to the PET fibers:

- The tissue response is the result of an inflammatory and fibrotic response to the PET fibers. It is believed that the tissue in-growth into the insert caused by the PET fibers results in both insert retention and pregnancy prevention. PET fibers have had widespread use in the clinical setting.

**Confirmation coils in uterine cavity**

**Tubal ostium**

**UTJ**

**SUTJ**

**Deployed Essure**

**Interstitial portion of fallopian tube**

*Ideal Essure insert placement*
PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
Two clinical trials (Phase II trial and Pivotal trial) have demonstrated the efficacy and safety of Essure® permanent birth control. 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.

**STUDY DESIGNS**

**Phase II with modified HSG**
- Prospective, multi-center, single-arm, non-randomized, international study
- Study objectives: 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; and effectiveness of the inserts in preventing pregnancy

**Pivotal with modified HSG**
- 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, and safety of insert wearing. Secondary endpoints included: participant satisfaction with procedure, participant satisfaction with insert wearing, bilateral device placement rate, and profile development for appropriate procedure candidates

In both studies, an Essure Confirmation Test with modified HSG was performed 3 months post-insert placement to evaluate insert location and fallopian tube occlusion. If bilateral fallopian tubes were occluded and bilateral inserts were in satisfactory location, then the patient was instructed to discontinue use of alternative contraception and rely on the Essure inserts for prevention of pregnancy.

**ESSTVU Study with TVU/HSG Confirmation Test 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

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.
CLINICAL DATA

PATIENT CHARACTERISTICS

The study population of the Phase II and Pivotal trials combined consisted of 664 women in whom bilateral insert placement was achieved after one or more attempts (200 in the Phase II trial and 464 in the Pivotal trial). All study participants were between 21 and 45 years of age and were seeking permanent birth control prior to enrollment in the study. Additionally, all women had at least 1 live birth, had regular, cyclical menses, and were willing to use alternative contraception for the first 3 months following Essure insert placement.

Age Distribution  (Combined data from Pivotal trial and Phase II trial); Average age: 33

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

**Demographics**

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Phase II and Pivotal Trials Combined (N=745)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RACE*</td>
<td></td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>428</td>
</tr>
<tr>
<td>Latin</td>
<td>31</td>
</tr>
<tr>
<td>Black</td>
<td>24</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
</tr>
<tr>
<td>Gravidity</td>
<td>Mean=2.91 (0-11)</td>
</tr>
<tr>
<td>Parity</td>
<td>Mean=2.23 (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 trial only; race not collected in Phase II trial.

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.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
CLINICAL DATA

PHASE II AND PIVOTAL STUDIES COMBINED RESULTS

Reliance Rate (Phase II and Pivotal Studies Combined)
97% of patients with successful bilateral placement were able to rely on Essure® for permanent birth control (n=643/664)*

Adverse Events that Prevented Reliance in the Phase II and Pivotal Studies

<table>
<thead>
<tr>
<th>Adverse Events Preventing Reliance</th>
<th>Phase II</th>
<th>Pivotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforation</td>
<td>7/206 (3.4%)†</td>
<td>5/476 (1.1%)</td>
</tr>
<tr>
<td>Expulsion</td>
<td>1/206 (0.5%)</td>
<td>14/476 (2.9%)‡</td>
</tr>
<tr>
<td>Unsatisfactory insert location</td>
<td>1/206 (0.5%)</td>
<td>3/476 (0.6%)</td>
</tr>
<tr>
<td>Initial tubal patency</td>
<td>7/200 (3.5%)§</td>
<td>16/456 (3.5%)§</td>
</tr>
</tbody>
</table>

*The reliance rate is the number of women who relied on Essure for birth control divided by the number of women with bilateral insert placement.
† Included 1 patient that relied for 31 months before laparotomy and cornual resection due to pain; the other 6 never relied.
‡ 9 out of 14 patients underwent a successful second placement procedure after expulsion.
§ Patients with initial tubal patency were instructed to continue with alternative contraception and undergo a repeat Confirmation Test at 6 months. All patients were found to have tubal occlusion at the repeat Essure Confirmation Test with modified HSG 6-7 months post-procedure.

Efficacy (Phase II and Pivotal Studies Combined)

No pregnancies were reported in 5-year clinical study data
- However, no method of contraception is 100% effective and pregnancies have occurred in the commercial setting. Refer to Essure Effectiveness in the Commercial Setting at the end of this section

Phase II / Pivotal With Modified HSG Confirmation Testing:
Effectiveness Results Among Women Told to Rely (Cumulative Failure Rates)

<table>
<thead>
<tr>
<th>Phase II and Pivotal Trials Combined N=643§</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>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>N=635§</td>
<td>N=605§</td>
<td>N=586§</td>
<td>N=567§</td>
<td>N=567§</td>
<td></td>
</tr>
<tr>
<td>(95% CI 0-0.10%)§</td>
<td>(95% CI 0-0.20%)§</td>
<td>(95% CI 0-0.30%)§</td>
<td>(95% CI 0-0.40%)§</td>
<td>(95% CI 0-0.50%)§</td>
<td></td>
</tr>
</tbody>
</table>

* The number of women, “N”, who were told to rely.
§ 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 ≥59 months.
| 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.

ESSURE WAS SHOWN TO BE OVER 99% EFFECTIVE AT PREVENTING PREGNANCY IN PATIENTS TOLD TO RELY, BASED ON CLINICAL STUDY DATA

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
CLINICAL DATA

ESSTVU Study Results

547 trial participants were instructed to rely on Essure for contraception. The Essure Confirmation Test was performed with TVU or modified HSG as determined by the TVU/HSG Confirmation Test Algorithm.

Insert Placement Rate and Reliance Rate (ESSTVU Trial)

<table>
<thead>
<tr>
<th>Placement Status</th>
<th>ESSTVU Study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
</tr>
<tr>
<td>Placement Rate: Assessed at the time of placement</td>
<td></td>
</tr>
<tr>
<td>Procedure Initiated&lt;sup&gt;a&lt;/sup&gt;</td>
<td>597</td>
</tr>
<tr>
<td>Insert Placement Attempted&lt;sup&gt;b&lt;/sup&gt;</td>
<td>594/597</td>
</tr>
<tr>
<td>Successful bilateral placement after first attempt</td>
<td>574/597</td>
</tr>
<tr>
<td>Successful bilateral placement after first or second attempt</td>
<td>582&lt;sup&gt;c&lt;/sup&gt;/597</td>
</tr>
<tr>
<td>Reliance Rate: Assessed at the Essure Confirmation Test (at least 3 months after placement)</td>
<td></td>
</tr>
<tr>
<td>Reliance in women who had procedure initiated</td>
<td>547&lt;sup&gt;d&lt;/sup&gt;/597</td>
</tr>
<tr>
<td>Reliance in women with successful bilateral placement after first or second attempt</td>
<td>547&lt;sup&gt;d&lt;/sup&gt;/582&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup>Intent to treat (ITT) population in the ESSTVU trial includes all participants who had the Essure procedure initiated (ie, all study subjects who entered the procedure room/operating room with the intent to undergo the procedure).

<sup>b</sup>All subjects where the Essure system was passed through the working channel of the hysteroscope.

<sup>c</sup>Excludes 15/597 subjects with no insert placement attempt 3/597 (0.5%) and nonbilateral placement after 1 or 2 procedures 12/597 (2.0%).

<sup>d</sup>Excludes 50/597 subjects who were unable to reliably for the following reasons: No insert placement attempt 3/597 (0.5%), nonbilateral placement after 1 or 2 procedure 12/597 (2.0%), incomplete or no confirmation testing (28/597; 4.7%), unsatisfactory device location/occlusion identified at confirmation testing (perforation, expulsion, distal placement, proximal placement) (7/597; 1.2%).

ESSTVU Trial With TVU/HSG Confirmation Testing Algorithm: Effectiveness Results Among Women Told to Rely (Cumulative Failure Rates)

<table>
<thead>
<tr>
<th>ESSTVU Trial N=547&lt;sup&gt;+&lt;/sup&gt;</th>
<th>One-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.67% (N=503&lt;sup&gt;e&lt;/sup&gt;; 95% CI: 0.16-1.53%)</td>
</tr>
</tbody>
</table>

<sup>e</sup>The number of women, “N”, who were told to rely.

<sup>f</sup>The number of women, “N”, who attended follow-up at 1 year.

Three pregnancies were reported in the 1 year follow up in the ESSTVU trial based on 518 woman-years of follow up. In all 3 pregnancies, TVU was utilized as the confirmation test, and the insert locations were deemed “optimal” in the initial assessment. In 2 of the 3 pregnancies, perforation not detected by initial TVU assessment was determined to be the cause. In the third pregnancy, insert placement was unsatisfactory, and not detected by initial TVU. One additional pregnancy was reported 16 months after the subject was told to rely. As it occurred after the 1-year follow up, this pregnancy was not included in the 1-year effectiveness rate calculation.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
CLINICAL DATA

PATIENT TOLERANCE AND RECOVERY

Pivotal Study
Prospective, multicenter, single-arm, nonrandomized international study of women seeking permanent birth control (N=518).5

• 88% of patients rated tolerance of the placement procedure as good, very good, or excellent
• Women were typically discharged from the medical facility 45 minutes after the procedure
• 92% of working women missed no more than 1 day of work after the procedure day
• 75% of patients resumed normal activity by day 2
• 99% of women rated their comfort as good to excellent at all follow-up visits

ADVERSE EVENTS, DAY OF ESSURE PLACEMENT PROCEDURE

<table>
<thead>
<tr>
<th>Adverse Event/Side Effect</th>
<th>Phase II</th>
<th></th>
<th>Pivotal</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number (N=233 procedures)</td>
<td>Percent</td>
<td>Number (N=544 procedures)</td>
<td>Percent</td>
</tr>
<tr>
<td>Cramping</td>
<td>*</td>
<td>*</td>
<td>161</td>
<td>29.6%</td>
</tr>
<tr>
<td>Pain</td>
<td>2</td>
<td>0.9%</td>
<td>70</td>
<td>12.9%</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>*</td>
<td>*</td>
<td>59</td>
<td>10.8%</td>
</tr>
<tr>
<td>Dizziness/light headed</td>
<td>*</td>
<td>*</td>
<td>48</td>
<td>8.8%</td>
</tr>
<tr>
<td>Bleeding/spotting</td>
<td>*</td>
<td>*</td>
<td>37</td>
<td>6.8%</td>
</tr>
<tr>
<td>Other</td>
<td>*</td>
<td>*</td>
<td>16†</td>
<td>2.9%</td>
</tr>
<tr>
<td>Vasovagal response</td>
<td>2</td>
<td>0.9%</td>
<td>7</td>
<td>1.3%</td>
</tr>
<tr>
<td>Hypervolemia</td>
<td>*</td>
<td>*</td>
<td>2</td>
<td>0.4%</td>
</tr>
<tr>
<td>Band detachment</td>
<td>3</td>
<td>1.3%</td>
<td>2</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

*Data not collected.
†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).

Most women experienced mild to moderate pain during and immediately following the procedure. Pain was managed with oral nonsteroidal anti-inflammatory drugs (NSAIDs) or oral narcotic pain reliever.

The majority of women experienced spotting for an average of 3 days after the procedure.
CLINICAL DATA

ADVERSE EVENTS, FIRST YEAR OF RELIANCE (PIVOTAL TRIAL)*
The following adverse events were 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.

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Events</th>
<th>Number (N=476 patients implanted with at least one insert)</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal</td>
<td>Abdominal pain/abdominal cramps</td>
<td>18</td>
<td>3.8%</td>
</tr>
<tr>
<td></td>
<td>Gas/bloating</td>
<td>6</td>
<td>1.3%</td>
</tr>
<tr>
<td>Musculo-skeletal</td>
<td>Back pain/low back pain</td>
<td>43</td>
<td>9.0%</td>
</tr>
<tr>
<td></td>
<td>Arm/leg pain</td>
<td>4</td>
<td>0.8%</td>
</tr>
<tr>
<td>Nervous/Psychiatric</td>
<td>Headache</td>
<td>12</td>
<td>2.5%</td>
</tr>
<tr>
<td></td>
<td>Premenstrual syndrome</td>
<td>4</td>
<td>0.8%</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>Dysmenorrhea/amenstrual cramps (severe)</td>
<td>14</td>
<td>2.9%</td>
</tr>
<tr>
<td></td>
<td>Pelvic/lower abdominal pain (severe)</td>
<td>12</td>
<td>2.5%</td>
</tr>
<tr>
<td></td>
<td>Persistent increase in menstrual flow</td>
<td>9*</td>
<td>1.9%</td>
</tr>
<tr>
<td></td>
<td>Vaginal discharge/vaginal infection</td>
<td>7</td>
<td>1.5%</td>
</tr>
<tr>
<td></td>
<td>Abnormal bleeding—timing not specified (severe)</td>
<td>9</td>
<td>1.9%</td>
</tr>
<tr>
<td></td>
<td>Menorrhagia/prolonged menses (severe)</td>
<td>5</td>
<td>1.1%</td>
</tr>
<tr>
<td></td>
<td>Dyspareunia</td>
<td>17</td>
<td>3.6%</td>
</tr>
<tr>
<td>Pain/discomfort—uncategorized</td>
<td></td>
<td>14</td>
<td>2.9%</td>
</tr>
</tbody>
</table>

*Only events occurring in ≥0.5% are reported.

†8 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
Other 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 have been reported to the 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.

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, vasovagal response/syncope, pain, dysmenorrhea, uterine bleeding/spotting, infection, fluid overload, anesthetic complications, detachment difficulties and unsatisfactory insert location.

- Anesthesia, intra-operative and post-operative symptoms, device properties and deployment, unsatisfactory insert location, infection, fluid overload

RISKS ASSOCIATED WITH 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, pain, bleeding, infection, hypersensitivity, sterilization regret

POSSIBLE RISKS ASSOCIATED WITH FOLLOW-UP PROCEDURES
Essure Confirmation Test with modified HSG (Please refer to the Instructions for Use on www.essuremd.com)

POSSIBLE RISKS ASSOCIATED WITH FUTURE PROCEDURES
Patients who undergo placement of the Essure insert may, in future years, be offered gynecological therapies that pose additional risk due to the presence of the insert. (Please refer to the Instructions for Use on www.essuremd.com)

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE® EFFECTIVENESS IN THE COMMERCIAL SETTING

In the commercial setting, unintended pregnancies have been reported in women who have worn the inserts. The table below summarizes the reasons for pregnancy from reports received by the manufacturer and from additional reports from the published scientific literature.

Summary of Pregnancies Reported in Commercial Use of Essure®

<table>
<thead>
<tr>
<th>Potential Contributing Factor</th>
<th>United States (US)</th>
<th>Outside the United States (OUS)†</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Percent of US causes</td>
<td>n</td>
</tr>
<tr>
<td>Patient non-compliance (eg, 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>32%</td>
<td>88</td>
</tr>
</tbody>
</table>

*Table includes pregnancy reports received directly by the manufacturer, 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, the Essure Confirmation Test may be an x-ray or transvaginal ultrasound; device location alone, not occlusion, is primarily used to determine whether the patient may rely on Essure. Use of an x-ray or transvaginal ultrasound in the United States is not in accordance with approved labeling.

‡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.

§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.

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

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 of the IFU. 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.
PATIENT SELECTION AND COUNSELING
PATIENT SELECTION AND COUNSELING

ESSURE® MAY BE AN APPROPRIATE OPTION FOR WOMEN WHO DESIRE PERMANENT BIRTH CONTROL:

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 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
• Patient must use alternative contraception for at least 3 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 noncompliance 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

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
PATIENT SELECTION AND COUNSELING

Important Factors to be discussed with the Patient (continued)

• 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 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

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

For more detailed information about the Essure Confirmation Test, please refer to the Essure Confirmation Test section.
Women who undergo sterilization at a younger age are at greater risk of regretting their decision to undergo sterilization. If there is any chance that the patient may want to have children in the future, she should choose a reversible method of birth control.
PATIENT SELECTION AND COUNSELING

The review and completion of this form is a critical step in helping the patient decide whether or not to have Essure implanted. Please see the Essure Patient Information Booklet to complete the Patient-Doctor Discussion Checklist with the patient. For your review, the full Checklist is below:

PATIENT-DOCTOR DISCUSSION CHECKLIST

TO THE PATIENT CONSIDERING THE “ESSURE SYSTEM FOR PERMANENT BIRTH CONTROL” (“ESSURE”):
The review and completion of this form is a critical step in helping you decide whether or not to have Essure permanently implanted. You should carefully consider the benefits and risks associated with the device before you make that decision. After reviewing the Essure Patient Information Booklet, please read and discuss the items in this checklist with your doctor. You should not initial or sign the form, and should not undergo the procedure, if you do not understand each of the elements listed below.

Birth Control Options
I understand that Essure is a permanent form of birth control (referred to as “sterilization”). I understand that sterilization must be considered permanent and not reversible.

I was told about other permanent sterilization procedures, such as surgical bilateral tubal ligation (“getting tubes tied”), and their benefits and risks.

I am aware that there are highly effective methods of birth control which are not permanent and which may allow me to become pregnant when stopped.

Requirements for Essure
I understand that I am not a candidate for Essure if:
• I am uncertain about ending my fertility
• I have had a tubal ligation procedure (“tubes tied”)
• I cannot have two inserts placed due to my anatomy
• I am pregnant or suspect that I may be pregnant
• I have delivered or terminated a pregnancy within the last 6 weeks
• I have an active pelvic infection on the date of the scheduled implantation
• I have unexplained vaginal bleeding
• I have suspected or known cancer of the female reproductive organs
• I have a known allergy to contrast dye used during x-ray procedures

Essure only works when the inserts are successfully placed in both fallopian tubes. I understand that if this is not possible in my case, I may need to undergo a repeat attempt at Essure placement or consider a different form of birth control.

I understand that the placement procedure is only the first step in relying on Essure for birth control. After placement I must:
• Use an alternative form of birth control until my doctor tells me I can stop (typically for 3 months)
• Schedule and undergo a confirmation test after 3 months to determine whether I may rely on Essure. I understand that payment for this test may or may not be covered by my insurance company

I understand that a satisfactory confirmation test is needed before I can rely on Essure alone. I also understand that after the confirmation test my doctor may inform me that I may not be able to rely on Essure. If this occurs, I will have to use an alternative form of contraception.

I understand that, based on clinical studies, 8% of women who undergo attempts at Essure placement are not able to rely on the device.

Pregnancy Risks
I understand that no form of birth control is 100% effective. Even if my doctor tells me I am able to rely on Essure, there is still a small chance that I may become pregnant. Based on clinical studies, the chance of unintended pregnancy for women who have been told they can rely on Essure is less than 1% at 5 years.

I understand that the risks of Essure on a developing fetus have not been established. If I become pregnant with Essure, there may be a risk for the pregnancy to occur outside of the uterus (“ectopic pregnancy”). This may result in serious and even life-threatening complications. I understand that I should contact my doctor immediately if I think I may be pregnant.

Patient Initials ______

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
PATIENT SELECTION AND COUNSELING

What to Expect During and After the Procedure

I understand that in clinical studies supporting device approval, the following events were reported to occur during the Essure® placement procedure and/or in the hours or days following placement:

- Cramping (reported in 29.6% of procedures)
- Mild to moderate pain (9.3%) or moderate pain (12.9%)
- Nausea/Vomiting (10.8%)
- Dizziness/Lightheadedness (8.8%)
- Vaginal bleeding (6.8%)

If I experience worsening of any of the events listed above or I continue to have the symptoms, I understand that I should contact my doctor.

Patient Initials ______

Long-term Risks

I understand that some women may experience continued pain or develop new pain later after Essure placement. I understand that I should contact my doctor if abdominal, pelvic or back pain continues or worsens after placement or if I develop the onset of new pain.

I understand that the Essure inserts contain metals including nickel, titanium, stainless steel (iron, chromium, nickel), platinum and silver-tin, as well as a material called polyethylene terephthalate (PET). I understand that some women may develop allergic reactions to the inserts following implantation and have signs or symptoms such as rash and itching. This may occur even if there is no prior history of sensitivity to those materials. I also understand that there is no reliable test to predict ahead of time who may develop a reaction to the insert.

I understand that persistent or new pain, and/or allergic reaction may be a sign of an Essure-related problem which might require further evaluation and treatment, including possibly the need to have the inserts removed by surgery.

I recognize that other symptoms have been reported to the 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.

I understand that because Essure contains metals, I should tell all my doctors that I have the device before getting an MRI.

I understand there is a small possibility that the insert could poke through the wall of the uterus or fallopian tubes (“perforation”), and/or may be found in other locations in the abdomen or pelvis. The rate of perforation in the original premarket studies was 1.8%. The rate for an insert being found in the abdomen or pelvis has not been determined but its occurrence is uncommon. I understand that should one of these events occur, the insert may become ineffective in preventing pregnancy and may lead to serious adverse events such as bleeding or bowel damage, which may require surgery to address.

I understand that should my doctor and I decide that Essure should be removed after placement, an additional surgical procedure may be required. In complicated cases, my doctor may recommend a hysterectomy (removal of the entire uterus).

I also understand that elective device removal may not be covered by my insurance company.

Patient Initials ______

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the Essure Patient Information Booklet, and that I have had time to discuss the items in it and on this document with my doctor. I have had the opportunity to ask questions and understand the benefits and risks of the device and procedure, and understand that alternative methods of birth control are available.

______________________________
Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of Essure as described in the Essure System Patient Information Booklet as well as this document. I have also explained the benefits and risks of other birth control methods. Should device removal become necessary, I may perform the removal myself, or provide a referral to a physician who is willing and able to perform device removals. I have encouraged the patient to ask questions, and I have addressed all questions.

______________________________
Physician Signature and Date

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE PROCEDURE

PRE-PROCEDURE

Optimal Timing
Good visualization is important when performing hysteroscopic sterilization because both fallopian tubes need to be clearly identified. The optimal time for the Essure procedure is during the early proliferative phase of the menstrual cycle to increase ostia visualization and decrease the potential for placement in a patient with an undiagnosed (luteal phase) pregnancy. Women with menstrual cycles shorter than 28 days should undergo careful ovulation day calculations. Placement should not be performed during menstruation.

Pretreatment of the patient with medications that suppress endometrial proliferation may enhance visualization and scheduling flexibility.

Facility Requirements
The Essure insert placement procedure can be performed in an outpatient or in-office setting. As with all procedures, appropriate equipment, medications, staff, and training should be in place to handle emergency situations.

Distension media
Use a bag of 0.9% sterile saline that has been pre-warmed to body temperature, preferably 3 liters, to distend the uterine cavity enough for evaluation. It is strongly recommended that the saline solution be pre-warmed to body temperature (but no higher than body temperature) and introduced under gravity feed to minimize spasm of the fallopian tubes.

Staff Responsibilities
The Essure procedure should be supported by knowledgeable and qualified support staff

- In addition to passing all sterile instruments to the physician, a sterile assistant may also provide assistance to insert the DryFlow™ introducer and the Essure® delivery system through the sealing cap of the hysteroscope working channel while the physician manipulates the hysteroscope to maintain visualization of the tubal ostia
- A non-sterile assistant hangs the bag of saline that has been pre-warmed to body temperature, operates the light source, monitor, and recorder (if available), in addition to obtaining and providing supplies that may not already be in the sterile field

HCP Responsibilities
A urine pregnancy test administered by the physician or designee should be conducted within 24 hours prior to the insert placement procedure. In order to 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.

The Patient Information Booklet with Patient-Doctor Discussion Checklist is intended to be carefully reviewed with patients to ensure they are aware of the benefits and risks of Essure, and the checklist should be completed in its entirety before beginning the Essure procedure. Refer to the Patient Selection and Counseling section in this guide for more information.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE PROCEDURE

PROCEDURE SETUP

Review the following list to help make sure you have what you need to begin the Essure procedure.

Equipment and Supplies

General

- Urine pregnancy test
- Under-buttocks pouch drape
- Leg drapes
- Drape sheet (optional)

- Essure® kit
  - DO NOT open until ostia have been visualized
  - Have a back-up kit available

- Tall IV pole
- Stirrups
- Pressure bag (if needed)

Essure procedure tray/mayo stand

- 2 sterile field drapes
  (one to cover tray until needed)
- Sterile single-hinged (open-sided) speculum
- Sterile gloves

- Sterile tenaculum
- Sterile ring forceps
- Sterile 4” x 4”
- Sterile cervical dilators (small sizes)

Paracervical block supply items (optional)

- Sterile speculum—warmed if possible
- Sterile tenaculum
- Supplies to clean off cervix (ie, antibacterial swabs or antibacterial solution in a specimen cup with sterile 4” x 4”)
- 18G needle for drawing up local anesthetic agent—1 or 1.5 inch

- 22G 1.5-inch needle
- 6-inch-long needle extender
- Sterile control syringe
- Local anesthetic, per physician

Hysteroscopy equipment

- Sterile 12- or 30-degree rigid, continuous flow hysteroscope with a ≥5 French operating channel
- Sterile sealing cap for instrument port
- Camera (white balance; use sterile drape if camera is not sterile)
- Sterile light cord

- Sterile inflow tubing
- Sterile outflow tubing
- Warm, normal saline bag (preferably 3 liters)
- Pressure bag or cuff for saline infusion
- Monitor

Have available

- Hysteroscopic grasper
- Second sterile tenaculum

- Cervical dilation set
- Sterile Allis tissue forceps

IMPORTANT: Bayer is providing this information to you for informational and educational purposes only. This document is not intended to be used as part of training or certification requirements for Essure®, or to establish a standard of care. You are solely responsible for ensuring that you and your staff have been properly trained in all aspects of performing the Essure procedure to your patients in the office setting. For complete instructions, please refer to the Instructions for Use.
ESSURE PROCEDURE

PATIENT COMFORT
It is important to consider the comfort of the patient when inserting Essure. Recommended options, if appropriate for patient, for the Essure procedure include:

- NSAIDs 1-2 hours pre-procedure
- Anxiolytic pre-procedure
- Paracervical block with or without IV sedation

Local anesthesia is the preferred method for placement of the inserts.

*In the Essure Pivotal Trial*

**NSAIDs WERE ADMINISTERED PRIOR TO THE PROCEDURE**
- In 84% of 544 procedures, patients received pre-operative NSAIDs

**PREDOMINANT ANESTHESIA USED**

<table>
<thead>
<tr>
<th>Anesthesia Type</th>
<th>n</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local anesthesia</td>
<td>283</td>
<td>52.0%</td>
</tr>
<tr>
<td>IV sedation and/or analgesia</td>
<td>222</td>
<td>40.8%</td>
</tr>
<tr>
<td>None*</td>
<td>38</td>
<td>7.0%</td>
</tr>
<tr>
<td>General anesthesia</td>
<td>1</td>
<td>0.2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>544</td>
<td>100%</td>
</tr>
</tbody>
</table>

*Other than pre-operative oral NSAID.

**RECOVERY ROOM MEDICATION**
- 75% of patients required no pain medication in the recovery room

Ensure that office staff members are properly trained and that emergency equipment is on hand in accordance with the level of anesthesia selected and pursuant to any state requirements.
## ESSURE PROCEDURE

### PATIENT COMFORT (CONTINUED)

*Summary of literature for pain management during hysteroscopic sterilization procedures*

<table>
<thead>
<tr>
<th>Publication</th>
<th>Trial design</th>
<th>NSAID</th>
<th>Local anesthesia</th>
<th>Sedation</th>
<th>Anxiolytic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arjona J. Satisfaction and tolerance with office hysteroscopic tubal sterilization. <em>Fertility and Sterility.</em> 2008.6</td>
<td>Prospective analysis of case series (N=1630)</td>
<td>Ibuprofen 600 mg, 1 hour pre-procedure</td>
<td></td>
<td></td>
<td>Benzodiazepine 10 mg, 1 hour pre-procedure</td>
</tr>
<tr>
<td>Chudnoff S. Paracervical block efficacy in office hysteroscopic sterilization. <em>Obstetrics and Gynecology.</em> 2010.7</td>
<td>Double-blind, randomized, placebo-controlled trial (N=80)</td>
<td>Ketorolac 60 mg IM, immediately before procedure</td>
<td>Paracervical block with 1% lidocaine at 12:00, 4:00, and 8:00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isley MM. Intrauterine lidocaine infusion for pain management during outpatient transcervical tubal sterilization: a randomized controlled trial. <em>Contraception.</em> 2012.8</td>
<td>Randomized, double-blind, placebo-controlled trial (N=58)</td>
<td>Ibuprofen 800 mg PO, 30-45 min pre-procedure</td>
<td>Paracervical block with buffered 1% lidocaine at 4:00 and 8:00 5 mL 4% intrauterine lidocaine*</td>
<td></td>
<td>Lorazepam 2 mg PO, 30-45 minutes pre-procedure</td>
</tr>
<tr>
<td>Miño M. Success rate and patient satisfaction with the Essure sterilisation in an outpatient setting: a prospective study of 857 women. <em>BJOG.</em> 2007.9</td>
<td>Prospective, single-center cohort (N=857)</td>
<td>Ibuprofen 600 mg, 1 hour pre-procedure</td>
<td></td>
<td></td>
<td>Diazepam 10 mg, 1 hour pre-procedure</td>
</tr>
<tr>
<td>Schneider EN. Nitrous oxide for pain management during in-office hysteroscopic sterilization: a randomized controlled trial. <em>Contraception.</em> 201610</td>
<td>Double-blind, randomized controlled trial (N=72)</td>
<td>Ketorolac 30 mg IM at least 30 min pre-procedure</td>
<td>Paracervical block with 9 mL of buffered 1% lidocaine at 4:00 and 8:00</td>
<td></td>
<td>At least 30 min prior to the procedure: 50% of patients received N₂O/O₂ via nasal mask, titrated to a maximum 70%:30% mixture 50% of patients received 5/325 mg hydrocodone/acetaminophen tablet and 1 mg lorazepam tablet</td>
</tr>
</tbody>
</table>

*Did not significantly reduce pain.

**Note:** This selection of literature is not a comprehensive list nor intended to provide a conclusive approach to pain management, but rather, a range of examples.

**PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.**
ESSURE PROCEDURE

PROCEDURE COMPONENTS

The Essure® procedure is made up of 2 components: the Essure insert placement procedure ("procedure") and the Essure Confirmation Test. Both are equally important, and instructions for completing each should be followed exactly. Please adhere to the steps outlined in this section for the procedure as well as the Essure TVU/HSG Confirmation Test Algorithm in this guide.

PLACEMENT PROCEDURE

Universal precautions and sterile technique should be used during the insert placement procedure. Face and eye protection should be worn.

If distension fluid deficit exceeds 1500 cc or total hysteroscopic procedure time (scope in-scope out) exceeds 20 minutes, the procedure should be terminated and potentially rescheduled.

BEFORE BEGINNING THE PROCEDURE:

• Check all of the necessary equipment to ensure that there is no damage or missing parts
• Hang bag of 0.9% sterile saline that has been pre-warmed to body temperature; a 3-liter bag may be preferable
• Place the patient in the lithotomy position using either standard stirrups or ski boot-style stirrups

Ensure that the patient’s legs and hips are comfortable. The position of the patient’s legs may need to be widened to allow hysteroscopic access to fallopian tubes.

• Drape the patient per standard procedure; an under-buttocks drape with a fluid control pouch is recommended for fluid management

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE PROCEDURE

PLACEMENT STEPS

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.

While waiting for the paracervical block to take effect, connect the camera, light source, and sealing cap. Focus the hysteroscope, perform a white balance, open the fluid inflow port, close the outflow port, and flush the scope of all air bubbles.

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

Remember, when the camera buttons are in the 12 o’clock position, the view from a 12- or 30-degree scope is above the scope lens, so it’s important to keep the cervical lumen at the 6 o’clock position.
ESSURE PROCEDURE

PLACEMENT STEPS (CONTINUED)

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.

Visualization of the tubal ostia with an angled hysteroscope can be accomplished by simply rotating the light cord, eliminating the need for potentially uncomfortable lateral scope movement.

The Essure® system is for single use only. Do not use the Essure system if the sterile package is open or damaged. Do not use if the insert is damaged. Never attempt to resterilize an Essure insert or delivery system. 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. Do not attempt placement in one tubal ostium unless expectation of contralateral tubal patency exists.

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 1).

Figure 1: Insert the introducer through sealing cap on the hysteroscope operating channel, then place delivery catheter through the introducer.
ESSURE PROCEDURE

PLACEMENT STEPS (CONTINUED)

10 Insert delivery catheter through the introducer; avoid bending the insert tip.

The DryFlow introducer must be used in order to avoid damage to the insert tip. The hysteroscope operating channel stopcock should remain in the open position (the insert and/or introducer can be damaged if the stopcock closes on either device).

Under direct visualization, advance catheter through the operating channel into 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. 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.

For information on tubal spasm or other technical issues, please see the Managing Technical Issues section.

11 Advance the delivery system until the black positioning marker on the delivery catheter reaches the fallopian tube ostium (see Figure 2).

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.

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.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE PROCEDURE

PLACEMENT STEPS (CONTINUED)

Uterine or fallopian tube anomalies may make it difficult to place the Essure®
inserts. 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 there is a reasonable expectation that the contralateral
tube is accessible and patent. If it appears unlikely that successful bilateral insert
placement can be achieved, then the procedure should be terminated.

Do not advance the Essure system if the patient is experiencing excessive pain or
discomfort. Terminate the procedure and examine the patient for possible perforation.

When introducing the Essure insert into the fallopian tube, never advance the
insert against excessive resistance. If tubal or uterine perforation occurs or is
suspected, immediately discontinue the Essure placement procedure and
examine the patient for a perforation.

Note: Proper alignment of the delivery catheter with the tubal lumen is suggested by the ability to
advance the catheter under direct visualization without undue resistance. Resistance to advancement is
usually apparent if:

- The black positioning marker on the outside surface of the catheter does not advance forward towards
  the tubal ostium, and/or
- The delivery catheter bends or flexes excessively, thus preventing the physician from applying forward
  pressure on the delivery catheter. When such resistance to forward advancement of the catheter is observed
  or felt, no further attempts should be made to place the insert in order to avoid the possibility of uterine
  perforation or inadvertently placing the insert in the uterine musculature rather than within the tubal lumen.
  A follow-up Essure Confirmation Test with modified HSG should be undertaken to determine location and
  tubal patency.

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 3).

Note: While stabilizing the handle, do not grasp or bend the delivery
catheter outside of the hysteroscope. This could result in unwanted
movement of the distal tip of the delivery catheter.

Note: Do not roll thumbwheel until marker is properly aligned.

Note: Do not move in any direction (forward or backward) while
releasing the Essure device from the delivery catheter. This could result
in detachment difficulties.

Figure 3: Stabilize handle
against camera head or
some other fixed object to
prevent inadvertent forward
movement of the Essure
system.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING,
ON PAGES 2 AND 3.
ESSURE PROCEDURE

PLACEMENT STEPS (CONTINUED)

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.

**Rotate thumbwheel**

The black positioning marker will move away from the tubal ostium (towards the hysteroscope) and disappear out of view into the hysteroscope operating channel, exposing 1 cm of wound-down insert.

Once you begin to roll the thumbwheel, do not attempt to reposition the insert until the delivery catheter is fully retracted. If the positioning marker is not moving towards you with each thumbwheel rotation, check that the handle is properly stabilized.

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 4) (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.

**Figure 4: Rotate thumbwheel to retract delivery catheter, exposing wound-down insert.**

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE PROCEDURE

PLACEMENT STEPS (CONTINUED)

15 Stop and check proper positioning, which corresponds to the symbol 2 on the delivery system handle. Confirm placement of the gold marker band just outside the ostium (see Figure 5), 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

Note: If the gold band is not just outside the ostium and more of the wound-down insert is visible (indicating a too proximal placement) or if the green release catheter has been advanced into the tubal ostium (indicating a too distal placement), the wound-down insert should be gently repositioned, if possible, before proceeding to the next step (depressing the button). Do not depress the button if adequate positioning has not been achieved.

16 Press the button on the delivery handle which corresponds to the symbol 3 on the handle button (see Figure 6). This enables the thumbwheel to be rotated further for insert deployment.

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

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE PROCEDURE

PLACEMENT STEPS (CONTINUED)

17 Rotate the thumbwheel once more (symbol 4) until the thumbwheel cannot turn any further (see Figure 7). 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.

Rotate thumbwheel

Figure 7: Rotate thumbwheel to allow outer coils to expand and release the insert from the delivery system.

Do not place more than one insert in a single fallopian tube.

18 Repeat procedure in contralateral fallopian tube.

ASSESSMENT OF INSERT AFTER DEPLOYMENT

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 8).

Figure 8: Ideal placement of insert.

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ESSURE PROCEDURE

ASSESSMENT OF INSERT AFTER DEPLOYMENT (CONTINUED)

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 9 below to determine if the insert has been deployed from the delivery system.

IMPORTANT: If insert was inadvertently deployed in the uterine cavity and not in the tube, remove from uterus and attempt another placement.

Figure 9: Delivery systems showing absence of insert after deployment (top) and with insert attached (bottom).

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 IFU section XVII INSERT REMOVAL for additional information.
ESSURE PROCEDURE

ASSESSMENT OF INSERT AFTER DEPLOYMENT (CONTINUED)

WARNING: Do not attempt insert removal hysteroscopically unless 18 or more coils of the Essure insert are trailing into the uterine cavity.

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 (as described in steps 1-4 below). 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

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.

If the Essure system must be removed, each deployed insert should be pulled out of the fallopian tube by gentle, continuous backward movement of the delivery system.

- 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 IFU section XVII INSERT REMOVAL. Monitor fluids to reduce the risk of hypervolemia; terminate procedure if fluid deficit exceeds 1500cc or hysteroscopic time exceeds 20 minutes.
**ESSURE PROCEDURE**

**MANAGEMENT OF CASE WITH UNSUCCESSFUL INSERT PLACEMENT DURING THE INITIAL PROCEDURE**

Bilateral attempt results in either unilateral or bilateral placement failure  
**Note:** Each fallopian tube should contain only 1 insert.

Offer to attempt second placement procedure

If patient accepts, perform Essure Confirmation Test with modified HSG to assess if tube(s) is/are patent

Does Essure Confirmation Test with modified HSG show that tube(s) without insert(s) is/are patent?

- **Yes**  
  Proceed with second placement procedure
  Bilateral placement achieved?
  - **Yes**  
    Discuss alternative contraception options
  - **No**  
    Discuss alternative contraception options

- **No**  
  Discuss alternative contraception options

**Warning:** The patient must use alternative contraception until a satisfactory Essure Confirmation Test is documented.

**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 she 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 unilaterally placed 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.

**PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.**
ESSURE PROCEDURE

POST-PROCEDURE

Physician Responsibilities
Document procedural concerns. Review during Essure Confirmation Test. Note possible perforations due to: excessive or sudden loss of resistance, inability to visualize coils, problems with identification of tubal ostium, poor distension, poor illumination, or poor visualization secondary to endometrial debris.

Although recording notes in a patient chart may seem like a basic requirement for any procedure, it is particularly important for Essure® so that the information can be utilized to help assess and understand potential placement issues in conjunction with the 3-month Essure Confirmation Test TVU/modified HSG Algorithm.

The following should be recorded in the patient chart:

- **Number of coils visible in the uterine cavity**
- **Visualization**: Note if identification of the tubal ostium at the insert placement procedure was compromised due to poor distension, poor illumination, or poor visualization secondary to endometrial debris
- **Possible perforation**: Concern at the time of insert placement of possible perforation due to excessive force required on the delivery catheter, a sudden loss of resistance, or no visible trailing length in the uterus as seen hysteroscopically after insert placement

Staff Responsibilities

- Monitor patient during recovery
- Give ID card to patient
- Provide any prescriptions to patient (including birth control)
- Counsel patient on significance of birth control compliance until satisfactory Essure Confirmation Test is documented
- Schedule 3-month Essure Confirmation Test with TVU/modified HSG
- Discharge patient
- Break down and clean room
- Sterilize equipment

Essure Insert Information Card

The Insert Information Card is a pre-paid business reply postcard that will be included in the product packaging. By filling out the card after the procedure and sending it back through the mail, the physician acknowledges that the Patient-Doctor Discussion Checklist was reviewed with the patient.

Information to be added to this card includes the physician's name, location, procedure date, and lot number of the Essure unit.

Note: Prescribe the most appropriate form of contraception for at least the first 3 months following the insert placement procedure until a satisfactory Essure Confirmation Test has been documented. Counsel the patient regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all steps of the Essure procedure, including use of her alternative contraception.

Please review the staff responsibilities listed above and ensure they are done.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE PROCEDURE

ELECTROSURGICAL PROCEDURES
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.

ENDOMETRIAL ABLATION AND OTHER PROCEDURES
• 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 inserts. This could cause bowel or bladder injury if there is an unrecognized tubal perforation and part of the insert lies outside of the tubal serosa. Endometrial ablation (if medically appropriate) should only be performed after correct location of the Essure insert is confirmed by a satisfactory Essure Confirmation Test, in order to minimize 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 (e.g., cryotherapy). There is a risk of fragmentation of the insert and/or conduction of energy to surrounding structures if these energy sources are used adjacent to or in contact with the insert. There may be risks associated with such procedures that, at this time, have not been identified. Avoid direct contact between the Essure inserts and monopolar radio frequency (RF) when performing endometrial ablation during operative hysteroscopy, as this may cause injury to surrounding tissue
• Endometrial ablation using microwave energy is contraindicated when an Essure insert is in place
• Other surgical instruments such 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, intraoperative 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 hysterectomy when the adnexa are being retained

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)

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OTHER INTRAUTERINE PROCEDURES

Direct visualization of inserts during intrauterine procedures is optimal. Blind insertion of instruments into the uterus with the inserts in place should be undertaken with caution and care to avoid disruption of the inserts.

Any intrauterine procedure performed without hysteroscopic visualization following Essure implantation could interrupt the ability of the Essure inserts to prevent pregnancy. Following such procedures, insert retention and location should be verified by hysteroscopy, x-ray, or ultrasound. In addition, the presence of the Essure inserts could involve risks associated with intrauterine procedures that, at this time, have not been identified.

MRI

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, 19428.

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 minutes 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 reported 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.

INSERT(S) 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, or if removal is clinically indicated, (see IFU section XVII INSERT REMOVAL 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, intraoperative 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.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE PROCEDURE

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 7 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 IFU section XVII INSERT REMOVAL. 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 11 in the next section [Essure Confirmation Test]: 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.

1. To perform a linear salpingotomy, make a small incision (approximately 2 cm in length) along the antimesenteric border of the fallopian tube overlying the insert. Use of vasoconstrictive agents is at the discretion of the operating surgeon. The insert needs to be exposed and may need to be freed from the surrounding tissue prior to grasping the coils. During removal, the inner and outer coils should be grasped together. Once the insert is exposed, a grasping instrument may be used to extract the insert using gentle traction along the axis of the fallopian tube. The insert should be gently extracted in small increments to prevent fragmentation of the insert or excessive stretching of the coils. If excessive resistance is encountered, this may be due to the platinum band (largest diameter of the insert) not being able to pass through the cornual region. The platinum band may break off if excessive traction is applied during laparoscopic removal. Hysteroscopic excision of the platinum band may facilitate removal of the entire insert (see IFU section XVII INSERT REMOVAL 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.

3. Removal via salpingectomy:

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

When removing the insert via salpingectomy, the location of the proximal and distal portions of the insert within the fallopian tube should be reconfirmed 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 IFU section XVII INSERT REMOVAL 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.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE PROCEDURE

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 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 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 IFU section XVII INSERT REMOVAL 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 IFU 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 11 in the next section [Essure Confirmation Test]). 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 which 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 IFU Section XVII INSERT REMOVAL 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.
ESSURE CONFIRMATION TEST

PERFORMING THE ESSURE CONFIRMATION TEST

The Essure Confirmation Test is an integral part of the Essure® permanent birth control procedure. The test must show either bilateral satisfactory insert location (when using a transvaginal ultrasound (TVU)) or bilateral satisfactory insert location and occlusion (when using a modified hysterosalpingogram (modified HSG)) in the fallopian tubes before the patient can rely on Essure for contraception.

• An Essure Confirmation Test should be performed 3 months after insert placement to evaluate insert retention and location
• The Essure Confirmation Tests (TVU* or 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 educational materials on the Essure Confirmation Test are available through Bayer.
• The Essure Confirmation Test may be performed with TVU or modified HSG as determined by the TVU/HSG Confirmation Test Algorithm.

ESSURE TVU/HSG CONFIRMATION TEST ALGORITHM

Bilateral Essure placement

Determine at placement if patient is an appropriate candidate for the Essure Confirmation Test with TVU per criteria outlined on the TVU Eligibility Checklist (See page 50)

Yes

Essure Confirmation Test with TVU at 3 months post-placement

Both inserts in optimal or satisfactory position (See TVU criteria on page 54)

Yes

Patient may rely on Essure for birth control and discontinue alternative contraception

No

• Both inserts in satisfactory location AND
• Bilateral tubal occlusion (See modified HSG checklist on page 68)

Yes

• Patient cannot rely on Essure for birth control and should remain on alternative contraception
• Proceed to clinical management per guidance in the Instructions for Use

No

Essure Confirmation Test with modified HSG at 3 months post-placement

Patient cannot rely on Essure for birth control and should remain on alternative contraception, and must proceed to a Confirmation Test with modified HSG

*Healthcare providers who utilize the Essure Confirmation with TVU must complete training administered by Bayer and documented by a certificate of completion.
ESSURE CONFIRMATION TEST

USING THE ESSURE TVU/HSG CONFIRMATION TEST ALGORITHM

• When using the TVU/HSG Confirmation Test Algorithm, TVU may be performed as a first-line confirmation test 3 months after a bilateral insert placement procedure if all of the following criteria are met:
  —Placement procedure was not difficult, including all of the following:
    • No concern at the time of placement of possible perforation due to excessive force required for insert delivery and/or a sudden loss of resistance
    • No difficulty identifying the tubal ostia during placement due to anatomical variation or technical factors such as poor distention, suboptimal lighting, or endometrial debris
    • Physician is certain about placement
  —Procedure time ≤ 15 minutes (scope in–scope out)
  —Placement with 1-8 trailing coils for each insert
  —No 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 (eg, 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 used for confirmation, as this test cannot confirm tubal occlusion. Clinical trials were not conducted with patients undergoing immunosuppressive therapy.

• 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

• Patient must use alternative contraception until a satisfactory Essure Confirmation Test is documented

• Discuss the 2 methods used 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)

Remember that a modified HSG is always an acceptable first-line option for the Essure Confirmation Test. If TVU is performed and the results are equivocal or unsatisfactory, the patient cannot rely on Essure® for birth control and a modified HSG is required to evaluate insert location and tubal occlusion. The patient must also be instructed not to discontinue her alternative contraception.

For additional information about Essure and the Essure Confirmation Test, refer to the Instructions for Use or contact your Bayer Sales Consultant.

The TVU Eligibility Checklist on page 50 can be used to assess if the patient meets the criteria for confirmation using TVU.

Consider establishing a protocol in your office for scheduling Essure Confirmation Test appointments, calling with reminders, and tracking Essure Confirmation Test compliance.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
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.

For more information, ask your Bayer Sales Consultant or go to the Medical Affairs Site in EssureMD.com.
### TVU Eligibility Checklist for the Essure Confirmation Test

Immediately after Essure® bilateral placement, complete the checklist below to help determine whether the patient is eligible for the Essure Confirmation Test with TVU (see TVU/HSG Confirmation Test Algorithm on pages 59-60). The Essure Confirmation Test should be performed at 3 months post-placement.

<table>
<thead>
<tr>
<th>TVU Eligibility</th>
<th>AGREE</th>
<th>DISAGREE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Describe Insertion Procedure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There was no concern at the time of placement of possible perforation due to excessive force and/or sudden loss of resistance.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>There was no difficulty in identifying the tubal ostia due to anatomical variation or technical factors (eg, poor distension, suboptimal lighting, or endometrial debris).</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>You are certain about bilateral placement.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The procedure time (scope in–scope out) was ≤15 minutes.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Placement occurred with 1-8 trailing coils for both left and right inserts.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>There was no unusual post-operative pain, transient or persistent, or onset at some later time post-procedure, without any other identifiable cause.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The patient was not on active immunosuppressive therapy (eg, systemic corticosteroids or chemotherapy).</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>Final Determination</strong></td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>If you answered “Disagree” to any of the statements above, the patient is not eligible for TVU and a modified HSG is required to evaluate insert location and tubal occlusion. Transabdominal ultrasound cannot be substituted for TVU. Does the patient meet the above criteria for the option of an Essure Confirmation Test with TVU?*</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

*Refer to the TVU/HSG Confirmation Test Algorithm included on pages 59-60 for the full set of criteria and to determine whether the patient is a candidate for an Essure Confirmation Test using TVU.

- Counsel the patient to remain on alternative contraception until a satisfactory Essure Confirmation Test is documented
- Discuss the 2 methods used 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 used

Remember to include a procedural note in the patient’s chart indicating whether she is an appropriate candidate for the Essure Confirmation Test with TVU, or if she must proceed directly to a modified HSG. A modified HSG is always an acceptable first-line option for the Essure Confirmation Test. If TVU is performed and the results are equivocal or unsatisfactory, the patient cannot rely on Essure® for birth control and a modified HSG is required to evaluate insert location and tubal occlusion. The patient must also be instructed not to discontinue her alternative contraception.

**PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.**
ESSURE CONFIRMATION TEST WITH TVU

Before proceeding with the Essure Confirmation Test with TVU at 3 months, confirm that the patient meets the criteria for the option of an Essure Confirmation Test with TVU (see TVU/HSG Confirmation Test Algorithm on pages 47-48). If TVU is not indicated, a modified HSG is required to evaluate insert location and tubal occlusion.

PERFORMING THE ESSURE CONFIRMATION TEST WITH TVU

As the treating physician, it is your responsibility to confirm the results from the TVU Confirmation Test report. Based on the clinical trial protocol, the TVU Confirmation Test has 3 components: orientation, identification, and location. A minimum of 3 required images (TVU scout image, image of left insert, image of right insert) must be obtained and retained for documentation of the TVU Confirmation Test. It is also useful to obtain real-time video, including the 3 required images, if technically possible.

<table>
<thead>
<tr>
<th>Orientation (assessment of uterine orientation)</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midline sagittal view</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indicate the uterine orientation (check one):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Anteverted ☐ Midplane ☐ Retroverted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can you confirm that the linear axis of either insert was not visualized in this view?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If no, please describe below.

If the linear axis of an insert is visualized in the uterine cavity, proximal placement should be suspected. If the linear axis is visualized in the fundal myometrium, fundal perforation should be suspected. Visualization of the proximal end of 1 or both inserts in cross-section may indicate trailing coils in the uterine cavity.

<table>
<thead>
<tr>
<th>Identification (visualization of a portion of both inserts simultaneously)</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transverse or oblique transverse view</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1. TVU scout image</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Was a portion of both inserts identified within the cornua or interstitial portion of the tubes?

Was a TVU scout image captured to document the presence of 2 inserts?

Can you clearly see that the inserts are not in contact with each other, with the linear axes of the inserts relatively symmetric and on opposite sides of the uterus?

If 0 or only 1 insert is identified, expulsion or perforation should be suspected.

If the inserts are in contact with each other, proximal location or expulsion is suspected.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE CONFIRMATION TEST WITH TVU

PERFORMING THE ESSURE CONFIRMATION TEST WITH TVU (CONTINUED)

<table>
<thead>
<tr>
<th>Location (location of the right and left inserts)</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transverse or oblique transverse view</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 2. Right insert image**

- Was the linear axis of the right insert identified as a contiguous echogenic structure? [ ] [ ]
- Was an image of the linear axis of the right insert captured for documentation? [ ] [ ]

**Figure 3. Left insert image**

- Was the linear axis of the left insert identified as a contiguous echogenic structure? [ ] [ ]
- Was an image of the linear axis of the left insert captured for documentation? [ ] [ ]

*Note the positions of the right and left inserts in the cornua and the relationships with the endometrium and the serosal utero-tubal junction (SUTJ).*
ESSURE CONFIRMATION TEST WITH TVU

PERFORMING THE ESSURE CONFIRMATION TEST WITH TVU (CONTINUED)

<table>
<thead>
<tr>
<th>Classification (classification of right and left inserts location)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Right insert</strong>: Please indicate the category of the right insert location (check one):</td>
</tr>
<tr>
<td>☐ Optimal  ☐ Satisfactory  ☐ Unsatisfactory  ☐ Equivocal</td>
</tr>
<tr>
<td>If unsatisfactory, please indicate the category (check one):</td>
</tr>
<tr>
<td>☐ Distal  ☐ Proximal  ☐ Perforation  ☐ Expulsion  ☐ Unclassified</td>
</tr>
<tr>
<td><strong>Left insert</strong>: Please indicate the category of the left insert location (check one):</td>
</tr>
<tr>
<td>☐ Optimal  ☐ Satisfactory  ☐ Unsatisfactory  ☐ Equivocal</td>
</tr>
<tr>
<td>If unsatisfactory, please indicate the category (check one):</td>
</tr>
<tr>
<td>☐ Distal  ☐ Proximal  ☐ Perforation  ☐ Expulsion  ☐ Unclassified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Confirmation</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirmation Test with TVU (Continued): if you answered “No” to any of the questions above (pages 51-52), or if the TVU results were equivocal or unsatisfactory, inform the patient that she cannot rely on Essure® for birth control and must remain on alternative contraception, and an Essure Confirmation Test with modified HSG is required to evaluate insert location and tubal occlusion.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Can the patient rely on Essure for birth control? |
| ☐ Yes | ☐ No |

| Does the patient need to proceed to an Essure Confirmation Test with modified HSG? |
| ☐ Yes | ☐ No |
**ESSURE CONFIRMATION TEST WITH TVU**

**CLASSIFICATION OF TVU LOCATIONS**

**Figure 4**

**Satisfactory location**
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. The portion of the insert located in the fallopian tube may or may not be visualized. The linear axis of the insert must be visualized to confirm it is not coiled or elongated.

**Figure 5**

**Optimal location**
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 and can be visualized at or crossing the SUTJ. The portion of the insert located in the fallopian tube may or may not be visualized. The linear axis of the insert must be visualized to confirm it is not coiled or elongated.

**How to manage the TVU evaluations with satisfactory or optimal locations of both inserts:**
The patient may be told to discontinue her alternative contraception and rely on Essure® for birth control. 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.
ESSURE CONFIRMATION TEST WITH TVU

CLASSIFICATION OF TVU LOCATIONS (CONTINUED)

UNSATISFACTORY LOCATION

The 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. There are 5 types of unsatisfactory placement locations: distal, proximal, perforation, expulsion, and unclassified.

**Distal**
Distal placement is suspected if the proximal end of the insert is not located in the myometrium in the cornua and not crossing or in contact with the SUTJ.

**Proximal**
Proximal placement is suspected if >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.

**Perforation**
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.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
CLASSIFICATION OF TVU LOCATIONS (CONTINUED)

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

Unclassified
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.

How to manage the TVU evaluations with unsatisfactory locations for one or both inserts:
If the TVU 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 told to continue her alternative contraception and that she cannot rely on Essure® until a satisfactory Essure Confirmation Test is documented.

If TVU is performed and the results are equivocal or unsatisfactory, the patient cannot rely on Essure for birth control and must remain on alternative contraception, and a modified HSG is required to evaluate insert location and tubal occlusion.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE CONFIRMATION TEST WITH MODIFIED HSG
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

The Essure Confirmation Test with modified HSG is used to evaluate both the location of the inserts and occlusion of the fallopian tubes. Every patient must have an Essure Confirmation Test 3 months following the Essure® procedure. The Essure Confirmation Test may be performed with TVU or modified HSG as determined by the TVU/HSG Confirmation Test Algorithm; however, modified HSG is always an acceptable first-line option. The patient must use alternative contraception until the Essure Confirmation Test verifies that the patient may rely on Essure for permanent birth control. Per the TVU/HSG Confirmation Test Algorithm, modified HSG is also required after TVU if the TVU results are equivocal or unsatisfactory.

If bilateral insert location is satisfactory and bilateral fallopian tube occlusion is demonstrated, instruct your patient that she may discontinue alternative contraception and rely on Essure for birth control.

PERFORMING THE ESSURE CONFIRMATION TEST WITH MODIFIED HSG

To evaluate insert location and tubal occlusion, Essure Confirmation Test with modified HSG images must show the relationship of the proximal end of the inner coil to the uterine cornua.

To produce adequate images, adherence to the following guidelines is recommended:

1. Obtain good cornual filling so that uterine cavity silhouette is clearly seen.
2. Place fluoroscopy beam as close to A/P projection as possible.
3. Do not dilate cervix unless necessary; if dilation occurs, maintain a good cervical seal.
4. Downward traction on cervical tenaculum may be required for midpositional uteri. Remove speculum prior to fluoroscopy for best visualization of uterine anatomy.
5. Take a minimum of 6 radiographs to assess insert location and tubal occlusion.

Unlike an infertility HSG, the Essure Confirmation Test with modified HSG is performed by instilling contrast media (dye) slowly and gently until the uterine cornua are distended. An increase in intrauterine pressure beyond that needed to produce cornual distention should be avoided.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

RADIOGRAPHIC MARKERS
There are 4 radiographic markers on the device to help evaluate insert location and tubal occlusion:

Figure 1. Proximal and distal radiographic markers.

During the evaluation of the modified HSG films, the 4 radiopaque markers should be identified for each insert. Note that the 2 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.

IMPORTANT: Bayer is providing this information to you for informational and educational purposes only. This document is not intended to be used as part of training or certification requirements for Essure®, or to establish a standard of care. You are solely responsible for ensuring that you and your staff have been properly trained in all aspects of performing the Essure procedure to your patients in the office setting. For complete instructions, please refer to the Instructions for Use and the Physician Training Manual.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

RADIOGRAPH IMAGING
Take a minimum of 6 radiographs to assess insert location and tubal occlusion. In some cases, additional images may be necessary to evaluate insert location. This might include oblique views or lateral views.

Figure 2

Scout film
Scout film is the first image captured, before injecting the contrast. Capture an image of the uterus and inserts. The Essure® inserts should be clearly seen; note the lie and curvature of the inserts. During evaluation, note the 4 radiographic markers on each insert.

Figure 3

Minimal fill
Capture an image of the uterus after a small amount of contrast infusion. No contrast should be leaking from the cervix if an adequate seal is maintained. The uterine cavity should start to opacify. Contrast may not have reached the uterine cornua. If the uterine cavity silhouette is not seen in a nearly A/P projection, adjust the fluoroscopy beam and/or the patient.

Figure 4

Partial fill
Capture an image of the uterus when it is nearly full of contrast or opacified. The cornua may not yet have been adequately distended. Proximal portions of the Essure inserts may not yet be obscured by the advancing contrast.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

RADIOGRAPH IMAGING (CONTINUED)

Figure 5

Total fill
Capture an image of the uterus when the cavity is completely filled and the cornua are distended. Ideally, contrast should reach the proximal end of the inserts.

CAUTION: Avoid excessive intrauterine pressure beyond Radiograph 4 (Figure 5) to avoid undue patient discomfort and vasovagal reaction.

Figure 6

Magnification of the uterine cornua
Once the uterine cornua are filled to maximum distension, obtain magnified views of both right and left cornua with the distal ends of the insert in view.

Note: Assessment of the location of the inserts on the Essure Confirmation Test with modified HSG is not the same as noted on hysteroscopy. Therefore, a correctly placed insert may appear to be more distal on the Essure Confirmation Test with modified HSG than noted at the time of hysteroscopy.

The Radiology Report must include:

1. Number of inserts
2. Location of each insert
3. Tubal occlusion assessment for each side
4. Description of unusual findings

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

EVALUATING ESSURE CONFIRMATION TEST WITH MODIFIED HSG FILMS QUALITY

When evaluating the Essure Confirmation Test with modified HSG films, first confirm that the appropriate radiographs previously described are provided, a good A/P image of the uterine silhouette is obtained, and the uterus is completely filled in at least one view.

The Essure Confirmation Test with modified HSG will need to be immediately repeated if:

• The appropriate sequence of radiographs was not taken
• One or both uterine cornua were not maximally distended
• The uterine silhouette is fundal rather than A/P
• The image of the uterine cornua is obscured in any way
• Insert cannot be located or position is unclear

Examples of Essure Confirmation Tests with modified HSG that need to be repeated

Figure 8. Filling defect in the left cornua

Figure 9. Inadequate filling

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

EVALUATING INSERT LOCATION
Distance from the filled uterine cornua to the proximal end of the inner coil can be measured in several ways:

1. Using the inner coil as a point of reference. The inner coil measures 30 mm in length (most commonly used method)
2. Calipers
3. Using the distal 2 markers as a measuring reference point. The distance between the 2 distal markers measures 5 mm

Figure 10. Satisfactory bilateral insert location and tubal occlusion

Note the 4 radiopaque markers and inner coil length. The inserts are symmetrical with a normal curvature. Ideal insert location is where the inner coil crosses the uterotubal junction. Note that the 2 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.

Note: The insert may shift in response to fallopian tube movement following placement.

SATISFACTORY LOCATION
A satisfactory location is defined as the distal end of the inner coil being within the fallopian tube with <50% of the inner coil trailing into the uterine cavity, OR the proximal end of the inner coil being ≤30 mm into the tube from where contrast fills the uterine cornua.

Figure 11 Figure 12 Figure 13

Note the normal curvature and symmetrical appearance of both inserts

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

EVALUATING INSERT LOCATION (CONTINUED)

UNSATISFACTORY LOCATION

There are 4 types of unsatisfactory location: proximal location, expulsion, distal location, and perforation or peritoneal location.

Proximal location

Proximal location is defined as: \( \geq 50\% \) of the inner coil is trailing into the uterine cavity.

How to manage:
Advise patient not to rely on Essure®; continue alternative contraception or consider incisional sterilization.

Expulsion

One or both inserts are not present or insert lies completely in the uterine cavity.

How to manage:
Advise patient not to rely on Essure. Obtain an image of the abdomen to differentiate a device that has been expelled from the body versus one that is in a peritoneal location. If corresponding tube is patent, counsel patient on repeat Essure placement procedure. If corresponding tube is occluded, counsel patient about potential false-positive Essure Confirmation Test with modified HSG results. Also counsel patient on incisional sterilization or remaining on alternative contraception.

Distal location

Distal location is defined as: the insert is in the tube, but the proximal end of the inner coil is \( >30 \) mm from the cornua.

How to manage:
Advise patient not to rely on Essure. Counsel patient on incisional sterilization or remaining on alternative contraception. If tube is occluded, advise patient on potential false-positive Essure Confirmation Test with modified HSG results.
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

EVALUATING INSERT LOCATION (CONTINUED)

UNSATISFACTORY LOCATION

Perforation or peritoneal location
When a perforation occurs, the insert has completely or partially perforated the uterus or tube (e.g., embedded in the myometrium or completely in the peritoneal cavity). Peritoneal location means the insert is found within the peritoneal cavity and is not located within the tube.

How to manage:
Advise patient not to rely on Essure® for contraception. If tube is patent and no part of an Essure insert is in the fallopian tube, counsel patient on repeat placement procedure. If tube is occluded, advise patient on potential for false-positive diagnosis of occlusion. Also counsel patient on incisional sterilization or remaining on alternative contraception. Location of insert(s) should be evaluated and a decision should be made as to whether the insert should be left in situ or removed.

Figure 17. Fundal perforation
Figure 18. Embedded in myometrium
Figure 19. Right insert perforation; note the coiled configuration insert
Figure 20. Left insert perforation; insert has a sharp bend and there is tubal patency. The right insert is also curled and suspicious for perforation
Figure 21. Right insert perforation with stretched outer coil
Figure 22. Right and left bilateral perforation noted on scout film: note the distance between the 2 inserts, their lack of normal curvature, their asymmetrical lie, and the reversed orientation of the right insert

Note: Additional radiographs might include oblique and lateral images, and may be helpful to evaluate location if a perforation is suspected.
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

EVALUATING TUBAL OCCLUSION
After evaluating insert location, determine whether contrast is visible beyond the insert and note any degree of proximal tubal filling, even if the tube is occluded. Satisfactory occlusion is when the tube is occluded at the cornua or contrast is seen within the tube but not past the distal end of the outer coil.

SATISFACTORY OCCLUSION

Figure 23. Bilateral tube occlusions at the cornua
Figure 24. Contrast is visible within the tube but not past the distal end of the outer coil (arrow)

Note: The 2 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.
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

EVALUATING TUBAL OCCLUSION (CONTINUED)
After evaluating insert location, determine whether contrast is visible beyond the distal end of the outer coil or in the peritoneal cavity. Peritoneal location means the insert is found within the peritoneal cavity and is not located within the tube.

UNSATISFACTORY OCCLUSION

Figure 25. Unsatisfactory occlusion
Figure 26. Satisfactory bilateral location of inserts; unsatisfactory occlusion. Note the outer coils are visible on this image; they are not radiopaque, but they are radiolucent when contrast fills the tube

How to manage:
If insert location is satisfactory but there is patency beyond the distal end of the outer coil or free spill of contrast into the peritoneal cavity, advise the patient not to rely on Essure®. The patient should remain on alternative contraception for at least 3 more months and have a repeat Essure Confirmation Test with modified HSG. If patency is again documented on the repeat Essure Confirmation Test with modified HSG, continue to advise the patient not to rely on Essure.

Evaluating Ability to Rely on Essure
- If insert location and tubal occlusion are satisfactory, instruct the patient to discontinue alternative contraception and rely on Essure for contraception
- If insert location is unsatisfactory, instruct the patient not to rely on Essure for contraception
- If insert location is satisfactory but occlusion is unsatisfactory, instruct the patient to remain on alternative contraception. Repeat the Essure Confirmation Test with modified HSG in 3 months. If occlusion is still unsatisfactory, instruct the patient not to rely on Essure for contraception
ESSURE CONFIRMATION TEST WITH MODIFIED HSG

ESSURE CONFIRMATION TEST WITH MODIFIED HSG CHECKLIST

<table>
<thead>
<tr>
<th>LOCATION</th>
<th>LEFT</th>
<th>RIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Satisfactory Location</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Distal end of the inner coil is within the fallopian tube, with &lt;50% of the inner coil trailing into the uterine cavity, OR the proximal end of the inner coil is ≤30 mm into the tube from where contrast fills the uterine cornua</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Unsatisfactory Location</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Proximal location: ≥50% of the inner coil is trailing into the uterine cavity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expulsion: insert is not present or lies completely in the uterine cavity</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Distal location: Insert is in the fallopian tube, but the proximal end of the inner coil is &gt;30 mm from the contrast filling the uterine cornual</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Perforation/peritoneal location: Insert is completely or partially perforating the uterus or tube (eg, embedded in the myometrium or completely in the peritoneal cavity)</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

OCCLUSION

<table>
<thead>
<tr>
<th>OCCLUSION</th>
<th>LEFT</th>
<th>RIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Satisfactory Occlusion</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Tube is occluded at the cornua OR contrast is visible within the tube but not past the distal end of the outer coil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Unsatisfactory Occlusion</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Contrast is visible past the insert OR in the peritoneal cavity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Assessing patient ability to rely on Essure®:

- If location and tubal occlusion are both rated satisfactory, instruct patient to discontinue 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 with modified HSG in 3 months. If occlusion is still unsatisfactory, instruct patient to not rely on inserts for contraception

To avoid confusion with an infertility HSG, the OB/GYN and radiologist should be familiar with this guide and the Essure Confirmation Test With Modified HSG Checklist to ensure both insert location and tubal occlusion are noted in the radiology report.
MANAGING TECHNICAL ISSUES
MANAGING TECHNICAL ISSUES

The following troubleshooting guide provides potential solutions and is not a complete list. At all times, the physician should use professional judgment to determine proper care for the patient, which may include stopping the procedure.

TROUBLESHOOTING GUIDE

A variety of technical and/or procedural issues may arise while performing the Essure procedure. Troubleshooting has been categorized into the following major steps of the procedure:

- Introducing the hysteroscope
- Achieving uterine distension
- Achieving ostial visualization
- Advancing the insert into the fallopian tube
- Deploying the insert

INTRODUCING THE HYSTEROSCOPE

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
</table>
| Inability to introduce the hysteroscope into the uterus | Inadequate cervical dilation | • Use hysteroscope with smaller outer diameter  
|                                                   |                            | • Attempt hydrodilation of the cervix     |
|                                                   |                            | • Dilate cervix (do not overdilate)      |
|                                                   |                            | • Try a plastic os finder              |
| Severely retroverted or anteverted uterus         |                            | • Use tenaculum to straighten the angulation between the uterus and cervix |

*Use solutions individually, simultaneously, or sequentially as appropriate.

This may not be all inclusive of technical issues you may encounter. Please call the Bayer Product Information department at (877) 377-8732 with any additional questions.
# Managing Technical Issues

## Achieving Uterine Distension

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate intrauterine pressure</td>
<td>Patulous cervix</td>
<td>• Gently twist tenaculum 45° or use additional tenaculum to seal cervix</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Place tenaculum at 1 &amp; 5 o’clock or 7 &amp; 11 o’clock position (or both)</td>
</tr>
<tr>
<td><strong>DO NOT OVER-DILATE CERVIX</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excessive Cramping</td>
<td></td>
<td>• Consider reducing distension</td>
</tr>
</tbody>
</table>

*Use solutions individually, simultaneously, or sequentially as appropriate.

## Achieving Uterine Cornual Visualization

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor uterine visualization</td>
<td>Blood in uterus</td>
<td>• Open outflow port and flush</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Increase fluid flow</td>
</tr>
<tr>
<td></td>
<td>Shaggy endometrium</td>
<td>• Flush uterine cavity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Aspirate debris</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Flush uterus again and increase pressure</td>
</tr>
</tbody>
</table>

*Use solutions individually, simultaneously, or sequentially as appropriate.

This may not be all inclusive of technical issues you may encounter. Please call the Bayer Product Information department at (877) 377-8732 with any additional questions.

---

**PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.**
# MANAGING TECHNICAL ISSUES

## ACHIEVING OSTIAL VISUALIZATION

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Poor uterine distension</strong></td>
<td>• See “Inadequate intrauterine pressure” (refer to p. 71)</td>
<td></td>
</tr>
</tbody>
</table>
| **Debris, endometrial fluff, or clots** | • Flush uterus  
• Aspirate  
• Gently remove debris with graspers  
  – Do not use a curette  
• Consider abandoning procedure and rescheduling during early proliferative phase of the menstrual cycle and consider pretreating the patient with medications that suppress endometrial proliferation which may enhance visualization |                                                                                       |
| **Filmy tissue covering ostia** | • Gently probe with an insert tip  
• Gently push insert forward.  
  – Proceed only if insertion meets minimal resistance |                                                                                       |
| **Abnormal ostial location**   | • Adjust/rotate hysteroscope  
• Rotate insert tip  
• Adjust patient position |                                                                                       |
| **Lateral tubal ostia**        | • Rotation of the lens (30 degrees) aids in targeting  
• Rotate purple handle to change trajectory of Essure® insert towards ostium  
• Use surrounding myometrium wall to “guide” the Essure® insert into ostium  
• Adjust patient position |                                                                                       |
| **Only one ostium visualized** | • Procedure SHOULD NOT move forward unless both ostia can be visualized  
• Pull back hysteroscope to obtain full uterine view |                                                                                       |

*Use solutions individually, simultaneously, or sequentially as appropriate.

This may not be all inclusive of technical issues you may encounter. Please call the Bayer Product Information department at (877) 377-8732 with any additional questions.
MANAGING TECHNICAL ISSUES

ADVANCING THE INSERT INTO THE TUBE

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
</table>
| *Inability to advance insert into tube†* | • Advance system into fallopian tube with gently, constant forward movement  
• If excessive resistance occurs, no further attempts should be made to place insert to avoid possibility of uterine or tubal perforation or inadvertent placement in the uterine muscle rather than within the tubal lumen | |
| **Tubal Spasm** | 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. Once the delivery catheter starts advancing, keep the slow, steady pressure on until the solid black positioning marker reaches the proximal edge of the tubal ostium.  
• If gentle, constant forward pressure on the delivery catheter does not resolve the tubal spasm, you can rotate the entire scope clockwise or counterclockwise, depending on which fallopian tube is being cannulated, to gain better alignment between the catheter and the tube.  
• The delivery catheter should never be forced into the tube and the case should be terminated if the patient is experiencing severe pain under attempted cannulation and the patient worked up for possible perforation. | |
| **Tracking into false passage** | • If uncertain about ostial location and/or true tubal lumen, remove system and abandon procedure | |
| **Bent Tip** | A device with a bent tip may be considered damaged and should not be used. While you are able to see the bend in the tip of the device, the force that caused the tip to bend may have also damaged the internal delivery mechanism (which you cannot see) and might lead to detachment issues.  
• If the tip is bent in the package:  
  - Check for proper storage of packages  
  - Report as a Product Technical Complaint to Bayer  
• If tip gets bent as it goes through working channel of hysteroscope:  
  - Make sure introducer is properly seated in working channel and does not have a defect  
  - Make sure working channel is fully opened  
  - Make sure hysteroscope does not have a defect in the working channel  
  - Make sure device is fed through working channel slowly and without bending (by either physician or assistant)  
• If tip gets bent as it exits working channel and hit uterine wall:  
  - Hysteroscope may be too far into the uterine cavity  
  - Physician may be inserting device through operating channel too quickly  
• If tip bends as you attempt to cannulate the tube:  
  - Hysteroscope may be too far from the ostium  
  - Scope may not be lined up with the ostium  
  - Device should be advanced slowly  
  - Patient may have difficult anatomy | |

*Use solutions individually, simultaneously, or sequentially as appropriate.  
†If the positioning marker does not advance all the way to the tubal ostium but is within a black marker’s length away from ostium, adequate placement may still be achieved.

This may not be all inclusive of technical issues you may encounter. Please call the Bayer Product Information department at (877) 377-8732 with any additional questions.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
### DEPLOYING THE INSERT

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Warning: Never attempt to use a bent or damaged delivery catheter, as this can result in detachment issues</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inability to retract delivery catheter</td>
<td>Delivery catheter twisted</td>
<td>• Slowly rotate catheter to relieve twisting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Remove and replace system</td>
</tr>
<tr>
<td></td>
<td>Delivery catheter damaged</td>
<td>• Remove and replace system</td>
</tr>
<tr>
<td>Delivery catheter stretches</td>
<td>Delivery catheter damaged in hysteroscope working channel</td>
<td>• Verify that operating channel is open</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Remove and replace system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Slowly advance delivery catheter through working channel to avoid damage to the tip as it exits the scope</td>
</tr>
<tr>
<td>Inadvertent forward movement of insert (feed forward)</td>
<td>Handle not stabilized during retraction</td>
<td>• Pull system back to proper position before deployment</td>
</tr>
<tr>
<td>Inability to fully depress button</td>
<td>Delivery catheter not fully retracted</td>
<td>• Roll thumbwheel until it stops</td>
</tr>
<tr>
<td></td>
<td>System failure</td>
<td>• Remove and replace system</td>
</tr>
<tr>
<td>Outer coils do not deploy</td>
<td>Delivery catheter not fully retracted</td>
<td>• Continue rolling thumbwheel until it stops fully</td>
</tr>
<tr>
<td></td>
<td>Outer coils are pressed against uterine wall</td>
<td>• Pull hysteroscope back to maintain visualization</td>
</tr>
<tr>
<td></td>
<td>Technical insert failure</td>
<td>• Straighten system and allow coils to fully expand</td>
</tr>
<tr>
<td>Insert stuck in hysteroscope</td>
<td>Hysteroscope is too far forward during deployment</td>
<td>• Rotate system slowly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Gently jiggle system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Remove and replace system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Push insert out of hysteroscope using appropriately sized grasper</td>
</tr>
</tbody>
</table>

*Use solutions individually, simultaneously, or sequentially as appropriate.

This may not be all inclusive of technical issues you may encounter. Please call the Bayer Product Information department at (877) 377-8732 with any additional questions.
MANAGING TECHNICAL ISSUES

CONFIRMING DEPLOYMENT

Ideal placement of the Essure insert results in 3 to 8 trailing coils into the uterus; 0 to 17 trailing coils are acceptable and should be evaluated via the Essure Confirmation Test.

- Placements showing 0 to 17 coils should not be removed at the time of placement
- While 0 trailing coils is considered adequate, one of the difficulties is confirming whether or not the device has actually deployed

If there are no coils visible in the uterine cavity, confirm deployment of the device by visually inspecting the delivery catheter (Figure 1).

- If after inspecting the delivery catheter, you are STILL unsure if the device deployed or not, do not attempt another placement in the tube until you are certain
- If the insert has been deployed, it will be visible on x-ray or ultrasound. This is not the same as the confirmation test—this is a way of confirming deployment of the device
- Do not place more than one insert into a single fallopian tube

Figure 1

![Delivery system with insert](image)

![Delivery system after deployment of insert](image)

CONFIRM DEPLOYMENT BY LOOKING FOR THE GOLD BAND

When the device gets stretched, it is sometimes difficult to determine if the device has deployed or not.

Look for the gold band (Figure 2, yellow arrows). When the device has deployed, the gold band will be at the distal most end of the delivery catheter.

- Note the location of the gold band in the top photo; the insert has not deployed
- In the center photo, the insert has deployed; however, the delivery catheter itself was stretched and unwound. While this may look like a coil, it is not part of the insert and in this situation, the insert has deployed and is in the tube
- In the bottom photo, the device has not deployed. This is verified by looking at the gold band. Here, the insert is still attached to the delivery catheter. The inner coil of the insert has stretched

Figure 2

![Insert and Delivery Catheter](image)

Not Deployed

Deployed

Not Deployed

Note: The yellow arrows in Figure 2 indicate gold band locations

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
MANAGING TECHNICAL ISSUES

INSERT DEPLOYED BUT WILL NOT RELEASE FROM SYSTEM

Difficulty detaching inner coil from delivery wire

If tubal spasm is suspected, WAIT and allow tube time to relax. After waiting, gently pull back on the delivery catheter. If the tube continues to hold onto the distal end of the delivery catheter while pulling, the green sheath of the delivery catheter may break, causing the delivery catheter to unwind. It is important to distinguish between the coil that is part of the insert and the coil that is part of the delivery catheter (See Figure 3).

- If the delivery catheter unwinds and you have pulled the catheter back as far as possible; and the proximal end is still caught in the tube, you may choose to cut the unwound delivery catheter wire in order to remove the delivery system/handle. This process can be done with hysteroscopic scissors.
- As the tube relaxes, the proximal portion of the delivery catheter may eventually fall out into the uterine cavity and may be expelled. Please warn the patient.
- If desired, you may attempt to hysteroscopically remove the catheter pieces at a later date. There are no data on prolonged presence of catheter materials in the uterus or fallopian tubes.

The patient should continue alternative contraception and return for the Essure Confirmation Test with the modified HSG in 3 months.

Figure 3

![Delivery Catheter and Insert Diagram]

TO MAKE A MEDICAL OR PRODUCT COMPLAINT:

1. Report a medical or product complaint as soon as possible. The complaint(s) should be directed to the Bayer Product Information department at (877) 377-8732, option 5.
2. Save and return the Essure® system that was used. If possible, include the original packaging with the lot number, or obtain the lot number from the patient chart and send that number along with the Essure system. You may request a product return kit by calling (877) 377-8732, option 5.

You are encouraged to report negative side effects or quality complaints to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ADMINISTRATIVE PROCESSES

ACCOUNT SETUP AND ORDERING

ORDER DIRECTLY VIA:

Phone: 855-406-2861
Email: essuredistribution@lashgroup.com
Fax: 888-281-8199

FOR OUR NEW CUSTOMERS

• Shipping/billing address (including facility name)
• Name of certified/trained Essure® provider and date of certification or scheduled training
• Facility license, in-house pharmacy license, or provider license*
• Letter of Affiliation form†
• Copy of resale certificate or Department of Revenue letter proving tax exemption
  (if applicable)

FOR OUR EXISTING CUSTOMERS

• Facility license, in-house pharmacy license, or provider license*
• Letter of Affiliation form†
• Copy of resale certificate or Department of Revenue letter proving tax exemption
  (if applicable)

• Shipping is FREE
• Orders received prior to 3:30 PM ET will ship the SAME DAY, unless otherwise requested
• Standard delivery is 2 business days; expedited delivery may be available upon request

A Facility LICENSE, in-house pharmacy LICENSE, or provider license is REQUIRED for shipping

*Once the license is on file, it is not necessary to provide another copy until the license has expired.
†For all states except Florida, a Letter of Affiliation form is needed if there is not an address on the license or if the address on the license does not match the shipping location. Please note that some offices are slow to return this document. Due to the E-Pedigree law in the state of Florida, Florida customers must submit their HCCE permit or the Declaration of Intent Letter before orders can be released.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ADMINISTRATIVE PROCESSES

VENDOR LISTING
Although the majority of supplies for the Essure® procedure may already be available in your practice, there are several items you may need to order. Please contact the vendor for the most up-to-date pricing, order numbers, and availability.

MEDICAL OFFICE RESOURCES (MOR) HYSTEROSONIC STERILIZATION PACKS
Pre-assembled, sterile trays designed specifically for Essure office procedures.
Tel: 419-367-8249
Website: http://www.medofficeresources.com/essu001.htm

Product #ESSU001
Prep tray components:
1 tray, 2 compartments
1 gloves, exam LG
12 oz Betadine solution
20 gauze, 4 x 4 12 ply
4 swab 8"
1 wrap 30 x 30

Pack components:
1 back table cover
2 10-cc control syringes L/L
1 needle, spinal 22G x 3.5
1 pad, prep alcohol
1 large-bore cystoscopy tubing set
1 tubing suction
1 gown, XLG
1 drape, camera
1 needle, 18G x 1.5 short
1 drape, under-buttocks 40 x 44 w/pouch
1 Lidocaine® 1% HCl 20 mL
1 17” x 11” x 2.5” platform tray
3 towels OR blue 17” x 26”
1 label, 3 ¼” x 2 ½”
1 label, custom kit
1 bag, header 19 x 24

Product #ESSU006
Prep tray components:
1 tray, 2 compartments
1 gloves, exam LG
12 oz Betadine solution
15 gauze, 4 x 4 12 ply
4 swab 8"
1 wrap 30 x 30

Pack components:
1 back table cover
2 10 cc control syringes L/L
1 needle, spinal 22G x 3.5
1 pad, prep alcohol
1 large-bore cystoscopy tubing set
1 tubing suction
1 drape, camera
1 drape, under-buttocks 40 x 44 w/pouch
3 towels OR blue 17” x 26”
1 label, 3 ¼” x 2 ½”
1 label, custom kit
1 bag, header 19 x 24
1 17” x 11” x 2.5” platform tray

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ADMINISTRATIVE PROCESSES

VENDOR LISTING (CONTINUED)

OBP MEDICAL OFFICEPACK HYSTEROSCOPY KIT
Pre-assembled sterile kits for use in office hysteroscopy.
Tel: 1-888-300-2946
Website: www.obpmedical.com

Product #C040101

OfficePACK Hysteroscopy Kit includes:
1 disposable Mayo tray
1 Mayo tray drape
2 plastic cotton tips
15 gauze 100 x 100 mm
1 surgical lubricant, 3 g
1 povidone iodine solution w/ plastic cotton tips
1 alcohol prep pad
2 control syringes, 10 mL
1 hypodermic needle 18G
1 spinal needle 22G
1 sanitary paper
1 OR towel
1 cysto irrigation set in-flow w/ Luer lock
1 OutflowBAG drainage collection bag w/ tubing & Luer lock
2 pair gloves
1 OfficeSPEC disposable side-opening speculum w/ light
1 endoscopic seal GYN 1-size-fits-all w/ Luer lock
1 item tray
1 under-buttocks drape w/ graded collection bag

LARGE-BORE INFLOW/OUTFLOW TUBING

Baxter Healthcare Corporation
Tel: 1-800-933-0303
Saline 3000cc bags; cat #2B7126
Cysto/Bladder Irrigation set; cat #2C4040

Hospira Inc.
Address: Lake Forest, IL 60045
TUR Y-Set; cat #6543-01

McKesson
Irrigation set/cysto; cat #208806

(continued on next page)
VENDOR LISTING (CONTINUED)

SUCTION TUBING

Cardinal Health
Tel: 1-800-964-5227
Suction tubing for outflow; cat #N56A 3/16"

CONMED
Tel: 1-315-797-8375
Website: www.conmed.com
Suction tubing, 10 feet, 3/16"; ref #0036770

Kendall Tyco/Healthcare
Tel: 1-800-962-9888
Argyle non-conductive connecting tubing, 3/16" x 6'; cat #284513

UNDER-BUTTOCKS DRAPES

3M
Tel: 1-800-228-3957
Fluid pouch 3M Steri-Drape; cat #1016

Mölnlycke Healthcare
Website: www.molnlycke.com/us/
Under-buttocks drape with pouch, latex free; ref #229

Allegiance
Address: McGaw Park, IL 60085
Under-buttocks drape with fluid control; pouch II; cat #8482

Medline
Tel: 1-800-MEDLINE (633-5463)
Proxima under-buttocks drape with pouch and drainage port; reorder #DYNJP6002

Gyrus ACMI
Tel: 1-888-524-7266
DISTEN-U-FLO fluid management system
(set includes under-buttocks drape and outflow tubing); ref #GY5-TUB

McKesson
Under-buttocks drape; #314027

CAMERA DRAPES

McKesson
Camera drape; arthroscopy covers; part #577706
ADMINISTRATIVE PROCESSES

REPROCESSING HYSTEROSCOPIC EQUIPMENT

It is important to establish a protocol for reprocessing your hysteroscopy equipment. Refer to the manufacturer’s Instructions for Use for recommended guidelines for your particular hysteroscope and/or accessory.

The following contacts are provided for your convenience:

**Richard Wolf Medical Instruments**
Tel: 1-800-323-9653
Website: www.richardwolfusa.com

**Karl Storz Endoscopy**
Tel: 1-800-421-0837
Website: www.karlstorz.com

**Olympus**
Tel: 1-800-848-9024
Website: www.olympusamerica.com/msg_section/msg_ask.asp

**Gyrus ACMI, an Olympus Company**
Tel: 1-888-524-7266
Website: www.olympusamerica.com/msg_section/msg_ask.asp
ADMINISTRATIVE PROCESSES

PHYSICIAN CODING GUIDE

ESSURE PROCEDURE CODING


CPT-4 is a listing of descriptive terms and codes for reporting services and procedures performed by healthcare providers.

The following code may be used to report procedures associated with Essure®:

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure</td>
<td>58565</td>
<td>Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
</tr>
</tbody>
</table>

Healthcare Common Procedure Coding System (HCPCS) codes

Level II HCPCS codes are published and updated annually by CMS. These alphanumeric codes are used to report drugs, supplies, and services.

Please note that Medicare does not allow for separate reporting and billing of the permanent implantable contraception. Private payers and Medicaid will make their own determination on whether or not to use the HCPCS code. Please confirm with your payer that A4264 is allowed for billing and will be paid.

The HCPCS code used by facilities and some Medicaid plans to report Essure is:

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure</td>
<td>A4264</td>
<td>Permanent implantable contraceptive intratubal occlusion device(s) and delivery system</td>
</tr>
</tbody>
</table>

Diagnosis Codes

The International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) codes are used to classify diagnoses and conditions, and support medical necessity for specific procedures and services. They are used to indicate the reason for performing a given procedure and may be used by payers to determine coverage.

The following ICD-10-CM codes may be applicable to women who receive Essure:

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z30.2</td>
<td>Encounter for sterilization</td>
</tr>
</tbody>
</table>

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ADMINISTRATIVE PROCESSES

PHYSICIAN CODING GUIDE (CONTINUED)

ESSURE CONFIRMATION TEST CODING


The following codes may be used to report procedures associated with Essure®.

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure</td>
<td>58565</td>
<td>Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
</tr>
<tr>
<td>TVU</td>
<td>76830</td>
<td>Ultrasound: Transvaginal</td>
</tr>
<tr>
<td>Modified HSG</td>
<td>58340</td>
<td>Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or HSG</td>
</tr>
<tr>
<td>Modified HSG, interpretation and supervision</td>
<td>74740</td>
<td>HSG, radiologic supervision and interpretation</td>
</tr>
<tr>
<td>Modified HSG, interpretation</td>
<td>74740-26</td>
<td>HSG, radiologic supervision and interpretation, professional component only</td>
</tr>
<tr>
<td>Modified HSG, supervision</td>
<td>74740-TC</td>
<td>HSG, radiologic supervision and interpretation, technical component only</td>
</tr>
</tbody>
</table>

ICD-10-CM diagnosis codes

For many payers, the following codes may be used to identify the Essure Confirmation Test as a preventive service:

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Code Description</th>
<th>Recognized by†:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z30.8</td>
<td>Other specified contraceptive management</td>
<td>Most payers</td>
</tr>
<tr>
<td>Z98.51</td>
<td>Tubal ligation status</td>
<td>UHC</td>
</tr>
<tr>
<td>Z30.42</td>
<td>Encounter for surveillance of injectable contraceptive</td>
<td>Cigna</td>
</tr>
<tr>
<td>Z30.2</td>
<td>Encounter for sterilization</td>
<td>Cigna</td>
</tr>
</tbody>
</table>

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†Subject to change.

IMPORTANT: The information in this guide is for informational purposes and does not guarantee payment or coverage. Offices should research coding, coverage, and payment for individual patients prior to initiating treatment since policies and guidelines vary by payer and health plan. Offices are responsible for submitting accurate, complete, and appropriate claims to payers and for compliance with any obligations required by law, contract, or otherwise.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
ADMINISTRATIVE PROCESSES

PHYSICIAN CODING GUIDE (CONTINUED)

MODIFIERS

Preventive services

CPT Modifier 33 is applicable for the identification of preventive services without cost sharing and may be added to the following codes as shown below.

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure</td>
<td>58565-33</td>
<td>Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
</tr>
<tr>
<td>Modified HSG</td>
<td>58340-33</td>
<td>Catheterization and introduction of saline or contrast material for SIS or HSG</td>
</tr>
<tr>
<td>TVU</td>
<td>76830-33</td>
<td>Ultrasound, transvaginal</td>
</tr>
</tbody>
</table>

Note: Not all commercial payers will require the use of Modifier 33. Some will automatically process Essure® and the Essure Confirmation Test without patient cost sharing.

Incomplete procedure

In some cases, the Essure procedure is initiated but cannot be completed. In these cases, it may be appropriate to bill within Modifier 52 or 53 as described below.

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure, reduced services</td>
<td>58565-52</td>
<td>This modifier is used to report a service or procedure that is partially reduced or eliminated at the physician’s election. An example of the correct use of Modifier 52 would be a failure of placement on one side, resulting in unilateral placement of Essure.</td>
</tr>
<tr>
<td>Essure procedure, discontinued</td>
<td>58565-53</td>
<td>This modifier is used to report a procedure that is discontinued by the physician because of extenuating circumstances. Modifier 53 can only be used after anesthesia has been administered. An example of the correct use of Modifier 53 would be an Essure procedure being discontinued because the ostium of the fallopian tube is not visible.</td>
</tr>
</tbody>
</table>

LOCAL CODING

Some state Medicaid programs may require the use of state-specific coding. Providers should research Medicaid coding guidelines on a state-specific basis.

To access state Medicaid coding and reimbursement information, please go to EssureMD.com.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
RESOURCES

Essure® Instructions for Use

Essure Patient Information Booklet

www.EssureMD.com

www.Essure.com

American Congress of Obstetricians and Gynecologists (ACOG)
409 12th Street SW, Washington, DC 20024-2188
Mailing Address: PO Box 70620, Washington, DC 20024-9998
(800) 673-8444
(202) 638-5577
www.acog.org


American Association of Gynecologic Laparoscopists (AAGL)
6757 Katella Ave
Cypress, CA 90630
(800) 554-2245
www.aagl.org

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 2 AND 3.
REFERENCES

