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.
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
- Conducting and evaluating results of the Essure Confirmation Test

If you have any questions that cannot be answered by this manual or the Instructions for Use, please do not hesitate to contact your Clinical Sales Specialist using the business card provided.

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

Important Safety Information
Who should not use Essure

- Essure is contraindicated in patients who are uncertain about ending fertility, can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicornuate uterus), have previously undergone a tubal ligation, are pregnant or suspect pregnancy, delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure, have an active or recent upper or lower pelvic infection, or have a known allergy to contrast media.
- Patients undergoing immunosuppressive therapy (e.g. systemic corticosteroids or chemotherapy) are discouraged from undergoing the Essure procedure.
- Uterine or fallopian tube anomalies may make it difficult to place Essure inserts.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON NEXT PAGE.
Important Safety Information (cont’d)

Prescription Only

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.

Pregnancy Considerations

• The Essure procedure should be considered irreversible. Patients should not rely on Essure inserts for contraception until an Essure Confirmation Test (modified hysterosalpingogram [HSG]) demonstrates bilateral tubal occlusion and satisfactory location of inserts.
• Effectiveness rates for the Essure procedure are based on patients who had bilateral placement. If Essure inserts cannot be placed bilaterally, then the patient should not rely on Essure inserts for contraception.
• Effects, including risks, of Essure inserts on in vitro fertilization (IVF) have not been evaluated.
• Pregnancies (including ectopic pregnancies) have been reported among women with Essure inserts in place. Some of these pregnancies were due to patient non-compliance or incorrect clinician interpretation of the Essure Confirmation Test (modified HSG).

Procedural Considerations

• Perform the Essure procedure during early proliferative phase of the menstrual cycle. Terminate procedure if distension fluid deficit exceeds 1500cc or hysteroscopic time exceeds 20 minutes as it may signal uterine or tubal perforation. Never attempt to advance Essure insert(s) against excessive resistance. If tubal or uterine perforation occurs or is suspected, discontinue procedure and work-up patient for possible complications related to perforation, including hypervolemia. Do not attempt hysteroscopic Essure insert removal once placed unless 18 or more trailing coils are seen inside the uterine cavity due to risk of fractured insert, fallopian tube perforation or other injury.
• DO NOT perform the Essure procedure concomitantly with endometrial ablation. Avoid electrosurgery on uterine cornua and proximal fallopian tubes without visualizing inserts.

Nickel Allergy

Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. In addition, some patients may develop an allergy to nickel if this device is implanted. Typical allergy symptoms reported for this device include rash, pruritus, and hives.

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.

Clinical Trial Experience

• Safety and effectiveness of Essure is not established in patients under 21 or over 45 years old, nor in patients who delivered or terminated a pregnancy less than 8-12 weeks before procedure. Women undergoing sterilization at a younger age are at greater risk of regretting their decision.
• 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.
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Placement procedure
Post-procedure

ESSURE CONFIRMATION TEST

APPENDIX
Managing technical issues
Resources
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PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
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:

• Women who are uncertain about ending fertility
• Women who can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicornuate uterus)
• Women who have previously undergone a tubal ligation
• Women who are pregnant or suspect pregnancy
• Women who have delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure
• Women who have an active or recent upper or lower pelvic infection
• Women who have a known allergy to contrast media

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.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
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 picture 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 protect the Essure insert and minimize fluid splash-back as the Essure insert passes through the sealing cap of the hysteroscope working channel.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
PRODUCT OVERVIEW

HOW ESSURE® WORKS

Using a hysteroscopic approach, one Essure insert is placed in the proximal section of each fallopian tube lumen across the uterotubal junction (UTJ)

• Placement at the UTJ allows for the insert to be distal enough to prevent expulsion due to uterine contractions during menses, yet proximal enough to visualize trailing coils to show placement

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 a chronic 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.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
Two clinical trials (Phase II trial and Pivotal trial) have demonstrated the efficacy and safety of Essure® permanent birth control. A post-approval study using the current delivery system is also presented below.

**STUDY DESIGNS**

**Phase II**
- Prospective, multicenter, single-arm, nonrandomized international study of women seeking permanent birth control
- Study objectives: patient tolerance of, and recovery from, the insert placement procedure, safety of the insert placement procedure, patient tolerance of the implanted inserts, long-term safety and stability of implanted inserts, effectiveness of the inserts in preventing pregnancy

**Pivotal**
- Prospective, multicenter, single-arm, nonrandomized international study of women seeking permanent birth control.
  - The study used findings from the US Collaborative Review of Sterilization (CREST study) as a qualitative benchmark
- Primary end points: prevention of pregnancy, safety of insert placement procedure, safety of insert wearing
- Secondary end points: patient satisfaction with insert placement procedure, patient satisfaction with insert wearing, bilateral insert placement rate, development of a profile for an appropriate candidate for the Essure procedure

In both studies, an Essure Confirmation Test (modified hysterosalpingogram [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.

**Post Approval**
- Prospective, multicenter, single-arm, nonrandomized US study intended to document the bilateral placement rate using the current delivery system
- Primary end point: successful bilateral placement rate at first attempt

**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 able and 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 Group</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;28 years old</td>
<td>14%</td>
</tr>
<tr>
<td>28-33 years old</td>
<td>40%</td>
</tr>
<tr>
<td>≥34 years old</td>
<td>46%</td>
</tr>
</tbody>
</table>

**Demographics** *(Phase II and Pivotal Trials Combined (N=745))*

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RACE</strong></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><strong>Gravidity</strong></td>
<td>Mean=2.91 (0-11)</td>
</tr>
<tr>
<td><strong>Parity</strong></td>
<td>Mean=2.23 (0-6)</td>
</tr>
<tr>
<td><strong>Body mass index (BMI) (kg/m²)</strong></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 Essure Post-Approval Study consisted of 581 women in whom insert placement was attempted using the current delivery system. A total of 70 investigators performed the procedures at 70 US sites. All study participants were between 21 and 51 years of age and were seeking permanent contraception prior to enrollment.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
CLINICAL DATA

RESULTS

Bilateral Placement Rate (Post-Approval Study)

95.8% of patients had a successful bilateral Essure® placement on the first attempt (n=593/619)*

*Intent-to-treat bilateral placement rate includes all participants who underwent hysteroscopy, regardless of whether insert placement was attempted.

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)†

<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></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 Confirmation Test 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

Essure was shown to be 99.83% effective in patients told to rely, based on 5-year clinical study data²

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
CLINICAL DATA

PATIENT TOLERANCE AND RECOVERY

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

- 88% of patients rated tolerance of the placement procedure as good, very good, or excellent3
- Women were typically discharged from the medical facility 44 minutes after the procedure3
- 92% of working women missed no more than 1 day of work after the procedure day3
- 75% of patients resumed normal activity by day 23
- 99% of women rated their comfort as good to excellent at all follow-up visits3

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</td>
<td>Percent</td>
<td>Number</td>
<td>Percent</td>
</tr>
<tr>
<td></td>
<td>(N=233</td>
<td>(N=544</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>procedures)</td>
<td>procedures)</td>
<td></td>
<td></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>

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.

*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).
# 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)</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></td>
<td>Dysmenorrhea/menstrual cramps (severe)</td>
<td>14</td>
<td>2.9%</td>
</tr>
<tr>
<td>Genitourinary</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>Pain/discomfort—uncategorized</td>
<td>Abnormal bleeding—timed 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>
</tbody>
</table>

Adverse Events by Body System

*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.

## POTENTIAL ADVERSE EVENTS NOT OBSERVED IN CLINICAL STUDIES

The following adverse events were not experienced by clinical trial participants but are still possible and/or have occurred in the commercial setting:

- Pregnancy and ectopic pregnancy in women relying on Essure inserts
- Perforation of internal bodily structures other than the uterus and fallopian tube
- Adnexal infection/salpingitis
- Adverse events associated with the Essure Confirmation Test or x-rays
- Pregnancy due to uterine or fallopian tube procedures causing failure of insert
- Adverse events associated with surgery attempted to reverse the procedure, pregnancy following a reversal, or an IVF procedure
- Adverse events associated with gynecological surgical procedures (eg, endometrial ablation). 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 by hysteroscopy, x-ray, or ultrasound following intrauterine procedures. There could be risks associated with intrauterine procedures and the presence of inserts not currently identified.

Please see additional important safety information about Essure on pages 2-3 of PDF.
ESSURE® EFFECTIVENESS IN THE COMMERCIAL SETTING

Data from the clinical trials show there have been no pregnancies among trial participants with up to 5 years of reliance. However, unintended pregnancies have been reported in women who have worn the inserts in the commercial setting. The table below summarizes the reasons for pregnancy from reports received by Conceptus (acquired by Bayer HealthCare in 2013), and additional reports from the published scientific literature.

<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><strong>Total</strong></td>
<td>660</td>
<td></td>
<td>88</td>
</tr>
</tbody>
</table>

*Table includes pregnancy reports received directly by Conceptus (acquired by Bayer HealthCare in 2013), 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 properly counseled in accordance with Section XI of the Instructions for Use. It is also important to evaluate both insert location and occlusion carefully before telling the patient that she may rely on Essure for contraception.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
PATIENT SELECTION AND COUNSELING
PATIENT SELECTION AND COUNSELING

ESSURE® IS AN APPROPRIATE OPTION FOR WOMEN WHO DESIRE PERMANENT BIRTH CONTROL:
• The patient must be certain that her family is complete, and understand that the procedure should be considered irreversible
• The patient must be willing to use alternative contraception until the Essure Confirmation Test confirms that the Essure inserts are in the proper position and her tubes are blocked
• Evaluate the patient for pelvic infection, cervicitis, undiagnosed vaginal bleeding, anatomical variants and/or uterine pathology that may make her unsuitable for the procedure

For more detailed information about the Essure Confirmation Test, please refer to the Essure Confirmation Test section.

ESSURE IS CONTRAINDICATED FOR PATIENTS WHO:
• Are uncertain about ending their fertility
• Can have only one insert placed (including contralateral proximal tube occlusion or suspected unicorne uterus)
• Have previously undergone a tubal ligation
• Are pregnant or suspect pregnancy
• Delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure
• Have an active or recent upper or lower pelvic infection
• Have a known allergy to contrast media

<table>
<thead>
<tr>
<th>Your patient</th>
<th>Why Essure may be right for her</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certain that her family is complete and that she does not want any more children</td>
<td>Essure is 99.83% effective based on 5-year clinical study data²</td>
</tr>
</tbody>
</table>
| Does not want to worry about getting pregnant again | After her 3-month Essure Confirmation Test verifies correct insert location and tubal occlusion, she can rely on Essure
  • Counsel her to use alternative birth control (except an IUD/IUS, due to the theoretical risk of insert disruption upon removal) until confirmation is received |
| Would prefer to avoid surgery, general anesthesia, and/or lengthy recovery time | Essure is a 10-minute, nonsurgical procedure that can be done in the doctor’s office, with most women recovering in 1-2 days. Women were typically discharged from the medical facility about 45 minutes after the procedure³ |

Women who undergo sterilization at a relatively young 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.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
PATIENT SELECTION AND COUNSELING

PATIENTS MAY HAVE QUESTIONS AND CONCERNS ABOUT THE ESSURE® PROCEDURE. IT IS IMPORTANT TO MANAGE THEIR EXPECTATIONS WITH THE FOLLOWING INFORMATION:

- Explain what Essure is and how it works, and be sure to distribute the Patient Information Booklet to detail the benefits and risks of Essure.
- Essure is a permanent birth control procedure that works with the body to create a natural barrier against pregnancy.
- The Essure procedure should be considered irreversible.
- The procedure involves placing soft, flexible inserts into the fallopian tubes.
- Over a period of about 3 months, tissue forms around the inserts. The build-up of tissue creates a barrier that keeps sperm from reaching the eggs and prevents conception.
- After 3 months, an Essure Confirmation Test will verify that the inserts are in the correct location and the fallopian tubes are blocked.
  - **IMPORTANT:** MEET WITH PATIENTS TO CONFIRM THE RESULTS OF THE ESSURE CONFIRMATION TEST. UNTIL CONFIRMATION IS RECEIVED, PATIENTS MUST CONTINUE TO USE ALTERNATIVE CONTRACEPTION (EXCEPT AN IUD OR IUS) TO PREVENT PREGNANCY.
- Most women are able to leave the doctor’s office about 45 minutes after the procedure is completed.
- Most women return to normal activities within 1-2 days.
- The Essure procedure is 99.83% effective in patients told to rely on Essure, based on 5-year clinical study data.
  - No pregnancies were reported in 5-year clinical study data among women with successful bilateral placement told to rely on Essure.
    - However, no method of contraception is 100% effective and pregnancies have occurred in the commercial setting.
- **IMPORTANT:** Not all women will achieve successful placement of both Essure inserts. Discuss a management plan with the patient in the event that bilateral placement is not achieved.

*Reasons that prevented women from relying on Essure after the Essure Confirmation Test are: expulsions, perforations, incorrect location, and inadequate tubal blockage.*
PATIENT SELECTION AND COUNSELING

• Like all birth control methods, there is a risk of pregnancy
• Women whose Essure® Confirmation Tests show correct insert location but not tubal blockage at 3 months can continue to use alternative contraception for another 3 months and repeat the Confirmation Test. In clinical trials, all women in this situation were found to have blocked tubes at 6-7 months
• If inserts are not successfully placed, or confirmed by the Essure Confirmation Test, women may choose to undergo the Essure procedure again, or choose an incisional sterilization, or choose another method of contraception
• A patient may need a surgical procedure to manage a situation where Essure has perforated the fallopian tube or uterus or there is persistent pelvic pain. One patient in clinical trials requested removal for pain. Removal will likely require surgery, and may necessitate abdominal incision, general anesthesia, or possible hysterectomy
• Counsel patients that this product does not protect against human immunodeficiency virus (HIV) or other sexually transmitted infections (STIs)

ADDITIONAL CONSIDERATIONS:

• Pregnancies (including ectopic pregnancies) have been reported among women with inserts in place. Some of these pregnancies were due to patient non-compliance, which included failure to:
  — Use alternative contraception during the 3-month “waiting period” prior to the Essure Confirmation Test
  — Return for the Essure Confirmation Test to determine if the inserts are in the correct location and tubal occlusion is present
  — Use alternative contraception or undergo sterilization by another method if the Essure Confirmation Test reveals tubal patency. In this case, the clinician should inform the patient of the Essure Confirmation Test finding and counsel her not to rely on Essure for permanent birth control
Therefore, it is critical that clinicians properly counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all stages of the Essure procedure.
• Patients undergoing immunosuppressive therapy (eg, systemic corticosteroids or chemotherapy) are discouraged from undergoing the Essure procedure because the immunosuppressant may lead to decreased tissue in-growth
• The effects of the Essure inserts on the success of in vitro fertilization are unknown. If pregnancy is achieved, the risks of the inserts to the patient, to the fetus, and to the continuation of the pregnancy are also unknown
• Do not perform the Essure procedure concomitantly with endometrial ablation. Ablation causes uterine synechiae, which can compromise the Essure Confirmation Test
• The Essure insert includes nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from the device. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. In addition, some patients may develop an allergy to nickel if this device is implanted. Typical allergy symptoms reported for this device include rash, pruritus, and hives

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
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 prevent 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.

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. The following criteria can be used to confirm a patient with no signs or symptoms of pregnancy is not pregnant: it is ≤7 days after the start of patient’s normal menses; patient has not had sexual intercourse since the start of last normal menses; patient has been correctly and consistently using a reliable form of contraception; it is ≤7 days after patient had a spontaneous or induced abortion; patient is within 4 weeks postpartum and/or is fully or nearly fully breastfeeding,* amenorrheic, and <6 months postpartum.5

*Exclusively breastfeeding or the vast majority (>85%) of feeds are breastfeeds.5

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® PROCEDURE

PRE-PROCEDURE (CONT’D)

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

Suggested 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

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 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 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

Have available
- Hysteroscopic grasper

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
PATIENT COMFORT

Patient comfort is an important part of a successful Essure placement. Recommended options for the Essure procedure include:

- NSAIDs 1-2 hours pre-procedure
- Anxiolytic 30 minutes pre-procedure
- Paracervical block with or without IV sedation

An NSAID given prior to the procedure has been shown to increase the likelihood of bilateral placement success in clinical trials.

*In the Essure Pivotal trial*

**NSAIDs WERE ADMINISTERED PRIOR TO THE PROCEDURE**³

- In 84% of 544 procedures, patients received pre-operative NSAIDs³

**PREDOMINANT ANESTHESIA USED**³

<table>
<thead>
<tr>
<th></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**³

- 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.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
### ESSURE® PROCEDURE

#### PATIENT COMFORT (CONT’D)

*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>. 2008.⁸</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 the tenaculum site, at 4:00, and 8:00 5 mL 4% intrauterine lidocaine⁸</td>
<td>Lorazepam 2 mg PO, 30-45 minutes pre-procedure</td>
<td></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>. 2007.⁷</td>
<td>Prospective, single-center cohort (N=857)</td>
<td>Ibuprofen 600 mg, 1 hour pre-procedure</td>
<td></td>
<td>50.5% of patients received paracervical block with mepivacaine cloridrate 3%</td>
<td>Diazepam 10 mg, 1 hour pre-procedure</td>
</tr>
</tbody>
</table>

*Did not significantly reduce pain.*

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*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.

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**PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.**
**ESSURE® PROCEDURE**

**PLACEMENT PROCEDURE**

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

If insert placement is not successful after 20 minutes, the case 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 ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.**
ESSURE® PROCEDURE

PLACEMENT STEPS

1. Introduce a speculum into the vagina to allow access to the cervix. A bivalve, open-sided speculum is recommended to allow removal once the hysteroscope is in place. Prep the cervix with betadine or other suitable antibacterial solution according to standard practice.

2. 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.

3. Insert the hysteroscope through the cervical os.

   • Do not perform cervical dilation unless necessary to allow hysteroscope insertion
   • Consider utilizing hydrodilation to introduce the hysteroscope under direct visualization and minimize mechanical dilation
   • If dilation is necessary, dilate only as much as is required to insert the hysteroscope. In order to reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation, eg, in the case of stenotic cervix

   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.

4. Once the hysteroscope has entered the uterine cavity, remove the speculum.

   Adequate uterine distension with sterile saline pre-warmed to body temperature must be achieved and maintained throughout the procedure in order to allow identification of and access to the fallopian tube ostia. Standard fluid-monitoring procedures should be followed throughout the procedure.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
In order to reduce the risk of hypovolemia, the procedure should be immediately aborted if the fluid deficit exceeds 1500cc or hysteroscopic time exceeds 20 minutes. Consider using gravity feed instead of a pressure cuff to minimize the risk of overdistension and tubal spasm.

Identify the bilateral fallopian tube ostia. Once both ostia have been visualized, your support staff can open the sterile Essure packaging.

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. Do not attempt placement in one tubal ostium unless expectation of contralateral tubal patency exists.

Insert the DryFlow™ introducer through the sealing cap on the hysteroscope working channel.

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).

The sterile assistant should insert the Essure delivery catheter through the DryFlow introducer and advance the system through the operating channel of the hysteroscope.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® PROCEDURE

PLACEMENT STEPS (CONT’D)

8 Using the thumb and forefinger, gently grasp the Essure delivery catheter and advance the Essure delivery catheter into the fallopian tube with gentle, constant forward movement (to prevent tubal spasm). If excessive resistance occurs (ie, catheter does not advance toward tubal ostium and/or catheter bends or flexes excessively), terminate procedure to avoid uterine perforation or placement into a false passage. **Align the proximal end of the black positioning marker with the ostium.** Do not rotate the thumbwheel until the marker is properly aligned.

**Black positioning marker at tubal ostium is visual indicator for proper position for deployment**

Do not continue to advance the Essure delivery system once the positioning marker on the catheter has reached the tubal ostium. Advancement beyond this point could result in unsatisfactory insert placement and/or tubal/uterine perforation. If tubal or uterine perforation occurs or is suspected, immediately discontinue the Essure placement procedure and examine the patient for a perforation.

This visual marker indicates that the Essure insert is spanning the intramural and the proximal isthmic segments of the fallopian tube, with the outer coil spanning the uterotubal junction. This is the ideal placement for the Essure insert.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
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 should be undertaken to determine location and tubal patency.

ESSURE® PROCEDURE

PLACEMENT STEPS (CONT’D)

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 extraordinary 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.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® PROCEDURE

PLACEMENT STEPS (CONT’D)

9 Stabilize the handle of the Essure insert against the hysteroscope or camera to prevent inadvertent forward movement of the insert during retraction of the delivery catheter. Confirm that the black positioning marker is at the fallopian tube ostium.

**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.

10 Roll the thumbwheel on the handle back towards you until a hard stop. Clicking sounds may be heard as the thumbwheel rolls back.

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.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® PROCEDURE

PLACEMENT STEPS (CONT’D)

11 Stop and check proper positioning: a gold marker band should now be located just outside the ostium. Confirm positioning of the gold marker and visualization of the distal tip of the green delivery catheter.

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.

12 Press the button on the handle. This enables the thumbwheel to further roll back for insert deployment.

Do not press the button until the delivery system is in the correct position for insert placement.

13 Roll the thumbwheel back towards you until it won’t roll back any further. This will allow the coils to expand and the insert to be released from the delivery catheter.

It is important to continue to stabilize the handle as you roll the thumbwheel back.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
PLACEMENT STEPS (CONT’D)

Remove the delivery catheter when the thumbwheel cannot be rolled back any further and the expanded outer coils are visible. If expansion is not observed, gently move the delivery catheter away from the uterine wall to release pressure on the outer coil.

**Note:** Two distinct operations will take place during this step:
- Retraction of the green delivery catheter away from the insert
- Actual release of the insert, after retraction of the catheter

Only after release of the insert has occurred can you remove the delivery system.

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

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

Once the delivery catheter has been removed, assess the position of the Essure insert. Count the number of expanded coils that appear trailing into the uterine cavity. Do not count the most proximal half coil. Ideally, 3 to 8 expanded outer coils should be trailing into the uterus. Inserts showing 0-17 trailing coils should be left in place and evaluated via Essure Confirmation Test (modified HSG).

Unless the insert has a trailing length that is 18 or more expanded outer coils, the insert should be left in place and evaluated via an Essure Confirmation Test 3 months post-procedure.

If there are no coils visible in the uterine cavity, then confirm deployment of device by visually inspecting the delivery catheter (see image to the right).

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

If a distal placement is suspected, instruct the patient to continue with their birth control and evaluate placement at 3-month Essure Confirmation Test. **Do not place more than one insert into a single fallopian tube during the same procedure.**

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® PROCEDURE

PLACEMENT STEPS (CONT’D)

16 Record the number of coils of the insert trailing into the uterine cavity, noting any issues with identifying or confirming either tubal ostium or any concern regarding potential perforation. These should be noted in patient records for subsequent reference when reviewing the 3-month Essure Confirmation Test. Additionally, the following information should be noted in the patient records:

- 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, as seen hysteroscopically after insert placement
- If identification of the tubal ostium during the insert placement procedure was compromised due to poor distension, poor illumination, or poor visualization secondary to endometrial debris

Insert removal should not be attempted hysteroscopically once the insert has been placed (ie, detached from the delivery wire). The only exception is during the actual placement procedure when removal may be attempted if 18 or more coils of the insert are trailing into the uterine cavity. Because of insert anchoring, however, removal may not be possible even immediately after placement. Attempted removal of an insert having fewer than 18 coils trailing into the uterine cavity may result in fallopian tube perforation or other patient injury.

17 Repeat the Essure insert placement procedure in the contralateral fallopian tube.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® PROCEDURE

ESSURE SYSTEM EXTRACTION

If there are 18 or more expanded outer coils trailing into the uterus, then the insert should be immediately removed from the uterus (as described in steps 1-5 below) and another attempt made at insert placement in the tube. Insert removal may not always be possible.

Removal of an insert should only be attempted during the same procedure in which the insert was placed.

STEPS FOR EXTRACTION:

1. As necessary, administer analgesia/anesthesia to reduce or prevent patient discomfort.

   Do not attempt insert removal hysteroscopically unless 18 or more coils of the Essure insert are trailing into the uterine cavity. Removal of insert may not be possible; attempted removal of inserts having fewer than 18 trailing coils may cause insert to fracture or patient injury.

2. Introduce a grasping instrument through the hysteroscope working channel.

3. Try to grasp the outer and inner coils of the insert together. If not possible, grasp the outer coil of the Essure insert.

4. Slowly pull back on the grasping instrument and withdraw the hysteroscope at the same time. Since the expanded insert is too large to be removed through the operating channel, the entire Essure system, together with the hysteroscope, should be removed from the uterus.

5. The outer coil and/or the inner coil of the Essure insert may stretch or elongate as insert removal is being attempted.

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

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

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® PROCEDURE

MANAGING UNSUCCESSFUL CASES

Bilateral attempt results in either unilateral or bilateral placement failure

Offer to attempt second placement procedure

If patient accepts, perform Essure Confirmation Test to assess if tube(s) without insert(s) is/are patent

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

Yes

Proceed with second placement procedure

Bilateral placement achieved?

Yes

No

Discuss alternative contraception options

No

Discuss alternative contraception options

BILATERAL ATTEMPT RESULTS IN INSERT PLACEMENT FAILURE

• In the event of placement failure (unilateral or bilateral), inform the patient that permanent contraception is not complete. 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 an Essure Confirmation Test (modified HSG). Schedule after patient’s next menses. 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

• Three months after bilateral placement, follow-up patient with a second Essure Confirmation Test (modified HSG) to verify insert location and tubal occlusion

• 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 ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® PROCEDURE

POST-PROCEDURE

Staff responsibilities

- Monitor patient during recovery
- Give ID card to patient
- Provide any prescriptions to patient (including birth control)
- Schedule 3-month Essure Confirmation Test
- Discharge patient
- Break down and clean room
- Sterilize equipment

Physician responsibilities

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.

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

**Note:** Instruct the patient to use an alternative form of contraception (except an IUD or IUS) for the first 3 months following the insert placement procedure until insert location and tubal occlusion have been verified by the 3-month Essure Confirmation Test. The patient should also be counseled that there is a theoretical increased risk of ectopic pregnancy during this time period, so compliance with her contraception regimen is critical.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® PROCEDURE

ELECTROSURGICAL PROCEDURES
The Essure insert will conduct energy if directly or closely contacted by an active electrosurgical device. If this occurs, then there is a risk of patient injury. Therefore, electrosurgery should be avoided in procedures undertaken on the uterine cornua and proximal fallopian tubes without either hysteroscopic visualization of the inserts, or visualization of the proximal portion of the fallopian tube via open surgical procedures or laparoscopy. During laparoscopy-assisted vaginal hysterectomy and other procedures in which electrosurgical instruments could contact the serosa of the fallopian tube, instruments should not be placed more proximal than the ampullary portion of the tube.

ENDOMETRIAL ABLATION
• Do not perform the Essure procedure concomitantly with endometrial ablation. Ablation causes intrauterine synechiae that can compromise the ability to later perform the Essure Confirmation Test. Women cannot rely on Essure for permanent birth control until insert location and tubal occlusion are verified by the Essure Confirmation Test

• Bench and clinical studies demonstrate balloon thermal (THERMACHOICE® Uterine Balloon System) and hydrothermal (HTA® System) endometrial ablation can be safely and effectively performed with Essure inserts in place. However, balloon thermal and hydrothermal endometrial ablation should be performed only after insert location and tubal occlusion have been verified by the Essure Confirmation Test

• Bench and clinical studies have been conducted which demonstrate that the bipolar radiofrequency (RF) NovaSure® Impedance Controlled Endometrial Ablation System can be safely performed with Essure inserts in place. However, thermal injury to the proximal portion of the fibrotic in-growth that causes tubal occlusion may occur. It is unknown whether partial thermal injury will interfere with tubal occlusion. Contraception rates following NovaSure with Essure inserts in place are under investigation

• Bipolar RF ablation device may contact inserts. As a result of contact, heat from a bipolar RF device may be propagated along the insert. This could cause bowel or bladder injury if there is an unrecognized tubal perforation and part of the insert lies outside of the tubal serosa. Therefore, do not perform bipolar RF ablation in patients who may have undiagnosed perforation (eg, patients whose Essure procedure was difficult or atypical), even if placement appears normal on the Essure Confirmation Test

• Performing intrauterine ablation procedures without direct visualization may result in trailing coils of insert being ensnared in another device. When the device is withdrawn, the insert may be removed and tubal patency be restored. In one study, the risk of insert being ensnared by a bipolar RF endometrial ablation array was approximately 3%

• Safety of cryoaiblation, laser ablation, or microwave ablation with Essure inserts in place is unknown and little data exist. Microwave energy near metallic implants may pose risk of serious patient injury; therefore, avoid use of microwave endometrial ablation devices near inserts

Note: All trademarks are property of their respective companies.

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OTHER INTRAUTERINE PROCEDURES

Diagnostic procedures under direct visualization are optimal with the Essure inserts in place. 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

INSERT(S) REMOVAL

A very small percentage of women in the Essure clinical trials reported recurrent or persistent pelvic pain; one woman requested device removal due to pain; however, if device removal is required for any reason, it will likely require surgery. Linear salpingotomy or salpingectomy via laparoscopy or laparotomy can be used to remove the insert. Do not remove insert(s) unless patient is experiencing an adverse event(s) associated with its presence, or if removal is demanded. A cornual resection of the proximal fallopian tube may be required for removal.

1. To perform a linear salpingotomy, make a small incision (approximately 2 cm in length) along the antimesenteric border of the fallopian tube directly overlying the insert.

2. To perform total or partial salpingectomy, use a transabdominal approach (ie, laparotomy or laparoscopy). Removal may be along with, or independent of, an incisional sterilization procedure.
ESSURE® CONFIRMATION TEST
OVERVIEW

The Essure Confirmation Test is a modified HSG used to evaluate the location of the inserts and occlusion of the fallopian tubes. Every patient must have an Essure Confirmation Test 3 months following the Essure insert placement procedure. The patient must use alternative contraception until the Essure Confirmation Test verifies correct insert location and tubal occlusion.

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

Note: Unlike an infertility HSG, the Essure Confirmation Test is a modified HSG that is performed by instilling contrast media (dye) slowly and gently until the uterine cornua are distended.

PERFORMING THE ESSURE CONFIRMATION TEST

In order to evaluate satisfactory insert location and tubal occlusion, Essure Confirmation Test images must show the relationship of the proximal marker of the inner coil to the uterine cornua.

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

1. Do not dilate cervix unless necessary; if dilation occurs, maintain a good cervical seal.
2. Obtain good cornual filling; uterine cavity silhouette should be clearly visualized. Instill contrast slowly and gently until the uterine cornua are distended. An increase in intrauterine pressure beyond that should be avoided due to patient discomfort and the possibility of resultant vasovagal reaction.
3. Place fluoroscopy beam as close to anterior/posterior (A/P) projection as possible. If patient has a midpositional uterus, downward traction with tenaculum may be required to achieve adequate images. Remove speculum prior to fluoroscopy for best visualization of uterine anatomy.
4. Take a minimum of 6 radiographs to assess insert location and tubal occlusion.
5. Report must include reference to satisfactory location and occlusion.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® CONFIRMATION TEST

RADIOGRAPHIC MARKERS

There are 4 radiographic markers on the device to help confirm satisfactory insert location and tubal occlusion:

1. Proximal end of outer coil
2. Proximal marker of inner coil
3. Distal marker of outer coil
4. Distal end of inner coil ("ball tip")

Length of inner coil = 30 mm

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® CONFIRMATION TEST

RADIOGRAPH IMAGING
The following 6 radiographs are recommended. In some cases, additional images may be necessary to evaluate insert location. This might include oblique views or lateral views.

1. SCOUT FILM
Scout film is the first image captured, before injecting the contrast. Capture an image of the uterus and fallopian tubes. 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.

2. 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.

3. 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.

4. TOTAL FILL
Capture an image of the uterus when the uterine cavity is completely filled to patient tolerance or the cornua has reached maximal distension, whichever comes first. Ideally, contrast should reach the proximal end of the inserts.

   Note: You may need to gently increase contrast volume in the uterine cavity to obtain a satisfactory image.

5. 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 Essure Confirmation Test is not the same as noted on hysteroscopy. Therefore, a correctly placed insert may appear to be more distal on the Essure Confirmation Test than noted at the time of hysteroscopy.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® CONFIRMATION TEST

EVALUATING ESSURE CONFIRMATION TEST IMAGE QUALITY

When evaluating the Essure Confirmation Test 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 maximally distended in at least one view.

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

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

EXAMPLES OF ESSURE CONFIRMATION TESTS THAT NEED TO BE REPEATED

- Filling defect in the left cornua
- Inadequate filling

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ESSURE® CONFIRMATION TEST

EVALUATING INSERT LOCATION

Distance from the filled uterine cornua to the proximal end of the insert 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

Note the 4 radiopaque markers and inner coil length. The inserts are symmetrical with a normal curvature. Ideal insert location is when the inner coil crosses the uterotubal junction. Note that the distal markers are fixed in relation to one another, but the proximal markers 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 marker of the inner coil being ≤30 mm into the tube from where contrast fills the uterine cornua.

Note the normal curvature and symmetrical appearance of both inserts.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
Essure® Confirmation Test

Unsatisfactory Location

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

1. Proximal Location of the Insert

Proximal location is defined as ≥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.

2. Expulsion of the Insert

One or both inserts are not present in the radiographic image.

How to manage:
Advise patient not to rely on Essure. 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 results. Also counsel patient on incisional sterilization or remaining on alternative contraception.

3. Distal Location of the Insert

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. If tube is patent, counsel patient on repeat Essure placement procedure. If tube is occluded, advise patient on potential false-positive Essure Confirmation Test results. Also counsel patient on incisional sterilization or remaining on alternative contraception.

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ESSURE® CONFIRMATION TEST

PERFORATION OR PERITONEAL LOCATION OF THE INSERT

When perforation occurs, the insert has punctured the uterine cavity. Peritoneal location means the insert is within the peritoneal cavity through a uterine perforation.

How to manage:
Advise patient not to rely on Essure for contraception. If tube is patent, 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.

Myometrial perforation

Right insert perforation; note the circular configuration of the inner coil

Left insert perforation; insert has a sharp bend and there is tubal patency. The right insert is also curled and suspicious for perforation

Right insert perforation with stretched outer coil

Left insert perforation; note the distance between the two inserts, their lack of normal curvature, their asymmetrical lie, and the reversed orientation of the right insert

Note: Additional radiographs that include oblique and lateral images may be helpful to evaluate location if a perforation is suspected.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
ESSURE® CONFIRMATION TEST

EVALUATE 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

Bilateral tube occlusions at the cornua

Right insert is <30 mm from the cornua, and contrast is seen in the tube and along the insert, but not beyond

Note: The distal markers are fixed in relation to one another, but the proximal markers may move or seem stretched because of the flexibility of the outer coil.
ESSURE® CONFIRMATION TEST

UNSATISFACTORY OCCLUSION

Patency seen beyond the insert; note the distal marker of the outer coil (arrow)

Satisfactory bilateral location of inserts; unsatisfactory bilateral 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 3 more months and have a repeat Essure Confirmation Test. If patency is again documented on the repeat Essure Confirmation Test, 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 in 3 months. If occlusion is still unsatisfactory, instruct the patient not to rely on Essure for contraception

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
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>
<tbody>
<tr>
<td>Inability to introduce the hysteroscope into the uterus</td>
<td>Inadequate cervical dilation</td>
<td>• Use hysteroscope with smaller outer diameter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Attempt hydrodilation of the cervix</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Dilate cervix (do not overdilate)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Try a plastic os finder</td>
</tr>
<tr>
<td></td>
<td>Severeley retroverted or anteverted uterus</td>
<td>Use tenaculum to straighten the angulation between the uterus and cervix</td>
</tr>
<tr>
<td></td>
<td>Stenosis of cervix</td>
<td>Use pediatric dilators or even ocular dilators to gain access to cervix</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 ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
# MANAGING TECHNICAL ISSUES

## ACHIEVING UTERINE DISTENSION

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patulous cervix</td>
<td>• Gently twist tenaculum 45° or use additional tenaculum to seal cervix • Place tenaculum at 1 &amp; 5 o’clock or 7 &amp; 11 o’clock position (or both)</td>
<td></td>
</tr>
<tr>
<td>Inadequate flow</td>
<td>• Ensure hysteroscope valves are fully open • Inspect tubing • Increase bag height or pressure • Make sure that large tubing is being used (large bore, cyto, TURP) • Closely inspect cavity for false channels due to possible perforation</td>
<td></td>
</tr>
<tr>
<td>Pinched tubing</td>
<td>• Inspect tubing and replace if necessary</td>
<td></td>
</tr>
<tr>
<td>Small or empty saline bags</td>
<td>• Replace empty bags • Use two bags with “Y” connector • Use 3-liter bags</td>
<td></td>
</tr>
<tr>
<td>Inflow/outflow ports clogged or closed</td>
<td>• Open closed ports • Flush ports</td>
<td></td>
</tr>
<tr>
<td>Leakage at hysteroscope valves</td>
<td>• Check connections • Replace tubing</td>
<td></td>
</tr>
<tr>
<td>Incorrect pump type or settings</td>
<td>• Inspect pump and stopcocks • Read pump operator’s manual</td>
<td></td>
</tr>
<tr>
<td>Pump tubing reversed</td>
<td>• Change tubing direction</td>
<td></td>
</tr>
<tr>
<td>IV pole for gravity feed is too low</td>
<td>• Raise IV pole • Use pressure bag</td>
<td></td>
</tr>
<tr>
<td>Defective pressure bag</td>
<td>• Replace pressure bag • Use gravity feed</td>
<td></td>
</tr>
<tr>
<td>Obstruction in hysteroscope channel</td>
<td>• Flush channel • Remove hysteroscope and clean</td>
<td></td>
</tr>
</tbody>
</table>

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PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.
## MANAGING TECHNICAL ISSUES

### ACHIEVING UTERINE CORNUAL VISUALIZATION

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Debris, clots, or fogged lens</td>
<td>• Remove camera head and clean&lt;br&gt;• Remove hysteroscope and clean proximal and distal lens</td>
<td></td>
</tr>
<tr>
<td>Inadequate light source and/or cable</td>
<td>• Inspect equipment before procedure&lt;br&gt;• Replace light source bulb or cable&lt;br&gt;• Check light/cable connections</td>
<td></td>
</tr>
<tr>
<td>White balance not performed</td>
<td>• Perform white balance</td>
<td></td>
</tr>
<tr>
<td>View not in focus</td>
<td>• Adjust focus mechanism on camera head</td>
<td></td>
</tr>
<tr>
<td>Blood in uterus</td>
<td>• Open outflow port and flush&lt;br&gt;• Increase fluid flow</td>
<td></td>
</tr>
<tr>
<td>Outflow port is not open</td>
<td>• Open outflow port&lt;br&gt;• Inspect hysteroscope to ensure channel is not clogged</td>
<td></td>
</tr>
<tr>
<td>Light gain on low</td>
<td>• Turn gain to high&lt;br&gt;• Switch autogain off&lt;br&gt;• Inspect equipment to ensure auto-feedback is functional</td>
<td></td>
</tr>
<tr>
<td>Shaggy endometrium</td>
<td>• Flush uterine cavity&lt;br&gt;• Aspirate debris&lt;br&gt;• Flush uterus again and increase pressure</td>
<td></td>
</tr>
<tr>
<td>Hysteroscope in cervical canal</td>
<td>• Advance hysteroscope past cervical ostium</td>
<td></td>
</tr>
</tbody>
</table>

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

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### MANAGING TECHNICAL ISSUES

#### ACHIEVING OSTIAL VISUALIZATION

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor uterine distension</td>
<td>• See “Inadequate intrauterine pressure” and “Poor uterine visualization”</td>
<td></td>
</tr>
<tr>
<td>Debris, endometrial fluff, or clots</td>
<td>• Flush uterus</td>
<td>• Aspirate</td>
</tr>
<tr>
<td></td>
<td>• Gently remove debris with graspers (do not use a curette)</td>
<td>• Consider abandoning procedure and rescheduling during early proliferative phase of the menstrual cycle</td>
</tr>
<tr>
<td></td>
<td>• Filmy tissue covering ostia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Gently probe with an insert tip</td>
<td>• Gently push insert forward. Proceed only if insertion meets minimal resistance</td>
</tr>
<tr>
<td>Abnormal ostial location</td>
<td>• Adjust/rotate hysteroscope</td>
<td>• Rotate insert tip</td>
</tr>
<tr>
<td>Only one ostium visualized</td>
<td>• Pull back hysteroscope to obtain full uterine view</td>
<td>• Adjust patient position</td>
</tr>
</tbody>
</table>

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

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# 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>
| Lateral or abnormally located tubes | • Pull hysteroscope back and adjust/rotate  
• Pull system back and rotate insert tip  
• Adjust patient position |

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
</table>
| Suspected tubal stenosis, tortuosity, or occlusion | • If tube appears patent, move hysteroscope closer and apply gentle, constant forward movement of catheter  
• If tube appears non-patent, abandon procedure  
• Gently pull on the tenaculum in attempt to straighten |

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
</table>
| Inability to advance insert into tube† (tracking) | • Pull hysteroscope back and adjust/rotate  
• Pull system back and rotate insert tip  
• Adjust patient position |

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hysteroscope is too far back</td>
<td>• Advance hysteroscope as close to ostium as possible</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insert tip bent, or catheter bent or damaged</td>
<td>• Use new system</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hysteroscope at incorrect angle</td>
<td>• Rotate hysteroscope to achieve proper angle</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tracking into false passage</td>
<td>• If uncertain about ostial location and/or true tubal lumen, remove system and abandon procedure</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
</table>
| Excessive cramping | • Reduce distension  
• Increase pain medication |

*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.
## MANAGING TECHNICAL ISSUES

### DEPLOYING THE INSERT

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
</table>
| Inability to retract delivery catheter | Delivery catheter twisted | • Slowly rotate catheter to relieve twisting  
• Remove and replace system |
| | Delivery catheter damaged | • Remove and replace system |
| Delivery catheter stretches (necking) | Delivery catheter damaged in hysteroscope working channel | • Verify that operating channel is open  
• Remove and replace system |
| | Delivery catheter sticks in tube during retraction | • Retract catheter slowly  
• Remove and replace system |
| Inadvertent forward movement of insert (feed forward) | Handle not stabilized during retraction | • Pull system back to proper position before deployment |
| | Delivery catheter bent proximal to hysteroscope | • Straighten system prior to attempting catheter retraction |
| | Delivery catheter gripped external to hysteroscope | • Do not hold catheter external to scope |
| Inability to fully depress button | Delivery catheter not fully retracted | • Roll thumbwheel until it stops |
| System failure | | • Remove and replace system |
| Outer coils do not deploy | Delivery catheter not fully retracted | • Continue rolling thumbwheel until it stops  
• Pull hysteroscope back to maintain visualization |
| | Outer coils are pressed against uterine wall | • Straighten system and allow coils to fully expand |
| | Technical insert failure | • Rotate system slowly  
• Gently jiggle system  
• Remove and replace system |

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

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## MANAGING TECHNICAL ISSUES

### DEPLOYING THE INSERT (CONT’D)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Potential Solutions*</th>
</tr>
</thead>
</table>
| **Insert deployed but will not release from system** | Difficulty detaching inner coil from delivery wire | Straighten delivery system to avoid contact between insert and uterine wall  
*If difficulty still occurs:*  
• Apply light backward tension to handle  
*If difficulty still occurs:*  
• Separately advance hysteroscope gently towards uterine cornua to compress outer coils of insert  
• Apply gentle backwards tension of delivery handle system  
• Obtain hysteroscopic panoramic view to verify separation of delivery wire  
*If unsuccessful:*  
• Administer additional pain medication. Pull out insert by gentle, continuous backward movement of delivery system. Do NOT pull expanded insert through operating channel. Remove entire Essure® system and hysteroscope as a unit |
| **Outer coils coming out of tube** | Retraction of system prior to detaching insert | • Roll thumbwheel back to a hard stop prior to applying retraction |
| **Insert stuck in hysteroscope** | Hysteroscope is too far forward during deployment | • Push insert out of hysteroscope using appropriately sized graspers |

*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.

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Please see additional important safety information about Essure on pages 2-3 of PDF.
USE OF HYSTEROSCOPE TIP

For those rare occasions when the delivery wire does not detach from the insert, the hysteroscope tip may be used to aid in separation of the insert from the delivery wire:

- Maintain the position of the delivery wire
- Separately advance the hysteroscope gently towards the uterine cornua so as to compress the outer coils of the insert (see diagram below)

Note: To avoid perforation, do not push the hysteroscope into the uterine wall. Maintain visibility of the insert and the surrounding uterine tissue at all times.

• With the hysteroscope held in this position against the insert, apply gentle backward tension on the handle of the delivery system. The purpose of this maneuver is to use the hysteroscope tip to steady the insert while backward tension is applied to the delivery wire
• If separation is visualized, completely remove the delivery wire while applying gentle backward tension on the handle
• If separation is not visualized, repeat this maneuver using the hysteroscope tip as necessary to detach the delivery wire from the Essure® insert; however, to reduce the risk of hypovolemia, hysteroscopic procedure time should not exceed 20 minutes

Use of hysteroscope tip to compress outer coils to aid detachment
MANAGING TECHNICAL ISSUES

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.
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
REFERENCES


PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.