ESSURE®
CLINICAL RESOURCE

Physician Training Manual

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.

essure®

ESSURE® CLINICAL RESOURCE

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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PRODUCT OVERVIEW

PRODUCT OVERVIEW

WHAT IS ESSURE®?

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

Essure is contraindicated for:

- 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

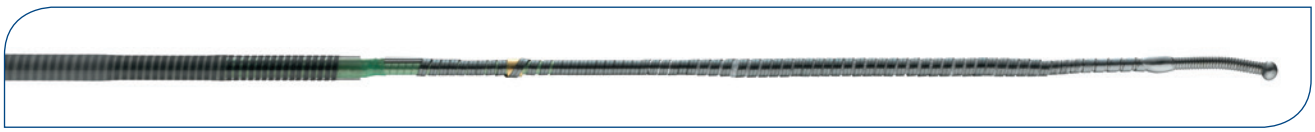
Before you begin the Essure procedure, it's important to be able to identify the components of the Essure delivery system and understand how they work.

- Essure insert
- Disposable delivery system
- DryFlow™ introducer

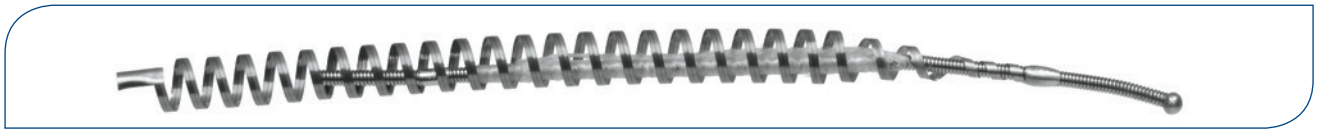
A rigid hysteroscope with a ≥5 French working channel, continuous flow, and a 12- or 30-degree angled lens is used to place Essure.

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.



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



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

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

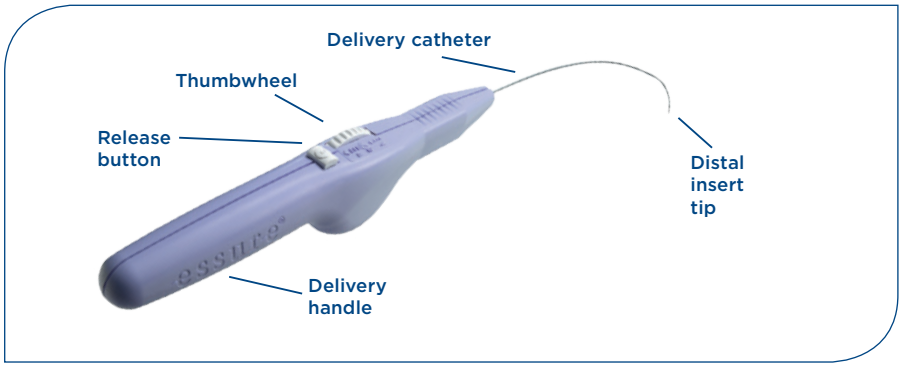
PRODUCT OVERVIEW

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.

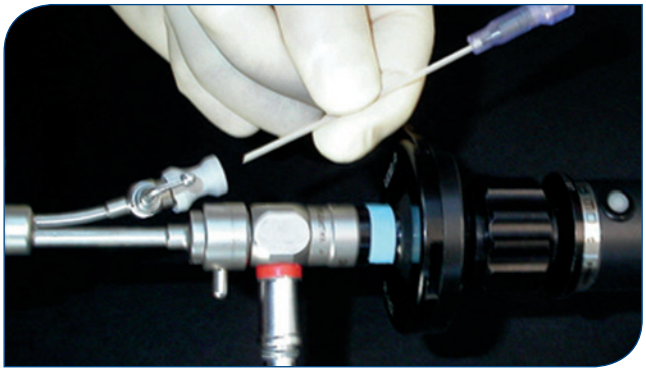
The delivery handle controls the delivery and release mechanism. The thumbwheel on the delivery handle retracts the delivery catheter. The button allows the physician to change the function of the thumbwheel from retracting the delivery catheter to deploying the outer coils. The delivery wire is detached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



Disposable delivery system (not to scale)

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.



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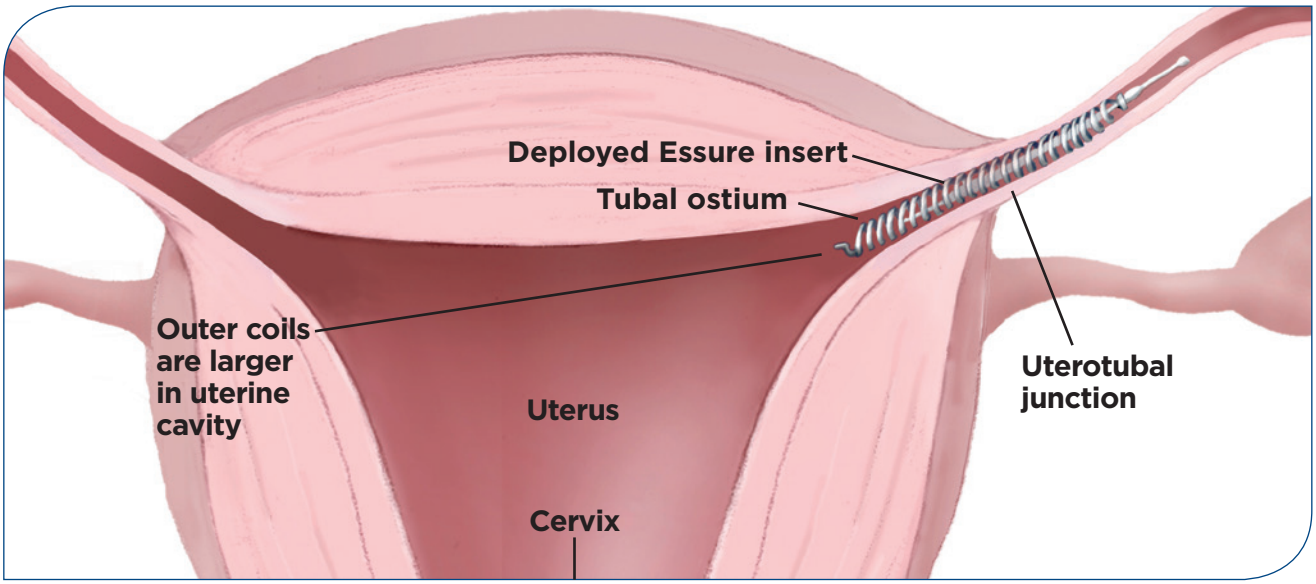
PRODUCT OVERVIEW

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.



Ideal Essure insert placement

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[1]

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CLINICAL DATA

CLINICAL DATA

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**

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

Demographics	Phase II and Pivotal Trials Combined (N=745)
RACE*	
White/Caucasian	428
Latin	31
Black	24
Other	9
Gravidity	Mean=2.91 (0-11)
Parity	Mean=2.23 (0-6)
Body mass index (BMI) (kg/m²)	Mean=27 (16-57)

*Data from Pivotal 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.

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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)†

Adverse Events Preventing Reliance	Phase II	Pivotal
Perforation	7/206 (3.4%)‡	5/476 (1.1%)
Expulsion	1/206 (0.5%)	14/476 (2.9%)§
Unsatisfactory insert location	1/206 (0.5%)	3/476 (0.6%)
Initial tubal patency	7/200 (3.5%)‖	16/456 (3.5%)‖

†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 data[2]

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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 excellent[3]
- Women were typically discharged from the medical facility 44 minutes after the procedure[3]
- 92% of working women missed no more than 1 day of work after the procedure day[3]
- 75% of patients resumed normal activity by day 2[3]
- 99% of women rated their comfort as good to excellent at all follow-up visits[3]

ADVERSE EVENTS, DAY OF ESSURE® PLACEMENT PROCEDURE

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

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).

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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.

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

*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.

Potential Contributing Factor*	United States (US)		Outside the United States (OUS)†		Total	
	n	Percent of US causes	n	Percent of OUS causes	n	Percent
Patient non-compliance (eg, failure to use alternative contraception or return for Essure Confirmation Test)	213	32%	16	18%	229	31%
Perforation‡§	91	14%	4	5%	95	13%
Unsatisfactory placement‡	32	5%	13	15%	45	6%
Physician non-compliance	22	3%	13	15%	35	5%
Pregnant at time of placement (luteal)	26	4%	6	7%	32	4%
Inadequate Confirmation Test‡	28	4%	0	0%	28	4%
Expulsion‡	20	3%	4	5%	24	3%
Tubal patency‡	19	3%	1	1%	20	3%
Insufficient Information to determine	209	32%	31	35%	240	32%
Total	660		88		748‖	

*Table includes pregnancy reports received directly by 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.

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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 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
- Have a known allergy to contrast media

Your patient	Why Essure may be right for her
Certain that her family is complete and that she does not want any more children	**Essure is 99.83% effective based on 5-year clinical study data[2]**
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 procedure[3]**

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.

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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[2]
- 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.

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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

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ESSURE® PROCEDURE

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.[4] 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]

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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

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ESSURE® PROCEDURE

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 NSAIDs[3]

PREDOMINANT ANESTHESIA USED[3]

	n	Percent
Local anesthesia	283	52.0%
IV sedation and/or analgesia	222	40.8%
None*	38	7.0%
General anesthesia	1	0.2%
Total	544	100%

*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.

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ESSURE® PROCEDURE

PATIENT COMFORT (CONT'D)

Summary of literature for pain management during hysteroscopic sterilization procedures

Publication	Trial design	NSAID	Local anesthesia	Sedation	Anxiolytic
Arjona J. Satisfaction and tolerance with office hysteroscopic tubal sterilization. *Fertility and Sterility*. 2008.[6]	Prospective analysis of case series (N=1630)	Ibuprofen 600 mg, 1 hour pre-procedure			Benzodiazepine 10 mg, 1 hour pre-procedure
Chudnoff S. Paracervical block efficacy in office hysteroscopic sterilization. *Obstetrics and Gynecology*. 2010.[7]	Double-blind, randomized, placebo-controlled trial (N=80)	Ketorolac 60 mg IM, immediately before procedure	Paracervical block with 1% lidocaine at 12:00, 4:00, and 8:00		
Isley MM. Intrauterine lidocaine infusion for pain management during outpatient transcervical tubal sterilization: a randomized controlled trial. *Contraception*. 2012.[8]	Randomized, double-blind, placebo-controlled trial (N=58)	Ibuprofen 800 mg PO, 30-45 min pre-procedure	Paracervical block with buffered 1% lidocaine, at the tenaculum site, at 4:00, and 8:00 5 mL 4% intrauterine lidocaine*		Lorazepam 2 mg PO, 30-45 minutes pre-procedure
Miño M. Success rate and patient satisfaction with the Essure sterilisation in an outpatient setting: a prospective study of 857 women. *BJOG*. 2007.[9]	Prospective, single-center cohort (N=857)	Ibuprofen 600 mg, 1 hour pre-procedure	50.5% of patients received paracervical block with mepivacaine cloridrate 3%		Diazepam 10 mg, 1 hour pre-procedure

*Did not significantly reduce pain.

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

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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

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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.

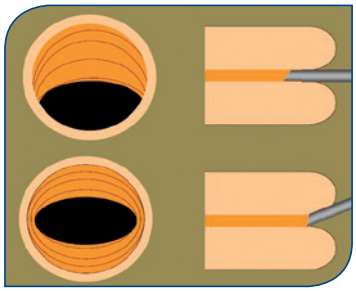
2 A local anesthetic (eg, paracervical block), with or without IV sedation, can be used for placement of the inserts. Inform the patient that a local anesthetic is about to be placed to reduce discomfort and pain.

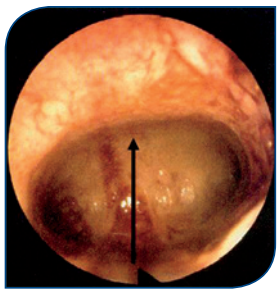
While waiting for the paracervical block to take effect, connect the camera, light source, and sealing cap. Focus the hysteroscope, perform a white balance, open the fluid inflow port, close the outflow port, and flush the scope of all air bubbles.

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.[10] Standard fluid-monitoring procedures should be followed throughout the procedure.

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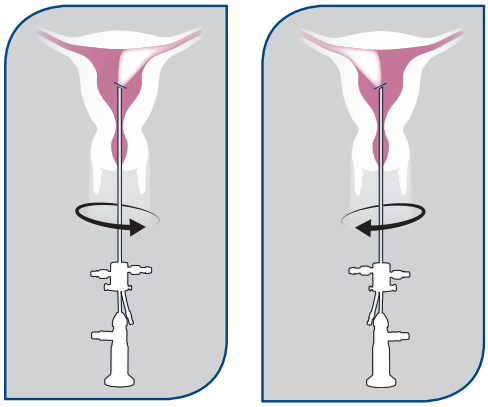
ESSURE® PROCEDURE

PLACEMENT STEPS (CONT'D)

In order to reduce the risk of hypervolemia, 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.

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

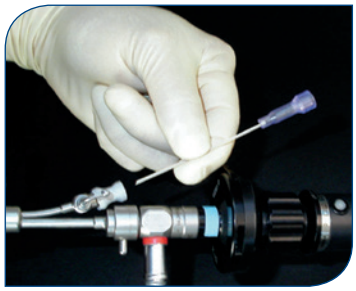
Visualization of the tubal ostia with an angled hysteroscope can be accomplished by simply rotating the light cord, eliminating the need for potentially uncomfortable lateral scope movement.



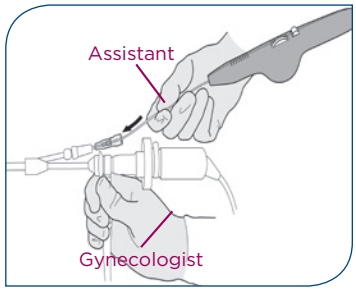
The Essure system is for single use only. Do not use the Essure system if the sterile package is open or damaged. Do not use if the insert is damaged. Never attempt to resterilize an Essure insert or delivery system. Do not attempt placement in one tubal ostium unless expectation of contralateral tubal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

6 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).



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



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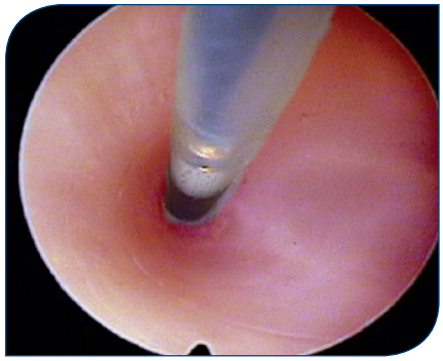
ESSURE® PROCEDURE

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.

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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.

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

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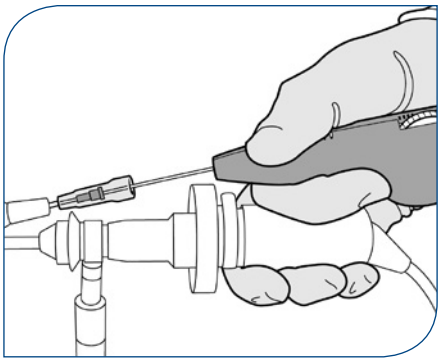
ESSURE® PROCEDURE

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.

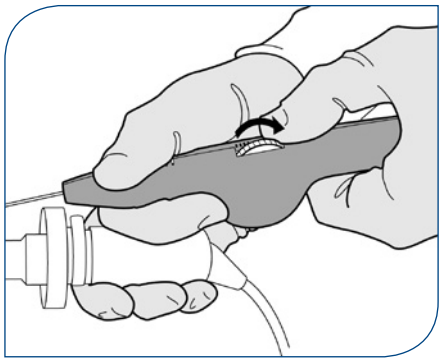
Note: Do not roll thumbwheel until marker is properly aligned.



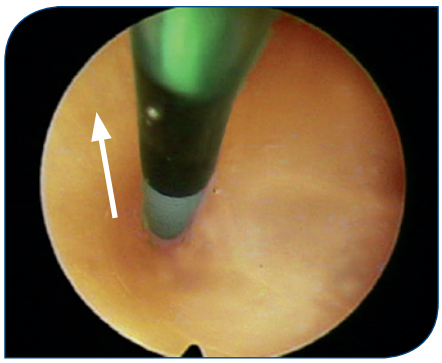
Stabilize handle to prevent forward movement of the insert

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.



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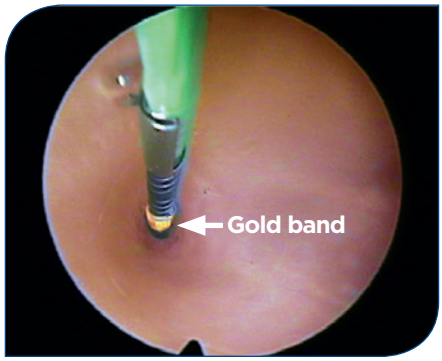
ESSURE® PROCEDURE

PLACEMENT STEPS (CONT'D)

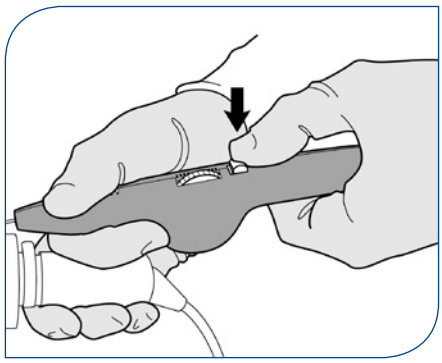
11 Stop and check proper positioning: a gold marker band should now be located just outside the ostium. Confirm positioning of the gold marker and visualization of the distal tip of the green delivery catheter.



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.

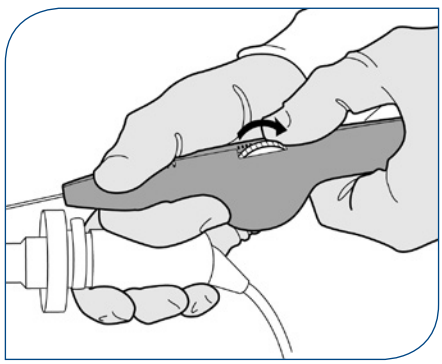
12 Press the button on the handle. This enables the thumbwheel to further roll back for insert deployment.

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.



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