ESSURE® PROCEDURE

PLACEMENT STEPS (CONT'D)

14 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:

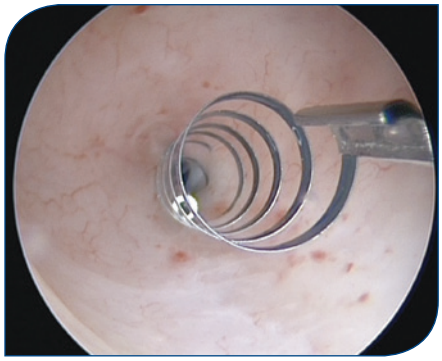
- Retraction of the green delivery catheter away from the insert
- Actual release of the insert, after retraction of the catheter

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Note: Hold the DryFlow™ introducer in place during removal of the delivery catheter as it may also be inadvertently withdrawn.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.

15 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).



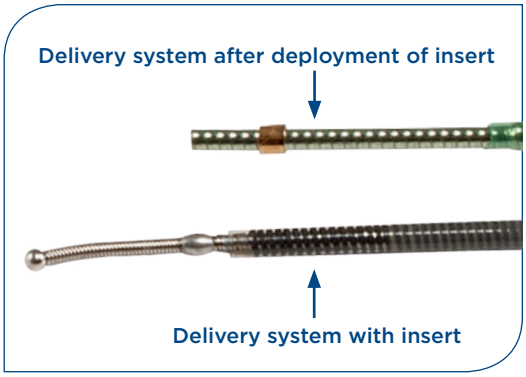
Count trailing coils; ideal placement is 3-8 coils

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.**



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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.

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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

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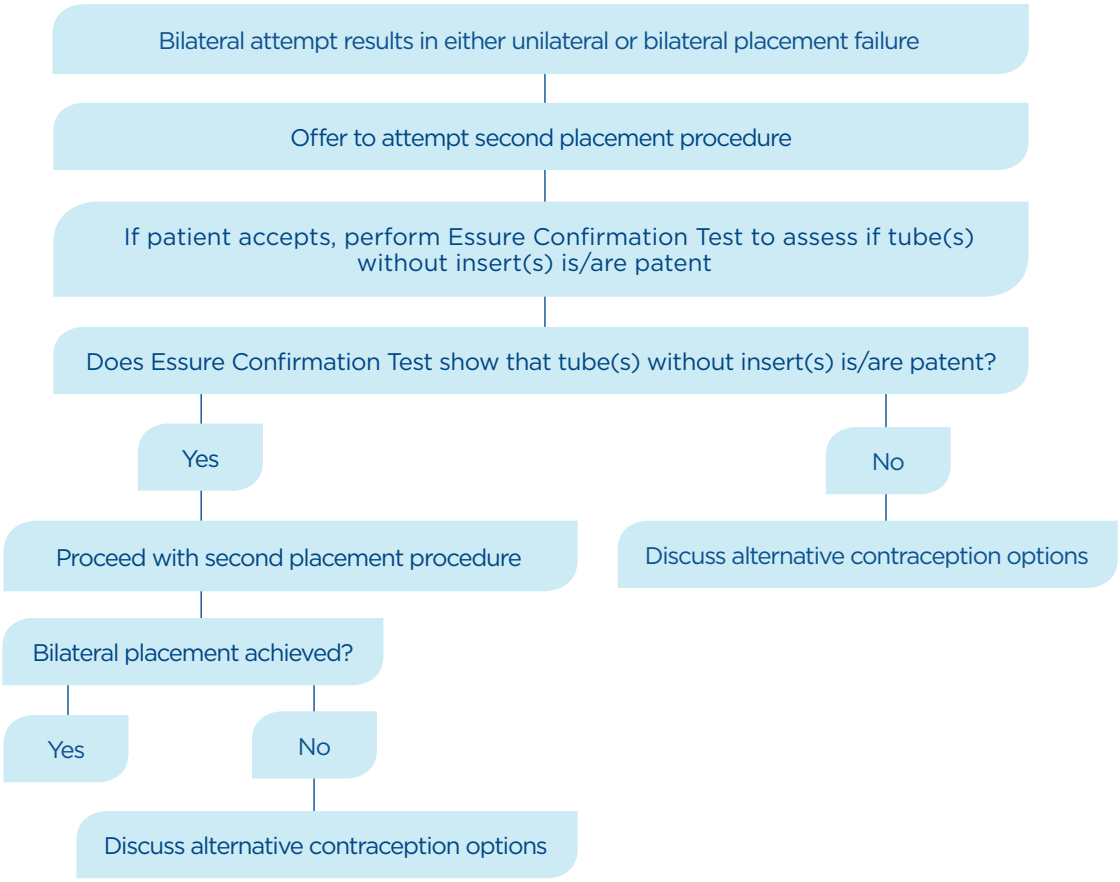
ESSURE® PROCEDURE

MANAGING UNSUCCESSFUL CASES



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[3]
- Give ID card to patient
- Provide any prescriptions to patient (including birth control)
- Schedule 3-month Essure Confirmation Test
- Discharge patient[3]
- 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 cryoablation, 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

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

ESSURE® PROCEDURE

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.

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ESSURE® CONFIRMATION TEST

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.

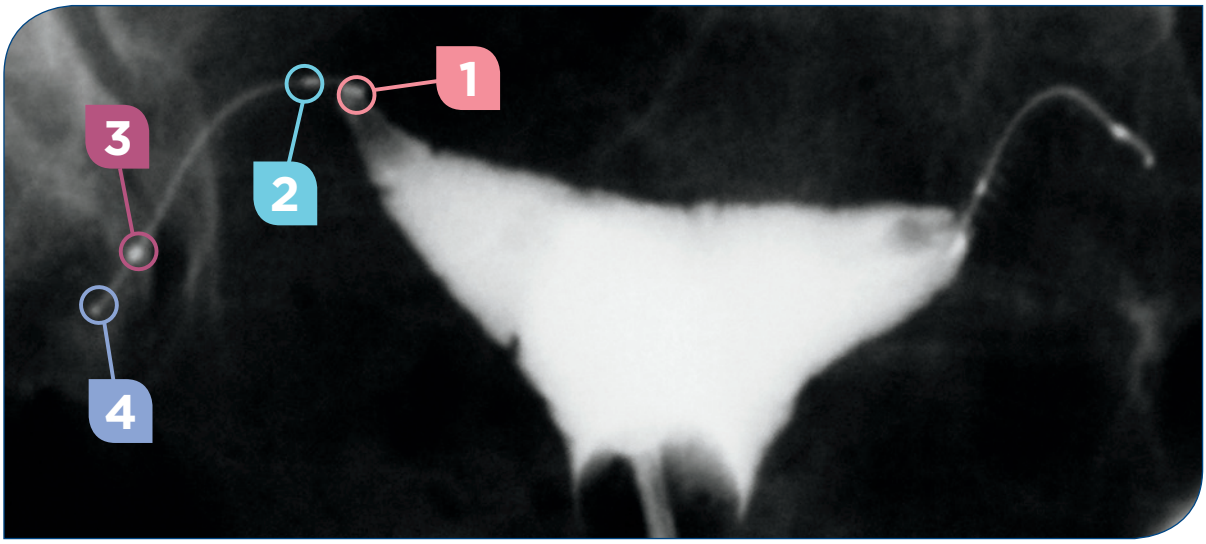
PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON PAGES 2-3 OF PDF.

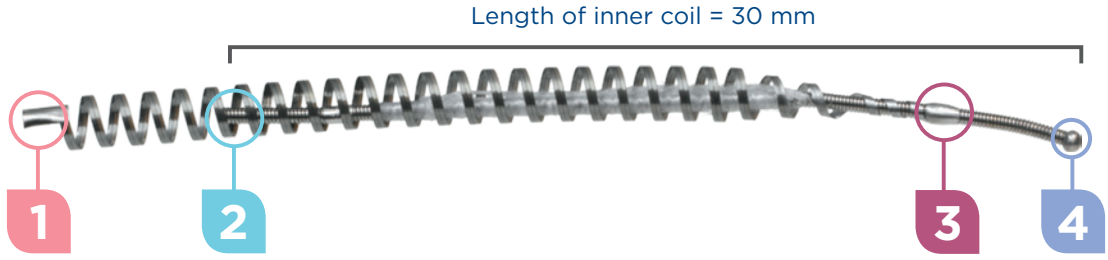
ESSURE® CONFIRMATION TEST

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”)





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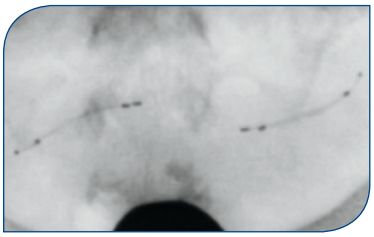
ESSURE® CONFIRMATION TEST

RADIOGRAPH IMAGING

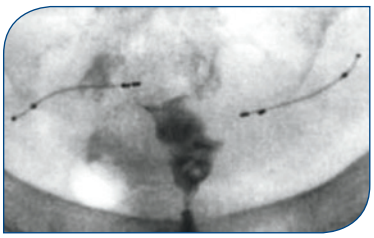
The following 6 radiographs are recommended. In some cases, additional images may be necessary to evaluate insert location. This might include oblique views or lateral views.



1

SCOUT FILM

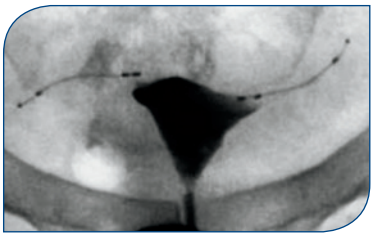
Scout film is the first image captured, before injecting the contrast. Capture an image of the uterus and fallopian tubes. The Essure inserts should be clearly seen; note the lie and curvature of the inserts. During evaluation, note the 4 radiographic markers on each insert.



2

MINIMAL FILL

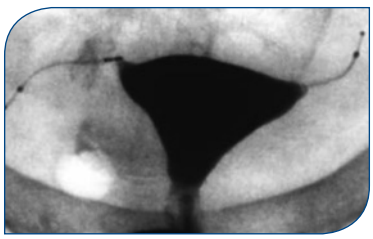
Capture an image of the uterus after a small amount of contrast infusion. No contrast should be leaking from the cervix if an adequate seal is maintained. The uterine cavity should start to opacify. Contrast may not have reached the uterine cornua. If the uterine cavity silhouette is not seen in a nearly 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.

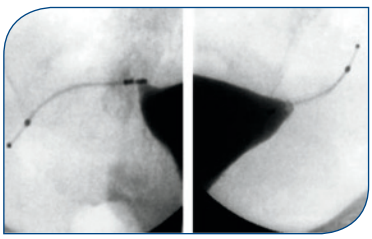


4

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

6

MAGNIFICATION OF THE UTERINE CORNUA

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

Note: Assessment of the location of the inserts on 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.

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ESSURE® CONFIRMATION TEST

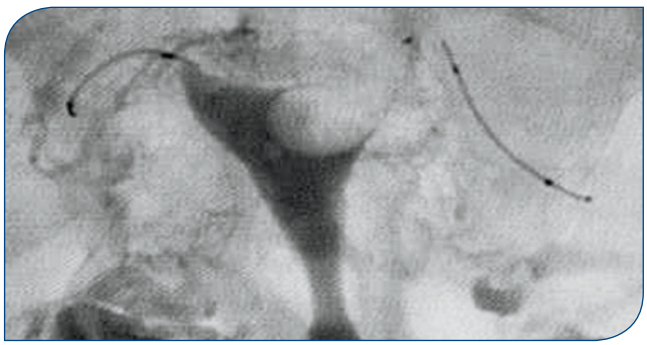
EVALUATING ESSURE CONFIRMATION TEST IMAGE QUALITY

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.

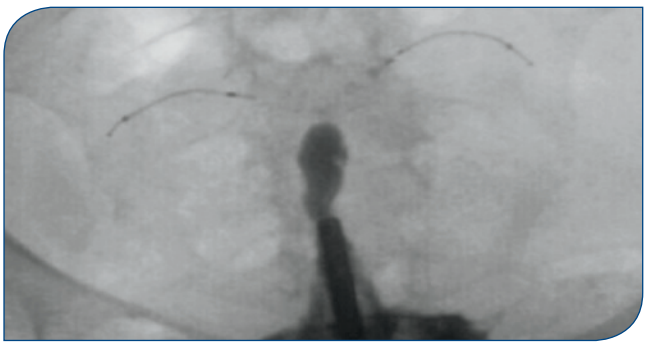
The Essure Confirmation Test will need to be immediately repeated if:

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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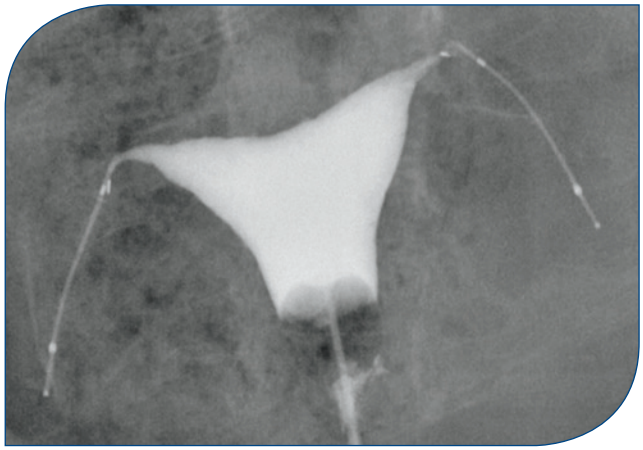
ESSURE® CONFIRMATION TEST

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.

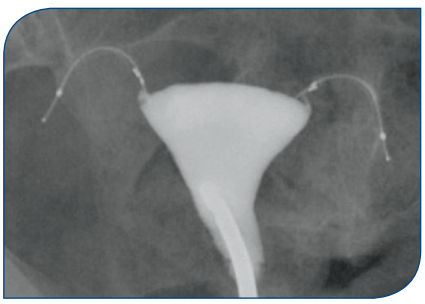


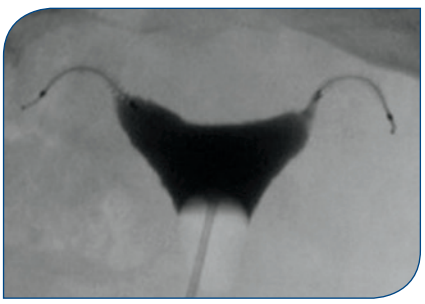
Satisfactory bilateral insert location and tubal occlusion

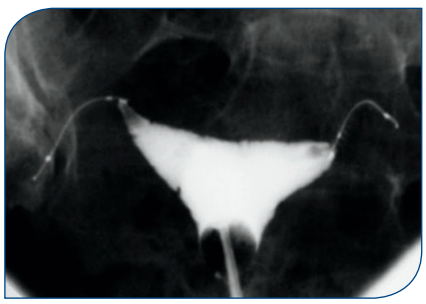
Note: The insert may shift in response to fallopian tube movement following placement.

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

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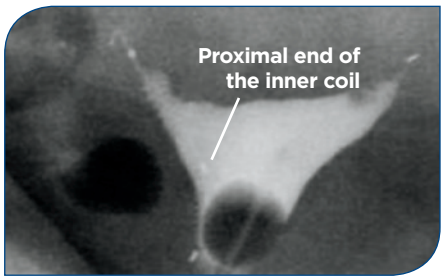
ESSURE® CONFIRMATION TEST

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.



Proximal location of the right insert, with ≥50% of the inner coil trailing into the uterine cavity

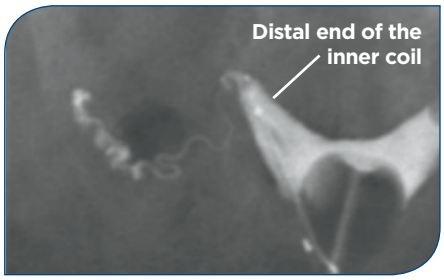
1

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.



Expulsion of the right insert with tubal patency

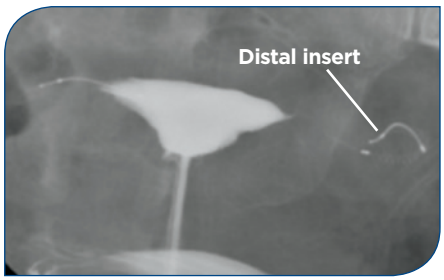
2

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.



Distal location of the left insert

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.

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

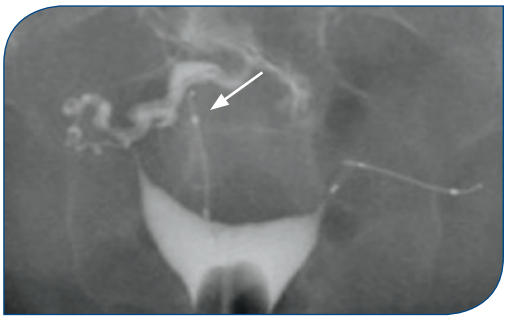
ESSURE® CONFIRMATION TEST

4 PERFORATION OR PERITONEAL LOCATION OF THE INSERT

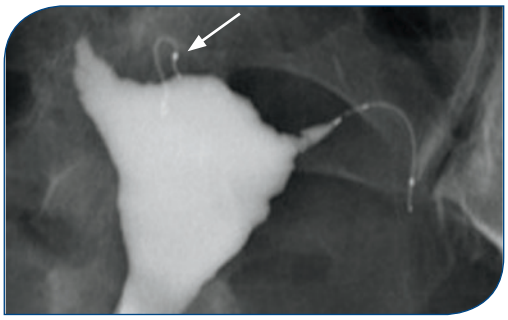
When perforation occurs, the insert has punctured the uterine cavity. Peritoneal location means the insert is within the peritoneal cavity through a uterine perforation.

How to manage:

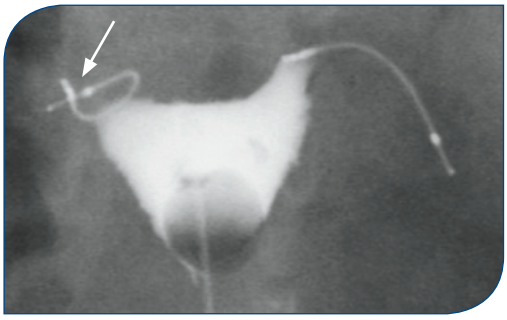
Advise patient not to rely on Essure for contraception. If tube is patent, counsel patient on repeat placement procedure. If tube is occluded, advise patient on potential for false-positive diagnosis of occlusion. Also counsel patient on incisional sterilization or remaining on alternative contraception.



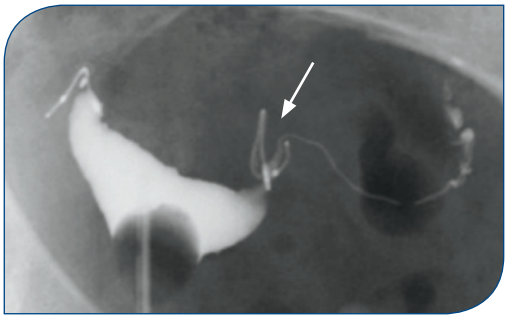
Myometrial perforation



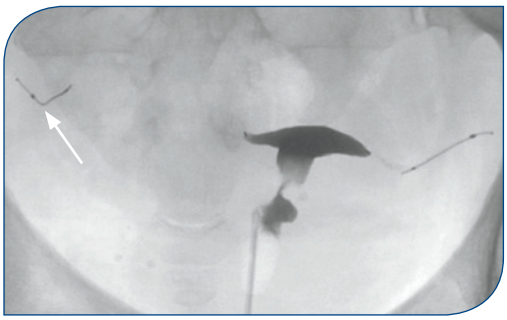
Myometrial perforation



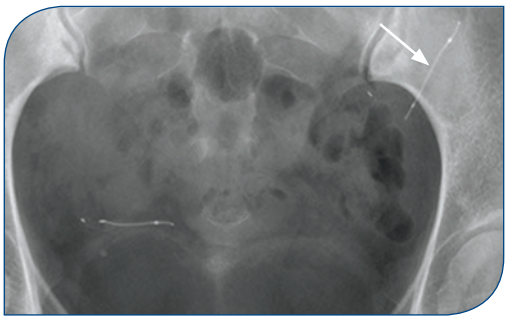
Right insert perforation; note the circular configuration of the inner coil



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.

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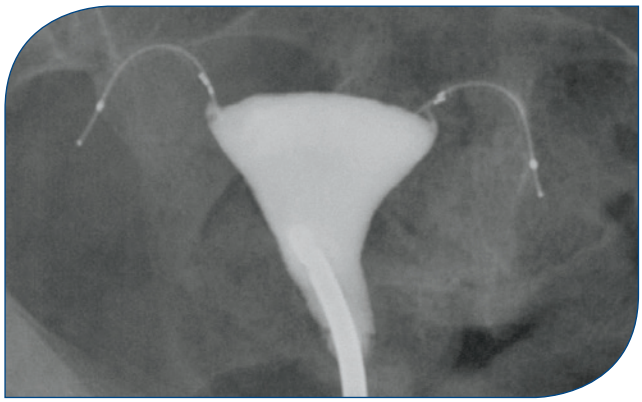
ESSURE® CONFIRMATION TEST

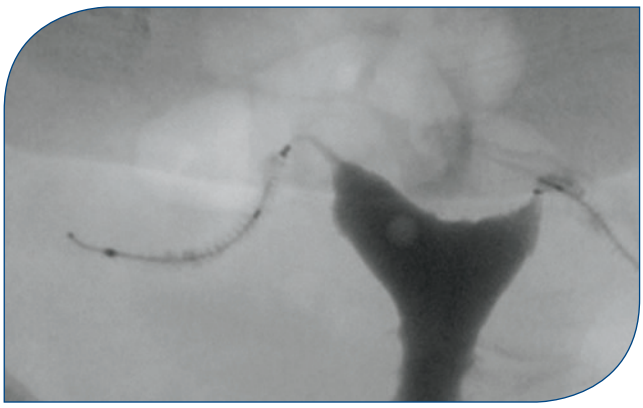
EVALUATE TUBAL OCCLUSION

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.

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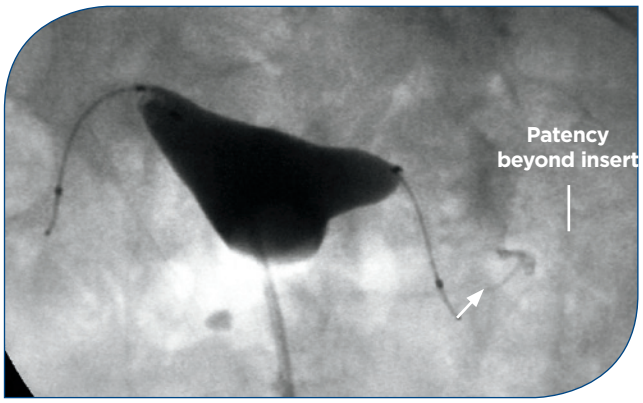
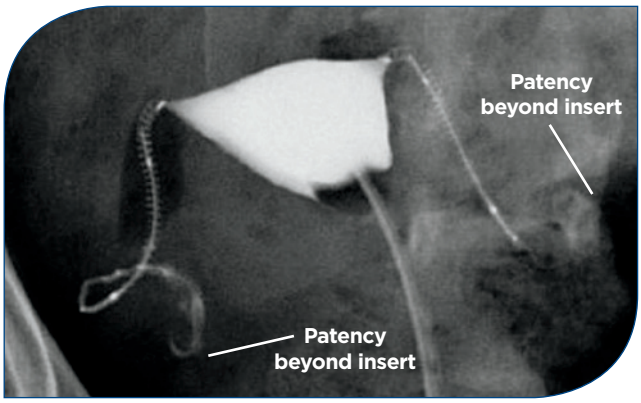
ESSURE® CONFIRMATION TEST

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

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APPENDIX

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

Problem	Cause	Potential Solutions*
Inability to introduce the hysteroscope into the uterus	**Inadequate cervical dilation**	• Use hysteroscope with smaller outer diameter • Attempt hydrodilation of the cervix • Dilate cervix (do not overdilate) • Try a plastic os finder
	Severely retroverted or anteverted uterus	• Use tenaculum to straighten the angulation between the uterus and cervix
	Stenosis of cervix	• Use pediatric dilators or even ocular dilators to gain access to cervix

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

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

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MANAGING TECHNICAL ISSUES

ACHIEVING UTERINE DISTENSION

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

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

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MANAGING TECHNICAL ISSUES

ACHIEVING UTERINE CORNUAL VISUALIZATION

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

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

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MANAGING TECHNICAL ISSUES

ACHIEVING OSTIAL VISUALIZATION

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

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

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MANAGING TECHNICAL ISSUES

ADVANCING THE INSERT INTO THE TUBE

Problem	Cause	Potential Solutions*
Inability to advance insert into tube† (tracking)	**Lateral or abnormally located tubes**	• Pull hysteroscope back and adjust/rotate • Pull system back and rotate insert tip • Adjust patient position
	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
	Hysteroscope is too far back	• Advance hysteroscope as close to ostium as possible
	Insert tip bent, or catheter bent or damaged	• Use new system
	Hysteroscope at incorrect angle	• Rotate hysteroscope to achieve proper angle
	Tracking into false passage	• If uncertain about ostial location and/or true tubal lumen, remove system and abandon procedure
	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.

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MANAGING TECHNICAL ISSUES

DEPLOYING THE INSERT

Problem	Cause	Potential Solutions*
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)

Problem	Cause	Potential Solutions*
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.

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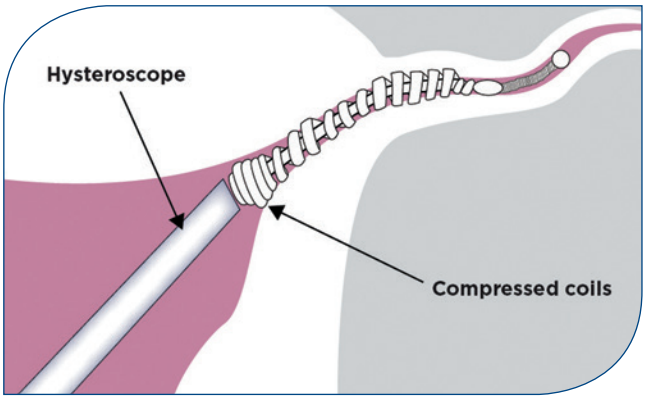
MANAGING TECHNICAL ISSUES

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.



Use of hysteroscope tip to compress outer coils to aid detachment

- 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 hypervolemia, hysteroscopic procedure time should not exceed 20 minutes

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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.

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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

ACOG Practice bulletin no. 133: benefits and risks of sterilization. American College of Obstetricians and Gynecologists. *Obstet Gyn*. 2013;121(2 Pt 1):392-404.

ACOG Report of the Presidential Task Force on Patient Safety in the Office Setting. 2010.

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

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REFERENCES

References: 1. Valle RF, Carignan CS, Wright TC; and STOP Prehysterectomy Investigation Group. Tissue response to the STOP microcoil transcervical permanent contraceptive device: results from a prehysterectomy study. *Fertil Steril*. 2001;76(5):974-980. **2.** Data on file. Bayer HealthCare Pharmaceuticals Inc. **3.** Cooper JM, Carignan CS, Cher D, Kerin JF; Selective Tubal Occlusion Procedure 2000 Investigators Group. Microinsert nonincisional hysteroscopic sterilization. *Obstet Gynecol*. 2003;102(1):59-67. **4.** Palshetkar N, Pai RD, Pai HD, eds. *Textbook of Hysteroscopy*. New Delhi, India: Jaypee Brothers Medical Publishers; 2013. **5.** Centers for Disease Control and Prevention. U.S. selected practice recommendations for contraceptive use, 2013. *MMWR*. 2013;62(5):1-60. **6.** Arjona JE, Miño M, Cordón J, Povedano B, Pelegrin B, Castelo-Branco C. Satisfaction and tolerance with office hysteroscopic tubal sterilization. *Fertil Steril*. 2008;90(4):1182-1186. **7.** Chudnoff S, Einstein M, Levie M. Paracervical block efficacy in office hysteroscopic sterilization: a randomized controlled trial. *Obstet Gynecol*. 2010;115(1):26-34. **8.** Isley MM, Jensen JT, Nichols MD, Lehman A, Bednarek P, Edelman A. Intrauterine lidocaine infusion for pain management during outpatient transcervical tubal sterilization: a randomized controlled trial. *Contraception*. 2012;85(3):275-281. **9.** Miño M, Arjona JE, Cordón J, Pelegrin B, Povedano B, Chacon E. Success rate and patient satisfaction with the Essure sterilisation in an outpatient setting: a prospective study of 857 women. *BJOG*. 2007;114(6):763-766. **10.** Perez-Medina T, Cayuela Font E, eds. *Diagnostic and Operative Hysteroscopy*. New Delhi, India: Jaypee Brothers Medical Publishers; 2012.

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