Tips and Troubleshooting

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PP-250-US-1851
April2018

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Indication and Important Safety Information

Indication

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

Important Safety Information

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

IMPORTANT:

- **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.
- The sale and distribution of this device are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bayer.

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Important Safety Information

Contraindications

- Essure is contraindicated in patients who are uncertain about ending fertility, can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicornuate uterus), have a known abnormal uterine cavity that makes visualization of the tubal ostia impossible, and/or abnormal tubal anatomy or previous tubal ligation (including failed ligation), are pregnant or suspect pregnancy, delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure, have an active upper or lower genital tract infection, have unexplained vaginal bleeding, have a gynecological malignancy, or have a known allergy to contrast media.

General Warnings

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

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Important Safety Information (cont'd)

General Warnings (cont'd)

- Patients with known hypersensitivity to nickel, titanium, platinum, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the Essure system may experience an allergic reaction to the insert. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Symptoms reported for this device that may be associated with an allergic reaction include hives, urticaria, rash, angioedema, facial edema and pruritus. Patients should be counseled on the materials contained in the insert prior to the Essure procedure. Currently there is no test that reliably predicts who may develop a hypersensitivity reaction to the materials contained in the insert.
- Patients on immunosuppressive therapy may experience delay or failure of the necessary tissue ingrowth for tubal occlusion. For these patients, physicians must use the modified HSG as the Essure Confirmation Test. Transvaginal ultrasound (TVU) should not be used as the Essure Confirmation Test, as TVU cannot confirm tubal occlusion.

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Important Safety Information (cont'd)

Pregnancy Risk

- Pregnancies, including ectopic pregnancies, have been reported among women who have undergone the Essure procedure.
- The patient must use alternative contraception until a satisfactory Essure Confirmation Test is documented. If the Essure inserts are not properly placed or are not in a satisfactory location, then the patient should be advised to not rely on Essure and to use alternative contraception.
- Counsel the patient on the need for the Essure Confirmation Test, the options for the confirmation test including their risks and benefits, and the possibility that the Essure Confirmation Test may be unsatisfactory.
- Effectiveness rates for the Essure procedure are based on patients who had bilateral placement and a satisfactory Essure Confirmation Test.

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Important Safety Information (cont'd)

Procedure Warnings

- Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or is suspected, discontinue procedure and monitor the patient for signs and symptoms of possible complications related to perforation which may include unusual post-operative pain.
- To reduce the risk of hypervolemia, terminate procedure if distension fluid deficit exceeds 1500cc or total hysteroscopic procedure time exceeds 20 minutes. Excess fluid deficit may signal uterine or tubal perforation. If noted, discontinue procedure and evaluate patient for possible perforation.
- Do not attempt hysteroscopic Essure insert removal during the placement procedure unless 18 or more trailing coils are seen inside the uterine cavity due to risk of a fractured insert, fallopian tube perforation, or other injury.
- DO NOT perform the Essure procedure concomitantly with endometrial ablation.

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Important Safety Information (cont'd)

MRI Information

The Essure insert was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05.

Adverse Events

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

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

Prescription Only

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Managing Technical Issues with the Essure Procedure

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Overview of Topics Covered

Technical issues with the Essure procedure reviewed in the following slides are categorized according to the major steps of the procedure:

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

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Tips for Managing Technical Issues

- **Essure® should be used only by physicians who[1]:**
  - Are knowledgeable hysterocopists
  - Have read and understood the Essure® Instructions for Use and the Essure Clinical Resource/Physician Training Manual
  - Have successfully completed the Essure training program, including preceptoring in placement until competency is established, typically 5 cases
  - Provide information to patients about the risks and benefits of Essure in the form and manner specified in the approved labeling provided by Bayer
- **This module may not be all inclusive of technical issues that may be encountered[2]**
  - The troubleshooting reviewed herein 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
- **Refer to the Essure Clinical Resource/Physician Training Manual for additional information**
- **Please call the Bayer Product Information department at (877) 377-8732 with any additional questions**

1. Essure [Instructions for Use].
2. Data on file, Bayer HealthCare Pharmaceuticals Inc.

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Technical Issues with Introducing the Hysteroscope into the Uterus

Inability to introduce the hysteroscope into the uterus

- Cervical dilation should not be performed unless necessary. If cervical dilation is necessary, dilate only enough for hysteroscope insertion
- To prevent uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilation

- For inadequate cervical dilation*
  - Use a hysteroscope with smaller outer diameter
  - Attempt vaginoscopy or hydrodilation of the cervix
  - Dilate cervix (do not over-dilate)
  - Try a plastic os finder

- For severely retroverted or anteverted uterus
  - Use tenaculum to straighten the angulation between the uterus and cervix

*Use these steps individually, simultaneously, or sequentially, as appropriate per your medical judgment.

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Technical Issues with Achieving Uterine Distension

Inadequate intrauterine pressure

- For patulous cervix*
  - Gently twist the tenaculum 45° or use an additional tenaculum to seal cervix
  - Place the tenaculum at 1 and 5 o'clock or 7 and 11 o'clock position (or both)

DO NOT OVER-DILATE THE CERVIX.

- For excessive cramping
  - Consider reducing distension

*Use these steps individually, simultaneously, or sequentially, as appropriate per your medical judgment.

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Technical Issues with Achieving Ostial Visualization

Poor uterine visualization

- For blood in the uterus*
  - Open outflow port and flush
  - Increase fluid flow
- For shaggy endometrium*
  - Flush uterine cavity
  - Aspirate debris
  - Flush uterus again and increase pressure
- Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to Essure® insert placement

NO ATTEMPT SHOULD BE MADE TO PLACE AN INSERT IN ONE TUBAL OSTIUM UNLESS BOTH TUBES ARE ACCESSIBLE.

*Use these steps individually, simultaneously, or sequentially, as appropriate per your medical judgment.

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Technical Issues with Achieving Ostial Visualization (cont'd)

Inadequate visualization of ostia

- For poor uterine distension
  - See "Inadequate intrauterine pressure" section
- For debris, endometrial fluff, or clots*
  - Flush uterus
  - Aspirate
  - Gently remove debris with graspers
    - Do not use a curette
  - Consider abandoning the procedure and rescheduling during early proliferative phase of the menstrual cycle and consider pretreating the patient with medications that suppress endometrial proliferation, which may enhance visualization

*Use these steps individually, simultaneously, or sequentially, as appropriate per your medical judgment.

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Technical Issues with Achieving Ostial Visualization (cont'd)

Inadequate visualization of ostia (cont'd)

- For filmy tissue covering ostia*
  - Gently probe with an insert tip
  - Gently push insert forward
    - Proceed only if insertion meets minimal resistance
- For abnormal ostial location*
  - Adjust/rotate hysteroscope
  - Rotate insert tip
  - Adjust patient position
  - (These skills may be practiced in training simulation)
- For only one ostium visualized
  - Procedure **SHOULD NOT** move forward unless both ostia can be visualized
  - Pull back hysteroscope to obtain full uterine view

*Use these steps individually, simultaneously, or sequentially, as appropriate per your medical judgment.

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Technical Issues with Achieving Ostial Visualization (cont'd)

Inadequate visualization of ostia (cont'd)

- For lateral tubal ostia*
  - Rotation of the lens (30 degrees) aids in targeting
  - Rotate purple handle to change the trajectory of the Essure® insert towards the ostium
  - Use the surrounding myometrium wall to "guide" the Essure® insert into the ostium
  - Adjust the patient position

*Use these steps individually, simultaneously, or sequentially, as appropriate per your medical judgment.

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Technical Issues with Advancing the Insert into the Fallopian Tube

Inability to advance the insert into the fallopian tube

- Advance system into fallopian tube with gentle, constant, forward movement
- If excessive resistance occurs, no further attempts should be made to place the insert to avoid the possibility of uterine or tubal perforation or inadvertent placement in the uterine muscle rather than within the tubal lumen
- 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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Technical Issues with Advancing the Insert into the Fallopian Tube (cont'd)

Inability to advance the insert into the fallopian tube (cont'd)

- If tubal spasm is suspected
  - Move the hysteroscope closer to the tubal ostium
  - **Apply gentle**, constant forward pressure on the delivery catheter and wait
    - Repeatedly removing and attempting to re-cannulate may irritate the tube
  - It may take more than a minute for a spasm to resolve and the catheter to advance
  - Once the delivery catheter starts advancing, keep the slow, steady pressure on until the solid black positioning marker reaches the proximal edge of the tubal ostium
  - If gentle, constant forward pressure on the delivery catheter does not resolve the tubal spasm, you can rotate the entire scope clockwise or counterclockwise, depending on which fallopian tube is being cannulated, to gain better alignment between the catheter and the tube
  - The delivery catheter should never be forced into the tube and the case should be terminated if the patient is experiencing severe pain under attempted cannulation and the patient worked up for possible perforation

*Use these steps individually, simultaneously, or sequentially, as appropriate per your medical judgment.

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Technical Issues with Advancing the Insert into the Fallopian Tube (cont'd)

Inability to advance the insert into the tube

- For tracking into a false passage
  - If uncertain about ostial location and/or true tubal lumen, remove the system and abandon the procedure
- Never attempt to advance Essure® insert(s) against excessive resistance
- If a perforation occurs or is suspected, discontinue procedure and monitor the patient for signs and symptoms of possible complications related to perforation, which may include unusual post-operative pain
  - If unusual post-operative pain occurs, imaging to localize the insert should be performed prior to the 3-month confirmation test

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Technical Issues: Bent Tip

- A device with a bent tip may be considered damaged and should not be used. While you are able to see the bend in the tip of the device, the force that caused the tip to bend may have also damaged the internal delivery mechanism (which cannot be seen) and might lead to detachment issues
- If the tip is bent in the package (ie, bent beyond the 15-degree angle at the tip that is designed to facilitate placement within the fallopian tube):
  - Check for proper storage of packages
  - Report it as a Product Technical Complaint to Bayer
- If the tip gets bent as it goes through the working channel of the hysteroscope:
  - Make sure the introducer is properly seated in the working channel and does not have a defect
  - Make sure the working channel is fully opened
  - Make sure the hysteroscope does not have a defect in the working channel
  - Make sure the device is fed through the working channel slowly and without bending (by either yourself or your assistant)

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Technical Issues: Bent Tip (cont'd)

- If the tip gets bent exiting the working channel and hits the uterine wall:
  - The hysteroscope may be too far into the uterine cavity
  - The device may have been guided through the operating channel too quickly
- If the tip bends while attempting to cannulate the fallopian tube:
  - The hysteroscope may be too far from the ostium
  - The scope may not be lined up with the ostium
  - The device should be advanced slowly
  - The patient may have difficult anatomy

Do not use the Essure® system if the sterile package is open or damaged. Do not use if the insert is damaged.

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Technical Issues with Deploying the Insert: Procedure Steps

Details on the Essure procedure are provided in Module 4. The information presented here focuses on certain steps of the Essure procedure during which issues may rise. This information is not an exhaustive list of all potential issues that may be encountered. Physicians should use professional judgment and medical experience to determine the proper care for the patient, which may include stopping the procedure.

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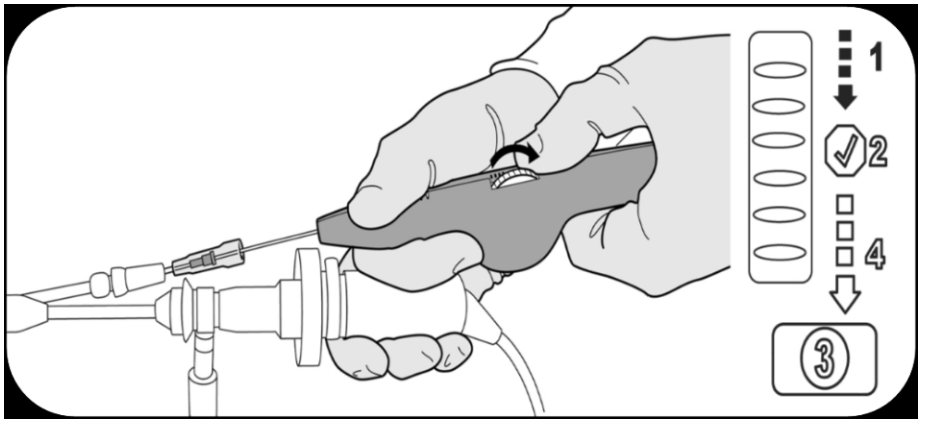
Technical Issues with Deploying the Insert: Procedure Steps (cont'd)

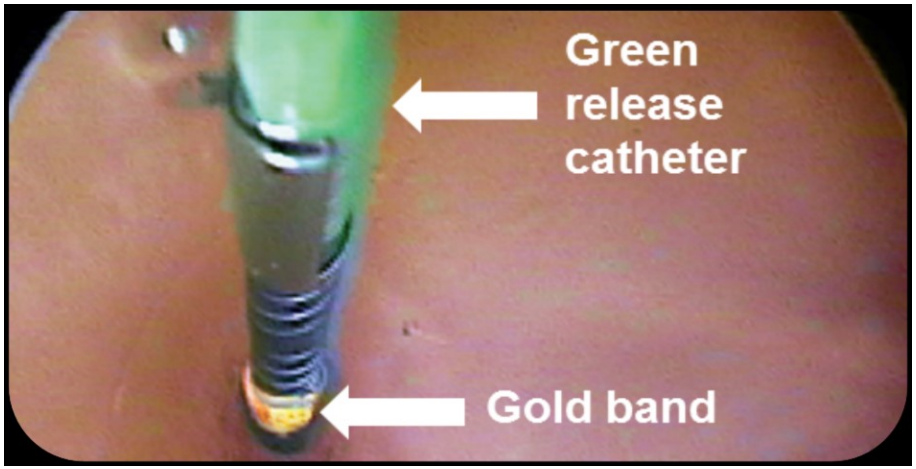
Retract catheter

- After stabilizing the handle of the delivery system, the delivery catheter is retracted by rotating the thumbwheel toward you to the point where you cannot rotate the thumbwheel any further



Check for proper insert positioning

- Gold marker band must be just outside the ostium
- Distal tip of the green release catheter should be visible



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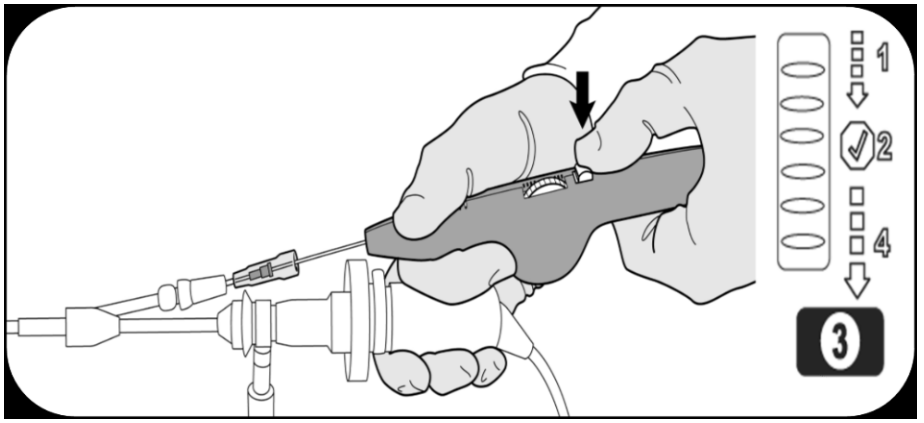
Technical Issues with Deploying the Insert: Procedure Steps (cont'd)

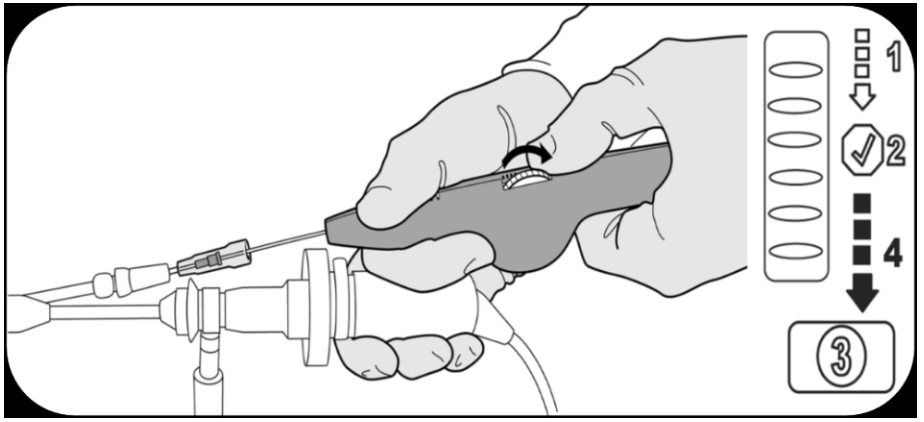
Depress button

- Press button on delivery handle
- Enables thumbwheel to be further rotated for insert deployment



Deploy insert

- Rotate the thumbwheel once more until the thumbwheel cannot turn any further
- Allows coils to expand and insert to be released



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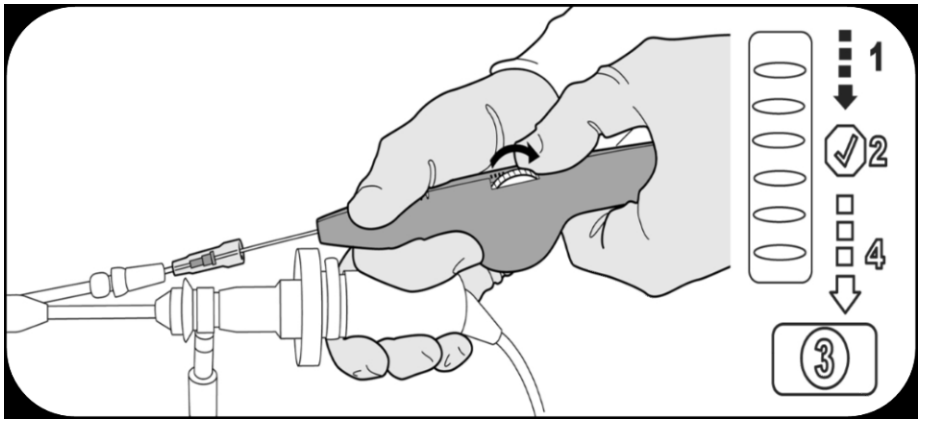
Technical Issues with Deploying the Insert*

Inability to retract the delivery catheter

- For a twisted delivery catheter
  - Slowly rotate catheter to relieve twisting
  - Remove and replace system
- For a damaged delivery catheter
  - Remove and replace system



Warning:
Never attempt to use a bent or damaged delivery catheter as this can result in detachment issues.

*Use these steps individually, simultaneously, or sequentially, as appropriate per your medical judgment.

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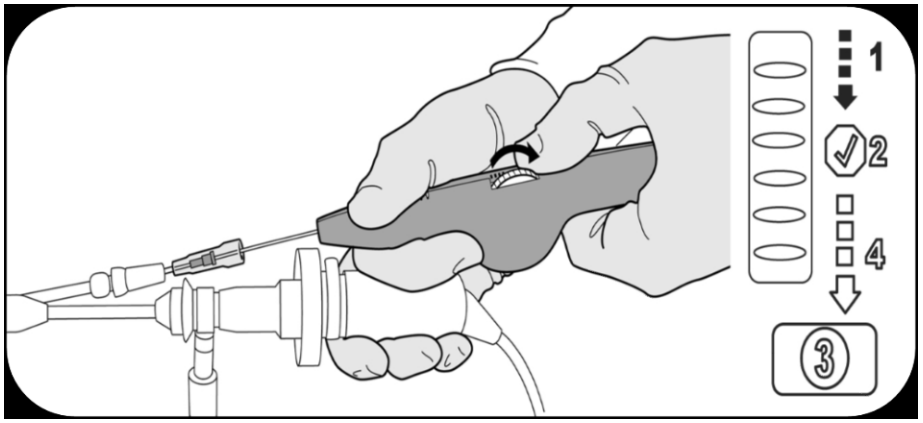
Technical Issues with Deploying the Insert (cont'd)*

Delivery Catheter Stretches

- For a damaged delivery catheter in the hysteroscope working channel:
  - Verify that the operating channel is open
  - Remove and replace system
- Slowly advance delivery catheter through working channel to avoid damage to the tip as it exits the scope



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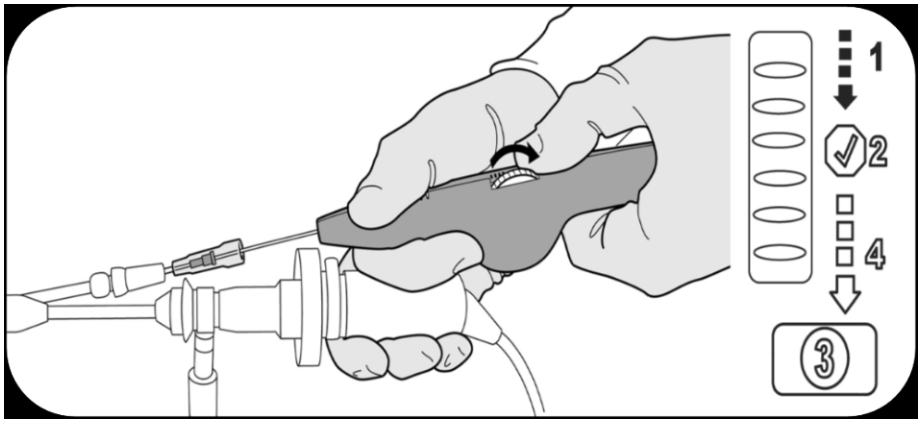
Technical Issues with Deploying the Insert (cont'd)*

Inadvertent forward movement of the insert (feed forward)

- When the handle is not stabilized during retraction
  - Pull system back to proper position before deployment
  - Stabilize the delivery system handle against the hysteroscope to prevent inadvertent forward movement



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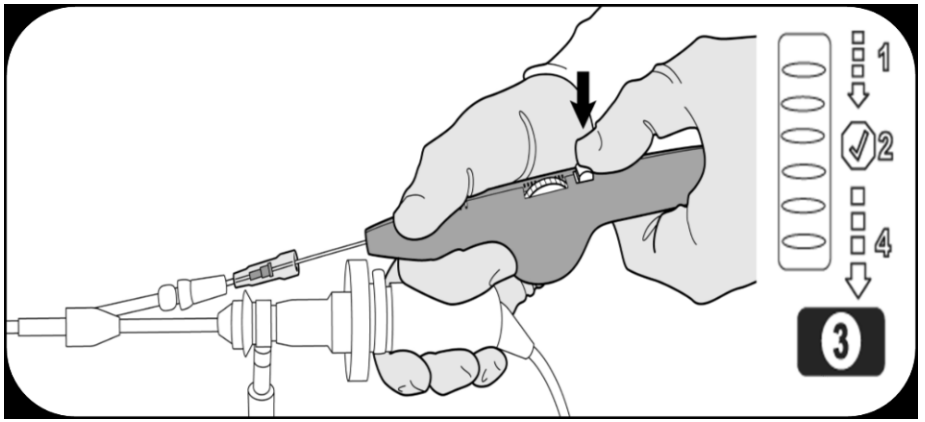
Technical Issues with Deploying the Insert (cont'd)*

Inability to fully depress the button

- If the delivery catheter is not fully retracted
  - Roll the thumbwheel until it stops
- System failure
  - Remove and replace system
  - Report failure



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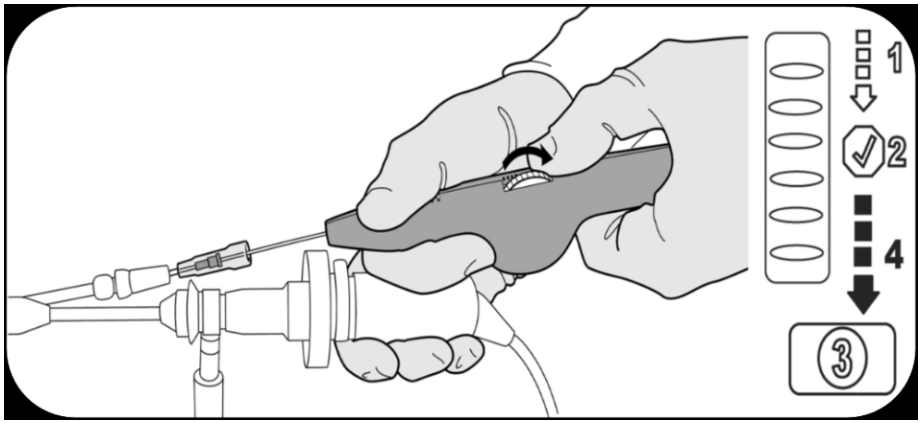
Technical Issues with Deploying the Insert (cont'd)*

Outer coils do not deploy



- If the delivery catheter is not fully retracted
  - Continue rolling thumbwheel until it stops fully
  - Pull hysteroscope back to maintain visualization
- If the outer coils are pressed against the uterine wall
  - Straighten system and allow coils to fully expand
- For technical insert failure
  - Rotate system slowly
  - Gently jiggle system
  - Remove and replace system

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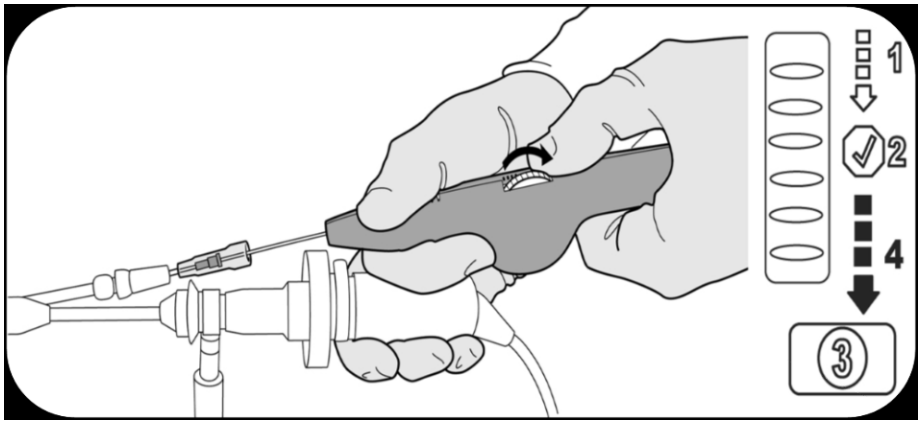
Technical Issues with Deploying the Insert (cont'd)*

Insert stuck in hysteroscope

- If the hysteroscope is too far forward during deployment:
  - Push the insert out of the hysteroscope using appropriately sized graspers



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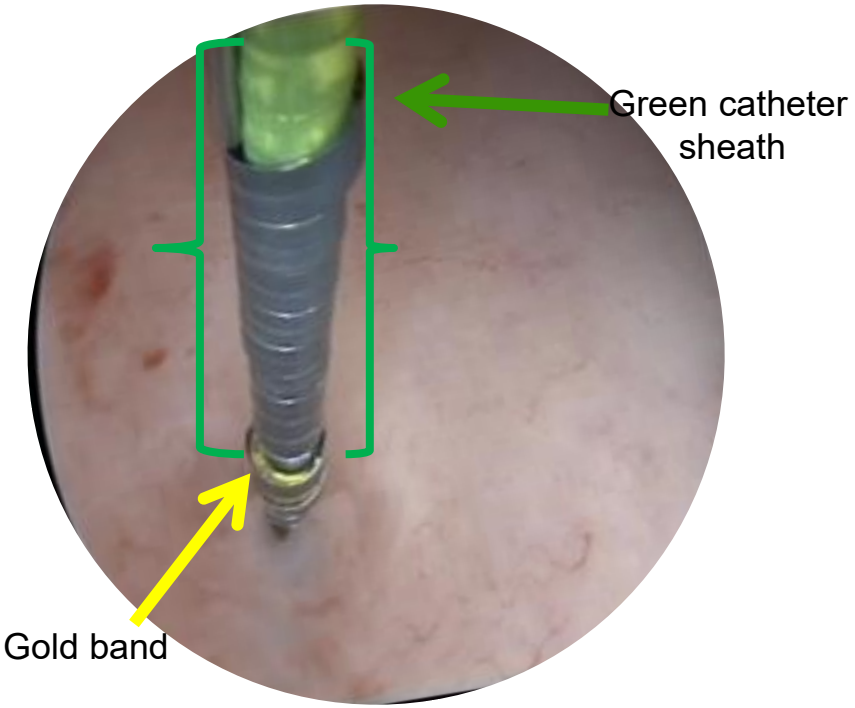
The Essure Delivery System

- The distal most end of the green catheter sheath is covered by the gold band
- The gold band protrudes slightly from the rest of the delivery catheter. If the gold band is inside the fallopian tube at the time of deployment, the tube can “hold onto” the gold band, especially if there is a tubal spasm, making removal of the delivery catheter difficult
- The gold band should always be visible just outside of the tube prior to deployment



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Confirming Deployment

Ideal placement of the Essure® insert results in 3 to 8 trailing coils into the uterus

- 0 to 17 coils are acceptable
  - Placement showing 0 to 17 coils should be evaluated via the Essure Confirmation Test
  - While 0 trailing coils is considered adequate, one of the difficulties is confirming whether or not the device has actually deployed

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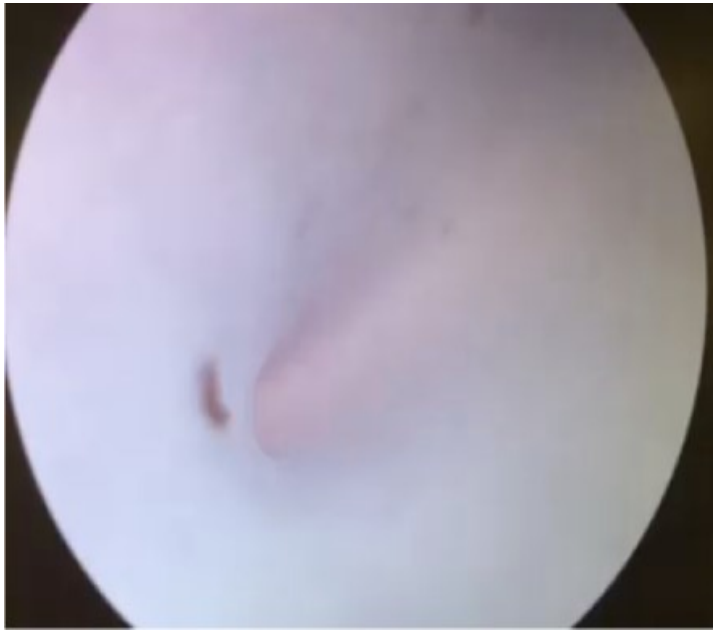
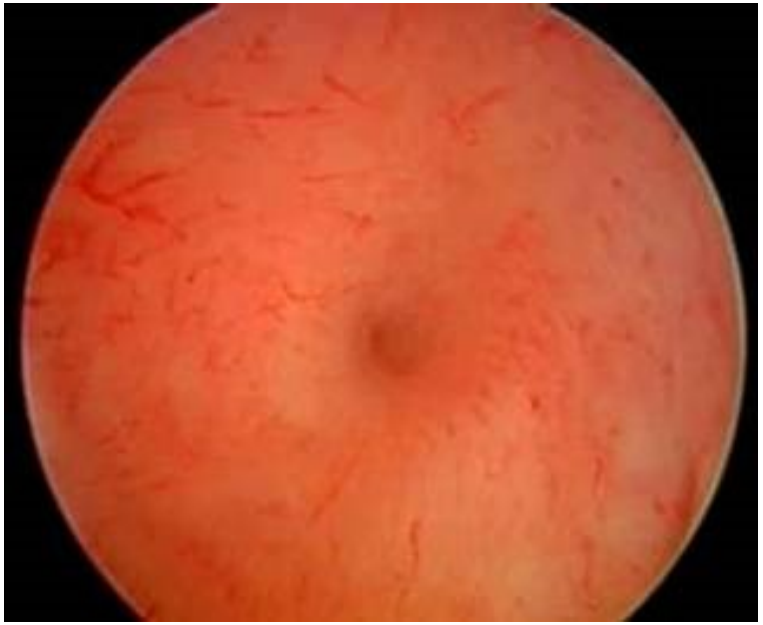
Confirming Deployment (cont'd)

- If there are no coils visible in the uterine cavity, confirm deployment of the device by visually inspecting the delivery catheter





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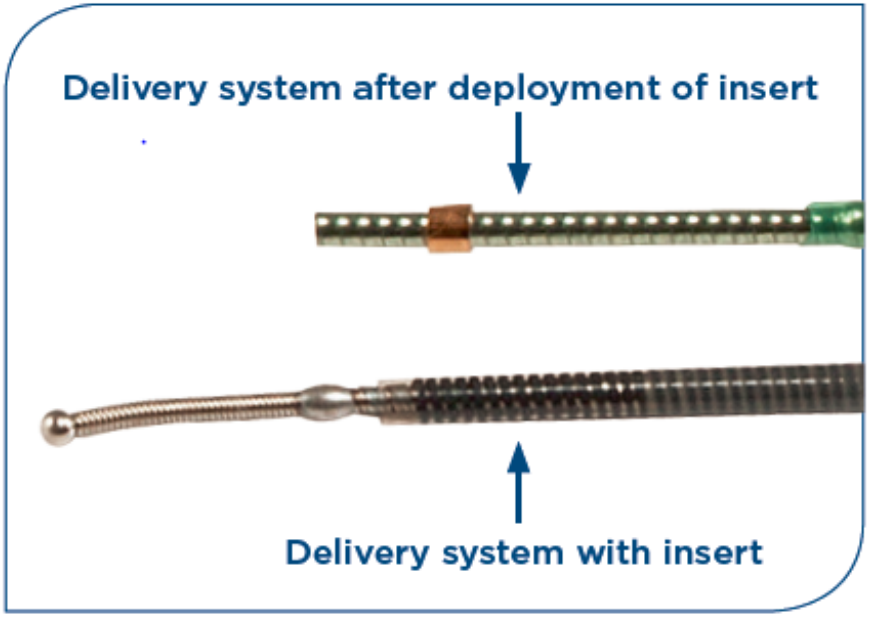
Confirming Deployment (cont'd)

- In order to help you determine if the device has deployed, look at the end of the delivery catheter and note the position of the gold band
  - When the device has deployed, the gold band will be at the distal most end of the delivery catheter
- If after inspecting the delivery catheter you are STILL unsure if the device deployed or not, do not attempt another placement in the tube until you are certain



- If the insert has been deployed (in the tube or elsewhere in the body), it will be visible on x-ray or ultrasound
  - This is not the same as the confirmation test; this is a way of confirming deployment of the device

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

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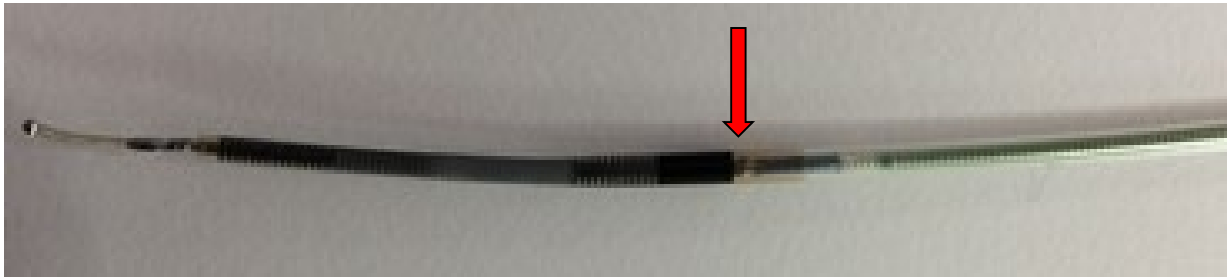
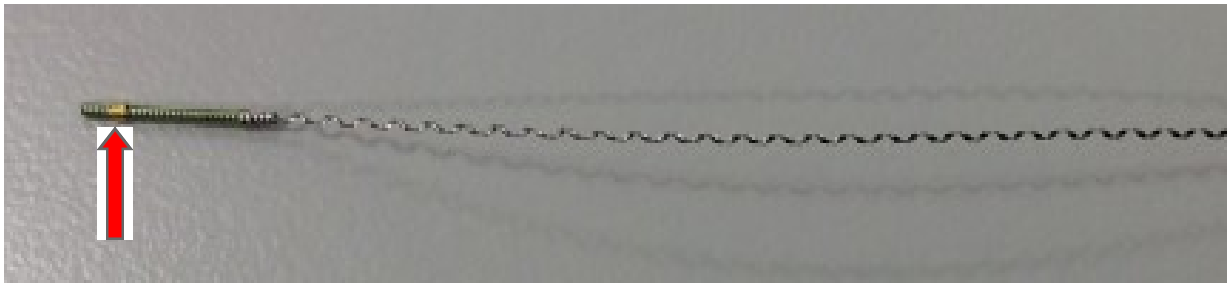
Confirming Deployment (cont'd)

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



NOT deployed



Deployed

NOT deployed

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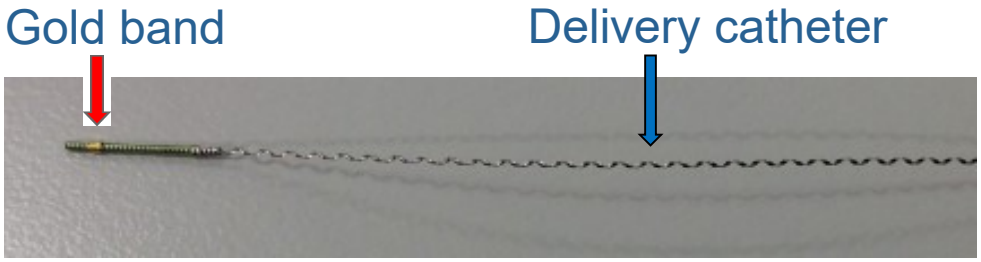
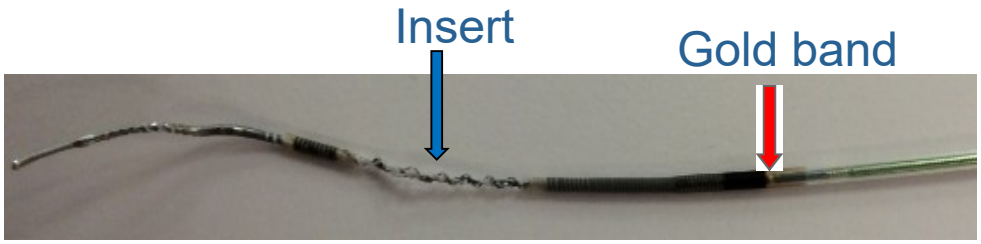
Insert Deployed but Will Not Release from System

Difficulty detaching the inner coil from the delivery wire

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





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Insert Deployed but Will Not Release from System (cont'd)

Difficulty detaching the inner coil from the delivery wire

- If the delivery catheter unwinds and you have pulled the catheter back as far as possible, and the proximal end is still caught in the tube, you may choose to cut the unwound delivery catheter wire in order to remove the delivery system/handle
  - This process can be done with hysteroscopic scissors
- As the tube relaxes, the proximal portion of the delivery catheter may eventually fall out into the uterine cavity and may be expelled. Please warn the patient
  - If desired, you may attempt to hysteroscopically remove the catheter pieces at a later date. There are no data on the prolonged presence of catheter materials in the uterus or fallopian tubes
- The patient should continue alternative contraception and return for the Essure Confirmation Test with the modified HSG in 3 months

The patient should use alternative contraception, and an Essure Confirmation Test with modified HSG should be performed in 3 months.

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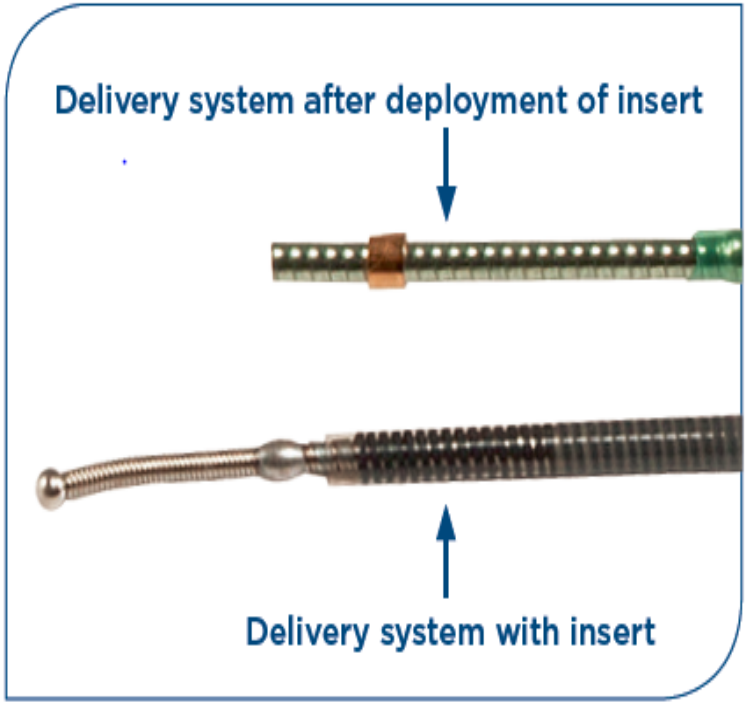
Technical Issues with Deploying the Insert: Summary

In summary:

- If there are no coils visible in the uterine cavity, then confirm deployment of the device by visually inspecting the delivery catheter (see image to the right)
- If, after inspecting the delivery catheter, you are STILL unsure if the device has deployed or not, do not attempt another placement in the tube until you are certain
- If the insert is in the tube or elsewhere in the body, it will be visible on x-ray or ultrasound. This is not the same as the confirmation test—this is a way of confirming deployment of the device
- **Do not place more than one insert into a single fallopian tube**



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Medical Product Complaint

To make a medical or product complaint:

- 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
- Save and return the Essure® system that was used
  - If possible, include the original packaging with the lot number, or obtain a 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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