Essure Post-Procedure Management

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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.

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Important Safety Information (cont'd)

General Warnings

- The Essure procedure should be considered irreversible.
- Pain (acute or persistent) of varying intensity and length of time may occur following Essure placement. This is also more likely to occur in individuals with a history of pain. If device removal is indicated, this will require surgery.
- Patients with known hypersensitivity to nickel, titanium, platinum, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the Essure system may experience an allergic reaction to the insert. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Symptoms reported for this device that may be associated with an allergic reaction include hives, urticaria, rash, angioedema, facial edema and 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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Essure Post-Procedure Responsibilities

The following information on post-procedure recommendations are guidelines for physicians and their office. Ultimately, patient management decisions are up to each physician's judgement and expertise.

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Assessment of Insert After Deployment

Assess position of inserts under hysteroscopic visualization

Inserts showing 0-17 trailing coils

- Leave in place and evaluate via Essure Confirmation Test

Ideal placement of inserts

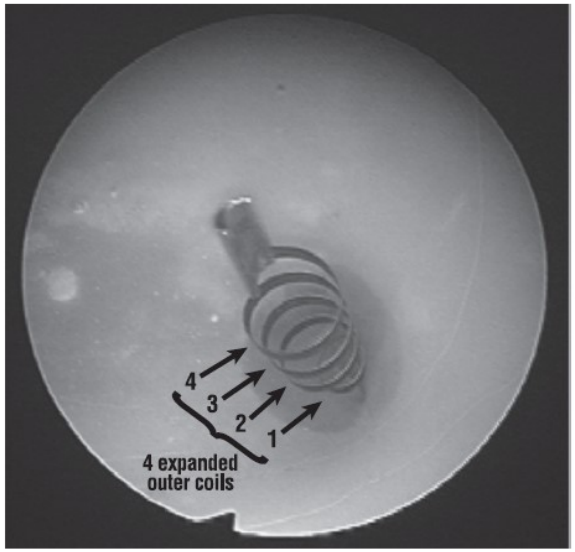
- Ideally, 3 to 8 expanded outer coils should be trailing into the uterine cavity

Based on the hysteroscopic view, if insert placement is not ideal but has fewer than 18 trailing coils

- Leave in place and evaluate via Essure Confirmation Test

Perforation suspected

- Monitor patient for complications related to perforation, including unusual post operative pain



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Assessment of Insert After Deployment (cont'd)

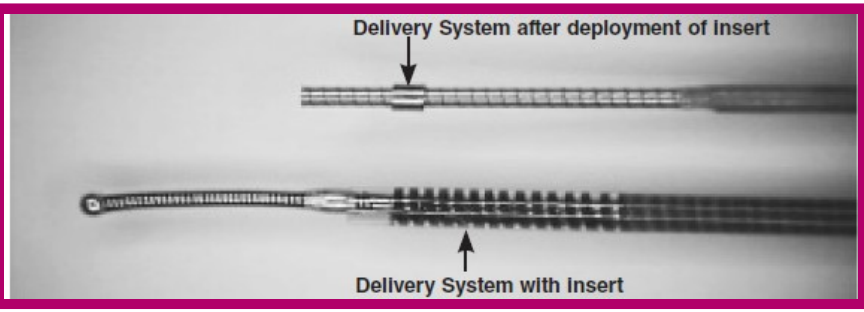
Unusual post-operative pain

- Perform imaging prior to the 3-month confirmation test to localize insert

No visible trailing coils

- Examine the delivery system upon removal from the hysteroscope

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



WARNING: Do not attempt insert removal hysteroscopically unless 18 or more coils of the Essure® insert are trailing into the uterine cavity. An attempted removal of inserts having fewer than 18 trailing coils may cause insert to fracture or patient injury. If 18 or more coils are trailing into the uterine cavity, removal should be attempted immediately during the placement attempt. However, removal of inserts may not be possible. Please refer to section XVII. INSERT REMOVAL for additional information.

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Immediate Insert Removal Indicated

Insert removal indicated

- Perform removal immediately after failed placement as follows:

    1. As necessary, administer analgesia/anesthesia to reduce or prevent patient discomfort
    2. Introduce a grasping instrument through hysteroscope operating channel
    3. Grasp both the outer and inner coils of the insert together
    4. Withdraw the grasping instrument and hysteroscope simultaneously; the insert may stretch or elongate. Do not pull insert through the operating channel

Insert removal successful

- Repeat the Essure insert placement procedure

Insert removal not accomplished

- Leave insert in place
- If insert is not completely removed, do not place additional inserts
- Take a diagnostic X-ray to determine if insert fragment remains in the patient. If fragment remains, refer to section XVII. INSERT REMOVAL

1. Essure [Instructions for Use].

Post-Procedure Recommendations

Document procedural concerns. Review during Essure Confirmation Test.

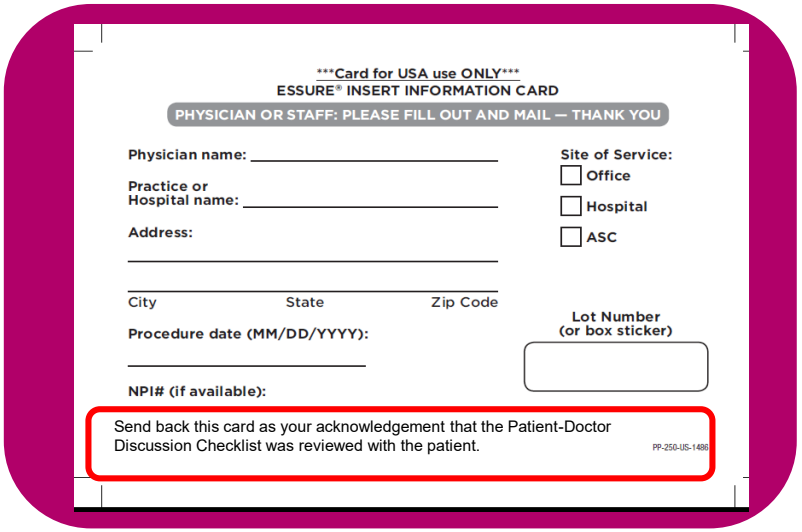
Note possible perforations due to:

- Excessive or sudden loss of resistance
- Inability to visualize coils
- Problems with identification of tubal ostium
- Poor distension
- Poor illumination
- Poor visualization secondary to endometrial debris

1. Essure [Instructions for Use].

Post-Procedure Recommendations (cont'd)

- Monitor patient during recovery
- Give Patient Identification Card to patient
- Provide any prescriptions to patient (eg, birth control)
- Schedule 3-month Essure Confirmation Test
- Complete and mail back the Essure® Insert Information Card, following each Essure procedure
  - Utilization of the Patient-Doctor Discussion Checklist-Acceptance of Risk and Informed Decision Acknowledgement, will be tracked by the Essure® Insert Information Card, included in the product packaging



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

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Post-Procedure Instructions and Patient Counseling

Alternative contraception

- Ensure patient uses alternative contraception until the Essure Confirmation Test
- Physician should counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to noncompliance during all steps of the Essure procedure
- Schedule patient for an Essure Confirmation Test 3 months following the procedure to evaluate insert location (TVU), or location and occlusion (modified HSG) of the fallopian tubes

Patient Identification Card

- Provide patient with the Patient Identification Card and instruct her to show it to her physicians

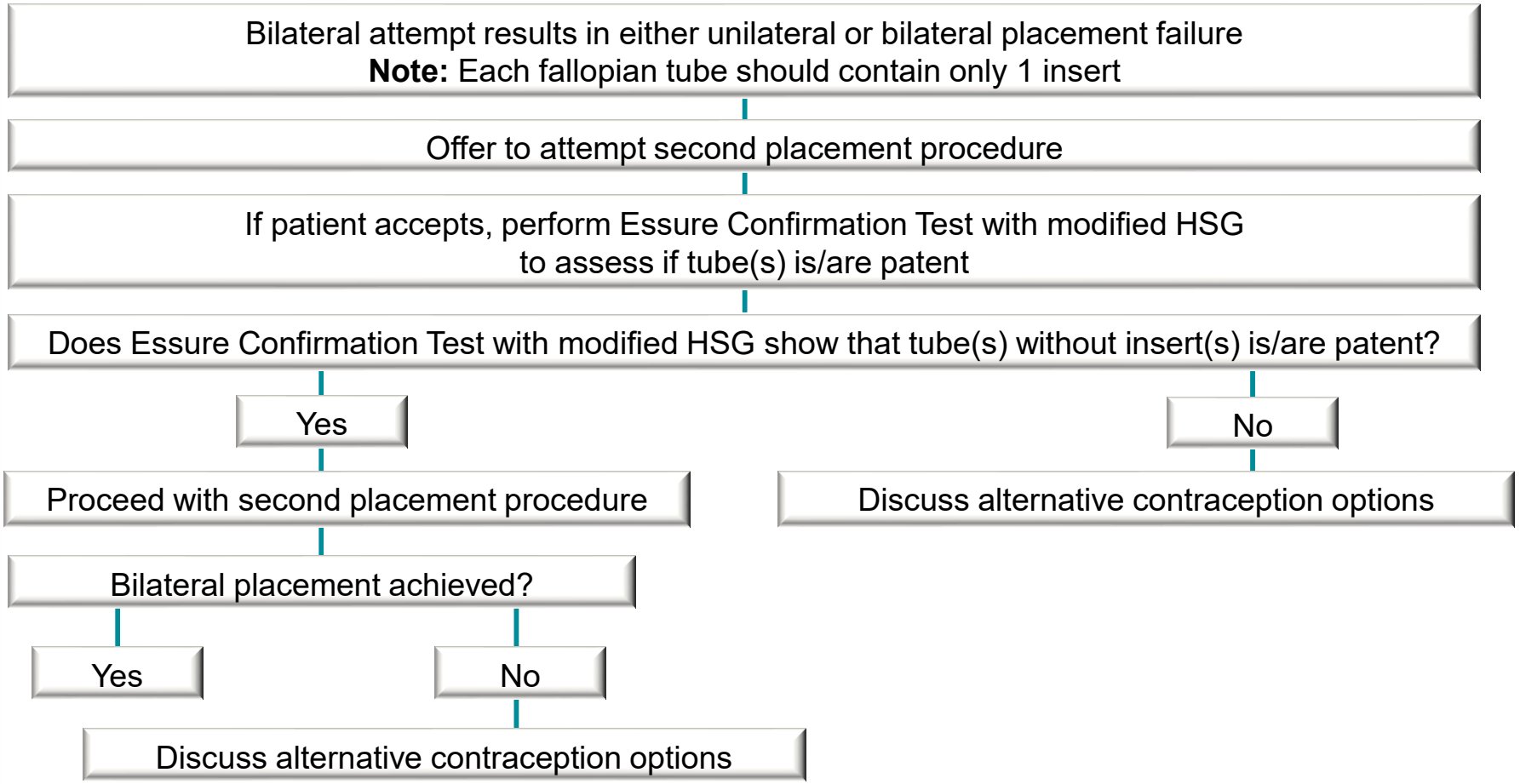
Post-procedure Symptoms

- Encourage the patient to call if she experiences pain, bleeding, fever, vaginal discharge, or other symptoms following the procedure. Listen to the patient's concerns and symptom reports and evaluate the patient if unusual symptoms are reported

1. Essure [Instructions for Use].

Management of Unsuccessful (First Attempt) Bilateral Placement

Inform the patient that the Essure placement procedure has not been successful and she should continue to use alternative contraception



1. Essure [Instructions for Use].

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Post-Procedure Adverse Events

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What should your patient expect post-procedure?

Post-procedure Recovery: Results from a Pivotal Study

- Post-procedure bleeding
  - Stopped in a mean of 3 days
  - Persisted to 7 days in 19% of women
  - Primarily spotting or light bleeding

- Post-procedure pain
  - First day post-procedure: ~33% reported pain during daily activities
  - 60% reported return to normal function within 1 day
  - 92% missed no more than 1 day of work after the procedure day
  - >75% resumed normal activities by day 2

1. Cooper JM, et al. *Obstet Gynecol*. 2003;102(1):59-67.

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Post-Procedural Bleeding

- Abnormal bleeding has been reported following Essure placement[1]
  - Changes in the pattern or the amount of menstrual bleeding have been reported.
- Discontinuation of hormonal contraception may lead to changes in the bleeding pattern[2]
- While abnormal bleeding occurs in the general population and increases with age, evaluation of any changes to bleeding pattern changes post-procedure is appropriate[3]
- With any woman, any significant changes in the bleeding pattern warrants appropriate evaluation

1. Al-Safi ZA, et al. *J Minim Invasive Gynecol*. 2013;20(6):825-829; 2. Sulak PJ, et al. *Obstet Gynecol*. 2000;95(2):261-266; 3. Marret H, et al. *Eur J Obstet Gynecol Reprod Biol*. 2010;152(2):133-137.

Post-Procedural Pain

Pain (acute or persistent) of varying intensity and length of time may occur and persist following Essure placement[1-5]

- Patients with a history of pain are more likely to experience both acute and chronic pelvic pain following Essure placement[1]
  - Retrospective cohort study (N=458)[6]:
    - Patients with a history of chronic pain (chronic pelvic pain, chronic low back pain, chronic headache, and fibromyalgia) were more likely to report both acute (2 weeks to 3 months) and chronic pain (>3 months) post-procedure

- Discontinuation of hormonal contraception may lead to the return of pelvic pain previously suppressed by hormonal treatment[7]

1. Essure [Instructions for Use]; 2. Povedano B et al. *BJOG*. 2012;119(7):795-799; 3. Arjona Berral JE, et al. *J Obstet Gynaecol*. 2014;34(8):712-713; 4. Adelman MR, et al. *J Minim Invasive Gynecol*. 2014;21(5):733-743; 5. Al-Safi ZA, et al. *J Minim Invasive Gynecol.* 2013;20(6):825-829; 6. Yunker AC, et al. *J Minim Invasive Gynecol*. 2015;22(3):390-394; 7. Sulak PJ et al. *Obstet Gynecol.* 2000;95(2):261-266.

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Post-Procedural Pain (cont'd)

- In addition to pain associated with Essure®, unrelated gynecological (eg, endometriosis, adenomyosis) or nongynecological (eg, irritable bowel syndrome, interstitial cystitis) conditions that may result in pain should be considered during evaluation.
- Pain and cramping may be more likely to occur during the menstrual period, and during and after sexual intercourse or with other physical activity.
- Unsatisfactory device location, including perforation, uterine embedment, and expulsion may result in pain.
- Surgery, including device removal, hysterectomy or other procedures, may be required to treat the pain

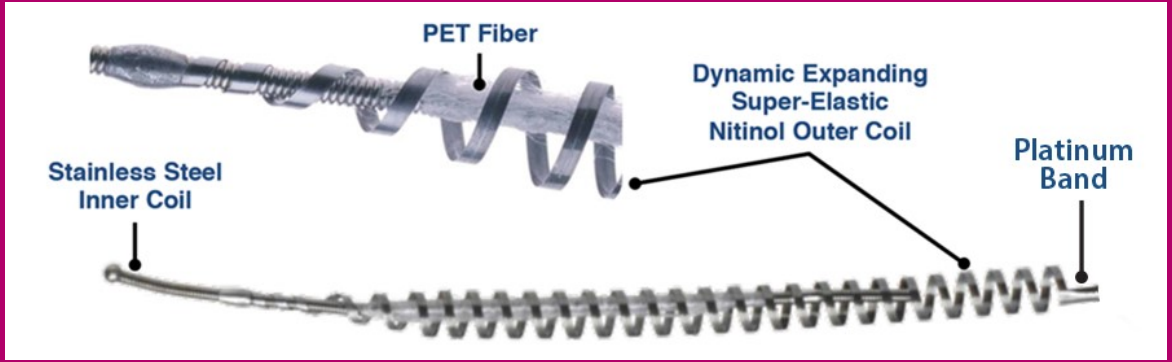
Patient should be advised to contact her physician if she experiences significant pain or if pain persists

1. Essure [Instructions for Use].

Post-Procedural Hypersensitivity

- **Patients with known hypersensitivity to nickel, titanium, platinum, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the Essure® system may experience an allergic reaction to the insert**
  - This includes both patients with or without a history of metal allergies
  - There are no known diagnostic tests that are predictive of allergic reactions to any of the components of Essure®
- Patients may develop an allergy to nickel or other components of the insert
- Allergic reaction symptoms reported 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



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Essure Confirmation Test

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Essure Confirmation Tests

Procedure[1]:

- Required at 3 months post-placement to evaluate insert retention and location
- Performed only by an experienced healthcare provider, including gynecologist, ultrasonographer, and/or radiologist
  - Training and/or educational materials on the Essure Confirmation Test are available through Bayer

Possible tips to help increase confirmation test compliance

- Electronic reminder for patient[2]
  - In a retrospective cohort study (N=211), implementation of an electronic reminder increased the odds of post-Essure HSG adherence by almost 3-fold in the resident clinic patient population[2]
- Dedicated staff to schedule/track[2,3]
  - In a retrospective chart review (N=228), patients followed by a dedicated staff nurse were more likely to undergo HSG compliance[3]

Pregnancies, including ectopic pregnancies, have been reported among women who have undergone the Essure procedure. Clinicians must counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all stages of the Essure procedure

1. Essure [Instructions for Use]; 2. Mahmud S, et al. *J Min invasive Gynecol*. 2015;22(2):250-254; 3. Guiahi M, et al. *Contraception*. 2010;81(6):520-524.

TVU and Modified HSG

Determine which Essure Confirmation Test is appropriate for your patient based on the TVU/HSG Confirmation Test Algorithm

Inform patients of the differences between the methods, including:

- Benefits and risks
- Possible increased risk of pregnancy if TVU is the only method utilized

TVU

- An option for patients who meet criteria specified in the Essure TVU/HSG Confirmation Test Algorithm
- May only be performed by healthcare providers who have separately completed the Essure Confirmation Test with TVU training
- Transabdominal ultrasound cannot be substituted for TVU

Modified HSG

- If TVU is not indicated, or if results are equivocal or unsatisfactory:
  - Modified HSG is required to evaluate insert location and tubal occlusion
- Modified HSG is always an acceptable first-line option for the Essure Confirmation Test

1. Essure [Instructions for Use].

Interactions with Other Procedures

Patients who undergo placement of the Essure® insert may, in future years, be offered gynecological therapies that may pose additional risk due to the presence of the insert

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Interaction with Other Procedures: Warnings

DO NOT perform the Essure procedure concomitantly with endometrial ablation

Ablation causes intrauterine synechiae

- Can compromise (ie, prevent the proper interpretation of) the modified HSG, which may be required for the Essure Confirmation Test. Women with inadequate confirmation tests cannot rely on Essure® for contraception

Endometrial ablation can result in thermal injury to the gastrointestinal tract or abscess formation around the inserts. This could cause bowel or bladder injury if there is an unrecognized tubal perforation and part of the insert lies outside of the tubal serosa

- Endometrial ablation (if medically appropriate) should only be performed after correct location of the Essure® insert is confirmed by a satisfactory Essure Confirmation Test, in order to minimize injury to the surrounding tissue (eg, bowel)

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Interaction with Other Procedures: Warnings (cont'd)

During endometrial ablation, thermal injury to the proximal portion of the fibrotic in-growth that causes tubal occlusion may occur

- It is unknown whether thermal injury will interfere with tubal occlusion
- Bench and clinical studies have been conducted, which demonstrate that endometrial ablation of the uterus can be safely performed with Essure® inserts in place after a satisfactory confirmation test has been performed
- Contraception rates following NovaSure Endometrial Ablation System with Essure® inserts in place are under investigation

Intrauterine procedures, such as endometrial ablation, endometrial biopsy, dilation and curettage (D&C), and hysteroscopy (diagnostic or operative) may result in trailing coils of the insert being ensnared in another device

- When the device/instrument is withdrawn, the insert may be stretched or removed and tubal patency may be restored

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Interaction with Other Procedures: Warnings (cont'd)

Some surgical instruments utilize energy sources such as electrical current, radio frequency, thermal energy, or freezing (eg, cryotherapy)

- There is a risk of fragmentation of the insert and/or conduction of energy to surrounding structures if these energy sources are used adjacent to or in contact with the insert
- There may be risks associated with such procedures that, at this time, have not been identified
- Avoid direct contact between the Essure® inserts and monopolar radio frequency (RF) when performing endometrial ablation during operative hysteroscopy as this may cause injury to the surrounding tissue

Endometrial ablation using microwave energy is contraindicated when an Essure® insert is in place

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Interaction with Other Procedures: Warnings (cont'd)

Other surgical instruments such as a morcellator, clamp, or scissors can result in fragmentation of the inserts and should therefore be avoided or used with caution in proximity to the insert

- If fragmentation occurs, intraoperative imaging to localize the fragments should be performed and the fragments should be removed, as determined by the physician's judgment
- Care must be taken to completely remove the inserts when performing a hysterectomy when the adnexa are being retained
- The Essure® insert may conduct energy and cause patient injury if contacted by an active electrosurgical device
- Avoid electrosurgery on uterine cornua and proximal fallopian tubes without visualizing inserts
- During Laparoscopically Assisted Vaginal Hysterectomy, do not place instruments more proximal than the ampullary portion of the tube

1. Essure [Instructions for Use].

Interaction with Other Procedures: Precautions

Intrauterine procedures:

- Procedures such as endometrial biopsy, dilation and curettage (D&C), and hysteroscopy may involve the use of instrumentation that may come into contact with the inserts. If the inserts are displaced or removed by such instrumentation, the patient's ability to rely may be affected

Blind intrauterine procedures:

- Use caution and avoid the Essure® inserts when undertaking blind intrauterine procedures as disturbing the inserts could interrupt their ability to prevent pregnancy. Direct visualization of inserts during intrauterine procedures is optimal. Insert retention and location should be verified following intrauterine procedures if there is a concern of entanglement with the insert. Modalities that may be used for this purpose include hysteroscopy, x-ray, HSG, or TVU. There could be risks associated with intrauterine procedures and the presence of inserts not currently identified

1. Essure [Instructions for Use].

Interaction with Other Procedures: Precautions (cont'd)

Endometrial ablation:

- Performing endometrial ablation following Essure® insert placement may increase the risk of post-ablation tubal sterilization syndrome, a rare condition that has been reported in women with a history of tubal sterilization who undergo endometrial ablation

In vitro fertilization (IVF):

- Patients may decide, in future years, to undergo in vitro fertilization (IVF) to become pregnant. There are limited data related to the effects, including risks, of Essure® inserts on in vitro fertilization (IVF)

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Interaction with Other Procedures: Precautions (cont'd)

MRI Safety 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
- 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, 2005
- Nonclinical 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

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Management of Patients Unable to Rely

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Second Placement Attempt

Performed only:

- If the insert is determined to be perforated or expulsed
- Tubal patency is seen on modified HSG
- No part of an Essure® insert is in the fallopian tube

If a portion of the insert is in the fallopian tube, counsel the patient on incisional sterilization or to remain on alternative contraception

1. Essure [Instructions for Use].

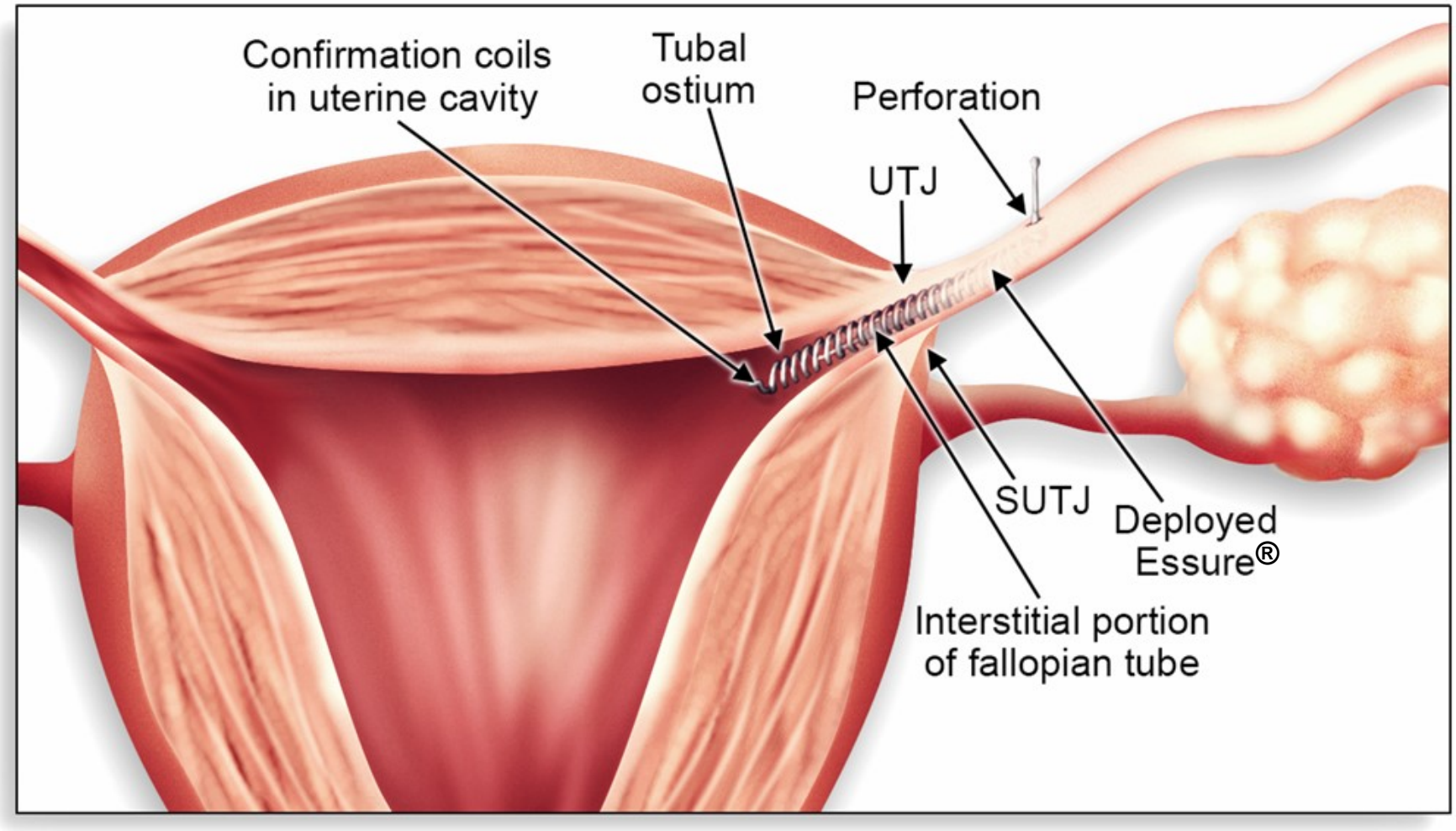
Incisional Sterilization or Remain on Alternative Contraception

- If the insert is in an unsatisfactory location (distal, perforation, proximal/expulsion), but occlusion is seen on modified HSG, advise the patient of potential for false-positive diagnosis of occlusion
- Inserts should be clearly identified prior to performing the sterilization procedure
- Do not clamp, cut, or coagulate directly over the insert to avoid transecting or fracturing the insert
- Insert removal may be required to achieve complete ligation of the fallopian tube

Caution must be taken not to leave any perforations proximal to the tubal ligation

1. Essure [Instructions for Use].

Incisional Sterilization or Remain on Alternative Contraception (cont'd)



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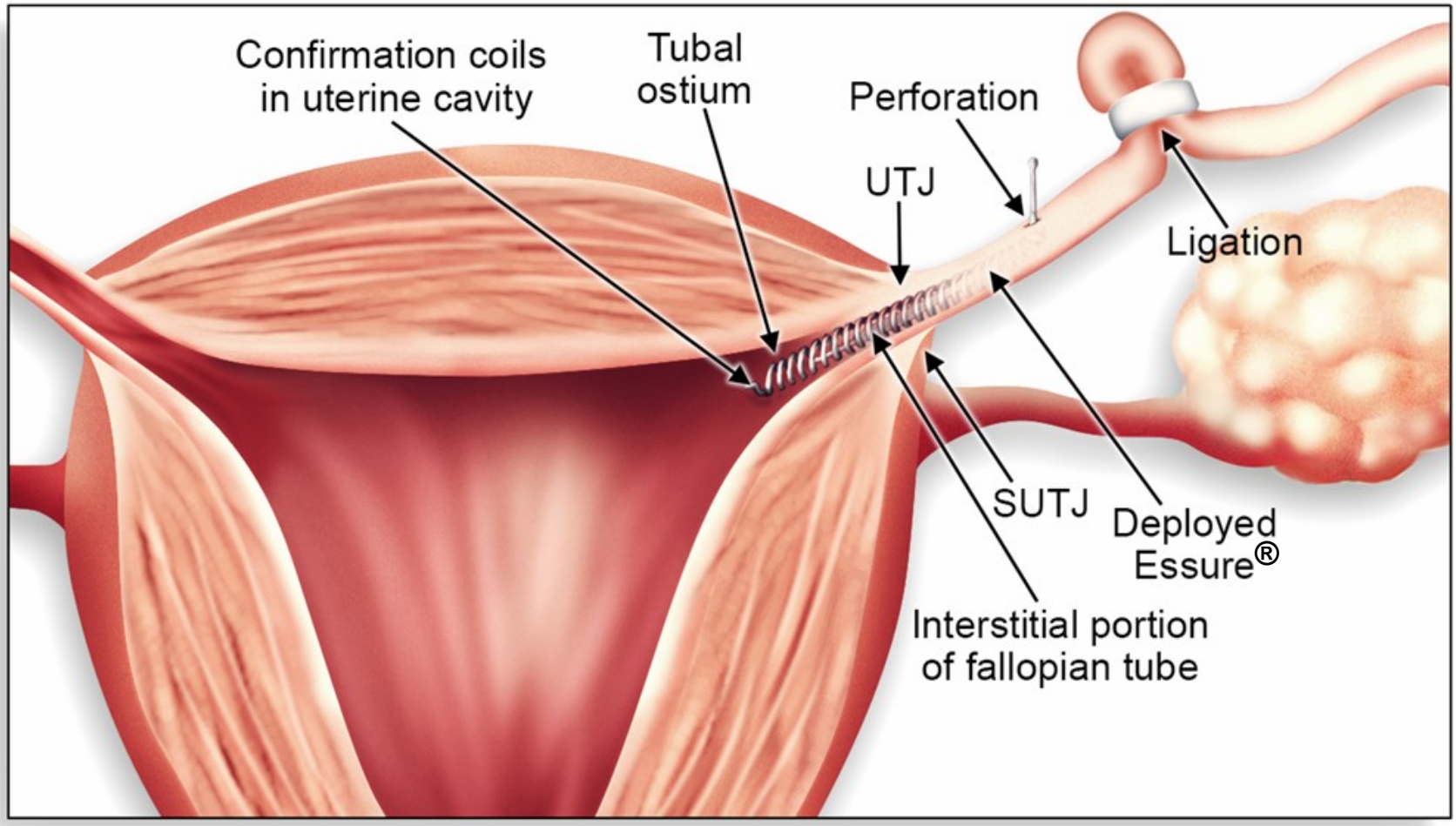
Incisional Sterilization or Remain on Alternative Contraception (cont'd)



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Peritoneal Location

Inform the patient that the Essure placement procedure has not been successful and she should continue to use alternative contraception

- Location of insert(s) should be evaluated and decision should be made as to whether the insert should be left in situ or removed

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Insert Removal

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Insert Removal

WARNING: Essure® inserts are intended to be left in place permanently. Do not remove insert(s) unless patient is experiencing an adverse event(s) associated with its presence, or if removal is clinically indicated, or if requested by the patient

- If the insert removal is planned, the patient should be counseled on the risks of surgery
- Clinical judgment as to the appropriate procedure must be used:
  - Physicians should be thoroughly familiar with the characteristics and performance of any instrument they select for the removal procedure
  - Consultation with a physician familiar with removal techniques may be appropriate
- For all surgical removal procedures:
  - Care should be taken to avoid transecting the insert during removal
- For all removal procedures:
  - Inspection of removed insert is essential
  - If the entire insert is not removed, intraoperative imaging to localize remaining fragments should be performed and fragments removed as determined by physician judgment

1. Essure [Instructions for Use].

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Insert Removal: Potential Surgical Approaches

At time of placement procedure

Subsequent to placement procedure

At the Time of Placement Procedure

Hysteroscopic insert removal should not be attempted at the time of insert placement, unless 18 or more coils of the insert are trailing into the uterine cavity, indicating placement is too proximal.

- Removal may be attempted immediately following placement
- However, if the removal is not achieved with gentle traction, the insert may be left in place and subsequent hysteroscopic removal attempted at a later date

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Steps for Hysteroscopic Removal

1. As necessary, administer analgesia/anesthesia
2. Introduce grasping instrument through the hysteroscope's working channel
3. Try to grasp outer and inner coils together
   - May help prevent excessive stretching of outer coil, which can cause fragmentation
4. Gently pull back insert in small increments to prevent fragmentation of the insert or excessive stretching of the outer coil
   - Once the insert is removed from the fallopian tube, pull back on the hysteroscope and the grasping instrument at the same time
   - Do not attempt to pull the deployed insert through the working channel of the hysteroscope. The hysteroscope, along with the grasper containing the deployed insert, should be removed from the uterus together
5. If, upon inspection of the removed insert, the physician is not completely satisfied that the entire Essure® insert has been removed from the fallopian tube, an x-ray should be taken to determine if an insert fragment remains in vivo
6. If complete insert removal is accomplished, an attempt may be made to place another Essure® insert

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Subsequent to Placement Procedure

- Location of Essure® inserts should be confirmed through imaging prior to any attempted surgical removal, as the appropriate surgical approach will be influenced by the location
- Availability of intraoperative fluoroscopy and/or intraoperative x-ray is recommended to identify the location of the insert or fragments of the insert during the removal procedure
- Attempt to remove the entire insert to avoid the potential need for subsequent surgical procedures
- Insert removal may be performed along with, or independent of, an incisional sterilization procedure (eg, tubal ligation)

Following insert removal, the patients should be counseled about risk of pregnancy, including ectopic pregnancy

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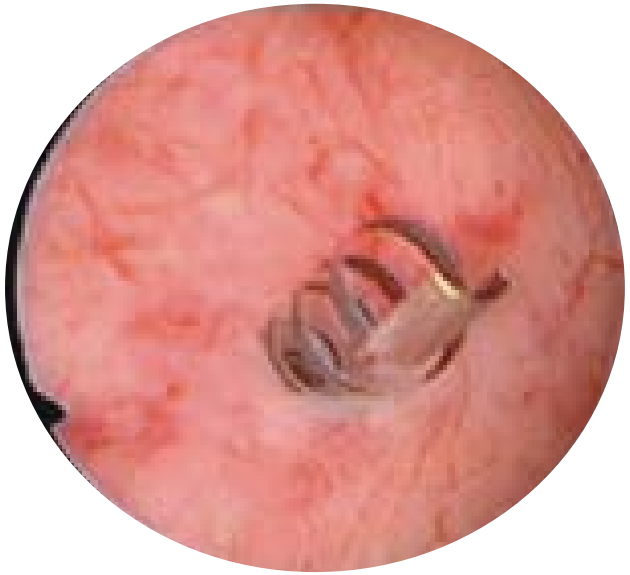
Removal of Insert Located Within the Fallopian Tube(s)

Hysteroscopic Removal

- Limited case reports describe hysteroscopic removal up to 7 weeks' post-placement
- In these cases, proximal coils were visible within uterine cavity and easily removed with gentle traction
- Hysteroscopic removal should only be attempted when proximal coils are visible within the uterine cavity
  - Refer to steps for *"Hysteroscopic Removal""* in Section XVII. INSERT REMOVAL, subsection "At time of Placement Procedure"



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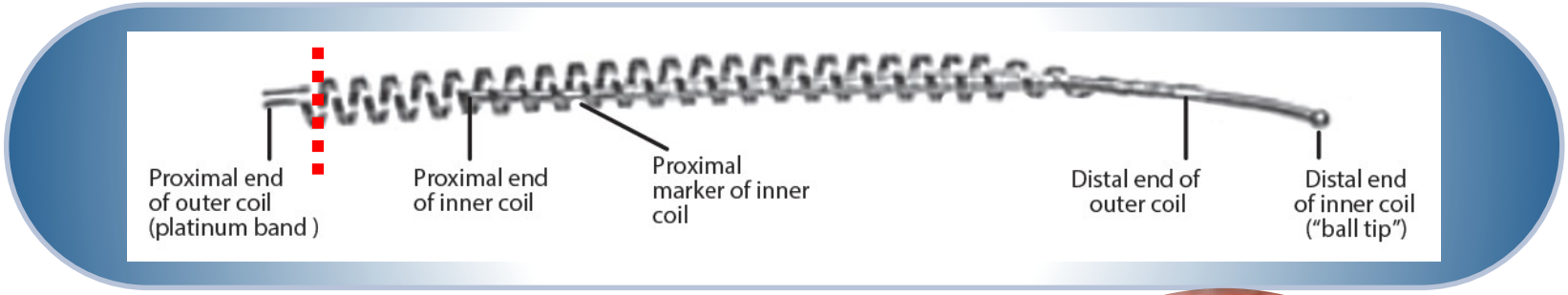
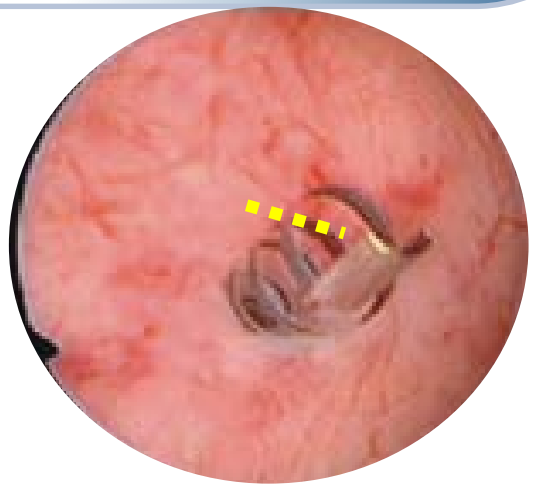
Removal of Insert Located Within the Fallopian Tube(s) (cont'd)

Combined hysteroscopic/laparoscopic removal:

When planning a laparoscopic removal, consideration should be given to first excising the most proximal part of the outer coil (the "platinum band") hysteroscopically with scissors



This may facilitate laparoscopic removal of the insert as the platinum band is the widest portion of the outer coil, which can be the most difficult portion to pass through the cornual region of the fallopian tube.



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Removal of Insert Located Within the Fallopian Tube(s) (cont'd)

Laparoscopic Removal: Performing Linear Salpingotomy

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

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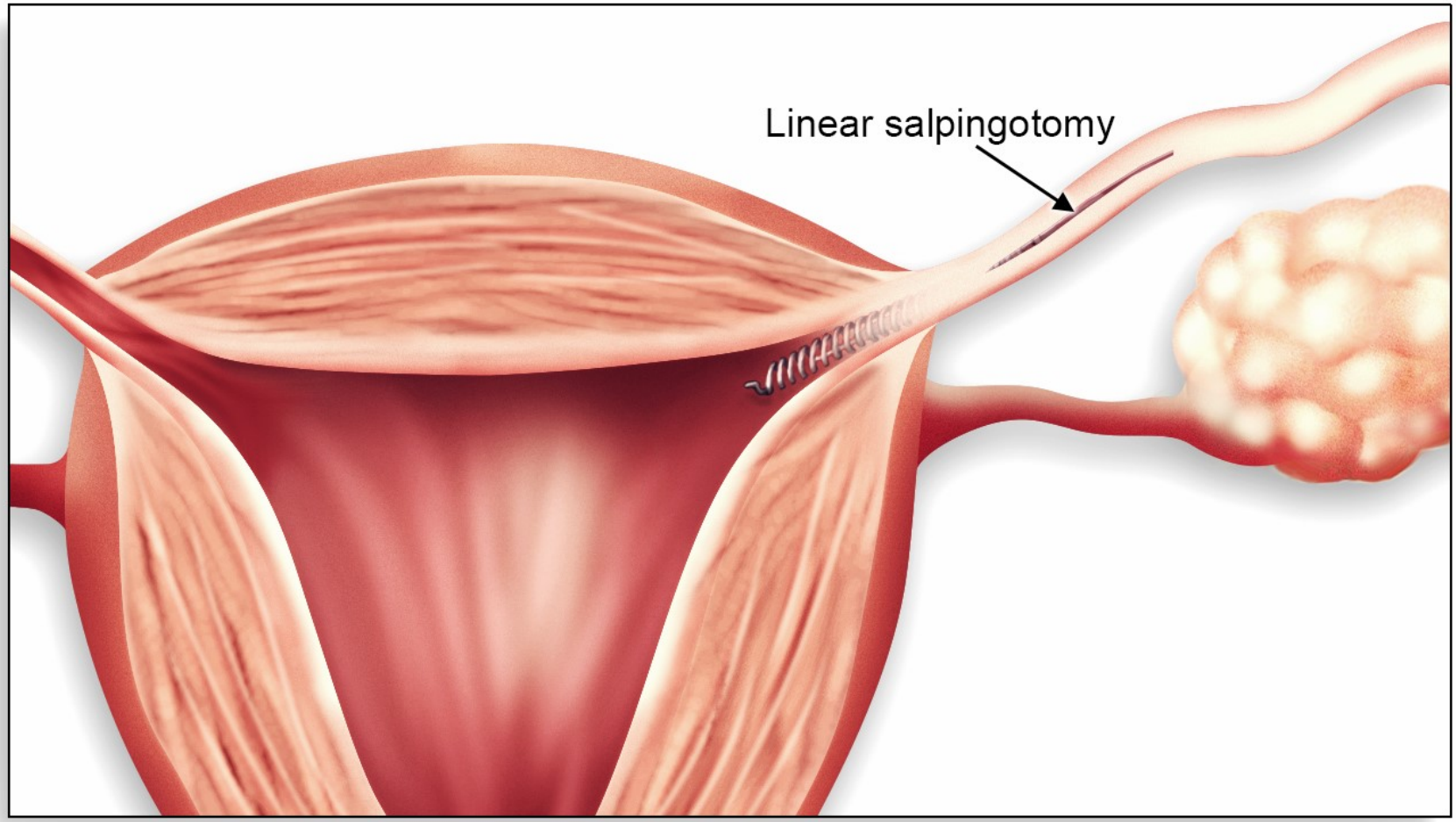
Removal of Insert Located Within the Fallopian Tube(s) (cont'd)



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Removal of Insert Located Within the Fallopian Tube(s) (cont'd)

Laparoscopic Removal: Cornual Resection

In some cases, a cornual resection of the proximal fallopian tube may be required for insert removal. In these cases, patients should be counseled about the risk of hysterectomy in order to achieve hemostasis.

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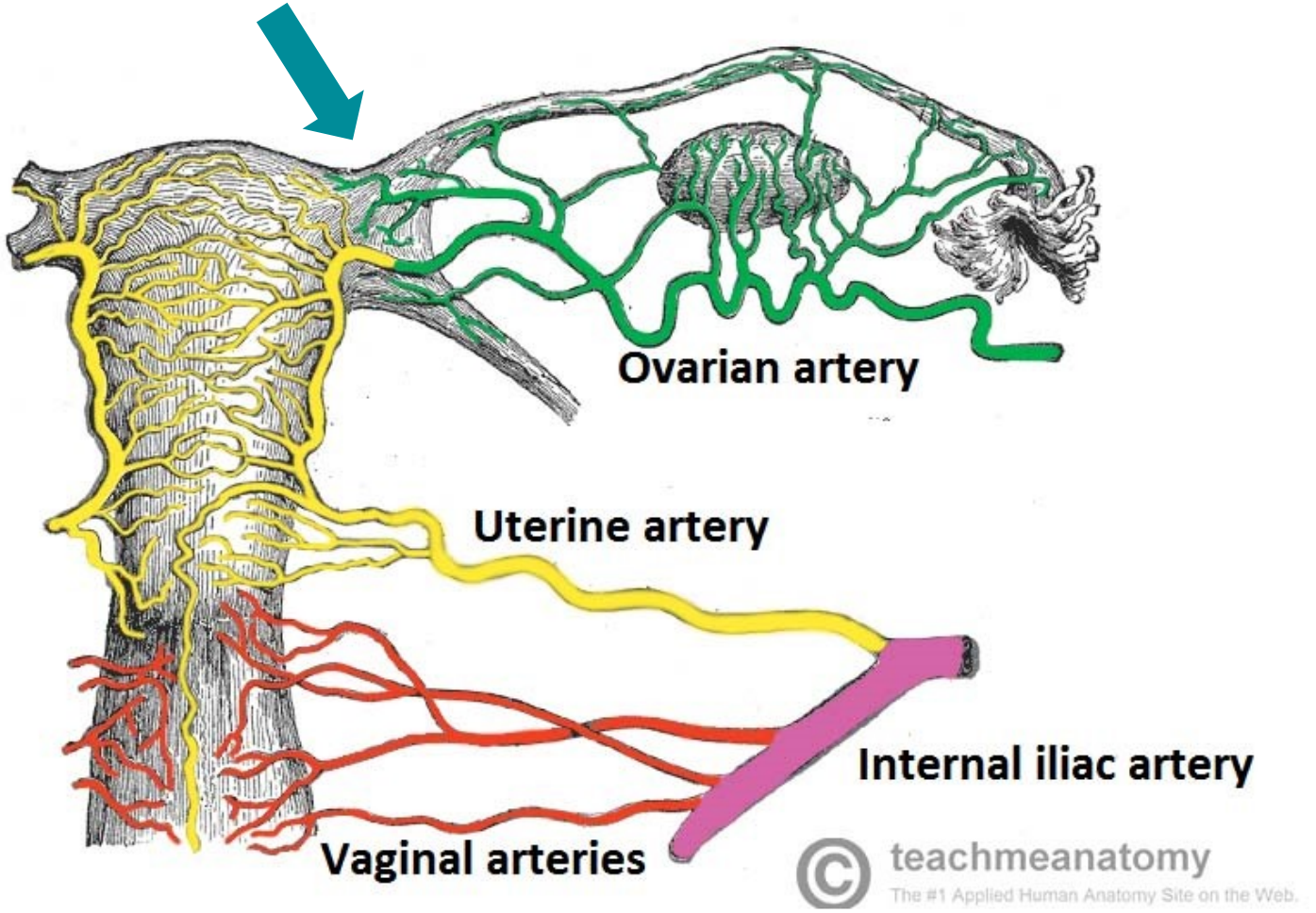
Removal of Insert Located Within the Fallopian Tube(s) (cont'd)



Teachmeanatomy (2016). The Uterus. Available at: http://teachmeanatomy.info/pelvis/female-reproductive-tract/uterus. Accessed November 15, 2016.

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Removal of Insert Located Within the Fallopian Tube(s) (cont'd)

Laparoscopic removal: removal via salpingectomy

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

- When removing the insert via salpingectomy, the location of the proximal and distal portions of the insert within the fallopian tube should be reconfirmed intraoperatively by palpation, visualization, and/or imaging prior to transecting the fallopian tube containing the insert to avoid transecting or fracturing the insert. The insert may be exposed and visualized via salpingotomy prior to transection or removal of the fallopian tube

Insert(s) partially located within the cornual region of the tube:

- When the proximal end of the insert is within the cornua, consideration should be given to performing a combined hysteroscopic/laparoscopic procedure (see Section XVII. INSERT REMOVAL "Combined hysteroscopic/laparoscopic removal"). Laparoscopic exposure and visualization of the insert may then be achieved via salpingotomy. Another option could be a circumferential incision made adjacent to the cornua, thus exposing the insert
- Once the insert is exposed, it can be grasped with forceps and slowly extracted in small increments to prevent fragmentation of the insert or excessive stretching of the coils. After removal of the proximal portion of the insert from the cornual region, the salpingectomy can be completed

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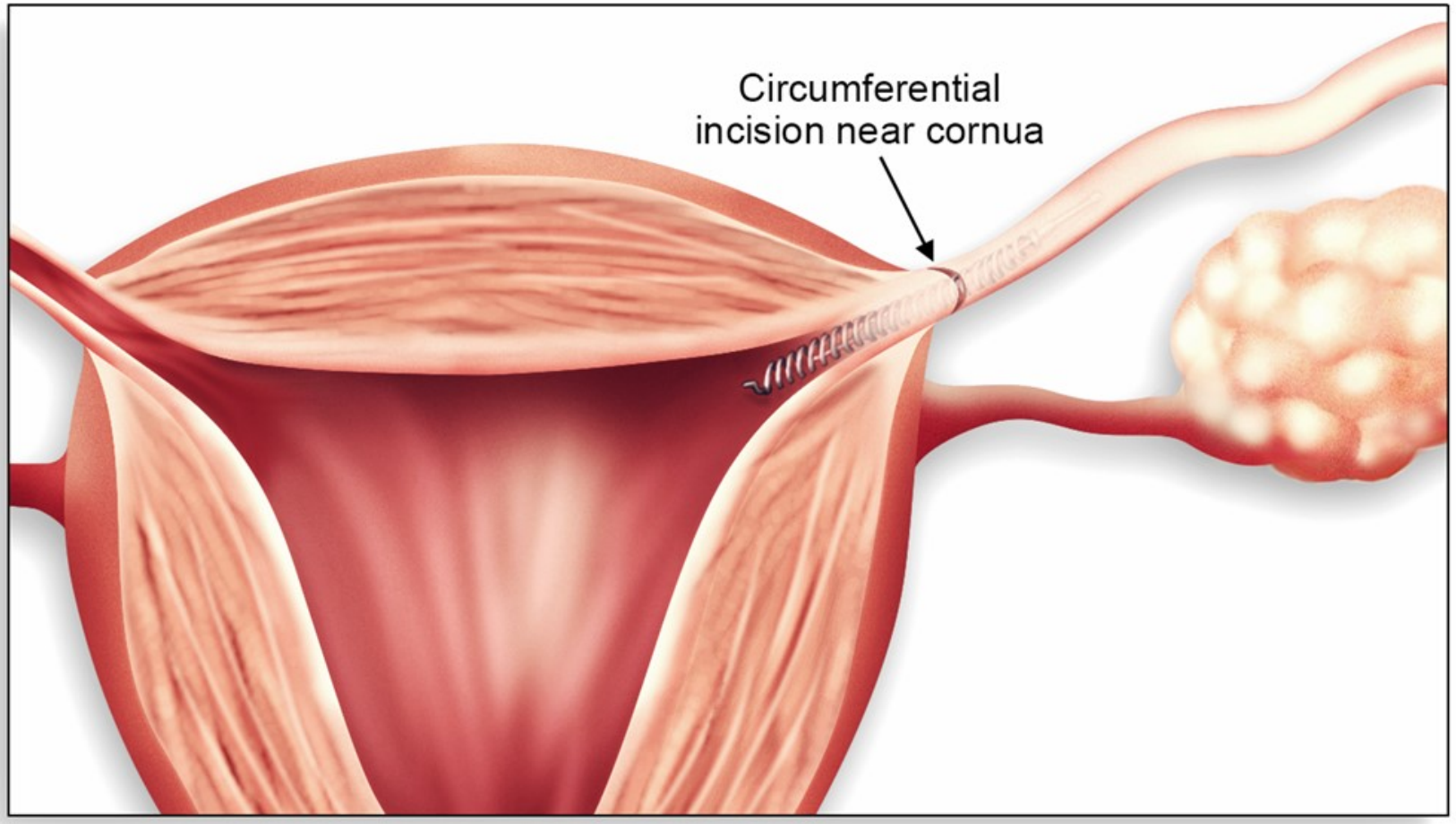
Removal via Salpingectomy: Inserts Partially Located Within the Corneal Region of the Tube



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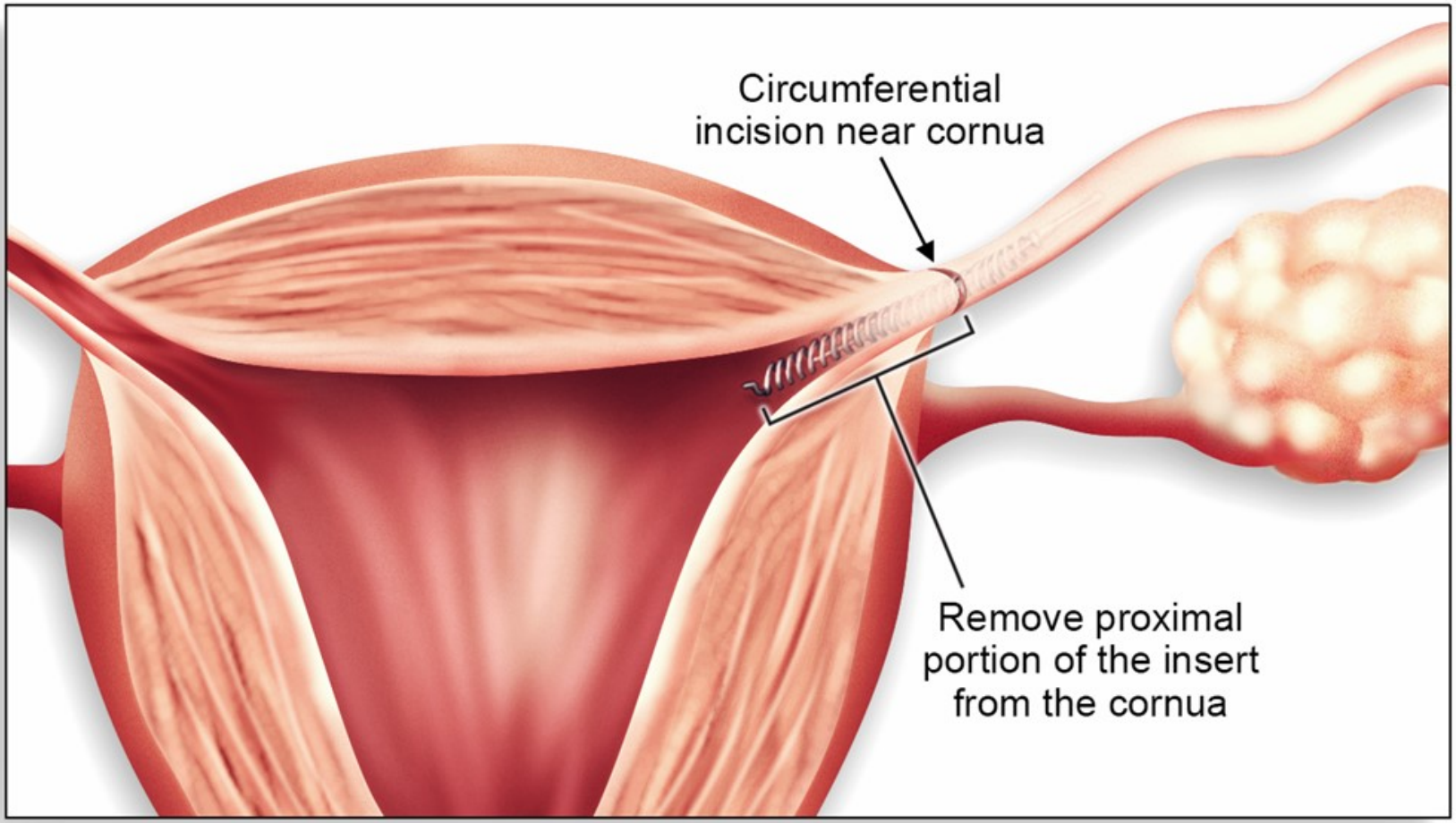
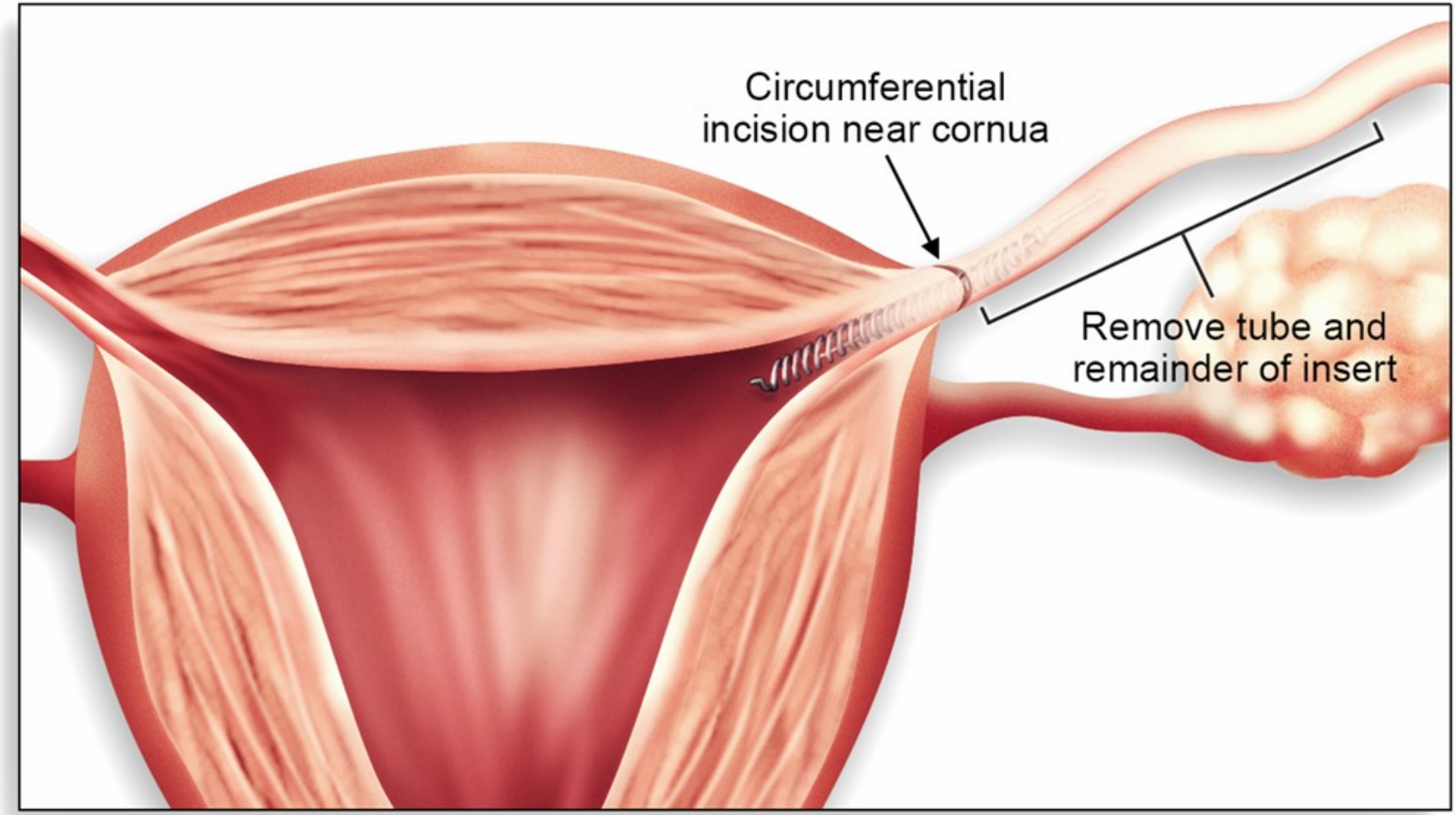
Removal via Salpingectomy: Inserts Partially Located Within the Corneal Region of the Tube (cont'd)



Removal via Salpingectomy: Inserts Partially Located Within the Corneal Region of the Tube (cont'd)



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Removal of Inserts: Perforations

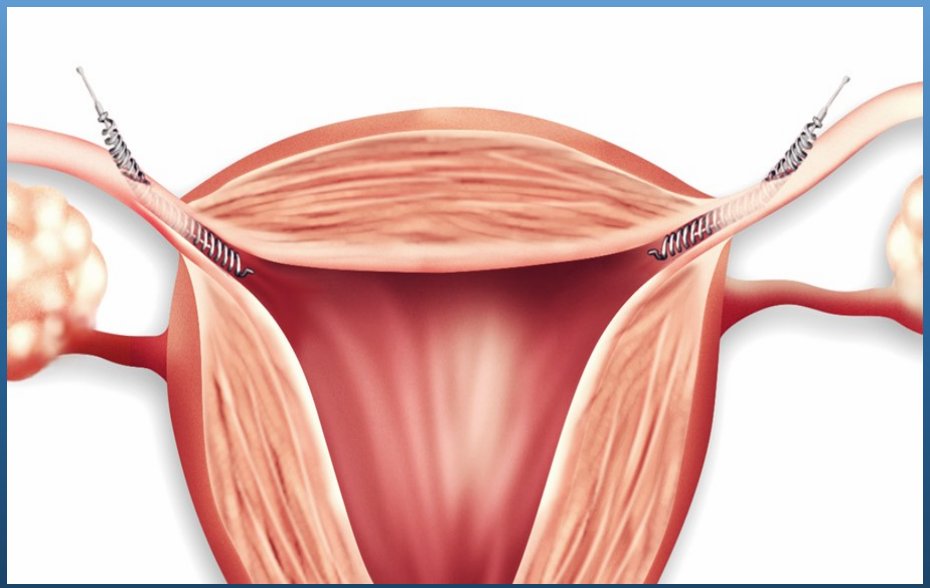
The technique for removal of the insert will depend on the location of the insert.

Localization should be assessed with imaging prior to the surgical procedure and confirmed intraoperatively

Availability of intraoperative fluoroscopy and/or x-ray is recommended to identify the location of insert or insert fragments during surgery

Tubal Perforations

- Inserts perforating the fallopian tube, but still partially within the tube, can be removed by salpingotomy, salpingectomy, cornual resection, or combined hysteroscopic/laparoscopic technique, depending on the location of the insert



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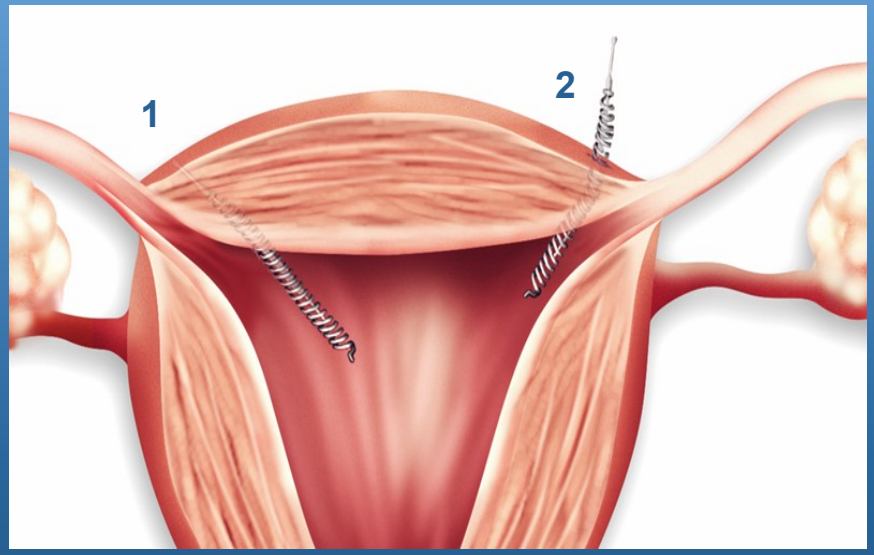
Removal of Inserts: Perforations (cont'd)

Uterine Perforations

- Inserts that penetrate the myometrium may be embedded and difficult to remove
- For cases of insert primarily within uterine cavity **(Example 1),** hysteroscopic removal should be attempted



- For cases in which the insert is partially within the endometrial cavity/uterine wall and partially in peritoneal cavity **(Example 2)**, hysteroscopic excision of the platinum band, if visible, should be considered prior to planned laparoscopic removal
- Cornual resection may be required for perforations within or adjacent to the cornual region. If the primary removal procedure is not successful, then hysterectomy may be required

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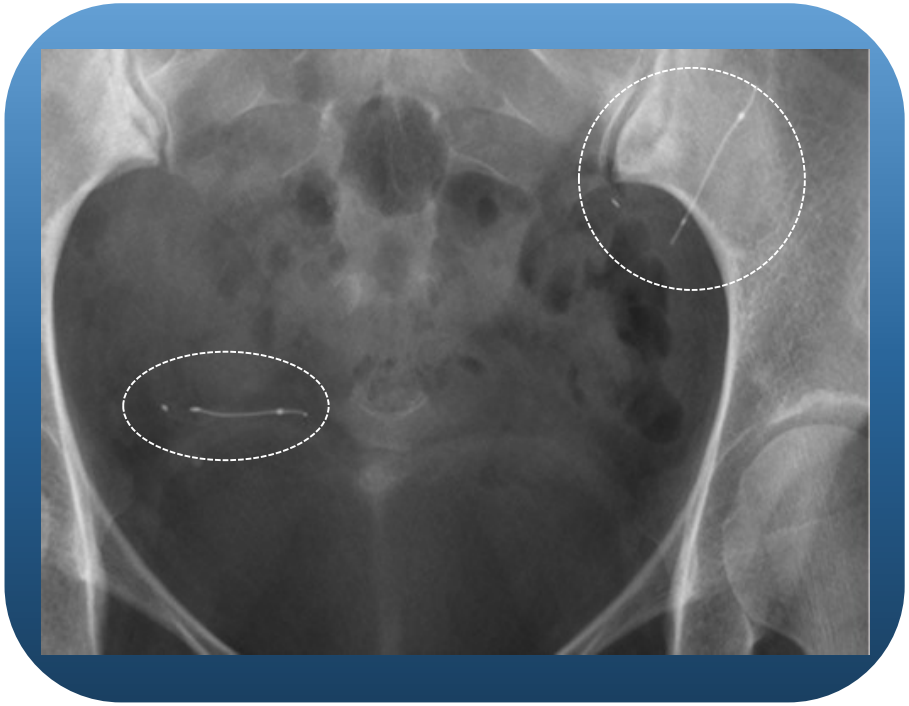
Removal of Insert Located Within Peritoneal Cavity

Removal of inserts in asymptomatic cases may not be necessary

If removal is planned:

- If removal is planned, the technique for removal of an insert within the peritoneal cavity will depend on the location of the insert
- Localization should be assessed with imaging prior to surgical procedure and may need to be confirmed intraoperatively
- Availability of intraoperative fluoroscopy and/or x-ray is recommended to identify the location of the insert or insert fragments during surgery



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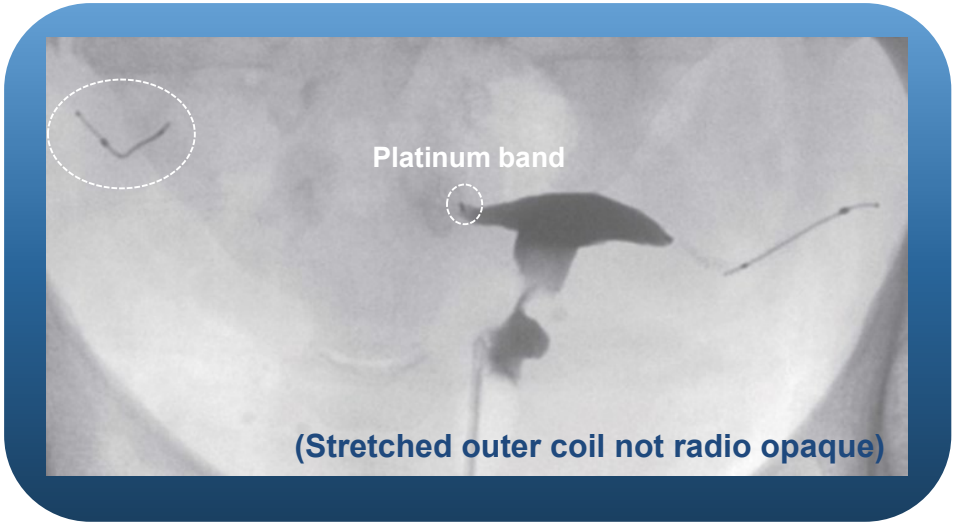
Removal of Insert Located Within Peritoneal Cavity

In rare instances:

- The outer coil of the insert may be stretched within the abdominal/pelvic cavity and the bowel may be entrapped
- A stretched insert can be identified on the x-ray by the location of the “platinum band” marker being several centimeters away from the remainder of the insert
  - Consideration should be given to removing the insert, even if the patient is asymptomatic



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Hysterectomy

While a hysterectomy is generally not required to remove the Essure® inserts, there may be situations in the physician's medical judgment when a hysterectomy is appropriate

Possible situations:

- Inability to remove insert using described techniques
- Excessive bleeding
- Other gynecological pathology that may be best managed with hysterectomy (eg, uterine fibroid, uterine prolapse, chronic pain, or bleeding)

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Hysterectomy (cont'd)

When performing a hysterectomy:

- Important that inserts be identified prior to surgery
  - Use care not to transect or cauterize insert as this may cause fragmentation
- Removal through one of the techniques described in Section XVII. INSERT REMOVAL "Subsequent to Placement" section may be required prior to completion of the hysterectomy, with or without bilateral salpingectomy, in order to avoid transecting or fracturing insert

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