

# Essure Confirmation Testing

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**Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.**

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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.

# Important Safety Information

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## **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.

# 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.

# Important Safety Information (cont'd)

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## **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.

# Important Safety Information (cont'd)

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## **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.

# 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 ( $\geq 10\%$ ) adverse events resulting from the placement procedure were cramping, pain, and nausea/vomiting. The most common adverse events ( $\geq 3\%$ ) 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**

# The Essure Confirmation Test Overview

NOTE: Patients must use alternative contraception until a satisfactory Essure Confirmation Test is documented

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# The Essure Confirmation Test: Overview

An Essure Confirmation Test is required for all patients at 3 months postplacement

**Past**



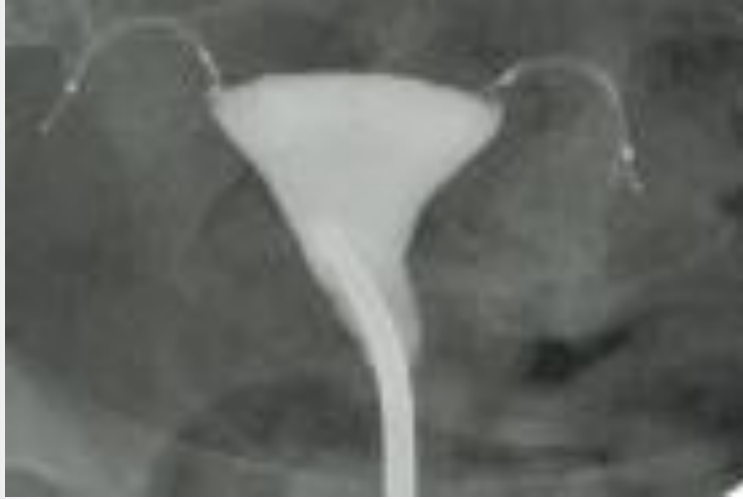
**Present<sup>1,2</sup>**

- A modified HSG was the only option in the United States for determining whether a patient can rely on Essure for birth control
- The TVU/HSG Confirmation Test Algorithm:
  - Confirmation Test can be performed using modified HSG or TVU in patients meeting specific criteria
  - If TVU is not indicated, or results are equivocal or unsatisfactory, a modified HSG is required to evaluate insert location and tubal occlusion

**NOTE:** Healthcare providers who utilize the Essure Confirmation Test with TVU must complete training administered by Bayer and documented by a certificate of completion.<sup>3</sup>

1. US FDA Approves Alternate Confirmation Test for Essure® Permanent Birth Control. <http://www.bayer.us/en/article.php?id=122890>. Accessed January 5, 2017.
2. Data on file, Bayer HealthCare Pharmaceuticals Inc.
3. Essure [Instructions for Use].

# The Essure Confirmation Test: Overview (cont'd)



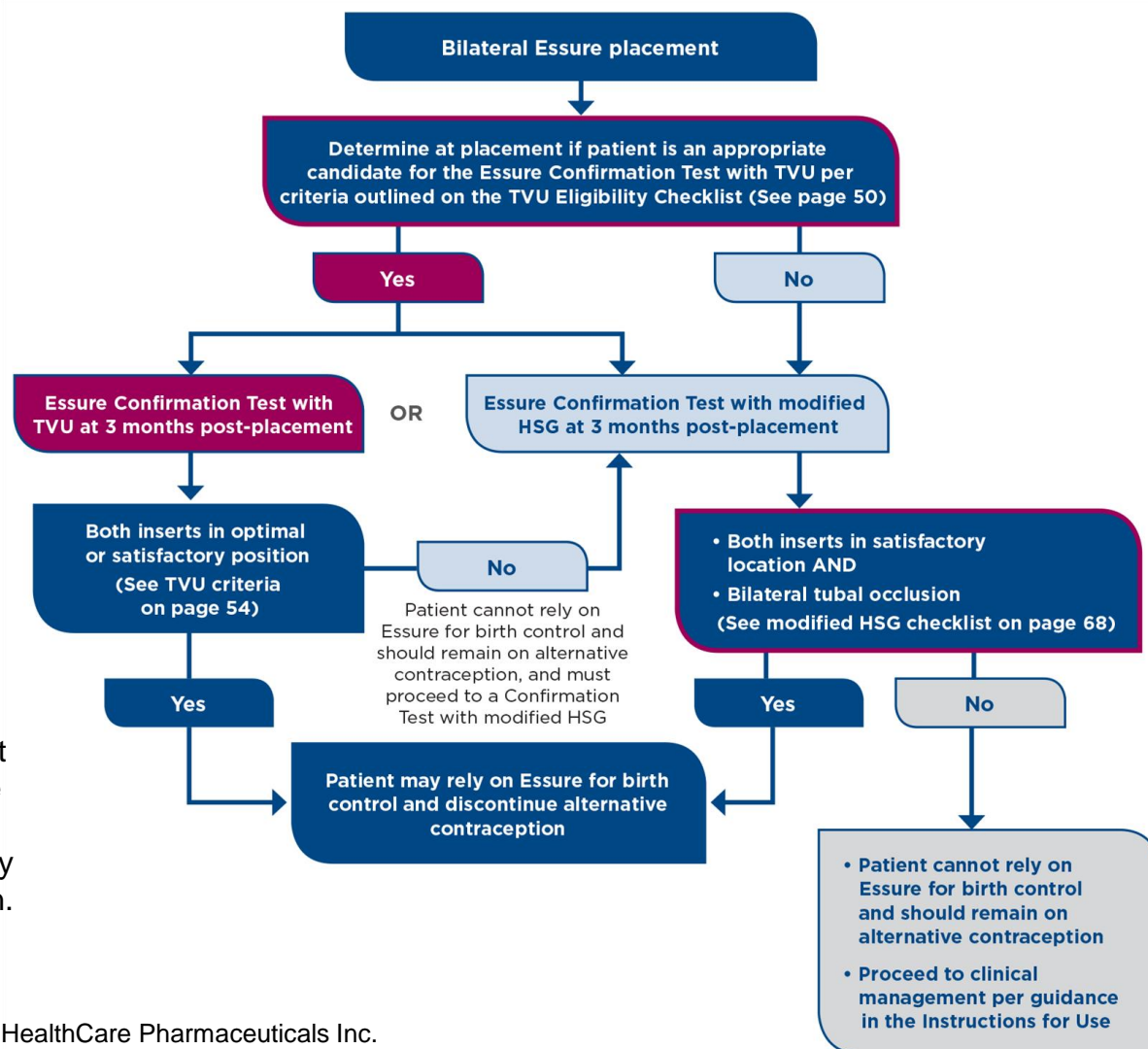
- Required 3 months post-placement to determine whether a patient can rely
- Evaluates insert retention and location
- Performed by an experienced healthcare provider using transvaginal ultrasound (TVU) or modified hysterosalpingogram (modified HSG)
- Counsel your patients on the use of alternative contraception until a satisfactory Essure Confirmation Test is documented

Pregnancies (including ectopic pregnancies) have been reported among women who have undergone the Essure procedure. Some of these pregnancies were due to patient non-compliance or incorrect clinician interpretation of the Essure Confirmation Test. DO NOT perform the Essure procedure concomitantly with endometrial ablation.

**Note:** Endometrial ablation (if medically appropriate) should only be performed after correct location of the Essure® insert is confirmed by a satisfactory Essure Confirmation Test.

Essure [Instructions for Use].

# TVU/HSG Confirmation Test Algorithm



NOTE: Healthcare providers who utilize the Essure Confirmation Test with TVU must complete training administered by Bayer and documented by a certificate of completion.

Data on file, Bayer HealthCare Pharmaceuticals Inc.

# Essure Confirmation Test: TVU

NOTE: Healthcare providers who utilize the Essure Confirmation Test with TVU must complete training administered by Bayer and documented by a certificate of completion.

Essure [Instructions for Use].

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# Essure Confirmation Test: TVU

- In certain circumstances (according to the TVU/HSG Confirmation Test Algorithm), TVU may be performed as a first-line confirmation test three months after a bilateral insert placement procedure
- TVU should not be used as the Essure Confirmation Test if the placement procedure was difficult, including:
  - Concern at the time of placement of possible perforation due to excessive force required for insert delivery and/or a sudden loss of resistance
  - Difficulty identifying the tubal ostia during placement due to anatomical variation or technical factors such as poor distension, suboptimal lighting, or endometrial debris
  - Physician is uncertain about placement

TVU  
(at 3 months postplacement)



*Essure Instructions for Use (with TVU)*

Essure [Instructions for Use].

# Essure Confirmation Test: TVU (cont'd)

- Additional circumstances in which TVU should not be used as the Essure Confirmation Test include:
  - Procedure time >15 minutes (scope in-scope out)
  - Placement with zero or >8 trailing coils
  - Unusual post-operative pain, transient or persistent, or onset at some later time post procedure, without any other identifiable cause

Patients on active immunosuppressive therapy may experience delay or failure of the necessary tissue in-growth needed for tubal occlusion

- For these patients, physicians must use the modified HSG as the Essure Confirmation Test
- TVU should not be utilized for confirmation, as this test cannot confirm tubal occlusion in these patients
- Clinical trials were not conducted with patients undergoing immunosuppressive therapy

Essure [Instructions for Use].

# Essure Confirmation Test: TVU (cont'd)

## Other Important Points

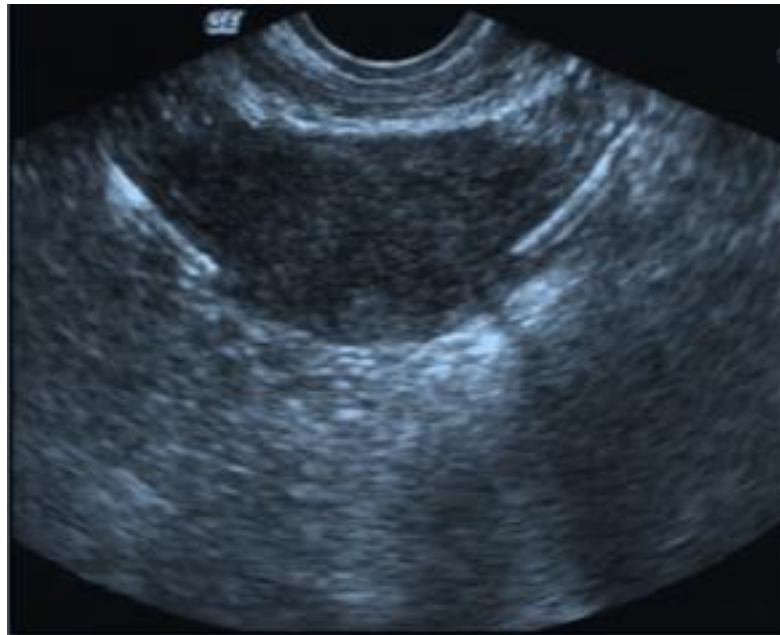
- Trans-abdominal ultrasound cannot be substituted for TVU
- If ultrasound is not indicated, proceed to modified HSG to evaluate insert location and tubal ligation
- If ultrasound evaluation is equivocal or unsatisfactory, proceed to modified HSG to evaluate insert location and tubal occlusion
- Patients must use alternative contraception until a satisfactory Essure Confirmation Test is documented
- Discuss the 2 methods used in the Essure Confirmation Test (TVU and modified HSG). Inform patients of the differences between the methods, including benefits and risks (including possible increased risk of pregnancy if TVU is the only confirmation method utilized)
- TVU evaluates placement of the insert only; it cannot be used to confirm occlusion of the fallopian tubes

Essure [Instructions for Use].

# Performing the Essure Confirmation Test with TVU

A minimum of three images must be obtained and retained for documentation:

1. A transverse or oblique transverse view demonstrating a portion of each insert in the cornua labeled “scout image”

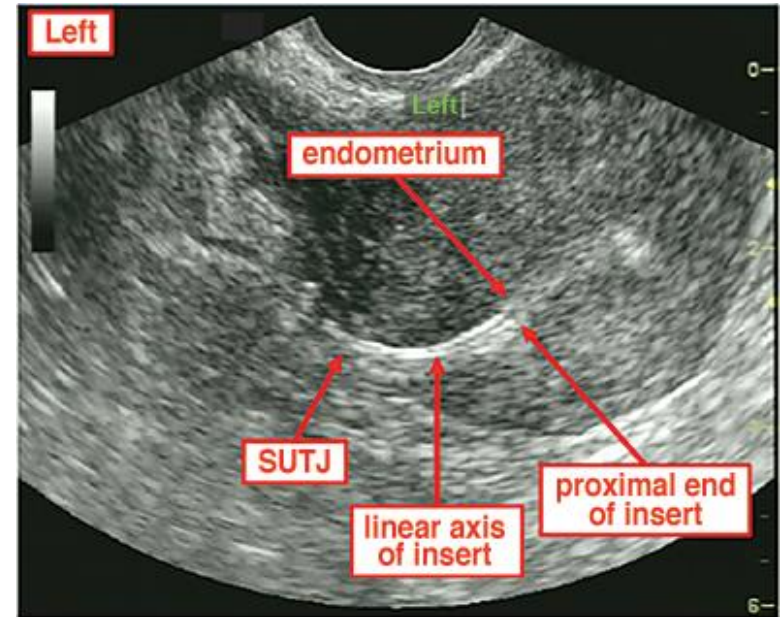


Essure [Instructions for Use].

# Performing the Essure Confirmation Test with TVU (cont'd)

A minimum of three images must be obtained and retained for documentation (cont'd):

2. A transverse or oblique transverse image of the linear axis of the left insert, labeled “left,” including the proximal end crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with SUTJ
3. A transverse or oblique transverse image of the linear axis of the right insert, labeled “right,” including the proximal end crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with SUTJ

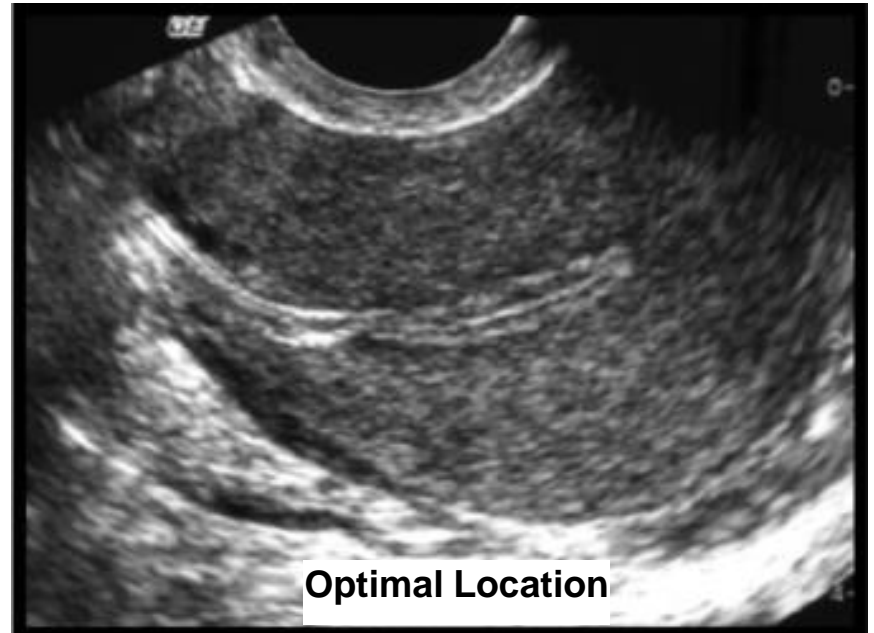


All 3 images should be captured on film and placed in the subject's medical record to document satisfactory insert retention and location

Essure [Instructions for Use].

# Classification of Insert Location: TVU

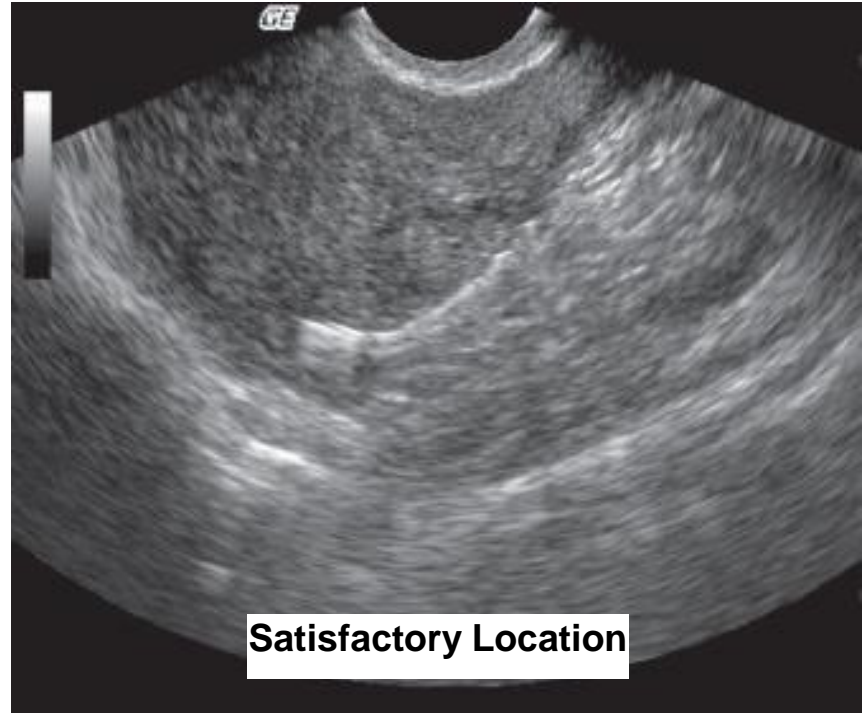
- 1. Insert Identification:** In a single scout image, a portion of each insert must be visualized in the cornua in the transverse or oblique transverse view to ensure bilateral placement and reduce the risk of duplicate imaging of the same insert. The linear axis of the inserts should appear relatively symmetric.
- 2. Optimal Location:** Insert location is optimal when the proximal end of the insert is in contact with the uterine cavity or endometrium, and the linear axis is within the myometrium in the cornua (interstitial portion of the fallopian tube) and can be visualized at or crossing the SUTJ. The portion of the insert located in the fallopian tube may or may not be visualized. The linear axis of the insert must be visualized to confirm it is not coiled or elongated.



Essure [Instructions for Use].

# Classification of Insert Location: TVU (cont'd)

3. **Satisfactory Location:** Insert location is satisfactory when the proximal end of the insert is distal to the endometrium; however, the linear axis is within the myometrium in the cornua (interstitial portion of the fallopian tube) and can be visualized at or crossing the SUTJ. The portion of the insert located in the fallopian tube may or may not be visualized. The linear axis of the insert must be visualized to confirm it is not coiled or elongated.



Essure [Instructions for Use].

# Classification of Insert Location: TVU (cont'd)

4. **Unsatisfactory Location** (insert location is unsatisfactory if a portion of each insert cannot be visualized in the cornua in the transverse or oblique transverse view in one scout image):
- a) **Expulsion:** Suspected if one or both inserts are not identified in the cornua in a transverse view in a single scout image
  - b) **Distal:** Suspected if the proximal end of the insert is not located in the myometrium in the cornua and not crossing or in contact with the SUTJ
  - c) **Proximal:** Suspected if >50% or the majority of the insert is visualized in the uterine cavity or if the linear axis of the insert(s) is visualized in the midline sagittal view
  - d) **Perforation:** Suspected if the linear axis of one or both inserts are parallel to the endometrial stripe in the sagittal view or if the linear axis of an insert is visualized crossing the myometrium in the midline sagittal view
  - e) **Unclassified:** If the linear axis of an insert cannot be identified, suggesting it is coiled, bent, or elongated, insert location is considered unsatisfactory. If the surrounding soft tissue cannot be clearly defined, position is considered unsatisfactory.

Essure [Instructions for Use].

# Assessing Ability to Rely: TVU

- For TVU evaluations with **satisfactory** or **optimal** locations of both inserts:
  - The patient may be told to discontinue her alternative contraception and rely on Essure® for contraception
- If ultrasound evaluation is equivocal or unsatisfactory:
  - The patient must proceed to a modified HSG to evaluate insert location and tubal occlusion
  - The patient must also be instructed not to discontinue her alternative contraception
- **The Essure Confirmation Test with TVU does not assess tubal occlusion**
- Satisfactory and optimal placement, as assessed by TVU, has been demonstrated in clinical studies to be an effective measure of the patient's ability to rely when utilizing the TVU/HSG Confirmation Test Algorithm

Essure [Instructions for Use].

# Essure Confirmation Test: Modified HSG

Essure<sup>®</sup> is contraindicated for patients who have a known allergy to contrast media.

Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure<sup>®</sup>, please see the accompanying [Instructions for Use](#), including Boxed Warning.

# Essure Confirmation Test with Modified HSG

- Essure Confirmation Test with modified HSG evaluates<sup>1</sup>:
  - Bilateral insert location
  - Bilateral tubal occlusion
- According to the Essure TVU/HSG Confirmation Test Algorithm, a modified HSG is required when<sup>1</sup>:
  - The patient is not a candidate for confirmation testing with TVU
  - The findings of confirmation testing with TVU are equivocal or unsatisfactory
- A modified HSG is always an acceptable first-line option for the Essure Confirmation Test
- When using a modified HSG for the Essure Confirmation Test, both insert location and tubal occlusion must be rated satisfactory for the patient to discontinue alternative contraception<sup>1</sup>

1. Essure [Instructions for Use].

# Performing the Essure Confirmation Test with Modified HSG

- Unlike an infertility HSG, the Essure Confirmation Test with modified HSG is performed by instilling contrast media (dye) slowly and gently until the uterine cornua are distended. An increase in intrauterine pressure beyond that needed to produce cornual distention serves no purpose and should be avoided<sup>1,2</sup>
- To produce satisfactory images, adherence to the following guidelines is recommended<sup>1</sup>:
  1. Obtain good cornual filling so that uterine cavity silhouette is clearly seen
  2. Place fluoroscopy beam as close to anterior/posterior (A/P) projection as possible
  3. Do not dilate cervix unless necessary; if dilation occurs, maintain a good cervical seal
  4. Downward traction on cervical tenaculum may be required for midpositional uteri
  5. Remove speculum prior to fluoroscopy for best visualization of uterine anatomy
  6. Take a minimum of 6 radiographs to assess insert location and tubal occlusion

1. Essure [Instructions for Use].

2. Data on file, Bayer HealthCare Pharmaceuticals Inc.

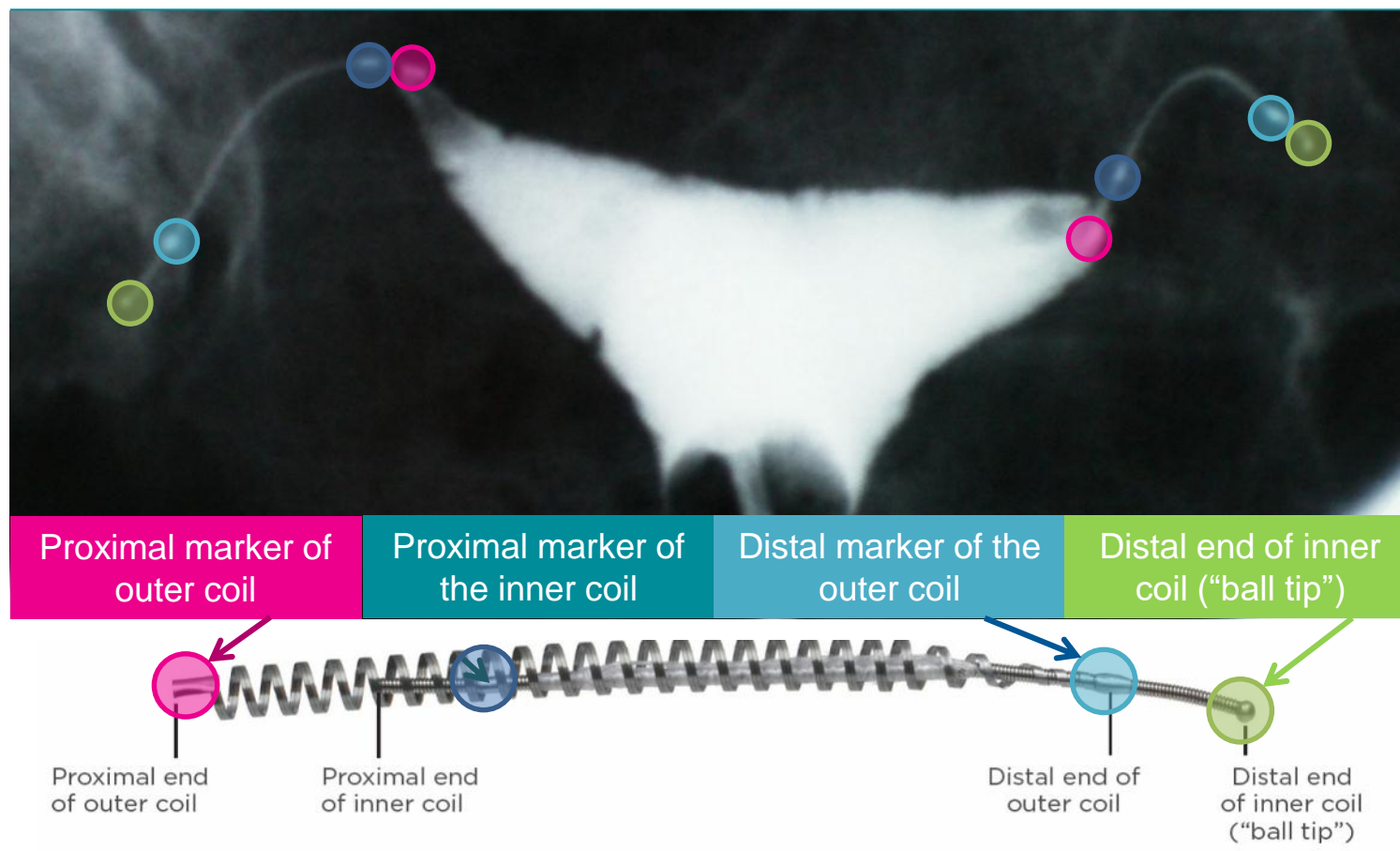
# Performing the Essure Confirmation Test with Modified HSG

- 6 specific images recommended<sup>1</sup>:
  1. Scout film
  2. Minimal fill
  3. Partial fill
  4. Total fill
  5. Magnification of the right uterine cornua showing the insert in the right fallopian tube
  6. Magnification of the left uterine cornua showing the insert in the left fallopian tube
- Radiology report must include:
  - Number of inserts
  - Location of each insert
  - Tubal occlusion assessment for each side, and
  - Description of unusual findings

During the evaluation of the modified HSG films, the 4 radiopaque markers should be identified for each insert.

1. Essure [Instructions for Use].

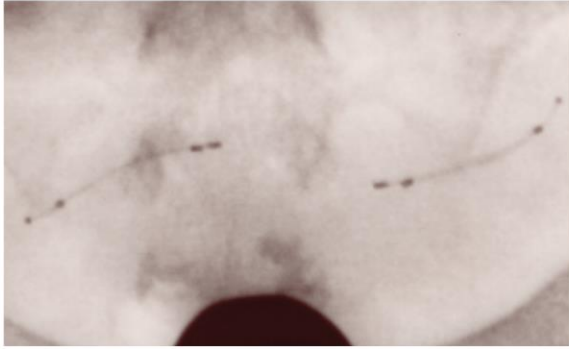
# Radiographic Markers: Modified HSG



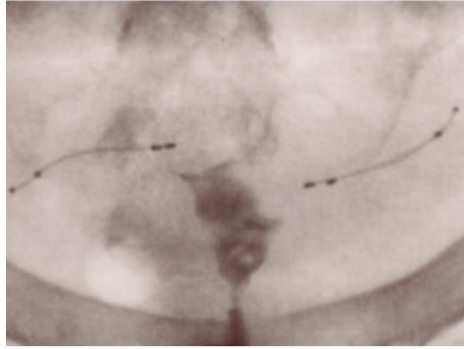
1. Essure [Instructions for Use].

27 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

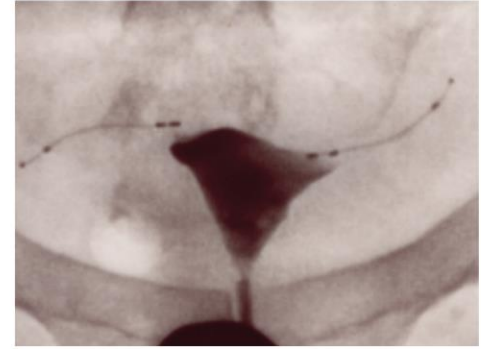
# Recommended Views: Modified HSG



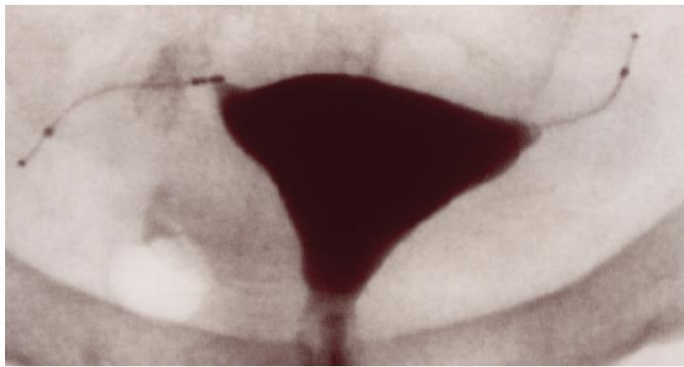
Scout Film



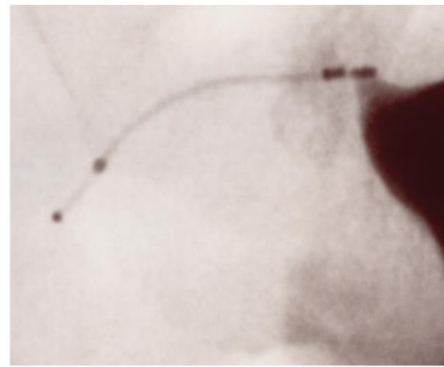
Minimal Fill



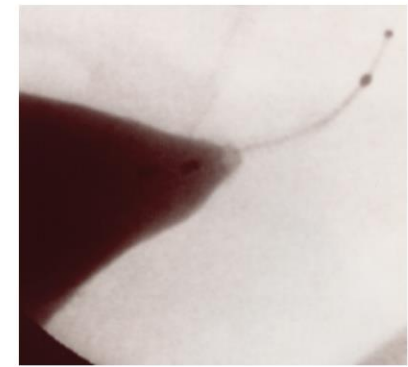
Partial Fill



Total Fill

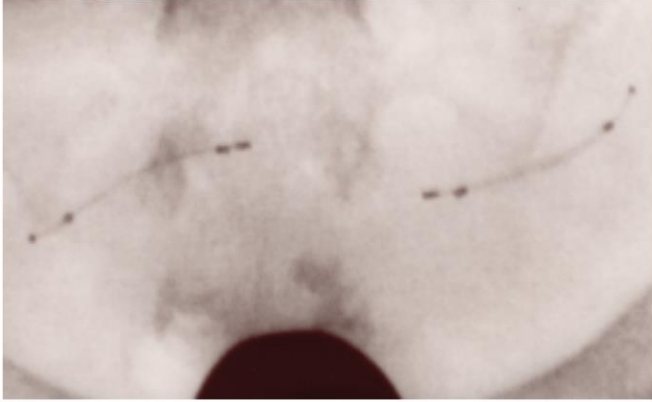


Magnification of  
the Right Cornua



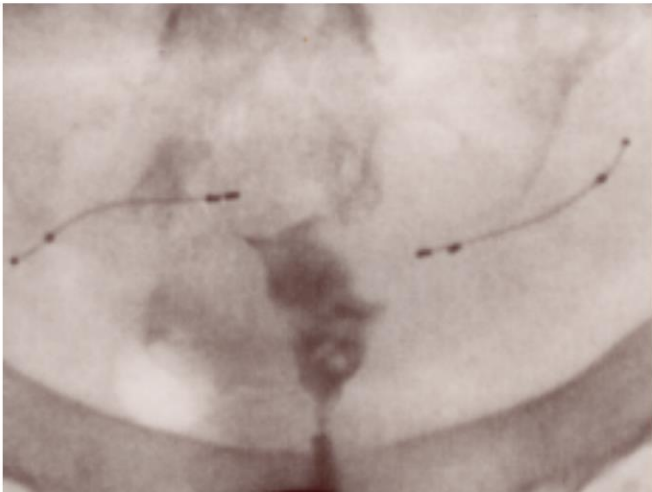
Magnification of  
the Left Cornua

# Recommended Views: Modified HSG (cont'd)



## Scout film

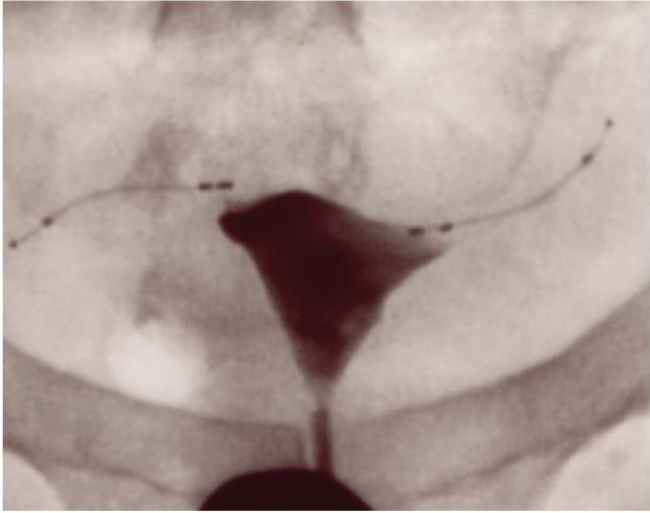
- First image captured, before injecting contrast
- Capture image of uterus and inserts without contrast
- Inserts should be clearly seen; note the lie and curvature of the inserts
- Note the 4 radiographic markers on each insert



## Minimal fill of the Cavity

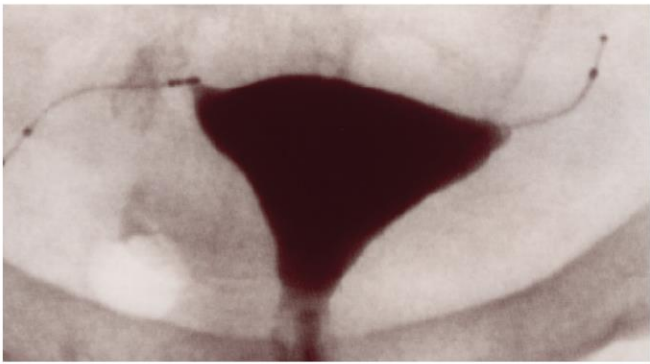
- Capture an image of the uterus after a small amount of contrast infusion
- No contrast should be leaking from the cervix if an adequate seal is maintained
- The uterine cavity should start to opacify. Contrast may not have reached the uterine cornua
- If the uterine cavity silhouette is not seen in a nearly A/P projection, adjust the fluoroscopy beam and/or the patient

# Recommended Views: Modified HSG (cont'd)



## Partial fill of the Cavity

- 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

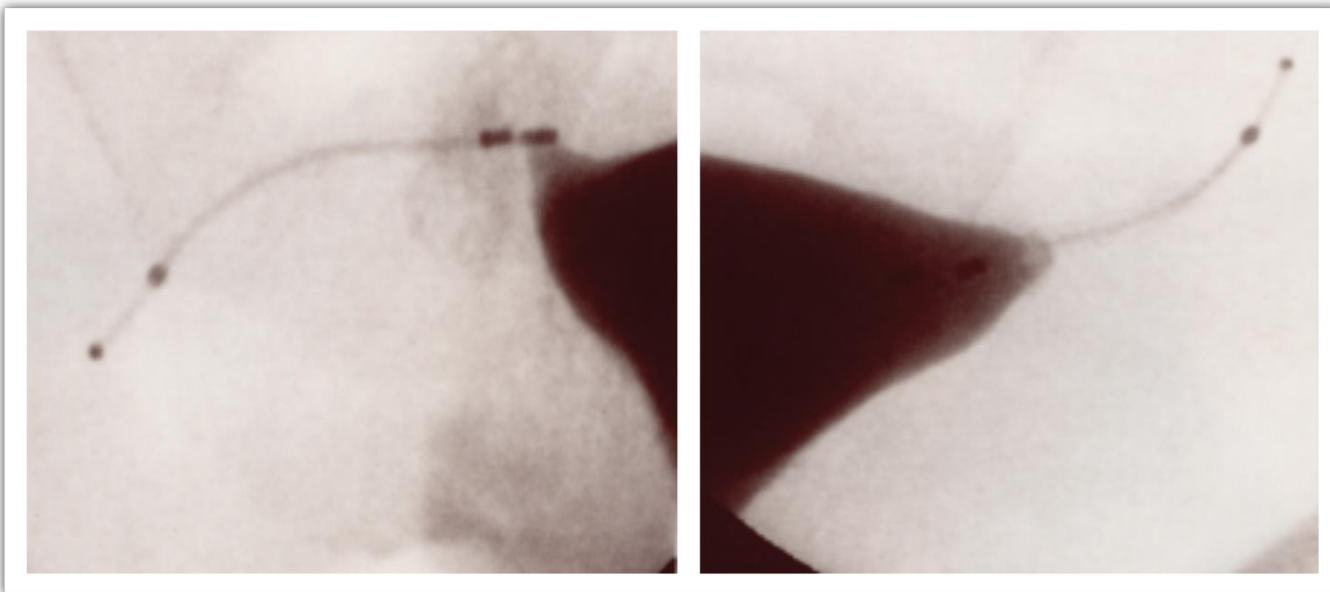


## Total fill of the Cavity

- Capture an image of the uterus when the cavity is completely filled and the cornua are distended
- Ideally, contrast should reach the proximal end of the inserts

**CAUTION:** Avoid excessive intrauterine pressure beyond this point to avoid undue patient discomfort and vasovagal reaction.

## Recommended Views: Modified HSG (cont'd)



### Magnifications of 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

# Interpreting the Essure Confirmation Test with Modified HSG

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- Interpreting the Essure Confirmation Test involves several steps:
  - Assessing the quality of the study
  - Assessing insert location
  - Assessing tubal occlusion
  - Assessing ability to rely

1. Essure [Instructions for Use].

# Assessing Test Image Quality: Modified HSG

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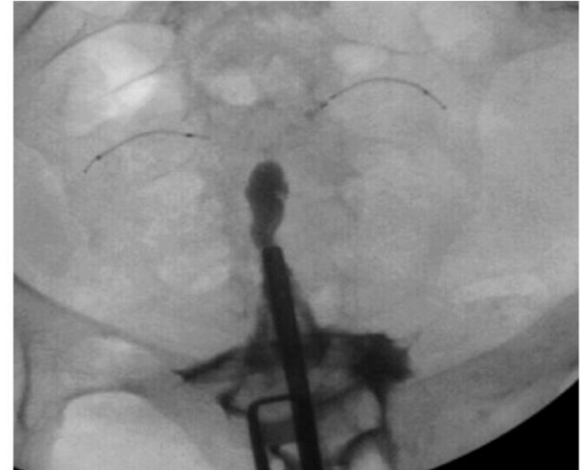
The Essure Confirmation Test is considered inadequate/indeterminate and will need to be immediately repeated if:

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

# Inadequate or Indeterminate Test Films: Modified HSG



Filling defect in the left cornua

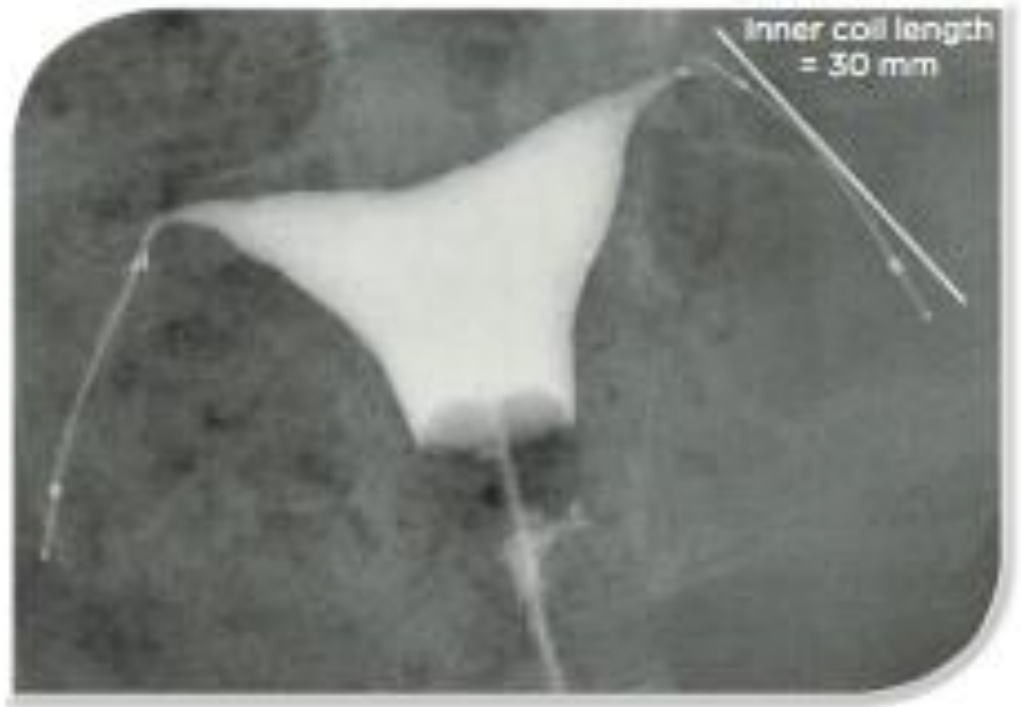


Inadequate filling

# Evaluating Insert Location: Modified HSG

The distance from the filled uterine cornua to the proximal end of the inner coil 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 in length



# Evaluating Insert Location: Modified HSG

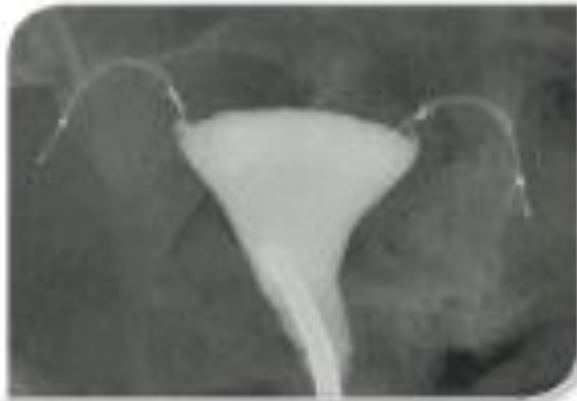
Possible insert locations<sup>1</sup>:

1. Satisfactory
2. Unsatisfactory
  - Proximal location
  - Expulsion
  - Distal location
  - Perforation
  - Peritoneal location

If location is unsatisfactory, instruct patient to not rely on the inserts for contraception.<sup>2</sup>

1. Essure [Instructions for Use].

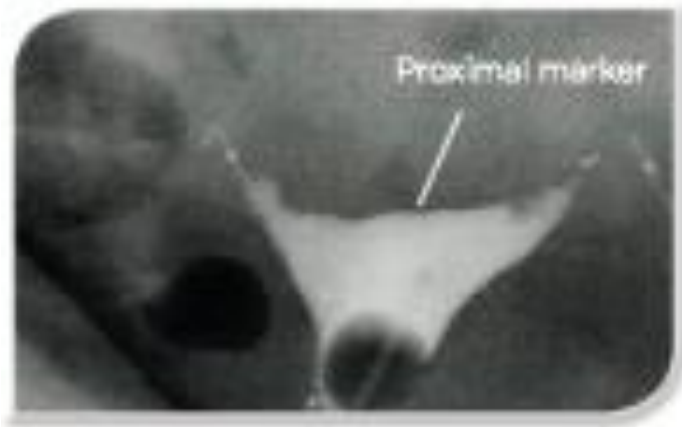
# Satisfactory Location<sup>1,2</sup>



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 end of the inner coil is  $\leq 30$  mm into the tube from where contrast fills the uterine cornua.

1. Essure [Instructions for Use].

# Unsatisfactory Location: Proximal



- **Proximal location**
  - A proximal location is defined as:  $\geq 50\%$  of the inner coil is trailing into the uterine cavity
- **Management**
  - Advise the patient not to rely on Essure<sup>®</sup>; continue alternative contraception or consider incisional sterilization

# Unsatisfactory Location: Expulsion

- **Expulsion of the insert**

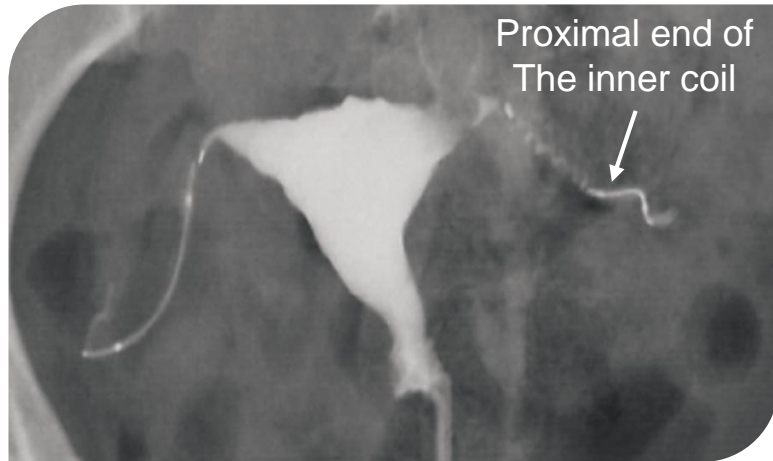
- One or both inserts are not present in the radiographic image or insert lies completely in the uterine cavity

- **Management**

- Advise patient not to rely on Essure®
- Obtain an image of the abdomen to differentiate a device that has been expelled from the body versus one that is in a peritoneal location
- 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 with modified HSG results
- Also counsel patient on incisional sterilization or remaining on alternative contraception



# Unsatisfactory Location: Distal



- **Distal location of the insert**
  - The insert is in the tube, but the proximal end of the inner coil is >30 mm from the cornua
- **Management**
  - Advise patient not to rely on Essure®
  - Counsel patient on incisional sterilization or remaining on alternative contraception
  - If tube is occluded, advise patient on potential false-positive Essure Confirmation Test with modified HSG results

# Unsatisfactory Location: Perforation

- **Perforation**

- The insert has completely or partially perforated the uterus or tube (eg, embedded in the myometrium or completely in the peritoneal cavity)

- **Management**

- Advise patient not to rely on Essure® for contraception
- If tube is patent and no part of an Essure® insert is in the fallopian tube, 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
- Location of insert(s) should be evaluated and a decision should be made as to whether the insert should be left in situ or removed



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

# Managing Unsatisfactory Location: Peritoneal

- **Peritoneal location**

- Peritoneal location means the insert is found within the peritoneal cavity and is not located within the tube

- **Management**

- Advise patient not to rely on Essure® for contraception
- If tube is patent and no part of an Essure® insert is in the fallopian tube, 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
- Location of insert(s) should be evaluated and a decision should be made as to whether the insert should be left in situ or removed

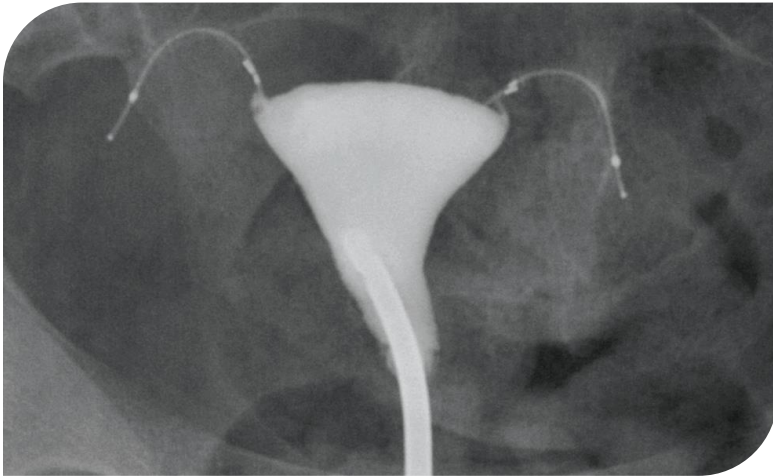


# Evaluating Tubal Occlusion

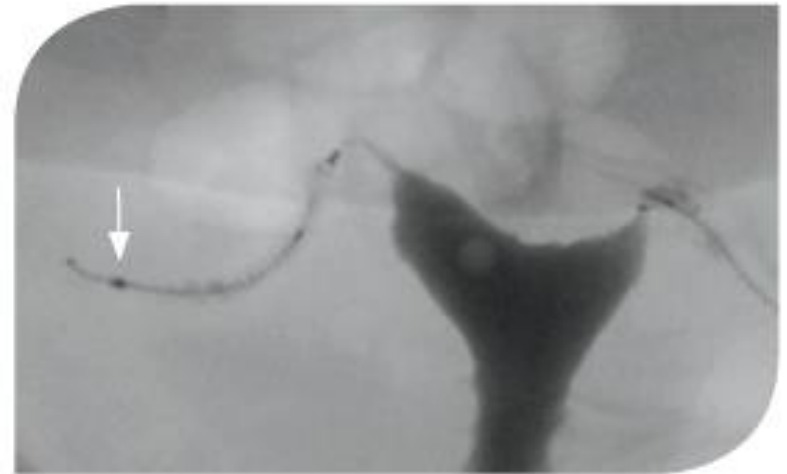
---

- After evaluating insert location, determine whether contrast is visible beyond the insert
  - Note any degree of proximal tubal filling, even if the tube is occluded
- Satisfactory occlusion is when:
  - The tube is occluded at the cornua, or
  - Contrast is seen within the tube but not past the distal end of the outer coil

# Evaluating Tubal Occlusion: Satisfactory Occlusion



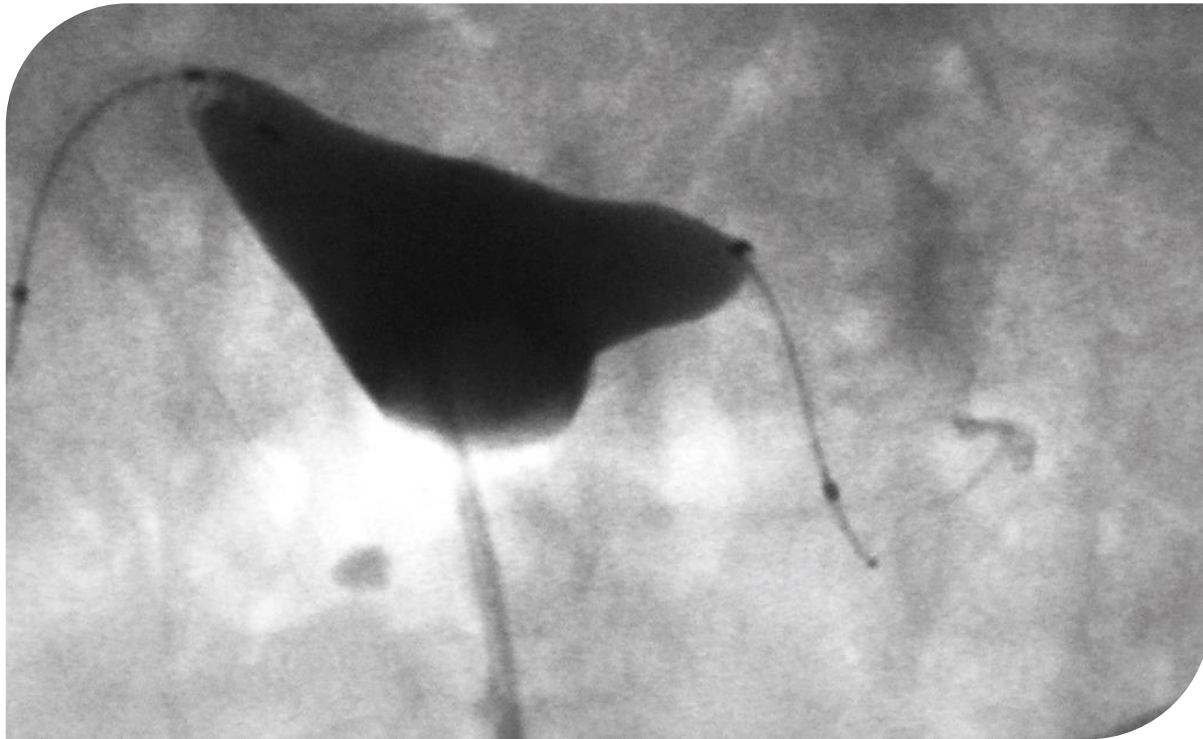
Bilateral tube occlusions  
at the cornua



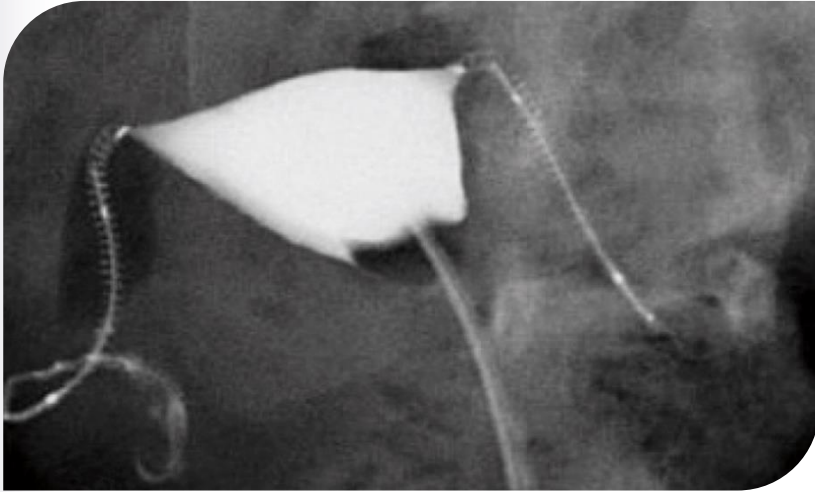
Contrast is visible within the  
tube but not past the distal  
end of the outer coil

# Evaluating Tubal Occlusion: Unsatisfactory Occlusion

Unsatisfactory occlusion is noted when contrast is visible beyond the distal end of the outer coil or in the peritoneal cavity.



# Evaluating Tubal Occlusion: Unsatisfactory Occlusion (cont'd)



- **Management**

- 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 at least 3 more months and have a repeat Essure Confirmation Test with modified HSG
- If patency is again documented on the repeat Essure Confirmation Test with modified HSG, continue to advise the patient not to rely on Essure

# Assessing Ability to Rely on Essure® Based on Modified HSG

If the 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 with modified HSG in 3 months. If occlusion is still unsatisfactory, instruct the patient not to rely on Essure® for contraception

Essure [Instructions for Use].

# Essure Confirmation Test: Summary

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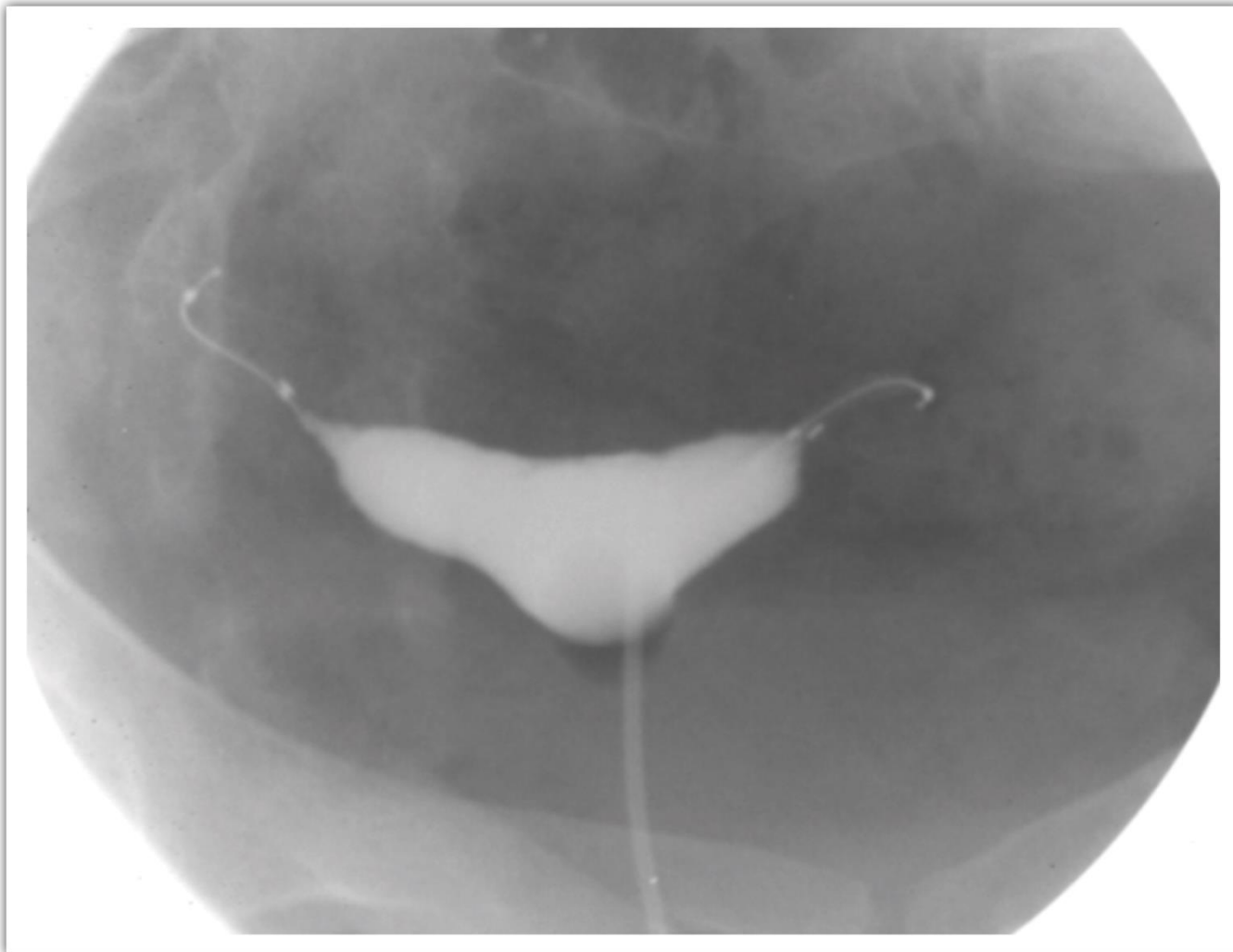
- Required 3 months post-placement to determine whether a patient can rely on Essure®
  - Evaluate insert retention and location
- The test must show either bilateral satisfactory insert location (when using TVU) or bilateral satisfactory insert location and occlusion (when using a modified HSG) in the fallopian tubes before the patient can rely on Essure for contraception
  - Healthcare providers who utilize the Essure Confirmation Test with TVU must complete training administered by Bayer and documented by a certificate of completion
- It is important to understand how to manage a patient if the Essure Confirmation Test does not show satisfactory location and/or occlusion
- Please see the Essure® Instructions for Use and Clinical Resource/Physician Training Manual for full details

# Essure Confirmation Test Images and Case Studies

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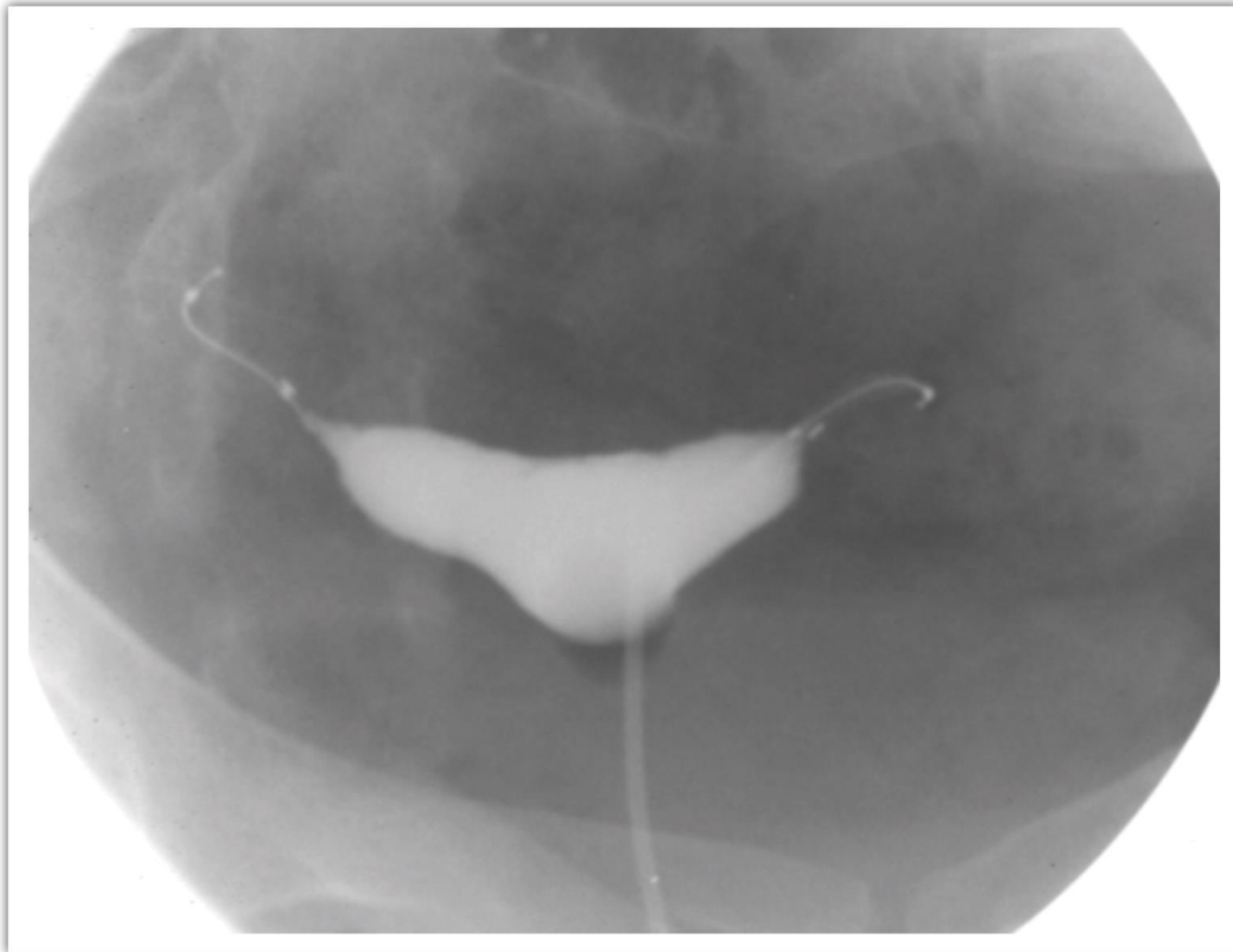
Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

# Case #1



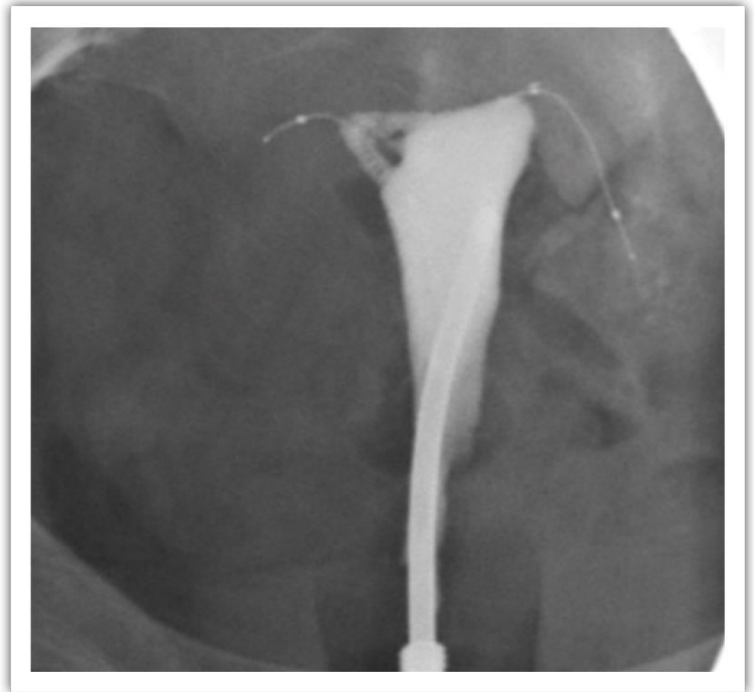
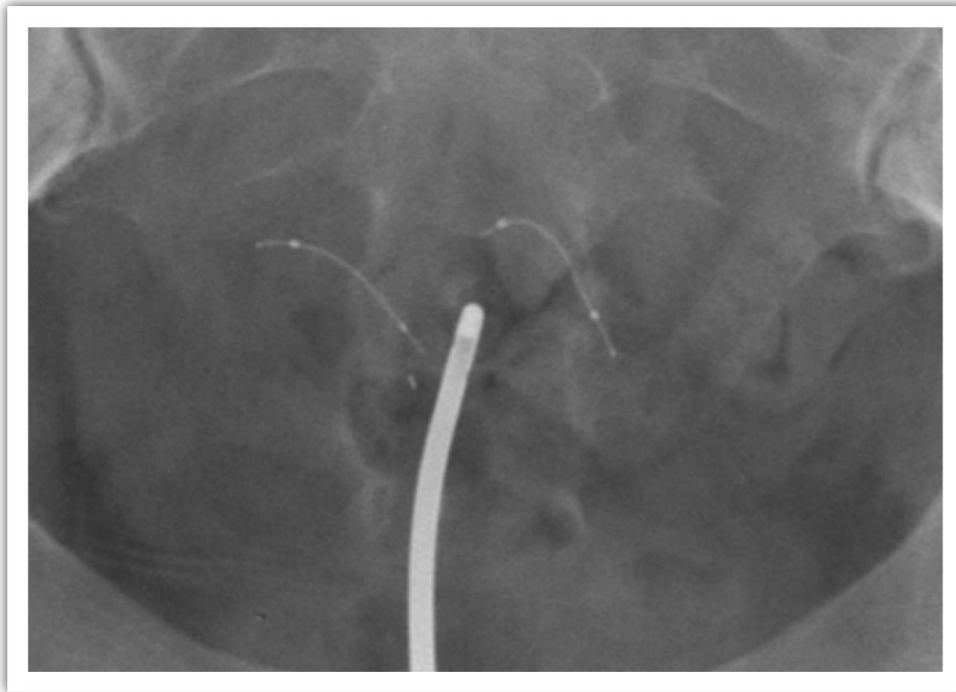
50 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

# Case #1: Satisfactory Location and Occlusion

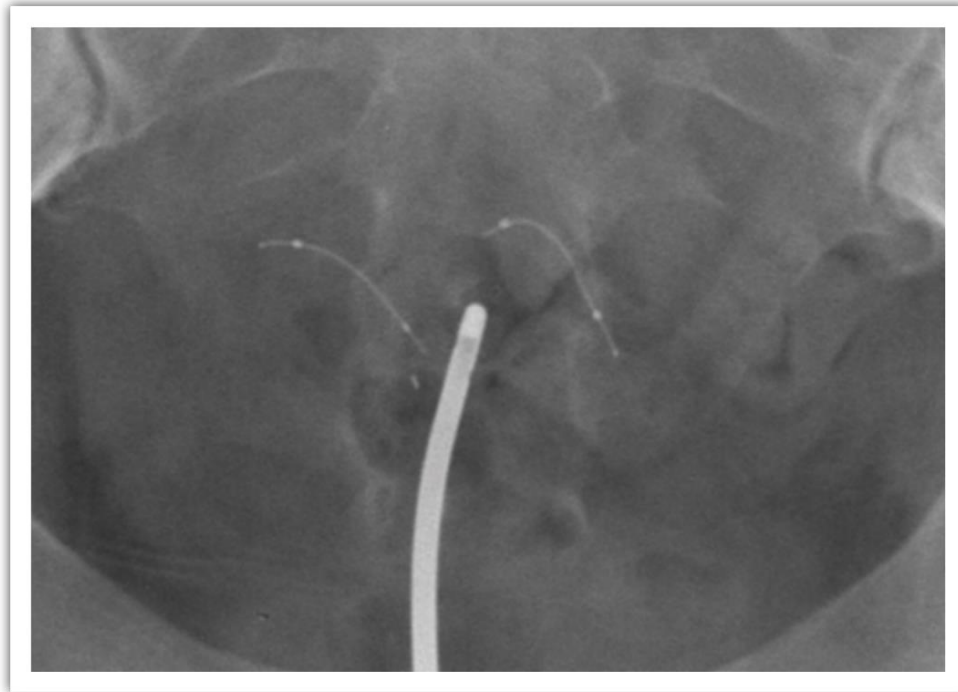


51 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #2



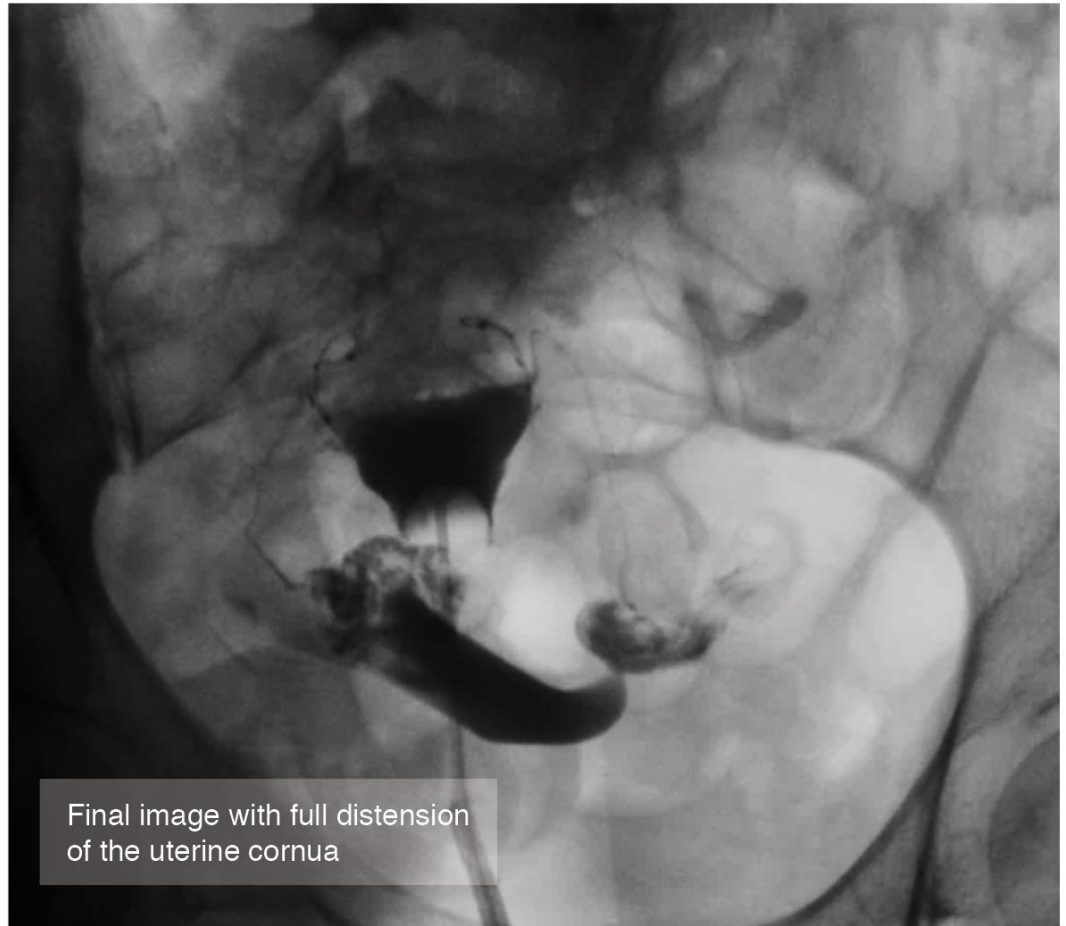
## Case #2: Proximal Location



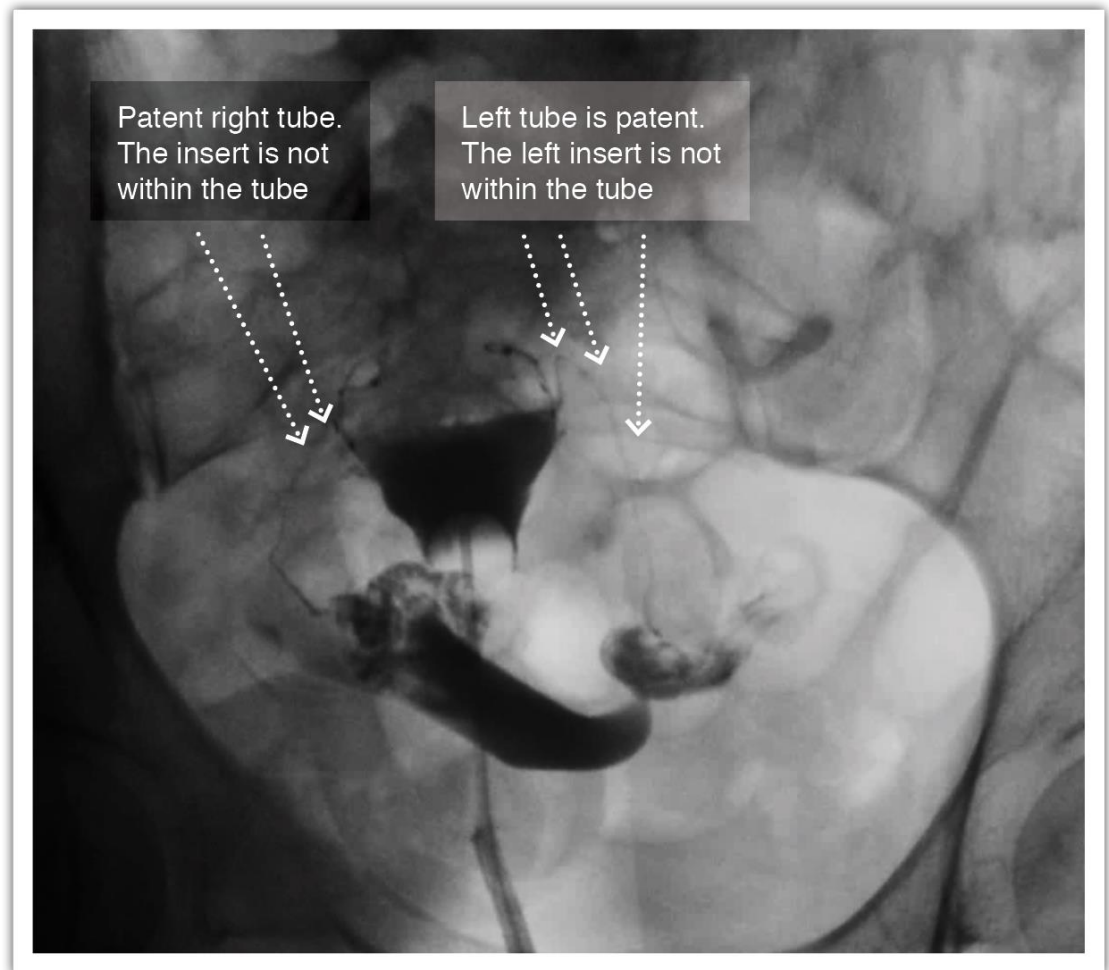
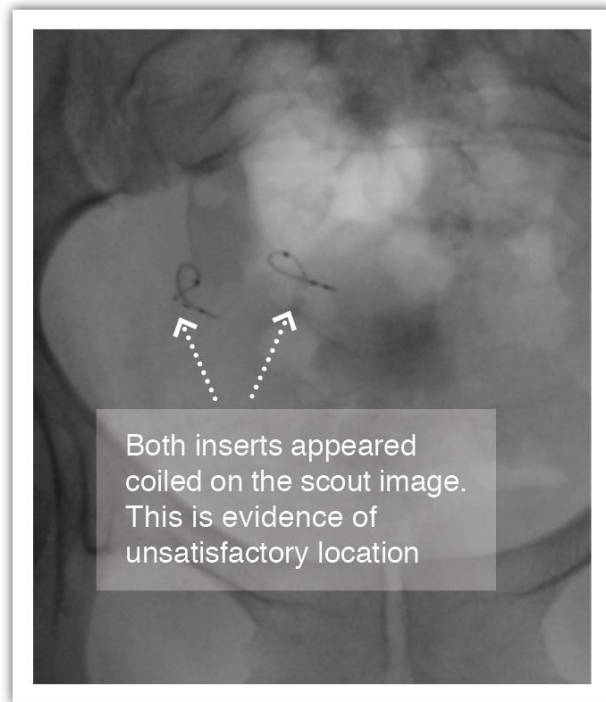
## Case #3



Scout image



## Case #3: Bilateral Perforation

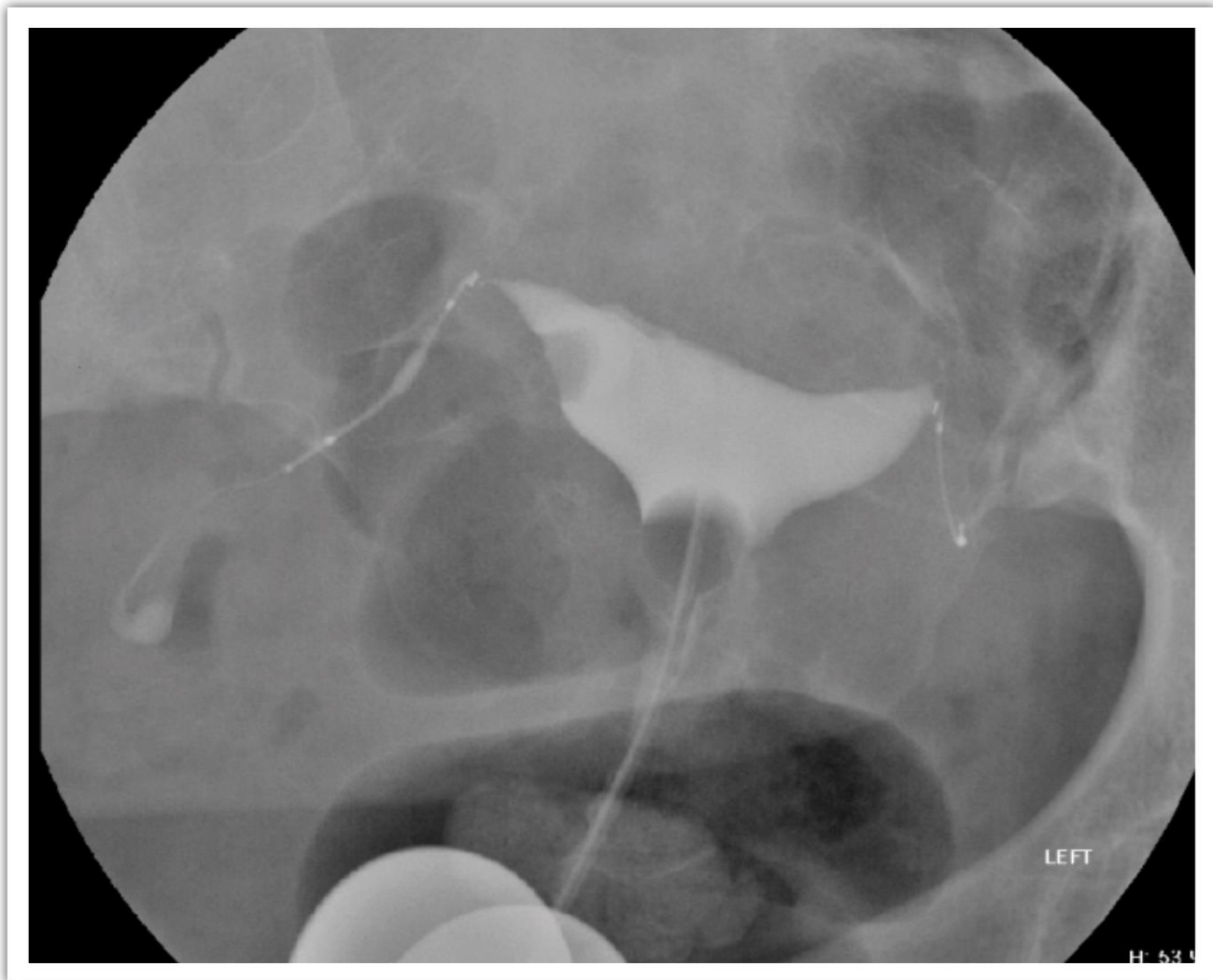


## Case #4



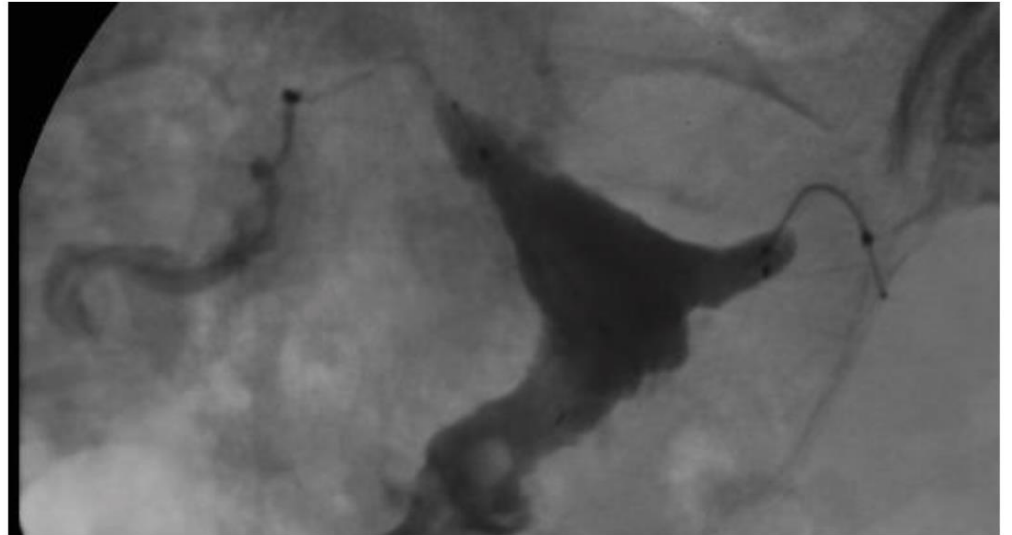
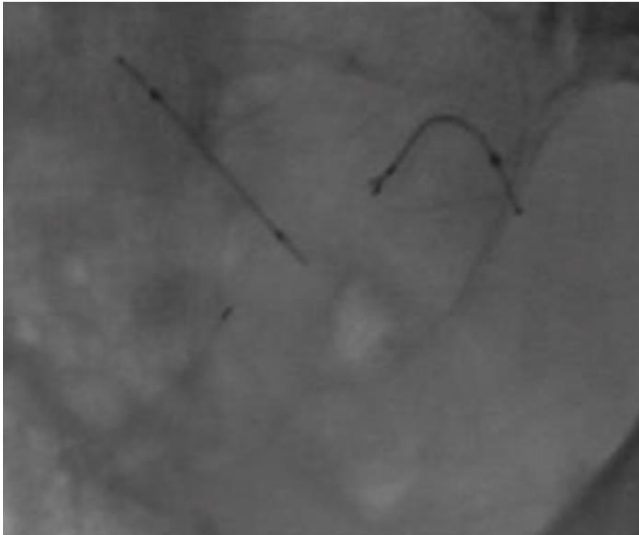
56 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #4: Patency With Satisfactory Location

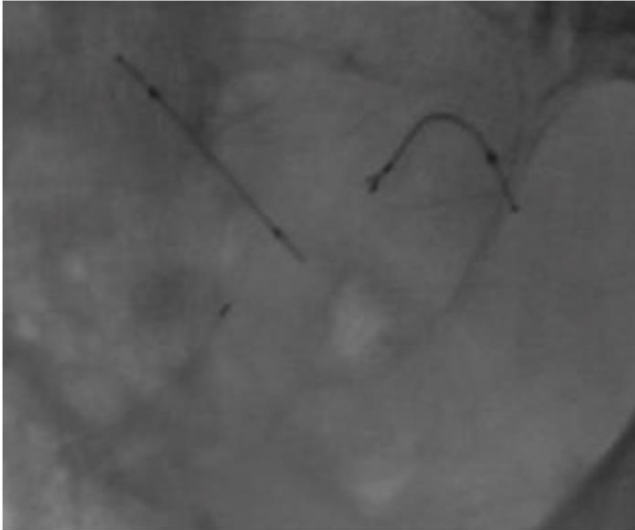


57 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

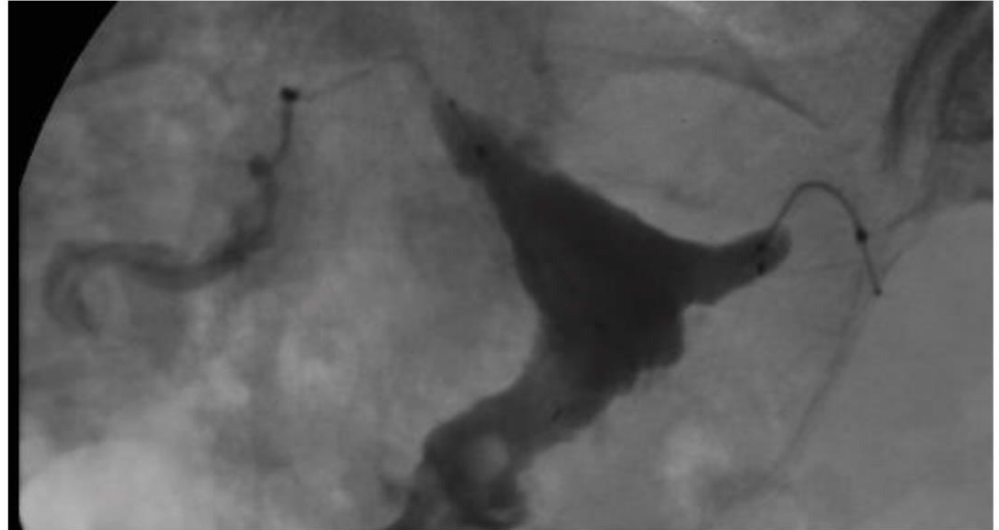
## Case #5



## Case #5: Expulsion

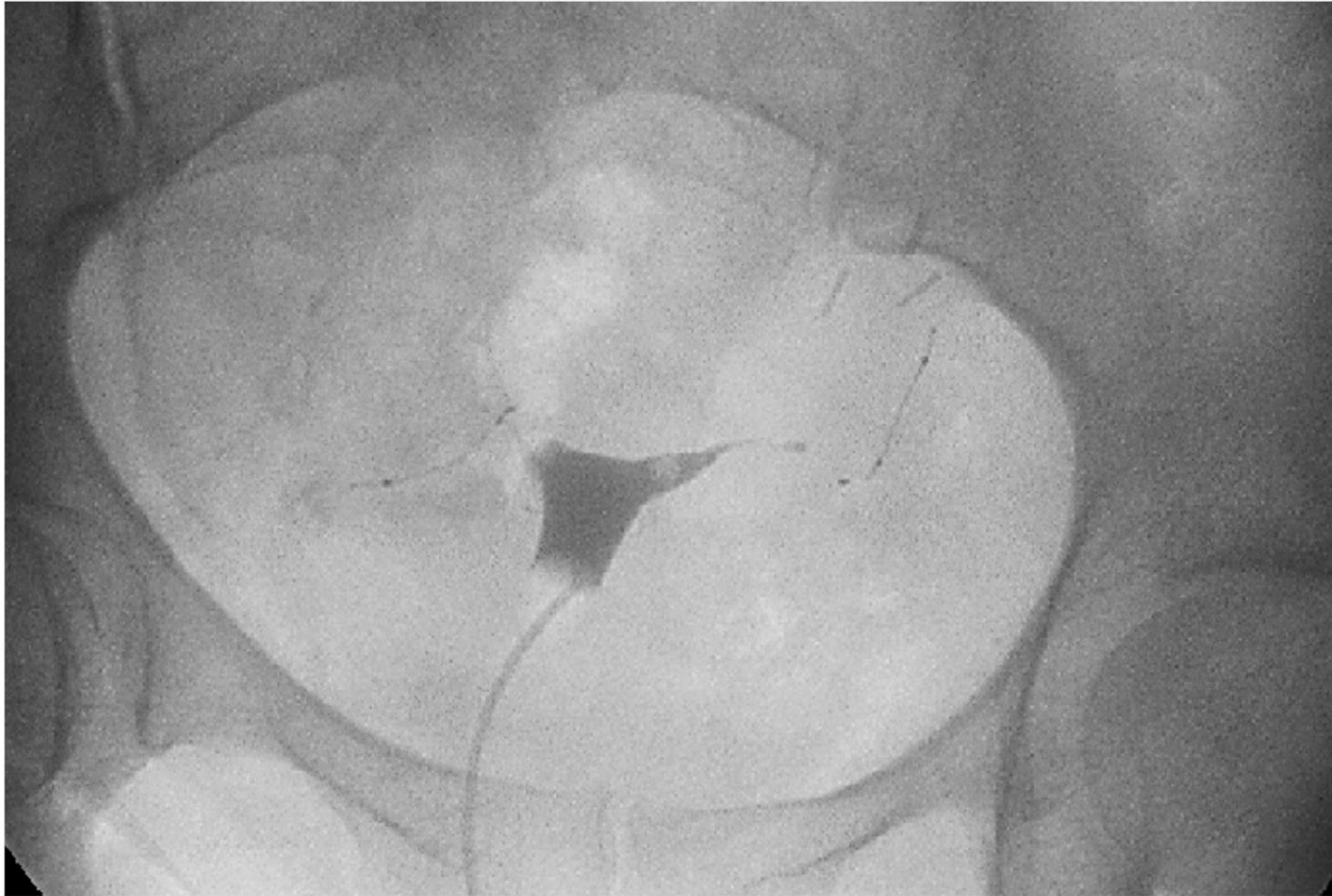


Right insert looks very straight on the scout image and the four markers do not line up. Inserts are asymmetrical



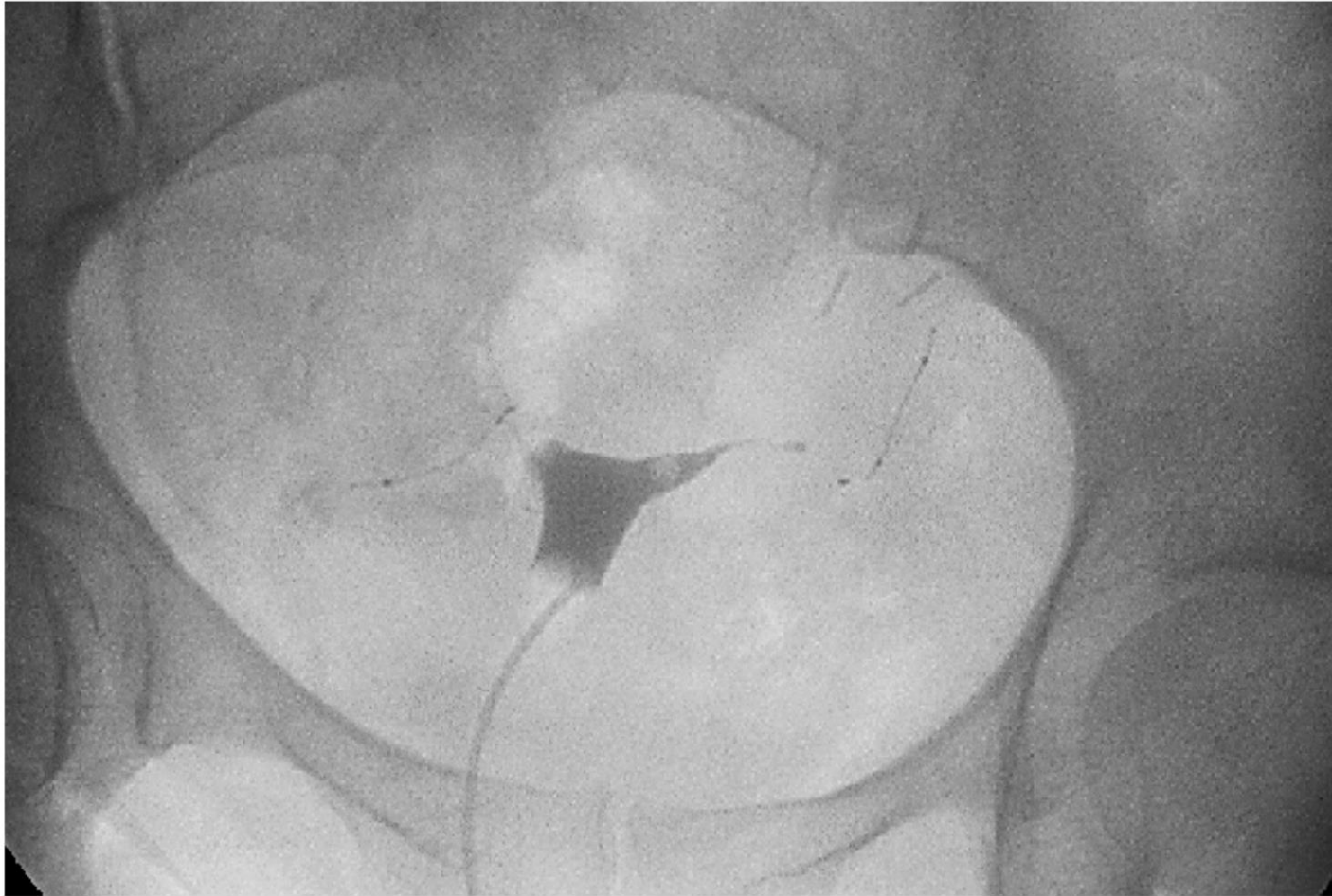
The entire right insert is within the uterine cavity and the right tube is patent

## Case #6



60 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #6: Distal Location

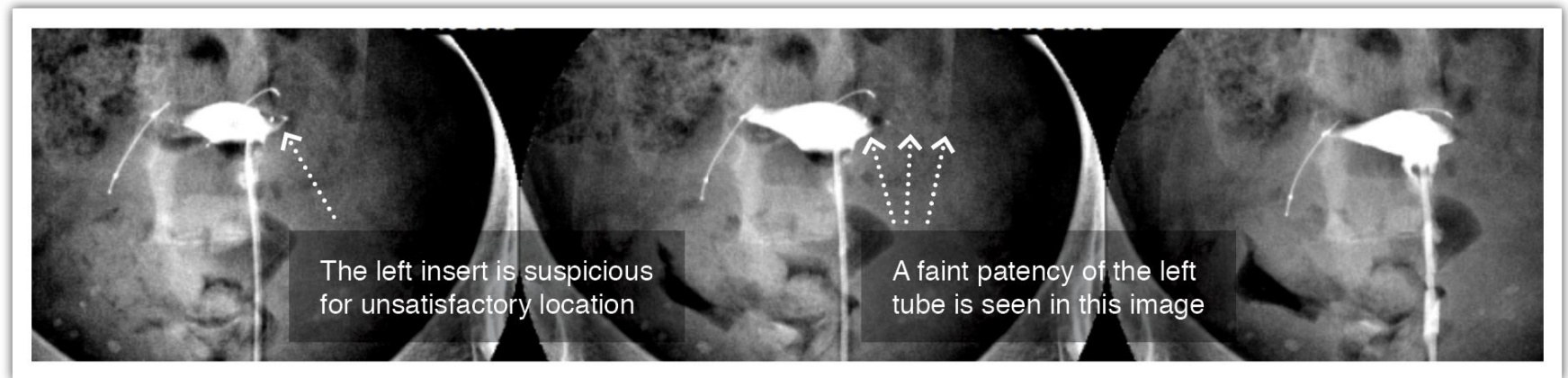


61 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #7

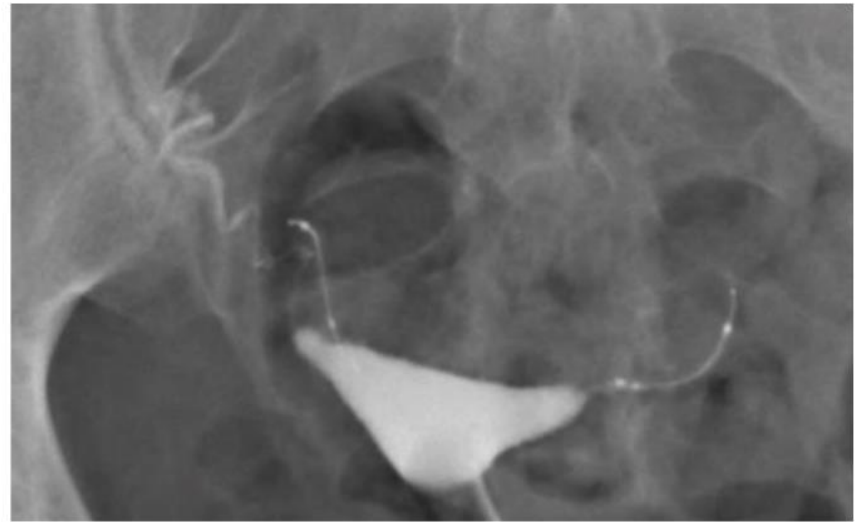


## Case #7: Perforation

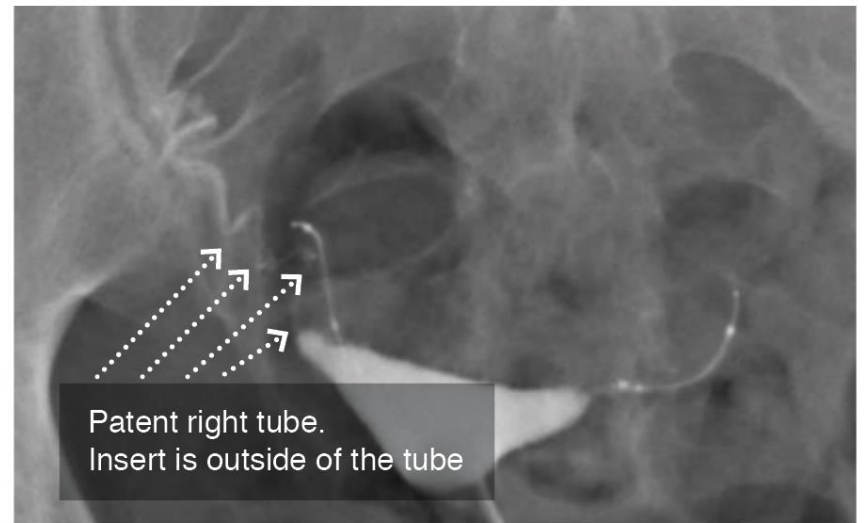
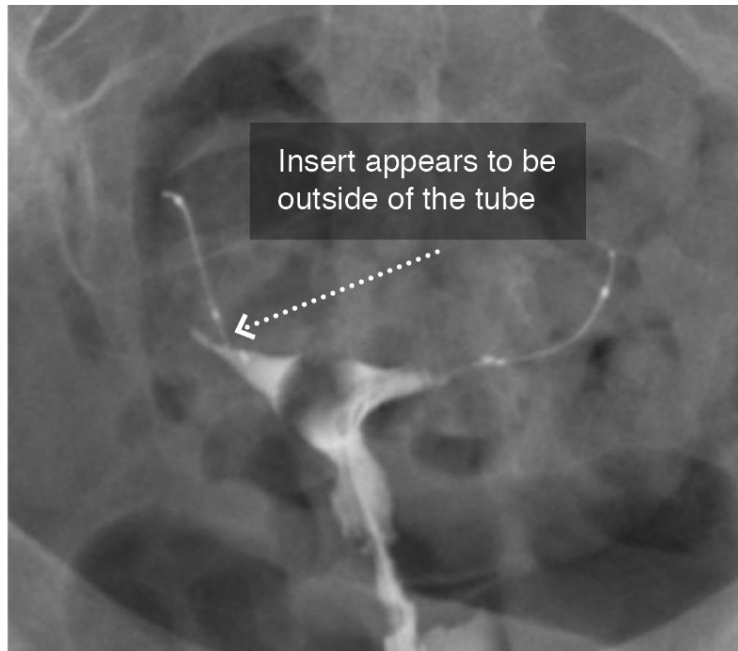


Radiology report noted bilateral occlusion of tubes. Patient told to rely. Patient returned to doctor 12 weeks pregnant 18 months after Essure® placement

## Case #8



## Case #8: Perforation



## Case #9



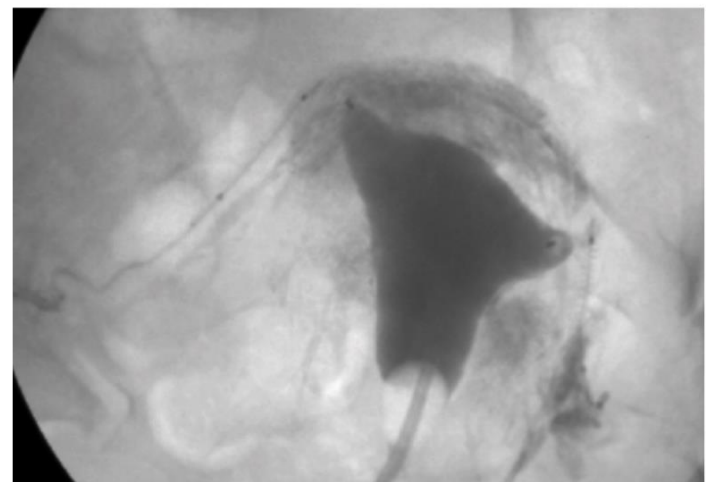
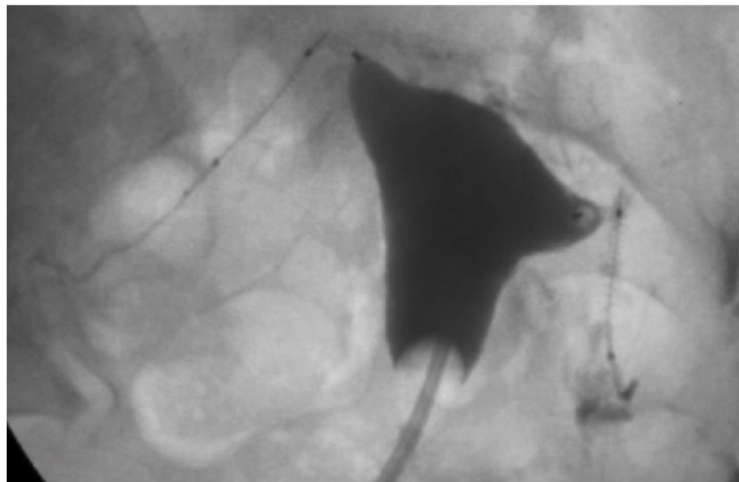
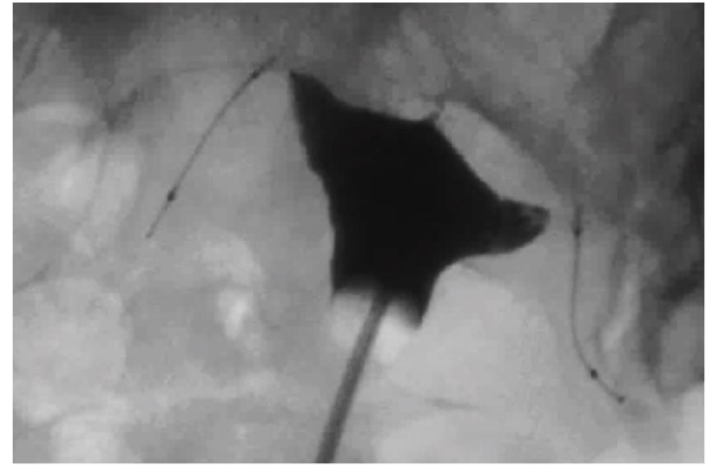
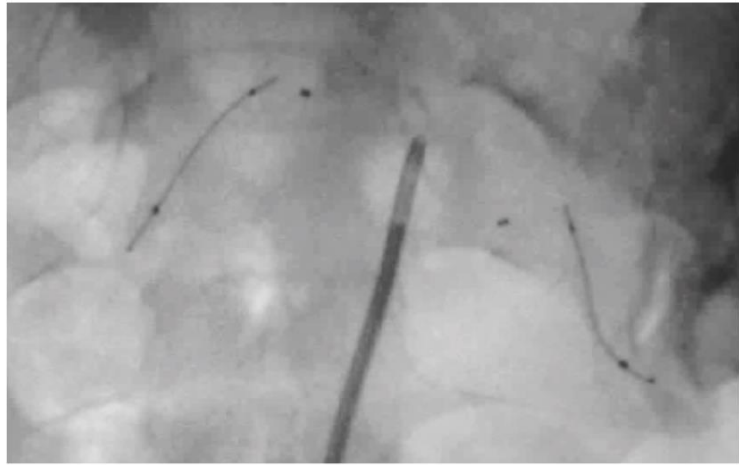
66 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #9: Satisfactory Location and Occlusion



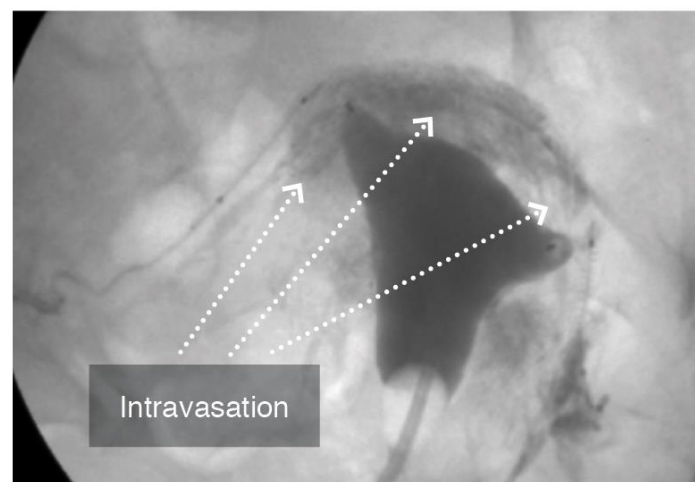
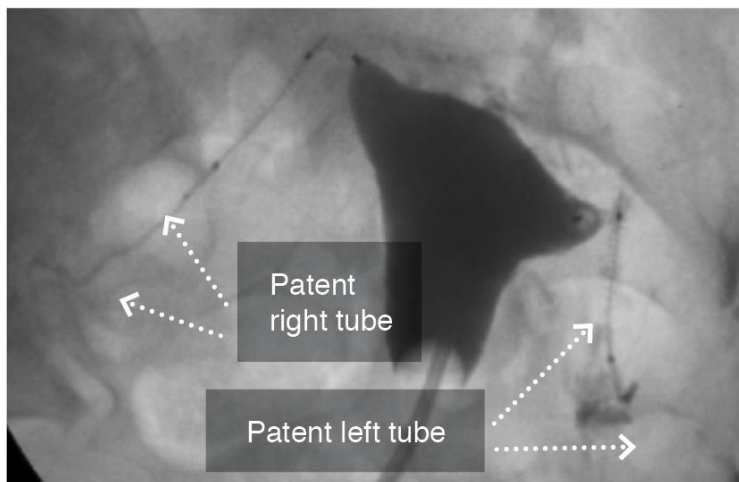
67 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

# Case #10

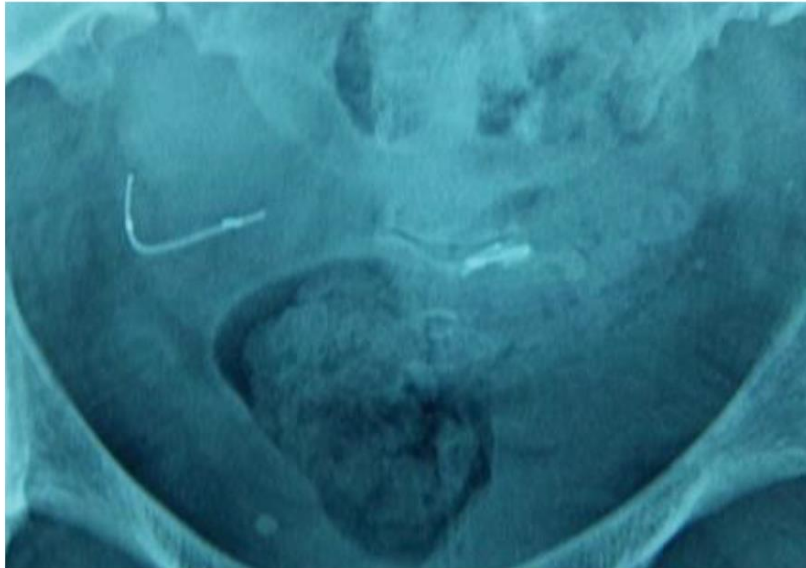


68 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

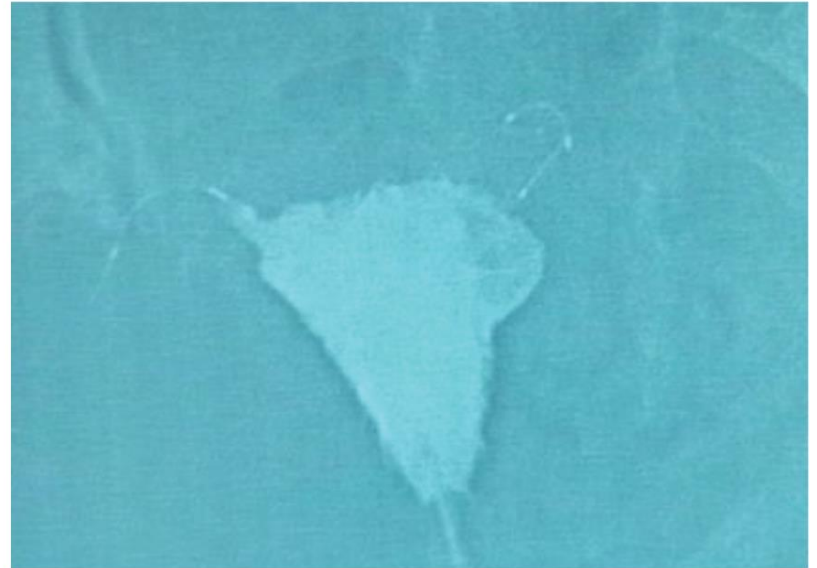
## Case #10: Eventual Patency With Satisfactory Location



# Case #11

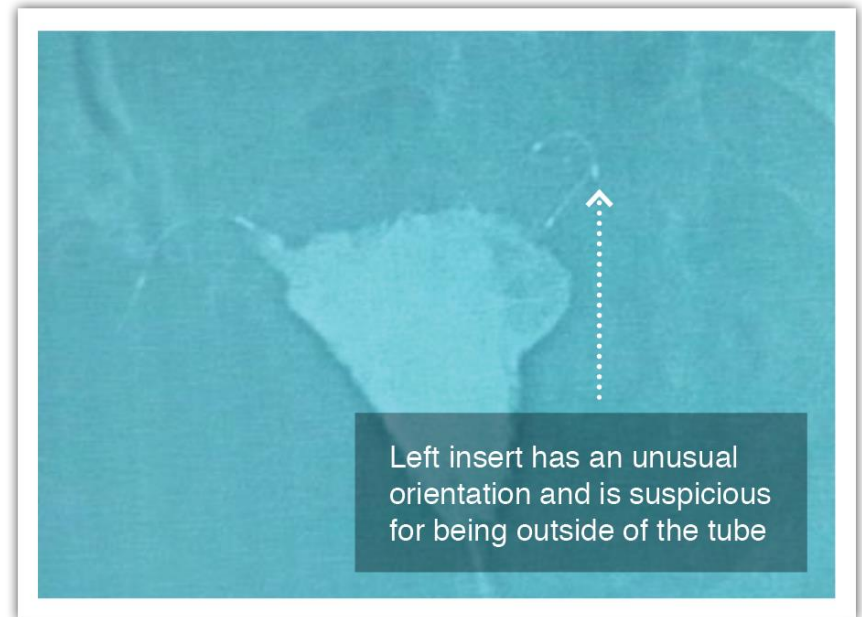
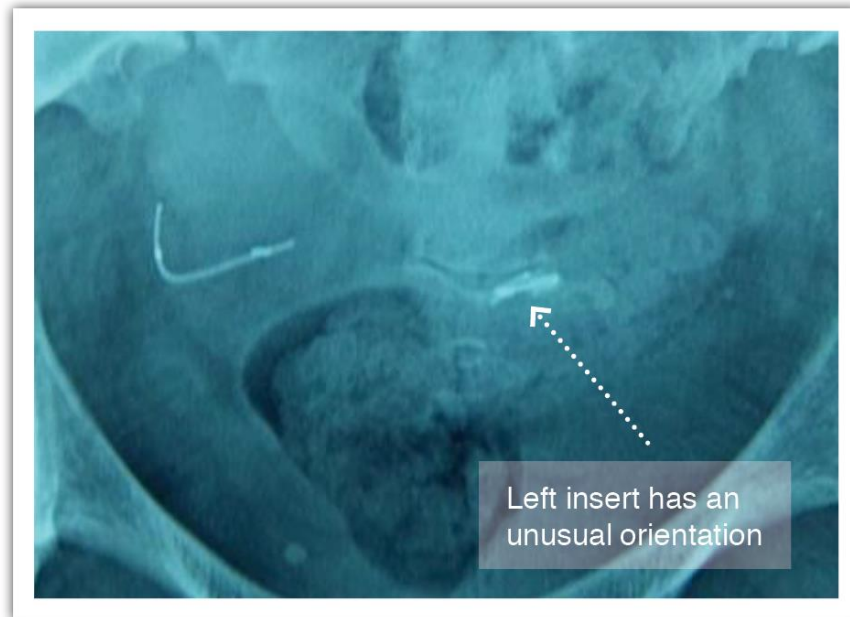


Scout image



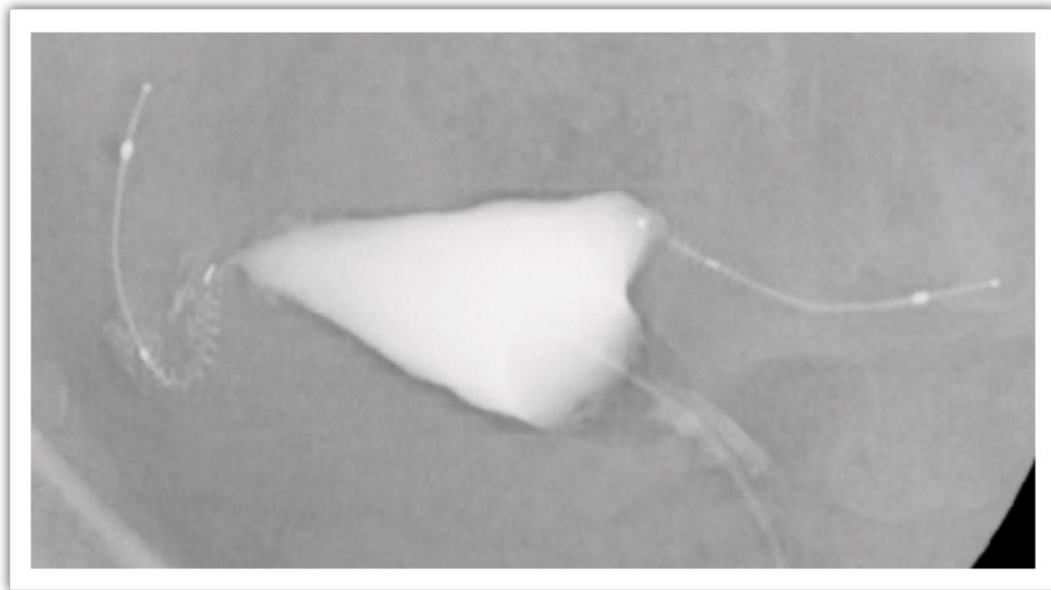
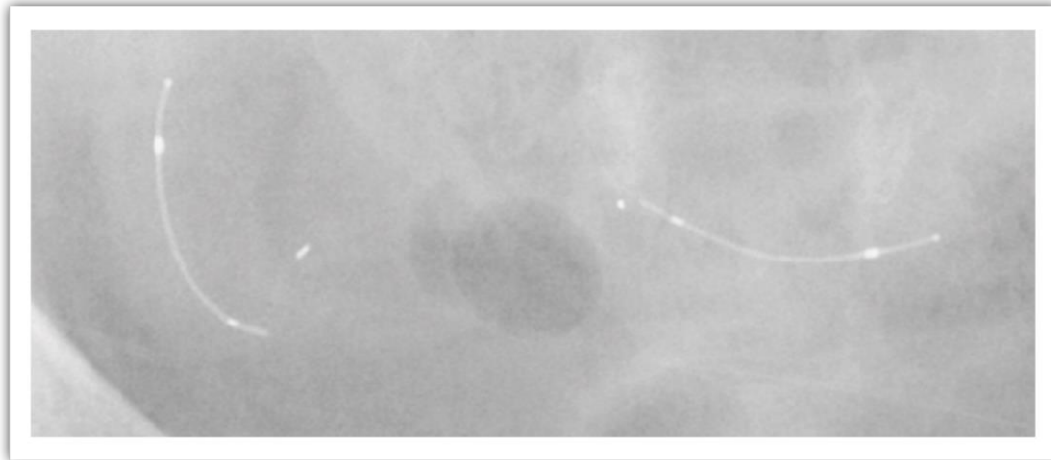
Final image

# Case #11: Perforation



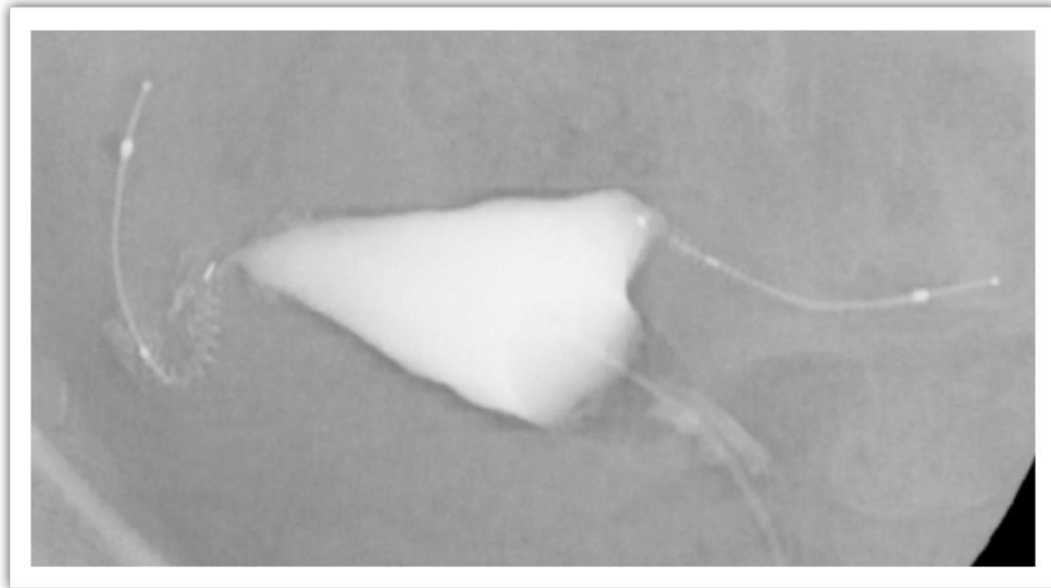
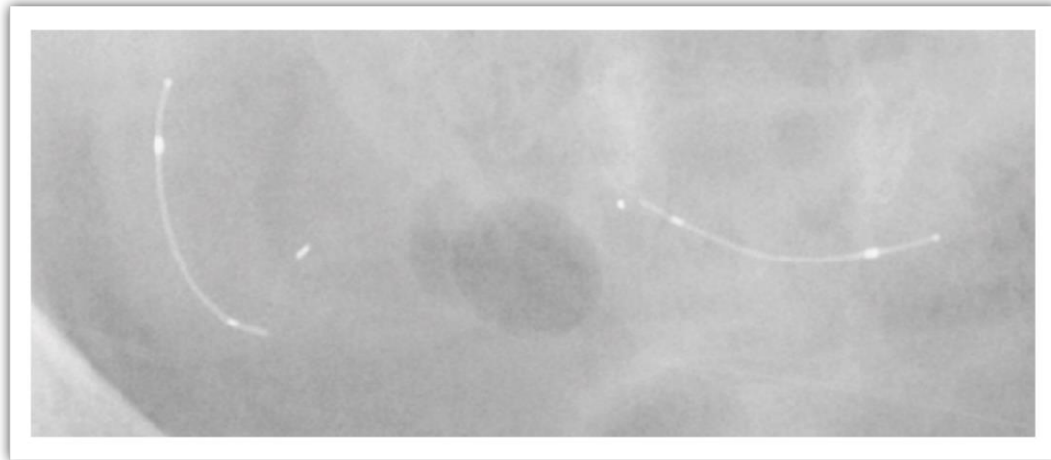
Radiology report noted two inserts with bilateral tubal occlusion. Patient told to rely on Essure® for contraception. She returned to her MD six months later and was diagnosed with an intrauterine pregnancy

## Case #12



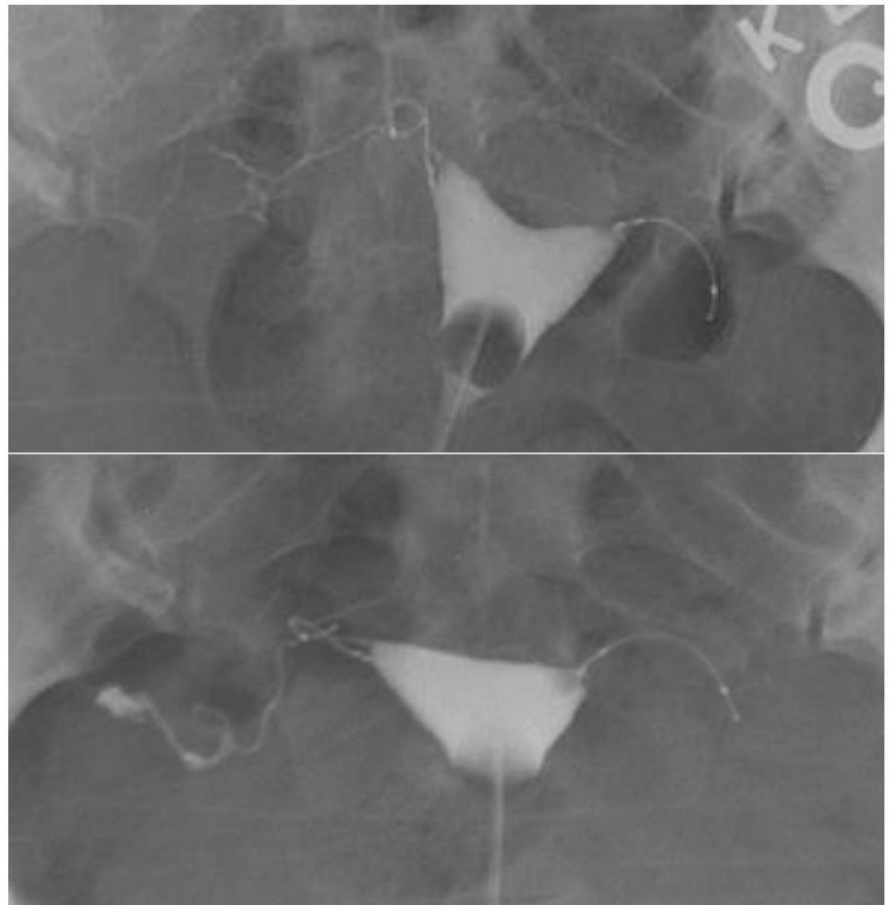
72 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #12: Stretched Outer Coils



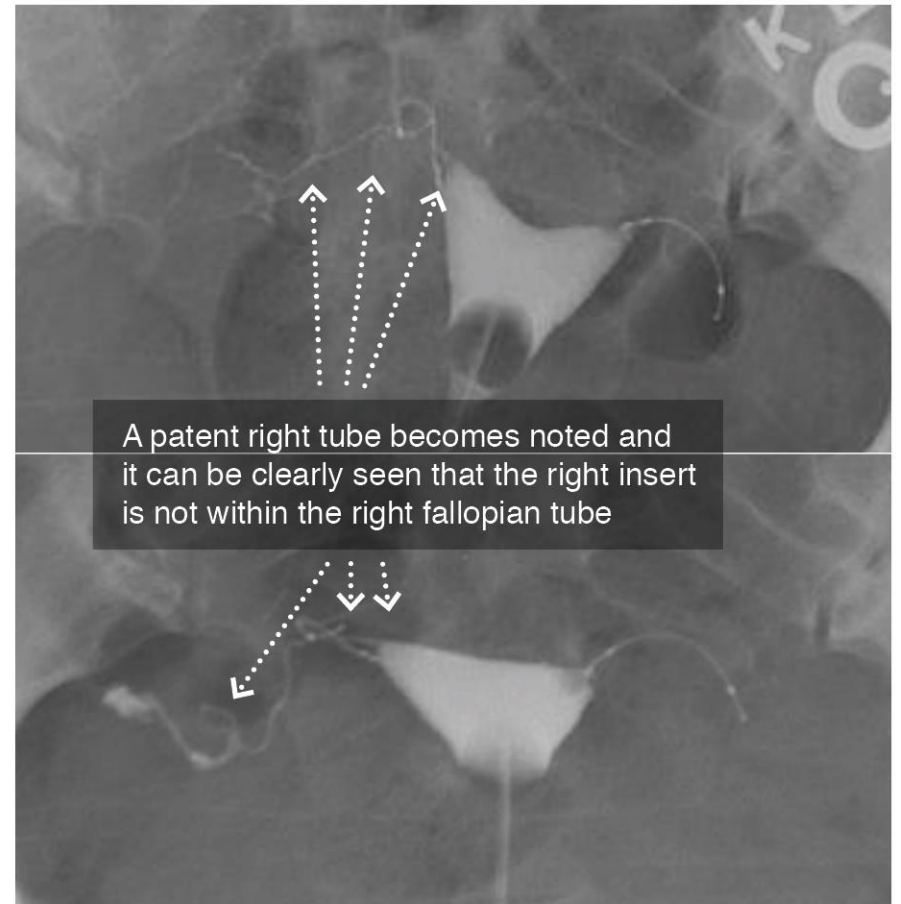
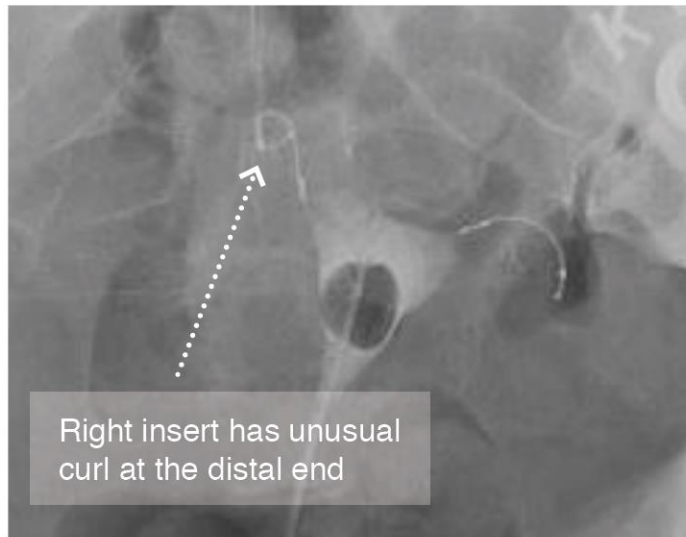
73 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #13

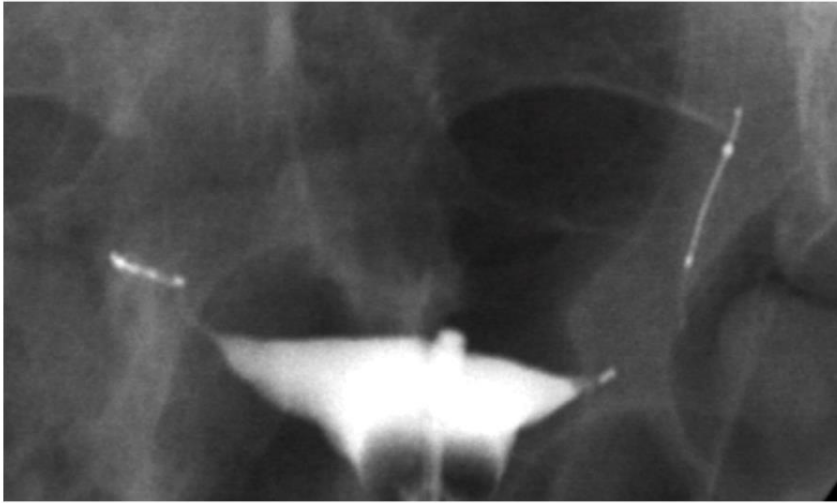


74 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

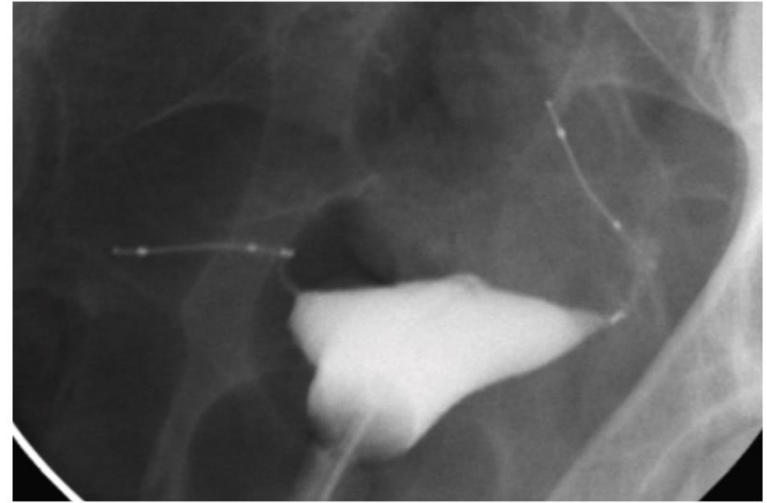
## Case #13: Perforation



# Case #14

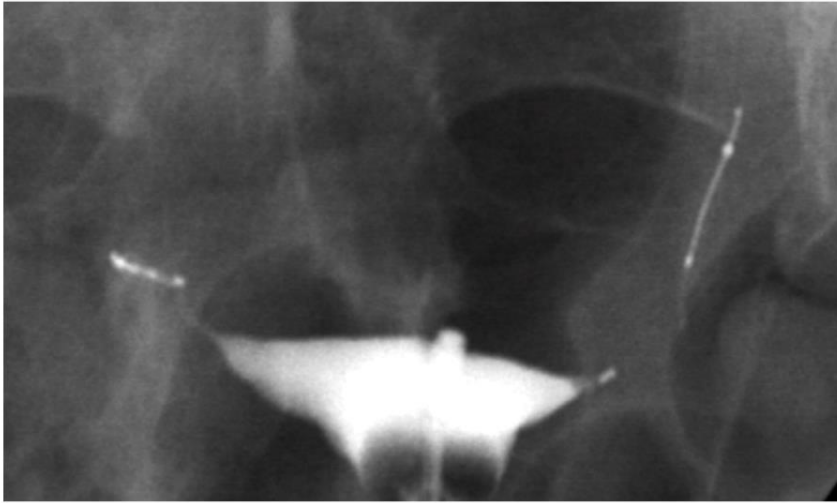


A/P view

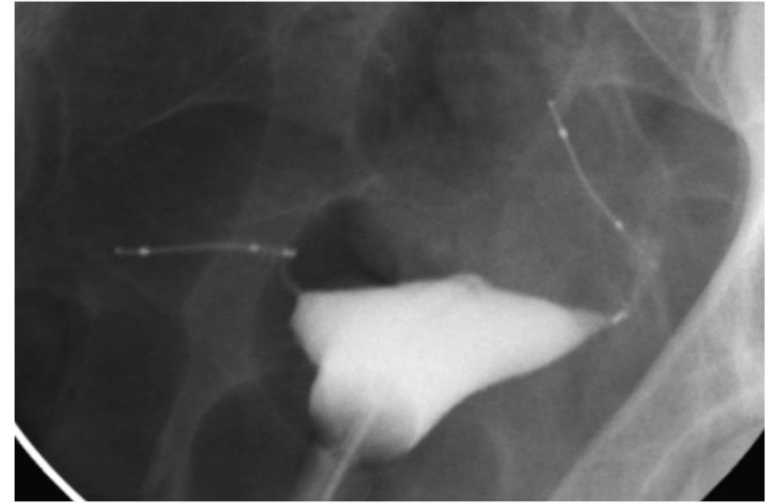


Oblique view

## Case #14: Additional Views May Be Needed

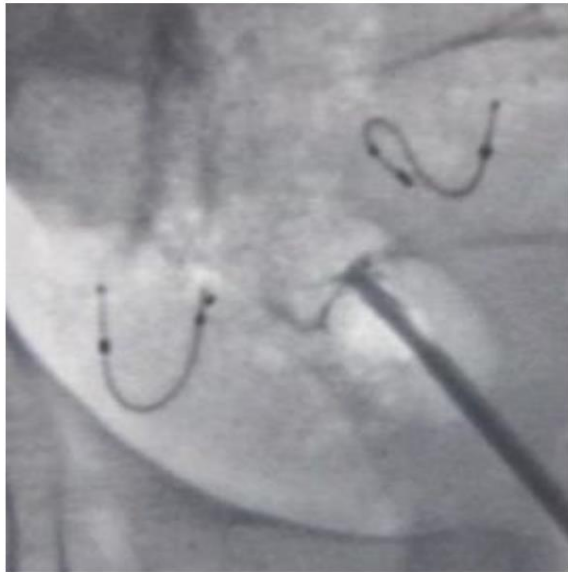


Radiologist was concerned regarding the possibly fractured left insert and the shortened length of the right insert



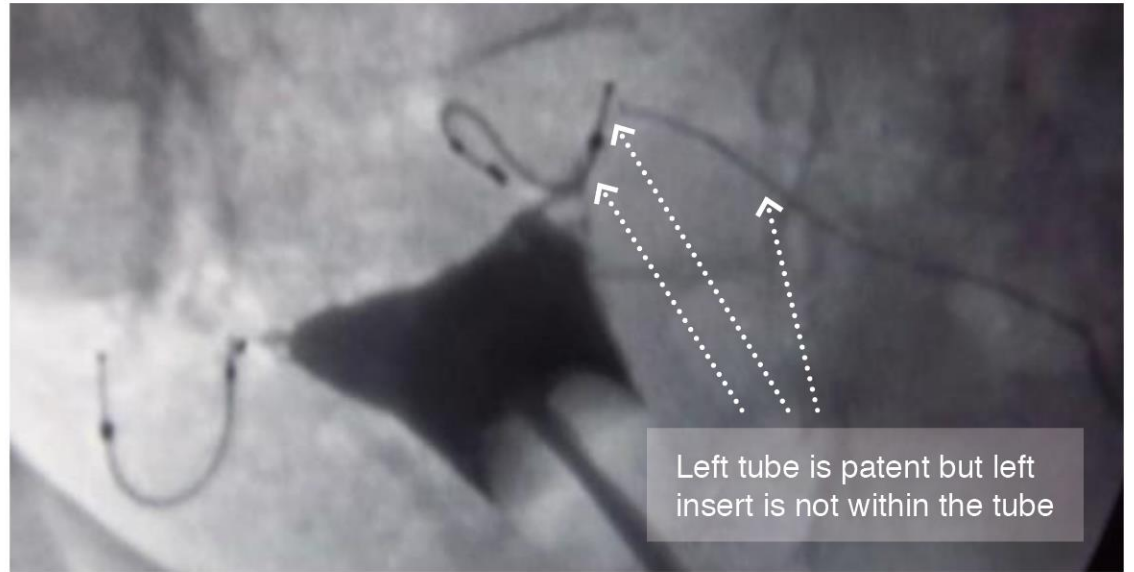
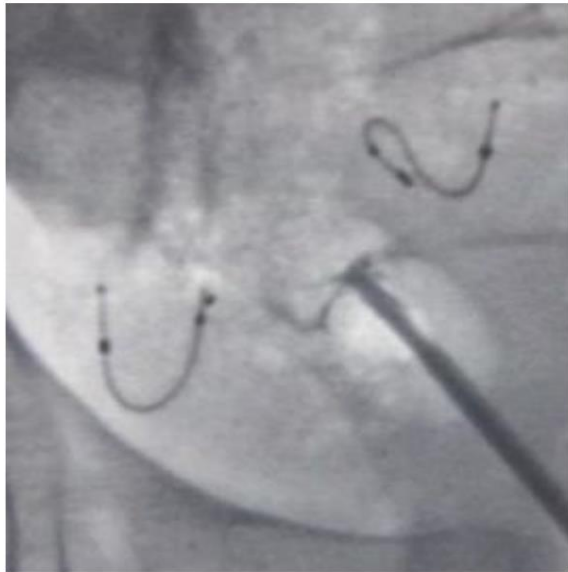
In the additional views, the right insert appears to meet the criteria for satisfactory location and the left insert, though slightly distal, also meets the criteria for satisfactory location. As contrast tracks through the proximal portion of the insert, the stretched outer coils become highlighted

## Case #15

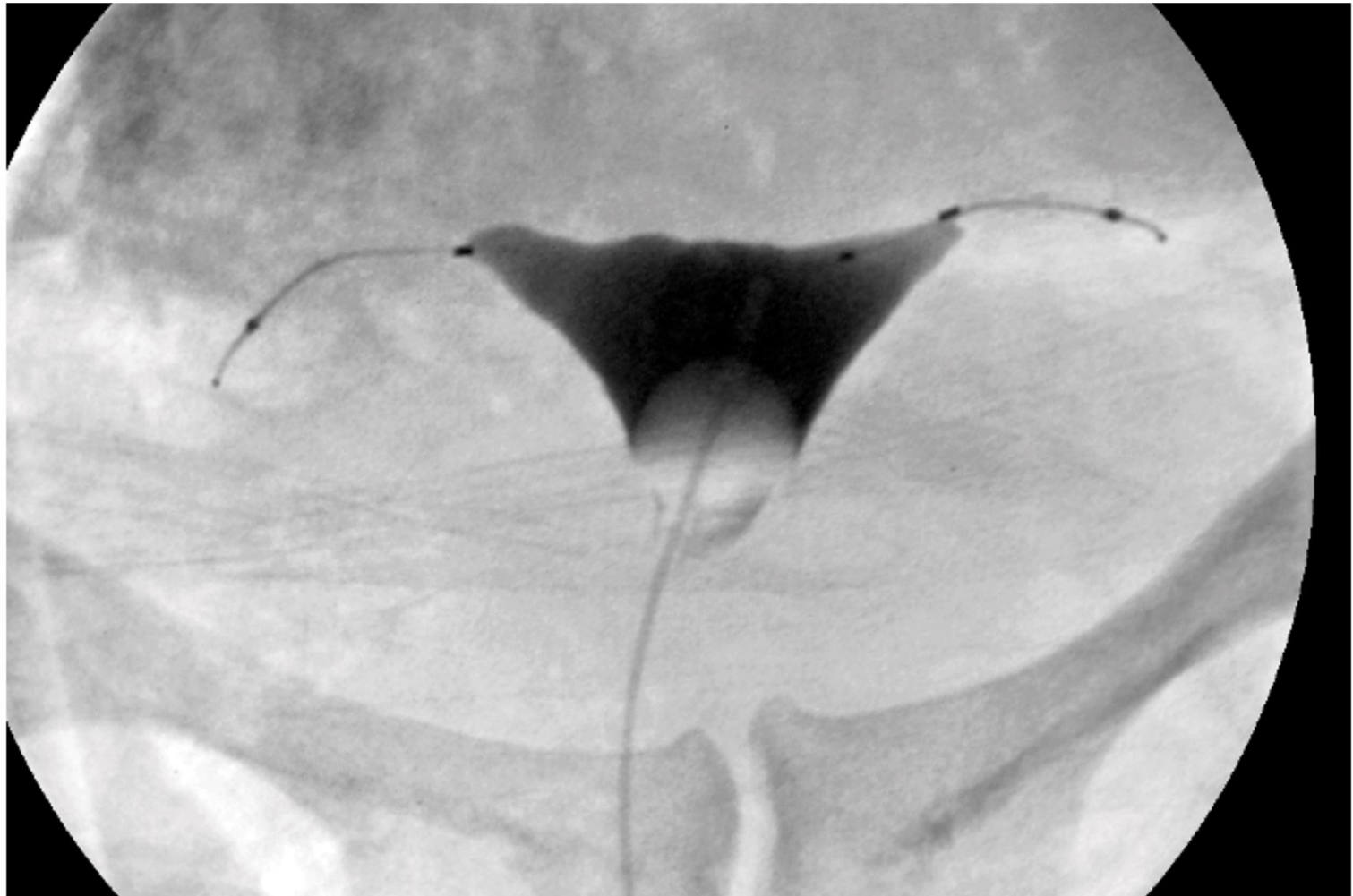


78 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #15: When Patency Is Seen, Be Sure to Confirm Correct Location of the Inserts to Rule Out a Perforated Insert

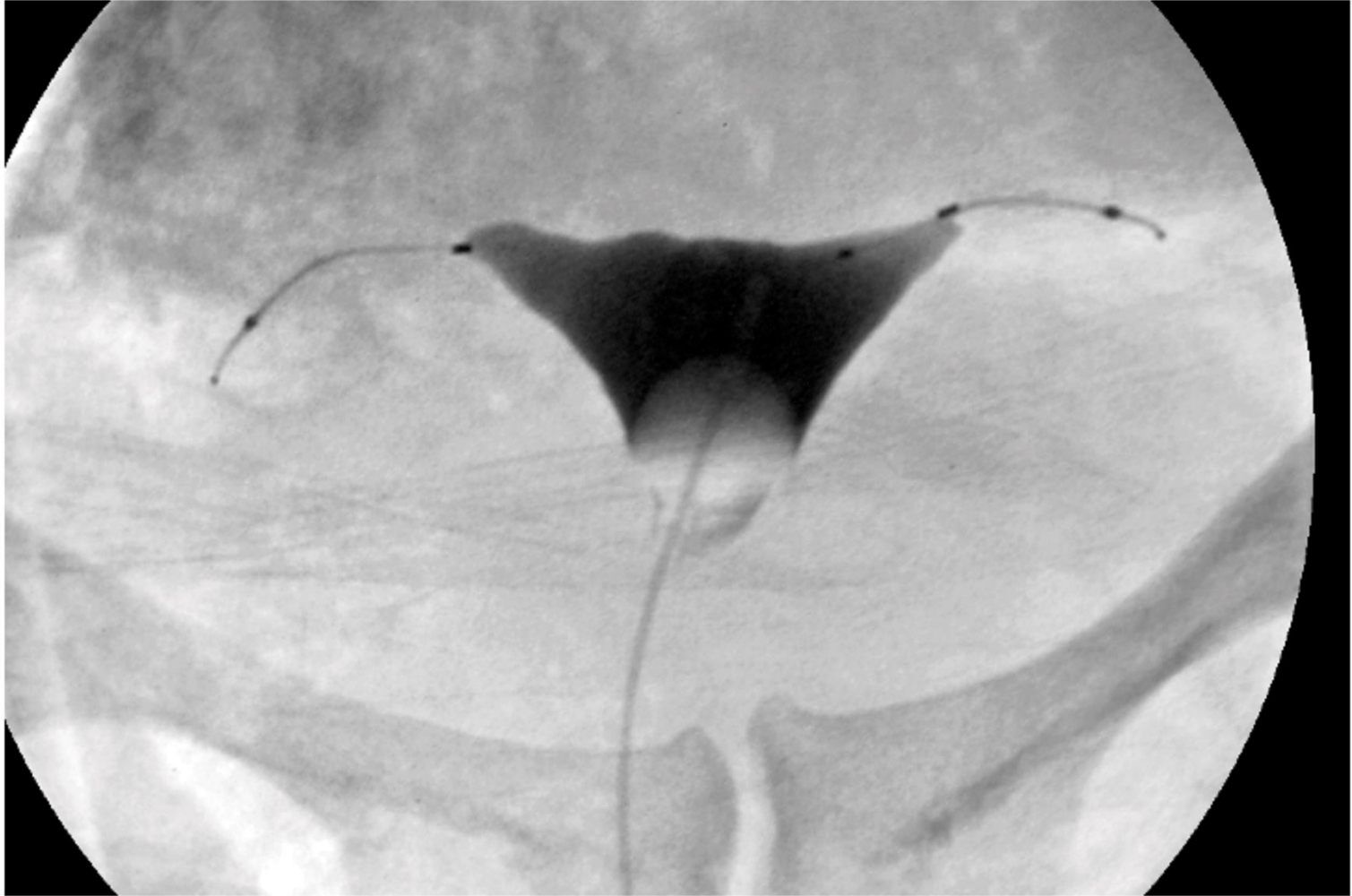


## Case #16



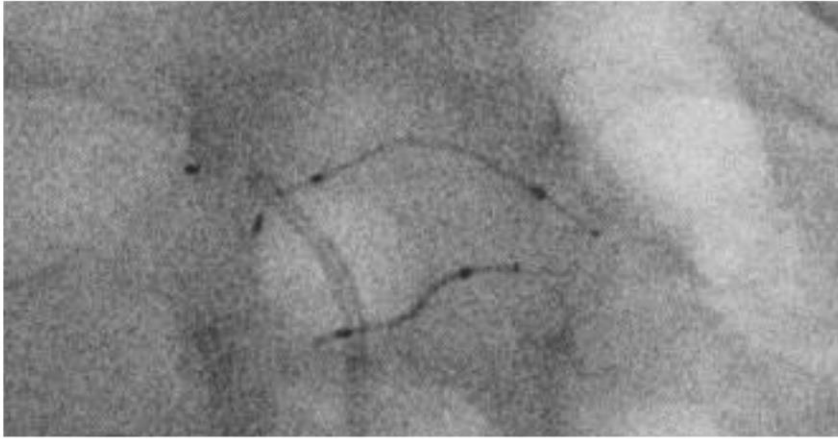
80 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #16: Satisfactory Location and Occlusion



81 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

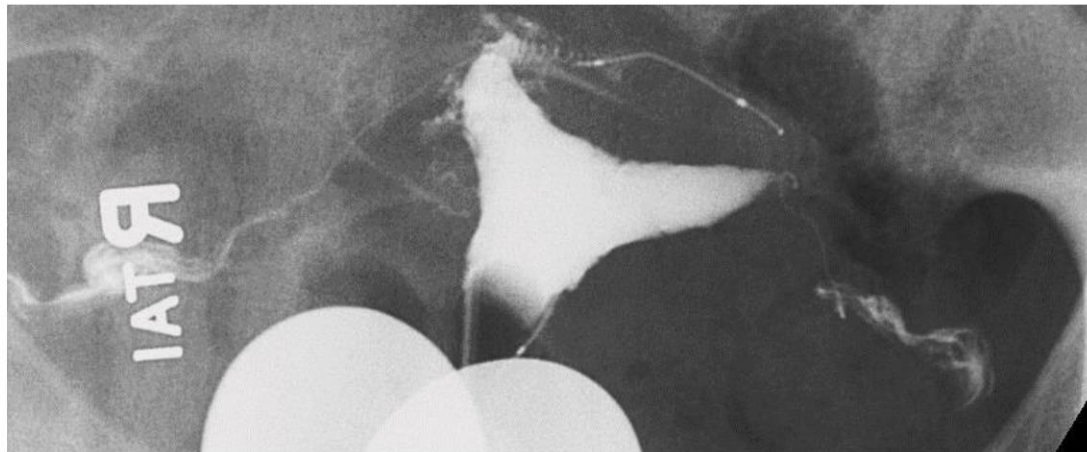
# Case #17



Scout image

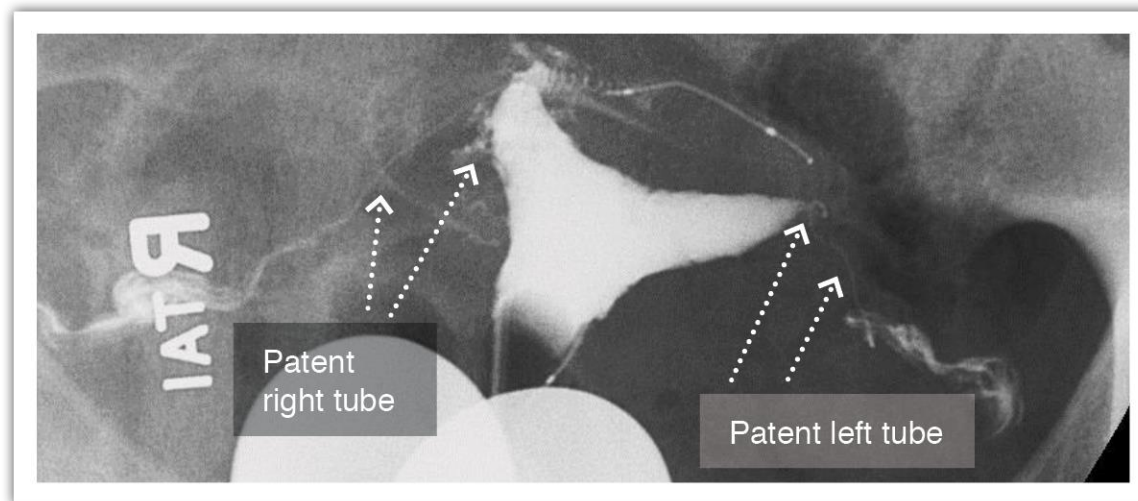
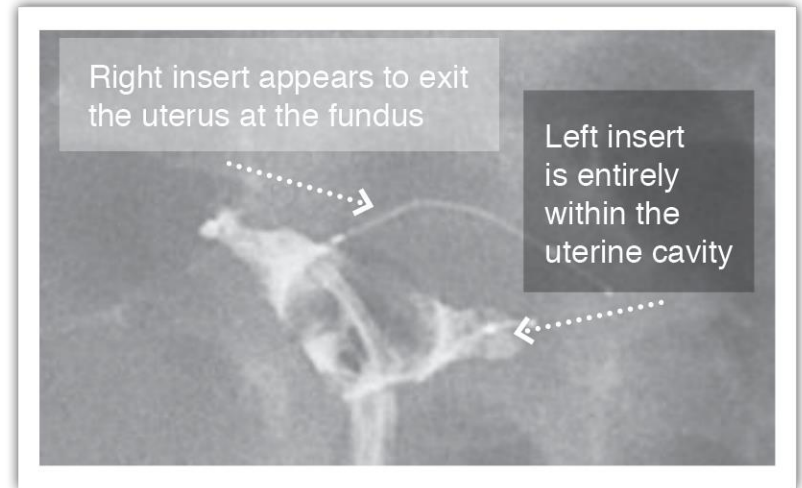
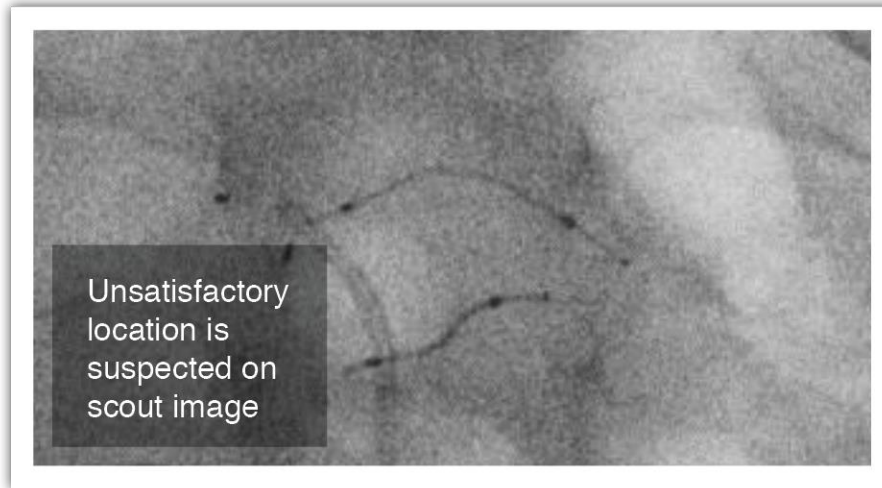


Partial fill image



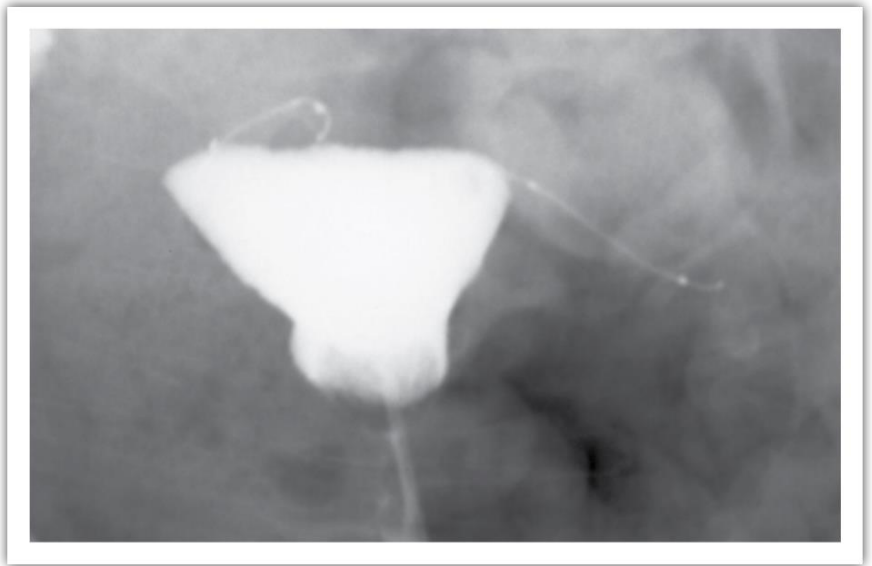
Full distension of  
the uterine cornua

# Case #17: Expulsion and a Perforation



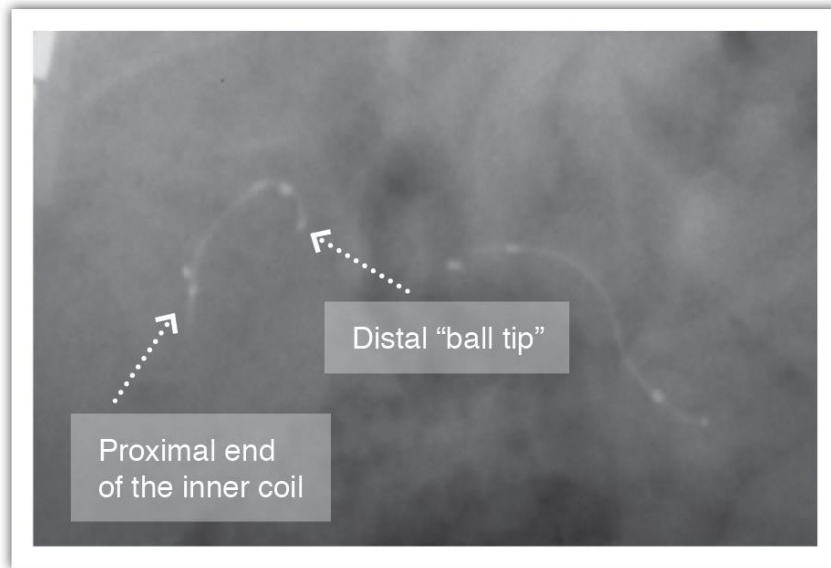
83 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #18

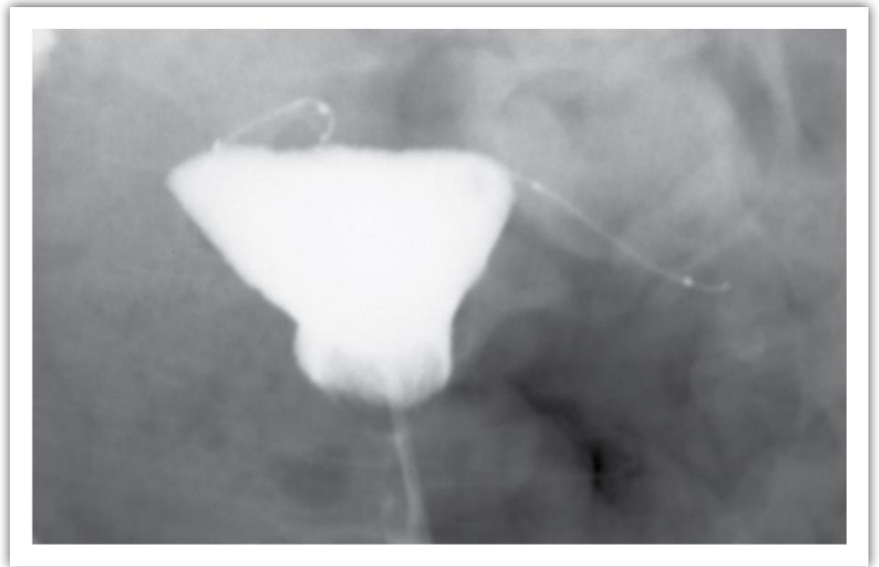


Radiology report notes “fallopian tubes are occluded at the cornua bilaterally.” Patient told to rely on Essure® for contraception

# Case #18: This Is a False-Positive

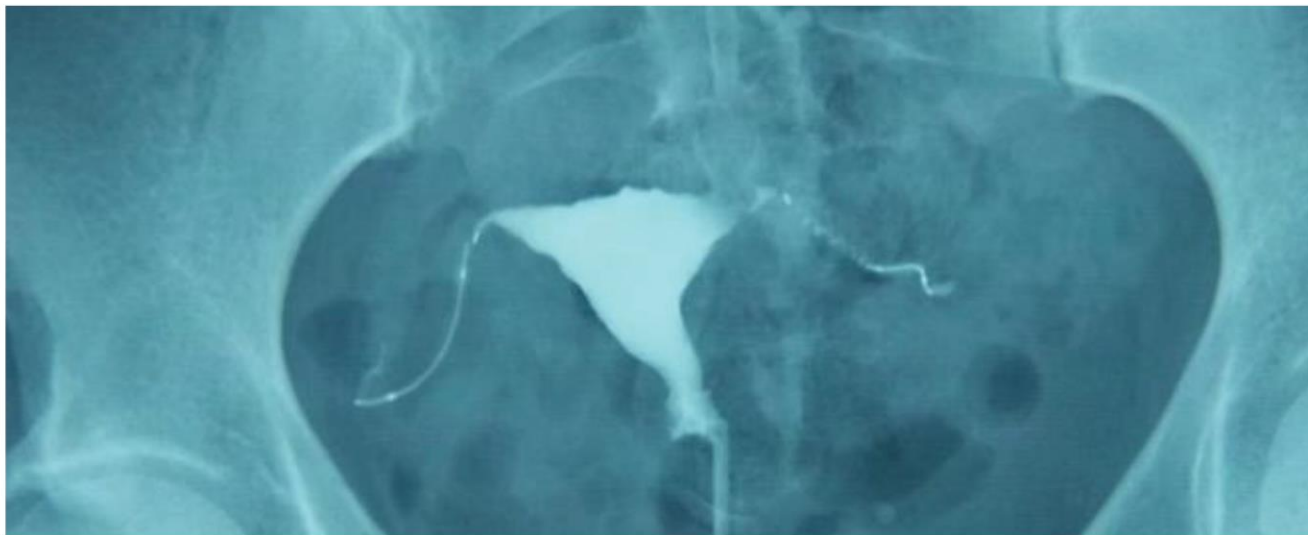


The right insert is curved off to the left and is suspicious for unsatisfactory location in the scout image



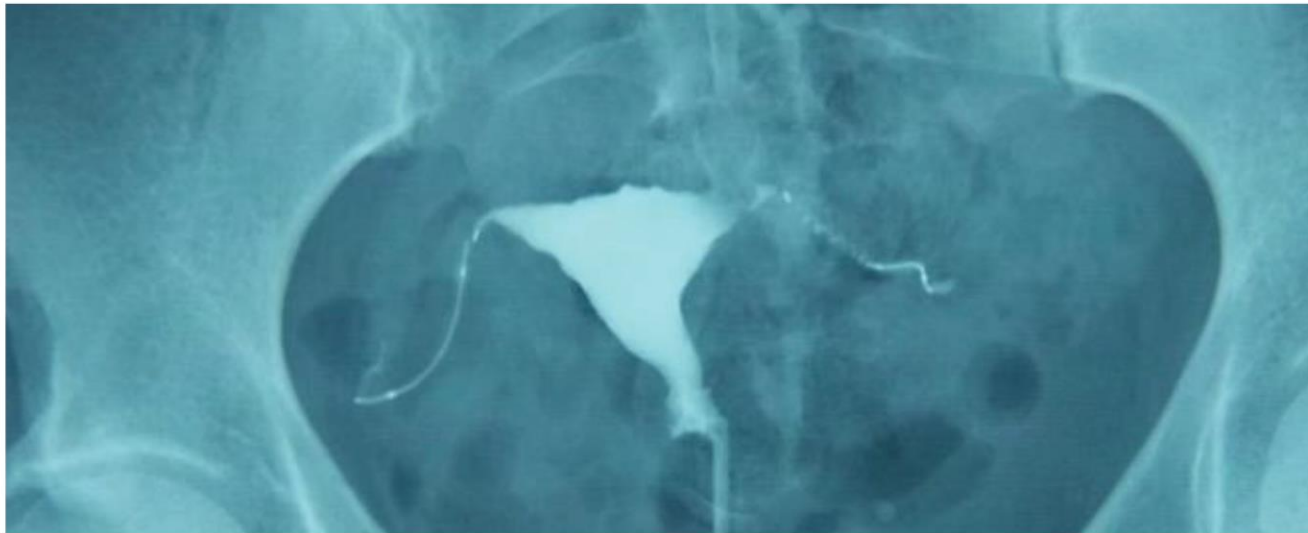
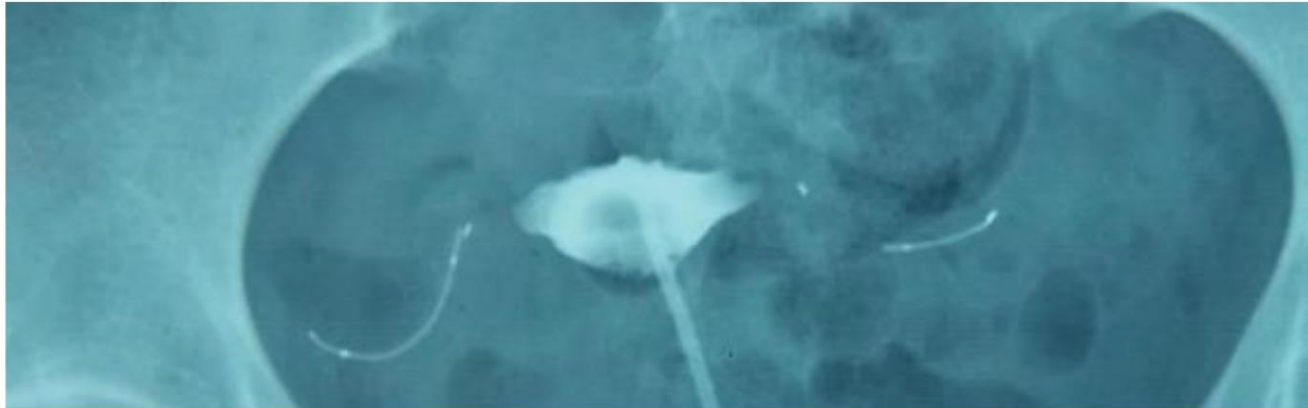
The right insert appears to exit the uterus through the fundus

## Case #19



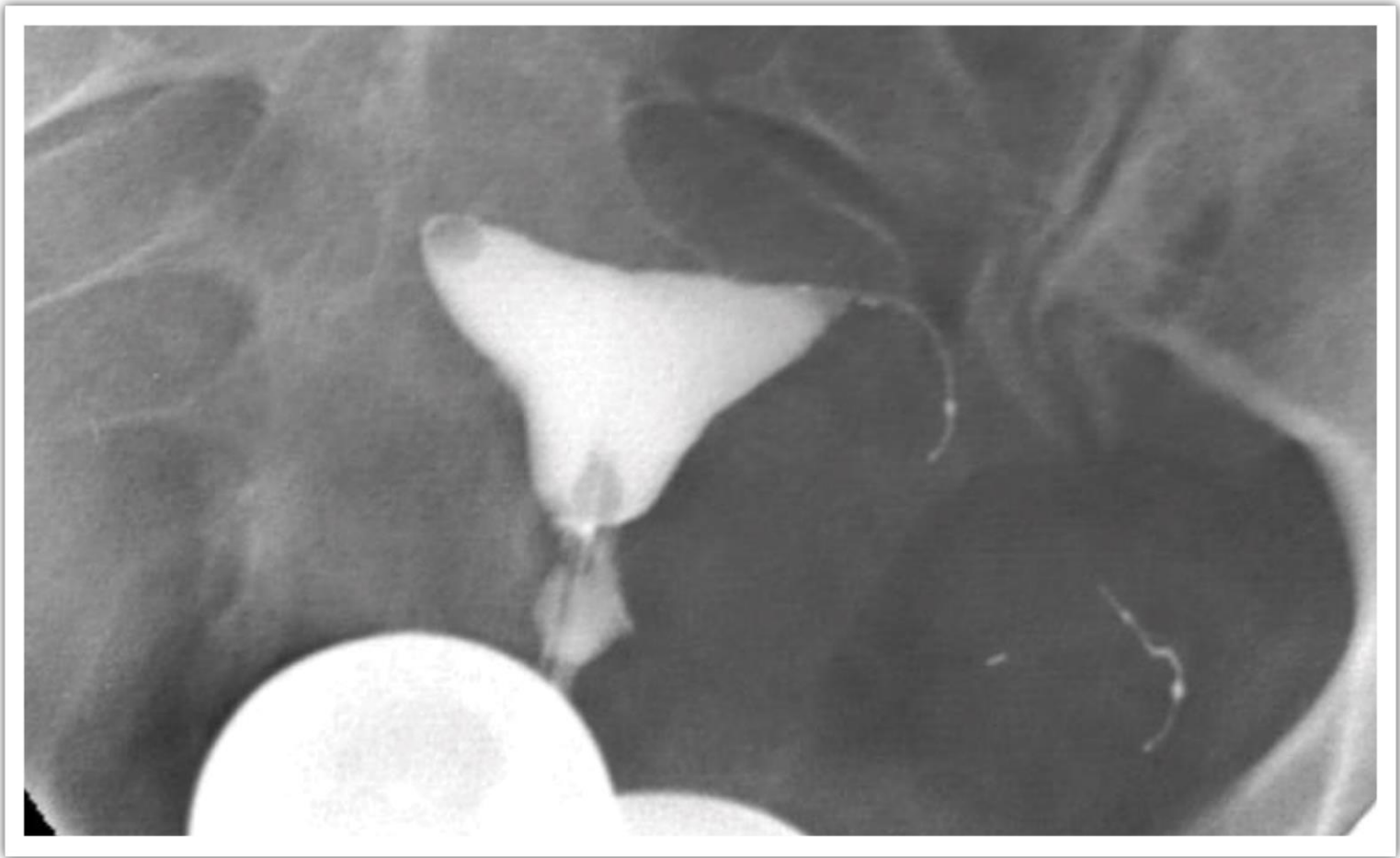
86 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #19: Distal Location



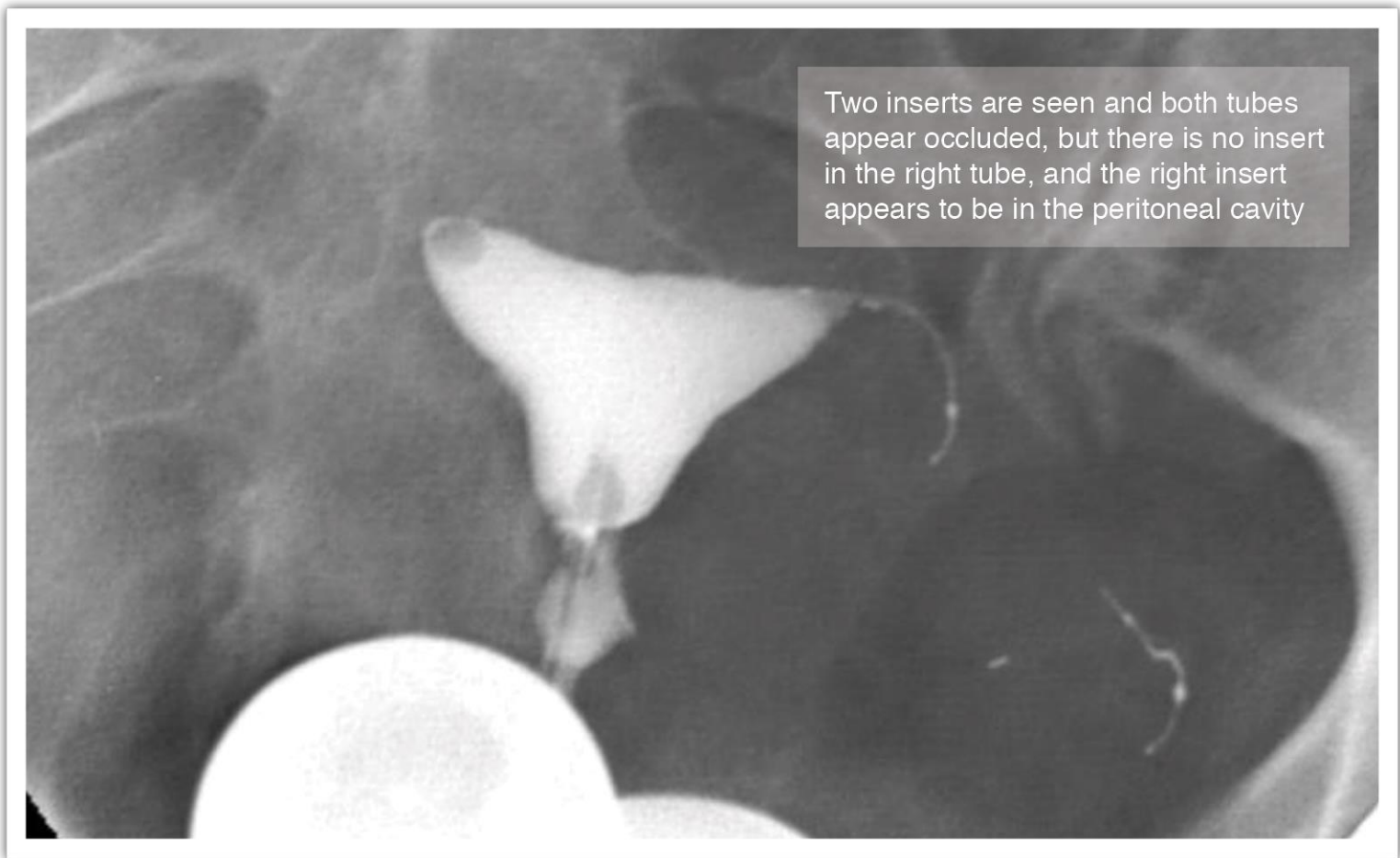
87 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #20

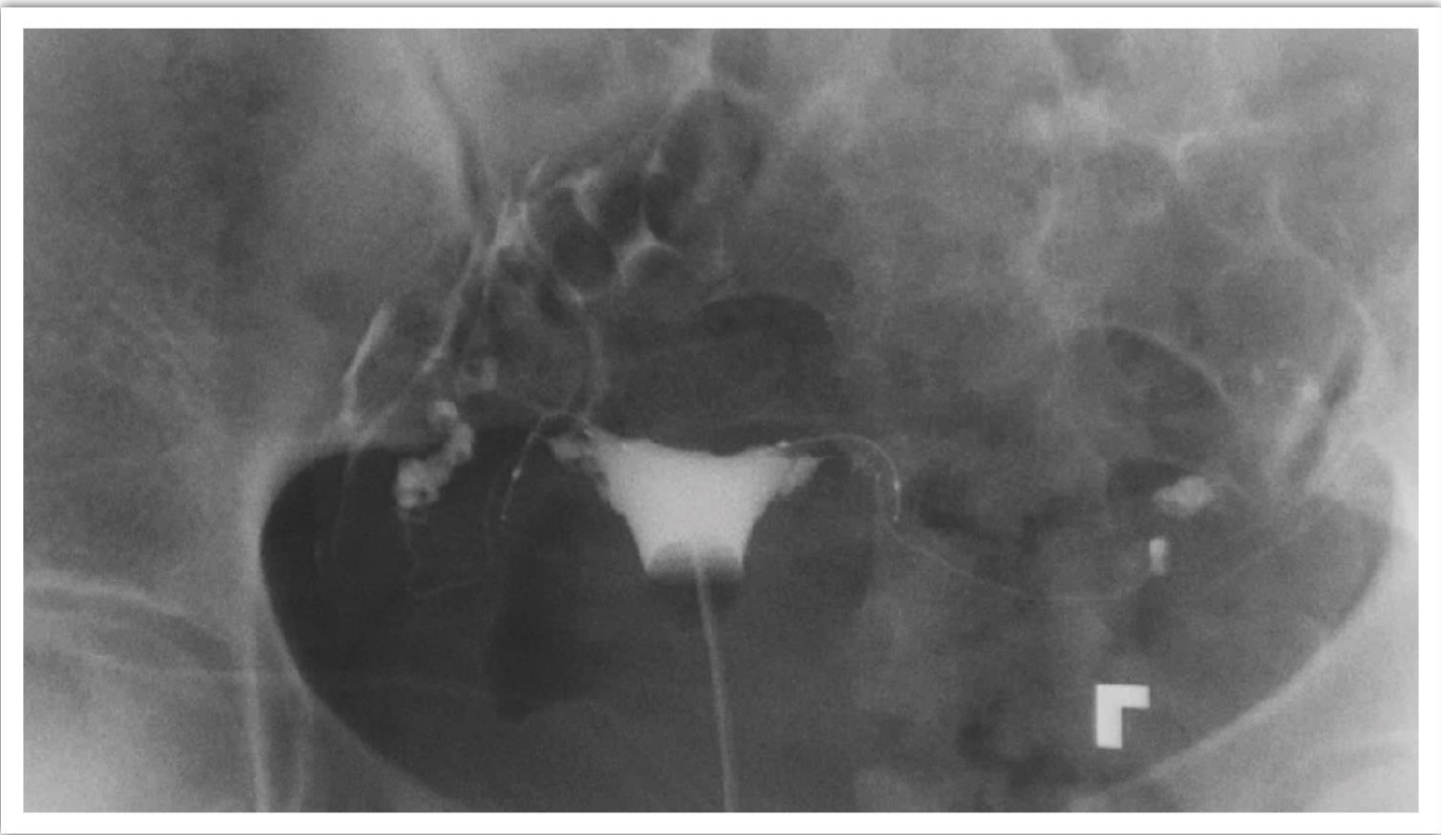


88 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #20: Perforation

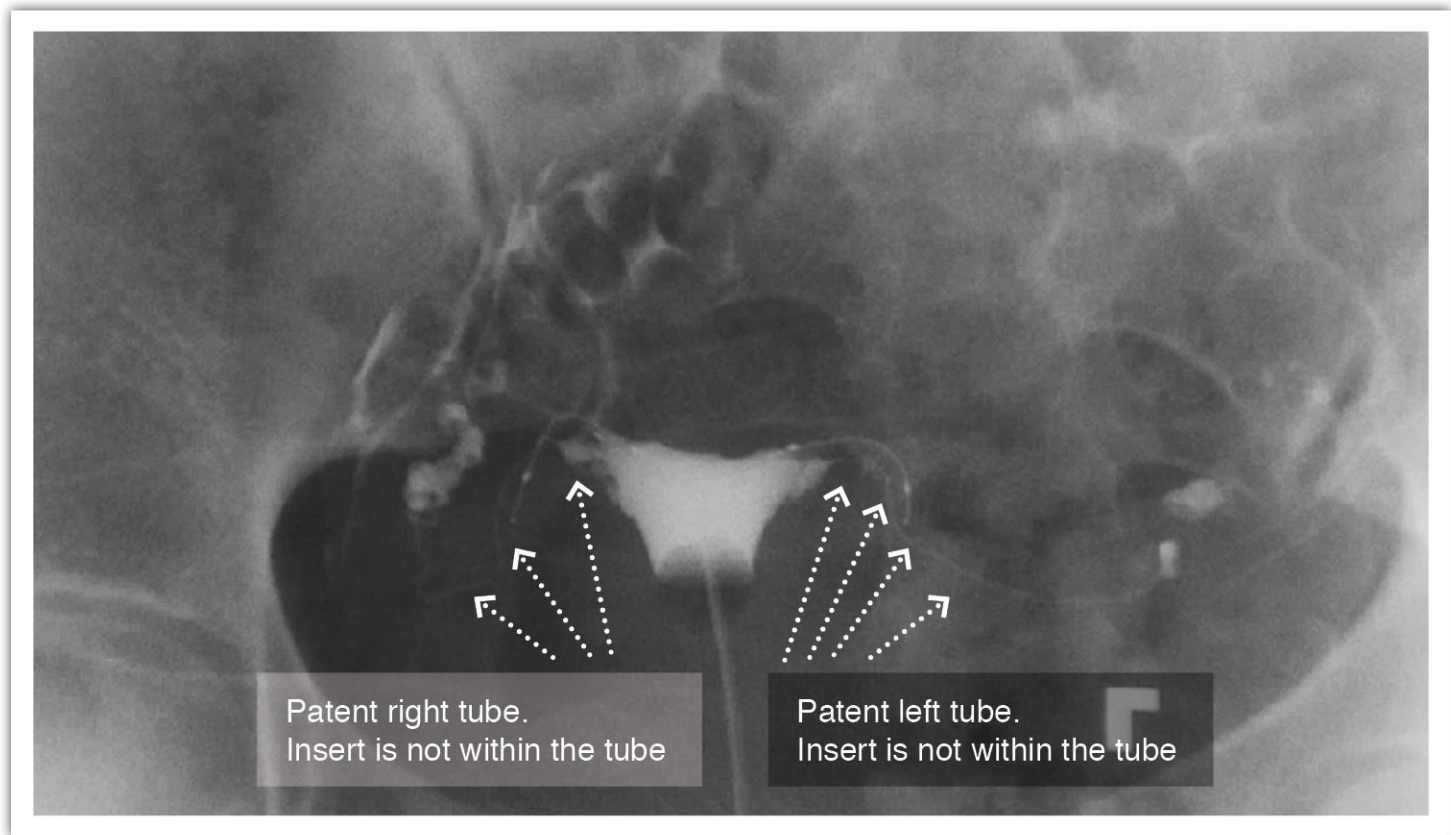


## Case #21

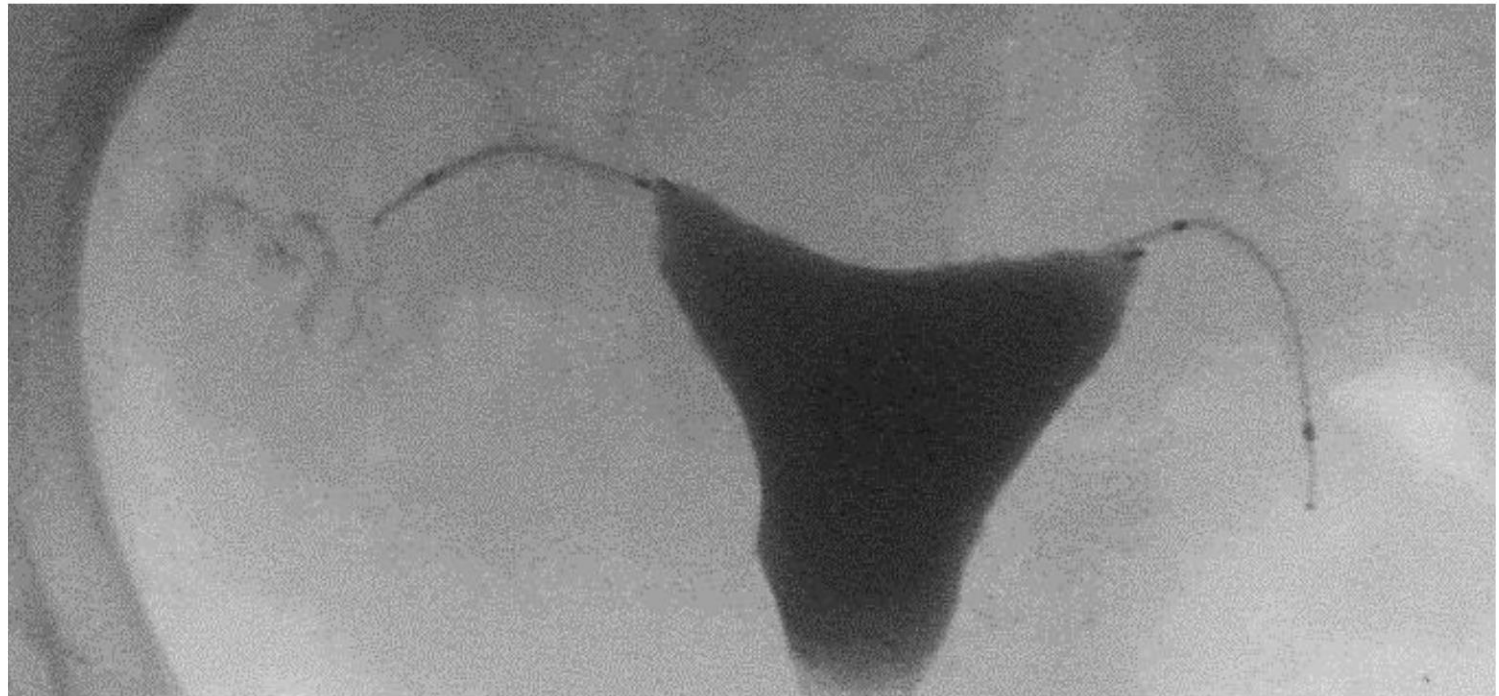


90 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #21: When Patency Is Seen, Be Sure to Confirm Correct Location of the Inserts to Rule Out a Perforated Insert

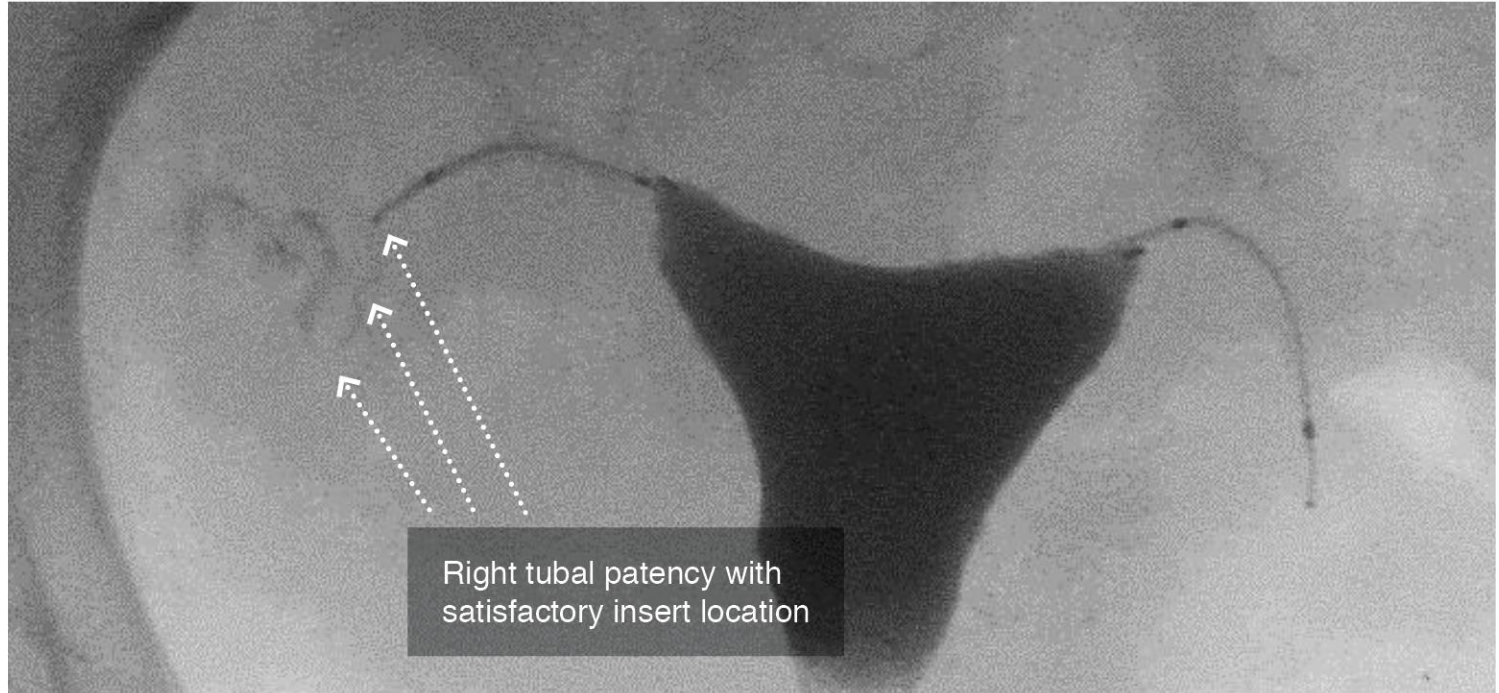


## Case #22

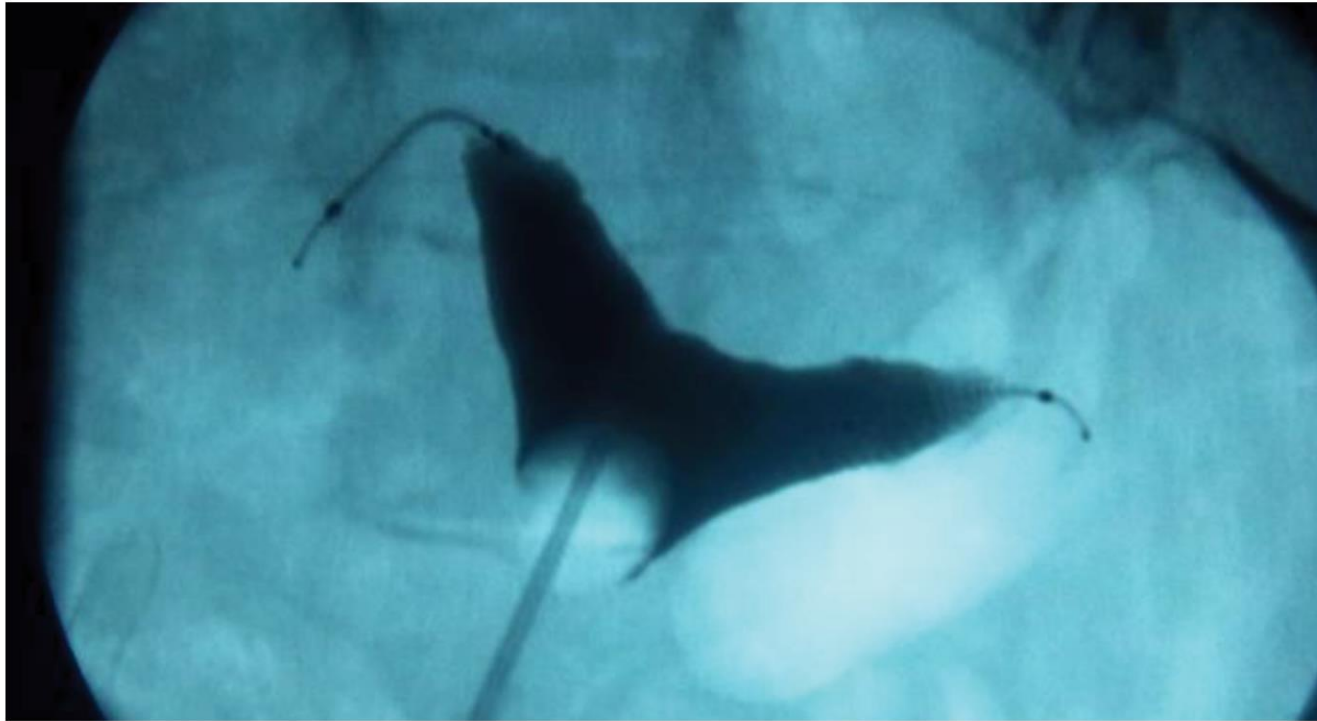


92 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #22: Patency With Satisfactory Location

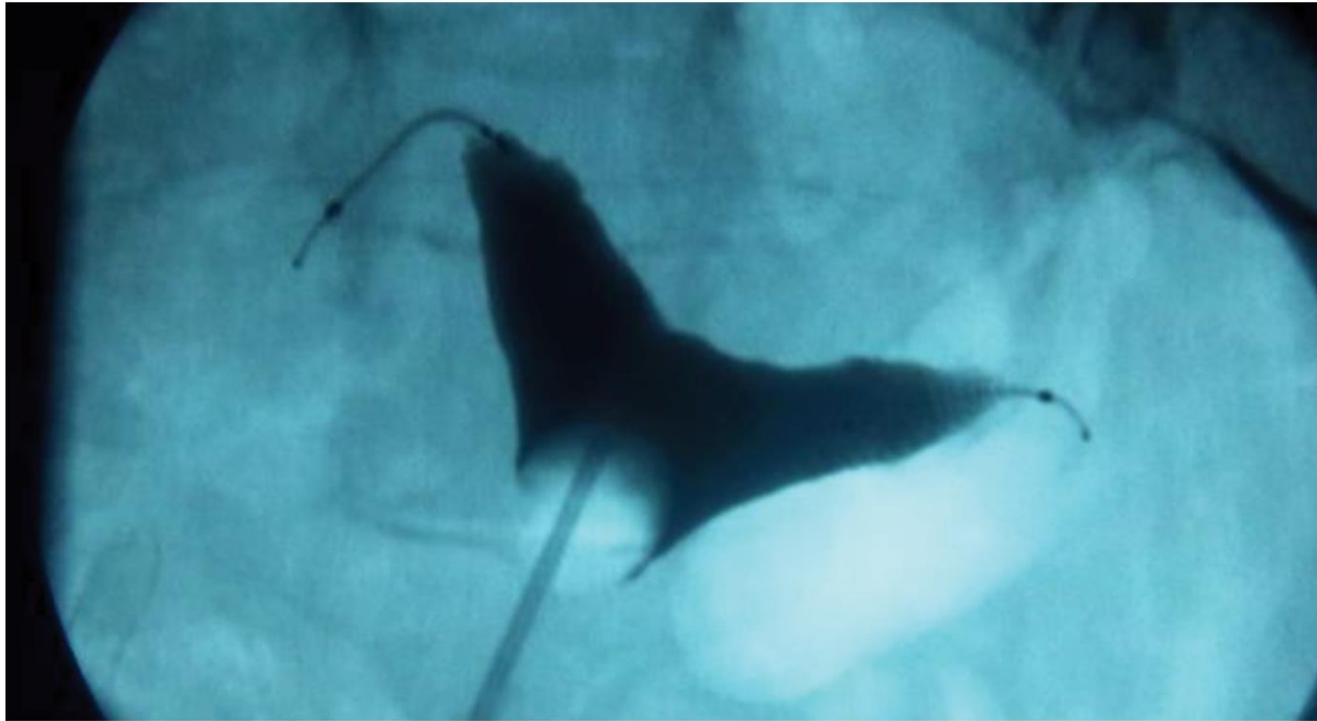


## Case #23



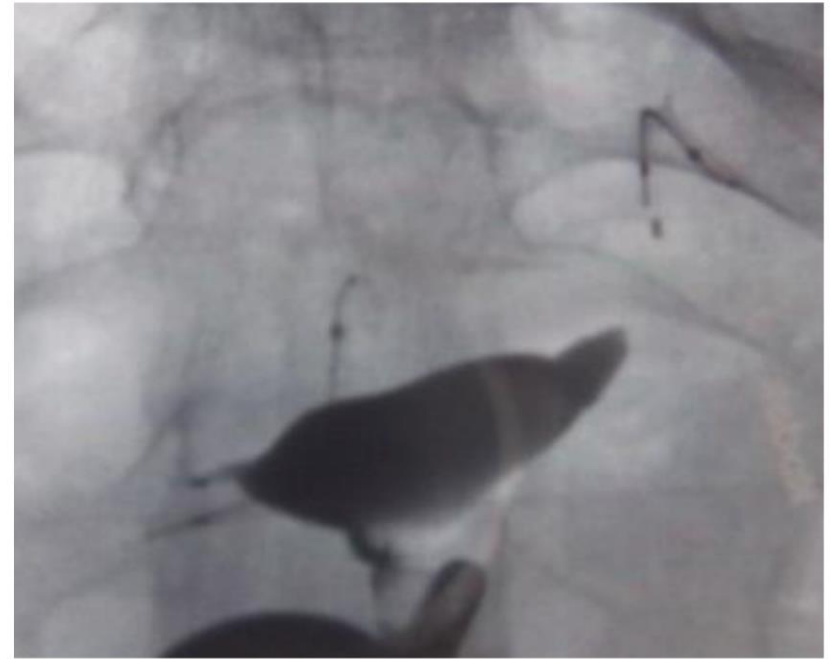
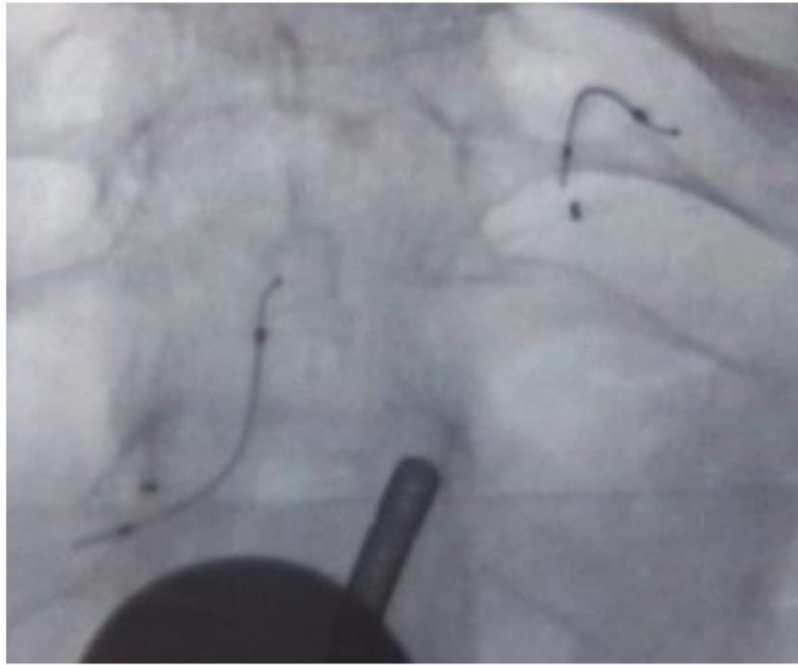
94 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #23: Proximal Location



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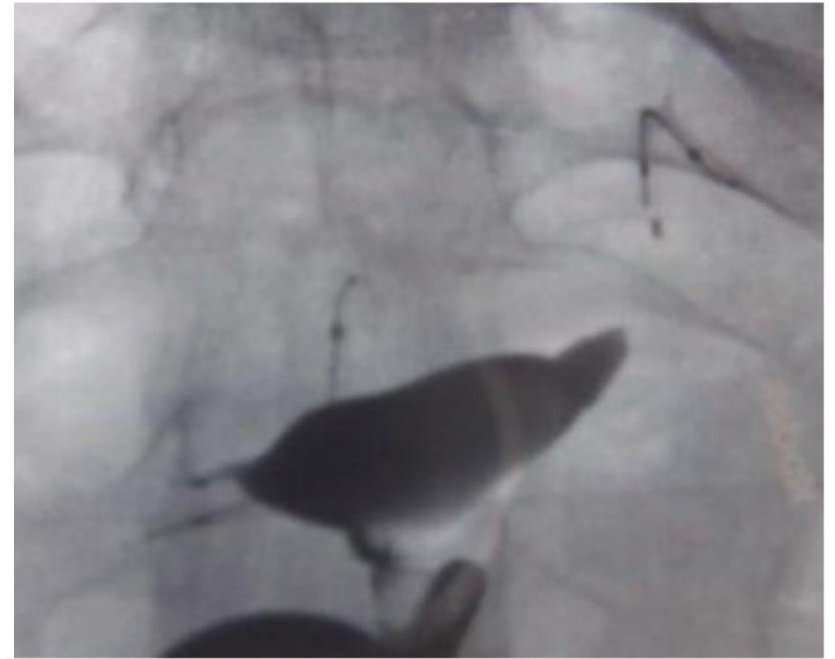
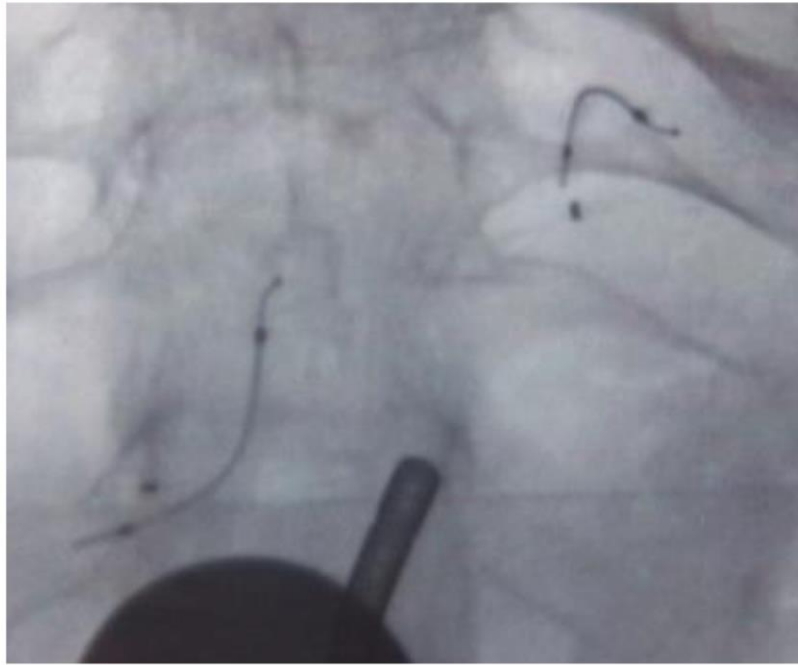
## Case #24



MD did not note difficulty with placement and noted 3 trailing coils were seen from the right and left ostia after placement

The radiology report noted that two inserts were seen, and bilateral tubal occlusion was confirmed. The patient was told that she could rely on Essure® for contraception

## Case #24: Perforation



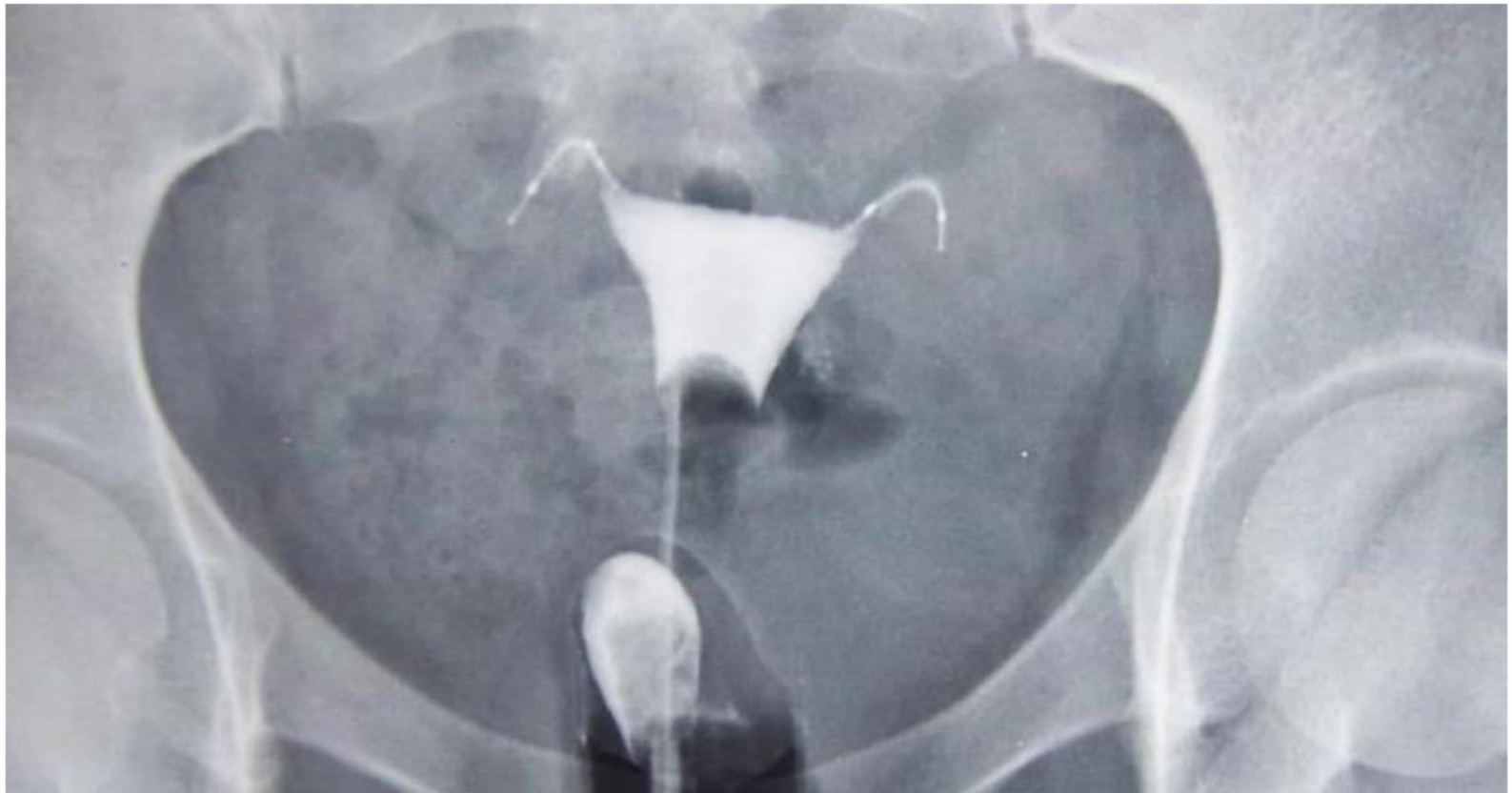
Patient returned to MD 3 years after placement with positive IUP

In the scout image, the right insert is reversed (with the distal end oriented to the right)

When the uterus is fully filled with contrast, the right insert appears to be positioned posterior to the uterus and is highly suspicious for being outside of the tube. The left insert is either distal into the tube or outside of the tube. It is difficult to say from these images

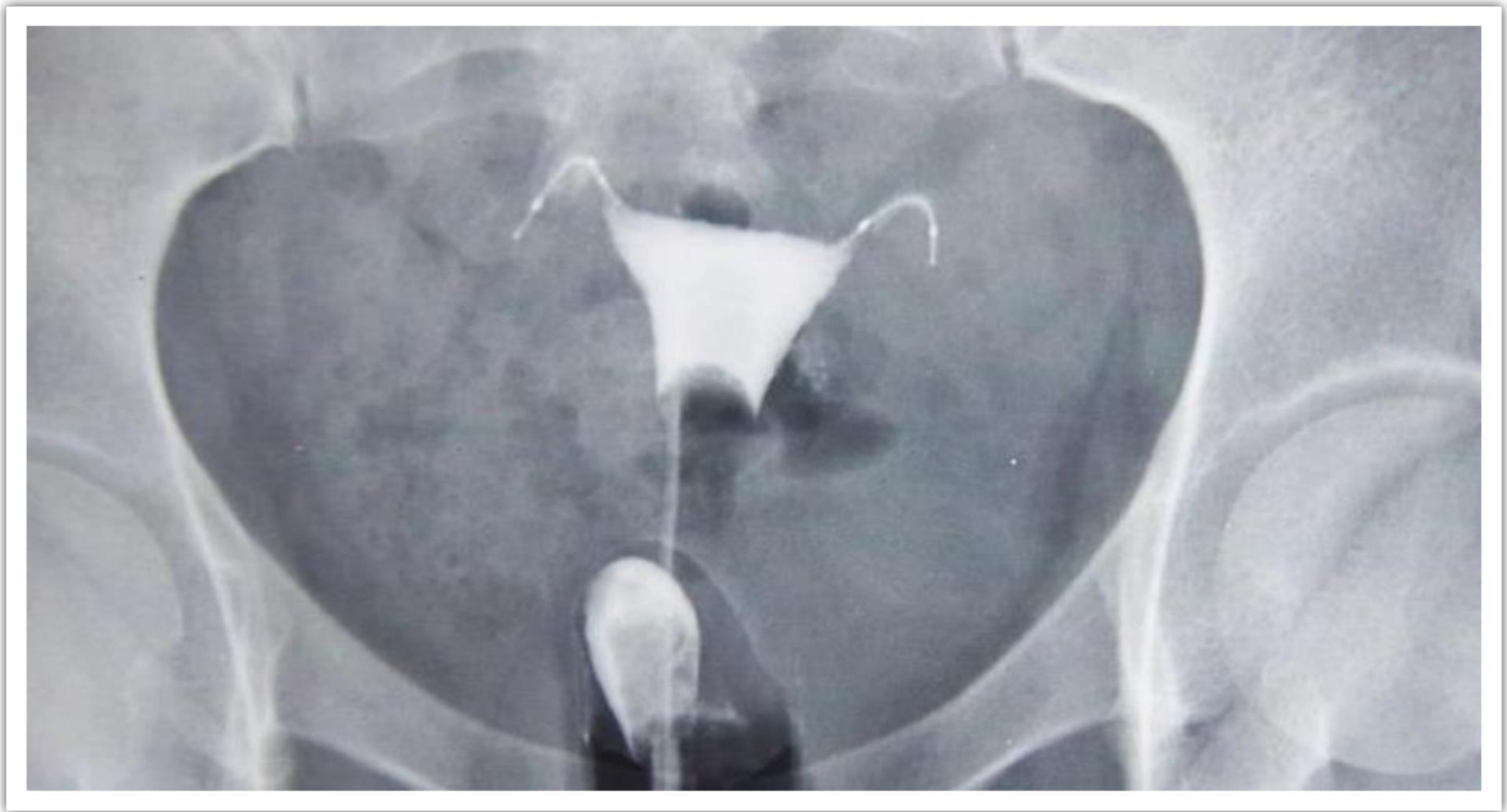
**97** Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #25



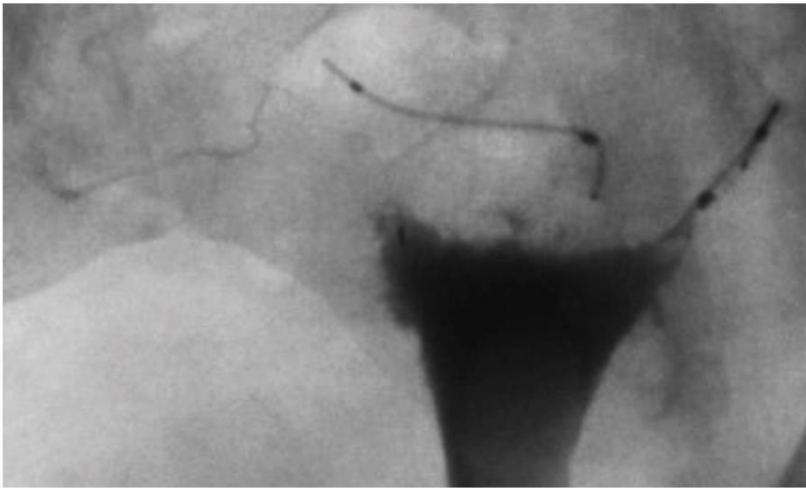
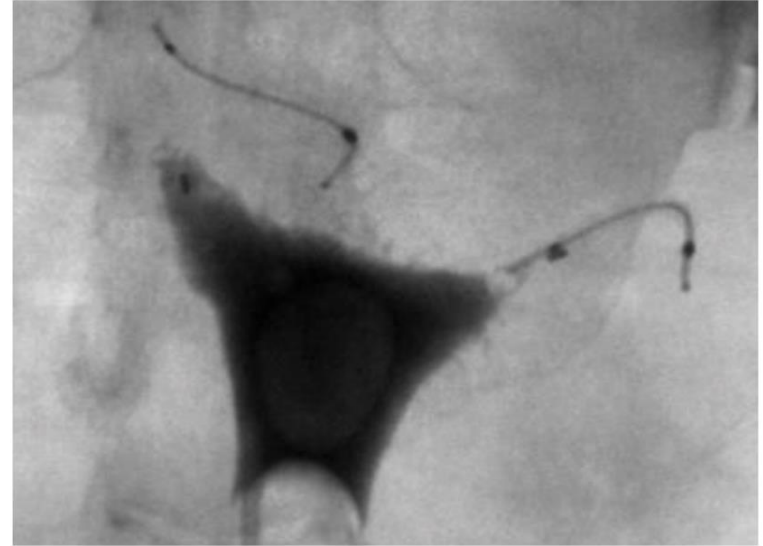
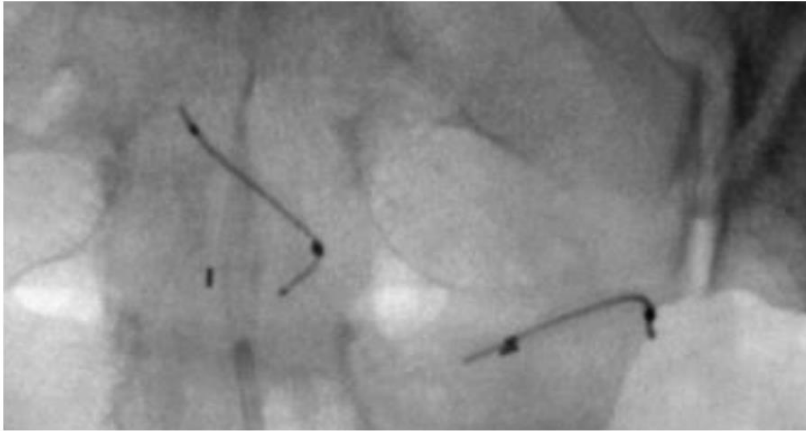
98 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #25: Satisfactory Location and Occlusion

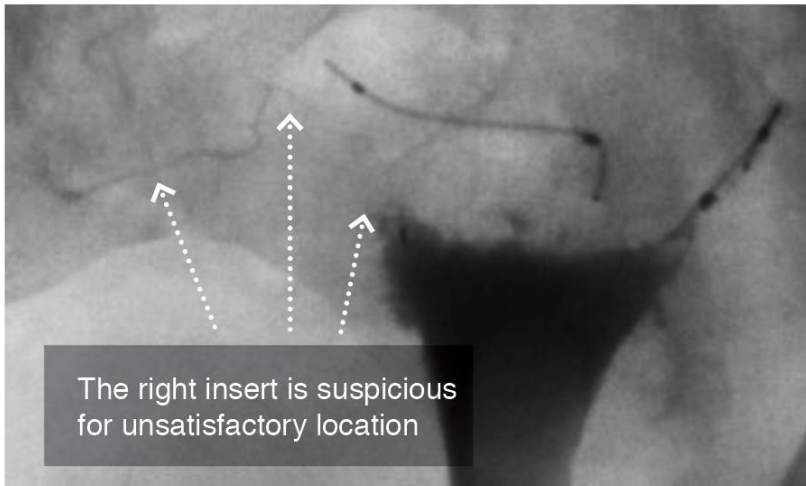
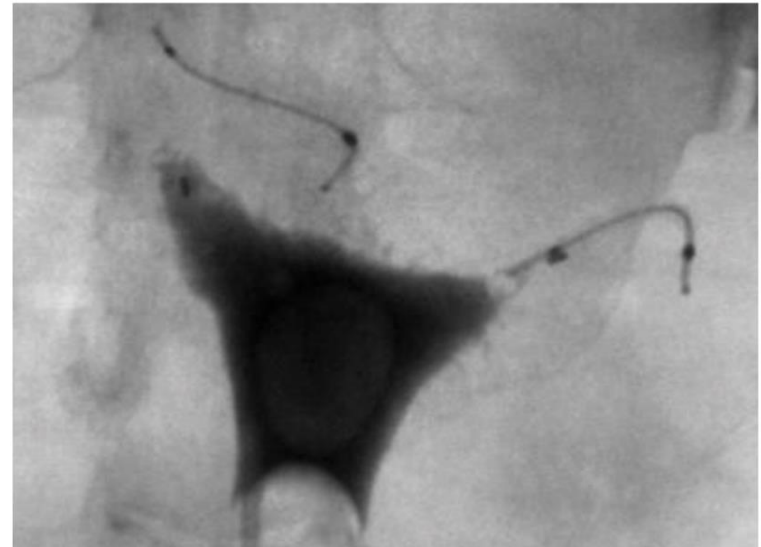
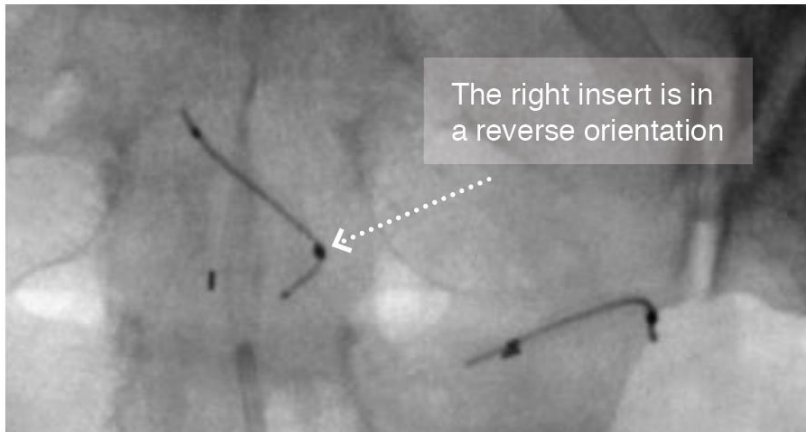


99 Please see Important Safety Information, including Boxed Warning, on slides 3-8 of this presentation. For important information about Essure®, please see the accompanying [Instructions for Use](#), including Boxed Warning.

## Case #26

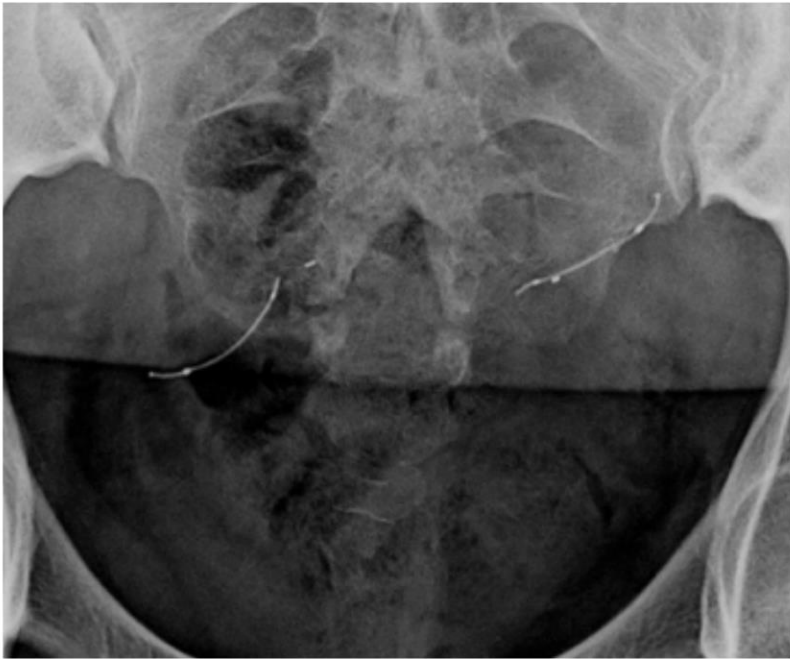


## Case #26: Perforation

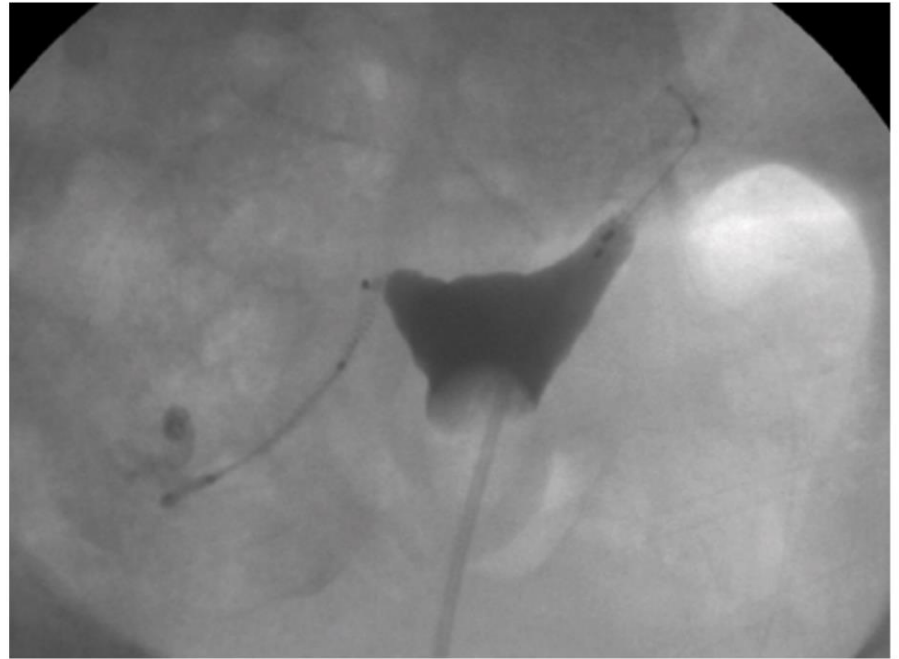


Radiology report noted, “slightly atypical configuration of the right insert with apparent bilateral tubal occlusion.” Patient was told that she could rely

## Case #27

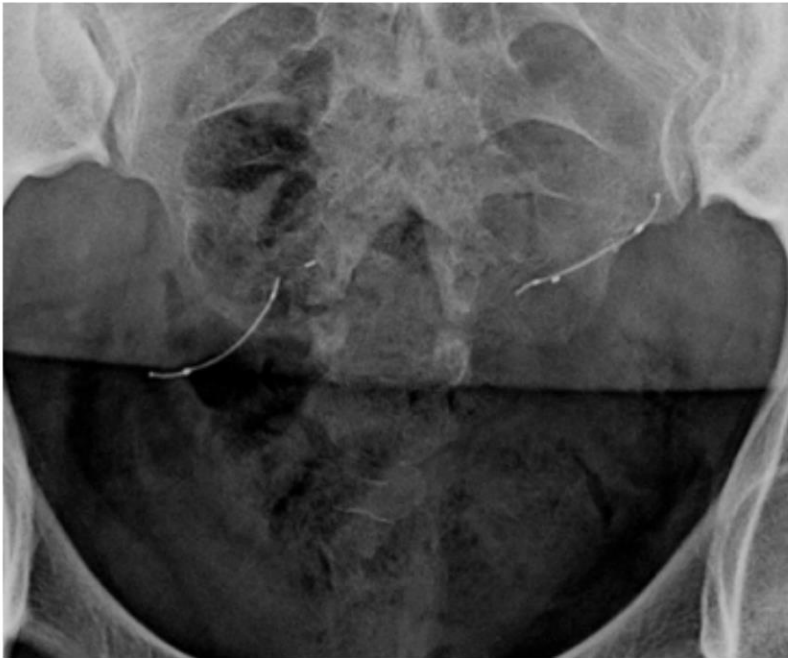


Scout image

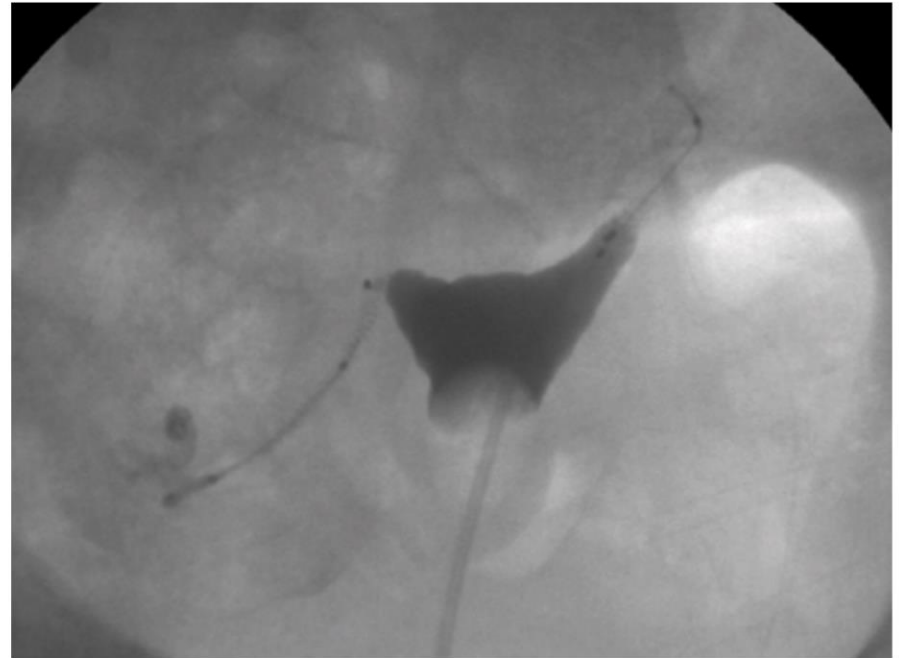


Final image with full distension of the  
uterine cornua

## Case #27: Stretched Outer Coil

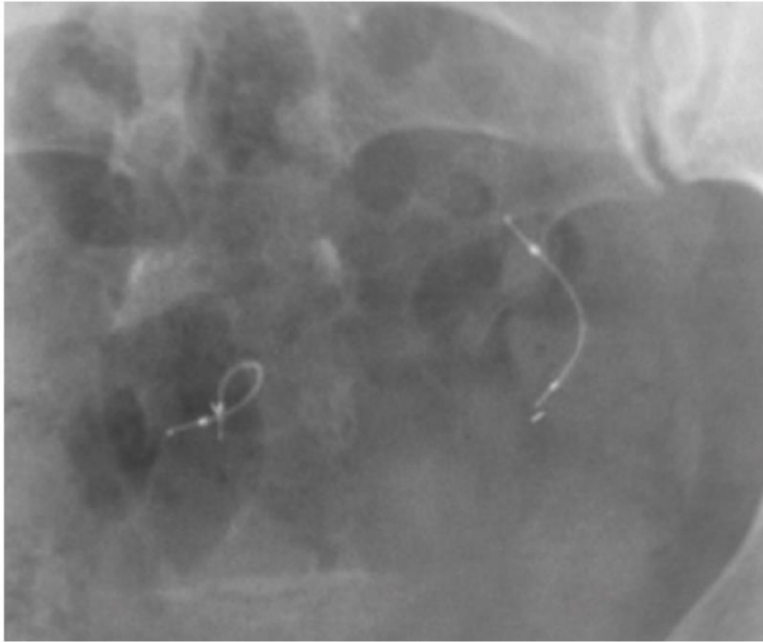


Right insert appears “fractured”

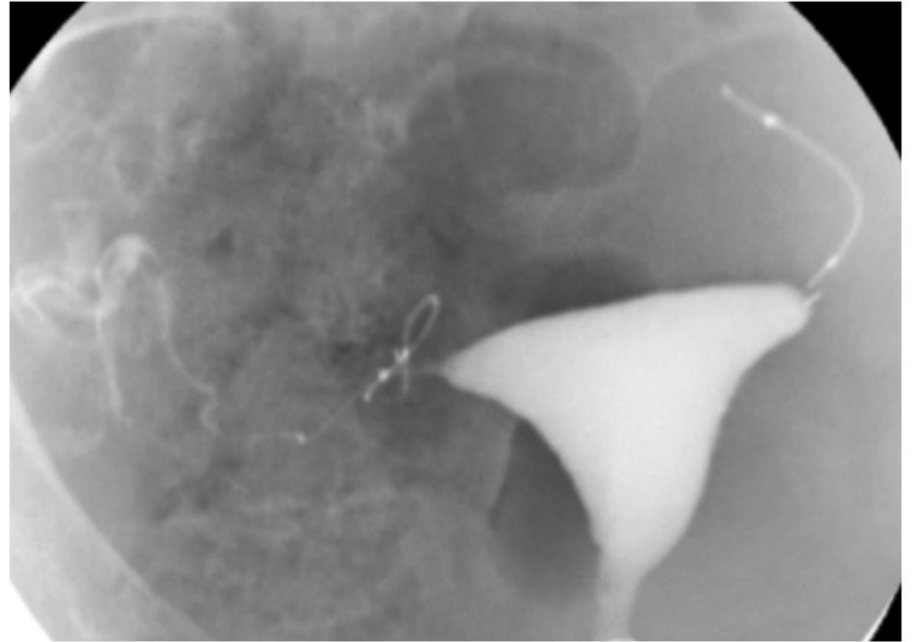


Stretching of outer coils can be seen when contrast tracks through the insert

## Case #28

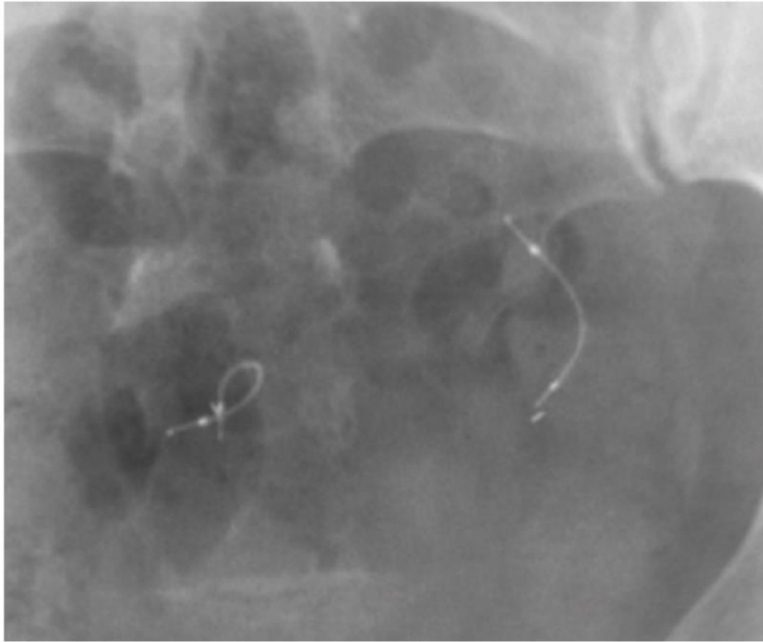


Scout image

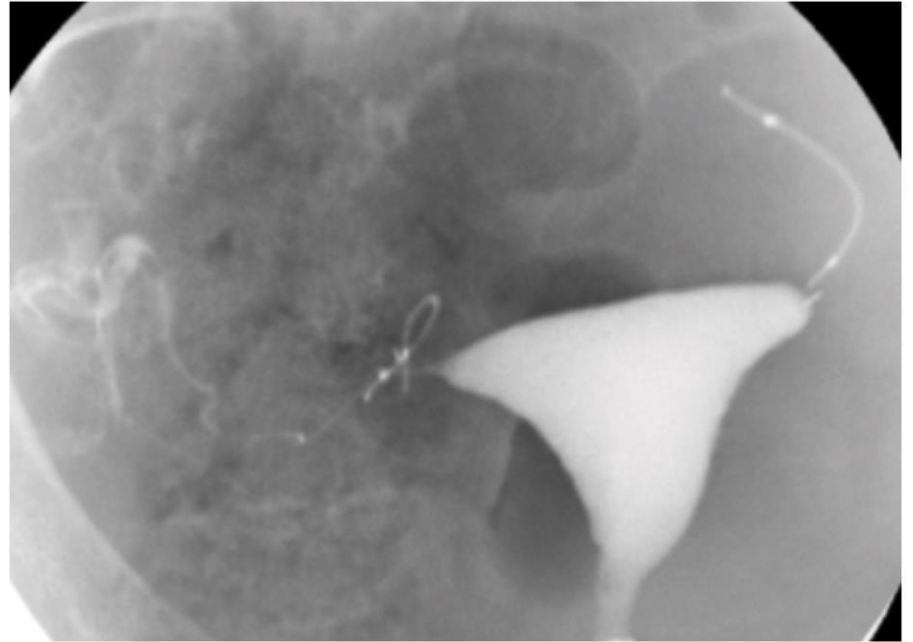


A/P image with full distension of the  
uterine cornua

## Case #28: Perforation



The inserts are asymmetrical on the scout image, and the right insert appears to be curled back over itself

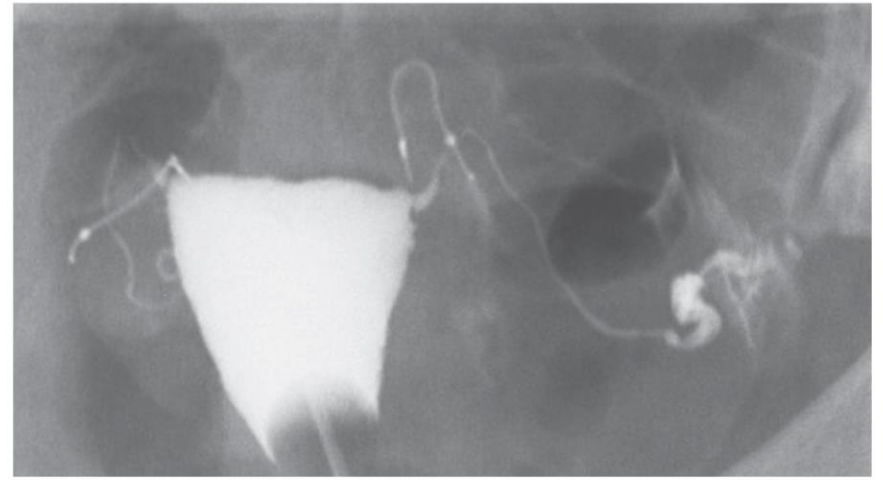


The right insert is clearly outside of the tube, and the right tube is patent

## Case #29



Scout image

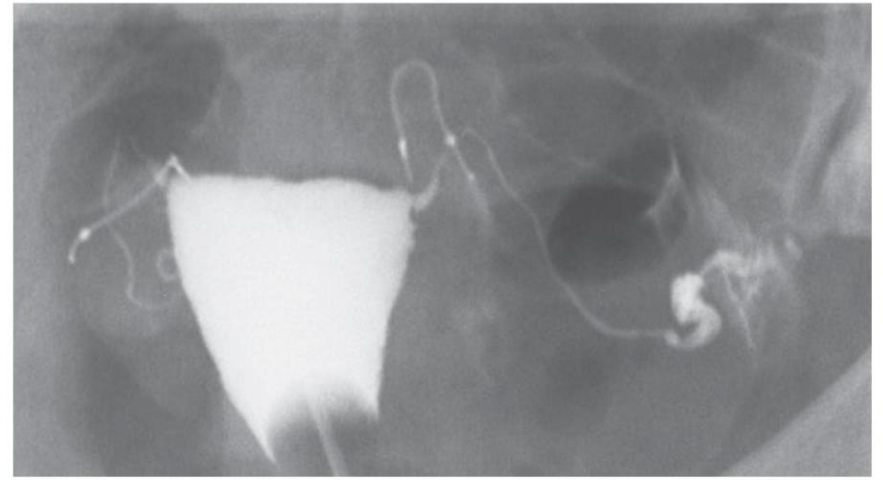


Final image with both uterine cornua  
fully distended

## Case #29: Bilateral Perforations

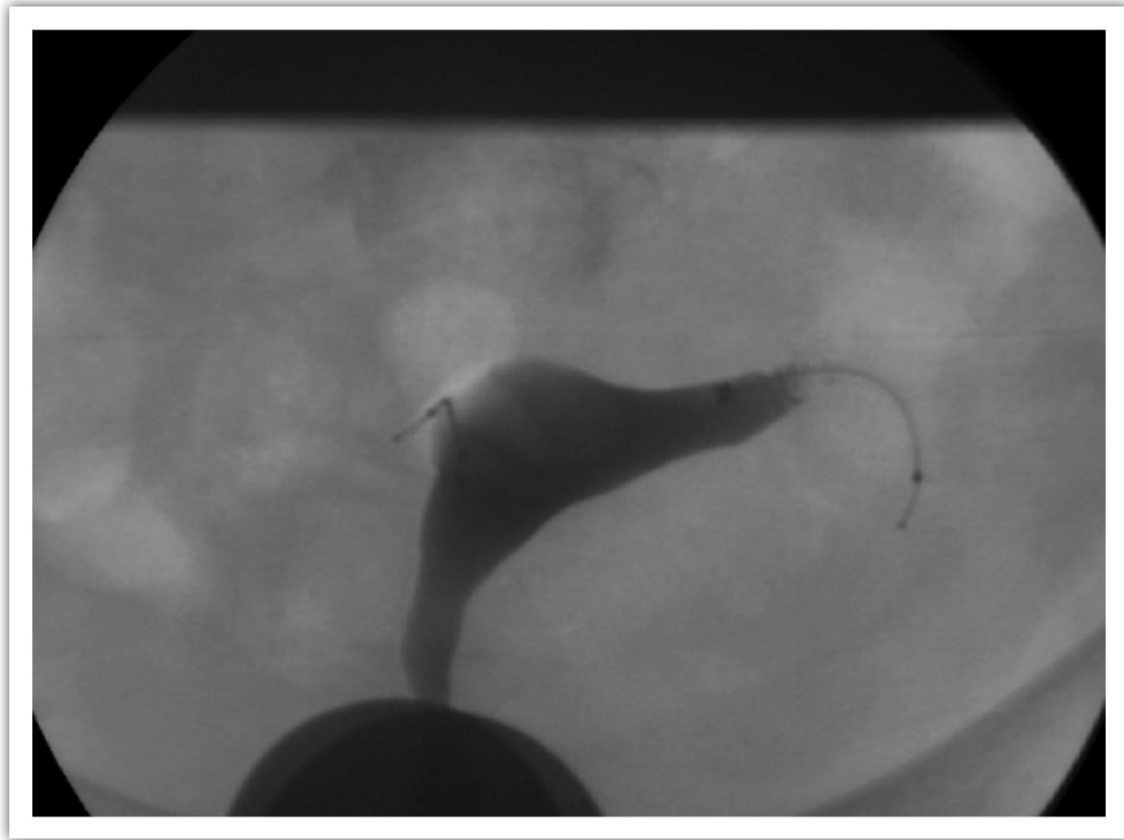


Inserts appear asymmetrical with unusual sharp bends

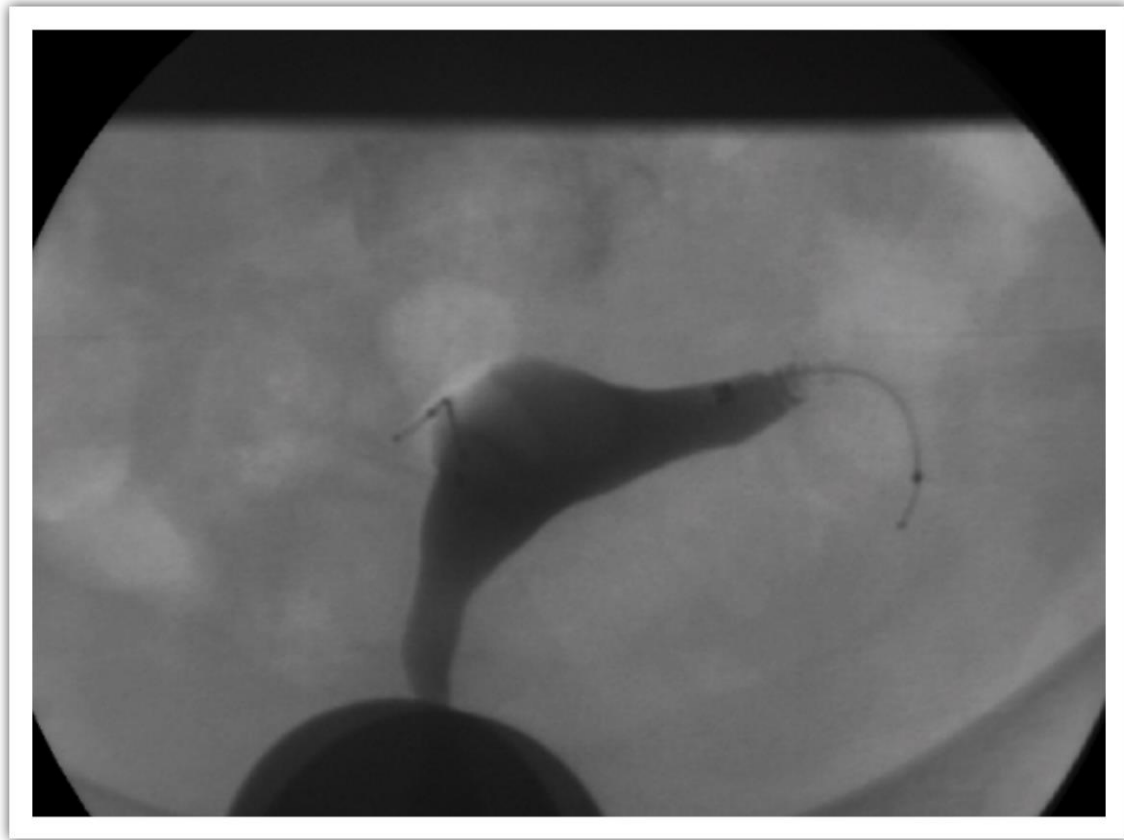


Inserts are clearly outside of the tubes, and the tubes are patent

## Case #30

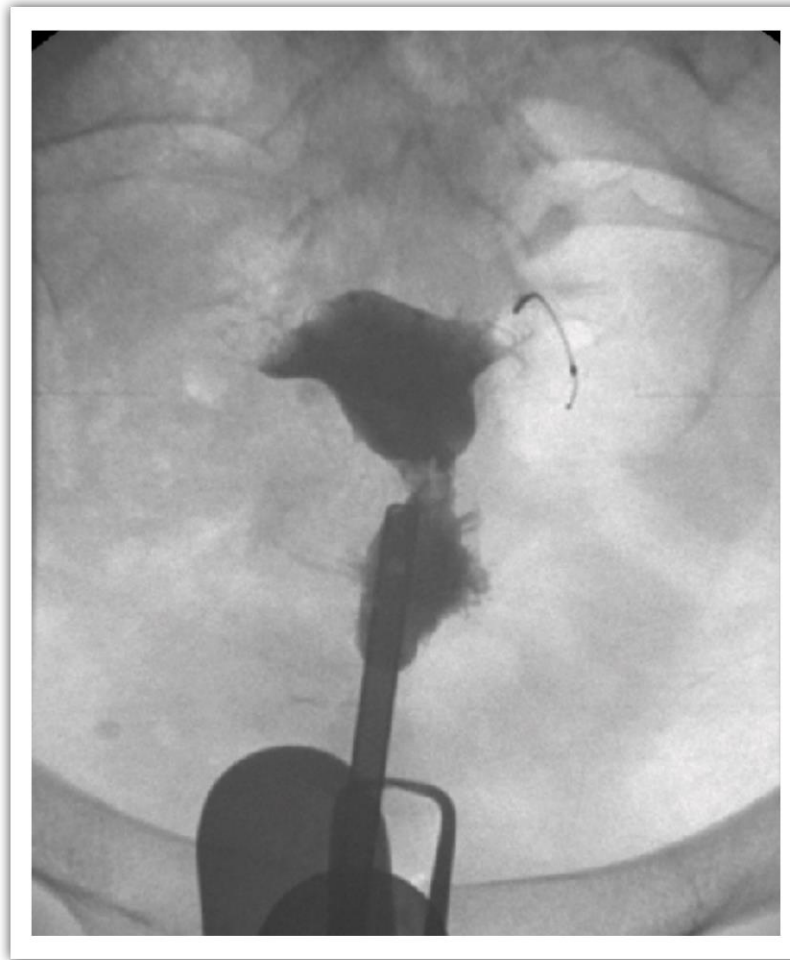


## Case #30: Expulsion



MD states that patient had Essure<sup>®</sup> placed 4 years ago and she documented 9 trailing coils on left and 12 trailing coils on right. Patient recently returned to clinic with 1 device that she states expelled during her menstrual cycle. A repeat modified HSG was ordered

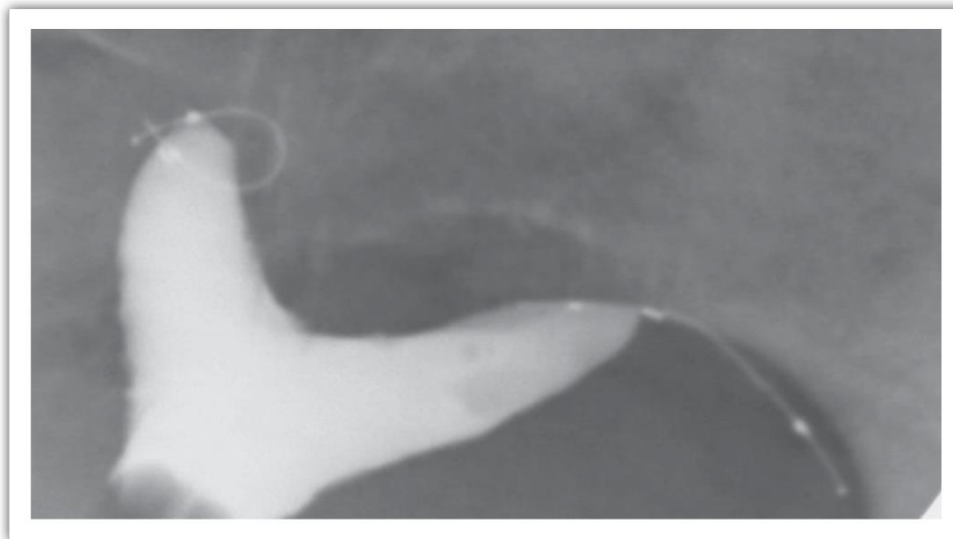
## Case #30: Expulsion



Modified HSG after expelled insert

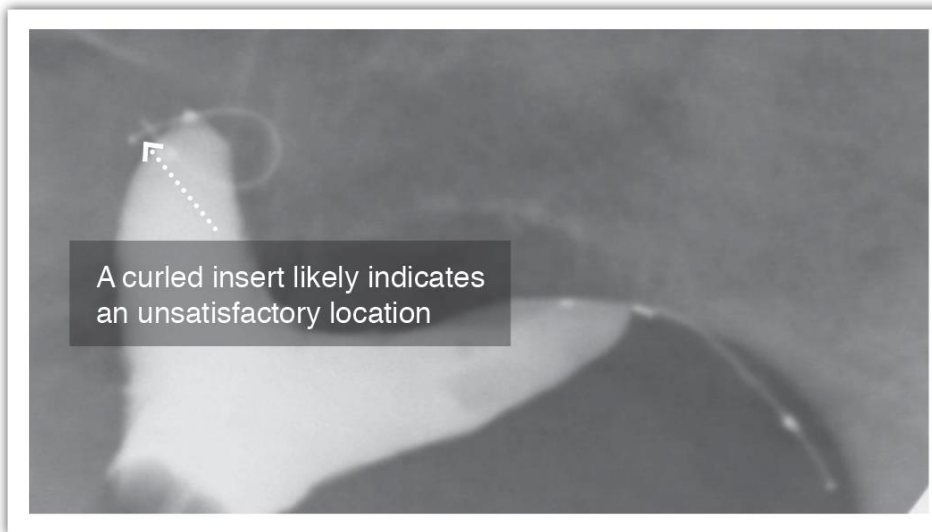
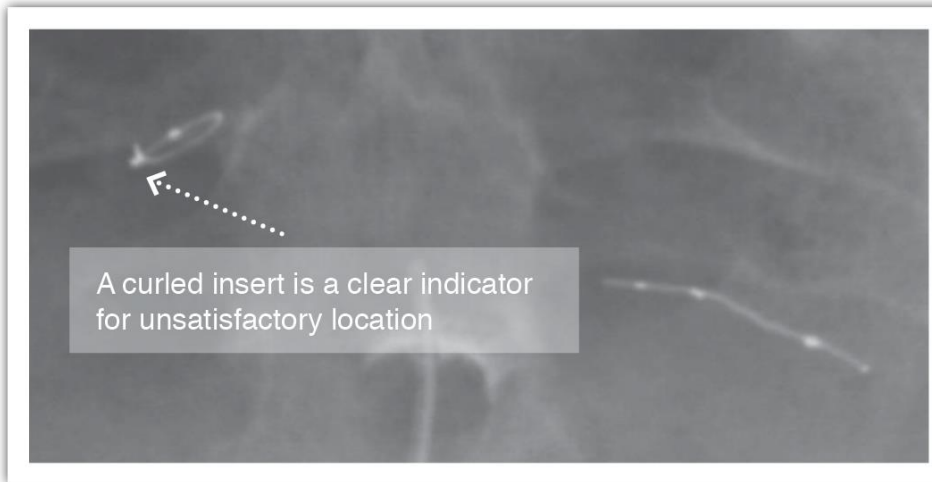
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## Case #31

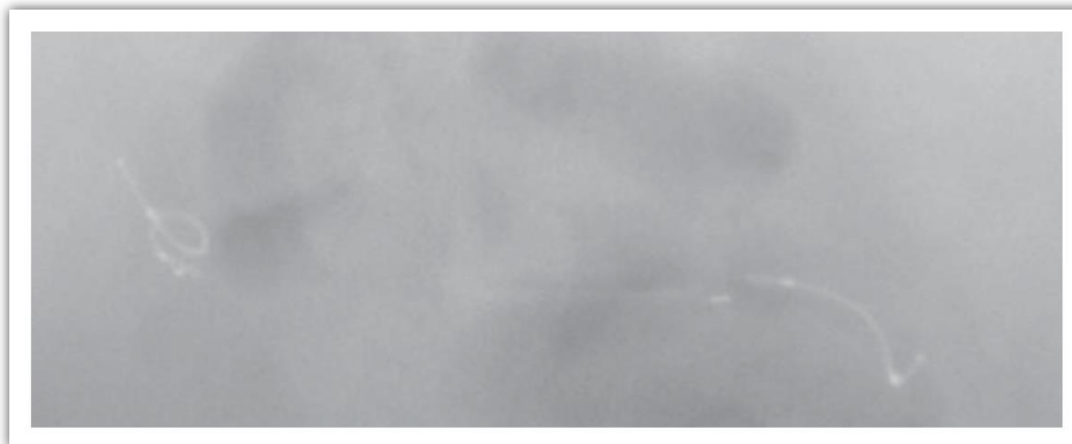


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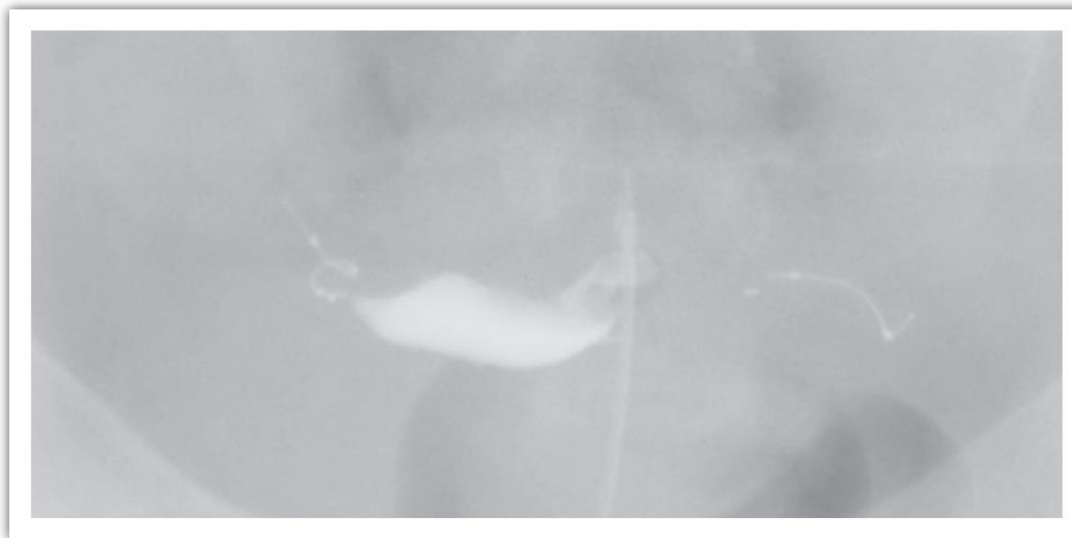
# Case #31: Perforation



## Case #32

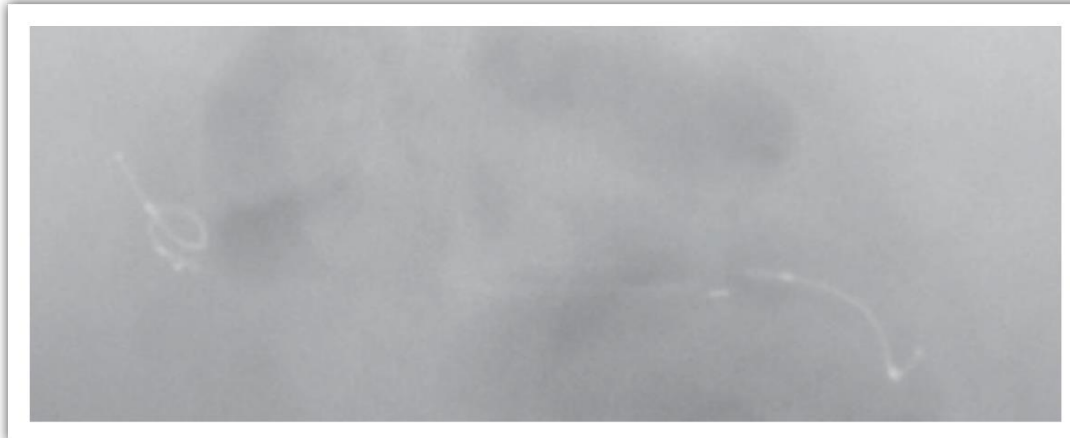


Scout image

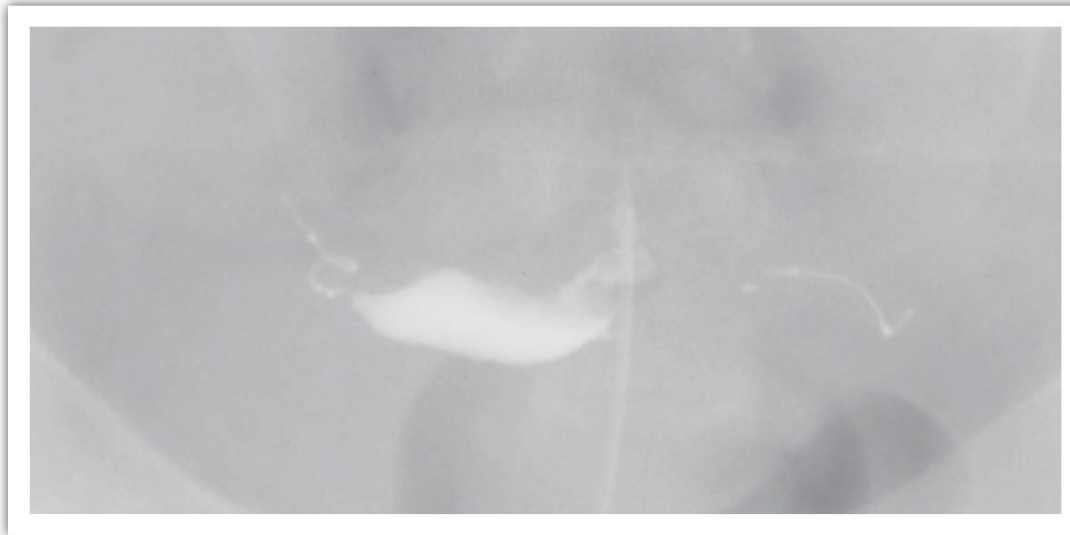


Final image

## Case #32: Perforation

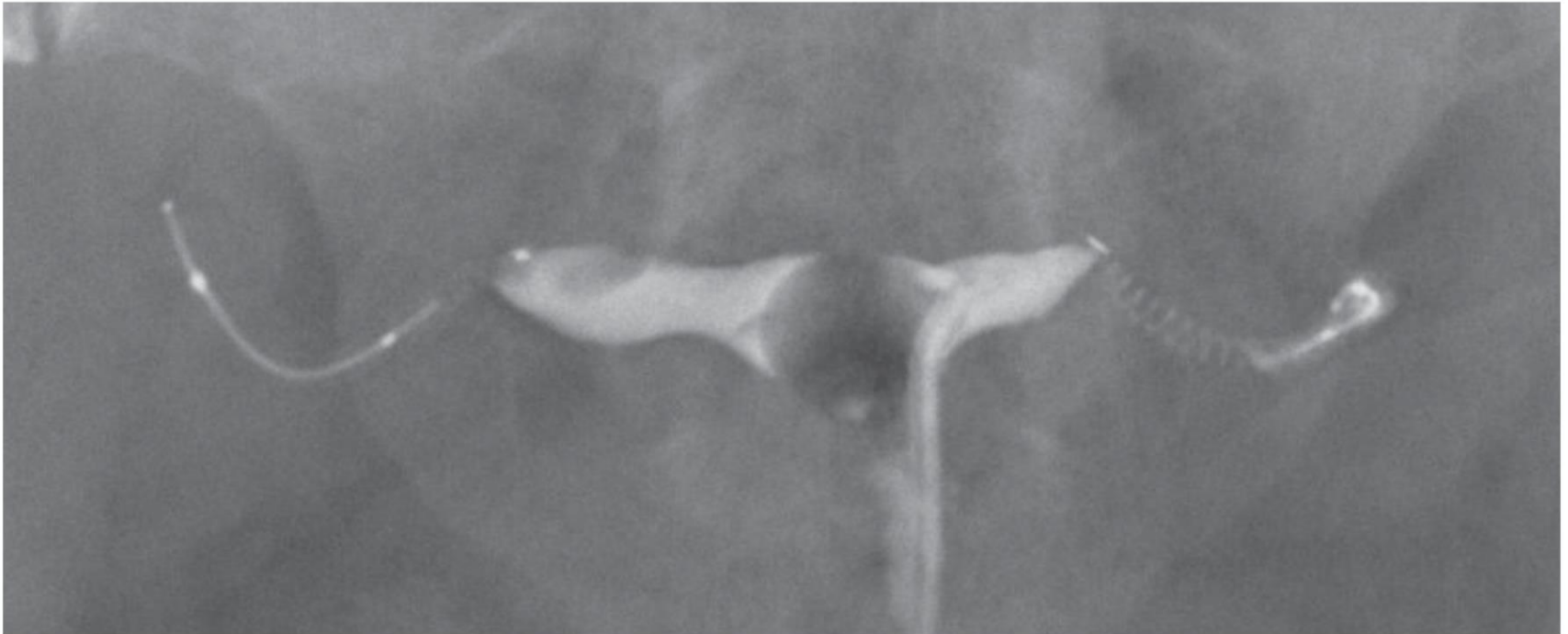


The right insert is curled and is suspicious for unsatisfactory location



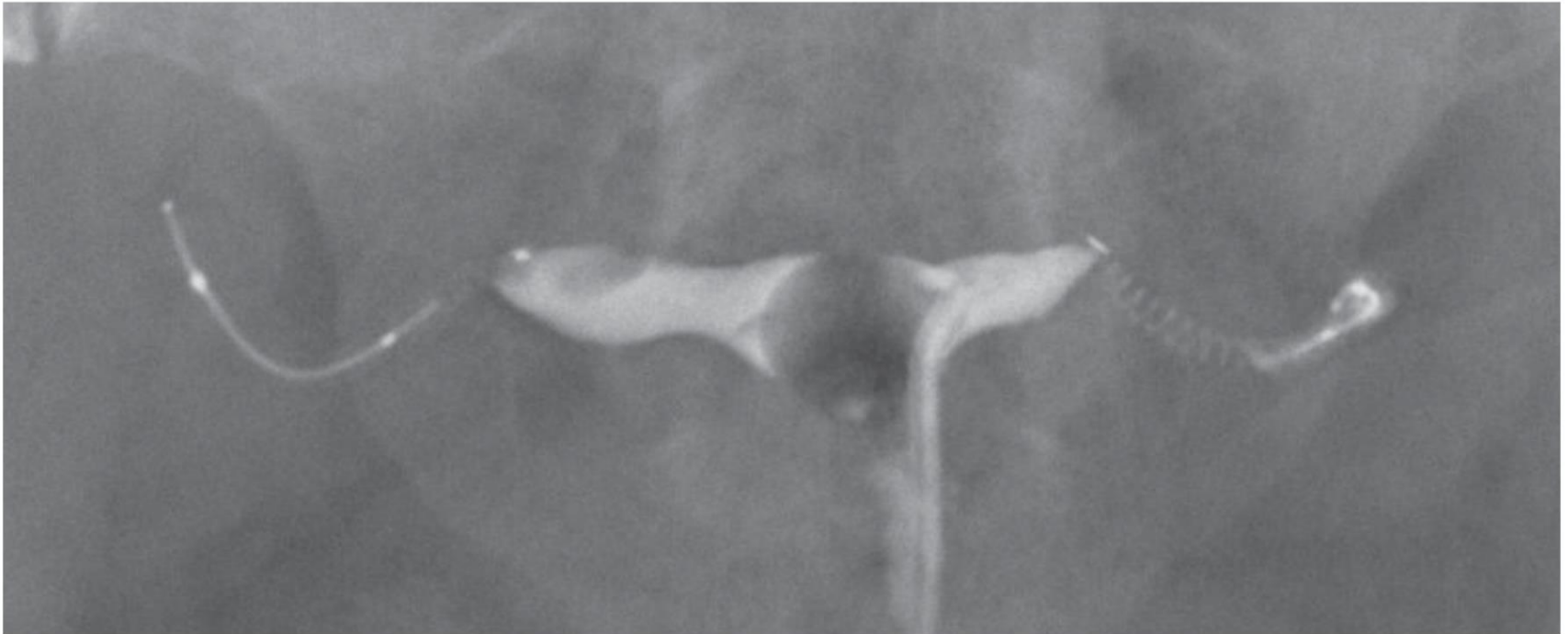
No A/P images were obtained. These fundal images do not confirm satisfactory insert location

## Case #33

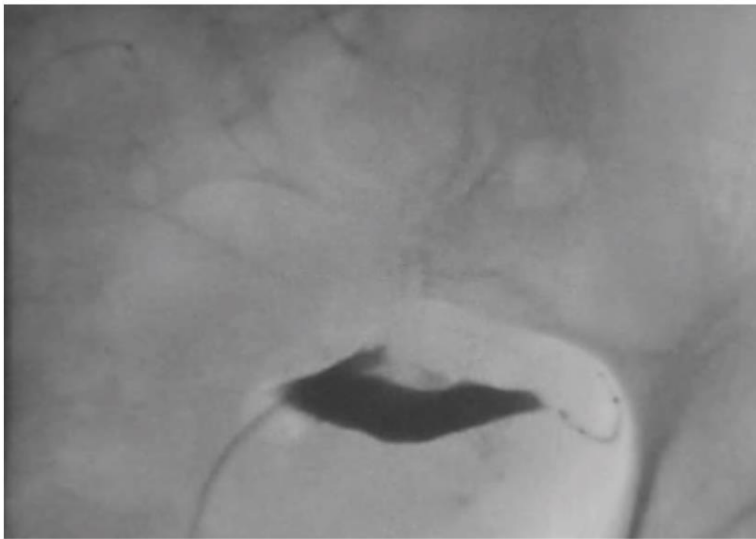
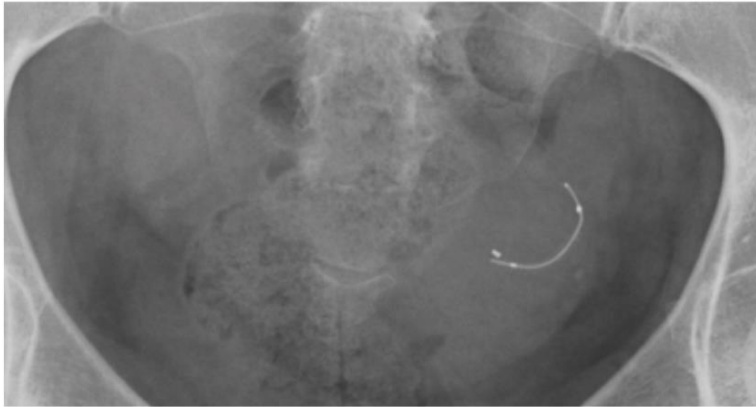


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## Case #33: Distal Location

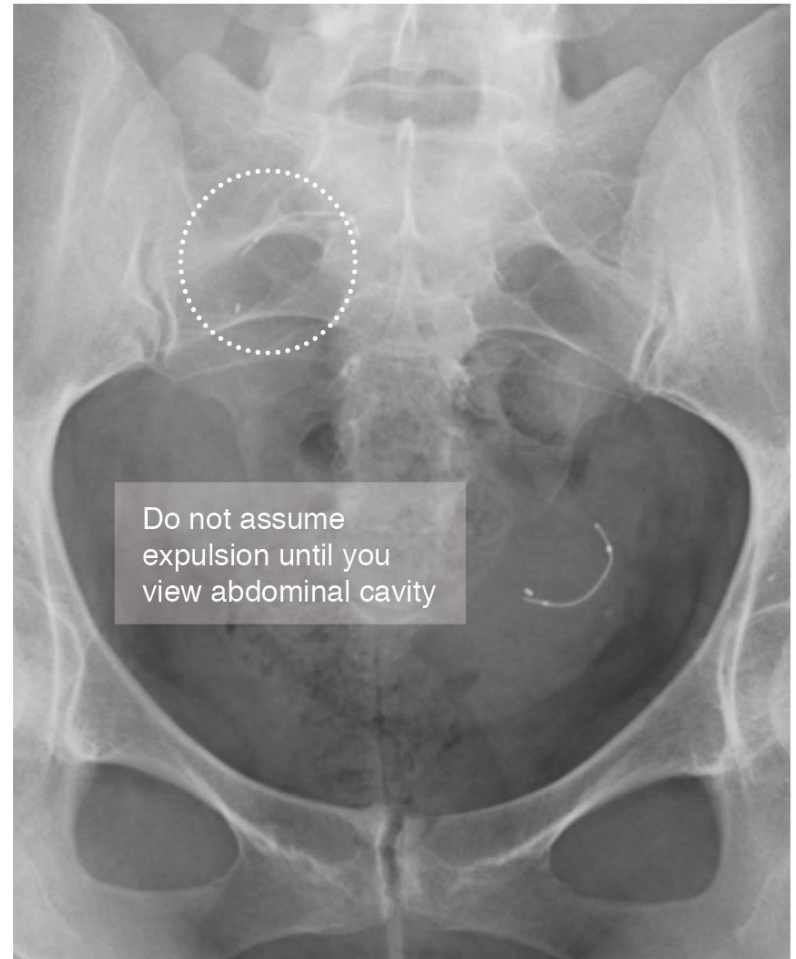
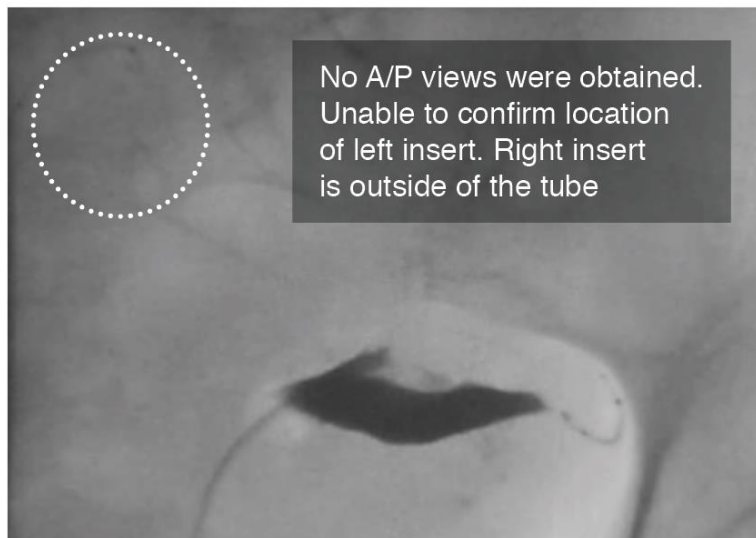
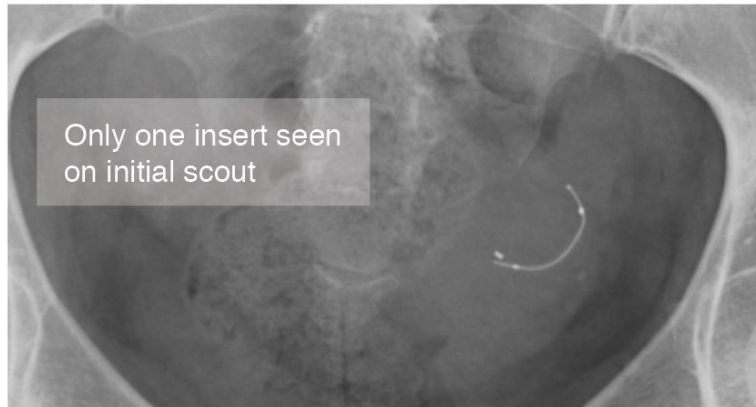


## Case #34



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## Case #34: Perforation



## Case #35



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## Case #35: Satisfactory Location and Occlusion

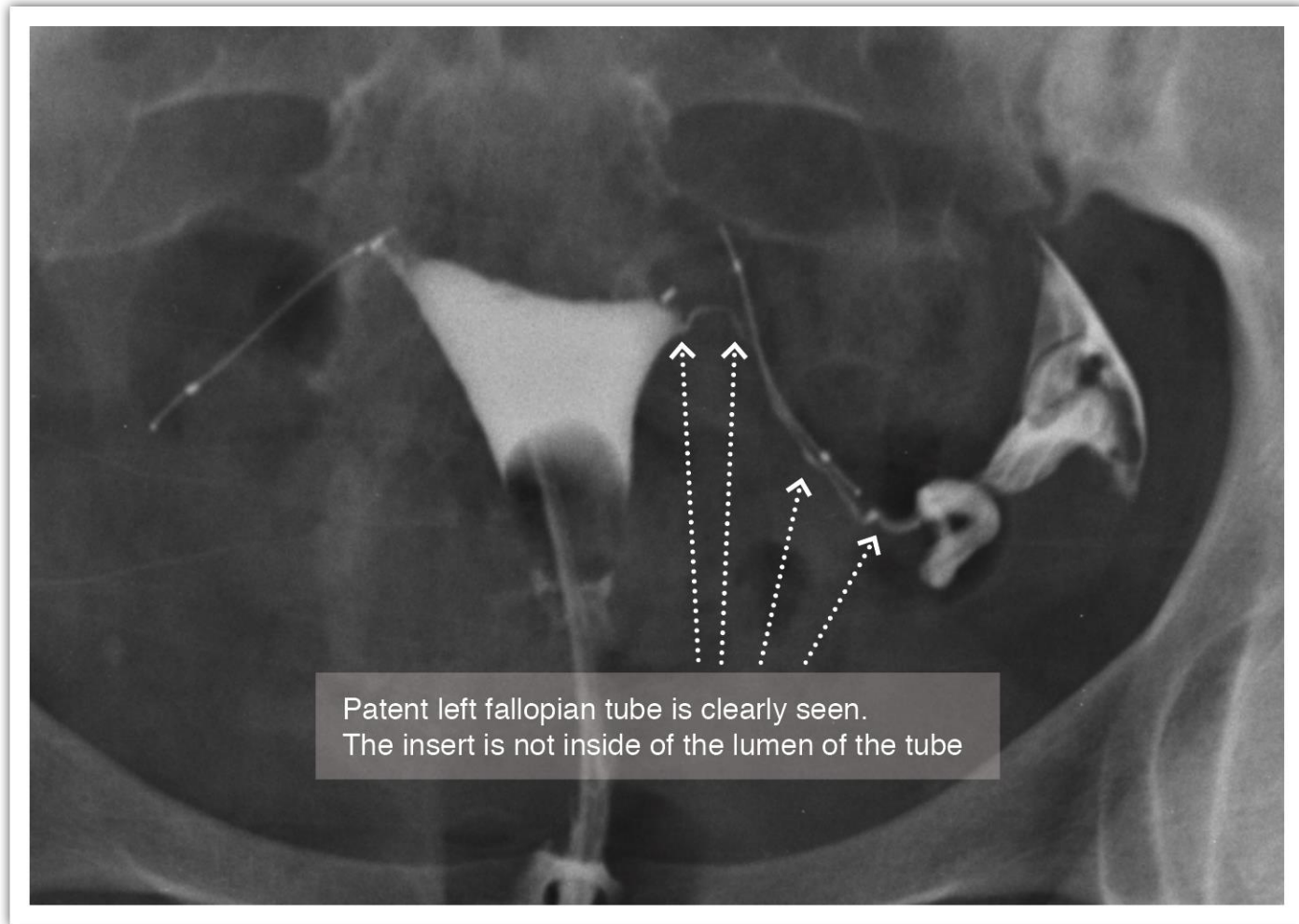


## Case #36



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## Case #36: Perforation

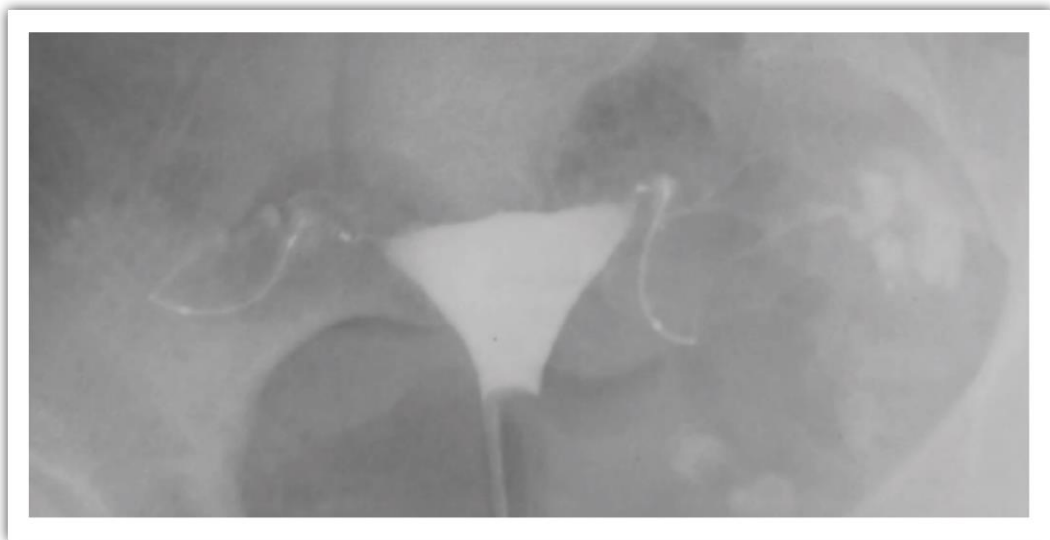


## Case #37

A/P view

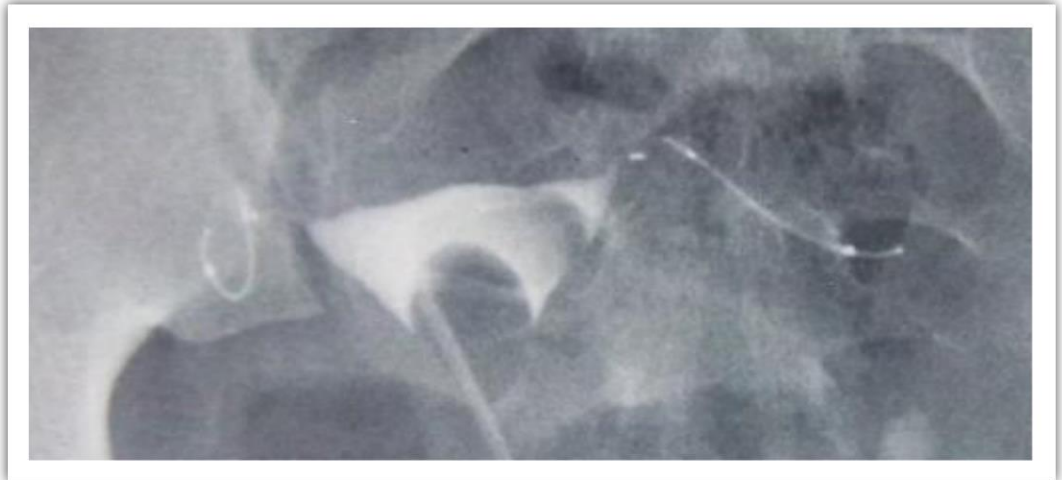


Oblique view

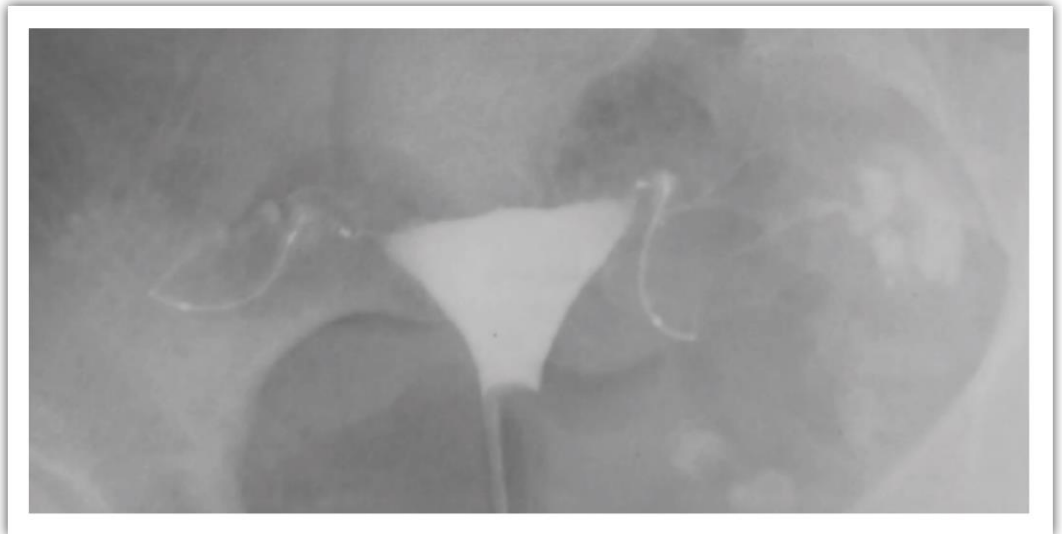


## Case #37: Additional Views May Be Needed

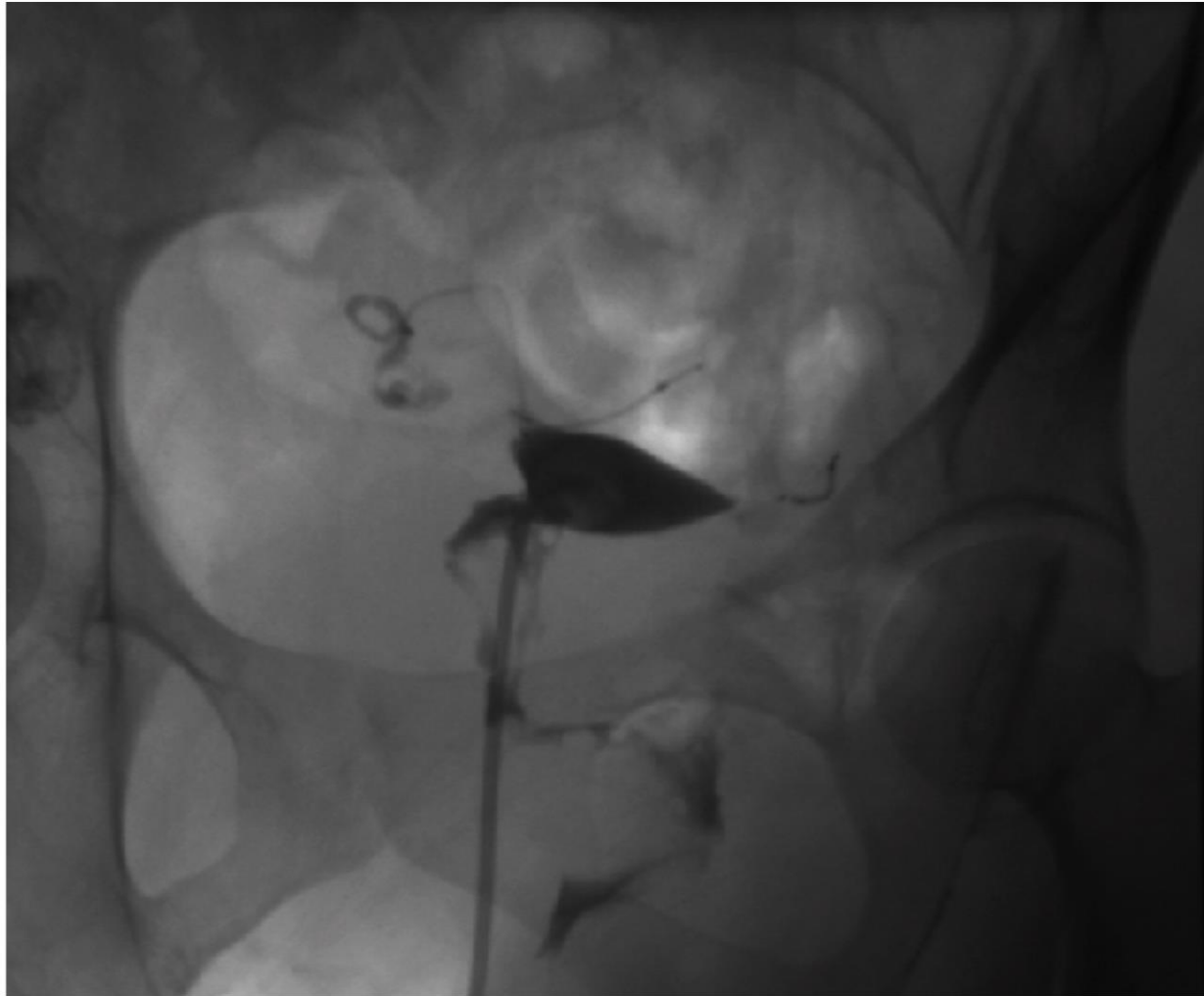
In the A/P view, the right insert appeared to have an unusual orientation. The radiologist was not able to confirm satisfactory tubal location on the right by only capturing images in the A/P view



When an oblique image was taken, it became clear that both inserts were in a satisfactory location within the fallopian tubes. Here you can also see bilateral patency

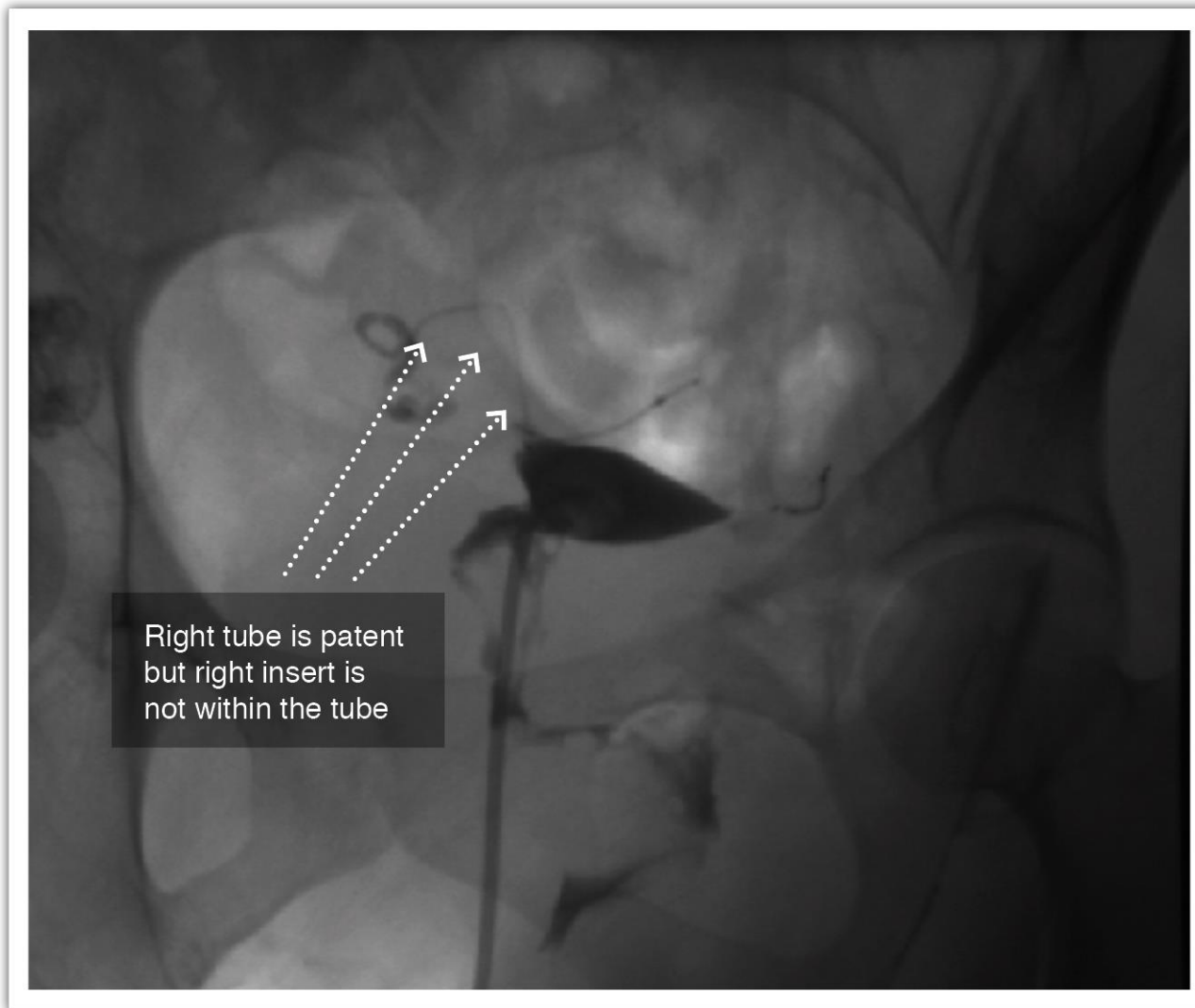


## Case #38

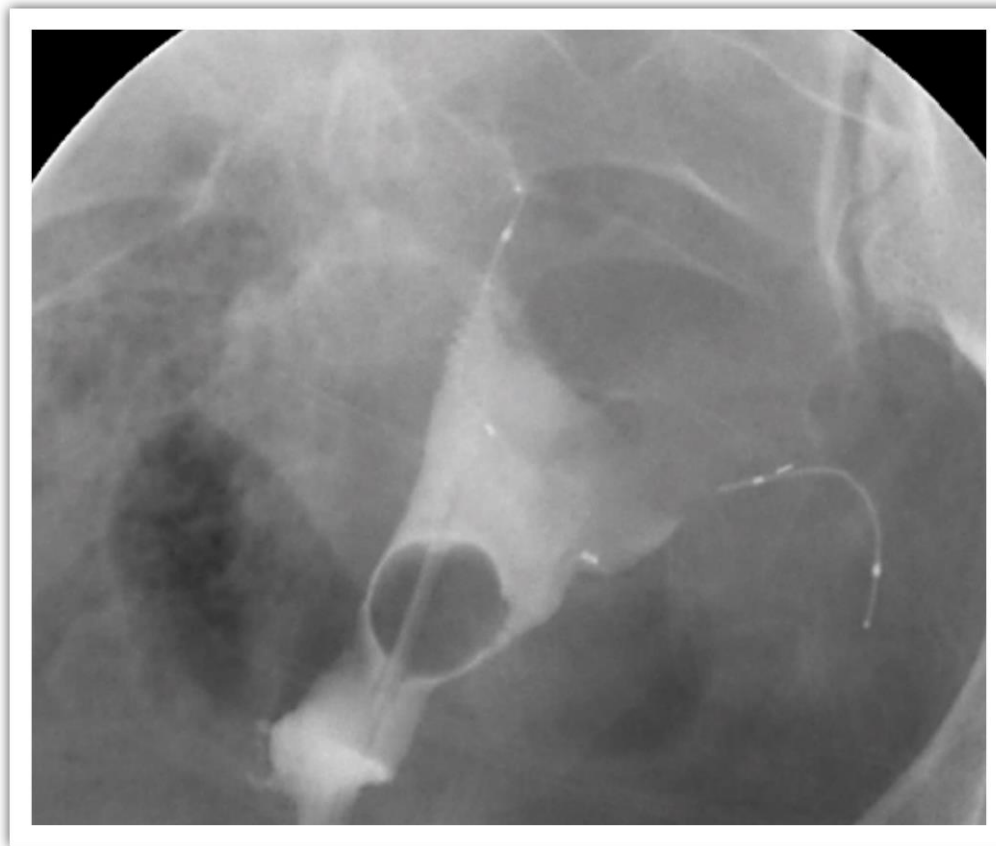


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## Case #38: When Patency Is Seen, Be Sure to Confirm Correct Location of the Inserts to Rule Out a Perforated Insert



## Case #39



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## Case #39: Proximal Location



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