ESSURE CONFIRMATION TEST

USING THE TRANSVAGINAL ULTRASOUND (TVU)/ HYSTEROSALPINGOGRAM (HSG) ALGORITHM

A GUIDE FOR HEALTHCARE PROFESSIONALS

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 beused 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.

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.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON NEXT PAGE.

essure® permanent birth control

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 pruritis. 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 in-growth 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.

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 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

Procedure Warnings

- Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or is suspected, do not continue 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

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

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 1 AND 2.

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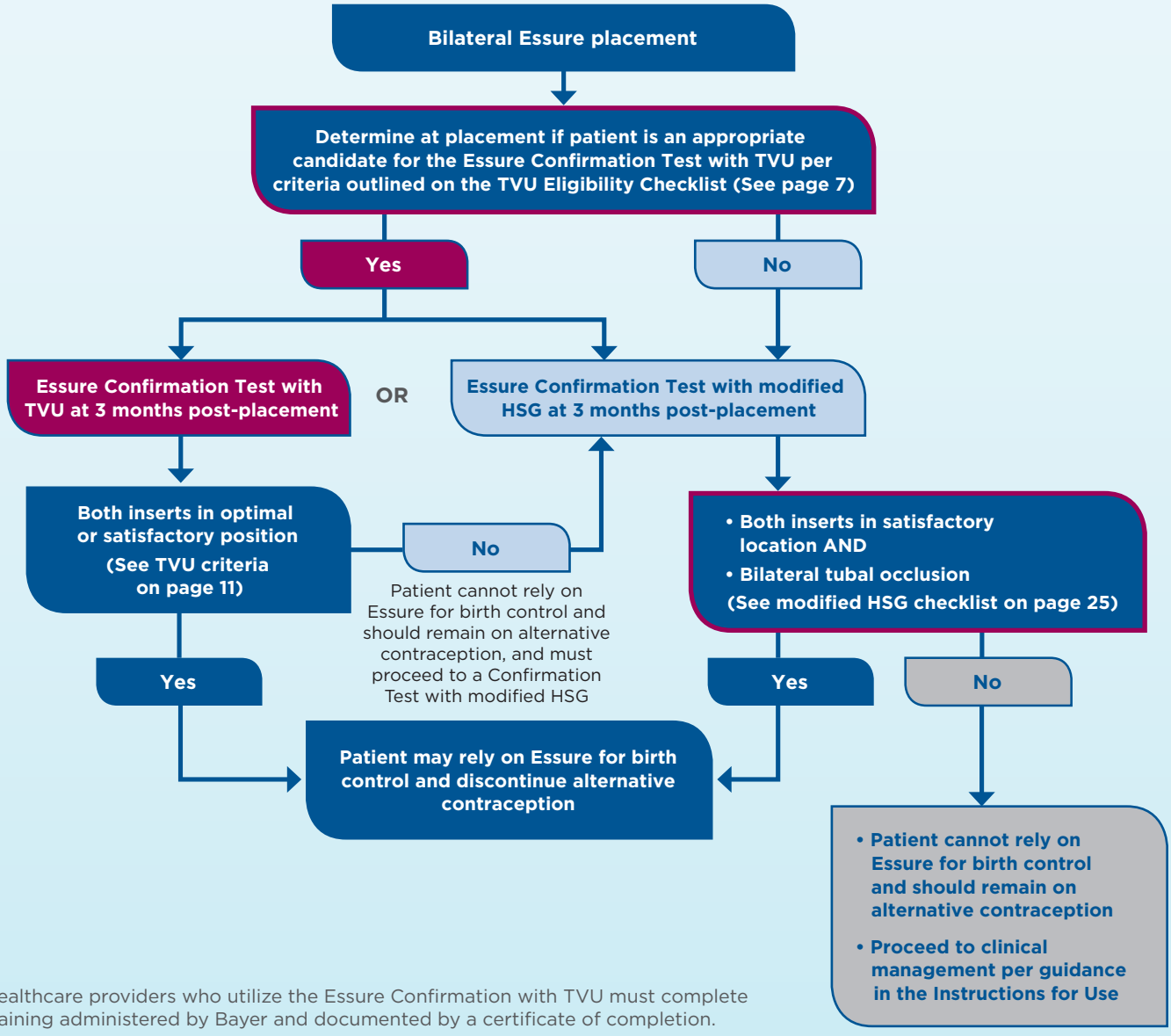
Performing the Essure Confirmation Test

The Essure Confirmation Test is an integral part of the Essure® permanent birth control procedure. The test must show either bilateral satisfactory insert location (when using a transvaginal ultrasound (TVU)) or bilateral satisfactory insert location and occlusion (when using a modified hysterosalpingogram (modified HSG)) in the fallopian tubes before the patient can rely on Essure for contraception.

- An Essure Confirmation Test should be performed 3 months after insert placement to evaluate insert retention and location
- The Essure Confirmation Tests (TVU* or modified HSG) should be performed only by an experienced healthcare provider, including gynecologist, ultrasonographer, and/or radiologist who knows how to perform the appropriate Essure Confirmation Test. Training and educational materials on the Essure Confirmation Test are available through Bayer.
- The Essure Confirmation Test may be performed with TVU or modified HSG as determined by the TVU/HSG Confirmation Test Algorithm.

Essure TVU/HSG Confirmation Test Algorithm



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

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 1 AND 2.

Using the Essure TVU/HSG Confirmation Test Algorithm

- When using the TVU/HSG Confirmation Test Algorithm, TVU may be performed as a first-line confirmation test 3 months after a bilateral insert placement procedure if **all** of the following criteria are met:
  - —Placement procedure was not difficult, including **all** of the following:
    - No concern at the time of placement of possible perforation due to excessive force required for insert delivery and/or a sudden loss of resistance
    - No difficulty identifying the tubal ostia during placement due to anatomical variation or technical factors such as poor distention, suboptimal lighting, or endometrial debris
    - Physician is certain about placement
  - —Procedure time ≤15 minutes (scope in–scope out)
  - —Placement with 1-8 trailing coils for each insert
  - —No 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 (eg, systemic corticosteroids or chemotherapy), 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 used for confirmation, as this test cannot confirm tubal occlusion. Clinical trials were not conducted with patients undergoing immunosuppressive therapy.
- Trans-abdominal ultrasound cannot be substituted for TVU. If ultrasound is not indicated, patient must proceed to a modified HSG to evaluate insert location and tubal occlusion. If ultrasound evaluation is equivocal or unsatisfactory, patient must proceed to a modified HSG to evaluate insert location and tubal occlusion
- Patient 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)

Remember that a modified HSG is always an acceptable first-line option for the Essure Confirmation Test. If TVU is performed and the results are equivocal or unsatisfactory, the patient cannot rely on Essure® for birth control and a modified HSG is require d to evaluate insert location and tubal occlusion. The patient must also be instructed **not** to discontinue her alternative contraception.

For additional information about Essure and the Essure Confirmation Test, refer to the Instructions for Use or contact your Bayer Sales Consultant.

The TVU Eligibility Checklist on page 7 can be used to assess if the patient meets the criteria for confirmation using TVU.

Consider establishing a protocol in your office for scheduling Essure Confirmation Test appointments, calling with reminders, and tracking Essure Confirmation Test compliance.

ESSURE CONFIRMATION TEST WITH TVU

Healthcare providers who utilize the Essure Confirmation Test With TVU must complete training, which is administered by Bayer and documented by a certificate of completion.

For more information, ask your Bayer Sales Consultant or go to the Medical Affairs Site in EssureMD.com.

TVU Eligibility Checklist for the Essure Confirmation Test

Immediately after Essure® bilateral placement, complete the checklist below to help determine whether the patient is eligible for the Essure Confirmation Test with TVU (see TVU/HSG Confirmation Test Algorithm on pages 4-5). The Essure Confirmation Test should be performed at 3 months post-placement.

TVU Eligibility		
Describe Insertion Procedure	**AGREE**	**DISAGREE**
There was no concern at the time of placement of possible perforation due to excessive force and/or sudden loss of resistance.	☐	☐
There was no difficulty in identifying the tubal ostia due to anatomical variation or technical factors (eg, poor distension, suboptimal lighting, or endometrial debris).	☐	☐
You are certain about bilateral placement.	☐	☐
The procedure time (scope in–scope out) was ≤15 minutes.	☐	☐
Placement occurred with 1-8 trailing coils for both left and right inserts.	☐	☐
There was no unusual post-operative pain, transient or persistent, or onset at some later time post-procedure, without any other identifiable cause.	☐	☐
The patient was not on active immunosuppressive therapy (eg, systemic corticosteroids or chemotherapy).	☐	☐
Final Determination	**YES**	**NO**
If you answered "Disagree" to any of the statements above, the patient is not eligible for TVU and a modified HSG is required to evaluate insert location and tubal occlusion. Transabdominal ultrasound cannot be substituted for TVU. Does the patient meet the above criteria for the option of an Essure Confirmation Test with TVU?*	☐	☐

*Refer to the TVU/HSG algorithm included on pages 4-5 for the full set of criteria and to determine whether the patient is a candidate for an Essure Confirmation Test using TVU.

- Counsel the patient to remain on 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 used

Remember to include a procedural note in the patient's chart indicating whether she is an appropriate candidate for the Essure Confirmation Test with TVU, or if she must proceed directly to a modified HSG. A modified HSG is always an acceptable first-line option for the Essure Confirmation Test. If TVU is performed and the results are equivocal or unsatisfactory, the patient cannot rely on Essure® for birth control and a modified HSG is required to evaluate insert location and tubal occlusion. The patient must also be instructed not to discontinue her alternative contraception.

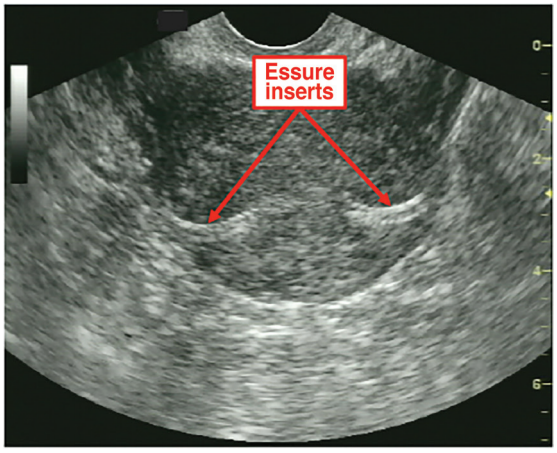
PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 1 AND 2.

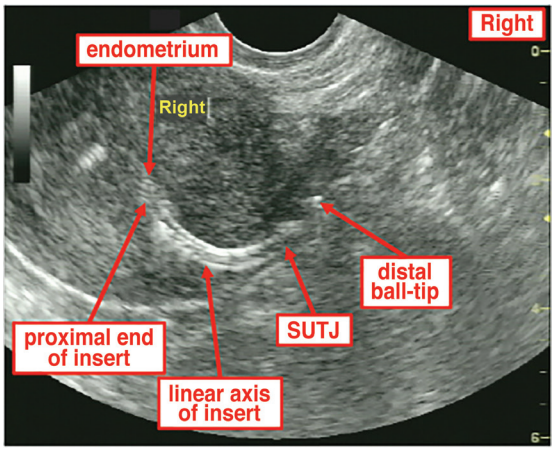
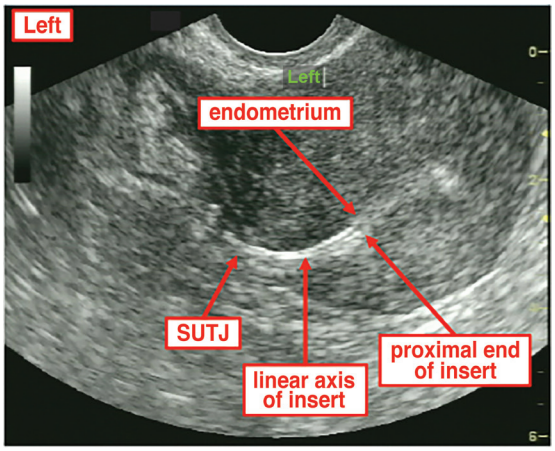
Performing the Essure Confirmation Test With TVU

Before proceeding with the Essure Confirmation Test with TVU at 3 months, confirm that the patient meets the criteria for the option of an Essure Confirmation Test with TVU (see TVU/HSG Confirmation Test Algorithm on pages 4-5). If TVU is not indicated, a modified HSG is required to evaluate insert location and tubal occlusion.

Performing the Essure Confirmation Test With TVU

As the treating physician, it is your responsibility to confirm the results from the TVU Confirmation Test report. Based on the clinical trial protocol, the TVU Confirmation Test has 3 components: orientation, identification, and location. A minimum of 3 required images (TVU scout image, image of left insert, image of right insert) must be obtained and retained for documentation of the TVU Confirmation Test. It is also useful to obtain real-time video, including the 3 required images, if technically possible.

Orientation (assessment of uterine orientation) *Midline sagittal view*	**YES**	**NO**
Indicate the uterine orientation (check one): ☐ Anteverted ☐ Midplane ☐ Retroverted		
Can you confirm that the linear axis of either insert was not visualized in this view? *If no, please describe below.* *If the linear axis of an insert is visualized in the uterine cavity, proximal placement should be suspected. If the linear axis is visualized in the fundal myometrium, fundal perforation should be suspected. Visualization of the proximal end of 1 or both inserts in cross-section may indicate trailing coils in the uterine cavity.*	☐	☐
Identification (visualization of a portion of both inserts simultaneously) *Transverse or oblique transverse view*		
Figure 1. TVU scout image 		
Was a portion of both inserts identified within the cornua or interstitial portion of the tubes?	☐	☐
Was a TVU scout image captured to document the presence of 2 inserts?	☐	☐
Can you clearly see that the inserts are not in contact with each other, with the linear axes of the inserts relatively symmetric and on opposite sides of the uterus? *If 0 or only 1 insert is identified, expulsion or perforation should be suspected.* *If the inserts are in contact with each other, proximal location or expulsion is suspected.*	☐	☐

Location (location of the right and left inserts) *Transverse or oblique transverse view*	**YES**	**NO**
Figure 2. Right insert image 		
Was the linear axis of the right insert identified as a contiguous echogenic structure?	☐	☐
Was an image of the linear axis of the right insert captured for documentation?	☐	☐
Figure 3. Left insert image 		
Was the linear axis of the left insert identified as a contiguous echogenic structure?	☐	☐
Was an image of the linear axis of the left insert captured for documentation?	☐	☐
Note the positions of the right and left inserts in the cornua and the relationships with the endometrium and the serosal utero-tubal junction (SUTJ).		

Classification (classification of right and left inserts location)

Right insert: Please indicate the category of the right insert location (check one):

☐ Optimal ☐ Satisfactory ☐ Unsatisfactory ☐ Equivocal

If unsatisfactory, please indicate the category (check one):

☐ Distal ☐ Proximal ☐ Perforation ☐ Expulsion ☐ Unclassified

Left insert: Please indicate the category of the left insert location (check one):

☐ Optimal ☐ Satisfactory ☐ Unsatisfactory ☐ Equivocal

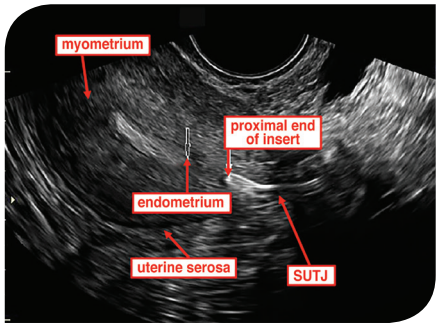
If unsatisfactory, please indicate the category (check one):

☐ Distal ☐ Proximal ☐ Perforation ☐ Expulsion ☐ Unclassified

Confirmation	YES	NO
If you answered **"No"** to any of the questions above (pages 8-9), or if the TVU results were equivocal or unsatisfactory, inform the patient that she cannot rely on Essure® for birth control and must remain on alternative contraception, and an Essure Confirmation Test with modified HSG is required to evaluate insert location and tubal occlusion.		
Can the patient rely on Essure for birth control?	☐	☐
Does the patient need to proceed to an Essure Confirmation Test with modified HSG?	☐	☐

Classification of TVU Locations

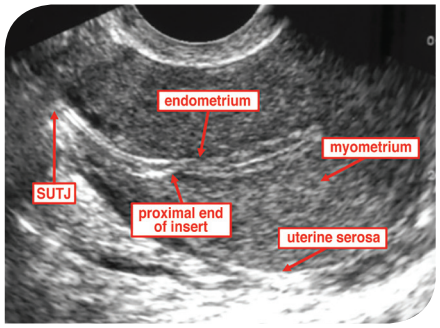
Figure 4



Satisfactory location

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.

Figure 5



Optimal location

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 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.

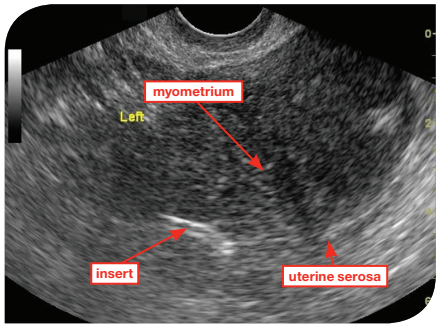
How to manage the TVU evaluations with satisfactory or optimal locations of both inserts:

The patient may be told to discontinue her alternative contraception and rely on Essure® for birth control. 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.

Unsatisfactory location

The 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. There are 5 types of unsatisfactory placement locations: distal, proximal, perforation, expulsion, and unclassified.

Figure 6

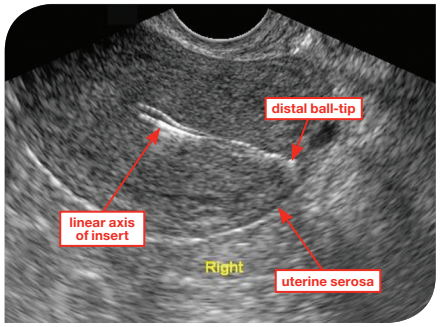


Transverse focused view

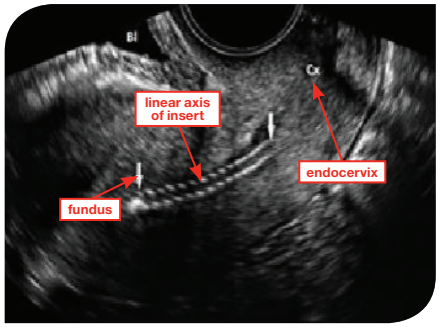
Distal

Distal placement is 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.

Figure 7



Transverse focused view

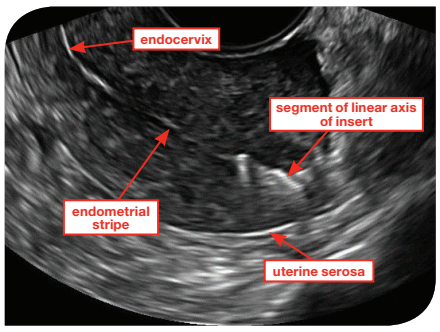


Midline sagittal view

Proximal

Proximal placement is 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.

Figure 8

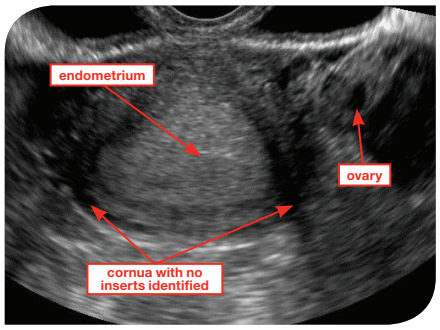


Midline sagittal view

Perforation

Perforation is 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.

Figure 9

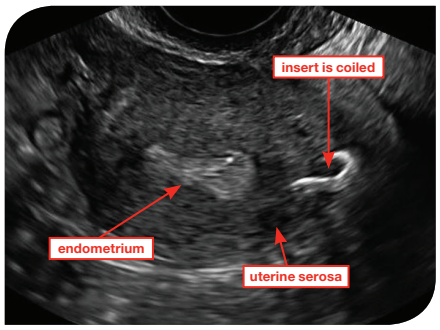


Transverse fundal view

Expulsion

Expulsion is suspected if one or both inserts are not identified in the cornua in a transverse view in a single scout image.

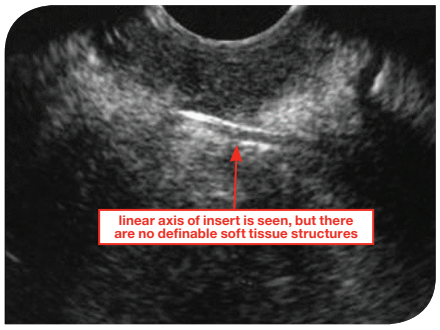
Figure 10



Oblique transverse view

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.



Transverse view

How to manage the TVU evaluations with unsatisfactory locations for one or both inserts:

If the TVU 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 told to continue her alternative contraception and that she cannot rely on Essure® until a satisfactory Essure Confirmation Test is documented.

If TVU is performed and the results are equivocal or unsatisfactory, the patient cannot rely on Essure for birth control and must remain on alternative contraception, and a modified HSG is required to evaluate insert location and tubal occlusion.

ESSURE CONFIRMATION TEST WITH MODIFIED HSG

Performing the Essure Confirmation Test With Modified HSG

The Essure Confirmation Test with modified HSG is used to evaluate both the location of the inserts and occlusion of the fallopian tubes. Every patient must have an Essure Confirmation Test 3 months following the Essure® procedure. The Essure Confirmation Test may be performed with TVU or modified HSG as determined by the TVU/HSG Confirmation Test Algorithm; however, modified HSG is always an acceptable first-line option. The patient must use alternative contraception until the Essure Confirmation Test verifies that the patient may rely on Essure for permanent birth control. Per the TVU/HSG Confirmation Test Algorithm, modified HSG is also required after TVU if the TVU results are equivocal or unsatisfactory.

If bilateral insert location is satisfactory and bilateral fallopian tube occlusion is demonstrated, instruct your patient that she may discontinue alternative contraception and rely on Essure for birth control.

Performing the Essure Confirmation Test With Modified HSG

To evaluate insert location and tubal occlusion, Essure Confirmation Test with modified HSG images must show the relationship of the proximal end of the inner coil to the uterine cornua.

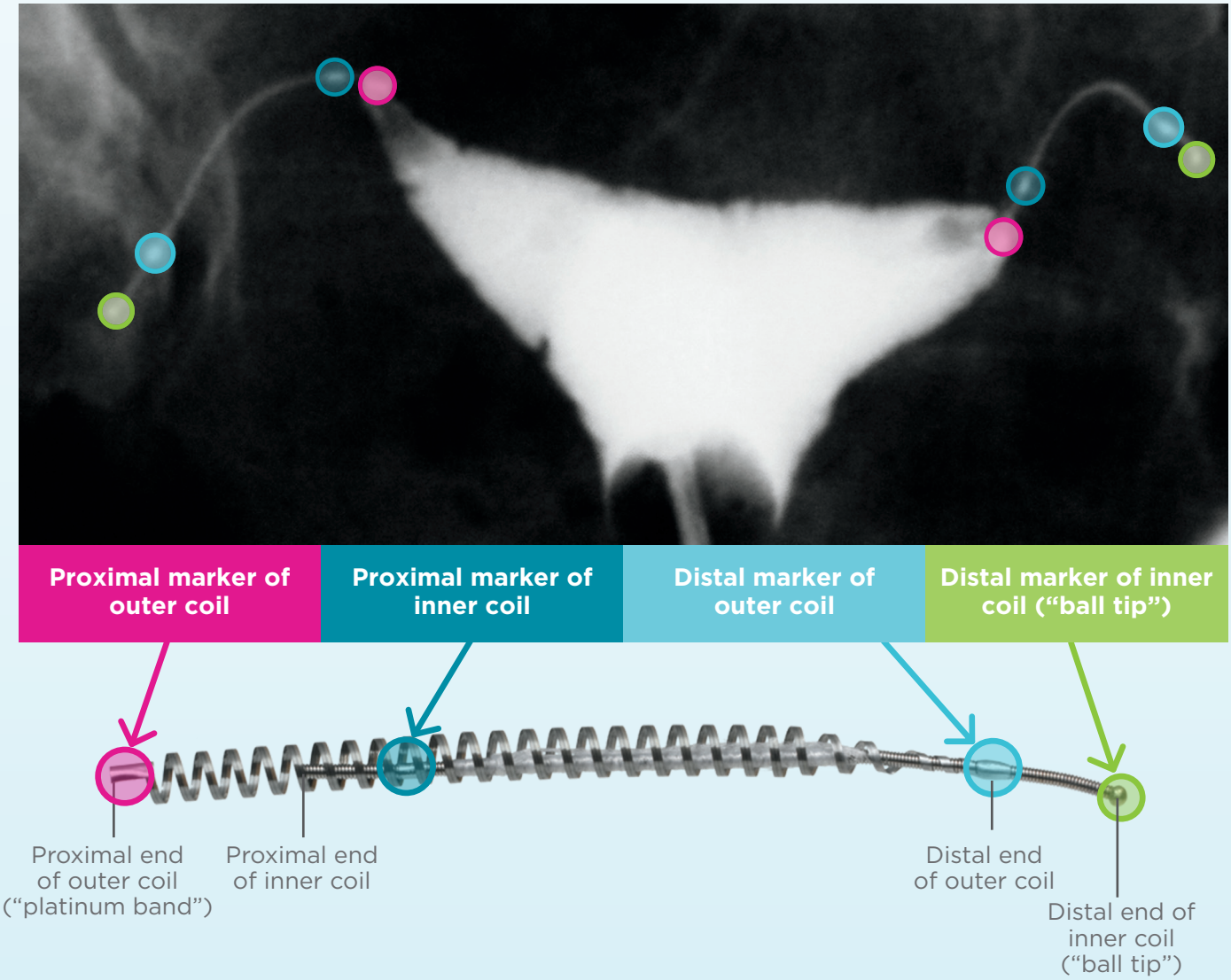
To produce adequate images, adherence to the following guidelines is recommended:	
1.	Obtain good cornual filling so that uterine cavity silhouette is clearly seen.
2.	Place fluoroscopy beam as close to A/P projection as possible.
3.	Do not dilate cervix unless necessary; if dilation occurs, maintain a good cervical seal.
4.	Downward traction on cervical tenaculum may be required for midpositional uteri. Remove speculum prior to fluoroscopy for best visualization of uterine anatomy.
5.	Take a minimum of 6 radiographs to assess insert location and tubal occlusion.

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 should be avoided.

Radiographic Markers

There are 4 radiographic markers on the device to help evaluate insert location and tubal occlusion:

Figure 11. Proximal and distal radiographic markers.



During the evaluation of the modified HSG films, the 4 radiopaque markers should be identified for each insert. Note that the 2 distal markers and the proximal marker of the inner coil are fixed in relation to one another, but the proximal marker of the outer coil may move or seem stretched because of the flexibility of the outer coil.

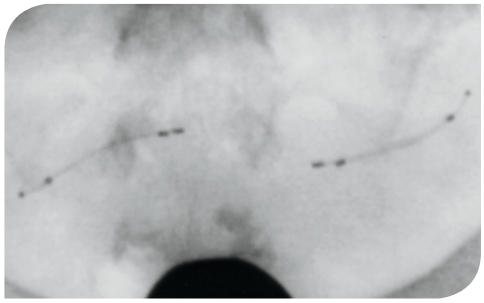
IMPORTANT: Bayer is providing this information to you for informational and educational purposes only. This document is not intended to be used as part of training or certification requirements for Essure®, or to establish a standard of care. You are solely responsible for ensuring that you and your staff have been properly trained in all aspects of performing the Essure procedure to your patients in the office setting. For complete instructions, please refer to the Instructions for Use and the Physician Training Manual.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 1 AND 2.

Radiograph Imaging

Take a minimum of 6 radiographs to assess insert location and tubal occlusion. In some cases, additional images may be necessary to evaluate insert location. This might include oblique views or lateral views.

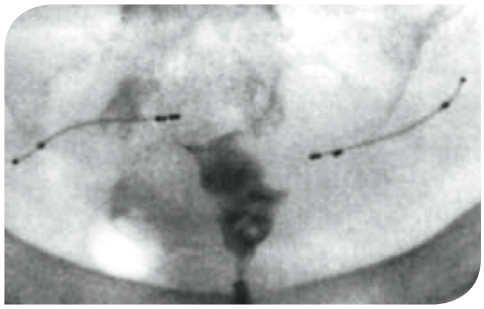
Figure 12



Scout film

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

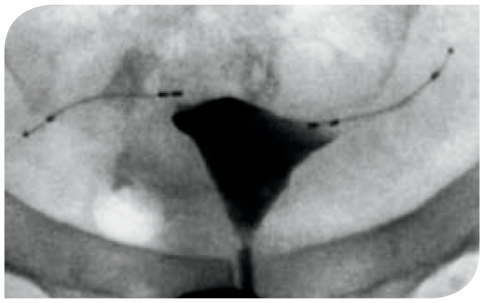
Figure 13



Minimal fill

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

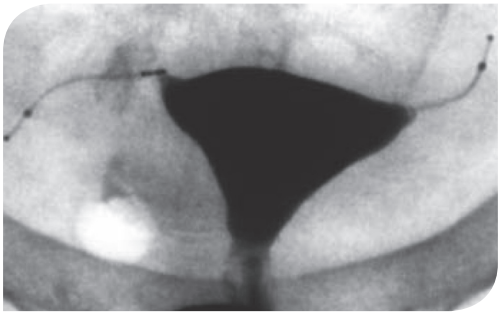
Figure 14



Partial fill

Capture an image of the uterus when it is nearly full of contrast or opacified. The cornua may not yet have been adequately distended. Proximal portions of the Essure inserts may not yet be obscured by the advancing contrast.

Figure 15



Total fill

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 Radiograph 4 (Figure 15) to avoid undue patient discomfort and vasovagal reaction.

Figure 16

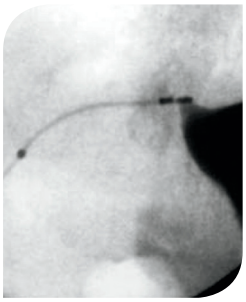
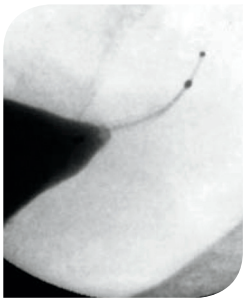


Figure 17



Magnification of the uterine cornua

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

Note: Assessment of the location of the inserts on the Essure Confirmation Test with modified HSG is not the same as noted on hysteroscopy. Therefore, a correctly placed insert may appear to be more distal on the Essure Confirmation Test with modified HSG than noted at the time of hysteroscopy.

The Radiology Report must include:

1. **Number of inserts**
2. **Location of each insert**
3. **Tubal occlusion assessment for each side**
4. **Description of unusual findings**

Evaluating Essure Confirmation Test With Modified HSG Films Quality

When evaluating the Essure Confirmation Test with modified HSG films, first confirm that the appropriate radiographs previously described are provided, a good A/P image of the uterine silhouette is obtained, and the uterus is completely filled in at least one view.

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

- The appropriate sequence of radiographs was not taken
- One or both uterine cornua were not maximally distended
- The uterine silhouette is fundal rather than A/P
- The image of the uterine cornua is obscured in any way
- Insert cannot be located or position is unclear

Examples of Essure Confirmation Tests with modified HSG that need to be repeated

Figure 18. Filling defect in the left cornua

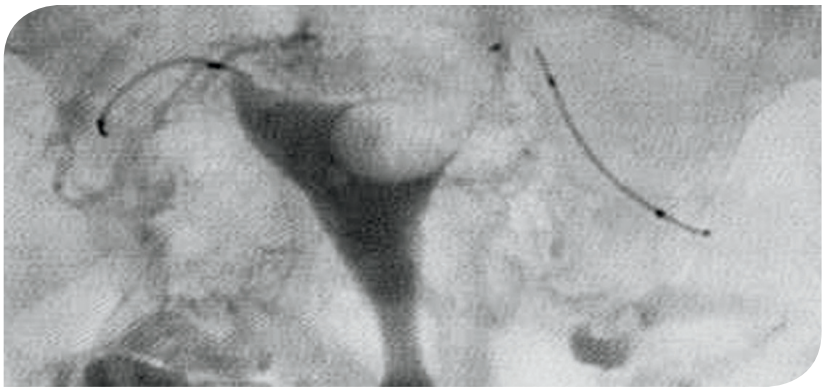
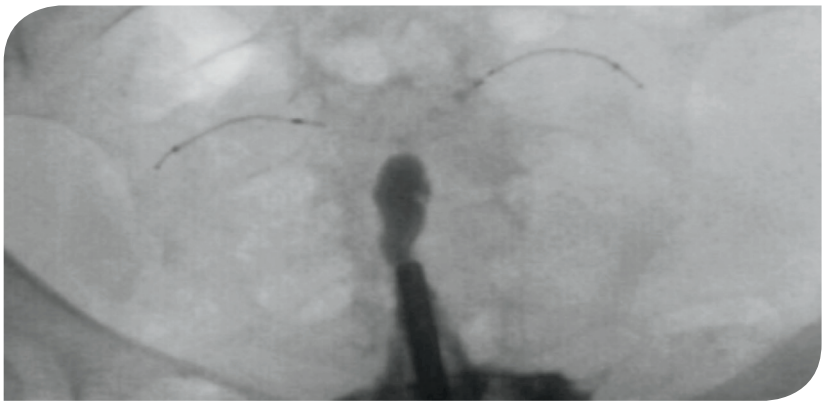


Figure 19. Inadequate filling

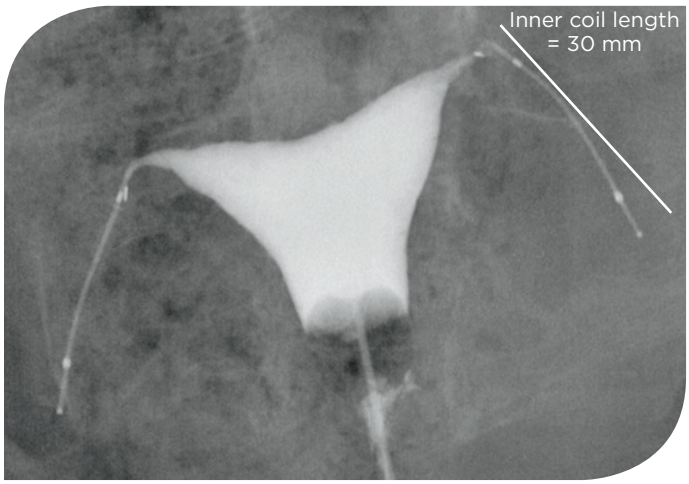


Evaluating Insert Location

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

Figure 20. Satisfactory bilateral insert location and tubal occlusion



Note the 4 radiopaque markers and inner coil length. The inserts are symmetrical with a normal curvature. Ideal insert location is where the inner coil crosses the uterotubal junction. Note that the 2 distal markers and the proximal marker of the inner coil are fixed in relation to one another, but the proximal marker of the outer coil may move or seem stretched because of the flexibility of the outer coil.

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

Satisfactory location

A satisfactory location is defined as the distal end of the inner coil being within the fallopian tube with <50% of the inner coil trailing into the uterine cavity, OR the proximal end of the inner coil being ≤30 mm into the tube from where contrast fills the uterine cornua.

Figure 21

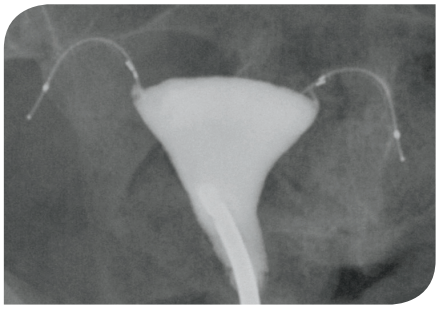


Figure 22

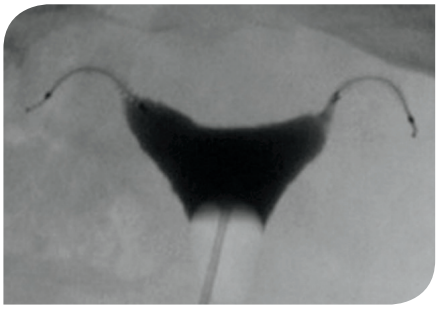
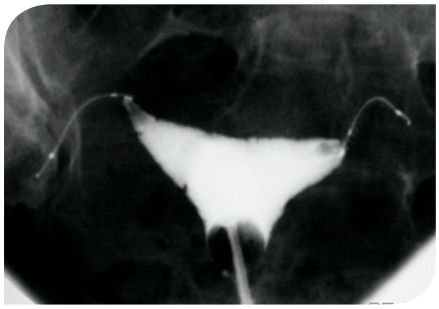


Figure 23



Note the normal curvature and symmetrical appearance of both inserts

Unsatisfactory location

There are 4 types of unsatisfactory location: proximal location, expulsion, distal location, and perforation or peritoneal location.

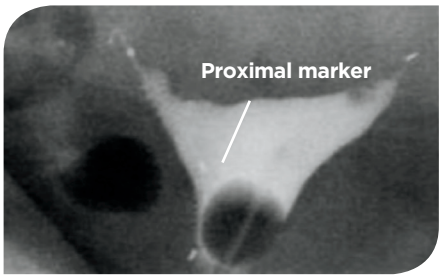


Figure 24. Proximal location of the right insert, with ≥50% of the inner coil trailing into the uterine cavity

Proximal location

Proximal location is defined as: ≥50% of the inner coil is trailing into the uterine cavity.

How to manage:

Advise patient not to rely on Essure®; continue alternative contraception or consider incisional sterilization.

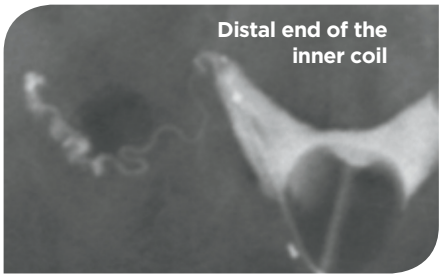


Figure 25. Expulsion of the right insert with tubal patency

Expulsion

One or both inserts are not present or insert lies completely in the uterine cavity.

How to manage:

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.

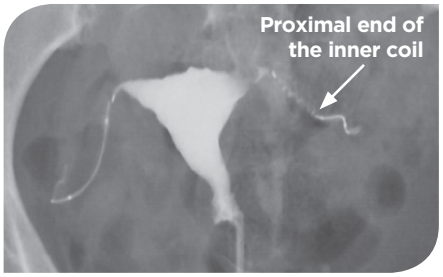


Figure 26. Distal location of the left insert

Distal location

Distal location is defined as: the insert is in the tube, but the proximal end of the inner coil is >30 mm from the cornua.

How to manage:

Advise patient not to rely on Essure. 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 (continued)

Perforation or peritoneal location

When a perforation occurs, the insert has completely or partially perforated the uterus or tube (eg, embedded in the myometrium or completely in the peritoneal cavity). Peritoneal location means the insert is found within the peritoneal cavity and not located within the tube.

How to manage:

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.

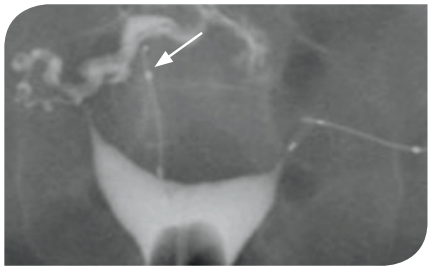


Figure 27. Fundal perforation

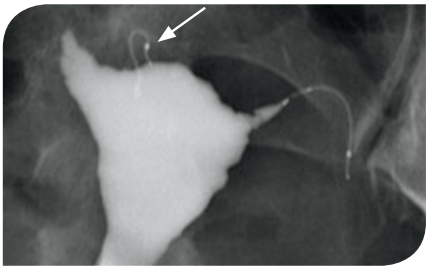


Figure 28. Embedded in myometrium

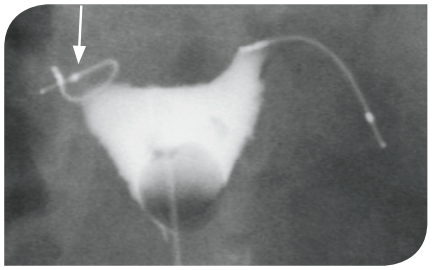


Figure 29. Right insert perforation; note the coiled configuration insert

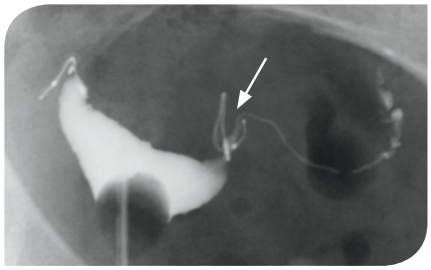


Figure 30. Left insert perforation; insert has a sharp bend and there is tubal patency. The right insert is also curled and suspicious for perforation

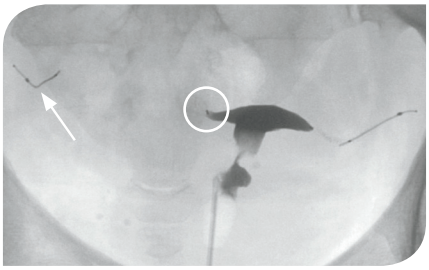


Figure 31. Right insert perforation with stretched outer coil

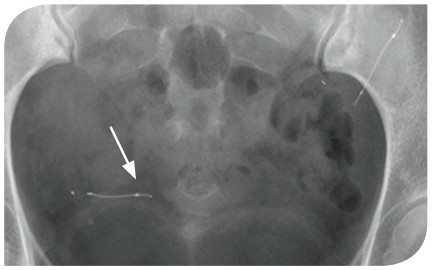


Figure 32. Right and left bilateral perforation noted on scout film: note the distance between the 2 inserts, their lack of normal curvature, their asymmetrical lie, and the reversed orientation of the right insert

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

Evaluating Tubal Occlusion

After evaluating insert location, determine whether contrast is visible beyond the insert and note any degree of proximal tubal filling, even if the tube is occluded. Satisfactory occlusion 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.

Satisfactory occlusion

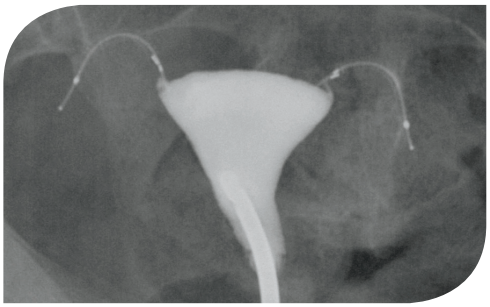


Figure 33. Bilateral tube occlusions at the cornua

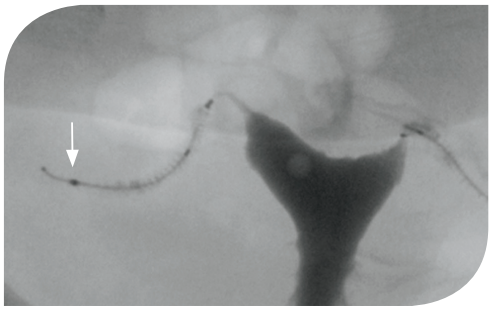


Figure 34. Contrast is visible within the tube but not past the distal end of the outer coil (arrow)

Note: The 2 distal markers and the proximal marker of the inner coil are fixed in relation to one another, but the proximal marker of the outer coil may move or seem stretched because of the flexibility of the outer coil.

Evaluating Tubal Occlusion (continued)

After evaluating insert location, determine whether contrast is visible beyond the distal end of the outer coil or in the peritoneal cavity.

Unsatisfactory occlusion

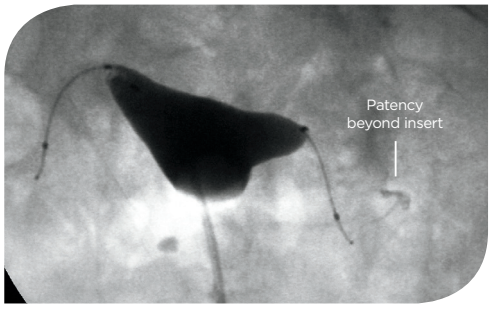


Figure 35. Unsatisfactory occlusion

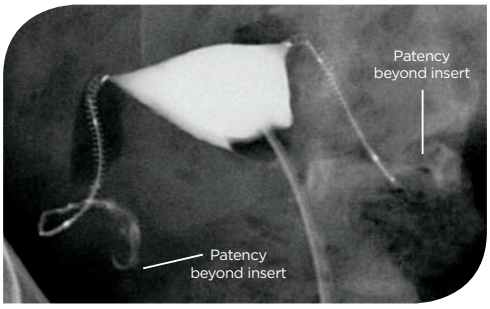


Figure 36. Satisfactory bilateral location of inserts; unsatisfactory occlusion. Note the outer coils are visible on this image; they are not radiopaque, but they are radiolucent when contrast fills the tube

How to manage:

If insert location is satisfactory but there is patency beyond the distal end of the outer coil or free spill of contrast into the peritoneal cavity, advise the patient not to rely on Essure®. The patient should remain on alternative contraception for 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.

Evaluating Ability to Rely on Essure

- If insert location and tubal occlusion are satisfactory, instruct the patient to discontinue alternative contraception and rely on Essure for contraception
- If insert location is unsatisfactory, instruct the patient not to rely on Essure for contraception
- If insert location is satisfactory but occlusion is unsatisfactory, instruct the patient to remain on alternative contraception. Repeat the Essure Confirmation Test with modified HSG in 3 months. If occlusion is still unsatisfactory, instruct the patient not to rely on Essure for contraception

Essure Confirmation Test With Modified HSG Checklist

LOCATION	LEFT	RIGHT
☐ **Satisfactory Location** Distal end of the inner coil is within the fallopian tube, with <50% of the inner coil trailing into the uterine cavity, OR the proximal end of the inner coil is ≤30 mm into the tube from where contrast fills the uterine cornua	☐	☐
☐ **Unsatisfactory Location** Proximal location: ≥50% of the inner coil is trailing into the uterine cavity	☐	☐
Expulsion: insert is not present or lies completely in the uterine cavity	☐	☐
Distal location: Insert is in the fallopian tube, but the proximal end of the inner coil is >30 mm from the contrast filling the uterine cornual	☐	☐
Perforation/peritoneal location: Insert is completely or partially perforating the uterus or tube (eg, embedded in the myometrium or completely in the peritoneal cavity)	☐	☐
OCCLUSION		
☐ **Satisfactory Occlusion** Tube is occluded at the cornua OR contrast is visible within the tube but not past the distal end of the outer coil	☐	☐
☐ **Unsatisfactory Occlusion** Contrast is visible past the insert OR in the peritoneal cavity	☐	☐

Assessing patient ability to rely on Essure®:

- If location and tubal occlusion are both rated satisfactory, instruct patient to discontinue alternative contraception
- If location is unsatisfactory, instruct patient to not rely on the inserts for contraception
- If location is satisfactory but occlusion is unsatisfactory, instruct patient to remain on alternative contraception. Repeat the Essure Confirmation Test with modified HSG in 3 months. If occlusion is still unsatisfactory, instruct patient to not rely on inserts for contraception

To avoid confusion with an infertility HSG, the OB/GYN and radiologist should be familiar with this guide and the Essure Confirmation Test With Modified HSG Checklist to ensure both insert location and tubal occlusion are noted in the radiology report.

Coding Information for Essure Confirmation Tests

Accurate diagnosis, procedure, and product coding are essential to help ensure prompt claims processing and reimbursement. Proper coding will differentiate the Essure Confirmation Test with modified HSG from an infertility HSG, identify TVU as a procedure, and help with appropriate coverage by insurers.

Current Procedural Terminology (CPT®) Fourth Edition* codes

The following codes may be used to report procedures associated with Essure®:

Product/Service	CPT Code	Code Description
Essure procedure	58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
Modified HSG	58340	Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or HSG
Modified HSG, interpretation and supervision	74740	HSG, radiologic supervision and interpretation
Modified HSG, interpretation	74740-26	HSG, radiologic supervision and interpretation, professional component only
Modified HSG, supervision	74740-TC	HSG, radiologic supervision and interpretation, technical component only
TVU	76830	Ultrasound: Transvaginal

The following Healthcare Common Procedural Coding System (HCPCS) code may be used in addition to the CPT code listed above for selected payers that, including some state Medicaid programs, allow for separate payment. Please check with the payer to confirm whether payment is separate or bundled.

Product/Service	HCPCS Code	Code Description
Essure procedure	A4264	Permanent implantable contraceptive intratubal occlusion device(s) and delivery system

CPT Modifier 33 is applicable for the identification of preventive services without cost sharing and may be added to the following codes as shown below.

Product/Service	CPT Code	Code Description
Essure procedure	58565-33	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
Modified HSG	58340-33	Catheterization and introduction of saline or contrast material for SIS or HSG

Note: Not all commercial payers will require the use of Modifier 33. Some will automatically process Essure and the Essure Confirmation Test with modified HSG without patient cost sharing.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 1 AND 2.

Coding Information for Essure Confirmation Tests (continued)

ICD-10-CM Diagnosis codes

For many payers, the following codes may be used to identify the Essure Confirmation Test with modified HSG as a preventive service:

ICD-10-CM Code	Code Description	Recognized by*:
Z30.8	Other specified contraceptive management	Most payers
Z98.51	Tubal ligation status	UHC
Z30.42	Encounter for surveillance of injectable contraceptive	Cigna
Z30.2	Encounter for sterilization	Cigna

And the Essure Confirmation Test with TVU:

ICD-10-CM Code	Code Description	Recognized by*:
Z30.2	Encounter for sterilization	Cigna

Although this information should help make filing claims easier and help reduce claim rejection, its use does not guarantee payment. It is important to research coverage and payment for each patient, since policies and guidelines vary by payer and plan. You are responsible for submitting accurate, complete, and appropriate claims to payers, and for compliance with any obligations you may have as required by law, contract, or otherwise.

Because the Instructions for Use states that an HSG is a required part of the Essure® procedure, it is considered typical and usual, and will not be paid separately if it is performed within the 90-day global period of the Essure procedure.

Pursuant to the Affordable Care Act (ACA), the Essure Confirmation Test With Modified HSG or TVU May Be Available to Many Patients at No Cost

Many payers may cover both Essure and the Essure Confirmation Test with modified HSG or TVU if the patient is eligible under their plan. When verifying patient benefits, it is important to specifically inquire as to whether the Essure Hysteroscopic Sterilization Procedure (CPT 58565 and/or A4264†) and the Essure Confirmation Test with modified HSG (58340 and 74740) or TVU (76830) are covered at **NO COST SHARE to the patient as part of the preventive services.** Inquire about limitations or exemptions.

For more information, call our reimbursement hotline at 1-877-ESSURE2 and press "#" or visit EssureMD.com.

*Subject to change.

†If required by Medicaid plans.

PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 1 AND 2.

IMPORTANT: Bayer is providing this information to you for informational and educational purposes only. This document is not intended to be used as part of training or certification requirements for Essure, or to establish a standard of care. You are solely responsible for ensuring that you and your staff have been properly trained in all aspects of performing the Essure procedure to your patients in the office setting. For complete instructions, please refer to the Instructions for Use and the Clinical Resource/ Physician Training Manual.

PLEASE SEE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, ON PAGES 1 AND 2.

essure®
permanent birth control