THE ESSURE® CONFIRMATION TEST

Indication

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

Important Safety Information

Prescription Only

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.

Who should not use Essure

- 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 previously undergone a tubal ligation, are pregnant or suspect pregnancy, delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure, have an active or recent upper or lower pelvic infection, or have a known allergy to contrast media.
- Patients undergoing immunosuppressive therapy (e.g. systemic corticosteroids or chemotherapy) are discouraged from undergoing the Essure procedure.
- Uterine or fallopian tube anomalies may make it difficult to place Essure inserts.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ON PAGE 8.

essure®
permanent birth control

IMPORTANT: Bayer is providing this information to you for informational and educational purposes only. This document is not intended to be a training document. You and your staff must be properly trained in all aspects of providing the Essure procedure. For complete Essure Confirmation Test process, please refer to Instructions for Use and Physician Training Manual.

CONDUCTING THE ESSURE® CONFIRMATION TEST

OVERVIEW

The Essure Confirmation Test is an important post-procedure step that provides the patient with the information she needs to confidently rely on Essure as permanent birth control. The Essure Confirmation Test should be performed 3 months post-procedure to confirm satisfactory bilateral insert location and tubal occlusion.

Unlike an infertility hysterosalpingogram (HSG), the Essure Confirmation Test is a modified HSG that is performed by instilling contrast media (dye) slowly and gently until the uterine cornua are distended. The Essure Confirmation Test images are used to evaluate insert location and fallopian tube occlusion.

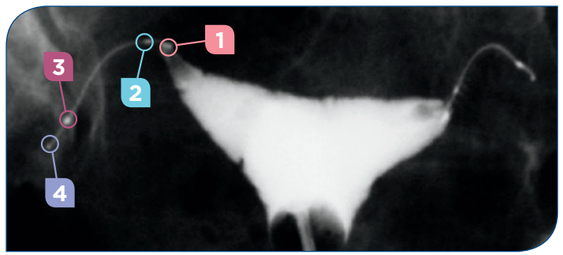
If satisfactory bilateral insert location and tubal occlusion are demonstrated, the patient can discontinue alternative contraception and rely on Essure.

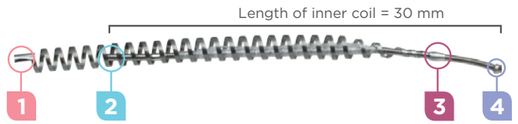
RADIOGRAPHIC MARKERS

In order to confirm satisfactory insert location, Essure Confirmation Test images must show the relationship of the proximal marker of the inner coil to the distended uterine cornua. To confirm bilateral tubal occlusion, contrast should be visualized up to, but not beyond, the distal marker of the outer coil.

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

1. Proximal end of outer coil
2. Proximal marker of inner coil
3. Distal marker of outer coil
4. Distal end of inner coil (“ball tip”)





To produce satisfactory images, adherence to the following guidelines is recommended:

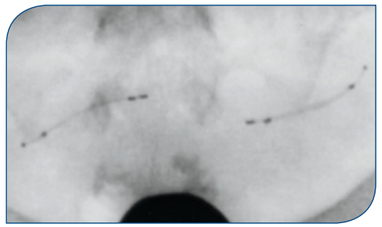
1. Do not dilate cervix unless necessary; if dilation occurs, maintain a good cervical seal.
2. Obtain good cornual filling; uterine cavity silhouette should be clearly visualized. Instill contrast slowly and gently until the uterine cornua are distended. An increase in intrauterine pressure beyond that should be avoided due to patient discomfort and the possibility of resultant vasovagal reaction.
3. Place fluoroscopy beam as close to anterior/posterior (A/P) projection as possible. If patient has a midpositional uterus, downward traction with tenaculum may be required to achieve adequate images. Remove speculum prior to fluoroscopy for best visualization of uterine anatomy.
4. Take a minimum of 6 radiographs to assess insert location and tubal occlusion.
5. Report must include reference to satisfactory location and occlusion.

Bayer HealthCare

PLEASE SEE IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON COVER AND PAGE 8.

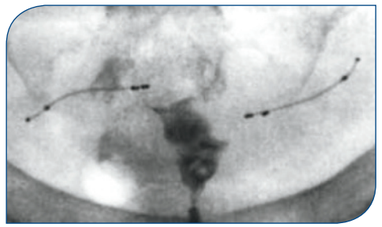
RADIOGRAPH IMAGING

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



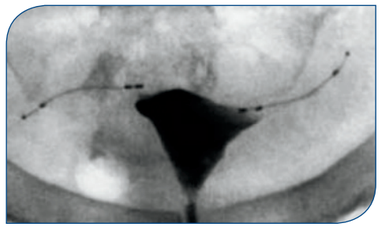
1 SCOUT FILM

Image of uterus and fallopian tubes taken **before** injecting the contrast. The Essure inserts should be clearly seen; note the 4 radiographic markers on each insert.



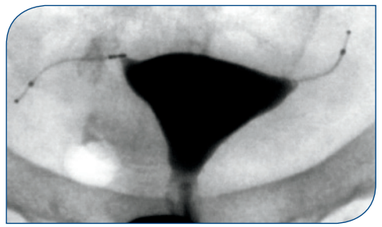
2 MINIMAL FILL

Image of the uterus after a small amount of contrast infusion. The uterine cavity should start to opacify; contrast may not have reached the cornua. If cavity silhouette is not seen in a nearly A/P projection, adjust the fluoroscopy beam and/or the patient.



3 PARTIAL FILL

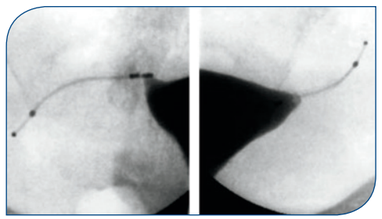
Image of the uterus when nearly full of contrast, or opacified.



4 TOTAL FILL

Image of the uterus when the uterine cavity is completely filled to patient tolerance or the cornua is filled to maximum distension. Contrast should reach the proximal end of each insert.

Note: You may need to gently increase contrast volume in the uterine cavity to obtain a satisfactory image.



5 6 MAGNIFICATION OF THE UTERINE CORNUA

Once maximally distended, obtain magnified views of both right and left cornua with the distal end of each insert in view.

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

IMPORTANT: Bayer is providing this information to you for informational and educational purposes only. This document is not intended to be a training document. You and your staff must be properly trained in all aspects of providing the Essure procedure. For complete Essure Confirmation Test process, please refer to Instructions for Use and Physician Training Manual.

essure® permanent birth control

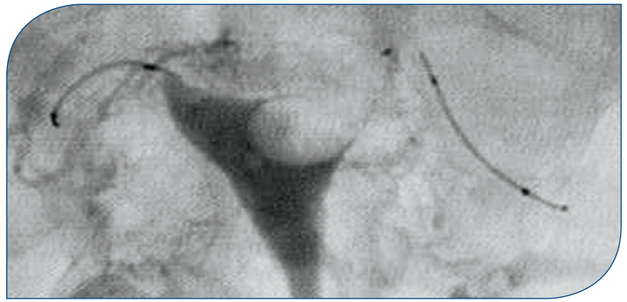
EVALUATING ESSURE® CONFIRMATION TEST IMAGE QUALITY

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

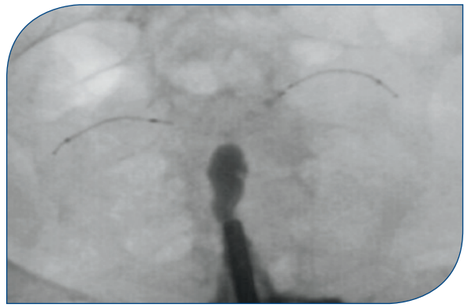
The Essure Confirmation Test will need to be immediately repeated if:

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

Examples of Essure Confirmation Tests that need to be repeated:



▲ *Filling defect in the left cornua*



▲ *Inadequate filling*

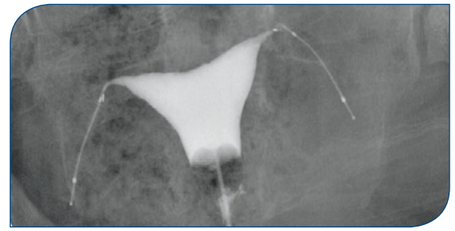
EVALUATING INSERT LOCATION AND OCCLUSION

Begin by evaluating the lie, curvature, orientation, and symmetry of the inserts, and the location of the 4 radiographic markers on the scout image, then progress to evaluation of the opacified images.

The inserts should be symmetrical, with an eyebrow-like curve. **Red flags for unsatisfactory insert location may include: a twisted, curled, circular, or completely straight insert; the 4 radiographic markers not being in a linear position; or the orientation of the insert being reversed or backwards.**

Distance from the filled uterine cornua to the proximal end of the insert can be measured in several ways:

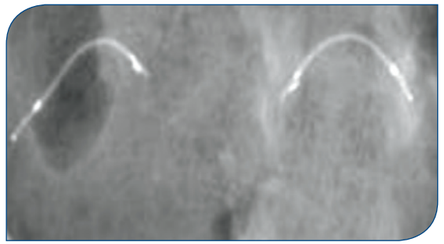
1. Using the inner coil as a point of reference. The inner coil measures 30 mm in length (most commonly used method)
2. Calipers
3. Using the 2 distal markers as a measuring reference point. The distance between the 2 distal markers measures 5 mm



Note:
- Ideal insert location is when the inner coil crosses the uterotubal junction
- The insert may shift in response to fallopian tube movement following placement
- The distal markers are fixed in relation to one another, but the proximal markers may move or seem stretched because of the flexibility of the outer coil
- The outer coils (which are not radio-opaque) can stretch, which may give the appearance that the proximal marker is separated from the rest of the insert

SATISFACTORY LOCATION AND OCCLUSION

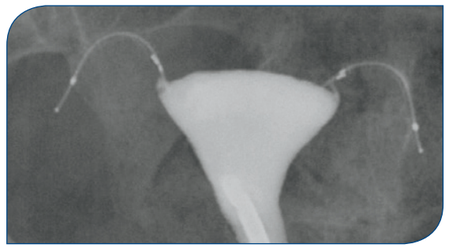
A satisfactory location is defined as when the distal end of the inner coil is within the fallopian tube with <50% of the inner coil trailing into the uterine cavity, OR when the proximal marker of the inner coil is ≤30 mm from the cornua from where contrast fills the uterine cornua. Tubal occlusion is confirmed if the tube is occluded at the cornua, or if contrast is visualized up to, but not beyond, the distal marker of the coil.



EXAMPLE OF SATISFACTORY LOCATION

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.

◀ *Note the normal curvature and symmetrical appearance of both inserts*



EXAMPLE OF SATISFACTORY OCCLUSION

Tubal occlusion is confirmed if the tube is occluded at the cornua or if contrast is visualized up to, but not beyond, the distal marker of the outer coil.

◀ *Bilateral tube occlusions at the cornua*

IMPORTANT: Bayer is providing this information to you for informational and educational purposes only. This document is not intended to be a training document. You and your staff must be properly trained in all aspects of providing the Essure procedure. For complete Essure Confirmation Test process, please refer to Instructions for Use and Physician Training Manual.

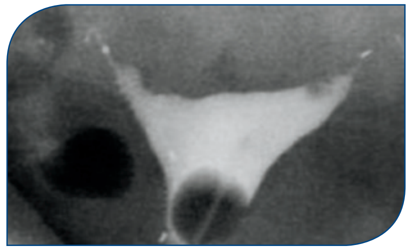
Bayer HealthCare

essure® permanent birth control

PLEASE SEE IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON COVER AND PAGE 8.

UNSATISFACTORY LOCATION AND OCCLUSION

In the unlikely event that an insert is not placed in a satisfactory location, the patient should be advised not to rely on Essure® for permanent birth control, regardless of whether or not her fallopian tubes appear occluded. The radiologist performing the Essure Confirmation Test should communicate the details of the insert location and tubal occlusion in the radiology report. There are 4 types of unsatisfactory location: proximal location of the insert, expulsion of the insert, distal location of the insert, and perforation or peritoneal location of the insert.



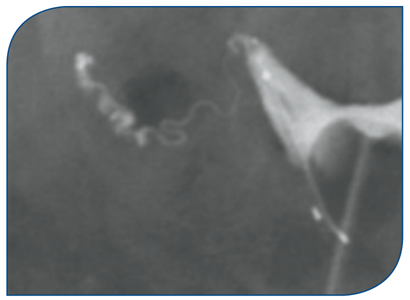
PROXIMAL LOCATION OF THE INSERT

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

How to manage

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

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



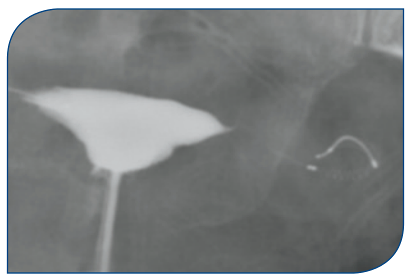
EXPULSION OF THE INSERT

One or both inserts are not present in the radiographic image.

How to manage

Advise the 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 tube is patent, counsel patient on repeat Essure placement procedure. If tube is occluded, advise patient on potential false-positive Essure Confirmation Test results. Also counsel patient on incisional sterilization or remaining on alternative contraception.

◀ *Expulsion of the right insert with tubal patency*



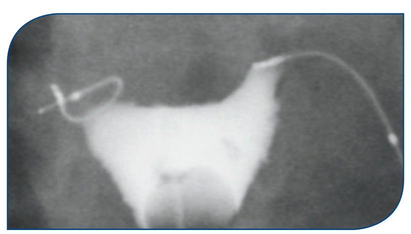
DISTAL LOCATION OF THE INSERT

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

How to manage

Advise the patient not to rely on Essure. If tube is patent, counsel patient on repeat Essure placement procedure. If tube is occluded, advise patient on potential false-positive Essure Confirmation Test results. Also counsel patient on incisional sterilization or remaining on alternative contraception.

◀ *Distal location of the left insert*

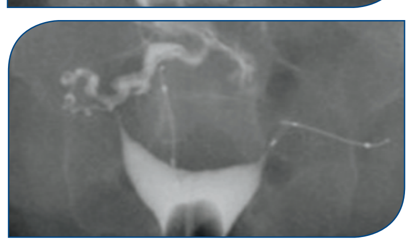


PERFORATION OR PERITONEAL LOCATION OF THE INSERT

When perforation occurs, the insert has punctured the uterine cavity or fallopian tube, and may be in the peritoneal cavity.

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

◀ *Right insert perforation; note the circular configuration*



How to manage

Advise the patient not to rely on Essure. If tube is patent, counsel patient on repeat placement procedure. If tube is occluded, advise patient on potential false-positive Essure Confirmation Test results. Also counsel patient on incisional sterilization or remaining on alternative contraception.

◀ *Myometrial perforation*

UNSATISFACTORY OCCLUSION

How to manage

If insert location is satisfactory, but there is patency beyond the distal end of the outer coil or free spill of contrast into the peritoneal cavity, advise the patient not to rely on Essure. The patient should remain on alternative contraception for 3 more months and have a repeat Essure Confirmation Test. If patency is again documented on the repeat Essure Confirmation Test, then the patient should be advised not to rely on Essure.

◀ *Satisfactory bilateral location of inserts; unsatisfactory bilateral occlusion*

Bayer HealthCare

PLEASE SEE IMPORTANT SAFETY INFORMATION ABOUT ESSURE ON COVER AND PAGE 8.

EVALUATING ABILITY TO RELY ON ESSURE

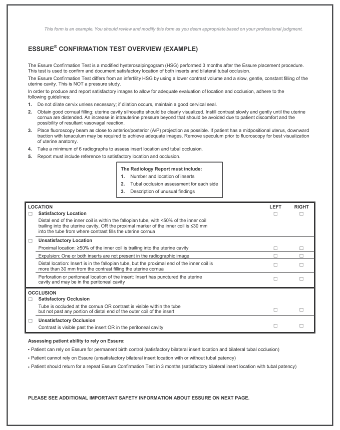
- **If insert location and tubal occlusion are satisfactory, instruct the patient to discontinue alternative contraception and rely on Essure for contraception**
- **If insert location is unsatisfactory, instruct the patient not to rely on Essure for contraception**
- **If insert location is satisfactory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

ADVERSE EVENTS PREVENTING RELIANCE

The table below presents adverse events that prevented reliance on Essure inserts as permanent birth control in the phase II and pivotal studies, respectively.

	PHASE II		PIVOTAL	
Event	**Number**	**Percent**	**Number**	**Percent**
Perforation	7/206	3.4%*	5/476	1.1%
Expulsion	1/206	0.5%	14/476	2.9%†
Other unsatisfactory insert location (proximal or distal)	1/206	0.5%	3/476	0.6%
Initial tubal patency	7/200	3.5%‡	16/456	3.5%§

* One patient relied on Essure inserts for permanent birth control for 31 months prior to laparotomy and cornual resection due to monthly pain associated with presence of the devices. The other 6 patients never relied on Essure inserts for permanent birth control.
† Fourteen patients experienced an expulsion; however, 9 of these 14 patients chose to undergo a second insert placement procedure, which was successful in all 9 cases.
‡ Tubal patency was demonstrated in 7 patients at the 3-month Essure Confirmation Test, but all 7 patients were shown to have tubal occlusion at a repeat Essure Confirmation Test performed 6 months after Essure insert placement.
§ Tubal patency was demonstrated in 16 patients at the 3-month Essure Confirmation Test, but all 16 patients were shown to have tubal occlusion at a repeat Essure Confirmation Test performed 6-7 months after Essure insert placement.



◀ESSURE CONFIRMATION TEST CHECKLIST

This checklist, which can be used to document the Essure Confirmation Test results for the patient's record, can be accessed at: **EssureMDResources.com**.

ADVERSE EVENT REPORTING

Please consult the Instructions for Use for additional safety information about Essure. In order to monitor the safety of Essure, we encourage clinicians to report adverse events to Bayer at 1-877-377-8732, option 5.

To access a more detailed guide to the Essure Confirmation Test, please go to EssureMDResources.com and click on the Clinical Resource.

IMPORTANT: Bayer is providing this information to you for informational and educational purposes only. This document is not intended to be a training document. You and your staff must be properly trained in all aspects of providing the Essure procedure. For complete Essure Confirmation Test process, please refer to Instructions for Use and Physician Training Manual.

essure® permanent birth control

Important Safety Information (continued)

Pregnancy Considerations

- The Essure® procedure should be considered irreversible. Patients should not rely on Essure inserts for contraception until an Essure Confirmation Test [modified hysterosalpingogram (HSG)] demonstrates bilateral tubal occlusion and satisfactory location of inserts.
- Effectiveness rates for the Essure procedure are based on patients who had bilateral placement. If Essure inserts cannot be placed bilaterally, then the patient should not rely on Essure inserts for contraception.
- Effects, including risks, of Essure inserts on in vitro fertilization (IVF) have not been evaluated.
- Pregnancies (including ectopic pregnancies) have been reported among women with Essure inserts in place. Some of these pregnancies were due to patient non-compliance or incorrect clinician interpretation of the Essure Confirmation Test (modified HSG).

Procedural Considerations

- Perform the Essure procedure during early proliferative phase of the menstrual cycle. Terminate procedure if distension fluid deficit exceeds 1500cc or hysteroscopic time exceeds 20 minutes as it may signal uterine or tubal perforation. Never attempt to advance Essure insert(s) against excessive resistance. If tubal or uterine perforation occurs or is suspected, discontinue procedure and work-up patient for possible complications related to perforation, including hypervolemia. Do not attempt hysteroscopic Essure insert removal once placed unless 18 or more trailing coils are seen inside the uterine cavity due to risk of fractured insert, fallopian tube perforation or other injury.
- DO NOT perform the Essure procedure concomitantly with endometrial ablation. Avoid electrosurgery on uterine cornua and proximal fallopian tubes without visualizing inserts.

Nickel Allergy

Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. In addition, some patients may develop an allergy to nickel if this device is implanted. Typical allergy symptoms reported for this device include rash, pruritus, and hives.

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.

Clinical Trial Experience

- Safety and effectiveness of Essure is not established in patients under 21 or over 45 years old, nor in patients who delivered or terminated a pregnancy less than 8-12 weeks before procedure. Women undergoing sterilization at a younger age are at greater risk of regretting their decision.
- 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.

IMPORTANT: Bayer is providing this information to you for informational and educational purposes only. This document is not intended to be a training document. You and your staff must be properly trained in all aspects of providing the Essure procedure. For complete Essure Confirmation Test process, please refer to Instructions for Use and Physician Training Manual.

Bayer HealthCare

essure® permanent birth control