ESSURE® CONFIRMATION TEST (MODIFIED HSG) PROTOCOL

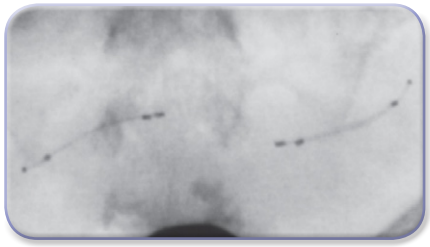
The Essure Confirmation Test is an important component to the Essure procedure and provides the patient with the information she needs to confidently rely on Essure for permanent contraception. It is performed 3 months after Essure is placed to document location of both inserts and bilateral tubal occlusion. It is recommended that all physicians involved in performing and interpreting this confirmation test review the full Essure Confirmation Test Guide available on EssureMD.com.

PERFORMING THE ESSURE CONFIRMATION TEST

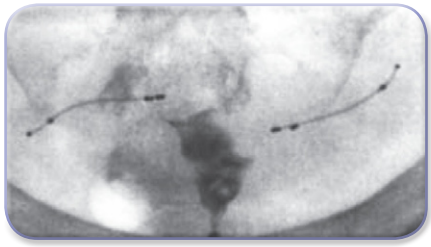
Unlike an infertility hysterosalpingogram ("HSG"), the Essure Confirmation Test is a modified HSG that is performed by instilling contrast slowly and gently until the uterine cornua are distended. An increase in intrauterine pressure beyond that needed to produce cornual distention serves no purpose and should be avoided.

In order to evaluate satisfactory insert location and tubal occlusion, HSG images must show the relationship of the proximal end of the inner coil to the uterine cornua as the uterine cavity fills with contrast. In order to produce satisfactory images to allow for adequate evaluation of location and occlusion, adhere to the following guidelines:

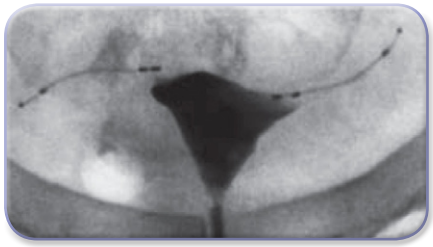
1. Do not dilate cervix unless necessary; if dilation occurs, maintain a good cervical seal.
2. Obtain good cornual filling: Uterine cavity silhouette should be clearly visualized. Instill contrast slowly and gently until the uterine cornua are distended.
3. Place fluoroscopy beam as close to A/P projection 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 six radiographs to assess insert location and tubal occlusion. **The following six radiographs are recommended.**



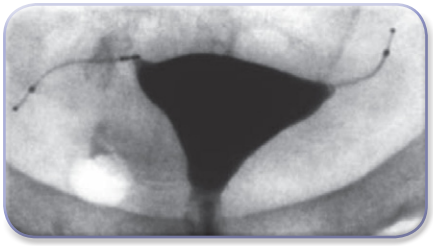
SCOUT



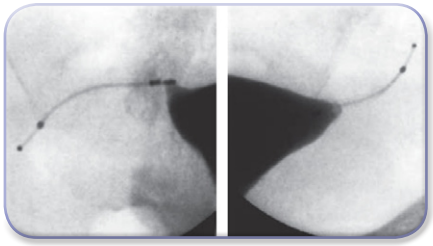
MINIMAL FILL



PARTIAL FILL



COMPLETE FILL/AP VIEW



MAGNIFIED CORNUAL VIEWS

In some cases additional images may be necessary to evaluate the Essure insert location. This may include oblique views or lateral views.

EVALUATING ESSURE CONFIRMATION TEST IMAGE QUALITY

When evaluating the 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 maximally distended in at least one view.

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

1. The appropriate sequence of radiographs has been captured but one or both uterine cornua are not maximally distended;
2. Uterine silhouette is fundal rather than A/P;
3. The appropriate sequence of radiographs was not taken, and/or the uterine cornua are not distended or are otherwise obscured, making evaluation of insert location impossible or equivocal.

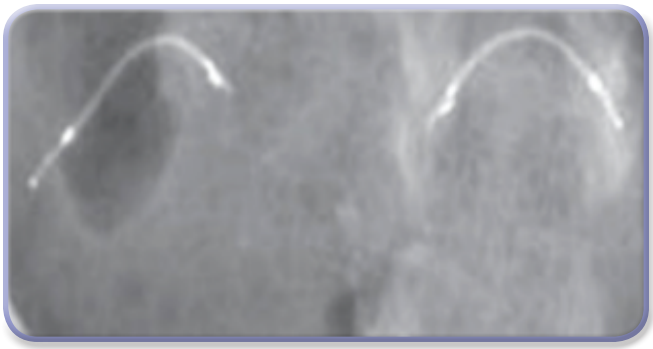
TIP: Additional radiographs, including oblique images, may be necessary to evaluate location if a perforation is suspected.

EVALUATING THE ESSURE CONFIRMATION TEST IMAGES

Evaluation of Essure insert location initially includes evaluating lie, curvature, orientation, symmetry, and the location of the 4 radiopaque markers on scout image, then progressing to evaluation of opacified images. The inserts should be symmetrical with an eyebrow like curve. Red flags for unsatisfactory insert location include, but are not limited to: a twisted, curled, circular or completely straight insert, if the 4 radiopaque markers are not in a linear position, or if the orientation of the microinsert is reversed or backwards.

Evaluate insert location relative to the distended uterine cornua. Ideally, the inner coil should cross the utero-tubal junction to ensure that the PET fibers, which cause fibrosis and occlusion, are located in the isthmic portion of the tube. It is also beneficial to have contrast meet the proximal end of the inner coil, but it is not required.

Satisfactory Location and Occlusion

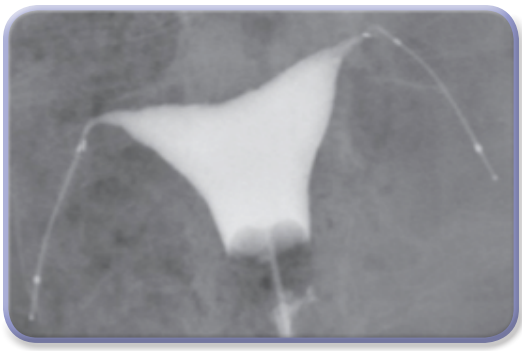


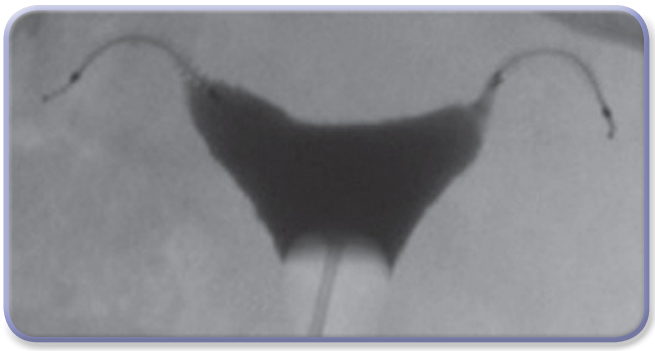
Satisfactory Location *(left)*

The insert is considered to be in a satisfactory location if it is within the fallopian tube and less than half of the inner coil is trailing into the uterine cavity or if the proximal end of the inner coil is less than 30 mm from the uterine cornua. Note: the inner coil itself is 30 mm in length.

Satisfactory Occlusion *(below)*

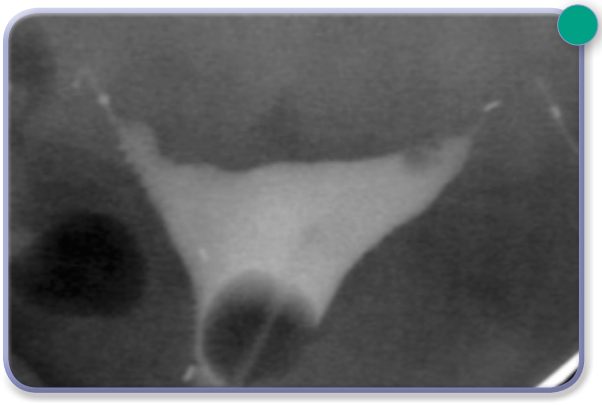
Tubal occlusion is confirmed if the tube is occluded at the cornua or if contrast is visualized up to, but not beyond, the distal marker of the outer coil.





Unsatisfactory Location and Occlusion

In the unlikely event that this study reveals an insert is not in a satisfactory location, the patient should be instructed that she cannot rely on Essure for her permanent contraception regardless of whether or not her fallopian tubes appear occluded. The radiologist performing the Confirmation Test should communicate the details of the insert location and tubal occlusion in the radiology report. **The following are the four categories of unsatisfactory location:**



Proximal Location

If more than 50% of the inner coil trails into the uterine cavity then the insert is considered to be too proximal. The patient should be informed that there is an increased risk for complete expulsion of the insert and she should either continue her alternative contraception or consider incisional sterilization.

(continued next page)

Unsatisfactory Location and Occlusion *(continued)*

Expulsion

The number of inserts localized should be noted. If there are less than two devices localized on the scout film of the pelvis, an image of the abdomen should be obtained to differentiate a device that has expelled from the body verses one that is in a peritoneal location. The physician should note if there is a missing device or if they find a device located entirely in the uterine cavity.

If the Essure Confirmation Test demonstrates patency in the tube from which the insert was expelled, the patient may be offered the opportunity to return for a repeat insert placement procedure. If the Essure Confirmation Test demonstrates tubal blockage in the tube from where the insert was expelled, the patient should be informed that there is a potential for a false positive diagnosis of tubal occlusion and she should be counseled regarding the option to undergo incisional sterilization or remain on alternative contraception.

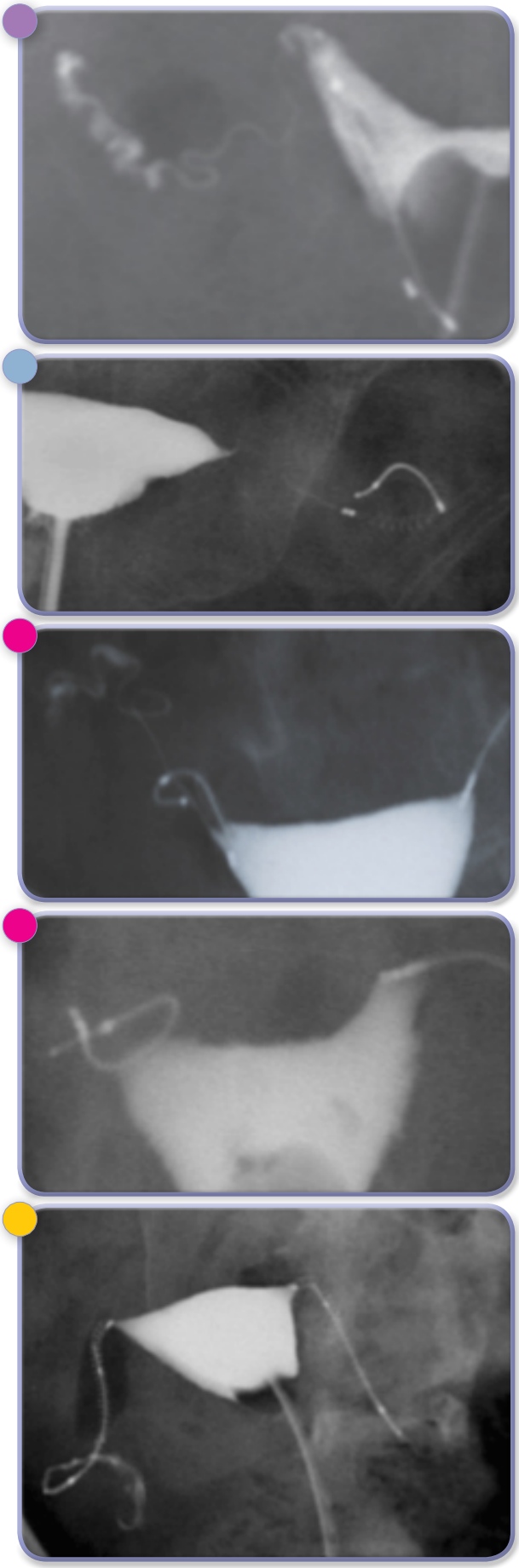
Distal Location

If the proximal end of the inner coil is more than 30 mm from the cornua, the insert is considered to be too distal. If the tube is patent, the patient may be considered for an additional insert placement procedure to properly position an insert in the patent tube. If the tube is occluded, the patient should be counseled that there is a potential for a false positive diagnosis of tubal occlusion. She should also be counseled about the option to have incisional sterilization or remain on alternative contraception.

Perforation

If the insert is found to have completely or partially perforated through the fallopian tube or uterus, the details of this finding should be communicated clearly in the radiology report. If the Essure Confirmation Test demonstrates tubal patency in the tube that should have been placed with an insert, the patient may be offered the opportunity to return for an additional procedure to reattempt placement.

If the study demonstrates occlusion in the tube that should have been placed with an insert, the patient should be informed that there is a potential for a false positive diagnosis of tubal occlusion. She should be counseled about the option to have incisional sterilization or remain on alternative contraception.



Unsatisfactory Occlusion

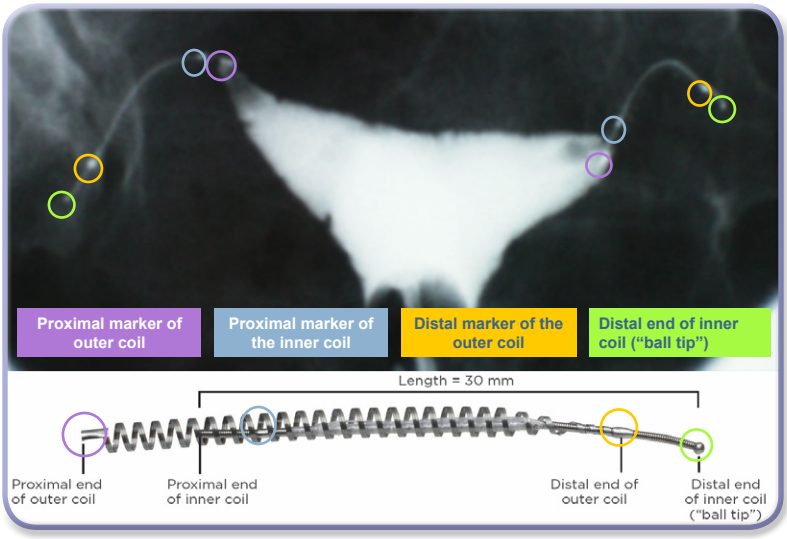
Fallopian tubes are considered to be occluded if contrast is not seen past the distal end of the outer coil. Contrast may be seen within the tube but there should be no contrast past the distal end of the outer coil.

If the inserts meet the criteria for satisfactory location but one or more tubes are patent, then the patient should remain on her alternative contraception and have the study repeated in 3 months. If the tubes remain patent on the repeat confirmation test, than she should be advised to not rely on the Essure inserts for contraception.

Please see the Essure IFU for full details on the Essure Permanent Birth Control procedure and the Essure Confirmation Test. Additional resources are available on our website, www.essuremd.com

HELPFUL INFORMATION

There are 4 radiographic markers on the device: the distal end of the inner coil (sometimes referred to as the ball tip), the distal end of the outer coil, the proximal end of the inner coil and the proximal end of the outer coil. The proximal end of the outer coil is not fixed to the inner coil so this marker can vary in distance from the rest of the insert.



CLINICAL DATA

Observed Adverse Events

The table below presents adverse events that prevented reliance on Essure micro-inserts for contraception 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 micro-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 micro-inserts for contraception 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 micro-inserts for contraception.

**Tubal patency was demonstrated in seven women at the 3-month Essure Confirmation Test (HSG), but all seven women were shown to have tubal occlusion at a repeat Essure Confirmation Test (HSG) performed 6 months after Essure micro-insert placement.

*Fourteen women experienced an expulsion, however nine of these 14 women chose to undergo a second micro-insert placement procedure, which was successful in all nine cases.

** Tubal patency was demonstrated in sixteen women at the 3-month Essure Confirmation Test (HSG), but all sixteen women were shown to have tubal occlusion at a repeat Essure Confirmation Test (HSG) performed 6-7 months after Essure micro-insert placement.

ADDITIONAL INFORMATION AND RESOURCES

- Visit **www.essuremd.com**
  - » View the **Essure Confirmation Test Training video**, download the full **Essure Confirmation Test Guide** as well as additional information on Essure and the Essure procedure.
- **Essure Instructions for Use**
  - » Provides comprehensive information regarding Essure Permanent Birth Control
  - » Found in each Essure kit or available on our website, www.essuremd.com
- **Physician Consult Line** - A resource for physicians to receive answers to clinical questions regarding Essure
  - » **1-877-377-8732, option 3** or clinicalconsult@conceptus.com
- Send a blank e-mail to MRIsafety@conceptus.com to receive information regarding Essure and **MRI safety**
- Essure Customer Service **1-877-Essure2**
- Conceptus, Inc. **650-962-4000**

ADVERSE EVENT REPORTING

Please consult the Product Information for the complete safety and prescribing information for the Essure Permanent Birth Control device. In order to monitor the safety of the Essure Permanent Birth Control device, we encourage clinicians to report adverse events to Conceptus at **1-877-377-8732**. Adverse events may also be forwarded to the FDA MEDWATCH program by phone at **1-800-FDA-1088** or fax at **1-800-FDA-0178**.

Conceptus® Inc.