

ESSURE[®] CONFIRMATION TEST OVERVIEW (EXAMPLE)

The Essure Confirmation Test is a modified hysterosalpingogram (HSG) performed 3 months after the Essure placement procedure. This test is used to confirm and document satisfactory location of both inserts and bilateral tubal occlusion.

The Essure Confirmation Test differs from an infertility HSG by using a lower contrast volume and a slow, gentle, constant filling of the uterine cavity. This is NOT a pressure study.

In order to produce and report 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. 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.

The Radiology Report must include:

1. Number and location of inserts
2. Tubal occlusion assessment for each side
3. Description of unusual findings

LOCATION	LEFT	RIGHT
<input type="checkbox"/> 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 marker of the inner coil is ≤30 mm into the tube from where contrast fills the uterine cornua	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Unsatisfactory Location Proximal location: ≥50% of the inner coil is trailing into the uterine cavity	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Expulsion: One or both inserts are not present in the radiographic image	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Distal location: Insert is in the fallopian tube, but the proximal end of the inner coil is more than 30 mm from the contrast filling the uterine cornua	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Perforation or peritoneal location of the insert: Insert has punctured the uterine cavity and may be in the peritoneal cavity	<input type="checkbox"/>	<input type="checkbox"/>
OCCLUSION		
<input type="checkbox"/> Satisfactory Occlusion Tube is occluded at the cornua OR contrast is visible within the tube but not past any portion of distal end of the outer coil of the insert	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Unsatisfactory Occlusion Contrast is visible past the insert OR in the peritoneal cavity	<input type="checkbox"/>	<input type="checkbox"/>

Assessing patient ability to rely on Essure:

- Patient can rely on Essure for permanent birth control (satisfactory bilateral insert location and bilateral tubal occlusion)
- Patient cannot rely on Essure (unsatisfactory bilateral insert location with or without tubal patency)
- Patient should return for a repeat Essure Confirmation Test in 3 months (satisfactory bilateral insert location with tubal patency)

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

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.

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 ($\geq 10\%$) 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.