

Essure

Highly-effective: 99.83% effective based on a 5-year clinical data

Minimally invasive: Can be performed in the office without incisions or general anesthesia

Non-hormonal: Does not contain hormones

Convenient: A quick 10 minute office procedure with most patient returning to normal activities in 1-2 days

Affordable to more women: The Essure procedure is included in the women's preventive benefit coverage under the contraceptive service provision of the Affordable Care Act (ACA) without co-pay or deductible. The ACA may impact most women with private insurance whose plans renew on or after August 1, 2012. Essure is also covered by every state Medicaid and many state Family Planning Waivers.

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.