ESSURE PLACEMENT STEPS

**INTRODUCE**

Hysteroscopically visualize and assess both fallopian tube ostia.

Place introducer through working channel.

Carefully insert Essure catheter.

**PLACE**

Advance the catheter until the black positioning marker is at the tubal ostium. If excessive force is encountered, terminate procedure to avoid uterine perforation or placement into a false passage.

**Stabilize the Essure handle to the hysteroscope to prevent inadvertent forward movement.** Roll thumbwheel back so black positioning marker moves towards you until reaching a hard stop.

**Stop and check placement of insert.** The entire gold band must be just outside the ostium with the green release catheter in view. If the gold band is not in view, reposition catheter prior to deployment.

Press button to release thumbwheel. Insert will not yet expand.

Roll thumbwheel back to a hard stop that expands and detaches insert.

**DOCUMENT**

Document placement and visible coils.

Ideally, 3 to 8 coils should be trailing into the uterus. Inserts showing 0-17 trailing coils should be left in place. 18 or more visible coils may be removed.

Withdraw Essure catheter.

Repeat steps with second catheter for contralateral ostium.

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

Important Safety Information About Essure®
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.

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
• 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.
• 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 during the placement procedure 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.
• Some Essure patients have reported pelvic pain that may be device related. If device removal is indicated, this will require surgery.

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.
ESSURE PLACEMENT STEPS

TIPS AND TECHNIQUES

• Insert placement should be performed during the early proliferative phase of the menstrual cycle to decrease the potential of an undiagnosed (luteal phase) pregnancy and enhance visualization of the fallopian tubes. DO NOT perform during menstruation

• Administer a nonsteroidal anti-inflammatory drug (NSAID) 1-2 hours prior to procedure. Data suggests this will increase the likelihood of placement success

• A bivalve, open-sided speculum is recommended so that it can be readily removed once the hysteroscope is in place

• Do not dilate cervix unless necessary. If necessary, dilate only enough for hysteroscope insertion

• Use warm saline for uterine distension medium—preferably a 3-liter bag

• If having difficulty advancing insert into tube, advance the hysteroscope closer to provide column strength, then apply gentle, constant forward movement of the Essure® catheter

• Operative notes should include the number of visible coils, and the need for an Essure Confirmation Test 3 months post-placement

• Counsel patient on the need to use alternative contraception (except an IUD or IUS) until a satisfactory Essure Confirmation Test is documented

If no trailing coils are visible after deployment, examine delivery system upon removal from the hysteroscope to verify device deployment (see picture).

Do not place more than one insert in each fallopian tube unless an Essure Confirmation Test has been performed.

Please see Important Safety Information on page 2.