



Re: Voluntary Discontinuation of Essure® Sales

July 20, 2018

Dear Essure Provider,

We are writing to inform you that Bayer has made a voluntary commercial decision to discontinue sales of the Essure System for Permanent Birth Control, effective December 31, 2018. Bayer continues to believe that Essure's benefit-risk profile remains positive and unchanged. Our decision is not based on concerns about the safety or effectiveness of the device, which have been demonstrated in extensive clinical trials, post-approval studies, and analyses of real world evidence over the past 20 years.

Bayer has informed the U.S. Food and Drug Administration (FDA) of the Company's decision. The FDA has maintained for several years that the benefits of Essure outweigh the risks.

Women who currently have Essure in place may continue to rely on the device, and Bayer will continue to support Essure patients and providers. Our ongoing support services will include our consumer and healthcare provider websites (Essure.com and EssureMD.com), the Bayer Customer Care Call Center, and continued access to the Essure Consultants Network.

Given that this announcement comes in the same timeframe that Bayer is implementing a restricted sales and distribution process for Essure, we want to take this opportunity to provide an overview of the new distribution process. Starting on August 1, 2018, in order for an account to purchase Essure, we will need to have the following documentation on file:

1. A signed Essure Physician Distribution Agreement (EPDA) for active Essure user(s) within the account stating that they will use the Patient Decision Checklist with all patients prior to the procedure.
2. A Facility Confirmation Form from the user facility, completed at the time of order, to confirm that the purchased product will only be distributed to a physician within the account that has a signed EPDA on file and that the product will be used within one year of the date of purchase.

We want to underscore that the decision to voluntarily discontinue sales is a business decision based on declining sales of Essure and that it should not raise concerns about the safety or effectiveness of the product. Bayer remains strongly committed to women's health, and we will continue our investment, innovation, and leadership in this important area.

If you have any questions, please visit EssureMD.com or contact the Bayer Customer Care Call Center at 1-888-84-BAYER (1-888-842-2937).

Sincerely,

Jon Stelzmler
Senior Vice President and General Manager
Bayer Women's Healthcare

Indication

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

Important Safety Information

WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device.

Please see additional Important Safety Information about Essure® on the next page.

Important Safety Information about Essure® (Continued)

Contraindications

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 a known abnormal uterine cavity that makes visualization of the tubal ostia impossible, and/or abnormal tubal anatomy or previous tubal ligation (including failed ligation), are pregnant or suspect pregnancy, delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure, have an active upper or lower genital tract infection, have unexplained vaginal bleeding, have a gynecological malignancy, or have a known allergy to contrast media.

General Warnings

- The Essure procedure should be considered irreversible.
- Pain (acute or persistent) of varying intensity and length of time may occur following Essure placement. This is also more likely to occur in individuals with a history of pain. If device removal is indicated, this will require surgery.
- Patients with known hypersensitivity to nickel, titanium, platinum, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the Essure system may experience an allergic reaction to the insert. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Symptoms reported for this device that may be associated with an allergic reaction include hives, urticaria, rash, angioedema, facial edema and pruritis. Patients should be counseled on the materials contained in the insert prior to the Essure procedure. Currently there is no test that reliably predicts who may develop a hypersensitivity reaction to the materials contained in the insert.
- Patients on immunosuppressive therapy may experience delay or failure of the necessary tissue in- growth for tubal occlusion. For these patients, physicians must use the modified HSG as the Essure Confirmation Test. Transvaginal ultrasound (TVU) should not be used as the Essure Confirmation Test, as TVU cannot confirm tubal occlusion.

Pregnancy Risk

- Pregnancies, including ectopic pregnancies, have been reported among women who have undergone the Essure procedure.
- The patient must use alternative contraception until a satisfactory Essure Confirmation Test is documented. If the Essure inserts are not properly placed or are not in a satisfactory location, then the patient should be advised to not rely on Essure and to use alternative contraception.
- Counsel the patient on the need for the Essure Confirmation Test, the options for the confirmation test including their risks and benefits, and the possibility that the Essure Confirmation Test may be unsatisfactory.
- Effectiveness rates for the Essure procedure are based on patients who had bilateral placement and a satisfactory Essure Confirmation Test.

Procedure Warnings

- Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or is suspected, discontinue procedure and monitor the patient for signs and symptoms of possible complications related to perforation which may include unusual post-operative pain.
- To reduce the risk of hypervolemia, terminate procedure if distension fluid deficit exceeds 1500cc or total hysteroscopic procedure time exceeds 20 minutes. Excess fluid deficit may signal uterine or tubal perforation. If noted, discontinue procedure and evaluate patient for possible perforation.
- 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 a fractured insert, fallopian tube perforation, or other injury.
- DO NOT perform the Essure procedure concomitantly with endometrial ablation.

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.

Adverse Events

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.

Prescription Only

IMPORTANT

- **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 preceptorship in placement until competency is established, typically 5 cases.
- The sale and distribution of this device are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bayer.