# News Release

**Intended for U.S. Media Only**

**Bayer to voluntarily discontinue U.S. sales of Essure at end of 2018 for business reasons**

*The safety and efficacy of Essure have not changed*

**Whippany, N.J., July 20, 2018** – Bayer has made a business decision to voluntarily discontinue sales and distribution of the Essure® System for Permanent Birth Control in the United States after December 31, 2018. This decision is based on a decline in U.S. sales of Essure in recent years and the conclusion that the Essure business is no longer sustainable. Essure is the only FDA-approved non-incisional form of permanent birth control.

The benefit-risk profile of Essure has not changed, and we continue to stand behind the product's safety and efficacy, which are demonstrated by an extensive body of research, undertaken by Bayer and independent medical researchers, involving more than 200,000 women over the past two decades.

Several factors have contributed to declining interest in Essure among women in the U.S., including decreased use of permanent contraception overall, increased reliance on other birth control options, such as long-acting reversible contraceptives (LARCs), and inaccurate and misleading publicity about the device.

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 its risks. Bayer is also informing healthcare providers directly of the business decision to discontinue sales of Essure.

The health and safety of the patients who rely on our products is our top priority. Most importantly, we want to let the many women who have chosen Essure for their reproductive health know that our decision to discontinue sales is for business reasons, and not for any safety or efficacy concerns about Essure. Essure's safety profile has remained consistent over time. Women who currently have Essure in place may continue to confidently rely on the device, and Bayer will continue to support women with Essure and their healthcare providers.

We encourage women who have any questions about Essure to speak first with their healthcare provider. Bayer's ongoing support services will include our consumer and healthcare provider websites (Essure.com and EssureMD.com), the Bayer Customer Care Call Center (1-888-84-BAYER), and continued access to the Essure consultant's network for providers who have questions.

Bayer will continue to enroll patients in the Essure postmarket surveillance study and will work closely with the FDA to ensure appropriate follow up. Bayer will also continue to fully comply with its other regulatory responsibilities regarding Essure.

Bayer remains strongly committed to women's health where we have long been a leader. We recognize that women want safe and effective options that best meet their individual needs, and we are committed to continuing our investment, innovation and leadership in this important area of health.

**About Essure**

Essure is indicated for women who desire permanent birth control (female sterilization) by blocking 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 of Permanent Birth Control during discussion of the benefits and risks of the device.**

Essure is not right for you if you are uncertain about ending your fertility, suspect you are pregnant, can have only one insert placed, have had your tubes tied, have a known allergy to contrast dye, are unwilling to undergo the Essure Confirmation Test, have unexplained vaginal bleeding, or have suspected or known cancer of the female reproductive organs.

You should delay having the Essure procedure if you are or have been pregnant within the past 6 weeks, have an active gynecological infection, or are in the second half of your menstrual cycle.

Tell your doctor if you are taking immunosuppressants, have, or think that you may have, a history of metal allergies, or an allergy to polyester fibers, nickel, titanium, platinum, silver-tin, or stainless steel or any other components of the Essure system, are currently using an IUD for contraception, or have had or are considering a procedure to reduce bleeding from the uterus such as endometrial ablation.

**WARNING: Be sure you are done having children before you undergo the Essure procedure. Essure is a permanent method of birth control.**

**WARNING: You must continue to use another form of birth control until you have your Essure Confirmation Test (3 months after the procedure) and your doctor tells you that you can rely on Essure for birth control. For some women, it may take longer than 3 months for Essure to be effective, requiring a repeat confirmation test at 6 months.** Talk to your doctor about which method of birth control you should use during this period. If you rely on Essure for birth control before receiving confirmation from your doctor, you are at risk of getting pregnant.

**During the Procedure:** In the premarketing study, some women experienced mild to moderate pain (9.3%). Your doctor may be unable to place one or both Essure inserts correctly. In rare cases, part of an Essure insert may break off during placement. If breakage occurs, your doctor will remove the piece, if appropriate. There is a risk of perforation of the uterus or fallopian tube by the hysteroscope, Essure system or other instruments used during the procedure. In the original premarket studies, perforation due to the Essure insert occurred in 1.8% of women. A perforation may lead to bleeding or injury to bowel or bladder, which may require surgery. Your doctor may recommend a local anesthesia. Ask your doctor about the risks associated with this type of anesthesia.

**Immediately Following the Procedure:** In the premarketing study, some women experienced mild to moderate pain (12.9%) and/or cramping (29.6%), vaginal bleeding (6.8%), and pelvic or back discomfort for a few days. Some women experience headaches, nausea and/or vomiting (10.8%), or dizziness and/or fainting. You should arrange to have someone take you home after the procedure. In rare instances, an Essure insert may be expelled from the body.

**During the Essure Confirmation Test:** As one of the Essure Confirmation Tests (a modified HSG) requires an x-ray, you may be exposed to very low levels of radiation, as with most x-rays, if this test is used. Some women may experience nausea and/or vomiting, dizziness and/or fainting, cramping, pain or discomfort. In rare instances, women may experience spotting and/or infection.

**Long-term Risks:** Pain (acute or persistent) of varying intensity and length of time may occur and continue following Essure placement. This is also more likely to occur in women with a history of pain. There are reports of an Essure insert being located in the lower abdomen and pelvis. If this occurs, you cannot rely on Essure for birth control. Patients with known hypersensitivity to 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 in women using Essure that may be associated with an allergic reaction include hives, rash, swelling and itching. There is no reliable test to predict who may develop a reaction to the inserts. No birth control method is 100% effective. Ectopic pregnancies (pregnancy outside the uterus) may occur with Essure. This can be life-threatening. If insert removal is indicated, surgery will be necessary.

The safety and effectiveness of Essure has not been established in women under 21 or over 45 years old.

**Essure does not protect against HIV 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 preceptoring 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.

Talk to your doctor about Essure and whether it is right for you. Review the Patient-Doctor Discussion Checklist in the Patient Information Booklet with your doctor before deciding to have the Essure procedure.

**About Bayer**

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2017, the Group employed around 99,800 people and had sales of EUR 35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to www.bayer.us.

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