News Release

Intended for U.S. Media Only

Bayer reaffirms safety profile of Essure

Women with Essure who have questions should consult their healthcare providers and be cautious about relying upon misinformation online

Whippany, N.J., July 27, 2018 – Bayer is reminding women with Essure that the safety profile of Essure, the only Food and Drug Administration (FDA)-approved non-incisional form of permanent birth control, remains positive and unchanged. The Company also is expressing concern about comments made by third parties promoting Essure removal, which combined with the spread of inaccurate or misleading information, may drive women who have relied on Essure as their birth control option to seek risky and unnecessary surgery to remove the device.

Our greatest priority is the safety of patients who rely on our medicines and devices. Over the past two decades, the efficacy and safety of Essure has been demonstrated in 40 published studies involving more than 200,000 women. Essure's positive safety profile has remained consistent since it first came to market and, to this day, the U.S. Food and Drug Administration has maintained that Essure's benefits outweigh any potential risks.

Women with Essure can continue to rely on it confidently for their reproductive health and should speak with their healthcare providers if they have any questions or concerns. Bayer's ongoing support services for women with Essure 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.

Bayer is concerned about the ongoing public promotion of Essure removal, along with inaccurate or misleading information spread by third parties, that could lead women to pursue unwarranted, invasive surgery, primarily via hysterectomy, and potentially cause new or additional health problems. The singular focus on hysterectomy is inconsistent with Essure's Instructions for Use (IFU), which states that 'hysterectomy generally is not required to remove

the Essure inserts,' as there are other methods identified in the IFU. The IFU is based on scientific data and opinions from medical experts worldwide.

There is no reliable scientific evidence to suggest that any new safety concerns exist with Essure. Women with Essure and their healthcare providers should know that concerns raised in recent years regarding the Essure device have been based on anecdotal reports, rather than science.

While Bayer takes any adverse event report seriously, the FDA has repeatedly cautioned that adverse event reports can be 'incomplete, inaccurate, untimely, unverified or biased' and duplicative, and that adverse event reports alone cannot be used to determine rates of events or causation. Indeed, in 2015 FDA reviewed the safety data for Essure and did not identify new safety or efficacy concerns.

The full body of scientific evidence confirms that Essure is an effective option for women seeking permanent birth control. In the Phase II and Pivotal trials, at least 99% of women were reported to have rated comfort of wearing the Essure inserts as 'good' or 'excellent.' In the Pivotal trial, at least 97% of women were reported to be 'somewhat' to 'very satisfied' at all study visits through 5 years. This is summarized in the FDA's executive summary prepared in advance of the 2015 Advisory Committee.

All birth control options have risks, including both Essure and laparoscopic tubal ligation, which is an invasive surgery and the only other available option for women who want permanent birth control. The potential risks associated with Essure have been appropriately communicated in the label to doctors and patients.

Bayer remains strongly committed to women's health where we have long been a leader; this includes ensuring that women have the information -- grounded in science and research -- that they need to choose the birth control method that best fits their individual needs. On July 20, 2018, the Company announced it had 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.

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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