News Release

Bayer Statement about Essure® Label Update

Whippany, N.J., April 9, 2018 – Bayer announced today that the U.S. Food and Drug Administration (FDA) has approved a label update for the Essure® System for Permanent Birth Control requiring healthcare providers to use the Patient-Doctor Discussion Checklist in order to purchase the product. The label now states that the sale and distribution of Essure is restricted to healthcare providers who counsel patients according to the approved label. The benefit/risk profile of Essure has not changed and remains positive.

Patients deserve the most accurate and comprehensive information to help them make their healthcare decisions, and Bayer has educated and continues to educate healthcare providers about the importance of appropriately counseling each patient on the benefits and risks of Essure. The FDA requested we update the label to emphasize this point.

The Patient-Doctor Discussion Checklist, which was added to the Essure label in November 2016, now includes the sub-title “Acceptance of Risk and Informed Decision Acknowledgement” to emphasize the importance of this tool. Bayer will continue to reinforce the use of the Checklist with healthcare providers and will inform them about this important label update.

Choosing a birth control method is a very important and personal decision. Bayer is deeply committed to providing women with safe and effective healthcare options that meet their individual needs, and is dedicated to ensuring the continued safe, effective and appropriate use of Essure as an important option for permanent contraception. As the FDA has repeatedly determined – after a rigorous review of the scientific evidence – Essure, the only non-incisional option available for those who seek permanent birth control, is a safe and effective medical device that benefits women by providing them with a valuable contraception option.

About Essure
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 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

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.

Bayer: Science For A Better Life
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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