BAYER

Protecting the health of women is paramount. Science must be the driver.

An Open Letter to Patients and Providers About Essure

Last week, Bayer announced its decision to stop the sale of the Essure® System for Permanent Contraception at the end of 2018. We know that women and their physicians may have questions about this decision, which was a difficult one for us. Our goal always has been to ensure that women and their healthcare providers have as many contraception options available as possible.

Since its approval, Essure has been an important option for women seeking permanent birth control, offering a less invasive alternative to tubal ligation. In recent years, however, the demand for Essure has decreased due to a number of factors, including decreased use of permanent contraception overall, the increasing popularity of long-acting, reversible birth control options, and inaccurate or misleading publicity about the device.

Our decision was not based on concerns about the safety and efficacy of Essure. Essure has been on the market for more than 15 years and has been successfully used by hundreds of thousands of women.

Any effort to protect and promote women's health must be rooted in science. More than 40 studies, involving more than 200,000 women, have been conducted to evaluate the safety and efficacy of Essure. The data demonstrates Essure's positive safety profile as confirmed by highly respected medical organizations such as the American College of Obstetricians and Gynecologists. FDA also has maintained that Essure's benefits outweigh any potential risks.

Like all medical products, Essure use is associated with certain potential risks, which have been appropriately communicated in the label to doctors and patients. There is no reliable scientific evidence of any new safety issues related to Essure.

Over the last few years, Essure has been the subject of conversation on both social and mainstream media platforms. The concerns raised about Essure are based primarily on anecdotal reports from individual patients. Bayer takes all such reports seriously. It is important to understand, however, that anecdotal reports have limitations. While such reports can raise questions about potential issues with a product, they do not provide answers. Such questions can only be answered through evidence-based medicine, including clinical trials and observational studies.

In 2015, the FDA conducted a thorough review of the reports related to Essure and held an Advisory Committee meeting to discuss those reports. After completing its review, FDA confirmed that the benefits outweigh the risks associated with the device, but did request a new study to evaluate the comparative risks of Essure and tubal ligation. Since that time, a number of large-scale studies have generated new data addressing many of FDA's questions and provided further reassurance about the safety and efficacy of Essure.

We understand that women who currently have Essure may still have concerns, particularly given the recent media coverage related to our decision to wind down Essure sales. If you have questions, we strongly recommend that you discuss them with your physician before making any medical decisions. In particular, we are aware that a number of posts and websites are recommending that women who have an Essure device undergo a hysterectomy (or other procedure) to have the device removed, even if they are not experiencing any symptoms. This is extremely troubling to us, as Essure removal should only be performed in consultation with a physician experienced with the device. There is no evidence to support removal of the device in asymptomatic patients. It also is important to emphasize that all surgical procedures, including removal of the Essure device, are associated with risks, some of which are potentially serious, and should only be performed by a trained surgeon when medically indicated.

Bayer has been a trusted name in healthcare for more than 150 years, and the safety of patients always has been our first priority. Our primary goal is to ensure that our products are safe and effective, and that patients and physicians are made fully aware of the associated risks and benefits. We stand behind the safety and efficacy of Essure, and we will continue to support Essure patients and their physicians in any and all ways possible. If you have further questions, please discuss them with your physician or contact Bayer directly at our Customer Care Call Center (**1-888-84-BAYER**).

Please see Important Risk Information for Essure on the following page.

Science for a ***better life***

Important Safety Information About Essure

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.