

At Bayer, our mission is to create medicines and devices that help people. Patient safety is our top priority, and we have great sympathy for anyone who is experiencing pain, regardless of the cause. We have also read the stories from women who are sharing their personal experiences with Essure. These stories, while compelling, are not representative of the hundreds of thousands of women who have relied on Essure since its FDA approval in 2002.

As the manufacturer of this product, we have a responsibility to share the facts about Essure with you and your viewers:

- ***We take all adverse events seriously. Most of the side effects that have been reported recently about Essure are known and included in the Essure Instructions for Use information.*** This was confirmed by the FDA which found that “[a]lthough there is evidence of complications, as there are with all medical devices, overall results from [a five-year] study did not demonstrate any new safety problems or an increased incidence of problems already known.” None of the information the FDA reviewed from the manufacturer safety database, the 5 year study, and available clinical literature established a causal connection between Essure and certain reported problems such as extreme fatigue, depression and weight gain. For further information on FDA’s position on Essure, please click on:  
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/ucm371014.htm><sup>1</sup>
- ***Essure has more than a decade of research and development in addition to a decade of real world experience.*** Based on the total units sold since launch, approximately 750,000 women worldwide have had Essure placed. Essure has been shown to be highly effective in preventing pregnancy (99.83% based on five-year clinical study data) and the safety profile has been documented through numerous clinical trials. The American College of Obstetricians and Gynecologists (ACOG) has recognized that “hysteroscopic tubal occlusion for sterilization [Essure] has high efficacy and low procedure-related risk....”<sup>2</sup>
- ***More than 600,000 tubal ligation procedures are performed in the United States each year.***<sup>3</sup> We stand by the benefit-risk profile of Essure as an important option available to women who want non-surgical permanent contraception.
- ***Bayer conducts hands on training with physicians across the United States and provides ongoing support in the appropriate use of Essure.*** In addition, trained Bayer medical specialists conduct continuous outreach to healthcare professionals in order to learn more about how Essure is used in their practice and to answer their questions.

No form of contraception should be considered appropriate for every woman. No form of birth control is without risk or 100 percent effective. As with any medicine or device, it is important that women discuss the benefits and risks of any birth control option with their physicians.

Below is a link to a video statement on our website from Edio Zampaglione, MD, FACOG, US Medical Affairs, Bayer HealthCare, for your use:

<http://www.bayer.us/en/news-room/video-gallery/>

## About Essure®

### Indication

Essure® is permanent birth control that works with your body to create a natural barrier against pregnancy.

### Important Safety Information

Essure is not right for you if you are uncertain about ending your fertility, can have only one insert placed, are or have been pregnant within the past 6 weeks, have had your tubes tied, have an active or recent pelvic infection, or have a known allergy to contrast dye.

Talk to your doctor if you are taking immunosuppressants.

**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.** It can take longer than three months for Essure to be effective. Talk to your doctor about which method of birth control you should use during this period. Women using an intrauterine device need to switch to another method. If you rely on Essure for birth control before receiving confirmation from your doctor, you are at risk of getting pregnant.

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

**During the procedure:** In clinical trials some women experienced mild to moderate pain (9.3%). Your doctor may be unable to place one or both Essure® inserts correctly. Although uncommon, part of an Essure insert may break off or puncture the fallopian tube requiring surgery to repair the puncture. Your doctor may recommend a local anesthetic. Ask your doctor about the risks associated with this type of anesthesia.

**Immediately following the procedure:** In clinical trials 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 experienced nausea and/or vomiting (10.8%) or fainting. In rare instances, an Essure insert may be expelled from the body.

**During the Essure Confirmation Test:** You will be exposed to very low levels of radiation, as with most x-rays. In rare instances, women may experience spotting and/or infection.

**Long-term Risks:** There are rare reports of chronic pelvic pain in women who have had Essure. In rare instances, an Essure insert may migrate through the fallopian tubes and may require surgery. No birth control method is 100% effective. Women who have Essure are more likely to have an ectopic pregnancy (pregnancy outside the uterus) if they get pregnant. This can be life-threatening. The Essure insert is made of materials that include a nickel-titanium alloy. Patients who are allergic to nickel may have an allergic reaction to the inserts. Symptoms include rash, itching and hives.

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.**

Click here for [Essure Instructions for Use](#)

Click here for [Essure Patient Information Brochure](#)

Talk to your doctor about Essure and whether it is right for you.