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

 **FDA Outlines Actions for Continued Safe, Effective and Appropriate Use of
Essure® for Permanent Birth Control**

**Whippany, N.J., February 29, 2016 –** The U.S. Food and Drug Administration (FDA) issued a communication outlining actions on Essure® permanent birth control today, following a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee on September 24, 2015. The FDA outlined actions including the collection of additional data and proposed updates to the Essure labeling. Essure is an important permanent birth control option with a positive benefit-risk profile. Bayer will continue to work with the FDA to implement measures to support the continued safe, effective and appropriate use of Essure.

“Patient safety and appropriate use of Essure are our greatest priorities,” said Dario Mirski, M.D., senior vice president and head of medical affairs Americas at Bayer. “A woman’s decision to choose a birth control method is a very important and personal one, and Bayer is committed to providing physicians with resources, tools and information to help them counsel women about Essure.”

Bayer encourages anyone who has questions about Essure to speak directly with a trained Essure medical specialist. Individuals can call 1-877-ESSURE1 if they have questions.

**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, suspect you are pregnant 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.

Tell your doctor if you are taking immunosuppressants or think you may have a nickel allergy.

 **Please See Important Safety Information Continued on the Next Page.**

**Important Safety Information (continued)**

**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 can take longer than three 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. 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 the original 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 or it may puncture the fallopian tube requiring surgery to repair. If breakage occurs, your doctor may remove the piece or let it leave your body during your period. Your doctor may recommend a local anesthetic. Ask your doctor about the risks associated with this type of anesthesia.

**Immediately following the procedure**: In the original 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 experienced nausea and/or vomiting (10.8%) 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 confirmation tests requires an x-ray, you may be exposed to very low levels of radiation, as with most x-rays, if this test is used. In rare instances, women may experience spotting and/or infection.

**Long-term Risks**: There are reports of chronic pelvic pain in women possibly related to Essure. An Essure insert may migrate into the lower abdomen and pelvis and may require surgery for removal. 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](http://www.hcp.essure-us.com/assets/pdf/Link%20Essure%20IFU.pdf) for Essure Instructions for Use | [Click here](http://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf) for Essure Patient Information Brochure

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

**About Essure Permanent Birth Control**Essure was approved by the FDA in 2002 as a permanent birth control option for women who have completed their families. The Essure procedure is over 99 percent effective based on clinical study data, making it one of the most effective methods of permanent birth control available. The safety and efficacy of Essure is supported by more than a decade of research and development and real world clinical experience. Essure has been studied in more than 10,000 women since it was first developed.

 **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 2015, the Group employed around 117,000 people and had sales of EUR 46.3 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.3 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to [www.bayer.com](http://www.bayer.com).

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