**Re: Update - Bayer Receives FDA Approval on Essure Labeling**

November 15, 2016

Dear Healthcare Provider,

Bayer has been working with the U.S. Food and Drug Administration (FDA) to support the continued safe, effective and appropriate use of Essure® for permanent birth control. The FDA has approved the revised Essure Instructions for Use (IFU) and Patient Information Booklet (PIB) in accordance with the final guidance on "Labeling for Permanent Hysteroscopically Placed Tubal Implants Intended for Sterilization", recently issued by FDA. The IFU and PIB have also been updated with additional information.

A summary of changes to the labeling includes:

1. The addition of a **Boxed Warning** listing adverse events that have been reported either in clinical studies or through post market surveillance. Please refer to the second page of this letter for the language of the boxed warning.

2. The **Essure Instructions for Use (IFU)** and **Patient Information Booklet (PIB)** have also been updated with additional information on safety (contraindications, warnings and precautions), clinical data, and instructions. Important modifications have been made to the patient counseling and device removal sections of the IFU to provide physicians with additional guidance in these areas.

3. The inclusion of a **Patient-Doctor Discussion Checklist** within the PIB. The Discussion Checklist, along with the PIB, is designed to support appropriate patient counseling, and to facilitate a patient's understanding of birth control options, benefits and risks associated with Essure, as well as what to expect during and after the Essure procedure.

Please review the revised IFU and PIB with Patient-Doctor Discussion Checklist at http://www.EssureMD.com prior to performing your next Essure procedure. Additionally, Essure Educational Webinars will be offered to provide a comprehensive overview of the labeling changes including the Discussion Checklist. We encourage you to visit www.EssureWebinars.com to register for a webinar that fits your schedule.

Given the importance of appropriate patient counseling, we will track the utilization of the Discussion Checklist through an updated **Essure Insert Information Card** that will be included in the product packaging. The Insert Card should be completed and mailed back following each Essure procedure. You will receive revised insert cards from your Bayer Representative and in your Essure shipments until the product packaging has been updated. For an additional supply of the updated cards, please contact your Bayer Sales Representative.

Patient safety is Bayer's top priority. Thank you for your ongoing support of Essure®, the only FDA-approved, non-incisional method of permanent birth control. The safety and efficacy of Essure is supported by more than a decade of science, as well as real world clinical experience, with the product studied in more than 10,000 women since Essure was first developed. Please do not hesitate to contact our Medical Information team at **888-84-BAYER (842-2937)** with any questions related to Essure or the procedure.

Sincerely,

Edio Zampaglione, MD
Vice President, U.S. Medical Affairs for Women's Healthcare and Neurology
Bayer HealthCare Pharmaceuticals Inc.

**Please see Important Safety Information including the Boxed Warning about Essure® on the next page.**

**Indication**
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 for Permanent Birth Control during discussion of the benefits and risks of the device.**

**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.

**Contraindications**
Essure is contraindicated in patients who are uncertain about ending fertility, can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicornuate uterus), have a known abnormal uterine cavity that makes visualization of the tubal ostia impossible, and/or abnormal tubal anatomy or previous tubal ligation (including failed ligation), are pregnant or suspect pregnancy, delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure, have an active upper or lower genital tract infection, have unexplained vaginal bleeding, have a gynecological malignancy, or have a known allergy to contrast media.

**General Warnings**
- The Essure procedure should be considered irreversible.
- Pain (acute or persistent) of varying intensity and length of time may occur following Essure placement. This is also more likely to occur in individuals with a history of pain. If device removal is indicated, this will require surgery.
- Patients with known hypersensitivity to nickel, titanium, platinum, stainless steel, and PET (polyethylene terephthalate) fiber or 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 for this device that may be associated with an allergic reaction include hives, urticaria, rash, angioedema, facial edema and pruritis. Patients should be counseled on the materials contained in the insert prior to the Essure procedure. Currently there is no test that reliably predicts who may develop a hypersensitivity reaction to the materials contained in the insert.
- Patients on immunosuppressive therapy may experience delay or failure of the necessary tissue in-growth for tubal occlusion. For these patients, physicians must use the modified HSG as the Essure Confirmation Test. Transvaginal ultrasound (TVU) should not be used as the Essure Confirmation Test, as TVU cannot confirm tubal occlusion.

**Pregnancy Risk**
- Pregnancies, including ectopic pregnancies, have been reported among women who have undergone the Essure procedure.
- The patient must use alternative contraception until a satisfactory Essure Confirmation Test is documented. If the Essure inserts are not properly placed or are not in a satisfactory location, then the patient should be advised to not rely on Essure and to use alternative contraception.
- Counsel the patient on the need for the Essure Confirmation Test, the options for the confirmation test including their risks and benefits, and the possibility that the Essure Confirmation Test may be unsatisfactory.
- Effectiveness rates for the Essure procedure are based on patients who had bilateral placement and a satisfactory Essure Confirmation Test.

**Procedure Warnings**
- Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or is suspected, discontinue procedure and monitor the patient for signs and symptoms of possible complications related to perforation which may include unusual post-operative pain.
- To reduce the risk of hypervolemia, terminate procedure if distension fluid deficit exceeds 1500cc or total hysteroscopic procedure time exceeds 20 minutes. Excess fluid deficit may signal uterine or tubal perforation. If noted, discontinue procedure and evaluate patient for possible perforation.
- Do not attempt hysteroscopic Essure insert removal during the placement procedure unless 18 or more trailing coils are seen inside the uterine cavity due to risk of a fractured insert, fallopian tube perforation, or other injury.
- DO NOT perform the Essure procedure concomitantly with endometrial ablation.

**MRI Information**
The Essure insert was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05.

**Adverse Events**
The most common (≥10%) adverse events resulting from the placement procedure were cramping, pain, and nausea/vomiting. The most common adverse events (≥3%) in the first year of reliance were back pain, abdominal pain, and dyspareunia.

**This product does not protect against HIV infection or other sexually transmitted diseases.**

**Prescription Only**