Rx

Update on the Essure System for Permanent Birth Control

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In 2002, the U.S. Food and Drug Administration (FDA) approved Essure (Bayer, Whippany, NJ), a minimally invasive procedure that provides a form of permanent female contraception. Unlike tubal ligation, which involves general anesthesia and small abdominal incisions, the Essure procedure is accomplished by a trained physician in an outpatient setting. Completed in an average of 10 to 15 minutes, this hysteroscopic procedure involves the placement of hormone-free, flexible metallic inserts into the fallopian tubes without incisions. The approval of Essure provided women with a noninvasive option for permanent birth control that did not require significant recovery time or discomfort.

The availability of another permanent contraceptive option for women was important,

Abstract In 2002, the U.S. Food and Drug Administration approved the Essure system for permanent birth control. Implantation with this device offers a minimally invasive option for permanent female contraception that is placed during a brief office visit. Unlike laparoscopic tubal sterilization, the Essure procedure requires no hospitalization or general anesthesia, resulting in minimal recovery time. After a decade of stability in the report of adverse effects, the U.S. Food and Drug Administration noted a sharp increase in patient-reported adverse events, including chronic pelvic pain, irregular bleeding, allergic reactions, and autoimmune-like reactions. In response to this increase in complaints, the U.S. Food and Drug Administration issued updated guidelines for patient education and counseling. This article discusses those updates, as well as implications for nurses who provide health care to women seeking permanent contraception. http://dx.doi.org/10.1016/j.nwh.2017.07.006

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especially for women who were interested in sterilization but had risk factors for anesthesia or surgery, such as obesity, pelvic adhesions, and cardiovascular disease (American Association of Gynecologic Laparoscopists, 2016; Basinski & Bradley, 2016; Walter, Ghobadi, Hayman, & Xu, 2017). In the first 10 years after the FDA's approval of Essure, the number of provider-reported and voluntary patient-reported complaints about the device remained stable, with approximately 100 to 200 complaints per year; however, in 2013 voluntary complaints from women increased 400% from the previous year. As of 2015, more than 5,000 complaints had been received about the Essure device. Most complaints (>4,600) were related to possible patient injury and a much smaller amount (474) were related to device malfunctions (Walter et al., 2017). The sharp rise in injury complaints included pain, irregular menstrual bleeding, allergic reactions, and autoimmune-type symptoms (e.g., fatigue, joint pain; FDA, 2016). In response to these complaints, the FDA re-evaluated the research data on Essure.

Overview of Essure

The Essure system consists of soft, flexible inserts that contain stainless steel coils that are wrapped in polyethylene terephthalate (i.e., PET) fibers. The fibers are covered in an outer layer of nickel–titanium alloy (Bayer, 2002). The inserts are 4 cm in length, and when placed into the fallopian tubes via hysteroscopy the outer coil expands to conform to the shape of the fallopian tube. Once expanded after deployment, the insert anchors to the wall of the fallopian tube. The PET fibers facilitate tissue growth into and around the inserts. This assists with retention of the insert in the fallopian tube and eventually results in tubal occlusion. A confirmation test of insert retention, correct placement, and tubal occlusion should be performed by transvaginal ultrasound or modified hysterosalpingogram 3 months after the procedure (Bayer, 2002).

Adverse Effects

Essure is associated with adverse effects. Varying levels of discomfort are commonly reported and include pain during and immediately after the procedure (sharp or cramping), chronic pelvic pain, dyspareunia, dysmenorrhea, and low back pain. In addition to pain, dizziness, nausea/vomiting, and a vasovagal response have been documented during the placement procedure. Reports of change in menstrual pattern, including irregular bleeding/spotting and heavier menstrual periods, have also been reported, as well as immediate and delayed allergic reactions to components of the device, especially nickel (Bayer, 2002). These reactions have manifested as pruritus, nausea, fatigue, and maculopapular and urticarial rashes (Siemons, Vleugels, & van Eijndhoven, 2017).

In response to a sharp rise in voluntary, patient-provided complaints after a decade of stability in reports of adverse effects, the FDA worked with its Obstetrics and Gynecology Advisory Committee to re-examine the original clinical trial data for when Essure was initially evaluated for safety (Walter et al., 2017). Although no methodologic issues related to the research were discovered, the FDA acknowledged that some of the data were limited, and it made recommendations for improved patient selection, education, and follow-up.

Summary of New Guidance From the FDA

First, Essure was required to carry a black box warning, the highest level of warning issued when there is the possibility of a serious event associated with a medication or device. This warning highlights reported adverse events such as perforation of the uterus or fallopian tubes during placement, migration of the inserts into the pelvic or abdominal cavity, persistent pain, and suspected allergic and/or hypersensitivity reactions. It also carries a recommendation

Box 1.

How to File a Concern With the FDA

Reports of negative side effects or concerns about the Essure device can be submitted to the FDA at **www.fda.gov/medwatch** or by calling **1-800-FDA-1088**.

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