More data sought on birth control device Essure

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Drastic as it may sound, sterilization is the second-most-popular birth control method among U.S. women, and more than 10 million have opted for it.

For many decades, that meant surgery to "tie the tubes." But in 2002, the U.S. Food and Drug Administration fast-tracked approval of a seeming breakthrough in sterilization: metal coils implanted in the fallopian tubes through the vagina.

The Essure procedure could be done in a doctor's office, required no incisions or general anesthesia, and maker Conceptus Inc. said it was 97 percent effective at preventing pregnancy.

The FDA and Bayer HealthCare, which acquired Essure in 2013, are now under fire because of evidence the implants are less effective and less safe than women have been told.

How much less, and what should be done in response, are subjects of intense, ongoing debate, not to mention lawsuits. Thousands of women who claim serious harm want Essure taken off the market. An FDA advisory committee met last month and rejected that idea, saying the coils were an important option for women who can't have tubal surgery.

But the panel saw a need for more data on Essure's risks, improved physician training and better information for patients.

As women mulling sterilization know, deciding how and when to end fertility is complicated and personal. Essure is no exception.

Tubal surgery, which involves cutting, burning or clipping the fallopian tubes so eggs can't reach the uterus, is immediately effective at preventing pregnancy.

Essure is not.

The process starts with the doctor threading a visualization instrument, or hysteroscope, through the vagina and cervix to each fallopian tube. A coil made of polyester fiber and nickel-titanium alloy is inserted into each tube.

When placement in both tubes succeeds - sometimes it doesn't - the coils trigger scarring that typically takes three months to block those gateways. Women must use another birth control method in the interim, then get a special X-ray with dye to confirm blockage. If blockage is incomplete, alternative birth control continues for another three months, then the X-ray is repeated.

A high-profile Essure failure occurred in 2010.

That January, Olympian skier Picabo Street, a mother of three, announced she had opted for Essure.

"I have no room for downtime associated with surgery or an unplanned pregnancy," she said in an Essure news release that boasted 99.74 percent effectiveness.

About eight months later, Street - by then gone from Essure's website - appeared visibly pregnant on the sports network ESPN. Conceptus issued a release asserting that Street had conceived before the

confirmation test and that "if all protocols are followed" the procedure is "99.8 percent effective."

The American College of Obstetricians and Gynecologists and Planned Parenthood - groups that expressed support for Essure at the FDA meeting - also make it sound almost foolproof.

"Less than 1 woman out of 1,000 will become pregnant within five years of the procedure," the ACOG website says.

Aileen M. Gariepy, an OB-GYN at the Yale School of Medicine, was skeptical, based on what she saw in her own practice. So she analyzed data from the company's two studies that led to approval, and later studies done in the U.S. and abroad.

She found that most results were biased and incomplete because researchers excluded women who had unsatisfactory coil placement, or no confirmation test, or who became pregnant before the test.

Factoring in such potential pitfalls, Gariepy published a paper in 2011 that estimated about 85 percent of women would be able to rely on Essure coils for contraception at three months. In a 2014 paper, she estimated 57 out of every 1,000 Essure patients would get pregnant within a year - a rate eight to 19 times higher than with tubal surgery methods.

"Eighty-five percent effective is not horrible, but it's not the 99 percent that the company reports," said Gariepy, who still offers Essure to her patients.

OB-GYN Edio Zampaglione, Bayer's vice president for U.S. medical affairs, dismissed Gariepy's analysis as "a mathematical model that makes a lot of assumptions."

Yet the company's own real-world data show that only 421 of 518 women in the pivotal study - 81 percent - had complete tubal blockage confirmed at three months. The rate rose to 86 percent at six months.

Those data were part of what the FDA ordered the company to collect by following the 518 women for five years. The results were published in the Journal of Minimally Invasive Gynecology this year - seven years after the follow-up study ended and was submitted to the FDA.

Although that mandated study reported no pregnancies, four pregnancies that did occur before the confirmation test were excluded, and some additional pregnancies may have been missed because 29 percent of the women dropped out or cut contact during the five-year period.

The safety of Essure is an even more complex, conflicted issue.

Essure is the latest product to raise questions about the adequacy of FDA regulation of medical devices. Postmarketing safety problems have forced the agency to issue warnings, revise labeling, require more studies and even order recalls of products such as vaginal mesh, heart pacemakers and a gynecological surgical tool called a power morcellator.

The FDA has received more than 5,000 complaints of "adverse events" regarding Essure. A Facebook group called Essure Problems has 23,000 members and counting.

Bayer says the occurrence of problems is low considering the wide use of Essure. But the company also says it doesn't know how many women actually have implants, just that about a million Essure kits have been sold worldwide, 70 percent of them in the U.S.

"While we are saddened that women have had adverse events, the rates are within what would be expected with the procedure," Zampaglione

said. "You see a very consistent picture of a low level of adverse events."

In the five-year follow-up study, 99 percent of women rated their comfort with Essure "good" or "excellent." But again, because of attrition, more than a quarter of the original group was not polled.

Over the five years, 15 women had hysterectomies, although researchers deemed only two "possibly" related to Essure. Eighty-five women had recurring pelvic pain, and 177 had recurring heavy menstrual bleeding, although researchers believed Essure was possibly linked to only a small minority of the cases.

In the Essure Problems group, many women complain not only of debilitating pelvic pain and bleeding, but of a syndrome including hair loss, dermatitis, headaches, aching joints, endometriosis, fatigue, confusion and depression.

Tamara Monroe, 35, a mother of five from Levittown, was suffering those symptoms and more when she faced another predicament common in the group: She had trouble finding a doctor willing to try to extract her coils.

She finally had her fallopian tubes surgically removed, but fragments of the coils remain in her uterus.

"You feel like you're dying from the inside out," she said.

Monroe and many Essure patients blame their miseries on an inflammatory reaction to nickel in the coils. Essure's labeling warns that the nickel can trigger allergic symptoms including rash, itching and hives.

That caveat used to be stronger, warning doctors against using Essure in

women with known nickel allergies. But in 2011, the FDA agreed to remove that warning after reviewing data, including a recently published analysis of adverse event reports by a Conceptus consultant who found a "very low incidence" of suspected and confirmed nickel reactions in Essure patients.

Last month, the FDA advisory panel hedged on the question of who should steer clear of Essure implants.

"The panel suggested that patients with a known hypersensitivity to metal, autoimmune disease, history of pelvic inflammatory disease, and those with a history of abnormal uterine bleeding may be less suitable candidates," said an FDA summary of the meeting.

The FDA is accepting public comments on Essure, submitted online or by mail, through Oct. 24. It has no deadline or time frame for taking action after that.