**Women With Essure Contraceptive Implant Needed More Surgeries, Study Finds**

*By*

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October 13, 2015 7:38 pm October 13, 2015 7:38 pm 22 Comments

Women who sought permanent sterilization through a contraceptive implant called Essure were 10 times as more likely to be back for surgery within a year than women who had their tubes tied, according to a new study of 52,326 women sterilized in hospitals and ambulatory surgery centers in New York State from 2005 to 2013.

The findings add to growing concerns about the device, which has been on the market for over a decade. Thousands of women who claim they have been hurt by it have [urged the Food and Drug Administration](http://www.nytimes.com/2015/05/04/us/long-term-data-on-complications-adds-to-criticism-of-contraceptive-implant.html) to warn the public about potential complications and pull the device from the market.

The new analysis found that 2.4 percent of the 8,048 women who had Essure implanted returned for an operation within a year. Only 0.2 percent of the 44,278 women who had more traditional, minimally invasive sterilization needed another operation. The analysis did not include women treated in private doctors’ offices.

Dr. Art Sedrakyan, the paper’s senior author and a researcher at Weill Cornell Medicine, said most of the repeat operations were required because of complications from the device, a small metal and polyester coil placed into a woman’s fallopian tubes, or because of a device failure. Many of them involved removing the fallopian tubes, though a precise breakdown of the follow-up operations has not yet been published, which some experts criticized as a weakness in the paper.

The study, [published Tuesday in The BMJ](http://www.bmj.com/cgi/doi/10.1136/bmj.h5162), reported that Essure, which can be inserted vaginally without a surgical incision, was as effective at preventing pregnancy as laparoscopic tubal ligation. But the implant was associated with significantly higher hospital charges, with median charges of $7,832, compared with $5,068 for a surgical tubal ligation. More than half of the patients received general anesthesia, although Essure is promoted as an easy 10-minute office procedure that does not require anesthesia.

“This study is important because it looked at Essure women in the real world, not the more ideal world of clinical trials,” said Diana Zuckerman, president of the National Center for Health Research, a nonprofit consumer research group. “The very high rate of reoperations — 10 times as high with Essure — is likely to add to concerns about the accuracy of the clinical trial data provided to the F.D.A.” when the device was approved.

Officials at Bayer HealthCare, which owns and markets Essure, said that the research was of “poor quality” and that comparing the two methods of sterilization was equivalent to “comparing apples and oranges.”

Dr. Edio Zampaglione, a vice president at Bayer, said: “There is a very high likelihood the placement will go well and the patient will benefit from Essure. What you’ve got with Essure is a noninvasive procedure, and you try to do most things in medicine with the least invasive method for the least harm.”

Over half a million American women are sterilized each year, and Essure has been growing in popularity.

Since the device went on the market 13 years ago, the F.D.A. has received more than 5,000 complaints about serious complications, including severe back and pelvic pain; painful intercourse; heavy, prolonged menstrual bleeding; chronic fatigue; autoimmune diseases. It has also received reports that the device’s coils have pierced the fallopian tubes and lodged in organs, leading to hysterectomies and other surgeries. Bayer officials have said repeatedly that the device is safe and that the complications are in line with those from surgical sterilization.

Just last month, the Food and Drug Administration held a daylong meeting about Essure, and its expert panelists lashed out at Bayer for not collecting data that could have helped predict the risks for women using the device. Critics have called on officials to pull it off the market, but the F.D.A. has not taken any action so far.

Some experts familiar with Essure said the new study may have underestimated or failed to capture all of the complications related to the device.

The analysis would not have captured the outcome for Lisa Saenz, 46, who experienced health problems for six years before having surgery to remove the device. Ms. Saenz, a social worker and mother of three from the Bronx, said she had Essure implanted in 2008 because she was promised her busy life would not be disrupted. But she developed an endless series of problems, from excessive, painful menstrual bleeding that lasted 10 to 15 days a month to extreme fatigue and painful intercourse. “I was living on ibuprofen,” she said.

She was 38 at the time, and the doctor who had implanted the device told her that her health problems were age-related. Another doctor referred her to a sex therapist. She had to consult several physicians before one agreed to perform a hysterectomy.

Ms. Saenz finally had a hysterectomy last year, and after her uterus was removed, the surgeon and pathologist told her that an Essure coil was embedded in the organ and that scar tissue had grown all around it. She has since recovered her health, but said: “I wasn’t myself for years. I lost so much quality of life.”