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Essure-Related Complications Still A Problem, Latest FDA Data Show

More women have had the device removed

by Brian Bossetta

Interim data from two ongoing studies show more women have had the Essure birth control device removed while many are still experiencing adverse events, such as pain and bleeding.

Though no longer on the market, the Essure birth control device is still causing problems for many women who had them implanted, such as chronic abdominal pain, pelvic pain, and abnormal uterine bleeding. And many women are opting to have the devices removed.

Designed as an alternative to permanent birth control surgery, the tiny spring-like devices inserted into the fallopian tubes to block the fertilization of eggs received FDA-approval in 2002. However, after a flood of complaints from women with the devices, *Bayer AG* stopped selling Essure in December 2018, though providers were still allowed to implant the device for up to a year after it was taken off the market.

As of December 2019, all unused Essure devices were returned to Bayer and since then have not been available for implantation.

In August 2020, Bayer documented numerous social media complaints that included serious injuries and deaths from the device. (Also see "*Social Media Posts Showed Almost 1,500 Adverse Events, 53 Deaths Linked To Essure: FDA Report*" - Medtech Insight, 12 Aug, 2020.)

Due to the many issues with the device, the FDA has continued to monitor patient safety.

On 14 February, the FDA posted its most recent *update*, titled “Information for Patients and Health Care Providers: Essure,” based on data from patients who had completed one year of

follow-up from the agency's 2020 interim analysis. The next round of results is scheduled for release after all patients complete three years of follow-up.

The agency's update includes data from two studies. One *study* of 1,129 women is broken into two cohorts – those implanted with Essure and those that opted for laparoscopic tubal sterilization (LST), a permanent surgical procedure blocking the fallopian tubes to prevent pregnancy. Another *study* of 620 women is being conducted to determine the rate of device removal after 10 years.

> ***"If you have been using Essure successfullyto prevent pregnancy you can and should continue to do so." – The FDA***

For the study comparing the Essure and LST groups, the rate of women experiencing chronic lower abdominal and/or pelvic pain in 2021 was 12.5% in the Essure group, compared to 8.7% in the LST group. In 2020, 9.1% of Essure women reported pain, compared to 4.5% of those in the LST group.

More women with the Essure device, 20.5%, also reported abnormal uterine bleeding post-procedure in 2021 than those in the LST group, 18.6%. In 2020, 16.3% of Essure women reported uterine bleeding, compared to 10.2% in the LST group.

Many women who received Essure, however, have since had it removed.

In 2016, the FDA approved a change to the Essure post-approval study to gather more information on removal of the device. Nevertheless, the agency advises that women "using Essure successfully to prevent pregnancy can and should continue to do so."

As of the 2021 interim analysis, 21 women have had 26 Essure removal procedures. As the FDA notes, some patients may have undergone more than one removal procedure at a time, such as hysterectomy (removal of uterus) and salpingectomy (removal of fallopian tubes).

The reasons for device removals, according to the FDA, range from patient requests, management of adverse events, removal in conjunction with other gynecologic surgeries, and the unreliability of the device to prevent pregnancy.

Results from the other study of 620 women find 17.8% had the device removed after eight years

of receiving it, which is higher than the 15.5% the FDA reported in 2020 after seven years of implantation. The FDA expects to post the final results from this study in July 2023.

The results from the larger study comparing the Essure and LST groups are expected to be released in June 2025.