



Protecting the health of women is paramount. Science must be the driver.

An Open Letter to Patients and Providers About Essure

Last week, Bayer announced its decision to stop the sale of the Essure® System for Permanent Contraception at the end of 2018. We know that women and their physicians may have questions about this decision, which was a difficult one for us. Our goal always has been to ensure that women and their healthcare providers have as many contraception options available as possible.

Since its approval, Essure has been an important option for women seeking permanent birth control, offering a less invasive alternative to tubal ligation. In recent years, however, the demand for Essure has decreased due to a number of factors, including decreased use of permanent contraception overall, the increasing popularity of long-acting, reversible birth control options, and inaccurate or misleading publicity about the device.

Our decision was not based on concerns about the safety and efficacy of Essure. Essure has been on the market for more than 15 years and has been successfully used by hundreds of thousands of women.

Any effort to protect and promote women's health must be rooted in science. More than 40 studies, involving more than 200,000 women, have been conducted to evaluate the safety and efficacy of Essure. The data demonstrates Essure's positive safety profile as confirmed by highly respected medical organizations such as the American College of Obstetricians and Gynecologists. FDA also has maintained that Essure's benefits outweigh any potential risks.

Like all medical products, Essure use is associated with certain potential risks, which have been appropriately communicated in the label to doctors and patients. There is no reliable scientific evidence of any new safety issues related to Essure.

Over the last few years, Essure has been the subject of conversation on both social and mainstream media platforms. The concerns raised about Essure are based primarily on anecdotal reports from individual patients. Bayer takes all such reports seriously. It is important to understand, however, that anecdotal reports have limitations. While such reports can raise questions about potential issues with a product, they do not provide answers. Such questions can only be answered through evidence-based medicine, including clinical trials and observational studies.

In 2015, the FDA conducted a thorough review of the reports related to Essure and held an Advisory Committee meeting to discuss those reports. After completing its review, FDA confirmed that the benefits outweigh the risks associated with the device, but did request a new study to evaluate the comparative risks of Essure and tubal ligation. Since that time, a number of large-scale studies have generated new data addressing many of FDA's questions and provided further reassurance about the safety and efficacy of Essure.

We understand that women who currently have Essure may still have concerns, particularly given the recent media coverage related to our decision to wind down Essure sales. If you have questions, we strongly recommend that you discuss them with your physician before making any medical decisions. In particular, we are aware that a number of posts and websites are recommending that women who have an Essure device undergo a hysterectomy (or other procedure) to have the device removed, even if they are not experiencing any symptoms. This is extremely troubling to us, as Essure removal should only be performed in consultation with a physician experienced with the device. There is no evidence to support removal of the device in asymptomatic patients. It also is important to emphasize that all surgical procedures, including removal of the Essure device, are associated with risks, some of which are potentially serious, and should only be performed by a trained surgeon when medically indicated.

Bayer has been a trusted name in healthcare for more than 150 years, and the safety of patients always has been our first priority. Our primary goal is to ensure that our products are safe and effective, and that patients and physicians are made fully aware of the associated risks and benefits. We stand behind the safety and efficacy of Essure, and we will continue to support Essure patients and their physicians in any and all ways possible. If you have further questions, please discuss them with your physician or contact Bayer directly at our Customer Care Call Center (**1-888-84-BAYER**).

Please see Important Risk Information for Essure on the following page.