

## Essure FAQs

### **1. Why did Bayer decide to stop the sales and distribution of Essure?**

Bayer made a business decision to voluntarily discontinue sales and distribution of Essure in the United States after Dec. 31, 2018. This decision is based on a decline in U.S. sales of Essure in recent years and the conclusion that the Essure business is no longer sustainable. The benefit-risk profile for Essure has not changed, and we continue to stand behind the product's safety and efficacy, which are demonstrated by an extensive body of research, undertaken by Bayer and independent medical researchers, involving more than 200,000 women over the past two decades.

Several factors have contributed to declining patient interest in Essure in the U.S., including decreased use of permanent contraception overall, increased reliance on other birth control options such as long-acting reversible contraceptives (LARCs) and inaccurate and misleading publicity about the device.

### **2. Does FDA know about this decision?**

Bayer has informed the U.S. Food and Drug Administration of the Company's voluntary decision. The FDA has maintained for several years that the benefits of Essure outweigh its risks. Since the initial application for Essure was approved in 2002, the FDA has continued to review the safety and efficacy of Essure most recently in April 2018. The FDA consistently has concluded that the product has a favorable benefit-risk profile.

Importantly, women with Essure can continue to rely on the device. Bayer's decision to voluntarily discontinue sales is for business reasons, and not for any safety or efficacy concerns about Essure.

### **3. How does this voluntary decision affect the postmarket surveillance study (522 study) of Essure required by FDA?**

Bayer will continue enrolling patients in the Essure postmarket surveillance study and will work closely with the FDA to ensure appropriate follow up. Bayer will also continue to fully comply with its other regulatory responsibilities regarding Essure.

### **4. What does this voluntary decision say about the safety and effectiveness of Essure?**

Bayer made a business to voluntarily discontinue sales and distribution of Essure in the United States after Dec. 31, 2018 based on a decline in U.S. sales of Essure in recent years and the conclusion that the Essure business is no longer sustainable. The benefit-risk profile for Essure has not changed. Women who currently have Essure in place may continue to rely on the device, and Bayer will continue to support women with Essure and their healthcare providers. Bayer continues to stand behind the product's safety and efficacy, which are demonstrated by an extensive body of research, undertaken by Bayer and independent medical researchers, involving more than 200,000 women over the past two decades. The FDA has maintained for several years that the benefits of Essure outweigh its risks.

**5. What advice does Bayer have for women who already have the device?**

Women who currently have Essure in place may continue to rely on the device, and Bayer will continue to support women with Essure and their healthcare providers. The safety profile of Essure has not changed, and has remained consistent over time. We continue to stand behind the product's safety and efficacy, which are demonstrated by an extensive body of research undertaken by Bayer and independent medical researchers, involving more than 200,000 women over the past two decades. Bayer has informed the U.S. Food and Drug Administration of the company's voluntary decision. The FDA has maintained for several years that the benefits of Essure outweigh its risks.

We encourage women who have any questions about Essure to speak first with their healthcare provider. Bayer's ongoing support services will include our consumer and healthcare provider websites ([Essure.com](http://Essure.com) and [EssureMD.com](http://EssureMD.com)), the Bayer customer care call center, which is staffed by nurses and other health professionals, at 1-888-84-BAYER, and continued access to the Essure consultant's network for providers who have questions.

**6. Will Bayer continue to provide support to women and healthcare providers about Essure?**

Yes, we are strongly committed to supporting women who continue to rely on Essure for permanent birth control. Bayer's ongoing support services will include our consumer and healthcare provider websites ([Essure.com](http://Essure.com) and [EssureMD.com](http://EssureMD.com)), the Bayer customer care call center, which is staffed by nurses and other health professionals at 1-888-84-BAYER, and continued access to the Essure consultant's network for providers who have questions.

**7. How does this announcement affect the availability of Essure as an option for women?**

Healthcare providers will be able to purchase Essure until the end of this year. Bayer will continue to support Essure patients and providers. Our ongoing support services will include our consumer and healthcare provider websites ([Essure.com](http://Essure.com) and [EssureMD.com](http://EssureMD.com)), the Bayer Customer Care Call Center at the Bayer customer care call center, which is staffed by nurses and other health at 1-888-84-BAYER, and continued access to the Essure consultant's network.

As a result of this announcement and the recent sales restrictions approved by the FDA, the following procedures and timelines will be in place until the end of the year. As of Aug. 1, 2018, in order for an account to purchase Essure, Bayer will need to have the following documentation on file:

1. A signed Essure Physician Distribution Agreement (EPDA) for active Essure users within the account that states they will use the Patient Decision Checklist with all patients prior to the procedure.
2. A Facility Confirmation Form from the user facility, at the time of order, to confirm that the purchased product will only be distributed to a physician within the account that has a signed EPDA on file and that the product will be used within one year of the date of purchase.

**8. Has Bayer informed healthcare providers of this voluntary decision?**

Bayer is informing healthcare providers directly of our business decision to voluntarily discontinue sales of Essure. Our provider communication says that we will continue to provide support to healthcare providers and their patients. Our ongoing support services will include our consumer and healthcare provider websites ([Essure.com](http://Essure.com) and [EssureMD.com](http://EssureMD.com)), the Bayer Customer Care Call Center, which is staffed by nurses and other health professionals at 1-888-84-BAYER, and continued access to the Essure consultant's network.

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**9. What are the reasons for the decline in sales of Essure that has made the business unsustainable?**

Several factors have contributed to declining patient interest in Essure in the U.S., including decreased use of permanent contraception overall, increased reliance on other birth control options such as long-acting reversible contraceptives (LARCs) and inaccurate and misleading publicity about the device.

**10. Will this voluntary decision impact Bayer's commitment to or innovation in women's reproductive health?**

Bayer remains strongly committed to women's health where we have long been a leader. We recognize that women want safe and effective options that best meet their individual needs, and we are committed to continuing our investment, innovation and leadership in this key area of health.

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