ES-547

FDA News Release

FDA restricts sale and distribution of Essure to protect women and to require that patients receive risk information

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Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm604169.htm)

The U.S. Food and Drug Administration today **issued an order (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S051)**to restrict the sale and distribution of the Essure device to ensure that all women considering use of the permanent contraception device are provided with adequate risk information so that they can make informed decisions. The FDA is taking this step after becoming aware that some women were not being adequately informed of Essure's risks before getting the device implanted, despite previous significant efforts to educate patients and doctors about the risks associated with this device. The FDA is requiring a unique type of restriction, using its authority to restrict the sale and distribution of a device to impose additional requirements needed to provide a reasonable assurance of its safety and effectiveness. The FDA is committed to continuing to use its full authorities to ensure the post-market safety of medical products.

Since the FDA **ordered Bayer to conduct (/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm)** a post-market study, and then to add a boxed warning and a patient decision checklist to the labeling, there has been an approximately 70 percent decline in sales of Essure in the U.S. The FDA has determined, however, that some women still are not receiving information about the known risks of Essure before implantation.

"We've been closely evaluating new information on the use of Essure, and based on our review of a growing body of evidence, we believe this product requires additional, meaningful safeguards to ensure women are able to make informed decisions about risk when considering this option," said FDA Commissioner Scott Gottlieb, M.D. "We take the concerns of all women affected by Essure very seriously. I've personally had the opportunity to meet with several women and hear their important concerns about this product. Despite previous efforts to alert women to the potential complications of

Essure, we know that some patients still aren't receiving this important information. That is simply unacceptable. Every single woman receiving this device should fully understand the associated risks."

The new Essure labeling, which will now be legally required when this product is offered to a patient, restricts the sale and distribution of the device to only health care providers and facilities that provide information to patients about the risks and benefits of this device. Specifically, the **patient brochure, (http://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf)** titled "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement," must be reviewed with the prospective patient by the health care provider to ensure the patient understands the risks, benefits and other information about Essure implantation. The patient must be given the opportunity to sign the acknowledgment, and it must be signed by the physician implanting the device. Bayer, the device manufacturer, is required to implement the restrictions immediately and ensure that the process going forward results in health care provider compliance with the sales restriction. The FDA will review and monitor Bayer's plan to ensure the company complies with the restriction. The FDA plans to enforce these requirements and will take appropriate action for a failure to comply, including applicable criminal and civil penalties.

Essure is the only permanently implanted birth control device for women on the market that does not require a surgical incision. In the procedure, a health care provider inserts flexible coils through the vagina and cervix and into the fallopian tubes – the tubes that carry the eggs from the ovaries to the uterus. Over a period of approximately three months, tissue forms around the inserts. The build-up of tissue creates a barrier that keeps sperm from reaching the eggs, thus preventing conception. Some patients implanted with Essure have experienced adverse events, including perforation of the uterus and/or fallopian tubes, migration of inserts to the abdominal or pelvic cavity, persistent pain and suspected allergic or hypersensitivity reactions. In addition, women have also reported experiencing headache, fatigue, weight changes, hair loss and mood changes, such as depression. It is unknown whether these symptoms are related to Essure.

"Ensuring informed decision making is just one important step in our ongoing efforts to monitor this device. We remain committed to carefully and thoroughly considering all new data and evidence and will continue to work with patients affected by this device as part of our process," said Terri Cornelison, M.D., Ph.D., assistant director for the health of women in the FDA's Center for Devices and Radiological Health. "While some women may continue to choose Essure as their birth control option based on current information, as new information becomes available, the FDA will continue to keep the public informed of the agency's evaluation and findings, and consider regulatory options that appropriately balance benefits and risks for Essure."

Since Essure's approval in 2002, the agency has continued to monitor the product's safety and effectiveness by reviewing the medical literature, clinical trial information, post-approval study data and medical device reports submitted to the agency. Based on this review, in February 2016, the agency ordered Bayer to conduct a **post-marketing (522) study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=356&c_id=3854)** to better evaluate the safety profile of the device when used in the real world. The agency is currently monitoring the company's progress. In November 2016, the FDA also required Bayer to add **a boxed warning (http://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf)** to the product labeling stating information about adverse events associated with the device "including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions." In addition to the warning, the FDA also required a more comprehensive **patient decision (http://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf)** checklist be added to the device labeling to provide

women considering Essure information about the benefits and risks of this device before deciding to use it. Although Bayer's post-market study currently has demonstrated adequate progress, including tripling of the total number of enrolled patients over the past six months, the FDA plans to require Bayer to increase the number of participating study sites to account for the declining sales volume.

The FDA is committed to continuing to communicate publicly on this issue and will provide updates related to the safety of Essure when available.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- **FDA Activities: Essure (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm)**
- **Commissioner statement on FDA activities related to post-market review of Essure (/NewsEvents/Newsroom/PressAnnouncements/ucm600052.htm)**
- **PMA supplement (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S051)**

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