

[Alerts and Recalls](#)

Generic Name (Trade Name—Company)

April 12, 2018

Implanted birth control device

(Essure—Bayer)

FDA restricts sale and distribution of Essure, requires women to be informed of risks

Uses/Notes

FDA continues to monitor the safety of Essure. FDA stated that it continues to believe the benefits of the device outweigh its risks, and that Essure's updated labeling and the sales restriction will ensure that women are appropriately informed of the risks.

Some women have received the Essure device without being adequately informed of its risks. FDA has taken steps, including labeling changes in 2016 adding a boxed warning and patient decision checklist, to better inform health care providers and patients about these risks. For this device to meet reasonable assurance of safety and effectiveness, all women considering Essure should receive this important information.

On April 9, 2018, FDA [restricted sales](#) of the Essure device to only doctors and health care facilities who use the FDA-approved "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement," which is part of the patient information booklet. It includes key items about the device, its use, and safety and effectiveness outcomes. Sale and distribution of Essure is limited to health care providers who agree to review this checklist with patients, and give them the opportunity to sign it, before Essure implantation.

FDA also [approved Bayer's new labeling](#) that includes the following statement: "The sale and distribution of this device are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bayer."

Source URL:

<http://aphanet.org/alerts-and-recalls/fda-restricts-sale-and-distribution-essure-requires-women-be-informed-risks>

APhA DrugInfoLine is an official publication of, and is owned and copyrighted by the American Pharmacists Association, the national professional society of pharmacists. Materials in APhA DrugInfoLine do not necessarily represent the policy, recommendations, or endorsement of APhA. The publisher, authors, editors, reviewers, and

contributors have taken care to ensure that information contained in APhA DrugInfoLine is accurate and current; however, they shall have no liability to any person or entity with regard to claims, losses, or damages caused or alleged to be caused, directly or indirectly, by use of any information contained in the publication. All decisions about drug therapy must be based on the independent judgment of the clinician. Copyright © 2000–2011, American Pharmacists Association. All rights reserved.