Essure Permanent Birth Control: Information for Health Care Providers

Bayer announced that they will no longer sell or distribute Essure in the U.S. after December 31, 2018, for business reasons. Health care providers can contact Bayer for more information about device distribution.

The FDA takes concerns about Essure very seriously; ensuring the safety and effectiveness of medical products is an agency priority and a core part of our consumer protection role. Bayer will continue to implement the **restriction on sale and distribution (/NewsEvents/Newsroom/PressAnnouncements/ucm604098.htm)** placed by the FDA on the device in April 2018, to ensure women are fully informed of the risks associated with the device.

Health care provider labeling states that Essure is to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use and Physician Training manual; and have successfully completed the Essure training program, including preceptoring in placement until competency is established, typically 5 cases.

- Essure is contraindicated in patients who:
  - are uncertain about their desire to end fertility
  - would be able to have only one micro-insert placed due to their anatomy (including patients with apparent contralateral proximal tubal occlusion or suspected unicornuate uterus)
  - have previously undergone tubal ligation
  - are pregnant or suspect pregnancy
  - have delivered or terminated a pregnancy less than 6 weeks prior to the Essure placement procedure
  - have an active upper or lower genital tract infection
  - have a known allergy to contrast media
  - have suspected or known cancer of the female reproductive organs
  - have unexplained vaginal bleeding
- The Essure inserts contain metals, including nickel, titanium, iron, chromium, silver-tin, platinum and a material called polyethylene terephthalate (PET). Patients who are allergic or sensitive to any of these materials may have a reaction to this device following implantation. Typical symptoms may include rash, itching, and hives but may also include other symptoms not reported in the clinical trials such as chest pain, breathing difficulties and intestinal discomfort such as nausea, diarrhea or vomiting. Physicians should ask whether patients have an allergy to nickel or other metals and materials when discussing their sterilization options.
  - While some patients with nickel sensitivity can tolerate Essure, physicians should discuss with their patients the potential for a reaction to the nickel component as they weigh the benefits and the risks of Essure in each individual case.
- *When discussing Essure and the procedure, make sure the patient understands:*
  - Essure benefits and risks
  - Essure is a permanent form of birth control
  - Importance of the Essure Confirmation Test

The FDA recommends that health care providers thoroughly discuss available sterilization and birth control methods with their patients, including their benefits and risks. The FDA-approved **Decision Checklist (/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/UCM488065.pdf)** based on the **Final Guidance (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020.pdf)** should be used to facilitate these discussions and ensure patients understand the benefits and risks.

In November 2016, the FDA approved Bayer's labeling which is consistent with the recommendations in the final guidance. If you are considering Essure for your patients, use Bayer's Patient-Doctor Discussion Checklist, which is available in the **Patient Information Booklet (http://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf)**

(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
For more information about these labeling changes, read Bayer's 'Dear Healthcare Provider (http://www.hcp.essure-us.com/assets/pdf/EssureLabelUpdate.pdf)' (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) letter.

In April 2018, the FDA restricted sales (/NewsEvents/Newsroom/PressAnnouncements/ucm604098.htm) of the Essure device to only doctors and healthcare facilities who use the FDA-approved "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement". Sale and distribution of Essure is limited to healthcare providers who agree to review this checklist with patients, and give them the opportunity to sign it, before Essure implantation. The FDA has approved this new safety measure to ensure that the device meets our standards for a reasonable assurance of safety and effectiveness.

Additional Information:

- Bayer Healthcare's Dear Healthcare Provider Letter. Update - Bayer Receives FDA Approval on Essure Labeling. November 15, 2016. (http://www.hcp.essure-us.com/assets/pdf/EssureLabelUpdate.pdf) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

More in Essure Permanent Birth Control (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm)

Essure Benefits and Risks (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452250.htm)

Essure Permanent Birth Control: Information for Patients (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452251.htm)

Essure Permanent Birth Control: Information for Health Care Providers (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452252.htm)

FDA Activities: Essure (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm)

Essure Permanent Birth Control: Reporting Problems to the FDA (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452269.htm)

Regulatory History (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm)

Essure Labeling Information for Patients and Health Care Providers (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452280.htm)