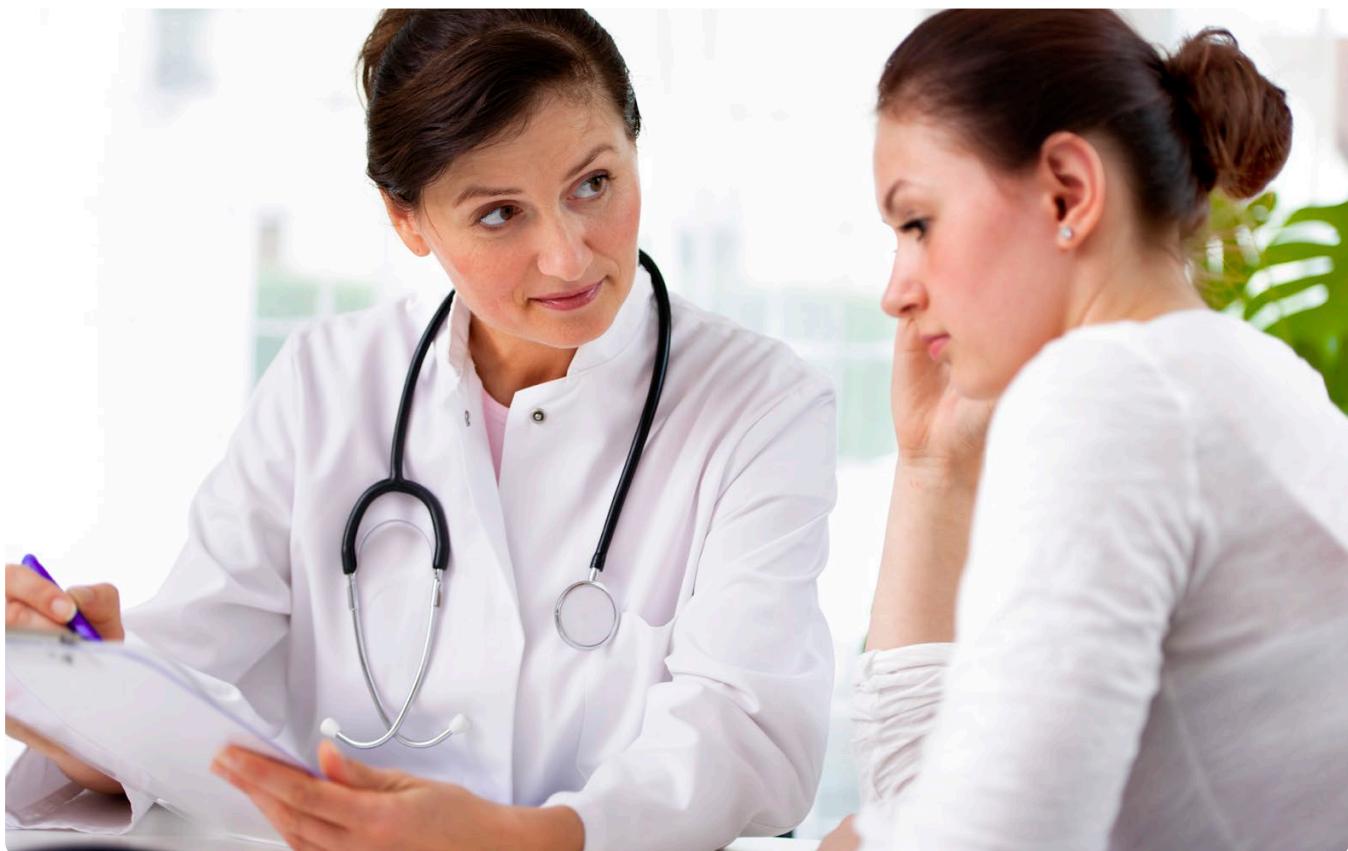


What Women Should Know About Essure Permanent Birth Control



The U.S. Food and Drug Administration continues to advise women to carefully consider the benefits and risks associated with permanent birth control devices, like the FDA-approved Essure device, along with other birth control options.

That's why FDA recently approved important labeling changes for Essure. Among other changes, Bayer, the company that makes Essure, will include a boxed warning and patient decision checklist in the labeling to help ensure that women receive and understand the benefits and risks of these permanent birth control devices

(<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020.pdf>).

What does this mean? Bayer's new checklist in the patient information brochure summarizes key benefit and risk information about Essure. The checklist aims to encourage women to read the information brochure, understand Essure's benefits and risks, and discuss the information with their doctor before making an informed decision on whether to use this device. Here are some things to consider when choosing birth control.

Whatever your choice in contraception, make sure you understand the risks and benefits of your options and discuss them with your health care provider.

What Is Essure, and How Does It Work?

Essure is a permanently implanted birth control device and is not intended to be removed. Its flexible coils are made of metals, including nickel and titanium. If you are sensitive or allergic to nickel or other metals, discuss this allergy with your health care provider.

To implant Essure, a health care provider inserts the flexible coils into the fallopian tubes (the tubes that carry the eggs from the ovaries to the uterus). In about three months, tissue forms around the inserts, blocking sperm from reaching the eggs and preventing pregnancy.

One of the most important things to know about Essure is that it's not immediately effective in preventing pregnancy. You'll need to use another form of birth control for at least three months after the device is implanted.

After three months, women must undergo an X-ray test so their doctor can verify if the device is placed correctly and blocking the fallopian tubes. The test results will help your doctor decide whether you can rely on Essure alone and can stop using alternative birth control.

What Are the Benefits and Risks of Essure?

Implanting Essure is typically done in a doctor's office. This procedure doesn't require an incision and can be done without general anesthesia.

Some women who use Essure have reported serious complications, including:

- poking through the fallopian tubes or uterus
- persistent pain after the procedure (including pain for weeks or months after the procedure)
- change in menstrual cycles (bleeding patterns)
- symptoms similar to those of allergic reactions
- symptoms similar to those in autoimmune diseases, such as joint pain and fatigue.

In addition, some women who reported complications have had surgery to remove the device.

What Are My Other Options?

No form of contraception or sterilization is 100% effective. For permanent birth control, another option for women is tubal ligation (traditional surgical sterilization).

FDA has also approved effective long-acting reversible contraception. This includes the intrauterine device (IUD) and the birth control implant. Both are highly effective in preventing pregnancy, last for several years, and are easy to use. These forms of birth control are also reversible. If you want to become pregnant or if you want to stop using them, you can have the device removed.

In addition, traditional birth control options are available. They include oral contraceptives, hormonal patches, vaginal rings, condoms, and diaphragms.

Whatever your choice in contraception, make sure you understand the risks and benefits of your options and discuss them with your health care provider. 

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