

Department of Health and Human Services

[FDA Update on the status of FDA's evaluation of the Essure System](#)

Essure is a permanent birth control method for women (female sterilization). Implantation of Essure 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 about 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. Essure is considered a permanent form of birth control and therefore is not intended to be removed.

Over the past several years, the FDA has been examining the growing number of adverse event reports associated with the use of Essure. Reported adverse events include persistent pain, perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, abnormal or irregular bleeding, and allergy or hypersensitivity reactions. Some women have had surgical procedures to remove the device. In addition, Essure failure, and, in some cases, incomplete patient follow-up, have resulted in unintended pregnancies.

The FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee on September 24, 2015, to hear expert scientific and clinical opinions as well as patients' experiences regarding the benefits and risks of Essure. In addition, a public docket soliciting comments on the device remained open from July 22, 2015 until October 24, 2015. FDA received more than 2,800 comments in this docket and reviewed each comment and considered all views and perspectives expressed.

The panel meeting and docket provided valuable information to inform the FDA's decision-making and consideration of potential risk mitigation strategies for Essure. Additional information about the Agency's next steps can be found on our [status update page](#) and in the [FDA Activities](#) section of this website.