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Review Article

# Essure® Permanent Sterilization. A not Evidence-Based Argument Controversy

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## Abstract

Permanent sterilization is a very common form of family planning. Hysteroscopic sterilization has been an ongoing target for litigation, complaints and adverse publicity. To establish a positive correlation between Essure® insertion and any given side effect, it must be demonstrated that the incidence of the specific symptom is higher in patients who underwent Essure® insertion than in the general population. There are many confounders that must be taken into consideration before concluding that a given symptom is related to an intervention. A review of different clinical conditions regarding Essure® is presented.

**Conclusion:** Evidence based support linking the use of Essure® to adverse events is lacking when placed in appropriate selected candidates. Adequate patient selection and thorough inform consent is strongly encouraged before inserting Essure®.

Permanent sterilization is a very common form of family planning. It is the second most common contraceptive method used by women in the United States [1]. For many years, laparoscopic tubal ligation was the standard of care for permanent sterilization. In 2002, a hysteroscopic permanent sterilization option was made available: The Essure® System. It consists of a set of 2 coil designated to induce fallopian tube fibrosis and subsequent tubal occlusion. Three months after placement, the tubal occlusion must be confirmed with a hysterosalpingogram which will then ensuretubal blockage and the consequent permanent sterilization [2]. The coils could be inserted in an office setting with only minor sedation, providing a safe alternative for otherwise high risk surgical candidates. According to the FDA, Essure® sterilization is 99.8% effective at permanently preventing pregnancy over 5 years.

Over the last few years, the Essure® procedure for hysteroscopic sterilization has been an ongoing target for litigation, complaints and adverse publicity. Recently a group of women who claim had adverse effects after placement of Essure® devices, demanded the withdrawal of the device off the market. The United States Food and Drug Administration (FDA) have received many reports of adverse effects, which include: chronic pelvic pain (26%), fatigue (27%), hair loss (20%), heavy menstrual periods (14%), depression (14%) and method failure resulting in undesired pregnancy. Similarly, there are social networking groups who support these claims, including one lead by a famous activist Erin Brockovich.

As of June 2015, a total of 5093 adverse event reports related to Essure® had been reported to MAUDE. In September 2015, the FDA hosted a meeting of the Obstetrics and Gynecology Advisory Board Committee to address the increase of reported adverse events related to the use of Essure®. The FDA concluded that there was insufficient objective evidence to support to remove Essure® off the market, however, required a black box warning for the device and ordered further postmarked research to compare Essure® safety and efficacy to laparoscopic tubal sterilization [3].

To establish a positive correlation between Essure® insertion and any given side effect, it must be demonstrated that the incidence of the specific symptom is higher in patients who underwent Essure® insertion than in the general population. There are many confounders that must be taken into consideration before concluding that a given symptom is related to an intervention.

## Heavy menstrual bleeding

A frequently reported complication is the presence of heavy menstrual bleeding after having Essure® inserted. It is important to consider that many patients were using hormonal contraceptives or had a levonorgestrel IUD as their form of contraception before having Essure® inserted, so their menstrual cycles were medically controlled. After Essure® insertion many patients stop using the hormonal treatment which may result in heavy menstrual bleeding. There is no scientific evidence to support higher incidence of heavy menstrual bleeding after placement of Essure®.

## Chronic Pelvic Pain

Another frequently reported complaint is Chronic Pelvic Pain (CPP). The prevalence of CPP in the general population is 3.5 % [4]. When considering that more than 800,000 Essure® had been placed it is expected that approximately 28,000 women who carry the Essure® would have CPP. However, in some cases it has been noted, the pain resolves with removal of Essure®, which is particularly true when CPP appears after insertion of the device [5]. Moreover, history of Pelvic Inflammatory Disease (PID), have been linked to an increased incidence of chronic pelvic pain, which makes patient with history of PID not ideal candidates for Essure®. It is important to acknowledge that the present of a foreign body can cause pain, so when a patient reports pelvic pain after insertion of Essure®, the gynecologist should investigate the cause of pelvic pain. In the absence of a reason for the pain the Essure® implants must be removed. Essure® removal can be done by laparoscopy or using a hysteroscopy approach [6]. It is recommended to offer laparoscopic bilateral salpingectomy to ensure effective permanent sterilization after removal of the devices.

## Nickel Allergy

Nickel allergy, has been reported in approximately 15% of normal female population [7]. Most women who are allergic to nickel and do not know it. Therefore, if the nickel contained in the Essure® device produces an allergic reaction in all patients with nickel hypersensitivity who had Essure®, this type of allergic reaction would have affected over 100,000 women but only a very small number of women have reported nickel allergy symptoms after Essure® insertion.

## Safety during insertion

Safety during insertion was also questioned by the FDA. Franchini M et al [5] reported 4 uterine perforations in 1968 women who have Essure® inserted. (0.2%) A very difficult and painful insertion suggests the possibility of perforation. All gynecologists should master the insertion technique before attempting insertion without supervision to decrease chance of perforation. The presence of excruciating pain during or immediately after the insertion should alert the provider and consider uterine perforation as the cause of the pain. Chudnoff S et al [8] reported a 5 years follow-up study, revealed no new safety issue or higher incidence of complication from the ones already known and described in the insertion package instructions for use of Essure®.

## Conclusion

Evidence based support linking the use of Essure® to adverse events is lacking when placed in appropriate selected candidates. Adequate patient selection and thorough inform consent describing in detail and comprehensively possible complications in the short and long term as well as the actions to take for resolution is strongly encouraged before inserting Essure®.

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