

# Patient Outcomes Following Injury from Hysteroscopic Sterilization

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## ABSTRACT

**Objective:** We present clinical data on two patients who underwent hysteroscopic sterilization (HS) 11 years apart using the Essure<sup>®</sup> (Bayer Inc., Whippany, NJ) device.

**Materials and Methods:** Symptoms and resolution are described for symptomatic Essure<sup>®</sup> patients.

**Results:** Case 1 (G3P1) underwent HS in 2004 at age 21. Performed in a physician's office without anesthesia, HS involved placement of >2 Essure<sup>®</sup> devices which was followed by severe, unrelenting pelvic pain. Confirmatory hysterosalpingogram (HSG) three months after HS revealed five devices. Surgical costs for laparoscopic assisted vaginal hysterectomy (LAVH) were fully reimbursed by the device manufacturer seven months later. Case 2 (G8P4) underwent HS in 2015 at age 32. One year earlier, the patient's right fallopian tube was removed due to ectopic pregnancy. Essure<sup>®</sup> devices were placed bilaterally in a physician's office without anesthesia; HS was accompanied by sharp pelvic pain. The patient obtained HSG three weeks after HS due to constant discomfort. Bilateral tubal occlusion was verified, but abnormal device loop configuration suggesting myometrial penetration was noted on the right. At laparoscopy, the left Essure<sup>®</sup> device was

excised intact but the right coil could not be located. Thus far, there has been no offer in Case 2 from the device manufacturer to offset medical expenses.

**Conclusions:** While HS has been FDA approved for use in the United States since 2002, this is the first description of clinical sequela when FDA labeling for the Essure<sup>®</sup> procedure is ignored. These cases illustrate the importance of proper physician training in HS and underscore the need for improved tracking of Essure<sup>®</sup> associated symptoms.

## INTRODUCTION

More than 300,000 women request permanent surgical sterilization in the United States each year,<sup>1</sup> and until recently, laparoscopic bilateral tubal ligation was the only method available to meet this need. However, in 2002 a technique for bilateral tubal occlusion via hysteroscopic placement of metal inserts at the utero-tubal junction presented another option. Hysteroscopic sterilization was welcomed as an important alternative as it eliminated the need for abdominal access,<sup>2,3</sup> reduced overall cost,<sup>4</sup> and minimized anesthesia requirements.<sup>5</sup> At present, the only HS method available is Essure<sup>®</sup>.

Although FDA guidelines for Essure<sup>®</sup> have existed since 2002, this is the first report to present patient outcomes when this product labeling is not followed. The current research contributes to a larger understanding of Essure<sup>®</sup> by validating the central importance of physician training in the proper use of this device, describing clinical

scenarios associated with abnormal device use, and by illustrating what can go wrong when this contraceptive implant is used outside established FDA-approved guidelines. In addition, we provide background on the FDA's premarket approval (PMA) process for Class III medical devices and place the Essure<sup>®</sup> device within this regulatory framework.

## CLINICAL PRESENTATIONS

### Case one

This 21-year-old married G3P1021 female underwent HS in January 2004. At the time of the Essure<sup>®</sup> procedure, she was a smoker with BMI = 30 and had no known allergies. The patient was in good general health, took no regular medications, and had no previous surgery. At the time of HS, the patient was considering laparoscopic tubal ligation but was persuaded to have the Essure<sup>®</sup> procedure instead. This was

performed in a physician's office with no anesthesia. Due to difficult visualization of tubal ostia, the patient was informed that additional Essure<sup>®</sup> devices were needed to complete the procedure. This resulted in immediate discomfort by the patient, although the gynecologist contacted an Essure<sup>®</sup> representative during the procedure and this reassurance was conveyed to the patient.

Within 24 hours, the patient's discomfort escalated and she contacted the treating physician to report severe, sharp bilateral pelvic pain. There was no vaginal bleeding or fever. Mild analgesics were recommended although the pelvic pain was not alleviated. Within one week following HS, the patient described considerable disability and became unable to rotate her upper body. Hysterosalpingogram was performed three months after HS and the patient received a verbal confirmation that bilateral tubal blockage had been achieved, as well as the presence of an "extra" coil. This was consistent with



Figure 1. Hysterosalpingogram obtained three months after hysteroscopic sterilization by the Essure<sup>®</sup> procedure, showing placement of five contraceptive devices.

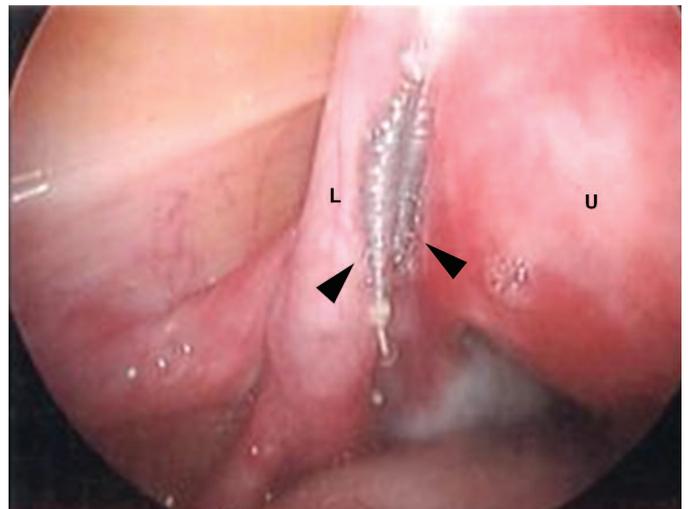


Figure 2. Laparoscopic view of left fallopian tube (L) and two Essure<sup>®</sup> implants (arrows) which have perforated the uterus (U).

how the Essure<sup>®</sup> procedure had been described to her; however, neither the formal radiology report detailing this study nor the HSG films were provided to the patient.

For the following several months, the patient's condition deteriorated. Posture continued to be affected such that she was "unable to stand up straight" for nearly a year following the Essure<sup>®</sup> procedure. Dysmenorrhea and dyspareunia worsened and a second opinion was sought. At this stage the earlier HSG films were obtained and reviewed. It was at this point that the patient learned that five contraceptive coils were present in the reproductive tract (Fig. 1). She underwent laparoscopic assisted vaginal hysterectomy in February 2005. At hysteroscopy, it was noted that contraceptive coils were present at both ostia. Laparoscopy revealed grossly normal ovaries, but the left adnexa included two Essure<sup>®</sup> implants which had apparently perforated the uterus and were situated adjacent to the fallopian tube (Fig. 2). The devices on the right could not be seen laparoscopically and were presumed to be within myometrial tissue (intramural). This was confirmed by pathology when the uterine specimen was evaluated post-operatively.

Approximately seven months after her LAVH, the patient received correspondence from the device manufacturer which included a check for \$14,104.01 (Fig. 3). This payment was intended to offset costs encumbered by the patient for consultations, surgical charges, and other expenses associated with Essure<sup>®</sup> removal.

### Case two

This 32-year-old unmarried G8P4044 nonsmoker underwent HS in September 2015. She had no known allergies. Her BMI was 32, she was in good general health, and took no regular medications. Before presenting for the Essure<sup>®</sup> procedure, the patient had two ectopic pregnancies (one each in 2009 and 2014), the most recent of which resulted in surgical removal of the right fallopian tube. HS was completed in a physician's office and pre-treatment included oral analgesics (no anesthesia). The procedure was immediately accompanied by severe right-sided pelvic pain and back pain; this discomfort resulted in near syncope over the next two weeks despite

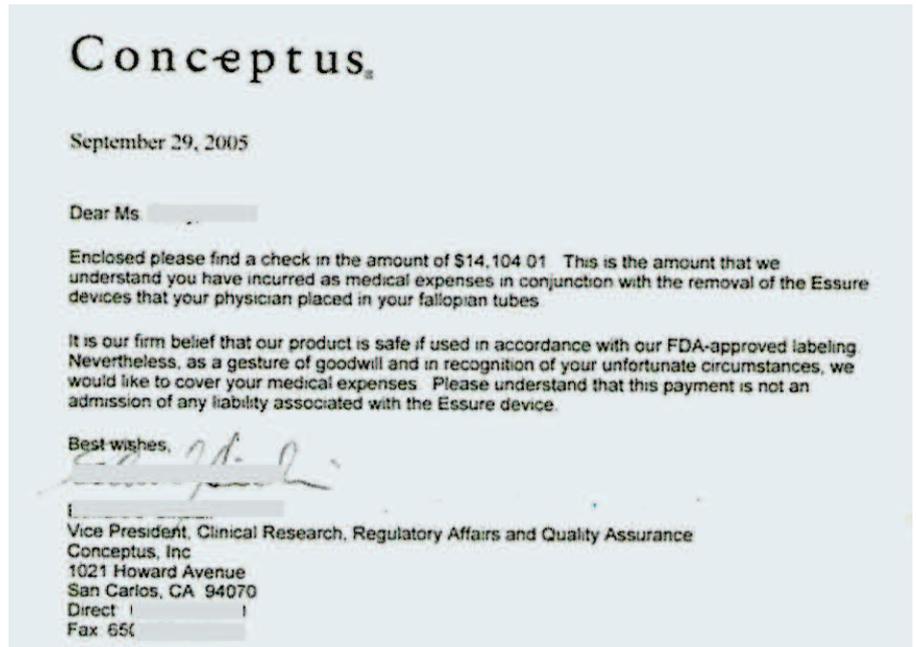


Figure 3. Correspondence received from medical device manufacturer describing payment details after hysterectomy.

increased oral pain medications. The patient was advised to reduce physical activity and consider "seeing a counselor for stress."

Although the patient intended to keep her standard HSG appointment scheduled for three months after Essure<sup>®</sup>, waiting this long became problematic as her sharp pelvic pain

had already reached debilitating levels soon after. Accordingly, she arranged for HSG three weeks after Essure<sup>®</sup> with a view to provide her physician with additional diagnostic information. This study did confirm bilateral tubal occlusion, but abnormal Essure<sup>®</sup> placement (loop configuration) was evident at the right adnexa (Fig. 4).

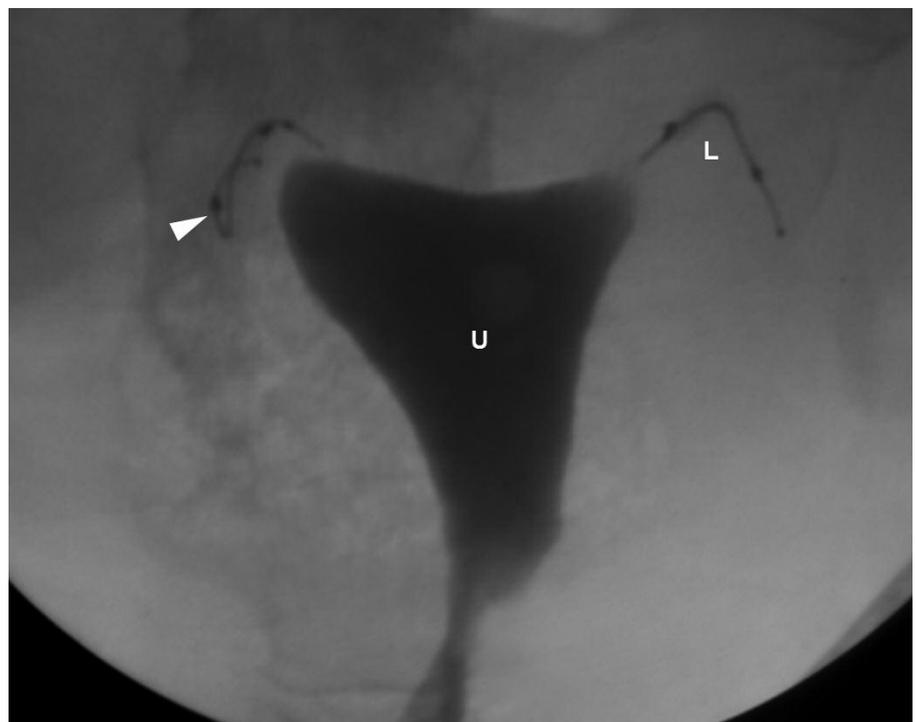


Figure 4. Hysterosalpingogram obtained within one month of hysteroscopic sterilization performed on a patient with right salpingectomy (due to ectopic pregnancy), showing normal uterine cavity (U), occluded left tube (L), and loop configuration of contraceptive implant on right side (arrow).

In October 2015, the patient sought a second opinion and underwent laparoscopy in an attempt to address her pelvic pain symptoms (it was her preference not to undergo hysterectomy, which had been recommended initially). At laparoscopy, substantial pelvic fibrosis was noted including adhesive disease involving bowel and adnexal structures. Both ovaries were grossly normal and the proximal right tube was absent. The left Essure<sup>®</sup> device was removed as described previously,<sup>6</sup> but the right coil could not be located and was thought to be imbedded within the myometrium. The patient's post-operative course has been unremarkable, although she is now considering further surgery options for definitive excision of the remaining Essure<sup>®</sup> implant on the right. There has been no communication from the device manufacturer regarding her medical expenses and the patient remains hopeful for assistance.

## DISCUSSION

The regulatory process for medical devices like Essure<sup>®</sup> in the United States is more streamlined and less stringent than for pharmaceuticals. It has been estimated that the "concept to market" interval for medical devices is three to seven years.<sup>7</sup> The Medical Device Amendments (1976) established the FDA policies regarding medical device approval which are currently in effect. From this, Essure<sup>®</sup> and many other devices have been classified as Class III, which is defined as a device that "supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury."<sup>7</sup> Because Class III applications entail premarket approval requirements, the medical device pathway offers a fast-track method to obtain FDA approval and enter the US market.

It is important to understand these issues when patients ask "How did this product get approved?" PMA is the FDA's most stringent type of device marketing application procedure, and is required for novel inventions like Essure<sup>®</sup> for which there is no existing equivalent. For Essure<sup>®</sup>, PMA approval was granted only after the FDA determined that it had sufficient scientific

evidence demonstrating safety and effectiveness for its intended use (permanent sterilization). It is possible to receive PMA approval without an active comparator or control group (this was the case with Essure<sup>®</sup>). Evidence-based medicine specialists have noted that this raises significant potential limitations to the quality of safety data regarding some PMA-approved devices. Additionally, there is no absolute requirement for post-marketing surveillance studies to validate the premarketing experience.<sup>7,8</sup>

All FDA-approved devices have mandatory manufacturer and facility reporting requirements. Most notably, manufacturers and the facility must report all device-related deaths, serious injury, and adverse events secondary to device failure or adverse events to which the device may have contributed. Device manufacturers are required to report device-related deaths, serious injuries, or malfunctions to the FDA within specified time intervals. Unfortunately, this monitoring is largely dependent upon physicians reporting any events back to the company and is probably sporadic at best.<sup>7</sup>

Agency factors notwithstanding, the role of operator experience in determining device safety and effectiveness is often overlooked in the FDA clearance debate. Most new medical technologies like Essure<sup>®</sup> have a "learning curve" wherein clinicians receive initial training once the device is released for use, and then subsequently improve as experience is gained. Thus, new practitioners using new devices would be more likely to cause patient harm compared to more experienced providers with increased proficiency obtained from greater device familiarity and use. This "learning curve" effect could play a significant role with the Essure<sup>®</sup> device, although it is unclear if this is due to the need for advanced skills. Indeed, the two cases presented here highlight a lack of basic awareness concerning indications and contraindications for the device.

Specifically, the placement of five contraceptive devices as described in Case 1 is a clear violation of Essure<sup>®</sup> manufacturer guidelines. For Case 2, her previous diagnosis of salpingectomy and ectopic pregnancy are contraindications to placement of Essure<sup>®</sup> coils. Thus, albeit for different reasons, both patients described here experienced an

adverse outcome secondary to medical device usage that was not in compliance with FDA labeling.

As these two clinical cases are considered, several issues emerge. First, while both patients' experience with Essure<sup>®</sup> entailed an application outside FDA-approved guidelines, only the first event (in 2005) resulted in reimbursement for reparative surgery. The possibility exists that additional factors contributed to this resolution. Might there have been other patients who sustained similar Essure<sup>®</sup> injury and who also received reimbursement from the device manufacturer? While the Essure<sup>®</sup> patient from 2015 (Case 2) may still receive relief from the product manufacturer, thus far nothing has been provided. In addition, it should be noted that the device manufacturer changed between 2004 and 2015, as Bayer AG acquired ownership of the device when it purchased Conceptus Inc. (the original maker) in 2013.<sup>9</sup>

Although there are clinical similarities between the two cases presented here, one important distinction is noteworthy. As a condition for the original PMA approval for Essure<sup>®</sup> in 2002, the device manufacturer was required by the FDA to gather information over five years on all participants in the two premarket clinical trial patient cohorts and to evaluate Essure<sup>®</sup> placement rate for newly trained physicians.<sup>10</sup> Thus, Case 1 occurred during an interval during which outcomes were monitored particularly closely by the FDA, while Case 2 did not.

For Case 1, the device manufacturer's response in the form of payment to offset the costs she encountered during hysterectomy (performed to remove contraceptive coils) appears consistent with that expected of a good corporate citizen. The manufacturer's letter expresses goodwill and acknowledges no admission of liability, highlighting the safety of the device when "used in accordance with...FDA-approved labeling." Importantly, the manufacturer did not make the reimbursement conditional on a non-disclosure agreement. The patient described in Case 1 was assured by the manufacturer that they would process the reporting of her outcome and surgery directly to the FDA on her behalf. We were unable to locate a formal record of this filing with the FDA, however.

The two physicians who performed

the Essure<sup>®</sup> procedure for Case 1 and Case 2—surgical encounters separated by more than a decade—both failed to follow FDA-approved indications for the medical devices implanted in their respective clinics. Specifically, ectopic pregnancy and tubal surgery appear in the Essure<sup>®</sup> product instructions as contraindications for the procedure (Case 2), and placing five implants in one patient (Case 1) is also not in agreement with manufacturer guidelines. It is therefore not surprising that both women required subsequent surgical interventions to correct problems associated with this device.

### CONCLUSION

The limited number of published studies on Essure<sup>®</sup> makes patient counseling difficult and highlights the need to increase awareness of the successes and failures of HS. At present, tabulating the frequency of pelvic surgeries performed secondary to the Essure<sup>®</sup> procedure is impossible. Consideration should therefore be given to the assignment of unique ICD-10 modifiers for pain associated with this device. In the United States, all official

disease classification activities relating to ICD-10 is under the remit of the National Center for Health Statistics (NCHS). Including a code for Essure<sup>®</sup>-related symptoms would offer an accurate, inexpensive data capture tool to enable proper monitoring of this phenomenon. As this contraceptive option becomes more widely used, future studies regarding Essure<sup>®</sup> will be more informative with systematic data collection. **STI**

### AUTHORS' DISCLOSURES

The authors have no conflicts of interest to disclose.

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