

Surgical Management After Hysteroscopic Sterilization: Minimally Invasive Approach Incorporating Intraoperative Fluoroscopy for Symptomatic Patients with >2 Essure[®] Devices

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ABSTRACT

Objective: To describe a non-hysterectomy surgical technique for symptomatic patients with >2 Essure[®] (Bayer Healthcare, Whippany, New Jersey) devices.

Design: Patients (n=4) presented with sharp pelvic pain, irregular vaginal bleeding, dyspareunia, weight gain, hair loss, fatigue, and/or diffuse skin rash, all of which were absent before undergoing hysteroscopic sterilization (HS). Hysterosalpingogram obtained before surgical excision of contraceptive tubal implants confirmed more than two Essure[®] devices in all patients. Except for HS-associated complaints, all patients were in otherwise good general health and none had any history of prior pelvic pathology. Hysteroscopy was followed by 5mm triple-port laparoscopic cornual dissection, modified partial bilateral salpingectomy, and foreign body removal under fluoroscopy and/or radiographic guidance.

Results: In this group, mean±SD patient age was 41±8yrs and interval between HS and device removal was 6.4±2.7yrs. At the conclusion of each case (mean±SD operative time=179±11min), imaging studies were reviewed by an attending radiologist and verified no retained metal in the abdomen. Conversion to laparotomy, hysterectomy, or blood transfusion was unnecessary for any patients, and all were discharged home within three hours. Their postoperative course continues to be satisfactory.

Conclusion: Patients with more than two Essure® devices comprise an unusual group with a complex pelvic foreign body presentation. This is the first report on surgical management for such patients, underscoring the importance of localizing these contraceptive devices with careful imaging before, during, and after surgery. Moreover, hysterectomy is not absolutely mandatory in this setting and intraoperative fluoroscopy/radiography can facilitate complete, safe removal of all implants on an out-patient basis. Creation of ICD-10 modifiers for various post-HS complaints would allow for improved surveillance of the Essure® phenomenon.

INTRODUCTION

More than 300,000 women seek permanent surgical sterilization in the United States each year.¹ While laparoscopic bilateral tubal ligation is the most common technique to provide permanent female contraception, in November 2002, a revolutionary new birth control option became available—tubal occlusion by hysteroscopy. The interest in hysteroscopic sterilization (HS) was a response to the acute need for reproductive options in addition to tubal ligation for permanent female birth control. The Essure® (Bayer Healthcare, Whippany, New Jersey) system received US FDA approval in 2002 and remains the only available HS method in the world (but is currently restricted to use in the United States). The procedure involves placing a pair of small, flexible inserts consisting of nickel-titanium and polyethylene terephthalate (PET) fibers through the fallopian tubal ostia via a transcervical approach. These implants soon elicit a tubal inflammatory response resulting in tubal fibrosis and eventual occlusion.²

While HS experience initially appeared favorable, concerns with the Essure® device began to accumulate after an unplanned pregnancy was reported for a celebrity spokesperson

who endorsed (and had personally undergone) the Essure® procedure.³ Three years later, complaints reached a crescendo and the FDA subsequently convened a meeting of its obstetrics and gynecology advisory board to investigate the uptick in reported adverse events linked to Essure®. While the expert panel found insufficient evidence to remove the device from the US market, they did issue new guidance requiring a “black box” warning for Essure® and recognized the need for additional post-marketing research.⁴

In the meantime, one area requiring urgent attention is how best to address the surgical needs of those who request removal of Essure® implants. Surgical removal of Essure® has been shown to resolve symptoms for many patients,^{5,6} but there remains no agreement on how best to achieve this. It should be noted that even for standard Essure® placements (i.e., those with two devices), hysterectomy is the most common method to resolve associated symptoms.⁷ In contrast, no recommendation or consensus has been proposed for patients with an atypical number of Essure® devices. The current research thus contributes to the HS literature by advancing a non-hysterectomy option for women with a complex, irregular presentation where more than two Essure® devices are present.

CLINICAL PRESENTATION AND SURGICAL MANAGEMENT

Case 1

A 43-year-old Caucasian patient (G5P3023) underwent HS in December 2009 without sedation in a physician's office. Her sterilization required less than 30 minutes to complete. Soon afterward, another implant was placed on this same side and a single insertion was carried out for the opposite (left) ostia. When queried later about the extra device on the right, the doctor replied, “It will probably just pass outside the vagina or attach to the wall.” No further explanation was given and the recommended HSG three months later was not done. Thus, follow-up regarding tubal status after HS was unclear, even though the patient continued to have multiple clinic encounters at that office. Although previously in excellent health, after Essure®, the patient reported generalized weakness, fatigue, right lower quadrant and hip discomfort, intermittent sharp pelvic pain, dyspareunia, and abdominal distention. She also registered a post-HS weight gain of approximately 35lbs. Preoperative HSG (obtained seven years after Essure®) established the presence of three devices within the pelvis, one of which demonstrated separation or fragmentation of the medial terminal marker (Fig. 1).

Case 2

A 34-year-old patient (G2P2002) sought permanent sterilization in August 2010 and underwent HS the same month. All Essure[®] implants were placed without anesthesia by the same physician during one 45-minute clinic encounter. The patient left the doctor's office with the understanding that HS was completed without incident and that only two devices had been placed. Although a transvaginal ultrasound was performed three months after device placement, no confirmatory hysterosalpingogram (HSG) was ordered to validate tubal occlusion. Within one month of HS, the patient reported gradually increasing pelvic cramping, irregular vaginal spotting/bleeding, fatigue, impaired cognition, and diffuse skin changes. She had been in excellent health prior to the Essure[®] procedure. Six years later, as part of a preoperative assessment, HSG discovered three Essure[®] devices in the pelvis (Fig. 2).

Case 3

A 52-year-old patient (G1P1001) initially sought laparoscopic tubal ligation, but underwent HS instead in 2009. There is some confusion regarding informed consent as the patient had general anesthesia for HS, and three devices were placed. Of note, this was not immediately disclosed to the patient and the recommended HSG was not performed three months later. Within several weeks of HS, the patient began to experience headaches, fatigue, severe back pain, hair loss, and a 25lb weight gain. The patient switched medical providers and subsequent assessments by other physicians and chiropractors resulted in a series of pelvic radiographs being ordered (Fig. 3). The patient was then alerted to the presence of three devices *in situ*, a realization that triggered a redoubled interest in seeking non-hysterectomy removal of all foreign bodies.

Case 4

A 36-year-old patient (G3P3003) underwent HS in January 2013 under general anesthesia and two devices were placed. Approximately two months after the Essure[®] procedure, the patient began to experience fatigue, severe back pain, and progressively worsening pelvic cramping. She did obtain an HSG three months after HS and this radiograph found that the left tube was not

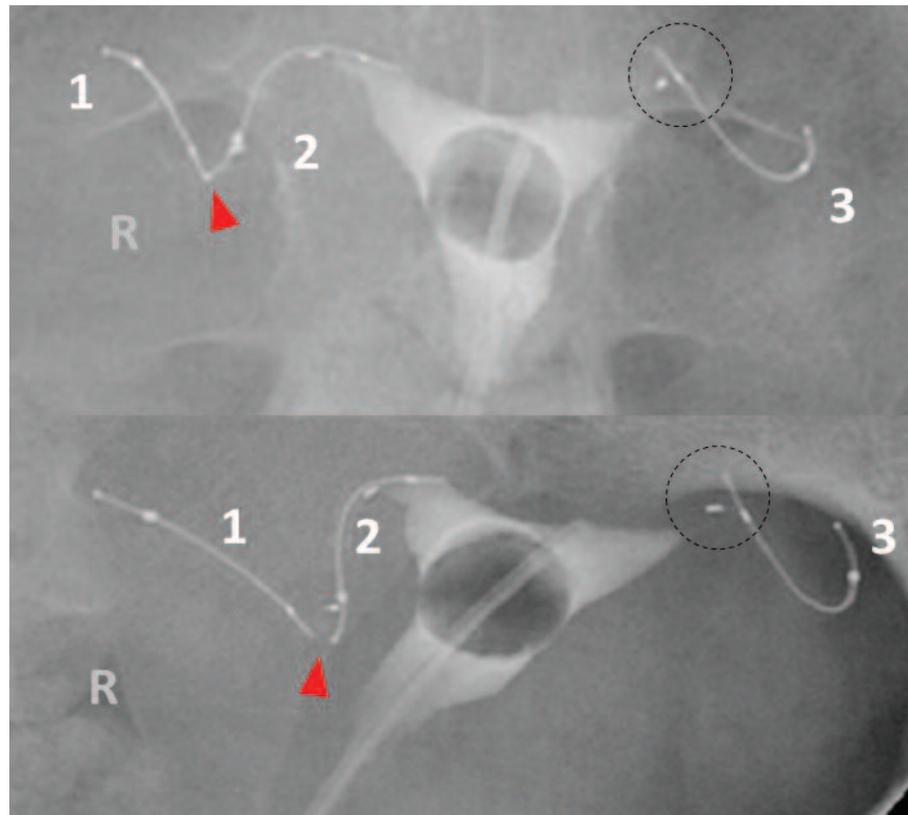


Figure 1. Preoperative hysterosalpingogram for Case 1, showing the status of implants after more than seven years *in situ*. Note appearance of device interlock on the right (arrow) where two Essure[®] devices have been placed. Additionally, the single device on the left has a medial terminal marker (circle) which appears to have separated.

fully occluded after bilateral Essure[®] placement. Her doctor recommended a second Essure[®] procedure “just to be sure”, so the patient underwent a second HS in June 2013. This additional HS procedure was characterized by incomplete passage of the extra device through the left tube (where a previous attempt to place a device had already

been made). The medial aspect of the aftercoming Essure[®] therefore could not be fully advanced, resulting in part of the device extending into the uterine compartment. The surgeon cut this “dangling wire” with hysteroscopic scissors, apparently attempting to normalize the endometrial cavity. Accordingly, when her second HS operation had

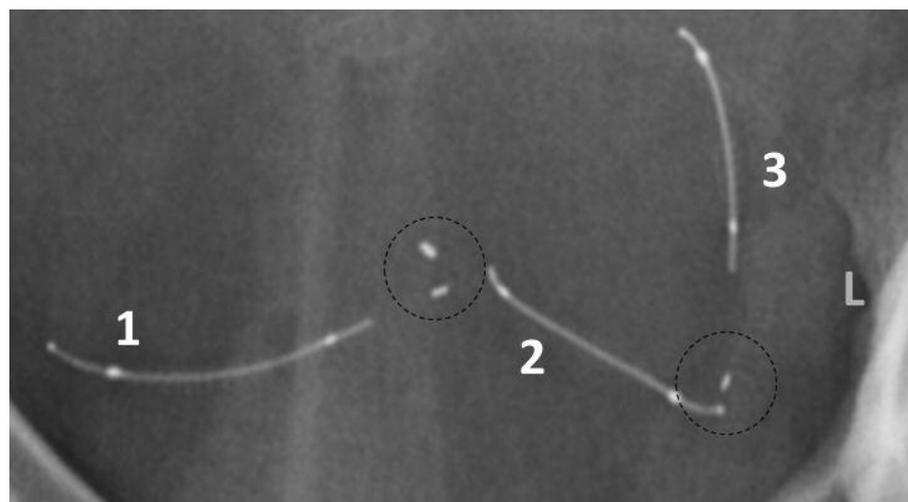


Figure 2. Prefill hysterosalpingogram for Case 2, showing implant status after six years *in situ*. Note two devices on the left as well as fragmentation of terminal markers (circles).

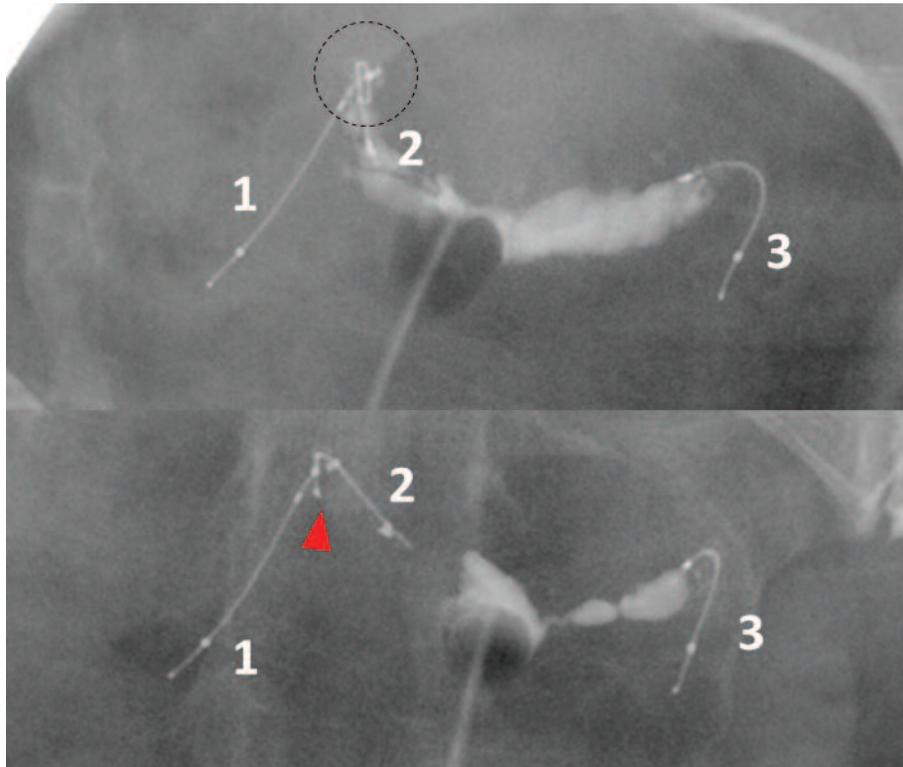


Figure 3. Representative hysterosalpingogram images for Case 3, demonstrating irregular uterine contours and three Essure® devices. The two implants within the right fallopian tube appear interlocked (arrow/circle).

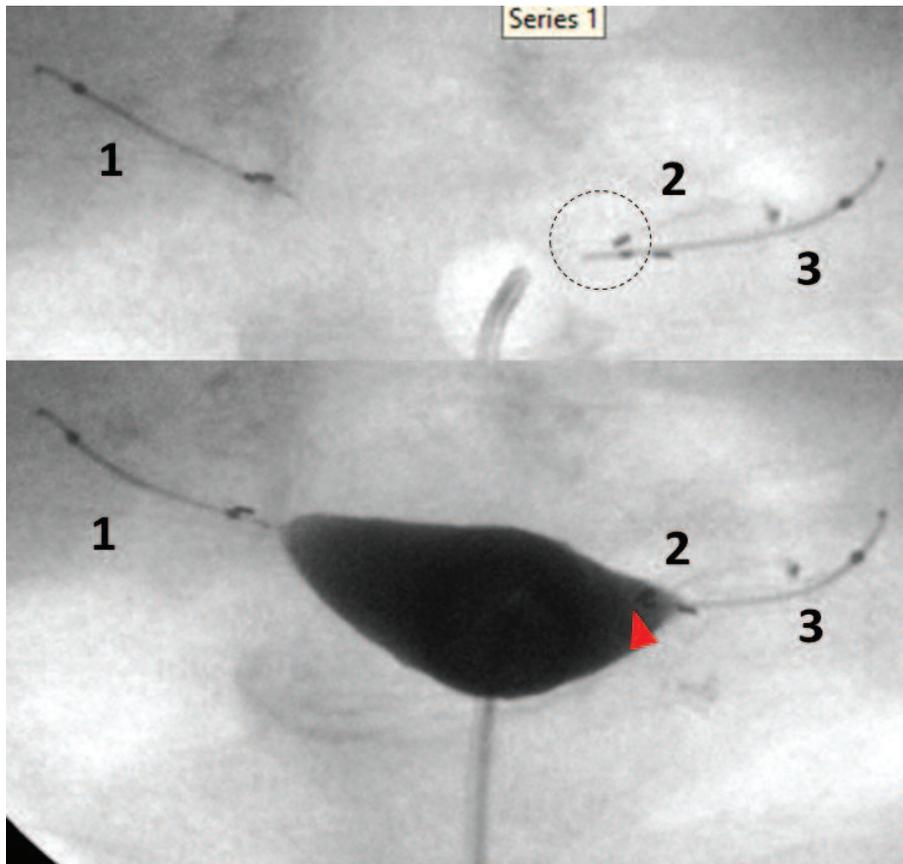


Figure 4. Prefill (upper) and late fill view (lower) hysterosalpingogram images showing a truncated Essure® device (#2) within the left fallopian tube. This implant was intentionally cut (arrow and circle) during a second hysteroscopy performed three months after initial Essure® placement.

concluded, the patient had 2½ Essure® devices (Fig. 4).

Operative approach

Informed consent was obtained from all patients for hysteroscopy and laparoscopy, minimally-invasive removal of Essure® devices, bilateral partial salpingectomy, and excision of abnormal or diseased tissue (if any). Patients were accompanied by a family member during the preoperative appointment, which included a review of the most recent HSG films as the surgical approach was explained. All patients were counseled about the potential need for laparotomy and hysterectomy in case of emergency only. Selected clinical features in this group are summarized in Table I.

Diagnostic hysteroscopy was performed first, followed by 5mm triple port laparoscopy for partial bilateral salpingectomy for removal of all Essure® implants. The intrauterine compartment appeared grossly normal in all cases and both tubal ostia were visualized. At laparoscopy, no gross pelvic pathology was observed, consistent with findings anticipated from the preoperative assessment via transvaginal sonogram.

With attention turned to the adnexa known to have the supernumerary contraceptive device, a tissue folding technique was used to estimate the lateral extent of the outermost Essure® implant. Having determined the devices geometry relative to tubal structure, the fallopian tube was fulgurated with bipolar forceps (40W power) and then divided. Because device interlock was suspected where two Essure® devices resided in the same fallopian tube, no attempt was made to disentangle them; adnexal specimens here were removed *en bloc*. As previously described,⁸ the medial aspect of the inner (proximal) implant for each patient was visualized after layer-by-layer circumferential dissection with Maryland scissors and limited bipolar cautery. Care was taken to avoid traction, especially on the inner Essure® rod during release, to reduce potential dispersion of polyethylene terephthalate (PET) fibers within the abdominopelvic cavity. Generous tissue irrigation and aspiration with ≥1.0 liter (0.9% normal saline) was used to minimize peritoneal contamination by PET.

Intraoperative radiography and/or

Table I
Clinical features associated with hysteroscopic sterilization patients with >2 Essure® devices, confirmed by preoperative radiograph

Case	Pregnancies at time of Essure®	HSG obtained 3mo after HS?	Age at device removal (yrs)	Duration of Essure® removal surgery (min)	Interval between Essure® placement & removal (yrs)
1	5	No	43	173	7.75
2	2	No	34	166	5.8
3	2	No	52	186	9.1
4	3	Yes	36	190	2.75*

Notes: HSG = hysterosalpingogram; HS = hysteroscopic sterilization; Essure®. Mean±SD age at device removal = 41±8yrs; HS interval to surgery = 6.4±2.7yrs; Essure® removal surgery = 179±11min.

*this patient underwent two separate HS procedures, so interval between HS and subsequent device removal surgery was calculated based on a placement date intermediate between HS#1 and HS#2.

fluoroscopy using a mobile nonisocentric C-arm^{9,10} was performed as needed, permitting intact excision of all three devices in each case. This equipment was comparable to a C-arm cone-beam computed tomography (CT) scan (10mGy to isocenter) used in neurosurgery, orthopedic, or vascular surgery settings, with ambient radiation exposure between 29mR (0.26 mSv) at 35cm from isocenter to <0.5 mR (<0.005 mSv) at 2m from isocenter.^{9,10} Each patient was discharged home after Essure® removal surgery within three hours; the postoperative course was uncomplicated and all three patients continue to do well.

DISCUSSION

Because no Essure® patient registry exists, the exact number of women with this contraceptive device is not known. Thus, it was impossible to calculate a rate of how often supernumerary Essure® devices might be encountered in clinical practice. Even as more than half a million women worldwide have undergone the Essure® procedure, the sun seems to be setting for HS on the global contraceptive stage. Indeed, during the past year, international access to this contraceptive method has contracted greatly and now the device is only available in the United States.¹¹ Elsewhere, either the manufacturer has preemptively withdrawn it from the market or government regulators have banned the device altogether.¹² Interestingly, the

cumulative published experience with Essure® remains somewhat limited considering it has been in use for more than a decade. While the number of papers describing complications with, and surgical removal of, Essure® have increased in recent years, the current series is the first to focus specifically on women with more than two Essure® devices.

Study of surgical strategies for symptomatic HS patients is important because other investigators have shown that the reoperation rate following Essure® is significantly higher than the rate of subsequent surgery after standard tubal ligation.¹³ Recent research has found the most common surgery after Essure® to be hysterectomy.⁷ Our group has previously described how an outpatient, minimally invasive (uterus conserving) approach is possible even where device fragmentation or migration is documented.¹⁰ Yet, an even more complex challenge exists when Essure® patients have supernumerary implants (i.e., more than two devices *in situ*). The current work is the first to describe a non-hysterectomy approach for these difficult cases. While intraoperative imaging in this setting is not mandatory, it can provide rapid reassurance for intact removal that is important when more than two implants are present.

CONCLUSION

Performing the Essure® procedure safely may be outside the skillset for some gynecologists, as evidenced by the

cases summarized here. The fact that most HS patients in this cohort did not receive any confirmatory HSG after Essure® (as recommended by the device manufacturer) is also concerning. Perhaps more worrisome is that these women continued to have regular clinical encounters for years, yet this lack of essential follow-up was ignored. Given the manifold symptoms reported following HS, it is easy to see how many women soon regretted their decision to undergo the Essure® procedure—not necessarily for reasons of lost fertility potential, but because quality of life was so adversely affected after insertion of this medical device. **STI**

AUTHORS' DISCLOSURES

The authors have no conflicts of interest to disclose.

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