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Case Report

# Transcervical Migration of an Essure® Coil

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## Abstract

**Introduction:** Essure® device malposition is a rare, but clinically significant complication, for which management is idiosyncratic. This case report describes an unusual example of Essure® migration in order to clarify reasonable management options.

**Case Presentation:** A 50-year old $G_4P_{2022}$ underwent hysteroscopic sterilization using the Essure® device. Insertion was complicated by fragmentation of both coils. Two years later, one of the coils was incidentally discovered protruding through the cervical os. The visible portion was clipped when attempts to remove the entire coil were unsuccessful.

**Conclusion:** Difficult placement increases the risk of Essure® malposition. In asymptomatic patients, conservative management with removal of only a portion of the device is a rational approach.

**Keywords:** Adverse Effects, Contraceptive Devices, Hysteroscopy, Gynecologic Surgical Procedures

## 1. Introduction

The Essure® hysteroscopic sterilization system (Bayer AG) was approved in November 2002 by the U.S. Food and Drug Administration (FDA). It is designed for permanent contraception by physical occlusion of the fallopian tubes. Using a transvaginal approach, a flexible insert is placed in the proximal lumen of each fallopian tube. This insert then expands upon release, conforming to the lumen and anchoring within it. Subsequent benign tissue ingrowth results in permanent tubal occlusion. Follow-up hysterosalpingogram at three months is required for confirmation of proper placement before the patient can rely on Essure® for contraception.[1]

The manufacturer reports that approximately 750 000 patients have received Essure® with a 96% rate of successful placement after the first attempt and a 5-year rate of successful tubal occlusion ranging from 84% to 99.8%.[1] These outcomes have been subsequently duplicated in retrospective studies.[2] Notable, the product has been removed from all markets due to patient complaints and post-marketing reports of complications, however, the large population of women who have received the device renders continued relevance to a discussion regarding the management of its long-term complications, as clinicians are still likely to encounter such patients and may be called upon to manage adverse events stemming from the device.[3]

Failed placement can lead to unintended or ectopic pregnancy, additional procedures, perforation of internal organs, or chronic pelvic pain, in which case removal of the device improves symptoms in the majority of patients.[4] Very few cases of uterine migration (i.e. expulsion) of the Essure® device have been described, even fewer are discussed at length, and management of malposition remains idiosyncratic, especially in asymptomatic patients.[5] We present herein a case of Essure® migration into the endometrial cavity with a brief review of the literature and a discussion of clinical management.

## 2. Case Presentation

The patient is a 50-year old $G_4P_{2022}$ with a BMI of 22.1 kg/m$^2$ who initially presented for removal of an intrauterine device at age 47, more than 10 years after insertion. She had experienced no adverse clinical effects from the device and was considering permanent sterilization. She did report an inability to find the device's strings, and hysteroscopic dilation was required for removal due to a stenotic cervix and inability to tolerate attempts at vaginal extraction. Her intrauterine device was successfully removed with no intraoperative complications 36 days after her initial presentation. She returned for permanent sterilization using the Essure® device one month later.

Device coils were placed bilaterally. The left coil was

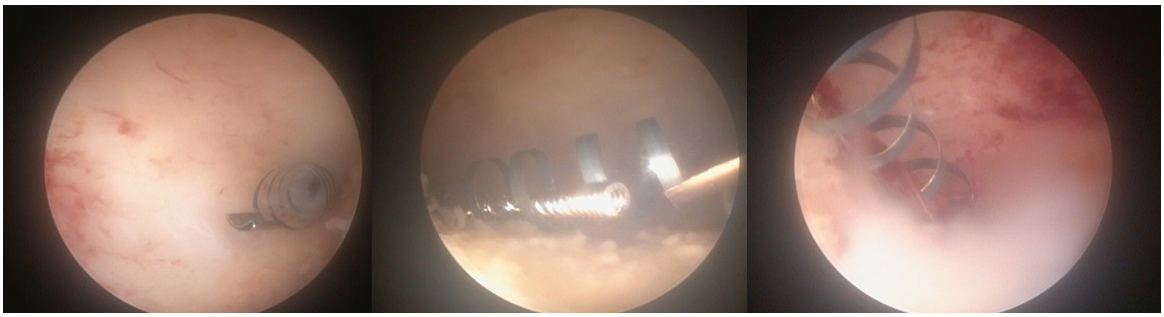

**Figure 1.** Left and Middle: Left ostium and coil placement. Right: Right ostium and coil placement.

placed with no complications, however on placement of the right coil, a small piece fragmented and was immediately removed (Figure 1). As the majority of the coil remained in place, it was determined that this segment would be sufficient to induce tubal occlusion. Abdominal X-ray was ordered to search for fragments with a follow-up appointment scheduled at two weeks and a hysterosalpingogram scheduled at three months post-insertion. The cervical os was clear at this time. The patient reported dyspareunia at her three-month follow-up visit.

Abdominal X-ray 3.5 months post-insertion showed fracture of the right device coil in the midportion of the Fallopian tube with separation of the radiopaque tip from the distal fragment more than 5 cm and a wire density extending from the tip of the coil inferiorly into the pelvis an additional 7 cm. The left coil was also fractured with an approximately 1.2-cm migration of the most proximal segment relative to the distal fragment. Radiology advised a non-contrast computed tomography (CT) scan to more exactly localize the fragments, but this was never attained.

Hysterosalpingogram at five months post-insertion showed the device coils in place bilaterally with both right and left fallopian tubes no longer patent. Annual exam at one year post-insertion showed no significant findings other than minor vaginal atrophy and insertional dyspareunia that was resolved with the use of silicone lubrication.

At 25 months post-insertion, the patient presented for her annual exam with vulvovaginal pruritus, and it was later determined that she had bacterial vaginosis. On vaginal examination, one of the device coils was seen protruding out of the cervical os and into the vaginal canal. When it could not be removed via gentle traction, the visible portion was clipped at the level of the os and removed. A follow-up pelvic ultrasound was then ordered. The patient was not experiencing any symptoms from the remaining portion of the coil at that time. Ultrasound two weeks later showed the right coil to be in a satisfactory position. The left coil was fractured with one fragment lying in the lower uterus and cervix and another fragment located in the uterine fundal serosal area.

Hysteroscopy three weeks later showed the left coil fragment in the uterus (Figure 2). The coil was grasped and gently pulled, but could not be extracted, and it was suspected that it trailed up the intrauterine cavity to left ostial attachments. The patient remained asymptomatic, and after a discussion with her regarding the best available clinical options, it was decided that she should be managed conservatively with observation only and close follow-up.

## 3. Discussion

One of the most significant challenges of hysteroscopic sterilization is achieving proper device placement. A recent meta-analysis found that the weighted average rate of successful bilateral micro-insert placement on first attempt was 92% (0.92 [95% confidence interval: 0.904-0.931]) with newer device models, higher body mass index, and a higher percentage of patients receiving local anesthesia associated with successful bilateral placement.[6] Unsuccessful placement of the device may result in either

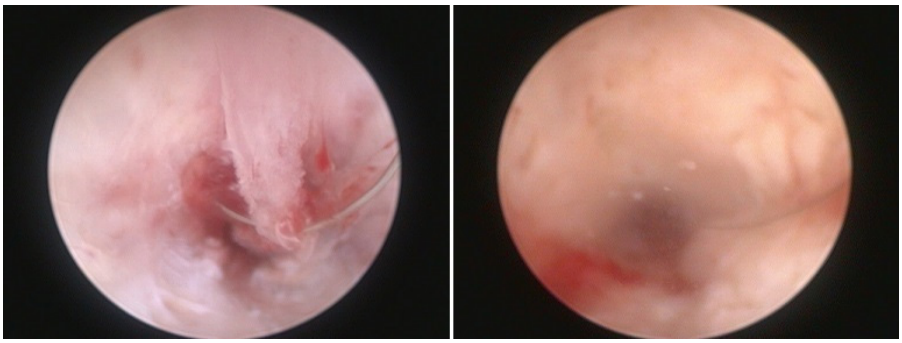

**Figure 2**. Left: Uterine cavity showing curved portion of micro-insert coil extending from the left ostium. Right: Endocervical canal showing left coil exiting uterus and entering cervix.

malposition or fragmentation of the coils, and migration may occur even with successful placement. Any of these outcomes may result in device failure, which may in turn necessitate repeat procedures or lead to unintended pregnancy. Device migration may also lead to organ perforation. Such complications are rare and often underreported, making it difficult to determine the best practices regarding their management.[7] Of the 457 adverse events reported to the Manufacturer and User Facility Device Experience (MAUDE) database (a system mandated by the FDA for post-market surveillance), 90 (19.7%) were due to perforation, while 33 (7.2%) were related to micro-insert malposition.[8] Endometrial expulsion as a subset of improper placement is an especially rare complication. In a retrospective study of 4306 women, 19 device expulsions into the endometrial cavity were reported (0.4%). In two of these cases, expulsion was incomplete, and the portion of the coils trailing into the endometrial cavity were cut rather than attempting to remove them *in toto*.[9]

Unsurprisingly, device malposition is often associated with a difficult insertion. A retrospective study with 237 participants who received hysterosalpingogram following device insertion found that of the 22 abnormal hysterosalpingographic examinations, 20 had operative reports available, of which 11 (55%) described difficulties with device insertion, as in our case.[10] Another smaller case report series with 100 participants similarly found that incorrect position of micro-inserts was only seen when initial placement was difficult.[11] In cases where malposition is detected within 5-6 weeks of initial insertion, attempts are typically made to remove the misplaced device and insert a replacement.[12] This was not possible in our case because of the extended period of time between insertion and discovery of the migrated coil.

Because micro-insert malposition and migration are rare, management is idiosyncratic. Symptomatic coils are always removed (laparoscopically, if necessary), but no clear consensus exists on the management of asymptomatic malposition. In our case, the micro-insert was detected incidentally in an asymptomatic patient. Furthermore, the coil had migrated through the cervical os and was protruding into the vaginal cavity with potential risks including ascending infection, dyspareunia, and chronic pelvic pain (as seen in Figure 2). In such a scenario, careful discussion of the risks and benefits of further operation as well as the physician's clinical judgment are paramount to achieving an outcome that is both free of complications and acceptable to the patient. After careful discussion with our patient, it was determined that the benefits of removing the migrated coil did not outweigh the potential trauma that would likely result from the attempt. Thus, the protruding portion was clipped close to the cervix without further attempts to remove it.

## 4. Conclusion

Careful examination of hysteroscopic sterilization device micro-inserts should be performed in patients with chronic pelvic pain, especially in the context of a difficult device placement, whether due to device fragmentation, poor visibility, or challenging anatomy. Hysteroscopic examination for symptomatic patients should focus on ensuring that no migration or fragmentation of the device has occurred. Asymptomatic migration into the endometrial cavity may reasonably be treated by clipping the protruding portion of the device, while migration into the cervical os represents an extremely rare and challenging situation in which a careful discussion of the risks and benefits with the patient is warranted. In this scenario, we chose to trim the asymptomatic coil close to the cervical os and leave the remaining fragment in place rather than risking the trauma of further operation.

## Authors' Contributions

TAP, LW, GK, SA: study conception and design, data collection and analysis, interpretation of results, and critical revisions. All authors read and approved the final version of the manuscript.

## Conflict of Interest Disclosures

The authors declare that they have no conflicts of interest.

## Ethical Approval

As this is a single case report, the institutional review boards for both Florida State University College of Medicine and Florida Hospital have deemed this report exempt from review.

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