

ESSURE® AND ENDOMETRIAL ABLATION: Clinical studies and case reviews of Essure with 118 NovaSure® procedures

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Disclosure

Dr Saunders reports that he has no financial relationships to disclose.

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ESSURE® HYSTEROSCOPIC STERILIZATION

Understanding and applying the evidence

Hysteroscopic sterilization with Essure® represents a safe, well-tolerated in-office option for women who desire permanent contraception.¹ This review summarizes short- and long-term clinical research concerning key aspects of the Essure system:

- Effectiveness and safety profiles
- Applicability to the office setting
- Performance in conjunction with endometrial ablation
- Key recommendations for success

Concluding this supplement is a retrospective review of patient case studies that apply the findings of relevant research to clinical practice.

Effectiveness: Evidence from short- and long-term data

In the 8 years since Essure was approved by the US Food and Drug Administration (FDA) for hysteroscopic sterilization, its safety and effectiveness have been supported by data from numerous US and international studies (TABLE). Essure (FIGURE 1) has an effectiveness rate of 99.74%,² and unintended pregnancies have occurred primarily due to noncompliance with labeling guidelines, misread hysterosalpingograms (HSGs), and undetected preprocedure

pregnancies.^{3,4} The phase 2 study evaluated the effectiveness of hysteroscopic sterilization with Essure. The authors reported that correct micro-insert placement was confirmed at 3 months by HSG in 97% of women. No pregnancies were reported among study participants after 6015 woman-months of exposure to intercourse.⁵

Subsequent studies reconfirmed Essure's effectiveness. A retrospective observational cohort study conducted in the Kaiser Permanente Northern California system revealed that, between January 2003 and December 2007, no pregnancies occurred among 1359 women in whom the micro-insert had been placed correctly and in whom tubal occlusion was confirmed by HSG.⁶ A significantly larger worldwide retrospective cohort study of the Essure procedure reviewed pregnancies reported from the date of FDA approval in November 2002 through 2008. A total of 305 pregnancies were reported,⁴ nearly all of which were attributable to patient or physician noncompliance with the manufacturer's procedure and/or follow-up protocol. The effectiveness rate described in this study was 99.85%.

Keys to success:
Satisfactory placement and protocol compliance

Endometrial preparation. Some studies/data suggest that the accuracy of micro-insert placement has been shown to increase with prior endometrial preparation. A chart review of 194 patients documented correct placement of the micro-insert in 94% of women who received hormone therapy before the Essure procedure, compared with 65% of women who had received no hormone therapy ($P < .0001$).⁷

Micro-insert placement. A recent prospective trial involving 571 women at 71 sites also demonstrated that the third-generation Essure micro-insert improved placement rates on first attempt to 96.2%, from the 94.6% rate reported with the second-generation delivery system.⁸ Other studies reported successful Essure micro-insert placement rates of 95%⁹ and 99%.¹⁰

Protocol compliance critical to success. Unexpected pregnancy postprocedure typically stems from several aspects of noncompliance with the Essure procedure.^{1,3} Patients may fail to return as directed for HSG confirmation of micro-insert placement and occlusion, or they may neglect to use alternative contraception in the 3 months immediately following the procedure. It is also vital that an HSG be performed at 3 months postprocedure and interpreted accurately to confirm correct device placement and tubal occlusion (FIGURE 2).

TABLE Key Essure Statistics

5-year effectiveness	99.74% ²
Tubal occlusion rate	
At 3 mo	96.5% ¹¹
At 6 mo	100% ¹¹
Placement rate	94.6%-99% ^{10,11}
Satisfaction rate	≥97% ¹⁰
Total average scope time	~9 min ^{8,9}
Time to return to normal activity	≤1 day ¹⁰
No. of procedures performed	~400,000 ¹²

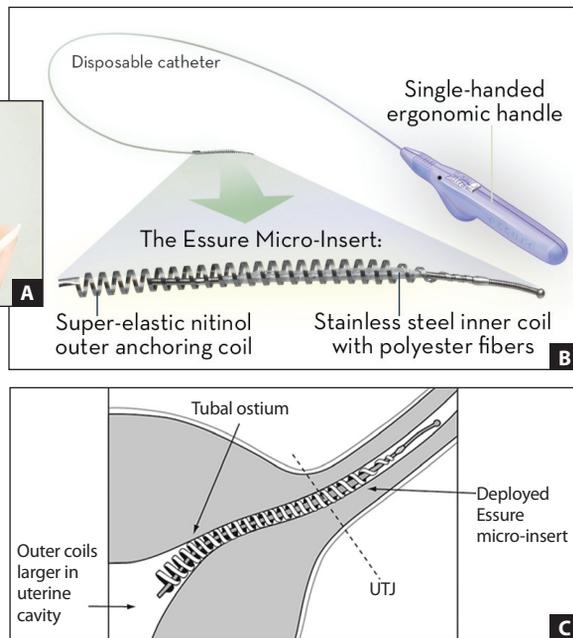


FIGURE 1 Essure micro-insert size (A), components (B), and placement (C).

Courtesy of Conceptus Incorporated.

Patient tolerance and safety: Trial data

Trials of hysteroscopic sterilization with Essure have consistently demonstrated excellent patient tolerance and safety; no major adverse events have been reported.¹⁰⁻¹² In a 2007 survey of 40 patients, half of whom underwent Essure hysteroscopic sterilization and half of whom had laparoscopic sterilization, the average pain score immediately postprocedure was significantly ($P < .0001$) lower among patients using the Essure procedure.

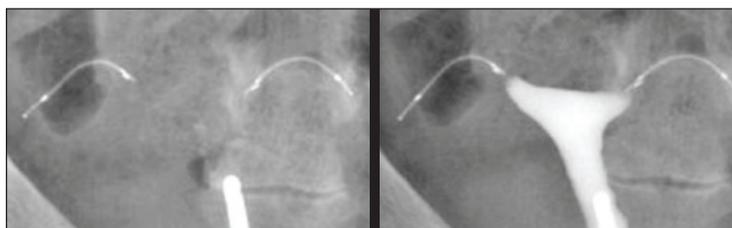


FIGURE 2 Appropriate bilateral placement (L) and complete tubal occlusion (R) identified by hysterosalpingogram.

Courtesy of Conceptus Incorporated.

Similarly, compared with laparoscopic sterilization patients, none of the Essure patients experienced pain at 1 week ($P < .0001$) or at 4 weeks ($P = .004$) postprocedure.¹³ In a study of 209 women undergoing in-office Essure hysteroscopic sterilization under local anesthesia, 98% said they would recommend the procedure to a friend. Most patients reported they were “extremely satisfied” and 70% reported their pain was less than or equal to menses.¹⁴ In the pivotal clinical trial, more than half of the 507 women who underwent the procedure said they experienced only mild or no pain. The majority reported tolerability as good to excellent. Ninety-two percent of participants returned to work within 1 day or less. At all follow-up visits, 99% of the women described comfort as good to excellent. The study authors concluded that the procedure was “well tolerated and results in rapid recovery [and] high patient satisfaction.”¹⁵

In a 4-year retrospective study of 90 women who had undergone hysteroscopic sterilization using the Essure micro-insert, 90% of the women reported that the procedure was “very well tolerated” or “well tolerated.” In addition, 98% reported being “very satisfied” or “satisfied” with the procedure.¹⁶

In a Swedish study, 61 women who underwent the procedure in an outpatient setting were asked to complete a questionnaire that included inquiries about bleeding patterns and side effects. The mean follow-up was 23 months. Fifty women (82%) completed the questionnaire; all reported overall satisfaction.¹⁷

Essure is contraindicated in patients with nickel hypersensitivity.¹¹ However, a retrospective review of pre- and postmarketing data showed that, at the time of publication, just 12 patients (or 0.04/1000 of kits sold at that time) have been reported to have experienced adverse events “possibly related” to nickel hypersensitivity.¹⁸

Proven success in clinical trials

In the phase 2 trial and the pivotal clinical trial for Essure, procedures typically were performed in out-

patient settings, primarily with local analgesia but also with occasional intravenous sedation.^{5,15} In a 2007 report, Miño and colleagues noted a 99% success rate in placing the Essure micro-inserts for 857 outpatients. At follow-up, all participants reported either high (6%) or very high (94%) levels of satisfaction.¹⁹

A 2008 prospective study evaluated use in the office setting. The authors noted that 99% of 1630 women successfully underwent the Essure procedure; 86.5% said they experienced minimal or

no pain. As measured by visual analog scale in subsequent evaluation, 91% of participants rated the procedure a 10 (highly satisfied), and none rated it less than 8. More than 97% indicated they would recommend the procedure to others. The option to have the procedure performed in a nonsurgery setting was highly important to 52.7% of the participants.¹⁰

Essure use in conjunction with endometrial ablation

Simultaneous sterilization is often indicated for women who elect to undergo endometrial ablation for menorrhagia. Current Essure labeling states that endometrial ablation of the uterus using ThermoChoice® or the HydroThermAblator® System can be safely and effectively performed with the Essure micro-inserts in place. However, these procedures should not be performed concomitantly due to the risk of intrauterine synechiae, which can compromise the 3-month Essure confirmation test (HSG).¹¹ Recent studies have demonstrated the value of Essure use in conjunction with a variety of endometrial ablation technologies.

Use with NovaSure®

In a feasibility study designed to assess the safety of combining the Essure procedure with NovaSure ablation, 13 women scheduled for abdominal hysterectomy had a micro-insert placed in one fallopian tube and then underwent endometrial ablation. The investigators monitored serosal temperatures, using the contralateral tube as a control. Mean serosal temperatures did not exceed 40°C. Thirty-one percent of the tubes with micro-inserts evidenced minor thermal injury that did not involve the serosa. In addition, the micro-inserts did not affect performance of the ablative procedure.²⁰

Two retrospective analyses of patients in private practices confirmed the safety and feasibility of use of the Essure procedure in conjunction with NovaSure.^{21,22} In these studies, women ages 25 to 52 had bilateral

micro-insert placement followed by endometrial ablation. No complications occurred during or after the procedures. Following the prescribed period of alternative contraception, all patients in one study²¹ have subsequently relied on Essure contraception during follow-up, and no pregnancies have been reported. In the second study,²² 25 of 59 patients had a follow-up HSG, with 24 out of 25 completing the test successfully. One patient could not tolerate the test to completion. No pregnancies have been reported. The authors are continuing to follow up on this cohort for 12 months. Ablation following micro-insert placement was deemed the optimal sequence so as to allow adequate visualization of tubal ostia during the Essure procedure, enhancing placement success. The authors of both studies concluded that NovaSure ablation following Essure micro-insert placement is a safe and effective treatment for meeting the needs of women who experience menorrhagia and desire permanent birth control.^{21,22}

One study involving 66 women ages 20 to 52 tested the feasibility of performing HSG following combined Essure and radiofrequency ablation procedures.²³ Of 65 women who had micro-inserts successfully implanted bilaterally, 50 (77%) returned as directed for HSG at 3 months. Forty-eight were able to undergo HSG, which adequately demonstrated proper placement and occlusion. Thus, the recommended use of HSG with the Essure procedure alone applies as well with the combined modalities.²³

Hydro ThermAblator

The Essure procedure is also compatible with the Hydro ThermAblator system. In a perihysterectomy safety study, researchers evaluated uterine and fallopian tube serosal temperatures, distal fallopian tube leakage, and thermal injury in 7 women during ablation after micro-inserts had been placed in one fallopian tube. The contralateral tube provided control data. Mean serosal temperatures remained below 44°C, and no saline leakage was detected. No implanted fallopian tubes showed detectable thermal injury following HTA. However, 3 control tubes exhibited proximal thermal injury (though no primary serosal injury resulted), compared with injury-free implanted tubes. The author concluded that the study results support an acceptable safety profile for HTA with Essure.²⁴

Microwave Endometrial Ablation System

The safety of Microwave Endometrial Ablation (MEA) following

Essure placement was evaluated in the perihysterectomy setting. Nine women underwent unilateral Essure placement followed by MEA. Mean serosal temperatures ranged from 35°C to 36°C. Histology results showed the expected degree of ablation and no significant increase in fallopian tube injury.²⁵

Evaluation of multiple endometrial ablation procedures

Another investigation followed 59 women treated simultaneously with Essure sterilization and endometrial ablation with one of 4 methods—ThermaChoice, NovaSure, Hydro ThermAblator, or the Microwave Endometrial Ablation System. There were no intraoperative or postoperative complications. At 3 months, bilateral occlusion was confirmed in 89% of cases, and amenorrhea, hypomenorrhea, and eumenorrhea rates were 47.5%, 42.5%, and 10%, respectively.²⁶

Implications for practice

The research findings reviewed here have clear implications for clinical practice.

Increasing patient satisfaction

Hysteroscopic sterilization with Essure has proven effective, safe, and highly acceptable for most women. It can be performed as an in-office procedure, usually with just oral or locally administered analgesia. The Essure procedure normally requires about 9 minutes to perform^{8,9} (FIGURE 3), and most patients return to daily activities within 24 hours.^{10,15} In comparison, laparoscopic tubal ligation (LTL) must be performed in a surgical suite under general anesthesia and necessitates a recovery period of several days with limited activity.

In a prospective cohort trial involving 89 women, 82% of women receiving Essure micro-inserts rated

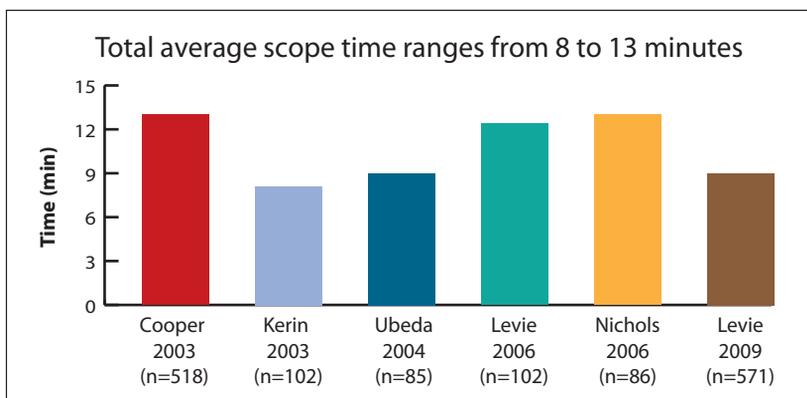


FIGURE 3 Essure procedure time

their tolerance of the procedure as excellent to good; just 41% of LTL patients said the same. After 90 days, every Essure patient was satisfied, compared with 80% of LTL patients.²⁷

Lowering costs

As anticipated, hysteroscopic sterilization with Essure in the office setting lowers costs compared with LTL. At one institution, actual procedural costs for LTL (not billing or reimbursement) amounted to \$3449, compared with \$1374 for Essure.²⁸ Other studies have confirmed statistically significant cost reductions in using Essure instead of laparoscopic sterilization.^{29,30} One study concluded that substantial cost savings over 5 years could be obtained with office-based Essure hysteroscopic sterilization compared with laparoscopic bilateral tubal ligation.³¹

Enhancing patient services

Many women place great value on the benefits of in-office hysteroscopic sterilization, including the following¹⁰:

- Brief procedure
- Minimal discomfort
- Rapid return to activities
- Hormone-free

Therefore, it is not surprising that the Essure procedure has increased in popularity. Between 2002 and 2007 at the Detroit Medical Center, the use of laparoscopic sterilization declined from 97.9% of all interval procedures to 48.5%, whereas Essure sterilization increased from 0.0% to 51.3% of all such procedures ($P < .001$).³²

Adding hysteroscopic sterilization makes your practice more valuable to your patient population. At the same time, the procedure expands the practice revenue base in the office setting.³³ Patients and insurers, too, benefit from this arrangement. Time and resource savings are also realized for patients and families, as well as physicians and staff, in avoiding the early arrivals and delayed departures customary for the hospital setting.

In addition, the Essure procedure may be an option for women who cannot undergo anesthesia for medical reasons.³⁴⁻³⁶

Key points to emphasize

The success of sterilization with Essure depends on adherence to the protocol both by patients and clinicians.

Key points for patient counseling

It is clear that protocol compliance is critical to success; therefore, it is essential that patients are counseled to remain on alternative contraception until they return for their HSG 3 months after micro-insert placement.

HSG results must demonstrate satisfactory micro-insert placement and tubal occlusion before the patient can be counseled to rely on Essure for contraception. It is notable that no pregnancies occurred in the phase 2 or pivotal trials. However, pregnancies following the Essure procedure have occurred in commercial use, and the majority are due to nonadherence to the manufacturer's protocol. Physicians who have made the Essure procedure a successful part of their practice emphasize to patients that the procedure is not complete until the HSG confirms both placement and occlusion at 3 months postprocedure.^{11,37}

Collaborating with the radiologist

Accurate interpretation of the HSG is also critical to successful sterilization with Essure. The radiologist must be aware that HSG will be used only to confirm proper placement of Essure micro-inserts and their blockage of fallopian tubes; thus, the pressure used will be less than normal³⁷ and patient comfort will be enhanced. For the best patient care and final outcome of the Essure procedure, collaboration between the gynecologist and radiologist is key. ■

A RECENT RETROSPECTIVE CASE REVIEW

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Along with many other physicians, I have had interest in providing expanded in-office services for patients. Procedures performed in our office have included diagnostic laparoscopy, tubal ligation, and diagnostic and operative hysteroscopy. Changes in insurance reimbursement that include payment for some devices led to the natural movement of hysteroscopic tubal occlusion and global endometrial ablation into the office setting. Because of these changes, more patients have taken advantage of these minimally invasive procedures.

Procedure safety and patient satisfaction with hysteroscopic tubal occlusion for family-complete contraception and global endometrial ablation for menorrhagia performed individually has been established. Experience performing Essure® along with ThermoChoice® and Essure with the HydroThermAblator® (HTA) System is well documented. There are a limited number of studies of patients having undergone Essure followed by NovaSure®.

In an effort to better understand and quantify the results of these procedures, I undertook a case review study of 118 sequential patients who had

Essure micro-insert placement followed by NovaSure endometrial ablation.

Symptoms suggestive of menorrhagia in these patients included 7 or more days of bleeding per cycle, heavy bleeding requiring a tampon and pad together to control flow, leaking through at night, use of more than 5 tampons per day, documented anemia, or interference with work or activities. Subjective complaints of exhaustion and dysmenorrhea were also considered. Patients were counseled about options. The options offered were observation, hormone manipulation, an intrauterine device (IUD; ie, Mirena®), and hysterectomy. These patients then underwent evaluation for medical causes of abnormal bleeding.

Over a 30-month period, our practice performed 767 NovaSure endometrial ablation procedures (527 in the office and 240 in a hospital/surgical center) and 371 Essure procedures (288 in the office and 83 in a hospital/surgical center). Indications for the 240 out-of-office NovaSure procedures included patient choice, insurance requirement, and coincidental surgery for pelvic relaxation/urinary incontinence or laparoscopy for adnexal pathology or tubal ligation. Indications for the out-of-office Essure procedures were insurance requirement and patient choice.

Patients were then scheduled for ultrasonography and hysteroscopy with endometrial biopsy to rule out pelvic pathology. If the patient needed family-complete contraception, the option of Essure tubal occlusion was discussed and, in these patients, was done at the time of the hysteroscopy. Patients were given options for permanent birth control and chose Essure.

If ultrasonography revealed more than 3 fibroids or a fibroid of 3.0 cm or larger, the patient was counseled regarding the increased failure rate of the ablation procedure and hysterectomy was recommended. The Essure procedure was not performed in these women. All endometrial biopsy results were reviewed prior to the NovaSure procedure. No biopsies showed pathology.

NovaSure endometrial ablation was scheduled at the patient's convenience, pending the biopsy results. The interval between Essure and NovaSure was typically 3 to 7 days, with the range being 2 to 108 days. All patients were made aware of the manufacturer's recommendation to complete the ablation procedure after the Essure confirmation test; however, most patients chose not to wait because of a desire to eliminate excessive uterine bleeding sooner.

It should be noted that our protocol—in which the pelvic ultrasound is performed, an endometrial biopsy is taken, and the Essure micro-insert is placed, followed by the separate visit for endometrial ablation—means that only 2 office visits are required, representing cost efficiencies for the patient by limiting the number of copays.

Unlike a previous study showing that interpretation of the Essure confirmation test (ECT) was not affected by

NovaSure, we found that our radiologists frequently had difficulty either placing the intrauterine catheter or being able to completely evaluate Essure micro-insert location and tubal occlusion. To evaluate micro-insert placement, a pelvic ultrasound was performed within 1 month after the NovaSure procedure. This timing would allow replacement of the micro-insert if it was not visualized. Replacement of the micro-insert was necessary for 2 patients at the time of the NovaSure procedure because the micro-insert was attached to the NovaSure instrument when it was withdrawn (one of those patients had previously had ECT confirming proper micro-insert placement and tubal occlusion). A second device was placed without difficulty, and patients have not reported complications or pregnancy. All patients were instructed to use backup contraception and to have a hysterosalpingogram (HSG) at 90 days following Essure placement, even if the ultrasound confirmed placement.

As stated, a total of 118 patients had Essure micro-insert placement followed by NovaSure. Patient age ranged from 28 to 48. Our patient records do not designate an ethnic category for all patients. An overwhelming majority of all patients were Caucasian, with about 8% of all patients having a Hispanic surname. This is a reflection of the suburban location of our practice.

At follow-up—2 years for the earliest study participants—none of the participants have had a pregnancy. Only one patient did not have a completed Essure procedure: in that case, we were able to place a micro-insert, but the patient became anxious and asked that the procedure be terminated. She did go forward with the ablation, choosing to use oral contraception.

No complications occurred in this cohort and no adverse events have required treatment or hospitalization.

Four patients have undergone hysterectomy for menorrhagia. All of those patients had an ultrasound suggesting leiomyomata, which was confirmed by a pathology test.

We did experience challenges in scheduling patients for confirmation of tubal occlusion by HSG. Barriers to confirmation testing included the need to visit another facility for the procedure, as well as potential issues related to changing insurance and noncompliance. We counseled patients that the HSG is a required part of the sterilization procedure and is necessary to ensure completion of the procedure. The requirement of this test is included in patient information. The confirmation testing requirement is also included in our patient consent form. All patients confirm that they understand the need for the confirmation test. Patients were counseled that a secondary method of birth control is essential until occlusion can be confirmed by HSG. If the patient had an IUD prior to the Essure procedure, it was left in place during the placement of the micro-insert and left until

the NovaSure procedure was performed. When the confirmation test could not be completed for technical reasons and the ultrasound confirmed proper placement of the micro-insert, the patient was counseled regarding the potential for an increased risk of pregnancy.

Incorporating Essure into an ob/gyn practice

Prior to introducing Essure and NovaSure into our practice, we evaluated research demonstrating the micro-insert's effectiveness and safety and its compatibility with NovaSure. Our belief was that it would lend itself to in-office usage. Our protocol has evolved to include the following steps:

- **Femara**, 2.5 mg daily for 5 days ending the day prior to the Essure placement. Significant endometrial atrophy makes visualization of tubal ostia much easier and facilitates proper placement of Essure micro-inserts. It also seems to shorten the procedure length because of the ease of visualization. If the patient has been on a low-dose combination oral contraceptive for an extended time or has had a Mirena IUD in place, Femara is not prescribed.
- **Ibuprofen**, 800 mg BID the day prior to and the morning of both the Essure and NovaSure procedures.
- **Vicodin**, 2 tablets, 1 hour prior.
- **Xanax**, 0.5 mg, 1 hour prior.
- **Ketorolac**, 30 mg IM, 1 hour prior.
- **Lidocaine** 0.5% with epinephrine paracervical block, 15 minutes prior.
- **Lidocaine 2% gel intrauterine**, 15 minutes prior.
- **Atropine**, 0.5 mg IM, for a pulse less than 60 prior to initiation of paracervical anesthesia.
- **Doxycycline** prophylaxis, 100 mg twice daily for 3 days beginning the morning of the NovaSure procedure.
- **A continuous pulse oximeter** is used to monitor the patient.
- **An automated external defibrillator** is present in the procedure suite along with a resuscitation cart.
- **Medical assistants:** One is present for the NovaSure procedure and 2 for the Essure procedure.
- **Ultrasound** (3D or sonohystogram) 1 month after NovaSure for micro-insert location.
- **HSG** 3 months after the Essure procedure.

A positive practice experience

Our experience—and the results of reports in the medical literature—demonstrates that this technology for the treatment of menorrhagia when there is a need for family-complete contraception offers both safety and effectiveness, along with significant patient satisfaction.

Essure micro-insert placement followed by NovaSure endometrial ablation

Study period	30 mo
No. of patients	118
Age range of patients	28-48 y
Typical interval between procedures	3-7 d
Incomplete procedures	1
Micro-insert replacement	2
Adverse events	0
Pregnancies	0

We chose to move these procedures into our office to make better use of time. The inefficient use of time in the hospital or surgical center is frustrating. Being able to see patients between cases was a prime motivator. That benefit was obvious. What we were surprised to see was that the number of patients having Essure and ablation procedures in the office increased dramatically. Although all patients are offered the option of in-office as well as in-hospital locations for these procedures, almost all have chosen to have the procedure in the office. The primary reason given was the significantly lower copay when the procedure is done in the office. Other reasons include familiarity with the location and with office staff, shorter visit length since no registration at another facility is required, a friend's experience, preferring oral medications rather than conscious sedation, and wanting a friend or family member present. Many who had considered these options in the past have returned to have the procedure performed in the office.

Referrals from primary care as well as from other gynecologists who do not perform the procedure in the office have increased. But the main increase in referrals has been from patients, reflecting satisfaction with the experience. Patients perceive the practice as being more "up to date" because of these procedures. They have stated that this perception has also led them to us for other problems, which has resulted in an increase in major surgery volume. We continue to meet with primary care physicians for continuing education about these and other minimally invasive procedures. Education of both the patient and referring physician is key.

We initially set aside a particular day as "procedure day." But the volume of cases and need to be flexible for patient scheduling led us to perform procedures all days of the week. In a typical day, 5 to 9 Essure procedures or ablations are done.

In addition to the number of patients undergoing the procedure, the reimbursement per procedure is significantly higher. (This additional reimbursement is for facility, staffing, and patient recovery.) These increases have had a dramatic impact on revenue, but more important is the positive impact these procedures have had on our patients' health. ■

REFERENCES

- Palmer SN, Greenberg JA. Transcervical sterilization: a comparison of Essure® Permanent Birth Control System and Adiana® Permanent Contraception System. *Rev Obstet Gynecol.* 2009;2:84-92.
- US Food and Drug Administration. Device Approvals and Clearances. Essure System—PMA P020014, Supplement 9, approved July 12, 2005. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=8754>.
- Levy B, Levie M, Childers M. A summary of reported pregnancies after hysteroscopic sterilization. *J Minim Invasive Gynecol.* 2007;14:271-274.
- Munro MG, Casas L. Retrospective analysis of 2008 worldwide pregnancy reports in women with Essure micro-inserts. *J Minim Invasive Gynecol.* 2009;16(suppl):S69.
- Kerin JF, Cooper JM, Price T, et al. Hysteroscopic sterilization using a micro-insert device: results of a multicentre Phase II study. *Hum Reprod.* 2003;18:1223-1230.
- Holmes H, Heinlein PK. Contraceptive effectiveness of the Essure procedure within Kaiser Permanente Northern California. *J Minim Invasive Gynecol.* 2009;16(suppl):S71.
- Qato R, Bochenska K. Choice of endometrial preparation and Essure placement success. *J Minim Invasive Gynecol.* 2009;16(suppl):S114.
- Levie M, Chudnoff S. Post-approval FDA clinical trial of 3rd generation Essure system (Essure 305). *J Minim Invasive Gynecol.* 2009;16(suppl):S71.
- Ubeda A, Labastida R, Dexeus S. Essure: a new device for hysteroscopic tubal sterilization in an outpatient setting. *Fertil Steril.* 2004;82:196-199.
- Arjona JE, Miño M, Cerdón J, et al. Satisfaction and tolerance with office hysteroscopic tubal sterilization. *Fertil Steril.* 2008;90:1182-1186.
- Essure [instructions for use]. Mountain View, CA: Conceptus Incorporated; 2009.
- Data on file. Conceptus Incorporated, with permission.
- Syed R, Levy J, Childers ME. Pain associated with hysteroscopic sterilization. *JSL.* 2007;11:63-65.
- Levie M, Weiss G, Kaiser B, et al. Analysis of pain and satisfaction with office-based hysteroscopic sterilization. *Fertil Steril.* 2009. [Epub ahead of print.]
- Cooper JM, Carignan CS, Cher D, et al. Microinsert nonincisional hysteroscopic sterilization. *Obstet Gynecol.* 2003;102:59-67.
- Ménard S, Waddell G. Efficiency and satisfaction of hysteroscopic tubal sterilization with the Essure® System: a four years retrospective study. *J Minim Invasive Gynecol.* 2009;16(suppl):S113.
- Andersson S, Eriksson S, Mints M. Hysteroscopic female sterilization with Essure in an outpatient setting. *Acta Obstet Gynecol Scand.* 2009;88:743-746.
- Zurawin RK. Adverse events due to suspected nickel hypersensitivity in patients with Essure micro-inserts. *J Minim Invasive Gynecol.* 2009;16(suppl):S3-54.
- Miño M, Arjona JE, Cerdón J, et al. Success rate and patient satisfaction with the Essure sterilisation in an outpatient setting: a prospective study of 857 women. *BJOG.* 2007;114:763-766.
- Garza-Leal J, Hernandez I, Castillo L, et al. Essure® transcervical sterilization combined with NovaSure® endometrial ablation: a perihysterectomy safety study. *J Minim Invasive Gynecol.* 2008;15(suppl):S44.
- Kulbersh DL. NovaSure® endometrial ablation following Essure® hysteroscopic sterilization: retrospective analysis of a case series. *J Minim Invasive Gynecol.* 2008;15 (suppl):S25.
- Basinski CM, Price P. Essure® tubal sterilization combined with subsequent NovaSure® endometrial ablation: a retrospective analysis. Presented at: 38th Annual Global Congress on Minimally Invasive Gynecology; November 15-19, 2009; Orlando, FL.
- Carey ET, El-Nashar S, Creedon DJ, et al. Feasibility of hysterosalpingography following a combined radiofrequency global endometrial ablation and hysteroscopic sterilization procedure. *J Minim Invasive Gynecol.* 2009;16(suppl):S38.
- Garza-Leal J, Castillo I, Hernandez I, et al. Essure® transcervical sterilization combined with the Hydro Thermablator® system for endometrial ablation: A perihysterectomy safety study. *J Minim Invasive Gynecol.* 2008;15(suppl):S1.
- Garza-Leal JG, Coad JE. Concomitant Essure tubal sterilization and Microwave Endometrial Ablation (MEA): A peri-hysterectomy safety study. *J Minim Invasive Gynecol.* 2007;14:S49-S50.
- Donnadieu AC, Gervaise A, Deffieux X, et al. Concomitant Essure® tubal sterilization and endometrial ablation: a new approach of therapy of dysfunctional uterine bleeding. *J Minim Invasive Gynecol.* 2008;15(suppl):S56.
- Duffy S, Marsh F, Rogerson I, et al. Female sterilisation: a cohort controlled comparative study of Essure versus laparoscopic sterilisation. *BJOG.* 2005;112:1522-1528.
- Levie MD, Chudnoff SG. Office hysteroscopic sterilization compared with laparoscopic sterilization: a critical cost analysis. *J Minim Invasive Gynecol.* 2005;12:318-322.
- Hopkins MR, Creedon DJ, Wagle AE, et al. Retrospective cost analysis comparing Essure hysteroscopic sterilization and laparoscopic bilateral tubal coagulation. *J Minim Invasive Gynecol.* 2007;14:97-102.
- Thiel JA, Carson GD. Cost-effectiveness analysis comparing the Essure tubal sterilization procedure and laparoscopic tubal sterilization. *J Obstet Gynaecol Can.* 2008;30:581-585.
- Kraemer DF, Yen P-Y, Nichols M. An economic comparison of female sterilization of hysteroscopic tubal occlusion with laparoscopic bilateral tubal ligation. *Contraception.* 2009;80:254-260.
- Shavell VI, Abdallah ME, Shade GH, et al. Trends in sterilization since the introduction of Essure hysteroscopic sterilization. *J Minim Invasive Gynecol.* 2009;16:22-27.
- Levy B, Dobbins B, Greenberg JA, et al. Protocols for in-office hysteroscopic sterilization: a roundtable discussion. *OBG Management.* 2005;October (suppl).
- Famuyide AO, Hopkins MR, El-Nashar SA, et al. Hysteroscopic sterilization in women with severe cardiac disease: experience at a tertiary center. *Mayo Clin Proc.* 2008;83:431-438.
- Hennes AR, Robbins IM. Hysteroscopic sterilization in women with pulmonary vascular disease [letter]. *Mayo Clin Proc.* 2008;83:1188-1189.
- El-Nashar SA, Hopkins MR, Creedon DJ, et al. Hysteroscopic sterilization in morbidly obese women: a cohort study. *J Minim Invasive Gynecol.* 2009;16(suppl):S73.
- Famuyide AO, Lipman JC. Hysteroscopic sterilization: what you need to know about HSG confirmation. *OBG Management.* 2008;20(suppl):1-8.