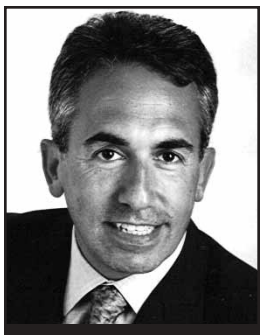


BY CHARLES E. MILLER, M.D.

MASTER CLASS

Essure Offers Easier Sterilization

Despite many advances in minimally invasive tubal ligation surgery, it remains a more complicated procedure than vasectomy to achieve sterilization, the most common contraceptive option in the United States today.

The introduction of a transcervical method of sterilization through the use of the Essure procedure is changing that. We can now offer patients a quick, exceedingly safe, incisionless tubal occlusion procedure that has been found 99.8% effective at 3 years, and, in one report, 99.74% effective at 5 years of follow-up.

I am incorporating Essure into my practice, and have found it so useful that I have chosen to share it in this month's Master Class.

In general terms, Essure is a microinsert placed into the fallopian tube via a hysteroscopically guided catheter.

The microinsert consists of a flexible stainless-steel inner coil, a dynamic outer coil made of nickel titanium alloy (nitinol), and an innermost layer of polyethylene terephthalate (PET) fibers. These fibers gradually elicit a benign localized tissue ingrowth that occludes the tubal lumen.

This quick, exceedingly safe incisionless procedure has been found 99.8% effective at 3 years, and, in one report, 99.74% effective at 5 years.

A follow-up hysterosalpingogram (HSG) 3 months post procedure confirms proper device placement and tubal occlusion.

The concept that led to the development of Essure tubal occlusion evolved from neurosurgery, in which coils have been used to block vessels. However, specialized coils had to be designed that would expand to the diameter and length of the fallopian tube.

The tissue response that is seen following placement of the microinsert is comparable to what has long been seen with heart valves and vascular grafts. Thus, even though this precise indication is new, the technology has been around for quite some time, and has been found to be safe and effective.

When I talk with a potential candidate for Essure tubal occlusion, our discussion is much the same as it would be for tubal ligation: The patient must desire permanent, nonreversible contraception.

She must be at least 3 months post pregnancy, and must not have tubal disease or scarring inside the uterus that would preclude visualization of the tubal ostia.

The patient cannot have a severe nickel allergy, because nitinol makes up the outer coil of the microinsert. Moreover, women who have a history of a severe allergic response to iodine are poor candidates because iodine is used during the follow-up HSG.

Finally, women who are on immunosuppressive therapy may take longer than 3 months to have an occlusive response. As long as such patients understand this potential limitation, immunosuppressive therapy is not a contraindication. In fact, my first Essure patient was on immunosuppressive therapy secondary to breast cancer.

Presurgical steps can be taken to improve visualization of the ostia. I sometimes prescribe oral, transdermal, or injectable contraception for 3 months before the procedure to thin the endometrium. Visualization also is enhanced by scheduling the procedure within the first 2 weeks of a patient's menstrual cycle.

General anesthesia is not required for the procedure. I instruct patients to take an NSAID 1 hour before surgery. I perform the procedure with intravenous sedation (30 mg IV ketorolac) in an outpatient surgical suite. However, many physicians are simply using a paracervical block and performing the Essure procedure in their offices.

If visualization is inadequate because of debris, endometrial fluff, or clots, simply flush the uterus, aspirate, and gently remove the obstructive material with graspers. Confirm visibility of both ostia before placing either microinsert. Start with the tube that appears to be the most difficult.

Use 2-3 liters of warmed saline to enhance uterine dilatation and tubal cannulation; the warmth will minimize tubal spasm as well as increase patient comfort. Avoid uterine overdistention by using gravity feed rather than pump-delivered saline for input and output.

Inadequate uterine distention resulting from a patulous cervix may be overcome by gently twisting the tenaculum 45 degrees, either by using an additional tenaculum to seal the cervix, or by placing the tenaculum at the 1 o'clock and 5 o'clock positions or the 7 o'clock and 11 o'clock positions (or both).

Feed the introducer through the cervix and uterus into the fallopian tube.

To minimize "splash back" of fluid when inserting the Essure catheter into the introducer, leave the stylet within the introducer until the last minute, just before you are ready to deliver the catheter into it. When you remove the stylet, squeeze the end of the introducer and then insert the Essure catheter. Do not use the stopcock to block the fluid until the introducer is withdrawn; otherwise, the introducer might be severed while in the hysteroscope.

Depending on the size of the hysteroscope, the introducer may be a tight fit. To minimize the risk of damage to the tip of the Essure catheter, do not force the introducer when resistance is felt. In such a case, simply withdraw the introducer/stylet unit approximately 1 mm. This may mean the introducer/stylet extends more than halfway outside the sealing cap of the working channel, but this is not a problem. Just insert the catheter through the introducer as usual once the stylet is removed.

Approach the ostia as closely as possible, waiting until the ostium occupies most of the hysteroscope's screen.

The Essure catheter includes visual cues to guide you, including a flat black positioning marker.

Before you deploy the microinsert by depressing the button on the handle, check the position of the catheter by looking for the marker just outside the tubal ostia. You should also see the distal tip of the orange release catheter in the same visual field.

Reducing tubal spasm will greatly improve the ease of placement. Wait a few seconds for a spasm to pass, then approach the tube very closely and gently rotate the device inside the tube.

Once the procedure is complete, patients should remain in the office for about 45 minutes before returning home. Some can return to work and daily activities immediately; virtually all will be back to their normal routines within 24 hours.

Almost always, ibuprofen is the strongest medication required for postprocedural pain.

The procedure is exceedingly safe. There is a small risk (less than 1%) of tubal perforation at the time of the procedure; however, no interventional therapy is required.

Likewise, the risks of infection, bleeding, and uterine perforation are extremely low.

Schedule patients for a return visit in 3 months for an HSG, during which you will inspect the tubes for evidence of tissue ingrowth. In the meantime, stress the importance of using an alternative form of contraception, as sterilization cannot be guaranteed until tubal occlusion can be confirmed.

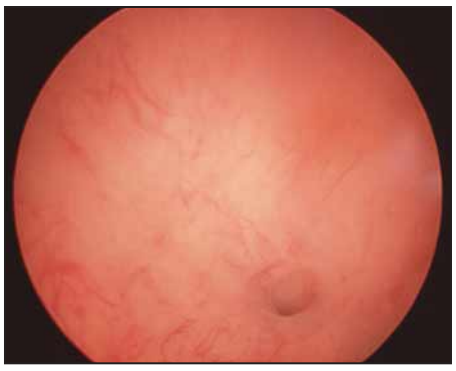
When performing the postprocedure HSG, use minimal volume and pressure. Doing so serves two purposes: avoiding unnecessary patient discomfort, and minimizing the chance of a false-positive result because of high-pressure instillation.

If you refer patients to a radiologist for HSGs, emphasize the importance of these key points. When capturing images, the clinician should ensure proper occlusion by magnifying the cornual region of each implanted tube.

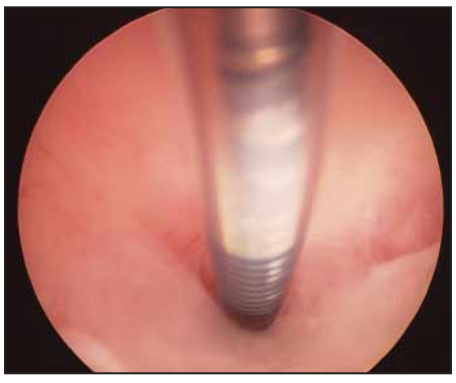
With proper technique, competency in this procedure can be achieved quickly. I have found patient satisfaction to be very high.

The ease and efficacy of the procedure, lack of necessity for general anesthetic, and rapid patient recovery all combine to make Essure tubal occlusion a valuable technique for gynecologists to master. ■

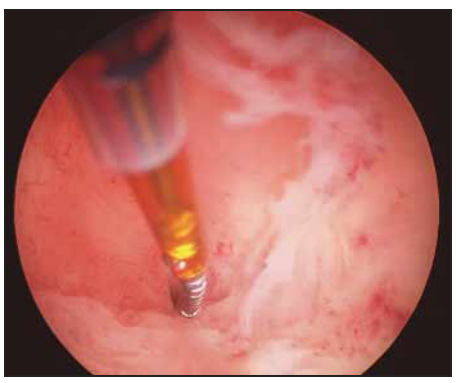
DR. MILLER, *a reproductive endocrinologist in private practice in Arlington Heights, Ill., and Naperville, Ill., is the medical editor of this column.*



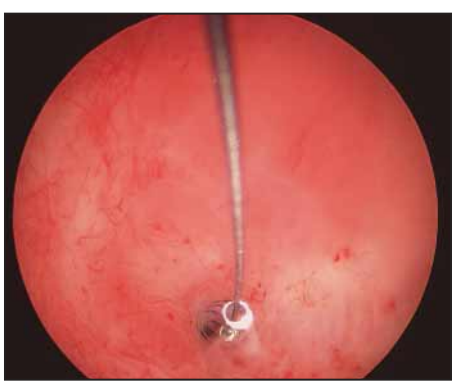
Confirm visibility of both ostia before placing either microinsert.



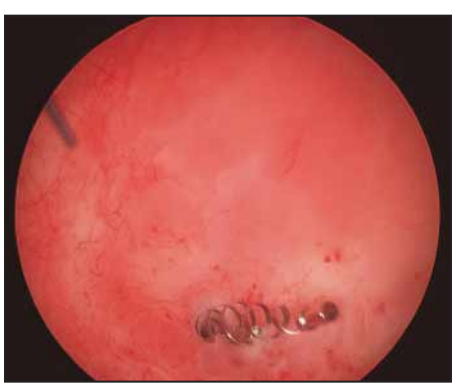
The Essure microinsert is inserted into the tubal ostia at the level of the black marker.



The delivery catheter is retracted. The notch at the opening of the tubal ostia shows correct placement.



The delivery wire is retracted from the microinsert.



The microinsert is now firmly embedded in the fallopian tube.

PHOTOS COURTESY DR. CHARLES E. MILLER