

Introducing *Essure*[®]

The only hysteroscopic approach to sterilization

Until now, women considering permanent birth control have had limited options, and research has highlighted their concerns about general anesthesia and recovery time.*

Now there's a nonincisional alternative to tubal ligation—the *Essure* procedure. *Essure* does not require general anesthesia, takes an average of 35 minutes to perform, and may be done as an outpatient surgery procedure. Best of all, in clinical trials most employed patients returned to work the very next day.^{1,3}

Essure uses a hysteroscopic approach to place micro-inserts into the fallopian tubes. During the next 3 months, benign tissue growth in and around the micro-inserts blocks the fallopian tubes, thus providing the patient with permanent protection against pregnancy.^{1,2,3}

Multiple benefits

- No incisions are required.^{1,3,4}
- Does not require general anesthesia.^{1,3,4}
- Takes approximately 35 minutes to perform.^{1,3}
- May be performed as an outpatient surgery procedure.^{1,3,4}
- Quick recovery—average post operative recovery time is 45 minutes.^{1,3}

Results to date

Two separate clinical studies—Phase II and Pivotal—have been conducted in the United States, Australia and Europe to evaluate the safety and effectiveness of *Essure*.^{1,3,4} The following has been demonstrated in these trials involving more than 700 women.

Effective

- *Essure* has been proven 99.8% effective at 2 years of follow-up.¹
- None of the women who relied on *Essure* for contraception during the clinical trials became pregnant over the 1-2 years of follow-up.^{1,3,4}

Quick

- Total procedure time was approximately 35 minutes.^{1,3}
- Recovery time averaged 45 minutes post operative.^{1,3}
- 92% of employed patients resumed work in 24 hours or less after the day of the procedure.^{1,3}

High patient satisfaction

- 99% of study participants rated their long-term comfort as “good” to “excellent”.^{1,3}
- 95% of patients were satisfied with the speed of recovery after 1 week.¹

Basic steps of the procedure



1. After a paracervical block is administered, a hysteroscope, with attached camera, is inserted through the cervix into the uterine cavity.



2. A catheter is passed through the hysteroscope and directed to the ostium. The micro-insert is positioned in the proximal portion of the fallopian tube, then detached and the catheter is removed. This process also occurs for the other fallopian tube. The entire procedure takes approximately 35 minutes, with only 15 minutes typically required to place the micro-inserts.



3. During the next 3 months, the fibers in the micro-insert cause a benign tissue response, resulting in tissue growing into the device and occluding the fallopian tube. An HSG is done after 3 months to evaluate tubal occlusion and satisfactory micro-insert location.

Important considerations

- The procedure should be considered irreversible.
- Like all methods of birth control, *Essure* should not be considered 100% effective.
- Not all women who undergo the *Essure* placement procedure will achieve successful placement of both micro-inserts.
- Patients must use another method of birth control for at least 3 months after the procedure.
- The *Essure* procedure is newer than other procedures.
- Removal of the *Essure* micro-inserts requires surgery.
- As with all procedures, there are risks associated with *Essure*.

essure[®]
The alternative to incision



W O M E N ' S H E A L T H
S P E C I A L I S T S

901-682-9222

References:

* Lewis, Mobilio & Associates, LLC, 2001. 1. Data on File, Essure PMA Submission, October 2002. Conceptus Incorporated. 2. Valle RF, Carignan CS, Wright TC, and the STOP Prehysterectomy Investigation Group. Tissue response to the STOP microcoil transcervical permanent contraceptive device: results from a prehysterectomy study. *Fertil Steril* 2001;76:974-980. 3. Cooper JM, Carignan CS, Cher D, Kerin, JF. Microinsert nonincisional hysteroscopic sterilization. *Obstet Gynecol* 2003;102:1:59-67. 4. 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;18:6:1223-1230.