

Transcervical Female Sterilization

Researchers are pursuing new methods of permanent contraception for women that provide protection comparable to surgical sterilization but are safer or easier to provide. The new developments focus on transcervical methods—that is, methods that reach the fallopian tubes through the vagina and uterus. They include chemicals, such as quinacrine, and plugs, such as the Adiana procedure. Microcoils, such as Essure®, are already on the market.

Currently, most female sterilization procedures involve tubal ligation, in which a woman's fallopian tubes are surgically cut or blocked by applying clips, rings, or heat. The two most common surgical approaches are minilaparotomy and laparoscopy. These approaches require skilled medical professionals and sterile conditions. Minilaparotomy requires local anesthesia, and laparoscopy requires general anesthesia (168). The newer approaches, because they do not involve surgery, can increase access to sterilization (269).

Essure—A Microcoil

The microcoil Essure (formerly named STOP), developed by the US firm Conceptus, is a spring-like device that a trained clinician using a hysteroscope inserts through the vagina into the uterus and then into each fallopian tube. Over the three months following the procedure, scar tissue grows into the device. The scar tissue permanently plugs the fallopian tubes so that sperm cannot pass through to fertilize an egg (252).

The insertion procedure can be performed with a local anesthetic in an outpatient setting in less than one hour, with rapid return to normal activities for the client (55, 127). Clinicians need to be skilled in hysteroscopy to place the microcoil properly, however.

In clinical trials some women required two attempts for successful insertion but ultimately microcoil insertion was successful in 90% to 95% of women (55, 126, 246). The most common reasons for placement failure are tubal obstruction and stenosis—a narrowing or constriction of the fallopian tube. Placement of Essure must always be confirmed, usually with an x-ray test or ultrasound imaging three months after insertion (126, 241).

Once successfully inserted, Essure appears to be at least as effective as surgical sterilization (52). Women need to use a temporary contraceptive method for three months after insertion to allow time for scar tissue to form. After the scar tissue is formed, Essure is not reversible (252). About three-fourths of women experience some pain after the procedure (127).

Essure has been approved by regulatory agencies in Europe and in Australia, Canada, Indonesia, Singapore, Turkey, and the US (52, 55, 278). Essure is unlikely to

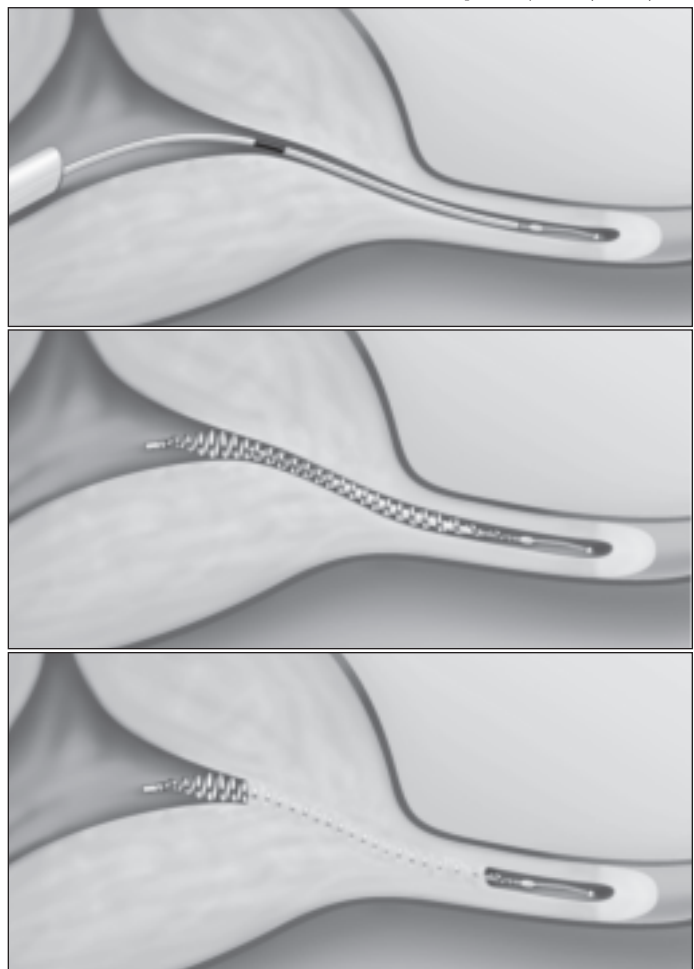
be introduced in developing countries any time soon, however, because of the high cost and complexity of the hysteroscope required for insertion (206).

Quinacrine—A Chemical Compound

Quinacrine is a chemical compound in the form of pellets that, when inserted into the uterus, results in permanent sterilization by producing scarring to block the fallopian tubes (286). Quinacrine can be provided by most trained health care providers and does not require a physician (105).

Quinacrine is already US FDA-approved for oral anti-malarial treatment and is available worldwide. Researchers have been studying quinacrine for sterilization over the last 20 years in many countries, including Chile, Egypt, India, Indonesia, Iran, Malaysia, and Vietnam (4, 18, 36, 75, 77, 105, 230, 286). Its regulatory approval by the US FDA and other agencies for use as a sterilization method, however, will depend on the results of safety evaluations and toxicology studies. These studies are underway, as well as clinical trials approved by the US FDA. A phase I clinical trial ended in 2003 (140), and additional trials are planned (139, 226).

Images courtesy of Conceptus Incorporated



Essure, a new nonsurgical sterilization method, is a spring-like device inserted through the uterus into each fallopian tube. Scar tissue then blocks the passage of eggs down the tubes.



Claudia Ramos de Carvalho Ferreira

A health care provider discusses quinacrone insertion with a client. Quinacrone is a chemical compound in the form of a pellet that, when inserted into the uterus, results in sterilization by producing scarring that blocks the fallopian tubes.

The precise effectiveness rate of quinacrone as a sterilization agent is debated because different insertion procedures result in different rates. A review of studies concluded that the pregnancy rate is one to two pregnancies per 100 women after two years of use (129, 287)—less effective than surgical sterilization. A study that included all types of quinacrone insertion procedures, regardless of how well the provider was trained, found that 9.8 women per 100 become pregnant within five years of use (227).

Reported side effects after insertion are usually brief and mild. They include lower abdominal pain, headache, dizziness, backache, vaginal itching or irritation, vaginal discharge, and fever. Some women report menstrual pattern changes, usually reduced bleeding (75, 229, 230). Serious complications related to quinacrone appear to be fewer than with surgical sterilization (105, 128).

The safety of quinacrone as a sterilization method is still in question (32). FHI is currently conducting research, including toxicology studies, to determine whether intrauterine use of quinacrone poses a risk of cancer. Results from these studies are expected in 2007 (32, 226). Long-term follow-up done in 1995–96 of almost 1,500 Chilean women who had the quinacrone sterilization procedure found no increased risk of cancer up to 19 years later (228).

Some women's rights groups have opposed quinacrone on the grounds that toxicology and animal studies did not precede clinical trials, which is the established research procedure; that large-scale clinical trials began before smaller safety studies were complete; and that in some places women were not informed of its experimental nature or offered other contraceptives (34, 184, 185). If current toxicology and clinical trials show quinacrone to be safe and effective, this evidence could help resolve these objections (226).

The Adiana Procedure

The Adiana procedure is a transcervical sterilization procedure in which a clinician delivers a catheter through a hysteroscope into the fallopian tube and uses the catheter to apply low-level radiofrequency energy, creating a superficial lesion. Then the clinician places a porous, plastic implant, called a matrix, into the lesion. The matrix remains in the fallopian tube, and the surrounding tissue grows into it over the next 12 weeks. The ingrown tissue results in total closure of the fallopian tube.

Because it requires use of an expensive hysteroscope, the Adiana procedure is unlikely to be introduced in developing countries in the foreseeable future. Clinical studies are underway, and its developers, Adiana, Inc., expect US FDA approval in 2005 (21, 194). ❖❖

Transcervical Sterilization

Description: Procedures that prevent pregnancy permanently by reaching and blocking the fallopian tubes through the vagina and uterus.

Stage of development: Some methods on the market and others in clinical trials.

Effectiveness: 0.2 to 2 pregnancies per 100 women in the first year of use.

How they work: Blocks the egg from descending a fallopian tube.

What's new? Sterilization procedures for women that do not require surgery.

