Informed Consent

A. Condition
Desirous of permanent sterilization

B. Procedure
Your doctor will use hysteroscopy which is a technique used to look inside the uterus to visualize the fallopian tube openings and place a micro-insert into the tube. A hysteroscope is a thin, telescope-like device that is placed into the uterus through the vagina and cervix. A speculum is first inserted into the vagina. The hysteroscope is then inserted and gently moved through the cervix into your uterus. Warm saline (salt water), will be put through the hysteroscope into your uterus to expand it. This will allow your doctor to see the inside of the uterus clearly. The amount of fluid used is carefully checked throughout the procedure. Your doctor can see the lining of your uterus and the openings of the fallopian tubes by looking through the hysteroscope. Once both openings are visualized, one Essure micro-insert is placed in the proximal section of each fallopian tube lumen. The micro-insert expands upon release, acutely anchoring itself in the fallopian tube.

The micro-insert subsequently elicits a benign natural tissue response. Tissue in-growth into the micro-insert permanently anchors the device and occludes the fallopian tube, resulting in sterilization. The method cannot be relied upon until a confirmatory HSG for tubal patency and correct placement of the micro-inserts is performed at 3 months. This is a test where a special radio-opaque dye is placed through the cervix and radiographs are taken.

The procedure does not require an incision and can be performed under a local anesthetic with sedation, or a general anesthesia if preferred. It must be scheduled for the brief time between the period ending and ovulation. If you are on the birth control pill it can be any time as long as you are not bleeding.
C. Procedure success rate and efficacy
The Essure system was 99.80% effective after 4 years of follow up and has been demonstrated to be 99.74% effective at 5 years follow up with a small portion of the women undergoing clinical studies.

D. Adverse events, which prevent reliance on the Essure device for contraception
- failure to place 2 micro-inserts in first procedure (14%)
- initial tubal patency (3.5%)
- expulsion (2.2%)
- perforation (1.8%)
- or other unsatisfactory device location (0.6%).

All of the patients who experienced tubal patency at the 3-month HSG were found to have bilateral occlusion at a repeat HSG performed at approximately 6 months after the Essure procedure.

E. The most frequent adverse events and side effects
- cramping (29.6%)
- pain (12.9%)
- nausea/vomiting (10.8%),
- dizziness/lightheadedness (8.8%)
- bleeding/spotting (6.8%)

During the first year of reliance on the Essure micro-inserts for contraception (approximately 15 months after micro-insert placement), the following episodes were reported as at least possibly related to the Essure micro-inserts:
- Back pain (9.0%)
- abdominal pain (3.8%)
- dyspareunia (3.6%)
F. Alternatives: The following are considered to be alternative procedures. Please feel free to discuss these procedures with your doctor

- Tubal ligation by laparoscopy
- Male sterilization by vasectomy
- Non permanent birth control such as oral contraceptives, barrier methods, or intrauterine device

___I understand that the Essure permanent birth control procedure has been clinically tested for four years and shown to be 99.8% effective in preventing pregnancy during that time period.

___I understand that the Essure procedure involves placing a micro-insert (small, flexible coil) into each fallopian tube which over time causes the tubes to close, thereby preventing pregnancy.

___I understand that to be sure the Essure micro-insert has worked to close off my fallopian tubes and that I can rely on the Essure procedure for my birth control, an Essure Confirmation Test (hysterosalpingogram (HSG)) must be performed three months following the procedure. During this test, a special fluid (dye) and x-ray will be used to show that my fallopian tubes are occluded and that the micro-inserts are in the correct location.

___I understand that until the Essure Confirmation Test (HSG) has confirmed my tubes are closed another form of birth control must be used.

___I understand that some women may not have successful placement of both Essure micro-inserts, and should this occur I should seek the advice of my physician.

___I understand that should I become pregnant, I should immediately seek medical care for evaluation of the pregnancy.

___I understand that the Essure procedure is considered to be permanent and cannot be reversed.

___I understand that the other risks associated with placement of the Essure device include, but are not limited to: bleeding, infection, perforation, and pain similar to menstrual cramping.

___I understand that Essure does not protect against sexually transmitted diseases and that barrier methods such as condoms should be used for protection against sexually transmitted diseases.

___I have received the patient information booklet.

___I have had the opportunity to ask questions regarding the Essure permanent birth control procedure and wish to proceed with the placement of the Essure devices.
G. Changing Your Mind
There is no obligation to undergo the procedure once you have signed this form. Please feel free to contact us at any time if you change your mind about your decision to undergo the procedure.

PATIENT SIGNATURE __________________________________________
Please Print and Sign

PHYSICIAN SIGNATURE ________________________________________

WITNESS SIGNATURE _________________________________________
Please Print and Sign
DATE ____________