

Summary of Risks and Other Important Information

The Essure System

This product is meant only to keep you from getting pregnant. It does not protect you against HIV infection (AIDS) or other sexually transmitted diseases.

IMPORTANT NOTE: Below is a brief summary of the complete product prescribing information (Instructions for Use). It is for patients only. It should not be used to prescribe the product. Your doctor should be well versed in the complete Instructions for Use before prescribing this product.

INDICATIONS FOR USE

The *Essure* system should be used only if you want to be sterile (not able to conceive a child) for the rest of your life. The *Essure* system involves placing a "micro-insert" in each fallopian tube. These inserts cause tissue growth that blocks the tubes. Placement is done using a technique called hysteroscopy. This technique does not use incisions.

CONTRAINDICATIONS FOR USE

You should not use the *Essure* system if you:

- Are not sure you want to become sterile
- Cannot have an *Essure* micro-insert placed in both of your tubes (even if one tube is thought to be closed or you have only one tube)
- Have had a tubal ligation ("tubes tied") in the past
- Are pregnant or think you might be pregnant
- Have been pregnant during the past 6 weeks
- Have an active or recent pelvic infection
- Have an allergy to contrast dye (used for x-ray testing)
- Have a sensitivity to nickel as shown by skin testing

WARNINGS

- You must use a temporary form of birth control for at least 3 months after the *Essure* procedure. Discuss this temporary form of birth control with your doctor. A special type of x-ray test called a hysterosalpingogram (HSG) is done 3 months after the *Essure* procedure. This test confirms that the *Essure* micro-inserts have blocked both tubes. If they are blocked, your doctor will tell you that you can stop the temporary birth control method. If you get pregnant before your tubes are fully blocked, you may have an ectopic pregnancy (pregnancy outside of your uterus). This can be life-threatening.
- The *Essure* procedure should be thought of as irreversible. If you want to have the *Essure* procedure reversed, you must have major surgery. And it is not known if the reversal will work. If it does work and you become pregnant, there is a risk of problems for both you and your fetus.
- Tell all of your doctors that you have *Essure* micro-inserts. Be sure to mention that you have *Essure* micro-inserts before you have any pelvic procedure. Care must be taken to keep certain medical instruments away from the micro-inserts. Some procedures have not been studied for use with the *Essure* micro-inserts. And other types of procedures should be avoided. Ask your doctor more about this.
- Studies have shown that the GYNECARE THERMACHOICE® Uterine Balloon System can be used safely for endometrial ablation right after the *Essure* procedure. But it is not known what effect this procedure has on the micro-inserts or tubal blockage over time. No other uterine ablation system has been studied with the *Essure* procedure or micro-inserts.
- If you do get pregnant after the *Essure* procedure, there is a small chance an ectopic pregnancy could occur. No cases of this type of pregnancy have been reported in clinical trials.
- If the *Essure* micro-inserts need to be removed for any reason, surgery may be needed. This means having general anesthesia. An incision may also be needed. In rare cases, the uterus might need to be removed.
- If you have the *Essure* procedure and later decide you want to get pregnant, you may choose to try in-vitro fertilization (IVF). It is not known whether the *Essure* device affects the success of IVF. If you did get pregnant with this technique, it is not known whether the micro-inserts would harm your health or the health of your fetus.

PRECAUTIONS

- Before using the *Essure* system, you should know that:
 - No form of birth control works 100% of the time. Though not likely, you can become pregnant even years after the *Essure* micro-inserts are placed. And the pregnancy may be inside or outside your uterus.

–Very little is known about how well the *Essure* micro-inserts work beyond the first 5 years. What is currently known about the *Essure* micro-inserts may change as new information becomes available.

–The younger a woman is when she chooses to become sterile, the more likely she is to regret her choice later.

- You should always tell your doctor that you have the *Essure* micro-inserts. There are risks involved with procedures in your uterus where the doctor does not use hysteroscopy and cannot see the micro-inserts. These types of medical procedures done in your uterus can affect the micro-inserts. The micro-inserts may then not be able to keep you from becoming pregnant. After these procedures, you might be asked to have an imaging test to check the location of the micro-inserts. Also, the *Essure* micro-inserts could cause other risks during pelvic procedures that are not known at this time.
- Having the *Essure* micro-inserts in your tubes may increase your risk for post-ablation tubal sterilization syndrome. This rare syndrome can happen in women who have endometrial ablation after any type of tubal sterilization.
- Always tell your doctor that you have the *Essure* micro-inserts before having a test called magnetic resonance imaging (MRI). The *Essure* micro-inserts were found to be safe during this test. But *Essure* micro-inserts may make nearby tissues harder to see. The exact conditions under which MRI can be safely done are explained for your doctor in the *Essure* Instructions For Use.

ADVERSE EVENTS

Two clinical trials were done to check the safety and effectiveness of the *Essure* system. A total of 745 women had the *Essure* micro-inserts placed. Certain problems with the micro-inserts were reported during these trials. These were:

- Failure to place both micro-inserts during the first procedure (14%)
- Tubes not becoming blocked at 3 months after placement (*patency*) (3.5%)
- One or both micro-inserts not staying in the body (*expulsion*) (2.2%)
- One or both micro-inserts poking through wall of tube or uterus (*perforation*) (1.8%)
- One or both micro-inserts outside the tube or not in the correct place in the tube (0.6%)

These problems kept women from being able to rely on the *Essure* micro-inserts for birth control. Some of the women who had the device come out of their bodies chose to have a second placement. The second placement worked in all cases. These women were then able to rely on the *Essure* micro-inserts for birth control.

During these trials, some women were found to have one or both tubes still open 3 months after the *Essure* procedure. But all had closed tubes when checked about 6 months after *Essure* micro-insert placement.

A very small number of women in the trials had pelvic pain. Only 1 woman asked that the *Essure* micro-inserts be removed because of this pain.

During the trials, some problems or side effects were reported due to the procedure used to place the micro-inserts (hysteroscopy). The most common of these were cramping (29.6%), pain (12.9%), nausea/vomiting (10.8%), dizziness/lightheadedness (8.8%), and bleeding/spotting (6.8%). Rarely, too much of the fluid used to expand the uterus during placement was absorbed by the body. This occurred in less than 1% of cases.

During the first year of relying solely on the *Essure* micro-inserts for birth control (about 15 months after the *Essure* procedure), a few problems were reported. The following could have been due to the presence of micro-inserts: back pain (9.0%), abdominal pain (3.8%), and pain with intercourse (3.6%). All other problems occurred in less than 3% of women.

ADDITIONAL PATIENT INFORMATION

Please see Patient Information Booklet.

PHYSICIAN INFORMATION

For complete prescribing information, physicians should refer to the *Essure* system Instructions for Use.

Conceptus Incorporated
331 East Evelyn Avenue, Mountain View, CA 94041 USA

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