Information for informed consent for Essure procedure to permanently prevent pregnancy

What is the Essure procedure?
The Essure procedure (also known as “tubal occlusion”) is a type of permanent birth control, or sterilization. It will prevent you from ever getting pregnant and it cannot be reversed or undone. This is because it will permanently block your fallopian tubes. Pregnancy can only occur when a man’s sperm fertilizes a woman’s egg which she releases every month. The sperm travels from the vagina, through the cervix, and into the uterus. However, the actual fertilization of the egg occurs in the fallopian tubes which are attached to the uterus. Essure prevents fertilization by blocking the opening of the fallopian tube so that no sperm can ever reach the egg.

How does the Essure procedure work?
Your doctor places a small coiled device called a micro-insert into the opening of the fallopian tube. Over time, usually about 3 months, the body creates scar tissue around the micro-insert. The scar tissue blocks the tube. Your body continues to release an egg each month just as it always has, but it cannot be fertilized and dissolves in the tube.

What are my choices other than Essure?
The choice to be permanently sterilized is a big decision for any woman. We recommend that before you choose permanent sterilization, you think carefully about all of your long-term birth control options. This is important because some women regret their decision afterwards. This can happen if a woman chooses permanent sterilization during a difficult time in a relationship, after having problems with a pregnancy, or if someone else pressures her to make a decision. Women younger than 30 years old often change their mind at a later time. This is important to know because the Essure procedure is permanent and cannot be reversed.

Your other choices for longer-term birth control include:
- Hormonal options such as the pill, or Depo-Provera shots.
- Inserting an IUD or implantable hormones.

Your other choices for permanent sterilization include:
- Tubal ligation (having your fallopian tubes tied).
- Vasectomy for your partner.

There are advantages, disadvantages, and potential risks for each option. Your doctor can help you choose which one may be best for you.

What are the benefits of the Essure procedure?
The benefits of Essure to prevent pregnancy include:
- It is a highly effective method of permanent birth control.
• It is a convenient way to prevent pregnancy because you do not need to remember to take anything to have effective birth control.
• You can usually return to your normal activities right after the procedure.
• Unlike other forms of sterilization, you won’t have a scar on your belly.
• It can be done in the doctor’s office without the need for general anesthesia.

What are the risks of the Essure procedure?
Like any procedure there are some risks involved with the placement of the Essure micro-inserts. They include:

Rarely
• During the procedure your doctor may not be able to place one or both of the micro-inserts. After placement, the micro-inserts may move out of place and you may need to have another micro-insert placed in order for it to be effective.
• Your cervix or uterus may become infected. Medication or another procedure could be needed to treat an infection.
• While placing the micro-insert, it can unintentionally be pushed through the top of the uterus or tube and end up inside the belly. This could require an additional surgery to remove.
• No birth control is 100 percent effective. If you were to become pregnant, the pregnancy is more likely to occur in the fallopian tube. This would mean you would have to end your pregnancy. It might also mean that you would need medical treatment or surgery to treat the ectopic pregnancy.
• Some forms of birth control can make your periods lighter. Birth control pills, Depo-Provera and the Mirena IUD tend to make your periods lighter. If you were using one of these methods, once discontinued, your period may become heavier.

Are there alternatives to the Essure procedure?
Yes, there are many alternatives for birth control, each with risks and benefits.
• Temporary forms of hormonal birth control like the pill, patches, vaginal ring and Depo-Provera.
• Barrier forms of birth control like condoms and diaphragms.
• Long-term contraceptives like the IUD and implantable forms of hormonal contraception.
• Other permanent birth control choices like tubal ligation and vasectomy.

Be sure to tell your doctor if you have…
• A bleeding disorder
• Allergies to local anesthesia, latex, iodine, or antibiotics
• A vaginal infection, an active herpes virus infection, or a history of pelvic infection
• Allergies to metals, especially nickel
• A history of any procedure being done on your cervix, uterus, or fallopian tubes
• If you are currently using an IUD for birth control
• If you have been pregnant or had a tubal infection within the last 6 weeks
• If you have a compromised immune system (HIV or other autoimmune disease) or use medications that interfere with your immune system (steroids).

**How do I prepare for the procedure?**
The procedure is usually scheduled for a few days after you expect a period. This is so your doctor can see the opening of the fallopian tubes clearly. It is important to make sure you are not pregnant at the time of the procedure. Make sure you also have a reliable form of birth control to use for at least 3 months after the procedure because it takes this long for Essure to start working fully. You and your doctor will decide on what type of medication will be used to keep you comfortable during the procedure. Your choices may include local anesthesia, oral pain medication, injectable pain medication or intravenous pain medication.

**What happens during the Essure procedure?**
Placing the Essure micro-inserts usually takes 15 to 30 minutes. It is a simple office procedure performed using a hysteroscope, a very small tube with a camera and light that is placed through the cervix and into the uterus. This allows your doctor to see inside the uterus and to view the opening of the fallopian tubes on a TV monitor.

Before the procedure your doctor may want to slightly stretch open the cervix (opening of the uterus) to make the procedure easier. This can be done with medication or by temporarily placing a small sponge (“laminaria”) that will slowly expand and open the cervix. At the start of the procedure, your doctor may gently inject a local anesthetic and a medication (epinephrine) to reduce bleeding into the cervix. Epinephrine can cause your heart to race. It may also cause a metallic taste in your mouth, ringing in your ears, or your legs to shake. These are normal side effects of the medication and this feeling typically passes quickly.

After the opening of your cervix is slightly stretched, the small camera is placed through the cervix into the uterus. This allows the doctor to clearly see the opening of the fallopian tubes. The doctor places the micro-inserts into the openings of the fallopian tubes under direct visualization to make sure they are in the right place.

**What happens after the procedure is over?**
Most women have little or no pain immediately after the procedure. It is common to have cramps in your lower belly for several days after the procedure. (It is OK to use Tylenol, Motrin or Advil.) It is normal to have spotting for several days after the procedure. You can resume normal activity after your Essure procedure, but remember that it takes at least 3 months for Essure to become effective so continue to use birth control until your doctor does a confirmation test to make sure the procedure has been successful. This is a test done by taking an x-ray of the uterus that shows the tubes are blocked and it is safe for you to rely on Essure for permanent birth control.
Continue to use an effective form of birth control until you doctor tells you that you can rely on the micro-inserts for birth control.

Call our advice center right away if you have any of these symptoms:
- Vaginal bleeding greater than 1 pad per hour for more than 3 hours
- Vaginal bleeding for more than 3 weeks
- Pain that is not controlled with Tylenol, Advil, or the prescription pain medication that might have been given after the procedure
- A temperature greater than 100.4 degrees Fahrenheit
- Pus (yellow or green discharge) or foul smelling discharge coming from the vagina

What if I ever think I might be pregnant?
If you ever think you may be pregnant it is important to notify your doctor immediately.
If you ever miss a period, or have symptoms of pregnancy, it is important to do a home pregnancy test and call your doctor. This is because if you do get pregnant, there is a higher risk that it could be an ectopic pregnancy, or one that develops in the fallopian tube. Ectopic pregnancies must be treated because they can be life threatening.

Where can you learn more?
- Visit your doctor’s home page at kp.org/mydoctor. On click on “Prepare for your Procedure” (Emmi) to link to an interactive online program (The Essure Procedure) that provides information for you and your family.