

essure®

Permanent Birth Control



Patient Information Booklet

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Laura,
Essure Woman

Essure®: A Simple Option for Permanent Birth Control

The *Essure* procedure is a method for permanent birth control (also known as sterilization). It is meant to prevent pregnancy for the rest of your life. This booklet will provide you with information about the *Essure* procedure, including its benefits and risks. This information, however, is not meant to take the place of a thorough talk with your doctor. All women have individual needs and concerns. Your doctor will advise you whether the *Essure* procedure is right for you with regard to your circumstances and health history. The *Essure* procedure is the first non-incisional permanent birth control procedure approved by the FDA.

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How Does the *Essure* Procedure Work?

During the *Essure* procedure, soft, flexible coils called “micro-inserts” are passed through the body’s natural pathways (vagina, cervix, and uterus). They are then placed into each fallopian tube. The micro-inserts are made with materials that have been used in medical devices for many years. They do not contain or release hormones.

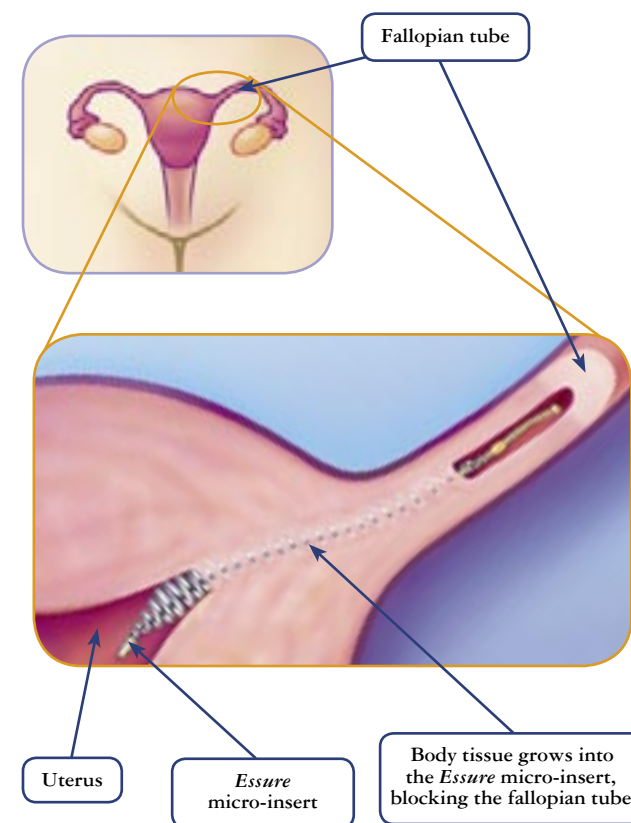
During the first 3 months following the procedure, your body and the micro-inserts work together to form a tissue barrier (like scar tissue) so that sperm cannot reach the egg. This prevents you from getting pregnant. You will need to use another form of birth control during this time. After 3 months, your doctor will perform a special type of x-ray test called an HSG. This test will assure you that your tubes are completely blocked and you can rely on the *Essure* micro-inserts for birth control.

Is the *Essure* Procedure Reversible?

The *Essure* procedure is not reversible. Women should be sure that they do not want to have any children in the future.

Does *Essure* Have Any Effect on Periods?

After an *Essure* procedure the ovaries will continue to produce eggs. The eggs will be absorbed by your body. Because the micro-inserts do not contain hormones, you will continue to have a period. However, some women do have temporary changes in their periods. They may have shorter or longer periods, heavier or lighter periods, or spotting between periods. Only a few women will experience permanent changes in their periods.



What Are the Benefits of the *Essure* Procedure?

Since FDA approval of the *Essure* system, tens of thousands of women worldwide have had the procedure. Two studies of the safety and effectiveness of the *Essure* Permanent Birth Control system were conducted in women from the United States, Australia, and Europe. Women who have had the procedure have reported the benefits outlined below.

Effective

- The *Essure* procedure is 99.80% effective at preventing pregnancy, based on 4 years of clinical data.

Covered by most insurance plans

- Many insurance plans cover the *Essure* procedure. When you have decided that the *Essure* procedure is right for you, please review your insurance coverage with your doctor. Confirm your insurance plan benefits before the procedure.

No cutting into the body

- The *Essure* procedure is unlike tubal ligation (“getting your tubes tied”) or vasectomy (sterilization for men). It does not involve cutting or puncturing the body, and does not cut, crush, or burn the fallopian tubes.
- Because there is no cutting, the *Essure* procedure does not cause scars.

Rapid recovery

- On average, it takes 35 minutes to place the *Essure* micro-inserts. Most women are able to leave the medical facility 45 minutes after the procedure.
- Most women returned to normal activities within 1 to 2 days.
- Almost all women rated their comfort as “good” to “excellent” within 1 week of the procedure.

Can be done in an office setting

- The *Essure* procedure can be performed in the comfort and convenience of a doctor’s office.

Confirmation of placement

- A confirmation test is done to check the placement of the *Essure* micro-inserts. This test confirms that you can rely on the micro-inserts for birth control. Knowing that this has been confirmed often gives women peace of mind.

High patient satisfaction

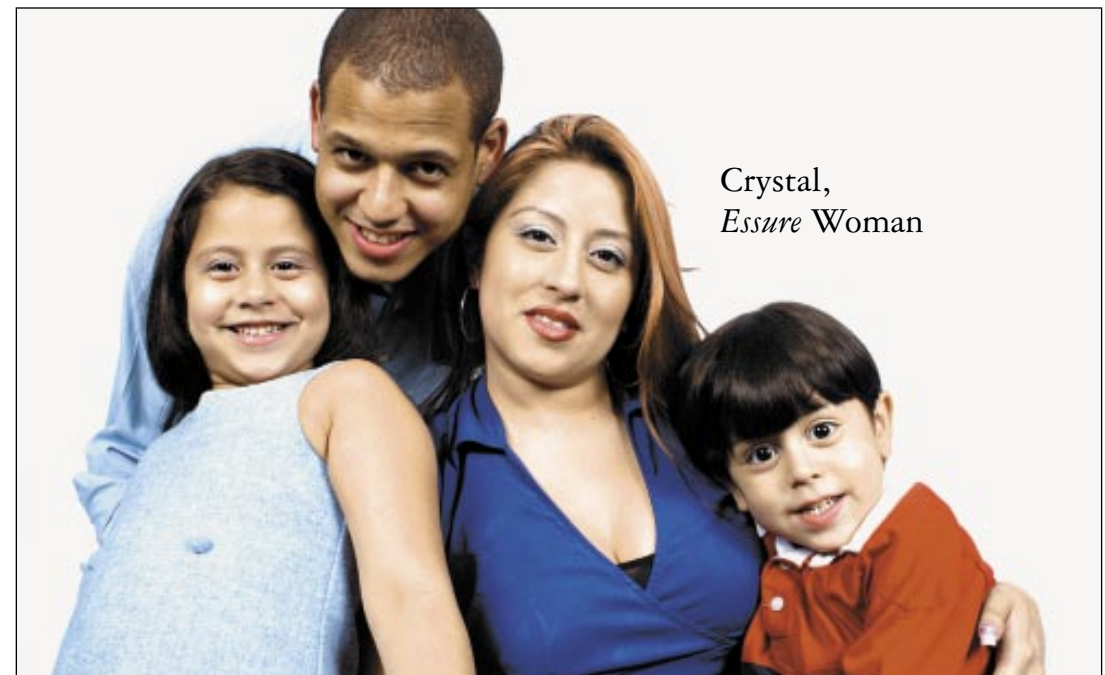
- Women consistently rate their overall satisfaction with the *Essure* micro-inserts as very high.

Hormone-free

- The *Essure* micro-inserts do not contain or release any hormones.

No general anesthesia required

- The *Essure* procedure can be performed with minimal anesthesia. Talk to your doctor if you have any questions.



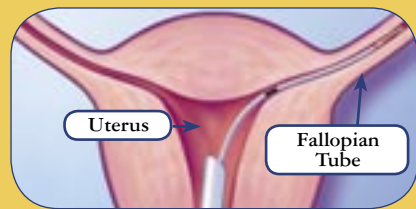
Crystal,
Essure Woman

Before the Procedure

You are given medication to take 1 to 2 hours before the procedure. This medication helps to keep your tubes open and reduce cramping during the procedure. Before the procedure, talk to your doctor about what type of pain medication is best for you. General anesthesia is not required.

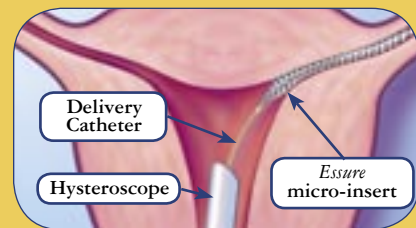
Note: The *Essure* procedure should be scheduled during the first half of your menstrual cycle. This will reduce the risk of having an undiagnosed pregnancy at the time of the procedure. It will also make it easier to see the opening to the fallopian tubes. Your doctor will give you a pregnancy test before the procedure to confirm that you are not pregnant.

During the Procedure



Once the procedure begins:

- An instrument called a speculum may be used to gently expand the opening of your vagina. The doctor then inserts a narrow telescope-like instrument called a hysteroscope through your vagina and cervix and into the uterus. The hysteroscope is attached to a video camera that sends pictures to a monitor. This lets the doctor see inside your uterus.
- Fluid (called normal saline or saltwater) flows through the hysteroscope and into your uterus. The fluid expands the uterus to let your doctor see the openings to your fallopian tubes clearly. You may feel some cramping during this time.
- A small, flexible tube (delivery catheter) is passed through the hysteroscope and into your fallopian tube. The micro-insert is attached to the end of this delivery catheter. The micro-insert is placed in the fallopian tube. When the micro-insert is in place, the delivery catheter is removed.
- A second delivery catheter and micro-insert is passed into your other fallopian tube, and the second micro-insert is placed. The delivery catheter is removed.
- After each micro-insert is placed, the doctor may take a picture of the opening of the fallopian tube into the uterus. A small piece of the micro-insert extends into this opening. By viewing this area, the doctor can check the location of the micro-insert.



After the Procedure

Most women are able to leave the doctor's office about 45 minutes after the procedure is completed. Most women return to normal activities within 1 to 2 days.

Note: Call your doctor if you notice unusual pain, bleeding, fever, vaginal discharge, or other symptoms.

The Next 3 Months

You will need to use another form of birth control during this period until your doctor confirms that the procedure has worked. During the time after your procedure, tissue will begin to grow into the micro-inserts. It will eventually block your fallopian tubes. The tissue barrier will keep sperm from reaching and fertilizing the egg. This will prevent you from getting pregnant.

Three months after the procedure, a special type of x-ray test called a hysterosalpingogram (HSG) is done. This test is required before your doctor can tell you whether you may begin relying on the *Essure* micro-inserts for permanent birth control. During an HSG, your doctor fills your uterus with a special fluid (dye) that shows up on x-rays. This test confirms two things. First, it verifies whether both of your *Essure* micro-inserts are in the correct location. Second, it shows whether both of your fallopian tubes are blocked.



Dye entering the uterus during the HSG.



In a successful HSG, the dye fills the uterus but does not enter the fallopian tubes.



X-ray image of the HSG showing that the dye does not go past the micro-inserts.

You should NOT use the *Essure* Permanent Birth Control 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.
- Have a known allergy to contrast dye (commonly used for x-ray [HSG] testing).
- Have a sensitivity to nickel as shown by skin testing.
- Are unwilling to have an HSG (confirmation test).
- Are unwilling to use alternative birth control.

Delay having the *Essure* procedure if you:

- Are pregnant or think you might be pregnant.
- Have been pregnant during the past 6 weeks.
- Have an active or recent pelvic infection.



Making the Decision
 Don't make the decision to have permanent birth control during times of stress. Don't decide during a divorce or after a miscarriage. NEVER decide due to pressure from a partner or others.
 If you are being treated for a medical condition that involves taking steroids or undergoing chemotherapy, ask your doctor whether the *Essure* procedure is right for you.

Kendra,
Essure Woman

Permanent Birth Control Options

	Tubal Ligation	Essure	Vasectomy
How is the procedure performed?	Usually performed as a laparoscopic procedure, under general anesthesia. Gas is used to expand the abdomen so surgical tools can be inserted. The fallopian tubes are blocked by one of these methods: <ul style="list-style-type: none"> • Clamping with metal clips or plastic rings • Cutting away a section of the tube • Burning a portion of the tube The clamps, rings, or clips remain in the body. Stitches or staples are used to close the cuts.	A soft, flexible micro-insert is delivered through the vagina and uterus and placed into each fallopian tube. The spring-like micro-insert expands during placement to fit the tube. A small trailing portion of the micro-insert remains in the uterus. This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus. Scar tissue grows into the micro-insert (usually over 3 months) and forms a barrier so the sperm cannot reach the egg.	The scrotal area is shaved and cleaned with an antiseptic solution. An incision or puncture is made into the scrotum (the sac containing the testicles). The vas deferens tubes, one from each testicle, are tied in two places with permanent sutures. The tubes are severed between the ties by: <ul style="list-style-type: none"> • Cauterization (burning or searing of the tubes) • Cutting • Blocking with clips or clamps If an incision is made, it is then closed with stitches.
Effectiveness	99.45% at 1 year 98.82% at 4 years 98.15% at 10 years	99.95% at 1 year 99.80% at 4 years	99.26% at 1 year 98.87% at 5 years
Procedure Time	30–45 minutes	35 minutes	20–30 minutes
Recovery Time	4–6 days	1–2 days or sooner	2–3 days
Post-procedure pain/discomfort	<ul style="list-style-type: none"> • Cramps • Discharge • Pain at the wound • Bloating abdomen and/or sharp pains in the neck or shoulder (due to gas used) • Bruising around the wound • Feeling tired and achy 	<ul style="list-style-type: none"> • Cramps • Discharge 	<ul style="list-style-type: none"> • Swelling • Bruising • Pain in the testicles (Ice packs and/or an athletic supporter may need to be used to decrease bruising and swelling.)
Reliance and Test	Immediate/no test	Reliance can begin at 3 months when the <i>Essure</i> confirmation test confirms placement and blockage of the tubes.	Reliance can begin at 3 months when a follow-up sperm test confirms no sperm is evident.

Temporary Birth Control Options*

(Pregnancy Rates for 1 Year of Use)

The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for 1 year. These estimates are based on a variety of studies. For a complete list, visit the FDA website at www.fda.gov and search on *Birth Control Guide*.

Method	Description	Failure Rate	Some Risks	Convenience
Oral contraceptives—combined pill	A pill that suppresses ovulation by the combined actions of the hormones estrogen and progestin.	1–2%	Dizziness; nausea; changes in menstruation, mood, and weight. Rare: cardiovascular disease, including high blood pressure, blood clots, heart attack, and stroke.	Must be taken daily regardless of frequency of intercourse.
Oral contraceptives—progestin-only (minipill)	A pill containing only the hormone progestin that reduces and thickens cervical mucus to prevent the sperm from reaching the egg.	2%	Irregular bleeding, weight gain, breast tenderness, less protection against ectopic pregnancy.	Must be taken daily regardless of frequency of intercourse.
Injection (Depo-Provera)	An injectable progestin that inhibits ovulation, prevents sperm from reaching the egg, and prevents the fertilized egg from implanting in the uterus.	<1%	Irregular bleeding, weight gain, breast tenderness, headaches.	One injection every 3 months.
Injection (Lunelle)	An injectable form of progestin and estrogen.	<1%	Changes in menstrual cycle, weight gain (similar to oral contraceptives—combined pill).	Injection given once a month.
Vaginal contraceptive ring (NuvaRing)	A flexible ring about 2 inches in diameter that is inserted into the vagina and releases the hormones progestin and estrogen.	1–2%	Vaginal discharge, vaginitis, irritation (similar to oral contraceptives—combined pill).	Inserted by the woman; remains in the vagina for 3 weeks, then is removed for 1 week. If the ring is expelled and remains out for more than 3 hours, another birth control method must be used until the ring has been used continuously for 7 days.
The Patch (Ortho Evra)	Skin patch worn on the lower abdomen, buttocks, or upper body that releases the hormones progestin and estrogen into the bloodstream.	1–2% (Appears to be less effective in women weighing >198 lbs.)	Similar to oral contraceptives—combined pill.	New patch is applied once a week for 3 weeks. Patch is not worn during the fourth week, and woman has a menstrual period.

Method	Description	Failure Rate	Some Risks	Convenience
IUD (Intrauterine Device)	A T-shaped device inserted into the uterus by a health professional.	<1%	Cramps, bleeding, pelvic inflammatory disease, infertility, perforation of uterus.	After insertion, can remain in place for up to 1 or 10 years, depending on type.
Male condom (latex/polyurethane)	A sheath placed over the erect penis blocking the passage of sperm.	11%	Irritation and allergic reactions. Oil-based lubricants weaken latex condoms and should not be used with these methods.	Applied immediately before intercourse; used only once and discarded. Polyurethane condoms are available for those with latex sensitivity.
Diaphragm with spermicide	A dome-shaped rubber disk with a flexible rim that covers the cervix so that sperm cannot reach the uterus. A spermicide is applied to the diaphragm before insertion.	17%	Irritation and allergic reactions, urinary tract infection. Risk of toxic shock syndrome, a rare but serious infection, when kept in place longer than recommended. Spermicide can cause irritation.	Inserted before intercourse and left in place at least 6 hours after. Can be left in place for 24 hours, with additional spermicide for repeated intercourse.
Female condom	A lubricated polyurethane sheath shaped similarly to the male condom. The closed end has a flexible ring that is inserted into the vagina.	21%	Irritation and allergic reactions.	Applied immediately before intercourse; used only once and discarded.
Spermicide alone	A foam, cream, jelly, film, suppository, or tablet that contains nonoxynol-9, a sperm-killing chemical.	20–50%	Irritation and allergic reactions, urinary tract infections.	Instructions vary; check labeling. Inserted 5 to 90 minutes before intercourse and usually left in place at least 6 to 8 hours after.
Periodic abstinence	Deliberately refraining from having sexual intercourse during times when pregnancy is more likely.	20%	None.	Requires frequent monitoring of body functions such as body temperature.

*Data adapted from FDA's Uniform Contraceptive Table (revised 9/17/98) and Birth Control Guide (12/03)

Please note: Not all temporary methods of birth control can be used during the 3-month waiting time following the *Essure* procedure. Please talk to your physician about what form of temporary birth control you should use during this time.

Key Considerations and Risks

Before you have the *Essure* procedure, you need to be sure it's right for you. Below are some considerations to think about. As with all procedures, there are risks associated with the *Essure* procedure. Know what these risks are and discuss them in detail with your doctor before you decide.

The *Essure* procedure is permanent (not reversible).

- There are no data on the safety or effectiveness of surgery to reverse the *Essure* procedure. Any attempt to reverse the *Essure* procedure will require surgery and has a poor chance for success. This surgery will require an abdominal incision and, most likely, general anesthesia.
- There are no data on the safety or effectiveness of in vitro fertilization (IVF) after the *Essure* procedure has been performed.
- The younger a woman is when she chooses to become sterile, the more likely she is to regret her choice later.

Like all methods of birth control, the *Essure* procedure should not be considered 100% effective.

- No method of birth control is 100% effective. As with all permanent birth control procedures, there is a small chance that you can become pregnant even many years after the procedure.
- If you do become pregnant, the risk of the *Essure* micro-inserts to you, the continuation of the pregnancy, the fetus, or childbirth are not known.
- Women who have sterilization by the *Essure* procedure or incisional tubal ligation are more likely to have an ectopic pregnancy if they get pregnant. Ectopic pregnancy is when the pregnancy occurs outside of the uterus (womb). The pregnancy usually happens in one of the fallopian tubes. Ectopic pregnancies can be very serious, even life-threatening.

The *Essure* procedure is newer than other procedures.

- *Essure* is a non-incisional method of tubal sterilization that has been studied in clinical trials since 1997.
- The *Essure* product was approved in the U.S. in 2002. The follow-up clinical data (collected on women who have been relying on *Essure*) spans 5 years.
- Other incisional sterilization procedures, such as tubal ligation, have been used for over 50 years.

You must use another method of birth control for at least 3 months after the procedure.

- Before the procedure is performed, you will need to talk to your doctor about another birth control method to use with the *Essure* procedure during this time. During this 3-month period, intrauterine devices (IUDs) and intrauterine systems (IUSs) cannot be used.
- You will need to have a special type of x-ray test called an HSG 3 months after your *Essure* procedure. This test confirms two things. It verifies whether both of your *Essure* micro-inserts are in the correct location and whether both of your fallopian tubes are blocked.
- If you rely on the *Essure* micro-inserts for birth control before you complete the HSG test, you may get pregnant or have an ectopic pregnancy.

Not all women who have the *Essure* procedure will achieve successful placement of both micro-inserts.

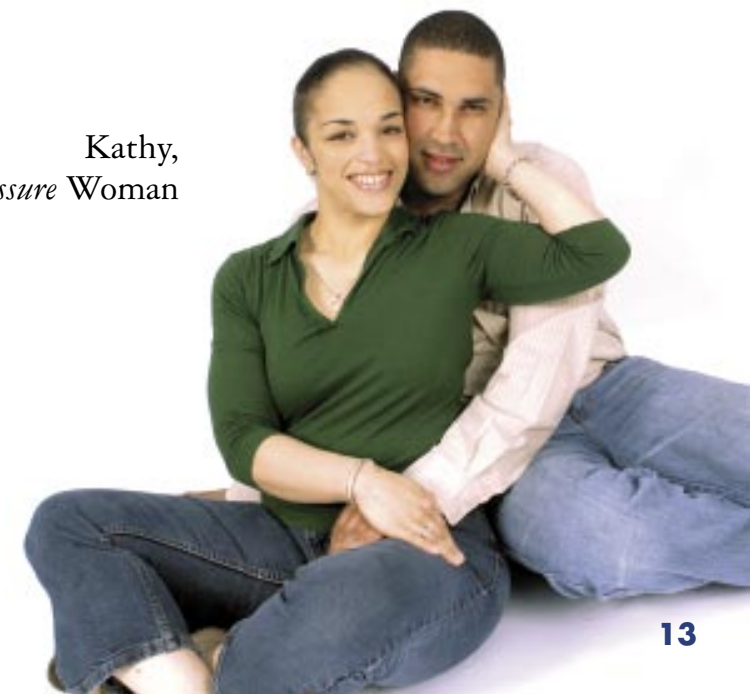
- Approximately 1 out of 7 women were not able to have one or both of the micro-inserts placed.
- One or both of the *Essure* micro-inserts may not be in the right place or may fail to block the fallopian tubes by 3 months after the procedure. As a result, you may not be able to rely on the micro-inserts for birth control.
- A small percentage of women had fallopian tubes that were not fully blocked until 6 months after the *Essure* procedure.

If any of these situations occur, a woman can talk to her doctor about a second *Essure* procedure or confirmation test (HSG).

Important

- The *Essure* micro-inserts do not protect against HIV or other sexually transmitted diseases.
- If at any time you think you are pregnant, see a doctor immediately to help rule out the possibility that you have an ectopic pregnancy.

Kathy,
Essure Woman



As with all procedures, there are risks associated with the *Essure* procedure.

You should be well informed about these risks and discuss them in detail with your doctor before you make your decision. Below are complications that may occur during the *Essure* procedure.

- In the clinical studies, most women reported mild to moderate pain during the *Essure* micro-insert procedure.
- Rarely in the clinical studies, a portion of the *Essure* micro-insert broke off during the procedure.
- Women who have the *Essure* procedure or any other sterilization procedure during the second half of their menstrual cycle (after ovulation) are at an increased risk of being pregnant at the time of the procedure.
- Anesthesia (medicine to control sensation or consciousness) is used during the *Essure* procedure. Discuss with your doctor the risks of the anesthesia method recommended for you. Note that the *Essure* procedure doesn't require general anesthesia, which has a higher risk than other types of anesthesia.
- A small percentage (1.8%) of women in the clinical studies experienced tubal perforations related to *Essure* micro-insert placement. Most of these women underwent laparoscopic sterilization and about half had the devices removed. If it is necessary to remove *Essure* micro-inserts that perforate the uterus or fallopian tubes, major surgery may be required.

Below are complications that may occur after the *Essure* procedure:

- Many women reported mild to moderate pain and/or cramping and vaginal bleeding for a few days after the procedure.
- Some women in the clinical studies reported nausea and/or vomiting or fainting following the procedure.
- For a small percentage (2.9%) of women in the clinical studies the micro-inserts came out of the body (expulsion).
- Rarely, women in the clinical studies absorbed too much of the fluid used to expand the uterus during the procedure. If this condition occurs, it should be treated immediately to prevent serious complications.
- Some women in the clinical studies reported one or more episodes of pelvic, back, or abdominal pain.
- Problems with the HSG test are rare, but may include infection, spotting, and allergic reaction to the dye. You should also be aware that you will be exposed to very low levels of radiation.

Questions for Your Doctor

Choosing permanent birth control is an important decision. As you consider having the *Essure* procedure, here are some questions you might ask your doctor.

- Where will my *Essure* procedure be performed?
- What type of anesthesia will be used during my procedure?
- What do I need to do to prepare for the procedure?
- When is the best time of the month to schedule my procedure based on my menstrual cycle?
- What are my options if both micro-inserts cannot be placed on the first attempt?
- Can I continue to use my current method of birth control until my HSG confirmation test?
- Who will perform the HSG?



Tia,
Essure Woman

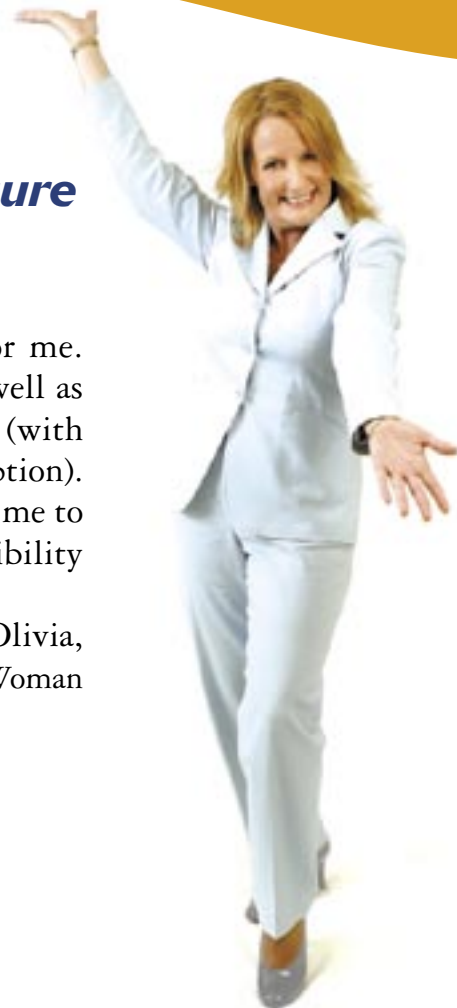
Future Medical Care

After having the *Essure* procedure you will be given a patient identification card. You should keep this card with you at all times and show it to your doctors when discussing your medical care. Your doctor should be aware that you have the *Essure* micro-inserts in place before performing procedures that involve your uterus or fallopian tubes. Make sure your doctor knows you have micro-inserts before you undergo an MRI, a D&C, hysteroscopy, endometrial biopsy, or endometrial ablation. The *Essure* micro-inserts are MRI-safe but may cause an obscure image of tissue near or at the micro-inserts.

What Women Say About *Essure*

Essure was simply the only valid choice for me. *Essure* offered me everything I required, as well as the added bonus of very little recovery time (with 2 toddlers, this was an extremely attractive option). I love the complete freedom *Essure* has given me to move forward and no longer revisit the possibility of pregnancy.

—Olivia,
Essure Woman



I felt there were many positive benefits of the *Essure* procedure. I was happy there was no cutting, no pain, no scars, no uncomfortable gas, and same day recovery. I have been recommending the *Essure* procedure to all of my friends and they are all amazed when I tell them about it.

—Mari,
Essure Woman

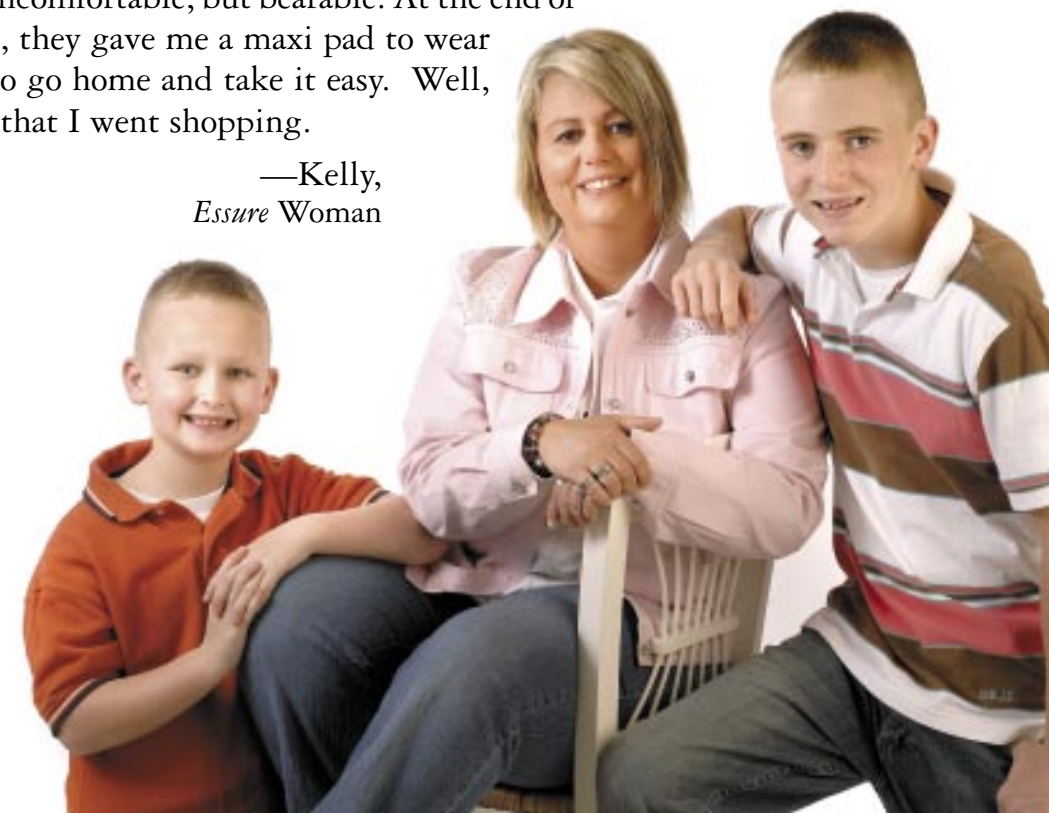


I didn't want to keep taking birth control pills, so we decided my husband would have a vasectomy. I made an appointment with an Ob/Gyn who performed vasectomies. At the consultation, he was very informative of the *Essure* procedure. He made it perfectly clear that he was not trying to change our minds, but that *Essure* was less invasive and had less recovery time than a vasectomy. After thinking it over, my husband and I decided that the *Essure* procedure was the way to go for us.

—Angie,
Essure Woman

In the consultation, my doctor explained everything quite clearly and I decided *Essure* was right for me. I went to his office for the procedure and the whole thing took approximately 45 minutes. There was no general anesthesia, only the local numbing of the cervix. The actual procedure was slightly uncomfortable, but bearable. At the end of the procedure, they gave me a maxi pad to wear and told me to go home and take it easy. Well, I felt so good that I went shopping.

—Kelly,
Essure Woman



Glossary

- **Anesthesia:** Medically induced partial or complete loss of sensation, in all or part of the body, with or without loss of consciousness. General anesthesia is total loss of consciousness and sensation.
- **Cervix:** The passageway that connects the vagina to the uterus.
- **Contraceptive:** Any process, device, or method that reduces the likelihood of pregnancy.
- **Delivery Catheter:** A long tubelike device that helps the doctor place the *Essure* micro-inserts in the fallopian tubes.
- **Ectopic Pregnancy:** The development of a fertilized egg outside of the uterus, but inside the body.
- **Expulsion:** Forcing (expelling) something out.
- **Fallopian Tubes:** The tubes that carry the eggs from the ovaries to the uterus.
- **Hysterosalpingogram (HSG):** An x-ray of the uterus and fallopian tubes after they have been filled with dye (contrast medium).
- **Hysteroscope:** A telescope-like instrument that is used to view the inside of the uterus.
- **In Vitro Fertilization (IVF):** Fertilization of an egg outside of the body, followed by placement of the fertilized egg into the uterus.
- **Intrauterine Device (IUD)/Intrauterine System (IUS):** A medical device that is put into the uterus to prevent pregnancy.
- **Local Anesthetic:** Medicine that is applied to or injected in a certain spot in the body to cause a loss of sensation in that part of the body.
- **Major Surgery:** A procedure that requires general anesthesia and incisions in the body.
- **Micro-insert:** A small, flexible, coil-type device that is put into your fallopian tube for permanent pregnancy prevention.
- **Occlusion:** A closed or blocked part of a hollow tube.
- **Perforation:** Creation of a hole.
- **Permanent:** Not able to change back and forth.
- **Reversible:** Able to change back and forth.
- **Tubal Ligation:** Permanent female sterilization by means of cutting, tying, burning, or clipping the fallopian tubes.
- **Uterus:** The womb in which a developing fetus grows.
- **Vasectomy:** Permanent male sterilization by means of cutting or blocking a segment of the vas deferens (the tubes that carry the sperm).