When your family is complete, ask your doctor about Essure® permanent birth control.

Important Safety Information

WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device.

Important Safety Information continued on next page.
Indication

Essure® is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.

Important Safety Information, continued

Essure is not right for you if you are uncertain about ending your fertility, suspect you are pregnant, can have only one insert placed, have had your tubes tied, have a known allergy to contrast dye, are unwilling to undergo the Essure Confirmation Test, have unexplained vaginal bleeding, or have suspected or known cancer of the female reproductive organs.

Please see Important Safety Information on pages 10-15.

What is Essure?

Essure is a permanent birth control procedure that works with your body to prevent pregnancy

- **Minimally Invasive Procedure**- Essure placement requires no cutting, leaves no visible scars, and can be performed in your doctor’s office.

- **No General Anesthesia Required**- You can remain fully conscious during the procedure. Your doctor may recommend a medication to reduce anxiety and/or use a local (numbing) anesthetic to reduce potential discomfort.

- **Non-Hormonal**- For patients who prefer or need non-hormonal birth control, Essure inserts do not contain or release hormones.

- **Return to Normal Activity within 1 to 2 days**- The majority of women (60%) return to normal activity within 1 day or less, and more than 75% return to normal activities within 2 days.

- **Short Placement Time**- Total procedure time on average is 36 minutes. In the most recent clinical study, over 96% of women were able to have both inserts placed at the first attempt.

- **Highly Effective**- The Essure procedure is 99.3% effective at preventing pregnancy in patients who were told to rely on Essure for birth control (based on first year reliance in the most recent clinical study).
**How does Essure work?**

Essure works with your body to create a natural barrier against pregnancy. Over a period of about 3 months, your body creates a natural barrier around the Essure inserts, which prevents pregnancy by blocking sperm from reaching eggs. While this natural barrier forms, you **must** continue using another form of birth control to prevent pregnancy.

**Shape**

The Essure inserts are designed to bend and conform to the shape of your body while remaining securely in place.

**Placement**

Your doctor will permanently place a small Essure insert into each of your fallopian tubes. These soft, flexible inserts are inserted through the natural pathways of your vagina and cervix so no incisions are needed for placement.

**Material**

The inserts are made from polyester fibers, nickel-titanium, platinum, silver-tin and stainless steel. These same materials have been used in cardiac stents and other medical devices placed in other parts of the body.

Patients with a known hypersensitivity to any of the materials listed above may experience an allergic reaction to the insert. This includes patients with a history of metal allergies. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Some women using Essure have reported symptoms that could be linked to an allergic reaction. Symptoms of an allergic reaction may include hives, rash, swelling and itching. There is no reliable test to predict who may develop a reaction to the inserts.

Please see Important Safety Information on pages 10–15.
The Essure procedure can be done right in your doctor’s office and placement doesn’t require cutting or incisions or the use of general anesthesia. You can remain fully conscious during the procedure. Your doctor may recommend a medication to reduce anxiety and/or use a local (numbing) anesthetic to reduce potential discomfort. Total procedure time on average is 36 minutes. Most women are able to leave the office about 45 minutes after their procedure and the majority of women return to normal activity within 1-2 days.

1 Placing the Essure inserts

Your doctor will permanently place a soft and flexible insert into each of your fallopian tubes. No incisions are needed because the inserts are placed through the natural pathway of your vagina and cervix.

2 Formation of the natural barrier

Over the next 3 months, your body forms a natural barrier around the Essure inserts that prevents sperm from reaching your eggs. During the 3-month period, you must continue using another form of birth control to prevent pregnancy.

Since Essure does not contain hormones that interfere with your body’s menstrual cycle, your ovaries will continue to release eggs. Since the eggs cannot be fertilized, they are simply absorbed back into your body.

Please see Important Safety Information on pages 10–15.
Three months after your Essure procedure, you will need to have an Essure Confirmation Test to determine if you can rely on Essure for birth control. Your doctor will advise you on the type of test that is right for you. You may have an ultrasound test that verifies that your Essure inserts are in the correct location, or, your doctor may recommend a test that uses contrast dye and a special type of x-ray to determine both that your inserts are in the correct location and that your fallopian tubes are blocked. In some cases, it may be necessary to have both tests.

IMPORTANT: FOR SOME WOMEN, IT MAY TAKE LONGER THAN 3 MONTHS FOR ESSURE TO COMPLETELY BLOCK THE FALLOPIAN TUBES, REQUIRING A REPEAT CONFIRMATION TEST AT 6 MONTHS. YOU MUST SEE YOUR DOCTOR FOR THE ESSURE CONFIRMATION TEST BEFORE YOU CAN RELY ON ESSURE FOR BIRTH CONTROL. YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY UNTIL YOUR DOCTOR TELLS YOU THAT YOU CAN RELY ON ESSURE FOR BIRTH CONTROL.

What potential risks may occur during the procedure?

- You may experience mild to moderate pain.
- Your doctor may be unable to place one or both Essure inserts correctly.
- In rare cases, part of an Essure insert may break off during placement. Your doctor will remove the piece if appropriate.
- There is a risk of perforation of the uterus or fallopian tube by the hysteroscope, Essure system or other instruments used during the procedure. In the original premarket studies, perforation due to the Essure insert occurred in 1.8% of women. A perforation may lead to bleeding or injury to bowel or bladder, which may require surgery.
- Your body may absorb a large amount of the salt water solution used during the procedure.
- Your doctor may recommend a local anesthesia, which numbs the cervix. Ask your doctor about the risks associated with this type of anesthesia.
When you know your family is complete, you may be ready to consider permanent birth control. Essure can help you stop worrying about an unplanned pregnancy.

Essure may be right for you if:

- You are certain you do not want any more children.
- You desire permanent birth control.
- You would like to stop worrying about getting pregnant.
- You prefer a method or procedure that:
  - Does not take a lot of time.
  - Can be done in your doctor’s office.
  - Does not require cutting and leaves no visible scars.
  - Does not contain hormones.

Essure is NOT right for you if:

- You are uncertain about ending your fertility.
- You suspect you are pregnant.
- You have only one fallopian tube.
- You have one or both fallopian tubes closed or obstructed.
- You have had your “tubes tied” (tubal ligation).
- You are allergic to contrast dye used during x-ray exams.
- You are unwilling to undergo the Essure Confirmation Test.
- You have unexplained vaginal bleeding.
- You have suspected or known cancer of the female reproductive organs.

You should wait to have the Essure procedure if:

- You are or have been pregnant within the past 6 weeks.
- You have an active gynecological infection.
- You are in the second half (weeks 3 and 4) of your menstrual cycle. During that time there is an increased risk of being pregnant prior to having the Essure procedure.

Please see Important Safety Information on pages 10–15.
You should speak to your doctor if:

- You are taking or receiving therapy that suppresses your immune system. Examples include chemotherapy or corticosteroids, such as prednisone. Therapy that suppresses the immune system may make the Essure procedure less effective for birth control.
- You have, or think that you may have, a history of metal allergies, or an allergy to polyester fibers, nickel-titanium, platinum, silver-tin, or stainless steel or any other components of the Essure system.
- You are currently using an IUD for contraception.
- If you have already had, or are considering a procedure to reduce bleeding from the uterus (such as endometrial ablation) tell your doctor as it may affect the Essure procedure.
  - The ablation procedure should not be performed on the same day as your Essure placement procedure.
  - If you have Essure placed, your doctor must confirm that it is in a satisfactory location (via the Essure Confirmation Test) before performing an ablation procedure.

Talk to your doctor about Essure and whether it is right for you.

Refer to the Patient-Doctor Discussion Checklist in the Patient Information Booklet and review it with your doctor.

IMPORTANT: Essure inserts do not protect against HIV or other sexually transmitted diseases.

Prescription Only.
Take a look at some commonly asked questions and safety information about Essure®. There’s more information on our website at essure.com.

**How effective is Essure?**

The Essure procedure is 99.3% effective at preventing pregnancy in patients who were told to rely on Essure for birth control.*

**Is the Essure procedure painful?**

There may be some pain associated with placing Essure. Some women report mild to moderate discomfort, pain, and cramping, during or after the placement procedure. Symptoms may be similar to what they might experience in their normal monthly cycle. There are reports of chronic pelvic pain in women, possibly related to Essure. In these cases, it may be necessary to remove the insert.

**How long is the recovery?**

The majority of women (60%) return to normal activity within 1 day or less and more than 75% return to normal activities within 2 days.

**Is Essure reversible?**

No, the Essure procedure is not reversible. Like having your tubes tied or a vasectomy, Essure is permanent birth control. You need to be sure you are done having children before you decide to have the Essure procedure.

**Will I still get my period?**

Yes, you will still have a period. Some women find that their period may become slightly lighter or heavier after their procedure. These changes are often temporary. They may also be due to stopping your previous hormonal birth control, rather than the Essure procedure.

**Will my partner be able to feel the Essure inserts?**

No, since the Essure inserts are placed in the fallopian tubes (and not in your vagina), your partner will not be able to feel the Essure inserts.

Please see Important Safety Information on pages 10–15.
Is Essure covered by my insurance?

Essure is covered by most health insurance providers, including Medicaid. Essure may be covered by insurance without co-pays, deductibles, or out-of-pocket costs** under the Affordable Care Act. Go to essure.com/aca to learn more.

What are the most common side effects?

In the premarketing study, the most common side effect reported by women was mild to moderate pain during the procedure (9.3%). Some of the women in the study reported moderate pain (12.9%) and/or cramping (29.6%) on the day of the procedure. A smaller percentage of women reported nausea/vomiting (10.8%) and vaginal bleeding (6.8%). Eighty-eight percent of women rated tolerance of the placement procedure as good, very good, or excellent. For additional risk information, please see pages 10-15.

Where can I find more information?

Talk to your doctor to learn more about whether Essure may be right for you. Visit essure.com to see more FAQs, get information about insurance coverage, and even find an Essure-trained doctor near you!

Do I need to have the Essure Confirmation Test?

Yes. The Essure Confirmation Test is an important and necessary step in the Essure procedure. You must continue to use another form of birth control until you have your Essure Confirmation Test and your doctor tells you that you can rely on Essure for birth control.

*Based on first year reliance in the most recent clinical study.
**Some restrictions may apply. Visit essure.com/aca to learn more, or contact your health insurance provider.
Important Safety Information, continued

You should delay having the Essure® procedure if:

• You are or have been pregnant within the past 6 weeks.
• You have an active gynecological infection.
• You are in the second half (weeks 3 and 4) of your menstrual cycle. During that time, there is an increased risk of being pregnant prior to having the Essure procedure.

You should speak to your doctor if:

• You are taking or receiving therapy that suppresses your immune system. Examples include chemotherapy or corticosteroids, such as prednisone. Therapy that suppresses the immune system may make the Essure procedure less effective for birth control.
• You have, or think that you may have, a history of metal allergies, or an allergy to polyester fibers, nickel-titanium, platinum, silver-tin, or stainless steel or any other components of the Essure system.
• You are currently using an IUD for contraception.
• If you have already had, or are considering a procedure to reduce bleeding from the uterus (such as endometrial ablation) tell your doctor as it may affect the Essure procedure.
  - The ablation procedure should not be performed on the same day as your Essure placement procedure.
  - If you have Essure placed, your doctor must confirm that it is in a satisfactory location (via the Essure Confirmation Test) before performing an ablation procedure.

Talk to your doctor about Essure and if it is right for you. Refer to the Patient-Doctor Discussion Checklist in the Patient Information Booklet and review it with your doctor.

IMPORTANT: Essure inserts do not protect against HIV or other sexually transmitted diseases.

Prescription only.
WARNING: You must continue to use another form of birth control until you have your Essure Confirmation Test and your doctor tells you that you can rely on Essure for birth control.

• You can rely on Essure for birth control only after your doctor has reviewed your Essure Confirmation Test results and told you that you can rely. If you rely on Essure for birth control before having your Essure Confirmation Test, you are at risk of getting pregnant.

• Talk to your doctor about which method of birth control you should use for the 3 months after the procedure. Some women can remain on their current birth control.

• It can take longer than three months for the Essure procedure to be effective. In rare cases, it has taken up to 6 months. Make sure to continue using an alternate form of birth control until your doctor has reviewed your Essure Confirmation Test results and confirmed that you can rely on Essure for birth control.

WARNING: Be sure you are done having children before you undergo the Essure procedure. Essure is a permanent method of birth control.

Important Safety Information continued on next page
**Risks: During the Essure® procedure**

- You may experience mild to moderate pain.
- Your doctor may be unable to place one or both Essure inserts correctly.
- In rare cases, part of an Essure insert may break off during placement. Your doctor will remove the piece, if appropriate.
- There is a risk of perforation of the uterus or fallopian tube by the hysteroscope, Essure system or other instruments used during the procedure. In the original premarket studies, perforation due to the Essure insert occurred in 1.8% of women. A perforation may lead to bleeding or injury to bowel or bladder, which may require surgery.
- Your body may absorb a large amount of the salt water solution used during the procedure.
- Your doctor may recommend a local anesthesia, which numbs the cervix. Ask your doctor about the risks associated with this type of anesthesia.

**Risks: Immediately following the procedure**

- You may experience mild to moderate pain and/or cramping, vaginal bleeding, and pelvic or back discomfort for a few days after the procedure. Some women experience headaches, nausea and/or vomiting or dizziness and/or fainting. You should arrange to have someone available to take you home after the procedure.
- In rare instances, an Essure insert may be expelled from the body. This is usually detected during the Essure Confirmation Test.
Risks: During the Essure Confirmation Test

- Because one of the Essure Confirmation Tests (a modified HSG) requires an x-ray, you may be exposed to very low levels of radiation if an x-ray is performed. This is standard with most x-rays.

- The following additional risks are associated with the modified HSG: some women may experience nausea and/or vomiting, dizziness and/or fainting, cramping, pain or discomfort. In rare instances, women may experience spotting and/or infection.

Risks: Long-term

- Pain (acute or persistent) of varying intensity and length of time may occur and continue following Essure placement. Women with a history of pain prior to placement of Essure are more likely to experience both acute and persistent pelvic pain following Essure placement. In addition to pain associated with Essure, unrelated gynecological (for example: endometriosis, adenomyosis) or nongynecological (for example: irritable bowel syndrome, interstitial cystitis) conditions may result in pain. Contact your doctor if you are experiencing significant pain or if the pain persists.

- There are reports of an Essure insert being located in the lower abdomen and pelvis. If this happens, you cannot rely on Essure for birth control and surgery may be necessary to remove the insert.

Important Safety Information continued on next page
Risks: Long-term, continued

• Patients with known hypersensitivity to polyester fibers, nickel, titanium, stainless steel (iron, chromium nickel), platinum, silver-tin and or any of the components of the Essure® system may experience an allergic reaction to the insert. This includes patients with a history of metal allergies. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Symptoms reported in women using Essure that may be associated with an allergic reaction include hives, rash, swelling and itching. There is no reliable test to predict who may develop a reaction to the inserts.

• If you and your doctor decide that the inserts should be removed after placement, surgery will be necessary. This may include looking in the uterus (hysteroscopy), removal of the insert alone, removal of the insert with the fallopian tube, and/or, in complicated cases, removal of the uterus (hysterectomy). The doctor who placed Essure may not be the doctor performing the removal.
• No birth control method is 100% effective. There is a chance that you can become pregnant after completing the Essure procedure. In the most recent clinical trial, three women out of 503 (0.6%) became pregnant within the first year of relying on Essure. While successful pregnancies with healthy deliveries have been reported with Essure devices in place, there have been reports of pregnancy loss, pre-term labor, premature delivery, stillbirth, neonatal complications, and genetic and developmental abnormalities in pregnancies with Essure. You should contact your doctor immediately if you think you may be pregnant.

• Ectopic pregnancies may occur with Essure. Ectopic pregnancy is when the pregnancy occurs outside of the uterus. The pregnancy usually happens in one of the fallopian tubes. Ectopic pregnancies can be very serious or life threatening.

• If you have endometrial ablation, a procedure that removes the lining of the uterus to lighten or stop menstrual bleeding, after the Essure procedure, it is unknown if this will affect the blockage in your tubes, and effect your risk of pregnancy.

Essure does not protect against HIV or other sexually transmitted diseases.

Prescription Only.

Talk to your doctor about Essure and whether it is right for you.

Please see Important Safety Information on pages 10–15.
If you know your family is complete...

Ask your doctor about Essure

Essure is the only permanent birth control that does not require cutting or incisions for placement. And, it may be covered by your insurance plan, including Medicaid under the Affordable Care Act!*

Notes:

Visit essure.com to learn more

• Get information about insurance coverage
• Find an Essure-trained doctor near you

Call 877-ESSURE-1 to speak to an Essure counselor or find an Essure-trained doctor in your area.

Please see Important Safety Information on pages 10-15.

*Some restrictions may apply.