

About Essure®

Indication

Essure is a permanent birth control procedure that works with your body to create a natural barrier against pregnancy.

Important Safety Information

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. Your doctor will confirm that the inserts are properly placed and both of your fallopian tubes are blocked. 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. Other women, such as those using an intrauterine device or contraceptive (IUD or IUC), will need to switch to another method
- 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 up until your doctor has reviewed your Essure Confirmation Test results and confirmed that you can rely on Essure for birth control

What is Essure?

Essure is the only non-surgical permanent birth control available.

- Non-surgical—Essure is a short 10-minute procedure that can be performed right in your doctor's office. There's no downtime to recover—most women go home within 45 minutes and resume normal activities in 1-2 days
- Proven—Essure is 99.83% effective*
- Non-hormonal—Essure inserts do not contain or release hormones
- May be available at no cost—Essure may be covered by your health insurance plan at no cost†
- FDA-approved and available for over 10 years

What makes Essure effective?

Shape

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

Over time, Essure works with your body to form a natural barrier that keeps sperm from reaching the eggs, preventing pregnancy. While the natural barrier forms, another form of birth control must be used.

Placement

The soft, flexible Essure inserts are designed to be placed through the natural pathways of your vagina and cervix so no incisions are needed.

Material

The Essure inserts do not contain hormones and are made from some of the same material that is used in heart stents and other medical devices.

The Essure insert is made of materials that include a nickel-titanium alloy. Patients who are allergic to nickel may have an allergic reaction to the inserts. Symptoms include rash, itching, and hives.

*Based on 5-year clinical study data.

† Some restrictions may apply. Visit essure.com/aca to learn more or contact your health insurance provider.

What's the Essure procedure like?

The Essure procedure takes about 10 minutes. There's no downtime to recover—most women go home 45 minutes after the procedure and resume normal activities within 1-2 days.

1. Placing the Essure inserts



The Essure procedure can be performed in your doctor's office. During the procedure your doctor will 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. The barrier prevents the sperm from reaching your eggs. During the 3-month period, you must continue using another form of birth control to prevent pregnancy while this barrier forms.

3. Essure Confirmation Test



After 3 months, a doctor administers the Essure Confirmation Test using contrast dye and a special X-ray test. The test confirms that the inserts are placed correctly, your fallopian tubes are blocked, and that you can start relying on Essure to prevent pregnancy. Until you receive confirmation from your doctor, you must continue to use another form of birth control to prevent pregnancy.

Essure inserts do not contain hormones, so you'll continue to have your normal period and your ovaries will continue to release eggs. Since the eggs cannot be fertilized, they are simply absorbed back into your body.

During the procedure, potential risks may include:

- You may experience mild to moderate pain
- Your doctor may be unable to place one or both Essure inserts correctly
- Your body may absorb a large amount of the salt water solution that is used during the insertion
- Your doctor may recommend a local anesthetic which numbs the cervix. Ask your doctor about the risks associated with this type of anesthesia
- In rare cases, part of an Essure insert may break off or puncture the fallopian tube requiring surgery to repair the puncture

Is Essure right for you?

When you know your family is complete, you may be ready to consider a permanent birth control. Essure can help you stop worrying about an unplanned pregnancy.

Essure might be right for you if:

- You are certain you do not want any more children
- You desire permanent birth control
- You prefer a method or procedure that:
 - Does not require surgery or general anesthesia
 - Does not take a lot of time
 - Does not contain hormones

Essure is NOT right for you if:

- 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 are uncertain about ending your fertility

Before scheduling your Essure procedure, make sure you:

- Are not or have not been pregnant within the past 6 weeks
- Have not had a recent pelvic infection
- Are not 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
- Are not 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

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

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

Frequently asked questions

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?

Essure is 99.83% effective.*

*Based on 5-year clinical study data.

Is the Essure procedure painful?

Some women report mild discomfort, pain, or cramping, similar to a normal monthly cycle during or after the procedure.

How long is the recovery?

Most women go home within 45 minutes of the Essure procedure and return to normal activities within 1-2 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 your normal menstrual period.

Some women report slightly lighter or heavier bleeding after the procedure, but these changes might be the result of discontinuing hormone-based birth control and returning to your normal cycle.

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.

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 Women's Preventive Services provision of the Affordable Care Act. Go to essure.com/aca to learn more.

† Some restrictions may apply. Visit essure.com/aca to learn more or contact your health insurance provider.

What are the most common side effects?

During the procedure, the most common problem reported was mild to moderate pain (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%). For additional Important Safety Information, please see essure.com/safety.

Where can I find more information?

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

Please see the following page for more frequently asked questions.

Frequently asked questions, continued

What are the potential risks of Essure?

During the procedure:

- You may experience mild to moderate pain, your doctor may be unable to place one or both Essure inserts correctly, part of an Essure insert may break off or puncture the fallopian tube requiring surgery to repair the puncture, or your body may absorb a large amount of the salt water solution. Your doctor may recommend a local anesthesia which numbs the cervix. Ask your doctor about the risks associated with this type of anesthesia

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. Some women experience nausea and/or vomiting or fainting. In rare instances, an Essure insert may be expelled from the body

During the Essure Confirmation Test:

- You will be exposed to very low levels of radiation, as with most x-rays. In rare instances, women may experience spotting and/or infection

What are the potential long-term risks?

- There are rare reports of chronic pelvic pain in women who have had Essure
- In rare instances, an Essure insert may migrate through the fallopian tubes into the lower abdomen and pelvis. It may be necessary to surgically remove the migrated device if the patient is experiencing an adverse event
- No birth control method is 100% effective. If you do become pregnant after Essure, the risks to you, the fetus, the pregnancy and childbirth are unknown
- Women who have the Essure procedure are more likely to have an ectopic pregnancy if they get pregnant. Ectopic pregnancy is when the pregnancy occurs outside of the uterus. Ectopic pregnancies can be very serious or life threatening
- If you have the NovaSure[®] procedure, a procedure that removes the lining of the uterus to lighten or stop menstrual bleeding, after the Essure procedure, your risk of pregnancy may increase
- The Essure insert is made of materials that include a nickel-titanium alloy. Patients who are allergic to nickel may have an allergic reaction to the inserts. Symptoms include rash, itching and hives

Unknown risks:

- The safety and effectiveness of Essure has not been established in women under 21 or over 45 years old
- The safety and effectiveness of reversing the Essure procedure are not known
- The safety and effectiveness of in vitro fertilization (IVF) after the Essure procedure are not known
- The risks to you and your fetus if you get pregnant after the Essure procedure are not known

WARNING: Be sure you are done having children before you undergo the Essure procedure. Essure is a permanent method of birth control. The younger a woman is when she chooses to end her fertility, the more likely she is to regret her choice later.

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

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