



The Essure Confirmation Test

essure[®]

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Please see Boxed Warning and Important
Safety Information throughout this booklet

What is the Essure Confirmation Test?

Three months after you have the Essure procedure, you will need to have the 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 a transvaginal ultrasound test (TVU) 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 called a hysterosalpingogram, or modified HSG, 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.

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.

Important Safety Information

Indication

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

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.

2 Please see additional Important Safety Information on pages 6-7.

Why do I need the Essure Confirmation Test?

After getting Essure placed, it usually takes about 3 months for your body to form a natural barrier around the inserts.

However, it could take longer. That's why **you need this test**. The Essure Confirmation Test verifies whether you can rely on Essure for birth control.



Important Safety Information

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 additional Important Safety Information on pages 6-7.

How do the tests work?

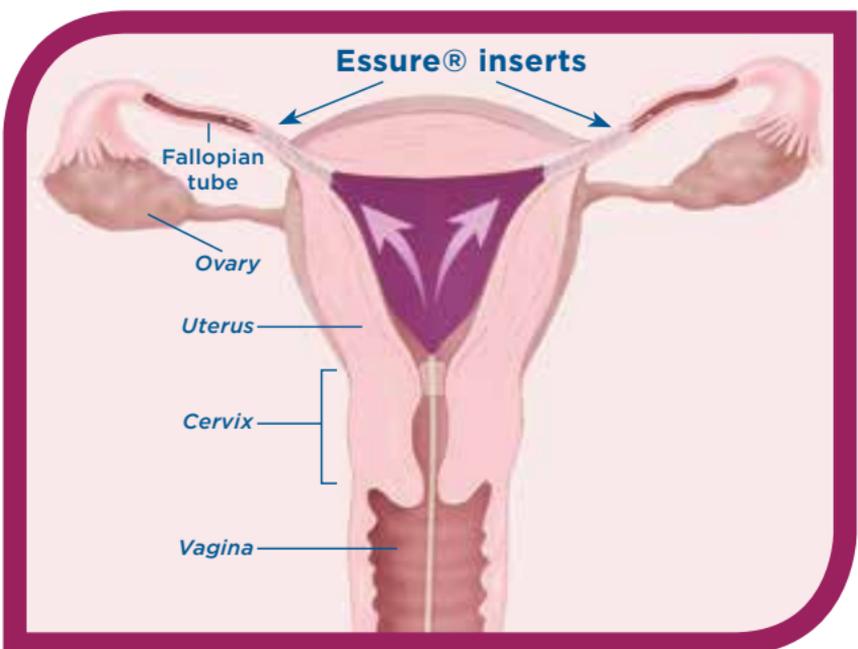
Transvaginal ultrasound (TVU)

- During this test, an ultrasound device will be placed in your vagina
- The ultrasound will enable your doctor to see the Essure inserts within your fallopian tubes and determine if the inserts are in the proper place
- If the doctor is unable to determine if the inserts are in the proper place with the TVU, he/she will need to order an additional confirmation test using an x-ray and contrast dye (see below)
- If you have experienced unusual post-procedure pain or have undergone treatment that suppresses your immune system such as chemotherapy or use of corticosteroids such as prednisone, talk to your doctor before scheduling the Essure Confirmation Test. The TVU test is not appropriate for you

X-ray exam (modified HSG)

- Just as during a routine Pap smear, a speculum will be placed in your vagina
- A special type of contrast dye that is visible on X-rays is passed through your cervix into your uterus

(continued on next page)



- Using an x-ray, the doctor will determine if the Essure® inserts are in the correct location and confirm that dye can't flow through your tubes and your tubes are blocked
- if your doctor confirms that the inserts are in the correct location and the tubes are blocked, you may rely on Essure for birth control

Until you receive this confirmation from your doctor, you must use another form of birth control to prevent pregnancy.

Please discuss any questions you may have about the Essure Confirmation Test, or any aftercare you may need, with your doctor.

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.



Important Safety Information (cont'd)

You should delay having the Essure procedure if you are or have been pregnant within the past 6 weeks, have an active gynecological infection, or are in the second half of your menstrual cycle.

Tell your doctor if you are taking immunosuppressants, 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, are currently using an IUD for contraception, or have had or are considering a procedure to reduce bleeding from the uterus such as endometrial ablation.

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

WARNING: You must continue to use another form of birth control until you have your Essure Confirmation Test (3 months after the procedure) and your doctor tells you that you can rely on Essure for birth control. For some women, it may take longer than 3 months for Essure to be effective, requiring a repeat confirmation test at 6 months. Talk to your doctor about which method of birth control you should use during this period. If you rely on Essure for birth control before receiving confirmation from your doctor, you are at risk of getting pregnant.

During the Procedure: In the premarketing study, some women experienced mild to moderate pain (9.3%). 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. If breakage occurs, 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 doctor may recommend a local anesthesia. Ask your doctor about the risks associated with this type of anesthesia.

Important Safety Information (cont'd)

Immediately Following the Procedure: In the premarketing study, some women experienced mild to moderate pain (12.9%) and/or cramping (29.6%), vaginal bleeding (6.8%), and pelvic or back discomfort for a few days. Some women experience headaches, nausea and/or vomiting (10.8%), or dizziness and/or fainting. You should arrange to have someone take you home after the procedure. In rare instances, an Essure insert may be expelled from the body.

During the Essure Confirmation Test: As one of the Essure Confirmation Tests (a modified HSG) requires an x-ray, you may be exposed to very low levels of radiation, as with most x-rays, if this test is used. 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.

Long-term Risks: Pain (acute or persistent) of varying intensity and length of time may occur and continue following Essure placement. This is also more likely to occur in women with a history of pain. There are reports of an Essure insert being located in the lower abdomen and pelvis. If this occurs, you cannot rely on Essure for birth control. Patients with known hypersensitivity to any of the components of the Essure system may experience an allergic reaction to the insert. 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. No birth control method is 100% effective. Ectopic pregnancies (pregnancy outside the uterus) may occur with Essure. This can be life-threatening. If insert removal is indicated, surgery will be necessary.

The safety and effectiveness of Essure has not been established in women under 21 or over 45 years old.

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. Review the Patient-Doctor Discussion Checklist in the Patient Information Booklet with your doctor before deciding to have the Essure procedure.

Additional information

Other information or instructions from your doctor about your Essure Confirmation Test:

Notes:

Be sure to schedule your appointment for 3 months after your Essure procedure. Remember, until you receive confirmation from your doctor, you must continue to use another form of birth control to prevent pregnancy.

ESSURE CONFIRMATION TEST APPOINTMENT

Date _____ Time _____

Doctor name _____

Location _____

Phone _____

