# Patient Information Booklet

When you're done having children, consider Essure permanent birth control.

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

You should read the Patient-Doctor Discussion Checklist at the end of this document. Reviewing and completing the checklist is an important step in helping you decide whether or not to have Essure implanted.

**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 of Permanent Birth Control during discussion of the benefits and risks of the device.**

Your complete guide
to the Essure procedure

essure

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## Glossary

Anesthesia: Medically-induced partial or complete loss of sensation in all or part of the body. Loss of sensation may occur with or without loss of consciousness.

Cervix: The passageway that connects the vagina with the uterus.

Contraceptive: Any process, device, or method that reduces the likelihood of pregnancy.

Ectopic Pregnancy: The development of a fertilized egg outside the uterus, such as in a fallopian tube. Ectopic pregnancies can be dangerous and possibly life threatening.

Endometrial Ablation: A procedure that removes the lining of the uterus to lighten or stop your periods.

Essure® Insert: The small, soft, flexible device that is placed in your fallopian tubes for permanent pregnancy prevention.

Fallopian Tubes: The tubes that carry the eggs from the ovaries to the uterus.

General Anesthesia: Medication that induces total loss of consciousness and sensation.

Hysteroscope: An instrument that is passed through the vagina and cervix to view the inside of the uterus.

In Vitro Fertilization (IVF): Fertilization of an egg outside the body. Once fertilized, the egg is placed into the uterus.

Local Anesthetic: Medication that is applied or injected to numb a certain part of the body.

Modified Hysterosalpingogram (modified HSG): An x-ray of the uterus and fallopian tubes after contrast dye has been given for the Essure Confirmation Test.

Occlusion: An obstruction or a closure of a passageway or a vessel.

Transvaginal Ultrasound (TVU): A test used to look at a woman's reproductive organs. An ultrasound device is placed into the vagina, and sound waves are used to see the uterus and fallopian tubes.

Tubal Ligation: A form of permanent birth control by means of cutting, tying, burning or clipping the fallopian tubes so that they are blocked.

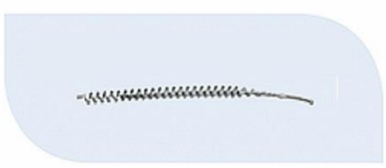
Uterus: The womb, where a developing fetus grows.

Vasectomy: Permanent birth control for men that involves cutting or blocking a segment of the vas deferens (the tubes that carry the sperm).

## What is Essure® (Essure)?

Essure is a permanent birth control procedure that works with your body to create a natural barrier against pregnancy. The Essure procedure involves placing soft, flexible inserts into your fallopian tubes. Over a period of about three months, tissue forms around the inserts. The build-up of tissue creates a barrier that keeps sperm from reaching the eggs and prevents conception.

Essure was approved in 2002 by the FDA. Over 750,000 women and their doctors have chosen Essure for permanent birth control (based on units sold worldwide).



Essure Insert

## Essure may be right for you if:

- You are certain you do not want any more children.
- You desire a permanent form of 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 any 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 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 this booklet and review it with your doctor.**

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

## The benefits of Essure

**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 placement attempt.

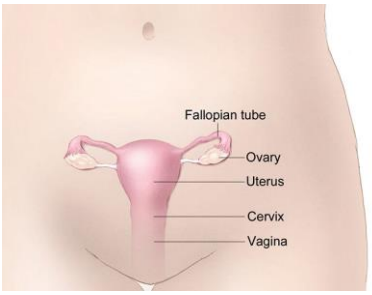
**Benefit of Confirmation**

An Essure Confirmation Test will verify if both inserts are placed correctly and whether you can rely on Essure for birth control. In the most recent clinical study, 92% of women who had placement attempted were told to rely on Essure for birth control.

**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).

## Essure procedure overview



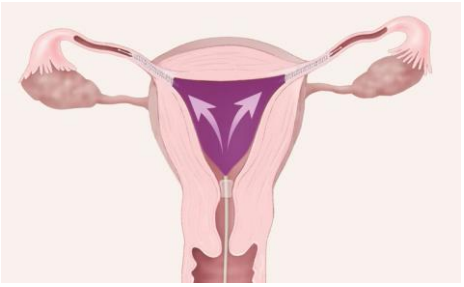

**Step 1: Placing the Essure inserts**

The Essure procedure is usually performed in your doctor's office. During the procedure, the doctor will place a tiny insert into each of your fallopian tubes. The inserts are soft and flexible, and are delivered with a tube through your vagina and cervix, and into your fallopian tubes. No incisions are needed.

**Step 2: Waiting for the natural barrier to form**

Over the next 3 months, your body will form tissue around the Essure inserts. The tissue forms a natural barrier within the fallopian tubes. The barrier prevents sperm from reaching the eggs that are produced every month. 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.



**Step 3: Essure Confirmation Test**

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.

**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.**

## Warnings, Precautions and other Potential Risks

**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.

**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.

**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 (e.g. 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.
- 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.

**Unknown Risks:**

- Other symptoms have been reported to FDA by women implanted with Essure, although they were not seen in the clinical trials supporting Essure approval. The more common symptoms reported include headache, fatigue, weight changes, hair loss and mood changes such as depression. It is unknown if these symptoms are related to Essure or other causes.
- 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. There are limited data related to the effects, including risks, of Essure inserts on in vitro fertilization (IVF).

## Questions to ask your doctor

If you are considering having the Essure procedure, here are some questions you might ask your doctor:

- Is Essure right for me compared to other birth control methods?
- Where will my Essure procedure be performed?
- What type of medications will be used before and/or during my procedure?
- How should I prepare?
- What are my options if both inserts cannot be placed on the first attempt?
- How do I schedule my Essure Confirmation Test?
- Can I continue to use my current method of birth control until I have the results of my Essure Confirmation Test?
- How will having Essure impact future gynecological procedures I may have?

**Talk to your doctor about Essure and if it is right for you. Review the Patient-Doctor Discussion Checklist in this booklet with your doctor before deciding to have the Essure procedure.**

## What to expect with Essure

**Preparing for your procedure**
Your doctor will schedule your Essure procedure for a time soon after your menstrual period ends. This will make it easier for your doctor to see the openings of your fallopian tubes and place the inserts.

**The day of your procedure**
You will take a pregnancy test before or on the day of your procedure. This will ensure you are not pregnant. Your doctor may also give you medication before your procedure to reduce discomfort. Talk to your doctor about the types of medications that are right for you.

**During your procedure**
Your doctor may first insert an instrument called a speculum inside your vagina. The speculum helps the doctor widen the opening of your vagina and see inside. Then your doctor will insert a narrow instrument (hysteroscope) through your cervix and into your uterus. A camera attached to the hysteroscope lets your doctor see the inside of your uterus. A salt water solution is used to expand the uterus. This makes it easier for your doctor to find the openings of your fallopian tubes.

The Essure insert is attached to the end of a small, flexible tube that passes through the hysteroscope and into your fallopian tube. Once the insert is placed, the flexible tube is removed. The procedure is then repeated to place an insert in your other fallopian tube.

The average total procedure time is 36 minutes.

Your doctor will schedule an Essure Confirmation Test to be performed about 3 months after the placement procedure.

**IMPORTANT: Not all women will achieve successful placement of both Essure inserts.** In the most recent clinical study, in only a few instances (about 1 out of 25 women), the doctor was unable to place one or both Essure inserts in the fallopian tubes at the first placement attempt. In some women, a second placement attempt was performed. If this occurs, talk to your doctor.

**After your procedure**
Most women are able to leave the doctor's office about 45 minutes after the procedure is completed. Most return to normal activities within one to two days. Call your doctor if you experience pain, bleeding, fever, abnormal vaginal discharge, or other symptoms following the procedure.

It takes about 3 months (sometimes longer) for your body to produce tissue around the inserts and form a barrier to prevent pregnancy. During that time you can still get pregnant. You must rely on another type of birth control to prevent pregnancy during this time period.

**IMPORTANT: 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.

**The Essure Confirmation Test**
The Essure Confirmation Test verifies that the inserts are in the correct location and sometimes tests whether the tubes are blocked. The Essure Confirmation Test can be a modified HSG or a transvaginal ultrasound (TVU). Your doctor will determine which Essure Confirmation Test is appropriate for you. In some cases, it may be necessary to have both tests.

During the modified HSG, a special contrast dye is injected into your uterus. The dye is visible on x-rays. This lets the doctor confirm that the inserts are properly placed and that your tubes are blocked.

During theTVU, an ultrasound device will be placed into 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, you will need to have a modified HSG.

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, as the TVU test is not appropriate for you.

**Essure patient ID card and procedures after Essure**
After your Essure procedure, you will be given an Essure ID card. The ID card tells doctors and others that you have Essure inserts. Show the card when undergoing any procedure involving your abdomen, pelvis, uterus or fallopian tubes. These include an MRI, D&C, hysteroscopy, endometrial biopsy, or endometrial ablation. Body areas near the inserts may be obscured when they are seen on x-rays, MRIs and other imaging.

**IMPORTANT: Women with Essure inserts who undergo MRI procedures should tell their doctor they have been implanted with Essure inserts.**

## Frequently asked questions

**Can I trust Essure to prevent pregnancy?**
Yes, the Essure procedure is 99.33% effective based on a recent clinical study.

Pregnancies have been reported among the hundreds of thousands of women who have completed the procedure since it became commercially available. Many of those pregnancies were a result of not having completed the procedure (for example not undergoing the Essure Confirmation Test) or not following instructions. In some cases, the Essure Confirmation Test results were misinterpreted by the person reading the test.

**Is Essure 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.

**Is Essure reversible?**
No, the Essure procedure is not reversible. Like having your tubes tied or a vasectomy for men, 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 after the Essure procedure?**
Yes, you will still have a period. Some women find that their period may become slightly lighter or heavier after the procedure. These changes are often temporary. They may also be due to you stopping your previous hormonal birth control, rather than the Essure procedure.

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

**Is Essure covered by my insurance?**
Some or all of the costs of the Essure procedure are covered by most insurance providers. When the Essure procedure is done in a doctor's office, your cost may be as low as the usual co-pay amount for an office visit/procedure. This depends on your insurance plan.

Review your insurance coverage with your doctor and provider before having the procedure. When you speak with your insurance provider, ask for your plan’s specific coverage and reimbursement guidelines for hysteroscopic sterilization (code 58565). This is the code that most plans use to categorize the Essure procedure. Specify if the procedure will be done in a doctor's office, clinic, hospital, etc. The location may affect the amount you will need to cover out of your own pocket.

## How Essure performed in clinical studies

The effectiveness and safety of Essure was measured in clinical studies in the United States, Australia, and Europe. Over 700 women between the ages of 21 and 45 were studied.

**Was Essure effective in preventing pregnancy?**
The primary goal of any birth control method is to prevent pregnancy. Every birth control method has a measured effectiveness rate.

In the most recent clinical trial, three women out of 503 (0.6%) became pregnant within the first year of relying on Essure.

**Was the Essure placement procedure successful?**
In the most recent clinical study, in only a few instances (about 1 out of 25 women), the doctor was unable to place one or both Essure inserts in the fallopian tubes at the first placement attempt. In some women, a second placement attempt was performed. In this study 94% of women with successful placement were told they could rely on Essure for birth control.

**Was the Essure procedure safe?**
In the premarketing study, some women reported mild to moderate adverse events during and after the procedure. During the procedure, the most common problem reported was mild to moderate pain (9.3% of women). Some of the women in the study reported moderate pain (12.9% of women) and/or cramping (29.6% of women) on the day of the procedure. A smaller percentage of women reported nausea/vomiting (10.8%) and vaginal bleeding (6.8%). Eighty-eight (88%) of women rated tolerance of the placement procedure as good, very good, or excellent.

## How Essure has performed outside of clinical trials between (2002 – 2010)

Pregnancies have been reported with "real world" use of Essure. The table below shows the number of **reported** pregnancies and the most likely reason the pregnancy occurred. The actual number of pregnancies in women with Essure may be higher.

### Pregnancies Reported with Essure, 2002-2010*

| Potential Contributing Factor | Within the U.S. Number (%)*** | Outside The U.S. Number (%)**** | Total Number (%) |
|---|---|---|---|
| Patient did not comply with instructions | 213 (32%) | 16 (18%) | 229 (31%) |
| Essure insert perforated fallopian tube** | 91 (14%) | 4 (5%) | 95 (13%) |
| Essure inserts were not placed correctly** | 32 (5%) | 13 (15%) | 45 (6%) |
| Doctor did not comply with instructions | 22 (3%) | 13 (15%) | 35 (5%) |
| Pregnant at time of placement | 26 (4%) | 6 (7%) | 32 (4%) |
| Essure Confirmation Test misinterpreted or incomplete** | 28 (4%) | 0 (0%) | 28 (4%) |
| Essure insert was expelled from the fallopian tube** | 20 (3%) | 4 (5%) | 24 (3%) |
| Fallopian tube was open/unobstructed** | 19 (3%) | 1 (1%) | 20 (3%) |
| Unable to determine cause | 209 (32%) | 31 (35%) | 240 (32%) |
| **Total** | 660 (100%) | 88 (100%) | 748 (100%) |

*Number of pregnancies reported worldwide since commercial launch in 2001 through the end of 2010. Over that time period, 497,306 Essure kits were sold. This works out to be a "reported" pregnancy rate of 0.15%. The "true" overall pregnancy rate is unknown, because the actual number of pregnancies and the number of devices actually implanted is not known.

** Most of these pregnancies are due to Essure Confirmation Tests that were misinterpreted. In most cases, the Essure inserts were not properly placed but the x-ray indicated that fallopian tubes were blocked.
*** Only HSG was used for these procedures
**** TransVaginal Ultrasound, HSG, and/or x-ray were acceptable confirmation tests.

Many pregnancies reported by women who had the Essure procedure were preventable. For example, the patient or doctor did not follow the Instructions for Use. So it is important that you follow the instructions provided to you by your doctor.

Make sure to:

- Continue to use an alternative form of birth control for at least 3 months following the placement of the Essure inserts.
- See your doctor to have your Essure Confirmation Test 3 months after your Essure inserts are placed.
- Have your doctor confirm that you can rely on Essure inserts for your birth control.

## Comparison of Permanent Birth Control Methods

The following table provides information about a variety of permanent birth control methods. It includes data on the percentage of women likely to become pregnant within a year and five years while utilizing that method. For a complete list, visit the FDA website at www.fda.gov and search for the Birth Control Guide.

## Essure

Soft, flexible inserts are delivered through the vagina and uterus and placed in each fallopian tube. A natural barrier forms around the inserts and prevents sperm from reaching the eggs.

No incision is necessary to deliver or place the inserts. General anesthesia is not necessary during the procedure.

Failure Rate*
0.3 out of 1,000 women at 1 year
1.7 out of 1,000 women at 5 years

Recovery time
1–2 days or sooner

Pain/discomfort

- Cramping
- Discharge

Proof that the method was effective
Yes. Three months after the procedure, the Essure Confirmation Test confirms correct insert location and blockage of the fallopian tubes.

## Tubal Ligation

The fallopian tubes are blocked so that sperm is unable to reach the eggs. One of three methods is used to block the tubes:

- Clamping with metal clips or plastic rings that remain in the body.
- Cutting away a section of the tube.
- Burning a portion of the tube.

The procedure requires an incision and is performed under general anesthesia. Gas is used to expand the abdomen. Stitches or staples are then used to close the incision.

Failure Rate*
5.5 out of 1,000 women at 1 year
13.1 out of 1,000 women at 5 years
18.5 out of 1,000 women at 10 years
Recovery time
4–6 days

Pain/discomfort

- Cramping
- Discharge
- Pain at the incision area
- Bruising near the incision area
- Bloated abdomen and/or sharp pains in the neck or shoulder (due to gas used)
- Tired and achy feeling

Proof that method was effective
None.

## Vasectomy (Men)

The two vas deferens tubes that propel sperm through the urethra are tied in two places with permanent sutures. Between the ties, the tubes are severed using one of three methods:

- Burning a portion of the tube.
- Cutting the tube.
- Blocking the tube with clips or clamps that remain in the body.

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). Stitches or staples are used to close the cuts.

Failure Rate*
7.4 out of 1,000 women at 1 year
11.3 out of 1,000 women at 5 years

Recovery time
2-3 days

Pain/discomfort

- Bruising
- Pain and swelling in the testicles

Proof that method was effective
Yes. A follow-up sperm count test is performed 3 months after the vasectomy to confirm no sperm are evident.

*Expected number of pregnancies with this method over time.

## Comparison of Temporary Birth Control Methods

The following table provides information about a variety of temporary birth control methods. It includes data on the percentage of women likely to become pregnant within a year while utilizing that method. For a complete list, visit the FDA website at www.fda.gov and search for the Birth Control Guide.

Not all temporary methods of birth control listed below can be used during the 3-month waiting period before the Essure Confirmation Test. Talk to your doctor about which form of temporary birth control is right for you.

**Oral contraceptives(combination estrogen/progestin pill)**

An estrogen/progestin-based pill that suppresses ovulation.

Failure rate*
80 out of 1,000 women

Risks
Dizziness, nausea, changes in menstruation, mood, and weight gain. Rare events include cardiovascular disease, including high blood pressure, blood clots, heart attack, and stroke.

Routine
Must be taken daily.

**Oral contraceptives (progestin-only pill)**

A progestin-based pill that inhibits fertilization.

Failure rate*
80 out of 1,000 women

Risks
Irregular bleeding, weight gain, breast tenderness, and less protection against ectopic pregnancy.

Routine
Must be taken daily.

**Injection (Depo Provera®)**

A progestin-containing injection that inhibits ovulation and fertilization.

Failure rate*
30 out of 1,000 women

Risks
Irregular bleeding, weight gain, breast tenderness, and headaches.

Routine
One injection every 1-3 months.

**Vaginal contraceptive ring (NuvaRing®)**

A flexible ring inserted in the vagina that releases progestin and estrogen to prevent ovulation and fertilization.

Failure rate*
80 out of 1,000 women

Risks
Vaginal discharge, vaginitis, irritation, and other risks similar to those posed by oral contraceptives.

Routine
Inserted by the woman and kept in place for 3-week intervals. If expelled for more than 3 hours during the 3-week interval, another method of birth control must be used.

**Patch (Ortho Evra®)**

A patch worn on the body that releases progestin and estrogen to prevent ovulation and fertilization.

Failure rate*
80 out of 1,000 women

Risks
Similar to the oral estrogen-progestin pill.

Routine
A new patch must be applied every week other than the week of the menstrual period.

**Levonogestrel – Releasing IUD**

A device placed in the uterus (by a doctor)that emits hormones, preventing ovulation.

Failure rate*
2 out of 1,000 women

Risks
Ovarian cysts, pelvic inflammatory disease, perforation of the uterus, embedding into the uterus, cramps, bleeding, miscarriage, premature birth, breast cancer, nausea, mood swings,

headaches, nervousness, inflammation/pain of vagina/uterus, back pain, weight gain, acne, hypertension, and changes in menstrual cycle.

Routine
Remains in place for 1 to 5 years.

**Copper IUD (Paraguard®)**

A device placed in the uterus (by a doctor) that releases copper, preventing ovulation and fertilization.

Failure rate*
8 out of 1,000 women

Risks
Pelvic inflammatory disease, perforation of the uterus, embedding into the uterus, cramps, bleeding, vaginal discharge, allergic reaction, expulsion, anemia, ectopic pregnancy, life-threatening infection, miscarriage, premature birth, Wilson's disease, vaginal infection, inflammation/pain of vagina/uterus, back pain, pain during sex, fainting, and changes in menstrual cycle.

Routine
Remains in place for 1 to 10 years.

**Male condom**

A sheath placed over the penis that prevents passage of sperm.

Failure rate*
150 out of 1,000 women

Risks
Irritation, allergic reactions, and reduced effectiveness if used with oil-based lubricants.

Routine
Applied immediately before intercourse and used only once.

**Female condom**

A lubricated sheath placed in the vagina to prevent sperm from entering the uterus.

Failure rate*
210 out of 1,000 women

Risks
Irritation and allergic reactions.

Routine
Applied immediately before intercourse and used only once.

**Diaphragm with spermicide**

A dome-shaped rubber disk with a flexible rim that covers the cervix. The disk prevents sperm from reaching the uterus. A spermicide must be applied to the dome of the diaphragm before insertion.

Failure rate*
160 out of 1,000 women
Risks
Irritation, allergic reactions, urinary tract infection, and risk of toxic shock syndrome.

Routine
Inserted before intercourse and left in place for 6 to 24 hours afterward. For repeated intercourse, spermicide must be added without removing the diaphragm.

**Spermicide**

A foam, cream, jelly, film, suppository or tablet containing a sperm-killing chemical (nonoxynol-9).

Failure rate*
290 out of 1,000 women

Risks
Irritation, allergic reactions, and urinary tract infections.

Routine
Instructions vary. Inserted 5 to 90 minutes before intercourse and usually left in place for at least 6 to 8 hours afterward.

**Periodic abstinence/rhythm method**

Deliberately refraining from having sexual intercourse during times when pregnancy is more likely.

Failure rate*
250 out of 1,000 women

Risks
None

Routine
Requires continuous monitoring of ovulation cycle and body temperature.

*Expected number of pregnancies with this method over time

Data adapted from Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. *Contraceptive Technology: Nineteenth Revised Edition.* New York NY: Ardent Media, 2007.

# PATIENT-DOCTOR DISCUSSION CHECKLIST

To the patient considering the "Essure System for Permanent Birth Control" ("Essure"):
The review and completion of this form is a critical step in helping you decide whether or not to have Essure inserts permanently implanted. You should carefully consider the benefits and risks associated with the device before you make that decision. After reviewing the Essure Patient Information Booklet, please read and discuss the items in this checklist with your doctor. You should not initial or sign the document, and should not undergo the procedure, if you do not understand each of the elements listed below.

_____

Birth Control Options

I understand that Essure is a permanent form of birth control (referred to as "sterilization") I understand that sterilization must be considered permanent and not reversible.

I was told about other permanent sterilization procedures, such as surgical bilateral tubal ligation ("getting tubes tied"), and their benefits and risks.

I am aware that there are highly effective methods of birth control which are not permanent and which may allow me to become pregnant when stopped.

Patient Initials _____

Requirements for Essure Placement and Reliance
I understand that I am not a candidate for Essure if:

- I am uncertain about ending my fertility.
- I have had a tubal ligation procedure ("tubes tied").
- I cannot have two inserts placed due to my anatomy.
- I am pregnant or suspect that I may be pregnant.
- I have delivered or terminated a pregnancy within the last 6 weeks.
- I have an active pelvic infection on the date of the scheduled implantation.
- I have unexplained vaginal bleeding.
- I have suspected or known cancer of the female reproductive organs.
- I have a known allergy to contrast dye used during x-ray procedures.

Essure only works when the inserts are successfully placed in both fallopian tubes. I understand that if this is not possible in my case, I may need to undergo a repeat attempt at Essure placement or consider a different form of birth control.

I understand that the placement procedure is only the first step in relying on Essure for birth control. After placement I must:

- Use an alternative form of birth control until my doctor tells me I can stop (typically for 3 months).
- Schedule and undergo a confirmation test after three months to determine whether I may rely on Essure. I understand that payment for this test may or may not be covered by my insurance company.

I understand that a satisfactory confirmation test is needed before I can rely on Essure alone. I also understand that after the confirmation test my doctor may inform me that I may not be able to rely on Essure. If this occurs, I will have to use an alternative form of contraception.

I understand that based on clinical studies, approximately 8% of women who undergo attempts at Essure placement are not able to rely on the device.

Patient Initials _____

Pregnancy Risks

I understand that no form of birth control is 100% effective. Even if my doctor tells me I am able to rely on Essure, there is still a small chance that I may become pregnant. Based on clinical studies, the chance of unintended pregnancy for women who have been told they can rely on Essure is less than 1% at 5 years.

I understand that the risks of Essure on a developing fetus have not been established. If I become pregnant with Essure, there may be a risk for the pregnancy to occur outside of the uterus ("ectopic pregnancy"). This may result in serious and even life-threatening complications. I understand that I should contact my doctor immediately if I think I may be pregnant.

Patient Initials _____

What to Expect During the Procedure and the Days Afterwards

I understand that in clinical studies supporting device approval, the following events were reported to occur during the Essure placement procedure and/or in the hours or days following placement:

- Cramping (Reported in 29.6% of procedures)
- Mild to moderate pain (9.3%) or moderate pain (12.9%)
- Nausea/Vomiting (10.8%)
- Dizziness/Lightheadedness (8.8%)
- Vaginal bleeding (6.8%)

If I experience worsening of any of the events listed above or I continue to have the symptoms, I understand that I should contact my doctor.

Patient Initials _____

Long-Term Risks

I understand that some women may experience continued pain or develop new pain after Essure placement. I understand that I should contact my doctor if abdominal, pelvic or back pain continues or worsens after placement or if I develop the onset of new pain.

I understand that the Essure inserts contain metals including nickel, titanium, stainless steel (iron, chromium, nickel), platinum and silver-tin, as well as a material called polyethylene terephthalate (PET). I understand that some women may develop allergic reactions to the inserts following implantation and have signs or symptoms such as rash and itching. This may occur even if there is no prior history of sensitivity to those materials. I also understand that there is no reliable test to predict ahead of time who may develop a reaction to the insert.

I understand that persistent or new pain, and/or allergic reaction may be a sign of an Essure-related problem which might require further evaluation and treatment, including possibly the need to have the inserts removed by surgery.

I recognize that other symptoms have been reported to FDA by women implanted with Essure, although they were not seen in the clinical trials supporting Essure approval. The more common symptoms reported include headache, fatigue, weight changes, hair loss and mood changes such as depression. It is unknown if these symptoms are related to Essure or other causes.

I understand that because Essure contains metals, I should tell all my doctors that I have the device before getting an MRI.

I understand there is a small possibility that the insert could poke through the wall of the uterus or fallopian tubes ("perforation"), and/or may be found in other locations in the abdomen or pelvis. The rate of perforation in the original premarket studies was 1.8%. The rate for an insert being found in the abdomen or pelvis has not been determined but its occurrence is uncommon. I understand that should one of these events occur, the insert may become ineffective in preventing pregnancy and may lead to serious adverse events such as bleeding or bowel damage, which may require surgery to address.

I understand that should my doctor and I decide that Essure should be removed after placement, an additional surgical procedure may be required. In complicated cases, my doctor may recommend a hysterectomy (removal of the entire uterus).

I also understand that device removal may not be covered by my insurance company.

Patient Initials _____

## CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the Essure Patient Information Booklet, and that I have had time to discuss the items in it and on this document with my doctor. I have had the opportunity to ask questions and understand the benefits and risks of the device and procedure, and understand that alternative methods of birth control are available.

_____
Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of Essure as described in the Essure System Patient Information Booklet as well as this document. I have also explained the benefits and risks of other birth control methods Should device removal become necessary, I may perform the removal myself, or provide a referral to a physician who is willing and able to perform device removals. I have encouraged the patient to ask questions, and I have addressed all questions.

_____
Physician Signature and Date

## References

**1.Cooper JM, Carignan CS, Cher D, KerinJF.**Microinsertnonincisionalhysteroscopicsterilization.*Obstet Gynecol*. 2003;102:59-67. **2.**Kerin JF, Cooper JM, Price T, et al. Hysteroscopic sterilization using a micro-insert device: results of a multicentre phase II study. *Hum Rep*. 2003;18:1223-1230. **3.** Syed R, Levy J, Childers ME. Pain associated with hysteroscopic sterilization. *JSLS*. 2007;11:63-65. **4.** PMA: P020014/S9. **5.** Peterson HB, Xia Z, Hughes JM, et al. The risk of pregnancy after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. *Am J Obstet Gynecol*. 1996;174:1161-1170. **6.**Essure ESS305: Instructions For Use 2015: 1-10.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