References:

4. DHA: D020014/S9
Stop worrying about unplanned pregnancy for good

Essure® is permanent birth control you can trust—without hormones, cutting or the risks of getting your tubes tied...
Stop worrying about unplanned pregnancy for good

Essure® is permanent birth control you can trust—without hormones, cutting or the risks of getting your tubes tied...
Essure offers women what no other birth control ever has . . .

What is Essure?

Essure is a permanent birth control procedure that works with your body to create a natural barrier against pregnancy. This gentle procedure can be performed in a doctor’s office in about 13 minutes.*

Essure has been trusted by women and doctors since 2002. The Essure procedure involves placing soft, flexible micro-inserts in your fallopian tubes. Over a period of approximately three months, tissue forms around the micro-inserts, creating a barrier that keeps sperm from reaching the eggs, so conception never occurs.

The benefits of Essure

Essure offers women what no other birth control ever has . . .

No cutting or burning

The Essure procedure does not involve cutting into or puncturing your body, and does not cut, crush or burn your fallopian tubes, unlike tubal ligation (“getting your tubes tied”) or vasectomy (permanent birth control for men). All parts of your body remain intact because the Essure micro-inserts are delivered through your vagina and cervix and placed in your fallopian tubes. Since there is no incision, you will have no scarring or other visible signs as a result of having the procedure.

No going under general anesthesia

You can remain fully conscious during the procedure, thus avoiding the risks of general anesthesia when performed in a doctor’s office.

No slowing down to recover

You can go home 45 minutes after the procedure. Women in follow-up studies reported that they returned to normal activity within one to two days.†

No hormones

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

No guessing

The Essure Confirmation Test is performed three months after your procedure to verify placement of the Essure micro-inserts and that your fallopian tubes are completely blocked—so you can be sure you can rely on Essure for birth control.

Short procedure time

Essure only takes about 13 minutes to perform.*

Essure procedure overview: three steps

1. An Essure-certified doctor inserts soft, flexible micro-inserts into your fallopian tubes. No incision is needed because these tiny inserts are delivered through your vagina and cervix. The micro-inserts do not contain or release hormones, and are made with materials that have been used in medical devices for many years. See page 8 for more information about the placement of the Essure micro-inserts.

2. Over the next three months, you must continue using another form of birth control. During this time your body will form a natural barrier around the micro-inserts that will eventually prevent sperm from reaching the eggs. Since Essure does not interfere with your body’s natural cycle, your ovaries continue to release eggs which are simply absorbed back into your body.

3. After 3 months, complete the Essure Confirmation Test to verify that you’re protected from unplanned pregnancy. Until you receive confirmation, you must continue to use another form of birth control.

The Essure Confirmation Test uses dye and a special type of x-ray to ensure both Essure micro-inserts are in the correct location and your fallopian tubes are blocked. See page 6 for more information about the Essure Confirmation Test.

†Average hysteroscope time
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How Essure performed in studies

Since FDA approval of Essure in 2002, hundreds of thousands of women worldwide have had the procedure. Follow-up studies in the United States, Australia, and Europe have shown the following results:

High effectiveness
99.8% effective with zero pregnancies after four years among the women in the Essure clinical studies.2

Rapid recovery
Most women returned to normal activities within one to two days and almost all rated their comfort as “good” to “excellent” within one week of the procedure.1

High patient satisfaction
94% of women rated their overall satisfaction with the procedure as “very satisfied.”1

Frequently asked questions

Can I trust the Essure procedure?
Yes, Essure is 99.8% effective. In four years of clinical trials, there have been no pregnancies among Essure users who successfully completed all three steps of the Essure procedure.

Is the procedure painful?
Generally, no. Some women report mild discomfort or cramping, similar to a normal monthly cycle, during or after the procedure.3

Is Essure reversible?
No, the Essure procedure is not reversible. Like a vasectomy or tubal ligation, Essure is permanent birth control, so you should be sure you do not want to have children in the future.

Will I still have a period?
Yes, you will still have a period, though some Essure users find that their period changes afterward, becoming slightly lighter or heavier. These changes are often temporary and may be due to your body’s natural response to the discontinuation of hormonal birth control.

What are the micro-inserts made of?
The micro-inserts are made from polyester fibers, nickel-titanium and stainless steel. These materials have been used successfully for many years in cardiac stents and medical devices in other parts of the body.

Is Essure covered by my insurance?
The Essure procedure is covered by most insurance providers whether performed in a doctor’s office or hospital. If the Essure procedure is done in a doctor’s office, depending on the insurance plan, your payment may be as low as a simple co-pay. It is best to review your insurance coverage with your doctor and insurance carrier before receiving the procedure. When you speak with your insurance provider, ask for your plan’s specific coverage and payment guidelines for hysteroscopic sterilization, code 58565. You must specify where you will have the procedure (doctor’s office, hospital outpatient, or ambulatory care clinic), because this may affect the amount of reimbursement.
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Preparing for your procedure

You should have your Essure procedure soon after your menstrual period ends. This will make it easier for your doctor to see the openings of your fallopian tubes.

The day of your procedure

You will be given a pregnancy test the day of your procedure to ensure you are not pregnant. To help you relax and to open your fallopian tubes, you may also be given medication to take one to two hours before your procedure. This will assist in reducing cramping during your procedure. Talk to your doctor about which type of medication is best for you.

During your procedure

The same instrument used during your annual gynecologic check-up, a speculum, will be gently inserted into your vagina by your doctor. Your doctor then inserts a narrow telescope-like instrument, called a hysteroscope, through your cervix. A video camera attached to the hysteroscope sends pictures to a monitor, allowing your doctor to see inside your uterus.

To help your doctor see the openings of your fallopian tubes clearly, fluid (normal saline or salt water) flows through the hysteroscope and expands your uterus. The Essure micro-insert is attached to the end of a small, flexible tube that is then passed through the hysteroscope and into your fallopian tube. The procedure is then repeated to place the second micro-insert in your other fallopian tube.

After your 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 one to two days. Call your doctor if you notice unusual pain, bleeding, fever, vaginal discharge, or other symptoms.

You must continue to use another form of birth control for three months following the procedure, until you have your Essure Confirmation Test to confirm you are protected from unplanned pregnancy for good.

Three months later:

The Essure Confirmation Test

The Essure Confirmation Test verifies that the micro-inserts are in place and that your fallopian tubes are completely blocked—so you can have the peace of mind you deserve.

The Essure Confirmation Test is a gentle procedure involving little to no pressure or discomfort. While the test is a type of HSG (hysterosalpingogram), it is different from the HSG used to diagnose and treat infertility—and is considerably more comfortable.

During the Essure Confirmation Test, the radiologist introduces a special dye into your uterus that shows up on x-rays. This allows the radiologist to look at your fallopian tubes to confirm that the micro-inserts are properly placed and your tubes are blocked.

Important considerations

The Essure micro-inserts do not protect against HIV or other sexually transmitted infections

Your Essure procedure is permanent (not reversible)

- You must be sure that your family is complete.
- The safety or effectiveness of trying to reverse the Essure procedure is unknown.
- The safety or effectiveness of in vitro fertilization (IVF)* after the Essure procedure is unknown.

You should delay having the Essure procedure if you:

- Are pregnant or have been pregnant during the past six weeks.
- Have an active or recent pelvic infection.
- Are not right for you if:
  - You have had a tubal ligation (“tubes tied”).
  - Can not have the Essure micro-inserts placed in both of your tubes (even if one tube is thought to be closed or you have only one tube).
  - Have had a hysterosalpingogram (HSG). The radiologist will introduce a special dye into your uterus by x-ray imaging (not reversible).
  - Are allergic to nickel or contrast dye (dye used during x-rays).
  - Are unwilling to have the Essure Confirmation Test.
  - Cannot have the Essure micro-inserts placed in both of your tubes (even if one tube is thought to be closed or you have only one tube).

Your Essure procedure is complete only after you receive the results of your Essure Confirmation Test

- You must continue to use another form of birth control for at least three months after your procedure.
- Talk to your doctor about remaining on your current birth control, or discuss which interim birth control method is right for you if you are using an intrauterine device (IUD) or intrauterine contraceptive (IUC).
- If you rely on Essure for birth control before having your Essure Confirmation Test, you are at risk of getting pregnant or having an ectopic pregnancy.
- In rare cases (3.5%), it can take longer than three months—up to six months at times—for the Essure micro-inserts to completely block the fallopian tubes. However, in all cases, blockage was complete after six months.
- You should be aware that because you are receiving an x-ray during your Essure Confirmation Test, you will be exposed to very low levels of radiation, which is standard with most x-rays.

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

- Approximately 1 out of 12 women were not able to have one or both of the micro-inserts placed. If this occurs, you can talk to your doctor about a second Essure procedure.
- The younger a woman is when she chooses to end her fertility, the more likely she is to regret her choice later

* Fertilization of an egg outside the body, followed by placement of the fertilized egg into the uterus.
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- You must be sure that your family is complete.
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- The safety or effectiveness of in vitro fertilization (IVF)* after the Essure procedure is unknown.

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- You have had a tubal ligation ("tubes tied").
- You are allergic to nickel or contrast dye (dye used during x-rays).
- You are unwilling to have the Essure Confirmation Test.
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Important considerations
- The safety or effectiveness of in vitro fertilization (IVF)* after the Essure procedure is unknown.
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As with all medical procedures, there are risks associated with the Essure procedure. Learn about these risks and discuss them in detail with your doctor.

Preparing for the procedure
- You should have the Essure procedure soon after your menstrual period ends and must take a pregnancy test prior to having the procedure.
- As with all birth control procedures, women who have the Essure 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.

During the procedure
- During the procedure, you may experience mild to moderate pain.
- Additional risks include an inability to have one or both micro-inserts placed or incorrect placement of one or both micro-inserts.
- In rare instances, part of an Essure micro-insert may break off. A puncture to the fallopian tubes may occur which could require surgery to repair (this occurred in 1.8% of women in clinical studies, many of whom underwent tubal ligation and/or had the micro-inserts removed).6
- The Essure procedure does not require general anesthesia, which carries higher risks than other types of anesthesia. Your doctor may recommend a local anesthesia, which numbs the cervix. Ask your doctor about the risks associated with this type of anesthesia.

After the Essure 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 nausea and/or vomiting or fainting.
- In rare instances, a micro-insert may be expelled from the body (occurred in 2.9% of cases during the clinical studies).6
- Other risks include excessive absorption of the fluid used during the procedure (rare), incomplete or delayed blockage of both fallopian tubes after more than three months, and an increased risk of ectopic pregnancy.

No birth control method is 100% effective. With all birth control, there is a small chance that you can become pregnant. If you do become pregnant, it is unknown what kind of risks a permanent birth control procedure, such as Essure, may pose to you, the pregnancy, the fetus or childbirth.

Note: Women who have 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.

During the Essure Confirmation Test
In rare instances, women may experience spotting and/or infection.

If you are considering having the Essure procedure, here are some questions you might ask your doctor:
- Where will my Essure procedure be performed?
- What type of medication will be used before and/or during my procedure?
- How should I prepare?
- What are my options if both micro-inserts cannot be placed on the first attempt?
- How can I schedule my Essure Confirmation Test?
- Can I continue to use my current method of birth control until my Essure Confirmation Test?

Patient identification card
After your Essure procedure, you will be given a patient identification card. The Essure micro-inserts are MRI-safe, but may cause an obscured image at or near the micro-inserts. Show the card to your doctors so they are aware of the Essure micro-inserts before performing an MRI, D&C, hysteroscopy, endometrial biopsy, endometrial ablation, or any procedures involving your uterus or fallopian tubes.
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After the Essure 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.
- Testing is recommended to confirm the placement of the micro-inserts.
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Important safety information

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### Permanent Birth Control Comparison

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<tr>
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<th>Recovery time</th>
<th>Pain/discomfort</th>
<th>Proof of effectiveness</th>
</tr>
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</table>
| **Essure**  | 0.05% at 1 year | 1–2 days or sooner | • Cramps  
• Discharge | Yes. Three months after the procedure, the Essure Confirmation Test confirms placement and blockage of the fallopian tubes. |
| Soft, flexible micro-inserts are delivered through the vagina and uterus and placed in each fallopian tube, without an incision. A natural barrier forms around the micro-inserts that prevents sperm from reaching the egg. | 0.20% at 4 years | | |

| **Tubal Ligation** | 0.55% at 1 year | 4–6 days | • Cramps  
• Discharge  
• Pain at the wound  
• Bloated abdomen and/or sharp pains in the neck or shoulder (due to gas used)  
• Bruising around the wound  
• Tired and achy feeling | No. |
| An incision-based procedure performed under general anesthesia. Gas is used to expand the abdomen. The fallopian tubes are then blocked by one of three methods:  
• 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  
| Stitches or staples are then used to close the cuts. | 1.18% at 4 years | | |
| | 1.85% at 10 years | | | |

| **Vasectomy** | 0.74% at 1 year | 2–3 days | • Bruising  
• Pain and swelling in the testicles | Yes. A follow-up sperm count test is performed three months after the vasectomy to confirm no sperm is evident. |
| 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 two vas deferens are tied in two places with permanent sutures. The vas deferens are severed between the ties by one of three methods:  
• Burning a portion of the tube  
• Cutting  
• Blocking with clips or clamps that remain in the body  
| Stitches or staples are used to close the cuts. | 1.13% at 5 years | | |

*Percentage of women who became pregnant.
### Permanent birth control comparison

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Bloated abdomen and/or sharp pains in the neck or shoulder (due to gas used)  
Bruising around the wound  
Tired and achy feeling | No. |
| **Vasectomy**  |               |               |                 |                        |
| 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 two vas deferens are tied in two places with permanent sutures. The vas deferens are severed between the ties by one of three methods:  
- Burning a portion of the tube  
- Cutting  
- Blocking with clips or clamps that remain in the body  
Stitches or staples are used to close the cuts. | 0.74% at 1 year  
1.13% at 5 years | 2–3 days | Bruising  
Pain and swelling in the testicles | Yes. A follow-up sperm count test is performed three months after the vasectomy to confirm no sperm is evident. |

*Percentage of women who became pregnant.
Temporary birth control comparison

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

<table>
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<tr>
<th>Method</th>
<th>Description</th>
<th>Failure rate*</th>
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<td>An estrogen/progestin-based pill that suppresses ovulation</td>
<td>8%</td>
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<tr>
<td>Injection (Depo-Provera®)</td>
<td>A progestin-containing injection that inhibits ovulation and fertilization</td>
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<td>Vaginal contraceptive ring (NuvaRing®)</td>
<td>A flexible ring inserted in the vagina that releases progestin and estrogen to prevent ovulation and fertilization</td>
<td>8%</td>
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<td>IUD/IUC® (Mirena®)</td>
<td>A device placed in the uterus by a healthcare professional emits hormones, preventing ovulation</td>
<td>0.2%</td>
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<td>IUD/IUC® (Paraguard®)</td>
<td>A device placed in the uterus by a healthcare professional that releases copper, preventing ovulation and fertilization</td>
<td>0.8%</td>
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<tr>
<td>Male condom</td>
<td>A sheath placed over the penis that prevents passage of sperm</td>
<td>15%</td>
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<td>Female condom</td>
<td>A lubricated sheath placed in the vagina to prevent sperm from entering the uterus</td>
<td>21%</td>
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<tr>
<td>Diaphragm with spermicide</td>
<td>A dome-shaped rubber disk with a flexible rim that covers the cervix so sperm cannot reach the uterus – a spermicide must be applied to the dome of the diaphragm before insertion</td>
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<td>A foam, cream, jelly, film, suppository or tablet containing nonoxynol-9, a sperm-killing chemical</td>
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<td>Deliberately refraining from having sexual intercourse during times when pregnancy is more likely</td>
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Please note: Not all temporary methods of birth control can be used during the three-month three-month waiting period before the Essure Confirmation Test. Please talk to your doctor about what form of temporary birth control you should use during this time.

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<td>Vaginal discharge, vaginitis, irritation, other risks similar to those posed by oral contraceptives</td>
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References:
4 PMA: PO20014/S9
6 Essure ESS305: Information For Use, 2007: 1-10