

When you're done
having children,
choose Essure[®]
permanent birth control

YOUR COMPLETE GUIDE TO THE ESSURE[®] PROCEDURE

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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.

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.

Hysterosalpingogram (HSG): An x-ray of the uterus and fallopian tubes after they have been filled with contrast dye.

Hysteroscope: A telescopic instrument that is used 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.

Intrauterine Device (IUD)/Intrauterine Contraceptive (IUC): A medical device that is placed in the uterus for temporary prevention of pregnancy.

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

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

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

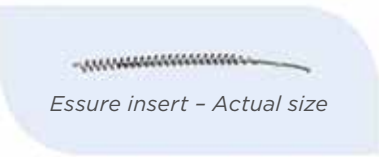
Tubal Ligation: A form of permanent birth control by means of cutting, tying, burning or clipping the fallopian tubes so that they are blocked.

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 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 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
 - Is simple and does not take a lot of time.
 - Does not require surgery or exposure to its potential risks.
 - Does not involve taking hormone therapy.

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.

You should delay having the Essure procedure if:

- You are or have been pregnant within the past 6 weeks.
- You have had a recent pelvic 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 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.

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

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

THE BENEFITS OF ESSURE

Highly Effective

The Essure procedure is 99.83% effective based on five-year clinical study data.

Available for Over 10 Years

Since FDA approval in 2002, over half a million woman have relied on Essure.

Non-Surgical

Essure is a simple procedure that can be done in 10 minutes in your doctor's office.

Non-Hormonal

Essure inserts do not contain or release hormones.

No General Anesthesia Required

You can remain fully conscious during the procedure.

No Downtime to Recover

You can go home 45 minutes after the procedure, and return to normal activity within one to two days.

Benefit of Confirmation

An Essure Confirmation Test will verify that the inserts are placed correctly and your fallopian tubes are completely blocked.

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.

The inserts do not contain or release hormones. They are made of some of the same materials that are used in other medical devices that remain implanted or inserted in your body.



Step 2
Waiting for the natural barrier to form

Over the next 3 months, your body will form tissue around the Essure inserts. This will develop 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 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

After 3 months, a doctor will administer the Essure Confirmation Test. The test will verify that the inserts are in their correct location and your fallopian tubes are blocked. The doctor will use contrast dye and a special type of x-ray during the confirmation test.



IMPORTANT: YOU MUST SEE YOUR DOCTOR FOR THE ESSURE CONFIRMATION TEST BEFORE YOU CAN RELY ON ESSURE FOR BIRTH CONTROL. UNTIL YOU RECEIVE CONFIRMATION FROM YOUR DOCTOR, YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY.

WARNINGS, PRECAUTIONS AND OTHER POTENTIAL RISKS

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.

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.

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.
- In rare cases, part of an Essure insert may puncture the fallopian tube. Surgery may be necessary to repair the puncture.
- 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 nausea and/or vomiting or fainting.
- In rare instances, an Essure insert may be expelled from the body.

Risks: During the Essure Confirmation Test

- Because the Essure Confirmation Test requires an x-ray, you will be exposed to very low levels of radiation. This is standard with most x-rays.
- In rare instances, women may experience spotting and/or infection.

Risks: Long-term

- 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. While none of the women in the Essure clinical trials became pregnant, there is a small chance that you can become pregnant after completing the Essure procedure. If you do become pregnant, 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. The pregnancy usually happens in one of the fallopian tubes. 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. Once placed inside the body, small amounts of nickel are released from the inserts. 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.

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 to help you relax and open (dilate) your fallopian tubes 1 to 2 hours before your procedure. This will also help to reduce cramping. Talk to your doctor about the types of medications that are right for you.

During your procedure

Your doctor will first insert an instrument called a speculum inside your vagina. The speculum helps the doctor widen the opening and see inside. Then your doctor will insert a narrow, telescope-like instrument (hysteroscope) through your cervix and into your uterus. A camera attached to the hysteroscope sends video images to a video monitor that lets your doctor see inside 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 tube is removed.

The procedure is then repeated to place an insert into your other fallopian tube. The entire process usually takes less than ten minutes.

Your doctor will schedule you for an Essure Confirmation Test for about 3 months after the procedure.

IMPORTANT: Not all women will achieve successful placement of both Essure inserts. Fewer than 1 out of 12 women are not able to have one or both of the inserts placed. If this occurs, talk to your doctor about a second Essure procedure.

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 notice unusual pain, bleeding, fever, 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. UNTIL YOU RECEIVE CONFIRMATION FROM YOUR DOCTOR, YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY.

The Essure Confirmation Test

The Essure Confirmation Test verifies that the inserts are in the correct location and that your fallopian tubes are completely blocked.

The Essure Confirmation Test is a type of x-ray exam involving little to no pressure or discomfort. Although the test is similar to the HSG (hysterosalpingogram) test used to diagnose and treat infertility, it is considerably more comfortable.

During the test, a radiologist injects a special contrast dye into your uterus. The dye is visible on x-rays. This lets the radiologist look at your fallopian tubes to confirm that the inserts are properly placed and that your tubes are blocked.

ESSURE PATIENT ID CARD

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 uterus or fallopian tube. 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.

FREQUENTLY ASKED QUESTIONS

Can I trust Essure to prevent pregnancy?

Yes, the Essure procedure is 99.83% effective. In five years of clinical trials, there have been no pregnancies among women who successfully completed all 3 steps of the Essure procedure.

A few pregnancies have been reported among the hundreds of thousands of women who have completed the procedure since it became commercially available. Most of those pregnancies were a result of not having completed the procedure or not following instructions.

Is Essure painful?

Generally, there is little pain associated with Essure since the procedure does not require any incisions. Some women report mild discomfort, pain, and cramping during and after the procedure. Symptoms may be similar to what they might experience in their normal monthly cycle.

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 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.

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 types 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 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 Essure clinical studies, zero (0) pregnancies were reported in women who had the Essure inserts for up to 5 years. The effectiveness rate with Essure was estimated to be 99.83%.

Was the Essure placement procedure successful?

In only a few instances (fewer than 1 out of 12 women), the doctor was unable to place one or both Essure inserts in the fallopian tubes.

The majority of women (96.5%) were able to achieve complete blockage of their fallopian tubes within the expected 3-month period. A small percentage of women (3.5%) took up to 6 months.

Were women comfortable and satisfied with Essure?

The studies measured the level of satisfaction with Essure at follow-up visits. More than nine out of ten women (>90%) said they were “very satisfied” with Essure throughout the 5-year study period.

Most women (77%) returned to normal activities within one to two days following the procedure. Almost all women rated their comfort as “good” to “excellent” within one week of the procedure.

Was Essure safe and well tolerated?

The studies tracked any adverse events associated with Essure. This included any problems that arose during the Essure procedure, as well as any long-term issues. During the procedure and for the 5-year study period, no serious adverse events related to the Essure inserts were reported.

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%).

HOW ESSURE HAS PERFORMED SINCE FDA APPROVAL IN 2002

Although zero (0) pregnancies were reported during the Essure clinical trials, there have been pregnancies reported with “real world” use. 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*

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 as 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.

Many pregnancies reported by women who had the Essure procedure were preventable. For example, the patient or physician 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*	Recovery Time	Pain/discomfort	Proof that method was effective
<ul style="list-style-type: none">• 0.3 out of 1,000 women at 1 year• 1.7 out of 1,000 women at 5 years	1-2 days or sooner	<ul style="list-style-type: none">• Cramping• Discharge	Yes. Three months after the procedure, the Essure Confirmation Test confirms correct insert location and blockage of the fallopian tubes.

TUBAL LIGATION⁵

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*	Recovery time	Pain/discomfort	Proof that method was effective
<ul style="list-style-type: none">• 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	4-6 days	<ul style="list-style-type: none">• Cramping• Discharge• Pain at the incision area• Bruising near the incision area• Bloating abdomen and/or sharp pains in the neck or shoulder (due to gas used)• Tired and achy feeling	None.

*Expected number of pregnancies with this method over time.

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*	Recovery time	Pain/discomfort	Proof that method was effective
<ul style="list-style-type: none">• 7.4 out of 1,000 women at 1 year• 11.3 out of 1,000 women at 5 years	2-3 days	<ul style="list-style-type: none">• Bruising• Pain and swelling in the testicles	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 on 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*	Risks	Routine
80 out of 1,000 women	Dizziness, nausea, changes in menstruation, mood, and weight gain. Rare events include cardiovascular disease, including high blood pressure, blood clots, heart attack, and stroke.	Must be taken daily.

ORAL CONTRACEPTIVES (PROGESTIN-ONLY PILL)

A progestin-based pill that inhibits fertilization.

Failure rate*	Risks	Routine
80 out of 1,000 women	Irregular bleeding, weight gain, breast tenderness, and less protection against ectopic pregnancy.	Must be taken daily.

INJECTION (DEPO PROVERA®)

A progestin-containing injection that inhibits ovulation and fertilization.

Failure rate*	Risks	Routine
30 out of 1,000 women	Irregular bleeding, weight gain, breast tenderness, and headaches.	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*	Risks	Routine
80 out of 1,000 women	Vaginal discharge, vaginitis, irritation, and other risks similar to those posed by oral contraceptives.	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.

*Expected number of pregnancies with this method over time.

PATCH (ORTHO EVRA®)

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

Failure rate*	Risks	Routine
80 out of 1,000 women	Similar to the oral estrogen-progestin pill	A new patch must be applied every week other than the week of the menstrual period.

IUD/IUC (MIRENA®)

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

Failure rate*	Risks	Routine
2 out of 1,000 women	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.	Remains in place for 1 to 5 years.

IUD/IUC (PARAGUARD®)

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

Failure rate*	Risks	Routine
8 out of 1,000 women	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.	Remains in place for 1 to 10 years.

*Expected number of pregnancies with this method over time.

MALE CONDOM

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

Failure rate*	Risks	Routine
150 out of 1,000 women	Irritation, allergic reactions, and reduced effectiveness if used with oil-based lubricants.	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*	Risks	Routine
210 out of 1,000 women	Irritation and allergic reactions.	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*	Risks	Routine
160 out of 1,000 women	Irritation, allergic reactions, urinary tract infection, and risk of toxic shock syndrome.	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*	Risks	Routine
290 out of 1,000 women	Irritation, allergic reactions, and urinary tract infections.	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*	Risks	Routine
250 out of 1,000 women	None	Requires continuous monitoring of ovulation cycle and body temperature.

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.

*Expected number of pregnancies with this method over time.



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