

FDA-Approved Patient Labeling

Patient Information

Mirena® (mur-ā-nah)

(levonorgestrel-releasing intrauterine system)

Mirena does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).

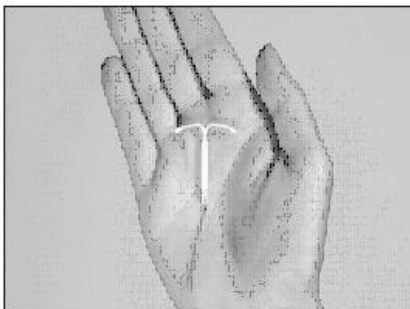
Read this Patient Information carefully before you decide if Mirena is right for you. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women's health. If you have any questions about Mirena, ask your healthcare provider. You should also learn about other birth control methods to choose the one that is best for you.

What is Mirena?

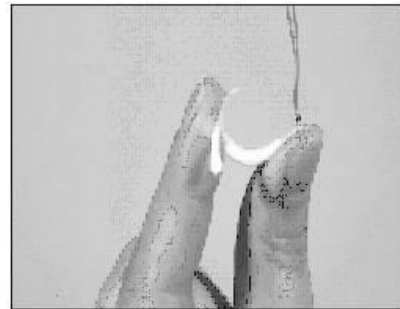
- Mirena is a hormone-releasing system placed in your uterus by your healthcare provider to prevent pregnancy for up to 5 years.
- Mirena can also lessen menstrual blood loss in women who have heavy menstrual flow and who also want to use a birth control method that is placed in the uterus to prevent pregnancy.
- Mirena can be removed by your healthcare provider at any time.
- Mirena is recommended for women who have had at least one child.

Mirena is a small flexible plastic T-shaped system that slowly releases a progestin hormone called levonorgestrel that is often used in birth control pills. Because Mirena releases levonorgestrel into your uterus, only small amounts of the hormone enter your blood. Mirena does not contain estrogen.

Two thin threads are attached to the stem of Mirena. The threads are the only part of Mirena you can feel when Mirena is in your uterus; however, unlike a tampon string, the threads do not extend outside your body.



Mirena is small



and flexible

What if I need birth control for more than 5 years?

Mirena must be removed after 5 years. Your healthcare provider can place a new Mirena during the same office visit if you choose to continue using Mirena.

What if I want to stop using Mirena?

Mirena is intended for long-term use but you can stop using Mirena at any time by asking your healthcare provider to remove it. You could become pregnant as soon as Mirena is removed, so you should use another method of birth control if you do not want to become pregnant.

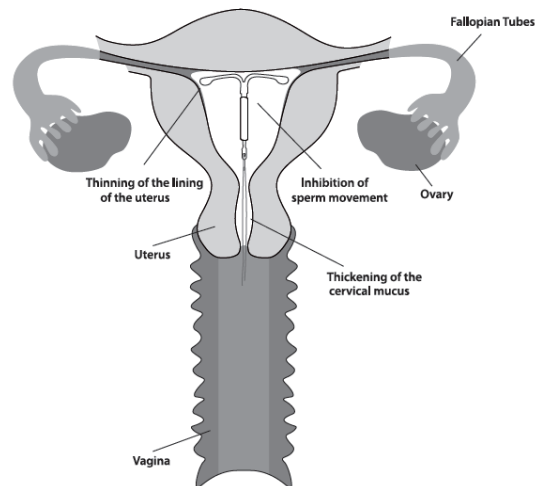
What if I change my mind about birth control and want to become pregnant in less than 5 years?

Your healthcare provider can remove Mirena at any time. You may become pregnant as soon as Mirena is removed. About 8 out of 10 women who want to become pregnant will become pregnant sometime in the first year after Mirena is removed.

How does Mirena work?

Mirena may work in several ways including thickening cervical mucus, inhibiting sperm movement, reducing sperm survival, and thinning the lining of your uterus. It is not known exactly how these actions work together to prevent pregnancy.

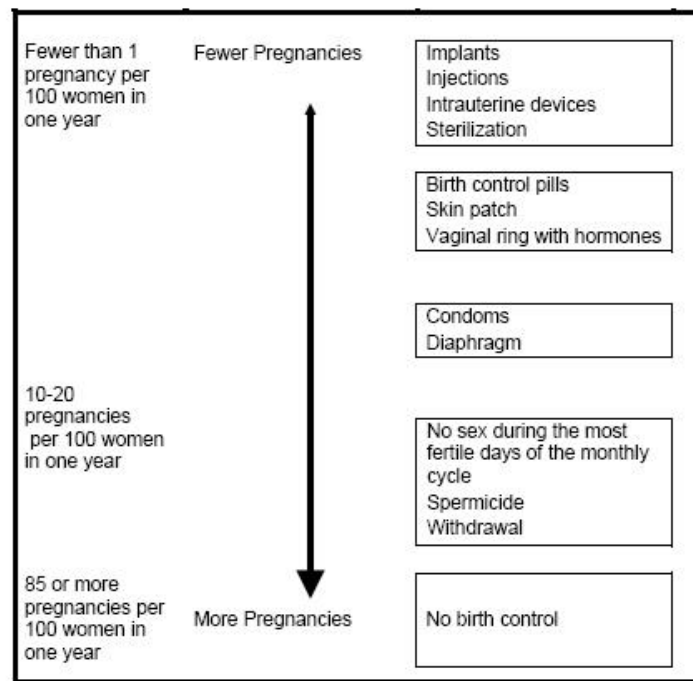
Mirena can cause your menstrual bleeding to be less by thinning the lining of the uterus.



How well does Mirena work for contraception?

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.

Mirena, an intrauterine device (IUD), is in the box at the top of the chart.



How well does Mirena work for heavy menstrual bleeding?

In the clinical trial performed in women with heavy menstrual bleeding and treated with Mirena, almost 9 out of 10 were treated successfully and their blood loss was reduced by more than half.

Who might use Mirena?

You might choose Mirena if you:

- Want long-term birth control that provides a low chance of getting pregnant (less than 1 in 100)
- Want birth control that works continuously for up to 5 years
- Want birth control that is reversible
- Want a birth control method that you do not need to take daily
- Have had at least one child
- Want treatment for heavy periods and are willing to use a birth control method that is placed in the uterus
- Want birth control that does not contain estrogen

Who should not use Mirena?

Do not use Mirena if you:

- Are or might be pregnant; Mirena cannot be used as an emergency contraceptive
- Have had a serious pelvic infection called pelvic inflammatory disease (PID) unless you have had a normal pregnancy after the infection went away
- Have an untreated pelvic infection now
- Have had a serious pelvic infection in the past 3 months after a pregnancy
- Can get infections easily. For example, if you have:
 - Multiple sexual partners or your partner has multiple sexual partners
 - Problems with your immune system

- Intravenous drug abuse.
- Have or suspect you might have cancer of the uterus or cervix
- Have bleeding from the vagina that has not been explained
- Have liver disease or liver tumor
- Have breast cancer or any other cancer that is sensitive to progestin (a female hormone), now or in the past
- Have an intrauterine device in your uterus already
- Have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumors
- Are allergic to levonorgestrel, silicone, polyethylene, silica, barium sulfate or iron oxide

Before having Mirena placed, tell your healthcare provider if you:

- Have had a heart attack
- Have had a stroke
- Were born with heart disease or have problems with your heart valves
- Have problems with blood clotting or take medicine to reduce clotting
- Have high blood pressure
- Recently had a baby or if you are breastfeeding
- Have severe migraine headaches.

How is Mirena placed?

Mirena is placed by your healthcare provider during an in-office visit.

First, your healthcare provider will examine your pelvis to find the exact position of your uterus. Your healthcare provider will then clean your vagina and cervix with an antiseptic solution, and slide a slim plastic tube containing Mirena into your uterus. Your healthcare provider will then remove the plastic tube, and leave Mirena in your uterus. Your healthcare provider will cut the threads to the right length. Placement takes only a few minutes.

You may experience pain, bleeding or dizziness during and after placement. If your symptoms do not pass within 30 minutes after placement, Mirena may not have been placed correctly. Your healthcare provider will examine you to see if Mirena needs to be removed or replaced.

Should I check that Mirena is in place?

Yes, you should check that Mirena is in proper position by feeling the removal threads. It is a good habit to do this once a month. Your healthcare provider should tell you how to check that Mirena is in place. First, wash your hands with soap and water. You can check by reaching up to the top of your vagina with clean fingers to feel the removal threads. Do not pull on the threads. If you feel more than just the threads or if you cannot feel the threads, Mirena may not be in the right position and may not prevent pregnancy. Use non-hormonal back-up birth control (such as condoms and spermicide) and ask your healthcare provider to check that Mirena is still in the right place.

How soon after placement of Mirena should I return to my healthcare provider?

Call your healthcare provider if you have any questions or concerns (see "When should I call my healthcare provider"). Otherwise, you should return to your healthcare provider for a follow-up visit 4 to 6 weeks after Mirena is placed to make sure that Mirena is in the right position.

Can I use tampons with Mirena?

Tampons may be used with Mirena.

What if I become pregnant while using Mirena?

Call your healthcare provider right away if you think you are pregnant. If you get pregnant while using Mirena, you may have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain may be a sign of ectopic pregnancy.

Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.

There are also risks if you get pregnant while using Mirena and the pregnancy is in the uterus. Severe infection, miscarriage, premature delivery, and even death can occur with pregnancies that continue with an intrauterine device (IUD). Because of this, your healthcare provider may try to remove Mirena, even though removing it may cause a miscarriage. If Mirena cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy, see your healthcare provider regularly. Call your healthcare provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection.

It is not known if Mirena can cause long-term effects on the fetus if it stays in place during a pregnancy.

How will Mirena change my periods?

For the first 3 to 6 months, your period may become irregular and the number of bleeding days may increase. You may also have frequent spotting or light bleeding. Some women have heavy bleeding during this time. After you have used Mirena for a while, the number of bleeding and spotting days is likely to lessen. There is a small chance that your periods will stop altogether.

In some women with heavy bleeding, the total blood loss per cycle progressively decreases with continued use. The number of spotting and bleeding days may initially increase but then typically decreases in the months that follow.

Is it safe to breastfeed while using Mirena?

You may use Mirena when you are breastfeeding if more than six weeks have passed since you had your baby. If you are breastfeeding, Mirena is not likely to affect the quality or amount of your breast milk or the health of your nursing baby. However, isolated cases of decreased milk production have been reported among women using progestin-only birth control pills.

Will Mirena interfere with sexual intercourse?

You and your partner should not feel Mirena during intercourse. Mirena is placed in the uterus, not in the vagina. Sometimes your partner feels the threads. If this occurs, talk with your healthcare provider.

What are the possible side effects of using Mirena?

Mirena can cause serious side effects including:

- **Pelvic inflammatory disease (PID).** Some IUD users get a serious pelvic infection called pelvic inflammatory disease. PID is usually sexually transmitted. You have a higher chance of getting PID if you or your partner have sex with other partners. PID can cause serious problems such as infertility, ectopic pregnancy or pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID may require surgery. A hysterectomy (removal of the uterus) is sometimes needed. In rare cases, infections that start as PID can even cause death.
- Tell your healthcare provider right away if you have any of these signs of PID: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal (stomach area) pain, painful sex, chills, or fever.
- **Life-threatening infection.** Life-threatening infection can occur within the first few days after Mirena is placed. Call your healthcare provider immediately if you develop severe pain or fever shortly after Mirena is placed.
- **Perforation.** Mirena may become attached to (embedded) or go through the wall of the uterus. This is called perforation. If this occurs, Mirena may no longer prevent pregnancy. If perforation occurs, Mirena may move outside the uterus and can cause internal scarring, infection, or damage to other organs, and you may need surgery to have Mirena removed. The risk of perforation is increased in breastfeeding women.

Common side effects of Mirena include:

- Pain, bleeding or dizziness during and after placement. If these symptoms do not stop 30 minutes after placement, Mirena may not have been placed correctly. Your healthcare provider will examine you to see if Mirena needs to be removed or replaced.
- Expulsion. Mirena may come out by itself. This is called expulsion. You may become pregnant if Mirena comes out. If you think that Mirena has come out, use a backup birth control method like condoms and spermicide and call your healthcare provider.
- Missed menstrual periods. About 2 out of 10 women stop having periods after 1 year of Mirena use. If you do not have a period for 6 weeks during Mirena use, call your healthcare provider. When Mirena is removed, your menstrual periods will come back.
- Changes in bleeding. You may have bleeding and spotting between menstrual periods, especially during the first 3 to 6 months. Sometimes the bleeding is heavier than usual at first. However, the bleeding usually becomes lighter than usual and may be irregular. Call your healthcare provider if the bleeding remains heavier than usual or increases after it has been light for a while.
- Cysts on the ovary. About 12 out of 100 women using Mirena develop a cyst on the ovary. These cysts usually disappear on their own in a month or two. However, cysts can cause pain and sometimes cysts will need surgery.

This is not a complete list of possible side effects with Mirena. For more information, ask your healthcare provider.

Call your doctor for medical advice about side effects. You may report side effects to the manufacturer at 1-888-842-2937, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

After Mirena has been placed, when should I call my healthcare provider?

Call your healthcare provider if you have any concerns about Mirena. Be sure to call if you:

- Think you are pregnant
- Have pelvic pain or pain during sex
- Have unusual vaginal discharge or genital sores
- Have unexplained fever, flu-like symptoms or chills

- Might be exposed to sexually transmitted infections (STIs)
- Cannot feel Mirena's threads
- Develop very severe or migraine headaches
- Have yellowing of the skin or whites of the eyes. These may be signs of liver problems.
- Have had a stroke or heart attack
- Or your partner becomes HIV positive
- Have severe vaginal bleeding or bleeding that lasts a long time

General advice about prescription medicines

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. This leaflet summarizes the most important information about Mirena. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about Mirena that is written for health providers.

For more information, go to www.mirena-us.com or call 1-888-842-2937

This Patient Information has been approved by the U.S. Food and Drug Administration.

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Manufactured in Finland

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