

FDA-Approved Patient Information

PATIENT INFORMATION

Mirena® (Mur-ā-nah)

(levonorgestrel-releasing intrauterine system)

Mirena does not protect against HIV infection (AIDS) and other sexually transmitted diseases (STDs).

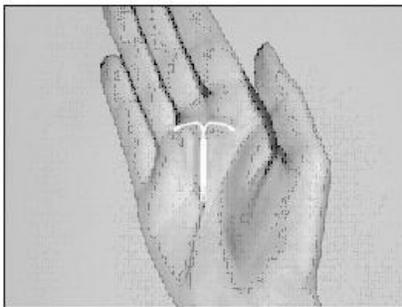
Read this Patient Information carefully before you decide if Mirena is right for you. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women's health. If you have any questions about Mirena, ask your healthcare provider. You should 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 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 is recommended for women who have had at least one child.

Mirena is T-shaped. It is made of flexible plastic and contains a progestin hormone called levonorgestrel that is often used in birth control pills. Mirena does not contain estrogen. Mirena releases the hormone into the uterus. Only small amounts of the hormone enter your blood.

Two 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.



Mirena is small...



and flexible

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

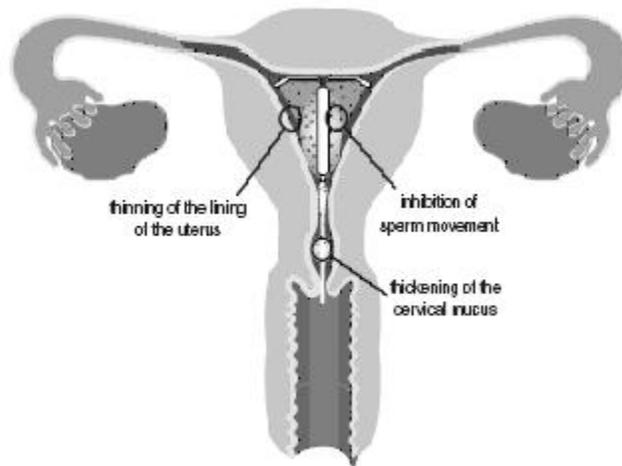
Mirena must be removed after 5 years. Your healthcare provider can insert a new Mirena during the same office visit if you choose to continue using Mirena.

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 some time in the first year after Mirena is removed.

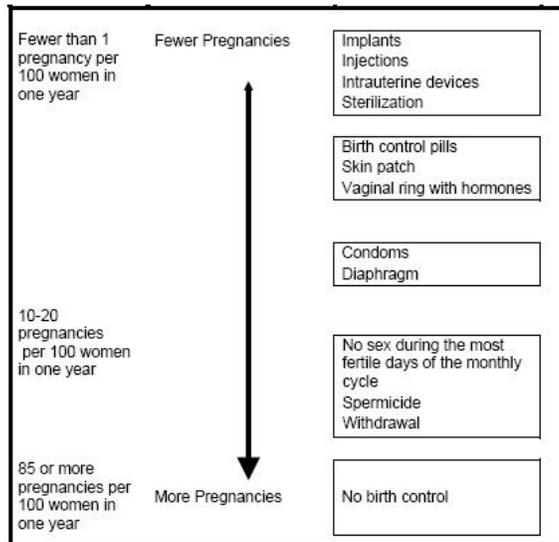
How does Mirena work?

It is not known exactly how Mirena works. Mirena may work in several ways. It may thicken your cervical mucus, thin the lining of your uterus, inhibit sperm movement and reduce sperm survival. Mirena may stop release of your egg from your ovary, but this is not the way it works in most cases. Most likely, 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 in the box at the top of the chart. Mirena, an intrauterine device, is in the box 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.



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 birth control that provides a low chance of getting pregnant (less than 1 in 100)
- Want birth control that is reversible
- Want a birth control method that does not require taking it daily
- Have had at least one child
- Want treatment for heavy periods and want to use a birth control method that is placed in the uterus to prevent pregnancy.

Who should not use Mirena?

Do not use Mirena if you:

- Might be pregnant
- 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:
 - More than one sexual partner or your partner has more than one partner

- 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 now or in the past or suspect you have breast cancer
- 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, or polyethylene.

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 breast feeding
- Have diabetes (high blood sugar)
- Use corticosteroid medications on a long-term basis
- Have severe migraine headaches.

How is Mirena placed?

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 thin 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 during an office visit.

You may experience pain, bleeding or dizziness during and after placement. If these symptoms do not pass 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 the proper position?

Yes, you should check that Mirena is in proper position by feeling the removal threads. You should do this after each menstrual period. First, wash your hands with soap and water. Feel for the threads at the top of your vagina with your clean fingers. The threads are the only part of Mirena you should feel when Mirena is in your uterus. Be careful not to pull on the threads. If you feel more than just the threads, Mirena is not in the right position and may not prevent pregnancy. Call your healthcare provider to have it removed. If you cannot feel the threads at all, ask your healthcare provider to check that Mirena is still in the right place. In either case, use a non-hormonal birth control method (such as condoms or spermicide) until otherwise advised by your healthcare provider.

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 12 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 monthly period may become irregular and the number of bleeding days may increase at first. You may also have frequent spotting or light bleeding. A few women have heavy bleeding during this time. After your body adjusts, the number of bleeding days is likely to lessen, and you may even find that your periods 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 breast-feed 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 male partners feel the threads.

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 if you develop severe pain within a few hours after Mirena is placed.
- *Embedment*. Mirena may become attached to the uterine wall. This is called embedment. If embedment happens, Mirena may no longer prevent pregnancy and you may need surgery to have it removed.
- *Perforation*. Mirena may go through the uterus. This is called perforation. If your uterus is perforated, Mirena may no longer prevent pregnancy. It 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 notice that Mirena has come out, use a backup birth control method like condoms 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 if the bleeding becomes heavy after it has been light for a while.
- *Cyst 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.
- Might be exposed to sexually transmitted diseases (STDs).
- 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 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.

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Manufactured for:

Bayer HealthCare Pharmaceuticals Inc.
Wayne, NJ 07470

This patient information booklet was updated February 2013.

Fill out the following checklist. Your answers will help you and your healthcare provider decide if Mirena is a good choice for you.

Do you have any of these conditions?

| | Yes | No | Don't know— will discuss with my healthcare provider |
|--|--------------------------|--------------------------|--|
| Abnormalities of the uterus | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Acquired immune deficiency syndrome (AIDS) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Anemia or blood clotting problems | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Bleeding between periods | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Cancer of the uterus or cervix | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| History of other types of cancer | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Steroid therapy (for example, prednisone) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Possible pregnancy | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Diabetes | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Ectopic pregnancy in the past | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Fainting attacks | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Genital sores | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Heart disease | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Heart murmur | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Heavy menstrual flow | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Hepatitis or other liver disease | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Infection of the uterus or cervix | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| IUD in place now or in the past | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| IV drug abuse now or in the past | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Leukemia | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| More than one sexual partner | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| A sexual partner who has more than one sexual partner | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Pelvic infection | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Abortion or miscarriage in the past 2 months | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Pregnancy in the past 2 months | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Severe menstrual cramps | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Severe Headache | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Sexually transmitted disease (STD), such as gonorrhea or chlamydia | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Stroke | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Abnormal Pap smear | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Unexplained genital bleeding | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Uterine or pelvic surgery | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Vaginal discharge or infection | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| HIV infection | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Breastfeeding | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| High blood pressure | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Manufactured for:

Bayer HealthCare Pharmaceuticals Inc.
Wayne, NJ 07470

Manufactured in Finland

Bayer HealthCare Pharmaceuticals Mirena Hotline - 1-866-647-3646

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