

4. Removal of Mirena

- Remove Mirena by applying gentle traction on the threads with forceps. The arms will fold upward as it is withdrawn from the uterus. Mirena should not remain in the uterus after 5 years.
- If the threads are not visible and Mirena is in the uterine cavity, it may be removed using a narrow forceps, such as an alligator forceps. This may require dilation of the cervical canal (see **PRECAUTIONS, Continuation and Removal**).

IMPORTANT!

- If Mirena is removed mid-cycle and the woman has had intercourse within the preceding week, she is at a risk of pregnancy unless a new Mirena is inserted immediately following removal.

5. Continuation of Contraception After Removal

- You may insert a new Mirena immediately following removal.
- If a patient with regular cycles wants to start a different birth control method, remove Mirena during the first 7 days of the menstrual cycle and start the new method.
- If a patient with irregular cycles or amenorrhea wants to start a different birth control method, or if you remove Mirena after the seventh day of the menstrual cycle, start the new method at least 7 days before removal.

HOW SUPPLIED

Mirena (levonorgestrel-releasing intrauterine system), containing a total of 52 mg levonorgestrel, is available in a carton of one sterile unit NDC# 50419-421-01. Each Mirena is packaged together with an inserter in a thermoformed blister package with a peelable lid.

Mirena is supplied sterile. Mirena is sterilized with ethylene oxide. Do not resterilize. For single use only. Do not use if the inner package is damaged or open. Insert before the end of the month shown on the label.

STORAGE AND HANDLING

Store at 25°C (77°F); with excursions permitted between 15-30°C (59-86°F) [See USP Controlled Room Temperature].

PATIENT INFORMATION

Mirena® (Mur-ā-nah)
(levonorgestrel-releasing intrauterine system)

Mirena is used to prevent pregnancy. Mirena does not protect against HIV infection (AIDS) and other sexually transmitted diseases (STDs).

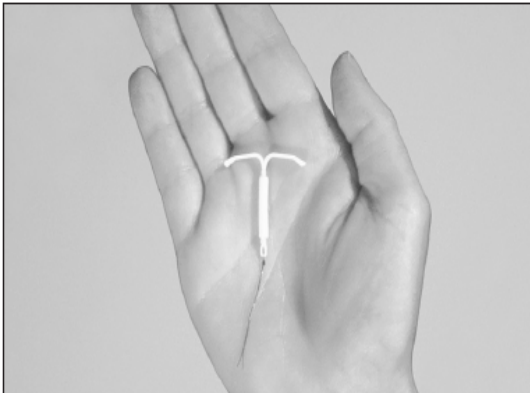
Read this Patient Information carefully before you decide if Mirena is right for you. This information does not take the place of talking with your gynecologist or other health care provider who specializes in women's health. If you have any questions about Mirena, ask your health care provider. You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

What is Mirena?

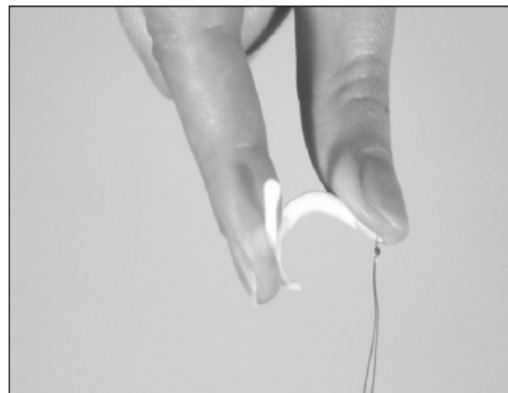
Mirena is a hormone-releasing system placed in your uterus to prevent pregnancy for up to 5 years.

Mirena is T-shaped. It is made of flexible plastic and contains a progestin hormone called levonorgestrel. Levonorgestrel is a progestin hormone often used in birth control pills; however, unlike many birth control pills, Mirena does not contain an 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?

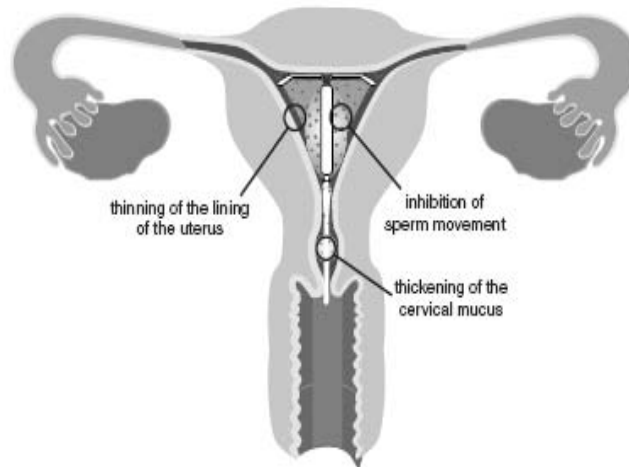
You must have Mirena removed after 5 years, but your health care provider can insert a new Mirena during the same office visit if you choose to continue using Mirena.

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

Your health care 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.

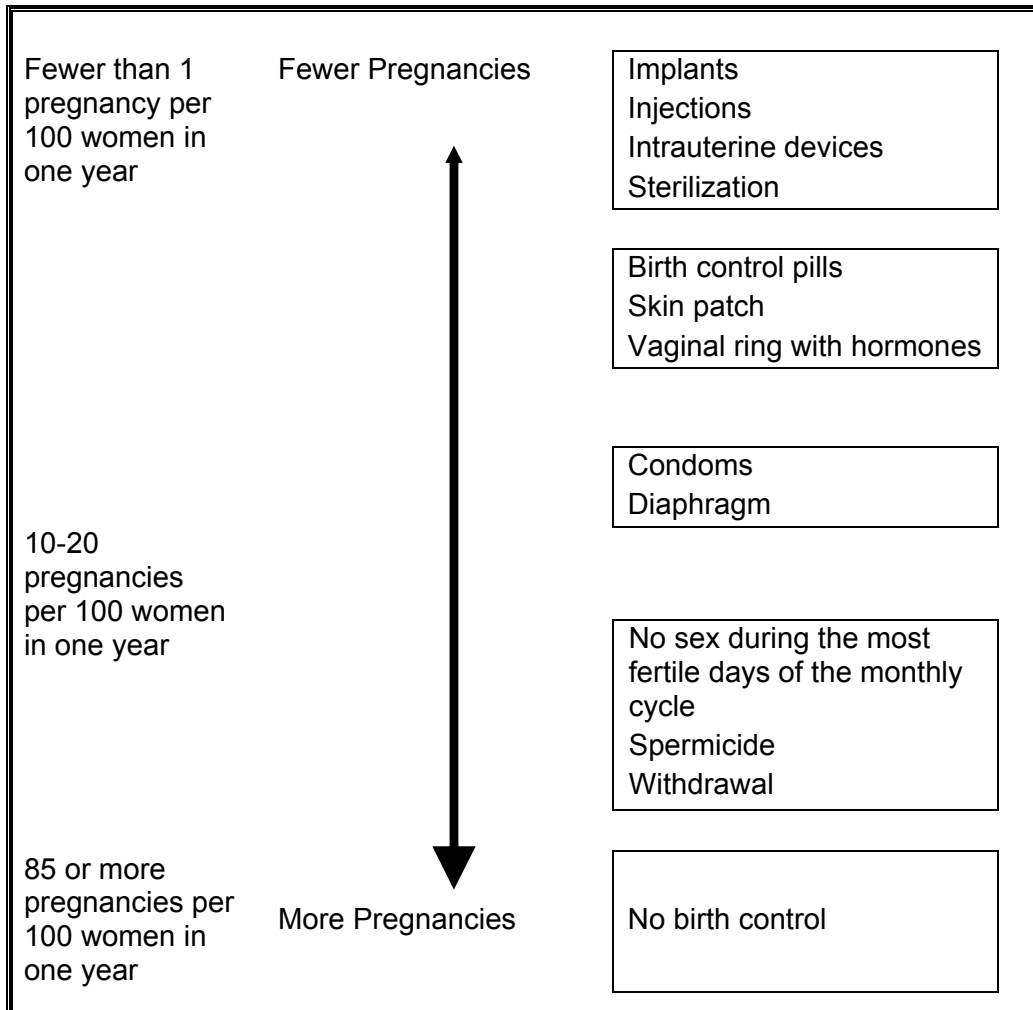
How does Mirena work?

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.



How well does Mirena work?

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.



Who might use Mirena?

You might choose Mirena if you

- need birth control that is highly effective
- need birth control that is reversible
- need birth control that is easy to use
- have had at least one baby

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
 - leukemia
 - AIDS
 - 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

Tell your health care provider if you

- recently had a baby or if you are breast feeding
- have diabetes (high blood sugar)
- 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**

How is Mirena placed?

First, your health care provider will examine your pelvis to find the exact position of your uterus. Your health care provider will then clean your vagina and cervix with an antiseptic solution, and slide a thin plastic tube containing Mirena into your uterus. Your health care 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.

Some women may experience pain, bleeding and/or dizziness during and after placement. If these symptoms do not pass within half an hour while in a resting position, Mirena may not have been correctly placed. If necessary, your health care provider will examine you to determine if Mirena needs to be removed.

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 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 health care 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 health care provider.

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

Call your health care provider if you have any question or concerns (see "When to call your health care provider"). Otherwise, you should return to your health care 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 health care 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 an 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 health care provider may try to remove Mirena, even though removing it may cause a miscarriage. If Mirena cannot be removed, talk with your health care provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy, see your health care provider regularly. Call your health care 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.

We do not know 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. 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 decrease, and you may even find that your periods stop altogether.

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.

Will Mirena interfere with sexual intercourse?

Neither you nor your partner should feel Mirena during intercourse, as 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?

The following are serious but uncommon side effects of Mirena:

- *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 constant pelvic pain. 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 health care 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 health care provider if you develop severe pain within a few hours after placement.
- *Embedment*. Mirena may adhere to the uterine wall. This is called embedment. If embedment occurs, 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.

Common side effects of Mirena include:

- *Discomfort during placement*. Dizziness, faintness, bleeding or cramping may occur during placement. This is common. Let your health care provider know if the cramping is severe.
- *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 health care provider.
- *Missed menstrual periods*. About 2 out of 10 women stop having periods after 1 year of Mirena use. The periods come back when Mirena is removed. If you do not have a period for 6 weeks during Mirena use, contact your health care provider.
- *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 health care 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.** Approximately 12% (12 out of 100) of 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 health care 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.

When should I call my health care provider?

Call your health care 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
- miss a menstrual period

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 health care provider. You can ask your health care provider for information about Mirena that is written for health providers.

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Manufactured for:



**Bayer HealthCare
Pharmaceuticals**

Bayer HealthCare Pharmaceuticals Inc.
Wayne, NJ 07470

Telephone number: 1-888-842-2937

Manufactured in Finland

This patient information booklet was updated July 2008.

Fill out the following checklist. Your answers will help you and your health care 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 health care 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"/>

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