

WHAT IS MIRENA®?

Mirena® is an intrauterine system (IUS) used for the prevention of pregnancy for up to 5 years.

Mirena® is also used to treat heavy menstrual bleeding without a known reason in women who are able to use a hormonal birth control method and have had their first period.

Mirena® is not for use in postmenopausal women.

What does Mirena® look like?

Mirena® consists of a small, white, T-shaped frame made from soft, flexible plastic. The vertical arm is surrounded by a reservoir that contains a hormone called levonorgestrel. Two brown-coloured fine plastic threads are attached to the tip of the vertical arm.



Important aspects of Mirena®:

- Releases a low amount of levonorgestrel directly into the uterus every day
- Does not contain any estrogen

Mirena® menstrual diary

Use the Mirena® menstrual diary to keep track of any spotting or bleeding that may occur in the next few months.

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Month 1																															
Month 2																															
Month 3																															
Month 4																															
Month 5																															
Month 6																															

Patient instructions

Record your menstrual blood flow or any bleeding that occurs between periods by marking in the appropriate square (day) of the calendar, using the following guide.

■ Heavy Flow – Fill in the box	• Spotting – Mark a dot
X Normal Flow – Mark an X	No Bleeding – Leave blank



The box holds more than just Mirena®

It also includes the insertion device



Serious Warnings and Precautions

- Hormonal contraceptives including Mirena® DO NOT PROTECT against Sexually Transmitted Infections (STIs), including HIV/AIDS. To protect yourself against STIs, you can use condoms with Mirena®.
- Cigarette smoking increases the risk of serious side effects on the heart and blood vessels. You should talk to your healthcare professional about the risks of smoking.
- Mirena® may become attached to (embedded) or go through the wall of the uterus. This is called perforation. If you experience severe abdominal or pelvic pain with or without vaginal bleeding, contact your healthcare professional immediately.

Mirena® may be reimbursed – patients should contact their insurance provider for more information

Please refer to the Mirena® Patient Information leaflet for full indications, contraindications, warnings, precautions, side effects and patient selection criteria.

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MIR240E



Mirena®
Levonorgestrel-releasing intrauterine system

Mirena®
Levonorgestrel-releasing intrauterine system



A GUIDE TO YOUR INTRAUTERINE CONTRACEPTIVE

PLACEMENT

Some important information you should know about starting Mirena®

When should Mirena® be placed?

Mirena® should be placed within 7 days of starting your period. In this case, no backup birth control is needed. If it is certain that you are not pregnant, Mirena® may also be placed at any other time during your cycle.



Tell your healthcare professional if you have had unprotected sex since your last period. If Mirena® is placed more than 7 days since your period started, use a condom or diaphragm, or do not have sex for the next 7 days. Mirena® cannot be used as emergency birth control.

- When replacing an existing system for a new one, it is not necessary to wait for your period
- Following childbirth, Mirena® should be placed only after the uterus has returned to its normal size, and not earlier than 6 weeks after delivery
- Mirena® can be placed immediately after a first-trimester abortion; if an abortion takes place in the second trimester, placement of Mirena® should be delayed for 6 weeks or until the uterus has returned to normal size

How is Mirena® placed?

- Before Mirena® is placed, your doctor will perform a pelvic exam to determine the position and size of your uterus; they may also do a Pap smear and breast exam, as well as other tests (e.g., for infections including STIs), if necessary
- Your healthcare professional will then place a thin flexible plastic tube containing Mirena® into your uterus – during this procedure you may feel some discomfort

After placement, you may feel some cramp-like menstrual pain; however, this usually disappears within a few days

WHAT ARE THE SIDE EFFECTS OF MIRENA®?

These are not all the possible side effects that you may feel when taking Mirena®. For any unexpected effects while taking Mirena®, contact your healthcare professional.

- acne/oily skin
- skin disorder, dark patches of skin
- nausea
- hair loss
- infection of the ovaries, fallopian tubes or uterus
- painful periods
- discharge from the vagina
- vaginal bleeding
- excess hair on the face, chest, stomach or legs
- breast pain and tenderness
- lower sex drive
- feeling nervous
- weight gain
- breakage of the device
- increased blood pressure

Side effects with Mirena® are more common during the first months of use and gradually decrease over time. Differences in your menstrual bleeding are the most common side effects of Mirena® during the first months after the system is placed, but these effects should also decrease over time.

Other common side effects might include abdominal pain and absence of menstruation. If these symptoms do not go away, or if you think you are reacting poorly to Mirena® or having other problems that are not listed above, please tell your healthcare professional.

Few women using Mirena® after delivery have reported less milk production.

Refer to the Mirena® Patient Medication Information leaflet for details on serious warnings and precautions – and what to do about them

YOUR NEXT FEW YEARS WITH MIRENA®

Your usual level of fertility should return soon after Mirena® is removed

What if I decide to have a baby?

If you wish to become pregnant, ask your healthcare professional to remove Mirena®. Nearly 90% of women wishing to become pregnant conceive within 24 months after removal of the system.

How is Mirena® removed? How do I continue with Mirena® after 5 years?

Mirena® should not be left in place for more than 5 years. Mirena® can be easily removed by your healthcare professional if you wish to become pregnant.

You may become pregnant upon removal of Mirena® if you have had sexual intercourse during the previous week. 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.



Talk to your healthcare professional about the best birth control methods for you, because your new method may need to be started 7 days before Mirena® is removed to prevent pregnancy.

Tell your healthcare professional if you have had sexual intercourse during the preceding week.

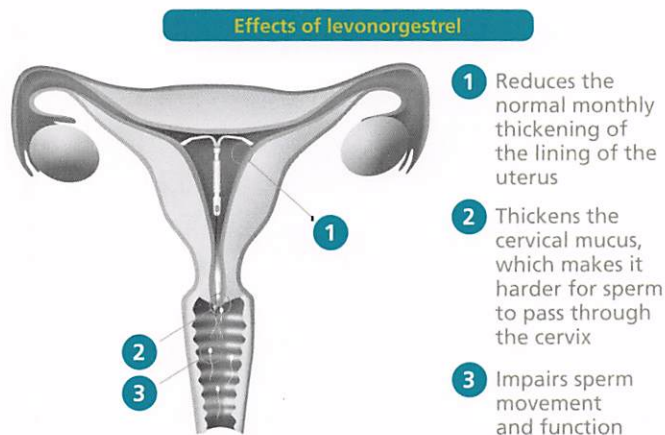
Mirena® may break, most often during a difficult removal. Broken pieces must be found and removed. Surgery may be needed to do this.

If you wish to continue using Mirena® after 5 years, your healthcare professional can place a new system after removing the old system

If the same Mirena® system has been left in place for longer than 5 years, you may become pregnant. Pregnancy should be ruled out before placement of a new system.

How does Mirena® work?

Mirena® works by slowly releasing a low amount of levonorgestrel directly into the uterus every day.



These actions work together to prevent the sperm and egg from coming into contact as a means of preventing pregnancy.

These effects also decrease abnormally heavy menstrual blood loss.

How effective is Mirena®?

Clinical trials found that there were about 2 pregnancies per year for every 1,000 women using Mirena®.

TYPICAL PREGNANCY RATES for different methods of birth control, and pregnancy rate when no birth control is used

Product	Reported pregnancies per 100 women within the first year of use
Hormonal intrauterine system (IUS)	Less than 1
Copper intrauterine device (IUD)	Less than 1
Progesterone injection	6
Combined hormonal contraceptive (pill, patch or ring)	9
Diaphragm	12
Male condom	18
Female condom	21
Sponge, spermicide	12–28
Withdrawal method	22
Natural family planning	24
No birth control	85

PID can cause serious problems such as difficulty getting pregnant, development of a pregnancy outside the uterus (ectopic pregnancy), or pelvic pain that does not go away. PID is usually treated with antibiotics; however, more serious cases of PID may require surgery.

Tell your healthcare professional right away if you have any signs of PID, including: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal (stomach area) pain, painful sex, chills or fever.

Is there a risk of ectopic pregnancy with Mirena®?

While using Mirena®, the risk of pregnancy is low. However, if you do accidentally become pregnant while using Mirena®, an ectopic pregnancy is more likely. This means that the pregnancy is not in the uterus. Ectopic pregnancy is a serious condition. Tell your healthcare professional if you have lower abdominal pain, especially if you have missed a period and/or have unexpected bleeding, as these can be signs of an ectopic pregnancy.

YOUR FIRST FEW DAYS AND MONTHS WITH MIRENA®

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Here are some additional things you should know as you continue with Mirena®

How will Mirena® affect my periods?

Mirena® will affect your menstrual cycle. In the first 3 to 6 months, your period may become irregular and the number of bleeding days may increase. You might also experience frequent spotting (a small amount of blood loss) or light bleeding. In some cases, you may have heavy or prolonged bleeding over this time. Contact your healthcare professional if this persists.

Overall, you are likely to have a gradual reduction in the number of bleeding days and in the amount of blood loss each month. Some women using Mirena® eventually find that their periods stop altogether. When Mirena® is removed, periods should return to normal.

How long will it take before I notice a difference in my monthly bleeding?

A reduction in menstrual blood loss should be apparent from the first menstrual cycle.

What if I stop having periods?

Over time, your menstrual period may gradually disappear when using Mirena®. This is the effect of the hormone on the lining of the uterus. The normal monthly thickening of the uterine lining with blood is reduced; therefore, there is little or no bleeding that happens during a usual menstrual period. It does not necessarily mean you are pregnant or have reached menopause.

If, however, you are having regular menstrual periods with Mirena® and then do not have one for 6 weeks or longer, it is possible that you may be pregnant. You should speak to your healthcare professional.

Can Mirena® fall out?

Although unlikely, Mirena® may fall out on its own. Mirena® could be pushed out either fully or partially during your period. This is called expulsion. This is more likely to occur if you are overweight or have heavy periods. If Mirena® is out of place, it may not work as expected. If this happens, you are not protected against pregnancy.

Some symptoms of an expulsion are pain and abnormal bleeding. Mirena® may also come out without you noticing. An unusual increase in the amount of bleeding during your period might be a sign that this has happened.

If you think Mirena® has come out (fully or partially), avoid intercourse or use another method of nonhormonal birth control, such as a condom or diaphragm, until you see your healthcare professional. They might do an x-ray to confirm if it has fallen out. Mirena® should be removed if it is pushed out partially. Mirena® can be replaced with a new one once pregnancy is ruled out. Your healthcare professional will decide what is best for you.

How can I check if Mirena® is in place?

After each menstrual period or about once a month, you should check by feeling if the two threads are still in place. Your healthcare professional will show you how to do this. Do not pull on the threads as you may accidentally pull Mirena® out.

If you cannot feel the threads, this may indicate that Mirena® has fallen out (expulsion) or gone through the uterus (perforation). See your healthcare professional and in the meantime use another method of nonhormonal birth control (like condoms). You should also see your healthcare professional if you can feel the lower end of Mirena® itself.

How often should I have Mirena® checked?

You should have Mirena® checked approximately 4 to 12 weeks after placement, again at 12 months and then once a year until it is removed.

Mirena® can stay in place for up to 5 years before it must be removed. You should receive a patient reminder card from your healthcare professional after the placement of Mirena®. Bring this card to every appointment and be sure to hang on to it until Mirena® is removed.

During sexual intercourse, you or your partner should not be able to feel Mirena®

Will Mirena® be felt during sexual intercourse?

If you can feel Mirena®, or if you feel any pain or discomfort that you suspect may be caused by it, then you should not have sexual intercourse until you see your healthcare professional to verify it is still in the correct position.

SAFE SEX: Does Mirena® protect against sexually transmitted infections (STIs)?

Hormonal contraceptives including Mirena® DO NOT PROTECT against sexually transmitted infections (STIs) including HIV/AIDS. Be safe. To protect yourself against STIs, you can use condoms with Mirena®.

- Once Mirena® is in the correct position, your healthcare professional will withdraw the tube and leave Mirena® in your uterus
- Finally, your healthcare professional will trim the removal threads to a suitable length; this procedure will only take a few minutes
- Some people may feel faint after Mirena® is placed – this goes away after a short rest. The placement procedure may cause a seizure in people with epilepsy

How long does placement take?

The placement procedure usually takes a few minutes after your healthcare professional has completed a pelvic examination.

How quickly does Mirena® start to work?

Mirena® starts to work right away if it is placed within 7 days of the start of your period. It is best to wait 24–48 hours before having intercourse in case of discomfort. If Mirena® is placed more than 7 days after the start of your period, use a condom or diaphragm for the next 7 days, or abstain from intercourse for 7 days following the placement of Mirena®.

What is the risk of uterine perforation?

During placement, Mirena® may become attached to, penetrate or perforate the wall of the uterus, but this is uncommon. If this happens, Mirena® must be removed.

The risk of perforation is higher in women who are breastfeeding at the time of Mirena® placement and when Mirena® is placed up to 36 weeks following delivery.

The risk of perforation may be increased in women with a differently shaped uterus or with a uterus that is fixed and leaning backwards.

Is there a risk of infection with Mirena®?

There is an increased risk of a serious pelvic infection called pelvic inflammatory disease (PID) in the first 3 weeks after placement of an intrauterine system or device. Other known risk factors include multiple sexual partners, frequent intercourse, and young age.