

 **Mirena**[®]
Levonorgestrel-releasing intrauterine system



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A GUIDE TO YOUR
INTRAUTERINE
CONTRACEPTIVE

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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 contraceptive method and have had their first menstrual period.

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 total of 52 mg of levonorgestrel – enough hormone to prevent pregnancy for up to five years. Two brown-coloured fine plastic threads are attached to the tip of the vertical arm.

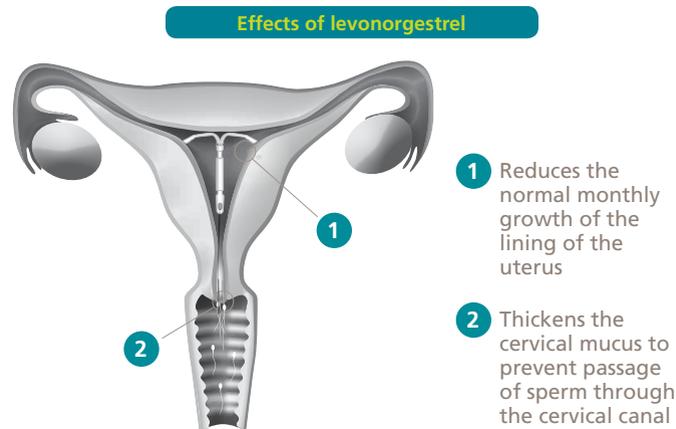


Important aspects of Mirena®:

- Releases a low amount (approximately 20 micrograms) of a hormone called levonorgestrel directly into the uterus every day (Mirena® contains 52 mg of levonorgestrel)
- Does not contain any estrogen

How does Mirena® work?

Mirena® works by slowly releasing levonorgestrel into the uterus at a rate of approximately 20 micrograms per day.



These effects of levonorgestrel prevent pregnancy and 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

PLACEMENT

Some important information you should know about starting with Mirena®

When should Mirena® be placed?

Mirena® should be placed within seven 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 womb has returned to its normal size, and not earlier than six 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?

- After a pelvic examination, your healthcare professional will place a thin flexible plastic tube containing Mirena® into your uterus. At this point you may feel a little discomfort.
- Once Mirena® is in the correct position, your healthcare professional will withdraw the tube, leaving the system in place in the uterus.
- Finally, your healthcare professional will trim the removal threads to a suitable length.

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

How long does placement take?

The placement procedure usually takes a few minutes after your healthcare professional has completed the 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. Alternatively, do not have sex for the next 7 days.

What is the risk of uterine perforation?

Most often during placement, Mirena® may penetrate or perforate (punch a hole in) 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/or when Mirena® is placed up to 36 weeks after a delivery.

The risk of perforation may be increased in women with an abnormally shaped uterus or with the uterus 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 three weeks after placement of an intrauterine system or device. Other known risk factors include multiple sexual partners, frequent intercourse, and young age.

PID can cause serious problems such as infertility, ectopic pregnancy, or constant pelvic pain. 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 of these signs of PID: 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®?

Ectopic pregnancy (development of a fertilized egg outside the uterus) is possible when using Mirena®, as it is in women using no contraception. However, if you do accidentally become pregnant while using Mirena®, an ectopic pregnancy is more likely. Ectopic pregnancy is a serious condition. Therefore, you should tell your healthcare professional if you have lower abdominal pain, especially if you have missed a period and/or have unexpected bleeding, since these can be signs of an ectopic pregnancy.

YOUR FIRST FEW DAYS & MONTHS WITH MIRENA®

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 three to six months, you might experience frequent spotting (a small amount of blood loss) or light bleeding in addition to your periods.

In some cases, you may have heavy or prolonged bleeding over this time, but 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 because of the effect of the hormone on the lining of the uterus. The normal monthly thickening of the uterine lining with blood does not happen; therefore, there is little or no bleeding which happens during a usual menstrual period. It does not necessarily mean you have reached menopause or are pregnant.

If, however, you are having regular menstrual periods 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?

It is unlikely, but possible, that Mirena® can come out either completely or partially. If this happens, you are not protected against pregnancy.

An unusual increase in the amount of bleeding during your period might be a sign that it has happened.

If you think it has come out, use another method of nonhormonal contraception until you see your healthcare professional.

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 or uterine perforation has occurred. See your healthcare professional and in the meantime use another method of nonhormonal contraception. 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 5 years before it must be removed.

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

Will Mirena® interfere with 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. For protection against STIs, it is advisable to use latex or polyurethane condoms while using Mirena®.

WHAT ARE THE SIDE EFFECTS OF MIRENA®?

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Menstrual bleeding irregularities are the most common side effects of Mirena® during the first months after the system is placed, but these effects should decrease over time. Other common side effects might include abdominal pain and absence of menstruation.

The following side effects have been observed in studies of women taking Mirena®: breast pain, complication associated with the presence of an intrauterine device, pain, painful periods, altered mood, headache, acne, genital discharge, back pain, withdrawal bleeding, ovarian cyst, decreased sex drive, weight increase, heavy menstrual bleeding (menorrhagia), depression, vaginal infection, nervousness, nausea, vaginal hemorrhage, skin disorder.

Side effects of unknown frequencies include: device breakage.

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

Side effects such as irregular menstrual bleeding and nausea should go away as your body adjusts to Mirena®. If these symptoms do not go away or if you think you are reacting poorly to Mirena® or having other problems which are not listed above, please tell your healthcare professional.

This is not a complete list of side effects. For any unexpected effects while taking Mirena®, contact your healthcare professional or pharmacist.

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®. Approximately 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. You should see your healthcare professional when you want to have Mirena® taken out.

Removal of Mirena® is very easy; however, you should be aware that you may become pregnant upon removal of Mirena® if you have had sexual intercourse during the previous week. 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.

Mirena® menstrual diary

Use the Mirena® menstrual diary to keep track of any spotting or bleeding which 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. For protection against STIs, it is advisable to use latex or polyurethane condoms while using Mirena®. Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. Women should be counseled not to smoke.

Mirena® may penetrate or perforate (punch a hole in) the wall of the uterus.

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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