



Patient Information



Mirena[®]
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Information on PrMIRENA®

The following information is provided to answer the most commonly asked questions about MIRENA® (levonorgestrel-releasing intrauterine system). The information provided applies only to the MIRENA® system. If you have any questions or are not sure about something, please ask your doctor.

What is MIRENA®?

MIRENA® is an intrauterine system which prevents pregnancy by slowly releasing levonorgestrel into the uterus.

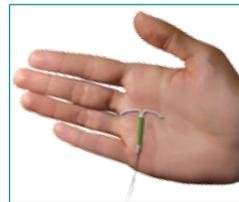
- **Levonorgestrel** is a hormone commonly used in combination with oral contraceptives (the “Pill”) and is similar to progesterone, a sex hormone produced naturally by the body.
- **Intrauterine** means within the uterus.

MIRENA® is also used to treat heavy menstrual bleeding without a known reason in women who want to use a hormonal contraceptive method and have started having menstrual periods.

MIRENA® can stay in place for five years before it must be removed.



What does MIRENA® look like?



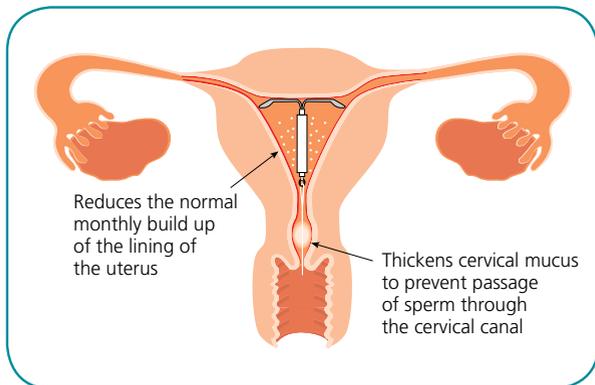
MIRENA® consists of a small, white T-shaped frame made from soft, flexible plastic. The vertical and horizontal arms of the T are approximately 3 cm in length. The vertical arm is surrounded by a narrow cylindrical shaped reservoir that contains levonorgestrel. Two fine plastic threads are attached to the tip of the vertical arm.

These threads are intended to be used for removal of the system and also serve to check its presence once it is in place.



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

How does MIRENA® work?



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

This amount of levonorgestrel:

- Reduces the normal monthly build up of the lining of the uterus
- Thickens the cervical mucus which prevents passage of sperm through the cervical canal (opening to the uterus)

These effects of levonorgestrel prevent pregnancy and decrease abnormally heavy menstrual blood loss.

How effective is MIRENA®?

For preventing pregnancy, MIRENA® is as effective as oral contraceptives.

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

MIRENA® contains a total of 52 mg of levonorgestrel which is enough hormone to prevent pregnancy for up to five years.

MIRENA® is also used to treat heavy menstrual bleeding without a known reason in women who want to use a hormonal contraceptive method and have achieved menarche (i.e., have had a first menstrual period).

MIRENA® decreases abnormally heavy menstrual blood loss. A reduction in menstrual blood loss should be apparent from the first menstrual cycle.



Will MIRENA® interfere with sexual intercourse?

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

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 doctor to verify it is still in the correct position.

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

MIRENA® does not protect you against sexually transmitted infections (STIs) including HIV/AIDS. Be safe. For protection against STIs, it is advisable to use a latex or polyurethane condom.

What if I want a baby?

MIRENA® is fully reversible.

If you want a baby, ask your doctor to remove MIRENA®. Your usual level of fertility will return soon after MIRENA® is removed. Women requesting the removal of MIRENA® for reasons of planning a pregnancy were followed for 24 months. During the 24-month period, nearly 90% of these women were able to get pregnant.

Can I breast-feed while using MIRENA®?

Hormonal contraceptives are not recommended as a birth control method of first choice in women who are breast-feeding. Small quantities of levonorgestrel, the medicinal ingredient in MIRENA®, have been found in the milk of breast-feeding women using MIRENA®; however, there does not appear to be a detrimental effect on growth or development of breast-fed infants whose mothers started using the product six weeks after delivery. The risk of perforation is increased in breast-feeding women.



MIRENA® insertion

How is MIRENA® inserted?

Pre-insertion

Before MIRENA® is inserted, your doctor will perform an examination, which may include:

- A Pap smear
- A breast examination
- Blood pressure check
- Pelvic exam
- Abdominal exam
- Other tests, i.e., a test to make sure you aren't pregnant, tests for infections, including sexually transmitted infections, as necessary

Insertion

- Your doctor will insert 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 doctor will withdraw the tube leaving the system in place in the uterus.
- Finally, your doctor will trim the removal threads to a suitable length.



Discomfort and pain relief during insertion

Most women find that the insertion procedure causes minor discomfort; however, for some it may be more uncomfortable.

If concerned, you may wish to discuss the need for a pain killer or local anesthetic with your doctor. Some women may feel faint after MIRENA® is inserted, but this feeling subsides after a short rest.

In epileptic patients, the insertion procedure may precipitate a seizure.

After insertion, you may feel some cramp-like menstrual pain; but don't worry, this usually disappears within a few days. If the pain does not disappear, speak to your doctor.

Post-insertion

MIRENA® should be used only under the supervision of a doctor, with regular follow-up visits to identify side effects associated with its use.

These visits may include:

- Blood pressure check
- Breast exam
- Abdominal exam
- Pelvic exam, including a Pap smear

Visit your doctor 4 to 12 weeks after the initial examination. Afterward, visit your doctor at least once a year.

Carefully follow all directions given to you regarding MIRENA®. Otherwise, you may become pregnant.

Uterine Perforations

It's rare but MIRENA® may penetrate or perforate (punch a hole through) the wall of the uterus (occurring at a rate of between 1 in 1,000 and 1 in 10,000) and part or all of the system may come to rest outside the uterus. If this happens, the system must be removed; surgery may be required. The risk of perforation is increased in breast-feeding women.

When should MIRENA® be inserted?

Remember, the MIRENA® system should generally be inserted during your period or within seven days of it starting.

- When replacing an existing system for a new one, it is not usually necessary to wait for your period.
- Following childbirth, MIRENA® should not be fitted until six weeks after delivery.

How long does insertion take?

The insertion procedure usually takes a few minutes after your doctor has completed the pelvic examination.

How quickly does MIRENA® start to work?

You will be protected from pregnancy as soon as insertion of the system is complete; however, it is best to wait 24 to 48 hours before having sexual intercourse.

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

How often should I have MIRENA® checked?

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

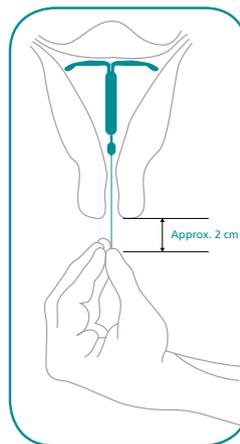
MIRENA® can stay in place for five years before it must be removed.

How can I check if MIRENA® is in place?

Your doctor will show you how to do this. Do not pull on the threads as you may accidentally pull the system out.

After each menstrual period or about once a month, you should check by feeling if the two threads are still in place.

If you cannot feel the threads, go to your doctor and in the meantime use another method of nonhormonal contraception. You should also go to your doctor if you can feel the lower end of the system itself.



Removal of MIRENA®

You should see your doctor when you want to have MIRENA® taken out. Removal is very easy; however, you should be aware that you may become pregnant upon removal of the system if you have had sexual intercourse during the previous week.

If you are having MIRENA® removed, tell your doctor if you have had sexual intercourse during the preceding week.

More on MIRENA®

Can any woman use MIRENA®?

Most women can use MIRENA®, but it is not suitable for everyone. Your doctor will examine you and ask about your medical history in order to decide whether or not you can use it.

Tell your doctor if you:

- Have any allergies to the hormone levonorgestrel, or to any of the other ingredients of MIRENA®, or to components of the container
- Are pregnant, or if you suspect that you may be pregnant
- Currently have pelvic inflammatory disease (PID) or have had recurrent PID
- Have an infection of your lower genital tract
- Had an infection of the uterus (womb) after delivering a baby
- Have bleeding from the vagina that has not been explained
- Have a condition of the uterus that distorts the uterine cavity, such as large fibroids
- Have an infection of the cervix (neck of the womb)
- Have cell abnormalities in the cervix (your doctor can tell you if you have this)
- Have a known or suspected progestogen-dependent tumour, including breast cancer
- Have liver disease or liver tumour
- Have had an infection of the uterus (womb) after having an abortion during the past three months
- Have bacterial endocarditis (an infection of the heart valves or lining of the heart)
- Have immunodeficiency (a doctor will have told you if you have this)
- Have cancer affecting the blood, or if you have leukemia
- Have or have had trophoblastic disease (a doctor will have told you if you have this)
- Have cancer of the uterus or the cervix (uterine or cervical malignancy)

In a small number of women, serious side effects may occur. Your doctor can advise you if you have any conditions that would pose a risk to you.

Before you use MIRENA®...

Talk to your doctor or pharmacist if you:

- Are breast-feeding
- Have ever had an ectopic pregnancy (ectopic pregnancy is more likely if you accidentally become pregnant while using MIRENA®)
- Have a history of ovarian cysts (there is an increased risk of cysts on the ovary)
- Have had surgery on your fallopian tubes
- Have an unusual menstrual bleeding pattern
- Have an unusual or unpleasant vaginal discharge (e.g., smelly) or vaginal itching
- Have had a stroke, heart attack or any heart problems
- Have or have had jaundice (a yellowing of the skin, whites of the eyes and/or nails)
- Are diabetic, have a family history of diabetes, have high blood pressure or abnormal blood lipid levels
- Have a history of blood clots (thrombosis)
- Are taking any other medications
- Have or have had a history of migraine, dizziness or blurred vision
- Have severe headaches
- Have a history of depression
- Wear contact lenses
- Have a heart abnormality or any problem with your heart valves
- Smoke

You should also inform your doctor about a family history of blood clots, heart attacks, or strokes.

Tell your doctor if you are scheduled for any laboratory tests, since certain tests may be affected by hormonal contraceptives. Also tell your doctor if you are scheduled for surgery requiring prolonged bed rest.

If you see a different doctor, inform him or her that you are using MIRENA®.

Circulatory Disorder

Some studies have suggested that women who use progestogen-only oral contraceptives might have a slightly higher risk of blood clots (which may occur in legs, lungs, heart, eyes, or brain), however, the results are not certain. You should discuss risk factors for blood clots with your doctor.

Be alert for the following symptoms and signs of serious adverse effects. Contact a doctor immediately if they occur:

- Sharp pain in the chest, coughing blood, or sudden shortness of breath (these symptoms could indicate a possible blood clot in the lung)
- Pain and/or swelling in the calf (these symptoms could indicate a possible blood clot in the leg)
- Crushing chest pain or heaviness (these symptoms could indicate a possible heart attack)
- Sudden severe or worsening headache or vomiting, dizziness or fainting, disturbances of vision or speech, or weakness or numbness in an arm or leg (these symptoms could indicate a possible stroke)
- Sudden partial or complete loss of vision (these symptoms could indicate a possible blood clot in the eye)

Breast Cancer

The most significant risk factors for breast cancer are increasing age and a strong history of breast cancer in the family (mother or sister). Other established risk factors include onset of menstrual periods before the age of 12, never having children, having your first full-term pregnancy after the age of 30, never having breast-fed a child, and daily alcohol consumption.

Some studies have shown that the risk of developing breast cancer does not appear to be increased by using progestogen-only forms of birth control like MIRENA®. However, more thorough studies are needed to confirm that there is no increased risk. You should notify your doctor if you notice any breast lumps. You should also discuss breast self-examination with your doctor. A yearly breast examination by a healthcare professional is recommended for all women.

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 the system is removed, periods should return.

Can tampons be used?

Use of sanitary pads is recommended. If tampons are used, you should change them with care so as not to pull the threads of MIRENA®.



Will I stop having periods?

Gradually, over time, your menstrual period may 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, as happens during a usual menstrual period.

If you are having regular menstrual periods while using MIRENA® and then do not have one for six weeks or longer, it is possible that you may be pregnant. You should speak to your doctor.

Do other drugs interfere with MIRENA®?

You should inform your doctor or pharmacist if you are taking or have recently taken any medications or herbal products, even those without a prescription.

Hormonal contraceptives may become less reliable if you are also taking drugs that affect the liver (such as primidone, barbiturates, phenytoin, carbamazepine, rifampicin and griseofulvin) at the same time. The influence of these drugs on the reliability of MIRENA® has not been studied, but is unlikely since MIRENA® releases a very small amount of hormone, and delivers the hormone inside the uterus.

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. Women should be counselled not to smoke.



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 MIRENA® has fallen out of your uterus, either completely or partially. You can check that MIRENA® is in place by feeling for the threads as explained by your doctor.

If you think the MIRENA® system has come out, use another method of nonhormonal contraception until you see your doctor.

Infections

There is an increased risk of a serious pelvic infection called pelvic inflammatory disease (PID) in the first three weeks after insertion 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 doctor 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*

The inserter provided with MIRENA® helps protect the system from contamination, thereby minimizing the risk of pelvic infection.

What about side effects?

Menstrual bleeding irregularities are the most common side effects of MIRENA® during the first months after the system is inserted, 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. Device breakage has also been reported.

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 doctor.



MIRENA® Menstrual Diary

Use the MIRENA® menstrual diary to keep track of any spotting or bleeding which may occur in the next few months. Please keep in mind that every woman's body is unique and that your bleeding patterns might be different.

J	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
F	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		
M	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
A	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	
M	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
J	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	
J	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
A	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
S	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	
O	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
N	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	
D	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



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:

● Spotting
Mark a dot

■ Heavy Flow
Fill in the box

□ No Bleeding
Leave blank

× Normal Flow
Mark an X



Serious Warnings and Precautions

MIRENA® DOES 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 counselled not to smoke.

The insertion of MIRENA® may cause the system to penetrate or perforate (punch a hole) in the wall of the uterus.

Physicians: Please consult prescribing information for warnings, precautions, contraindications, adverse events and important selection criteria before prescribing.

References: **1.** MIRENA® Product Monograph. Bayer Inc. July 15, 2013. **2.** Health Canada. Screening for cervical cancer. 2006. http://www.hc-sc.gc.ca/iyh-vsv/diseases-maladies/cervical-uterus_e.html (Accessed March 30, 2007). **3.** Black A, Francoeur D, Rowe T. SOGC Clinical Practice Guidelines: Canadian Contraception Consensus. *JOGC* 2004;Part 2 of 3:219-54.

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