



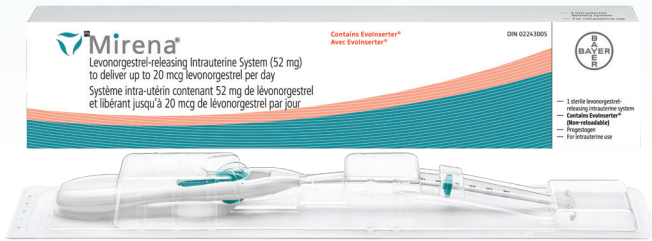
GET TO KNOW MIRENA[®]

A GUIDE TO YOUR
**INTRAUTERINE
CONTRACEPTIVE**

Getting started with MIRENA®



What's in the box?



The box holds more than just MIRENA® – it also includes the Evolnserter® (which is used to insert MIRENA®).

MIRENA® is an intrauterine system (IUS) used for the prevention of pregnancy for up to 8 years.

MIRENA® is also used to treat heavy menstrual bleeding without a known reason, for up to 5 years, in individuals who are able to use a hormonal birth control method and have had their first period.

MIRENA® has not been studied in individuals over the age of 65 years.

To find a placement clinic where you can have MIRENA® inserted by a healthcare professional, visit kyleenaandmirena.ca.





How effective is MIRENA®?

Clinical trials found that there were about 0.2 pregnancies per year for every 100 MIRENA® users.

Typical pregnancy rates for different methods of birth control and when no birth control is used

Product	Reported pregnancies per 100 individuals within the first year of use
Hormonal intrauterine system (IUS)	Less than 1
Copper intrauterine device (IUD)	Less than 1
Subdermal implant	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

A closer look at MIRENA®

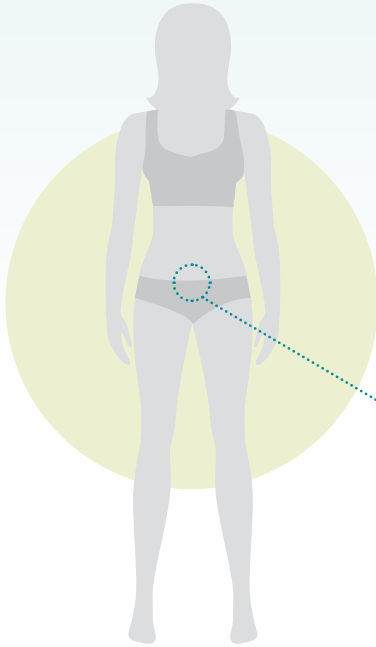
- Small, white, T-shaped frame
- Made from soft, flexible plastic
- The vertical arm is surrounded by a narrow, a reservoir that contains a hormone called levonorgestrel
- Two brown-coloured fine plastic threads are attached to the tip of the vertical arm



MIRENA® is placed in the uterus

MIRENA®:

- Is placed in the uterus by a healthcare professional
- Works by slowly releasing a low amount of levonorgestrel directly into the uterus every day
- Does not contain any estrogen



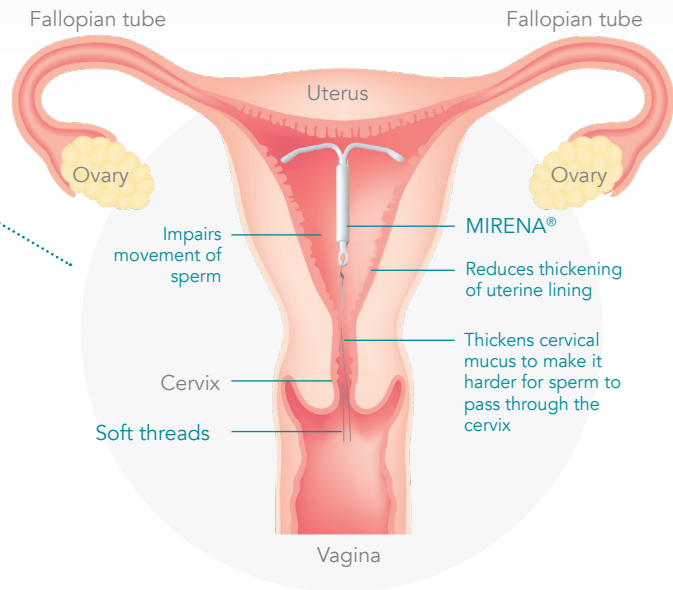
While using MIRENA®, the risk of pregnancy is low. However, if you do accidentally become pregnant while using MIRENA®, an ectopic pregnancy is more likely. This means that the pregnancy is not in the uterus. Ectopic pregnancy is a serious condition. Tell your healthcare professional if you have lower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

How may MIRENA® help prevent pregnancy?

MIRENA® may work to prevent pregnancy in several ways:

1. Reducing the normal monthly thickening of the lining of the uterus
2. Thickening the cervical mucus, which makes it harder for sperm to pass through the cervix
3. Impairing sperm movement and function

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



What to expect during placement

MIRENA® is inserted in the uterus by your healthcare professional. The procedure only takes a few minutes.

- Before MIRENA® is placed, your healthcare professional 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
- A thin flexible plastic tube containing MIRENA® will be inserted into your uterus – you may feel some discomfort
- Once in the correct position, your healthcare professional will withdraw the tube and leave MIRENA® in your uterus
- Finally, the removal threads will be trimmed to a suitable length

Most individuals experience either no pain or only mild pain during placement of MIRENA®. Some individuals may experience some discomfort. You may wish to discuss the need for a painkiller or local anesthetic with your healthcare professional.

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

MIRENA® is reversible any time in case your plans change. Once your healthcare professional removes MIRENA®, you can try to get pregnant right away.

During placement, MIRENA® may become attached to or penetrate (perforate) the wall of the uterus, but this is uncommon. If this happens, MIRENA® must be removed. The risk of perforation is higher in breastfeeding individuals and when MIRENA® is placed up to 36 weeks following delivery, and may be increased in individuals with a differently shaped uterus or with a uterus that is fixed and leaning backwards.



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.

If replacing MIRENA® or inserting after pregnancy:

- When replacing an existing system for a new one, it is not necessary to wait for your period
- After childbirth, wait until the uterus has returned to its normal size, at least 6 weeks after delivery
- After a first-trimester abortion, MIRENA® can be placed immediately. However, if the abortion takes place in the second trimester, placement should be delayed for 6 weeks or until the uterus has returned to normal size

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 inserted more than 7 days after the start of your period, use a condom or diaphragm, or do not have sex, for the next 7 days.



How MIRENA® may affect your period

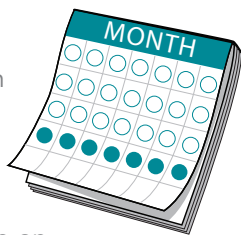
In the first 3 to 6 months, your period may become irregular and the number of bleeding days may increase. You might also experience frequent spotting (a small amount of blood loss) or light bleeding. In some cases, you may have heavy or prolonged bleeding over this time. Contact your healthcare professional 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 MIRENA® users eventually find that their periods stop altogether.

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.

However, if 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.

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



When MIRENA® is removed, periods should return to normal.

Use of sanitary pads is recommended while using MIRENA®. You can still use tampons or menstrual cups, however, be careful not to pull the threads of MIRENA® when changing them.



Checking if MIRENA® is in place

You should have MIRENA® checked by your healthcare professional approximately 4–12 weeks after placement, again at 12 months and then once a year until it is removed.

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 non-hormonal birth control (like condoms). You should also see your healthcare professional if you can feel the lower end of MIRENA® itself

For prevention of pregnancy, MIRENA® can stay in place for up to 8 years before it must be removed. You should receive a 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.

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.

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.

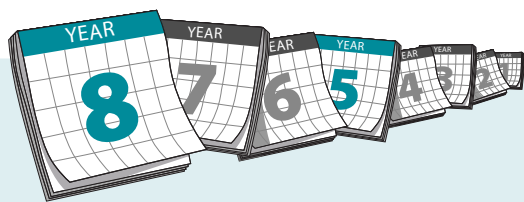
Removing and replacing MIRENA®

MIRENA® can be easily removed by your healthcare professional at any time if you wish to become pregnant.

- For prevention of pregnancy, MIRENA® should be removed or replaced after 8 years
- For treatment of heavy menstrual bleeding, MIRENA® should be removed or replaced after 5 years

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 week before.

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



Your healthcare professional can place a new system after removing the old system if you wish to continue using MIRENA®:

- After 8 years for prevention of pregnancy
- After 5 years for treatment of heavy menstrual bleeding

If the same MIRENA® system has been left in place for longer than 8 years, you may become pregnant. Pregnancy should be ruled out before placement of a new system.

Possible side effects from using MIRENA®

These are not all the possible side effects you may feel when taking MIRENA®. If you experience any side effects not listed here, 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; they 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 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® please tell your healthcare professional.

Few MIRENA® users 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.



Other things to know about MIRENA®

Will MIRENA® be felt during sexual intercourse?

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

After MIRENA® is placed, it is recommended to wait 24–48 hours before having 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.

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
- Right after the birth of a baby or after a second trimester abortion

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 non-hormonal 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.

MIRENA® menstrual diary

Use the MIRENA® menstrual diary to keep track of any spotting or bleeding over the first 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																																

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

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.



For more information about MIRENA[®], visit [mirena.ca](https://www.mirena.ca) (for full access, enter the Drug Identification Number [DIN] 02243005 when requested).

Scan the QR code to download a digital copy of this brochure or to access it in other languages



MIRENA[®] may be reimbursed. Contact your insurance provider for more information.

Serious warnings and precautions

- Hormonal birth control including MIRENA[®] **DOES 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

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

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