



 **Mirena**[®]
intrauterine levonorgestrel delivery system

**Your Questions
Answered**

About This Booklet

This booklet is designed as a resource for people who have been prescribed Mirena® or may want information about Mirena®.

The information in this booklet does not replace a healthcare professional's advice. Speak to your healthcare professional to find out if Mirena® is right for you or if you have any other questions.

You can also refer to the Mirena® Consumer Medicine Information available at www.medsafe.govt.nz or scan the QR code.



Table of Contents

About Mirena®	5
What is Mirena®?	5
What is Mirena® used for?	5
How long can Mirena® be used for?	6
What are the key features of Mirena®?	6
How long has Mirena® been available in New Zealand?	6
What are the ingredients in Mirena®?	7
How is Mirena® fitted?	7
Can any woman use Mirena®?	7
What are the possible side effects from using Mirena®?	8
About contraception	9
How does Mirena® prevent pregnancy?	9
How effective is Mirena® for contraception?	10
Do I need to use extra contraception after Mirena® is fitted?	10
Does Mirena® protect against sexually transmitted infections (STIs)?	10
What if I want to become pregnant or want to remove Mirena® for other reasons?	10
Can I breastfeed while using Mirena®?	11
About heavy menstrual bleeding (HMB)	12
What is HMB?	12
What causes HMB?	12
How does Mirena® work to treat HMB?	12
How effective is Mirena® for the treatment of HMB?	12
About hormone replacement therapy (HRT) or menopause hormone therapy (MHT)	14
What is menopause?	14
What is HRT (or MHT)?	15
How does Mirena® work to protect the lining of the uterus as part of HRT (or MHT)?	15
How effective is Mirena® as part of HRT (or MHT)?	15
Frequently asked questions	16
What happens to my periods while I am using Mirena®?	16
Isn't it abnormal not to have a period?	17
Can I fall pregnant with Mirena® in place?	17
Can I become pregnant after stopping use of Mirena®?	18
When should Mirena® be fitted?	18

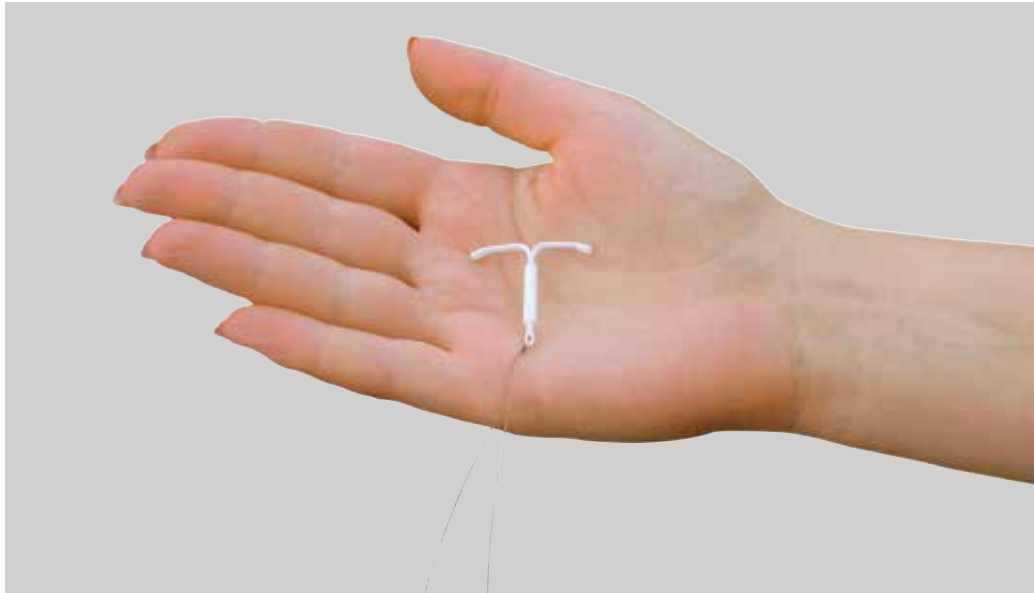
How can I check if Mirena® is in place?.....	18
Should my Mirena® be checked regularly by my healthcare professional?.....	18
Can Mirena® become dislodged (expelled) or fall out?.....	18
Can Mirena® cause perforation?.....	18
Can Mirena® cause pelvic infections?.....	19
What are some other things I should be aware of while using Mirena®?.....	20
Can Mirena® interact with other medicines I may be taking?.....	21
Will Mirena® interfere with sexual intercourse?.....	21
Can I use tampons or menstrual cups?.....	21
Does Mirena® contain any latex?.....	21
Can Mirena® be seen on x-ray?.....	21
Will Mirena® cause me to gain weight?.....	22
Will any of the hormones be absorbed by my body?.....	22
I have had my Mirena® for 5 years. Should I have it replaced?.....	22
How will I remember when it is time to have my Mirena® replaced?.....	22
If I have an operation, should my Mirena® be removed?.....	22
I have reached perimenopause. Must I have Mirena® removed?.....	23
Getting off to a good start with Mirena®	24
Insertion guide.....	24
Post-insertion guide.....	26
Bleeding pattern diary	28
References	30
Notes	31

About Mirena®

What is Mirena®¹

Mirena® is an intrauterine system (IUS) which is fitted by a healthcare professional into your uterus.

It is a small, T-shaped frame made from polyethylene, which is a soft flexible plastic. Attached to the stem of the frame is a cylinder that contains the hormone levonorgestrel. There are also two fine threads attached to the base of the frame, designed to help your healthcare professional with removal and to help you check that Mirena® is in position whilst it is in place in your uterus.



What is Mirena® used for?^{1,2}

Mirena® has three approved indications in New Zealand. It can be used for:

- Contraception (prevention of pregnancy);
- Heavy menstrual bleeding when no cause can be found;
- Preventing thickening of the lining of the uterus as part of hormone replacement therapy during menopause.

How long can Mirena® be used for?^{1,2}

Mirena® is approved for up to 5 years continuous use for all of the registered indications. However, if your circumstances change or you change your mind, Mirena® can be removed at any time. Speak to your healthcare professional about the timing of the removal if you are not planning to try for a pregnancy.



What are the key features of Mirena®?¹⁻³

- It is approved for up to 5 years continuous use, but can be removed at any time if you wish to stop using the method for any reason.
- It doesn't interfere with sex, because while the system is fitted and in place you have constant contraceptive cover.
- It does not require daily pill taking or regular injections.
- It is over 99% effective at preventing pregnancy (99.8% at year 1 and 99.3% at year 5).
- It is quickly reversible, does not change your usual baseline level of fertility and does not alter your chance of future fertility.
- It may reduce your period pain.
- While many women experience frequent spotting or light bleeding in addition to their periods for the first 3–6 months, over time 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 find that their periods stop altogether.

How long has Mirena® been available in New Zealand?²

Mirena® was first registered in New Zealand in 1998.

What are the ingredients in Mirena®?^{1,2}

Mirena® contains the hormone called levonorgestrel. Levonorgestrel is also found in some oral contraceptive pills and is similar to the progesterone hormone made by your body. It belongs to the class of hormones called progestogens.

Mirena® also contains barium sulfate, used as a contrast medium so that it can be seen on an x-ray.

The two fine threads attached to the base of the frame are made of iron oxide and polyethylene.

Mirena® also contains the following ingredients:

- Dimethylsiloxane/methylvinylsiloxane (cross-linked) elastomer
- Silica – colloidal anhydrous.

How is Mirena® fitted?

Refer to the insertion guide on page 24 of this booklet.

Can any woman use Mirena?¹

As with all methods of contraception or hormone treatments, Mirena® will not be suitable for everyone. For example, if you are pregnant or suspect you may be pregnant, you cannot use Mirena®. You should also avoid Mirena® if you have an allergy to any of the ingredients, outlined in the question above (see *What are the ingredients in Mirena®?*).

If you are unsure whether Mirena® is suitable for you, discuss this with your healthcare professional. You can also refer to the Consumer Medicine Information leaflet for further information on your potential suitability for Mirena®, available at www.medsafe.govt.nz.



What are the possible side effects from using Mirena®?¹

All medicines can have side effects. Some people may experience side effects while using Mirena®, while others may not experience any. Side effects are most common during the first months after Mirena® is placed and decrease as time goes on. Do not be alarmed by the following side effects, you may not experience any of them.

Some possible side effects of Mirena® may include:

- pain, bleeding, dizziness and fainting during placement or removal of Mirena®
- genital tract infection
- ovarian cysts
- nervousness
- depressed mood, mood swings
- lower abdominal/pelvic pain or back pain
- bleeding changes including increased or decreased menstrual bleeding, spotting, infrequent or light periods, absence of bleeding
- headache, migraine
- nausea
- acne
- excessive hairiness
- tender or painful breasts
- period pain
- itching, redness and/or swelling of the vagina
- vaginal discharge
- weight gain
- decreased libido
- expulsion (falling out) of Mirena®

Tell your doctor, nurse or pharmacist if you notice any of the above side effects, particularly if they worry you.



For more information about possible side effects, refer to the Consumer Medicine Information leaflet available at www.medsafe.govt.nz or scan the QR code.



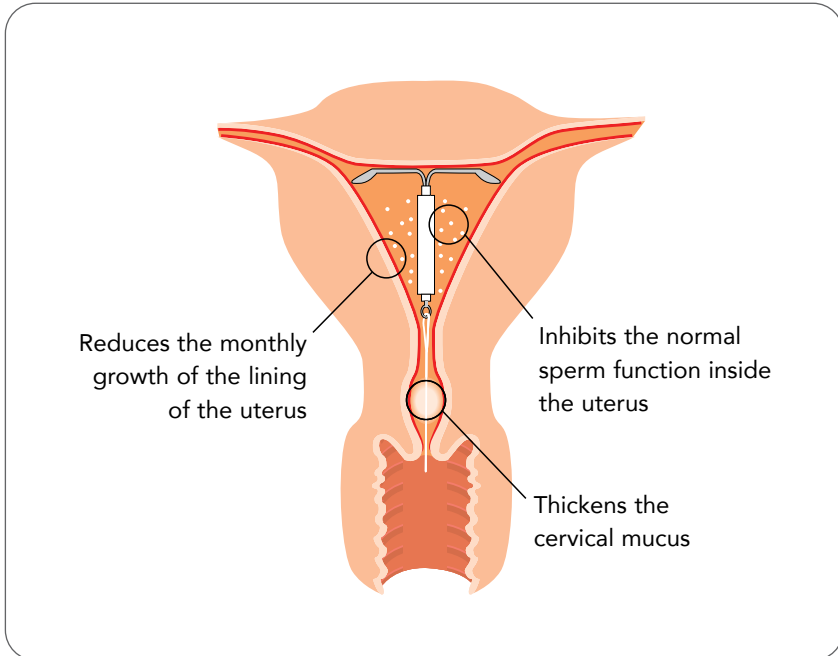
About Contraception

For women who have been prescribed or are considering Mirena® as a long term and reversible method of contraception.¹

How does Mirena® prevent pregnancy?¹

Mirena® contains a synthetic hormone called levonorgestrel which is a progestogen. This hormone prevents pregnancy by:

- Controlling the monthly development of the lining of the uterus, so that it is not thick enough for you to become pregnant;
- Making the normal mucus in the cervical canal (the opening to the uterus) thicker, so that the sperm cannot get through to fertilise the egg;
- Affecting the movement of sperm inside the uterus, preventing fertilisation.



How effective is Mirena® for contraception?^{2,4}

Mirena® is one of the most effective and reliable methods of contraception available. Studies have shown that of 1,000 women who use Mirena® for 1 year, no more than two are likely to become pregnant. This is similar to female sterilisation.

Once Mirena® is properly fitted, and provided it stays in position, it is approved for up to 5 years of continuous use and the reliability remains over 99% over this time.



Mirena® is over 99% effective at preventing pregnancy when fitted properly and in the correct position

Do I need to use extra contraception after Mirena® is fitted?¹⁻³

If Mirena® is fitted as recommended during the first 7 days of your period, it will provide immediate protection against pregnancy. Generally there is no need for extra precautions although you should always discuss your own situation with your healthcare professional.

However, it is best to wait at least 48 hours before having sexual intercourse to minimise the risk of infection.

Does Mirena® protect against sexually transmitted infections (STIs)?²

Mirena® does not protect against HIV infection (AIDS) and other STIs. Additional methods should be used (i.e. condoms) to prevent transmission of STIs.

What if I want to become pregnant or want to remove Mirena® for other reasons?^{1,2}

Mirena® can be removed at any time by your healthcare professional at your request. Although it is a long-acting contraceptive, the use of Mirena® does not alter the course of your future fertility. After removal, you can begin trying to get pregnant. If you choose to remove Mirena® in order to try for a pregnancy, the chance of falling pregnant at 1 year is similar to women who do not use contraception.

If you don't want to try for a pregnancy in the near future, Mirena® should be removed within 7 days of the onset of menstruation, provided you are experiencing regular periods. If Mirena® is removed at some other time during the cycle or if you do not experience regular periods and you have had intercourse within the previous week, you may not be protected against pregnancy. If contraception is still required after removal of Mirena®, make sure you discuss other methods of contraception with your healthcare professional before it is removed.

Can I breastfeed while using Mirena®?^{1,2}

Speak to your doctor or midwife if you plan to breastfeed or are breastfeeding. Progestogen-only methods of contraception such as Mirena® do not appear to affect the quantity or quality of breast milk.

When Mirena® is used while breastfeeding, there is a small amount of the progestogen hormone levonorgestrel which will be absorbed by babies who are breastfeeding. This is lower than that received by babies when the mother is using the mini-pill (another progestogen-only contraceptive). There has been extensive experience with the mini-pill during breastfeeding, indicating no harmful effects to breastfed babies.

Your doctor or midwife will advise if Mirena® is a suitable method for you, and when to have Mirena® fitted.





About Heavy Menstrual Bleeding (HMB)

For women who have been prescribed or are considering Mirena® for the treatment of HMB when no underlying cause can be found.¹

What is HMB?⁵

Menstrual bleeding is considered to be heavy when it interferes with a woman's physical, social and/or emotional quality of life. It is a common condition, affecting approximately 1 in 4 women of reproductive age.

Periods are a very personal experience and women who have always had heavy periods may often consider this as normal. Symptoms such as flooding through clothing, being unable to leave the house on the heaviest days, and having to change pads and tampons frequently (including at night) are indicative of HMB.

What causes HMB?⁵⁻⁷

There are a number of possible causes for HMB, including hormone imbalances, gynaecological conditions such as fibroids, polyps or endometrial hyperplasia (thickening of the lining of the uterus), or clotting abnormalities. However, in 40–60% of cases, no underlying cause can be found.

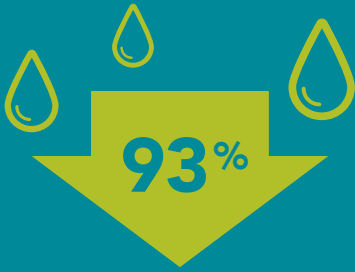
How does Mirena® work to treat HMB?¹

Mirena® works in the treatment of HMB with no underlying cause by slowly releasing the progestogen hormone levonorgestrel, within the uterus. Levonorgestrel suppresses the response of the cells in the lining of the uterus to estrogen. This stops the growth of the lining of the uterus, which results in a reduction in the volume and duration of menstrual bleeding.

How effective is Mirena® for the treatment of HMB?^{2,5}

In women who have HMB with no underlying cause, Mirena® has been shown to reduce menstrual blood loss by approximately 93% over the course of 3–12 menstrual cycles, compared to before treatment. In some women, Mirena® may result in periods stopping altogether.

Australian Guidelines recommend Mirena® as the most effective way to manage HMB (when no cause can be found) without surgery.



.....

Mirena® reduces menstrual blood loss by approximately 93% over the course of 3–12 menstrual cycles, compared to before treatment.

.....





About Hormone Replacement Therapy (HRT) or Menopause Hormone Therapy (MHT)

For women who have been prescribed or are considering Mirena® for protection from endometrial hyperplasia (excessive growth of the lining of the uterus) during HRT (or MHT).¹

What is menopause?⁸

Menopause is marked by when a woman's periods stop naturally or she has had medical or surgical therapy that permanently stops her from having a normal cycle. Most women reach menopause between 45–55 years.

There is an interval of a few years before this happens, when gradual changes occur as the ovaries produce lower amounts of hormones and the frequency of ovulation may change. This is called perimenopause. During this time, it may still be possible to become pregnant, so contraception is still important.

Apart from changes in bleeding patterns, many women have noticeable signs of menopause due to the decrease in the female hormone oestrogen, e.g. hot flushes, mood changes, unusual sweating and other symptoms.



What is HRT (or MHT)?^{1,9}

HRT (or MHT) is the medical replacement of female hormones to help manage menopausal symptoms, such as hot flashes and night sweats, when they are interfering with your life.

HRT consists of the hormone estrogen, with or without a progestogen. Unless you have had a hysterectomy, it is likely you will need hormone therapy with both estrogen and progestogen. These two hormones are used together because estrogen may result in excessive thickening of the endometrium (the lining of the uterus). Mirena[®] contains a progestogen which may be recommended to protect the lining of your uterus from the effects of the estrogen therapy.

Your doctor will discuss which type of HRT may be suitable for you.

How does Mirena[®] work to protect the lining of the uterus as part of HRT (or MHT)?¹

Mirena[®] works to protect the endometrium (the lining of the uterus) during estrogen replacement therapy by slowly releasing the progestogen hormone levonorgestrel, within the uterus. Levonorgestrel suppresses the response of the cells in the lining of the uterus to estrogen. This protects against overstimulation of the lining of the uterus in estrogen replacement therapy.

How effective is Mirena[®] as part of HRT (or MHT)?^{2,10}

Estrogen therapy alone can result in endometrial hyperplasia (excessive growth of the lining of the uterus) in as many as 1 in 5 women after 1 year of continuous use.

When Mirena[®] was added to estrogen therapy in clinical studies of up to 5 years duration, no cases of endometrial hyperplasia were reported.

Frequently Asked Questions

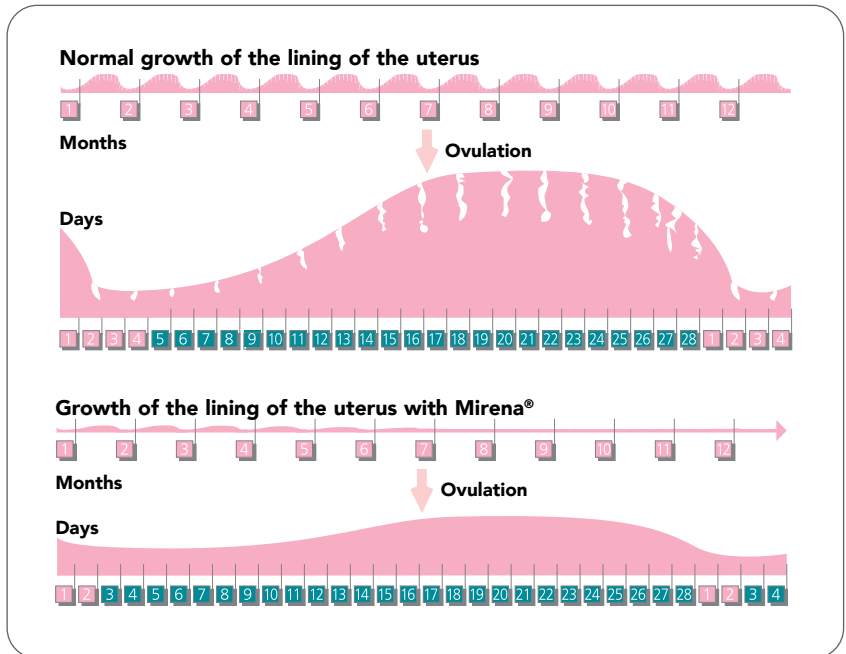
What happens to my periods while I am using Mirena®?^{1,2,11}

Mirena® will affect your periods. Initially you are likely to have an increase in the number of days with bleeding each month. Most women have frequent spotting (a small amount of menstrual blood loss) or light bleeding (requiring panty liners) in addition to their periods for the first 3–6 months after Mirena® is fitted.

However over time, 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 eventually find that their periods stop altogether.

If you have been using Mirena® for 5 years and are having it replaced, any initial increase in bleeding you may have experienced with your first Mirena® is unlikely to recur.

When Mirena® is removed, your periods can be expected to return to what is normal for you, unless you have reached menopause.



Graph adapted from <https://www.thewomens.org.au/health-information/periods/periods-overview/about-periods/>¹ and Mirena® Consumer Medicine Information.²

The diagram in the previous page shows the normal growth of the lining of the uterus each month and the growth of the uterus lining with Mirena®. You may also find the chart at the back of this booklet useful to mark the days of spotting and light bleeding in the months after insertion so you can discuss the changes with your healthcare professional at your follow up visit.

Isn't it abnormal not to have a period?^{1,2}

When using Mirena®, some women find that over time their periods stop altogether. Others find that their bleeding patterns change to a more infrequent, lighter period whilst using Mirena®.

If you find that you do not have periods while using Mirena®, it's because of the effect of the hormone on the lining of your uterus. The thickening of the lining with blood is greatly reduced, and in some women does not happen at all, so there may be very little or no blood to come away as a period.

Since the effect of Mirena® is mainly localised in the uterus, the production of ovarian hormones still remains within normal limits and most women of fertile age will ovulate regularly even though they may not be menstruating. If you have not had a period for 6 weeks, and you are concerned, you should consider having a pregnancy test. If this is negative, there is no need to have another test unless you have other signs of pregnancy e.g. sickness, tiredness or breast tenderness.

If you are concerned, you should speak with your healthcare professional.

Can I fall pregnant with Mirena® in place?^{1,2}

It is very rare for a woman to become pregnant while using Mirena®.

Missing a period may not mean you are pregnant as some women find their periods stop completely and most others notice their bleeding patterns change to a lighter period whilst using Mirena®.

If you have not had a period for 6 weeks, and you are concerned, you should consider having a pregnancy test. If this is negative, there is no need to have another test unless you have other signs of pregnancy e.g. sickness, tiredness or breast tenderness.

Although it is very unlikely, if you are worried that you have become pregnant while using Mirena®, you should consult your healthcare professional as soon as possible.

Can I become pregnant after stopping use of Mirena®?²

Yes. After Mirena® is removed, it does not interfere with your normal level of fertility. In women who discontinue Mirena® for planned pregnancy, the chance of falling pregnant at 1 year is similar to those who do not use contraception. You may become pregnant during the first menstrual cycle after Mirena® is removed.

When should Mirena® be fitted?

Refer to the insertion guide on page 24 of this booklet.

How can I check if Mirena® is in place?

Refer to the post-insertion guide on page 26 of this booklet.

Should my Mirena® be checked regularly by my healthcare professional?

Refer to the post-insertion guide on page 26 of this booklet.

Can Mirena® become dislodged (expelled) or fall out?^{1,3}

If Mirena® comes out either partially or completely there may be some signs to alert you, like an unusual increase in bleeding, possibly some pain, you or your partner may be able to feel the lower end of the system itself, the removal threads may seem longer, or you may not be able to feel them at all. It is also rare but possible for this to happen without you noticing during your menstrual period.

Each month, you can check Mirena® is in place by feeling for the two thin threads attached to the lower end of Mirena®. Your healthcare professional will show you how to do this. Do not pull on the threads because you may accidentally pull it out.

If Mirena® comes out partially or completely, you will not be protected against pregnancy. You should avoid intercourse or use another form of contraception (e.g. condoms) and see your healthcare professional as soon as you can.

Can Mirena® cause perforation?¹⁻³

There is a small risk (around 2 in 1000) that Mirena® may perforate (be pushed through the wall of) your uterus. This occurs most often during placement of Mirena®, although it may not be detected until sometime later. The risk of perforation increases in breastfeeding women and when Mirena® is inserted after giving birth. The risk may also be increased in women with a fixed retroverted uterus (tilted uterus). If you experience excessive pain or bleeding during or after insertion, or at any time during the use of Mirena®, tell your healthcare professional immediately.

Can Mirena® cause pelvic infections?^{1,3}

Mirena® itself will not increase your risk of pelvic infection. However, the insertion procedure itself may result in a slightly increased risk of pelvic infection during the first month after Mirena® is fitted.

You have an increased risk of pelvic infections if you have multiple sexual partners, acquire an STI or have a history of pelvic inflammatory disease. When having sex with anybody who is not a long-term partner, a condom should be used to minimise the risk of infection.

It is also recommended that you do not insert anything into your vagina for 48 hours after Mirena® is fitted to minimise your risk of infection. This includes avoiding sexual intercourse, tampons, menstrual cups, swimming and baths.

Tell your healthcare professional without delay if you have persistent lower abdominal pain, fever, pain during sexual intercourse or abnormal bleeding – these may be signs of infection and should be treated promptly.



What are some other things I should be aware of while using Mirena®?

Ectopic pregnancy¹

It is very rare to become pregnant while using Mirena®. However, if you become pregnant while using Mirena®, the risk of the foetus being carried outside of your uterus is increased (ectopic pregnancy).

See your healthcare professional without delay if you notice your menstrual periods cease and then you start having persistent bleeding or pain, if you have vague or very bad pain in your lower abdomen, or if you have normal signs of pregnancy but you also have bleeding and feel dizzy.

Ovarian cysts¹

Ovarian cysts or enlarged groups of cells (follicles) have been reported with the use of Mirena®. You may not experience any symptoms with ovarian cysts or follicles, but in some cases they may cause pelvic pain or pain during intercourse. In most cases, the follicles resolve spontaneously.

Breast cancer¹

Available data is not conclusive for whether Mirena® increases your risk for breast cancer. If you are using Mirena® for HRT or MHT, you should refer to the Consumer Medicine Information of the estrogen component for additional information. Should breast cancer be diagnosed, your healthcare professional may consider removal of Mirena®.



For more information, including things to tell your healthcare professional about before and while you are using Mirena®, refer to the Consumer Medicine Information leaflet available at www.medsafe.govt.nz or scan the QR code.



Can Mirena® interact with other medicines I may be taking?¹

Some medicines and Mirena® may interact with each other. Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. For more information about medicines that can interact with Mirena®, refer to the Consumer Medicine Information leaflet available at www.medsafe.govt.nz.

Will Mirena® interfere with sexual intercourse?¹⁻³

If Mirena® is fitted within the first 7 days of the menstrual cycle, it will protect against pregnancy as soon as it is inserted. However, it is best to wait about 48 hours before having sexual intercourse.

Neither you or your partner should feel your Mirena® during intercourse. If you do, intercourse should be avoided or another contraceptive should be used (e.g. condoms) until your healthcare professional has checked that your Mirena® is still in the correct position.

Occasionally it may be possible for your partner to feel the ends of the threads. If this causes concern or discomfort, the length of the threads can be adjusted for you.

Can I use tampons or menstrual cups?^{3,15,16}

Nothing should be inserted into the vagina for 48 hours following insertion of Mirena®, including tampons and menstrual cups. After this time, tampons and menstrual cups can be used.

Tampons will not change the position or effectiveness of Mirena®. However, while it is unlikely to happen, care must be taken when changing them so the threads of Mirena® are not pulled and Mirena® accidentally removed.

There have been some studies which have shown there may be a higher risk of intrauterine devices (IUDs), including Mirena®, being expelled with menstrual cup use, particularly during its removal. Talk to your healthcare professional if you use a menstrual cup for advice on what to do when you have your period. As Mirena® should result in your periods being lighter you may choose to use a different form of period protection.

Does Mirena® contain any latex?¹

No. Mirena® is completely free from latex and is made from a type of soft, flexible plastic.

Can Mirena® be seen on x-ray?¹

Yes. Mirena® can be seen on x-ray and can also be located using ultrasound. It can also be visualised with MRI and PET scans.

Will Mirena® cause me to gain weight?^{2,12-14}

Mirena® should generally not cause any change in your weight, although it has been reported as a side effect by some women. Studies have shown that women using Mirena® have not changed their weight any more than women using a conventional copper intrauterine device (IUD), a non-hormonal method of contraception.

Will any of the hormones be absorbed by my body?²

Although the hormonal effect of Mirena® is mainly localised inside the uterus, a small amount of the hormone is absorbed into your blood circulation. Most women will still ovulate because the amount absorbed into the blood stream is not enough to suppress ovulation.

As the level of hormone in circulation is very low, the hormonal side effects are generally mild in nature and are more commonly reported in the first few weeks and months of use. If they do occur, they usually settle after the first few months.

I have had my Mirena® for 5 years. Should I have it replaced?^{2,11}

Mirena® is approved in New Zealand for up to 5 years of use for all of its registered indications. If you wish to continue using Mirena®, the system should be removed and replaced by your healthcare professional. (For more information on removal please refer to '*What if I want to become pregnant or want to remove Mirena® for other reasons?*' on page 10).

If your healthcare professional inserts a new Mirena® during the same visit, any initial increase in bleeding you experienced with your first Mirena® is unlikely to recur. Additionally, after the second year of use with their second Mirena®, up to 60% of women reported that their periods stopped altogether.

How will I remember when it is time to have my Mirena® replaced?²

There is a Mirena® Reminder Card inside the box your Mirena® comes in. Please ask your healthcare professional to give you this card and record the date. Your Mirena® should be removed 5 years from the date it was fitted.

If I have an operation, should my Mirena® be removed?²

There is usually no need for Mirena® to be removed before surgery, but discuss this with your surgeon or family doctor.

I have reached perimenopause. Must I have Mirena® removed?^{2,8}

No, but if you do choose to have it removed, you need to use another form of contraception if required as you could still fall pregnant in this time.

During perimenopause, periods can start to change and may become heavier and irregular. Mirena® may help improve this pattern while still providing contraception. If you want to continue using Mirena®, it should be replaced every 5 years.



Getting off to a Good Start with Mirena®

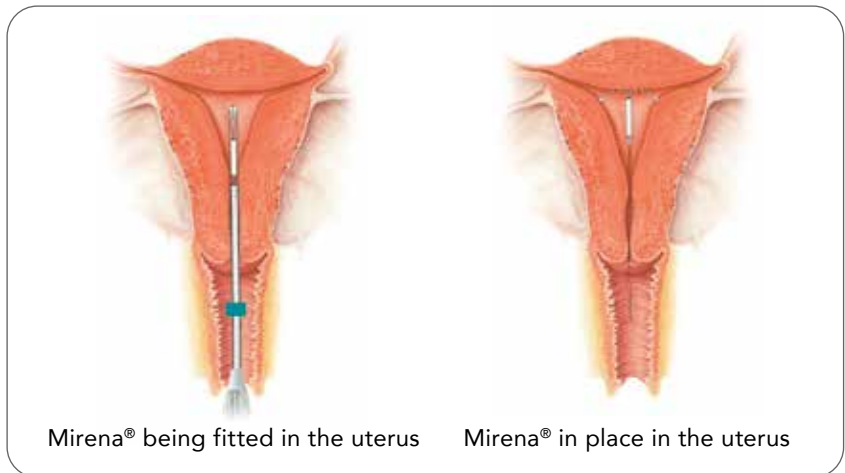
Insertion guide²

Mirena® is a small T-shaped device about 3 cm long. When you collect Mirena® from a pharmacy, you'll notice it is supplied in a long thin box as the device comes with its own special insertion tube, used to place Mirena® into your uterus.

Insertion should only be carried out by a healthcare professional who has been trained to do so.

The insertion process²

1. To help fit your Mirena® in the correct position, your healthcare professional will perform an examination to determine the size and position of your uterus.
2. Under sterile conditions, your healthcare professional will insert the plastic tube containing Mirena® into your uterine cavity. You may feel some discomfort or cramping at this time.
3. Once Mirena® is in the correct position, your healthcare professional will withdraw the plastic insertion tube, leaving the Mirena® in your uterus. They will then trim the threads of the Mirena®. The threads are there to let you check your Mirena® is still in place and help your healthcare professional remove the system when required.



Insertion: Frequently Asked Questions

When should Mirena® be inserted?^{1,2}

Mirena® is usually inserted within 7 days from the beginning of your period. Insertion outside of this time (e.g. if your cycles are not regular or you are changing from another method of contraception) should be discussed with your healthcare professional. If you already have Mirena® and it is time to replace it with a new one, it can be replaced at any time during the cycle. A new Mirena® can be inserted as soon as your old system is removed, at the same appointment.

After having a baby, Mirena® can usually be inserted from 6 weeks after a vaginal or 'natural' delivery and usually after about 12 weeks if you have had a caesarean section.

Mirena® may also be inserted immediately after a first trimester termination of pregnancy or at the follow up visit after a medical termination of pregnancy, provided there are no genital or pelvic infections.

When Mirena® is used to protect the lining of the uterus during HRT, it can be inserted at any time if you do not have monthly bleeding, or during the last days of menstruation or withdrawal bleeding.

Is it painful to insert?¹⁻³

The insertion of Mirena® can be uncomfortable, although half of women experience little or no pain during the procedure. Women who have delivered a baby only via caesarean section or those who have not had children may find it more uncomfortable, and may wish to discuss options for pain relief before the procedure.

How long does insertion take?

Preparations for the insertion usually take about 5 to 10 minutes, and the actual insertion of Mirena® will usually take only a few minutes.



If you have any other questions about Mirena® and what to expect or are not sure about anything to do with the procedure, please ask your healthcare professional. You can also refer to the Consumer Medicine Information leaflet available at www.medsafe.govt.nz or scan the QR code.





Post-insertion Guide

A few things to remember...

- After your Mirena® has been inserted, it is recommended that you do not insert anything into your vagina for 48 hours to minimise your risk of infection. This includes avoiding sexual intercourse, tampons, menstrual cups, swimming and baths.³
- Your healthcare professional will also have told you to expect some spotting or light bleeding at first which will typically settle during the first 3–6 months of use.¹ Panty liners should be all that is required for protection during the first week after fitting.
- Use the bleeding chart in the patient booklet to record your bleeding pattern. This is really important as it can help you and your healthcare professional know how your body is adjusting to Mirena®.

Post-insertion: Frequently Asked Questions

How will I feel after insertion of Mirena®?^{1,3}

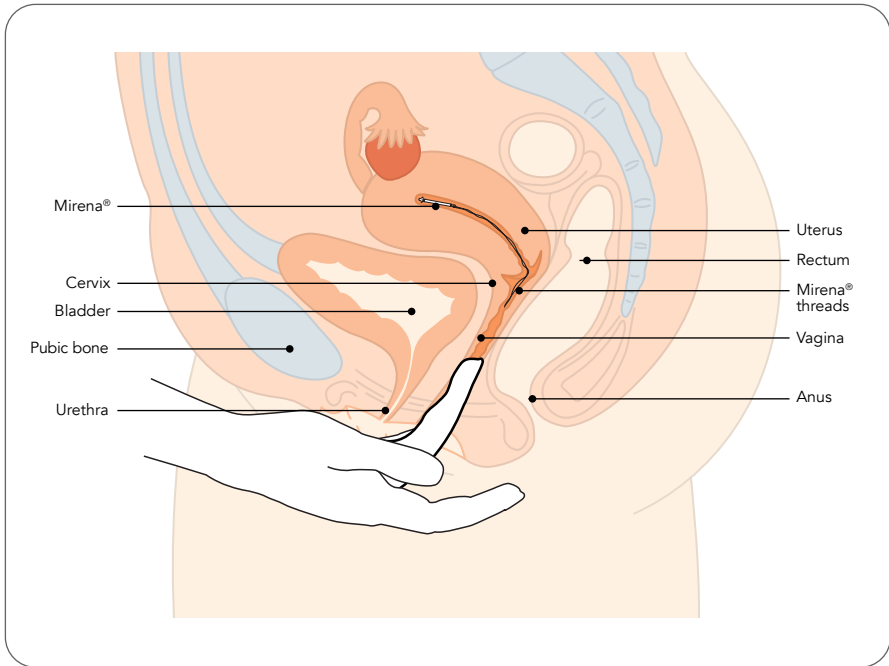
The insertion of Mirena® can be uncomfortable, although half of women experience little or no pain during the procedure. Afterwards you may feel some cramping, similar to period pain, and occasionally some dizziness may also occur. These symptoms usually disappear after a few hours but if they persist or you are concerned, please contact your healthcare professional.

Should my Mirena® be checked regularly by my healthcare professional?¹

You should have your Mirena® checked for the first time 4-12 weeks after insertion and again every 12 months by your healthcare professional. They will advise you when they would like to see you for an initial follow up visit.

How can I check Mirena® is in place?¹

After each period or about once a month, you can feel for the two fine threads. Your healthcare professional can teach you how to do this. Do not pull on the threads as you may accidentally pull your Mirena® out. If you can't feel the threads, please see your healthcare professional to make sure your Mirena® is still in position.



Tell your healthcare professional without delay if you have persistent lower abdominal pain, fever or pain during sexual intercourse, or abnormal bleeding as this may indicate an infection.



If you have any other questions about Mirena® and what to expect or are not sure about anything to do with the procedure, please ask your healthcare professional. You can also refer to the Consumer Medicine Information leaflet available at www.medsafe.govt.nz or scan the QR code.





Bleeding Pattern Diary

Use this diary page to record your bleeding pattern after you start Mirena®. Don't forget to have the diary with you when you call or visit your healthcare professional, because they are likely to ask you about your bleeding patterns. Keeping track of your bleeding pattern can help you and your healthcare professional know how your body is adjusting to Mirena®.

You can use these symbols when you enter information in the diary:

- X** Mirena® insertion date
- S** Spotting
- L** Light bleeding
- N** Normal bleeding
- H** Heavy bleeding
- No bleeding at all

Type of Bleeding

- Spotting** is less than your normal period.
Minimal sanitary protection is needed (i.e. panty liners).
- Light** is less bleeding than your normal period but more than spotting.
- Normal** is the usual amount of bleeding during your period.
- Heavy** is more bleeding than your normal period.

	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
Jan																															
Feb																															
Mar																															
Apr																															
May																															
Jun																															
Jul																															
Aug																															
Sep																															
Oct																															
Nov																															
Dec																															

X Mirena® insertion date S Spotting L Light bleeding N Normal bleeding H Heavy bleeding • No bleeding at all



References

1. Mirena® Consumer Medicine Information, 19 October 2021.
2. Mirena® Data Sheet, 19 October 2021.
3. Family Planning New South Wales, Family Planning Victoria and True Relationships and Reproductive Health. Contraception: An Australian Clinical Practice Handbook, 4th Edition. Ashfield, NSW, 2016.
4. Trussel J. *Contraception*. 2011;83:397–404.
5. Australian Commission on Safety and Quality in Health Care. Heavy Menstrual Bleeding Clinical Care Standard. Sydney: ACSQHC; 2017.
6. Oehler MK & Rees MCP. *Acta Obstetrica et Gynecologica Scandinavica*. 2003;doi.org/10.1034/j.1600-0412.2003.00097.x.
7. Hickey M *et al*. *Cochrane Database Syst Rev*. 2007 Oct 17;(4):CD001895.
8. Jean Hailes for Women’s Health. About menopause, updated August 2018. Available at <https://jeanhailes.org.au/health-a-z/menopause/about-menopause>. Accessed December 2021.
9. Jean Hailes for Women’s Health. Menopause management, updated August 2018. Available at <https://jeanhailes.org.au/health-a-z/menopause/menopause-management>. Accessed December 2021.
10. Varila E *et al*. *Fertil Steril*. 2001;76:969–973.
11. Ronnerdag M & Odland V. *Acta Obstet Gynecol Scand*. 1999;78:716–721.
12. Silva dos Santos PN *et al*. *Contraception*. 2017;95:382–389.
13. Vickery Z *et al*. *Contraception*. 2013;88:503–508.
14. Modesto W *et al*. *Eur J Contracept Reprod Health Care*. 2015;20:57–63.
15. Long J *et al*. *Obstetrics and Gynaecology*. 2020;135:1S.
16. Seale R *et al*. *Contraception*. 2019;100(1):85-87.
17. <https://www.thewomens.org.au/health-information/periods/periods-overview/about-periods/> Accessed January 2022.

MIRENA® (levonorgestrel)

MIRENA® is an intrauterine system containing 52 mg levonorgestrel, which is slowly released over 5 years at an initial rate of 20 mcg/24 hours. MIRENA is a **Prescription Medicine** for contraception. MIRENA is also a treatment for unexplained heavy menstrual bleeding where no underlying pathology causing excessive bleeding can be found and provides protection of the lining of the womb when oestrogen therapy is prescribed for menopausal symptoms. MIRENA must not be used during pregnancy, if there is any sign of pelvic or genital tract infection, inflammation or cancer, if there is womb or cervical abnormality, confirmed or suspected hormone-sensitive cancer including breast cancer, undiagnosed abnormal bleeding, active liver disease or if you are allergic to any ingredients in MIRENA. MIRENA should be inserted by a doctor who has been trained in the insertion technique. Removal of MIRENA is recommended if the following medical conditions occur: an increased susceptibility to infections, acute infection not responding to treatment. Migraine or severe headaches, jaundice, increased blood pressure, hormone-sensitive cancer, stroke, severe heart or blood vessel disease, blood clots may occur during MIRENA use, should this happen; your doctor may consider removal of MIRENA. MIRENA should be used with caution if you have diabetes or a heart condition from birth and are at risk of infection. MIRENA must be removed if pregnancy (which might be outside the womb) or puncture of the womb is suspected or if MIRENA is partially expelled. MIRENA does not protect against HIV infections (AIDS) and other sexually transmitted infections. The pattern of side effects, which are more common in the first months of use, should be explained to you. Commonly reported side effects include changes to menstrual patterns, painful menstruation, genital discharge, redness, or itching, headache/migraine, abdominal, breast or back pain, depressed mood, nervousness, nausea, acne, weight changes, decreased libido, excessive hair growth, benign ovarian cysts and expelled device. The possibility of side effects such as puncture of the womb, allergic reactions, bacterial infection of the blood, breast cancer, or pregnancy outside the womb should be discussed with your doctor, pharmacist or health professional. If symptoms persist or you have side effects, see your doctor for advice. MIRENA is a fully funded medicine – a pharmacy charge and normal Doctor's visit fees and insertion fees may apply. MIRENA has both risks and benefits. Use only as directed. Consult your doctor to see if MIRENA is right for you. For more information, read the Consumer Medicine Information available at <https://www.medsafe.govt.nz/Consumers/cmi/m/Mirena.pdf>. Bayer New Zealand Limited, PO Box 2825, Shortland Street, Auckland 1140, telephone 0800 229 376.

Bayer New Zealand Limited, B:HIVE Building, 72-74 Taharoto Road, Takapuna, Auckland 0622.
Mirena® is a Registered Trademark of the Bayer Group, Germany.
PP-MIR-NZ-0073-1. TAPS NP18590. October 2022. BY11252.

