



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

YOUR QUESTIONS ANSWERED



ABOUT THIS BOOKLET

This booklet is designed as a resource for women who have been prescribed Mirena. You may be receiving Mirena for the first time, or you may have already used it before.

Your doctor has given you this booklet to help answer some of the questions you may have. Keep it in a safe place so you can refer to it at any time, and always speak to your doctor if you are unsure or have any other questions.

TABLE OF CONTENTS

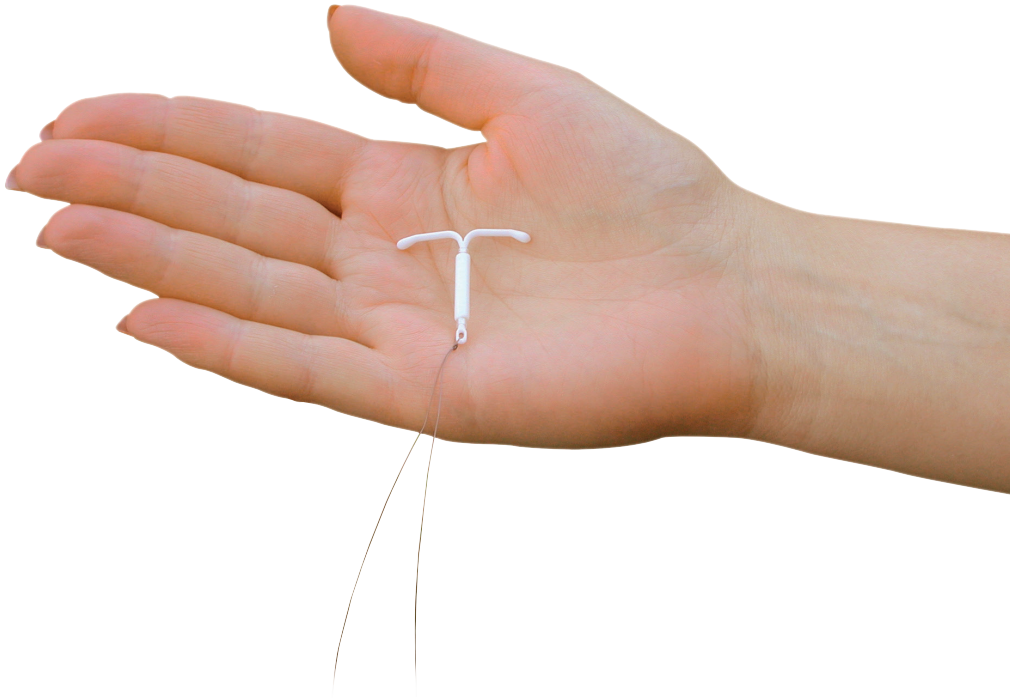
About Mirena	5
What is Mirena?.....	5
What is Mirena used for?.....	5
How long can Mirena be used for?.....	6
What are the key features of Mirena?.....	6
How long has Mirena been available in New Zealand?.....	6
What are the ingredients in Mirena?.....	7
How is Mirena fitted?.....	7
Can any woman use 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
Do I need to have Mirena checked regularly by my doctor?.....	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 doctor 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 doctor 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;
- to prevent 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 approved indications, after which it has to be removed and/or replaced if you wish to continue using Mirena.

However, if your circumstances change or you change your mind, Mirena can be removed at any time. Speak to your doctor 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 one 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 approved 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 your doctor can view it 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 doctor. 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 cyst
- 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 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.

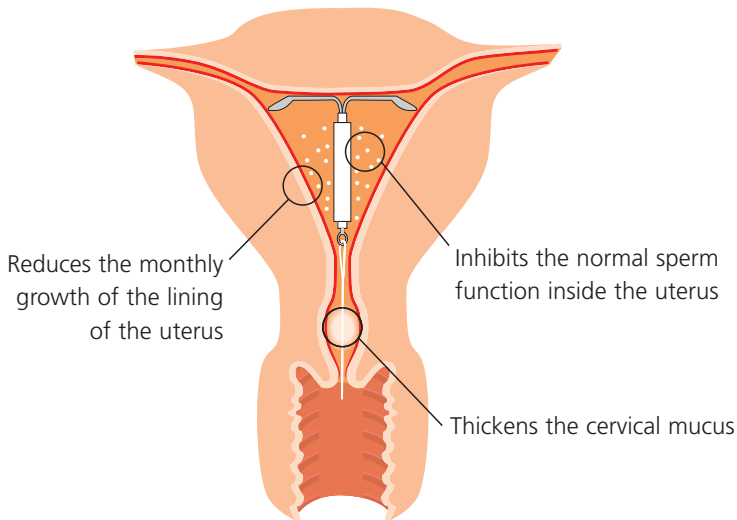
ABOUT CONTRACEPTION

For women who have been prescribed 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 2 are likely to become pregnant. This is similar to female sterilisation.

Once Mirena is properly fitted, and provided it stays in position, it is effective 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 correct position

Do I need to use extra contraception after Mirena is fitted?^{2,3}

If Mirena is fitted as recommended during the first seven 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 doctor.

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 doctor or nurse 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 one 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 seven 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 doctor 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 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 heavy menstrual bleeding.

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 oestrogen. 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 71-95% at the end of 6 months of use, 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 up to 71-95% at the end of 6 months of use, compared to before treatment.

ABOUT HORMONE REPLACEMENT THERAPY (HRT) OR MENOPAUSE HORMONE THERAPY (MHT)

For women who have been prescribed 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; the average age of menopause for women in Australia is 51–52 years.

There is an interval of a few years before this happens, when gradual changes occur as your ovaries produce lower amounts of hormones and the frequency of ovulation may change. This is called perimenopause. During this time, some women may still be able 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 flashes, 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 flushes and night sweats, when they are interfering with your life.

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

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

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

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

FREQUENTLY ASKED QUESTIONS

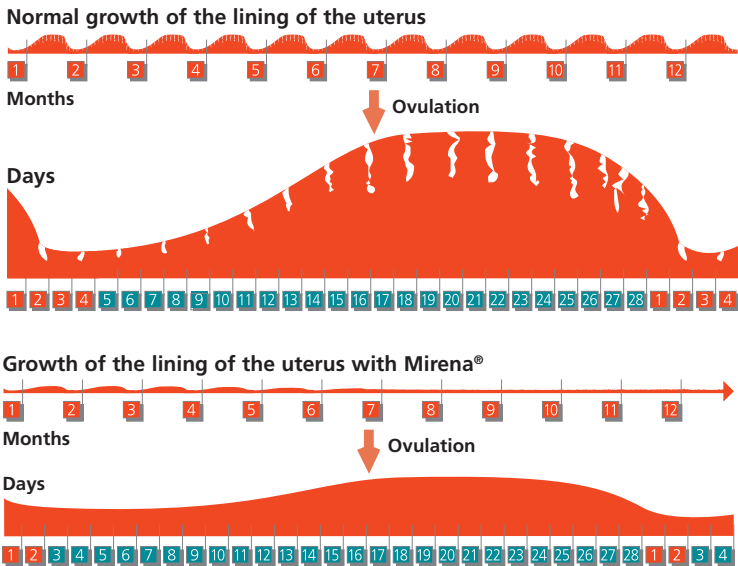
What happens to my periods while I am using Mirena?^{1,2,11}

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, the initial increase in bleeding you 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.



The diagram above 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 doctor 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 Mirena's effect 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 doctor.

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 women 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 doctor 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 one 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.

Do I need to have Mirena checked regularly by my doctor?

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

Can Mirena become dislodged (expelled) or fall out?^{2,3}

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 doctor 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 doctor as soon as you can.

Can Mirena cause perforation?¹⁻³

There is a small risk (around 2 in 1000) that Mirena may perforate or 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 doctor 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 a sexually transmitted infection (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 doctor 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 doctor 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 hormone replacement therapy or menopause hormone therapy, you should refer to the Consumer Medicine Information (CMI) of the oestrogen component for additional information. Should breast cancer be diagnosed, your doctor may consider removal of Mirena.

For more information, including things to tell your doctor about before and while you are using Mirena, refer to the Consumer Medicine Information leaflet available at www.medsafe.govt.nz.

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

Some medicines and Mirena may interact with each other. Tell your doctor 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?^{2,3}

If Mirena is fitted within the first seven 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 doctor 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

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.

While there is no evidence that the use of menstrual cups is associated with a risk of Mirena being expelled or falling out, caution may be warranted in the first few weeks after insertion of Mirena.

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 the 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}

If you have been using Mirena for 5 years you will need to have it removed. If you wish to continue using this method, the system needs to be removed and replaced by your doctor. (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 doctor inserts a new Mirena during the same visit, the 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 doctor 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 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, a woman may start to experience a change in her periods, sometimes finding they are heavier and irregular. Mirena may help improve this pattern while still providing contraception. If you want to continue using Mirena, you must have it replaced every 5 years.



GETTING OFF TO A GOOD START WITH MIRENA

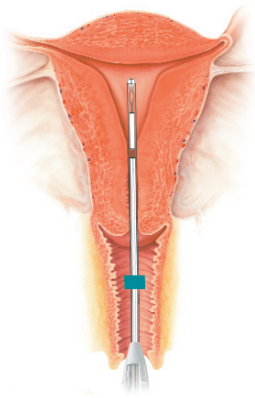
INSERTION GUIDE

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.²

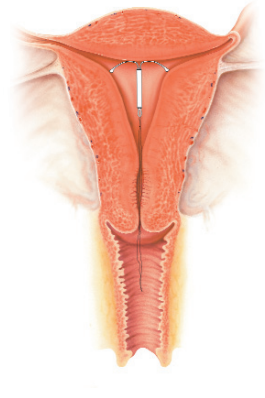
Insertion should only be carried out by a medical professional who has been trained to do so.²

The insertion process²

1. To help fit your Mirena in the correct position, your doctor will perform an examination to determine the size and position of your uterus.
2. Under sterile conditions, your doctor 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 doctor will withdraw the plastic insertion tube, leaving the Mirena in your uterus. Your doctor 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 doctor remove the system when required.



Mirena being fitted in the uterus



Mirena in place in the uterus

Insertion: frequently asked questions

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

Mirena is usually inserted within seven 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 doctor. 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. Your doctor will be able to insert a new Mirena 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 hormone replacement therapy, 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 doctor. You can also refer to the Consumer Medicine Information leaflet available at www.medsafe.govt.nz.

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 doctor 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 Doctor know how your body is adjusting to Mirena.

Post-insertion: frequently asked questions

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

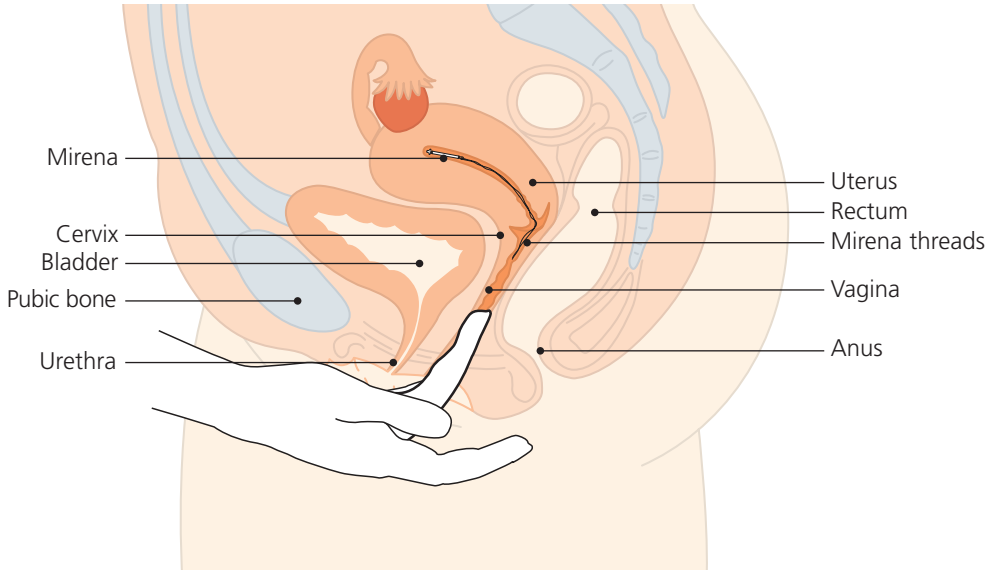
The insertion of Mirena can be uncomfortable, although half of women experience little or no pain during the procedure. Afterwards you may feel some cramping, similar to period pain, and occasionally some dizziness may also occur. These symptoms usually disappear after a few hours but if they persist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

Do I need to have Mirena checked regularly by my doctor?¹

You should have your Mirena checked for the first time 4-12 weeks after insertion and again every 12 months by your doctor. 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 doctor 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 doctor to make sure your Mirena is still in position.



Tell your doctor 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 doctor. You can also refer to the Consumer Medicine Information leaflet available at www.medsafe.govt.nz.

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 doctor, because they are likely to ask you about your bleeding patterns. Keeping track of your bleeding pattern can help you and your doctor 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, dated May 2018.
2. Mirena Data Sheet, dated February 2018.
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 Scandinavia 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 October 2018.
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 October 2018.
10. Varila E et al. Br J Obstet Gynaecol 2001;76:969–73.
11. Ronnerdag M & Odland V. Acta Obstet Gynecol Scand 1999;78:716–21.
12. Silva dos Santos PN et al. Contraception 2017;95:382–89.
13. Vickery Z et al. Contraception 2013;88:503–8.
14. Modesto W et al. Eur J Contracept Reprod Health Care 2015;20:57–63.



Mirena®

intrauterine levonorgestrel delivery system

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 fully funded – normal pharmacy dispensing fees and Doctor's charges 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 www.medsafe.govt.nz. Bayer New Zealand Limited, 3 Argus Place, Hillcrest, Auckland 0627. Phone 0800 233 988.

Mirena® is a Registered Trademark of the Bayer Group, Germany. PP-MIR-NZ-0001-1. TAPS NA11149 BY9361

Date of preparation October 2019