Package leaflet: Information for the user

Mirena® 52 mg intrauterine delivery system

levonorgestrel

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mirena is and what it is used for
2. What you need to know before you use Mirena
3. How to use Mirena
4. Possible side effects
5. How to store Mirena
6. Contents of the pack and other information

1. What Mirena is and what it is used for

Mirena is an intrauterine delivery system (IUS) placed inside the womb (uterus) where it slowly releases the hormone levonorgestrel. It can be used in the following three ways:

1. As an effective long-term and reversible method of **contraception**.
   It is used for prevention of pregnancy (contraception) for a maximum of 8 years.
2. For **reducing menstrual blood flow**, so it can be used if you suffer from heavy periods (heavy menstrual bleeding). This is called menorrhagia.
   It is used for heavy menstrual bleeding (idiopathic menorrhagia) for up to 5 years. If symptoms have not returned after 5 years of use, continued use may be considered. Your Mirena should be removed or replaced after a maximum of 8 years.
3. If you are going through the **menopause**, a gradual process which usually takes place between the ages of about 45 and 55. It is used for protection from excessive growth of the lining of the womb (*endometrial hyperplasia*) during oestrogen replacement therapy for a maximum of 5 years.

If you like, you may have a new Mirena inserted when the old one is removed.

Oestrogens can be taken to relieve menopausal symptoms. However, taking oestrogens alone increases the risk of abnormal growth or cancer of the lining of the womb (*endometrial hyperplasia*). Using a progestogen such as Mirena in combination with oestrogen replacement therapy lowers this risk.

How does Mirena work?
As a **contraceptive**, the hormone in Mirena prevents pregnancy by:
- controlling the monthly development of the womb lining so that it is not thick enough for you to become pregnant
- making the mucus in the opening to the womb (the cervical canal) thicker, so that the sperm cannot get through to fertilise the egg
- preventing the release of the eggs (ovulation) in some women

There are also some effects on the lining of the womb caused by the presence of the T-shaped frame of the Mirena device.

In the treatment of **heavy menstrual bleeding:**
The hormone in Mirena reduces menstrual bleeding by controlling the monthly development of the womb lining, making it thinner, so that there is less bleeding every month.

The hormone in Mirena helps you through the **menopause** by:
- replacing the hormone (progestogen) that your body no longer makes
- protecting the lining of your womb from abnormal growth or cancer

2. What you need to know before you use Mirena

Your doctor will ask you some questions about your own personal health / family history and may carry out some tests before you have Mirena fitted to make sure that it is suitable for you.

Do not use Mirena and please tell your doctor if you:
- are pregnant or suspect that you may be pregnant
- have or have had progestogen-dependent tumours, e.g. breast cancer
- currently have or previously had recurrent pelvic inflammatory disease
- have or have had inflammation of the neck of the womb (cervix)
- have an unusual or unpleasant vaginal discharge, or vaginal itching, as this may indicate an infection
- have or have had an infection of the womb after delivery or after termination of pregnancy during the past 3 months
- have any condition which makes you susceptible to infections. A doctor will have told you if you have this
- have or have had an abnormal smear test (changes in the cervix)
- have or have had cancer of the womb or cervix
- have an unusual uterine bleeding pattern
- have an abnormal womb or abnormal growths in the womb (fibroids)
- have or have had liver disease or cancer
- are allergic to levonorgestrel or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Mirena may not be suitable for all women.
Talk to your doctor before using Mirena if you:
- are breast-feeding - the risk of perforation is increased if you are breast-feeding at the time Mirena is fitted
- have or develop migraine, dizziness, blurred vision, unusually bad headaches or if you have headaches more often than before
- yellowing of the skin or whites of the eyes (jaundice)
- have high blood pressure
- have had a stroke or heart attack, or if you have any heart problems
- have congenital heart disease or valvular heart disease, your doctor will tell you if you need to take antibiotics when Mirena is being inserted or removed
- have blood clots (thrombosis), refer to section 4, which contains important information about blood clots
- have ever had a fertilised egg develop outside the womb (ectopic pregnancy) or a history of fluid filled sacks in the ovary (ovarian cysts)
- are a diabetic as the blood glucose concentration should be monitored. There is generally no need to change your diabetic treatment while using Mirena
- are a woman after the menopause with advanced thinning of the womb.

You may still be able to use Mirena if you have or have had some of these conditions. Your doctor will advise you.

You must also tell your doctor if any of these conditions occur for the first time while you have Mirena in place.

Mirena, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or other sexually transmitted diseases.

Medical Examination/Consultation
Examination before insertion may include a cervical smear test (Pap smear), examination of the breasts and other tests, e.g. for infections, including sexually transmitted diseases, pregnancy test, as necessary. A gynecological examination should be performed to determine the position and size of the womb. Mirena is not suitable for use as an emergency contraceptive (postcoital contraceptive).

If you have a tendency to chloasma (brown patches on your face or body), you should avoid exposure to the sun or UV light.

It is advisable to give up smoking when using hormonal contraception.
If you are immobilised (long term) as a result of surgery or ill health your doctor may decide to remove Mirena.

Breast Cancer
It is important to regularly check your breasts and you should contact your doctor if you feel any lump.
Breast cancer has been seen slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example, it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination pill. There may be similar risks using contraceptives that contain progesterone only, such as Mirena.
The risk of breast cancer is increased in post-menopause women taking hormonal replacement therapy. Although the risk of developing breast cancer is higher with combined oestrogen/progestogen HRT, than with oestrogen-only HRT, the risk of breast cancer developing when Mirena is prescribed to provide the progestogen component of HRT is not yet known. The patient information leaflet of the oestrogen component of the treatment should also be consulted for additional information.

Expulsion
The muscular contractions of the womb during your period may sometimes push Mirena out of place or expel it. This is more likely to occur if you are overweight at the time of Mirena insertion or have a history of heavy periods. If Mirena is out of place, it may not work as intended and therefore, the risk of pregnancy is increased. If Mirena is expelled, you are not protected against pregnancy anymore.
Possible symptoms of an expulsion are pain and abnormal bleeding but Mirena may also come out without you noticing. As Mirena makes periods lighter, heavier periods than usual may mean that Mirena is no longer in place.
It is recommended that you check for the threads with your finger, for example while having a shower. See also section 3 “How to use Mirena – How can I tell whether Mirena is in place?”. If you have signs indicative of an expulsion or you cannot feel the threads, you should avoid intercourse or use another contraceptive (such as condoms), and consult your healthcare professional.

Perforation
Perforation or penetration of the wall of the womb may occur, most often during placement, although it may not be noticed until sometime later. If Mirena becomes lodged outside the womb, it will not be effective in preventing pregnancy and must be removed as soon as possible. You may need surgery to have Mirena removed. The risk of perforation is higher in women who are breast-feeding, in those who had a child up to 36 weeks before insertion, and may be increased in women whose womb is fixed and leaning backwards (fixed retroverted uterus). If you suspect you may have experienced a perforation, seek prompt advice from a healthcare provider and remind them that you have Mirena inserted, especially if they were not the person who inserted it.

Possible signs and symptoms of perforation may include:
- severe pain (like menstrual cramps) or more pain than expected
- heavy bleeding (after insertion)
- pain or bleeding which continues for more than a few weeks
- sudden changes in your periods
- pain during sex
- you can no longer feel the Mirena threads (see section 3 ”How to use Mirena - How can I tell whether Mirena is in place?").

Psychiatric disorders
Some women using hormonal contraceptives including Mirena have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Can tampons or menstrual cups be used?
Use of sanitary pads is recommended. If tampons or menstrual cups are used, you should change them with care so as not to pull the threads of Mirena. If you think you may have pulled Mirena out of place (see “What happens if Mirena comes out by itself?” and “How can I tell whether Mirena is in place?” for possible signs), avoid intercourse or use a barrier contraceptive (such as condoms), and contact your doctor.

Can I change my mind?
Your doctor can remove Mirena at any time. The removal is very easy.

<u>Continuation of contraception after removal</u>
If pregnancy is not desired, Mirena should not be removed after the seventh day of the menstrual cycle (monthly period) unless contraception is covered with other methods (e.g. condoms) for at least 7 days before the removal. If you have irregular periods (menses) or no periods, you should use barrier methods of contraception for 7 days before removal until your menstruation reappears. A new Mirena can also be inserted immediately after removal, in which case no additional protection is needed. If you do not wish to continue using the same method, ask your doctor for advice about other reliable contraceptive methods.

Children and adolescents
Mirena is not indicated for use before the first menstrual bleeding (menarche).

Other medicines and Mirena
The mechanism of action of Mirena is mainly local, the intake of other medicines is not believed to increase the risk of pregnancy while using Mirena.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

Pregnancy
Mirena should not be used during pregnancy or if you think you are pregnant.
It is very rare for women to become pregnant with Mirena in place.

Missing a period may not mean that you are pregnant. Some women may not have periods at all while using Mirena.

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

If you do become pregnant with Mirena in place, contact your healthcare professional immediately so that ectopic pregnancy can be excluded and to have Mirena removed.
The removal may cause a miscarriage. However, if Mirena is left in place during pregnancy, not only is the risk of having a miscarriage higher, but also the risk of preterm labour. If Mirena cannot be removed, talk with your healthcare professional about the benefits and risks of continuing the pregnancy.
If the pregnancy is continued, you will be closely monitored during your pregnancy and you should contact your doctor right away if you experience stomach cramps, pain in your stomach or fever.
Mirena contains a hormone, called levonorgestrel, and there have been isolated reports of effects on the genitalia of female babies if exposed to levonorgestrel intra-uterine devices while in the womb.

Breast-feeding
Very small amounts of the hormone in Mirena are found in breast milk but the levels are lower than with any other hormonal contraceptive method.
Please ask your doctor for advice if you wish to breast-feed while using Mirena.

Fertility
If you wish Mirena to be removed so that you can get pregnant, your usual level of fertility will return very quickly after it is removed.

Driving and using machines
No studies on the effects on the ability to drive or use machines have been performed.

3. How to use Mirena

Mirena should be inserted by a healthcare professional who is experienced in Mirena insertion. They will explain the fitting procedure and any risks associated with its usage.

If you have any concerns over its usage, you should discuss it with your doctor (see section 2 ”What you need to know before you use Mirena – Perforation”).

After insertion of Mirena you should receive a patient reminder card from your doctor for follow-up examinations. Bring this with you to every scheduled appointment.

If you have epilepsy, tell the doctor or nurse fitting the Mirena because, although rare, a fit can occur during insertion. Some women might feel faint after the procedure. This is normal and your doctor will tell you to rest for a while.

In very rare cases during fitting, part or all of the Mirena could penetrate the wall of the womb. If this happens it will be removed.

The release of levonorgestrel is about 19 micrograms per day 1 year after insertion, reducing to about 11 micrograms per day after 5 years and 7 micrograms per day after 8 years. Therefore you receive an average of 15 micrograms per day levonorgestrel for 5 years and an average of 13 micrograms per day for 8 years.

When should Mirena be inserted?

Contraception or heavy menstrual bleeding:

<u>Starting to use Mirena</u>
- Before Mirena is inserted, it needs to be ensured that you are not pregnant.
- You should have Mirena inserted within 7 days from the start of your menstrual period. When Mirena is inserted on these days, Mirena works right away and will prevent you getting pregnant.
- If you cannot have Mirena inserted 7 days from the start of your menstrual period or if your menstrual period comes at unpredictable times, then Mirena can be inserted on any

other day. In this case, you must not have had sexual intercourse without contraception since your last menstrual period, and you should have a negative pregnancy test before insertion. Also, Mirena may not reliably prevent pregnancy right away. Therefore, you should use a barrier method of contraception (such as condoms) or abstain from vaginal intercourse during the first 7 days after Mirena is inserted.
- Mirena is not suitable for use as an emergency contraceptive (postcoital contraceptive).

Starting to use Mirena after giving birth
- Mirena can be inserted after giving birth once the uterus has returned to normal size, but not earlier than 6 weeks after delivery (see section 2 “What you need to know before you use Mirena – Perforation”).
- See also “Starting to use Mirena” above for what else you need to know about the timing of insertion.

Starting to use Mirena after an abortion or miscarriage
Mirena can be inserted immediately after an abortion or miscarriage if the pregnancy was less than 3 months along provided that there are no genital infections. Mirena will then work right away.

Replacing Mirena
Mirena can be replaced by a new Mirena at any time of your menstrual cycle. Mirena will then work right away.

Changing from another contraceptive method (such as combined hormonal contraceptives, implant)
- Mirena can be inserted immediately if it is reasonably certain that you are not pregnant.
- If it has been more than 7 days since your menstrual bleeding began, you should abstain from vaginal intercourse or use additional contraceptive protection for the next 7 days.

Protection the lining of your womb during the menopause:
If you no longer have menstrual periods, then Mirena can be inserted at any time.
If you still have menstrual periods, Mirena should be inserted during the last days of bleeding.

Additional information on special populations

Elderly patients (65 years or older): Mirena has not been studied in women over the age of 65 years.

Patients with impaired liver function: Mirena must not be used in women with liver impairment.

Patients with impaired kidney function: Mirena has not been studied in women with kidney impairment.

How quickly does Mirena work?
Contraception:
Mirena will work right away and will prevent you from getting pregnant when:
– it is inserted within 7 days from the start of your menstrual period. If this is not possible, or if your menstrual period comes at unpredictable times, see section 3 “Starting to use Mirena”.
– it is inserted immediately after an abortion or miscarriage if the pregnancy was less than 3 months along, provided that there are no genital infections.
- it is replacing a previously fitted Mirena at any time in your menstrual cycle.
For more information see section 3 “When should Mirena be inserted?”. The possibility of becoming pregnant is approximately 0.2 % (2 in 1000) in the first year. The failure rate may increase in case of expulsion (see section 2 “Expulsion”) or perforation (see section 2 “Perforation”).

Heavy menstrual bleeding:
Mirena usually achieves a significant reduction in menstrual blood loss in 3 to 6 months of treatment.

Protection of the lining of your womb during the menopause:
The hormone in Mirena will begin to protect the lining of your womb as soon as it is fitted.

How often should I have Mirena checked?
You should have it checked 6 weeks after it is fitted, again at 12 months and then once a year until it is removed. Your doctor will decide how often and what kind of check-ups are required in your particular case.
Bring the patient reminder card you have received from your doctor to every scheduled appointment.

What happens if Mirena comes out by itself?
If it comes out either completely or partially you may not be protected against pregnancy.

It is rare but possible for this to happen without you noticing during your menstrual period. An unusual increase in the amount of bleeding during your period might be a sign that this has happened. Tell your doctor or clinic if there are any unexpected changes in your bleeding pattern.

How can I tell whether Mirena is in place?
You can check yourself if the threads are in place. Gently put a finger into your vagina and feel for the threads at the end of your vagina near the opening of your womb (cervix).

Do not pull the threads because you may accidentally pull it out. If you cannot feel the threads, this may mean that it is no longer in place or has pierced the wall of the womb.
In this case you should either not have intercourse or use a barrier contraceptive (such as condoms), and contact your doctor.

Contact your doctor if you can feel the lower end of Mirena itself or you or your partner feel pain or discomfort during sexual intercourse.

How will Mirena affect my periods?
Mirena will affect your menstrual cycle. You might experience spotting (light bleeding in between periods), shorter or longer periods, painful periods, lighter periods or no periods at all.

If you have had Mirena fitted for **contraception:**
Many women have spotting for the first 3-6 months after it is fitted. Others will have prolonged or heavy bleeding. You may have an increase in bleeding, usually in the first 2 to 3 months, before a reduction in blood loss is achieved. Overall you are likely to have fewer days bleeding in each month and you might eventually have no periods at all. This is due to the effect of the hormone (levonorgestrel) on the lining of the womb.

If you have had Mirena fitted for **heavy menstrual bleeding:**
Mirena usually achieves a significant reduction in menstrual blood loss in 3 to 6 months of treatment.
You may have an increase in bleeding however usually in the first 2 to 3 months, before a reduction in blood loss is achieved. If a significant reduction in blood loss is not achieved after 3 to 6 months, alternative treatments should be considered.

If you have had Mirena fitted to protect the lining of your womb during the **menopause**:
You may have some spotting and irregular bleeding during the first few months after Mirena is fitted.
Overtime, this bleeding will become less and you might eventually have no periods at all.

If you have had Mirena fitted for quite a long time and then start to have bleeding
problems, contact your doctor for advice.

There is a calendar on the last page of this patient information leaflet. Your doctor may ask you to fill this in to check your pattern of bleeding. If you are asked to do so, mark the date of insertion with an "X" in the appropriate date square. Mark days of spotting with "O" and bleeding with ” ● ”.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. With Mirena these are most common during the first months after it is fitted and decrease as time goes on.

Seek immediate medical attention if you experience the following side effects and remind your healthcare provider that you have Mirena inserted, especially if they were not the person who inserted it:
- **Severe pain or fever developing shortly after insertion** may mean that you have a severe infection which **must** be treated immediately. In rare cases very severe infection (sepsis) can occur.
- **Severe pain and continued bleeding** as this might be a sign of damage or tear in the wall of the womb (**perforation**). This occurs most often during the fitting of the Mirena, although the perforation may not be detected until sometime later. If this happens the Mirena will be removed. The risk of perforation is higher in women who are breast-feeding, in those who had a child up to 36 weeks before insertion, and in women whose womb is fixed and leaning backwards (towards the bowel).
- **Lower abdominal pain especially if you also have a fever or have missed a period or have unexpected bleeding,** as this might be a sign of ectopic pregnancy. The absolute risk of ectopic pregnancy in Mirena users is low. However, when a woman becomes pregnant with Mirena in place, the relative likelihood of ectopic pregnancy is increased.
- **Lower abdominal pain or experience painful or difficult sex** as this might be a sign of ovarian cysts or pelvic inflammatory disease. This is important as pelvic infections can reduce your chances of having a baby and can increase the risk of ectopic pregnancy.
- **Painful swelling in your leg, sudden chest pain, difficulty breathing, unusual severe prolonged headache or sudden partial or complete loss of vision** may be a sign of a blood clot. It is important that any blood clots are treated promptly.

Very common: may affect more than 1 in 10 people
- Headache
- Abdominal or pelvic pain
- Bleeding changes including vaginal bleeding including spotting; absent, light or infrequent menstrual periods, discharge, inflammation of the vulva and vagina.

Common: may affect up to 1 in 10 people
- Depressed mood / depression
- Migraine
- Dizziness
- Back pain
- Nausea (feeling sick)
- Weight increase
- Libido decreased
- Acne, excessive hair growth
- Upper genital tract infections which may cause vaginal itching; pain on passing urine; painful periods, breast pain, Mirena coming out by itself.

Uncommon: may affect up to 1 in 100 people
- Uterine perforation
- Hair loss (alopecia), brown patches on your skin (chloasma)

Not known: frequency cannot be estimated from the available data
- Allergic reaction including rash, hives and angioedema (characterized by sudden swelling of e.g. the eyes, mouth, throat)
- Increased blood pressure.

Description of selected possible side effects:

The removal threads may be felt by your partner during intercourse.

The following side effects have been reported in connection with Mirena insertion or removal procedures:
Pain; bleeding; insertion-related vasovagal reactions with dizziness or fainting (syncope). The procedure may result in a seizure (fit) in an epileptic patient.

The risk of breast cancer is unknown when Mirena is used during the menopause with oestrogen replacement therapy. Cases of breast cancer have been reported though the frequency is unknown. See section 2.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Mirena

- Keep this medicine out of the sight and reach of children.
- Do not open the Mirena pack. Only your doctor or nurse should do this.
- Do not use this medicine after the expiry date which is stated on the outer carton and foil package after EXP. The expiry date refers to the last day of that month.
- *Product imported from Greece*: Do not store above 30 °C Store in the original package in order to protect from moisture and direct sunlight.
  Product imported from France and Spain: Store in the original package in order to protect from moisture and direct sunlight.
- Do not use Mirena if the seam of the package is broken.
- Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will dispose Mirena for you. These measures will help protect the environment.

6. Contents of the pack and other information

What Mirena contains
The active substance is levonorgestrel. Each intrauterine delivery system device contains 52 mg levonorgestrel.
The other ingredients are:
- polydimethylsiloxane elastomer
- polydimethylsiloxane tubing
- polyethylene
- barium sulfate
- iron oxide (E 172).

Mirena consists of a small white T-shaped frame made from a plastic called polyethylene. The T-shaped frame also contains barium sulfate so that it can be seen on X-rays.

What Mirena looks like and contents of the pack
There are two fine brown removal threads, made of iron oxide and polyethylene, attached to the bottom of the frame. These allow easy removal and allow you or your doctor to check that Mirena is in place.

Each sterile pack contains one Mirena intrauterine delivery system and should not be opened until required; each pack also contains an inserter.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer
Bayer Oy, Pansiontie 47, 20210 Turku, Finland

Parallel Product Authorisation Number: PPA0465/292/001

Mirena is a registered trademark of Bayer Oy

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Other sources of information
Detailed and updated information on this medicine is available by scanning the QR Code included in the package leaflet, outer carton and patient reminder card with a smartphone. The same information is also available on the following URL: www.pi.bayer.com/mirena/ie-mt and on the HPRA website: www.hpra.ie.

Date of insertion = X Spotting = ○ Bleeding = ●

Month 1

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 2

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 3

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 4

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				

The following information is intended for healthcare professionals only:

Mirena® 52 mg Intrauterine Delivery System

levonorgestrel

Insertion Instructions

To be inserted by a healthcare professional using aseptic technique.

Mirena is supplied within an inserter in a sterile package which should not be opened until needed for insertion. Do not resterilize. As supplied, Mirena is for single use only. Do not use if the inner package is damaged or open. Do not insert after the date which is stated on the outer carton and foil package after "EXP". The "EXP" date refers to the last day of that month.
For timing of insertion, please consult the Mirena prescribing information.
Mirena is supplied with a patient reminder card in the outer carton. Complete the patient reminder card and give it to the patient, after insertion.

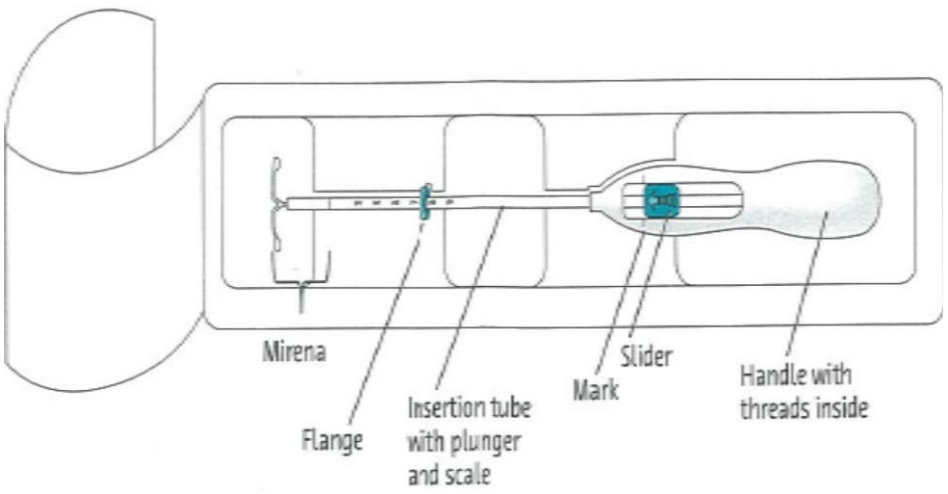
Preparation for insertion

- Examine the patient to rule out contraindications for the insertion of Mirena and to exclude pregnancy (see Summary of Product Characteristics section 4.3 and section 4.4 under Medical examination/consultation).
- Insert a speculum, visualize the cervix, and then thoroughly cleanse the cervix and vagina with a suitable antiseptic solution.
- Employ an assistant as necessary.
- Grasp the anterior lip of the cervix with a tenaculum or other forceps to stabilize the uterus. If the uterus is retroverted, it may be more appropriate to grasp the posterior lip of the cervix. Gentle traction on the forceps can be applied to straighten the cervical canal. The forceps should remain in position and gentle counter traction on the cervix should be maintained throughout the insertion procedure.
- Advance a uterine sound through the cervical canal to the fundus to measure the depth and confirm the direction of the uterine cavity and to exclude any evidence of intrauterine abnormalities (e.g., septum, submucous fibroids) or a previously inserted intrauterine contraceptive which has not been removed. If difficulty is encountered, consider dilation of the canal. If cervical dilation is required, consider using analgesics and/or a paracervical block.

Insertion

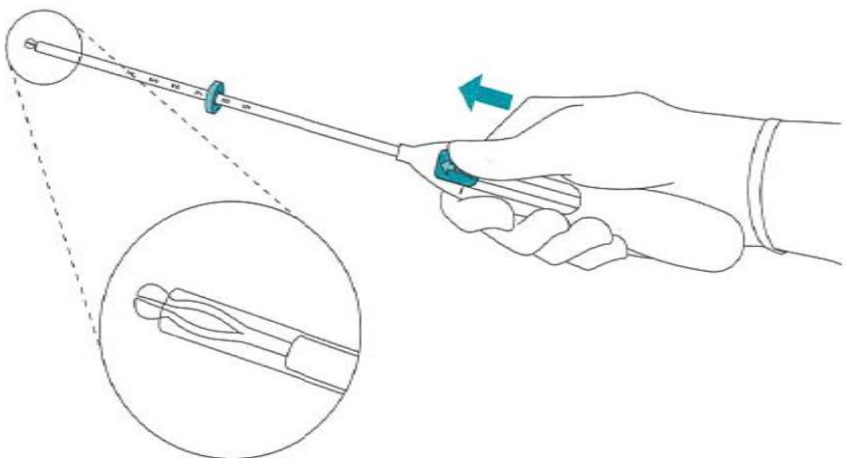
1. First, open the sterile package completely (Figure 1). Then use sterile technique and sterile gloves.

Figure 1



2. Push the slider **forward** in the direction of the arrow to the furthest position to load Mirena into the insertion tube (Figure 2).

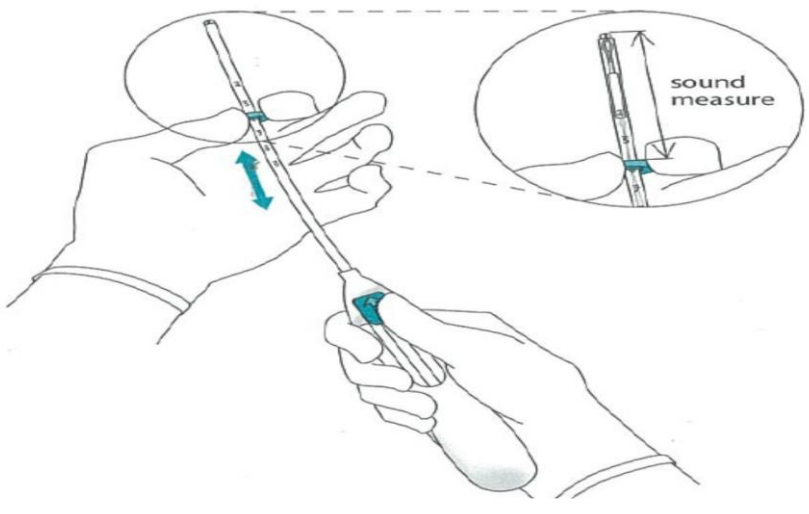
Figure 2



IMPORTANT!
Do not pull the slider downwards as this may prematurely release Mirena. Once released, Mirena cannot be re-loaded.

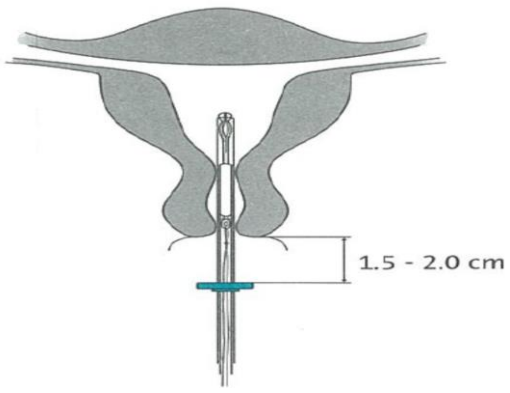
3. Holding the slider in the furthest position, set the **upper** edge of the flange to correspond to the sound measurement of the uterine depth (Figure 3).

Figure 3



4. While holding the slider in the **furthest** position, advance the inserter through the cervix until the flange is approx. 1.5-2.0cm from the uterine cervix (Figure 4).

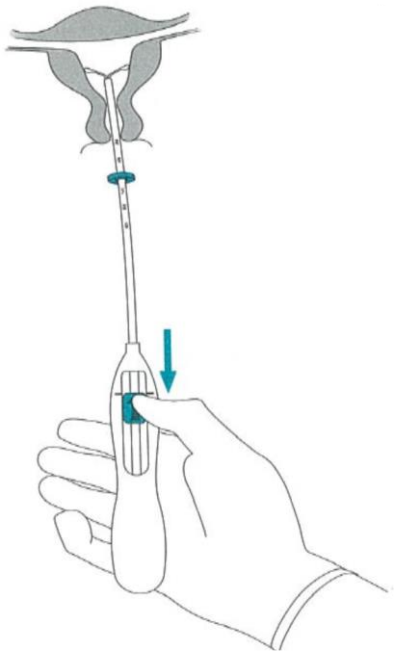
Figure 4



IMPORTANT! Do not force the inserter. Dilate the cervical canal, if necessary.

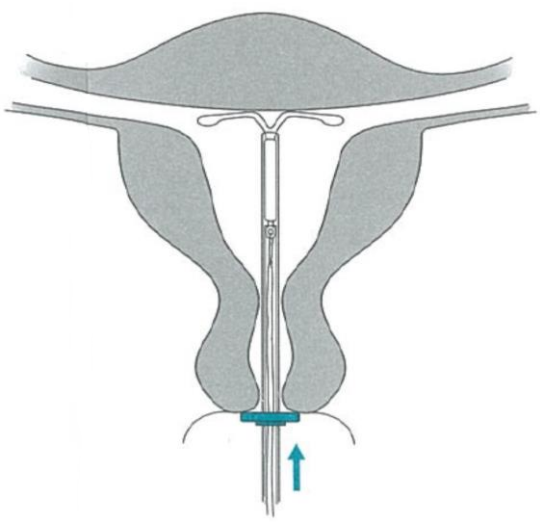
5. While holding the inserter steady, **pull the slider to the mark** to open the horizontal arms of Mirena (Figure 5). Wait 5 – 10 seconds for the horizontal arms to open completely.

Figure 5



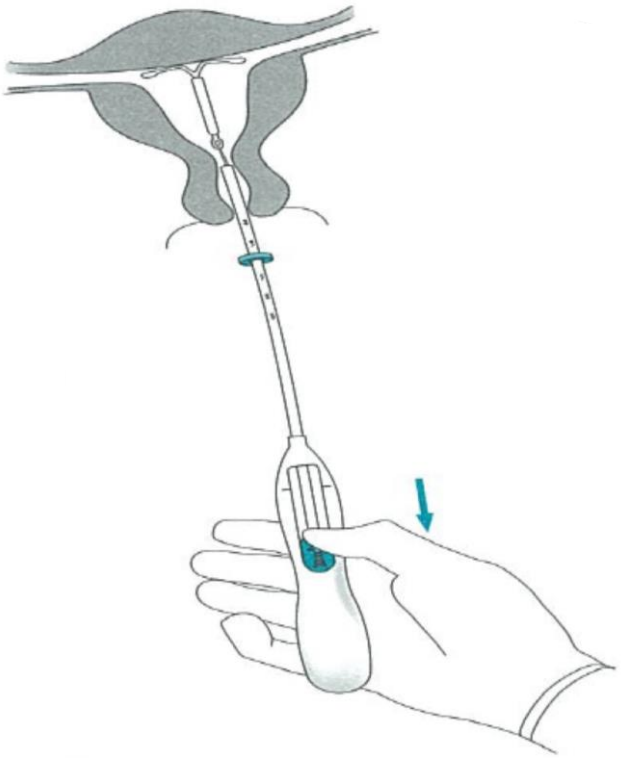
6. Advance the inserter gently towards the fundus of the uterus **until the flange touches the cervix.** Mirena is now in the fundal position (Figure 6).

Figure 6



7. Holding the inserter in place, release Mirena by pulling **the slider all the way down** (Figure 7). While holding the slider all the way down, gently remove the inserter by pulling it out. **Cut the threads** to leave about 2-3 cm visible outside of the cervix.

Figure 7

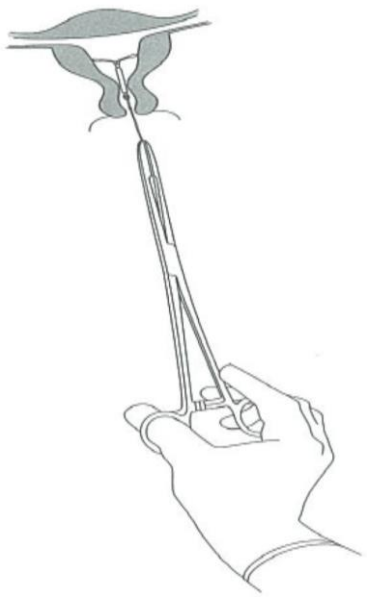


IMPORTANT! Should you suspect that the system is not in the correct position, check placement (e.g. with ultrasound). Remove the system if it is not positioned properly within the uterine cavity. A removed system must not be re-inserted.

Removal / Replacement
For removal / replacement, please consult the Mirena prescribing information.

Mirena is removed by gently pulling on the threads with forceps (Figure 8).
You may insert a new Mirena immediately following removal.
After removal of Mirena, the device should be examined to ensure that it is removed entirely. See Summary of Product Characteristics for further information.

Figure 8



What Mirena looks like and contents of the pack
There are two fine brown removal threads, made of iron oxide and polyethylene, attached to the bottom of the frame. These allow easy removal and allow you or your doctor to check that Mirena is in place.
Each sterile pack contains one Mirena and should not be opened until required; each pack also contains an inserter.
Mirena is individually packed into a thermoformed blister package with a peelable lid.

Product procured from within the EU and repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer
Bayer Oy, Pansiontie 47, 20210 Turku, Finland

Parallel Product Authorisation Number
PPA0465/292/001

Mirena is a registered trademark of Bayer Oy

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The following information is intended for healthcare professionals only.

Fertility, pregnancy and lactation

Pregnancy
The use of Mirena during an existing or suspected pregnancy is contraindicated (see section 4.3 of the Bayer SmPC).
If the woman becomes pregnant when using Mirena, the system should be removed as soon as possible, since any intrauterine contraceptive left *in situ* may increase the risk of abortion and preterm labour. Removal of Mirena or probing of the uterus may also result in spontaneous abortion. Ectopic pregnancy should be excluded. If the woman wishes to continue the pregnancy and the system cannot be withdrawn, she should be informed about the risks and the possible consequences of premature birth to the infant. The course of such a pregnancy should be closely monitored. The woman should be instructed to report all symptoms that suggest complications of the pregnancy, like cramping abdominal pain with fever.
In addition, an increased risk of virilising effects in a female foetus because of the intrauterine exposure to levonorgestrel cannot be excluded. There have been isolated cases of masculinization of the external genitalia of the female foetus following local exposure to levonorgestrel during pregnancy with an LNG-IUS in place.

Breast-feeding
Levonorgestrel daily dose and blood concentrations are lower with Mirena than with any other hormonal contraceptive, although levonorgestrel has been identified in breast milk.
About 0.1 % of the levonorgestrel dose is transferred to the infant during breast-feeding. However, it is not likely that there will be a risk for the infant with the dose released from Mirena, when it is inserted in the uterine cavity.
There appears to be no deleterious effects on infant growth or development when using Mirena after six weeks postpartum.
Progestogen-only methods do not appear to affect the quantity or quality of breast milk. Uterine bleeding has rarely been reported in women using Mirena during lactation.

Fertility
Upon removal of Mirena, women return to their normal fertility. Clinical data from 310 women discontinuing use of Mirena for want of pregnancy has demonstrated a pregnancy rate of 79-96 % after 12 months.

Other sources of information
Detailed and updated information on this medicine is available by scanning the QR Code included in the package leaflet, outer carton and patient reminder card with a smartphone. The same information is also available on the following URL: www.pi.bayer.com/mirena/ie-mt and on the HPRA website: www.hpra.ie.