MIRENA COIL FOR HEAVY PERIODS

Questions & Answers for Patients

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What is the Mirena® IUS?

1. An IUS (intrauterine system), commonly know as a coil, is a small T-shaped plastic device which slowly releases a progestogen hormone. This is similar to the natural progesterone your ovaries produce.
2. In UK, the IUS is available as Mirena. In fact, Mirena contains 52 milligrams of levonorgestrel, a hormone used in many contraceptive pills. The hormone is housed within a substance called polydimethylsiloxane. This is surrounded by a membrane (skin) also made of polydimethylsiloxane. Levonorgestrel is released from IUS at an initial rate of 20 mcg/day.
3. The T-shaped frame also contains barium sulphate so that it can be seen on x-rays.
4. There are two fine threads, made of iron oxide and polyethylene, attached to the bottom of the frame. The fine threads allow easy removal and allow you or your gynaecologist to check that the IUS is in place.

Picture of a Mirena Coil

What is the Mirena IUS used for?

It has three main licensed uses:

- Contraception: This is the main use, which is an effective, long term and reversible method of contraception. Once Mirena coil is placed inside the womb, it slowly releases the hormone levonorgestrel over a period of 5 years or until it is removed.
- Heavy menstrual bleeding (Menorrhagia): It reduces the menstrual blood flow.
- Protects the uterine (womb) lining from overstimulation in women who have a uterus (womb) and wish to use Oestrogen replacement therapy HRT

Mirena has also been shown to be effective in managing symptoms of other gynaecological conditions, such as fibroids, endometriosis, adenomyosis, endometrial hyperplasia and premenstrual syndrome. However, Mirena is presently not licensed to be used as a treatment for these conditions

How does Mirena work?

- The hormone in the Mirena coil reduces heavy menstrual bleeding by controlling the monthly development of the lining of your womb, making it thinner.
- The hormone in the coil prevents pregnancy by the following actions:
    - It makes the lining of your womb thinner and in doing so it makes the uterus lining less likely to accept a fertilised egg.
    - It also thickens the mucus from your cervix, which makes it difficult for the sperm to reach the egg.
    - In some cases, it stops ovulation and as the result your periods stop and there are no eggs for fertilisation.

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How effective is Mirena for heavy bleeding?

There is strong scientific evidence showing that it reduces the monthly blood loss in 90% of women who use the system. In 20% of women fitted with Mirena, periods may stop altogether with the reduction in blood loss being gradual over a period of time.

Generally, you see reduction in blood loss in 3 to 6 months after insertion. There is evidence showing about 86% reduction in blood flow at 3 months and 97% reduction at 12 months after fitting. You may have an increase in bleeding. however, usually in the first 2-3months, before a reduction in blood loss is achieved. If a significant reduction in blood loss in not achieved after 3-6 months, alternative treatments should be considered.

Many gynaecologists now believe that Mirena is an important alternative to a hysterectomy and other surgical treatments.

What are the benefits of having a Mirena for heavy bleeding?

It is very effective in reducing menstrual blood loss therefore preventing anaemia.

Once fitted, it lasts 5 years. Women who are in their forties will require one or two Mirena IUS before their menopause.

Menopause brings about a natural cure for the heavy menstrual bleeding problem, and decreases the need for a hysterectomy.

You get the benefit of contraception in addition to treating heavy menstrual bleeding.

"Be warned, if contraception is not what you want or unacceptable then Mirena coil is NOT for you"

Will Mirena affect my period pain?

Typically, about half of the women who suffer with heavy bleeding also complain of painful periods. Experience shows that Mirena significantly improves period pains in over 96% of users, in addition to reducing the monthly blood loss.

What are the side-effects or risks of Mirena?

- Acne (usually less common after 3 months of treatment, and may improve if acne already exists).
- Breast pain, tenderness or swelling.
- Headaches or migraines (although headaches may lessen in many users; in others, they may increase in number or become worse).
- Dizziness.
- Depression. If you have a history of emotional disturbances, it may be more likely for you to have a recurrence while using the Mirena device
- Weight gain.
- Loss of fertility.
- Some develop small fluid-filled cysts on the ovaries. Often, these cysts do not cause symptoms but some women experience pelvic pains. These cysts are not dangerous and usually do not need to be treated and disappear without treatment. Women using the Mirena coil are more likely to develop benign 'simple' ovarian cysts. The most common symptom of a simple cyst is abdominal pain that does not resolve with simple painkillers. Such cysts usually disappear without treatment in 2-3 months
- Pelvic infection. The Mirena coil is designed to minimise the risk of infection, but there is still a slight risk of developing a pelvic infection while using the coil, particularly in the first 3 weeks after fitting. Such infections are usually related to sexually transmitted diseases, and you are more likely to develop an infection if you or your partner has several sexual partners. Overall, about 1.5% of women will develop an infection with 5 years use of the coil. You can reduce your risk of developing an infection by using a condom when having sex with anybody other than your long-term sexual partner.
- Embedment of Mirena in the myometrium may occur. When this happens the Mirena should be removed. Embedment can result in difficult removal and, in some cases surgical removal may be necessary.

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Side Effects (Continued)

- Decreased libido (sex drive). This is not officially reported but was raised by a number of women on health's forum.

What situations prevent me from having Mirena IUS?

You can not have an IUS if you have or in the past had the following:

- Cancer of or presence of abnormal cells in the womb, cervix, ovary or breast.
- Active liver disease or a liver tumour.
- Unexpected bleeding from your vagina between periods or after sex.
- Blood clot problems (e.g. thrombosis, DVT or PE) or leukaemia or other cancers affecting the blood.
- A heart attack or stroke or infection of the heart valves.
- Pelvic infection or untreated sexually transmitted disease.
- Inflammation of the lining of the womb or cervix.

I am diabetic, am I not suitable for Mirena coil for my heavy menstrual bleeding symptom?

Levonorgestrel may affect glucose tolerance, and the blood glucose concentration should be monitored in diabetic users of Mirena.

Can I change my mind once I have had Mirena fitted?

Mirena can be removed at any time. Ideally it should be removed during the time of a period, or another reliable form of contraception used for seven days leading up to the time of the Mirena removal. This ensures that there is no risk of an unplanned pregnancy.

What are the risks associated with the procedure of inserting the Mirena coil?

- During 20 days after fitting, there is a small chance of getting an infection. It is advisable to make sure there is no existing infection before fitting.
- The IUS can be expelled (pushed) out by your womb or can move. This is more likely to happen soon after fitting, You may not be aware of it. It is important you learn how to check your IUS threads every month.
- While fitting, there is low risk of perforation (puncture) of your womb or cervix. The risk of perforation may be increased in lactating women, in women with fixed retroverted uteri, and during the postpartum period. The risk is low when the coil is fitted by an experienced gynaecologist or gynaecology practice nurse. Perforation can cause pain but often you get no symptoms. If perforation occurs, the IUS has to be removed by surgery.
- There is a small risk of ectopic pregnancy if you fall pregnant while you are on the IUS.

What are the alternatives to Mirena for heavy menstrual bleeding caused by fibroids?

There are alternative medical or surgical options. The common medical options include:

- The combined oral contraceptive pill.
- Tranexamic acid.
- Prostaglandin synthetase inhibiotrs (NSAIDs) such as Mefenamic acid or ibuprofen.

Surgical options include:

- Endometrial ablation.
- Myomectomy of sub-mucosal fibroids.
- UAE/UFE.
- Hysterectomy to remove the fibroids and womb.

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How is a Mirena coil put in?

Usually, fitting is arranged within 7 days after the start of your period.

- Before putting it in the gynaecologist or nurse check for:
  - Pregnancy
  - Existing infection
  - Position and size of your womb.
- You may be given antibiotics at the same time of the procedure.
- A pain killer or local anaesthetic may be given to make you feel comfortable during the procedure.
- The procedure takes about 15-20 minutes.

After fitting, what are the signs for immediate medical attention?

Seek immediate medical attention if any of the followings occurs:

- Abdominal or stomach pain (sudden, severe, or continuing)
- Signs of a blood clot in the leg (sudden unexplained pain in the leg, especially in the calf)
- Signs of a blood clot in the lungs (sudden or unexplained shortness of breath; chest pain; coughing up of blood)
- Signs of a heart attack (pain or discomfort in the chest or upper body; shortness of breath; nausea; cold sweats; or light headedness)
- Signs of a stroke (such as sudden slurring of speech; sudden unexplained weakness, numbness, or pain in the arm or leg; sudden loss of coordination; severe, sudden headache).

My partner can feel the string(s) during sex, what should I do?

If this is problematic, see your gynaecologist. He/she may tuck the strings behind the cervix, cut the strings shorter, or in more extreme cases cut the strings to level with the cervix. The disadvantages of cutting the strings even with the cervix include your difficulty in checking the IUS in correct placement, and the subsequent complicated removal at the later stage.

How do I keep track to ensure the coil is in place?

- Visit your gynaecologist. You should visit your gynaecologist about 6 weeks after having the Mirena coil inserted, and every 12 months thereafter.
- Check in place. In about 5-6% of women, the muscular contractions of the womb push the coil out of place or expel it from the uterus. This is most likely to occur in the first few months after fitting.
  - Each month, you should check that the coil is in place. This can be done by feeling the two fine black threads hanging from the IUS at the top of the vagina. Your gynaecologist and/or gynaecology practice nurse in the clinic shows you how.
  - Don't ever pull on the threads, because you may accidentally pull out the coil.

How can I tell if the Mirena coil has been dislodged or felt out?

Signs of dislodgment or expulsion:

- You may be able to feel the lower end of the Mirena can be felt (this often feels like a matchstick) or
- Your partner experiences any discomfort or pain during sexual intercourse or
- you may experience persistent pain or abnormal bleeding or
- In some cases, you may not be aware of the expulsion initially, but later you will probably experience changes in your bleeding pattern and eventually a return to your previous bleeding pattern.

If dislodgement or expulsion happens, contact your gynaecologist immediately. In the absence of the coil, you loose the protection against pregnancy and it is advisable to use another method of contraception until you see your gynaecologist or doctor.

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What if I become pregnant while I am on the Mirena coil?

There is a small risk of you becoming pregnant (less than 0.2%). However, if you do, there is a small increased risk of you having an ectopic pregnancy (development of fertilised egg outside the uterus) and your gynaecologist will have to remove the coil whether you want to continue with the pregnancy or not.

If you think you might be pregnant or have a sudden or unusual pain in your lower abdomen, seek medical advice immediately. This might be the warning signs of an ectopic pregnancy.

What medications are interacting with the hormone in the Mirena?

The following medications may interact with Mirena:

- Anti-epileptics: Lamotrigine (Lamictal), carbamazepine (Tegretol), topiramate (Topimax), phenytoin (Epanutin), primidone (Mysoline), phenobarbital, rufinamide (Inovelon).
- Immunosuppressants: mycophenolic acid, mycophenolate Mofetil (CellCept).
- Anti-fungals: griseofulvin.
- Cholesterol lowering drugs (statins): Rosuvastin (Crestor).
- Anxiolytics (anti-anxiety): alprazolam.
- Vasodilator anti-hypertensives (blood pressure medicines): bosentan (Tracleer).
- Anti-neoplastics (anticancer):bexarotene (Targretin).
- Anti-HIV: Nevirapine (Viramune).
- CNS stimulants: modafinil (Provigil).
- Acne medications: Isotretinoin

What should I do if I get pelvic infection while on the Mirena coil?

If you develop a pelvic infection, it must be treated promptly. Contact your doctor immediately if you begin experiencing persistent lower abdominal pain, fever, pain with intercourse or abnormal bleeding as these symptoms may indicate a pelvic infection. If you develop a pelvic infection, the coil should be removed.

Under what medical reasons, should the Mirena coil be removed?

If you experience any of the following, check with your gynaecologist/doctor to see if you should have your IUS removed.

- Development of heavy menstrual bleeding (regular or irregular cycle lengths) or inter-menstrual (between your periods) bleeding, which persists after 6 months of coil insertion.
- Migraines or severe headaches.
- Confirmed or suspected breast or endometrial cancer.
- Stroke or heart attack.
- Significantly elevated blood pressure.
- Recurrent pelvic infections.
- Recurrent inflammation of the lining of the uterus.
- Jaundice.

How is the Mirena coil removed?

Generally, IUS removal is easiest if it is done towards the end of your period. Your gynaecologist or gynaecology practice nurse uses a pair of forceps to take hold of the IUS's thread and gently retract.

If for some reasons, the coil is "lost" because the thread can not be felt or seen on speculum examination. Your gynaecologist may use various thread collector devices or simple forceps to try to grasp the IUS device through the cervix. When this fails, which is rare, an ultrasound scan may be arranged to check the position of the coil and exclude its perforation through into the abdominal cavity or its unrecognised previous expulsion. Hysteroscopy is very rarely needed.

How soon can I try for a baby after removal of the Mirena coil?

After removal, normal fertility returns within 3-6 weeks. Nearly 80% of women are able to conceive within 12 months. This might not be the case for you because the presence of fibroids may further compromise your fertility potential.

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Should I have my Mirena coil removed before my UAE /UFE procedure?

So far, the normal practice has been to remove the coil **a month** before UAE procedure, which is in accordance to the joint RCR/RCOG guidelines. This conservative approach has not been based on any robust scientific evidence.

No definite conclusion can be drawn from a recent investigation by Smeets et al.(Ref. 3).

The final decision whether to remove the coil before UAE procedure or not rests solely on your interventional radiologist who will carry out the UAE/UFE, taking into consideration your symptoms, the sizes and locations of your fibroids.

Medical Terms

The following is a list of medical terms used in this factfile, accompanied by a brief definition.

CNS. Central Nervous System.

DVT. Deep Vein Thrombosis.

Endometrial. Related to lining of the womb.

Endometrial ablation. A procedure to destroy the lining of the womb by using energy source from electrical current, heat, laser or microwaves to stop menstrual bleeding.

Fibroids. Non-cancerous (benign) growths on or in the muscle layer of the uterus (womb).

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GMC & MHRA Risk Grading

Low risk <5%
Very low risk <1%
Extremely low risk <0.1%

HMB. Heavy Menstrual Bleeding.

Hyperplasia. Excessive proliferation of cells. Endometrial hyperplasia results in thickening of the lining of the womb.

IUS. Intrauterine system or a coil.

Myomectomy. A surgical removal of fibroids.

NICE. National Institute for Health and Clinical Excellence.

PE. Blood clots in the lungs.

UAE (Uterine Artery Embolisation). A procedure to block the blood supply to the fibroids.

UFE (Uterine Fibroid Embolisation). See UAE.

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