Mirena®
(levonorgestrel-releasing intrauterine system) 52 mg

Information and resources for offices and clinics providing Mirena®

INDICATIONS FOR MIRENA

Mirena® is indicated for prevention of pregnancy for up to 8 years; replace after the end of the eighth year. Mirena is indicated for the treatment of heavy menstrual bleeding for up to 5 years in women who choose to use intrauterine contraception as their method of contraception; replace after the end of the fifth year if continued treatment of heavy menstrual bleeding is needed.

IMPORTANT SAFETY INFORMATION ABOUT MIRENA

Who is not appropriate for Mirena. Use of Mirena is contraindicated in women with: known or suspected pregnancy and cannot be used for post-coital contraception; congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity; known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; known or suspected uterine or cervical malignancy; liver disease, including tumors; untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled; postpartum endometritis or infected abortion in the past 3 months; unexplained uterine bleeding; current IUD; acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of Mirena.

Important Safety Information continued throughout. Please click to see full Prescribing Information for Mirena

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Important Safety Information (cont.)

Clinical considerations for use and removal of Mirena. Use Mirena with caution after careful assessment in patients with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia; exceptionally severe headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removing the intrauterine system if these or the following arise during use: uterine or cervical malignancy or jaundice. If the threads are not visible or are significantly shortened they may have broken or retracted into the cervical canal or uterus. If Mirena is displaced (e.g., expelled or perforated the uterus), remove it.

Pregnancy related risks with Mirena. If pregnancy should occur with Mirena in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Advise her of isolated reports of virilization of the female fetus following local exposure to LNG during pregnancy with an LNG IUS in place. Removal or manipulation may result in pregnancy loss. Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with Mirena. Also consider the possibility of ectopic pregnancy in the case of lower abdominal pain, especially in association with missed menses or if an amenorrheic woman starts bleeding. Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

Properties of the Mirena Inserter and T-body

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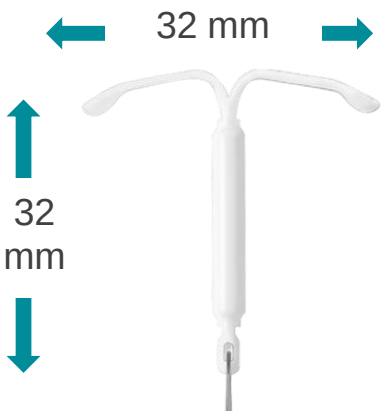
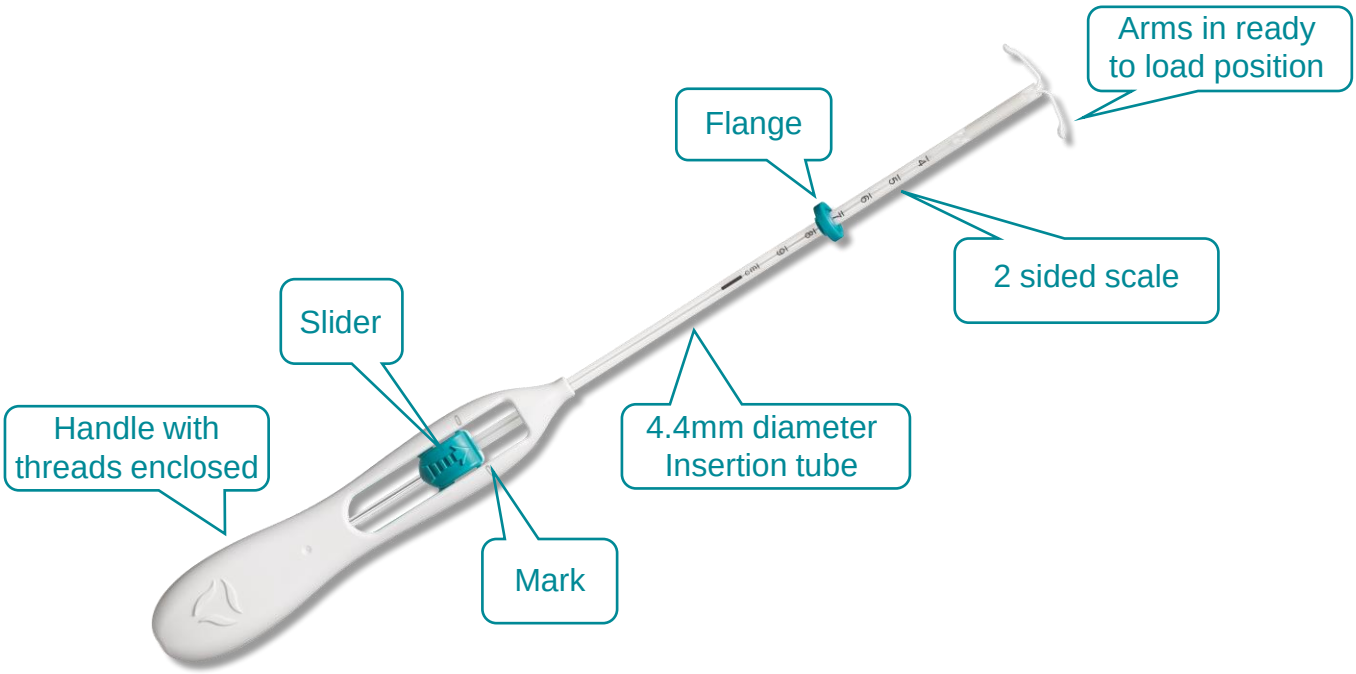


Prevention of pregnancy	Up to 8 years
Hormone Reservoir (total amount)	52mg Levonorgestrel
Insertion tube diameter	4.4mm
Release rate after 1 year	19 mcg/d
Thread Color	brown
Mirena does not contain metal	



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Timing of Insertion

	Insertion Timing	Backup Contraception?
Patients not currently using hormonal or intrauterine contraception	Insert any time there is reasonable certainty that they are not pregnant Consider the possibility of ovulation and conception prior to initiation	**YES** If not inserted during the 7 days of the menstrual cycle, a barrier method should be used or patient should abstain from vaginal intercourse for 7 days
		NO if inserted during the first 7 days of the menstrual cycle or immediately after first trimester abortion
Switching From:		
Oral, transdermal, or vaginal hormonal contraception	Insert any time, including the hormone-free interval of the previous method	**YES** if inserted during active use of the previous method, continue previous method for 7 days after insertion, or until the end of the treatment cycle
		YES if inserted during use of continuous hormonal contraception, continue method for 7 days after insertion
Injectable progestin contraceptive	Insert any time	**YES** if inserted > 3 months (13 weeks) after the last injection, backup contraception (such as condoms or spermicide) should also be used for 7 days
		NO if inserted <3 months after last injection
Implant or IUS (Intrauterine system)	Insert anytime during the menstrual cycle Insert Mirena on the same day as removal of the implant or IUS	**NO** there is no need for backup contraception

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Timing of Insertion

	Insertion Timing	Backup Contraception?
After first trimester abortion or miscarriage	Insert immediately, unless it's a septic abortion	**NO** there is no need for backup contraception
After second trimester abortion, miscarriage, or delivery	Insert after removal of the placenta	**NO** there is no need for backup contraception
Interval insertion following complete involution of the uterus	Wait a minimum of 6 weeks, or until the uterus is fully involuted before inserting Mirena. Insert any time there is reasonable certainty the patient is not pregnant	**YES** If not inserted during the 7 days of the menstrual cycle, a barrier method should be used or patient should abstain from vaginal intercourse for 7 days
		NO if inserted during the first 7 days of the menstrual cycle or immediately after first trimester abortion

IMPORTANT SAFETY INFORMATION (Cont.) Educate her about PID. Mirena is contraindicated in the presence of known or suspected PID or in women with a history of PID unless there has been a subsequent intrauterine pregnancy. IUDs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. Promptly examine users with complaints of lower abdominal pain or pelvic pain, odorous discharge, unexplained bleeding, fever, genital lesions or sores. Inform women about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death. PID is often associated with sexually transmitted infections (STIs); Mirena does not protect against STIs, including HIV. PID may be asymptomatic but still result in tubal damage and its sequelae.

In Mirena clinical trials, upper genital infections, including PID, occurred more frequently within the first year. In a clinical trial with other IUDs and a clinical trial with an IUD similar to Mirena, the highest rate occurred within the first month after insertion.

Patient Questions About Insertion

How is a Mirena placed?

Mirena is placed by your healthcare provider during an in-office visit or immediately after giving birth.

First, your healthcare provider will examine your pelvis to find the exact position of your uterus. Your healthcare provider will then clean your vagina and cervix with an antiseptic solution and slide a slim plastic tube containing Mirena through the cervix into your uterus. Your healthcare provider will then remove the plastic tube and leave Mirena in your uterus. Your healthcare provider will cut the threads to the right length.

You may experience pain, bleeding or dizziness during and after placement. If your symptoms do not pass within 30 minutes after placement, Mirena may not have been placed correctly. Your healthcare provider will examine you to see if Mirena needs to be removed or replaced.

Patient Questions About Bleeding

How will Mirena change my periods?

For the first 3 to 6 months, your period may become irregular and the number of bleeding days may increase. You may also have frequent spotting or light bleeding, and some women have heavy bleeding during this time. You may also have cramping during the first few weeks. After you have used Mirena for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether. When Mirena is removed, your menstrual periods should return. If symptoms continue or are severe, you should report them to your healthcare provider

In some women with heavy bleeding, the total blood loss per cycle progressively decreases with continued use. The number of spotting and bleeding days may initially increase but then typically decreases in the months that follow.

Can I use tampons or menstrual cups with Mirena?

Yes, tampons or menstrual cups may be used. Change tampons or menstrual cups with care to avoid pulling the threads of the Mirena. If you think you may have pulled Mirena out of place, avoid intercourse or use a non-hormonal back-up birth control (such as condoms or spermicide), and contact your healthcare provider

Check here to learn more about other patient questions about Mirena:

https://www.mirena-us.com/about-mirena/faqs

Tools for Insertion

Sterile Gloves

Sterile gloves should be used to lift the handle of the sterile inserter and remove it from the sterile packaging.

Speculum

The speculum is gently inserted vaginally to visualize the cervix.

Antiseptic solution and applicator

A suitable antiseptic solution is applied prior to placing the tenaculum and sounding the uterus.

Sterile tenaculum

A sterile tenaculum is applied to the cervix and used to stabilize and align the cervical canal with the uterus. Gentle traction should be maintained on the tenaculum during both sounding and IUD insertion.

Uterine Sound

A uterine sound is used to check the patency of the cervix, measure the depth of the uterine cavity in centimeters, confirm cavity direction, and detect the presence of any uterine anomaly.

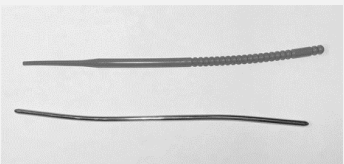
Sterile, sharp, curved scissors

Sterile, sharp, curved scissors are used for a perpendicular cut of the IUD threads after IUD placement is complete.

Optional Tools For Insertion:

Instruments and anesthesia for a paracervical block, if anticipated

Cervical dilators: may be used if difficulty or stenosis is encountered during sounding or insertion. If cervical dilatation is required, a paracervical block may be considered



Note:

The inserter provided with Mirena, is not applicable for immediate insertion after childbirth or second-trimester abortion or miscarriage. For immediate insertion, remove the Mirena from the inserter, and insert according to accepted practice.

Important Safety Information continued throughout. Please click to see full Prescribing Information for Mirena

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Tools for Removal

speculum	gloves	forceps

Alligator Forceps

May be used for removal if strings are not visible, and the IUD has been confirmed to be in the uterine cavity on ultrasound. This may require dilatation of the cervical canal.
May be used to assist in removal if IUD is broken or embedded

Insertion & Removal Video

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https://www.mirenahcp.com/insertion-and-removal

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Bayer US Patient Assistance Foundation

https://www.patientassistance.bayer.us/

The Bayer US Patient Assistance Foundation is a charitable organization that helps eligible patients get their Bayer prescription medicine at no cost. Bayer understands that sometimes people face financial challenges, and we are here to help

Important Safety Information (cont)

Expect changes in bleeding patterns with Mirena

Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months. Periods may become shorter and/o lighter thereafter. Cycles may remain irregular, become infrequent, or even cease. Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation. If a significant change in bleeding develops during prolonged use take appropriate diagnostic measures to rule out endometrial pathology.

Be aware of other serious complications and most common adverse reactions

Some serious complications with IUDs like Mirena are sepsis, perforation and expulsion. Severe infection, or sepsis, including Group A streptococcal sepsis (GAS) have been reported following insertion of Mirena. Aseptic technique during insertion of Mirena is essential in order to minimize serious infections, such as GAS.

Perforation (total or partial, including penetration/embedment of Mirena in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. The risk of uterine perforation is increased in women who have recently given birth, and in women who are breastfeeding at the time of insertion. In a large US retrospective, postmarketing safety study of IUDs, the risk of uterine perforation was highest when insertion occurred within ≤6 weeks postpartum, and also higher with breastfeeding at the time of insertion. The risk of perforation may be increased if Mirena is inserted when the uterus is fixed, retroverted or not completely involuted. If perforation occurs, locate and remove Mirena. Surgery may be required. Delayed detection or removal of Mirena in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. In addition, perforation may reduce contraceptive efficacy and result in pregnancy.

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Important Safety Information (cont)

Be aware of other serious complications and most common adverse reactions (cont.)

Partial or complete expulsion of Mirena may occur resulting in the loss of contraceptive protection. The risk of expulsion is increased with insertions immediately after delivery and appears to be increased with insertion after second-trimester abortion based on limited data. In the same postmarketing study, the risk of expulsion was lower with breastfeeding status. Remove a partially expelled Mirena. If expulsion has occurred, a new Mirena can be inserted any time the provider can be reasonably certain the woman is not pregnant

Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent enlarged ovarian cysts

The most common adverse reactions reported in ≥5% of users were alterations of menstrual bleeding patterns [including unscheduled uterine bleeding (31.9%), decreased uterine bleeding (23.4%), increased scheduled uterine bleeding (11.9%), and female genital tract bleeding (3.5%)], abdominal/pelvic pain (22.6%), amenorrhea (18.4%), headache/migraine (16.3%), genital discharge (14.9%),vulvovaginitis (10.5%), breast pain (8.5%), back pain (7.9%), benign ovarian cyst and associated complications (7.5%),acne (6.8%), dysmenorrhea (6.4%), and depression/depressive mood (6.4%).

A separate study with 362 women who have used Mirena for more than 5 years showed a consistent adverse reaction profile in Years 6 through 8. By the end of Year 8 of use, amenorrhea and infrequent bleeding are experienced by 34% and 26% of users, respectively; irregular bleeding occurs in 10%, frequent bleeding in 3%, and prolonged bleeding in 3% of users. In this study, 9% of women reported the adverse event of weight gain, it is unknown if the weight gain was caused by Mirena.

Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions. Evaluate patients 4 to 6 weeks after insertion of Mirena and then yearly or more often if clinically indicated.

Important Safety Information continued throughout. Please click to see full Prescribing Information for Mirena

BAYER

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