Intrauterine Device (IUD) Insertion Tools Overview

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg | Mirena® (levonorgestrel-releasing intrauterine system) 52 mg

Please see below for an overview of insertion tools utilized during IUD insertion.

Note: The tools below do not apply to immediate insertion after childbirth or second-trimester abortion or miscarriage.

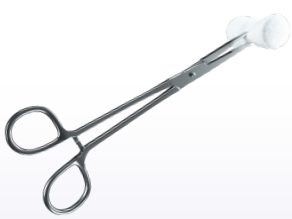
Sterile gloves

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

Speculum

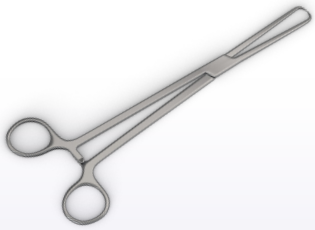
The speculum is gently inserted vaginally to visualize the cervix.

Antiseptic solution and applicator



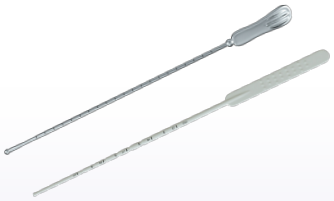
A suitable antiseptic solution is applied prior to placing the tenaculum and sounding the uterus.

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.

Also consider having sterile forceps (shown above), if needed for removal. Additional items not pictured include a light source to get a good visualization of the vagina and cervix, instruments and anesthesia for paracervical block (if anticipated), and dilators to dilate the cervical canal if difficulty or stenosis is encountered during sounding.

For complete insertion instructions, please refer to the accompanying Full Prescribing Information for Kyleena or Mirena. Review the preparatory steps to ensure that the patient is appropriate for Kyleena or Mirena. Follow the insertion instructions exactly as described in order to ensure proper placement and avoid premature release of the IUD (Kyleena or Mirena) from the inserter.

INDICATION FOR KYLEENA

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg is indicated for the prevention of pregnancy for up to 5 years. Replace the system after 5 years if continued use is desired.

INDICATIONS FOR MIRENA

Mirena® (levonorgestrel-releasing intrauterine system) 52 mg 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 KYLEENA AND MIRENA

Who is not appropriate for Kyleena and Mirena

Use of Kyleena or 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 Kyleena or Mirena.

Please see Important Safety Information continued on the next page.
Please click for Full Prescribing Information for Kyleena and Mirena.

Clinical considerations for use and removal of Kyleena and Mirena

Use Kyleena or 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 Kyleena or Mirena is displaced (e.g., expelled or perforated the uterus), remove it. Kyleena can be safely scanned with MRI only under specific conditions.

Pregnancy related risks with Kyleena and Mirena

If pregnancy should occur with Kyleena or 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 Kyleena or 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.

Educate her about PID

Kyleena and Mirena are 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); Kyleena and Mirena do not protect against STIs, including HIV. PID may be asymptomatic but still result in tubal damage and its sequelae.

In clinical trials with:

- Kyleena—PID occurred more frequently within the first year and most often within the first month after insertion.
- Mirena—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.

Expect changes in bleeding patterns with Kyleena and Mirena

Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months. Periods may become shorter and/or 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 Kyleena and Mirena are sepsis, perforation and expulsion. Severe infection, or sepsis, including Group A streptococcal sepsis (GAS) have been reported following insertion of a LNG-releasing IUS. Aseptic technique during insertion of the IUD is essential in order to minimize serious infections, such as GAS.

Perforation (total or partial, including penetration/embedment of Kyleena or 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 inserted when the uterus is fixed, retroverted or not completely involuted. If perforation occurs, locate and remove the intrauterine system. Surgery may be required. Delayed detection or removal of the intrauterine system 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.

Partial or complete expulsion of Kyleena or 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 IUD. If expulsion has occurred, a new Kyleena or 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.

In clinical trials with:

- Kyleena—the most common adverse reactions (≥5%) were vulvovaginitis (24%), ovarian cyst (22%), abdominal/pelvic pain (21%), headache/migraine (15%), acne/seborrhea (15%), dysmenorrhea/uterine spasm (10%), breast pain/breast discomfort (10%), and increased bleeding (8%).
- Mirena
  - Adverse reactions reported in ≥5% users are 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%), depression/depressive mood (6.4%) and dysmenorrhea (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 Kyleena or Mirena and then yearly or more often if clinically indicated.

Please see additional Important Safety Information throughout and click for Full Prescribing Information for Kyleena and Mirena.

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