



# Step by Step Insertion & Removal Guide

for Bayer's Intrauterine Devices:  
Kyleena<sup>®</sup>, Mirena<sup>®</sup>, and Skyla<sup>®</sup>

**INDICATION FOR KYLEENA:** Kyleena<sup>®</sup> (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<sup>®</sup> (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.

**INDICATION FOR SKYLA:** Skyla<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5 mg is indicated for the prevention of pregnancy for up to 3 years. Replace the system after 3 years if continued use is desired

## IMPORTANT SAFETY INFORMATION ABOUT KYLEENA, MIRENA, AND SKYLA

**Who is not appropriate for Kyleena, Mirena and Skyla.** Use of Kyleena, Mirena or Skyla 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, Mirena or Skyla.

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**Skyla<sup>®</sup>**  
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# Patient Scenarios: Insertion Procedure



Gravida 1 (G1), Para 1 (P1), 35 years old, in good general health with no significant medical history. Currently on oral contraceptives. Has been counseled, and presents for Kyleena insertion

40 yo, G3, P3. No significant past medical history and in good general health. Has been counseled on Mirena, and presents for Mirena insertion. Currently using condoms for birth control.



Preparation for Insertion

Insertion Steps

Important Information to Consider during or after Insertion

## Preparation for Insertion

### Patient discussion:

- Review insertion procedure, address any questions
- Confirm which IUD patient will be receiving
- Review medical & social history (screen for contraindications); for patients with persistent uncharacteristic bleeding, exclude endometrial pathology prior to insertion
- If indicated perform physical exam and appropriate tests for any forms of genital or other sexually transmitted infections (STI)

### Insertion timing:

- Can the IUD be placed today? [Refer to insertion timing chart in prescribing information]
- Do they need to use back-up contraception? If yes, for how long?

### Pause to review you have all the needed equipment:

- Suitable cleansing solution & applicator
- Sterile gloves
- Sterile tenaculum
- Sterile uterine sound
- Speculum
- Prescribed IUD
- Sterile, Sharp Curved Scissors

**NOTE:** The inserters provided with the Bayer IUDs, and steps described here are not applicable for insertion after childbirth or second trimester abortion or miscarriage. For immediate insertions, the IUD is removed from the inserter and placed according to accepted practice

### Bimanual exam (non-sterile gloves)

- What is the size, shape and position of the uterus?

**Place speculum and perform visual inspection of cervix** (screen for signs of infection which may contraindicate patient from use of a Bayer IUD)

### Cleanse cervix and vagina with suitable antiseptic solution

**Tenaculum placement** (tenaculum remains in position with gentle traction on the cervix maintained throughout the insertion procedure)

**Sound the patient** (assess patency of cervix, depth of uterine cavity (in cm), confirm cavity direction, detect any uterine anomaly)

- If resistance is encountered use dilatation not force (if dilating cervix, consider paracervical block)
- If placing Mirena, uterus should sound to 6-10cm; there is no sounding depth requirement for Kyleena or Skyla, however all patients must be sounded

## IMPORTANT SAFETY INFORMATION (CONTINUED)

**Clinical considerations for use and removal of Kyleena, Mirena and Skyla.** Use Kyleena, Mirena or Skyla 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, Mirena or Skyla is displaced (e.g., expelled or perforated the uterus), remove it. Kyleena and Skyla can be safely scanned with MRI only under specific conditions.



Important Safety Information continued throughout. Please click to see full Prescribing Information for [Kyleena](#), [Mirena](#), and [Skyla](#)

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Gravida 1 (G1), Para 1 (P1), 35 years old, in good general health with no significant medical history. Currently on oral contraceptives. Has been counseled, and presents for Kyleena insertion

40 yo, G3, P3. No significant past medical history and in good general health. Has been counseled on Mirena, and presents for Mirena insertion. Currently using condoms for birth control.



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## Insertion Steps

- Check the IUD packaging:
  - Ensure IUD is not expired
  - Do not use if sterile package is broken or appears compromised
- **Use strict aseptic techniques during insertion**
- **Step 1:** open the package and lift the handle of the inserter to remove it from the package
- **Step 2:** load the Bayer IUD into the tube by pushing forward on the slider, thereby moving the insertion tube over the T-body. The tips of the arms will meet to form a rounded end that extends slightly beyond the insertion tube.
  - Maintain forward pressure, and do not move the slider downward (if slider is moved below the mark, the IUD cannot be reloaded)
- **Step 3:** set the upper edge of the flange to correspond to the uterine depth (in cm) measured during sounding
- **Step 4:** hold the slider forward as you slowly and gently advance the inserter until the flange is ~1.5-2cm from the cervix; then pause
  - Do not force the inserter; dilate the cervical canal if necessary
- **Step 5:** hold the inserter steady and move the slider down to the mark to release the IUD arms.
  - Wait 10 seconds for arms to open completely
- **Step 6:** advance the inserter gently towards the fundus until the flange touches the cervix (fundal position is important to prevent expulsion)
  - If resistance is met, do not continue to advance
- **Step 7:** Release the IUD & withdraw the inserter
  - pull the slider **all the way down** to release the IUD
  - Hold the slider down as you slowly and gently withdraw the inserter
- Using a sharp curved scissor, cut the threads so that 3cm is left visible outside the cervix
  - Cut straight across (avoid cutting threads at an angle)
  - Do not apply tension or pull on the threads when cutting to prevent displacing the IUD
- Record the lot number in the patient records; prescribe analgesics if indicated

### IMPORTANT SAFETY INFORMATION (CONTINUED)

#### Pregnancy related risks with Kyleena, Mirena and Skyla

If pregnancy should occur with Kyleena, Mirena or Skyla 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, Mirena or Skyla. 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.



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# Patient Scenarios: Insertion Procedure



Gravida 1 (G1), Para 1 (P1), 35 years old, in good general health with no significant medical history. Currently on oral contraceptives. Has been counseled, and presents for Kyleena insertion

40 yo, G3, P3. No significant past medical history and in good general health. Has been counseled on Mirena, and presents for Mirena insertion. Currently using condoms for birth control.



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## Important Information to Consider during or after Insertion

### Do you have a suspicion that the Bayer IUD is not in the correct position?

- If yes, then check placement (for example, using transvaginal ultrasound) and remove if not positioned completely within the uterus (a removed Bayer IUD must not be re-inserted)
- If not, then patients should be reexamined and evaluated 4-6 weeks after insertion and once a year thereafter or more frequently if clinically indicated

### Is there any clinical concern, exceptional pain or bleeding during or after insertion?

- If yes, then take appropriate steps (such as physical examination and ultrasound) to immediately exclude perforation
- If not, then patients should be reexamined and evaluated 4-6 weeks after insertion and once a year thereafter or more frequently if clinically indicated

**Schedule patient for a follow-up visit 4-6 weeks**

## Patient Counseling After Insertion

### Advise the patient of the following:

- Bayer LNG-IUS do not protect against STI (sexually transmitted infections)
- Risk of Ectopic and Intrauterine Pregnancy
- Sepsis
- Pelvic Infection
- Perforation & Expulsion
- Ovarian Cysts
- Bleeding Pattern Alterations
- Kyleena and Skyla can be safely scanned with MRI only under certain conditions

### Advise patients to contact their healthcare provider if they experience any of the following:

- stroke or heart attack,
- very severe or migraine headaches,
- unexplained fever
- yellowing of the skin or whites of the eyes
- pregnancy or suspected pregnancy,
- pelvic or abdominal pain or pain during sex
- HIV positive seroconversion (herself/ partner)
- possible exposure to STIs,
- unusual vaginal discharge or genital sores,
- severe bleeding or bleeding that lasts a long time, if they've missed a period,
- if they can't feel the IUD threads

## IMPORTANT SAFETY INFORMATION (CONTINUED)

**Educate her about PID** Kyleena, Mirena and Skyla 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, Mirena and Skyla 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.
- Skyla – PID occurred more frequently within the first year and most often within the first month after insertion.



Important Safety Information continued throughout. Please click to see full Prescribing Information for [Kyleena](#), [Mirena](#), and [Skyla](#)

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# Patient Scenarios: Removal & Continuation of Contraception



G1, P1, 38 years old, in good general health with no significant medical history. Desires pregnancy and wants the IUD removed.

42 yo, G3, P3. Requests IUD removal and wants to start birth control pills.



## Removal

### Does the patient need birth control after removal of the IUD?

- Yes, they want a new Bayer IUD: place the new Bayer IUD immediately after removal any time during their cycle (back-up contraception is not needed)
- Yes, they want to switch methods:
  - Start the new method at least 7 days prior to removal; or
  - Remove the Bayer IUD in the first 7 days of their cycle (if patient has regular cycles) and start the new method immediately. If removed at other times of the cycle and the patient has had intercourse in the week prior to removal, they are at risk of pregnancy
- No they don't

### Is all of the needed equipment available for removal:

- Gloves, Speculum, Sterile forceps

### Are the threads visible:

- Yes: remove by applying gentle traction on the threads with forceps. If unable to remove by gentle traction, determine location and exclude perforation by ultrasound or other imaging
- No: determine location of the Bayer IUD by ultrasound
  - If found to be in the uterine cavity on ultrasound exam, the Bayer IUD may be removed using narrow forceps (such as alligator forceps); this may require dilation of the cervical canal
  - The hormone cylinder may slide up and cover the horizontal arms of Mirena, giving the appearance of missing arms – this generally does not require further intervention once the system is verified to be intact.

**Verify the Bayer IUD is intact after removal (T-body, hormone cylinder and threads are present). Breakage or embedment of the Bayer IUD in the myometrium may make removal difficult. Analgesia, paracervical anesthesia, cervical dilation, alligator forceps or other grasping instrument, or hysteroscopy may be used to assist in removal.**

## IMPORTANT SAFETY INFORMATION (CONTINUED)

### Expect changes in bleeding patterns with Kyleena, Mirena and Skyla

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 serious complications and most common adverse reactions

Some serious complications with IUDs like Kyleena, Mirena and Skyla 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, Mirena or Skyla 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.



Important Safety Information continued throughout. Please click to see full Prescribing Information for [Kyleena](#), [Mirena](#), and [Skyla](#)

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# Visit these websites for additional instruction on insertion and removal of

**Kyleena**<sup>®</sup>  
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[www.kyleenahcp.com/  
insertion-removal](http://www.kyleenahcp.com/insertion-removal)

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[www.mirenahcp.com/  
insertion-and-removal](http://www.mirenahcp.com/insertion-and-removal)

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[Full Prescribing  
Information](#)

## **IMPORTANT SAFETY INFORMATION ABOUT KYLEENA, MIRENA AND SKYLA (CONTINUED)** **Be aware of other serious complications and most common adverse reactions (cont.)**

Partial or complete expulsion of Kyleena, Mirena or Skyla 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, Mirena or Skyla 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 ( $\geq 5\%$ ) 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  $\geq 5\%$  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.

- **Skyla** – the most common adverse reactions ( $\geq 5\%$  users) were vulvovaginitis (20.2%), abdominal/pelvic pain (18.9%), acne/seborrhea (15.0%), ovarian cyst (13.2%), headache (12.4%), dysmenorrhea (8.6%), breast pain/discomfort (8.6%), increased bleeding (7.8%), and nausea (5.5%).

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

**Important Safety Information continued throughout. Please click to see full Prescribing Information for [Kyleena](#), [Mirena](#), and [Skyla](#)**

