

# Educational presentation on Bayer levonorgestrel-releasing intrauterine systems (LNG-IUS)

## Insertion Instructions

**Mirena**<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52 mg

**Kyleena**<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5 mg

**Skyla**<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5 mg

This presentation will refer to Bayer LNG-IUS when information pertains to Mirena, Kyleena and Skyla

**Please see Important Safety Information on slides 3-14 of this presentation.  
For important information about Mirena<sup>®</sup>, Kyleena<sup>®</sup>, and Skyla<sup>®</sup> please see the Full  
Prescribing Information for each product available at this presentation.**

PP-270-US-0855  
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# Indications and Important Safety Information about Bayer LNG-IUS

**Mirena**<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52 mg

**Kyleena**<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5 mg

**Skyla**<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5 mg

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# Indications

## **Indications for Mirena® (levonorgestrel-releasing intrauterine system) 52 mg**

- Mirena is indicated for intrauterine contraception for up to 5 years
- Mirena is also indicated to treat heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception
- Mirena should be replaced after 5 years if continued use is desired

## **Indication for Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg**

- Kyleena is indicated for the prevention of pregnancy for up to 5 years
- Replace the system after 5 years if continued use is desired

## **Indication for Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg**

- Skyla is indicated for the prevention of pregnancy for up to 3 years
- Replace the system after 3 years if continued use is desired

**Please see Important Safety Information on slides 3-14 of this presentation.  
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# Important Safety Information

**Who is not appropriate for Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg, Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla<sup>®</sup> (levonorgestrel-releasing system) 13.5mg**

**Use of Mirena, Kyleena, 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 neoplasia
- Liver disease, including tumors

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## Important Safety Information

**Who is not appropriate for Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg, Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla<sup>®</sup> (levonorgestrel-releasing system) 13.5mg**

**Use of Mirena, Kyleena, or Skyla is contraindicated in women with:**

- 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
- Hypersensitivity to any component of Mirena, Kyleena, or Skyla

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## Important Safety Information (continued)

**Clinical considerations for use and removal of Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg, Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla<sup>®</sup> (levonorgestrel-releasing system) 13.5mg**

- Use Mirena, Kyleena, 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
  - 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, Kyleena, 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.

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## Important Safety Information (continued)

### **Pregnancy related risks with Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg, Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla<sup>®</sup> (levonorgestrel-releasing system) 13.5mg**

- If pregnancy should occur with Mirena, Kyleena, or Skyla in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor
- 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, Kyleena, 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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# Important Safety Information (continued)

## Educate her about PID

- Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg, Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla<sup>®</sup> (levonorgestrel-releasing system) 13.5mg 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); Mirena, Kyleena, and Skyla do not protect against STIs, including HIV
- PID may be asymptomatic but still result in tubal damage and its sequelae.

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# Important Safety Information (continued)

## Educate her about PID (continued):

### In clinical trials with:

- Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg – 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
- Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg – PID occurred more frequently within the first year and most often within the first month after insertion
- Skyla<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5mg – PID occurred more frequently within the first year and most often within the first month after insertion

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## Important Safety Information (continued)

**Expect changes in bleeding patterns with Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg, Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5mg**

- 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
- Because irregular bleeding/spotting is common during the first months of Mirena, Kyleena, or Skyla use, exclude endometrial pathology (polyps or cancer) prior to the insertion of the IUD in women with persistent or uncharacteristic bleeding.
- If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology.

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## Important Safety Information (continued)

### **Be aware of other serious complications and most common adverse reactions**

- Some serious complications with IUDs like Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg, Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5mg 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.

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## Important Safety Information (continued)

### Be aware of other serious complications and most common adverse reactions (continued)

- Perforation (total or partial, including penetration/embedment of Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg, Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg, or Skyla<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5mg in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later.
- Perforation may reduce contraceptive efficacy. 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.
- The risk of perforation may be increased if inserted when the uterus is not completely involuted or fixed retroverted.

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## Important Safety Information (continued)

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

- A postmarketing safety study over a 1-year observational period reported that lactation at the time of insertion of an IUS/IUD was associated with an increased risk of perforation.
  - In this study, for Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg users, the incidence of uterine perforation was reported as 6.3 per 1,000 insertions for lactating women, compared to 1.0 per 1,000 insertions for non-lactating women.
- Partial or complete expulsion of Mirena, Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg, or Skyla<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5mg may occur resulting in the loss of contraceptive protection.
- Delay insertion a minimum of six weeks or until uterine involution is complete following a delivery or a second trimester abortion.
- Remove a partially expelled IUD. If expulsion has occurred, a new Mirena, Kyleena or Skyla can be inserted anytime 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.

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# Important Safety Information (continued)

## Be aware of other serious complications and most common adverse reactions (continued)

- In clinical trials with:
  - Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg – 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%)
  - Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5 mg – 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%)
  - Skyla<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5mg – the most common adverse reactions (≥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 Mirena, Kyleena, or Skyla and then yearly or more often if clinically indicated

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# Insertion Instructions

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**Kyleena<sup>®</sup>** (levonorgestrel-releasing intrauterine system) **19.5 mg**,  
**Skyla<sup>®</sup>** (levonorgestrel-releasing intrauterine system) **13.5 mg**

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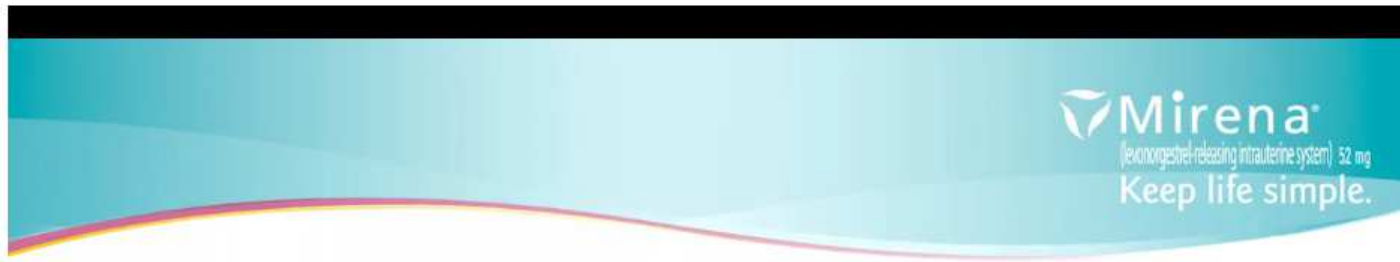
# Preparations for insertion of Bayer LNG-IUS

- Counsel patient, have patient sign consent form in the Patient Information Booklet, and note the lot number
- Rule out contraindications and pregnancy
- Check the expiration date of the IUD prior to initiating insertion
- Perform bimanual exam to assess size/position of uterus
- Perform speculum exam to rule out genital contraindications
- Thoroughly cleanse the cervix and vagina with a suitable antiseptic solution
- Sound the uterine cavity to assess cavity size and direction
  - The uterus should sound to a depth of 6 to 10 cm. Insertion of Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52 mg into a uterine cavity less than 6 cm by sounding may increase the risk of expulsion, bleeding, pain, perforation, and possibly pregnancy
- Then open package

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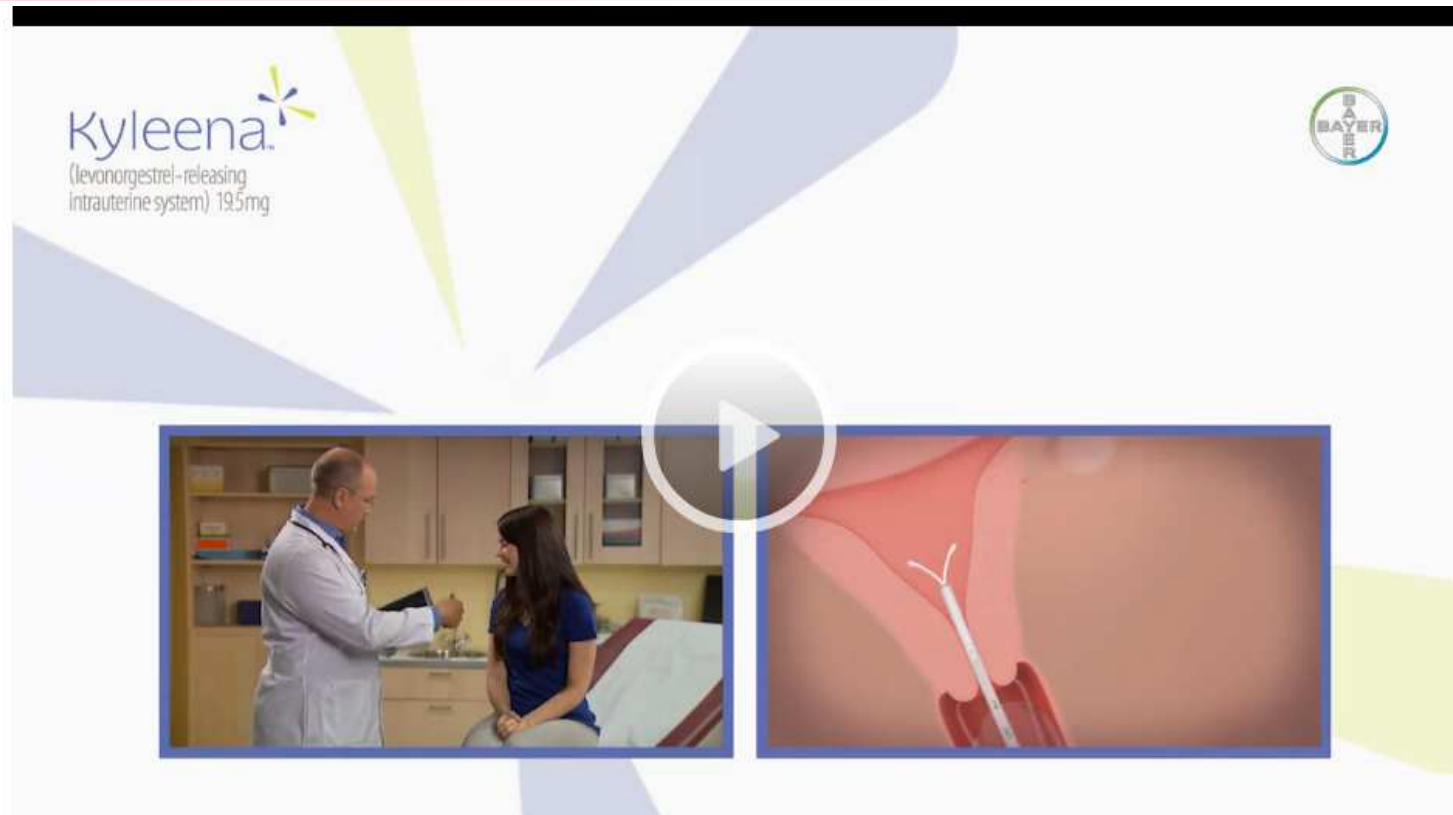
# Insertion procedure for Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52 mg



<https://hcp.mirena-us.com/mirena-insertion-removal-video/>

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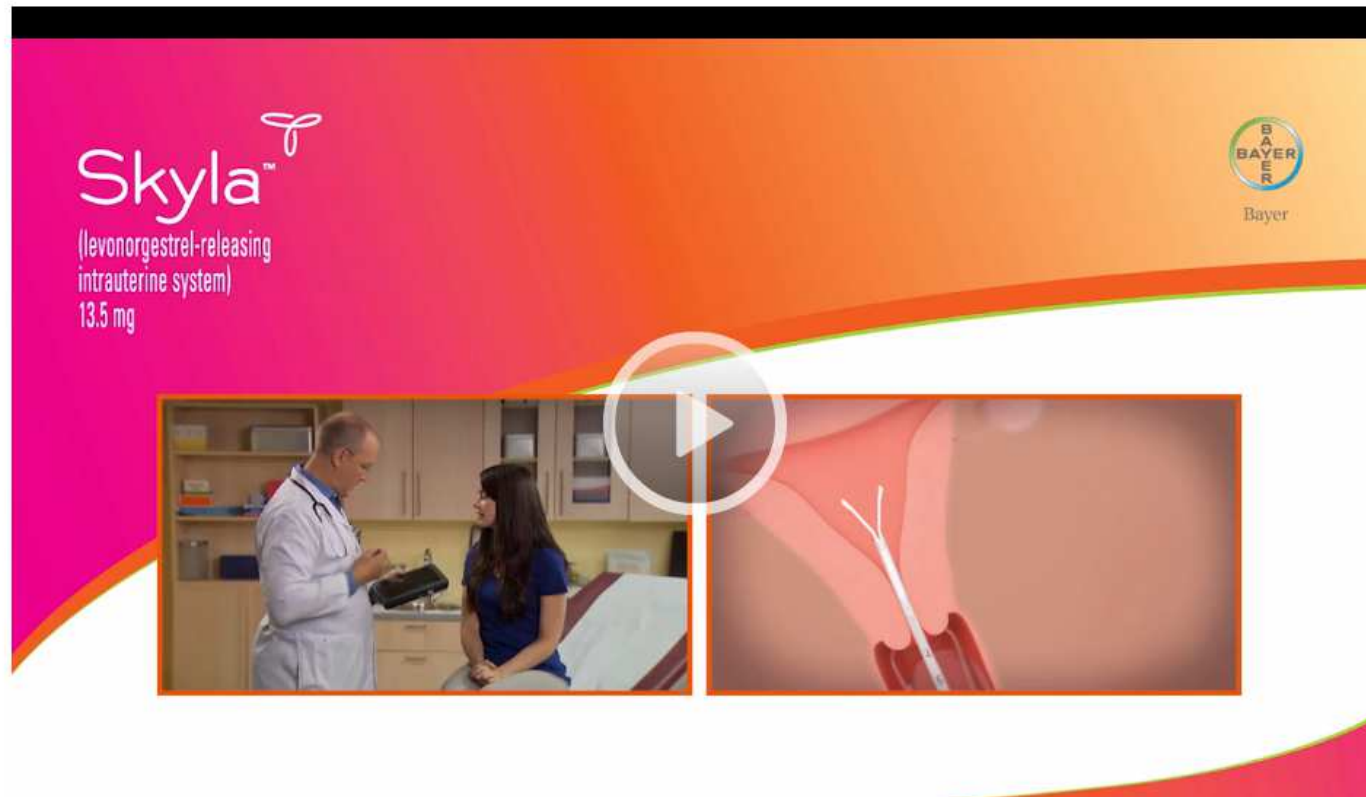
# Insertion procedure for Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg



<https://hcp.kyleena-us.com/insertion-removal/>

**Please see Important Safety Information on slides 3-14 of this presentation. For important information about Mirena®, Kyleena®, and Skyla® please see the Full Prescribing Information for each product available at this presentation.**

# Insertion procedure for Skyla<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5 mg



<http://hcp.skyla-us.com/insertion-and-removal/skyla-insertion-and-removal-video.php>

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# Postinsertion instructions for Bayer LNG-IUS

## Patient Follow-Up

Counsel the patient on how she can check that the threads still protrude from the cervix

- Give the patient the Follow-up Reminder Card that is provided with the product. Discuss expected bleeding patterns during the first months following insertion
- Prescribe analgesics, if indicated
- Record lot number. Keep a copy of the signed consent form with the lot number for your records

### *Important Information to consider during or after insertion*

- Check placement (eg, using transvaginal ultrasound) if there is concern that Bayer LNG-IUS is not in the correct position. Remove if not positioned completely within the uterus. A removed Bayer LNG-IUS must not be re-inserted
- If there is clinical concern, exceptional pain or bleeding during or after insertion, appropriate steps (eg, physical examination and ultrasound) should be taken immediately to exclude perforation
- Reexamine and evaluate patients 4 to 6 weeks after insertion and once a year thereafter, or more frequently if clinically indicated

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# Prescribing Information

**Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 52mg**

[https://labeling.bayerhealthcare.com/html/products/pi/Mirena\\_PI.pdf](https://labeling.bayerhealthcare.com/html/products/pi/Mirena_PI.pdf)

**Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5mg**

[http://labeling.bayerhealthcare.com/html/products/pi/Kyleena\\_PI.pdf](http://labeling.bayerhealthcare.com/html/products/pi/Kyleena_PI.pdf)

**Skyla<sup>®</sup> (levonorgestrel-releasing intrauterine system) 13.5mg**

[http://labeling.bayerhealthcare.com/html/products/pi/Skyla\\_PI.pdf](http://labeling.bayerhealthcare.com/html/products/pi/Skyla_PI.pdf)

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