

Bayer Intrauterine Devices (IUDs): An Overview for Medical Support Staff

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

intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg

THIS PRESENTATION WILL REFER TO BAYER LNG-IUD (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) WHEN INFORMATION PERTAINS TO KYLEENA, MIRENA AND SKYLA

Please see Important Safety Information throughout.

For important information about <u>Kyleena⁶, Mirena⁶</u>, and <u>Skyla⁶</u>, please see the Full Prescribing Information for each product available at this presentation.

The program may refer to women, she, or her. We recognize that gender identity is diverse and not all people with a uterus identify as women.

PP-PF-WHC-IUS-US-1725-1 January 2025



Purpose: To review clinical & safety information for Bayer's LNG-IUDs, including how to provide personcentered contraceptive counseling and address questions using patient-friendly language

Agenda:

- Person-centered Contraceptive Counseling
- Review of Clinical Information to address Patient Questions about Bayer's LNG-IUDs including:
 - What is it, and how does it work?
 - Placement Procedure & Timing
 - Who are appropriate individuals
 - Reversibility of Bayer's LNG-IUDs
 - Bleeding Patterns
 - Important Safety Information

Kyleena° (levonorgestrel-releasing intrauterine system) 19.5 mg (levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg

During a Healthcare Visit, Patients Interact with Multiple Healthcare Providers





Medical Support Staff



Medical Assistants

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Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

During a Healthcare Visit, Patients Interact with Multiple Healthcare Providers







Medical Support Staff

Medical Assistants

- Take patient's vitals, review health history
- Prepare exam room (tests, instruments which may be needed for the visit)
- Answer calls placed to a nurse staffed phone number

(levonorgestrel-releasing intrauterine system) 19.5 mg (levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg



One of the steps of providing quality person-centered contraceptive care involves assessing an individual's contraceptive preferences based on their desires, needs, and prior experiences.

Shown here are several open-ended questions that can be used to elicit preferences:

Romer SE et al. Am J Prev Med. 2024;67(6S):S41-S86

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Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg



One of the steps of providing quality person-centered contraceptive care involves assessing an individual's contraceptive preferences based on their desires, needs, and prior experiences.

Shown here are several open-ended questions that can be used to elicit preferences:

Can you tell me something (or some things) that are important to you in your contraception?

Is there anything else you're hoping to get out of your contraception?



Is there anything you don't want (or want to avoid) in a method?

What else are you looking for?

Romer SE et al. Am J Prev Med. 2024;67(6S):S41-S86

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Long-Acting Reversible Contraception (LARC)





Romer SE et al. Am J Prev Med. 2024;67(6S):S41-S86

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 For reproductive aged individuals wishing to prevent or delay pregnancy, OPA recommends offering the full range of hormonal and nonhormonal contraceptive methods, including permanent and reversible methods, such as IUDs and implants.

- Individuals who are not seeking pregnancy for the next year, may be interested in a long-acting reversible contraceptive method (LARC).
 - Bayer offers three different IUD options, Mirena, Kyleena and Skyla, for individuals seeking long-term reversible contraception.

(levonorgestrel-releasing intrauterine system) 13.5 mg

Example Questions about Bayer IUDs





A new patient calls to schedule an IUD insertion and asks what the procedure is like.



A patient recently delivered and is breast feeding. Can she have an IUD at her next visit?



A patient is at your clinic for an annual visit and asks about the difference between Bayer's IUDs.

Kyleena° (levonorgestrel-releasing intrauterine system) 19.5 mg



(levonorgestrel-releasing intrauterine system) 13.5 mg



Commonly asked questions about Bayer LNG-IUD

Kyleena° (levonorgestrel-releasing intrauterine system) 19.5 mg

(levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg

THIS PRESENTATION WILL REFER TO BAYER LNG-IUD WHEN INFORMATION PERTAINS TO KYLEENA, MIRENA AND SKYLA

Please see Important Safety Information throughout.



What is a Bayer LNG-IUD?

(levonorgestrel-releasing intrauterine system) 19.5 mg

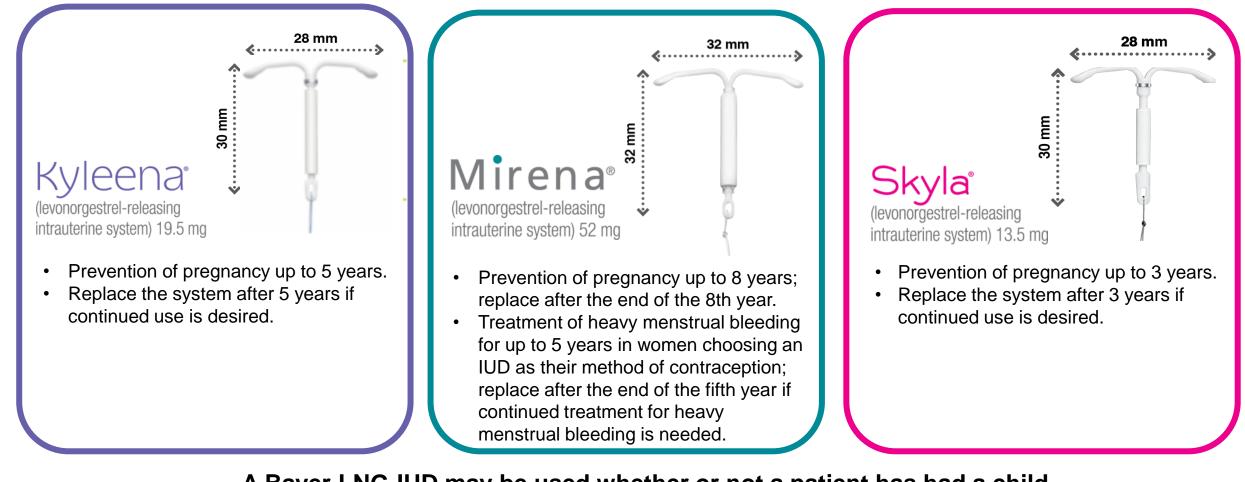
(levonorgestrel-releasing intrauterine system) 52 mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

Please see Important Safety Information throughout.

Indications





A Bayer LNG-IUD may be used whether or not a patient has had a child.

Please see Important Safety Information throughout.

Discussing Bayer LNG-IUD Using Patient-friendly Language



32 mm 28 mm Mirena is a hormone-28 mm releasing system placed Kyleena is a 32 mm Skyla is a in your uterus to prevent hormone-releasing hormone-releasing pregnancy up to 8 years. system placed in system placed in your uterus to your uterus to Mirena can also decrease menstrual blood loss prevent pregnancy prevent pregnancy for up to 5 years in women who have heavy up to 5 years. up to 3 years. menstrual flow and who also want to use a birth control method that is placed in the uterus to prevent pregnancy.

A Bayer LNG-IUD can be removed by your physician or healthcare provider at any time, and can be used whether or not you have had a child.

A Bayer LNG-IUD is a small flexible plastic T-shaped system, that slowly releases a progestin hormone called levonorgestrel (LNG) that is often used in birth control pills. Because it releases LNG into your uterus, only small amounts of hormone enter your blood.

Bayer LNG-IUD do not contain estrogen.

(levonorgestrel-releasing intrauterine system) 19.5 mg

(levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg



How does a Bayer LNG-IUD work?

Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5 mg (levonorgestrel-releasing intrauterine system) 52 mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

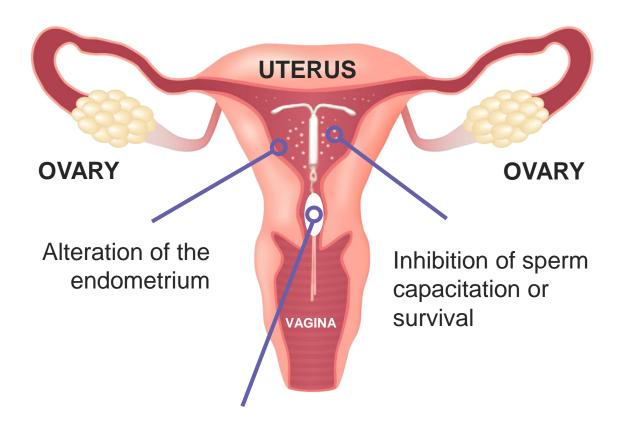
Please see Important Safety Information throughout.

Suggested Mechanism of Action



The local mechanism of action has not been conclusively demonstrated.

Studies of Kyleena, Mirena, Skyla and similar LNG-IUD prototypes have suggested several mechanisms that may prevent pregnancy.



Thickening of cervical mucus preventing passage of sperm into the uterus

Please see Important Safety Information throughout. For important information about Kyleena^{®,} Mirena[®], and Skyla[®], please see the Full Prescribing Information for each product available at this presentation.

Mirena® eena® (levonorgestrel-releasing

intrauterine system) 19.5 mg

(levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg

Discussing How a Bayer LNG-IUD Works Using Patient-friendly Language



- Bayer LNG-IUD may work in several ways including thickening cervical mucus, inhibiting sperm movement, reducing sperm survival and thinning the lining of your uterus.
- It is not known exactly how these actions work together to prevent pregnancy.
- Mirena can cause your menstrual bleeding to be less by thinning the lining of your uterus.



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(levonorgestrel-releasing intrauterine system) 13.5 mg



What are some considerations during patient selection for a Bayer LNG-IUD?

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(levonorgestrel-releasing intrauterine system) 13.5 mg

Please see Important Safety Information throughout.



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.

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- 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 Kyleena, Mirena, or 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.
- 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.

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How is a Bayer LNG-IUD placed? What should I expect after insertion?

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(levonorgestrel-releasing intrauterine system) 13.5 mg

Please see Important Safety Information throughout.

Tools for Insertion*





If anticipated, also have instruments & anesthesia for paracervical block available.

*NOTE: The inserter provided with Kyleena, Mirena, and Skyla and the insertion procedure described here, are not applicable for immediate insertion after childbirth or second-trimester abortion or miscarriage. For immediate insertion the Bayer IUD should be removed from the inserter and inserted according to accepted practice.

eena (levonorgestrel-releasing intrauterine system) 19.5 mg Mirena[®] (levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg

Please see Important Safety Information throughout. For important information about Kyleena^{®,} Mirena[®], and Skyla[®], please see the Full Prescribing Information for each product available at this presentation.

CansiCare

Insertion Video For Kyleena and Mirena





For insertion and removal steps for Skyla, please refer to the full Prescribing Information for Skyla.

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(levonorgestrel-releasing intrauterine system) 13.5 mg

Discussing How a Bayer LNG-IUD is Placed Using Patient-friendly Language





A Bayer LNG-IUD is placed by your physician or healthcare provider during an in-office visit or immediately after delivery.



During an in office placement, your physician or healthcare provider will first examine your pelvis to find the exact position of your uterus, and then clean the vagina and cervix with an antiseptic solution before sliding a slim plastic tube, containing the IUD, through the cervix into the uterus. A physician or healthcare provider will then remove the plastic tube, leave the IUD in the uterus, and cut the IUD threads.



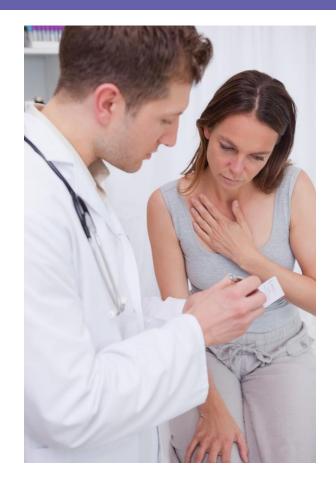
Patients may experience pain, bleeding, or dizziness during and after placement. If these symptoms do not resolve within 30 minutes, the IUD may not have been placed correctly. Your physician or healthcare provider will determine if the IUD needs to be removed or replaced.

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

(levonorgestrel-releasing intrauterine system) 13.5 mg

Bleeding and Cramping Following Insertion

- Patients should be advised that irregular or prolonged bleeding and spotting, and/or cramps may occur during the first few weeks after insertion.
- Inform the patient that, during the first 6 months of use, the number of bleeding and spotting days may be higher and bleeding patterns may be irregular.
 - Thereafter, the number of bleeding and spotting days may decrease, however bleeding can be irregular.
- If symptoms continue or are severe, they should be reported to their physician or healthcare provider.



Kyleena° (levonorgestrel-releasing intrauterine system) 19.5 mg



(levonorgestrel-releasing intrauterine system) 13.5 mg





What if a pregnancy occurs with a Bayer LNG-IUD in place?

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(levonorgestrel-releasing intrauterine system) 13.5 mg

Please see Important Safety Information throughout.

Important Safety Information (continued) PREGNANCY RELATED RISKS



- 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-IUD 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.

Kyleena° (levonorgestrel-releasing intrauterine system) 19.5 mg



(levonorgestrel-releasing intrauterine system) 13.5 mg



When can a Bayer LNG-IUD be inserted? How soon will it start working?

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(levonorgestrel-releasing intrauterine system) 13.5 mg

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Timing of Insertion



| IUD insertion timing | Backup contraception? | |
|---|--|--|
| Any time there is reasonable certainty they are not pregnant. Consider the possibility of equilation | YES if not inserted during the first 7 days of the menstrual cycle, a barrier method should be used or patient should abstain from vaginal intercourse for 7 days. | |
| Consider the possibility of ovulation and conception prior to initiation. | NO If inserted during the first 7 days of the menstrual cycle, or immediately after first trimester abortion. | |
| | | |
| Any time, including the hormone-free Interval of the previous method. | YES if inserted during active use of previous method, continue previous method for 7 days after insertion, or until the end of the current treatment cycle. | |
| | YES if inserted during use of continuous hormonal contraception, continue method for 7 days after insertion. | |
| 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. | |
| Anytime during the menstrual cycle. Insert Bayer IUD on the same day as removal of the implant or IUD. | NO there is no need for backup contraception. | |
| | Any time there is reasonable certainty they are not pregnant. Consider the possibility of ovulation and conception prior to initiation. Any time, including the hormone-free Interval of the previous method. Any time. Any time. Any time during the menstrual cycle. Insert Bayer IUD on the same day as | |

Kyleena° (levonorgestrel-releasing intrauterine system) 19.5 mg (levonorgestrel-releasing intrauterine system) 52 mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

Please see Important Safety Information throughout. For important information about <u>Kyleena[®], Mirena[®]</u>, and <u>Skyla[®]</u>, please see the

Full Prescribing Information for each product available at this presentation.

Timing of Insertion



| | Insertion timing | | Backup contraception? |
|--|---|-----|--|
| After 1st trimester abortion or miscarriage | Can be inserted immediately, unless it's a septic abortion. | NO | There is no need for backup contraception. |
| After childbirth or 2 nd trimester abortion or miscarriage | | | |
| Immediate insertion after childbirth, or 2 nd trimester abortion or miscarriage | Insert after removal of placenta. | NO | There is no need for backup contraception. |
| Interval insertion following complete involution of the uterus | ete involution of the uterus is fully involuted before insertion. | YES | If not inserted during the first 7 days of the menstrual cycle, a back-up method of contraception should be used, or the patient should abstain from vaginal intercourse for 7 days. |
| | | NO | If inserted during the first 7 days of the menstrual cycle. |

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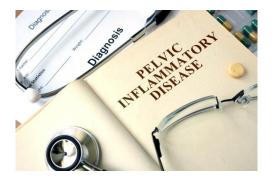
Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

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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.

(levonorgestrel-releasing intrauterine system) 19.5 mg (levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg



Educate her about PID (continued):

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.

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Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg



What if my plans change and I want to become pregnant?

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Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

Please see Important Safety Information throughout.



A physician or healthcare provider can remove the IUD at any time. Patients may become pregnant as soon as it's removed.

Among women using Kyleena:

 7 out of 10 women who want to become pregnant will become pregnant sometime in the first year after Kyleena is removed.

About **71%** of 163 women desiring pregnancy after study discontinuation and who provided follow-up information, became pregnant within 12 months of removal.

Kyleena° (levonorgestrel-releasing intrauterine system) 19.5 mg (levonorgestrel-releasing intrauterine system) 52 mg

Among women using Mirena:

 8 out of 10 women who want to become pregnant will become pregnant sometime in the first year after Mirena is removed.

In two studies, return to fertility was investigated in a total of 229 women who desired pregnancy after study discontinuation and provided follow-up information. The probability to conceive within 12 months after removal of Mirena was approximately **80%**.

Skyla (levonorgestrel-releasing intrauterine system) 13.5 mg Among women using Skyla:

 About 3 out of 4 women who want to become pregnant will become pregnant sometime in the first year after Skyla is removed.

About **77%** of women desiring pregnancy after study discontinuation and who provided follow-up information, became pregnant within 12 months of removal.

Tools and Steps for Removal





8

Alligator Forceps:

May be used to remove IUD if strings are not visible, and the IUD has been confirmed to be in the uterine cavity (for example by ultrasound). May be used to assist in removal if IUD is embedded or broken.

 Bayer LNG-IUD may be removed by applying gentle traction on the threads with forceps, and withdrawing the IUD from the uterus. If unable to remove with gentle traction, determine location and exclude perforation by ultrasound or other imaging.

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(levonorgestrel-releasing intrauterine system) 13.5 mg



Will a Bayer LNG-IUD interfere with intercourse? May I use tampons or menstrual cups?

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Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

Please see Important Safety Information throughout.

BAYER E R

Use During Intercourse:

- Should not be felt during intercourse.
- Patients should be directed to talk with their physician or health care provider if the threads are felt during intercourse or if pain is experienced during sex.



Tampons & Menstrual Cups:

- Tampons & Menstrual Cups may be used with a Bayer LNG-IUD in place.
- Change them with care to avoid pulling the threads of the Bayer LNG-IUD.
- If patients think they may have pulled the Bayer LNG-IUD out of place, they should avoid intercourse or use a non-hormonal back-up birth control (such as condoms or spermicide) and contact their physician or health care provider.

(levonorgestrel-releasing intrauterine system) 19.5 mg (levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg



Will my periods change while using a Bayer LNG-IUD?

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Important Safety Information (continued) EXPECT CHANGES IN BLEEDING PATTERNS





- 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.

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Counseling Patients on Bleeding Pattern Alterations Using Patientfriendly Language



| Will my periods change? | For the first 3-6 months, your period may become irregular and the number of bleeding days may increase. You may also have frequent spotting or light bleeding and cramping. Some users have heavy bleeding during this time. You may also have cramping during the first few weeks. After you have used Kyleena, Mirena or Skyla for a while, the number of bleeding and spotting days is likely to lessen. For some users, periods will stop altogether. |
|----------------------------|--|
| How might | In some patients with heavy bleeding who use Mirena, the total blood loss |
| Mirena affect | per cycle progressively decreases with continued use. The number of |
| heavy | spotting and bleeding days may initially increase but then typically |
| bleeding? | decreases in the months that follow. |

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What effects does an LNG-IUD have on breastfeeding?

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Breastfeeding With Bayer LNG-IUD





- Published studies report presence of LNG in human milk.
 - Small amounts of progestins (~0.1% of total maternal doses) detected in the breast milk of nursing mothers who used Mirena, resulting in exposure of LNG to the breastfed infants.
- There are no reports of adverse effects in breastfed infants with maternal use of progestin-only contraceptives.
- Isolated cases of decreased milk production have been reported with Mirena.

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Explaining Bayer LNG-IUD and Breastfeeding using Patient-friendly Language





- You may use a Bayer LNG-IUD while breastfeeding.
- It is not likely to affect the quality or amount of your breast milk or the health of your nursing baby.
- However, isolated cases of decreased milk production have been reported.
- The risk of the Bayer LNG-IUD going into the wall of the uterus (becoming embedded) or going through the wall of the uterus, is increased if the Bayer LNG-IUD is inserted while breastfeeding.

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Will a Bayer LNG-IUD protect me from sexually transmitted infections (STIs)?

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STI Counseling



 Patients should be counseled that Bayer LNG-IUD do not protect against HIV infection (AIDS) and other STIs.



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What are some of the serious complications and adverse reactions from using a Bayer LNG-IUD?

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Please see Important Safety Information throughout.



Be aware of other serious complications and most common adverse reactions

 Some serious complications with IUDs like Kyleena[®], Mirena[®], and Skyla[®] are sepsis, perforation, and expulsion.

Sepsis

Severe infection, or sepsis, including Group A streptococcal sepsis (GAS), have been reported following
insertion of a LNG-releasing IUD. Aseptic technique during insertion of the IUD is essential in order to
minimize serious infections, such as GAS.

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(levonorgestrel-releasing intrauterine system) 13.5 mg



Perforation

- 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.

(levonorgestrel-releasing intrauterine system) 19.5 mg (levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg



Expulsion

- 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

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

(levonorgestrel-releasing intrauterine system) 19.5 mg (levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg



Kyleena: the most common adverse reactions (≥5% users)

| were: | |
|----------------------------|-----|
| Vulvovaginitis | 24% |
| Ovarian Cyst | 22% |
| Abdominal/pelvic pain | 21% |
| Headache/migraine | 15% |
| Acne/seborrhea | 15% |
| Dysmenorrhea/uterine spasm | 10% |
| Breast pain/discomfort | 10% |
| Increased bleeding | 8% |

Kyleena° (levonorgestrel-releasing intrauterine system) 19.5 mg (levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg

Important Safety Information (continued) BE AWARE OF OTHER SERIOUS COMPLICATIONS AND MOST COMMON ADVERSE REACTIONS



In clinical trials with Mirena®:

| Adverse reactions reported in ≥5% of users were: | | | | | |
|--|---------------------------------|--|------|--|--|
| Alterations in menstrual bleeding patterns Unscheduled uterine bleeding Decreased uterine bleeding Increased scheduled uterine bleeding Female genital tract bleeding | 31.9% 23.4% 11.9% 3.5% | Breast pain | 8.5% | | |
| Abdominal/pelvic pain | 22.6% | Back pain | 7.9% | | |
| Amenorrhea | 18.4% | Benign ovarian cyst and associated complications | 7.5% | | |
| Headache/migraine | 16.3% | Acne | 6.8% | | |
| Genital discharge | 14.9% | Depression/depressive mood | 6.4% | | |
| Vulvovaginitis | 10.5% | Dysmenorrhea | 6.4% | | |

(levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing

intrauterine system) 19.5 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg

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.

Please see Important Safety Information throughout. For important information about Kyleena[®], Mirena[®], and Skyla[®], please see the

Full Prescribing Information for each product available at this presentation.



Skyla – 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% |
| 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, and Skyla and then yearly or more often if clinically indicated.

(levonorgestrel-releasing intrauterine system) 19.5 mg

(levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg



Resources

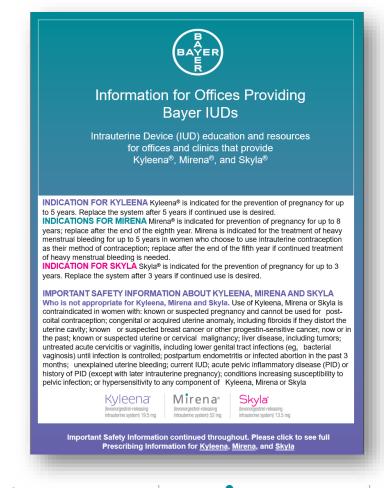
Kyleena° (levonorgestrel-releasing intrauterine system) 19.5 mg Mirena® (levonorgestrel-releasing intrauterine system) 52 mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

Please see Important Safety Information throughout.

Resources





go.bayer.com/BayerIUDResources

- Information packet with summary of information provided here, including:
 - Indications
 - Bayer LNG-IUD Properties Chart
 - Insertion Timing Chart
 - Tools needed for Insertion and Removal
 - Important Safety Information



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

(levonorgestrel-releasing intrauterine system) 13.5 mg



Thank you

Please see Important Safety Information throughout. For important information about <u>Kyleena[®]</u>, <u>Mirena[®]</u>, and <u>Skyla[®]</u>, please see the Full Prescribing Information for each product available at this presentation.

> (levonorgestrel-releasing intrauterine system) 19.5 mg

✓Mirena[®]

(levonorgestrel-releasing intrauterine system) 52 mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

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