



Bayer IUDs (Intrauterine Devices): Safety Overview

Mirena® (levonorgestrel-releasing
intrauterine system) 52mg

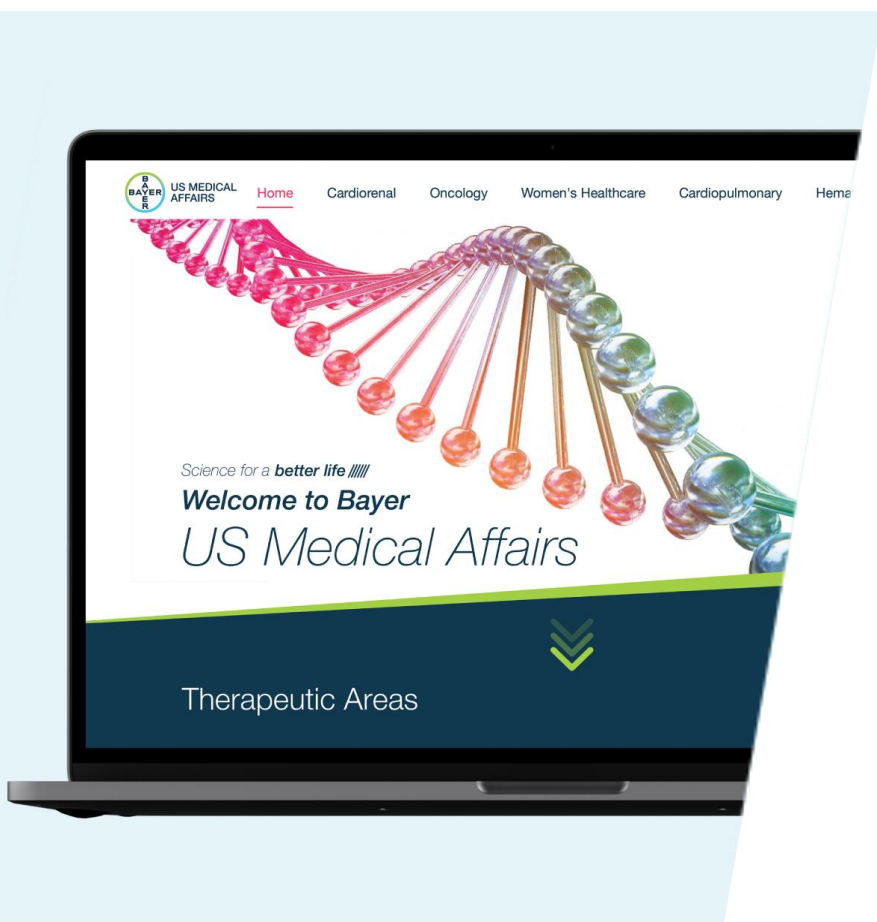
Kyleena® (levonorgestrel-releasing
intrauterine system) 19.5mg

Skyla® (levonorgestrel-releasing
intrauterine system) 13.5mg

Please see Important Safety Information throughout. Please see full Prescribing Information for Mirena, Kyleena, and Skyla that is available at this presentation.

MA-PFM-IUS-US-0037-2; Nov 2024

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.



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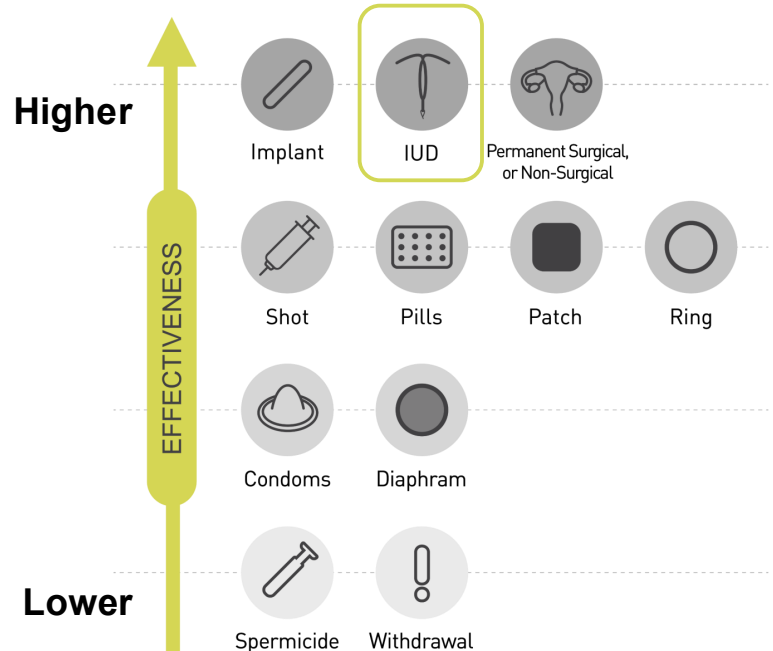
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Contraceptive Options



An Intrauterine Device (IUD) is a long acting method of birth control, and is considered to be one of the most effective methods of reversible birth control¹



[1] Obstet Gynecol. 2017 Nov;130(5):e251-e269

What are Mirena, Kyleena, & Skyla?

Indications



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

- Prevention of pregnancy for up to 8 years; replace after the end of the eighth year
- 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

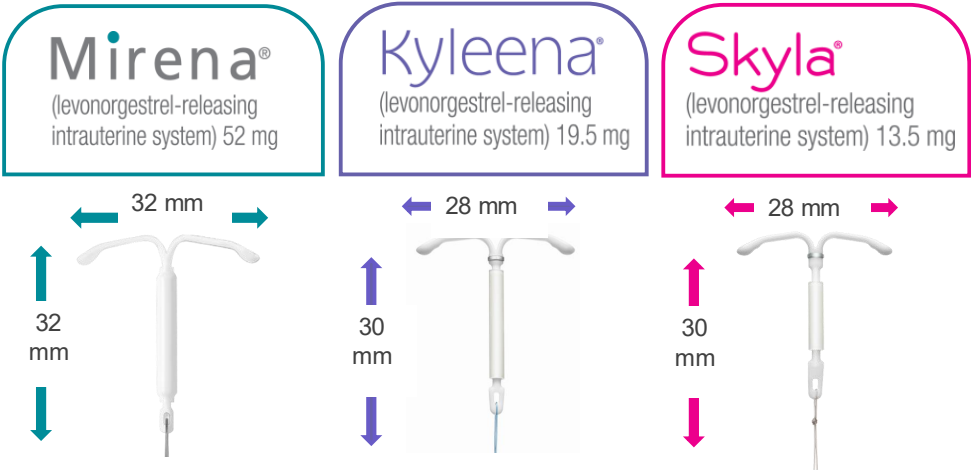
Kyleena[®]
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- Prevention of pregnancy up to 5 years
- Replace the system after 5 years if continued use is desired

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

- Prevention of pregnancy up to 3 years
- Replace the system after 3 years if continued use is desired

Properties



Hormone Reservoir (Total Amount)	52mg LNG	19.5mg LNG	13.5mg
Insertion Tube Diameter	4.4 mm	3.8 mm	3.8mm
Release Rate After 1 Year	19 mcg/d	9.8 mcg/d	~6 mcg/d
Thread color	Brown	Blue	Brown
Silver Ring / MR Compatibility	No Silver Ring	Yes / MR Conditional	Yes / MR Conditional

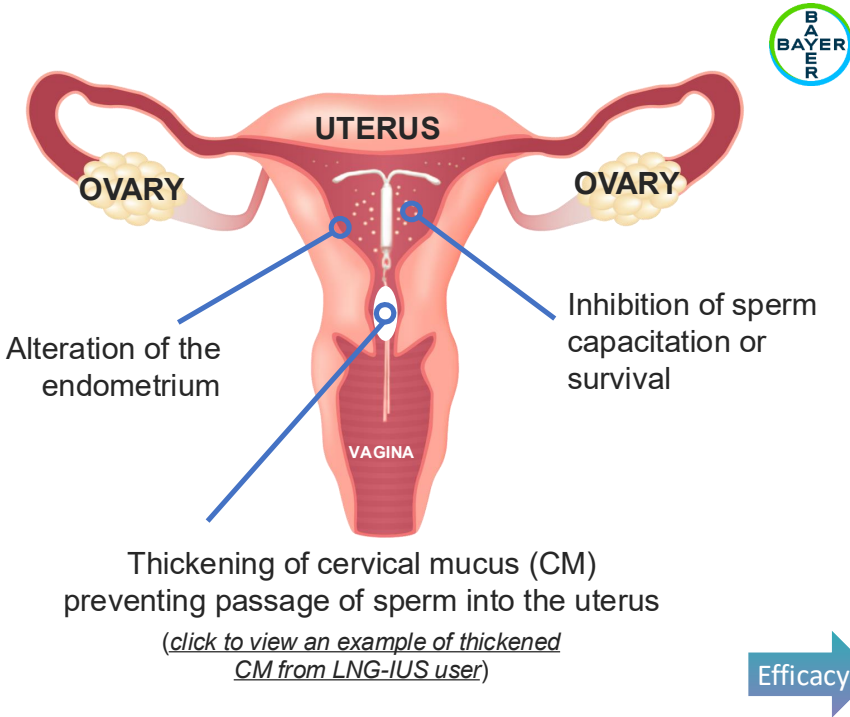
The combination of silver ring and thread color will help identify the brand of IUD.

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Suggested Mechanism of Action

The local mechanism of action has not been conclusively demonstrated

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



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(levonorgestrel-releasing intrauterine system) 52 mg

(levonorgestrel-releasing intrauterine system) 19.5 mg

(levonorgestrel-releasing intrauterine system) 13.5 mg

Cervical Mucus Changes During LNG-IUS Use

The local mechanism of action has not been conclusively demonstrated. Thickening of cervical mucus is one of the several suggested mechanisms that may prevent pregnancy

These examples show how cervical mucus from an LNG-IUS user is thick, compared to a control patient (not using contraception)

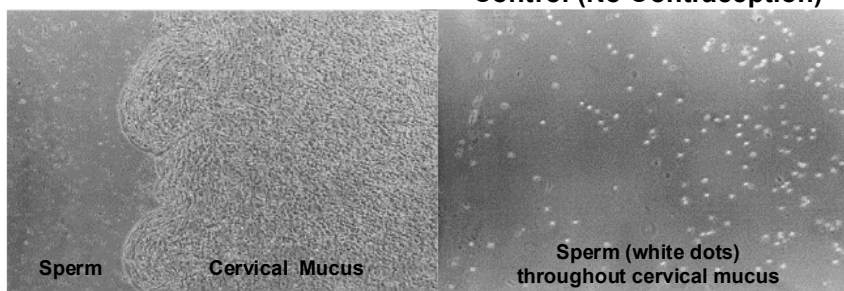
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Examples of Cervical Mucus

LNG-IUS user

Control (No Contraception)



Lewis et al., 2010. Used with permission.

- Mid-cycle Cervical Mucus (CM) from LNG-IUS user (left) and control patient (right) were placed on slide and surrounded by sperm
- Sperm are unable to penetrate CM from LNG-IUS user, but swim throughout control CM

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*Who is an
appropriate
candidate for Mirena,
Kyleena, or Skyla?*

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Important Safety Information

Contraindications



- 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 tumor
- Untreated acute cervicitis or vaginitis, including lower genital tract infections (e.g. 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 a history of PID (except with later intrauterine pregnancy)
- Conditions increasing susceptibility to pelvic infections
- Hypersensitivity to any component of the Mirena, Kyleena, or Skyla

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Important Safety Information

Clinical Considerations for Use and Removal



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, 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, 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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When can I place a place a Mirena, Kyleena, or Skyla?

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Timing of Insertion

Consider same day insertion if there is reasonable certainty the patient is not pregnant



	Insertion timing	Backup contraception?
Patients not currently using hormonal or intrauterine contraception	- 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 first 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 contraceptive	Any time, including the hormone-free interval of the previous method	YES If inserted during active use of previous method, continue that method for 7 days after insertion, or until the end of the current treatment cycle YES If inserted during use of continuous hormonal contraception, discontinue method 7 days after insertion
Injectable progestin contraceptive	Any time	YES If inserted >3 months (13 weeks) after the last injection, non-hormonal back-up birth control (such as condoms or spermicide) should also be used for 7 days NO If inserted <3 months after last injection
Implant or another IUS	- Anytime during the menstrual cycle - Insert the IUD on the same day the implant or IUS is removed	NO There is no need for backup contraception

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Timing of Insertion

After First or Second Trimester Abortion or miscarriage, and Childbirth



	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	- Wait a minimum of 6 weeks, or until the uterus is fully involuted before insertion - Insert any time there is reasonable certainty that the patient is not pregnant	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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*What should I do if
my patient is
pregnant with the
Bayer IUD in place?*

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Important Safety Information

Pregnancy Related Risks



Intrauterine Pregnancy

- 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
- 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.



Ectopic Pregnancy

- 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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*How should I counsel
my patients about PID
(Pelvic Inflammatory
Disease)?*

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Important Safety Information

Educate her about Pelvic Inflammatory Disease (PID)



- Mirena, Kyleena, 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

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Important Safety Information

Educate her about Pelvic Inflammatory Disease (PID) (cont.)



- 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
- In clinical trials with:
 - **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
 - **Kyleena** – PID occurred more frequently within the first year and most often 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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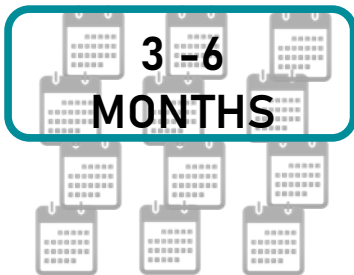
How would counsel your patients about changes in bleeding patterns?

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Important Safety Information

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



**Bleeding &
spotting
charts**

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Mirena



5-Year Contraception Trial (n=1,169 women):

- ~20% of women developed amenorrhea by the end of the first year

Extension Trial (separate study of n=362 women who used Mirena for more than 5 years):

By the end of 8 years of use:

- 34% of women experienced amenorrhea
- 26% experienced infrequent bleeding
- 10% experienced irregular bleeding
- 3% experienced frequent bleeding
- 3% experienced prolonged bleeding

Heavy Menstrual Bleeding Patterns:

- Mirena should be replaced at the end of the fifth year if continued treatment of heavy menstrual bleeding is needed, because data on use in this indication beyond 5 years are limited
- In most women with HMB, the number of bleeding and spotting days may also increase during the initial months of therapy but usually decrease with continued use. The volume of blood loss per cycle progressively becomes reduced

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Return to
Bleeding
Changes

Kyleena



Bleeding Pattern Alterations reported in Contraception Studies (by 90 day reference periods)

Kyleena	First 90 days (n=1,566)	Second 90 days (n=1,511)	End of year 1 (n=1,371)	End of year 3 (n=975)	End of year 5 (n=530)
Amenorrhea (subject with no bleeding/spotting throughout 90 day reference period)	<1%	5%	12%	20%	23%
Infrequent bleeding (subjects with 1 or 2 bleeding/spotting episodes in 90 day reference period)	10%	20%	26%	26%	26%
Frequent bleeding (subjects with > 5 bleeding/spotting episodes in 90 day reference period)	25%	10%	4%	2%	2%
Prolonged bleeding (subjects with bleeding/spotting episodes lasting more than 14 days in the 90 day reference period; may also be included in other category, excluding amenorrhea)	57%	14%	6%	2%	1%
Irregular Bleeding (subjects with 3-5 bleeding/spotting episodes and less than 3 bleeding/spotting free intervals of 14 or more days)	43%	25%	17%	10%	9%

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How would you counsel your patients regarding potential serious adverse reactions?

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Important Safety Information



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

PERFORATION:

- Perforation (total or partial, including penetration/embedment of Mirena, Kyleena, 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

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Important Safety Information



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

PERFORATION:

- 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

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

EXPULSION:

- Partial or complete expulsion of Mirena, Kyleena, 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 Mirena, Kyleena, or Skyla can be inserted any time the provider can be reasonably certain the woman is not pregnant

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OVARIAN CYSTS:

- 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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Common adverse reactions observed from clinical studies

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Important Safety Information



Be aware of other serious complications and most common adverse reactions (cont.): In clinical trials with:

Mirena – adverse reactions reported in ≥5% of users were:

Alterations in menstrual bleeding patterns			
Unscheduled uterine bleeding	31.9%	Breast pain	8.5%
Decreased uterine bleeding	23.4%		
Increased scheduled uterine bleeding	11.9%		
Female genital tract bleeding	3.5%		
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%

A separate study with 362 women who have used Mirena for more than 5 years showed a consistent adverse reaction profile in years 6 - 8. By the end of Year 8 of use:

- Amenorrhea and infrequent bleeding were experienced by 34% and 26% of users, respectively;
 - Irregular bleeding occurs in 10%,
 - Frequent bleeding occurs 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

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



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%

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Thank you!

Any Questions?

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Appendix: Bleeding Patterns

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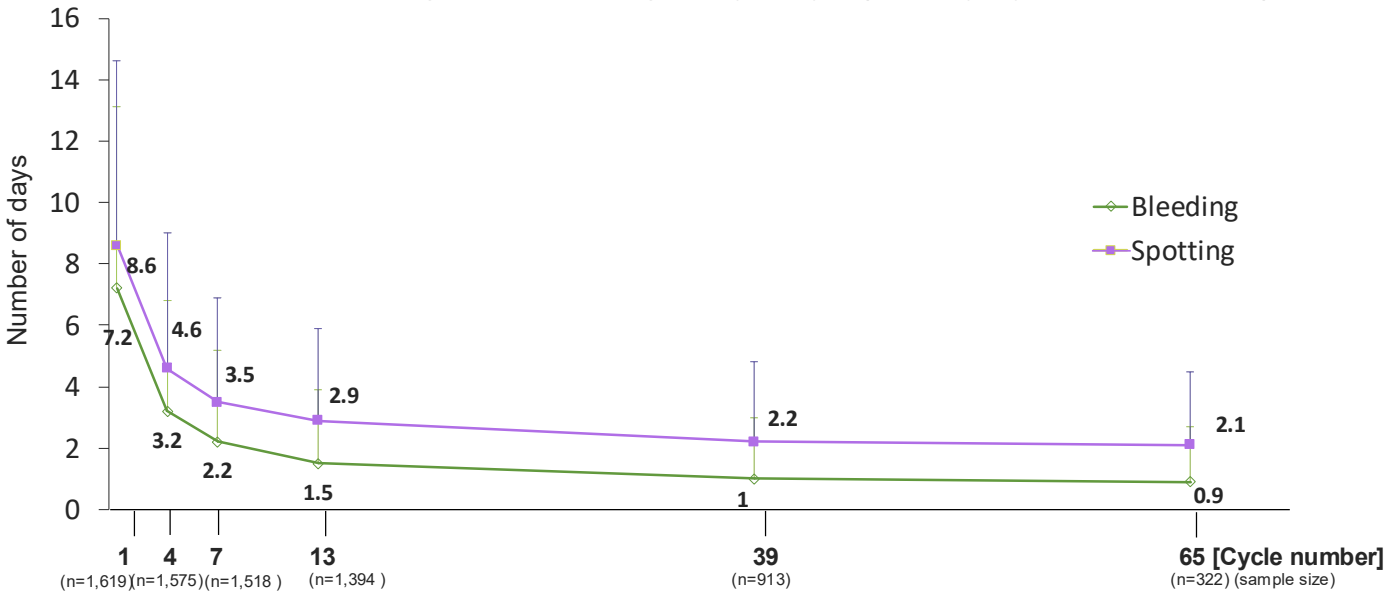
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Kyleena



Mean Number of Bleeding and Spotting-Only Days (28 day cycle equivalent)



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena®
(levonorgestrel-releasing intrauterine system) 52 mg

Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5 mg

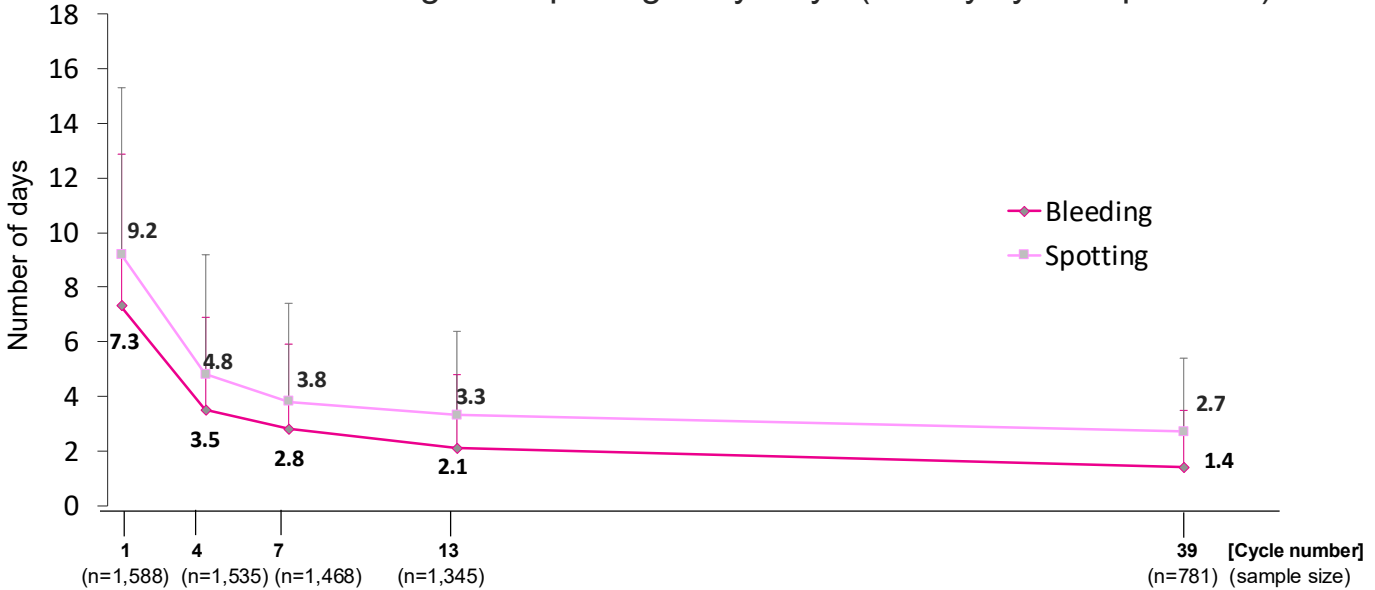
Skyla®
(levonorgestrel-releasing intrauterine system) 13.5 mg

Return to Bleeding Changes

Skyla



Mean Number of Bleeding and Spotting-Only Days (28 day cycle equivalent)



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena®
(levonorgestrel-releasing intrauterine system) 52 mg

Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5 mg

Skyla®
(levonorgestrel-releasing intrauterine system) 13.5 mg

Return to Bleeding Changes

Skyla

Bleeding Pattern Alterations reported in Contraception Studies (by 90 day reference periods)



Skyla	First 90 days (n=1,531)	Second 90 days (n=1,475)	End of year 1 (n=1,329)	End of year 3 (n=903)
Amenorrhea (subjects with no bleeding/spotting throughout 90 day reference period)	<1%	3%	6%	12%
Infrequent bleeding (subjects with 1 or 2 bleeding/spotting episodes in 90 day reference period)	8%	19%	20%	22%
Frequent bleeding (subjects with > 5 bleeding/spotting episodes in 90 day reference period)	31%	12%	8%	4%
Prolonged bleeding (subjects with bleeding/spotting episodes lasting more than 14 days in the 90 day reference period; may also be included in one of the other categories -excluding amenorrhea)	55%	14%	6%	2%
Irregular Bleeding (subjects with 3-5 bleeding/spotting episodes and less than 3 bleeding/spotting free intervals of 14 or more days)	39%	25%	18%	15%



Return to
Bleeding
Changes

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