

FREQUENTLY ASKED QUESTIONS ABOUT KYLEENA



T ABOUT IUDS

What is an IUD, like Kyleena?

An [IUD \(intrauterine device\)](#) is a small, T-shaped device that's placed in your uterus by your healthcare provider to prevent pregnancy. Getting an IUD does not involve surgery, but instead, can be placed during a routine in-office visit or immediately after giving birth. Once in place, it provides continuous, highly effective birth control.

You may experience pain, bleeding, or dizziness during and after placement. If your symptoms do not pass within 30 minutes after placement, Kyleena may not have been placed correctly. Your healthcare provider will examine you to see if Kyleena needs to be removed or replaced.

✦ GETTING KYLEENA®

Will it hurt to have Kyleena placed?

You may experience pain, bleeding, or dizziness during and after placement. If your symptoms do not pass within 30 minutes after placement, Kyleena may not have been placed correctly. Your healthcare provider will examine you to see if Kyleena needs to be removed or replaced.

If pain is a concern for you, ask your healthcare provider about taking over-the-counter pain medication before the procedure.

[Find more information about the insertion process.](#)

Do I have to use Kyleena for 5 years?

No. [Kyleena can be removed](#) at any time by your healthcare provider. You could become pregnant as soon as Kyleena is removed, so you should use another

method of birth control if you do not want to become pregnant.

INDICATION FOR KYLEENA

Kyleena® (levonorgestrel-releasing intrauterine system) is a hormone-releasing IUD that prevents pregnancy for up to 5 years.

IMPORTANT SAFETY INFORMATION

- If you have a pelvic or genital infection, get infections easily, or have certain cancers, don't use Kyleena. Less than 1% of users get a serious pelvic infection called pelvic inflammatory disease (PID).
- If you have persistent pelvic or stomach pain, or excessive bleeding after placement tell your healthcare provider (HCP). If Kyleena comes out, call your HCP and avoid intercourse or use non-hormonal back-up birth control (such as condoms or spermicide). Kyleena may go into or through the wall of the uterus and cause other problems.
- Pregnancy while using Kyleena is uncommon but can be life threatening and may result in loss of pregnancy or fertility.
- Ovarian cysts may occur but usually disappear.
- Bleeding and spotting may increase in the first 3 to 6 months and remain irregular. Periods over time usually become shorter, lighter, or may stop

Please see additional Important Safety Information on Page 5 and [Full Prescribing Information](#) for Kyleena.

SAFETY CONSIDERATIONS FOR KYLEENA® (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 19.5 MG

Who should not use Kyleena?

Kyleena is not right for everyone. Do not use Kyleena if you:

- are or might be pregnant; Kyleena cannot be used as an emergency contraceptive
- have a serious pelvic infection called pelvic inflammatory disease (PID) or have had PID in the past unless you have had a normal pregnancy after the infection went away
- have an untreated genital infection now
- have had serious pelvic infections in the past 3 months after a pregnancy
- can get infections easily. For example, if you:
 - have multiple sexual partners or your partner has multiple sexual partners
 - have problems with your immune system
 - use or abuse intravenous drugs
- have or suspect you might have cancer of the uterus or cervix
- have bleeding from the vagina that has not been explained
- have liver disease or liver tumor
- have breast cancer or any other cancer that is sensitive to progestin (a female hormone), now or in the past
- have an intrauterine device in your uterus already
- have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumors
- are allergic to levonorgestrel, silicone, polyethylene, silver, silica, barium sulfate, polypropylene, or copper phthalocyanine

What are the possible serious side effects of Kyleena?

Kyleena can cause serious side effects, including:

- **Ectopic pregnancy and intrauterine pregnancy risks.** There are risks if you become pregnant while using Kyleena (see "[What if I become pregnant while using Kyleena?](#)").
- **Life-threatening infection.** Life-threatening infection can occur within the first few days after Kyleena is placed. Call your healthcare provider immediately if you develop severe pain or fever shortly after Kyleena is placed.
- **Pelvic inflammatory disease (PID).** Some IUD users get a serious pelvic infection called pelvic inflammatory disease. PID is usually sexually transmitted. You have a higher chance of getting PID if you or your partner has sex with other partners. PID can cause serious problems such as infertility, ectopic pregnancy or pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID may require surgery including removal of the uterus (hysterectomy). In rare cases, infections that start as PID can even cause death. Tell your healthcare provider right away if you have any of these signs of PID: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal (stomach area) pain, painful sex, chills, fever, genital lesions or sores.
- **Perforation.** Kyleena may go into the wall of the uterus (become embedded) or go through the wall of the uterus. This is called perforation. If this occurs, Kyleena may no longer prevent pregnancy. If perforation occurs, Kyleena may move outside the uterus and can cause internal scarring, infection, or damage to other organs, and you may need surgery to have Kyleena removed. Excessive pain or vaginal bleeding during placement of Kyleena, pain or bleeding that gets worse after placement, or not being able to feel the threads may happen with perforation. The risk of perforation is increased if Kyleena is inserted while you are breastfeeding, or if you have recently given birth.
- **Expulsion.** Kyleena may come out by itself. This is called expulsion. Expulsion occurs in about 4 out of 100 women. Excessive pain or vaginal bleeding during placement of Kyleena, pain or bleeding that gets worse after placement, or not being able to feel the threads may happen with expulsion. You may become pregnant if Kyleena comes out. If you think that Kyleena has come out, avoid intercourse or use a non-hormonal back-up birth control (such as condoms or spermicide) and call your healthcare provider. The risk of expulsion is increased with insertion right after delivery or second trimester abortion.

What are the common side effects of Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg?

Common side effects of Kyleena include:

- **Pain, bleeding, or dizziness during and after placement.** If these symptoms do not stop 30 minutes after placement, Kyleena may not have been placed correctly. Your healthcare provider will examine you to see if Kyleena needs to be removed or replaced.
- **Changes in bleeding.** You may have bleeding and spotting between menstrual periods, especially during the first 3 to 6 months. Sometimes the bleeding is heavier than usual at first. However, the bleeding usually becomes lighter than usual and may be irregular. Call your healthcare provider if the bleeding remains heavier than usual or increases after it has been light for a while.
- **Missed menstrual periods.** About 12 out of 100 women stop having periods after 1 year of Kyleena use. If you have any concerns that you may be pregnant while using Kyleena, do a urine pregnancy test and call your healthcare provider. If you do not have a period for 6 weeks during Kyleena use, call your healthcare provider. When Kyleena is removed, your menstrual periods should return.

- **Cysts on the ovary.** About 22 out of 100 women using Kyleena develop a cyst on the ovary. These cysts usually disappear on their own in 2 to 3 months. However, cysts can cause pain and sometimes need surgery.

Other common side effects include:

- inflammation or infection of the outer part of your vagina (vulvovaginitis)
- abdomen or pelvic pain
- headache or migraine
- acne or greasy skin
- painful periods
- sore or painful breasts

In the clinical trials of 1,697 healthy women aged 18-41, the most common adverse reactions (occurring in $\geq 5\%$ women) were vulvovaginitis (24%), ovarian cyst (22%), abdominal pain/pelvic pain (21%), headache/migraine (15%), acne/seborrhea (15%), dysmenorrhea/uterine spasm (10%), breast pain/breast discomfort (10%), and increased bleeding (8%).

These are not all of the possible side effects with Kyleena. For more information, please see [Full Prescribing Information](#) or ask your healthcare provider.

How will Kyleena change my periods?

For the first 3 to 6 months, your period may become irregular, and the number of bleeding days may increase. You may also have frequent spotting or light bleeding.

Some women have heavy bleeding during this time. You may also have cramping during the first few weeks.

After you have used Kyleena for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether.

When Kyleena is removed, your menstrual periods should return.

Does Kyleena protect against HIV or STIs?

Kyleena does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).

Can I have an MRI with Kyleena in place?

Kyleena can be safely scanned with magnetic resonance imaging (MRI) only under specific conditions. Before you

have an MRI, tell your healthcare provider that you have Kyleena, an intrauterine device (IUD), in place.

AFTER GETTING KYLEENA

Can I use tampons or menstrual cups with Kyleena?

Yes, tampons or menstrual cups may be used with Kyleena. Change tampons or menstrual cups with care to avoid pulling the threads of Kyleena. If you think you may have pulled Kyleena out of place, avoid intercourse

or use a non-hormonal back-up birth control (such as condoms or spermicide), and contact your healthcare provider.

Will my partner be able to feel Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg during sex?

You and your partner should not feel Kyleena during intercourse. Kyleena is placed in the uterus, not in the vagina. Sometimes your partner may feel the threads.

If this occurs, or if you or your partner experience pain during sex, talk with your healthcare provider.

Does Kyleena start working right away, or do I need to use back-up birth control?

It depends on whether you were using hormonal birth control prior to getting Kyleena and also when Kyleena is placed during your menstrual cycle. Your healthcare

provider will confirm if you need to use back-up birth control after Kyleena is placed.

Should I check that Kyleena is in place?

Yes, you should check that Kyleena is in the proper position by feeling the removal threads. It is a good habit to do this once a month. Your healthcare provider should teach you how to check that Kyleena is in place. First, wash your hands with soap and water. You can check by reaching up to the top of your vagina with clean fingers to feel the removal threads. Do not pull on

the threads. If you feel more than just the threads or if you cannot feel the threads, Kyleena may not be in the right position and may not prevent pregnancy. Avoid intercourse or use non-hormonal back-up birth control (such as condoms or spermicide) and ask your healthcare provider to check that Kyleena is still in the right place.

How soon should I return to see my healthcare provider after Kyleena has been placed?

Call your healthcare provider if you have any questions or concerns (see "[When should I call my healthcare provider?](#)"). Otherwise, you should return to your

healthcare provider for a follow-up visit 4 to 6 weeks after Kyleena is placed to make sure that Kyleena is in the right position.

GETTING PREGNANT AND NEW MOMS

What if I change my mind and want to try to get pregnant?

Kyleena can be removed at any time by your healthcare provider, and you can try getting pregnant right away. About 7 out of 10 women who tried to become

pregnant conceived within a year of having Kyleena removed.

What if I become pregnant while using Kyleena?

Call your healthcare provider right away if you think you are pregnant. If possible, also do a urine pregnancy test. If you get pregnant while using Kyleena, you may have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain may be a sign of ectopic pregnancy. Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.

There are also risks if you get pregnant while using Kyleena and the pregnancy is in the uterus. Severe infection, miscarriage, premature delivery, and even death can occur with pregnancies that continue with

an intrauterine device (IUD). Because of this, your healthcare provider may try to remove Kyleena, even though removing it may cause a miscarriage. If Kyleena cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy and possible effects of the hormone on your unborn baby.

If you continue your pregnancy, see your healthcare provider regularly. Call your healthcare provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection.

Is it safe to breastfeed while using Kyleena?

You may use Kyleena when you are breastfeeding. Kyleena 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 Kyleena going into the wall of the uterus (becoming embedded) or going through the wall of the uterus is increased if Kyleena is inserted while you are breastfeeding.

COST AND INSURANCE COVERAGE

Will my health insurance plan cover Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg?

[Follow these steps](#) to check if Kyleena is covered by your insurance. If Kyleena isn't covered or if you don't have insurance, Bayer may be able to [help](#).

How much does Kyleena cost?

95% of women were covered for a Bayer IUD, like Kyleena, with little or no out-of-pocket costs (based on past benefit investigation submissions to Bayer in 2017). If you do not have health insurance, or if Kyleena is not covered by your insurance, the cost of Kyleena is \$1,049.24. This comes to \$17.49 per month over a 5-year period.

The Affordable Care Act (ACA) generally requires health plans to cover FDA-approved contraceptives, including intrauterine devices (IUDs) at low or no cost to the patient (eg, co-payment, coinsurance). Depending on the specific health insurance plan, patients may still be responsible for the cost of the product and/or product-related costs, such as insertion or removal procedure fees.

Is there a savings program for Kyleena?

Yes, the Co-pay Savings Program for Kyleena may help if you have health insurance but still have high out-of-pocket costs for Kyleena.

Eligible patients may be able to pay as little as \$20 out of pocket for Kyleena.*

[Enroll now >](#)

*Eligible patients may pay as little as \$20 for the cost of the Kyleena IUD. Benefit limitations apply. For full terms and conditions, please reference copayforkyleena.com. Patients who are enrolled in any

type of government insurance or reimbursement programs are not eligible. As a condition precedent of the co-payment support provided under this program, e.g., co-pay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payers of any benefits they receive and the value of this program, and may not participate if this program is prohibited by or conflicts with their private insurance policy, as required by contract or otherwise. Void where prohibited by law, taxed, or restricted. Patients enrolled in the Bayer US Patient Assistance Foundation are not eligible. Bayer may determine eligibility, monitor participation, equitably distribute product and modify or discontinue any aspect of the Co-pay Savings Program for Kyleena at any time, including but not limited to this commercial co-pay assistance program.

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Kyleena does not protect against HIV or STIs.

Only you and your HCP can decide if Kyleena is right for you. Kyleena is available by prescription only.

For important risk and use information about Kyleena, please see [Full Prescribing Information](#).

