Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5 mg

THE SMALLEST LOWEST-HORMONE 5-YEAR IUD











IUD = Intrauterine Device.

BAYER



PLAN ON YOUR TERMS WITH THE LOWEST-HORMONE 5-YEAR IUD

Choosing birth control is personal, and for a lot of women, it's important to have a low-hormone option. Based on where you are in your life, if you don't want to get pregnant right now, get to know Kyleena®:

- Lowest-hormone 5-year IUD
- Is over 99% effective at preventing pregnancy for each year of use, and 98.6% effective over 5 years
- Can be used whether or not you've had a baby
- Can be removed by your healthcare professional any time in case your plans change

DID YOU KNOW?

Millions of women have already used IUDs–including women who have had a baby and those who haven't.

Important Safety Information

- If you have an untreated 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 professional (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 go through the uterus and cause other problems.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23 and the full Prescribing Information here.

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(levonorgestrel-releasing intrauterine system) 19.5mg

A CLOSER LOOK AT KYLEENA

- The smallest, lowest-hormone 5-year IUD
- T-shaped and made of soft, flexible plastic
- Placed in your uterus by a healthcare professional who can remove it at any time

Important Safety Information

- 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.

DID YOU KNOW?

Kyleena® is 1.18″—about the size of an earbud.



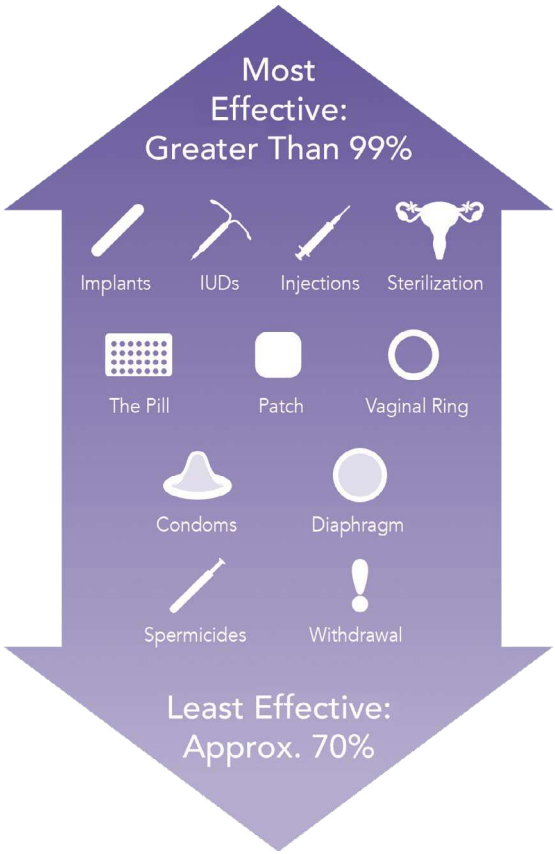
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For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23 and the full Prescribing Information here.

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(levonorgestrel-releasing intrauterine system) 19.5mg

HIGHLY EFFECTIVE AND LOW-HORMONE BIRTH CONTROL

- Kyleena® is one of the most effective forms of birth control
- Kyleena lasts up to 5 years, and eliminates the responsibility of taking a daily pill—that's 1,826 daily pills over 5 years vs 1 Kyleena IUD
- Make sure Kyleena is in place with a monthly thread check
- Return for a follow-up visit 4 to 6 weeks after placement of Kyleena



Important Safety Information

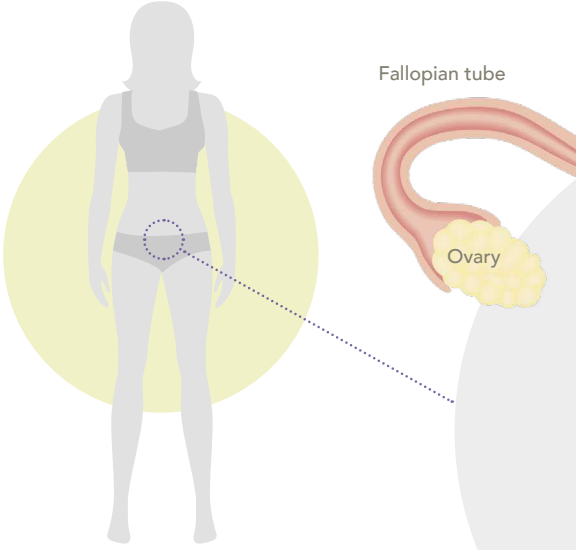
- Bleeding and spotting may increase in the first 3 to 6 months and remain irregular. Periods over time usually become shorter, lighter, or may stop.

Kyleena does not protect against HIV or STIs.

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

KYLEENA WORKS IN THE UTERUS

- Is placed in the uterus by a healthcare professional
- Works by giving you a continuous low dose of a hormone called progestin
- Because Kyleena® releases progestin hormones locally in the uterus at a slow rate, only small amounts enter the bloodstream



Common and serious side effects 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 professional will examine you to see if Kyleena needs to be removed or replaced.
- **Expulsion.** Kyleena may come out by itself. This is called expulsion. Expulsion occurs in about 4 out of 100 women. You may become pregnant if Kyleena comes out. If you think that Kyleena has come out, use a back-up birth control method like condoms and spermicide and call your healthcare professional. The risk of expulsion is increased with insertion right after delivery or second-trimester abortion.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23 and the full Prescribing Information here.

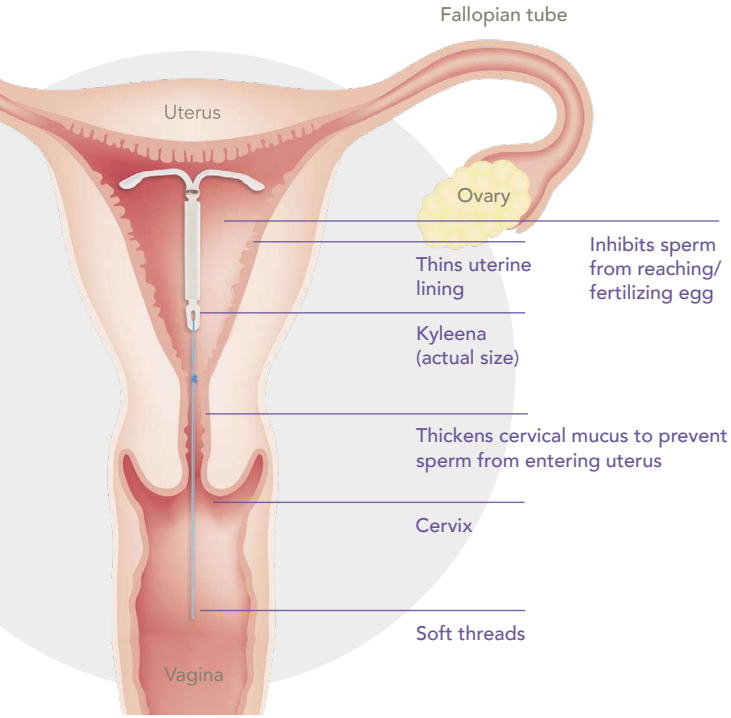
Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5 mg

HOW DOES KYLEENA PREVENT PREGNANCY?

Kyleena® prevents pregnancy most likely by:

- Thickening cervical mucus, preventing sperm from entering the uterus
- Inhibiting sperm from reaching and fertilizing the egg
- Thinning the uterine lining

It is not known exactly how these actions work together to prevent pregnancy.



Common side effects include:

- **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.

If you experience any of these side effects or want more information, talk to your healthcare professional.



DID YOU KNOW?

Kyleena® is reversible any time in case your plans change. Once your healthcare professional removes Kyleena, you can try to get pregnant right away.

Other common side effects include:

- **Changes in bleeding.** You may have bleeding and spotting between menstrual periods, especially during the first 3–6 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 professional if the bleeding remains heavier than usual or increases after it has been light for a while.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23 and the full Prescribing Information here.

Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5 mg

WHAT TO EXPECT WHEN GETTING KYLEENA

- Kyleena® is inserted in the uterus by your healthcare professional
- Kyleena is a non-surgical procedure and can be placed by your healthcare professional during an in-office visit or immediately after giving birth
- After 4–6 weeks, you should return for a follow-up
- After placement, your healthcare professional will show you how to perform a monthly thread check to ensure Kyleena is still in your uterus
- If you can't locate the threads, contact your healthcare professional. Your IUD 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 professional to check that Kyleena is still in the right place.

WHAT TO EXPECT DURING PLACEMENT

- Common side effects experienced by women are pain, bleeding, or dizziness during or after placement
- If your symptoms do not pass within 30 minutes after placement, Kyleena may not have been placed correctly
- Your healthcare professional will examine you to see if Kyleena needs to be removed or replaced

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

Other common side effects include:

- **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.

If you experience any of these side effects or want more information, talk to your healthcare professional.

HOW KYLEENA MAY AFFECT YOUR PERIOD

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 periods should return. Call your healthcare professional right away if you think you may be pregnant. If possible, also do a urine pregnancy test.

DID YOU KNOW?

You can still use tampons or menstrual cups while using Kyleena.

Some serious risk considerations about Kyleena

- Although pregnancy while using Kyleena is uncommon (less than 1 in 100), it can be serious. Call your healthcare professional 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.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23 and the full Prescribing Information here.

Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5mg



Because Kyleena is in your uterus, not your vagina:

- You shouldn't be able to feel it
- You and your partner should not feel Kyleena® during intercourse. Sometimes your partner may feel the threads. If this occurs, or if you or your partner experiences pain during sex, talk with your healthcare professional.

Some serious risk considerations about Kyleena

- 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 professional may try to remove Kyleena, even though removing it may cause a miscarriage. If Kyleena cannot be removed, talk with your healthcare professional 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 professional regularly. Call your healthcare professional 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.

CHECK IF KYLEENA IS COVERED BY YOUR INSURANCE

1. Call the phone number on the back of your insurance card.
2. Tell them that Kyleena® is a healthcare professional-administered method of birth control.
3. Ask them to check if Kyleena is covered at no cost* under the Affordable Care Act.
4. Provide them with the J code for Kyleena: J7296.
5. Ask if you will have any out-of-pocket costs, if Kyleena is only partially covered under your plan.

*Please note: Other product-related costs may apply.

If you need help understanding your insurance coverage, visit **CoverHer.org**.

DID YOU KNOW?

You may be able to get Kyleena with no out-of-pocket cost. Call your insurance company.

Other serious risk considerations about 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.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23 and the full Prescribing Information here.

Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5mg



Other serious risk considerations about Kyleena®

- **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 professional 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.

NO INSURANCE? BAYER MAY BE ABLE TO HELP

The Bayer US Patient Assistance Foundation is a charitable organization that helps eligible patients get Bayer prescription medicine at no cost.

Please contact the program at 1-866-2BUSPAF (228-7723) Monday–Friday, 9:00 AM–6:00 PM ET, or visit the foundation website at **patientassistance.bayer.us** for information. Apply online and see if you may qualify for assistance.

Learn more at **kyleena.com** or call **1-844-MY-KYLEENA**.



Other serious risk considerations about Kyleena®

- **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.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23 and the full Prescribing Information here.

Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5 mg





If you're a new mom considering Kyleena®:

- You can breastfeed while using Kyleena, but be sure to discuss it with your healthcare professional first.
- Kyleena can be placed by your healthcare professional during an office visit or immediately after giving birth.
- 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.

Also consider this:

- The risk of Kyleena going into the wall of the uterus (becoming embedded) or going through the wall of the uterus is increased when Kyleena is placed in breastfeeding women.

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

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23 and the full Prescribing Information here.

Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5 mg

HOW TO KNOW IF KYLEENA IS RIGHT FOR YOU

I'm looking for birth control that:

- ☐ Is highly effective
- ☐ Is low in hormones
- ☐ Is reversible if my plans change
- ☐ I can use while breastfeeding
- ☐ Is helpful in planning the time in between my pregnancies

If you checked any of the boxes above, ask your healthcare professional about Kyleena® today. Only you and your healthcare professional can decide if Kyleena is right for you.

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

- have had a serious pelvic infection 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 a 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

You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Bayer Healthcare Pharmaceuticals at 1-888-842-2937.

I HAVE HEAVY PERIODS, WHAT CAN I DO?

If you are considering using an IUD for birth control, but also struggle with heavy periods, consider Mirena® (levonorgestrel-releasing intrauterine system) 52 mg. Mirena is a hormone-releasing IUD that prevents pregnancy for up to 7 years. Mirena is the first and only IUD that is FDA-approved to treat heavy periods, also known as heavy menstrual bleeding (HMB), for up to 5 years, in women who choose intrauterine contraception.

What is HMB?

HMB is excessive menstrual blood loss (≥ 80 mL, or about 6 tablespoons) during a single cycle. You may have HMB if you:

- Need to double up on pads to control your menstrual flow
- Have menstrual periods lasting more than 7 days
- Need to change pads or tampons during the night

Many symptoms can indicate HMB, so talk to your healthcare professional (HCP).

WITH MIRENA, YOUR HEAVY PERIODS MAY CHANGE

Mirena rapidly reduces heavy periods. In a clinical trial of Mirena in women with heavy periods, the majority experienced:



Mirena may also affect heavy periods in other ways.

The number of spotting and bleeding days may initially increase but then typically decrease in the months that follow. Bleeding may also continue to be irregular.

Call your healthcare professional if bleeding remains heavier than usual or you do not have a period for 6 weeks during Mirena use. If you have any concerns that you may be pregnant while using Mirena, do a urine pregnancy test and call your HCP.

After your body adjusts, the number of bleeding and spotting days is likely to decrease, but may remain irregular, and you may even find that your periods stop altogether for as long as Mirena is in place. By the end of year one, about 20% of users have no period at all. Your periods will return once Mirena is removed.

WHICH IUD FOR BIRTH CONTROL IS RIGHT FOR ME?

I want a 5-year IUD with the lowest dose of hormones

Ask your HCP about **Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg**, a hormone-releasing IUD that prevents pregnancy for up to 5 years.

I want an IUD that will also help with my heavy periods

Ask your HCP about **Mirena® (levonorgestrel-releasing intrauterine system) 52 mg**, a hormone-releasing IUD that prevents pregnancy for up to 7 years. Mirena also treats heavy periods for up to 5 years in women who choose intrauterine contraception.

Learn more at **Mirena.com**

Mirena and Kyleena Important Safety Information

- If you have an untreated genital infection, get infections easily, or have certain cancers, don't use Mirena or 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 professional (HCP). If Mirena or Kyleena comes out, call your HCP and avoid intercourse or use non-hormonal back-up birth control (such as condoms or spermicide). Mirena or Kyleena may go into or go through the wall of the uterus and cause other problems.
- Pregnancy while using Mirena or 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.

Mirena and Kyleena do not protect against HIV or STIs.

Only you and your HCP can decide if Mirena or Kyleena is right for you. Mirena and Kyleena are available by prescription only. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23 and the full Prescribing Information here.

IMPORTANT FACTS ABOUT KYLEENA® (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 19.5 MG AND MIRENA® (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 52 MG

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

This information does not take the place of talking with your gynecologist or other healthcare provider (HCP) who specializes in women's health. If you have any questions about Kyleena or Mirena, ask your HCP.

INDICATION FOR KYLEENA

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

INDICATIONS FOR MIRENA

Mirena is a hormone-releasing IUD that prevents pregnancy for up to 7 years. Mirena also treats heavy periods for up to 5 years in women who choose intrauterine contraception.

Who might use Kyleena or Mirena?

You might choose Kyleena or Mirena if you:

- want long-term birth control that provides a low chance of getting pregnant (less than 1 in 100)
- want birth control that works continuously for up to 5 years for Kyleena, or 7 years for Mirena
- want birth control that is reversible
- want a birth control method that you do not need to take daily
- are willing to use a birth control method that is placed in the uterus
- want birth control that does not contain estrogen

Do not use Kyleena or Mirena if you:

- are or might be pregnant; Kyleena or Mirena 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 a serious pelvic infection 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 a 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 these ingredients:
  - do not use Kyleena if you're allergic to levonorgestrel, silicone, polyethylene, silver, silica, barium sulfate, polypropylene, or copper phthalocyanine
  - do not use Mirena if you're allergic to levonorgestrel, silicone, polyethylene, silica, barium sulfate, or iron oxide

Before having Kyleena or Mirena placed, tell your HCP about all of your medical conditions including if you:

- have any of the conditions listed above
- have had a heart attack
- have had a stroke

- were born with heart disease or have problems with your heart valves
- have problems with blood clotting or take medicine to reduce clotting
- have high blood pressure
- recently had a baby or are breastfeeding
- have severe headaches or migraine headaches
- have AIDS, HIV, or any other sexually transmitted infection

Tell your HCP about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Should I check that Kyleena or Mirena is in place?
Yes, you should check that Kyleena or Mirena is in proper position by feeling the removal threads. It is a good habit to do this 1 time a month. If you feel more than just the threads or if you cannot feel the threads, be sure to call your HCP and avoid intercourse or use non-hormonal back-up birth control, as Kyleena or Mirena may not be in the right position and may not prevent pregnancy.

How soon after placement should I return to my HCP?
Call your HCP if you have questions or concerns (see "After placement, when should I call my HCP?"). Otherwise, return for a follow-up 4-6 weeks after placement to make sure Kyleena or Mirena is in the right position.

Can I use tampons or menstrual cups with Kyleena or Mirena?
Yes, tampons or menstrual cups may be used with Kyleena or Mirena. Change tampons or menstrual cups with care to avoid pulling the threads of Kyleena or Mirena. If you think you may have pulled Kyleena or Mirena out of place, avoid intercourse or use a non-hormonal back-up birth control (such as condoms or spermicide), and contact your healthcare professional.

What if I become pregnant while using Kyleena or Mirena?
Call your HCP right away if you think you may be pregnant. If possible, also do a urine pregnancy test. If you get pregnant while using Kyleena or Mirena, you may have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain, especially with missed periods 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 or Mirena 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 HCP may try to remove Kyleena or Mirena, even though removing it may cause a miscarriage. If Kyleena or Mirena cannot be removed, talk with your HCP 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 HCP regularly. Call your HCP 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.

How will Kyleena or Mirena 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 or Mirena for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether. When Kyleena or Mirena is removed, your menstrual periods should return.

In some women with heavy bleeding who are using Mirena, the total blood loss per cycle progressively decreases with continued use. The number of spotting and bleeding days may initially increase but then typically decreases in the months that follow.

Important Facts continued on next page.

IMPORTANT FACTS ABOUT KYLEENA® (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 19.5 MG AND MIRENA® (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 52 MG (CONT.)

Is it safe to breastfeed while using Kyleena or Mirena?

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

Will Kyleena or Mirena interfere with sexual intercourse?

You and your partner should not feel Kyleena or Mirena during intercourse. Kyleena or Mirena 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 HCP.

Can I have an MRI with Kyleena in place?

Kyleena can be safely scanned with MRI under specific conditions. Before you have an MRI, tell your HCP that you have a Kyleena in place.

What are the possible serious side effects of Kyleena or Mirena?

- **Ectopic pregnancy and intrauterine pregnancy risks.** There are risks if you become pregnant while using Kyleena or Mirena (see "What if I become pregnant while using Kyleena or Mirena?").
- **Life-threatening infection.** Life-threatening infection can occur within the first few days after placement. Call your HCP immediately if you develop severe pain or fever shortly after placement.
- **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 HCP 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 or Mirena 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 or Mirena may no longer prevent pregnancy. If perforation occurs, Kyleena or Mirena may move outside the uterus and can cause internal scarring, infection, or damage to other organs and you may need surgery to have Kyleena or Mirena removed. Excessive pain or vaginal bleeding during placement of Kyleena or Mirena, 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 or Mirena is inserted while you are breastfeeding, or if you have recently given birth.
- **Expulsion.** Kyleena or Mirena 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 or Mirena, 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 or Mirena comes out. If you think that Kyleena or Mirena has come out, avoid intercourse or use a non-hormonal back-up birth control (such as condoms or spermicide) and call your healthcare professional. The risk of expulsion is increased with insertion right after delivery or second-trimester abortion.

Common side effects of Kyleena or Mirena include:

- **Pain, bleeding or dizziness during and after placement.** If these symptoms do not stop 30 minutes after placement, Kyleena or Mirena may not have been placed correctly. Your HCP will examine you to see if Kyleena or Mirena needs to be removed or replaced.
- **Changes in bleeding.** You may have bleeding and spotting between menstrual periods, especially during the first 3-6 months. Sometimes the bleeding is heavier than usual at first. However, the bleeding usually becomes lighter than usual and may be irregular. Call your HCP 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. About 2 out of 10 women stop having periods after 1 year of Mirena use. If you have any concerns that you may be pregnant while using Kyleena or Mirena, do a urine pregnancy test and call your HCP. Your periods may stop after 1 year of Kyleena or Mirena use. If you do not have a period for 6 weeks during Kyleena or Mirena use, call your HCP. When Kyleena or Mirena is removed, your menstrual periods should return.
- **Cysts on the ovary.** Some women develop painful cysts on the ovary. These cysts usually disappear on their own in 2-3 months. However, cysts can cause pain and sometimes cysts will need surgery.

Other common side effects for Kyleena include:

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

Other common side effects for Mirena include:

- abdominal or pelvic pain
- inflammation or infection of the outer part of your vagina (vulvovaginitis)
- headache or migraine
- vaginal discharge

These are not all of the possible side effects with Kyleena or Mirena. For more information, ask your HCP. Tell your HCP if you have any side effect that bothers you or does not go away.

Call your HCP for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Bayer Healthcare Pharmaceuticals at 1-888-842-2937, or **www.fda.gov/medwatch**.

After placement, when should I call my HCP?

If Kyleena or Mirena is accidentally removed and you had vaginal intercourse within the preceding week, you may be at risk of pregnancy, and you should talk to a HCP. Call your HCP if you have any concerns about Kyleena or Mirena. Be sure to call if you:

- think you are pregnant
- have pelvic pain, abdominal pain, or pain during sex
- have unusual vaginal discharge or genital sores
- have unexplained fever, flu-like symptoms or chills
- might be exposed to sexually transmitted infections (STIs)
- are concerned that Kyleena or Mirena may have been expelled (came out)
- cannot feel Kyleena's or Mirena's threads
- develop very severe or migraine headaches
- have yellowing of the skin or whites of the eyes. These may be signs of liver problems
- have had a stroke or heart attack
- become HIV positive or your partner becomes HIV positive
- have severe vaginal bleeding, bleeding that lasts a long time or concerns you

To learn more, talk about Kyleena or Mirena with your HCP and see the FDA-approved Full Prescribing Information found on www.kyleena.com and www.mirena.com, or call 1-866-647-3646.

Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5 mg



Scan the QR code with your phone's camera to visit Kyleena.com

If you have any questions about Kyleena® 19.5 mg or Mirena® (levonorgestrel-releasing intrauterine system) 52 mg, you should ask your healthcare professional. You should also learn about other birth control methods, and choose the one that is right for you.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23 and the full Prescribing Information here.

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