

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

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



## Looking for birth control that helps with heavy periods?

Get to know Mirena<sup>®</sup> — the only IUD that is FDA-approved to treat heavy menstrual bleeding (HMB) for up to 5 years in women who choose an IUD for birth control.

Learn more at [Mirena.com](https://www.Mirena.com)



Scan the QR code with your phone's camera to visit [Mirena.com](https://www.Mirena.com)

If you have any questions about Mirena<sup>®</sup> 52 mg or Kyleena<sup>®</sup> (levonorgestrel-releasing intrauterine system) 19.5 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.



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Mirena<sup>®</sup> is a hormone-releasing IUD (intrauterine device) that prevents pregnancy for up to 7 years. Mirena also treats heavy periods for up to 5 years in women who choose intrauterine contraception.

# Effective birth control that helps with heavy periods

Choosing birth control is personal, and for women who want to prevent pregnancy and get help with heavy periods, it's important to know there are options that can do both. If you're considering an IUD but also struggle with heavy periods, get to know Mirena®:

- Over 99% effective at preventing pregnancy for up to 7 years
- The first and only hormone-releasing 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 an IUD for birth control
- 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?

Mirena is the #1 prescribed IUD in the U.S.\*

## IMPORTANT SAFETY INFORMATION

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

\*Supported by 2017–2019 SHS data.

For additional Important Safety information, please see throughout brochure. Please see Important Facts on pages 20–23.

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

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For more information, visit [Mirena.com](http://Mirena.com).

Patient: Murphy, Ashley Blythe, DOB: 5/25/1988

# A closer look at Mirena

- Small and T-shaped
- Made of soft, flexible plastic
- Placed in your uterus by a healthcare professional who can remove it at any time

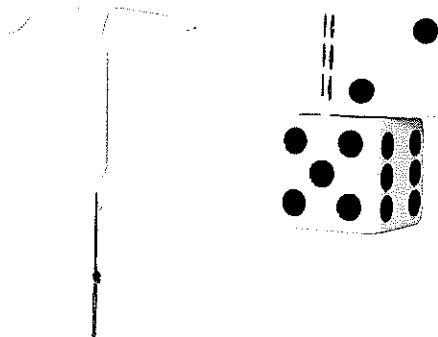
## IMPORTANT SAFETY INFORMATION

- Pregnancy while using Mirena® 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?

Mirena is 1.26" — about the same height as a set of stacked dice.

Actual size

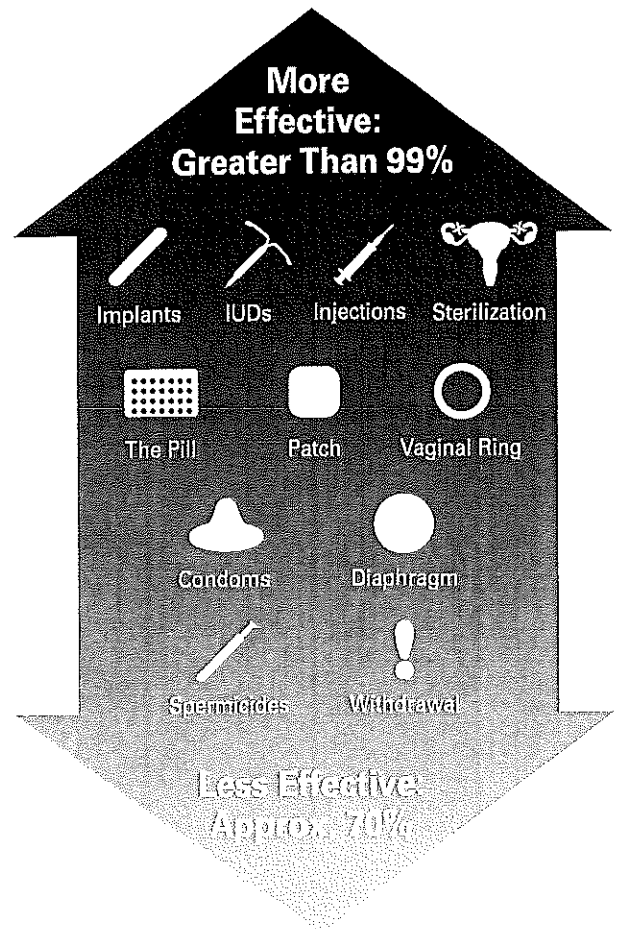


For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23.

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

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For more information, visit [Mirena.com](http://Mirena.com).



## DID YOU KNOW?

IUDs are considered one of the most effective forms of birth control by the American College of Obstetricians and Gynecologists (ACOG).

## 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.

*Mirena® does not protect against HIV or STIs.*

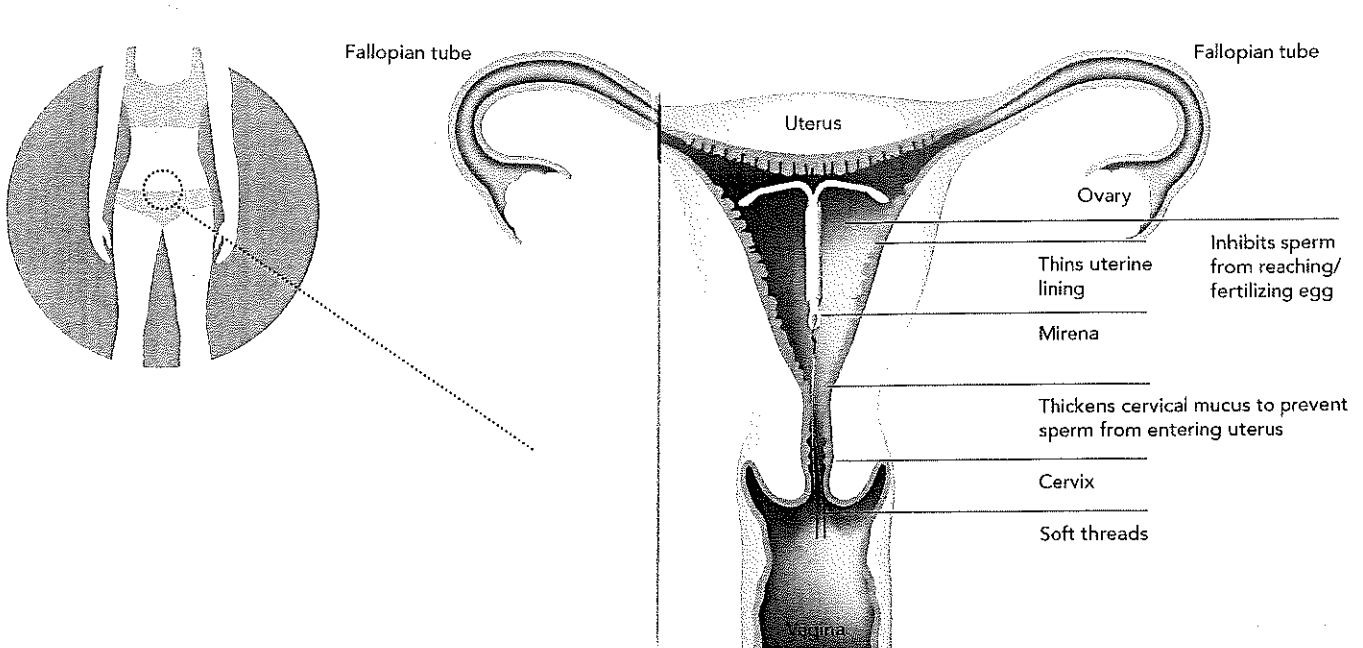
Only you and your HCP can decide if Mirena is right for you. Mirena is available by prescription only.

**You are encouraged to report negative side effects of prescription drugs to the FDA.**

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. 5

## Mirena works in the uterus

- Mirena® is placed in the uterus by a healthcare professional
- It works by giving you a continuous dose of a hormone called progestin
- Because Mirena releases hormones locally in the uterus at a slow rate, only small amounts enter the bloodstream



### Common side effects include:

- **Pain, bleeding or dizziness during and after placement.** If these symptoms do not stop 30 minutes after placement, Mirena may not have been placed correctly. Your healthcare professional will examine you to see if Mirena needs to be removed or replaced.

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For more information, visit [Mirena.com](http://Mirena.com).

## How does Mirena prevent pregnancy?

Mirena prevents pregnancy most likely by:

- Thickening the mucus in the cervix, 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:

- **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 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.

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# What is Heavy Menstrual Bleeding (HMB)?

Heavy menstrual bleeding, also known as HMB, is excessive menstrual blood loss ( $\geq 80$  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

If you have any of these symptoms, talk to your healthcare professional.



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For more information, visit [Mirena.com](http://Mirena.com).

# 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:

80%  
reduction  
in bleeding

after 3 months

>90%  
reduction  
in bleeding

after 6 months

## 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.

### Other common side effects include:

- **Missed menstrual periods.** 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 Mirena, do a urine pregnancy test and call your healthcare professional. If you do not have a period for 6 weeks during Mirena use, call your healthcare professional. When Mirena is removed, your menstrual periods should return.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23.

 **Mirena**<sup>®</sup>  
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## What to expect when getting Mirena

- Mirena® is inserted in the uterus by your healthcare professional
- Mirena is a non-surgical procedure and can be placed during an in-office visit or immediately after giving birth
- After 4–6 weeks, you should return for a follow-up visit
- After placement, your healthcare professional will show you how to perform a monthly thread check to ensure Mirena 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 Mirena is still in the right place.

### DID YOU KNOW?

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

#### Other common side effects include:

- **Cysts on the ovary.** Some women using Mirena develop a painful cyst on the ovary. These cysts usually disappear on their own in 2 to 3 months. However, cysts can cause pain and sometimes cysts will need surgery.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23.

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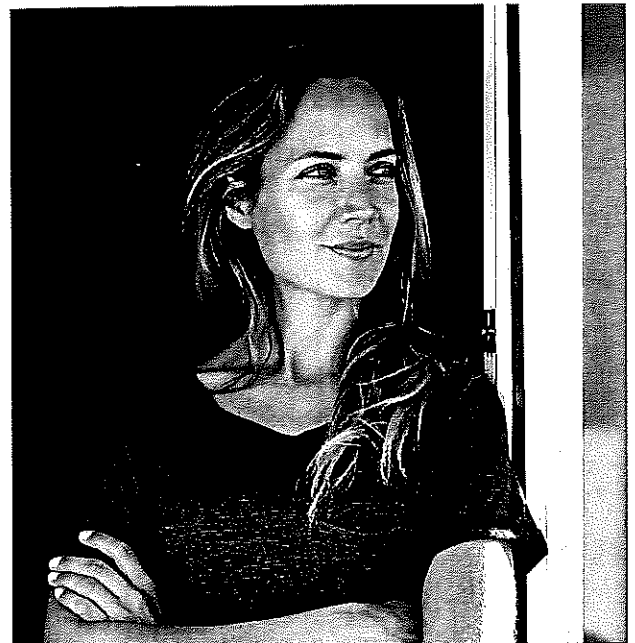
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For more information, visit [Mirena.com](http://Mirena.com).

## 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, Mirena may not have been placed correctly
- Your healthcare professional will examine you to see if Mirena 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 to help minimize any discomfort.



#### Other common side effects 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 Mirena. For more information, ask your healthcare professional.

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# How Mirena 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, and some women have heavy bleeding during this time. You may also have cramping during the first few weeks. Call your healthcare professional (HCP) if the bleeding remains heavier than usual or increases after it has been light for a while.



After you have used Mirena for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether. When Mirena is removed, your menstrual periods should return. This is because the hormone in Mirena reduces the monthly thickening of your uterine lining.



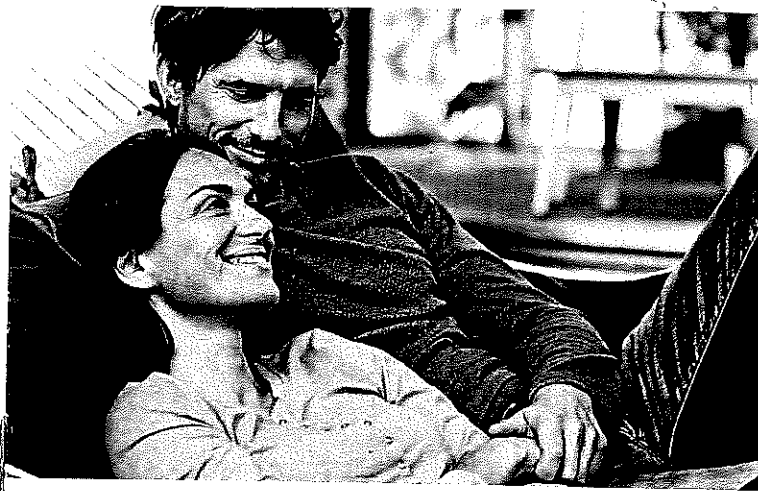
By the end of year one, about 20% of users have no period at all. If you have any concerns that you may be pregnant while using Mirena, do a urine pregnancy test and call your HCP. If you do not have a period for 6 weeks during Mirena use, call your HCP. Your periods will return once Mirena is removed.

In some women with heavy bleeding, 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.

## Some serious risk considerations about Mirena

- Call your healthcare professional right away if you think you may be pregnant. If possible, also do a urine pregnancy test. If you get pregnant while using 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.

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## DID YOU KNOW?

You can still use tampons or menstrual cups while using Mirena®.

## Because Mirena is in your uterus, not your vagina:

- You and your partner should not feel Mirena during sex
- 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 Mirena

- There are also risks if you get pregnant while using 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 healthcare professional may try to remove Mirena, even though removing it may cause a miscarriage. If Mirena 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.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20-23.

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For more information, visit [Mirena.com](http://Mirena.com).

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## Check if Mirena is covered by your insurance

1. Call the number on the back of your insurance card and tell them that Mirena® is a healthcare professional-administered method of birth control.
2. Ask them to check if Mirena is covered at no cost.
3. Provide them with the J code for Mirena: J7298; and the Current Procedural Terminology (CPT) code for Mirena placement: 58300.
4. Ask if you will have any out-of-pocket costs if Mirena is only partially covered under your plan.

If you need help understanding your insurance coverage, visit [CoverHer.org](http://CoverHer.org).

### DID YOU KNOW?

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

#### Other serious risk considerations about Mirena

- **Ectopic pregnancy and intrauterine pregnancy risks.** There are risks if you become pregnant while using Mirena (see "What if I become pregnant while using Mirena?") on page 21.
- **Life-threatening infection.** Life-threatening infection can occur within the first few days after Mirena is placed. Call your healthcare professional immediately if you develop severe pain or fever shortly after Mirena 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 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, 8:30 AM–5:00 PM ET, or visit the foundation website at [patientassistance.bayer.us](http://patientassistance.bayer.us) for information. Apply online and see if you may qualify for assistance.

### LEARN MORE

at [Mirena.com](http://Mirena.com) or call 1-866-647-3646

#### Other serious risk considerations about Mirena

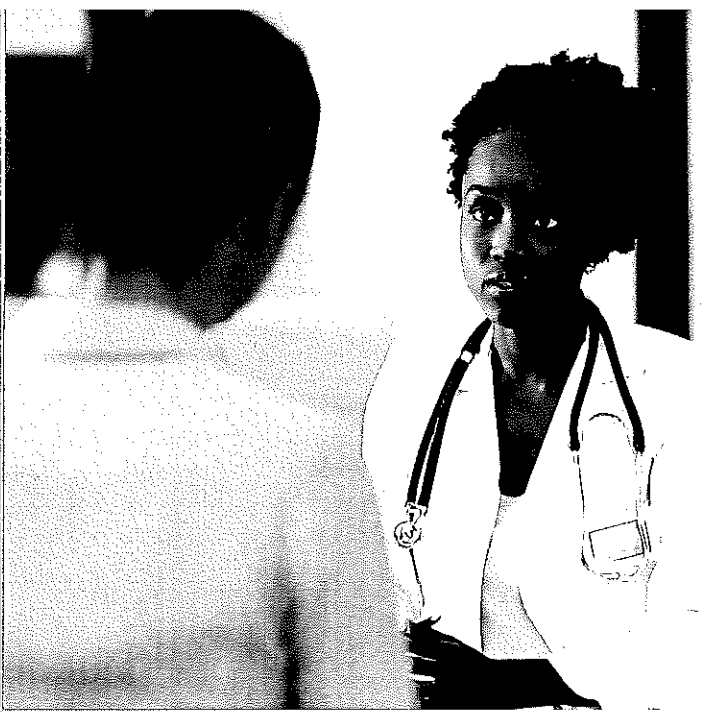
- **Perforation.** Mirena may go into the wall of the uterus (become embedded) or go through the wall of the uterus. This is called perforation. If this occurs, Mirena may no longer prevent pregnancy. If perforation occurs, Mirena may move outside the uterus and can cause internal scarring, infection, or damage to other organs and you may need surgery to have Mirena removed. Excessive pain or vaginal bleeding during placement of 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 Mirena is inserted while you are breastfeeding, or if you have recently given birth.
- **Expulsion.** 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 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 Mirena comes out. If you think that 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.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23.

 **Mirena®**  
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intrauterine system) 52 mg

For more information, visit [Mirena.com](http://Mirena.com).





## Is Mirena right for me?

### I'm looking for birth control that:

- Is highly effective
- Helps alleviate my heavy periods
- Is reversible if my plans for my family change
- I can use while breastfeeding
- Is helpful in planning the time in between my pregnancies

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

### If you're a new mom considering Mirena®:

- You may use Mirena when you are breastfeeding.
- 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.

### Also consider this:

- The risk of Mirena going into the wall of the uterus (become embedded) or going through the wall of the uterus (called perforation) is increased when Mirena is placed in breastfeeding women.

### Mirena is not right for everyone. Do not use Mirena if you:

- are or might be pregnant; 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

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23.

 **Mirena**<sup>®</sup>  
(levonorgestrel-releasing  
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For more information, visit [Mirena.com](http://Mirena.com).

### Mirena is not right for everyone. Do not use Mirena 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, silica, barium sulfate, or iron oxide

**You are encouraged to report negative side effects of prescription drugs to the FDA.**  
Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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Patient: Murphy, Ashley Blythe, DOB: 5/25/1988

## Looking for birth control, but don't have HMB?

Meet Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg — the smallest, lowest-hormone 5-year IUD approved to prevent pregnancy:

- Over 99% effective at preventing pregnancy for each year of use, and 98.6% effective over 5 years
- The lowest hormone-dose available in a 5-year IUD
- 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

### Kyleena and Mirena Important Safety Information

- If you have an untreated genital infection, get infections easily, or have certain cancers, don't use Kyleena or Mirena. Less than 1% of users get a serious pelvic infection called pelvic inflammatory disease (PID).



For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 20–23.

## Which IUD birth control is right for me?

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

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

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.

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

### Kyleena and Mirena Important Safety Information

- If you have persistent pelvic or stomach pain, or excessive bleeding after placement, tell your healthcare professional (HCP). If Kyleena or Mirena comes out, call your HCP and avoid intercourse or use non-hormonal back-up birth control (such as condoms or spermicide). Kyleena or Mirena may go into or through the wall of the uterus and cause other problems.
- Pregnancy while using Kyleena or Mirena 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.

*Kyleena or Mirena do not protect against HIV or STIs.*

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

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

**Mirena and Kyleena 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 professional (HCP) who specializes in women's health. If you have any questions about Mirena or Kyleena, ask your HCP.

**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.

**INDICATION FOR KYLEENA**

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

**Who might use Mirena or Kyleena?**

You might choose Mirena or Kyleena 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 7 years for Mirena, or 5 years for Kyleena
- 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 Mirena or Kyleena if you:**

- are or might be pregnant; Mirena or 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 a serious pelvic infection in the past 3 months after a pregnancy
- can get infections easily. For example, if you:
  - 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 Mirena if you're allergic to levonorgestrel, silicone, polyethylene, silica, barium sulfate, or iron oxide
  - do not use Kyleena if you're allergic to levonorgestrel, silicone, polyethylene, silver, silica, barium sulfate, polypropylene, or copper phthalocyanine

**Before having Mirena or Kyleena 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 Mirena or Kyleena is in place?**

Yes, you should check that Mirena or Kyleena 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 Mirena or Kyleena 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 Mirena or Kyleena is in the right position.

**Can I use tampons or menstrual cups with Mirena or Kyleena?**

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

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 Mirena or Kyleena, 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 Mirena or 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 HCP may try to remove Mirena or Kyleena, even though removing it may cause a miscarriage. If Mirena or Kyleena 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 Mirena or 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, and some women have heavy bleeding during this time. You may also have cramping during the first few weeks. After you have used Mirena or Kyleena for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether. When Mirena or Kyleena 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 MIRENA® (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 52 MG AND KYLEENA® (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 19.5 MG (CONT.)**

**Is it safe to breastfeed while using Mirena or Kyleena?**

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

**Will Mirena or Kyleena interfere with sexual intercourse?**

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

**Can I have an MRI with Kyleena in place?**

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

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

- **Ectopic pregnancy and intrauterine pregnancy risks.** There are risks if you become pregnant while using Mirena or Kyleena (see "What if I become pregnant while using Mirena or Kyleena?").
- **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.** Mirena or 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, Mirena or Kyleena may no longer prevent pregnancy. If perforation occurs, Mirena or Kyleena may move outside the uterus and can cause internal scarring, infection, or damage to other organs and you may need surgery to have Mirena or Kyleena removed. Excessive pain or vaginal bleeding during placement of Mirena or 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 Mirena or Kyleena is inserted while you are breastfeeding, or if you have recently given birth.
- **Expulsion.** Mirena or 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 Mirena or 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 Mirena or Kyleena comes out. If you think that Mirena or Kyleena 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 Mirena or Kyleena include:**

- **Pain, bleeding or dizziness during and after placement.** If these symptoms do not stop 30 minutes after placement, Mirena or Kyleena may not have been placed correctly. Your HCP will examine you to see if Mirena or Kyleena 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 2 out of 10 women stop having periods after 1 year of Mirena use. 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 Mirena or Kyleena, do a urine pregnancy test and call your HCP. Your periods may stop after 1 year of Mirena or Kyleena use. If you do not have a period for 6 weeks during Mirena or Kyleena use, call your HCP. When Mirena or Kyleena 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 Mirena include:

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

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

These are not all of the possible side effects with Mirena or Kyleena. 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](http://www.fda.gov/medwatch).

**After placement, when should I call my HCP?**

If Mirena or Kyleena 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 Mirena or Kyleena. 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 Mirena or Kyleena may have been expelled (came out)
- cannot feel Mirena's or Kyleena'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 Mirena or Kyleena with your HCP and see the FDA-approved Full Prescribing Information found on [www.mirena.com](http://www.mirena.com) or [www.kyleena.com](http://www.kyleena.com), or call 1-866-647-3646.