

THINKING ABOUT BIRTH CONTROL OPTIONS?

Consider a Mirena® IUD



A Mirena IUD is over 99% effective at preventing pregnancy

Mirena is a hormone-releasing IUD that prevents pregnancy for up to 8 years. Mirena also treats heavy periods for up to 5 years in women who choose intrauterine contraception.

Rx only. IUD=Intrauterine Device.



BIRTH CONTROL WITH YOU IN MIND

The choice to go on birth control is personal. If you're considering an IUD, get to know Mirena®:

- Over 99% effective at preventing pregnancy
- Lasts up to 8 years
- Can be used whether or not you've had a baby
- Reversible by your healthcare provider at any time, in case plans change, and you can try to get pregnant right away*
- *About 8 out of 10 women who use Mirena and want to become pregnant usually can become pregnant in the first year after Mirena is removed.

For women who want to prevent pregnancy and have heavy menstrual bleeding (HMB), it's important to know that Mirena is also FDA approved to treat heavy bleeding for up to 5 years in women who choose an IUD for birth control.

Mirena is the #1 prescribed IUD[†]

[†]Supported by 2021-2024 SHS data.

IMPORTANT SAFETY INFORMATION

- If you have an untreated pelvic or 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 provider (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.

For additional Important Safety Information, please see throughout brochure.

Please see Important Facts on pages 16-19 and the full Prescribing Information here.



A CLOSER LOOK AT MIRENA®

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

Not actual size.
Actual size
1.26"

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

More effective: Greater than 99%



Less effective: Approx 70%

IMPORTANT SAFETY INFORMATION (cont'd)

- 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.
- 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.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 16-19 and the full Prescribing Information here.



IMPORTANT SAFETY INFORMATION (cont'd)

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.

For important risk and use information about Mirena, please see **Full Prescribing Information**.

You are encouraged to report side effects or quality complaints of products to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088. For Bayer products, you can report these directly to Bayer by clicking here.

MIRENA® WORKS IN THE UTERUS

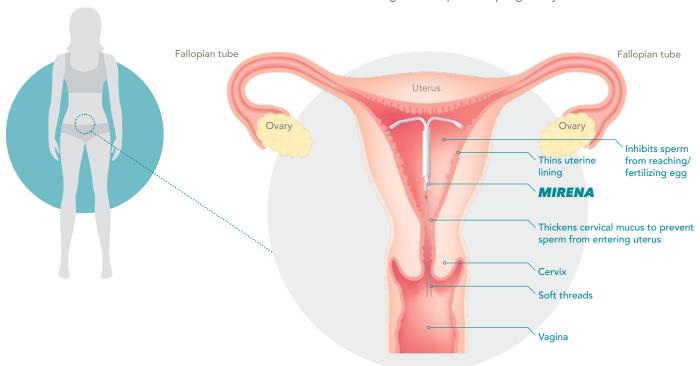
- Mirena is placed in the uterus by a healthcare provider
- It works by giving you a continuous dose of a hormone called progestin
- Because Mirena releases hormones locally in the uterus at a slow rate, only small amounts enter the bloodstream

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:

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 provider will examine you to see if Mirena needs to be removed or replaced.

For additional Important Safety Information, please see throughout brochure.

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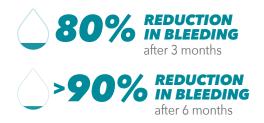
Common side effects include:

 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 provider if the bleeding remains heavier than usual or increases after it has been light for a while.

MIRENA® AND HEAVY MENSTRUAL BLEEDING

Heavy Periods

For women who want to prevent pregnancy and have heavy menstrual bleeding (HMB), it's important to know that Mirena is also FDA approved to treat heavy bleeding for up to 5 years in women who choose an IUD for birth control. HMB is excessive menstrual blood loss (≥80 mL, or about 6 tablespoons) during a single cycle. Mirena rapidly reduces heavy periods. In a clinical trial of Mirena in women with heavy periods, the majority experienced:



Talk to your doctor if you think you may have heavy periods or HMB.

Mirena may also affect 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 provider 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 provider. If you do not have a period for 6 weeks during Mirena use, call your healthcare provider. When Mirena is removed, your menstrual periods should return.

Some serious risk considerations about Mirena

Call your healthcare provider 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.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 16-19 and the full Prescribing Information here.



THINGS TO CONSIDER WITH MIRENA



Low maintenance

Mirena is a pill-free birth control that doesn't require a daily routine.*

*You will have to check for the thread

Business as usual

During your period, you can still use tampons or menstrual cups.

Sex with Mirena

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 provider.

Some serious risk considerations about Mirena

- 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 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 Mirena, even though removing it may cause a miscarriage. If Mirena 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.



WHAT TO EXPECT WHEN GETTING MIRENA®

- Mirena is inserted in the uterus by your healthcare provider
- Mirena is a non-surgical procedure and can be placed during an in-office visit or immediately after giving birth
- After 4 to 6 weeks, you should return for a follow-up visit
- After placement, your healthcare provider 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 provider. Your IUD may not be in the right position and may not prevent pregnancy. Avoid intercourse or use nonhormonal back-up birth control (such as condoms or spermicide) and ask your healthcare provider to check that Mirena 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, Mirena may not have been placed correctly
- Your healthcare provider will examine you to see if Mirena needs to be removed or replaced

Have an open and honest conversation with your provider if pain is a concern for you.

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 16-19 and the full Prescribing Information here.



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 provider.

CONCERNED ABOUT COSTS?

There are options to support you. A Mirena® IUD may be covered under your current plan. You can check with your insurance company to see what your coverage looks like.

Provide your insurance company with the J code for Mirena: J7298; and the Current Procedural Terminology (CPT) code for Mirena placement: 58300.

coverage, visit CoverHer.org.



ENROLL IN THE CO-PAY SAVINGS PROGRAM FOR **MIRENA®**

You may be able to get Mirena for little to no out-of-pocket costs. Ask your provider for guidance on applying to our Co-Pay Savings Program.

Eligible patients may be able to pay

as little **\$20** OUT OF POCKET as **\$70** FOR MIRENA.*

LEARN MORE

*Does not include other out-of-pocket costs such as patient visits. For full terms and conditions please visit <u>copayformirena.com</u>.

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 17.
- **Life-threatening infection.** Life-threatening infection can occur within the first few days after Mirena is placed. Call your healthcare provider 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 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.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 16-19



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 backup 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.

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

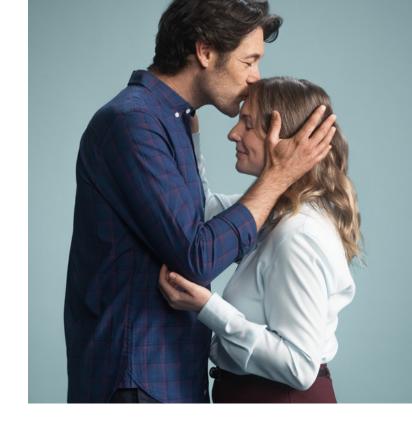
Only you and your healthcare provider can decide if Mirena is right for you. If you checked any of the boxes above, ask your healthcare provider about Mirena today.

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

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
- 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



Also consider this:

• The risk of Mirena going into the wall of the uterus (becoming 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:

- 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 or call 1-800-FDA-1088.

For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 16-19 and the full Prescribing Information here.



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

Mirena does 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 who specializes in women's health. If you have any questions about Mirena, ask your healthcare provider.

INDICATIONS FOR MIRENA

Mirena is a hormone-releasing IUD that prevents pregnancy for up to 8 years. Mirena also treats heavy periods for up to 5 years in women who choose intrauterine contraception.

Who might use Mirena?

You might choose 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 8 years
- 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 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
- 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

Before having Mirena placed, tell your healthcare provider 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 healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Should I check that Mirena is in place?

Yes, you should check that 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 healthcare provider and avoid intercourse or use non-hormonal back-up birth control, as Mirena may not be in the right position and may not prevent pregnancy.

How soon after placement should I return to my healthcare provider?

Call your healthcare provider if you have questions or concerns (see "After placement, when should I call my healthcare provider?" on page 19). Otherwise, return for a follow-up 4 to 6 weeks after placement to make sure Mirena is in the right position.

Can I use tampons or menstrual cups with Mirena?

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

What if I become pregnant while using Mirena?

Call your healthcare provider 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.

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 provider may try to remove Mirena, even though removing it may cause a miscarriage. If Mirena 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.

How will 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, and some women have heavy bleeding during this time. You may also have cramping during the first few weeks. 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.

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 ABOUT MIRENA® (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 52 MG (Cont'd)

Is it safe to breastfeed while using 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. The risk of Mirena going into the wall of the uterus (becoming embedded) or going through the wall of the uterus is increased if Mirena is inserted while you are breastfeeding.

Will Mirena interfere with sexual intercourse?

You and your partner should not feel Mirena during intercourse. 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 healthcare provider.

What are the possible serious side effects of 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 17).
- Life-threatening infection. Life-threatening infection can occur
 within the first few days after placement. Call your healthcare provider
 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 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. 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 provider. The risk of expulsion is increased with insertion right after delivery or second-trimester abortion.

Common side effects of Mirena 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 provider will examine you to see if Mirena 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 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 provider. Your periods may stop after 1 year of Mirena use. If you do not have a period for 6 weeks during Mirena use, call your healthcare provider. When 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 to 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

These are not all of the possible side effects with Mirena. For more information, ask your healthcare provider. Tell your healthcare provider if you have any side effects that bother you or do not go away.

Call your healthcare provider 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 healthcare provider?

If 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 healthcare provider. Call your healthcare provider if you have any concerns about 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 Mirena may have been expelled (came out)
- cannot feel 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 or bleeding that lasts a long time or concerns you

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

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LEARN MORE A MIRENA.COM



If you have any questions about Mirena®, you should ask your healthcare provider. You should also learn about other birth control methods and choose the one that is right for you.

FIND US HERE:













For additional Important Safety Information, please see throughout brochure. Please see Important Facts on pages 16-19 and the full Prescribing Information here.

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