

Welcome.



**Mirena**<sup>®</sup>

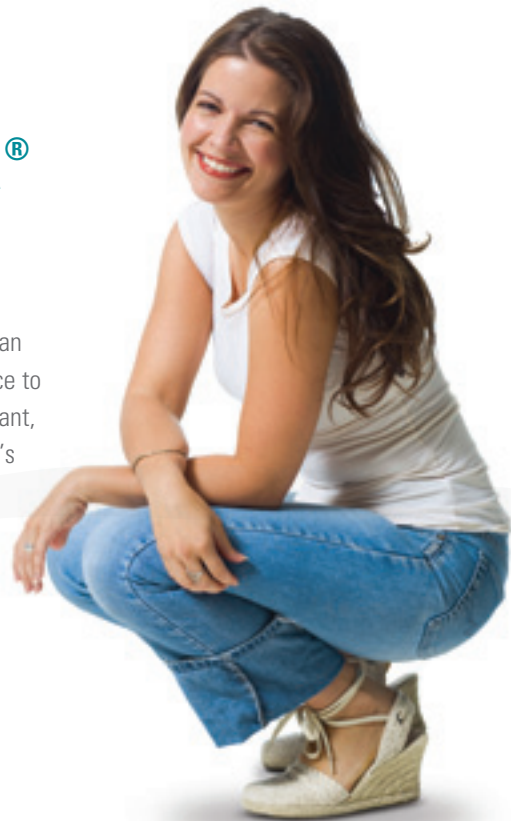
(levonorgestrel-releasing intrauterine system)

Keep life simple.

# Welcome to Mirena®

Congratulations, you've chosen birth control that may help simplify your life.

You're now part of a special group of women—the more than 15 million women worldwide who have also made the choice to use Mirena® for birth control that lasts for as long as you want, for up to 5 years. You've chosen a birth control method that's convenient, effective and proven safe.



## Join myMirena™ online today.

Mirena is a new part of your life, and with anything new, you're bound to have questions. We're here to give you the answers. Keep this booklet handy to help you understand what to expect during your first few months with Mirena. And be sure to join **myMirena**, a special online resource for ongoing support, plus tips and tools to help keep your life simple.

As a member of the myMirena online community, you'll have all the support you need right at your fingertips. And guess what: we'll give you free access to some great e-magazines just for joining! See page 24 for details.

## Enroll at **myMirena.com**, and start enjoying all that it has to offer.

Remember, you can always visit us online or talk with your healthcare provider for more information about Mirena.

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Please see Important Safety Information about Mirena on page 29. For important risk and use information, please see page 16 of this booklet and the accompanying Patient Prescribing Information.

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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## Once Mirena® is in place.

What you can expect and what you need to do.

Mirena® is birth control without a daily routine. We know life isn't simple, but now your birth control *can* be. Because now you can cross off "take birth control" from your daily to-do list. From the first day and every day, Mirena is there for you.

### Q: What can I expect right after Mirena is placed?

A: Some women may experience cramps or pain, bleeding, and/or dizziness during and right after Mirena is placed. Tell your healthcare provider if your cramps are severe. To help minimize the cramps, ask about medications that may be used. If these symptoms last for more than 30 minutes, let your healthcare provider know. Mirena may not have been properly placed and your healthcare provider may want to examine you.

### Q: What do I have to do once Mirena is in place?

A: All you have to do is check the threads of Mirena once a month to make sure it is still positioned correctly. Your healthcare provider can show you how. If you have trouble finding the threads, call your healthcare provider. And in the meantime, be sure to use a backup form of birth control.

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### Q: How often should I see my healthcare provider once Mirena is placed?

A: As a follow-up, you should visit your healthcare provider once in the first 4 to 12 weeks after Mirena is placed to make sure it is in the right position. After that, Mirena can be checked once a year as part of your routine exam.

### Q: What else should I know once Mirena is placed?

A: Be sure to tell your healthcare provider if you have signs of a vaginal infection or pelvic inflammatory disease (PID). Signs of PID include long-lasting or heavy bleeding, unusual vaginal discharge, abdominal pain, or painful sex, chills or fever.

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## You and Mirena®

### Changes to your periods and bleeding patterns.

It's important to keep track of your periods and bleeding patterns. Are they lighter? Heavier? Are you spotting between periods? Knowing this will help you and your healthcare provider follow your progress with Mirena®.

#### **Q: Will my periods change with Mirena?**

A: For the first 3 to 6 months, your monthly period may become irregular. You may also have frequent spotting or light bleeding. A few women have heavy bleeding during this time. Call your healthcare provider if the bleeding remains heavier than usual. After your body adjusts, the number of bleeding 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. Around the end of the third month of use, you may see up to a 75% reduction in the amount of menstrual bleeding.<sup>1</sup> Call your healthcare provider if the bleeding becomes heavy after it has been light for a while.

Approximately 1 in 5 women will have no period at all after 1 year of Mirena use. If it has been 6 weeks or longer since your last period, contact your healthcare provider to rule out the possibility of pregnancy. If pregnancy is ruled out, repeated pregnancy tests are generally not necessary unless other signs of pregnancy or pelvic pain develop. Your periods will return once Mirena is removed.

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#### **Q: Can I still use tampons?**

A: Yes. However, if you use tampons you should change them with care so as not to pull the threads of Mirena when removing the tampon.

#### **Q: Will Mirena interfere with sexual intercourse?**

A: Neither you nor your partner should feel Mirena during intercourse, as Mirena is placed in the uterus, not in the vagina. Sometimes male partners feel the threads.

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### Q: Why do menstrual cycle changes happen?

A: The reason many women may have lighter periods or stop having periods altogether with Mirena® centers on the uterine lining.

#### Your cycle without Mirena

- Every month, the lining of the uterus thickens during the first half of your menstrual cycle
- The lining is shed as menstrual flow
- On average, a woman's menstrual flow lasts 3 to 4 days. It may be shorter or longer, depending on the woman

#### Your cycle with Mirena

- The levonorgestrel in Mirena reduces the monthly thickening of the lining of your uterus
- Less thickening means less menstrual flow
- Eventually your menstrual flow may stop completely
- Once Mirena is removed, your periods will come back

If you have not gotten your period or have other symptoms of pregnancy during the first 6 weeks of use, contact your healthcare provider to rule out pregnancy.

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## How's it going?

A diary to track your periods and bleeding patterns.

Use this simple daily diary to keep track of what's going on with your periods. Remember to take it with you to your next doctor's appointment. Also remember that if you do not have a period for 6 weeks after having Mirena® placed, contact your healthcare provider to rule out pregnancy.

Put an "X" on your placement date. Then each day write the number that best represents your bleeding:

0 – No bleeding.

1 – Spotting: less than your normal period, no sanitary protection needed.

2 – Light: less than your normal period, but requires sanitary protection (panty liners).

3 – Normal: the usual amount of bleeding during your period.

4 – Heavy: more bleeding than your normal period.

### Sample:

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Month 1					X	0	0	0	0	0	0	0	1	1	0	0	0	0	0	3	3	3	3	3	0	0	1	1	0	0	0

## Diary

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Month 1																															
Month 2																															
Month 3																															
Month 4																															
Month 5																															
Month 6																															

You can also download a copy of this diary at [mirena-us.com](http://mirena-us.com).

Notes: \_\_\_\_\_  
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## Keeping your options open.

When it comes to planning a family, you're in control.

Mirena® works for up to 5 years, giving you the flexibility you want throughout the different stages of your reproductive life. Mirena is recommended for women who have had at least one child. This is because most of the medical research conducted on Mirena for FDA approval was among women who had at least one child.

### Q: What if I decide I want to try to get pregnant?

A: When you decide you want to try to have another child, Mirena can be removed by your healthcare provider at any time. It typically takes just a few minutes during an office visit. After that, you can begin trying to get pregnant right away. A woman's chances of getting pregnant within 12 months of having Mirena removed are approximately 80%.



### Q: What if I need birth control for more than 5 years?

A: Mirena must be removed after 5 years. If you want to continue using Mirena after those 5 years, you can choose to have another one placed. Talk with your healthcare provider about replacing your Mirena before your scheduled appointment to have your current Mirena removed. He or she can then place your new Mirena during the same office visit.



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**Q: What if I become pregnant while using Mirena®?**

A: Unfortunately, no birth control method, not even getting your tubes tied, is 100% perfect. If you do get pregnant while using a birth control method, there may be risks to you and your baby. Here we talk about the risks of getting pregnant while Mirena® is still in place.

About 2 in 1,000 women using Mirena for 1 year may become pregnant. One risk of getting pregnant while using Mirena is called ectopic pregnancy, when the pregnancy is not in the uterus. It may occur in the fallopian tubes. Signs of ectopic pregnancy may include unusual bleeding or abdominal pain. Ectopic pregnancy is an emergency that requires immediate medical attention and often surgery. Ectopic pregnancy can cause internal bleeding, infertility and even death. Call your healthcare provider right away if you think you're pregnant.

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) in place. 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.

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## Safety with Mirena®.

Risk and use information you should know about Mirena.

### Q: Are there any potential serious side effects with Mirena®?

A: Mirena may be associated with serious but uncommon side effects:

- *Pelvic inflammatory disease* (PID). Use of Mirena and other IUDs has been associated with an increased risk of PID. The percentage of women who develop PID while using Mirena is less than 1%. The risk is highest shortly after insertion—especially within the first 20 days—and if you have a vaginal infection at the time of placement. After the first 20 days, the risk of PID is reduced.

PID is an infection of the uterus and other organs of the upper reproductive system. It is caused by bacterial infections that are usually sexually transmitted, such as gonorrhea or chlamydia, that travel beyond the vagina and cervix into the uterus and other organs in the reproductive system. The risk of PID is greater if you or your partner have sex with multiple partners. If not treated quickly and appropriately, PID can lead to serious problems, including infertility, ectopic pregnancy or constant pelvic pain. Serious cases of PID may require surgery. A hysterectomy (removal of the uterus) is sometimes needed. In rare cases, infections that start as PID may even cause death.<sup>2</sup>

Be sure to tell your healthcare provider if you have signs of a vaginal infection or PID. Signs of PID include long-lasting or heavy bleeding, unusual vaginal discharge, abdominal pain, or painful sex, chills or fever.

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## Serious but uncommon side effects of Mirena® (continued)

- A rare life-threatening infection called sepsis may occur within the first few days after Mirena is placed. As of September 2006, 9 sepsis cases out of an estimated 9.9 million Mirena users had been reported. Call your healthcare provider immediately if you experience severe pain or unexplained fever after Mirena is placed.
- *Embedment* is when Mirena attaches to the uterine wall. If embedment occurs, Mirena may no longer prevent pregnancy and you may need surgery to have it removed.
- *Perforation*. Mirena may go through (perforate) the uterine wall. If your uterus is perforated, Mirena may no longer prevent pregnancy. It may move outside the uterus and can cause scarring, infection or damage to other organs. Surgery may be needed to have Mirena removed.

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## Q: What are the more common side effects of Mirena?

A: Some of the more common side effects are:

- *Discomfort during placement*. Dizziness, faintness, bleeding or cramping may occur during placement. This is common. Let your healthcare provider know if the cramping is severe.
- *Expulsion*. Mirena may come out by itself and no longer prevent pregnancy. Symptoms of partial or complete expulsion may include bleeding, pain and an increase in menstrual flow. If this occurs, Mirena may be replaced within 7 days of a menstrual period after pregnancy has been ruled out. If you notice Mirena has come out, use a backup form of birth control like condoms and call your healthcare provider.

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## Common side effects of Mirena® (continued)

### More than 10% of Mirena users may experience:

- *Missed menstrual periods.* About 2 out of 10 women stop having periods after 1 year of Mirena use. Your periods come back when Mirena is removed. If you do not have a period for 6 weeks after having Mirena placed, contact your healthcare provider to rule out pregnancy.
- *Changes in bleeding.* Your period may become irregular and you may have bleeding and spotting between menstrual periods, especially during the first 3 to 6 months. A few women have heavy bleeding during this time. After your body adjusts, periods usually get lighter and the number of bleeding days is likely to decrease, but may remain irregular. Or you may even find that your periods stop altogether—in which case, you should contact your healthcare provider to rule out pregnancy. Call your healthcare provider if the bleeding remains heavier than usual or if the bleeding becomes heavy after it has been light for a while.
- *Cyst on the ovary.* These cysts may develop as long as Mirena is in place. They are generally harmless and usually disappear in a month or two. However, cysts can cause pain and may sometimes require surgery.



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### Between 5% and 10% of Mirena users may experience:

- *Cramps or pelvic pain*  
*Call your healthcare provider if you have cramps that worsen during the first couple of weeks. He or she may want to examine you and check if Mirena has been properly placed.*
- *Vaginal discharge*
- *Nausea*
- *Headache*
- *Nervousness*
- *Back pain*
- *Weight increase*
- *Breast pain or tenderness*
- *Acne*
- *Decreased sex drive*
- *Depressed mood*
- *Inflammation of cervix, vulva or vagina*
- *Pelvic pain during your period*
- *High blood pressure*

### Less than 5% of Mirena users may experience:

- *Migraine*
- *Vomiting*
- *Anemia*
- *Pain during intercourse*
- *Unusual hair growth or loss*
- *Skin irritations (such as hives, rash, eczema or itching)*
- *Swelling of hands and feet*
- *Feeling bloated*
- *Mood swings*

**This booklet does not include a complete list of possible side effects with Mirena. For more information, ask your healthcare provider.**

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**Q: How can I be sure Mirena® is properly in place?**

A: Once Mirena is placed, you should check the threads once a month to make sure it is still positioned correctly. Your healthcare provider can show you how. If you have trouble finding the threads, call your healthcare provider. And in the meantime, be sure to use a backup form of birth control.

**Q: Can Mirena protect me from HIV or STDs (sexually transmitted diseases)?**

A: No. Mirena does not protect against HIV or STDs. So, if while using Mirena you think you and your partner might be at risk of getting an STD, use a condom and call your healthcare provider.

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## The myMirena™ program.

Be a part of it.

Mirena® is a new part of your life, and the myMirena program was developed to help you make life a little simpler. myMirena is all about giving you useful resources and valuable tools created with your busy life in mind.

Maybe you've got more questions about your first months with Mirena, or you want tips on balancing family, friends, a job and time for yourself—*whatever that is*. Either way, myMirena is right there with you.

As a member of the myMirena online community, you'll have the support you need right at your fingertips.

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## Sign up and get a free gift. Make that 4 free gifts!

Join myMirena and get access to free e-magazines just for signing up. Choose from up to 4 of your favorites, including *Working Mother* and *Yoga Journal*.



## Enroll online at myMirena.com. Getting started is simple.

**Join today** and start enjoying all that myMirena has to offer.

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## Tell a friend about Mirena®.

Now that you're on your way with Mirena®, do you have a friend who might appreciate knowing what you know about Mirena?

Is your friend someone who:

- Would benefit from having safe and effective birth control that lasts for as long as she wants, for up to 5 years?
- Would appreciate birth control that's convenient and reversible?
- Is looking for birth control that she doesn't have to think about taking every day?

Then she'd probably like to hear from you about how Mirena may help her keep life simple, plus all the support and valuable resources she can get as a member of the myMirena™ online community.

Even letting your friend know about Mirena is simple. Just log on to **mirena-us.com**, and click on **Tell a Friend About Mirena**. We've got an e-mail all ready for you to send.

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## What you should know about Mirena<sup>®</sup>

### INDICATIONS AND USAGE

Mirena<sup>®</sup> (levonorgestrel-releasing intrauterine system) is a hormone-releasing system placed in your uterus to prevent pregnancy for as long as you want for up to 5 years. Mirena also treats heavy periods in women who choose intrauterine contraception.

### IMPORTANT SAFETY INFORMATION ABOUT MIRENA

Only you and your healthcare provider can decide if Mirena is right for you. Mirena is recommended for women who have had a child.

- Don't use Mirena if you have a pelvic infection, get infections easily or have certain cancers. Less than 1% of users get a serious infection called pelvic inflammatory disease. Talk to your healthcare provider about problems related to this condition.
- Mirena may attach to or go through the wall of the uterus and cause other problems. If Mirena comes out, use back-up birth control and call your healthcare provider.
- Although uncommon, pregnancy while using Mirena can be life threatening and may result in loss of pregnancy or fertility.
- Pelvic and/or abdominal pain may occur. Talk to your healthcare provider if the pain is persistent.
- Ovarian cysts may occur and usually disappear.
- Bleeding and spotting may increase in the first few months and continue to be irregular. Periods over time may become shorter, lighter or even stop.

*Mirena does not protect against HIV or STDs.*

**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.**

## Notes

Use these pages for notes and questions.

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2. PID (Pelvic inflammatory disease)—CDC fact sheet. Centers for Disease Control and Prevention Web site. <http://cdc.gov/STD/PID/stdfact-pid.htm>. Updated April 7, 2008. Accessed July 24, 2009.



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For more information about Mirena®:  
mirena-us.com  
1-888-84-BAYER

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