

## FDA-Approved Patient Labeling

### Patient Information

#### Skyla (sky-lah)

(levonorgestrel-releasing intrauterine system)

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

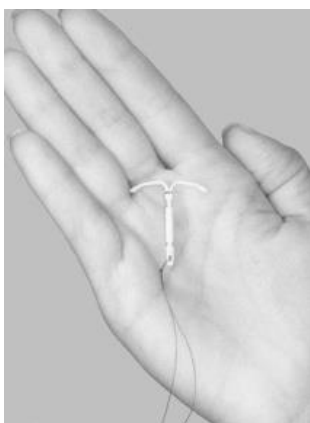
Read this Patient Information carefully before you decide if Skyla is right for you. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women's health. If you have any questions about Skyla, ask your healthcare provider. You should also learn about other birth control methods to choose the one that is best for you.

#### **What is Skyla?**

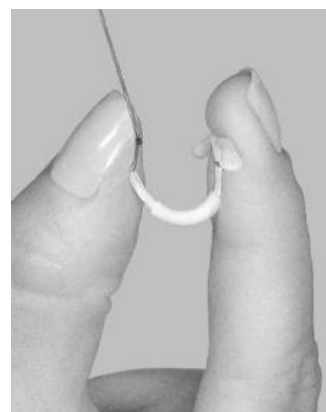
- Skyla is a hormone-releasing system placed in your uterus by your healthcare provider to prevent pregnancy for up to 3 years.
- Skyla can be removed by your healthcare provider at any time.
- Skyla can be used whether or not you have given birth to a child.

Skyla is a small, flexible plastic T-shaped system that slowly releases a progestin hormone called levonorgestrel (LNG) that is often used in birth control pills. Because Skyla releases LNG into your uterus, only small amounts of the hormone enter your blood. Skyla does not contain estrogen.

Two thin threads are attached to the stem (lower end) of Skyla. The threads are the only part of Skyla you can feel when Skyla is in your uterus; however, unlike a tampon string, the threads do not extend outside your body.



Skyla is small



and flexible

### **What if I need birth control for more than 3 years?**

Skyla must be removed after 3 years. Your healthcare provider can place a new Skyla during the same office visit if you choose to continue using Skyla.

### **What if I want to stop using Skyla?**

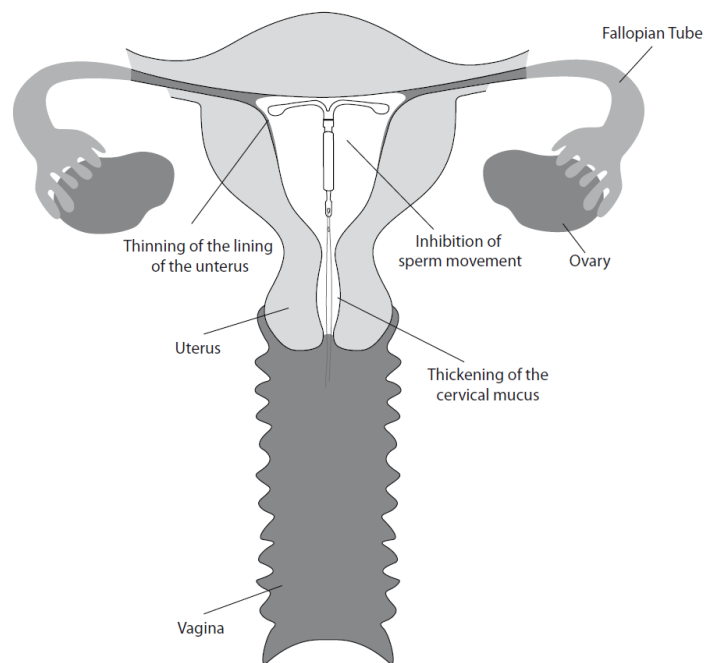
Skyla is intended for use up to 3 years but you can stop using Skyla at any time by asking your healthcare provider to remove it. You could become pregnant as soon as Skyla is removed, so you should use another method of birth control if you do not want to become pregnant. Talk to your healthcare provider about the best birth control methods for you, because your new method may need to be started 7 days before Skyla is removed to prevent pregnancy.

### **What if I change my mind about birth control and want to become pregnant in less than 3 years?**

Your healthcare provider can remove Skyla at any time. You may become pregnant as soon as Skyla is removed. About 3 out of 4 women who want to become pregnant will become pregnant sometime in the first year after Skyla is removed.

### **How does Skyla work?**

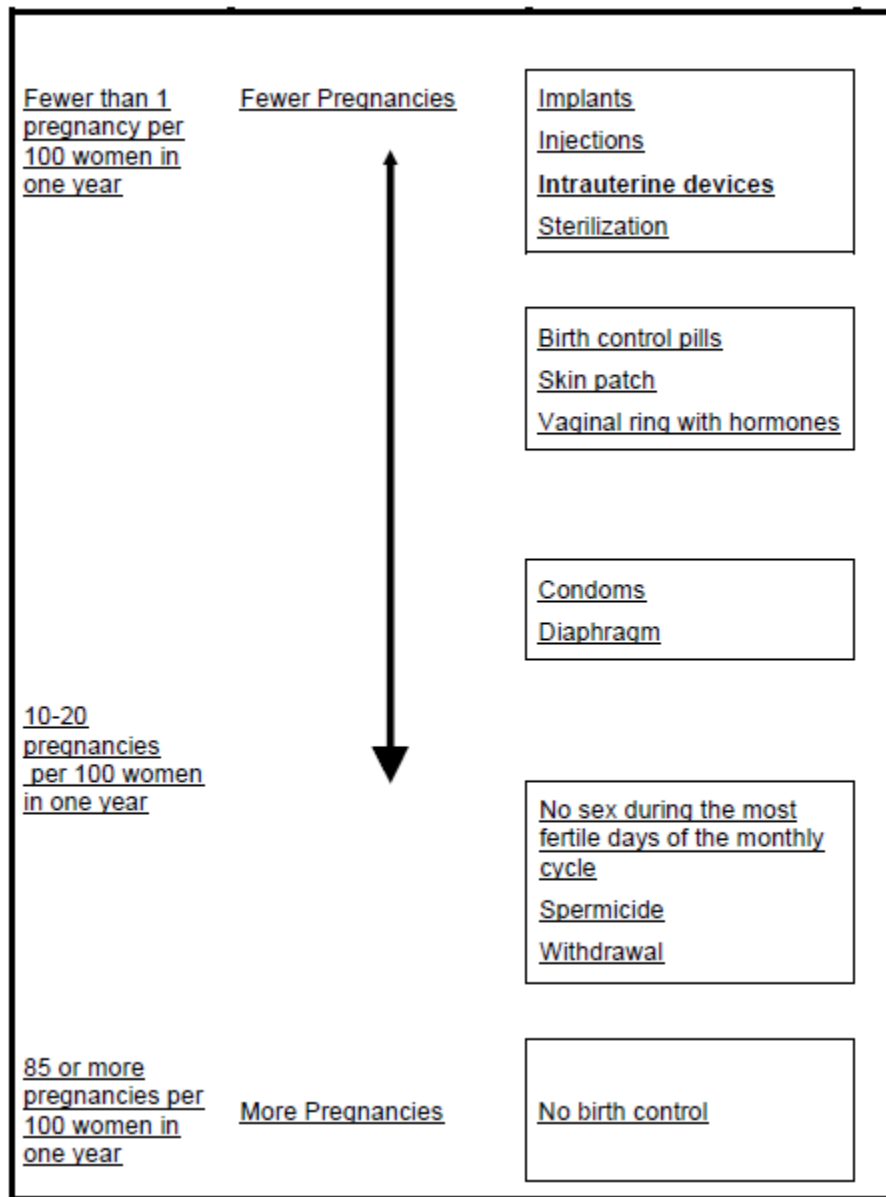
Skyla may work in several ways including thickening cervical mucus, inhibiting sperm movement, reducing sperm survival, and thinning the lining of your uterus. It is not known exactly how these actions work together to prevent pregnancy.



## How well does Skyla work for contraception?

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.

Skyla, an intrauterine device (IUD), is in the box at the top of the chart.



## Who might use Skyla?

You might choose Skyla 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 3 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 Skyla if you:**

- Are or might be pregnant; Skyla cannot be used as an emergency contraceptive
- Have had a serious pelvic infection called pelvic inflammatory disease (PID) unless you have had a normal pregnancy after the infection went away
- Have an untreated pelvic 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
  - 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 or iron oxide

**Before having Skyla placed, tell your healthcare provider 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 migraine headaches

**How is Skyla placed?**

Skyla is placed by your healthcare provider during an in-office visit.

First, your healthcare provider will examine your pelvis to find the exact position of your uterus.

Your healthcare provider will then clean your vagina and cervix with an antiseptic solution and slide a slim plastic tube containing Skyla into your uterus. Your healthcare provider will then remove the plastic tube, and leave Skyla in your uterus. Your healthcare provider will cut the threads to the right length. Placement takes only a few minutes.

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

### **Should I check that Skyla is in place?**

Yes, you should check that Skyla is in proper position by feeling the removal threads. It is a good habit to do this 1 time a month. Your healthcare provider should teach you how to check that Skyla is in place. First, wash your hands with soap and water. You can check by reaching up to the top of your vagina with clean fingers to feel the removal threads. Do not pull on the threads. If you feel more than just the threads or if you cannot feel the threads, Skyla may not be in the right position and may not prevent pregnancy. Use non-hormonal back-up birth control (such as condoms and spermicide) and ask your healthcare provider to check that Skyla is still in the right place.

### **How soon after placement of Skyla should I return to my healthcare provider?**

Call your healthcare provider if you have any questions or concerns (see “When should I call my healthcare provider?”). Otherwise, you should return to your healthcare provider for a follow-up visit 4 to 6 weeks after Skyla is placed to make sure that Skyla is in the right position.

### **Can I use tampons with Skyla?**

Yes tampons may be used with Skyla.

### **What if I become pregnant while using Skyla?**

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 Skyla, you may have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain may be a sign of ectopic pregnancy.

Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.

There are also risks if you get pregnant while using Skyla 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 Skyla, even though removing it may cause a miscarriage. If Skyla cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy.

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.

It is not known if Skyla can cause long-term effects on the fetus if it stays in place during a pregnancy.

### **How will Skyla 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. After you have used Skyla for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether. When Skyla is removed, your menstrual periods should return.

### **Is it safe to breastfeed while using Skyla?**

You may use Skyla when you are breastfeeding if more than 6 weeks have passed since you had your baby. If you are breastfeeding, Skyla 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 Skyla becoming attached to (embedded) or going through the wall of the uterus is increased if Skyla is inserted while you are breastfeeding.

### **Will Skyla interfere with sexual intercourse?**

You and your partner should not feel Skyla during intercourse. Skyla 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.

### **Can I have an MRI with Skyla in place?**

Skyla can be safely scanned with MRI only under specific conditions. Before you have an MRI, tell your healthcare provider that you have Skyla, an intrauterine device (IUD), in place.

### **What are the possible side effects of Skyla?**

#### **Skyla can cause serious side effects, including:**

- **Ectopic pregnancy and intrauterine pregnancy risks.** There are risks if you become pregnant while using Skyla (see “What if I become pregnant while using Skyla?”).
- **Life-threatening infection.** Life-threatening infection can occur within the first few days after Skyla is placed. Call your healthcare provider immediately if you develop severe pain or fever shortly after Skyla 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. A hysterectomy (removal of the uterus) is sometimes needed. 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, or fever.

**Perforation.** Skyla may become attached to (embedded) or go through the wall of the uterus. This is called perforation. If this occurs, Skyla may no longer prevent pregnancy. If perforation occurs, Skyla may move outside the uterus and can cause internal scarring, infection, or damage to other organs, and you may need surgery to have Skyla removed. The risk of perforation is increased if Skyla is inserted while you are breastfeeding.

#### **Common side effects of Skyla include:**

- **Pain, bleeding or dizziness during and after placement.** If these symptoms do not stop 30 minutes after placement, Skyla may not have been placed correctly. Your healthcare

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

- **Expulsion.** Skyla may come out by itself. This is called expulsion. Expulsion occurs in about 3 out of 100 women. You may become pregnant if Skyla comes out. If you think that Skyla has come out, use a backup birth control method like condoms and spermicide and call your healthcare provider.
- **Missed menstrual periods.** About 1 out of 16 women stop having periods after 1 year of Skyla use. If you do not have a period for 6 weeks during Skyla use, call your healthcare provider. When Skyla is removed, your menstrual periods should return.
- **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 provider if the bleeding remains heavier than usual or increases after it has been light for a while.
- **Cysts on the ovary.** About 14 out of 100 women using Skyla develop a cyst on the ovary. These cysts usually disappear on their own in two to three months. However, cysts can cause pain and sometimes cysts will need surgery.

This is not a complete list of possible side effects with Skyla. For more information, ask your healthcare provider. Tell your healthcare provider if you have any side effect that bothers you or does 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 the manufacturer at 1-888-842-2937 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### **After Skyla has been placed, when should I call my healthcare provider?**

If Skyla 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 Skyla. 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 Skyla may have been expelled (came out)
- Cannot feel Skyla'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 concerns you

**General advice about the safe and effective use of Skyla**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. You can ask your healthcare provider for information about Skyla that is written for healthcare providers.

For more information, go to [www.skyla-us.com](http://www.skyla-us.com) or call 1-888-842-2937.

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