



# Fact Sheet

English

**Meet the Paragard® IUD (intrauterine device)** — the only birth control that uses just 1 simple active ingredient to prevent pregnancy over 99% of the time with no hormones.

## What is Paragard?



### 100% Hormone-Free

Paragard is a birth control that works to prevent pregnancy without any hormones.



### Over 99% Effective

It's over 99% effective — one of the most effective methods of birth control available.



### Lasts Up to 10 Years

Lasts up to 10 years but can be removed by a healthcare provider at any time sooner if you decide you want to get pregnant. After removal, the effects of Paragard are immediately reversible.



### No Daily Routines

No daily routines or refill hassles—just a simple monthly thread check.



### FDA-Approved for Over 30 Years

## How Paragard Works



### 1 Simple Active Ingredient

It works using copper, instead of hormones, so it won't prevent your natural menstrual cycle.\* Paragard prevents the sperm from reaching and fertilizing the egg and may also prevent implantation.

## Paragard Placement



### Non-Surgical Placement

It's placed in your uterus by a healthcare provider during a routine office visit.

## What to Expect

Once in place, you shouldn't be able to feel Paragard inside your uterus aside from the two thin threads that extend from your cervix. You can continue to use tampons and you or your partner shouldn't be able to feel it during sex.

At first, your period may be heavier and longer with spotting in between; usually this decreases over time.

## Cost



### Most Women with Insurance Get Paragard at No Cost

Paragard is fully covered under most insurance plans—which may mean no co-pay, deductible, or out-of-pocket costs.

Check with your insurance provider to confirm coverage related to your individual plan. Fees for the Paragard placement procedure may apply.

## Important Safety Information

- Don't use Paragard if you are or may be pregnant, have fibroids, a pelvic infection including pelvic inflammatory disease (PID), get infections easily, certain cancers, unexplained bleeding, Wilson's disease, or a copper allergy. IUDs, including Paragard, have been associated with an increased risk of PID.
- Pregnancy with Paragard is rare but can be life threatening and cause infertility or loss of pregnancy.
- Paragard may attach to or go through the uterus and cause other problems.
- Tell your healthcare provider (HCP) if you develop severe pain or fever shortly after placement, miss a period, have abdominal pain, or if Paragard comes out. If it comes out, use backup birth control.
- Tell your HCP you have Paragard before having an MRI or a medical procedure using heat therapy.
- At first, periods may become heavier and longer with spotting in between.
- Additional common side effects include anemia, pain during sex, backache, and vaginal discharge.
- **Paragard does not protect against HIV or STDs.**

Only you and your HCP can decide if Paragard is right for you. Available by prescription only.

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

**See next page for Brief Summary of Patient Information.**



Paragard is made mostly of flexible plastic wrapped with a thin layer of copper around the arms and stem.

\*At first, periods may become heavier and longer with spotting in between.



## Brief Summary

Paragard (ˈpar-uh-gahrd) (intrauterine copper contraceptive)

**Paragard T380A intrauterine copper contraceptive is used to prevent pregnancy. It does not protect against HIV infection (AIDS) or other sexually transmitted infections (STIs).**

This information is not comprehensive. Please see the full prescribing information at [paragard.com](http://paragard.com) for additional information.

*Read this Patient Information carefully before you decide if Paragard 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 Paragard, ask your healthcare provider. You should also learn about other birth control methods to choose the one that is best for you.

## What is Paragard?

- Paragard is a copper-releasing system that is placed in your uterus by your healthcare provider to prevent pregnancy for up to 10 years.
- Paragard can be removed by your healthcare provider at any time.
- Paragard does not contain any hormones.
- Paragard can be used whether or not you have given birth to a child.

Paragard is a small, flexible plastic "T" shaped intrauterine system with copper wrapped around the stem and placed on arms of the "T". Two thin white threads are attached to the stem (lower end) of Paragard. The threads are the only part of Paragard you can feel when Paragard is in your uterus; however, unlike a tampon string, the threads do not extend outside of your body.

## How long can I keep Paragard in place?

You can keep Paragard in your uterus for up to 10 years. After 10 years, you should have Paragard removed by your healthcare provider. If you wish and if it is still right for you, you may get a new Paragard during the same visit.

## How does Paragard work?

Paragard works by preventing sperm from reaching the egg, preventing sperm from fertilizing the egg, or possibly preventing attachment (implantation) in the uterus. Paragard does not stop your ovaries from making an egg (ovulating) each month.

## Who might use Paragard?

You might choose Paragard 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 10 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 inserted in the uterus
- want birth control that does not contain hormones

## Who should not use Paragard?

**Do not use Paragard if you:**

- are or might be pregnant
- have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumors
- have an untreated pelvic infection called pelvic inflammatory disease (PID) now
- have had an infection in your uterus after a pregnancy or abortion in the past 3 months
- can get infections easily. For example, if you:
  - have problems with your immune system
  - have multiple sexual partners or your partner has multiple sexual partners
  - use or abuse intravenous drugs
- have or suspect you might have cancer of the uterus or cervix
- have unexplained bleeding from your vagina
- have an untreated lower genital infection now in your cervix
- have Wilson's disease (a disorder in how the body handles copper)
- are allergic to copper, polyethylene, or barium sulfate
- have an intrauterine system in your uterus already

**Before having Paragard placed, tell your healthcare provider if you have:**

- any of the conditions listed above
- slow heart beat (bradycardia)
- dizziness (syncope)
- seizures
- recently had a baby or if you are breastfeeding
- AIDS, HIV, or any other sexually transmitted infection

## How is Paragard placed in the uterus?

Paragard is placed in your uterus 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 cleanse your vagina and cervix with an antiseptic solution and then, measure your uterus. Your healthcare provider will then slide a plastic tube containing Paragard into your uterus. The tube is removed, leaving Paragard inside your uterus. Two white threads will extend into your vagina. The threads are trimmed so they are just long enough for you to feel with your fingers when doing a self-check. As Paragard goes in, you may feel cramping or pinching. You may have some bleeding. Some women feel faint, nauseated, or dizzy for a few minutes afterwards. Your healthcare provider may ask you to lie down until you are feeling better, and to get up slowly.

## Should I check that Paragard is in place?

Yes, you should check that Paragard is in the proper position by feeling the threads. It is a good habit to do this 1 time a month. Your healthcare provider should teach you how to check that Paragard 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 2 threads. Do not pull on the threads.

## How soon after placement of Paragard 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 after your first menses after Paragard is placed to make sure that Paragard is in the right position.

## What if I become pregnant while using Paragard?

Call your healthcare provider right away if you think you may be pregnant. If you get pregnant while using Paragard, you may have an ectopic pregnancy. This means the pregnancy is not in your 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 Paragard and the pregnancy is in the uterus. Severe infection, miscarriage, premature delivery, and even death can occur with pregnancies that continue with an intrauterine system (IUS). Because of this, your healthcare provider may try to remove Paragard, even though removing it may cause a miscarriage. If Paragard 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 Paragard can cause long-term effects on the fetus if it stays in place during a pregnancy.

## How will Paragard change my periods?

Your period may become heavier and longer. You may also have frequent spotting between periods.

## Is it safe to breastfeed while using Paragard?

You may use Paragard when you are breastfeeding. The risk of Paragard becoming attached to (embedded) or going through the wall of the uterus is increased if Paragard is placed while you are breastfeeding.

## Will Paragard interfere with sexual intercourse?

You and your partner should not feel Paragard during intercourse. Paragard 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 Paragard in place?

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

**Before you have a medical procedure using heat therapy tell your healthcare provider that you have Paragard in place.**

## What are the possible side effects of Paragard?

**Paragard can cause serious side effects, including:**

- **ectopic pregnancy and intrauterine pregnancy risks:** There are risks if you become pregnant while using Paragard (see "What if I become pregnant while using Paragard?").
- **life-threatening infection:** Life-threatening infection can occur within the first few days after Paragard is placed. Call your healthcare provider immediately if you develop severe pain or fever shortly after Paragard is placed.
- **pelvic inflammatory disease (PID) or endometritis:** Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID) or endometritis. PID

and endometritis are usually sexually transmitted. You have a higher chance of getting PID and endometritis if you or your partner has sex with other partners. PID and endometritis can cause serious problems such as infertility, ectopic pregnancy, and pelvic pain that does not go away. PID and endometritis are usually treated with antibiotics. More serious cases of PID or endometritis 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 or endometritis: low abdominal (stomach area) or pelvic pain, pelvic tenderness, painful sex, unusual or bad smelling vaginal discharge, chills, long-lasting or heavy bleeding, fever, genital lesions or sores.

- **embedding:** Paragard may become attached to (embedded) the wall of the uterus. This may make it hard to remove Paragard. Surgery may sometimes be needed to remove Paragard.
- **perforation:** Paragard may go through the wall of the uterus. This is called perforation. If this occurs, Paragard may no longer prevent pregnancy. If perforation occurs, Paragard may move outside the uterus and cause internal scarring, infection, damage to other organs, pain, or infertility and you may need surgery to have Paragard removed. Excessive pain or vaginal bleeding during placement of Paragard, pain or bleeding that gets worse after placement, or not being able to feel the threads may happen with perforation. You are not protected from pregnancy if Paragard moves outside the wall of the uterus. The risk of perforation is increased in breastfeeding women.
- **expulsion:** Paragard may partially or completely fall out of the uterus by itself. This is called expulsion. Expulsion occurs in about 2 out of 100 women. Excessive pain, vaginal bleeding during placement of Paragard, pain that gets worse, bleeding after placement, or not being able to feel the threads may happen with expulsion. You are not protected from pregnancy if Paragard is expelled.
- **changes in bleeding:** You may have heavier and longer periods with spotting in between. Sometimes the bleeding is heavier than usual at first. Call your healthcare provider if the bleeding remains heavier or longer and spotting continues.
- **reactions after placement or removal:** Some women have had reactions such as dizziness (syncope), slowed heart rate (bradycardia), or seizures, immediately after Paragard was placed or removed. This happened especially in women who have had these conditions before.

## Common side effects of Paragard include:

- anemia (low red blood cell count)
- pain during sex
- prolonged periods
- vaginal irritation
- backache
- expulsion (complete or partial)
- spotting
- painful periods
- vaginal discharge
- pain and cramping

This is not a complete list of possible side effects with Paragard. For more information, ask your healthcare provider. Tell your healthcare provider about any side effect that bothers you or does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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

Call your healthcare provider if you have any concerns about Paragard. Be sure to call if you:

- think you are pregnant
- have pelvic 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 Paragard may have been expelled (came out)
- cannot feel Paragard's threads or can feel the threads are much longer
- can feel any other part of the Paragard besides the threads
- become HIV positive or your partner becomes HIV positive
- have severe bleeding that lasts a long time, or bleeding that concerns you
- miss a menstrual period

To learn more, talk about Paragard with your healthcare provider and see the FDA-approved Full Prescribing Information found on [paragard.com](http://paragard.com) or call CooperSurgical, Inc. at 1-877-PARAGARD (727-2427). Paragard® is a registered trademark of CooperSurgical, Inc. The other brands listed are trademarks of their respective owners.

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