



# Paragard<sup>®</sup>

intrauterine copper contraceptive

simple, honest  
pregnancy prevention™



Birth control  
that's  
**ABSOLUTELY,  
POSITIVELY  
100%  
HORMONE  
FREEEEE**



Paragard is a small IUS (intrauterine system) that prevents pregnancy for as long as you want up to 10 years. It works differently using one simple active ingredient—copper—instead of hormones.

IUSs, including Paragard, have been associated with an increased risk of pelvic inflammatory disease (PID). Don't use Paragard if you have a pelvic infection, certain cancers, a copper allergy, Wilson's disease, or PID.

Please see additional Important Safety Information throughout this brochure and accompanying Full Prescribing Information in pocket.

## What Is Paragard?

Paragard is a small, 100% hormone-free IUS (intrauterine system) that uses just 1 simple active ingredient to prevent pregnancy over 99% of the time.

It's placed in your uterus by a healthcare provider during a routine office visit in just a few minutes. Once in place, it provides continuous pregnancy prevention for as short or long as you want—up to 10 years.

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



## Why Paragard?



Absolutely, positively **100% hormone free**



**Over 99% effective**



Works differently using just **1 simple active ingredient**—copper



No hormones, **no hormone-related side effects**



**No hassle** and **low maintenance**—no daily pills, monthly refill, or birth control routine



**Lasts up to 10 years** but can be removed anytime sooner if you decide you want to get pregnant\*



**Quick nonsurgical placement** done during a routine office visit in just a few minutes



The only IUS **FDA approved for over 30 years**



Most women with insurance can get Paragard at **no cost\***

IUS=IUD

\*Must be removed by a healthcare provider.

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

### Important Safety Information

- If you miss a period, have persistent abdominal pain, or if Paragard comes out, tell your healthcare provider (HCP). If it comes out, use backup birth control.

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[Paragard.com](https://www.paragard.com)

# How Paragard Works



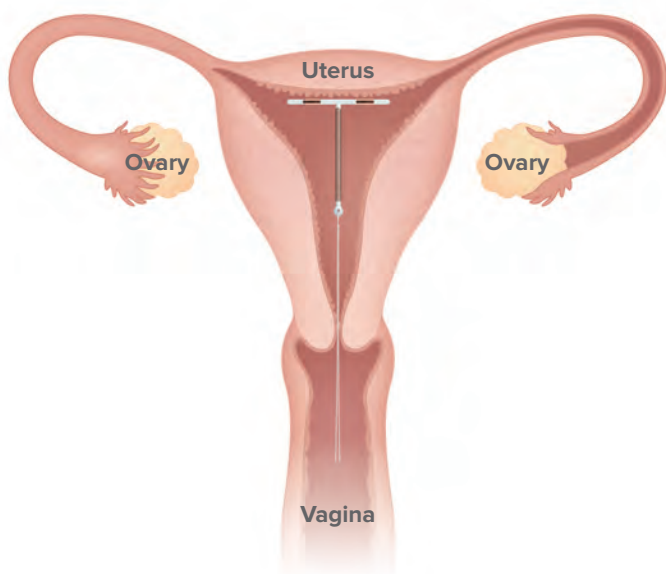
Paragard works using just 1 simple active ingredient—copper—instead of hormones.



Paragard works by preventing the sperm from reaching and fertilizing the egg and may also prevent implantation.



Because Paragard is 100% hormone free, it won't prevent your natural menstrual cycle\* or stop you from ovulating each month.



## Did you know?

Paragard is an FDA-approved copper IUS that has been clinically proven safe and effective for over 30 years.

\*Periods with Paragard may become heavier and longer with spotting in between. Bleeding may be heavier than usual at first.

### Important Safety Information

- Paragard may attach to or go through the uterus and cause other problems.

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# What to Expect With Paragard

With Paragard, there's...

0

**daily  
routines**  
or refill  
hassles



1

**monthly  
thread  
check**  
you do  
yourself



2

**appointments**

- one for placement
- one about a month afterward to make sure Paragard is in the right place\*



## Important Safety Information

- Pregnancy with Paragard is rare but can be life threatening and may cause infertility or loss of pregnancy.

**Please see additional Important Safety Information throughout this brochure and accompanying Full Prescribing Information in pocket.**

## Paragard placement

Paragard placement is nonsurgical and done by a healthcare provider during a routine office visit in just a few minutes. Everyone is different, and some women may experience discomfort during or after insertion. As Paragard goes in, you may feel cramping or pinching; some women feel faint, nauseated, or dizzy for a few minutes afterward.

## After placement

Once in place, you shouldn't be able to feel Paragard. You can continue to use tampons and you or your partner shouldn't be able to feel it during sex.

At first, you may have heavier and longer periods with spotting in between; usually it decreases over time. If it continues, contact your healthcare provider.

## Following up

Visit your healthcare provider for a checkup about one month after placement to make sure Paragard is in the right place.\*

It's a good habit to check that Paragard is in the uterus by doing a monthly self-check of the threads. After washing your hands with soap and water, reach up to the top of the vagina with clean fingers to feel the 2 threads.

\*Depending on your experience, additional appointments may be necessary to ensure Paragard is in the correct position.

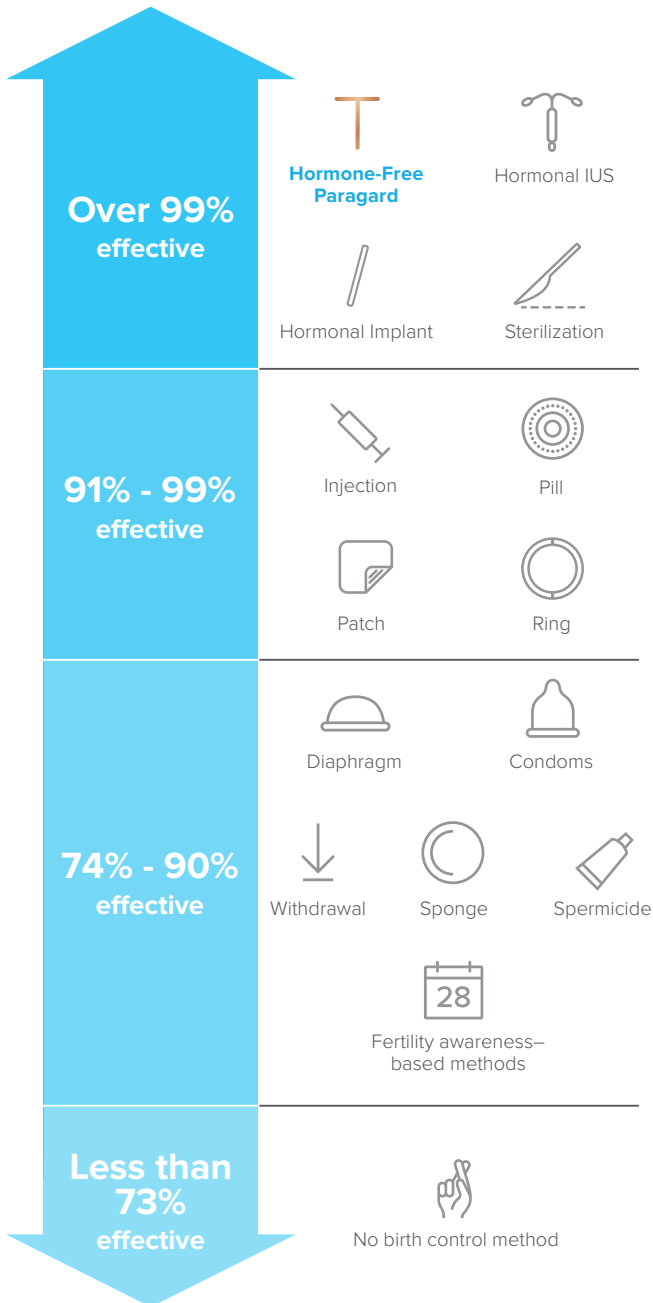
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## How Does Paragard Compare?

Paragard is over 99% effective—one of the most effective methods of birth control available.



Trussell J. Contraceptive failure in the United States. *Contraception*. 2011;83:397-404.

### Important Safety Information

- Periods may become heavier and longer with spotting in between. Bleeding may be heavier than usual at first.

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## Is Paragard Right for You?

If you answer “agree” to any of these statements, talk to your healthcare provider about whether Paragard is right for you.

1. I'm interested in a birth control that's **100% hormone free**  
☐ Agree ☐ Disagree
2. I want a birth control method that's **highly effective**  
☐ Agree ☐ Disagree
3. I've **experienced negative side effects** from hormonal birth control in the past  
☐ Agree ☐ Disagree
4. I want to give my body a **break from hormonal birth control** because I've been using it for many years  
☐ Agree ☐ Disagree
5. I want a birth control that's **low maintenance** and doesn't require a daily routine  
☐ Agree ☐ Disagree
6. I want a birth control that's the **longest lasting but reversible** if I change my mind  
☐ Agree ☐ Disagree

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# Cost & Insurance Coverage



## Most women with insurance can get Paragard at no cost

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

You can check your insurance coverage for Paragard in 2 ways:

### 1 Contact your insurance company directly

1. Call the customer service number on the back of your insurance card
2. Tell them that Paragard is a healthcare provider—administered method of birth control
3. Ask them to check if Paragard is covered under the Affordable Care Act
4. Provide them with the J code for Paragard: **J7300**
5. Ask if you will have any out-of-pocket costs, or if Paragard is only partially covered under your plan

### 2 Request a free Paragard Benefits Verification<sup>SM</sup> Report

#### By phone:

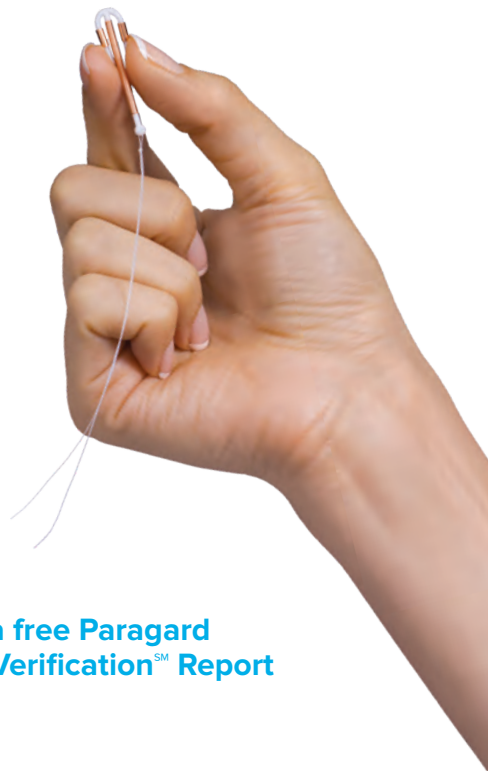
1. Call **1-877-PARAGARD**
2. Our benefits verification specialists will assist you in confirming coverage related to your individual plan

#### Online:

1. Visit **Paragardbvsp.com**
2. Complete and submit an electronic Patient Authorization Form
3. Ask your healthcare provider to submit a Patient Referral Form
  - Once both forms are received, you will be sent a detailed report that shows your insurance coverage for Paragard
  - If you have any questions or need help with this process, call **1-877-PARAGARD**

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

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Want hormone free?  
Ask for Paragard.

100%  
HORMONE FREE

OVER 99%  
EFFECTIVE

1 SIMPLE  
ACTIVE INGREDIENT

Visit [Paragard.com](http://Paragard.com)  
or call 1-877-PARAGARD.



**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.

Please see additional Important Safety Information throughout  
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in pocket.

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## PATIENT INFORMATION

**Paragard®** ('par-uh-gahrd)  
(intrauterine copper contraceptive)

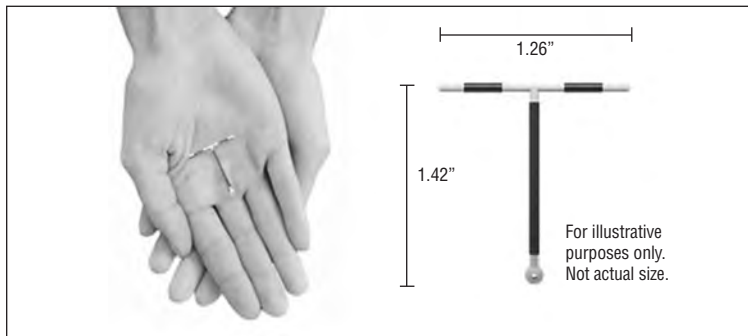
### Paragard does not protect against HIV infection (AIDS) or other sexually transmitted infections (STIs).

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.



#### What if I need birth control for more than 10 years?

Paragard must be removed on or before 10 years from the date of insertion. Your healthcare provider can place a new Paragard during the same office visit if you choose to continue using Paragard.

#### What if I want to stop using Paragard?

Paragard is intended for use up to 10 years, but you can stop using Paragard at any time by asking your healthcare provider to remove it. You could become pregnant as soon as Paragard is removed; however, if you do not want to become pregnant you should use another method of birth control. Talk to your healthcare provider about the best birth control methods for you.

#### What if I change my mind about birth control and want to become pregnant in less than 10 years?

Your healthcare provider can remove Paragard at any time before the 10 years after placement. You may become pregnant as soon as Paragard is removed.

#### How does Paragard work?

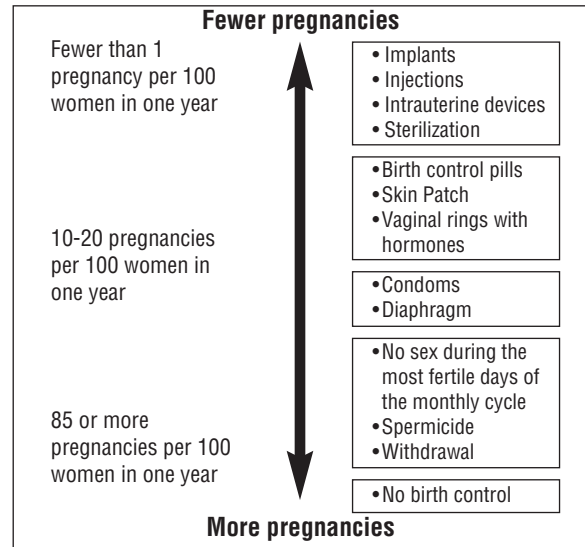
Paragard works by preventing sperm from reaching the egg, preventing sperm from fertilizing the egg, or possibly preventing attachment (implantation) in the uterus. Paragard does not stop your ovaries from making an egg (ovulating) each month.

#### How well does Paragard 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.

Paragard, an intrauterine system (IUS), is in the box at the top of the chart.



#### 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

#### 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
- have AIDS, HIV, or any other sexually transmitted infection

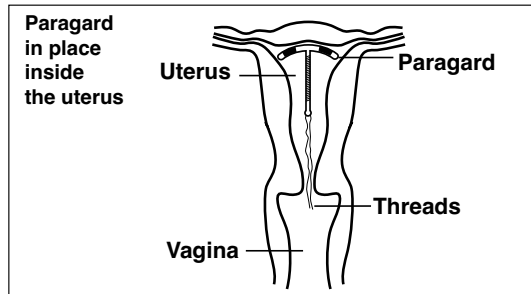
#### How is Paragard placed?

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

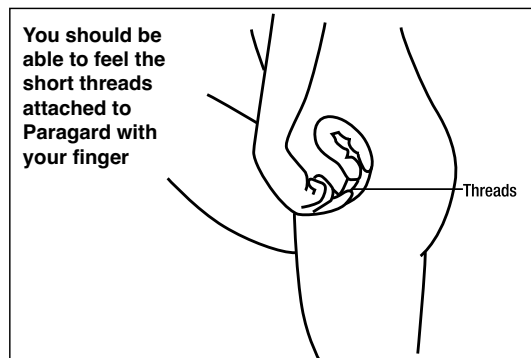


Paragard into your uterus. The tube is removed, leaving Paragard inside your uterus. Two white threads will extend into your vagina. The threads are trimmed so they are just long enough for you to feel with your fingers when doing a self-check. As Paragard goes in, you may feel cramping or pinching. 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 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.



If you feel changes in the length of the 2 threads, you cannot feel the threads, or you can feel any other part of Paragard other than the threads, Paragard may not be in the right position and may not prevent pregnancy. Use back-up birth control (such as condoms or spermicide) and ask your healthcare provider to check that Paragard is still in the right place.

If Paragard is accidentally removed, you may be at risk of pregnancy, and should talk to a healthcare provider.

### 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 device (IUD). 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) | • expulsion (complete or partial) |
| • pain during sex                   | • spotting                        |
| • prolonged periods                 | • painful periods                 |
| • vaginal irritation                | • vaginal discharge               |
| • backache                          | • 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

**General information about the safe and effective use of Paragard.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your healthcare provider for information about Paragard that is written for health professionals.

Paragard and its components are not made with natural rubber latex.

Paragard® is a registered trademark of CooperSurgical, Inc. The other brands listed are trademarks of their respective owners.

**CooperSurgical**

Manufactured by:

CooperSurgical, Inc.

Trumbull, CT 06611

P/N 1016806

For more information, call CooperSurgical, Inc. at 1-877-727-2427.

This Patient Information has been approved by the U.S. Food and Drug Administration

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