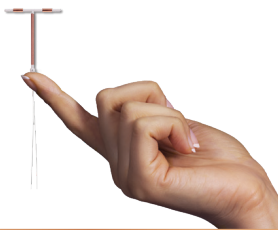


 Paragard<sup>®</sup>

intrauterine copper contraceptive

simple, honest  
pregnancy prevention™



安全可靠，  
绝对  
节育，  
100%  
不含激素



Paragard 是一款小型 IUS (宫内节育器)，可以根据要求提供最长 10 年的避孕作用。它的作用原理不同，因为使用了一种简单的活性成分 — 铜，而不是激素。

包括 Paragard 在内的 IUS 都会增加盆腔炎 (PID) 的患病风险。如果您患有盆腔感染、某种癌症、铜过敏、威尔森氏症或 PID，请勿使用 Paragard。

请参阅本手册随附的《重要安全信息》以及口袋中随附的《完整处方信息》。

Paragard 是一款 100% 不含激素的小型 IUS (宫内节育器), 只使用一种简单的活性成分即可在超过 99% 的时间内防止怀孕。

由医疗服务提供者在常规就诊过程中将其放入子宫, 只需几分钟。一旦放置到位, 就可以根据您的时长需求提供持续的避孕效果, 最长可达 10 年。

Paragard 主要由柔软、易弯曲的塑料制成, 在臂和杆周围包裹了一层薄薄的铜。



绝对 **100% 不含激素**



节育率高达 **99% 以上**



作用原理不同, 仅使用 **一种简单的活性成分** — 铜



不含激素, **无激素相关副作用**



**无忧、低维护** — 无需每日吃药、每月替换或日常检查



**时效最长达 10 年**但如果您决定要怀孕, 可以随时提早摘除\*



**快速非手术放置**在常规就诊时仅需几分钟就可以完成



唯一经 **FDA 认证安全有效期超过 30 年**的 IUS



大部分有保险的女性均可**免费**†获得 Paragard

IUS=IUD

\*必须由医疗服务提供者摘除。

†请咨询您的保险供应商, 以确认与您个人套餐相关的承保范围。可能会收取 Paragard 放置术的费用。

## 重要安全信息

- 如果您经期未至, 持续感到腹痛, 或者如果 Paragard 掉出, 请告知您的医疗服务提供者 (HCP)。
- 如果掉出, 请采用备用节育方法。

请参阅本手册随附的《重要安全信息》以及口袋中随附的《完整处方信息》。

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# Paragard 的作用原理



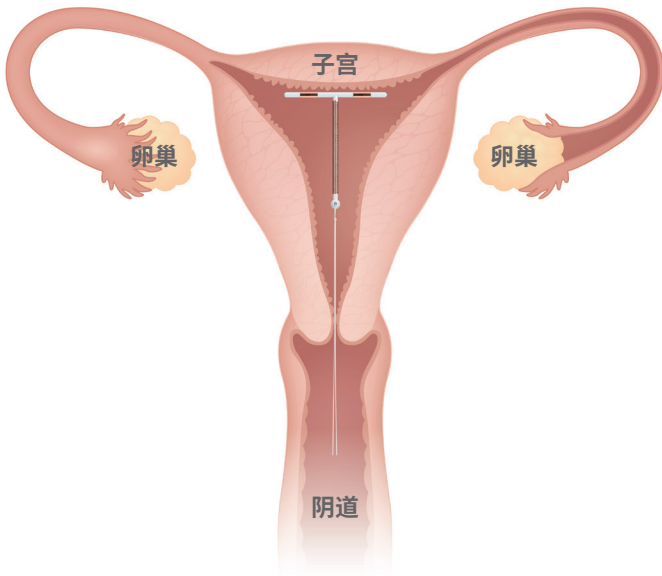
Paragard 仅使用一种简单的活性成分——铜，而不是激素。



Paragard 的作用原理是阻止精子到达卵子并使其受精，还可能阻止着床。



因为 Paragard 100% 不含激素，所以它不会影响您的自然月经周期\*或影响您每月排卵。



## 您知道吗？

Paragard 是经 FDA 认证的铜质 IUS，临床实践证明其安全有效期长达 30 年。

\*使用 Paragard 时，月经可能会变多或经期变长，并且在两次月经期间伴随点滴出血。起初出血可能比平时多。

### 重要安全信息

• Paragard 可能会附着在子宫上或穿过子宫而引起其他问题。

请参阅本手册随附的《重要安全信息》以及口袋中随附的《完整处方信息》。

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# 放置 Paragard 后有哪些注意事项

## 放置 Paragard 后...

0

日常  
常规避孕  
或替换  
的麻烦



1

每月  
引线  
检查  
由您自己  
进行



2

就诊

- 一次用于放置
- 一次用于在大概一个月后确保 Paragard 放置到位\*



### 重要安全信息

- 在放置了 Paragard 后基本上不会再受孕, 但可能危及生命, 而且可能会造成不孕或流产。

请参阅本手册随附的《重要安全信息》以及口袋中随附的《完整处方信息》。

## 放置 Paragard

Paragard 的放置无需手术, 由医疗服务提供者在常规就诊过程中完成, 只需几分钟。因人而异, 有些女性在插入期间或之后可能会感到不适。随着 Paragard 的进入, 您可能会感到收缩或挤压; 几分钟后, 有些女性会感到虚弱、恶心或头晕。

## 放置后

一旦放置到位, 您应该不会感觉到 Paragard 的存在。您可以继续使用卫生棉条, 您或您的伴侣在性生活中也不会感觉到它的存在。

起初, 您的月经可能会变多或变长, 并且在两次月经期间伴随点滴出血; 通常这会随着时间减轻。如果这些现象持续, 请联系您的医疗服务提供者。

## 随访

放置后大概一个月, 请前往您的医疗服务提供者处进行检查, 以确保 Paragard 置于正确的位置。\*

养成好习惯, 每月对引线进行一次自检, 从而检查 Paragard 是否在子宫里。用肥皂和水将手洗干净后, 将干净的手指伸到阴道顶部, 感觉 2 根引线的存在。

\*根据您的体验, 可能需要额外就诊以确保 Paragard 在正确的位置。

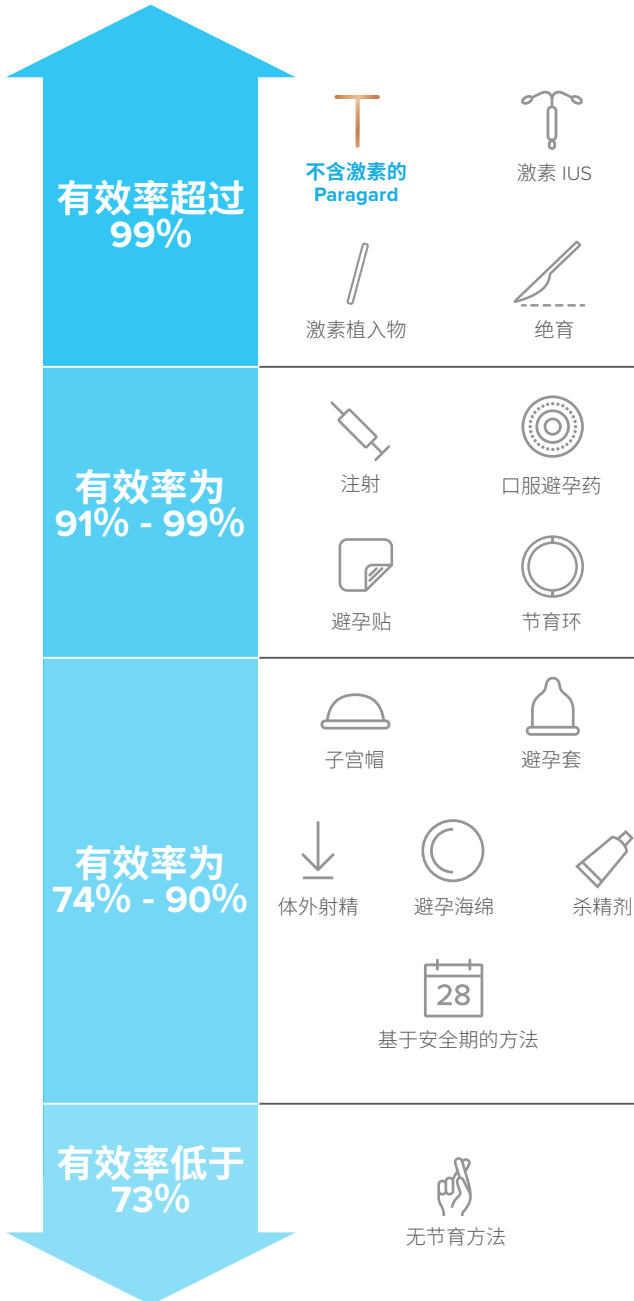
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simple, honest  
pregnancy prevention™

Paragard.com

Paragard 的有效率超过 99%，是目前最有效的节育方法之一。

如果您对这些陈述中的任何一项回答“同意”，请与您的医疗服务提供者讨论 Paragard 是否适合您。



1. 我对 **100% 不含激素** 的节育方法感兴趣

同意  不同意

2. 我想要一种**高效**的节育方法

同意  不同意

3. 我曾经使用激素节育方法后出现**不良副作用**

同意  不同意

4. 我想让我的身体**免受激素节育方法的伤害**，因为我已经用这种方法很多年

同意  不同意

5. 我想要一种**低维护**且不需要每天检查的节育方法

同意  不同意

6. 我想要一种**时效最长且可摘除**的节育方法，以防万一我改变主意

同意  不同意

Trussell J.《美国的避孕失败情况》.避孕.2011;83:397-404。

### 重要安全信息

• 月经可能会变多和变长，且两次月经之间伴随点滴出血。起初出血可能比平时多。

请参阅本手册随附的《重要安全信息》以及口袋中随附的《完整处方信息》。

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intrauterine copper contraceptive

simple, honest pregnancy prevention™

# 费用与承保范围



## 大多数有保险的女性都可以免费获得 Paragard

Paragard 在大多数保险计划中都是完全承保的,这可能意味着没有共同支付、免赔或自理费用\*

您可以通过以下两种方式核实您的保险范围是否覆盖 Paragard:

### 1 直接联系您的保险公司

1. 拨打保险卡背面的客服电话
2. 告诉他们 Paragard 是一种由医疗服务提供者管理的节育方法
3. 要求他们核实 Paragard 是否在《平价医疗法案》的覆盖范围内
4. 向他们提供 Paragard 的 J 代码: **J7300**
5. 询问您是否需要支付任何自理费用, 或者您的计划是否仅承担部分 Paragard 费用

或者

### 2 申请免费 Paragard Benefits Verification<sup>SM</sup> 报告

电话:

1. 致电 **1-877-PARAGARD**
2. 我们的受益核实专家将协助您确认与您个人套餐相关的承保范围

在线:

1. 访问 [Paragardbvsp.com](http://Paragardbvsp.com)
2. 填写并提交电子版《患者授权书》
3. 请您的医疗服务提供者提交《患者治疗安排表》
  - 收到两份表格后,我们将向您发送一份详细报告,说明您的承保范围是否覆盖 Paragard
  - 如果您对此流程有任何问题或需要帮助,请致电 **1-877-PARAGARD**



\*请咨询您的保险提供商,以确认与您个人套餐相关的承保范围。可能会收取 Paragard 放置术的费用。

请参阅本手册随附的《重要安全信息》以及口袋中随附的《完整处方信息》。

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 **Paragard**<sup>®</sup>  
intrauterine copper contraceptive

simple,  
honest  
pregnancy  
prevention™

想要无激素避孕吗？  
Paragard 是您的不二选择。

100%  
不含激素

99%  
避孕率高达  
以上

含 1  
种简单的有效成分

请访问 [Paragard.com](http://Paragard.com)  
或致电 1-877-PARAGARD。



Paragard 不能预防艾滋病或性传播疾病。

只有您和您的医疗服务提供者才能决定 Paragard 是否适合您。  
仅凭处方提供。

欢迎您通过 [www.fda.gov/medwatch](http://www.fda.gov/medwatch) 或致电 1-800-FDA-1088  
向 FDA 报告处方药的不良反应。

请参阅本手册随附的《重要安全信息》以及口袋中随附的《完整  
处方信息》。

Paragard 是 CooperSurgical, Inc. 的注册商标

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## PATIENT INFORMATION

**Paragard**<sup>®</sup> ('par-uh-gahrd)  
(intrauterine copper contraceptive)

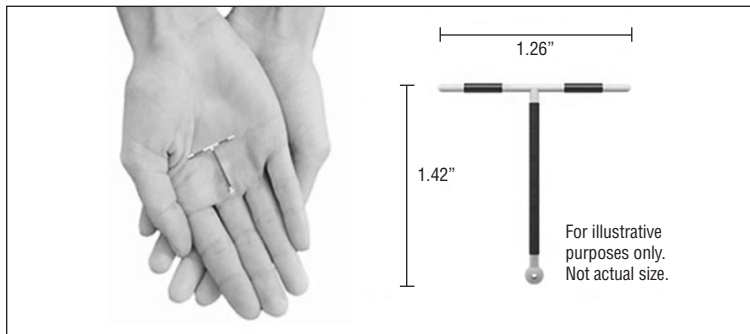
### Paragard does not protect against HIV infection (AIDS) or other sexually transmitted infections (STIs).

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?

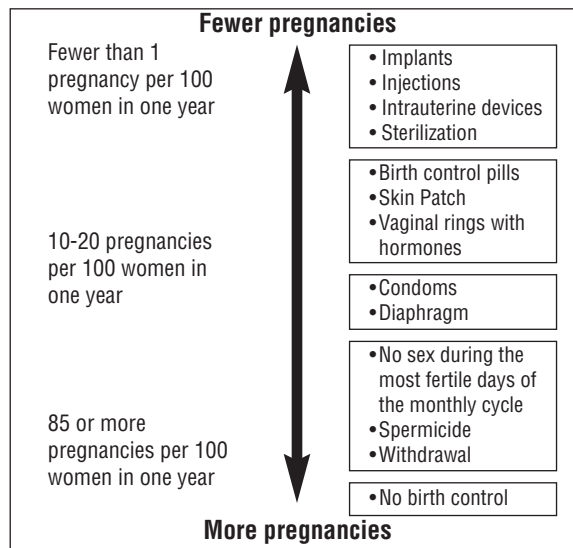
Paragard works by preventing sperm from reaching the egg, preventing sperm from fertilizing the egg, or possibly preventing attachment (implantation) in the uterus. Paragard does not stop your ovaries from making an egg (ovulating) each month.

### 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

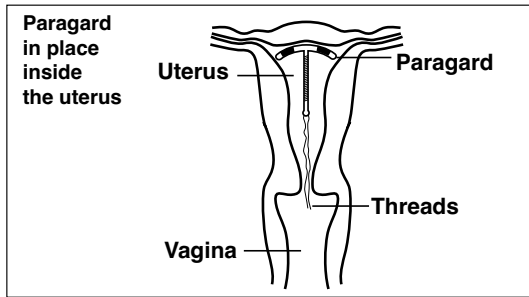
### How is Paragard placed?

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

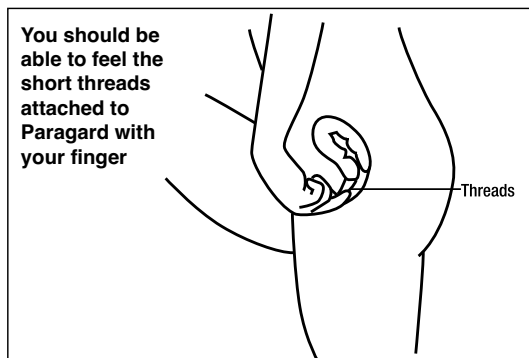


Paragard into your uterus. The tube is removed, leaving Paragard inside your uterus. Two white threads will extend into your vagina. The threads are trimmed so they are just long enough for you to feel with your fingers when doing a self-check. As Paragard goes in, you may feel cramping or pinching.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

**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.



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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