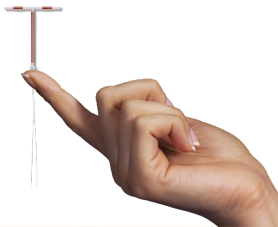


 **Paragard®**

intrauterine copper contraceptive

simple, honest
pregnancy prevention™



100%
무호르몬으로
뛰어난 효과를
발휘하는
피임법



Paragard는 필요에 따라 최장 10년까지 임신을 막아주는 작은 IUS (intrauterine system) 입니다. 이 제품은 호르몬 대신 단일 활성 성분인 구리를 이용하는 독특한 방식으로 효과를 나타냅니다.

Paragard와 같은 IUS는 골반염(PID)의 위험을 높이는 것으로 알려져 있습니다. 골반 감염, 특정 암, 구리 알레르기, 월슨병 또는 PID가 있는 경우 Paragard를 사용하지 마십시오.

이 브로셔 및 함께 제공된 포켓용 상세 처방 정보에 나온 중요 안전 정보를 확인해 주십시오.

Paragard는?

Paragard는 작은 크기의 100% 무호르몬 IUS (intrauterine system) 로 간단한 단일 활성 성분을 이용해 99% 이상 임신을 막아줍니다.

일반 진료 방문으로 수 분 만에 의료 서비스 제공자가 자궁 내에 삽입해 드립니다. 삽입 후에는 원하는 기간만큼 최장 10년까지 지속적인 피임 효과를 제공합니다.

Paragard는 기본적으로 부드럽고 찰랑거리는 플라스틱 소재의 암과 줄기 부분에 얇은 구리를 씌운 형태로 되어 있습니다.

Paragard를 사용해야 하는 이유



완전한 **100% 무호르몬**



99% 이상의 피임 효과



간단한 단일 활성 성분인 구리만 사용



무호르몬이므로 **호르몬과 관련된 부작용 없음**



간단한 시술 및 간편한 사후 관리—매일 알약을 복용하거나, 매월 새로 충전하거나, 따라야 할 피임 규칙 없음



최장 10년까지 지속, 하지만 다시 임신을 하고 싶을 때는 언제든지 제거 가능*



빠른 비수술적 삽입 - 일반 진료 방문으로 수 분 만에 완료



FDA가 30년 이상 승인한 유일한 IUS



보험에 가입한 대부분의 여성은 Paragard를 **무료**로 이용할 수 있습니다.

IUS=IUD

*의료 서비스 제공자가 제거해야 합니다.

†보험 적용 여부는 해당 보험사에 문의하십시오. Paragard 삽입을 위한 시술 비용이 적용될 수 있습니다.

중요 안전 정보

- 생리를 건너뛰거나 지속적으로 복부 통증이 있거나 Paragard가 빠져 나오는 경우, 의료 서비스 제공자(HCP)에게 연락하십시오. 빠져 나온 경우에는 대체 피임 방법을 이용하십시오.

이 브로셔 및 함께 제공된 포켓용 상세 처방 정보에 나온 중요 안전 정보를 확인해 주십시오.

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Paragard의 작용 기전



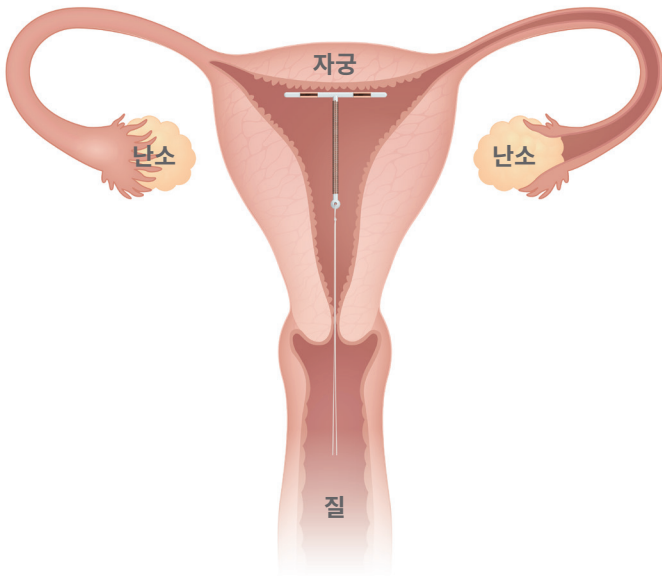
Paragard는 호르몬 대신 단일 활성 성분인 구리를 사용하여 효과를 나타냅니다.



Paragard는 정자가 난자까지 도달하여 수정하는 것을 막는 기능을 하며 착상도 막아줄 수 있습니다.



Paragard는 100% 무호르몬 방식이기 때문에 자연적인 생리 주기*를 방해하거나 매달 배란하는 것을 막지 않습니다.



알고 계셨습니까?

Paragard는 30년 이상 임상적으로 안전성과 효과성을 입증하여 FDA 승인을 얻은 구리 IUS입니다.

*Paragard 사용 시 생리량이 많아지고 긴 기간에 걸쳐 조금씩 생리가 비칠 수 있습니다. 사용 초기에는 출혈이 더 많아질 수 있습니다.

중요 안전 정보

- Paragard가 자궁에 붙거나 안으로 들어갈 수 있으며 다른 문제를 일으킬 수 있습니다.

이 브로셔 및 함께 제공된 포켓용 상세 처방 정보에 나온 중요 안전 정보를 확인해 주십시오.

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Paragard를 사용하게 되면...

0

**일상적
관리**
또는 재충전의
불편



1

**매월
스레드
점검**
스스로
할 수 있음



2

진료 방문

- 삽입 시 한 번
- 이 Paragard가 제 위치에 있는지 확인하기 위해 한 달 후 한 번*



중요 안전 정보

- Paragard 사용시 임신하는 경우는 매우 드물지만 생명을 위협할 수 있으며 불임이나 유산으로 이어질 수 있습니다.

이 브로셔 및 함께 제공된 포켓용 상세 처방 정보에 나온 중요 안전 정보를 확인해 주십시오.

Paragard 삽입

Paragard 삽입은 수술 없이 이루어지며 일반 진료 방문 시 의료 서비스 제공자가 수 분 만에 해드립니다. 사람마다 차이가 있어서 일부 여성은 삽입 과정이나 삽입 후에 불편감을 느낄 수 있습니다. Paragard가 들어가는 과정에서 조이거나 눌리는 느낌을 받을 수 있습니다. 일부 여성은 이후 잠시 동안 현기증이나 구토감을 느낍니다.

삽입 후

삽입 후에는 Paragard가 있다는 것이 느껴지지 않습니다. 탐폰을 계속 사용할 수 있고 본인과 파트너 모두 성관계 중에 삽입물이 있다는 것을 느끼지 못합니다.

처음에는 생리량이 많고 긴 기간에 걸쳐 조금씩 생리가 비칠 수 있지만 이러한 현상은 일반적으로 시간이 지나면서 줄어듭니다. 해당 현상이 지속되는 경우, 의료 서비스 제공자에게 문의하십시오.

후속 관리

한 달 후 검사를 위해 의료 서비스 제공자를 방문하여 Paragard가 제 위치에 잘 있는지 확인하십시오.*

매달 스레드를 자가 점검하여 Paragard가 자궁 내에 있는지 확인하는 습관을 들이십시오. 비누와 물로 손을 씻고 깨끗한 손가락을 질 상부까지 집어 넣어 두 개의 스레드가 만져지면 됩니다.

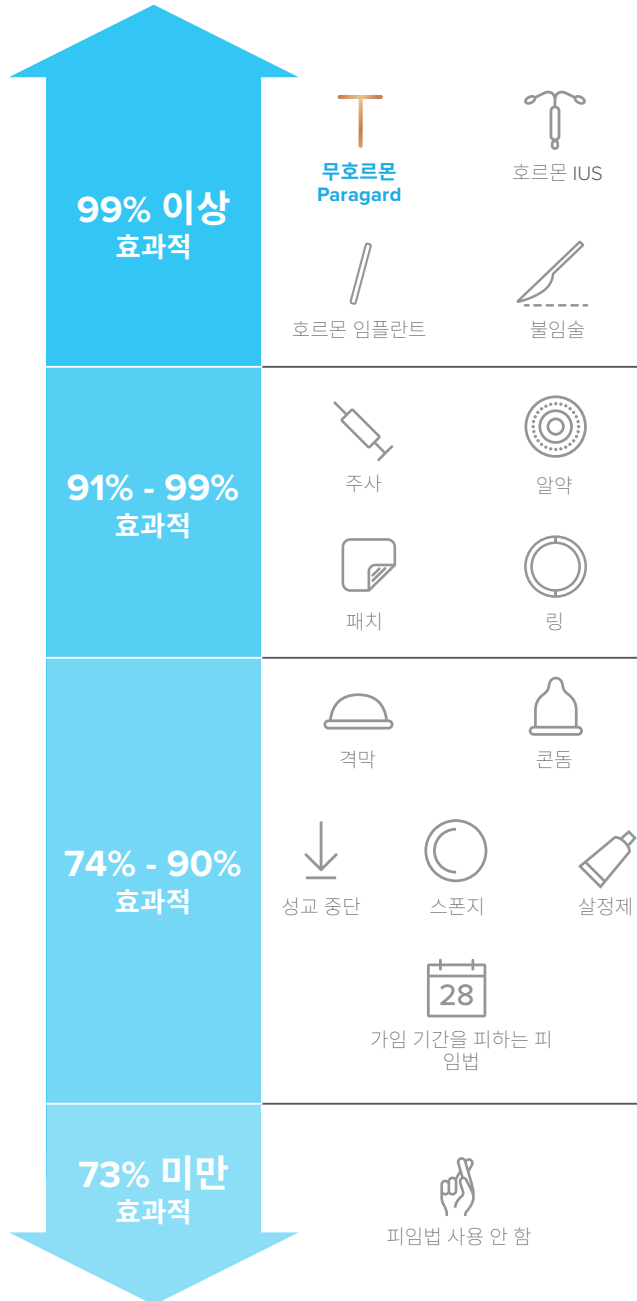
*개인에 따라 Paragard가 제 위치에 잘 있는지 확인하기 위해 추가 방문이 필요할 수도 있습니다.

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타 제품과 비교해 Paragard가 가진 이점은?

Paragard는 99% 이상의 효과를 발휘하여 가장 효과적인 피임 방법 중 하나로 추천됩니다.



미국의 Trussell J. 피임 실패율 *Contraception*, 2011;83:397-404.

중요 안전 정보

• 생리량이 많아지고 긴 기간에 걸쳐 조금씩 생리가 비칠 수 있습니다. 사용 초기에는 출혈이 더 많아질 수 있습니다.

이 브로셔 및 함께 제공된 포켓용 상세 처방 정보에 나온 중요 안전 정보를 확인해 주십시오.

Paragard가 나에게 맞나요?

이 질문 중 어느 하나에라도 “맞음”을 선택하는 경우, Paragard가 자신에게 적합한 피임법인지 의료 서비스 제공자와 상의하십시오.

1. 100% 무호르몬 피임법에 관심이 있습니다.

☐ 맞음 ☐ 틀림

2. 매우 효과적인 피임법을 원합니다.

☐ 맞음 ☐ 틀림

3. 이전에 호르몬 피임법을 이용하고 부작용을 겪은 적이 있습니다.

☐ 맞음 ☐ 틀림

4. 몇 년 동안 호르몬 피임법을 이용하고 있어 건강을 생각해 잠시 중단하고 싶습니다.

☐ 맞음 ☐ 틀림

5. 평상시 별다른 관리가 필요 없는 피임법을 원합니다.

☐ 맞음 ☐ 틀림

6. 가장 오래 지속되면서도 원할 때 제거 가능한 피임법을 원합니다.

☐ 맞음 ☐ 틀림

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pregnancy prevention™

비용 및 보험 적용



보험에 가입한 대부분의 여성은 Paragard를 무료로 이용할 수 있습니다.

Paragard는 대부분 100% 보험 적용을 받습니다. 즉, 본인 부담금을 내거나 자기 돈을 지불할 필요가 없습니다.*

Paragard 비용을 보험으로 처리할 수 있는지 알아보는 두 가지 방법이 있습니다.

1 보험 회사에 직접 연락

또는

2 무료 Paragard Benefits VerificationSM 보고서 요청

1. 보험 카드 뒷면에 있는 고객 서비스 번호로 전화를 겁니다.
2. Paragard는 의료 서비스 제공자가 처방한 피임법이라고 말합니다.
3. Affordable Care Act에 따라 Paragard가 보험 적용 대상인지 물어봅니다.
4. 다음 Paragard J 코드를 알려줍니다: **J7300**
5. 본인 부담금이 있는지, 또는 해당 보험으로 Paragard가 일부만 보장되는지 물어봅니다.

전화:

1. **1-877-PARAGARD** 이용
2. 보험 적용 확인 전문가가 개별 보험상품과 관련된 보험 적용 여부를 친절하게 안내해 드립니다.

온라인:

1. **Paragardbvsp.com** 방문
2. 환자 인증 온라인 양식을 작성하여 제출
3. 의료 서비스 제공자에게 환자 의뢰 양식 제출을 요청
 - 두 양식이 모두 수신되면 Paragard 보험 보장 내용을 안내하는 상세 안내서를 보내드립니다.
 - 질문이 있거나 이 과정에 도움이 필요하면 **1-877-PARAGARD**로 연락주시기 바랍니다.



*보험 적용 여부는 해당 보험사에 문의하십시오. Paragard 삽입을 위한 시술 비용이 적용될 수 있습니다.

이 브로셔 및 함께 제공된 포켓용 상세 처방 정보에 나온 중요 안전 정보를 확인해 주십시오.

 **Paragard[®]**
intrauterine copper contraceptive
simple, honest
pregnancy prevention[™]

 **Paragard**[®]
intrauterine copper contraceptive

simple,
honest
pregnancy
prevention[™]

호르몬 피임법을 원하지 않으십니까?
Paragard를 요청하세요.

100%
무호르몬

99% 이상
피임 효과

단일 유효
성분

Paragard.com을 방문하거나
1-877-PARAGARD로 전화하세요.



Paragard는 HIV 또는 STD를 막아주지 못합니다.

본인과 담당 HCP만이 Paragard가 자신에게 적합한지 결정할 수 있습니다. 의사의 처방이 필요합니다.

처방약에 부작용이 발생했을 때는 FDA로 보고해 주십시오.

www.fda.gov/medwatch를 방문하거나 1-800-FDA-1088로 전화하시면 됩니다.

이 브로셔 및 함께 제공된 포켓용 상세 처방 정보에 나온 중요 안전 정보를 확인해 주십시오.

Paragard는 CooperSurgical, Inc.의 등록 상표입니다.

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PATIENT INFORMATION

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

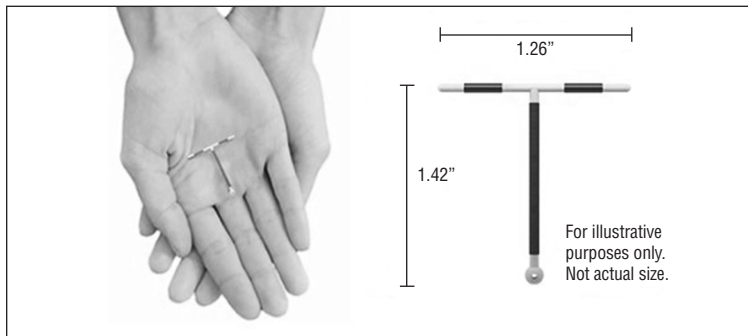
Paragard does not protect against HIV infection (AIDS) or other sexually transmitted infections (STIs).

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?

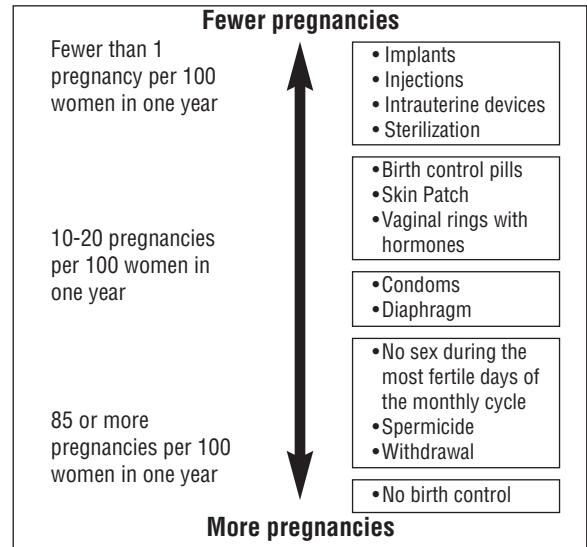
Paragard works by preventing sperm from reaching the egg, preventing sperm from fertilizing the egg, or possibly preventing attachment (implantation) in the uterus. Paragard does not stop your ovaries from making an egg (ovulating) each month.

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:

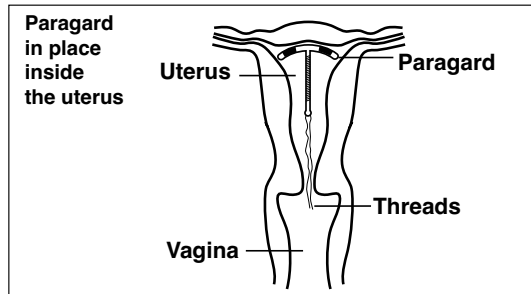
- any of the conditions listed above
- slow heart beat (bradycardia)
- dizziness (syncope)
- seizures
- recently had a baby or if you are breastfeeding
- have AIDS, HIV, or any other sexually transmitted infection

How is Paragard placed?

Paragard is placed in your uterus during an in-office visit.

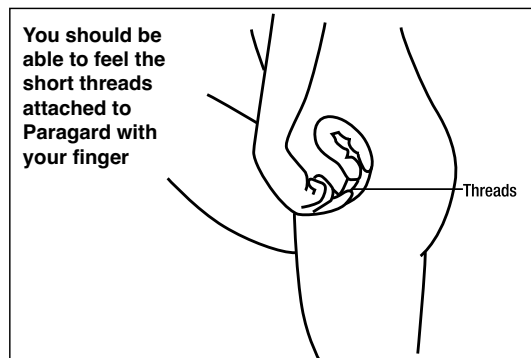
First, your healthcare provider will examine your pelvis to find the exact position of your uterus. Your healthcare provider will then cleanse your vagina and cervix with an antiseptic solution and then, measure your uterus. Your healthcare provider will then slide a plastic tube containing

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:

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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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