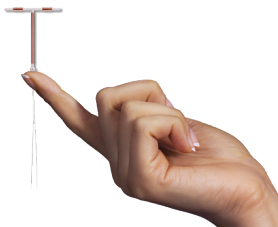




Paragard®

intrauterine copper contraceptive

simple, honest
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*Yon metòd
ki kontwole*

**POU W PA ANSENT,
KI SAN DANJE EPI
100%
SAN ÒMÒN**



Paragard se yon ti IUS (sistèm andedan matris) ki anpeche w ansent toutotan ou vle pandan yon peryòd tan ki rive jiska 10 lane. Li fonksyone yon lòt jan avèk yon sibstans aktif senp—kwiv—nan plas òmòn yo.

IUS yo, tankou Paragard, yo te mete yo nan kategori enfeksyon nan zo basen (pelvic inflammatory disease, PID) ak risk akselere. Pinga w sèvi ak Paragard si w gen enfeksyon nan zo basen), kèk kalite kansè, si w alèji ak kwiv, gen maladi Wilson, oswa PID (enfeksyon nan zo basen). Tanpri verifye Enfòmasyon Enpòtan adisyonèl sou Sekirite yo ki nan depliyan sa a ansanm ak Enfòmasyon Preskripsyon Konplè ki akonpaye li yo.

Kisa Paragard ye ?

Paragard se yon ti IUS (sistèm andedan matris) 100% san òmòn ki sèvi sèlman ak yon (1) senp konpozan ki anpeche ou ansent nan 99% ka yo.

Yon pwofesyonèl swen sante ap mete li nan matris ou pandan vizit regilye ou nan biwo a nan annik kèk minit. Kote yo fin mete li nan matris ou an, sa ap anpeche ou tonbe ansent pou yon ti tan oswa toutotan ou vle—jiska 10 lane.

Yo fabrike Paragard esansyèlman an plastik lejè, elastik ki gen yon ti kouch kwiv ki vlope li nan nivo bra yo ak tij la.



IUS=IUD

*Se yon pwofesyonèl swen sante ki dwe retire li.

*Verifye ansanm ak pwofesyonèl asirans ou an pou w konnen ki kouvèti asirans ki gen rapò ak plan asirans endividyèl ou an. Pou yo mete Paragard pou ou yo kapab pran kèk frè pou pwosedi a.

Enfòmasyon Enpòtan sou Sekirite

- Si w pa gen règ ou pou yon mwa, ou gen doule anba ti vant san rete, oswa si Paragard sòti, di pwofesyonèl swen sante (healthcare provider, HCP) ou a sa. Si li sòti, itilize yon lòt metòd ki kontwole pou w pa ansent pou ranplase li.

Tanpri verifye Enfòmasyon Enpòtan adisyonèl sou Sekirite yo ki nan depliyans a a ansanm ak Enfòmasyon Preskripsyon Konplè ki akonpaye li yo.

Poukisa pou w chwazi Paragard ?



Li san danje, epi **100% san òmòn**



Li efikas a plis pase **99%**



Li fonksyone yon lòt jan avèk annik **yon (1) senp konpozan aktif kis se**—kwiv



Pa genyenvòmòn, **pa gen efè segondè ki gen rapò ak òmòn**



Pa genyen traka epi **pa mande anpil tan**—pa genyen grenn, ale ranplase chak mwa, oswa pratik regilye ki kontwole pou w pa ansent



Li dire jiska 10 lane men w kapab retire li nenpòt kilè avan dis lane a si w ta renmen ansent*



Yo mete li byen rapid san yo pa fè chiriji pandan yon vizit regilye nan biwo a annik nan kèk minit



Se sèl IUS **FDA apwouve pou plis pase 30 lane**



Majorite fanm ki gen asirans kapab resevwa Paragard **gratis***



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Kijan Paragard Fonksyone



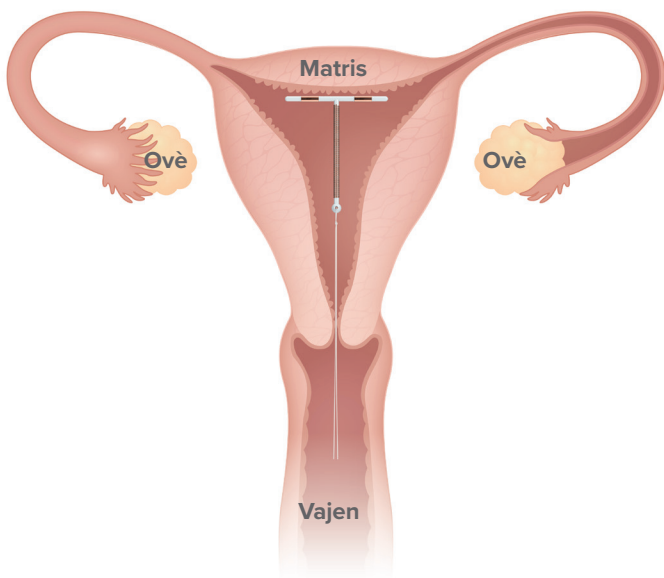
Li fonksyone annik avèk yon (1) senp konpozan aktif—kwiv—nan plas òmòn yo.



Paragard anpeche espèm lan rive jwenn epi fètilize ak ovil la epi kapab anpeche fekondasyon an tou.



Paske Paragard 100% san òmòn, li p ap anpeche w gen règ ou chak mwa* oswa anpeche w ovile chak mwa.



*Avèk Paragard règ ou kapab koule pi plis epi pi lontan avèk tach ladan li. Nan kòmansman, san an kapab koule pi plis pase òdinèman.

Enfòmasyon Enpòtan sou Sekirite

- Paragard kapab tache oswa rantre nan matris la epi bay lòt pwoblèm.

Tanpri verifiye Enfòmasyon Enpòtan adisyonèl sou Sekirite yo ki nan depliyon sa a ansanm ak Enfòmasyon Preskripsyon Konplè ki akonpanye li yo.



Èske w te konnen ?

Paragard se yon IUS ki fèt ak kwiv FDA apwouve ki fè prèv li pou plis pase 30 lane ki san danje epi efikas.

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Kisa pou Espere ak Paragard

Ak Paragard, gen...



pratik regilye

oswa ranplase
ak traka



verifikasyon kijan fil yo ye

fè li pou
kont ou



randevou

- youn pou mete li
- lèt la se sou yon mwa annapre plasman an pou asire w Paragard toujou menm kote li dwe ye a*



Enfòmasyon Enpòtan sou Sekirite

- Li difisil pou ansent ak Paragard men li kapab mete lavi an danje epi li kapab rann esteril oswa fè avòtman.

Tanpri verifiye Enfòmasyon Enpòtan adisyonèl sou Sekirite yo ki nan depliyon sa a ansanm ak Enfòmasyon Preskripsyon Konplè ki akonpanye li yo.

Plasman Paragard

Yon pwofesyonèl swen sante ap mete Paragard san li pa fè chiriji pandan yon vizit regilye nan biwo a annik nan kèk minit. Tout moun pa menm, kèk fanm kapab pa alèz pandan y ap mete li oswa apre. Pandan Paragard ap rantre, ou kapab gen kranp oswa yon ti pike; kèk fanm kapab santi yo yon jan anvi endispoze, gen vètij, oswa toule de pou kèk minit annapre.

Apre plasman

Menm kote yo fin mete Paragard, ou pa ta dwe santi li ankò. Ou kapab toujou kontinye sèvi ak kotèks epi ni ou ni patnè ou a pa ta dwe santi li pandan rapò seksyèl yo.

Nan kòmansman, san an kapab koule pi plis epi pi lontan avèk tach ladan li; òdinèman l ap diminye tanzantan. Si sa pèsiste, kontakte pwofesyonèl swen sante ou an.

Suivi

Vizite pwofesyonèl swen sante ou an pou yon tchekòp sou yon mwa pou asire w Paragard toujou menm kote li dwe ye a.*

Li bon pou w verifiye si Paragard nan matris la pandan w ap fè sa pou kont ou pandan w ap verifiye fil yo. Apre w fin lave men w ak dlo epi savon, rive nan tèt vajen an ak dwèt ou yo pwòp pou w manyen 2 fil yo.

*Selon jan w ye ak li, ou kapab pran randevou adisyonèl pou asire Paragard toujou menm kote li ta dwe ye a.

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Ki Kote yo Klase Paragard?

Èske Paragard Bon pou Ou ?

Paragard efikas a plis pase 99%—se youn nan metòd pi efikas pou kontwòl pou w pa ansent ki disponib.

Si w reponn "dakò" "avèk" youn nan kondisyon sa yo, chita pale sou Paragard ak pwofesyonèl swen sante ou an pou w konnen si l ap bon pou ou.



1. Mwen enterese nan metòd ki kontwòl pou m pa ansent ki **100% san òmòn**

☐ Dakò

☐ Pa Dakò

2. Mwen bezwen yon metòd ki kontwòl pou m pa ansent ki **efikas anpil**

☐ Dakò

☐ Pa Dakò

3. Mwen **te fè yon move eksperyans** ak yon metòd ki kontwòl pou m pa ansent otrefwa ki te gen òmòn ki te gen yon efè segondè

☐ Dakò

☐ Pa Dakò

4. Mwen vle bay kò mwen yon **repo ak metòd ki kontwòl pou m pa ansent ki gen òmòn** paske m ap itilize li sa gen lontan

☐ Dakò

☐ Pa Dakò

5. Mwen vle yon metòd ki kontwòl pou m pa ansent **ki pa mande anpil tan** epi ki pa egzije yon pratik regilye

☐ Dakò

☐ Pa Dakò

6. Mwen vle yon metòd k ap kontwòl pou m pa ansent **ki rete plis lontan posib menm kapab chanje li** si mwen chanje lide

☐ Dakò

☐ Pa Dakò

Trussell J. Echèk kontraseptif Ozetazini. *Planin*. 2011;83:397-404.

Enfòmasyon Enpòtan sou Sekirite

• Avèk Paragard règ ou kapab koule pi plis epi plis lontan avèk tach ladan li. Nan kòmansman, san kapab koule pi plis pase òdinèman.

Tanpri verifie Enfòmasyon Enpòtan adisyonèl sou Sekirite yo ki nan depliyon sa a ansanm ak Enfòmasyon Preskripsyon Konplè ki akonpanye li yo.

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Pri Ak Kouvèti Asirans



Pifò fanm ki gen asirans kapab resevwa Paragard gratis

Pifò plan asirans kouvri Paragard nèt—sa a kapab vle di ou pa genyen pou bay kopeman, dediktib, oswa frè ak lajan ki sòti nan pòch.*



Ou kapab verifeye Paragard nan kouvèti asirans ou an nan 2 fason:

1 Kontakte konpayi asirans ou an dirèk

oswa

2 Mande yon Rapò Verifikasyon Avantaj Paragard yo gratis

1. Rele Sèvis Kliyantèl la nan nimewo ki nan do kat asirans ou an
2. Di yo Paragard se yon metòd ki kontwole pou w pa ansent yon pwofesyonèl swen sante bay
3. Mande pou yo verifeye si Lwa Swen Abòdab la kouvri Paragard
4. Ba yo kòd J a pou Paragard: **J7300**
5. Mande si w pral gen pou w peye nenpòt frè ak lajan ki sòti nan pòch, oswa si plan asirans ou an annik kouvri Paragard an pati

Nan telefòn :

1. Rele nan **1-877-PARAGARD**
2. Espesyalis verifikasyon avantaj nou yo pral ede w konfime kouvèti asirans ki gen rapò ak plan asirans endividyèl ou an

Anliy :

1. Ale Vizite **Paragardbvsp.com**
2. Ranpli epi soumèt Fòm elektwonik Otorizasyon Pasyan
3. Mande pwofesyonèl swen sante ou an pou li soumèt yon Fòm Rekòmandasyon Pasyan pou ou
 - Menm kote yo resevwa toude fòm yo, w ap resevwa yon rapò detaye k ap di ki kouvèti asirans ou gen nan Paragard
 - Si w gen nenpòt kesyon oswa gen bezwen èd ak pwosesis sa a, rele nan **1-877-PARAGARD**

*Verifeye ansanm ak pwofesyonèl asirans ou an pou w konnen ki kouvèti asirans ki gen rapò ak plan asirans endividyèl ou an. Pou yo mete Paragard pou ou, yo kapab pran kèk frè pou pwosedi a.

Tanpri verifeye Enfòmasyon Enpòtan adisyonèl sou Sekirite yo ki nan depliyon sa a ansanm ak Enfòmasyon Preskripsyon Konplè ki akonpaye li yo.

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Ou ta renmen elimine òmòn ?
Kontakte Paragard.

100%
SAN ÒMÒN

LI EFIKAS
A PLIS PASE
99%

1 KONPOZAN
AKTIF SENP

Vizite Paragard.com oswa rele nan
1-877-PARAGARD.



Paragard p ap pwoteje w kont VIH oswa MST yo.

Ou menm sèlman ak HCP ou an ki an mezi pou deside si Paragard ap bon pou ou. San preskripsyon li pa disponib.

Yo ankouraje ou pou w deklare efè segondè negatif medikaman sou preskripsyon yo nan FDA sou www.fda.gov/medwatch oswa rele nan 1-800-FDA-1088.

Tanpri verifye Enfòmasyon Enpòtan adisyonèl sou Sekirite yo ki nan depliyon sa a ansanm ak Enfòmasyon Preskripsyon Konplè ki akonpaye li yo.

Paragard se yon mak anrejistre CooperSurgical, Inc.

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PATIENT INFORMATION

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

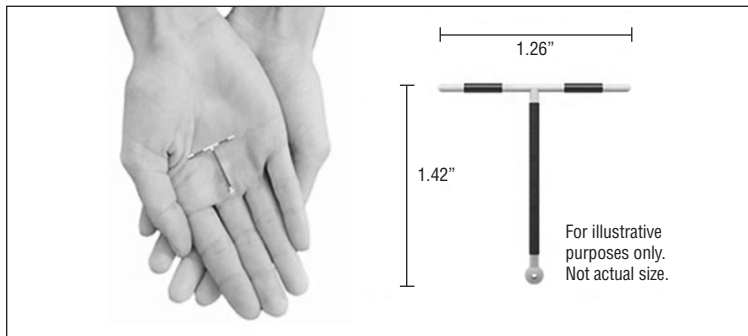
Paragard does not protect against HIV infection (AIDS) or other sexually transmitted infections (STIs).

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?

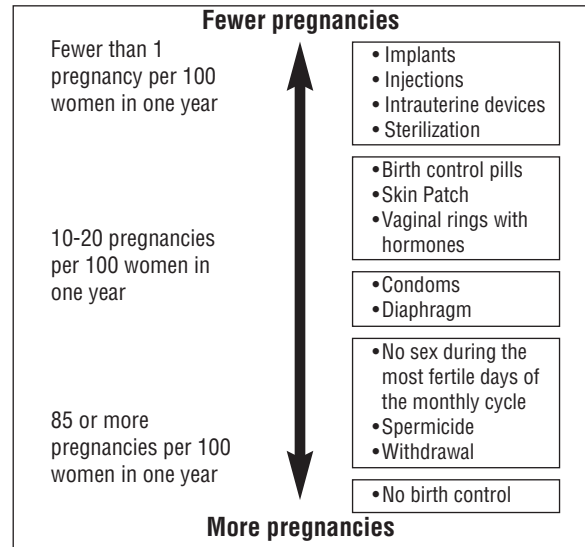
Paragard works by preventing sperm from reaching the egg, preventing sperm from fertilizing the egg, or possibly preventing attachment (implantation) in the uterus. Paragard does not stop your ovaries from making an egg (ovulating) each month.

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:

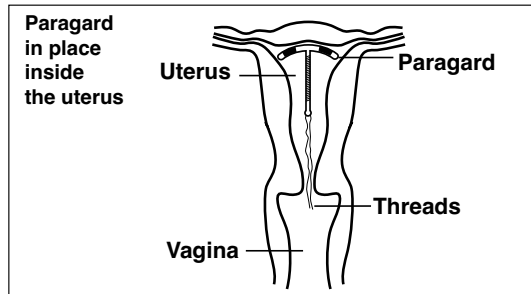
- any of the conditions listed above
- slow heart beat (bradycardia)
- dizziness (syncope)
- seizures
- recently had a baby or if you are breastfeeding
- have AIDS, HIV, or any other sexually transmitted infection

How is Paragard placed?

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

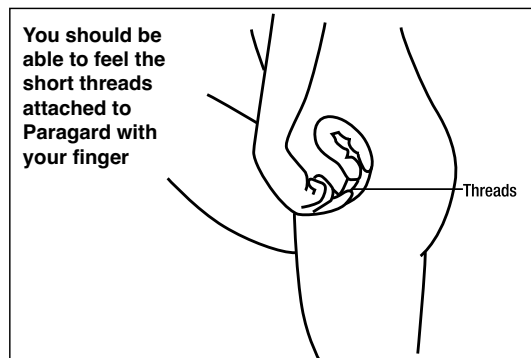
First, your healthcare provider will examine your pelvis to find the exact position of your uterus. Your healthcare provider will then cleanse your vagina and cervix with an antiseptic solution and then, measure your uterus. Your healthcare provider will then slide a plastic tube containing

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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