

Hoja informativa

Spanish

Le presentamos al DIU (dispositivo intrauterino) Paragard® – el único método anticonceptivo que utiliza solo 1 sencillo ingrediente activo para prevenir el embarazo con más de 99 % de efectividad sin hormonas.

¿Qué es Paragard?



100 % libre de hormonas

Paragard es un anticonceptivo que impide el embarazo sin usar hormonas.



Más del 99 % de efectividad

Tiene más del 99 % de efectividad: uno de los métodos anticonceptivos más eficaces disponibles.



Dura hasta 10 años

Dura hasta 10 años, pero puede ser retirado por un profesional médico en cualquier momento si decide que desea quedar embarazada. Después de retirarlo, los efectos de Paragard son reversibles de inmediato.



Sin rutinas diarias

No es necesario seguir una rutina diaria, ni tendrá problemas para surtir medicamentos; solo una revisión mensual de los hilos.



Aprobado por la FDA por más de 30 años

Cómo funciona Paragard



1 sencillo ingrediente activo

Funciona con cobre en lugar de hormonas, por lo que no detendrá su ciclo menstrual natural.* Paragard evita que el espermatozoides llegue al óvulo y lo fertilice, y también puede prevenir la implantación.

Colocación de Paragard



Colocación no quirúrgica

Un proveedor de atención médica lo coloca en su útero durante una consulta de rutina.

Qué esperar

Cuando esté colocado, no debería sentir el dispositivo Paragard dentro del útero, excepto por los dos hilos delgados que se extienden desde su cuello uterino. Puede seguir usando tampones y usted y su pareja no deben sentirlo durante las relaciones sexuales.

Al principio los períodos pueden ser más abundantes y prolongados, con manchas entre ellos; usualmente eso disminuye con el tiempo.

Costo



La mayoría de las mujeres que tienen seguro pueden recibir Paragard sin costo

Paragard está totalmente cubierto por la mayoría de los planes de seguro, por lo que podría no tener que cubrir copagos, deducibles ni desembolsos por cuenta propia.

Consulte a su compañía de seguros para confirmar la cobertura de su plan individual. Podría tener que cubrir honorarios por el procedimiento de colocación de Paragard.

Información importante de seguridad

- No use Paragard si está o podría estar embarazada, si tiene fibroides o una infección pélvica, incluyendo enfermedad inflamatoria pélvica (EIP), si contrae infecciones con facilidad o si tiene ciertos cánceres, hemorragias inexplicadas, enfermedad de Wilson o alergia al cobre. Los DIU, entre los que se encuentra Paragard, se han asociado con un mayor riesgo de EIP.
- El embarazo con Paragard es raro, pero puede poner en peligro la vida y causar infertilidad o pérdida del embarazo.
- Paragard puede adherirse o atravesar el útero y causar otros problemas.
- Consulte a su proveedor de atención médica (HCP) si siente un dolor intenso o tiene fiebre poco después de la colocación, si omite un periodo, siente dolor abdominal, o si el dispositivo Paragard se sale. Si se sale, use un método anticonceptivo alternativo.
- Informe a su proveedor de atención médica (HCP) que tiene Paragard antes de hacerse un estudio de IRM o un procedimiento médico que use terapia térmica.
- Al principio los períodos pueden ser más abundantes y prolongados, con manchas entre ellos.
- Otros efectos secundarios comunes son anemia, dolor durante las relaciones sexuales, dolor de espalda y secreciones vaginales.
- Paragard no protege contra el VIH ni contra enfermedades de transmisión sexual.

Solo usted y su proveedor de atención médica pueden decidir si Paragard es la mejor opción para usted. Disponible solo con receta médica.

Le recomendamos reportar los efectos secundarios negativos de los medicamentos recetados a la FDA, en www.fda.gov/medwatch o llamando al 1-800-FDA-1088.

Puede consultar un resumen de información para pacientes en la siguiente página.

* Al principio los periodos pueden ser más abundantes y prolongados, con manchas entre ellos.





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 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 intra-uterine 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 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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