Paragard[®]

simple, honest pregnancy prevention™

Planin ki ABSOLIMAN POZITIVMAN 100% SAN OKENN OMON

Paragard se yon esterilè (dispozitif entra-iterin) ki pa gen okenn òmòn ladan I e ki gen plis pase 99% chans pou I efikas nan anpeche gwosès. Li fonksyone diferaman paske li itilize yon sèl engredyen senp—kwiv—alaplas de òmòn.

Piga itilize Paragard si w gen yon enfeksyon nan basen oswa si w gen sèten kansè. Pami moun ki itilize li, gen mwens pase 1% ladan yo ki gen yon enfeksyon grav yo rele maladi enflamatwa pèlvyen (PID).

Tanpri gade lòt Enfòmasyon Enpòtan sou Sekirite ki nan bwochi sa a ak Enfòmasyon sou Preskripsyon Konplè yo.

Kisa Paragard ye?

Pouki pou w chwazi Paragard?

Paragard se yon ti esterilè (dispozitif entra-iterin) ki 100% san okenn òmòn ladan l e ki itilize 1 senp engredyan aktif pou anpeche gwosès plis pase 99% nan fwa yo.

Yon pwofesyonèl swen sante mete I nan matris ou pandan yon vizit klinik woutin e sa pran detwa minit sèlman. Yon fwa yo fin mete I, li anpeche gwosès regilyèman pandan yon ti tan oswa pandan lontan; selon sa w vle—jiska 10 lane.

> Paragard konpoze avèk yon plastik mou, fleksib ki vlope nan yon ti kouch kwiv. Yon fwa li fin anplas, ou pa sipoze santi l ditou.

Li absoliman, pozitivman **100% san okenn òmòn**

Gen plis pase 99% chans pou l efikas—li pi efikas pase kèlkeswa lòt metòd planin ki pa gen òmòn ladan l*—ak pifò metòd òmonal yo



Li fonksyone diferaman paske li itilize sèlman **1** senp engredyan aktif—kwiv



Pa gen òmòn ladan l, **pa gen efè segondè ki gen rapò ak òmòn**



San traka e li mande yon antretyen minim pa gen grenn pou pran chak jou ni pa gen preskripsyon pou renouvle chak mwa



Li dire jiska 10 lane men ou ka retire l nenpòt lè, pi bonè si w deside ou vle tonbe ansent⁺



Plasman rapid san okenn chiriji ke yo fè pandan yon vizit klinik woutin ki dire detwa minit sèlman



Sèl Esterilè (IUD) **ke FDA apwouve pou plis ke** 30 Iane

Li ka koute \$0 avèk laplipa plan asirans yo‡



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*Esterilizasyon pa ladan l.

*Se yon pwofesyonèl swen sante ki pou retire l.

[‡]Verifye avèk konpayi asirans ou an pou konfime si plan endividyèl ou a kouvri I. Ka gen frè ki aplike pou pwosedi plasman Paragard Ia.

Enfòmasyon Enpòtan sou Sekirite

 Si w rate yon règ, si w gen doulè nan abdomèn k ap pèsiste oswa si dispozitif Paragard la sòti, fè pwofesyonèl swen sante (HCP) w la konn sa. Si li sòti, itilize yon metòd planin kòm bakòp.

Tanpri gade lòt Enfòmasyon Enpòtan sou Sekirite ki nan bwochi sa a ak Enfòmasyon sou Preskripsyon Konplè yo.

Kijan Paragard Fonksyone

Yon fwa li fin anplas, Paragard kòmanse travay imedyatman



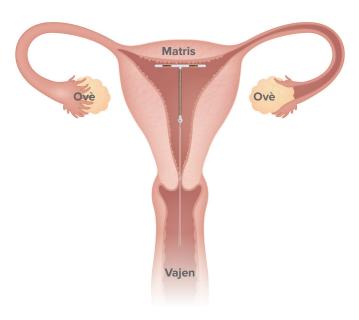
Kwiv ki nan Paragard lan fonksyone pou l anpeche espèm la kontre ak ovil la pou l fètilize l e li ka anpeche enplantasyon tou



Kòm Paragard 100% san okenn òmòn, li pa entèfere ak sik natirèl kò w ni li pa anpeche w ovile chak mwa



Ovilasyon mennen tout kalite byennèt ak bèl avantaj—ki afekte imè w, po w, zo w yo, sante kè a, ak menm apeti seksyèl ou





Èske w te konnen?

Kwiv ki nan Paragard la gen apwobasyon FDA pou plis pase 30 lane e yo pwouve ke li san danje ak efikas pou rezon klinik.

Enfòmasyon Enpòtan sou Sekirite

 Nan ka ki prezante raman, Paragard ka tache oswa li ka pase nan matris la epi l ka lakòz lòt pwoblèm. Gwosès avèk Paragard pa rive souvan men li ka menase lavi epi koze enfètilite oswa foskouch.

Tanpri gade lòt Enfòmasyon Enpòtan sou Sekirite ki nan bwochi sa a ak Enfòmasyon sou Preskripsyon Konplè yo.

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Ak kisa pou w atann ou avèk Paragard

Avèk Paragard, genyen...









Enfòmasyon Enpòtan sou Sekirite
Paragard pa pwoteje kont VIH ni kont Maladi ki Seksyèlman Transmisib (STD yo).

Tanpri gade lòt Enfòmasyon Enpòtan sou Sekirite ki nan bwochi sa a ak Enfòmasyon sou Preskripsyon Konplè yo.

Plasman Paragard

Plasman Paragard fèt san chiriji e se yon pwofesyonèl swen sante ki mete l pandan yon vizit klinik woutin ki pran detwa minit sèlman. Gen sèten fanm ki ka gen kranp, doulè ak/oswa toudisman pandan ak apre yo fin plase Paragard. Pou ede minimize kranp yo, mande pwofesyonèl swen sante w la pou rekòmande w medikaman pou soulaje doulè ke yo vann san preskripsyon.

Apre plasman an

Yon fwa li fin anplas, ou pa sipoze santi Paragard ditou. Ou ka kontinye itilize tanpon e oumenm oswa patnè w la pa sipoze santi l lè n ap fè sèks.

Ou ka senyen epi w ka gen ti tach san anplis pandan 2-3 premye mwa yo, men anjeneral sa diminye apre yon tan. Si efè segondè yo kontinye, kontakte pwofesyonèl swen sante w la.

Swivi

Ale kay pwofesyonèl swen sante w la pou yon tchèkòp apeprè yon mwa apre plasman an pou asire Paragard rete kote l dwe ye a.*

Li toujou bon pou pran abitid pou verifye ke Paragard nan matris la lè w fè ti kontwòl oumenm pou fil yo. Pou fè sa: avèk dwèt ou yo ki byen pwòp foure yo jouk anlè nan vajen w pou w santi fil yo, men asire w ke w pa rale yo. Si w gen difikilte pou w jwenn oswa si w santi plis pase fil yo, rele pwofesyonèl swen sante w la touswit epi itilize lòt metòd planin kòm bakòp.

*Toudepannde eksperyans ou, li ka nesesè pou w gen randevou adisyonèl pou asire Paragard nan bon pozisyon an.



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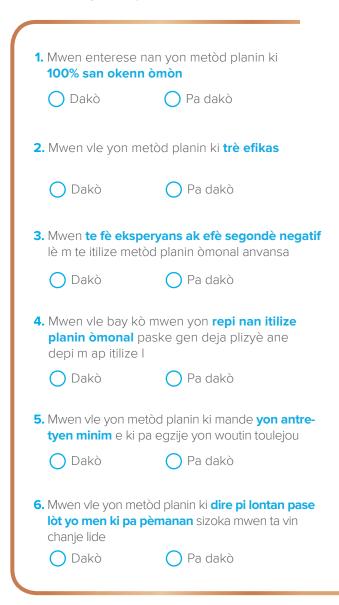
Kijan Paragard Konpare ak lòt metòd yo?

Èske Paragard se bon chwa a pou Ou?

Paragard gen plis pase 99% chans pou li efikas youn nan metòd planin ki pi efikas ki disponib la.



Si ou reponn "dakò" pou nenpòt nan deklarasyon sa yo, pale avèk pwofesyonèl swen sante w la pou konnen si Paragard se yon bon chwa pou ou.



Enfòmasyon Enpòtan sou Sekirite

• Ou ka senyen epi w ka gen ti tach san anplis pandan 2-3 premye mwa yo, men anjeneral sa diminye apre yon tan.

Tanpri gade lòt Enfòmasyon Enpòtan sou Sekirite ki nan bwochi sa a ak Enfòmasyon sou Preskripsyon Konplè yo.

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Paragard.

pregnancy prevention™

intrauterine copper contraceptive

Pri sa Koute ak Pwoteksyon Asirans



Laplipa fanm ki gen asirans peye **\$0**

Pifò plan asirans yo kouvri pri sa koute pou Esterilè Paragard la okonplè—sa ka vle di, ou pa peye okenn kopeman, franchiz, oswa depans pou frè k ap soti nan pòch ou.*

Ou kapab verifye pwoteksyon asirans ou an pou Paragard, nan 2 fason:

Mande yon Rapò Paragard Benefits Verification[™] (Verifikasyon sou Avantaj Paragard) ki gratis

Nan telefòn:

- 1. Rele nan 1-877-PARAGARD
- Espesyalis nou yo ki responsab verifikasyon avantaj yo pral ede w konfime si w gen pwoteksyon nan plan endividyèl ou a

Sou entènèt la:

- 1. Ale nan sitwèb la nan Paragardbvsp.com
- **2.** Ranpli epi soumèt yon Fòmilè Otorizasyon Pasyan sou fòm elektwonik
- Mande pwofesyonèl swen sante w la pou l soumèt yon Fòmilè Rekòmandasyon pou Pasyan
 - Dèke nou resevwa toude fòmilè yo, yo pral voye yon rapò detaye ba ou ki montre pwoteksyon asirans ou pou Paragard
 - Si w gen nenpòt kesyon oswa si w bezwen èd avèk pwosesis sa a, rele nan
 1-877-PARAGARD

*Verifye avèk konpayi asirans ou an pou konfime si plan endividyèl ou a kouvri I. Ka gen frè ki aplike pou pwosedi plasman Paragard Ia.

Tanpri gade lòt Enfòmasyon Enpòtan sou Sekirite ki nan bwochi sa a ak Enfòmasyon sou Preskripsyon Konplè yo.

2

oswa

Kontakte konpayi asirans ou an dirèkteman

- 1. Rele nimewo sèvis kliyan an ki sou do kat asirans ou an
- **2.** Di yo ke Paragard se yon metòd planin ke pwofesyonèl swen sante administre
- Mande yo verifye si Paragard kouvri anba Lwa sou Swen pou Pri Abòdab (Affordable Care Act) la
- 4. Ba yo kòd J a pou Paragard: J7300
- Mande si w ap gen pou fè depans ak lajan k ap soti nan pòch ou, oswa si Paragard kouvri pasyèlman nan plan w lan



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Ou vie yon metòd ki pa gen okenn òmòn ladan i? Ensiste pou yo ba w Paragard.

100% SAN OKENN ÒMÒN

GEN PLIS PASE 9970 CHANS POU LI EFIKAS

1 SENP ENGREDYAN AKTIF

Ale sou sitwèb Paragard.com oswa rele nan 1-877-PARAGARD

Se sèl oumenm ak Pwofesyonèl Swen Sante (HCP) w la ki kapab deside si Paragard se bon chwa pou ou. Li disponib sou preskripsyon sèlman.

Nou ankouraje w pou rapòte bay FDA efè segondè negatif medikaman sou preskripsyon konn bay, nan www.fda.gov/medwatch oswa ou ka rele nan 1-800-332-1088.

Paragard se yon mak komèsyal anrejistre pou CooperSurgical, Inc. ©operSurgicol © 2019 CooperSurgical, Inc. US-PAR-1900052 Jen 2019



Patient Package

Este panfleto también lo hay en español

INFORMATION FOR PATIENTS

Paragard® T 380A Intrauterine Copper Contraceptive

Paragard[®] T 380A Intrauterine Copper Contraceptive is used to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

It is important for you to understand this brochure and discuss it with your healthcareprovider before choosing Paragard® T 380A Intrauterine Copper Contraceptive (Paragard®). You should also learn about other birth control methods that may be an option for you.

What is Paragard[®]?

Paragard[®] is a copperreleasing device that is placed in your uterus to prevent pregnancy for up to 10 years.



. . . .

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Paragard[®] is made of white plastic in the shape of a "T." Copper is

wrapped around the stem and arms of the "T". Two white threads are attached to the stem of the "T". The threads are the only part of Paragard[®] that you can feel when Paragard[®] is in your uterus. Paragard[®] and its components do not contain latex.

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.

What if I change my mind and want to become pregnant?

Your healthcare provider can remove Paragard[®] at any time. After discontinuation of Paragard[®], its contraceptive effect is reversed.

How does Paragard® work?

Ideas about how Paragard[®] works include preventing sperm from reaching the egg, preventing sperm from fertilizing the egg, and possibly preventing the egg from attaching (implanting) in the uterus. Paragard[®] does not stop your ovaries from making an egg (ovulating) each month.

How well does Paragard® work?

Fewer than 1 in 100 women become pregnant each year while using Paragard $^{\circledast}\!\!\!$.

The table below shows the chance of getting pregnant using different types of birth control. The numbers show *typical* use, which includes people who don't always use birth control correctly.

Number of women out of 100 women who are likely to get pregnant over one year

Method of birth control	Pregnancies per 100 women over one year		
No Method	85		
Spermicides	26		
Periodic abstinence	25		
Cap with Spermicides	20		
Vaginal Sponge	20 to 40		
Diaphragm with Spermicides	20		
Withdrawa	19		
Condom without spermicides (female)	21		
Condom without spermicides (male)	14		
Oral Contraceptives	5		
IUDs, Depo-Provera, implants, sterilization	less than 1		

Who might use Paragard®?

You might choose Paragard® if you

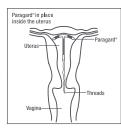
- need birth control that is very effective
- need birth control that stops working when you stop using it
- need birth control that is easy to use
- Treed birth control that is easy to us

Who should not use Paragard®?

- You should not use $\mathsf{Paragard}^{\circledast}$ if you
- Might be pregnant
- · Have a uterus that is abnormally shaped inside
- Have a pelvic infection called pelvic inflammatory disease (PID) or have current behavior that puts you at high risk of PID (for example, because you are having sex with several men, or your partner is having sex with other women)
- Have had an infection in your uterus after a pregnancy or abortion in the past 3 months
- Have cancer of the uterus or cervix
- Have unexplained bleeding from your vagina
- · Have an infection in your cervix
- · Have Wilson's disease (a disorder in how the body handles copper)
- Are allergic to anything in Paragard®
- Already have an intrauterine contraceptive in your uterus

How is Paragard[®] placed in the uterus?

Paragard[®] is placed in your uterus during an office visit. Your healthcare provider first examines you to find the position of your uterus. Next, he or she will cleanse your vagina and cervix, measure your uterus, and then slide a plastic tube containing Paragard[®] into your uterus. The tube is removed, leaving Paragard[®] inside your uterus. Two white threads 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. Some women feel faint, nauseated, or dizzy for a few minutes afterwards. Your healthcare provider may ask you to lie down for a while and to get up slowly.

How do I check that Paragard[®] is in my uterus?

Visit your healthcare provider for a check-up about one month after placement to make sure Paragard[®] is still in your uterus.

You can also check to make sure that $Paragard^{\otimes}$ is still in your uterus by reaching up to the top of your vagina with clean fingers to feel the two threads. Do not pull on the threads.

If you cannot feel the threads, ask your healthcare provider to check if $Paragard^{\oplus}$ is in the right place. If you can feel more of $Paragard^{\oplus}$ than

ECR #2521 P/N 1016806

just the threads, Paragard[®] is *not* in the right place. If you can't see your healthcare provider right away, use an additional birth control method. If Paragard[®] is in the wrong place, your chances of getting pregnant are increased. It is a good habit for you to check that Paragard[®] is in place once a month.

You may use tampons when you are using Paragard[®].

What if I become pregnant while using Paragard[®]?



If you think you are pregnant, contact your healthcare professional *right away*. If you are pregnant and Paragard[®] is in your uterus, you may get a severe infection or shock.

have a miscarriage or prematurelabor and delivery, or even die. Because of these risks, your healthcare provider will recommend that you have Paragard[®] removed, even though removal may cause miscarriage.

If you continue a pregnancy with Paragard[®] in place, see your healthcare provider regularly. Contact your healthcare provider right away if you get fever, chills, cramping, pain, bleeding, flu-like symptoms, or an unusual, bad smelling vaginal discharge.

A pregnancy with Paragard[®] in place has a greater than usual chance of being ectopic (outside your uterus). Ectopic pregnancy is an emergency that may require surgery. An ectopic pregnancy can cause internal bleeding, infertility, and death. Unusual vaginal bleeding or abdominal pain may be signs of an ectopic pregnancy.

Copper in Paragard[®] does not seem to cause birth defects.

What side effects can I expect with Paragard®?

The most common side effects of Paragard® are heavier, longer periods and spotting between periods; most of these side effects diminish after 2-3 months. However, if your menstrual flow continues to be heav or long, or spotting continues, contact your healthcare provider.

Infrequently, serious side effects may occur:

- Pelvic inffammatory disease (PID): Uncommonly, Paragard[®] and other IUDs are associated with PID. PID is an infection of the uterus, tubes, and nearby organs. PID is most likely to occur in the first 20 days after placement. You have a higher chance of getting PID if you or your partner have sex with more than one person. PID is treated with antibiotics. However, PID can cause serious problems such as infertility, ectopic pregnancy, and chronic pelvic pain. Rarely, PID may even cause death. More serious cases of PID require surgery or a hysterectomy (removal of the uterus). Contact your healthcare provider right away if you have any of the signs of PID: abdominal or pelvic pain, painful sex, unusual or bad smelling vaginal discharge, chills, heavy bleeding, or fever.
- Difficult removals: Occasionally Paragard[®] may be hard to remove because it is stuck in the uterus. Surgery may sometimes be needed to remove Paragard[®].
- P erforation: Rarely, Paragard[®] goes through the wall of the uterus, especially during placement. This is called perforation. If Paragard[®] perforates the uterus, it should be removed. Surgery may be needed. Perforation can cause infection, scarring, or damage to other organs. If Paragard[®] perforates the uterus, you are not protected from pregnanoy.
- Expulsion: Paragard[®] may partially or completely fall out of the uterus. This is called expulsion. Women who have never been pregnant may be more likely to expel Paragard[®] than women who have been pregnant before. If you think that Paragard[®] has partly or completely fallen out, use an additional birth control method, such as a condom and call your healthcare provider.

You may have other side effects with Paragard[®]. For example, you may have anemia (low blood count), backache, pain during sex, menstrual cramps, allergic reaction, vaginal infection, vaginal discharge, faintness, or pain. This is not a complete list of possible side effects. If you have questions about a side effect, check with your healthcare provider.

When should I call my healthcare provider?

Call your healthcare provider if you have any concerns about ${\sf Paragard}^{\circledast}.$ 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
- Might be exposed to sexually transmitted diseases (STDs)
- 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 or prolonged vaginal bleeding
- Miss a menstrual period

General advice about prescription medicines

This brochure summarizes the most important information about Paragard[®]. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about Paragard[®] that is written for healthcare professionals.

Checklist

This checklist will help you and your healthcare provider discuss the pros and cons of Paragard[®] for you. Do you have any of the following conditions?

	Yes	No	Don't know
Abnormal Pap smear			
Abnormalities of the uterus			
Allergy to copper			
Anemia or blood clotting problems			
Bleeding between periods			
Cancer of the uterus or cervix			
Fainting attacks			
Genital sores			
Heavy menstrual flow			
HIV or AIDS			
Infection of the uterus or cervix			
IUD in place now or in the past			
More than one sexual partner			
Pelvic infection (PID)			
Possible pregnancy			
Repeated episodes of pelvic infection (PID)			
Serious infection following a pregnancy or abortion in the past 3 months			
Severe menstrual cramps			
Sexual partner who has more than one sexual partner			
Sexually transmitted disease (STD) such as gonorrhea or chlamydia			
Wilson's disease			

<u>CoperSurgical</u>

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