

IS PARAGARD® RIGHT FOR YOU?

Ask your doctor about the only reversible birth control that's more than 99% effective and 100% hormone free.

WHAT TO TELL YOUR DOCTOR

- How you feel about hormones
- How you feel about daily routines
- How you feel about having your period on its natural cycle
- Your likes and dislikes concerning past birth control options you've used
- Relationship basics and your views on family planning
- Your lifestyle and attitude toward health

WHAT TO ASK YOUR DOCTOR

- How does ParaGard® compare with other non-hormonal birth control options?
- Is ParaGard® as effective as hormonal birth control methods?
- Will my period be different, especially if I used to be on hormonal birth control?
- What can I expect once ParaGard® is placed?
- How would I do the monthly self-checks?
- Is ParaGard® safe?
- Do you think hormone-free ParaGard® is right for me?

You may find that you're ready to join other women like you who have discovered ParaGard®, birth control that fits your life, naturally.

ParaGard^{T 380A} 
intrauterine copper contraceptive



ParaGard^{T 380A}

intrauterine copper contraceptive

BIRTH CONTROL THAT FITS YOUR LIFE, NATURALLY.

Important Safety Information

- Do not use ParaGard[®] if you have a pelvic infection, get infections easily or have certain cancers. Less than 1% of users get a serious infection called pelvic inflammatory disease.
- If you have persistent pelvic or stomach pain, or if ParaGard[®] comes out tell your healthcare provider. If it comes out, use back-up birth control.
- In rare cases, ParaGard[®] may attach to or go through the uterine wall and cause other problems.
- Although uncommon, pregnancy while using ParaGard[®] can be life threatening and may result in loss of pregnancy or fertility.
- Bleeding or spotting may increase at first but should decrease in 2 to 3 months.
- **ParaGard[®] does not protect against HIV or STDs.**

You are encouraged to report negative side effects of prescription drugs to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying full prescribing information.

ParaGard[®] is a registered trademark of Teva Women's Health, Inc.



Women's Health

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- Establish the size and position of the uterus by pelvic examination.
- Insert a speculum and cleanse the vagina and cervix with an antiseptic solution.
- Apply a tenaculum to the cervix and use gentle traction to align the cervical canal with the uterine cavity.
- Gently insert a sterile sound to measure the depth of the uterine cavity.
- The uterus should sound to a depth of 6 to 9 cm except when inserting ParaGard® immediately post-abortion or post-partum. Insertion of ParaGard® into a uterine cavity measuring less than 6 cm may increase the incidence of expulsion, bleeding, pain, and perforation. If you encounter cervical stenosis, avoid undue force. Dilators may be helpful in this situation.

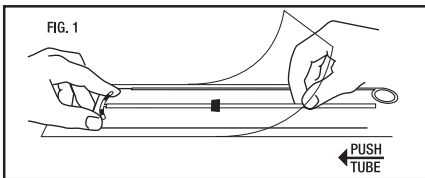
How to Load and Place ParaGard®:

Do not bend the arms of ParaGard® earlier than 5 minutes before it is to be placed in the uterus. Use aseptic technique when handling ParaGard® and the part of the insertion tube that will enter the uterus.

STEP 1

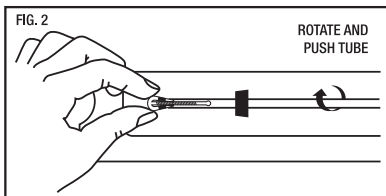
Load ParaGard into the insertion tube by folding the two horizontal arms of ParaGard against the stem and push the tips of the arms securely into the inserter tube.

If you do not have sterile gloves, you can do STEPS 1 and 2 while ParaGard® is in the sterile package. First, place the package face up on a clean surface. Next, open at the bottom end (where arrow says OPEN). Pull the solid white rod partially from the package so it will not interfere with assembly. Place thumb and index finger on top of package on ends of the horizontal arms. Use other hand to push insertion tube against arms of ParaGard® (shown by arrow in Fig. 1). This will start bending the T arms.



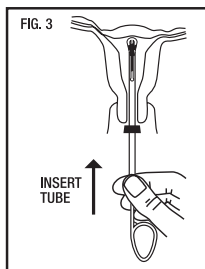
STEP 2

Bring the thumb and index finger closer together to continue bending the arms until they are alongside the stem. Use the other hand to withdraw the insertion tube just enough so that the insertion tube can be pushed and rotated onto the tips of the arms. Your goal is to secure the tips of the arms inside the tube (Fig. 2). Insert the arms no further than necessary to insure retention. Introduce the solid white rod into the insertion tube from the bottom, alongside the threads, until it touches the bottom of the ParaGard®.



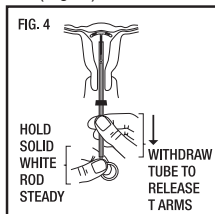
STEP 3

Grasp the insertion tube at the open end of the package; adjust the blue flange so that the distance from the top of the ParaGard® (where it protrudes from the inserter) to the blue flange is the same as the uterine depth that you measured with the sound. Rotate the insertion tube so that the horizontal arms of the T and the long axis of the blue flange lie in the same horizontal plane (Fig. 3). Now pass the loaded insertion tube through the cervical canal until ParaGard® just touches the fundus of the uterus. The blue flange should be at the cervix in the horizontal plane.



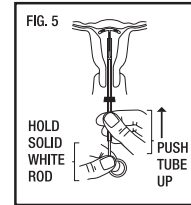
STEP 4

To release the arms of ParaGard®, hold the solid white rod steady and withdraw the insertion tube no more than one centimeter. This releases the arms of ParaGard® high in the uterine fundus (Fig. 4).



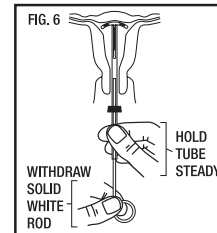
STEP 5

Gently and carefully move the insertion tube upward toward the top of the uterus, until slight resistance is felt. This will ensure placement of the T at the highest possible position within the uterus (Fig. 5).



STEP 6

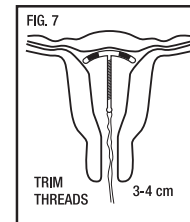
Hold the insertion tube steady and withdraw the solid white rod (Fig. 6).



STEP 7

Gently and slowly withdraw the insertion tube from the cervical canal. Only the threads should be visible protruding from the cervix. (Fig. 7). Trim the threads so that 3 to 4 cm protrude into the vagina. Note the length of the threads in the patient's records.

If you suspect that ParaGard® is not in the correct position, check placement (with ultrasound, if necessary). If ParaGard® is not positioned completely within the uterus, remove it and replace it with a new ParaGard®. Do not reinsert an expelled or partially expelled ParaGard®.



CAUTION

Instrumentation of the cervical os may result in vasovagal reactions, including fainting. Have the patient remain supine until she feels well, and have her get up with caution.

Continuing Care:

Following placement, examine the patient after her first menses to confirm that ParaGard® is still in place. **You should be able to see or feel only the threads.** If ParaGard® has been partially or completely expelled, remove it. You can place a new ParaGard® if the patient desires and if she is not pregnant. Do not reinsert a used ParaGard®.

Evaluate the patient promptly if she complains of any of the following:

- Abdominal or pelvic pain, cramping, or tenderness; malodorous discharge; bleeding; fever
- A missed period

(See **WARNINGS, Pelvic Infection, Intrauterine Pregnancy and Ectopic Pregnancy.**)

The length of the visible threads may change with time. However, no action is needed unless you suspect partial expulsion, perforation, or pregnancy.

If you cannot find the threads in the vagina, check that ParaGard® is still in the uterus. The threads can retract into the uterus or break, or ParaGard® can break, perforate the uterus, or be expelled. Gentle probing of the cavity, radiography, or sonography may be required to locate the IUD.

If there is evidence of partial expulsion, perforation, or breakage, remove ParaGard®.

How to Remove ParaGard®

Remove ParaGard® with forceps, pulling gently on the exposed threads. The arms of ParaGard® will fold upwards as it is withdrawn from the uterus. You may immediately insert a new ParaGard® if the patient requests it and has no contraindications.

Embedment or breakage of ParaGard® in the myometrium can make removal difficult. Analgesia, paracervical anesthesia, and cervical dilation may assist in removing an embedded ParaGard®. An alligator forceps or other grasping instrument may be helpful. Hysteroscopy may also be helpful.

HOW SUPPLIED

ParaGard® is available in cartons of 1 (one) sterile unit (NDC 51285-204-01). Each ParaGard® is packaged together with an insertion tube and solid white rod in a Tyvek® polyethylene pouch.

REFERENCES

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INFORMATION FOR PATIENTS

ParaGard® T 380A

Intrauterine Copper Contraceptive

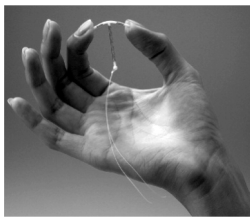
ParaGard® T 380A Intrauterine Copper Contraceptive is used to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

It is important for you to understand this brochure and discuss it with your healthcare provider 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 copper-releasing device that is placed in your uterus to prevent pregnancy for up to 10 years.

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 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®.

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
Withdrawal	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

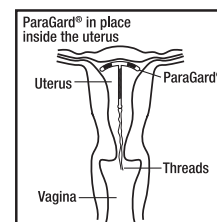
Who should not use ParaGard®?

You should not use ParaGard® 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?

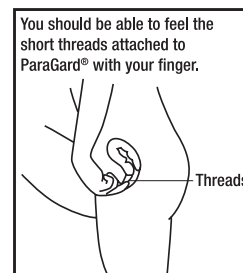
ParaGard® is placed in your uterus during an office visit. Your healthcare provider first examines you to find the position of your uterus. Next, he or she will cleanse your vagina and cervix, measure your uterus, and then slide a plastic tube containing ParaGard® into your uterus. The tube is removed, 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® 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® is in the right place. If you can feel more of ParaGard® than 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 premature labor 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 heavy or long, or spotting continues, contact your healthcare provider.

Infrequently, serious side effects may occur:

- Pelvic inflammatory 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®.
- Perforation: 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 pregnancy.
- 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 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
- 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

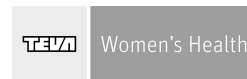
General advice about prescription medicines

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?

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



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Sellersville, PA 18960

PARA0111G - ADV

	Yes	No	Don't know
Abnormal Pap smear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abnormalities of the uterus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Allergy to copper	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>