ParaGard® T 380A
Intrauterine Copper Contraceptive

This product is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Your physician has determined that this product is likely to help your personal health. USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR PHYSICIAN. If you have any questions about alternates, consult your physician.

Introduction
The ParaGard® T 380A is the third generation of a family of copper-bearing IUDs which have been used extensively around the world. It is the first to contain copper on both the arms and the stem of the T. Tested in more than 3,500 women in the United States, the ParaGard® T 380A is the product of over a decade of research involving an international group of scientists and family-planning specialists. However, as with all methods of contraception, its use is associated with some risk. The purpose of this brochure is to explain those risks to you.

Important Notice
To understand the risks and benefits of the ParaGard® T 380A (Intrauterine Copper Contraceptive) you will need to read and understand this entire brochure and discuss it with your clinician. It contains information vital to your health. A more technical leaflet is available which is written for the medical professional. If you would like to read that leaflet, ask your clinician for a copy. You will need his/her help to understand some of the information.

If you have difficulty understanding any of the technical terms in this brochure, check the glossary on page 7 and ask your clinician for clarification.

Many clinicians consider IUDs to be the best contraceptive choice for certain women. The ParaGard® T 380A is most appropriately used by women who have had at least one child and are in a stable, mutually monogamous relationship, and those who require a reversible form of contraception, whether or not they feel they have completed their family.

In addition to reading this brochure, you should also learn about other reversible birth control methods. One of these methods may be more suitable or safer for you than the ParaGard® T 380A. In order to make the appropriate decision, you must discuss your questions about IUDs and other kinds of birth control with your clinician. Also, have the clinician explain to your satisfaction anything you do not understand in this brochure.

Under certain conditions you should not have the ParaGard® T 380A inserted; the risks to your health or your ability to bear children may be too great. Such conditions are described under *Special Risk Factors* and *What You Should Discuss With Your Clinician*. Even if none of these conditions applies to you, you may still experience serious problems while using the ParaGard® T 380A which will require immediate medical treatment. These medical problems could cause damage to your reproductive organs and the ability to bear children, or in some cases, could cause death. You may have to undergo major surgery, and you may become temporarily or permanently sterile (see *Special Risk Factors*). Prompt medical treatment, though absolutely necessary, may not be effective.

To become familiar with the danger signs of ParaGard® T 380A use, read *Side Effects*, *Adverse Reactions*, and *Warnings*. Always discuss these and other sections of the brochure with your clinician.

Description
The ParaGard® T 380A (Intrauterine Copper Contraceptive) is a type of IUD that contains copper, and is inserted into the uterus (womb) to prevent pregnancy. Like all other contraceptives it is not 100% effective. (See *Effectiveness* for pregnancy rates.)

The ParaGard® T 380A is flexible and T-shaped with copper on both of the arms and stem of the T. The T itself is made of a flexible plastic material. The ParaGard® T 380A must be replaced every 10 years to maintain its contraceptive effectiveness. Two white threads extend from the base of the ParaGard® T 380A. They will extend into your vagina to indicate the presence of the ParaGard® T 380A, and aid in its removal. The ParaGard® T 380A (Intrauterine Copper Contraceptive) is 36 mm in the vertical direction and 32 mm in the horizontal direction.

The Copper in the ParaGard® T 380A
Available data indicate that the contraceptive effectiveness of ParaGard® T 380A is enhanced by copper released continuously from the IUD into the uterine cavity. The ParaGard® T 380A differs from earlier copper IUDs in that it contains copper on the stem and horizontal arms of the T. The placement of the copper on the arms of the ParaGard® T 380A increases effectiveness.

How the ParaGard® T 380A Acts as a Contraceptive
How the ParaGard® T 380A prevents pregnancy is not completely understood at the present time. Several theories have been suggested, including interference with sperm transport, fertilization, and implantation. Clinical studies with copper-bearing IUDs suggest that fertilization is affected either due to an altered number or lack of viability of spermatozoa. IUDs do not prevent ovulation (production and release of an egg by the ovary).

The ParaGard® T 380A does not always prevent ectopic pregnancy (pregnancy outside the uterus, sometimes called tubal pregnancy). Ectopic pregnancy can require surgery, and can make you unable to bear children; in some cases it can cause death. (See *Special Risk Factors for Ectopic Pregnancy*.)

Effectiveness
In clinical trials the incidence of unplanned pregnancies in women who have used the ParaGard® T 380A continuously for one year was less than 1 per 100 woman-years. This means that if 100 women use the ParaGard® T 380A for a period of one year, one of these women would become pregnant. Data suggest that the pregnancy rate is higher in women under 20. The typical failure rates for all methods of birth control during the first year are listed below in Table 1.

Table 1 *Failure Rates for All Methods*

Oral Contraceptives	less than 3%	Condom alone	12%
ParaGard® T 380A	less than 1%	Periodic abstinence	20%
Diaphragm with Spermicides	18%	No method	85%
Vaginal Sponge	18% to 28%		

Continuation Rates
In clinical trials 5 to 6 women out of 100 expelled the system during the first year. During the first year the number of women in the clinical trials who used the ParaGard® T 380A continuously for one year was 77 to 80 per 100 users. 12% of the women discontinued use because of bleeding and pain.

Lack of Contraceptive Effect After ParaGard® T 380A Removal
After discontinuation of ParaGard® T 380A use, its contraceptive effect on the uterus is reversed. Usually, but not always, a woman is able to become pregnant. In a study of 293 women, 78.4% of women seeking pregnancy became pregnant within a year following discontinuation.

Special Risk Factors
The conditions discussed below can significantly increase your chances of developing serious complications while using an IUD. Some of these conditions can necessitate surgery, can make you unable to have children, or can cause death. Read the information carefully and discuss it with your clinician.

Special Risk Factors for Pelvic Infection
(Pelvic Inflammatory Disease)

Evidence indicates that ParaGard® T 380A users are more likely than other women to suffer a serious infection called pelvic inflammatory disease (PID), particularly in women with multiple sexual partners. PID is the medical term for infection in the upper pelvic area. This area includes the uterus (womb), fallopian tubes, ovaries, and surrounding tissues. (Vaginitis, local infection of the vagina, is not PID, but may lead to it.) Studies indicate that the highest rate of PID occurs shortly after insertion and up to 4 months thereafter. A study suggests the highest incidence occurs within 20 days post insertion, then falls, remaining constant thereafter. PID can cause permanent blockage of the tubes; sterility; ectopic pregnancy; or, in infrequent cases, death. If you have now or have ever had PID, you must not use the ParaGard® T 380A. PID is a serious infection caused by gonorrhea, chlamydia, or other microscopic organisms. Your chances of getting PID increase greatly if you have more than one sexual partner. Your risk of getting PID also increases if you have a sexual partner who has sexual intercourse with others. If you are exposed to such situations, you have an increased risk of getting PID and must not use the ParaGard® T 380A. You should consider the use of a barrier method which may provide partial protection against sexually transmitted diseases. Treatment of PID may require surgical removal of your uterus (hysterectomy), tubes, and ovaries. Such surgery may have to be done on an emergency basis, and may result in death. Removing the ovaries may result in a lifelong need for hormonal treatments. Symptoms of PID include pelvic or lower abdominal pain, chills, fever, abnormal vaginal discharge, abnormal menstrual bleeding, or painful sexual intercourse. PID can occur even without these symptoms.

If you are using the ParaGard® T 380A and develop any of these symptoms, see your clinician as soon as possible. If you have PID, you should receive appropriate antibiotics promptly, and the IUD should be removed at the appropriate time. Failure to seek and receive prompt and adequate treatment will greatly increase the chances that you will become sterile, require surgery, or have life-threatening or fatal PID. Even prompt and adequate treatment cannot guarantee that these events will not occur.

Special Risk Factors in Ectopic Pregnancy

Ectopic pregnancy is an infrequent, but dangerous type of pregnancy that develops outside the uterus. Current data indicate that the rate of ectopic pregnancy in women using ParaGard® T 380A is lower than among fertile women not using contraception. A pregnancy that occurs with the ParaGard® T 380A in place is more likely to be ectopic than a pregnancy occurring without the ParaGard® T 380A. If you have ever had an ectopic pregnancy, you have an increased risk of having another one. You also have an increased risk of an ectopic pregnancy if you have ever had certain types of infections. These infections include pelvic inflammatory disease (PID) or any venereal disease (VD) or sexually transmitted disease (STD) caused by, for example, gonorrhea or chlamydia. If you have ever had PID, you must not use the ParaGard® T 380A. Other contraceptive methods may be more suitable for you. Discuss this matter with your clinician.

Other Conditions that Increase Risk of Infection

Some conditions make you more susceptible to infection during ParaGard® T 380A use or following ParaGard® T 380A insertion. These conditions include leukemia and acquired immune deficiency syndrome (AIDS). In addition, certain defects or diseases

of the heart valves, such as rheumatic heart disease, and diabetes and long-term steroid therapy, make you more likely than other ParaGard® T 380A users to develop an infection which may involve the heart. If you have any of these conditions you should probably not use the ParaGard® T 380A. Discuss this matter with your clinician.

Side Effects

The following may occur while the ParaGard® T 380A is being inserted and while it is in place.

1. Pain, usually uterine cramps or low backache, occurs at the time of insertion and may persist. (Pain and cramping may also occur at removal.) If pain is severe, becomes worse, or persists, contact your clinician.

2. Fainting may occur at the time of insertion or removal of the ParaGard® T 380A.

3. Some bleeding occurs following insertion in most women.

4. Partial or total perforation of the ParaGard® T 380A through the wall of the uterus may occur at the time of, or after, insertion. If you think the ParaGard® T 380A is displaced, check with your clinician (see *Warnings – tail or thread disappearance*). Perforation could result in abdominal adhesions (scars), intestinal obstruction or penetration, inflammation, serious infection, and loss of contraceptive protection. Perforation and its complications may require surgery and, in infrequent cases, may result in serious illness or death.

5. Bleeding between menstrual periods may occur during the first 2 or 3 months after insertion. The first few menstrual periods after insertion may be heavier and longer than usual. If these conditions continue for longer than 2 or 3 months, consult your clinician.

6. Occasionally, you may miss a menstrual period while using the ParaGard® T 380A. It is important to determine if you are pregnant; report this without delay to your clinician.

7. The ParaGard® T 380A may come out of your uterus through the cervical opening. This is called expulsion, and is most likely to occur during the first 2 or 3 menstrual cycles following insertion. Expulsion leaves you unprotected against pregnancy. Refer to the section called *Directions for Use* for information on how to check to see if your ParaGard® T 380A has been expelled. If you think the ParaGard® T 380A has come out or has been displaced, use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), until you can be checked by your clinician. (These alternative methods are usually not as effective in preventing uterine pregnancy as the ParaGard® T 380A.) Call your clinician for an examination.

What You Should Discuss With Your Clinician

Before you have the ParaGard® T 380A inserted, indicate below if you have ever had – or suspect you have ever had – any of the conditions listed below. Conditions listed are not necessarily contraindications.

	Yes	No	Not Sure
Heart disease	☐	☐	☐
Heart murmur	☐	☐	☐
Hepatitis or severe liver disease	☐	☐	☐
Wilson's disease	☐	☐	☐
Allergy to copper	☐	☐	☐
Diabetes	☐	☐	☐
Leukemia	☐	☐	☐
Fainting attacks	☐	☐	☐
Steroid therapy	☐	☐	☐
Anemia or blood clotting problems	☐	☐	☐
Current suspected or possible pregnancy	☐	☐	☐
Ectopic pregnancy (pregnancy outside of the uterus)	☐	☐	☐
Recent pregnancy	☐	☐	☐
Recent abortion or miscarriage	☐	☐	☐
Abnormalities of the uterus	☐	☐	☐
Bleeding between periods	☐	☐	☐
Cancer of the uterus (womb) or cervix	☐	☐	☐
Suspicious or abnormal Pap smear	☐	☐	☐

	Yes	No	Not Sure
Prior IUD use	☐	☐	☐
IUD in place now	☐	☐	☐
Heavy menstrual flow	☐	☐	☐
Severe menstrual cramps	☐	☐	☐
Multiple sexual partners	☐	☐	☐
A sexual partner who has multiple sexual partners, or is at high risk for acquiring HIV	☐	☐	☐
Pelvic infection (including pus in fallopian tubes)	☐	☐	☐
Infection of the uterus (womb) or cervix	☐	☐	☐
Genital sores or lesions	☐	☐	☐
Sexually transmitted disease (venereal disease), such as herpes, gonorrhea, chlamydia, or acquired immune deficiency syndrome (AIDS)	☐	☐	☐
Unexplained genital bleeding	☐	☐	☐
Uterine or pelvic surgery	☐	☐	☐
Vaginal discharge or infection	☐	☐	☐
I.V. drug abuse	☐	☐	☐

Make certain you discuss any items you're not sure about.

Adverse Reactions

The following adverse reactions have been reported and may be caused by the ParaGard® T 380A:

- Abdominal infection or adhesions (scar tissue)
- Allergy to copper
- Anemia
- Backache
- Blood poisoning
- Bowel obstruction
- Cervical infection or erosion
- Cysts on ovaries and tubes
- Death
- Delayed menstruation
- Difficult removal
- Ectopic pregnancy
- Embedment (IUD surrounded by uterine tissue)
- Expulsion (IUD comes completely or partially out of the uterus)
- Fainting and pain at the time of insertion or removal
- Fragmentation (breakage) of the ParaGard® T 380A
- Infertility
- Spotting between periods
- Miscarriage
- Pain and cramps
- Painful intercourse
- Pelvic infection (PID), which may result in surgical removal of your reproductive organs, including hysterectomy
- Perforation of the uterus (womb) or cervix (IUD passes through uterine tissue)
- Pregnancy
- Prolonged or heavy menstrual flow
- Infected miscarriage followed, in some cases, by blood poisoning, which can lead to death
- Vaginal discharge

Warnings

This product is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B and syphilis.

If you have the ParaGard® T 380A inserted, call your clinician immediately for any of the following reasons:

1. A missed period. This may mean you are pregnant and the ParaGard® T 380A should be removed.

2. Unexplained or abnormal vaginal bleeding or discharge. This could indicate a serious complication, such as an infection or ectopic pregnancy.

3. A delayed period followed by scanty or irregular bleeding. This could indicate an ectopic pregnancy.

4. Pelvic or lower abdominal pain or cramps or unexplained fever. Such symptoms could mean that an ectopic pregnancy or infection has developed, requiring immediate treatment.

5. Exposure to venereal disease (VD), also called sexually transmitted disease (STD). The use of the ParaGard® T 380A does not prevent venereal disease. If exposure to venereal disease is suspected, report for examination and treatment promptly. Failure to do so could result in serious pelvic infection.

6. If your relationship ceases to be mutually monogamous or should your partner become HIV positive or acquire a sexually transmitted disease, you should report this change to your clinician immediately. It may be advisable to use a barrier method of contraception as a partial protection from acquiring STD until the ParaGard® T 380A can be removed by your clinician.

7. Genital sores or lesions, or fever with vaginal discharge. These may indicate an infection.

8. Severe or prolonged menstrual bleeding. If the flow is heavier and lasts much longer than your usual menstrual flow, you may need to have the ParaGard® T 380A removed to prevent anemia.

9. Tail or thread disappearance or pain during sex. If you cannot feel the threads coming through the cervix, or have pain during sex, the ParaGard® T 380A may have been expelled or displaced, or may have perforated the uterus. If any of these has occurred, you are no longer protected from pregnancy. Use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers) until you can be checked. (These alternative methods are not as effective against uterine pregnancy as the ParaGard® T 380A.) If perforation has occurred, removal of the ParaGard® T 380A is necessary, usually by surgery.

Table 2

Annual Number of Birth-Related or Method-Related Deaths Associated with Control of Fertility per 100,000 Nonsterile Women, by Fertility Control Method, According to Age.

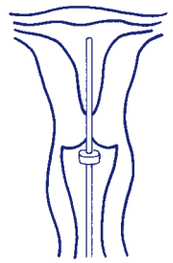
Method of control and outcome	15-19	20-24	25-29	30-34	35-39	40-44
No fertility control methods*	7.0	7.4	9.1	14.8	25.7	28.2
Oral contraceptives, nonsmokers**	0.3	0.5	0.9	1.9	13.8	31.6
Oral contraceptives, smokers**	2.2	3.4	6.6	13.5	51.1	117.2
IUD**	0.8	0.8	1.0	1.0	1.4	1.4
Condom*	1.1	1.6	0.7	0.2	0.3	0.4
Diaphragm/spermicide*	1.9	1.2	1.2	1.3	2.2	2.8
Periodic abstinence*	2.5	1.6	1.6	1.7	2.9	3.6

* Deaths are birth related ** Deaths are method related

Risk of death. Available data from a variety of sources have been analyzed to estimate the risk of death associated with various methods of contraception. The estimates of risk of death include the combined risk of the contraceptive method plus the risk of pregnancy or abortion in the event of method failure.

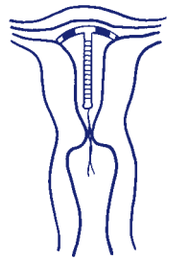
How the ParaGard® T 380A Is Inserted and Removed

The ParaGard® T380A should be inserted, managed and removed by clinicians that are thoroughly familiar with these procedures.



Before insertion, your clinician will perform a pelvic examination. Its purpose is to determine the size, shape, and position of the uterus. An instrument called a speculum will hold your vagina open so that the cervix (the entrance to the uterus) can be seen. (You will probably feel pressure from the speculum throughout the insertion procedure.)

The cervix is then cleaned with an antiseptic solution and an instrument called a tenaculum is attached to it. This instrument assists in holding the uterus steady during insertion. You may feel pain or a pinching sensation as the tenaculum is attached. Then the clinician will guide a narrow instrument called a sound through the opening of the cervix into the uterus. The sound measures the depth and position of the uterus. You can expect to feel cramping similar to menstrual cramps as the sound is inserted and withdrawn.



Then the clinician will guide the ParaGard® T 380A (with the cross arms of the T folded down) through the vagina and the cervix into the uterus.

As the ParaGard® T 380A is inserted, the arms of the T will unfold. During insertion you will have some pain or cramping. You may feel nauseated, weak or faint. After the inserter is removed, the threads attached to the end of the ParaGard® T 380A will be clipped. The threads will extend into the vagina from the cervical opening. The tenaculum and speculum will then be removed. You may feel pain or pinching when the tenaculum is removed. You should remain lying down for a while and rise slowly to prevent fainting. During intercourse, neither you nor your partner should be aware of the threads. You should also not be aware of any other part of the ParaGard® T 380A. If you are, promptly follow the instructions under the heading, *Checking Your ParaGard® T 380A*, in the section *Directions for Use*.

When it is time to remove the ParaGard® T 380A, your clinician must remove it. Its removal may cause pain or cramping. The arms of the ParaGard® T 380A should fold upward as it is withdrawn from the uterus.

Directions for Use

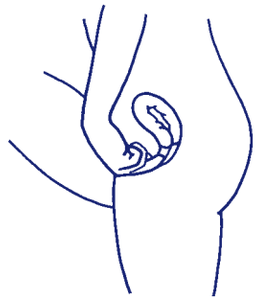
Please read the following information and instructions carefully. Keep a copy of this brochure so that you may refer to it. If you have any questions, consult your clinician.

Checking Your ParaGard® T 380A

The ParaGard® T 380A can come out of the uterus (womb) without your knowing it. When this occurs, it is most often during or right after a menstrual period. Therefore, at least after each menstrual period, check to make sure the threads can be felt at the cervix. You may check more often, and especially if you have some concern, or think you have an expulsion.

Follow these steps to make sure that the ParaGard® T 380A has not been expelled without your knowing it:

1. Wash your hands.
2. Squat down or seat yourself on the toilet.
3. Insert the index or middle finger high into your vagina and locate your cervix. The cervix is the mouth of the uterus (womb). It feels firm, like the tip of your nose.
4. Feel for the threads of the ParaGard® T 380A. The threads should extend from the cervix and be high in your vagina. The threads may be difficult to feel.
5. If you can feel the threads, the ParaGard® T 380A is probably, but not always, in place. You should not pull on the threads. Doing so may displace the ParaGard® T 380A.
6. If you cannot feel the threads, or if you can feel the ParaGard® T 380A itself, it has probably been displaced from the uterus. Also, if you or your partner can feel the ParaGard® T 380A during intercourse, it is displaced. If so, you are not being protected against pregnancy. Until you can be examined, use another birth control method, such as a contraceptive vaginal foam, cream, or jelly, or condoms (rubbers). (These alternative methods are not as effective against pregnancy as the ParaGard® T 380A.) Call your clinician for an examination.



Follow-up Visits to the Clinician

1. You should return to see your clinician as soon as possible after your first menstrual period following insertion of your IUD, but no later than 3 months after insertion. This will allow the clinician to check on the location of the ParaGard® T 380A.
2. The ParaGard® T 380A requires replacement every 10 years. Check with your clinician concerning an appointment to have the ParaGard® T 380A replaced or removed.
3. The ParaGard® T 380A should not interfere with the proper use of tampons and douches. You may want to discuss this with your clinician.

Special Warning About Uterine Pregnancy With the ParaGard® T 380A in Place

Some women become pregnant while using the ParaGard® T 380A. If you miss your menstrual period, or if you suspect you are pregnant, see your clinician right away. When a pregnancy continues with the ParaGard® T 380A in place, serious complications may occur, including severe blood infection, spontaneous miscarriage, infected miscarriage, and death. These may occur at any time during the pregnancy.

When the ParaGard® T 380A remains in the uterus during conception or pregnancy, the long-term effects on the child (or fetus) are not known. Under such conditions some birth defects have occurred. Their relationship to the ParaGard® T 380A has been suggested but not established.

If your clinician confirms that you are pregnant, the ParaGard® T 380A should be removed. Removal of the ParaGard® T 380A may cause a miscarriage. However, successful ParaGard® T 380A removal in pregnancy decreases the likelihood of subsequent complications.

In some cases removal of the ParaGard® T 380A may prove to be difficult. If so, you and your clinician should discuss at that time the question of continuing the pregnancy in view of the serious complications (described above) that may occur. In reaching a decision about termination of pregnancy, you should be aware that the risks associated with abortion increase with the length of time you have been pregnant.

If you continue your pregnancy with the ParaGard® T 380A in place, your clinician will have to follow your course more closely than usual throughout your pregnancy. Be sure to report immediately to the clinician if you have any of the following symptoms or signs:

- Bleeding from the vagina
- Pelvic or lower abdominal pain or cramping
- Flu-like symptoms such as chills or fever
- Unusual vaginal discharge
- Ruptured membranes (your water breaks)
- Any other sign/symptom which gives you concern

Any of these symptoms could indicate that you are having a miscarriage or that you are beginning, or about to begin, premature labor. Premature labor may lead to delivery of a premature infant. Premature infants have a higher chance of dying, mental retardation, cerebral palsy, or other serious medical problems. Additionally, infection can cause infertility or death. Therefore, report any symptoms without delay to your clinician, so that you can obtain immediate treatment.

Glossary

Cervix – Lower portion of the uterus visible in the vagina
Conception – Pregnancy
Contraceptive – Means of preventing conception
Ectopic Pregnancy – Pregnancy outside of the uterus
Expel – To force out
Fallopian Tubes – Tubes which carry the egg from the ovary to the uterus
Fertilization – The process of the sperm penetrating the egg of the female
Genital – Organs concerned with reproduction
HIV – Human Immunodeficiency Virus which causes AIDS
Implantation – Embedding of the fertilized egg into the lining of the uterus
Intrauterine – Within the uterus
Microscopic – Can be seen only by using a microscope
Monogamous – Practicing sexual relations with only one partner
Ovary – Almond-shaped organ. One ovary is located on each side of the uterus. Produces and releases human eggs.
Ovulation – Release of an egg by the ovary
STD – Sexually transmitted disease – also called venereal disease
Spermatozoa – Male reproductive cells
Uterus (womb) – Pear-shaped organ, located deep in the pelvis, that contains and nourishes a fetus during pregnancy
VD – Venereal disease – also called sexually transmitted disease
Viability – Ability to live