The ParaGard® T 380A is flexible and T-shaped with copper on both 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. 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 two white threads extend from the base of the ParaGard® T 380A. They will extend into your vagina to indicate the presence 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. The Copper in the ParaGard® T 380A<br>The ParaGard® T 380A 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 Special Risk Factors for Ectopic Pregnancy.)

Side Effects (Adverse Reactions):<br>Side effects that indicate that the contraceptive effectiveness of ParaGard® T 380A is reduced 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<br>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).
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 evoke 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, if 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.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
<th>Sure</th>
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<tbody>
<tr>
<td>Heart disease</td>
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<tr>
<td>Heart murmur</td>
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<td></td>
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<tr>
<td>Hepatitis or severe liver disease</td>
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<tr>
<td>Wilson's disease</td>
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<td></td>
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<tr>
<td>Allergy to copper</td>
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<td></td>
<td></td>
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<tr>
<td>Diabetes</td>
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<td>Leukemia</td>
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<tr>
<td>Fainting attacks</td>
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<tr>
<td>Sore throat</td>
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<tr>
<td>Anemia or blood clotting problems</td>
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<td></td>
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<tr>
<td>Current suspected or possible pregnancy</td>
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<tr>
<td>Ectopic pregnancy (pregnancy outside of the uterus)</td>
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<tr>
<td>Recent pregnancy</td>
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<tr>
<td>Recent abortion or miscarriage</td>
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<td></td>
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<tr>
<td>Abnormalities of the uterus</td>
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<td></td>
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<tr>
<td>Bleeding between periods</td>
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<tr>
<td>Cancer of the uterus (womb) or cervix</td>
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<tr>
<td>Suspicous or abnormal Pap smear</td>
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<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
<th>Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior IUD use</td>
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<td></td>
<td></td>
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<tr>
<td>IUD in place now</td>
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<td></td>
<td></td>
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<tr>
<td>Heavy menstrual flow</td>
<td></td>
<td></td>
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<tr>
<td>Severe menstrual cramps</td>
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<td></td>
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<tr>
<td>Multiple sexual partners</td>
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<tr>
<td>A sexual partner who has multiple sexual partners, or is at high risk for acquiring HIV</td>
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<tr>
<td>Pelvic infection (including pus in fallopian tubes)</td>
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<td></td>
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<tr>
<td>Infection of the uterus (womb) or cervix</td>
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<tr>
<td>Genital sores or lesions</td>
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<tr>
<td>Sexually transmitted disease (venereal disease), such as herpes, gonorrhea, chlamydia, or acquired immune deficiency syndrome (AIDS)</td>
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<td></td>
<td></td>
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<tr>
<td>Unexplained genital bleeding</td>
<td></td>
<td></td>
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<tr>
<td>Uterine or pelvic surgery</td>
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<td></td>
<td></td>
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<tr>
<td>Vaginal discharge or infection</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>I.V. drug abuse</td>
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</table>

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
- Dehydration
- Delayed menstruation
- Difficult removal
- Ectopic pregnancy
- Embryonic death (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
- Pelvic infection (PID), which may result in surgical removal of your reproductive organs, including hysterecetomy
- 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

**Warning**

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 a serious complication, such as an infection or 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.

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>No fertility control methods*</td>
<td>7.0</td>
<td>7.4</td>
<td>9.1</td>
<td>14.8</td>
<td>25.7</td>
<td>28.2</td>
</tr>
<tr>
<td>Oral contraceptives, nonsmokers**</td>
<td>0.3</td>
<td>0.5</td>
<td>0.9</td>
<td>1.9</td>
<td>13.8</td>
<td>31.6</td>
</tr>
<tr>
<td>Oral contraceptives, smokers**</td>
<td>2.2</td>
<td>3.4</td>
<td>6.6</td>
<td>13.5</td>
<td>51.1</td>
<td>117.2</td>
</tr>
<tr>
<td>IUD**</td>
<td>0.8</td>
<td>0.8</td>
<td>1.0</td>
<td>1.0</td>
<td>1.4</td>
<td>1.4</td>
</tr>
<tr>
<td>Condom*</td>
<td>1.1</td>
<td>1.6</td>
<td>0.7</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Diaphragm/Spermidine*</td>
<td>1.9</td>
<td>1.2</td>
<td>1.2</td>
<td>1.3</td>
<td>2.2</td>
<td>2.8</td>
</tr>
<tr>
<td>Periodic abstinence*</td>
<td>2.5</td>
<td>1.6</td>
<td>1.6</td>
<td>1.7</td>
<td>2.9</td>
<td>3.6</td>
</tr>
</tbody>
</table>

* Deaths are birth related  ** Deaths are method related
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 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 can expect to feel cramping similar to menstrual cramps as the sound is inserted and withdrawn.

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 in place, and 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 not 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
- 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