631-40-410-5

PRESCRIBING INFORMATION

ParaGard® T 380A

INTRAUTERINE COPPER CONTRACEPTIVE

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

The ParaGard® T380A should only be inserted, managed, and removed by clinicians that have demonstrated clinical competence for these procedures received under supervision.

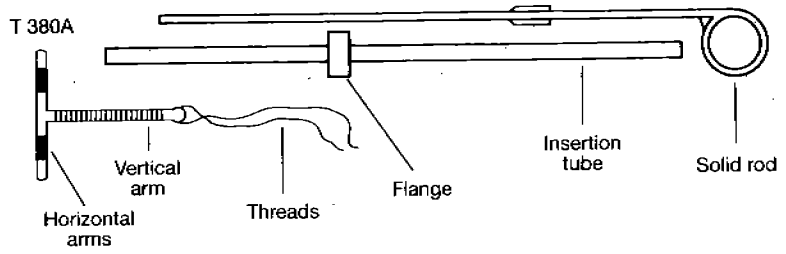
NOTICE

You have received a Patient Package Insert that Federal Regulations (21 CFR 310.502) require you to furnish to each patient who is considering the use of the ParaGard® T 380A.

The Patient Package Insert contains information on the safety and efficacy of the ParaGard® T 380A. Before inserting the ParaGard® T 380A:

- You should read the physician prescription labeling and be familiar with all the information it contains.
- You should counsel the patient and answer her questions about contraception, the ParaGard® T 380A, and the information in the Patient Package Insert.
- You and the patient should read each section of the Patient Package Insert, and if the patient agrees, she may sign a consent form provided for your convenience.

The Patient Package Insert is also available in Spanish and other foreign languages. Address requests to Ortho-McNeil Pharmaceutical, Inc. or telephone 1-800-322-4966.



DESCRIPTION

The polyethylene body of the ParaGard® T 380A is wound with approximately 176 mg of copper wire and carries a copper collar of approximately 68.7 mg of copper

the first postpartum month, particularly during lactation, has been associated with an increased risk of perforation.[8,9] Thus, unless performed immediately postpartum, insertion should be delayed to the second postpartum month. IUD insertion immediately postabortion in the first trimester is not known to be associated with increased risks of perforation, but insertion after second trimester abortion should be delayed until the second postabortion month.

The possibility of perforation must be kept in mind during insertion and at the time of any subsequent examination. If perforation occurs, the ParaGard® T 380A should be removed as soon as possible. A surgical procedure may be required. Abdominal adhesions, intestinal penetration, intestinal obstruction, and local inflammatory reaction with abscess formation and erosion of adjacent viscera may result if the ParaGard® T 380A is left in the peritoneal cavity. There are reports of migration after insertion.

6. MEDICAL DIATHERMY

The use of medical diathermy (short-wave and microwave) in a patient with a metal-containing IUD may cause heat injury to the surrounding tissue. Therefore, medical diathermy to the abdominal and sacral areas should not be used on patients with a ParaGard® T 380A in place.

7. EFFECTS OF COPPER

Additional amounts of copper available to the body from the ParaGard® T 380A may precipitate symptoms in women with Wilson's disease. The incidence of Wilson's disease is approximately 1 in 200,000. The long term effects of intrauterine copper to a child conceived in the presence of an IUD are unknown.

8. RISKS OF MORTALITY

The 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. The findings of the analysis are shown in Table I.[10]

TABLE I – Annual Number of Birth-Related or Method-Related Deaths Associated with Control of Fertility per 100,000 Non-sterile Women, by Fertility Control Method According to Age

	Age Group					
Methods	**15-19**	**20-24**	**25-29**	**30-34**	**35-39**	**40-44**
No Birth Control Method/Term	4.7	5.4	4.8	6.3	11.7	20.6
No Birth Control Method/AB	2.1	2.0	1.6	1.9	2.8	5.3
IUD	0.2	0.3	0.2	0.1	0.3	0.6
Periodic Abstinence	1.4	1.3	0.7	1.0	1.0	1.9

on each of its transverse arms. The exposed surface areas of copper are 380 ± 23 mm.[2] The dimensions of the ParaGard® T 380A are 36 mm in the vertical direction and 32 mm in the horizontal direction. The tip of the vertical arm of the ParaGard® T 380A is enlarged to form a bulb having a diameter of 3 mm. The ParaGard® T 380A is equipped with a monofilament polyethylene thread which is tied through the bulb, resulting in two threads at the tip to aid in removal of the IUD. The ParaGard® T 380A contains barium sulfate to render it radiopaque.

The ParaGard® T 380A is packaged together with an insertion tube and solid rod in a Tyvek®-polyethylene pouch and then sterilized. The insertion tube is equipped with a movable flange to aid in gauging the depth to which the insertion tube is inserted through the cervical canal and into the uterine cavity.

CLINICAL PHARMACOLOGY

Available data indicate that the contraceptive effectiveness of the ParaGard® T 380A is enhanced by copper being released continuously from the copper coil and sleeves into the uterine cavity. The exact mechanism by which metallic copper enhances the contraceptive effect of an IUD has not been conclusively demonstrated. Various hypotheses have been advanced, including interference with sperm transport, fertilization, and implantation. Clinical studies with copper-bearing IUDs also suggest that fertilization is prevented either due to an altered number or lack of viability of spermatozoa.[1]

INDICATIONS AND USAGE

The ParaGard® T 380A is indicated for intrauterine contraception. ParaGard® T 380A is highly effective. Table II and Table III list an expected pregnancy rate for one year between 0.7 and 0.5, respectively. ParaGard® T 380A should not be kept in place longer than 10 years.

RECOMMENDED PATIENT PROFILE

The ParaGard® T 380A is recommended for women who have had at least one child, are in a stable, mutually monogamous relationship, and have no history of pelvic inflammatory disease.

CONTRAINDICATIONS

The ParaGard® T 380A should not be inserted when one or more of the following conditions exist:

1. Pregnancy or suspicion of pregnancy.
2. Abnormalities of the uterus resulting in distortion of the uterine cavity.
3. Acute pelvic inflammatory disease or a history of pelvic inflammatory disease.
4. Postpartum endometritis or infected abortion in the past 3 months.
5. Known or suspected uterine or cervical malignancy, including unresolved, abnormal "Pap" smear.
6. Genital bleeding of unknown etiology.
7. Untreated acute cervicitis or vaginitis, including bacterial vaginosis, until infection is controlled.
8. Copper-containing IUDs should not be inserted in the presence of diagnosed Wilson's disease.
9. Known allergy to copper.
10. Patient or her partner has multiple sexual partners.
11. Conditions associated with increased susceptibility to infections with microorganisms. Such conditions include, but are not limited to, leukemia, acquired immune deficiency syndrome (AIDS), and I.V. drug abuse.
12. Genital actinomycosis.
13. A previously inserted IUD that has not been removed.

WARNINGS

Periodic Abstinence	1.4	1.3	0.7	1.0	1.0	1.9
Withdrawal	0.9	1.7	0.9	1.3	0.8	1.5
Condom	0.6	1.2	0.6	0.9	0.5	1.0
Diaphragm/Cap	0.6	1.1	0.6	0.9	1.6	3.1
Sponge	0.8	1.5	0.8	1.1	2.2	4.1
Spermicides	1.6	1.9	1.4	1.9	1.5	2.7
Oral Contraceptives	0.8	1.3	1.1	1.8	1.0	1.9
Implants/Injectables	0.2	0.6	0.5	0.8	0.5	0.6
Tubal Sterilization	1.3	1.2	1.1	1.1	1.2	1.3
Vasectomy	0.1	0.1	0.1	0.1	0.1	0.2

PRECAUTIONS

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

1. Patient Counseling

Prior to the insertion, the physician, nurse, or other trained health professional must provide the patient with the Patient Package Insert. The patient should be given the opportunity to read the information and discuss fully any questions she may have concerning the ParaGard® T 380A as well as other methods of contraception.

2. Patient Evaluation and Clinical Considerations

a. A complete medical and social history, including that of the partner, should be obtained to determine conditions that might influence the selection of an IUD. A physical examination should include a pelvic examination, a "Pap" smear, and appropriate tests for any other forms of genital disease, such as gonorrhea and chlamydia laboratory evaluations, if indicated. If actinomyces-like organisms are detected on the Pap smear, they should be cultured to determine whether genital actinomyces is present. The physician should determine that the patient is not pregnant.

b. The uterus should be carefully sounded prior to the insertion to determine the degree of patency of the endocervical canal and the internal os, and the direction and depth of the uterine cavity. In occasional cases, severe cervical stenosis may be encountered. Do not use excessive force to overcome this resistance.

c. The uterus should sound to a depth of 6 to 9 centimeters (cm). Insertion of an IUD into a uterine cavity measuring less than 6.0 cm by sounding may increase the incidence of expulsion, bleeding, pain, perforation, and possibly, pregnancy.

d. Clinicians are cautioned that it is imperative for them to become thoroughly familiar with the instructions for use before attempting placement of the ParaGard® T 380A. To reduce the possibility of insertion in the presence of an existing undetermined pregnancy, the optimal time for insertion is the latter part of the menstrual period, or one or two days thereafter. The ParaGard® T 380A should not be inserted postpartum or postabortion until involution of the uterus is complete. The incidence of perforation and expulsion is greater if involution is not complete. Data also suggest that there may be an increased risk of perforation and expulsion if the woman is lactating.[8,9] Other recent studies report no increased incidence of perforation or expulsion in lactating women.[11,12]

The ParaGard® T 380A should be placed at the fundus of the uterine cavity. Proper placement enhances contraceptive effectiveness and helps avoid perforation and partial or complete expulsion that could result in pregnancy.

e. Patients experiencing menorrhagia and/or metrorrhagia following IUD insertion may be at risk for the development of hypochromic microcytic anemia. Careful consideration of this risk must be given before insertion in patients with anemia or a history of menorrhagia or hypermenorrhea. Patients receiving anticoagulants or having a coagulopathy may have a greater risk of menorrhagia or hypermenorrhea.

f. Someone [illegible]

WARNINGS

1. PREGNANCY

Effects on the offspring when pregnancy occurs with the ParaGard® T 380A in place are unknown.

a. **Septic Abortion**

Reports indicate an increased incidence of septic abortion with septicemia, septic shock, and death in patients becoming pregnant with an IUD in place. Most of these reports have been associated with, but are not limited to, the mid-trimester of pregnancy. In some cases, the initial symptoms have been insidious and not easily recognized. If pregnancy should occur with an IUD *in situ*, the IUD should be removed if the string is visible and removal is easily accomplished. Of course, manipulation may result in spontaneous abortion. If removal proves to be difficult, or if threads are not visible, interruption of the pregnancy should be considered and offered as an option. Rates of mortality with and without contraception are shown in Table I.

b. **Continuation of Pregnancy**

If the patient elects to maintain the pregnancy and the IUD remains *in situ*, she should be warned that there is an increased risk of spontaneous abortion and sepsis. In addition, she is at increased risk of premature labor and delivery. As a consequence of premature birth, the fetus is at increased risk of damage. She should be followed more closely than the usual obstetrical patient. The patient must be advised to report immediately all abnormal symptoms, such as flu-like syndrome, fever, abdominal cramping or pain, bleeding or vaginal discharge, because generalized symptoms of septicemia may be insidious.

2. ECTOPIC PREGNANCY

a. Patients with a history of ectopic pregnancy are at an increased risk of subsequent pregnancies being ectopic. Although current data indicate that there is no increased risk of ectopic pregnancy in patients using the ParaGard® T 380A and some data suggest there may be a lower risk than the general population using no method of contraception, a pregnancy which occurs with the ParaGard® T 380A in place is more likely to be ectopic than a pregnancy occurring without ParaGard® T 380A.[2-4] Therefore, patients who become pregnant while using the ParaGard® T 380A should be carefully evaluated for the possibility of an ectopic pregnancy.

b. Special attention should be directed to patients with delayed menses, slight metrorrhagia and/or unilateral pelvic pain, and to those patients who wish to terminate a pregnancy because of IUD failure, to determine whether ectopic pregnancy has occurred.

3. PELVIC INFECTION (PELVIC INFLAMMATORY DISEASE, PID)

The ParaGard® T 380A is contraindicated in the presence of PID or in women with a history of PID. Use of all IUDs, including the ParaGard® T 380A, has been associated with an increased incidence of PID. Therefore, a decision to use the ParaGard® T 380A must include consideration of the risks of PID. The highest rate of PID has been reported to occur after insertion and up to four months thereafter. A study suggests that the highest incidence occurs within 20 days postinsertion, then falls, remaining constant thereafter.[5] Administration of prophylactic antibiotics has been reported, although studies do not confirm the utility of this prophylactic measure in reducing PID. PID can necessitate hysterectomy and can also lead to tubo-ovarian abscesses, tubal occlusion and infertility, and tubal damage that can predispose to ectopic pregnancy. PID can result in peritonitis and, infrequently, in death. The effect of PID on fertility is especially important for women who may wish to have children at a later date.

a. **Women at special risk of PID**

The risk of PID appears to be greater for women who have multiple sexual partners and also for those women whose sexual partners have multiple sexual partners, as PID is most frequently caused by sexually transmitted diseases.

f. Syncope, bradycardia, or other neurovascular episodes may occur during insertion or removal of IUDs, especially in patients with a previous disposition to these conditions or cervical stenosis.

g. Use of an IUD in patients with cervicitis should be postponed until treatment has eradicated the infection.

h. Patients with valvular or congenital heart disease are more prone to develop subacute bacterial endocarditis than patients who do not have valvular or congenital heart disease. Use of an IUD in these patients may represent a potential source of septic emboli. Patients with known congenital heart disease who may be at increased risk should be treated with appropriate antibiotics at the time of insertion.

i. Patients requiring chronic corticosteroid therapy or insulin for diabetes should be monitored with special care for infection.

j. Since the ParaGard® T 380A may be partially or completely expelled, patients should be reexamined and evaluated shortly after the first postinsertion menses, but no later than 3 months afterwards. Thereafter, annual examination with appropriate evaluation, including a "Pap" smear, should be carried out. The ParaGard® T 380A should be kept in place no longer than 10 years.

k. The patient should be told that some bleeding or cramps may occur during the first few weeks after insertion. If these symptoms continue or are severe she should report them to her physician. She should be instructed on how to check to make certain that the threads still protrude from the cervix and cautioned that there is no contraceptive protection if the ParaGard® T 380A has been expelled. She should check frequently, at least after each menstrual period. She should be cautioned not to dislodge the ParaGard® T 380A by pulling on the thread. If a partial expulsion occurs, removal is indicated.

l. Rarely, a copper-induced urticarial allergic skin reaction may develop in women using a copper-containing IUD. If the symptoms of such an allergic response occur, the patient should be instructed to tell the consulting physician that a copper-containing device is being used.

m. The effect of magnetic resonance imaging of the pelvis was investigated in one study[13] in women with the CU-7® (Intrauterine Copper Contraceptive) and the LIPPES LOOP™ IUD. The CU-7® has a different configuration and contains less copper than the ParaGard® T 380A. The results of the study indicate that neither the CU-7® nor the LIPPES LOOP™ were moved under the influence of the magnetic field nor did they heat during the spin-echo sequences usually employed for pelvic imaging.

3. Insertion Prophylaxis

Observe strict asepsis at insertion; clean the endocervix with an antiseptic solution, because the presence of organisms capable of establishing PID cannot be determined by appearance, and because IUD insertion may be associated with introduction of vaginal bacteria into the uterus. Data do not confirm the utility of prophylactic administration of antibiotics in reducing the incidence of PID, and their use in nursing women is not recommended.

4. Requirements for Continuation and Removal

a. The ParaGard® T 380A must be replaced before the end of the tenth year of use. There is no evidence of decreasing contraceptive efficacy with time before ten years, but the contraceptive effectiveness at longer times has not been established; therefore, the patient should be informed of the known duration of contraceptive efficacy and be advised to return in 10 years for removal and possible insertion of a new ParaGard® T 380A.

b. The ParaGard® T 380A should be removed for the following medical reasons: menorrhagia- and/or metrorrhagia-producing anemia; pelvic infection; genital actinomycosis; intractable pelvic pain; dyspareunia; pregnancy, endometrial or cervical malignancy; uterine or cervical perforation; increase in length of the

on each of its transverse arms. The exposed surface areas of [illegible] mm.[2] The dimensions of [illegible]

b. **PID warning to ParaGard® T 380A users**

All women who choose the ParaGard® T 380A must be informed prior to insertion that IUD use has been associated with an increased incidence of PID and that PID can necessitate hysterectomy, can cause tubal damage leading to ectopic pregnancy or infertility or, in infrequent cases, can cause death. Patients must be taught to recognize and report to their physician promptly any symptoms of pelvic inflammatory disease. These symptoms include development of menstrual disorders (prolonged or heavy bleeding), unusual vaginal discharge, abdominal or pelvic pain or tenderness, dyspareunia, chills, and fever.

c. **Asymptomatic PID**

PID may be asymptomatic but still result in tubal damage and its sequelae.[6,7]

d. **Treatment of PID**

Following diagnosis of PID, or suspected PID, bacteriologic specimens should be obtained and antibiotic therapy should be initiated promptly. Removal of the ParaGard® T 380A after initiation of antibiotic therapy is usually appropriate. Time should be allowed for therapeutic blood levels to be reached prior to removal. Guidelines for PID treatment are available from the Center for Disease Control (CDC), Atlanta, Georgia. A copy of the printed guidelines has been provided to you by Ortho-McNeil Pharmaceutical, Inc. The guidelines were established after deliberation by a group of experts and staff of the CDC, but they should not be construed as rules suitable for use in all patients. Adequate PID treatment requires the application of current standards of therapy prevailing at the time of occurrence of the infection with reference to the prescription labeling of the antibiotic selected.

Genital actinomycosis has been associated primarily with long-term IUD use. If actinomycosis occurs, promptly institute appropriate antibiotic therapy and remove the ParaGard® T 380A.

4. EMBEDMENT

Partial penetration or embedment of the ParaGard® T 380A in the endometrium or myometrium can result in difficult removal. In some cases this can result in breakage of the IUD, necessitating surgical removal.

5. PERFORATION

Partial or total perforation of the uterine wall or cervix may occur with use of the ParaGard® T 380A. The rate of perforation in randomized trials of the ParaGard® T 380A has been 1 in 1,360. Insertions immediately after the expulsion of the placenta are not known to be associated with increased risks of perforation, but insertion later in

threads extending from the cervix, or any other indication of partial expulsion. Insertions immediately following placental delivery or first trimester abortion may result in threads becoming slightly longer as the uterus involutes and may not represent expulsion or partial expulsion.

c. If the retrieval threads cannot be visualized, they may have retracted into the uterus or have been broken, or the ParaGard® T 380A may have been broken, or the ParaGard® T 380A may have been expelled. Localization may be made by feeling with a probe, X-ray, or sonography. When the physician elects to recover a ParaGard® T 380A with the threads not visible, the removal instructions should be reviewed.

d. Should the patient's relationship cease to be mutually monogamous, or should her partner become HIV positive, or acquire a sexually transmitted disease, she should be instructed to report this change to her clinician immediately. It may be advisable to recommend the use of a barrier method as a partial protection against acquiring sexually transmitted diseases until the ParaGard® T 380A can be removed.

5. Continuing Care of Patients Using ParaGard® T 380A

a. Any inquiries regarding pain, odorous discharge, bleeding, fever, genital lesions or sores, or a missed period should be promptly responded to and prompt examination is recommended.

b. If examination during visits subsequent to insertion reveals that the length of the threads has visibly or palpably changed from the length at time of insertion, the ParaGard® T 380A should be considered displaced and should be removed. A new ParaGard® T 380A may be inserted at that time or during the next menses if it is certain that conception has not occurred. Under no circumstances should reinsertion with an expelled ParaGard® T 380A be attempted. A new ParaGard® T 380A should be inserted.

c. Since the ParaGard® T 380A may be partially or completely expelled, patients should be reexamined and evaluated shortly after the first postinsertion menses, but no later than 3 months afterwards. Thereafter, at least annual examination with appropriate evaluation, including a "Pap" smear, and if indicated, gonococcal and chlamydial laboratory evaluations, should be carried out. The ParaGard® T 380A should be kept in place no longer than 10 years.

d. In the event a pregnancy is confirmed during ParaGard® T 380A use, the following steps should be taken:
   - Determine whether the pregnancy is ectopic and take appropriate measures if it is.
   - Inform patient of the risks of leaving an IUD *in situ* or removing it during pregnancy, and of the lack of data on the long term effects of the ParaGard® T 380A on the offspring of women who have had it *in utero* during conception or gestation (see WARNINGS). This information should include the risk of septic spontaneous abortion with the IUD *in situ*.
   - If possible, the ParaGard® T 380A should be removed after the patient has been warned of the risks of removal. If removal is difficult, the patient should be counseled about and offered pregnancy termination.
   - If the ParaGard® T 380A is left in place, the patient's course should be followed closely.

ADVERSE REACTIONS

These adverse reactions are not listed in any order of frequency or severity.

Reported adverse reactions with intrauterine contraceptives include: endometritis; spontaneous abortion; septic abortion; septicemia; perforation of the uterus and cervix; embedment; fragmentation of the IUD; pelvic infection; tubo-ovarian abscess; tubal damage; vaginitis; leukorrhea; cervical erosion; pregnancy; ectopic pregnancy; fetal damage; difficult removal; complete or partial expulsion of the IUD, particularly in those patients with uteri measuring less than 6.0 cm by sounding; menstrual spotting; prolongation of menstrual flow; anemia; amenorrhea or delayed menses; pain and cramping; dysmenorrhea; backaches; dyspareunia; neurovascular episodes, including bradycardia and syncope secondary to insertion. Uterine perforation and IUD displacement into the abdomen have been followed by peritonitis, abdominal adhesions, intestinal penetration, intestinal obstruction, and cystic masses in the pelvis. (Certain of these adverse reactions can lead to loss of fertility, partial or total removal of reproductive organs, hormonal imbalance, or death.) Urticarial allergic skin reaction may occur.

CLINICAL STUDIES

Different event rates have been reported with the use of different intrauterine contraceptives. Inasmuch as these rates are usually derived from separate studies conducted by different investigators in several populations, they cannot be compared with precision. Considerably different rates are likely to be obtained because event rates per unit of time tend to decrease as studies are extended, since more susceptible subjects discontinue due to expulsions, adverse reactions, or pregnancy, leaving the study population richer in less susceptible subjects. In clinical trials conducted by The Population Council[14,15] and WHO, use-effectiveness of the ParaGard® T 380A as calculated by the life table method was determined through ten (10) years of use.

Data suggest a higher pregnancy rate in women under 20.[14,15,17]

CAUTION

Any intrauterine procedure can result in severe pain, bradycardia, and syncope.

It is generally believed that perforations, if they occur, are encountered at the time of insertion, although the perforation may not be detected until some time later. The position of the uterus should be determined during the preinsertion examination. Great care must be exercised during the preinsertion sounding and subsequent insertion. No attempt should be made to force the insertion.

HOW TO LOAD AND INSERT ParaGard® T 380A

STEP 1

To minimize the chance of introducing contamination, do not remove the ParaGard® T 380A from the insertion tube prior to placement in the uterus. Do not bend the arms of the ParaGard® T 380A earlier than 5 minutes before it is to be introduced into the uterus.

In the absence of sterile gloves, this can be accomplished without destroying sterility by folding the arms in the partially opened package. Place the partially opened package on a flat surface and pull the solid 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. Push insertion tube against arms of ParaGard® T 380A as indicated by arrow in Fig. 1A to start arms folding.

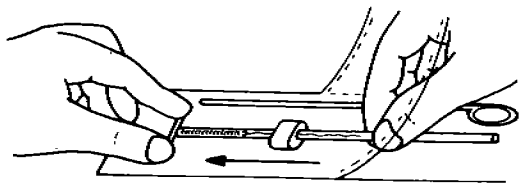


Fig. 1A

Complete the bending by bringing the thumb and index finger together using the other hand to maneuver the insertion tube to pick up the arms of the ParaGard® T 380A (Fig. 1B). Insert no further than necessary to insure retention of the arms. Introduce the solid rod into the insertion tube from the bottom alongside the threads until it touches the bottom of the ParaGard® T 380A.

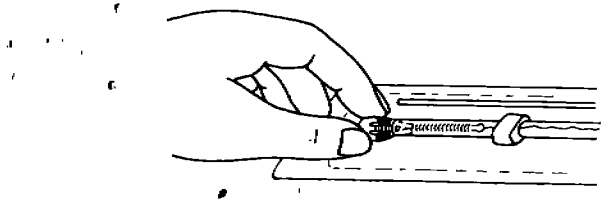


TABLE II

ParaGard® T 380A
(Intrauterine Copper Contraceptive)

GROSS ANNUAL TERMINATION AND CONTINUATION RATES PER 100* USERS
All Copper T 380A IUD Acceptors
Combined Population Council and WHO Studies

	YEAR									
Rate of Item	1	2	3	4	5	6	7	8	9	10
Pregnancy	0.7	0.3	0.6	0.2	0.3	0.2	0.0	0.4	0.0	0.0
Expulsion	5.7	2.5	1.6	1.2	0.3	0.0	0.6	1.7	0.2	0.4
Bleeding/Pain	11.9	9.8	7.0	3.5	3.7	2.7	3.0	2.5	2.2	3.7
Other Medical	2.5	2.1	1.6	1.7	0.1	0.3	1.0	0.4	0.7	0.3
Continuation	76.8	78.3	81.2	86.2	89.0	91.9	87.9	88.1	92.0	91.8
No. of Women:										
At Start of Year	4932	3149	2018	1121	872	621	563	483	423	325
At End of Year	3149	2018	1121	872	621	563	483	423	325	230

*Rates were calculated by weighing the annual rates by the number of subjects starting each year for each of the Population Council (3536 acceptors) and the World Health Organization (1396 acceptors) trials.

TABLE III

GROSS ANNUAL EVENT RATES PER 100 CONTINUING USERS BY YEAR AND PARITY

	1 Year Parous
Pregnancy	0.5
Expulsion	2.3
Bleeding/Pain	3.4
Infection	0.3
Other Medical	0.5
Planning Pregnancy	0.6
Other Personal	0.7
Continuation	92.1
No. Completed	1842.0

Rates were calculated by combining the experience on a weighted basis from both an international study by the World Health Organization (2110 women) and a U.S. study by GynoPharma Inc. (230 women).

The lowest expected and typical failure rates during the first year of continuous use of all contraceptive methods are listed in Table IV (Adapted from Reference 16).

TABLE IV - Percentage of women experiencing a contraceptive failure during the first year of typical use and the first year of perfect use and the percentage continuing use at the end of the first year, United States.[16]

Method	% of Women Experiencing an Accidental Pregnancy Within the First Year of Use		% of Women Continuing Use at One Year[3]
	Typical Use[1]	Perfect Use[2]	
Chance[4]	85	85	
Spermicides[5]	21	6	43
Periodic Abstinence	20		67
Calendar		9	
Ovulation Method		3	
Sympto-Thermal[6]		2	
Post-Ovulation		1	
Withdrawal	19	4	
Cap[7]			
Parous Women	36	26	45
Nulliparous Women	18	9	58
Sponge			
Parous Women	36	20	45
Nulliparous Women	18	9	58
Diaphragm[7]	18	6	58
Condom[8]			

Fig. 1B

STEP 2

Adjust the movable flange so that it indicates the depth to which the ParaGard® T 380A should be inserted and the direction in which the arms of the ParaGard® T 380A will open. At this point, make certain that the horizontal arms of the ParaGard® T 380A and the long axis of the flange lie in the same horizontal plane. Introduce the loaded insertion tube through the cervical canal and upwards until the ParaGard® T 380A lies in contact with the fundus. The movable flange should be at the cervix (Fig. 2). DO NOT FORCE THE INSERTION.

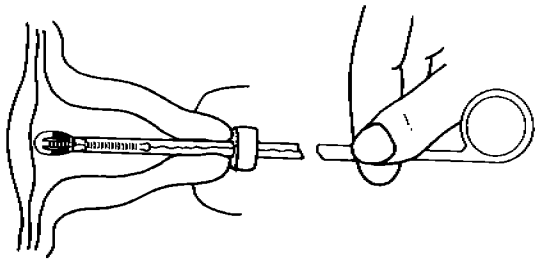


Fig. 2

STEP 3

To release the arms of the ParaGard® T 380A, withdraw the insertion tube not more than ½ inch while the solid rod is not permitted to move. This releases the arms of the ParaGard® T 380A (Fig. 3).

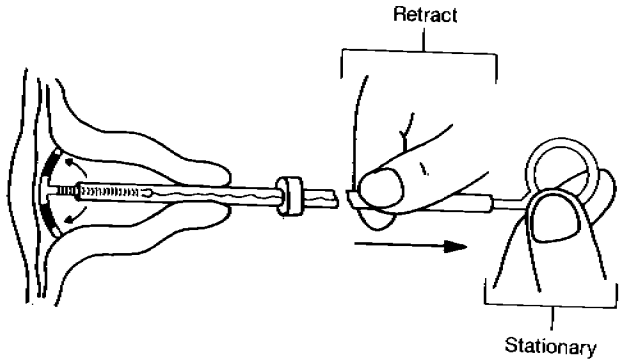


Fig. 3

STEP 4

After the arms are released, the insertion tube should be moved upward gently, until the resistance of the fundus is felt. This will assure placement of the T at the highest possible position within the endometrial cavity (Fig. 4).

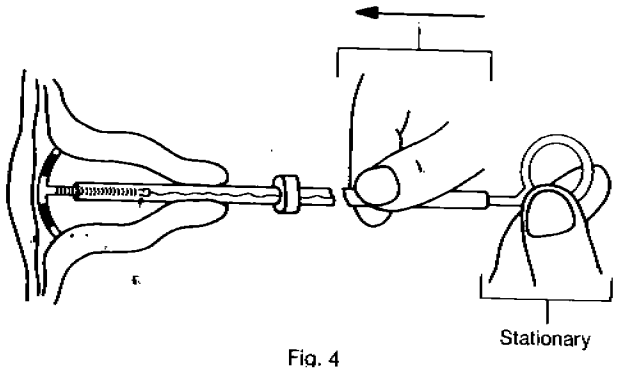


Fig. 4

Female (Reality)	21	5	56
Male	12	3	63
Pill	3		72
Progestin Only		0.5	
Combined		0.1	
IUD			
Progesterone T	2.0	1.5	81
Copper T 380A (ParaGard® T 380A)	0.8	0.6	78
Depo-Provera®	0.3	0.3	70
Norplant® (6 Capsules)	0.09	0.09	85
Female Sterilization	0.4	0.4	100
Male Sterilization	0.15	0.10	100

Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%.[9]

Lactational Amenorrhea Method: LAM is a highly effective temporary method of contraception.[10]

Footnotes to Table IV:

1. Among *typical* couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.
2. Among couples who initiate use of a method (not necessarily for the first time) and who use it *perfectly* (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.
3. Among couples attempting to avoid pregnancy, the percentage who continue to use a method for one year.
4. The percentages failing in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within one year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.
5. Foams, creams, gels, vaginal suppositories, and vaginal film.
6. Cervical mucous (ovulation) method supplemented by calendar in the pre-ovulatory and basal body temperature in the post-ovulatory phases.
7. With spermicidal cream or jelly.
8. Without spermicides.
9. The treatment schedule is one dose as soon as possible (but no more than 72 hours) after unprotected intercourse, and a second dose 12 hours after the first dose. The hormones that have been studied in the clinical trials of postcoital hormonal contraception are found in Nordette, Levlen, Lo/Ovral (1 dose is 4 pills), Triphasil, Tri-Levlen (1 dose is 4 yellow pills), and Ovral (1 dose is 2 pills).
10. However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches 6 months of age.

HOW SUPPLIED

Available in cartons of one (NDC 54765-380-01) or five (NDC 54765-380-05) sterile units. Each ParaGard® T 380A is packaged in a Tyvek®-polyethylene pouch, together with an insertion tube and solid rod.

STEP 5

Withdraw the solid rod while holding the insertion tube stationary (Fig. 5).

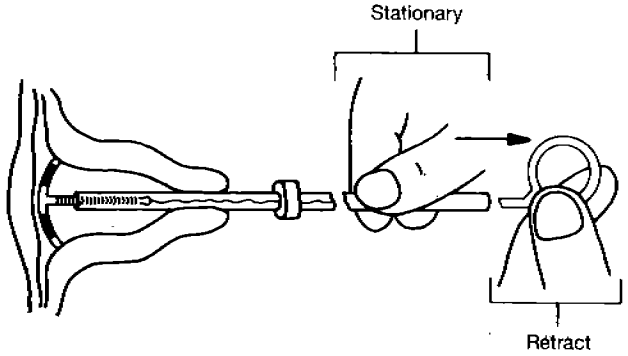


Fig. 5

STEP 6

Withdraw the insertion tube from the cervix. Be sure sufficient length of the threads are visible (approximately 1 in. or 2.5 cm.) to facilitate checking for the presence of the ParaGard® T 380A (Fig. 6). Notation of length of the threads should be made in patient record.

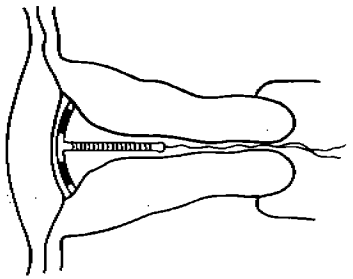


Fig. 6

HOW TO REMOVE ParaGard® T 380A

To remove the ParaGard® T 380A, pull gently on the exposed threads. The arms of the ParaGard® T 380A will fold upwards as it is withdrawn from the uterus. Even if removal proves difficult, the ParaGard® T 380A should not remain in the uterus after 10 years.

REFERENCES

1. Alvarez F et al: New insights on the mode of action on intrauterine contraceptives in women. *Fertil Steril* 1988; 49:768-773.
2. World Health Organization's Special Programme of Research, Development and Research

INSTRUCTIONS FOR USE

ParaGard® T 380A

(Intrauterine Copper Contraceptive)

CLINICIANS SHOULD HAVE DEMONSTRATED CLINICAL COMPETENCE IN PARAGARD® T 380A INSERTIONS, MANAGEMENT, AND REMOVAL RECEIVED UNDER SUPERVISION. PREVIOUS EDUCATION RE: SURGICAL PROCEDURES WILL REQUIRE VARYING LEVELS OF EXPERIENCE.

The ParaGard® T 380A (Intrauterine Copper Contraceptive) represents a different design in intrauterine contraceptives. Physicians are, therefore, cautioned that they should become thoroughly familiar with instructions for insertion before attempting placement of the ParaGard® T 380A. The insertion technique is different in several respects from that employed with other intrauterine contraceptives and the physician should pay particular attention to the drawings and commentary accompanying these instructions.

A single ParaGard® T 380A is placed at the fundus of the uterine cavity.

The ParaGard® T 380A may be inserted at any time during the cycle. However, it is essential that pregnancy be ruled out before insertion.

The ParaGard® T 380A is indicated for use up to 10 years. Therefore, the ParaGard® T 380A must be removed and a new one inserted on or before 10 years from the date of insertion.

PRELIMINARY PREPARATION AND INSERTION

1. Before insertion, you and the patient will want to review the Patient Package Insert. If the patient agrees, she may sign the Consent Form provided for your records.
2. Take a medical and social history.
3. Refer to CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS.
4. Pelvic examination is to be performed prior to insertion of the ParaGard® T 380A, including a cervical "Pap" smear, and gonococcal and chlamydial evaluations, if indicated, and any other necessary specific tests.
5. If appropriate, commence antibiotic prophylaxis one hour before insertion.
6. Use of aseptic technique during insertion is essential.
7. The endocervix should be cleansed with an antiseptic solution and a tenaculum applied to the cervix with downward traction for correction of the angulation as well as stabilization of the cervix.
8. With a speculum in place, gently insert a sterile sound to determine the depth and direction of the uterine canal. Be sure to determine the position of the uterus before insertion.

Training In Human Reproduction: A multinational case-control study of ectopic pregnancy. *Clin Reprod Fertil* 1985; 3:131-143.

3. Ory HW, Women's Health Study: Ectopic pregnancy and intrauterine contraceptive devices: New perspectives. *Obstet Gynecol* 1981; 57:137-144.
4. Marchbanks PA et al: Risk factors for ectopic pregnancy: A population-based study. *JAMA* 1988; 259:1823-1827.
5. Farley TMM et al: Intrauterine devices and pelvic inflammatory disease: An international perspective. *Lancet* 1992; 339:785-788.
6. Cramer DW et al: Tubal infertility and the intrauterine device. *N Engl J Med* 1985; 312:941-947.
7. Daling JR et al: Primary tubal infertility in relation to the use of an intrauterine device. *N Engl J Med* 1985; 312:937-941.
8. Heartwell SF, Schlesselman S: Risk of uterine perforation among users of intrauterine devices. *Obstet Gynecol* 1983; 61:31-36.
9. Chi I-C, Kelly E: Is lactation a risk factor of IUD and sterilization-related uterine perforations? A hypothesis. *Int J Gynaecol Obstet* 1984; 22:315-317.
10. Harlap S, Kost K, Forrest JD: Preventing pregnancy, protecting health: a new look at birth control choices in the United States. The Alan Guttmacher Institute 1991; 1-129.
11. Chi I-C et al: Performance of the Copper T 380A Intrauterine device in breast feeding women. *Contraception* 1989; 39:603-618.
12. Farr G, Rivera R: Interactions between intrauterine contraceptive device use and breast-feeding status at time of intrauterine contraceptive device insertion. Analysis of TCu-380A acceptors in developing countries. *Am J Obstet Gynecol* 1992; 167:144-151.
13. Mark AS, Hricak H: Intrauterine contraceptive devices: MR imaging. *Radiology* 1987; 311-314.
14. Sivin I, Stern J: Long-acting, more effective Copper T IUDs: A summary of US experience, 1970-1975. *Stud Fam Plann* 1979; 10:263-281.
15. Sivin I, Schmidt F: Effectiveness of IUDs: A review. *Contraception* 1987; 36:55-84.
16. Trussell J: The Essentials of Contraception, in R.A. Hatcher, et al: *Contraceptive Technology*, 16th Revised Ed., New York, Irvington, 1994, p. 113-114.
17. World Health Organization (WHO): Mechanism of action, safety, and efficacy of intrauterine devices. Report of a WHO Scientific Group. Technical Report Series 753. Geneva; World Health Organization, 1987, p. 22.

ORTHO-McNEIL

Manufactured for
ORTHO-McNEIL PHARMACEUTICAL, INC.
Raritan, New Jersey 08869
by FEI Products, Inc.
N. Tonawanda, New York 14120

Revised September 2000 Printed in U.S.A. 10U0732 631-40-410-5

PATIENT PACKAGE INSERT

ParaGard® T 380A

INTRAUTERINE COPPER CONTRACEPTIVE

Este panfleto también lo hay en español.

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.

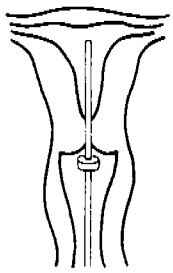
Method of control and outcome	15-19	20-24	25-29	30-34	35-39	40-44
No fertility control methods*	7.0	7.4	9.1	14.8	25.7	28.2
Oral contraceptives, nonsmokers**	0.3	0.5	0.9	1.9	13.8	31.6
Oral contraceptives, smokers**	2.2	3.4	6.6	13.5	51.1	117.2
IUD**	0.8	0.8	1.0	1.0	1.4	1.4
Condom*	1.1	1.6	0.7	0.2	0.3	0.4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

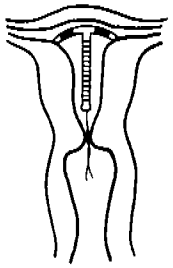
How the ParaGard® T 380A Is Inserted and Removed

The ParaGard® T380A should only be inserted, managed and removed by clinicians that have demonstrated clinical competence for these procedures received under supervision.



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

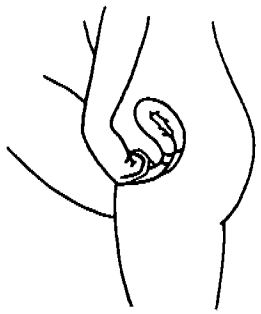
Please read the following information and instructions carefully. Keep a copy of this brochure so that you may refer to it. If you have any questions, consult your clinician.

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.

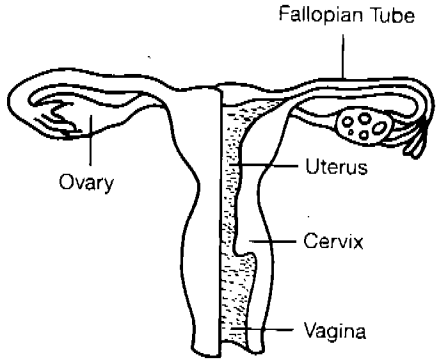
In some cases removal of the ParaGard® T 380A may prove to be difficult. If so, you and your clinician should discuss at that time the question of continuing the pregnancy in view of the serious complications (described above) that may occur. In reaching a decision about termination of pregnancy, you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

ORTHO-McNEIL

Manufactured for
ORTHO-McNEIL PHARMACEUTICAL, INC.
Raritan, New Jersey 08869
by FEI Products, Inc.
N. Tonawanda, New York 14120

 Revised September 2000 Printed in U.S.A.

10U0733
548-10-410-5