PREGNA Copper T Model T Cu 380A
INTRAUTERINE CONTRACEPTIVE DEVICE

INDICATION: "Intrauterine contraception in women of childbearing age"

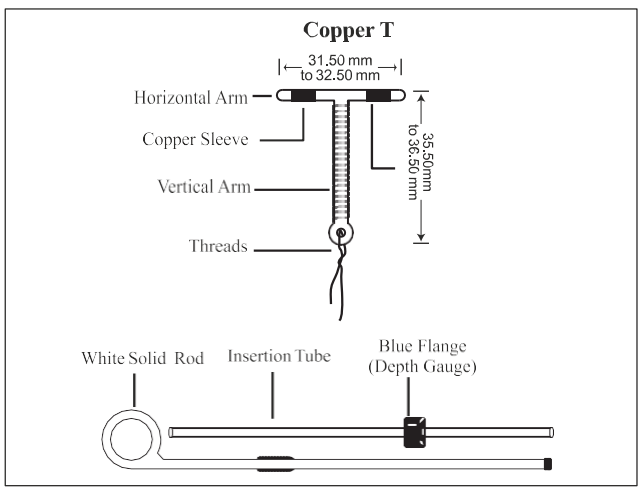
INTENDED USER
Trained Medical Professionals

INTENDED USE:

Pregna Model T Cu 380A IUDs offer almost complete protection against pregnancy, having a shelf life of 7 years and it remains effective for a period of 10 years. Correctly inserted, **Pregna Model T Cu 380A IUDs**.

DESCRIPTION OF DESIGN, DIMENSIONS & COMPOSITION OF IUD

The Pregna Model T Cu 380A IUD is an intrauterine contraceptive device made of polyethylene. The stem is covered with copper wire and there are copper sleeves on each of the horizontal arms. A monofilament (HDPE/ Nylon 66) suture is tied at the bottom of the vertical arm for removal of IUD having length of 105 to 110 mm.The total surface area of the copper is approx. 380 mm2. The side arms are flexible and shaped in such away as to keep the Pregna Model T Cu 380A IUD adjacent to the fundus, without stretching the uterine cavity or touching the cornua. The contraceptive action of the device is probably due to a number of foreign body reactions with the uterine endometrium and the presence of metallic copper.



CONTRAINDICATIONS (Absolute)

1. Malignant diseases of the genital tract
2. Undiagnosed vaginal bleeding
3. Pregnancy
4. Past history of ectopic pregnancy or predisposing factors
5. Infections of the genital tract
6. Sexually transmitted diseases during the last 12 months (except bacterial vaginitis, repeated herpes infection, Hepatitis B)
7. Abortion with infection during the last 3 months, pelvic inflammatory disease
8. Uterine malformations (congenital or acquired)
9. Allergy to copper

CONTRAINDICATIONS (RELATIVE)

1. Anaemia
2. Valvular heart disease
3. Coagulation disorders
4. Wilson's disease
5. Multiple exposures to different sexual partners

DIRECTIONS FOR IUD USERS

1. Longer and heavier menstrual periods, or bleeding or spotting between periods may occur during the first weeks after insertion. If they continue or are severe, report to the clinic.
2. Cramping may occur following insertion, usually for short time, but could last for several hours to even days. This can be relieved by taking mild analgesic tablets, using hot compresses on abdomen, and/or exercising moderately.
3. Check periodically, and particularly after menstruation, to make certain that the threads still protrude from the cervix. If threads are missing, shorter or longer, return to the clinic.
4. If Copper T is expelled, return to the clinic. There is no continuing protection after expulsion.
5. Return to the clinic for checkup or for replacement of the Copper T **(end of ten years after insertion)**, as instructed by physician.
6. If your period is delayed (with symptoms of pregnancy, such as nausea, tender breasts, etc...) report immediately to the clinic.
7. If there is abdominal pain, pain during intercourse, infections (such as gonorrhea), abnormal discharge, fever, chills consult your physician.
8. Pregna Model T Cu 380A Intrauterine Contraceptive device doesn't interact with any medicine the woman may be taking.
9. The user and/ or patient should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of your Member State.
   For more information: https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_enhttps://health.ec.europa.eu/medical-devices-sec- tor/new-regulations/contacts_en

MECHANISM OF ACTION

Copper IUD's act by greatly reducing the likelihood of fertilization. Data and analysis indicate that the main antifertility effect of copper bearing IUD's involve inhibition of egg or sperm transport and/or the capacity of sperm to fertilize egg. Reduced gamete transport and capacitation inhibits fertilization and occurs before the ovum reaches the uterine cavity. Continuous copper release in uterine cavity from the copper wire and copper sleeves enhance the contraceptive effect of Copper T 380A.

FOLLOWUP GUIDELINE FOR PHYSICIANS

The Physician should encourage the user to come for 4 to 6 weeks follow up after the IUD insertion. In case of any problem or doubt regarding usages of Pregna Model T Cu 380A. During followup the physician should Pay particular attention to the following points -

1. Heavier bleeding, indicates the possibility of anemia.
2. If pregnancy has occurred, the Copper T should be removed, if possible.
3. If a woman gets pregnant with IUD in place, there is a chance of having an ectopic pregnancy, which should be evaluated. If the patient wishes to continue her pregnancy, she must be monitored closely by the physician. She should be informed about the risks of keeping the IUD in situ. Beyond the first trimester, the patient should be informed of the possible risks of maintaining a pregnancy with the device in situ and termination of the pregnancy should be considered.
4. Removal of Copper T is advisable, if user is exposed to conditions that substantially increase the risk of pelvic inflammatory disease.

UNDESIRABLE EFFECTS OF THE PRODUCT, INCLUDING THEIR FREQUENCY AND TIMING

Adverse effects of intrauterine devices, including Pregna Model T Cu 380A IUD, are low but include the following:

1) Bleeding :

Menstrual bleeding is sometimes stronger and of longer duration than normal, or is more painful. Iron deficiency anemia may then occur in individual cases. Slight intermenstrual bleeding, often in the form of spotting, may occur but usually subsides spontaneously.

2) Pelvic Infection :

The risk of pelvic infection (salpingitis), usually requiring removal of the intrauterine device and appropriate antibiotic treatment, may occur and may lead to subsequent infertility. Randomized, controlled studies indicate that any risk of genital tract infection after the first month of IUD is low. Exposure to sexually transmitted infections (STIs), and not the use of IUD itself, is responsible for PID occurring after the first month of use.

3) Pain or Dysmenorrhea :

Pain in the lower abdomen or sacral area may occur initially after insertion but usually subsides with time or with analgesic treatment. Pain may be a physiological response to the presence of the device, but the possibility of infection, improper positioning of the device (including perforation and migration), and pregnancy should be excluded. Delayed detection of perforation may lead to IUD migration outside the uterine cavity and/or injury to other adjacent organs, and unintended pregnancy.

4) Other :

Certain women, in particular nulliparous women, are more susceptible to syncope, bradycardia and other neurovascular episodes during and immediately after insertion or removal of an intrauterine device.

Isolated cases of skin reactions have been described in the literature which may be attributable to copper allergy.

PROCEDURE FOR INSERTION

CAUTION

- Do not pick up and use any component that has fallen on the floor or table.
- Do not pour the contents of the pouch in the instrument tray.
- Do not use the white solid rod to measure uterine cavity length.

A) TIMING OF INSERTION

1. Verify that the user is not pregnant. The IUD must not be inserted if there is the possibility of pregnancy.
2. The best time for insertion is during menstruation to prevent insertion during non-diagnosed pregnancy. At this time the external and internal cervical is physiologically dilated. This facilitates the insertion of the IUD without the need to dilate the canal in most instances.
3. When using the Pregna Model T Cu 380A for emergency contraception, the IUD may be introduced within 5 days of unprotected coitus. Insertion immediately after unprotected coitus can increase the risk of PID.
4. Pregna Model T Cu 380A can also be inserted within 15 minutes of delivery of the placenta or abortion in the first trimester. Note that there is a higher rate of expulsion in these instances. If the Pregna Model T Cu 380A cannot be inserted immediately after delivery of the placenta or abortion, insertion should be delayed for at least six weeks. In case of caesarean section insertion should be delayed for 12 weeks after delivery.

B) PREPARING THE USER

1. Operator should wear sterile gloves and use aseptic technique. He/She should gently explain to the client what he/she is doing.
2. Prior to insertion the vagina and cervix should be cleansed with an antiseptic solution.
3. The cervix should be visualized by means of speculum and its anterior lip grasped with a tenaculum. Gentle traction on the tenaculum will tend to reduce the angle between the cervical canal and endometrial cavity and will greatly facilitate introduction of the uterine sound. The tenaculum should remain on the cervix, throughout the insertion of the Copper T so that gentle traction on the cervix can be maintained.
4. The uterine sound should then be introduced in the endocervical cavity until it reaches the fundus. As soon as the direction and length of the cervical canal and endometrial cavity have been determined, the Copper T may be prepared for insertion.

C) LOADING THE IUD

Do not open the sterile package or bend the arms of 'T' in to the insertion tube until immediately before it is introduced into the uterus. The Copper T can be prepared for insertion inside the sterile package as per the instructions given below.

Step 1

Ensure that the vertical arm of 'T' is fully inside the insertion tube and the opposite end of the insertion tube will be close to the package bottom seal.

Step 2

Place the package on a clean, hard, flat surface with the clear plastic side up. Partially open the package from the end marked OPEN, approximately halfway to the flange depth gauge.

Step 3

Holding the package with open end up, and the flaps away from each other as shown in fig. 1 put the white solid rod into the insertion tube to almost touch the bottom of the 'T'. Be careful not to touch tip of solid rod or brush it against another surface as this could lead to the white solid rod losing its sterility.

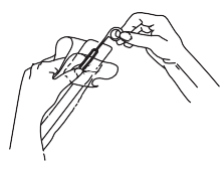


Fig. 1

PREGNA Copper T Model T Cu 380A
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Step 4
Place the package on the clean, hard, flat surface once again with the clear plastic side up.

Step 5
Through the plastic clear cover, place your thumb and index finger over the ends of the horizontal arms of the 'T' and bend the arms towards the stem of 'T' as indicated on the package label insert. Use your other free hand to push the insertion tube against the arms of 'T' as shown in fig. 2.
Note that the arms should not be bent untill 5 minutes before insertion.

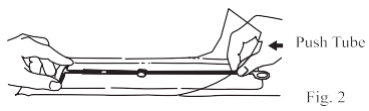


Fig. 2

Step 6
Complete the bending of the arms of 'T' by bringing the thumb and index finger together as shown in fig. 3 while using the other hand to maneuver the insertion tube to pick up the arms of 'T'. Insert the folded arms of the 'T' into the insertion tube only as far necessary to ensure the retention of the arms. **Do not try to push the copper bands (sleeves) of the 'T' arms in to the insertion tube, they will not fit.**

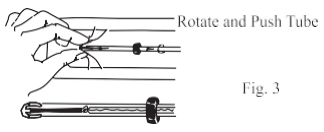


Fig. 3

Step 7
Adjust the movable flange depth guage with the help of scale printed on label insert or use the preprinted scale on the insertion tube so that it indicates the depth of uterus (as measured earlier by uterine sound). The flange should be positioned so that it is on the same plane as the arms of the 'T' as shown in fig. 4.

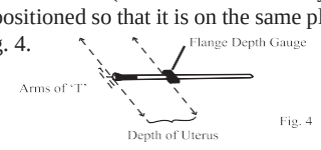


Fig. 4

Step 8
The T Cu 380A is now ready for insertion. Peel the remaining cover of the package and lift the loaded insertion tube, keeping it horizontal; so that the 'T' or white solid rod does not fall out and also be careful not to dislodge the 'T' by pushing the white solid rod upward. Do not let insertion assembly touch any unsterile surface that may contaminate it.
Maximum time the IUD can be in the insertion instrument of 5 minutes.

D) INSERTING THE LOADED T Cu 380A

Step 1
Gently introduce the loaded insertion assembly through the cervical canal and advance upwards until the 'T' lies in contact with the fundus, and flange comes in contact with the cervix. Ensure that the flange is in the horizontal plane as shown in fig. 5.

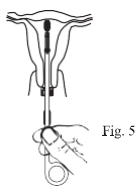
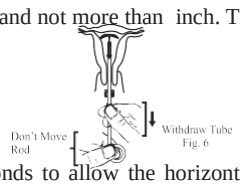


Fig. 5

Step 2
Holding the white solid rod stationary by one hand withdraw the insertion tube by your free hand not more than ½ inch. This release the arms of the 'T' as shown in fig. 6.



Step 3
Wait approximately 10 seconds to allow the horizontal arms of Pregna Model T Cu 380A to open and regain its T-shape once the arm has been released, carefully push the insertion tube upwards, towards the top of the uterus you feel a slight resistance as shown in fig. 7. This step ensures that the arms of the 'T' are as high as possible in the uterus. Excessive force could cause perforation of the fundus.

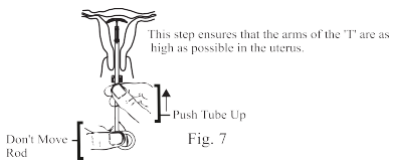


Fig. 7

Step 4
Gently withdraw first the white solid rod (hold the insertion tube stationary while removing the white solid rod), and then the insertion tube from the cervical canal. Cut the threads so that they protrude only 3-4 cm into the vagina as shown in fig. 8.

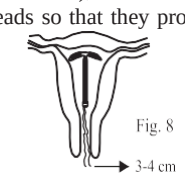


Fig. 8

Step 5
Assist woman from the table slowly (be alert to possible dizziness) and instruct her how and when to check threads. Have her check the threads. Invite questions and instruct about return visit as well as what to do, whom and how to contact for her help if needed.

E) REMOVAL INSTRUCTIONS

Using gentle, "no-touch" (aseptic) technique throughout, perform the following steps to remove IUD:

STEP 1: Give the woman a brief overview of the procedure, encourage her to ask questions, and provide reassurance as needed. Remind her to let you know if she feels any pain.
STEP 2: Put clean/ high-level disinfected gloves on both hands.
STEP 3: Insert a high-level disinfected (or sterile) speculum and visualize the cervix and the IUD strings. If the strings cannot be seen, manage as missing strings.
STEP 4: Thoroughly apply an appropriate antiseptic (e.g., povidone iodine or chlohexidine) two or more times to the cervix (wiping from inside the os outward) and vagina. If povidone iodine is used, ensure that the woman is not allergic to iodine and wait 2 minutes for the solution to act. Ask her to take slow, deep breaths and relax. Inform her that she may feel some discomfort and cramping, which is normal.
Do not use force at any stage of this procedure. Grasp the strings of the IUD with a high-level disinfected (or sterile) straight artery forceps. Apply steady but gentle traction, gently pulling the strings toward you with the forceps. The device can usually be removed without difficulty.If the strings break off but the IUD is visible, grasp the device with the forceps and remove it. If removal is difficult, do not use excessive force.

ACTIONS TO BE TAKEN DURING DIFFICULTY IN REMOVING

- Attempt a gentle, slow twisting of the IUD while gently pulling.
- Continue as long as the woman remains comfortable.
  If the IUD can still not be removed, refer the woman to a specially trained provider who can dilate the cervix.

If there seems to be a sharp angle between the uterus and cervix:
- Place a high-level disinfected (or sterile) volsellum on the cervix, and apply gentle traction downward and outward.
- Attempt a gentle, slow twisting of the IUD while gently pulling.
- Continue as long as the woman remains comfortable.
  If the IUD can still not be removed, refer the woman to a specially trained provider.

WARNING & PRECAUTION

Prior to use inspect package for any visible damage or defect.

- Do not re-sterilize, re-sterilization can lead to product degradation which can result in unwanted pregnancy.
- Ectopic Pregnancy: If a woman gets pregnant with IUD in place, there is a chance of having an extra-uterine pregnancy which should be evaluated.
- Pelvic Infection: IUD's may be associated with an increased relative risk of Pelvic Inflammatory Disease (PID) compared to other forms of contraception.
- Expulsion: Sometimes an IUD is pushed out of the Uterus into the vagina during heavy flow of menses as Uterus remains slightly open during the menstrual period.
- Perforation: Partial or total perforation of the uterine wall or cervix may occur rarely during placement, though it may be detected later.

RISK OF RE-USE

1. Loss of sterility & corresponding risk of infection .
2. Loss of efficacy due to lesser copper than the designed specification.

On completion of shelf life or on removal after use, dispose the items as per the local regulations governing disposal of non recyclable waste/-medical waste.

INCOMPATIBILITIES

1) An anatomical abnormality that distorts the uterine cavity might preclude proper IUD placement.
2) Incompatibility between the IUD and the uterine cavity can lead to partial or total expulsion, pain, unintended pregnancy, and abnormal or heavy uterine bleeding leading to removal of the device.

MRI COMPATIBILITY

Radiotherapy or electrotherapy using high frequency current is contraindicated especially when it is applied in the area of the lower pelvis. With regard to use of the continuous low-frequency current (ionizations), it appears that it cannot have a harmful effect on women using a copper IUD. The energetic state of copper will not be modified by MRI, therefore the effect of MRI on IUD cannot be estimated. In addition, based on the non-ferric characteristic of copper, scintigraphy obtained by MRI is not considered to be impacted by the presence of the IUD.

MEDICAL BENEFITS

Benefits from our device T Cu 380A
1. Intrauterine contraception in women is safe, effective method when compared to other existing methods.
2. It can be used as emergency contraception device.
3. Less infection rates.
4.Prevention of unintended pregnancy
5.Long term efficacy

Benefits from Similar Device related to T Cu 380A
1. Less Expulsion.
2. Provide the highest contraceptive efficacy and rates of satisfaction.
3. No IUD-related artifacts were found.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Intrauterine Contraceptive Device.
T Cu 380A comply with all the Safety and Performance requirements with respect to the intended use of the device from the Clinical Evaluation study. The clinical evaluation is complete and conforms to the essential requirements. The Clinical evidence is demonstrated with the relevant essential requirements as per Annex I of MDR. Risk Mitigation has been established as per the guidlines of EN ISO 14971.

Complication and pathologies evaluated during the PMCF study is given below:
- Dislocation of IUD
- Migration Of IUD
- Anemia
- Back ache
- Vaginal inflammation/infection
- Uterine perforation

PERFORMANCE CHARACTERISTICS OF THE DEVICE

- Effective in preventing pregnancy
- Prevention of unintended pregnancy
- Long term efficacy

Quantitative Information (where applicable):
- Cu Wire, Cu Sleeves and Polyethylene dimensions are constant over the 10 year duration.
- Length of Monofilament Suture (HDPE/Nylon 66) remains consistent for the entire period.
- Insertion Tube and Flange is only for the transient contact (less than 60 minutes) with human body.

Qualitative Information:
- Copper components sustain their contraceptive functionality through prolonged interaction with the uterine environment.
- Polyethylene maintains its structural integrity and flexibility over the extended 10-year lifespan.
- Monofilament suture, made of HDPE or Nylon 66, remains in place for the full duration, providing reliability during removal.

Patient Exposure Considerations:
- Patients are continuously exposed to copper, polyethylene, and the monofilament suture throughout the 10-year period.
- Prolonged exposure to these materials is designed to ensure the ongoing effectiveness and safety of the Pregna Model T Cu 380A IUD.

The device is for single use only.

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