Lydia Copper T 380 A DKT Nigeria, IFU: SPE/QA/6538/D, 215 X 275 mm

**INDICATION**

Lydia Copper T 380 A IUD is indicated for contraception.

**INTENDED USE**

Lydia Copper T 380 A IUD offers almost complete protection against pregnancy, having a shelf life of 7 years and is remains effective for a period of 10 years. Correctly inserted, Lydia Copper T 380 A IUDs are safe for women at low risk of sexually transmitted disease.

The Lydia Copper T 380 A is a non-eradicative contraceptive device made of polyethylene. The stem is covered with copper wire, the total surface of the copper is approx. 380 A. The side areas are filled and shaped in a way to keep the Lydia Copper T 380 A IUD adjacent to the uterus, without restricting the uterine cavity or widening the canal. The contraceptive action of the device is probably due to a number foreign body reactions with the uterine endometrium and the presence of wound copper.

**MECHANISM OF ACTION**

Copper IUDs act by greatly reducing the likelihood of fertilization. Data and analysis indicate that the main anti-fertility effect of having IUDs involve inhibition of egg or sperm transport and/or the capacity of sperm to fertilize egg. Reduced sperm and transport capacity inhibit fertilization and occurs before the ovum reaches the uterine cavity. Continuous copper release in uterine cavity from the copper wire and copper shows increases the contraceptive effect of Lydia Copper T 380 A IUD.

**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 your doctor.
2. Cervix may occur following insertion, usually for a short time, but could last for several hours or days. This can be followed by taking mild analgesics, using hot compresses or elevation, and not smoking or drinking.
3. Check periodically, and particularly after menstruation, to make certain that the threads do not come from the cervix. If threads are missing, shorter or longer, return to the clinic.
4. Lydia Copper T 380 A IUD is removed, return to the clinic. There is no continuing protection after removal.
5. Return to the clinic for check-ups or for replacement of the Lydia Copper T 380 A IUD (end of your first year inserted), as instructed by healthcare provider.
6. First year period is delayed (with symptoms of pregnancy, such as nausea, tender breasts, etc.), report immediately to the clinic.
7. If there is abdominal pain, dizziness, discomfort, such as nausea, abdominal discomfort, fever, chills or severe pain, report to your doctor.

**Contraceptives (Absolute)**

1. Malignant Gastrointestinal disease
2. Uterine Polyps or Endometrial disease
3. Pregnancy
4. History of severe or pre-existing cysts
5. Infections of genital tract
6. Any surgery on the genital tract
7. Abnormal liver function tests or high liver function enzymes
8. History of allergy to Copper

**Contraceptives (Relative)**

1. Amenorrhea
2. Vaginal tract diseases
3. Complication of abortion
4. Anti-inflammatory treatment
5. Wilson’s disease
6. Multiple sex partners

**FOLLOW UP GUIDELINES FOR HEALTHCARE PROVIDERS**

The healthcare provider should ensure the user to come for a follow up visit in case of any problem or doubt regarding usage of Lydia Copper T 380 A IUD. During follow up the healthcare provider should pay particular attention to the following points:

1. Heavy bleeding indicates the possibility of miscarriage.
2. If pregnancy has occurred and the threads are still visible, the Lydia Copper T 380 A IUD should be removed.
3. If there is evidence of poor intrauterine device usage, remove Lydia Copper T 380 A IUD due to accidental retention in the chance of pregnancy. However, should pregnancy occur, it is improbable to safely perform the abortion.
4. Removal of Lydia Copper T 380 A IUD is advisable. If user is exposed to conditions that substantially increase the risk of pelvic inflammatory disease.

**PROCEDURE FOR INSERTION**

**CAUTION**

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

**A) PREPARING THE USER**

1. Operator should wear sterile gloves and use aseptic technique. He/she should gently explain the client what’s going to happen.
2. Prior to insertion the vagina and cervix should be cleaned with an antiseptic solution.
3. The cervix should be visualized by means of speculum and to exteriorized by grasping with a tenaculum. Cervical traction on the tenaculum will tend to reduce the distance between the cervical canal and endometrial cavity and will greatly facilitate introduction of the intrauterine device. The tenaculum should remain on the cervix, throughout the insertion of the Lydia Copper T 380 A IUD to that gesture traction on the cervix can be maintained
4. The sterile 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 Lydia Copper T 380 A IUD may be prepared for insertion.

**B) LOADING THE T 380 A**

Do not open the sterile package or bend the arm of “T” in to the insertion tube until immediately before it is introduced into the uterus. The Lydia Copper T 380 A IUD can be prepared for insertion inside the sterile package 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, the surface with the sterile static side up. Partially open the package from and marked OPEN, approximately half way 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 reach the bottom of the "T". Be careful not to touch tip of solid rod or thrust it against any surface as this could lead to the white solid rod losing its memory.

C) INSERTING THE LOADED T Cu 380 A

Step 1
Gently introduce the loaded insertion assembly through the cervical canal and advance upwards until the "T" bore is in contact with the fundus, and flange comes in contact with the cervix. Ensure that the flange is in the horizontal place as shown in fig. 3.

Step 2
Holding the white solid rod stationary by one hand withdraw the insertion tube by your free hand not more than 1/4 inch. This releases the arms of the "T" as shown in fig. 4.

Step 3
Once the arms have been released, carefully push the insertion tube up, towards the top of the uterus until 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.

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.

Step 5
Assist woman from the table (check for possible disorientation) 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, when and how to contact for her help if needed.

D) REMOVAL INSTRUCTIONS FOR T Cu 380A

Lydia Copper T Cu 380 A IUD must be removed by a trained health care provider. This can be done easily and safely in the clinic and takes only a few minutes. Removal is effected by pulling gently at one of the exposed threads. Excessive force or pulling threads could result in breakage of threads, force crowning or bending may be experienced during removal.

The sterile Copper T is for single use only and should not be reused. It may result in loss of efficacy and infections.

On the 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.