COPPER Y Mini Cu 380

Intrauterine Contraceptive Device

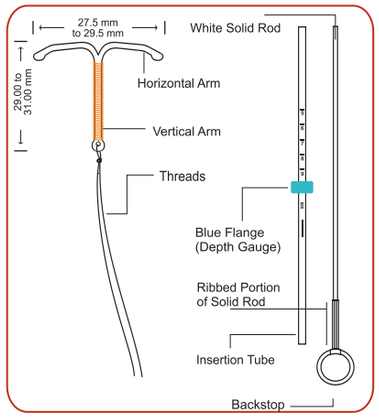
INDICATION

Intrauterine contraception in women of childbearing age.

INTENDED USE

Copper Y Mini offers almost complete protection against pregnancy, having a shelf life of 5 years and effective period of 5 years. Copper Y Mini does not affect lactation. This is fully reversible method and protection is reveres on its removal.

INTRODUCTION:



MECHANISM OF ACTIONS

Copper Y Mini act by gently 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 reached the uterine cavity. Continuous copper release in the uterine cavity from the copper wire enhances the contraceptive effect of Copper Y Mini

CONTRAINDICATIONS (ABSOLUTE)

1. Malignant disease 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 disease during the last 12 months (except bacterial vaginitis, repeats 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 Anti-inflammatory treatment
5. Wilson's disease
6. 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 IUD 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 IUD (end of five 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. Copper Y Mini intrauterine contraceptive device doesn't interact with any medicine the woman may be taking.

FOLLOW UP GUIDLINE FOR PHYSICIAN

The physician should encourage the user to come for 4 to 6 weeks follow up after the IUD insertion. During follow-up the physician should pay particular attention to the following points;

- Havier bleeding indicates the possibility of anaemia.
- If pregnancy has occurred, the Copper Y Mini should be removed, if possible.
- If a woman gets pregnant with IUD in place, there is a chance of having ectopic pregnancy, which should be evaluated.
- Removal of Copper Y Mini is advisable, if user is exposed to conditions that substantially increase the risk of pelvic inflammatory disease.

UNDESIRABLE EFFECTS OF THE PRODUCT AND THEIR FREQUENCY AND TIMING

Adverse effects of intrauterine devices, including Copper Y Mini, are uncommon but include the following:

1. Bleeding:
Menstrual bleeding is sometimes heavier and longer lasting than normal, or is more painful. Iron deficiency anaemia 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. Randomised, controlled studies indicate that the risk of genital tract infection after the first month of using an IUD is low. Exposure to sexually transmitted infections (STIS) is responsible for PID occurring after the first month of use, and not the use of IUD itself.

3. Pain or dysmenorrhoea:
Pain in the lower abdomen or sacral region may occur initially after insertion but usually subsides with time or with the use of painkillers. 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 the IUD to migrate outside of the uterine cavity and/or cause 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 the insertion or removal of an intrauterine device. Isolated cases of skin reactions have been described in the literature which may be attributable to a copper allergy.

PROCEDURE FOR INSERTION CAUTION

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

TIMING OF INSERTION

- The best time for insertion is during menstruation, as this prevents insertion during an undiagnosed pregnancy. At this time the external and internal cervical os are physiologically dilated.
- This facilitates the insertion of the IUD without the need to dilate the canal in most instances.
- Alternatively, the IUD may be introduced within 5 days of unprotected intercourse. Insertion immediately after unprotected intercourse can increase the risk of PID (pelvic inflammatory disease).
- Copper Y Mini can also be inserted within 15 minutes of delivery of the placenta or abortion during the first trimester. Note that there is a higher rate of expulsion in these instances.
- If the IUD cannot be inserted immediately after delivery of the placenta or abortion, the insertion should be delayed for at least 6 weeks. In case of a C section, the insertion should be delayed for 12 weeks delivery

A). PREPARING THE USER

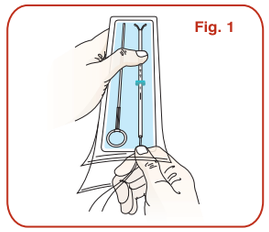
- Operator should wear sterile gloves and use aseptic technique.
- He/she should gently explain to the client what he/she is doing.
- Prior to insertion, the vagina and cervix should be cleaned with an antiseptic solution.
- The cervix should be visualising by means of speculum and its anterior lip grasped with a tenaculum. Gentle fraction 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 Copper Y Mini so than gentle fraction on the cervix can be maintained.
- The uterine sound then be introduced in the endo cervical 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 Y Mini may be preparing for insertion.

B). LOADING – COPPER Y Mini

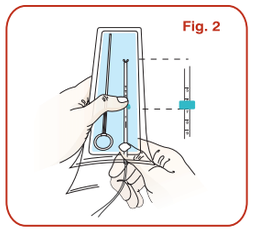
Open the sterile package and pull the arm of the "Frame" in the insertion tube, just before it is to be introduced into the uterus. The Copper Y Mini can be prepared for insertion inside the sterile package as per the instructions given below.

STEP 1
Ensure the vertical arm of the frame is fully inside the insertion tube and the opposite end of the insertion tube and should be closer to the package bottom seal.

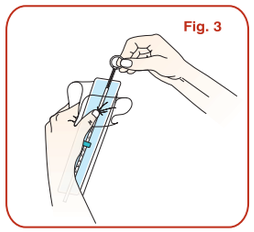
STEP 2
Place the package on the clean, hard, flat surface, partially open the plastic covering from the end marked "OPEN" till half way to the blue flange. However, IUD and insertion tube are not to be withdrawn, as shown in fig. 1 while holding the tube firmly with one hand, release the thread from flange and draw the device into the insert tube by grasping both the threads and gently pulling the device into the insertion tube until the knobs at the ends of horizontal arm cover the opening of the tube.



STEP 3
Steadying the flange with one hand. Pull the insertion tube until the lower edge of the flange indicates the measure obtain with the uterine sound, on the scale printed on insertion tube as shown in Fig. 2.

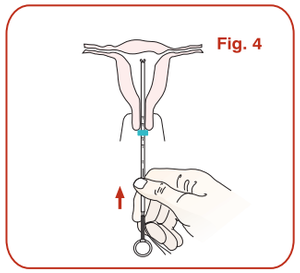


STEP 4
Holding the package with open end up, and the flaps away from the each other, hold the threads slightly starched with one hand, as shown in Fig. 03. Put the solid rod in to the insertion tube to almost touch the bottom of pulled frame. This will ensure that the thread are lying straight in the tube and will not be disarranged by the solid rod. Be careful not to touch the tip of solid rod or brush against another surface as this could lead to the solid rod losing its sterility. Ensure that the longer dimension of the flange is in direction in which the horizontal arm will open in the uterus.

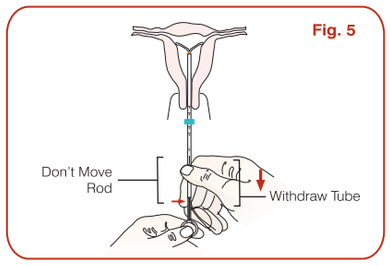


C). INSERTING THE LOADED COPPER Y Mini

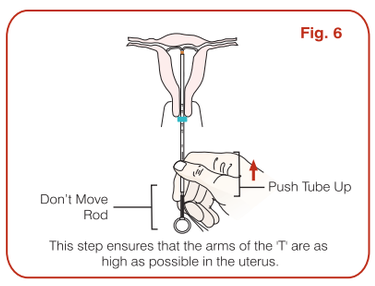
STEP 1
Gently introduced the loaded insertion assembly through the cervical canal and advance upward until flange comes into contract with cervical os. Ensure that the flange is in the horizontal plane as shown in Fig. 4.



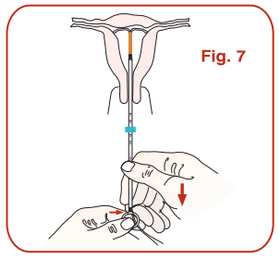
STEP 2
Holding the solid rod stationary by one hand withdraw the insertion tube by your free hand to touch ribbed part of solid rod there by the flange is remove from cervical os as well (approx. 1.5 cm). The arms of frame are now unfolded as shown in fig.05



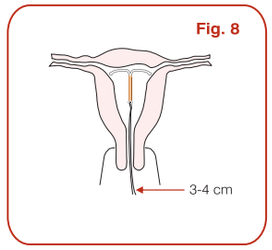
STEP 3
Advance the insertion tube until the flange is touching the cervical os again. The Copper Y Mini is now in contact with fundus as shown in fig.06



STEP 4
To release the device entirely from the insertion tube, hold the solid rod firmly and draw the tube back as far as the backstop as shown in fig.07.



STEP 5
First, gently withdraw the solid rod (hold the insertion tube stationary while removing the solid rod) and then the insertion tube from the cervical canal to prevent pulling the device from the fundal position. Cut the thread so that they are visible only 3-4 cm outside the cervix shown in fig. 8.



STEP 6
Assist women 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 the help if needed.

D). REMOVAL INSTRUCTIONS

Copper Y Mini must be removed by a trained health-care provider. This can be done easily and safely in the clinic and takes only few minutes; removal is done by gently pulling one of the exposed threads. Excessive force in pulling the thread could result in breakage of threads. Some cramping or bleeding may be experienced during removal.

ACTIONS TO BE TAKEN FOR DIFFICULT REMOVAL

Using a gentle, aseptic non-touch technique throughout, perform the following steps to remove the 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 visually inspect the cervix and the IUD strings. If the strings cannot be seen proceed with management for missing strings.

STEP 4: Thoroughly apply an appropriate antiseptic (e.g., povidone iodine or chlorhexidine) to The cervix and vagina at least twice (wiping from inside the os outward). If povidone Iiodine 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 the procedure. Grasp the strings of the IUD with high-level disinfected (or sterile) straight artery forceps. Apply steady but gentle traction, gently pulling the strings towards 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 it proves difficult to remove, do not use excessive force.

- 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.

WARNING & PRECAUTION

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

RISK OF RE-USE

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

DISPOSAL

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

INCOMPATIBILITIES

1. An anatomical abnormality that distorts the uterine cavity may preclude proper IUD placement.
2. An 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 the 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.

The device is for single use only.

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COPPER Y
Mini Cu 380

Intrauterine Contraceptive Device

Instructions for Use