



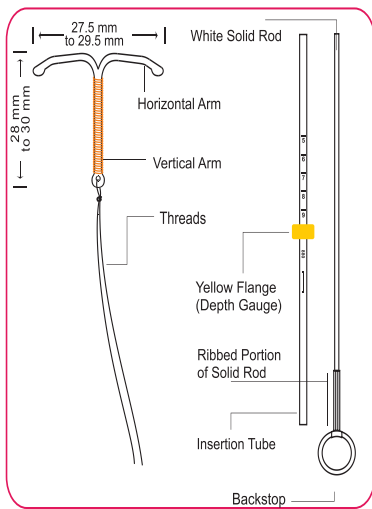
**INDICATION**

Intrauterine contraception in women of childbearing age.

**INTENDED USE**

Silverline mini Cu 380Ag offers almost complete protection against pregnancy, having a shelf life of 5 years and effective period of 5 years. Silverline does not affect lactation. This is a fully reversible method and protection is reversed on its removal.

**INSTRUCTION**



**UNDESIRABLE EFFECTS OF THE PRODUCT, INCLUDING THEIR FREQUENCY AND TIMING**

Adverse effects of intrauterine devices, including Silverline Mini Cu 380 Ag 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: controlled studies indicate that any risk of genital may lead to subsequent infertility. Randomized, controlled studies indicate that any risk of genital tract infection after the first month of IUD use is small. 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) 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 empty the contents of the pouch in the instrument tray.
- Do not use the solid rod to measure uterine cavity length.

**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 Silverline Mini Cu 380 Ag 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. Silverline Mini Cu 380 Ag 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 Silverline Mini Cu 380 Ag 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

**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 cleansed with an antiseptic solution.
- 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 Silverline so that gentle traction on the cervix can be maintained.
- 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 Silverline may be prepared for insertion.

**B) LOADING- SILVERLINE MINI CU 380AG**

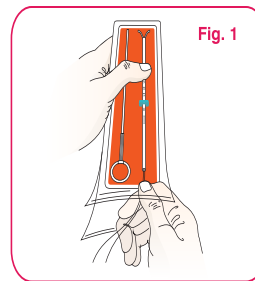
Open the sterile package or pull the arm of "Frame" in the insertion tube, just before it is to be introduced into the uterus. The Silverline mini Cu 380Ag can be prepared for insertion inside the sterile package as per the instructions given below.

**STEP 1**

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

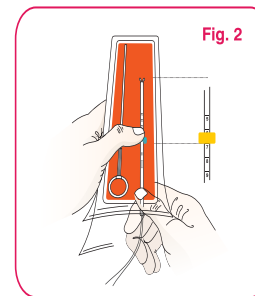
**STEP 2**

Place the package on a clean, hard, flat surface, partially open the plastic covering from the end marked "OPEN" till half way to the yellow 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 threads from flange and draw the device into the insertion 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**

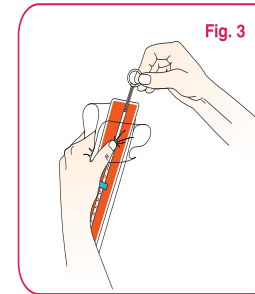
Steadying the flange with one hand, pull the insertion tube until the lower edge of the flange indicates the measure obtained with the uterine sound, on the scale printed on insertion tube as shown in fig. 2.



**STEP 4**

Holding the package with open end up, and the flaps away from each other, hold the threads slightly stretched with one hand, as shown in fig. 3. Put the solid rod into the insertion tube to almost touch the bottom of pulled frame. This will ensure that the threads 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.



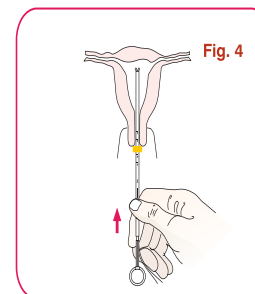
**STEP 5**

The Silverline mini Cu 380 is now ready for insertion. Peel the remaining cover of the package and lift the loaded tube, keeping it horizontal so that the frame or solid rod does not fall out. Be careful not to dislodge the frame by pushing the solid rod upward. Do not let insertion assembly touch any unsterile surface that may contaminate it.

**C) INSERTING THE LOADED SILVERLINE MINI CU 380 AG**

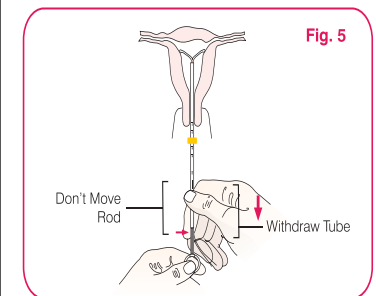
**STEP 1**

Gently introduce the loaded insertion assembly through the cervical canal and advance upward until flange comes into contact with cervical os. Ensure that the flange is in the horizontal plane as shown in the fig. 4.



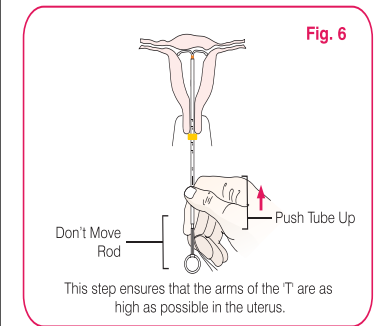
**STEP 2**

Holding the solid rod stationary by one hand withdraw the insertion tube by your free hand to touch ribbed part of solid rod thereby the flange is removed from cervical os as well (approx 1.5 cm). The arms of Frame are now unfolded as shown in fig. 5.



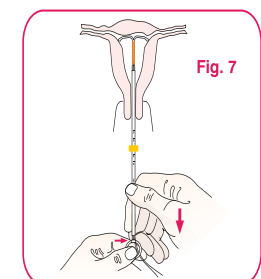
**STEP 3**

Advance the insertion tube until the flange is touching the cervical os again. The Silverline mini Cu 380Ag is now in contact with fundus as shown in fig. 6.



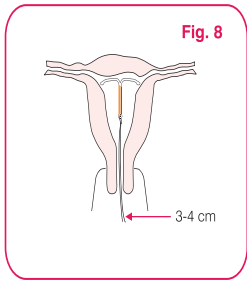
**STEP 4**

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. 7.



**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 threads so that they are visible only 3-4 cm outside the cervix as shown in fig. 8.



#### STEP 6

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 the help if needed.

#### D) REMOVAL INSTRUCTIONS

Silverline Mini Cu 380 Ag must be removed by a trained healthcare 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 threads could result in breakage of threads. Some cramping or bleeding may be experienced during removal.

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 chlorhexidine) 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.

#### E) DO NOT RE-USE

Do not re-use the Silverline Mini Cu 380 Ag. It may result in loss of efficacy and infections.

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

#### DIRECTIONS FOR IUD USERS

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.

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.

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.

If Silverline Mini Cu 380 Ag is expelled, return to the clinic. There is no continuing protection after expulsion.

Return to the clinic for checkup or for replacement of the Silverline Mini Cu 380 Ag (end of five years after insertion), as instructed by physician.

If your period is delayed (with symptoms of pregnancy, such as nausea, tender breasts, etc...) report immediately to the clinic.

If there is abdominal pain, pain during intercourse, infections (such as gonorrhoea), abnormal discharge, fever, chills consult your physician.

#### MECHANISM OF ACTIONS

Silverline 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 with silver core enhances the contraceptive effect of Silverline Mini Cu 380 Ag.

#### FOLLOW UP 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 usage of Silverline Mini Cu 380 Ag. During followup the physician should pay particular attention to the following points.-

- Heavier bleeding, indicates the possibility of anemia.
- If pregnancy has occurred, the Silverline Mini Cu 380 Ag should be removed, if possible.
- If a woman gets pregnant with IUD in place, there is a chance of having an ectopic pregnancy, which should be evaluated.
- Removal of Silverline Mini Cu 380 Ag is advisable, if user is exposed to conditions that substantially increase the risk of pelvic inflammatory disease.

#### 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. Anti-inflammatory treatment
5. Wilson's disease
6. Multiple exposures to different sexual partners

#### WARNING & PRECAUTION

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

#### RISK OF RE-USE

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

#### 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.

The device is for single use only.



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PT/QA/672:03  
Effective Date: 24/03/2023

Silverline  
Mini Cu 380 Ag

Instructions  
for Use