

Silverline Cu 380Ag IFU with CE Mark - Size 285 x 210 mm - CMYK Colour



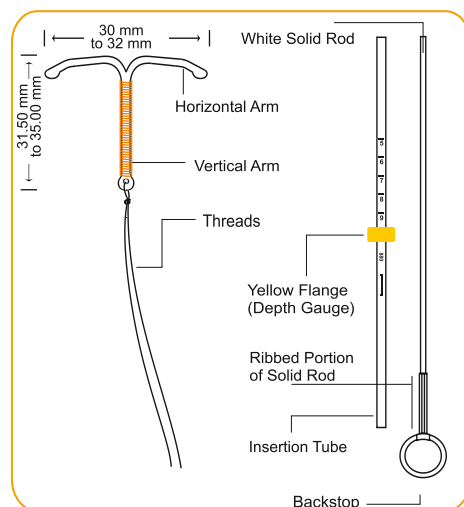
INDICATION

Intrauterine contraception in women of childbearing age.

INTENDED USE

Silverline Cu 380 Ag 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.

INTRODUCTION



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.

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 Cu 380 Ag

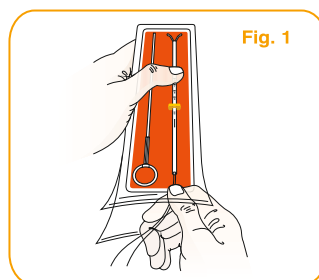
Open the sterile package or pull the arm of "Frame" in the insertion tube, just before it is to be introduced into the uterus. The Silverline Cu 380 Ag can be prepared for insertion inside the sterile package as per the instructions given below.

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.

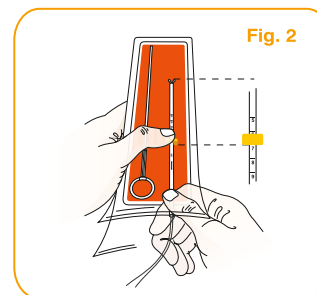
STEP 2

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.



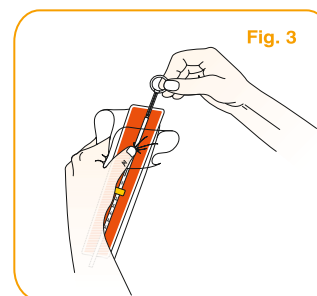
STEP 3

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.



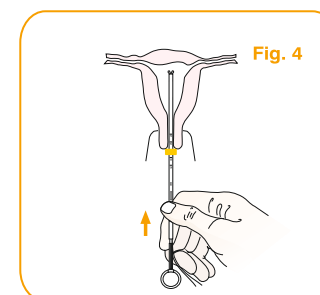
STEP 5

The Silverline Cu 380 Ag 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 Cu 380 Ag

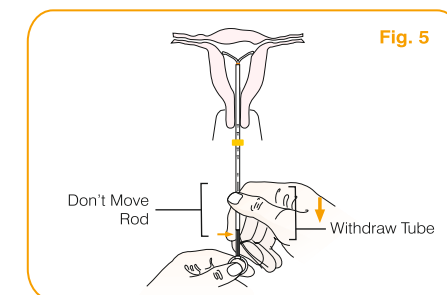
STEP 1

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.



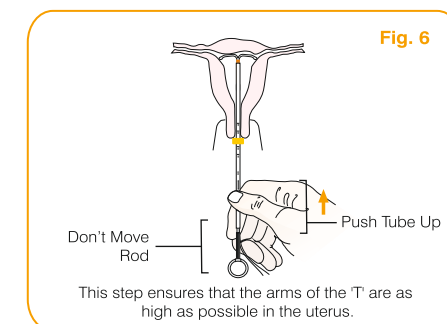
STEP 2

Holding the solid rod stationery 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 Cu 380 Ag 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.

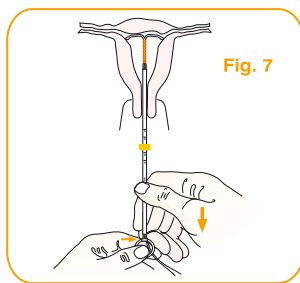


Fig. 7

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.

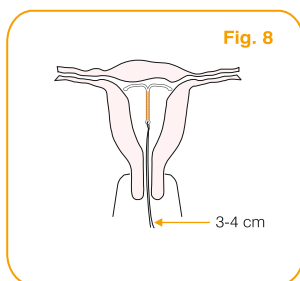


Fig. 8

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 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.

E) DO NOT RE-USE

Do not re-use the Silverline 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 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 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 gonorrhea), 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 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 usages of Silverline Cu 380Ag. 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 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 Cu 380 Ag is advisable, if user is exposed to conditions that substantially increase the risk of pelvic inflammatory disease.

CONTRAINDICATIONS (ABSOLUTE)

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

CONTRAINDICATIONS (RELATIVE)

- Anaemia
- Valvular heart disease
- Coagulation disorders
- Anti-inflammatory treatment
- Wilson's disease
- Multiple exposures to different sexual partners

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.

The device is for single use only.



STERILE R

Manufactured by
PREGNA
INTERNATIONAL LTD.

Plot No.: 219, Survey No.: 168
Dabhel Industrial Co-Operative Society Ltd.,
Dabhel, Daman (U.T) - 396 210 - India

Email: sales@pregna.com
Website: www.pregna.com

Silverline
Cu 380 Ag

Instructions for Use