aureline

Cu 380 Au/Mini Cu 380 Au

Intrauterine Contraceptive Device

A) INDICATION

Intrauterine contraception in women of childbearing age.

B) INTENDED USER

Trained Medical Professionals

C) INTENDED USE

Aureline Cu 380 Au/Mini Cu 380 Au IUDs offer almost complete protection against pregnancy.

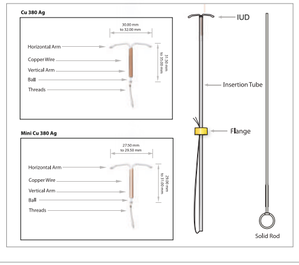
D) DEVICE DESCRIPTION OF DESIGN, DIMENSIONS & COMPOSITION OF IUD

The Aureline Cu 380 Au/Mini Cu 380 Au Intrauterine Contraceptive Devices (IUDs) is effective for a period of 5 years. Correctly inserted, Aureline Cu 380 Au/Mini Cu 380 Au IUDs are safe for women at low risk of sexually transmitted disease. Cu 380 Au/Mini Cu 380 Au is the smaller version of the standard IUD.

The Aureline Cu 380 Au/Mini Cu 380 Au has a "Y" shape frame made of polyethylene. The stem is covered with copper wire with a gold core and the total surface area of the copper is approx. 380 mm^2. The copper wire with gold core delays the fragmentation of the wire and prolongs the life span of device. A nylon thread is attached to the bottom of the frame's vertical arm for removal of the IUD. The side arms are flexible and shaped in such a way as to keep the Aureline Cu 380 Au/Mini Cu 380 Au adjacent to the fundus, without stretching the uterine cavity or touching the cornua. The contraceptive action of the device is probably due to a presence of foreign body reactions with the uterine endometrium and the presence of metallic copper.

Quantity of Implanted Material

Material	Unit Weight
Polyethylene (T Frame)	0.130 to 0.150 gms.
Copper Wire with Gold Core	300 to 370 mg
Nylon or Polythene (Suture Thread)	0.014 to 0.016 gms.



E) 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

F) CONTRAINDICATIONS (RELATIVE)

1) Anemia
2) Valvular heart disease
3) Coagulation disorders
4) Anti-inflammatory treatment
5) Wilson's disease
6) Multiple exposures to different sexual partners

G) DIRECTION 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 the 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 IUD is expelled, return to the clinic. There is no continuing protection after expulsion.
5) Return to the clinic for a checkup or for replacement of the IUD (end of five years after insertion), as instructed by a 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) IUD doesn't interact with any medicine the woman may be taking.

H) MECHANISM OF ACTION

Copper IUDs 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, enhance the contraceptive effect of IUDs.

I) 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 IUD. During follow-up the physician should pay particular attention to the following points –

1) Heavier bleeding, indicates the possibility of anemia.
2) If pregnancy has occurred, the IUD 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 IUD is advisable, if user is exposed to condit ions that substantially increase the risk of pelvic inflammatory disease.

J) UNDESIRABLE EFFECTS OF THE PRODUCT, INCLUDING THEIR FREQUENCY AND TIMING

Adverse effects of Intrauterine Devices, including IUDs 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 menstrual 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 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) 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.

K) PROCEDURE FOR INSERTION

CAUTION

1) Do not pick up and use any component that has fallen on the floor or table.
2) Do not pour the contents of the pouch in the instrument tray.
3) Do not use the white 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 possi bility 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.
4) When using the IUD 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.
5) IUD 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 IUD 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.

PREPARING THE USER

1) Provider 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.
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 IUD may be prepared for insertion.

LOADING OF THE IUD

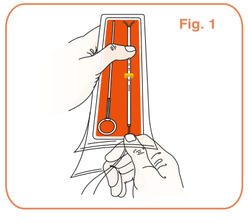
Do not open the sterile package or bend the arms of 'IUD' in to the insertion tube until immediately before it is introduced into the uterus. The IUD can be prepared for insertion inside the sterile package as per the instructions given below.

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.

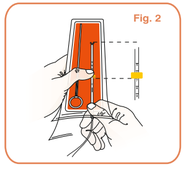
STEP 2

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.



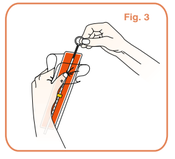
STEP 3

Steadying the flange with one hand, pull the insertion tube until the lower edge of the flange indicates the measured value on the 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, insert 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 it sterility. Ensure that the longer dimension of the flange is in direction in which the horizontal arm will open in the uterus.



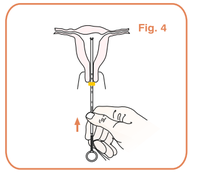
STEP 5

The IUD is now ready for insertion. Do not keep the IUD loaded in the insertion tube for more than 5 minutes. 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.

INSERTING THE LOADED IUD

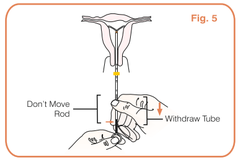
STEP 1

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



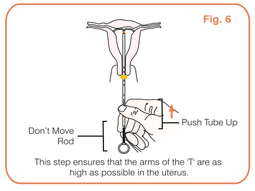
STEP 2

Holding the solid rod stationary by one hand withdraw the insertion tube by your free hand to touch ribbed part of solid rod. The flange will now be approximately 1.5 cm away from cervical os. The arms of Frame are now unfolded as shown in fig. 5.



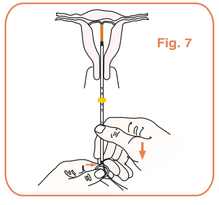
STEP 3

Advance the insertion tube until the flange is touching the cervical os again. The IUD is now in contact with fundus as shown in fig. 6.



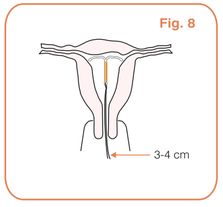
STEP 4

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

L) REMOVAL INSTRUCTIONS

Using a 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 them 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.

M) ACTIONS TO BE TAKEN DURING DIFFICULTY IN REMOVING

1) Attempt a gentle, slow twisting of the IUD while gently pulling.
2) 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:

1) Place a high-level disinfected (or sterile) vulsellum on the cervix, and apply gentle traction downward and outward.
2) Attempt a gentle, slow twisting of the IUD while gently pulling.
3) Continue as long as the woman remains comfortable.

If the IUD can still not be removed, refer the woman to a specially trained provider.

N) WARNING & PRECAUTION

Before use inspect the package for any visible damage or defect.

O) RISK OF RE-USE

1) Loss of sterility & corresponding risk of infection.
2) Loss of efficacy due to lesser copper than the designed specification.
3) The sterile IUD is for single use only and should not be reused.

P) DISPOSAL

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.

Q) 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 the removal of the device.

R) 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.

S) 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 efficac y

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.

T) SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Intrauterine Contraceptive Device Cu 380 Au/Mini 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 guidelines of EN ISO 14971.
Complication and pathologies evaluated during the PMCF study is given below:
1)Dislocation of IUD
2) Migration of IUD Aneamia
3) Back ache
4) Vaginal inflammation/infection
5) Uterine perforation

U) PERFORMANCE CHARACTERISTICS OF THE DEVICE

1) Effective in preventing pregnancy
2) Prevention of unintended pregnancy
3) Long term efficacy

V) QUANTITATIVE INFORMATION (WHERE APPLICABLE):

1) Cu Wire, Cu Sleeves, and Polyethylene dimensions are constant over the 5 year duration.
2) Length of Monofilament Suture (HDPE/Nylon 66) remains consistent for the entire period.
3) Insertion Tube and Flange is only for the transient contact (less than 60 minutes) with human body.

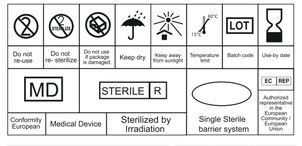
W) QUALITATIVE INFORMATION:

1) Copper components sustain their contraceptive functionality through prolonged interaction with the uterine environment.
2) Polyethylene maintains its structural integrity and flexibility over the extended 5-year lifespan.
3) Monofilament suture, made of HDPE or Nylon 66, remains in place forthe full duration, providing reliability during removal.

X) PATIENT EXPOSURE CONSIDERATIONS:

1) Patients are continuously exposed to copper, polyethylene, and the monofilament suture throughout the 5-year period.
Prolonged exposure to these materials is designed to ensure the ongoing effectiveness and safety of the
2) Aureline Cu 380 Au IUD.

The device is for single use only.



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