aureline

Cu 380 Au/Mini Cu 380 Au With Loader With Disposable Uterine Sound

INDICATION:

"Intrauterine contraception in women of childbearing age"

INTENDED USER:

Trained Medical Professionals.

INTENDED USE:

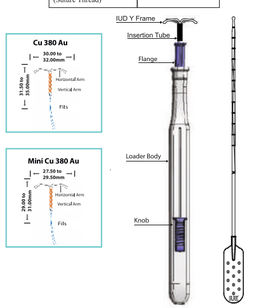
Aureline Cu 380 Au/Mini Cu 380 Au with loader offers almost complete protection against pregnancy, having a shelf life of 1 year and efficacy up to 5 years.

DESCRIPTION OF DESIGN , DIMENSIONS &COMPOSITION OF IUD

Aureline IUDs Intrauterine Contraceptive Device is ready-to-use in sterile package and comes with a unique loader for single hand loading and insertion of device. The Aureline IUDs device is available in 2 sizes-standard and Mini as shown below. The copper wire with gold core is wound on the vertical arm of Y shape frame having a surface area approximately of 380 mm^2. A nylon thread is tied at the bottom of the frame for the retrieval of the IUD.
Disposable Uterine Sound is supplied with the pack for sounding of uterus.

Quantity of Implanted Material

Material	Unit Weight
Polyethylene (Y 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.



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.

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 tablet, using hot compresses on abdomen, and/or exercising moderately.
3. Check periodically, and particularly after menstruation, to make certain that the thread 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 check-up or for replacement of the 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, infection (such as gonorrhoea), abnormal discharge, fever, chills consults your physician.
8. Intrauterine contraceptive device doesn't interact with any medicine the woman may be taking

MECHANISM OF ACTION

IUD 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 IUD.

FOLLOWUP GUIDELINE FOR PHYSICIANS

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;

1. Heavier bleeding indicates the possibility of anaemia.
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 ectopic pregnancy, which should be evaluated.
4. Removal of IUD is advisable, if user is exposed to conditions that substantially increase the risk of pelvic inflammatory disease.

UNDESIRABLE EFFECTS OF THE PRODUCT, INCLUDING THEIR FREQUENCY AND TIMING

Adverse effects of intrauterine contraceptive devices, 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:

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 low. 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

1. Do not pick and use any component that has fallen on the floor or table.
2. Do not empty the contents of the pouch in the instrument tray.

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 IUD for emergency contraception, the IUD may be introduced within 5 days of unprotected coitus. Insertion immediately after unprotected coitus can increase risk the of PID.
4. 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 the delivery of the placenta or abortion, insertion should be delayed for at least six weeks. In case of cesarean section insertion should be delayed for 12 weeks

A) PREPARING THE USER

1. Operator should wear sterile gloves and use aseptic technique
2. He/she should gently explain to the client what he/she is doing.
3. Prior to insertion, the vagina and cervix should be cleaned with an antiseptic solution.
4. The cervix should be visualising 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 IUD so than gentle fraction on the cervix can be maintained.
5. The Disposable Uterine Sound 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.

B)LOADING OF INTRAUTERINE CONTRACEPTIVE DEVICE

Step 1

Place the package on a clean, hard, flat surface, open the cover up to the marking from the end marked "OPEN" as shown in fig.1

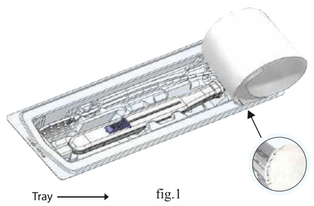


fig.1

Step 2

Remove the Disposable Uterine Sound first from the tray, as shown in the fig. 2. to measure the depth of the Uterus.

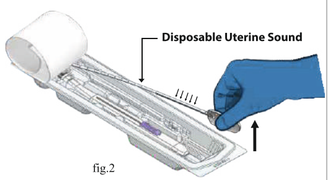
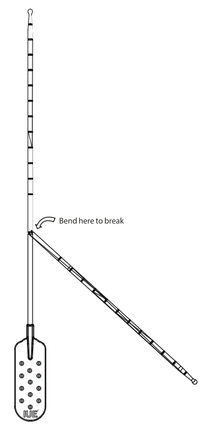


fig.2

SOUNDING THE UTERINE CAVITY

1. Take (The Disposable Uterine Sound) out of the tray
2. Gently insert the uterine sound to determine the direction of the cervical canal and the depth of the uterine cavity by inserting it will it reaches the fundal position.
3. Check the patency of the cervix, measure the depth of the uterine cavity and confirm its direction.
4. Rule out the possibility of Uterine septum, synechiae or sub musous fibroids.
5. Should the cervical canal be too narrow, dilation of the canal may be necessary. Consider the use of anelgesics / paracervical block.
6. Pull out the Disposable Uterine Sound gently through the cervix
7. Note the reading on the sound up to the wet area on it
8. Break the Disposable Uterine Sound into two mark before discarding to prevent reuse.



How to break Disposable Uterine Sound.

Step 3

Remove the device from the Tray by holding it firmly near the knob with your hand and lift it slightly, and move it backward ensuring the upper part of IUD rubs against the cover during removal, as shown in the fig.3. Do not let IUD touch any unsterile surface that may contaminate it.

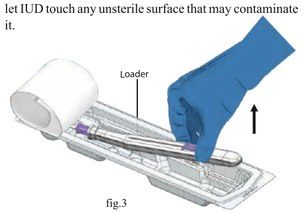


fig.3

Step 4

Grab the device at the end, ensure that the Knob is facing upward as shown in fig.4

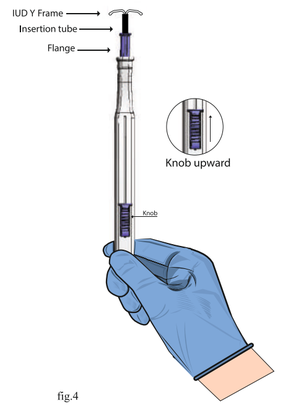


fig.4

Step 5

Place the thumb on the Knob. Gently move the knob in a forward motion to fold the arms of the IUD into the Insertion tube as shown in fig.5

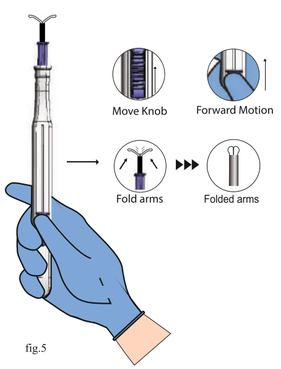


fig.5

Step 6

For accurate measurement, we have provided a scale printed with an interval of 1 cm. To make this device more accurate, we have provided a click sound with an interval of 0.5 cm. As you slide it, you'll hear clicking sounds. The first click will be at 5 cm for Standard, whereas the first click will be at 4.5 cm for Mini, and each subsequent click represents a measurement of 0.5 cm. If the measured depth is 7 cm, set the flange at 7 cm by moving the knob upward until you see the 7 cm marking on the insertion tube. The standard can be adjusted up to 10 cm, whereas the Mini can be set up to 9.5 cm.

-Once you achieve the measured number on Insertion tube your device is ready for insertion.

- Make sure to hold the knob all the time with thumb till IUD is placed inside the uterus.

-Do not keep IUD in loaded position (folded arm) for more than 5 mins. It distorts the arms of the IUD and may lead to incorrect placement of the IUD in the uterine cavity.

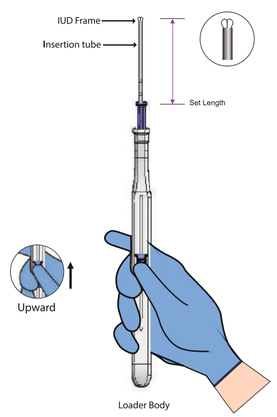


fig.6

C) INSERTING THE LOADED Cu 380 Au

Step 1

While holding the Knob with thumb, gently introduce the loaded device through the cervix and advance upward until flange is approximately 1.5-2 cm from the cervical Os as shown in the fig.1. Ensure that the flange is in the horizontal plane.

- Make sure to hold the knob all the time with thumb till IUD is placed inside the uterus.

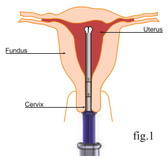


fig.1

Step 2

Now move the knob back until the Flange goes inside the Loader this will release the arms of the IUD fig 2. Then advance the device slowly until the resistance is not felt or the flange is touching to the cervical Os again the IUD is now in contact with the fundus as shown in fig.3.

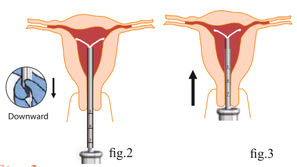


fig.2 fig.3

Step 3

Then, to release the IUD slowly move the knob back until the resistance is felt in knob, then pull back the device as far as until the suture end is released from the insertion tube as shown in the fig.4

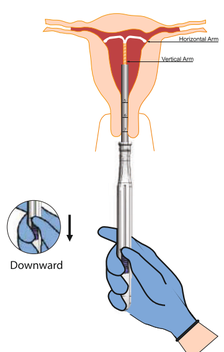


fig.4

Step 4

Cut the threads so that they are visible only 3-4 cm outside the cervix as shown in fig.5

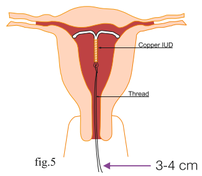


fig.5

Step 5

Assist women from the table slowly (be alert to possible dizziness) and instruct how and when to check threads. Invite questions and instruct about return visits as well as what to do, when and how to contact for the help if needed.

D) REMOVAL INSTRUCTIONS

IUD 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 thread could result in breakage of threads. Some cramping or bleeding maybe experienced during removal.

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) volsellum 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.

WARNING & PRECAUTION

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

RISK OF RE-USE

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

The sterile IUD is for single use only and should not be reused.

DISPOSAL

On completion of Shelf Life or on removal after use, dispose the item as per the local regulations governing dispose on non-recyclable waste/medical waste.

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.

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 efficacy

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.

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 guidlines of EN ISO 14971.

Complication and pathologies evaluated during the PMCF study is given below:

1. Dislocation of IUD
2. Migration Of IUD
3. Anemia
4. Back ache
5. Vaginal inflammation/infection
6. Uterine perforation

PERFORMANCE CHARACTERISTICS OF THE DEVICE

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

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.

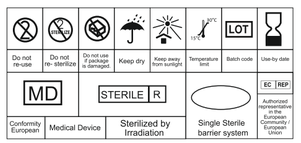
QUALITATIVE INFORMATION:

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.

PATIENT EXPOSURE CONSIDERATIONS:

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

The device is for single use only.



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Cu 380 Au/Mini Cu 380 Au With Loader With Disposable Uterine Sound

Intrauterine Contraceptive Device

Instructions for Use