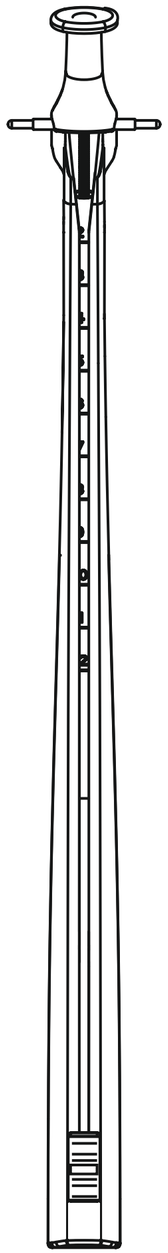
Etherena T Cu 380A IFU with CE Mark in English language. Size - 210mm x 390mm | Black Colour | SPE/QA/6518/D | PT/QA/997:01 | Date : 15/03/2021



Etherena Inserter

INTRA UTERINE ENABLERS

STERILE R

MD

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2460

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PT/QA/997:01
Effective Date: 15/03/2021

etherena
T Cu 380A

Intrauterine
Contraceptive
Device

To be inserted and removed by or under the supervision of a trained physician.

READ THIS FIRST

INSTRUCTION FOR USE

INDICATION
Intrauterine contraception in women of child bearing age.

INTENDED USER
Trained Medical Professionals

INTENDED USE

Etherena T Cu 380 A IUDs offer almost complete protection against pregnancy, having a shelf life of 5 years and it remains effective for a period of 10 years.

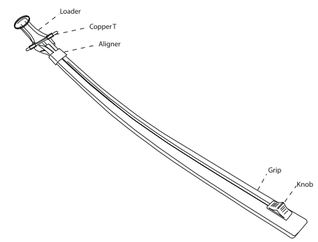
The loading is performed without human touch to the T Cu 380 A, resulting in aseptic loading.

T Cu 380 A can be inserted at any time during the menstrual cycle.

It can be replaced by a new one at any time during the menstrual cycle.

CONTENTS OF THIS PACKAGE

Etherena - 1 Unit



T Cu 380 A ADVANTAGES

- Convenient for a woman having one or more children who wants to plan birth control.
- Effective contraception for upto 10 years.
- Little to remember.
- No hormonal side effects.
- No interactions with any medicines.
- Immediately reversible.
- Easy quick and aseptic T Loading.
- Single handed loading no direct touch.
- Easy to set depth of uterus.
- Easy insertion.

MECHANISM OF ACTION

Copper 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 enhance the contraceptive effect of Etherena T Cu 380 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.

After examining the uterus to determine its position, size and condition, a speculum is inserted into the vagina (as for a Pap smear) and the cervix . The vagina is cleansed with antiseptic lotion. The uterus is held steady while depth is sounded. The doctor uses a slender flexible transparent plastic tube to insert Etherena T Cu 380 A into the uterus.

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.

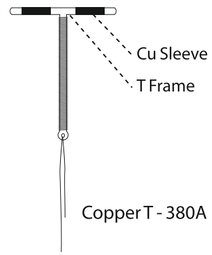
The uterine sound then be introduced in the endocervical cavity until it reaches the fundus.

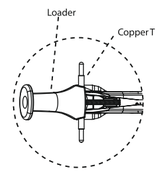
As soon as the direction and length of the cervical canal endometrial cavity have been determined, the Copper T may be prepared for insertion.

CAUTION

- Do not pick up and use any component that has fallen on the floor or table
- Do not pour the contents of the pouch in the instrument tray
- Do not use if inner package is damaged or open
- Do not resterilize

PARTS OF ETHERENA





Etherena Inserter

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 ten years after insertion)**, 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. Etherena T Cu 380A intrauterine contraceptive device doesn't interact with any medicine the woman may be taking.

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 **Etherena T Cu 380 A.** During followup 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 conditions that substantially increase the risk of pelvic inflammatory disease.

UNDESIRABLE EFFECTS OF THE PRODUCT, INCLUDING THEIR FREQUENCY AND TIMING

Adverse effects of intrauterine devices, including Etherena T Cu 380 A, 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) 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.

PROCEDURE FOR INSERTION

TIMING OF INSERTION

The best time for insertion is during menstruation, to prevent insertion during a non-diagnosed 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 coitus. Insertion immediately after unprotected coitus can increase the risk of PID (pelvic inflammatory disease).

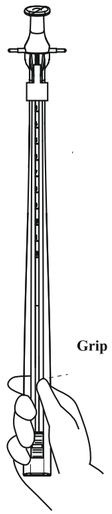
Etherena T Cu 380 A can also be inserted within 15 minutes of delivery of the placenta or abortion in the first trimester. Note that there is a higher rate of expulsion in these instances.

If the IUD cannot be inserted immediately after delivery of the placenta or abortion, insertion should be delayed for at least 6 weeks. In case of caesarean section, insertion should be delayed for 12 weeks after delivery.

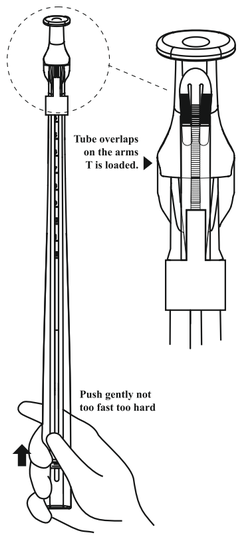
Prior to insertion, the vagina and cervix should be cleansed with an antiseptic solution. The cervical canal should also be cleansed with the same solution. It is essential to determine the exact position of the uterus by bimanual pelvic palpation so that the Etherena T Cu 380 A can be inserted along its longitudinal axis. This can be accomplished by grasping the anterior or posterior lip of the cervix, depending on whether the uterus is anteverted or retroverted. In case of vasovagal reactions after the use of forceps, a local anaesthetic can be injected in and around the cervix.

LOADING THE INSERTION PROCEDURE

1. Open the sterile package fully. Then wear the sterile gloves. Take Etherena out of the package while gripping it in the lower grip area. Check if the arms of the 'T' and the Frame are in the center and well aligned with the loader.

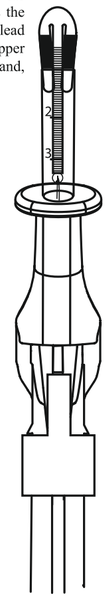


2. Slide the Knob gently forward till it reaches the first resistance. Apply slight force to move it further forward. This will fold the arms of the Copper T inside the insertion tube. The T is loaded. Do not move the knob backwards.

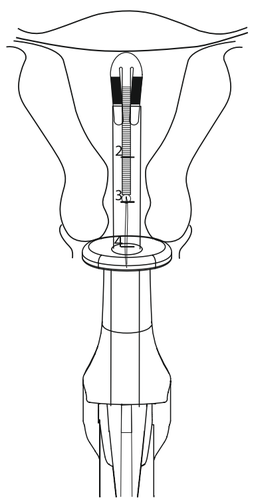


3. Move the knob forward. Marked tube with loaded 'T' comes out of the Loader. Move the knob further till you see the number measured by Uterine Sound. After 4cm you will hear click sounds. each click is measured as 0.5cm. Once you see the desired measurement at the flange position, Etherena is ready for insertion.

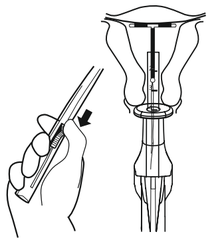
Do not keep Etherena loaded for more than 5 minutes. It distorts the arms of the Copper T. This may lead to incorrect placement of the Copper T in the uterine cavity and, subsequently, expulsion.



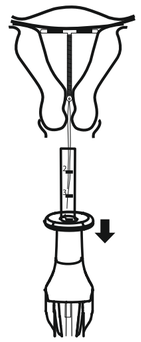
4. Insert the tube with 'T' very gently inside the uterine cavity till the flange touches the cervix. DO NOT FORCE the inserter. The T should now be in fundal position.



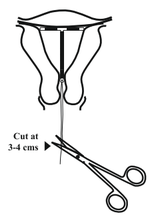
5. Pull the knob back once firmly to release 'T' at the fundul position in the uterine cavity. You will feel a click and the knob will not move any further down.



6. Gently pull out the Etherena from the uterine cavity leaving the threads of Copper T hanging out of the cervix.



7. Cut the threads perpendicular to the thread length approximately 3-4 cm visible outside the cervix.



8. Discard the inserter and the packaging carefully.

9. Assist the client to get uo slowly (be alert for possible dizziness). Instruct her how and when to check threads.

CONTRAINDICATION (ABSOLUTE)

1. Malignant diseases of the gential tract
2. Undiagnosed vaginal bleeding
3. Pregnancy
4. Past history of ectopic pregnancy or predisposing factor
5. Infections of genital tract
6. Sexually transmitted diseases during the last 12 months (except bacterial vaginitis repeated herpes infections, Hepatitis B)
7. Abortion with infection during the last 3 months.
8. Uterine malformations (congential acquired)
9. Allergy to copper

CONTRAINDICATION (RELATIVE)

1. Anaemia
2. Valvular heart disease
3. Coagulation disorders
4. Wilson's disease
5. Multiple Exposures to different sexual parners.

CONTRAINDICATION (RELATIVE)

1. Anaemia
2. Valvular heart disease
3. Coagulation disorders
4. Anti-inflammatory treatment
5. Wilson's disease
6. Multiple Exposures to different sexual parners.

ADVERSE REACTION

- Bleeding/spotting between periods
- Missed/late periods
- Heasvy/Prolonged/Painful periods
- Pian or cramps when inserted or insertion
- Vaginal discharge or infection
- Leg pain and soreness
- Allergic reaction to the copper
- Backache
- Anemia

COMPATIBILITY WITH MRI ENVIRONMENT

MRI can be done with Etherena T Cu 380 A in place..

REMOVAL INSTRUCTIONS INCLUDING ACTIONS TO BE TAKEN DURING DIFFICULTY IN REMOVING

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 chlohexidine) 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.

F) 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.

F) WARNING & PRECAUTION

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

- Do not re-sterilize, re-sterilization can lead to product degradation which can result in unwanted pregnancy.
- Ectopic Pregnancy: If a woman gets pregnant with IUD in place, there is a chance of having an extra-uterine pregnancy which should be evaluated.
- Pelvic Infection: IUD's may be associated with an increased relative risk of Pelvic Inflammatory
- Disease (PID) compared to other forms of contraception.
- Expulsion: Sometimes an IUD is pushed out of the Uterus into the vagina during heavy flow of menses as Uterus remains slightly open during the menstrual period.

Perforation: Partial or total perforation of the uterine wall or cervix may occur rarely during placement, though it may be detected later.

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

G) RISK OF RE-USE

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

H) On completion of shelf life or on removal after aw, dispose the items as per the local regulations governing disposal of non recyclabel waste/medical waste. The sterile IUD is for single use only and should not be reused.

I) 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.

ETHERENA USERS SHOULD

Check for longer or heavier menstrual periods, or bleeding or spotting between periods during the first week after insertion.

Report to the clinic, if the bleeding continues or is severe.

Take mild analgesic tablets, use hot compress on abdomen, and/or exercise moderately for cramping following insertion, usually for a short time, but could last for several hours to a few days.

Check periodically, especially after menstruation, to make certain that the threads still hang out from the cervix.

Report to the clinic immediately, if the threads are missing, longer or shorter or Copper T is expelled.

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

Consult the physician for abdominal pain, pain during intercourse, infections (such as gonorrhea), adnormal discharge, fever, or chills.

Return to the clinic for checkup or replacement of Copper T after five years of insertion or as instructed by the physician.

FOLLOWUP GUIDELINES FOR PHYSICIANS

Encourage the user to come for 4 to 6 weeks follow up visits as directed or when in doubt.

Check for heavier bleeding. It could indicate anemia.

Remove Copper T immediately if there is substan - tial increase in the risk of pelvic inflammatory disease.

Etherena is packaged sterile with a sterile T Cu 380A.

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 Etherena 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 Etherena T Cu 380A

1. Less Expulsion.
2. Provide the highest contraceptive efficacy and rates of satisfaction.
3. No IUD-related artifacts were found.

Intrauterine Contraceptive Device-

Etherena T Cu 380A 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:

- Dislocation of IUD
- Migration Of IUD
- Anemia
- Back ache
- Vaginal inflammation/infection
- Uterine perforation

etherena

T Cu 380A

Intrauterine
Contraceptive
Device