



with CrossGlide inserter Standard and Mini size

INDICATION

Hormone free intrauterine contraception in women of childbearing age.

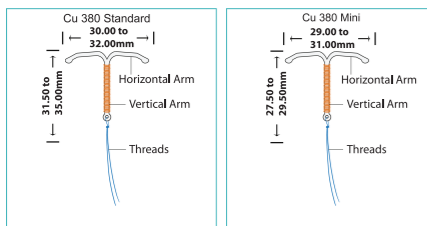
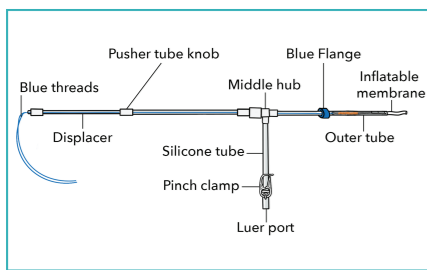
INTENDED USE

Yanae is a hormone free contraceptive for women of childbearing age. It offers an almost complete protection against pregnancy, having an effective period of 5 years. Yanae does not affect lactation. This is fully reversible method and protection is reversed on its removal.

Yanae does not protect against Sexually transmitted diseases.

COMPOSITION OF THE DEVICE

The device is composed of a Y-shape copper IUD and an inserter as describe bellow.



UNDESIRABLE EFFECTS:

Adverse effects of intrauterine devices, including Yanae 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:

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 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.

TIMING OF INSERTION

Verify that the user is not pregnant. The IUD must not be inserted if there is the possibility of pregnancy.

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.

When using the Yanae 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.

Yanae 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 Yanae 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

- Operator should wear sterile gloves and use aseptic technique.
- He/she should gently explain to the patient what he/she is doing.
- Perform an examination of the uterus to determine its position, form and size and the flexion of the uterine axis (manual or by echography)
- Prior to insertion, the vagina and cervix should be cleaned with sterile swab soaked in an antiseptic solution.

- The cervix should be visualised by means of speculum. The length of the cervical canal and endometrial cavity should be determined using a uterine sound.

PROCEDURE FOR INSERTION

Insertion of Yanae is a two-step procedure:

- Step 1 is the preparation of the device. It is an external procedure
- Step 2 is the insertion of IUD Yanae in the uterine cavity.

CAUTION

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

STEP 1: PREPARATION OF THE DEVICE: LOADING THE IUD INTO THE INSERTER

0. Measuring the uterine length

1. Opening the pouch

Place the package on clean and flat surface. For right-handed operator, place the pouch with the IUD facing left. For left-handed operator, place the pouch with the IUD facing right.

2. Balloon inflation

Lift inflation tube upward as shown in (Figure 1). Take the 3 CC syringe prefilled with saline in the ancillary pack.

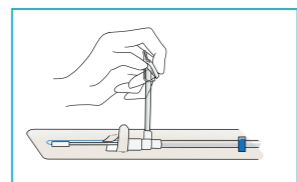


Figure 1

Connect the syringe to the luer port (Figure 2). Fully depress the syringe and simultaneously close the pinch clamp. Check the distension in the inflation tube. This will fill the balloon with saline.

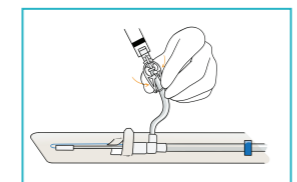


Figure 2

Disconnect the syringe and keep the inflation tube position upward.

3. Loading the IUD into the balloon

Grab the threads and hold the device firmly with the left hand (right-handed) or right hand (left-handed) at the middle hub and release both threads. Pull the IUD into the distal part of the inserter by pulling both threads (see Figure 3).

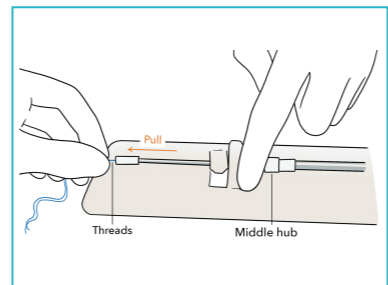


Figure 3

Pull back the threads as much as you can until the IUD is entirely into the inserter tube and that the base of the IUD is close to the blue flange (Figure 4).

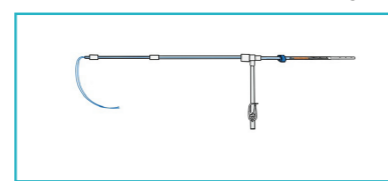


Figure 4

4. Final step before insertion procedure

Peel the remaining cover of the package and remove the device while keeping it horizontal. Be careful not to dislodge the IUD by pushing the displacer forward. Do not let the device touch any unsterile surface that may contaminate it.

STEP 2: INSERTION OF THE IUD

0. Preparation for inserter insertion into the uterus (optional)

If measurement of uterine cavity has been made, set the blue flange to uterine length. Otherwise, leave the flange on its current position.

1. Place the inserter at the external cervical os

With your non-dominant hand (left for right-handed, right for left-handed operator) grab the device at the middle hub and position it at the cervical opening as shown in (Figure 5).

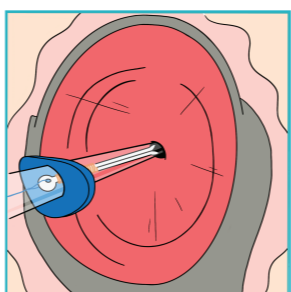


Figure 5

2. Introduction of the IUD

Use your dominant hand (right for right-handed, left for left-handed operator) and ADVANCE the pusher tube until it stops against the hub (Figure 6 yellow arrow).

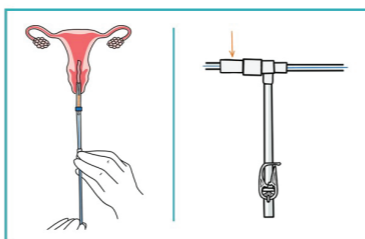


Figure 6

3. Deployment of the IUD

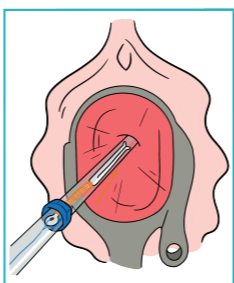


Figure 7

Without moving the displacer, pull back the inserter by 1.5 cm. Then push the displacer to deploy the IUD into the uterine cavity.

The IUD is now in contact with the fundus and in place (Figure 8).

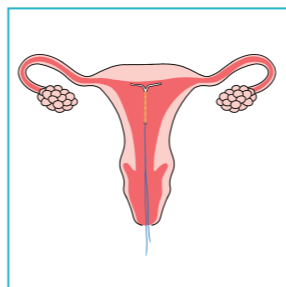


Figure 8

4. Withdrawal of the inserter

Withdraw gently the displacer and then the whole inserter without displacing the IUD until the threads are entirely exit from the device.

CUT the threads so that they are visible only 3-4 cm outside the cervix as shown in (Figure 9).

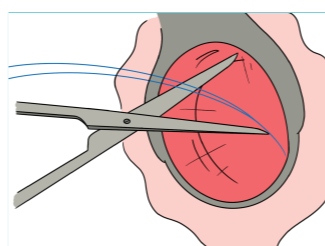


Figure 9

5. End of the procedure

Assist women 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.

REMOVAL INSTRUCTIONS

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 threads. If the threads cannot be seen, manage as missing threads.

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 threads of the IUD with a high-level disinfected (or sterile) straight artery forceps. Apply steady but gentle traction, gently pulling the threads toward you with the forceps. The device can usually be removed without difficulty. If the threads 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

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.

D. 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 tablet, using hot compresses on abdomen, and/or exercising moderately.

- 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.

- If Copper Y is expelled, return to the clinic. There is no continuing protection after expulsion.

- Return to the clinic for check-up or replacement of the Copper Y (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, infection (such as gonorrhoea), abnormal discharge, fever, chills consult your physician.
- Yanae Intrauterine Contraceptive device doesn't interact with any medicine the woman may be taking.

MECHANISM OF ACTIONS

Yanae acts 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.

FOLLOW UP 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:

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

CONTRAINDICATIONS (ABSOLUTE)

1. Malignant disease of the genital tract
2. Vaginal bleeding of unknown origin
3. Polyps or fibroids inside the uterus
4. Pregnancy
5. Past history of ectopic pregnancy or predisposing factors.
6. Infections of the genital tract
7. Sexually transmitted disease during the last 12 months (except bacterial vaginitis, repeats herpes infection, Hepatitis B)
8. Abortion with infection during the last 3 months, pelvic inflammatory disease.
9. Uterine malformations (congenital or acquired)
10. Allergy to copper

CONTRAINDICATIONS (RELATIVE)

1. Anaemia
2. Valvular heart disease
3. Coagulation disorders

4. Wilson's disease
5. Anti-inflammatory treatment
6. 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.

DISPOSAL

On completion of shelf life or on removal after use dispose the item as per the local regulations governing disposal 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.

The device is for single use only.

Manufactured by
PREGNA
INTERNATIONAL LTD
Plot No.: 219, Survey No.: 168
Dabhal Industrial Co-Operative Society Ltd.,
Dabhal, Daman (U.T) - 396 210 - India
Email: sales@pregna.com
Website: www.pregna.com

PT/CA/909/02
Effective Date: 20/04/2022

EC REP: Authorized Representative
MT Promed Consulting GmbH
Altenhofstrasse 80
D-66386 St. Ingbert
Germany
Tel: +49 (0) 6884 583020 • Fax: +49 (0) 6884 583021
E-mail: info@mt-promed.com • www.mt-promed.com



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Instructions for Use



