Inara
Cu 375 Sleek

INDICATION

Intrauterine contraception in women of child bearing age.

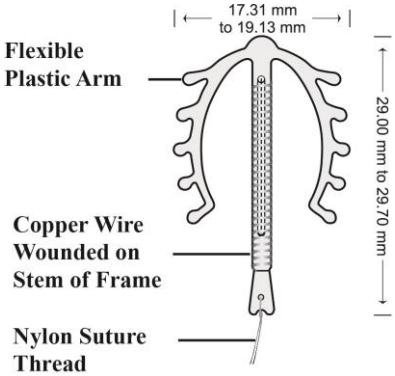
INTENDED USER

Trained Medical Professionals

INTENDED USE

Inara Model Cu 375 Sleek intrauterine device (IUD) offers almost complete protection against pregnancy, and it remains effective for a period of 5 years. Correctly inserted, Inara Model Cu 375 Sleek IUDs are safe for women at low risk of sexually transmitted diseases.

The Inara Model Cu 375 Sleek is intrauterine contraceptive devices made of polyethylene. The stem is covered with copper wire, the total surface of the copper is approx. 375 mm2. The side arms are flexible and shaped in such a way as to keep the Inara Model Cu 375 Sleek IUD adjacent to the fundus, without stretching the uterine cavity or touching the cornua. The contraceptive action of the device is probably due to a number of foreign body reactions with the uterine endometrium and the presence of metallic copper.



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 Inara Model Cu 375 Sleek.

UNDESIRABLE EFFECTS OF THE PRODUCT, INCLUDING THEIR FREQUENCY AND TIMING

Adverse effects of intrauterine devices, including Inara Model Cu 375 Sleek, 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).

Inara Model Cu 375 Sleek 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 Inara Model Cu 375 Sleek 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 anesthetic can be injected in and around the cervix.

PREPARING THE USER

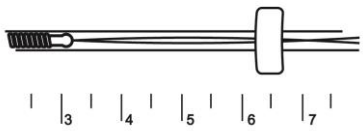
Operator should wear sterile gloves and use aseptic technique. He/She should gently explain to the client what he/she is doing.

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 Inara Model Cu 375 Sleek into the uterus.

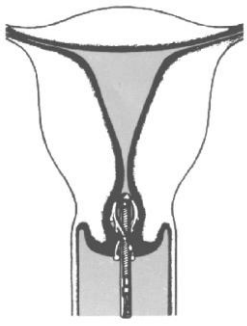
Hysterometry should be carried out and the depth of the uterus marked in the cursor around the Inara Model Cu 375 Sleek inserter. The Inara Model Cu 375 Sleek IUD is then gently inserted until the marker touches the cervix, which means that the tip of the IUD has reached the fundus. The applicator is then pulled off, releasing the Inara Model Cu 375 Sleek in the uterus. After the insertion, the two strings attached to the device extend into the vagina so that the presence of the device is felt by the doctor or for self-examination. The threads protruding from the cervical canal are then cut, leaving 3-4 cm outside the cervical os.

INSERTING STEPS

1. Lay the Inara Model Cu 375 Sleek pack on a flat surface. Strip the wrapping from the device by lifting the transparent sheet of the pack from the end marked open.
2. The vertical stem of the device is already preloaded in the insertion tube. The side arms do not require loading into the tube. They are sufficiently flexible to adapt to the shape of the cervical canal.
3. Pick up the insertion tube (with pre-loaded IUD) grasping the tube at the distal end and move the flange to the distance corresponding to the sound length in cm.

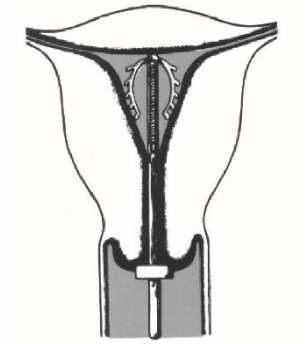


4. 4. Lift the insertion tube (with pre-loaded IUD) from its pack. Make sure that the tube is held with the Inara Model Cu 375 Sleek upwards so that it does not fall from the tube.



5. Carefully insert the Inara Model Cu 375 Sleek into the uterus until it touches the fundus and the flange rests against the external os while maintaining the steady downward traction with the tenaculum to straighten the uterine axis. No attempt should be made to force insertion. Maximum time the IUD can be in the insertion instrument of 5 minutes.

6. When Inara Model Cu 375 Sleek touches the fundus, it is released into the uterine cavity by simply withdrawing the insertion tube. During this procedure continue to apply onward traction with the tenaculum. No inserter rod is required to insert the Inara Model Cu 375 Sleek. Check the cervical canal with the sound to ensure that the tail of Inara Model Cu 375 Sleek is entirely within the uterine cavity. Trim the threads of the Inara Model Cu 375 Sleek to 3-4 cm measured from the external os.



7. It is imperative to follow precisely the recommended insertion procedure in order to minimize the risks of sub-endometrial insertion which will lead to partial embedding of the IUD and may increase the risk of perforations.

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 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, infections (such as gonorrhea), abnormal discharge, fever, chills consult your physician.

8.Inara Model Cu 375 Sleek intrauterine contraceptive device doesn't interact with any medicine the woman may be taking.

PRECAUTIONS

A thorough medical history and pelvic examination are mandatory to exclude women with contraindications, i.e. vaginal and cervical infections. It is also advisable to take a vaginal and cervical culture before inserting the IUD to prevent PID. Finally, a pelvic examination to determine the position of the uterus will enable the IUD to be inserted correctly.

Inara Model Cu 375 Sleek is designed for women with a uterine cavity depth of 6-9 cm. One month after the insertion of an IUD the woman must be re-examined to determine whether the IUD is properly placed and if there are signs of infection.

Pelvic inflammatory diseases during IUD use should be treated without delay, for this reason the user must be instructed to report to her physician if there are suspicious signs or symptoms.

This can be ascertained by gynecological examination and/or ultrasound (if available). If there is no response after 48 hours of antibiotic treatment, or if there are signs of PID, the Inara Model Cu 375 Sleek must be removed immediately. Excessive bleeding or dysmenorrhea during the first cycle after insertion should also be carefully assessed to see if it is caused by the IUD, in which case it might have to be removed.

The possibility of perforation of the uterus during insertion should always be considered, especially if the nylon thread is invisible or cannot be pulled out of the cervical canal. If there are any doubts (if the IUD is extremely difficult or painful to insert) the appropriate diagnostic techniques should be used (flat X-ray of the pelvis, ultra-sonography, hysteroscopy, laparoscopy).

If the nylon thread appears to be longer than it was when it was inserted, an ultra-sonogram should be carried out to determine if the IUD has been displaced, which might decrease its contraceptive efficacy.

PHYSICIAN'S INSTRUCTIONS TO IUD USERS

Users should be informed in detail as to the advantages and disadvantages of IUD contraception, not only so that they understand how it works but, above all, so that any complications can be detected early. The user must learn how to feel the thread emerging from the cervical canal.

REMOVAL INSTRUCTIONS

The Inara Model Cu 375 Sleek should be replaced every 5 years. Again, during menstruation is the most appropriate time to remove the IUD, since both the internal and cervical so are fully dilated.

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 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.

ACTIONS TO BE TAKEN DURING DIFFICULTY IN REMOVING

- 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 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.

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 Inara Model Cu 375 Sleek. 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 Copper 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 Copper IUD is advisable, if user is exposed to conditions that substantially increase the risk of pelvic inflammatory disease.

CONTRAINDICATIONS (ABSOLUTE)

1. Malignant diseases of the genital tract
2. Undiagnosed vaginal bleeding
3. Pregnancy
4. Past history of ectopic pregnancy or predis posing 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

CONTRAINDICATIONS (RELATIVE)

1. Anemia

2. Valvular heart disease
3. Coagulation disorders
4. Wilson's disease
5. Multiple exposures to different sexual partners

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.

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 Copper T is for single use only and should not be reused.

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.

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 Inara Model Cu 375 Sleek

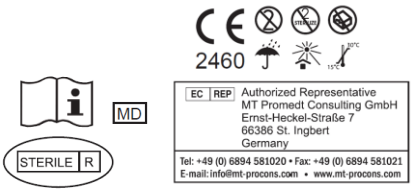
1. Intrauterine contraception in women is safe, effective method when compared to other existing methods.
2. It can be used as emergency contraception device.
3. Less infection rates.
4.Prevention of unintended pregnancy
5.Long term efficacy

Benefits from Similar Device related to Inara Model Cu 375 Sleek

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

Intrauterine Contraceptive Device-
Cu 375 Sleek 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:

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



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