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Mona Lisa® 10 (CuT 380A QL)

Intrauterine Contraceptive Device

PHYSICIAN INSTRUCTIONS

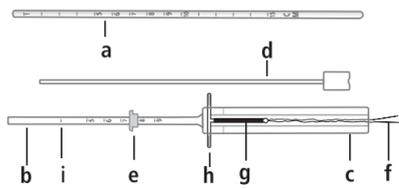
Description

The Mona Lisa® 10 (CuT 380A QL) Intrauterine Device (IUD) is made of a T-shaped frame of polyethylene and barium sulphate. The vertical arm is wound with copper wire. There are two additional copper sleeves fixed to the side arms of the Mona Lisa® 10 (CuT 380A QL). The copper surface is 380 mm². Dimensions: 31.85 mm ± 0.25 mm wide, 35.85 mm ± 0.25 mm long.

The polyethylene frame and the wire are radiopaque.

The following insertion accessories are provided with the IUD:

- hystrometer,
- inserter tube with insertion body,
- insertion rod (plunger).



- a) hystrometer
b) insertion tube
c) insertion body
d) insertion rod (plunger)
e) blue sliding flange
f) nylon threads
g) IUD stem
h) IUD side arms
i) blue marking on insertion tube

Mechanism of Action

The Mona Lisa® 10 (CuT 380A QL) is an intrauterine contraceptive device made of polyethylene and barium sulphate. The side arms are flexible and shaped in such a way as to keep the IUD adjacent to the fundus, without stretching the uterine cavity or touching the entrance of the fallopian tubes.

Mona Lisa® 10 (CuT 380A QL) IUD prevents pregnancy by blocking fertilization.

The contraceptive effect is likely due to a pronounced sterile inflammatory reaction, which takes place as a result of a foreign body response in the uterus. The concentration of various types of white blood cells, prostaglandins and enzymes in uterine and tubal fluids increases markedly. These changes interfere with the movement of sperm in the genital tract, reducing their potential fertilizing capacity, so that fertilization is not possible.

In the fallopian tubes, where fertilization is thought to take place, fewer sperm are found in copper IUD users than in non-users. Thus, the primary action is most likely altering the function or survival of sperm and ova before they can meet.

After removal of the Mona Lisa® 10 (CuT 380A QL), fertility is promptly restored to the patient's normal fertility rate prior to insertion of the device.

Correctly inserted, the Mona Lisa® 10 (CuT 380A QL) IUD is safe for women at low risk of sexually transmitted infection.

Indication

- Mona Lisa® 10 (CuT 380A QL) is indicated for:
- Intrauterine contraception in nulliparous and parous women;
 - Women who require contraception but have contraindications or sensitivities to estrogen and/or progestin;
 - Women who require contraception and are breast feeding;
 - Postpartum and post-abortion contraception.
 - Emergency contraception

Mona Lisa® 10 (CuT 380A QL) provides effective contraception for 10 years.

Long-term studies indicate that annual pregnancy rates with the Mona Lisa® 10 (CuT 380A QL) are 0.4 or less per 100 women for 12 years. No pregnancies reported after 8 years.¹

The cumulative pregnancy rate up to 10 years of use of the Mona Lisa® 10 (CuT 380A QL) was 2.2 per 100 women-years. The comparative cumulative pregnancy rates after 5, 7 and 9 years were 1.5, 1.7 and 2.1 per 100 women-years.¹

Contraindications

Mona Lisa® 10 (CuT 380A QL) is contraindicated in the following situations:

1. Pregnancy or suspicion of pregnancy
2. Past history of ectopic pregnancy
3. Cervical or endometrial cancer
4. Malignant trophoblastic disease
5. Puerperal sepsis
6. Immediate post septic abortion
7. Acute, subacute and chronic pelvic inflammatory disease (including a history of such an infection within the last 3 months)
8. Presence or suspicion of sexually transmitted infection.
9. Heavy or profuse menstrual bleeding
10. Uterine or cervical malformations (congenital or acquired)
11. Endometriosis
12. Vaginal bleeding of unknown origin
13. Wilson's disease
14. Known allergy to copper
15. Conditions that can lead to or promote bacteremia (e.g. valvular defects, congenital heart disease)

Warnings and Precautions

The Patient Package Insert must be given to the patient at the time of insertion.

Mona Lisa® 10 (CuT 380A QL) should be used with caution in patients undergoing anticoagulant therapy or suffering from a coagulation disorder.

Before inserting the IUD, a thorough medical history and an examination of the pelvic and abdominal cavity as well as a cervical smear are mandatory. Pregnancy, genital infections or sexually transmitted infections have to be excluded. The position of the uterus and the size of the uterine cavity must be determined to ensure correct insertion of the IUD.

Mona Lisa® 10 (CuT 380A QL) is designed for women with a uterine cavity depth of 6.5-9 cm.

Post-partum and post-abortion application:

Postpartum women are at a higher risk of expulsion and uterine perforation. For post-partum and post-abortion application, placement may be delayed until complete involution of the uterus that is 6 weeks after an abortion or childbirth, and 12 weeks after a caesarean. Current data suggest that the risk of perforation of the uterus may be increased when insertions are made before normal uterine involution occurs.²

It is recommended that the patient return for a follow-up visit after the first menstruation after insertion. The patient must be re-examined to determine whether the IUD is properly placed and if there are signs of infection. Subsequent follow-up examinations are recommended to be performed annually.

Spotting, light bleeding, heavier or longer periods may occur in the first 3 to 6 months following insertion. These bleeding patterns are not harmful and usually decrease with time. If these events continue or are severe, they should be reported to the physician.

After insertion, the threads should remain outside the cervical canal, in the vagina. After each menstrual period the patient should be instructed to verify with a finger whether the threads of the device can be felt in the vagina. If the patient can not feel the threads or the patient senses the device, she should contact her physician.

If the threads are not visible in front of the cervix at a follow-up examination, they have been drawn up into the cervical canal or uterus and usually reappear during the next menstruation. The device may also have been expelled unnoticed. An ultrasound or an x-ray diagnostics should be performed to assess the situation after exclusion of a pregnancy. If the nylon threads appear to be longer than at insertion, an ultrasound examination should be carried out to determine if the IUD has been displaced, which might decrease its contraceptive efficacy.

Pelvic inflammatory disease during IUD use should be treated without delay with appropriate antibiotics. There is no need to remove the intrauterine device unless symptoms fail to resolve within the following 72 hours.

Do not re-use the IUD device or its accessories.

Pregnancy occurring with the device in situ

Diagnosis of ectopic or intrauterine pregnancy must be determined. Up to the end of the first trimester, if the threads are visible, the IUD should be removed. 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.

Perforation

Perforation or penetration of the uterine corpus or cervix by the IUD may occur, most often during insertion. The number of uterine perforations is related to the experience of the person inserting the device.

In a large prospective comparative non-interventional cohort study in IUD users (N = 61448 women), the incidence of perforation was 1.3 (95% CI: 1.1 – 1.6) per 1000 insertions in the entire cohort; 1.4 (95%CI: 1.1 – 1.8) per 1000 insertions in the LNG IUS cohort and 1.1 (95% CI: 0.7 – 1.6) per 1000 insertions in the copper IUD cohort.²

The study showed that both breastfeeding at the time of insertion and insertion up to 36 weeks after giving birth were associated with an increased risk of perforation (see Table). These risk factors were independent of the type of IUD inserted.

Table: Incident of perforation per 1000 insertions for the entire study cohort, stratified by Breastfeeding and time since delivery at insertion (parous women)

	Breast feeding at time of insertion	Not breastfeeding at time of insertion
Insertion ≤ 36 weeks after delivery	5.6 (95% CI 3.9-7.9; N=6047 insertions)	1.7 (95% CI 0.8-3.1; N=5927 insertions)
Insertion > 36 weeks after delivery	1.6 (95% CI 0.0-9.1; N=608 insertions)	0.7 (95% CI 0.5-1.1; N=41910 insertions)

The risk of perforation may be increased in women with abnormal uterine anatomy or with fixed retroverted uteri.

In the event of suspected perforation during insertion, remove the IUD immediately. There is a small risk of perforation occurring post-insertion. If perforation is suspected, the device should be located and its removal considered.

Uterine perforation may result in pregnancy. Delayed detection of perforation may lead to IUD migration outside the uterine cavity and/or injury to other adjacent organs.²

Interactions

Published reports have indicated diminished efficacy in the presence of long term use of non-steroidal anti-inflammatory drugs (especially acetyl salicylic acid) and of corticoids. Short term use in the treatment of dysmenorrhoea with non-steroidal anti-inflammatory drugs does not appear to reduce contraceptive efficacy.

Do not perform diathermy (short wave or microwave) of the sacral or abdominal region since heating of the copper can damage the IUD and may cause heat injury to the surrounding tissue.

Adverse effects

Adverse effects of intrauterine devices, including Mona Lisa® 10 (CuT 380A QL), are low but include the following:

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.

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.

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.

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.

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 os are physiologically dilated. This facilitates the insertion of the IUD without the need to dilate the canal in most instances.

When using the Mona Lisa® 10 (CuT 380A QL) 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. Mona Lisa® 10 (CuT 380A QL) 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 Mona Lisa® 10 (CuT 380A QL) 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. Prior to insertion, the vagina, cervix and cervical canal should be cleansed with an antiseptic solution, using e.g. a sterile cotton bud.

It is essential to determine the exact position of the uterus by bimanual pelvic palpation so that the Mona Lisa® 10 (CuT 380A QL) 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 a forceps a local anaesthetic can be injected in and around the cervix.

Step-by-Step IUD insertion instructions

The Mona Lisa® 10 (CuT 380A QL) must be inserted by trained medical staff only.

In order to minimize the risk of contamination, use sterile gloves. Use the enclosed sterile hystrometer (sound) to determine the depth and the direction of the uterus. Apply a tenaculum to the cervix and use gentle traction to align the cervical canal with the uterine cavity. Gently insert the hystrometer into the cervical canal to measure the depth. Mark the uterus depth on the inserter tube using the sliding blue flange on the insertion tube. The upper end of the sliding flange should correspond with the measured uterus length (see fig. 1).

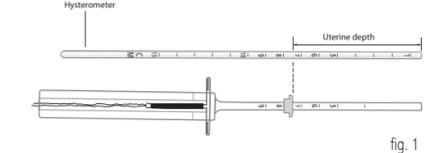


fig. 1

The uterus should sound to the depth of 6.5 to 9 cm except when inserting Mona Lisa® 10 (CuT 380A QL) post-partum or post-abortion. Insertion of Mona Lisa® 10 (CuT 380A QL) into a uterine cavity measuring less than 6.5 cm may increase the incidence of expulsion, bleeding, pain and perforation. If you encounter cervical stenosis, avoid undue force. Dilators may be helpful in this situation.

1. Open the sterile pouch containing the IUD and insertion accessories.
2. While holding the nylon threads straight so as to not disarrange the threads, place the plunger into the insertion body up to the lower end of the IUD stem. By carefully pushing the plunger up to the blue marking on the inserter tube, both side arms of the IUD slip into the tube. The upper end of the now ready loaded IUD must just only 2 mm out of the inserter tube. (fig.2)

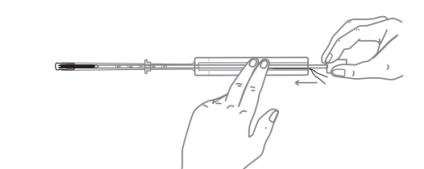


fig. 2

Note:

Due to the soft and flexible insertion tube the side arms may twist inside the insertion tube while being pushed upwards. Adjust the sliding blue flange as described below in Step 3.

The side arms of the Mona Lisa® 10 (CuT 380A QL) must not remain bent for more than five minutes within the insertion tube; otherwise

they may not bend back completely and may not return to their original 90° angle.

3. Adjust the sliding blue flange so that the length of the insertion tube above it corresponds to the depth of the uterus as previously measured using the hystrometer. Ensure that the wider part of the flange is parallel to the side arms of the ready-loaded IUD as this indicates the direction in which the side arms of the IUD will open in the uterus.

4. With the tenaculum fixed to the cervix and using gentle traction to align the cervical canal with the uterine cavity, carefully introduce the inserter tube with the loaded Mona Lisa® 10 (CuT 380A QL) into the uterine cavity until it touches the fundus of the uterus. The sliding flange must be in contact with the cervix (see fig. 3).

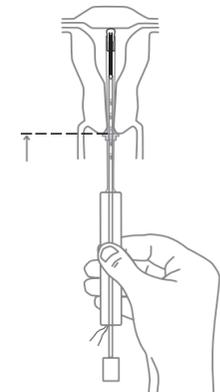


fig. 3

5. Holding the plunger steady, pull the insertion body downwards to the base of the plunger. The side arms of the IUD are now entirely released in the uterus (see fig.4).

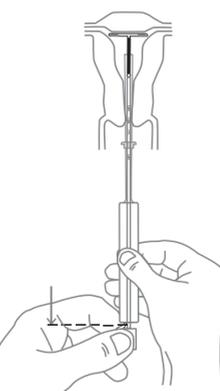


fig.4

6. To prevent pulling the device from its fundal position, first remove the plunger while keeping the insertion body steady and only then remove the inserter body. Cut the threads leaving 2-3 cm visible outside the cervix.

Removal

Mona Lisa® 10 (CuT 380A QL) should be replaced after ten years.

The Mona Lisa® 10 (CuT 380A QL) can be removed at any time during the cycle. The most appropriate time to remove the IUD is during menstruation, since both the internal and external cervical os are fully dilated. Grasp the threads of the IUD with a tenaculum and pull it along the longitudinal axis of the uterus. Try to insert the forceps at the entrance to the cervical canal in order to grasp the vertical arm of the Mona Lisa® 10 (CuT 380A QL) as soon as it has passed the internal cervical os. This avoids excessive tension on the threads, which could cause them to break. While doing this, distract the patient by asking her to cough and then remove the Mona Lisa® 10 (CuT 380A QL) with one firm tug.

The removal of the IUD could cause slight pain and bleeding. The removal procedure may also precipitate a vasovagal attack or an epileptic seizure.

After removal is complete, inspect the Mona Lisa® 10 (CuT 380A QL) to see that none of its arms have been left in the uterine cavity.

In case of a lost IUD or lost parts of an IUD in the uterine cavity either hysteroscopy or ultrasonography or x-rays should be used to determine its location; curettage may be advisable. In very rare cases of uterine perforation, laparoscopy may be needed.

Packaging

1 x 1 sterile Mona Lisa® 10 (CuT 380A QL) with insertion accessories.

The following insertion accessories are provided with the IUD:

- hystrometer,
- inserter tube with inertions body,
- insertion rod (plunger).

Pharmaceutical information

Each IUD is sterilized with ethylene oxide and is intended for single use only. Do not sterilize. Do not use if the pouch is damaged or open since it will not be sterile. Do not insert after the expiry date printed on the sterile pouch. After removal, the Mona Lisa® 10 (CuT 380A QL) should be disposed of as biomedical waste.

Storage

Store in a dry place, between 0 °C and 35 °C. Protect from direct sunlight and moisture.

List of excipients

Copper, Polyethylene, Barium Sulphate, Polyamide 6.

Nature and contents of container

The device (IUD) with accessories has been packed in heat sealed sterilized pouches made of Tyvek + PET/PE.

Date of revision of the text: August 2016

Sterile

References

- 1 UNDP et al., Long-Term Reversible Contraception Twelve years of Experience with TCu 380 A and TCu 220C, Contraception 1997;56:341-352
- 2 Heinemann et al. Risk of uterine perforation with levonorgestrel-releasing and copper intrauterine devices in the European Active Surveillance Study on Intrauterine Devices, Contraception 2015; 91: 274-279

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Mona Lisa® 10 CuT 380A QL

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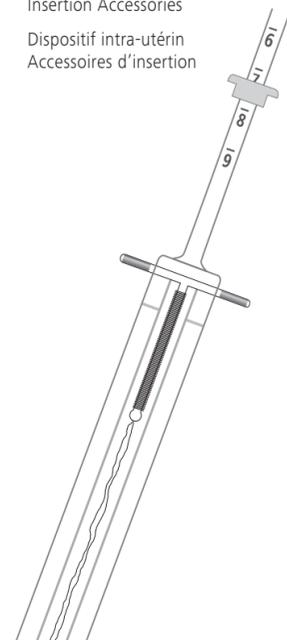
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Mona Lisa® 10 CuT 380A QL

Intrauterine Device
Insertion Accessories

Dispositif intra-utérin
Accessoires d'insertion



PHYSICIAN INSTRUCTIONS
DIRECTIVES AU MÉDECIN

