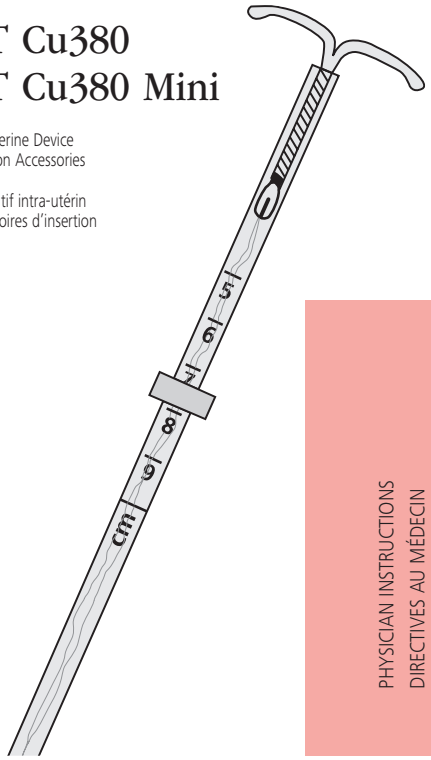
Mona Lisa® 5 Standard
Mona Lisa® 5 Mini

NT Cu380
NT Cu380 Mini

Intrauterine Device
Insertion Accessories

Dispositif intra-utérin
Accessoires d'insertion



PHYSICIAN INSTRUCTIONS
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Mona Lisa® 5 Standard (NT Cu380)
Mona Lisa® 5 Mini (NT Cu380 Mini)

Intrauterine Contraceptive Device

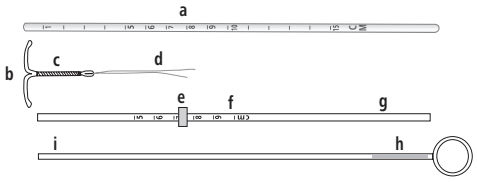
PHYSICIAN INSTRUCTIONS

Description

The Mona Lisa® 5 Standard / Mini Intrauterine Device (IUD) is made of a T-shaped frame of polyethylene and barium sulphate. The vertical arm is wound with copper wire. The copper surface is 380 mm².
Dimensions:
Mona Lisa® 5 Standard: 31.8 mm ± 0.2 mm wide, 31.9 mm ± 0.2 mm long.
Mona Lisa® 5 Mini: 24.0 mm ± 0.2 mm wide, 30.0 mm ± 0.2 mm long.

The polyethylene frame and the wire are radiopaque.

The following insertion accessories are provided with the IUD:
- hysterometer,
- insertion tube,
- insertion rod.



a) hysterometer
b) IUD side arms
c) IUD stem
d) nylon threads
e) blue sliding flange
f) centimetre scale
g) insertion tube
h) marked part on the insertion rod
i) insertion rod

Mechanism of Action

The Mona Lisa® 5 Standard / Mini 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® 5 Standard / Mini 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® 5 Standard / Mini, fertility is promptly restored to the patient's normal fertility rate prior to insertion of the device.

Correctly inserted, the Mona Lisa® 5 Standard / Mini IUD is safe for woman at low risk of sexually transmitted infection.

Indication

Mona Lisa® 5 Standard / Mini 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® 5 Standard / Mini provides effective contraception for 5 years.

The cumulative pregnancy rates at the end of the first and the fifth year of use of the Mona Lisa® 5 Standard / Mini ranged from 0.5 to 1.4 and 1.9 to 4.4 per 100 women, respectively.[1,2,3]

Contraindications

Mona Lisa® 5 Standard / Mini 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® 5 Standard / Mini 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® 5 Standard is designed for women with a uterine cavity depth of 6.5-9 cm.
Mona Lisa® 5 Mini is designed for women with a uterine cavity depth of less than 7 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.4

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.[4]
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.[4]

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® 5 Standard / Mini, 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® 5 Standard / Mini 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® 5 Standard / Mini 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® 5 Standard / Mini 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® 5 Standard / Mini 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® 5 Standard / Mini must be inserted by trained medical staff only.
In order to minimize the risk of contamination, use sterile gloves.
Use the enclosed sterile hysterometer (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 hysterometer into the cervical canal to measure the depth. Mark the uterus depth on the inserter tube using the sliding blue flange on the IUD. The lower end of the sliding flange should correspond with the measured uterus length (see fig. 1).

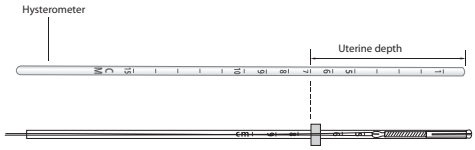


fig. 1

The uterus should sound to the depth of 6.5 to 9 cm except when inserting Mona Lisa® 5 Standard post-partum or post-abortion and less than 7 cm except when inserting Mona Lisa® 5 Mini post-partum or post-abortion. Insertion of Mona Lisa® 5 Standard into a uterine cavity measuring less than 6.5 cm or Mona Lisa® 5 Mini into a uterine cavity measuring less than 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 halfway. Grasp the nylon threads and draw the device gently into the insertion tube (fig.2) until the knobs at the end of the side arms cover the opening of the tube. The knobs should not be pulled into the tube.

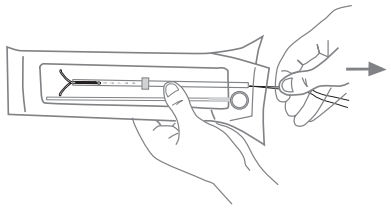


fig. 2

2. Steadying the sliding blue flange with one hand, pull the insertion tube until the lower end of the flange indicates the previously measured length of the uterus using the hysterometer (see fig. 1). 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. Holding the threads straight in the tube, place the insertion rod into the insertion tube. This prevents the threads from being displaced by the insertion of the insertion rod.

Prior to insertion, the tube can be bent to conform to the position of the uterus. The bending must be performed while the device remains in the sterile pouch after placing the insertion rod into the insertion tube.

3. Remove the insertion tube with the loaded IUD from the pouch and insert it through the cervical canal into the uterus until the blue flange touches the cervical os (fig. 3)

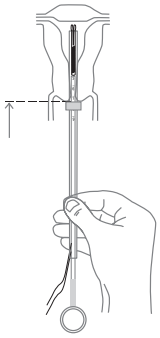
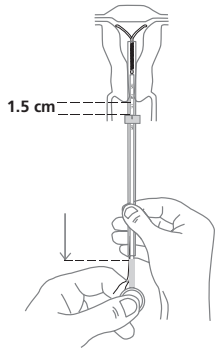


fig. 3

4. Holding the insertion rod steady, pull the insertion tube downwards to the marked part at the base of the insertion rod. The side arms of the IUD are now entirely released in the uterus (see fig.4).



ig. 4

Observe that the distance between the flange and the cervical os is now about 1,5 cm.

5. Holding the tube and the insertion rod together, gently push both until the blue flange again touches the cervical os (fig. 5). The IUD is now in the correct position.

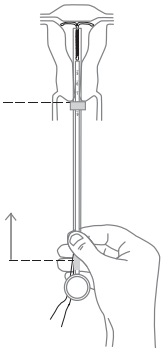


fig. 5

6. **Holding the insertion rod steady, pull the insertion tube down to the ring of the insertion rod!**
The IUD is now entirely released in the uterus (fig. 6). To prevent pulling the device from the fundal position, first remove the insertion rod while keeping the insertion tube steady and only then remove the insertion tube. Cut the threads leaving 2-3 cm visible outside the cervix.

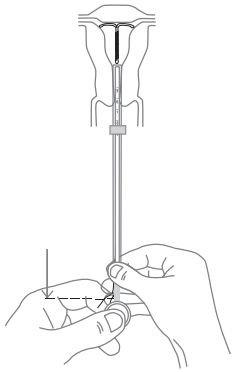


fig. 6

Removal
Mona Lisa® 5 Standard / Mini should be replaced after five years.

The Mona Lisa® 5 Standard / Mini 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® 5 Standard / Mini 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® 5 Standard / Mini 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® 5 Standard / Mini 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® 5 Standard / Mini with insertion accessories.

The following insertion accessories are provided with the IUD:
- hysterometer,
- insertion tube,
- insertion rod.

Pharmaceutical information
Each IUD is sterilized with ethylene oxide and is intended for single use only. Do not resterilize. 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® 5 Standard / Mini 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: July 2015

Sterile

References

[1] Haugan et al, A randomized trial on the clinical performance of Nova T® 380 and Gyne T® 380 Slimline copper IUDs, Contraception 2007; 75:171-176.

[2] Batar et al. Five-year clinical experiences with Nova T® 380 copper IUD, Contraception 2002; 66: 309-314.

[3] Cox et al. Clinical performance of the Nova T 380 intrauterine device in routine use by the UK Family Planning and Reproductive Health Research Network: 5-year report, The Journal of Family Planning and Reproductive Healthcare 2002;28:69-72.

[4] 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® 5 Standard (NT Cu380)
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