

Mona Lisa[®] Cu375

Mona Lisa[®] Cu375 SL

Intrauterine Contraceptive Device

INFORMATION FOR THE USER

Design and dimensions

The Mona Lisa[®] Cu375/375 SL Intrauterine Device (IUD) is made of a frame of polyethylene and barium sulphate. The vertical arm is wound with copper wire. The copper surface is 375 mm². Two nylon threads are attached to the lower end of the vertical arm.

Dimension:

Mona Lisa[®] Cu375: 19,5 mm wide and 35,2 mm long.

Mona Lisa[®] Cu375 SL: 19,5 mm wide and 29,4 mm long.

The polyethylene frame and the wire are radio-opaque.

Mode of action and possible effects

There are different types of intrauterine contraceptive devices. Wide-ranging international studies still verify that Copper-IUDs are not only safe but also effective over long periods. In addition, it is also generally recognized that Mona Lisa[®] Cu375/375 SL IUDs are one of the most effective means of contraception. The Mona Lisa[®] Cu375/375 SL is shaped in such a way as to prevent irritation of the uterus. It is usually inserted during menstruation. The insertion is normally painless. The opening of the uterus is examined, the length of the uterine cavity is determined and the Mona Lisa[®] Cu375/375 SL is carefully inserted into the uterine cavity, until it is in the correct position and touches the fundus. As soon as the Mona Lisa[®] Cu375/375 SL has been inserted, you are protected against pregnancy.

Mona Lisa[®] Cu375/375 SL is effective for 5 years.

IUDs are highly effective and can only be compared with the oral contraceptive pill for the prevention of pregnancy. No contraceptive method offers 100% safety. However, in practical terms, with a Mona Lisa[®] Cu375/375 SL you are protected.

It is not fully known how IUDs work. However, nowadays it is assumed that the most probable effect is that it disrupts the normal function of the male gametes (sperm), which become incapable of fertilizing the female egg. It is also assumed that copper ions influence the development of the egg so that fertilization does not take place: IUDs are no longer considered a method of abortion.

Contraindications

Mona Lisa[®] Cu375/375 SL should not be used in the case of:

1. Malignant diseases of the genital tract
2. Vaginal bleeding
3. Pregnancy
4. Past history of ectopic pregnancy or predisposing 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 (PID)
8. Uterine malformations (congenital or acquired)
9. Allergy to copper

The application should be reconsidered in:

1. Valvular heart disease
2. Anaemia
3. Coagulation disorders
4. Anti-inflammatory treatment
5. Wilson's disease
6. Multiple sexual partners
7. Nulliparity

Possible complications and precautions

The first three cycles following insertion are usually different from your normal cycles. Periods can be heavier, cramps and spotting may occur both before and afterwards. Three to four cycles after insertion of the IUD, menstruation normally resumes as before insertion. Sometimes these changes are experienced between the menstrual periods during the cycle.

You should contact your doctor if:

- you cannot feel the threads of the IUD,
- you or your partner are able to feel the lower end of the IUD,
- you think you are pregnant,
- you experience abdominal pain, fever or unusual vaginal discharge,
- you or your partner feel pain or discomfort during sexual intercourse,
- your menstruation is delayed, since rarely a pregnancy outside the uterine cavity, e.g. in a fallopian tube (ectopic pregnancy) may occur,
- you wish to have the IUD removed and / or want to become pregnant.



MR Conditional

Non-clinical testing has demonstrated the Mona Lisa intrauterine device, represented by CuT 380 A QL as worst case, is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, with
- Maximum spatial field gradient of 12,700 G/cm (127 T/m)
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Mona Lisa intrauterine device is expected to produce a maximum temperature rise of less than:

- 1.7°C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of $\approx 1.4^\circ\text{C}$ (2 W/kg, 1.5 Tesla)
- 1.2°C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of $\approx 0.8^\circ\text{C}$ (2 W/kg, 3 Tesla)

after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 1.99 mm from the Mona Lisa intrauterine device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

In non-clinical testing, the magnetically induced displacement force and magnetically induced torque were tested and no clinically significant displacement or torque was measured.

Insertion and removal

Before the insertion, you must be informed on the efficacy, risks and side effects of Mona Lisa[®] Cu375/375 SL. A gynaecological examination including pelvic examination and a cervical smear

should be performed. Pregnancy, genital infections and sexually transmitted diseases should be excluded. The position of the uterus and the size of the uterine cavity should be determined.

The instructions for insertion should be carefully taken into account and the patient card be filled out together with the attending doctor. You should return for check-up 4 to 12 weeks after insertion and once a year thereafter or more frequently if clinically indicated.

Insertion is recommended during or shortly following menstruation. If pregnancy is excluded, Mona Lisa[®] Cu375/375 SL may be inserted at any time of the cycle. It can be also inserted immediately after first trimester abortion. After having a baby, insertion should be postponed until six weeks after delivery, as this is associated with greater rates of perforation and expulsion. There are no contraindications to breastfeeding with an IUD in situ, but the risk of perforation for insertion while breastfeeding is increased.

Mona Lisa[®] Cu375/375 SL is removed by gently pulling on the threads. If the threads are not visible, and the device is in the uterine cavity, removal should be postponed until after the next menstrual bleeding since the threads usually become visible immediately after menstruation. If they are still not visible, the device may be removed using a narrow tenaculum. This may require dilatation of the cervical canal. After removal, pregnancy is immediately possible.

If you wish to continue using the method, a new device can be inserted at the same time. If pregnancy is not desired, the removal should be carried out during the menstruation.

Insertion and removal may be associated with some pain and bleedings. Occasionally, the procedure may precipitate fainting or a seizure if you suffer from epilepsy.

It is recommended that you visit your doctor for a check-up one month after Mona Lisa[®] Cu375/375 SL was inserted to make sure the IUD is still in your uterus and is positioned correctly. An annual visit is recommended thereafter. You should also check to make sure that the Mona Lisa[®] Cu375/375 SL is still in your uterus by reaching up to the top of your vagina, while in a squatting position, with clean fingers to feel the threads. Do not pull on the threads.

If you can not feel the threads or you can feel more of the Mona Lisa[®] Cu375/375 SL than just the threads, consult your doctor immediately. This suggests that your Mona Lisa[®] Cu375/375 SL is not in the uterus or is incorrectly positioned which would increase your chances of getting pregnant. It is recommended that you use an additional birth control method until you have seen your doctor. It is good practice to check that Mona Lisa[®] Cu375/375 SL is in place once a month.

Interactions

The available experience indicates that, in general, drugs do not interfere with the contraceptive efficacy of Mona Lisa[®] Cu375/375 SL IUDs. However, there are published reports, which appear to show diminished efficacy with long-term use of non-steroidal anti-inflammatory drugs (especially acetylsalicylic acid) and corticosteroids. Short-term use in the treatment of dysmenorrhoea with non-steroidal anti-inflammatory drugs does not appear to reduce contraceptive efficacy.

Side effects

In rare cases, pain or dizziness may occur after insertion. If these complaints do not abate within half an hour of resting, the position of the IUD should be checked and the IUD may have to be removed.

Pregnancy can occur accidentally with an IUD inserted. It is then mandatory to contact your doctor to determine whether this is a rare pregnancy outside the uterine cavity or not. Up to the end of the first trimester, if the threads are visible, the IUD should be removed. After that you have the

possibility of elective abortion as soon as possible, since there is an increased risk of pelvic inflammatory disease and many other obstetrical problems. However, if you wish to continue the pregnancy, close monitoring is mandatory.

The risk of a pregnancy outside the uterine cavity is increased.

Undetected partial or complete expulsion of the IUD can occur and can lead to unplanned pregnancy. Expulsion is most likely to occur in the first year after insertion and can occur at any time during the 5-year period of use. Expulsion tends to occur at the time of menstruation and is often associated with cramping, vaginal discharge, and bleeding.

The IUD may rarely cause allergic skin reactions.

The IUD is sterile and is intended for one-off use. Do not use it more than once.

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Manufacturer:

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