

Mona Lisa® 10 (CuT 380A QL)

Intrauterine Contraceptive Device

INFORMATION FOR PATIENTS

Mona Lisa® 10 (Intrauterine Contraceptive Device) is used to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections.

This leaflet is written for your information and will answer some of your questions. If you have additional questions please consult your doctor. Please record the date of insertion of Mona Lisa® 10 on the card provided and keep it in a safe place for future reference.

What is intrauterine contraception?

There are different types of intrauterine contraceptive devices (IUDs). Wide-ranging international studies confirm that copper IUDs are not only safe but also effective over long periods. Intrauterine contraception works by inserting an IUD in the uterus; the characteristics of the IUD oppose the onset of pregnancy. However, like all contraceptive methods, intrauterine contraception does not provide absolute protection and if there is any delay in your period you must consult your doctor.

What is Mona Lisa® 10?

Mona Lisa® 10 is a copper releasing IUD that is placed in your uterus to prevent pregnancy for up to ten years.

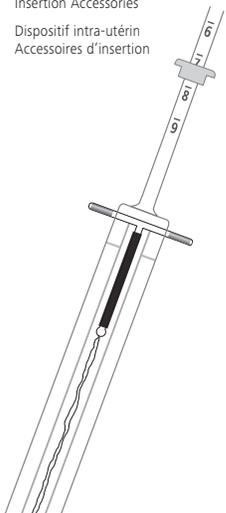
The Mona Lisa® 10 Intrauterine Device (IUD) is a T-shaped frame made of polyethylene and barium sulphate. The vertical stem and the arms of the "T" are approximately 3 cm in length. The vertical stem is wound with copper wire and two additional copper sleeves are fixed on the two arms of the "T". Nylon thread is attached to the lower end of the vertical stem. You can feel the threads with your fingers when Mona Lisa® 10 is in your uterus.

The manufacturer of Mona Lisa® 10 meets recognized standards in terms of quality and sterility.

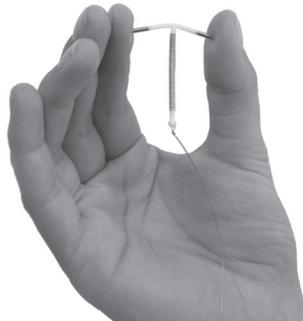
Mona Lisa® 10

CuT 380A QL

Intrauterine Device
Insertion Accessories
Dispositif intra-utérin
Accessoires d'insertion



INFORMATION FOR PATIENTS
INFORMATION À L'INTENTION DE LA PATIENTE



How long can I keep Mona Lisa® 10 in place?

You can keep Mona Lisa® 10 in place for up to 10 years. After this period of time you should ask your doctor to remove your Mona Lisa® 10. If you require continued protection from pregnancy, you may ask your doctor to insert a new Mona Lisa® 10 during the same visit.

What if I change my mind and want to become pregnant?

Your doctor can remove the Mona Lisa® 10 at any time. After discontinuation of Mona Lisa® 10, your level of fertility will return to the way it was prior to using Mona Lisa® 10.

How does Mona Lisa® 10 work?

Copper IUDs, including Mona Lisa® 10, prevent fertilization by acting on the motility and normal function of the sperm. Mona Lisa® 10 does not affect ovulation.

How well does Mona Lisa® 10 work?

Long-term studies indicate that fewer than 1 in 100 women become pregnant when using Mona Lisa® 10. Mona Lisa® 10 is a highly effective method of birth control. In fact, in long-term users of Mona Lisa® 10, the failure rate approaches that of sterilization.

Who might use Mona Lisa® 10?

Women who:

- require birth control that is very effective
- require birth control that is easy to use
- require a reversible form of long-term birth control; when you have it removed, you quickly return to your normal fertility rate.
- wish to have an effective form of birth control that does not contain hormones (estrogen and/or progestin)

Who should not use Mona Lisa® 10?

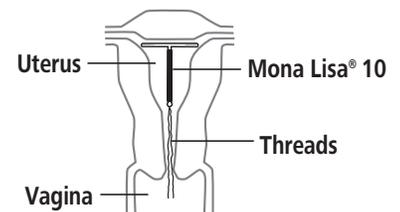
You should not use Mona Lisa® 10 if you:

- think you might be pregnant
- have a uterus that is abnormally shaped inside
- have or suspect you have a sexually transmitted infection
- have or had in the last three months a pelvic infection called pelvic inflammatory disease (PID) or have a current behaviour that puts you at high risk of PID (for example, because you having sex with several men or your partner is having sex with several women)
- have had an infection in your uterus after a pregnancy or abortion in the past 3 months
- have a cancer of the uterus or cervix
- have unexplained bleeding from your vagina
- have an infection in your cervix
- have Wilson's disease
- are allergic to copper

How will Mona Lisa® 10 be placed into the uterus?

Your doctor can insert the Mona Lisa® 10 during an office visit. Mona Lisa® 10 will be inserted during your period (usually during the last few days) or immediately after your period. Your doctor will examine you to determine the position of your uterus. After disinfecting your cervix and vagina, your doctor will measure the depth of your uterus. Then a thin plastic tube containing Mona Lisa® 10 will be inserted into your uterus. The tube is removed leaving the Mona Lisa® 10 in your uterus. Nylon thread, attached to the lower end of the vertical stem, will extend into your vagina. The thread is trimmed so that they are just long enough for you to feel with your fingers when doing a self check to ensure the IUD is properly positioned. When Mona Lisa® 10 is being inserted you may feel cramping or pinching. Some women feel faint, nauseated, or dizzy for a few minutes after the insertion. Your doctor may ask you to lie down for a while and to get up slowly.

Mona Lisa® 10 in place inside the uterus



What might be some of the risks associated with the insertion of Mona Lisa® 10?

- In rare cases certain women, in particular women who have never given birth, are more susceptible to fainting, a slowing of their pulse and other neurovascular episodes during and immediately after insertion or removal of an intrauterine device.
- **Perforation:** In rare cases, Mona Lisa® 10 can penetrate the wall of your uterus during insertion. This rare complication occurs at a rate of 0.7 to 1.6 per 1000 insertions. If Mona Lisa® 10 perforates the uterus, it should be removed.
- **Expulsion:** Mona Lisa® 10 may partially or completely fall out of your uterus. Expulsion of any intrauterine device is most common in the first year of use. The expulsion rates are often higher in women who have never been pregnant, in women who have the IUD inserted immediately after giving birth and in women who have had a previous expulsion of an intrauterine device. If you think the Mona Lisa® 10 has been partially or completely fallen out, use an additional form of birth control, such as a condom, and call your doctor.

Can I have Mona Lisa® 10 inserted right after giving birth?

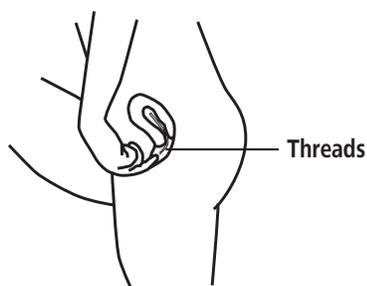
Your doctor will discuss the appropriate time for you to have Mona Lisa® 10 inserted after giving birth. You may have to wait 6 weeks or in the case of a caesarean section, the insertion should be delayed 12 weeks after delivery.

How do I check that Mona Lisa® 10 is in my uterus?

It is recommended that you visit your doctor for a check-up one month after the Mona Lisa® 10 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® 10 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® 10 than just the threads, consult your doctor immediately. This suggests that your Mona Lisa® 10 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® 10 is in place once a month. You may use tampons when you are using Mona Lisa® 10.



What will happen during my first menstrual cycles after the insertion of Mona Lisa® 10?

The first three cycles following insertion are usually different from your normal cycles. Menstruation can be heavier, your periods may last longer and you may experience spotting in between periods. These menstrual changes usually diminish and disappear after 2-3 months. However, if your menstrual flow continues to be heavy or unusually long, or spotting continues, contact your doctor.

What side effects can I expect from Mona Lisa® 10?

Side effects of intrauterine devices, including Mona Lisa® 10, are not common but include the following:

- **Menstrual changes:** The most common side effects of Mona Lisa® 10 are heavier menstrual bleeding and periods of longer duration than normal, and more painful periods. You may also experience spotting between periods. These menstrual changes usually diminish and disappear after 2-3 months. However, if your menstrual flow continues to be heavy or unusually long, or if spotting continues, contact your doctor.
- **Abdominal Pain:** 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 IUD, but if the pain persists contact your doctor to rule out the possibility of infection or improper positioning of the IUD.
- **Genital tract infection / PID:** During the first month after insertion there may be a small risk of a genital tract infection. There may be a risk of PID (Pelvic Inflammatory disease), which is an infection that affects the uterus, fallopian tubes and nearby organs. PID is most likely to occur in the first 20 days after insertion of Mona Lisa® 10. **Exposure to sexually transmitted infections (STIs), and not the use of IUD itself, is responsible for PID occurring after the first month of use.** The incidence of PID among intrauterine devices users is less than 2 episodes per 1000 years of use, which is similar to that of the general population. PID is treated with antibiotics, but if left untreated, PID can cause serious problems such as infertility. Contact your doctor if you have abdominal or pelvic pain, painful sex, unusual or bad smelling vaginal discharge, chills, heavy bleeding, or fever.

What if I become pregnant while using Mona Lisa® 10?

If you think you are pregnant, contact your doctor immediately. Your doctor will discuss possible options that are best suited for you. If you decide to continue with the pregnancy, the Mona Lisa® 10 should be removed if possible.

When should I call my doctor?

You should contact your doctor if:

- you can not 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,
- you experience a sudden change in your periods,
- you wish to have the IUD removed and / or want to become pregnant.

Date of revision of the text: July 2015

MO/1157d

Mona Lisa® 10

CuT 380A QL

Imported by:
BESINS Healthcare Canada
Kirkland, Quebec, Canada
www.besinshealthcare.ca

Manufacturer:
Mona Lisa N.V.
Graaf de Theuxlaan 25, bus 2
3550 Heusden-Zolder
Belgium



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Patient Instructions ML10 2015-july/2-2