

• An IUD should be tolerated well after two cycles. If this is not the case, the persistence of bleeding and/or pain are reasons to consider removing the IUD.

• Signs of movement or even expulsion of the IUD have been reported in women with a menstrual cup, but there is no certainty as to the link between the cups and the reported incidents. The possibility of a suction effect on the IUD when the menstrual cup is withdrawn has been suggested.

Importante note:

▲ Radiotherapy or electrotherapy is contraindicated especially if it's applied to the lower pelvic region. The MR status of the device has not been tested; however, the materials of the device (Copper and Silver) and design of the device have been found to be 1.5T MRI is safe for women with IUDs in independent study. Without sufficient clinical data, 3T MRI is contraindicated.

7 - INFORMATION TO BE GIVEN TO THE USER BY THE HEALTHCARE PROFESSIONAL

The healthcare professional must inform the user of the benefits and risks of intrauterine contraception. He or she must give the package leaflet for the user to the user and the patient card and have her read it completely.

It is especially important that the users be able to recognise the onset of a complication as quickly as possible.

Users must learn to feel for the strings to make sure that the IUD has not been expelled.

8 - PREGNANCIES DURING IUD USE

When a pregnancy is confirmed, the IUD must be removed as soon as possible, without an invasive procedure, from the pregnant woman. A pregnancy that continues with an IUD in place is subject to complications (spontaneous abortion, septic abortion) and is associated with a high rate of at-risk pregnancy.

9 - DRUG INTERACTIONS AND HEALTH PRODUCTS

Important Note: Radiotherapy or electrotherapy is contraindicated especially if it's applied to the lower pelvic region. The MR status of the device has not been tested; however, the materials of the device (Copper and Silver) and design of the device have been found to be 1.5T MRI is safe for women with IUDs in independent study. Without sufficient clinical data, 3T MRI is contraindicated.

• Non-steroidal anti-inflammatories cannot be used during treatment. During short-term treatment, they do not impact the contraceptive efficacy of IUDs.

• Intrauterine devices must be used with caution in users receiving anticoagulant treatment or with a coagulation disorder.

10 - UNDESIRABLE EFFECTS

The complication rate is low, however the known side effects are:

The side effects rarely seen in 1 to 10 women in 100,000 are:

▲ **Infectious risk:** The onset of pelvic inflammatory disease (P.I.D.), endometritis, salpingitis, peritonitis, oophoritis ... can occur mainly during the 20 days following the insertion of the I.U.D It is associated with infections of the upper genital tract that generally follow an infection due to sexually transmitted bacteria originally located in the vagina and endocervix.

P.I.D. can be a cause of sterility and requires removal of the I.U.D and the administration of suitable antibiotherapy.

▲ Inflammatory reaction

▲ **Expulsion or movement of the device:** The very low expulsion rate is in part related to the insertion technique. A few cases of expulsion may occur especially during menstrual period and in particular during the first three cycles. After birth or abortion, the insertion increases the risk of expulsion. Expulsion and migration are associated with the risk of pregnancy.

Postpartum and post-abortion insertion increases the risk of eviction.

Expulsion and migration are associated with pregnancy risks.

▲ **Uterine perforation:** Uterine perforation may occur when the I.U.D is inserted or secondarily. A uterine perforation can lead to pregnancy. When a perforation is detected late, the I.U.D can move outside the uterine cavity and / or adjacent

organs can be damaged. In case of suspected perforation during insertion, remove the I.U.D immediately. Perforation can also occur in woman with an I.U.D. If it's happened, the I.U.D. should be located and its removal considered.

The risk of perforation is increased in case of:

- Hasty I.U.D insertion,
- Insertion carried out before normal uterine involution,
- Breastfeeding at the time of insertion and insertion carried out up to 36 weeks after birth,
- Atypical uterine anatomy or fixed retroverted uterus.

The following side effects have also been reported but the frequency cannot be determined:

▲ **Effect related to the I.U.D insertion:** Pelvic and abdominal pain, back pain, bleeding, neuro-vascular episodes (during insertion and withdrawal of the I.U.D, nausea, vomiting, uterine contractions, vaginal discomfort.

▲ **Ectopic Pregnancy (E.P.):** The Risk of E.P. is very low but when a woman is pregnant with an I.U.D , the probability of an E.P. is increased.

▲ **Hypermenorrhoea / menorrhagia (heavy and prolonged menstrual period):** Hypermenorrhoea is 70 to 100% compared to menstrual flow before insertion of the I.U.D and only returns to normal after one year. Hypermenorrhoea can cause anemia.

▲ **Dysmenorrhoea** (menstrual pain)

▲ **Mastodynia** (Breast pain)

▲ **Intermittent bleeding, spotting, no menstruation**

▲ **Other effects:** Weight gain, heavy legs, back pain, bloating, vaginal discharge, nausea, headache, migraines, no menstruation, low moral, depressed mood, small mood changes (irritability, nervousness) and low libido, seizure, bradycardia (during insertion).

Any serious incident should be the subject of a notification to the manufacturer and to the Competent Authority.

By reporting side effects, you can help provide more information on the safety of the medicine.

11 - CLASSIFICATION AND PACKAGING

The CHOICE 380 7 MED NSTA® (Standard) and CHOICE 380 7 MED NSHA® (Short) are class III medical devices as per the regulation (EU) 2017/745.

Labelling: CE 0459 since 2005.

The IUD and its accessories are packaged in a Tyvek + PET/PE sachet that has been sterilised and sealed.

Each package contains a sterile, single-use I.U.D, the insertion date of which is indicated on the box. Do not use if the sachet is damaged or unintentionally opened before use.

Store in a dry place at a temperature below 40°C.

The IUD and its accessories must not be reused. In case of reuse, the patient is exposed to multiple risks of infection and the IUD loses its claimed performance.

The IUD and its accessories must be eliminated after use, as per the regulations in force for the handling of potentially infectious material.

CHOICE 380 7 MED NSTA® (Standard) and CHOICE 380 7 MED NSHA® (Short) are registered trademarks.

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CE 0459

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CHOICE 380
7 MED NSTA® (STANDARD)

CHOICE 380
7 MED NSHA® (SHORT)

PACKAGE LEAFLET
FOR THE HEALTHCARE PROFESSIONAL



PACKAGE LEAFLET INTENDED FOR THE HEALTHCARE PROFESSIONAL

CHOICE 380 7 MED NSTA® (Standard)

CHOICE 380 7 MED NSHA® (Short) Intrauterine Devices (IUDs)

1 - DESCRIPTION

Intrauterine devices: ready-to-use in a sterile sachet and composed of two flexible arms made of polyethylene branching off of a vertical stem, opaque to X-rays, around which a 380 mm² silver/copper thread is wound and a single-strand nylon string attached to the base of the device.

Dimensions CHOICE 380 7 MED NSTA® (Standard): 31,5 mm wide, 32 mm long.

Dimensions CHOICE 380 7 MED NSHA® (Short): 27,5 mm wide, 28 mm long.

Composition: copper, silver, polyethylene, barium sulphate, polyamide 6.

2 - INDICATIONS

▲ Intrauterine contraception intended for women who have had no children or one or more children.

CHOICE 380 7 MED NSTA® (Standard) is an intrauterine device suitable for uterine cavities with a height greater than or equal to 7 cm.

CHOICE 380 7 MED NSHA® (Short) is an intrauterine device suitable for uterine cavities with a height of less than 7 cm.

CHOICE 380 7 MED NSTA® (Standard) and CHOICE 380 7 MED NSHA® (Short) can be inserted after a birth or abortion.

CHOICE 380 7 MED NSTA® (Standard) and CHOICE 380 7 MED NSHA® (Short) can also be used as emergency contraception. However, the risk of pelvic inflammatory disease is higher in this case.

3 - MECHANISM OF ACTION

The contraceptive activity of the IUD is mainly due to the presence of a foreign body in the intrauterine cavity.

This action is reinforced in an ancillary manner by the presence of copper. After oxidation, the copper atoms are distributed locally in the cervical mucus and endometrium.

However, like all methods of contraception, intrauterine contraception does not guarantee absolute protection.

According to ISO standard 7439: 2015, during the lifetime of the in situ device, the clinical performance claimed must be as follows:

- Pearl index <2% per woman per year,
- Eviction rate <10% per woman per year,

- Interruption rate <35% per woman per year, for a withdrawal requested for reasons other than personal convenience.

List of the claimed Clinical Benefit : Contraception long term

4 - INSERTION AND REMOVAL

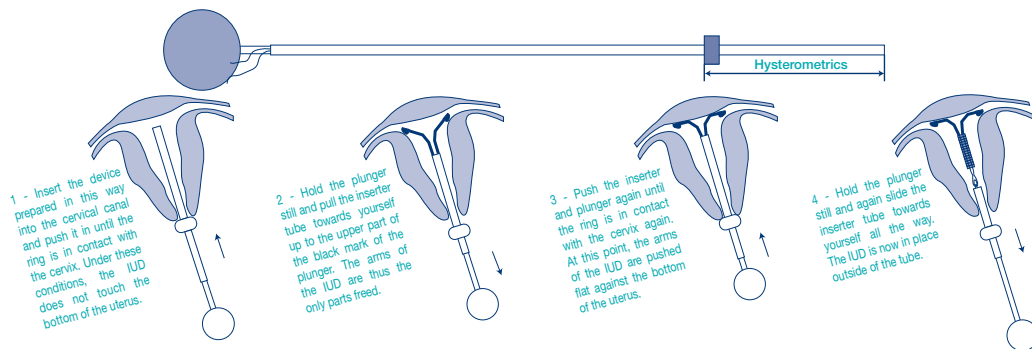
▲ Insertion period: Insertion must take place during the first part of the menstrual cycle. It is recommended that insertion be carried out at the end of the menstrual period, which is the most suitable time.

Reinsertion can take place immediately or preferably after one or two cycles.

After birth or abortion, insertion can be delayed until the involution of the uterus is complete, i.e. 6 weeks after an abortion or birth and 12 weeks after a Caesarean section.

In case of greatly delayed uterine involution, consider waiting 12 weeks before inserting the IUD.

If insertion is difficult and/or if the patient feels abnormal pain, or if there is bleeding during or after insertion, a physical examination and an ultrasound must be carried out immediately to rule out a possible perforation.



In the case of emergency contraception, CHOICE 380 7 MED NSTA® (Standard) and CHOICE 380 7 MED NSHA® (Short) must be inserted within 5 days of poorly protected or unprotected sexual intercourse.

▲ Time of removal: removal can take place within the few days following the menstrual period.

▲ Note: The CHOICE 380 7 MED NSTA® (Standard) and CHOICE 380 7 MED NSHA® (Short) IUDs must be replaced, at most after 5 years.

4.1 - INSERTION TECHNIQUE

Insertion must absolutely be carried out by a qualified healthcare professional equipped with the appropriate instruments under aseptic conditions.

The packaging of the IUD must not have been opened or damaged. Insertion must not be carried out if the IUD or its accessories are damaged.

• Before to insert the IUD, the health professional must perform a **thorough gynecological examination**, search and eliminate pregnancy, genital infection / sexually transmitted infection and determine the position of the uterus and the size of the uterine cavity to ensure correct insertion of the device. The practice of careful hystero-metry makes it possible to determine the direction and depth of the uterus.

• After opening the packaging, hold the device flat or upwards to avoid the risk of dropping it on the ground.

• Hold the distal end of the inserter tube and place the lower part of the ring above the value corresponding to the depth of the patient's uterus.

• Pull simultaneously on the 2 nylon strings in order to pull the body and arms of the IUD into the inserter tube. **Allow the extremity of the arms to come up just above the extremity of the inserter tube** to facilitate the atraumatic passage through the cervix. The IUD should not be left more than 5 minutes in the inserter tube. Slide the plunger into the inserter tube along the nylon strings.

• Firmly hold the anterior lip of the cervix with a Pozzi forceps and **exert sufficient traction towards the bottom to straighten the uterine axis** until the end of insertion, then **follow the instructions in the diagrams below**.

• Remove the plunger from the inserter tube and cut the strings 2 or 3 cm from the external orifice of the cervix after checking the proper positioning of the IUD.

4.2 - REMOVAL TECHNIQUE

Removal can take place whenever the user would like to become pregnant or at the time of replacement. **Complications reported in the section «undesirable effects» also justify removal.**

Hold the strings with forceps as close as possible to the external orifice of the cervix.

Regular traction of the strings along with traction towards the bottom with the Pozzi forceps make it possible to remove the IUD without difficulty.

If it is very difficult, removal under general anaesthesia should be considered as per the most appropriate method.

5 - CONTRAINDICATIONS

▲ Absolute contraindications:

- Pregnancy
- Post-partum beyond 48 h and up to 4 weeks
- Puerperal sepsis
- Immediately after a septic abortion (The IUD will have to be inserted only once the uterine cavity is suitable for, and the infection controlled).
- Dysmenorrhoea at the beginning, menorrhagia and unexplained vaginal bleeding
- Gestational trophoblastic disorders
- Gynaecological cancers (cervical, endometrial, ovarian) or suspected cancers: tumours, neoplasia...
- Morphological/anatomical abnormalities: uterine abnormalities, malformations, fibromas with distortion of the uterine cavity, polyps, scarring of the uterus
- PID at the beginning
- Infections/inflammation at the beginning, pelvic tuberculosis, declared AIDS, etc.
- Wilson's disease, copper

▲ Relative contraindications:

- Complicated heart disease (ex: endocarditis)
- Thalassaemia
- Anaemia
- Unexplained vaginal bleeding, occurring during use, abundant vaginal bleeding or prolonged vaginal bleeding, severe dysmenorrhoea
- Endometriosis
- Anatomical abnormality without distortion of the uterine cavity (cervical stenosis, cervical laceration)
- Gynaecological cancers during use
- PID occurring during use, history of PID
- Infection or inflammation occurring during use (with antibiotic treatment), STI and increased risk of STI, high-risk HIV.
- Vaginitis
- Antiretroviral treatment
- History of ectopic pregnancy

6 - WARNINGS AND PRECAUTIONS FOR USE

Warnings: The company LABORATOIRE 7 MED asks the healthcare professional to read the information in this package leaflet and

to inform the patient of the benefits and risks of an IUD. LABORATOIRE 7 MED cannot be held responsible if this information is not complied with.

The onset of an adverse event must be reported to the company LABORATOIRE 7 MED.

Nulliparous, young women:

In women who have never had a baby, the expected benefits should be weighed against the possible risks of treatment. In young women, the main risk is related to sexually transmitted infections, especially if there are multiple partners.

The IUD in a young woman is associated with a higher rate of complications (pain and bleeding, greater risk of expulsion, premature withdrawal of the IUD), increased in children under the age of 20.

Other precautions:

• The presence of Actinomyces organisms on a cervical smear in a woman with an IUD requires an assessment to exclude pelvic infection.

• It is recommended that the user be seen again after the menstrual period following insertion, and then on a regular basis.