

Based on the clinical examination and the size of your uterus, your healthcare professional will choose the Standard model (7 MED 380° TSTA) or the Short model (7 MED 380° TSHA) which will be the most suited to your anatomy.

How are the 7 MED 380° TSTA and 7 MED 380° TSHA IUDs inserted?

The IUD is inserted during the last days of your menstrual period or right after. Your healthcare professional will insert a speculum. After having disinfected the cervix and vagina and measured the depth of the uterus, he or she will insert the IUD into the uterus using a thin tube that passes through the cervix. After insertion, which only lasts a few seconds, the inserter tube and plunger are withdrawn and your healthcare professional will cut the strings to a suitable length, thus ending the insertion. The IUD can be removed whenever you wish by your healthcare professional by simply pulling on the removal strings.

What will happen during the first cycles after insertion of 7 MED 380° TSTA and 7 MED 380° TSHA?

The contraceptive efficacy of the IUD is present starting from the first day of insertion. Some abdominal pain may occur after insertion. If this happens, it should disappear rapidly. You may also have some minor bleeding. These are rare effects that are not cause for concern and that disappear on their own. However, do not hesitate to consult your healthcare professional if you are unsure of anything or if this continues beyond the first few cycles.

Please note that women using IUDs generally have heavier menstrual periods. This is a known effect that is not serious. You can use tampons if you so choose if you check for the strings of the IUD at the back of the vagina after your menstrual period.

What are the contraindications?

- ▲ **Do not use 7 MED 380° TSTA and 7 MED 380° TSHA in case of:**
- Pregnancy
 - Post-partum beyond 48 h and up to 4 weeks
 - Puerperal sepsis
 - Immediately after a septic abortion
 - 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 allergy
- ▲ **Use of 7 MED 380° TSTA and 7 MED 380° TSHA is not recommended in case of:**
- Complicated heart disease (ex: endocarditis)
 - Thalassemia
 - 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

Are there any special precautions to take?

- ▲ After your menstrual period, it is necessary to check using two fingers inserted in the vagina while squatting down that you do in fact feel the strings of the IUD, which shows that it is present and in the proper position. If you do not feel the strings, consult your healthcare professional.
- ▲ Tell your healthcare professional that you have an IUD if you are prescribed anticoagulants.
- ▲ 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.
- ▲ Non-steroidal anti-inflammatories cannot be used during treatment. During short-term treatment, they do not impact the contraceptive efficacy of IUDs.
- ▲ The appearance of abnormal discharge is a reason to consult to screen for and treat any infections, especially if the discharge is accompanied by fever and pain.

▲ As with all IUDs, a late menstrual period is in principle a reason to consult your doctor to rule out a rare but possible risk of the development of a pregnancy. 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.

▲ 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 16.

▲ Radiotherapy or electrotherapy using high-frequency current (diathermy or short waves) is contraindicated, especially when it is applied on the area of the lower pelvis. With regard to the use of continuous low-frequency current (ionisation), it appears that it cannot have a harmful effect on women using a copper contraceptive IUD.

▲ The energetic state of the copper will not be modified by magnetic resonance imaging (MRI). You can therefore not take into account the effect of MRI on the intrauterine device. In addition, based on the non-ferric characteristics of copper, scintigraphy obtained by MRI is not considered to be impacted by the presence of an IUD.

What interference can 7 MED 380° TSTA and 7 MED 380° TSHA IUDs have during sexual intercourse?

▲ 7 MED 380° TSTA and 7 MED 380° TSHA are intrauterine devices whose recognised efficacy authorises sexual intercourse with great safety with regard to the risk of pregnancy.

▲ Intrauterine contraception does not protect against the risk of sexually transmitted diseases. It is therefore recommended that you protect yourself with a condom outside of a stable sex life.

Possible side effects

The complication rate is not very high, but the known side effects are as follows:

▲ **Risk of infection:** the onset of pelvic inflammatory disease (PID), endometritis, salpingitis, peritonitis, oophoritis, etc. can occur mainly during the 20 days following the insertion of the IUD. 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. PID can be a cause of sterility and requires the removal of the IUD and the administration of a suitable antibiotherapy.

▲ Inflammatory reaction

▲ **Ectopic pregnancy:** the risk of ectopic pregnancy is very low, but when a woman is pregnant with an IUD, the probability of an ectopic pregnancy is increased.

▲ **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 the 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.

▲ **Uterine perforation:** uterine perforation may occur when the IUD is inserted or secondarily. A uterine perforation can lead to a pregnancy. When perforation is detected late, the IUD can move outside the uterine cavity and/or adjacent organs can be damaged. In case of suspected perforation during insertion, the healthcare professional must remove the IUD immediately. Perforation can also occur in women with an IUD. If this happens, the IUD should be located and its removal considered.

▲ The risk of perforation is increased in case of:

- hasty IUD insertion,
- insertion carried out before normal uterine involution,
- breast-feeding at the time of insertion and insertion carried out up to 36 weeks after birth,
- atypical uterine anatomy or fixed retroverted uterus.

▲ **Effects related to IUD insertion:** pelvic and abdominal pain, back pain, bleeding, neuro-vascular episodes (during insertion and withdrawal of the IUD), nausea, vomiting, uterine contractions.

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

▲ **Dysmenorrhoea** (menstrual pain).

▲ **Intermittent bleeding, spotting.**

When should I consult a healthcare professional and replace my IUD?

- ▲ The first consultation is a control consultation planned after the first menstrual period following the insertion of the IUD.
- ▲ Outside of regular visits, 5 symptoms should lead you to consult your doctor:
- persistent abdominal pain
 - abnormal discharge
 - a menstrual period more than 7 days late
 - disappearance of the IUD strings when palpated after the menstrual period
 - unexplained fever

▲ The 7 MED 380° TSTA must be replaced, at most after 10 years, and the 7 MED 380° TSHA must be replaced, at most after 5 years. A new IUD can be inserted immediately.

If you would like to become pregnant, you can ask your healthcare professional to remove the IUD at any time.

Classification and packaging

The 7 MED 380° TSTA and 7 MED 380° TSHA are class III medical devices as per the Directive related to medical devices 93/42/EEC amended by Directive 2007/47/EC.

Labelling: EC 0459 since 2002 for the Standard version and since 2007 for the Short version.

Each package contains a sterile, single-use I.U.D., the insertion date of wich is indicated on the box.

I FILL IN MY PERSONAL FOLLOW-UP TABLE AND KEEP IT

Laste name:

First name:

Date of insertion:

Type de IUD

☐ 7 MED 380° TSTA (Standard)

☐ 7 MED 380° TSHA (Short)

Batch No.:

First check-up after the first menstrual period following insertion:

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Regular follow-up visits:

- ☐ Every year
- ☐ Every 6 months
- ☐ Other

I will consult my healthcare professional in principle in case of:

- ☐ persistent abdominal pain
- ☐ bloody and/or nauseating abnormal discharge
- ☐ a menstrual period more than 7 days late
- ☐ disappearance of the IUD strings
- ☐ unexplained fever

I can keep my IUD 7 MED 380° TSTA safely for a maximum of 10 years and 7 MED 380° TSHA for a maximum of 5 years.

The planned replacement date is:

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Date de révision : 12 Mai 2017

Date of revision: 12 May 2017

Date renouvellement d'autorisation : 29 Janvier 2013

Date of renewal of the authorisation: 29 January 2013

CE 0459

STERILE R

Fabrication : LABORATOIRE 7 MED



Le BioParc
03270 Hauterive
France



7 MED 380° TSTA (Standard)
7 MED 380° TSHA (Short)

**NOTICE
POUR L'UTILISATRICE**

**PACKAGE LEAFLET
FOR THE USER**



