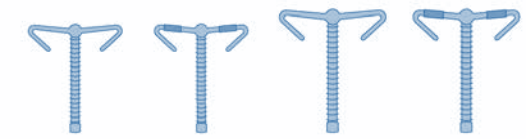
Flexi-T®

(+) 300, 300D and + 380

Intrauterine Contraceptive Device (IUD)



PROSAN
female health care
Therapeutic systems/Medical devices

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INSTRUCTIONS FOR THE PHYSICIAN

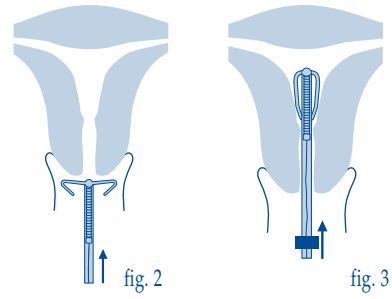


fig. 1

fig. 2

fig. 3

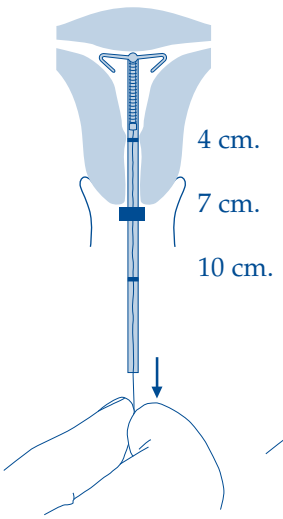
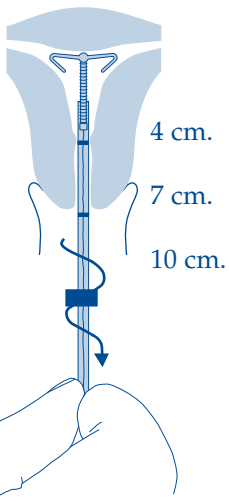


fig. 4



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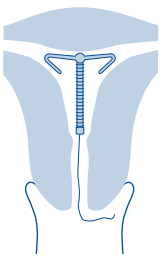
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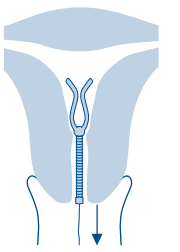
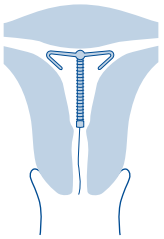


fig. 7



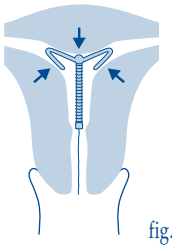


fig. 8

DESCRIPTION

The Flexi-T is an intrauterine device made of polypropylene mixed with barium sulphate which makes it visible to X-ray. The dimensions of the Flexi-T 300/300D are 29 mm in length and 23 mm in width. The dimensions of the Flexi-T+ 300/380 are 32 mm in length and 28 mm in width. A copper wire of highest purity (99.9%) with a diameter of 0.3 mm is coiled around the shaft. On the Flexi-T(+) 300 the wire provides a surface area of 300 mm^2. On the Flexi-T 300D the wire plus two copper collars of 99.9% purity on the transverse arms provide a total surface area of 300 mm^2. For the Flexi-T+ 380 the wire and two copper collars of 99.9% purity on the transverse arms provide a surface area of 380 mm^2.

One monofilament thread, without a knot, is embedded in the shaft. The polypropylene inserter tube is only ca. 3,5 mm in diameter and the Flexi-T can therefore also be used for women with a narrow endocervical canal. The simple one-hand "push in" technique does not require a plunger. As a means of reference to the uterine sound length (to be determined prior to insertion) the inserter tube has a centimeter scale and is specially marked at 4 cm, 7 cm and 10 cm. These marks and the cervical stop allow the physician to ascertain whether the device has passed the internal os and has reached the uterine fundus.

The design of the Flexi-T is based on data obtained through extensive in vivo measurements of the transverse and longitudinal dimensions of the uterine cavities in thousands of fertile women of all ages and parity groups, resulting in an optimal compatibility. The shape of the Flexi-T avoids irritation of the uterine mucosa and provides a "fundus-seeking" and anti-expulsive mechanism (fig. 8).

INDICATION

Flexi-T 300/300D; Intrauterine contraception for uniparous and nulliparous women, and as an emergency contraceptive.

Flexi-T+ 300/380; Intrauterine contraception for uniparous and multiparous women, and as an emergency contraceptive.

MODE OF ACTION

The sperms regularly do not reach the Fallopian tubes in sufficient numbers if a copper IUD is present. The traces of copper continuously released by the Flexi-T immobilize sperms by interfering with mitochondrial energy production. Also, the Flexi-T, by affecting endometrial metabolism, renders the uterine mucosal surface hostile to gametes and interferes with fertilization and the further development of the ovum. No long-term deleterious effects on the mucosal cells are reported.

TIME OF INSERTION

The Flexi-T can be inserted on any day of the menstrual cycle. However, insertion during the menstrual period offers the following advantages:

(a) the probability of a pregnancy is at its lowest;

(b) insertion is easy and additional bleeding can be avoided.

Postcoital use as an emergency contraceptive has been recommended within five days.

Postpartum insertion can be carried out after 6 - 8 weeks, or may be delayed until uterine involution is complete.

If involution is substantially delayed, consider waiting 12 weeks to insert Flexi-T. In case of a difficult insertion and/or exceptional pain or bleeding during or after insertion, physical examination and ultrasound should be performed immediately to exclude perforation.

After a first trimester therapeutic abortion a Flexi-T can in general be inserted immediately.

DURATION OF USE

The Flexi-T IUD has a maximum in situ time of five years. A new Flexi-T can be inserted immediately after removal

INSERTION PROCEDURE

Prior to insertion, women should be examined for the presence of pelvic inflammatory disease before inserting Flexi-T. In cases of infection (e.g. subsequent to a septic abortion, abortion with infection <3 months or a sexually transmitted disease <12 months) appropriate treatment should be given before inserting the Flexi-T.

Care must be taken to ensure an aseptic insertion procedure.

- Perform a bimanual examination of the uterus to determine its position, form and size and the flexion of the uterine axis.
- Expose the cervix with a speculum.
- Fix a tenaculum to the cervix and pull gently to straighten the uterine axis (fig. 1).
- Cleanse the cervix and vagina with a sterile swab soaked in an antiseptic solution.
- With the help of a probe determine the uterine sound length and the flexion of the axis.
- Move the cervical stop to the numbered mark corresponding to the sounded length in cm. By doing so the blue thread, which is fixed to the inserter tube, is released. Releasing the thread is necessary to prevent pulling back the Flexi-T when removing the inserter tube. If the cervical stop is not used, it has to be removed in order to release the thread.
- Stretch the uterus into the straight position by pulling the tenaculum (fig. 1), fix the blue thread between thumb and forefinger on the inserter tube and introduce the inserter tube with the IUD into the uterine cavity until it touches the fundus and the cervical stop rests against the external os (fig. 2/3/4). The disappearance of the mark at 4 cm usually shows when the internal os has been passed.
- If insertion is problematic, a dilator can be used to dilate the internal cervical os.
- Gently pull on the thread protruding from the inserter tube in order to check whether the arms are unfolded and the device is held by the lateral muscular wall of the uterus (fig. 4).
- After this check has been performed, gently push the inserter tube with the device towards the fundus, make sure the blue thread is loose and then re-

move the inserter tube cautiously using a rotating movement, in order to prevent the IUD being pulled downwards or out (fig. 5).
- After removing the inserter tube check whether it is intact.
- Cut the control thread to the length required, normally about 2 cm from the external os (fig. 6).
- If available, ultrasonography performed immediately after insertion will establish whether the device is correctly positioned within the uterine cavity(fig 8).
- Note the lot number of the device in the patients file!

REMOVAL

The Flexi-T can be removed easily at any time by gentle traction on the thread (fig. 7) (Clinically tested the forces needed were between 0.6 - 1.6 Newton only). The Flexi-T must be removed in the event of: continuous bleeding, persistent painful cramps, and persistent infection of the upper genital tract or a perforation. The ability to become pregnant is regained immediately after removal of the Flexi-T. In the rare case of a missing or broken thread the following protocol should be observed:
1) Exclude pregnancy. 2) Use ultrasound to determine the intrauterine presence and position of the Flexi-T or with the help of pelvic radiography. 3) If wanted remove the Flexi-T with a small clamp like an "Alligator forceps" or the "COP IUD Remover" which is successful in most cases. Hysteroscopic removal under local anesthesia is indicated only in rare cases. Note: General anesthesia is neither recommended nor necessary for the removal of a Flexi-T without visible thread.
In the unlikely event of breakage of the device, a gynaecologist should be consulted to ensure complete removal.
In the event of pregnancy first determine if the pregnancy is intrauterine or ectopic using ultrasound. The Flexi-T can best be carefully removed within the first three months if it is positioned below the gestational sac. Since there is an increased risk of PID and other obstetric problems in case of pregnancy with a Flexi-T in situ, the patient should be offered the option of
elective abortion as soon as possible after removal.
Continuation of the pregnancy with the IUD left in the uterus is possible but carries extra risks and needs additional supervision. Note: If a pregnancy occurs with a Flexi-T in situ the device is placed in the uterine cavity outside of the gestational sac. Further copper has no teratogenic properties. The placenta is rich of e.g. zinc and copper.

CONTRA-INDICATIONS

Absolute contraindications: Pregnancy; Acute or recurrent infection of the upper female genital tract; Uterine bleeding of unknown origin; Uterine polyps or fibroids (myoma); subacute, acute and chronic pelvic inflammatory disease (PID); history of ectopic pregnancy or predisposing factors (tubal damage). Malformation of the uterus or cervix; Suspected or proven cancer of the genital tract;
Relative contraindications: Proven copper allergy; Anemia; Uterine sound length less than 5 cm for the Flexi-T 300, and less than 6 cm for the Flexi-T+ 300/+ 380.

WARNINGS

If the insertion is painful, local anesthesia and dilatation of the internal cervical os may be helpful. Careful selection is recommended for women at risk of acute or chronic infections of the upper female genital tract. To avoid ascending contamination and a later, possible infection being provoked by the insertion procedure extra preventive measures might be useful (e.g. dipping the inserter with the Flexi-T in an iodine solution prior to insertion). Users with a history of menorrhagia and women taking anticoagulants must be warned against the possibility of prolonged and/or increased bleeding and spottings. If the patient or her partner can feel the device during intercourse, or if there is complaint of pain or discomfort during intercourse, the patient should not have intercourse until she can see her physician. The possibility of displacement or cervical perforation should be ruled out, as the displacement could result in cervical perforation or reduced performance since the copper is not released close to the fallopian tubes, necessary to prevent pregnancy.
Symptoms which could be indicative for PID are abnormal vaginal discharge, fever and pelvic pain. In this case, the user has to report this immediately to her medical professional who can perform gynecological examination and/or ultrasound.
Women taking corticosteroids or having immunosuppressive therapy could have diminished resistance to genital infections. Interactions with therapeutic or diagnostic radiation: Copper IUD's have been classified as MR conditional. Safety has been demonstrated in magnetic resonance imaging (MRI) systems 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 Prosan 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 ≈ 1.4°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 ≈ 0.8°C (2 W/kg, 3 Tesla) after 15 minutes of continuous scanning.

SIDE EFFECTS

Mild post-insertional cramps or a vasovagal syncope may occur in rare cases. This menstrual-type discomfort should diminish after some time. Usually, no marked increase in menstrual pain or cramps is experienced, owing to the physical properties of the Flexi-T. Increased menstrual bleeding or spottings may occur, mainly during the first 1-2 cycles after insertion. Uterine perforation is very rare and is principally caused by a traumatic insertion procedure using a plunger (not used for the insertion of Flexi-T) and occurs mainly during lactation. Copper belongs, like iron and zinc, to the trace elements essential for the life of any cell. The daily intake of copper in food is ~ 100 times higher than the daily release of a copper IUD.

The possibility of a broken thread cannot be discounted.
The risk of perforation is increased with women during lactation and postpartum, and in women with fixed and retroverted uterus.
If perforation happens, pregnancy may occur. IUD needs to be located and removed. Delayed detection of perforation may result in IUD migration outside the uterine cavity and/or injury to other adjacent organs.
A study performed in Europe showed that both breastfeeding at the time of insertion and insertion up to 36 weeks after giving birth are associated with a possible increased risk of perforation, see table 1.
Table 1: Incident of perforation per 1000 insertions for the entire study cohort, stratified by breastfeeding and time since delivery at insertion (parous women)

	Breastfeeding 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)

Reference: "European Active Surveillance Study on Intrauterine Devices, Contraception 2015; 91: 274-279" (EURAS-IUD)

PATIENT CHECK-UP

The presence and position of the Flexi-T should be verified at least after the first cycle and after ± six months, preferably using ultrasound. Further checks are to be indicated by the physician.

INSTRUCTIONS FOR THE USER

The medical professional shall inform the (potential) user about the risks and benefits of the Flexi-T. This means that the woman should be made aware of the mode of action of the Flexi-T, the very slight possibility of pregnancy (<1%), the possibility of expulsion especially during menstruation, and those side effects which should lead to the removal of the device. Advice shall be given to perform a periodic check on the presence of the Flexi-T. Furthermore, it shall be explained which clinical signs and symptoms require consultation with a medical professional (see also warnings section).
The (potential) user should be informed that a Flexi-T does not protect against sexually transmitted infections.
Informed and written consent might be obtained from the potential user prior to insertion. For further information please contact your physician or Prosan International B.V.

PHARMACEUTICAL PRECAUTIONS

If the package is damaged do not use the Flexi-T. The Flexi-T is for single use only and cannot be resterilized.

LEGAL CATEGORY CE 0344

Medical device class III. In compliance with Medical Device Directive 93/42/EEC.
Date of first authorization: 15 April 1996
Date of last renewal: 1 December 2019

PACKAGING

Each blister contains one Ethylene Oxide sterilized Flexi-T.
Expiry date is indicated on the package. When stored in a dry place at room temperature the maximum shelf life is 5 years.
Cartons containing: 1 x 1 sterile Flexi-T
10 x 1 sterile Flexi-T