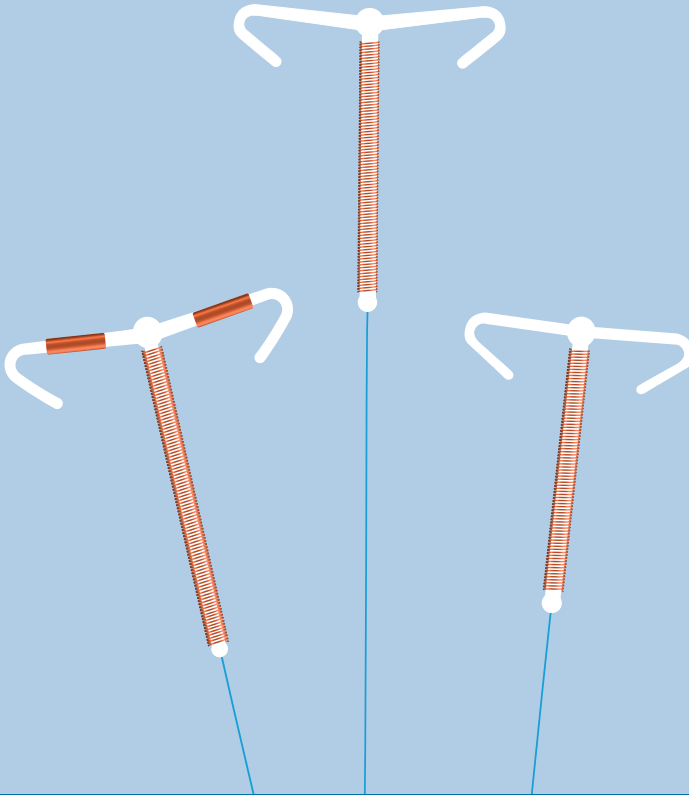


## *Flexi~T*® the woman friendly IUD

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„SUSTAINABLE, RELIABLE AND HORMONE FREE“



# *Flexi~T*<sup>®</sup> sustainable, reliable and hormone free

## Flexi-T IUDs

Intrauterine Contraceptive Devices are mostly T-shaped and made of plastic with copper.

The Flexi-T was developed based on data obtained through a study using the Kurz-Cavimeter with 795 fertile women of all ages and parity groups. The data show that the size of the uterus mostly depends on the number of pregnancies.

Based on the above knowledge the Flexi-T was designed. 2 different sizes were developed to have an optimal fit for nulliparous, uniparous and multiparous women. Due to the optimal fit and the flexible material used, expulsions and unwanted side effects like bleedings and pain are reduced to a minimum.

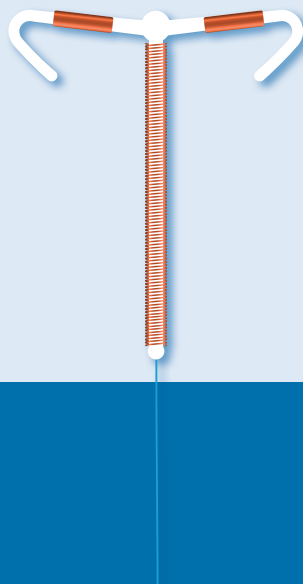
## Physical and Clinical Characteristics

The Flexi-T is a soft and small flexible T-shaped copper intrauterine contraceptive device made of white polypropylene with smooth rounded ends, which correspond with the shape of the uterus.

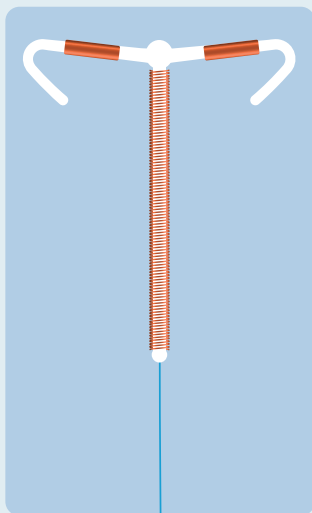
The vertical part has smooth fine copper wire coiled around it and the Flexi-T+ 380 and 300D also has copper tubes on the arms. The copper provides an optimal contraception without disrupting the hormone cycle. The Flexi-T is inserted with a small inserter tube of 3.5 mm in diameter without a plunger. The risk of perforation and expulsion is very low because of the shape of the Flexi-T. The removal process is easy and requires a tensile force of less than 3 Newton (fig. 7). The Flexi-T IUD offers protection up to 5 years.

## Mode of action

The copper on the Flexi-T IUD releases traces of copper in the immediate vicinity of the fallopian tubes, causing sperms to lose mobility and preventing fertilisation. In addition, in the unlikely event that an egg is fertilised, the copper on the Flexi-T prevents the fertilised egg from implanting in the uterine wall. As a result, this IUD is also an excellent 'morning after' option in the event of an accident. This dual effect starts immediately after the Flexi-T is inserted.



# *Flexi~T*<sup>®</sup> the woman friendly IUD



## *Flexi~T*<sup>®</sup> +380

### **Dimensions:**

Length of shaft: 32 mm  
Transverse arms: 28 mm

### **Copper surface:**

380 mm<sup>2</sup>

### **Bioactive component:**

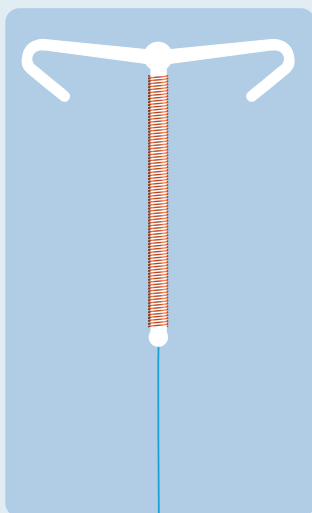
Copper wire of highest purity (99.9 %) on the shaft and 2 copper tubes on the transverse arms.

### **Material of the carrier:**

Polypropylene mixed with barium sulfate for visibility to X-ray.

### **Recommended application:**

Contraception for multiparous and uniparous women.  
Uterine sound length (≥ 6 cm).  
Postcoital interception.



## *Flexi~T*<sup>®</sup> +300

### **Dimensions:**

Length of shaft: 32 mm  
Transverse arms: 28 mm

### **Copper surface:**

300 mm<sup>2</sup>

### **Bioactive component:**

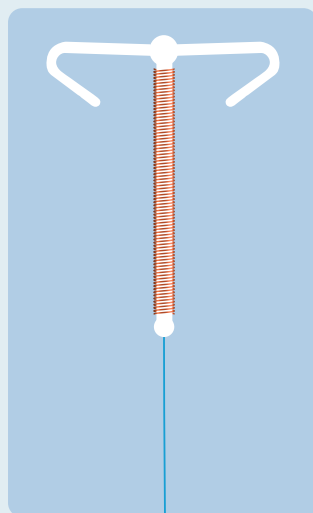
Copper wire of highest purity (99.9 %) on the shaft.

### **Material of the carrier:**

Polypropylene mixed with barium sulfate for visibility to X-ray.

### **Recommended application:**

Contraception for multiparous and uniparous women.  
Uterine sound length (≥ 6 cm).  
Postcoital interception.



## *Flexi~T*<sup>®</sup> 300

### **Dimensions:**

Length of shaft: 29 mm  
Transverse arms: 23 mm

### **Copper surface:**

300 mm<sup>2</sup>

### **Bioactive component:**

Copper wire of highest purity (99.9 %) on the shaft.

### **Material of the carrier:**

Polypropylene mixed with barium sulfate for visibility to X-ray.

### **Recommended application:**

Contraception for nulliparous women.  
Uterine sound length (≥ 5 cm).  
Postcoital interception.

# *Flexi~T*<sup>®</sup> optimal safety and user acceptance

## **Advantages of the Flexi-T:**

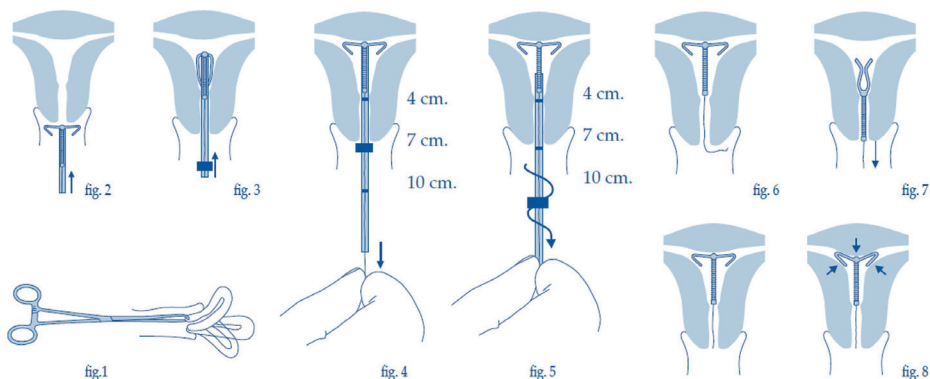
- ✓ Hormone free
- ✓ Small and flexible
- ✓ Easy to insert
- ✓ Narrow insertion tube (3.5 mm in diameter)
- ✓ No plunger, so negligible risk of perforation during insertion
- ✓ Little to no discomfort
- ✓ Good shape
- ✓ Reliable
- ✓ Visible on X-ray and ultrasound
- ✓ Protection lasts for 5 years
- ✓ Offers protection as soon as it's place
- ✓ Fully fertile again immediately after removal

## **Do not insert Flexi-T in the event of:**

- ✗ Pregnancy
- ✗ Infection of the uterus (including PID)
- ✗ Bleeding of unknown origin
- ✗ Polyps or fibroids (myoma) inside the uterus
- ✗ Possibility of ectopic pregnancy
- ✗ Malformation of the uterus
- ✗ Cancer of the uterus
- ✗ Copper allergy
- ✗ Anaemia

# Flexi-T<sup>®</sup> sustainable, reliable and hormone free

## Instructions for the physician



## Flexi-T<sup>®</sup> IUD: insertion procedure

- Perform a bimanual examination of the uterus to determine its position, form and size and the flexion of the uterine axis or use an echo apparatus if available.
- 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, is released. Releasing the thread is necessary to prevent pulling back the IUD when removing the inserter. 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) and introduce the inserter 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.
- Gently pull on the thread protruding from the inserter 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 again towards the fundus and remove the inserter cautiously using a rotating movement, in order to prevent the IUD being pulled downwards or out (fig. 5).
- After removing the inserter tube check if 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!

# *Flexi-T*<sup>®</sup> optimal safety and user acceptance

## **Prosan International B.V.**

Prosan International B.V., a medical device company, was founded in 1989 in The Netherlands.

The mission of Prosan International B.V. is to produce and sell (newly designed) copper Intrauterine Contraceptive Devices (IUDs) under the brand name Flexi-T, we can assure the users of our products, that these may be used safely and that the products function according to their intended use.

Flexi-T IUDs are produced in The Netherlands, according to the requirements of the Medical Device Directive 93/42/EEC and EN-ISO 7439. Our copper IUDs are classified as Class III „Medical Devices“ as stated in article 1 of the MDD 93/42/EEC.

CE Marking of Conformity was obtained in 1996 and renewed ever since; numbers of certificates 92494CE01 and 92494DE01. This is supported by the EN-ISO 13485:2016-12 2019 and CAN/CSA ISO 13485:12-2019. Notified body number 0344, DEKRA Certification B.V.

## **The Flexi-T has proven to be the optimal Copper IUD for more than 1 million women.**

### **References:**

1. Kurz, K.H., Tadesse E., Haspels, A.A.:

In vivo measurements of uterine cavities in 795 women of fertile age. Contraception 29: 495, 1984

2. Van Kets, H.E., van der Pas, H., Delborge, W., Thiery, M.:

A randomized comparative study of the TCu 380A and Cu-Safe 300 (Flexi-T 300) IUDs. Adv. In Contraception, 11:123, 1995

3. Kurz, K.H., Meier-Oehlke, P.A.: The Cu-Safe 300 (Flexi-T 300) IUD, a new concept in intrauterine contraception.

Adv. In Contraception 7:291, 1991

4. Kimmerle, R., Weiss, R., Berger, M. and Kurz, K.H.:

Effectiveness, Safety, and acceptability of a Copper Intrauterine Device (Cu-Safe 300) in Type I Diabetic Women. Diabetes Care, volume 16, number 9, September 1993.

Remark :

In 1998 the name Cu-Safe was changed to Flexi-T.

### **Prosan International B.V.**

IJsselburcht 3 • 6825 BS Arnhem • The Netherlands

**Tel.:** +31 (0) 26 365 3363

**Fax:** +31 (0) 26 365 3369

**E-Mail:** [info@prosan.nl](mailto:info@prosan.nl)

**Web:** [www.prosan.nl](http://www.prosan.nl)

