

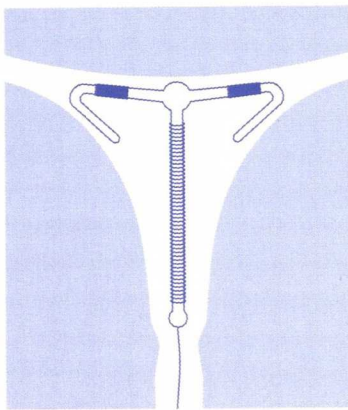


## *Times are changing—IUDs too*

Flexi-T IUDs provide safe and effective contraception for multiparous, uniparous and nulliparous women of high and low fertile age



# *The optimal IUD for parous women: Flexi~T+ 380*



Lengths of shaft 32 mm,  
transverse arm 28 mm.  
Size 1:1.

## **Flexi~T+ 380 specifications**

Intrauterine device for contraception

Material of the plastic carrier

Polyethylene mixed with barium sulfate for visibility to x-ray

Dimensions

Lengths of shaft 32 mm, transverse arm 28 mm

Bioactive compound

Copper wire of highest purity (99.9%) on the shaft and two copper sleeves on the transverse arm

Surface area of copper

~380 mm<sup>2</sup>

Indications

Intrauterine contraception, postcoital interception

Recommended application

Parous 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 380 A and CU-Safe 300 (Flexi~T 300).* Adv. Contracept., 11: 123, 1995
3. Kurz, K.H.:  
*Cavimeter Uterine Measurements and IUD Clinical Correlation.* In: Zatuchni, G.I., Goldsmith, A., Sciarra, J.J. (eds): Intrauterine Contraception, Advances and Future Prospects; Proceedings of an International Workshop, pp.: 142 – 162, Chicago, Illinois, 1984; Harper & Row, Publishers, Philadelphia
4. Kurz, K. H., Meier-Oehlke, P. A.:  
*The Cu-Safe 300 (Flexi~T 300) IUD, a new concept in intrauterine contraception.* Adv. Contracept. 7: 291, 1991

# The optimal IUD for parous women: *Flexi~T+ 380*

The uterus of fertile women including the uterine cavity and its dimensions have become increasingly smaller in the last decade. This is due to the, on average, ever later first delivery and the substantially reduced number of births per women, both in developed and developing countries.

Therefore the time had come to create an intrauterine contraceptive device (IUD) for parous women with reduced dimensions and a copper surface of 380 mm<sup>2</sup>.

Prosan International is proud to provide an optimal IUD which combines both high efficacy and safety, the

## *Flexi~T+ 380*

One of the most effective contraceptives, the world-wide distributed TCu 380 IUD, has the maximum dimensions as laid down in the European Standard EN ISO 7439: "The nominal length of an IUD (shaft) shall not be greater than 36 mm, the nominal width (transverse arm) not greater than 32 mm."

In vivo measurements of the uterine cavities of women of fertile age, conducted with the help of a *Cavimeter*, showed that, e.g. the maximum width at the fundus uteri of parous women is 28 mm, about half a centimeter shorter than the actual length of the relatively stiff transverse arm of the TCu 380 IUD.

Therefore the TCu 380, the so called "gold standard" in regard to efficacy (not safety), has an oversized plastic body. It irritates the endometrium and the nerve-triggered tissues at the uterine tubal junctions/ internal os. These are the main causes for additional bleeding, painful uterine cramps and related early removals in a substantial number of users of this device.

The Flexi~T+ 380 combines the proven Flexi~T IUDs with the high effectiveness of the TCu 380 IUD (Pearl Index < 1.0 in the first year).

Safety has been neglected in the past. Nevertheless it is of utmost importance for the IUD user and her sexual partner. The Flexi~T+ 380 is highly flexible. Its size is compatible with the uterine cavity of parous women. It has one thread only, without a knot. No plunger is needed for insertion. These properties ensure easy insertion and removal, fewer expulsions, and reduced events of male dyspareunia as well as early removals due to bleeding / pain. The improved continuation rates reflect the satisfaction of the users and physicians. So far no perforation has been reported.

## Flexi~T+ 380 specifications

Intrauterine device for contraception

### Material of the plastic carrier

Polyethylene mixed with barium sulfate for visibility to x-ray

### Dimensions

Lengths of shaft 32 mm, transverse arm 28 mm

### Bioactive compound

Copper wire of highest purity (99.9%) on the shaft and two copper sleeves on the transverse arm

### Surface area of copper

~380 mm<sup>2</sup>

### Indications

Intrauterine contraception, postcoital interception

### Recommended application

Parous 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 380 A and CU-Safe 300 (Flexi~T 300). *Adv. Contracept.*, 11: 123, 1995
3. Kurz, K.H.: *Cavimeter Uterine Measurements and IUD Clinical Correlation*. In: Zatuchni, G.I., Goldsmith, A., Sciarra, J.J. (eds): *Intrauterine Contraception, Advances and Future Prospects; Proceedings of an International Workshop*, pp.: 142 – 162, Chicago, Illinois, 1984; Harper & Row, Publishers, Philadelphia
4. Kurz, K. H., Meier-Oehlke, P. A.: *The Cu-Safe 300 (Flexi~T 300) IUD, a new concept in intrauterine contraception*. *Adv. Contracept.* 7: 291, 1991

# *General Properties of Flexi~T IUDs*

## **Modern Technology**

- Uterine cavity compatible
- High flexibility, fundus seeking design
- No anchoring mechanism
- Integrated control thread without knot
- Copper of 99.99% purity
- Small inserter of 3 mm diameter
- Light weight (ca. 0.3g)

## **Clinical Properties**

- High contraceptive effectiveness
- Optimal safety
- Simple insertion without plunger
- Easy removal
- High continuation rates
- Low expulsion rate
- Useful also in small uterine cavities
- > 1,000,000 Users



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# *The optimal, safe and effective Flexi~T 200*

Higher copper loads of a surface area of 300 mm<sup>2</sup> up to 380 mm<sup>2</sup> on IUDs lead to a reduction of failures (unwanted pregnancies) of about 0.5 % in comparison to IUDs with a copper surface of 200 mm<sup>2</sup> up to 250 mm<sup>2</sup>. On the other hand the higher loaded Cu-IUDs increase the rates of ongoing bleeding disturbances and/or pain by a substantial percentage. The higher the copper load the higher are the rates of unwanted side effects may they lead to early removals or e.g. to anaemia only.

Low fertile women of 35 years up to about 50 years of age do not need overloaded Cu-IUDs having a copper surface of 300 mm<sup>2</sup> up to 380 mm<sup>2</sup>. These women tend already to additional bleeding due to an increasing dysfunction of the ovaries. The uterus and its cavity is shrinking due to a relative lack of estrogen.

IUDs medicated with a copper surface of less than 300 mm<sup>2</sup> have shown a high effectiveness and a unique safety—provided the plastic body is not oversized—especially in low fertile women of 35 years of age and more. Therefore the inauguration of the

## *Flexi~T 200*

was justified. The dimensions of the plastic body 23 mm (crossbar) x 28 mm (shaft) are identical with the plastic body of the Flexi~T 300 IUD. The Flexi~T 200 has proven to be an optimal, safe and effective IUD with uniquely high continuation rates.

### **Flexi~T 200 specifications**

Intrauterine device for contraception

**Material of the plastic carrier**

Polyethylene mixed with barium sulfate for visibility to x-ray

**Dimensions**

Length of the shaft 28 mm, transverse arm 23 mm

**Bioactive compound**

Copper wire of highest purity (99.9%)

**Surface area of copper**

~300 mm<sup>2</sup>

**Number of windings**

~35

**Indications**

Intrauterine contraception, postcoital interception

**Recommended application**

The application of the Flexi~T 200 IUD is recommended in low fertile women (more than 35 years of age) and as replacement IUD for uniparous and nulliparous women with ongoing bleeding and / or pain using IUDs with a copper surface of 300 mm<sup>2</sup> up to 380 mm<sup>2</sup>.

### **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. Meier-Oehlke P. A., Kurz, K. H.,  
*The Flexi~T 200 IUD. Results of a prospective study of 1 150 users.*  
Unpublished data.

# *General Properties of Flexi-T IUDs*

## **Modern Technology**

- Uterine cavity compatible
- High flexibility, fundus seeking design
- No anchoring mechanism
- Integrated control thread without knot
- Copper of 99.99% purity, surface of 300 mm<sup>2</sup>
- Small inserter of 3 mm diameter
- Light weight (ca. 0.3g)

## **Clinical Properties**

- High contraceptive effectiveness
- Optimal safety
- Simple insertion without plunger
- Easy removal
- High continuation rates
- Low expulsion rate
- Useful also in small uterine cavities
- > 1,000,000 Users



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# *The new, larger Flexi~T+ model: Flexi~T+ 300*

In the past Prosan has received inquiries regarding a somewhat larger Flexi~T model particularly for women having, due to two and more deliveries, a larger uterus with a respective increased size of the uterine cavity (Uterine sound length ~8 cm and more).

The proven Flexi~T 300/200 with a transverse arm of 23 mm length and a shaft of 28 mm length, mainly recommended as the optimal intrauterine device for uniparous and nulliparous women, provided the basic device for the larger, new model:

## *Flexi~T+ 300*

T+ stands for the increased size of the plastic body:  
Length of transverse arm 28 mm, shaft length 32 mm

### **Flexi~T+ 300 specifications**

Intrauterine device for contraception

Material of the plastic carrier

Polyethylene mixed with barium sulfate for visibility to x-ray

Dimensions

Length of the shaft 32 mm, transverse arm 28 mm

Bioactive compound

Copper wire of highest purity (99.9%)

Surface area of copper

~300 mm<sup>2</sup>

Number of windings

~50

Indications

Intrauterine contraception, postcoital interception

Recommended application

Multiparous women (two deliveries and more)

### **Reference**

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

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

# *General Properties of Flexi-T IUDs*

## **Modern Technology**

- Uterine cavity compatible
- High flexibility, fundus seeking design
- No anchoring mechanism
- Integrated control thread without knot
- Copper of 99.99% purity, surface of 300 mm<sup>2</sup>
- Small inserter of 3 mm diameter
- Light weight (ca. 0.3g)

## **Clinical Properties**

- High contraceptive effectiveness
- Optimal safety
- Simple insertion without plunger
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# *Prosan's unique standard IUD: Flexi~T 300*

In industrialized and increasingly in developing countries women postpone their first delivery to the age of twenty-five to thirty-five years on average. The uterus and the cavity of these low parity, uniparous and nulliparous women is relatively small. Regularly the uterine sound length is 7.5 cm and less.

Extensive in vivo longitudinal and transversal measurements of uterine cavities of all age and parity groups have shown that the uterine cavities of the today's women is too small for IUD models widely used. A relative lack of safety, meaning additional bleeding and pain leading to a substantial rate of early removal, especially in uniparous and nulliparous women, are the consequences.

The above mentioned basic research led to the invention of a very flexible plastic body having one thread without knot only. A copper wire of 300 mm<sup>2</sup> surface is coiled around the shaft of the novel

## *Flexi~T 300*

The length of the shaft is 28 mm and of the transverse arm 23 mm. (The usual Cu-T IUD models have dimensions of 32 mm x 36 mm). Flexi~T 300, the standard IUD of Prosan, has proven to be the optimal IUD for more than a million women of low parity worldwide. It is effective and considered to be one of the safest IUD models of today.

### Note:

"CU-Safe" was changed to the trademark "Flexi~T" in 1998

## **Flexi~T 300 specifications**

Intrauterine device for contraception

**Material of the plastic carrier**

Polyethylene mixed with barium sulfate for visibility to x-ray

**Dimensions**

Length of the shaft 28 mm, transverse arm 23 mm

**Bioactive compound**

Copper wire of highest purity (99.9%)

**Surface area of copper**

~300 mm<sup>2</sup>

**Number of windings**

~50

**Indications**

Intrauterine contraception, postcoital interception

**Recommended application**

Uniparous and nulliparous women (one or no delivery)

## **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 380 A and CU-Safe 300 IUDs.* *Adv. Contracept.*, 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. Contracept.* 7: 291, 1991

# *General Properties of Flexi-T IUDs*

## **Modern Technology**

- Uterine cavity compatible
- High flexibility, fundus seeking design
- No anchoring mechanism
- Integrated control thread without knot
- Copper of 99.99% purity, surface of 300 mm<sup>2</sup>
- Small inserter of 3 mm diameter
- Light weight (ca. 0.3g)

## **Clinical Properties**

- High contraceptive effectiveness
- Optimal safety
- Simple insertion without plunger
- Easy removal
- High continuation rates
- Low expulsion rate
- Useful also in small uterine cavities
- > 1,000,000 Users



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## *The Flexi~T range of advanced copper bearing IUDs for safe and effective, long acting and reversible contraception*

The size of the uterine cavity of fertile women depends on the parity. Low parity women (uniparous and nulliparous) have a relative short and narrow uterine cavity (uterine sound length between 5 cm to 7.5 cm). Also the uterus and its cavity shrinks after 35 years of age even in multiparous women due to an increasing lack of estrogen.

Multiparous women (two and more deliveries) have an uterus with a larger uterine cavity (uterine sound length 8 cm to 11 cm).

To reach an optimal effectiveness for high fertile women (age 18 to 35 years) IUDs with a copper surface area of 300 mm<sup>2</sup> are necessary.

Women of low fertility (age 35 years and more) who increasingly tend to irregular bleeding are effectively and safely protected by IUDs with a copper surface area of 200 mm<sup>2</sup>.

In general the different Flexi~T IUDs are recommended for the use in the following subgroups of fertile women:

### **Flexi~T 300**

(28 mm x 23 mm) for uniparous and nulliparous women of high fertility (age 18 to 35 years)

### **Flexi~T 200**

(28 mm x 23 mm) for low fertile women (more than 35 years of age) and for women who cannot bear the Flexi~T 300 (ongoing bleeding and/or pain)

### **Flexi~T+ 300**

(28 mm x 32 mm) for multiparous women (two and more deliveries)

### **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. Mishell D.R.:  
*Intrauterine Devices: Medicated and Nonmedicated*  
*Int. J. Gynaecol. Obstet* 16: 1979
3. Kaivola S., Hirvonen E.:  
*Influence of Age on the Clinical Performance of IUD in Nulliparous and Parous Women; An Analysis of 1 144 Insertions*  
*Contracept. Deliv. Syst.* 5, 1984
4. *Aging and Infertility in Women: A Practice Committee Report of the American Society for Reproductive Medicine*, January 2002

### **Note:**

The final decision to insert a smaller Flexi~T 300/200 or a larger Flexi~T+ 300 must be left to the physician.



# *General Properties of Flexi-T IUDs*

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- Small inserter of 3 mm diameter
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