

## **FSRH statement: Guidance to support clinical practice during copper intrauterine device shortages 22 September 2023**

### **Background**

There is a current shortage of banded copper intrauterine devices (Cu-IUDs) licensed for 10 years of use for contraception. This is thought to be due to a shortfall in global copper supply and may also start to affect other types and brands of Cu-IUD.

### **What is the standard guidance about choice of Cu-IUD?**

Banded T-framed copper IUDs licensed for 10 years for contraception are often chosen in preference to other Cu-IUDs because the longer duration of use reduces frequency of replacement and its associated risks. In addition, the evidence suggests that the banded 10-year devices TCu380A and TCu380S may be the most effective for contraception. It is not known whether any type of Cu-IUD is more effective for emergency contraception than any other.

### **What are the most effective alternative Cu-IUD options to 10-year banded copper T devices?**

**The available evidence indicates that any copper intrauterine device with copper surface area 300mm<sup>2</sup> or greater is likely to have high contraceptive effectiveness. More detailed comparison of contraceptive is not possible.**

Robust direct evidence is lacking to inform in any detail how different copper IUDs compare in terms of contraceptive effectiveness. Cochrane systematic review of randomised controlled trials (RCTs)<sup>1</sup> reported overall high contraceptive effectiveness for framed copper devices with copper surface area 300mm<sup>2</sup> or more; first year contraceptive failure rates were typically between 0.1% and 1%, with the TCu380A and TCu380S at the lower end of this range. The evidence is too limited to tell us whether banded 5-year Cu-IUDs are any more effective for contraception than devices with copper surface 300mm<sup>2</sup> or greater that have copper on the stem only. However devices with less than 300mm<sup>2</sup> copper surface area appeared less effective.

There is not enough evidence to inform whether “short” or “mini” Cu-IUDs are as effective as standard devices for individuals with longer uterine cavities.

Contraceptive failure rates reported for the frameless Cu-IUD Gynefix<sup>®</sup> are similar to those for framed devices<sup>2,3</sup>, although Cochrane meta-analysis reported a non-significantly higher first year pregnancy rate for the frameless devices.<sup>4</sup> Note that studies have suggested a higher early expulsion rate for Gynefix than for framed devices.<sup>1</sup> It is recommended that clinicians considering use of Gynefix should be trained in the insertion technique.

The intrauterine ball Ballerine® is not currently distributed in the UK but could potentially become available. Robust direct comparison of effectiveness with other copper devices is lacking, but contraceptive effectiveness appears broadly comparable.

**Types of copper intrauterine device listed in the British National Formulary<sup>5</sup> (amended from FSRH Clinical Guideline Intrauterine Contraception<sup>6</sup>)**

| Device                             | Copper surface area (mm <sup>2</sup> ) | Uterine length (cm)    | Licensed use duration (years) |
|------------------------------------|--|------------------------|-------------------------------|
| <b>Framed, banded copper arms</b>  |  |                        |                               |
| Copper T380 A ®                    | 380                                    | 6.5–9                  | 10                            |
| T-Safe® 380A QL                    | 380                                    | 6.5–9                  | 10                            |
| T-Safe® 380 A                      | 380                                    | 6.6–9                  | 10                            |
| TT 380® Slimline                   | 380                                    | ≥7                     | 10                            |
| Flexi-T ® +380                     | 380                                    | ≥6                     | 5                             |
| Mini TT380® Slimline               | 380                                    | 5–7                    | 5                             |
| <b>Framed, copper in stem only</b> |  |                        |                               |
| Nova-T ® 380                       | 380                                    | 6.5–9                  | 5                             |
| UT380 Standard®                    | 380                                    | 6.5–9                  | 5                             |
| Neo-Safe® T380                     | 380                                    | 6.5–9                  | 5                             |
| Novaplast T 380®Cu                 | 380                                    | 6.5–9                  | 5                             |
| Novaplast T 380®Cu 'mini'          | 380                                    | 5                      | 5                             |
| UT380 Short®                       | 380                                    | ≥5                     | 5                             |
| Novaplast T380® Ag                 | 380                                    | 6.5–9 ("normal" size)  | 5                             |
| Multiload® Cu375                   | 375                                    | 6–9                    | 5                             |
| Multi-Safe® 375                    | 375                                    | 6–9                    | 5                             |
| Ancora® 375 Cu                     | 375                                    | ≥6.5                   | 5                             |
| Load® 375                          | 375                                    | ≥7                     | 5                             |
| Flexi-T ® 300                      | 300                                    | 6.6–9                  | 5                             |
| <b>Frameless</b>                   |  |                        |                               |
| GyneFix® 330                       | 330                                    | Suitable for all sizes | 5                             |

**Can extended use of Cu-IUDs that are already in situ be advised at this time of shortage?**

Contraceptive providers are reminded that established guidance indicates that any Cu-IUD with copper surface area ≥300 mm<sup>2</sup> can be used for contraception until menopause.<sup>6,7</sup> The FSRH supports extended use of the Cu-IUD when inserted at age 40 years or over. A Cu-IUD containing ≥300 mm<sup>2</sup> copper inserted at or after age 40 years can be used for contraception until menopause.<sup>6,7</sup> This includes Cu-IUDs containing ≥300 mm<sup>2</sup> copper that are licensed for 5 years. In the absence of evidence, extended use of Cu-IUDs licensed for 5 years and inserted before age 40 cannot be recommended.

In two studies with a total of 473 subjects there were no pregnancies during 650 person-years of extended use up to 12 years of the 10-year banded Cu-IUD TCu380A. Many of the subjects were aged >35 years.<sup>6</sup> Individuals aged 35 or over who have a 10-year device in situ might opt to retain the existing device for contraception for an additional 2 years if shortage meant that a replacement copper IUD was not available. They should be aware that such use is off label, and that while the evidence suggests low pregnancy risk, contraceptive effectiveness cannot be guaranteed. They may wish to use condoms in addition.

### **What important information is there about contraceptive alternatives to the copper IUD?**

Unfortunately there are few effective alternative non-hormonal contraceptive options to the Cu-IUD. Barrier contraceptives and contraception apps have high typical use failure rates: the estimated first year typical use failure rate for condoms is about 18% and for diaphragms about 12%.<sup>8</sup> Male and female sterilisation are highly effective, but should be considered permanent and as waiting lists for these procedures can be long, effective bridging contraception is required.

Patients can be reminded that the etonogestrel implant and levonorgestrel-releasing IUDs offer even more effective, user-independent contraception than the Cu-IUD, with extremely low first year pregnancy rates.

People that have had side effects with one type of hormonal contraception can be advised that they may have a completely different experience with another type that contains a different progestogen or has a different mechanism of action: it is worth trying different types of effective hormonal contraception.

### **What about different types of Cu-IUD and alternatives to the Cu-IUD for emergency contraception?**

Evidence does not inform whether any framed Cu-IUD is more effective for emergency contraception (EC) than any other, nor the effectiveness of unframed devices for EC.

Under normal circumstances, a Cu-IUD should always be offered for EC if the individual meets insertion criteria, because it is the most effective EC method. During times of Cu-IUD shortage, the following considerations may be relevant to provision of the Cu-IUD for EC:-

1. Oral emergency contraception works by delaying ovulation until sperm from unprotected sex (UPSI) that has already taken place are no longer viable. (Viability of sperm in the upper female genital tract is about 5 days).

If an individual presenting for EC is estimated to be several days or more before the earliest likely ovulation date, oral EC has a good chance of being able to delay that ovulation and thus prevent pregnancy from the UPSI that has already taken place. Ulipristal acetate EC can act to delay ovulation until closer to the time of ovulation than levonorgestrel oral EC.

It is, however, crucial after oral EC has been taken that there is then abstinence or reliable condom use until effective ongoing contraception is established, as further UPSI risks pregnancy.

2. Oral emergency contraception cannot delay ovulation if taken too close to the onset of ovulation. It may not be effective for an individual who presents for emergency contraception within about 24-48 hours prior to likely ovulation, or after ovulation is likely to have occurred. In this situation, if there has been UPSI in the 5 days prior to likely ovulation or in the few days after likely ovulation there is high risk of pregnancy and it is strongly recommended that a Cu-IUD is offered if they meet insertion criteria.

See algorithm 2 of the [UKMEC \(2016\)](#)<sup>9</sup> to support choice of oral EC.

Guidance currently advises against LNG-IUD insertion if there is any risk of pregnancy and use of an LNG-IUD for EC is not currently recommended. One study has suggested that pregnancy risk is low if a 52mg LNG-IUD is inserted at the time of presentation for EC and therefore it is possible that future guidance might potentially support insertion in some specific circumstances when an individual presents for EC.<sup>10</sup>

## References

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*The Clinical Effectiveness Unit (CEU) was formed to support the Clinical Effectiveness Committee of the Faculty of Sexual & Reproductive Healthcare (FSRH), the largest UK professional membership organisation working at the heart of sexual and reproductive healthcare. The FSRH CEU promotes evidence based clinical practice and it is fully funded by the FSRH through membership fees. It is based in Edinburgh and it provides a members' enquiry service, evidence-based guidance, new SRH product reviews and clinical audit/research. [Find out more here.](#)*