

Faculty of Sexual and Reproductive Healthcare New Product Review: Intrauterine Ball (IUB™) SCu300B MIDI 8 February 2019

1. Description

Manufactured by OCON Medical Ltd, the Intrauterine Ball (IUB™) SCu300B MIDI is a copper intrauterine device (Cu-IUD) comprised of copper beads with a total exposed copper surface of 300mm² strung on a flexible Nitinol (nickel/titanium alloy), PET-coated frame. Once the IUB is released from the 3.2mm diameter insertion tube into the uterus it coils into a spherical shape measuring 15mm in diameter.¹ A monofilament blue polypropylene double tail thread is attached to one end of the IUB frame to aid detection and removal of the device.

The SCu300B MIDI has been available in the UK since March 2017. The IUB also comes in 2 other sizes, 12mm and 18mm, which are not available in the UK.

Indication

The IUB is indicated for intrauterine contraception for up to 5 years.

Cost

The unit price of the IUB is £38 (or £7.60/year for full 5 year use).

What is the evidence for safety and effectiveness of the SCu300B MIDI IUB?

Currently there are no published safety or effectiveness data from clinical trials of this specific model of the IUB. One small study which included 51 women using a 12mm IUB device (the SCu380A) suggested high expulsion rates of 27% (14/51) for that device at 12 months.² Notably, seven women were lost to follow-up by 12 months and it is unknown if expulsion has occurred in any of these women.

On the basis of post-marketing surveillance data, the manufacturer suggests that the IUB SCu300B MIDI appears to have a favourable safety profile and similar effectiveness to other currently available Cu-IUDs.³ However, the FSRH CEU is unable to comment as to the reliability with which adverse events were reported for inclusion in this dataset.

Conclusion

The novel, spherical, flexible design of the SCu300B MIDI IUB has potential to broaden contraceptive choice for women seeking effective, hormone-free contraception; however safety, effectiveness and acceptability data from robust, independent studies and studies comparing the SCu300B MIDI with other Cu-IUD are lacking. The CEU will continue to monitor evidence relating to the IUB and provide an update when new evidence is published.

References

1. OCON Medical Ltd. IUB Ballerin[®]. Website available [here](#). [Accessed 7 February 2019]
2. Wiebe E and Trussell J. Discontinuation rates and acceptability during 1 year of using the intrauterine ball (the SCu380A). *Contraception* 2016;**93**:364-366.
3. OCON Medical Ltd. Update: Safety and Efficacy of the IUB[™] SCu300B MIDI Following Widespread Use. August 2017. Available online [here](#) [Accessed 7 February 2019]

The Clinical Effectiveness Unit (CEU) was formed to support the Clinical Effectiveness Committee of the Faculty of Sexual and Reproductive Healthcare (FSRH), the largest UK professional membership organisation working at the heart of sexual and reproductive healthcare. The 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 member's enquiry service, evidence based guidance, new SRH product reviews and clinical audit/research. [Find out more here.](#)