Faculty of Sexual and Reproductive Healthcare
New Product Review: Intrauterine Ball (IUB™) Ballerine® MIDI
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Description

Manufactured by OCON Medical Ltd, the Intrauterine Ball (IUB™) Ballerine® MIDI (previously the IUB SCu300B) is a copper intrauterine device (Cu-IUD) comprised of 17 copper beads with a total exposed copper surface of 300mm², strung on a flexible Nitinol (nickel/titanium alloy), PET-coated frame. Once the IUB Ballerine 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 IUB Ballerine® is not currently available for sale in the UK, but was previously distributed in the UK in 2017 and is likely to become available again in the UK in the future. 12mm and 18mm IUB devices were also produced and studied, but were not marketed in the UK.

Indication

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

What is the evidence for safety and effectiveness of the IUB Ballerine?

One small study, published in 2016, included 51 users of a 12mm IUB device (the SCu380A) and suggested high expulsion rates of 27% (14/51) for that device at 12 months.[2] Notably, seven subjects were lost to follow-up by 12 months and it is unknown if expulsion occurred in any of these subjects. This model of the IUB is no longer available.

On the basis of post-marketing surveillance data published in 2017, the manufacturer suggests that the IUB Ballerine 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.

Two retrospective observational studies[4,5] report data from questionnaires issued to healthy individuals who had had IUB Ballerine inserted at least a year previously and to their clinicians. Both studies were funded and conducted by the manufacturer, and one was conducted in Switzerland (in various clinical settings) and the other in Israel (single clinic).

In the Swiss study of 207 subjects, 26.1% used the IUB for less than 12 months, and by the time of the questionnaire 13-27 months after insertion, one third no longer had the IUB in situ. 6.5% of subjects had the IUB removed because the device was found to be “displaced” at ultrasound assessment 1-3 months after insertion; 5.3% of devices were expelled spontaneously, and 1.4% were removed because of an incident pregnancy. The most common reasons for intentional removal were heavy menstrual bleeding and/or severe pain - 42% and 56% reported heavy and moderate menstrual bleeding respectively, and

19% and 21% reported severe and moderate dysmenorrhea respectively. Amongst the 140 subjects still using the IUB at the time of the questionnaire, about two thirds described themselves as satisfied with the device. Clinicians reported that 87% of insertions were uneventful and "elicited no pain".

Using the same methodology, the second study issued questionnaires to 175 subjects in Israel and their clinicians.[5] 16% used the device for <12 months; 75% were still using the device at follow up. Two devices were removed because they were "displaced" on USS at 1-3 months after insertion, 3.4% of the IUBs inserted were expelled spontaneously and one pregnancy was reported. Heavy menstrual bleeding was a common reason for IUB removal, but few devices were removed because of severe dysmenorrhea - 39% and 57% reported heavy and moderate menstrual bleeding respectively, and 10% and 19% reported severe and moderate dysmenorrhea respectively. Among 131 subjects still using the device at the time of the questionnaire, almost three quarters described themselves as satisfied with the device. Clinicians described 87% of insertions as "uneventful".

The studies collected no comparator data for other types of IUD.

Conclusion

The novel, spherical, flexible design of the IUB Ballerine has potential to broaden contraceptive choice for individuals seeking effective, hormone-free contraception. The limited available data suggest similar effectiveness and safety to existing IUDs and good user satisfaction, but safety, effectiveness and acceptability data from robust, independent studies comparing the IUB Ballerine 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. The IUB Ballerine is not currently being marketed in the UK.

References

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4. Yaron M, Viviano M, Guillot C, Aharon A, Shkolnik K. Real-world experience with the IUB Ballerine MIDI copper IUD: an observational study in the French-speaking region of Switzerland. The European Journal ofContraception & Reproductive Health Care. 2019;**24**:288-93.
5. Baram I, Aharon A, Klein R, Shkolnik K. Real-world experience with the IUB Ballerine MIDI copper IUD: an observational, single-centre study in Israel. The European Journal of Contraception & Reproductive Health Care. 2020;**25**:49-53.

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.