PRELIMINARY SAFETY PERFORMANCE OF THE IUB™ SCu300

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Introduction
Before and particularly since market approval of the first IUB™ SCu300 Intrauterine Device variant in May 2014 numerous devices have been inserted in clinical and commercial use. Through ongoing vigilance the manufacturer (OCON Medical Ltd., Modiin, Israel) has accumulated data which is herein presented for initial performance assessment.

Materials and Methods
Data in this report is available for a total of 1,531 IUB™ SCu300 devices that were inserted between April 2012 and early May 2015. Of all inserted devices 97% were of the SCu300A variant and 3% were of the SCu300B variant. Insertions were conducted in Austria, Romania, Bulgaria and Israel. 258 devices were inserted as part of clinical trials and 1,273 were commercially used. Adverse event reporting was obtained through study CROs and distributors.

Results
A total of 68 expulsions were reported during the period representing a rate of 4.4%. A total of three pregnancies were reported representing an efficacy rate of 99.81%. No perforations were reported.

Discussion
The IUB™ SCu300 intrauterine device product line is based on a three dimensional spherical frame which offers several advantages over current technologies. The SCu300A and SCu300B variants differ in diameter and rigidity with the latter being approximately 25% larger and stiffer than the former. In this report limited use of the SCu300B precludes a separate analysis for each variant. Data analysis demonstrated significantly higher expulsion rates during initial clinical and commercial use that was sourced to an insertion practice customarily used with T-shaped IUDs in which the insertion tube is withdrawn prior to IUD deployment. This practice may adversely affect IUB™ expulsion rates since it deploys retrograde. Data suggests that emphasis placed on proper insertion subsequently reduced expulsion rates. Nevertheless, safety results so far indicate that the IUB™ SCu300 overall performs similarly or better than standard copper IUDs that carry an overall expulsion rate of 6% to 10.2% and a 1% pregnancy rate. While published expulsion rates are accumulative over a longer period, expulsions are more likely to occur during the first few months after insertion.

Conclusion
The IUB™ SCu300 has so far shown equal or improved safety performance compared to copper IUD published safety parameters. Emphasis on proper insertion technique has been shown to reduce initial higher rates of expulsion. Ongoing clinical study data collection and commercial experience vigilance are conducted to further support these encouraging initial safety results. Quality of life parameters are also collected and shall be analyzed separately.

1Aoun et al. Effects of age, parity, and device type on complications and discontinuation of intrauterine devices. Obstetrics & Gynecology (123;3) 2014, 585-592
2Madden et al. Association of age and parity with Intrauterine device expulsion. Obstetrics & Gynecology (124;4) 2014, 718-726