

Real-World Experience Using the IUB Ballerine MIDI Copper IUD: A Multicenter, Multinational Observational Study

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Abstract

Objective: The aim of the study was to assess efficacy, safety and patient acceptability of the intrauterine ball (IUB) Ballerine MIDI copper intrauterine device (IUD), using real-world data collected from users and physicians.

Study design: Retrospective analysis of two cross-sectional survey studies conducted in seven private clinics in Israel or Switzerland, and in one Swiss hospital between January and October 2018. Participants were healthy women who had the non-hormonal IUB Ballerine MIDI inserted >12 months before enrolment. In total, 382 participants and their 19 physicians completed questionnaires relating to device insertion, user experience and performance.

Results: Mean age at insertion was 31.8 ± 7.1 years, the survey was answered 16.0 ± 4.7 months following IUB insertion. Most women were married (56.8%) and multigravid (83.5%). In 20 (5.2%) cases premature removal was due to desire to conceive. Excluding these women, the >12-month continuation rate was 71%. The expulsion rate was 17 (4.5%) and pregnancy rate was 4 (1.1%). The IUB was associated with high tolerability, 31% of current users reported no menstrual cramps/pain or light (34%) to moderate (20%) dysmenorrhea. The majority of women (69%) reported moderate to high satisfaction with the device, and 79% said they would recommend it to friends and relatives. Physicians reported in 87% of procedures the device was simple to deploy, with no difficulties encountered.

Conclusions: The IUB Ballerine MIDI was demonstrated to be safe, effective and highly accepted in a cohort of women in different clinical settings and among a socioeconomically and demographically diverse population of contraception seekers.

Implications Statement

Overall, the non-hormonal intrauterine ball IUB Ballerine MIDI copper IUD proved simple to deploy, safe, and was both effective and highly accepted by users. The high user-reported tolerability, likely due to improved device conformity with uterine anatomy, will inevitably promote long-term user persistence, subsequently reducing unintended pregnancy rates.

1. Introduction

Approximately half of all pregnancies and one-third of all births in developed countries are unintended [1]. As such, pregnancies bear higher rates of adverse maternal and infant psychosomatic and economic consequences. Therefore, reducing the rates of unintended and mistimed pregnancies has become the focus of family planning programs worldwide [1, 2].

Due to reduced independence of user adherence and low failure rates, the long-acting reversible contraception (LARC) options, such as, copper intrauterine devices (IUDs) and hormonal releasing intrauterine systems are safe and placed in the highest tier of contraceptive effectiveness [3].

Subsequently, LARCs are recommended as first line contraceptives to women of all age groups and parity status [4]. Indeed, when offered for free, among the Contraceptive CHOICE cohort, which included teenagers and young adults, 75% chose one of the LARC options [5]. Moreover, copper IUD users showed high rates of satisfaction with reported 12 and 24 months continuation rates of 84% and 77%, respectively [5].

Nonetheless, reports on increased cramping and menstrual bleeding especially in the first 3 months following copper IUD insertion have been considered as key factors leading to discontinuation within the first 2 years of use [6, 7]. However, premature removal of the device, leaves these women unprotected or dependent on a method with a significantly higher failure rate [8].

The underlying causes of menstrual changes occurring after copper IUD insertion remain largely unknown, yet it had been suggested that the conventional T-shaped IUD might be incompatible with the uterine contours and dimensions, and thus could illicit endo- or myometrial trauma and lead to device malposition or embedment within the uterine tissue [9, 10]. In efforts to minimize these adverse effects and enhance user comfort, the intrauterine ball IUB Ballerine MIDI, (OCON Medical [OCON Healthcare], Modiin, Israel) a spherical copper IUD was uniquely designed to overcome uterine dimensional incompatibility, and subsequently minimize endometrial irritation and malposition [11].

Two cross-sectional user surveys performed in Switzerland and Israel have demonstrated consistently high device effectiveness, safety and tolerability [12, 13]. The present retrospective analysis of the data accumulated during the two studies, sought to add to the current data on non-hormonal IUDs by providing a point-in-time profile of satisfaction and experience ratings of the 382 users, covering a broad range of ages, cultures, socioeconomic statuses, gynecological histories treated by 19 physicians in different healthcare systems.

2. Methods

2.1 Study design and participants

This retrospective analysis includes data collected from 382 women with regards to their experiences with the IUB Ballerine MIDI, as reported in two cross-sectional survey studies, conducted between January and October 2018. Both studies were approved by their respective institutional ethics committees.

Inclusion criteria: healthy, nulliparous or parous women, aged ≥ 18 years, who had an IUB inserted at least 12 months prior to the enrolment date. Participants were recruited to participate in the survey by their medical providers at one of seven private clinics in Israel or Switzerland, and one Swiss hospital, which enrolled women from its affiliated family planning clinic, as well as women who had the device inserted at the operating theatre immediately after a surgical abortion.

After providing their consent, participants were asked to complete a password-secured web-based or paper-based questionnaire inquiring about their experiences regarding IUB insertion, and if relevant,

removal, expulsion or pregnancy since insertion. Questions relating to current menstrual patterns, physical comfort and satisfaction associated with use of the IUB were only presented to women using the device at the time of the survey. In these questions, participants rated blood loss and pain/cramp patterns of their last three menstrual periods. A 10-point Likert scale was used to rate change in menstrual pattern (1 indicating 'much better' and 10 indicating 'much worse') and satisfaction (1 indicating 'very satisfied' and 10 indicating 'very dissatisfied').

In parallel, the 19 treating physicians completed a short electronic case report documenting each participant's demographic data, gynaecological and obstetric history, as well as details relating to device insertion, follow-up findings and, if relevant, removal procedure.

2.2 The intrauterine ball IUB device

The IUB Ballerine MIDI is comprised of 17 copper beads, with a copper surface area of 300 mm², strung on a flexible, polymer-coated nickel titanium wire frame, with a double-tailed monofilament removal thread attached to its tip. The device is preloaded in a 3.2-mm-diameter insertion tube. After inserting the tube into the uterine cavity, the device is deployed using a push-rod, after which it retrogradely curls to form a spherical shape composed of four perpendicular semicircular lobes, forming an anatomically compliant sphere with a diameter of 15 mm (Fig. 1). The IUB Ballerine MIDI is commercially available within the European Union, Asia and Africa, as a class III medical device.

2.3 Statistical analysis

Statistical analyses were conducted using R software (version 3.3.3; R Development Core Team, Vienna, Austria) and were descriptive in nature. For continuous variables, arithmetic means, standard deviation (SD), median, minimum and maximum values and 95% confidence intervals were calculated. A sub-analysis was performed for data collected from women aged 18–35 years.

3. Results

A total of 382 women participated in the two studies, which took place at an average of 16.0 ± 4.7 months following IUB device insertion. Mean age at device insertion was 31.8 ± 7.1 years. At the time of the survey the majority 233 (61%) were women younger than 35 (27.1 ± 4.2 years) while 149 (39%) were over 35 (39.0 ± 3.6 years). Most women were married (56.8%) and multigravid (83.5%) and all were in good health. History of at least one abortion, of any kind, was reported by 42.7% of the women. Sociodemographic details and baseline characteristics are summarised in Table 1.

Table 1
Sociodemographic and baseline characteristics of the study participants

	Entire cohort (age ≥ 18) <i>n</i> = 382	Younger subset (age 18–35) <i>n</i> = 233	Older subset (age > 35) <i>n</i> = 149
Age at insertion, years			
Mean (SD)	31.8 (7.1)	27.1 (4.2)	39.0 (3.6)
Minimum, maximum	15.9, 51.2	15.9, 34.5	32.9, 51.2
Age at survey, years			
Mean (SD)	33.1 (7.1)	28.4 (4.2)	40.4 (3.7)
Minimum, maximum	17.0, 53.0	17.0, 34.8	35.0, 53.0
Time from insertion, months			
Mean (SD)	16.0 (4.7)	15.6 (4.3)	16.7 (5.2)
Minimum, maximum	8.1, 33.4	8.1, 32.5	11.7, 33.4
Marital status, <i>n</i> (%)			
Single	114 (29.8)	111 (47.6)	14 (9.4)
Married	217 (56.8)	100 (42.9)	106 (70.4)
Divorced	25 (6.5)	4 (1.7)	21 (14.1)
Other	24 (6.3)	17 (7.3)	7 (4.7)
Unknown	2 (0.5)	1 (0.4)	1 (0.7)
Gravidity, <i>n</i> (%)			
Multigravid	319 (83.5)	174 (74.7)	145 (97.3)
Nulligravid	63 (16.5)	59 (25.3)	4 (2.7)
Number of previous term deliveries, <i>n</i> (%)			
1	47 (12.3)	31 (13.3)	16 (10.7)
2	114 (29.8)	61 (26.2)	53 (35.6)
3	56 (14.7)	21 (9.0)	35 (23.5)
4	28 (7.3)	13 (5.6)	15 (10.1)
5	8 (2.1)	2 (0.9)	6 (4.0)
6	7 (1.8)	1 (0.4)	6 (4.0)

	Entire cohort (age ≥ 18) <i>n</i> = 382	Younger subset (age 18–35) <i>n</i> = 233	Older subset (age > 35) <i>n</i> = 149
7	4 (1.1)	2 (0.9)	2 (1.3)
8	3 (0.8)	-	3 (2.0)
9	1 (0.3)	-	1 (0.7)
Any	268 (70.2)	131 (56.2)	137 (92.0)
Previous abortion, <i>n</i> (%)			
1	98 (25.7)	61 (26.2)	37 (24.8)
2	46 (12.0)	21 (9.0)	25 (16.8)
3	15 (3.9)	6 (2.6)	9 (6.0)
4	3 (0.8)	1 (0.4)	2 (1.3)
5	1 (0.3)	-	1 (0.7)
Any	163 (42.7)	89 (38.2)	74 (49.7)
Most recent abortion, <i>n</i> (%)			
Spontaneous	57 (14.9)	22 (9.4)	35 (23.5)
Surgically induced	47 (12.3)	31 (13.3)	16 (10.7)

3.1 IUB insertions and short-term follow-up

IUB device insertions were performed in one of seven private gynecological practices (47.3%), a hospital outpatient family planning clinic (38.7%) or in an operating theatre immediately after a surgical abortion (14%). In the vast majority of cases the procedures were uneventful (86.9%), and well tolerated (Table 2). The need for cervical dilation, a vagal reflex response and severe pain during the insertion procedure were more common among younger (18–35 year) (5.2%, 3.4%, and 6.9% respectively) as compared to older (age > 35 years) participants (2.7%, 1.3% and 4.0%, respectively).

Table 2
IUB insertion data and follow-up

	Entire cohort (age ≥ 18) <i>n</i> = 382	Younger subset (age 18–35) <i>n</i> = 233	Older subset (age > 35) <i>n</i> = 149
Difficulty during insertion ^a			
None	332 (86.9)	196 (84.1)	136 (91.3)
Cervical dilation required	16 (4.2)	12 (5.2)	4 (2.7)
Severe pain	22 (5.8)	16 (6.9)	6 (4.0)
Vagal reflex	10 (2.6)	8 (3.4)	2 (1.3)
Severe bleeding	2 (0.5)	1 (0.4)	1 (0.7)
More than one IUB needed	1 (0.3)	1 (0.4)	-
Other	9 (2.4)	8 (3.4) ^b	1 (0.7) ^c
Ultrasound immediately after insertion			
Ultrasound performed	371 (97.1)	227 (97.4)	144 (96.6)
In place	369 (99.5)	225 (99.1)	144 (100)
Displaced	2 (0.5)	2 (0.9)	
Ultrasound 1–3 months after insertion			
Ultrasound performed	271 (71.1) ^d	166 (71.6) ^e	105 (70.5)
In place ^a	256 (94.5)	156 (94.0)	100 (95.2)

Data presented as *n* (%)

^a Percentages were calculated in relation to the total number of ultrasound scans performed 1–3 months post-insertion (entire cohort, *n* = 271; younger cohort, *n* = 166; older cohort, *n* = 105).

^b Use of Pozzi forceps for dilation (*n* = 3), need to anesthetize cervix (*n* = 2), insertion under nitrous oxide (*n* = 1), vomiting (*n* = 1), hypotension/vomiting/diarrhea immediately after the procedure (*n* = 1).

^c Use of Pozzi forceps for dilation

^d Percent calculated in relation to total number of women included in this analysis (*n* = 381); during one procedure, more than one IUB was deployed.

^e Percent calculated in relation to total number of women included in this analysis (*n* = 232); during one procedure, more than one IUB was deployed

	Entire cohort (age ≥ 18) <i>n</i> = 382	Younger subset (age 18–35) <i>n</i> = 233	Older subset (age > 35) <i>n</i> = 149
Displaced ^a	15 (5.5)	10 (6.0)	5 (4.8)
IUB removed	12 (3.1)	8 (3.4)	4 (2.7)
Data presented as <i>n</i> (%)			
^a Percentages were calculated in relation to the total number of ultrasound scans performed 1–3 months post-insertion (entire cohort, <i>n</i> = 271; younger cohort, <i>n</i> = 166; older cohort, <i>n</i> = 105).			
^b Use of Pozzi forceps for dilation (<i>n</i> = 3), need to anesthetize cervix (<i>n</i> = 2), insertion under nitrous oxide (<i>n</i> = 1), vomiting (<i>n</i> = 1), hypotension/vomiting/diarrhea immediately after the procedure (<i>n</i> = 1).			
^c Use of Pozzi forceps for dilation			
^d Percent calculated in relation to total number of women included in this analysis (<i>n</i> = 381); during one procedure, more than one IUB was deployed.			
^e Percent calculated in relation to total number of women included in this analysis (<i>n</i> = 232); during one procedure, more than one IUB was deployed			

Post-insertion ultrasound-based confirmation that the IUB was properly positioned was achieved in nearly all cases 369 (99.5%). Of the 271 devices assessed on ultrasound 1–3 months following insertion, 256 (94.5%) were properly positioned (Table 3). When describing device positioning, physicians were instructed to consider as misplaced, devices that were near to the internal cervical os, yet still inside the cavity on ultrasound follow-up. Twelve of the fifteen misplaced devices were removed.

Table 3
Duration of use of IUB and reasons for early removal

	Entire cohort (age ≥ 18) <i>n</i> = 382	Younger subset (age 18–35) <i>n</i> = 233	Older subset (age > 35) <i>n</i> = 149
Duration of IUB use ^a			
>12 months	299 (78.5)	177 (76.3)	122 (81.9)
≤12 months	82 (21.5)	55 (23.7)	27 (18.1)
Reason for removal ^b			
Spontaneous/Partial expulsion	17 (4.5)	14 (6.0)	3 (2.0)
Heavy menstrual bleeding	47 (12.3)	28 (12.0)	19 (12.8)
Severe cramps	21 (5.5)	16 (6.9)	5 (3.4)
Desire to conceive	20 (5.2)	17 (7.3)	3 (2.0)
Pregnancy	4 (1.1)	3 (1.3)	1 (0.7)
Other	44 (11.5)	29 (12.5)	15 (10.1)
Data presented as <i>n</i> (%).			
^a Percentages were calculated in relation to the total number of women for whom duration of use was available (entire cohort: <i>n</i> = 381; younger subset: <i>n</i> = 232; older subset: <i>n</i> = 149); one woman was unaware of the fact that the device had been expelled.			
^b Women were allowed to indicate more than one reason for removal.			

3.2 Discontinuation rates

In total, 271 (70.9%) women were still using the IUB at the time of the survey. They were of an average age of 32.3 ± 7.2 at the time of insertion, were mostly multigravid (82.3%) and married (53.9%) and mean duration of use was 15.6 ± 4.4 months.

In total 29% of devices were intentionally removed. Of these, 20 (5.2%) requested premature ablation of the IUB due to desire to conceive; the majority (17/20) were in the younger age group (< 35 years). The return to fertility was rapid, in 16/20 with a median time to pregnancy of 2 months post-removal. Three of four women (1.1%) who conceived while using the IUB were also in the younger age group.

When excluding women seeking to become pregnant, the IUB removal rate was 23.8%. Average discontinuation was after 9.1 ± 5.3 months. As depicted in Table 3 most common reasons for premature removal were heavy menstrual bleeding 47(12.3%) and/or severe cramps 21(5.5%). The expulsion rate

was 4.5%; 14/17 who had experienced spontaneous or partial expulsion were in the younger age group (Table 3).

3.3 Menstrual patterns and user satisfaction

Among 271 women still using the IUB 3% reported light or moderate (56.3%) menstrual flow. At baseline 14.4% experienced dysmenorrhea, while at 16.0 ± 4.7 months following IUB insertion 31% of the women reported none, or minor (34%) to moderate (20%) menstrual cramps/pain. Although 68% recollected more tolerable menstrual patterns prior to IUB insertion, the overall reports show tolerable menstruation (mean score = 6.5) (Table 4).

Table 4
Menstrual patterns and user satisfaction with the IUB

	Entire cohort (age ≥ 18) <i>n</i> = 271 ^a	Younger subset (age 18–35) <i>n</i> = 158 ^a	Older subset (age > 35) <i>n</i> = 113
Blood flow			
Light	8 (3.0)	1 (0.6)	7 (6.2)
Moderate	152 (56.3)	85 (54.1)	67 (59.3)
Heavy	110 (40.7)	71 (45.2)	39 (34.5)
Menstrual pain/cramps			
None	83 (30.7)	36 (22.9)	47 (41.6)
Light	93 (34.4)	53 (33.8)	40 (35.4)
Moderate	54 (20.0)	34 (21.7)	20 (17.7)
Severe	36 (13.3)	31 (19.8)	5 (4.4)
Unbearable	4 (1.5)	3 (1.9)	1 (0.9)
Tolerability of menstruation			
1–3	51 (18.9)	26 (16.6)	25 (22.1)
4–5	95 (35.2)	53 (33.8)	42 (37.2)
6–7	64 (23.7)	45 (28.7)	19 (16.8)
8–10	60 (22.2)	33 (21.0)	27 (23.9)
Change in menstrual pattern			
1–3	29 (10.7)	1 (5.0)	12 (10.7) ^b
4–5	56 (20.7)	5 (25.0)	29 (25.9) ^b
6–7	84 (31.1)	5 (25.0)	29 (25.9) ^b

Data presented as *n* (%)

^a Calculated as percent of women who answered these questions; for menstruation-related questions, one participant was still carrying the device but was not menstruating due to breastfeeding and therefore, did not reply to these questions.

^b Calculated as percent of women who answered these questions; one participant was still carrying the device but was not menstruating due to breastfeeding and one participant did not remember. ^c Measured on a 10-point Likert scale (ranging from 1 'very satisfied' to 10 'very dissatisfied').

	Entire cohort (age ≥ 18) <i>n</i> = 271 ^a	Younger subset (age 18–35) <i>n</i> = 158 ^a	Older subset (age > 35) <i>n</i> = 113
8–10	100 (37.0)	9 (45.0)	42 (37.5) ^b
Satisfaction ^c			
1–3	134 (49.6)	77 (48.7)	57 (50.4)
4–5	53 (19.6)	34 (21.5)	19 (16.8)
6–7	41 (15.2)	26 (16.5)	15 (13.3)
8–10	43 (15.9)	21 (13.3)	22 (19.5)
Recommend to friends and family			
Yes	217 (79.0)	134 (84.8)	80 (70.8)
No	26 (9.6)	10 (6.3)	16 (14.2)
Prefer not to respond	31 (11.4)	14 (8.9)	17 (15.0)
Data presented as <i>n</i> (%)			
^a Calculated as percent of women who answered these questions; for menstruation-related questions, one participant was still carrying the device but was not menstruating due to breastfeeding and therefore, did not reply to these questions.			
^b Calculated as percent of women who answered these questions; one participant was still carrying the device but was not menstruating due to breastfeeding and one participant did not remember. ^c Measured on a 10-point Likert scale (ranging from 1 'very satisfied' to 10 'very dissatisfied').			

Satisfaction of current users was high, with 69% of women ranking their experiences satisfactory to very satisfactory, with a higher majority in the younger users (85% vs 71%) reporting they would recommend the IUB device to friends and relatives. (Table 4).

4. Discussion

In the present analysis of real-world user experience, the non-hormonal IUB Ballerine MIDI, proved safe and simple to deploy achieving proper positioning, regardless of patient parity. Due to the spherical IUB downward curving away from the uterine fundus upon insertion, there were no reports of uterine perforation. Overall, the IUB was found suitable and highly effective in a cohort of women in different clinical settings and among a socioeconomically and demographically diverse population of contraception seekers.

There was a high user-reported tolerability, most women describing none/light or moderate dysmenorrhea and more than two-thirds being highly satisfied or satisfied, following mean duration of use of 15.6 ± 4.4 months. Indeed, reduced discomfort, likely due to the three-dimensional IUB's elasticity to conform to the uterine anatomy, lead to high (71%) continuation rates. These positive outcomes are expected to extend duration of use, as compared with other LARC methods, subsequently reducing unintended pregnancy rates. Our results are similar to previously reported among copper IUD users, with 2-year continuation rates between 70%-77% [14, 15], and considerably higher than self-reported adherence to oral contraceptives (43%-52%) [16].

The IUB expulsion rate was low 17(4.5%) compared to the overall reported > 12 months copper IUD expulsion rates (4%-10%) [17, 18]. Additionally, compared to high discontinuation rates often due to dislocation (20%) that have been reported within the first year with the copper T shape IUD [19], dislocation rates of the IUB were low (5.5%), likely due to improved uterine dimensional compatibility.

Failure was rare, four women (1.1%) conceived while using the device, which aligns with the pregnancy rates reported for other intrauterine contraceptives [20, 21].

Increased awareness, promotion and access to LARCs in recent years by governments, health protection agencies and family planning organizations worldwide are believed to underlie the recent marked global decrease in the incidence of unintended pregnancies [1, 2]. Nonetheless, worldwide surveys and reviews have identified several barriers to provision of LARC methods to women seeking contraception. Among these, the healthcare providers associated factors include, gaps in knowledge and appropriate training, as well as clinician reluctance to provide intrauterine contraception, particularly to young, nulliparous and single women [22–24].

Continuation rates are greatly impacted by user expectations [25]. Not all women are well prepared for the immediate and future side effects they may experience with the IUD. Physicians anticipatory advice is of great value adding to a higher acceptance rate of LARCs [26]. Providing pre-insertion counselling and anticipatory guidance about short- and long-term side effects and potential treatment for these side effects will lead to higher continuation rates [26].

Well-informed users, together with positive provider attitudes and high-quality family planning counselling are likely to have influenced the sustainability of the IUB use reported in the current study.

The vast majority of women were satisfied with the IUB (69%) and would recommend it to others (79%). Notably a higher majority (85%) of the younger users < 35 stated following their positive experience they would recommend the IUB to friends and relatives.

4.1 Limitations and strengths

Reliance on subjective, retrospective user ratings is a key limiting element inherent to the study design. Nonetheless, the presented real-world evidence of IUB acceptance and performance is likely broadly

generalizable as the current analysis encompassed a diverse study population, covering a broad age range, gravidity statuses, obstetrics histories, clinical settings, geographic regions and cultures, healthcare systems and socioeconomic ranks. Moreover, given the involvement of 19 physicians, practitioner preferences and attitudes were likely divergent which further strengthens the validity of the outcomes.

Conclusions

Overall, the IUB Ballerine MIDI proved safe and simple to deploy and was found suitable and highly effective in a diverse population of contraception seekers. The associated high overall satisfaction and tolerability reported by the majority of users are likely due to improved conformity of the IUB with the uterine anatomy. These positive outcomes will inevitably promote long-term user persistence and secure contraceptive protection. Future longer-term follow-up of larger cohorts are warranted, to further assess the durability of the IUB Ballerine MIDI benefits, efficacy and long-term user quality-of-life variables. Such studies will likely increase awareness and acceptance of LARC methods and foster global efforts to reduce unintended pregnancy rates.

List Of Abbreviations

IUB - intrauterine ball , IUD - intrauterine device, LARC - long-acting reversible contraception

Declarations

Ethics approval and consent to participate: The study was approved by the Geneva regional ethics committee (CCER–2017-01956) and Helsinki committee in Israel ref. number 0057-17-BBL

Consent for publication – not applicable

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Conflict of interest: Dr Yaron has presented on behalf of OCON the results of the Swiss survey in INFOGYN, Pau, France in 2019. Dr Baram Ilan is the inventor of the IUB Ballerine device and was chief Medical Officer at OCON Medical, during study conduct.

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Authors' contributions -*M.Y and I.B are both co-authors and both have substantial contribution in the design of the study, analysis and interpretation of the data and writing the manuscript. Z.P has been involved in drafting the manuscript, editing and revising it critically for important intellectual content. All authors read and approved the final manuscript.

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Figures



Figure 1

The IUB Ballerine MIDI is comprised of 17 copper beads, with a copper surface area of 300 mm², strung on a flexible, polymer-coated nickel titanium wire frame, with a double-tailed monofilament removal thread attached to its tip. The device is preloaded in a 3.2-mm-diameter insertion tube. After inserting the tube into the uterine cavity, the device is deployed using a push-rod, after which it retrogradely curls to form a spherical shape composed of four perpendicular semicircular lobes, forming an anatomically

compliant sphere with a diameter of 15 mm (Figure 1). The IUB Ballerine MIDI is commercially available within the European Union, Asia and Africa, as a class III medical device.