OCON Medical Ltd
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Ref: FSN20-01

Date: 25-May-2020

Field Safety Notice
IUB™ Ballerine® Intrauterine Device

For Attention of all users

Risk addressed by FSN

1. Device Type(s)*
The IUB™ Ballerine® is intended for long-term intrauterine contraception. The IUB™ Ballerine® takes a spherical shape once deployed from its insertion tube as opposed to the common T shape IUD. As with current IUDs, a double-tailed monofilament thread is attached to the frame tip, each tail is 20cm in length, to aid in device removal. The frame is made of nitinol wire. A polymer sleeve coats the entire length of the frame and couple copper balls are threaded onto the coated frame. The IUB™ Ballerine® is supplied in a sterile pouch, pre-loaded into an insertion tube with a flange and packaged together with a push rod. The IUB™ Ballerine® is intended for long term intrauterine contraception.
2. Commercial name(s)
IUB Ballerine MIDI intrauterine device
3. Unique Device Identifier(s) (UDI-DI)
N.A.
4. Primary clinical purpose of device(s)*
The IUB™ Ballerine® is a copper intrauterine device (IUD) indicated for intrauterine contraception for up to 5 years for women aged 15 and older.
5. Device Model/Catalogue/part number(s)*
IUB SCu300B
6. Software version
N.A.
7. Affected serial or lot number range
N.A.
8. Associated devices
N.A.

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	The device functions as intended. No new risk was identified. This FSN intends to make the user aware of the correct procedure for removal of the IUB™ Ballerine®. Incorrect removal may have consequences. Please follow the procedure described in the manual to avoid any adverse events.
2.	2. Hazard giving rise to the FSCA*
	Details of the hazard reflect in: Damage to uterine wall, more aggressive/surgical procedure, patient minor injury, Ballerine more difficult to remove, misplacement of copper beads within the uterine cavity.
2.	3. Probability of problem arising
	OCON's risk management report identifies the potentially hazardous situations above as remote events (estimated 0% - 0.5% chance failure will occur during the product lifecycle). The projection is based on incident data or prospective modelling.
2.	4. Predicted risk to patient/users
	The anticipated risk acceptability level requires research and mitigation. The implemented mitigations are inclusion of Quality Control measures during assembly to ensure product

	compliance with international standard tension requirements and removal instructions and warnings in IFU.
2.	5. Further information to help characterise the problem
	The accumulated number of reported events with the product, in relation with removal difficulty and device breakage in the 22 territories in which the product is marketed is 39 cases. The calculated current rate/frequency is of 0.04% (39 cases out of a total of 90,822 estimated insertions [from launch and up to the end of Q1 2020]).
2.	6. Background on Issue
	OCON became aware via customer complaints and incident reports. Since launch up to date many resources were invested in user training and emphasizing of the correct technique of insertion and removal. Device breakage is a potential hazardous situation in all IUDs and not specific to the IUB Ballerine.
2.	7. Other information relevant to FSCA
	The information on the IFU is also available via multiple channels such as marketing materials, training materials, user frontal training sessions, sales representative's tool kit, etc.

3. Type of Action to mitigate the risk*

1. Action To Be Taken by the User*

☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device
☐ On-site device modification/inspection
☐ Follow patient management recommendations
☒ Take note of amendment/reinforcement of Instructions For Use (IFU)
☐ Other ☐ None

2. By when should the action be completed?	N.A.
3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No	
4. Is customer Reply Required? * (Form attached specifying deadline for return)	Yes

5. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☒ Other ☐ None
additional training to physicians

6. By when should the action be completed?	September 2020
7. Is the FSN required to be communicated to the patient /lay user?	No

8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?

N.A.

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N.A.
4.	**3.** For Updated FSN, key new information as follows:	
	N.A.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N.A.	
4	6. Anticipated timescale for follow-up FSN	N.A.
4.	**7.** Manufacturer information	
	a. Company Name	**OCON Medical**
	b. Address	**15 Hashdera Hamerkazit Modiin ISRAEL**
	c. Website address	**www.oconmed.com**
4.	8. The concerned Competent (Regulatory) Authority has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	N.A
4.	10. Name/Signature	……..

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.