



OCON Medical Ltd

15 Hashdera Hamerkazit, POBox 552, Modiin 7171801, Israel
T: +972 722 150 105 | F: +972 722 150 400 | www.oconmed.com

Ref: FSN20-01

Date: 25-May-2020

EN

Field Safety Notice **IUB™ Ballerine® Intrauterine Device**

For Attention of all users

Risk addressed by FSN

1. Device Type(s)*
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



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	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.	<p>7. Other information relevant to FSCA</p> <p>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.</p>

3. Type of Action to mitigate the risk*	
<p>1. Action To Be Taken by the User*</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None </p>	
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
<p>5. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> None additional training to physicians </p>	
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	Orna Landau, QA\RA Director

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>

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