COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
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TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2019FA0008

Date: 03 Oct 2019

Urgent Field Safety Notice

Guardia™ Access Embryo Transfer Catheter & Guardia™ Access Nano Embryo Transfer Catheter

For Attention of: Chief Executive / Risk Management / Purchasing

Contact details of local representative (name, e-mail, telephone, address etc.)
Cook Medical Europe Ltd. O'Halloran Road National Technology Park Limerick, Ireland E-mail: European.FieldAction@CookMedical.com Phone: Please refer to the attached EUSC Contacts List For any further information or support concerning the information within this FSN, please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.

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Risk Addressed by FSN

Information on Affected Devices	
1.	**1. Device Type(s)**
	The Guardia Access™ Embryo Transfer Catheter and Guardia Access™ Nano Embryo Transfer Catheter are sterile, single-use products comprised of a guide catheter and a transfer catheter.
1.	**2. Commercial name(s)**
	Guardia™ Access Embryo Transfer Catheter Guardia™ Access Nano Embryo Transfer Catheter
1.	**3. Primary clinical purpose of device(s)**
	Intended to place in vitro fertilized (IVF) embryos into the uterine cavity.
1.	**4. Device Model/Catalogue/part number(s)**
	K-JETS-7019 (G34783) K-JETS-551910-S (G24216)
1.	**5. Affected serial or lot number range**
	8361746 9502915

Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	Embryo transfer catheters from lots 8361746 and 9502915 may exhibit a bent distal tip. This can lead to difficult advancement of the transfer catheter through the guide catheter.
2.	**2. Hazard giving rise to the FSCA**
	Potential adverse events that may occur if an affected product is used include increased procedural time, the need for a repeat embryo transfer procedure, or the need for a patient to undergo an additional IVF cycle.
2.	**3. Background on Issue**
	Cook has received five customer complaints involving [redacted] devices from two affected lots. The two affected lots consist of [redacted] devices in total. Customers have reported that the transfer catheters did not fit properly with the guide catheters because the tip of the transfer catheter was bent.

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Type of Action to Mitigate the Risk		
3.	**1. Action To Be Taken by the User** ☒ Identify Devices ☒ Quarantine Devices ☒ Return Devices ☒ Other Please complete the enclosed Customer Response Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Response form. Returned Product should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY Credit will be provided for the returned affected products where applicable.	
3.	**2. Is Customer Reply Required?** Form is attached specifying deadline for return.	Yes
3.	**3. Action Being Taken by the Manufacturer** ☒ Product Removal	

General Information		
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information For contact details of local representative refer to page 1 of this FSN	
	a. Company Name	Cook Incorporated
	b. Address	750 Daniels Way Bloomington, IN 47402, United States
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	[redacted] Larry D. Pool Director, Post Market Cook Incorporated

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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.

Please transfer this notice to other organisations on which this action has an impact.

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.