COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
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 30 devices from two affected lots. The two affected lots consist of 640 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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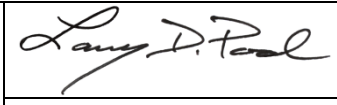
Type of Action to Mitigate the Risk		
3.	**1. Action To Be Taken by the User** ☒ Identify Devices ☒ Quarantine Devices ☒ Return Devices ☒ Other Please complete the enclosed Customer Response Form. Where product is indicated as being returned, our Customer Services department will contact you to organize 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	 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.

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Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2019FA0008
FSN Date	03 Oct 2019
Product/Device name	Guardia™ Access Embryo Transfer Catheter Guardia™ Access Nano Embryo Transfer Catheter
Product Part Number(s)	K-JETS-7019 K-JETS-551910-S
Batch/Serial Number(s)	8361746 9502915

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation
Please mark boxes below to indicate actions have been completed.
If action is not applicable, please write N/A in the column on the right.

☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I have affected devices to return - enter Lot number and quantities in table below.	
☐	No affected devices remain in our organisation's inventory	

Print Name	
Signature	
Date	

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4. Return acknowledgement to sender	
Email	European.FieldAction@CookMedical.com
Fax	+ 353 61 239294
Deadline for returning the customer reply form	Please return this form within 5 business days of receipt, even if you do not have any of the affected product(s).
Customer Helpline	Please refer to the attached EUSC Contacts List

If you are returning any affected product, please indicate the part number, lot number and quantity:

Product Part Number	**Product Lot Number**	**Quantity**

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.