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: 2021FA0011

Date: 08 October 2021

Urgent Field Safety Notice – Medical Device Recall

Transseptal Needle & Transseptal Needle with 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 Country 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

1. Information on Affected Devices

1. Device Type(s)

1. The products are sterile, single-use devices. The Transseptal Needle (TSNC-18-71.0 & TSNC-19-56.0) consists of a needle and obturator. The Transseptal Needle with Catheter (TSN-17-75.0-ENDRYS) is a coaxial set consisting of an outer catheter, curved-tip metal cannula, and a tapered-tip inner needle.

	2. Commercial name(s)	3. Primary clinical purpose of device(s)	4. Device Model / Catalogue / Part Number(s)	5. Affected lot number range
1.	Transseptal Needle	Intended for transseptal left heart access in both diagnostic and interventional procedures	TSNC-18-71.0	All lots
			TSNC-19-56.0	
	Transseptal Needle with Catheter	Intended to facilitate transseptal entry into the left atrium	TSN-17-75.0-ENDRYS	

2. Reason for Field Safety Corrective Action (FSCA)

1. Description of the product problem

2. Cook Medical has identified that the transseptal needles may contain rust on the interior and/or exterior of the needle.

2. Hazard giving rise to the FSCA

2. Potential adverse events that may occur if an affected product is used include increased procedural time (to obtain a replacement device) and inflammatory reactions ranging from local / self-limited reactions to systemic reactions requiring medical intervention. Systemic reactions could potentially lead to permanent impairment or be life-threatening.

To date, Cook has received no complaints reporting adverse patient effects. Cook has received four complaints where the presence of rust was identified prior to patient contact. However, please be advised that the presence of rust may go undetected by the user.

3. Type of Action to Mitigate the Risk

1. Action To Be Taken by the User

3. ☒ Identify Device
☒ Quarantine Device
☒ Return Device
☒ Other

Please complete the enclosed Customer Reply 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 Reply 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.

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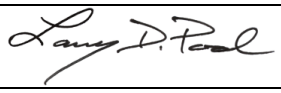
3. Type of Action to Mitigate the Risk Continued		
3.	**2. Is Customer Reply Required?** Form is attached specifying deadline for return.	Yes
3.	**3. Action Being Taken by the Manufacturer** ☒ Product Removal	

4. 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

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	2021FA0011
FSN Date	08 October 2021
Product/Device name	Transseptal Needle, Transseptal Needle with Catheter
Product Part Number(s)	TSNC-18-71.0, TSNC-19-56.0, TSN-17-75.0-ENDRYS
Batch/Serial Number(s)	All lots

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 Country 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.