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: 2019FA0009

Date: 22 Oct 2019

Urgent Field Safety Notice

Product Removal - Torcon NB® Advantage 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.

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: 2019FA0009

Urgent Field Safety Notice

Product Removal - Torcon NB® Advantage Catheter

Risk Addressed by FSN

Information on Affected Devices		
1.	**1. Device Type(s)**	
	The Torcon NB® Advantage Catheters are sterile, single-use products. The catheters are available in a variety of French sizes, endhole sizes, lengths, materials and designs (e.g., polyethylene or nylon, non-braided or braided with 1:1 torque).	
1.	**2. Commercial name(s)**	
	Torcon NB® Advantage Catheter	
1.	**3. Primary clinical purpose of device(s)**	
	Per the Instructions for Use T_NBADV_REV0: Intended for use in the peripheral and coronary vascular system, including the carotid arteries, in angiographic procedures by physicians trained and experienced in angiographic techniques. Per the Instructions for Use T_CE_ANGIO88_REV5: Intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques.	
1.	**4. Device model / Catalogue / Part number(s)**	**5. Affected serial or lot number range**
	HNB5.0-38-100-P-NS-DAV (G08895)	9708139
	HNB5.0-38-100-P-NS-H1 (G06005)	9714540
	HNB5.0-38-100-P-NS-JB1 (G05997)	9726996
	HNB5.0-38-100-P-NS-JL4 (G05923)	NS9701376
	HNB5.0-38-100-P-NS-SIM1 (G04922)	9700385, 9713001
	HNB5.0-38-100-P-NS-SIM2 (G05976)	9713002
	HNB5.0-38-100-P-NS-VERT (G06074)	9710402
	HNB5.0-38-110-P-12S-PIG (G10741)	9709328
	HNB5.0-35-65-P-NS-TIPS (G19706)	9890919
	HNB5.0-38-65-P-2S-C1 (G06827)	NS9906241
	HNB5.0-38-65-P-NS-SHK1.0 (G05975)	9900974
	HNB5.0-35-100-P-8S-NEFF (G11026)	NS9720276
	HNB6.0-38-65-P-NS-BMC (G32465)	9908469, 9911359, 9936124
	HNB7.0-38-100-P-NS-MPA (G08591)	9713048

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: 2019FA0009

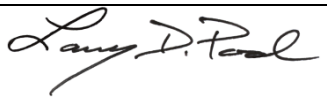
Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem** Pouches may be undersealed, potentially compromising the sterility of the product. This issue is related specifically to the chevron seal.
2.	**2. Hazard giving rise to the FSCA** Use of an affected product could pose significant risk to the patient, as local or systemic infection may occur.

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 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 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.	
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

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: 2019FA0009

General Information Continued		
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.

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

Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2019FA0009
FSN Date	22 Oct 2019
Product/Device name	Torcon NB® Advantage Catheter
Product Part Number(s)	HNB5.0-38-100-P-NS-DAV (G08895) HNB5.0-38-100-P-NS-H1 (G06005) HNB5.0-38-100-P-NS-JB1 (G05997) HNB5.0-38-100-P-NS-JL4 (G05923) HNB5.0-38-100-P-NS-SIM1 (G04922) HNB5.0-38-100-P-NS-SIM2 (G05976) HNB5.0-38-100-P-NS-VERT (G06074) HNB5.0-38-110-P-12S-PIG (G10741) HNB5.0-35-65-P-NS-TIPS (G19706) HNB5.0-38-65-P-2S-C1 (G06827) HNB5.0-38-65-P-NS-SHK1.0 (G05975) HNB5.0-35-100-P-8S-NEFF (G11026) HNB6.0-38-65-P-NS-BMC (G32465) HNB7.0-38-100-P-NS-MPA (G08591)
Batch/Serial Number(s)	9700385, 9708139, 9709328, 9710402, 9713001, 9713002, 9713048, 9714540, 9726996, 9890919, 9900974, 9908469, 9911359, 9936124, NS9701376, NS9720276, NS9906241

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

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

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	

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.