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: 2023FA0001

Date: 01 March 2023

Urgent Field Safety Notice

Advance Micro™ 14 Ultra Low-Profile PTA Balloon Catheter
Ultrathane Cook-Cope Type Locking Loop Multipurpose Drainage 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.	**1. Device Type(s)**
	The Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter is a double-lumen catheter with a balloon near its distal tip. The catheter consists of two independent lumens, which are labelled "DISTAL" and "BALLOON." The distal lumen extends the length of the catheter and is used for placement of wire guides. The balloon lumen is used to expand the balloon. Inscribed on the tip of the manifold are the balloon diameter (mm) and the balloon length (cm). The balloon is manufactured from an extra-thinwall, high-strength, minimally-compliant material. Multipurpose Drainage Catheters are constructed from Ultrathane® or polyethylene and come in a range of French sizes, lengths and sideport quantities.
1.	**2. Commercial name(s)**
	Advance Micro™ 14 Ultra Low-Profile PTA Balloon Catheter Ultrathane Cook-Cope Type Locking Loop Multipurpose Drainage Catheter
1.	**3. Primary clinical purpose of device(s)**
	The Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter has been designed for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including internal pudendal, iliac, renal, popliteal, femoral, iliofemoral, anterior tibial, posterior tibial, peroneal, pedal, radial, brachial, and ulnar, as well as in obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary arteries. Multipurpose drainage catheters are intended for percutaneous drainage in a variety of drainage applications (e.g., nephrostomy, biliary, and abscess), either by direct stick or Seldinger access technique.
1.	**4. Device Model/Catalogue/Part Number(s)**
	Reference Part Numbers (RPNs): PTA3-14-150-2.5-8, PTA3-14-150-2.5-3, and ULT16.0-38-25-P-6S-LMCL Order Numbers (GPNs): G26677, G26646, and G07340, respectively
1.	**5. Affected serial or lot number range**
	14110999, 14111001, NS13527160, 14012749, and 14007378.

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2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem** Specific product lots were distributed throughout Europe, Middle East, and Africa (EMEA) after Cook removed the products from the Declaration of Conformity. As such, the products should not have been distributed.
2.	**2. Hazard giving rise to the FSCA** There is no health hazard associated with this issue; impacted products conform to manufacturing tolerances and specifications. Products are being removed from the market due to a regulatory/compliance issue.

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

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4. General Information		
4.	1. FSN Type	Update
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information Refer to page 1 of this FSN for contact details of local representative.	
	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	2023FA0001
FSN Date	01 March 2023
Product/Device name	Advance Micro™ 14 Ultra Low-Profile PTA Balloon Catheter Ultrathane Cook-Cope Type Locking Loop Multipurpose Drainage Catheter
Product Part Number(s)	PTA3-14-150-2.5-8 PTA3-14-150-2.5-3 ULT16.0-38-25-P-6S-LMCL
Batch/Serial Number(s)	14110999 14111001 NS13527160 14012749 14007378

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

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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

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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.