COOK MEDICAL EUROPE LTD.
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NATIONAL TECHNOLOGY PARK
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FSN & FSCA Ref: 2024FA0008

Date: 02 October 2024

Urgent Field Safety Notice – Medical Device Removal

Approach® CTO Micro Wire Guides
Approach® Hydro ST Micro Wire Guides

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 Approach® CTO Micro Wire Guide is 0.014 inches (0.36 mm) in diameter and is available in a variety of lengths and tip configurations. The product has a TFE-coated stainless-steel shaft and distal stainless-steel and platinum coils on the tip. The tips' configurations differ in stiffness. The Approach® Hydro ST Micro Wire Guide is 0.014 inches (0.36 mm) in diameter and is available in a variety of lengths and configurations. Refer to the product label for product specifications (wire guide length, wire guide diameter, shaft configuration and tip length). Approach® Hydro ST incorporates a stainless-steel shaft with distal stainless steel and platinum coils and a hydrophilic floppy tip, used for general peripheral vascular interventions.
1.	**2. Commercial name(s)**
	Approach® CTO Micro Wire Guide Approach® Hydro ST Micro Wire Guide
1.	**3. Primary clinical purpose of device(s)**
	The Approach® CTO Micro Wire Guide is intended for use in facilitating delivery of percutaneous catheters into the peripheral vasculature and is also indicated for the intra-luminal placement of percutaneous catheters or other therapeutic devices beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Approach® Hydro ST Micro Wire Guide is intended for use in facilitating delivery of percutaneous catheters into the peripheral vasculature.
1.	**4. Device Model/Catalogue/Part Number(s)**
	Please refer to Attachment 1 – Product Information Table for information on the impacted devices.
1.	**5. Affected serial or lot number range**
	Please refer to Attachment 1 – Product Information Table for information on the impacted devices.

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2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem** Cook Medical identified that devices from the affected device lots have labels that state the incorrect expiration dates. You are receiving this letter as Cook Medical records indicate that impacted products were shipped to your facility.
2.	**2. Hazard giving rise to the FSCA** If an impacted device is used past its true expiration date, potential adverse events that may occur include harms associated with fragmentation / separation, harms associated with flaking of the hydrophilic coating (HMW- products only), and increased procedural time. To date, Cook Medical has not received any customer complaints related to the adverse patient effects listed above for the affected lots.

3. Type of Action to Mitigate the Risk		
3.	**1. Actions To Be Taken by the User** ☒ Identify Device(s) ☒ Quarantine Device(s) ☒ Return Device(s) to Cook Medical ☒ Other Please complete the enclosed Customer Reply Form. Where devices are 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 Device(s) should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY Credit will be provided for the returned affected device(s) 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	New
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

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 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.