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: 2025FA0003

Date: 13 May 2025

Urgent Field Safety Notice – Medical Device Removal

Cook Beacon® Tip 5.0 Fr Angiographic 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)**
	Beacon Tip catheters are designed to facilitate diagnostic and therapeutic procedures. Catheters are available in various configurations. Configurations include different shaft lengths and tip curves and some catheters are manufactured with a hydrophilic coating. Refer to the product label for product specifications (e.g., catheter length, distal curve configuration).
1.	**2. Commercial name(s)**
	Cook Beacon® Tip 5.0 Fr Angiographic Catheter
1.	**3. Primary clinical purpose of device(s)**
	Beacon Tip Catheters are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.
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.

2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	Cook Medical identified that catheters supplied in the affected device lots may experience tip separation. This issue was identified via four field complaints; users have reported tip separation to have occurred both prior to and during patient contact. Further investigation revealed this issue to be the result of process deviation by one specific operator. Applicable parts manufactured by this operator are in scope. 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**
	Potential adverse events that may occur if an affected product is used include harms associated with device fragmentation/separation and vessel injury. To date, Cook Medical has received three customer complaints related to the adverse patient effects listed above for the affected lots.

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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	

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

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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 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.