COOK MEDICAL EUROPE LTD.
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NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2020FA0007

Date: 25 Nov 2020

Urgent Field Safety Notice

Flexor® Check-Flo® Introducer
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle Select®)

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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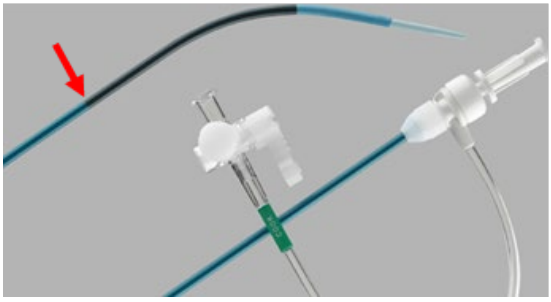
Risk Addressed by FSN

1. Information on Affected Devices	
1.	**1. Device Type(s)**
	The products are sterile, single-use devices. The introducers incorporate a hydrophilic coated Flexor shaft involving varying stiffnesses with distal radiopaque markers. They contain a hemostasis valve and are provided with a single dilator. The products range from 55 cm to 90 cm in length; 4, 5, 6, 7, or 8 French; and have two different tip configurations.
1.	**2. Commercial name(s)**
	Flexor® Check-Flo® Introducer Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle Select®)
1.	**3. Primary clinical purpose of device(s)**
	The products are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.
1.	**4. Device Model/Catalogue/Part Number(s)**
	Refer to Attachment 1.
1.	**5. Affected serial or lot number range**
	Refer to Attachment 1.

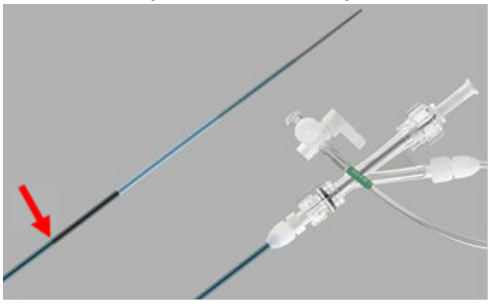
2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	For the impacted product lots listed in Attachment 1, Cook Medical has identified that there is an increased likelihood of the introducer sheath separating at the proximal bond site. The location of the proximal bond site is shown by the arrows in the images provided below.

Flexor® Check-Flo® Introducer



~8cm from distal end of introducer sheath

Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle Select®)



~11cm from distal end of introducer sheath

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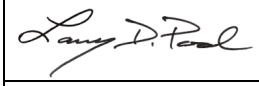
	2. Hazard giving rise to the FSCA
2.	If separation occurs during use, it could result in life-threatening adverse events. The potential adverse events that may occur include, but are not limited to increased procedural time, intervention to retrieve a separated segment, embolization occluding blood flow to a vital organ, vessel injury, and hemorrhage.

	3. Type of Action to Mitigate the Risk	
3.	**1. Action 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	

	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. List of attachments/appendices:	Attachment 1 – Affected Lot Numbers Globally This Attachment includes the list of affected Part Numbers (RPN), Order Numbers (GPN), and Lot Numbers.
4.	6. 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.