COOK MEDICAL EUROPE LTD.
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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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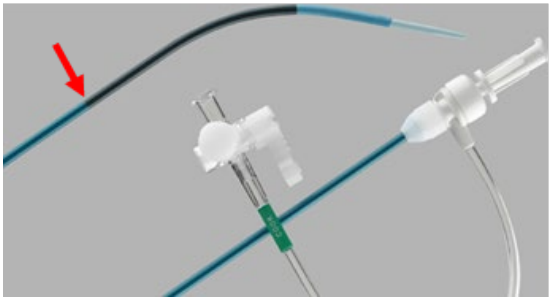
Risk Addressed by FSN

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.

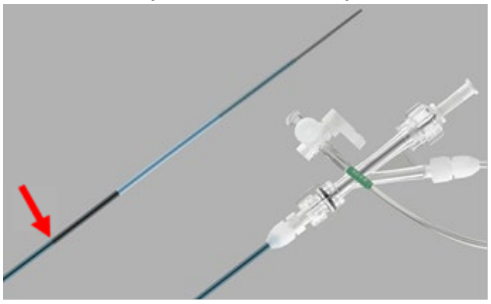
2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	For the impacted product lots listed in Attachment 1, Cook Medical has identified that there is an increased likelihood of the introducer sheath separating at the proximal bond site. The location of the 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	[redacted] [redacted] 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	2020FA0007
FSN Date	25 Nov 2020
Product/Device name	Flexor® Check-Flo® Introducer Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle Select®)
Product Part Number(s)	Refer to Attachment 1
Batch/Serial Number(s)	Refer to Attachment 1

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

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	

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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.

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Shared Service Centre by Country:

Country	Phone	Fax	E-mail
Austria	+43 179567121	+43 179567126	oe.orders@cookmedical.com
Belgium/French	+32 27001633	+32 27001634	be.orders@cookmedical.com
Belgium/Flemish	+32 27001633	+32 27001634	nl.orders@cookmedical.com
Denmark	+45 38487607	+45 38487608	da.orders@cookmedical.com
Distributors	+353 61239240	+353 61239227	ssc.distributors@cookmedical.com
France	+33 171230269	+33 171230270	fr.orders@cookmedical.com
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Sweden	+46 858769468	+46 858769467	se.orders@cookmedical.com
Switzerland/French	+41 448009609	+41 448009610	fr.orders@cookmedical.com
Switzerland/Italian	+41 448009609	+41 448009610	it.orders@cookmedical.com
Switzerland/German	+41 448009609	+41 448009610	de.orders@cookmedical.com
United Kingdom	+44 2073654183	+44 2073654184	uk.orders@cookmedical.com

Customer service lines are available (excluding national holidays) Monday through Thursday between the hours of 08:30 CET and 17:30 CET, and from 08:30 CET to 16:00 CET on Fridays.

Please note: For all other countries, contact the nearest customer service center or your local Cook Medical representative.