



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: 2021FA0013

Date: 12 November 2021

**Urgent Field Safety Notice – Medical Device Recall**  
**Flexor® Check-Flo® Introducer – Ansel Modification**

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](mailto: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.



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: 2021FA0013

## **Urgent Field Safety Notice – Medical Device Recall** **Flexor® Check-Flo® Introducer – Ansel Modification**

### **Risk Addressed by FSN**

<b>1. Information on Affected Devices</b>	
<b>1. Device Type(s)</b>	
1.	The products are sterile, single-use devices. The introducers incorporate a hydrophilic coated Flexor shaft with a hemostasis valve and are provided with a dilator.
<b>2. Commercial name(s)</b>	
1.	Flexor® Check-Flo® Introducer – Ansel Modification
<b>3. Unique Device Identifier(s) (UDI-DI)</b>	
1.	(01)00827002441552(17)240422(10)13911710
<b>4. Primary clinical purpose of device(s)</b>	
1.	Intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.
<b>5. Device Model/Catalogue/part number(s)</b>	
1.	RPN: KCFW-7.0-18/38-45-RB-ANL0-HC GPN: G44155
<b>6. Affected serial or lot number range</b>	
1.	13911710

<b>2. Reason for Field Safety Corrective Action (FSCA)</b>	
<b>Description of the product problem</b>	
2.	Cook Medical has identified that products labeled as KCFW-7.0-18/38-45-RB-ANL0-HC Lot 13911710 may contain a 6FR device instead of a 7FR device.
<b>2. Hazard giving rise to the FSCA</b>	
2.	<p>Potential adverse events that may occur with use of an affected device include increased procedural time, pain at the access site, self-limiting vessel injury, and/or hematoma.</p> <p>Cook has received no reports of serious injury associated with affected product. Cook has received five (5) complaints where the issue (i.e. incorrect sized product) was detected prior to patient contact.</p>



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: 2021FA0013

<b>3. Type of Action to mitigate the risk</b>	
3.	<p><b>1. Action To Be Taken by the User</b></p> <p><input checked="" type="checkbox"/> Identify Device    <input checked="" type="checkbox"/> Quarantine Device    <input checked="" type="checkbox"/> Return Device <input checked="" type="checkbox"/> Other</p> <p>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.</p> <p>Returned Product should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY</p> <p>Credit will be provided for the returned affected products where applicable.</p>
3.	<p><b>2. Is Customer Reply Required?</b> Reply Form is attached specifying deadline for return.</p> <p style="text-align: right;">Yes</p>
3.	<p><b>3. Action Being Taken by the Manufacturer</b></p> <p><input checked="" type="checkbox"/> Product Removal</p>

<b>4. General Information</b>					
4.	<p>1. FSN Type</p> <p style="text-align: right;">New</p>				
4.	<p>2. Further advice or information already expected in follow-up FSN?</p> <p style="text-align: right;">No</p>				
4.	<p>3. Manufacturer information For contact details of local representative refer to page 1 of this FSN</p> <table border="1" style="width: 100%;"> <tr> <td style="text-align: center; vertical-align: middle;">a. Company Name</td> <td style="text-align: right;">Cook Incorporated</td> </tr> <tr> <td style="text-align: center; vertical-align: middle;">b. Address</td> <td style="text-align: right;">750 Daniels Way Bloomington, IN 47402, United States</td> </tr> </table>	a. Company Name	Cook Incorporated	b. Address	750 Daniels Way Bloomington, IN 47402, United States
a. Company Name	Cook Incorporated				
b. Address	750 Daniels Way Bloomington, IN 47402, United States				
4.	<p>4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.</p>				
4.	<p>5. Name/Signature</p> <div style="background-color: black; width: 100%; height: 100%; min-height: 100px;"></div>				



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: 2021FA0013

**Transmission of this Field Safety Notice**

This notice needs to be passed on to 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.



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

## Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2021FA0013
FSN Date	12 November 2021
Product/Device name	Flexor® Check-Flo® Introducer – Ansel Modification
Product Part Number(s)	RPN: KCFW-7.0-18/38-45-RB-ANL0-HC GPN: G44155
Batch/Serial Number(s)	Lot: 13911710 UDI: (01)00827002441552(17)240422(10)13911710

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.	
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.
<input type="checkbox"/>	I have affected devices to return - enter Lot number and quantities in table below.
<input type="checkbox"/>	No affected devices remain in our organisation's inventory
Print Name	
Signature	
Date	



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

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.