



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: 2022FA0004

Date: 23 September 2022

Urgent Field Safety Notice **Check-Flo Performer® Introducer**

For Attention of: Chief Executive / Risk Management / Purchasing

Contact details of local representative (name, e-mail, telephone, address etc.)
<p>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</p> <p>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.</p>



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Check-Flo Performer® Introducer

Risk Addressed by FSN

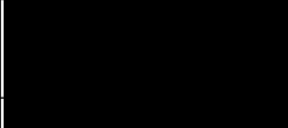
1. Information on Affected Devices	
1.	1. Device Type(s) Check-Flo Performer Introducers and Guiding Sheaths have a Check-Flo® valve and a radiopaque tip incorporated within the sheath material to identify the location of the sheath's distal tip. The intended purpose of these devices is to serve as a pathway for other devices to be inserted into the cardiovascular system, either through the vasculature or via a transseptal approach following transseptal puncture. Check-Flo Performer® Introducers are supplied sterilized by ethylene oxide gas in peel-open pouches.
1.	2. Commercial name(s) Check-Flo Performer® Introducer
1.	3. Primary clinical purpose of device(s) Check-Flo Performer Introducers and Guiding Sheaths are indicated for the percutaneous introduction of therapeutic or diagnostic devices to all heart chambers, including the left atrium via transseptal puncture.
1.	4. Device Model/Catalogue/Part Number(s) Reference Part Numbers (RPNs): RCFW-6.0-38-75-RB-MTS, RCFW-11.0-38-63-RB-MTS Order Numbers (GPNs): G09532, G10011
1.	5. Affected serial or lot number range 14709527, 14734696
2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem Specific product lots were distributed to the European Union after their Declaration of Conformity certificates expired. Active Declaration of Conformity certificates are required as proof of registration to sell product in the European Union. As such, the products should not have been distributed within the European Union.
2.	2. Hazard giving rise to the FSCA There is no health hazard associated with this issue; impacted products conform to manufacturing tolerances and specifications. Products are being removed from the market due to a regulatory/compliance issue.



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3. Type of Action to Mitigate the Risk		
3.	1. Actions To Be Taken by the User <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input checked="" type="checkbox"/> 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 <input checked="" type="checkbox"/> 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	 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.



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Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2022FA0004
FSN Date	23 September 2022
Product/Device name	Check-Flo Performer® Introducer
Product Part Number(s)	<u>Reference Part Numbers (RPNs):</u> RCFW-6.0-38-75-RB-MTS, RCFW-11.0-38-63-RB-MTS
Batch/Serial Number(s)	14709527, 14734696

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		



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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.