COOK®

Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441

Urgent Field Safety Notice

Commercial name of the affected product:

- **Check-Flo® Hemostasis Assembly**
- **Flexor® Radial Access Sets**
- **TriForce™ Peripheral Crossing Set**
- **Check-Flo® Introducer Hausdorf-Lock Atrial**

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2017FA0002
Type of action: Field Safety Corrective Action

Date: 06 February 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Reference Part Number	GPN	Lot Number
Check-Flo® Hemostasis Assembly	CFM-200	G23121	Please see attached listing for the specific lot numbers that are affected
Flexor® Radial Access Set	KCFN-4.0-18-13-RA-HC	G35597	
	KCFN-4.0-18-23-RA-HC	G35598	
	KCFN-4.0-18-7-RA-HC	G35596	
	KCFN-5.0-18-13-RA-HC	G35600	
	KCFN-5.0-18-13-RA-S-HC	G35607	
	KCFN-5.0-18-23-RA-HC	G35601	
	KCFN-5.0-18-7-RA-HC	G35599	
	KCFN-6.0-18-13-RA-HC	G35603	
	KCFN-6.0-18-13-RA-S-HC	G35608	
	KCFN-6.0-18-23-RA-HC	G35604	
	KCFN-6.0-18-23-RA-S-HC	G35609	
	KCFN-6.0-18-7-RA-HC	G35602	
	KCFN-7.0-18-13-RA-HC	G35605	
	KCFN-7.0-18-23-RA-HC	G35606	
TriForce™ Peripheral Crossing Set	KCXS-5.0-35-100-RB-0/0-HC	G56416	
	KCXS-5.0-35-65-RB-0/0-HC	G56412	
	KCXS-5.0-35-65-RB-0/DAV-HC	G56413	
	KCXS-5.0-35-65-RB-MPB/DAV-HC	G56415	
Check-Flo® Introducer Hausdorf-Lock Atrial	RCFW-7.0-38-75-RB-HLA-091100-BV	G03769	
	RCFW-8.0-38-75-RB-HLA-091100-BV	G03770	

*Please note this potential adverse event applies only to specific devices with the hemostatic blue valve (polyisoprene) design.

Please see attached complete product listing of all products impacted by this field action.

Description of the problem:

Cook Medical is initiating a voluntary recall of specific products and lot numbers as listed above. We identified an increase in reports of blood loss associated with devices using a specific hemostatic valve design (referred to as the "blue" valve or polyisoprene valve). In November 2015, products manufactured with the hemostatic blue valve design were either obsoleted or changed to incorporate a different valve design with improved hemostasis. Cook has continued to receive reports of blood loss associated with the earlier generation products containing the "blue" valve and therefore has initiated this action on those devices.

The devices associated with this recall include Flexor® radial artery introducer sheaths, along with Check-Flo® Hemostasis Assembly, Performer guiding sheaths, and TriForce™ peripheral crossing sets. Potential adverse events that may occur with the Flexor radial artery introducer sheaths include delay in procedure and blood loss. The Check-Flo® Hemostasis Assembly, Performer sheaths, and TriForce™ peripheral crossing sets may potentially be used in the central venous system; therefore adverse events that may occur with these devices include delay in procedure, blood loss, or air embolism.

This notice is directed to you because our records indicate that you have received product of the listed catalog numbers identified that have not expired.

Advise on action to be taken by the user:

1. Immediately collect all remaining affected products as per the specified lot listing from your inventory.

2. Please complete the enclosed Customer Response 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 Response form.

   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. Send the Customer Response Form via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61 334441). Do not enclose the response form with the returned product.

4. Please report any adverse event to Cook Medical Customer Relations by contacting our Customer Services Department.

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.

Contact reference person:

Marianne Høy
Manager, Support
Regulatory Affairs
William Cook Europe
Bjaeverskov, DENMARK

Or

Annemarie Beglin
Quality Systems Manager
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@cookmedical.com, phone +353 61 334440).

We confirm that this notice has been notified to the appropriate Regulatory Agency.

Annemarie Beglin
Quality Systems Manager

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FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2017FA0002
Affected device:

- **Check-Flo® Hemostasis Assembly**
- **Flexor® Radial Access Sets**
- **TriForce™ Peripheral Crossing Set**
- **Check-Flo® Introducer Hausdorf-Lock Atrial**

*Please note this potential adverse event applies only to specific devices with the hemostatic blue valve (polyisoprene) design.

Please see attached complete product listing of all products impacted by this field action.

Please indicate the following:

Customer Number (As Indicated on the attached product list): _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____
(Please Print)

Please indicate which of the following applies to your facility:

☐ None of the affected product remains in our inventory

☐ We are returning our remaining inventory for credit, see details listed below

***Proforma Invoice Required for Return of Product(s):* ☐ Yes ☐ No

**If you are a distributor, have your customers been notified of this Field Safety Corrective Action?

☐ Yes ☐ No

If you are returning any affected product, please indicate the part number, lot number and quantity:

Product Part Number	Product Lot Number	Quantity

Signed: _____ Date: _____

Please return the completed Customer Response Form to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 334441.