COOK®

Cook Medical Europe
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Limerick, Ireland.
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Urgent Field Safety Notice

Commercial name of the affected product:

- **TriForce™ Peripheral Crossing Set**

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2017FA0002_1
Type of action: Field Safety Corrective Action Recall Extension

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Date: 17 March 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Reference Part Number	GPN	Lot Number
TriForce™ Peripheral Crossing Set	KCXS-5.0-35-100-RB-0/0-HC	G56416	Please see attached listing for the specific lot numbers that are affected
	KCXS-5.0-35-100-RB-0/DAV-HC	G56417	
	KCXS-5.0-35-100-RB-MPB/DAV-HC	G56419	
	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/0-HC	G56414	
	KCXS-5.0-35-65-RB-MPB/DAV-HC	G56415	

*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 and lot numbers impacted by this field action.

Description of the problem:

Cook Medical is extending the voluntary recall of specific products and lot numbers of 06 February 2017 to include additional lot numbers of the TriForce™ Peripheral Crossing Set

The TriForce™ Peripheral Crossing Set is intended to be percutaneously introduced into blood vessels and support a wire guide while performing percutaneous peripheral interventions. This device is also intended for injection of radiopaque contrast media for the purpose of angiography.

Potential adverse events that may occur if these devices are used in the arterial system include delay in procedure and blood loss. If devices are used in the central venous system, adverse events that may occur 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 product 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