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: CXI® Support Catheter
Manufacturer : Cook Incorporated
Cook Reference Number: 2015FA0007
Type of action: Field Safety Corrective Action

Date: 28 October 2015

Attention: Risk Management/Recall Administration

Details on affected devices:

Product Name:

Brand Name	Catalog Number	GPN	Lot Number
CXI® Support Catheter	CXI-4.0-35-90-P-NS-0	G52546	5505279, 5505279X

Description of the problem:

Cook Medical is initiating a voluntary recall of the CXI® Support Catheter for the specific lot numbers due to a labeling issue. Cook Medical has received six product complaints associated with reports of the 2.6FR curved catheter being mixed with the 4.0FR straight catheter and vice versa. Investigation revealed the products were mixed during processing. To avoid further occurrence and potential harm, Cook Medical is initiating a voluntary recall of the specific affected lots in distribution.

This event is not likely to lead to an adverse patient/user outcome and/or is obvious to the user. The likelihood of harm occurring is rare and the overall risk is negligible to low.

Our records indicate that your facility has received devices that are subject to this field action.

Advise on action to be taken by the user:

1. Please review the attached list of affected products and lot numbers that were shipped to your account, and quarantine any affected product that remains unused.

2. Immediately collect and return all unused affected products to Cook Medical as soon as possible for credit. Please contact our Customer Services Department to arrange pick up.

   Send the removed products to:
   Cook Medical EUDC
   Robert-Koch-Straße, 2
   52499 Baesweiler
   GERMANY

   Please attach the enclosed Recall Product Return Form referencing RA # 2015FA0007 to the outside of the shipping carton.

   Credit will be provided for the returned devices where applicable.

3. Please complete the enclosed Customer Response Form and send via email to European.Complaints@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61 334441).

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 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.

Contact reference person:

Marianne Høy
Manager, Support Services
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.Complaints@CookMedical.com, phone +353 61 334440).

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

Signature

COOK®

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FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2015FA0007

Affected device:

Brand Name	Catalog Number	GPN	Lot Number
CXI® Support Catheter	CXI-4.0-35-90-P-NS-0	G52546	5505279, 5505279X

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:

I have read and understand the instructions provided in the October 28, 2015 letter: ☐ Yes ☐ No

☐ None of the affected product remains in our inventory

☐ We are returning our remaining inventory, please see details listed below (page 2)

Proforma Invoice Required for Return of Product(s): ☐ 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 by e-mail to European.Complaints@cookmedical.com or by fax to + 353 61 334441.