COOK

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

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Urgent Field Safety Notice

Commercial name of the affected product:
Beacon® Tip Torcon NB® Advantage Catheters; Catalog Prefix HNBR5.0
Beacon® Tip Royal Flush® Plus High-Flow Catheters; Catalog Prefix HNR4.0
Slip-Cath® Beacon® Tip Catheters; Catalog Prefix SCBR5.0

Manufacturer: Cook Incorporated
FSCA-identifier: 2015FA0005
Type of action: Field Safety Corrective Action (Recall)

Date: 02nd July 2015

Attention: Chief Executive

Details on affected devices:

Product Name:
Beacon® Tip Torcon NB® Advantage Catheters; Catalog Prefix HNBR5.0
Beacon® Tip Royal Flush® Plus High-Flow Catheters; Catalog Prefix HNR4.0
Slip-Cath® Beacon® Tip Catheters; Catalog Prefix SCBR5.0
Product Code: HNBR5.0, HNR4.0 & SCBR5.0
Lot Numbers: Please see attached product list, only specific Lot numbers are impacted by this field action.

Description of the problem:
The above referenced catheters are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques. Cook Medical has received reports of catheter splits and/or separation. Based on these reports Cook Medical is initiating a voluntary recall of specific lots in distribution.

Potential adverse events that may occur as a result of catheter tip splitting and/or separation may include loss of device function, medical intervention to retrieve separated segment, or complications resulting from separated tip occluding blood flow to end organs.

Advice on action to be taken by the user:

1. Please review the attached list of affected products and lot numbers 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 # 2015FA0005 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 61334441).

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:

Emmett Devereux
Director, Government and Regulatory Affairs, EMEA
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

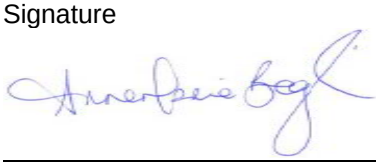
Or

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



Annemarie Beglin
Quality Systems Manager