COOK®

**Cook Medical Europe**
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Limerick, Ireland.
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# Urgent Field Safety Notice Extension

**Commercial name of the affected product:**
Torcon NB® Advantage Beacon® Tip Catheters: catalog prefixes HNBR4.0, HNBR4.1, and only HNBR5.0 w/RUC suffix
Royal Flush® Plus Beacon® Tip High-Flow Catheters: catalog prefix HNR4.0
Slip-Cath® Beacon® Tip Hydrophilic Catheters: catalog prefixes SCBR4.0, SCBR4.1, and only SCBR5.0 w/RUC suffix
Shuttle® Select Slip-Cath® Catheters; catalog prefix SCBR4.5

**Manufacturer :** Cook Incorporated
**Cook Reference Number:** 2015FA0005_1
**Type of action:** Field Safety Corrective Action (Recall Extension)

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**Date**: 08 October 2015

**Attention:** Risk Management/Recall Administration

**Details on affected devices:**
**Product Name:**
Torcon NB® Advantage Beacon® Tip Catheters: catalog prefixes HNBR4.0, HNBR4.1, and only HNBR5.0 w/RUC suffix
Royal Flush® Plus Beacon® Tip High-Flow Catheters: catalog prefix HNR4.0
Slip-Cath® Beacon® Tip Hydrophilic Catheters: catalog prefixes SCBR4.0, SCBR4.1, and only SCBR5.0 w/RUC suffix
Shuttle® Select Slip-Cath® Catheters; catalog prefix SCBR4.5

**Product Code:**
- HNBR4.0, HNBR4.1, and only HNBR5.0 w/RUC suffix
- HNR4.0
- SCBR4.0, SCBR4.1, and only SCBR5.0 w/RUC suffix
- SCBR4.5

**Lot Numbers:** Please see attached product list, only specific Lot Numbers are impacted by this field action.

**Description of the problem:**
Cook Medical is extending the voluntary recall of July 2, 2015, to include additional lots and catheter prefixes as listed above. These catheters are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques. Cook Medical has received additional reports of catheter tip splits and/or separation. On the basis of these reports, Cook Medical is extending our voluntary recall of specific affected lots that are 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 a separated segment, or complications resulting from a separated tip occluding blood flow to end organs.

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 # 2015FA0005_1 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

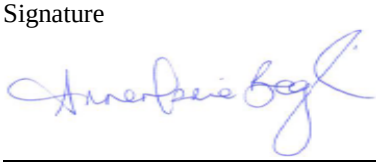
Or

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



Annemarie Beglin
Quality Systems Manager