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:

Manufactured by Cook Incorporated:

- **Aprima™ Access Nonvascular Introducer Set**
- **Beacon® Tip Centimeter Sizing Catheter**
- **Beacon® Tip Royal Flush® Plus High-Flow Catheter**
- **Beacon® Tip Torcon NB® Advantage Catheter**
- **Beacon® Tip Vessel Sizing Catheter**
- **Beacon® Tip White Vessel Sizing Catheter**
- **Haskal Transjugular Intrahepatic Portal Access Set**
- **Liver Access and Biopsy Needle Set**
- **Shuttle® Select Slip-Cath**
- **Slip-Cath® Beacon® Tip Catheter**
- **Transluminal Biliary Biopsy Forceps Set**
- **White Lumax® Guiding Coaxial Catheter**

Manufactured by William Cook Europe Aps:

- **Transjugular Intrahepatic Portosystemic Shunt Procedure Pack**
- **Zenith Alpha™ AAA Endovascular Graft Procedure Pack**
- **Zenith Alpha™ TAA Endovascular Graft Procedure Pack**
- **Zenith® AAA Endovascular Graft Procedure Pack**
- **Zenith® AAA Endovascular Graft Start Up Kit**
- **Zenith® t-Branch Endovascular Graft Procedure Pack**
- **Zenith® Thoracic Endovascular Graft Procedure Pack**

Manufacturers :
Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
William Cook Europe Aps, Sandet 6, 4632 Bjaeverskov, Denmark
Cook Reference Numbers: 2016FA0002, 2016FA0002_WCE
Type of action: Field Safety Corrective Action

Date: 21Apr2016

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Catalog Identifier	Lot Number
Aprima™ Access Nonvascular Introducer Set	NPAS-/-SST NSSW-/-SST	All lots

Beacon® Tip Centimeter Sizing Catheter, Beacon® Tip White Vessel Sizing Catheter, Beacon® Tip Vessel Sizing Catheter	NR5.0	All lots
Beacon® Tip Royal Flush® Plus High-Flow Catheter	HNR5.0	All lots
Beacon® Tip Torcon NB® Advantage Catheter	HNBR5.0 HNBR6.0	All lots
Haskal Transjugular Intrahepatic Portal Access Set	HTPS	All lots
Liver Access and Biopsy Needle Set	LABS	All lots
Shuttle® Select Slip-Cath	SCBR5.5-/-SHTL SCBR6.5-/-SHTL	All lots
Slip-Cath® Beacon® Tip Catheter	SCBR5.0 SCBR5.5 SCBR6.5	All lots
Transjugular Intrahepatic Portosystemic Shunt Procedure Pack	TIPSS-100 TIPSS-200	All lots
Transluminal Biliary Biopsy Forceps Set	BBFS	All lots
White Lumax® Guiding Coaxial Catheter	LMGRF-7.0C-80-MPA-PULM	All lots
Zenith Alpha™ AAA Endovascular Graft Procedure Pack*	ZAPP-A	All lots
Zenith Alpha™ TAA Endovascular Graft Procedure Pack*	ZAPP-T	All lots
Zenith® t-Branch Endovascular Graft Procedure Pack*	ESSK-T-BRANCH	All lots
Zenith® Thoracic Endovascular Graft Procedure Pack*	ESSK-T	All lots
Zenith®AAA Endovascular Graft Procedure Pack*	ESSK-3FR ESSK-AAA	All lots
Zenith®AAA Endovascular Graft Start Up Kit*	ESSK-2 ESSK-3	All lots

*Please note that this potential adverse event applies only to the catheters with Beacon Tip technology supplied within the procedure pack or kit.

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 the products listed above. We have identified an increase in reports of polymer degradation of the catheter tip, resulting in tip fracture and/or separation. Our preliminary investigation into this matter has identified that environmental conditions, such as storage temperature, humidity, and the use of Vaporized Hydrogen Peroxide (VHP) for whole-room decontamination within healthcare facilities, may be contributing to the occurrence. We also recognize that there may be other undetermined contributors to this issue and continue to investigate.

These devices are intended for use by physicians who are trained and experienced in each of the procedures for which the following devices are indicated for use.

Product Family	Intended Use
Beacon® Tip Torcon NB® Advantage Catheter	The catheters are intended for use in the peripheral and coronary vascular system including the carotid arteries in angiographic procedures by physicians trained and experienced in angiographic techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.
Beacon® Tip Royal Flush® Plus High-Flow Catheter Beacon® Tip Centimeter Sizing Catheter Beacon® Tip White Vessel Sizing Catheter Beacon® Tip Vessel Sizing Catheter	The catheters are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.
Shuttle® Select Slip-Cath Slip-Cath® Beacon® Tip Catheter	The catheters are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques.
Haskal Transjugular Intrahepatic Portal Access Set	Intended for transjugular liver access in diagnostic and interventional procedures.
Liver Access and Biopsy Needle Set	Intended for use in obtaining liver histology samples via a jugular vein approach.
Aprima™ Access Nonvascular Introducer Set	Intended for single-puncture percutaneous access to facilitate placement of an .038 inch (0.97 mm) diameter working wire guide for interventional radiology procedures.
Transluminal Biliary Biopsy Forceps Set	Intended for access to and biopsy of tissue within the biliary ductal system.
White Lumax® Guiding Coaxial Catheter	Intended for the delivery of angioplasty balloons and other types of interventional devices.
Zenith®AAA Endovascular Graft Start Up Kit Zenith®AAA Endovascular Graft Procedure Pack Zenith® Thoracic Endovascular Graft Procedure Pack Zenith® t-Branch Endovascular Graft Procedure Pack Zenith Alpha™ AAA Endovascular Graft Procedure Pack Zenith Alpha™ TAA Endovascular Graft Procedure Pack	These CE marked single components in the procedure pack are used to support the procedure for the implantation of a Zenith endovascular Stent graft. *Please note that this potential adverse event applies only to the catheters with Beacon Tip technology supplied within the procedure pack or kit.*
Transjugular Intrahepatic Portosystemic Shunt Procedure Pack	These CE marked single components in the procedure pack are used to create a Transjugular Intrahepatic Porto Systemic Shunt. *Please note that this potential adverse event applies only to the catheters with Beacon Tip technology supplied within the procedure pack or kit.*

Potential adverse events that may occur as a result of catheter polymer degradation could include loss of device function, separation of a device segment leading to medical intervention, or complications resulting from a separated segment. Such complications include device fragments in the vascular system or other soft tissues. Fragments within the vascular system could result in embolization to the heart or lungs, or occluding blood flow to end organs.

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

Advise on action to be taken by the user:

1. Immediately collect all remaining affected products from your inventory. For the procedure packs or kits either the involved catheter or the entire procedure pack or kit should be collected.

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 devices 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 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
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.

Signature

Annemarie Beglin
Quality Systems Manager

