HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Beacon Tip Angiographic Catheters / William Cook Procedure packs

Priority 2 – Warning

HPRA Safety Notice: SN2016(30) **Issue Date: 23 September 2016**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Cook Incorporated and William Cook Europe	V27566

ISSUE

In April 2016, Cook Medical initiated a recall of all catheters with Beacon Tip technology due to an increase in reports of polymer degradation of the catheter tip, resulting in tip fracture and/or separation. This recall also applies to William Cook Procedure packs that contain Beacon Tip Angiographic Catheters.

Cook Medical has not received an FSN response from all affected customers / hospitals in Ireland. The HPRA wishes to remind users to check their facility for remaining stock.

Please note that Cook Medical has conducted two recent recalls (July & October 2015) relating to the Beacon tip device. The HPRA has confirmation that those actions were completed for all Irish customers.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Please read and follow the steps outlined in the field safety notice (FSN).

2 Check your inventory for the affected product codes.

3 Immediately stop use of these products and quarantine all identified product codes.

4	Complete the FSN Customer Response Form and return it to Cook Medical Europe to arrange for return of the affected product.
5	Ensure that this HPRA Safety Notice and the attached Field Safety Notice is passed on to any organisation or end user where the potentially affected devices have been transferred.

TARGET GROUPS

Interventional Radiologists	Hospital Managers / CEOs
Vascular Surgeons	Risk Managers
Cardiologists	Clinical Directors
Supplies Officers / Managers	Clinical Engineers
Purchasing / Procurement Managers	Nursing Managers
Hospital Personnel	
Theatre Staff	

BACKGROUND

Cook Medical are recalling all Beacon Tip Catheters and procedure packs containing Beacon Tip Catheters from the market.

There has been an increase in reports of polymer degradation of the catheter tip, resulting in tip fracture and/or separation.

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.

Affected products:
Aprima™ Access Nonvascular Introducer Set
Beacon® Tip Centimeter Sizing Catheter,
Beacon® Tip White Vessel Sizing Catheter,
Beacon® Tip Vessel Sizing Catheter
Beacon® Tip Royal Flush® Plus High-Flow Catheter
Beacon® Tip Torcon NB® Advantage Catheter
Haskal Transjugular Intrahepatic Portal Access Set
Liver Access and Biopsy Needle Set
Shuttle® Select Slip-Cath
Slip-Cath® Beacon® Tip Catheter
Transjugular Intrahepatic Portosystemic Shunt Procedure Pack
Transluminal Biliary Biopsy Forceps Set
White Lumax® Guiding Coaxial Catheter
Zenith Alpha™ AAA Endovascular Graft Procedure Pack
Zenith Alpha™ TAA Endovascular Graft Procedure Pack
Zenith® t-Branch Endovascular Graft Procedure Pack
Zenith® Thoracic Endovascular Graft Procedure Pack
Zenith®AAA Endovascular Graft Procedure Pack
Zenith®AAA Endovascular Graft Start Up Kit

For a full list of affected products codes and catalogue identifiers please see the field safety notice and affected product lists.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Cook Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

Telephone: +353 61 334440
Fax: +353 61 334441
E-mail: European.FieldAction@cookmedical.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie