

**Cook Medical Europe**

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

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



Cook Medical Europe
O'Halloran Road,
National Technological
Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441

FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2016FA0002 and 2016FA0002_WCE

Affected devices:

Please reference the Field Safety Notice(s) or list of Product Catalogue Numbers for affected devices.

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:

- None of the affected product remains in our inventory
- We are returning our remaining inventory, please see details listed below

Proforma Invoice Required for Return of Product(s): Yes No

If you are a distributor, have your customers been notified of this Field Safety Corrective Action?

- 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 to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 334441.

Beacon® Tip Torcon NB® Advantage Catheter - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
HNBR5.0-35-100-P-NS-0	G09916	HNBR5.0-35-65-P-NS-SIM2	G11478	HNBR5.0-38-125-P-NS-SIM2	G11517
HNBR5.0-35-100-P-NS-C1	G08623	HNBR5.0-35-70-P-NS-DAV	G27820	HNBR5.0-38-125-P-NS-VERT	G12170
HNBR5.0-35-100-P-NS-C2	G08796	HNBR5.0-35-80-P-NS-C1	G10063	HNBR5.0-38-125-P-NS-VTK	G11642
HNBR5.0-35-100-P-NS-CANADA-041480	G12570	HNBR5.0-35-80-P-NS-C2	G11202	HNBR5.0-38-40-P-NS-0	G24825
HNBR5.0-35-100-P-NS-DAV	G08699	HNBR5.0-35-80-P-NS-CHG4	G13711	HNBR5.0-38-40-P-NS-KMP	G09548
HNBR5.0-35-100-P-NS-FC3	G11204	HNBR5.0-35-80-P-NS-JR3.5	G11453	HNBR5.0-38-65-P-NS-C1	G08446
HNBR5.0-35-100-P-NS-H1	G08421	HNBR5.0-35-80-P-NS-MPA	G09888	HNBR5.0-38-65-P-NS-C2	G08447
HNBR5.0-35-100-P-NS-H3	G08918	HNBR5.0-35-80-P-NS-RDC	G13703	HNBR5.0-38-65-P-NS-C3	G08448
HNBR5.0-35-100-P-NS-HN1	G09741	HNBR5.0-35-80-P-NS-RIM	G12595	HNBR5.0-38-65-P-NS-DAV	G11435
HNBR5.0-35-100-P-NS-HN4	G08917	HNBR5.0-38-100-P-NS-C1	G09344	HNBR5.0-38-65-P-NS-FINCK-101979	G11437
HNBR5.0-35-100-P-NS-HNK1	G27811	HNBR5.0-38-100-P-NS-C2	G09967	HNBR5.0-38-65-P-NS-H1	G11395
HNBR5.0-35-100-P-NS-JB1	G08472	HNBR5.0-38-100-P-NS-CK1	G08839	HNBR5.0-38-65-P-NS-JB1	G11208
HNBR5.0-35-100-P-NS-JB2	G08809	HNBR5.0-38-100-P-NS-DAV	G08581	HNBR5.0-38-65-P-NS-KMP	G09469
HNBR5.0-35-100-P-NS-JB3	G08577	HNBR5.0-38-100-P-NS-H1	G08419	HNBR5.0-38-65-P-NS-LEV1	G11194
HNBR5.0-35-100-P-NS-MAN	G08511	HNBR5.0-38-100-P-NS-H3	G11199	HNBR5.0-38-65-P-NS-LEV2	G11207
HNBR5.0-35-100-P-NS-MIK	G11652	HNBR5.0-38-100-P-NS-HN4	G11200	HNBR5.0-38-65-P-NS-LEV3	G11461
HNBR5.0-35-100-P-NS-MPA	G11468	HNBR5.0-38-100-P-NS-HN5	G09899	HNBR5.0-38-65-P-NS-MPA	G11195
HNBR5.0-35-100-P-NS-SIM1	G08471	HNBR5.0-38-100-P-NS-JB1	G08583	HNBR5.0-38-65-P-NS-MPB	G11470
HNBR5.0-35-100-P-NS-SIM2	G08422	HNBR5.0-38-100-P-NS-JB2	G09654	HNBR5.0-38-65-P-NS-RC1	G08641
HNBR5.0-35-100-P-NS-SIM3	G08597	HNBR5.0-38-100-P-NS-JB3	G11192	HNBR5.0-38-65-P-NS-RC2	G08642
HNBR5.0-35-100-P-NS-VERT	G11483	HNBR5.0-38-100-P-NS-JIM	G11446	HNBR5.0-38-65-P-NS-RDC	G08578
HNBR5.0-35-100-P-NS-WAIKATO	G13803	HNBR5.0-38-100-P-NS-JR4	G10874	HNBR5.0-38-65-P-NS-RH	G10080
HNBR5.0-35-100-P-NS-WNBG	G08805	HNBR5.0-38-100-P-NS-KMP	G11457	HNBR5.0-38-65-P-NS-RIM	G10082
HNBR5.0-35-125-P-NS-C2	G12899	HNBR5.0-38-100-P-NS-MAN	G11201	HNBR5.0-38-65-P-NS-RLG	G09371
HNBR5.0-35-125-P-NS-C-PS	G31970	HNBR5.0-38-100-P-NS-MPA	G11205	HNBR5.0-38-65-P-NS-SHK1.0	G11476
HNBR5.0-35-125-P-NS-DAV	G11375	HNBR5.0-38-100-P-NS-MPB	G11206	HNBR5.0-38-65-P-NS-SIM1	G08677
HNBR5.0-35-125-P-NS-H1	G13258	HNBR5.0-38-100-P-NS-RDC	G11379	HNBR5.0-38-65-P-NS-SIM2	G08625
HNBR5.0-35-125-P-NS-SIM2	G11658	HNBR5.0-38-100-P-NS-RIM	G12870	HNBR5.0-38-65-P-NS-SIM3	G08849
HNBR5.0-35-125-P-NS-VS1	G35974	HNBR5.0-38-100-P-NS-SHETTY-050181	G11475	HNBR5.0-38-65-P-NS-TEGT	G11377
HNBR5.0-35-125-P-NS-WAIKATO	G27813	HNBR5.0-38-100-P-NS-SIM1	G08584	HNBR5.0-38-65-P-NS-VERT	G11485
HNBR5.0-35-40-P-NS-KMP	G09751	HNBR5.0-38-100-P-NS-SIM2	G08420	HNBR5.0-38-65-P-NS-VS1	G11486
HNBR5.0-35-40-P-NS-TEGT	G13804	HNBR5.0-38-100-P-NS-SIM3	G08585	HNBR5.0-38-65-P-NS-VS2	G12715
HNBR5.0-35-60-P-NS-BELL-1.5	G27815	HNBR5.0-38-100-P-NS-TEGT	G11193	HNBR5.0-38-65-P-NS-VSC1	G20791
HNBR5.0-35-65-P-NS-C1	G08441	HNBR5.0-38-100-P-NS-VERT	G11484	HNBR5.0-38-65-P-NS-VSC2	G20038
HNBR5.0-35-65-P-NS-C2	G08442	HNBR5.0-38-100-P-NS-VS2	G11487	HNBR5.0-38-65-P-NS-VSC3	G21042
HNBR5.0-35-65-P-NS-C3	G08443	HNBR5.0-38-100-P-NS-VS3	G11488	HNBR5.0-38-75-P-NS-CHG2.5	G27848
HNBR5.0-35-65-P-NS-DAV	G11414	HNBR5.0-38-100-P-NS-VTK	G27829	HNBR5.0-38-75-P-NS-CHG3	G30040
HNBR5.0-35-65-P-NS-KMP	G11458	HNBR5.0-38-100-P-NS-WNBG	G08582	HNBR5.0-38-75-P-NS-CHG-D	G27846
HNBR5.0-35-65-P-NS-LEV1	G11459	HNBR5.0-38-110-P-NS-VERT	G12128	HNBR5.0-38-80-P-NS-C1	G11203
HNBR5.0-35-65-P-NS-LEV2	G11460	HNBR5.0-38-120-P-NS-DAV	G27830	HNBR5.0-38-80-P-NS-C2	G08586
HNBR5.0-35-65-P-NS-RC1	G08469	HNBR5.0-38-125-P-NS-H1	G11378	HNBR5.0-38-80-P-NS-CHG2.5	G11430
HNBR5.0-35-65-P-NS-RC2	G08470	HNBR5.0-38-125-P-NS-HN2	G11523	HNBR5.0-38-80-P-NS-CHG3	G13573
HNBR5.0-35-65-P-NS-RDC	G08596	HNBR5.0-38-125-P-NS-HN5	G13119	HNBR5.0-38-80-P-NS-CHG-A	G13559
HNBR5.0-35-65-P-NS-RIM	G08444	HNBR5.0-38-125-P-NS-JB1	G11726	HNBR5.0-38-80-P-NS-CHG-B	G13560
HNBR5.0-35-65-P-NS-RLG	G11380	HNBR5.0-38-125-P-NS-JB2	G11883	HNBR5.0-38-80-P-NS-CHG-C	G13561
HNBR5.0-35-65-P-NS-SHK0.8	G32368	HNBR5.0-38-125-P-NS-MPA	G12154	HNBR5.0-38-80-P-NS-CHG-D	G13562
HNBR5.0-35-65-P-NS-SIM1	G09853	HNBR5.0-38-125-P-NS-SIM1	G12072	HNBR5.0-38-80-P-NS-CHG-E	G13563

Beacon® Tip Torcon NB® Advantage Catheter - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
HNBR5.0-38-80-P-NS-JR1	G13370	HNBR5.0-38-80-P-NS-SIM2	G11886	HNBR5.0-35-65-P-NS-VANSCHIE2	G13794
HNBR5.0-38-80-P-NS-MIK	G09312	HNBR5.0-38-80-P-NS-VS	G11209	HNBR5.0-35-65-P-NS-VANSCHIE3	G13792
HNBR5.0-38-80-P-NS-MK1A	G11465	HNBR5.0-38-80-P-NS-VS1	G11189	HNBR5.0-35-65-P-NS-VANSCHIE4	G13783
HNBR5.0-38-80-P-NS-MPA	G11467	HNBR5.0-38-80-P-NS-VS2	G11190	HNBR5.0-35-65-P-NS-VANSCHIE5	G13793
HNBR5.0-38-80-P-NS-MPB	G11469	HNBR5.0-38-80-P-NS-VS3	G11191	HNBR5.0-35-40-P-NS-VANSCHIE1	G31410
HNBR5.0-38-80-P-NS-RC1	G11530	HNBR5.0-35-125-P-NS-VANSCHIE1	G35733	HNBR5.0-35-40-P-NS-VANSCHIE2	G31409
HNBR5.0-38-80-P-NS-RC2	G11471	HNBR5.0-35-125-P-NS-VANSCHIE2	G35734	HNBR5.0-35-40-P-NS-VANSCHIE3	G31408
HNBR5.0-38-80-P-NS-RDC	G12293	HNBR5.0-35-125-P-NS-VANSCHIE3	G35735	HNBR6.0-38-40-P-NS-KMP	G27856
HNBR5.0-38-80-P-NS-RH	G27852	HNBR5.0-35-125-P-NS-VANSCHIE4	G35736	HNBR6.0-38-65-P-NS-0	G27858
HNBR5.0-38-80-P-NS-RIM	G10028	HNBR5.0-35-125-P-NS-VANSCHIE5	G35737	HNBR6.0-38-65-P-NS-KMP	G27860
HNBR5.0-38-80-P-NS-RLG	G27853	HNBR5.0-35-65-P-NS-VANSCHIE1	G13795		

Beacon® Tip Royal Flush® Plus High-Flow Catheter - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
HNR5.0-35-100-P-10S-PIG	G09059	HNR5.0-35-70-ST-10S-PIG	G09050	HNR5.0-38-100-P-10S-CFP	G11268
HNR5.0-35-100-P-8S-VCF	G31403	HNR5.0-35-70-P-4S-PED	G11281	HNR5.0-38-100-P-10S-PIG	G09285
HNR5.0-35-100-P-NS-0	G10313	HNR5.0-35-80-P-8S-NEFF-CANADA-082098	G11860	HNR5.0-38-100-P-NS-0	G27874
HNR5.0-35-100-ST-10S-0	G09565	HNR5.0-35-90-P-10S-0	G09412	HNR5.0-38-110-P-10S-0	G09461
HNR5.0-35-100-ST-10S-PIG	G09525	HNR5.0-35-90-P-10S-CFP	G11266	HNR5.0-38-110-P-10S-PIG	G11269
HNR5.0-35-110-P-10S-0	G11241	HNR5.0-35-90-P-6S-PED	G11729	HNR5.0-38-70-P-10S-0	G11270
HNR5.0-35-110-P-10S-PIG	G11265	HNR5.0-35-90-P-10S-PIG	G09408	HNR5.0-38-70-P-10S-CFP	G11271
HNR5.0-35-65-P-8S-VCF	G12129	HNR5.0-35-90-P-10S-PIG-RICKETTS-081983	G11282	HNR5.0-38-70-P-10S-PIG	G11272
HNR5.0-35-70-P-10S-0	G09411	HNR5.0-35-90-P-8S-VCF	G12799	HNR5.0-38-70-P-NS-0	G11289
HNR5.0-35-70-P-10S-CFP	G11262	HNR5.0-35-90-ST-10S-0	G11641	HNR5.0-38-80-P-10S-OPC	G27877
HNR5.0-35-70-P-10S-PIG	G08832	HNR5.0-35-90-ST-10S-PIG	G09197	HNR5.0-38-90-P-10S-0	G11273
HNR5.0-35-70-P-10S-PIG-RICKETTS-081983	G11280	HNR5.0-35-100-P-10S-0	G09697	HNR5.0-38-90-P-10S-CFP	G11274
HNR5.0-35-70-P-NS-0	G11959	HNR5.0-35-100-P-10S-CFP	G11264	HNR5.0-38-90-P-10S-PIG	G11275
HNR5.0-35-70-ST-10S-0	G09564	HNR5.0-38-100-P-10S-0	G11267		

Slip-Cath® Beacon® Tip Catheter - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
SCBR5.0-38-100-P-NS-0	G12005	SCBR5.0-38-100-P-NS-TEGT	G23694	SCBR5.0-38-65-P-NS-H1	G13319
SCBR5.0-38-100-P-NS-C2	G12008	SCBR5.0-38-100-P-NS-VERT	G12007	SCBR5.0-38-65-P-NS-KMP	G12156
SCBR5.0-38-100-P-NS-DAV	G11996	SCBR5.0-38-100-P-NS-VTK	G13163	SCBR5.0-38-65-P-NS-LEV1	G12798
SCBR5.0-38-100-P-NS-H1	G11991	SCBR5.0-38-125-P-NS-0	G32366	SCBR5.0-38-65-P-NS-MPA	G23689
SCBR5.0-38-100-P-NS-HN4	G23693	SCBR5.0-38-125-P-NS-SIM1	G32369	SCBR5.0-38-65-P-NS-RC2	G13272
SCBR5.0-38-100-P-NS-JB1	G11997	SCBR5.0-38-125-P-NS-SIM2	G13200	SCBR5.0-38-65-P-NS-RDC	G13092
SCBR5.0-38-100-P-NS-JB2	G11998	SCBR5.0-38-125-P-NS-TEGT	G32367	SCBR5.0-38-65-P-NS-RIM	G11995
SCBR5.0-38-100-P-NS-KMP	G28535	SCBR5.0-38-125-P-NS-VERT	G12168	SCBR5.0-38-65-P-NS-SIM1	G12716
SCBR5.0-38-100-P-NS-MAN	G11999	SCBR5.0-38-125-P-NS-VTK	G12082	SCBR5.0-38-125-P-NS-DAV	G13413
SCBR5.0-38-100-P-NS-MPA	G12002	SCBR5.0-38-40-P-NS-KMP	G11993	SCBR5.0-38-125-P-NS-H1	G23696
SCBR5.0-38-100-P-NS-NTR	G23695	SCBR5.0-38-65-P-NS-0	G12009	SCBR5.0-38-125-P-NS-JB1	G13530
SCBR5.0-38-100-P-NS-RVC	G43120	SCBR5.0-38-65-P-NS-C1	G12003	SCBR5.0-38-65-P-NS-TEGT	G12179
SCBR5.0-38-100-P-NS-SIM1	G12000	SCBR5.0-38-65-P-NS-C2	G11994	SCBR5.0-38-80-P-NS-C2	G12006
SCBR5.0-38-100-P-NS-SIM2	G11992	SCBR5.0-38-65-P-NS-C3	G12004	SCBR5.0-38-80-P-NS-MPA	G23692
SCBR5.0-38-100-P-NS-SIM3	G12001	SCBR5.0-38-65-P-NS-DAV	G23688	SCBR5.0-38-80-P-NS-RH	G36214

Slip-Cath® Beacon® Tip Catheter - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
SCBR5.0-38-65-P-NS-SIM2	G23691	SCBR5.0-38-80-P-NS-VS	G13431	SCBR5.0-38-80-P-NS-VS3	G13434
SCBR5.0-38-65-P-NS-TC	G36320	SCBR5.0-38-80-P-NS-VS1	G13432	SCBR5.5-35-60-P-NS-PATEL	G51570
SCBR5.0-38-65-P-NS-TC-BNK	G36322	SCBR5.0-38-80-P-NS-VS2	G13433	SCBR6.5-35-60-P-NS-PATEL	G51571

Shuttle® Select Slip-Cath - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
SCBR5.5-35-125-P-NS-H1-SHTL	G31129	SCBR5.5-35-125-P-NS-VTK-SHTL	G36359	SCBR6.5-35-125-P-NS-JB2-SHTL	G36364
SCBR5.5-35-125-P-NS-JB1-SHTL	G31130	SCBR5.5-35-135-P-NS-ANG-SHTL	G48154	SCBR6.5-35-125-P-NS-SIM1-SHTL	G23701
SCBR5.5-35-125-P-NS-JB2-SHTL	G36361	SCBR5.5-35-150-P-NS-0-SHTL	G23705	SCBR6.5-35-125-P-NS-SIM2-SHTL	G36363
SCBR5.5-35-125-P-NS-MPA-SHTL	G23697	SCBR5.5-35-150-P-NS-ANG-SHTL	G23704	SCBR6.5-35-125-P-NS-VERT-SHTL	G23700
SCBR5.5-35-125-P-NS-SIM1-SHTL	G23699	SCBR5.5-35-75-P-NS-ANG-SHTL	G48152	SCBR6.5-35-125-P-NS-VTK-SHTL	G36362
SCBR5.5-35-125-P-NS-SIM2-SHTL	G36360	SCBR6.5-35-125-P-NS-H1-SHTL	G31134		
SCBR5.5-35-125-P-NS-VERT-SHTL	G23698	SCBR6.5-35-125-P-NS-JB1-SHTL	G31135		

Beacon® Tip Centimeter Sizing Catheter - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
NR5.0-35-100-P-10S-0-CSC-20	G31214	NR5.0-35-100-P-10S-VCF-CSC-20	G31221	NR5.0-35-70-P-10S-PIG-CSC-20	G31215
NR5.0-35-100-P-10S-PIG-CSC-20	G31216	NR5.0-35-70-P-10S-0-CSC-20	G31213	NR5.0-35-70-P-10S-VCF-CSC-20	G31220

Beacon® Tip White Vessel Sizing Catheter - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
NR5.0-35-100-P-10S-PIG-WSC	G31226	NR5.0-35-70-P-10S-0-WSC	G31228	NR5.0-35-70-P-10S-PIG-WSC	G31224
NR5.0-35-65-P-6S-VCF-WSC	G31229	NR5.0-35-70-P-10S-CFP-WSC	G31227		

Beacon® Tip Vessel Sizing Catheter - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
NR5.0-35-70-P-10S-VCF-CAVA	G31232	NR5.0-35-90-P-10S-PIG-CAVA	G31231	NR5.0-35-90-P-10S-VCF-CAVA	G31233
NR5.0-35-70-P-10S-PIG-CAVA	G31230				

Liver Access and Biopsy Needle Set - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
LABS-100	G08283	LABS-200	G08284	LABS-200-CHP-A	G10590

Haskal Transjugular Intrahepatic Portal Access Set - All lots affected
White Lumax® Guiding Coaxial Catheter - All lots affected
Transluminal Biliary Biopsy Forceps Set - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
HTPS-100	G36126	LMGRF-7.0C-80-MPA-PULM	G11164	BBFS-100	G26088

Aprima™ Access Nonvascular Introducer Set - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
NPAS-100-HC-NT-U-SST	G52963	NPAS-104-HC-NT-JWG-U-SST	G52966	NPAS-108-HC-NT-U-SST	G25516
NPAS-100-HC-U-SST	G52962	NPAS-104-HC-NT-U-SST	G52965	NPAS-120-HC-NT-U-SST	G25517
NPAS-101-HC-NT-U-SST	G23067	NPAS-104-HC-U-SST	G52964	NSSW-4.0-18-NPAS-100-HC-SST	G34253
NPAS-101-HC-U-SST	G23066	NPAS-105-HC-NT-U-SST	G52967		

Transjugular Intrahepatic Portosystemic Shunt Procedure Pack - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
TIPSS-100	G19708	TIPSS-200	G19846

Zenith Alpha™ AAA Endovascular Graft Procedure Pack - All lots affected

Reference Part Number	Global Product Number
ZAPP-A	G34907

Zenith Alpha™ TAA Endovascular Graft Procedure Pack - All lots affected

Reference Part Number	Global Product Number
ZAPP-T	G34908

Zenith® AAA Endovascular Graft Start Up Kit - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
ESSK-2	G33036	ESSK-3	G33037

Zenith® AAA Endovascular Graft Procedure Pack - All lots affected

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
ESSK-3FR	G50630	ESSK-AAA	G50631

Zenith® t-Branch Endovascular Graft Procedure Pack - All lots affected

Reference Part Number	Global Product Number
ESSK-T-BRANCH	G24065

Zenith® Thoracic Endovascular Graft Procedure Pack - All lots affected

Reference Part Number	Global Product Number
ESSK-T	G39775