



April 15, 2016

URGENT: MEDICAL DEVICE RECALL

ATTENTION:
Risk Management / Recall Administration

Our records indicate that you may have received some of the affected products listed below.

Details on affected devices:

Product Brand Name	Catalog Identifier*	Lot Number
Beacon [®] Tip Torcon NB [®] Advantage Catheter	HNBR5.0 HNBR6.0	All lots
Beacon [®] Tip Royal Flush [®] Plus High-Flow Catheter	HNR5.0	All lots
Beacon [®] Tip Centimeter Sizing Catheter, Beacon [®] Tip White Vessel Sizing Catheter, Beacon [®] Tip Vessel Sizing Catheter	NR5.0	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
FluoroSet [®] Radiographic Tubal Assessment Set	J-RTAS-100	All lots
Haskal Transjugular Intrahepatic Portal Access Set	HTPS	All lots
Kumpe Access Catheter	023565-BT	All lots
Liver Access and Biopsy Needle Set	LABS	All lots
Neff D'Agostino Percutaneous Access Set	NPAS-100-D'Agostino-B-050393	All lots
Aprima [™] Access Nonvascular Introducer Set	NPAS/-SST NSSW/-SST	All lots
Selective Salpingography Catheter with Beacon [®] Tip	J-SSG-504000	All lots
Transluminal Biliary Biopsy Forceps Set	BBFS	All lots
White Lumax [®] Guiding Coaxial Catheter	LMGRF-7.0C-80-MPA-PULM	All lots

**Please refer to the complete product listing for further information.*

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.

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, genitourinary 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.



Intended use for affected products:

Catheters with Beacon Tip technology are intended for use by physicians who are trained and experienced in each of the procedures for which these devices are indicated for use. See below for a complete list of intended uses for the affected products.

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.
FluoroSet® Radiographic Tubal Assessment Set	Used for instillation of contrast media into the uterine cavity for radiographic evaluation of the uterine cavity and for injection of appropriate contrast media into the fallopian tubes for evaluation of tubal patency.
Haskal Transjugular Intrahepatic Portal Access Set	Intended for transjugular liver access in diagnostic and interventional procedures.
Kumpe Access Catheter	Used in combination with a HiWire®, Bentson, or other flexible-tipped wire guide to gain difficult ureteral access beyond a redundant or tortuous ureteral segment.
Liver Access and Biopsy Needle Set	Intended for use in obtaining liver histology samples via a jugular vein approach.
Neff D'Agostino Percutaneous Access Set 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.
Selective Salpingography Catheter with Beacon® Tip	Used for injection of contrast medium into the fallopian tube(s) for selective salpingography.
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.

Action to be taken:

1. Examine inventory immediately to determine if you have affected product and quarantine affected product(s).
2. Return affected product(s) to Stericycle Expert Solutions (a third party Recall administration service provider) using the enclosed label with a copy of the Acknowledgement and Receipt Form to receive a product credit.
3. **Even if you do not have affected product on hand**, you must still complete the Acknowledgement and Receipt Form and return via fax to 888-679-5277 or email to cookmedical4674@stericycle.com.
4. Report adverse events to Cook Medical Customer Relations at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30 am and 5:00 pm (Eastern Time), or by email to: CustomerRelationsNA@cookmedical.com.



COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 USA
OFFICE 812.339.2235 PHONE 800.468.1379 EXT 102232
FAX 812.335.5710
WWW.COOKMEDICAL.COM

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA:

- Online at: <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail)
- Call the FDA at: 1-800-FDA-1088

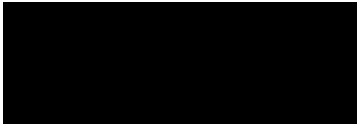
Transmission of this notice:

This notice must be shared with appropriate personnel, including down to the user level, within your organization or to any organization where the potentially affected devices have been transferred.

This action is being taken with the knowledge of the Food and Drug Administration.

We recognize this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. Should you have any medical questions or concerns, please contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235. For information regarding the recall, please contact *Stericycle Expert Solutions* at 866.201.9067. We look forward to your response.

Cook Medical



B. Thomas Roberts
Vice President, Quality Assurance

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
NR5.0-35-100-P-10S-0-CSC-20	G31214
NR5.0-35-100-P-10S-PIG-CSC-20	G31216
NR5.0-35-100-P-10S-VCF-CSC-20	G31221
NR5.0-35-70-P-10S-0-CSC-20	G31213
NR5.0-35-70-P-10S-PIG-CSC-20	G31215
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
NR5.0-35-100-P-10S-PIG-WSC	G31226
NR5.0-35-65-P-6S-VCF-WSC	G31229
NR5.0-35-70-P-10S-0-WSC	G31228
NR5.0-35-70-P-10S-CFP-WSC	G31227
NR5.0-35-70-P-10S-PIG-WSC	G31224

Beacon® Tip Vessel Sizing Catheter - All lots affected

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

Liver Access and Biopsy Needle Set - All lots affected

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

Haskal Transjugular Intrahepatic Portal Access Set - All lots affected

Reference Part Number	Global Product Number
HTPS-100	G36126

White Lumax® Guiding Coaxial Catheter - All lots affected

Reference Part Number	Global Product Number
LMGRF-7.0C-80-MPA-PULM	G11164

FluoroSet® Radiographic Tubal Assessment Set - All lots affected

Reference Part Number	Global Product Number
J-RTAS-100	G51608

Kumpe Access Catheter - All lots affected

Reference Part Number	Global Product Number
023565-BT	G18074

Neff D'Agostino Percutaneous Access Set - All lots affected

Reference Part Number	Global Product Number
NPAS-100-D'AGOSTINO-B-050393	G08403

Selective Salpingography Catheter with Beacon® Tip - All lots affected

Reference Part Number	Global Product Number
J-SSG-504000	G17868

Transluminal Biliary Biopsy Forceps Set - All lots affected

Reference Part Number	Global Product Number
BBFS-100	G26088

Aprima™ Access Nonvascular Introducer Set

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		



COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 USA
OFFICE 812.339.2235 PHONE 800.468.1379 EXT 102232
FAX 812.335.5710
WWW.COOKMEDICAL.COM

URGENT: PLEASE RETURN THIS FORM

Acknowledgement and Receipt Form

Response is required.

Please refer to the complete product listing for further information.

Please complete the following information regarding the Medical Device Recall on the products listed above:

Date:	Customer Account #:
Customer Name:	Street Address:
City:	State, Postal Code:
Form Completed By:	Department/Phone Number:

Actions Taken:

1. I have received the April 15, 2016 Medical Device Recall and understand the recall instructions provided in the letter.

Yes

☐

No

☐

2. Have you experienced any adverse events associated with the recalled product?

Yes

☐

No

☐

3. If yes, please explain the adverse event below:

Distributors:

This Medical Device Recall should be shared with appropriate personnel within your organization or to any organization where the potentially affected devices have been transferred.

Please confirm the following:

1. I have checked my stock and have quarantined inventory.

Yes

☐

No

☐

2. I have notified my customers of the recall.

Yes

☐

No

☐

3. If no, please provide justification:



- Upon completion, please return this Acknowledgement and Receipt Form and the Product List to Stericycle Expert Solutions via fax to 888-679-5277 or email to cookmedical4674@stericycle.com.
- For information regarding the recall, contact *Stericycle Expert Solutions* at 866.201.9067.
- For medical questions or to report adverse events contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235.

Please list the quantity of affected product at your facility to be returned or indicate "NONE" if product is no longer in your inventory or with your customers.

[illegible]