Important Safety Information on Cook Catheters with Beacon Tip Technology – Recall due to Degradation of Catheter Tip

2016/04/29

Audience
Healthcare professionals in hospitals and health care facilities who use Cook catheters with Beacon Tip technology.

Please distribute to relevant Departments and appropriate personnel and to any organization where the potentially affected devices have been transferred.

Key messages

- **Cook Catheters with Beacon Tip technology have been recalled due to polymer degradation of the catheter tip, which could result in tip fracture and/or separation.**
- **As outlined in the Recall Notice issued by Cook Medical on April 19, 2016, healthcare professionals should return the devices.**
- **Health Canada is aware that this may cause a shortage issue. To obtain information on other products that can be used as alternatives, healthcare professionals should contact Cook Medical directly.**

What is the issue?
Cook Medical has initiated a recall on catheters with Beacon Tip technology following 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 could include loss of device function and separation of a device segment. Complications resulting from a separated segment could 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.

Products affected
The following products manufactured by Cook Incorporated and distributed by Cook Medical are impacted:

Product Brand Name	Catalog Identifier	Lot Number
Beacon® Tip Torcon NB® Advantage Catheter	All beginning HNBR5.0- All beginning HNBR6.0-	All lots
Beacon® Tip Royal Flush® Plus High-Flow Catheter	All beginning HNR5.0-	All lots
Beacon® Tip Centimeter Sizing Catheter, Beacon® Tip White Vessel Sizing Catheter, Beacon® Tip Vessel Sizing Catheter	All beginning NR5.0-	All lots
Slip-Cath® Beacon® Tip Catheter and Shuttle® Select Slip-Cath	All beginning SCBR5.0- All beginning SCBR5.5- All beginning SCBR6.5-	All lots
FluoroSet® Radiographic Tubal Assessment Set	J-RTAS-100	All lots
Haskal Transjugular Intrahepatic Portal Access Set	All beginning HTPS-	All lots
Kumpe Access Catheter	023565-BT	All lots
Liver Access and Biopsy Needle Set	All beginning LABS-	All lots
Neff D'Agostino Percutaneous Access Set	NPAS-100-D'AGOSTINO-B-050393	All lots
Aprima™ Access Nonvascular Introducer Set	All with both beginning NPAS- and ending -SST All with both beginning NSSW- and ending -SST	All lots
Selective Salpingography Catheter with Beacon® Tip	J-SSG-504000	All lots
Transluminal Biliary Biopsy Forceps Set	All beginning BBFS-	All lots
White Lumax® Guiding Coaxial Catheter	LMGRF-7.0C-80-MPA-PULM	All lots

Background information
Cook Medical has identified an increase in reports of polymer degradation of the catheter tip, resulting in tip fracture and/or separation. A comprehensive investigation by the company is ongoing to determine the root cause, including review of materials, manufacturing variables, and environmental factors. While Cook has not been able to replicate the failure, preliminary investigation indicates that environmental conditions such as storage temperature, humidity, and the use of Vaporized Hydrogen Peroxide (VHP) for whole-room decontamination may be contributing to the occurrence.

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 a .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	Intended for access to and biopsy of tissue within the

Set	biliary ductal system.
White Lumax® Guiding Coaxial Catheter	Intended for the delivery of angioplasty balloons and other types of interventional devices.

Information for consumers
The products affected by this recall are sold directly to healthcare professionals and are intended strictly for professional use.

Information for health care professionals
Health care professionals should:

- examine inventory immediately to identify and quarantine affected product(s).
- return affected product(s) to Stericycle Expert Solutions (a third party Recall administration service provider) using the label provided with the recall letter.
- complete the Acknowledgement and Receipt Form (provided with the recall letter) and return via fax to 888-679-5277 or email to cookmedical4674@stericycle.com.
- contact Cook Medical directly (at 800-457-4500 or +1-812-339-2235 or by email at CustomerRelationsNA@cookmedical.com) or your Sales Representative for information on products that can be used as alternatives.

Action taken by Health Canada
Health Canada is communicating this important recall information to healthcare professionals and to the public through its MedEffect Canada website and MedEffectTM e-Notice. Health Canada is also monitoring the recall and the implementation of necessary corrective and preventive actions.

Report health or safety concerns
Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of tip fracture and/or separation or other serious or unexpected side effects in products with Beacon Tip technology should be reported to **Cook Medical** and/or Health Canada.

Cook (Canada) Inc.
165 Mostar Street
Stouffville, ON L4A 0Y2

Cook Medical Customer Relations:
Telephone: 1-800-457-4500 or +1-812-339-2235
Email: CustomerRelationsNA@cookmedical.com

To correct your mailing address or fax number, contact Cook Medical Customer Relations

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php)

For other health product inquiries related to this communication, contact Health Canada at:

Regulatory and Operations Regions Branch
E-mail: mdcu_ucim@hc-sc.gc.ca
Telephone: 1-800-267-9675
Fax: 1-613-946-5636

Original signed by,

Bill A. Bobbie
President, Cook (Canada) Inc.