



Michael R. Pence  
Governor

Jerome M. Adams, MD, MPH  
State Health Commissioner

**DATE:** October 14, 2015  
**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer  
**FROM:** Laurie Kidwell, RRT Supervisor  
Food Protection Program  
**SUBJECT:** Cook Medical – RECALL [Medical Device]

\*\*\*EXPANDED RECALL\*\*\*

**AFFECTED PRODUCT:** Beacon® Tip Angiographic Catheters

**SUMMARY:** Unclassified Recall; The recall has been initiated because the Beacon Tip Angiographic Catheters have been found to exhibit tip splitting or separation, which has resulted in 42 Medical Device Reports. Tip splitting has the potential to lead to loss of device function.

This recall includes all lots of these select sizes of the Beacon® Tip Angiographic Catheters. This recall is an expansion of the voluntary lot-specific recall issued on July 2, 2015. The products include specific versions of the Torcon NB® Advantage Beacon®Tip Catheters (catalog prefix HNBR4.0, HNBR4.1 and only HNBR5.0 with the RUC suffix), Royal Flush® Plus Beacon®Tip High-Flow Catheters (catalog prefix HNR4.0), and Slip-Cath® Beacon® Tip Hydrophilic Catheters (catalog prefix SCBR4.0, SCBR4.1, and only SCBR5.0 with the RUC suffix), and Shuttle®Select Slip-Cath® catheters (catalog prefix SCBR4.5). Below is a list of product catalog numbers.

The recalled products have been distributed nationwide.

**SUGGESTED ACTION:** For consumer inquiry only. Consumers with questions may contact Cook Medical Customer Relations at 1-800-457-4500 or 1-812-339- 2235, Monday through Friday, between 7:30 a.m. and 5:00 p.m. Eastern time or by email at [CustomerRelationsNA@cookmedical.com](mailto:CustomerRelationsNA@cookmedical.com).

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### Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

For Immediate Release

October 9, 2015



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[www.statehealth.in.gov](http://www.statehealth.in.gov)

To promote and provide essential public health services.

Contact

## Consumers

Cook Medical Customer Relations  
[CustomerRelationsNA@cookmedical.com](mailto:CustomerRelationsNA@cookmedical.com)  
1-800-457-4500 or 1-812-339- 2235

## Media

Marsha Lovejoy, Global Manager, Corporate Content Strategy  
[marsha.lovejoy@cookmedical.com](mailto:marsha.lovejoy@cookmedical.com)  
812.339.2235 ext. 2750  
Firm Press Release

## Original Recall

Purpose of the Press Release:

On October 7, 2015, Cook Medical initiated a voluntary recall for select sizes of Beacon® Tip Angiographic Catheters. This recall includes all lots of these select sizes of the Beacon® Tip Angiographic Catheters. This recall is an expansion of the voluntary lot-specific recall issued on July 2, 2015. The products include specific versions of the Torcon NB® Advantage Beacon®Tip Catheters (catalog prefix HNBR4.0, HNBR4.1 and only HNBR5.0 with the RUC suffix), Royal Flush® Plus Beacon®Tip High-Flow Catheters (catalog prefix HNR4.0), and Slip-Cath® Beacon® Tip Hydrophilic Catheters (catalog prefix SCBR4.0, SCBR4.1, and only SCBR5.0 with the RUC suffix), and Shuttle®Select Slip-Cath® catheters (catalog prefix SCBR4.5).

The Beacon Tip Angiographic Catheters have been found to exhibit tip splitting or separation, which has resulted in 42 Medical Device Reports. Tip splitting has the potential to lead to loss of device function. Tip separation may require medical intervention to retrieve a separated segment or, if not retrieved, has the potential to occlude blood flow to end organs.

The Beacon Tip Angiographic Catheters in this recall were distributed globally between September 2012 and September 2015. Product can be identified by the part number provided on the outer package product label. The part numbers for products subject to this recall are those with catalog number prefixes and suffixes listed in the initial paragraph above. All lots currently in distribution are affected.

Cook Medical has notified its customers and distributors by recall notification letters. The letters requested that all customers and distributors quarantine and discontinue use of all potentially affected units and return the affected product to the company as soon as possible for credit.

The FDA and other regulatory agencies around the world have been notified of this action.

Consumers with questions may contact Cook Medical Customer Relations at 1-800-457-4500 or 1-812-339-2235, Monday through Friday, between 7:30 a.m. and 5:00 p.m. Eastern time or by email at [CustomerRelationsNA@cookmedical.com](mailto:CustomerRelationsNA@cookmedical.com). Adverse reactions or quality problems experienced with the use

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Complete and submit the report online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) or via regular mail or fax. Download the form at [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, and then complete and return to the address on the preaddressed form, or submit by fax to 1-800-FDA-0178. Adverse events may also be reported to Cook Medical Customer Relations at 1-800-457-4500 or 1-812-339-2235, Monday through Friday, between 7:30 a.m. and 5:00 p.m. Eastern time or by email at [CustomerRelationsNA@cookmedical.com](mailto:CustomerRelationsNA@cookmedical.com).

## Beacon® Tip Angiographic Catheters Recall Extension - Affected Lot Numbers

### Beacon® Tip Royal Flush® Plus High-Flow Catheter

#### Product Catalog Numbers

HNR4.0-35-100-P-10S-0, HNR4.0-35-100-P-10S-CFP, HNR4.0-35-100-P-10S-PIG, HNR4.0-35-100-P-6S-VCF, HNR4.0-35-100-P-NS-0, HNR4.0-35-100-P-NS-DAV, HNR4.0-35-100-P-NS-SIM1, HNR4.0-35-100-P-NS-SIM2, HNR4.0-35-100-ST-10S-0, HNR4.0-35-100-ST-10S-PIG, HNR4.0-35-100-ST-6S-PED, HNR4.0-35-110-P-10S-PIG, HNR4.0-35-120-P-6S-PED, HNR4.0-35-120-ST-6S-PED, HNR4.0-35-125-P-10S-0, HNR4.0-35-125-P-10S-PIG, HNR4.0-35-50-P-NS-0, HNR4.0-35-65-P-8S-VCF, HNR4.0-35-70-P-10S-0, HNR4.0-35-70-P-10S-CFP, HNR4.0-35-70-P-10S-PIG, HNR4.0-35-70-P-4S-PED, HNR4.0-35-70-P-6S-PED, HNR4.0-35-70-P-NS-0, HNR4.0-35-70-ST-10S-0, HNR4.0-35-70-ST-10S-PIG, HNR4.0-35-70-ST-6S-PED, HNR4.0-35-90-P-10S-0, HNR4.0-35-90-P-10S-CFP, HNR4.0-35-90-P-10S-PIG, HNR4.0-35-90-P-6S-PED, HNR4.0-35-90-P-8S-VCF, HNR4.0-35-90-P-NS-0, HNR4.0-35-90-ST-10S-0, HNR4.0-35-90-ST-10S-PIG

All  
Lots

### Beacon® Tip Torcon NB® Advantage Catheter

#### Product Catalog Numbers

HNBR4.0-35-100-P-NS-0, HNBR4.0-35-100-P-NS-C1, HNBR4.0-35-100-P-NS-C2, HNBR4.0-35-100-P-NS-CANADA-041480, HNBR4.0-35-100-P-NS-DAV, HNBR4.0-35-100-P-NS-H1, HNBR4.0-35-100-P-NS-JB1, HNBR4.0-35-100-P-NS-JB2, HNBR4.0-35-100-P-NS-JB3, HNBR4.0-35-100-P-NS-JIM, HNBR4.0-35-100-P-NS-KMP, HNBR4.0-35-100-P-NS-MPA, HNBR4.0-35-100-P-NS-O1, HNBR4.0-35-100-P-NS-SIM1, HNBR4.0-35-100-P-NS-SIM2, HNBR4.0-35-100-P-NS-SIM3, HNBR4.0-35-100-P-NS-VERT, HNBR4.0-35-100-P-NS-VTK, HNBR4.0-35-100-P-NS-WNBG, HNBR4.0-35-125-P-NS-0, HNBR4.0-35-125-P-NS-DAV, HNBR4.0-35-125-P-NS-H1, HNBR4.0-35-125-P-NS-JB1, HNBR4.0-35-125-P-NS-JB2, HNBR4.0-35-125-P-NS-MPA, HNBR4.0-35-125-P-NS-SIM2, HNBR4.0-35-125-P-NS-VERT, HNBR4.0-35-125-P-NS-VTK, HNBR4.0-35-125-P-NS-WNBG, HNBR4.0-35-40-P-NS-KMP, HNBR4.0-35-65-P-NS-0, HNBR4.0-35-65-P-NS-C1, HNBR4.0-35-65-P-NS-C2, HNBR4.0-35-65-P-NS-C3, HNBR4.0-35-65-P-NS-DAV, HNBR4.0-35-65-P-NS-H1, HNBR4.0-35-65-P-NS-JB1, HNBR4.0-35-65-P-NS-KMP, HNBR4.0-35-65-P-NS-MPA, HNBR4.0-35-65-P-NS-RC1, HNBR4.0-35-65-P-NS-RC2, HNBR4.0-35-65-P-NS-RDC, HNBR4.0-35-65-P-NS-RIM, HNBR4.0-35-65-P-NS-SIM1, HNBR4.0-35-65-P-NS-SIM2, HNBR4.0-35-80-P-NS-C1, HNBR4.0-35-80-P-NS-C2, HNBR4.0-35-80-P-NS-JL2, HNBR4.0-35-80-P-NS-JL2.5, HNBR4.0-35-80-P-NS-JL3, HNBR4.0-35-80-P-NS-JR1, HNBR4.0-35-80-P-NS-JR2, HNBR4.0-35-80-P-NS-JR3.5, HNBR4.0-35-80-P-NS-RH, HNBR4.0-35-80-P-NS-RLG, HNBR4.0-35-80-P-NS-VS, HNBR4.0-35-80-P-NS-VS1, HNBR4.0-35-80-P-NS-VS2, HNBR4.0-35-80-P-NS-VS3, HNBR4.0-NT-100-P-NS-H1, HNBR4.0-NT-80-P-NS-RC1, HNBR4.0-NT-80-P-NS-RIM, HNBR4.0-NT-80-P-NS-RLG, HNBR4.1-35-100-P-NS-0, HNBR4.1-35-100-P-NS-C1, HNBR4.1-35-100-P-NS-C2, HNBR4.1-35-100-P-NS-DAV, HNBR4.1-35-100-P-NS-H1, HNBR4.1-35-100-P-NS-JB1, HNBR4.1-35-100-P-NS-JB2, HNBR4.1-35-100-P-NS-JB3, HNBR4.1-35-100-P-NS-KMP, HNBR4.1-35-100-P-NS-MPA, HNBR4.1-35-100-P-NS-O1, HNBR4.1-35-100-P-NS-SIM1, HNBR4.1-35-100-P-NS-SIM2, HNBR4.1-35-100-P-NS-SIM3, HNBR4.1-35-100-P-NS-VERT, HNBR4.1-35-100-P-NS-WNBG, HNBR4.1-35-110-P-NS-JB1, HNBR4.1-35-110-P-NS-JB2, HNBR4.1-35-110-P-NS-WNBG, HNBR4.1-35-120-P-NS-JB2, HNBR4.1-35-130-P-NS-DAV-T, HNBR4.1-35-40-P-NS-KMP, HNBR4.1-35-65-P-NS-C1, HNBR4.1-35-65-P-NS-C2, HNBR4.1-35-65-P-NS-DAV, HNBR4.1-35-65-P-NS-H1, HNBR4.1-35-65-P-NS-JB1, HNBR4.1-35-65-P-NS-KMP, HNBR4.1-35-65-P-NS-LEV1, HNBR4.1-35-65-P-NS-MPA, HNBR4.1-35-65-P-NS-RC1, HNBR4.1-35-65-P-NS-RC2, HNBR4.1-35-65-P-NS-RDC, HNBR4.1-35-65-P-NS-RIM, HNBR4.1-35-65-P-NS-SHK1.0, HNBR4.1-35-65-P-NS-SIM1, HNBR4.1-35-75-P-NS-CHG-D, HNBR4.1-35-80-P-NS-C1, HNBR4.1-35-80-P-NS-C2, HNBR4.1-35-80-P-NS-JL2, HNBR4.1-35-80-P-NS-JL2.5, HNBR4.1-35-80-P-NS-JL3, HNBR4.1-35-80-P-NS-JR1, HNBR4.1-35-80-P-NS-JR2, HNBR4.1-35-80-P-NS-JR3.5, HNBR4.1-35-80-P-NS-RC1, HNBR4.1-35-80-P-NS-RH, HNBR4.1-35-80-P-NS-RLG, HNBR4.1-35-80-P-NS-VS, HNBR4.1-NT-100-P-NS-H1, HNBR4.1-NT-80-P-NS-C1, HNBR4.1-NT-80-P-NS-RC1, HNBR4.1-NT-80-P-NS-RH, HNBR4.1-NT-80-P-NS-RIM, HNBR4.1-NT-80-P-NS-RLG, HNBR5.0-35-65-P-NS-RUC, HNBR5.0-35-90-P-NS-RUC

All  
Lots

### Shuttle® Select Slip-Cath® Catheter

#### Product Catalog Numbers

SCBR4.5-35-135-P-NS-ANG-SHTL, SCBR4.5-35-135-P-NS-ANG-SHTL-JP, SCBR4.5-35-150-P-NS-0-SHTL, SCBR4.5- All  
35-150-P-NS-ANG-SHTL, SCBR4.5-35-75-P-NS-ANG-SHTL, SCBR5.0-35-90-P-NS-RUC Lots

## Slip-Cath® Beacon® Tip Catheter

### Product Catalog Numbers

SCBR4.0-35-150-P-NS-0, SCBR4.0-35-65-P-NS-RC2, SCBR4.0-38-100-P-NS-0, SCBR4.0-38-100-P-NS-C2, SCBR4.0-38-100-P-NS-AV, SCBR4.0-38-100-P-NS-H1, SCBR4.0-38-100-P-NS-HN4, SCBR4.0-38-100-P-NS-JB1, SCBR4.0-38-100-P-NS-JB2, SCBR4.0-38-100-P-NS-KMP, SCBR4.0-38-100-P-NS-MAN, SCBR4.0-38-100-P-NS-MPA, SCBR4.0-38-100-P-NS-MPB, SCBR4.0-38-100-P-NS-SIM1, SCBR4.0-38-100-P-NS-SIM2, SCBR4.0-38-100-P-NS-SIM3, SCBR4.0-38-100-P-NS-VERT, SCBR4.0-38-125-P-NS-0, SCBR4.0-38-125-P-NS-DAV, SCBR4.0-38-125-P-NS-JB1, SCBR4.0-38- All  
125-P-NS-SIM1, SCBR4.0-38-125-P-NS-SIM2, SCBR4.0-38-125-P-NS-TEGT, SCBR4.0-38-125-P-NS-VERT, SCBR4.0- Lots  
38-125-P-NS-VTK, SCBR4.0-38-40-P-NS-KMP, SCBR4.0-38-65-P-NS-0, SCBR4.0-38-65-P-NS-C2, SCBR4.0-38-65-P-NS-KMP, SCBR4.0-38-65-P-NS-MPA, SCBR4.0-38-65-P-NS-RIM, SCBR4.0-38-65-P-NS-TC, SCBR4.0-38-65-P-NS-TC-BNK, SCBR4.0-38-65-P-NS-VERT, SCBR4.0-38-80-P-NS-RH, SCBR4.0-38-80-P-NS-VS, SCBR4.0-38-80-P-NS-VS1, SCBR4.0-38-80-P-NS-VS2, SCBR4.0-38-80-P-NS-VS3, SCBR4.1-35-65-P-NS-C2, SCBR4.1-35-75-P-NS-CHG2.5

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