

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Cook Medical, Beacon Tip Angiographic Catheters, Catheter Tip May Slip or Separate

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e EMAIL ([MAILTO:?SUBJECT=COOK%20MEDICAL%20BEACON%20TIP%20ANGIOGRAPHIC%20CATHETERS%20CATHETER%20TIP%20MAY%20SLIP%20OR%20SEPARATE&BODY=HTTP%3A%2F%2FWWW.FDA.GOV%2FMEDICALDEVICES%2FSAFETY%2FLISTOFRECALLS%2FUCM457629.HTM](mailto:?subject=cook%20medical%20beacon%20tip%20angiographic%20catheters%20catheter%20tip%20may%20slip%20or%20separate&body=http%3a%2f%2fwww.fda.gov%2fmedicaldevices%2fsafety%2flistofrecalls%2fucm457629.htm))

Recall Class: Class I

Date Recall Initiated: July 2, 2015

Device: Beacon Tip Torcon NB Advantage Catheters, Beacon Tip Royal Flush Plus High-Flow Catheters, Slip-Cath Beacon Tip Catheters

- Lot numbers: [Complete list of lot numbers \(https://www.cookmedical.com/newsroom/wp-content/uploads/sites/2/2015/08/Beacon-Tip-Angiographic-Catheters-Affected-Lot-Numbers-FINAL.pdf?905860\)](https://www.cookmedical.com/newsroom/wp-content/uploads/sites/2/2015/08/Beacon-Tip-Angiographic-Catheters-Affected-Lot-Numbers-FINAL.pdf?905860) (<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)
- Manufactured from: May 9, 2013 to September 1, 2014
- Distributed from: June 6, 2013 to June 25, 2015
- Devices Recalled in the U.S.: 38,895

Catalog numbers:

- Beacon Tip Torcon NB Advantage Catheters – Catalog Prefix HNBR5.0
- Beacon Tip Royal Flush Plus High-Flow Catheters – Catalog Prefix HNR4.0
- Slip-Cath Beacon Tip Catheters – Catalog Prefix SCBR5.0

Use: Beacon Tip Angiographic Catheters are used to inject contrast dye into blood vessels in the heart to prepare it for a type of X-ray used to diagnose heart conditions (cardiac angiogram).

The catheter is inserted into the body through a small puncture made in the skin and placed into the blood vessel along a guide wire before injecting the contrast dye.

Recalling Firm:

Cook, Inc.
750 N. Daniels Way
Bloomington, IN 47404

Reason for Recall: Cook Medical has received complaints that the catheter tip may split or separate from the catheter. If this occurs, the tip could enter the patient's bloodstream. This could cause serious injury to the patient and require additional medical intervention to retrieve the tip, or cause death. Tip splitting or separation may also cause the device to stop working.

Cook Medical has received 26 reports of the device malfunctioning, with 14 resulting in reports of adverse events.

Public Contact:

Customers can contact Cook Medical Customer Relations at 800-457-4500 or 812-339-2235, Monday through Friday between 7:30 a.m. and 5:00 p.m., Eastern Time.

FDA District: Detroit District Office

More Information about this Recall:

On July 2, 2015, Cook Medical sent their customers an Urgent: Medical Device Recall letter. The letter instructed customers to:


- Review the list of affected products and lot numbers
- Immediately quarantine unused products from their inventory
- Collect and return all unused products to Cook Medical as soon as possible
- Complete the Recall Response Form attached to the letter and return it to Cook Medical
- Report any adverse event to Cook Medical Customer Relations 800-457-4500 or 812-339-2235, Monday through Friday between 7:30 a.m. and 5:00 p.m., Eastern Time or CustomerRelationsNA@cookmedical.com (<mailto:CustomerRelationsNA@cookmedical.com>)
- Adverse events or quality problems experienced with use of the product may also be reported to the FDA
 - [MedWatch Online \(/Safety/MedWatch/HowToReport/default.htm\)](#)
 - Phone: 800-FDA-1088

About Class I Recalls



Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.



Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program \(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home\)](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) online, by regular mail or by FAX.

Additional Resources:

- [Firm Press Release \(https://www.cookmedical.com/newsroom/cook-medical-issues-global-recall-of-beacon-tip-angiographic-catheter-products/\)](https://www.cookmedical.com/newsroom/cook-medical-issues-global-recall-of-beacon-tip-angiographic-catheter-products/) 
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More in Medical Device Recalls
(</MedicalDevices/Safety/ListofRecalls/default.htm>)

2015 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm429489.htm>)

2014 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm384921.htm>)