

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

Cook Medical Expands Recall for Beacon Tip Angiographic Catheters to Include Additional Product Lots

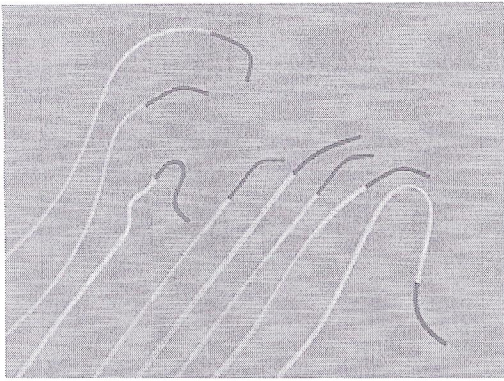
The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

- Torcon NB Advantage Beacon Tip Catheters; Royal Flush Plus Beacon Tip High-Flow Catheters; Slip-Cath Beacon Tip Hydrophilic Catheters; Shuttle Select Slip-Cath Catheters
- Catalog Numbers: HNBR4.0, HNBR4.1, HNBR5.0, HNR4.0, SCBR4.0, SCBR4.1, SCBR5.0, SCBR4.5
- Lot Numbers: 4323524 4325406 4334525 4338030 4339752 4360231 4364180 4368348 4393439 4413850 4423906 4428682 4448476 4469769 4482723 4578086 4578087 4586710 4587403 4594134 4598548 4600573 4605628 4605629 4605630 4605631 4611045 4611046 4613055 4616267 4619949 4625448 4629806 4631548 4640682 4643656 4648596 4655177 4655178 4661955 4661956 4677333 4693109 4698226 4723849 4727230 4732759 4732760 4746640 4751364 4760057 4774047 4786287 4791878 4803817 4803818 4807780 4812101 4816904 4819314 4830214 4834317 4869214 4878637 4917038 5149580 F4732758
- Manufacturing Dates: August 10, 2012 to September 10, 2015
- Distribution Dates: September 12, 2012 to September 22, 2015
- Devices Recalled in the U.S.: 408,011 units distributed nationwide

Device Use

Beacon Tip Angiographic Catheters are used to inject contrast dye into blood vessels in the heart to prepare it for a cardiac angiogram, a type of X-ray used to diagnose heart conditions. The catheter is inserted into the body through a small puncture made in the skin and into a blood vessel.



Torcon NB® Advantage Beacon® Tip Catheter

Reason for Recall

Cook Medical has expanded its original July 2015 recall for the Beacon Tip Catheter to include additional product lots. The recall now affects 408,011 total catheters distributed in the US.

Cook Medical started the original recall after it received complaints that the catheter tip may split or separate, and could potentially 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.

Who May be Affected

- Healthcare professionals using the catheters
- All patients undergoing procedures involving these catheters

What to Do

On October 7, 2015, Cook Medical sent their customers an Urgent: Medical Device Recall Extension 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 \(http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm\)](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)
 - Phone: 800-FDA-1088

Date Recall Initiated:

October 9, 2015

Additional Resources:

- [Full List of Affected Devices \(https://www.cookmedical.com/newsroom/wp-content/uploads/sites/2/2015/10/BeaconTipRecallExtension2.pdf?905860\)](https://www.cookmedical.com/newsroom/wp-content/uploads/sites/2/2015/10/BeaconTipRecallExtension2.pdf?905860)
- [Cook Medical Press Release \(https://www.cookmedical.com/newsroom/cook-medical-extends-global-recall-of-select-sizes-of-beacon-tip-angiographic-catheters/\)](https://www.cookmedical.com/newsroom/cook-medical-extends-global-recall-of-select-sizes-of-beacon-tip-angiographic-catheters/)
- Original [FDA Recall Notice \(/MedicalDevices/Safety/ListofRecalls/ucm457629.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm457629.htm) from August 2015

More in [Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/default.htm\)](/MedicalDevices/Safety/ListofRecalls/default.htm)

[2016 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm480134.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)

[2015 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm429489.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

[2014 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm384921.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)