Vascular Solutions Inc. Recalls Venture Catheters due to Excess Material that May Split or Separate During Use

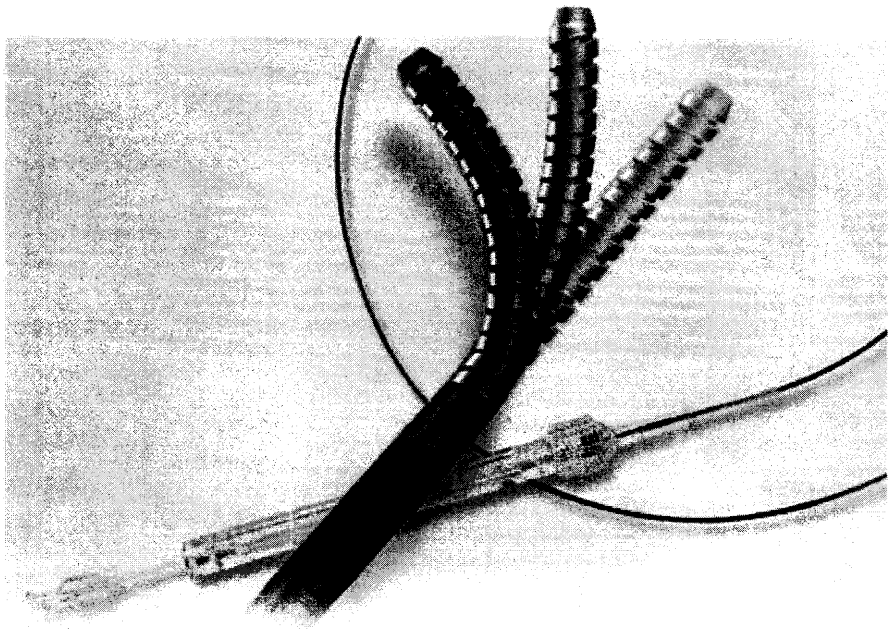
The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Venture RX Catheter (Model 5820), Venture OTW (Model 5821), and Venture CS Catheter (Model 5822)
- Lot Numbers: **See Full List Below**
- Distribution Dates: May 7, 2015 to April 19, 2017
- Manufacturing Dates: May 7, 2015 to March 31, 2017
- Devices Recalled in the U.S.: 7054 nationwide

Device Use

The Venture catheter is intended for directing, steering, controlling, and supporting a guidewire to access veins and arteries in the arms, legs, hands, feet, and heart muscle (myocardium). Certain models may also administer saline fluids or drugs into blood vessels.



Reason for Recall

Vascular Solutions Inc. is recalling the Venture catheter because there is a risk of the catheter tip splitting or separating during use. Excess material at the tip of the catheter may separate and could enter the patient's bloodstream. This can result in serious adverse health consequences such as the development of blood clots, embolism of the excess material to vital organs, or death.

Who May be Affected

- Health care providers using this device during vascular procedures
- All patient groups undergoing procedures involving Venture catheters

What to Do

On April 25, 2017, Vascular Solutions Inc. sent an Urgent Medical Device Recall letter to all affected customers. The letter asked distributors and customers to:

- Identify and remove any affected Venture catheters from inventory and quarantine.
- Ensure all customers who received any affected Venture catheters receive the Field Safety Notice and complete the Customer Inventory Form.
- After all the affected catheters are returned, complete the Vascular Solutions Inc. Distributor Inventory Form, and return it via email to regops@vasc.com.
- Upon receipt of the Vascular Solutions Inc. Distributor Inventory Form, Vascular Solutions' Customer Service Department will provide a Return Authorization number and arrange for return of affected Venture catheters. A credit will be offered after affected devices have been returned.

Contact Information

Health care professionals and consumers may contact Vascular Solutions at 1-888-240-6001 Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time or by email at **customerservice@vasc.com (mailto:customerservice@vasc.com)** with any questions related to this recall.

Date Recall Initiated

April 25, 2017

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)** either online, by regular mail or by FAX to 1-800-FDA-0178.

Full list of Product Codes and Lot Numbers

Product Code	Lot
5820	582455

Product Code	Lot
5820	582588
5820	583022
5820	583409
5820	584469
5820	584470
5820	585180
5820	585458
5820	585787
5820	587035
5820	587036
5820	587775
5820	588097
5820	588098
5820	588794
5820	589885
5820	589886
5820	590172
5820	590776
5820	591196
5820	591198
5820	592080
5820	592526
5820	593080
5820	593519
5820	593720
5820	594204
5820	594421
5820	595195
5820	595418
5820	597293
5820	597771
5820	597967

Product Code	Lot
5820	598903
5820	599045
5820	599466
5820	599903
5820	601745
5820	603987
5820	603988
5820	603991
5820	604500
5821	581713
5821	583410
5821	584471
5821	585459
5821	586408
5821	586972
5821	587408
5821	588099
5821	589268
5821	589754
5821	590404
5821	591197
5821	592081
5821	592924
5821	593520
5821	595196
5821	595419
5821	596020
5821	597294
5821	599650
5821	601196
5821	601746
5821	602260

Product Code	Lot
5821	603990
5821	604049
5821	605617
5822	588100
5822	590562
5822	597905
5822	599777
5822	604862

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

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

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