Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Vascular Solutions, Inc. Issues Recall of Twin-Pass® Dual Access Catheters

For Immediate Release

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Announcement

On September 16, 2016, Vascular Solutions, Inc. (Nasdaq:VASC), initiated a nationwide recall of Twin-Pass Dual Access catheters used in catheterization procedures. All unexpired lots of the product have been recalled because there is a potential for excess manufacturing material to remain at the tip of the catheter or within the distal portion of the rapid exchange lumen. It is possible that the excess material may separate from the catheter during use and pose a potential risk of embolism, which could result in serious injury or death. No injuries have been reported in association with this issue to date.

Healthcare facilities that have the affected Twin-Pass dual access catheters should

remove the products from their inventory and return them to Vascular Solutions.

The recalled products were manufactured from October 2014 to August 2016 and distributed from October 2014 to September 2016.

The recalled products are all unexpired lots of Model Numbers 5200, 5210, and 5230. A listing of the recalled lots is available from Vascular Solutions and has been provided to each facility that purchased the affected products. A total of 15,896 devices have been manufactured, with 5,784 distributed in the United States and currently unexpired. The condition that led to the recall may affect approximately 9.2% of recalled devices.

Vascular Solutions, Inc. voluntarily initiated the recall on September 16, 2016 through an Urgent Medical Device Recall notification distributed to purchasers of the affected products. The notification identified the specific unexpired lots subject to the recall and included instructions on how to return the affected products.

The U.S. Food and Drug Administration (FDA) classified this as a Class I recall. FDA defines Class I recalls as “a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.”

Consumers with questions may contact the company by phone 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. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program:

- Online at http://www.fda.gov/medwatch/report.htm (form available to fax (1-800-FDA-0178) or mail), or
- Call FDA 1-800-FDA-1088 to request a reporting form

About Vascular Solutions

Vascular Solutions, Inc. is an innovative medical device company that focuses on developing unique clinical solutions for coronary and peripheral vascular procedures. The company has launched more than 100 products that are sold to interventional cardiologists, interventional radiologists, electrophysiologists, and vein specialists through its direct U.S. sales force and international independent distributor network. For further information, connect to www.vasc.com.

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