URGENT: Medical Device Field Safety Notice

This communication will be distributed in electronic medium only, no fax or hardcopy will be made.

April 25, 2017

Distributor's Name
Address
City, Country and Postal Code

Medical Device Field Safety Corrective Action – Removal of Venture RX Catheter (Model 5820), Venture OTW Catheter (Model 5821) and Venture CS Catheter (Model 5822)

Dear Ladies and Gentlemen,

Vascular Solutions, Inc. (VSI) is voluntarily removing all lots of Venture catheters due to a potential problem. Venture RX (Model 5820), Venture OTW (Model 5821), and Venture CS (Model 5822) catheters manufactured with the following lot numbers are unexpired and affected by this removal:

List of Unexpired Lots within Scope of Recall							
581713	582455	582588	583022	583409	583410	584469	584470
584471	585180	585458	585459	585787	586408	586972	587035
587036	587408	587775	588097	588098	588099	588100	588794
589268	589754	589885	589886	590172	590404	590562	590776
591196	591197	591198	592080	592081	592526	592924	593080
593519	593520	593720	594204	594421	595195	595196	595418
595419	596020	597293	597294	597771	597905	597967	598903
599045	599466	599650	599777	599903	601196	601745	601746
602260	603987	603988	603990	603991	604049	604500	604862
605617							

After an internal investigation, VSI has concluded there is a potential for excess material used to manufacture the catheter to be present within the inner lumen of the distal catheter tip. It is possible that the excess material may separate from the catheter during a procedure, posing a potential risk of an embolism to the patient. Although there have been no reports of adverse patient events related to this issue, VSI is voluntarily recalling all potentially affected Venture catheters due to the potential harm.

Our records indicate that the Venture catheters listed immediately below were shipped to your location and are affected by this voluntary product removal. Further distribution or use of the following affected units should cease immediately:

Affected Units Shipped to Your Location				
Lot Number	**Model Number**	**Order Number**	**Order Date**	**Order Quantity Shipped (Units)**
[Insert Data]	[Insert Data]	[Insert Data]	[Insert Data]	[Insert Data]
			Total	

Immediate Action Required:

- Identify the location of all unused Venture catheters in your possession.
- Remove any unused Venture catheters from your current inventory and place in a secure area.
- Identify your customers or end users who received Venture catheters from your organization.
- Use the Customer Inventory Form and Field Safety Notice (samples provided below) to notify each of your customers who received Venture catheters. Fill in your organization's details and translate if necessary.
- Ensure your customers receive the Field Safety Notice and account for unused Venture catheters. This should be done with the Customer Inventory Form.
- Collect Venture catheters returned from your customers and place in a secure area.
- After all affected customers have returned their unused Venture catheters, complete the VSI Distributor Inventory Form, below, and provide it to regops@vasc.com.
- Upon receipt of your VSI Distributor Inventory Form, our Customer Service Department will contact you to provide a Return Authorization number and arrange for return of unused Venture catheters. A credit will be offered after unused devices have been returned.

Important: Please use the enclosed "SAMPLE" Field Safety Notice and Customer Inventory Form as a template to notify your customers, who have or may have received the affected product. Please update the items highlighted in green, have both documents translated at your earliest convenience and distribute to your customers. A copy of the translated Field Safety Notice and Customer Inventory Form sent to your customers must be returned to Vascular Solutions as soon as possible by e-mail to regops@vas.com. Upon completion of the field action activities, please return the filled-in Distributor Inventory Form.

This notice needs to be passed on to all individuals within your organization or to any organization where the potentially affected devices have or may have been transferred. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersigned confirms the relevant regulatory agencies have been advised of this field action, as required.

Sincerely,

Tracy Brinkmeyer

Tracy Brinkmeyer
Director of Quality Assurance
Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, Minnesota 55369
(763) 656-4300 (Tel.)
www.vasc.com