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

Distributor Inventory Form

Removal of Venture RX (Model 5820), Venture OTW (Model 5821) and Venture CS (Model 5822)

Section 1: ***(Completed by VSI)***	
VSI Account Number:	[VSI Account Number]
Distributor Name:	[Distributor Name]
Distributor Address, City, County & Postal Code:	[Distributor Address]

Section 2: ***(Completed by VSI and Distributor)***

A Lots Shipped to Distributor	**B** Total Number of Units Shipped to Distributor	**C** Total Number of Units Received by Distributor	**D** Total Number of Units in Distributor's Inventory & **NEVER** Sent to Customers	**E** Total Number of Units Distributed to Customers	**F** Total Number of Customer's Units to be Returned to Distributor and then to VSI
(Completed by VSI)		***(Completed by Distributor)*** *Indicate "0" Where Applicable*			
[Lot #]	[# of Units]				
TOTALS:	[Total # of Units]				
	[Sum of Columns 'D' and 'E']				-

Section 3: ***(Completed by Distributor)***

Note: Refer to the totals in Section 2 to answer Sections 3 and 4 below

If the total number of units shipped to the distributor (column 'B') do not match the total number of units received (column 'C'), please explain.	
If the sum of the total number of units in inventory & never sent to customers (column 'D') plus the total number of units distributed to customers ('column 'E') do not match the total number of units shipped (column 'B'), please explain.	

Section 4: *(Completed by Distributor)*

Note: Provide the following information, for each customer, who has or may have received the affected product.

Hospital/Medical Facility Name	Address (Including City, Country & Postal Code)	A Total Number of Units Shipped to Customer	B Number of Units Used in Patient Procedures	C Number of Units in Customer Inventory	D Number of Units Returned Prior to Field Action	E Number of Units Destroyed by Customer	F Number of Units to be Returned as a Result of Field Action
TOTALS: *The total of columns "B" through "E" should equal "A". Column "F" should equal "C".*	*N/A*						

Section 5: *(Completed by Distributor)*

1. Print name and title below of individual completing form
2. Sign and date completed form below
3. Return completed form to regops@vasc.com
4. Upon receipt of this completed form and in the event product is to be returned, VSI Customer Service will contact Distributor with a return authorization number (RA)
5. VSI must receive the returned units prior to replacement

Print Name & Title:			
Contact Telephone Number:		**Contact E-mail:**	
Signature:		**Date:**	

Section 6: *(Completed by VSI)*

Form Received By:		**Date Received:**	
RMA # Issued:		**Date Issued:**	

"SAMPLE" Field Safety Notice

URGENT - Medical Device Field Safety Notice

Date

Customer's Name
Address
Postal Code / City

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							
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605617							

After an internal investigation, VSI has concluded there is a potential for excess material used to manufacture the Venture catheter to be present within the inner lumen of the distal catheter tip. It is possible that the material may separate from the catheter during a procedure, which poses 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]				
			Total	

Immediate Action Required:

- Identify the location of all Venture catheters in your possession indicated in the table above.
- Remove all Venture catheters from your current inventory and place in a secure area.
- Complete the Customer Inventory Form and return to Distributor's Contact Details.
- Distributor will arrange for return of affected devices indicated in the Customer Inventory Form.
- Return all affected devices to Distributor. A credit will be offered for unused devices after their return.

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 complete the enclosed Customer Inventory Form at your earliest convenience and return to:

Distributor's Contact Name / Distributor's Name, Address, and Contact Details

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersigned confirms this notice has been sent to the appropriate Regulatory Agencies.

Sincerely,

Distributor's Contact Signature

Customer Inventory Form

Removal of Venture RX (Model 5820), Venture OTW (Model 5821) and Venture CS (Model 5822)

Section 1: *(Completed by Distributor)*	
Customer Account Number:	[Add Customer Account Number Here]
Customer Name:	[Add Customer Name Here]
Customer Address, City, Country & Zip:	[Add Customer City, State & Zip Here]

Section 2: *(Completed by Distributor and Customer)*			
Lots Shipped to Customer	**Total Number of Units Shipped to Customer**	**Total Number of Units to be Returned to Distributor from Customer Inventory** *(Indicate "0" where applicable)*	**Total Number of Units Used in Patient Procedures** *(Indicate "0" where applicable)*
Completed by Distributor		***Completed by Customer***	
[Insert Lot Number Here]	[Insert Total Units Shipped Here]		

Section 3: *(Completed by Customer)*

1. Print name and title of individual completing form
2. Sign and date the completed form
3. Return completed form to Distributor at:
   a. E-mail: [Insert distributor's e-mail address]
   OR
   b. Fax: [Insert distributor's fax number]
4. Upon receipt of the completed form and assuming units are available for return, Distributor will contact the individual below, at the contact number provided, with a Return Authorization Number (RMA).

Print Name & Title:			
Contact Telephone Number:		**Contact E-Mail:**	
Signature:		**Date:**	

Section 4: *(Completed by Distributor)*			
Form Received By:		**Date Received:**	
RMA # Issued:		**Date Issued:**	