URGENT: Medical Device Field Safety Notice – Lot Specific

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

March 3, 2016

[Distributor's Name]
[Distributor's Address]

Medical Device Field Safety Corrective Action – Recall of Guardian® II Hemostasis Valve, Model Numbers FH101, FH101-T, FH101-25, FH101-50

Dear Distributor Partner,

Investigation of a recent complaint has made Vascular Solutions, Inc. aware of a potential problem with the click version of our Guardian II hemostasis valve. The low pressure seal may not close properly, which may allow air to be introduced into the device and may lead to risk of an air embolism. No air ingress or patient harm has been reported; however, due to the potential harm VSI is voluntarily recalling Guardian II hemostasis valves manufactured with the following lot number(s):

Guardian II Lot Numbers Within Scope of Field Safety Corrective Action				
41817	42029	42068	42409	42410
42687	42688	42689	42691	42692
42693	42699	42700	42701	42986
42987	42988	42989	43186	43187
43188	43408	-	-	-

Our records indicate that the following Guardian II hemostasis valves were shipped to your location and are affected by this field action. Further distribution or use of these units should cease immediately:

Affected Units Shipped to Your Location				
Lot Number	Model Number	Order Number	Order Date	Order Quantity Shipped (Units)
[fill in]	[fill in]	[fill in]	[fill in]	[fill in]
			Total	[fill in]

Immediate Action Required:

1. Identify the location of all Guardian II hemostasis valves in your possession shown in the table above.
2. Remove all Guardian II hemostasis valves from your current inventory and place in a secure area.
3. Identify your customers or end users who received affected product from your organization.
4. Fill in your section of the Customer Inventory Form and Field Safety Notice (sample provided below) for each of your affected customers, and send the completed forms to your customers.
5. Communicate with your customers to complete the Customer Inventory Form and collect devices returned from your customers.

6. Once all affected customers have provided Customer Inventory Forms and returned affected devices, complete the VSI Distributor Inventory Form below and provide to regops@vasc.com.
7. Upon receipt of your VSI Distributor Inventory Form, our Customer Service Department will contact you to provide a Return Material Authorization number and arrange return of affected units. All devices will be replaced upon receiving your returned devices.

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@vasc.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,

[redacted]

Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, Minnesota 55369
[redacted]
www.vasc.com

Distributor Inventory Form

Recall of Guardian® II Hemostasis Valve, Model Numbers FH101, FH101-T, FH101-25, FH101-50

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
   Return completed form to regops@vasc.com
3. 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 (RMA)
4. 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 – Recall of Guardian® II Hemostasis Valve, Model Numbers FH101, FH101-T, FH101-25, FH101-50

Dear Ladies and Gentlemen,

Investigation of a recent complaint has made Vascular Solutions, Inc. aware of a potential problem with the click version of our Guardian II hemostasis valve. The low pressure seal may not close properly, which may allow air to be introduced into the device and may lead to risk of an air embolism. No air ingress or patient harm has been reported; however, due to the potential harm VSI is voluntarily recalling Guardian II hemostasis valves manufactured with the following lot number(s):

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43188	43408	-	-	-

Our records indicate that the following Guardian II hemostasis valves were shipped to your location and are affected by this field action. 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:

1. Identify the location of all Guardian II hemostasis valves in your possession indicated in the table above.
2. Remove all Guardian II hemostasis valves from your current inventory and place in a secure area.
3. Complete the Customer Inventory Form and return to Distributor's Contact Details.
4. Distributor will arrange for return of affected devices indicated in the Customer Inventory Form
5. Return all affected devices to Distributor. All devices will be replaced upon receiving your returned devices.

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

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:**	