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,

Carrie Powers
Sr. Vice President of Marketing
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