URGENT - Medical Device Field Safety Notice

7th March 2016

[customer name]
[customer address]

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):

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 the following affected units should cease immediately:

Affected Units Shipped to Your Location				
Lot No.	Model No.	Order No.	Date	Total
			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 M3 Medical, Unit F4 Calmount Park, Ballymount, Dublin 12.
4. M3 Medical will arrange for return of affected devices indicated in the Customer Inventory Form
5. Return all affected devices to M3 Medical. 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:

Mr. Aidan Mulloy
M3 Medical
Unit F4
Calmount Park
Ballymount
Dublin 12.

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,

Aidan Mulloy
Managing Director
M3 Medical

Customer Inventory Form

Section 1: *(Completed by Distributor)*	
Customer Account Number:	
Customer Name:	
Customer Address, City, Country & Zip:	

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***	

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: orders@m3.ie

   OR

   b. Fax: 01-2930304
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:**	