URGENT - Medical Device Field Safety Notice

September 21,2016

Centre/Hospital,
Address
Address

Medical Device Field Safety Corrective Action – Removal of Twin-Pass (5200), Twin-Pass RX (5210) and Twin-Pass .023" (5230)

Dear Ladies and Gentlemen,

Investigation of recent Device Experience Reports has made Vascular Solutions, Inc. (VSI) aware of a potential problem with our Twin-Pass (5200), Twin-Pass RX (5210) and Twin-Pass .023" (5230) dual access catheters manufactured with the following lot numbers:

List of Unexpired Lots within Scope of Field Safety Corrective Action				
575653	577278	577279	577761	577762
578419	578996	578997	579472	579787
580186	580612	580613	581252	582138
582579	582580	583021	583785	584155
584156	584463	584812	585176	585784
585785	586310	586399	587030	587407
587772	588499	588542	588962	589457
589884	590169	590350	590561	590717
590739	591037	591261	591262	591521
591739	592078	592525	592920	593076
593678	593695	593696	593717	593985
594678	595191	595412	595413	596317
596930	596936	597006	597034	597035
597036	597037			

Upon investigation of Twin-Pass units, it's been concluded there is a potential for excess manufacturing material to remain at the tip of the catheter or inside the distal part of the rapid exchange lumen of Twin-Pass dual access catheters. It is possible that the excess 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, due to the potential harm, Vascular Solutions is voluntarily recalling and replacing all affected units of Twin-Pass, Twin-Pass RX and Twin-Pass .023".

Our records indicate that the Twin-Pass dual access catheters listed immediately below were shipped to your location and are affected by this 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)**
			Total	

Immediate Action Required:

- Identify the location of all Twin-Pass dual access catheters in your possession indicated in the table above.
- Remove all Twin-Pass dual access catheters from your current inventory and place in a secure area.
- Complete the Customer Inventory Form and return to M3 Medical.
- M3 Medical will arrange for return of affected devices indicated in the Customer Inventory Form.
- 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:

M3 Medical,
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,

Killian O'Dowd.

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: mark@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:**	