August 23, 2017

URGENT:

MEDICAL DEVICE RECALL

Bridge™ Occlusion Balloon

«Delivery_debtor_name»
«Delivery_addressline_1»
«Delivery_addressline_2»
«Delivery_addressline_3»
«Delivery_city» «Delivery_postcode»
«Delivery_Country»

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Spectranetics is voluntarily recalling the Bridge Occlusion Balloon which is indicated for:

Bridge Occlusion Balloon catheter Indications:
Temporary vessel occlusion of the superior vena cava (SVC) in applications including perioperative occlusion and emergency control of hemorrhage. Any use for procedures other than those indicated in the instructions is not recommended.

Serious injuries and/or deaths could occur due to the failure mode associated with this recall. We have received no reports of deaths and/or serious injuries.

Reason for the Voluntary Recall:

Spectranetics has issued this Field Action due to a potentially blocked guidewire lumen of the BRIDGE occlusion balloon. To date, Spectranetics has received 9 customer complaints, none of which have resulted in any serious injury to the patient. Based on inspection, the frequency of a potentially blocked guidewire lumen is estimated to be approximately 10%. Additional investigations are required prior to implementing a fix. Spectranetics believes it is in the best interest of the patient to continue to have access to the Bridge device. Orders of Bridge devices, subject to potential guidewire blockage, will continue to be placed (inventory permitting).Once we can confirm that a solution is available, your existing inventory will be swapped out.

Risk to Health:

If a device with a compromised guidewire lumen were to be utilized, there would be a possibility the device would not be able to pass over a needed guidewire required to position the balloon. If the balloon is unable to be utilized, it would result in a delay of potentially lifesaving treatment. The issue can be identified by removing the product from the packaging and attempting to fully pass a guidewire through the lumen before the procedure. If a guidewire blockage is noted, swap the device out for another unit.

Actions to be taken by the Customer/User:

As the Bridge Occlusion Balloon serves an important role in preventing blood loss in the event that a patient requires emergent surgery as a result of an SVC tear during a lead extraction, Spectranetics does not want to remove product from the field until replacements can be provided. Therefore, this recall will be staged and additional mitigations will be implemented in the meanwhile:

1. We recommend following product instructions to place a guide wire through the venous access site prior to the start of the procedure. Physicians may consider removing Bridge from packaging and placing the Bridge balloon over the wire prior to the start of the procedure to ensure a patent guidewire lumen if they believe the case is high risk.
2. You may continue to order Bridge devices during this time and orders will be filled as inventory allows. All Bridge inventory, including new shipments, will continue to have the potential for a guidewire lumen blockage until a solution is implemented.
3. Please bring your inventory into the case so that you have the back-up on hand, should you need it.
4. Always follow appropriate complication prevention and management protocols as it relates to patient preparation and surgical back up for lead extraction procedures.
5. Your Spectranetics' Sales Representative will be contacting you to facilitate the return and replacement of any remaining product in inventory once new inventory becomes available with an implemented fix; however, you may also reach Customer Service at +31 33 43 47 050.

These actions are temporary and should be continued moving forward until further communication is provided. A long term correction is being investigated, and all effected lots will be replaced once it is complete.

Type of Action by the Company:
A Spectranetics representative will contact you to coordinate the exchange of impacted devices once the current guidewire issue has been resolved. The failure investigation concluded that this issue is linked to a supplier and is being investigated to identify and implement the final correction.

CONTACT INFORMATION:
We understand the trust that you place in Spectranetics for the delivery of safe and effective products. This field action is consistent with our commitment to you and your patients. If you have additional questions please feel free to discuss with your local Spectranetics' Sales Representative, or call me directly. The Spectranetics Customer Service Department is also available to support you with any assistance you may need.

Customer Service Contact Information:
Phone: +31 33 43 47 050
Fax: +31 33 43 47 051
Email: order@bv.spnc.com
Hours of Operation- Monday- Friday 8:00AM – 5:00PM Central European Time Zone

Sincerely,
The Spectranetics Corporation

Lindsay K. Pack
Vice President Quality Assurance
9965 Federal Drive
Colorado Springs, CO, 80921
Tel. 1.719.447.2469

Enclosure 1: Acknowledgement and Receipt Form

Enclosure 1:
MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

«Delivery_debtor_name»
Customer Number: «Debtor_number»
«Delivery_addressline_1»
«Delivery_addressline_2»
«Delivery_addressline_3»
«Delivery_city» «Delivery_postcode»
«Delivery_Country»

Bridge™ Occlusion Balloon

I have read and understand the recall instructions provided in the August 23, 2017 letter. Yes _ No_

Any adverse events not previously reported associated with recalled product? Yes _ No _
If yes, please explain:

_____
_____
_____

For Distributors Only:

I have identified and notified my customers that were shipped or may have been shipped this product by (**Include attachment with date and method of notification**). __Yes __No

Return Response Box:

Please provide any additional information, if applicable.

Questions:

☐ Please have Customer Service contact me.

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE EMAIL OR FAX COMPLETED RESPONSE FORM TO:
order@bv.spnc.com, or FAX # +31 33 43 47 051