August 11, 2017

URGENT:

MEDICAL DEVICE RECALL

Bridge™ Occlusion Balloon

«Customer_Name»
«Address1»
«Address2»
«Address3»
«City», «State» «Postal_Code»

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Spectranetics is voluntarily recalling specific lots of 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 to voluntarily remove and replace specific lot numbers of our Bridge Occlusion Balloon due to a potentially blocked guidewire lumen of the device. To date, Spectranetics has received 6 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%.

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. For current Bridge inventory, we recommend following product instructions to place a guide wire through the venous access site prior to the start of the procedure AND 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.

2. You will be receiving a new unit to have on hand as a back-up should you determine that your existing unit has a blocked guidewire lumen (we strongly recommend that you use the current inventory before switching to your back-up unit to ensure that you always have at least one unit available for an emergency). (Please note, your back-up unit has been verified to be patent and will have a checkmark sticker adjacent to the label for easy identification.)
3. Please bring your inventory into the case so that you have the back-up on hand, should you need it.
4. Please complete the attached *Acknowledgement and Receipt Form* to facilitate the product return and exchange. 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 (approximately 2 months to complete the replacement of existing inventory); however, you may also reach Customer Service at +31 33 43 47 050, Option 2.

These actions are temporary and limited to the specific lots identified. A long term correction has already been implemented; therefore, newly manufactured units are not impacted.

Type of Action by the Company:

In order to correct this issue Spectranetics is providing you an additional unit as a back up to ensure that you have at least one unit available. Upon availability of additional inventory, Spectranetics is requesting return and replacement of all potentially impacted lots. Replacement units will be provided at the time of the return. A Spectranetics representative will contact you to coordinate the exchange of devices. The failure investigation concluded that this issue is linked to a supplier and thus it was immediately correctable.

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, Option 2
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

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9965 Federal Drive
Colorado Springs, CO, 80921
Tel. 1.719.447.2469

Enclosure 1: Acknowledgement and Receipt Form
Enclosure 2: List of Bridge Occlusion Balloon lot numbers being recalled

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

Response is Required

«Customer_Name»
Customer Number: «Customer_Number»
«Address1»
«Address2»
«Address3»
«City», «State» «Postal_Code»

Bridge™ Occlusion Balloon

I have read and understand the recall instructions provided in the August 11, 2017 letter. Yes _ No_

Any adverse events not previously reported associated with recalled product? Yes _ No _

If yes, please explain:

_____

_____

_____

Were the affected lots of this device used? _____

Affected Product Information: Include information that is applicable for affected product.

Affected Product Information Table				
Product/Brand Names, UDI (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number shipped to Customer	Quantity shipped	Quantity remaining on-site

The remaining affected product that is no longer in inventory has been used. Yes No

For Distributors Only:
I have checked my stock and have quarantined inventory consisting of_____units.

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**).

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

Enclosure 2

Bridge™ Occlusion Balloon

List of Bridge Occlusion Balloon lot numbers being recalled

Model Number	Device Description	Lot Number
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17B13A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17C08A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17C28A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17D07A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17D12A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17D19A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17D27A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17E02A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17E23A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17E31A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17E31B
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17F06A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17F20A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17F21A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17G12A
590-001	Bridge Occlusion Catheter - 80 mm Length Balloon	FMN17G18A