November 14, 2016

URGENT:
MEDICAL DEVICE RECALL
Turbo Elite™ Atherectomy Catheter ELCA™ Coronary Atherectomy Catheter

Customer Name
Customer Number
Addr Line 1
Addr Line 2
Addr Line 3
City, State ZIP
Customer Number

Dear Customer,

The purpose of this letter is to advise you that Spectranetics is voluntarily recalling specific lots of the Turbo Elite Atherectomy Catheter and ELCA Coronary Atherectomy Catheter which are indicated for:

ELCA Indications (OTW and RX (including 0.9 without 80Hz repetition))
The Laser Catheters are used in conjunction with the Spectranetics CVX-300® Excimer Laser System are intended for use in patients with single or multivessel coronary artery disease, either as a stand-alone modality or in conjunction with Percutaneous Transluminal Coronary Balloon Angioplasty (PTCA), and who are acceptable candidates for coronary artery bypass graft (CABG) surgery. Adjunctive balloon angioplasty was performed, at the clinical investigator's discretion, for 85% of the lesions treated. The following Indications for Use have been established through multicenter clinical trials. Clinical experience has provided reasonable assurance that the Spectranetics CVX-300® Excimer Laser System and the multifiber laser catheter models are safe and effective for the following indications:

- Occluded saphenous vein bypass grafts
- Ostial lesions

- Long lesions - (greater than 20 mm in length)
- Moderately calcified stenoses - (Heavily calcified stenoses are those lesions that demonstrate complete calcification when identified under fluoroscopy by angiography prior to the procedure. Moderately and slightly calcified stenoses are all others.)
- Total occlusions traversable by a guidewire
- Lesions which previously failed balloon angioplasty - (This includes those lesions that were treated unsuccessfully by PTCA. Lesions that have undergone a complicated PTCA procedure are not included in this category.)
- Restenosis in 316L stainless steel stents, prior to the administration of intravascular brachytherapy.
- These lesions must be traversable by a guidewire and composed of atherosclerotic plaque and/or calcified material. The lesions should be well defined by angiography.

ELCA Indications (0.9 with 80Hz repetition (X80))

The X-80 Laser Catheters used in conjunction with the Spectranetics CVX-300® Excimer Laser System are intended for use in patients with single or multivessel coronary artery disease, either as a stand-alone modality or in conjunction with Percutaneous Transluminal Coronary Balloon Angioplasty (PTCA), and who are acceptable candidates for coronary artery bypass graft (CABG) surgery. Adjunctive balloon angioplasty was performed, at the clinical investigator's discretion, for 85% of the lesions treated. The following Indications for Use have been established through multicenter clinical trials. Clinical experience has provided reasonable assurance that the Spectranetics CVX-300® Excimer Laser System and the multifiber laser catheter models are safe and effective for the following indications:

- Occluded saphenous vein bypass grafts
- Ostial lesions
- Long lesions - (greater than 20 mm in length)
- Moderately calcified stenoses - (Heavily calcified stenoses are those lesions that demonstrate complete calcification when identified under fluoroscopy by angiography prior to the procedure. Moderately and slightly calcified stenoses are all others.)
- Total occlusions traversable by a guidewire
- Lesions which previously failed balloon angioplasty - (This includes those lesions that were treated unsuccessfully by PTCA. Lesions that have undergone a complicated PTCA procedure are not included in this category.)
- These lesions must be traversable by a guidewire and composed of atherosclerotic plaque and/or calcified material. The lesions should be well defined by angiography.

Turbo Elite Indications:

For atherectomy of infrainguinal arteries.

Reason for the Voluntary Recall:

Spectranetics has issued this Field Action to voluntarily remove specific lot numbers of our

ELCA and Turbo Elite Atherectomy Catheters due to potentially compromised integrity of the outer sterile packaging. To date, Spectranetics received no customer complaints, and there is no reason to believe that any patients have been adversely impacted. Based on bench testing the frequency of potentially compromised pouch integrity is estimated to be approximately 20%. Based on input from physician advisors, the potential for infection as a result of this breach in sterility is extremely low. The risk potential is considered remote and is estimated between 0.002% and 0.02%.

Risk to Health:

If a device with a compromised outer package sterile barrier were to be utilized, there would be a possibility for a patient risk of infection. It would be difficult to visually identify a package with compromised integrity; therefore, although the risk is remote, customers are requested to return the potentially impacted lots prior to use.

Actions to be taken by the Customer/User:

Please discontinue use of the potentially impacted lots and return the product for replacement. These actions are temporary and limited to the lots identified. This recall is not expected to cause an interruption to device supply and replacement units will be provided shortly after the product is returned.

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 of any remaining product in inventory; however, you may also reach Customer Service at +31 33 43 47 050.

Product and Distribution Information:

PRODUCT	QUANTITY RECEIVED
ELCA Coronary Atherectomy Catheter	QTY FIELD – ELCA
Turbo Elite Atherectomy Catheter	QTY FIELD – TURBO ELITE

Type of Action by the Company:

In order to correct this issue Spectranetics is requesting return of all potentially impacted lots. Replacement units will be provided shortly after the product is returned. The failure investigation concluded that this issue is linked to a specific packaging 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
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: List of ELCA Coronary Laser Atherectomy Catheter lot numbers being recalled
Enclosure 2: List of Turbo Elite Laser Atherectomy Catheter lot numbers being recalled
Enclosure 3: Acknowledgement and Receipt Form

Enclosure 3:

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

Customer Name
Customer Number
Addr Line 1
Addr Line 2
Addr Line 3
City, State ZIP
Customer Number

Turbo Elite Atherectomy Catheter &
ELCA Coronary Atherectomy Catheter

I have read and understand the recall instructions provided in the November 14, 2016 letter. Yes __No__

Any adverse events not previously reported associated with recalled product? Yes ____ No____

If yes, please explain:

_____
_____
_____

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

<u>For Completion Only by Distributors</u>:

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**).

Affected Product Information Table						
Product/Brand Name	Manufacturer's Model Number	Lot/Serial Number	Customer Reference Number	Quantity Remaining in inventory	Quantity Shipped to Distributor Customers	Quantity returned to SPNC

ENCLOSURE 3 (continued)

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