Spectranetics®

Product Recall Notice: EU Shipments of Turbo-Booster® Laser Guide Catheters
Product Model Numbers: 518-043 & 518-063

15July 2011

Dear Healthcare Professional:

Spectranetics has identified a possible sterility issue involving Turbo-Booster Laser Guide Catheter product shipped to countries in the European Union. The specific lots impacted are attached to this letter and include production lots from 30 October 2009 through 12 July 2011 totaling a maximum of 180 units. For this reason, we are contacting you as an account who received devices from the affected lots to notify you that Spectranetics is initiating a voluntary recall of these devices. No other Turbo-Booster lots or other Spectranetics products are involved in this voluntary field action. Spectranetics has taken the appropriate corrective actions to correct this sterility issue for future production lots of the Turbo-Booster devices. While "Turbo" is used in other brand names of Spectranetics' products, this voluntary action affects only international Turbo-Booster product shipped from Spectranetics BV, Leusden, The Netherlands, to the EU and only the specific lots attached to this memo.

Spectranetics has identified through internal analysis that the weight of the multi-language Instructions for Use booklet included in the Turbo-Booster package sent to customers in the European Union may cause damage to the sterile packaging. We believe this poses a potential risk to patients due to a possible loss of device sterility if the packaging is damaged

We have received no customer complaints about the package integrity or sterility of our Turbo-Booster devices. No adverse events have been reported to Spectranetics for these products. We are initiating this field recovery of products based upon internal quality reviews and analysis. We are reporting this action to the U.S. Food and Drug Administration, Denver District, to our notified body, BSi, and to the Competent Authorities in the countries affected.

We ask you to please review your Turbo-Booster inventories and set aside these specific lots. Your Spectranetics sales representative or your distributor of these products will contact you to recover these specific devices and replace the product. Please work with them to coordinate the return of the requested devices and their replacement.

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 representative, or call me directly.

Sincerely,
The Spectranetics Corporation

[redacted]

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Attachment 1, List of Turbo-Booster lot numbers being recalled:

RECALL FORM FOR FIELD USE

Document Identifier: D003380
Responsible Department: Quality

Model Numbers: 518-043, 518-063

Product Name: Turbo-Booster Laser Guide Catheter, 7Fr, 8Fr

Hospital Name	Country	Model Number	Lot Number	Original Number of Devices Sent to Customer	Number Returned to SPNC BV	Number Used

Name of distributor filling out form: _____

Name of individual filling out form: _____

Signature: _____ Date: _____

Fax to Spectranetics BV after signing and mailing product
FAX: +31-33-43-47-051
Attn: [redacted]