



Product Advisory – Important Medical Device Information

Please post this letter in a prominent location

WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Stent Systems

December 4, 2017

Dear Materials Manager/Field Action Contact:

Boston Scientific is initiating a voluntary Advisory related to the above referenced products. Boston Scientific has determined that certain WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Stent Systems were shipped with labeling that includes indications for Venous and Transjugular Intrahepatic Portosystemic Shunt (TIPS), neither of which are authorized by Health Canada. The only authorized indications for use in Canada are Transhepatic Biliary and Tracheobronchial indications, as described in the table below. There have been no reports of patient injuries related to this labeling issue.

The below Affected Product Listing provides a list of all UPNs within the scope of this Advisory as well as the indications for use that are authorized by Health Canada. No other products or countries are affected by this action.

Affected Product Listing

Material Number (UPN)	Product Description	Indications for Use	
		Tracheobronchial	Transhepatic
H965402100	12X20/8FR UNI PLUS HALO 75CM	Tracheobronchial	Transhepatic
H965402110	12X40/8FR UNI PLUS HALO 75CM	Tracheobronchial	Transhepatic
H965402120	12X60/8FR UNI PLUS HALO 75CM	Tracheobronchial	Transhepatic
H965402130	12X90/8FR UNI PLUS HALO 75CM	Tracheobronchial	Transhepatic
H965403100	14X20/9FR UNI PLUS HALO 75CM	Tracheobronchial	
H965403110	14X40/9FR UNI PLUS 75CM	Tracheobronchial	
H965403120	14X60/9FR UNI PLUS 75CM	Tracheobronchial	
H965403130	14X90/9FR UNI PLUS 75CM	Tracheobronchial	
H965403300	16X20/9FR UNI PLUS 75CM	Tracheobronchial	
H965403310	16X40/9FR UNI PLUS 75CM	Tracheobronchial	
H965403320	16X60/9FR UNI PLUS 75CM	Tracheobronchial	
H965403330	16X90/9FR UNI PLUS 75CM	Tracheobronchial	
M001711320	10x20x75/ 6F Unistep Plus	Tracheobronchial	Transhepatic
M001711340	10x42x75/ 7F Unistep Plus	Tracheobronchial	Transhepatic
M001711360	10x68x75/ 7F Unistep Plus	Tracheobronchial	Transhepatic
M001711380	10x94x75/ 7F Unistep Plus	Tracheobronchial	Transhepatic

Boston Scientific
92185740-FA WALLSTENT™ RP Endoprosthesis and
WALLSTENT™ Endoprosthesis Stent Systems

We ask that you read this letter carefully and post it in a visible location that is easily accessible to all users of these devices. **Please Note: No product is being removed from the market and you are not required to return product to Boston Scientific.**

We also ask that you complete and return the enclosed Customer Acknowledgement Form as per the attached Advisory Instructions.

Affected regulatory authorities are being notified of this Advisory as required.

Boston Scientific is committed to continuing to offer products that meet the highest quality standards and we appreciate your understanding as action is taken to ensure customer satisfaction. If you have additional questions regarding this communication please contact your local Boston Scientific Sales Representative.

Sincerely,



John Zagala
Quality Assurance Canada
john.zagala@bsci.com

Encl: Advisory Instructions
Customer Acknowledgement Form

Product Advisory – Important Medical Device Information

Advisory Instructions

The Acknowledgment Form enclosed with this notification must be completed and returned **even if you no longer have any of the product.**

- 1. Immediately post this letter in a visible location near the product to ensure this information is easily accessible to all users of the device.**
- 2. Complete and return the Acknowledgment Form.**
 - Complete the enclosed Acknowledgment Form (even if you no longer have any of the products), following the directions on this page and on the form.
 - Return the Acknowledgment Form to:

Email: **CanadaBSCQuality@bsci.com**

or

Fax to: **(905) 696-1899**

Please email or fax your Customer Acknowledgment Form immediately upon completing the steps above.