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«Hospital_Name»
«Users_Name» - «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

Reference: 91098167-FA XX October 2015

Field Safety Notice
Urgent Medical Device Recall
RotaWire Elite™ Guidewire and wireClip™ Torquer Guidewire Manipulation Device

Dear «Users_Name»,

Boston Scientific is voluntarily initiating a recall removal for its recently released RotaWire Elite™ Guidewire and wireClip™ Torquer Guidewire Manipulation Device that is used in conjunction with the Rotablator™ Rotational Atherectomy System. During the limited market release, Boston Scientific has received three complaints for wire fracture. One fracture occurred during device prep, and the other two fractures occurred during the procedure resulting in burr migration into the pericardium. One of these involved placement of a covered stent to address vessel perforation. That patient subsequently expired. The other required surgery for removal of the fragment.

Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all affected products**, including Product Description, Material Number (UPN), Lot/Batch numbers and Expiration date. **Please note that only the material listed in the table below is affected. No other Boston Scientific product is involved by this Field Safety Notice**.
Further distribution or use of any remaining product affected by this action should cease immediately.

PLEASE NOTE: We are aware that, often times, hospitals will remove product from the outer carton and store on the shelves in the inner-pouch only. If this is a practice at your facility**, it is very important that you carefully use the product table and consider both the inner and outer packaging UPN codes when searching for affected/recalled product, as the UPN numbers on the inner and outer labelling may be different. The product information listed on your specific Verification Form (enclosed with this letter) provides outer package product coding only** and should be utilized when reporting product to return.

Verify by product batch/lot number in product table to determine if the batch within your inventory is affected. If so, indicate on your Verification Form the quantity of units from each batch that you will be returning. **As the product within these batches is sold as 5-packs, it is important that all reported quantities represent the actual number of single catheters being returned and not the number of cartons/boxes or multi-packs.**

Product Description	Material Number (UPN)		Lot/Batch	Expiration Date
	Outer carton label of 5 packs	Inner Pouch Single		
RotaWire Elite™ Guidewire and wireClip™ Torquer Guidewire Manipulation Device	H802223301	H802223300	18201519	25 June 2017 through 9 September 2017
			18212726	
			18256610	
			18261218	
			18271412	
			18282032	
			18362094	
			18378161	
			18379210	
			18384443	
	H802233301	H802233300	18141187	
			18194620	
			18220238	
			18261834	
			18285502	
			18303265	
			18390089	

INSTRUCTIONS:

1- **Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, irregardless of where these units are stored in your facility. **Segregate the units in a secure place, pending return to Boston Scientific**.

2- **Please complete the attached Verification Form** even if you do not have any product to return.

3- **When completed, please return the Verification Form to your local Boston Scientific office** to the attention of «Customer_Service_Fax_Number» on or before **XX October 2015**.

4- **If you have products to return,** please package them in an appropriate shipping box and **contact** «Customer_Service_Tel» **of your local Boston Scientific office,** to arrange return.

5- Please pass this notice to any health professional of your organization that need to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

[redacted]
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

Please Complete the form even if you do not have any affected product & send it to Your Local **Office**:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Verification Form – Urgent Medical Device Recall
"Name of the Product"

91098167-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated «Date_notif_sent».

2. **Boston Scientific records indicate you have received the following affected product** *(additionally please check inventory against complete list of affected product provided)*

/!\ REPORT ALL RETURNS IN SINGLE DEVICE UNITS AND NOT IN CARTON/BOX/MULTIPACK QUANTITIES

Product Description	**Material N° (UPN)**	**Lot / Batch N°**	**Customer PO**	**Qty Sent** (Box)	**Qty to return** (Units)
«DESCRIPTION»					

3. We confirm that all areas where affected product could be located have been checked.

4. **TICK ONE OF THESE STATEMENTS*****, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»

- ❑ We do not have any affected product.

- ❑ We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please **add the UPN, Lot/Batch/Serial number and the quantity to return.***

TO RETURN PRODUCTS:
1. Contact «Customer_Service_Tel» of your Local Office to arrange return of any affected product
2. Prepare the package
3. Follow the instructions given by your Local Office about collection of the package

NAME* _____Title _____

Telephone _____ Department _____

Customer' **SIGNATURE*** _____ **DATE*** _____
* Required field dd/mm/yyyy