

«Hospital\_Name»  
«Users\_Name»- «Department»  
«Customer\_Address»  
«Zip\_Code» «City» - «Country\_name»

**Reference: 91167229-FA**

xx April 2017

## **Field Safety Notice (for Distributor) - Urgent Medical Device Recall JETSTREAM™ XC 2.1mm and JETSTREAM™ SC 1.85mm Atherectomy Catheters**

Dear «Users\_Name»,

Boston Scientific is initiating a voluntary removal of two lots of JETSTREAM SC 1.85mm and one lot of JETSTREAM XC 2.1mm Atherectomy Catheters due to these units being mislabelled. Some 1.85mm JETSTREAM SC catheters may have been labelled as 2.1mm catheters, and some 2.1mm JETSTREAM XC catheters may have been labelled as 1.85mm catheters. **Only the UPN & lot in bold below is affected in Europe.**

To date, Boston Scientific has received two complaints related to this mislabelling issue. As supported by the complaints the most reasonably foreseeable consequence of this situation would be an insignificant prolongation of the procedure to exchange the device for another. There have been no reported patient adverse events as a result of this issue.

Boston Scientific acquired the Interventional Division of Bayer AG, which included the JETSTREAM Atherectomy System. The affected units that were distributed between January and September 2016 are labelled as Bayer product.

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) and Lot numbers. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

**Further distribution or use of any remaining product affected by this action should cease immediately.**

### **Affected Product Listing - only the UPN & lot in bold below is affected in Europe**

Product Description	UPN	Lot Number	Region Affected	Expiration Date Range
JETSTREAM SC Catheter, 1.85mm	112262-001	18775553	USA	27 December 2017
	<b>112262-003</b>	<b>18775552</b>	<b>Europe</b>	
JETSTREAM XC Catheter, 2.1mm	112264-001	18822086	USA	

**INSTRUCTIONS:**

- 1- **Check your Inventory for the products affected by this Field safety Notice.**
- 2- **Please segregate and do not distribute any of the affected products found in your inventory.**
- 3- **Please notify all your customers that have received affected product of this Field Safety Notice.** To effectively manage this Field Safety Notice, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this recall to the medical facility level.
- 4- **Have all affected product returned to your facility** and held in quarantine for reconciliation
- 5- **Please complete the attached Verification Form, even if you do not have any product to return.**
- 6- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer\_Service\_Fax\_Number» on or before **xx April 2017.**
- 7- **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.

Your Competent Authority is being notified of this Field Safety Notice (applicable for EU countries).

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act 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,

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Attachment: Verification Form