

**Urgent Medical Device Removal - Immediate Action Required**

**JETSTREAM™XC 2.1mm and JETSTREAM™SC 1.85mm Atherectomy Catheters**

April 5, 2017

Dear Materials Manager / Field Action Contact:

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 mislabeled. Some 1.85mm JETSTREAM SC catheters may have been labeled as 2.1mm catheters, and some 2.1mm JETSTREAM XC catheters may have been labeled as 1.85mm catheters.

To date, Boston Scientific has received two complaints related to this mislabeling 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 labeled as Bayer product. This removal affects only the lots listed in Table 1 below.

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

**Table 1: Affected Product Listing**

Product Description	Material Number (UPN)	Lot	Expiration Date
JETSTREAM SC Catheter, 1.85mm	112262-001	18775553	12/27/2017
	112262-003	18775552	
JETSTREAM XC Catheter, 2.1mm	112264-001	18822086	

If you identify any product from the listed lots within your inventory, please segregate it immediately and return it to Boston Scientific in accordance with the enclosed removal instructions. You will receive a replacement for any JETSTREAM catheter from the listed lot numbers that is returned to Boston Scientific.

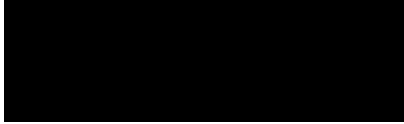
**If you are a distributor or hospital, please note that this recall is to the customer level. Please notify any customer who has received affected product.**

Regulatory authorities will be notified as required.

Please read carefully through the enclosed Removal Instructions. Your local Sales Representative can answer any questions that you may have regarding this Removal.

We regret the inconvenience caused by this action, and we appreciate your understanding as we take action to ensure customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,



Brendan Smith  
Boston Scientific Quality Systems  
763-494-1133  
[MapleGroveFieldActionCenter@bsci.com](mailto:MapleGroveFieldActionCenter@bsci.com)

Encl: Removal Instructions  
Account Reply Verification Tracking Form

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to Boston Scientific by calling 1-866-868-4004 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)

Regular Mail: use postage-paid FDA form 3500 available at [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787

Fax: (800) FDA-0178

Phone: (800) FDA-1088

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### **Removal Instructions**

The Account Reply Verification Tracking Form enclosed with this Customer Removal Notice must be completed and returned **even if you do not have any of the units from the removed lots.**

1. **Immediately discontinue use of and segregate removed product.**
  - Immediately remove all affected product from your inventory (whether in Central Service, Shipping and Receiving, or any other location).
  - Segregate this product in a secure location for return to Boston Scientific.
2. **Complete and return the Account Reply Verification Tracking Form (RVTF).**
  - Complete the enclosed Account Reply Verification Tracking Form (even if you do not have any product to return), following the directions on this page and the Account Reply Verification Tracking Form.
  - Return the Account Reply Verification Tracking Form:
    - Email:**            [MapleGroveFieldActionCenter@bsci.com](mailto:MapleGroveFieldActionCenter@bsci.com)
    - or
    - Fax to:**            **Field Action Center 1-866-213-1806**

**Please email or fax your Account Reply Verification Tracking Form(s) immediately. You will be contacted by Boston Scientific and provided a Returned Goods Authorization (RGA) Number after your RVTF is received. When returning the product, place the original form with returned products.**

3. **Package/Ship the Removed Product.**
  - Package any product that is being returned in an appropriate shipping box.
  - Affix a shipping label to the outside of the shipping box.
  - Write the **RGA number** in large print on the outside of the box, either on or near the shipping label.
  - Feel free to use our Federal Express Number 0554-0315-5 to return this package via second day delivery.
  - Seal the box, and return it to: **Boston Scientific Corporation**  
**US Distribution Center**  
**Boston Scientific Marina Bay**  
**Customer Fulfillment Center**  
**500 Commander Shea Blvd.**  
**Quincy, Massachusetts 02171**  
**RGA: \_\_\_\_\_**