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«Hospital_Name»
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Reference: 90893927-FA

XXXX, 2013

Field Safety Notice
Urgent Medical Device Recall
Boston Scientific 13F/15F Navigator™ HD Ureteral Access Sheath Set

Dear «Users_Name»,

Boston Scientific is conducting a Recall Removal of the 13F/15F Navigator™ HD Ureteral Access Sheath Set. No other sizes of Navigator HD are impacted by this recall. Boston Scientific has received reports from the field where the tip of the dilator has separated from the body of the dilator. To date, we have received five (5) complaints for this issue. The most common adverse health consequence that is reasonably expected to occur due to this device issue would be a secondary intervention to remove the tip.

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.

Product Description	Material # (UPN)	Catalog Number	Lot/Batch			Expiration Date
13F/15F x 28cm Navigator™ HD Ureteral Access Sheath Set	M0062502270	250-227	15708431	15708432	15708433	18-Jan-2015 to 21-Feb-2015
			15812875	15836355	15855545	
			15876213	15896950	15935564	
			16028474	16044445	16046280	
13F/15F x 36cm Navigator™ HD Ureteral Access Sheath Set	M0062502280	250-228	15753725	15819257	15840833	14-Dec-2013 to 8-Aug-2015
			15877193	15918445	15931128	
			16008343	16015286	16065866	
			16141201	16295107	16319657	

13F/15F x 46cm Navigator™ HD Ureteral Access Sheath Set	M0062502290	250-229	15579545	15579546	15615465	18-Jan-2015 to 26-Jun-2015
			15630771	15630772	15688533	
			15688534	15813601	15823202	
			15880464	15927981	16159896	
			16175942	16196763	16373048	

INSTRUCTIONS:

1. **Please immediately discontinue use of the Boston Scientific product** listed above **and remove all of the affected units from your inventory** (whether in Interventional Operating Room, Central Supply, Shipping & Receiving and any other relevant location). **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 **fax the Verification Form** to your local Boston Scientific Office to the attention of «Customer_Service_Fax_Number» on or before **November xx, 2013.**

4. **If you have products to return,** please package them in 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,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form