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

Reference: 90872934-FA (PI) INSERT DATE

Field Safety Notice
Urgent Medical Device Recall
4.00mm x 15mm Small Peripheral Cutting Balloon™ Monorail™ Microsurgical Dilatation Device

Dear «Users_Name»,

Boston Scientific is initiating a recall removal of the 4.00mm x 15mm size of Small Peripheral Cutting Balloon™ Monorail™ Microsurgical Dilatation Device. Boston Scientific has determined that users may experience significant difficulty or inability to remove the protector cap from the device prior its use in the patient, which may result in damage to the device. We have received 45 complaints related to this issue from April 2013 to current date, none of which have resulted in patient injury and no additional risk to the patient is expected to occur as a result of this issue which is detected at the preparation phase of the device prior its use inside of the body. Other dimensions of similar device including smaller OD profile (3.5 mm and 3.75 mm) are excluded from this field safety action since they present less constraint by the fit of the balloon inside of the protector cap and that no issue has been reported with the protector cap removal of these devices.

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
Small Peripheral Cutting Balloon Monorail Microsurgical Dilatation	M001BPM4015140F0	BPM4015140F	15735527	15774378	15778169	16-Nov-2015 to 03-Jun-2016
			15788826	15812347	15824636	
			15825277	15836626	15873338	
			15891705	15931291	15945240	
			16057260			

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 Cath Lab., Radiology, Fluoroscopy Suite, 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 **August 20, 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,

Quality Department
Boston Scientific International S.A.

Attachment: Verification Form