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

Reference: 90859089-FA May xx, 2013

Field Safety Notice
Urgent Medical Device Recall
RIGIFLEX™ II Single Use Achalasia Balloon Dilator

Dear «Users_Name»,

Boston Scientific is initiating a medical device recall of the RIGIFLEX™ II Single Use Achalasia Balloon Dilator. Boston Scientific has become aware that the pouch label expiration date on a single lot/batch of RIGIFLEX™ II Single Use Achalasia Balloon Dilators is labeled with the incorrect expiration date, 0213-12. Boston Scientific has confirmed that the correct expiration date is 2013-12 (in the year-month format, YYYY-MM). Therefore, the product is not expired and there is no patient risk related to the labeling issue if the product is used prior to 2013-12. However, to avoid any potential for use of expired product we are initiating a recall of affected 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), 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 Number (UPN)	Catalog Number	Lot/Batch	Expiration Date
RIGIFLEX™ II Single Use Achalasia Balloon Dilator	M00554510	5451	091541	2013-12

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 **June 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,

Quality Department
Boston Scientific International S.A.

Attachment: Verification Form