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

Reference: 90631300-FA

October XX, 2010

Field Safety Notice
Urgent Medical Device Recall
Matrix^{2}™ Detachable Coil

Dear «Users_Name»,

Boston Scientific is initiating a Medical Device Recall on **Matrix^{2}™ Detachable Coils.**
Matrix2 Detachable Coils are platinum coils which are covered with a bioactive material called Polyglycolic-polylactic Acid (PGLA). Two product complaints regarding the Matrix^{2} Detachable Coils were confirmed to have had PGLA degradation prior to the shelf-life expiration date. There have been no patient injuries reported to date associated with these complaints. However, a potential clinical risk of foreign body embolization of the PGLA covering during the implant procedure exists. Embolism may occur if partially degraded PGLA material is introduced into the circulation. The clinical consequence of an embolism of PGLA material could vary from none to catastrophic stroke. The probability of occurrence of a catastrophic stroke is estimated to be remote. The highest risk of embolic stroke due to use of affected Matrix^{2} coils is likely limited to the peri-procedural period. It is recommended that implanted patients be followed as per standard of care.

Please be advised that we currently have more than eight months of unaffected inventory on hand to serve our global markets, and replacement product will be made available for recalled product that is properly returned to Boston Scientific. There will be periods of backorder by product mix before all affected products can be replaced.

Our records indicate that your facility received some of the concerned product. **Attachment A provides a complete list of all affected products**, including Product Description, Material Number (UPN) and Batch numbers and expiration date. **Please note that only the material listed in Attachment A is affected. No other Boston Scientific product is involved by this Field Safety Notice.**

INSTRUCTIONS:

1. **Please immediately discontinue use of the Boston Scientific product** listed in the Attachment A **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 **November XX, 2010.**

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 A - Affected products