

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

Reference: 90497811-FA

May xx, 2009

Field Safety Notice Urgent Medical Device Recall Neuroform³ Microdelivery Stent System

Dear «Users_Name»,

Boston Scientific is initiating a recall on the Neuroform³ Microdelivery Stent System. We determined that an isolated number of Neuroform³ units were packaged in the wrong product carton – a green Wingspan product carton. Although the Neuroform³ labelling is correct on each individual unit, the carton is wrong. The most reasonable expected outcome is a clinically insignificant delay of procedure. To date, Boston Scientific has received four (4) customer complaints relating to this packaging error.

Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all recalled products**, including Product Description, Material Number (UPN), Catalog Numbers and Lot Numbers. Please note that only the material and Lot/Batch/Serial numbers listed in the table below are affected. No other Boston Scientific product is involved in this voluntary Field Safety Notice.

Product Description	Material Number (UPN)	Catalog Number	Lot/Batch Number
Neuroform ³ Microdelivery Stent System 4.0 x 30 mm	M003E3400300	E340030	12304877

INSTRUCTIONS:

1. **Please immediately discontinue use of the Boston Scientific product listed in the table 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, 2009.**
4. **If you have products to return, please package them in an 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.

Attachments: Verification Form