

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

Reference: 90505407-FA

20 July, 2009

Field Safety Notice
Urgent Medical Device Recall
RF Ablation System Foot Switch
used with EPT-1000 Cardiac Ablation systems

Dear «Users_Name»,

Boston Scientific is conducting a voluntary Recall of the **RF Ablation System Foot Switches** used with the EPT-1000™ Cardiac Ablation System. To date, there have been no reported patient injuries. However, two customer foot switch complaints associated with the RF delivery have been confirmed. As a result, Boston Scientific will replace Model M0048400 Foot Switches over the next several months.

During the product complaint investigation, it was discovered that there was a potential to deliver RF energy without depressing the foot switch. Under normal operating conditions, the operator can hear a distinct audible sound and a light on the generator turns on when RF is being delivered. If the foot switch is not depressed, and the audible sound is heard and/or the indicator light is on, the foot switch is not functioning properly. This failure mode has been confirmed on two units that are more than seven years old. As a result, Boston Scientific will be replacing all affected units over several months.

While we have not had any reported injuries, with the Cardiac Ablation System in ready mode, and the foot switch attached, with the ablation catheter already placed inside the patient, there is the potential to inadvertently ablate tissue in the heart or the vasculature if the ablation catheter is inside the patient. This may cause bleeding and possibly perforate the heart tissue which can lead to tamponade.

Please note that the Boston Scientific RF Cardiac Ablation Systems may be operated without the use of a foot switch. Please refer to the Operator's Manuals for details.

Our records indicate that your facility received some of the concerned products. Attachment A includes a full 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 Attachment A are affected. No other Boston Scientific product is involved in this voluntary Field Safety Notice.

INSTRUCTIONS:

1. **Please complete the attached Verification Form even if you do not have any product to return.**
2. **When completed, please fax the Verification Form to your local Boston Scientific Office** to the attention of «Customer_Service_Fax_Number» on or before **03 August, 2009.**
3. **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.
4. 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.

Please be assured that we will work with you in the coming months to replace the affected footswitches. 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,

Attachment: - Attachment A

Quality Department
Boston Scientific International S.A.

Product Description	Material Number (UPN)	Catalog Number	Lot/Batch Number									
			91017	91018	91019	91020	91021	91022	91023	91024	91025	91026
RF Ablation System Foot Switch used with EPT-1000 Cardiac Ablation systems	M0048400	840	91027	91028	91029	91030	91230	91231	91232	91233	91234	91235
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			91502	91503	91504	91505	91506	91507	91508	91509	91510	91511
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			94407	94408	94409	94410	94411	94412	94413	94414	94415	94416
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