



Boston Scientific International S.A.
 European Headquarters – Paris
 55, Avenue des Champs Pierreux
 TSA 51101
 92729 Nanterre Cedex
 France

Tél. 33 (0)1 57 66 80 00
 Fax 33 (0)1 57 66 84 99
www.bostonscientific.com

«Sold_to» - CP

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

Reference: 90511546-FA

08 July, 2009

Field Safety Notice Urgent Medical Device Recall LeVeen™ Needle Electrodes – 5.0cm

Dear «Users_Name»,

Boston Scientific Corporation is conducting a Medical Device Recall of the LeVeen™ Needle Electrodes – 5.0cm. Boston Scientific has become aware that during a procedure, the umbrella of the LeVeen™ Needle Electrode – 5.0cm may become detached from the core wire. The potential clinical effects of this product issue are bleeding or soft tissue trauma which may require intervention. To date there has been one reported complaint for this issue.

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 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					
LeVeen™ Needle Electrode – 5.0cm/15	M001262160	6216	8745076	8745077	8745078	8745082	8745083	8764662
			8764663	8840136	8840210	8888632	8922046	8922047
			8922048	8925499	8946944	8952359	8960112	8991516
			9007921	9023847	9051903	9063250	9080980	9103385
			9103712	9103713	9103714	9135758	9153911	9160547
			9275203	9288929	9300199	9303597	9406392	9447228
			9464347	9484064	9502208	9516123	9591056	9629225
			9643197	9659590	9708545	9727738	9763201	9776097
			9783671	11001461	11005784	11034758	11042785	11091132
			11114016	11128377	11128379	11178425	11203868	11230657
			11356155	11403788	11440970	11460060	11551315	11580328
			11620899	11711276	11766589	11851200	11881851	11900344
			11916630	11931597	11943359	11947005	12324021	12450298
			12517661	12621268				

LeVeen™ Needle Electrode – 5.0cm/25	M001262170	6217	8839481	8900349	9043740	9084603	9296400	9300554
			9442864	9531903	9569178	9707800	9746026	9787308
			11182329	11203869	11350192	11403787	11518357	11559944
			12219051	12475134				

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 Quality Assurance/Regulatory Affairs on 01442 411 816 on or before **23 July, 2009.**
4. **If you have products to return**, please package them in an appropriate shipping box and **contact** Quality Assurance/Regulatory affairs on 01442 411 731 **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,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form