

«Hospital_Name»

«Users_Name» - «Department»

«Customer_Address»

«Zip_Code» «City» - «Country_name»

Reference: 91038589 -FA

xx April 2015

Urgent Field Safety Notice Medical Device Removal Lotus™ Valve System

Dear «Users_Name»,

Boston Scientific is initiating a medical device recall of seven (7) units of the **Lotus™ Valve System**. Boston Scientific has become aware that the box carton labels for these seven units display an incorrect expiration date that is one month past the actual expiration date. Please note the expiration date on the pouch for these units is correct. No adverse health consequence is expected to occur from this issue. To date, Boston Scientific has received no complaints for the incorrect expiration date on the box carton label.

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), Catalog number and Lot/Batch numbers. **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
Lotus™ Valve System	H749LTV230	LTV23	17520706
	H749LTV230	LTV23	17520708
	H749LTV230	LTV23	17520709
	H749LTV230	LTV23	17520717
	H749LTV230	LTV23	17520781
	H749LTV230	LTV23	17520785
	H749LTV230	LTV23	17520787

INSTRUCTIONS:

1. **Please immediately discontinue use of the Boston Scientific product listed above and remove all of the affected units from your inventory, irregardless of where these units are stored in your facility. 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 send the Verification Form to your local Boston Scientific Office to the attention of «Customer_Service_Fax_Number» on or before 4 May 2015.**
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,

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

Attachment: Verification Form