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«Hospital\_Name»

«Users\_Name» - «Department»

«Customer\_Address»

«Zip\_Code» «City» - «Country\_name»

**Reference: 90973990AB-FA**

xx November 2014

## **Field Safety Corrective Action Important Medical Device Information Lotus™ Valve System**

Dear «Users\_Name»,

Boston Scientific is initiating a Field Safety Corrective Action (FSCA) for the Lotus™ Valve System to remove units from the field that were manufactured prior to a recent design change. Product manufactured after the design change is not impacted and therefore you can continue to treat patients with these units. The specific list of units affected is included in this letter. There are no safety issues for patients who previously received a Lotus implant.

This action is related to a previous Field Safety Notice that was initiated in July 2014 in response to a very low rate of cases for the Lotus™ Valve becoming unlocked during the release phase of the implantation procedure, thereby necessitating additional intervention to implant another valve. At that time, Boston Scientific informed all users of updates to the Physician Training materials to clarify the step-by-step instructions for implanting the Lotus™ Valve. The revised training was effective and no further incidents of a valve becoming unlocked during the procedure have been reported.

Boston Scientific implemented a design change to prevent a locked valve from becoming unlocked during the procedure. This design change received regulatory approval and was implemented in September 2014. Boston Scientific is now taking additional action to remove all units from the field that were manufactured prior to this design change.

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), Lot/Batch numbers and expiration date. **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	Expiration Date
Lotus TAVR 23mm	H749LTV230	LTV23	14113043, 14118011, 14118012, 14119047, 14119048, 14119049, 14119050, 14119051, 14120027, 14120028, 14120029, 14120030, 14120031, 14121035, 14121036, 14121037, 14121038, 14121039, 14121040, 14121041, 14125040, 14125041, 14125042, 14125043, 14125044, 14125045, 14125046, 14125047, 14125048, 14125049, 14127073, 14127077, 14127078, 14127079, 14127080, 14127081, 14127082, 14127083, 14127084, 14127085, 14127086, 14141044, 14141045, 14141046, 14141047, 14141048, 14141049, 14141050, 14141051, 14141052, 14141053, 14148034, 14148035, 14148036, 14148037, 14148039, 14153054, 14153055, 14153057, 14153058, 14153059, 14153075, 14153076, 14153077, 14153078, 14153079, 14157003, 14157015, 14157016, 14157017, 14157019, 14157020, 14157021, 14157022, 14157023, 14178024, 14178025, 14178026, 14178027, 14178028	Nov. 15, 2014 to Jan. 24, 2015
Lotus TAVR 25mm	H749LTV250	LTV25	14126051, 14126052, 14126053, 14127058, 14128047, 14128048, 14128049, 14128050, 14129004, 14129005, 14129006, 14129007, 14129008, 14133006, 14133007, 14133008, 14133009, 14133010, 14134042, 14134043, 14134044, 14134045, 14134047, 14134049, 14134050, 14134054, 14148005, 14148006, 14148007, 14148008, 14148009, 14148010, 14148011, 14148012, 14148013, 14148014, 14148015, 14148019, 14148020, 14148021, 14148022, 14148023, 14148024, 14148026, 14148027, 14156025, 14156026, 14157007, 14157008, 14157009, 14157010, 14157011, 14157012, 14157013, 14160009, 14160011, 14160012, 14160015, 14161036, 14161037, 14161038, 14161040, 14162050, 14162051, 14162053, 14162054, 14163052, 14163053, 14163054, 14163055, 14165004, 14165005, 14165006, 14165007, 14165008, 14167012, 14167013, 14167015, 14167016, 14167017, 14167018, 14167019, 14167020, 14167021, 14170001, 14170002, 14170003, 14170004, 14170005, 14170031, 14170032, 14170034, 14170035, 14170036, 14170037, 14170038, 14170039, 14170040, 14171031, 14171032, 14171033, 14171036, 14171037, 14171038, 14171039, 14171040, 14172017, 14172018, 14172019, 14172020, 14172021, 14172022, 14172023, 14172024, 14176021, 14176022, 14176023, 14176024, 14176025, 14176029, 14176030, 14176031, 14176032, 14176033, 14178036, 14178038, 14178039, 14178040, 14178041, 14178042, 14178043, 14178045,	Nov. 15, 2014 to Jan. 24, 2015

Product Description	Material Number (UPN)	Catalog Number	Lot	Expiration Date
Lotus TAVR 25mm, cont.	H749LTV250, cont.	LTV25, cont.	14179048, 14179050, 14179051, 14179052, 14179053, 14179054, 14179055, 14179057, 14182027, 14182029, 14182031, 14183011, 14183013, 14183014, 14183015, 14184003, 14184004, 14184005, 14184006, 14184007, 14184008, 14184009, 14184010, 14184011, 14188009, 14188010, 14188012, 14188013, 14188014, 14188015, 14188016, 14188017, 14188018, 14191021, 14191022, 14191023, 14191024, 14191030, 14193002, 14193003, 14193007, 14193011, 14193012, 14193013, 14193014, 14193022, 14197042, 14197047, 14197048, 14197049	Nov. 15, 2014 to Jan. 24, 2015
Lotus TAVR 27mm	H749LTV270	LTV27	14076030, 14076031, 14079012, 14079013, 14149023, 14149031, 14149038, 14149040, 14150028, 14150029, 14153080, 14153081, 14153082, 14154040, 14157024, 14157025, 14157026, 14157027, 14157029, 14157030, 14157031, 14157032, 14157033, 14165041, 14165042, 14165043, 14165044, 14175039, 14175040, 14175041, 14175042, 14175043, 14175044, 14175045, 14175047, 14178019, 14178020, 14198066, 14198067, 14198068, 14198069	Nov. 15, 2014 to Jan. 24, 2015

**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 fax the Verification Form to your local Boston Scientific Office to the attention of «Customer\_Service\_Fax\_Number» on or before **xx November 2014.****
4. **If you have products to return, please 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 Field Clinical Specialist.

Yours sincerely,



Quality Department  
Boston Scientific International S.A.

Attachment: Verification Form