

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

Reference: 92036067-FA

31 October 2016

Field Safety Notice - Urgent Medical Device Recall LOTUS™ Edge Valve System

Dear «Users_Name»,

Boston Scientific is implementing a voluntary Field Safety Corrective Action (FSCA) for the recently launched LOTUS™ Edge Valve System to remove all units from the field. The specific list of units is included in this letter.

There have been seven reports where the valve could not be fully locked and released. In six cases, the valve was retrieved and removed, resulting in procedure prolongation. In one case the valve was positioned in the descending aorta. In all seven cases, the patient was successfully treated with a new valve. Boston Scientific has not received any reports of other serious adverse events associated with this failure mode; however potential complications could include stroke and/or vessel trauma.

There is no safety issue for patients who previously received a LOTUS Edge valve since the issue only occurs during the implant procedure and does not impact the performance of the implanted valve.

This FSCA affects all UPNs and batches of the LOTUS Edge Valve System.

Note: The current generation LOTUS Valve System continues to be available and is not affected by this removal.

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) and Lot numbers. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

Further distribution or use of any remaining product affected by this action should cease immediately.

Product Description	UPN	Lot Number	Expiration Date Range
LOTUS™ Edge Valve System	H749LVS230	See attached listing for lot numbers	13 February 2017 through 14 July 2017
	H749LVS250		
	H749LVS270		
	H749LVSCL230		
	H749LVSCL250		
	H749LVSCL270		

INSTRUCTIONS:

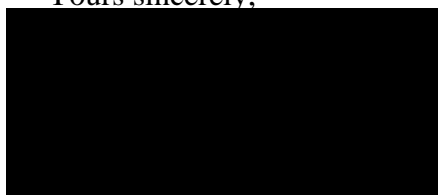
- 1- **Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.
- 2- **Please complete the attached Verification Form even if you do not have any product to return.**
- 3- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **15 November 2016**.
- 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 healthcare professional from your organization that needs 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 act 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: - Verification Form

Boston Scientific International S.A.

Affected Product Listing

UPN H749LVS230									
LOT NUMBER									
19607049	19607053	19607054	19607057	19607059	19607281	19607282	19607283	19607284	19607285
19607286	19607287	19616582	19616583	19616584	19629155	19629156	19629158	19634292	19634294
19634297	19634298	19643114	19643115	19643116	19643117	19643118	19643119	19643240	19643241
19643242	19643243	19662048	19662049	19671954	19671955	19671956	19672250	19672252	19672254
19672622	19672707	19672824	19672957	19677699	19677920	19677921	19678613	19678614	19678615
19678867	19687079	19687180	19687181	19687182	19687183	19687184	19697182	19697184	19697185
19697186	19697187	19697188	19697189	19697191	19697192	19697193	19697194	19697195	19697196
19697197	19697198	19697260	19697261	19697263	19717226	19717227	19717229	19717230	19717231
19717232	19717233	19717235	19717236	19717237	19717238	19733040	19733041	19740617	19740729
19740730	19740732	19740733	19740735	19740736	19740737	19740739	19741001	19741002	19741003
19741004	19741005	19741006	19741007	19741008	19741009	19741010	19750116	19750117	19750118
19750173	19750174	19750175	19750176	19750177	19750178	19750260	19750261	19750262	19750263
19750264	19750265	19750266	19750501	19750502	19750503	19750504	19769317	19769318	19769319
19769580	19769581	19769582	19769583	19769584	19769585	19769586	19769587	19769588	19769589
19769590	19769591	19775315	19790425	19790426	19790427	19790428	19790429	19790430	19790431
19790432	19790433	19790434	19790435	19790436	19790437	19790438	19790439	19790460	19790461
19790462	19790463	19790465	19790466	19790467	19790468	19790470	19790471	19790472	19790473
19790502	19802385	19802386	19802387	19802388	19802390	19802391	19802393	19808813	19808814
19808815	19808816	19808817	19808818	19808819	19808920	19808921	19808922	19817646	19817647
19817648	19817650	19817652	19817653	19817655	19817657				

UPN H749LVS250									
LOT NUMBER									
19606554	19606555	19606670	19606671	19606672	19606673	19607551	19607552	19607553	19607554
19607555	19607556	19607557	19607558	19607559	19607621	19607622	19607623	19616586	19616587
19616588	19616589	19616590	19616591	19616592	19616593	19616594	19616595	19616596	19616597
19616598	19616599	19616660	19623504	19623505	19623506	19623507	19623508	19623509	19623510
19623511	19623512	19623513	19623514	19623515	19623517	19623519	19623663	19629159	19629280
19629282	19629283	19634299	19634601	19634605	19643245	19643246	19643247	19643248	19643249
19643250	19643251	19643252	19643253	19643254	19643255	19643256	19643257	19643258	19643259
19643300	19643301	19643302	19643303	19643304	19643305	19643306	19662101	19662102	19662103
19662104	19662105	19662107	19662108	19662109	19662110	19662111	19662112	19662113	19662114
19717225	19750505	19750506	19750508	19761481	19761482	19761483	19761484	19769592	19769593
19769594	19769595	19769596	19775316	19775317	19775318	19775319	19775380	19775381	19790474
19790475	19790476	19790477	19790478	19790479	19790500	19790501	19802394	19802395	19802396
19802397	19802398	19802460	19802461	19802462	19802463	19802464	19802465	19802466	19802467
19802468	19802469	19802470	19802471	19808924	19808925	19808926	19808927	19808928	19808929
19808930	19808931	19808932	19808933	19808934	19808935	19808936	19808937	19808939	19809000
19809002	19809003	19809004	19809005	19809007	19817658	19817659	19818620	19818621	19818622
19818623	19818624	19818625	19818626	19818627	19818628	19818629	19818631	19826395	19826398
19826399	19826593	19826595	19826596	19826597	19826598				

UPN H749LVS270

LOT NUMBER

19643111	19643112	19643113	19662051	19662052	19662053	19662054	19662056	19662059	19662100
19733042	19733043	19733044	19733046	19733047	19733048	19733050	19733051	19733052	19733053
19733054	19733055	19733056	19733057	19733058	19733059	19733100	19733102	19733103	19733104
19733105	19741300	19741301	19741302	19741304	19741305	19741306	19741307	19741309	19741311
19741313	19741314	19741315	19741316	19741318	19750510	19750511	19750512	19750513	19750515
19750516	19750517	19750518	19761485	19761486	19761487	19761488	19761489	19761490	19761491
19761492	19761493	19761494	19761495	19761496	19761497	19761498	19761499	19761520	19761521
19761522	19761523	19761524	19761525	19761526	19769599	19769700	19769701	19769702	19769703
19769704	19769705	19769706	19769707	19769708	19769709	19769710	19769711	19769712	19769713
19769714	19769715	19769717	19769718	19769740	19769741	19769742	19769743	19769744	19769745
19769746	19769747	19769748	19775354	19775391	19775392	19775393	19775394	19775395	19775396
19775397	19775398	19775399	19775540	19775541	19775542	19775543	19775544	19775545	19775546
19775547	19775548	19775549	19775550	19775551	19775552	19775553	19775554	19775555	19775556
19775557	19775558	19775559	19775660	19775661	19775662	19775663	19775664	19775665	19775666
19775667	19790228	19790229	19790230	19790231	19790232	19790233	19790234	19790235	19790236
19790237	19790238	19790239	19790720	19790722	19790723	19802473	19802474	19802475	19802476
19802477	19802478	19802479	19802540	19802541	19802542	19802543	19802544	19802545	19802546
19802547	19802548	19802549	19809188	19809189	19809190	19809191	19809192	19809193	19809194
19809195	19809196	19809198	19809199	19809461	19809462	19809463	19809464	19809465	19809466
19809467	19809468	19817733	19817735	19817736	19817738	19817739	19818761	19818762	19818764
19818767	19818768	19818769	19818773	19818778					

UPN H749LVSCL230

LOT NUMBER

19257109	19257226	19257236	19257237	19257238	19257239	19257260	19257261	19257262	19305279
19409736	19410202	19410203	19410204	19410205	19410206	19410207	19410208	19410209	19410210
19410211	19410212	19410213	19410214	19410215	19410216	19410217	19410218	19410219	19410340
19441397	19441399	19441500	19452602	19454183	19468871	19468872	19468873	19490067	19490068
19510890	19672951	19672952	19672953	19775305	19775306	19775307	19775308	19775309	

UPN H749LVSCL250

LOT NUMBER

19424188	19424189	19424190	19453757	19454189	19454191	19454192	19454193	19454195	19454196
19454197	19454198	19454199	19454260	19454261	19454263	19468874	19468875	19468877	19468878
19489838	19489839	19490060	19490061	19490062	19490063	19500174	19500175	19500176	19500177
19500178	19510891	19672954	19672955						

UPN H749LVSCL270

LOT NUMBER

19453758	19453908	19453909	19453910	19453911	19453912	19453913	19453914	19453915	19453916
19453917	19453918	19453919	19454540	19454541	19454542	19454543	19468879	19469080	19469081
19473186	19489837	19500179	19500460	19500461	19500462	19500463	19510892	19677922	19686441
19716644	19716645	19721822	19721823	19721824	19721825	19721826	19721827	19721828	19721829
19775310	19775311	19775312	19775313	19775314					



Please Complete the form even if you do not have any affected product & send it to Your Local Office:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Verification Form – Urgent Medical Device Recall
"Name of the Product"
92036067-FA

- 1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated «Date_notif_sent».
- 2. **Boston Scientific records indicate you have received the following affected product** (additionally please check inventory against complete list of affected product provided)

Product Description	Material N° (UPN)	Lot / Batch N°	Customer PO	Qty Sent (Units)	Qty to return (Units)
«DESCRIPTION»					

- 3. We confirm that all areas where affected product could be located have been checked.
- 4. **TICK ONE OF THESE STATEMENTS*, SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»
 - We do not have any affected product.
 - We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please **add the UPN, Lot/Batch/Serial number and the quantity to return.***

TO RETURN PRODUCTS:

- 1. Contact «Customer_Service_Tel» of your Local Office to arrange return of any affected product
- 2. Prepare the package
- 3. Follow the instructions given by your Local Office about collection of the package

NAME* _____ Title _____

Telephone _____ Department _____

Customer' SIGNATURE* _____ DATE* _____
* Required field dd/mm/yyyy