



Urgent Field Safety Corrective Action - Immediate Action Required

Lotus™ Valve System

24-Feb-2017

Dear Doctor,

Boston Scientific (BSC) is implementing a voluntary Field Safety Corrective Action for the Lotus™ Valve System to remove all units from the field. The specific list of UPNs and batches are included in Attachment 1.

BSC has recently received a higher than anticipated number of reports of early pin release prior to locking the valve in the final position. If this occurs, the valve is unable to be fully locked, which requires the valve to be resheathed and removed from the patient prolonging the procedure. Removal of the valve was successful in all but one case; in that case, the valve embolized and was secured in the descending aorta. All patients were successfully treated with another valve, except for one reported case where the affected valve was removed, but an aortic dissection occurred during implantation of the second valve and the patient died.

Further distribution or use of any remaining affected product should cease immediately. This action affects all UPNs and batches of the Lotus Valve System.

There are no safety concerns for patients who have previously received a Lotus Valve and the issue **does not impact the performance of the implanted valve**. It is only a potential issue during the implant procedure itself.

If you identify any product from the affected lots within your inventory, please segregate/quarantine the product immediately and return it to Boston Scientific in accordance with the enclosed instructions. **If you are a distributor, please note that the depth of this action is to the hospital level and this notification should be forwarded to your customers.**

Affected worldwide regulatory authorities are being notified of this action as required.

Please read carefully through the enclosed instructions. Your local Boston Scientific Representative can answer any questions that you may have regarding this notification.

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. We are committed to continuing to offer products that meet the highest quality standards you expect from Boston Scientific.

Thank you.


Shauna Kon
Senior Therapy Development Specialist, TAVI, ASEAN

Urgent Medical Device Removal Instructions

The Reply Verification Tracking Form enclosed with this Removal Notice must be completed and returned **even if you do not have any of the devices from the affected lots.**

1. **Immediately discontinue use of and segregate affected product.**
 - Immediately remove all affected product from your inventory
 - Segregate this product in a secure location for return to Boston Scientific.
2. **Complete and return the Reply Verification Tracking Form (RVTF).**
 - Complete the enclosed Reply Verification Tracking Form (even if you do not have any product to return), following the directions on this page and the Reply Verification Tracking Form.
 - Return the Account Reply Verification Tracking Form:
 Email:
 or
 Fax to:

Please email or fax your Account Reply Verification Tracking Form(s) immediately. You will be contacted by Boston Scientific and provided a Returned Goods Authorization (RGA) Number after your RVTF is received. When returning the product, place the original form with returned products.

3. **Package/Ship the Affected Product.**
 - Package any product that is being returned in an appropriate shipping box.
 - Affix a shipping label to the outside of the shipping box.
 - Write the **RGA number** in large print on the outside of the box, either on or near the shipping label.
 - Feel free to use our Federal Express Number 0554-0315-5 to return this package via second day delivery.
 - Seal the box, and return it to:

Attachment 1

Lotus™ Valve System Affected Product Listing

H749LTV230									
19223528	19223532	19223533	19223534	19224559	19224820	19224821	19224822	19224823	19228563
19228564	19228565	19228566	19228567	19228568	19240303	19240304	19240305	19240306	19240307
19240308	19240309	19240310	19240311	19240312	19240313	19240314	19240315	19240317	19267282
19267283	19267284	19267285	19267286	19267287	19267288	19267289	19267290	19267291	19267292
19267293	19267294	19267295	19267296	19275029	19275030	19275031	19275032	19275033	19275034
19276687	19276688	19276690	19276691	19289060	19289061	19289062	19289063	19289064	19289065
19289066	19289067	19289068	19289069	19289070	19289071	19289072	19289073	19289074	19313981
19313982	19314255	19314256	19314257	19314258	19314259	19314268	19314269	19314271	19314272
19314273	19314275	19319468	19319469	19319470	19319471	19319472	19319473	19319474	19319475
19319476	19319477	19319478	19319479	19319540	19319541	19319542	19329691	19329692	19329694
19329695	19329696	19329697	19329698	19329699	19329841	19329842	19329843	19329844	19329845
19329846	19329847	19329848	19330580	19341680	19341681	19341682	19341683	19341684	19341685
19341686	19341687	19341689	19341693	19354007	19354008	19354010	19354011	19354012	19354013
19354014	19354016	19354017	19354018	19354019	19354140	19361022	19361023	19361024	19361025
19361026	19361027	19361028	19361029	19361030	19361031	19361032	19361033	19361034	19361035
19361036	19361037	19361038	19361039	19361160	19361161	19361162	19361163	19361164	19361165
19361166	19383355	19383356	19383357	19383359	19383440	19383441	19383442	19383443	19392382
19392383	19392384	19392385	19392386	19394206	19394207	19394413	19394414	19401531	19401532
19401533	19401535	19401536	19401537	19401538	19401539	19401681	19401689	19401690	19401691
19401692	19401693	19401694	19401695	19401696	19401697	19401698	19401699	19401880	19401881
19401882	19401883	19401884	19401885	19401886	19401887	19402039	19402140	19402142	19402143
19401882	19401883	19401884	19401885	19401886	19401887	19402039	19402140	19402142	19402143
19402144	19402145	19402146	19402863	19415098	19415099	19415120	19415121	19415122	19415123
19415124	19434525	19434526	19434527	19434528	19434530	19440828	19440829	19440830	19440831
19440832	19440833	19440834	19440835	19440836	19440837	19440838	19442066	19442067	19445723
19453795	19453796	19453797	19453798	19453799	19454120	19454121	19454122	19454123	19454124
19454125	19454126	19454127	19454128	19454129	19454132	19454133	19454135	19454136	19454138
19458340	19469089	19469090	19469091	19469092	19469093	19469094	19469095	19469096	19469097
19469098	19469099	19469160	19469161	19469162	19469163	19478777	19478778	19478779	19479660
19479662	19479663	19479664	19479665	19479666	19479667	19479668	19479669	19479670	19479671
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19500912	19520168	19520169	19520170	19520171	19520172	19520173	19520174	19520175	19520176
19520177	19520179	19520302	19520304	19520305	19520308	19520310	19520312	19520313	19520314
19520315	19521158	19521159	19521282	19521283	19521284	19521285	19521287	19521288	19521289

H749LTV230 (continued)									
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19550187	19574602	19574603	19574604	19574605	19623839	19624000	19624001	19624003	19624004
19624005	19624006	19624007	19624008	19624009	19624010	19624012	19624015	19624044	19624045
19624047	19624048	19624049	19624051	19624052	19624053	19624054	19624055	19624056	19624057
19624058	19624059	19624120	19624121	19624122	19624123	19624124	19624125	19624126	19624128
19624367	19624368	19624369	19624370	19624371	19624372	19624373	19624374	19628649	19628650
19628651	19628652	19628653	19629298	19629623	19629625	19629626	19629627	19629628	19629629
19629630	19629631	19629632	19629633	19629634	19630040	19634607	19634608	19634741	19634742
19634743	19634744	19634745	19634746	19634747	19634748	19634749	19634750	19634751	19634752
19671949	19686217	19696763	19696929	19696930	19696931	19696932	19696933	19696934	19696935
19726618	19726619	19740132	19740133	19740134	19740135	19740136	19740137	19740138	19740139
19740460	19749791	19749792	19749793	19749794	19749795	19749796	19749797	19749798	19750161
19750162	19761182	19761183	19761184	19848249	19848250	19848251	19848252	19861463	19861464
19861465	19861466	19861467	19885045	19885046	19885048	19885052	19885053	19890312	19890313
19890315	19890316	19890317	19890319	19890380	19890383	19890384	19890385	19890386	19890387
19890388	19890389	19890391	19890392	19890393	19890394	19890395	19890396	19890397	19890398
19890399	19890503	19890504	19895428	19895429	19895430	19895431	19895432	19895433	19895434
19895435	19895436	19895437	19895438	19895439	19895620	19895621	19895622	19895623	19895624
19895625	19895626	19895627	19916375	19916376	19916377	19916378	19916379	19917040	19917041
19917042	19917043	19917044	19917045	19917046	19917047	19917048	19917049	19935901	19935902
19935903	19935904	19935905	19935906	19935907	19935909	19935910	19948872	19948873	19948874
19948875	19948876	19948877	19948878	19948879	19949140	19949141	19949142	19949143	19949144
19949145	19949146	19949147	19949148	19949149	19949150	19949151	19960098	19960099	19960360
19960361	19960362	19960363	19960364	19960365	19960366	19960367	19960368	19960369	19960370
19960371	19960372	19960373	19960374	19960375	19960376	19960377	19972094	19972096	19972098
19972420	19972422	19972424	19972426	19972428	19972429	19972432	19972433	19972434	19972435
19972440	19972446	19972447	19972448	19972449	19972450	19972451	19972452	19972454	19972457
19972460	19972463	19972466	19972467	19972468	19972469	19972470	19972471	19972472	19972473
19972474	19972475	19979283	19979284	19979285	19979286	19979287	19979288	19979289	19979290
19979291	19979292	19988417	19988418	19988419	19988460	19988461	19988462	19988463	19988464
19988465	19988466	19996029	19996031	19996032	19996033	19996034	19996035	19996036	19996037
19997010	20004021	20004022	20004023	20004024	20004025	20004026	20004027	20004028	20004029
20005581	20005832	20005833	20005834	20005835	20005836	20005837	20005838	20005839	20005881
20005882	20005884	20005885	20030905	20030906	20030907	20030908	20030909	20030910	20030911
20030912	20030913	20030914	20030915	20030916	20030917	20030918	20030919	20031060	20045129
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20045300	20045301	20045302	20045304	20045305	20045306	20045307	20045308	20045309	20045310
20045311	20045312	20045313	20045314	20045315	20048495	20048496	20048497	20048498	20048499

H749LTV230 (continued)									
20048660	20048661	20066454	20066457	20066760	20066763	20066764	20066765	20066766	20066767
20066768	20066769	20066770	20066773	20066774	20066775	20066776	20066777	20066778	20066779
20066800	20066801	20072639	20073060	20073061	20073062	20073063	20073064	20073065	20073066
20106300	20106302	20106303	20106304	20106305	20106308	20106309	20106310	20106311	20106312
20106313	20106314	20106315	20106316	20106317	20106318	20106319	20106460	20106461	20106462
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20106548	20106549	20106550	20106551	20106552	20106553	20106554	20106555	20106556	20106557
20106558	20106559	20106560	20106561	20106562	20106563	20106564	20106567	20106568	20106569
20106570	20106571	20106572	20106573	20106574	20106575	20106576	20106577	20106578	20106579
20106680	20106681	20121075	20121076	20121077	20121300	20121302	20121303	20121307	20121311
20121312	20121313	20121314	20121315	20121316	20121317	20121318	20121319	20121320	20121321
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20126882	20126883	20126884	20126885	20145465	20145466	20145467	20145468	20145469	20145470
20145471	20145472	20145473	20145474	20145476	20145477	20145541	20145543	20145544	20145545
20145546	20145547	20145548	20145549	20145550	20145551	20145552	20145553	20145554	20145555
20145556	20145557	20145558	20145559	20145600	20145601	20145603	20145605	20145607	20145608
20145609	20145610	20145611	20145612	20145614	20145615	20145616	20145617	20145618	20145619
20145640	20145642	20145653	20145654	20145655	20145656	20145657	20145658	20145659	20149224
20149225	20149228	20149229	20149230	20149231	20149232	20149233	20149234	20149235	20149236
20149237	20149238	20149260	20149261	20149263	20149266	20149268	20149270	20149272	20149273
20149274	20149275	20149276	20149277	20149278	20149279	20149280	20149281	20149282	20150756
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20165408	20165409	20166298	20171027	20171028	20171029	20171030	20193283	20193287	20193289
20193290	20193293	20193296	20193297	20193298	20193441	20193442	20193443	20193444	20193445
20193447	20193448	20193455	20193458	20204916	20204918	20205416			

H749LTV250									
19212899	19212943	19212946	19212947	19212948	19212949	19212950	19212952	19213238	19223535
19223537	19223538	19223622	19223623	19223626	19223628	19223629	19223630	19223631	19223632
19223633	19223634	19223635	19223636	19223637	19223638	19223639	19223660	19223661	19223662
19223663	19223664	19224824	19228569	19240099	19240300	19240301	19240302	19259112	19259113
19259114	19259115	19259116	19259117	19259118	19259119	19259560	19267297	19267298	19267299
19267420	19267421	19267422	19267423	19267424	19267425	19267426	19267427	19267428	19267429
19267430	19267431	19275039	19275440	19275441	19275442	19275444	19275445	19275446	19275447
19275448	19275449	19275450	19275451	19276692	19276693	19276694	19276695	19276696	19276697
19288990	19288993	19289000	19289001	19289075	19289076	19289077	19289078	19289079	19289140
H749LTV250 (continued)									

19289141	19289142	19289143	19289144	19289145	19289146	19289147	19313983	19313984	19313985
19313987	19313988	19313989	19313990	19313991	19313992	19313993	19313994	19313995	19314241
19314242	19314243	19314244	19314245	19314246	19314247	19314253	19314254	19314262	19314265
19319548	19319549	19319550	19319551	19319552	19319553	19319554	19319555	19319556	19319557
19319558	19320652	19320654	19329853	19329854	19329855	19329856	19329857	19329858	19329859
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19330010	19330011	19330012	19330013	19330014	19330016	19330017	19330018	19330019	19330060
19330581	19341696	19341698	19341699	19341700	19341701	19341702	19341703	19341704	19341705
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19354149	19354150	19354151	19354152	19354153	19354154	19354155	19354156	19361167	19361168
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19361179	19361200	19361201	19361202	19361203	19364944	19364945	19364946	19364947	19364948
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19364959	19364960	19364961	19364962	19364963	19372437	19372438	19372439	19372880	19372881
19372882	19372883	19372884	19372885	19372886	19372887	19372888	19372889	19372890	19372891
19372892	19372893	19372894	19372895	19372896	19372897	19372898	19372899	19372900	19372901
19372902	19372903	19372904	19372905	19372906	19372907	19372908	19372909	19372910	19372911
19372912	19372913	19372914	19372915	19372916	19372918	19372919	19372921	19372922	19383055
19383056	19383057	19383058	19383059	19383101	19383103	19383104	19383105	19383106	19383107
19383108	19383109	19383110	19383111	19383112	19383113	19383114	19383115	19383116	19383340
19383341	19383342	19383343	19383344	19392388	19392389	19392390	19392391	19392392	19392393
19392394	19394406	19394407	19394408	19394409	19394410	19402025	19402026	19402027	19402028
19402029	19402030	19415125	19415126	19415127	19415128	19415129	19415130	19424739	19424840
19424841	19424842	19424843	19424844	19424845	19424846	19424847	19424848	19424849	19424850
19424851	19424852	19424853	19424854	19424855	19434533	19434534	19434536	19434537	19434538
19434539	19434580	19434581	19434582	19434583	19434584	19434585	19434586	19434587	19434588
19434589	19434590	19440839	19440900	19440901	19440902	19440903	19440904	19440905	19440906
19440907	19440908	19440909	19440910	19440911	19440912	19445916	19445917	19445918	19445919
19445921	19445922	19445923	19445924	19445925	19445926	19445928	19445929	19445930	19445931
19445932	19445933	19445934	19445935	19445936	19458402	19458404	19458405	19458406	19458407
19458408	19458409	19458410	19458411	19458412	19458413	19458414	19469164	19469165	19469167
19469168	19469170	19469171	19469263	19469264	19469265	19469266	19479645	19479649	19479650
19479651	19479653	19479654	19479656	19479657	19479658	19479860	19479861	19479862	19479871
19479880	19479881	19479882	19479883	19490226	19490227	19490228	19490229	19490230	19490231
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19500572	19500640	19500641	19500642	19500643	19513654	19513655	19513656	19513657	19513658
19513659	19513800	19513801	19513802	19513803	19513804	19513805	19513806	19513807	19513808
19513809	19513810	19513811	19514905	19514906	19514907	19514908	19514909	19514910	19514911
19520316	19520317	19520319	19520340	19520341	19522101	19522102	19522103	19550192	19550193
19550194	19550195	19550196	19550198	19550199	19550260	19550261	19550262	19550263	19550264
H749LTV250 (continued)									
19550265	19550266	19550267	19550268	19550269	19550270	19550271	19550272	19550273	19550275

19550276	19550277	19550278	19550279	19564520	19564521	19564522	19564523	19564524	19564525
19564526	19564527	19564528	19564529	19564530	19564531	19564532	19564533	19564534	19564535
19564536	19564537	19564538	19564539	19564640	19564641	19564642	19564643	19564644	19574606
19574607	19574608	19574609	19574610	19574611	19574612	19574613	19574614	19574616	19574617
19574618	19574619	19574620	19574621	19574623	19574624	19574625	19574626	19574627	19574628
19583692	19583693	19583694	19583695	19583696	19583697	19583698	19583699	19583940	19583941
19583942	19583943	19583944	19583945	19583946	19583947	19583948	19583949	19583950	19583951
19583952	19583953	19583954	19583955	19605753	19605754	19605755	19605756	19605758	19605840
19605841	19605842	19605843	19616441	19616442	19616443	19616444	19616445	19616446	19616447
19616448	19616449	19616450	19616451	19616452	19616453	19616454	19616455	19616456	19616457
19616458	19616459	19616580	19616581	19617175	19623833	19623834	19629635	19629636	19629637
19629638	19629639	19629640	19634658	19634659	19634740	19634886	19686219	19686440	19686452
19686453	19686454	19686455	19686456	19686457	19686458	19686459	19686540	19686541	19686542
19696769	19696770	19696772	19696773	19696774	19696775	19696776	19696936	19696937	19715233
19725739	19726603	19726604	19726605	19726606	19726607	19726608	19726609	19726610	19726611
19726612	19726613	19726616	19726617	19726640	19733106	19733107	19733108	19733109	19733110
19733111	19733112	19733113	19733114	19733115	19733116	19733117	19733118	19733119	19733140
19733141	19740461	19740462	19740463	19750163	19750164	19750165	19750166	19751281	19751296
19761464	19761465	19761466	19761467	19761468	19802550	19802551	19818779	19848253	19848254
19848256	19848257	19848258	19848259	19848260	19848261	19848262	19856996	19856997	19856998
19856999	19857040	19857368	19857369	19857370	19857371	19857372	19861468	19861470	19861471
19861472	19885054	19885059	19885201	19885202	19885203	19885204	19885205	19885206	19885207
19885208	19896125	19896126	19896127	19896128	19899945	19926675	19926676	19926677	19926678
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19761470	19761471	19761472	19761473						

**RECALL REMOVAL REPLY VERIFICATION TRACKING FORM****PRODUCT NAME: Lotus Valve****Instructions:** This form must be completed and returned in all cases even if you do not have any affected product.

Immediately complete form and Scan/e-mail to: _____ OR Fax to #: _____

Account #:**Customer Name:**

Contact Name:

Address:

City:

State:

Province:

Postal Code:

Country:

Our records indicate you have received the following affected product:

UPN/Material Number	Lot/Batch/Serial Number	Quantity Shipped	Shipment Date	P.O. Number	Quantity Single Units to be Returned
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Section to be filled out by Customer:**1. Please Indicate:**

- ☐ We have checked all areas where affected product could be located and have determined we do not have any affected product.

OR

- ☐ We have found affected product and have quarantined as instructed in this Recall Notification. Please indicate the quantity to be returned (in single units) in the above table. To return affected product, follow the instructions provided within this notification or from your (country) local office.

Please also indicate:

Are you a Distributor? ☐ Yes, and we have notified all customers that have been shipped/sold affected product
☐ No

2. Sign and Date to acknowledge this Field Action Notification (must be completed):

Print Name: _____ Signature: _____ Date: _____

Phone: _____ Fax: _____ E-mail: _____

BSC OFFICE USE ONLY:

RGA Number: _____ RGA# Issued By: _____ Date: _____

Replacement Order # (if applicable): _____

Date: _____

Field Action #:

Customer Name:

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Date:

Account #:

Field Action #:92066792-FA

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