

«Hospital\_Name»

«Users\_Name»- «Department»

«Customer\_Address»

«Zip\_Code» «City» - «Country\_name»

**Reference: 91131010AC-FA**

8 August 2016

## **Field Safety Notice - Urgent Medical Device Recall Lotus™ Valve System**

Dear «Users\_Name»,

Boston Scientific is implementing a voluntary Field Safety Corrective Action (FSCA) for the Lotus™ Valve System, to remove units from the field that were manufactured prior to a component related change made in March 2016. Products manufactured after the implementation of this change are not impacted and therefore you can continue to treat patients with those units. The specific list of units affected is included in this letter. There is no additional safety issue for patients who previously received a Lotus implant since the issue only involves the delivery system and is not related to the performance of the implanted valve.

This action is related to release mandrel breaks. The release mandrel is a component of the delivery system that is connected to the release pin which facilitates release of the valve from the delivery system.

There were a number of release mandrel breaks reported for product manufactured prior to the component change. The most common outcome was resheathing and removing the device without difficulty, resulting in procedural prolongation. However, the most severe outcome was catastrophic vessel trauma associated with patient death, which was reported in three cases.

Since the component change in March 2016, Boston Scientific has not received any reports of release mandrel breaks for units built after this change. Boston Scientific is now taking action to remove all units from the field that were manufactured prior to this 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) 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.**

<b>Product Description</b>	<b>UPN</b>	<b>Lot Number</b>
Lotus™ Valve System	H749LTV230	See below Affected Product Listing
	H749LTV250	
	H749LTV270	

## **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 Fax: 80 30 80 05 - Email: NordicProdQuality@bsci.com on or before **22 August 2016**.
- 4- **If you have products to return**, please package them in an appropriate shipping box and **contact Victoria Bolin** - Tel: +46 (0)70-25 96 732 **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.

**There is no impact to previously implanted devices.**

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,



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

Attachment: - Verification Form

«Hospital\_Name»  
«Users\_Name» - «Department»  
«Customer\_Address»  
«Zip\_Code» «City» - «Country\_name»

Reference: 9191131010AC-FA

8 August 2016

## **Field safety notice - Øjeblikkelig tilbagekaldelse af medikoteknisk produkt Lotus™ Valve System**

Kære «Users\_Name»,

Boston Scientific iværksætter en frivillig, sikkerhedsrelateret, korrigerende handling (Field Safety Corrective Action - FSCA) for Lotus™ Valve System for at fjerne enheder, der er fremstillet, før der blev udført en komponentændring i marts 2016. Produkter, der er fremstillet efter realiseringen af denne ændring, er ikke påvirkede, og patienter kan derfor fortsat behandles med disse enheder. Den specifikke liste over de enheder, der er påvirket, følger med dette brev. Der er ingen yderligere sikkerhedsrisiko for patienter, der tidligere har modtaget et Lotus-implantat, da problemet kun omfatter leveringssystemet og ikke er forbundet med funktionen af den implanterede klap.

Denne handling er relateret til brud på udløsningsdornen. Udløsningsdornen er en komponent i leveringssystemet, der er forbundet til udløsertappen, som letter frigørelsen af klappen fra leveringssystemet.

Der er rapporteret om brud på udløsningsdornen for produkter, der er fremstillet, inden komponenten blev ændret. Det mest almindelige resultat er genovertrækning og fjernelse af enheden uden problemer, hvilket forlænger proceduren. Det mest alvorlige resultat var dog et catastrophic vessel trauma, der resulterede i patientens død. Dette er rapporteret i tre tilfælde.

Siden komponenten blev ændret i marts 2016 har Boston Scientific ikke modtaget nogen rapport om brud på udløsningsdornen for enheder, der er fremstillet efter denne dato. Boston Scientific har taget skridt til at fjerne alle enheder, der er fremstillet før denne ændring, framarkedet.

Vore optegnelser viser, at din enhed har modtaget nogle af de omfattede produkter. **Den følgende tabel er en komplet liste over alle tilbagekaldte produkter**, herunder produktbeskrivelse, materialenummer (UPN) og Lot/Batch-numre. **Bemærk venligst, at det kun er nedenstående produkt, og batchnumre, der er påvirkede. Intet andet produkt fra Boston Scientific er involveret.**

**Yderligere distribution eller brug af ethvert resterende produkt berørt af denne sag skal ophøre omgående.**

<b>Produktbeskrivelse</b>	<b>Katalognummer</b>	<b>Lot/Batch-numre</b>
Lotus™ Valve System	H749LTV230	Se nedennævnte liste over omfattede produkter
	H749LTV250	
	H749LTV270	

## **INSTRUKTIONER:**

1- I bedes med øjeblikkelig virkning standse brugen af de Boston Scientific produkter der er angivet i listen over omfattede produkter, og fjerne alle de berørte enheder fra jeres lagre, uanset hvor disse enheder opbevares i jeres bygninger. Isolér enhederne et sikkert sted, og afvent returnering til Boston Scientific.

2- Udfyld venligst den medfølgende bekræftelsesblanket selvom i ikke har nogle af de omfattede produkter.

3- Når bekræftelsesblanketten er udfyldt, sendes den via fax til den lokale Boston Scientific kundeservice til Fax: 80 30 80 05 - Email: NordicProdQuality@bsci.com før den **22 August 2016**.

4- Hvis du har produkter, der skal returneres, så pak dem i en passende forsendelsesæske og kontakt Victoria Bolin - Tel: +46 (0)70-25 96 732 hos din lokale Boston Scientific kundeservice, for at arrangere tilbagesendelsen.

5- Lad denne meddelelse gå videre til andre sundhedsfaglige medarbejdere indenfor jeres organisation, der har behov for at være opmærksomme på dette og til enhver organisation, hvortil potentielt omfattede produkter kan være overført (hvis relevant). Giv venligst Boston Scientific detaljerede oplysninger (pr. telefon eller fax) om ethvert påvirket produkt, der er overført til andre organisationer (hvis relevant).

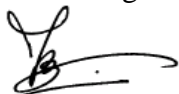
Din kompetente myndighed er ved at blive underrettet om denne tilbagekaldelse.

### **Dette påvirker ikke tidligere implanterede enheder.**

Vi beklager enhver ulejlighed som denne aktion måtte medføre, og vi sætter pris på jeres forståelse, da vi handler for at sikre patientsikkerheden og kundernes tilfredshed.

Skulle du have nogle spørgsmål eller ønsker hjælp med denne tilbagekaldelse af en medicinsk anordning, så kontakt din lokale salgsrepræsentant.

Med venlig hilsen,



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

Vedlagt: Bekræftelsesformular

## Liste over omfattede produkter

UPN H749LTV230									
LOT NUMBER									
18557226	18557228	18557229	18557230	18557231	18557232	18557233	18557234	18557235	18557236
18557237	18557238	18557239	18557280	18557281	18557282	18557283	18557284	18557285	18557286
18557287	18557288	18557289	18557290	18567314	18567315	18567316	18567317	18567318	18567319
18567720	18567721	18567722	18567723	18567724	18567725	18567727	18567728	18567729	18567730
18573213	18573821	18573822	18573824	18573825	18573826	18573827	18573828	18573829	18588493
18588494	18588495	18588496	18588497	18588498	18588499	18588680	18588681	18588682	18588685
18588690	18592144	18592145	18592146	18592147	18592148	18603353	18603355	18603357	18603359
18603400	18603401	18603402	18603403	18603404	18603405	18603406	18603407	18603408	18603409
18603410	18603411	18603412	18603413	18603414	18603415	18603442	18603454	18603467	18603487
18618297	18618666	18618667	18618668	18618669	18618670	18618671	18618672	18618673	18618674
18618675	18619167	18641434	18641435	18641436	18641437	18641438	18641439	18641620	18641621
18641622	18641623	18641624	18641625	18641626	18641627	18641628	18672720	18672721	18672722
18672723	18672724	18672725	18672726	18672727	18672728	18672729	18672730	18672731	18672732
18672733	18672734	18688244	18688245	18688246	18688248	18688250	18688251	18688252	18688253
18688255	18688256	18699492	18699493	18699494	18699495	18699496	18699497	18699498	18699499
18699940	18699941	18699942	18699943	18699944	18699945	18699946	18699947	18699948	18699949
18699950	18699951	18715720	18715721	18715722	18715723	18715724	18715725	18715726	18715727
18715728	18715729	18715730	18715731	18715732	18715733	18715734	18732514	18732515	18732516
18732517	18732518	18732519	18732580	18732581	18732582	18732583	18732584	18732585	18732586
18744340	18744341	18744342	18777049	18777050	18777051	18777052	18777053	18793919	18794240
18794241	18794242	18794243	18794244	18794245	18794246	18794247	18794248	18803932	18803933
18803934	18803935	18803936	18803937	18803938	18803939	18804200	18804202	18804204	18804206
18804207	18804208	18804209	18804210	18804211	18804212	18804213	18804214	18804215	18819873
18819874	18819875	18821307	18821310	18841468	18841469	18841470	18841471	18841474	18841475
18841476	18841478	18856896	18856897	18856898	18856899	18857300	18872643	18872644	18872645
18872646	18872647	18872648	18872649	18872650	18872651	18872652	18872654	18872655	18872656
18872657	18872658	18872659	18872760	18872761	18872762	18872763	18872764	18872765	18872766
18872767	18872768	18872769	18872770	18872771	18872772	18872773	18872828	18872831	18872832
18872835	18872837	18895480	18895481	18895482	18895483	18895484	18895485	18895486	18895487
18895488	18895489	18895490	18895491	18895492	18895493	18895494	18895495	18895496	18895497
18895498	18895499	18903458	18903459	18903720	18903721	18903722	18903723	18903725	18903726
18903727	18903728	18903729	18903730	18903732	18903733	18903735	18903736	18903738	18903739
18903821	18903822	18903824	18907360	18907362	18907363	18907364	18907365	18907857	18907858
18931268	18942924	18942925	18942926	18942927	18942928	18942929	18942930	18942931	18942932
18942933	18942934	18942935	18942936	18942937	18942938	18943060	18943063	18943067	18943068
18943070	18943071	18943072	18943074	18943075	18943076	18943077	18943078	18943079	18943120
18943121	18943534	18943535	18943536	18947899	18948520	18948521	18948522	18948523	18948721
18948722	18948723	18966037	18966038	18966039	18966180	18966181	18966182	18966183	18966184
18966185	18966186	18966187	18966188	18966189	18966190	18966191	18966192	18966193	18966196
18966197	18966198	18976719	18977460	18977461	18977462	18977463	18977464	18977465	18977467
18977471	18977472	18991759	18992120	18992121	18992122	18992123	18992124	19008926	19008927

19008933	19020264	19020265	19020270	19020272	19020273	19020274	19020275	19020276	19020277
19020278	19020279	19020380	19020381	19020382	19020383	19020384	19020385	19020386	19020978
19020979	19021460	19021461	19021462	19021463	19021466	19021468	19021470	19021473	19021474
19021475	19021476	19021478	19021479	19025730	19025731	19025732	19025733	19025734	19031644
19031645	19031646	19031647	19031649	19031650	19031651	19031652	19031653	19031655	19031656
19031657	19031659	19039911	19039912	19039914	19041577	19041578	19041579	19041680	19041681
19041682	19041683	19041684	19041685	19041686	19041687	19041688	19041689	19060430	19060431
19060432	19060433	19060434	19060435	19060436	19060437	19060438	19060439	19060701	19060702
19060703	19060704	19060732	19060733	19060734	19061503	19061831	19074396	19081090	19091059
19103035									

UPN H749LTV250									
LOT NUMBER									
18557291	18557292	18557293	18557295	18557296	18557297	18557298	18557299	18557320	18567731
18567732	18567733	18567734	18567735	18567736	18567737	18567738	18567760	18567761	18573830
18573832	18573833	18573834	18573835	18573836	18573837	18573838	18573839	18573940	18573941
18573942	18573943	18573944	18573945	18573946	18573947	18573948	18573949	18573950	18588699
18588740	18588741	18588742	18588743	18588744	18588745	18588746	18588748	18588749	18588750
18588751	18602962	18602963	18602964	18602965	18602966	18602967	18602968	18602969	18602970
18602971	18602973	18602974	18602975	18602976	18602978	18603302	18603304	18603305	18603307
18603309	18603315	18603316	18603317	18603318	18618676	18618677	18618678	18618679	18618680
18618682	18618683	18618685	18618687	18641426	18641427	18641428	18641429	18641430	18641431
18641432	18641433	18672735	18672737	18672738	18672739	18672740	18672741	18672742	18672743
18672744	18672746	18672747	18672748	18672749	18672753	18672755	18672756	18672757	18672758
18672759	18672820	18672821	18672822	18688117	18688118	18688119	18688240	18688241	18688242
18688243	18699793	18699794	18699795	18699796	18699797	18714732	18714733	18714734	18714735
18714736	18714738	18714739	18715240	18715241	18715242	18715243	18715244	18715245	18715246
18715247	18715248	18715249	18715250	18715251	18715252	18715253	18715254	18715255	18715256
18715257	18732587	18732588	18732589	18732590	18732591	18732592	18732593	18732594	18732595
18732596	18732597	18732598	18732599	18732620	18732622	18732623	18732624	18732625	18732626
18732627	18732628	18732629	18732630	18732632	18744344	18744345	18744346	18744347	18744348
18744349	18744350	18744351	18744352	18744353	18744354	18744355	18744356	18744357	18744358
18744359	18767514	18767515	18767516	18767517	18767518	18767519	18767820	18767821	18767823
18767826	18767827	18767828	18776656	18776657	18776658	18776659	18777182	18777185	18777186
18777187	18777188	18777189	18777190	18777191	18777192	18777193	18777194	18777195	18777196
18777197	18777198	18777199	18777260	18777261	18777262	18777263	18777264	18777265	18777266
18777267	18777268	18777269	18777270	18777271	18777272	18777273	18777274	18777275	18777277
18777322	18777324	18777325	18794249	18794250	18794251	18794252	18794253	18794254	18794255
18794256	18794257	18794258	18794259	18794300	18794301	18804219	18804260	18804262	18804266
18804268	18804269	18804270	18804271	18804889	18804891	18804893	18819877	18819878	18819879
18819960	18819961	18819962	18819963	18819964	18819965	18820536	18841479	18841681	18841682
18841683	18841684	18841685	18841686	18841687	18841688	18841689	18853154	18853155	18853156
18853157	18853158	18853159	18853600	18853601	18853602	18853603	18872547	18872548	18872549
18872550	18872551	18895500	18895501	18895502	18895503	18895504	18895505	18895506	18895507
18896545	18896572	18903827	18903831	18903833	18903834	18903835	18914073	18914074	18914075
18914076	18914077	18914078	18914079	18914180	18914183	18914184	18914185	18914186	18914187

18914188	18914189	18914190	18914191	18914192	18917618	18917619	18917981	18917983	18918480
18918481	18931269	18931270	18931271	18931273	18931274	18931275	18931276	18931277	18931278
18931279	18931500	18931501	18931502	18931503	18931504	18931505	18931506	18948524	18948525
18948526	18948527	18948528	18948529	18948530	18948531	18948532	18948533	18948534	18948535
18948536	18948537	18948538	18948539	18948660	18948661	18948662	18948663	18948664	18948667
18966407	18966408	18966409	18966410	18966411	18966666	18966667	18966670	18966672	18966673
18977920	18977921	18977922	18977923	18977924	18981687	18981693	18981695	18981696	18981697
18981699	18981840	18981841	18991746	18991747	18991748	18991749	18991750	18991751	18991752
18991753	18991754	18991755	18991756	18991757	18991758	18992728	18992729	18993052	18993053
18993054	18993055	18993056	18993057	18993058	18993059	18993180	18993181	18993182	19004618
19004721	19004723	19004724	19004725	19004726	19004727	19004728	19008934	19008935	19008936
19008937	19008938	19020387	19020388	19020389	19020391	19020393	19020394	19020395	19020396
19020397	19020398	19020399	19020520	19020521	19020522	19020523	19020524	19020525	19031109
19031110	19031111	19031112	19031113	19031760	19031761	19031762	19031763	19031764	19031765
19031766	19031767	19031768	19031769	19031770	19031771	19031772	19031773	19031774	19031775
19031776	19040018	19040019	19040060	19040061	19040062	19040063	19040064	19040065	19040067
19040068	19040069	19041572	19041573	19041574	19041575	19041690	19041691	19041692	19041693
19041695	19041696	19060705	19060706	19060707	19060708	19060709	19060710	19060711	19060712
19060713	19060714	19060735	19081165	19081166	19081239				

<b>UPN H749LTV270</b>									
<b>LOT NUMBER</b>									
18557321	18557322	18557323	18557324	18557325	18557326	18557327	18557328	18557329	18557330
18557331	18557332	18557333	18557334	18557335	18557336	18557337	18557338	18557339	18557360
18557361	18557364	18557366	18557368	18567762	18567763	18567764	18567765	18567766	18567767
18567768	18567769	18567770	18567771	18567772	18567773	18567774	18567775	18567776	18567777
18567778	18567779	18567780	18567781	18567782	18567783	18567784	18567785	18567786	18567787
18567788	18567789	18567790	18567791	18573952	18573953	18573954	18573955	18573956	18573959
18574020	18574021	18574022	18574023	18574024	18574025	18574026	18574027	18574028	18574029
18574030	18574031	18574032	18574033	18574034	18574035	18574036	18574037	18574038	18574039
18574060	18574062	18588752	18588753	18588754	18588755	18588756	18588758	18588759	18588780
18588781	18588783	18588784	18588785	18592149	18592152	18592420	18592421	18603681	18603683
18603685	18603688	18603689	18618688	18618693	18618694	18618695	18618696	18618697	18618698
18618699	18618720	18618721	18618722	18618723	18618724	18618725	18618726	18618727	18618728
18618729	18618730	18618731	18618732	18618733	18618734	18618735	18618736	18619163	18619164
18619165	18619166	18641650	18641651	18641863	18641864	18641865	18641867	18641869	18641870
18641871	18641872	18641873	18641874	18641875	18641876	18641877	18641878	18641879	18641901
18641903	18641904	18641905	18666906	18666907	18666908	18666909	18666910	18666911	18666912
18666913	18666914	18666915	18666916	18666917	18666918	18666919	18667140	18668306	18672823
18672824	18672825	18672826	18672827	18672830	18672831	18672832	18672833	18672834	18672835
18672836	18672837	18672838	18672839	18672860	18672861	18672862	18672863	18672864	18688257
18688258	18688259	18688300	18688301	18688302	18688303	18688304	18688305	18688306	18688307
18688308	18688309	18688310	18688311	18689723	18699987	18699988	18699989	18699990	18699992
18699993	18699994	18699995	18699996	18699997	18699998	18699999	18700380	18700381	18700382
18705003	18705004	18705005	18705006	18705007	18715258	18715259	18715400	18715401	18715402

18715403	18715404	18715405	18715406	18715407	18715408	18715409	18715410	18715411	18715412
18732503	18732504	18732506	18732508	18732509	18732510	18732511	18732512	18732513	18734561
18734562	18734563	18734564	18744360	18744362	18744363	18744365	18744366	18744367	18744368
18744369	18744371	18744373	18744374	18744375	18744376	18744377	18744378	18744379	18744400
18744401	18744402	18744403	18744404	18744416	18744417	18767954	18767955	18767956	18767957
18767958	18767959	18768060	18768061	18768062	18768063	18768064	18768065	18768066	18768067
18768069	18768070	18768071	18768072	18768073	18768074	18768075	18768076	18768077	18768078
18768079	18768140	18768141	18768142	18768143	18768144	18768145	18768146	18768147	18768148
18768149	18768150	18768151	18777054	18777055	18777056	18777057	18777058	18777059	18777060
18777067	18777068	18777069	18777070	18794604	18794605	18794606	18794607	18794608	18794610
18794611	18794612	18794613	18794614	18794615	18794616	18794617	18794618	18794619	18794640
18794641	18794642	18794643	18794644	18794645	18794646	18794647	18794648	18794649	18795841
18795842	18795843	18795844	18804588	18804589	18804590	18804591	18804592	18804593	18804594
18804595	18804598	18804700	18804702	18804703	18810746	18819966	18819967	18819968	18819969
18819970	18819971	18819972	18819973	18819974	18819975	18819976	18819978	18820040	18820045
18820046	18820047	18820048	18820049	18820050	18820051	18820052	18820053	18820054	18820055
18820056	18820057	18820058	18841692	18841693	18841694	18841695	18841696	18841697	18841698
18841820	18841821	18841822	18841823	18841824	18841825	18841826	18841827	18841828	18841829
18841830	18841831	18841832	18841833	18841834	18841835	18841836	18841837	18841838	18841839
18841860	18841861	18841862	18841872	18841876	18841877	18853604	18853605	18853606	18853607
18853608	18853609	18853610	18853611	18853612	18853613	18853614	18853615	18853616	18853617
18853618	18853680	18857307	18857308	18857309	18857310	18858164	18858165	18858166	18858167
18872552	18872554	18872555	18872556	18872557	18872558	18872559	18895508	18895509	18895510
18895511	18895512	18895513	18895514	18895515	18895516	18895517	18896546	18896547	18896548
18896549	18896550	18896551	18896552	18896553	18896555	18896556	18903838	18903839	18903880
18903881	18903882	18914193	18914194	18914195	18914196	18914197	18914198	18914220	18914221
18914222	18914223	18914224	18914225	18914226	18914227	18914228	18914229	18914230	18914231
18914232	18914233	18914234	18914235	18914236	18914237	18914238	18918482	18918483	18918484
18931507	18931508	18931509	18931510	18931511	18931512	18931513	18931514	18931515	18931516
18931517	18931518	18931519	18931580	18931581	18931582	18931583	18931585	18931586	18931587
18931588	18931589	18931590	18931591	18931592	18931593	18931594	18931595	18931596	18931597
18931598	18931599	18931760	18931761	18931762	18931763	18931764	18931765	18943451	18943453
18943454	18943456	18943457	18943458	18943459	18943520	18943521	18943522	18943523	18943524
18943525	18943526	18943527	18943528	18943529	18943530	18943531	18943532	18943533	18966493
18966494	18966495	18966496	18966497	18966498	18966499	18966661	18966662	18966663	18966664
18970047	18970048	18977925	18977926	18977927	18977928	18977929	18981843	18981844	18992280
18992282	18992283	18992284	18992285	18992286	18992288	18992289	18992290	18992291	18993126
19004206	19004207	19004208	19004209	19004210	19004281	19004282	19004283	19004284	19004285
19004286	19004287	19004288	19004289	19004293	19004294	19004295	19004296	19004297	19004298
19004299	19004360	19031115	19031116	19031117	19031118	19031119	19031340	19031341	19031342
19031343	19031344	19031345	19031346	19031347	19031348	19031349	19031350	19031351	19031352
19031353	19031354	19031355	19040000	19040001	19040002	19040005	19040006	19040007	19040008
19040011	19040012	19040013	19040015	19040016	19041567	19041568	19041569	19041570	19041571
19060715	19060716	19060717	19060718	19060719	19060720	19060721	19060722	19060723	19060724
19060725	19060726	19060727	19060728	19060729	19060730	19060731	19074511	19074512	19074514
19074516	19074562	19081171	19081176	19114004	19129472				