

<Reference: 97171742-FA>

21 March 2024

Urgent Field Safety Notice - Urgent Medical Device Recall EXPO™ Angiographic Catheter

Dear Customer,

Boston Scientific is initiating a removal of certain batches of EXPO™ 5F Angiographic Catheters due to an increase in complaints related to an inability to advance the guidewire through the lumen of the device. Our internal investigation has revealed that there is evidence of the polyurethane layer delaminating and in some instances material detachment in the catheters inner lining.

The most common observed adverse health consequence is a prolongation in the procedure to exchange the device for another due to inner diameter blockage. While no patient harms have been reported in the complaints received, the most serious adverse health consequences could be stroke or myocardial infarction due to embolization of detached material, though unlikely.

In all cases, reported to date issues occurred while the device was outside of the patient's body. No action is needed for EXPO 5F Angiographic Catheters that were successfully used.

Our records indicate that your facility received some of the concerned product. **The table below (Attachment 1) provides a complete list of all affected products, including Product Description, Material Number (UPN), GTIN, Lot/Batch numbers and expiration date. 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.

PLEASE NOTE: We are aware that hospitals often remove products from the outer carton and store on the shelves in the inner-pouch only. If this is a practice at your facility, **it is very important that you carefully use the product table and consider both the inner and outer packaging UPN codes when searching for affected product, as the UPN numbers on the inner and outer labelling may be different.**

Verify by product batch/lot number in the product table to determine if the batch within your inventory is affected. If so, indicate on your Verification Form the quantity of units from each batch that you will be returning. **As the product within these batches are sold as Single packs, 5-packs and 15-packs, it is important that all reported quantities represent the actual number of single unit being returned and not the number of cartons/boxes or multi-packs.**

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 uk-quality@bsci.com on or before 8 April 2024.**

4- **If you have products to return**, please package them in an appropriate shipping box. **After receipt of the Verification Form, Boston Scientific will contact you 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,



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

Attachment: Verification Form

Attachment 1 : Affected Product Listing

Outer UPN #	Inner UPN #	Material Description	Batch				GTIN	Expiration Date Range
H74908526012	H74908526011	MODEL - 5F EXPO FR3.5 (5PK)	60425778	60427256	60427594	60427745	08714729187684	05/Jan/25 - 06/Dec/25
			60430877	60430933	60438674	60440972		
			60449235	60456279	60465783	60465784		
			60465785	60472599	60474047	60474048		
			60476456	60479447	60479448	60522588		
H74908526022	H74908526021	MODEL - 5F EXPO FR4 (5PK)	60423767	60423768	60423772	60425128	08714729187691	26/Dec/24 - 15/Jan/26
			60425129	60425130	60425763	60425764		
			60425765	60427255	60427593	60427715		
			60427716	60427717	60427718	60427720		
			60430441	60430885	60430914	60432697		
			60432698	60432699	60432700	60432714		
			60433871	60433882	60436635	60436637		
			60437043	60437780	60437781	60438203		
			60438204	60438205	60438502	60438652		
			60438653	60438654	60440739	60440950		
			60442607	60442609	60443038	60443909		
			60445389	60445899	60445900	60445901		
			60445902	60445903	60445909	60445910		
			60445911	60445912	60445913	60449229		
			60449230	60449236	60449958	60449959		
			60449960	60449961	60449962	60449963		
			60449964	60453707	60456262	60457132		
			60461405	60461406	60461407	60461408		
			60463407	60463408	60463409	60463410		
			60463411	60463956	60463957	60463958		
			60463959	60463960	60463961	60464366		
			60464367	60464440	60464441	60465466		
			60467115	60467116	60467117	60467118		
			60467119	60467488	60467489	60467490		
			60469085	60472566	60473138	60474013		
			60474015	60474065	60474066	60474067		
			60474068	60474069	60474070	60474071		
			60476145	60476146	60476147	60476148		
			60476149	60476442	60479441	60479442		
			60479443	60479444	60479445	60479446		
			60481583	60481584	60481585	60481586		
			60481587	60481588	60482881	60482882		
			60482883	60483858	60483867	60483868		
60483869	60483870	60483871	60483872					
60485566	60486069	60486070	60487589					
60487590	60487591	60487592	60487593					
60488284	60488285	60488286	60488287					
60492194	60492195	60492196	60492197					
60493940	60493941	60495538	60495539					

Outer UPN #	Inner UPN #	Material Description	Batch				GTIN	Expiration Date Range
			60500723	60500724	60500725	60500726		
			60500727	60500728	60504878	60504879		
			60504880	60512235	60519445	60519446		
			60519447	60519448	60521830	60521831		
			60522903	60522904	60522905	60523275		
			60525055	60525056	60525058	60525078		
			60526117	60526118	60526119	60526120		
			60526121	60526189	60526190	60526191		
H74908526032	H74908526031	MODEL - 5F EXPO FR5 (5PK)	60429295	60430929	60452070	60459221	08714729187707	20/Jan/25 - 07/Feb/26
			60467044	60472581	60475390	60483688		
			60491910	60498233	60512378	60525061		
			60530044	60536198				
H74908526042	H74908526041	MODEL - 5F EXPO FR6 (5PK)	60493978	60530035			08714729187714	05/Sept/25 - 16/Jan/26
H749085261002	H749085261001	MODEL - 5F EXPO AL3 (5PK)	60448983	60461410	60476253	60486049	08714729187721	29/Mar/25 - 25/Nov/25
			60517315					
H749085261712	H749085261711	MODEL - 5F EXPO CAS1 (5PK)	60447174				08714729187776	25-Mar-25
H749085261802	H749085261801	MODEL - 5F EXPO KIMNY (5PK)	60504831	60515598	60533629		08714729249030	12/Oct/25 - 01/Feb/26
H749085261902	H749085261901	MODEL - 5F EXPO RCB (5PK)	60447160	60463413	60472609	60481602	08714729168928	22/Mar/25 - 01/Feb/26
			60493975	60511235	60517338	60533588		
H749085261952	H749085261951	MODEL - 5F EXPO LCB (5PK)	60443926	60463398	60472605	60473187	08714729187790	10/Mar/25 - 07/Feb/26
			60498234	60513387	60524982	60533587		
			60535875					
H749085262012	H749085262011	MODEL - 5F EXPO IM (5PK)	60432320	60438675	60440974	60447145	08714729187806	01/Feb/25 - 08/Feb/26
			60459197	60467093	60468840	60475371		
			60483661	60491659	60495554	60504885		
			60515603	60522591	60522595	60523996		
			60533644	60536197				
H749085262022	H749085262021	MODEL - 5F EXPO IMT (5PK)	60447151	60456265	60472610	60486304	08714729249191	24/Mar/25 - 25/Jan/26
			60522592	60531432				
H749085262032	H749085262031	MODEL - 5F EXPO IMC (5PK)	60448987	60467091	60476275	60486323	08714729249214	28/Mar/25 - 07/Feb/26
			60535894					
H74908526212	H74908526211	MODEL - 5F EXPO FL3.5 (5PK)	60423725	60427729	60427730	60427731	08714729187813	28/Dec/24 - 07/Feb/26
			60427732	60427733	60427734	60430886		
			60430922	60430923	60430925	60432701		
			60432702	60432716	60432719	60433872		
			60433875	60433885	60433886	60434235		
			60434236	60434237	60434238	60434239		
			60434480	60436638	60436639	60436640		
			60438645	60438646	60438647	60438648		
			60438649	60440943	60440944	60440945		
			60440946	60440947	60443002	60443027		
			60443028	60443029	60443030	60443031		
			60443897	60443898	60443899	60443900		

Outer UPN #	Inner UPN #	Material Description	Batch				GTIN	Expiration Date Range
			60443901	60443902	60445394	60445395		
			60445914	60445917	60448191	60448192		
			60449227	60449228	60449231	60449232		
			60449982	60449983	60449984	60453725		
			60453726	60461414	60461429	60463596		
			60463598	60463962	60463972	60463973		
			60464490	60464491	60467016	60467017		
			60467018	60467019	60467020	60469093		
			60469094	60470532	60470533	60470534		
			60470537	60473146	60474018	60474019		
			60474020	60474073	60474074	60474077		
			60474078	60474079	60474080	60475372		
			60475376	60475377	60475378	60475379		
			60476443	60476444	60477294	60477295		
			60477296	60477297	60479452	60479453		
			60479454	60479455	60481591	60481592		
			60481593	60481594	60483662	60483663		
			60483664	60486071	60486072	60486073		
			60488290	60488291	60488292	60488293		
			60490173	60490174	60490175	60490176		
			60490177	60490178	60490179	60491458		
			60491465	60491466	60491467	60493944		
			60495540	60495541	60495542	60495543		
			60495544	60495545	60496731	60496732		
			60496733	60496734	60497776	60497777		
			60497778	60500730	60500731	60504881		
			60504882	60507282	60507284	60507287		
			60507479	60507660	60507661	60507662		
			60507663	60511641	60511642	60511643		
			60511644	60515578	60515579	60515580		
			60517602	60517603	60517604	60517607		
			60522510	60522511	60522512	60522513		
			60522514	60522515	60523353	60523354		
			60523355	60526192	60526193	60526194		
			60526195	60536188				
H749085262202	H749085262201	MODEL - 5F EXPO FL4 125CM (5PK)	60438212	60449780	60491491	60491959	08714729007531	23/Feb/25 - 05/Dec/25
			60521828					
H74908526222	H74908526221	MODEL - 5F EXPO FL4 (5PK)	60427721	60427722	60427723	60427724	08714729187820	13/Jan/25 - 13/Feb/26
			60427725	60427726	60430878	60430926		
			60430927	60430928	60432308	60432309		
			60432310	60434240	60434481	60436641		
			60437784	60443032	60443033	60443034		
			60443905	60443035	60443036	60443903		
			60443904	60448204	60443906	60443907		
			60446725	60448203	60462014	60448205		
			60452064	60456288	60461431	60463955		

Outer UPN #	Inner UPN #	Material Description	Batch				GTIN	Expiration Date Range
			60470528	60463401	60463402	60463600		
			60463954	60473157	60463967	60463974		
			60464492	60470527	60476445	60470530		
			60470531	60472576	60473154	60479459		
			60481598	60474023	60474083	60474084		
			60474085	60488295	60477256	60479456		
			60479457	60479458	60492674	60479460		
			60479461	60481596	60481597	60498230		
			60512385	60481599	60481600	60481601		
			60488294	60522901	60488296	60488297		
			60488298	60492673	60527363	60492675		
			60492676	60492677	60498229	60500737		
			60505121	60512236	60512384	60521834		
			60521835	60521836	60522587	60522902		
			60525059	60525077	60527362	60533639		
			60538215					
H749085262252	H749085262251	MODEL - 5F EXPO FR4 125CM (5PK)	60430691	60447156	60463406	60488300	08714729192817	27/Jan/25 - 13/Feb/26
			60493468	60537513				
H749085262302	H749085262301	MODEL - 5F EXPO FR5 125CM (5PK)	60449785	60491507	60537491		08714729007562	04/avr/25 - 13/Feb/26
H74908526232	H74908526231	MODEL - 5F EXPO FL4.5 (5PK)	60443928	60457123	60464496	60473188	08714729187837	13/Mar/25 - 01/Feb/26
			60477305	60504888	60517337	60522597		
			60533589					
H749085262402	H749085262401	MODEL - 5F EXPO IM 125CM (5PK)	60444872	60451459	60451968	60511220	08714729007593	28/Mar/25 - 03/Nov/25
H749085262502	H749085262501	MODEL - 5F EXPO TIG4 (5PK)	60447162	60461412	60474054	60486303	08714729886082	23/Mar/25 - 22/Jan/26
			60495529	60511248	60511234	60531435		
H74908526252	H74908526251	MODEL - 5F EXPO FL6 (5PK)	60447163	60464498	60485991	60515607	08714729187851	22/Mar/25 - 01/Feb/26
			60517314	60533583				
H749085262532	H749085262531	MODEL - 5F EXPO JIG4 (5PK)	60500256	60536210			08714729886143	12/Oct/25 - 12/Feb/26
H749085263002	H749085263001	MODEL - 5F EXPO MULTIPACK (5PKX3)	60427727	60436627	60438198	60456253	08714729187868	17/Jan/25 - 13/Feb/26
			60460188	60461419	60462030	60474027		
			60475349	60476271	60477271	60486289		
			60500758	60502673	60515228	60530055		
			60537578					
H749085263012	H749085263011	MODEL - 5F EXPO MULTIPACK 145 (5PKX3)	60422723	60422730	60423803	60423804	08714729187875	29/Dec/24 - 13/Feb/26
			60438197	60438657	60438658	60440954		
			60442593	60442594	60449237	60452059		
			60453695	60456291	60459250	60463066		
			60463980	60463981	60465461	60470647		
			60472578	60476246	60476454	60477214		
			60477215	60477318	60478140	60480055		
			60486055	60486317	60490180	60490181		
			60490182	60496717	60498231	60500299		
			60500755	60500756	60500757	60502671		

Outer UPN #	Inner UPN #	Material Description	Batch				GTIN	Expiration Date Range
			60504886	60509543	60532101	60532102		
			60536194	60536195	60536196			
H749085263022	H749085263021	MODEL - 5F EXPO MULTIPACK 155 (5PKX3)	60447157	60447158	60462032	60477290	08714729187882	23/Mar/25 - 31/Jan/26
			60480056	60480062	60493500	60504860		
			60524948	60533592				
H74908526502	H74908526501	MODEL - 5F EXPO WR (5PK)	60437054	60437063	60437064	60438200	08714729249412	16/Feb/25 - 15/Feb/26
			60438201	60438202	60445390	60447181		
			60447182	60447183	60448980	60448981		
			60448982	60454958	60460144	60463963		
			60463964	60465472	60465473	60465481		
			60465482	60465483	60474107	60474501		
			60477273	60481568	60483603	60483604		
			60483634	60483635	60483638	60488390		
			60488497	60488498	60488499	60488500		
			60490167	60490169	60490170	60490171		
			60491660	60491661	60495555	60495556		
			60497690	60507240	60507657	60507658		
			60507659	60517310	60517311	60530050		
60538219								
H74908526511	H74908526511	MODEL - 5F EXPO WRP (SGL)	60442598	60442599	60448185	60451431	08714729249498	09/Mar/25 - 28/Aug/25
			60459199	60467097	60488391	60490137		
			60490138	60490168				
H74908526512	H74908526511	MODEL - 5F EXPO WRP (5PK)	60442603	60443053	60443054	60448186	08714729249504	09/Mar/25 - 04/Sept/25
			60448206	60457140	60457142	60463965		
			60463966	60467045	60467046	60481406		
			60481407	60485945	60488392	60488393		
			60491911	60492554	60492605	60492606		
			60492607	60492608				
H74908526842	H74908526841	MODEL - 5F EXPO AR1 (5PK)	60425143	60427595	60429297	60448984	08714729187929	03/Jan/25 - 8/Feb/26
			60448985	60463971	60474111	60477260		
			60479435	60482880	60502674	60511249		
			60525062	60530043	60536205			
H74908526862	H74908526861	MODEL - 5F EXPO AR2 (5PK)	60430930	60447168	60447169	60461420	08714729168874	25/Jan/25 - 19/Feb/26
			60462004	60474038	60475385	60486305		
			60515237	60522598	60525060	60531431		
			60540176					
H74908526892	H74908526891	MODEL - 5F EXPO AR MOD (5PK)	60443056	60452071	60464497	60467054	08714729007692	07/Mar/25 - 30/Jan/26
			60475380	60498235	60511251	60533590		
H74908526962	H74908526961	MODEL - 5F EXPO AL1 (5PK)	60438199	60438660	60440956	60445923	08714729187936	20/Feb/25 - 13/Feb/26
			60448986	60449233	60453733	60459203		
			60465786	60465788	60467041	60467087		
			60472577	60473158	60477280	60477281		
			60477282	60486299	60486300	60491662		
			60495526	60495527	60498225	60498226		
			60500754	60507655	60507656	60511179		
			60511181	60512377	60513563	60529457		

Outer UPN #	Inner UPN #	Material Description	Batch				GTIN	Expiration Date Range
			60533641	60538216	60538217			
H74908526982	H74908526981	MODEL - 5F EXPO AL2 (5PK)	60434245	60447166	60454961	60474029	08714729187943	17/Feb/25 - 20/Feb/26
			60477302	60483669	60510080	60533638		
			60536207	60540481				
H74908526242	H74908526241	MODEL - 5F EXPO FL5 (5PK)	60432312	60448988	60448989	60459201	08714729187844	02/Feb/25 - 26/Jul/25
			60464505	60465484	60467102	60467103		
			60467104	60467105	60467106	60467107		
			60467121	60469088	60477210	60477211		
			60477213	60479437	60479438	60481581		
60481582								

Attachment 2 : Substitute Ordering Reference

Recalled Product		Replacement Options (Subject to availability)	
UPN	UPN Description	UPN #1 (One-to-one swap)	UPN #1 Description
H74908526962	MODEL-5F EXPO AL1 (5PK)	H74916391962	MODEL-5F IMPULSE AL1 (5PK)
H74908526982	MODEL-5F EXPO AL2 (5PK)	H74916391982	MODEL-5F IMPULSE AL2 (5PK)
H749085261002	MODEL-5F EXPO AL3 (5PK)	H749163911002	MODEL-5F IMPULSE AL3 (5PK)
H74908526892	MODEL-5F EXPO AR MOD (5PK)	H74916391892	MODEL-5F IMPULSE AR MOD (5PK)
H74908526842	MODEL-5F EXPO AR1 (5PK)	H74916391842	MODEL-5F IMPULSE AR1 (5PK)
H74908526862	MODEL-5F EXPO AR2 (5PK)	H74916391862	MODEL-5F IMPULSE AR2 (5PK)
H749085261712	MODEL-5F EXPO CAS1 (5PK)	H749163911712	MODEL-5F IMPULSE CAS1 (5PK)
H74908526212	MODEL-5F EXPO FL3.5 (5PK)	H74916391212	MODEL-5F IMPULSE FL3.5 (5PK)
H74908526222	MODEL-5F EXPO FL4 (5PK)	H74916391222	MODEL-5F IMPULSE FL4 (5PK)
H749085262202	MODEL-5F EXPO FL4 125CM (5PK)	H749163912202	MODEL-5F IMPULSE FL4 125CM (5PK)
H74908526232	MODEL-5F EXPO FL4.5 (5PK)	H74916391232	MODEL-5F IMPULSE FL4.5 (5PK)
H74908526242	MODEL-5F EXPO FL5 (5PK)	H74916391242	MODEL-5F IMPULSE FL5 (5PK)
H74908526252	MODEL-5F EXPO FL6 (5PK)	H74916391252	MODEL-5F IMPULSE FL6 (5PK)
H74908526012	MODEL-5F EXPO FR3.5 (5PK)	H74916391012	MODEL-5F IMPULSE FR3.5 (5PK)
H74908526022	MODEL-5F EXPO FR4 (5PK)	H74916391022	MODEL-5F IMPULSE FR4 (5PK)
H749085262252	MODEL-5F EXPO FR4 125CM (5PK)	H749163912252	MODEL-5F IMPULSE FR4 125CM (5PK)
H74908526032	MODEL-5F EXPO FR5 (5PK)	H74916391032	MODEL-5F IMPULSE FR5 (5PK)
H749085262302	MODEL-5F EXPO FR5 125CM (5PK)	H749163912302	MODEL-5F IMPULSE FR5 125CM (5PK)
H74908526042	MODEL-5F EXPO FR6 (5PK)	H74916391042	MODEL-5F IMPULSE FR6 (5PK)
H749085262012	MODEL-5F EXPO IM (5PK)	H749163912012	MODEL-5F IMPULSE IM (5PK)
H749085262402	MODEL-5F EXPO IM 125CM (5PK)	H749163912402	MODEL-5F IMPULSE IM 125CM (5PK)
H749085262032	MODEL-5F EXPO IMC (5PK)	H749163912032	MODEL-5F IMPULSE IMC (5PK)
H749085262022	MODEL-5F EXPO IMT (5PK)	H749163912022	MODEL-5F IMPULSE IMT (5PK)
H749085262532	MODEL-5F EXPO JIG4 (5PK)	H749163912532	MODEL-5F IMPULSE JIG4 (5PK)
H749085261802	MODEL-5F EXPO KIMNY (5PK)	H749163911802	MODEL-5F IMPULSE KIMNY 110CM (5PK)
H749085261952	MODEL-5F EXPO LCB (5PK)	H749163911952	MODEL-5F IMPULSE LCB (5PK)
H749085263002	MODEL-5F EXPO MULTIPACK (5PKX3)	H749163913002	MODEL-5F IMPULSE MULTIPACK (5PKX3)
H749085263012	MODEL-5F EXPO MULTIPACK 145 (5PKX3)	H749163913012	MODEL-5F IMPULSE MULTIPACK 145 (5PKX3)
H749085263022	MODEL-5F EXPO MULTIPACK 155 (5PKX3)	H74916391422	MODEL-5F IMPULSE PIG 155 110CM (5PK)
H749085261902	MODEL-5F EXPO RCB (5PK)	H749163911902	MODEL-5F IMPULSE RCB (5PK)
H749085262502	MODEL-5F EXPO TIG4 (5PK)	H749163912502	MODEL-5F IMPULSE TIG4 (5PK)
H74908526502	MODEL-5F EXPO WR (5PK)	NA	NA
H74908526512	MODEL-5F EXPO WRP (5PK)	NA	NA
H74908526511	MODEL-5F EXPO WRP (SGL)	NA	NA

