

<Hospital_Name>

<Users_Name>

<Department>

<Customer_Address>

<Zip_Code> <City>

<Country_Name>

<Reference: 97322487-FA>

20 December 2024

Urgent Field Safety Notice - Urgent Medical Device Recall AXIOS™ Stent and Electrocautery Enhanced Delivery System

Dear <Users_Name>,

Boston Scientific is initiating a removal of specific lots of the AXIOS™ Stent and Electrocautery Enhanced Delivery System, detailed in Attachment 1, due to reports of the outer sheath distal black tip detaching from the device. Boston Scientific has received seven (7) reports of this issue between May 16, 2024, and present day. In cases where the stent was deployed, it was observed that the separated black sheath tip can remain around the stent saddle, preventing proper expansion.

The most common outcome reasonably foreseeable resulting from the sheath tip separation is prolongation of the procedure to exchange the device for a new one.

In cases where the stent is deployed with the separated black sheath tip remaining on the saddle of the stent, the nose cone tip of the delivery catheter is not able to pass through the stent. This can lead to breakage of the delivery catheter, which would result in the black sheath tip being left behind on the stent and the nose cone tip along with a portion of the delivery catheter being left behind within the stent. Therefore, the most serious reasonably foreseeable outcome from the black sheath tip separating and remaining on the stent is an additional intervention, either endoscopic or surgical, to remove the stent, retrieve any fragments, and close the puncture site.

If the patient exhibits clinical evidence of stent failure to expand or stent migration, and it is also unknown by the provider if there was difficulty removing the delivery system, an additional evaluation may be required. The additional evaluation may include imaging or repeat endoscopy to evaluate the stent expansion and placement.

Our records indicate that your facility has 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 and Lot/Batch numbers and expiry 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.**

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 **20 January 2025**.
- 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- Immediately post this information in a visible location near the affected products to ensure this information is readily accessible to all handlers and users of the device. Please pass this notice to any health 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,



Conor Dolan

Vice President, Global Quality

Boston Scientific International S.A.

Attachment: Verification Form

FOR BOSTON SCIENTIFIC INTERNAL USE ONLY
Account Email: <Contact Email>
Language: <Language(s)>
LFAC Team: <LFAC_Distribution_Email_Address>
Country Code-Sold to: <Country_Code>-<Sold_to_b>

Attachment 1 – Affected Product Listing

Product Description	UPN	GTIN	Lot #			Expiration Date Range
HOT AXIOS™ Stent and Electrocautery- Enhanced Delivery System	M00553520	08714729904540	33336402	33437479	34017089	November 15, 2024 through August 28, 2026
			33336404	33548501	34028458	
			33336405	33577903	34065579	
			33336411	33704371	34065660	
			33392916	33712822	34083271	
			33392917	33986537	34083272	
			33393302	34017087		
			33411607	34017088		
	M00553530	08714729904557	33335139	33511491	34068983	
			33335340	34015885	34101926	
			33336413	34065661		
	M00553540	08714729904564	33169261	33979055	34201917	
			33169263	34027245	34203537	
			33209127	34027246	34203539	
			33243075	34035523	34204795	
			33243077	34035524	34223677	
			33243856	34052776	34223679	
			33255964	34052778	34226399	
			33488328	34161831	34226540	
			33787031	34161832	34243427	
			33787032	34161833	34243428	
			33853395	34161834	34375175	
			33882221	34190943	34381803	
			33882222	34190944	34585408	
			33899656	34190945	34731098	
			33909280	34192326		
			33979053	34192327		
	M00553550	08714729904571	32868212	33747542	34074525	
			32947950	33747543	34074528	
			32998424	33749929	34083208	
			32998425	33749930	34085560	
			33177074	33756082	34085561	
			33177075	33756083	34086663	
			33177077	33765265	34093771	
			33185872	33765266	34095708	
			33185873	33804645	34095710	
			33185874	33805203	34095711	
			33185875	33805205	34116466	
			33185877	33805206	34126531	
			33187647	33805208	34126534	
			33187648	33893271	34126535	
HOT AXIOS™ Stent and Electrocautery- Enhanced Delivery System	M00553550	08714729904571	33195395	33902105	34128862	November 15, 2024 Through August 28, 2026
			33195397	33933459	34135087	
			33209120	33939639	34135090	
			33209135	33948084	34161836	
			33209138	33986699	34161837	
			33209139	33987798	34161838	
			33209840	33987799	34161839	

Product Description	UPN	GTIN	Lot #			Expiration Date Range
			33243859	33988020	34163750	
			33257462	33988021	34163751	
			33257474	33988022	34172106	
			33257477	33988779	34172107	
			33268719	33989320	34180838	
			33278543	34015887	34181501	
			33284513	34028520	34182330	
			33284514	34035525	34190948	
			33284517	34035526	34201919	
			33293229	34035529	34232994	
			33301038	34035530	34232995	
			33301039	34035965	34232997	
			33301341	34044970	34334695	
			33315855	34044971	34334696	
			33315856	34044972	34335369	
			33317299	34044973	34371098	
			33318093	34047717	34372194	
			33527177	34047718	34375171	
			33537640	34047819	34375173	
			33538743	34065662	34381805	
			33577557	34065663	34512950	
			33688060	34065664		
			33688061	34065665		
	M00553560	08714729951100	32865866	33581298	34103179	
			32874910	33581681	34103340	
			32875944	33601247	34111453	
			32876867	33657824	34111454	
			32876869	33686163	34111456	
			32876870	33686166	34111845	
			33195387	33765267	34116472	
			33195388	33804643	34116473	
			33195389	33806748	34126522	
			33195390	33909812	34180835	
			33209841	33909813	34190940	
33209843			33920980	34190949		
33215357			33948082	34201914		
33283337			33977789	34205933		
33284518			33981155	34205934		
33284519			33981156	34213826		
HOT AXIOS™ Stent and Electrocautery- Enhanced Delivery System	M00553560	08714729951100	33288532	34006718	34214585	November 15, 2024 through August 28, 2026
			33288534	34015882	34214586	
			33301346	34020432	34223572	
			33301347	34020433	34223574	
			33301348	34020434	34325972	
			33301351	34027240	34325974	
			33301352	34047363	34334692	
			33466658	34065574	34335366	
			33467021	34074522	34371087	
33470461	34076577	34371088				

Product Description	UPN	GTIN	Lot #			Expiration Date Range
			33470464	34083205	34371090	
			33470465	34085563	34523681	
			33486865	34101925	34545213	
			33487939	34102569	34649321	
			33519203	34102570	34815303	
			33528652	34102571		
	M00553570	08714729976684	32878539	33795273	34083270	
			33336847	33900261	34172108	
			33338446	33900262	34172109	
			33775901	34076575		
AXIOS™ Stent and Electrocautery-Enhanced Delivery System	M00553640	08714729904588	32891042	33520871	34116470	
			32900457	33520872	34251352	
			32908438	33537659	34251353	
			33215358	33538481	34261614	
			33215359	33538484	34261615	
			33216060	33559005	34261616	
			33216062	33813654	34263376	
			33219660	33813655	34263377	
			33219662	33871244	34277689	
			33219663	33948086	34277690	
			33315967	33996038	34297653	
			33315970	33996039	34297657	
			33324398	34004999	34512952	
			33500190	34116469	34526862	
	M00553650	08714729904595	32891503	33527176	33996104	
			32946481	33547873	33996109	
			32966087	33559652	34006713	
			32976911	33562171	34052770	
			32986912	33568700	34052771	
			32986913	33568705	34052772	
			32986914	33568709	34052773	
			32996152	33580106	34065575	
			33004776	33686169	34065576	
			33004777	33686170	34065577	
			33004779	33686171	34065578	
			33008425	33686172	34136366	
AXIOS™ Stent and Electrocautery-Enhanced Delivery System	M00553650	08714729904595	33008426	33686173	34136369	
			33008427	33686174	34136370	
			33013790	33765268	34142870	
			33013791	33765269	34142871	
			33038652	33765271	34144414	
			33158792	33765272	34144416	
			33161956	33765273	34251354	
			33219664	33765274	34261613	
			33219665	33766684	34261617	
			33223921	33775698	34261618	
			33223922	33813656	34261619	
			33223925	33813657	34263374	
			33233417	33813658	34271464	

Product Description	UPN	GTIN	Lot #			Expiration Date Range
			33233418	33813659	34271465	
			33233419	33825083	34276937	
			33233460	33825084	34276938	
			33233461	33825087	34277681	
			33235723	33825091	34286615	
			33487216	33873459	34286616	
			33487218	33873923	34286617	
			33489572	33881493	34286618	
			33527175	33996102	34308441	
	M00553660	08714729951179	32913258	33577901	34034896	
			32914587	33577905	34034897	
			32914588	33661063	34034898	
			32914951	33677043	34037953	
			32919344	33677044	34037954	
			33161778	33677045	34037955	
			33167722	33677046	34038584	
			33167723	33677047	34038795	
			33167724	33677048	34047362	
			33168696	33680523	34047364	
			33168697	33697485	34047365	
			33217106	33767880	34074520	
			33217107	33776935	34074521	
			33223926	33776936	34093768	
			33223927	33778737	34093769	
			33224949	33778738	34101923	
			33233462	33785758	34101924	
			33234152	33785759	34126523	
			33235720	33787022	34126524	
			33235721	33787023	34128158	
			33242497	33787024	34130337	
			33242560	33787025	34134859	
			33324868	33796610	34135080	
			33333642	33804642	34136360	
AXIOS™ Stent and Electrocautery-Enhanced Delivery System	M00553660	08714729951179	33333648	33827339	34142867	November 15, 2024 through August 28, 2026
			33470460	33883094	34144887	
			33488331	33899654	34161824	
			33509930	33902104	34161826	
			33509931	33902106	34165830	
			33509936	33908817	34165831	
			33509937	33908818	34172977	
			33510694	33908819	34172979	
			33510695	33930901	34262100	
			33517861	33931714	34307464	
			33517862	33939630	34344894	
			33568702	33998884	34356855	
			33568703	33998885	34364514	
			33571498	34004996	34772813	
			33577559	34006717		
			33577900	34027241		

Product Description	UPN	GTIN	Lot #			Expiration Date Range
	M00553670	08714729979333	32901294	33825089	34111481	
			33223930	33860266	34135618	
			33328461	33920983	34135619	
			33413626	33920984	34136372	
			33459702	33930917	34271635	
			33686175	34020982	34297652	
			33686176	34020983	34316296	
			33766912	34111459		
			33814306	34111480		
	M00553680	00191506008086	33457806	33512838	34035520	
	M00553690	00191506008093	33419782	33477824	34116467	
			33419783	33511487		
AXIOS™ Stent and Delivery System	M00553740	08714729904625	34477280			
	M00553750	08714729904632	33740402	33785754	34037422	

<Sold_to> - <Hospital_Name> - <City> - <Country_Name>

Please Complete the form even if you do not have any affected product & send it to your Local Office:
 <Customer_Service_Fax_Number>

Verification Form – Urgent Medical Device Recall
AXIOS™ Stent and Electrocautery Enhanced Delivery System
97322487-FA

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 20 December 2024.
2. **Boston Scientific records indicate you have received the following affected product** (*additionally please check inventory against complete list of affected product provided*)

Material N° (UPN)	Lot / Batch N° / Serial N°	Customer PO	Qty Sent (Units)	Qty to return (Units)

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. After receipt of the Verification Form, Boston Scientific will contact you to arrange return.
2. Prepare the package
3. Follow the instructions given by your Local Office about collection of the package

NAME* _____ Title _____

Telephone _____ Email _____

Customer' **SIGNATURE*** _____ **DATE*** _____

* Required field

dd/mm/yyyy