

## **Urgent Medical Device Removal - Immediate Action Required** **AXIOS™ Stent and Electrocautery Enhanced Delivery System**

December 19, 2025

Dear Materials Manager/Health Care Professional:

### **Description of Issue and Clinical Impact:**

Boston Scientific is initiating a removal of certain AXIOS™ Stent and Electrocautery Enhanced Delivery Systems (6 mm × 8 mm, 8 mm × 8 mm, and 20 mm × 10 mm), detailed in Attachment 1. This action is being taken due to increased reports of stent deployment and expansion issues with these configurations. This issue only occurs at the time of delivery of the stent and is expected to be noticed by the physician. Successfully implanted stents are not affected by this issue.

The most common outcome reasonably foreseeable resulting from difficulty deploying the stent is prolongation of the procedure to exchange the device for a new one.

The most serious reasonably foreseeable outcome in cases where the first flange is unable to deploy or expand would be a cascade of events resulting in additional intervention, either endoscopic or surgical, to remove the stent and close the puncture site.

The serious injury events also included 3 deaths; these events were associated with use outside of indication (EDGE procedure, gastrojejunostomy) or investigational use (AXIOS GE for GOO IDE study) and required a cascade of events with special circumstances such as decision for palliative care, altered anatomy or acute unrelated procedural complication, all of which limited further treatment options.

### **Recommendations:**

Patients who have been treated with a successfully implanted AXIOS™ stent should continue to follow standard of care, as the issue only occurs at the time of delivery of the stent. Any additional management should be at the discretion of their physician based on individual circumstances.

### **Instructions:**

- Immediately stop further distribution or use of any remaining affected devices (see Attachment 1). Remove them from your facility's inventory and segregate them in a secure location until they can be returned to Boston Scientific.
- 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.
- Share this notice with any health care professional within your organization and with any organization where the affected products may have been transferred.
- If you are a distributor, this notification must be forwarded to your customers to ensure notification of this product removal is carried out to the end-user level.
- If you are a facility that has sent products to another hospital or a facility within your network, ensure this notification is forwarded to them.
- Boston Scientific reminds healthcare professionals that AXIOS Stents should only be used as indicated in Instructions For Use.

This removal affects only the products listed in **Attachment 1**. **No other UPNs are impacted by this removal.**

Any adverse events or quality concerns associated with use of these devices should be reported to Boston Scientific via email at [ComplaintCallCenter@bsci.com](mailto:ComplaintCallCenter@bsci.com) or FDA's MedWatch Adverse Event Reporting program [[www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm) or 1.800.FDA.1088 (332.1088)].

Regulatory authorities of your country are being notified of this removal as required.

Patient safety is Boston Scientific's highest priority. As such, we are committed to transparent communication with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. If you require additional assistance or more information regarding this communication, please contact your local Boston Scientific representative.

Sincerely,



Conor Dolan  
Vice President, Global Quality

Encl: Removal Instructions  
Reply Verification Tracking Form

## Urgent Medical Device Removal - Instructions

The Reply Verification Tracking Form (RVTF) enclosed with this Removal Notice must be completed and returned even if you do not have any Affected Product.

1. Immediately discontinue use and segregate Affected Product.
2. Complete and return the RVTF to get a Return Goods Authorization (RGA) number.
  - Indicate the quantity of SINGLE units you will be returning for credit
  - If you have product that is listed in Attachment 1 (Affected Products) that is not included on your RVTF, provide the material number, lot number, and quantity you intend to return on your RVTF
  - Return the RVTF via:
    - Email:** [BSCFieldActionCenter@bsci.com](mailto:BSCFieldActionCenter@bsci.com)
    - or**
    - Fax:** **BSC Field Action Center 1-763-415-7708**
3. Once Boston Scientific receives your completed RVTF, you will be contacted within 2 business days and provided an RGA number for product return.
4. Package and ship affected product:
  - Write the RGA number in large print on the enclosed (red/white) return address label
  - Affix the return address label to the outside of box
  - Use our Federal Express account number: 9205-2515-6 to return package via second-day delivery
  - Seal box and return to:
    - Boston Scientific Corporation**
    - US Distribution Center**
    - 500 Commander Shea Blvd**
    - Quincy, MA 02171**
    - RGA:** \_\_\_\_\_
5. If you have sent a response to this Removal Notice to anyone other than Boston Scientific, we would not have received your response. Please ensure response is sent to email or fax indicated above.
6. Credit will be issued for all returned Affected Product once received and confirmed by Boston Scientific.

## Attachment 1 – Product List

Product Description	UPN	GTIN	Lot #				Expiration Date Range
AXIOS™ Stent and Electrocautery Enhanced Delivery System	M00553520	08714729904540	36067957	36459567	36680231	37427362	September 12, 2026 - April 28, 2027
			36067958	36459568	36680232	37437936	
			36067959	36459569	36683260	37438283	
			36067960	36461959	36683261	37438286	
			36067961	36462320	36683262	37438287	
			36099410	36468392	36693971	37439978	
			36102139	36468393	36693972	37440320	
			36111317	36468394	36717713	37451304	
			36111318	36502795	36717714	37456594	
			36111319	36506161	36717715	37457216	
			36132439	36506163	36717819	37457217	
			36132800	36509326	36721863	37457269	
			36136724	36520053	36731805	37459571	
			36136725	36523274	36731806	37463623	
			36144054	36528114	36738965	37463624	
			36154527	36536932	36738966	37463625	
			36154528	36536933	36743835	37463628	
			36154529	36548030	36750922	37469756	
			36156019	36548031	36750924	37469757	
			36164532	36548850	36753179	37469758	
			36164990	36548851	36753400	37470669	
			36176206	36552680	36781577	37472148	
			36176207	36559035	36781578	37475122	
			36177448	36559036	36781579	37481983	
			36191239	36567446	36784378	37486079	
			36199389	36567447	36784379	37518915	
			36217761	36567448	36788332	37518916	
			36241713	36574150	36788333	37518917	
			36251361	36581585	36788334	37519094	
			36252913	36581586	36792650	37532420	
			36271441	36582790	36799316	37532421	
			36271442	36582791	36832750	37533309	
36281910	36585188	36832837	37543372				
36281911	36585189	36832838	37558499				
36292639	36591087	36833682	37558542				
36292681	36592499	36834573	37567252				
36300838	36592660	36843542	37567253				
36317858	36596040	36844231	37567400				
36317859	36596041	36846161	37568848				
36318240	36609818	36846163	37568849				

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AXIOS™ Stent and Electrocautery Enhanced Delivery System	M00553520	08714729904540	36323786	36609819	36864951	37571930	September 12, 2026 - April 28, 2027	
			36323787	36610400	36864952	37685005		
			36331036	36610401	36865501	37686597		
			36331038	36621583	36865502	37689957		
			36397921	36621584	36865504	37689958		
			36397922	36634546	36865553	37698144		
			36397923	36634547	36868065	37704842		
			36421238	36664793	36916329	37761034		
			36424644	36673195	36916330	37775246		
			36424645	36673557	36917403	37776579		
			36427248	36673558	36917404	37776720		
			36446498	36675688	36917993	37776721		
			36447200	36675689	37423232	37780826		
			36447201	36675690	37423233	37785688		
			36449569	36675692	37427258	37785689		
			36449570	36677844	37427259	37811064		
			36449571	36677845	37427360	37817121		
	36458829	36677846	37427361					
		M00553530	08714729904557	35985705	36517139	36766371	37498192	September 2, 2026 - April 23, 2027
	35986358			36517220	36783265	37511243		
	36147098			36525208	36792467	37519095		
	36147222			36525209	36792468	37519096		
	36165642			36525210	36792469	37519097		
	36176423			36534514	36792470	37520927		
	36190575			36534518	36792471	37530320		
	36191222			36536259	36799315	37530321		
	36194448			36536480	36815090	37530333		
36218745	36536481			36815092	37533308			
36227778	36551000			36833683	37541933			
36227779	36551001			36845422	37571927			
36241500	36642564			36851792	37571928			
36271259	36642565			36873631	37579364			
36280398	36642756			36873632	37579366			
36293880	36645775			36873906	37579367			
36300839	36663654			36904228	37580630			
36301620	36677842	36904230	37585525					
36343103	36677843	36907002	37585526					
36343104	36682759	36907004	37589261					
36364646	36684887	36907028	37589262					
36425887	36684888	37102533	37594668					
36469811	36730665	37102534	37649481					

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AXIOS™ Stent and Electrocautery Enhanced Delivery System	M00553530	08714729904557	36471228	36730666	37102535	37649482	September 2, 2026 - April 23, 2027
			36491879	36747824	37102536	37649483	
			36492660	36747825	37102537	37650631	
			36506029	36753898	37459567	37694052	
			36510220	36753899	37459568	37699011	
			36510221	36757493	37459569	37699012	
			36513401	36757494	37459570	37708202	
			36513402	36761827	37463133	37779125	
	36513403	36766370	37470670				
	M00553560	08714729951100	35793920	36310764	36683263	37263554	February 6, 2026 - October 28, 2026
			35952745	36310765	36684615	37263555	
			35961004	36310766	36685905	37268080	
			35995006	36310767	36685906	37268081	
			35995007	36310768	36804376	37268098	
			35995165	36310769	36814735	37269066	
			36001950	36447543	36816919	37269068	
			36001951	36447544	36818381	37273840	
			36001952	36447545	36818382	37273841	
			36001953	36447546	36821877	37274479	
			36002902	36449567	36823193	37274863	
			36002903	36449568	36823194	37275620	
			36002904	36458833	36828324	37276239	
			36003946	36458834	36828325	37276361	
			36003947	36461125	36829194	37276363	
			36003948	36478581	36829196	37276364	
			36012845	36478582	36835382	37308911	
			36012846	36478583	36835383	37323226	
			36012847	36478584	36838544	37323227	
36012848			36478585	36838545	37323228		
36015761			36481333	36838546	37323229		
36021049			36481334	36838547	37324379		
36021050			36487762	36839663	37325180		
36021051			36487763	36839664	37325181		
36021052			36487764	36847979	37325182		
36027054			36487765	36848665	37325354		
36027055			36493311	36848666	37331113		
36027056			36493313	36851793	37379513		
36027057	36493314	36851794	37380940				
36027058	36494812	36853105	37380941				
36027059	36494813	36853106	37380942				
36027060	36503314	36853594	37382298				

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AXIOS™ Stent and Electrocautery Enhanced Delivery System	M00553560	08714729951100	36027061	36503315	36853595	37382299	February 6, 2026 - October 28, 2026
			36038410	36503316	36854299	37384504	
			36038411	36503317	36856185	37384505	
			36040000	36503459	36856186	37386277	
			36040001	36504640	36856187	37386278	
			36040002	36504702	36856188	37443960	
			36040003	36509327	36856340	37443961	
			36040004	36517739	36856341	37443962	
			36048795	36517821	36856342	37451306	
			36048796	36517822	36866851	37451307	
			36048797	36519644	36866852	37456598	
			36048798	36533327	36866853	37457260	
			36049282	36533328	36868980	37460647	
			36049283	36548037	36868981	37460648	
			36049284	36548038	36868982	37461035	
			36050387	36548039	36868983	37461036	
			36050388	36548060	36868984	37463128	
			36050389	36548061	36869884	37463129	
			36059222	36551002	36869885	37501715	
			36059223	36551003	36869886	37501716	
			36059224	36551004	36869887	37501717	
			36059225	36559039	36869888	37510239	
			36062077	36559580	36869889	37511240	
			36062078	36559581	36869890	37514184	
			36062079	36559582	36869891	37514185	
			36064449	36559583	36875736	37514972	
			36065116	36560842	36875737	37524755	
			36065117	36560843	36877081	37524756	
			36067962	36562844	36877082	37524758	
			36067963	36562845	36877084	37530261	
			36067964	36565931	36877085	37536574	
			36069958	36566528	36880763	37538606	
			36069959	36567449	36880764	37541652	
			36070600	36570785	36897772	37543964	
36070608	36570786	36897773	37543965				
36070609	36570787	36959806	37543966				
36070610	36572359	36959807	37544646				
36070611	36581587	37004726	37544647				
36072736	36583578	37004727	37544648				
36072737	36583579	37059011	37548357				
36092333	36591069	37060652	37548358				

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AXIOS™ Stent and Electrocautery Enhanced Delivery System	M00553560	08714729951100	36092334	36591070	37067633	37549491	February 6, 2026 - October 28, 2026
			36092335	36591071	37069356	37549492	
			36099411	36591072	37069357	37552245	
			36099412	36612260	37075264	37552246	
			36099413	36612261	37075265	37552247	
			36101743	36616444	37078233	37552248	
			36101744	36616445	37078234	37554898	
			36101745	36619789	37093209	37567401	
			36101746	36619790	37093210	37567402	
			36101747	36619791	37093302	37567403	
			36102812	36619792	37093303	37567404	
			36102813	36619793	37096513	37567405	
			36102814	36621321	37096514	37567406	
			36135590	36621322	37099739	37601264	
			36135591	36621323	37132500	37601265	
			36144122	36625032	37132501	37601266	
			36144123	36625033	37132502	37611305	
			36147096	36625034	37134087	37611306	
			36147097	36625035	37137422	37611308	
			36154534	36626350	37137423	37617701	
			36154536	36626351	37140068	37617702	
			36154537	36626352	37152588	37625483	
			36154538	36633245	37153325	37625484	
			36155116	36633246	37157514	37644410	
			36155117	36640831	37161889	37649490	
			36156264	36641049	37161890	37651467	
			36156265	36641909	37164067	37655139	
			36164534	36641910	37164068	37655281	
			36164535	36642073	37167102	37660774	
			36164536	36642074	37167103	37660775	
			36165655	36642075	37167775	37660777	
			36165656	36642562	37176653	37660778	
			36165657	36643731	37176657	37665497	
			36165658	36643732	37194095	37667998	
			36197586	36645532	37204177	37672121	
			36197587	36645533	37204178	37675664	
			36197588	36645534	37204179	37675665	
			36197589	36647015	37204240	37689944	
			36199391	36662774	37204241	37689945	
			36200602	36662775	37204809	37696688	
36200603	36662776	37204810	37720785				



## Attachment 1 – Product List

AXIOS™ Stent and Electrocautery Enhanced Delivery System	M00553560	08714729951100	36207756	36662778	37204811	37723579	February 6, 2026 - October 28, 2026
			36207757	36662779	37207470	37731195	
			36207758	36664061	37207471	37731196	
			36209378	36664062	37208948	37731197	
			36209379	36664063	37217600	37742018	
			36218689	36664064	37217605	37745174	
			36218690	36664065	37217607	37746915	
			36218746	36664567	37240010	37750340	
			36218747	36664568	37240011	37750341	
			36219228	36664794	37252330	37754384	
			36271447	36664796	37252331	37754385	
			36271448	36665694	37252333	37771353	
			36271456	36665695	37252334	37771355	
			36271457	36669412	37252335	37777208	
			36271458	36669413	37257420	37778063	
			36271459	36669414	37257421	37780175	
			36271840	36669415	37257422	37780176	
			36303991	36669416	37257423	37809877	
			36303992	36669417	37261686	37809878	
			36303993	36669418	37262942	37809879	
	36310699	36674810	37262943	37811060			
	36310760	36674811	37262949	37811061			
	36310761	36674812	37262950	37811062			
	36310762	36674813	37263184	37811063			
	36310763	36677847	37263185	37817124			
	M00553660	08714729951179	35961006	36359567	36895363	37340131	February 28, 2026 - October 29, 2026
			35961007	36362263	36895364	37340270	
			35962524	36362264	36958216	37340271	
			35967379	36362265	36958217	37341078	
			35968520	36363150	36962750	37341079	
			35968521	36363151	36970218	37344296	
			35968597	36364647	36970219	37344297	
			35968598	36372361	36980310	37346443	
			35971077	36372362	36981856	37346445	
35971078			36377757	36985933	37348330		
35971079			36378548	36988632	37348331		
35972100			36380549	36990382	37352140		
35982272			36388531	36990383	37352141		
35982273			36390612	36991168	37354943		
35982274	36396985	36991170	37354944				
35982275	36399492	36991683	37357958				

## Attachment 1 – Product List

AXIOS™ Stent and Electrocautery Enhanced Delivery System	M00553660	08714729951179	35982276	36403441	36992721	37357959	February 28, 2026 - October 29, 2026
			35982277	36408983	37014102	37358120	
			35982278	36408984	37014103	37359884	
			35982279	36417820	37014104	37359885	
			35982420	36417821	37027339	37365502	
			35982424	36418721	37028180	37365503	
			35982425	36418722	37028181	37365504	
			35985313	36424650	37030756	37365505	
			35985314	36424651	37032104	37375861	
			35993619	36424652	37036344	37388591	
			35993720	36425889	37036345	37388592	
			35993721	36425890	37037505	37388593	
			36109761	36425891	37037506	37400608	
			36109763	36425892	37040169	37402464	
			36109764	36462323	37041012	37402466	
			36109765	36462324	37041435	37410374	
			36109766	36469427	37041436	37411886	
			36111314	36469428	37046449	37411887	
			36111315	36469812	37046450	37415923	
			36118993	36472250	37046928	37415924	
			36118994	36472253	37046929	37415925	
			36122066	36472254	37048665	37427250	
			36122067	36475370	37049464	37429329	
			36122075	36478478	37049465	37429330	
			36132801	36478479	37049874	37438134	
			36132802	36572740	37050321	37438135	
			36132803	36572741	37050322	37439609	
			36132804	36573582	37050323	37439610	
			36134972	36573583	37055465	37439611	
			36144058	36573587	37055466	37451308	
			36144059	36573588	37055467	37451309	
			36144120	36573589	37056013	37454250	
			36144121	36573590	37056014	37454251	
			36174475	36591073	37057032	37456595	
			36174476	36591074	37059006	37456596	
			36178005	36591075	37059010	37459573	
			36187588	36603384	37094844	37567407	
			36187589	36603385	37106164	37573089	
			36187687	36603386	37106583	37573090	
			36187688	36604188	37131143	37573091	
36188887	36604189	37131144	37575640				

## Attachment 1 – Product List

AXIOS™ Stent and Electrocautery Enhanced Delivery System	M00553660	08714729951179	36188888	36604190	37131145	37578876	February 28, 2026 - October 29, 2026
			36188889	36604191	37131146	37578877	
			36194446	36604748	37177253	37578879	
			36194447	36604749	37177271	37579368	
			36197239	36607249	37177272	37579369	
			36198580	36607250	37179955	37579370	
			36217768	36607251	37179956	37582027	
			36217769	36607252	37180902	37585524	
			36217770	36607253	37180903	37588798	
			36227341	36610818	37182323	37588799	
			36227342	36610819	37183490	37589260	
			36227343	36611060	37188257	37592382	
			36228603	36615703	37188258	37592383	
			36228604	36615704	37197563	37596205	
			36228605	36621589	37197578	37596206	
			36235934	36621590	37198908	37596207	
			36236151	36623324	37199019	37596208	
			36240589	36623325	37199360	37601263	
			36240590	36623326	37199361	37602176	
			36241715	36693849	37199972	37602177	
			36241716	36693850	37199973	37602178	
			36241717	36693851	37209169	37602179	
			36251363	36693852	37209170	37603348	
			36251364	36694699	37209171	37607457	
			36253000	36695020	37211282	37607459	
			36253008	36695021	37211285	37607540	
			36253041	36695023	37212243	37625485	
			36260860	36698247	37212244	37625486	
			36260861	36698249	37212245	37626455	
			36260862	36698251	37212246	37626456	
			36261599	36698527	37213246	37631100	
			36261780	36698528	37213247	37631101	
			36261781	36698529	37213248	37633190	
			36261834	36698530	37213249	37633191	
			36261835	36698531	37240012	37638120	
			36280395	36698532	37240013	37638121	
36280396	36706712	37240236	37638122				
36280397	36706713	37240237	37639137				
36281912	36706714	37240249	37639138				
36281913	36706715	37240250	37644407				
36281914	36709766	37240252	37644408				

## Attachment 1 – Product List

AXIOS™ Stent and Electrocautery Enhanced Delivery System	M00553660	08714729951179	36283860	36709767	37240254	37649491	February 28, 2026 - October 29, 2026
			36292682	36709768	37242247	37649492	
			36292683	36709769	37242248	37686664	
			36292684	36713255	37242249	37686665	
			36292689	36713256	37243754	37686666	
			36292690	36713257	37243755	37700937	
			36292691	36713258	37243756	37700938	
			36294495	36717717	37247304	37706532	
			36301621	36717718	37247305	37706533	
			36301622	36717719	37247306	37706534	
			36301623	36717800	37283604	37708203	
			36301624	36717801	37283605	37708204	
			36302290	36717802	37291851	37716332	
			36302291	36718966	37291852	37716333	
			36302292	36718967	37292951	37718549	
			36319024	36723909	37292952	37720553	
			36319025	36723910	37296017	37720554	
			36319026	36728154	37296019	37720555	
			36320016	36764237	37297941	37727831	
			36320017	36764238	37300544	37730055	
			36323789	36767449	37300545	37754383	
			36323790	36767450	37300546	37758168	
			36324720	36771884	37302814	37758169	
			36325159	36771885	37308038	37758170	
			36325560	36771886	37308039	37759554	
			36325568	36785593	37325355	37761362	
			36325569	36788793	37328835	37761363	
			36332101	36788794	37328836	37785682	
			36332102	36788795	37328838	37785683	
			36341577	36795369	37331112	37787089	
			36342114	36795370	37332012	37787090	
			36342418	36796430	37333358	37789164	
			36352008	36796431	37333362	37789168	
36352009	36804013	37337364	37789169				
36355049	36804375	37340128	37820578				
36355050	36839665	37340129					
36355752	36895362	37340130					
M00553680	00191506008086	35950784	36408034	36536257	37429734	August 28, 2026 - April 23, 2027	
		35960771	36421237	36536258	37429735		
		35960772	36447549	36570788	37433804		
		36156260	36447550	36570789	37433805		

### Attachment 1 – Product List

AXIOS™ Stent and Electrocautery Enhanced Delivery System	M00553680	00191506008086	36156261	36520894	36578110	37451303	August 28, 2026 - April 23, 2027
			36165653	36530482	36581584	37456593	
			36167912	36530483	36603297	37495326	
			36241714	36530484	36611362	37519092	
			36401105	36533326	37014108	37780825	
	M00553690	00191506008093	35960775	36303192	36576474	36907032	August 29, 2026 - April 22, 2027
			35960777	36420219	36584299	37217612	
			35962525	36425888	36604665	37217613	
			36100561	36449561	36731807	37217614	
			36101748	36458830	36737997	37495327	
			36111316	36461449	36743059	37511242	
			36154532	36478580	36743200	37602825	
			36154533	36492661	36904231	37602826	
			36241501	36495673	36904232	37694053	
			36251362	36573597	36904233	37694054	
			36253016	36573598	36906587	37764852	
			36293839	36573599	36907000		
			36301625	36574152	36907001		