

URGENT:
MEDICAL DEVICE VOLUNTARY Recall
Recall Number: RA2023-XXXXXX

Guider Softip™ XF Guide Catheter

Attn: Risk Management/ Recall Coordinator/ Inventory Manager

Boston Scientific has initiated a Voluntary Field Action – Removal on certain lots of the Guider Softip™ XF Guide Catheter. The Guider Guide Catheter is manufactured by Boston Scientific Corporation and distributed by Stryker Neurovascular. Our records indicate that you have been supplied with the subject devices. We therefore request that you read this notice carefully and complete the actions requested.

Product affected:

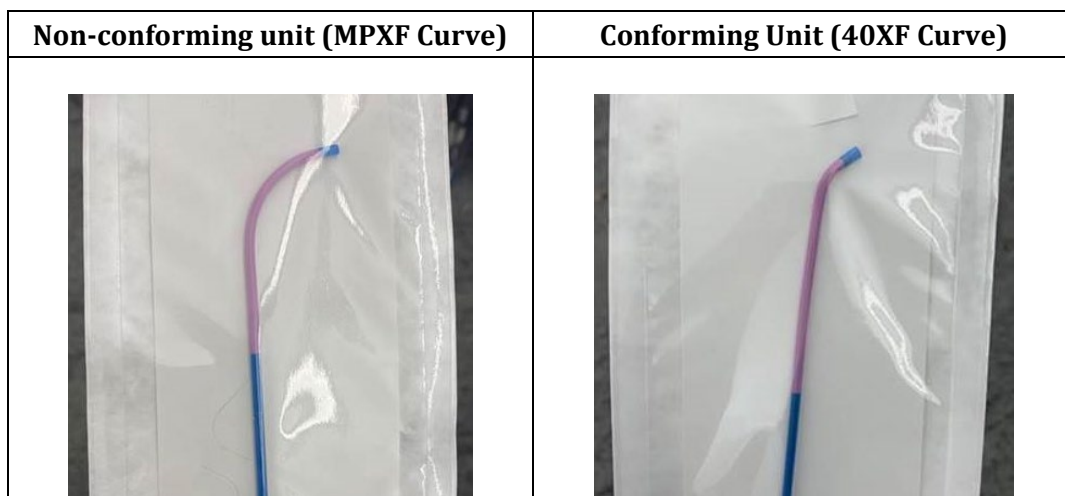
Please immediately cease further distribution or use of any remaining product listed below affected by this removal.

Catalog number	Product description	Lot Number
H965100420	GUIDER 6F PRE-SHAPED 40 90CM	See Attachment A
H965100430	GUIDER 7F PRE-SHAPED 40 90CM	
H965100440	GUIDER 8F PRE-SHAPED 40 90CM	
H965100460	GUIDER 6F 90CM MULTI PURPOSE	
H965100470	GUIDER 7F 90CM MULTI PURPOSE	
H965100480	GUIDER 8F 90CM MULTI PURPOSE	
M003100620	GUIDER 5F PRE-SHAPED 40 90CM	
M003100630	GUIDER 5F 90CM MULTI PURPOSE	
M003101420	GUIDER 6F PRE-SHAPED 40 100CM	
M003101430	GUIDER 7F PRE-SHAPED 40 100CM	
M003101440	GUIDER 8F PRE-SHAPED 40 100CM	
M003101460	GUIDER 6F 100CM MULTI PURPOSE	
M003101470	GUIDER 7F 100CM MULTI PURPOSE	
M003101480	GUIDER 8F 100CM MULTI PURPOSE	
M003101620	GUIDER 5F PRE-SHAPED 40 100CM	
M003101630	GUIDER 5F 100CM MULTI PURPOSE	

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Product description The Boston Scientific Guider Softip™ XF Guide Catheter is a neurovascular access catheter that creates a stable conduit through which interventional devices can pass. It is constructed with a polymer liner on the inside diameter for lubricity, stainless steel wire reinforcement within the wall for torque transmission and strength, and polymer materials along the length of the catheter for support and flexibility. The catheter has an atraumatic tip and a hub/strain relief combination for kink resistance (at the hub), device connectivity, and device handling.

Product issue Stryker Neurovascular has observed that certain lots of Guider Softip™ XF Guide Catheters appear to have the incorrect tip curve shape. The impacted products were distributed with a tip curve shape which differs from the labeled tip curve shape. See example images below.



Potential hazard As our customer, you may have received a device with an incorrect labeled tip curve shape. However, the non-conforming tip curve shape is easily identifiable upon product inspection/preparation. There have been no reported patient harms.

Potential risks Potential Risk: Patients previously treated with the impacted devices: None.

For potential patients: If the incorrect tip curve shape is used, the most serious anticipated outcome would be that the guide catheter may not navigate to the desired anatomy location and would be exchanged for another device. However, the tip curve shape is easily identifiable upon product inspection/preparation; therefore, the most serious and most common anticipated health consequence that could occur is procedural delay while the device is swapped for another with the correct tip curve shape prior to use on the patient. Device exchange can be performed with no significant delay, and within the expected duration of the procedure.

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Required Actions

1. Immediately check your internal inventory for affected devices.
2. Segregate the affected units in a secure location for return to Stryker.
3. Circulate this Recall-Removal notice internally to all interested/affected parties.
4. Maintain awareness of this communication internally until all required actions have been completed within your facility.
5. Inform Stryker if any of the subject devices have been distributed to other organizations. If yes, provide contact details so that Stryker can inform the recipients appropriately.
6. Please inform Stryker of any adverse events concerning the use of the subject devices.
7. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter.
8. Email the completed form to your local Stryker contact.
9. Product Return Information will be provided to you by your designated Sales Representative.

We request that you respond to this notice within 10 calendar days from the date of receipt. The target date for completion of this action is 31 December 2023 and your timely response will enable us to ensure that we meet this target.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action by the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours Sincerely,

Attachment A

Recall – Removal: Guider Softip™ XF Guide Catheter Lots

Catalog number: H965100420 Product description: GUIDER 6F PRE-SHAPED 40 90CM		Catalog number: H965100430 Product description: GUIDER 7F PRE-SHAPED 40 90CM	
25761340	27269743	25761346	28502667
25761341	27654465	26034355	28676577
25761342	27696356	26034356	28676578
25761343	27703700	26034358	28841172
25964544	27762224	26034832	28841173
25964545	27809357	26034833	28841174
25964546	27809358	26277184	28841175
25964547	27996305	26277185	28841176
26019584	28091480	26277186	28841177
26019585	28107548	26411753	28910752
26019586	28158175	26599620	28910754
26019587	28384635	26599621	28955941
26034354	28502662	26599622	
26034357	28502663	26599623	
26138841	28502664	26599624	
26138842	28502665	26745647	
26138843	28584619	26745648	
26138844	28737891	26745649	
26138845	28737892	26891296	
26338704	28737893	26891297	
26338705	28795035	26891498	
26338706	28795036	27081941	
26338707	28795037	27081942	
26338708	28886611	27081943	
26338709	28886612	27081944	
26411750	29112775	27081945	
26411751	29112777	27103346	
26411752	25651702	27645560	
26498390	25651703	27696357	
26745645	25651704	27754497	
26745646	25651705	27779955	
26891295	25651706	27780469	
26891496	25651708	27996306	
26891497	25651709	28049141	
27103345	25651710	28384636	
25651700	25651711	28384637	
25651701		28502666	

Attachment A

Recall – Removal: Guider Softip™ XF Guide Catheter Lots

Catalog number: H965100440 Product description: GUIDER 8F PRE-SHAPED 40 90CM		
26034834	26745656	27654466
26034835	26891492	27661666
26034836	26891493	27661667
26034837	26891494	27669282
26034838	26891495	27669283
26034839	26891499	27728491
26059640	26891760	27735227
26059641	26891761	27735228
26138712	26891762	27894534
26338710	26891763	27894535
26338711	26891764	27943983
26338712	26891765	28320869
26338713	26891766	28320870
26338714	26891767	28320871
26338715	27081946	28320872
26599625	27081947	28384638
26599626	27162090	28384639
26599627	27162091	28384660
26599628	27162092	28471410
26599629	27184893	28471411
26599630	27184895	28502668
26599631	27192450	28502669
26599632	27192451	28502670
26599633	27347761	28676785
26745650	27367346	28676786
26745651	27367347	28676787
26745652	27386636	28676788
26745653	27516584	29308869
26745654	27568838	29308872
26745655	27568839	29308874
25651712	25651715	25651718
25651713	25651716	25651719
25651714	25651717	

Attachment A

Recall – Removal: Guider Softip™ XF Guide Catheter Lots

Catalog number: H965100460 Product description: GUIDER 6F 90CM MULTI PURPOSE		Catalog number: H965100470 Product description: GUIDER 7F 90CM MULTI PURPOSE	
25822912	27504202	25761344	28384662
25822914	27568860	25761345	28502672
25822915	27754498	25964138	28676579
25822916	27816607	25964139	28676780
26059397	28100259	25964480	28832480
26059642	28320873	25964481	28832482
26338716	28384661	25964482	28886617
26584704	28502671	26059398	28886618
26585219	28584618	26059399	28886619
26745657	28737894	26130252	28886800
26745658	28737895	26130253	28955942
26745659	28795038	26138707	
26891768	28886615	26138708	
27177892	29112778	26277183	
27177893	29112779	26599634	
27412261		26599635	
		26599636	
		26599637	
		26746100	
		26746101	
		26746102	
		26746103	
		26891769	
		26891770	
		26997421	
		26997422	
		27129310	
		27129311	
		27144691	
		27144692	
		27269744	
		27585414	
		27779956	
		27779958	
		28007176	

Attachment A

Recall – Removal: Guider Softip™ XF Guide Catheter Lots

Catalog number: H965100480 Product description: GUIDER 8F 90CM MULTI PURPOSE			
25761255	26498387	27152183	27627222
25761256	26498388	27203534	27627223
25761257	26498389	27247812	27677022
25761258	26599638	27247813	27677023
25914833	26599639	27262276	27687781
25914834	26599700	27262277	27687782
25914835	26599701	27265388	27696121
25914836	26599702	27265390	27696122
25915124	26599703	27265391	27703701
25915125	26726579	27265392	27741721
25964498	26726620	27265393	27741722
25964499	26726621	27323834	27747953
25964540	26726622	27327740	27767764
25964541	26726623	27327741	27775275
25964542	26726624	27367348	27928345
25964543	26726625	27367349	27928346
26059648	26746104	27379023	27936345
26059651	26746105	27386633	27936346
26059653	26746106	27386634	27952564
26138719	26746107	27420627	27961071
26138804	26746108	27420628	27972713
26138808	26746109	27420629	27972714
26138811	26891771	27431146	28007177
26138815	26891772	27450919	28239957
26138816	26891773	27450920	28239958
26138817	27007548	27459237	28242517
26138818	27007549	27504209	28242518
26138819	27016490	27516636	28250416
26138840	27016491	27558591	28250417
26338717	27016624	27558592	28260600
26338718	27042423	27558593	28260601
26338719	27121007	27558594	28267426
26339260	27121008	27611878	28267427
26339261	27136897	27619799	28275299
26339262	27136898	27619841	28275300

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Recall – Removal: Guider Softip™ XF Guide Catheter Lots

Catalog number: H965100480 Product description: GUIDER 8F 90CM MULTI PURPOSE		Catalog number: M003100620 Product description: GUIDER 5F PRE-SHAPED 40 90CM	
28283283	29146658	25715235	26891778
28283284	29146659	25715236	27170548
28291108	29183520	25761247	27444248
28291109	29183521	25761248	27516585
28320779	29183522	26059690	28057178
28320860	29183523	26277194	28584686
28320861	29183524	26277195	28595475
28320862	29233903	26599706	28811944
28384663	29233906		
28384664	29233907		
28384665	29233908		
28384666	29233909		
28471406	29233910		
28471407	29233911		
28471408	29233912		
28471409	29233913		
28502673	29271762		
28502674	29271763		
28502675	29271764		
28502676	29271766		
28502677	29271770		
28502678	29418783		
28584616	29418789		
28616010	29418790		
28632173	25651742		
28632174	25651743		
28632175	25651744		
29146650	25651745		
29146651	25651746		
29146652	25651747		
29146653	25651748		
29146654	25651749		
29146655	25651750		
29146656	25651751		
29146657	25651752		
25651740	25651755		
25651741			

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Recall – Removal: Guider Softip™ XF Guide Catheter Lots

Catalog number: M003100630 Product description: GUIDER 5F 90CM MULTI PURPOSE		Catalog number: M003101420 Product description: GUIDER 6F PRE-SHAPED 40 100CM	
25761245	27412262	26059693	27203536
26059691	27412263	26138710	27203537
26409982	27412264	26138711	27219436
26599707	27412265	26276489	27431372
27219434	25651754	26276490	27431373
25651753		26276491	27526941
		26590802	27801040
		26590803	28141851
		26746110	28595681
		26746111	28737897
		26891804	28737898
		26891805	28811942
		27162093	28811943
		27162094	28886803

Catalog number: M003101430 Product description: GUIDER 7F PRE-SHAPED 40 100CM		Catalog number: M003101440 Product description: GUIDER 8F PRE-SHAPED 40 100CM	
26138318	28065090	25823580	26599711
26891812	28595471	25823581	26599712
27241919	28676781	25964485	26746112
27516638	28676782	25964486	26746113
27780467	28886804	25964487	26984240
27780470	28910751	26059694	26984241
		26059696	26984253
		26130254	27203538
		26130255	27203539
		26277190	27241920
		26277191	27379022
		26277192	28384669
		26599708	28632344
		26599709	28632346
		26599710	

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Recall – Removal: Guider Softip™ XF Guide Catheter Lots

Catalog number: M003101460 Product description: GUIDER 6F 100CM MULTI PURPOSE		Catalog number: M003101470 Product description: GUIDER 7F 100CM MULTI PURPOSE	
26059695	27558595	26411755	27444224
26059697	27592320	26746117	27558596
26339266	27592321	26746118	27585415
26339267	27767765	26891819	27585416
26339268	27824570	27121009	27611940
26339269	28115146	27435625	28676783
26498391	28132917	27435626	28955779
26590800	28384670		
26590801	28384671		
26746114	28632176		
26746115	28632177		
26746116	28632178		
26891816	28632179		
26891817	28737899		
26891818	28738180		
27065537	28738181		
27081948	28795500		
27254932	28886805		
27280217	28886806		
27288435	28886807		
27435623	29113162		
27535145	25715226		
25715225			

Attachment A

Recall – Removal: Guider Softip™ XF Guide Catheter Lots

Catalog number: M003101480 Product description: GUIDER 8F 100CM MULTI PURPOSE		Catalog number: M003101620 Product description: GUIDER 5F PRE-SHAPED 40 100CM	
26138706	27558597	25715223	26891844
26277188	27645561	25761249	27450921
26277189	27728492	25964483	27558598
26411756	27782880	25964484	27780463
26411757	27902047	26138315	27780468
26599713	27980980	26409983	28632343
26599714	27988374	26409984	28737896
26599715	28320864	26590809	
26709826	28320865		
26709827	28320866		
26746119	28320867		
26746120	28564218		
26891840	28564219		
26891841	28564380		
26984254	28584613		
27170547	28616007		
27203658	28616008		
27254933	28632340		
27339851	28632341		
27379026	28632342		
27379027	28632345		
27535146	29513117		

Catalog number: M003101630 Product description: GUIDER 5F 100CM MULTI PURPOSE		
25715222	27762225	27780464