

URGENT FIELD SAFETY NOTICE
RA2020-2430533

Attn: Risk Management/ Recall Coordinator/ Inventory Manager
Trevo XP ProVue Retriever

FSCA Identifier: RA2020-2430533
Type of Action: Field Safety Corrective Action - Recall
Products Affected: Trevo XP ProVue Retriever
Product Number(s): See Attachment 1
Affected Lot(s) LOT specific (see Attachment 2)

06th October 2020

Dear Customer,

Stryker Neurovascular division has initiated a Product Recall on specific lots of Trevo XP ProVue Retriever devices manufactured during the time period of 22-JUL-2019 to 09-SEP-2019. 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 description

The Trevo XP ProVue Retriever consists of a flexible, tapered core wire with a shaped section at the distal end. Platinum markers at the distal end allow fluoroscopic visualization. In addition, the shaped section is also radiopaque. The Trevo XP ProVue Retriever system is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA).

Product issue

Stryker Neurovascular has observed an increase in complaints involving fractures of the core wires of the Trevo XP ProVue Retriever for certain lots manufactured between the time period of 22-JUL-2019 to 09-SEP-2019 resulting in stent retriever separation from the core wire during use.

Potential hazard

The complaint rate for fracture in 2020 was noted to be higher than historical data for the identified lots manufactured during the above mentioned time period. A Health Hazard Evaluation was completed to assess the potential hazardous situation of retriever core wire fractures during use. It was determined that when the core wire fracture occurs, the stent retriever can be left behind in the vasculature.

Potential risks

Patients previously treated with the impacted devices: None

For potential patients: In the event of device fracture during use, there is a risk of serious injury or death.

Actions Needed:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following 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,

- a) Please provide contact details so that Stryker can inform the recipients appropriately.
 - b) If you are a Distributor, note that you are responsible for notifying your affected customers.
6. Please inform Stryker of any adverse events concerning the use of the subject devices.

Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.

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. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA.
 - a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within **7 calendar days** from the date of receipt.

The target date for completion of this action is **30 November 2020** and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Sharun Thavarajan
Position: Senior RAQA Specialist
E-mail: sharunyan.thavarajan@stryker.com
Phone: +44(0)7929 021 221

In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be cause. 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,

Sharun Thavarajan
Regulatory Affairs and Quality Assurance

RA2020-2430533 – Attachment 1

List of affected Product Codes

Trevo® XP ProVue Retriever Single Units List

Catalog Number	Product Description
90182	Trevo XP ProVue Retriever 4MM x 20MM
90185	Trevo XP ProVue Retriever 4MM x 30MM
90186	Trevo XP ProVue Retriever 6MM x 25MM

Trevo® XP ProVue Retriever Procedure Pack List

Catalog Number	Product Description
80052	TREVO XP PROVUE - RETRIEVER 4X20 + TREVO PRO 18 MC KIT
93067	TREVO XP PROVUE - RETRIEVER 4X30 + TREVO PRO 18 MC PROCEDURE KIT
93068	TREVO XP PROVUE - RETRIEVER 6X25 + EXCELSIOR XT-27 MC PROCEDURE KIT
M0032PK42010002	2 PACK TREVO XP 4 X 20 CAT 6 C
M0032PK43010002	2 PACK TREVO XP 4 X 30 CAT 6 C
M0032PK62510002	2 PACK TREVO XP 6 X 25 CAT 6 C
M0033PK42022002	3 PACK TREVO XP 4 X 20 PRO 18 CAT 6 C
M0033PK43022002	3 PACK TREVO XP 4 X 30 PRO 18 CAT 6 C
M0033PK62523002	3 PACK TREVO XP 6 X 25 XT 27 CAT 6 C

RA2020-2430533 – Attachment 2

List of affected LOT Numbers

Catalog number: 90182	Catalog number: 90185	Catalog number: 90186
Product description: Trevu XP ProVue Retriever 4MM x 20MM	Product description: Trevu XP ProVue Retriever 4MM x 30MM	Product description: Trevu XP ProVue Retriever 6MM x 25MM
Impacted Lots:	Impacted Lots:	Impacted Lots:
30024	30030	30032
30025	30031	30262
30251	30260	30406
30252	30261	30417
30253	30407	30418
30408	30415	30419
30409	30416	30927
30410	30924	30928
30921	30925	30929
30922	30926	30930
31336	31338	31339
31585	31588	31340
31761	31764	31341
31762	31765	31587
31763	32040	32046
32042	32041	32047
32043	32313	32314
32309		
32310		
32400		
32401		
32402		
32403		

Catalog: 80052

Product Description: TREVO XP PROVUE - RETRIEVER 4X20 ET TREVO PRO 18 MC KIT

Impacted Lots:

38131857	38166611	38261565	38290862	38408161	38531171	38623687
38134761	38174956	38261566	38290863	38408162	38531172	38623688
38146859	38174961	38261576	38290868	38408168	38531174	38636560
38146881	38174966	38261577	38309361	38408169	38531175	38636564
38157255	38174967	38271765	38311965	38408179	38531178	38636574
38157256	38174972	38271766	38311968	38408180	38539060	38636575
38157260	38174974	38271767	38311970	38408183	38539061	38636578
38157264	38185261	38271768	38311973	38408184	38544361	38636579

38157268	38191257	38271769	38322364	38408185	38544363	38636580
38157270	38191271	38271770	38322365	38408190	38544364	38636581
38157276	38195455	38271771	38322366	38408191	38557054	38636582
38157278	38195458	38271772	38322367	38418558	38557055	38636585
38157279	38205655	38271773	38322368	38418762	38557056	38649862
38166555	38210561	38271774	38322383	38429960	38572761	38649863
38166556	38210562	38271775	38334860	38429961	38572762	38649865
38166559	38210565	38271776	38334862	38429966	38572763	38649866
38166562	38210567	38271777	38343560	38429967	38572764	38660361
38166563	38210569	38271778	38343561	38429971	38572765	38660362
38166564	38210570	38271779	38343567	38439661	38572767	38660363
38166566	38210572	38271780	38343568	38439665	38572770	38660364
38166567	38210574	38271781	38343572	38449963	38572773	38660365
38166571	38221557	38271782	38343581	38449964	38572776	38660366
38166572	38221560	38271783	38352169	38449971	38572777	38660367
38166573	38221563	38271784	38352171	38449972	38572778	38660369
38166574	38226159	38271785	38363960	38453562	38586760	38660370
38166575	38226160	38271786	38363962	38461767	38586765	38660371
38166576	38226161	38271787	38363966	38461768	38586767	38660373
38166577	38226162	38271788	38363967	38461769	38586768	38660381
38166578	38226163	38271789	38363969	38461777	38586773	38660382
38166579	38226164	38271790	38363970	38461779	38610460	38671361
38166580	38226165	38271791	38363971	38461780	38610461	38671367
38166583	38226166	38271792	38363972	38461787	38610462	38671370
38166584	38226167	38271793	38363973	38461788	38610465	38671371
38166586	38226176	38271794	38363974	38461791	38619160	38671372
38166587	38229556	38271795	38363975	38461792	38623660	38671373
38166588	38229558	38271796	38363976	38476060	38623662	38682661
38166589	38229576	38271797	38363977	38492465	38623663	38682663
38166590	38239160	38271798	38363978	38492467	38623664	38682664
38166591	38250456	38271799	38363979	38492469	38623665	38682665
38166592	38250460	38271800	38363980	38492474	38623666	38682667
38166593	38250462	38271801	38371260	38492479	38623667	38682668
38166594	38250463	38271802	38377965	38492480	38623668	38682670
38166595	38250465	38271803	38377966	38503762	38623669	38682671
38166596	38250470	38271804	38377967	38503765	38623674	38682672
38166597	38250471	38271805	38377968	38503774	38623675	38682679
38166598	38250472	38271806	38377983	38503775	38623676	38763862
38166599	38250473	38271807	38377984	38516766	38623677	38763863
38166600	38250474	38271808	38377985	38525960	38623678	38813063
38166601	38250475	38271809	38377986	38525961	38623679	39030961
38166602	38250476	38271810	38394060	38531162	38623680	39030962
38166605	38250477	38271811	38395864	38531165	38623681	39030963
38166606	38250478	38271812	38395866	38531166	38623682	
38166607	38250479	38281756	38395867	38531167	38623683	
38166608	38253255	38281759	38395875	38531168	38623684	

38166609	38261563	38281761	38395880	38531169	38623685	
38166610	38261564	38281766	38395886	38531170	38623686	

Catalog: 93067

Product Description: TREVO XP PROVUE - RETRIEVER 4X30 ET TREVO PRO 18 MC
PROCEDURE KIT

Impacted Lots:

36448781	36529556	36799851	36912340	36984363	37108540	37125456
36461581	36547189	36799859	36912353	36984364	37108544	37125457
36461583	36547195	36799860	36912354	36984365	37108546	37125458
36498382	36547197	36836835	36930560	36984366	37108547	37125468
36498384	36547215	36836838	36930561	37003135	37108549	37141942
36498680	36632788	36836842	36930565	37003140	37108550	37158939
36498681	36632794	36836843	36930569	37003141	37108551	37158940
36498682	36652186	36857851	36930579	37003144	37108565	37158947
36529509	36691283	36857852	36947233	37011643	37108566	37174352
36529545	36714887	36857853	36947255	37032438	37108567	37195439
36529546	36735085	36857854	36947256	37049334	37108568	37195440
36529547	36735086	36857855	36947257	37049335	37108569	37195441
36529548	36735087	36857856	36947258	37049336	37108570	37195442
36529549	36735088	36875438	36967536	37049345	37108571	37195444
36529550	36735089	36875442	36967551	37049357	37108572	37195448
36529551	36753486	36875443	36984339	37056132	37108573	37228358
36529552	36753488	36875444	36984352	37077332	37125434	37228360
36529553	36753497	36875453	36984354	37089641	37125435	37329459
36529554	36799849	36891540	36984355	37108533	37125448	37495860
36529555	36799850	36912333	36984362	37108537	37125449	37510394

Catalog: 93068

Product Description: TREVO XP PROVUE - RETRIEVER 6X25 ET EXCELSIOR XT-27 MC
PROCEDURE KIT

Impacted Lots:

37032432	37244252	37479670	37543891	37713604	37833331	37954149
37032434	37244253	37479711	37543895	37713620	37833332	37969749
37032435	37263852	37479714	37575302	37733704	37849512	37969756
37049353	37263862	37479715	37575304	37733712	37849513	37969757
37049354	37263875	37479734	37575315	37733716	37849517	37969758
37065739	37281945	37479752	37575317	37754601	37849518	37969775
37077333	37297752	37480074	37610402	37754602	37849520	37969776
37077336	37313953	37480075	37610409	37754607	37849521	37969777
37108538	37313955	37480076	37628108	37754608	37849525	37969778
37108545	37329458	37480078	37628109	37754615	37849526	37984459
37108548	37329460	37480081	37644715	37754616	37849527	37984460

37125460	37329464	37480084	37659707	37754617	37849537	37984468
37125461	37329465	37480086	37676901	37754618	37849538	37984471
37125467	37344990	37480089	37676904	37754621	37849539	38000241
37141980	37344996	37480090	37676905	37777326	37849543	38013747
37158943	37345011	37480091	37676909	37777327	37849552	38013948
37195438	37345012	37480092	37676912	37777335	37850811	38013951
37195443	37345013	37480093	37693604	37795612	37850812	38013952
37212242	37364784	37480094	37693620	37795619	37863830	38013962
37212245	37364785	37480095	37693621	37795620	37863831	38028310
37228338	37364786	37495864	37693622	37795621	37863838	38045557
37228344	37364787	37495867	37693623	37795622	37863842	38045558
37228345	37384855	37495868	37693624	37814519	37863850	38045566
37228346	37384864	37510391	37693625	37814520	37882547	38045567
37228357	37402863	37510392	37693630	37814521	37882548	38045570
37228359	37402864	37539290	37693634	37814522	37882554	
37228361	37424965	37539291	37693635	37814544	37919235	
37244247	37479669	37539301	37713603	37814545	37923331	

Catalog: M0032PK42010002

Product Description: 2 PACK TREVO XP 4 X 20 CAT 6 C

Impacted Lots:

38166585
38191261
38191264
38449970
38636576

Catalog: M0032PK43010002

Product Description: 2 PACK TREVO XP 4 X 30 CAT 6 C

Impacted Lots:

36967533
36967572
36967573
36967574
36967575
36967576
36967577
36967578
36967579
36967580

Catalog: M0032PK62510002

Product Description: 2 PACK TREVO XP 6 X 25 CAT 6 C

Impacted Lots:

36967569
37011639
37882543
37938251

Catalog: M0033PK42022002

Product Description: 3 PACK TREVO XP 4 X 20 PRO 18 CAT 6 C

Impacted Lots:

38146882	38174975	38195456	38391767	38392960	38453765	38516767
38146883	38185258	38229563	38391769	38392961	38476062	38572772
38166603	38185259	38261557	38391770	38395862	38476065	38586764
38166604	38185260	38281762	38391771	38395871	38476066	38599024
38166612	38185263	38311966	38391772	38408188	38476067	38636571
38174955	38185267	38391766	38392064	38453760	38492462	38649867

Catalog: M0033PK43022002

Product Description: 3 PACK TREVO XP 4 X 30 PRO 18 CAT 6 C

Impacted Lots:

36431078	36514194	36714883	36787186	36912346	37017833	37158946
36431081	36529540	36714884	36787189	36912351	37032440	37174338
36431082	36529541	36714886	36799835	36912352	37049350	37174350
36448779	36547182	36735105	36799840	36984337	37049355	37174353
36448780	36547187	36735106	36836844	36984348	37077337	37174355
36498687	36547204	36753494	36836845	36984349	37077339	37228363
36498688	36614192	36753495	36875448	36984350	37125462	
36498689	36632790	36753496	36875449	36984351	37125463	
36498690	36632797	36769792	36875450	36984353	37125464	
36498691	36672623	36769793	36875451	37011640	37158944	

Catalog: M0033PK62523002

Product Description: 3 PACK TREVO XP 6 X 25 XT 27 CAT 6 C

Impacted Lots:

37011644	37174354	37281954	37364788	37644701	37938250	38057455
37017836	37228342	37313949	37479672	37676913	38000243	
37032443	37228343	37329456	37479677	37693605	38028262	
37032444	37263855	37329457	37479679	37713605	38028271	
37077341	37263856	37364754	37575306	37777339	38028303	
37174339	37263858	37364768	37610411	37882544	38045556	

BUSINESS REPLY FORM - RA2020-2430533

FSCA Identifier: RA2020-2430533
Type of Action: Field Safety Corrective Action - Recall
Products Affected: Trevo XP ProVue Retriever
Product Number(s): See Attachment 1
Affected Lot(s) LOT specific (see Attachment 2)

I acknowledge receipt of the Field Safety Notice for RA2020-2367146 and can confirm that:

We have not located any of these devices in our inventory: (please delete if not applicable)			
We have located the following devices:			
Catalog number	Description	Serial/LOT number	Qty

We have further distributed subject devices to the following organizations. I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the devices noted in this letter.	
Facility Name	
Facility Address	

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE THIS FORM WITHIN **7 CALENDAR DAYS** AND RETURN IT BY
 USING THE EMAIL: **nby_qara@stryker.com**