stryker

URGENT

Field Safety Notice

Color Cuff® Sterile Disposable Tourniquet Cuffs

Attn: Risk Manager, Materials Manager, OR Director | July X, 2025

Recall Number: RA2025- 4010746

This notification is to inform you that Stryker Instruments is voluntarily recalling specific products of the Tourniquet Cuffs.

Catalog Number	Product Description	GTIN	Lot Number
5921-024-235	DIS 24"X4",1BLA,2PRT QUICK	07613154599370	Appendix A
5921-018-135	DISP 18X3,1BLA,1PRT QUICK	07613154599257	Appendix A
5921-018-235	DISP 18X3,1BLA,2PRT QUICK	07613154599295	Appendix A

Product Description

The Stryker Disposable Tourniquet Cuff is indicated for use in surgical procedures that require the temporary occlusion of blood flow in a patient's extremities during surgical procedures to produce greater visualization of the operative field.

Product Issue

There is potential for the Tourniquet Cuffs flange to detach from the bladder where the welding connection is, which may result in the cuff not able to maintain air pressure.

Potential Risks

User harm may occur upon the deflation of a tourniquet during a procedure, increasing the risk of hemorrhaging. Medical/surgical intervention may be needed to correct these injuries.

Actions Needed

1. Review your inventory to locate and quarantine any affected products at your facility. Reach out to your Sales Representative for assistance in locating your serial number(s).
2. Return the enclosed Business Reply Form (BRF), even if the affected product is no longer in inventory, to the email xxx@stryker.com.
3. Upon receipt of your BRF, Stryker will provide a shipping label to return recalled product(s) on-hand.
4. A Credit will be issued upon receipt of the recalled product.
5. Maintain awareness of this communication internally and inform Stryker if any of the subject devices have been distributed to other organizations. If so, provide contact details so Stryker can inform the recipients accordingly.

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: Position: email:

In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 2017/745, 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 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 and your expectations, remain on the market.

Sincerely,
Richard Kensinger | Recall Coordinator | (269) 454-1523 |

Business Reply Form

Color Cuff® Sterile Disposable Tourniquet Cuffs July X, 2025

RA2025- 4010746

Please select from the options below and complete this form. Email the completed form to xxx@stryker.com.
RESPONSE IS REQUIRED.

- ☐ **No remaining affected products on-hand.**
- ☐ **I, the customer, choose to return the following product(s) for credits:**

Catalog Number	Product Description	Affected Lots	Qty on Hand*	
			EA	PACKS
5921-024-235	DIS 24"X4",1BLA,2PRT QUICK			
5921-018-135	DISP 18X3,1BLA,1PRT QUICK			
5921-018-235	DISP 18X3,1BLA,2PRT QUICK			

Form completed by:

Facility Name			
Facility Address			
Printed Name		**Title**	
Email		**Phone**	
Signature		**Date**	

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

If you have further distributed any affected product, please indicate to whom:

Facility Name		**Contact Person**	
Full Address			

☐ **I have read and understand the instructions provided and acknowledge receipt of the subjected FSN.**

☐ **I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter.**

Name (print)_____ Signature _____ Date: _____.

Appendix A

DIS 24"X4",1BLA,2PRT QUICK (5921-024-235)								
2023112401	2023112402	2023112403	2023121501	2023121502	2023121503	2023121504	2023121505	2023121506
2023121507	2024020901	2024020902	2024020903	2024020904	2024020905	202402090	2024020907	202402090
2024032101	2024032102	2024032103	2024032104	2024032105	2024032106	2024032107	2024032108	2024032109
2024032110	2024032111	2024032112	2024032113	2024071804				

DISP 18X3,1BLA,1PRT QUICK (5921-018-135)								
2023121801	2023121802	2023121803	2023121804	2023121805	2023121806	2023121807	2024020913	2024020914
2024021601	2024021602	2024021603	2024021604	2024021605	2024021606	2024040801	2024040802	2024040803
2024040804	2024040805	2024040806	2024050301	2024050302	2024050303	2024050304	2024050305	2024050306
2024050307	2024070507	2024070508	2024070509	2024070510				

DISP 18X3,1BLA,2PRT QUICK (5921-018-235)								
2023120501	2023120502	2023120503	2023121601	2023121602	2023121603	2023121604	2023121605	2023121606
2023121607	2023121901	2023121902	2023121903	2023121904	2023121905	2023121906	2023121907	2024021607
2024021608	2024021609	2024021610	2024021611	2024021612	2024042609	2024042612		