

Color Cuff® Sterile Disposable Tourniquet Cuffs



Dear Customer,

Cc: Chairman Medical Board and relevant Head-of-Department of the affected healthcare facilities

Recall Number: PFA 4010746

Date: 27th JUNE 2025

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 asean.pms@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.

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.

Electronically signed
by: Qi Fang Cheong
Reason: I am signing
as the Author of this
document
Date: Jul 2, 2025
13:48 GMT+8

Sincerely,

Cheong Qi Fang | Senior Quality Assurance Manager, East Asia

Business Reply Form

Color Cuff® Sterile Disposable Tourniquet Cuffs

Recall Number: PFA 4010746

Date: 27th JUNE 2025

Please select from the options below and complete this form. Email the completed form to asean.pms@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 | | | |

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 | | |