

Urgent Medical Device Voluntary Recall
Immediate Action Required



This is a Recall Advisory Packet.
You need to read this entire packet carefully and follow each step.

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Table of Contents

This packet contains the necessary items to successfully complete the RA2017-1619154 Trevo Procedure Pack Recall. They are as follows:

- Attachment 1: Customer Recall Notice
Letter to be sent to each affected account which includes instructions to remove the procedure pack carton sleeve.
- Attachment 2: Customer Acknowledgement Form
Form to be completed by customers to document products which have been consumed and products which have been corrected.

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21 Jun 2017

URGENT MEDICAL DEVICE RECALL- REMOVAL

FSCA identifier: RA2017-1619154

Type of Action: RECALL-REMOVAL

Description: Trevo Procedure Packs and Stroke Fast Packs

Catalog/Serial (S/N) #:

M0033PK42022002 – S/N QPC30200039	M0033PK62523002 – S/N QXC10200044 S/N QXC10200043	93068 – S/N QPC30200114
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Dear customer:

Stryker Neurovascular has initiated a voluntary recall and removal for the devices identified above. Our records indicate that you have been supplied with at least one of the subject devices. We therefore request that you read this notice carefully and complete the actions requested by the manufacturer.

The intent of this letter is to instruct you to remove the carton sleeve from your Trevo Procedure Packs and Stroke Fast Packs

Issue:

Stryker Neurovascular has become aware that some Trevo Procedure Packs and Stroke Fast Packs were manufactured using a carton sleeve where the sleeve label contents did not match the physical contents within pack. An example of one observation was for a Trevo XP 6x25 mm & Excelsior XT-27 pack which had a label that stated that the products within the carton should be a "Trevo XP 4x30 mm & Trevo Pro 18."

Note: The individual devices within each procedure pack unit are labeled correctly.

Potential Risk

Patients previously treated with the impacted devices are not affected by this issue.

For potential patients: The most likely negative effect is prolongation of procedure should the incorrect procedure pack be selected.

Completed Corrective Action

This impacts four individual units (4 specific serial numbers) that have been assembled in Venlo, Stryker's European Distribution Center. The product quality of the individual devices within the Trevo Procedure Packs and Stroke Fast Packs are not impacted. All units were manufactured to specification.

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

1. Immediately check your internal inventory for impacted Catalog/Serial Numbers.

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2. Remove and discard the procedure pack carton sleeve.
3. Circulate this Field Safety Notice internally to all interested/affected parties.
4. Maintain awareness of this notice 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.
 - a) *Please 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. Therefore please complete the form even if you no longer have any of the subject devices in your physical inventory.
8. Return the completed form to your nominated Stryker Representative or to NVFieldActions@stryker.com.

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 08 Dec 2017 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 within 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,

Geraldine Ahern
Quality Manager

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STRYKER® NEUROVASCULAR
URGENT MEDICAL DEVICE RECALL- REMOVAL
ACKNOWLEDGMENT FORM

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Product Traceability					
Ordered Item	Serial Number	Qty	Qty on hand and carton sleeve destroyed	Qty Used	Qty not located

I have received the notification from Stryker stating that they have initiated a product field action for the above referenced product and I acknowledge receipt of the of this **URGENT MEDICAL DEVICE RECALL-REMOVAL**

Form completed by:			
Contact Name		Facility	Customer specific information to be added
Contact address		Signature	
		Phone	
Date		Email	

Please email this signed and dated form to NVFieldActions@stryker.com