

**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 RA2017-1657902 Trevo XP Provue System (kit) Recall. They are as follows:

- Attachment 1:            Customer Recall Notice  
Letter to be sent to each affected account which includes instructions to return product to Stryker.
- Attachment 2:            Customer Acknowledgement Form  
Form to be completed by customers to document products which have been consumed and products which have been corrected.

# Urgent Medical Device Voluntary Recall

## Immediate Action Required

28 Nov 2017

### URGENT MEDICAL DEVICE RECALL- REMOVAL

**FSCA identifier:** RA2017-1657902

**Type of Action:** RECALL-REMOVAL

**Description:** Trevo XP Provue System (kit) Recall

**Catalog #:** 80052 - TREVO XP PROVUE RETRIEVER 4X20 + TREVO PRO 18 MC KIT

**Lot #:** 63034

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.

Issue:

Stryker Neurovascular has become aware that at least 1 (one), Trevo XP Provue System was manufactured where the carton sleeve did not match the physical contents of the pack. Through our customer complaint process we were informed that 1 (one) Trevo XP Provue System from lot 63034 contained 2 x TREVO PRO 18 Micro Catheters. As a result it is likely that there is 1 (one) Trevo XP Provue System from lot 63034 containing 2 x TREVO XP PROVUE RETRIEVER 4X20 at a customer location.

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 Fast pack be selected.

Completed Corrective Action

Process improvements are being put in place to through the CAPA program to prevent recurrence of this issue. The product quality of the individual products in the System is 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 numbers.
2. Segregate the affected units in a secure location for replacement by Stryker personnel.
3. Circulate this Field Safety Notice internally to all interested/affected parties.

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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](mailto: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 22 December 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

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STRYKER® NEUROVASCULAR

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#### ACKNOWLEDGMENT FORM

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Product Traceability				
Ordered Item	Qty	Qty on hand	Qty Used	Qty not located
80052				

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**

<b>Form completed by:</b>			
<b>Contact Name</b>		<b>Facility</b>	
<b>Contact address</b>		<b>Signature</b>	
		<b>Phone</b>	
<b>Date</b>		<b>Email</b>	

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