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 92193002-FA - Guider Catheter Recall. They are as follows:

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11 Dec 2017

URGENT MEDICAL DEVICE RECALL- REMOVAL

FSCA identifier: Product Field Action 92193002-FA

Type of Action: RECALL-REMOVAL

Description: Guider Softip™ XF Guide Catheters

Dear customer:

Stryker Neurovascular, as the distributor of the Guider Guide Catheter product, is initiating this Medical Device Recall in coordination with Boston Scientific, the manufacturer of this device. 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 return all impacted product to Stryker.

Issue:
Stryker Neurovascular has become aware that certain lots of Guider 7F and 8F product may be at risk of degrading within their shelf-life period. The root cause of the issue is exposure of components to UV light while in storage between 2014 and October 2017.

Potential Risk
Patients previously treated with the impacted devices are not at risk.

For potential patients- The reported issue can cause the embolization of degraded polymer fragments into the neurovasculature which can cause stroke. There have been no reports of catheter degradation or injury.

Completed Corrective Action
This is a lot-specific storage issue that has been corrected.

Regulatory Actions
Affected worldwide regulatory authorities are being notified of this removal as required.

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

1. Immediately check your internal inventory for impacted catalog and lot numbers. When searching your inventory, please note that the Guider product label displays Boston Scientific, not Stryker.

2. Segregate the affected units in a secure location for return to Stryker.

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 31 Jan 2018 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

URGENT MEDICAL DEVICE RECALL- REMOVAL

ACKNOWLEDGMENT FORM

FSCA identifier: Product Field Action 92193002-FA

Type of Action: RECALL-REMOVAL

Description: Guider Softip™ XF Guide Catheters

Product Traceability				
Product Code/Cat No.	**Lot/ Serial No**	**Qty to be returned**	**Qty /Used Implanted**	**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**	
Contact address		**Signature**	
		Phone	
Date		**Email**	

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

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