XX December 2017

URGENT Field Safety Notice: RA1690954

FSCA Identifier: Product Field Action RA1690954

Type of Action: RECALL-REMOVAL

Product description: Guider Softip™ XF Guide Catheters

Item No.: See attached list

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.

Immediate Actions

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

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

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.

2. Circulate this Field Safety Notice internally to all interested/affected parties.

3. Maintain awareness of this notice internally until all required actions have been completed within your facility.

4. Inform Stryker if any of the subject devices have been distributed to other organisations.
    a) Please provide contact details so that Stryker can inform the recipients appropriately.
    b) If you are a Distributor, note that you are responsible for notifying your affected customers.

5. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a)Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

6. 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 even if you no longer have any of the subject devices in your physical inventory.

7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a) On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

We request that you respond to this notice within XX calendar days from the date of receipt. The target date for completion of this action is XX XXX 2017 and your timely response will enable us to ensure that we meet this target.

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:	XXXXXXX
Position:	XXXXXXX
Telephone:	XXXXXXX
Fax:	XXXXXXX
E-mail:	XXXXXXX

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, 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 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 faithfully,

RA1690954 - Acknowledgement Form

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Item No.: See attached list

I acknowledge receipt of the Field Safety Notice for RA1690954 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*				
We have located the following devices:				
Product Description	Product Reference	Lot Number	Qty Implanted	Qty to return
We have further distributed subject devices to the following organisations:				
Facility Name				
Facility Address				

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO XXXXXX
OR EMAIL TO XXXXXX