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 RA2016-124 Guider Guide Catheter 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 to be returned to Stryker.

Attachment 3: Impacted Catalog and Lot numbers
List of catalog numbers, product names and lot numbers which are required to be recalled.

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05 Oct 2016

URGENT MEDICAL DEVICE RECALL- REMOVAL

FSCA identifier: Product Field Action RA2016-124

Type of Action: RECALL-REMOVAL

Description: Guider Guide Catheter

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 of some potentially defective Guider Guide Catheter product. This product is manufactured by Boston Scientific and the defect was caused by a manufacturing non-conformance that could lead to hub leaks in the resulting product.

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

For potential patients: The most likely negative effect from an incomplete seal at the hub is prolongation of the procedure without long term health consequences. The most severe potential effect is insignificant blood loss after introducing the device into the patient. It will be evident during the normal device preparation process that a device is defective by following the standard device inspection steps or flushing the guider catheter with saline.

Completed Corrective Action
This is a lot-specific manufacturing issue that has been corrected. Guider Guide Catheter quality has been maintained.

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.
2. Segregate the affected units in a secure location for return to Stryker via the RMA process.
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 01 December 2016 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,

[redacted]

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STRYKER® NEUROVASCULAR

URGENT MEDICAL DEVICE RECALL- REMOVAL

ACKNOWLEDGMENT FORM

FSCA identified: Product Field Action RA2016-124

Type of Action: RECALL-REMOVAL

Description: Guider Guide Catheter

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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Impacted Catalog and Lot numbers

Material	Material Description	Batch
M003101640	GUIDER STRAIGHT XF 5F 100CM	18903166
M003101630	GUIDER MPXF 5F 100CM	18753510
M003101630	GUIDER MPXF 5F 100CM	18847876
M003101500	GUIDER/ST XF/6FR/100 cm	18829078
M003101500	GUIDER/ST XF/6FR/100 cm	18831032
M003101500	GUIDER/ST XF/6FR/100 cm	18831033
M003101480	GUIDER/MP XF/8FR/100 cm	18713574
M003101480	GUIDER/MP XF/8FR/100 cm	18848795
M003101480	GUIDER/MP XF/8FR/100 cm	18849984
M003101430	GUIDER/40 DEG XF/7FR/100 cm	18786335
M003101430	GUIDER/40 DEG XF/7FR/100 cm	18790229
M003101430	GUIDER/40 DEG XF/7FR/100 cm	18790450
M003101430	GUIDER/40 DEG XF/7FR/100 cm	18851082
M003101420	GUIDER/40 DEG XF/6FR/100 cm	18771332
M003101420	GUIDER/40 DEG XF/6FR/100 cm	18771915
M003101420	GUIDER/40 DEG XF/6FR/100 cm	18903165
M003101420	GUIDER/40 DEG XF/6FR/100 cm	18928715
M003100640	GUIDER STRAIGHT XF 5F 90CM	18846232
M003100630	GUIDER MPXF 5F 90CM	18845284
M003100630	GUIDER MPXF 5F 90CM	18845814
M003100620	GUIDER 40XF 5F 90CM	18932470
M003100620	GUIDER 40XF 5F 90CM	18932472
H965100520	GUIDER/ST XF/8FR/90CM	18725364
H965100520	GUIDER/ST XF/8FR/90CM	18904600
H965100470	GUIDER/MP XF/7FR/90CM	18713978
H965100470	GUIDER/MP XF/7FR/90CM	18714267
H965100470	GUIDER/MP XF/7FR/90CM	18716054
H965100470	GUIDER/MP XF/7FR/90CM	18786405
H965100470	GUIDER/MP XF/7FR/90CM	18786441
H965100460	GUIDER/MP XF/6FR/90CM	18716056
H965100460	GUIDER/MP XF/6FR/90CM	18752458
H965100460	GUIDER/MP XF/6FR/90CM	18752804
H965100440	GUIDER/40XF/8FR/90CM	18775812
H965100440	GUIDER/40XF/8FR/90CM	18775993

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Material	Material Description	Batch
H965100440	GUIDER/40XF/8FR/90CM	18904219
H965100440	GUIDER/40XF/8FR/90CM	19025649
H965100440	GUIDER/40XF/8FR/90CM	19025651
H965100430	GUIDER/40DEG XF/7FR/90CM	18709130
H965100430	GUIDER/40DEG XF/7FR/90CM	18709234
H965100430	GUIDER/40DEG XF/7FR/90CM	18709643
H965100430	GUIDER/40DEG XF/7FR/90CM	18774858
H965100430	GUIDER/40DEG XF/7FR/90CM	18775292
H965100430	GUIDER/40DEG XF/7FR/90CM	18785727
H965100430	GUIDER/40DEG XF/7FR/90CM	18785933
H965100430	GUIDER/40DEG XF/7FR/90CM	18849986
H965100420	GUIDER/40DEG XF/6FR/90CM	18725976
H965100420	GUIDER/40DEG XF/6FR/90CM	18726252
H965100420	GUIDER/40DEG XF/6FR/90CM	18726453
H965100420	GUIDER/40DEG XF/6FR/90CM	18771999
H965100420	GUIDER/40DEG XF/6FR/90CM	19022528