Urgent Medical Device Voluntary Recall
Immediate Action Required

30 May 2017

URGENT MEDICAL DEVICE RECALL- REMOVAL

FSCA identifier: Product Field Action - 1521899

Type of Action: RECALL - REMOVAL

Description: Medela AG Tubing

Product Code/ Name 077.0193 - AXS Universal Aspiration Tubing

Dear customer:

Stryker Neurovascular has initiated a voluntary recall on behalf of Medela AG. 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.

Issue:
Medela AG has made Stryker Neurovascular aware of 2 defective units in another vendor's inventory of tubing. This product uses the same pouch and carton materials as the tubing distributed by Stryker Neurovascular. The integrity of the tubing pouch may be compromised. As a result Stryker Neurovascular is taking a precautionary action to recall and replace this product. This product is manufactured by Medela AG and distributed by Stryker Neurovascular. The pouch defect is likely caused by a combination of design and production factors. No complaints have been received for any product distributed by Stryker Neurovascular.

Potential Risk
Patients previously treated with the impacted devices**:** None

For potential patients: Risk of Infection

Completed Corrective Action
Manufacturing of future lots has been stopped pending implementation of corrective actions.

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 replacement by Stryker personnel.
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 09 June 2017 and your timely response will enable us to ensure that we meet this target.

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 Sincerely,

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STRYKER® NEUROVASCULAR
URGENT MEDICAL DEVICE RECALL- REMOVAL
ACKNOWLEDGMENT FORM

FSCA identified: Product Field Action - 1521899

Type of Action: RECALL - REMOVAL

Description: Medela AG Tubing

Product Code/Name	Lot/ Serial No	Qty to be returned	Qty not located
077.0193 AXS Universal Aspiration Tubing	116359		

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 fax or email this signed and dated form to fax number: 1 (866) 876-4355 or NVFieldActions@stryker.com