URGENT FIELD SAFETY NOTICE: RA2020- 2552304: MEDICAL DEVICE VOLUNTARY RECALL

AXS Universal Aspiration Tubing

AXS Universal Aspiration Tubing 300cm (118.11 in)

Attn: Risk Management/ Recall Coordinator/ Inventory Manager

Date: December 18, 2020

Dear Customer,

Stryker Neurovascular has initiated a voluntary recall on behalf of Medela AG. Our records indicate that you have been supplied with the subject devices. We therefore request that you read this notice carefully and complete the actions requested.

Product affected:

Catalog number	Universal Device Identifier (UDI) Number	Product description	Lot number
077.0193	07612367052719	AXS Universal Aspiration Tubing 300cm (118.11 in)	W-024423

Product description

Medela AXS Universal Aspiration Tubing is a Co-branded (Medela and Stryker) tubing accessory set for the Medela Dominant Flex Pump.

Product issue

Medela AG has made Stryker Neurovascular aware that the label of the lot number W-024423 has the wrong human readable sterility expiration date. The human readable shelf life is: **07-24-2023(24-JUL-2023)**, whereas the barcode printed on the label shows the correct shelf life of **07-24-2021(24-JUL-2021)**. The lot W-024423 should have the correct expiry date of **07-24-2021 (24-JUL-2021).** The sterility of the tubing will be impacted post expiry date. As a result, Stryker Neurovascular is taking a precautionary action to recall this product. This product is manufactured by Medela AG and distributed by Stryker Neurovascular. No complaints have been received for the product that is distributed by Stryker Neurovascular.

Potential risks

Potential Risk: Patients previously treated with the impacted devices**:** None
For potential patients: Sterility of the affected tubing lot cannot be assured post expiry date of 07-24-2021(24-JUL-2021).

Required 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 to locate the product listed on the attached business reply form and remove them from their point of use, pending its return to Stryker.
2. Circulate this Recall- Correction notice internally to all interested/affected parties.
3. Maintain awareness of this communication 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 organizations. If yes, provide contact details so that Stryker can inform the recipients appropriately.
5. Please inform Stryker of any adverse events concerning the use of the subject device.
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 the form even if you no longer have any of the subject devices in your physical inventory.
7. Email the completed form to your local Stryker representative.
8. Product replacement information will be provided to you by your designated Stryker Representative.

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 March 2021 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: *Beatriz Gonçalves*
Position: *RAQA Specialist*
E-mail: *beatriz.goncalves@stryker.com*

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 sincerely thank you for your help and support in completing this action 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 and your expectations, remain on the market.

Sincerely,

Nina Goddard
RAQA Manager UK Benenord

Business Reply Form

FSCA Identifier: RA2020 – 2552304

Account number:
Account name:

Product: AXS Universal Aspiration Tubing

Please check your inventory and fill out the table below

Catalog number	Product	Serial/Lot number(s)	Qty Received	Qty Used	Qty Available*	Qty not located
077.0193	AXS Universal Aspiration Tubing 300cm (118.11 in)	W-024423				

*If all devices have been used and no affected devices are available, please enter 0 (zero).

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

_____ _____
Printed name Title

_____ _____
Contact phone number Signature Date

_____ _____
Email address Phone Number

If you have loaned or sold any of the units listed, please, forward a copy of this notice to the new users and advise Stryker of their new location.

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL, beatriz.goncalves@stryker.com