

Urgent Field Safety Notice

Affected product: AXS Universa! Aspiration Tubing, art. 077.0193
FSCA-identifier: 01-2020
Type of action: Recall

Date: 01-Dec-2020

Attention: Recipients of the affected lot of the Aspiration Tubing

Details on affected devices and description of the problem:

The labels of following lots of AXS Universa! Aspiration Tubing have the wrong human readable sterility expiring date.

- W-024423

The human readable shelf life is: **2023-07-24**, whereas the barcode printed on the label shows the correct shelf life "**2021-07-24**."

Risk to patient:

There is no risk to patient if the product is used prior to 2021-07-24. Beyond this date the shelf life is expired, and the sterility of these lots cannot be assured.

Advise on action to be taken by the user:

Confirm that you received this Field Safety Notice
Removed from our inventory, put in quarantine and send back affected lots to your local distributor or confirm that you destroyed affected lots. You find the lot number directly at the product label.

Acknowledgement			
By signing below, you acknowledge that			
<ul style="list-style-type: none">You have received, read and understood the Field Safety Notice-Voluntary Medical Device Recall related to FSCA 01-2020, AXS Universa! Aspiration Tubing, art. 077.0193Any health care professional within your organization that needs to be aware of this Field Safety Notice has been informed.			
Contact name		Organization	
Address		Phone	
		Email	
Date		Signature	

Please immediately complete, date and sign this page. Then submit it via email to vigilance@medela.ch or by Fax to +41 41 562 51 00 (to attn. Manager PMS and Auditing),

Customer Response Form

Part 2

Field Safety Notice - Voluntary Medical Device Recall

AXS Universal Aspiration Tubing

Sales Article Numbers: REF 077.0193

You have received by your distributor xxx pieces of the affected lots of AXS Universal! Aspiration Tubing

Please complete the following text:

You confirm, you will send back to the distributor or have destroyed_____ pieces of the affected lot

You already used_____ pieces of the affected lot.

Acknowledgement			
By signing below, you acknowledge that			
<ul style="list-style-type: none"> • All affected products have been removed from our inventory and put in quarantine (to be returned to Medela or have been destroyed terminally). • Any other facility or organization that has received from you products of the affected production lots has been informed and that this facility or organization has removed all affected products from its inventory and put in quarantine (to be returned to Medela or have been destroyed terminally). 			
Contact name		Organization	
Address		Phone	
		Email	
Date		Signature	

Please immediately complete, date and sign this page. Then submit it via email to vigilance@medela.ch or by Fax to +41 41 562 51 00 (to attn. Head of PMS & Complaint Handling)