HELPING SURGEONS TREAT THEIR PATIENTS BETTER

[Addressee name, address]

Urgent Field Safety Notice
Notification About a Voluntary Recall

Purpose

This Field Safety Notice (FSN) is to inform you of a voluntary recall issued by Citra Labs and Nuo Therapeutics (formely known as Cytomedix, Inc.). If you use or distribute the products referenced below, this is to notify you that Arthrex GmbH is a distributor of these products and is assisting in the voluntary recall of these products.

List of products affected by the issue identified

Product Name	Part No.	Lot No.	Expiration Date	Manufacturer per product label
Angel Blood Access Kit	976000602	14081-1	2015/03	Cytomedix, Inc.
	ABS-10068	14262-1	2016/01	Cytomedix, Inc.
	ABS-10068	14262-2	2016/05	Cytomedix, Inc.
	ABS-10068	15097-2	2016/11	Cytomedix, Inc.

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Bankverbindung
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Description of the issue

Citra Labs has identified a defect in the glass bottle containers known as a split finish that could compromise the sterility of the anticoagulant used in these devices and could lead to patient infection.

Based on the Citra Labs communication, the risk of patient injury is remote (<0.1%), and the recall is being initiated to mitigate any potential patient concerns. There have been no reported complaints, injuries, Medical Device Reports (MDRs), or deaths associated with this defect.

According to Citra Labs, the split-finish defect is difficult to see. It cannot be seen in the finished product state (filled bottle with stopper and crimp seal). The split finish is a defect at the top lip of the vial surface which is covered and protected by the stopper insertion.

This action requires the immediate location and discontinued use or distribution of the affected Angel Blood Access Kit product and its return to Arthrex GmbH. This recall does **not** require either reviewing previous patients' treatment results or following up with them.

Advise on action to be taken by the addressee of this notice

1. Immediately discontinue using the indicated Part Numbers/Lot Numbers and collect all affected items that are in your possession.
   Return all affected items under return number "Alert # 179" to:

   [Address of local distributor]

2. Complete the attached acknowledgement form and return to Arthrex GmbH by e-mail (complaints@arthrex.de) or fax (+49 89 90 90 05 52 01), even if you don't have inventory. Returning the form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

The exchange of affected products is at no charge. In case of questions for replacement, please contact your sales representative or customer service.

Transmission of this Field Safety Notice

Please forward this Field Safety Notice (FSN) to all those who need to be aware of it within your organization or to any organization where the potentially affected devices have been transferred.

The relevant National Competent Authorities have been advised of this voluntary recall.

Contact information

If you have any questions please call Arthrex GmbH at +49 89 90 90 05 52 40 and ask for Florian Diemer or Alexander Salomon. You can also send questions by email to complaints@arthrex.de.

Sincerely,

[redacted]

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