

[Addressee name, address]

Date XX-XXX-XXXX

Urgent Voluntary Field Safety Notice

Reference: R538

Purpose

This Field Safety Notice (FSN) is to inform you about a recall of the Disposable Cerclage Tensioner AR-7820

The FiberTape cerclage single-use tensioner provides a simple and efficient way to deliver reproducible and controlled compression on the cerclage construct during fracture management and sternal closure procedures.

Products affected by the issue

Product Name	Part No.	Lot No.	UDI
DISPOSABLE CERCLAGE TENSIONER	AR-7820	3039129043	00888867373976



Description of the issue

The device may lock up due to friction between components, preventing the tensioning of sutures.

If the tensioner locks up the user will notice the issue and the suture can be unwrapped and the tensioner removed without affecting the patient. In this case the device can be easily replaced with another single-use

Arthrex GmbH

Erwin-Hielscher-Str. 9
81249 Munich
Germany

Contact

tel + 49 89 90 90 05 0
fax + 49 89 90 90 05 2801
info@arthrex.de
www.arthrex.de

Management

Reinhold Schmieding
Commercial Register Munich
HRB 76983

Registered Office

Erwin-Hielscher-Str. 9
81249 Munich
VAT-ID: DE129288919

Banking Details

Bank of America
IBAN DE45 5001 0900 0020 9490 11
SWIFT/BIC BOFADEFX

device AR-7820, or a reusable device AR-7800 found in the AR-7800S tensioner set which could result in a procedural delay less than 15 minutes.

To date, Arthrex is not aware of any adverse events associated with this issue.

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

1. Immediately identify indicated product/batch numbers you have in your control.
2. Immediately identify and quarantine all the indicated product/batch numbers you have in your control.
3. Please complete the "Arthrex customer's response form" below and fax it back to +49 (89) 90 90 05 52 01 or email to vigilance@arthrex.de.
4. In case you have already experienced any issues with the related devices, please make sure to submit a complaint via email to complaints@arthrex.de.

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 Field Safety Notice.

Contact information

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

Sincerely,

i.V. Sarah Merkle

Manager Vigilance & Product Surveillance

Arthrex GmbH
Oskar-von-Miller-Str. 6
85235 Odelzhausen
Phone: +49 89 90 90 05 52 40
Fax: +49 89 90 90 05 52 01
Email: complaints@arthrex.de

Arthrex customer's response form

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Return To		From	
To	Arthrex GmbH Product Surveillance Oskar-von-Miller-Str. 6 85235 Odelzhausen Germany	Facility Name	
Email	vigilance@arthrex.de	Address City	
Fax	+49 89 90 90 05 52 01	Name	
		Title	

Please complete the form as follows and return it by fax or email to the addressee above:

- The products in question of the field safety notice are not on our stock anymore
- We are returning the following products (please specify quantity) **to our local responsible Arthrex Distributor:**

Part Number	Batch Number	Quantity
AR-7820	3039129043	

Date

Name

Signature

Arthrex GmbH

Erwin-Hielscher-Str. 9
81249 Munich
Germany

Contact

tel + 49 89 90 90 05 0
fax + 49 89 90 90 05 2801
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Management

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