

[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
<b>DISPOSABLE CERCLAGE TENSIONER</b>	<b>AR-7820</b>	<b>3039129043</b>	<b>00888867373976</b>



## 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

**Kontakt**  
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 BOFADE33

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 discontinue use, sale, and distribution of the affected product.
2. Immediately identify and quarantine all the indicated product/batch numbers you have in your control.
3. **For German Customers:** Please contact Arthrex Customer Returns Department at +49 (89) 90 90 05 89 00 or via e-mail under [CustomerReturns@arthrex.de](mailto:CustomerReturns@arthrex.de) for a Return Merchandise Authorization No. (RMA) and product return instructions.  
Our Customer Returns Specialists can provide assistance regarding alternative solutions and are available to answer questions regarding credit for affected devices in your possession.  
  
**For Customers outside Germany:** Please contact your local responsible Arthrex Representative.
4. Please complete the "Arthrex customer's response form" and fax it back to +49 (89) 90 90 05 52 01 or email to [vigilance@arthrex.de](mailto:vigilance@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 [REDACTED] and ask for [REDACTED]. You can also send questions by email to [complaints@arthrex.de](mailto:complaints@arthrex.de).

Sincerely,

i.V. [REDACTED]

Manager Vigilance & Product Surveillance

Arthrex GmbH  
Oskar-von-Miller-Str. 6  
85235 Odelzhausen  
Phone: [REDACTED]  
Fax: [REDACTED]  
Email: [complaints@arthrex.de](mailto:complaints@arthrex.de)

Arthrex GmbH  
Erwin-Hielscher-Str. 9  
81249 Mun ch  
Germany

Contact  
tel + 49 89 90 90 05 0  
fax + 49 89 90 90 05 2801  
[info@arthrex.de](mailto:info@arthrex.de)  
[www.arthrex.de](http://www.arthrex.de)

Management  
Reinhold Schmieding  
Commercial Register Munich  
HRB 76983

Registered Office  
Erwin-Hielscher-Str. 9  
81249 Mun ch  
VAT-ID: DE129288919

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

# Arthrex customer's response form

## Field Safety Notice

Reference: R538

Return To		From	
<b>To</b>	<b>Arthrex GmbH</b> Product Surveillance Oskar-von-Miller-Str. 6 85235 Odelzhausen Germany	<b>Facility Name</b>	
<b>Email</b>	<a href="mailto:vigilance@arthrex.de">vigilance@arthrex.de</a>	<b>Address City</b>	
<b>Fax</b>		<b>Name</b>	
		<b>Title</b>	

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  
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

**Arthrex GmbH**

Erwin-Hielscher-Str. 9  
81249 Munich  
Germany

**Kontakt**

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