Urgent Voluntary Field Safety Notice

Reference: R518

Purpose

This Field Safety Notice (FSN) is to inform you about a voluntary recall of the Arthrex Suture Anchor, Nano Corkscrew® FT, Ti, w 3-0 FW.

The Arthrex Nano Corkscrew suture anchors are intended to be used for soft tissue fixation to bone in the hand and wrist. Indications are: Digital Tendon Transfers, Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Carpal Ligament Reconstruction, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Transfers and Carpometacarpal Joint Arthroplasty (Basal Thumb Joint Arthroplasty).

Products affected by the issue

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Part No.</th>
<th>Lot / Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suture Anchor, Nano Corkscrew® FT, Ti, w 3-0 FW</td>
<td>AR-1317FT</td>
<td>• 10175216</td>
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Description of the issue

Device (AR-1317FT) may include an oversized driver, which could result in anchor breakage during insertion. Potential patient harms identified include: Part Left in Patient (At Surgeon’s Discretion), Part Remaining in Patient (Fragments Unretrieved), and Revision Surgery. Previous use of suspect devices may have introduced anchor fragments that may or may not have been retrieved by the surgeon.

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. Please contact Arthrex Customer Returns Department at +49 (89) 90 90 05 89 00 or via e-mail under 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.

4. Please complete the “Arthrex customer’s response form” and fax it back to +49 (89) 90 90 05 52 01 or email to complaints@arthex.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 recall.
Contact information

Product-specific questions: Jörg Mietzner
Senior Product Manager Distal Extremities
Phone: +49 (89) 909005 - 4119
E-mail: Joerg.Mietzner@arthrex.de

Customer Returns Service: Robert Mann
Manager Customer Returns Service Specialists
Phone: +49 (89) 90 90 05 89 00
E-mail: CustomerReturns@arthrex.de

Product Surveillance: Alexander Salomon
Supervisor Product Surveillance
Phone: +49 (89) 90 90 05 52 40
E-mail: complaints@arthrex.de

We appreciate your cooperation and apologize for any inconvenience.

Sincerely,
Arthrex GmbH
# Arthrex customer’s response form

## Field safety notice / voluntary recall

Reference: R518

### Return To

| To | Arthrex GmbH  
Product Surveillance  
Oskar-von-Miller-Str. 6  
85235 Odelzhausen  
Germany |
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:complaints@arthrex.de">complaints@arthrex.de</a></td>
</tr>
<tr>
<td>Fax</td>
<td>+49 89 90 90 05 52 01</td>
</tr>
</tbody>
</table>

### From

<table>
<thead>
<tr>
<th>Facility Name</th>
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<tbody>
<tr>
<td>Address</td>
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<td>City</td>
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<td>Name</td>
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<td>Title</td>
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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 the addressee above:

<table>
<thead>
<tr>
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<th>Batch Number</th>
<th>Quantity</th>
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Date         Name                                                      Signature  
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Arthrex GmbH  
Oskar-von-Miller-Str. 6  
85235 Odelzhausen  
Germany

Management  
Reinhold Schmieding  
Commercial Register Munich  
HRB 76983

Registered Office  
Enwin-Hielscher-Str. 9  
81249 Munich  
VAT-ID: DE129288919