[Addressee name, address]

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

Product Name	Part No.	Lot / Batch No.
Suture Anchor, Nano Corkscrew® FT, Ti, w 3-0 FW	**AR-1317FT**	• **10175216** • **10175219** • **10199557** • **10199558**

Arthrex GmbH
Erwin-Hielscher-Str. 9
81249 Munich
Germany

Contakt
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
HSBC Trinkaus & Burkhardt KGaA
BLZ 300 308 80 | Acc. 700 090 019
IBAN DE24300308800700090019
SWIFT/BIC TUBDDEDD

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.

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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

[redacted]

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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
Email	complaints@arthrex.de
Fax	+49 89 90 90 05 52 01

From	
Facility Name	
Address **City**	
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 the addressee above:

Part Number	Batch Number	Quantity
AR-1317FT	10175216	
	10175219	
	10199557	
	10199558	

Date Name Signature

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