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

Clinic / Company
Position / Department
Title First name Last name
Street
Zip Code City

your contact
Jane Doe

E-Mail
Jane.Doe@arthrex.com

date
DD.MM.YYYY

Field Safety Notice

Reference: A322

Purpose

This Field Safety Notice (FSN) is issued to inform you about a recall concerning the AR-8933L-16 Low Profile Locking Screw™, Ti, 3.0 mm x 16 mm.

The Arthrex low profile screws (2.0-3.0 mm solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist.

Products affected by the issue

Product Number	Product Name
AR-8933L-16	LO-PRO LOCK SCRW, TI,3.0MMX 16MM
Batch	
101248	

Description of the issue

It was identified that the packaging contained an AR-8933L-18 (18 mm) screw instead of the intended AR-8933L-16 (16 mm) screw.

To date, Arthrex has not received any complaints related to the affected device. The device is supplied non-sterile and is typically measured prior to placement on the surgical tray. If the mismatch is not detected during this step, the device may be used in surgery.

In such a case, an 18 mm screw could be implanted instead of the intended 16 mm screw. Due to the 2 mm deviation in length, there is a potential risk of the screw being inserted beyond the intended depth which may result in damage to surrounding anatomical structures. The worst credible harm associated with this issue is joint damage.

Advice 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 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.

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 Surveillance GmbH:
Sarah Merkle
Manager Vigilance & Product Surveillance
Phone +49 89 90 90 05 52 40
E-Mail: vigilance@arthrex.de

Product-specific questions:
Roman Sieger-Krumpholz
Product Manager Distal Extremities EMEA
Phone +49 (89) 909005 - 4141
E-Mail: Roman.SiegerKrumpholz@arthrex.de

Sincerely,

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: vigilance@arthrex.de

Arthrex customer's response form

Field Safety Notice

Reference: A322

Return To	
To	**Arthrex GmbH** Product Surveillance Oskar-von-Miller-Str. 6 85235 Odelzhausen Germany
E-Mail	vigilance@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

☐ We are returning the following products (please specify quantity) **to our local responsible Arthrex Distributor:**

Part Number	Batch Number	Quantity
AR-8933L-16	101248	

Date Signature

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Managing Director Torgeir Erlandsen | Registration court: Munich | HRB 76983 | **Corporate Office** Erwin-Hielscher-Str. 9 | 81249 Munich | VAT ID DE129288919
Bank Details Bank of America | IBAN DE45 5001 0900 0020 9490 11 | SWIFT/BIC BOFADEFX