[Addressee name, address]

Date

Urgent Voluntary Field Safety Notice

Reference: R535

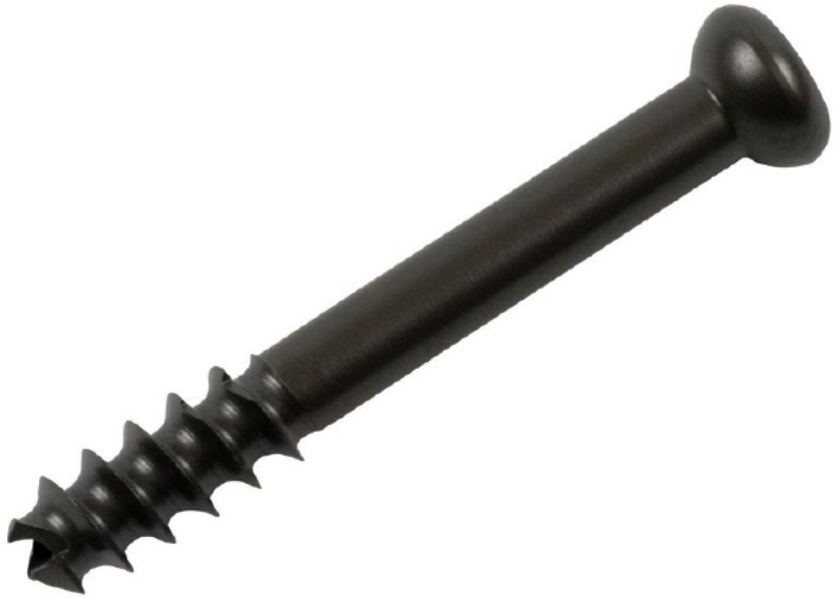
Purpose

This Field Safety Notice (FSN) is to inform you about a recall of the Low Profile Screw™, Ti, 4.5 mm x 32.0 mm, Cannulated, Partially Threaded, sterile, IM AR-8945-32PTS.

The Arthrex low profile screw (3.5 mm and larger, cannulated) are intended to be used as stand-alone bone screw for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur, fibula, and patella fractures.

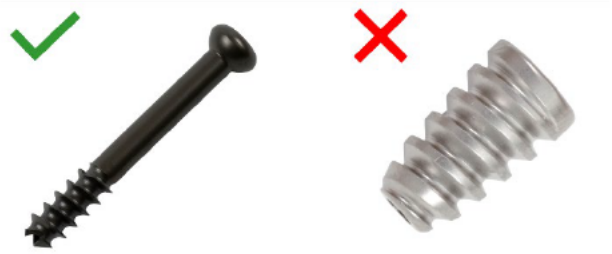
Products affected by the issue

Product Name	Part No.	Lot No.	UDI
LOW PROFILE SCREW™, TI, 4.5 MM X 32.0 MM, CANNULATED, PARTIALLY THREADED, STERILE, IM	AR-8945-32PTS	13540729	(01)00888867053533(17)260531(10)13540729



Description of the issue

It was found that the AR-8945-32PTS Low Profile Screw packaging may contain the wrong implant.



Correct screw Incorrect screw

The user will notice the difference in the device; however, as these are sterile devices it may only be noticed during surgery which could result in a procedural delay less then 15 minutes.

To date, Arthrex is not aware of adverse events associated with this issue. The complaint data shows that no adverse events have been occurred.

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 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.

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:	Immanuel Görens Product Manager Distal Extremities Phone: +49 (89) 909005 - 1411 E-mail: immanuel.goerens@arthrex.de
Customer Returns Service:	Daniel Exner Supervisor Customer Returns Service Center Phone: +49 (89) 90 90 05 89 00 E-mail: CustomerReturns@arthrex.de
Product Surveillance:	Sarah Merkle Manager Vigilance & Product Surveillance Phone: +49 (89) 90 90 05 52 40 E-mail: vigilance@arthrex.de

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 vigilance@arthrex.de.

Sincerely,

[redacted]

Director of Quality Assurance – EMEA

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