[Addressee name, address]

Date

Urgent Voluntary Field Safety Notice

Reference: R529

Purpose

This Field Safety Notice (FSN) is to inform you about a recall of the Arthrex K-Wire 1.35 x 170 mm.

The AR-8610K-43 Arthrex K-Wire 1.35 x 170 mm is intended to be used during bone preparation for the insertion of headless compression screws.

Products affected by the issue

Product Name	Part No.	Lot No.	UDI
K-Wire 1.35 x 170 mm	AR-8610K-43	1298116640	00888867197084

Arthrex GmbH
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Germany

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

Description of the issue

It was found that the AR-8610K-43 K-Wire length and diameter of the batch in scope do not meet specifications. As the K-Wire will not fit into the cannulated drill bit and cannulated screw with which it is designed to function, there is a potential patient risk of a delay of 15 minutes or more during the procedure. To date, Arthrex is not aware of 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 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 Distributor.

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 Manager Product Group Distal Extremities Phone: +49 (89) 909005 - 4119 E-mail: Joerg.Mietzner@arthrex.de
Customer Returns Service:	Daniel Exner Customer Returns Service Specialist Supervisor Phone: +49 (89) 90 90 05 89 00 E-mail: CustomerReturns@arthrex.de
Product Surveillance:	Sarah Merkle Supervisor Vigilance & Product Surveillance Phone: +49 (89) 90 90 05 52 40 E-mail: complaints@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 complaints@arthrex.de.

Sincerely,

xxx

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