Arthrex GmbH | Erwin-Hielscher-Str. 9 | 81249 Munich | Germany
Clinic / Company
Street
Zip Code City

your contact E-Mail

date

Field Safety Notice

Reference: A335

Purpose

This Field Safety Notice (FSN) is issued to inform you about a recall concerning specific batches of the NanoNeedle Scope, 125 mm (AR-3210-0043), and NanoNeedle Scope 2.0, 125 mm (AR-3210-0070).

The NanoNeedle Scope is an active, invasive single-use endoscope for short term use to illuminate and visualize surgical sites during diagnostic and surgical procedures. The NanoNeedle Scope is designed to be operated together with compatible Arthrex imaging console and accessories as a complete Imaging System.

Products affected by the issue

Product Number	Product Name / Batch Number
AR-3210-0043	NanoNeedle Scope, 125 mm Batch: YS26070005
AR-3210-0043	NanoNeedle Scope, 125 mm Batch: YS26070006
AR-3210-0043	NanoNeedle Scope, 125 mm Batch: YS26080002
AR-3210-0043	NanoNeedle Scope, 125 mm Batch: YS26080005
AR-3210-0070	NanoNeedle Scope 2.0, 125 mm Batch: F126080004

Description of the issue

It was identified that affected devices may be missing the required programming. Consequently, the device may not be recognized by the imaging console and will not function when connected at the beginning of the procedure. In this situation, an error message will be displayed and the affected device cannot be used as intended.

A review of 163 known occurrences in which a NanoNeedle Scope failed to function, irrespective of batch or cause, found that a replacement device was available in all cases. Another NanoNeedle Scope or a conventional reusable scope is expected to be available as a backup, generally resulting in a procedural delay of less than 15 minutes.

A procedural delay of more than 15 minutes is nevertheless considered a credible outcome. In the unlikely event that a suitable backup device is not available, the surgeon may need to use an alternative surgical technique, including conversion to an open procedure. This could result in a moderate deviation from the planned procedure.

To prevent use of affected devices and the potential procedural consequences described above, Arthrex is recalling the catalog and batch numbers listed in this notice.



Advice on action to be taken by the addressee of this notice

1. Immediately discontinue use, sale, and distribution of the affected products.

2. Immediately identify and quarantine all affected catalog and batch numbers in your control.

3. Please return all affected devices to your local responsible Arthrex representative or Arthrex distributor in accordance with the provided return instructions.

4. Please complete the “Arthrex customer’s response form” and return it by fax to +49 (89) 90 90 05 52 01 or by 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 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: Joscha Erbis
Product Manager Imaging & Resection
Phone +49 (89) 909005 - 4117
E-Mail: Joscha.Erbis@arthrex.de

Sincerely,

Arthrex customer's response form

Field Safety Notice

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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-3210-0043		
AR-3210-0070		

Date

Signature