[Addressee name, address]

Date

Urgent Voluntary Field Safety Notice

Reference: R537

Purpose

This Field Safety Notice (FSN) is to inform you about a labeling issue of the outer packaging of the Arthrex Knee Scorpion™, AR-12990.

The Suture Passing Instruments product family consists of suture passers designed to grasp, deliver suture stitching, and perform suture retrieval in a single efficient step during an arthroscopic procedure.

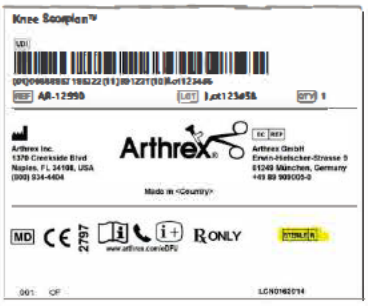
Products affected by the issue

Product Name	Part No.	Lot No.	UDI
KNEE SCORPION™	AR-12990	15089076 15089069 15095444 15095447 15095450 15095547 15096955 15096951 15096956 15103245 15104165 15104167 15112381 15112380	00888867196322

Description of the issue

Associated outer labels and label content document for indicated batches display a sterility statement indicating “sterile” via irradiation but should indicate “nonsterile”.

DEFECTIVE



CORRECT (REFERENCE ONLY)

According to the Direction for use:
Devices provided non-sterile must be cleaned and sterilized prior to use or re-use; this is required as well for the first use after delivery of the unsterile instruments. Devices provided sterile must be cleaned and sterilized prior to each subsequent re-use (not for first use). Effective cleaning is an indispensable requirement for an effective sterilization of the instruments.

The change is recent for a product that has a long market history, so users may not recognize the change in label. Users should be familiar with the way the devices are packaged and are typically familiar with the devices before use and their status of being sterile or non-sterile.

The packaging is also not a peel pack and appears in a cardboard box and could be recognized as being unlikely to be sterile based on the packaging materials.

Knee Scorpions which are contained in loan sets are transferred to trays with other instruments and sterilized together before use.

All of this leads to the assessment for an improbable occurrence value.

Nevertheless, we would like to inform our customers that the label is incorrect and ensure that the device is reprocessed as described in the DFU.
To date, Arthrex is not aware of any adverse events associated with this issue.

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

1. Immediately identify indicated product/batch numbers you have in your control.
2. Please make sure that the affected items are sterilized before used on patient as described in the DFU and discard the incorrect outer boxing.
3. Please complete the "Arthrex customer's response form" below and fax it back to +49 (89) 90 90 05 52 01 or email to vigilance@arthrex.de.
4. In case you have already experienced any issues with the related devices, please make sure to submit a complaint via email to complaints@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 Field Safety Notice.

Contact information

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,

Arthrex customer's response form

Field Safety Notice

Reference: R537

Return To	
To	**Arthrex GmbH** Product Surveillance Oskar-von-Miller-Str. 6 85235 Odelzhausen Germany
Email	vigilance@arthrex.de
Fax	+49 89 90 90 05 52 01

From	
Facility Name	
Address **City**	
Name	
Title	

Please complete the form and return it by fax or email to the addressee above.

Hereby I confirm that we have been made aware of this Field Safety Notice that all affected devices must be sterilized prior to use and the outer boxing with the incorrect label must be discarded.

Date Name Signature