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

email
Jane.Doe@arthrex.com

date
DD.MM.YYYY

tel
+49 89 90 90 05 0

Urgent Voluntary Field Safety Notice

Reference: R544

Purpose

This Field Safety Notice (FSN) is to inform you about a recall of the AR-1510F-02 Femoral ACL Marking Hook, AM Portal, 7 mm Offset.

The Femoral ACL Marking Hook, AM Portal, 7 mm Offset is used to aid in the placement, insertion, capture, or control of other devices during a surgical procedure. AR-1510F-02 is used in conjunction with ACL and PCL repair devices.

Products affected by the issue

Product Name	Part No.	Lot No.	UDI
Femoral ACL Marking Hook, AM Portal, 7 mm Offset	**AR-1510F-02**	**1068582412**	**(01)00888867445762(11)240605(10)1068582412**

Description of the issue

Potential for the device not mating with the AR-1510H and AR-1510HR handles. Due this failure the device could not function, and the user would need to replace the device.

By now two complaints regarding the reported device were reported to Arthrex. No harm was reported in either of these complaints as both were identified prior to use. It is credible to consider the user will test the device before surgery, but it cannot not be guaranteed. If the reported issue is not identified prior to the surgery, the user will realize during the procedure that the device does not mate with the handle and will have the ability to replace it with other available hooks in the sets. Therefore, the worst credible harm is thus a procedural delay < 15 minutes.

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. 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: Tobias Räth
Product Manager Knee & Hip EMEA
Phone: +49 89 90 90 05 22 09
E-Mail: tobias.raeth@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