[Addressee name, address]

Date

Urgent Voluntary Field Safety Notice

Reference: R542

Purpose

This Field Safety Notice (FSN) is to inform you about a recall of

- AR-3600-2 FiberTak™ Suture Anchor with #2 FiberWire® CL (Double Loaded),
- AR-3602-2 FiberTak™ Suture Anchor, Double Loaded with 1.3 mm SutureTape™ (White and White/Blue),
- AR-3602-2-1 FiberTak™ Suture Anchor, Double Loaded with 1.3 mm SutureTape™ (White and White/Blue), and
- AR-3600-2-1 FiberTak™ Suture Anchor #2 FiberWire® CL (Double Loaded), VE1.

The Bio-FASTak, FASTak, SutureTak and FiberTak suture anchors are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip.

Products affected by the issue

Product Name	Part Number	Lot Number	UDI
FiberTak™ Suture Anchor with #2 FiberWire® CL (Double Loaded)	**AR-3600-2**	**15239087** **15239094** **15243399** **15243869** **15248425** **15249276** **15259453**	**10888867206967**

Product Name	Part Number	Lot Number	UDI
FiberTak™ Suture Anchor, Double Loaded with 1.3 mm SutureTape™ (White and White/Blue)	AR-3602-2-1	15243186	00888867287112

Product Name	Part Number	Lot Number	UDI
FiberTak™ Suture Anchor #2 FiberWire® CL (Double Loaded), VE1	AR-3600-2-1	15251276	00888867287129

Product Name	Part Number	Lot Number	UDI
FiberTak™ Suture Anchor, Double Loaded with 1.3 mm SutureTape™ (White and White/Blue)	AR-3602-2	15243185 15243187 15258308 15258315	10888867206950

Description of the issue

The stability sleeve does not fit the intended drill guide due to a design issue. All double-loaded devices with the stability sleeve are impacted and will not fit with any spears.
As the device will not fit into the guide/spear, the most likely scenario is the user having to replace the device, either with an identical, older design device or similar anchor/suture device. A worst-case scenario is the user trying to push the device through with a mallet and potentially creating a larger hole than intended. The user will be able to prepare another hole without complications and without deviating from the technique by using a swapping for another similar device. As such, the worst credible harm is 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: Sebastian Landsgesell
Senior Product Manager Shoulder & Elbow EMEA
Phone: +49 (89) 909005 - 4123
E-Mail: Sebastian.Landsgesell@arthrex.de

Sincerely,

Sarah Merkle
Manager Vigilance & Product Surveillance

Arthrex GmbH
Oskar-von-Miller-Str. 6
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Phone: +49 89 90 90 05 52 40
Fax: +49 89 90 90 05 52 01
Email: vigilance@arthrex.de

Arthrex customer's response form

Field Safety Notice

Reference: R540

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 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-3600-2	15239087 15239094 15243399 15243869 15248425 15249276 15259453	
AR-3602-2	15243185 15243187 15258308 15258315	
AR-3602-2-1	15243186	
AR-3600-2-1	15251276	

Date Name Signature