



HELPING SURGEONS TREAT THEIR PATIENTS BETTER

[Addressee name, address]

Urgent Voluntary Recall

Reference: Alert 190

Purpose

This Field Safety Notice (FSN) is to inform you about a voluntary recall of Arthrex SwiveLock® SP Suture Anchor (Applies to Self-Punching SwiveLocks® Only- Limited to Specific Part and Batch Numbers).

Products affected by the issue

Part Number	Description	Batch Number
AR-2323BSLM	Bio-SwiveLock SP Vented, 5.5 mm x 25.5 mm, Self-Punching	10078259
AR-2323PSLM	PEEK SwiveLock SP Vented, 5.5 mm x 25.5 mm, Self-Punching	10078258
AR-2324BCM	BioComposite SwiveLock SP Vented, 4.75 mm x 25.5 mm, Self-Punching	10072425 10077133 10078077 10078340 10075792 10073992
AR-2324PSLM	PEEK SwiveLock SP Vented, 4.75 mm x 24.5 mm, Self-Punching	10072597
AR-2600SBS-5	SpeedBridge Implant System with BioComposite SwiveLock AP, 5.5 mm x 24 mm	10074288 10074291 10076753 10076852 10081420 10075965 10077252 10084027

Arthrex GmbH

Erwin-Hielscher-Str. 9
81249 München
Germany

Contact

tel + 49 89 90 90 05 0
fax + 49 89 90 90 05 2801
info@arthrex.de
www.arthrex.de

President

Reinhold Schmieding
Handelsregister München
HRB 76983

Corporate office

Erwin-Hielscher-Str. 9
81249 München
Tax ID no.: DE129288919

Bankdetails

HSBC Trinkaus & Burkhardt KGaA
BLZ 300 308 80 | Konto 700 090 019
IBAN DE24300308800700090019
SWIFT/BIC TUBDDE33

AR-2600SBS-7	AR-2600SBS-7 SpeedBridge Implant System with PEEK SwiveLock Self-Punching	10070003
--------------	--	----------

Description of the issue

We have recently determined that there is an issue with the self-punching eyelet contained within the Arthrex SwiveLock® Suture Anchor. This may cause the eyelet to break on insertion in hard cortical bone.

Based on our post market surveillance data, there is a remote probability of occurrence for the failure mode (<0,1%). In the event of failure, the severity of potential harm is considered to be low.

There is no impact to the patient if the device has been implanted successfully.

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

Immediately discontinue use of these devices.

Immediately identify and return all the indicated product / batch numbers you have in inventory. Contact Arthrex Customer Returns Department via e-mail under CustomerReturns@arthrex.de for a Return Merchandise Authorization no. (RMA) and product return instructions.

Please complete the "Recall Acknowledgement of Receipt" facsimile and fax it back to +49 89 90 90 05 7 5201 or email to complaints@arthrex.de.

There is no impact to the standard PEEK eyelet SwiveLock® anchors and these are excellent replacements. Please contact the Arthrex International Customer Service team for assistance.

There is no impact to the patient if the device has been implanted successfully.

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

If you have any questions please call Arthrex GmbH at +49 89 90 90 05 52 40 and ask for Alexander Salomon. You can also send questions by email to complaints@arthrex.de.

Sincerely,

i.V. Michael Wöhrer

Arthrex GmbH
Erwin-Hielscher-Str. 9
81249 München
Germany

Contact
tel + 49 89 90 90 05 0
fax + 49 89 90 90 05 2801
info@arthrex.de
www.arthrex.de

President
Reinhold Schmieding
Handelsregister München
HRB 76983

Corporate office
Erwin-Hielscher-Str. 9
81249 München
Tax ID no.: DE129288919

Bank details
HSBC Trinkaus & Burkhardt KGaA
BLZ 300 308 80 | Konto 700 090 019
IBAN DE24300308800700090019
SWIFT/BIC TUBDDEDD

Divisional Manager, Quality Assurance

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: complaints@arthrex.de

Arthrex GmbH
Erwin-Hielscher-Str. 9
81249 München
Germany

Contact
tel + 49 89 90 90 05 0
fax + 49 89 90 90 05 2801
info@arthrex.de
www.arthrex.de

President
Reinhold Schmieding
Handelsregister München
HRB 76983

Corporate office
Erwin-Hielscher-Str. 9
81249 München
Tax ID no.: DE129288919

Bank details
HSBC Trinkaus & Burkhardt KGaA
BLZ 300 308 80 | Konto 700 090 019
IBAN DE24300308800700090019
SWIFT/BIC TUBDDEDD

Arthrex customer's response form

Field safety notice / voluntary recall

Reference: Alert 190

Return To		From	
To	Arthrex GmbH Product Surveillance Oskar-von-Miller-Str. 6 85235 Odelzhausen Germany	Facility Name	
Email	complaints@arthrex.de	Address City	
Fax	+49 89 90 90 05 7 52 01	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 anymore
- We are returning the following products (please specify quantity) to the addressee above:

Part Number	Batch Number	Quantity
AR-2323BSLM	10078259	
AR-2323PSLM	10078258	
AR-2324BCM	10072425	
	10073992	
	10075792	
	10077133	
	10078077	
	10078340	
AR-2324PSLM	10072597	
AR-2600SBS-5	10074288	
	10074291	
	10075965	
	10076753	
	10076852	
	10077252	
	10081420	
	10084027	
AR-2600SBS-7	10070003	

Date

Name

Signature