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<br>10077133<br>10078077<br>10078340<br>10075792<br>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<br>10074291<br>10076753<br>10076852<br>10081420<br>10075965<br>10077252<br>10084027 |

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

| | | |
|---|---|---|
| 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@arthex.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

Divisional Manager, Quality Assurance

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Fax: +49 89 90 90 05 52 01
Email: complaints@arthrex.de

# Arthrex customer's response form

## Field safety notice / voluntary recall

Reference: Alert 190

| Return To | |
|---|---|
| **To** | **Arthrex GmbH**<br>Product Surveillance<br>Oskar-von-Miller-Str. 6<br>85235 Odelzhausen<br>Germany |
| **Email** | complaints@arthrex.de |
| **Fax** | +49 89 90 90 05 7 52 01 |

| From | |
|---|---|
| **Facility Name** | |
| **Address**<br>**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 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