



[Addressee name, address]

Date

Urgent Voluntary Field Safety Notice

Reference: 527

Purpose

This Field Safety Notice (FSN) is to inform you about a recall of the Arthrex Suture Anchor, BioComposite SwiveLock® C, 5.5 mm x 19.1 mm, Closed Eyelet.

The intended use of the AR-2323BCC Arthrex Suture Anchor, BioComposite SwiveLock® C, 5.5 mm x 19.1 mm, Closed Eyelet, is for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist elbow, shoulder and hip.

Products affected by the issue

Product Name	Part No.	Lot No.	UDI
Arthrex Suture Anchor, BioComposite SwiveLock® C, 5.5 mm x 19.1 mm, Closed Eyelet	AR-2323BCC	12758314 13022357	00888867026728





Description of the issue

It was discovered that there was variation in the AR-2323BCC sealing process for the Tyvek header / foil pouch, resulting in the potential for variability in the sterility levels and EO residuals within the package of the device. Arthrex is executing this recall because we are unable to guarantee the sterility of these devices at this time. To date Arthrex is not aware of any adverse events or complaints associated to the affected batches of product.

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 Arthrex Customer Returns Department at +49 (89) 90 90 05 89 00 or via e-mail under CustomerReturns@arthrex.de for a Return Merchandise Authorization No. (RMA) and product return instructions.
Our Customer Returns Specialists can provide assistance regarding alternative solutions and are available to answer questions regarding credit for affected devices in your possession.
4. Please complete the "Arthrex customer's response form" and fax it back to +49 (89) 90 90 05 52 01 or 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 recall.

Contact information

Product-specific questions: Alexander Campagnoli
Product Manager Shoulder & Elbow
Phone: +49 (89) 909005 - 4013
E-mail: Alexander.Campagnoli@arthrex.de

Customer Returns Service: Robert Mann
Manager Customer Returns Service Specialists
Phone: +49 (89) 90 90 05 89 00
E-mail: CustomerReturns@arthrex.de



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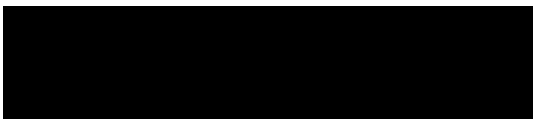
GmbH
Effective

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Product Surveillance:

Sarah Merkle
Supervisor Vigilance & Product Surveillance
Phone: +49 (89) 90 90 05 52 40
E-mail: complaints@arthrex.de

Sincerely,



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

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Management

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Banking Details

Bank of America
IBAN DE45 5001 0900 0020 9490 11
SWIFT/BIC BOFADEFX



Arthrex customer's response form

Field safety notice / voluntary recall

Reference: R527

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 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-2323BCC	12758314	
AR-2323BCC	13022357	

Date

Name

Signature