



[Addressee name, address]

Date

# Urgent Voluntary Field Safety Notice

Reference: R524

## Purpose

This Field Safety Notice (FSN) is to inform you about a recall of the Low Profile Screw AR-8967-2865S.

The AR-8967-2865S is used as a stand-alone bone screw, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions.

## Products affected by the issue

Product Name	Part No.	Lot No.	UDI
<b>Sterile Low Profile Screw, Titanium, 6.7 x 65mm</b>	<b>AR-8967-2865S</b>	<b>10706233</b>	<b>00888867056411</b>

## Description of the issue

The screws provided in the package are 5 mm shorter than intended. The highest potential harm for the patient, associated with the use of this device, would be that a bone fracture or osteotomy requires additional stabilization. However, given the clinical factors that mitigate the risk, the most likely harm to occur if the affected device is used during a surgical procedure is a procedural delay.

## 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.



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2.0

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Effective

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3. Please contact Arthrex Customer Returns Department at +49 (89) 90 90 05 89 00 or via e-mail under [CustomerReturns@arthrex.de](mailto: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.

## 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:	Jörg Mietzner Senior Product Manager Distal Extremities Phone: +49 (89) 909005 - 4119 E-mail: <a href="mailto:Joerg.Mietzner@arthrex.de">Joerg.Mietzner@arthrex.de</a>
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Sincerely,



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