



[Addressee name, address]

Date

# Urgent Voluntary Field Safety Notice

Reference: R526

## Purpose

This Field Safety Notice (FSN) is to inform you about a recall of the products as listed below in section *Products affected by the issue*.

## Products affected by the issue

Product Name	Part Number	Expiry Date until	UDI
Angel System with Aspiration Kit	ABS-10062	April 2023 or before	00888867083998
Angel cPRP Processing Set EU	ABS-10064	April 2024 or before	00888867084018
Arthrex Angel PRP Kit	ABS-10071	April 2023 or before	00888867175693
Arthrex Angel BMC Kit	ABS-10072	April 2023 or before	00888867175495



## Description of the issue

Arthrex recently became aware that the devices may not have been sterilized appropriately by a 3<sup>rd</sup> party organization and is therefore unable to guarantee the sterility of these devices and is removing them from the market. As Arthrex is unable to guarantee the sterility of these devices, there is a potential risk to patients of infection.

## 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](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.
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@arthex.de](mailto:complaints@arthex.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:

Dr. Sabine Schaumann  
Senior Product Manager Orthobiologics  
Phone: +49 (89) 909005 - 4124  
E-mail: [Sabine.Schaumann@arthrex.de](mailto:Sabine.Schaumann@arthrex.de)

Dr. Sebastian Konrad  
Product Manager Orthobiologics  
Phone: +49 (89) 909005 - 4127  
E-mail: [Sebastian.Konrad@arthrex.de](mailto:Sebastian.Konrad@arthrex.de)

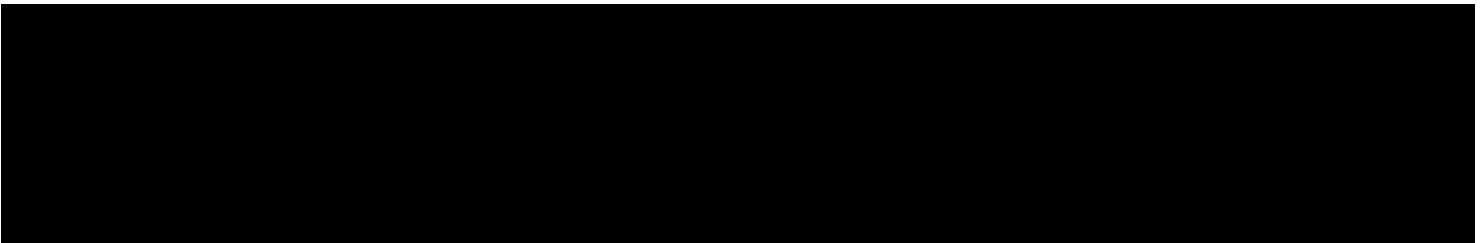
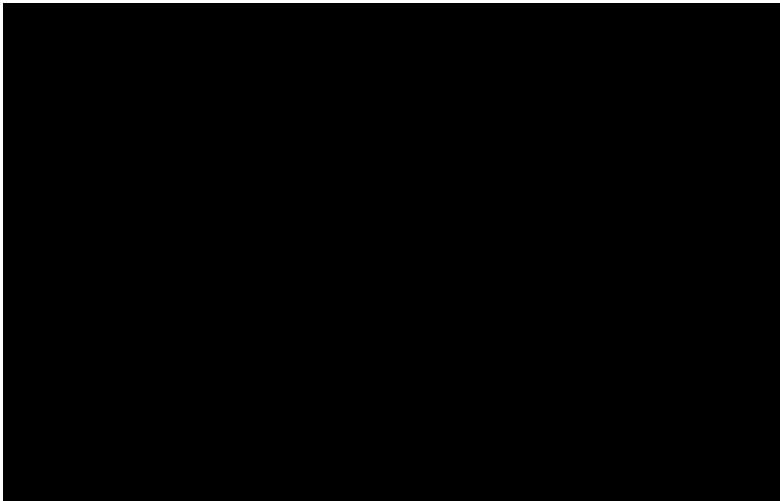
Customer Return Service:

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

Product Surveillance:

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

Sincerely,





## Arthrex customer's response form

### Field safety notice / voluntary recall

Reference: R526

Return To	
<b>To</b>	<b>Arthrex GmbH</b> Product Surveillance Oskar-von-Miller-Str. 6 85235 Odelzhausen Germany
<b>Email</b>	<a href="mailto:complaints@arthrex.de">complaints@arthrex.de</a>
<b>Fax</b>	+49 89 90 90 05 52 01

From	
<b>Facility Name</b>	
<b>Address City</b>	
<b>Name</b>	
<b>Title</b>	

Please complete the form as follows and return it by fax or email to the addressee above:

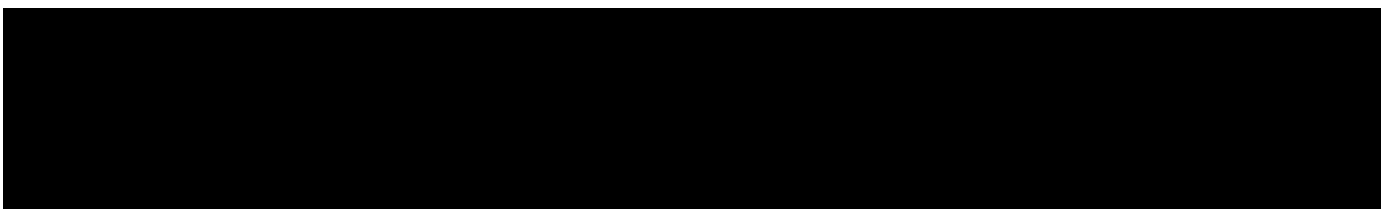
- The products in question of the field safety notice are not on our stock anymore
- We are returning the following products (please specify quantity) to the addressee above:

Part Number	Batch Number	Quantity
ABS-10062		
ABS-10064		
ABS-10071		
ABS-10072		

Date

Name

Signature





Document Number

FORM-000106994

Urgent Voluntary Field Safety Notice

Version

2.0

GmbH

Effective

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