Arthrex GmbH | Erwin-Hielscher-Str. 9 | 81249 Munich | Germany

Clinic / Company
Position / Department
Title First name Last name
Street
Zip Code City

your contact
Jane Doe

email
Jane.Doe@arthrex.com

date
DD.MM.YYYY

tel
+49 89 90 90 05 0

Urgent Voluntary Field Safety Notice

Reference: R545

Purpose

This Field Safety Notice (FSN) is to inform you about a recall of the ABS-8981-12S OATS® 2.0 Single-Use Set, 12 mm.

The Single-Use OATS® (Osteochondral Autograft Transfer System) set facilitates harvesting of 12 mm osteochondral cartilage cylinders from a donor site superior and lateral to the notch or above the sulcus terminalis. A recipient socket, sized to the appropriate depth, is created in the chondral defect to accept the donor graft.

Products affected by the issue

Product Number		Product Name	
ABS-8981-12S		OATS® 2.0 Single-Use Set, 12 mm	
Lot Numbers			
935299772	2014118703	2355127732	3310136226
0116103228	2027119000	3020128459	3339136932
0350108612	2097120954	3023128543	4022138078
1158112963	2164122745	3023128544	4046138815
1182113671	2193123383	3104130735	4057139050
1239115174	2250125005	3130131560	4099140203
1280116282	2307126644	3219134032	4239152180
1305116887	2326127030	3233134390	
1319117264	2355127731	3268135199	

Description of the issue

Interference between collared pin and donor harvester may prevent the device from functioning as intended.

By now six complaints regarding the affected devices were reported to Arthrex. Neither of these complaints have resulted in a serious incident. Due to this issue, there may be interference between the collared pin and harvester ID from the edge of the harvester to 4-5mm below the edge. If the issue is noticed prior to use, the device may be replaced by the user. If the issue is not identified as it is expected in most cases, the device will likely be used. In this case the collared pin and harvester ID will have interference starting 4-5mm below the edge of the harvester due to a decrease in the ID dimension. This is resulting in increases force needed to harvest the bone graft when the device is used. Therefore, the worst credible harm is thus a Deviation from Intended Procedure – Minimal.

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 your local responsible Arthrex Representative.

4. Please complete the “Arthrex customer’s response form” and fax it back to +49 (89) 90 90 05 52 01 or email to vigilance@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 Surveillance GmbH: Sarah Merkle
Manager Vigilance & Product Surveillance
Phone +49 89 90 90 05 52 40
E-Mail: vigilance@arthrex.de

Product-specific questions: Dr. Sabine Schaumann
Senior Product Manager Orthobiologics EMEA
Phone +49 (89) 909005 - 4124
E-Mail: sabine.schaumann@arthrex.de

Sincerely,

Sarah Merkle
Manager Vigilance & Product Surveillance

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: vigilance@arthrex.de

Arthrex customer's response form

Field Safety Notice

Reference: R545

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

From	
Facility Name	
Address **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

☐ We are returning the following products (please specify quantity) **to our local responsible Arthrex Distributor:**

Part Number	Batch Number	Quantity
ABS-8981-12S		