[Addressee name, address]

Date

Urgent Voluntary Field Safety Notice

Reference: R532

Purpose

This Field Safety Notice (FSN) is to inform you about a recall of the OATS Sets AR-8981-06S and AR-8981-08S.

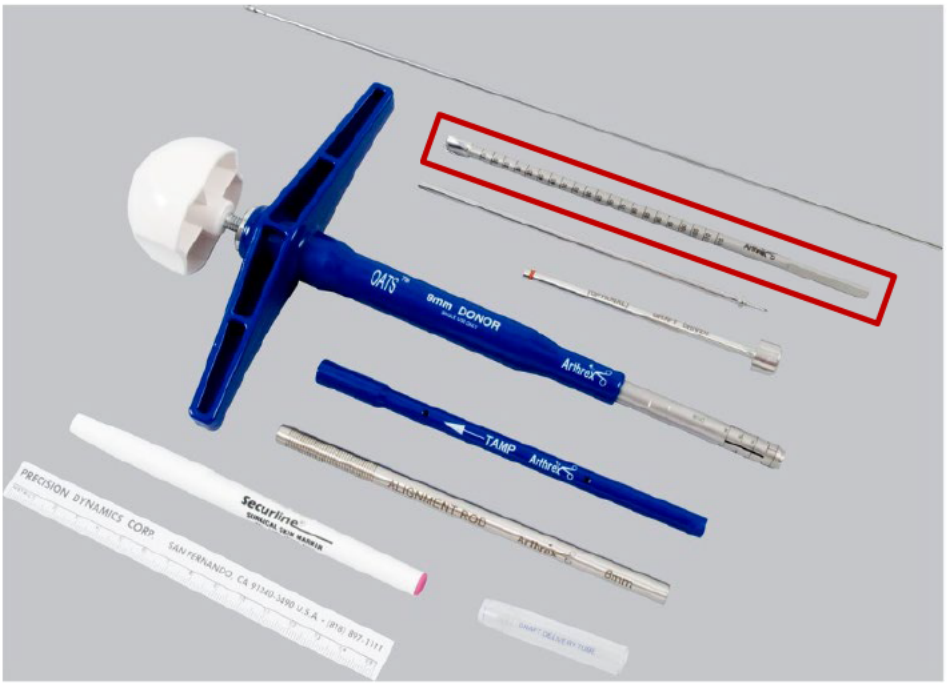
The OATS system is designed for Osteochondral Autograft Transplantation.

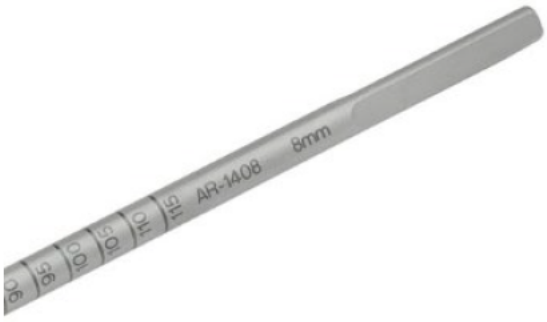
The Coring Reamer System is designed to harvest a cylinder of cancellous bone while simultaneously creating the tibial tunnel. The harvested bone core can then be used to fill the patellar tendon harvest site, construct a bone-hamstring tendon-bone allograft, or used to enhance biological fixation of ACL grafts.

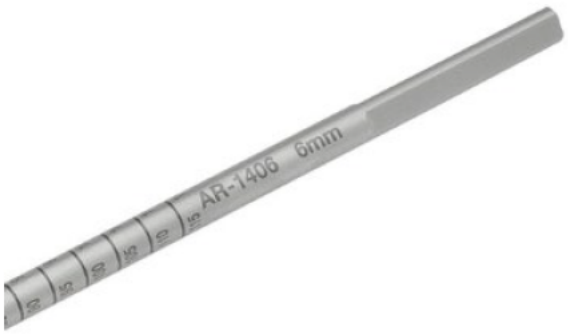
The Bone Graft Harvester is designed to be used for various autograft bone harvesting procedures.

Products affected by the issue

Product Name	Part No.	Lot No.	UDI
SMALL JOINT OATS SET, 8MM	AR-8981-08S	2014118685	(10)00888867056824 (17)270228(10)2014118685
SMALL JOINT OATS SET, 6MM	AR-8981-06S	2003118198	(10)00888867056817 (17)261231(10)2003118198







Description of the issue

It was found that the sets may be packaged with an incorrect reamer which has a different size than expected.
In set AR-8981-08S an AR-1408 should be included but instead, the different-sized reamer AR-1406 was packaged. In set AR-8981-06S an AR-1406 should be included but instead, the different-sized reamer AR-1408 was packaged.

As the user will harvest the graft first and then use the drill this could result in an abortion of the procedure.

To date, Arthrex is not aware of adverse events associated with this issue. Even though the reamer size is indicated by laser marking and complaint data shows that no adverse event has occurred, the user may not necessarily recognize the issue before drilling.

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. **For German Customers:** 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.

   For Customers outside Germany: 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-specific questions:	Dr. Sebastian Konrad Product Manager Orthobiologics Phone: +49 (89) 90 90 05 - 4127 E-mail: sebastian.konrad@arthrex.de
Customer Returns Service:	Daniel Exner Supervisor Customer Returns Service Center Phone: +49 (89) 90 90 05 89 00 E-mail: CustomerReturns@arthrex.de
Product Surveillance:	Sarah Merkle Manager Vigilance & Product Surveillance Phone: +49 (89) 90 90 05 52 40 E-mail: vigilance@arthrex.de

If you have any questions please call Arthrex GmbH at +49 89 90 90 05 52 40 and ask for Sarah Merkle. You can also send questions by email to vigilance@arthrex.de.

Sincerely,

[redacted]

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