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[Addressee name, address]

Urgent Field Safety Notice

Reference: R519

Purpose

This Field Safety Notice (FSN) is to inform you about a voluntary recall of the Arthrex Burr, Oval, 12 Flute, 5.5 mm x 13 cm.

The Arthrex Burr devices are rotary cutting devices for use in arthroscopic surgical applications for the resection of bone. These devices are indicated for resection of osseous tissues in both large and small articular cavities during arthroscopic procedures.

Products affected by the issue

Product Name	Part No.	Lot No.
Burr, Oval, 12 Flute, 5.5 mm x 13 cm	**AR-8550OBT**	**10211276** **10202784**

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

Contakt
tel + 49 89 90 90 05 0
fax + 49 89 90 90 05 2801
info@arthrex.de
www.arthrex.de

Management
Reinhold Schmieding
Commercial Register Munich
HRB 76983

Registered Office
Erwin-Hielscher-Str. 9
81249 Munich
VAT-ID: DE129288919

Banking Details
HSBC Trinkaus & Burkhardt KGaA
BLZ 300 308 80 | Acc. 700 090 019
IBAN DE24300308800700090019
SWIFT/BIC TUBDDEDD

Description of the issue

The affected devices have a potential to overheat, which has been observed to result in two potential outcomes:

1) The surgeon may notice the increase in temperature of the device tip and opt to discontinue the use of the device – switching to another device to complete the intended surgical procedure.
2) The surgeon may not notice the increase in temperature of the device tip. The tip may come into contact with patient, user, or 3rd party tissues, causing a minor burn.

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 a replacement 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.

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.

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Contact information

Product-specific questions:	Stefan Weiß Senior Product Manager Imaging & Resection Phone: +49 (89) 90 90 05 41 25 Email: Stefan.weiss@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
Product Surveillance:	Alexander Salomon Supervisor Product Surveillance Phone: +49 (89) 90 90 05 52 40 Email: Complaints@arthrex.de

We appreciate your cooperation and apologize for any inconvenience.

Sincerely,

i.V. Michael Wöhrer
Divisional Manager, Quality Assurance

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: complaints@arthrex.de

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Arthrex customer's response form

Field safety notice / voluntary recall

Reference: R519

Return To	
To	**Arthrex GmbH** Product Surveillance Oskar-von-Miller-Str. 6 85235 Odelzhausen Germany
Email	complaints@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 anymore

☐ We are returning the following products (please specify quantity) to the addressee above:

Part Number	Batch Number	Quantity
AR-8550OBT	10211276	
	10202784	

Date Name Signature

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