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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



MAF-8.2.1-19-1Rev.0

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

**Kontakt**  
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 TUBDDE33

## 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 3<sup>rd</sup> 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](mailto: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@arthrex.de](mailto:complaints@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:                   Stefan Weiß  
Senior Product Manager Imaging & Resection  
Phone: +49 (89) 90 90 05 41 25  
Email: [Stefan.weiss@arthrex.de](mailto: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](mailto:CustomerReturns@arthrex.de)

Product Surveillance:                       Alexander Salomon  
Supervisor Product Surveillance  
Phone: +49 (89) 90 90 05 52 40  
Email: [Complaints@arthrex.de](mailto:Complaints@arthrex.de)

We appreciate your cooperation and apologize for any inconvenience.

Sincerely,

[Redacted Signature]

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](mailto:complaints@arthrex.de)

MAF-8.2.1-19-1Rev.0

## Arthrex customer's response form

### Field safety notice / voluntary recall

Reference: R519

Return To		From	
<b>To</b>	<b>Arthrex GmbH</b> Product Surveillance Oskar-von-Miller-Str. 6 85235 Odelzhausen Germany	<b>Facility Name</b>	
<b>Email</b>	<a href="mailto:complaints@arthrex.de">complaints@arthrex.de</a>	<b>Address City</b>	
<b>Fax</b>	+49 89 90 90 05 52 01	<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
AR-8550OBT	10211276	
	10202784	

Date

Name

Signature