

[Addressee name, address]

Urgent Voluntary Field Safety Notice

Reference: R517

Purpose

This Field Safety Notice (FSN) is to inform you about a **voluntary recall** of the Li-ion Battery Housing AR-400UBH for the AR-400 Power Tool System.

This battery housing is used to house the battery that powers the AR-400 DrillSaw Sports 400 device.

Products affected by the issue

Product Name	Part No.	Lot / Batch No.
DrillSaw Sports 400 System Li-ion Battery Housing for AR-400	AR-400UBH	<ul style="list-style-type: none"> • GB4091590 • GB4103994 • GB4211089 • GB4260648 • GB4241346 • GB4279490 • GB4320568 • GBP3854432 • GBP3854435 • GBP3854434



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 TUBDDEDD

Description of the issue

The battery housing may not provide a complete seal around the battery, allowing for potential fluid ingress and egress, posing a remote potential risk of contamination and patient infection.

Please note that Arthrex has not received any adverse event reports related specifically to this potential issue.

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.
Note: The part and batch number of the device are located on the inside of the battery housing lid.
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 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@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.

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Contact information

Product-specific questions: Rainer Schneider
Senior Product Manager Power & Resection
Phone: +49 (89) 90 90 05 41 25
E-mail: rainer.schneider@arthrex.at

Customer Returns Service: Robert Mann
Manager Customer Returns Service Specialists
Phone: +49 (89) 90 90 05 89 10
E-mail: robert.mann@arthrex.de

Product Surveillance: Alexander Salomon
Supervisor Product Surveillance
Phone: +49 (89) 90 90 05 52 40
E-mail: complaints@arthrex.de

We appreciate your cooperation and apologize for any inconvenience.

Sincerely,

Arthrex GmbH

i.V. Michael Wöhrer
Divisional Manager, Quality Assurance

Arthrex customer's response form

Field safety notice / voluntary recall

Reference: R517

Return To		From	
To	Arthrex GmbH Product Surveillance Oskar-von-Miller-Str. 6 85235 Odelzhausen Germany	Facility Name	
Email	complaints@arthrex.de	Address City	
Fax	+49 89 90 90 05 52 01	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-400UBH	GB4091590	
	GB4103994	
	GB4211089	
	GB4260648	
	GB4241346	
	GB4279490	
	GB4320568	
	GBP3854432	
	GBP3854435	
	GBP3854434	

Date

Name

Signature