

Richard Wolf GmbH • Postfach 11 64 - 65 • 75434 Knittlingen, Germany

Department: Customer Service  
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Your reference • Your correspondence dated • Our reference • Date  
QM700022361 2024-02-28

**Field safety notice**

**Affected product:** ARTICULATING BURR Ø 4MM  
**Product number:** 899751754  
**Lot number:** 1548421

**Our reference no.:** QM 700022361  
**Actor ID/SRN:** DE-MF-000007048

Dear Sir / Madam,

As part of our continuous product monitoring procedure, our attention has been drawn to a potential defect on the ARTICULATING BURR Ø 4MM. The ARTICULATING BURR Ø 4MM product (899751754) is used for therapy during endoscopic or endoscopically supported spinal surgery. The ARTICULATING BURR is mainly used to remove tissue parts (prolapse material, bone, cartilage, etc.) to decompress neural structures. According to our records, you operate using the potentially affected product. The procedure for rectifying the defect is set out in this letter.

The affected electrodes have the product label 899751754, lot: 1548421.

**The problem**

A production defect was identified in the course of market surveillance. The ARTICULATING BURR Ø 4MM (899751754) from lot 1548421 were not programmed correctly. As a result, the ARTICULATING BURR is not recognised by the handle, which poses a serious risk for surgical procedures. If this occurs, a delay in the operation or even cancellation of the operation can be expected; the user cannot identify the faulty products without a functional test. We want to pre-empt this situation by implementing this measure.

**Measures to be taken by the addressee**

Read through both this letter and the attached reference documents (see list of attachments) and keep them on file until the measure has been implemented.

Please follow the steps below:

1. Check your stock of ARTICULATING BURR Ø 4MM products with the product label 899751754 from lot 1548421. If you find an ARTICULATING BURR Ø 4MM, block it for further use and then dispose of it via a documented process.

2. Make sure, within your organization, that all users of the aforementioned product and other persons to be informed have received knowledge of this emergency safety notice. If you have passed on this product to third parties, please forward a copy of this notice and inform the contact persons stated below accordingly.
3. Make sure that this notice is retained within your facility until all the in-house measures required have been implemented.
4. To verify that you have received this emergency safety notice, we require you to return the enclosed **response form by March 18, 2024**. You can send this to us **via e-mail to FSCA700022361@richard-wolf.com**. We also ask that you complete this form even if you no longer have the product in stock. In doing so, you will be confirming receipt of this safety notice and you will not receive any further reminders from Richard Wolf.
5. Please inform Richard Wolf GmbH of any adverse events.

**The affected ARTICULATING BURR Ø 4MM from lot 1548421 must no longer be used.**

Two days after sending the emergency safety notice, Richard Wolf will automatically send you the replacement product free of charge in the relevant quantity.

The relevant national authorities have been informed of this **emergency safety notice**.

Your contact for

Questions concerning safety:

Mr. Marco Bruxmeier  
Head of Quality Engineering Department

Tel.: +49 7043 35 4011  
E-mail: FSCA700022361@richard-wolf.com

Questions concerning the procedure:

Mr. Thilo Musikant  
Head of Customer Service Department and Service Center

Tel.: +49 7043 35 4189  
E-mail: thilo.musikant@richard-wolf.com

Please accept our apologies for any inconvenience caused by this measure. On behalf of Richard Wolf GmbH, thank you in advance for your support in ensuring its timely implementation.

Equipment:  
Response form

# Response form



spirit of excellence

**Emergency safety notice concerning  
ARTICULATING BURR Ø 4MM 899751754, lot number 1548421**

**Our reference no.: QM 700022361**

- We hereby confirm receipt of this emergency safety notice.
- Furthermore, we confirm that we have properly disposed of the affected products in the quantity listed below in order to prevent them from being used in clinical applications.
- If you do not have any products in your stocks, please check the **“No stock”** box.
- Please send the response form **via e-mail to FSCA700022361@richard-wolf.com**

Product number	Lot	Quantity disposed of	Quantity used
899751754	1548421	_____	_____
		_____	_____
<b>No stock</b>	<input type="checkbox"/>		
<b>Comment:</b>			

Company  
.....

Dept./Name  
.....

Address  
.....

Tel./e-mail  
.....

Place/date  
.....

Signature/  
stamp  
.....

Richard Wolf GmbH would like to thank you for your understanding and cooperation. Please accept our apologies for any inconvenience caused!