

spirit of excellence

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Your reference	• Your letter dated	• Our reference	• Date
		QM700012374	May 27, 2019

**Urgent Safety Information**

**Product affected:** Cutting Electrode Mono 11.5 CH 0°  
**Product numbers:** 8416.03  
**Lot numbers:** 1390827 and 1391906

**Our reference no.: QM 700012374**

Ladies and Gentlemen,

In the course of our continuous product surveillance we became aware of a potential deficiency of our Cutting Electrode Mono 11.5 CH 0° 8416.03. In accordance with our documents you are using the product affected. This letter will inform you about the rectification procedure for this deficiency.

The electrodes affected are labeled as 8416.03 and additionally as lot 1390827 or 1391906, respectively.

## Problem

The product labeling describes a cutting electrode. Early on during equipment assembly you may find out that it is not the required cutting electrode. This may cause the surgical procedure to be delayed or made impossible. This measure is aiming at preemptively countering this situation.

### Measures to be carried out by the addressee

Please read this letter as well as its reference documents completely (see list of appended documents) and keep these documents until the measure is completed.

Please carry out the following:

1. Check your inventory of electrodes labeled 8416.03 from lots 1390827 and 1391906. Should you find out that there is a hook electrode under this model/type number, make sure you quarantine it to prevent further use and discard it in a documented manner.
2. Please make sure in your organization that all users of the product mentioned and other persons to be informed gain knowledge of this urgent safety information. If you have passed on the product to third parties, please pass on a copy of this document to them, and inform the contacts listed below.

3. Please make sure that this information is observed in your organization until all necessary internal measures have been completed.
4. To verify receipt of this urgent safety information we need the included **answer form** which we kindly ask you to return to **fax number 07043 351360**, or via e-mail to **vigilance@richard-wolf.com by June 11, 2019**. Please fill out this form even if the product is no longer in your inventory. With the answer form you confirm receipt of this urgent safety information and avoid getting further reminder letters from Richard Wolf GmbH.
5. Inform Richard Wolf GmbH about any adverse events.

**Do not use the affected electrode from lot numbers 1390827 and 1391906 !**

Two days after returning this urgent safety information, Richard Wolf GmbH will send you the corresponding number of free replacement products. For illustrated instructions on how to proceed please see the document attached and included in each shipment.

The competent national authorities (amongst others the Federal Institute for Drugs and Medical Devices in Bonn) have been informed about this **urgent safety information**.

Your contact persons

for questions about the handling:

Herr Oliver Ehrlich  
Safety Officer for Medical Products  
Tel.: +49 7043 35 1013  
Fax: +49 7043 35 4300  
E-Mail: [oliver.ehrlich@richard-wolf.com](mailto:oliver.ehrlich@richard-wolf.com)

for safety-relevant inquiries:

Herr Thilo Musikant  
Head of Customer Service and Service Center  
Tel.: +49 7043 35 4189  
Fax: +49 7043 35 1360  
E-Mail: [thilo.musikant@richard-wolf.com](mailto:thilo.musikant@richard-wolf.com)

We apologize for the inconvenience caused by this measure and thank you on behalf of Richard Wolf GmbH for your support by ensuring a timely implementation.

Kind regards,

**Richard Wolf GmbH**

  
i.A. Oliver Ehrlich  
Safety Officer for Medical Products

  
i.V. Thilo Musikant  
Head of Customer Service and  
Service Center

Appended:  
Answer form  
Test instructions for identification

# Answer form



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via fax back to 07043 351360 or  
via email back to [vigilance@richard-wolf.com](mailto:vigilance@richard-wolf.com)

**Urgent safety information regarding  
CUTTING ELECTRODE MONO 11.5 CH 0° 8416.03, lot numbers 1390827 and 1391906**

**Our reference no.: QM 700012374**

- We hereby confirm receipt of this urgent safety information.
- We furthermore confirm that we have duly discarded the number of products specified in the list below, making sure that they are not used for clinical purposes.
- Please list the number of the quarantined and discarded products affected in your organization. If you do **not have** any such products in your inventory any more then please check off the following box below.

**No inventory** (please check off) ☐

Model/Type	Lot	Number discarded
8416.03	_____	_____
	_____	_____
<b>Remark:</b>		

Company  
.....

Dept. / Name  
.....

Address  
.....

Phone / Email  
.....

Place / Date  
.....

Signature /  
Stamp  
.....

We at Richard Wolf GmbH thank you for your understanding and support, and apologize for the inconvenience caused by this measure.