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Your reference • Your correspondence dated • Our reference • Date  
QM700018783 2022-12-09

**Field safety notice**

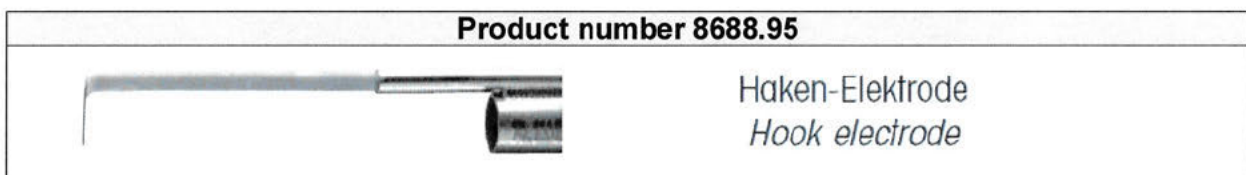
**Affected product:** HOOK ELECTRODE MONO 9 FR 0°  
**Product number:** 8688.95  
**Lot number:** 1510892

**Our reference no.:** QM 700018783

Dear Sir / Madam,

As part of our continuous product monitoring procedure, our attention has been drawn to a potential defect on the HOOK ELECTRODE MONO 9 FR 0°. The HOOK ELECTRODE MONO product (868895) is used for urological applications involving infants, children, and adolescents. These include applications through the urethra (i.e., a natural body orifice) and percutaneous applications in the kidneys, bladder, and ureter. According to our records, you operate the potentially affected product. The procedure for rectifying the defect is set out in this letter.

The affected electrodes have the product label 868895, lot: 1510892.



**The problem**

A production defect was identified in the course of market surveillance. Specifically, the solder joint on the HOOK ELECTRODE MONO 9 FR 0° from lot 1510892 may fail if it is exposed to persistent strain during use or reprocessing, or if the hook is exposed to sudden strain. Even if the hook on the hook electrode does not appear to be loose at first, the strain caused by use and subsequent reprocessing cycles (i.e., product aging/wear) will end up weakening the connection. 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 HOOK ELECTRODE MONO 9 FR 0° products with the product label 8688.95 from lot 1510892. If you find a HOOK ELECTRODE MONO 9 FR 0°, 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 December 22, 2022**. You can send this to us **via e-mail to FSCA700018783@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 HOOK ELECTRODES MONO 9 FR 0° from lot 1510892 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:

  
Head of Quality Engineering Department


Tel.: +49 7043 35 4011  
E-mail: FSCA700018783@richard-wolf.com

Questions concerning the procedure:

  
Head of Customer Service Department and Service Center

Tel.: +49 7043 35 4189  
E-mail: @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  
HOOK ELECTRODE MONO 9 FR 0° 8688.95, lot number 1510892**

**Our reference no.: QM 700018783**

- 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 FSCA700018783@richard-wolf.com**

Product number	Lot	Quantity disposed of	Quantity used
8688.95	1510892	_____	_____
		_____	_____
<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!