

Your Ref.: • Your Letter Dated: • Our Ref.: QM700007936 • Date: 13.03.2017

**Urgent Safety Information**

**Product concerned:** Atraumatic Compact Cysto-Urethroscope 25°  
**Product number:** 8645403  
**Serial number:** (is added individually)  
**Our reference no.:** QM 700007936

Ladies and Gentlemen,

In the course of our continuous product surveillance we became aware of a production-related deficiency in a number of serial-number-specific endoscopes of the aforementioned type.

This only concerns the current models of the production period from December 2016 and later with a green color coding ring on the light connector:



**Problem**

Certain types of forceps of the accessories program for rigid auxiliary instruments cannot be inserted into the probe channel of endoscope 8645403, or only be inserted with difficulty. These are the grasping forceps with alligator jaws, 7 Fr., model 86456508 and the grasping forceps with alligator jaws, 6 Fr., model 89686808.

This problem has occurred only in a few cases so far. It cannot be excluded however that individual products from the aforementioned production period are also affected by this fault.

You may continue using the product if you do not use the aforementioned auxiliary instruments. In this case the described problem will not occur.

### Measures taken by the addressee

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

Please carry out the following steps:

1. Check your stock for the aforementioned Endoscope 8645403 and auxiliary instruments (Grasping forceps with alligator jaws) 86456508 and 89686808.
2. Make sure within your organization that all users of the product mentioned above and other persons to be informed gain knowledge of this urgent safety information.  
If the product has been passed on to third parties, please pass on a copy of this information, and inform the contacts listed below.
3. Make sure that this information is observed in your organization until all necessary in-company measures are 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 **+49 7043 354467**, or via e-mail to **marek.rast@richard-wolf.com** by **xx.xx.2017**. Please fill in this form even if the product is no longer in your stock. With the answer form you confirm receipt of this urgent safety information and avoid getting further reminder letters from Richard Wolf.
5. Inform Richard Wolf GmbH about any adverse events.

Currently the product is not on stock. As soon as it is available we will inform you and replace the product with a fault-free endoscope.

The competent national authorities (amongst others the *Bundesinstitut für Arzneimittel und Medizinprodukte* in Bonn) have been informed about this urgent safety information.

Your contact person for

safety-relevant inquiries is:

Herr Heiko Sailer  
Head of Quality Management  
and Safety Officer  
Tel.: +49 7043 35 1108  
Fax: +49 7043 93 0048  
E-Mail: heiko.sailer@richard-wolf.com

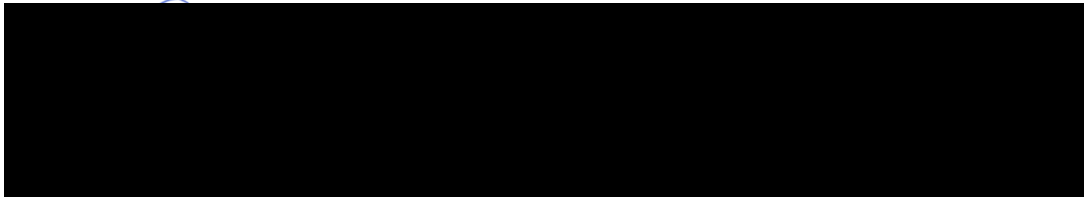
for questions about the handling:

Herr Marek Rast  
Head of Technical Service  
and Training  
Tel.: +49 7043 35 1046  
Fax: +49 7043 35 4467  
E-Mail: marek.rast@richard-wolf.com

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

Kind regards,

**Richard Wolf GmbH**



Enclosures:  
Answer form

# Response

Fax back to +49 7043 354467 or  
by e-mail to [marek.rast@richard-wolf.com](mailto:marek.rast@richard-wolf.com)

**Urgent safety information regarding  
Atraumatic Compact Cysto-Urethroscope 25°8645403 Seriennr.:** (wird indiv. Eingefügt)

**Our reference no.:** QM 700007936

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- We hereby confirm receipt of the urgent safety information.

Note:

Company

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Dept./Name

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Address

.....

Phone/e-mail

.....

Place/Date

.....

Signature/

Stamp .....

Thank you for your understanding and cooperation. We apologize for any inconvenience caused!