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
		QM700020652	15.03.2023

Emergency safety notice

Affected products:

828051	**FLEX. GRASPING FORCEPS 5 FR WL 550 MM**
8735685	**FLEX. GRASPING FORCEPS 5 FR WL 550 MM**
829051	**FLEX. BIOPSY FORCEPS 5 FR WL 550 MM**
8736685	**FLEX. GRASPING FORCEPS 6.6 FR WL 550 MM**

Dear Sir / Madam,

As part of our continuous product monitoring procedure, our attention has been drawn to potential difficulties that arise when the aforementioned flexible grasping and biopsy forceps are used under certain conditions. According to our records, you operate the potentially affected product. This letter provides information on how to safely use the forceps in the event that the problem being referred to arises during use.

The flexible forceps are used for grasping and manipulating, and for the dissection and biopsy of tissue parts, organs, or foreign bodies via natural, artificial, or surgically created access passages.

The affected forceps are combined with the following products for use on patients:

7305001	FIBER CYSTOSCOPE 15 FR WL 400 MM
7305006	FIBER CYSTOSCOPE 15 FR WL 400 MM
7315001	SENSOR CYSTOSCOPE 16.2 FR WL 400 MM (MAMBA PF)
7315006	SENSOR CYSTOSCOPE 16.2 FR WL 400 MM (MAMBA PF)
73151001	SENSOR CYSTOSCOPE 16.2 FR WL 400 MM (MAMBA EF)
73151006	SENSOR CYSTOSCOPE 16.2 FR WL 400 MM (MAMBA EF)

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Affected batches:

Product number:	Batches:
828051	4500377299 4500377299 4500371834 4500374645 4500369724 4500367397 4500363662 4500363096 4500359201 4500356582 4500353558 4500350415 4500347760 4500345769 4500341314 4500341314 4500338447 4500336245 4500334737 4500334002
8735685	4500377618 4500377296 4500374239 4500371819 4500367415 4500363102 4500367414 4500363666 4500363102 4500359744 4500357831 4500354319 4500352415 4500349678 4500344619 4500347121 4500349678 4500348605 4500344619 4500347121 4500344619 4500341300 4500338554 4500337773 4500335110
829051	4500377840 4500377840 4500377840 4500376297 4500371970 4500363663 4500363098 4500361404 4500353562 4500349168 4500347747 4500338560 4500333999
8736685	4500377853 4500371811 4500377297 4500371813 4500367418

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	4500367417 **4500363668** **4500363104** **4500359203** **4500356576** **4500353566** **4500352416** **4500350353** **4500347761** **4500347761** **4500346491** **4500344550** **4500341309** **4500338558** **4500334010**

The problem

We have received complaints from users stating that the forceps can no longer be opened during use.

Our investigation has shown that the affected forceps can be opened when handled properly. This means that the endoscope and flexible forceps must not be bent at an angle that is not required for the application in question, even when the endoscope tip is fully angled.

If the endoscope tip is fully angled and the endoscope sheath is also bent by more than approximately 90°, it may no longer be possible to fully open the jaw section. From this position onward, use begins to be restricted.
If the proximal forceps sheath is also bent, it is no longer possible to open the forceps; use may even begin to be restricted with a smaller endoscope bending angle (Figure 2).

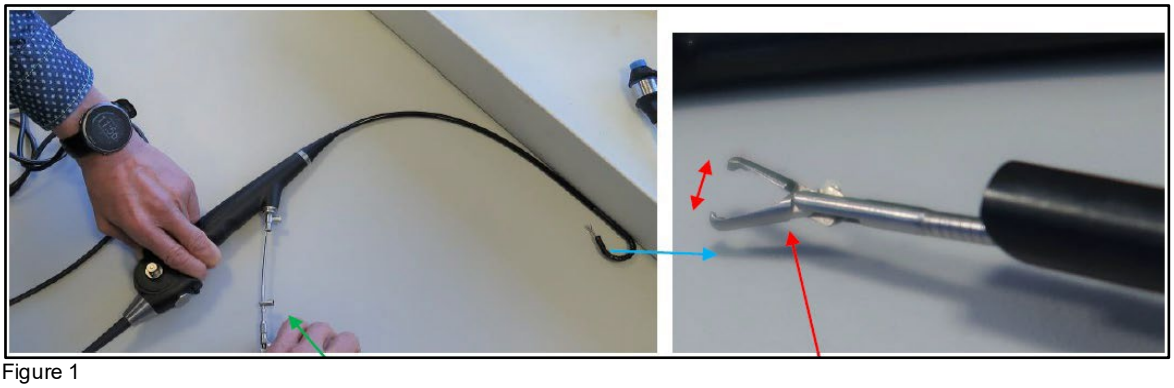

Figure 1

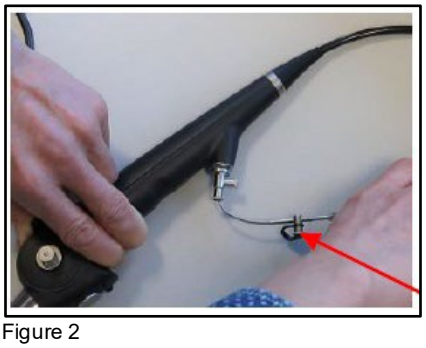

Figure 2

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WARNING:

To ensure that you can continue to safely use the products and to prevent exposing patients to improper handling, please perform the following steps.

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. Carry out a visual and function check before each use in accordance with instructions for use GA-S004. Incorrect product reprocessing or care can also lead to a loss of forceps function.

2. Before use, check whether the jaw section can be opened at the angle required for the application.
   Alternatively, insert the forceps into the working channel of your endoscope to create the configuration shown in Figure 1 (above). To do this, angle the distal end with the endoscope to the maximum and bend the endoscope sheath another 90°.
   If the jaw section can be opened, the forceps are working and can be used without any unnecessary angling.
   If the jaw section cannot be opened in this position, the forceps should not be used unless you can work with a reduced angle.

3. If you can no longer open the forceps during use in the patient, move both the proximal endoscope sheath and proximal forceps sheath into a straighter position; i.e., without any additional angling. In this position, the jaw section can still be opened and closed even in distal, fully angled applications.

4. Within your organization, make sure that all users of the product referred to here and any other persons who require this information have been made aware 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 person stated below accordingly.

5. Make sure that this notice is retained within your facility until all the in-house measures required have been implemented.

6. To verify that you have received this emergency safety notice, we require you to return the enclosed **response form by March 31, 2023**. You can send this to us **via e-mail to FSCA700020652@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.

7. Please inform Richard Wolf GmbH of any other adverse events.

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Richard Wolf is already optimizing the forceps design. Further batches of these forceps can be used with the expected maximum flexibility.
The procedure described here does not expose patients to risks from jaw sections that do not open.

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: FSCA700020652@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.

Yours faithfully,
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Attachments:
Response form

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