spirit of excellence

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

Departmemt: Technical Service
Person in charge: Marek Rast

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E-mail: marek.rast@richard-wolf.com

• Your reference	• Your letter dated	• Our reference	• Date
		QM 700011073	Sept. 24, 2018

Urgent Safety Information

Product concerned: **TEXAS Bronchoscope Tube**
Product numbers: **825200641, 825200841, 825200842, 825201041, 825201241, 825201441, 825210830, 825211230, 825211430**
Lot numbers: **in accordance with included list**

Our reference no.: **QM 700011073**

Ladies and Gentlemen,

In the course of our continuous product surveillance we became aware of a potential deficiency of our TEXAS Bronchoscope Tube product. Individual piece numbers of defined deliveries of certain production lots are affected. For these please see the enclosed list.

In accordance with our documents you are using the product affected. This letter will inform you about the rectification procedure for this defect.

Problem
Non-functionally relevant bonding points / cemented areas of the aforementioned Bronchoscope Tubes may loosen. 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 stock of Bronchoscope Tubes of the affected product numbers and lot numbers of the deliveries made to you which are listed in the appendix. Please send these products to Richard Wolf GmbH.

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 institution 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 354467**, or via e-mail to **marek.rast@richard-wolf.com by October 01, 2018**. 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 GmbH.

5. Inform Richard Wolf GmbH about any adverse events.

Do not use the affected Bronchoscope tubes listed.

Please return the products to Richard Wolf GmbH. We will perform the corresponding corrective measures on the affected tubes and send them back to you. Please send the products to:

Richard Wolf GmbH
Customerservice
Pforzheimer Straße 32
75438 Knittlingen

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

for safety-relevant inquiries:

Herr Heiko Seider-Biedermann
Deputy Safety Officer for Medical Products
Tel.: +49 7043 35 4112
Fax: +49 7043 35 4300
E-Mail: heiko.seider-biedermann@richard-wolf.com

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

Kind regards,

Richard Wolf GmbH

p.p. Marek Rast
Dept. Manager Technical Service

p.p. Heiko Seider-Biedermann
Deputy Safety Officer for Medical Products

Appended: answer form, listing of affected products

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