

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

Department: Technical Service  
Person in charge: Marek Rast

Phone: +49 70 43 35 1046  
Fax: +49 70 43 35 4467  
E-mail: marek.rast@richard-wolf.com

- Your reference
- Your letter dated
- Our reference  
QM 700011073
- Date  
Dec. 6, 2018

**Urgent Safety Information**

**Product concerned:** TEXAS Bronchoscope Tube  
**Product numbers:** 825200641, 825200841, 825200842, 825201041, 825201241,  
825201441, 825210830, 825211230, 825211030, 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 products, please see part number information above.

In accordance with our documents you are using the product affected, please see the enclosed list for facility specific information. 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 manufacturer:**

**Bronchoscope Tubes delivered from 2006 up to December 2017**

Returned Bronchoscope Tubes are checked for the aforementioned problem. If we find an issue at the bonding points we will send you a replacement free of charge. If the product is ok it will clearly identified to indicate product acceptance. Acceptable product will be returned to you free of charge.

**Bronchoscope Tubes delivered since January 2018**

These tubes have already been addressed by our urgent safety information dated Sept. 24, 2018 and are replaced free of charge. Customers affected by this measure have already been informed separately.

**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 steps:

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:

Richard Wolf GmbH  
Kundenservice  
Pforzheimer Straße 32  
75438 Knittlingen, Germany

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.

2. Please make sure that this information is observed in your organization until all necessary internal measures have been completed.
3. 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 [vigilance@richard-wolf.com](mailto:vigilance@richard-wolf.com)  
by December 14, 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.

4. Please inform Richard Wolf GmbH about any adverse events.

**Do not use the affected Bronchoscope tubes listed !**

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 are

for questions about the handling:

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

for safety-relevant inquiries:

Mr. Oliver Ehrlich  
Safety Officer for Medical Products  
Tel.: +49 7043 35 1013  
Fax: +49 7043 35 4300  
E-Mail: oliver.ehrlich@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  
Director of Technical Service

  
p.p. Oliver Ehrlich  
Safety Officer for Medical Products

Appended: answer form, listing of affected products