

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

Dept.: Technical Service
Person in charge: Marek Rast

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Your reference • Your letter dated • Our reference • Date
QM700005647 04.04.2016

Urgent Safety Information

Product concerned: Pump tube
Product number: 8170,861
Lot number: 1275623

Our reference no.: QM 700005647

Dear Sir or Madam,

within the scope of our continuous product monitoring activities we became aware of a potential defect of our TEM pump tube 8170,861 for our TEM pump 2232,244. According to our documents you operate at the potentially affected product. This letter is to inform you about how to eliminate the potential defect.

A luer connector with the wrong diameter is fitted to the affected pump tube. Instead of the necessary outer diameter of 12 mm, the diameter is only 10 mm. An adaptation is not possible with the Tube Set 8170,841.

Problem

If the pump tube 8170,861 is only unpacked shortly before the commencement of the intervention on the patient in the operating theater and the function check is carried out by means of the tube connection, there is a risk that the length of the operation could be extended due to defect. We want to prevent this situation by instituting this measure.

Measures to be taken by the addressee

Please read this letter and the pertaining reference documents in full (see list of appended documents) and keep them until the measure has been completed.

Please carry out the following steps:

1. You are requested to check your inventory of pump tubes 8170,861 for TEM pump 2232,244 with the luer lock tube fitting 891,011 which you receive from us. **IMPORTANT:** no product data are printed on the affected pump tube. The defective pump tube 8170,861 should be disposed of.
2. Please make sure that all users of the aforementioned products and other persons to be informed in your organization become aware of this urgent safety information. If you have passed on products to third parties please pass on a copy of this information and inform the contact persons listed below.

3. Please make sure that this information is observed in your organization until all necessary internal measures have been completed.
4. To verify receipt of this urgent safety information we need the enclosed **answer form** which we kindly ask you to fax back to us **under fax ++49 07043 354467** or **via e-mail to marek.rast@richard-wolf.com, by 22 April 2016**. Please also fill in this form if the product is no longer in your inventory. You thereby confirm receipt of this safety information and avoid receiving more reminders from Richard Wolf.
5. Please inform Richard Wolf GmbH about any adverse effects.

The affected TEM pump tube 8170,861 lot number 1275623 must not be used any longer.

Richard Wolf will send you the appropriate number free of charge. Together with this delivery you will also receive the luer lock tube fitting 891,011 free of charge with which you can identify the affected pump tube from the TEM accessories. You will find an illustrated instruction of the procedure in the enclosures with this letter and in the relevant delivery.

The competent national authorities (such as the *Bundesinstitut für Arzneimittel und Medizinprodukte* i.e. the Federal Institute for Drugs and Medical Devices in Bonn) have been informed about this **urgent safety information**.

Your contact for

Safety-related inquiries:

Mr. 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

Questions on handling:

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

We apologize for any inconvenience caused by this measure and would like to thank you on behalf of Richard Wolf for supporting us in timely implementation of this measure.

Yours sincerely,
Richard Wolf GmbH


i.V. Heiko Sailer
Head of Quality Management
and Safety Officer


i.V. Marek Rast
Head of Technical Service
and Training

Enclosures:
Answer form
Test instruction for identification

Response



spirit of excellence

Fax back to +49 7043 354467 or
by e-mail to marek.rast@richard-wolf.com

Urgent safety information regarding
TEM pump tube 8170861 Lot-Number 1275623

Our reference no.: QM 700005647

- We hereby confirm receipt of the urgent safety information.
- We also confirm to dispose the affected so it no longer get in clinical use.

Note:

Company

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Dept./Name

.....

Address

.....

Phone/e-mail

.....

Place/Date

.....

Signature/

Stamp

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