

Department: Customer Service
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Your ref. • Your communication dated • Our ref. VKK/mu-jes • Date 13.03.2014

Urgent Safety Information

**Recall of the disposable scissor blades 4393040
Defective seal on the sterile pack**

Recipients:

Users, Operators, Distributors

Identification of the affected medical products:

4393040 ModuBlades "Metzenbaum", disposable product packed sterile. Lot 983021 / Lot 983349 / Lot 984224

Description of the problem:

Ladies and Gentlemen,

on the basis of information received from our service provider supplying the sterile pack for the **disposable scissor blades 4393040** we were alerted to the fact that **there may be defects in the seal of the sterile packaging.**

This Safety Information is based on results provided by our service provider and not on an incident with effects on patients. Investigations have demonstrated that insufficient energy was applied for the welded seal for a small number of disposable scissor blades. As a result, it is possible that the sterile packaging may only have been partially sealed properly. This would mean that the sterile conditions for the scissor blades are no longer guaranteed for these products.

We have therefore decided to recall all the affected scissor blades in order to avoid any risks whatsoever to patients.

This recall relates to the scissor blades from following production batches:

Lot 983021 / Lot 983349 / Lot 984224.

Our records indicate that you have received deliveries from the affected production batches. We therefore request that you segregate the **scissor blades 4393040** in these batches from your stocks and that you no longer use them in any operations whatsoever. We further request that you return to us the segregated scissor blades (also packaging units that have been opened). Naturally, you will receive in return a replacement from us free of charge.

We ask you to ensure within your organization that all users of the products specified above and any other persons due to receive relevant information are immediately informed about the content of this notice of **Urgent Safety Information**. If you have passed any products on to third parties, you are requested to forward a copy of this information notice and inform one of the contacts listed below.

In order to provide verification for implementation of this measure and for fast availability of the scissor blades, we are obliged to request you to complete the enclosed response form by fax to the specified **Fax no. +49 7043 351360**. You should also state on this form the required volume for the replacement delivery. We will then take all appropriate action required in accordance with the information you provide.

If you have any questions, the following **contacts** will be very pleased to assist you:

If you have any questions relating to safety issues, please contact:

If you have any questions relating to processing:

Mr. Heiko Sailer
Head of Quality Management and Regulatory Affairs
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Email: heiko.sailer@richard-wolf.com

Mr. Thilo Musikant
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This recall measure must be notified to the regulatory authority, and accordingly the relevant government agencies have been informed.

We very much regret the inconvenience caused to you as a result of this recall measure and we will do everything in our power to ensure that the recall runs as smoothly as possible.

Yours sincerely,
Richard Wolf GmbH



p.p. Heiko Sailer
Head of Quality Management and Regulatory Affairs



p.p. Thilo Musikant
Head of Customer Service

Enclosure