

Department: Technical Service

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Your ref. • Your communication dated • Our ref. VKT/ras • Date 17.02.2014

Urgent Safety Information

Safety measure relating to the RIWomobil Product nos. 32116004, 32116005, 32116014 and 32116015

Addressed to:

Users, operators, distributors

Identification of the affected medical devices:

Equipment Cart **RIWomobil product nos. 32116004, 32116005, 32116014 and 32116015.**
See enclosed list for affected series numbers.

Description of the problem:

Ladies and Gentlemen,

on the basis of a customer complaint, it has come to our notice that in two cases the power cable has been disconnected from the panel-mounted socket due to mechanical overload. This led to complete failure of the **RIWomobil product no. 32116** equipment cart, as a result of the associated interruption of the power supply.

Measures to be taken by the addressees:

The product can continue to be used. However, we expressly draw your attention to the fact that until receipt and assembly of the new **Mounting Kit for Power Cables Product no. 643301191** the correct plug connection for the power cable to the panel-mounted socket should be checked before the equipment cart is used.

We hereby draw your attention to the fact that we have revised our Instruction Manual in light of this information. An updated version will be sent to you together with the mounting kit. You should replace the existing manual with the revised Instruction Manual.

In order to comply with the requirement to have a record of verification for the receipt of this **Urgent Safety Information**, we require the enclosed response form, and we ask you to return this to us by fax to the **fax number +49 7043 351360** by **04.03.2014**.

You are requested to retain this information at least until the measure has been carried out and completed.

Forwarding the information described here:

We ask you to ensure within your organization that all users of the products specified above and any other persons in a position to communicate 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 or inform the contact persons listed below.

Measures by the manufacturer:

This Urgent Safety Information will be sent to all the affected customers by 18.02.2014.

Richard Wolf is modifying the equipment cart **RIWomobil product no. 32116004, 32116005, 32116014 und 32116015**. We will send you the mounting kit and the revised Instruction Manual free of charge within the next 4 weeks including Mounting Instructions for the Power Cable Product no. 643301191.

Customer Service of instrument maker Richard Wolf will get in contact with you within 3 weeks of sending this letter and will then make arrangements for dispatch.

The responsible national government agency (Federal Institute for Drugs and Medical Devices in Bonn) has been informed about this **Urgent Safety Information**.

Your contacts:

For safety-related questions:

Mr. Heiko Sailer
Head of Quality Management and Regulatory Affairs
Tel.: +49 7043 35 1108
Fax: +49 7043 93 0048
Email: heiko.sailer@richard-wolf.com

For technical questions:

Mr. Marek Rast
Head of Technical Service
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We very much regret the inconvenience that you incur or have incurred as a result of the circumstances described above.

Yours sincerely,
Richard Wolf GmbH


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


p.p. Marek Rast
Head of Technical Service

Enclosure