

medica Medizintechnik GmbH
Blumenweg 8 | 88454 Hochdorf

To:
Importers and End customers

Ihr Ansprechpartner
Dirk Neurohr
07355-93 14-67

Datum
07. Juli 2018

Ref: Urgent Safety Information THERA-Trainer balo / THERA-Trainer verto

Dear Sir or Madam,

We need to implement a corrective action for our products THERA-Trainer balo / THERA-Trainer verto in the field. Please note following references.

Identification of the concerned medical products:

Movement therapy device – THERA-Trainer balo, THERA-Trainer verto

Manufacturing date of all relevant medical devices is between CW21/2013 and CW04/2018 and can clearly be identified by serial number.

Serial numbers consist of A002-308-XX-YYCWXXXX or A002-678-XX-YYCWXXXX

YY = the last two figures of the manufacturing year (e.g. 2015)

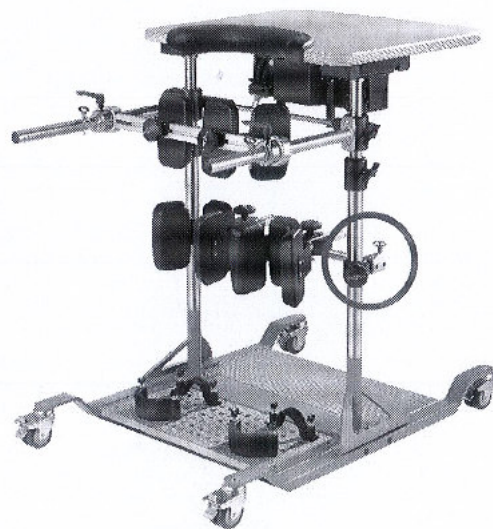
CW = Calendar week of production (e.g. 07)

Description of the problem including the determined cause:

The hexagon socket set screw of the mounting mechanism of the knee support is broken.



Picture: THERA-Trainer balo



Picture: THERA-Trainer verto

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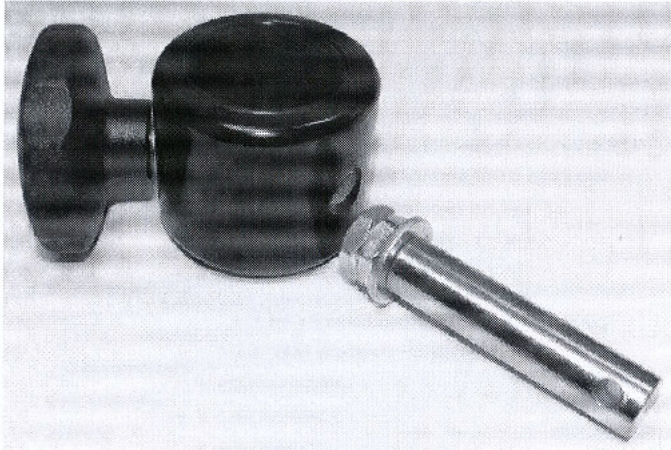
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Geschäftsführer
Peter Kopf / Otto Höbel
Rgr. Ulm
HRB 640839
USt.-IdNr. DE144890393

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Picture: Broken hexagon socket set screw

As a cause, we detected a hydrogen embrittlement of the galvanized hexagon socket set screw with the strength ≥ 10.9 . This hydrogen embrittlement can occur irregularly. The damage can happen during low load already. If the hexagon socket set screw breaks, the knee support can fall off on one side and the patient will become instable during lifting process or during therapy.

Health risk:

We carried out an evaluation of the health risk, in order to identify potentially harmful situations that might occur if the hexagon socket set screw breaks suddenly. The highest possible level of harmful situation for the patient is injury to the skin (e.g. laceration) which needs medical attendance.

Until now, we faced no injuries in connection to this problem.

There are no risks for patients that were already treated with the device, as well as for users and third persons.

Which measurements need to be taken in action by the receiver?

During this corrective action, we kindly ask you to do the following:

- Please stop exercising with THERA-Trainer balo/THERA-Trainer verto until a modification was done.
- We, medica Medizintechnik GmbH, will send you within the next 2-3 weeks spare parts incl. service manual in order to exchange the relevant components. Please exchange the components and return the original components incl. the completed answer form to us.

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Transferring the information described above:

Please take care that the safety information provided reaches all persons necessary within your organization or other organizations that were in touch with the relevant products.

Please distribute this safety information to other organizations, which might be concerned by the action, and ensure that the corrective action stays public until it is closed.

The Federal Institute for Drugs and Medical Devices received a copy of this „urgent safety information“.

Contact Person:

Dirk Neurohr, Head of Service & Quality

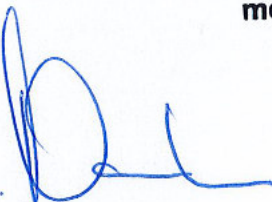
medica Medizintechnik GmbH

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Phone: 07355/9314-67

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With kind regards,

i.A. 

i.A. Dirk Neurohr

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Customer Answer Form

Ref: Urgent safety information THERA-Trainer balo / THERA-Trainer verto

Product description: THERA-Trainer balo / THERA-Trainer verto
Manufactured between CW21/2013 and CW04/2018
Serial number: Beginning with A002-308-...-..... or A002-678-...-.....
Our reference no.: PKOHDN20180515

CONFIRMATION OF RECEIPT OF THE SAFETY INSTRUCTIONS AND COMPLETION OF THE ANSWER FORM

Please tick the applying boxes below and return the completed form to us:

We read the medica-safety instructions and understand the information given as well as the required actions. We confirm the receipt of the spare parts and the implementation of the exchange.

If you ticked this box: Please inform us which device, when and who did the exchange.

| | |
|---------------------------------------|--|
| Serial number: | |
| Company/Facility: | |
| Date of the exchange: | |
| Name / Title of the person in charge: | |

We sold/moved the THERA-Trainer balo / THERA-Trainer verto to a different facility.

If you ticked this box: Please give us the contact date of the new facility.

| | |
|---------------------------------|--|
| Serial number: | |
| Name of the new facility: | |
| Name / Title of contact person: | |
| Address: | |
| City, Zip Code, Country: | |
| Phone: | |
| E-Mail: | |

The THERA-Trainer balo / THERA-Trainer verto is no longer in the field!

| | |
|-------------------------------------|--|
| Serial number: | |
| Company/Facility: | |
| Name / Title of the contact person: | |

We offer following ways of contact:

Mail: medica Medizintechnik GmbH, Blumenweg 8, D-88454 Hochdorf
Fax: +49 7355-93 14-15
E-Mail: service@thera-trainer.de

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