

Safety notification

concerning: SELEXA bed chair

Dear customer,

at LiKAMED, product quality and safety are of the highest priority. In addition to the company certifications according to EN ISO 13485 and EN ISO 9001, we have our chairs tested for the safety of LiKAMED products by the external TÜV SÜD testing centre before series production is approved. This, for example, ensures that the chairs and bed chairs not only comply with current safety standards, but that you can truly rely on safe use by staff and patients.

To keep this safety standard for you at the highest level and to ensure safe use of our products, we would like to inform you about **a possible risk of our SELEXA bed chair** via this safety notification.

The following serial numbers are affected: 14XBL0001 to 19XBL0023

Prior to 2019, a too weak screw was used in the production of the SELEXA bed chair, and this could have been damaged prematurely by overtightening of the screw. This can cause the SELEXA to tilt forwards. There have been two complaints where a screw broke and caused the SELEXA to tilt forwards.

Risks:

In an improbable event, the SELEXA bed chair can tilt forwards. If a patient is on the SELEXA at this time, the patient could be startled and in the most hardly imaginable case slide off the SELEXA and injure him/herself. Tipping over of the SELEXA is impossible.

Procedure until the cause is remedied:

You can still use the SELEXA bed chair, but you may only move the SELEXA in the lowest position. The back, seat, and foot parts as well as the footrest can still be adjusted without danger in the lowest height position. The height adjustment function should not be used until the temporary retrofit kit or the permanent retrofit kit have been fitted.

Remedy of the cause:

LiKAMED will immediately provide every dealer with a retrofit kit. This retrofit kit consists of a permanent retrofit kit and a temporary retrofit kit. LiKAMED recommends retrofitting the affected SELEXA bed chair with the permanent retrofit kit (working time approx. 45 minutes) at the next routine maintenance. If the next maintenance is not scheduled within the next 90 days, you should secure the affected SELEXA with the temporary retrofit kit (working time approx. 5 minutes). We thank you for your understanding for this retrofit.

Passing on the described information:

Please ensure that every member of your organisation and every user is aware of this safety notification. If the SELEXA bed chair is not being used on your premises, please also forward a copy of this safety notification to the users.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Safety Notification".

If you have any questions, please contact us at:

LiKAMED GmbH

Your LiKAMED customer contact

Raußmühlstraße 7

D-75031 Eppingen

Telephone: +49 (0) 7262/9189-0

Fax: +49 (0) 7262/9189-917

e-mail: complaint@likamed.de

Feedback form Safety notification SELEXA bed chair

Company / Hospital: _____

Name, first name: _____

Address: _____

Postal code, Place: _____

Country: _____

Serial number/s:

- I have received and read this safety notification.
- I have ensured that all my staff are fully informed about this safety notification.
- I have received the temporary and permanent retrofit kit.
- I have installed the temporary retrofit kit.
- I have installed the permanent retrofit kit.
- I will contact LiKAMED GmbH if I have any questions.
- I have done a visual inspection of the affected screws (see following instructions).

Signature: _____

Date: _____

PLEASE RETURN THIS COMPLETED FEEDBACK FORM BY E-MAIL

To: complaint@likamed.de

Subject: Feedback form safety notification

Or per FAX +49 (0) 7262/9189-917

Visual inspection Screws Safety notification SELEXA bed chair

1. Remove the cover cap on the side panel



2. Unscrew screw



3. Release the two snap fasteners that hold the panel by pulling gently.



4. Lower the side panel.



5. Check Screws, that these are not damaged
Broken screw (not okay)



Screw okay

