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UFSK_FSN_500 XLE_head-side lowering lying
surface_SN2000-4506_230427_en.docx

27.04.2023

Safety notice

Restricted use for Treatment chairs 500 XLE with serial numbers 2000-4506

Affected are only:

Art.no. / REF no.: 15000004 Serial number range: 2000- 2999

Art.no. / REF no.: 15000006 Serial number range: 3000-4506

Recipient:

This safety notice is addressed to all affected healthcare institutions, UFSK-OSYS distributors and their customers.

Description of the problem:

Within the scope of our continuous worldwide market observation and the evaluation of information from the field, we have determined that in the case of **500 XLE treatment chairs** with the **serial number ranges 2000-2999 and 3000-4506** (date of manufacture between 2012-10 to 2020-07), increased, externally undetectable wear of the seat drive can occur under certain circumstances in the event of exceptionally heavy use. In very rare individual cases, this can lead to a **possibly sudden head-side lowering of the lying surface** when positioning a patient with the seat part in an inclined position (see attachment).

Even though the likelihood of such wear-related subsidence is very low and we have no information about any personal injuries that have occurred, we would like to live up to the high quality standards of our products and, as a highly precautionary measure, inform you about this problem and about safety measures to be observed with this letter.

Description of the identified causes:

We have received information that in very rare individual cases, the intended service life of the seat drive may be shortened after several years of use. According to information from our supplier, this may result in a wear-related reduction in the self-locking of the seat part drives that are factory-fitted in the above-mentioned treatment chairs (manufacturing dates between 2012-10 and 2020-07). In the individual cases known to us, it can be assumed that there was an unusually high stress due to various deterioration parameters (collision, incorrect lifting during transport, improper use). Potentially increased wear or preliminary damage to the seat drive may remain undetected under certain circumstances, especially if the recommended maintenance of the treatment chairs has not been carried out or has been carried out inadequately.

A worsened self-locking of the seat drive can lead to overriding the end position of the seat drive when positioning the patient with the seat part in an inclined position. This can result in a possibly sudden head-side lowering of the lying surface (see attachment).

In the very few individual cases that came to our attention, there was no patient injury or other personal damage.

The possibly increased wear only affects seat drives that have been installed ex works in the above-mentioned treatment chairs. Treatment chairs with other serial numbers are not affected by this problem.

Identification of the affected treatment chairs:

You will find the serial number of your treatment chair on the nameplate (see attachment). The affected treatment chairs are also marked on the nameplate with manufacturing dates between 2012-10 and 2020-07.

What safety measure should be taken immediately?

The above-mentioned 500 XLE treatment chairs can still be used safely if you observe the following safety measure:

The seat part drive is retracted so far with the patient in position that the seat part is in a horizontal position; the seat part may no longer be adjusted with the positioned patient (see attachment: Illustration of safe and critical patient positions).

All other adjustment functions of the treatment chair can be fully used.

This safety notice should also be attached to the instructions for use of the respective treatment chair. In addition, we recommend that the treatment chair will be appropriately labelled using the information in the attachment to ensure safe use by changing users. **Please complete the enclosed reply form and send it to the address given there.**

Optional follow-up measure - replacement of the seat part drive

If you want to use the inclined seat position during treatment, we recommend replacing the seat drive at the latest when the next safety inspection is carried out (interval 12 months). A replacement drive can be installed easily and without great effort.

For an individual spare part quotation, you can contact our customer service as follows:

Spare parts procurement -contact: UFSK customer service

For your questions, please contact our customer service:

Tel: 0049 941 78862-47

E-Mail: fabian.lang@ufsk-osys.com

Passing on this safety notice:

Please ensure that this safety notice is passed on to the medical device safety officer, if applicable, as well as to all users of the treatment chairs within the healthcare institutions where the concerned treatment chairs are operated.

Please keep this notice, at least until the safety measure is completed.

For distributors:

As a distributor, please immediately forward this safety notice to all healthcare institutions to which you have supplied one of the affected treatment chairs and confirm to us that you have forwarded the letter using the reply form attached below. Note: Check your stocks for potentially affected demo- and pre-owned devices.

We apologize in advance for any inconvenience caused and thank you for your support.

With kind regards

UFSK-International OSYS GmbH



Diane Compala
Regulatory Affairs & Quality Management

Reply Form

I have received the **safety notice for Treatment chairs 500 XLE with serial numbers: 2000-4506** and have forwarded this information to the affected users and all other affected persons or healthcare institutions.

Organization/Company:

Name and address

(Stamp)

Please tick the relevant box

Healthcare institution

Distributor

Signatory person

Name, First name (in block letters):

Function:

City, Date:

Signature:

Please return this page promptly as confirmation to:

UFSK-International OSYS GmbH

Department Regulatory Affairs

Attn: Diane Compala

Kirchhoffstraße 1, 93055 Regensburg, Germany

E-Mail: md-vigilance@ufsk-osys.com

fax: 0049 941 78862-35

Attachment to: Safety notice-Treatment chair 500 XLE-SN 2000-4506-27.04.2023

Safe patient positions of 500 XLE (SN 2000 - 4506)



ATTENTION! The seat part must be in a horizontal position to the floor (see green cushion), the seat part drive remains in the retracted position (green marked component). Adjustment movements, e.g. into the reset position, are still possible (see adjustment positions of back and leg part shown in grey).

PROHIBITED - Critical patient positions!



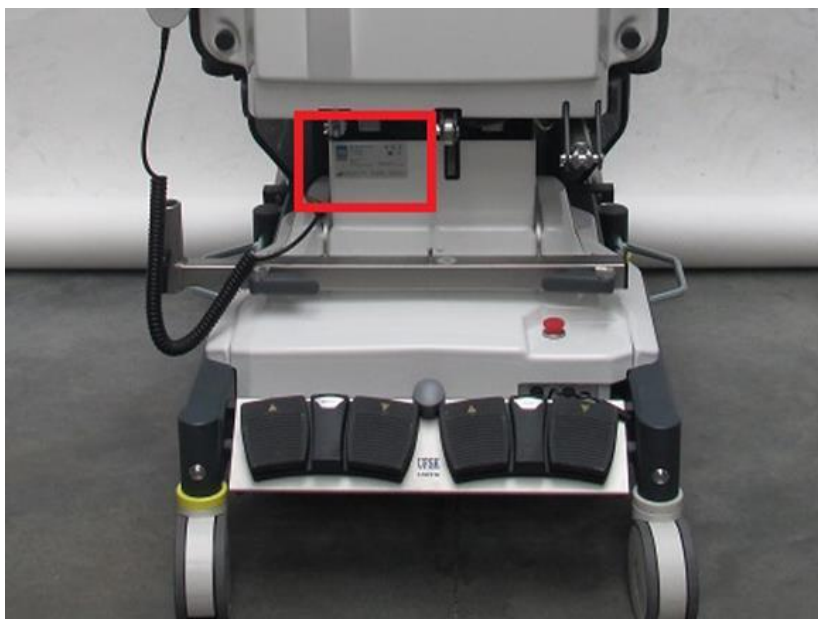
PROHIBITED! Tilting of the seat part by extending the seat part drive is prohibited. Memory positions that have been saved must be adjusted

ATTENTION - WORST CASE!



If the safe patient positions are not observed - in "worst case scenario" - this will cause the separation of the seat drive.

Where is the nameplate with the serial number (SN)?



Here you can find the nameplate of Treatment chair 500 XLE.
Identify the SN number! **Only SN-range of SN 2000 - 4506 is affected!**