

FIELD SAFETY NOTICE

Products Affected: CAPS II and MiniCAPS Seating System
Active Design Ref: FSN0002
MHRA Ref: 2018-007-025-401-012
Date Issued: 12th November 2018
Issued By: Active Design Ltd
Attention: Organisations providing, adjusting, maintaining and operating special seating systems and tilt-in-space wheelchairs.

Background

There has been an incident involving the CAPS II Seating System when used with tilt-in-space wheelchairs.

Potential Stability Issue with Tilt in Space Bases:

An incident occurred during transfer of the user into the seating system on a tilted wheelchair. It had been tilted to maximum rearwards tilt to facilitate positioning. The hoist was removed before the pelvic strap and other postural support components were engaged. The client extended suddenly, up and over the headrest, causing the wheelbase to tip rearwards. There was no resultant injury on this occasion.

Both the CAPS II and tilt-in-space wheelchairs are Class 1 Medical Devices.

Action Required

General Recommendations

This advice is relevant to most special seating systems used on tilt-in-space wheelchairs.

- Ensure the process of transferring a user into the seating system is appropriate and safe. It should ensure the user is correctly positioned in the seating system, with relevant postural support components (including lap straps) correctly attached before removing a hoist sling.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

**TO ACKNOWLEDGE RECEIPT OF THIS NOTICE AND CONFIRM RELEVANT ACTION
HAS BEEN TAKEN PLEASE COMPLETE THE SHORT ONLINE FORM AT:**

<http://activedesign.co.uk/fsn-november-2018/>

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The undersigned confirms this notice has been notified to the MHRA.

Martin Seabrook

12th November 2018

