

# FIELD SAFETY NOTICE

Products Affected: CAPS II and MiniCAPS Seating System  
Active Design Ref: FSN0001  
MHRA Ref: 2018/006/004/401/013  
Date Issued: 12<sup>th</sup> 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 Otto Bock Discovery tilt-in-space wheelbase.

Potential Finger Trap on Discovery Base:

Tilting the Discovery wheelchair created a gap between the CAPS II front interface fixing clamp and Discovery frame, just in front of the main pivot point. In this incident the user put their fingers into this gap, whilst the wheelchair was tilted rearwards, when the wheelchair was returned to upright position the gap closed, trapping the user's finger between the tube clamp on the front fixing and the apex of the Discovery side frame.

Both the CAPS II and Otto Bock Discovery wheelbase are Class 1 Medical Devices.

## Action Required

The interface design was changed in 2016 to ensure the front fixing did not create a finger trap, although it is possible this could occur on some size combinations, depending on where the interface is positioned. The Passive Locking Interface Instructions have been updated accordingly.

We recommend that existing interface boards older issued prior to January 2016 used on Discovery wheelbases are reviewed to ensure they are positioned in a way that does not create a finger trap, as described above, when the base is move through the full range of tilt.

Any interface boards that are identified that could cause an injury should have the front clamps repositioned either by re-drilling the board and remounting the clamps or simply sliding the interface on the seat rails. Alternatively the board should be replaced with a new interface board with repositioned clamps. Please get in touch and we will supply a replacement interface board without charge.

## General Recommendations

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

- Ensure seating components are positioned in a way that does not create a finger trap that could cause injury during use, for example when tilting the wheelchair.

### **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

12<sup>th</sup> November 2018

