

Field Safety Notice - Sorrento

Shower Chair / Shower Stool Aquatec® Sorrento – Leg Fixation at Seat

Date: November 2017
Ref: Internal #563905

INVACARE PROVIDER INFORMATION

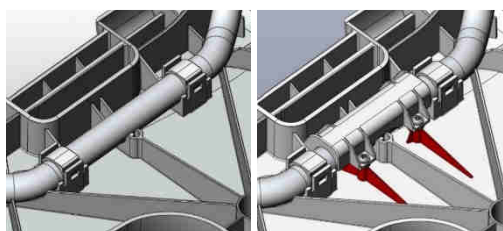
Affected products

Please find below an important information about the Shower Chairs / Shower Stools Aquatec® Sorrento manufactured before June 2016 (up to Lot 16ECL002).

Description

During our Post Market Surveillance Process, we received notification of the seat leg fixation breaking. This can lead to the user falling from the chair in the shower and being injured.

In order to reduce the potential for this defect, the seat leg fixation was reinforced for all products manufactured after June 2016.



Previous design

Current design (after June 2016)



Advice on actions to be taken

We have voluntarily decided to provide repair kits in Sweden for all products manufactured prior to June 2016 and still within their expected service life of 3 years, means 28th August 2014 (Lot 14ICL001) until end of May 2016 (16ECL002). The Medical Product Agency (MPA) has been informed of this measure. Only the seat with assembled legs must be exchanged; the armrest and backrest (if available on the product) plus leg height adjustment tubes will need to be retained and reused. After the exchange of the seat neither the warranty nor the expected service life of the product will be extended.

You should verify if you, or any of your customers, hold a product manufactured in the described period, and if so, please proceed in the following way:

- Order a replacement seat kit following your regular order process
Item 1606983 for replacement seats without hygiene recess (1532728, 1532729, 1532730)
Item 1606984 for replacement seats with hygiene recess (1532633; 1532660, 1532661)
- Remove and dispose the existing seat and transfer the product label to the new seat according to instruction
- Mount the retained height adjustment tubes plus arm-and backrest plus (if available on the product) on the replacement seat. See also the detailed exchange instruction Aquatec® Sorrento R001.
- Confirm the exchange to the Invacare address below.

The exchange should be performed as soon as possible, but not later than 8th June 2018.

Field Safety Notice - Sorrento

Transmission of this Notification

Please ensure that this notification is made available to all relevant personnel within your organization and customer base and to any organisation where the potentially affected products have been transferred, and that awareness is maintained for an appropriate period. We have provided a letter to the end user that we suggest you translate and distribute.

Contact details

If you have any questions relating to this Field Safety Notification, or should you require any additional information, please contact:

Invacare AB
Box 66
163 91 Spånga
Sweden
Telefon: 08-761 70 90
Fax: 08-761 81 08