

June 15, 2015

To our partners

Field Safety Notice

Regarding ReTurnBelt, wipeable



Affected devices

Belt for support, ReTurnBelt, wipeable, in plastic coated nylon with heat welded adjustment straps. All belts in LOT 1402S, distributed during 2014 and until March 2015 are affected.

Affected article numbers	Size
6133	S
6134	M
6135	L
6136	XL

Background information and reason for the Field safety corrective action

When exposed to high load, the adjustment strap of ReTurnBelt, wipeable may rip at the heat welded seam.

For the strap to rip, three conditions must be met:

- the belt must be attached to the frame of ReTurn, Fig. 1
- the patient must weigh around 100kg or more
- the patient must actively push himself backwards, Fig. 2

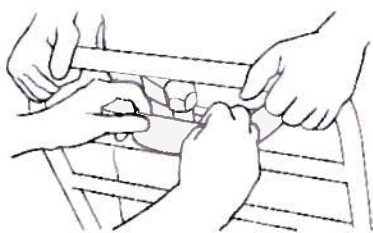


Fig.1



Fig. 2

The belt is load tested according to the marked weight, but it is not intended to carry the weight of the patient, with the belt attached to the ReTurn ladder. In the user manual for ReTurn, it is specified that the product is intended for patients that are able to:

- support weight while standing
- stand up and maintain balance (with support)
- grasp handles
- understand instructions

When these instructions are followed the risk for the adjustment strap of ReTurnBelt, wipeable to rip is minor, but as a measure of precaution, Handicare AB has decided to retrieve all belts in LOT 1402S.

Actions to be taken by our partners

All belts with the affected LOT number should be taken out of service and be returned to Handicare AB. Check your distribution records and warehouses to determine the location of all the affected belts. In the attachment "Response form" you will find further information on how to proceed when reporting back and returning belts to Handicare AB.

A new solution for attachment of the adjustment strap is under work. While waiting for replacement products, returned belts will be refunded with the amount paid.

Transmission of this Field Safety Notice

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

Further information

Please contact our customer service at customerservice@handicare.se or telephone +46 (0)8-557 62 200.

This notice has been notified the appropriate Regulatory Agency.

Handicare AB sincerely apologizes for any inconvenience this may cause our partners, but we appreciate your understanding as we take action to ensure patient safety.

For and on behalf of
Handicare AB



Malin Wallström
Quality and Environment manager