Urgent Field Safety Notice

Invacare XLT wheel chair

Date: 2010-06-18
Invacare ref: FSN031
Ref : 2009/003/010/301/001

Urgent Safety Information:

In the interests of the safety of our customers we would like to advise owners of XLT wheelchairs that some of the configurations are not suitable to be used as seat in transportation.

By this notification we would also like to point out that there is always risk involved in being transported seated in the wheelchair!
The risk for injury during an accident increases when the wheelchair is with a low backrest.
INVACARE strongly advise against the use of XLT as a seat in a vehicle if the backrest is lower than 40 cm.

Advice on action to take:

If you are owner of an XLT wheelchair with backrest lower then 40 cm we would like you to cover the “hook” label with a warning label. The warning label is provided by INVACARE customer service.

Hook label

The instructions for use and the prescription form have been amended accordingly. Current revision of the user manual, part no 1512799-4 can be downloaded from the INVACARE website – www.invacare.co.uk . Alternatively, please contact Technical Service Department, where you may request a copy of the latest revision of the user guide for your wheelchair.

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base.

Affected National Competent Authorities will be advised by FSCA and FSN.
If you have any questions relating to this bulletin, or should you require any additional information, please contact Customer Service Department at Invacare sales XXXXXX Phone number

Invacare confirms that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.

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Customer response to Field Safety Corrective Action – FSN 031

Action Completed – please tick below	
Distribution of amended IFU	
Replacement kit / parts fitted	

This is to confirm that the necessary corrective action, as documented in the Field Safety Notice, FSN 031, dated 2010-06-18, is now complete.

Please send fax-back form to the customer service at Invacare XXX, fax number XXXXXX

The serial number(s) of the inspected / repaired product(s) are as follows:

Action Completed

Signed……

Company……

Contact No…….. Date……

You have a responsibility under the Medical Device Directive to notify the manufacturer when corrective actions have been completed.

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