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NOTICE**

Storm³ Range (including Storm³ TT), Typhoon I & Typhoon II Power Wheelchairs

IMB Safety Notice: SN2011(25)

Circulation Date: 11 November 2011

MANUFACTURER/SUPPLIER

Invacare Ireland Limited

TARGET GROUPS

General public
Hospital CEOs
Risk Managers
Procurement Managers
Loan Store Managers
HSE Offices
Community Care Centres
Occupational Therapists
Community Care Managers
Community Therapists
Health Visitors
Carers
Educational Establishments

ISSUE

Invacare issued a field safety notice informing their customers of an update to transportation information provided in the user manual for the Storm³ and Typhoon Range power wheelchairs. Users of Storm³ and Typhoon Range power wheelchairs should read the attached Invacare field safety notice to determine if this information may have an impact on their transportation requirements.

BACKGROUND

Until 2008, the four point tie-down systems generally available on the market were only rated to 140 kg. The actual weight of highly configured Invacare® power wheelchairs exceeds 140 kg. Therefore, there is a risk of failure of the existing tie-down system if the vehicle is involved in an accident while using a four-point tie down system with the Storm³ and Typhoon Range power wheelchairs.

A new 4 point tie down system is now available from Invacare, which has been tested to ISO 10542-5 and ISO 7176-19. This crash capable system is designed specifically for Storm³ Range and Typhoon Range power wheelchairs. As outlined in the attached

S A F E T Y NOTICE

field safety notice, this issue only affects power wheelchairs purchased before 21st July 2008 and these affected Storm³, Typhoon I and II must be upgraded if users wish to use the power wheelchair as a seat in a vehicle during transportation. All relevant information relating to this upgrade can be found in the attached field safety notice, FSN014, issued by Invacare on the 8th November 2008.

Invacare have been unsuccessful in their attempts to date to locate all devices in Ireland affected by this field safety corrective action. There are approximately 50 Storm³ and Typhoon Range power wheelchairs on the Irish market, where this upgrade is outstanding.

ACTION OR RECOMMENDATIONS

The IMB advises that users:

1. Ensure the appropriate personnel are made aware of this notice.
2. Identify the location of all affected power wheelchairs.
3. If you / your institution have affected power wheelchairs, follow the manufacturer's recommendations as outlined in the attached field safety notice and ensure that the corrective action is completed on all affected medical devices.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Neil Harvey
Invacare Ireland Limited
5 Seatown Business Campus
Seatown Road
Swords
Co. Dublin

Telephone: 01-8107084
Fax: 01-8107085
Email: nharvey@invacare.com

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie