

Medical Device Alert

Ref: MDA/2012/060 Issued: 22 August 2012 at 14:00

Device

Powered wheelchairs.

All chairs in the Harrier range.

Manufactured by Invacare.



Problem	Action
The drive wheel may detach from the wheelchair, as a result of being incorrectly refitted due to inadequate service/maintenance instructions in the technical manual. The manufacturer published a Field Safety Notice (FSN) in April 2012 to notify technicians of the revised removal / refitting procedure. The manufacturer has not received sufficient confirmation that this FSN had been received and acted upon. All those involved in the maintenance of these wheelchairs. In particular: wheelchair service managers, rehabilitation engineers and	 Ensure that technicians responsible for maintenance of Harrier wheelchairs: have a copy of the amended procedure – this is attached to the Field Safety Notice, and can also be downloaded from the Invacare website are aware of the revised guidance regarding removal and refitting of the drive wheel inform Invacare that the FSN has been received and that the revised procedure has been reviewed and understood.
maintenance staff.	
CAS deadlines	Contact
Action underway: 24 September 2012 Action complete: 22 October 2012	Manufacturer Technical Services Department Invacare Ltd
Note: These deadlines are for the revised procedure to be obtained and reviewed, and Invacare informed.	Tel: 0165 677 6333 Fax: 0165 677 6330 Email: serviceuk@invacare.com

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)
- Social services in Scotland (Directors)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Equipment stores
- Rehabilitation engineers
- Wheelchair service managers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Equipment libraries and stores
- Maintenance staff

Social services

Liaison officers for onward distribution to all relevant staff including:

- Disability equipment stores
- Equipment stores
- Loan store managers
- Loaned equipment store managers
- Wheelchair and seating service managers

Contacts

Manufacturer

Technical Services Department Invacare Ltd Pencoed Technology Park Pencoed Bridgend CF35 5AQ Tel: 0165 677 6333 Fax: 0165 677 6330 Email: serviceuk@invacare.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/060** or **2012/002/006/081/013**

Technical aspects

Emma Rooke and Patrick Sweeney Medicines & Healthcare products Regulatory Agency Floor 4 151 Buckingham Palace Road London SW1W 9SZ Tel: 020 3080 6609 and 6898 Fax: 020 8754 3965 Email: emma.rooke@mhra.gsi.gov.uk patrick.sweeney@mhra.gsi.gov.uk

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Clinical aspects Jonathan Plumb Medicines & Healthcare products Regulatory Agency Floor 4 151 Buckingham Palace Road London SW1W 9SZ Tel: 020 3080 6648

Fax: 020 8754 3965

Email: jonathan.plumb@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system. Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre Health Estates Investment Group Room 17 Annex 6 Castle Buildings Stormont Estate Dundonald BT4 3SQ Tel: 02890 523 704

Fax: 02890 523 704

Email: NIAIC@dhsspsni.gov.uk http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre Health Facilities Scotland NHS National Services Scotland Gyle Square 1 South Gyle Crescent Edinburgh EH12 9EB

Tel: 0131 275 7575 Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to: Improving Patient Safety Team Medical Directorate Welsh Government Cathays Park Cardiff CF10 3NQ Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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