

Medical Device Alert

Ref: MDA/2014/025 Issued: 02 July 2014 at 14:00

Device

Turning aids: ReTurn 7400 and ReTurn 7500.

Manufactured by Handicare AB.

Specific design is affected.



Problem

The wing handle on the ladder part of the turning aid may become loose, with a risk of harm to the patient and the person operating the device.

The manufacturer has developed an inspection protocol, which is set out in its [Field Safety Notice](#) (FSN) dated 19 March 2014.

Handicare has not had sufficient confirmation from users that they have received and acted upon the information contained in the FSN.

Action by

Those responsible for the use, care and maintenance of these devices.

CAS deadlines

Action underway: 23 July 2014

Action complete: 02 September 2014

Note: These deadlines are for systems to be in place to identify, inspect and replace affected parts.

Action

- Identify and inspect affected devices as described in the [FSN](#).
- Where appropriate, remove affected components and contact Handicare for replacements.
- If you service or recondition these devices, make sure you use the latest version of the service manual to inspect the wing handles, catches and ladders.

Contact

Manufacturer
Malin Wallström
Handicare AB

Tel: +46 (0)8-557 62 200

Email: customerservice@handicare.se

Device

What is affected:

- The spare part 'wing handles', article number 7322, delivered from June 2009 to July 2011 inclusive.
- Any ReTurn 7400 or ReTurn 7500 with the ladder attached to the chassis, delivered until May 2011, might have the affected wing handle (see [FSN](#) for further details).

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Health and Safety Executive
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)
- OFSTED (directors of children's services) for information
- Social services in England (directors)
- Special health authorities for information

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:

- Clinical governance leads
- Equipment libraries and stores
- Equipment stores
- Health and safety managers
- In-house maintenance staff
- Maintenance staff
- Nursing executive directors
- Occupational therapists
- Physiotherapists
- Risk managers
- Supplies managers
- Wheelchair service managers

NHS England area teams

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

- Occupational health departments

Social services

Liaison officers for onward distribution to all relevant staff including:

- Back care/manual handling advisors
- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Disability equipment stores
- Equipment stores
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers
- Occupational health departments
- Occupational therapists
- Transport managers
- Wheelchair and seating service managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector

Establishments registered with OFSTED

This alert should be read by:

- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

Malin Wallström
Handicare AB
Sweden

Tel: +46 (0)8-557 62 200

Email: customerservice@handicare.se

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/025** or **2014/003/024/081/029**

Technical aspects

Sara Vincent and Andy Marsden
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7169 or 7205

Fax: 020 8754 3965

Email: sara.vincent@mhra.gsi.gov.uk
andy.marsden@mhra.gsi.gov.uk

Clinical aspects

Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

Email: mark.grumbridge@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 523 900

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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

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

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate, Welsh Government

Cathays Park

Cardiff CF10 3NQ

Email: improvingpatientsafety@wales.gsi.gov.uk

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