

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/032

Issued: 30th April 2008

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Walking frames for adults and children manufactured by Trulife Limited.</p>	▶ ①
<p>Problem: The plastic height adjustment clips can fail, causing the user to fall.</p>	▶ ②
<p>Action by: All those involved in the provision and maintenance of walking frames. In particular: nurses, physiotherapists, occupational therapists and managers of equipment stores.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Trace all Trulife Limited walking frames manufactured from 02 April 2007 to 07 November 2007 that are in use or in storage. Contact Trulife Limited to arrange for the walking frames to be modified (see contact on page 3). 	▶ ④
<p>Distributed by NIAIC to:</p> <p>Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p> <p style="text-align: right;">Hospices</p>	▶ ⑤
<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>	
<p>Acknowledge Receipt of Alert: 2nd May 2008</p>	▶ ⑦
<p>Action Under Way: 16th May 2008</p>	
<p>Action Complete: 30th July 2008</p>	

This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

All standard models of walking frames manufactured by Trulife Limited from 02 April 2007 to 07 November 2007 (inclusive) with plastic height adjustment clips are affected. This includes models with or without wheels and walking frames with arm support troughs. All standard model product codes begin with RJ or RM.

Made to measure walking frames are not affected.

The manufacturer's name, product code and the date of manufacture can be found on the identification label on one of the front legs of the walking frame (see appendix).

2. PROBLEM:

In April 2007 Trulife Limited changed the metal clips used to set the height adjustment on all of their walking frames to a plastic clip. The MHRA has investigated reports of incidents where the plastic clips have either snapped in use or did not engage correctly, causing the frame to collapse and the user to fall.

In November 2007 Trulife Limited changed back to using metal adjustment clips.

Following investigation, the manufacturer has agreed to replace all plastic clips on frames already in use. Trulife Limited will arrange one of the following options:

- their engineers to modify the walking frames on site
- return of the walking frames to the factory to be modified
- supply of replacement clips and fitting instructions. (No tool is required and it is easy to replace the clips.)

3. ACTION BY:

All those involved in the provision and maintenance of walking frames. In particular: nurses, physiotherapists, occupational therapists and managers of equipment stores.

4. ACTION:

- Trace all Trulife Limited walking frames manufactured from 02 April 2007 to 07 November 2007 that are in use or in storage.
- Contact Trulife Limited to arrange for the walking frames to be modified (see contact on page 3).

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- All wards
- Clinical governance leads
- Equipment stores
- Health and safety managers
- Maintenance staff or contractors
- Nursing executive directors
- Occupational therapists
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Community hospitals
- Community nurses (children and adults)
- Nursing agencies
- Care management team managers
- Children's disability services
- Community care staff
- Independent Health and Social Care Providers – Private Hospitals & Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Brian Bradley
Trulife Limited
41 Amos Road
Sheffield S9 1BX

Tel: 0114 261 8100

Fax: 0114 261 0074

E-mail: sales@trulife.co.uk

Enquiries to NIAIC should quote reference number MDEA(NI)2008/32 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

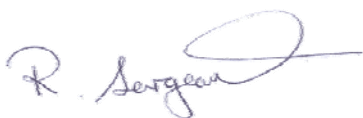
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
2nd May 2008

Action Under Way:
16th May 2008

Action Complete:
30th July 2008



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

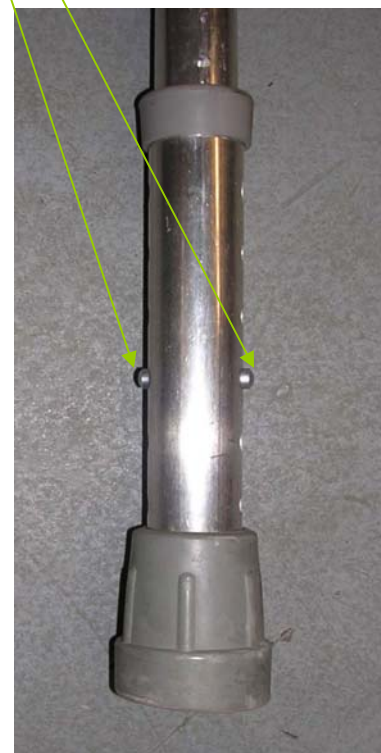
APPENDIX to MDEA(NI)2008/032



Identification label
with manufacture
date

Product Code

Manufacture
date



Height adjustment
clips