

Medical Device Alert

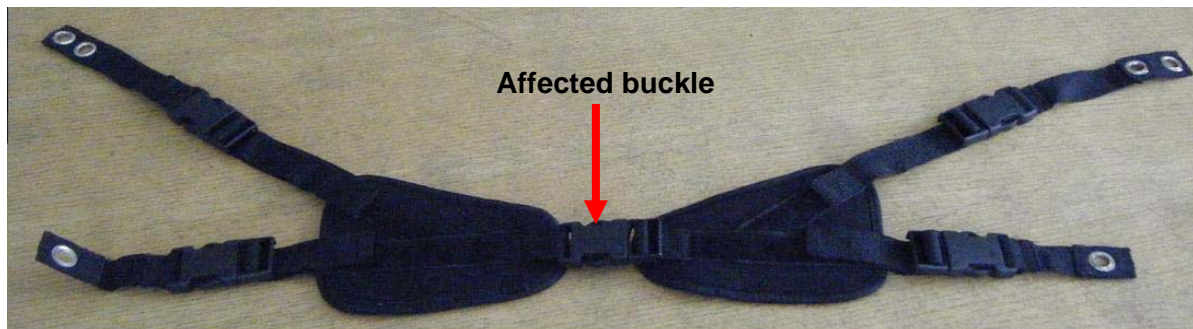
Immediate action

Ref: MDA/2009/022 Issued: 31 March 2009 at 11:00

Device

Posture belt manufactured by James Leckey Designs Ltd for use on their paediatric seating systems:

Mobile Advance Seat
 Contoured Advance Seat
 Squiggles Early Sitting System
 Squiggles Saddle Seat



Problem

The central plastic buckle degrades and can fail in use. This may result in the occupant falling from the seat and injuring themselves.

Action by

All involved in the provision, prescription, use and maintenance of the above equipment. In particular users/carers, occupational therapists, rehabilitation engineers, wheelchair and seating service managers, equipment store managers and maintenance staff/contractors.

CAS deadlines

Action underway: 07 April 2009
 Action complete: 28 April 2009

Action

1. Trace all affected seating systems supplied by the manufacturer between September 2007 and December 2008.
2. Contact James Leckey Designs Ltd to arrange for supply of a replacement belt (free of charge).
3. Arrange for the replacement belt to be fitted in accordance with the original instructions for use supplied with each seating system.

Contact

Manufacturer

Mr Stephen Robinson
 Customer Service Manager
 James Leckey Designs Ltd

Tel: 0800 318 265

E-mail: stephen.robinson@leckey.com

<http://www.mhra.gov.uk>

Device

These four-point fixing posture belts were supplied from September 2007 to December 2008 inclusive. The belts are used in the following seating systems with serial numbers from LEC/019910 to LEC/043681 inclusive.

Note: The serial number range is used across all models.



Mobile Advance Seat



Contoured Advance Seat



Squiggles
Early Sitting System



Squiggles
Saddle Seat

Problem

James Leckey Designs has identified a batch of posture belts that were supplied with buckles manufactured from plastic that degrades with use. The degradation would not be apparent to the user or carer until the buckle failed. The failure could result in the occupant losing postural support, falling from the seat and suffering serious injury.

James Leckey Designs has issued a [Field Safety Notice](#) to inform users of the need to obtain replacement belts. However, they do not have full traceability for all seating systems, especially where they have been passed on to second or subsequent users.

General information on the use of posture belts is also given in the MHRA's Medical Device Alert [MDA/2008/037](#).

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Commission for Social Care Inspection (CSCI) (Headquarters)
- Healthcare Commission (CHAI) (Headquarters)
- NHS Boards in Scotland (Chief Executives)
- OFSTED (Directors of Children's Services)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

Onward distribution

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

Trusts to:

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

- Equipment store managers
- Health and safety managers
- Maintenance staff and contractors
- Occupational therapists
- Paediatrics departments
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair and seating service managers

Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Domiciliary care providers
- Nursing agencies

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospices
- Hospitals in the independent sector

OFSTED to:

Directors of children's services for onward distribution to:

- Children's services
- Educational establishments with facilities for disabled children
- Residential special schools

Primary care trusts to:

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

- Community children's nurses
- Equipment store managers
- Health and safety managers
- Maintenance staff and contractors
- Occupational therapists
- Paediatric departments
- Physiotherapists
- Risk managers
- Wheelchair and seating service managers

Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Children's disability services
- Equipment stores managers
- In-house domiciliary care providers (personal care services in the home)
- Maintenance staff and contractors
- Occupational therapists
- Wheelchair and seating service managers

Change of address or removal from address list for CSCI and Healthcare Commission:

CSCI Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 0845 015 0120

E-mail: enquiries@csci.gsi.gov.uk

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

Contacts

Manufacturer

Mr Stephen Robinson
Customer Service Manager
James Leckey Designs Ltd
Kilwee Business Park
Dunmurry
Belfast
BT17 0HD

Tel: 0800 318 265

E-mail: stephen.robinson@leckey.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/022 or 2008/011/027/061/008.**

Brian Mather or Jonathan Smith
Medicines & Healthcare products Regulatory Agency
Centre for Assistive Technology
241 Bristol Avenue
Bispham
Blackpool
FY2 0BR

Tel: 01253 596 000

Fax: 01253 596 177

E-mail: brian.mather@mhra.gsi.gov.uk
jonathan.smith@mhra.gsi.gov.uk

Northern Ireland

Enquiries in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast

BT16 1US

Tel: 02890 523 704

Fax: 02890 523 900

E-mail: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

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

E-mail: iric@shs.csa.scot.nhs.uk

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

Wales

Enquiries in Wales should be addressed to:

National Assembly for Wales

HIMTE 3 Division

NHS Directorate

Cathays Park

Cardiff

CF10 3NQ

Tel: 029 2082 3373

Fax: 029 2082 5479

E-mail: Haz-Aic@wales.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>

MHRA is an executive agency of the Department of Health

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