

# Medical Device Alert

## Immediate action

Ref: MDA(NI)2009-022 Issued: 1st April 2009 10:00

### 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.

### SABS 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](mailto:stephen.robinson@leckey.com)

## 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



## 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 NIAIC's Medical Device/Equipment Alert [MDEA/2008/041](#).

## Distribution

The NIAIC has sent this MDA via SABS to:

- HSC Trust, HSS Board, and Agency's Chief Executive's
- HSC Trust, HSS Board, and Agency's SABS Liaison Officer
- Selected members of the DPSSPSNI
- Hospitals in the independent sector
- Hospices

## 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:

SABS 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
- Community children's nurses

### The Regulation and Quality Improvement Authority (RQIA) to:

Headquarters for onward distribution to:

- All Nursing and Residential Home providers
- Domiciliary care providers
- Independent treatment centres
- Nursing agencies

### Boards to:

SABS liaison officers for onward distribution to:

- Risk manager

### Central Services Agency (CSA) to:

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

- Staff with responsibility for purchasing

## 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](mailto:stephen.robinson@leckey.com)

**NIAIC**

Enquiries in Northern Ireland, please send enquiries about this notice to the NAIC quoting reference number **MDA(NI)2009-022** and addressed to:

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

Tel: 02890 523868  
Fax: 02890 523900  
E-mail: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)  
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

**How to report adverse incidents**

Incidents relating to medical devices in Northern Ireland must be reported to the Northern Ireland Adverse Incident Centre (NIAIC) as soon as possible.

Further information about reporting incidents can be found in DB(NI)2008-001; and downloadable report forms are available from the NIAIC's website (<http://www.dhsspsni.gov.uk/niaic>).

Alternatively, further information and printed incident report forms are available from: NIAIC at the address above.

(An answerphone service operates outside normal office hours)

**Medical Device Alerts are available in full text on the NIAC website**

Further information about SABS can be found at <http://sabs.dhsspsni.gov.uk>

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