

Arjo or Mechanoids Ambulift Hoists

The Medical and Healthcare products Regulatory Agency (MRHA) have issued the attached Medical Device Alert regarding Ambulift hoists manufactured by Arjo or Mechanoids.

SPC Managers should ascertain whether any such devices are being used on LSTRillium projects, and advise the responsible service providers to follow the action advised in the MRHA Alert.

Action to be taken:

SPC Manager:

- **Inform relevant Service Providers that the MRHA have issued this Device Alert**
- **Ascertain whether any Arjo or Mechanoid Ambulift hoists are in use on LSTRillium projects**
- **Ensure that the relevant Service Providers follow the advice provided in the MRHA Device Alert**

MEDICAL DEVICE ALERT

Issued: **03 March 2008 at 10:30**

Ref: **MDA/2008/010**

<input type="checkbox"/>	Immediate action
<input checked="" type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input type="checkbox"/>	Information request

Device: Ambulift hoist. All models manufactured by Arjo or Mechanaid.	► Page 2												
Problem: Risk of the occupant slipping from the seat during use.	► Page 2												
Action by: All those involved in the use of patient hoists, in particular nurses, care staff and moving and handling co-ordinators.													
Action: <ul style="list-style-type: none"> Trace all mobile and static Ambulift hoists. Contact Arjo Huntleigh to arrange supply of a safety seat belt and revised instructions for use. Arrange for the new seat belt to be fitted to all Ambulifts in use or in storage. Ensure all users are aware of the need to use the safety belt in accordance with the latest instructions for use. 													
Distributed to: <table> <tr> <td>NHS trusts in England</td> <td>- Chief Executives*</td> </tr> <tr> <td>OFSTED</td> <td>- Directors of Children's Services</td> </tr> <tr> <td>Commission for Social Care Inspection (CSCI)</td> <td>- Headquarters</td> </tr> <tr> <td>Healthcare Commission (CHA)</td> <td>- Headquarters</td> </tr> <tr> <td>Primary care trusts in England</td> <td>- Chief Executives*</td> </tr> <tr> <td>Social services in England</td> <td>- Directors*</td> </tr> </table> <p style="text-align: right;">* via CE Bulletin</p>	NHS trusts in England	- Chief Executives*	OFSTED	- Directors of Children's Services	Commission for Social Care Inspection (CSCI)	- Headquarters	Healthcare Commission (CHA)	- Headquarters	Primary care trusts in England	- Chief Executives*	Social services in England	- Directors*	► Page 2
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Contacts: Details of manufacturer contacts and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.	► Page 3												

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway) : 03 April 2008

Deadline (action complete): 03 June 2008

This notice is also on our website: <http://www.mhra.gov.uk>

Device:

All models of Ambulift mobile and fixed (static) hoists previously marketed as Mechanoids Ambulift, Arjo Mechanoids Ambulift or Arjo Ambulift. Arjo Huntleigh is the present manufacturer.

Problem:

The MHRA investigated a fatality involving an occupant being transferred into a bath using an Ambulift hoist. The tubular armrests fitted to the hoist which curve around the front of the occupant are hinged at the rear of the seat and do not have a positive lock to keep them in place during the hoist operation. The armrests pushed up allowing the occupant to slip down and out of the seat and sustain fatal injuries. The hoist operator was unable to stop the occupant sliding out. This incident could easily reoccur unless a safety device is fitted to all hoists.

The manufacturer has agreed to provide a new safety seat belt and updated instructions for use for all Ambulift hoists. The belt is anchored to the hoist behind the seat. The belt needs to be adjusted to suit the occupant before each hoist operation, in accordance with the new instructions for use. The new belt should be fitted to all Ambulift hoists to remove the possibility of the reoccurrence of a similar incident.

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:

- All wards
- Equipment stores
- Estates and facilities managers
- Health and safety managers
- Maintenance staff and contractors
- Moving and handling co-ordinators
- Nursing executive directors
- Nursing staff
- Occupational therapists
- Physiotherapists
- Purchasing managers
- Risk managers
- Safety officers

Primary care trusts to:

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

- Community equipment stores
- Community hospitals
- District nurses
- Estates and facilities managers
- Health and safety managers
- Maintenance staff and contractors
- Moving and handling co-ordinators
- Nursing staff
- Occupational therapists
- Physiotherapists
- Purchasing managers
- Risk managers

OFSTED to:

- Director of children's services for onward distribution
- Schools with facilities for the disabled

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospices
- Hospitals in the independent sector

Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Care homes

Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care homes
- Care management team managers
- Day centres
- Equipment stores
- Equipment supplies managers
- In-house residential care homes
- Loaned equipment store managers
- Maintenance staff and contractors
- Manual handling trainers
- Nursing staff
- Occupational therapists

Contacts:

Enquiries to the manufacturer should be addressed to:

Customer Support
Arjo Huntleigh
St Catherine Street
Gloucester
GL1 2SL

Tel: 08702 430 430
Fax: 01452 428 344

E-mail: uksales@arjo.co.uk

Enquiries to the MHRA should quote reference number **MDA/2008/010** or **2007/002/028/291/001** and be addressed to:

Technical aspects:

John Ward or Sharon Knight
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3232 / 3202
Fax: 020 7084 3209

E-mail: john.ward@mhra.gsi.gov.uk
sharon.knight@mhra.gsi.gov.uk

Clinical aspects:

Dr Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3123
Fax: 020 7084 3111

E-mail: susanne.ludgate@mhra.gsi.gov.uk

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

How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:
MHRA Adverse Incident Centre

Medicines and Healthcare products Regulatory Agency
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7084 3080 or Fax 020 7084 3109
or e-mail: aic@mhra.gsi.gov.uk

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: <http://www.mhra.gov.uk>

Further information about **SABS** can be found at www.info.doh.gov.uk/sar2/cmopatie.nsf