Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/004 Issued: 30 January 2019 at 11:00

Arjo Minstrel passive floor lift (portable hoist) – risk of spreader bar detachment from lifts WITHOUT a scale

Summary

Manufactured by ArjoHuntleigh AB – spreader bar may detach from the lift arm during patient transfer with the potential for serious injuries to the patient.

Action

Check which version of the spreader bar your lifts have, using the manufacturer's instructions in their Field Safety Notice (FSN).

If your device requires replacement, please **stop using it immediately, quarantine** it and contact Arjo UK.

If your device does **not** need replacement, fill in and return the customer response form in the FSN to Arjo UK to confirm this.

Action by
All those responsible for maintaining these medical devices.

Deadlines for actions
Actions underway: 27 February 2019
Actions complete: 29 July 2019

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Device details

Affected devices were manufactured between January 2008 and March 2010 inclusive, with serial numbers shown in Appendix A of the FSN. The label contains the manufacture date.

Manufacturer contacts

Arjo representative for the United Kingdom:
Arjo UK Ltd
Houghton Hall Business Park
Houghton Regis
Beds
LU5 5XF
Email: UKSSUComplaintHandling@arjo.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

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

- A&E departments
- A&E nurses
- Adult intensive care units
- All departments
- All staff
- All wards
- Clinical governance leads
- Community hospitals
- Equipment stores
- Equipment libraries and stores
- In-house maintenance staff
- Maintenance staff
- Medical libraries
- Occupational therapists
- Rehabilitation engineers
- Risk managers
- Supplies managers
- Theatres

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
- Education departments for equipment held in schools
- Environmental health officers
- 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
- Schools with hoists
- Transport managers
- Wheelchair and seating service managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED
- Children's services
- 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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/004** or **2018/011/023/601/005**.

Technical aspects
Dr Crina Cacou MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health, Social Services and Public Safety

Tel: 0208 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 250986 / 03000 255510

Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).