Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/020 Issued: 01 May 2019 at 11:30 Valid until: May 2020

Hoists: Molift Mover 180/205 mobile hoist and Molift Air ceiling hoist - all sizes of 2-point sling bars – risk of fracture of hooks in use

Summary

Manufactured by Etac and supplied in UK by R82 UK Ltd – if the hooks connecting the spreader bar to the hoist break during use, the patient could fall.

Action

- Identify affected devices, listed in the manufacturer's Field Safety Notice (FSN).
- Read the manufacturer's FSN so you know the risks and are aware of the correct use of the sling bar.
- Contact R82 UK Ltd for spare parts and follow their instructions for fitting and confirmation.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by

All those responsible for maintaining these medical devices.

Deadlines for actions

Actions underway: 30 May 2019
Actions complete: 26 June 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

The affected devices were supplied between May 2013 and October 2018 with the following item codes: 1430016, 1430017, 1430021, 1830001, 1830002, 1830002C, 1830003.

Problem / background

Several incidents have been reported to the manufacturer where the hooks on the spreader bar have broken during use. Investigation by the manufacturer has shown that the device was not being used appropriately at the time. As a result, the manufacturer has amended the instructions for use to clarify the correct use of these devices. The updated instructions are available from the manufacturer.

Additionally, a replacement spreader bar is to be supplied to customers who respond to the FSN.

Supplier and Manufacturer contacts

Supplier
Andrew Goode
R82 UK Ltd
Email: ago@R82.com
Tel: 07825 199 427

Manufacturer
Etac AS
Email: molift.qa@etac.com
Tel: +47 40001004

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:

- Community hospitals
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Health and safety managers
- Health visitors
- Hospital at home units
- In-house maintenance staff
- Maintenance staff
- Medical libraries
- Occupational therapists
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Supplies managers

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/2019/020 or 2019/002/028/487/035.

Technical aspects

Sara Vincent or 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).