MEDICAL DEVICE ALERT

Issued: **01 February 2007 at 11:00** Ref: **MDA/2007/009**

☐	**Immediate action**
☑	**Action**
☐	**Update**
☐	**Information request**

Device:
Beds rails and grab handles.

►Page 2

Problem:
Bed rails can successfully prevent falls, but their incorrect use has resulted in the deaths of bed occupants by asphyxiation due to entrapment.

►Page 2

Action by:
All those purchasing, supplying, selecting, using and maintaining bed rails and grab handles, especially in the community. This includes nursing staff, care at home staff, physiotherapists, occupational therapists, equipment stores managers and equipment purchasers.

Action:
- Obtain the latest MHRA guidance on the safe use of bed rails, DB 2006(06), (see links on page 2) and ensure that appropriate procedures are in place.
- Ensure that a risk assessment is carried out before the issue and use of the equipment. The assessment should include the needs of the occupant and the risks generated by the combination of the bed rails, grab handles, the bed and the mattress.
- Existing equipment combinations should also be reviewed to ensure that they are compatible with the bed, are properly fitted and maintained and do not have gaps or traps that may allow an occupant to become entrapped.
- Repeat the risk assessment if the equipment combination or the occupant's condition changes.

►Page 2

Distributed to:

NHS trusts in England	– Chief Executives*
Commission for Social Care Inspection (CSCI)	– Headquarters
Healthcare Commission (CHAI)	– Headquarters
Primary care trusts in England	– Chief Executives*
Social services in England	– Directors*

* via CE Bulletin

►Page 3

Contacts:
Details of 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): 14 March 2007	**Deadline (action complete): 01 June 2007**

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

Device:

Bed rails and grab handles used with beds in hospitals or in the community.

Problem:

Entrapment and asphyxiation of bed occupants has occurred in gaps present in bed rails and bed grab handles or created by the combination of bed rails or bed grab handles with a bed and mattress.

Bed rails are used extensively in care environments to prevent bed occupants falling out of bed and injuring themselves. They usually achieve this very successfully. However, MHRA continues to receive adverse incident reports of entrapment of bed occupants, which have included fatalities of children and adults.

The most common type of incident reported has involved care home residents becoming entrapped in divan type bed rails or when using a metal framed bed fitted with bed rails from a third party supplier.

Inappropriate, incorrect, poorly fitted or poorly maintained bed rails can produce gaps which do not prevent occupants slipping underneath, through or past the bed rail. These gaps can be large enough to allow part of the occupant to slip past or through the bed rail but are not large enough for them to pass fully through to the floor. The occupant then becomes wedged in the gap and, if not found in time, can suffer positional asphyxiation.

Risk assessment is key to ensure safe use. This starts with the bed occupant and includes the combination of the proposed bed rail or bed grab handle, the bed and the mattress (or mattresses where overlays are used). Existing combinations should also be reviewed to ensure that they are compatible with the user, the bed, and are properly fitted and maintained without gaps or traps that may allow an occupant to become entrapped.

The risk assessment is to be repeated if the bed, mattress, bed rail or condition of the occupant changes.

Purchasing procedures should ensure that only appropriate equipment is obtained. These procedures should include experience and knowledge gained from previous risk assessments and use.

Action:

This Alert replaces the following safety warnings:
SN 1999(36), HN 2000(10), SN 2001(11), SN 2001(35).

Two updated guidance documents have been produced. The Device Bulletin, DB 2006(06) ‘Safe use of bed rails’, is a detailed 30 page publication. This is complemented by a poster (size A2), designed for wall display in suitable locations.

Copies of the poster have recently been sent direct to all social, residential and nursing care providers.

Both publications are available free of charge from the MHRA website.

Hyperlinks (in PDF document):
Device Bulletin DB 2006(06), ‘Safe use of bed rails’, and **Poster, ‘Safe use of bed rails’**

To navigate from the MHRA home page:
www.mhra.gov.uk > Publications > Safety Guidance > Device Bulletins
www.mhra.gov.uk > Publications > Posters and leaflets

Alternatively e-mail **dts@mhra.gsi.gov.uk** or telephone 020 7084 3272.

Distribution:

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

Trusts to:

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

- All wards
- Clinical governance leads
- Equipment stores
- Estates departments
- Health and safety managers
- Maintenance staff
- Nursing executive directors
- Occupational therapy managers
- Physiotherapy managers
- Purchasing managers
- Risk managers
- Supplies managers

Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Equipment stores managers
- Equipment supplies and purchasing managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Occupational therapists

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Children's hospices
- Hospices
- Hospitals in the independent sector

Primary care trusts to:

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

- Community equipment stores
- Community nurses
- Maintenance staff

Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- All care homes (adults, older people and children)
- Domiciliary care providers
- Inspectors
- Residential special schools

Contacts:

Enquiries to the MHRA should quote reference number **2006/010/025/121/001** and be addressed to:

Technical aspects:
Andy Marsden or Simon Holmes
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Tel: 020 7084 3205 / 3240
Fax: 020 7084 3209

E-mail: andy.marsden@mhra.gsi.gov.uk
simon.holmes@mhra.gsi.gov.uk

Clinical aspects:
Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Tel: 020 7084 3128
Fax: 020 7084 3111

E-mail: jonathan.plumb@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

MHRA is an executive agency of the Department of Health