

# Medical Device Alert

## Action

Ref: MDA/2010/002

Issued: 05 January 2010 at 11:00

### Device

All types of bed mattresses.

### Problem

If mattress covers are damaged, body or other fluids can pass through and contaminate the inner core.

There is the potential for cross-infection if contaminated mattresses remain in use.

### Action by

All those responsible for the provision, inspection, use and maintenance of bed mattresses.

In particular: nurses, tissue viability staff, stores managers, care staff, decontamination managers, infection control staff and maintenance staff and contractors.

### CAS deadlines

Action underway: 12 January 2010  
Action complete: 05 March 2010

### Action

- Inspect the exterior surface of each mattress cover for signs of damage, such as holes or cuts.
- Remove the cover and inspect its inside surface and the mattress core for staining or contamination.
- Safely dispose of any covers showing signs of damage or staining.
- Arrange for contaminated mattress cores to be either: cleaned and decontaminated in accordance with the manufacturer's instructions; or safely disposed of.
- Ensure that a frequent inspection regime is established for all mattresses before and during use.
- Distribute the attached poster within your organisation.

## Problem

The MHRA has received numerous reports of damaged covers and associated interior mattress contamination.

Three Medical Device Alerts have already been issued on specific models:

[MDA/2007/065 - Hospital beds: Hill-Rom TotalCare Duo 2](#)

[MDA/2008/026 - Birthright birthing bed mattresses manufactured by Huntleigh Healthcare](#)

[MDA/2009/051 - Thermo contour mattress for hospital beds manufactured by Barrington Healthcare International Ltd](#)

Investigations have revealed that there is a widespread lack of inspection regimes that incorporate frequent checks for external damage and internal contamination.

Mattress covers can become damaged at any time during use or storage, for example from: needle stick; strike-through; damage from sharp objects; abrasion during handling, transport or movement; inappropriate cleaning and decontamination procedures.

If mattresses with non-removable covers are in use it is impossible to check the level of contamination on the inside.

## Action

A [poster](#) to help raise awareness of this problem is attached here as a PDF file, which should be distributed within your organisation. If you print the poster yourself, please print it in colour to show the contamination.

## Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- HSC trusts in Northern Ireland (Chief Executives) – for information only
- NHS Boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- OFSTED
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

### 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:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- All wards
- Day surgery units
- EBME departments
- Equipment store managers
- Infection control staff
- Infection prevention and control directors
- Intensive care units
- Maintenance staff and contractors
- Medical directors
- Nursing executive directors
- Purchasing managers
- Risk managers
- Tissue viability staff

**Care Quality Commission (CQC) (England only) to:**

The MHRA considers this to be important to:

- Care homes providing nursing care (adults)
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Infection control staff

**Primary care trusts to:**

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

- Community hospitals
- Community nurses
- Equipment store managers
- Infection control staff
- Maintenance staff and contractors
- Palliative care teams
- Tissue viability staff

**Social services to:**

Liaison officers for onward distribution to all relevant staff including:

- Equipment store managers
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Care staff
- Nursing staff
- Maintenance staff and contractors
- Infection control staff

**OFSTED to:**

The MHRA considers this to be important to:

- Residential special schools

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/002 or 2009/011/017/301/001**.

20 copies of the poster will be distributed to liaison officers in acute care trusts, PCTs and social services by the end of January 2010. Further copies are available from the Department of Health Orderline [www.orderline.dh.gov.uk](http://www.orderline.dh.gov.uk) – product code MATTRESS-POSTER. Alternatively download the PDF for local printing.

**Technical aspects**

Andy Marsden  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ  
Tel: 020 7084 3205  
Fax: 020 7084 3209  
E-mail: [andy.marsden@mhra.gsi.gov.uk](mailto:andy.marsden@mhra.gsi.gov.uk)

Brian Mather  
Medicines & Healthcare products Regulatory Agency  
Centre for Assistive Technology  
241 Bristol Avenue  
Bispham  
Blackpool FY2 0BR  
Tel: 01253 596 000  
Fax: 01253 596 177  
E-mail: [brian.mather@mhra.gsi.gov.uk](mailto:brian.mather@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](mailto:jonathan.plumb@mhra.gsi.gov.uk)

## How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Enquiries in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast BT16 1US

Tel: 02890 523 704

Fax: 02890 523 900

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 in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

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

## Scotland

The MDA referred to on page 2, [MDA/2007/065 - Hospital beds: Hill-Rom TotalCare Duo 2](#) has a Scottish equivalent Hazard Notice, issued on 5 Sept 2007: [HAZ\(SC\)07/14 Hill-Rom TotalCare® Duo 2® pressure relieving hospital beds: risk of cross infection](#).

Requests for copies of the poster should not be directed to MHRA. The poster should be downloaded from the MHRA website for local printing as described on page 3.

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

E-mail: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

National Assembly for Wales

HIMTE 3 Division

NHS Directorate

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3373

Fax: 029 2082 5479

E-mail: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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