

# Medical Device Alert

## Immediate action

Ref: MDA/2009/051 Issued: 03 August 2009 at 10:00

### Device

Thermo contour mattress for hospital beds.

Manufactured by Barrington Healthcare International Ltd.

Supplied by Hill-Rom.



### Problem

Due to a material fault some Thermo contour mattress covers have developed small holes, allowing fluids to pass through and contaminate the foam core.

There is a potential infection risk to patients if contaminated mattresses remain in use.

### Action

- Identify all Thermo contour mattress covers with lot numbers from 3162 to 3626 inclusive.
- Remove the cover and inspect the inside and the foam core for contamination.
- Mattresses with contaminated foam cores or damaged covers must be removed from use and replaced.
- Contact Hill-Rom to schedule the replacement of the remaining covers within the affected lots.

### Action by

All those using, providing and maintaining hospital beds. In particular: infection control staff, nurses, maintenance staff and contractors.

### Contact

**Supplier**  
Hill-Rom

Tel: 01530 562 167

E-mail: [uk.customer.care@hill-rom.com](mailto:uk.customer.care@hill-rom.com)

### CAS deadlines

Action underway: 10 August 2009

Action complete: 24 August 2009

[Link to full Medical Device Alert](#)

## Problem

The mattress manufacturer (Barrington Healthcare International Ltd) has identified that there is a problem with premature ageing of the material used to make the covers supplied with Thermo contour mattresses purchased after March 2007 with lot numbers from 3162 to 3626.

The lot number is clearly marked on the cover, circled in red in the photograph.



Barrington Healthcare has arranged for replacement mattresses and covers to be manufactured and delivered to Hill-Rom, which is the sole UK supplier. If, following inspection, the numbers of contaminated mattresses and covers are greater than the manufacturer's production capacity, local action may be required. Risk management and infection control teams should work with Hill-Rom to establish an appropriate plan of replacement including safe storage and appropriate disposal of contaminated mattresses. This may necessitate using mattresses from other manufacturers.

Trusts should ensure that appropriate audit procedures are in place and are used to routinely inspect all mattresses and their covers for damage and 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)
- 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 stores
- Infection control nurses
- Infection prevention and control directors
- Intensive care units
- Maintenance staff and contractors
- Medical directors
- Nursing executive directors
- Purchasing managers
- Risk managers

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

The MHRA considers this to be important to:

- Care homes providing nursing care (adults)
- FECs registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

**Primary care trusts to:**

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

- Community hospitals
- Community nurses
- Equipment libraries and stores
- Infection control nurses
- Maintenance staff and contractors

**Social services to:**

Liaison officers for onward distribution to all relevant staff including:

- Equipment stores
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Maintenance staff and contractors

## Contacts

Hill-Rom

Tel: 01530 562 167

E-mail: [uk.customer.care@hill-rom.com](mailto:uk.customer.care@hill-rom.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/051** or **2009/004/024/401/016**.

**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](mailto:andy.marsden@mhra.gsi.gov.uk)  
[simon.holmes@mhra.gsi.gov.uk](mailto:simon.holmes@mhra.gsi.gov.uk)

**Clinical aspects**

Jonathan Plumb

Medicines & Healthcare products Regulatory Agency

Market Towers

1 Nine Elms Lane

London SW8 5NQ

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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

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports 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

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:

Dr Jane Ludlow

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3505 / 3922

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

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