

# MEDICAL DEVICE ALERT

Issued: **22 December 2008 at 15:00**

Ref: **MDA/2008/088**

<input checked="" type="checkbox"/>	<b>Immediate action</b>
<input type="checkbox"/>	<b>Action</b>
<input type="checkbox"/>	<b>Update</b>
<input type="checkbox"/>	<b>Information request</b>

<b>Device:</b> Oxford disposable slings supplied by Joerns Healthcare.	▶ Page 2														
<b>Problem:</b> The sling material can tear resulting in the occupant falling out of the sling.	▶ Page 2														
<b>Action by:</b> All those involved in the supply, maintenance or use of these slings, in particular: nurses, care staff and maintenance staff or contractors.															
<b>Action:</b> <ul style="list-style-type: none"> <li>Trace all Oxford disposable slings.</li> <li>Immediately remove the slings from use.</li> <li>Contact Joerns Healthcare for further instruction on 01384 446 622.</li> </ul>															
<b>Distributed to:</b> <table border="0"> <tr> <td>NHS trusts in England</td> <td>– Chief Executives*</td> </tr> <tr> <td>OFSTED</td> <td>– Directors of Children’s Services</td> </tr> <tr> <td>Commission for Social Care Inspection (CSCI)</td> <td>– Headquarters</td> </tr> <tr> <td>Healthcare Commission (CHAI)</td> <td>– Headquarters</td> </tr> <tr> <td>Primary care trusts in England</td> <td>– Chief Executives*</td> </tr> <tr> <td>Social services in England</td> <td>– Directors*</td> </tr> <tr> <td>NHS Boards in Scotland</td> <td>– Chief Executives</td> </tr> </table> <p style="text-align: right;">* via CE Bulletin</p>	NHS trusts in England	– Chief Executives*	OFSTED	– Directors of Children’s Services	Commission for Social Care Inspection (CSCI)	– Headquarters	Healthcare Commission (CHAI)	– Headquarters	Primary care trusts in England	– Chief Executives*	Social services in England	– Directors*	NHS Boards in Scotland	– Chief Executives	▶ Page 2
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<b>Contacts:</b> Details of manufacturer contacts and contacts for technical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.	▶ Pages 2-3														
<b>Appendix:</b> Joerns Healthcare – urgent Field Safety Notice.	▶ Pages 4-6														

### Action deadlines for the Central Alerting System (CAS)

**Deadline (action underway): 29 December 2008**

**Deadline (action complete): 12 January 2009**

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

## Device:

All Oxford disposable slings. They have been supplied since December 2006.

## Problem:

The material can tear in use without warning leading to a fall for the occupant. Even barely visible damage to the material can lead to a serious failure.

The manufacturer has issued a Field Safety Notice stating that these slings must be immediately withdrawn from use (see appendix). The manufacturer cannot provide an alternative sling replacement in all cases but will arrange an appropriate reimbursement.

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

- All wards
- Equipment stores managers
- Health and safety managers
- Maintenance staff and contractors
- Moving and handling co-ordinators
- Nursing executive directors
- Nursing staff
- Occupational therapists
- Physiotherapists
- Purchasing managers
- Risk manager
- Safety officers

### Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospices
- Hospitals in the independent sector

### Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Domiciliary care providers
- FECs registered as care homes
- Nursing agencies

### OFSTED to:

Directors of children's services for onward distribution to:

- Residential special schools

### Primary care trusts to:

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

- Community equipment stores
- Community hospitals
- District nurses
- Health and safety managers
- Maintenance staff and contractors
- Moving and handling co-ordinators
- Nursing staff
- Occupational therapists
- Physiotherapists
- Risk managers

### Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care homes
- Care management team
- Day centres
- Equipment stores managers
- In-house residential care
- Maintenance staff and contractors
- Moving and handling co-ordinators
- Nursing staff
- Occupational therapists
- Risk managers

## Contacts:

### Enquiries to the manufacturer should be addressed to:

Joerns Customer Services Department  
High Street  
Wollaston  
West Midlands DY8 4PS

Tel: 01384 446 622

Fax: 01384 446 601

E-mail: [info@joerns.co.uk](mailto:info@joerns.co.uk)

## **Contacts (continued):**

Enquiries to the MHRA should quote reference number **MDA/2008/088** or **2008/012/011/301/002** and be addressed to:

Jonathan Smith or 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: [jonathan.smith@mhra.gsi.gov.uk](mailto:jonathan.smith@mhra.gsi.gov.uk)  
[brian.mather@mhra.gsi.gov.uk](mailto:brian.mather@mhra.gsi.gov.uk)

### **Enquiries for Scotland should be directed 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: [iric@shs.csa.scot.nhs.uk](mailto:iric@shs.csa.scot.nhs.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

Healthcare Commission  
Finsbury Tower  
103-105 Bunhill Row  
London EC1Y 8TG

Tel: 0845 015 0120

Tel: 020 7448 0842

E-mail: [enquiries@csci.gsi.gov.uk](mailto:enquiries@csci.gsi.gov.uk)

E-mail: [contacts@healthcarecommission.org.uk](mailto: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](mailto: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 **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

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Addressees may take copies for distribution within their own organisations

## **Urgent Field Safety Notice (FSN)**

### **OXFORD Disposable Slings.**

**FSN Reference: 000005**

**Type of action: Immediate withdraw from use – Return to Manufacturer**

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Date: 17<sup>th</sup> December 2008

**Attention:** All distributors, installers, therapists, carers and users of OXFORD Disposable Slings

#### **Details on affected devices:**

All the OXFORD Disposable Slings to be used with hoist products.

#### **Description of the problem:**

Following reports of an injury to a patient who had fallen from a disposable sling. Investigations have shown that the sling material can tear during normal use if damaged. Please note that this damage may not be observed by the carer whilst conducting a patient transfer.

If the sling material does tear or becomes punctured during handling or repositioning of a patient, it may cause a potential risk to the patient and/or carer since it could compromise the structural integrity of the sling.

In view of the potential risk to patient and carer, Joerns Healthcare has taken the decision to withdraw all Oxford disposable slings until further notice.

#### **Action to be taken by the therapist/carer/user:**

Identify all OXFORD disposable slings currently in circulation or in use.

#### **Immediately withdraw all Oxford Disposable Slings**

##### **For all OXFORD disposable slings currently in use:-**

- Cut out the label as proof of purchase and send to Joerns Healthcare. Decommission and then dispose of the sling.
- Upon satisfactory receipt of the labels, Joerns Healthcare will arrange an appropriate reimbursement.

##### **For all unused or unopened OXFORD disposable slings:-**

- Contact Joerns Healthcare to arrange collection of all unused/unopened disposable slings.
- Upon satisfactory receipt of the slings, Joerns Healthcare will arrange an appropriate reimbursement.

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### In all cases:-

- Confirm your understanding and compliance to this FSN by completing the enclosed FSN Receipt Form and return it to Oxford Customer Services dept. as instructed.

### Transmission of this Field Safety Notice (FSN):

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. This includes a copy of the FSN Receipt Form.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

### Contact reference person:

Nigel Heales CEng MIMechE  
Quality and Technical Manager  
Joerns Healthcare Ltd  
Tel: +44 (0)1384 446751  
Fax: +44 (0)1384 446601

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency

This FSN will be made available on the MHRA website ([www.mhra.gov.uk](http://www.mhra.gov.uk))

Additional contact information: Oxford customer services dept. +44 (0)1384 44 66 22 or via email [infor@joerns.co.uk](mailto:infor@joerns.co.uk)



Nigel Heales CEng MIMechE  
Quality and Technical Manager

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## FSN Receipt Form

URGENT FIELD SAFETY NOTICE: Ref No. 000005

Date: 17<sup>th</sup> December 2008

Re: Oxford Disposable Slings – Withdrawal from use.

Joerns Healthcare requires your acknowledgement as confirmation that you have received (and understood) the important safety information contained within the above Field Safety Notice (FSN). Please complete the details below (**print clearly**): -

I, \_\_\_\_\_, acknowledge I am in receipt of the above FSN and that the information contained within this FSN has been communicated to all users who I /or my company have supplied the above products to. (This includes spares)

*(If required, this blank form may be copied and distributed to end users as part of your management activity in communicating this FSN)*

In respect of this product, I am the:-

Please specify: \_\_\_\_\_ (carer, partner, relative, friend, dealer etc)

Organisation/Facility Name: \_\_\_\_\_

Address (include post code): \_\_\_\_\_

\_\_\_\_\_

Collection of Disposable Slings required? (if yes how many?) **YES/NO** Qty: \_\_\_\_\_.

The information forwarding has been completed.

Date completed: \_\_\_/\_\_\_/\_\_\_

Completed by (Print): \_\_\_\_\_

Signature: \_\_\_\_\_

Please return this completed form to Joerns Healthcare Ltd  
by faxing to **01384 446601** or emailing to: [nigel.heales@joerns.co.uk](mailto:nigel.heales@joerns.co.uk)

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