

Urgent Field Safety Notice (FSN)

OXFORD Slings – Updated User Guides

FSN Reference: **000007**

Type of action: **Guidance for correct usage information**

Date: **11th November 2009**

Attention: All distributors, installers, therapists, carers and users of OXFORD slings.

Details on affected devices:



OXFORD slings - all types

Description of the problem:

Following an incident which resulted in a patient injury, investigations identified that the risks in using the sling and method of use had not been fully identified.

In reviewing the current User Guides provided with each sling and in keeping with continually improving products and the information provided, the following information has been added.

1.

	<p><i>For the safety of the patient and carer; before using a sling a full risk assessment must be conducted to ensure that the correct sling choice, method of positioning in the sling and procedure for transfer has been determined for the patient.</i></p> <p><i>Check sling before each use. Bleached, torn, cut, frayed or broken slings are unsafe and could result in serious injury or death to the patient.</i></p> <p><i>Destroy and discard worn slings. Do not alter slings.</i></p> <p><i>Never leave a patient unattended.</i></p>	
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2. For slings where an alternative seated position is identified in the User Guide, the following additional warning has been added.



There is an increased risk of slipping out of the sling using this method of transfer. Assess the patient's capabilities carefully.

Additional Important Safety Information

Following Medical Device Alerts on other manufacturers' slings, it is important that users of Oxford Slings always follow the instructions in the User Manuals provided with each sling and also the labels which are stitched into each Oxford sling.

In particular, it is critical to the safety of the patient that the sling is checked each and every time prior to use. Failure to do so may result in patient injury.

If any of the following faults are identified, the sling should not to be used and destroyed:

- There are signs of general wear and tear.
- There is loose or broken stitching on any part of the sling (including the straps)
- There are worn areas on the attachment points.
- There are discoloured areas
- There are areas of frayed or torn material
- There are areas of bleached material
- The label is illegible

Inspection is required on all areas of the sling. The following information provides some guidance on key areas for inspection:

	<p>Example of an Oxford Sling.</p> <p>Key areas for inspection include:</p> <ol style="list-style-type: none"> 1. Sling strap attachment point 2. Seams 3. Handle attachment points 4. End loops on sling straps
	<p>Stitching on the sling straps on the sling body should be secure.</p> <p>Stitching is cross-stitched and not to be frayed.</p>  <p>Cross-stitching</p>

	<p>Typical seam stitching.</p> <p>Photograph shows example of correct stitching in place and not frayed.</p>	
	<p>Typical stitching on the main body of the sling.</p> <p>Photographs shows example of correct stitching in place and not frayed.</p>	
	<p>Attachment of the strap to a net style sling.</p> <p>Example of correct stitching on the colour binding.</p>	
		<p>Stitching of the end loops on the sling straps.</p> <p>Stitching is cross-stitched and not to be frayed.</p> <p>Ensure end loops are not worn or frayed.</p>

Cleaning Instructions are clearly detailed in the User Manual and on the label stitched on the back of the sling. Failure to follow these instructions may result in the sling becoming damaged and unsafe for use.

Action to be taken by the distributor/installer:

- Communicate this Field Safety Notice to all end users that have been provided the Oxford slings.
- When installing any Oxford product identify that the requirements specified in the User Guides supplied with the slings are to be followed.

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

- Read, understand and communicate this Field Safety Notice and instructions for use to all persons involved with using an Oxford Sling.
- To confirm your understanding and compliance to this FSN, complete the FSN Receipt form enclosed, and return it to Oxford Customer Services dept. as instructed.

Transmission of this Field Safety Notice:

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 any 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)

Additional contact information: Oxford Customer Services dept. +44 (0)1384 44 66 22 or via email info@joerns.co.uk



Nigel Heales CEng MIMechE
Quality and Technical Manager

FSN Receipt Form

URGENT FIELD SAFETY NOTICE: Ref No. 000007

Date: 11th November 2009

Re: OXFORD Slings – Updated User Guides

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, _____ (Name), 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/provided 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 (if applicable): _____

Address: _____

_____ Post Code: _____

The information forwarding has been completed.

Date completed: ___/___/___

Completed by (Print clearly): _____

Signature: _____

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

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