

Urgent Field Safety Notice (4th February 2015)

This potentially affects all slings manufactured by Mackworth Healthcare Limited. Please note that this notice is designed to draw attention to all slings, their relative fittings and the essential reference to the use of the Mackworth Healthcare General User Safety Guide and Individual Product Instructions.

FSCA-identifier (4th February 2015)

Type of action (Advice regarding safe use of the device - In line with MEDDEV 2.12-1 rev 8 - Section 4.6 FSCA).

Date: 4th February 2015

Attention: All relevant Directors & Managers responsible for implementation and acknowledgment of Field Safety Notices.

Details on affected devices:

All Mackworth Healthcare Ltd Slings when fitted with a DOSEC clip fitting.

i.e: Oak, Elm, Yew, Hazel, Willow, Maple, Holly, Poplar, Pine, Beech, including all variants e.g Universal with head, Junior range.

For more product information please refer to our website <http://www.mackworth-healthcare.com>

Description of the problem:

This FSN has been issued as a result of an incident that has occurred whilst a patient handling sling was in use, which is still under investigation.

Mackworth Healthcare Ltd are pro-actively issuing this Field Safety Notice in order to raise general awareness of the need to ensure that appropriate product equipment checks are completed, i.e. sling and hoist compatibility, both prior to ordering and essentially before use. In addition, appropriate moving and handling plans need to be in place prior to using any of this type of equipment. May we draw attention as a guide only to all Directors and Managers of any organisation to the following legislation and remind all users of their own obligations with regards to safe use and servicing of this type of equipment (slings & hoists are classified as lifting equipment):

LOLER (Lifting Operations & Lifting Equipment Regulations) 1998
Manual Handling Operations Regulations 1992 (MHOR) as amended 2002
Health & Safety at Work Act 1974 (HSWA)

Advise on action to be taken by the user:

To re-inforce awareness, a detailed General User Safety Guide has been produced to improve understanding and to encourage the safest possible use of our products. A copy of this guide has been sent out with this communication and accompanies all sling orders from November 2014. All product specific user guides have also been updated with an additional statement in the "Prior To Use" section on the front page, i.e:

"Please ensure that these User Instructions and the General User Safety Guide are read prior to first use of any moving and handling practice. Mackworth Healthcare Ltd recommend that prior to using any sling, a full risk assessment must be completed by a qualified professional,

in order to determine that the correct sling, positioning and transfer procedure is suitable for each individual.”

All product specific user guides have also been updated to now refer to the use of both loop and clip fittings on all slings, as follows:

Prior To Use text now states:

“Ensure you are aware of the hoist manufacturer's fitting instructions. Please identify if the hoist requires a loop or clip fitting. If a clip fit sling is required, please refer to the enclosed clip instructions for use. (Do NOT use a clip fit sling on a loop designed spreader bar. Do NOT use a loop designed sling on a stud/clip designed spreader bar.) For all other sling information/clip & hoist size compatibility, please refer to pages 8 & 9 of the General User Safety Guide. To view our clip fitting video please visit: www.mackworth-healthcare.com/training. For general guidance for how to fit a sling, please visit: www.mackworth-healthcare/category/guides.”

Instructions For Use text now states, where applicable:

“With the sling now in place, attach the desired loops to the hooks or clips to the studs on the spreader bar to replicate the sitting position that the user is in whilst seated.”

Mackworth Healthcare have always provided users with guides and instructions for use in accordance with EN10535. However, it is important that this information is both available and importantly understood by users prior to putting the equipment into use. This information should be kept on file and made accessible to all users during the products life.

In order to achieve best practice and of course follow health and safety guidelines, Mackworth recommends that a thorough risk assessment and pre inspection of product suitability is conducted prior to the use and application of all manufacturers sling or patient handling devices.

It is very important that every user inspects the sling or lifting device thoroughly before each and every use, regardless of the age of product. You must ensure that particular attention is paid to the sling body, all lifting points, loop and or clip fittings and of course any sewing and relative labelling involved within the product is fit for use. If you are in any doubt about the standard of the sling, or have not received appropriate training from your employer, do not use. In the instance of identifying a defective product, please place the product aside (where it cannot accidentally be used by others) and mark DO NOT USE or destroy accordingly.

Training videos and guides are also available at the bottom right section of the home page (under all education sections) on the Mackworth Website: www.mackworth-healthcare.com.

FSN receipt form – This is to be completed and returned to Mackworth Healthcare to acknowledge end user receipt and full understanding of this FSN.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

For further information or for a relevant contact reference person within Mackworth Healthcare (The manufacturer), please contact Lee Reeves (Director) on 0800 779 7218 or as below.

Mrs Rhianydd Smith – Head of Marketing & Communications



Mackworth Healthcare Ltd,
Mackworth House
Millers Avenue
Brynmenyn Industrial Estate
Brynmenyn, Bridgend
Wales, CF32 9TD

Tel +44 (0) 800 779 7218 or visit the website at www.mackworth-healthcare.com.

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

Signature:

A handwritten signature in dark ink, appearing to read "Rhianydd", is written on a light yellow rectangular background.

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Receipt Confirmation

I confirm that I have read and understood the information contained in the Field Safety Notice referred to above and have passed it on to appropriate individuals in my organisation.

Company:

Address:

Position:

Signature:

Date:

Please scan the signed receipt and e-mail to:

rhianydd.smith@mackworth-healthcare.com

Alternatively, please sign and return this receipt within 30 days to:



Mrs Rhianydd Smith – Head of Marketing & Communications

Mackworth Healthcare Ltd,
Mackworth House,
Millers Avenue,
Brynmenyn Industrial Estate,
Brynmenyn,
Bridgend,
Wales
CF32 9TD

Tel +44 (0) 800 779 7218

Fax +44(0) 1656 721 918

www.mackworth-healthcare.com