Joerns Healthcare Limited
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Urgent Field Safety Notice (FSN)

OXFORD Easytrack 2, 3 & 4 Post Systems Installation & Repositioning and Maintenance & Inspection requirement.

FSN Reference: 000015

Type of action: Device Modification

Date: 8th April, 2011

Attention: All Distributors, Installers, Service Providers and End Users of Oxford Easytrack 2, 3 & 4 Post Systems.

Details on affected devices:

Easytrack 2 Post - VOY-700.9220010

Easytrack 2 Post with Lower Rail - VOY-700.9225010

Easytrack 3 Post - VOY-700.9330010

Easytrack 4 Post - VOY-700.9440030

Easytrack 2 with Post & Wall Bracket - VOY-700.9211010

Easytrack 2 with Post & Bath Bracket - VOY-700.9220110

Easytrack 3 with Two Posts & Wall Bracket - VOY-700.9321010

Easytrack 3 with Two Posts & Bath Bracket - VOY-700.9330110

Description of the problem:

There has been a reported incident of an Easytrack 3 Post system collapsing whilst repositioning the system to another location of a room.

It should be noted that, if all of the above highlighted products are installed or repositioned in accordance with the revised User Instruction manual, there is no potential risk to Users or Patients from the systems collapsing.

To minimise any potential risk of any Easytrack systems collapsing after repositioning, the actions listed in this FSN should be carried out as soon as possible.

This FSN falls into two categories:

- 1. Installation & Repositioning of Oxford Easytrack systems.
- 2. General requirements of Inspection and Maintenance of Oxford Easytrack systems.

Failure to comply with the requirements on Installation & Repositioning and Inspection & Maintenance outlined in this FSN may result in patient and/or carer injury.



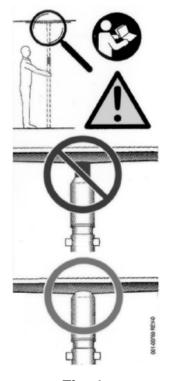
1. Installation & Repositioning of Oxford Easytrack systems:

The person who carries out either the initial **installation** or **subsequent repositioning** of Oxford Easytrack systems with compression posts (See relevant products and part numbers in **Details on affected devices** above) **must** ensure that the systems are erected in strict accordance with both the detailed User Instruction manual for that product and the recently added safety decals which are to be affixed to each Post. (See Fig. 1 below)

Particular attention must be paid to the recent addendum to the User Instructions (See Fig. 2 below) which details the correct installation instructions for assembly of the vertical posts to achieve to required compression on the Top Plate.

Note: The latest User Instruction manual for each particular product, which includes the recent addendum, is available to download from the Joerns Healthcare website or alternatively, can be requested by contacting Joerns Healthcare After Sales Department **(See address below)**

The self adhesive safety decals which **must be affixed** to each vertical post can be requested by contacting Joerns Healthcare After Sales Department (**See address below**)







This safety label, (see Figure 8)
apposed on each post, is to remind that
the red zone on top of each post must not
be visible when the system is assembled.

Never use the Easytrack system when a red mark is visible.

Fig. 2

The above instruction shown in Fig.2 is an extract from the recently revised User Instruction Manual (See Figure 4) for Easytrack Bath Adaptor.





2. General Inspection & Maintenance

The following requirements are in addition to LOLER (The Lifting Operations and Lifting Equipment Regulations 1998)

The following activities are to be carried out by an Authorised Oxford Dealer. Using an Authorised Servicing Dealer will ensure that Oxford products are serviced and maintained appropriately.

In line with the User Instruction Manuals for Oxford Hoists, a thorough inspection and test is to be carried out at least every six months.

All Users must ensure their hoists are adequately maintained and inspected by a competent person authorised to service the hoist, and in accordance with the manufacturer's instructions.

For further guidance, refer to the Easytrack User Manual for the particular product. The User Manual identifies the requirements for Daily & Monthly Checks and Maintenance of the products.

The **Service Provider** is required to inspect Easytrack installations to ensure they have been installed or repositioned in accordance with the User Instruction manual.

Particular attention must be paid to the recent addendum to the User Instructions (See Fig. 2 above) which details the correct installation instructions for assembly of the vertical posts to achieve to required compression on the Top Plate.

Note: The latest User Instruction manual for each particular product, which includes the recent addendum, is available to download from the Joerns Healthcare website or alternatively, can be requested by contacting Joerns Healthcare After Sales Department **(See address below)**

Additionally, the **Service Provider** is required to ensure Easytrack installations have the **safety decals (See Fig. 1 above)** affixed to each vertical post.



Action to be taken by the Distributor/Installer:

- Dealers/Installers should ensure that Easytrack systems have been installed or repositioned to comply with the requirements of this communication, as described above, as soon as possible, without undue delay.
- Dealers/Installers should ensure that the safety decals are affixed to all vertical posts. Again, this should be carried out as soon as possible, without undue delay. Safety decals are available to order free of charge by contacting Joerns Healthcare After Sales Department. (See address below)
- IMPORTANT: Please ensure to communicate this Field Safety Notice to all end user/customers that have been supplied Easytrack systems with compression posts highlighted in Details on affected devices above.

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

- If it is suspected any Easytrack system has not been installed or repositioned in accordance with the User Instruction manual, DO NOT USE THE HOIST and notify your Service Provider immediately. The hoist should not be used until the required Safety Checks have been carried out.
 - Maintain the hoist in line with User Instruction Manuals (in addition to LOLER).
 - Comply with the Health & Safety at Work Act which refers to current UK Legislation of LOLER (The Lifting Operations and Lifting Equipment Regulations 1998)
 - Compliance to LOLER examination and certified testing carried out by authorised service dealers. Details of you local Authorised Oxford Service Dealer can be obtained by contacting our Customer Services Department on 08448 111 158.
 - Carry out daily & monthly checks on the product in accordance with the instructions in the User Manual. User Manuals can be downloaded from the Joerns Website or obtained by contacting Customer Services.

Transmission of this Field Safety Notice:

This notice needs to be forwarded to 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.

It is the responsibility of the Distributor / Installer to communicate receipt of this FSN to any Organisation which the product may have been sold or transferred to.

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

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Joerns Healthcare After Sales Department:

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e-mail: info@joerns.co.uk

Fax: +44 (0)1905 111 157

e-mail: robert.ordish@joerns.co.uk

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

Rob Ordish **Technical Support Engineer**







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Receipt Form

URGENT FIELD SAFETY NOTICE: Ref No. 000015

Date: 27th May 2011

Re: Maintenance and Inspection of Products

Section A – Dealer to Complete and return to Joerns Healthcare (Address at foot of page)

If you have received or supplied the above products relating to FSN 000015 the following applies to you:

Joerns Healthcare requires your acknowledgement (in return of this completed form) 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 NAME) | , of (Name of Dealershi | nip :) | |
|---|-----------------------------|---|-----|
| Address: | | | |
| County: | Post Code: | Tel Number: | |
| been communicated to all r | | t the information contained within this FSN lany/organisation who are affected by the information to third parties. | has |
| communicated to end use our organisation. | ers / establishments who ha | mation and a copy of the FSN have been ave been supplied the above products by | y |
| complete and return to Jo | perns Healthcare (Address a | Frust Establishment, Service Agent etc. t at foot of page) | 0 |
| - | | ition: | |
| | | | |
| | Post Code: | | |
| The information forwarding | has been completed. | | |
| Completed by (Print): | | | |
| Signature: | | | |

Please return this completed form to Joerns Healthcare Ltd by faxing to **08448 111 157** or emailing to: chris.wassell@joerns.co.uk

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