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Field Safety Notice (FSN)

OXFORD ADVANCE - Security of Base Fasteners

FSN Reference: 000016

Type of action: Apply at next scheduled 6-monthly LOLER Inspection

Date: 11th February 2013

Attention: All Distributors, Installers & Service Providers of Oxford Advance hoists.

Details on affected devices:

Oxford Advance manufactured prior to July 2010 only (Prior to serial number **1007L0001**)

Description of the problem:

This relates to a previous Technical Bulletin 0155 distributed 26th May, 2006.
Maintenance/Service Notice - Oxford Pro' Series 'Advance & Arise'

RE: Visual Check: Centre base plate attachment

Two reported incidents have occurred since the product was first released in December 2004, where the upper base casting has fractured.

The looseness or removal of the four screws that locate the base plate to the upper base casting may allow the base casting to be distorted or weakened under load and possibly fracture if excessive force is applied.

Prevention of risk can be applied through scheduled maintenance to ensure all relevant fasteners are secure.

Joerns Healthcare recommends that the four base plate screws are replaced (as per the work instruction attached), at their next scheduled 6-monthly LOLER inspection.

Support from Joerns Healthcare:

Joerns Healthcare will supply all dealers who have purchased Oxford Advance product with a supporting quantity of screw fasteners in order to carry out this important service upgrade, along with a copy of the FSN and accompanying Receipt Form to be completed and returned to Joerns Healthcare on completion of the upgrade at the next scheduled LOLER inspection.

Action to be taken by the distributor/installer:

- Communicate this Field Safety Notice to all end users that you have identified as having been supplied an Oxford Advance hoist with a manufacturing date prior to July 2010.
- The date of manufacture and serial number is printed on a black decal, located behind the rear left hand castor wheel of the blue base assembly.
- Communicate the need to arrange for the FSN upgrade to be applied as part of the next scheduled LOLER inspection.
- Private customers will need to be notified to have their Oxford Advance product checked and upgraded as soon as possible, if not party to a 6-monthly LOLER maintenance programme.
- The four upgraded screw fasteners only need to be applied once.
- Complete the FSN Receipt Form and return it to Joerns Healthcare.

Action to be taken by the service provider:

- Communicate this Field Safety Notice to all end users that have been supplied an Oxford Advance hoist with a manufacturing date prior to July 2010.
- Communicate the need to arrange for the FSN upgrade to be applied as part of the next scheduled LOLER inspection.
- Complete the FSN Receipt Form and return it to Joerns Healthcare.

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

- Always conduct daily checks recommended in your user guide prior to using your Oxford Advance hoist.
- Identify the serial number of the hoist and contact your Distributor/Supplier/Service Provider with this information.
- Register your requirements with your Authorised Distributor/Supplier/Service Provider to enable the upgrade to be conducted at your next scheduled LOLER inspection.

Transmission of this Field Safety Notice:

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

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

Contact reference persons:

Chris Wassell
Quality Regulatory and Conformance
Manager
Joerns Healthcare Ltd
Tel: +44 (0) 1905 842 209
Fax: +44 (0) 844 811 1157
e-mail: chris.wassell@joerns.co.uk

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WORK INSTRUCTION

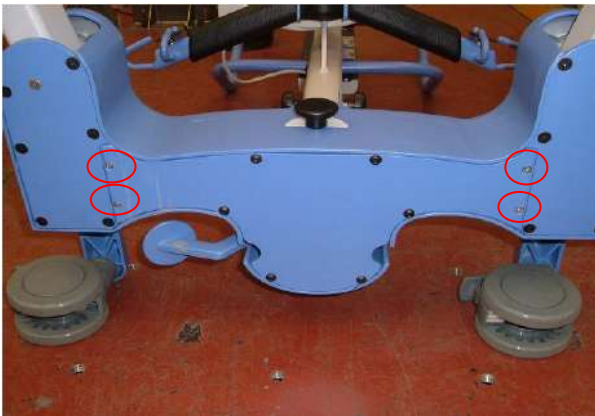
Visual check - Centre base plate attachment: Inspect the fitment of the Advance base plate to the base casting. Alignment of the plate should be square and flat to the casting.

Remove the centre base plate screws (x4) only if they are Pozi head type and silver in colour (shown circled in RED below).

If the circled fasteners already fitted to the base plate are **black in colour** and either Torx head (star profile) or hex head (hexagonal profile) type screws, they will **NOT** require replacement.

Inspect the base plate and base casting for any signs of wear or fracture.

Tool required: Pozi Screwdriver.



Using the replacement screws provided re-position the base plate and secure.

Ensure that the screws are fully inserted using a 2.5mm Allen key - socket specification to suit M4 hex head screw. (As shown below circled in green)



Hexagonal Head type screw (x4)

Should you require additional replacement screws, please notify Joerns Healthcare at orders@joerns.co.uk or contact Joerns Quality Dept on +44 (0) 1905 842 209.

Description of screw profile type:

NOTE:

- The black screw types shown in both Fig. 1 and Fig. 2 are the correct type to be used. If already fitted, they **DO NOT** require replacement.
- If fitted, the silver screw types shown in Fig. 3 **DO** require replacement.

1. Fig. 1: Black M4 x 10mm Torx Head (star head)
2. Fig. 2: Black M4 x 10mm Hex Head (hexagonal head)
3. Fig. 3: Silver M4 x 10mm Posi Head (cross head). **MUST BE REPLACED**



Fig. 1: ✓



Fig. 2: ✓



Fig. 3: ✗

NOTE: Screws pictured are not to scale

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

Additional contact information:

Oxford Customer Services: (Tel) +44 (0) 844 811 1158 or via email to info@joerns.co.uk

Yours faithfully,



Mr. Chris Wassell

Quality, Regulatory and Conformance Manager.

Receipt Form

FIELD SAFETY NOTICE: Ref No. 000016 - Date: 11th February 2013

Re: OXFORD ADVANCE HOISTS - Manufactured prior to July 01st 2010 (Pre- S/No: 1007L0001)

- Joerns Healthcare requires you to acknowledge that you have received and understood the important safety information contained within the above Field Safety Notice (FSN 000016).
- It is important that you complete both section of this form and return a copy to Joerns Healthcare via letter, e-mail or fax.
- Joerns Healthcare has a commitment to notify the MHRA of its customer's fulfilment to successfully complete the required actions within FSN 000016.

Section A (Please complete :)

Name of Dealership or Service Provider: _____

Address: _____

_____ Post Code: _____

I, NAME IN CAPITALS _____, acknowledge receipt of the FSN000016.

- All information within the FSN has been communicated to relevant associates within our organisation.
- Copies of this FSN have also been forwarded to third party care homes, hospitals, private addresses etc that we have supplied this product to and who may have to organise their own LOLER service maintenance schedules of the Advance product.

Section B (In respect of this product, I am the: - carer, partner, relative, friend, dealer etc)

The following Advance Hoists have been scheduled to be serviced to FSN000016 in their next LOLER visit:

SERIAL NUMBER/S _____

Location of Hoists (Care Home, Hospice, and Private Home address etc)

Name: _____

Address: _____

_____ Post Code: _____

Form completed by: (Print): _____

Signature: _____ Date: ___/___/2013

Please return this completed form to Joerns Healthcare Ltd
by letter, fax to +44 (0) 844 811 1157 or via email to: chris.wassell@joerns.co.uk