

Patient Safety Alert

Veterans Health Administration Warning System
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AL09-06

November 20, 2008

- Item:** Maxi Move patient lifts with “Lock and Load” system (Combi Hanger):
Manufactured by Arjo between November 2005 and April 2008.
- Specific Incident:** There is the potential for the “Lock and Load” hanger on the patient lift to unintentionally become dislocated when descending upon a rigid surface (e.g., a patient bed, the arm rest of a chair, the side rails of a toilet commode chair). If the hanger is partially dislodged there is a potential risk for complete detachment of the hanger while the patient is being moved. This could result in a patient fall. To date no patient injuries have been reported. Arjo has identified 75 VA facilities affected by this issue.
- Actions:**
1. By close of business December 2, 2008, Biomedical Engineering will ensure that replacement parts are ordered for affected Arjo patient lift units (see Attachment 1).
 - a. Units manufactured from November 2005, through August 4, 2006, require replacement of the entire T-bar assembly.
 - b. Units manufactured from August 6, 2006 to April 7, 2008, require replacement of the T-bar bushings.
 2. Until replacement components are installed, immediately inform users of the reported issue with this device and how to identify the issue (see Attachment 2).
- Note:** Only units with detachable hangers are affected, permanently mounted/dedicated hangers are not affected.
- Addl. Information:** Arjo will send parts to affected VA medical facilities. Please contact the Center for Engineering & Occupational Safety and Health (CEOSH) at (314) 543-6700 if your facility is affected and did not receive Arjo’s letter.
- Source:** CEOSH, NCPS and Manufacturer
- Attachments:**
- 1) Urgent Field Safety Notice from Arjo
 - 2) Photos depicting correctly and incorrectly attached hangers
- Contact:** Arjo Technical Support at (800) 323-1245 or Paul Sherman, VA Center for Engineering & Occupational Safety and Health (CEOSH) at (314) 543-6700.

URGENT FIELD SAFETY NOTICE

MAXI MOVE with Lock & Load system (Combi Hanger) ID [080811AHE]

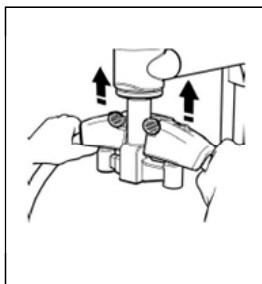
Date: 2008-08-11

Attention: To all customers using the above mentioned product

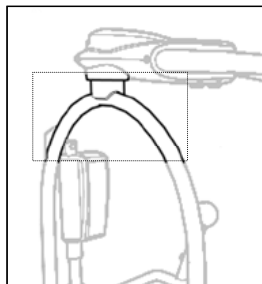
Description of problem

Arjo/ArjoHuntleigh has received a limited number of reports related to unintended dislocation of the hanger on Maxi Moves equipped with the Lock & Load system.

Maxi Moves with dedicated hangers are not affected by this Field Safety Notice.



Lock & Load hanger
(AFFECTED)

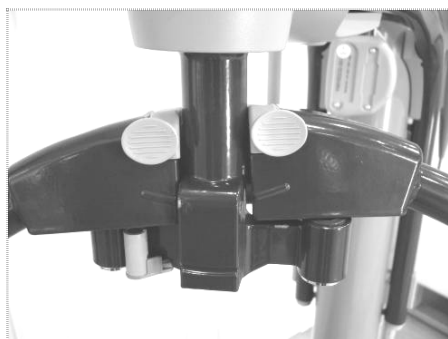


Dedicated Hanger
(Not Affected)

For a dislocation to occur, the Lock & Load hanger will have to be pushed upwards such as when being lowered onto a rigid surface (e.g. a bed, the arm rests of a chair or side rails of a toilet commode chair). In such a situation the hanger may completely detach from the jib.

This situation does not pose a safety hazard to the patient, as the patient cannot be lifted with the hanger completely detached.

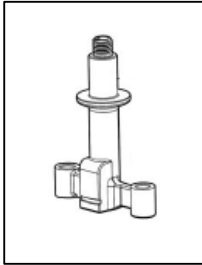
However, there is a remote possibility that, when pushed upwards, the hanger will be only partly detached, in which case a complete detachment may occur later, e.g. when a patient is being transferred. Such a detachment could result in a patient fall and there is a possibility the patient could sustain bumps, bruises, cuts, or more serious injuries, should a fall occur.



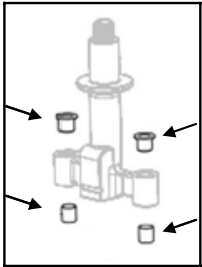
Partly Detached Hanger

Details on affected units:

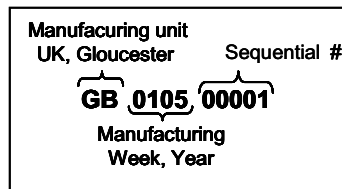
- All MAXI MOVE patient lifters equipped with a Lock & Load Hanger, manufactured up to and including week 32 of 2006 (August 4th) are affected and will have to have the hanger attachment device (T-bars) replaced.

**T-bar**

- All MAXI MOVE patient lifters equipped with a Lock & Load Hanger, manufactured between and including week 32 of 2006 (August 4th) and week 14 of 2008 (April 4th) are also affected but in a different way. The bushings in the T-bar of these devices will need to be replaced. No exchange of the complete T-bar component is needed.

**T-bar bushings**

- MAXI MOVES manufactured during and after week 15 of 2008 (April 7th) are not affected at all and require no activity.
- Serial number legend and affected ranges.



Serial Number Range, T-bar replacement:

GB 5105 xxxxx to GB 0106 xxxxx

(Distributed Worldwide except USA)

SEE 0547 xxx to SEE 0631 xxx

(Distributed World wide)

Serial Number Range, Bushings replacement:

SEE 0632 xxx to SEE 0814 xxx

(Distributed World wide)

Serial Number Range, not affected:

SEE 0815 xxx and onwards

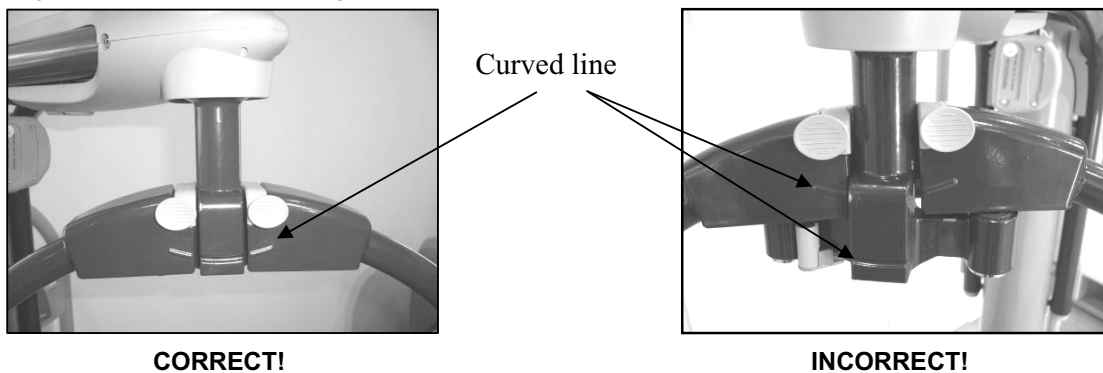
(Distributed World wide)

Due to order logistics the serial number ranges above are all a worst case scenario. An inspection by the Service Engineer might show that a T-bar replacement is not required for all units listed within the T-bar range.

Action to be taken by the user:

The instructions below are already present in the Operating and Product Care Instructions but a re-focus with users is warranted as Maxi Move can be used safely, provided the following instructions are followed:

- Re-train caregivers not to lower the hanger bar onto rigid surfaces, thereby avoiding the possibility that the hanger will be dislodged.
- Re-train caregivers on how to ensure the hanger is properly attached to the T-bar before and during the initial phase of all lifting operations. This is easily done by confirming that the hanger's curved line is aligned with the corresponding line in the T-bar.



If these instructions are revisited, the device is safe to use as the above described partial dislocation is only possible after the hanger bar has been pushed upwards.

Next step

For units needing T-bar replacement:

An Arjo / ArjoHuntleigh representative will contact you within 2 months of this notice to arrange a replacement of T-bars.

For units needing bushings replacement:

A package containing a repair/replacement-kit for the bushings in the T-bar will be sent to you shortly. The kit will include all the materials needed and easy-to-follow instructions for how to replace the bushings. The procedure can be done by anyone with reasonable technical knowledge and experience of common hand tools.

Should you not feel confident installing the bushings or have any problem doing so, please contact your local Arjo / ArjoHuntleigh representative for further instructions on how to proceed.

An Operating and Product Care instruction as well as a Preventive Maintenance Schedule document with updated information is enclosed with this notification. Please replace all other OPI's & PMS's for this lift. Your local Arjo / ArjoHuntleigh representative will supply you with additional copies if needed.

Transmission of Field Safety Notice

This notice and the Preventive Maintenance Schedule must to be passed on to all those who need to be aware within your organisation and/or to any organisation where potentially affected devices have been transferred.

Contact information:

Should you have any questions regarding the content of this notification or how to implement the advice described, please contact your local Arjo / ArjoHuntleigh representative. Contact details can be found on the next page or at www.arjohuntleigh.com.

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Fax: 1-888-594-2756

Eslöv 2008-08-11



Managing Director
Arjo Hospital Equipment AB

CUSTOMER RESPONSE FORM

Maxi Move with Lock and Load Hanger Assembly (Combi)

September 8, 2008

Please mark (☒) all that apply and complete the following information as required.
Please verify completeness and correctness of the contact and product information below.

- I have received the notification package and have reviewed its contents with appropriate personnel.
- I have received and installed the bushings kits in affected Maxi Moves at this facility.
- I have received the bushings kit(s) and would like an ARJO Service Technician to perform the installation.
- I do not have any Maxi Move devices in my facility

Please provide your facility information and the name of the person to whom the kits should be sent (please print):

Facility Name			
Contact Name			
Phone Number			
Street Address 1			
Street Address 2			
City, State, Zip			

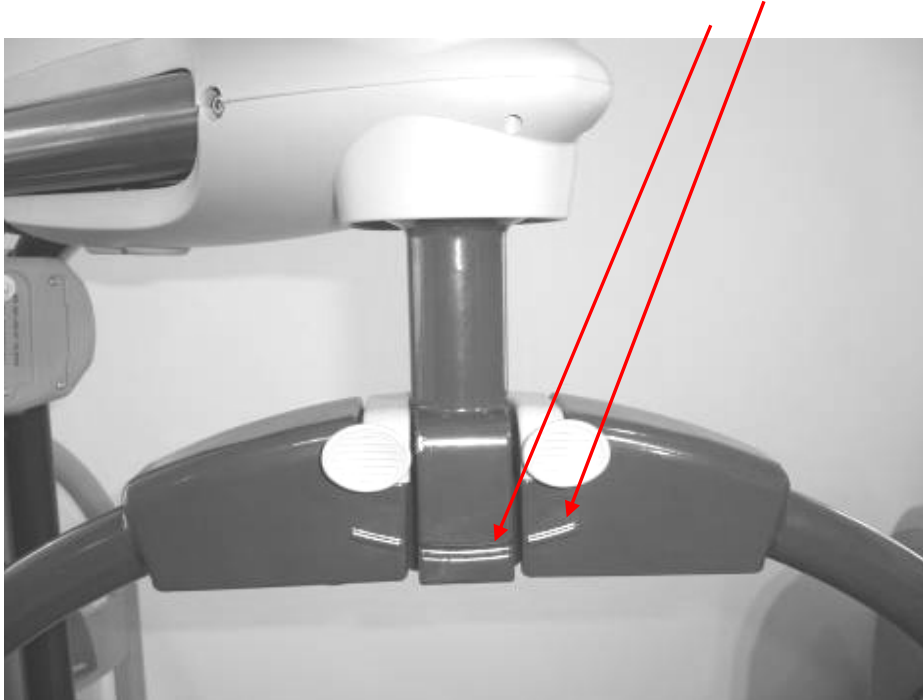
*FAX COMPLETED FORM TO 888.594.2756, OR MAIL TO:
ARJO INC USA
ATTN: QUALITY DEPARTMENT/MM FC
50 N. GARY AVENUE, SUITE A
ROSELLE, IL 60172
WITHIN 10 DAYS OF RECEIPT.*

Attachment 2

Photos depicting corrected and incorrectly attached hangers

Correctly attached hanger

(Curves line up)



Incorrectly attached hanger

(Curves do not line up)

