

Patient Safety Alert

Veterans Health Administration Warning System
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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]

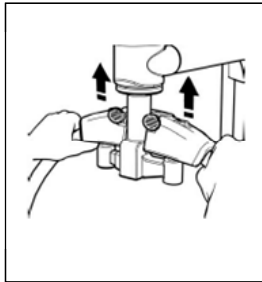
Date: 2008-08-11

Attention: To all customers using the above mentioned product

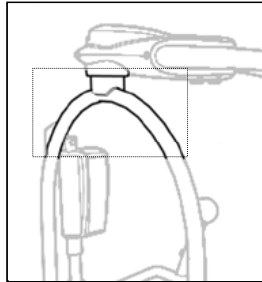
Description of problem

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)

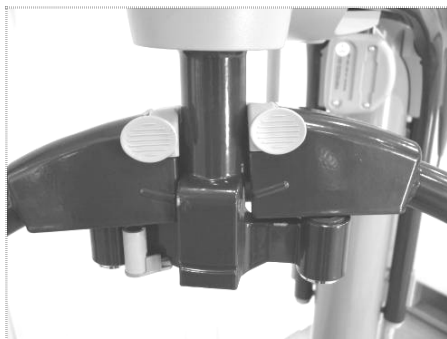


Dedicated Hanger
(Not Affected)

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.

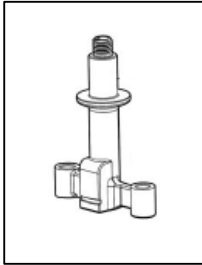
However, there is a remote possibility that, when pushed upwards, the hanger will be only partly detached, in which case a complete detachment may occur later, e.g. when a patient is being transferred. Such a detachment could result in a patient fall and there is a possibility the patient could sustain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



Partly Detached Hanger

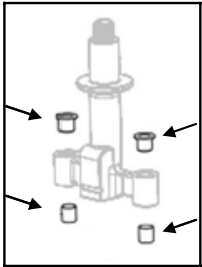
Details on affected units:

- 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.



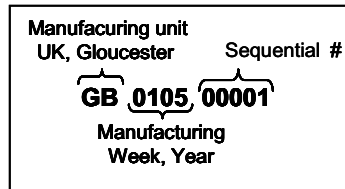
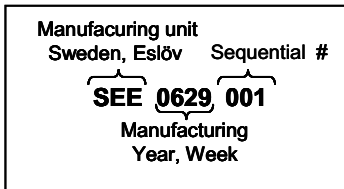
T-bar

- 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.

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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			

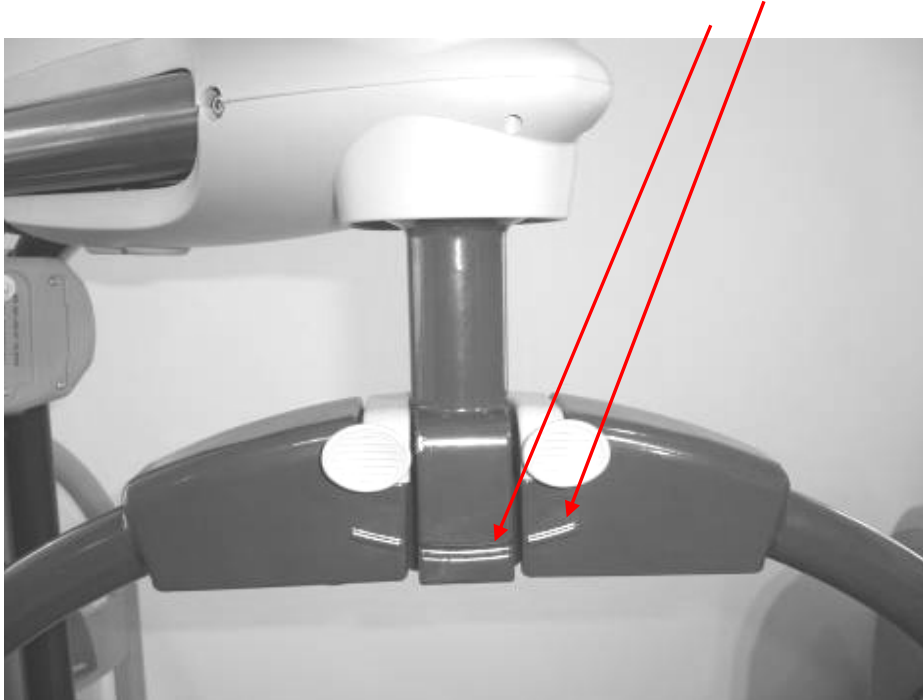
*FAX COMPLETED FORM TO 888.594.2756, OR MAIL TO:
ARJO INC USA
ATTN: QUALITY DEPARTMENT/MM FC
50 N. GARY AVENUE, SUITE A
ROSELLE, IL 60172
WITHIN 10 DAYS OF RECEIPT.*

Attachment 2

Photos depicting corrected and incorrectly attached hangers

Correctly attached hanger

(Curves line up)



Incorrectly attached hanger

(Curves do not line up)

