

URGENT - FIELD SAFETY NOTICE

ARJOHUNTLEIGH MINSTREL PATIENT TRANSFER LIFT WITH SCALE

Date: July 30th, 2014

Product Issue: Possible unscrewing of the spreader bar bolt connection under the scale, between scale and the spreader bar

Resolution: Offer discount to affected customers to replace near end of life (10 years) devices with new or comparable devices, or replace spreader bar to new design.

No. of affected devices: 18

Affected Serial No.:

Germany:
MPLAT0409W1177; MPLAT0410W1213; MPLAT0410W1228; MPLAT0410W1229;
MPLAT0410W1231; MPLAT0410W1232, MPLAT0504W1531

Italy:
MPLAT0412W1290; MPLAT0412W1296; MPLAT0412W1297; MPLAT0503W1485;
MPLAT0503W1486

USA:
MPLAT0503W1493

Australia:
MPLAT0502W1403; MPLAT0502W1404; MPLAT0504W1518; MPLAT0504W1519;
MPLAT0504W1520

Field Correction Notice: FSN/POZ/004-2014

Pages: 3

Dear Risk Manager / Materials Management / BioMed:

Our records indicate that you purchased a Minstrel Patient Transfer Lift with Scale (Model No. HMB002) with one of the serial numbers above from ArjoHuntleigh in a year 2005.

As part of our post market surveillance (complaint reporting) monitoring, ArjoHuntleigh received a limited number of reports where the bolt under the scale unscrewed from the scale. However, in all three cases there is at least one off-label use element that contributed to the bolt unscrewing and subsequent product malfunction. There were no serious injuries related to these incidents.

ArjoHuntleigh investigated the issue and determined there is a remote risk concerning the bolt unscrewing from the scale.

Complaint investigation indicated that there may be an issue with a batch of Minstrel lift scales, manufactured June to September 2005. This issue may cause the spreader bar bolt to unscrew from the scale and detach the spreader bar from the device, also dropping the person suspended in a sling which is attached to the spreader bar.

Although from our evaluation there is not likely to be an immediate risk, we suggest to stop using the product until the field action is carried out. Only the products listed are possibly involved, any other Minstrel can be used without the potential of this issue taking place.

ArjoHuntleigh would like to provide the following options to ensure continued safety and performance of your Minstrel Lift.

Option 1: The Minstrel Lift devices are close to their intended 10-year lifetime and ArjoHuntleigh would like to offer our customers a trade-in discount to purchase a new Minstrel ArjoHuntleigh patient transfer lift.

Option 2: An ArjoHuntleigh Service Technician will install a new scale with added locking features, to your existing Minstrel Lift, free of charge. If Option 2 is chosen, ArjoHuntleigh want to remind you that the Minstrel lift is near its intended 10-year lifetime and it should not be used past its lifetime, including installation of the new scale.

Next Steps

1. Please make sure that all caregivers and users of the Minstrel patient transfer lift referenced above are made aware of this field safety notice (FSN).
2. Please make sure that a copy of this field safety notice (FSN) is placed in the Minstrel Lift Instructions for Use manual for future reference and training.
3. Complete and sign the enclosed Customer Response Form and return this form to your ArjoHuntleigh representative. **Note:** An ArjoHuntleigh Sales Representative will contact the designated facility representative listed on the Customer Response Form to discuss the trade-in offer or an ArjoHuntleigh Service Technician will contact the facility representative to schedule service to replace your scale, free of charge.

Transmission of this Field Safety Notice:

The Minstrel Patient Transfer Lift Field Safety Notice needs to be distributed to those individuals who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

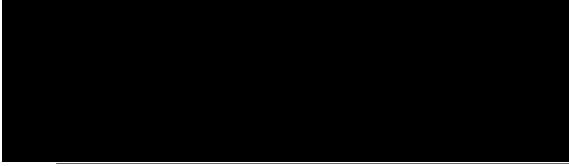
Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

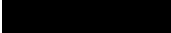
In cases where customers opt not to proceed with completion of the corrective action requirements described above, ArjoHuntleigh cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

We regret any inconvenience that this Field Safety Notice may cause. However, we ask that you please see this corrective action as an extended resident/patient safety action.

Additional Comment

If you have any further questions or require assistance completing the Customer Response Form, please contact your local ArjoHuntleigh Sales and Service office or representative.



 – Product Quality Director

Here will be added a contact person and an address of the Office in each country.