
Urgent Field Safety Notice

Molift 2-point Sling bar – all sizes:

Article	Name
1430016	2 Point Sling bar medium Mover 205
1430017	2 Point Sling bar large Mover 205
1430021	2 Point Sling bar medium Mover 205 w/scale
1830001	2 Point Sling bar large Mover 180/Air
1830002	2 Point Sling bar medium Mover 180/Air
1830002C	2 Point Sling bar clips medium Mover 180/Air
1830003	2 Point Sling bar small Mover 180/Air

Date: 4 July 2018

Attention: Users of Molift 2-point sling bars

Details on affected devices:

The Molift Mover 180/205 and Molift AIR are products that is used to transfer patients and users comfortably and safely. The lifters fit well both for moving seated and lying patients. It also fits as a standing and walking assistant in combination with accessories from Molift's extensive accessory program.

Description of the problem:

Etac have received reports of were the red composite hooks on our 2-point sling bars unintendedly have broken off.

The device meets its performance specifications and performs as intended but it has been found likely to indicate an increased risk from unintended use that may have contributed to a hazardous situation to the patient if the lifting sling becomes loose while transferring a person.

The risk is considered acceptable and the products are safe to use but the following information has been generated as preventive action for enhanced attentiveness.

Advise on action to be taken by the user:

By this field safety notice, we would like to inform users on the following preventative notification to reinforce the regular usage, pre-use inspections, and maintenance of the 2-point sling bars.

1. According to the attachment BM6901 revision C of the user's manual, before each use/lifting procedure, the caretaker must ensure that the hooks have no visual damage. It is most relevant to inspect the surfaces inside the hooks as well when looking for damage. Impaired products must not be used at any time.

2. The sling bars must not be applied/exposed to any abnormal forces and/or torques. The hooks are intended for vertical loads only and the loops for the lifting sling must be placed correctly on the hooks during lifting and transfers.
3. Do not place/store/hang the sling bars by the hooks, unless the hanger has been properly installed by a ETAC/Molift representative.
4. The sling bar must be handled with care and never utilized for any other purposes outside it's intended use.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please forward this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period (minimum 6 months) to ensure effectiveness of the advised actions by the user.

Please return any defective products for replacement and call your local ETAC/Molift representative for consultation in any case of uncertainty. See attached document ref: BM6901 Rev. C

Contact reference person:

Etac highly appreciates your attention to this issue. If you have any questions related to the Molift sling bars or the information associated with this notification, please contact QA manager: molift.qa@etac.com

The undersign confirms that this notice has been notified to the appropriate regulatory agency.

Signature



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