

Urgent Field Safety Notice

Molift Air – ceiling hoist

27.06.2016

Dear Customer,

The purpose of this letter is to advise you that Etac Supply Gjøvik is issuing a Field Safety Corrective Action (FSCA) for Molift Air ceiling hoist produced May 2013 until 31 December 2015. If you have any Molift Air at your facility, please read this notice carefully.

The FSN secures that all facilities and users using receives important background information and guidelines for the field action described.

Affected medical device:

Etac Article no.	Article denomination
Molift AIR 205	2501205, 2501210, 2501215, 2501220
Molift AIR 300	2501300, 2501310, 2501315, 2501320

Background information:

Etac Supply Gjøvik has received a total of 4 reports where the bolt on the suspension coupling on Molift Air has become loose in the coupling. All reports came after technical testing and inspection. Etac has not received any reports of patient injury resulting from this issue. Anyhow, there is a potential risk for harm or injury if the bolt inside the coupling comes loose from the housing.

Our records indicate that you have received product from the affected products. Please review your inventory for these products

REQUIRED ACTIONS:

To be able to reduce the risk for the coupling to come loose, Etac Supply Gjøvik voluntarily issues this field correction for all potentially affected products. All Molift Air products delivered by ETAC through Etac distributors and Etac subsidiaries between May 2013 and January 2016 are affected by this product correction.

In order to undertake this field correction Etac AS, Etac Supply Gjøvik requests your cooperation as a distributor in both tracking and executing this effort.

As a distributor of Molift Air, you are asked to complete and return the recipient confirmation acknowledging your receipt and understanding of these Instructions for Distributors.

Etac AS, Etac Supply Gjøvik asks that you supply a tracking list of customers (dealers, retailers, or individual users) who have purchased any of the subject Molift Air from you between May 2013 and

January 2016, including the most recent contact information you have for each dealer, retailer or individual user.

The following actions is required from you:

- 1) Read this instruction, and return the recipient confirmation on the last page
- 2) Report all serial numbers distributed in your region/country to Etac Supply Gjøvik
- 3) Order the upgrade kit from Etac Supply Gjøvik
- 4) Further, you are asked to follow up with the customers and users and confirm that all hoists in your market are upgraded. The efforts to contact your customers and obtaining confirmation must be documented: when, who, how.
- 5) Report to Etac Supply Gjøvik about upgraded products.

Any customer or user information that you provide in executing this Field Correction will be used by Etac AS, Etac Supply Gjøvik solely for purposes of conducting the correction described here. This information will not be used for any other purpose. Etac AS, Etac Supply Gjøvik will not sell or reuse any customer list or customer contact information you provide in responding to this correction.

The field correction of the affected Molift Air will be performed by customer at customer site. The competence level and skills for personnel performing the retainer ring installation is product knowledge and understanding of the provided replacement instruction.

The field corrective action shall be executed according to enclosed instruction (document id: 3004137175-230616-C-4 Mounting instruction and checklist). This is also your report, and should be collected for all systems after upgrade. Please collect and return to Etac Supply Gjøvik.

Orders of upgrade kit No: 2520110 as described in the replacement instruction can be done by customer at customer site.

After an upgrade, there is no need for load testing of the Molift Air hoist.

Tracking the Field Correction

According to the instructions above, all upgrades of Molift Air hoists in your region/country must be tracked. The Mounting instruction attached works as a checklist. Please collect 1 filled in and signed checklist per system.

Report back the status of all distributed Molift Air hoists in your region to Etac Supply Gjøvik.

Also return a scanned copy of each checklist to molift.qa@etac.com.

As the field correction progresses, Etac Supply Gjøvik may contact you to inform you of the status of the correction. In the event you have any questions, please contact Etac Supply Gjøvik in the contact information as shown below:

Your cooperation is essential and highly appreciated to this field correction effort.

ETAC apologize any inconvenience this FSN causes. ETAC request that you forward the FSN to all relevant personnel in your organization. This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have concerns, comments or questions, do not hesitate to contact your local ETAC representative.

The undersigned person hereby confirms that this notice has been notified the appropriate Regulatory Agency.

2016.06.27

Best regards,



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