

Ref.: INC2206-2_FSN

URGENT - Field Safety Notice

Molift Quick Release Coupling – risk of go apart

Dear Customer,

Purpose of this letter

Etac A/S has received feedback from the market that the Molift Quick Release Coupling mounted on our Molift Air hoists can come apart. If the Quick Release Coupling comes apart it can lead to the patient during transfer falls down and get injured. On this background we have decided to issue a Field Safety Corrective Action (FSCA).

This FSN secures that all facilities and clients having the potential malfunctional Quick Release Couplings receives important background information and guidelines for the field action described.

The affected items are those manufactured in the period March 21st, 2022, to June 21st, 2022 and have the following item no. 2510363, 2510384 and 2510077 mounted on below Molift Air motors:

Air 200: M26200, M26200-00 M26201

Air 350 and Air 350 Tilt: M26350, M26351, M26352, M26353, M26355

Air 205: M25205, 25205-00, M25205-2, M26205, M26205-2, M27205

Air 300: M25300, M25300-2, M26300

Air 500: M26500

Background Information

During a patient transfer the quick release coupling came apart. The quick release coupling is the swivel device on the hoist that connects lifting strap to sling bar. This caused the patient to fall to the floor and got injured. Investigation of the malfunctioned quick release coupling showed that it was not assembled correctly during manufacturing assembly process. This led the coupling to come apart. Etac therefore issue a FSN on the serial numbers that may have been assembled incorrectly from factory.

Our records indicate that you have received products affected by this FSN. Please review your inventory, sales records and take the required actions.

Affected motors in the market can still be in use as normal, as the risk of malfunction in such a degree that the Quick Release Coupling will come apart is very unlikely as this demands that the quick release coupling is turned 360 degrees the same way all time many times in a row. However, we recommend that potential affected motors are not distributed in your local market before replacement of the coupling has taken place.

Etac can confirm there have been no death or serious injuries reported from this failure.

Etac A/S hereby confirms that this notice has been forwarded to the appropriate Regulatory Agency.

Required actions distributor

The following actions are required by you as a distributor:

1. Read this instruction and return the attached "Recipient confirmation", attached to last page of this letter
2. Identify and contact end-customers/users and agree on date for replacement of the Quick Release Coupling based on this FSN
3. Order new Quick Release Coupling kits from Etac
4. Agree with Molift Certified Technician to go to end-customer for replacement of the Quick Release Coupling. The replacement must be conducted as described in Molift Technical Manual for the affected Air Motor, also attached to this FSN. After replacement, safety check must be conducted according to technical manual for the affected Air Motor as well.
5. Send back the "reply form" to Etac A/S confirming for each serial no. that replacement and safety check has been conducted.
6. Do not return replaced Quick Release Coupling but dispose it according to local regulation.

Required actions caregiver

1. Before use of motor, check that there is no gap in the Quick Release Coupling set. If a clear visible gap is noticed, then take the motor out of use and call your local distributor.

Receipt confirmation

As a distributor of Molift Air Motors, you are asked to complete and return the recipient confirmation acknowledging your receipt and understanding of these instructions, within one week of receiving this document. The receipt confirmation is located on the last page in this document.

Overview of replacement parts to be ordered

Quick Release Coupling	Molift Air Model	Replacement product to be ordered
2510363	Molift Air 200, 350, Tilt	2510500
2510077	Molift Air 205, 300	2510500
2510384	Molift Air 500	2510384

The replacement kit #2510500 is the component shown to the right:

Orders are to be sent to Molift@etac.com



Replacement of Quick Release Coupling

The field correction of the potential affected Quick Release Couplings must only be replaced by certified Molift Technicians who is familiar with conduction service and inspection of Molift hoists. The technical manuals (TM15701=Molift Air 200/350, TM16101=Molift Air 205/300 and TM16001= Molift Air 500) clearly shows how to replace the Quick Release coupling and conduct safety check after replacement.

Etac A/S
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8751 Gedved,
Denmark

Replacement guide and Safety checklist is also provided as an additional resource to facilitate local replacement of the Quick Release Coupling.

We sincerely regret any difficulties this may cause you. Etac A/S remains dedicated to patient and caregiver safety and will continue to monitor device performance to ensure product integrity and usage.

Yours sincerely,

Etac A/S

Vibeke Damgaard Nielsen

Quality & Compliance Manager, Patient Handling

Enclosed: *Reply form incl. list with affected serial no.*

Recipient confirmation

Replacement Guide

Recipient Confirmation – Ref. INC2206-2_FSN

- I have read and understood these instructions.
- We will report all affected units in our market to Etac A/S
- We will make sure all necessary actions are preformed according to the instructions provided.

Quantity of products in stock _____

Quantity of products in use in the market _____

Country/market: _____

Date/signature: _____ / _____

Please check all boxes above, sign, scan and send to vigilance.dk@etac.com before 2022-07-15