

Ref.: INC2206-2_FSCA

Extension Field Safety Notice

Molift Quick Release Coupling – risk of coming apart

Dear Customer,

Purpose of this letter

Etac A/S has received feedback from the market that there is a risk of the Molift Quick Release Coupling mounted on our Molift Air hoists coming apart. This risk is also detected outside the initial scope and on this basis we have decided to issue a Field Safety Corrective Action (FSCA) and extend the scope of potential affected motors.

This FSN is to ensure that all relevant parties who have the equipment with the potential defect are notified accordingly.

The affected items are those manufactured in the period March 2nd, 2020, to March 17th, 2022, and have the following item no. 2510363, 2510384 and 2510077 mounted on the following 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 the lifting strap to the sling bar. This caused the patient to fall which caused a minor injury. Investigation of the malfunctioned quick release coupling showed that it was not correctly assembled during the manufacturing assembly process. This led the coupling coming apart. Etac therefore is issuing an FSN on the serial numbers that may have been assembled incorrectly at the 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 used as normal, as the risk of malfunction to such a degree that the Quick Release Coupling comes apart is very unlikely. This would demand that the quick release coupling is rotated 360 degrees the same way repeatedly. However, we recommend that potential affected motors are not distributed until 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 for distributor

The following actions are required by you as a distributor:

1. Identify and contact end-customers/users and agree on date for replacement of the Quick Release Coupling based on this FSN
2. Order new Quick Release Coupling kits from Etac
3. Agree with a Molift Certified Technician to visit the end-customer for replacement of the Quick Release Coupling. The replacement and safety check must be conducted as described in the accompanying letter "Replacement guide".
4. Send back the "reply form" to Etac A/S confirming for each serial no. that replacement and safety check have been conducted.
5. Do not return replaced Quick Release Coupling but dispose of it according to local regulations.

Required actions for caregiver

1. Before using the 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.

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 are trained to carry out servicing and inspections of Molift hoists.

The Replacement guide and Safety checklist are also provided as an additional resource to assist with local replacement of the Quick Release Coupling.

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

Etac A/S
Parallevej 3
8751 Gedved,
Denmark

SRN DK-MF-000017724

Yours sincerely,

Etac A/S

...

Quality & Compliance Manager, Patient Handling

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

Replacement Guide