

Urgent Field Safety Notice

Molift 2-Point Sling Bars

2019.02.26

Dear Customer,

The purpose of this letter: Etac Supply Gjøvik (ESG) is issuing a Field Safety Corrective Action (FSCA) for 2-Point Sling Bars delivered as an option with Molift Mover 180/205 mobile hoist and Molift Air ceiling hoist manufactured from May 2013 until October 1st 2018. If you have any Molift Mover 180/205 or Molift Air, with 2-Point Sling Bars manufactured during this time at your facility, please read this notice carefully.

This FSN secures that all facilities and clients using our sling bars receives important background information and guidelines for the field action described.

AFFECTED MEDICAL DEVICES – Molift 2-Point Sling Bars, all sizes

Item number	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

BACKGROUND INFORMATION

Etac Supply Gjøvik has received reports claiming that parts of the composite hook of the 2-Point Sling Bar has unintentionally broken off. Etac has not received any reports of patient injury resulting from these incidents. The device meets its performance specifications and performs as intended. We have identified a possible risk related to unintended use of the device that can contribute to hazardous situations during lifting and transfer of patients.

This risk related to unintended use is considered unacceptable and Etac is therefore acting to remedy the situation. The product user manuals have previously been updated to emphasize intended use of the products. As part of a design upgrade, all new 2-Point Sling Bars are now equipped with metal alloy hooks replacing the previously used composite hooks. This new design reduces the risk of product failure due to unintended use. Etac Supply Gjøvik is now performing an FSCA with the purpose of replacing the related 2-Point Sling Bars in the market with the new design.

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

The author hereby confirms that this notice has been forwarded to the appropriate Regulatory Agency.

2019.02.26

Best regards,



Åsmund Amlien

QA-Manager

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REQUIRED ACTIONS

Etac Supply Gjøvik voluntarily issues this FSCA for replacing all potentially affected products in the market with the new product design. This will reduce the risk of product failures due to unintended use. As part of this FSCA Etac AS, Etac Supply Gjøvik requests your cooperation as a distributor in this matter.

The 2-Point Sling Bars affected by this FSCA are manufactured as part of a complete Molift Mover 180/205 mobile hoist or Molift Air ceiling hoist by Etac, through Etac distributors and Etac subsidiaries between May 2013 and October 1st 2018.

Any customer or client information that you provide in executing this FSCA 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.

If you have any questions, feel free to contact Etac Supply Gjøvik. The contact information is provided below.

The following actions are required from you as a distributor:

- 1) Read this instruction, and return the recipient confirmation on the last page of this document
- 2) Issue an information letter to your customers based on this FSCA
- 3) Review the list of sales records from Etac Supply Gjøvik and supply additional information from your records.
- 4) Identify and contact end-customers/users and decide the requirement for ordering new units
- 5) Order new 2-Point Sling Bars from Etac Supply Gjøvik
- 6) Ship replacement units to end customers accompanied by replacement instructions (see user manual) and the Consignee Form. The End-User/Customer must perform the replacement and fill the replacement records (green fields) in the consignee form and return a signed copy to the distributor.
- 7) Receive the signed Consignee Form from end-users/customers. Perform weekly reporting to Etac Supply Gjøvik in the same spreadsheet that contains the sales records. The signed Consignee Forms must be returned to Etac Supply Gjøvik as a complete package upon finalizing all replacements.

1. Receipt confirmation

As a distributor of Molift Mover 180/205 mobile hoist and Molift Air ceiling hoist, 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.

2. Internal information and information letter to customers

Etac request that you forward the information in the FSCA to all relevant personnel in your organization.

The end-users/customers must be notified of this FSN. The documents must be translated if necessary. A PowerPoint presentation has also been issued as an additional resource in this matter.

3. Sales records from Etac Supply Gjøvik

Etac AS, Etac Supply Gjøvik will supply a list of all affected products sold from Etac Supply Gjøvik. The affected products are sold both separately and as part of a complete system. We ask you as a dealer to review the list and add further details based on your own records. As the affected units are not equipped with serial numbers, the sales records are assigned a "Ticket-number" for each individual unit sold.

Note that the sales records will contain all invoiced products; not considering credit notes, warranty replacements and other special cases. This means that we expect the total number of units in the market will be lower than the number of units listed. Further we expect some units to be decommissioned and no longer in service.

4. Identify and contact end-customers/users

As part of processing the sales records, the end-user/customer should be identified. The end-customers/users must be contacted and informed about the FSCA, asked to specify the requirement for replacement parts and asked to perform a replacement of the affected unit.

5. Order replacement parts

Based on your correspondence with the end-user/customer, the required quantity and type of 2-Point Sling Bar should be identified. There is a total of 6 different replacement parts available.

Hoist system	Article no.	Description
Mover 180 / Air	1830041	2-Point Sling Bar with Metal alloy hook - Large (550mm)
Mover 180 / Air	1830042	2-Point Sling Bar with Metal alloy hook - Medium (450mm)
Mover 180 / Air	1830043	2-Point Sling Bar with Metal alloy hook - Small (350mm)
Mover 205	1430115	2-Point Sling Bar with Metal alloy hook - Large (550mm)
Mover 205	1430116	2-Point Sling Bar with Metal alloy hook - Medium (450mm)
Mover 205	1430117	2-Point Sling Bar with Metal alloy hook - Small (350mm)

Please include the designated Ticket-number for each individual unit ordered. The supplied order form in MS Word-format can be used. Orders are to be sent by the distributor to molift.orders@etac.com

6. Replacement by customer

The field correction of the affected Molift Mover 180/205 mobile hoist and Molift Air ceiling hoist is intended to be performed by the end-users/customers at their own premises. The required competence level and skills for personnel performing the replacement of the 2-Point Sling Bar on the affected systems is general product knowledge and understanding of the replacement instruction described in the user manual. We refer to the following English user manuals and the corresponding manuals in other languages: BM08101 (Molift Mover 180 User manual), BM05101 (Molift Mover 205 User manual) and BM16101 (Molift Air User Manual).

To clearly document individual replacements, the previously mentioned sales records are accompanied by a Consignee Form issued per record. The Consignee Form is assigned the same Ticket-number as the sales record. The end-user/customer must fill in the replacement records (green fields) in this Consignee Form and sign for the replacement and return the signed form to the distributor.

There are no requirements for load testing the replaced 2-Point Sling Bars after the replacement as they are already load tested after manufacturing.

7. Reporting

Progress reporting in the project requires the distributor to maintain the sales records (Excel-spreadsheet) and update it with the currently known information and return a copy to ESG every Friday until all tickets are closed. Upon receiving a signed Consignee Form from the end-user/customer, please make a checkmark in the "Status"-section in the bottom of the Consignee Form as this will act as the final closure of the ticket. The information provided in the Consignee Form must then be transferred to the spreadsheet as part of maintaining the records.

The signed Consignee Forms must be returned to ESG as a complete package upon finalizing all replacements.

The weekly reporting (Excel-spreadsheet) and the final documentation package (Excel-spreadsheet and scanned PDF's of all Consignee Forms) is to be sent to molift.qa@etac.com.

Recipient confirmation – FSCA Molift 2-Point Sling Bar

- I have read and understood these instructions
- We will report all affected units in our market/region/country to Etac Supply Gjøvik
- We will make sure all necessary actions are performed according to the instructions provided

Region / country / market: _____

Date / Signature: _____ / _____

Please check all boxes above, sign, scan and send to molift.qa@etac.com as soon as possible