

July 3rd, 2020

Field Safety Notice (FSN) SwiftHook - Product Removal

HANDICARE AB

MANUFACTURER FSCA/FSN REFERENCE: C083

FSN TYPE: UPDATE OF FIELD SAFETY NOTICE 2020-DEC-20

For the attention of customers and associated patients and caregivers, using Handicare mobile lifts and ceiling lifts equipped with SwiftHook.

The following document serves as communication that, with immediate effect, SwiftHook is discontinued. If you are in possession of SwiftHook, you should immediately follow the corrective action described overleaf.

AFFECTED DEVICES

| | | |
|---------------------------------|---|------------------|
| Brand name | SwiftHook | |
| Item number | 70200008 | |
| Technical description | Component which attaches spreader bar (SlingBar) to lift arm of a mobile or ceiling lift. Enables quick release of spreader bar. | |
| Intended use | Intended for swift detachment/attachment of spreader bar when mobile or ceiling lift is used for multiple patients of varying size, or when spreader bar is used in combination with attachable accessory. | |
| Associated mobile lifts | Vega | All item numbers |
| | Eva | |
| | Carina | |
| Associated ceiling lifts | RiseBasic | All item numbers |
| | RiseAtlas | |
| | RisePorto | |
| Affected units | <p>The affected units include all mobile lifts and ceiling lifts equipped with SwiftHook:</p> <ul style="list-style-type: none"> • SwiftHook as standard equipment for Vega505EE mobile lifts. • SwiftHook as an accessory to all other mobile lifts and ceiling lifts. | |

REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)

It has come to our attention that the spreader bar may detach during use of mobile lifts and ceiling lifts equipped with the SwiftHook attachment.

Attaching a weight load to the mobile lift or ceiling lift with SwiftHook in an unstable position could cause the SwiftHook and attached parts, including patient seated in the sling, to detach from the lift arm.

REQUIRED CORRECTIVE ACTIONS

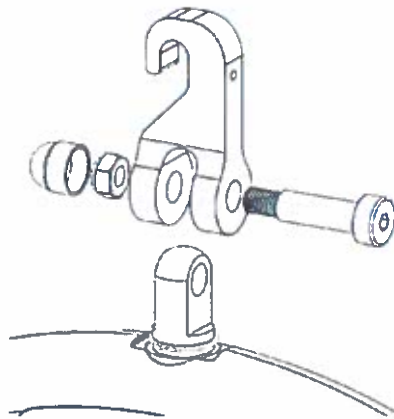
Users of affected units are urgently requested to perform the following corrective action for devices in their possession, without delay, upon receiving this notice.

Corrective Action - Direct Mounting of Spreader Bar onto Mobile Lift or Ceiling Lift

Please observe that users can mount the spreader bar directly onto the lift arm of the mobile/ceiling lift. This corrective action must be undertaken.

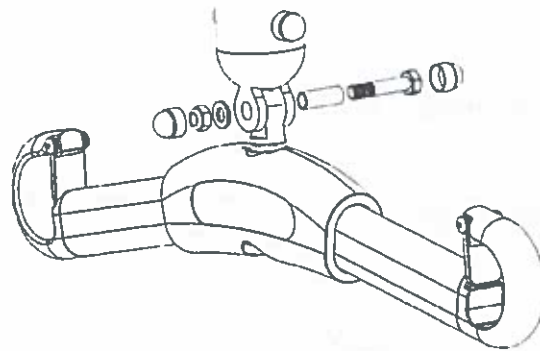
Please see below instructions to directly mount the spreader bar to the mobile/ceiling lift. If you require further help or instructions, please contact your local Handicare representative.

1. Remove the SwiftHook using the appropriate Allen key (5mm) and wrench (13mm). See figure below.



2. Use two wrenches (13mm). Remove the SwiftHook from the spreader bar as above. Remove the fastener from the lift's link arm as described in the figure below. Attach the spreader bar directly to the lift arm, as illustrated in the second figure below, by using the existing fasteners from the link arm.





3. Please note that the removed SwiftHook should not be used anymore and must be disposed of in accordance with local procedures. Do not send the component to the manufacturer.

TRANSMISSION OF THIS COMMUNICATION

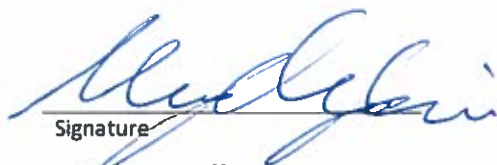
This communication should be passed on to all customers, and associated patients and caregivers, where SwiftHook components have been purchased or are used.

The Competent Authority/regulatory agency of your country has been informed of this communication to customers.

CUSTOMER REPLY

Each customer is required to communicate the content of this FSN to all end users. The end users shall be requested to complete and sign the form FSN C083-Customer Response Form attached with this FSN. The completed and signed FSN C083-Customer Response Form shall be returned by mail or email to Handicare AB.

For any questions in relation to this updated FSN C083 concerning removal of the SwiftHook, please contact quality@handicare.se



Signature

Regulatory Affairs PH,

Handicare AB

Title

Negar Klingenstierna

Printed Name

2020-July-03

Kista

Date, city

July 3rd, 2020

HANDICARE AB
FSN C083-CUSTOMER RESPONSE FORM

| Field Safety Notice (FSN) information | |
|--|---------------|
| Manufacturer FSCA/FSN Reference | C083 (update) |
| FSN Date | 2020-July-03 |
| Product/ Device name* | SwiftHook |
| Item number | 70200008 |

Please complete the below table. The fields marked with * are mandatory. Please enter N/A in case the field is not applicable.

| Customer action undertaken on behalf of Healthcare Organization | | | |
|--|--|------|-----------|
| <input type="checkbox"/> | The corrective action requested in the FSN has been performed by the end users. The units have been removed and disposed of in accordance with local procedures. (Please specify quantity) | Qty: | Comments: |
| <input type="checkbox"/> | I do not have any affected devices. | | |
| Printed Name* | | | |
| Signature* | | | |
| Date (DD/MM/YY)* | | | |

Please provide your contact details in below table.

| Customer Details | |
|--|--|
| Account Number | |
| Healthcare Organization Name* | |
| Organization Address* | |
| Department/Unit | |
| Shipping address if different to above | |
| Contact Name* | |
| Title or Function | |
| Telephone number* | |
| Email* | |

HANDICARE AB

Return this completed and signed Response Form to Handicare AB using contact details specified below.

| | |
|-------------------|---|
| E-mail | customerservice@handicare.se |
| Telephone | +46 (0)8 557 62 200 |
| Fax | +46 (0)8 557 62 299 |
| Address | Torshamnsgatan 35, SE-16440 Kista, Sweden |
| Web Portal | www.handicare.com |

Please return this signed form by mail or email to Handicare AB using contact details provided above.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Thank you for your kind cooperation.

