

December 20th, 2019

Urgent Field Safety Notice (FSN) SwiftHook

HANDICARE AB

MANUFACTURER FSCA/FSN REFERENCE: C083

FSN TYPE: NEW

For attention of patients and caregivers using Handicare mobile lifts and ceiling lifts equipped with the SwiftHook component. Please contact your local Handicare representative using contact details specified in the attached response form for any questions relating to the content of this letter.

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	Item number	All
	Eva	Item number	All
	Carina	Item number	All
Associated ceiling lifts	RiseBasic	Item number	All
	RiseAtlas	Item number	All
	RisePorto	Item number	All
Affected units	<p>Affected units comprise all mobile lifts and ceiling lifts equipped with SwiftHook.</p> <p>SwiftHook is provided with all Vega505EE mobile lifts per default.</p> <p>SwiftHook is provided as spare part for all other mobile and ceiling lifts.</p>		

REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)

It has come to our company's attention that the spreader bar may detach during use of mobile lifts and ceiling lifts equipped with the SwiftHook component. This may occur if the SwiftHook is not properly attached to lift arm before use – causing it to enter an unstable position (Fig. 1).

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

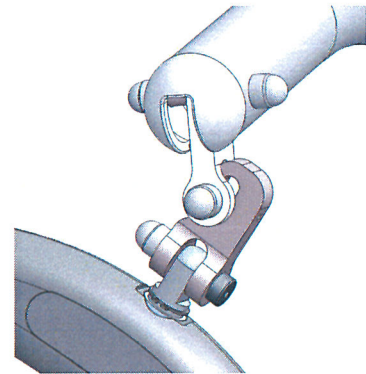


Figure 1. SwiftHook in unstable position

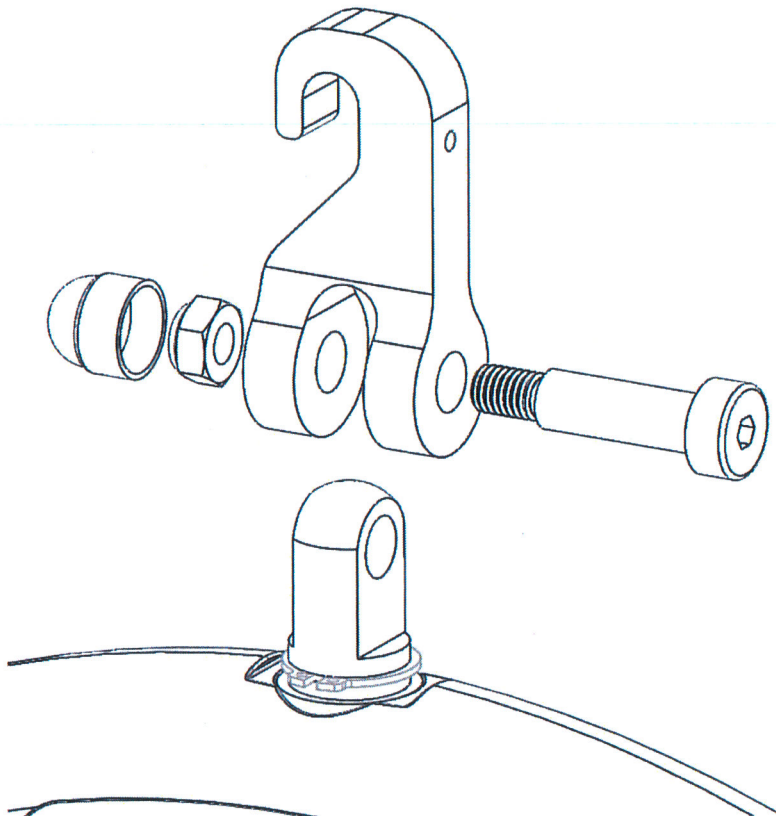
REQUIRED ACTIONS

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

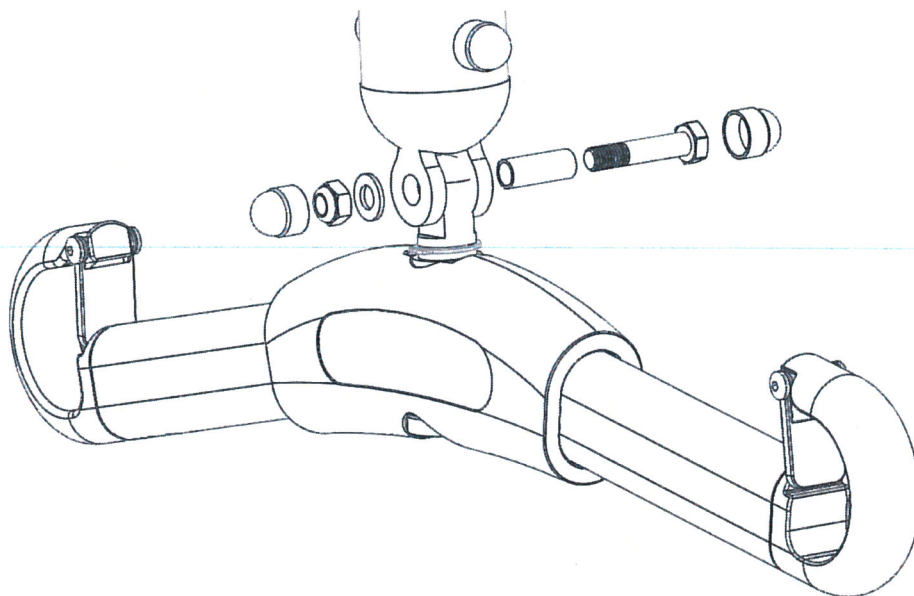
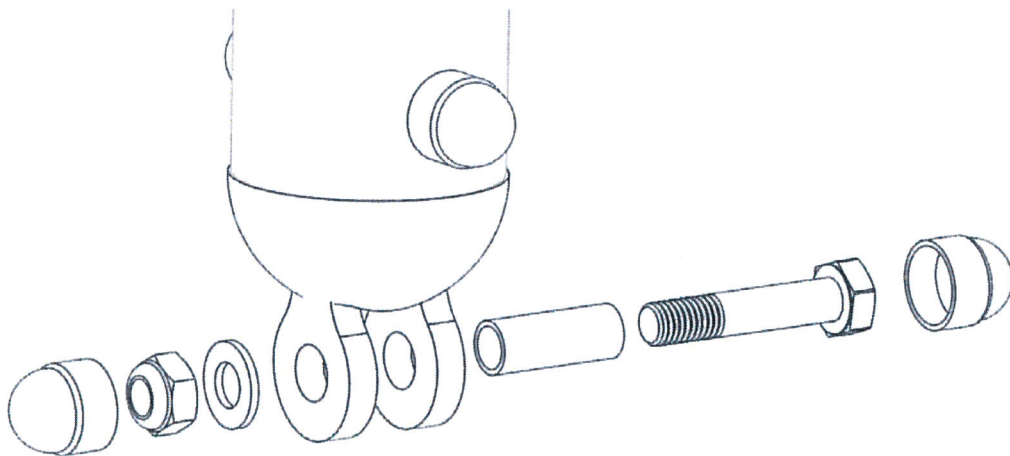
Action 1. Direct mounting of spreader bar onto mobile/ceiling lift

Please observe that users can mount the spreader bar directly onto the lift arm of mobile/ceiling lift if the spreader bar is not frequently exchanged. This configuration would eliminate the possibility of incorrectly mounted SwiftHook while gaining the advantage of increased lift height capacity. See instructions below, please contact your local Handicare representative if you need further instructions.

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



1.2 Use two wrenches (13mm). Remove the SwiftHook from the spreader bar as in the previous section. 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.



Action 2. SwiftHook inspection

If a user chooses to use the SwiftHook please observe that the following steps should be repeated before every use of mobile lift or ceiling lift equipped with SwiftHook to ensure safe use.

1. Inspect if the SwiftHook unit is mounted correctly onto the lift arm.

Correct position of SwiftHook

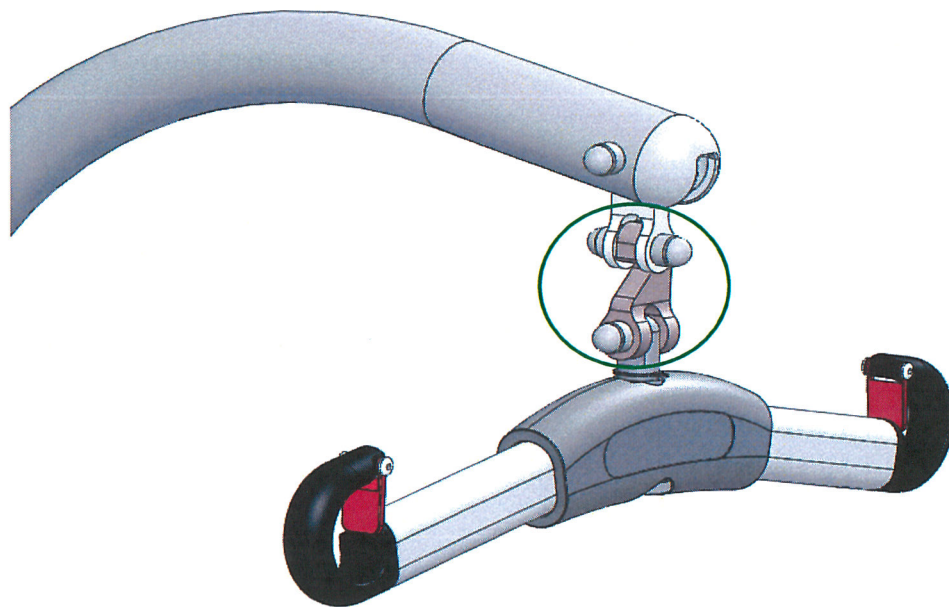


Figure 2. **Correctly mounted** SwiftHook seen from front left hand side. Connection point encircled in green.

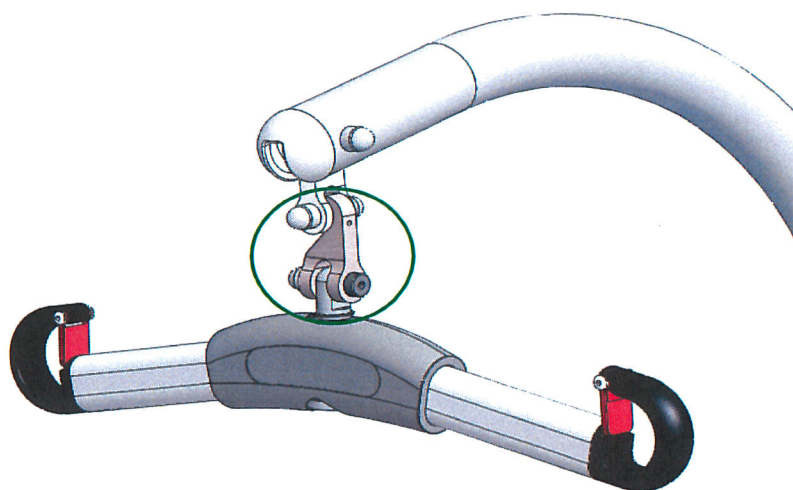


Figure 3. **Correctly mounted** SwiftHook seen from front right hand side. Connection point encircled in green.

Incorrect position of SwiftHook

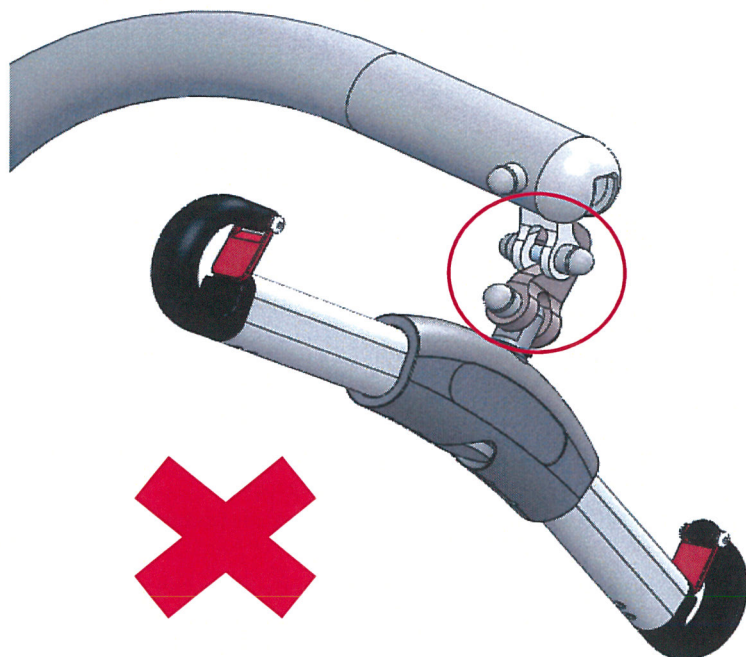


Figure 4. Incorrectly mounted SwiftHook seen from front left hand side. Connection point encircled in red.

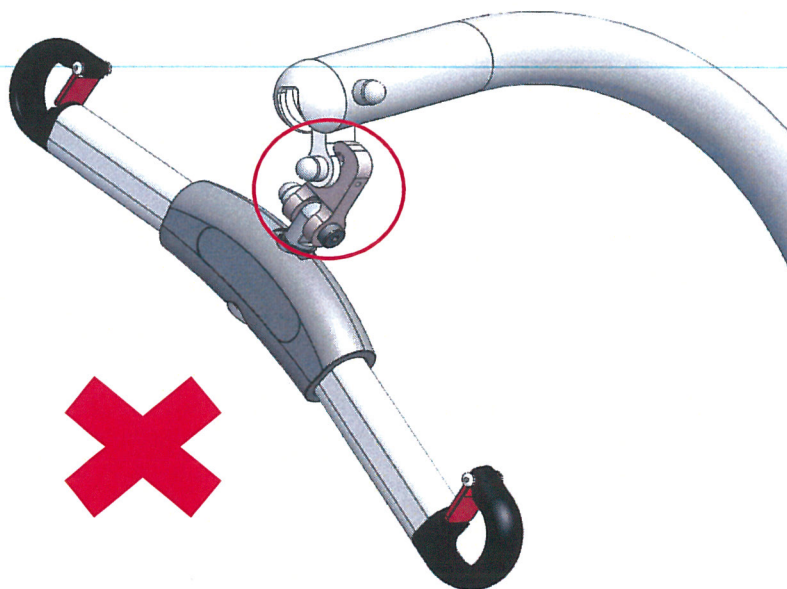


Figure 5. Incorrectly mounted SwiftHook seen from front right hand side. Connection point encircled in red.

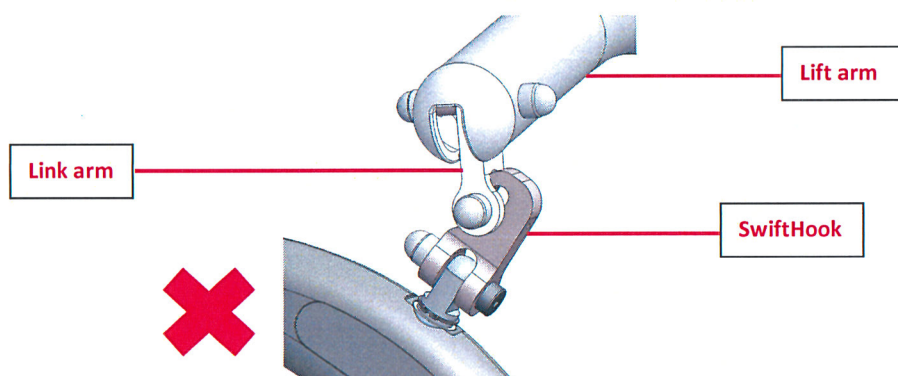


Figure 6. Close-up of incorrectly mounted SwiftHook in unstable position

2. If the inspected unit is mounted incorrectly, please correct the mounting by performing the following:
 - a. Ensure that no patient and no sling is attached to the spreader bar.
 - b. Gently angle the SwiftHook backwards before pushing the spreader bar in forward direction, in direction of the SwiftHook tip.
 - c. Ensure that the SwiftHook is completely hooked onto the link arm of lift arm.
3. Confirm that the corrected unit is mounted in accordance with figures 3 and 4 above.

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 Reply attached with this FSN. The completed and signed FSN C083 Customer Reply shall be returned by mail or email to Handicare AB using provided contact details no later than March 31st, 2020.

MANUFACTURER ACTION

The instructions for use (IFU) containing advise on correct attachment of SwiftHook will be introduced for Vega mobile lifts (IFU rev16) and for SwiftHook as a spare part (IFU rev1).

The updated IFUs are currently available on Handicare's website in English and Swedish from December 19th, and will be available in other languages at the earliest opportunity.

The service manual containing the following instructions will be available on the intranet of Handicare's website at the earliest opportunity:

- Inspecting the SwiftHook for wear damage during routine maintenance
- Instructions for mounting the spreader bar directly onto lift arm

TRANSMISSION OF THIS FIELD SAFETY NOTICE

This FSN must be passed on to all those who need to be aware within your organization and to any other organization where SwiftHook units have been provided, as appropriate.

Please maintain awareness of this FSN for an appropriate period to ensure effectiveness of the required customer actions.

Please report all device related incidents to the manufacturer, distributor or local representative, and the national Competent Authority/regulatory agency if appropriate, as this provides important feedback. The Competent Authority/regulatory agency of your country has been informed of this communication to customers.



Signature

VP Quality &
Title

Regulatory Affairs

MARVA JANSSON
Printed Name

2019-DEC-19 KISTA
Date, city