

December 20<sup>th</sup>, 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

<b>Brand name</b>	SwiftHook		
<b>Item number</b>	70200008		
<b>Technical description</b>	Component which attaches spreader bar (SlingBar) to lift arm of a mobile or ceiling lift. Enables quick release of spreader bar.		
<b>Intended use</b>	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.		
<b>Associated mobile lifts</b>	Vega	<b>Item number</b>	All
	Eva	<b>Item number</b>	All
	Carina	<b>Item number</b>	All
<b>Associated ceiling lifts</b>	RiseBasic	<b>Item number</b>	All
	RiseAtlas	<b>Item number</b>	All
	RisePorto	<b>Item number</b>	All
<b>Affected units</b>	Affected units comprise all mobile lifts and ceiling lifts equipped with SwiftHook. SwiftHook is provided with all Vega505EE mobile lifts per default. SwiftHook is provided as spare part for all other mobile and ceiling lifts.		

## 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.

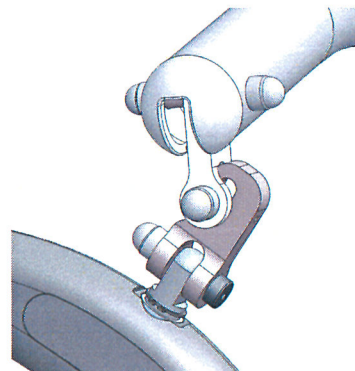


Figure 1. SwiftHook in unstable position

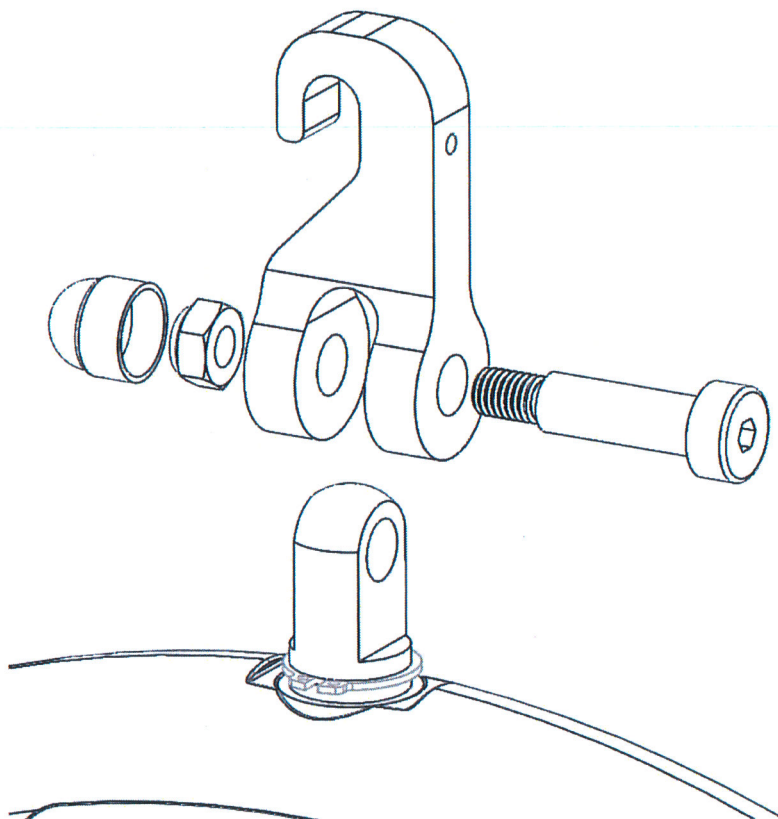
## REQUIRED ACTIONS

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

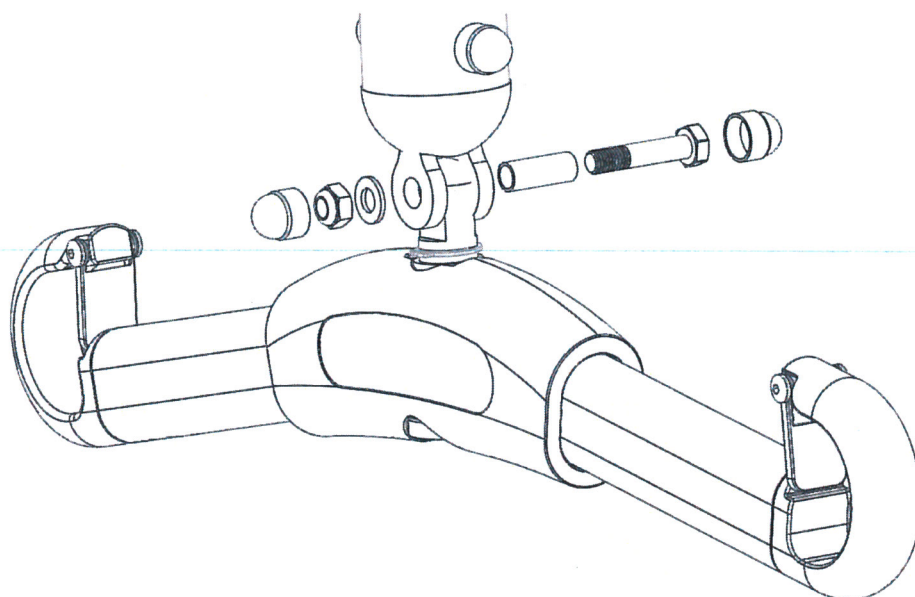
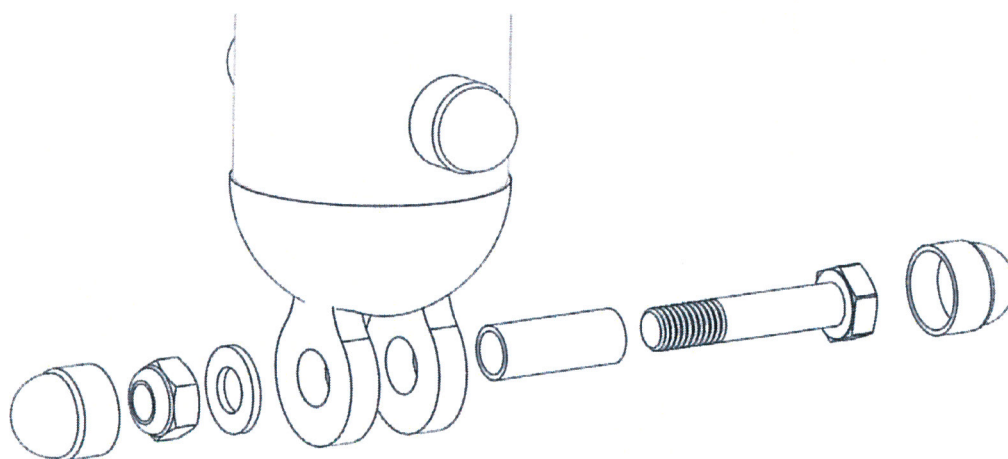
### Action 1. Direct mounting of spreader bar onto mobile/ceiling lift

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

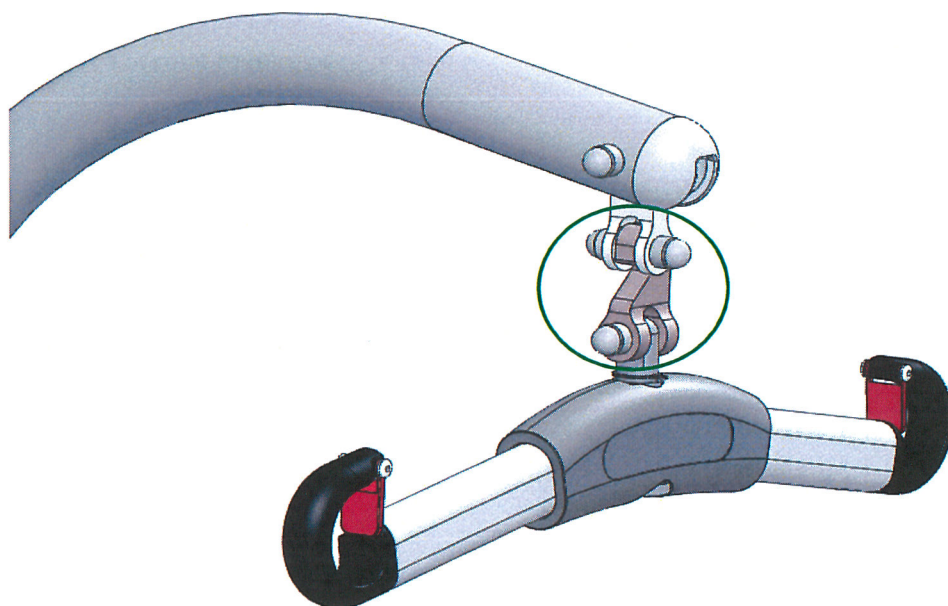


Figure 2. **Correctly mounted** SwiftHook seen from front left hand side. Connection point encircled in green.

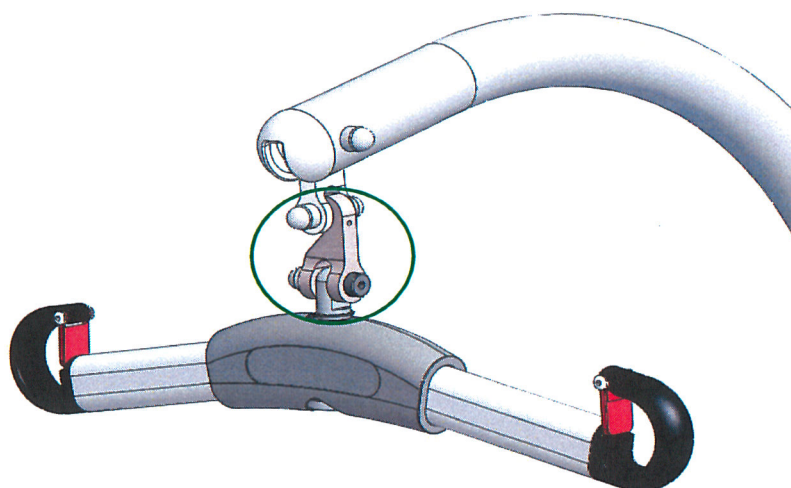
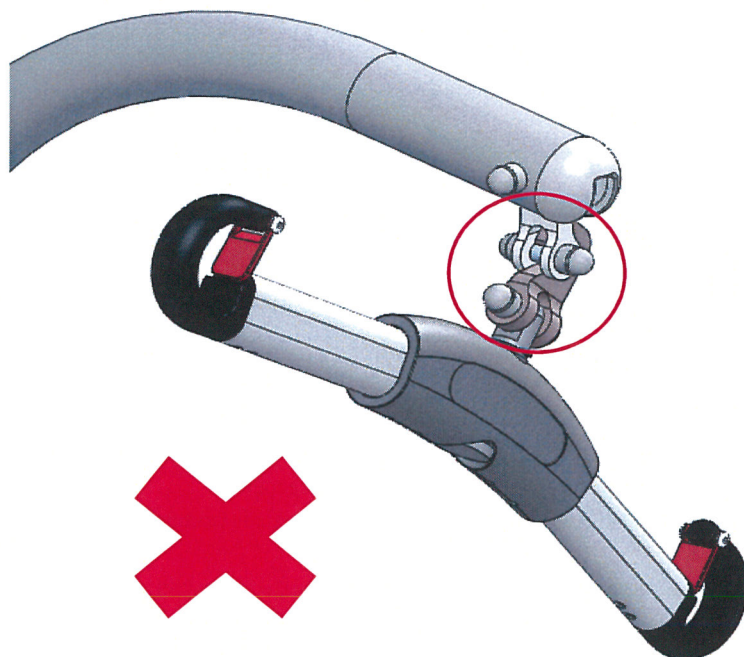


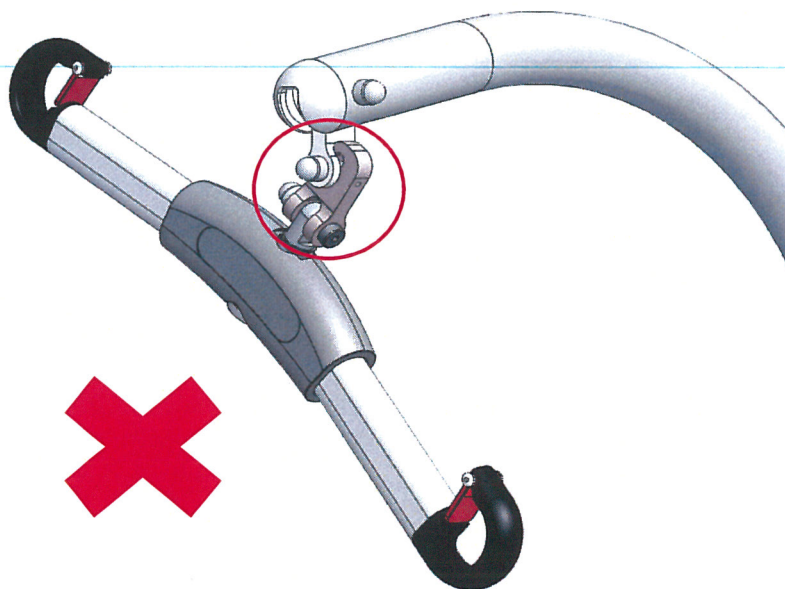
Figure 3. **Correctly mounted** SwiftHook seen from front right hand side. Connection point encircled in green.



**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.*

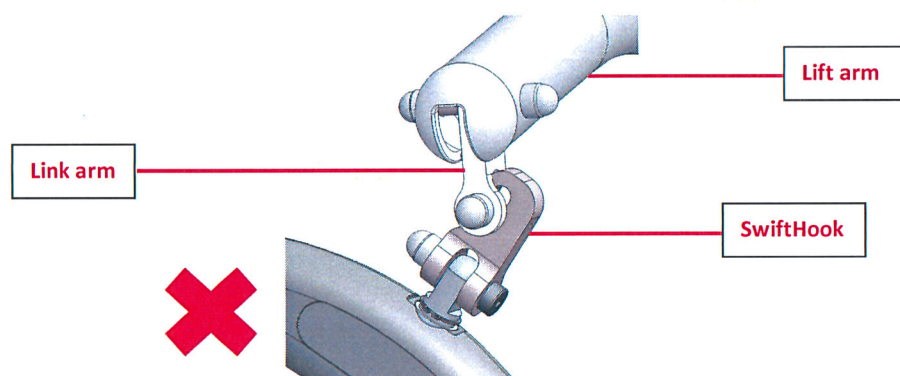


Figure 6. Close-up of incorrectly mounted SwiftHook in unstable position

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 31<sup>st</sup>, 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 19<sup>th</sup>, 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

MARIA JONSSON  
Printed Name

2019-DEC-19 KISTA  
Date, city

December 20<sup>th</sup>, 2019

**HANDICARE AB**

## CUSTOMER RESPONSE FORM

Field Safety Notice (FSN) information	
Manufacturer FSCA/FSN Reference	C083
FSN Date	December 20th, 2019
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 Organisation		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
<input type="checkbox"/>	I performed all actions requested by the FSN and I am aware of use errors associated with the SwiftHook.	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	
<input type="checkbox"/>	I have inspected and corrected affected device units, specify quantity.	Qty:
		N/A      Comments:
<input type="checkbox"/>	I do not have any affected devices.	
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	
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 LOCAL REPRESENTATIVE

Return this completed and signed Customer Response Form to your local Handicare representative using contact details specified below.

<b>Name of local representative</b>	Click or tap here to enter text.
<b>E-mail</b>	Click or tap here to enter text.
<b>Telephone</b>	Click or tap here to enter text.
<b>Fax</b>	Click or tap here to enter text.
<b>Address</b>	Click or tap here to enter text.
<b>Web Portal</b>	Click or tap here to enter text.
<b>Deadline for returning the customer response form</b>	June 30 <sup>th</sup> , 2020

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

It is important that your organisation takes the actions detailed in the FSN C083 and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Thank you for your kind cooperation.

