July 3rd, 2020

Field Safety Notice (FSN)
SwiftHook - Product Removal

HANDICARE AB

MANUFACTURER FSCA/FSN REFERENCE: C083

FSN TYPE: UPDATE OF FIELD SAFETY NOTICE 2019-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	The affected units include all mobile lifts and ceiling lifts equipped with SwiftHook: • 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.

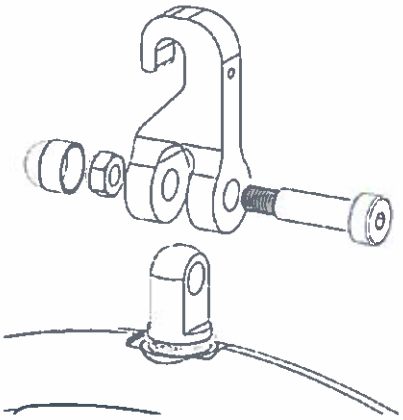
REQUIRED CORRECTIVE ACTIONS

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.

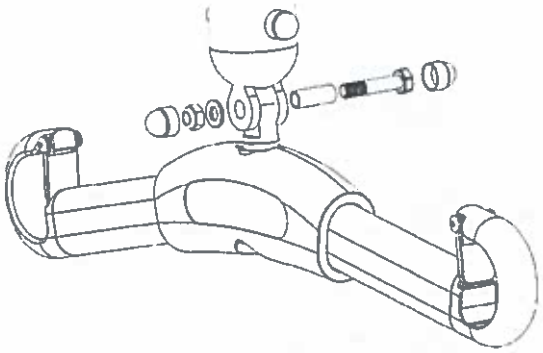
Please see below instructions to directly mount the spreader bar to the mobile/ceiling lift. If you require further help or instructions, please contact your local Handicare representative.

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.

HANDICARE AB Torshamnsgatan 35, SE-16440 Kista, Sweden
+46 (0)8 557 62 200 quality@handicare se www.handicare.com



3. **Please note that the removed SwifHook 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

Negar Klingenstierna

Printed Name

Regulatory Affairs PH,

Handicare AB

Title

2020-July-03 Kista

Date, city

HANDICARE AB Torshamnsgatan 35, SE-16440 Kista, Sweden
+46 (0)8 557 62 200 quality@handicare.se www.handicare.com

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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 Organisation			
☐	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:
☐	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*	

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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.