

## SwiftHook

### Affected Devices:

<b>Description:</b>	SwiftHook
<b>Article Numbers:</b>	70200008
<b>Date:</b>	20 March 2024
<b>Attention:</b>	All Customers and End-users
<b>Reason:</b>	Recall of SwiftHook sold during 2022 and 2023. Following a previous FSN, it was decided on 2020-07-03 that the SwiftHook (item number 70200101) would be removed from the market. Since then, it has come to our attention that three units of this product have been placed on the European market.

Dear Valued Customer:

The purpose of this letter is to advise you that Direct Healthcare Group Sverige AB (DHG) is executing a Field Safety Notice for the SwiftHook. This Field Safety Notice describes below the action advised to be taken by you.

- Immediately stop using the product and contact the manufacturer for a replacement product.

**Description of Issue** – On 2019-12-19, Handicare AB (now Direct Healthcare Group Sverige AB following a change of ownership) issued a Field Safety Notice for the SwiftHook due to repeated product defects related to the attachment of spreader bars to both floor and ceiling lifts from within the company's product portfolio.

Following a review of data related to defective SwiftHooks from between 2009-2019, the decision to discontinue production of the product was made on 2020-07-03.

It has now come to our attention that an unforeseeable conversion of the data pertaining to this product within our sales system has resulted in three units being placed on the European market due to a discrepancy in the management of our sales system.

**Actions to be taken by the user of the device** – Immediately stop using the SwiftHook. Contact your DHG representative or the DHG Sverige AB Head Office on +46 (0) 8 557 62 200 to arrange a replacement product. The replacement product is QuickLink, item No 70200101. Return the SwiftHook to the manufacturer on the manufacturer's account.

**Transmission of this Field Safety Notice** - Please assure within your organisation that this notice is communicated to all personnel who need to be aware of this Field Safety Notice. In case you have transferred products to a third party please communicate this information to them also, informing them of the below mentioned contact person.

Please maintain awareness on this notice for an appropriate period to ensure effectiveness of the above action.

A copy of this Field Safety Notice has been provided to the MPA.

# FIELD SAFETY NOTICE



Moving Health Forward

**Confirmation** - Please complete and return the attached Confirmation Form and table (see Appendix) via email to [quality.se@directhealthcaregroup.com](mailto:quality.se@directhealthcaregroup.com) to confirm that the above actions have been taken.

**Contact reference person** - *For questions regarding this Field Safety Notice, please contact:*

Elisabet Lindberg (Head of Quality and Environment EU/PRRC)  
Direct Healthcare Group Sverige AB  
Torshamnsgatan 35, 164 40, Kista, Sweden  
Tel: +46 (0) 8 557 62 200  
Email: [elisabet.lindberg@directhealthcaregroup.com](mailto:elisabet.lindberg@directhealthcaregroup.com)

Thank you for your cooperation in this matter. Direct Healthcare Group Sverige AB is committed to providing quality products and service to its customers and we apologise for any inconvenience this situation may have caused.

Yours faithfully,

Elisabet Lindberg  
Head of Quality and Environment EU

**Enclosures:**

Appendix: [Confirmation Form and Table](#)

## Appendix

### Field Safety Notice – Confirmation Form

Product Name: **SwiftHook**  
Manufacturer Reference: **NC 36**  
Date: **20 March, 2024**  
Type of Action: **Field safety corrective action**

<b>Hospital / Facility Name</b>		
<b>Hospital / Facility Address</b>		
<b>Telephone Number</b>		
<b>Name</b>		
<b>Signature</b>		<b>Date:</b>

I have read and understood the contents of this Field Safety Notice and confirm that I have checked the actions regarding the SwiftHook affected that I have in my possession. The results of the check are detailed below:

Status		
Quantity of slings from the affected batch in our possession:	Replacement required	Refund required
	<input type="checkbox"/>	<input type="checkbox"/>

Please return by **15 April 2024** to:

Direct Healthcare Group Sverige AB  
Torshamnsgatan 35, 164 40, Kista, Sweden

Or

Email: [quality.se@directhealthcaregroup.com](mailto:quality.se@directhealthcaregroup.com)