

## **Urgent Medical Device Correction – THIRD AND FINAL NOTIFICATION**

**Subject:**

**(1) Universal Sling Bar - Product # 3156074,  
3156075 or 3176076**

**(2) Universal Sling Bar with Quick Release Hook  
(QRH) - Product # 3156084, 3156085 or 3156086**



**FSCA-identifier:** Mod 408  
**Type of action:** Device Recall  
**Date:** May 27, 2009  
**To:** Facility Risk Manager/Facility Administrator/End User  
**Range of serial numbers affected:** 1200101–1245680, 121204–121499, 1222407–12225241  
**Production Dates:** N/A

NOTE: Universal SlingBar 350, 450, 600 (without Quick Release Hook) mounted on overhead lifts or Golvo mobile lifts are NOT affected.

**Background:**

Liko initiated a recall of the Universal Sling Bar products noted above on June 2, 2008 when it was determined that the sling bar could break in use, resulting in the potential for serious injury to a patient during a transfer. Our records indicate that you have purchased one or more of Universal Sling Bar products covered by this recall. We have sent you two prior notices and have not received a response. Your cooperation with this recall is extremely important to protect patients from possible harm. Liko is making one final attempt to enlist your cooperation in completing this recall. Liko is committed to patient safety and to compliance with regulatory and legal requirements. Your assistance will aid us in meeting these commitments.

**Action to be taken:**

We need your assistance to locate, inspect, and document affected Universal SlingBars which may be in use on equipment in your possession.

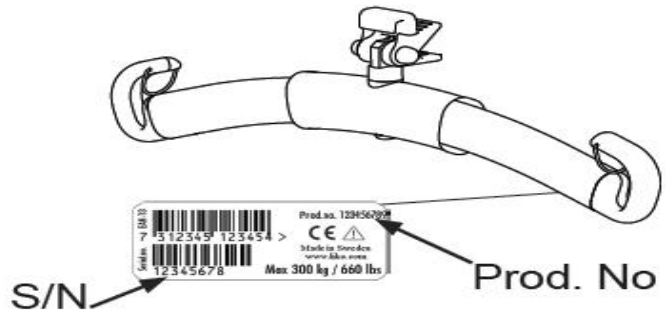
• *Locate affected sling bars:*

Verify the accuracy of our records by inspecting all Universal SlingBars permanently mounted, and those supplied with the Quick Release Hook (QRH) feature in your possession.

- **Inspect your sling bar:**

Each unit has an identification label affixed to the underside of the sling bar. Refer to picture shown to locate the product number (Prod. No) and serial number (S/N) on this label.

Check the label and determine if your sling bar is within the affected product number and serial number range as listed in this notification.



- **Document affected sling bars:**

Using the Verification Form attached, inform us of any product at your facility which you believe is affected by this correction and needs to be replaced. Inform us of any product which you may have disposed of or moved to another facility. Confirm that you have received this notification and understand it.

### **Instructions for Replacement:**

When the completed Verification Form is received at Liko and the information is verified, replacement product will be shipped via Federal Express to the address on the form. *(If there is a change in name or address, please make changes on the Verification Form.)*

### **Return of the affected Product:**

In order to expedite the return of affected sling bar(s), we will include an ARS Label in the box with the replacement product. **All old sling bars in the recall range from your facility MUST be returned to Liko, or you will be invoiced for the new sling bars.** Please use the ARS Label provided and Shipment Box for the return of the affected product, so that we may track its receipt to our location.

**Within 14 days from receipt of this Notification, it is critical that you complete and fax back the Verification Form to 508-590-0356, to ensure that regulatory documentation requirements are complied with.**

**If we do not receive any response from you following receipt of this *THIRD AND FINAL NOTIFICATION*, we will have no option but to include your company/home in our final close-out report to the FDA as having been “UNCOOPERATIVE” in completing this modification, as required by regulation.**

### **Transmission of this Field Safety Notice:**

Please forward a copy of this letter to any other facility personnel you deem appropriate. If you have any questions concerning this request, please contact Anne Jordan at 888-545-6671 or by email at Anne.Jordan@Liko.com.



We apologize for any inconvenience this Medical Device Correction may cause you. We sincerely appreciate your assistance and understanding as we take this precautionary measure to uphold our high safety standards for safe patient lifting.

Regards,

Liko, Quality & RA Department  
Reference: MOD 408

**MOD 408 - Verification Form - Page 1 of 2**  
**Fax all pages of this Verification Form to: 508-590-0356**  
 Attention: Anne Jordan

**URGENT: Field Correction Program – THIRD & FINAL NOTIFICATION**

<p align="center"><b>Universal SlingBar</b>          Product No's: 3156074, 3156075, 3156076          (when attached on any LikoLight, Viking L, M, S or XS mobile lift)</p> 	<p align="center"><b>Universal SlingBar, with Quick Release Hook (QRH)</b>          Product No's: 3156084, 3156085, 3156086</p> 
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**Affected sling bar serial # range: 1200101-1245680, 121204-121499, 12222407-12225241**

**Note:** Universal SlingBar 350, 450, 600 (without Quick Release Hook) mounted on overhead lifts or Golvo mobile lifts are **NOT** affected.

1. I have read and understood the Field Safety Notice.  Yes  No

Any questions, contact Anne Jordan at 888-545-6671, or by email at [anne.jordan@liko.com](mailto:anne.jordan@liko.com).

2. We have inspected the sling bars on our Liko lifts & they fall within the **recall range** and are **affected** by this modification. I need the following replacement sling bars:  Yes  No

Lift Model & Serial # (if known)	Product # on the <i>affected</i> sling bar? (31560 __ )	Serial # on the <i>affected</i> sling bar (12_____)	Replacement Sling Bar needed
			<input type="checkbox"/> Yes
			<input type="checkbox"/> Yes
			<input type="checkbox"/> Yes
			<input type="checkbox"/> Yes
			<input type="checkbox"/> Yes
			<input type="checkbox"/> Yes
			<input type="checkbox"/> Yes
			<input type="checkbox"/> Yes
			<input type="checkbox"/> Yes
			<input type="checkbox"/> Yes
			<input type="checkbox"/> Yes



**3. For Facilities/End Users who need Replacement sling bars: Replacement sling bar(s) will be shipped via Federal Express to the address below, and to the attention of the person completing this section.**

Facility / End User Name: <i>(Please Print)</i>	
Address:	
Phone #	
Person Completing this Form: <i>(Please Print)</i>	
Title:	

**4. For Facilities/End Users who have previously received replacement sling bar(s) but have not returned the old sling bar(s) to Liko, please select whichever option applies below and sign:**

- We have received replacement sling bars for our lifts and **will** return the old sling bars to Liko.  Yes
- We have received replacement sling bars from Liko and have placed them on the lift(s). We have destroyed/thrown away the old sling bars at our facility. They are no longer in use.  Yes
- Other (please explain): \_\_\_\_\_

Facility/End User Name: <i>(Please Print)</i>	
Address:	
Phone #	
Person Completing this Form: <i>(Please Print)</i>	
Title:	

We apologize for any inconvenience this Field Correction Program may cause you. We sincerely appreciate your assistance and understanding as we take this precautionary measure to uphold our high safety standards for safe patient lifting.

**MOD 408 - Verification Form – Page 2 of 2**  
***Fax all pages of this Verification Form to: 508-590-0356***  
**Attention: Anne Jordan**