Dear Sir/Madam,

Hill-Rom has become aware of a potential safety issue related to one of our products.

According to our database we can see that your medical device could potentially be affected by this field corrective action.

We kindly ask you to read the attached Field Safety Notice and take actions accordingly.

If you have any questions concerning this Field Safety Notice, please contact Hill-Rom Technical Support, your distributor, or your Hill-Rom representative.

Thank you in advance for your due diligence on this matter.

Regards,

Hill-Rom Technical Support

Medical Device Correction – Final Notice

Subject: Liko® Universal SlingBar 350, SlingBar 450 and SlingBar 600

FSCA-identifier: MOD1238

Type of action: Corrective action notification

Date:

To: Facility Risk Manager/Facility Administrator

We have previously attempted to contact you, but have not yet received a response.

Hill Rom's practice is to attempt to contact you three times, including certified letters, and/or telephone calls to obtain the current status of the correction.

If we do not receive a response after this attempt, we will determine that you do not intend to respond and will consider you non-cooperative in this matter.

Attached to this letter is a response form as in previous letters.

Please reply to this request within 2 weeks of receipt. If you have recently responded to us, we may not have received or processed it yet, so please accept our apologies.

If you have any questions concerning this request, please contact Hill-Rom Technical Support, your distributor, or your Hill-Rom representative.

Thank you for your support in this matter.

Regards,

Hill-Rom Technical Support

Medical Device Correction

Subject: Liko® Universal SlingBar 350, SlingBar 450 and SlingBar 600

FSCA-identifier: MOD1238

Type of action: Corrective action notification

Date:

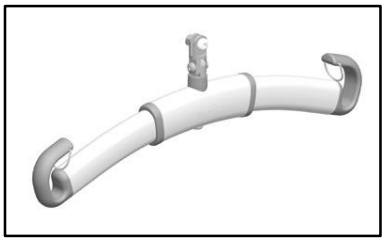
To: Chief Executive, Facility Administrator, Facility Engineer, Vigilance Manager, Biomedical Engineering and Medical Device Liaison Officer

Affected Devices: Serial number interval on sling bar 1200101 to 1370151

Models affected:
Universal SlingBar 350, p/n 3156074, 3156084 and 3156094
Universal SlingBar 450, p/n 3156075, 3156085 and 3156095
Universal SlingBar 600, p/n, 3156076 and 3156086

These may be bundled with the
Golvo™, Uno™, LikoLight™, Likorall™, Multirall™ and Viking™ XS/S/M/L mobile patient lifts.

Background:



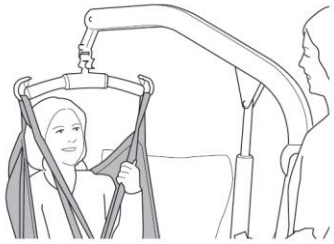
Hill-Rom has become aware of a potential safety issue related to the Universal SlingBar 350, SlingBar 450 and SlingBar 600 which could be attached to various Liko overhead and mobile patient lifts. Complaints have been received that the center bolt of the sling bar, which connects the bar to the patient lift, has failed during use. The potentially affected sling bars have been produced until May 2014.

Analysis has shown that the sling bar is reliable when used as intended with the sling bar level during the lift. However, if the sling bar is not used as intended, the bolt may be weakened. If the bolt is weakened there is a potential risk for breakage with the result of a free fall of the patient. This hazard could cause potentially minor to catastrophic injuries to a patient.

Non-approved usages include: lifting repeatedly with only one hook (a single side of the sling bar), lifting at angles, or using the sling bar to lift heavy equipment for servicing activities. Our design was not intended or indicated to withstand these uneven loads. Our test data indicates that on proper use of the sling bar, the bolt will not fail. It is important to highlight that the sling bar design is compliant with “ISO 10535: Hoists for the transfer of disabled persons—Requirements and test methods” and that the lift design requirement specifications (DRS) for symmetrical loading adhere to the specifications required by this international standard.

Hill-Rom therefore requests customers to always load the sling bar evenly and always lift using both hooks of the sling bar, see pictures extracted from instruction guide below. There are no hazards when using the device as intended. These are new instructions for

users with a lift manufactured prior to 19 November 2013. Complete instruction guides are available from www.hill-rom.com.



When performing a lift always load the sling bar evenly using both hooks.

Do not perform a lift with uneven load on the sling bar.

Do not perform a lift with one hook.

Action to be taken by user:

Phase 1: Inspection
Hill-Rom requires you to inspect all your Universal SlingBars within defined serial number interval (see affected devices above) according to attached Inspection Point Instruction. If you have affected units, identify your sling bar model according to attached Replacement Guide and confirm that the affected sling bar(s) will be scrapped. Fill in the response form and return it to Hill-Rom via Docapost. This will provide us with the necessary information to arrange further activities in phase 2.

Phase 2: Replacement of affected devices
If you have affected units and you have returned the response form, Hill-Rom will provide you with new sling bar(s) free of charge.

Transmission of this Field Safety Notice:
Please pass this notice on to all those who need to be aware within your organization and/or to any organization where the affected devices have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Hill-Rom confirms that the relevant Regulatory and Competent Authorities have been informed of this Field Safety Notice.

Contact reference person:
As part of its policy of continuous improvement, Hill-Rom has developed a partnership with Docapost (La Poste Group in France) for the distribution of the safety instructions or information related to the Hill-Rom medical devices.

You will find enclosed the response form which must be returned to our partner DocaPost via mail, email or fax, who will process the document management responses.

Please fill in the form clearly and legibly and check the proposed options.

This will allow our local coordinator to manage the necessary elements and to follow up in a timely manner.

If you have any questions concerning this Field Safety Notice, please contact Hill-Rom Technical Support, your distributor, or your Hill-Rom representative.

Regards,

Hill-Rom Technical Support

Attachments: Response Form/Receipt
Replacement Guide
Inspection Point Instruction

Response Form/Receipt

Subject: Liko® Universal SlingBar 350, SlingBar 450, and SlingBar 600 (Mod 1238)

It is important that you return this form/receipt as acknowledgement of your receipt and provide us with the necessary information.

Please complete the following with the correct information, and **return this Response Form** without delay. Please specify the delivery address, Facility Authorized person and contact person for the replacement sling bars. Thank you!

Name of the facility: _____

Address of the facility: _____

City: _____ Zip: _____

Facility Authorized Name: (print)_____

Contact person:_____

Signature: _____ Date: _____/_____/_____

Title: _____ Phone: _____

Email: _____ Fax: _____

We have inspected the products according to the Inspection Point Inspection and:

☐ we **do not have** any potentially affected products.

☐ we **have** potentially affected products identified according to Replacement Guide and we need to replace:

___ pcs Universal SlingBar 350 (item number 3156074)
___ pcs Universal SlingBar 350 QRH (item number 3156084)
___ pcs Universal SlingBar 350 R2R (item number 3156094)
___ pcs Universal SlingBar 450 (item number 3156075)
___ pcs Universal SlingBar 450 QRH (item number 3156085)
___ pcs Universal SlingBar 450 R2R (item number 3156095)
___ pcs Universal SlingBar 600 (item number 3156076)
___ pcs Universal SlingBar 600 QRH (item number 3156086)

☐ I hereby confirm that the affected Universal SlingBars **will be scrapped** and replaced with new SlingBars distributed by Hill-Rom.

☐ We have distributed potentially affected Universal SlingBars to the following consignees and have forwarded the letter to them (fill in name and address to the consignees, make copies of response form as needed):

Name / Contact: _____

Address: _____

City / State: _____

Phone: _____

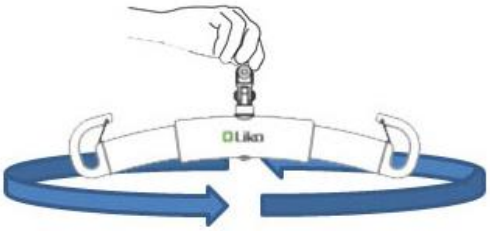
Return this Form to:

DOCAPOST BPO IS
HILL ROM MODS
Energy Park
150 Boulevard de Verdun
92400 Courbevoie – France
or Fax:+33(0)1 46 35 97 98
or Email: hill-rom.mods@docapost-bpo.com

Inspection Point Instruction

1. If the sling bar is attached on a lift, please detach it from the lift before start of test.

   Hold the sling bar horizontal. Rotate the sling bar slowly and let it spin freely according to picture.

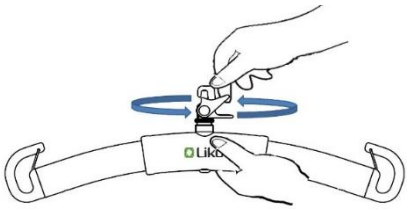


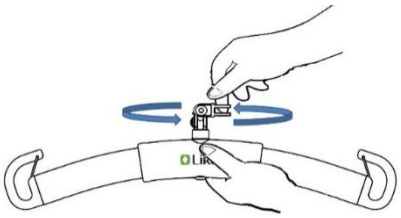
2. Does the sling bar rotate unevenly, wobble or does the spinning stop due to high friction?

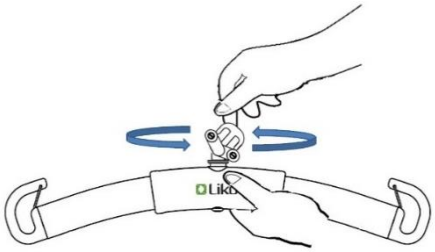
Yes → The sling bar needs to be replaced. Fill in the Response Form using the Replacement Guide and return to Hill-Rom via DocaPost.

NO ↓

3. Hold the sling bar in your hand and rotate the sling bar attachment slowly with one finger according to pictures below. Note that there are three different types of sling bar attachments, QRH, R2R and fixed link (thereof three pictures).







4. Does the sling bar attachment rotate with uneven or high resistance?

Yes → The sling bar needs to be replaced. Fill in the Response Form using the Replacement Guide and return to Hill-Rom via DocaPost.

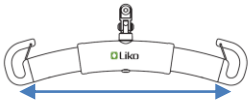
NO ↓

The sling bar rotates with ease and has even resistance. The sling bar does not need to be replaced.

Fill in the Response Form and return to Hill-Rom via DocaPost.

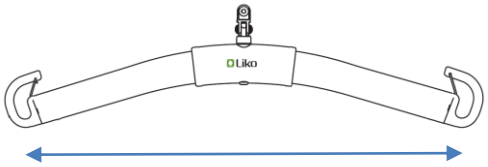
Replacement Guide

1. Identify your sling bar model



350 mm (¨~13.8 in)
Universal SlingBar 350

450 mm (¨~17.7 in)
Universal SlingBar 450



600 mm (¨~23.6 in)
Universal SlingBar 600

2. Identify Sling Bar attachment

Universal SlingBar 350
#3156074

Universal SlingBar 350 QRH
#3156084

Universal SlingBar 350 R2R
#3156094

Universal SlingBar 450
#3156075

Universal SlingBar 450 QRH
#3156085

Universal SlingBar 450 R2R
#3156095

Universal SlingBar 600
#3156076

Universal SlingBar 600 QRH
#3156086

3. Fill in Response form.

Fill in Response Form with correct number of each Universal SlingBar and return to Hill-Rom via DocaPost.