Urgent Field Safety Notice

Subject: Liko® Multirall™ 200 Q-link strap lock replacement

FSCA-identifier: MOD1322

Type of action: Device Modification
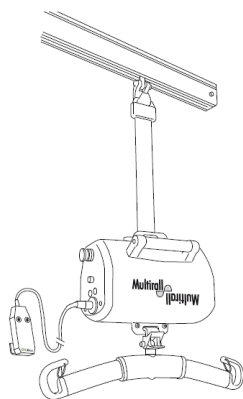
Affected devices:
Liko® Multirall 200 (product number 3130001)
Universal SlingBar 450 R2R (product number 3156095)
Universal SlingBar 350 R2R (product number 3156094)
Carriage D45 with Double Hook (product number 3136100)
Extension belt 300-400 mm (product number 3136226)
Extension belt 400-600 mm (product number 3136227)
Extension belt 600-1000 mm (product number 3136228)
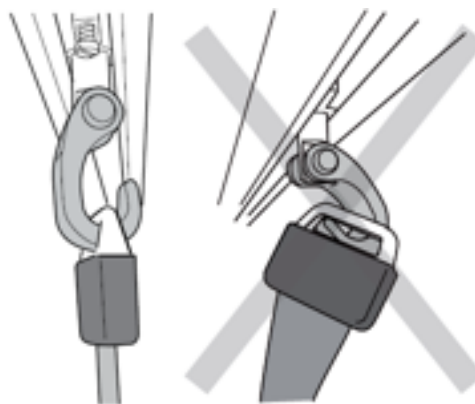Extension belt 1000-1400mm (product number 3136229)

Date:

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

Background:
Hillrom continues to receive complaints of incidents where the Multirall Q-link strap lock has not been correctly attached to the S65 rail carriage hook by user (illustrations below). This may lead to the Multirall lift becoming detached from the rail system, potentially resulting in the fall of both the lift motor and the patient. An advisory notice, with reinforcement of the instructions for use was shared with all customers of the Multirall 200 in 2017 (MOD1267), and since then additional complaints of serious incidents due to this use error have been received by Hillrom.
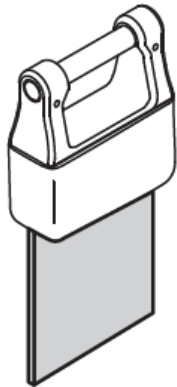

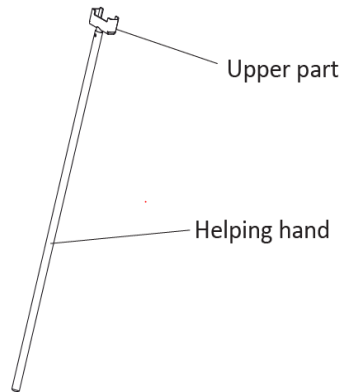Multirall 200 to attached S65 rail carriage hook

Correct vs incorrect attachment of Q-link strap lock of Multirall 200 to S65 rail carriage hook

The Q-link II strap lock (illustration below) was introduced on the Multirall overhead lift to resolve ease of use issues with the application of the Q-link strap lock to the S65 carriage
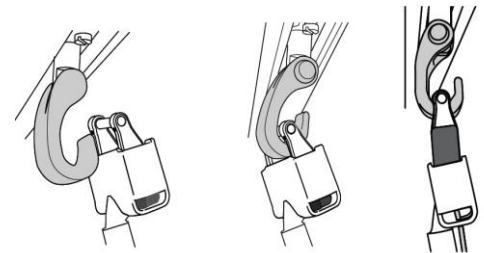
hook, particularly while applying the Q-link strap lock from the ground level with the Extension arm accessory (illustration below). The Q-link II has a larger opening which allows for better visibility while attaching the hook and the rolling feature of the Q-link II strap lock makes it easier to apply on the S65 rail carriage hook.

The Q-link 2 strap lock design

Upper part

Helping hand

Extension arm accessory

Attachment of Q-link 2 strap lock with the extension arm accessory

Hillrom will be replacing the Q-link on Multiralls to Q-link II to improve ease of use and mitigate potential risk to patient or caregiver.

*Note! Per the Service Manual and Design History File, the expected lifetime of Multirall™ 200 overhead lift is **10 years of normal use** provided that required **periodic inspection** and **preventive maintenance is** performed by personnel authorized by Hillom and using original Liko™ spare parts.*
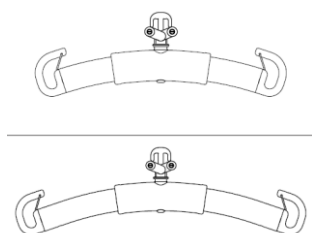
Action to be taken:

Hillrom will complete this field action in two phases.

Phase 1: Users inspect their Multirall installations, fill out the response forms and return it to Hillrom or official Hillrom distributor.
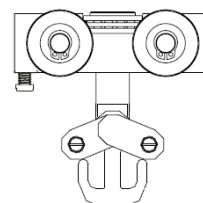
Kindly read carefully and perform the 2 actions ***within one month***:

Action 1: Please **inspect each Multirall installation in your facility and identify which category (A, B or C)** it belongs to:

Category A Multirall installations are used in combination with any of the room to room accessories, **Universal SlingBar 350 R2R** or **Universal SlingBar 450 R2R** or room to room rail **carriage D45 with Double Hook** (illustrations below).
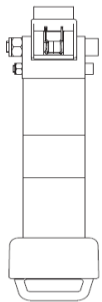

Room to room Universal SlingBar 350 and 450 R2R
(3156094 and 3156095)

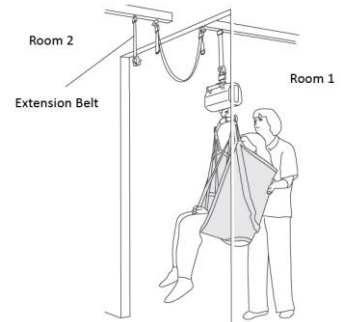Room to room rail carriage D45 with Double Hook
(3136100)

Category B Multirall installations are combined with an **extension belt** (illustrations below)

Extension Belt, adjustable. (3136226, 3136227, 3136228 and 3136229)

Extension Belt used on S65 rail carriage hook

Room to room installation with extension belts

Category C Multirall installations are **not combined with any of the accessories** in **A** or **B**

Action 2: Please fill out the attached response form and return it to Hillrom (MOD1322@hillrom.com) within one month. This will provide us with the necessary information to plan phase 2 of the field action.

Phase 2: Hillrom or an official Hillrom distributor will contact you to plan replacement.

Once you have identified units affected by this field corrective action and you have returned the response form, you will be contacted by Hillrom or an official Hillrom distributor, to schedule the replacement of the Q-link 1, R2R accessories and extension belts if present in the installations.

Transmission of this Field Safety Notice: (if appropriate)

Please transfer this notice to other organizations as appropriate. Please maintain awareness of this notice and additional resource for an appropriate period to ensure effectiveness.

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

Contact reference person:

If you have any questions regarding this safety notice, please contact Hillrom Technical Support, your distributor, or your local Hillrom representative

Yours sincerely

Hillrom Technical Support

Response Form / Receipt

Subject: Liko® Multirall 200 Q-link strap lock replacement (ref: MOD1322)

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

Please complete the following with the correct information and **return this Response Form** within one month. See specific instructions at bottom of page. Thank you!

Hillrom account number (if known): _____

Name of the facility:_____

Address of the facility: _____

City: _____ Zip: _____ Country: _____

Facility Contact Person Name: (print)

_____

Signature: _____Date: ____/____/ _____

Title: _____Phone:_____

Email: _____

Check actions taken:

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

Results from the inspection of our Multirall installations according to this Field Safety Notice show we have:
☐ Category **A: Room to Room Accessory**
☐ Category **B: Extension Belt Accessory**
☐ Category **C: None of the above**

☐ We have forwarded the letter to the following consignees that we have distributed the potentially affected lift to: (make copies as needed)

Name / Contact:
_____
Address:
_____
City / State:
_____
Phone:
_____

Response form shall be returned to MOD1322@hillrom.com within one month.