

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:

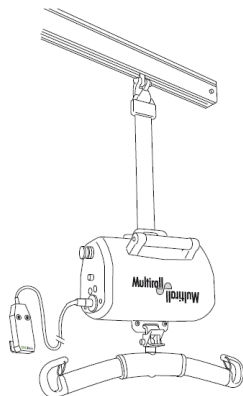
To: Hillrom Authorized Distributor

Dear Distributor,

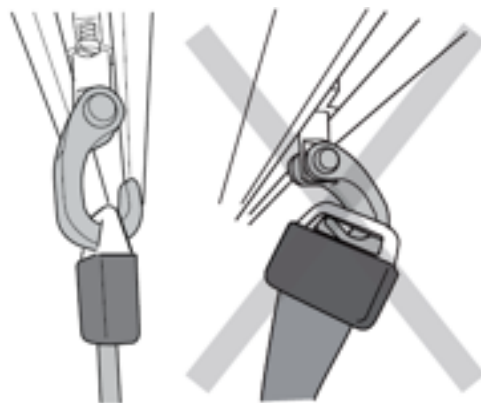
Hillrom has become aware of a potential safety issue related to one of our products. Our records indicate that your facility may have one or more affected devices. Please read this Field Safety Notice carefully and take all necessary actions.

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.

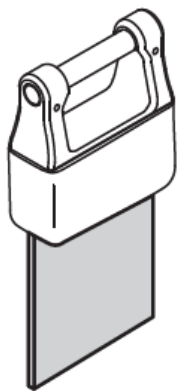


Multirall 200 attached to S65 rail carriage hook

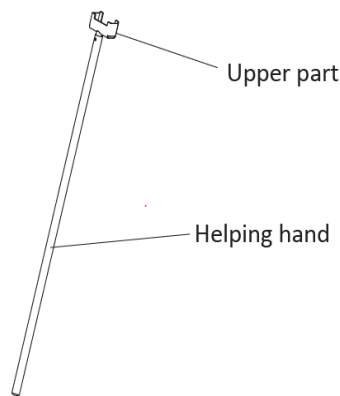


Correct vs incorrect attachment of Q-link strap lock of Multirall 200 to S65 rail carriage hook

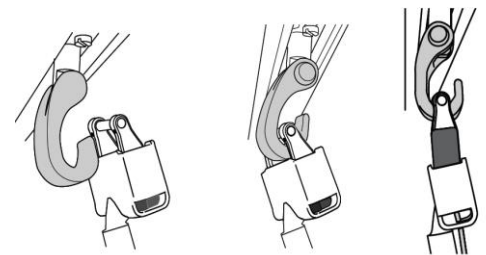
The Q-link II strap lock (illustration below) was introduced on the Multirall overhead lift to resolve ease of use issues with the application of the Q-link strap lock to the S65 carriage hook, particularly while applying the Q-link strap lock from the ground level with the Extension Arm accessory (illustration 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



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 Hillrom and using original Liko™ spare parts.*

Action to be taken by the distributor:

Hillrom is conducting this correction in two phases.

Phase 1 includes inspection by the users of their Multirall installations, the response received in Phase 1 will affect the continuation in Phase 2.

Please add your contact information to the customer response form at the end of this letter; forward the customer letter, added further down in this letter and including the customer response form, to your customers with affected products. A coordinator from Hillrom will contact you and provide a list of the affected units.

Update Hillrom on the status of the Field Corrective Action weekly. In the update the number of customers that have responded and the number of customers that have not yet responded should be stated in %. Updates on the status of the Field Corrective Action shall be received until 100% of the customers have responded or customers have been contacted three times without response.



Phase 2 includes replacement of the Multirall Q-link to Q-link II and R2R accessories and Extension belts if they are present in the installations. How to order spare parts will be communicated to you by your Hillrom coordinator.

Contact your coordinator on economic compensation.

If you have any questions about this letter contact your Hillrom coordinator.

Fill out the distributor response form below and return it to MOD1322@hillrom.com within 15 days.

Important: The distributor response form gives Hillrom information on the development of the Field Corrective Action. It is mandatory to return the response form to Hillrom.

If you have any questions concerning this Field Safety Notice, please contact Hillrom Technical Support, or your local Hillrom representative.

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

Yours sincerely

Hillrom Technical Support



Distributor 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 15 days**. 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 confirm the receipt of this letter, we have added our contact information to the customer response form and have forwarded the information to the affected customers.

We do not have any affected units

Response form shall be returned to MOD1322@hillrom.com within 15 days.

Urgent Field Safety Notice

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

FSCA-identifier: MOD1322

Type of action: Field Corrective Action

Affected devices:

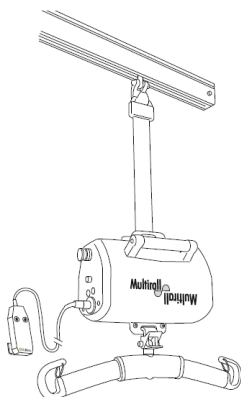
Liko® Multirall 200 (product number 3130001)
Universal SlingBar 450 R2R (product number 3156095)
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Carriage D45 with Double Hook (product number 3136100)
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Date:

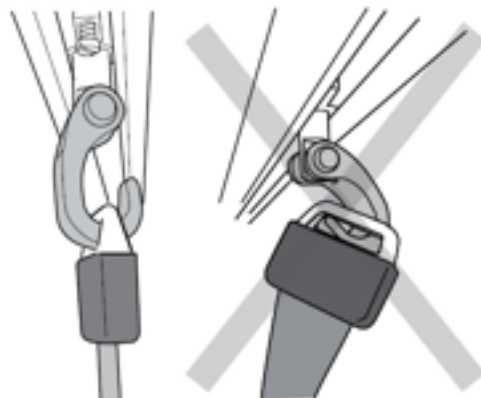
To: Chief Executive, Facility Risk Manager, Facility Administrator, Facility Engineer, Vigilance Manager, Biomedical Engineering and Medical Device Liaison Officer

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.



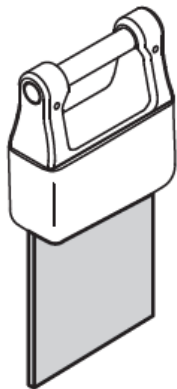
Multirall 200 to attached S65 rail carriage hook



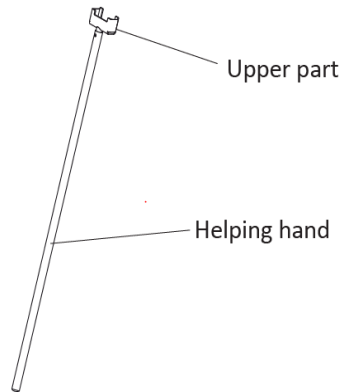
Correct vs incorrect attachment of Q-link strap lock of Multirall 200 to S65 rail carriage hook

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

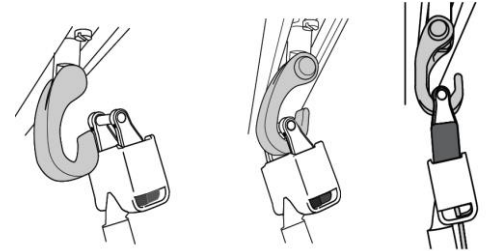
the hook and the rolling feature of the Q-link II strap lock makes it easier to apply on the S65 rail carriage hook.



The Q-link 2 strap lock design



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 Hillrom and using original Liko™ spare parts.*

Action to be taken:

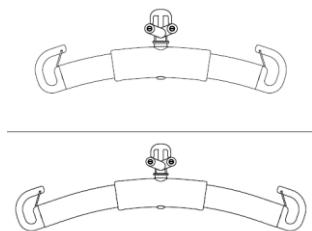
Hillrom will perform this field action in two phases.

Phase 1: Users inspect their Multirall installations, fill out the response forms and return it to Hillrom or official Hillrom distributor.

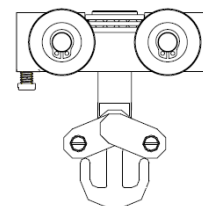
Kindly read carefully and take the 2 actions **within one month**:

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)

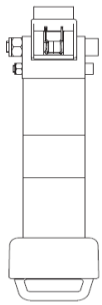


Room to room Universal SlingBar 350 and 450 R2R (3156094 and 3156095)



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

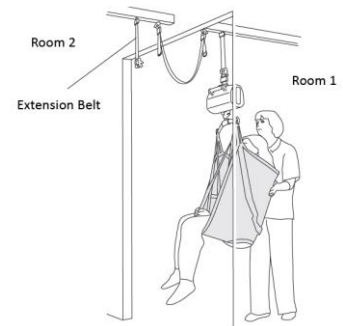
Category B Multirail installations are combined with an **extension belt** (illustrations below)



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 Multirail 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 your Hillrom distributor 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



Customer 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**. See specific instructions at bottom of page. Thank you!

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)

Response form shall be returned to the below contact

Name / Contact: _____
Address: _____
City / State: _____
Phone: _____
E-mail: _____