

Urgent Field Safety Notice

Subject: Strap Gripper 3136250, for Liko® MultiRall™ 200

FSCA-identifier : MOD1281

Type of action: Urgent Field Safety Notice

Date: _____

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

Details on affected devices:

Strap Gripper 3136250

Manufactured from 05NOV2015 to 28Jun2018

Description of the problem:

Hill-Rom has become aware the Strap Gripper accessory used with the Liko® Multirall™ 200 may have been assembled incorrectly during manufacturing. To date, Hill-Rom has received one complaint, where it was confirmed the accessory was incorrectly assembled. If the incorrectly assembled Strap gripper accessory as shown below is used during patient transfer, this could allow the patient to fall, resulting in potential injury to the patient. There have been no injuries reported to Hill-Rom for this issue. It is with an abundance of caution that Hill-Rom is notifying end users who have purchased any strap gripper accessories of this issue.



Action to be taken by the user:

- Immediately locate your Strap Gripper accessory. Use the photo above to inspect the strap gripper accessory to verify that the unit has been assembled correctly. The left side of the photo shows a correctly assembled unit, and the right side shows an incorrectly assembled unit.
- Immediately remove any incorrectly assembled units from use.
- Contact your Hill-Rom representative to coordinate the return and replacement of any incorrectly assembled units.
- Correctly assembled strap grippers accessories may continue to be used.
- Complete the attached response form and **return within 15 days**.

Transmission of this Urgent Field Safety Notice:

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

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

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

Regards,

Hill-Rom Technical Service

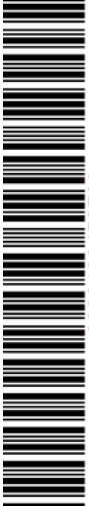


**Customer Response Form
(MOD1281)**

Subject: Strap Gripper Accessory (3136250) used with Liko® MultiRail™ 200

It is important that you return this form as acknowledgement of your Completion of the Inspection.

Please complete the following with the correct information, and **return this Response Form within 15 days**. See specific instructions at bottom of page for return information. Thank you!



Name of facility: _____

Address of facility: _____

City: _____ Zip: _____ Country: _____

Contact Person: *(print)* _____

Signature: _____ Date: ____/____/____

Title: _____ Phone: _____

E-mail: _____ Fax: _____

Check action(s) taken:

- We do not have or are not able to locate any potentially affected products.
- We have inspected our inventory based on the attached letter, and all units are **correctly assembled**.
- We have inspected our inventory and have found ____ **incorrectly assembled units** and are in the process of arranging for their return to the distributor.
- We have loaned/sold/donated affected units to: _____

Return this form to within 15 days:

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Please do not contact Docapost directly with enquiries, they will not be able to respond or assist you.