

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

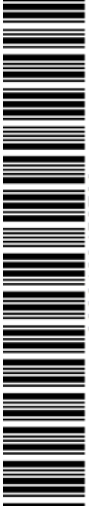


Customer Response Form (MOD1281)

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:

DOCAPOST BPO IS HILL ROM MODS

Energy Park

150 Boulevard de Verdun

92400 Courbevoie – France

or Fax +33(0)1 47 98 49 60

or Email: hill-rom.mods@docapost-bpo.com

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

URGENT FIELD SAFETY NOTICE

Dear Distributor:

This letter is to inform you of an Urgent Field Safety Notice related to the Strap Gripper accessory 3136250 used with the Liko[®] MultiRall™ 200. Our records indicate that you have purchased Strap grippers accessories manufactured and distributed between November 2015 and June 2018. Please immediately distribute the attached letter to your consignees requesting they inspect the potential affected Strap Gripper accessory and follow the instructions outlined in the communication.

Action to be taken by you the Distributor:

1. Immediately inform your customers using the enclosed **Urgent Field Safety Notice**. Please note that you will need to edit the customer letter by adding the date to the cover page and your Distributor contact information to the Customer Response Form.
2. Complete the attached **Distributor Response Form/Confirmation of Notification** and return to the address listed at the bottom of the form as confirmation of the actions you have taken **within 15 days of receipt**.
3. Please complete due diligence activities to obtain a completed **Customer Response Form** from your consignees **within 30 days**.
4. Using the **Inspection Response Form**, provide a summary of the inspection activities for each consignee and include the Customer Response forms that you received from your consignees. This should be returned **within 45 days**.

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

Thank you in advance for your attention on this matter.

Regards,

Hill-Rom Technical Service

*Attachment: (1) Distributor Response Form/Confirmation of notification
(2) Customer Urgent Field Safety Notice*



Distributor Response Form/Confirmation of notification (MOD1281)

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

It is important that you return this form/receipt as confirmation upon completion of your mailing to potentially affected accounts

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 address. Thank you!

Name of the Distributor: _____

Address: _____

City: _____ Zip: _____ Country: _____

Contact Person: (*print*) _____

Signature: _____ Date: *MM/DD/YY* ____/____/____

Title: _____ Phone: _____

E-mail: _____ Fax: _____

Check all action(s) that apply:

- We have **no inventory** of the strap gripper accessory.
- 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 have arranged for their return to Hill-Rom
- We **have notified** all potentially affected consignees and have records of the notifications.

Return this Form to:

DOCAPOST BPO IS HILL ROM MODS

Energy Park

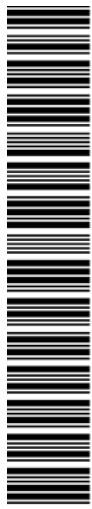
150 Boulevard de Verdun

92400 Courbevoie – France

or Fax +33(0)1 47 98 49 60

or Email: hill-rom.mods@docapost-bpo.com

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Inspection Response Form (MOD1281)

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

Complete the table below for each of your consignees and attach the customer response forms that you obtained from your consignees.

Consignee Name	Expected Total # of units	Response Received			
		No product / Cannot locate	Correctly assembled	Incorrectly assembled	Transferred to other location
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Qty:	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Qty:	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Qty:	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Qty:	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Qty:	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Qty:	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Qty:	<input type="checkbox"/>

By signing below, I am certifying that due diligence activities have been performed to obtain a customer response and the information in the above table is true and accurate.

Name of the Distributor: _____

Address: _____

City: _____ Zip: _____ Country: _____

Contact Person: *(print)* _____

Signature: _____ Date: MM/DD/YY) ____/____/____

Title: _____ Phone: _____

E-mail: _____ Fax: _____

Return the Inspection Response form and the Customer Response forms by email or mail to the addresses listed below.

Email:
se.quality@hill-rom.com

Physical address:

 Viktor Linde
 Hill-Rom Luleå
 Nedre vägen 100
 975 92 Luleå, Sweden.

Urgent Field Safety Notice

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FSCA-identifier : MOD1281

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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 accessory 3136250
Distributed between November 2015 and June 2018

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 grippers 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 authorized distributor as identified on the attached response form 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 to 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 the facility: _____

Address of the facility: _____

City: _____ Zip: _____ Country: _____

Name: (print) _____

Signature: _____ Date: ____/____/____

Title: _____

Phone: _____

Email: _____

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: _____

Please within the next 15 days; fax or email this form to:

Distributor Company:	
Contact Person:	
Phone:	
Fax:	
Email:	