

Urgent Field Safety Notice

Subject: Hill-Rom beds with Monkey Pole

FSCA-identifier MOD 426

Type of action Monkey Pole Recall

Date: January 2010

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

Affected devices:

Models: **ROLKO** Monkey Pole equipped with a roller
Type: TGN-R100GR

Production Dates: All ROLKO Monkey poles delivered by Hill-Rom between the 23rd July 2007 and the 24th February 2009 inclusive

Background:

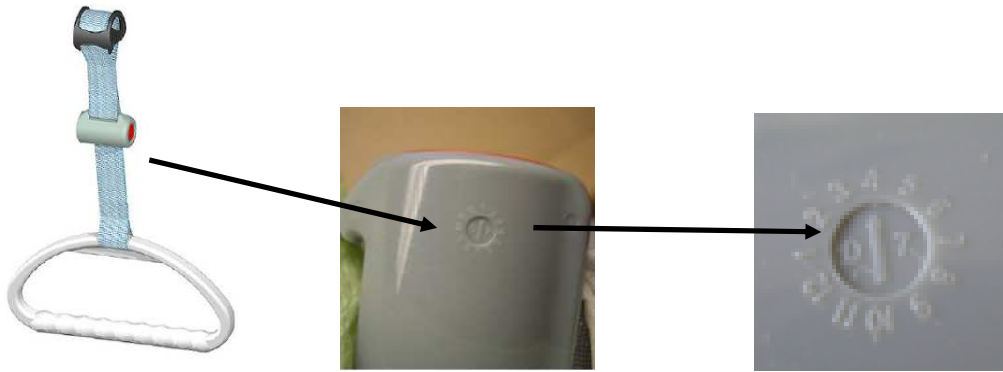
Our records indicate that your facility purchased one or more Monkey Poles mentioned above.

As part of our commitment to provide our customers with reliable and safe patient care solutions, Hill-Rom continually reviews the quality and performance of its products. Through these reviews, we have experienced a breakdown of the slit shape of the roller. This material failure, observed at the junction of the material in the mould, is caused by a deviation of the injection process performed by our supplier.

The defective Monkey Poles were produced **between January 2007 and January 2009** inclusive. These Monkey Poles have a red button on the side of the roller and can be easily identified with the traceability mark on the bottom of the roller as shown below, where the number in the centre represents the year of manufacturing and the numbers around pointed out with the arrow represents the month of manufacturing.



The red button is an easy way to identify the Monkey Poles



On this example: the roller has been produced in April 2007

Action to be taken by the user:

Given the risk of fall incurred by patients, Hill-Rom have decided to preventively replace all Monkey Poles mounted on the beds that were delivered during this period (see above).

- 1. Please remove those Monkey Poles, with a manufacturing date from January 2007 to January 2009 inclusive, from the bed. The bed may then remain in service.**
- 2. Complete and return Appendix 1 before February 26th, 2010.**

If you have relocated the beds and/or the accessories to another location or if the beds with its accessories has been sold or removed from service, please advise us immediately so we can take the appropriate steps to complete this action.

Transmission of this Field Safety Notice:

Please pass this notice on to all those who need to be aware within your organisation and/or to any organisation 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.

In cases where customers opt not to proceed with completion of this recall, Hill-Rom can not accept any responsibility for safety related issues or legal liabilities caused by the failure to respond.

Contact reference person:

If you have any questions regarding this safety notice, please contact Hill-Rom Technical Support using the attached listing for your geographical area.

We look forward to receiving your response.

Yours sincerely

Hill-Rom Technical Support

Technical Support Contact Information

Important: This is a comprehensive list of Technical Support contact information for Hill-Rom offices worldwide. If this is attached to another document or letter, it does **not** mean that every country listed below is affected by that document.

United States: 800-445-3720 (8:00 a.m. to 5:00 p.m. ET*)

Canada: 800-267-2337 (8:00 a.m. to 5:00 p.m. ET*)
or jeff.moorehead@hill-rom.com

Austria: 0810 00 10 23

France: 0820 01 23 45

Germany: 02152 144 255

Ireland: 01 413 6005

Italy: 02 950541

Netherlands: 0347 323532

Nordic Region: +46 (0)8 564 353 60
(Sweden, Norway, Denmark, Finland, Iceland)
or se.marketing@hill-rom.com

Spain: 902 193 423

Switzerland: 0848 81 15 30

United Kingdom: 01530 411000

All other countries requesting support for products manufactured in the U.S.: 812-934-1348 (8:00 a.m. to 5:00 p.m. ET*)
or gary.lakes@hill-rom.com

All other countries requesting support for products manufactured outside the U.S.: +33 (0) 2 97 50 92 45
or leny.rodriquez@hill-rom.com

* ET = New York time