
Urgent Field Safety Notice

Subject: Hill-Rom beds foot section collapsing

FSCA-identifier: Mod 428

Type of action: Plastic articulation replacement of AvantGuard™ 800 foot section

Date: December 4, 2009

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

Affected Devices:

Models: AvantGuard™ LI800A0, LI801A0, LI802A0

Range of serial numbers affected: HRP001337251 to HRP001358265 inclusive

Background:

Our records indicate that your facility purchased one or more AvantGuard™ 800, 801, and 802 bed frames mentioned above.

Through a quality review of our product, we have observed a number of instances involving a breakdown of the plastic part used to articulate the central section with the foot section of the bed. This material failure is caused by a deviation of the injection process performed by our supplier.

Action to be taken:

Our technical department will contact you in the coming weeks to make an appointment to replace affected parts.

Until we visit your facility, we ask that you do as follows:

- Locate the affected beds listed in this notice, and, if possible, remove the affected beds from service.
- If it is not possible to remove a bed from service, given the risk incurred by patients and caregivers, we strongly recommend that you **maintain the foot section of these beds in a flat position** until the part can be replaced.
- If you have scrapped, loaned, or sold any of the beds and/or accessories listed in this letter, please forward a copy of this letter to the new users, and tell us of their new locations or owners.



Transmission of this Field Safety Notice:

Please pass this notice on to all those who need to be aware within your organization and/or to any organization where the affected devices have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to make sure that this corrective action is effective.

Important: 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.

Regards,

Hill-Rom Technical Support

Attachment: DS119RD

Reference: MOD428

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.

Austria:	Tel: 0810 00 10 23 – Fax: + 43 (0)224 32 85 50 - 19 e-mail: austria@hill-rom.com
Canada:	Tel: 800-267-2337 (8 am – 5 pm ET (New York time)) e-mail: jeff.moorehead@hill-rom.com
Central & Eastern European Region:	Tel: +48 (0)692 414 826 – Fax: +44 (0)870 137 1872 e-mail: karolina_fenicka@hill-rom.com
France:	Tel: +33 (0)4 73 86 92 05 – Fax: +33 (0)4 73 86 92 05 e-mail: claude_martin@hill-rom.com
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Netherlands:	Tel: +31 (0)347 32 35 32 – Fax: +31 (0) 347 32 35 00 e-mail: info_nl@hill-rom.com
Nordic Region: (Sweden, Norway, Denmark, Finland, Iceland)	Tel: +46 (0)8 564 353 60 – Fax: +46 (0)8 564 353 61 e-mail: se.marketing@hill-rom.com.se
Spain:	Tel: +34 (0)902 193 423 – Fax: +34 (0)93 666 55 70 e-mail: asistencia@hill-rom.com
Switzerland:	Tel: 0848 81 15 30 – Fax: + 41 (0)21 7062132 e-mail: swiss_hotline@hill-rom.com
United Kingdom:	Tel: +44 (0)1530 411000 – Fax: +44 (0)1530 562029 e-mail: uk.customer.care@hill-rom.com
United States:	Tel: 800-445-3720 (8 am – 5 pm ET (New York time))
All other countries for support of products manufactured in the US:	Tel: 812-934-1348 (8 am – 5 pm ET (New York time)) e-mail: gary.lakes@hill-rom.com
All other countries for support of products manufactured outside the US:	Tel: +33 (0)2 97 50 92 45 e-mail: leny.rodriquez@hill-rom.com