



Urgent Field Safety Notice

Subject: Affinity® Birthing Bed (P3600 & P3700 Series) manufactured before 18-Oct-2007

FSCA-identifier: Mod 382

Type of action: Labor Grip Correction

Date: February 18, 2008

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

Affected devices:

This condition is present on all Affinity® Birthing Beds manufactured before October 18, 2007. Affinity beds manufactured with serial number I290AA7395 or greater are not impacted by this correction.

Background:

Hill-Rom has become aware of a potential safety issue involving the labor grip on all Affinity® Birthing Beds. A non-powered shear point has been identified with the labor grip. Hill-Rom has received one report of permanent injury with this condition.

The shear point is created by a 3/8" slot on the labor grip rotation mechanism, which is under the upper surface of the frame near the seat section of the bed inside of the labor grip housing.



Labor Grip without plug



Labor Grip with plug

With the labor grip in both the stored and use positions, the slot in the labor grip mechanism is visible through a hole in the labor grip housing. As the labor grip is rotated from the stored to the use position—or vice versa—the mechanism rotates inside the labor grip housing allowing the hole to become open then closed, thus creating a shearing point between the labor grip housing and the labor grip mechanism.

Action to be taken by the user:

Our records indicate that your facility purchased one or more Affinity® Birthing Beds manufactured before October 18, 2007. In order to facilitate the implementation of the labor grip correction with minimal disruption to your facility, the following actions are to be taken:

- Hill-Rom will provide a free upgrade kit for all of your Affinity® Birthing Beds. The kit includes two machined plugs per bed to insert into the hole, an insertion tool, and full written instructions to assist in the upgrade of the labor grips. The upgrade kit(s) will be addressed and shipped to your Biomedical/Clinical Engineering department in the near future. **Please complete and return the attached form to facilitate delivery to the correct person or department.**
- The upgrade should be performed on all Affinity® Birthing Beds manufactured before October 18, 2007, by your facility qualified personnel for the performance of maintenance activities. The upgrade should take approximately 10 minutes per bed.
- Upon request, Hill-Rom will provide training and assistance with this correction. In the interim period, you may continue to use your Affinity® Birthing beds.

If you have relocated the Affinity® Birthing beds to another location or if the beds have been sold or removed from service, please advise us immediately so we can take the appropriate steps to complete this action.

We apologise for any inconvenience this may cause your facility. We understand that our products and services are an integral part of many medical facilities, and are aware of the impact that any disruption may have on the facility and its caregivers' ability to care for their patients. Be assured that our first priority is to provide you with the high quality, safe and reliable products you have come to expect from us. We appreciate your patience and cooperation.

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. |

Contact reference person:

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

Yours sincerely,

Hill-Rom Technical Support

Attachments: 151447_1attachment, DS119RD
Reference: Mod 382

Fax Back

Customer A/C number: _____

Please select one of the following options:

- Please send me instructions to make the labor grip correction.

- Please contact me to discuss this Field Safety Notice.

Name
Position
Hospital or facility name
Address
Telephone
Fax
Date

Please fax this form to Customer Care at:
Or, scan and email to:

Thank you
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: (Sweden, Norway, Denmark, Finland, Iceland)	+46 (0)8 564 353 60 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