KayserBetten-U.S.

Beds & Cribs for Special Needs

Attn Dealer

Re: Voluntary Recall Campaign

Attached is a list of serial numbers, the purchase order number the bed was ordered under, and date you received. Please review as soon as possible. If there is a SN# listed that you are no longer able to service, please notify us as soon as possible with the SN# and reason why (client moved, etc) and any details possible by email to jennifer@kayserbettenus.com.

Parts will be shipping soon upon their arrival

Any questions or concerns please contact us

800-574-7880

jennifer@kayserbettenus.com

KayserBetten-U.S.
Beds & Cribs for Special Needs

Dealer: Binson's

Location: Center Line, MI

Receiving Date	SN#	Ordered PO#
4/2017	001975	254391
2/2021	008930	318726
3/2022	012966	335769

Mobility Unlimited, Inc. dba KayserBetten US
515 N. 12th Street
Allentown, PA 18102
1-800-574-7880

Urgent Field Safety Notice

Important safety information regarding the risk of injury and the necessity of locking the hand control,
concerning
Pediatric care bed KayserBett IDA

02.04.2026

Sender:
KayserBetten GmbH & Co. KG, Rieper Str. 12, 29683 Bad Fallingbostel, Germany
FDA Establishment Registration No.: 3006795806

Addressee:
U.S. dealers, operators, and users of KayserBett IDA pediatric care beds

Identification of the medical device concerned:

Product category	Product designation	Basis UDI-DI
Pediatric care bed	KayserBett IDA	426038961IDAGU

FDA Product Code: FNL | Device Class: 2 | Regulation Number: 880.5100 | 510(k) Exempt

Description of the problem including the identified cause:

Due to a serious incident with a KayserBett pediatric care bed, model Olaf sold outside the United States, which resulted in the death of a child, KayserBetten has conducted a comprehensive risk assessment and determined that the KayserBett IDA model marketed in the U.S. presents a comparable injury risk.

If the adjustment functions of the hand control, as instructed in the Manual, are not locked with the provided key when the patient (child) is unattended, there is an increased risk that the patient (child) or third parties (children) will operate the hand control and trap themselves or others under the bed frame or between the bed frame and the floor. This can lead to serious injuries or even death of the patient (child) or third parties (children).

This statement does not imply that any KayserBett IDA device in the U.S. has failed in any way. The risk arises solely from failure to follow the documented safety instructions for locking the hand control after use.

What measures are to be taken by the addressee?

Please inform all users and operators of a KayserBett IDA that by implementing the following safety measures, the above-mentioned risk to patients or third parties can be eliminated during further use of the product.

If the patient is unattended,

- the sleeping platform must be lowered to its lowest position.
- **the adjustment functions on the hand control must be locked using a key.**
- the doors must be closed.

Use the user safety instructions (Appendix I) to implement the measure.

Planned corrective action – Hand control replacement (Auto-Lock):

KayserBetten is implementing a corrective action to replace the hand control on all affected KayserBett IDA beds in the U.S. field with a modified hand control featuring an automatic locking function (Auto-Lock). With the new hand control, the adjustment functions lock automatically after each use, eliminating the dependence on the caregiver manually locking the hand control with a key.

The hand control replacement will be performed by an authorized service technician at no cost to the customer. Your U.S. distributor, Mobility Unlimited Inc. (DBA KayserBetten US), will contact you to schedule the replacement.

Until the hand control replacement has been completed on your bed, please strictly observe the interim safety measures described above and in Appendix I.

With this safety notice you will receive a feedback form and a table with the affected serial numbers (Appendix II), which you should complete in full and return to us once the hand control replacement has been successfully performed on your bed(s).

Passing on the information described here:

Please ensure in your organization that all users of the above-mentioned product and other persons to be informed are aware of this Field Safety Notice. If you have supplied the products to third parties, please forward a copy of this information or inform the contact person listed below.

Please keep this information at least until the hand control replacement has been completed.

The U.S. Food and Drug Administration (FDA) has been notified of this safety issue and the planned corrective action.

Contact person:
KayserBetten GmbH & Co. KG
Jens Lübben
Regulatory Affairs, PRRC
Phone: +49 5163 29004 14
E-mail: luebben@kayserbetten.de

U.S. distributor:
Mobility Unlimited, Inc. dba KayserBetten US
515 N. 12th Street
Allentown, PA 18102
Tel.: 1-800-574-7880
E-Mail: yadong@kayserbettenus.com

APPENDIX I: User safety instructions
APPENDIX II: Table of serial numbers

APPENDIX I

User safety instructions

IMPORTANT SAFETY NOTE!

If the adjustment functions of the hand control are not locked with a key when the patient (child) is unattended, there is an increased risk that the patient (child) or third parties (children) will operate the hand control and trap themselves or others under the bed frame or between the bed frame and the floor. This can lead to serious injuries or even death of the patient (child) or third parties (children).

If the patient is unattended,

- the sleeping platform must be lowered to its lowest position.
- **the adjustment functions on the hand control must be locked using a key.**
- the doors must be closed.

Safety instruction video

NOTE: A service technician will replace your current hand control with a new Auto-Lock hand control at no cost. Until the replacement is completed, the above safety measures must be strictly observed at all times.