

Theraposture Ltd
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Urgent Field Safety Notice

**Important safety information regarding the risk of injury
and the necessity of locking the hand control,
concerning
Paediatric care beds KayserBett OLAF and KayserBett Mascot**

[03.07.2026]

Sender:

KayserBetten GmbH & Co. KG, Rieper Str. 12, 29683 Bad Fallingbostel, Germany
SRN: DE-MF-000006910

Distributor (United Kingdom and Republic of Ireland):

Theraposture Ltd, Kingdom Avenue, Northacre Industrial Park,
Westbury, Wiltshire BA13 4WE, United Kingdom

Irish-market dealers:

Beechfield Healthcare, Clonminam Business Park, Portlaoise, Co. Laois, R32 FP5
Homecare Medical, Tooraree, Knock Road, Ballyhaunis, Co. Mayo, F35 KW83

Addressee:

Healthcare centres, operators, families, caregivers, and users of KayserBett OLAF and KayserBett Mascot paediatric care beds in the Republic of Ireland.

Identification of the medical devices concerned:

Product category	Product designation	Basis UDI-DI
Paediatric care bed	KayserBett OLAF 98	426038961OLAF98AE
Paediatric care bed	KayserBett OLAF 135	426038961OLAF135D5
Paediatric care bed	KayserBett Mascot 60	426038961MASCOT60WQ
Paediatric care bed	KayserBett Mascot 80	426038961MASCOT80WW
Paediatric care bed	KayserBett Mascot 90	426038961MASCOT90WZ
Paediatric care bed	KayserBett Mascot 98	426038961MASCOT98XH
Paediatric care bed	KayserBett Mascot 120	426038961MASCOT120CG

Classification: Class I medical device under Regulation (EU) 2017/745 (EU Medical Devices Regulation).

Scope: All KayserBett OLAF and KayserBett Mascot units delivered to the Irish market with the original (non-Auto-Lock) wired hand control. Units delivered with the new Auto-Lock hand control are not affected.

The KayserBett Mascot is a variant of the KayserBett IDA marketed for the United Kingdom and the Republic of Ireland; both models share the affected hand control design. The full list of affected units and serial numbers in the Republic of Ireland has been provided by KayserBetten and is held by Theraposture Ltd. Beechfield Healthcare and Homecare Medical will be provided the relevant lists by Theraposture Ltd as part of the FSN.

Description of the problem including the identified cause:

Due to a serious incident with a paediatric care bed (model KayserBett OLAF, Germany, late 2023) which resulted in the death of a child, KayserBetten has conducted a comprehensive risk assessment under ISO 14971 in consensus with the German Federal Institute for Drugs and Medical Devices (BfArM). The KayserBett OLAF care cot did not exhibit any technical malfunction at the time of the incident; a risk that was not foreseen at the time materialised solely because of several cumulative user errors. The scenario in which the hand control is operated by the patient (child / adult) or by a third party (children / adult) while the sleeping platform / adjustable bed elements are not in the lowest position has accordingly been reclassified as a “reasonably foreseeable misuse” for the KayserBett OLAF, KayserBett IDA, KayserBett Mascot and KayserBett EMMA models.

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

This statement does not imply that any KayserBett OLAF or KayserBett Mascot device in the Republic of Ireland 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?

Until the hand control replacement has been completed on your bed, please strictly observe the following interim safety measures, in accordance with the safety instructions in the user manual.

If the patient is unattended,

- the sleeping platform must be levelled and moved 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 OLAF and KayserBett Mascot beds in the Irish 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.

The corrective action is being organised by Theraposture Ltd as the UK and Ireland distribution partner of KayserBetten, in coordination with the Irish dealers Beechfield Healthcare and Homecare Medical, who placed the units with the end users. The Irish dealers will contact the affected centres and families directly to arrange the hand control exchange.

The replacement is provided free of charge.

You will be contacted by Beechfield Healthcare or Homecare Medical in due course to arrange the exchange. In the meantime, please observe the interim safety measures described above and in Appendix I.

Passing on the information described here:

Please ensure that all persons in your care setting who use the affected bed — family members, caregivers, healthcare staff — are aware of this Field Safety Notice and the interim safety instructions in Appendix I.

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

The Health Products Regulatory Authority of Ireland (HPRA) has been informed of this Field Safety Corrective Action under case reference CRN00HCZJ.

Contact — Distributor (United Kingdom and Republic of Ireland):

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Contact person — Manufacturer:

KayserBetten GmbH & Co. KG

Jens Lübben, Regulatory Affairs / PRRC

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APPENDIX I: User safety instructions

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 / adult) is unattended, there is an increased risk that the patient (child / adult) or third parties (children / adult) will operate the hand control and trap themselves or others under the mattress base or between the adjustable elements of the mattress base. This can lead to serious injury or fatality of the patient (child / adult) or third parties (children / adult).

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.

NOTE: Beechfield Healthcare or Homecare Medical will arrange the replacement of 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 always observed.