

Urgent Field Safety Notice: Kimba Spring

Otto Bock Healthcare Plc

Manufacturers Reference Number: TS8423

FSCA-identifier: 31st October 2007 Type of action: Devise modification

Attention: All customers that have been supplied Standard Kimba Springs between April

2003 and April 2007

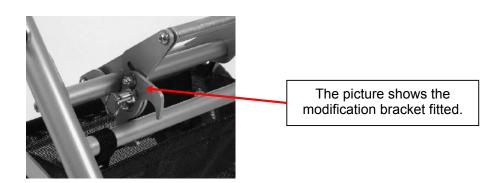
Model: Kimba Spring (paediatric buggy)

Part Number/s: HR32901000 (size 1 rigid), HR32911000 (size 1 swivelled) HR32931000 (size 2 swivelled) supplied between April 2003 – April 2007

Description of the problem:

Due to unexplained instances whereby sporadic cracks have occurred between the axle retainer for the seat adapter (porter cylinder) and the central frame, if left unattended it has the potential to lead to the seating system without warning becoming insecure allowing it to fully tilt forwards or backwards. Intensive tests have been carried out to try to reproduce these field problems but to no avail. However, in May 2007 Otto Bock introduced a construction change for the Kimba Spring, which improves the integrated child safety features of this product; as a result Otto Bock Healthcare Plc would like to offer a modification bracket kit (see picture below) to all units presently being used thus adding to the safety feature of this product.

Please note: The issuer/supplier of the above buggies will be implementing this necessary field modification, arranging a suitable time and date to have this modification bracket fitted. We estimate that all modifications will be completed by the end of October 2007.



Instructions for use plus fitting instructions will be supplied with each modification bracket.





Advise on action to be taken by the user:

Should your issuer/supplier not contact you before October 2007, please contact them direct; if not known please contact Otto Bock Healthcare Plc.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person: Russell Pizzey

Technical Services Manager
Otto Bock Healthcare Plc
32 Parsonage Road
Englefield Green
Egham SURREY
TW20 0LD

Telephone number: 01784 744900 Fax Number: 01784 744949 E-mail: bockuk@ottobock.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

Signature

Russell Pizzey

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