

URGENT – SAFETY ADVISORY NOTICE
SAN 01/2010/R2 MEDICAL BEDS DIVISION
7TH JULY 2011

PLEASE FORWARD THIS INFORMATION TO ALL USERS AND BIOMEDICAL STAFF CONCERNED.

Subject: ArjoHuntleigh lifting poles with an adjustable strap and handle

Products affected: ROLKO strap and handle, type TGN-R100GR, produced between January 2007 and January 2009 inclusive, sold as:-

ArjoHuntleigh part numbers 805.855, MB-ACC34, MB-ACC44, ENT-ACC01, ENT-ACC01/HK, ENT-ACC03, CM-ACC09-1, CM-ACC09-2, CM-ACC09-3, CM-ACC10-1, CM-ACC10-2, CM-ACC10-3

Dear Customer,

We are re-issuing this Field Safety Notice as we have only received a partial response to our previous publication of the notice. The purpose of the notice is to inform you that our records show that your facility purchased one or more of the adjustable strap and handles or the lifting pole accessories listed above. Lifting poles are sometimes referred to as a “monkey pole”.

A review of the performance of the strap and handle products has identified a risk that part of the strap retracting mechanism may break whilst in use.

Indications

The material around the slot in the strap retractor housing can break, which could in turn create an injury or fall hazard if the break were to occur whilst the handle was under load.

The potentially defective parts were produced by our supplier Rolko, between January 2007 and January 2009 and can be identified by the red button on the retractor housing as shown below (Fig 1) and the production date, shown by the traceability mark on the side of the housing (Fig 2 on page 2). Please note that only parts with a red button, made between these two dates are affected. **Any parts with a yellow button are not affected (Fig 3).**



Fig 1



Fig 2.

The number in the centre of the circle represents the year of manufacture and the number pointed out by an arrow represents the month of manufacture. In this example, the retractor was produced in April 2007



Fig 3

Any Strap & handle with a yellow button is not affected at all by this notice

Advice on action to be taken by the user

- 1) Examine all strap and handle combinations in use or in stock
- 2) Any parts with a red button, manufactured by Rolko between January 2007 and January 2009 and supplied by ArjoHuntleigh should be removed from use and destroyed.
- 3) Complete and return Appendix 1 to your nearest ArjoHuntleigh Sales office.

If you have redistributed these accessories to another location or if the accessories have been sold or removed from Service, please mark Appendix 1 appropriately and advise us immediately

Corrective action

Following your completion and return of Appendix 1 ArjoHuntleigh will supply free of charge replacements for all Rolko strap and handle combinations manufactured during the affected period and supplied by us.

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

Transmission of this Field Safety Notice

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

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

In cases where customers opt not to proceed with completion of these actions, ArjoHuntleigh cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond.

Contact reference person

Should you have questions or require additional information, please contact your local ArjoHuntleigh representative at this address:.

ArjoHuntleigh UK
Roy Ward Christie
Quality
310-312 Dallow Road
Luton
Bedfordshire, LU1 1TD
T: 01582 745790
F: 01582 745825

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

Sincerely,
Brian Acheson
Group Quality Manager

ARJOHUNTLEIGH Medical Beds Division
Unit 3 Britannia Park, Trident Drive
Wednesbury, West Midlands WS10 7XB
United Kingdom
www.ArjoHuntleigh.com

Appendix 1 - Completion Notification SAN 01 2010

Our records indicate that Adjustable straps and handles were shipped to your location. Please examine your stocks as per the attached Field Safety Notice to determine whether the affected parts are in use.

Please remove the affected parts and note the quantity affected in the table below.

<i>Part Description</i>	<i>Total Quantity checked</i>	<i>Quantity removed from use</i>
Adjustable strap & handle		

Please tick two boxes below:

- We have read the Field Safety Notice and understand the communication
- We checked our inventory and confirmed that we do have ArjoHuntleigh supplied straps and handles in use. We removed the affected parts and listed the quantity checked and removed in the table above.
- We do not have any ArjoHuntleigh supplied straps and handles in use

To signify compliance to this notification, please sign and date below and fax the signed copy of this notification to your local ArjoHuntleigh sales office, shown below:

Customer signature: _____

Print name: _____

Institution: _____

Full Address: _____

Contact Number: _____

Date: _____

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