

MEDICAL DEVICE SAFETY NOTICE

Mini Lift Stand Aid IMB Safety Notice: SN2007(04)

MANUFACTURER / SUPPLIER

Kjaerulff Rehabilitation A/S, Denmark / Beechfield Healthcare, Dublin

TARGET GROUPS

Hospital Chief Executive Officers
Hospital Risk Managers
Health Service Executive
Nursing Executive Directors
Occupational Therapists
Physiotherapists
Nursing Home Managers

ISSUE

Brass bolt connecting the lift arm to the lifting actuator may fail if bolt wear is overlooked during recommended annual inspections.

BACKGROUND

Following two separate incidents in the United Kingdom in September 2006, in which the bolt that connects the lifting arm to the lifting actuator failed due to wear and tear of the brass pin, the manufacturer has distributed service instructions and replacement steel bolts to all affected customers. Customers are asked to perform an immediate service check and replace the brass bolts with the steel bolts regardless of their condition. Although there have been no reports of failure of the brass pin connecting the lower frame to the actuator customers are also being asked to replace these as an added safety precaution. Affected article numbers which require bolt replacement are 400600434 and 400605434. Mini lifts with article number 400640434 supplied after March 2006 are not affected by this issue as they are equipped with the steel bolts.

S A F E T Y

Reference: V2961 Circulation Date: 27/07/07 Page 1 of 2

ACTION OR RECOMMENDATIONS

- Advise Kjaerulff Rehabilitation A/S Handicare A/S of the number and location of all affected devices in your institution.
- Ensure the modification is carried out on all affected devices.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

If you have any enquiries, you may contact the Medical Devices Department at:

Telephone: +353-1-6764971 Fax: +353-1-6344033 Email: vigilance@imb.ie Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Mr. Philip L. Harris Kjaerulff Rehabilitation A/S - Handicare A/S Ørkebyvej 6 DK-5450 Otterup Denmark

Telephone: +45-6382-1532 Fax: +45-6482-1449 Email: plh@kjaerulff.com **NOTICE**

Reference: V2961 Circulation Date: 27/07/07 Page 2 of 2