
URGENT – Field Safety Notice (FSN)

Product: Patient Handling Devices (PHD)
Models: **All models** Minstrel, Minerva, Excelsior, Gemini patient lifts.
Manufactured by Medibo Medical Products NV.
Issue Date: **May 2012**
Type of action: **Device Modification:**

- Update of product Intended Lifetime.
- Reminder of latest service requirement

Ref: **FSN002/2012/PHD**

Attention:

All those in possession of the above devices. Including but not limited to all those involved in the provision, prescription, use and maintenance of these devices. In particular: equipment store managers, nursing home managers, nurses, moving and handling staff, occupational therapists, care staff, maintenance staff/contractors and other end users.

Description of the problem(s):

Problem

Our Post Market Surveillance has shown that these devices are continued to be used beyond reasonable lifetime and without adequate service and maintenance.

We have received a small number of incidents involving lifts in excess of 10 years where the lift has failed in use. In general ArjoHuntleigh recommends a maximum of ten years lifetime for their product ranges and a similar lifetime can be expected for these devices that were previously manufactured by Medibo. (For some models this lifetime was unclear within the instructions for use.)

Our investigations have also identified that for many devices planned preventative maintenance has not been carried out leaving end users at an unacceptable risk of serious injury. If maintenance, including critical inspections, load test and component replacement activity has not been carried out regularly by Medibo and subsequently Arjohuntleigh Engineers then the lifetime may be significantly less than 10 years.

Action

ArjoHuntleigh recommend that devices outside the 10 year recommended lifetime are removed from use.

Make sure that all devices have a preventive maintenance plan in place and that this plan is carried out by a competent engineer using the latest ArjoHuntleigh service procedures. To arrange a service plan with Arjohuntleigh please see contact details below.

Review any devices that have not been serviced to make sure that continued use is appropriate.

Transmission of this Field Safety Notice:

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

Please transfer this notice to other organisations on which this action has an impact. Upon receipt, please formally inform us (manufacturer) that you have received and understood the requirements of this FSN.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Upon completion of the actions noted above, make sure that you have confirmed back to us (manufacturer) using the appropriate form supplied.

Contact reference person:

Name: XYZ
Organisation: ArjoHuntleigh
Address: ArjoHuntleigh House, Houghton Hall Office Park,
Houghton Regis, UK. LU5 5XF. (example)

Contact details:
E-mail: XYZ@arjohuntleigh.com
Telephone: +44 (0)1582 745599 (example)

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

Signature