IRISH MEDICINES BOARD

Notice Information: - Advisory
04 November 2011

Part 1. Product Information

a)	Title:	Contoura® 880 Series Hospital Bed Frames
b)	Product Name/Type:	Contoura® 880 Series Hospital Bed Frames
c)	Reference:	SN2011(24)
d)	Manufacturer/Supplier:	ArjoHuntleigh

Part 2. Target Audience

a)	Target Audience:	Hospital CEOs Risk Managers Procurement Managers

Part 3. Problem/Issue

a)	Problem/Issue:	ArjoHuntleigh is aware of an issue with the Contoura® 880 Series Hospital Bed Frames, whereby the CPR release arm on the backrest actuator could break during use and render the emergency CPR function inoperable.

Part 4. Background Information

a)	Background Information:	ArjoHuntleigh issued a field safety notice (SAN/02/10/MBD) in June 2010 notifying users of an issue with the Contoura® 880 Series Hospital Bed Frames, whereby the CPR release arm on the backrest actuator could break during use and render the emergency CPR function inoperable. This field safety notice notified users that a new part had to be fitted to the CPR release mechanism to prevent this issue from re-occurring in the future. One customer in Ireland has since reported an incident in which the CPR release on a bed with new parts fitted failed to work in an emergency situation. An investigation carried out by the manufacturer indicated that this incident occurred because the replacement CPR release arm was not installed in accordance with the instructions provided by ArjoHuntleigh. ArjoHuntleigh issued a second field safety notice (FSN/03/2011/MBD) in October 2011. This field safety notice requests: 1. Any outstanding upgrades should be carried out by an ArjoHuntleigh technician. 2. All upgrades previously carried out by the facility's own personnel should be inspected by an ArjoHuntleigh technician to ensure correct fitting and operation.

Part 5. Action to be taken

a)	Action to be taken:	ArjoHuntleigh have been unsuccessful in their attempts to date to locate all devices in Ireland affected by this field safety corrective action. The IMB advises that users: 1. Ensure the appropriate personnel are made aware of this notice. 2. Identify the location of all affected bed frames. 3. If your institution has affected medical devices, please contact ArjoHuntleigh to arrange to carry out the required modification to the bed frame.

Part 6. Enquiries

a)	All enquiries should be made to:	Enquiries to the manufacturer should be addressed to: Rachel Dempster ArjoHuntleigh (Ireland) Limited EA House Damastown Industrial Park Mulhuddart Dublin 15 Telephone: 01-8098960 Fax: 01-8098971 Email: complianceALIE@ArjoHuntleigh.com All adverse incidents relating to a medical device should be reported to the: Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 Telephone: +353-1-6764971 Fax: +353-1-6344033 E-mail: vigilance@imb.ie Website: www.imb.ie Please click here to download a PDF version of this Safet

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