IRISH MEDICINES BOARD

Notice Information: - Advisory
21 August 2009

Part 1. Product Information

a)	Title:	Contoura 880 Beds
b)	Product Name/Type:	Contoura 880 Beds
c)	Manufacturer/Supplier:	Huntleigh Healthcare Ltd

Part 2. Target Audience

a)	Target Audience:	Health Board CEOs, Community Care Managers, Community Therapists, Health Visitors, Carers of the Elderly, Risk Managers, Loan Store Managers, Children's Disability Services, Special Schools, Educational Establishments

Part 3. Problem/Issue

a)	Problem/Issue:	Some bed rail support brackets have been found to have poor welds causing them to fail in use. Patients are at risk of injury from a fall if the bed rails fail in use.

Part 4. Background Information

a)	Background Information:	In May 2007, Huntleigh Healthcare Limited in conjunction with the MHRA issued an MDA alert (MDA/2007/041) http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON2031264 in relation to their Contoura 880 beds manufactured between December 1999 and June 2001 with serial numbers in the range 167386 to 382938. The issue with the device is that some of the bed rail support brackets have been found to have poor welds causing them to fail in use. Patients are at risk of injury from a fall if the bed rails fail in use. The mounting brackets that connect the bed rails to the bed frame are beneath the mattress platform. The IMB is aware that several of these beds were placed on the market in Ireland, and while some customers who have these beds may have received the MDA alert that was circulated by the MHRA, the IMB is issuing this safety notice to ensure all Contoura 880 customers are aware of the issue

Part 5. Action to be taken

a) Action to be taken:

1) Ensure the appropriate personnel are made aware of this notice.

2) Identify the location of all Contoura 880 beds.

3) Determine if your institution has devices affected by this issue.

This can be determined by:

A) Checking the manufacturing date to see if it is between December 1999 and June 2001.

B) Checking if the Serial number lies in the range 167386 to 382938.

4) Check the support bracket on the frame and if cracking is found contact the manufacturer who will provide and fit replacement brackets free of charge.

5) Ensure that correction is completed on all affected devices.

Part 6. Enquiries

a)	All enquiries should be made to:	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 Enquiries to the manufacturer should be addressed to: Arjo (Ireland) Limited EA House Damastown Industrial Park Mulhuddart Dublin 15 Telephone: 01 809 8960 Fax: 01 809 8961 Email: dublin@arjo.ie

Part 7. Keywords

a) Keywords: Arjo (Ireland) Limited Contoura 880 Beds