IRISH MEDICINES BOARD

Notice Information: - Advisory
12 May 2011

Part 1. Product Information

a)	Title:	Ondal Acrobat 2000 (AC2000)
b)	Product Name/Type:	Ondal Acrobat 2000 (AC2000)
c)	Reference:	SN2011(07)

Part 2. Target Audience

a)	Target Audience:	General Surgeons Theatre and Nursing Staff Procurement Managers Nursing Managers Consultant General Surgeons Hospital Managers / CEOs Clinical Directors Risk Managers Medical Device Distributors Clinical / Biomedical Engineers

Part 3. Problem/Issue

a)	Problem/Issue:	Ondal has become aware that there is the risk that a welded seam at the pivot of the Acrobat 2000 spring-loaded arms could break. The Acrobat 2000 spring arm has been used by a number of different manufacturers to support operating lights and monitors which have been placed on the market in Ireland.

Part 4. Background Information

a) Background Information:

Ondal has confirmed that the affected spring arms were manufactured from January 2000 to June 2006. The affected serial numbers may be identified by the following convention:

0111 010 XXXXX to 0111 066 XXXXX

010 to 066 = month 01 / year 200 0 to month 06 / year 2006

XXXXX = 5-digit serial number

As outlined above, the Acrobat 2000 spring arm is used to support operating lights and monitors which have been placed on the market by various manufacturers. A number of manufacturers have initiated / completed field safety corrective actions in Ireland to address this issue. A listing of these manufacturers is provided below (please note that this is not an exhaustive list):

Trumpf Medizin Systeme –Manfred Fehn Ph: +49 3671 586 41211

Brandon Medical – Graeme Hall Ph: +44 113 277 7393

Maquet – Gerry O'Brien Ph: + 353 1 426 0032

Drager – Doug Sims Ph: +44 1442 213542

Gebrüder MARTIN – Sven Zehnder Ph: + 49 7461 706 453

The Irish Medicines Board (IMB) wishes to highlight these actions and requests that users remain vigilant for potentially affected devices in their facility.

Part 5. Action to be taken

a)	Action to be taken:	The IMB advises that users: • Identify the affected spring arms in your facility and contact the appropriate manufacturer for further guidance. • Follow the manufacturer's recommendations as outlined in the associated field safety notices. • Users are advised to exercise caution when moving or repositioning devices connected to these spring arms pending upgrade / inspection by the manufacturer.

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 Download PDF