IRISH MEDICINES BOARD

MEDICAL DEVICE

ADVISORY NOTICE

Coopers Walking Frames

IMB Advisory Notice: SN2008(04)

ADVISORY NOTICE

MANUFACTURER/SUPPLIER

Sunrise Medical Limited, United Kingdom

TARGET GROUPS

Care Homes
Community Hospitals
Equipment Stores
Equipment Supplies Manager
Health & Safety Managers
Health Service Executive
Hospital Chief Executive Officers
Hospital Risk Managers
Maintenance Staff and Contractors
Nursing Executive Directors
Nursing Home Managers
Occupational Health Departments
Occupational Therapists
Physiotherapists
Risk Managers

ISSUE

A number of incidents have been reported to the Irish Medicines Board (IMB) relating to the use of these frames. This purpose of this notice is to:

- Make users / prescribers aware of a quality improvement / design change implemented by the manufacturer in July 2006.
- Ensure that the instructions for safe and effective device use are communicated.

BACKGROUND

The IMB has been made aware of a number of incidents and complaints involving Coopers walking frames:

(a) Frame legs bending and / or fracturing
(b) Screws becoming loose
(c) Frames not balanced i.e. all feet not level with the floor

The manufacturer of Coopers walking frames implemented a number of design changes and quality improvements in July 2006. These included:

(a) Addition of insert into the back legs of frame to improve strength
(b) New screw specification
(c) Improved frame assembly and 100% inspection process

With regard to the wheeled version of Coopers walking frames, the manufacturer advises prescribers / users to be aware of the need to set the rear legs one position higher than the front leg to compensate for the increased wheel height. This is not possible if the front legs are set to the highest position. In this event a taller frame should be used to achieve the correct setting. When using wheeled frames, the rear legs should be lifted and wheeled forward as opposed to being used as a rolator.

ACTION OR RECOMMENDATIONS

- Ensure users / prescribers are aware of issues
- Familiarisation with the instructions for safe and effective device use, in particular the general safety and warning statements in the manufacturers' instructions for use.
- Ensure that device is in proper working order before being put into service as these frames can be damaged during shipment or storage.
- Highlight to users the need for regular inspection of the device for damage or signs of wear in accordance with manufacturers guidelines and where necessary to take appropriate remedial action (in the form of replacement / repair).

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

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Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Sunrise Medical Limited
High Street
Wollaston
West Midlands, DY8 4PS
United Kingdom

Telephone: +44 (0) 1384 446688
Fax: +44 (0) 1384 446699
Website: www.sunrisemedical.co.uk

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