

**Notice Information: Medical Devices - Advisory
02 April 2008**

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

- a) Problem/Issue:

Part 4. Background Information

a) Background Information:

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 rotator.

Part 5. Action to be taken

a) Action to be taken:

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).

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 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 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 SN2008(04): Coopers Walking Frames

Part 7. Keywords

a) Keywords:

Coopers Walking Frames