IRISH MEDICINES BOARD

Notice Information: - Advisory
09 December 2011

Part 1. Product Information

a)	Title:	Quickie Neon Swing-Away Wheelchairs
b)	Product Name/Type:	Quickie Neon Swing-Away Wheelchairs
c)	Reference:	SN2011(32)
d)	Manufacturer/Supplier:	Sunrise Medical

Part 2. Target Audience

a) Target Audience:

- General public
- Hospital CEOs
- Risk Managers
- Procurement Managers
- Loan Store Managers
- HSE Offices
- Community Care Centres
- Occupational Therapists
- Community Care Managers
- Community Therapists
- Health Visitors
- Carers
- Educational Establishments

Part 3. Problem/Issue

a)	Problem/Issue:	It has come to Sunrise Medical's attention through post-market surveillance activities that a small number of upper frame tubes that support the backrest have failed on the Quickie Neon Swing-Away wheelchair. There is the potential for frames to fail and users could potentially fall backwards resulting in serious injury.

Part 4. Background Information

a)	Background Information:	An upgrade kit is available from Sunrise Medical through MMS Medical Limited to address this potential failure of the upper frame tubes. As outlined in the attached field safety notice (FSN), this corrective action only affects the following wheelchairs: • Neon Swing-Away models • With seat depth up to 44cm (chairs above this seat depth are not affected) • Manufactured before June 2010 (wheelchairs made after this date have a strengthened upper frame tube) All relevant information relating to this upgrade can be found in the attached FSN, issued by Sunrise Medical in February 2011. Sunrise Medical and their distributor MMS Medical have been unsuccessful in their attempts to date to locate all devices in Ireland affected by this field safety corrective action. There are approximately 38 Quickie Neon Swing-Away wheelchairs on the Irish market, which require an upgrade kit from MMS Medical Limited to be fitted.

Part 5. Action to be taken

a)	Action to be taken:	The IMB advises that users: 1. Ensure the appropriate personnel are made aware of this notice. 2. Identify the location of all affected wheelchairs. 3. If you / your institution have affected wheelchairs, please follow the manufacturer's recommendations as outlined in the attached FSN and ensure that the corrective action is completed on all affected medical devices.

Part 6. Enquiries

a)	All enquiries should be made to:	Enquiries to the distributor should be addressed to: Rose Gilbert MMS Medical Limited 51 Eastgate Drive Little Island Cork Telephone: 021-4618000 Fax: 021-4618099 Email: info@mmsmedical.ie Enquiries to the manufacturer should be addressed to: Jeremy Fletcher Sunrise Medical Wollaston Stourbridge West Midlands DY8 4PS United Kingdom Telephone: +44-1384-446672 Email: jeremy.fletcher@sunmed.co.uk All adverse incidents relating to a medical device should be reported to the: Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort

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 the field safety notice.

Please click here to download a PDF version of this Safety Notice.