IRISH MEDICINES BOARD
SAFETY NOTICE

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Quickie Neon Swing-Away Wheelchairs

IMB Safety Notice: SN2011(32)
Circulation Date: 09 December 2011

MANUFACTURER/SUPPLIER
Sunrise Medical

TARGET GROUPS
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

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.

BACKGROUND
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.

SAFETY NOTICE

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.

ACTION OR RECOMMENDATIONS

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.

ENQUIRIES

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 Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie