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NOTICE

Static Mattresses

IMB Safety Notice: SN2011(22)
Circulation Date: 24 August 2011

MANUFACTURER/SUPPLIER

Park House Healthcare Ltd., United Kingdom

TARGET GROUPS

Hospital Managers / CEOs
Clinical Directors
Risk Managers
Purchasing Managers
Nursing Managers
Theatre and Nursing Staff
Clinical / Biomedical Engineers
Public and Private Nursing Homes
Hospices and Community Care Centres
Medical Device Distributors
Members of the Public

ISSUE

Park House Healthcare has issued a field safety notice (FSN) to notify users of the availability of an updated guide to correct mattress usage.

BACKGROUND

Park House Healthcare has indicated that mattress inspection instructions have been printed on mattress covers since December 2009. However, customers with static mattresses which predate this labelling may not be aware of the correct method to inspect mattresses. The updated guide, developed by Park House Healthcare, provides advice on how to complete these inspections correctly.

ACTION OR RECOMMENDATIONS

Park House Healthcare issued a FSN and copy of the updated guide to customers who purchased mattresses within the time period 2005 – 2009.

The Irish Medicines Board (IMB) advises that users:

- Identify the devices in your facility, which are within the scope of this field safety corrective action (FSCA).
- If you have devices affected by this FSCA, follow the manufacturer's recommendations, as outlined in the attached FSN.
- Maintain awareness of the updated guide within your facility and return the fax back form to Park House Healthcare, or your distributor, if you have not already done so.

S A F E T Y

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ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Roy Smith
Park House Healthcare Ltd.
Whitehall 26 Business Park
1 Heathfield Lane
Birkenshaw
West Yorkshire
BD11 2HW
United Kingdom

Telephone: +44 845 0600 333
Fax: +44 845 0600 334
E-mail: roy.smith@parkhouse-hc.com

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