

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/61

Issued: 13 October 2006

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section		
Medical Device/Equipment: Jenx Limited – seating support systems for children.	▶ ①		
Problem: The manufacturer's original instructions for use (IFU) do not give sufficient guidance on how to correctly set up the complete seating support system, adjust it and maintain adjustment during use, thus putting users at risk of death or serious injury.	▶ ②		
Action by: All those involved with the prescription, provision and supervision of use of Jenx Limited seating systems.	▶ ③		
Action: <ul style="list-style-type: none"> Identify all models of Jenx Limited seating support systems already in use. Obtain copies of the relevant IFU. Provide a copy of the latest IFU to all current users and their carers and alert them to the changes. 	▶ ④		
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers </td> <td style="width: 50%; border: none;"> Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users) </td> </tr> </table> <p>For onward distribution see Section 5</p>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users)	▶ ⑤
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Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.	▶ ⑥		
Feedback Requirements to NIAIC <i>Details of Compliance Assurance</i>	▶ ⑦		

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Seating support systems manufactured by Jenx Limited.

2. PROBLEM:

In April 2005 NIAIC issued a Medical Device Equipment Alert MDEA(NI)/2005/030 'Posture belts fitted to wheelchairs and seating', which highlighted the risk of death or serious injury arising from the incorrect fitting or adjustment of posture belts. The MHRA has since received reports of two deaths in such circumstances.

In the most recent case a child died whilst using a seating support system manufactured by Jenx Limited. The child is believed to have slipped down in the seat causing positional asphyxia. Investigation by MHRA found the thoracic support and pelvic straps to have been incorrectly fitted and adjusted. Also a footplate provided with the system was not capable of providing any support at the time as the clamping mechanism to locate it on the frame of the system was incorrectly adjusted.

The manufacturer's original IFU gave insufficient guidance on how to correctly set up the complete seating support system, adjust it and maintain adjustment during use. Also they did not include adequate warnings of the risks arising from the failure to maintain the adjustment of all the posture supports, the tilt of the seat unit and the footplate.

Jenx Limited undertook a wider review of all their system's IFU and found similar shortcomings. They have now updated the content of the IFU for all systems: Whale, Giraffe, Ladybird, Turtle, Lambda, Zeta, Beta 4, Beta X and Y bases, Gamma X and Y bases and Corner seats. The new IFU, with additional instructions and warnings, are divided into four parts,

- a section for all users giving general safety information
- a section for the prescriber (typically a qualified therapist),
- the home user (parents, carers or school staff),
- stores/maintenance staff (for initial inspection and maintenance provision).

This Alert reinforces the content of the guidance issued in Medical Device Equipment Alert MDEA(NI)/2005/030.

3. ACTION BY:

All those involved with the prescription, provision and supervision of use of Jenx Limited seating systems.

4. ACTION:

- Identify all models of Jenx Limited seating support systems already in use.
- Obtain copies of the relevant IFU.
- Provide a copy of the latest IFU to all current users and their carers and alert them to the changes.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Equipment stores
- Health and safety managers
- In-house maintenance staff
- Loan store managers
- Maintenance staff
- Occupational therapists
- Supplies managers
- School nurses
- Community children's nurses
- Education departments for equipment held in schools
- Care at home staff

- Paediatric nurse specialists
- Paediatric wards
- Physiotherapists
- Rehabilitation engineers
- Rehabilitation service managers
- Risk managers
- Seating service managers
- Care management team managers
- Children's disability services
- Community care staff
- Residential special schools
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Copies of all the new IFU are available on the manufacturer's website at:

<http://www.jenx.com/instructions.html>

Alternatively written or fax requests listing the numbers of each booklet required can be sent to:

New Instruction for Use Booklets
Jenx Limited
Wardsend Road
Sheffield S6 1RQ

Fax No: 0114 285 3528

or E-mail to: ifu@jenx.com

Enquiries to the manufacturer other than requests for booklets should be addressed to:

Catherine Jenkins
Jenx Limited
Wardsend Road
Sheffield S6 1RQ

Tel: 0114 285 3376

Fax: 0114 285 3528

E-mail: catherine@jenx.com

Enquires to NIAIC should quote reference number MDEA(NI)2006/61 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald, Belfast, BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

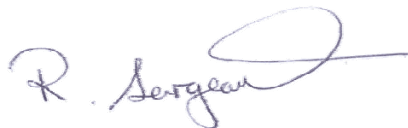
7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received) : 17 October 2006

Deadline (action underway) : 31 October 2006

Deadline (action complete): 1 December 2006



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety