

Medical Device/Equipment ALERT



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	

	Section								
<p>Medical Device/Equipment: “Infinity” pressure relieving wheelchair seat cushions. Manufactured by Invacare Limited</p>	▶ ①								
<p>Problem: These cushions have a lower resistance to ignition than originally intended by the manufacturer. Persons using these products, therefore, may be at risk because the cushions may not self extinguish if exposed to an open flame.</p>	▶ ②								
<p>Action by: Those involved with the provision and supply and record keeping of this type of wheelchair cushion.</p>	▶ ③								
<p>Action:</p> <ul style="list-style-type: none"> Trace all Infinity wheelchair seat cushions manufactured by Invacare Limited and supplied since March 2000. Obtain a K1 flame resistant interliner from Invacare Limited and fit between the outer and inner covers of the existing cushions, in line with the fitting instructions supplied with the new interliner. Attach the supplied label to the existing cushion label to show that the update has been carried out. 	▶ ④								
<p>Distributed by NIAIC to:</p> <table border="0"> <tr> <td>Chief Executive of each HSS Board</td> <td>General Medical Practices</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users)</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Hospices</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> <p>For onward distribution see Section 5</p>	Chief Executive of each HSS Board	General Medical Practices	Chief Executive of each HSS Trust	Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users)	Chief Executive of each Agency	Hospices	NIAIC Liaison Officers		▶ ⑤
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NIAIC Liaison Officers									
<p>Contacts Details of supplier contacts and NIAIC Contacts for technical aspects.</p>	▶ ⑥								
<p>Feedback Requirements to NIAIC Only if problems occur.</p>	▶ ⑦								

1. DEVICE/EQUIPMENT:

"Infinity" pressure relieving wheelchair seat cushions. Manufactured by Invacare Limited

2. PROBLEM:

Since the initial product launch in March 2000, Invacare Limited have introduced changes to the materials used in the construction of the Infinity range of seat cushions. At the time of the introduction of the materials no tests were carried out to verify that they met reasonable standards of fire retardancy. Subsequent testing has found that the cushions will not self extinguish when exposed to an open flame. Persons using these products, therefore, may be at risk.

To date, no actual incidents have been reported to NIAIC or MHRA.

The manufacturer has devised a solution, for those cushions already supplied, to remove the risk. This involves the fitting of a flameproof interliner between the two existing covers. Invacare will provide these free of charge, to all existing customers.

Invacare Limited are also attempting to notify all customers, that they have supplied with Infinity seat cushions, by means of their Safety Bulletin T1012. However, this may not reach all existing users where local records are incomplete or the cushion has been issued to a new user.

Materials used in future supplies will meet appropriate levels of resistance to ignition, to remove the need for an interliner.

3. ACTION BY:

As outlined on page 1.

4. ACTION:

As outlined on page 1.

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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Wheelchair Service Managers
- Occupational Therapists (involved in wheelchair provision)
- Physiotherapists (involved in wheelchair provision)
- Rehabilitation Engineers (wheelchairs)
- Medical Directors
- Nursing Directors
- Medical and Nursing Staff
- Supplies Staff (RSS)
- Directors of Public Health
- District Nurses
- Health Visitors
- Practice Nurses
- Social Care Staff
- Community Care Staff
- Day Care Centres
- Independent Health and Social Care Providers
- Residential and Nursing Homes

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Kevin Humphries
Director of Technical Services
Invacare Ltd
South Road
Bridgend Industrial Estate
Bridgend
Mid Glamorgan
CF31 3PY

Tel: 01656 753270
Fax: 01656 649016

Enquires to NIAIC should quote reference number MDEA(NI)2003/08 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

Tel: 028 9052 3704
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

Only if problems occur.



Brian Godfrey
NIAIC 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 Safety Notice SN (NI) 2003/01. 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