

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/36

Issued: 12 November 2003

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section		
<b>Medical Device/Equipment:</b> 'Personal Seat' wheelchair seat cushion manufactured by Invacare	▶ ①		
<b>Problem:</b> These cushions have a lower resistance to ignition than originally intended by the manufacturer. Persons using these cushions, therefore, may be at risk because the cushion may not self extinguish when exposed to an open flame.	▶ ②		
<b>Action by:</b> Those involved with the provision, supply, record keeping and use of this type of wheelchair cushion.	▶ ③		
<b>Action:</b> <ul style="list-style-type: none"> <li>Trace all 'Personal Seat' wheelchair seat cushions manufactured by Invacare.</li> <li>Obtain a flame retardant K1 interliner and new outer cover from Invacare and fit to existing cushions in line with the fitting instructions supplied with the kit.</li> </ul>	▶ ④		
<b>Distributed by NIAIC to:</b> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">                     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%;">                     General Medical Practices                      Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users)                      Hospices                 </td> </tr> </table> <p><b>For onward distribution see Section 5</b></p>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	General Medical Practices Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users) Hospices	▶ ⑤
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<b>Contacts</b> Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥		
<b>Feedback Requirements to NIAIC</b> Only if problems occur.	▶ ⑦		

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

## **1. DEVICE/EQUIPMENT:**

'Personal Seat' wheelchair seat cushion manufactured by Invacare

## **2. PROBLEM:**

These cushions were originally tested for flame retardancy against Californian Standard TB 117. Recent testing has found that the cushions will not self extinguish when exposed to an open flame as specified as the match flame equivalent test within the international standard ISO 7176-16, which covers the resistance to ignition of upholstered parts for wheelchairs. Persons using these products may therefore be at risk.

These 'Personal Seat' cushions, which can be used in a wide range of wheelchairs, have been supplied in the UK since January 1999 but to date no actual incidents have been reported to the NIAIC or MHRA.

The manufacturer has devised a solution for those cushions already supplied, to reduce the risk. This involves the fitting of a flame-retardant K1 interliner and new outer cover to the existing cushions. Invacare will provide this modification kit and fitting instructions free of charge to all existing customers and will reimburse reasonable fitting costs.

Invacare are also attempting to notify all customers that they have supplied with 'Personal Seat' wheelchair seat cushions, by means of their Safety Bulletin TI016. However, this may not reach all existing users where local records are incomplete or the cushion has been re-issued to a new user.

Supplies of the cushion are currently suspended and will be updated before delivery recommences by incorporating a new K1 interliner and outer cover.

## **3. ACTION BY:**

Those involved with the provision, supply, record keeping and use of this type of wheelchair cushion.

## **4. ACTION:**

- Trace all 'Personal Seat' wheelchair seat cushions manufactured by Invacare.
- Obtain a flame retardant K1 interliner and new outer cover from Invacare and fit to existing cushions in line with the fitting instructions supplied with the kit.

## **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 – Private Clinics and Residential and Nursing – through R&I Units

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Nicola Price  
Technical Services  
Invacare Ltd  
South Road  
Bridgend Industrial Estate  
Bridgend  
Mid Glamorgan  
CF31 3PY

Fax: 01656 753299

Enquires to NIAIC should quote reference number MDEA(NI)2003/36 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](mailto: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](http://www.dhsspsni.gov.uk/niaic)

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