

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/27

Issued: 19 September 2003

For:

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



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<b>Medical Device/Equipment:</b> Ulti-Mate and Essential wheelchair seat cushions 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 Ulti-Mate and Essential wheelchair seat cushions manufactured by Invacare.</li> <li>Obtain a K1 flame resistant interliner from Invacare and fit between the outer and inner covers of the existing cushions in line with the fitting instructions supplied with the new interliner.</li> <li>Attach the supplied label to the existing cushion label to show that the update has been carried out.</li> </ul>	▶ ④
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b>	Hospices ▶ ⑤
<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:**

Ulti-Mate and Essential wheelchair seat cushions 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 in 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 cushions have been supplied in the UK since December 1997 but to date no actual incidents have been reported to NIAIC in Northern Ireland or to the Medicines and Healthcare Products regulatory Agency in England.

The manufacturer has devised a solution for those cushions already supplied, to reduce the risk. This involves the fitting of a K1 flameproof interliner between the two existing covers. Invacare will provide these interliners free of charge to all existing customers along with fitting instructions.

Invacare is also attempting to notify all customers that they have supplied with Ulti-Mate and Essential seat cushions, by means of their Safety Bulletin T1015. However, this may not reach all existing users where local records are incomplete or the cushion has been re-issued to a new user.

Cushions supplied from 1 August 2003 have been updated to incorporate a K1 interliner by the manufacturer before despatch and hence are not affected.

## **3. ACTION BY:**

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

## **4. ACTION:**

- Trace all Ulti-Mate and Essential wheelchair seat cushions manufactured by Invacare.
- Obtain a K1 flame resistant interliner from Invacare 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.

## **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
- Estates Managers
- Wheelchair Service Managers
- Occupational Therapists
- Physiotherapists
- Rehabilitation Engineers
- Medical Directors
- Nurse Directors
- Supplies Staff (RSS)
- Day Care Centres
- Day Care Services
- District Nurses
- Practice Nurses
- Health Visitors
- Directors of Public Health
- Social Care Staff
- Community Care Staff
- Independent Health and Social Care Providers including private clinics and Residential and Nursing Homes (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)2003/27 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:

None required.



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*