

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/078

Issued: 23<sup>rd</sup> October 2008

For:

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



**HEALTH ESTATES**

creating healing environments

	Section		
<b>Medical Device/Equipment:</b> Savannah 2" and 4" raised toilet seats manufactured by Homecraft Rolyan.	▶ ①		
<b>Problem:</b> The rubber pad on the mounting brackets can become detached. This means the seat cannot be tightened securely to the toilet and may slip when used causing the user to fall and injure themselves.	▶ ②		
<b>Action by:</b> All those involved in the provision, use and maintenance of raised toilet seats. In particular: community care staff, nurses, occupational therapists, equipment stores managers and maintenance staff/contractors.	▶ ③		
<b>Action:</b> <ul style="list-style-type: none"> <li>Trace all Savannah raised toilets seats and all replacement brackets in use or in storage, purchased from 01 May 2007 to 31 January 2008 inclusive.</li> <li>Ensure the rubber pad is in place and secure on the bracket (see appendix) and that regular checks continue to be made in accordance with the manufacturer's instructions for use.</li> <li>If the rubber pad is missing or partially detached, remove the raised toilet seat from use until replacement brackets can be fitted.</li> <li>Contact Homecraft Rolyan on tel. number 08444 124 330 for replacement brackets.</li> </ul>	▶ ④		
<b>Distributed by NIAIC to:</b> <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                 </td> <td style="width: 50%; border: none;">                     Hospices                      Education and Library Boards (for onward distribution to educational establishments that have facilities for the disabled)                 </td> </tr> </table>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency	Hospices Education and Library Boards (for onward distribution to educational establishments that have facilities for the disabled)	▶ ⑤
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<b>Contacts</b> Details of manufacturer and NIAIC contacts for technical and clinical aspects.	▶ ⑥		
<b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b>			
Acknowledge Receipt of Alert: 27 October 2008	Action Under Way: 24 November 2008		
Action Complete: 23 January 2009			
	▶ ⑦		

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

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

All 2" and 4" Savannah raised toilet seats with or without lids purchased from 01 May 2007 to 31 January 2008 are affected.

The brackets are also sold as a spare part because the rubber pad can wear out through normal use. Any replacement brackets purchased from 01 May 2007 to 31 January 2008 fitted to older toilet seats, or held as spare parts, also need to be checked.

Affected product codes:

AA2112 and AA2112L size 2" (50mm)

AA2114Y and AA2114L size 4" (100mm)

AA211401 spare pair of brackets

Note:

The brackets are not identifiable by a batch/serial number or date of manufacture and therefore can only be traced by date of purchase.

The 6" Savannah raised toilet seat is a different design and is, therefore, not affected.

## **2. PROBLEM:**

The MHRA has investigated reports of incidents where rubber pads have detached from the brackets used to secure the toilet seat to the toilet. The rubber pad has either detached from the bracket soon after first use or was found to have partially or completely detached at later inspection. The toilet seat cannot be held securely in place if the rubber pad is missing from either of the brackets. This has caused users to fall from the toilet and be seriously injured.

Homecraft Rolyan has identified a manufacturing fault with the brackets sold from 01 May 2007 to 31 January 2008. Some of these brackets were found to be susceptible to detachment of the rubber pad. A design improvement in January 2008 increased the adhesion of the rubber pad to the plastic bracket. There have been no reports so far of the rubber pad detaching from the new design of bracket.

## **3. ACTION BY:**

All those involved in the provision, use and maintenance of raised toilet seats. In particular: community care staff, nurses, occupational therapists, equipment stores managers and maintenance staff/contractors.

## **4. ACTION:**

- Trace all Savannah raised toilets seats and all replacement brackets in use or in storage, purchased from 01 May 2007 to 31 January 2008 inclusive.
- Ensure the rubber pad is in place and secure on the bracket (see appendix) and that regular checks continue to be made in accordance with the manufacturer's instructions for use.
- If the rubber pad is missing or partially detached, remove the raised toilet seat from use until replacement brackets can be fitted.
- Contact Homecraft Rolyan on tel. number 08444 124 330 for replacement brackets.

## 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:

- All wards
- Equipment stores
- Maintenance staff and contractors
- Nursing executive directors
- Nursing staff
- Occupational therapists
- Risk managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics, Residential and Nursing Homes through RQIA

## 6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Customer Services  
Homecraft Rolyan  
Nunn Brook Road  
Huthwaite  
Sutton-in-Ashfield  
Nottinghamshire  
NG17 2HU

Tel: 08444 124 330  
Fax: 08448 730 100

E-mail : [homecraft.sales@patterson-medical.com](mailto:homecraft.sales@patterson-medical.com)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/ 078 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)

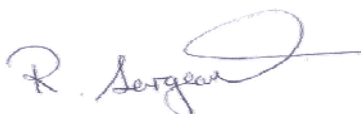
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

**Acknowledge Receipt of Alert:**  
27 October 2008

**Action Under Way:**  
24 November 2008

**Action Complete:**  
23 January 2009



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)2007/01. 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)

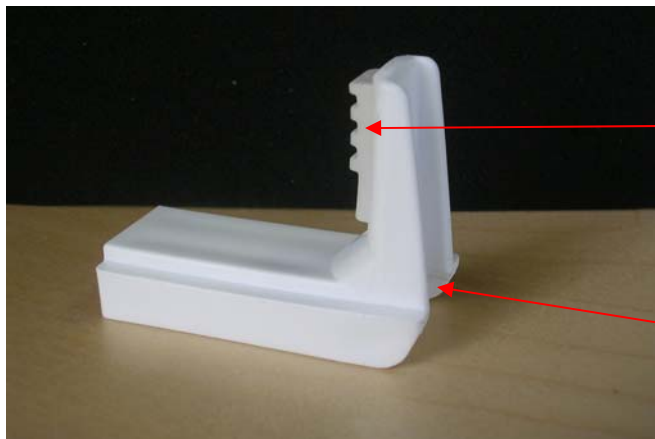
*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

## APPENDIX to MDEA(NI)2008/078

### 2" and 4" Savannah raised toilet seats

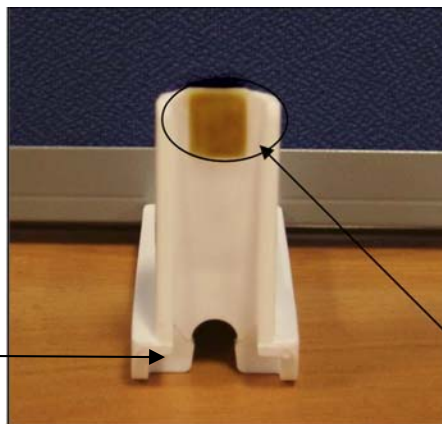


Two brackets to secure raised toilet seat to toilet



On the original design bracket (pre Jan 2008) the rubber pad can only be seen on one side.

Plastic screw is missing from this picture



Plastic screw is missing from this picture.

On the new design the rubber pad can be seen on both sides of the plastic bracket.