

Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/007

Issued: 14th Feb 2008

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
Medical Device/Equipment: Stretchers/trolleys manufactured by Stryker Medical. See page 2 for affected models.	▶ ①
Problem: The brake mechanism used on some models may not lock due to a component failure or excessive wear.	▶ ②
Action by: All those using, providing and maintaining Stryker stretchers.	▶ ③
Action: <ul style="list-style-type: none"> • Check all affected devices and take out of service those with brakes that fail to lock. • Contact the distributor to arrange fitting of the updated design of brake mechanism to all affected trolleys, whether or not they have failed. • Give priority to the upgrade of stretchers used for surgical procedures. • Continue to follow the instructions in the warnings/cautions section of the user manual – 'Push on stretcher to ensure that the brakes are securely locked'. 	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5	▶ ⑤
Contacts Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.	▶ ⑥
Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)	
Acknowledge Receipt of Alert: 18 th Feb 2008	▶ ⑦
Action Under Way: 28 th Feb 2008	
Action Complete: 14 th Mar 2008	

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

1. DEVICE/EQUIPMENT:

Stryker stretchers are used for patient transport and in clinical/surgical treatment areas. Model numbers of affected stretchers are:

Model numbers of affected stretchers are:	660 Atlas Stretcher
	721 Transport Stretcher
	735 Transport Stretcher
	1001 Advantage Stretcher
	1002 Trauma Stretcher
	1005 M Series Stretcher (SM104),
	1015 M Series Stretcher (SM204),
	1020 Trauma Stretcher
	1069 Eye Surgery Stretcher
Serial numbers	0309 to 0701 inclusive

2. PROBLEM:

The brake cam can crack whilst attempting to lock the stretcher brake. Each stretcher has two brake cams inside the brake assemblies – one for the head-end and one for the foot-end. If one or both of these cams break, the stretcher may not lock into position properly, which may lead to serious injury. Additionally, excessive wear of the bronze bushing in the brake cam mechanism may affect the operation of the brake.

The use of a stretcher with faulty brakes may lead to serious injury. The correct operation of the brakes may be checked by pushing on the stretcher after the brakes have been applied. If the stretcher moves, it should not be used.

Stryker has initiated a recall in relation to both of these problems. (Stryker reference number RA 2007-050. See appendix).

3. ACTION BY:

All those using, providing and maintaining Stryker stretchers.

4. ACTION:

- Check all affected devices and take out of service those with brakes that fail to lock.
- Contact the distributor to arrange fitting of the updated design of brake mechanism to all affected trolleys, whether or not they have failed.
- Give priority to the upgrade of stretchers used for surgical procedures.
- Continue to follow the instructions in the warnings/cautions section of the user manual – ‘Push on stretcher to ensure that the brakes are securely locked’.

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:

- A&E departments
- All wards
- Medical directors
- Nurse executive directors
- Estates and Facilities
- Operating clinics
- Operating theatres
- Radiology departments
- Theatres
- Community hospitals
- Maintenance staff
- Minor injury units
- Practice managers
- Practice nurses
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Jackie Fripp
Senior QA/RA Associate
Stryker UK Ltd
Stryker House
Hambridge Road
Newbury
Berkshire
RG14 5EG

Tel: 01635 262 465

Fax: 01635 262 464

E-mail: jacqueline.fripp@stryker.com

Website: <http://www.stryker.co.uk>

Enquiries to NIAIC should quote reference number MDEA(NI)2008/007 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

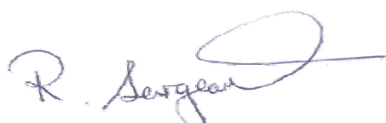
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
18th Feb 2008

Action Under Way:
28th Feb 2008

Action Complete:
14th Mar 2008



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

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

APPENDIX to MDEA(NI)2008-007

URGENT MEDICAL DEVICE CORRECTION

Chief Executive Officer

17 December 2007

Dear Customer

OUR REF: RA 2007-050
PRODUCT: STRYKER STRETCHERS
MODEL NO: 660, 721, 735, 1001, 1002, 1005, 1015, 1020, 1069
SERIAL NO: SERIAL NUMBERS BEGINNING WITH 0309 THROUGH 0701

Stryker Medical has identified the potential for the stretcher brake cam, used on the stretcher models and serial numbers listed below, to crack while attempting to lock the stretcher brake. Every stretcher has two brake cams inside of the brake assemblies - one for the head end of the stretcher, the other for the foot end. If one or both of these cams break, the stretcher will not lock into position properly, which may result in serious injury.

Additionally, we have received some reports regarding excessive brake cam wear due to a bronze bushing in the drive link (brake) system. This may affect whether the stretcher brake will lock firmly into position, potentially resulting in serious injury. As part of this field correction, we will be replacing bronze bushings with needle bearings for the applicable units.

To eliminate the problem with the brake cam, Stryker Medical is initiating a voluntary **Device Correction** for the following models of Stryker Stretchers, manufactured between 01 September, 2003, and 12 May, 2005, with serial numbers that begin with 0309 through 0505. The bronze bushings will be replaced with needle bearings for stretchers manufactured between 20 July, 2004 and 7 January, 2007, with serial numbers beginning with 0407 through 0701. The following model numbers may be affected by one or both of these field corrections.

- 660 – Atlas Stretcher
- 721 – Transport Stretcher
- 735 – Transport Stretcher
- 1001 – Advantage Stretcher

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- 1002 – Trauma Stretcher
- 1005 – M-Series Stretcher (SM104)
- 1015 – M-Series Stretcher (SM204)
- 1020 – Trauma Stretcher
- 1069 – Eye Surgery Stretcher

Our records indicate you have purchased a number of stretchers affected by this recall from Stryker UK. Please see the enclosed listing for model and serial number details.

Please note: If you have purchased any stretchers from an alternative distributor that fall within the model/serial numbers listed in this letter, these stretchers are also affected by this device correction. Please let us know the model(s) and serial number(s) of these units and we will arrange to perform the correction along with your Stryker purchased stretchers.

Once you have identified the location of the stretchers within your organisation, we would be grateful if you would complete the enclosed customer response form and fax it back to Stryker UK on 01635 262 464. A member of the Stryker Technical Services Department will then contact you to arrange a convenient time to visit your organisation to carry out the necessary correction.

Please find enclosed pictures of the models affected to assist you with identification. Please note that a label identifying the model and serial number of the stretcher can be found underneath the back rest or in the base of the stretcher.

If the stretchers have been transferred to another hospital or unit please provide their details so that we can trace these.

We apologise for any disruption that corrections may cause. We strive to make products that meet our customer's expectations for quality and durability and we want to ensure our products are as risk-free as possible. We would like to thank you for your co-operation in this matter. Should you require any further information or have any queries on the matter please do not hesitate to contact the undersigned on 01635 262 465.

Yours faithfully,

Quality Assurance & Regulatory Affairs

cc Estates & Facilities Manager