

URGENT MEDICAL DEVICE CORRECTION

08 January 2008

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
- 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 Stryker stretchers affected by this recall from our authorised distributor, Whelehan Surgical (formerly Unipharm Surgicare). Please see the enclosed listing for model and quantities.

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 Whelehan Surgical 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,

Jacqueline Fripp
Quality Assurance & Regulatory Affairs

660 ATLAS



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

