

Sunrise Medical Ltd High Street Wollaston Stourbridge West Midlands DY8 4PS England

Tel: 01384 44 66 88 Fax: 01384 44 66 99 www.sunrisemedical.co.uk

<u>Urgent Field Safety Notice</u>

SM/FSN/LBU

Sunrise Medical-Manual and Powered Wheelchairs

Re: Fitting of Lap Belt - Updated User Information

Type of action: Important Safety Information for Usage and Maintenance of Lap Belts

15/07/08

In the interests of safety for our wheelchair users, and for those who have purchased Sunrise Medicals lap belts as third party spares. We would like inform you of the updated user information for wheelchair lap belts supplied by Sunrise Medical for use on their range of powered and manual wheelchairs

The documentation has been revised to include more detailed information on the importance of the fitting maintenance and correct positioning of the lap belt for the user of a Sunrise Medical wheelchair. The updated information also includes warnings particularly in reference to the correct adjustment and securing of the lap belt prior to its use. Incorrectly adjusted lap belts i.e. loose could cause the user to slip down in the wheelchair and risk suffocation and or serious injury

The revised text is located in the Safety section of each product owner's manual. This additional information is to reduce the potential risk of serious injury or suffocation to the wheelchair user if the lap belt is fitted or used incorrectly.

An example of the updated user information for safe use and maintenance of lap belts is attached.





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Transmission of this Field Safety Notice:

This notice should be passed on to anyone within your organisation who needs to be aware and to any other organisation/institution where the potentially affected wheelchairs may have been transferred.

The information needs to be passed on until the wheelchair user and also anybody involved with the care of the wheelchair user, including family members, and healthcare professionals have been made aware of it. To ensure this information is passed on effectively please complete the attached response form and return it to Sunrise Medical via Fax or E-mail as detailed below

*This FSN will be made available on both the MHRA web site (http://www.mhra.gov.uk) (http://www.sunrisemedical.co.uk).

Users requiring an updated manual for their wheelchair can visit the Sunrise Medical web site products page (http://www.sunrisemedical.co.uk) for a free download of the manual.

For further paper copies or any other assistance, please contact: Jeremy Fletcher Regulatory and Conformance Sunrise Medical Business Park Wollaston, Stourbridge West Midlands DY8 1NW

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Email: jeremy.fletcher@sunmed.co.uk

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The undersigned confirms that this notice has been communicated to the appropriate Regulatory Agency





