

URGENT FIELD SAFETY NOTICE: SM/FSN/NSA

Sunrise Medical – Quickie Neon Swing-Away

Ref: 2010/011/022/081/001

Description of the Issue

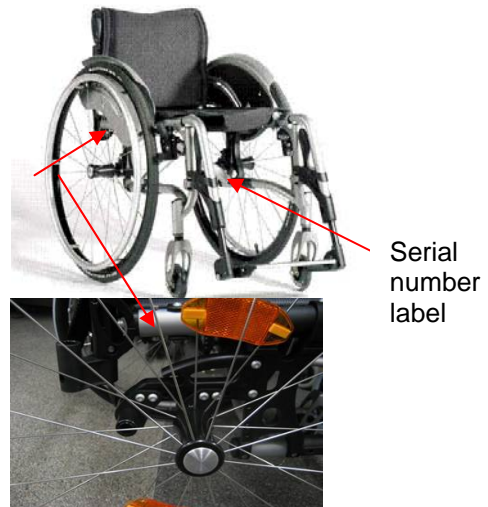
Through our post-market surveillance activities we have identified an issue on the Quickie Neon Swing-Away where a small number of upper frame tubes that support the backrest have failed. There is the potential for other frames to fail and users could potentially fall backwards resulting in serious injury.

Neon Fixed Front: **not affected**

Neon Swing-Away



area of concern



Serial
number
label

Please note that this FSN only affects:

- Neon Swing-Away models
- With seat depth up to 44cm (chairs above this seat depth are not affected)
- Manufactured before June 2010 (wheelchairs made after this date have a strengthened upper frame tube). The date of manufacture can be identified via the serial number label located as shown above.

An upgrade kit has been made available and needs to be fitted to all affected wheelchairs.

Action to be taken:

As our records show that you have purchased one or more of the affected wheelchairs you are requested to please carry out the following urgent actions:

1. Please inform any users to whom you have distributed this product about this Field Safety notice and the required corrective action.
2. Please arrange with the user to fit the upgrade kit to their wheelchair. Ask the user or their representative to sign the receipt form to confirm the work has been carried out.
3. Return the completed and signed receipt forms to us.
4. It is possible that some of the affected wheelchairs may have been removed from service. Therefore if this is found to be the case please confirm this by completing a receipt form and confirming the serial number/s of the wheelchairs no longer in service.

5. If you are unable or unwilling to carry out this work please let us know as we can complete it on your behalf if you provide us with the user's details. (We can sign an agreement to assure you that these details will not be used for any purpose other than to contact them to complete this corrective action.)

Upgrade Kits:

Upgrade kits and fitting instructions are available and can be requested by contacting our Customer Service department **quoting part number 054493-055**.

The kits will be supplied to you free of charge and a fitting fee will be paid to you on return of the signed receipt forms and an itemised invoice.

Please read this notice carefully and consider the necessary actions to be taken in order to ensure the safety of your customers. If you do not understand what is being asked of you please contact us.

We appreciate this is an inconvenience to you and to your customers; however the corrective action must be done immediately to prevent the remote chance of serious injury or death.

We therefore must ask that you complete this action within 60 days of receipt of this letter

Distribution of this Field Safety Notice:

Please ensure that this notice* is made available to all relevant personnel in your organisation and to the customers as detailed in the attached schedule.

Please keep this information and maintain awareness until all actions have been completed

*This FSN will also be made available on the Sunrise Medical web site at www.sunrisemedical.com

The relevant competent authorities have been informed of this notice

For further paper copies or any other assistance, please contact:

Jeremy Fletcher
Regulatory and Conformance Manager
Sunrise Medical
Wollaston, Stourbridge
West Midlands DY8 4PS
Tel: 01384 446672
Email: jeremy.fletcher@sunmed.co.uk

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

