



URGENT: MEDICAL DEVICE FIELD CORRECTION
Quickie® Q7™
Backrest Bracket

July 5, 2016

Dear Sunrise Dealer,

The purpose of this letter is to advise you that Sunrise Medical (US) LLC is voluntarily conducting a field correction for the Quickie® Q7™ rigid wheelchair in reference to the original backrest bracket design (2009-2013).

Reason for the Voluntary Field Correction:

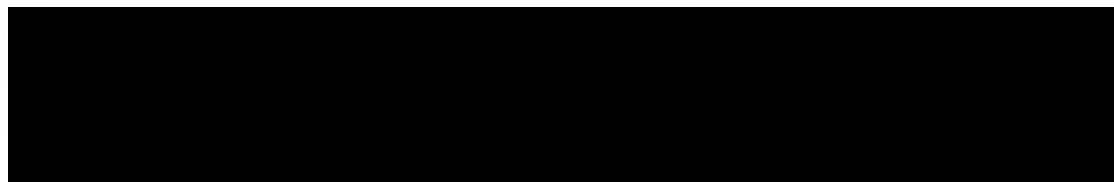
It is possible that, over time and with some end user loading conditions, the backrest brackets may break. This applies only to the Quickie Q7 manufactured prior to November 27, 2013.

Risk to Health:

If a backrest bracket breaks and goes unnoticed by the user or caregiver, there is a risk for the occupant to fall out of the seat and sustain an injury.

Actions to be taken by the Dealer:

Our records indicate that you have purchased for distribution one or more of the Quickie Q7 (Model EIR4) wheelchairs with the original backrest bracket design used before November 27, 2013. In addition, you may have wheelchairs on your list that were sold by companies that have been acquired since 2009. We have identified these wheelchairs and included in this email a listing (**Serial Number Verification Form**) of all Quickie Q7s that were sold to your company that will require replacement kits. We request that you immediately contact your customer(s) with serial numbers listed on the **Verification Form**.



If you are unable to contact the end user or the wheelchair is no longer available, please indicate this on the **Verification Form**. Please complete the **Serial Number Verification Form** with the appropriate box checked, according to disposition of each wheelchair as soon as the information becomes available. In order to keep the process flowing smoothly, please return the updated form to Sunrise Medical every seven to ten days.

Each time the form is received by Sunrise Medical, a correction kit that is matched by serial number will be sent. Please make arrangements with the end user to have the correction made to each wheelchair with the correction kit supplied by Sunrise Medical. We request that you dispose of the original hardware.

Each correction kit you receive will also have a separate **Acknowledgement and Response Form** enclosed in the correction parts box. Once the work is completed, please check the appropriate acknowledgment box on the form and send the signed form to Sunrise Medical according to instructions provided on the form.

Product and Distribution Information:

- Quickie Q7 (Model EIR4) manufactured between September 1, 2009 and November 27, 2013. Serial number range: R4-007239 to R4-022394

Action by the Company:

Sunrise Medical has designed improved backrest brackets which have sufficient material strength to resist the observed failure mode under normal conditions. (These improved backrest brackets are already installed on all chairs manufactured after November 27, 2013 including current production.) We will provide each dealer with sufficient correction kits to correct each identified wheelchair.

Sunrise Medical will reimburse dealers \$50.00 for each corrected Quickie Q7™ wheelchair after receipt of the respective **signed Acknowledgement and Response Form**.

improving people's lives



Other Information:

Please complete and return the enclosed **Serial Number Verification Form** indicating which wheelchairs need to have a correction kit sent. If you have any additional questions, please contact Sunrise Medical Regulatory Affairs at (888) 208-4901.



Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (Form available to fax or mail), or
- Call FDA 1-800-FDA-1088

