

24 November 2022

URGENT PRODUCT DEFECT CORRECTION NOTICE

TGA Recall Reference Number: RC-2022-RN-01425-1

Aspire Superlite Adjustable Seat Walker - WAF709650CH

ARTG Number: 313863, Serial Number Identification: beginning with 727584

Dear Customer,

Aidacare Pty Ltd, after consultation with the Therapeutic Goods Administration (TGA), is conducting a defect correction of the above Aspire Superlite Adjustable Seat Walker. We are contacting you as the potentially affected product may have been supplied to your organisation.

Problem

The nut securing the frame's cross brace in place may become loose over time leading to the frame becoming unstable. The health risk associated with this issue is increased falls risk that may lead to physical harm to the user.

A temporary fix is to remove and discard the washer that sits under the nuts either side of the cross brace. A permanent solution is to remove and discard the washer that sits under the nut as well as replace the second washer that sits in between the cross brace with a thinner washer (supplied by Aidacare) on either side of the cross brace.

For more details, see attached defect correction instructions.

This defect correction does not affect any other serial numbers of Aspire Superlite Adjustable Seat Walkers or any other Aidacare products (including those branded as Aidacare, Aspire, Freedom or other brands under the Aidacare family). This serial number range has been distributed to distributors and other customers since 2nd February 2022.

Action

Inspect your stock **immediately**.

Complete the attached acknowledgement form **immediately even if you do not have any affected stock** and return it to prodg@aidacare.com.au to reconcile this process.

Ensure relevant staff members are informed of this recall, including [locums, inwards goods staff, credit returns staff, biomedical engineers, relevant clinicians who may decide to monitor for adverse events, as applicable].

If you have supplied or transferred any potentially affected product to another facility or organisation, let that facility know of the defect correction **immediately** by providing a copy of this letter.

Place this letter in a prominent position for at least one month.

Product Defect Correction Kits

Aidacare will supply defect correction kits per the quantity of affected stock identified and reported and returned in the attached acknowledgement form.

Defect correction kits (contains 2 x 1.2mm thick steel washers and 1 x set of instructions) are available as below:

1. Sent out directly to your address, to facilitate the defect correction yourself, noting you will need a spanner.
2. In store, return to your local Aidacare store and they will be able to perform this defect correction for you

A digital version of this announcement is also available on the Aidacare website.

Aidacare Pty Ltd sincerely regrets any inconvenience caused and thank you in your assistance to correct this defect.

Regards,

A handwritten signature in grey ink, appearing to read 'David Owen', is positioned above the printed name and title.

David Owen
General Manager – Product Development

TGA WEB STATEMENT

Aspire Superlite Adjustable Seat Walker

Consumer Level Product Defect Correction - Securing nut incorrectly assembled

Aidacare Pty Ltd is providing corrective action on walkers with serial numbers starting with '727584-' because a securing nut in the frame may have been incorrectly assembled.

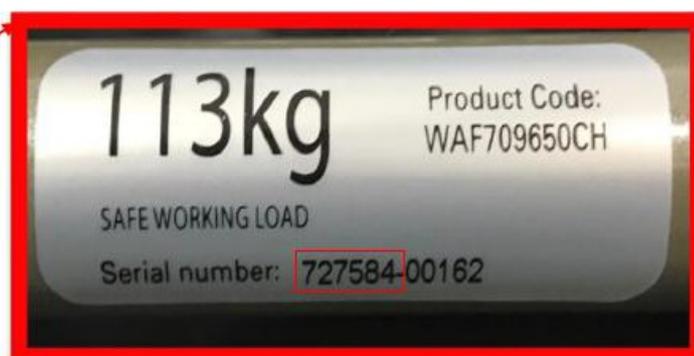
The Aspire Superlite Adjustable Seat Walker (ARTG 313863) is used to assist in the mobility of disabled or elderly people.

No other serial numbers of Aspire Superlite Adjustable Seat Walkers are affected by this corrective action.

What should I do?

- If you have an Aspire Superlite Adjustable Seat Walker with serial number beginning with 727584 (see picture below), **do not use it**.
- You can either
 - return it to the place of purchase (your local Aidacare store) and they will fix it for you
 - or
 - call the Aidacare customer service line (1300 133 120) to arrange for the correction kit to be sent to you.

The correction kits contain 2 x 1.2mm thick steel washers and a set of instructions. You will need a spanner to change the washers yourself.



What is the problem?

Due to a change in the washers used in manufacturing, the nut securing the frame's cross brace may become loose over time and lead to the frame becoming unstable.

Continued use of a walker with an unstable frame may lead to a fall or other harmful consequences.

Reporting problems

Consumers and health professionals are encouraged to [report problems with medical devices](#). Your report will contribute to the TGA's monitoring of these products. For more information see the [TGA Incident Reporting and Investigation Scheme \(IRIS\)](#).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.