

July 12, 2021

URGENT: MEDICAL DEVICE RECALL

Field Safety Notice to Consumers

Zippie Voyage® early intervention stroller

Model Nos.: **EIZ14**

Manufacture & Distribution Date Range: April 15, 2013 and December 20, 2016

Serial Nos: ZV-001340 to ZV-006153

Dear Zippie Voyage® Consumer,

The purpose of this letter is to inform you of a product correction (recall) involving the Zippie Voyage® early intervention stroller designed with a detachable seating system that were manufactured and distributed between April 15, 2013 and December 20, 2016.

IMPORTANT: You may receive a similar letter for the **EIZ14** model which will contain different instructions, serial numbers, and manufacture date ranges. Please follow the instructions in that letter if you have purchased any **EIZ14** models.

Reason for the Voluntary Field Correction

When the seating system is not adequately attached to the stroller base as described in the Owner's Manual, the seating system may slide off the base and fall to the ground.

We are writing to make you aware of this situation and to provide recommendations for how to prevent this situation from occurring. We are also making you aware that Sunrise Medical will be providing to all ZIPPIE® Voyage® customers, free of charge, a Safety Tether Kit so that you can install a safety tether on your stroller.

Risk to Health

If the seating system is inadequately locked onto the stroller base before placing the child in the stroller, the seating system can fall to the ground, injuring the child. It is always important to follow the instructions for use for properly attaching the seating system to the stroller base in order to minimize the risk of injury.

Serious injuries and/or deaths could occur due to the failure to properly attach the seating system to the stroller base. To date, a total of 21 complaints (4 involving an injury, 17 that did not involve an injury, and no deaths) have been received by Sunrise Medical's customer service since October of 2013.

Actions taken by the Company

Sunrise Medical will provide you with a safety tether that, when installed and used properly, is designed to prevent a seat that is inadequately attached to the stroller base from falling to the ground. The safety tether can be installed by you and no product needs to be returned.

This Safety Tether Kit will be provided free of charge to all ZIPPIE® Voyage® consumers starting the week of July 12, 2021. The Safety Tether Kit will be accompanied by instructions to guide you through installing and using the safety tether.

Actions to be taken by the Consumers

We are asking ZIPPIE® Voyage® owners to perform one of the following recommendations:

1. Choose to stop using the ZIPPIE® Voyage® early intervention stroller until a Safety Tether Kit has been provided to you and you have installed the safety tether.

OR

2. If you elect to continue to use the ZIPPIE® Voyage® early intervention stroller (before you receive your Safety Tether Kit and have installed the safety tether) and you ordered your ZIPPIE® Voyage® with a transit option, you can use the transit strap to securely attach the stroller seat to the stroller handle. The transit strap may function to prevent the seat, if inadequately attached to the stroller base, from falling to the ground. ***However, the transit strap is not intended to be a replacement for the safety tether that we will be providing to you. You should install the safety tether when you receive it.***

OR

3. Experienced users who do not have the transit option on their stroller may choose to continue to use the ZIPPIE® Voyage® (before you receive your Safety Tether Kit and have installed the safety tether), but you must ensure that the stroller seat is securely attached to the stroller base before every use (follow the instructions shown in **Figure 1** [from the Owner's Manual]). ***Please make sure that these steps are performed each and every time you attach the seat.***

Please retain this letter for reference until you receive your Safety Tether Kit and install the safety tether.

Figure 1: ZIPPiE® Voyage® EIZ14 Seating Installation

ENGLISH

VIII. SETUP & USE

E. SEATING SHELL INSTALLATION

⚠ WARNING

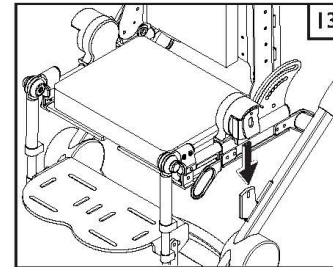
BEFORE installing the seating shell, always check that the mobility device is completely unfolded and in the locked position, and that all four wheels are locked in place. The seating shell should never be installed with a seated occupant. Always remember to stabilize the mobility device before performing this action.

- Rotate the front casters until they point forward.
- Engage the parking brake.

The seating shell has two latch blocks mounted on the outside of the assembly. The base frame has two posts mounted to the inside of the frame that mate with the latch blocks. The seating shell may be installed so that the child can face either frontwards or rearwards. Installation is the same in either direction.

Install the seating shell 13

1. Make sure the seat is in the fully upright position (no recline or tilt). Ensure all positioning straps and accessories are out of the way and will not prevent the seat from fully engaging the receivers.
2. Grasp both sides of the seating shell and line up the latch block receivers with the locking posts. Lower the seating shell evenly so that both sides engage at the same time. You should hear an audible click on both sides. Check the secure engagement to the base by pulling up on both sides, if it does not move or tilt, the seating shell has been installed properly.
3. The seating shell is now ready to accept an occupant for transportation and/or adjustment.



F. SEATING SHELL REMOVAL

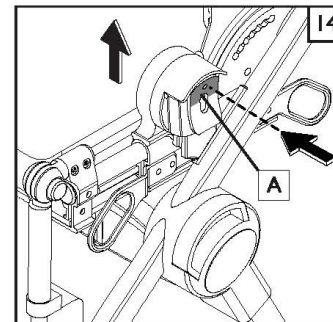
⚠ WARNING

BEFORE removing the seating shell, always remove the occupant to a safe location. Failure to do so may result in injury to the dependent, and/or caregiver. Always remember to stabilize the mobility device before performing this action.

- Rotate the front casters until they point forward.
- Engage the parking brake.

Removal of the seating shell: 14

1. Make sure the seat is in the fully upright position (no recline or tilt)
2. Push and hold both release levers (A) so that they disengage from the receiver posts. Once the seating shell has been disengaged from the receiver posts. Raise the seating shell evenly to clear the base.
2. The seating shell is now ready to be inspected and/or stored.



After receiving the Safety Tether Kit and installing the safety tether according to the provided instructions, please fill out and return the **User Acknowledgement and Response** form included in the Safety Tether Kit to the contact information provided on the form.

Product and Distribution Information

ZIPPIE® Voyage® early intervention stroller

- a. Model No.: EIZ14
- b. Manufacture and Distribution Date Range: April 15, 2013 to December 20, 2016
- c. Serial Nos.: ZV-001340 to ZV-006153

Other Information

If you experience any adverse events or quality problems with the use of this product, these events may be reported to:

- Sunrise Medical Customer Service at 1-800-333-4000
between the hours of 5 am and 5 pm Pacific Time (8 am and 8 pm Eastern)
- OR
- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>
- OR
- Call FDA at 1-800-FDA-1088

Your assistance is appreciated to prevent potential user harm.

Please complete and return applicable forms to the contact information printed on the form promptly. If you have any questions, please contact Stericycle (agency acting on behalf of Sunrise Medical):

Phone: 1-866-664-1407 (between 8 am and 5 pm Central Time)

Fax 1-866-215-7203

Email: SunriseMed4787@stericycle.com

We apologize for any inconvenience this may cause you. We also thank you in advance for your prompt attention to this matter.

Sincerely,



Devin I. McElroy

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