

July 12, 2021

## **URGENT: MEDICAL DEVICE RECALL**

### **Field Safety Notice to Consumers**

#### **Zippie Voyage® early intervention stroller**

Model Nos.: **EIZ16, EIZ18**

Manufacture & Distribution Date Range: May 18, 2016 and June 9, 2021

Serial Nos: ZV1-007000-ZV1-016036; ZV18-000001-ZV18-002220; and ZV18-02062

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 **EIZ16** and **EIZ18** models which will contain different instructions, serial numbers, and manufacture date ranges. Please follow the instructions in that letter if you have purchased any **EIZ16** and/or **EIZ18** 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 39 complaints (14 involving an injury, 26 that did not involve an injury, and no deaths) have been received by Sunrise Medical's customer service since May of 2016.

### 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® EIZ16/EIZ18 Seating Installation**

**ZIPPIE VOYAGE**

**I. SEATING INSTALLATION** 14 15 16 17 18 19 20

**⚠ 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 a latch mounted underneath the seat plate. The interface on the base is the counterpart to the latch and mates with the latch. The seating shell may be installed so that the child can face either frontwards or rearwards. Installation is the same in either direction.

**Using the latch lock**

NOTE - The latch under the seat plate has a lock that can be used to provide additional securement after the seat is installed.

- BEFORE attaching or removing the seat to or from the base, the latch lock (K) MUST be slid to the right (unlocked position) as shown in Fig 14.
- To prevent inadvertent activation of the seat latch, slide the latch lock to the left as shown in Fig 15 AFTER the seat is fully secured to the base (you cannot attach seat to base while lock is engaged).

**Rotating the seat shell direction**

- Lock the wheels, remove the seat.
- Be sure the Tilt setting is at the "home" or 0° position. Do this by squeezing the Tilt Release lever and letting the "Slide-n-Lock" (Receiver) Plate spring flat.
- STEP 1:** Press the Gold Button, Numbered 1 (A) on the Slide-n-Lock plate and rotate the plate until it stops (Fig 16).
- STEP 2:** Pull the Pin (B) with one hand and rotate the Tilt Limiter Sleeve (C) with your other hand\* (Fig 17 and 18).

NOTE - Only rotate the Tilt Limiter Sleeve in the process of Rotating the Plate.  
\*When the seat is forward facing the Tilt Limiter Sleeve should be rotated Rearward; when the seat is rearward facing the Sleeve should be rotated Forward.

- STEP 3:** Finish rotating the Plate 180° until it locks into place (Fig 19).

NOTE - When fitted with an Advanced Seating system, maximum posterior (forward) tilt range may be limited.

**Install the seating shell**

NOTE - When installing the Moderate Seating System in the rearward facing direction, raise the footrest to about a 5 degree angle, to clear the stroller base crossbar and allow seat to lock into the receiver.

- 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 interfere with the seat from fully engaging the receiver.
- For moderate seating system only:** Line up the alignment tag (D) with the support cross bar (E) on the base (Fig 20).
- Lower the seating shell so that the seating shell and mounting plate are in contact.
- Slide the seat backwards evenly. You should hear an audible click. Check the secure engagement to the base by pulling up on both sides. If it does not move or tilt, the seating shell is now locked and has been installed properly.
- Once locked into place, add the occupant for transportation and/or adjustment.

**VIII. USE AND MAINTENANCE**

**14**

**15**

**16**

**17**

**18**

**19**

**20**

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 Nos.: EIZ16, EIZ18
- b. Manufacture and Distribution Date Range: May 18, 2016 and June 9, 2021
- c. Serial Nos: ZV1-007000-ZV1-016036; ZV18-000001-ZV18-002220; and ZV18-02062

**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](mailto: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

Sr. Director, Regulatory Affairs and Quality Assurance, North America  
Sunrise Medical (US) LLC, 2842 N Business Park Avenue, Fresno, CA 93727