

## **CRITICAL PRODUCT CORRECTION**

**Product Name: Invacare Birdie lifter**

**ARTG number: 166395**

**Date:** 02-July-2025

**Ref. Invacare:** FSN\_01\_2025\_Birdie lifter\_Carabiner

**TGA Ref #:** RC-2025-RN-00545-1

### **Important information**

After becoming aware of a serious adverse event related to the Invacare Birdie lifter and carabiner attachment, Invacare wants to remind users of the importance in ensuring the correct assembly position of the carabiner in the Birdie lifter arm and correct attachment of the hanger bar into the carabiner.

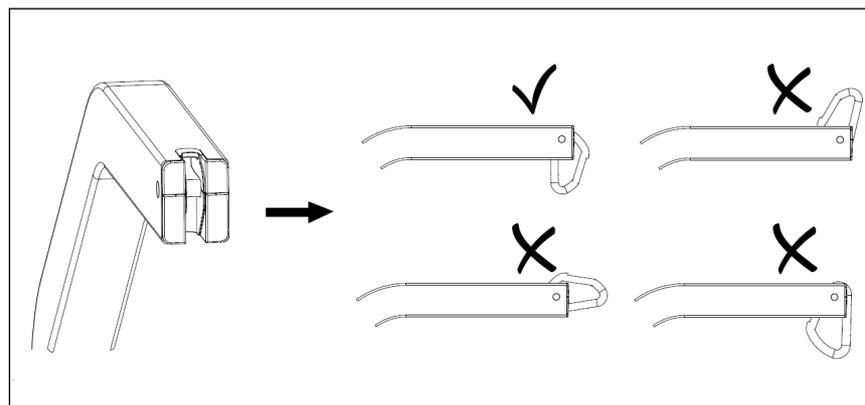
Invacare Birdie lifter Instructions For Use explains in detail the correct use and handling of the attachment of carabiner and hanger bar (*Section "4.4 – Mounting the Hanger bar"*).

The Instructions For Use supplied with the product must be read and understood before using the product. Invacare Birdie Instructions For Use provides all information for handling and operating the device in a proper and safe manner and must always be the basis when conducting any training on the device. To ensure good performance and safety, the product must only be used according to its intended use, and the information in the Instructions For Use must always be followed.

Furthermore, it is important to verify that the carabiner always remains in the correct assembly position. The carabiner should not be able to rotate within the plastic parts where it is assembled without resistance. If unimpeded rotation occurs, this indicates the plastic parts present wear and need to be replaced.

Therefore, Invacare has decided to improve the current Maintenance checklist included in the Instructions For Use of the device. An additional point to check the hanger bar during regular maintenance has been added under *"The hanger bar"* section. Images have also been included to show the correct and incorrect carabiner positions, according to the related Instructions For Use.

Please refer to the image below:



Attached to this Critical Product Correction, you can find an Addendum (Part number 60148538) to add to the Birdie lifter Instructions For Use, showing the above-mentioned update.

**What is the risk?**

If the updated Instructions for Use and Maintenance checklist are not followed appropriately, or the carabiner is incorrectly attached, this may lead to the spreader bar detaching resulting in a patient fall. Worldwide several adverse events have been recorded related to this problem, including a patient death.

**Why are you being contacted?**

This information is relevant for all users of the Invacare Birdie lifter (regardless of the Serial number), and according to our records you received one or more Invacare Birdie lifters.

**What actions are required?**

- Providers/distributors should inform all affected users about the content of this Critical Product Correction and provide a copy of the letter.
- This **Addendum should be kept together** with the current Birdie lifter Instructions For Use.
- This updated Maintenance checklist must always be used when performing the regular Maintenance of the device.
- Please complete the attached Customer Response Form immediately, even if you do not have any affected stock, and return it to [Compliance ANZ@invacare.global](mailto:Compliance_ANZ@invacare.global)

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and customer base, and that awareness is maintained.

Invacare is taking this action following consultation with the Therapeutic Goods Administration (TGA).

Thank you for your immediate attention to this important matter.

We appreciate your cooperation.

If you have any questions relating to this Critical Product Correction, or should you require any additional information, please call us on 1800 460 460 or contact:



**Aline Eulalia**

Quality Assurance Specialist

[Compliance\\_ANZ@invacare.global](mailto:Compliance_ANZ@invacare.global)