

Urgent Recall for Product Correction

Invacare Birdie Lifter Series— alert for the correct assembly of D-Clip and quick release pin.

ARTG: 166395

Models Involved	
Item Number	Item Name
3000503.E3B00-0125	LIFTER BIRDIE (180KG-EL-JC)
3000502.E3B00-0125	LIFTER BIRDIE 170KG EL
3000513.D3B02-0125	LIFTER BIRDIE CMPT (150-ML-JC)
3000512.D3B02-0125	LIFTER BIRDIE COMPACT 150KG ML
3000503D3B02-0125	LIFTER BIRDIE MAN(170KG-ML-JC)

Date: 06/10/2016

Dear Valued Customer

In the interests of the safety of our customers, we would like to bring to your attention the correct assembly of the D-Clip that connects the actuator to the Invacare Birdie lifter's arm (models included detailed in table above).

The lifter arm and actuator do not arrive assembled together at the Customer. The actuator is assembled at the European manufacturer with a screw on the bottom part, whilst the upper part is assembled by the User using the D-Clip and quick release pin.

As a result of some vigilance cases overseas, where the actuator's D-Clip becomes damaged and the lifter arm falls down, we have become aware that if the D-Clip is always placed backwards and pointing down towards the actuator, it can start to become damaged after a number of cycles – picture below. If the D-Clip becomes damaged to the extent that the lifter arm falls down then there is potential for a serious patient injury to occur. When the clip is in the wrong position the bending (damage) of D-Clip only happens if it is touching the actuator backwards and at its maximum height, the clip will also bend severely when over 140kg is used with the device. The complete Clevis Pin (quick release pin) doesn't detach immediately from the actuator, when the D-Clip becomes damaged - the pin stays in the arm's plates that hold the actuator.

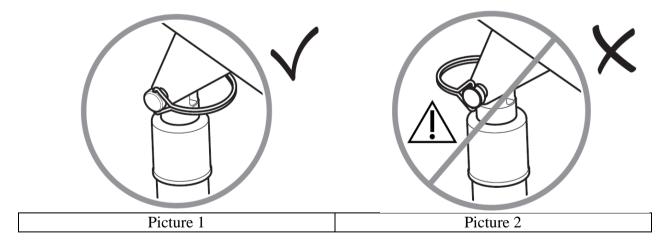




Whilst Australia has not received reports of customers incorrectly assembling the device, in order to prevent the possibility of the D-Clip becoming damaged the manufacturer has updated the product's instructions for use to communicate in more detail the correct way to assemble the D-Clip and quick release pin.

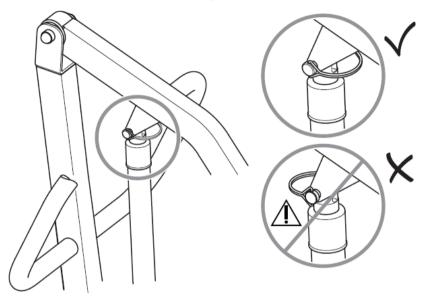
ACTION: Please check the following on each Invacare Birdie lifter:

- The actual state of the D-Clip (Does it appear bent or broken, like in the image above)
- The actual position of the D-Clip in the lifter (if mounted)
 - o If it is in the <u>correct position</u> shown below in <u>picture 1</u>, there is no need to change it
 - o If it is assembled in the <u>wrong position</u> shown below in <u>picture 2</u>,
 - Remove the D-Clip and reassemble it as shown in picture 1
- Complete the attached Customer Acknowledgement Form.
- If the D-Clip appears damaged or broken please contact Invacare on 1800 460 460 or email recalls@invacare.com.au.





Yes, you can:



A copy of the amended user manual will be available for download from the Invacare website http://www.invacare.com.au

Please ensure that the information in this notice is made available to all relevant personnel within your organization and / or customer base, and / or any organization where the mentioned device has been transferred. Please also ensure that this information is maintained for an appropriate period.

This action has been undertaken following consultation with the Therapeutic Goods Administration (TGA).

Thank you for your immediate attention to this important matter. Invacare sincerely regrets any inconvenience caused.

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