

## URGENT PRODUCT DEFECT CORRECTION

TGA RECALL REFERENCE NUMBER: RC-2024-RN-00105-1

PRODUCT NAME: OXFORD, CLASSIC RANGE

Description of items: ARTG 397230, Oxford Classic Range, All Units

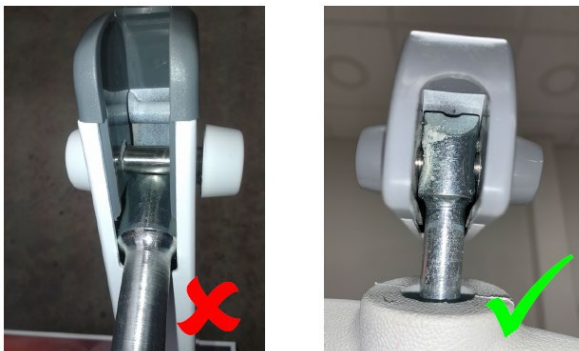
Enable Lifecare PTY LTD, after consultation with the Therapeutic Goods Administration (TGA), is conducting a product defect correction, pertaining to the instruction manual for the Oxford Classic Floor Lifters. We are contacting you as the potentially affected product has been supplied to your organisation.

### PROBLEM

The critical concern lies in the possibility of the fulcrum pin which secures the yoke to the boom being misaligned and held solely by a ridge within the plastic boom end cap Figure 2. This undependable securing mechanism could inevitably fail under operational loads, potentially leading to hoist malfunction and compromised load stability.

Inevitably, there will be instances when a spreader bar does require removal, possibly for replacement should there be signs of wear or damage for example. In this case, we must reemphasise a requirement to very carefully **ensure that the fulcrum pin is fully and securely inserted through the mating hole of the king pin** when reassembled. This warning has been made clear in the instruction user guide, attached.

**Fig. 2.** The correct fitment of the Classic series Fulcrum pin



### ACTION

1. Ensure all current and onward customers are advised as to the detail in this communication and the importance of reading and understanding of the updated user guide (attached to this letter) before use to avoid possible, inadvertent safety issues for both patient and caregiver.
2. Ensure those responsible for service and maintenance of Oxford Classic hoists, read and fully understand the updated service guidance contained in the latest revision (attached to this letter).
  - a. Please contact us at [Support@enablelifecare.com.au](mailto:Support@enablelifecare.com.au) to book Joerns Healthcare Accredited Service Technician Training.
3. Sign and return the attached Acknowledgement Letter to [Recall.AU@enablelifecare.com.au](mailto:Recall.AU@enablelifecare.com.au)

Thank you for your assistance in helping us to manage this product defect correction

Ruben Joyce  
Commercial Manager  
07<sup>th</sup> February 2024