



GOP016-F03 Issue 2

**Product Correction**

**TGA Ref: RC-2025-RN-00532-1**

**Product Name:** Able Spacers (Blue) AUS  
**Product Code:** 3609120AUS  
**ARTG:** 158422

**Flexicare Ref:** FSCA 2025-003 & FSN 2025-003

**Date:** (revision 2) 02 October 2025

**Attention:** Distributor

**Description of the problem:**

The Able Spacer carton contains an incorrect text, which covers a whistle statement, prior to the diagram (example below). The incorrect statement is as follows, “The new valve has an inbuilt whistle to help you use the spacer correctly. Each time the whistle sounds you are inhaling at the correct speed” (see Figure 1 – Able Spacer (Blue) AUS Label). There is currently no new valve with inbuilt whistle in the Able Spacer (Blue) AUS, 3609120AUS.

**There has been one failure mode related to the problem observed.**

- Annex Name: A
- Annex Title: Medical Device Problem

Term	FDA Code	NCIt Code	IMDRF Code	Definition
Labelling, Instructions for Use or Training Problem	1318	C63072	A21	Problem associated with device markings/labelling, instructions for use, training and maintenance documentation or guidelines.





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## Figure 1 – Able Spacer (Blue) AUS Label

There is no device impact relating to this carton labelling problem and therefore, Flexicare do not believe there is a safety or functional performance risk nor any potential harm to the user or patient.

**Scope of Problem :** All lots affected cover lots from 25-Aug-2023 to 20-May-2025  
All Lot numbers **from** first 4 digits **2308XXXXX**, where '2308...' = August 2023  
**to** Lot numbers starting with **2505XXXXX**, where **2505** = May 2025

### Distributor Action:

- **Please quarantine and relabel** existing stock before release to market
- **Please ensure that the details of this product correction notification** are made available to customers and facilitate customer response to the notification by means of the electronic methods via link or QR code below.



### Product Correction Response

- **PLEASE COMPLETE** the Acknowledgement Form shown on Page 3 and return within 30 days of receipt of this notice.

Please ensure this Product Correction details are made available to customers of the Able Spacer (Blue) AUS.

If you have any questions, please contact our Quality Team at [Recalls@Flexicare.com](mailto:Recalls@Flexicare.com)

Rebecca Concordia Funston (Nov 3, 2025 15:04:24 GMT)

Rebecca Funston

RAQA Director

Flexicare Medical Limited

# PRODUCT CORRECTION

RC-2025-RN-00532-1

## (FSN) DISTRIBUTOR ACKNOWLEDGEMENT FORM

### FSCA 2025-003 Able Spacers

I acknowledge receipt and understanding of this medical device Product Corrective FSCA 2025-003 and actions required.

I acknowledge that the Product correction FSN 2025-003 Notification (attachment) has been made available to customers and we have facilitated their response by means of electronic response via link or QR code. Responses will be retained for traceability compliance.

Distributor Name: \_\_\_\_\_ Position: \_\_\_\_\_

Facility Name: WyMedical Pty Ltd

Facility Address: \_\_\_\_\_

Email: \_\_\_\_\_

Please complete this form **within 30 days of receipt** and return to [Recalls@Flexicare.com](mailto:Recalls@Flexicare.com)

#### Flexicare Use Only

Reviewed By:

Date:

Comments

# FSCA 2025-003 Able Spacer 369120AUS FINAL v2.0 02-10-25

Final Audit Report

2025-11-03

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## "FSCA 2025-003 Able Spacer 369120AUS FINAL v2.0 02-10-25" History

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