



GOP016-F03 Issue 2

## **URGENT Field Safety Notice (FSN)**

**Product Name:** Y-Piece Breathing Trainers

**Product Code:** 8-402

**Ref:** FSN 2025-002

**Date:** 21-May-2025

**Attention:** All users and distributors of the product including adult and paediatric patients by medical carers and patients in hospital and out of hospital settings.

### ***Description of the problem:***

A number of **Y-piece Breathing Trainers** have been identified with loose fitting parts, related to the blue Y-Piece of the breathing trainer.


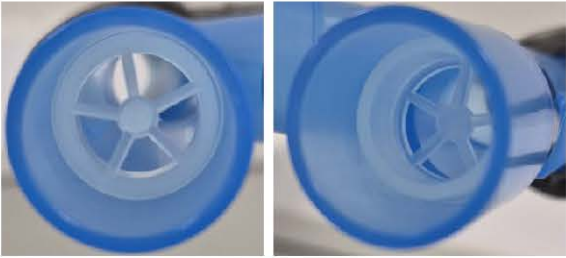


**There are 4 failure modes with associated IMDRF Codes which have been identified below, for reference**

Term	IMDRF Code	Definition
Defective Component	A0202	Problem associated with a device component having flaws of dimensional deviations greater than acceptable for the intended use.
Defective Device	A0203	Problem associated with having flaws or dimensional deviations greater than acceptable for the intended use of the device.
Device Misassembled During Manufacturing /Shipping	A0206	A device found incorrectly assembled when delivered to the user facility.
Component Misassembled	A020601	A device found to have one or more components incorrectly assembled when delivered to the user facility.
Detachment of Device or Device Component	A0501	Problem associated with the separation of the device from its physical construct, integrity, or chassis.
Separation Problem	A1503	Problem associated with the detachment or separation of the device.



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The following pictures demonstrate the issues highlighted: incorrect (✗), correct (✓)

<b>Figure 1</b>	<b>Poorly fitted valve detected prior to use</b>
<p>Valve In Body of the T-piece</p> 	
<b>Figure 2</b>	<b>Poorly fitted valve which becomes dislodged during use (No valve)</b>
<p>Exhalation = No Valve      Inhalation = No Valve</p> 	
<b>Figure 3</b>	<b>Valve body fitted incorrectly (orientation wrong)</b> <b>Correct (✓) = On the exhalation side, the hub and spoke are seated at the top of the valve and on the inhalation side, the hub and spoke are seated at the bottom of the valve</b>
<p>Exhalation = ✗      Inhalation = ✗</p> 	<p>Exhalation = ✗      Inhalation = ✓</p> 



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<p>Exhalation = ✓      Inhalation = ✗</p> <div style="display: flex; justify-content: space-around;"> </div> <div style="display: flex; justify-content: center; align-items: center; margin-top: 10px;"> </div>	<p>Exhalation = ✓      Inhalation = ✓</p> <div style="display: flex; justify-content: space-around;"> </div> <div style="display: flex; justify-content: center; align-items: center; margin-top: 10px;"> </div>
<p><b>Note :</b> incorrect (✗), correct (✓)</p>	
<p><b>Figure 4</b></p>	<p><b>Valve or Valve body missing from device as dislodged during transit potentially but found in device packaging</b></p>
<p>Valve in packaging</p>	<p>Valve Body in Packaging</p>

**All Lots of Y-Piece Breathing Trainers with Product Code 8-402, require pre-use checks. The following table is a list of all Lot numbers distributed to customers.**

Flexicare Part Number	LOT Number	Lot Number
<b>8-402</b>	230503990	240301378
	230601039	240401285
	230602890	240501691
	230700168	240600797
	230800844	240700221
	230802267	240700222
	230900398	240800761
	240301377	





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**ACTION REQUIRED: Prior to using the Breathing Trainer, please conduct the following checks:-**

- Refer to the IFU within the packaging: IP0000-562 Oxygen Therapy 8-402 Breathing Trainer IFU
- **Please follow the instructions below**
  - If you observe **any** plastic pieces that are loose, missing, incorrect fitting or individually present within the packaging prior to opening, apart from the 4 restrictor caps, please document the lot number and quantity on the Acknowledgement Form
  - The Acknowledgement Form is available attached to the FSN email, as an editable e-pdf version for ease of completing, signing, dating to **email back to Flexicare within 30 days of receipt**
  - Please quarantine the faulty product from use, whilst Flexicare further investigate the root cause and fix to the observed problem and return the product to Flexicare

If you identify a faulty device, **please return to the address below:-**

**Flexicare GmbH  
Otstrasse 36  
51674 Wiehl**

**ACTION REQUIRED: You must complete and return the Acknowledgment and Response Form of this notice to Flexicare Medical Ltd. The LOT number can be found on both the outer box label and the individual packaging.**

Please ensure this Field Safety Notice has been communicated to all users including those listed.

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

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Rebecca Concordia Funston (May21, 2025 17:08 GMT+1)

Rebecca Funston  
RAQA Director  
Flexicare Medical Limited



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☐ I acknowledge receipt and understanding of this medical device Field Safety Notice (FSN) and can confirm that I have forwarded this notice to all end users and have asked them to complete and send back to me and once received, I will forward the completed end users notices to you.

☐ I acknowledge receipt and understanding of this medical device Field Safety Notice (FSN) and have units for Collection & Return as per instructions (quantities specified in the above table).

☐ I acknowledge receipt and understanding of this medical device Field Safety Notice (FSN) and have identified that we do not have any of the listed product lot numbers

Customer Name: \_\_\_\_\_ Position: \_\_\_\_\_

Facility Name \_\_\_\_\_

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

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

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

**Flexicare Use Only**

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

Comments