



Australian Government

Department of Health, Disability and Ageing  
Therapeutic Goods Administration

**PulmonX Australia Pty Ltd – Prosthesis, internal, stent, bronchial (ARTG 165980) and Catheter, bronchial balloon (ARTG 165981)**

**Therapeutic Goods Act 1989**

**Approval under section 42DF for use of restricted representations by PulmonX Australia Pty Ltd**

I, Rowena Love, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from PulmonX Australia Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph **(A)**, for use in advertisements for the products identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated<sup>1</sup> in the advertisement in which any of the restricted representations are used.

**(A)**

- Endobronchial valve treatment is for carefully selected patients living with advanced emphysema/COPD
- Zephyr Valve is a device for the treatment of carefully selected patients with advanced emphysema/COPD
- Endobronchial Valve Treatment is a bronchoscopic procedure designed for a specific group of patients with severe emphysema who meet certain eligibility criteria
- Endobronchial Valve Treatment is a bronchoscopic treatment option for selected severe emphysema/COPD patients.
- Endobronchial Valve Treatment is an interventional surgical procedure for a select group of patients with advanced emphysema/COPD.
- The Zephyr Valve may help reduce hyperinflation in the lungs by letting trapped air escape while stopping new air from entering the damaged part of the lung.

**(B)**

- Prosthesis, internal, stent, bronchial (ARTG 165980)
- Catheter, bronchial balloon (ARTG 165981)

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<sup>1</sup> **prominently displayed or communicated**, in relation to a statement in an advertisement, means:

(a) either:

(i) for a visual statement—easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or

(ii) for a spoken statement—able to be clearly heard and understood; and

(b) repeated as often as necessary to be noticed by a viewer or listener

(C)

**Important Safety Information**

This information is not designed to replace the advice of your doctor or healthcare professional. The information presented is for educational purposes only. Please speak to your doctor or respiratory physician to decide if endobronchial valve therapy is right for you. Only your medical professional can make the medical judgment as to which products and treatments are right for your own individual condition. As with any surgery endobronchial valve treatment carries certain risks. Your physician will explain all of the possible complications of the surgery, as well as side effects. Individual results between patients may vary and endobronchial valve treatment may not be beneficial for some patients.

The risks associated with this interventional procedure include risks associated with but not limited to the bronchoscopy procedure, the use of anaesthetics, the placement of endobronchial valves within the respiratory system and post-anaesthesia care.

Complications of the Zephyr Endobronchial Valve treatment can include but are not limited to pneumothorax, worsening of COPD symptoms, haemoptysis, pneumonia, dyspnoea and, in rare cases, death. Your physician will explain all of the possible complications of the procedure, as well as side effects.

You cannot have this treatment if you:

- are unable to have a bronchoscopic procedure
- have an active lung infection
- have an allergy to Nitinol, nickel, titanium or silicone
- have not stopped smoking
- have an air pocket that is greater than 1/3 of the size of the lung.

Only a trained physician can decide whether a particular patient is an appropriate candidate for treatment with the Zephyr Valve. Zephyr Valve treatment is not suitable for all patients with severe emphysema/COPD, discuss with your respiratory specialist if endobronchial valve treatment is suitable for you.

Dated this 1st day of October 2025

*Signed electronically*

**Rowena Love**

Delegate of the Secretary to the Department of Health, Disability and Ageing  
Education Policy and Guidance Section  
Regulatory Compliance Branch