

# Patient Selection Guidance for COPD Healthcare Providers

## Zephyr Valve Indications for Use<sup>1</sup>

The Pulmonx Zephyr Endobronchial Valves are implantable bronchial valves indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.

## Patient Selection Criteria for the Zephyr<sup>®</sup> Valve Based on Multiple RCTs<sup>2-5</sup> and Expert Guidance<sup>6-8</sup>

Zephyr Valves have been clinically proven to be effective in:

- Patients with heterogeneous and homogeneous emphysema<sup>3,4</sup>
- Upper lobe and lower lobe predominant emphysema<sup>2</sup>

## Initial Referral Criteria


- Confirmed diagnosis of COPD
- FEV<sub>1</sub> of 50% predicted or less
- Breathless despite optimal medical management (mMRC ≥ 2)
- Non-smoking or willing to quit smoking

## Once Referred, An Interventional Pulmonologist Will Confirm:

- Diagnosis of severe emphysema as quantified by CT
- Appropriate Exercise Capacity (6MWD = 100-500m)
- Presence of hyperinflation (RV ≥ 150% predicted)
- Confirmation the target lobe has little to no collateral ventilation

Patients with varying levels of symptom burdens and disease patterns (including homogenous disease) can benefit from Zephyr Valve treatment. There is no need to restrict this treatment for only patients with the most severe symptoms.

### SPECTRUM OF QUALIFYING SYMPTOM BURDEN

Profiles of Patients who Qualified for Zephyr Valve Treatment			
mMRC	2	3	4
Shortness of Breath	On activity	On activity & at rest	Continuous
Activity Level	Limiting activities	Difficulty with activities of daily living	Inability to perform many activities of daily living
Oxygen Therapy	None	As needed	Continuous
Quality of Life Challenges	Difficulty keeping up with family and friends	Breathless even walking short distances; limited daily activities	Reliance on help for everyday activities

## Ask Your Patients About How COPD/Emphysema Is Affecting Their Quality of Life

Asking these questions at clinic visits may help patients better communicate about how breathlessness is impacting their quality of life:

- What activities could you do last year that are no longer possible?
- How often do you have to stop to catch your breath?
- Do you need help in order to do your regular chores and activities?
- Are you able to leave the house and go places without assistance?

### Warnings

The Zephyr Valve should be used with caution and only after careful consideration in patients with:

- Prior lung transplant, LVRS, median sternotomy, lobectomy, or pleurodesis on the target lung side
- Congestive heart failure or recent myocardial infarction
- $FEV_1 < 15\%$  of predicted value

### Contraindications

The Zephyr Valve is contraindicated for:

- Patients for whom bronchoscopic procedures are contraindicated
- Patients with evidence of active pulmonary infection
- Patients with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium)
- Patients with known allergies to silicone
- Patients who have not quit smoking
- Patients with large bullae encompassing greater than 30% of either lung

**Important Safety Information:** The Pulmonx Zephyr® Endobronchial Valves are implantable bronchial valves indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; those with evidence of active pulmonary infection; known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); known allergies to silicone; or with large bullae encompassing greater than 30% of either lung; Patients who have not quit smoking. The Zephyr Valve should be used with caution and only after careful consideration in treating patients with: Prior lung transplant, LVRS, median sternotomy, lobectomy, or pleurodesis on the target lung side; Congestive heart failure or recent myocardial infarction;  $FEV_1 < 15\%$  of predicted value. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial Valve System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.

**Caution:** Federal law restricts this device to sale by or on the order of a physician.

#### References:

- 1 Zephyr Valve IFU
- 2 LIBERATE (US pivotal), heterogeneous emphysema only: Criner, GJ et al. *Am J Resp Crit Care Med.* 2018; 198(9): 1151-1164.
- 3 TRANSFORM (OUS), heterogeneous emphysema: Kemp, SV et al. *Am J Resp Crit Care Med.* 2017; 196(12): 1535-43.
- 4 IMPACT (OUS), homogeneous emphysema: Valipour, A et al. *Am J Resp Crit Care Med.* 2017; 196(9): 1073-82.
- 5 Klooster, K et al. *N Engl J Med.* 2015; 373(24): 2325-35 + Supplementary Appendix.
- 6 Klooster, K, & Slebos, DJ. *CHEST.* 2021; 159(5): 1833-1842.
- 7 Klooster, K et al. *J Bronchology Interv Pulmonol.* 2021; 1(28): Letter to Editor.
- 8 Posthuma, R et al: *Curr Opin Support Palliat Care.* 2023; 17(4): 296–300.

