

Patient Selection Guidance

Zephyr Valve Indications for Use¹

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 Valve Based on Multiple RCTs²

- Diagnosis of emphysema confirmed by CT
- BMI <35 kg/m²
- Stable with ≤20mg prednisone (or equivalent) daily
- RV ≥175% predicted (≥200% if homogeneous)
- FEV₁ 15-45% predicted
- TLC ≥100% predicted
- 6MWD 100-500m (150-500m if homogeneous)
- Not actively smoking (for at least 4 months)
- Target lobe with little to no collateral ventilation

Patient Exclusion Criteria for the Zephyr Valve Based on Multiple RCTs²

- Prior lung transplant, LVRS, median sternotomy or lobectomy
- Congestive heart failure: Left Ventricular Ejection Fraction <45%; unstable cardiac arrhythmia, myocardial infarction or stroke
- Known allergies to Nitinol, Nickel, Titanium or Silicone
- Large bullae >30% of either lung
- Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for the procedure
- Contraindications for bronchoscopy; patient characteristics that may carry a high risk for postoperative morbidity and/or mortality
- Severe hypercapnia (PaCO₂ ≥50 mm Hg on room air) and/or severe hypoxemia (PaO₂ ≤45 mm Hg on room air)
- Uncontrolled pulmonary hypertension (sPAP >45 mm Hg)

1 Zephyr Valve IFU

2 Criner et al. Am J Resp Crit Care Med May 2018 as DOI: <https://doi.org/10.1164/rccm.201803-05900C>, Kemp et al. Am J Resp Crit Care Med 2017; (196)12 1535-1543, Valipour et al. Am J Respir Crit Care Med 2016; Vol 194, Iss. 9 pp 1073-1082 and data on file at Pulmonx, Klooster et al. N Engl J Med. 2015; 373: 2325-2335 + Supplementary Appendix.

Brief Statement: 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, or lobectomy; Congestive heart failure or recent myocardial infarction; FEV₁ <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.

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