

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 RCTs²⁻⁶ and Expert Guidance⁷⁻⁹

- Diagnosis of emphysema confirmed by CT
- BMI <35 kg/m²
- Stable with ≤20mg prednisone (or equivalent) daily
- RV ≥150% predicted (≥200% if homogeneous)
- FEV₁ 15-50% 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

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

Warnings

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

- Prior lung transplant, LVRS, median sternotomy, or lobectomy
- Congestive heart failure or recent myocardial infarction
- FEV₁ <15% of predicted value encompassing greater than 30% of either lung

- 1 Zephyr Valve IFU
 - 2 Criner, GJ et al. Am J Resp Crit Care Med. 2018; 198(9): 1151-1164 as DOI: <https://doi.org/10.1164/rccm.201803-05900C>
 - 3 Kemp, SV et al. Am J Resp Crit Care Med. 2017; 196(12): 1535-43.
 - 4 Valipor, A et al. Am J Resp Crit Care Med. 2017; 196(9): 1073-82.
 - 5 Data on file at Pulmonx.
 - 6 Klooster, K et al. N Engl J Med. 2015; 373(24): 2325-35 + Supplementary Appendix.
 - 7 Klooster, K, & Slebos, DJ. CHEST. 2021; 159(5): 1833-1842.
 - 8 Klooster, K et al. J Bronchology Interv Pulmonol. 2021; 1(28): Letter to Editor.
 - 9 Posthuma, R et al: Curr Opin Support Palliat Care. 2023; 17(4): 296–300.
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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; 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.

Pulmonx Corporation
700 Chesapeake Drive
Redwood City, CA 94063

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