

Clinical Summary

Consistent Outcomes Across 4 RCTs in Patients without Collateral Ventilation

zephyr[®]
valve

RCT	Design	Sample Size & Follow-up Period	Difference EBV vs Control Groups (ITT analysis)		
			LUNG FUNCTION (FEV ₁ %) MCID = 10%-15%	EXERCISE CAPACITY (6MWD) MCID = 26 m	QUALITY OF LIFE (SGRQ) MCID = -4 pts
LIBERATE¹	2:1 Randomization Heterogenous only Multicenter	n=190 12 months	18.0%	39 m	-7.1 pts
TRANSFORM²	2:1 Randomization Heterogenous only Multicenter	n=97 6 months	29.3%	79 m	-6.5 pts
IMPACT³	1:1 Randomization Homogenous only Multicenter	n=93 6 months	16.3%	28 m	-7.5 pts
STELVIO⁴	1:1 Randomization Heterogenous & Homogenous Single Center	n=68 6 months	17.8%	74 m	-14.7 pts*

*Completed Cases

Complications of the Zephyr Endobronchial Valve treatment can include but are not limited to pneumothorax, worsening of COPD symptoms, hemoptysis, pneumonia, dyspnea and, in rare cases, death.

Zephyr[®] valve treatment of severe emphysema is included in global and national guidance documents, such as those sponsored by:

- Global Initiative for Chronic Obstructive Lung Disease (GOLD)
- Australian Lung Foundation (COPD-X)
- German Respiratory Society (DGP)
- The UK's National Institute for Health and Care Excellence (NICE)
- National Health Care Institute of the Netherlands (Zorginstituut Nederland)



>15,000
patients treated globally

Contact us for more information: USCustomerService@pulmonx.com

- 1 Criner, GJ, Sue, R, Wright, S, Dransfield, M, Rivas-Perez, H, Wiese, T & Morrissey, B. A multicenter randomized controlled trial of Zephyr® endobronchial valve treatment in heterogeneous emphysema (LIBERATE). Am J Respir Crit Care Med, 2018; 198(9), 1151-1164.
- 2 Kemp, SV, Slebos, DJ, Kirk, A, Kornaszewska, M, Carron, K, Ek, L & Briault, A. A multicenter randomized controlled trial of Zephyr® endobronchial valve treatment in heterogeneous emphysema (TRANSFORM). Am J Respir Crit Care Med, 2017; 196(12), 1535-1543.
- 3 Valipour, A, Slebos, DJ, Herth, F, Darwiche, K, Wagner, M, Ficker, JH, & Eberhardt, R. Endobronchial valve therapy in patients with homogeneous emphysema. Results from the IMPACT study. Am J Respir Crit Care Med, 2016; 194(9), 1073-1082 and data on file at Pulmonx.
- 4 Klooster, K, ten Hacken, NH, Hartman, JE, Kerstjens, HA, van Rikxoort, EM, & Slebos, DJ. Endobronchial valves for emphysema without interlobar collateral ventilation. N Engl J Med, 2015; 373(24), 2325-2335.

United States

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; 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. 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.

International

Brief Statement: The Zephyr® Endobronchial Valve is an implantable bronchial valve intended to control airflow in order to improve lung functions in patients with hyperinflation associated with severe emphysema and/or to reduce air leaks. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; 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. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.



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