Clinical Summary

Consistent Outcomes Across 4 RCTs in Patients without Collateral Ventilation

zephyr®
by pulmonx

RCT	Design	Sample Size & Follow-up Period	Difference Between Zephyr® Valve vs Control Group (ITT analysis)		
			LUNG FUNCTION (FEV_1%) MCID=10%–15%	EXCERCISE CAPACITY (6MWD) MCID=26 m	QUALITY OF LIFE (SGRQ) MCID=-4 pts
LIBERATE[1]	2:1 Randomization Heterogenous Multicenter	n=190 12 months	**18.0%** p<0.001	**39 m** p=0.002	**-7.1 pts** p=0.004
TRANSFORM[2]	2:1 Randomization Heterogenous Multicenter	n=97 6 months	29.3% p<0.001	79 m p<0.001	-6.5 pts p=0.031
IMPACT[3]	1:1 Randomization Homogenous Multicenter	n=93 6 months*	16.3% p<0.001	28 m p=0.016	-7.5 pts p<0.001
STELVIO[4]	1:1 Randomization Heterogenous & Homogenous Single Center	n=68 6 months	17.8% p=0.001	74 m p<0.001	-14.7 pts** p<0.001

*Data on file at PMX (not in publication) **Completed cases, all other values listed are ITT population

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.

Endobronchial Valves, such as Zephyr Valves, are included in global and national guidelines for the treatment of severe COPD/emphysema, such as those sponsored by:

>40,000
patients treated globally

GOLD Report
EVIDENCE A
Since 2020

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

For more information visit Pulmonx.com

1. Criner, G et al. Am J Resp Crit Care Med. 2018 Nov 1;198(9):1151–1164
2. Kemp, SV et al. Am J Respir Crit Care Med. 2017 Dec 15;196(12):1535–1543
3. Valipour, A et al. Am J Respir Crit Care Med. 2016 Nov 1;194(9):1073–1082 and data on file at Pulmonx
4. Klooster, K et al. N Engl J Med. 2015 Dec 10;373(24):2325–2335

United States 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, or lobectomy; 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.

International Important Safety Information: 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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