

# Clinical Summary

Consistent Outcomes Across 4 RCTs in Patients without Collateral Ventilation

**zephyr**<sup>®</sup>  
valve

RCT	Design	Sample Size & Follow-up Period	Procedural Success (TLVR%)	Difference Zephyr <sup>®</sup> Valve vs Control Group (ITT analysis)		
				LUNG FUNCTION (FEV <sub>1</sub> %) MCID=10%–15%	EXERCISE CAPACITY (6MWD) MCID=26 m	QUALITY OF LIFE (SGRQ) MCID=-4 pts
<b>LIBERATE</b> <sup>1</sup>	2:1 Randomization <b>Heterogenous only</b> Multicenter	n=190 12 months	<b>84%</b>	<b>18.0%</b> p<0.001	<b>39 m</b> p=0.002	<b>-7.1 pts</b> p=0.004
<b>TRANSFORM</b> <sup>2</sup>	2:1 Randomization <b>Heterogenous only</b> Multicenter	n=97 6 months	<b>90%</b>	<b>29.3%</b> p<0.001	<b>79 m</b> p<0.001	<b>-6.5 pts</b> p=0.031
<b>IMPACT</b> <sup>3</sup>	1:1 Randomization <b>Homogenous only</b> Multicenter	n=93 6 months*	<b>89%</b>	<b>16.3%</b> p<0.001	<b>28 m</b> p=0.016	<b>-7.5 pts</b> p<0.001
<b>STELVIO</b> <sup>4</sup>	1:1 Randomization <b>Heterogenous &amp; Homogenous</b> Single Center	n=68 6 months	<b>88%</b>	<b>17.8%</b> p=0.001	<b>74 m</b> p<0.001	<b>-14.7 pts**</b> 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 emphysema, such as those sponsored by:



**>25,000**  
patients treated globally



- 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)

Contact us for more information: [USCustomerService@pulmonx.com](mailto:USCustomerService@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 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; FEV<sub>1</sub> <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 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.



**Pulmonx Corporation**

700 Chesapeake Drive  
Redwood City, CA 94063

© 2019-Present Pulmonx Corporation or its affiliates. All rights reserved.

All trademarks are property of their respective owners.

GLO-EN-175-v3 September 2021 Clinical Summary