

# Minimally Invasive Treatment for COPD/Emphysema



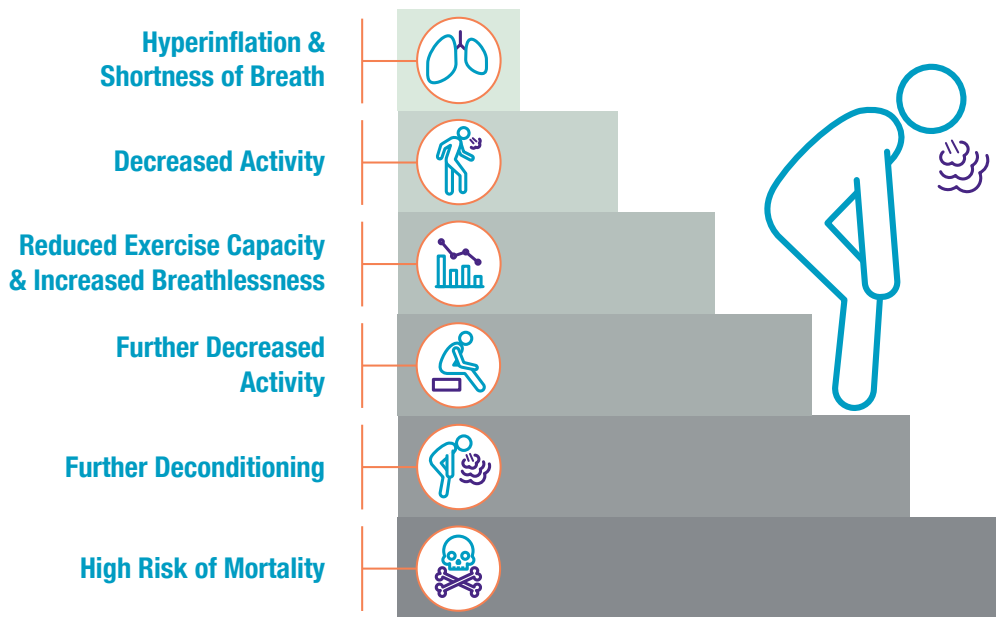
The clinically proven option for your patients who feel breathless despite medical therapy

- Does your patient frequently stop to catch their breath or go slowly while climbing stairs or doing other activities?
- Does your patient have a Forced Expiratory Volume ( $FEV_1$ ) of 50% of predicted or less?
- Has your patient been referred for a pulmonary function test and had abnormally high residual volume or total lung capacity?
- Has your patient been referred for a lung CT scan and had findings of emphysema on the radiology report?



**zephyr**<sup>®</sup>  
valve

# Disease Progression<sup>1</sup>

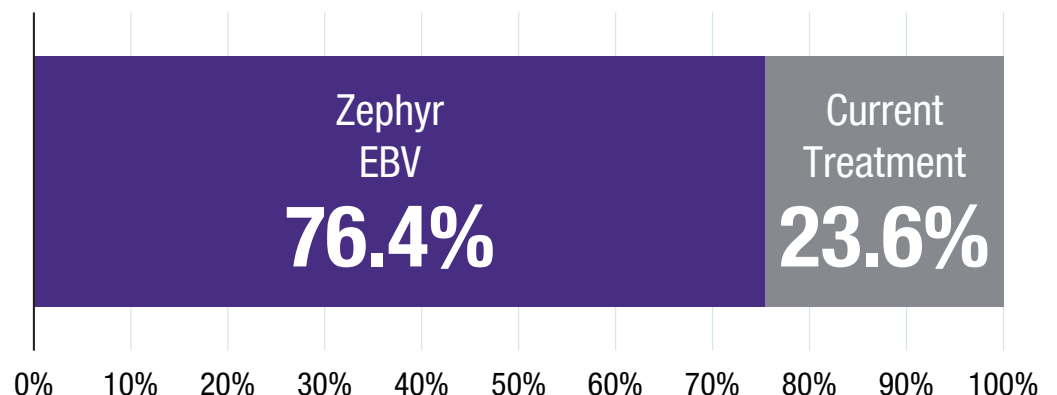


Emphysema is a form of COPD. Emphysema progressively erodes quality of life, and in patients with severe emphysema, the disease can cause patients to struggle to complete routine daily activities.

## Emphysema Patients Prefer Zephyr Valve Over Current Treatment Options

A detailed survey of over 300 severe emphysema patients evaluated how they balance potential risks and benefits. The study concluded that patients with severe emphysema value access to an interventional treatment that offers benefits above and beyond their current medical management, despite the risks associated with these treatments.

More than **3 in 4 patients** would select a treatment with the clinical benefits and risk profile of the Zephyr Valve over current treatment<sup>2</sup>



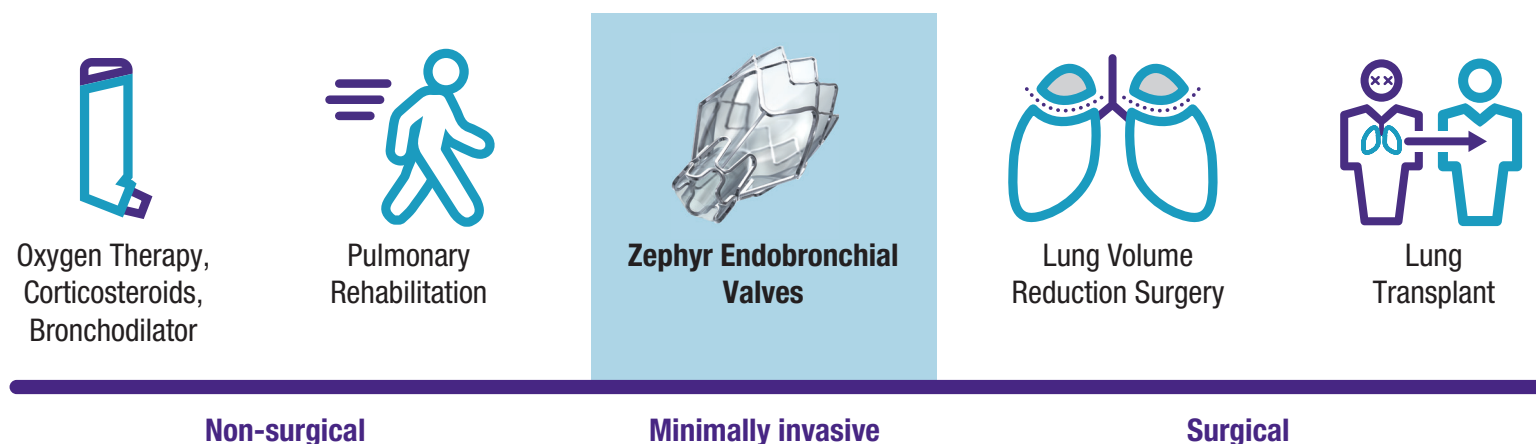
# Proven Treatment Option for Emphysema

In 2018, the FDA granted the Zephyr® Valve an expedited review because it “represents a breakthrough technology as the device offers bronchoscopic lung volume reduction without surgery and its associated risks. This device offers significant clinically meaningful advantage over the current standard of care and therefore its availability is also in the best interest of patients.”

Zephyr Valves have been clinically proven in:

- Heterogeneous and Homogeneous Emphysema
- Upper Lobe and Lower Lobe Predominant Emphysema

## Treatment Spectrum for Severe Emphysema



**>20,000**  
patients treated globally

A proven treatment for severe emphysema. Included in guidance documents worldwide including GOLD and NICE.

## Patients treated with Zephyr Valve reported they were able to:

- Breathe easier due to improved lung function
- Increase their exercise – they could walk farther
- Do more daily life activities, such as walking, bathing, and gardening
- Enjoy a better quality of life with more energy
- Feel more confident leaving their home

# Clinical Evidence

The Zephyr Valve is the most studied endobronchial device and has consistently been shown to be a safe and effective treatment for patients with severe emphysema.

## Consistent Clinical Findings Across Four Randomized Controlled Trials

For patients with little to no collateral ventilation

RCT	Sample size & follow-up period	Difference EBV vs. Control Groups		
		LUNG FUNCTION (FEV <sub>1</sub> %)	EXERCISE CAPACITY (6MWD)	QUALITY OF LIFE (SGRQ)
LIBERATE <sup>3</sup>	n=190 12 months	18.0%	39 m	-7.1 pts
TRANSFORM <sup>4</sup>	n=97 6 months	29.3%	79 m	-6.5 pts
IMPACT <sup>5</sup>	n=93 6 months	16.3%	28 m	-7.5 pts
STELVIO <sup>6</sup>	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.

# Patient Selection

## Key Patient Selection Criteria:

- Confirmed diagnosis of COPD
- Non-smoking or willing to quit smoking
- $FEV_1 \leq 50\%$  predicted
- Breathless despite optimal medical management ( $mMRC \geq 2$ )

## Once referred an interventional pulmonologist will confirm:

- Diagnosis of severe emphysema
- Presence of hyperinflation ( $RV \geq 175\%$  predicted)
- Confirmation the target lobe has little to no collateral ventilation

## Making a Referral

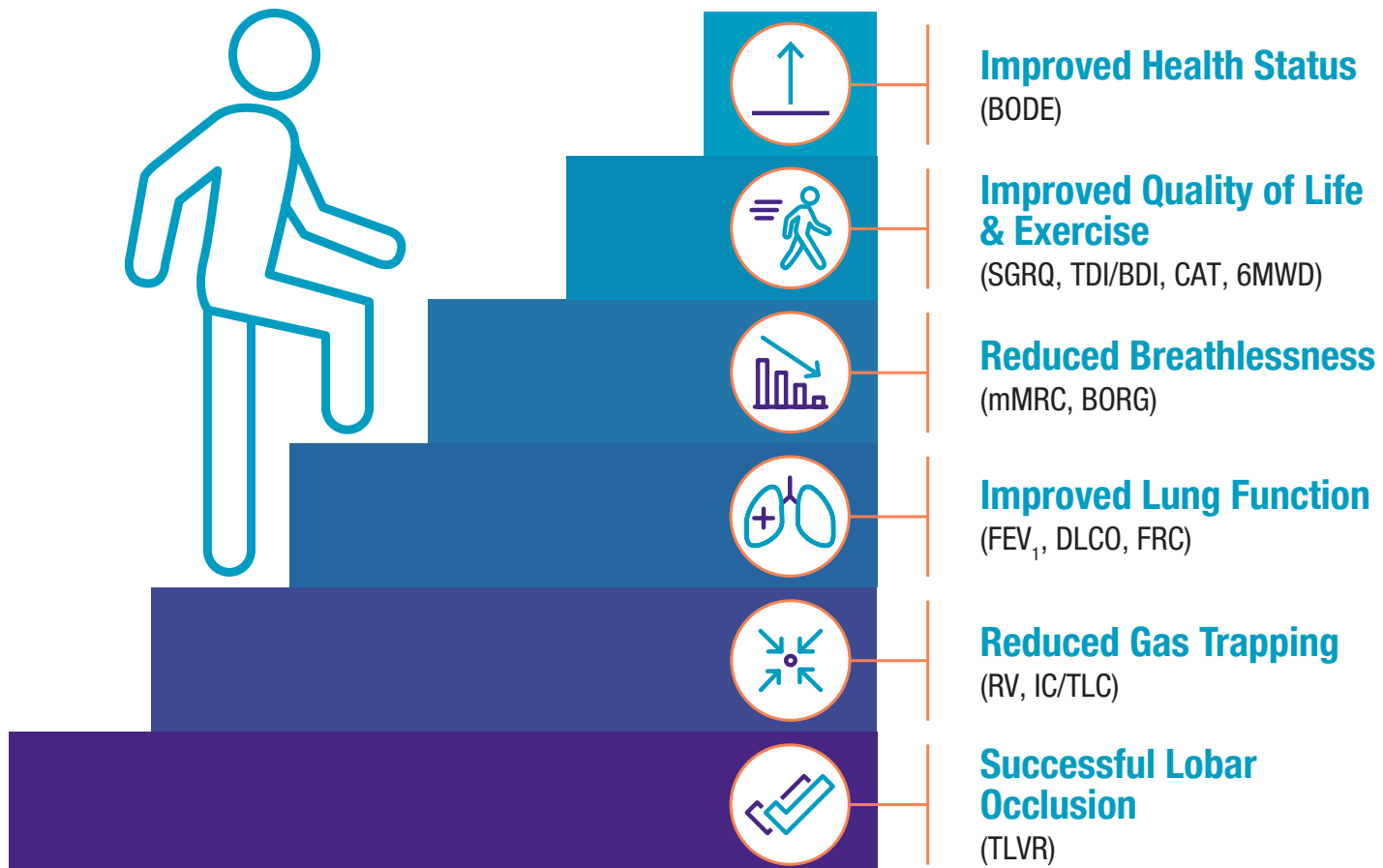
You're in the best position to identify patients who might benefit from Zephyr Valve treatment.

- Patients who are not responding to optimal medical management
- Patients who prefer additional treatment options

## More Information

For a list of centers offering the Zephyr Valve System, please visit [www.ZephyrCenters.com](http://www.ZephyrCenters.com)

## Help your patients to improved health status<sup>2</sup>



1. Adapted from Global Initiative for Chronic Obstructive Lung Disease (GOLD) - Global Strategy for the Diagnosis, Management & Prevention of COPD.
2. Mansfield, C, Sutphin, J, Shriner, K, Criner, GJ, Celli, BR. Patient preferences for endobronchial valve treatment of severe emphysema. *Chronic Obstr Pulm Dis*, 2019; 6(1), 51.
3. 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.
4. 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.
5. 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.
6. 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; 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.



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