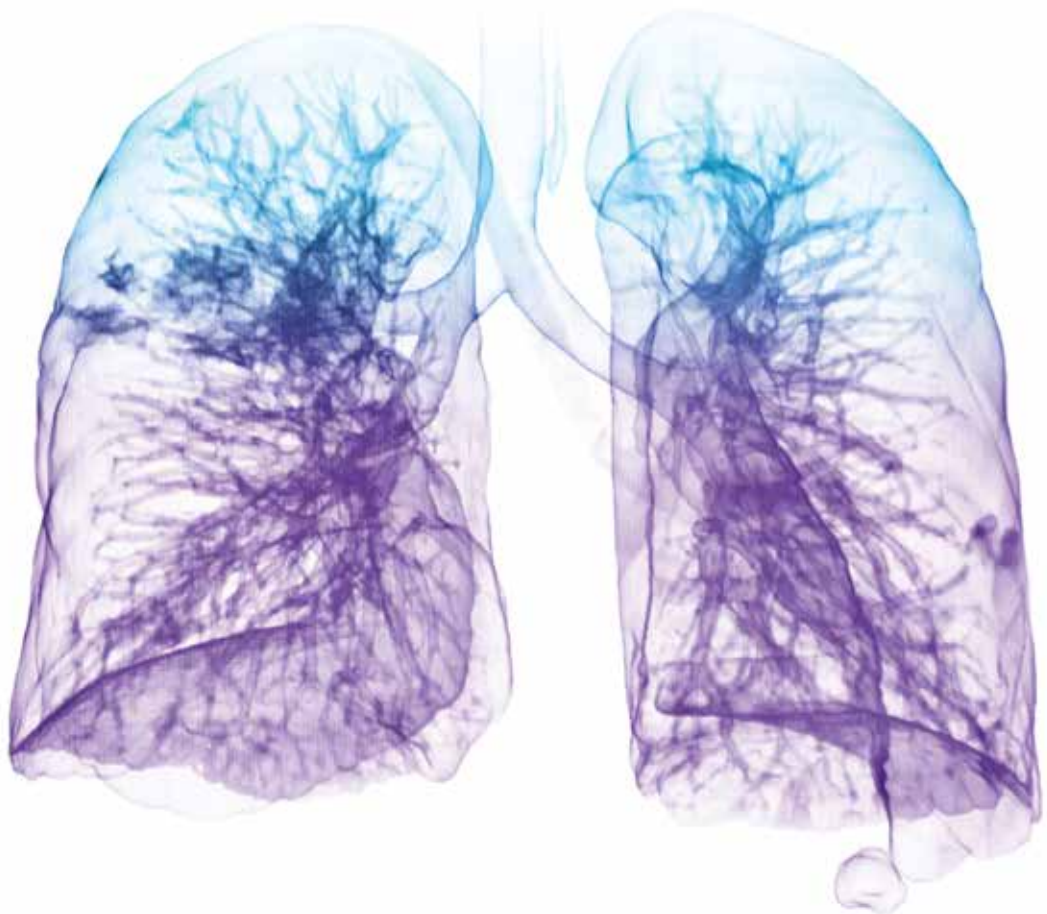
The Zephyr® Endobronchial Valve System

A Standard of Care Treatment Option for Severe COPD/Emphysema Patients

2023
GOLD UPDATE
EVIDENCE A



zephyr®
by pulmonx

Severe Emphysema:
The Clinical Need

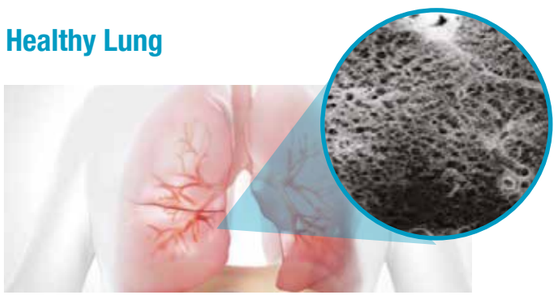
Emphysema, an advanced form of chronic obstructive pulmonary disease (COPD), is a progressive, debilitating disease characterized by irreversible destruction of alveolar tissue. This results in reduced elastic recoil, progressive lung hyperinflation, and gas trapping.

Breathlessness is the predominant and most troublesome symptom experienced by the majority of patients with severe emphysema.[1]

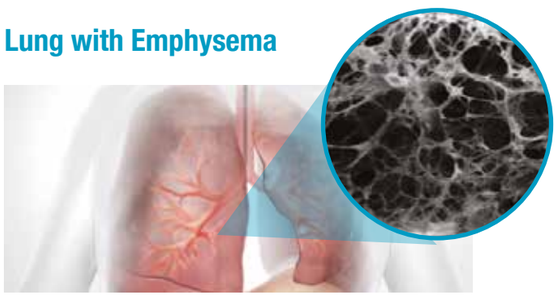
As a result, it becomes increasingly more difficult for patients to perform everyday tasks such as bathing, dressing, walking or climbing stairs.[2]

This can lead to social isolation and depression.[3] Severe emphysema also reduces life expectancy.[4,5] The quality of life for patients with emphysema is reported to be worse than those with lung cancer.[6]

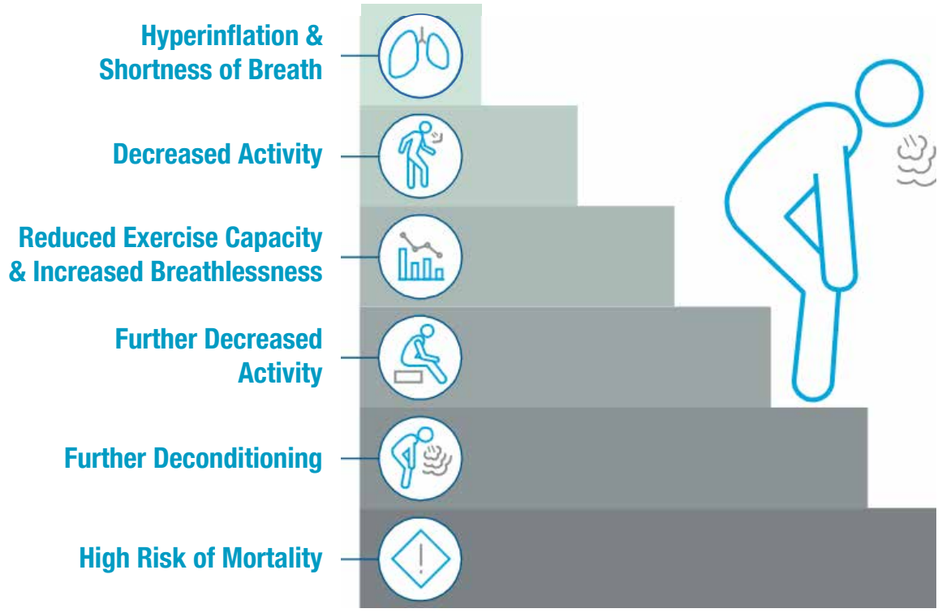
Healthy Lung



Lung with Emphysema



Disease Progression



Adapted from Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD)[7]

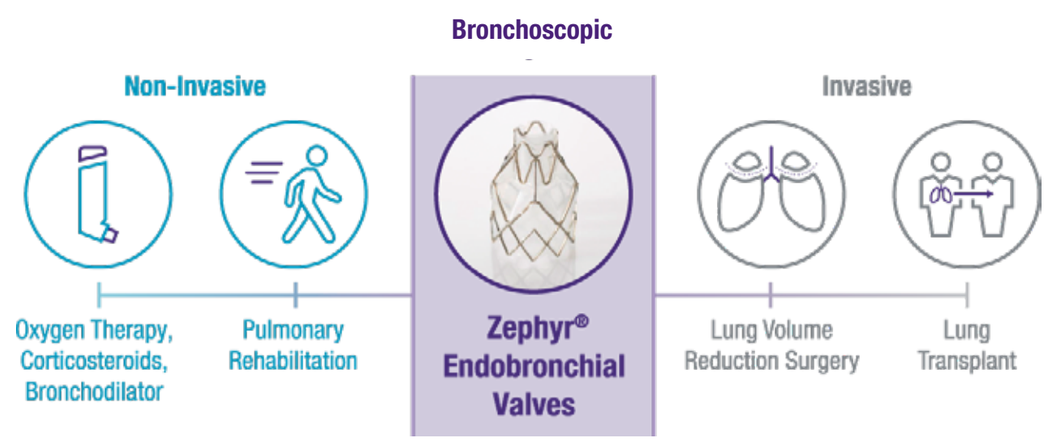
Current Treatment Options:
The Zephyr® Valve is a Breakthrough Medical Device for Severe COPD/Emphysema

Severe emphysema is currently treated with drugs (inhaled bronchodilators and inhaled corticosteroids), smoking cessation, pulmonary rehabilitation, oxygen therapy, lung volume reduction surgery (LVRS), or lung transplantation.[7]

None of these medical therapies reverse or remove the hyperinflation caused by the alveolar destruction and thus have limited impact on patient symptoms of dyspnea and exercise intolerance.[8] Consequently, patients with severe emphysema remain significantly disabled.

Once medical therapy has achieved maximal benefit, the only remaining current treatment options are procedural, including lung volume reduction surgery and lung transplantation. These options are known to have high-risk complications.[9,10]

As the disease progresses, treatments can become more invasive.



Proven to Help Severe COPD/Emphysema Patients Breathe Easier, Do More, and Enjoy Life[11]

The Zephyr Valve treatment is an alternative, breakthrough technique to achieve lung volume reduction using a bronchoscopic approach. The Zephyr Endobronchial Valve is registered with a CE Mark and is designated by the FDA as a “breakthrough medical device”[12], indicated for bronchoscopic treatment of patients with hyperinflation associated with severe COPD/emphysema in regions of the lung that have little to no collateral ventilation (CV).

The Zephyr® Valve System

The Zephyr Endobronchial Valve is an implantable device intended to occlude all airways feeding the hyperinflated lobe of the lung that is diseased with emphysema. When the lobe is occluded properly and isolated from airflow, trapped air in that lobe escapes only through the Zephyr Valves until the lobe volume is reduced. The remaining lobes are then able to expand more fully and work more efficiently, improving overall lung function.

Patients who have received the Zephyr Valve treatment experienced an increased exercise capacity — they could walk farther, could do more daily life activities, such as walking, gardening, and getting ready in the morning, with less shortness of breath — increased lung function, and a better quality of life.[11]

The Zephyr Valve System

1. **The Zephyr Valve:** available in 4 sizes, the 4.0 EBV, 4.0-LP EBV, 5.5 EBV and 5.5-LP EBV. The low profile (LP) sizes are for deployment in shorter airways.
2. **The Endobronchial Delivery System (EDC):** available in corresponding sizes, 4.0 and 5.5. The 4.0 EDC is also available in a "J" configuration to access more challenging anatomies.

Zephyr Endobronchial Valve (EBV)

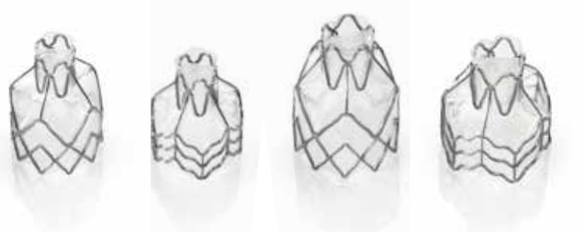
DESCRIPTION	DIAMETER RANGE	CATALOG NUMBER
Zephyr 4.0 Endobronchial Valve	4.0 - 7.0 mm	EBV-TS-4.0
Zephyr 4.0-LP Endobronchial Valve	4.0 - 7.0 mm	EBV-TS-4.0-LP
Zephyr 5.5 Endobronchial Valve	5.5 - 8.5 mm	EBV-TS-5.5
Zephyr 5.5-LP Endobronchial Valve	5.5 - 8.5 mm	EBV-TS-5.5-LP

Zephyr Delivery Catheter

DESCRIPTION	CATALOG NUMBER
Zephyr 4.0 Delivery Catheter	EDC-TS-4.0
Zephyr 4.0-J Delivery Catheter	EDC-TS-4.0-J
Zephyr 5.5-DM Delivery Catheter	EDC-TS-5.5-DM

* Not all product models available in all geographies

Available in 4 Sizes*:



Zephyr 4.0 EBV | Zephyr 4.0-LP EBV | Zephyr 5.5 EBV | Zephyr 5.5-LP EBV

Zephyr® Valve Body of 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.

Patients treated with Zephyr Valves have shown significant clinical and statistical improvements in lung function, exercise capacity, and quality of life compared to medical management alone.

Zephyr Valves have been clinically proven in:

- Heterogeneous and homogeneous emphysema
- Upper lobe and lower lobe predominant emphysema

With proper patient selection, the magnitude of clinical improvement with the Zephyr Valve treatment is comparable to lung volume reduction surgery — with less morbidity.[9,10,13]

Consistent Clinical Findings Across 4 Randomized Controlled Trials

RCT	Design	Sample size & follow-up period	Difference EBV vs Control Groups (ITT)		
			LUNG FUNCTION (FEV_1%) MCID = 10%-15%	EXCERCISE CAPACITY (6MWD) MCID = 26 m	QUALITY OF LIFE (SGRQ) MCID = -4 PTS
LIBERATE[11]	2:1 Randomization **Heterogenous only** Multicenter	n=190 12 months	**18.0%** p<0.001	**39 m** p=0.002	**-7.1 pts** p=0.004
TRANSFORM[14]	2:1 Randomization **Heterogenous only** Multicenter	n=97 6 months	29.3% p<0.001	79 m p<0.001	-6.5 pts p=0.031
IMPACT[15]	1:1 Randomization **Homogenous only** Multicenter	n=93 6 months	16.3% p<0.001	28 m p=0.016	-7.5 pts p<0.001
STELVIO[16]	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

* Completed cases, all other values listed are ITT population

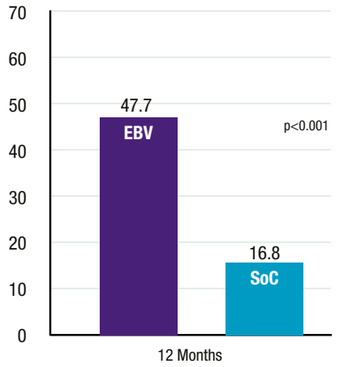
Complications of endobronchial valve treatment can include, but are not limited to, pneumothorax, worsening of COPD symptoms, pneumonia, dyspnea, and, in rare cases, death.

The LIBERATE Study

Study Design[11]

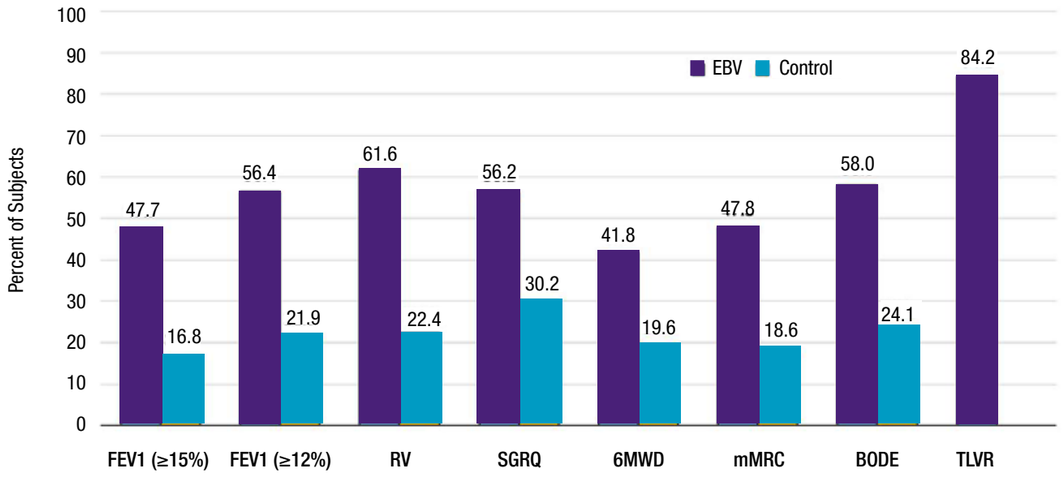
- First multicenter RCT to evaluate effectiveness and safety of Zephyr® Endobronchial Valves in patients with little to no collateral ventilation (CV) out to 12 months
- 190 severe emphysema subjects with hyperinflation (Average RV 225% pred.; FEV_1 27% pred.; DLCO 34% pred.) randomized 2:1 EBV to Standard of Care (SoC)
- Zephyr EBV n=128 : SoC n=62

Primary Endpoint



Percent of Subjects with FEV_1 Change from Baseline to 12 months of ≥15%

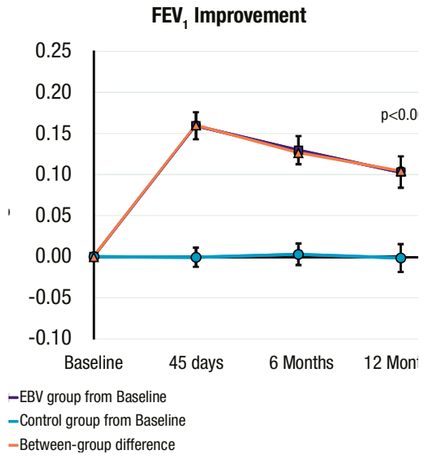
Responders at 12-Months

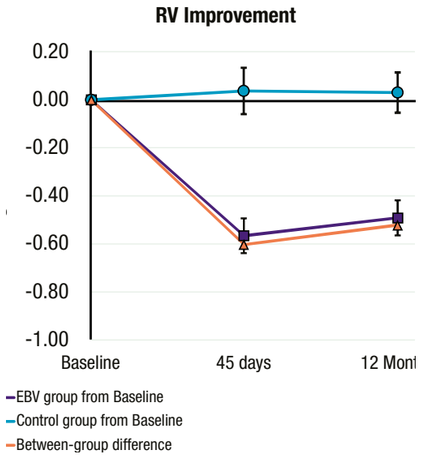


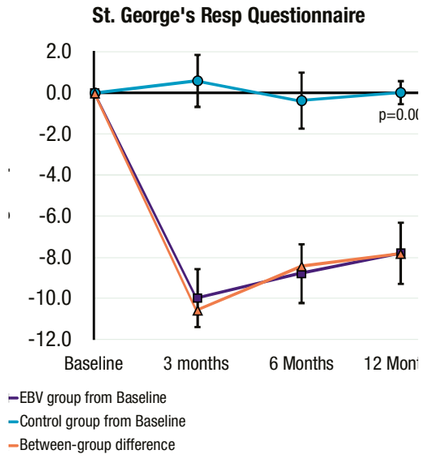
FEV_1: ≥15% and ≥12% Improvement
SGRQ Score: ≥ -4 points Improvement
mMRC: ≥ -1 points Improvement
BODE Index: ≥ -1 point Improvement

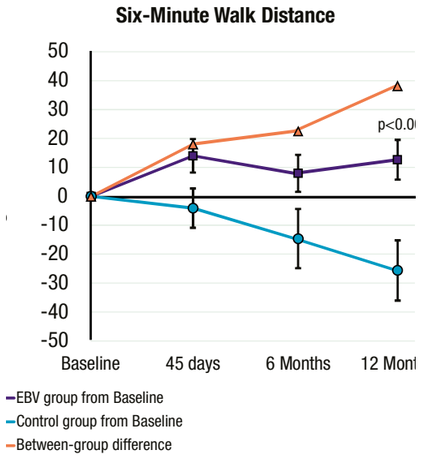
RV: ≥ -310 mL Improvement
6MWD: ≥25 meter Improvement
TLVR: ≥ -350 mL Improvement

Key Secondary Endpoints









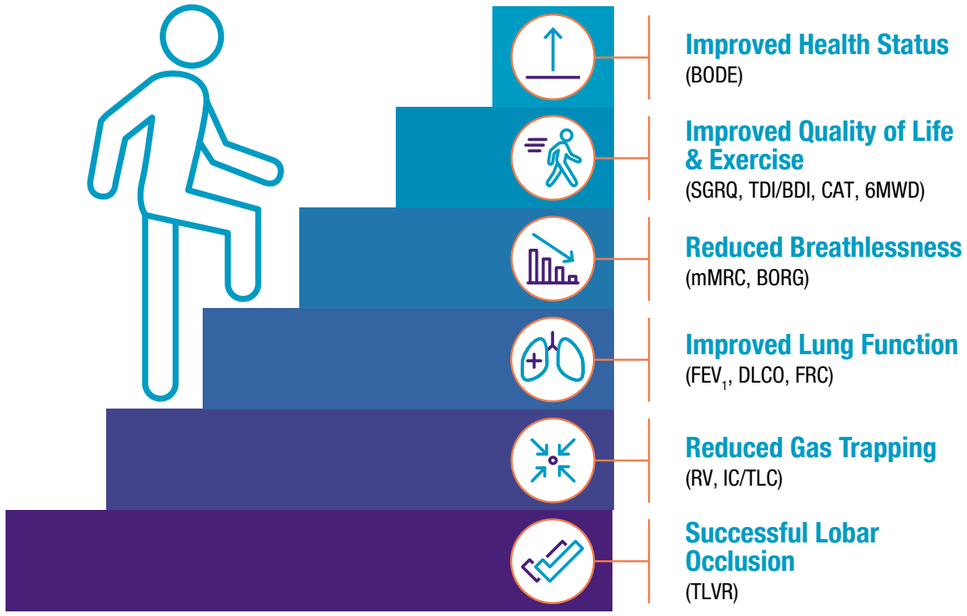
Safety: Pulmonary Serious Adverse Events Occurring in at Least 3.0% of Subjects in Either Group

	Treatment Period (0 - 45 days)		Longer-term Period (46 Days - 1 year)	
	EBV (N=128)	SoC (N=62)	EBV (N=122)	SoC (N=62)
Death	3.1%	0.0%	0.8%	1.6%
Pneumothorax	26.6%*	0.0%	6.6%	0.0%
COPD exacerbation	7.8%	4.8%	23.0%	30.6%
Pneumonia	0.8%	0.0%	5.7%	8.1%
Respiratory failure	1.6%	0.0%	0.8%	3.2%

*Statistically different from SoC

- Increased SAE rate with EBV treatment compared to standard of care in the short-term (first 45 days post-treatment)
- Reduced SAE rate long-term (46 days to 12 months) with EBV treatment compared to standard of care
- 5 of 8 subjects experiencing a pneumothorax in the longer-term period had recently undergone a secondary bronchoscopy for valve replacement and/or removal

Zephyr® Valve Treatment Leads to Improved Health Status



Criner, CJ et. al. Am J Respir Crit Care Med, 2018; 198(9), 1151-1164 and data on file at Pulmonx.[11]

The median survival time for BLVR treated patients is significantly longer than non-BLVR treated ones.

Single-center, non-randomized, retrospective analysis[18] of 1471 patients split in 2 arms: 483 patients who underwent a BLVR procedure (coils or endobronchial valves) - **BLVR Group** and 988 patients who have not had BLVR - **Non-BLVR Group.** The groups were followed over a 13-year period at University Medical Center Groningen, Groningen, Netherlands.

Results

- Median survival of the Zephyr Valve-treated group was 1.7 years longer than the non-treated group ($p<0.003$)
- Patients in the Zephyr Valve-treated group were 37% less likely to die over the course of the study than non-treated patients

Conclusion

Bronchoscopic lung volume reduction treatment that reduces lung volume in patients with COPD and severe hyperinflation and severely reduced life expectancy may lead to a survival benefit.

Patient Selection

Appropriate patient selection is critical to the success of Zephyr® Valve treatment. Over time, clinical trial data have helped define the successful patient profile.

Zephyr Valve treatment is for patients with pulmonary emphysema with a diagnosis of hyperinflation determined by CT scan, severe or very severe emphysema (FEV_1 15-45% predicted) who are symptomatic despite optimal medical management. In addition, candidates should have residual volume indicating hyperinflation (RV ≥ 175% predicted). Zephyr Valves can be used to treat patients with heterogenous or homogeneous emphysema and can be used in upper lobe or lower lobe predominant disease.

Suggested Patient Selection

Inclusion Criteria

ASSESSMENT	INCLUSION CRITERIA
Medical history and physical examination	• Consistent with emphysema • BMI <35 kg/m² • Stable with ≤20 mg prednisone (or equivalent) qd
Radiographic	• Evidence of emphysema on High Resolution Computed Tomography (HRCT) scan
Pulmonary function	• Forced expiratory volume in one second (FEV_1, % predicted) ≤45% predicted ≥15% • Total lung capacity (TLC) ≥100% predicted post-bronchodilator • Residual volume (RV) ≥175% predicted post-bronchodilator
Exercise	• 6-Minute Walk Distance ≥100 m and <500 m
Smoking	• Nonsmoking for 4 months prior to initial interview and throughout evaluation for the procedure
Collateral ventilation	• The lobe targeted for treatment must have little to no collateral ventilation (as measured by StratX® Lung Analysis Platform and Chartis® Pulmonary Assessment System)

Exclusion Criteria

- Prior lung transplant, LVRS, median sternotomy or lobectomy
- Congestive heart failure: Left Ventricular Ejection Fraction <45%; unstable cardiac arrythmia, myocardial infarction or stroke
- Known allergies to Nitinol, Nickel, Titanium or Silicone
- Large bullae >30% of either lung
- Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for the procedure
- Contraindications for bronchoscopy; patient characteristics that may carry a high risk for postoperative morbidity and/or mortality
- Severe hypercapnia ($PaCO_2$ ≥50 mm Hg on room air) and/or severe hypoxemia (PaO_2 ≤45 mm Hg on room air)
- Uncontrolled pulmonary hypertension (sPAP >45 mm Hg)

Note: Patients in whom the targeted lobe for treatment is not the most diseased (due to factors such as collateral ventilation or other abnormalities), and the contralateral lung has >60% emphysema destruction score (at -910 HU) could be at higher risk for a complex pneumothorax (defined as requiring removal of all valves or resulting in death) if a pneumothorax occurs. In the event the most diseased lobe is not the target lobe, Zephyr Valve treatment should only be performed after careful consideration and appropriate discussion of the risk with the patient. Patient should be observed more carefully post-procedure.

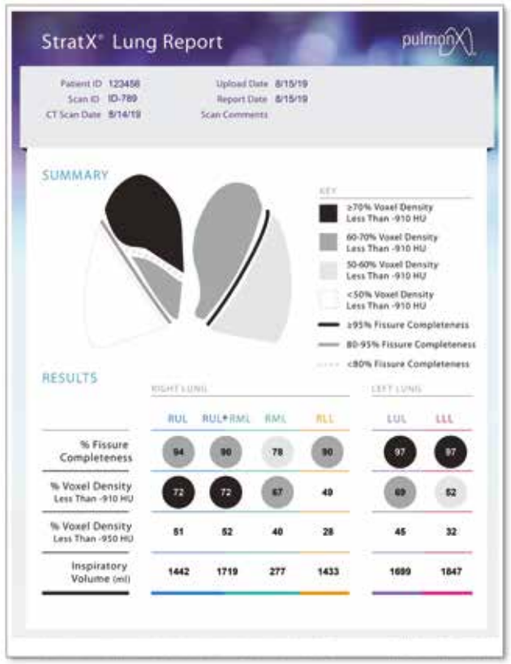
Tools for Optimal Patient Selection

The StratX® Lung Analysis Platform is used in combination with the Chartis® Pulmonary Assessment System to help properly identify patients appropriate for Zephyr® Valve treatment.

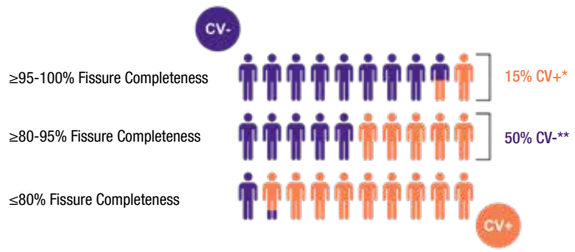
The StratX Lung Analysis Platform is a cloud-based quantitative CT analysis service that provides information on emphysema destruction, fissure completeness, and lobar volume to help identify target lobes for Zephyr® Valve Treatment. Patients with fissure completeness scores >80% are likely to be negative for collateral ventilation (CV-) and may be good candidates for Zephyr Valve treatment.[19] CV status in these patients should be confirmed with the Chartis Pulmonary Assessment System.

The Chartis Pulmonary Assessment System is a proprietary balloon catheter and console with flow and pressure sensors used to assess the presence of collateral ventilation (CV).

When the balloon is inflated, the target lobe is blocked, and air can only escape through the catheter's central lumen. Airflow and pressure are displayed on the Chartis Console allowing for a simulation of an 'occluded lobe' and the measurement of any collateral ventilation in the targeted lobe.



Chartis System identifies collateral ventilation in patients with high fissure completion scores[19]:



*Includes patients with "low plateau" Chartis assessments, typically not achieving TLVR when treated
**Includes patients with "low flow" Chartis assessments in the target lobe, typically resulting in TLVR when treated

Zephyr® Valve Procedure

Patient Selection & Treatment Process

Clinical Work Up

Step 1:
- Physical exam
- Lung function tests
- CT Scan

StratX®* Platform

Step 2:
StratX report to support lobe selection:
- Lobar volume
- Emphysema destruction score
- Fissure completeness

Chartis® System

Step 3:
Chartis System procedure
- Confirm target lobe has no collateral ventilation

Zephyr® Valve

Step 4:
Zephyr Valves placed to completely occlude the target lobe

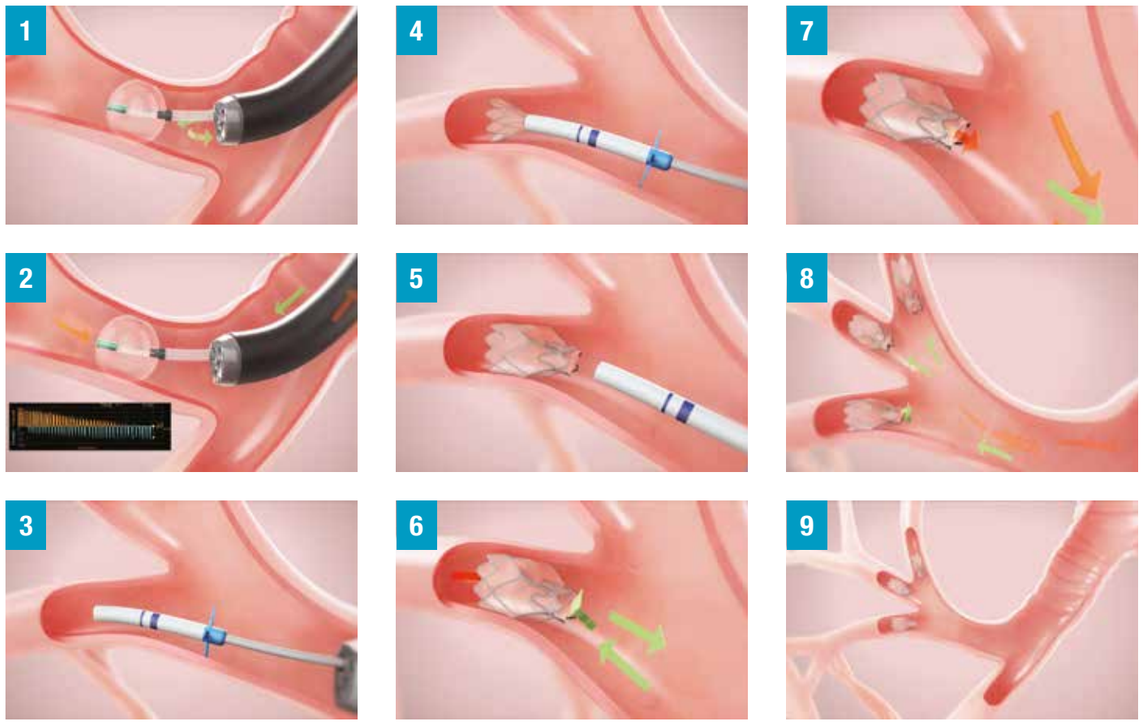
Post-procedure Management

Step 5:
Patient should remain in the hospital for a minimum of 3 nights following the procedure for observation

* StratX Platform not available in all geographies

Zephyr Valves are implanted using a bronchoscope, using either general anesthesia or conscious sedation. The procedure time is typically about one hour. Multiple valves (typically 3 to 5 valves) of varying sizes may be placed in segmental airways to completely occlude the entire lobe with the goal of target lobe volume reduction (TLVR).

The Zephyr Valve can be removed and retracted through the bronchoscope if needed.



Post-Procedure Management

After the procedure, the patient will stay at least 3 nights in the hospital under observation. This is important to monitor if the patient is experiencing any side effects post-procedure. The major significant side effect associated with the Zephyr® Valve procedure in the short-term is pneumothorax. Targeted lobar deflation likely causes inflation of the ipsilateral lobe, which can result in a tear of the already compromised parenchymal tissue of the emphysematous ipsilateral lobe, resulting in a pneumothorax.

In the LIBERATE Clinical Study, subjects experiencing a pneumothorax attained the same level of benefit over the long-term as those without pneumothorax.[11]

Patients should also be monitored for pneumonia, COPD exacerbations, and respiratory failure, as these events have been observed in patients treated with Zephyr Valves.

Patients report high satisfaction with Zephyr Valve treatment

In a survey[20] at one experienced center:

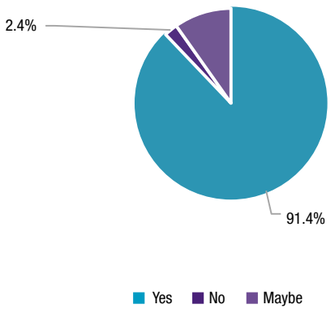
- 91% would recommend Zephyr Valve treatment to other patients
- 75% were satisfied or very satisfied with the Zephyr Valve treatment
- 53% were satisfied or very satisfied with symptom reduction

Patients prefer Zephyr Valves over current treatment

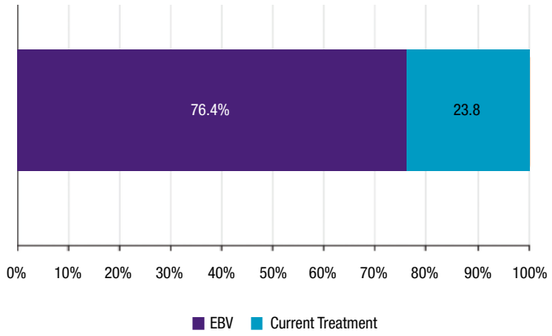
In a survey[21] of 294 US patients with severe emphysema:

- More than 3 in 4 patients would select a treatment with the clinical benefits and risk profile of Zephyr Valves over current treatment

Would You Recommend Zephyr Valves to Other Patients?



Preference Share Predictions for a Choice Between the Zephyr EBV and Current Treatment



Guidance Documents for the Management of Patients with Severe COPD/Emphysema

Patient Benefits

In a clinical study,[11] patients treated with the Zephyr® Valve compared to patients on medication alone were able to:

- **Return to activities** that were previously limited
- Feel **less shortness of breath**
- **Walk longer** distances
- Have **more energy**
- Feel **more confident** leaving their home

Patient Risks

Complications of endobronchial valve treatment can include, but are not limited to, pneumothorax, worsening of COPD symptoms, pneumonia, dyspnea, and, in rare cases, death.

Multiple independent networks have concluded that with proper patient selection, the Zephyr Valve procedure should be considered in the treatment of severe emphysema. These networks include:

- Global Initiative for Chronic Obstructive Lung Disease (GOLD)[7, 22]
- National Institute for Health and Care Excellence (NICE)[20]
- Australian Lung Foundation (COPD-X)
- German Respiratory Society (DGP)
- Austrian Respiratory Society (OGP)
- National Health Care Institute of the Netherlands (Zorginstituut Nederland)
- Milliman Care Guidelines (MCG)

Of particular interest are the GOLD and NICE recommendations.

In the 2017 GOLD Update, endobronchial valve treatment is recommended for select patients who are still symptomatic despite optimal medical management and who have hyperinflation and the absence of collateral ventilation.[7]

In the updated 2020 GOLD Report, endobronchial valve treatment was elevated to “Evidence A” affirming that endobronchial valves, like the Zephyr Valve, are a proven, viable minimally-invasive treatment option for severe emphysema.[22]

The NICE Final Guidance (2017) recommends a change from “special measures” to “standard measures” for the use of endobronchial valve insertion to reduce lung volume in emphysema. In 2018, NICE updated the guidelines to include a review of the LIBERATE study. The current guidance states[23]:

> “Current evidence on the safety and efficacy of endobronchial valve insertion to reduce lung volume in emphysema is adequate in quantity and quality to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.”

Zephyr® Endobronchial Valves

- The Zephyr Valve is CE Mark registered and the the first FDA approved minimally invasive device for the treatment of severe COPD/Emphysema.
- Zephyr Valves are clinically proven to improve dyspnea, increase exercise, improve lung function, and improve multiple measures of quality of life.
- Patients most likely to benefit from Zephyr Valve treatment can be identified with assessment tools also offered by Pulmonx — Chartis® Pulmonary Assessment System and StratX® Lung Analysis Platform.
- Zephyr Valve benefits have been proven in four randomized controlled trials — the most rigorous clinical evidence among endoscopic emphysema treatments.
- The Zephyr Valve is included in emphysema treatment guidance from GOLD, NICE and other leading health organizations worldwide.

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Get more information about the Zephyr® Valve treatment for severe COPD/Emphysema.

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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 with little to no collateral ventilation, 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.

Important Safety Information: The Chartis® System is indicated for use by bronchoscopists during a diagnostic bronchoscopy in adult patients with Chronic Obstructive Pulmonary Disease (COPD) and emphysema in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information. The Chartis System is contraindicated in the presence of active infection or major bleeding diathesis. There are no known interfering substances. Use is restricted to a trained physician. Prior to use, please reference the Chartis System Instructions for Use/ User Manual 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.

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