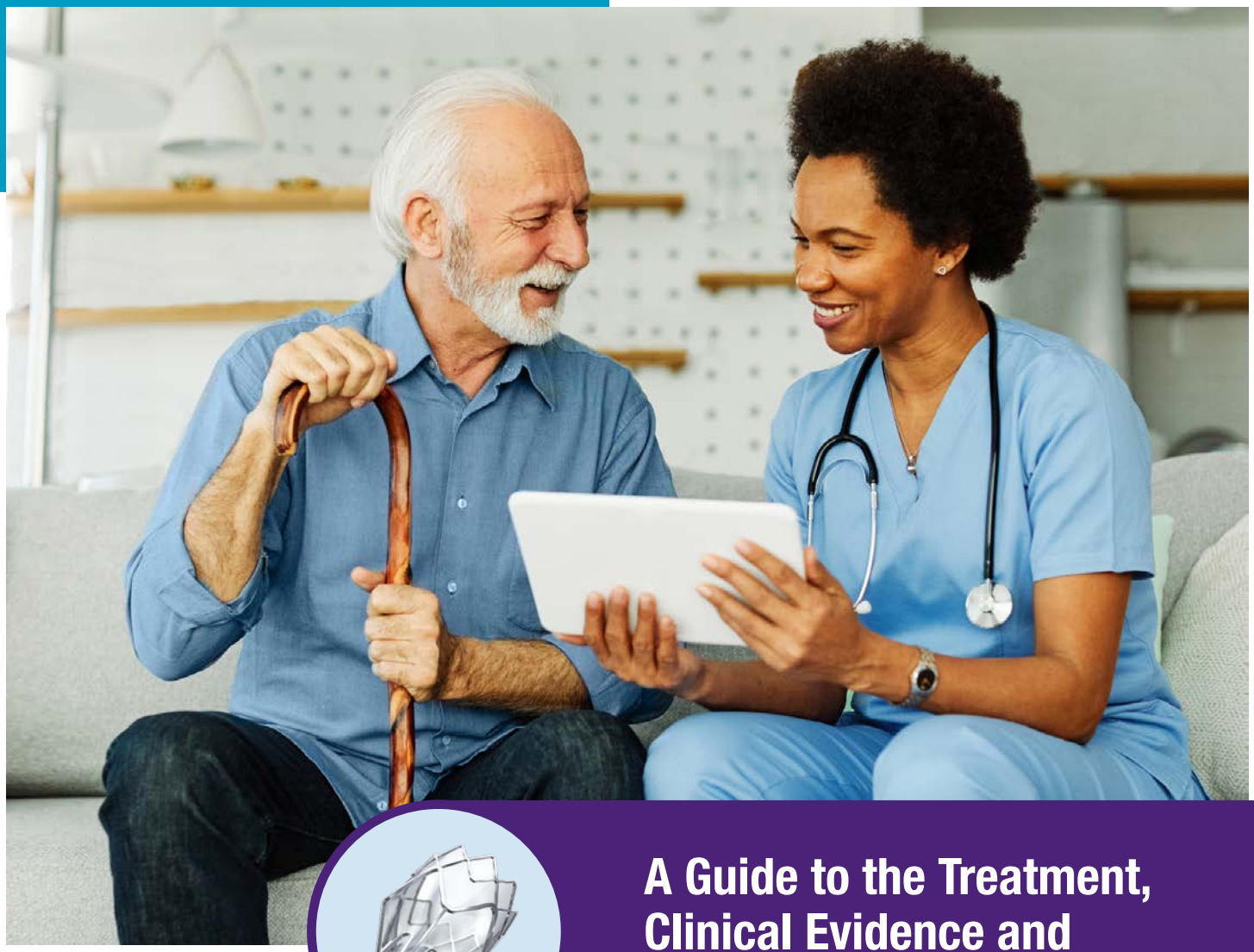
Zephyr® Endobronchial Valve

A Proven Treatment for Breathlessness from Severe COPD/Emphysema



A Guide to the Treatment, Clinical Evidence and Patient Selection

>25,000 patients treated GLOBALLY

GOLD Report EVIDENCE A Since 2020

CLINICALLY PROVEN 4 RCTs

zephyr® by pulmonx

Do You Have Severe COPD/Emphysema Patients Like These?

Meet Our Zephyr® Valve Treated Patients With Severe COPD/Emphysema.

Els, 59-year-old, Netherlands

“ I noticed a lot of differences at home. It was an eye-opener, it was fantastic. ”

Before Zephyr® Valve Treatment:

- She could do less and less – Basic tasks became difficult
- Made her feel tired
- Could no longer do her job at the post office
- Too physically demanding

After Zephyr® Valve Treatment:

- Can now shower and climb stairs without stopping
- Back to doing what she loves — cycling!
- 6 years later, she is still happy with her decision.

Jupp, 59-year-old, Germany

“ Despite my disease, I do not want to give up on anything. My greatest wish since the insertion of the valves was to climb the steps of Cologne cathedral. And I succeeded. My life’s philosophy: Have zest for life – despite and defy shortness of breath! ”

Before Zephyr® Valve Treatment:

- Difficulties when carrying heavy loads and walking up stairs
- Had to retire early
- Lung sports and pulmonary rehab with positive effect but disease progressed
- Was sent for lung volume reduction surgery but as he was eligible for valves, he received them
- Received valves January 2011

After Zephyr® Valve Treatment:

- He is breathing better and stays active
- Does respiratory exercises once a week
- Meets again with friends
- Leads a self-help group organizing large COPD patient days every other year

Results may vary.

Alessi, 70-year-old, Italy

"When I woke up, I was a different person. The results were immediate. I stopped suffering right there and then. This was my new beginning. My rebirth. It could not possibly be better than this."

Before Zephyr® Valve Treatment:

- Difficulty climbing up the stairs without help
- Could no longer travel – this was his greatest passion
- Standing up was uncomfortable because it made him breathless
- A general low mood and constant worrying

After Zephyr® Valve Treatment:

- Has slowly regained control over his activities
- Has regained his spirits
- Has regained his appetite for life
- Is eager to do more, travel more, enjoy more life.
- 7 years later, he still thinks this was a good decision

Patricia, 71-year-old, United Kingdom

"I felt simply smashing after the treatment! I saw a difference straight away. I barely had to use any oxygen any more. I was walking up the stairs, no problem. Showering, dressing, doing housework - all without a care in the world. I wasn't getting breathless. And what's more, I didn't get any more bothersome chest infections."

Before Zephyr® Valve Treatment:

- On oxygen therapy
- Kept getting chest infections
- Breathless when I was pottering around the garden or going shopping

After Zephyr® Valve Treatment:

- Barely uses oxygen
- Reduced chest infections
- No problem showering dressing or doing housework

Results may vary.

Zephyr® Endobronchial Valves: Most Studied. Most Proven. Most used valves for severe COPD/emphysema.[1]

The Zephyr Endobronchial Valve is a clinically-proven bronchoscopic treatment for patients with severe COPD/emphysema who suffer from dyspnea despite optimized medical therapy.

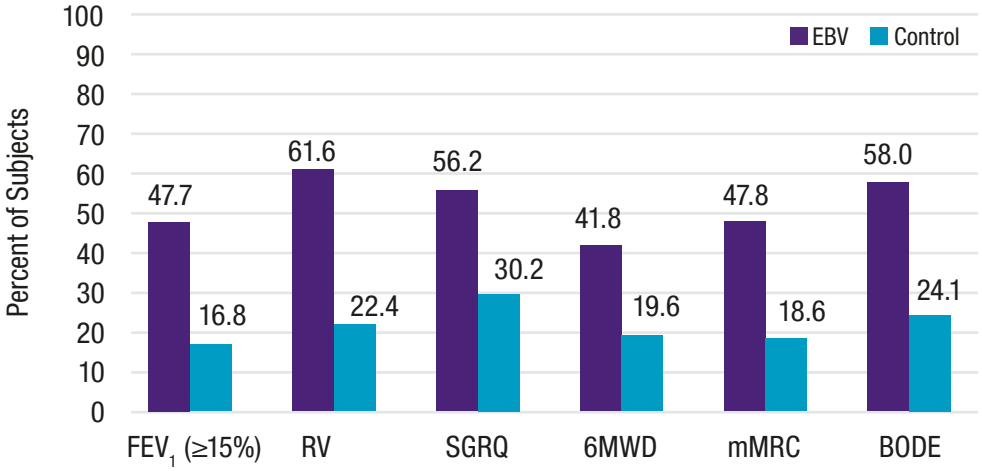
The **2024 GOLD Report** summarized the following patient benefits reported in clinical studies on Endobronchial Valve (EBV) Treatment for severe COPD/emphysema:[2]

- **Improved FEV_1, 6MWD, and health status** at 6 and 12 months*
- **Improved survival** after successful treatment (4 retrospective studies)
- **Decreased exacerbations**
- **Decreased respiratory failure** episodes

*Quality and quantity of data rated "Evidence Level A

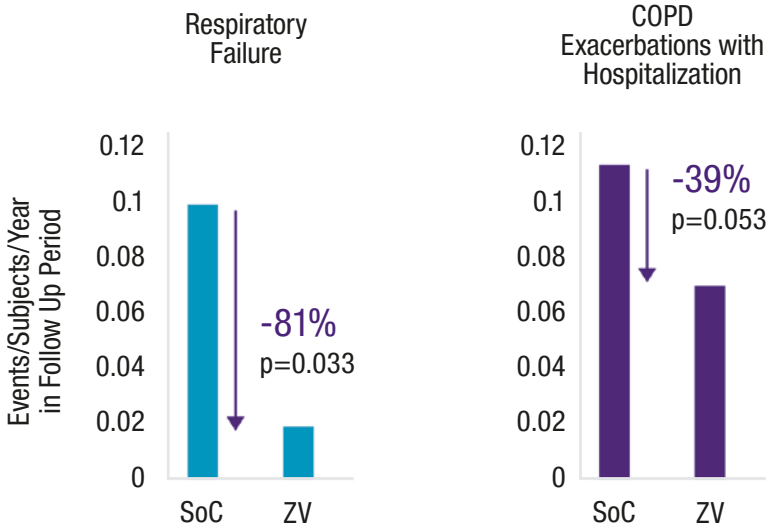
Complications of the Zephyr Endobronchial Valve treatment can include, but are not limited to, pneumothorax, worsening of COPD symptoms, hemoptysis, pneumonia, dyspnea and, in rare cases, death.

Zephyr Valve Responder Rate 12 Months After Treatment[3]
Randomized Controlled Trial Primary & Secondary Endpoints



Responders were those that met the MCID improvement for each endpoint. **FEV_1:** ≥15%, **SGRQ Score:** ≥ -4 points, **6MWD:** ≥25 meter, **mMRC:** ≥ -1 points, **BODE Index:** ≥ -1 point (Glossary at the end of the file)

Indications of Lower Long-Term Respiratory Serious Adverse Events Following Zephyr Valve Treatment[3]



Follow-up period started 46 days post treatment (after procedure recovery) and extended through the end of the 1-year study period.

Medications Alone Cannot Achieve the Same Benefits

Patients treated with the Zephyr® Valve in addition to medications, as compared to patients on medication alone, were able to:[3]

- Return to a more active lifestyle
- Feel less shortness of breath
- Walk longer distances
- Have more energy
- Feel more confident leaving their home

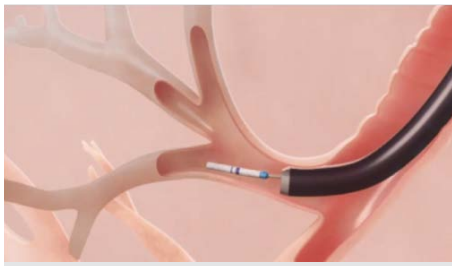
The **2024 GOLD Report** states that **hyperinflation** is clinically relevant in patients with COPD and contributes to dyspnea, impaired exercise capacity, increased hospitalizations, respiratory failure, increased mortality.[2]

Unlike medical treatments that only mildly improve shortness of breath symptoms, Zephyr Valves target the **root cause of breathlessness** – releasing trapped gasses that cause hyperinflation. They can provide a greater benefit than medications alone.[3-6]

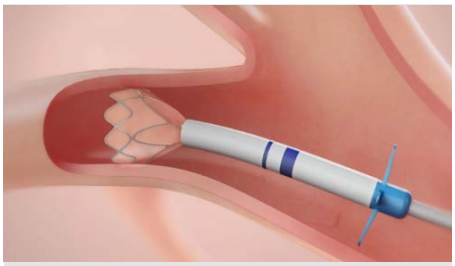
Zephyr Valve Improves Lung Function by Treating Hyperinflation

Zephyr Valves are one-way valves that treat hyperinflation. They are placed into the major airways of a diseased lobe via bronchoscopy, allowing trapped air to escape and preventing new air from entering. The lobe will deflate, allowing the rest of the lung to expand and the diaphragm to rise.[3-6]

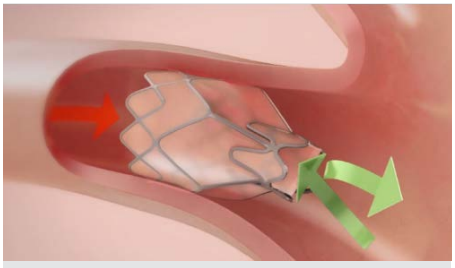
1 Bronchoscope introduced into lungs of patient with diseased, hyperinflated lobe



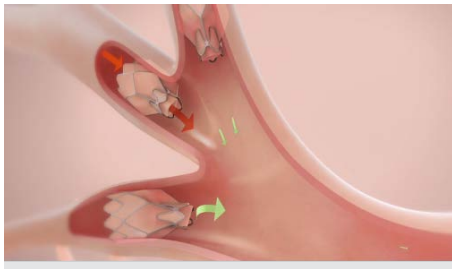
2 Delivery catheter advanced into target lobe through bronchoscope



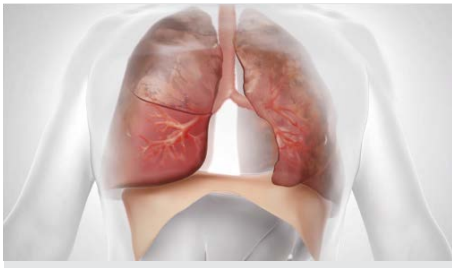
3 Valve size chosen in one step procedure and delivered to seal target airway



4 Zephyr® Valve allows trapped air to escape but not to re-enter



5 Typically 3-5 Zephyr Valves delivered to fully occlude diseased lobe



6 Hyperinflation in target lobe is reduced, improving lung function and breathlessness

Considering Zephyr® Endobronchial Valves for patients with severe COPD/Emphysema

Patients with varying levels of symptom burdens can benefit from Zephyr Valve Treatment. There is no need to restrict this treatment for only patients with the most severe symptoms.

Profiles of Patients

Spectrum of qualifying symptom burden

Profiles of patients that Qualified for Zephyr Valve Treatment

Shortness of Breath	On activity	On activity & at rest	Continuous
Activity Level	Limiting activities	Difficulty with activities of daily living	Inability to perform many activities of daily living
Oxygen Therapy	None	As needed	Continuous
Exacerbation History (Moderate & Severe)	None	Past ED visit(s)	Past hospitalization(s)
Quality of Life Challenges	Difficulty keeping up with family and friends	Breathless even walking short distances; doesn't go to grocery store or run errands anymore	Reliance on help for everyday activities; severe anxiety when showering
After Treatment Goals	Walk the dog, play with grandchildren	Have more confidence leaving the house	Be more independent

Ask Your Patients About How COPD/Emphysema is Affecting Their Quality of Life

Asking these questions at clinic visits may help patients better communicate about how breathlessness is impacting their quality of life.

- What activities could you do last year that are no longer possible?
- How often do you have to stop to catch your breath?
- Do you need help in order to do your regular chores and activities?
- Are you able to leave the house and go places without assistance?

Globally Recognized. Recommended by Medical Societies.

Endobronchial Valve Treatment is a **part of the standard of care** for severe COPD/emphysema.

2024 Report

The **2024 GOLD Report** summarized the following patient benefits reported in clinical studies on Endobronchial Valve (EBV) Treatment:[2]

- Improved FEV_1, 6MWD, and health status at 6 and 12 months*
- Improved survival after successful treatment (4 retrospective studies)
- Decreased exacerbations
- Decreased respiratory failure episodes

*Quality and quantity of data was rated "Evidence Level A."

Endobronchial valves are included in national and global guidance documents published by organizations such as:

- Global Initiative for Chronic Obstructive Lung Disease (GOLD)
- National Institute for Health Care and Excellence (NICE)
- German Respiratory Society (DGP)
- Haute Autorité de Sante (HAS, France)
- Spanish Respiratory Society
- Care Institute of the Netherlands (ZIN)
- Austrian Respiratory Society
- Danish Respiratory Society
- National Institute for Health and Invalidity (NIHDI, Belgium)
- Scottish Health Technologies Group
- National Clinical Effectiveness Guideline for the Management of COPD in Ireland

Zephyr® Valve has Broad Coverage

Reimbursement status varies per country. Please ask your Pulmonx representative how reimbursement is made in your country or contact us at **https://pulmonx.com/contact-us-2/**

Patient Benefits Proven in Four Randomized Controlled Trials

Consistent Outcomes Across 4 Randomized Controlled Trials in Patients Without Collateral Ventilation[3-6]

RCT	Design	Sample size & follow-up period	Difference EBV vs. Control Groups (ITT)		
			LUNG FUNCTION (FEV_1%)	EXERCISE CAPACITY (6MWD)	QUALITY OF LIFE (SGRQ)
LIBERATE[3]	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[4]	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[5]	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[6]	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

Reversible Procedure

While the majority of Zephyr® Valve patients do achieve a positive benefit, if a patient does not favorably respond to treatment, the procedure can be reversed by removing the valves via bronchoscopy.

Potential Risks

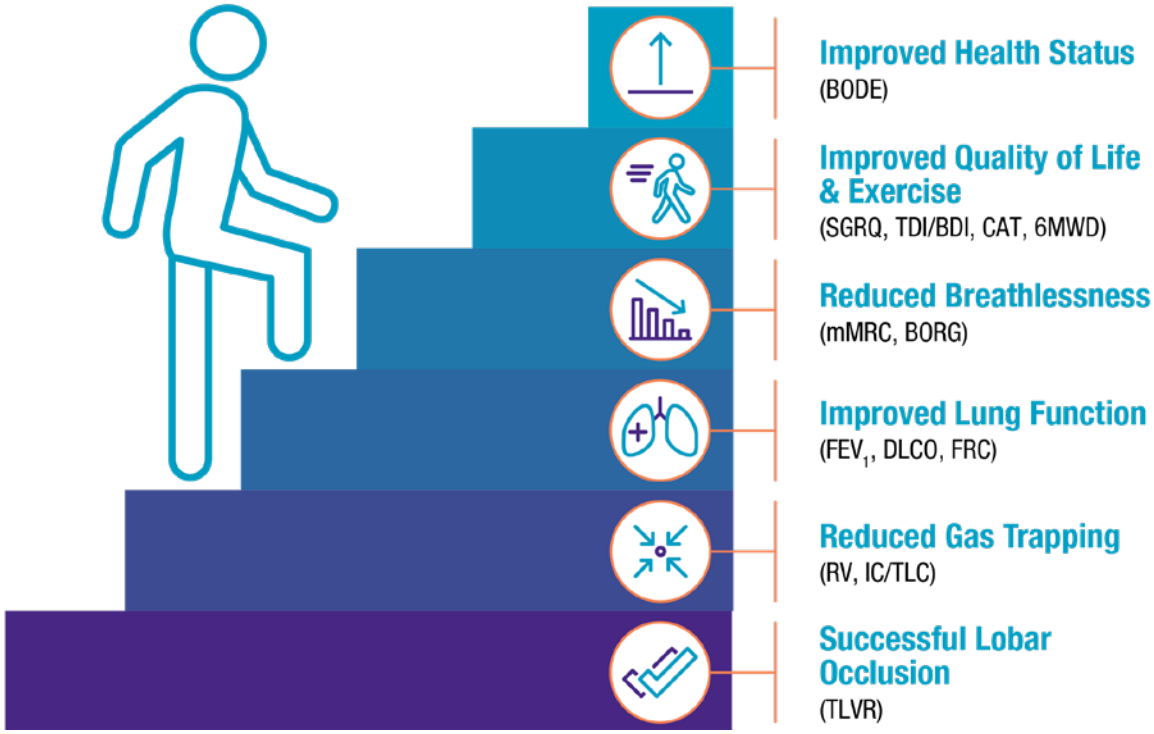
The major significant side effect associated with the Zephyr Valve procedure in the short-term is pneumothorax, which occurs in approximately one-third of patients. Targeted lobar deflation can cause inflation of the ipsilateral lobe, which can result in a tear of the already compromised parenchymal tissue of the emphysematous ipsilateral lobe, resulting in pneumothorax. In the LIBERATE clinical study, subjects experiencing a pneumothorax attained the same level of benefit over the long-term as those without pneumothorax. Patients typically remain in the hospital at least 3 nights after the procedure in order to monitor this or any other potential side effect.

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

Real Benefits that Make a Difference in Patients' Lives

Zephyr® Valve Treatment Leads to Improved Health Status[3]

Patients treated with Zephyr Valves **experienced clinical benefits and improved quality of life** when compared to patients who were on medications alone.[3]



Breathe Easier

Be less short of breath with increased lung function.[3]

Have More Freedom

Do more things on their own like bathing, cooking, and cleaning.[3]

Enjoy Life More

Have more energy and get back to their favorite hobbies and socializing.[3]

Feel More Confident

When leaving home and living life.[3]

Help Your Patients with Severe COPD/Emphysema to Achieve a Better Quality of Life with Zephyr Valves

Potential Impact on Exacerbations

Exacerbations drive the progression of COPD, resulting in lower quality of life and higher mortality. Clinical research suggests that treatment with endobronchial valves reduces the number of moderate and severe exacerbations in patients with severe emphysema.

A single-center retrospective analysis of 129 patients treated with endobronchial valves examined the number of exacerbations before and after Endobronchial Valve Treatment.

The primary endpoint of the study was the number of exacerbations one year after Endobronchial Valve Treatment compared to one year before. Below is a summary of these results[7].

Clinical Outcome 1 Year After Treatment Compared to Baseline

	n	Exacerbation Rate Year Before Treatment	Exacerbation Rate First Year After Treatment	Decrease in Exacerbation Rate (Percent)
All patients who received Endobronchial Valve Treatment	129	2.5 ± 2.2	1.8 ± 2.2	**-32%** p=0.009
Patients who received Endobronchial Valve Treatment and had complete lobal atelectasis	41	2.8 ± 2.0	1.4 ± 1.8	**-50%** p<0.001

Patient Impact: 90% of all patients experienced at least one exacerbation in the year before Endobronchial Valve Treatment compared to 68.2% one year after treatment.

Other Factors: The only factor clearly associated with the number of exacerbations in the year after ELVR, was the number of exacerbations in the year before ELVR ($r = 0.209$, $p = 0.018$) and roflumilast therapy ($r = 0.212$, $p = 0.016$).

***Exacerbations in this study refer to the combination of moderate and severe exacerbations, as defined above.**

**Study inclusion criteria required a complete exacerbation history one year before and one year after Endobronchial Valve Treatment. As a result, only 129 of the 244 patients treated between 2016-2019 were included in the study.

The study authors concluded treatment with Endobronchial Valves "appears promising to reduce the exacerbation rate in COPD patients, especially when the full treatment benefit of complete lobar atelectasis is achieved."

Title: Endobronchial lung volume reduction with valves reduces exacerbations in severe emphysema patients

Author: Brock, J et al.

Publication Date: September 2023

Journal: Respiratory Medicine

Endobronchial Valve Treatment is delivered in a procedure that is commonly called either "Endobronchial Lung Volume Reduction (ELVR)" or "Bronchoscopic Lung Volume Reduction (BLVR)." These procedure names are frequently referenced in clinical studies.

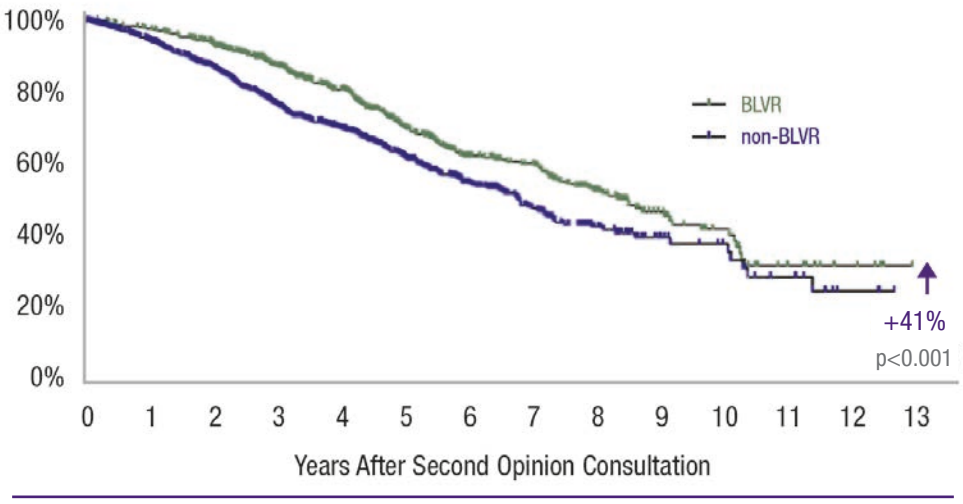
Potential Impact on Survival

In a first-of-its-kind study, researchers examined the survival rate of severe COPD/emphysema patients undergoing Bronchoscopic Lung Volume Reduction (BLVR) vs. patients who were evaluated for BLVR but not treated.

This single-center, non-randomized, retrospective analysis included 1,471 patients. The study found that patients treated with BLVR[8]:

- Had a statically significant survival rate of 1.7 years longer than the non-treated group
- Were 41% less likely to die over the course of the study

Retrospective Analysis of Long-Term Survival Following Bronchoscopic Lung Volume Reduction (BLVR) Treatment



The study authors concluded: **"BLVR treatment was found to be an independent predictor of survival when adjusting for other survival-influencing factors such as age, gender or severity of disease."**

Title: Survival in COPD patients treated with Bronchoscopic Lung-Volume Reduction

Author: Hartman, J et al.

Publication Date: March 2022

Journal: Respiratory Medicine

In the study described above, the BLVR group comprised 483 patients and the non-BLVR group comprised 988 patients.

Of the BLVR group, 73% of patients received BLVR with Zephyr® Valves and 27% received endobronchial coils.

Zephyr® Valve Treatment Screening Protocols

A common way to identify patients who may qualify for Zephyr Valves is to prospectively review the PFT tests for all severe COPD/emphysema patients.

Step 1: Prospective PFT Screening

Patients with the following characteristics could be flagged as meeting the baseline criteria for the Zephyr Valve Treatment:

- **Evidence of Severe Obstruction**
  - $FEV_1 \leq 50\%$ predicted (spirometry)
- **Evidence of Hyperinflation**
  - Body Plethysmography: RV ≥ 175% predicted; RV ≥ 200% for homogeneous patients

    Nitrogen Washout Lung Volumes are not recommended*
  - Imaging: Chest X-ray: Flattened Diaphram
  - HRCT: Evidence of emphysematous tissue

Step 2: Qualifying and Counseling Patients

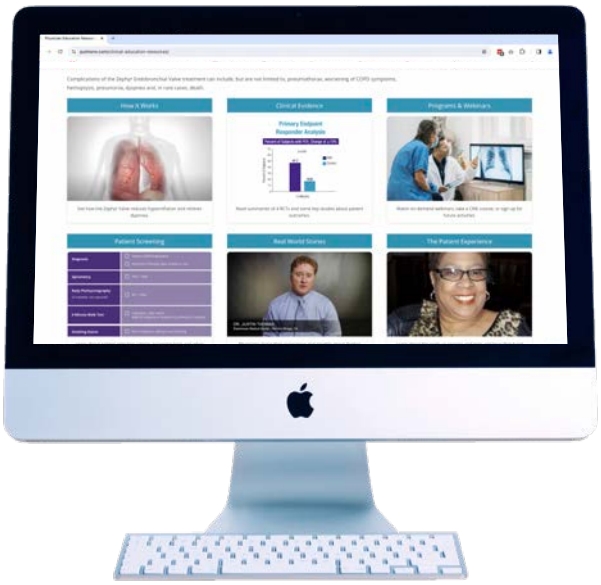
Patients who meets the above criteria should be further examined to determine if they meet the other Zephyr Valve eligibility criteria:

- Confirmed diagnosis of COPD/severe emphysema
- 6MWD = 100-500m or 328-640ft
- Non-smoking or willing to quit smoking

*Gas dilution PFT tests, like Nitrogen Washout or Helium Dilution, have been shown to underestimate TLC & RV because only communicating gas volume is measured in these tests. In the presence of severe airflow obstruction, TLC can be underestimated by a gas dilution method by as much as 3 liters.[9-11]

Zephyr Valve Patient Education & Clinical Resources

Clinical education resources, including videos, real-world stories, programs, and webinars are available at pulmonx.com/clinical-education-resources/



New Recommendation from GOLD: Simultaneously Screen for Both COPD & Lung Cancer

GOLD now recommends that **patients being screened for lung cancer should also simultaneously be screened for COPD**.

Studies show that when patients undergoing lung cancer screening are also evaluated for COPD symptoms and given spirometry: [2,14]

- **57% were found to have COPD**
  - **68-73% have emphysema**
  - **67% have undiagnosed COPD, and 50% of these patients were symptomatic**

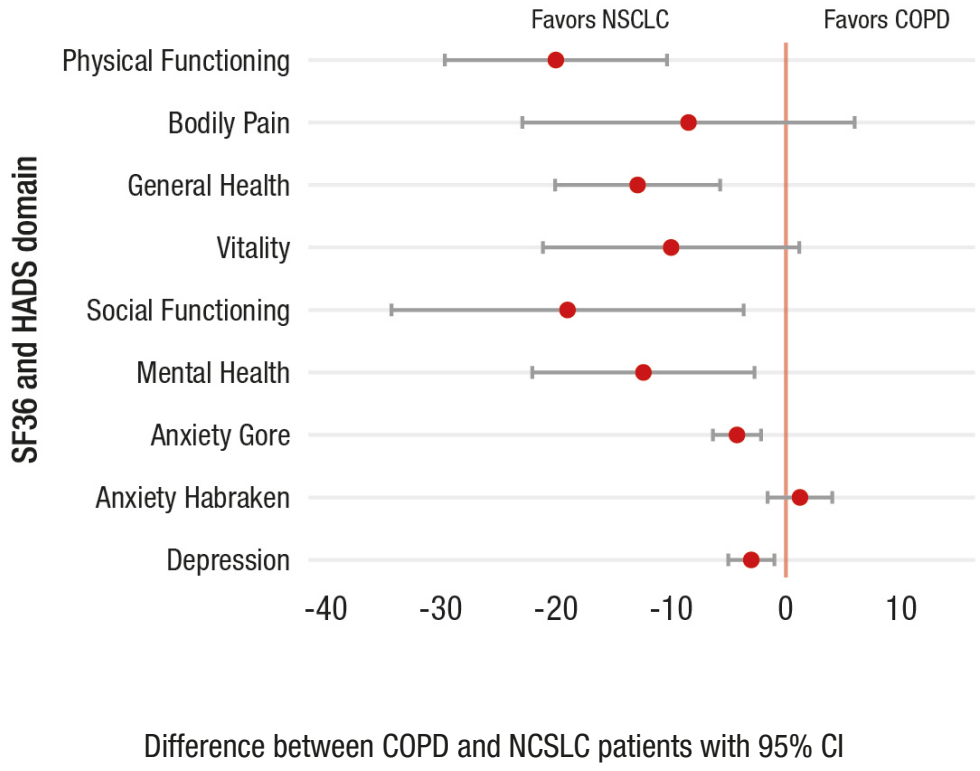
Patients with emphysema and a FEV1 ≤ 50% predicted may qualify for Zephyr® Valves, and could benefit from a full evaluation to see if they meet the other eligibility criteria.

COPD Patient's Quality of Life Worse than End-Stage Lung Cancer[12]

Lung cancer and COPD share common risk factors and a similar patient profile. Both are terrible diseases that worsen quality of life and shorten survival.

A clinical study found that end-stage (GOLD IV) COPD patients have comparable or worse health-related quality of life (HRQOL) scores than end-stage, non-small cell lung cancer patients.

Differences in Health Related Quality of Life Scores. End-Stage COPD vs End-Stage NSCLS Patient Groups. (95% CI)



Patient Eligibility Criteria for Zephyr® Valve Treatment

If shortness of breath is not controlled with medical management, patients may qualify for Zephyr Valve treatment based on the following:

Clinical Presentation

- Severe COPD/emphysema
- Shortness of breath upon activity or rest
- Limited in daily functions
- Dissatisfied with activity level and quality of life

Medical History

- Full medical treatment for COPD
- Periods of stable and/or unstable COPD
- Persistent COPD symptoms
- History of smoking or Alpha-1 antitrypsin (AAT) deficiency
- Usage of supplemental oxygen not required

Diagnosis and Symptoms	☐ Severe COPD/emphysema ☐ Shortness of breath upon activity or rest
Evidence of Obstruction	☐ Spirometry: $FEV_1 \leq 50\%$ predicted, post-bronchodilator
Evidence of Hyperinflation	☐ Hyperinflation confirmed by one of the following: • Body Plethysmography: RV ≥ 175% predicted; RV ≥ 200% for homogeneous patients Nitrogen Washout Lung Volumes are not recommended* • Imaging: Chest X-ray: Flattened Diaphram • HRCT: Evidence of emphysematous tissue
6 Minute Walk Test	☐ 100-500m / 328-1640ft Walk for distance on baseline O_2 without O_2 titration
Smoking Status	☐ Non-smoking or willing to quit smoking

Zephyr Valves have been clinically proven in:

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

Contraindications[13]

The Zephyr Valve is contraindicated

- Patients for whom bronchoscopic procedures are contraindicated
- Patients with evidence of active pulmonary infection
- Patients with known allergies to Nitinol, Nickel, Titanium, or Silicone
- Patients who have not quit smoking
- Patients with large bullae encompassing greater than 30% of either lung

Warnings[13]

The Zephyr Valve should be used with caution and only after careful consideration in patients with:

- Prior lung transplant, LVRS, median sternotomy or lobectomy
- Congestive heart failure (Left Ventricular Ejection Fraction <45%); myocardial infarction
- FEV_1< 15% of predicted value

*Gas dilution PFT tests, like Nitrogen Washout or Helium Dilution, have been shown to underestimate TLC & RV because only communicating gas volume is measured in these tests. In the presence of severe airflow obstruction, TLC can be underestimated by a gas dilution method by as much as 3 liters.[9-11]

Zephyr® Valve Treating Centers

Diagnostic Testing

Once the patient is referred to the Zephyr Valve Treating Center, the clinical team may confirm patient eligibility with additional testing that may include:

- Full pulmonary function testing
- 6-minute walk test
- High resolution CT scan with specialized protocols
- Echocardiogram
- Arterial blood gas
- Perfusion testing

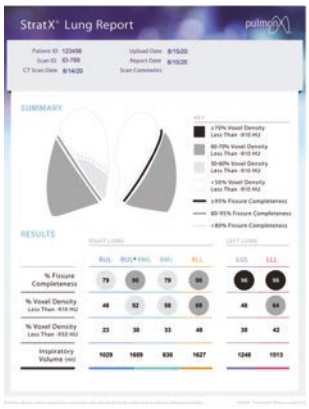
While these tests are typically performed at the hospital-based treating center, it may be possible to perform some of these diagnostics locally. Physicians should confirm protocols by contacting the treating center prior to ordering any tests.

Patients are seen in the post-procedure timeframe by the Zephyr Valve treating physician, but they also may return to their PCP or the physician who sent them for consultation.

To find a Zephyr Valve Treating Center, please visit:

Assess Patient Eligibility and Likelihood of Success

The Zephyr Valve Treating Center will use the following technologies to predict the likelihood that a patient will benefit from Zephyr Valves.



StratX® Lung Analysis Platform:

CT analysis provides information on emphysema destruction, fissure completeness, and lobar volume to help identify target lobes for Zephyr Valve treatment. Patients with fissure completeness scores of >80% are reviewed for collateral ventilation,* to confirm that they may be good candidates for Zephyr Valve treatment.

Chartis® Pulmonary Assessment System:

Immediately prior to the Zephyr Valve procedure, a Chartis System assessment is performed via bronchoscopy to confirm the absence of collateral ventilation.*

*Collateral ventilation happens when the fissure structure between lobes is not solid and air can pass through from one lobe to another. Patients who are positive for collateral ventilation (CV+) will not benefit from Zephyr Valves.

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.

Brief Statement: 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.

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Glossary

SoC = Standard of Care Treatment

ZV = Zephyr Valve Treatment

FEV1 = Forced Expiratory Volume in 1 second

RV = Residual Volume

SGRQ = St George's Respiratory Questionnaire On Quality of Life

6MWD = 6 Minutes Walking Distance

mMRC = Modified Medical Research Council Dyspnoea Scale

BODE = Body-mass index, airflow Obstruction, Dyspnea, and Exercise Index

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