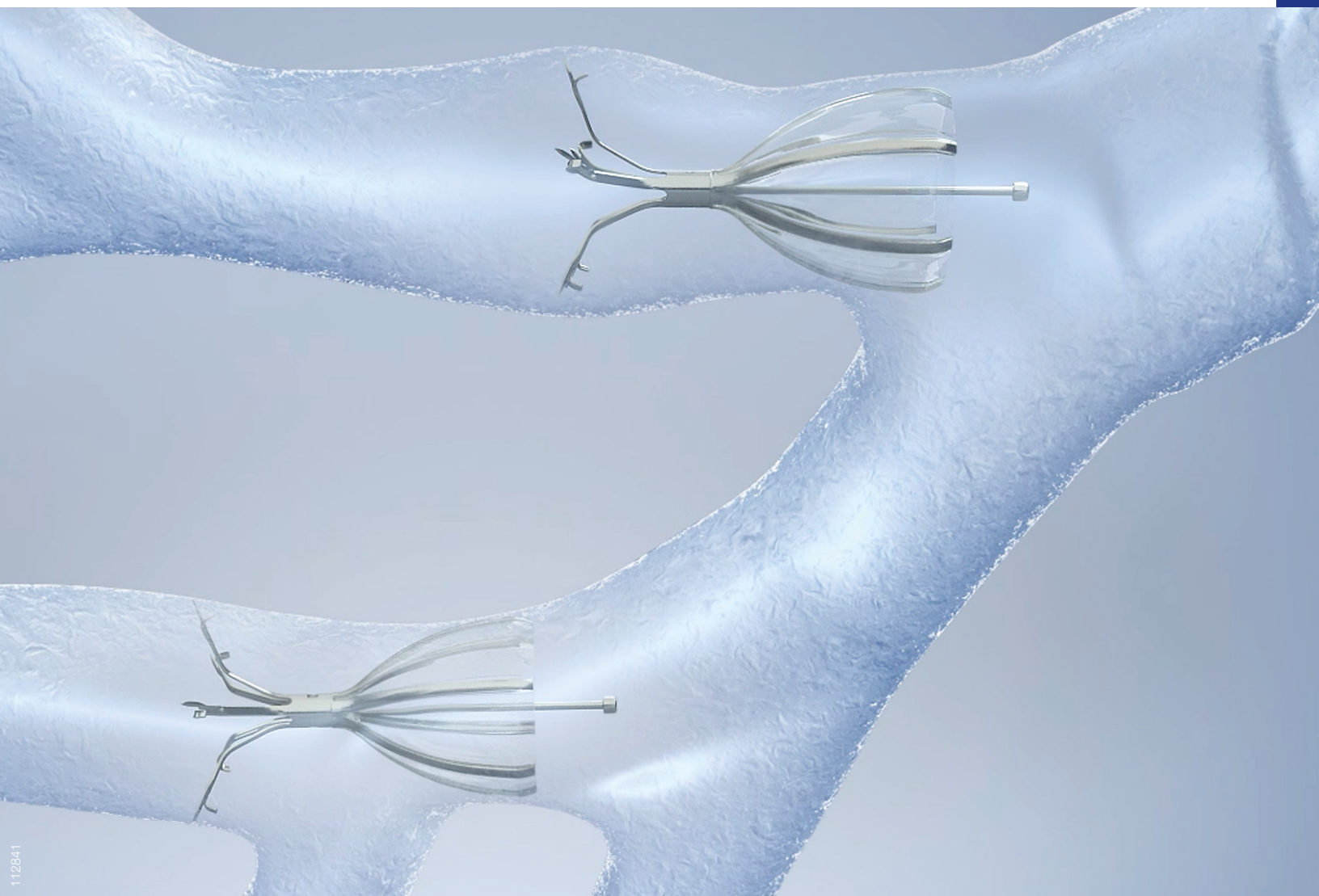
OLYMPUS

# Spiration Valve System

## A Proven Concept in Severe Emphysema Treatment



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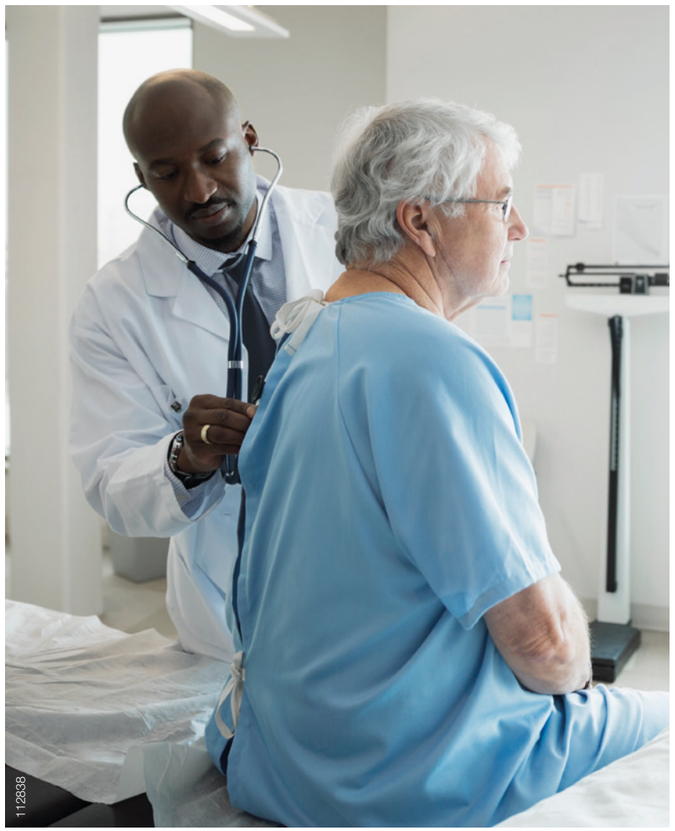
# Severe Emphysema

## A Progressive Disease with a Groundbreaking Treatment Horizon

Emphysema is a type of chronic obstructive pulmonary disease (COPD) that is progressive in nature and characterized by loss of elasticity and enlargement of the alveolar space in the lung. As a result, the diseased portion of the lung becomes hyperinflated, causing significant breathing challenges.




### Symptoms of Severe Emphysema

- Breathlessness
- Fatigue
- Limitations to daily activities
- Reduced quality of life
- Reduced life expectancy

### Current Treatment Options

- Smoking cessation
- Medical management
- Pulmonary rehabilitation
- Oxygen therapy
- Surgical intervention

# Endobronchial Valve Treatment

## Now a globally recommended therapy

*Based on safety and efficacy data from multiple international clinical studies– bronchoscopic lung volume reduction (BLVR), using endobronchial valves (EBV), is now recommended by numerous prominent guidelines as a treatment option for advanced emphysema.*

*These include:*

- *2019 Global Initiative for Chronic Obstructive Lung Disease (GOLD)*[1]
- *National Institute for Health and Care Excellence Interventional Procedures Guidance (NICE)*[2]

# The Spiration Valve System

## The Right Patient. The Right Valve. The Right Outcomes.

The Spiration Valve System (SVS) for bronchoscopic lung volume reduction is proven to improve lung function, reduce shortness of breath, and restore quality of life.[3]

The SVS has demonstrated a strong risk benefit profile, with a low rate of serious pneumothorax and minimal risk of valve migration and expectoration.*

It also offers noninvasive patient selection, a short procedure time, and the assurance of Olympus' expertise in medical and respiratory technology.

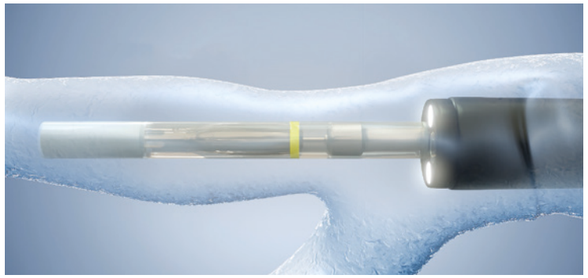


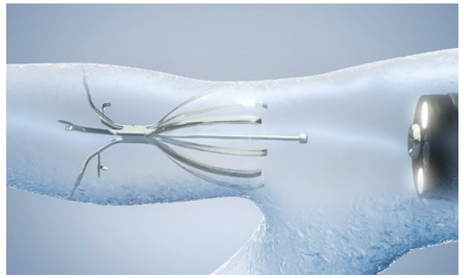
* Please refer to full prescriptive information in the back of this document

# The Spiration Valve System

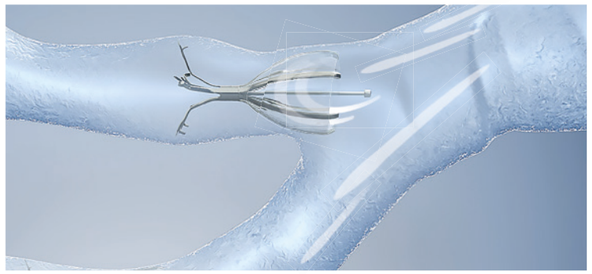
## Innovative Technology

The Spiration Valve System (SVS) is an innovative endobronchial technology that offers patients with severe emphysema a customized, minimally-invasive treatment option for lung volume reduction with a favorable risk-benefit profile.

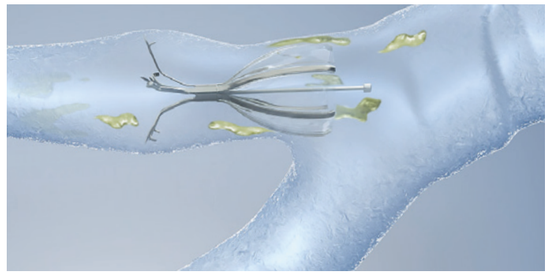




The Spiration Valve is delivered **to the target lobe** during a bronchoscopic procedure. The valve anchors are designed to **maintain position** and minimize expectoration.



On inhalation the valve **redirects air to healthier portions** of the lung enabling healthier tissue to expand.



On exhalation the valve **allows trapped air and secretions to escape** from the hyperinflated lobe.

By allowing air to leave but not re-enter diseased areas of the lung, it is possible to reduce hyperinflation in the targeted lobe. Treatment typically requires placement of multiple valves to achieve complete lobar occlusion in targeted lobe.

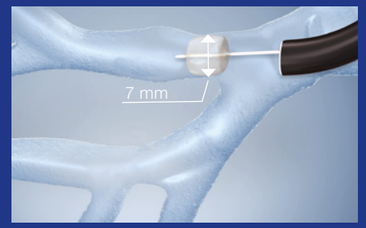
**Bronchoscopic Lung Volume Reduction With the SVS Has Been Shown To:**

- Allow healthier lung to re-expand
- Improve lung function
- Reduce dyspnea
- Increase the ability to perform daily activities

**In clinical trials, patients treated with the SVS experienced improved breathing, lung function, and quality of life.[3]**

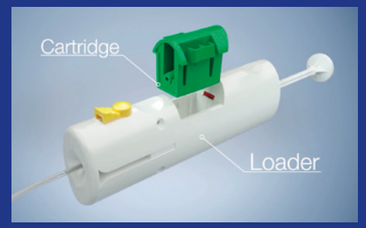
## Procedure Overview

A short bronchoscopic procedure under general anesthesia or deep sedation.



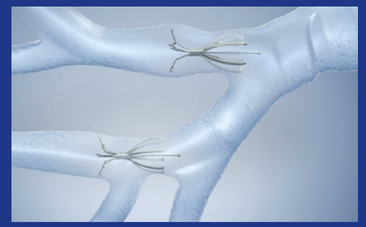

**Airway Sizing and Valve Selection for a Custom Fit**

A calibrated balloon is used to customize the appropriate valve size for placement.




**Easy, Reliable Valve Loading and Deployment**

The cartridge and loader work seamlessly to quickly compress the valve into the catheter in preparation for valve placement.



**Versatile Valve Placement**

Flexible valve design and delivery catheters enable placement in targeted airways.

**Easy Valve Removal**

Valve designed to facilitate retrieval with 360° access to removal rod.

# The Spiration Valve

## Engineered for Dynamic Lung Anatomy

**Stays in Place**
Anchor tips at the distal end prevent migration and expectoration.

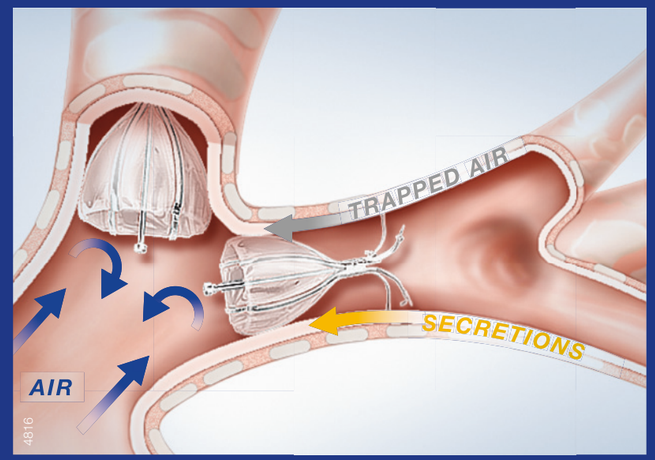
**Easy Airway Access**
Flexible catheters for 2.0mm and 2.6mm working channels.

**Redirects Air**
Valve designed with umbrella struts to minimize tissue contact and allow secretions to escape naturally along the bronchial wall.

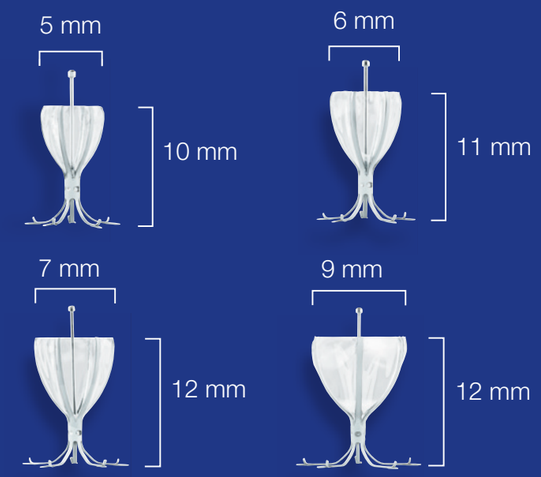
**Removal**
A center rod of the valve facilitates easy removal.

## Design Overview

The Spiration Valve is designed to allow flexible placement even in tortuous anatomy, such as the airways in the upper lobe segments of the lungs.




Multiple valve sizes accommodate variable lung anatomy with precision fit.

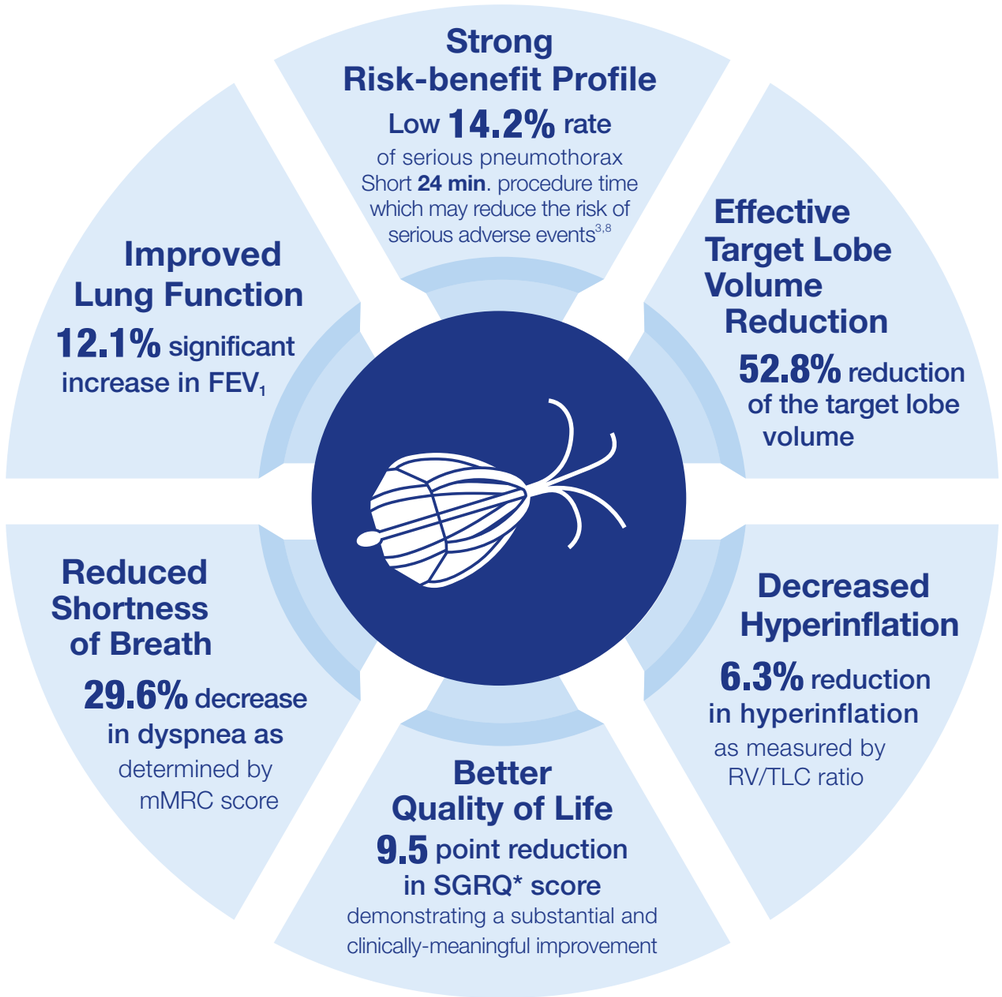


# Evidence Confirms Effectiveness[3]

## EMPROVE Clinical Trial

### Study Summary[4]

Randomized, controlled clinical trials (RCTs) demonstrate the SVS is a safe and effective treatment option for patients with severe emphysema and little-to-no collateral ventilation.




* A negative change in SGRQ represents an improvement in disease specific health status. A 4 point reduction is considered clinically meaningful.



### Study Overview

- EMPROVE evaluated the safety and effectiveness of the Spiration Valve System in 172 patients with severe emphysema
- 2:1 randomization into SVS treatment arm (n=113), and standard of care control arm (n=59)
- Alpha-1 antitrypsin deficiency non-randomized SVS treatment arm (n=20)
- Primary and secondary effectiveness endpoints measured six months following randomization
- Longer term durability of effectiveness measured at 12 months following randomization

### Patient Selection

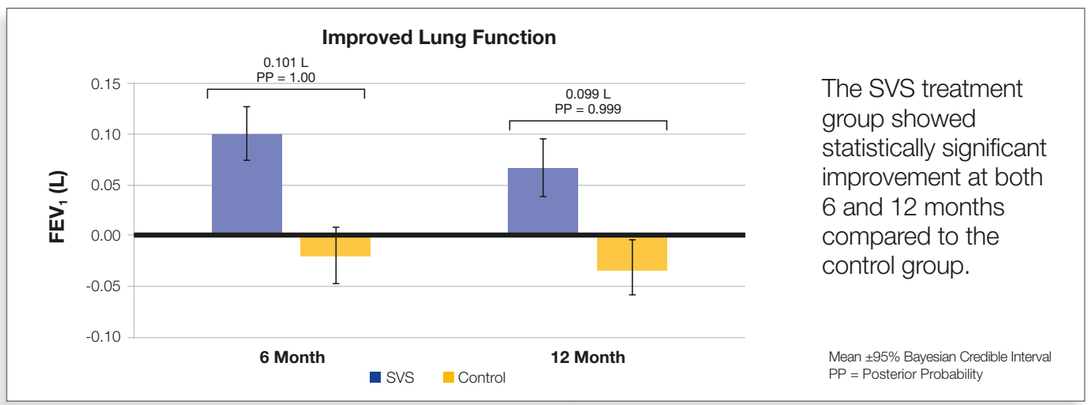
EMPROVE exclusively used high-resolution computed tomography (HRCT), a non-invasive approach to identifying patients with low to no collateral ventilation.

### Summary of Outcomes[3,4]

The EMPROVE clinical trial demonstrated that patients treated with the SVS benefited from significant clinical and statistical improvements in lung function and quality of life, compared to standard of care medical management.

## PRIMARY ENDPOINT

### Change in $FEV_1$




The SVS treatment group showed statistically significant improvement at both 6 and 12 months compared to the control group.

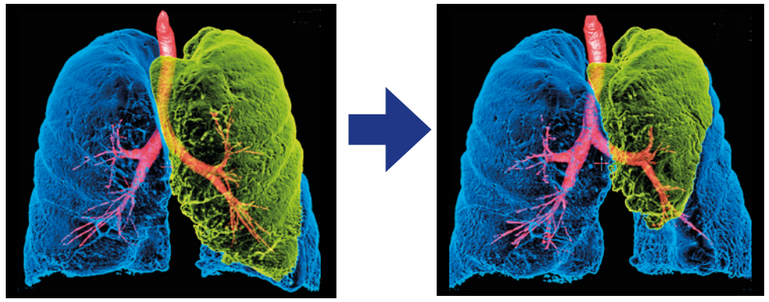
Mean ±95% Bayesian Credible Interval
PP = Posterior Probability

# Evidence Confirms Effectiveness[3]

## EMPROVE Clinical Trial

### SECONDARY ENDPOINTS

### Targeted Lobe Volume Reduction[3]



Pre-Treatment:
1.84 ± 0.6 L

Post-Treatment:
0.87 ± 0.9 L

**53%**
**Reduction**

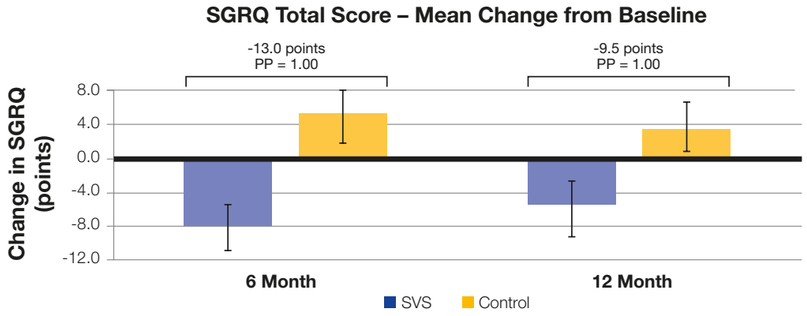
Difference: -0.974 L
95% BCI: -1.119, -0.829
PP: 1.0000

| Atelectasis | |
|---|---|
| Complete (≥99% TLVR) | 40/102 (39%) |
| Substantial (≥50% TLVR) | 51/102 (50%) |
| MCID Responder (≥350ml TLVR) | 76/102 (75%) |

| Pulmonary Adverse Events[3] | SVS Group % (N = 113) | Control Group % (N = 59) | SVS Group % (N = 113) | Control Group % (N = 47) |
|---|---|---|---|---|
| | Short-Term (0-6) Months | | Long-Term (6-12) Months | |
| Acute exacerbation of COPD | 16.8 | 10.2 | 13.6 | 8.5 |
| Death from procedure or device | 0.0 | — | 1.0 | — |
| Pneumonia - in the valve-treated lobe | 1.8 | — | 1.0 | — |
| Pneumonia - in the non-valve-treated lobe | 7.1 | 1.7 | 7.8 | 2.1 |
| Serious Pneumothorax | 14.2 | 0.0 | 0.0 | 0.0 |
| Respiratory failure | 2.7 | 0.0 | 1.0 | 0.0 |



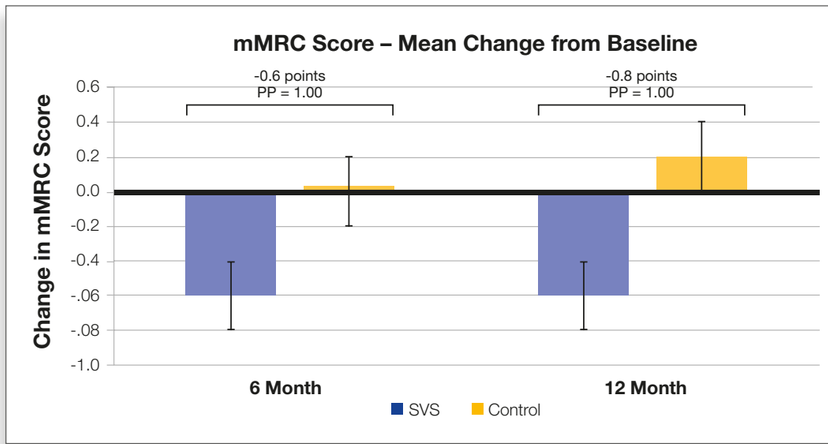
### St. George's Respiratory Questionnaire[3]




The SVS treatment group showed statistically significant improvement at both 6 and 12 months compared to the control group. A 4 point reduction is considered clinically meaningful.

Mean ±95% Bayesian Credible Interval
PP = Posterior Probability

### Dyspnea Score (mMRC)[3]




The SVS treatment group showed statistically significant improvement at both 6 and 12 months compared to the control group.

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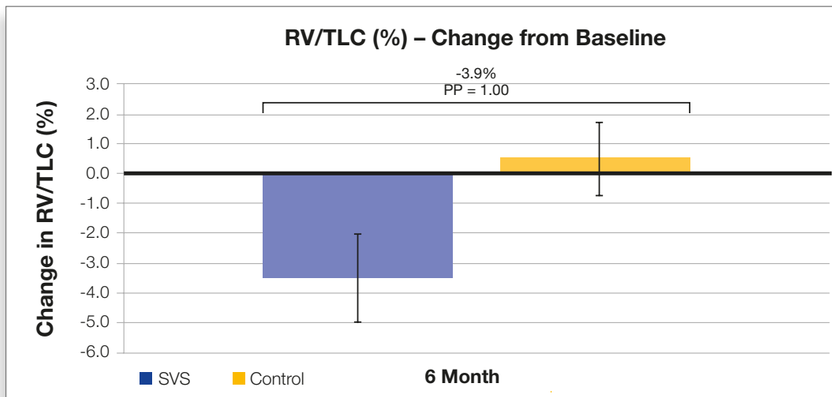
### Hyperinflation (RV/TLC)[3]




The SVS treatment group showed statistically significant improvement at 6 months compared to the control group.

Mean ± 95% Bayesian Credible Interval
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# Patient Selection

## The Key to Successful Outcomes

A decade of clinical studies shows appropriate patient selection to be one of the most important predictive factors of an effective response to bronchoscopic lung volume reduction.[6]

A thorough patient evaluation, examination for any comorbidities, and analysis of the patient's HRCT information and quantitative computed tomography (QCT) results are critical to successful outcomes. The below criteria may be used as a guide for appropriate patient selection based on the EMPROVE Trial.*

### EMPROVE Inclusion Criteria[3]

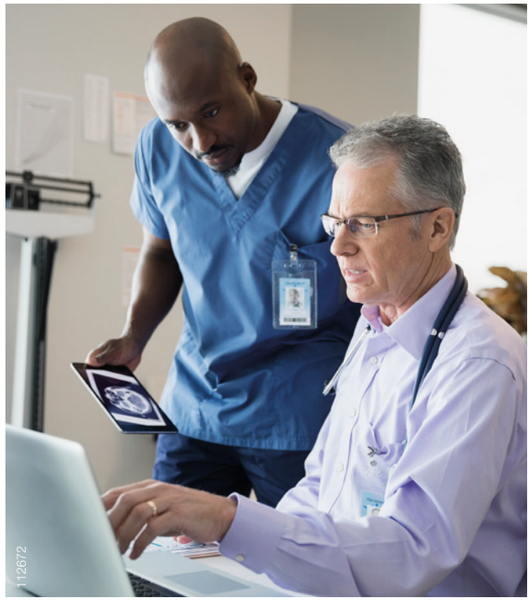
| Assessment | Inclusion Criteria | |
|---|---|---|
| **Medical History and Physical Exam** | ≥ 40 years of age<br>Diagnosed with severe emphysema<br>Considered to have "stable" COPD as defined by Guidelines for Management of Stable COPD[5]<br>≥ 6 weeks without exacerbation<br>Able to tolerate a bronchoscopic procedure | |
| **Radiographic** | Severe emphysema defined as target lobe with ≥ 40% emphysema involvement<br>High heterogeneity defined as ≥ 10 point disease severity difference with the ipsilateral lobe<br>Fissure integrity defined as ≥ 90% completeness of the fissure(s) separating the target lobe | |
| **Pulmonary and Exercise Evaluation** | $FEV_1$<br>Residual Volume (RV)<br>Total Lung Capacity (TLC)<br>6MWD | ≤ 45% predicted<br>≥150% predicted<br>≥100% predicted<br>≥140 meters |

### Exclusion Criteria

- Patient is an active smoker.
- Patient has a severe gas exchange abnormality in either $PCO_2$ or $PO_2$ as defined by $PCO_2$ >55 mm Hg, or $PO_2$ < 45 mm Hg on room air.
- Patient has a BMI < 15kg/m$^2$.
- Patient had a hospitalization for COPD exacerbation or respiratory infections in the past 3 months prior to baseline testing.
- Patient has bronchitis with sputum production > 4 tablespoons per 60 ml per day.
- Patient has an active asthma component to their disease or requires more than 15mg of prednisone daily.
- Patient has giant bulla considered to be > 1/3 volume in either lung.
- Patient has severe pulmonary hypertension based upon clinical evaluation.
- Patient has had prior lung volume reduction surgery or major lung procedures (lobectomy or greater).
- Patient has a diffuse emphysema pattern.
- Patient is classified as ASA Class greater than P4 including presence of co-morbidity that could significantly increase the risk of a bronchoscopy procedure.[3]

* These recommendations are not meant to replace patient-specific clinical judgement.

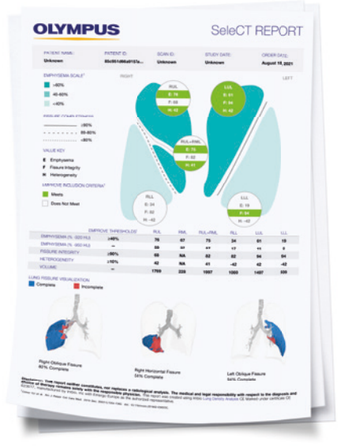





### SeleCT

SeleCT is a completely noninvasive patient screening solution that provides key measures of emphysema severity, fissure integrity, and heterogeneity.

These measures are provided in an easy-to-read report to assist with selecting qualified patients and potential target lobes for improved outcomes using bronchoscopic lung volume reduction (BLVR).




**Key quantitative measures to identify responders for the Spiration Valve System:**

- **EMPHYSEMA SEVERITY**
  Allows physician to quickly identify the most diseased lobe
- **HETEROGENEITY**
  Differentiates target and ipsilateral lobe emphysema to facilitate redirection of ventilation to healthier tissue[6,7]
- **FISSURE INTEGRITY**
  EMPROVE trial results confirmed radiographic assessment of fissure completeness to be a reliable surrogate for collateral ventilation[3]

# The Most Comprehensive Solution

## For Minimally Invasive Bronchoscopic Lung Volume Reduction

The Olympus Solution offers not only the state-of-the-art valve technology you need for effective BLVR, but also provides an entire portfolio of respiratory devices and bronchoscopes that ensure improved efficiency and quality patient care in the bronchoscopy suite.


### EVIS X1 Imaging Platform

EVIS X1 introduces a range of new, easy-to-use technologies that combines high imaging performance and ergonomic working in daily routine.


### Spiration Valves

The Spiration Valve is an umbrella-shaped, one-way valve that redirects air away from diseased area of the lung to healthier tissue, all while allowing trapped air and secretions to escape, so that patients can breathe easier.



### BF-1TH1100 Bronchoscope

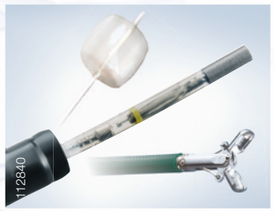
Fully rotatable, therapeutic bronchoscope with superb HDTV image quality and a 3.0mm working channel. This enables increased suction capabilities and contributes to better view in the bronchial airways.


### Olympus Respiratory Solutions

Olympus offers a versatile product line-up from EndoTherapy devices and bronchoscopes to reprocessing and service solutions. Olympus is a trusted partner in the bronchoscopy suite when it comes to endoscopic interventions.

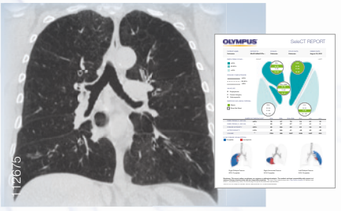
### Spiration Valve System Accessories

SVS offers a complete selection of supporting devices to ensure that valves can effectively be placed into the target airway, precisely deployed, and easily removed whenever deemed necessary.




### SeleCT Quantitative CT Analysis

The SeleCT QCT service offers rapid results, including a qualified over-read by a certified thoracic radiologist.



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