Spiration Valve System
A Proven Concept in Severe Emphysema Treatment
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.

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.

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.

In clinical trials, patients treated with the SVS experienced improved breathing, lung function, and quality of life.²

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

Procedure Overview
A short bronchoscopic procedure under general anesthesia or deep sedation.

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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.

- 5 mm
- 6 mm
- 7 mm
- 9 mm
- 10 mm
- 11 mm
- 12 mm

AIR
SECRETIONS
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

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 FEV1**

<table>
<thead>
<tr>
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<th>6 Month</th>
<th>12 Month</th>
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<tbody>
<tr>
<td>Improved Lung Function</td>
<td>-0.10 L</td>
<td>-0.09 L</td>
</tr>
<tr>
<td>FEV1 (L)</td>
<td>0.15</td>
<td>0.10</td>
</tr>
</tbody>
</table>

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

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

EMPROVE Clinical Trial

SECONDARY ENDPOINTS

Targeted Lobe Volume Reduction

53% Reduction

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

Atelectasis

Pre-Treatment: 1.84 ± 0.6 L
Post-Treatment: 0.87 ± 0.9 L

Complete (≥49% TLVR) 40/102 (39%)
Substantial (≥50% TLVR) 51/102 (50%)
MCID Responder (≥350 ml TLVR) 76/102 (75%)

St. George's Respiratory Questionnaire

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)

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

Mean ± 95% Bayesian Credible Interval
PP = Posterior Probability

Hyperinflation (RV/TLC)

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

Mean ± 95% Bayesian Credible Interval
PP = Posterior Probability

<table>
<thead>
<tr>
<th>Pulmonary Adverse Events</th>
<th>SVS Group % (N = 113)</th>
<th>Control Group % (N = 59)</th>
<th>SVS Group % (N = 113)</th>
<th>Control Group % (N = 47)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-Term (0-6) Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute exacerbation of COPD</td>
<td>16.8</td>
<td>10.2</td>
<td>13.6</td>
<td>8.5</td>
</tr>
<tr>
<td>Death from procedure or device</td>
<td>0.0</td>
<td>—</td>
<td>1.0</td>
<td>—</td>
</tr>
<tr>
<td>Pneumonia - in the valve-treated lobe</td>
<td>1.8</td>
<td>—</td>
<td>1.0</td>
<td>—</td>
</tr>
<tr>
<td>Pneumonia - in the non-valve-treated lobe</td>
<td>7.1</td>
<td>1.7</td>
<td>7.8</td>
<td>2.1</td>
</tr>
<tr>
<td>Serious Pneumothorax</td>
<td>14.2</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>2.7</td>
<td>0.0</td>
<td>1.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Long-Term (6-12) Months</td>
<td></td>
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</table>
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.¹

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 Criteria³

<table>
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<tr>
<th>Assessment</th>
<th>Inclusion Criteria</th>
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</table>
| Medical History and Physical Exam | ≥ 40 years of age  
Diagnosed with severe emphysema  
Considered to have “stable” COPD as defined by Guidelines for Management of Stable COPD⁷  
≥ 6 weeks without exacerbation  
Able to tolerate a bronchoscopic procedure |
| Radiographic                    | Severe emphysema defined as target lobe with ≥ 40% emphysema involvement  
High heterogeneity defined as ≥ 10 point disease severity difference with the ipsilateral lobe  
Fissure integrity defined as ≥ 90% completeness of the fissure(s) separating the target lobe |
| Pulmonary and Exercise Evaluation | FEV₁ ≤ 45% predicted  
Residual Volume (RV) ≥ 150% predicted  
Total Lung Capacity (TLC) ≥ 100% predicted  
6MWD ≥ 140 meters |

### Exclusion Criteria

- Patient is an active smoker.
- Patient has a severe gas exchange abnormality in either 
  PCO₂ or PO₂ as defined by PCO₂ >55 mm Hg, or PO₂ < 45 mm Hg on room air.
- Patient has a BMI < 15kg/m².
- 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 tissue⁶⁷

- **FISSURE INTEGRITY**  
  EMPROVE trial results confirmed radiographic assessment of fissure completeness to be a reliable surrogate for collateral ventilation⁹
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.

**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 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.

**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 OCT service offers rapid results, including a qualified over-read by a certified thoracic radiologist.
References