

Spiration[®] Valve System

A Proven New Direction in Severe Emphysema Treatment

Severe Emphysema

A Progressive Disease with a Groundbreaking New 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.



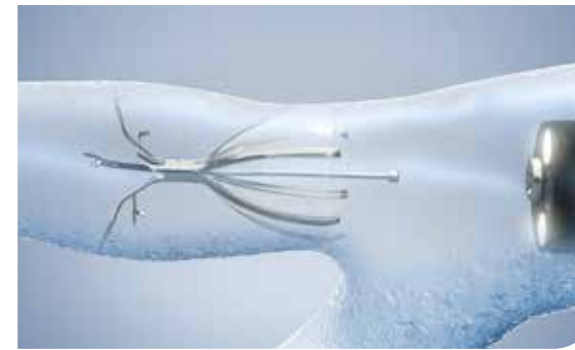
* Please refer to full prescriptive information in the back of this document



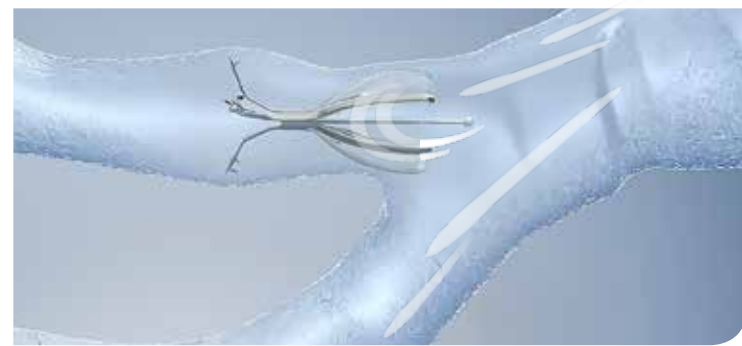
The Spiration® Valve System

Innovative Technology

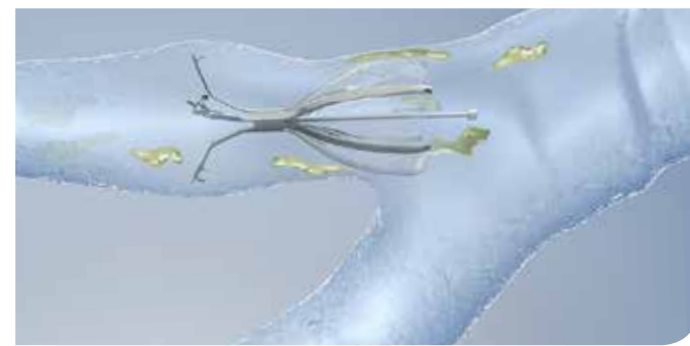
The Spiration Valve System (SVS) is an innovative endobronchial technology that offers patients with severe emphysema a customized, minimally-invasive treatment option for lung volume reduction with a favorable risk-benefit profile.



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.

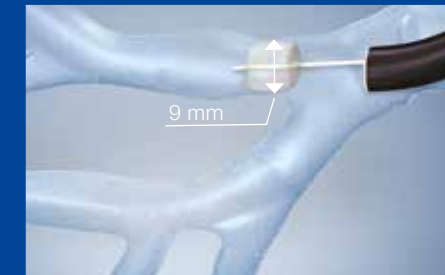
By allowing air to leave but not re-enter diseased areas of the lung, it is possible to reduce hyperinflation in the targeted lobe. Treatment typically requires placement of multiple valves to achieve complete lobar occlusion in targeted lobe.

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

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 catheter enable placement in targeted airways.



Easy Valve Removal

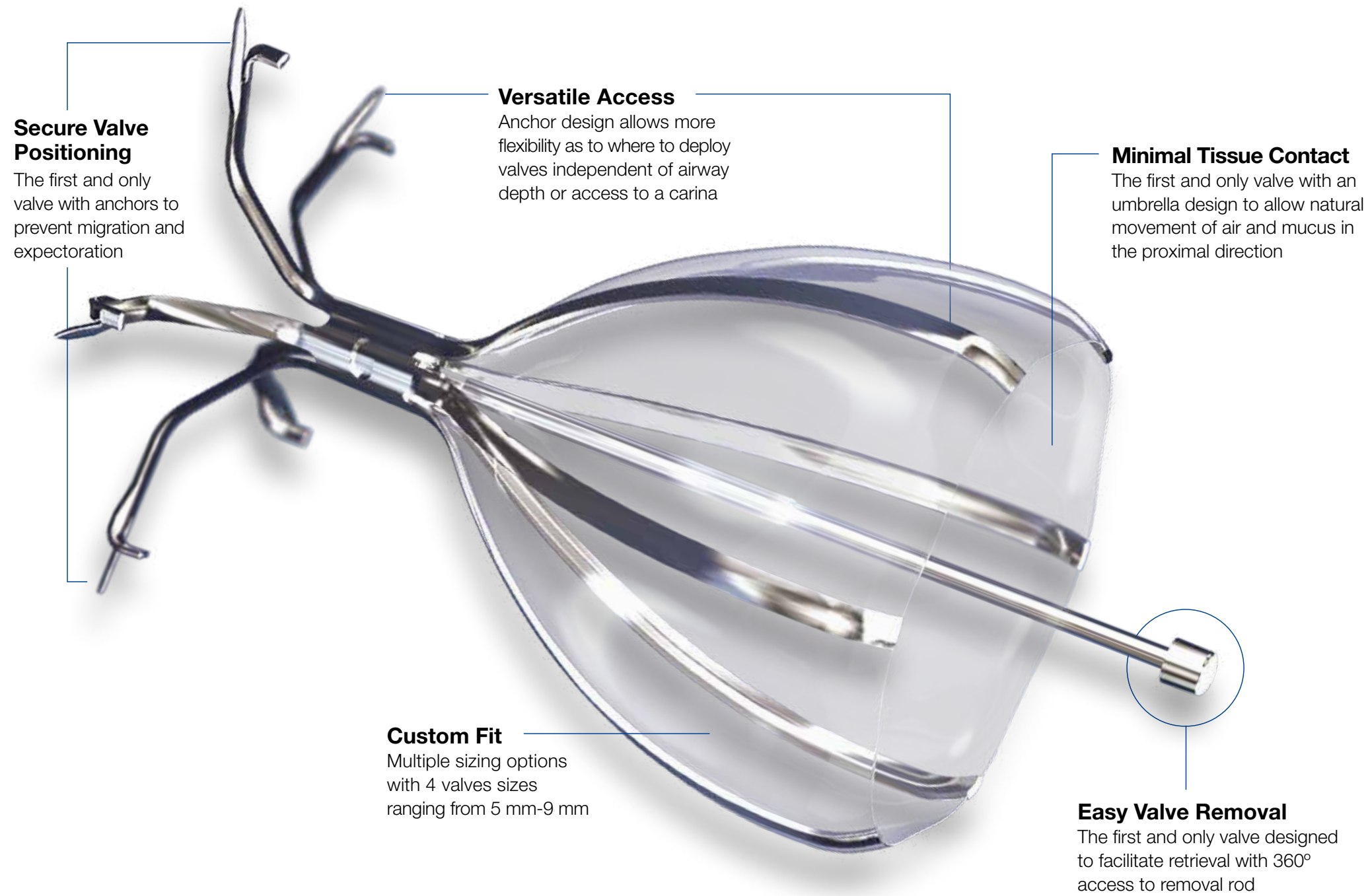
Valve designed to facilitate retrieval with 360° access to removal rod.



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

The Spiration® Valve

Engineered for Dynamic Lung Anatomy



Secure Valve Positioning
The first and only valve with anchors to prevent migration and expectoration

Versatile Access
Anchor design allows more flexibility as to where to deploy valves independent of airway depth or access to a carina

Minimal Tissue Contact
The first and only valve with an umbrella design to allow natural movement of air and mucus in the proximal direction

Custom Fit
Multiple sizing options with 4 valves sizes ranging from 5 mm-9 mm

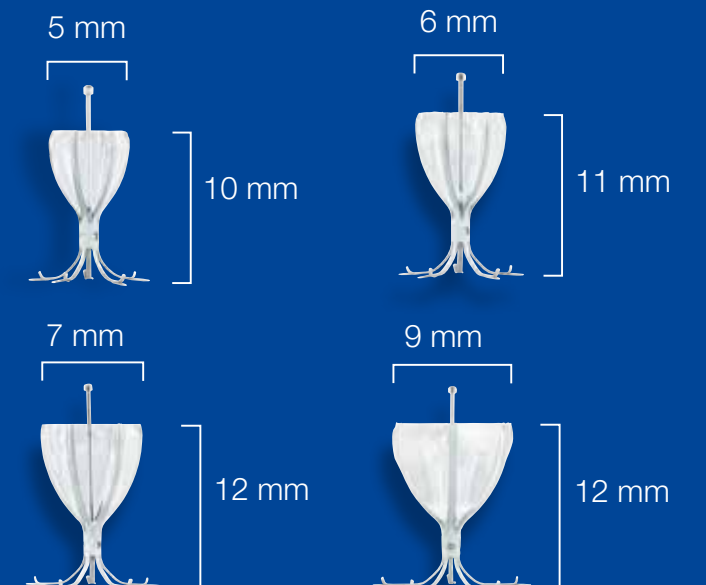
Easy Valve Removal
The first and only valve designed to facilitate retrieval with 360° access to removal rod

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.

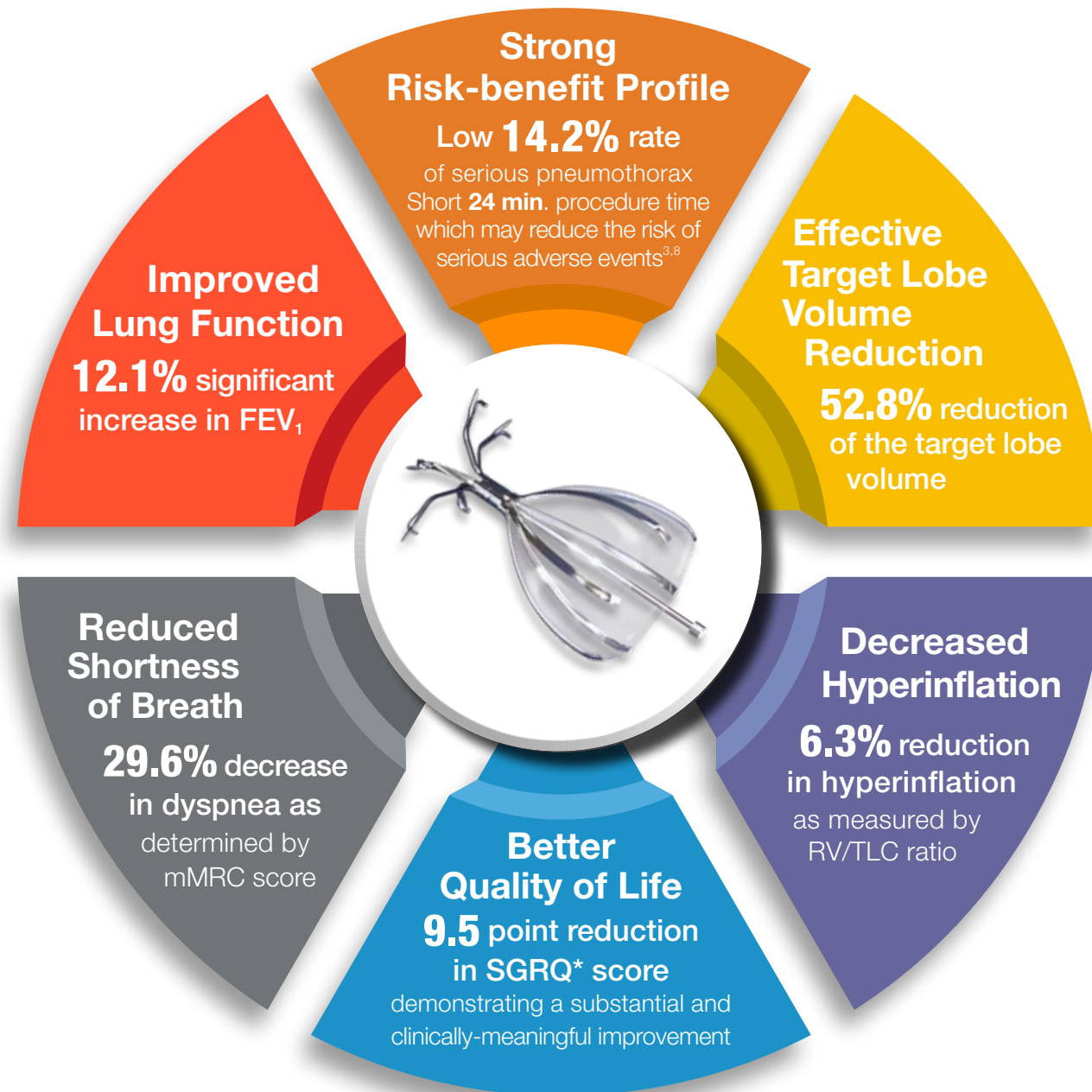


Evidence Confirms Effectiveness³

EMPROVE Clinical Trial

Study Summary⁴

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

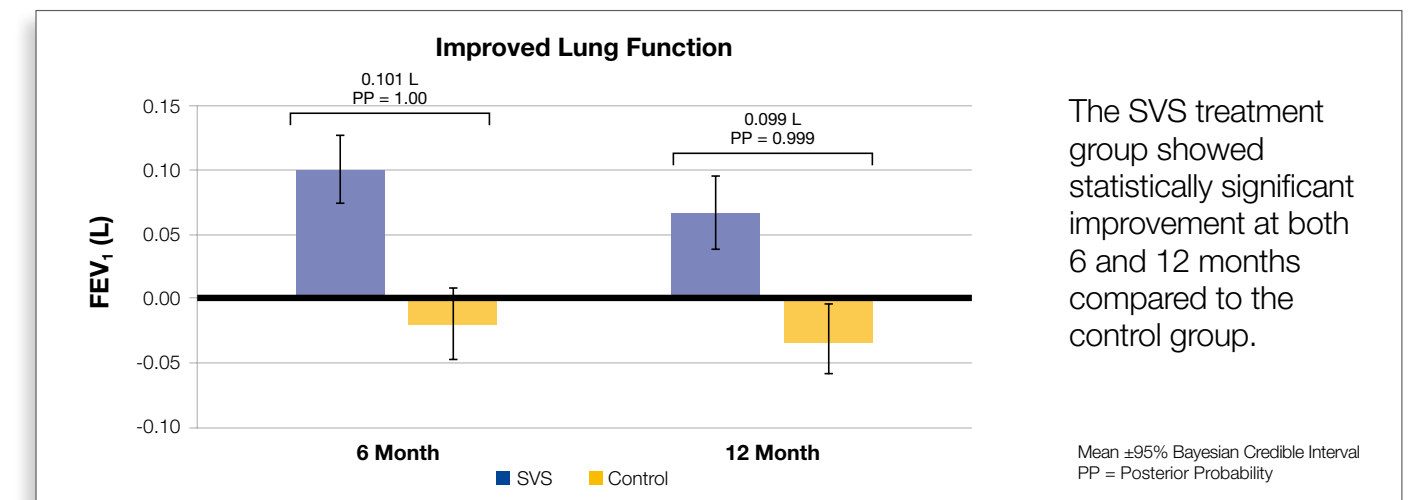
EMPROVE exclusively used high-resolution computed tomography (HRCT), a non-invasive approach to identifying patients with low to no collateral ventilation.

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 FEV₁

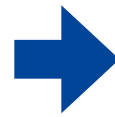


Evidence Confirms Effectiveness³

EMPROVE Clinical Trial

SECONDARY ENDPOINTS

Targeted Lobe Volume Reduction³



53% Reduction

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

Pre-Treatment:
1.84 ± 0.6 L

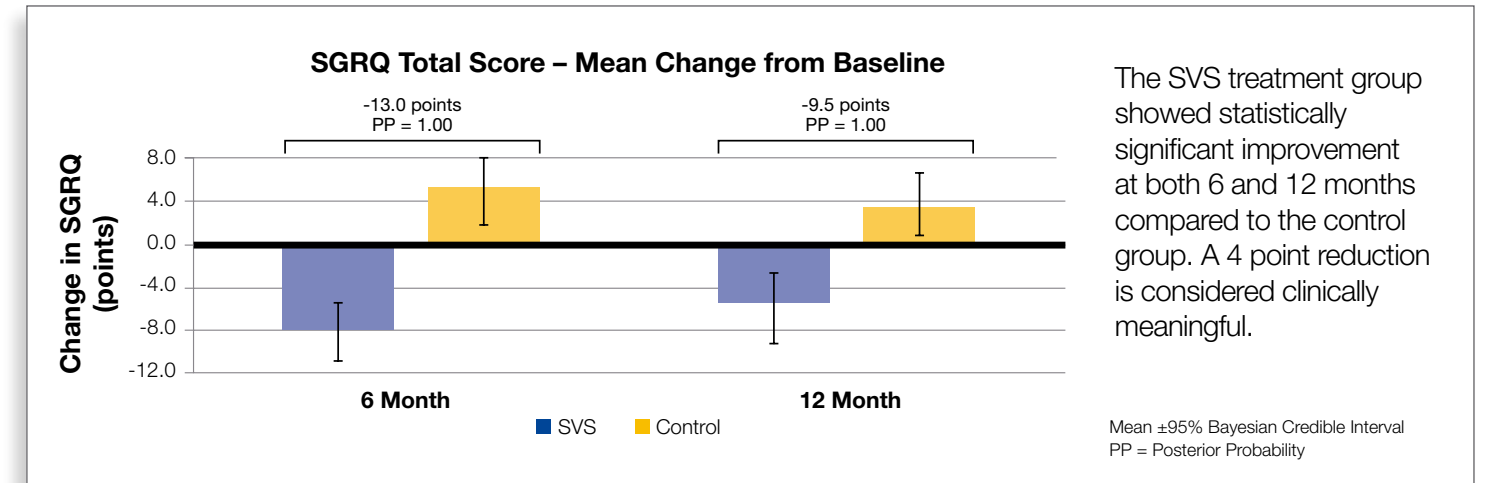
Post-Treatment:
0.87 ± 0.9 L

Atelectasis

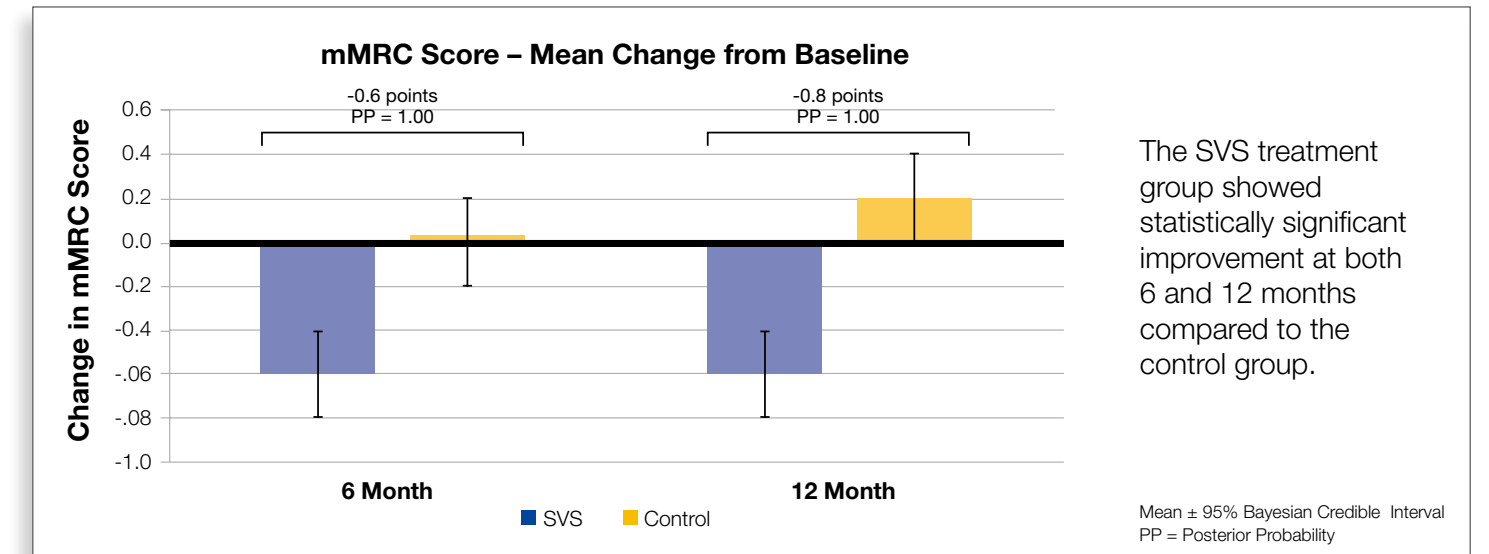
Complete (≥99% TLVR)	40/102 (39%)
Substantial (≥50% TLVR)	51/102 (50%)
MCID Responder (≥350ml TLVR)	76/102 (75%)

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

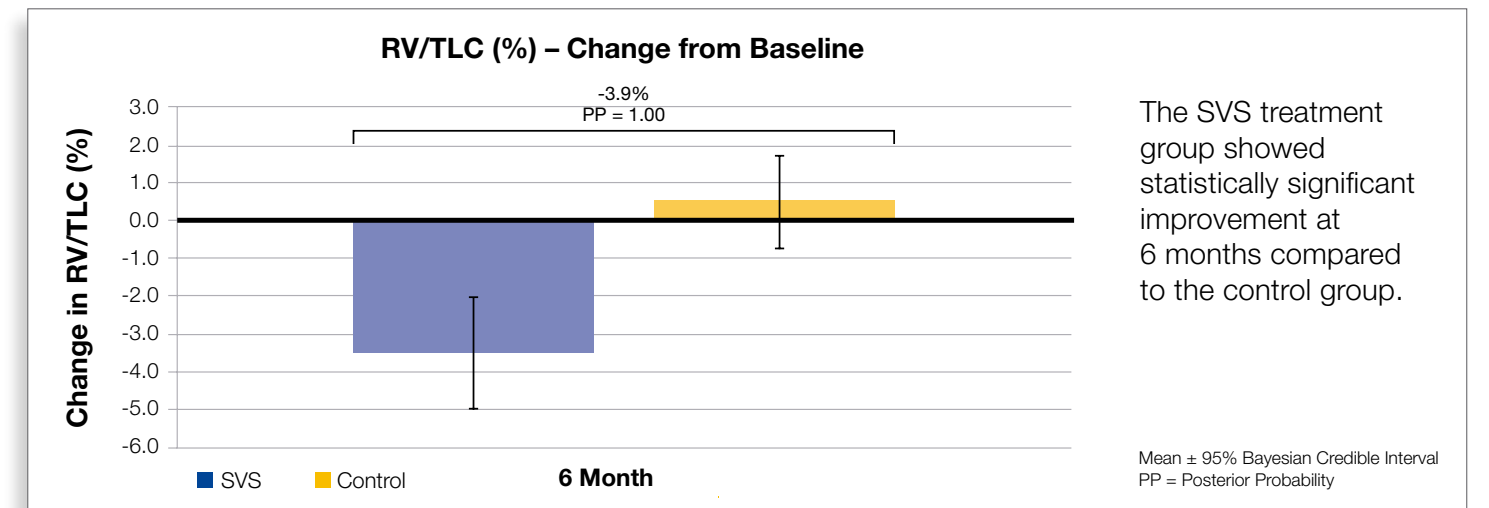
St. George's Respiratory Questionnaire³



Dyspnea Score (mMRC)³



Hyperinflation (RV/TLC)³



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 Criteria³

Assessment	Inclusion Criteria								
Medical History and Physical Exam	<ul style="list-style-type: none"> ≥ 40 years of age Diagnosed with severe emphysema Considered to have "stable" COPD as defined by Guidelines for Management of Stable COPD⁵ ≥ 6 weeks without exacerbation Able to tolerate a bronchoscopic procedure 								
Radiographic	<ul style="list-style-type: none"> 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	<table border="0"> <tr> <td>FEV₁</td> <td>≤ 45% predicted</td> </tr> <tr> <td>Residual Volume (RV)</td> <td>≥150% predicted</td> </tr> <tr> <td>Total Lung Capacity (TLC)</td> <td>≥100% predicted</td> </tr> <tr> <td>6MWD</td> <td>≥140 meters</td> </tr> </table>	FEV ₁	≤ 45% predicted	Residual Volume (RV)	≥150% predicted	Total Lung Capacity (TLC)	≥100% predicted	6MWD	≥140 meters
FEV ₁	≤ 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.



The only Quantitative CT (QCT) report with a qualified over-read

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 ventilation³

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 EXERA III Imaging Platform

The powerful endoscopy platform works seamlessly with a wide range of endoscopes across specialties to provide easier data management and cost efficiencies.



BF-1TH190 Bronchoscope

Fully rotatable, therapeutic bronchoscope with superb HDTV image quality and a 2.8mm working channel, which accommodates the Spiration® Valve System.



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.



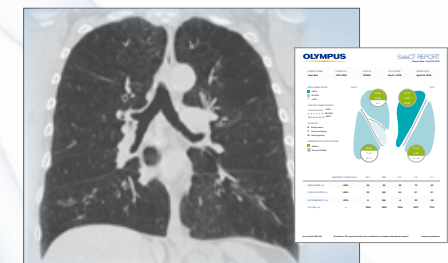
Spiration Valve System Accessories

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



Olympus Services

Dedicated Support Beyond Products

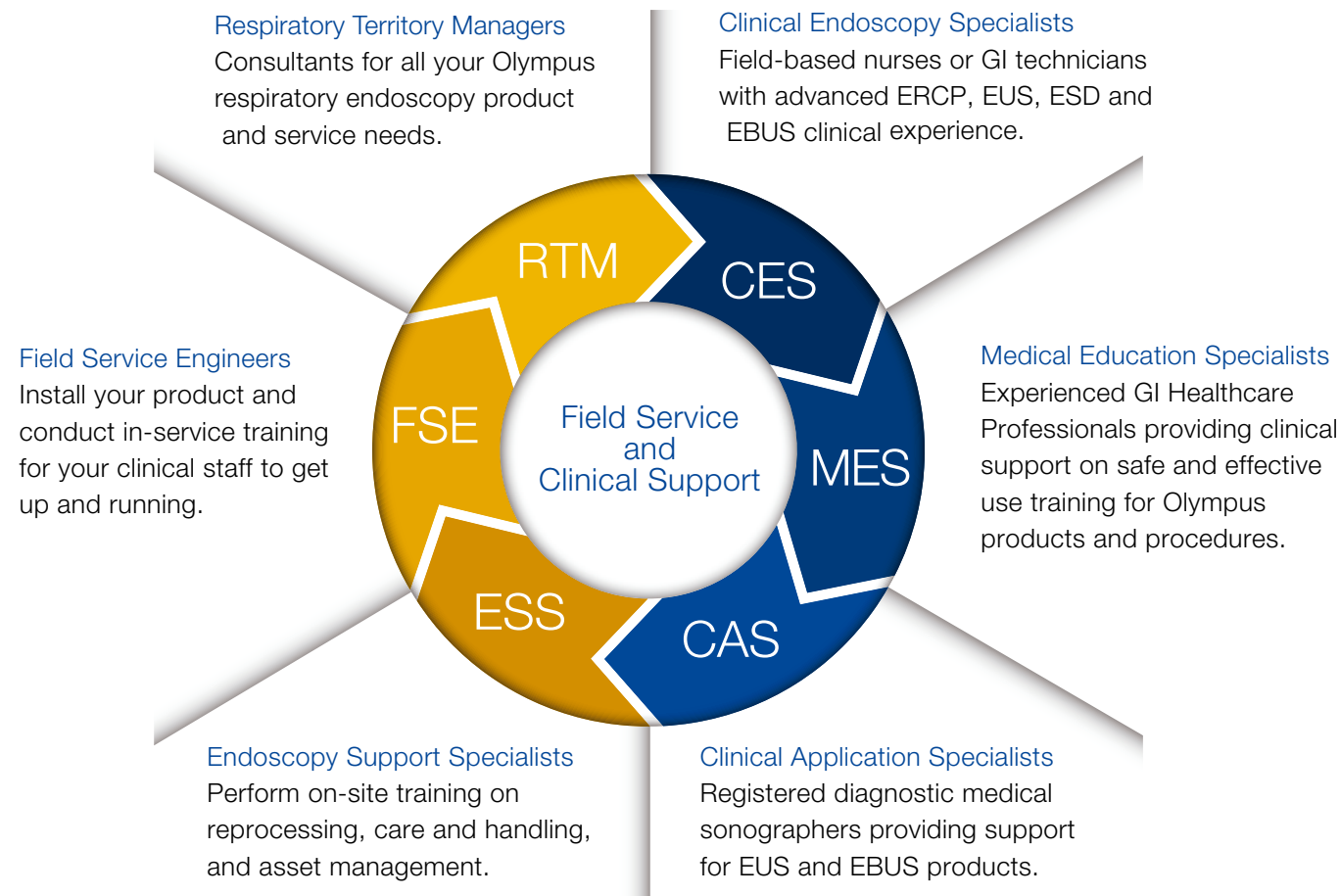
At Olympus, we strive to be more than just a medical equipment provider to our customers. We provide end-to-end support, from the purchasing process to the procedure and reprocessing services, to build a relationship of trust. Your success with our products means that you are able to help more patients, and we want to do everything we can to help you achieve those goals.



Field Service and Clinical Support

Phone: 800-848-9024

Olympus offers support over the phone and web, as well as on-site support services, to ensure that your team is well-prepared and has all of the tools they need for success.



Olympus Customer Service

Phone: 800-848-9024

Olympus Technical Assistance Center

Phone: 800-848-9024, ext 1

Specialists are available Monday-Friday 7am to 8pm EST to respond to calls and assist you in diagnosing and troubleshooting your entire range of Olympus products.

OlympusConnect.com

Web: olympusconnect.com

OlympusConnect.com is a web portal for Olympus customers to access corporate intelligence in order to improve business and clinical operations. This password-protected site contains a vast amount of resources including case studies, product catalogs and business-building marketing materials.

Financing Options

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Service Agreements

Phone: 800-401-1075

Email: service.contracts@olympus.com

Olympus provides comprehensive coverage for all endoscope repairs, whether caused by daily use or accidental damage. Our 24/7 technical support provides on-site options to meet your facility's needs.

Spiration® Reimbursement Helpline

Phone: 855-428-7346

Hours: 9:00 am – 5:00 pm Pacific Time

Email: Spirationvalvereim@olympus.com

Olympus has designated services and programs available for Spiration Reimbursement. Feel free to call or email us and our trained staff can assist you with questions on billing, coding, and reimbursement for the Spiration® Valve System.

Olympus University and Professional Education

Phone: 800-231-0016

Web: olympusuniversity.com

Product training and education programs provide safe and effective product use training on Olympus equipment and devices to healthcare professionals (HCPs), particularly physicians and nurses.

Spiration® Valve System

For the Treatment of Severe Emphysema

REFERENCES

1. 2019 Global Strategy for the Diagnosis, Management, and Prevention of COPD. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2018. <http://goldcopd.org>
2. National Institute for Health and Care Excellence (2017) Endobronchial valve insertion to reduce lung volume in emphysema (NICE guideline IPG 600) Available at: nice.org.uk/guidance/ipg600 [Accessed 16 November 2018].
3. Criner GJ, Delage A, Voelker K. Late Breaking Abstract - Endobronchial Valves for Severe Emphysema – 12-month Results of the EMPROVE Trial. Eur Respir J. 2018;52(suppl 62). doi:10.1183/13993003.congress-2018.OA4928
4. Spiration Valve System. Summary of Safety and Effectiveness; 2018. Data on File.
5. ACP/ACCP/ATS/ERS Guidelines for Management of Stable COPD. <http://www.thoracic.org/statements/resources/respiratory-disease-adults/179full.pdf>. Accessed 2018.
6. Eberhardt R, Gompelmann D, Schuhmann M, Heussel CP, Herth FJF. Complete unilateral vs partial bilateral endoscopic lung volume reduction in patients with bilateral lung emphysema. Chest. 2012;142(4):900-908. doi:10.1378/chest.11-2886
7. Thurnheer R, Engel H, Weder W, et al. Role of lung perfusion scintigraphy in relation to chest computed tomography and pulmonary function in the evaluation of candidates for lung volume reduction surgery. Am J Respir Crit Care Med 1999;159(1):301-10.
8. Wood DE, Nader DA, Springmeyer SC, et al. The IBV Valve trial: a multicenter, randomized, double-blind trial of endobronchial therapy for severe emphysema. J Bronchology Interv Pulmonol. 2014;21(4):288-297. doi:10.1097/LBR.000000000000110

PRESCRIPTIVE INFORMATION

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Indication for Use

Spiration Valves are one-way endobronchial valves indicated for adult patients with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung that have evidence of low collateral ventilation.

Contraindications

- Patient is not an appropriate candidate for, or unable to tolerate, flexible bronchoscopy procedures.
- Patients with known or suspected sensitivity or allergy to nickel.
- Patients with evidence of active pulmonary infection.
- Patients who have not quit smoking.
- Patients with large bullae encompassing greater than 30% of either lung.
- Patients with diffuse homogenous emphysema.

General Warnings and Precautions

The following are general warnings: The safety and effectiveness of the Spiration Valve System have not been studied in

- Prior major lung or chest surgery
 - Lung Volume Reduction Surgery (LVRS)
 - Transplant
 - Median sternotomy or thoracotomy
- Known cardiac history of myocardial infarction or congestive heart failure
- Implanted endobronchial valve currently treating a prolonged air leak

The following are general precautions:

- Do not use the Spiration Valve System for other than its intended use.
- The Spiration Valve System should not be used for patients who have active asthma, bronchitis or clinically significant bronchiectasis.
- Only use a bronchoscope with an instrument channel inner diameter of 2.6mm or larger.
- Valve placement should be done only after airway evaluation and sizing with the balloon catheter and Airway Sizing Kit (see Instructions for Use, Airway Sizing Kit).
- Valve placement and removal must be done under bronchoscopic observation with visualization of the target airway.
- Do not allow lubricants to contact the catheter, loader, or valve.
- Once a valve has been loaded and/or deployed, do not attempt to reuse or re-deploy the valve.
- The valve is not designed to be repositioned after it is deployed from the catheter. If the position of the deployed valve is not optimal or appropriate, the valve should be removed and discarded.
- Do not remove the valve from the cartridge.
- Do not reuse the catheter and loader for more than one patient procedure. The catheter and loader are not designed to be re-cleaned, reprocessed, or re-sterilized.
- Do not deploy more than 10 valves using the catheter and loader. If more than 10 valve deployments are needed, a new catheter and loader must be opened and used.

Potential Complications

Potential complications that may be associated with bronchoscopy and/or valve placement include, but are not limited to, the following:

- Altered arterial blood gas
- Anesthesia complications
- Arrhythmia
- Atelectasis
- Bronchial injury
- Bronchitis
- Bronchospasm
- Chest pain
- Chronic Obstructive Pulmonary Disease (COPD) exacerbation
- Death
- Dyspnea
- Empyema/lung abscess
- Hemoptysis (or bleeding)
- Hemothorax
- Hypoxemia
- Iatrogenic injuries
- Infection
- Migration of a valve out of the lung or within the lung
- Myocardial infarction
- Persistent cough
- Pleural effusion
- Pneumothorax
- Pneumonia
- Respiratory failure
- Sore throat
- Thoracic pain
- Tissue hyperplasia or other reaction at valve site
- Valve fracture
- Vocal cord injury
- Wheezing
- Other procedure-related adverse events may occur

Prior to using the Spiration Valve System, please review the Instructions for Use for additional information on indications, contraindications, warnings, precautions and potential complications.

Prior to ordering the Spiration Valve System, on-site product training with the treating physician(s) present must be completed.

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