OLYMPUS

Spiration® Valve System

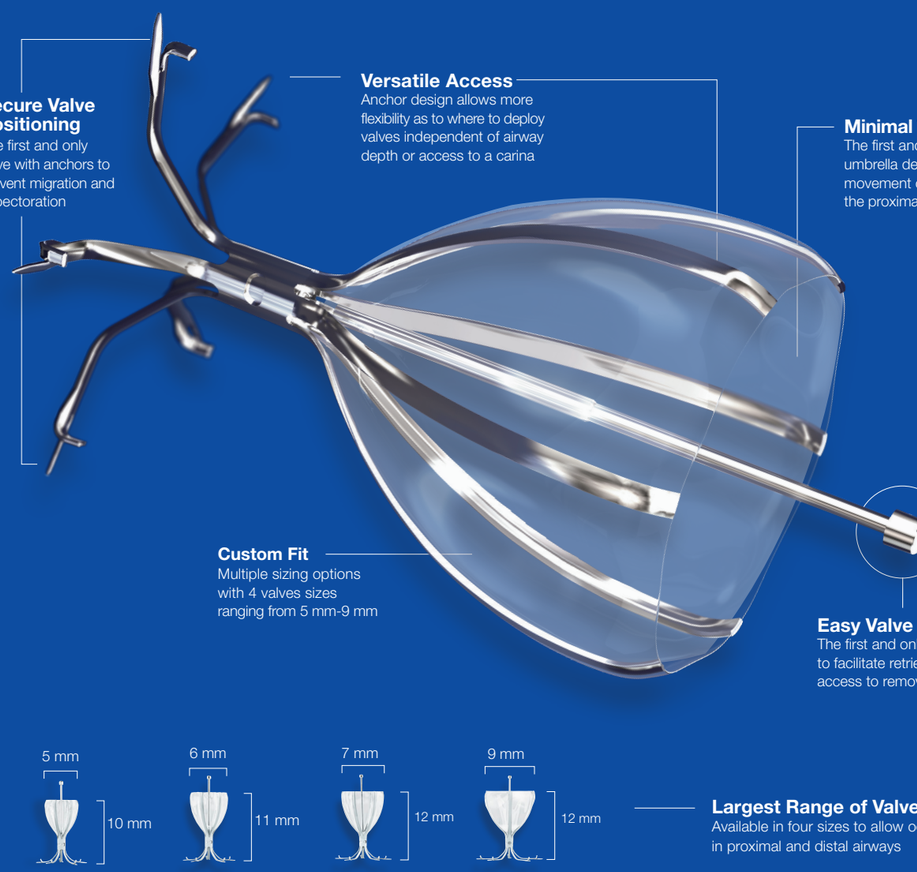
For the Treatment of Severe Emphysema and Management of Postoperative Air Leaks

The only valve on the market with two FDA indications.

The Spiration® Valve System (SVS) is an innovative endobronchial technology that redirects air away from diseased or damaged lungs to healthier tissue, all while allowing trapped air and secretions to escape so that patients may breathe easier. The unique design of the Spiration Valve minimizes contact with the bronchial wall, maintains position to redirect air even in complex airways and facilitates removal when needed.

The Spiration Valve is the only valve on the market approved by FDA for two separate indications. The Spiration Valve is indicated for patients with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung with evidence of low collateral ventilation (under the Premarket Approval). The Spiration Valve is also indicated to control air leaks of the lung or significant air leaks that are likely to become prolonged air leas following lobectomy, segmentectomy or Lung Volume Reduction Surgery (LVRS) under Humanitarian Device Exemption.

The procedure is considered minimally invasive and can be performed through a flexible bronchoscope.



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

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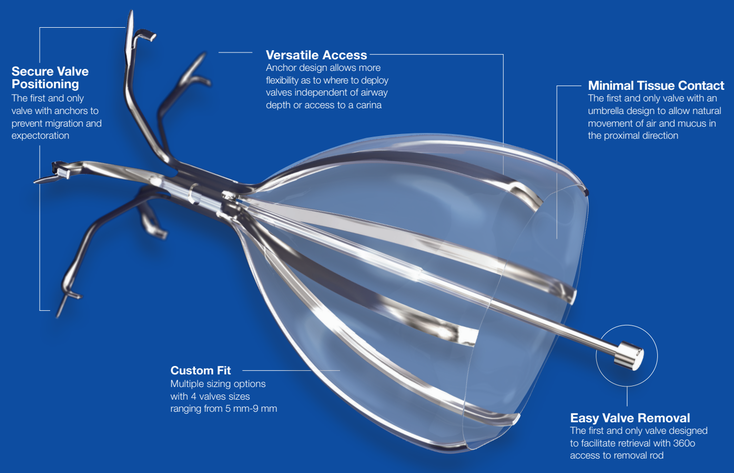


For Treatment of Severe Emphysema

Bronchoscopic Lung Volume Reduction

Emphysema is a progressive, debilitating disease that can have a significant impact on a patient's quality of life. It is difficult for these patients to engage in daily activities due to breathlessness and fatigue. Bronchoscopic Lung Volume Reduction with he Spiration Valve System offers a new minimally-invasive treatment option for severe emphysema patients.

For appropriate patients, the Spiration Valve has been shown in clinical trials to provide clinically meaningful improvements in lung function, shortness of breath, and overall quality of life.[1]

Patient Selection

SeleCT is a completely non-invasive patient screening solution that provides key measures of emphysema severity, fissure integrity and heterogeneity to identify responders for the Spiration Valve treatment.

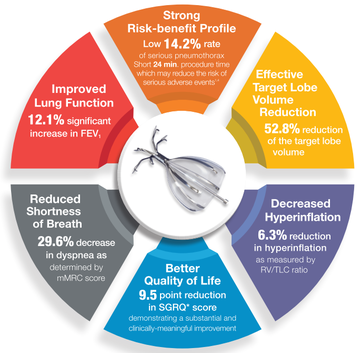
Key quantitative measures to identify responders:

- **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[2,3]
- **FISSURE INTEGRITY**
  EMPROVE trial results confirmed radiographic assessment of fissure completeness to be a reliable surrogate for collateral ventilation

Clinical Benefits

Randomized, controlled clinical trials (RCTs) demonstrate the Spiration Valve is a safe and effective treatment option for patients with severe emphysema and little-to-no collateral ventilation.[1]

> **Recent clinical trials have shown that endobronchial valve treatment is going to become part of the standard of care in patients with advanced emphysema and hyperinflation.**
>
> – Dr. Gerard J. Criner, MD, FACP, FACCP



For Management of Prolonged Air Leaks

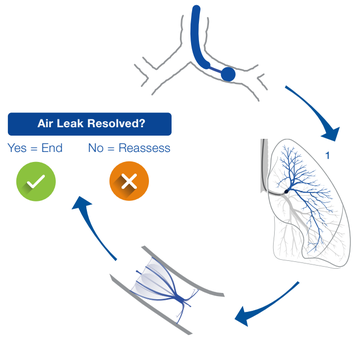
A Minimally Invasive Solution

Since 2008, the Spiration Valve System is the first and only FDA approved endobronchial valve for management of post-surgical prolonged air leaks. Over the past decade, the body of clinical evidence continues to grow for the use of endobronchial valves in management of post-surgical air leaks.

The Spiration Valve bronchoscopic procedure has proven to be a feasible effective, and safe approach that can favorably affect the course of patients with post-pulmonary resection air leaks.[5]

Airway Isolation Method

A systematic approach to locating and isolating air leaks is a critical step to successful treatment.

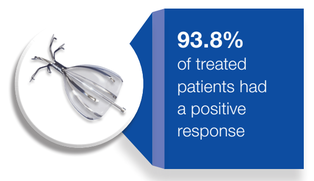


- **ASSESS**
  Block main bronchus to determine if the leak can be stopped or reduced and the length of time it takes to see a change in the water seal monitor.
- **ISOLATE**
  Systematically work from proximal to distal.
- **PLACE VALVE**
  Once an airway is identified, size the airway and place a valve.
- **REASSESS**
  Repeat process to isolate additional leaks as dynamics may have changed since valve placement.**

Clinical Benefits

Traditional "wait and see" approaches can lead to increased length of stay and frustration for both the provider and patient.[6,7]

> **Patients treated with SVS spent a median of four days in the hospital post-treatment, with 93.8% of treated patients having a positive response.**[5]



Spiration® Valve System **Disclaimer Information**

For more information contact your Olympus sales representative or visit our website at svs.olympusamerica.com.

For Treatment of Severe Emphysema:

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.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. In accordance with FDA requirements and the PMA approval, Olympus provides relevant training to HCPs who wish to perform Spiration Valve System procedures for emphysema patients.

Potential Complications: Potential complications which may be associated with bronchoscopy and/or the Spiration Valve System may include, but are not limited to, pneumothorax, worsening of COPD symptoms, hemoptysis, pneumonia, and dyspnea and in rare cases, death.

Contraindications:

- Patient is not 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

Prior to using the Spiration Valve System, please review the full list of prescriptive information at https://svs.olympusamerica.com for additional information on indications, contraindications, warnings, precautions and potential complications.

References:

1. Criner GJ, Delage A, Voelker K, et al. Improving Lung Function in Severe Heterogenous Emphysema with the Spiration Valve System (EMPROVE). A Multicenter, Open-Label Randomized Controlled Clinical Trial. Am J Respir Crit Care Med. 2019 Dec 1; 200(11): 1354–1362. doi: 10.1164/rccm.201902-0383OC
2. Slebos DJ, Shah PL, Herth FJ, et al. Endobronchial Valves for Endoscopic Lung Volume Reduction: Best Practice Recommendations from Expert Panel on Endoscopic Lung Volume Reduction. Respiration. 2017;93(2):138-150
3. Schuhmann M, Raffy P, Yi Y, et al. CT Predictors of Response to Endobronchial Valve Lung Reduction Treatment: Comparison with Chartis. Am J Respir Crit Care Med 2015; 191(7):767-774; doi:10.1164/rccm.201407-1205OC.
4. 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.0000000000000110
5. Abu-Hijleh M, Styrvoky K, Anand V, et al. Intrabronchial Valves for Air Leaks After Lobectomy, Segmentectomy, and Lung Volume Reduction Surgery. Lung, 2019: 197, 627-633.
6. Mahajan AK, Doeing DC, Hogarth DK. Isolation of persistent leaks and placement of intrabronchial valves. J Thorac Cardiovasc Surg 2013;145:626-30.
7. Dooms C, et al. Bronchial valve treatment for pulmonary air leak after anatomical lung resection for cancer. Eur Respir J 2014; 43: 1142-1148.

For Management of Prolonged Air Leaks:

INDICATION FOR USE: The Spiration Valve System is a device to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). An air leak present on post- operative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: 1) continuous, 2) present during normal inhalation phase of inspiration, or 3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. Spiration Valve System use is limited to 6 weeks per prolonged air leak.

CAUTION: Humanitarian Use Device. Authorized by Federal law for use in the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). The effectiveness of this device for this use has not been demonstrated. Federal law restricts this device to sale by or on the order of a physician.

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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.

** Treatment should be limited to no more than 3 segments by placing valves in segmental or sub-segmental bronchi in the target lung to avoid excessive isolation of tissue from ventilation.

Manufactured by Gyrus ACMI, Inc. as successor-in-interest to: Spiration, Inc d/b/a Olympus Respiratory America 6675 185th Avenue N.E. Redmond WA 98052

Specifications, design and accessories are subject to change without any notice or obligation on the part of the manufacturer.

Spiration Valve is a humanitarian use device.

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

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