

SPIRATION[®] VALVE SYSTEM CLINICAL OVERVIEW

Endobronchial Valve Therapy
for Treatment of Emphysema

Table of Contents

Publications for the Spiration® Valve System for Treatment of Severe Emphysema

- **Unilateral Treatment Studies Using HRCT Scans for Patient Selection** 4
 - Late Breaking Abstract – Endobronchial Valves for Severe Emphysema – 12-month Results of the EMPROVE Trial 5
 - Evaluation of the Safety and Effectiveness of the Spiration® Valve System for Single Lobe Treatment of Severe Emphysema in Patients with Alpha-1 Antitrypsin Deficiency 6
 - The REACH Study: A Randomized Controlled Trial Assessing the Safety and Effectiveness of the Spiration® Valve System Intra-Bronchial Therapy for Severe Emphysema 7

- **Unilateral Versus Partial Bilateral Treatment Study** 8
 - Complete Unilateral vs Partial Bilateral Endoscopic Lung Volume Reduction in Patients with Bilateral Lung Emphysema 9

- **Bilateral Partial Treatment Studies** 10
 - The IBV Valve Trial: A Multicenter, Randomized, Double-Blind Trial of Endobronchial Therapy for Severe Emphysema (IBV Pivotal I) 11
 - Multicentre European Study for the Treatment of Advanced Emphysema with Bronchial Valves (Euro IBV Bilateral) 12

- **Spiration Valve Pilot Studies** 13
 - A Multicenter Trial of an Intrabronchial Valve for Treatment of Severe Emphysema 14
 - Computed Tomography Assessment of Lung Volume Changes After Bronchial Valve Treatment 15
 - A Multicenter Pilot Study of a Bronchial Valve for the Treatment of Severe Emphysema (IBV Pilot) 16
 - Treatment of Heterogeneous Emphysema Using the Spiration® IBV Valves 17

Unilateral Treatment Studies Using HRCT Scans for Patient Selection

A decade of clinical studies has identified appropriate patient selection to be one of the most important predictive factors of an effective response to bronchoscopic lung volume reduction (BLVR) and helped define proper criteria.

A thorough patient evaluation, examination for any comorbidities, and an analysis of the patient's high-resolution computer tomography (HRCT) information as well as quantitative computed tomography (QCT) results are critical to successful outcomes.

The following trials used HRCT scans to select patients who should benefit from endobronchial valve therapy. These studies have shown that endobronchial valves provide statistical and clinically meaningful improvements in lung function, dyspnea, and overall quality of life for patients suffering from severe emphysema.

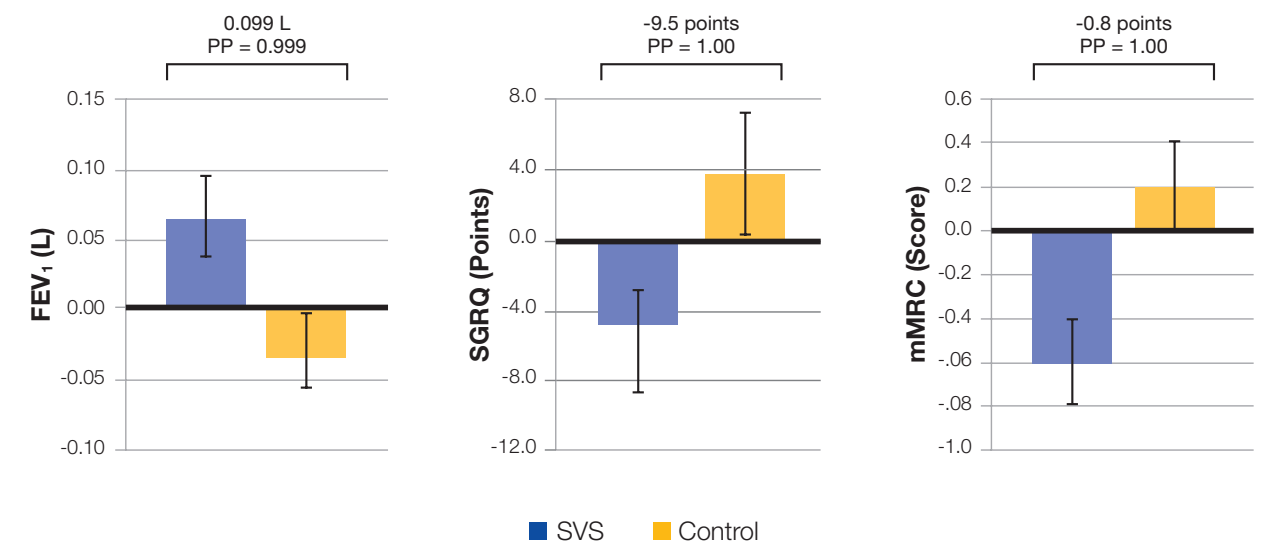
Late Breaking Abstract – Endobronchial Valves for Severe Emphysema – 12-month Results of the EMPROVE Trial

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.

■ **Abstract:** We report 12-month endpoint results of the EMPROVE study, a multicenter, randomized controlled trial that assessed safety and effectiveness of the Spiration® Valve System (SVS) compared to standard medical care in patients with severe emphysema.

172 subjects with hyperinflation and severe dyspnea without interlobar collateral ventilation determined by HCRT were randomized (2:1) to either treatment (SVS valves and medical management, N=113) or control (medical management alone, N=59).

Target lobe treatment, based on high resolution computed tomography (HRCT) was 70% upper lobe and 30% lower lobe resulting in a mean target lobe volume reduction of 53%. Lung function, disease specific health status and dyspnea scores reached statistical and clinically meaningful difference between the study groups.



Mean \pm 95% Bayesian Credible Interval, PP = Posterior Probability; SGRQ – St. George's Respiratory Questionnaire, mMRC – Modified Medical Research Council dyspnea score.

Through 12-months, 16.9% of control group patients had thoracic serious adverse events compared to 38.9% of the treatment group. Early onset pneumothorax rate (14.2%), a recognized marker for target lobe volume reduction was the main adverse event in the treatment group.

This study demonstrates that selecting patients for bronchoscopic lung volume reduction by HRCT assessment results in durable effectiveness through 12 months.

Unilateral Treatment Studies Using HRCT Scans for Patient Selection

Evaluation of the Safety and Effectiveness of the Spiration® Valve System for Single Lobe Treatment of Severe Emphysema in Patients with Alpha-1 Antitrypsin Deficiency

Hogarth DK, Delage A, Zgoda MA, Reed MF. Evaluation of the Safety and Effectiveness of the Spiration Valve System for Single Lobe Treatment of Severe Emphysema in Patients with Alpha-1 Antitrypsin Deficiency. In: C24. NEW TECHNOLOGIES FOR MANAGING COPD. American Thoracic Society International Conference Abstracts. American Thoracic Society; 2018:A7754-A7754. doi:10.1164/ajrccm-conference.2018.197.1_MeetingAbstracts.A7754.

- Rationale:** Alpha-1 Antitrypsin Deficiency (AATD) an inherited disorder raises the risk for lung disease and can often lead to emphysema. Many of these patients have severe gas trapping and limited exercise due to dyspnea. We report on the 6-month results of the AATD arm of the EMPROVE study, a multicenter, prospective, randomized controlled trial undertaken at 31 centers in US and Canada to assess the safety and effectiveness of the Spiration® Valve System (SVS) compared to standard medical care in patients with severe emphysema.
- Methods:** AATD patients with severe airflow obstruction, hyperinflation, and severe dyspnea without interlobar collateral ventilation were evaluated for enrollment in a separate treatment arm of the EMPROVE trial. A total of 20 AATD subjects already on optimal medical management were treated with SVS valves at 12 centers.
- Results:** Target lobe selection, based on high resolution computed tomography (HRCT) identified a lower lobe in 85% and an upper lobe in 15% of patients. A mean of 4.4 valves per patient were used to isolate the target lobe, with an average procedure time of 20 minutes. Through the 6-month primary study endpoint follow-up, there were statistical improvements in FEV₁, Target Lobe Volume (TLV) and disease specific quality of life measures – St. George's Respiratory Questionnaire (SGRQ), modified Medical Research Council dyspnea score (mMRC), and COPD Assessment Test (CAT).

Results					
	FEV ₁	TLV (L)	SGRQ (points)	mMRC Score	CAT Score
Baseline	0.87 ± 0.21	1.83 ± 0.45	55.2 ± 16.0	2.5 ± 0.7	20.9 ± 6.6
Change at Six Months	0.11 ± 0.17	-1.16 ± 0.84	-14.3 ± 12.9	-0.8 ± 1.1	-5.1 ± 5.5

- Mean ±SD:** Through 6-months, there was one death. Six (30%) of the AATD group (including the patient who died) had procedure/device related serious adverse events, consisting of acute COPD exacerbations (10%), pneumonia (5%), and pneumothorax (15%), with early onset pneumothorax resulting from acute reduction in lung volume due to valve therapy being a recognized indicator of target lobe occlusion.
- Conclusions:** This AATD sub-study arm of the EMPROVE Trial showed that implantation of the Spiration Valve System in patients with severe emphysema provides statistical improvements in FEV₁, target lobe volume reduction and quality of life parameters, with a good safety profile in this underserved patient population.

The REACH Trial: A Randomized Controlled Trial Assessing the Safety and Effectiveness of the Spiration® Valve System in the Treatment of Severe Emphysema

Li S, Wang G, Wang, C, et al. The REACH Trial: A Randomized Controlled Trial Assessing the Safety and Effectiveness of the Spiration® Valve System in the Treatment of Severe Emphysema. Respiration. 2018. doi:10.1159/000494327.

- Background:** Chronic obstructive pulmonary disease (COPD) has become a leading cause of morbidity and mortality in China, with tobacco smoke, air pollution, and occupational biohazards being the major risk factors.
- Objectives:** The REACH trial is a multicenter, prospective, randomized controlled trial undertaken in China to assess the safety and effectiveness of the Spiration® Valve System (SVS) compared to standard medical care in COPD patients with severe emphysema.
- Methods:** Patients with severe airflow obstruction, hyperinflation, and severe dyspnea with interlobar fissure integrity were evaluated for enrollment. A total of 107 subjects were randomized in a 2:1 allocation ratio to either the treatment group (SVS valves and medical management) or the control group (medical management alone).
- Results:** The 3-month primary endpoint showed statistically significant improvement in forced expiratory volume in 1 s in the treatment group compared to the control group (0.104 ± 0.18 vs. 0.003 ± 0.15 L, p = 0.001), with the difference being durable through 6 months. Statistically significant target lobe volume reduction was achieved at 3 months (mean change 684.4 ± 686.7 mL) and through 6 months (757.0 ± 665.3 mL). Exercise function and quality of life measures improved in the treatment group, but showed a deterioration in the control group. The serious adverse event (SAE) rate was 33% in the treatment group and 24.2% in the control group. The predominance of SAEs were acute exacerbations of COPD in both groups. There was 1 death in the control group and no deaths in the treatment group.
- Conclusions:** The SVS represents a novel approach for the treatment of severe emphysema with a clinically acceptable risk-benefit profile.

Unilateral Versus Partial Bilateral Treatment Study

Treatment approaches for bronchoscopic lung volume reduction (BLVR) included either bilateral therapy with partial lobar occlusion or a unilateral treatment with complete lobar occlusion. Previous single-lobe valve treatment studies targeting unilateral occlusion has shown clinically meaningful improvements in patient's lung function and quality of life. The following study compares unilateral and bilateral treatment modalities and attempts to establish patient selection criteria to improve clinical outcomes from BLVR.

Complete Unilateral vs Partial Bilateral Endoscopic Lung Volume Reduction in Patients with Bilateral Lung Emphysema

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.

- **Background:** Intrabronchial valve placement for endoscopic lung volume reduction is used for patients with severe lung emphysema. Different treatment approaches are unilateral valve placement with the goal of complete occlusion and subsequent atelectasis leading to true volume reduction vs bilateral partial closure aiming for redistribution of ventilation but avoiding atelectasis. In this prospective pilot trial, we compared the efficacy of these treatment approaches.
- **Methods:** Patients with severe bilateral heterogeneous emphysema were randomized to two groups. In the first group, patients received unilateral valves aiming for total occlusion of one lobe. In the other group, valves were placed in two contra-lateral lobes with incomplete closure. In all cases, one-way valves were placed via a flexible bronchoscope. Patients were followed at 30 and 90 days, end points being change in pulmonary function tests (PFTs), 6-min walk distance (6MWD), and dyspnea score as measured by the modified Medical Research Council (mMRC) dyspnea score, as well as quality of life as measured by the St. George Respiratory Questionnaire (SGRQ).
- **Results:** Twenty-two patients were treated in this study, 11 patients in each arm. At 30 days and 90 days, significant differences were seen in PFT and 6MWD, as well as in mMRC and SGRQ scores, in favor of unilateral treatment. At 90 days, FEV₁ was improved by 21.4% ± 10.7% in this group, but not in the bilateral group (20.03% ± 13.9%, P 5 .002). One patient in the unilateral group experienced a pneumothorax, and two patients in the bilateral group were treated for transient respiratory failure.
- **Conclusions:** Future studies should estimate the presence of collateral ventilation based on CT scan analysis and/or bronchoscopic measurements to predict the likelihood of volume reduction and improve the outcome of treated patients. Unilateral intrabronchial valve placement with complete occlusion appears superior to bilateral partial occlusion.

Bilateral-Partial Treatment Studies

The goal of bilateral-partial endobronchial valve treatment was to redistribute ventilation by avoiding atelectasis. Clinical data suggests that this procedure may result in significant lung volume shifts in both upper lobes of patient with severe emphysema¹.

Reference:

1. The IBV Valve trial: a multicenter, randomized, double-blind trial of endobronchial therapy for severe emphysema. Douglas E. Wood, Daniel A. Nader, Steven C. Springmeyer, Mark R. Elstad, Harvey O. Coxson, Andrew Chan, Navdeep S. Rai, Richard A. Mularski, Christopher B. Cooper, Robert A. Wise, et al. J Bronchology Interv Pulmonol. 2014 Oct; 21(4): 288–297. doi: 10.1097/LBR.000000000000110

The IBV Valve Trial: A Multicenter, Randomized, Double-Blind Trial of Endobronchial Therapy for Severe Emphysema (IBV Pivotal I)

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.

- **Background:** Lung volume reduction surgery improves quality of life, exercise capacity, and survival in selected patients but is accompanied by significant morbidity. Bronchoscopic approaches may provide similar benefits with less morbidity.
- **Methods:** In a randomized, sham procedure controlled, double-blind trial, 277 subjects were enrolled at 36 centers. Patients had emphysema, airflow obstruction, hyperinflation, and severe dyspnea. The primary effectiveness measure was a significant improvement in disease-related quality of life (St. George's Respiratory Questionnaire) and changes in lobar lung volumes. The primary safety measure was a comparison of serious adverse events.

Computed tomography (CT) and lung perfusion scans were visually assessed for upper lobe (UL) predominant emphysema for patient selection.
- **Results:** There were 6/121 (5.0%) responders in the treatment group at 6 months, significantly >1/134 (0.7%) in the control group [Bayesian credible intervals (BCI), 0.05%, 9.21%]. Lobar volume changes were significantly different with an average decrease in the treated lobes of -224mL compared with -17mL for the control group (BCI, -272, -143). The proportion of responders in St. George's Respiratory Questionnaire was not greater in the treatment group. There were significantly more subjects with a serious adverse event in the treatment group (n=20 or 14.1%) compared with the control group (n=5 or 3.7%) (BCI, 4.0, 17.1), but most were neither procedure nor device related.
- **Conclusions:** Bilateral-partial bronchial valve occlusion resulted in significant lung volume shifts in both upper lobes of patients with severe emphysema. However, the lobar volume shift of 200mL was not accompanied by an improvement in health-related quality of life as seen previously. This trial had technical and statistical success but partial-bilateral Endobronchial valve occlusion did not obtain clinically meaningful results. Safety results were acceptable and compare favorably to lung volume reduction surgery and other bronchial valve studies. Further studies need to focus on improved patient selection and a different treatment algorithm.

Bilateral-Partial Treatment Studies

Multicentre European Study for the Treatment of Advanced Emphysema with Bronchial Valves (Euro IBV Bilateral)

Ninane V, Geltner C, Bezzi M, et al. Multicentre European study for the treatment of advanced emphysema with bronchial valves. *Eur Respir J*. 2012;39(6):1319-1325. doi:10.1183/09031936.00019711.

- **Background:** The IBV Valve has been successfully used in 91 patients in a pilot study demonstrating clinical improvements in both lung volumes and health status outcomes. In this pilot study, an association between lobar atelectasis and pneumothorax, and deaths related to pneumothorax was described. The European study reported here is the first blinded, controlled evaluation of any bronchial valve therapy in advanced emphysema. Response to treatment was based on a composite end-point of health status as measured by the St George's Respiratory Questionnaire (SGRQ) and regional lung volume changes as measured by quantitative computed tomography (CT).
- **Design:** This was a prospective, randomized, multicentre, single-blinded, sham-controlled study performed to assess the safety and effectiveness of bronchial valve therapy using a bilateral upper lobe treatment approach without the goal of lobar atelectasis.
- **Methods:** Patients with upper lobe predominant severe emphysema were randomised to bronchoscopy with (n=37) or without (n=36) IBV Valves for a 3-month blinded phase. At 3 months, treatment assignment was unblinded and subjects on valve therapy were evaluated for a further 3 months. Eligible subjects in the control group could then receive bronchial valves un-blinded, and were then followed-up for 3 months.
- **Results:** A positive responder was defined as having both a ≥ 4 -point improvement in St George's Respiratory Questionnaire (SGRQ) and a lobar volume shift as measured by quantitative computed tomography. The study outcome measure showed a highly significant difference between treatment and control groups. At 3 months, there were eight (24%) positive responders in the treated group versus none (0%) in the control group ($p=0.002$). Also, there was a significant shift in volume in the treated group from the upper lobes (mean \pm SD $-7.3 \pm 9.0\%$) to the nontreated lobes ($6.7 \pm 14.5\%$), with minimal change in the control group ($p<0.05$). Mean SGRQ total score improved in both groups (treatment: -4.3 ± 16.2 ; control: -3.6 ± 10.7).
- **Conclusions:** The procedure and devices were well tolerated and there were no differences in adverse events reported in the treatment and control groups. Treatment with bronchial valves without complete lobar occlusion in both upper lobes was safe, but not effective in the majority of patients. These data suggest that additional studies are warranted to better identify the subgroup with a treatment response, to evaluate other bronchial valve treatment modalities and to improve patient selection criteria to achieve broader effectiveness.

Spiration® Valve Pilot Studies

The following are the first clinical trials that studied endobronchial valves with the Spiration Valve System for treatment of patients with severe emphysema. These trials designated the baseline data for future studies and established the basis for safety and effectiveness for this device.

A Multicenter Trial of an Intrabronchial Valve for Treatment of Severe Emphysema

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.

- **Objective:** Minimally invasive endoscopic treatment of emphysema could provide palliation with less risk than lung volume reduction surgery and offer therapy to patients currently not considered for lung volume reduction surgery. The Intrabronchial Valve is used to block bronchial airflow in the most emphysematous areas of lung.
- **Methods:** Patients with severe chronic obstructive pulmonary disease and heterogeneous upper lobe-predominant emphysema were eligible. Patients underwent flexible bronchoscopic placement of valves into segmental or subsegmental airways in both upper lobes. Outcomes assessed over a minimum of 6 months of follow-up included the safety, feasibility, tolerance, and success of valve placement; health-related quality of life; exercise capacity; pulmonary function; and gas exchange.
- **Results:** Five centers treated 30 patients. Patient follow-up ranged from 1 to 12 months. A mean of 6.1 valves were placed per patient. Valves were positioned by means of flexible bronchoscopy in 99% of desired airways, and the procedure duration ranged from 15 to 125 minutes (mean, 65 minutes). Hospital discharge occurred within 2 days in 27 of 30 patients. There were no deaths or episodes of valve migration, tissue erosion, or significant bleeding. Eighty-three percent of patients had no adverse events judged probably or definitely related to the device. Patients experienced significant improvement in health-related quality of life, although the physiologic and exercise outcomes did not show statistically significant improvements.
- **Conclusions:** These first multicenter results with the Intrabronchial Valve demonstrate significant improvements in health-related quality of life and acceptable safety, ease of use, and procedural complication rates. The valve might be a safer and less-invasive alternative to surgical therapy for patients with severe emphysema.

Computed Tomography Assessment of Lung Volume Changes After Bronchial Valve Treatment

Coxson HO, Nasute Fauerbach PV, Storness-Bliss C, et al. Computed tomography assessment of lung volume changes after bronchial valve treatment. *Eur Respir J*. 2008;32(6):1443-1450. doi:10.1183/09031936.00056008.

- **Abstract:** The aim of the present study was to correlate clinical outcome measures following treatment with bronchial valves with regional lung volume. Computed tomography (CT) scan data from 57 subjects with severe emphysema were obtained from nine North American clinical trial sites. IBV(R) Valves (Spiration, Inc., Redmond, WA, USA) were placed to occlude segmental and subsegmental bronchi in right and left upper lobes using a flexible bronchoscope. Subjects completed a St George's Respiratory Questionnaire (SGRQ), pulmonary function test (PFT) and exercise capacity test. CT scans were analysed at baseline and at 1, 3 or 6 months after treatment to measure total and lobar lung density, volume and mass. Total lung volumes measured using CT were strongly correlated with PFT and did not change with treatment. However, the treated upper lobes significantly decreased in volume in 88% of the observations, by mean+/-sd 335+/-444 mL, or a decrease of 10.2% in the 6 month data. The untreated lobes had an 11.6% increase in volume. Changes in regional lung volume were associated with clinically meaningful improvements in SGRQ (-8.95+/-16.22), but not clinically meaningful PFT changes. The significant health status improvements reported by subjects following bilateral bronchial valve treatment are associated with regional lung volume changes and interlobar shift measured using computed tomography.

A Multicenter Pilot Study of a Bronchial Valve for the Treatment of Severe Emphysema (IBV Pilot)

Sterman DH, Mehta AC, Wood DE, et al. A multicenter pilot study of a bronchial valve for the treatment of severe emphysema. *Respiration*. 2010;79(3):222-233. doi:10.1159/000259318.

- **Background:** Chronic obstructive pulmonary disease (COPD) affects millions of people and has limited treatment options. Surgical treatments for severe COPD with emphysema are effective for highly selected patients. A minimally invasive method for treating emphysema could decrease morbidity and increase acceptance by patients.
- **Methods:** A multicenter study treated 91 patients with severe obstruction, hyperinflation and upper lobe (UL)-predominant emphysema with 609 bronchial valves placed bilaterally into ULs.
- **Results:** Valves were placed in desired airways with 99.7% technical success and no migration or erosion. There were no procedure-related deaths and 30-day morbidity and mortality were 5.5 and 1.1%, respectively. Pneumothorax was the most frequent serious device-related complication and primarily occurred when all segments of a lobe, especially the left UL, were occluded. Highly significant health-related quality of life (HRQL) improvement (-8.2 +/- 16.2, mean +/- SD change at 6 months) was observed. HRQL improvement was associated with a decreased volume (mean -294 +/- 427 ml, p = 0.007) in the treated lobes without visible atelectasis. FEV₁, exercise tests, and total lung volume were not changed but there was a proportional shift, a redirection of inspired volume to the untreated lobes. Combined with perfusion scan changes, this suggests that there is improved ventilation and perfusion matching in non-UL lung parenchyma.
- **Conclusions:** Bronchial valve treatment of emphysema has multiple mechanisms of action and acceptable safety, and significantly improves quality of life for the majority of patients.

Treatment of Heterogeneous Emphysema Using the Spiration® IBV Valves

Springmeyer SC, Bolliger CT, Waddell TK, Gonzalez X, Wood DE, IBV Valve Pilot Trials Research Teams. Treatment of heterogeneous emphysema using the spiration IBV valves. *Thorac Surg Clin*. 2009;19(2):247-253, ix-x. doi:10.1016/j.thorsurg.2009.02.005.

- **Abstract:** Ninety-eight emphysema patients were treated at 13 international sites during a 3-year series of single-arm, open-label studies with the IBV valve and a multi-lobe treatment approach. Fifty six percent of subjects had a clinically meaningful improvement in health-related quality of life, but standard pulmonary function and exercise studies were insensitive effectiveness measures. Quantitative CT analyses of regional lung changes showed lobar volume changes in over 85% of subjects. Lung volume reduction was an uncommon mechanism for a treatment response with bilateral upper lobe treatment. A redirection of inspired air, an interlobar shift to health-ier lung tissue, was the most common mechanism for a valve treatment response.

Spiration® Valve System

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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