OLYMPUS®

Spiration® Valve System (SVS)

Patient Management Recommendations

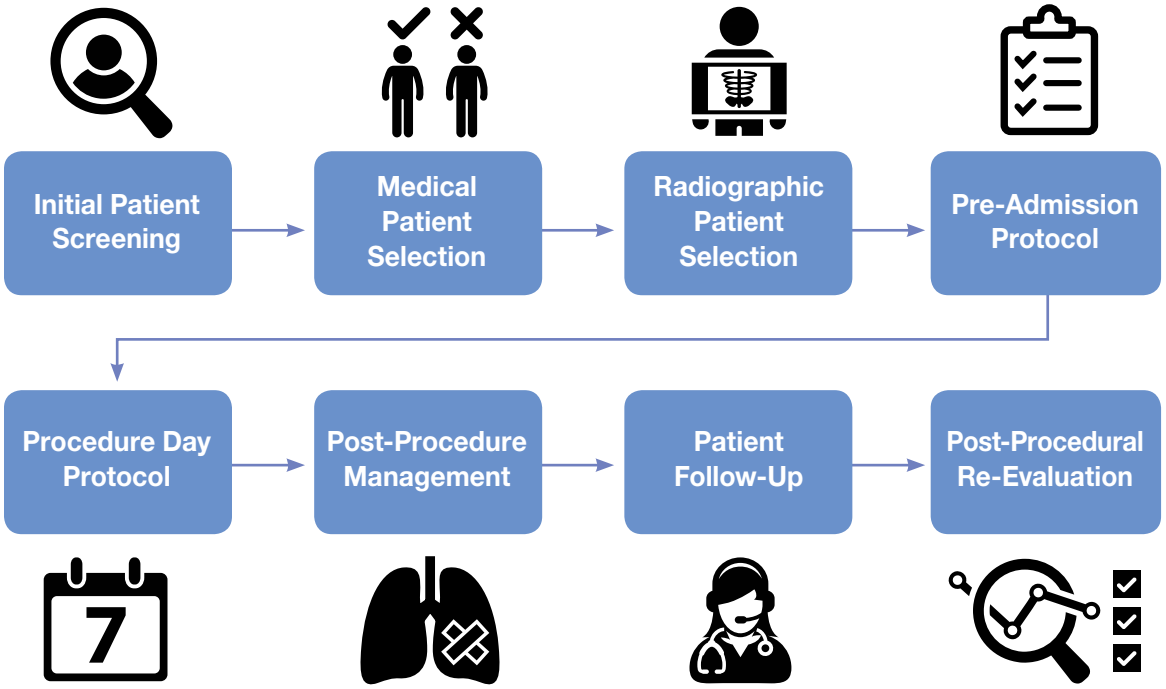
Patient Management Recommendations

Overview

Proper patient management is of the utmost importance for endobronchial valve treatment. Due to the complexity of this procedure, each step of the patient management process, from the initial patient screening to the post-procedure re-evaluation, requires a thorough assessment to ensure successful outcomes.

Patient Process

The information provided in this guide is based upon findings established by the EMPROVE clinical trial in combination with clinical subject matter expert's recommendations. This information is not meant to replace patient-specific clinical judgment. The following patient management workflow is recommended for optimal procedure results:



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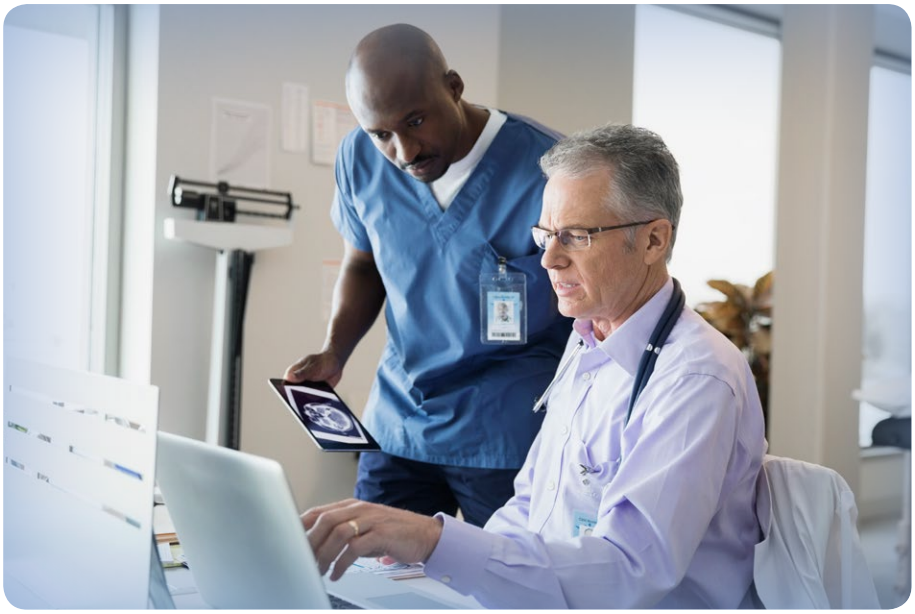
Initial Patient Screening

Medical History and Physical Exam

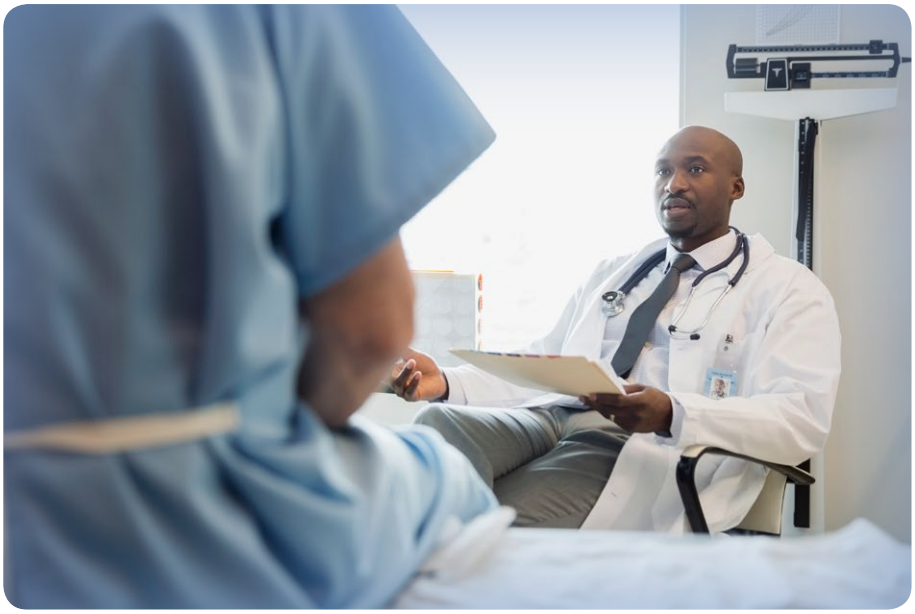
- Patient is 18 years of age or older
- Patient is not an active smoker
- Patient has GOLD stage III or IV COPD (emphysema)
- Patient has a BMI > 15 and < 35 kg/m^2
- Patient is on optimized medical management
- Patient has had no prior, ipsilateral lung volume reduction surgery or major lung procedures (e.g. lobectomy, segmentectomy, transplant)
- **Pulmonary function testing**
  - Spirometry (Post-BD)
    - FEV_1 > 15 and ≤ 45%
    - If change in FEV_1 > 200mL post-bronchodilator, patient not considered a good candidate for valve therapy
  - Body Plethysmography
    - RV ≥ 150%
    - TLC ≥ 100%
  - DLCO
    - Should be > 20%



Medical Patient Selection

Medical Work-Up

- Patient must perform a 6-minute walk distance of ≥ 100m
- Patient must have severe dyspnea which is defined as a mMRC ≥ 2
- Patient meets the criteria of the ATS/ERS Guidelines for Management of Stable COPD
- Complete medical history to rule out patient has no co-existing major medical disease, alcoholism, or drug abuse. This includes neurological or musculoskeletal conditions that may interfere with patient selection testing
- Patient does not have clinically significant bronchitis
- Patient does not have an active asthma component to their disease or requires more than 20 mg of prednisone daily
- Patient has had a complete cardiac workup including evaluation for severe pulmonary hypertension based (Pa pressure > 50 mmHg)
- Patient is classified as ASA Class greater than P4 including presence of co-morbidity that could significantly increase the risk of a bronchoscopy procedure
- Assess patient for Alpha-1 antitrypsin deficiency
- **Arterial Blood Gas level**
  - Collected on room air, discontinue supplemental O_2 for 10 minutes prior to sampling if needed
  - $PaCO_2$ < 55 mm HG
  - PaO_2 > 45 mm HG



Radiographic Patient Selection

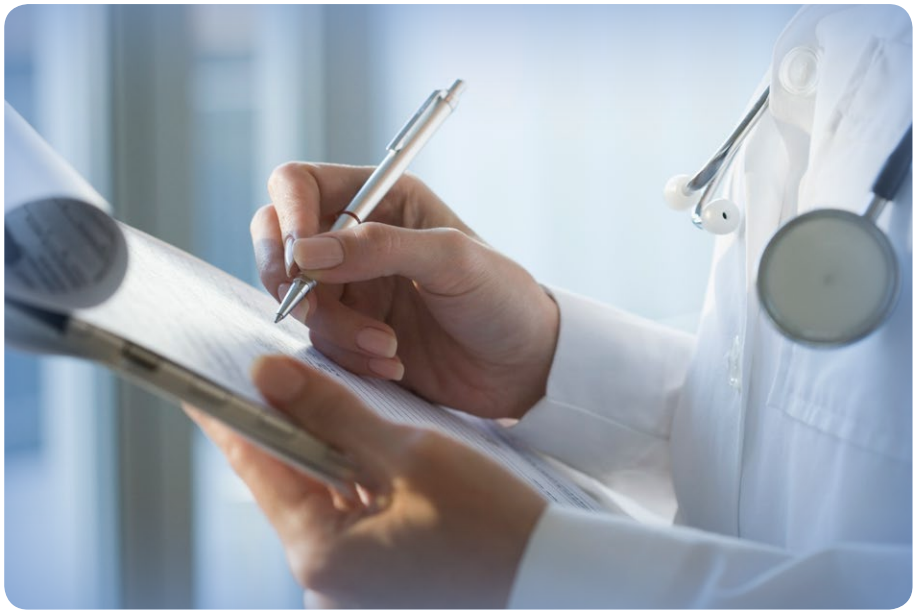
Radiographic Assessment

- Presence of any lung nodule or other clinically significant radiographic findings have been ruled out or treated
- Verify that there is no giant bulla (> 30% volume in either lung) present
- Based on the EMPROVE clinical trial result the patient should meet the following criteria:
  - Patient should have severe emphysema and high heterogeneity (measured at -920 HU) defined as:
    - A target lobe with ≥ 40% emphysema involvement
    - ≥ 10 percentage points disease severity difference with the ipsilateral lobe
  - Patients target lobe and ipsilateral lobe will be separated with an intact fissure
    - An intact fissure will be estimated visually to be ≥0 90% complete with no segmental vessels crossing from one lobe to the adjacent lobe after viewing the HRCT in 3 dimensions (use of the SeleCT report is the preferred method for determining fissure completeness)
  - Patient does not have a diffuse pattern of emphysema
- Perfusion Analysis (at physician's discretion)
  - Help to determine target lobe
  - Target the lobe with the lowest perfusion

Pre-Admission Protocol

Additional Tests Done within 30 Days of Procedure

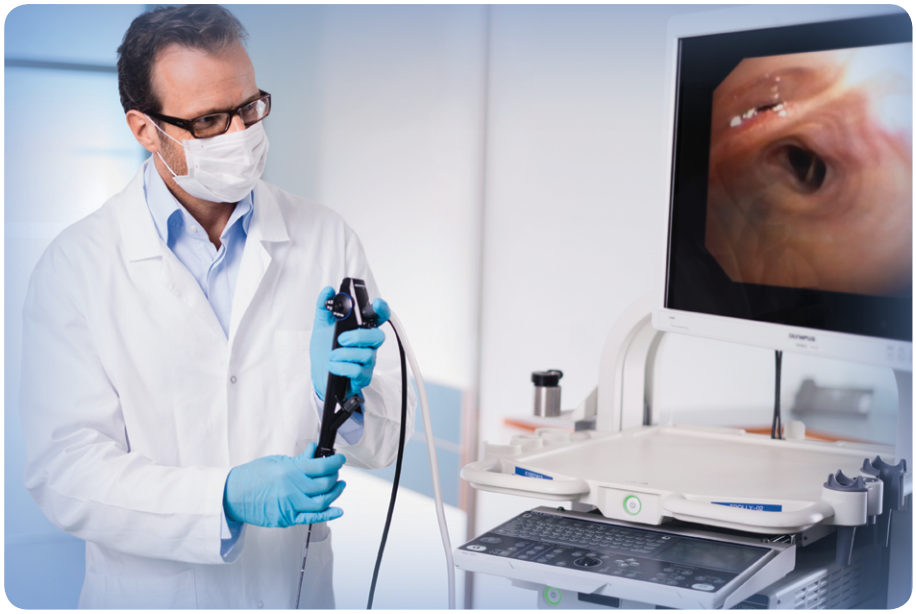
- Verify H&P is current
- Verify smoking cessation > 4 months
- Required lab work
  - CBC
  - Chem 7
  - PT/PTT/INR (at physician's discretion)
    - If patient is on anticoagulant, it should be confirmed with the primary care physician or cardiologist that anticoagulants have been safely stopped 5-7 days before procedure
- Patient has had no hospitalizations for COPD exacerbation or respiratory infections in the past 3 months
- **Cardiopulmonary assessment**
  - Oxygenation and ventilation
    - Oxygen saturation at rest and exercise
    - Arterial blood gas
    - Use of CPAP or BiPAP
  - Cardiac function
    - Echocardiogram
      - No congestive heart failure (LVEF < 45%)
    - Pulmonary hypertension
      - sPAP > 50mmHg on right heart catheterization



Procedure Day Protocol

Endobronchial Valve Treatment Preparations

- Prophylactic antibiotics and steroids (at physician's discretion)
  - Decreases incidence of AECOPD or Infection
  - Day of procedure and continue for 5 days
- Provide nebulized bronchodilators 20 minutes prior to case
  - Albuterol/Ipratropium bromide
- Consider a decrease in tidal volume by 20% after last valve placement to avoid non-targeted lobe overdistention until spontaneous ventilation resumes
- Provide post-procedural bronchodilators immediately after procedure in recovery area and then every 4–6 hours as needed
- **Anesthesia concerns**
  - ASA statement on NORA locations
    - Adequate space for all equipment and personnel
    - Reliable oxygen source and backup supply
    - Adequate and reliable suction source should meet OR standards
    - If inhaled anesthetics used, reliable scavenging system for waste anesthesia gases
    - Adequate illumination
    - Adequate electrical outlets with emergency backup power
    - Standard and emergency anesthesia supplies and drugs
    - Code cart and defibrillator
    - Back-up manual ventilation equipment



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Procedure Day Protocol (continued)

Endobronchial Valve Treatment Preparations

- Monitoring equipment that meets ASA standards
  - ECG continuously displayed
  - SpO_2 with audible tone with pitch determined by SpO_2
  - End-tidal carbon dioxide
  - BP at least every 5 minutes
  - Mechanical ventilator or anesthesia machine must have audible disconnect alarm
  - Temperature (ability to monitor if needed)

- General anesthesia (GA) vs. sedation, based on:
  - Both are acceptable
  - GA is more common and recommended
  - Determination of GA vs. sedation
    - Local preference and experience
    - Pre-anesthesia patient evaluation

- General Anesthesia
  - Total Intravenous Anesthesia (TIVA)
    - Does not require anesthesia machine
    - May be easier to implement in an endoscopy suite
    - Use of short acting medication can result in quick emergence with minimal hangover effect
    - If no anesthesia machine, a standard ventilator can be used
    - Requires one of more infusion pumps
  - Possible Anesthesia Options
    - Propofol
    - Opioid
    - Remi-fentanyl
    - Fentanyl
    - Sufentanil
    - Topical Anesthesia – 1% lidocaine
    - Others: Dexmedetomidine and ketamine

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Procedure Day Protocol (continued)

Endobronchial Valve Treatment Preparations

- Inhalational anesthetic
  - Volatile agents cause bronchodilation
  - Reliable
  - Easy to titrate
  - Requires use of an anesthesia machine and scavenging of waste anesthesia gases
  - Insertion/removal of bronchoscope, airway suction
  - possible fluctuating levels of anesthesia
  - potential pollution of room
- Airway Management
  - Endotracheal tube
    - Reliable oxygenation and ventilation
    - Minimum size 8 mm preferable 8.5–9 mm (air leaks require a minimum of 8.5 mm)
- Neuromuscular Blockade
  - Used to facilitate trachael intubation during induction of anesthesia
- Topical anesthesia
  - Will decrease cough and anesthetic requirements
- Anticholinergics may decrease secretions
  - Glycopyrrolate or atropine
  - May increase risk of tachyarrhythmias or urinary retention

■ Sedation

- Level of monitoring the same as GA
- Topical anesthesia
  - Upper airway
  - Tracheobronchial tree
- Technique
  - Benzodiazepines
  - Opioids (fentanyl, sufentanil, remifentanil)
  - Propofol
  - Dexmedetomidine
  - Ketamine
- Plan for managing apnea/hypoventilation

Post-Procedure Management

Pneumothorax Management

- Monitoring for pneumothorax
  - Chest x-ray
    - Within 4 hours of procedure
    - Daily until discharge
  - Chest ultrasound
    - Optional, if local expertise present
    - Immediate post-procedure assessment for lobar occlusion and check for lung sliding. In absence of sliding, re-inspection before waking up the patient
  - Chest CT scan
    - Low threshold for CT imaging if pneumothorax is suspected and patient has rapid major lobar collapse to rule out associated PTX
- Pneumothorax cart/tray should always be in patient room after the procedure
  - Always be prepared to place a chest tube within 15-30 minutes during hospital stay
  - Needle/catheter for needle decompression (16Ga)
  - Seldinger chest tubes 14Fr
  - Surgical chest tubes and tray 20–28Fr for “open” chest tubes
  - Gloves, scalpel, suture, dressing materials, pleuro vac

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Post-Procedure Management (continued)

Post-Operative Day 0

- Hospital admission
  - Hospital stay is based upon physician's discretion and should be considered if there is a persistent chest discomfort or pain on the treated side
- Place patient on telemetry monitoring and pulse oximetry
- Supplemental oxygen to maintain SpO_2 >92%
- Maintain bedrest
- Nebulized Ipratropium/Albuterol q4h, prn
- Restart home medications, LAMA/LABA/ICS
- DVT prophylaxis

Post-Operative Day 1–3

- Daily morning portable chest x-ray
- Day #1 ambulate in room with bathroom privileges
- Day #2-3 ambulate in hallway with PT assistance with telemetry
- Monitor for complications
  - Pneumothorax
  - COPD exacerbation symptoms
  - Valve settling
  - Rapid targeted lobe atelectasis
    - Consider obtaining a chest CT to rule out early minor pneumothorax
  - Increasing hypoxemia
    - Rule out pneumothorax
    - AECOPD
    - PNA
    - Airway kinking
    - CHF
    - Alveolar hemorrhage
    - Re-expansion edema of ipsilateral non-targeted lobe
    - Consider HFNC or NIV
    - Consider ICU care
- Increasing CO_2 retention
  - Rule out AECOPD
    - Increase BDA, systemic steroids
    - Consider BIPAP
    - ICU care

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Post-Procedure Management (continued)

Day of Discharge

- PA and lateral chest x-ray
- Review discharge medications
- Give patient, a family member and/or spouse, a wallet card and emergency information
  - Number of valves placed and their location
  - Shows what lobe was treated
  - Include treating physicians name and contact number
  - Includes MRI conditional information
- Schedule patient to return for follow-up visit with treating pulmonary physician in a week
- Inform patient to call if he/she has any increased symptoms of chest pain, shortness of breath, cough, purulent sputum, fever, chills or hemoptysis
- Inform patient to go to the nearest ER if symptoms are severe or persist
- If patient is from a remote area or long distance from the hospital, consider having them stay with a family member or friend for the first few days after discharge to be close to treating facility.
  - If patient does not have friends or family in the area, consider having them stay in a local hotel

Patient Follow-Up

Short-Term

- Call patient daily for first 10 days post procedure
- Clinic follow-up in 1 week
  - Perform chest x-ray
  - 6MWD
- Clinic follow-up in 1 month
  - H&P
  - HRCT between 30–45 days to check the positioning of the valves and lobar collapse (at physician's discretion)
- Clinic follow-up in 3 months
  - Chest x-ray
    - PA/LAT
  - PFTS
  - 6MWD
  - SGRQ, mMRC, CAT and BODE

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Patient Follow-Up (continued)

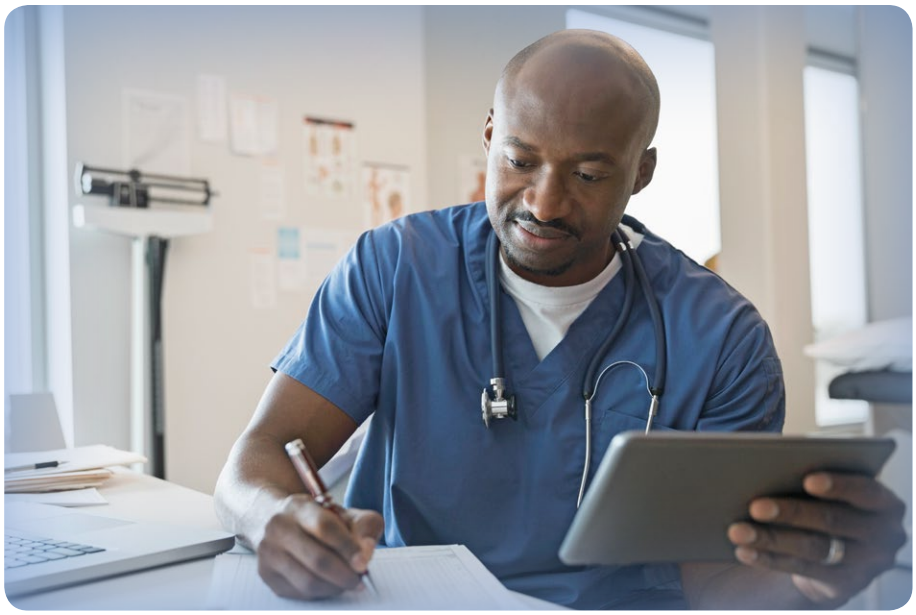
Long-Term

- Treating physician and referring pulmonologist should decide together on optimal approach for follow-up
  - Recommended follow-up at 1, 3, 6 months and yearly
  - Evaluate patient for outcomes and complications
- Restart maintenance pulmonary rehabilitation at outpatient center and maintenance at home
- Treating physician should request that referring physician send patient back for re-evaluation if there is any of the following:
  - Loss of effect or no effect
  - Sudden loss of volume reduction on CT scan
  - Persistent cough
  - Persistent hemoptysis
  - Persistent or recurrent pneumonia
  - Frequent exacerbations not consistent with patients usual pre-EBV course

Post-Procedural Re-Evaluation

Re-Evaluation Testing

- Recommend an additional low-dose HRCT scan to assess valve positioning if there is:
  - Breathing deterioration
  - No improvement
  - Cough
  - Hemoptysis
- Recommend the addition of bronchoscopic evaluation, valve adjustment or replacement if there is:
  - No or < 50% target lobe volume reduction on CT scan (at scheduled 30-45 day follow-up)
  - Sudden loss of benefit/loss of volume reduction on CT scan
  - Persistent cough
  - Persistent hemoptysis



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