

The criteria represented in this document are recommended for proper patient selection to determine whether a patient is a potential candidate for the Spiration Valve System treatment.

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.

OLYMPUS[®]

Spiration[®] Valve System

For the Treatment of Severe Emphysema



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Recommended Patient Selection Criteria

OLYMPUS[®]

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PATIENT SELECTION

Recommended Patient Selection Criteria

Spiration® Valve System

MEDICAL HISTORY AND PHYSICAL EXAM

- Patient is 18 years of age or older
- Patient is not an active smoker
- Patient is diagnosed with GOLD stage III or IV COPD (severe emphysema)
- Patient meets the criteria of the ATS/ERS Guidelines for Management of Stable COPD
- Patient is on optimized medical management within standard of care
- Patient has a BMI > 15 and < 35 kg/m²
- Patient has had no prior, ipsilateral lung volume reduction surgery or major lung procedures (lobectomy or greater)
- Patient does not have clinically significant bronchitis or bronchiectasis.
- Patient does not have an active asthma component to their disease or requires more than 20 mg of prednisone daily
- Patient does not have severe pulmonary hypertension (PA pressure > 50 mmHg) based upon clinical evaluation
- Patient is not classified as ASA Class > P4 including presence of co-morbidity that could significantly increase the risk of a bronchoscopy procedure
- Patient has had no hospitalizations for COPD exacerbation or respiratory infections in the past 3 months

- Patient does not have a known or suspected sensitivity or allergy to nickel
- Patient does not have evidence of an active pulmonary infection
- Patient is able to tolerate a bronchoscopic procedure



If these answers are NO, patient does not meet the selection criteria recommended for best results.



If these answers are YES, then proceed to next set of questions.

PFT & MEDICAL WORK UP

- FEV₁: >15 and ≤ 45% predicted
- Residual Volume (RV): >150% predicted
- Total Lung Capacity: ≥100% predicted
- 6MWD: >100 meters
- DLCO: > 20%
- mMRC: ≥ 2
- Arterial Blood Gas level: PCO₂ < 55 mm Hg, or PO₂ > 45 mm Hg on room air



If these answers are NO, patient does not meet the selection criteria recommended for best results.



If these answers are YES, then proceed to next set of questions.

RADIOGRAPHIC ASSESSMENT

- Fissure Integrity ≥ 90% completeness of the fissure separating the target lobe
- High Heterogeneity ≥10 point severity difference between target and the ipsilateral lobe
- Emphysema Severity – target lobe with ≥ 40% emphysema involvement
- Patient does not have a giant bulla > 30% volume in either lung
- Patient does not have a diffuse homogenous emphysema.



If these answers are NO, patient does not meet the selection criteria recommended for best results.



If these answers are YES, then proceed to next set of questions.

If the patient meets the recommended selection criteria for best results, they can be considered a candidate for Spiration Valve System treatment.



If the patient does not meet the recommended selection criteria, other options for treatment should be discussed and agreed upon.