

Initial Patient Screening Checklist

Spiration® Valve System for the Treatment of Severe Emphysema



Patient Name: _____ DOB: _____ MRN: _____

Note: If a patient is checked for each category, he or she fits the selection criteria recommended for best results and is a potential candidate for endobronchial valve treatment with the Spiration Valve System.

Medical History and Physical Exam	<input checked="" type="checkbox"/>
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/m ²	
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	



Pulmonary Function Testing & Medical Work Up	<input checked="" type="checkbox"/>
FEV ₁ : >15 and ≤ 45% predicted	
Residual Volume (RV): ≥150% predicted	
Total Lung Capacity: ≥100% predicted	
6MWT (distance): >100 meters	
DLCO: > 20%	
mMRC: ≥ 2	
Arterial Blood Gas level: PCO ₂ < 55 mm Hg, or PO ₂ > 45 mm Hg on room air	



Radiographic Assessment	<input checked="" type="checkbox"/>
Fissure Integrity - ≥ 90% completeness of the fissure separating the target lobe	
High Heterogeneity - ≥10 point decrease severity difference with 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.	

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If a CT scan is performed, please adhere to the following CT acquisition guidelines to ensure an optimal QCT analysis. It is important that the patient fully understands the breathhold and scanning procedure, and that any concerns are addressed prior to performing the CT scan. The technologist will ask women if they might be pregnant and will not scan them if they answer affirmatively.

CT Parameters

	SIEMENS	PHILIPS	TOSHIBA	GE
Breathhold at	TLC, Full Inspiration	TLC, Full Inspiration	TLC, Full Inspiration	TLC, Full Inspiration
Slice Thickness	≤1.5mm	≤1.5mm	≤1.5mm	≤1.5mm
Slice Spacing	Consistently spaced, no gaps	Consistently spaced, no gaps	Consistently spaced, no gaps	Consistently spaced, no gaps
Anatomic Coverage (For guidance see Scan Coverage section)	Full coverage of the lungs	Full coverage of the lungs	Full coverage of the lungs	Full coverage of the lungs
Smooth Kernel Reconstruction	≤ B45, ≤ I45, ≤ Br45	B, C	≤ FC08, FC18	Standard
Severe Motion Artifact	Absent	Absent	Absent	Absent
Contrast Enhanced	None	None	None	None
Image Orientation	Axial	Axial	Axial	Axial

Breath-Holding Instructions

- 1** For the static TLC scan, the patient is told to “take your biggest breath in until you feel your lungs are completely full, in the same way you do in the lung function laboratory and hold the breath.”
- 2** Technologist should watch the chest to ensure that the breath hold maneuver is done properly and that the scanning only starts when the patient has reached breath hold and relaxed their body.

Subject Positioning

- 1** The patient will lie in the **supine position** into the CT gantry.
- 2** Place patient in a supine position, arms positioned comfortably above the head in a head-arm rest, lower legs supported. Using the laser positioning lights, line up the patient so the chest is at the iso-center (in the middle: left-right; up-down) of the CT gantry. Move the table so the patient is in the correct position for a chest CT scan.

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