SPIRATION® VALVE SYSTEM
Patient Selection for the Treatment of Emphysema Based on Clinical Literature.
The Spiration Valve System is a device placed in the lung airway to treat severely diseased lung in patients with heterogeneous emphysema and complete fissures by limiting airflow to selected areas.

Spiration Valve System treatment benefits may include:

- Reduction in hyperinflation
- Improvements in pulmonary function as indicated by an improvement in FEV₁
- Improved exercise tolerance
- Improved quality of life as measured by SGRQ

**Patient Selection Overview**

The selection criteria are based on clinical experience gathered to date on bronchial valve therapy and on peer-reviewed studies with the Spiration Valve System¹ or the Zephyr® Endobronchial Valve²,⁷,⁸ in similar emphysematous patient populations. The highlighted evaluation factors below are some of the most important criteria for patient selection from the published literature.

Physicians should evaluate these studies and the selection criteria on their own. These recommendations are not meant to replace patient-specific clinical judgment, and may evolve with the release of new clinical study findings.

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**Patient evaluation**

- Pulmonary Function
- Exercise Testing
- HRCT Scan

**Identify Target Lobe**

Identifying whether the patient has a suitable lobe for treatment involves three parameters.

- 1. Complete Fissures
- 2. Severe Emphysema Involvement
- 3. High Heterogeneity
PATIENT EVALUATION

Pulmonary and Exercise Evaluation

Clinically studied patients have had:
- $\text{FEV}_1 \leq 45\% \text{ predicted}^2$
- Residual Volume (RV) $> 150\% \text{ predicted}^{1,2}$
- Total Lung Capacity (TLC) $> 100\% \text{ predicted}^{1,2}$
- $6\text{MWD} \geq 150 \text{ m}^{1,2}$
- Hypercapnia with $\text{PaCO}_2 \leq 50 \text{ mm Hg}^{1,2}$
- $\text{PaO}_2 > 45 \text{ mm Hg (6.0 kPa) on room air}^1$

HRCT Scanning

HRCT Scanning Parameters:
An HRCT scan is used to estimate the extent and distribution of emphysema and to identify whether there is a suitable treatment lobe that may respond favorably to Spiration Valve System treatment.

A suitable scanning protocol will include:
- Image taken at full suspended inspiration$^3$
- 1-1.25mm contiguous slices$^{3,4}$
- 70-100 milliampere seconds (mAs)$^{3,4}$
- 120 kVp$^{3,4}$
- 512 x 512 slice matrices$^3$

Perfusion Scanning

Perfusion Scintigraphy may also be conducted to confirm heterogeneity and very low perfusion in the region of the target lobe selected for treatment.$^{1,6}$
Identifying a Suitable Lobe for Treatment Involves Three Key Parameters

1. Complete Fissures
   - The selected lobe must have an intact fissure separation with the ipsilateral lobe.²
   - The Spiration Valve System has been demonstrated to enable significant lobar reduction in select patients.¹,⁵ Lobar volume reduction is most pronounced and clinically beneficial in patients where the targeted lobe is isolated from collateral ventilation through complete fissures.¹,²,⁷,⁸

Quantitative Analysis Strategies:
   - Fissures may be visually estimated to be intact if it is ≥ 90% complete after viewing the HRCT in three dimensions (sagittal, axial, and coronal).²,⁷
   - Automated methods to provide exact quantifications and support visual readings may also be used.⁷,⁸
2. Severe Emphysema

The lobe with the greatest amount of emphysema involvement should be evaluated first. If that lobe does not meet subsequent criteria, consider the second most diseased lobe.

Quantitative Analysis Strategies:
Target lobe has ≥ 50% emphysema severity, assessed quantitatively with HRCT at approximately −910 HU.

3. High Heterogeneity

A high heterogeneity difference between ipsilateral lobes is useful to verify that the non-target lobes that will expand are healthier than the lobe targeted for treatment and volume reduction.

Quantitative Analysis Strategies:
Target lobe has emphysema involvement ≥ 15 percent greater than the healthier ipsilateral lobe, assessed quantitatively with HRCT.

Perfusion Scintigraphy may also be conducted to confirm heterogeneity and very low perfusion of the target lobe region.
SeleCT by VIDA provides clinicians a method to submit High Resolution CTs (HRCTs) and receive quantitative measurements to support visual readings of lung parenchyma that may be suitable for bronchial valve treatment.

Each quantitative report contains lung parenchymal measurements at -910, and -950 HU for each lobe, such as:

- Lobar Volume (cc)
- Low Attenuation Area (%), as a marker of emphysema severity²,⁸
- Heterogeneity (∆)
- Fissure Integrity (%), as a marker of low collateral ventilation

Advantages of quantitative measurements include:

- More accurate and reproducible than visual CT analysis.⁸
- Comparable accuracy to Chartis.⁸
- Avoids an invasive procedure just to confirm collateral ventilation.⁸
- Not dependent on anatomy, coughing, or mucus where direct bronchoscopic measure may be unreliable or not possible.⁸
- Provides useful measures beyond complete fissures such as emphysema severity, heterogeneity and lobar volume that may improve the prediction of lung volume reduction.⁸
Step 1:
Clinicians select HRCTs to submit for quantitative CT analysis.
For optimal results, acquisition protocols are closely followed to assure that the scans can be analyzed appropriately.
It is the responsibility of the hospital to anonymize the CT scans and obtain patient consent where required under local laws and regulations.

Step 2:
HRCTs are uploaded through a secure, web-based image transfer system (lifeIMAGE).
lifeIMAGE works in partnership with the Radiological Society of North America, and has been used to exchange more than 1 billion images from over 90 countries.

Step 3:
A Radiological Service (VIDA Diagnostics, Inc.) analyzes the HRCT and prepares a report with quantitative measurements.
VIDA uses CE Marked software and ISO certified processes for validated, reproducible and consistent measurements.
The report is delivered within four business days as an attachment through the secure image transfer system.


