SPIRATION® VALVE SYSTEM
For the Treatment of Emphysema or Air Leaks.
ENGINEERED FOR AIRWAY MANAGEMENT

Inspired by aerodynamics, the Spiration Valve redirects air away from diseased or damaged lung to healthier tissue, all while allowing trapped air and secretions to escape, so that patients may breathe easier.

Unlike a stent, the unique design of the Spiration Valve minimizes contact with the bronchial wall, maintains position to redirect air even in complex patients, and facilitates removal when needed.

The Spiration Valve System is intended to treat severely diseased lung in patients with heterogeneous emphysema and evidence or markers of low collateral ventilation such as complete fissures, or damaged lung resulting in air leaks by limiting airflow to selected areas.

The procedure is considered minimally invasive and can be performed through a flexible bronchoscope.

On inhalation, the Spiration Valve conforms to the airway and redirects air to healthier tissues of the lung.

On exhalation, the Spiration Valve flexibly constricts with the airways, allowing trapped air and secretions to escape naturally along the bronchial wall between the umbrella struts.
The first and only valve with anchors for 0% migration and expectoration. \(^{2,14,15}\)

Greater Airway Access
Catheters for 2.0mm and 2.6mm working channels.

Redirscts Air
The first and only valve with umbrella struts to minimize tissue contact and allow secretions to escape naturally along the bronchial wall.

Removable
The first and only valve with a center rod to facilitate removal.

Largest Range of Valve Sizes
Now available in 9mm size for large airways.
THE CONFIDENCE YOU NEED FOR THE OUTCOMES YOU WANT.

- Target lobe will have severe, highly heterogeneous emphysema with complete fissures.¹²³
- Multiple valves are placed to occlude all the airways leading to the targeted lobe and enable atelectasis or significant lobar reduction.
- Significant lobar reduction can relieve hyperinflation, enable healthier tissue to expand, and make breathing easier.³
From reliable, non invasive evidence of low collateral ventilation...

SeleCT enables clinicians to submit HRCTs and receive quantitative measures of fissure integrity.

- More accurate and reproducible than visual CT analysis. ¹⁶
- Comparable accuracy to Chartis. ¹⁶
- Avoids an invasive procedure just to confirm collateral ventilation. ¹⁶
- Not dependent on anatomy, coughing, or mucus where direct bronchoscopic measure may be unreliable or not possible. ¹⁶
- Provides useful measures beyond complete fissures such as emphysema severity, heterogeneity and lobar volume that may improve the prediction of lung volume reduction. ¹⁶

...to 0% migration or expectoration ²,¹⁴,¹⁵ for effective lobar occlusion

Complete occlusion is a prerequisite for significant volume reduction, which correlates with improvement in clinical outcomes. ¹⁷

- FEV₁ was improved by 21.4% at 90 days, with statistically significant differences also seen across IVC, RV, RV/TLC, 6MWD, mMRC, SGRQ, BODE and ADO. ¹⁷
- 99% technical success. ²,¹⁴
- Now available in 9mm size for large airways.
THE PRECISION YOU NEED FOR THE OUTCOMES YOU WANT.

- Persistent air leaks impact inpatient and outpatient resources utilization, cost, and morbidity. \(^5,6,7\)
- An air leak present by day 5 should be considered for thoracic surgical consultation or treatment. \(^5,8,9,10\)
- A substantial reduction in an air leak using Spiration Valves may accelerate the resolution of an air leak. Complete cessation of an air leak may not be achievable, or necessary, for successful treatment. \(^9,11,12,13\)
A proven isolation technique\textsuperscript{5,18} to identify the source of air leak(s)... From the leader in valve therapy for air leaks with over two thousand procedures supported worldwide.

1. **Assess**
   Block main bronchus to determine if the leak can be stopped or reduced and the length of time it takes to see a change in the water seal monitor.

2. **Isolate**
   Systematically work from proximal to distal.

3. **Place Valve**
   Once an airway is identified, size the airway and place a valve.

4. **Reassess**
   Repeat process to isolate additional leaks as dynamics may have changed since valve placement.*

...to a minimally invasive solution with a center rod to facilitate removal upon resolution of the air leak.

Treatment with the Spiration Valve System has demonstrated a favorable responder rate\textsuperscript{12,13,18}:

- \textbf{100\%} (n=9/9) of treated patients met the primary endpoint, as identified as air leak cessation allowing chest tube removal.\textsuperscript{13}
- \textbf{77\%} (n=10/13) of treated patients were responders, as identified as successful chest tube removal without the need for further interventions.\textsuperscript{12}
- \textbf{100\%} (n=7/7) of treated patients had improvement in the air leak, as defined as improvement allowing Heimlich valve use, improvement of 1 Cerfolio classification, or complete cessation of the air leak.\textsuperscript{18}

*Treatment should be limited to no more than 3 segments by placing valves in segmental or sub-segmental bronchi in the target lung to avoid excessive isolation of tissues from ventilation.
Deployment Catheter and Loader

<table>
<thead>
<tr>
<th>Model Name</th>
<th>Article Number</th>
<th>Catheter Working Length</th>
<th>Bronchoscope Channel Inner Diameter</th>
<th>Valve Size Compatibility</th>
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</thead>
<tbody>
<tr>
<td>IBV-C26N</td>
<td>N5381300</td>
<td>1020mm</td>
<td>2.6mm or greater</td>
<td>For 5, 6, 7 and 9mm Valves</td>
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<tr>
<td>IBV-C20</td>
<td>N3521830</td>
<td>1140mm</td>
<td>2.0mm or greater</td>
<td>For 5, 6 and 7mm Valves</td>
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</table>

Spiration Valves

<table>
<thead>
<tr>
<th>Model Name</th>
<th>Article Number</th>
<th>Valve Size</th>
<th>Cartridge Color</th>
<th>Number Required Per Procedure</th>
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</thead>
<tbody>
<tr>
<td>IBV-V5</td>
<td>N3495330</td>
<td>5mm</td>
<td>Blue</td>
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<tr>
<td>IBV-V6</td>
<td>N3495430</td>
<td>6mm</td>
<td>Yellow</td>
<td></td>
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<tr>
<td>IBV-V7</td>
<td>N3495530</td>
<td>7mm</td>
<td>Green</td>
<td>Determined by number of target locations</td>
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<tr>
<td>IBV-V9</td>
<td>N5381200</td>
<td>9mm</td>
<td>Grey</td>
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Airway Sizing Kit

<table>
<thead>
<tr>
<th>Model Name</th>
<th>Article Number</th>
<th>Gauge Hole</th>
<th>Glass Syringe</th>
<th>Number Required Per Procedure</th>
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</thead>
<tbody>
<tr>
<td>IBV-VSK</td>
<td>N5534500</td>
<td>Sized for appropriate valve selection</td>
<td>500 microliters</td>
<td>1</td>
</tr>
</tbody>
</table>

Required Ancillary Equipment Needed for Each Procedure

- Flexible bronchoscope with a working channel inner diameter of 2.0mm or greater
- Olympus balloon catheter B5-2C
- Bronchoscopy forceps appropriate for valve removal
- Standard 10cc sterile syringe with Luer-lock for use in preparing the balloon catheter
- Sterile saline

References

11. Instructions for use, Humanitarian Use Device (HDE), Spiration Valve System.