INSTRUCTIONS FOR USE
IBV® VALVE SYSTEM

Humanitarian Device for Use in the Control of Air Leaks

1 Intended Use
The Spiration® IBV Valve System is a device to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery (LVRS). An air leak present on post-operative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: 1) continuous, 2) present during normal inhalation phase of inspiration, or 3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. IBV Valve System use is limited to 6 weeks per prolonged air leak.

2 IBV Valve System Description
The IBV Valve System consists of an IBV Valve (or valve) and a Deployment Catheter (or catheter). The Airway Sizing Kit is used to determine and measure target areas before valve deployment.

2.1 IBV Valve
The valve is designed to limit airflow to the portions of the lungs distal to the valve, while still allowing mucus and air movement in the proximal direction. The valve is comprised of a frame made from Nitinol and a polymer membrane (See Figure 1). The membrane is held against the airway mucosa by 6 elastic struts and will expand and contract with airway movement during breathing. The 5 anchors have tips that penetrate the airway wall to a controlled depth, preventing the valve from migrating. The valve is available in 5, 6, and 7 mm diameters. The valve can be removed by grasping the removal rod with flexible bronchoscopy forceps.

2.2 Deployment Catheter
The valve is provided sterile in a disposable loading tool that allows the operator to insert the valve into the distal tip of the catheter (See Figure 2). The deployment catheter can be passed through a flexible bronchoscope working channel with a diameter ≥ 2.6mm. After loading, the catheter is advanced through the bronchoscope working channel to the target implant site. The 5, 6, and 7 mm catheters include a feature, the Valve Deployment Guide (VDG), to aid the operator in identifying the location of the proximal end of the valve struts when compressed in the catheter. This feature is a mark on the distal outer surface of the catheter that is visible to the operator via the bronchoscope viewing system. The VDG is in addition to the standard visualization of the compressed valve's membrane struts inside the catheter. The valve is deployed when the operator actuates the deployment handle of the catheter, retracting the catheter sheath to release the valve.

2.3 Resolution of Air Leaks
Treatment of an air leak with a valve may not require complete blockage of all air leakage. Even if not completely sealed, a substantial rate reduction in an air leak using valves may accelerate the resolution of an air leak, as the progression through the clinical stages of the air leak is improved. For example, if a continuous (C) air leak is not completely resolved, but changed to an expiratory (E) or forced exhalation (FE) pattern after valve treatment, such a change will allow the physician to consider discharging the patient with the chest tube connected to a Heimlich valve. See Section 9 for definitions of (C), (E), and (FE) above.

3 Contraindications

4 Warnings

5 Precautions

5.1 General Precautions

6 Potential Adverse Effects

7 Items Required

7.1 Required for IBV Valve Deployment

7.2 Recommended for IBV Valve Removal
8 Handling
• This device is supplied sterile. Do not reuse or attempt to resterilize the catheter.
• Contact Spiration if the integrity of the packaging has been compromised.
• Do not reuse a valve once it has been deployed.
• Do not use the catheter if it has been exposed to temperatures above 50°C or below -15°C.

9 Clinical Use
Medical personnel can directly observe air leaks as air bubbles pass through the water seal system connected to the chest tubes.

The diagram below represents the clinical stages of air leak severity and progression towards resolution:

Continuous (C) → Inspiratory (I) → Expiratory (E) → Forced Expiratory (FE) → No air leak

An air leak present for 7 days or more is defined as prolonged. Treatment with the IBV Valve System is intended for those patients with post-operative air leaks that have not resolved spontaneously and are present at post-operative day 7. The exception is a prolonged air leak, which is observed only during forced exhalation or cough maneuvers (FE). This category of air leak has a high probability of resolving spontaneously, so additional treatment is not indicated. The definition for a significant air leak likely to be prolonged is based on severity and air leak characteristics.

IBV Valve System treatment for air leak is indicated on day 5 if an air leak corresponds to one of the following types:
• Continuous (C). The most severe type; observed during normal inhalation and exhalation.
• Inspiratory (I). Observed predominantly during the normal inhalation phase of respiration. These two types are indicated for treatment with the IBV Valve System in the presence or absence of complications.

In addition:
• Expiratory (E). Observed predominantly during the exhalation phase of respiration; is indicated for treatment with the IBV Valve System only in the presence of complications. See complications below the table.

A table to guide treatment is included below:

<table>
<thead>
<tr>
<th>Type of air leak</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7 or more (Prolonged)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C, without complications</td>
<td>Observation</td>
<td>Valve use indicated</td>
<td>Valve use indicated</td>
<td>Valve use indicated</td>
</tr>
<tr>
<td>I, without complications</td>
<td>Observation</td>
<td>Valve use indicated</td>
<td>Valve use indicated</td>
<td>Valve use indicated</td>
</tr>
<tr>
<td>E, without complications</td>
<td>Observation</td>
<td>Observation</td>
<td>Observation</td>
<td>Valve use indicated</td>
</tr>
<tr>
<td>*C, with complications</td>
<td>Observation</td>
<td>Valve use indicated</td>
<td>Valve use indicated</td>
<td>Valve use indicated</td>
</tr>
<tr>
<td>*I, with complications</td>
<td>Observation</td>
<td>Observation</td>
<td>Observation</td>
<td>Valve use indicated</td>
</tr>
<tr>
<td>*E, with complications</td>
<td>Observation</td>
<td>Valve use indicated</td>
<td>Valve use indicated</td>
<td>Valve use indicated</td>
</tr>
</tbody>
</table>

*Complications directly related to air leaks are subcutaneous emphysema and/or respiratory compromise, which are known to prolong hospitalization, and increase the risk of morbidity and mortality.

9.1 IBV Valve Deployment
• Using bronchoscopic techniques, and only after evaluation and sizing of airways, valves should be deployed in selected airways (See Operator’s Instructions, section 10).
• The location for the deployment of the valves may be determined by selective airway occlusion using a balloon catheter (See Instructions for Use, Airway Sizing Kit, Pt-01554).
• Treatment of an air leak may require deployment of a valve in one or more airways.

Valves may be deployed in any segment or sub-segment of the lung anatomy (including the lingular segments) that communicates with and contributes to the persistence of an air leak. A single or multiple airway segments of the lungs may be treated with valves.

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 tissue from ventilation (See Operator’s Instructions, section 10).

• A chest X-ray should be taken after valve placement to document valve locations.

9.2 IBV Valve Removal
All valves placed at any air leak will be removed using bronchoscopic techniques and biopsy forceps to grasp the removal rod tip (See Operator’s Instructions, section 10).

Conditions and criteria for valve removal:
• Air leak has resolved and damaged tissue is considered sealed.
• Six (6) weeks or less after valve implantation.
• Before further intervention to resolve an air leak, such as surgical repair or pleurodesis.

10 Operator’s Instructions

10.1 Selection of IBV Valve Size
• Use the Airway Sizing Kit to determine the locations for valve implant and the appropriate size valve to use for each airway (See Instructions for Use, Airway Sizing Kit, Pt-01554).
• Caution: Incorrect valve size will reduce device effectiveness.

10.2 Loading the IBV Valve

Note: Loading steps are outlined on tray label as well (See Figure 2).

1. Select package for desired valve size.
2. Peel back the Tyvek lid from the tray. IMPORTANT: Do not remove the catheter from the tray until the valve is loaded. Valves must be loaded while the catheter is still constrained in the loading tray.
3. Inspect the contents of the tray to ensure that there is no damage to the product. If damaged contact Spiration.
4. Review the loading steps outlined in the circular descriptive label located in the center of the loading tray.
5. Perform the following steps to load the valve:

   Step 1: Remove green plunger clip.
   Step 2: Depress the plunger fully to load the valve into the catheter.
   Step 3: Rotate the yellow loading lock downward to disengage the loading tool from the catheter. The catheter is now ready to be removed from the loading tray.
   Step 4: IMPORTANT. Do not remove the red safety clip from the deployment handle. Lift the deployment handle from the tray and pull the catheter out of its protective tube. The protective tube and loading tool may stay in the loading tray.
   Step 5: VISUALLY INSPECT the distal tip of the catheter to ensure that the valve is loaded correctly. If any anchors protrude from the distal tip, do not attempt to use the catheter. Repeat the loading steps with another IBV Valve System.

10.3 Delivery and Deployment of the IBV Valve

1. Carefully insert the catheter into the working channel of the bronchoscope. IMPORTANT: Only use a bronchoscope with a 2.6mm working channel or larger.

   IMPORTANT: Do not bend, kink or jam the distal end of the catheter while inserting. A kink may prevent the valve from deploying from the catheter. If this occurs, discard the catheter and valve.

2. While the bronchoscope is in a relaxed position, advance the catheter until the stabilization rod and removal rod tip are visible (See Figure 3).

3. Remove the red safety clip from the deployment handle. While looking at the removal rod tip through the catheter, slowly depress the white deployment handle to eliminate any gap between the removal rod tip and the stabilization rod (See Figure 3).

4. Retract the catheter until the end of the stabilization rod tip is visible at the end of the bronchoscope and does not interfere with its operation.

5. Under bronchoscopic observation, advance the bronchoscope to the deployment location.

6. Position the bronchoscope so that the target airway location is visible and the tip of the catheter can be directed into the target site without bending or kinking the catheter.

7. Advance the catheter to the target location for valve deployment.

8. Position the catheter so that the VDG or the proximal tips of the membrane struts (See Figure 3) are visible and align the VDG/struts with the target location in the airway. The valve should sit 2 to 3 cm distal over time.

9. Under bronchoscopic observation, depress the white deployment handle, which retracts the catheter sheath and releases the valve.

10. Once the valve is completely deployed, remove the catheter from the bronchoscope.

11. Examine the valve for opening, position, and fit. The valve should be opened and engaging against all borders of the airway.

12. After valve deployment, evaluate the reduction of the air leak and determine if additional valves should be deployed.

13. If needed, repeat the loading, delivery and deployment steps for each additional valve.

10.4 IBV Valve Removal

1. Removal of valves should be conducted under bronchoscopic observation. It is recommended that valves should be removed through an endotracheal (ET) tube. (See instructions for use provided by the forceps manufacturer).

2. Insert the appropriate forceps through the working channel of the bronchoscope, directing the forceps to the target location.

3. Grasp the removal rod with the appropriate forceps and gently pull the valve until it is dislodged from the airway wall. Use care to make sure that the removal rod does not get caught in the fenestration of the forceps when removing the valve (See Figure 4).

4. IMPORTANT: Before removing the valve from the target location, pull the valve as close as possible to the end of the bronchoscope (See Figure 5).

5. While still firmly holding onto the valve with the forceps, simultaneously remove the bronchoscope and the forceps from the patient. IMPORTANT: DO NOT release the valve from the forceps until the valve is completely removed. During removal, the valve struts may invert.

6. All valves are single use only.

11 Patient Information Pamphlet

An information pamphlet is available for patients. (Patient Information for the IBV Valve System, Humanitarian Device for Use in the Control of Air Leaks, Pt-01708)

CAUTION: Humanitarian Device. Authorized by Federal law for use in the treatment of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or lung volume resection surgery (LVRs). The effectiveness of this device for this use has not been demonstrated.

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