ISOLATION OF POST-OPERATIVE AIR LEAKS

Balloon Occlusion Method for Treatment with the IBV® Valve System
The IBV Valve System is a minimally invasive device for the treatment of specific postoperative air leaks.

The IBV Valve’s unique design allows it to limit distal airflow which may accelerate the resolution of an air leak.\(^3\)
Introduction

Isolation of air leaks is a critical step to successful treatment with IBV Valves. This brochure describes an IBV Valve isolation method, a systematic approach using balloon occlusion, to help physicians assess and isolate airways contributing to an air leak.

Assessing a Postoperative Air Leak\textsuperscript{1,2}

- A chest drainage system is the best tool to monitor and assess changes in an air leak, seen by changes in the water seal monitor
- Tidal volume is another tool that can help identify airways contributing to an air leak, so talk to your anesthesiologist
- Leaks in the chest drainage system can diminish your ability to assess leaks, promptly check connection points if you are unable to reduce a leak

Key Points in Isolation\textsuperscript{1,2}

- The source and number of air leaks will vary considerably between patients due to changing lung dynamics
- It is recommended to begin isolation with balloon occlusion at the main bronchus, as this will provide two key pieces of information:
  - Time it takes to evacuate air from the pleural space (note: It may take up to 10 breaths before residual air has exited the pleural space)
  - The amount of reduction expected at the end of the procedure
- Placement of a valve, in one suspect airway, may reveal additional leaks in other parts of the lung due to:
  - Redirection of air to another contributing airway
  - Collateral ventilation
  - Bigger air leaks “masking” smaller leaks
- Once a valve has been placed, any additional leaks should be located by returning to the main bronchus to reassess, and then moving from proximal to distal airways:
  - Previously tested airways that showed no evidence of an air leak before a valve was placed may now be visualized in the water seal monitor

Treatment of a Postoperative Air Leak\textsuperscript{1,2,3}

- Treatment of an air leak may require placement of multiple valves
- Complete cessation may not be achievable, or necessary, for successful treatment of an air leak
- A substantial 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

References

1. Recommendations associated to assessment, isolation and treatment of an air leak using the IBV Valve System are based on information from the Instructions for Use, IBV Valve System and clinical experience.
3. Instructions for Use, IBV Valve System
IBV Valve Isolation Method

1. **ASSESS**
   Block main bronchus to determine:
   - A. If the leak can be stopped or reduced
   - B. Length of time it takes to see a change in the water seal monitor

2. **ISOLATE**
   Systematically work from proximal to distal:
   1. Occlude upper lobe—if no change,
   2. Move to the lower lobe(s)
   3. Once a target lobe is identified, test the individual sub-segments

3. **PLACE VALVE**
   Once an airway is identified, size the airway and place a valve

   *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.*
### Case Example

52 year old male with a postoperative air leak on the left side

<table>
<thead>
<tr>
<th><strong>Assess</strong></th>
<th>Occlusion of the MAIN bronchus</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Action</strong></td>
<td>Occlude the left bronchus</td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>On inflation: 5–7 breaths to see visible reduction in bubbles 10 breaths for bubbles to stop completely</td>
</tr>
<tr>
<td><strong>Conclusion</strong></td>
<td>There is a leak on the left side</td>
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**Isolate**

<table>
<thead>
<tr>
<th>Occlusion of the LUL</th>
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**Place Valve**

<table>
<thead>
<tr>
<th>Place valve(s) in LB8</th>
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<tbody>
<tr>
<td><strong>Action</strong></td>
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**REASSESS** Repeat as dynamics may have changed since valve placement

**Assess**

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<table>
<thead>
<tr>
<th>Occlude to identify the segmental or sub-segmental airway(s) contributing to the leak</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Result</strong></td>
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</table>

**Place Valve**

<table>
<thead>
<tr>
<th>Place in LB5</th>
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<tbody>
<tr>
<td><strong>Action</strong></td>
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<td><strong>Result</strong></td>
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<tr>
<td><strong>Conclusion</strong></td>
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**Lesson**

The smaller leak in the left lingular segment had originally been masked by the larger leak in the lower lobe. When the air leak was stopped in the lower lobe, the LB5 was the only airway communicating with the pleural space and became visible in water seal monitor.
**IBV® Valve System**

**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 postoperative 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.

**Contraindications**
- Patient is unable to tolerate a flexible bronchoscopy procedure.

**Warnings**
- Atelectasis may occur after the air leak seals and patients should be monitored for this possible complication.

**General Precautions**
Use of the catheter requires bronchoscopy technical skills. The operator must be a physician or medical person under the supervision of a physician and be trained in clinical bronchoscopic techniques and the use of the IBV Valve System. The Instructions for Use, IBV Valve System will give technical guidelines but do not obviate formal training in bronchoscopic procedures. The IBV Valve System should not be used for patients who have active asthma, bronchitis or clinically significant bronchiectasis. Only use a bronchoscope with a working channel of 2.6mm or larger. Valve placement should be done only after airway evaluation and sizing with the balloon catheter (See Instructions for Use, Airway Sizing Kit). Do not remove the valve from the loading tool. The valve cannot be removed and placed in another catheter for deployment. Valve placement and removal must be done under bronchoscopic observation with visualization of the target airway. Once a valve has been deployed, do not attempt to reuse or re-deploy the valve again. If the position of the deployed valve is not optimal or appropriate; the valve should be removed and discarded. Do not use the IBV Valve System for other than its intended use.

**Potential Adverse Effects**
- Atelectasis
- Bleeding observed from an airway treated with a valve
- Bleeding due to valve removal and complications of such bleeding such as airway obstruction by blood clot
- Bronchitis
- Damage in the airway and/or tissue near a valve
- Death
- Infection in the tissue distal to a valve
- Local airway swelling or edema at site of valve implantation
- Migration of valve out of the lung or within the lung
- Persistent cough
- Pneumothorax
- Shortness of breath
- Tissue hyperplasia or other reaction at site of valve implantation

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**IBV Airway Sizing Kit**

**Intended Use:** The Spiration Airway Sizing Kit is intended to determine the appropriate size IBV Valve needed for an airway.

**Contraindications**
- Do not use this Airway Sizing Kit for other than its intended use.
- Patient is not an appropriate candidate for, or unable to tolerate, flexible bronchoscopy procedures.
- See contraindications for the Spiration IBV Valve System.

**Precautions**
- Use of the Spiration Airway Sizing Kit requires bronchoscopy technical skills. The operator of this System must be a physician or medical personnel under the supervision of a physician and be trained in clinical bronchoscopy techniques. The following instructions will give technical guidelines but do not obviate formal training in the use of this device.
- The Olympus balloon catheter contains natural latex rubber, which may cause allergic reactions. Do not use this product on a latex-sensitive patient. If the patient is latex-sensitive, the alternative, Applied Medical balloon catheter should be used.
- Only use the recommended balloon catheters with the Spiration Airway Sizing Kit.

**Potential Adverse Effects**
- Adverse effects associated with flexible bronchoscopy.
- Allergic reaction to latex specific to latex balloon use.

**Caution**
Humanitarian Use Device. Authorized by Federal (or United States) Law for the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged following lobectomy, segmentectomy, or lung volume reduction surgery. The effectiveness of this device for this use has not been demonstrated. Federal law restricts this device to sale by or on the order of a physician.

For additional product information go to: www.spiration.com/IFU