

Professional LABELING



Instructions for Use – IBV[®] Valve System

Humanitarian Device for Use in the Control of Air Leaks

STERILE EO Sterilized by EO. Sterile unless package opened or damaged.
Do Not Resterilize.

- ⊗ SINGLE USE ONLY
- ⚠ SEE INSTRUCTIONS FOR USE
- ⚡ TEMPERATURE LIMITS: -15°C to +50°C
- ⚠ MR CONDITIONAL

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IBV[®] Valve System is covered by U.S. Patents 6,258,100 - 6,293,951 - 6,592,594
6,929,637 and other Patents Pending.

1 Intended Use

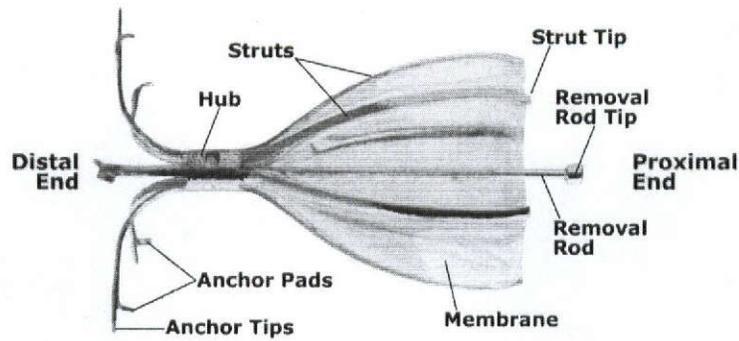
The Spiration[®] IBV Valve System is intended to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery (LVRS). An air leak present on post-operative day 7 is considered prolonged 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. (See Instructions for Use, Airway Sizing Kit, PI-01554).

2.1 IBV Valve

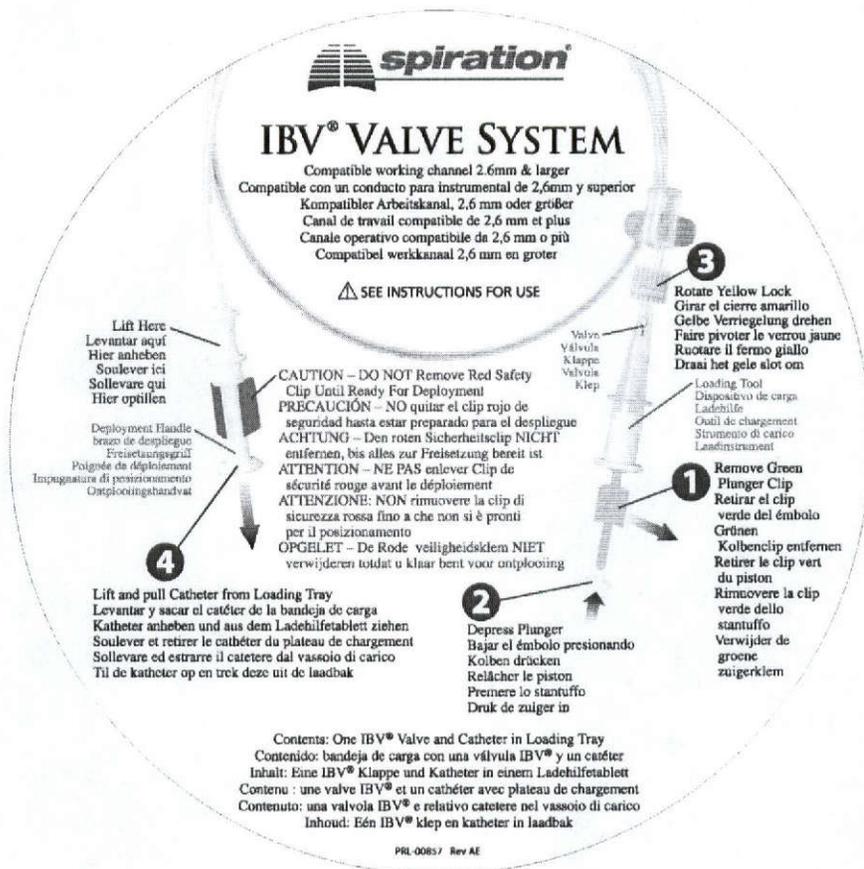
The valve is designed to limit airflow to the portions of the lungs distal to the valve, while still allowing mucus and air movement in the proximal direction. The valve is comprised of a frame made from Nitinol and a polymer membrane (*See Figure 1*). The membrane is held against the airway mucosa by 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.



Key Components of the IBV Valve (Figure 1)

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 $\geq 2.6\text{mm}$. 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.



IBV Valve System Tray Label (Figure 2)

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

- Patient is unable to tolerate a flexible bronchoscopy procedure.

4 Warnings

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

5 Precautions

5.1 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 bronchoscopy techniques and the use of the IBV Valve System. The following instructions 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, PI-01554).
- 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.

5.2 MRI Information

The IBV Valve was determined to be MR-Conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing has demonstrated that the IBV Valve is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial magnetic gradient field of 720-Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the IBV Valve produced a temperature rise of less than or equal to 0.5° C at a maximum MR system reported whole-body-average specific absorption rate (SAR) of 3-W/kg

for 15 minutes of MR scanning in a 3-Tesla MR system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the IBV Valve. Optimization of MR imaging parameters is recommended.

6 Potential Adverse Effects

- Atelectasis
- Bleeding observed from an airway treated with a valve
- 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

7 Items Required

7.1 Required for IBV Valve Deployment

- IBV Valve System
(Contains: Valve, Valve Loading Tool and Deployment Catheter all in Loading Tray)
- Airway Sizing Kit
(Contains: Calibration Gauge, 500µl Glass Syringe, and Syringe Plunger)

Additional ancillary equipment required:

- Flexible Bronchoscope with a working channel of 2.6mm or greater
- Balloon Catheter (See Instructions for Use, Airway Sizing Kit, PI-01554)

7.2 Recommended for IBV Valve Removal

- Cupped biopsy forceps compatible with bronchoscope
- Rat-tooth jaw grasping forceps compatible with bronchoscope
- Pediatric size biopsy forceps compatible with bronchoscope

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:

Type of air leak	Day 4	Day 5	Day 6	Day 7 or more (Prolonged)
C , without complications	Observation	Valve use indicated	Valve use indicated	Valve use indicated
I , without complications	Observation	Valve use indicated	Valve use indicated	Valve use indicated
E , without complications	Observation	Observation	Observation	Valve use indicated
*C , with complications	Observation	Valve use indicated	Valve use indicated	Valve use indicated
*I , with complications	Observation	Valve use indicated	Valve use indicated	Valve use indicated
*E , with complications	Observation	Valve use indicated	Valve use indicated	Valve use indicated

*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 airway (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, PI-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 location.

9.2 IBV Valve Removal

All valves placed for air leaks 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, PI-01554).

•**Caution:** Incorrect valve size will reduce device effectiveness.

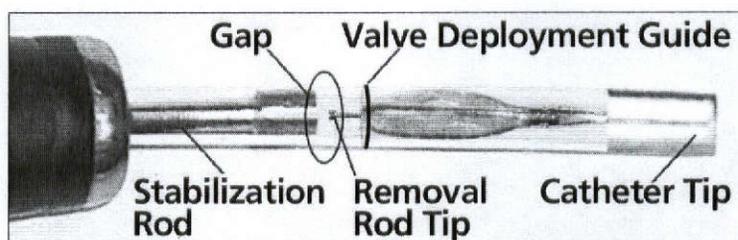
10.2 Loading the IBV Valve

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.
6. **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). Retract the catheter until the end of the catheter tip is just visible at the end of the bronchoscope and does not interfere with its operation.



Eliminate gap between Removal Rod Tip and Stabilization Rod (Figure 3)

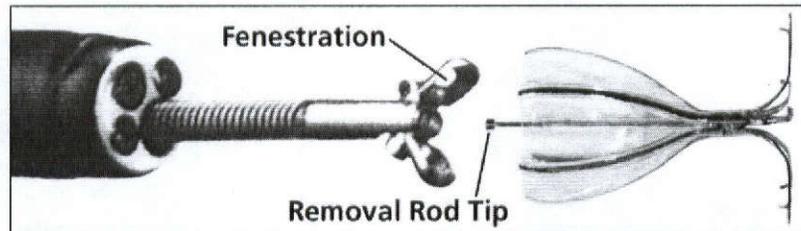
4. **Under bronchoscopic observation,** advance the bronchoscope to the deployment location.
5. Position the bronchoscope so that the target airway location is visible and the tip of the catheter can be directed into the target site without bending or kinking the catheter.
6. Advance the catheter to the target location for valve deployment.
7. 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 may settle 1–2mm distal over time.
8. **IMPORTANT: Hold the catheter in place at the opening of the insertion port of the bronchoscope.**
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 opposing 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.

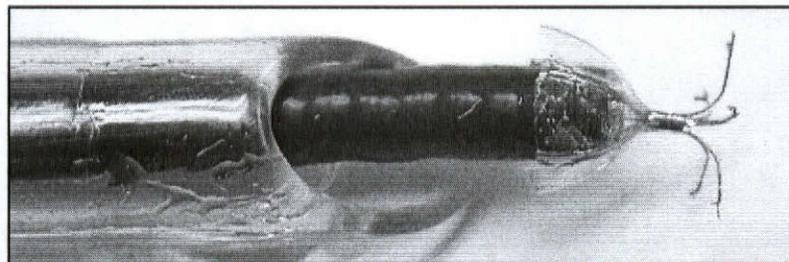
Forceps	Recommended Use
Cupped Biopsy	When the removal rod tip can be visualized and accessed by the biopsy forceps.
Rat-Tooth Jaw Grasping	When the removal rod shaft is being grasped.
Pediatric Biopsy	When the maneuverability of the bronchoscope is limited by standard sized forceps but the removal rod tip can be visualized.

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).



Valve removal with forceps (Figure 4)

4. **IMPORTANT: Before removing the valve from the trachea, 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.



Pull valve as close as possible to the end of the bronchoscope (Figure 5)

11 Patient Information Pamphlet

An information pamphlet is available for potential patients. (*Patient Information for the IBV Valve System. Humanitarian Device for Use in the Control of Air Leaks, PI-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 reduction surgery (LVRS). The effectiveness of this device for this use has not been demonstrated.

Patient LABELING

- The area of your airway and/or lung near or around the valve(s) may be damaged from handling of the valve(s).
- Area of your lung, which has a valve(s), may lose air and shrink. The areas of your lung without valve(s) may grow, which may tear the lung, and result in additional air leaks.
- Severe problems may require you to get medical treatment or even surgery. A severe problem may result in death.

Contraindications

The doctor will not place an IBV valve(s) into your airway, if you are unable to tolerate a flexible bronchoscopic procedure.

Precautions and Warnings

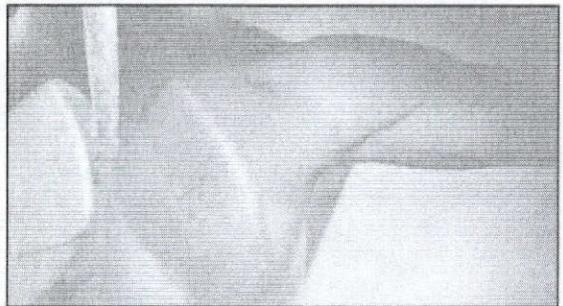
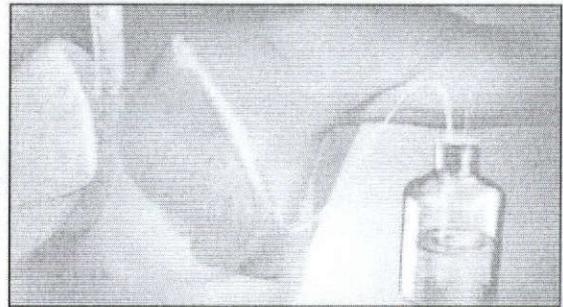
Use of the IBV Valve System requires technical skills with a bronchoscope. The operator of the system must be a doctor or medical person under the supervision of a doctor and be trained in bronchoscopic techniques and the use of the IBV Valve System. Sedation and/or anesthesia are used for this bronchoscopic procedure. Discuss with your doctor the risks that can occur with sedation and anesthesia. The doctor will not place an IBV valve(s) into your airway for any reason other than its intended use.

CAUTION: Humanitarian Device. Authorized by Federal law for use in the control 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 reduction surgery (LVRS). The effectiveness of this device for this use has not been demonstrated.

Patient Information for the:

IBV® VALVE SYSTEM

*Humanitarian Device
for use in the
Control of Air Leaks*



Spiration, Inc. Redmond, WA 98052



Glossary

- Airway:** The tubes in the lungs that pass air to and from the lung tissue.
- Anesthesia:** Technique to make the body insensitive to pain and makes you unconscious.
- Balloon Catheter:** A catheter with a balloon to measure airways inside of your lungs.
- Bronchoscope:** A thin flexible medical tool, with a camera and a hollow tube in the center, used to see the airways in the lungs.
- Catheter:** Thin, sterile, tubular-shaped tool used to deliver medicine or medical devices inside the body.
- Chest tubes:** A tube typically connected to a water trap valve system that allows continuous removal of air from the chest and helps avoid a build up of air between the chest wall and lungs.
- Contraindication:** Reason not to use the device/therapy.
- Intubation:** Placement of a plastic tube that connects the airflow from the mouth to the windpipe.
- Lobectomy:** Excision (cutting out) of a lobe of an organ or gland.
- Lung Volume Reduction Surgery (LVRS):** A major surgery done whereby some of the lung is removed.
- Pleurodesis:** Procedure to deposit a chemical directly on the lung surface to cause scarring; it is used to repair lung air leaks.
- Post-operative air leaks:** Air leaks that occur after a surgical procedure (operation).
- Prolonged air leak:** An air leak is one that lasts for 7 or more days.
- Re-operation:** The chest is surgically re-opened and a new attempt is made to close the leaking lung tissue by using staples and/or reinforcing materials and/or surgical glues.
- Sedation:** A medical procedure, giving sedative drugs to the patient to relax the central nervous system, can produce sleepiness.
- Segmentectomy:** Excision (cutting out) of a segment of an organ (like the lung) or a gland.
- Significant air leak:** An air leak that is severe and/or produces other health complications at the same time.
- Surgical glues:** Glue used inside the body to seal tissue.
- Surgical staples:** A medical grade staple used inside the body to seal tissue.
- Thorax:** The part of the body between the neck and the abdomen that contains the heart and lungs.

Intended Use

The Spiration® IBV® Valve System (See Figure 1) is intended 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

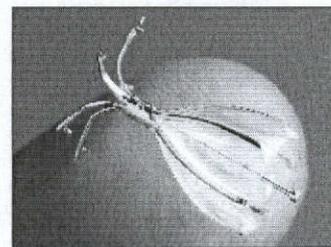


Figure 1

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.

What is a prolonged air leak?

In many surgeries, where portions of the lung have been cut, removed, or punctured, air leaks are common complications. Air leaks are caused because the lung tissue does not always completely close and seal using standard surgical tools, such as surgical staples and surgical glues. Most

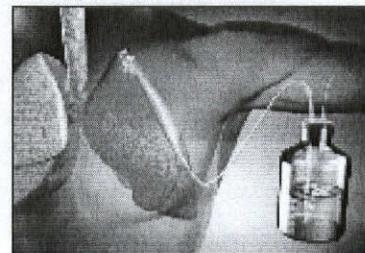


Figure 2

patients will have chest tubes put in their thorax after lung surgery, to prevent a build up of air inside the chest, which would make breathing difficult (See Figure 2). Chest tubes help remove the air from the chest and make breathing easier after surgery. In most cases, the air leak will seal and close after a few days. However, some patients will have a prolonged or severe air leak. If this is the case, the patient will need to keep the chest tubes in for a longer period, and may require a longer stay in the hospital.

Risks to patients from prolonged use of chest tubes

- If a patient is not able to move around because of the chest tubes, the reduced activity can lead to a higher chance of complications.
- If a patient needs pain medication for a longer period of time, the medication can lead to a higher chance of complications.
- If a patient spends a long time in the hospital, they have a higher chance of getting hospital-acquired infections.

Treatment choices for patients with a prolonged air leak

There are two common surgeries (operations) that are used to help fix prolonged or severe air leaks. They are pleurodesis and/or re-operation. Your doctor can give you more information about these two operations. To avoid the complications and risks of another surgery, your doctor is considering the use of the IBV Valve System to control your air leak.

Description of Device

The IBV Valves are very small, umbrella-shaped medical devices. When a valve is used, it is put into the part of your lung called an airway. The airways that will get the valve(s) placed in them are the ones that supply air to the tissue that is leaking (See Figure 3 & 4).



Figure 3



Figure 4

Finding the Air Leak

The airways in your lung can be reached and seen using a flexible instrument called a bronchoscope (See Figure 5). The bronchoscope is a narrow, flexible tube that has a camera on the end. This tool and the use of a balloon catheter, give information to the doctor about where to place the valve(s) so that the air leak can be reduced or stopped and the tissue can seal.

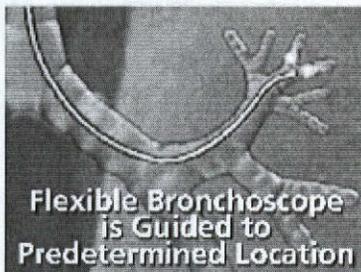


Figure 5

What to expect during the valve placement procedure

The flexible bronchoscope is inserted through your mouth or nose. This procedure is done under sedation or anesthesia, so that you do not feel severe discomfort (See Figure 6). Intubation tools, or a breathing machine (ventilator), may be used during sedation

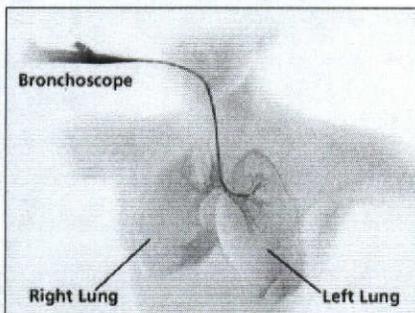


Figure 6

and/or anesthesia to help you breathe easier. The doctor performing the procedure will discuss with you the best type of sedation and/or anesthesia for you. The procedure to place valve(s) should take between 30 and 60 minutes.

First, the procedure doctor will check the suspected airways to identify the location of the air leak by inflating a small balloon (See Figure 7) that goes through the bronchoscope. The balloon used is very thin and may be made from latex. The balloon does two jobs at once. When the balloon is inflated, it will briefly block an airway to show the doctor if it

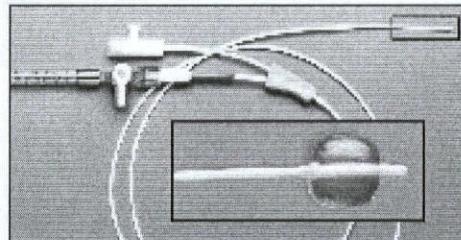


Figure 7

leads to the leaking tissue and it will also measure the size of that airway. The doctor will use this information to choose the best valve size(s) to fit the airway(s).

Next, the procedure doctor will place the correct size valve(s) into the selected airway(s) by using a small, thin flexible plastic tube (catheter).

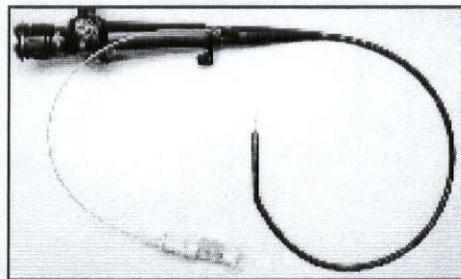


Figure 8

The catheter is passed through the bronchoscope to the selected airway (See Figure 8). The procedure doctor will be able to see the airway as each valve is placed (See Figure 3).

Once a valve is placed (implanted), it will open like a small umbrella and block the flow of air into the leaking lung tissue. This will decrease the air flow and/or stop the air leak helping the tissue to heal naturally. (See Figure 4).

What to expect after the valve placement procedure

During your recovery in the hospital, the doctor will check on you to see your progress. It is possible that your chest tubes will not be removed, even when the air leak has stopped, because your doctor wants to make sure that the tissue has time to heal. Your doctor, or the procedure doctor, will decide when you will be sent home (discharged) from the hospital. You may be sent home with the chest tubes still in place.

