



Patient Information for the:

ibv *valve system*

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



 **spiration**[®]

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 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 unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment

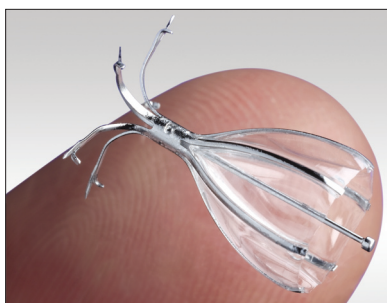


Figure 1

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



Figure 2

surgical glues. Most 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).

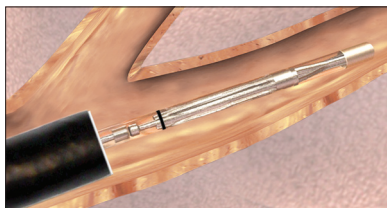


Figure 3. Valve is deployed in airway via catheter delivery.

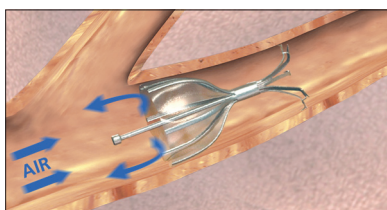


Figure 4. Valve blocks the flow of air into the leaking tissue.

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. Flexible bronchoscope is guided to predetermined location.

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 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.

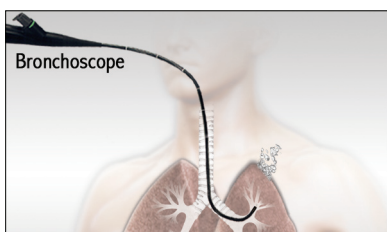


Figure 6

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

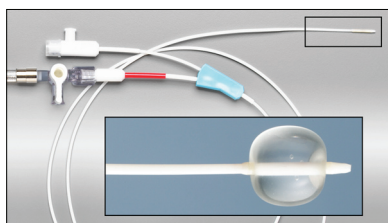


Figure 7

an airway to show the doctor if it 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). 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).

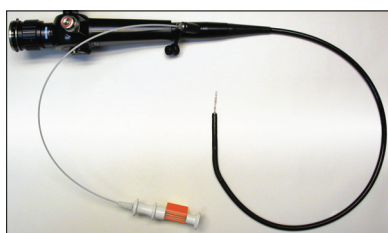


Figure 8

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.

Before you leave the hospital, you will be given instructions for your at-home care. This will include information on any medicines and follow-up visits. You will be given a wallet card that says you have one or more valves and will have the procedure doctor's contact information. Please keep this card with you at all times and show it to anyone who gives you medical care, including any emergency room medical staff (See Figure 9).



Figure 9

What to expect when the valve is removed

The valve(s) will be removed when your doctor thinks that the air leak has stopped and the tissue has healed. This should be in approximately 2-6 weeks. The procedure to remove the valve(s) will be the same as when the valve(s) was placed into your lungs. Removing the valve(s) should take less time. Valve removal may take place before the chest tubes are removed. The valve removal procedure is also done using sedation and a bronchoscope, as described above. The valve(s) will be removed using a very small tool called a grasping forceps, which is inserted through the bronchoscope (See Figure 10).

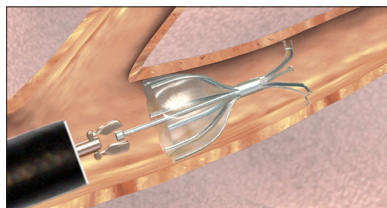


Figure 10. Common biopsy forceps are used for valve removal.

General risks

- You may receive no benefit by the insertion of a valve(s) to control your air leak and/or your condition may get worse (see potential risks associated with the valve(s)).
- There are risks associated with the bronchoscopy procedure (See potential risks associated with the procedure).
- Although rare, with all drugs and devices, it is possible that you may have an allergic reaction to the materials used in the IBV Valve System. If you are, or think you are allergic to latex, you must notify the doctor because the balloon used to measure the airways inside your lung may be made with latex.

Potential benefits

- The severity of your air leak may be reduced and heal in a shorter period of time.
- The need for additional surgery to control your air leak may be avoided.

Potential risks associated with the procedure

Please discuss these potential risks with your doctor.

- You may have problems from sedation, anesthesia and intubation, which may include the failure to be able to be taken off a breathing machine (ventilator).
- You may have swelling inside of your lungs that could make breathing hard and make your recovery time longer. This problem may require you to get breathing help and medicines.
- You may get bronchitis or pneumonia (infection/fever).
- You may have a cough that lasts a long time.
- You may develop shortness of breath or your shortness of breath may get worse.
- The area of your lung near or around the valve(s) may be damaged from handling of the bronchoscope.
- Heart problems, including changes in blood pressure and changes in heart rhythm, may make your recovery more difficult and require medicines.
- Severe problems may require you to get medical treatment or even surgery. A severe problem also may result in death.

Potential risks associated with the valves

Please discuss these potential risks with your doctor.

- The valve(s) may move or wear away your lung tissue. The valve(s) may become loose and may move out of place or be coughed out of your lungs.
- The valve(s) may cause swelling or irritate the inside of your airway or lung.
- Damage may occur to the inside of your airway from the normal movement of the valve(s).
- You may get bronchitis or pneumonia (infection/fever).
- You may have a cough that lasts as long as you have the valve(s) in place.
- You may experience shortness of breath or your shortness of breath may get worse.
- There may be some bleeding or a new air leak in the area(s) of your lung that has the valve(s), which may not stop and may require treatment or surgery.
- You may not get any better from having the valve(s). So, your air leak may not get better or may get worse after treatment.
- 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. Federal law restricts this device to sale by or on the order of a physician.



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