



Humanitarian Use Device for the Control of Post Surgical Air Leaks

PRODUCT INFORMATION

Provided by Spiration


IBV Valve System in Loading Tray



IBV Valve Deployment Catheter

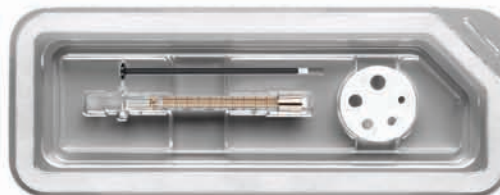


IBV Valve

	Catalog Number	Product Description
	HU-VS-5	IBV Valve System, 5mm
	HU-VS-6	IBV Valve System, 6mm
	HU-VS-7	IBV Valve System, 7mm

Airway Sizing Kit

The Airway Sizing Kit contains a calibration gauge and 500µL glass syringe.



Catalog Number HU-AS-U

Provided by Facility

Required ancillary equipment needed for each procedure

Olympus balloon catheter B5-2C (Applied Medical balloon catheter, Python EC 11mm/5F for latex sensitive patients)

Flexible bronchoscope with a working channel inner diameter of 2.6mm or greater

Bronchoscopy forceps appropriate for valve removal: cupped, rat tooth grasping, and pediatric

Sterile Luer-lock® 3-way stop-cock

Important: Luer-lock must have tight threads to provide the necessary "lock"

Standard 10cc sterile syringe with Luer-lock for use in preparing the balloon catheter

Sterile saline

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.

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 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
- ~ 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

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.

Cautions

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.

The IBV® Valve is not yet approved for use in emphysema, but is subject to an ongoing clinical investigation in which approval for use in emphysema will be sought.

For additional product information go to:

http://www.spiration.com/downloads/Instructions_for_Use_HDE_IBV_Valve_System.pdf

http://www.spiration.com/downloads/Instructions_for_Use_HDE_Airway_Sizing_IBV_Valve_System.pdf



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