



Humanitarian Use Device

Introducing the New
Spiration (IBV) Valve System

Same Valve...

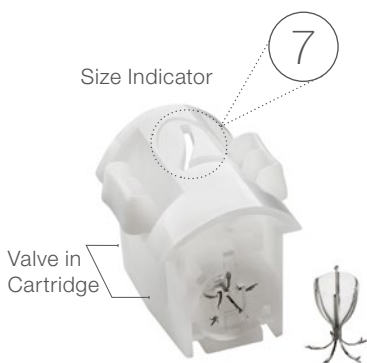
Now in a
Reloadable
Catheter



2.6 RELOADABLE SYSTEM

Multi-Use Loader

- ▶ **Intuitive Design**—Single patient multi-use loader engineered for quick, easy and reliable valve loading
- ▶ **Efficient**—Reloadable system reduces medical waste



Reloadable Catheter

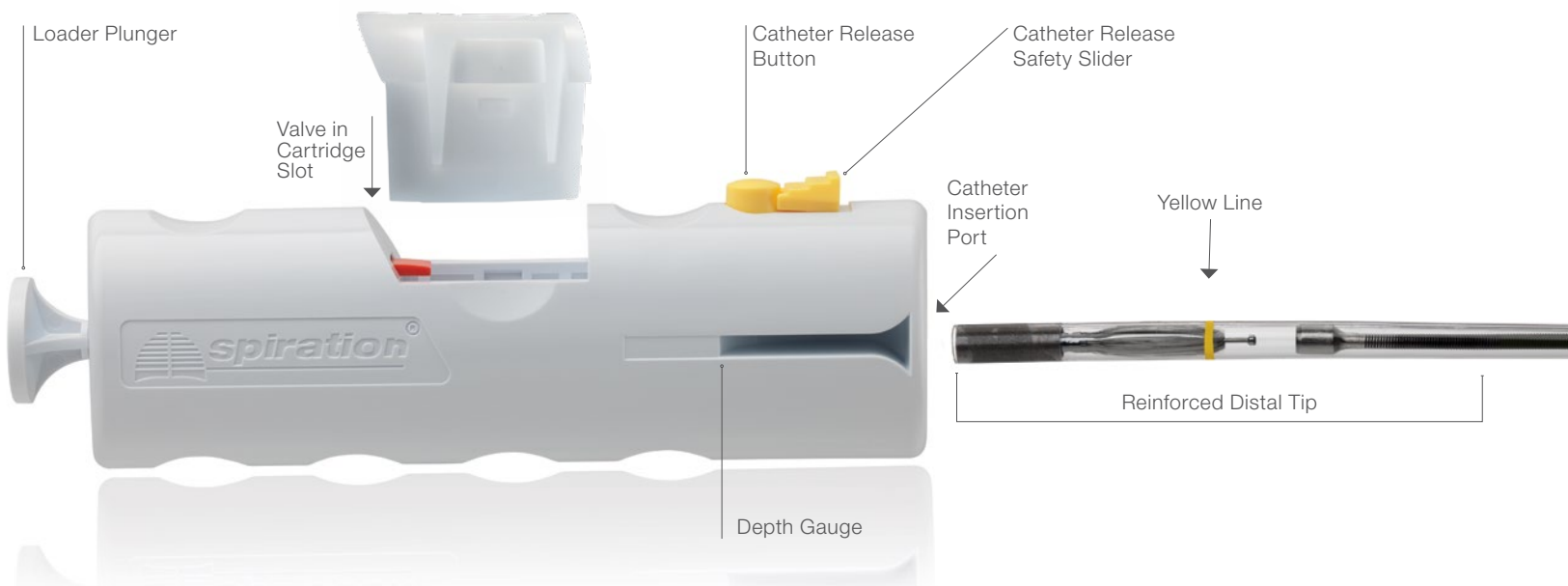
- ▶ **Reinforced Distal Tip**—Designed to easily navigate lung anatomy to the subsegmental level
- ▶ **Improved Visibility**—Yellow line provides better visualization for proper valve placement

Same Single-Use Valve

- ▶ The **first and only** valve designed to expand and contract with respiration allowing secretions to escape naturally along the bronchial wall¹
- ▶ The **first and only** valve with anchors to secure the valve in airway¹
- ▶ The **first and only** valve with a nitinol umbrella-like frame, designed to minimize contact with the bronchial wall and conform to complex airways¹

¹Spiration Valve System Instructions for Use

Read more on [spiration.com](https://www.spiration.com) or contact your Account Manager for more information.



Catheter Safety Clip



Spiration (IBV) Valve System (and ancillary equipment)

Valve in Cartridge



Catalog Number	Catalog Name
REF-HUS-V5	Valve in Cartridge, 5MM, HUD
REF-HUS-V6	Valve in Cartridge, 6MM, HUD
REF-HUS-V7	Valve in Cartridge, 7MM, HUD

Deployment Catheter and Loader



Catalog Number	Catalog Name
REF-HUS-C26	Deployment Catheter and Loader, HUD

Airway Sizing Kit



Catalog Number	Catalog Name
REF-HUS-SK	Airway Sizing Kit, HUD Note: Each Airway Sizing Kit is shipped with one Olympus B5-2C Balloon Catheter

Required ancillary equipment needed for each procedure

- Olympus Balloon Catheter (model B5-2C)
Note: Balloons will be shipped with Airway Sizing Kits directly from Spiration
- Flexible bronchoscope with a working channel inner diameter of 2.6mm or greater
- Bronchoscopy forceps appropriate for valve removal
- 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
- For latex sensitive patients use the Applied Medical Balloon Catheter Python EC 11mm/5F

Spiration Customer Support

Phone: 855-497-1616 | Monday–Friday, 8am–5pm Pacific Time

or

Email: customersupport@spiration.com



Spiration (IBV) Valve System Humanitarian Use Device for the Control of Postoperative Air Leaks

Spiration Valve System

Intended Use: The Spiration 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. Spiration 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 Spiration Valve System. The Instructions for Use, Spiration Valve System will give technical guidelines but do not obviate formal training in bronchoscopic procedures. The Spiration 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 Spiration 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

Airway Sizing Kit

The Airway Sizing Kit is an accessory to the Spiration Valve System used to determine the appropriate valve size to use for each target airway. A balloon catheter is used first in conjunction with the Airway Sizing Kit to determine, by selective airway occlusion, the location for the placement of valves to control prolonged air leaks.

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 Valve System.

Precautions

- Use of the Airway Sizing Kit 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. The following instructions will give technical guidelines but do not obviate formal training in the use of this device.
- The Olympus balloon catheters contain 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 Airway Sizing Kit.

Potential Adverse Effects

- Adverse effects associated with flexible bronchoscopy.
- Allergic reaction to latex specific to latex balloon 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.

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

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OLYMPUS[®]

Spiration Inc. d/b/a
OLYMPUS RESPIRATORY AMERICA
6675 185th Ave NE, Redmond, Washington 98052 USA
Phone: +1 (425) 497 1700
www.olympusrespiratory.com