

OLYMPUS

Your Vision, Our Future

Spiration[®]
Valve System

SPIRATION[®] VALVE SYSTEM

For the Treatment of Postoperative Air Leaks

Humanitarian Use Device



FOR THE TREATMENT OF PROLONGED AIR LEAKS

Postoperative air leaks continue to be the most common complication following surgical resection of the lung. Traditional management of prolonged air leaks involves chest drainage and observation followed by more invasive treatments when leaks do not resolve.^{1,2} This traditional “wait and see” approach can be associated with significant morbidity, increased mortality, prolonged hospital stay and increased use of healthcare resources.² An air leak present by day 5 should be considered for thoracic surgical consultation or treatment.¹

A minimally invasive solution for prolonged air leaks

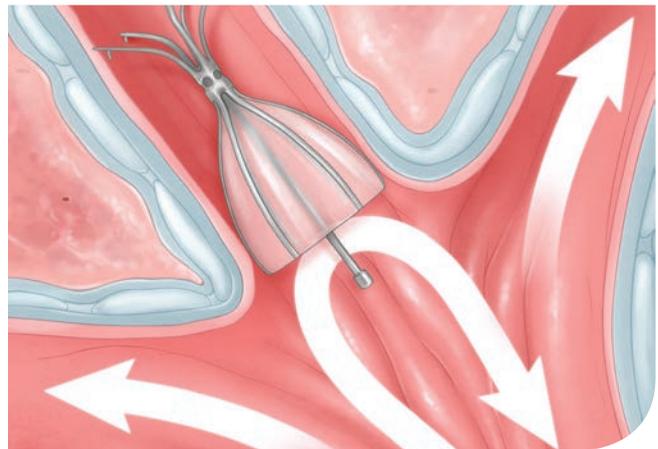
The Spiration Valve is an umbrella-shaped, one-way valve that is placed via a delivery catheter introduced through the working channel of a flexible bronchoscope. The valve consists of a nitinol frame covered with a polymer membrane and five anchors that securely engage the airway walls at the targeted treatment location. The unique design of the Spiration Valve minimizes contact with the bronchial wall, maintains position to redirect air even in complex patients, and facilitates removal when needed.

The right patient. The right product. The right outcomes.

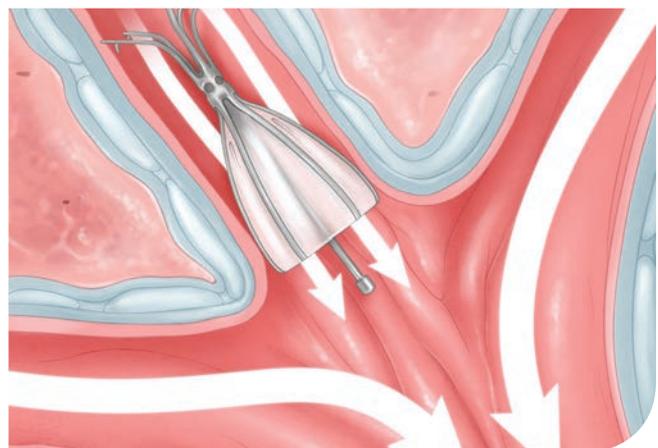
This treatment approach and algorithm based on quantitative air leak monitoring may lead to safe and successful air leak cessation at a median of 2 days after valve therapy and chest tube removal at a median of 4 days after valve therapy in the hands of trained physicians.¹

Valve treatment for prolonged air leaks is an easily reversible procedure.²

Interventions to reduce prolonged air leak may not only benefit patients by decreasing complications and hospital length-of-stay but also save health care resources with the potential to significantly preserve hospital margin.^{1,2}



On inhalation, the Spiration Valve may stop or reduce the amount of air flowing to portions of lung with an air leak.



On exhalation, the Spiration Valve flexibly constricts with the airways, allowing trapped air and secretions to escape naturally along the bronchial wall between the umbrella struts.

References

1. Dooms. Eur Respir J 2014; 43: 1142-1148.
2. Wood. ClinicoEconomics 2016;8 187-195.

THE PRECISION YOU NEED FOR THE OUTCOMES YOU WANT

- Persistent air leaks impact inpatient and outpatient resources utilization, cost, and morbidity.²
- A substantial reduction in an air leak using Spiration Valves may accelerate the resolution of an air leak. Complete cessation of an air leak may not be achievable, or necessary, for successful treatment.¹

Stays in Place

The **first and only** valve with anchors for 0% migration and expectoration.¹



Redirects Air

The **first and only** valve with umbrella struts to minimize tissue contact and allow secretions to escape naturally along the bronchial wall.^{1,2}

Greater Airway Access

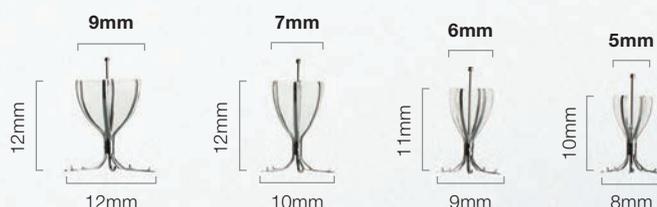
More Flexibility as to where to place a valve. Anchors can be in a separate airway than where sealing is.

Removable

The **first and only** valve designed to facilitate removal.^{1,2}

Largest Range of Valve Sizes

Available in four sizes to allow occlusion in proximal and distal airways.



SPIRATION® VALVE SYSTEM

Spiration Valves

A single-use, one-way bronchial valve preloaded in a disposable cartridge.

Catalog Number	Valve in Cartridge
REF-HUS-V5	5mm
REF-HUS-V6	6mm
REF-HUS-V7	7mm
REF-HUS-V9	9mm

Airway Sizing Kit

A kit used to determine the appropriate valve size for each target airway.

Catalog Number	Kit Includes
REF-HUS-VSK	500 microliter glass syringe with a plunger, a calibration gauge, and a sizing worksheet

Note: 1 Olympus B5-2C Disposable Balloon Catheter is shipped with each airway sizing kit

Deployment Catheter and Loader

A convenient deployment system for the delivery of multiple valves during a single patient procedure.

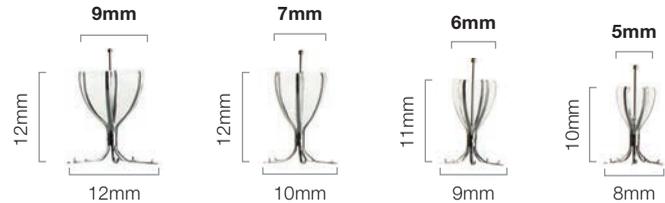
Catalog Number	Bronchoscope Working Channel
REF-HUS-C26N	2.6mm or greater inner diameter
	Deployment Catheter Length
	1020mm

Ancillary equipment needed for each procedure

- Flexible therapeutic bronchoscope with a working channel inner diameter of 2.6mm or greater
- Bronchoscopy forceps appropriate for valve removal
- Standard 10cc sterile syringe with Luer-lock
- Sterile saline (approximately 15–30cc used per procedure)
- A balloon catheter that inflates to 13mm or larger (for balloon occlusion only)

Note: Products are supplied sterile

CAUTION: Humanitarian Use 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 customer support:

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To request technical procedure support:

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For reimbursement support:

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Disclaimer: This is general reimbursement information only and is not legal advice nor is it advice about how to code, complete, or submit any particular claim for payment. The information provided represents Spiration's understanding of current reimbursement policies. It is a hospital and physician responsibility to determine appropriate codes, charges, and modifiers, and submit bills for the services consistent with the patient insurer requirements. Third-party payers may have different policies and coding requirements. Such policies can change over time. Spiration disclaims any responsibility for claims submitted by hospitals or physicians. Hospitals and physicians should check and verify current policies and requirements with the payer for any particular patient that will be using the Spiration IBV Valve System. Spiration is available to help in this process. The key in all coding and billing to payers is to be truthful and not misleading and make full disclosures to the payer about how the product has been used and the procedures necessary to deploy and remove the product when seeking reimbursement for any product or procedure.

For additional product information:

www.spiration.com/IFU

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