

# Spiration® Valve System

## Product Order Information

Humanitarian Use Device

### Spiration Valve System Air Leak Procedure Kit

Typical kit configuration shipped is listed below. Buyer to return all Returnable Product to Spiration with a completed Shipping and Product Utilization Form (SPUF). Buyer will be invoiced for all Used Product.<sup>1</sup>

#### SVS-C26N-9-VSK Kit

- 2 x 5 mm Spiration Valves
- 3 x 6 mm Spiration Valves
- 5 x 7 mm Spiration Valves
- 4 x 9 mm Spiration Valves
- 2 x C26N Deployment Catheters and Loaders
- 2 x VSK Airway Sizing Kits
- 2 x B5-2C Olympus Disposable Balloon Catheter

#### Forms/Documents

- 2 - Shipping and Product Utilization Form (SPUF) with instructions for return shipment of unused product – Blank
- 1 - Pink SPUF Example
- 1 – SVS Air Leak Procedure Overview document (LIT-04668-02)
- 1 - Packing List with product lot numbers
- 1 - Preprinted Return Waybill

### Spiration Valves

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

#### Catalog Number

#### Valve in Cartridge

REF-HUS-V5	5 mm
REF-HUS-V6	6 mm
REF-HUS-V7	7 mm
REF-HUS-V9	9 mm

### 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	2.6 mm or greater inner diameter
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### 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

**Note:** Products are supplied sterile

<sup>1</sup> Per definition of terms in Spiration, Inc TERMS AND CONDITIONS OF SALE document.



15½" x 13¼" x 13"



6" x 6¼" x 1¼"



12" x 12½" x 1¼"



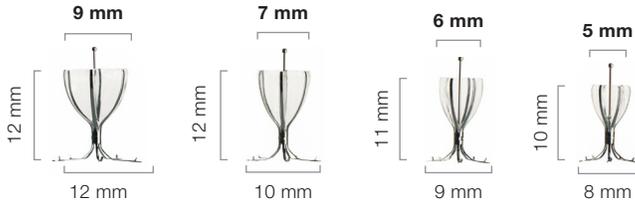
10¾" x 4" x 1¼"

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## 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	2.6 mm or greater inner diameter
	<b>Deployment Catheter Length</b>
	1020 mm

## Ancillary equipment needed for each procedure

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

**Note:** Products are supplied sterile

## For customer support:

Email: [HUD-customersupport@olympus.com](mailto:HUD-customersupport@olympus.com)  
Toll free: 855-497-1616 • Fax: 425-999-4545

## To request procedure support:

[svs.olympusamerica.com/support](http://svs.olympusamerica.com/support)

## For reimbursement support:

Toll free: 855.428.7346  
Email: [spirationvalvereim@olympus.com](mailto:spirationvalvereim@olympus.com)

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Coding recommendations, coverage policies, and reimbursement rates and methodologies vary by payer and are updated frequently. Providers should review applicable payer guidelines and instructions to ensure that billing practices comply with the payer’s requirements and contact the payer if they have any questions. The American Medical Association (AMA) is responsible for development and maintenance of Current Procedural Terminology (CPT®) codes. Providers should check the complete AMA CPT reference manual and/or another authoritative source for a complete listing of all CPT codes and their descriptors. It is the provider’s responsibility to report the code(s) that accurately describes the procedure(s) furnished and the patient’s diagnosis. Please note that the presence of a code, or billing a particular code, is not a guarantee of payment. Reimbursement will vary for each provider based on a number of factors, including the payer, site of service, geographic location and contractual terms.

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**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.

Manufactured by Gyirus ACMI, Inc. as successor-in-interest to: Spiration, Inc d/b/a Olympus Respiratory America 6675 185th Avenue N.E. Redmond WA 98052  
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