Spiration® Valve System

New Customer Initial Site Qualification

Humanitarian Use Device

Dear Physician:

Thank you for your interest in the Spiration® Valve System (SVS).

The steps outlined below must be completed to qualify a site to receive product. As the SVS is classified as a Humanitarian Use Device, some of these actions are required by the FDA:

1. Initial Site Qualification (documentation that on-label procedures are performed at the site) – please provide the following:

a. Make/model/number of therapeutic scopes (must have working channel inner diameter 2.6mm or greater)

b. Number of lobectomies, segmentectomies, and lung volume reduction surgeries performed at the site annually

Once we have the initial site qualification information, we can schedule physician training, provide the documentation to assist with an Institutional Review Board (IRB) submission for approval and provide a purchase agreement or Terms & Conditions of Sale with instructions to facilitate the ordering process.

2. Physician Training

a. Completion of the SVS professional education program by a minimum of 1 physician (didactic and hands on/virtual training is provided by Olympus)

3. Physician Compliance Agreement (provided at time of training)

4. Institutional Review Board (IRB) approval (local or commercial IRB)

5. Purchase Agreement, or no charge purchase order with agreement to Spiration's Terms & Conditions of Sale for each shipment

Olympus Field Representative:

Phone:

Email:

For Customer Support:

Email: **HUD-customersupport@olympus.com**
Toll Free: **855-497-1616**
Fax: **425-999-4545**

To Request Technical Procedure Support:

Visit: **svs.olympusamerica.com/support**

For Reimbursement Support:

Toll Free: **855-428-7346**
Email: **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.

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.

Manufactured by Gyrus ACMI, Inc. as successor-in-interest to: Spiration, Inc d/b/a Olympus Respiratory America 6675 185th Avenue N.E. Redmond WA 98052.
Specifications, design and accessories are subject to change without any notice or obligation on the part of the manufacturer.
Spiration Valve is a humanitarian use device.

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For more information, contact your local Olympus sales representative, or call 800-848-9024.
www.medical.olympusamerica.com

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