

Spiration[®] Valve System

Air Leak Procedure Kit Order Instructions

Humanitarian Use Device

Olympus Field Representative:

Phone:

Email:

Air Leak Procedure Kit Order Instructions

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

Placing an Order with a Valid Purchase Agreement

- Email, phone or fax order request to HUD Customer Support
- Provide no charge purchase order (if required by internal hospital policy)
- Indicate delivery instructions (standard overnight, first AM, Saturday delivery, alternate location)

Placing an Order without a Valid Purchase Agreement

- Email or fax request to HUD Customer Support
- Provide no charge purchase order number or purchase order document
- Indicate delivery instructions (standard overnight, first AM, Saturday delivery, alternate location)
- State acceptance of Spiration's standard Terms & Conditions of Sale
- Attach Spiration's standard Terms & Conditions of Sale document to email or include in faxed order

Example

"We would like to order a Spiration Valve System air leak procedure kit for ABC Hospital using PO#. First AM delivery. We agree to the attached terms and conditions."

To facilitate future orders, ask HUD Customer Support or your Olympus Field Representative about a purchase agreement.

Each SVS Air Leak Procedure Kit (SVS-C26N-9-VSK) includes:

Order Number	Product Description	Quantity
REF-HUS-V5	Valve in Cartridge, 5MM, HUD	2
REF-HUS-V6	Valve in Cartridge, 6MM, HUD	3
REF-HUS-V7	Valve in Cartridge, 7MM, HUD	5
REF-HUS-V9	Valve in Cartridge, 9MM, HUD	4
REF-HUS-C26N	Deployment Catheter and Loader, HUD	2
REF-HUS-VSK	Airway Sizing Kit, HUD Note: Each Airway Sizing Kit is shipped with one Olympus B5-2C Balloon Catheter 02-0764-00	2

After Order is Placed

HUD Customer Support will confirm receipt of order, shipping contact, address and required delivery date/time. Customers are responsible for inbound freight charges.

Invoicing Requirements

- Completed Shipping & Product Utilization Form (SPUF): A SPUF must be completed after each procedure recording product usage. Please fax completed SPUF to 425-999-4545 or email to <u>SPUF@spiration.com</u> immediately following procedure. A blank SPUF is included in the product shipment along with a completed sample (pink) for reference. Only used product (as defined in a valid Purchase Agreement or Spiration's standard Terms & Conditions of Sale) will be invoiced.
- **2. Return Unused Product:** Unused product must be returned to Spiration within 10 days of procedure. Preprinted labels are provided with the initial product shipment for your convenience. Reuse product shipment box for easy return.
- 3. Billable Purchase Order: Please issue a billable purchase order to billing@spiration.com within 30 days of procedure.

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

The information presented here is for illustrative purposes only and does not constitute reimbursement or legal advice. The reimbursement information provided by Olympus America Inc. and/or its direct or indirect (through one or more intermediaries) parent companies, affiliates or subsidiaries (collectively, the "Olympus Group") is gathered from third-party sources and is subject to change without notice. Reimbursement rules vary widely by insurer so you should understand and comply with any specific rules that may be set by the patient's insurer. You must also understand and comply with Medicare's complex rules. It is the provider's sole responsibility to determine medical necessity and to in turn identify which CPT codes to report and to submit accurate claims. You should always consult with your local payers regarding reimbursement matters. Under no circumstances shall the Olympus Group or its employees, consultants, agents or representatives be liable for costs, expenses, losses, claims, liabilities or otherwise) that may arise from or be incurred in connection with this information or any use thereof.

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.

CPT is a registered trademark of the American Medical Association. Copyright 2019–2020, American Medical Association, all rights reserved. Applicable FARS/DFARS apply to government 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.

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. Olympus and Spiration are registered trademarks of Olympus Corporation, Olympus America Inc., and/or their affiliates. I Medical devices listed may not be available for sale in all countries.



OLYMPUS AMERICA INC. 3500 Corporate Parkway, PO Box 610, Center Valley, PA 18034 For more information, contact your local Olympus sales representative, or call 800-848-9024. www.medical.olympusamerica.com

©2020 Olympus America Inc. All rights reserved. Printed in the USA OAIRES0320BR034628