2018 REIMBURSEMENT GUIDE
Spiration® Valve System
Humanitarian Use Device for Control of Air Leaks
Reimbursement Guide for the Spiration® Valve System

INTRODUCTION

Important Notice to Readers: This document is intended to help physicians, hospitals and ambulatory surgery centers better understand coding, billing, coverage policies and reimbursement methodologies for bronchial air leak valve procedures that involve Olympus bronchoscopy equipment.

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 other damages (whether direct, indirect, special, incidental, consequential 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.

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**Humanitarian Device for Use in the Control of Prolonged Air Leaks**

**HUD/HDE STATUS**
A Humanitarian Use Device (HUD) is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States per year. Spiration applied for and received U.S. Food and Drug Administration (FDA) designation as an HUD, and received Humanitarian Device Exemption (HDE) approval for the use of its minimally invasive Spiration® Valve System to control prolonged air leaks of the lung or significant air leaks that are likely to become prolonged, following lobectomy, segmentectomy and Lung Volume Reduction Surgery (LVRS). FDA approval of an HDE authorizes the applicant to market a HUD subject to certain profit and use restrictions.

**APPROVED INDICATION**
The Spiration® Valve System is indicated to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged, following lobectomy, segmentectomy and Lung Volume Reduction Surgery (LVRS). An air leak present on post-operative 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. The Spiration Valve System use is limited to 6 weeks per prolonged air leak.

**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 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.

- **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.
- **General Precautions:** 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 2.6 mm or larger. Do not use the Spiration Valve System for other than its intended use.
- **Potential Adverse Effects:** Atelectasis; Death; Infection in the tissue distal to a valve; Local airway swelling or edema at site of valve implantation; Pneumothorax.
- **For full prescribing information please see the Supporting Documentation Section of this guide.**
SPIRATION® VALVE PROCEDURE OVERVIEW

Postoperative air leaks continue to be the most common complication following lung resection surgery and a leading cause of increased hospitalization, morbidity and cost. Postoperative air leaks that are present 5-7 consecutive days following the surgery are typically classified as “prolonged” air leaks.¹

Conventional management of prolonged air leaks involves chest drainage and observation followed by more invasive treatments when leaks do not resolve.

The Spiration® Valve System is the only FDA approved device indicated to control prolonged air leaks of the lung following lobectomy, segmentectomy and Lung Volume Reduction Surgery (LVRS). The Spiration® valves are inserted proximal to an air leak through a minimally invasive bronchoscopic procedure. Once in place the one way valve limits distal airflow. The reduction of airflow may facilitate the resolution of the air leak.

SPIRATION® CODING OVERVIEW

There are four Category I CPT codes to report bronchoscopy services for insertion and removal of bronchial valve(s) in CPT® 2018 Professional Edition. The codes consist of a 2-code series for insertion (initial and each additional lobe), and a 2-code series for removal (initial and each additional lobe).

The Category I CPT codes are intended for billing on a per-lobe basis, including instances when multiple valve(s) are placed within or removed from a single lobe.

Physicians should consider all available coding options and select the appropriate CPT code based on the procedure(s) performed. Below are the coding descriptions for the insertion and removal of bronchial valves.

- **CPT 31647:** Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe

- **CPT 31651:** Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure[s])

- **CPT 31648:** Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe

- **CPT 31649:** Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure)

### 2018 MEDICARE PHYSICIAN AND OUTPATIENT HOSPITAL REIMBURSEMENT

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>CPT® Description</th>
<th>Physician Allowed Amount for Hospitals/ASC</th>
<th>Hospital Outpatient Allowed Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>31647</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe</td>
<td>$221</td>
<td>$4,864*</td>
</tr>
<tr>
<td>31651</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure)</td>
<td>$77</td>
<td>N/A</td>
</tr>
<tr>
<td>31648</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe</td>
<td>$202</td>
<td>$2,616*</td>
</tr>
<tr>
<td>31649</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure)</td>
<td>$70</td>
<td>$1,324</td>
</tr>
</tbody>
</table>

Represents National Average Medicare Fees Without Geographic Adjustment. Updated December 2017.

Sources:
- CPT & Description: Copyright 2017 American Medical Association. All rights reserved. Applicable FARS/DFARS apply to government use.
- Physician Fee Schedule: CMS-1676, addendum B published 2017-11-15
- Hospital Outpatient Fee Schedule: CMS-1678, addendum B published 2017-11-13
- Outpatient allowed amounts effective through 12/31/2018. Physician payment amounts based on $35.9999 conversion factor effective through 12/31/2018.
- Physician Fee Schedule Procedures and Facility Payments may be subject to Medicare’s Multiple Procedure Reduction Rules.

*J1 code status Outpatient Hospital C-APC procedure is a comprehensive APC limiting payment for other procedures performed that day.
DIAGNOSIS CODING

Potential ICD-10-CM Diagnosis Codes for Hospitals and Physicians

The Spiration® Valve System is indicated for the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged following lobectomy, segmentectomy, and Lung Volume Reduction Surgery (LVRS). Hospitals and physicians should check with payers for clinical application of diagnosis codes for payment and coverage. Applicability and usage of these codes may vary per case.

Potential ICD-10-CM Diagnosis Codes for Air Leaks

<table>
<thead>
<tr>
<th>ICD-10-CM CODE</th>
<th>ICD-10-CM Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J93.0</td>
<td>Spontaneous tension pneumothorax</td>
</tr>
<tr>
<td>J93.11</td>
<td>Primary spontaneous pneumothorax</td>
</tr>
<tr>
<td>J93.12</td>
<td>Secondary spontaneous pneumothorax</td>
</tr>
<tr>
<td>J93.81</td>
<td>Chronic pneumothorax</td>
</tr>
<tr>
<td>J93.82</td>
<td>Other air leak</td>
</tr>
<tr>
<td>J93.83</td>
<td>Other pneumothorax</td>
</tr>
<tr>
<td>J93.9</td>
<td>Pneumothorax, unspecified</td>
</tr>
<tr>
<td>J95.811</td>
<td>Postprocedural pneumothorax</td>
</tr>
<tr>
<td>J95.812</td>
<td>Postprocedural air leak</td>
</tr>
</tbody>
</table>
## INPATIENT CODING AND REIMBURSEMENT

### ICD-10-PCS Procedure Codes for Inpatient Hospital Providers

Hospitals use ICD-10-PCS procedure codes to describe procedures performed on inpatients. The table below identifies potential ICD-10-PCS procedure codes that may be used to describe the insertion and removal of the endobronchial valve(s). Hospitals are responsible for accurately selecting ICD-10-PCS procedure codes to describe the procedures performed during an inpatient stay.

The ICD-10-PCS procedure codes listed in this table are not intended to be an exhaustive list of all possible hospital procedure codes.

**Potential ICD-10-PCS Procedure Codes for Spiration® Valve System**

<table>
<thead>
<tr>
<th>ICD-10-PCS CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Valve Placement</strong></td>
<td></td>
</tr>
<tr>
<td>0BH38GZ</td>
<td>Insertion of Endobronchial Valve into Right Main Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0BH48GZ</td>
<td>Insertion of Endobronchial Valve into Right Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0BH58GZ</td>
<td>Insertion of Endobronchial Valve into Right Middle Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0BH68GZ</td>
<td>Insertion of Endobronchial Valve into Right Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0BH78GZ</td>
<td>Insertion of Endobronchial Valve into Left Main Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0BH88GZ</td>
<td>Insertion of Endobronchial Valve into Left Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0BH98GZ</td>
<td>Insertion of Endobronchial Valve into Lingula Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td><strong>Valve Removal</strong></td>
<td></td>
</tr>
<tr>
<td>0WPQ8YZ</td>
<td>Removal of Other Device from Respiratory Tract, Via Natural or Artificial Opening Endoscopic</td>
</tr>
</tbody>
</table>
Spiration® Valve System: Frequently Asked Questions

- What are the CPT® codes for bronchial valve insertion and/or removal?
  There are four Category I CPT codes to report bronchoscopy services for the insertion and removal of bronchial valve(s). The codes consist of a 2-code series for insertion procedures (initial and each additional lobe) and a 2-code series for removal procedures (initial and each additional lobe).
  These Category I CPT codes are intended for billing on a per-lobe basis, including instances when multiple valves are placed or removed from a single lobe.

- Can multiple CPT codes be reported when more than one valve is inserted or removed from a single lobe?
  No, the Category I CPT codes are intended for billing on a per-lobe basis, including instances when multiple valves are placed within or removed from a single lobe.

- Can balloon occlusion be billed separately in addition to the valve placement?
  No, the insertion of bronchial valve CPT codes description includes balloon occlusion as part of the procedure.

- What is the HCPCS code (or C code) for the valve?
  C codes are required for reporting of select devices only. There is no HCPCS code or C code for the Spiration® Valve System.

- Are prior authorizations required for the Spiration® Valve System?
  Under Medicare, prior authorizations are not required for any procedure; however, your local Medicare contractor may have specific processes that require submission of materials before a case is performed and billed to your local Medicare contractor.
  Commercial payers vary in their requirements for prior authorization for the Spiration® Valve System. The provider should contact the patient’s payer prior to performing any procedure that may require prior authorization.

- Are there Spiration® Valve System materials that we can use in our discussions with payers?
  Please see and review the detailed information in the Supporting Materials Section of this reimbursement guide.
OLYMPUS HELPLINE

Olympus has a designated helpline to assist you in answering questions about the Spiration Valve System:

**Spiration® Valve Reimbursement and Coding Helpline**

Phone: 855-428-7346  
Hours: 9:00 am - 5:00 pm Pacific Time  
Email: Spirationvalvereim@olympus.com

Olympus Reimbursement Services

- Review of the HDE process and payer submission materials.
- Identification of the correct coding for Spiration Valve System.
- Assistance with determining prior authorization policies.
- Review of your local payer’s specific coverage and reimbursement criteria.
- Provision of additional details relating to medical documentation.
- Review of payer explanation for denied or underpaid claims.
- Instructions on how to correct coding errors and reimbursement appeals guidance.
### Supporting Documentation

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<td>ATTACHMENT D:</td>
<td>Instructions For Use – Spiration® Valve System</td>
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<td>ATTACHMENT E:</td>
<td>Instructions For Use – Airway Sizing Kit</td>
</tr>
<tr>
<td>ATTACHMENT F:</td>
<td>Spiration® Valve System Procedure Overview</td>
</tr>
</tbody>
</table>
August 17, 2015

Cyndy Adams
Senior Regulatory Affairs Manager
Spiration, Inc.
6675 185th Avenue N.E.
Redmond, WA  98052

Re:  H060002.S007
Spiration Valve System
Filed: February 6, 2015
Amended: June 4, 2015

Dear Ms. Adams:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your humanitarian device exemption application (HDE) supplement, which requested approval for a modified version of the reloadable catheter and to introduce a 9mm valve. The device, as modified, will be marketed under the trade name Spiration Valve System and is indicated for 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 post-operative 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. Based upon the information submitted, the HDE supplement is approved subject to the conditions described in the approval order for your original HDE. You may begin commercial distribution of the device as modified by your HDE supplement upon receipt of this letter.

The sale, distribution, and use of this device are limited to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) under the authority of section 515(d)(1)(B)(ii) of the FD&C Act. In addition, in order to ensure the safe use of the device, FDA has further restricted the device within the meaning of section 520(e) of the FD&C Act under the authority of section 515(d)(1)(B)(ii) of the FD&C Act insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the FD&C Act.

Continued approval of this HDE is contingent upon the submission of periodic reports, required
under 21 CFR 814.126, at intervals of one year (unless otherwise specified) from the date of approval of the original HDE. Two copies of this report, identified as "Annual Report" and bearing the applicable HDE reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.126.

In addition to the above, an HDE holder is required to maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing institutional review boards (IRBs), as well as any other information requested by a reviewing IRB or FDA.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

Before making any change affecting the safety or effectiveness of the device, you must submit an HDE supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39 except a request for a new indication for use of for a humanitarian use device (HUD). A request for a new indication for use for an HUD shall comply with the requirements set forth in 21 CFR 814.110 which includes obtaining a new designation of HUD status for the new indication for use and submission of an original HDE application in accordance with §814.104. The application for the new indication for use may incorporate by reference any information or data previously submitted to the agency.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to:
Page 3 – Ms. Adams

(1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of an HDE. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that as soon as possible and before commercial distribution of your device you must submit an amendment to this HDE with copies of all approved labeling in final form. The labeling will not routinely be reviewed by FDA staff when HDE supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above HDE number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
HDE Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have questions concerning this approval order, please contact James Lee Ph.D. at (301) 796-8463.

Sincerely yours,

Erin I. Keith -S
Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health
B: REQUESTING PRIOR AUTHORIZATION

Prior authorization is a process that varies among different payers. It is always best to contact your payer representative to obtain a thorough understanding of the steps involved in making a prior authorization request. Here are some common requirements in obtaining prior authorization. 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.

Documentation

Identify the documentation that the payer requires in order to review the prior authorization request. Generally, a letter of medical necessity is needed. This document summarizes the rationale for the payer to provide coverage for the therapy in question.

Request Routing

Ensure that you understand who will review your request and how to route your request to the payer’s review staff. Some departments provide specific routing instructions and have a preference for fax, email or written correspondence. Requests are easily misplaced. Please follow-up with review staff to ensure your request has been received and periodically thereafter to ensure the request is being addressed.

Timelines

When speaking to the payer representative, clarify the timeframe in which original documentation and supplemental documents must be provided and how long it will take to receive an answer. Requests may be rejected if the applicant is not diligent in responding to requests for additional information.

Denials

Determine your avenues for payer appeal if the prior authorization is denied. Most payers have multiple levels of appeal that allow for review by different internal bodies. An initial denial can be subsequently overturned on appeal.

Recertification

When a prior authorization request has been approved, be aware that some decisions may have a limited timeframe for which the approval is effective. In some cases, recertification may be necessary if the initial timeframe is exceeded.
[DATE]
[prior authorization fax number or mailing address]
Patient Name: [Patient Name]
Member ID#: [Member ID]
Date of Birth:

Date of Service: [MM/DD/YYYY]
Place of Service: [Facility/Hospital Name], [Street address], [City], [State], [Zip]
Performing physician: [Physician Name], [NPI]

CPT Codes [Insert CPT Codes]
ICD-9- Procedure code: [Insert ICD-9 Procedure codes]
Diagnosis codes: [Insert diagnosis codes]

Prior Authorization for coverage for the assessment, insertion and removal of the Spiration Valve System

Dear [RECIPIENT],

I am writing to request a prior approval for coverage of the Spiration Valve System for treatment of a postoperative air leak. [Patient Name] has been diagnosed with [insert specific air leak diagnosis code description] on postoperative day [insert day]. The patient's current status is [insert detail of impairment and how it impacts quality of life, caregiver employment, etc].

It is my expert medical opinion that a prolonged hospital stay is not in the best interest of this patient's health and the placement of the Spiration Valve System will speed recovery and discharge from the hospital. The Spiration valves are delivered via a minimally invasive procedure that has shown to reduce or stop air leaks by limiting airflow to the damaged tissue. Given the condition of my patient I do not believe any other option will resolve their current medical issue.

A landmark study published in the European Respiration Journal demonstrated the use of the Spiration Valve as a safe and effective treatment for patients suffering from prolonged air leaks after anatomic resection of the lung.¹ After placement of the Spiration Valves, patients in the study experienced air leak cessation at a median of two days and chest tube removal at a median of four days. During the entire study there were no deaths, cardiovascular complications, or implant-related events such as infection distal to valve, lobar atelectasis, hemoptysis, pneumothorax or expectoration.¹

The Spiration Valve System has been available in the United States under Humanitarian Device Exemption since October 2008.

Based on the above information and my medical judgment, I recommend the use of the Spiration Valve in this patient for the control of his/her prolonged air leak and improvement in their clinical course.
C: SAMPLE LETTER OF MEDICAL NECESSITY (CONTINUED)

NOTE: The text below is only a guide and should not be replicated verbatim. Customize to individual patient and clinical opinions/justification.

We are requesting confirmation that this treatment be considered a covered benefit based on medical necessity and that associated professional fees for the procedure and follow-up will be covered. I ask that you concur with this rationale and consider the [PROCEDURE] using the Spiration Valve System and its associated materials and services to be a covered benefit for [PATIENT’S NAME].

I am enclosing a summary of procedures and dates of service that [PATIENT’S NAME] has already undergone and a bibliography of clinical literature supporting the use of the Spiration Valve System. [Note if relevant: prior treatments and outcomes, additional information on the patient’s history and implications of prolongation of the air leak. A timeline is useful.]

I would like to sincerely thank you for taking the time to review this information and for considering coverage. If you have any questions, please feel free to contact me so that I can be of further assistance.

Sincerely,

[Signature]


Caution

The Spiration Valve System is indicated 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. The effectiveness of this device for this use has not been demonstrated.

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 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.

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.

General Precautions: 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. Do not use the Spiration Valve System for other than its intended use. Potential Adverse Effects: Atelectasis; Death; Infection in the tissue distal to a valve; Local airway swelling or edema at site of valve implantation; Pneumothorax.

For full prescribing information go to: www.spiration.com
D: INSTRUCTIONS FOR USE – SPIRATION® VALVE SYSTEM

SPIRATION® VALVE SYSTEM

INSTRUCTIONS FOR USE

Humanitarian Device for Use in the Control of Air Leaks

1. INTENDED USE

The Spiration Valve System is a device to control persistent air leaks of the lung, or significant air leaks that are likely to cause or contribute to respiratory distress, hypertension, or subcutaneous emphysema and not responsive to other measures. The Spiration Valve System is designed to control air leaks, which can be caused by trauma, surgery, radiation therapy, or other causes. The Spiration Valve System is intended for use in adult patients.

2. SPIRATION VALVE SYSTEM DESCRIPTION

The Spiration Valve System consists of a Spiration Valve (IBV) in Cartridge (“Spiration Valve” or “valve”) and a Deployment Catheter (“catheter”) and Loader (“loader”). The Airway Sizing Kit is an accessory to the Spiration Valve System. The Airway Sizing Kit is intended for the exchange of catheters. The loader is used to deploy valves and the catheter is used to access the airway to deploy valves.

2.1. Spiration Valve in Cartridge

The valve is composed of a Nitinol frame and a polymer membrane. The valve is designed to limit airflow to the portions of the lungs distal to the valve, while still allowing mucus to pass through the valve for removal and air movement in the proximal direction. The valve is comprised of a Nitinol frame and a polymer membrane with a set of anchors that are compressed into the valve at the time of manufacture to help secure the valve to the airway wall. The valve is designed to minimize air leak after deployment. The valve is available in 5, 6, 7, and 9 mm diameters and is pre-packaged in a disposable cartridge that protects the valve during transit. The valve is designed to be inserted and removed using the loader and catheter.

2.2. Deployment Catheter and Loader

The catheter and loader are supplied sterile and packaged in a sealed pouch. The valve is also supplied sterile and is sterilized by EO. The catheter and loader are not steriley packaged and must be handled with care.

3. WARNINGS

• Valve placement and removal must be done under bronchoscopic observation with visualization of the targeted airway. 
• Oral or orotracheal intubation is required for the loader and catheter. 
• Oral or orotracheal intubation is required for the loader and catheter. 
• The Spiration Valve System should not be used in the catheter for more than one patient procedure. 
• Do not reuse the Spiration Valve System for other than its intended use. 
• Do not use the Spiration Valve System for any other than its intended use. 
• Do not remove the valve from the cartridge.

3.1. Contraindications

• Atelectasis may occur after the air leak seals; patients should be monitored for this possible complication.
• Do not use the Spiration Valve System for other than its intended use. 
• Do not do any valve deployment or valve removal in any patient with a history of valve deployment or valve removal.
• Do not use the Spiration Valve System for other than its intended use. 
• Do not remove the valve from the cartridge.

4. Warnings

• Atelectasis may occur after the air leak seals; patients should be monitored for this possible complication.
• Do not use the Spiration Valve System for other than its intended use. 
• Do not do any valve deployment or valve removal in any patient with a history of valve deployment or valve removal.
• Do not use the Spiration Valve System for other than its intended use. 
• Do not remove the valve from the cartridge.

5. GENERAL PRECAUTIONS

• Only use a loader with an instrument channel inner diameter of 2.6 mm or larger.
• The loader and catheter should be used only for patients who have active air leak, and not immediately adjacent to the airway.

6. PACKAGE INSPECTION, STORAGE, AND HANDLING

6.1. Checking the Package

• Medical device is included with the catheter and loader.

6.2. Storage Conditions

• The Spiration Valve System is stored at room temperature. Do not store the Spiration Valve System in the freezer or in a refrigerator. Do not store the Spiration Valve System in a dry environment.

6.3. Handling

• The Spiration Valve System should be handled with care.

7. PREPARATION FOR THE PROCEDURE

7.1. Items Required and Recommended for Spiration Valve Procedure

- An endotracheal (ET) tube (see section 11.1 for details)
- The loader and catheter (one per patient)
- The Spiration Valve in Cartridge (one per patient)
- Additional ancillary equipment required (not provided with the Spiration Valve System): 
  - A flexible bronchoscope with an inner diameter of 2.6 mm or larger.

7.2. Items Recommended for Spiration Valve Removal Procedure

- An endotracheal (ET) tube (see section 11.1 for details)

8. PACKAGING, REPROCESSING, AND HANDLING

8.1. Opening the Package

• Medical device is included with the catheter and loader.

8.2. Storage Conditions

• The Spiration Valve System is stored at room temperature. Do not store the Spiration Valve System in the freezer or in a refrigerator. Do not store the Spiration Valve System in a dry environment.

8.3. Handling

• The Spiration Valve System should be handled with care.

9. CHRONICAL USE OF THE SPIRATION® VALVE SYSTEM

9.1. Spiration Valve Deployment

• The Spiration Valve System is designed to control persistent air leaks of the lung, or significant air leaks that are likely to cause or contribute to respiratory distress, hypertension, or subcutaneous emphysema and not responsive to other measures. 
• The Spiration Valve System is designed to control persistent air leaks of the lung, or significant air leaks that are likely to cause or contribute to respiratory distress, hypertension, or subcutaneous emphysema and not responsive to other measures. 
• The Spiration Valve System is designed to control persistent air leaks of the lung, or significant air leaks that are likely to cause or contribute to respiratory distress, hypertension, or subcutaneous emphysema and not responsive to other measures. 
• The Spiration Valve System is designed to control persistent air leaks of the lung, or significant air leaks that are likely to cause or contribute to respiratory distress, hypertension, or subcutaneous emphysema and not responsive to other measures.

9.2. Spiration Valve Removal

• The Spiration Valve System is designed to control persistent air leaks of the lung, or significant air leaks that are likely to cause or contribute to respiratory distress, hypertension, or subcutaneous emphysema and not responsive to other measures.

9.3. Valve System Removal

• The Spiration Valve System is designed to control persistent air leaks of the lung, or significant air leaks that are likely to cause or contribute to respiratory distress, hypertension, or subcutaneous emphysema and not responsive to other measures.

9.4. Clearing the Airway

• The Spiration Valve System is designed to control persistent air leaks of the lung, or significant air leaks that are likely to cause or contribute to respiratory distress, hypertension, or subcutaneous emphysema and not responsive to other measures. 
• The Spiration Valve System is designed to control persistent air leaks of the lung, or significant air leaks that are likely to cause or contribute to respiratory distress, hypertension, or subcutaneous emphysema and not responsive to other measures. 
• The Spiration Valve System is designed to control persistent air leaks of the lung, or significant air leaks that are likely to cause or contribute to respiratory distress, hypertension, or subcutaneous emphysema and not responsive to other measures.
D: INSTRUCTIONS FOR USE – SPIRATION® VALVE SYSTEM (CONTINUED)

10. Operator Instructions

10.1 Installing the Air Leak by Balloon Occlusion

1. Select a catheter of the determined valve size. Remove the catheter from packaging. Insert the catheter into the instrument channel of the bronchoscope until the distal end is visible.

2. Inspect the valve prior to inserting it into the airway. Damage may include kinks, deformation, tears, or protrusions. If the catheter is damaged, use a new catheter.

3. If the air leak has not decreased or stopped, deflate the balloon, pull the balloon catheter into the bronchoscope, and evaluate the next airway segment.

4. Verify the catheter retractor is fully forward and the green safety clip is installed over the yellow portion of the catheter.

5. If a "click" is not heard, fully re-insert the shipping lock into the loader. Repeat step 2.

6. When the maneuverability of the bronchoscope is limited by standard sized fenestrations, advance the catheter retractor to maintain the valve line at the bronchoscope tip and remove rod tip from inside the bronchoscope. Do not release the valve from the forceps until the valve is completely removed from the patient.

7. During removal, the valve struts may invert. Do not release the valve from the forceps until the valve is completely removed from the airway.

8. As needed, the removal rod tip can be used to secure the valve on the airway wall. Use care to make sure that the removal rod does not get caught in the fenestration of the bronchoscope when removing the valve.
### 12. Clinical Studies

#### 12.1 Post Approval Study

Spiration conducted a post approval study of the Spiration Valve System. The study methods and results are summarized in Table 3.

<table>
<thead>
<tr>
<th>Study Methods</th>
<th>Objective</th>
<th>Design</th>
<th>Study Population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Characterize the safety profile of the Spiration Valve System</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Prospective Multi-Center Observational Study</td>
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</table>

### Table 3: Post Approval Study Methods and Results

<table>
<thead>
<tr>
<th>Study Population</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inclusion Criteria</strong></td>
</tr>
<tr>
<td>Subject has an air leak present on day 7 after lobectomy, segmentectomy, or lung volume reduction surgery (LVRS), or on day 5 if the air leak is continuous: (1) present during normal inspiration and expiration, or (2) present upon normal expiration with no inspiratory component.</td>
</tr>
<tr>
<td>Subject is unable to provide informed consent and there is no designated authority to act on their behalf</td>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>Exclusion Criteria</strong></td>
</tr>
<tr>
<td>Subject has air leak only on force exhalation or cough</td>
</tr>
<tr>
<td>Subject has significant active asthma, pneumonia, bacterial bronchitis, or clinically significant bronchiectasis</td>
</tr>
<tr>
<td>Subject is unable to provide informed consent and there is no designated authority to act on their behalf</td>
</tr>
<tr>
<td>Subject is not an appropriate candidate for, or unable to tolerate, flexible bronchoscopy procedures</td>
</tr>
<tr>
<td>Subject has co-morbidities or factors that will prevent follow-up during the study period</td>
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<tr>
<td></td>
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<tr>
<td><strong>Data Source</strong></td>
</tr>
<tr>
<td>Study specific case report forms</td>
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<tr>
<td></td>
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<tr>
<td><strong>Key Study Endpoints</strong></td>
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<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>Number of Study Sites, Subjects, and Follow-up Rate</strong></td>
</tr>
<tr>
<td>39 subjects were enrolled at 11 sites</td>
</tr>
<tr>
<td>100% (32/32 as per protocol)</td>
</tr>
<tr>
<td></td>
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<tr>
<td><strong>Study Visits and Length of Follow-up</strong></td>
</tr>
<tr>
<td>Following valve placement, subjects were followed through valve removal or 6 weeks, whichever was earlier</td>
</tr>
<tr>
<td></td>
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<tr>
<td><strong>Results</strong></td>
</tr>
<tr>
<td><strong>Final Safety Findings</strong></td>
</tr>
<tr>
<td>Two adverse events were reported for the 32 subjects treated.</td>
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<td></td>
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<tr>
<td><strong>Final Effectiveness Findings</strong></td>
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<tr>
<td>Of the 39 subjects enrolled, 32 received valves (as per protocol); 7 subjects did not receive valves due to inability to localize air leak (5), resolution of air leak (1), and inability to access air leak. 30 (94%) showed a positive response to valve placement. Two (6%) showed no improvement in air leak.</td>
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<td></td>
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<tr>
<td><strong>Study Endpoints / Weaknesses</strong></td>
</tr>
<tr>
<td>Strengths</td>
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<tr>
<td>Prospective, randomized</td>
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<tr>
<td>Through follow-up for adverse event determination</td>
</tr>
<tr>
<td>Limitations</td>
</tr>
<tr>
<td>Lack of control arms to determine underlying adverse event rate in comparison</td>
</tr>
<tr>
<td>Limitations</td>
</tr>
<tr>
<td>Limitation of study on efficacy</td>
</tr>
<tr>
<td>Number of female patients (10), small sample size (32)</td>
</tr>
</tbody>
</table>

### 13. Patient Information

A Patient Information Pamphlet is available for potential patients (Patient Information for the Spiration Valve System, Humanitarian Device for Use in the Control of Air Leaks). Patients who receive treatment will be given a wallet card that indicates the patient has valve(s) and lists the procedure doctor’s contact information.
E: INSTRUCTIONS FOR USE – AIRWAY SIZING KIT

1. Intended Use

The Airway Sizing Kit is an accessory to the Spiration Valve System used to determine the appropriate valve size to use for each targeted airway. A balloon catheter is used first in conjunction with the calibration gauge to establish a valve size reference. To ensure the appropriate valve size is selected for each targeted airway, the balloon catheter must be calibrated prior to use as a sizing tool. Calibration is a process used to measure all of the airways to be treated in a single patient.

A compliant balloon is acceptable to use for airway sizing: the Olympus ® B5-2C balloon. The Airway Sizing Kit consists of a glass syringe with a plunger and a calibration gauge (see Figure 1). The glass syringe has a volumetric scale (in microliters, μL) that is used with a balloon catheter as a measuring tool. Prolonged air leaks are treated by placement of valves to control prolonged air leaks. The Spiration Valve System is designed to work in conjunction with a flexible bronchoscopy tool. One balloon catheter is used to measure all of the airways to be treated for a single patient.

2. Device Description

The Airway Sizing Kit consists of a glass syringe with a plunger and a calibration gauge (see Figure 1). The glass syringe has a volumetric scale (in microliters, μL) that is used with a balloon catheter as a measuring tool. To calibrate the syringe, a 10cc syringe is filled with sterile saline and calibrated with the calibration gauge. During the sizing process, the calibrated balloon is inflated at the target airway location. The saline volume used to inflate the balloon indicates the appropriate valve size to use at the target location.

3. Contraindications

• Patient is allergic to latex.

4. Precautions

• Use of the Airway Sizing Kit requires knowledge and technical skills. The operator must be a physician or medical person under the supervision of a physician and trained in flexible bronchoscopy techniques. The following instructions will give technical guidelines but do not substitute for training in the use of the device.

5. Potential Adverse Effects

• Adverse effects associated with local anesthesia.

6. Items Required and Recommended for Use with the Airway Sizing Kit

Items required provided with the Airway Sizing Kit:

• Calibration gauge

Items required not provided with the Airway Sizing Kit:

• Standard 10cc sterile syringe with Luer lock fitting

Items on the Airway Sizing Kit:

• 10cc glass syringe

• Glass syringe plunger

• Calibration gauge

• Olympus balloon catheter B5-2C

Additional ancillary equipment recommended not provided with the Airway Sizing Kit:

• Olympus balloon catheter B7-2Q or a balloon catheter that inflates to 13mm or larger

7. Packaging Inspection, Storage, and Handling

• The Airway Sizing Kit is packaged sterile in a sealed tray. Do not attempt to resterilize the Airway Sizing Kit. Contact your local Spiration representative if the integrity of the packaging has been compromised.

• Do not use the Airway Sizing Kit if it has been exposed to temperatures above 50°C or below -15°C.

• Do not use the Airway Sizing Kit for more than one patient procedure.

• Do not use the Airway Sizing Kit if it has been exposed to temperatures above 50°C or below -15°C.

8. Preparation of the Balloon Catheter for Sizing

Please follow the instructions for use provided by the balloon catheter manufacturer.

8.1 Preparing the Balloon Catheter

1) Remove the balloon catheter and Airway Sizing Kit components from the packaging.

2) Place the item on a clean or sterile field.

3) Remove the lightproof cap from the balloon (see Figure 5).

4) Confirm that the device supplied with the system is firmly attached (see Figure 3).

5) Purge any air from the 10cc syringe.

6) Insert the 10cc syringe into the stopcock port on the balloon catheter (see Figure 4).

7) With the 10cc syringe oriented vertically, pull the syringe plunger to approximately the 10cc mark and hold for at least 10 seconds to create a vacuum removing the air from the balloon (see Figure 4).

8) While maintaining vacuum, tap on the side of the syringe to assist in freeing bubbles from the balloon (see Figure 4).

9) Preparing the Balloon Catheter

10) Set aside the balloon with the 10cc syringe still attached.

11) Using sterile saline, wet the plunger for the glass syringe from the Airway Sizing Kit and completely re-sterilize it with the 1000 microliter (µL) glass syringe.

12) Fill the glass syringe with at least 500 µL of sterile saline (see Figure 6).

9. Additional instructions

• Equipment is reusable. Do not discard the lightproof cap. This will be used later in the procedure.
8.2 Calibrating the Balloon

1. Allow the balloon to expand to its maximum volume as designed.
2. Align the middle of the balloon with the intended valve placement site in the target airway.
3. Connect the balloon to the stopcock connector. If necessary, steps 6–9 may be repeated.
4. Upon inflation, the balloon must contact the entire circumference of the target site for an entire breath cycle.
5. Deflate the balloon by returning the plunger to the 500 µL mark.
6. Look up the syringe volume on the worksheet table and select the indicated valve.
7. Before retracting the balloon inside the bronchoscope, fully deflate the balloon by returning the plunger to the 500 µL mark.

NOTE: If the inflated balloon is just touching the circumference of the target location, and the syringe volume falls off a calibration volume, choose the larger size valve.

8.3 Selecting the Valve Size

1. Insert the deflated balloon into the instrument channel of the bronchoscope. Keep the tip of the balloon catheter part inside of the distal end of the bronchoscope.
2. Maneuver the bronchoscope to the airway location. Advance the balloon into the target airway.
3. Align the middle of the balloon with the intended valve placement site in the target airway.
4. Upon inflation, the balloon must contact the entire circumference of the target site for an entire breath cycle.
5. The volume of the balloon will serve as a reference for choosing the size of the airway with the valve size that will fit as designed.
6. Look up the syringe volume on the worksheet table and select the indicated valve.

NOTE: If the inflated balloon is just touching the circumference of the target location and the syringe volume falls off a calibration volume, choose the larger size valve.

8.2 Calibrating the Balloon

1. Wet the balloon and calibration gauge with sterile saline.
2. Place the deflated balloon in the center of the "E" sizing gauge hole and then slowly draw back the glass syringe plunger to baseline while inflating the balloon until it just contacts the circumference of the gauge hole on the calibration gauge. Slowly inflate the balloon until it just touches all sides of the "E" gauge hole on the calibration gauge. Ensure no large bubbles are trapped in the syringe at 500 µL (see Figure 8).
3. Align the middle of the balloon with the intended valve placement site in the target airway.
4. Connect each of the points on the Balloon Calibration section with a straight line. Verify that the curve is continuous (see Figure 12).
5. Deflate the balloon by returning the plunger to the 500 µL mark.
6. Read the volume at the white end of the syringe plunger.
7. Repeat steps 2 through 5 for the remaining sizing gauge holes ("A", "B", "CAL", and "D").
8. Connect each of the points on the balloon calibration section with a straight line. Verify that the curve is continuous (see Figure 12).
9. Fully deflate the balloon by returning the plunger to the 500 µL mark. Cover the balloon with the lightproof cap and place it in a safe, clean area until ready to use in the airway.
10. Proceed to place valves according to the instructions for the Valve in Cartridge and Deployment Catheter and Loader (see Instruction Manual for the Spiration Valve System).

NOTE: Do not overtighten the syringe as it is possible to damage the luer fittings.

8.4 Recovery from pulling the plunger out of the glass syringe

1. If the plunger for the glass syringe is accidentally pulled out, do not reinsert the plunger. Reverse the balloon from the bronchoscope and disconnect the glass syringe from the stopcock connector. If necessary, steps 6–9 may be repeated.
2. Repeat steps 12–15 and 17–18 of the section 8.1 "Preparing the Balloon Catheter."
3. If evaluating other airway locations, repeat steps 2 through 7.
4. When the targeted airways have been evaluated, withdraw the balloon catheter from the bronchoscope. Place the balloon catheter in a safe, clean area until the procedure is completed.
5. Ensure that the syringe volume falls on a calibration volume according to the instructions for the Valve in Cartridge and Deployment Catheter and Loader (see Instruction Manual for the Spiration Valve System).
6. Do not pull the plunger beyond the 500 µL mark. If the plunger is pulled out, proceed to the next section for recovery steps. Do not reinsert the plunger while the syringe is still attached to the balloon. This will introduce excess air into the system which will affect the previous calibration.
7. Before retracting the balloon inside the bronchoscope, fully deflate the balloon by returning the plunger to the 500 µL mark.

NOTE: Do not pull the plunger beyond the 500 µL mark. If the plunger is pulled out, proceed to the next section for recovery steps. Do not reinsert the plunger while the syringe is still attached to the balloon. This will introduce excess air into the system which will affect the previous calibration.

8.3 Selecting the Valve Size

1. Insert the deflated balloon into the instrument channel of the bronchoscope. Keep the tip of the balloon catheter part inside of the distal end of the bronchoscope.
2. Maneuver the bronchoscope to the airway location. Advance the balloon into the target airway.
3. Align the middle of the balloon with the intended valve placement site in the target airway.
4. Upon inflation, the balloon must contact the entire circumference of the target site for an entire breath cycle.
5. The volume of the balloon will serve as a reference for choosing the size of the airway with the valve size that will fit as designed.
6. Look up the syringe volume on the worksheet table and select the indicated valve.

NOTE: If the inflated balloon is just touching the circumference of the target location and the syringe volume falls off a calibration volume, choose the larger size valve.

8.2 Calibrating the Balloon

1. Wet the balloon and calibration gauge with sterile saline.
2. Place the deflated balloon in the center of the "E" sizing gauge hole and then slowly draw back the glass syringe plunger to baseline while inflating the balloon until it just touches all sides of the "E" gauge hole on the calibration gauge. Slowly inflate the balloon until it just touches all sides of the "E" gauge hole on the calibration gauge. Ensure no large bubbles are trapped in the syringe at 500 µL (see Figure 8).
3. Align the middle of the balloon with the intended valve placement site in the target airway.
4. Connect each of the points on the Balloon Calibration section with a straight line. Verify that the curve is continuous (see Figure 12).
5. Deflate the balloon by returning the plunger to the 500 µL mark.
6. Read the volume at the white end of the syringe plunger.
7. Repeat steps 2 through 5 for the remaining sizing gauge holes ("A", "B", "CAL", and "D").
8. Connect each of the points on the balloon calibration section with a straight line. Verify that the curve is continuous (see Figure 12).
9. Fully deflate the balloon by returning the plunger to the 500 µL mark. Cover the balloon with the lightproof cap and place it in a safe, clean area until ready to use in the airway.
10. Proceed to place valves according to the instructions for the Valve in Cartridge and Deployment Catheter and Loader (see Instruction Manual for the Spiration Valve System).

NOTE: Do not overtighten the syringe as it is possible to damage the luer fittings.
Supporting Documentation

**F: SPIRATION® VALVE SYSTEM PROCEDURE STEPS OVERVIEW**

- Balloon Calibration
- Airway Isolation
- Airway Sizing
- Valve Loading
- Valve Placement
- Valve Removal

Last Revision February 2018
Reimbursement Guide for the Spiration® Valve System

Please see important Spiration® Valve System information on the next page.
Spiration® Valve System

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

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Valve in Cartridge</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF-HUS-V5</td>
<td>5mm</td>
</tr>
<tr>
<td>REF-HUS-V6</td>
<td>6mm</td>
</tr>
<tr>
<td>REF-HUS-V7</td>
<td>7mm</td>
</tr>
<tr>
<td>REF-HUS-V9</td>
<td>9mm</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Kit Includes</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF-HUS-VSK</td>
<td>500 microliter glass syringe with a plunger, a calibration gauge, and a sizing worksheet</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Bronchoscope Working Channel</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF-HUS-C26N</td>
<td>2.6mm or greater inner diameter</td>
</tr>
</tbody>
</table>

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

For customer support:
Toll Free: 855-497-1616
customersupport@spiration.com

To request technical procedure support:
www.spirationsupport.com

For reimbursement support:
Toll Free: 855-428-7346
spirationvalvereim@olympus.com

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

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.