To control prolonged air leaks of the lung or significant air leaks likely to become prolonged following lobectomy, segmentectomy and LVRS

Coding and Billing Guide

This guide is intended to provide coding and billing information for Hospital and Physician Providers:
Calendar Year (CY) 2014, beginning January 1, 2014

Reimbursement codes and billing practices change over time.

All information is subject to the descriptions and disclaimers contained in this guide.

If you have additional questions email reimbursementsupport@spiration.com or call 855-IBV-REIM (855-428-7346)
HUMANITARIAN DEVICE FOR USE IN THE CONTROL OF PROLONGED AIR LEAKS

Disclaimer
The information provided in this guide contains 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. Information provided is not intended to increase or maximize reimbursement by any payer. 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 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.

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 4,000 individuals in the United States per year. Spiration applied for and received U.S. Food and Drug Administration (FDA) designation as a HUD and 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, or lung volume reduction surgery (LVRS). FDA approval of a 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, 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. 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 2.6mm 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/ifu

Caution
Investigational Device. Limited by Federal law to investigational use. The Spiration Valve System is not approved for use in emphysema in the U.S. but is subject to ongoing clinical investigation in which approval for use in emphysema will be sought.
## CONTENTS

### Coding and Billing Guide

Spiration Valve System Reimbursement – Introduction .......................................................... 4

Overview of Coverage and Coding .......................................................................................... 5

Spiration Valve System Coding ................................................................................................. 6
  - Potential ICD-9-CM Diagnosis Codes (For Hospital and Physician Providers) .................. 6
  - Potential ICD-9-CM Procedure Codes (For Inpatient Hospital Providers) ......................... 6
  - Potential CPT Codes (For Outpatient Hospital and Physician Providers) ......................... 7
  - NCCI Edits .......................................................................................................................... 8
  - Modifiers ............................................................................................................................ 8
  - HCPCS Codes ................................................................................................................... 8

References and Attachments .................................................................................................. 9
  - Attachment A: FDA HDE Approval Letter ........................................................................ 10
  - Attachment B: Requesting Prior Authorization ................................................................. 13
  - Attachment C: Sample Letter of Medical Necessity ............................................................ 14
  - Attachment D: Instructions For Use – Spiration Valve System ......................................... 15
  - Attachment E: Instructions For Use – Airway Sizing Kit ................................................... 17
  - Attachment F: Spiration Valve System Procedure Overview ............................................. 19
INTRODUCTION

This guide provides coding and billing information to hospitals and physicians submitting claims for procedures involving the Spiration Valve System under the HDE approval.

This reimbursement information is distributed as a convenient reference for approved users of the Spiration Valve System. This information is subject to change, and providers are always responsible for determining coverage, selecting appropriate coding, modifiers and charges for services they provide. Please note that coding, coverage and payment policies may vary by insurer, by plan, and by location. Contacting payers to confirm the coverage, coding and payment requirements in each case is always a best practice.

Reimbursement describes the process by which healthcare providers are paid for the products and services they provide to patients during an episode of care. Two types of payments are generally made: a payment for facility resources and a payment for professional resources. Facilities such as hospitals are paid for the resources they contribute to an episode of care. Physicians are paid for the medical professional services they provide in the treatment of patients.
Providers should contact their local Medicare contractors or patient’s insurers to understand a payer’s policy on HUD use and any special instruction for claims submission.

Use of the Spiration Valve System to treat prolonged air leaks must meet the requirements established by Medicare and other third party payers to be a covered service. Payer coverage policies are available in either benefit policy manuals (Medicare) or insurance contracts (private payers) which identify the products and services eligible for payment. Health insurers generally provide coverage for services when they are medically reasonable and necessary for treatment or diagnosis of illness or injury.

In the case of inpatient hospital admissions specific to Spiration Valve System procedures (i.e., removal of the Spiration Valve System) the patient’s primary payer (BCBS plan, commercial payer, managed care payer) may need to be contacted to obtain prior authorization for the hospital admission. Please refer to Attachment B which contains information on the prior authorization process, and Attachment C which provides a sample letter of medical necessity.

When submitting claims to Medicare and other third party payers, hospitals and physicians list codes that describe patient condition and reflect procedures performed. The following sections of this guide will review some of the codes that may be appropriate for billing the Spiration Valve System. However, providers are ultimately responsible for choosing diagnosis and procedure codes that accurately describe the patient’s condition, underlying disease and treatment. 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.

Table 1. Reimbursement Code Overview

<table>
<thead>
<tr>
<th>CODING SYSTEMS</th>
<th>PURPOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD-9-CM diagnosis codes</td>
<td>Describes patient condition or underlying disease</td>
</tr>
<tr>
<td>ICD-9-CM procedure codes</td>
<td>Describes procedures performed (used for claims submitted for inpatient hospital procedures)</td>
</tr>
<tr>
<td>CPT codes</td>
<td>Describes procedures performed (used by physician professional services and for services provided in the hospital outpatient setting)</td>
</tr>
</tbody>
</table>
POTENTIAL ICD-9-CM DIAGNOSIS CODES
For Hospital and Physician Providers

The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis codes entered on physician and hospital claims are important in conveying information about the patient’s condition to payers. Payers use this information to evaluate the episode of care and the appropriateness of the treatment the patient received. Specialty societies worked with coding committees at the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) to revise and create diagnosis codes for air leak conditions. These codes, which became effective in October 2011, can be found for reference in the 512.00-513.00 range.

Recall that 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, or lung volume reduction surgery. Hospitals and physicians should check with specialty societies or payers for clinical application of diagnosis codes to actual patient encounters. Applicability and usage of these codes may vary per case. Hospitals and physicians also should check and verify current policies and requirements with the payer for any particular patient that will be using the Spiration 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.

POTENTIAL ICD-9-CM PROCEDURE CODES
For Inpatient Hospital Providers

Hospitals use ICD-9-CM procedure codes to describe procedures performed on inpatients. When coding inpatient hospital procedures related to the Spiration Valve System, hospitals need to consider proper coding for the appropriate steps. See Instructions for Use (Attachment D and E) and Spiration Valve System Procedure Overview (Attachment F).

Table 2 below identifies potential ICD-9-CM procedure codes that may be used to describe the insertion and removal of the bronchial valve(s). Hospitals are responsible for accurately selecting ICD-9-CM procedure codes to describe the procedures performed during an inpatient stay.

The ICD-9-CM procedure codes listed in this table are not intended to be an exhaustive list of all possible hospital procedure codes. Please refer to the ICD-9-CM book for a comprehensive list of hospital procedure codes.

Table 2: Potential ICD-9-CM Procedure Codes

<table>
<thead>
<tr>
<th>ICD-9-CM PROEDURE CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>33.71</td>
<td>Endoscopic insertion or replacement of bronchial valve(s), single lobe</td>
</tr>
<tr>
<td>33.73</td>
<td>Endoscopic insertion or replacement of bronchial valve(s), multiple lobes</td>
</tr>
<tr>
<td>33.78</td>
<td>Endoscopic removal of bronchial device(s) or substances</td>
</tr>
</tbody>
</table>

POTENTIAL CPT CODES
For Outpatient Hospital and Physician Providers

Physicians and outpatient hospital providers should consider the available coding options and select the appropriate CPT code based on the procedure(s) performed.

Inclusion of a descriptor and its associated five-digit code number in the CPT codebook is based on whether the procedure is consistent with contemporary medical practice and is performed by many practitioners in clinical practice in multiple locations. Inclusion in the CPT codebook does not represent endorsement by the American Medical Association (AMA) of any particular diagnostic or therapeutic procedure. Inclusion or exclusion of a procedure does not imply any health insurance coverage or reimbursement policy.²

Table 3: Physician Coding for Bronchial Valve Procedures

<table>
<thead>
<tr>
<th>CPT PROCEDURE CODE</th>
<th>DESCRIPTION</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>
</tr>
<tr>
<td>31651</td>
<td>...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>
</tr>
<tr>
<td>31648</td>
<td>...with removal of bronchial valve(s), initial lobe</td>
</tr>
<tr>
<td>31649</td>
<td>...with removal of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

**NCCI Edits**

National Correct Coding Initiative (NCCI) edits are released by CMS to indicate how payment might be affected when two CPT codes are billed by the same provider for the same patient on the same date of service. NCCI policies are based on AMA CPT guidance, coding guidelines developed by specialty societies, and reviews of current coding practices. The purpose of the NCCI edits is to prevent improper payment when incorrect code combinations are reported. Healthcare providers should check NCCI edits on any codes billed on claims for a given patient encounter to understand how payment might be affected by those code combinations.

**Modifers**

Depending on the actual procedure(s) performed with the Spiration Valve System, it may be necessary to append certain modifiers to the procedure codes indicated on claim forms. Modifiers are designed to provide payers with additional information that may be necessary in order to process claims. Healthcare providers should consult with their local Medicare contractor for a comprehensive list of modifiers.

**HCPCS Codes**

Healthcare Common Procedure Coding System (HCPCS) codes are used to describe supplies, materials, injections as well as certain services and procedures typically used in the Ambulatory Service Center (ASC) and hospital outpatient setting. Currently, there are no specific HCPCS codes (C code) associated with the Spiration Valve System.
References and Attachments

Attachment A: FDA HDE Approval Letter

Attachment B: Requesting Prior Authorization

Attachment C: Sample Letter of Medical Necessity

Attachment D: Instructions For Use – Spiration Valve System

Attachment E: Instructions For Use – Airway Sizing Kit

Attachment F: Spiration Valve System Procedure Overview
DEPARTMENT OF HEALTH & HUMAN SERVICES

January 29, 2014

SPIRATION, INC.
Ms. Cyndy Adams
Regulatory Affairs
6673 185th Avenue N.E.
Redmond, WA 98052

Re: H06002 S005
Spiration® (IBV) Valve System Reloadable Deployment Catheter System and Extended Shelf-Life for Airway Sizing Kit
Filed: April 11, 2013
Amended: July 30, 2013 and November 15, 2013

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 change in the configuration to a reloadable deployment catheter system, to include two component changes, the polytetrafluoroethylene (PTFE) coated plunger pan and new shipping lock. Also to change to the Airway Sizing Kit and name change for the device from IBV Valve System to Spiration™ Valve System. The device, as modified, will be marketed under the trade name Spiration® Valve System and 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 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. IBV 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 302(q) and (r) of the FD&C Act.
Attachment A: FDA HDE Approval Letter

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 PMA. 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.

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: (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 Mail 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,

Kwame O. Ulmer-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
Attachment 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.

1) 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.

2) Request Routing
Ensure that you understand who will review your request and how to route your requests 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 requests have been received and periodically thereafter to ensure the request is being addressed.

3) 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.

4) 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.

5) 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.
**Attachment C: Sample Letter of Medical Necessity**

[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 location, insertion and removal of the Spiration Valve System

Dear [RECIPIENT],

I am writing on behalf of my patient to request a prior approval for coverage for the location, insertion and removal of the Spiration Valve System.

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 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. The effectiveness of this device for this use has not been demonstrated.

**SAMPLE MEDICAL NECESSITY LANGUAGE**

*NOTE: Customize to individual patient and clinical opinions/justification. Please note that the text below is only a guide and should not be replicated verbatim.

[Patient Name] has been diagnosed with [insert specific air leak diagnosis code description] on post-operative day [insert day]. The patient’s current status is [insert status update]. [insert sentence about detail of impairment and how it impacts quality of life, caregiver employment, etc]

If not treated, studies show that his/her condition may result in an increased risk of morbidity or postoperative complications. Additionally, it is my expert opinion that a prolonged hospital stay is not in the best interest of patient health and the insertion of the Spiration Valve System may improve the patient’s health by speeding recovery. Studies show that the insertion of the Spiration valve system will help the air leak close within two days and within four days the patient will like have his/her chest tube removed. Therefore, I recommended the insertion of the Spiration Valve System to address the air leak and possibly help them recover from a pulmonary air leak after surgery.

The Spiration Valve System can benefit the patient by blocking distal air flow to the damaged portion of their lung. This is done through a minimally invasive bronchoscopy. (State how this therapy is an appropriate intervention at this point in the patient’s care. Note therapeutic goals, anticipated outcomes, risks of performing the procedure, risks of not performing the procedure and possible complications.)

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[Note if relevant which conservative treatment methods the patient has tried and failed, additional information on the patient’s history, interventional efforts/procedures, medications and/or therapies that have been previously rendered. Note the outcome of each. A timeline is useful.]

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

Sincerely,
_______________________, MD

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**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 2.6mm 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/ifu](http://www.spiration.com/ifu)
1. Intended Use

The Spiration Valve System is designed to close one or both air leaks(s) of a lung, or a significant air leak(s) that will likely become a persistent leak following inflation- deflation, surgical, or video-assisted thoracoscopic surgery (VATS) or open lung surgery. An air leak present on postoperatively 1 is considered persistent unless present only during intubation or during surgery. An air leak present on day 5 should be considered persistent if treated with a Spiration Valve Kit. If persistent, it should be treated with the Spiration Valve Kit. If persistent, it should be treated with the Spiration Valve Kit.

2. Spiration Valve System Description

The Spiration Valve System consists of a Spiration Valve® Kit (120 mL) and a Support Catheter Assembly (Huber® and Leader® cuffs). The Airway Valve Kit is an accessory to the Spiration Valve System and is used to improve the breathability of the patient. The Spiration Valve Kit is a retention device that is placed into the patient's airway. The retention device is designed to seal the airway against the tracheal mucosa to decrease air leak and to prevent the airway from collapsing.

3. Preparation for the Procedure

7.2 Items Required for Spiration Valve Removal Procedure

- Sterile equipment
- Sterile gloves
- Sterile tape

8. Packaging Inspection, Storage, and Handling

- The Spiration Valve System is stored in a stable environment at controlled room temperature in a dry, clean, and dust-free area.

9. Clinical Use of the Spiration Valve

Medical professionals can directly connect the Spiration Valve System to an air tube(s) and pass the tube(s) through the open incision. The Spiration Valve System can be used in a variety of applications, including: resection, thoracotomy, and thoracoscopic surgery.

10. Equipment

- Spiration Valve System
- Sterile equipment
- Sterile gloves
- Sterile tape

11. Troubleshooting

- The Spiration Valve System may not function properly if the valve is not properly placed or if the air leak is not properly sealed.

12. Disassembly and Cleaning

- The Spiration Valve System is disposable and should not be disassembled or cleaned.

13. Maintenance

- The Spiration Valve System is designed to be a one-time use device and should not be re-used.

14. Sterility

- The Spiration Valve System is designed to be sterile and should be used in a sterile environment.

15. Storage

- The Spiration Valve System should be stored in a dry, clean, and dust-free area at controlled room temperature.

16. Disposal

- The Spiration Valve System is disposable and should be disposed of according to local regulations.

17. Instructions For Use – Spiration Valve System

- The Spiration Valve System is designed to close one or both air leaks(s) of a lung, or significant air leak(s) that will likely become persistent after postoperative 1.

18. Advantages

- The Spiration Valve System is designed to seal the airway against the tracheal mucosa to decrease air leak and to prevent the airway from collapsing.

19. Disadvantages

- The Spiration Valve System is designed to be a one-time use device and should not be re-used.

20. Compliance

- The Spiration Valve System is designed to be used in a sterile environment and should be used in a sterile environment.
9.1 Spiration Valve Deployment
- Using bronchoscope techniques and in-fill technique, the valve should be deployed in the endotracheal tube's small nutrient arteries. (see Operator's instructions, section 10)
- Be sure the deployment of the valve may be carried out.
- The valve may be deployed into the small nutrient arteries through the bronchoscope.
- Place the valve into the bronchoscope, and then deploy it into the small nutrient arteries through the bronchoscope.
- Use a bronchoscope to perform the valve deployment.
- Use a bronchoscope to perform the valve deployment.
- Use a bronchoscope to perform the valve deployment.

9.2 Spiration Valve Removal
- After deployment of the valve is completed, the valve is removed using bronchoscope techniques and bronchoscopy through the
- The valve is removed using bronchoscope techniques and bronchoscopy through the
- The valve is removed using bronchoscope techniques and bronchoscopy through the
- The valve is removed using bronchoscope techniques and bronchoscopy through the

10. Operator's Instructions
10.1 Indications for the Use of Air Leak Observation
- Observation of air bubbles passing through the bronchoscope tip connected to the chest tube is needed for measuring air leak before insertion, size, and location.
- Insert the Spiration catheter into the instrument channel of the bronchoscope. Then, tap with the tip of the catheter to observe air leak or observe and adjust the size of the catheter before inserting it. Ensure that the catheter is not touching the bronchoscope.
- Evaluate air leak symptoms associated with any bronchoscopy intervention. Ensure the catheter is not touching the bronchoscope.
- Ensure that the catheter is not touching the bronchoscope.
- If the air leak is less than 5 ml per minute, inflation of the bronchoscope may not be necessary.
- If the air leak is less than 5 ml per minute, inflation of the bronchoscope may not be necessary.
- If the air leak is less than 5 ml per minute, inflation of the bronchoscope may not be necessary.

10.2 Selecting the Spiration Valve Size
- Use a balloon catheter (5 cm or 9 cm) inserted to the appropriate size in the appropriate size
- Use a balloon catheter (5 cm or 9 cm) inserted to the appropriate size in the appropriate size
- Use a balloon catheter (5 cm or 9 cm) inserted to the appropriate size in the appropriate size
- Use a balloon catheter (5 cm or 9 cm) inserted to the appropriate size in the appropriate size

10.3 Inserting the Spiration Valve
- Insert the catheter into the bronchoscope for air leak observation.
- Insert the catheter into the bronchoscope for air leak observation.
- Insert the catheter into the bronchoscope for air leak observation.
- Insert the catheter into the bronchoscope for air leak observation.

11.1 Recommended Use of ET Tube
- The catheter should be used with a laryngeal mask airway (LMA) or similar device.
- The catheter should be used with a laryngeal mask airway (LMA) or similar device.
- The catheter should be used with a laryngeal mask airway (LMA) or similar device.
- The catheter should be used with a laryngeal mask airway (LMA) or similar device.

11.2 Removing the Spiration Valve
- Insert the appropriate size catheter (5 cm or 9 cm) inserted to the appropriate size in the appropriate size
- Insert the appropriate size catheter (5 cm or 9 cm) inserted to the appropriate size in the appropriate size
- Insert the appropriate size catheter (5 cm or 9 cm) inserted to the appropriate size in the appropriate size
- Insert the appropriate size catheter (5 cm or 9 cm) inserted to the appropriate size in the appropriate size

11.3 Replacement
- The catheter should be replaced with a new Spiration valve.
- The catheter should be replaced with a new Spiration valve.
- The catheter should be replaced with a new Spiration valve.
- The catheter should be replaced with a new Spiration valve.

11.4 Cleaning and Storage
- The catheter should be cleaned and stored in a sterile environment.
- The catheter should be cleaned and stored in a sterile environment.
- The catheter should be cleaned and stored in a sterile environment.
- The catheter should be cleaned and stored in a sterile environment.

12. Patient Information
- Further information about the Spiration valve can be found in the Product Information Manual.
- Further information about the Spiration valve can be found in the Product Information Manual.
- Further information about the Spiration valve can be found in the Product Information Manual.
- Further information about the Spiration valve can be found in the Product Information Manual.
Attachment 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 size and its use for endotracheal airway. A balloon catheter is used first in conjunction with the Airway Sizing Kit to determine, by selection of balloons, the location for the placement of valves to control postobstructive air leaks.

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 screw-cap assembly (bottom) that is used with a balloon catheter and the calibration gauge to establish a size reference. To ensure the appropriate size is selected for each targeted airway, the balloon catheter must be calibrated prior to its use as a sizing tool. One balloon catheter is used to measure all of the airway to be treated for a single patient.

Two compliance balloons are available for use for simulating the Olympus® BS-EC balloon and the Applied Medical® Pyromax® EC Intermittent for late-synchronous patients. The balloon is filled with saline under constant inflation with the calibration gauge. During the sizing process, the calibrated balloon is inflated at the target airway location. The catheter volume used to inflate the balloon indicates the appropriate volume to use as the target location.

3. Contraindications
- Do not use this Airway Sizing Kit for other than its intended use.
- Patient is not an appropriate candidate for, or unable to tolerate, flexible bronchoscopy procedures.
- See contraindications for the Spiration Valve System.

4. Precautions
- Use of the Airway Sizing Kit requires bronchoscopy technical skills. The operation must be performed by a physician or medical person under the supervision of a physician and be trained in bronchoscopy techniques.
- The following instructions shall be followed by the physician):
- Do not use the Airway Sizing Kit on any patient with a latex-sensitive reaction.
- Do not use the Airway Sizing Kit on patients with a known sensitivity to latex.
- Do not use the Airway Sizing Kit on patients with a known sensitivity to latex.
- Do not use the Airway Sizing Kit on patients with a known sensitivity to latex.
- Do not use the Airway Sizing Kit on patients with a known sensitivity to latex.

5. Potential Adverse Effects
- Adverse reactions as with any medical procedure.
- Allergic reaction to latex specific to latex balloons.

6. Items Required and Recommended for Use with the Airway Sizing Kit
- A calibrated glass syringe
- A 50-cc syringe
- A syringe plunger
- A calibration gauge
- An Airway Sizing Kit

7. Packing Inspection, Storage, and Handling
- The Airway Sizing Kit is sealed and packaged in a sealed bag. Do not attempt to open the Airway Sizing Kit. Contact your local Spiration representative if the integrity of the packaging has not been compromised.
- Do not use the Airway Sizing Kit if damaged due to environmental damage (i.e., below 0°C).
- Do not use the Airway Sizing Kit if damaged due to environmental damage (i.e., below 0°C).
- Do not use the Airway Sizing Kit if damaged due to environmental damage (i.e., below 0°C).
- Do not use the Airway Sizing Kit if damaged due to environmental damage (i.e., below 0°C).

8. Preparation of the Balloon Catheter for Sizing
- Please familiarize yourself with the instructions for the balloon catheter provided by the balloon manufacturer. The Olympus balloon catheter contains natural latex rubber, which may cause allergic reactions. Do not use this product on a latex-sensitive patient. If the patient is latex-sensitive, the alternative, Applied Medical balloon catheter should be used.

8.1 Preparing the Balloon Catheter
1. Remove the balloon catheter and Airway Sizing Kit components from the packaging. Place the items in a clean, dry, and sterile field.
2. Remove the Airway Sizing Kit from the package. Place the Airway Sizing Kit in a clean, dry, and sterile field.
3. Introduce a 2-way stopcock to the balloon catheter (see Figure 1). Place the stopcock on a latex-sensitive patient. If the patient is latex-sensitive, the alternative, Applied Medical balloon catheter should be used.

4. Replace the 2-way stopcock (see Figure 3).
5. With the 160 cc syringe attached vertically, pull the syringe plunger back as far as possible. Do not ever inflate the balloon after the Airway Sizing Kit has been inflated.
6. Fill the 160 cc syringe with approximately 10 cc of sterile saline and purge any air from the balloon.
7. Attach the 160 cc syringe to the 3-way stopcock and at a 90-degree angle to the balloon.
8. Close the unused stopcock (see Figure 5).
9. Fill the 160 cc syringe with approximately 10 cc of sterile saline and purge any air from the balloon.
10. Attach the 160 cc syringe to the 3-way stopcock and at a 90-degree angle to the balloon.
11. Close the unused stopcock (see Figure 5).
12. With the 160 cc syringe attached vertically, pull the syringe plunger back as far as possible to create a vacuum and remove air from the balloon. Insert the syringe plunger back for about 10 seconds until no more bubbles are seen exiting the syringe or 3-way stopcock (see Figure 6). Push the side of the syringe to assist in freeing bubbles from the stopcock.
13. Open the unused stopcock (see Figure 5).
14. Introduce the balloon catheter with sterile saline using the 160 cc syringe (see Figure 7). If the balloon is about 12 mm in diameter, place larger than the size is opening in the calibration gauge. Let the balloon settle for a few seconds and check for air bubbles in the inflated balloon.
15. With the 160 cc syringe attached vertically, deflate the balloon, create a vacuum, and pull as far back on the syringe as possible. Continue up the balloon while it is deflated to assist in the removal of air bubbles (see Figure 8).
9. Repeat steps 7 and 8 until no air bubbles larger than 2 mm are seen in the balloon when inflated to approximately 10 mm (see Figure 9).

10. Completely deflate the balloon.

11. Close the port connected to the balloon catheter (see Figure 10).

12. Using sterile saline, wet the syringe plunger from the Airway Sizing Kit and completely insert it into the 50 μl glass syringe.

13. Fill the 50 μl glass syringe with sterile saline. Make sure the syringe is completely full (at least 50 μl of sterile saline) and purge any air bubbles from the syringe (see Figure 11).

14. While the balloon catheter port is shut off, slightly depress the 100 μl syringe plunger, purging air from the syringe (see Figure 12).

15. Attach the glass syringe to the open stopcock port without introducing air bubbles. Adjust the glass syringe so that the white end of the plunger is at the 50 μl mark (see Figure 13). Holding the glass syringe against a dark background may assist in reading the syringe volume.

16. Confirm that the glass syringe and balloon are firmly attached to the stopcock, the stopcock is set to block off the empty port and that the balloon is fully deflated when the syringe is at the 50 μl mark.

8.2 Calibrating the Balloon for Sizing

The Olympus 50 μl balloon catheter must be calibrated prior to its use as a sizing tool to ensure the correct valve size is selected.

For your convenience, an airway sizing worksheet (see PI-03717) is included with the Airway Sizing Kit.

1. Wet the balloon and calibration gauge with sterile saline.

2. Place the balloon in the center of the size “F” opening in the round calibration gauge. Using the gauge syringe plunger, slowly inflate the balloon until its diameter touches all sides of the size “F” calibration hole and the balloon drops when moved in and out of the gauge hole (see Figure 15).

3. When the balloon just fits the size “F” opening as it gently drags on all sides of the hole, check the volume of the white end of the syringe plunger on the glass syringe.

4. Record the glass syringe volume next to the “F” on the left axis of the graph on the Airway Sizing Worksheet (see Figure 15).

5. Repeat these steps (1-4) for the remaining calibration holes (7, 6, 5, 4, 3, 2, 1, 0, and 00) (see Figure 17).

6. Mark the recorded measurements on the worksheet graph for each of the volumes. Connect each of the points with a straight line. Verify that the curve is continuous and has the correct shape (see Figure 17).

9. Isolating the Air Leak by Balloon Occlusion

See Operator Instructions in the Spiration Valve System Instructions for Use (PI-03717).

10. Selecting the Spiration Valve Size

1. Insert the deflated sizing balloon into the instrument channel of the bronchoscope. Keep the tip of the balloon catheter just inside of the distal end of the bronchoscope.

2. Manoeuvre the bronchoscope to the target airway location. Advance the balloon into the airway.

3. Slowly inflate the balloon until it just touches and drags on all sides of the airway wall when moved in and out at the target location (see Figure 18). Inflate and deflate the balloon a few times to find the optimum fit, as shown below.

4. Identify the airway location on the Airway Sizing Worksheet and record the glass syringe volume on the appropriate line for the target airway location on the bronchoscope tree (see example in Figure 19: 150 μl on the Apical (RILB) tree). Taking multiple readings of the balloon will help in selecting the correct valve size.

5. Select and record the corresponding valve size by using the Valve Selection Guide of the Airway Sizing Worksheet (see Figure 15). The syringe volume matches one of the possible size ranges in the Valve Selection Guide. Always use the next larger valve size. If the airway size is too large for a 15 mm valve, move deeper or go into the next airway division under direct visualization of the bronchoscope. If the airway size is too small for a 5 mm valve, move proximally in the airway under direct visualization of the bronchoscope.

6. Before moving to the next airway, completely deflate the balloon. Hold the tip of the balloon catheter in a retracted position. Inside the bronchoscope, guiding movement between airways.

7. Repeat steps 2 through 6 for each additional target airway location.

8. When all target airways have been evaluated, deflate the balloon and withdraw the balloon catheter from the bronchoscope. Close the balloon with the lightproof cap and place the balloon catheter in a safe, clean area until the procedure is completed.

9. Proceed to place valves according to the Instructions for Use of the Spiration Valve System (PI-03717).

11. 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, PI-03721). 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.
Attachment F: Spiration Valve System Procedure Overview

STEPS FOR CONTROLLING SPECIFIC POSTOPERATIVE AIR LEAKS

Humanitarian Device for Use in the Control of Specific Postoperative Air Leaks

Balloon Calibration
Airway Isolation
Airway Sizing
Valve Loading
Valve Placement

CAUTION: Humanitarian Device. Authorized for use in the control of postoperative air leaks of the lung or significant air leaks that are likely to become prolonged air leaks, following bronchial, segmental/lobar, or Long Volume Resection Surgery (LVRS). The effectiveness of this device for this use has not been determined. Federal law restricts this device to sale by or on the order of physician. Contraindications: Patient is unable to tolerate a flexible bronchoscopy procedure. Warning: Air leaks 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, untreated, or clinically significant infections. Only use a bronchoscope with a working channel of 2.8 mm or larger. Do not use the Spiration Valve System for other than its intended use. Potential Adverse Effects: Accidental Death, Infection in the tissues distal to a valve, Local airway swelling or scarring at site of valve implantation. Precautionary. For full prescribing information go to: www.spiration.com/IPC

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