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 Outpatient Hospital and Physician Providers:
Calendar Year (CY) 2015, beginning January 1, 2015
And Inpatient Hospital Providers:
Fiscal Year (FY) 2016, beginning October 1, 2015

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 an 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 an HDE authorizes the applicant to market an 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 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. 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
# CONTENTS

## Coding and Billing Guide

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spiration Valve System Reimbursement – Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Overview of Coverage and Coding</td>
<td>5</td>
</tr>
<tr>
<td>Spiration Valve System Diagnosis Coding</td>
<td>6</td>
</tr>
<tr>
<td>Potential ICD-10-CM Diagnosis Codes (For Hospital and Physician Providers)</td>
<td>6</td>
</tr>
<tr>
<td>Spiration Valve System Inpatient Coding and Reimbursement</td>
<td>7</td>
</tr>
<tr>
<td>Potential ICD-10-PCS Procedure Codes (For Inpatient Hospital Providers)</td>
<td>7</td>
</tr>
<tr>
<td>Inpatient Reimbursement</td>
<td>8</td>
</tr>
<tr>
<td>Spiration Valve System Physician and Outpatient Coding and Reimbursement</td>
<td>9</td>
</tr>
<tr>
<td>Potential CPT Codes (For Physicians and Hospital Outpatient Departments)</td>
<td>9</td>
</tr>
<tr>
<td>NCCI Edits</td>
<td>9</td>
</tr>
<tr>
<td>Modifiers</td>
<td>9</td>
</tr>
<tr>
<td>HCPCS Codes</td>
<td>10</td>
</tr>
<tr>
<td>Physician Reimbursement</td>
<td>10</td>
</tr>
<tr>
<td>Outpatient Reimbursement</td>
<td>10</td>
</tr>
<tr>
<td>References and Attachments</td>
<td>11</td>
</tr>
<tr>
<td>Attachment A: FDA HDE Approval Letter</td>
<td>12</td>
</tr>
<tr>
<td>Attachment B: Requesting Prior Authorization</td>
<td>15</td>
</tr>
<tr>
<td>Attachment C: Sample Letter of Medical Necessity</td>
<td>16</td>
</tr>
<tr>
<td>Attachment D: Instructions For Use – Spiration Valve System</td>
<td>18</td>
</tr>
<tr>
<td>Attachment E: Instructions For Use – Airway Sizing Kit</td>
<td>19</td>
</tr>
<tr>
<td>Attachment F: Spiration Valve System Procedure Overview</td>
<td>21</td>
</tr>
</tbody>
</table>
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.
Overview of Coverage and Coding

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-10-CM</td>
<td>Describes patient condition or underlying disease</td>
</tr>
<tr>
<td>ICD-10-PCS</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-10-CM DIAGNOSIS CODES
For Hospitals and Physicians

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-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. Table 2 below identifies potential ICD-10-CM diagnosis codes for air leaks.

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 societies¹ 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 treated with 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.

Table 2: Potential ICD-10-CM Diagnosis Codes for air leaks

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>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>J95.81</td>
<td>Postprocedural pneumothorax and air leak</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>

¹Codes are listed on specialty society websites, for example: http://www.thoracic.org/clinical/coding-and-billing/resources/2011/august-2011.pdf
POTENTIAL ICD-10-PCS PROCEDURE CODES
For Inpatient Hospital Providers

Hospitals use ICD-10-PCS 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 (Attachments D and E) and Spiration Valve System Procedure Overview (Attachment F).

Table 3 below identifies potential ICD-10-PCS procedure codes that may be used to describe the insertion and removal of the bronchial 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. Please refer to the ICD-10-PCS book for a comprehensive list of hospital procedure codes.

<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>0BHB8GZ</td>
<td>Insertion of Endobronchial Valve into Left Lower Lobe 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>
INPATIENT REIMBURSEMENT

Medicare pays hospitals for inpatient services under a prospective payment system using Medicare Severity Diagnosis Related Groups (MS-DRGs). Each MS-DRG is associated with a payment rate. However, the actual payment may vary depending on the specifics of the patient encounter. The following payment rates are reflective of payment for hospitals that do not submit quality data and are not meaningful Electronic Health Record (EHR) users from the Fiscal Year (FY) 2016 Inpatient Prospective Payment System (IPPS) Final Rule, which was published in the Federal Register on July 31, 2015. These payment rates are effective starting October 1, 2015.

Based on ICD-10-PCS procedures and the patient's principle and secondary diagnosis, possible MS-DRGs for the Spiration Valve System can be found in Table 4.

Table 4: Potential MS-DRGs

<table>
<thead>
<tr>
<th>ICD-10-PCS CODE</th>
<th>DESCRIPTION</th>
<th>MS-DRG</th>
<th>DESCRIPTION</th>
<th>FY 2016 IPPS PAYMENT²</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Valve Placement</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0BH38GZ</td>
<td>Insertion of Endobronchial Valve into Right Main Bronchus, Via Natural or Artificial Opening Endoscopic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0BH48GZ</td>
<td>Insertion of Endobronchial Valve into Right Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0BH58GZ</td>
<td>Insertion of Endobronchial Valve into Right Middle Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0BH68GZ</td>
<td>Insertion of Endobronchial Valve into Right Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
<td>163 164 165</td>
<td>Major chest procedures w/ MCC Major chest procedures w/ CC Major chest procedures without CC/MCC</td>
<td>$29,199 $15,075 $10,595</td>
</tr>
<tr>
<td>0BH78GZ</td>
<td>Insertion of Endobronchial Valve into Left Main Bronchus, Via Natural or Artificial Opening Endoscopic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0BH88GZ</td>
<td>Insertion of Endobronchial Valve into Left Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0BH98GZ</td>
<td>Insertion of Endobronchial Valve into Lingula Bronchus, Via Natural or Artificial Opening Endoscopic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0BHB8GZ</td>
<td>Insertion of Endobronchial Valve into Left Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Valve Removal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0WPQ8YZ</td>
<td>Removal of Other Device from Respiratory Tract, Via Natural or Artificial Opening Endoscopic</td>
<td>166 167 168</td>
<td>Other respiratory system O.R. procedures w/ MCC Other respiratory system O.R. procedures w/ CC Other respiratory system O.R. procedures without CC/MCC</td>
<td>$21,481 $11,306 $7,560</td>
</tr>
</tbody>
</table>

² FY 2016 IPPS Payment Rates show unadjusted base payment rates for facilities that do not submit quality data and are not meaningful Electronic Health Record (EHR) users.
Spiration Valve System
Physician and Outpatient Coding and Reimbursement

POTENTIAL CPT CODES
For Physicians and Hospital Outpatient Departments

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.3

Table 5: 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.

Modifiers
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 codes) associated with the Spiration Valve System.

PHYSICIAN REIMBURSEMENT

Under Medicare, physicians are paid based on the Medicare Physician Fee Schedule (MPFS). Payments for CPT codes are determined by the review of the Relative Value Update Committee (RUC) and valuation by the Centers for Medicare and Medicaid Services (CMS).

Private insurers use a variety of reimbursement methodologies and guidelines to reimburse for physician services. Most private insurers negotiate contracts directly with the physician for payment of physician services. The most common payment methods are contractual rates, established fee schedules and percentage of allowable charges.

The following 2015 physician payment rates are reflective of the Calendar Year 2015 MPFS Final Rule, which was published in the Federal Register on October 31, 2014. Payments listed are national unadjusted fee schedule rates. Actual payments to physicians may vary. Multiple procedure payment reduction may apply when codes are billed together for a single patient encounter.

Table 6: Physician Payment for Spiration Valve System Procedures

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
<th>CY 2015 MPFS PAYMENT</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>$229.84</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>
<td>$76.26</td>
</tr>
<tr>
<td>31648</td>
<td>...with removal of bronchial valve(s), initial lobe</td>
<td>$209.44</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>
<td>$69.81</td>
</tr>
</tbody>
</table>

HOSPITAL OUTPATIENT DEPARTMENT REIMBURSEMENT

Under Medicare, hospital outpatient departments are paid based on the Outpatient Prospective Payment System (OPPS). Under OPPS, services are assigned to payment categories called Ambulatory Payment Classifications (APCs). The following 2015 outpatient payment rates are reflective of the Calendar Year 2015 Medicare Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Final Rule.

Private insurers use a variety of reimbursement methodologies and guidelines to reimburse for outpatient department services. While some private insurers may have contracted case rates which follow the Medicare model, other private insurers may pay hospitals on a charge-related basis.

Table 7: Outpatient Payment for Spiration Valve System Procedures

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
<th>SI</th>
<th>APC</th>
<th>CY 2015 OPPS PAYMENT</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>T</td>
<td>0415</td>
<td>$2,255.48</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>
<td>T</td>
<td>0415</td>
<td>$2,255.48</td>
</tr>
<tr>
<td>31648</td>
<td>...with removal of bronchial valve(s), initial lobe</td>
<td>Q2</td>
<td>0076</td>
<td>$1,054.71</td>
</tr>
<tr>
<td>31649</td>
<td>...with removal of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure)</td>
<td>N</td>
<td>None</td>
<td>$ --</td>
</tr>
</tbody>
</table>

*SI (Status Indicator)
T – Procedure or Service, Multiple Reduction Applies
Q2 – STV-Packaged Codes
N – Items and Services Packaged into APC Rates
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
Attachment A: FDA HDE Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

January 29, 2014

SPIRATION, INC.
Ms. Cyady Adams
Regulatory Affairs
6675 185th Avenue N.E.
Redmond, WA 98052

Re: H060002 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 pin 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 502(q) and (r) of the FD&C Act.
Attachment A: FDA HDE Approval Letter

Page 2 – Ms. Adams

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 A. 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 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.

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

*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.

[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 recent prospective 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. To date there have been over 1,700 procedures using the Spiration Valves with minimal reports of adverse events related to the procedure or product.2

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.

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,

2. Spiration Valve System, Patient Information Pamphlet and internal information.
**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/ifu](http://www.spiration.com/ifu)
Attachment D: Instructions For Use – Spiration Valve System

1. Intended Use

The Spiration Valve System is a device to control passively air leaks of the lung, or significant air leaks that are likely to become passively air leaks following thoracotomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). Air leaks are present on post-operative day 1 on chest x-ray is considered passively air leaks present only during the course of post-operative healing. Air leaks are passively present in the majority of patients undergoing thoracotomy or segmentectomy for the treatment of chronic obstructive pulmonary disease (COPD) or lung cancer. As an air leak is present during normal inflation phase of respiration, it is generally present during expiration and superseded by subpleural amyloplasia or emphysema-like emphysema and expiratory air leaks.

2. Spiration Valve System Description

The Spiration Valve System consists of a Spiration Valve (SV) in Cartridges (Expiration Valve) or "valves" and a Deployment Catheter (catheter) and (load) "loader". The Spiration Valve System is an accessory to the Spiration Valve System to achieve the appropriate valve size for each targeted area and to perform two procedures for each targeted area.

2.1 Spiration Valve in Cartridge

The valve is designed to fit above the portion of the lung to be sealed, while allowing access to the airway immediately to the patient. The valve is comprised of a flexibly strong and expandable endotube with a cut and a vent.

The catheter is held against the airway mucosa by flexible bands and will expand and contract with air movement during breathing. The flexible bands are preformed to provide support to the guidewire and subpleural amyloplasia and to control the valve opening. The valve is designed to be removed by grasping the removal handles and the flexiblebronchoscopy forceps.

The valve is available in 5.5, 8.5, and 11.5 mm diameters and packed in a disposable catheter that protects the valve from damage and stray. The valve is designed so that its unique markings distinguish it from the other valves. The appropriate valve size is selected after it has been indicated and the airways have been sized using the Spiration Opening Kit.

3. Spiration Valve in Cartridge

2.2.3 Deployment Catheter Loader and Loader

The loader is a tool used to insert the valve into the tip of the catheter. After the catheter is placed in the target site, the catheter guide is placed in the loader or loader and is assembled to the loader. Insert the valve into the tip of the catheter. The catheter is used to deliver the valve to the target location. The loader and catheter are designed so that in the event of a misalignment of the valve, the valve will seal in the event of a fail safe.
9.8 Spiration Valve Deployment

- Place the turnbuckle on the lever using the bronchoscope first, then fix the turnbuckle with the lever using the bronchoscope second.
- Grasp the turnbuckle with your left hand and the lever with your right hand.
- Gently turn the turnbuckle clockwise until it reaches the maximum deployment position, and then gently turn it counterclockwise to release it.
- The turnbuckle should be released to the fully deployed position, and the lever should be released to the fully deployed position. If the turnbuckle is not released to the fully deployed position, it may be difficult to deploy the valve.

9.9 Spiration Valve Removal

- To remove the valve, use the turnbuckle to turn the valve counterclockwise until it reaches the maximum removal position.
- Gently turn the turnbuckle clockwise to release the valve from the bronchoscope.
- The valve should be released from the bronchoscope when it reaches the maximum deployment position.
- The valve should be removed from the bronchoscope when it reaches the maximum deployment position.
- The valve should be removed from the bronchoscope when it reaches the maximum deployment position.

10. Operator's Instructions

10.1 Isolating the Air Leaks by Balloon Occlusion

- Place the turnbuckle on the lever using the bronchoscope first, then fix the turnbuckle with the lever using the bronchoscope second.
- Grasp the turnbuckle with your left hand and the lever with your right hand.
- Gently turn the turnbuckle clockwise until it reaches the maximum deployment position, and then gently turn it counterclockwise to release it.
- The turnbuckle should be released to the fully deployed position, and the lever should be released to the fully deployed position. If the turnbuckle is not released to the fully deployed position, it may be difficult to deploy the valve.

10.2 Selecting the Spiration Valve Size

- Use a bronchoscope with a diameter of 2.8 mm or larger and a balloon size of 3.2 mm or larger.
- Place the turnbuckle on the lever using the bronchoscope first, then fix the turnbuckle with the lever using the bronchoscope second.
- Grasp the turnbuckle with your left hand and the lever with your right hand.
- Gently turn the turnbuckle clockwise until it reaches the maximum deployment position, and then gently turn it counterclockwise to release it.
- The turnbuckle should be released to the fully deployed position, and the lever should be released to the fully deployed position. If the turnbuckle is not released to the fully deployed position, it may be difficult to deploy the valve.

10.3 Loading the Spiration Valve

- Place the turnbuckle on the lever using the bronchoscope first, then fix the turnbuckle with the lever using the bronchoscope second.
- Grasp the turnbuckle with your left hand and the lever with your right hand.
- Gently turn the turnbuckle clockwise until it reaches the maximum deployment position, and then gently turn it counterclockwise to release it.
- The turnbuckle should be released to the fully deployed position, and the lever should be released to the fully deployed position. If the turnbuckle is not released to the fully deployed position, it may be difficult to deploy the valve.

10.4 Deployment of the Spiration Valve

- Place the turnbuckle on the lever using the bronchoscope first, then fix the turnbuckle with the lever using the bronchoscope second.
- Grasp the turnbuckle with your left hand and the lever with your right hand.
- Gently turn the turnbuckle clockwise until it reaches the maximum deployment position, and then gently turn it counterclockwise to release it.
- The turnbuckle should be released to the fully deployed position, and the lever should be released to the fully deployed position. If the turnbuckle is not released to the fully deployed position, it may be difficult to deploy the valve.

10.5 Spiration Valve Removal

- To remove the valve, use the turnbuckle to turn the valve counterclockwise until it reaches the maximum removal position.
- Gently turn the turnbuckle clockwise to release the valve from the bronchoscope.
- The valve should be released from the bronchoscope when it reaches the maximum deployment position.
- The valve should be removed from the bronchoscope when it reaches the maximum deployment position.
- The valve should be removed from the bronchoscope when it reaches the maximum deployment position.

Preparing to Advance the Catheter to the Target Location

11.1 Preparing to advance the catheter to the target location, the catheter should be directed to the left side of the patient's mouth.

11.2 Positioning the Bronchoscope for Spiration Valve Deployment

6. Place the turnbuckle on the lever using the bronchoscope first, then fix the turnbuckle with the lever using the bronchoscope second.
7. Grasp the turnbuckle with your left hand and the lever with your right hand.
8. Gently turn the turnbuckle clockwise until it reaches the maximum deployment position, and then gently turn it counterclockwise to release it.
9. The turnbuckle should be released to the fully deployed position, and the lever should be released to the fully deployed position. If the turnbuckle is not released to the fully deployed position, it may be difficult to deploy the valve.

11.3 Spiration Valve Removal

8. To remove the valve, use the turnbuckle to turn the valve counterclockwise until it reaches the maximum removal position.
9. Gently turn the turnbuckle clockwise to release the valve from the bronchoscope.
10. The valve should be released from the bronchoscope when it reaches the maximum deployment position.
11. The valve should be removed from the bronchoscope when it reaches the maximum deployment position.
12. The valve should be removed from the bronchoscope when it reaches the maximum deployment position.

Checking Spiration Valve Placement

13. Visually examine the valve for position and fit. The valve should be opened and observed against a light source.
14. Check if the position of the deployed valve is not optimal or appropriate, reposition the valve.
15. Reconfirm the reading and deployment status for each additional valve required.
16. Check if the catheter and lever are designed to load and deploy up to 10 valves. After 10 valves are loaded and deployed from a single catheter and lever, a new catheter and lever must be used for the system.

12.2 Removing the Spiration Valve

1. Insert the appropriate forceps into the bronchoscope, directing the forceps to the pharmacological site and securing the long turnbuckle to the system (see instructions for use of the pharmacological site).

Table: Forceps Recommended Use

<table>
<thead>
<tr>
<th>Forceps</th>
<th>Recommended Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capped</td>
<td>When the removal tool can be visualized and accessed by the biopsy forceps.</td>
</tr>
<tr>
<td>Red Turn Jaw Forceps</td>
<td>When the removal tool is being grasped.</td>
</tr>
<tr>
<td>Pediak</td>
<td>When the removal tool is being grasped.</td>
</tr>
</tbody>
</table>

12.3 Spiration Valve Removal

13. To remove the forceps, insert the forceps into the bronchoscope, directing the forceps to the pharmacological site and securing the long turnbuckle to the system (see instructions for use of the pharmacological site).
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 valve size to use for each target airway. A balloon catheter is used first in conjunction with the Airway Sizing Kit to determine, by selective airway occlusion, the location for the placement of valves to control progression of 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 volumetric scale (in microliters, µL) that is used with a balloon catheter and 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 its use as a sizing tool. One balloon catheter is used to measure all of the airways to be treated for a single patient.

Two compliant balloonists are acceptable to use for airway sizing: the Olympic™ BS-3C balloon and the Applied Medical® Pyton™ EC 11mm/35F for latex-sensitive patients. The balloon is filled with saline and injected into the airway lumen. 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.

**Figure 1: Airway Sizing Kit**

**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 operator must be a physician or medical person under the supervision of a physician and be trained in bronchoscopy techniques. The following instructions will give technical guidance but do not obviate formal training in the use of this device.
- The Olympic 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.
- Only use the recommended balloon catheters with the Airway Sizing Kit.

**5. Potential Adverse Effects**

- Adverse events associated with flexible bronchoscopy.

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

- Calibration guide
- 50ìL glass syringe
- Syringe plunger
- Airway Sizing Workshop (PB-01519)
- Olympic balloon catheter BS-3C

**Additional accessory required (not provided with the Airway Sizing Kit):**

- If the patient is latex sensitive, Applied Medical balloon catheter, Pyton EC 11mm/35F for balloon-occlusion and sizing. For information, contact the manufacturer.
- Sterile 3-way stopcock
- Standard 10cc sterile syringe
- Sterile saline

**Additional accessory recommended (not provided with the Airway Sizing Kit):**

- Olympic balloon catheter BS-3Q or a balloon catheter that inflates to 13mm or larger for balloon-occlusion only.

**7. Packaging Inspection, Storage, and Handling**

- The Airway Sizing Kit is supplied sterile and packaged in a sealed tray. Do not attempt to repackage 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 85°C or below -15°C.
- Do not use the Airway Sizing Kit for more than one patient procedure.
- The Airway Sizing Kit is not designed to be reused, reprocessed, or reprocessed.

**8. Preparation of the Balloon Catheter for Sizing**

Please familiarize yourself with the instructions for Use provided by the balloon manufacturer. Use the Olympic 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 or sterile field.
2. Remove and discard the 3-way stopcock that comes with the Olympic balloon catheter (see Figure 2). The stopcock that is provided with the Olympic BS-3C balloon catheter cannot be used in this procedure. The Applied Medical balloon does not have a 3-way stopcock attached to it.

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**Figure 2**

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9. Repeat steps 7 and 8 until no air bubbles larger than 2mm are seen in the balloon when inflated to approximately 10mm (see Figure 9).

10. Completely deflate the balloon.

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

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

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

14. With the balloon catheter port shut off, slightly depress the 10cc syringe plunger, purging all air from the stopcock (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 50µl mark (see Figure 13). Holding the glass syringe against a dark background may assist in reading the syringe volume.

16. Close the 10cc syringe port (see Figure 14).

12. Remove the 10cc syringe from the 3-way locking stopcock (see Figure 15).

18. Confirm that the glass syringes 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 50µl mark.

8.2 Calibrating the Balloon for Sizing

The Olympus 85-12 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-0317W) 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 glass syringe plunger, slowly turn 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 16).

3. When the balloon just fits the size “F” opening so that it gently drops on all sides of the hole, check the volume at 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 17).

5. Repeat these steps (1-4) for the remaining calibration holes (7, 6, 5, 4H) (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-0317W).

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. Maneuver the bronchoscope to the target airway location. Advance the balloon into the airway.

3. Slowly inflate the balloon until it just touches and drops 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 (see example in Figure 19: “390 µl” on the Apical (8.0H) line). Taking multiple readings of the airway 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 19). If the syringe volume matches one of the gauge size volumes on the Valve Selection Guide, always select the next larger valve size. If the airway size is too large for a 7mm 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 5mm 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, during 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. Cover 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 for the Spiration Valve System (PI-0317W).

11. Patient Information

A Patient Information Pamphlet is available for potential patients (Patient Information for the Spiration Valve System, Humantarian Device for Use in the Control of Air Leaks, PI-0322). 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