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 prolonged 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 balloons are acceptable to use for airway sizing: the Olympus ® B5-2C balloon and the Applied Medical ® Python ® EC 11mm/5F for latex-sensitive patients. The balloon is filled with saline and calibrated with the calibration gauge. During the sizing process, the calibrated balloon is inflated at the target airway location. The saline volume used to inflate the balloon indicates the appropriate valve size to use at the target location.

3. **Contraindications**

- 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.

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 clinical bronchoscopy techniques. The following instructions will give technical guidelines but do not obviate formal training in the use of this device.
- The Olympus balloon catheters contain 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 effects associated with flexible bronchoscopy.
- Allergic reaction to latex specific to latex balloon use.

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

Items required (provided with the Airway Sizing Kit):
- Calibration gauge
- 500μl glass syringe
- Syringe plunger
- Airway Sizing Worksheet (PI-03178)
- Olympus balloon catheter B5-2C

Additional ancillary equipment required (not provided with the Airway Sizing Kit):
- If the patient is latex sensitive, Applied Medical balloon catheter, Python EC 11mm/5F for balloon occlusion and sizing (see Instructions for Use, Spiration Valve System, PI-03177)
- Sterile 3-way stop-cock
- Sterile 10cc sterile syringe
- Sterile saline

Additional ancillary equipment recommended (not provided with the Airway Sizing Kit):
- Olympus balloon catheter B7-2Q or a balloon catheter that inflates to 13mm or larger 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 re-sterilize the Airway Sizing Kit. Contact your local Spiration representative if the integrity of the packaging has been compromised.
- Do not use the Airway Sizing Kit if it has been exposed to temperatures above 50°C or below -15°C.
- Do not use the Airway Sizing Kit for more than one patient procedure.
- The Airway Sizing Kit is not designed to be re-cleaned, reprocessed or resterilized.

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

Please familiarize yourself with the Instructions for Use provided by the balloon manufacturer. Note: 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 or sterile field.
2. Remove and discard the 2-way stopcock that comes with the Olympus balloon catheter (see Figure 2). The stopcock that is provided with the Olympus B5-2C balloon catheter cannot be used in this procedure. The Applied Medical balloon does not have a 2-way stopcock attached to the inflation connector.

3. Replace with a 3-way stopcock (see Figure 3).

4. Remove the black lightproof cap from the balloon (see Figure 4). Do not discard the lightproof cap. This will be used later in the procedure.

5. Fill a standard 10cc syringe with approximately 5cc of sterile saline, and purge any air from the 10cc syringe.

6. Attach the 10cc syringe to the 3-way stopcock port at a 90-degree angle to the balloon. Close the unused stopcock port (see Figure 5).

7. Inflate the balloon catheter with sterile saline using the 10cc syringe (see Figure 7).

8. Keeping the 10cc syringe vertical, deflate the balloon, creating a vacuum, by pulling as far back on the syringe as possible. Continually tap the balloon while it is deflating to assist the removal of air bubbles (see Figure 8).

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**Note:** 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.
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 saline, wet the syringe plunger from the Airway Sizing Kit and completely
insert it into the 500µl glass syringe.

13. Fill the 500µl glass syringe with sterile saline. Make sure the syringe is completely full (at
least 500µl 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 against a dark background may assist in reading the syringe volume.

16. 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).

17. Transcribe the syringe volume for each gauge hole size (9, 7, 6, 5, and MIN) from the graph to
the Valve Selection Guide on the worksheet (see Figure 19 below). The size nine gauge hole
is necessary to visualize an appropriately shaped curve. There is no valve size associated
with the “9” gauge hole.

9. Isolating the Air Leak by Balloon Occlusion
See Operator instructions in the Spiration Valve System Instructions for Use (PI-03177).

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 drags on all sides of the airway wall when
moved in and out at the target location (see Figure 16). 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 bronchial tree (see example
in Figure 19: “380 µL” on the Apical (RB1) 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
volume is too large for a 5mm 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-03177).

11. Patient Information
A Patient Information Pamphlet is available for potential patients (Patient Information for the
Patients who receive treatment will be given a wallet card that indicates the patient has valve vej
and lists the procedure doctor’s contact information.