



INSTRUCTIONS FOR USE AIRWAY SIZING KIT

Humanitarian Device for Use in the Control of Air Leaks

STERILE EO Sterilized by EO. Sterile unless package opened or damaged. Do Not Resterilize.

- ⊗ SINGLE PATIENT USE ONLY
- ⚠ SEE INSTRUCTIONS FOR USE
- 🌡 TEMPERATURE LIMITS: -15°C to +50°C

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IBV[®] Valve System is covered by U.S. Patents 6,258,100 - 6,293,951 - 6,592,594, 6,929,637 and other Patents Pending.

1 Intended Use

The Spiration[®] Airway Sizing Kit is intended to determine the appropriate size IBV[™] Valve needed for an airway.

2 Device Description

IBV[™] Valves are supplied in different sizes and proper fit with the airway is important to ensure proper function. The sizing kit is used to determine the size of the airway at the target implant location so that the appropriate size valve can be implanted. The Airway Sizing Kit consists of a glass syringe and a calibration gauge (See Figure 1). A compliant balloon catheter is used in conjunction with the Airway Sizing Kit. Two compliant balloons are acceptable to use: the Olympus[®] B5-2C balloon and the Applied Medical[®] Python[®] EC 11mm/5F for latex sensitive patients. During the sizing process the balloon is calibrated with the gauge and then inflated at the target implant location. The saline volume used to inflate the balloon indicates the appropriate valve size to use at the target implant site.

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 IBV[™] Valve System.

4 Precautions

- Use of the Spiration Airway Sizing Kit requires bronchoscopy technical skills. The operator of this System must be a physician or medical personnel 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 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 Spiration 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

- (1) One calibration gauge
- (1) One 500µl glass syringe
- (1) One syringe plunger

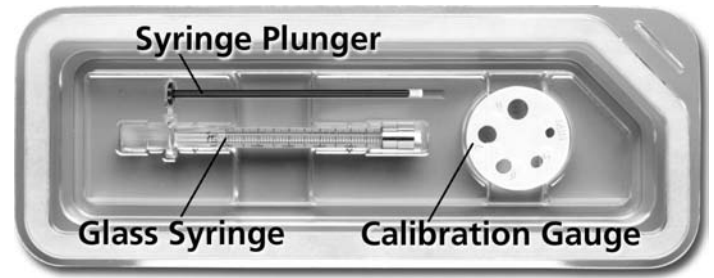
Additional ancillary equipment required:

- (1) One Olympus balloon catheter B5-2C or (1) One Applied Medical balloon catheter, Python EC 11mm/5F
- (1) One sterile Luer-lock[®] 3-way stop-cock
- (1) One standard 10cc sterile syringe with Luer-lock for use in preparing the balloon catheter
- Sterile saline

7 Handling

- This device is supplied sterile. Do not reuse or attempt to resterilize the Airway Sizing Kit. Contact your local Spiration representative if the integrity of the packaging has been compromised.
- Do not use the Airway Sizing Kit if it has been exposed to temperatures above 50° C or below -15° C.

8 Airway sizing

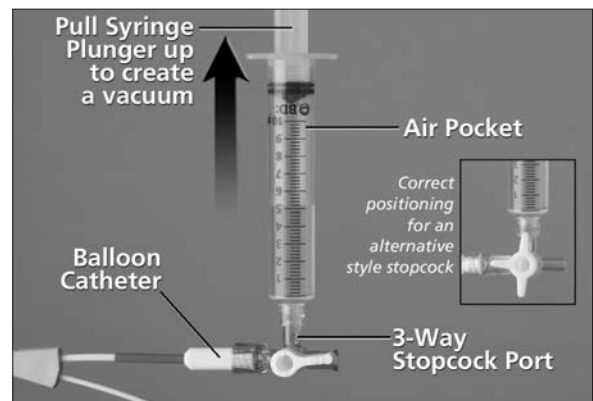


Airway Sizing Kit (Figure 1)

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. 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.

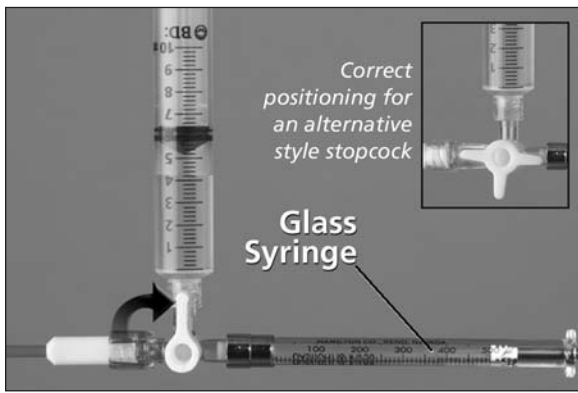
8.1 Preparation of the Sizing Balloon

1. Remove the outer packaging and place the items required for the sizing step in a clean or sterile field.
2. Remove and discard the 2-way stopcock from the Olympus balloon catheter's inflation Luer-lock[®] connector (the Applied Medical balloon does not have a 2-way stopcock attached to the inflation Luer-lock connector). Place a 3-way locking stopcock on the Luer-lock inflation connector.
3. Fill a standard 10cc syringe with approximately 5cc of sterile saline, and purge any air from the syringe.
4. Attach the 10cc syringe to the 3-way stopcock port at a 90-degree angle to the balloon (See Figure 2).



Balloon Catheter with 3-Way Stopcock and 10cc Syringe (Figure 2)

5. Close the empty Luer-lock fitting.
6. Pull the syringe plunger back as far as possible to create a vacuum and remove air. The syringe should be held with the Luer-lock down, and the plunger up so bubbles rise to the air pocket. Hold the syringe back for about 10 seconds until no more air bubbles are seen exiting the syringe or 3-way stopcock.
7. Inflate the balloon catheter using sterile saline. Fill the balloon to about 10mm in diameter (slightly larger than the size 9 opening in the calibration gauge). Let the balloon settle for a few seconds and check for air bubbles.
8. Deflate the balloon, creating a vacuum by pulling as far back on the syringe as possible. The syringe should be held with the Luer-lock down, and the plunger up. Hold the vacuum for about 10 seconds, drawing the air out of the balloon catheter.
9. Repeat until no air bubbles larger than 2mm are seen in the balloon when inflated to approximately 10mm.
10. Adjust the stopcock so that the balloon catheter is shut off.
11. Insert the 500µl glass syringe plunger into the syringe barrel.
12. Fill the 500µl glass syringe with sterile saline. Make sure the syringe is completely full (at least 500µl of sterile saline) and no air bubbles are seen.
13. With the balloon catheter shut off, slightly depress the 10cc syringe plunger, purging any air from the stopcock.
14. Attach the glass syringe to the open Luer-lock fitting without introducing air bubbles. Adjust the glass syringe so that the end of the plunger is at the 500µl mark (See Figure 3).



Balloon Catheter with 3-Way Stopcock, 10cc Syringe and Glass Syringe (Figure 3)

15. Adjust the stopcock so that the 10cc syringe is shut off.
16. Remove the 10cc syringe from the 3-way locking stopcock.
17. 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 500 μ l mark.

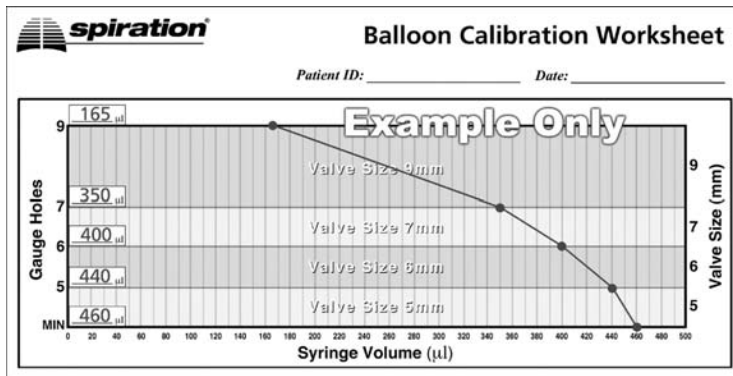
8.2 Calibrating the Balloon

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

For your convenience, two worksheets are included:

- Form 1: Balloon Calibration Worksheet
- Form 2: Airway Sizing Worksheet

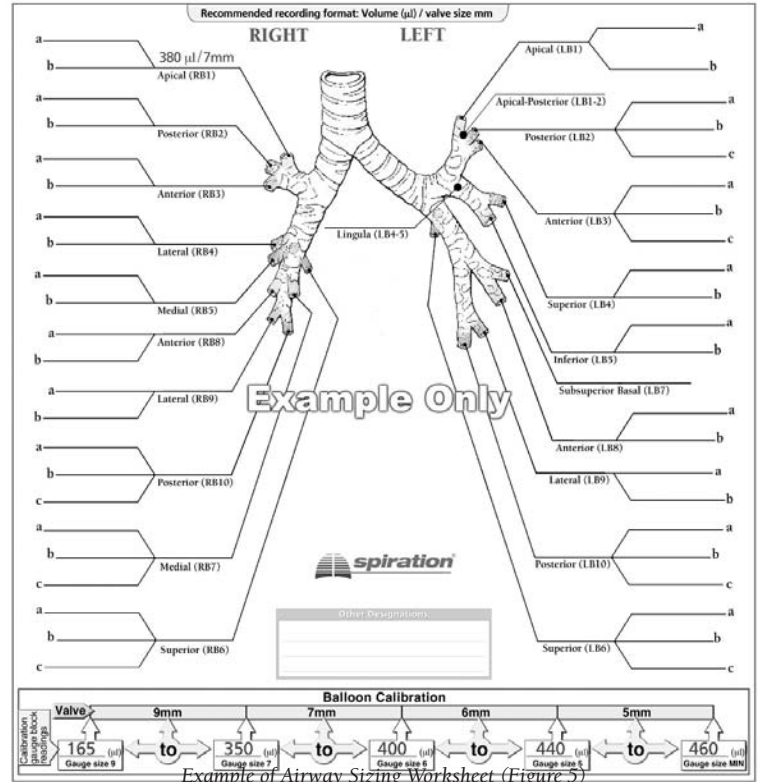
1. Wet the balloon and calibration block with sterile saline.
2. Place the balloon in the center of the size "9" opening in the round calibration gauge. Using the glass syringe plunger, slowly inflate the balloon until its diameter touches all sides of the size "9" calibration hole.
3. When the balloon just fills the size "9" opening so that it gently drags on all sides of the hole, check the volume on the glass syringe.
4. Record the glass syringe volume next to the "9" on the left axis of the graph on the Balloon Calibration Worksheet.
5. Repeat these steps (1-4) for the remaining calibration holes (7, 6, 5, MIN) (See Figure 4).
6. Mark the glass syringe volume on the Balloon Calibration Worksheet. A straight line should be drawn connecting each of the points from the glass syringe readings on the Balloon Calibration Worksheet. Verify that the curve is continuous and has the correct shape (See Figure 4).
7. Record the syringe volume for each size on the Airway Sizing Worksheet (See Figure 5).



Example Balloon Calibration Worksheet using an Olympus Balloon (Figure 4)

8.3 Measuring the Airways and Selection of Valve Size

1. Insert the deflated sizing balloon into the working channel of the bronchoscope. Keep the tip of the balloon catheter inside of the bronchoscope until the bronchoscope is in its final position.
2. Maneuver the bronchoscope to the target airway location. Advance the balloon into the center of the airway at the target implant location.
3. Slowly inflate the balloon until the balloon touches the airway wall on all sides. It may be helpful to slightly inflate and deflate the balloon a few times to find the optimum fit and to move the balloon back and forth until you observe it beginning to drag on all sides of the airway wall.
4. Record the glass syringe volume on the line of the target implant location on the Airway Sizing Worksheet (for example: 380 μ l on the Right Apical line).
5. Determine the appropriate valve size for that location and record it next to the syringe volume. The valve size is selected by finding the valve range that the glass syringe volume falls within on the Airway Sizing Worksheet (for example: 380 μ l/7mm on the Right Apical line, See Figure 5).



6. **IMPORTANT:** Before moving to the next measurement, completely deflate the balloon and draw a slight (approximately 10 μ l) vacuum with the glass syringe. Hold the tip of the balloon catheter in a retracted position, inside the bronchoscope, during movement between airways, to minimize wear or damage to the tip of the balloon catheter.
7. Repeat steps 1 through 6 for each additional target implant sites to be sized, recording the glass syringe volume and valve size at the appropriate location on the Airway Sizing Worksheet.
8. Remove the balloon from the bronchoscope.

9 Patient Information

Your physician will help you understand the effect of treatment on your symptoms. If this effect should worsen, or unexpected new symptoms develop, you should notify your physician promptly.

CAUTION: Humanitarian Device. Authorized by Federal law for use in the treatment of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or lung volume reduction surgery (LVRS). The effectiveness of this device for this use has not been demonstrated.