

Spiration[®] Valve System **PROCEDURE GUIDE**

For the Treatment of Post-surgical Air Leaks



Balloon Calibration



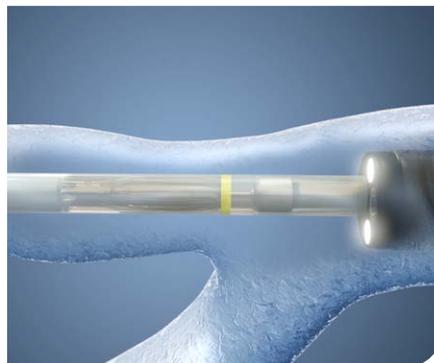
Airway Isolation



Airway Sizing



Valve Loading



Valve Placement

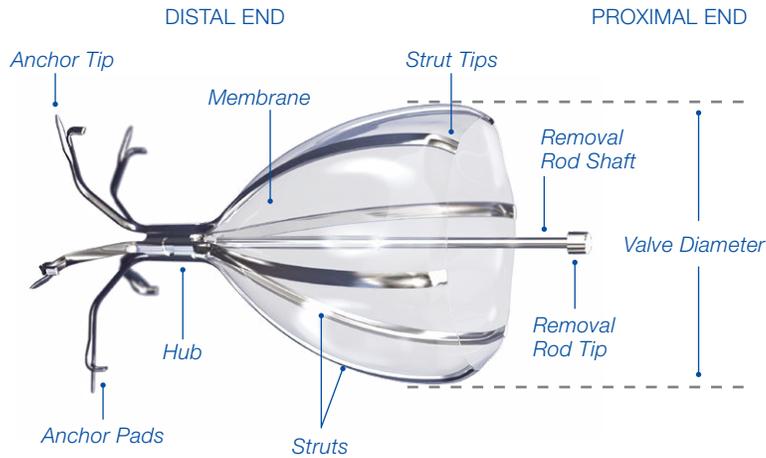


Valve Removal

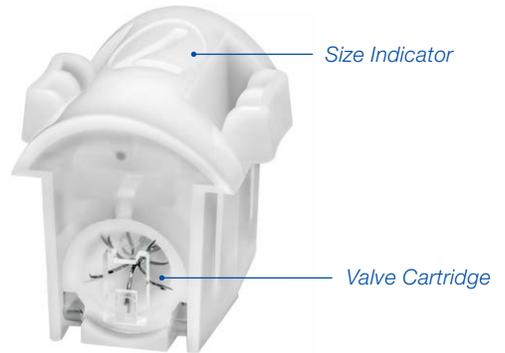
Spiration® Valve System Procedure Guide

For the Treatment of Post-surgical Air Leaks

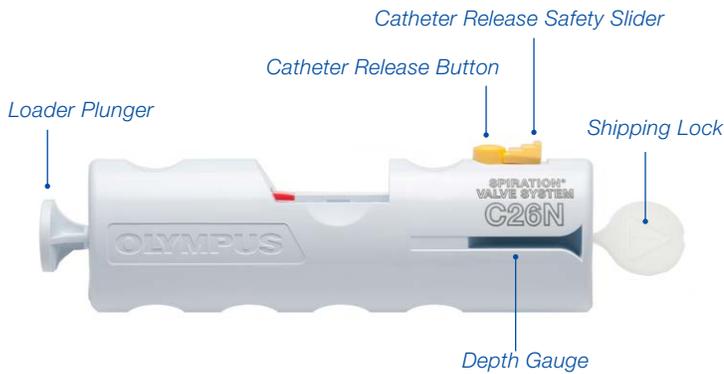
Valve



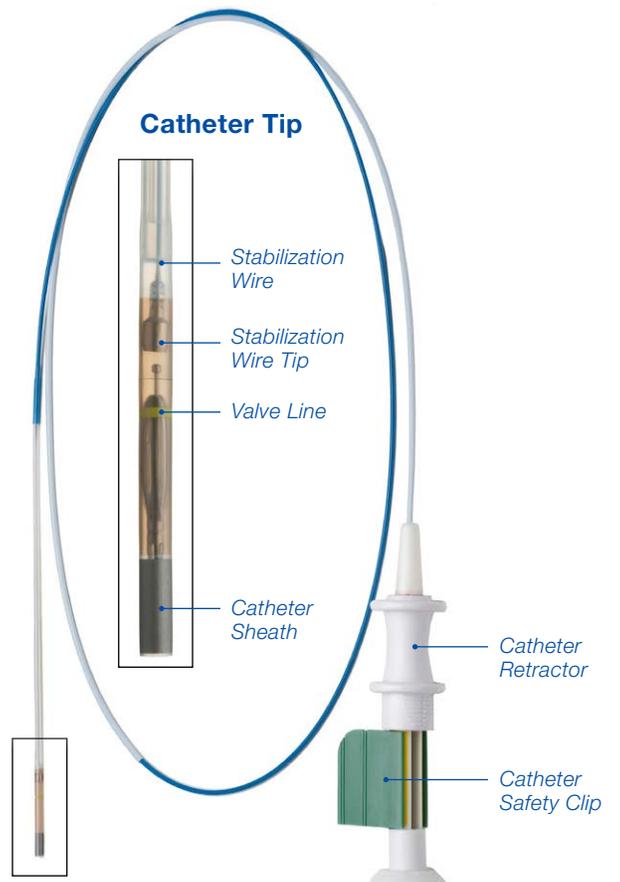
Valve in Cartridge



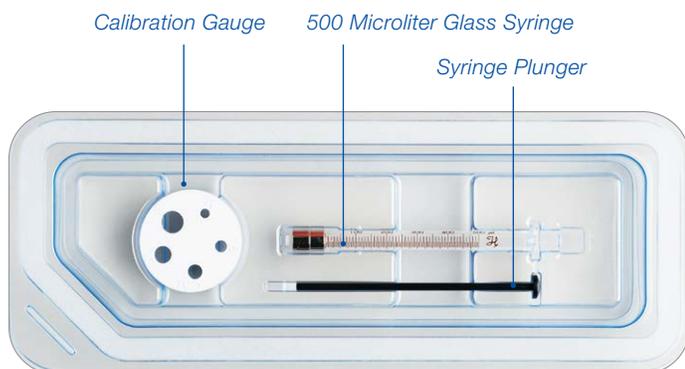
Loader



Deployment Catheter

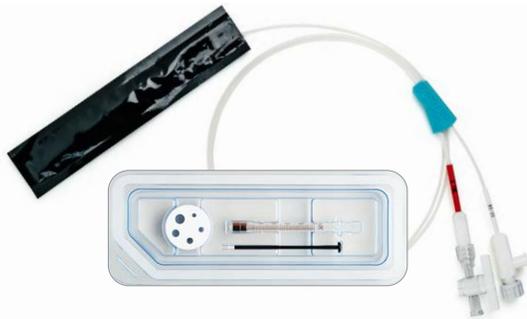


Airway Sizing Kit



Preparing the Balloon Catheter

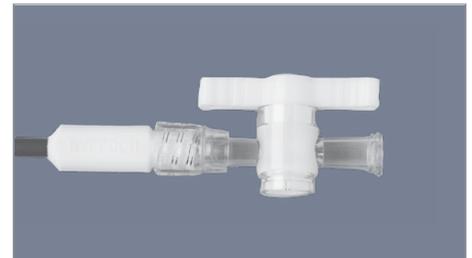
Instructions to Properly Prepare the Balloon Catheter for Airway Sizing



1. Remove the Balloon Catheter and Airway Sizing Kit components from the packaging. Place the items on a clean or sterile field.



2. Remove the black lightproof cap from the balloon. Do not discard.



3. Confirm that the stopcock supplied with the system is firmly attached.

4. Fill the 10cc syringe with approximately 3cc of sterile saline.
5. Purge any air from the 10cc syringe.
6. Connect the 10cc syringe to the stopcock port.

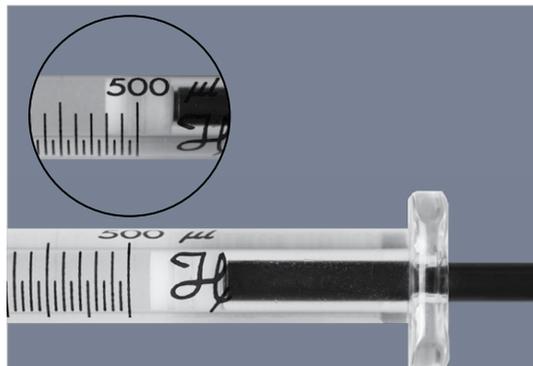


7. With the 10cc syringe oriented vertically, pull the syringe plunger to approximately the 10cc mark and hold for at least 10 seconds to create a vacuum removing the air from the balloon.
8. While maintaining vacuum, tap on the side of the syringe to assist in freeing bubbles from the stopcock.



9. Keeping the 10cc syringe vertical, slowly release the plunger on the 10cc syringe until the system is no longer under vacuum.

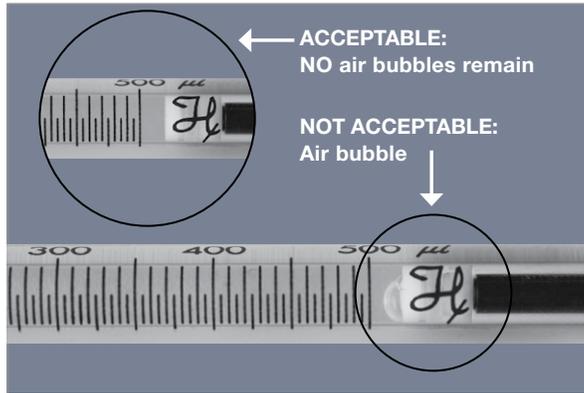
10. Set aside the balloon with the 10cc syringe still attached.
11. Using sterile saline, wet the plunger for the glass syringe from the Airway Sizing Kit and completely insert it into the 500 microliter (μL) glass syringe.



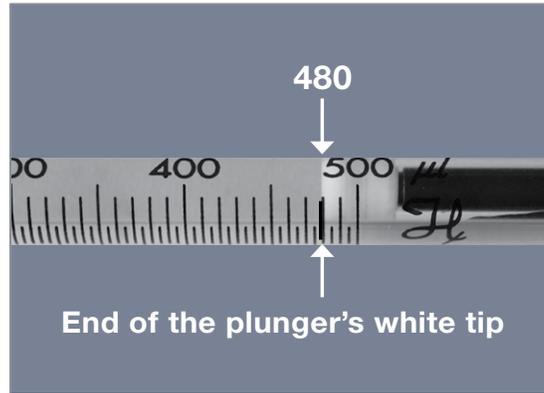
12. Fill the glass syringe with at least 500 μL of sterile saline.

Preparing the Balloon Catheter (Continued)

Instructions to Properly Prepare the Balloon Catheter for Airway Sizing



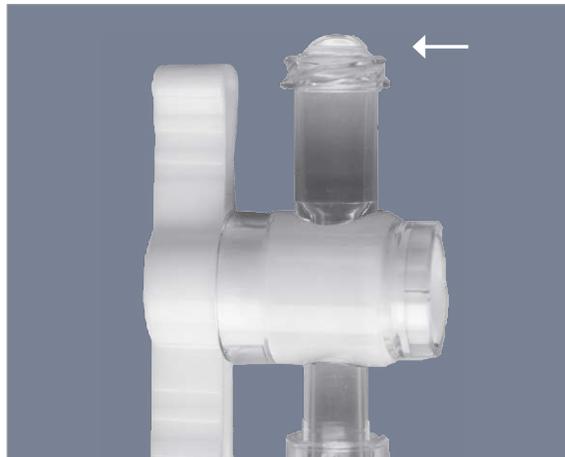
13. Remove any air bubbles from the syringe.



14. Set the 500µL syringe to the 480µL mark.

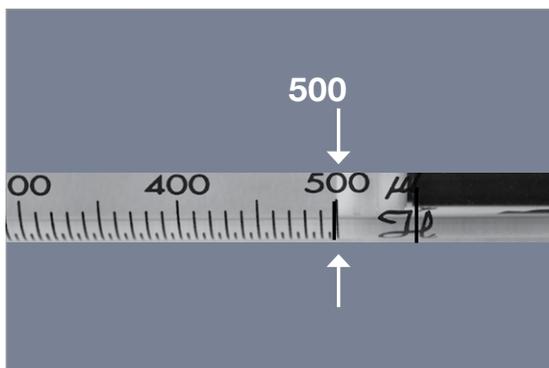
15. Set aside the glass syringe.

16. Remove the 10cc syringe from the balloon stopcock.



17. Fill the void space in the stopcock with saline from the 10cc syringe until it is full.

18. Attach the glass syringe to the stopcock port on the balloon.



19. Inflate the balloon once by fully injecting the contents of the syringe into the balloon and then slowly draw the plunger back on the glass syringe to baseline the syringe at 500µL. Ensure the balloon is fully deflated.

Note: If the syringe plunger is accidentally pulled out of the glass syringe during the procedure, do not reinsert the plunger. Repeat steps #12-15 and #17-18.

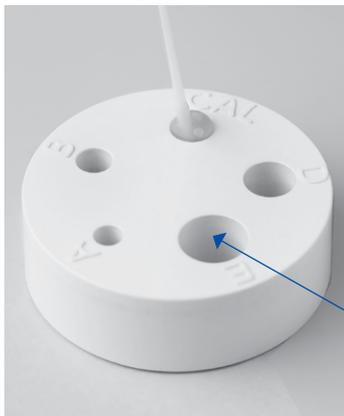
Balloon Calibration

Instructions to Properly Calibrate the Balloon for Airway Sizing

Note: Prior to “Balloon Calibration” prepare the balloon catheter according to the Instructions for Use, Airway Sizing Kit.

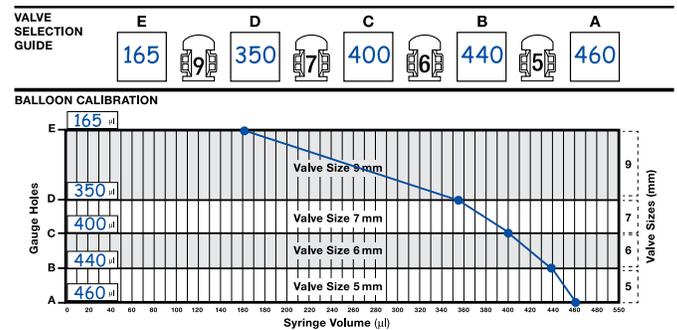


1. Wet the balloon and calibration gauge with sterile saline.
2. Place the deflated balloon in the center of the “E” gauge hole on the calibration gauge.



Slowly inflate the balloon until it just touches all sides of the “E” gauge hole and the balloon drags slightly when moved in and out of the gauge hole.

3. Read the volume at the white end of the syringe plunger.
4. Obtain the Airway Sizing Worksheet, and record the glass syringe volume next to the “E” on the Valve Selection Guide and on the Balloon Calibration sections.



5. Deflate the balloon by returning the plunger to the 500µL mark.
- 6 Repeat steps 2 through 5 for the remaining sizing gauge holes (“A”, “B”, “CAL”, and “D”).
7. Connect each of the points on the Balloon Calibration section.
8. Fully deflate the balloon by returning the plunger to the 500 µL mark. Cover the balloon with the lightproof cap and place it in a safe, clean area until ready to use in the airway.



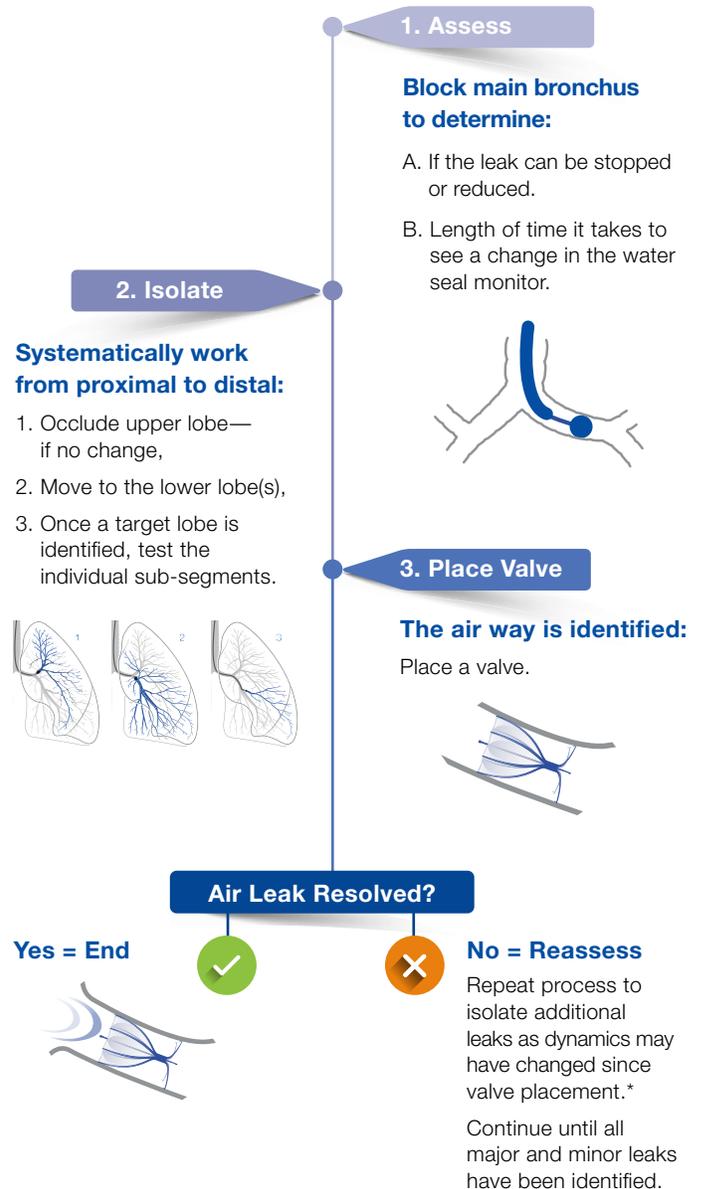
Airway Isolation Method

A Systematic Approach to Locating and Isolating Air Leaks

Key Points in Isolation¹⁻²

- The source and number of air leaks will vary considerably between patients due to changing lung dynamics
- It is recommended to begin isolation with balloon occlusion at the main bronchus, as this will provide two key pieces of information:
 - Time it takes to evacuate air from the pleural space (note: It may take up to two minutes before residual air has exited the pleural space)
 - The amount of reduction expected at the end of the procedure
- Placement of a valve, in one suspect airway, may reveal additional leaks in other parts of the lung due to:
 - Redirection of air to another contributing airway
 - Collateral ventilation
 - Bigger air leaks “masking” smaller leaks
- Once a valve has been placed, any additional leaks should be located by returning to the main bronchus to reassess, and then moving from proximal to distal airways:
 - Previously tested airways that showed no evidence of an air leak before a valve was placed may now be visualized in the water seal monitor

A systematic approach to locating and isolating air leaks is a critical step to successful treatment.



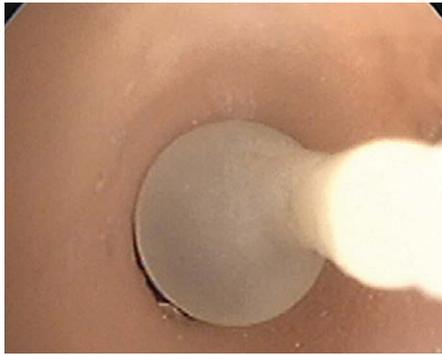
References:

1. Mahajan AK, Doeing DC, Hogarth DK. Isolation of persistent air leaks and placement of intrabronchial valves. J Thorac Cardiovasc Surg. 2013;145:626-30.
2. Dooms CA, Declauwe H, Yserbyt J, et. al. Bronchial valve treatment for pulmonary air leak after anatomical lung resection for cancer. Eur Respir J 2014; 43: 1142-1148.

*Treatment should be limited to no more than 3 segments by placing valves in segmental or sub-segmental bronchi in the target lung to avoid excessive isolation of tissue from ventilation.

Airway Sizing

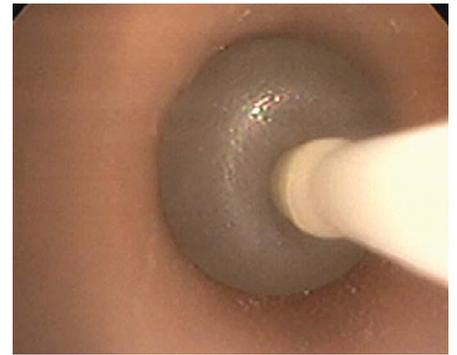
Instructions for Proper Airway Sizing Techniques to Determine the Correct Valve Size for Treatment



Under inflated balloon in airway

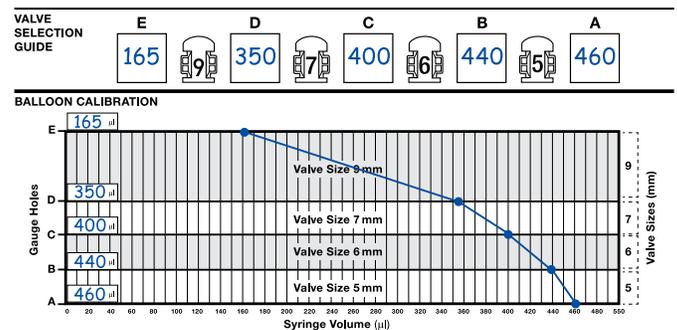


Correctly inflated balloon in airway



Over inflated balloon in airway

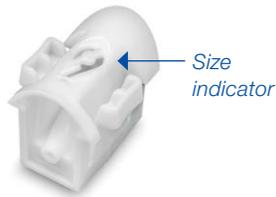
1. Insert the deflated balloon into the instrument channel of the bronchoscope. Keep the tip of the balloon catheter just inside of the distal end of the bronchoscope.
2. Maneuver the bronchoscope to the airway location. Advance the balloon into the target airway.
3. Align the widest part of the balloon with the intended valve placement site in the target airway.
4. Upon inflation, the balloon must contact the entire circumference of the target site for an entire breath cycle.
5. The volume of the balloon will serve as a reference for correlating the size of the airway with the valve size that will fit as designed.



6. Look up the syringe volume on the worksheet table and select the indicated valve.
7. Before retracting the balloon inside the bronchoscope, fully deflate the balloon by returning the plunger to the 500 μ L mark.
8. If evaluating other airway locations, repeat steps 2 through 7.

Loading Deployment Catheter

Instructions to Properly Load the Valve Cartridge into the Deployment Catheter



1. Select cartridge of the determined valve size.
2. Remove the cartridge from the packaging.
3. Remove loader and catheter from the packaging.



4. Remove the disposable shipping lock from the loader by pushing the catheter release safety slider on the loader forward, hold, and then press the catheter release button down.



5. Remove the catheter from the protective tube in the packaging. Insert the catheter into the loader until an audible "click" is heard.

Note: There is a depth gauge on the side of the loader that shows where the catheter should be grasped while inserting the catheter into the loader.



6. Pull the loader plunger all the way back. Insert the cartridge into the loader.



7. Fully push the loader plunger to load the valve into the catheter. Verify that the plunger cannot be pushed any further.



8. Release the catheter by pushing the catheter release safety slider forward, then pressing the catheter release button until an audible "click" is heard. Gently remove the catheter from the loader.

9.



Visually inspect the catheter tip to ensure that the valve is loaded correctly.

CAUTION: If any anchor tips protrude from the catheter tip, do not insert the deployment catheter into the bronchoscope. In this case, the valve must be replaced. Pull the catheter retractor handle to eject the valve for disposal. Direct the catheter tip into a container to avoid losing the ejected valve. Obtain a new cartridge and load the new valve into the deployment catheter by repeating previous steps.

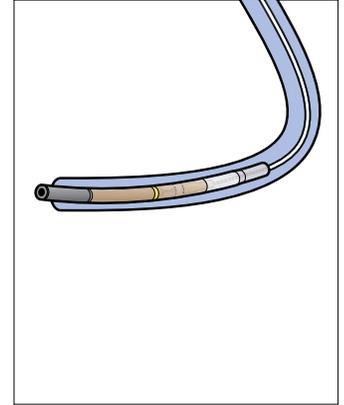
Proper Catheter Handling

Tips for How to Properly Handle the Catheter throughout the Entire Procedure



⚠ Holding the Catheter

When inserting the catheter into the bronchoscope and positioning for valve deployment, hold the proximal end of the deployment catheter below the retractor until you are ready to deploy the valve.



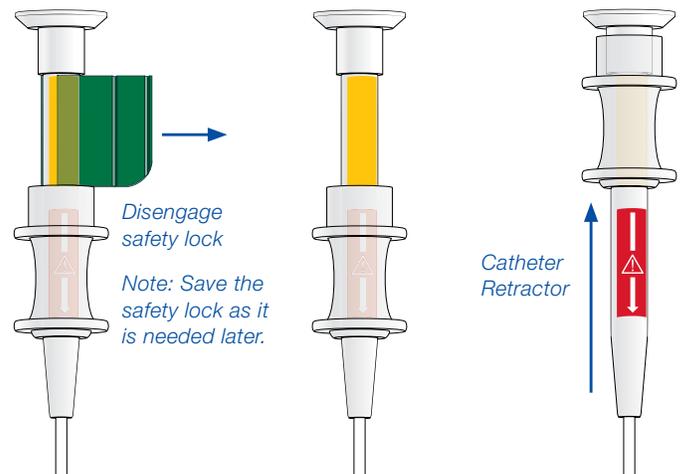
⚠ Inserting the Catheter

Applying excessive force to advance the catheter through a bend in the bronchoscope could result in damage to the deployment catheter and/or the instrument channel of the bronchoscope.



⚠ Deployment

Hold the catheter sheath at the instrument channel entry port to maintain the valve line at the target location so that the catheter does not move during deployment.



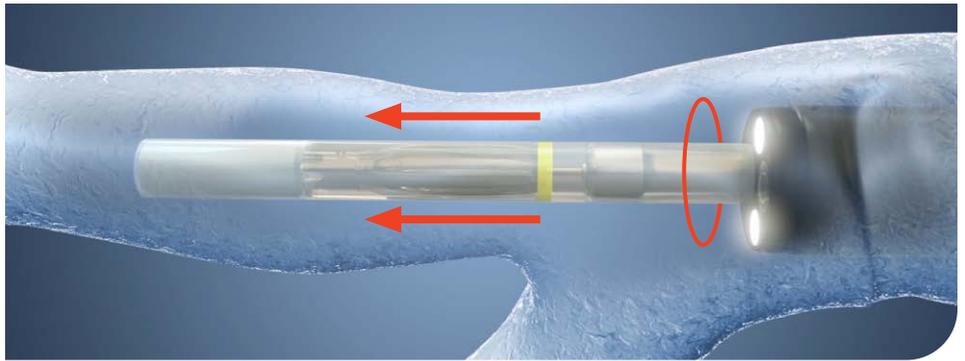
Deployment safety lock disengaged

Valve Placement

Tips for How to Properly Place the Valve into the Airway

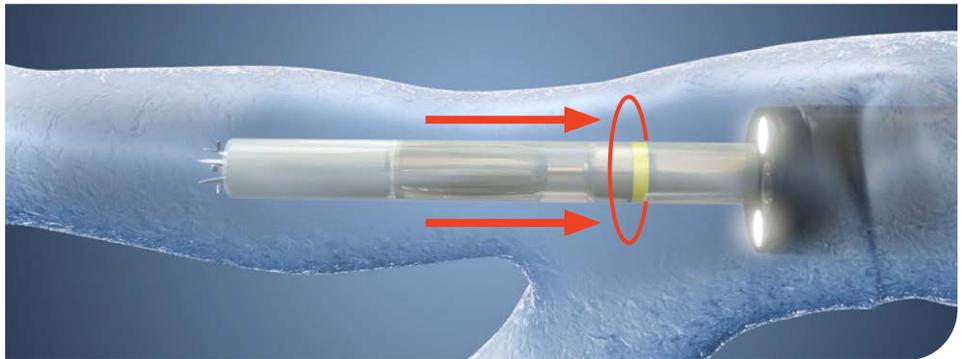
⚠ Advancing Catheter

Advance catheter **PAST** target deployment location.



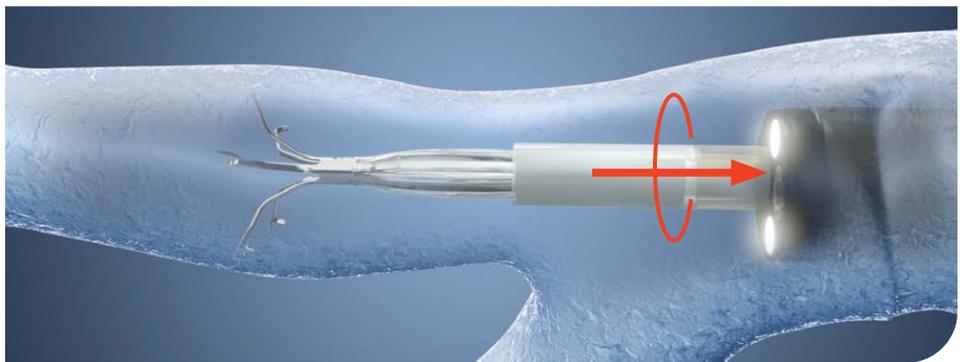
⚠ Aligning Valve

PULL catheter back to align yellow valve line with target deployment location taking valve settling into account.



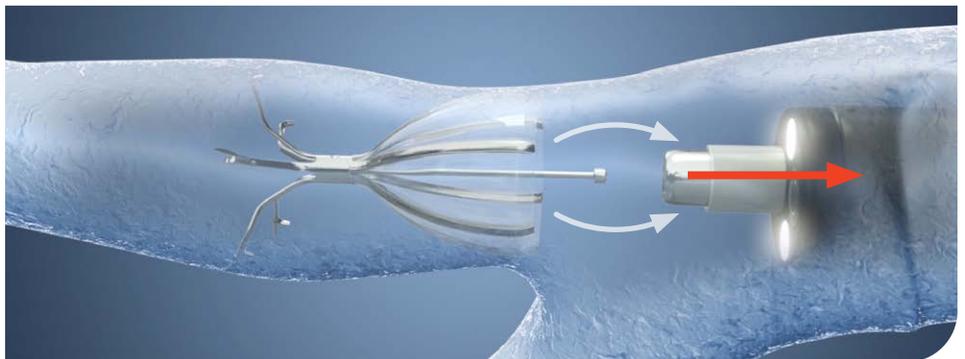
⚠ Deploy Valve

- Confirm the catheter is being held at the entry port of the bronchoscope
- Smoothly squeeze retractor handle (1–2 seconds) to unsheath the valve



⚠ Valve Position

Visually **EXAMINE** the valve for position and fit.



Removing The Spiration Valve

Instructions for How to Remove the Spiration® Valve from the Airway

1. Insert the appropriate forceps (see Table 1) through the instrument channel of the bronchoscope, directing the forceps to the target location (see Instructions for Use provided by the forceps manufacturer).
2. Grasp the removal rod shaft or removal rod tip with the appropriate forceps and gently pull the valve until it is dislodged from the airway wall. Use care to make sure that the removal rod does not get caught in the fenestration of the forceps when removing the valve (see Figure 1).

Important: Before removing the valve from the trachea, pull the valve close to the end of the bronchoscope

Forceps	Recommended Use
Cupped Biopsy	When the removal rod tip can be visualized and accessed by the biopsy forceps.
Rat-Tooth Jaw Grasping	When the removal rod shaft is being grasped.
Pediatric Biopsy	When the maneuverability of the bronchoscope is limited by standard sized forceps but the removal rod tip can be visualized and grasped.

Table 1: Forceps Selection



Figure 1: Spiration Valve Removal with Forceps

3. While still firmly holding onto the valve with the forceps, simultaneously remove the bronchoscope and the forceps from the patient.

Caution: Do not attempt to bring the whole valve through the instrument channel of the bronchoscope. This may cause damage to the bronchoscope.

Important: Do not release the valve from the forceps until the valve is completely removed from the patient. During removal, the valve struts may invert.

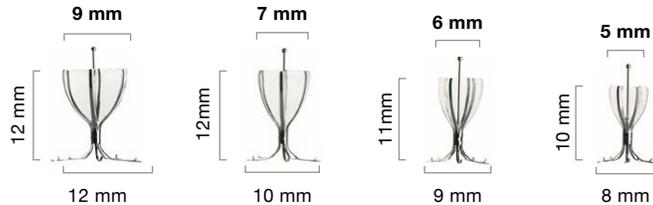
4. All valves are single use only.

Spiration® Valve System

Spiration Valves

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

Catalog Number	Valve in Cartridge
REF-HUS-V5	5 mm
REF-HUS-V6	6 mm
REF-HUS-V7	7 mm
REF-HUS-V9	9 mm



Airway Sizing Kit

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

Catalog Number	Kit Includes
REF-HUS-VSK	500 microliter glass syringe with a plunger, a calibration gauge, and a sizing worksheet Note: 1 Olympus B5-2C Disposable Balloon Catheter is shipped with each airway sizing kit

Deployment Catheter and Loader

A convenient deployment system for the delivery of multiple valves during a single patient procedure.

Catalog Number	Bronchoscope Working Channel
REF-HUS-C26N	2.6 mm or greater inner diameter

Deployment Catheter Length
1020 mm

Ancillary equipment needed for each procedure

- Flexible therapeutic bronchoscope with a working channel inner diameter of 2.6 mm or greater
- Bronchoscopy forceps appropriate for valve removal
- Standard 10cc sterile syringe with Luer-lock
- Sterile saline (approximately 15–30cc used per procedure)
- A balloon catheter that inflates to 13 mm or larger (for balloon occlusion only)

Note: Products are supplied sterile

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