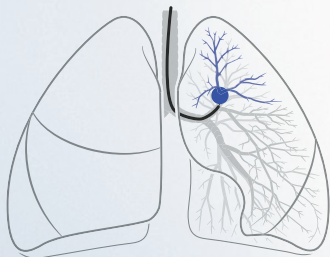
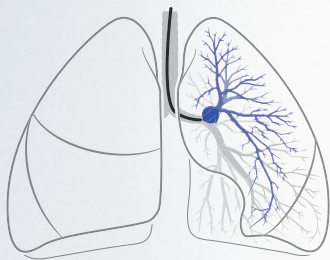
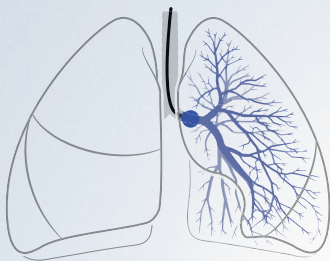


Spiration Valve System

Airway Isolation Method for the Treatment of Air Leaks



Introduction

Air Leak Isolation is a critical step to successful treatment with Spiration Valves. This brochure describes the Spiration Valve Isolation Airway Method, a systematic approach using balloon occlusion, to help physicians assess and isolate airways contributing to an air leak.

Assessing an Air Leak^{1,2}

- A chest drainage system is the best tool to monitor and assess changes in an air leak, seen by changes in the water seal monitor
- Tidal volume is another tool that can help identify airways contributing to an air leak, so talk to your anesthesiologist
- Leaks in the chest drainage system can diminish your ability to assess leaks, promptly check connection points if you are unable to reduce a leak

Key Points in Isolation^{1,2}

- 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 10 breaths 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

Treatment of an Air Leak^{1,2}

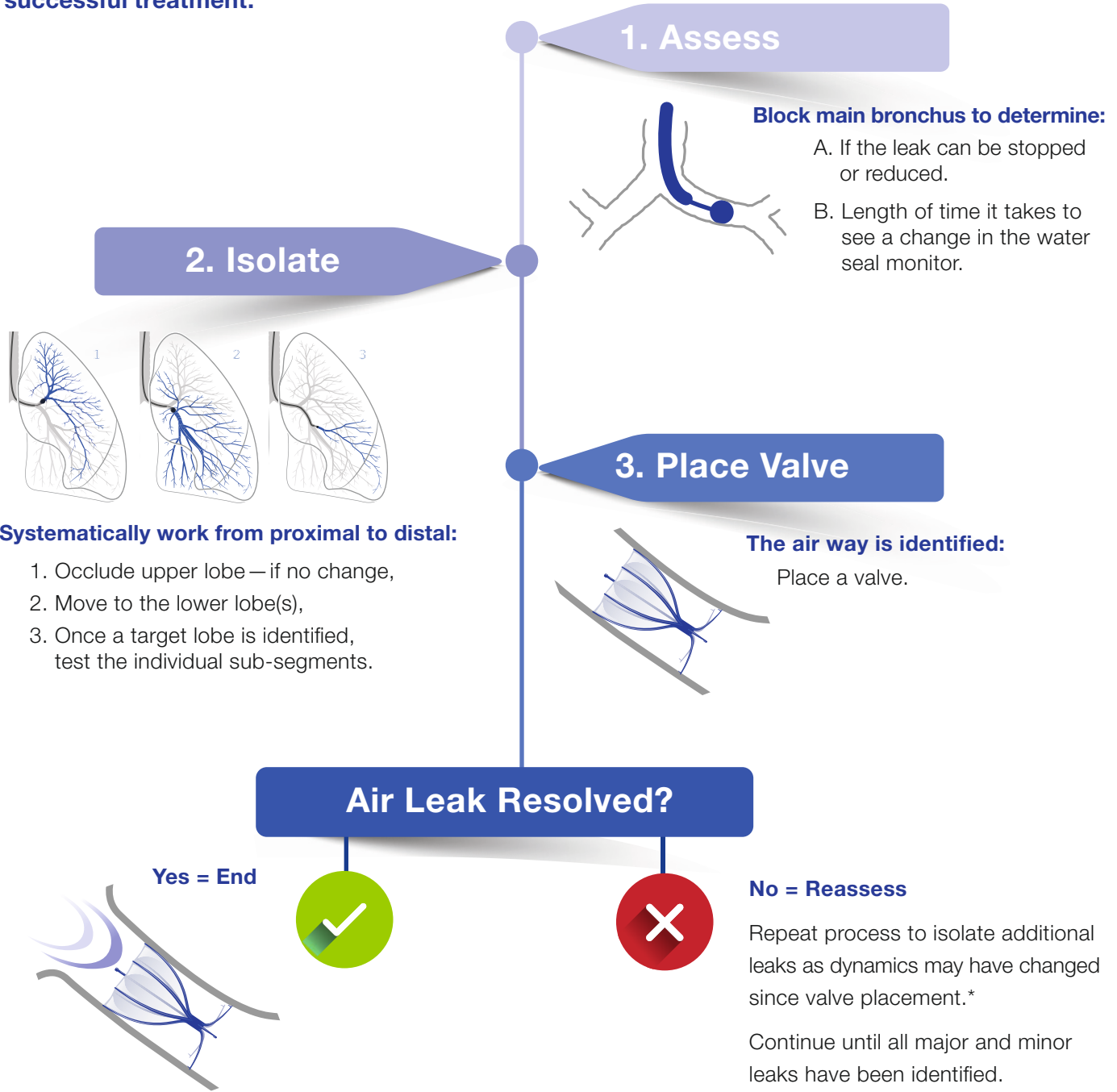
- Treatment of an air leak may require placement of multiple valves
- Complete cessation may not be achievable, or necessary, for successful treatment of an air leak
- A substantial reduction in an air leak using valves may accelerate the resolution of an air leak, as the progression through the clinical stages of the air leak is improved

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.

Spiration Valve Airway Isolation Method^{1,2}

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



*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.

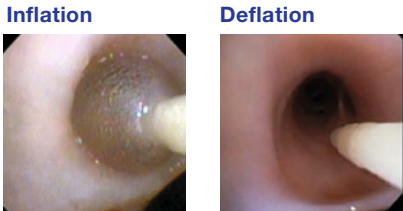
The Spiration Valve System is a minimally invasive device for the treatment of specific post-surgical air leaks.

The Spiration Valve’s unique design allows it to limit distal airflow which may accelerate the resolution of an air leak.^{1,2}

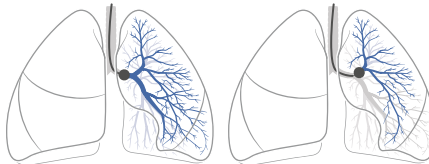


CASE EXAMPLE:
52 year old male with an air leak on the left side

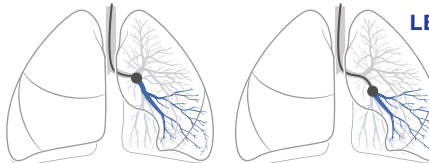
1. Assess	Occlusion of the MAIN bronchus
Action	Occlude the left bronchus
Results	On inflation: 5–7 breaths to see visible reduction in bubbles 10 breaths for bubbles to stop completely
Conclusion	On deflation: 2 breaths for bubbles to reappear There is a leak on the left side



2. Isolate	Occlusion of the LUL
Action	Occlude the upper lobe on the left side
Results	On inflation: 5–7 breaths for a visible reduction in bubbles Note: no complete loss of bubbles
Conclusion	There is a leak on the left side



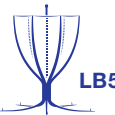
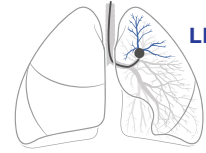
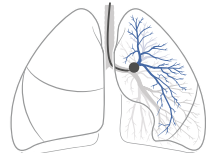
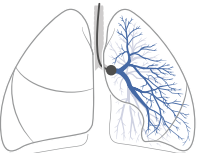
	Occlusion of the LLL
Action	Occlude the main bronchus of the LLL
Results	On inflation: 5–7 breaths for a visible reduction in bubbles Note: no complete loss of bubbles
Conclusion	There is a leak in the LLL
Results	LB8 reduced air leak



4. Place Valve	
Action	Place valve(s) in LB8
Results	Reduction in leak
Conclusion	There are more airways contributing to leak



Reassess	Repeat as dynamics may have changed since valve placement
1. Assess	Occlusion of the MAIN bronchus
Action	Occlude the left main bronchus
Results	On inflation: 2–3 breaths for bubbles to stop completely
Conclusion	A smaller leak remains on the left side
2. Isolate	Occlusion of the LUL
Action	Occlude the upper lobe on the left side
Results	On inflation: 2–3 breaths for bubbles to stop completely
Conclusion	There is a small leak in the LUL
Action	Occlude to identify the segmental or sub-segmental airway(s) contributing to the leak
Results	LB5 stopped air leak
4. Place Valve	
Action	Place valve in LB5
Results	Air leak stops
Conclusion	There are more airways contributing to leak



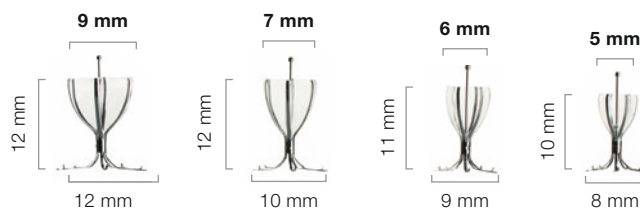
Lesson: The smaller leak in the left lingular segment had originally been masked by the larger leak in the lower lobe. When the air leak was stopped in the lower lobe, the LB5 was the only airway communicating with the pleural space and became visible in water seal monitor.

Spiration Valve System

Ordering Information

Spiration Valves

Article Name	Article Number	Valve in Cartridge
IBV-V5	N3495330	5 mm
IBV-V6	N3495430	6 mm
IBV-V7	N3495530	7 mm
IBV-V9	N5381200	9 mm



Airway Sizing Kit

Article Name	Article Number	Article Description
IBV-VSK	N5534500	Kit includes 500 microliter glass syringe with a plunger, a calibration gauge, and a sizing worksheet
B5-2C	N3530530	Balloon to be used in combination with airway sizing kit

Deployment Catheter and Loader

Article Name	Article Number	Min. Working Channel Ø	Working Length
IBV-C26N	N3495330	2.6 mm	1020 mm
IBV-C20	N3495430	2.0 mm	1140 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 10 cc sterile syringe with Luer-lock
- Sterile saline (approximately 15–30 cc 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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As medical knowledge is constantly growing, technical modifications or changes of the product design, product specifications, accessories and service offerings may be required.