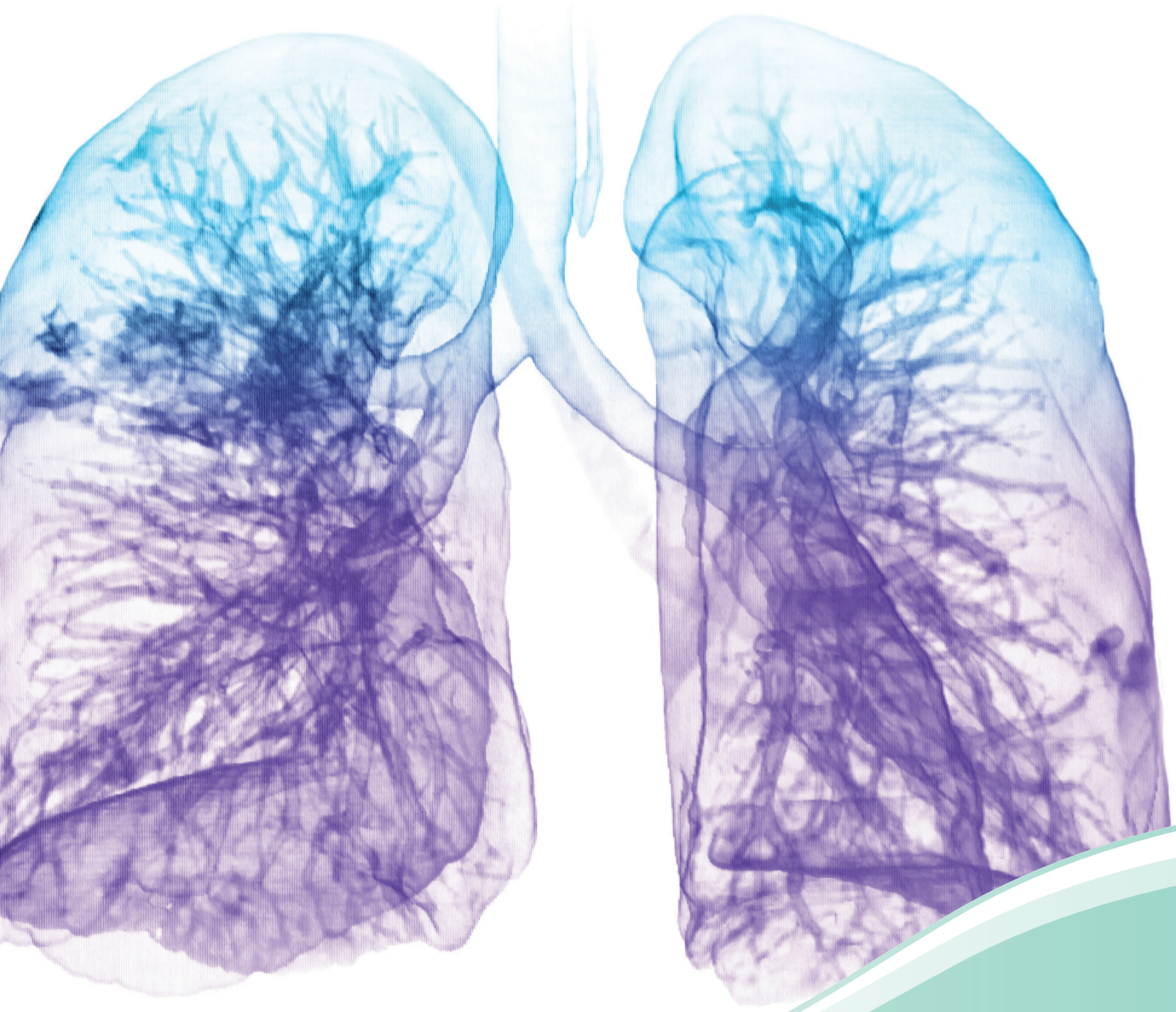
pulmonX®

The Zephyr® Valve

An Effective Solution for Persistent Air Leaks



zephyr® valve

The Problem with Persistent Air Leaks

A persistent air leak (PAL) is defined as an air leak (air escaping from the lung into the pleural cavity) that lasts for greater than 5 to 7 days.

Persistent air leaks are associated with significant morbidity and potentially lengthy hospital stays[1–3] negatively impacting healthcare costs.[4,5] They can also contribute to the development of complications such as pneumonia, atelectasis, empyema, prolonged chest tube duration, hypoventilation, and higher utilization of resources.[6–8]

Common causes of persistent air leaks include spontaneous pneumothorax from underlying lung disease (secondary spontaneous pneumothorax), pulmonary infections, lung nodules, complications of mechanical ventilation, following chest trauma or after pulmonary surgery.

Spontaneous pneumothorax occur more frequently in patients with COPD.[9]

The Zephyr® Valve — How it Works

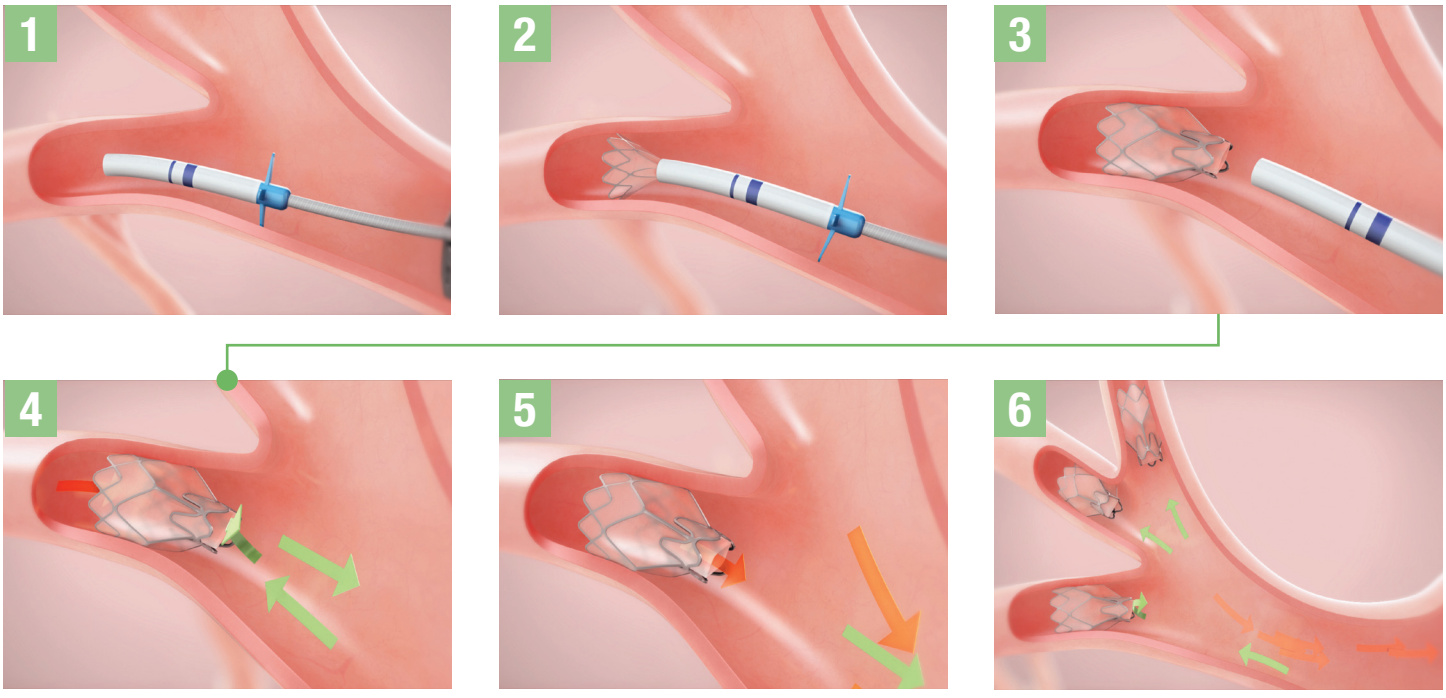
The Zephyr Valve presents an elegant and effective solution for managing persistent air leaks.

The Zephyr Valve(s) are designed to be permanent implants, but can be readily removed. The Zephyr Valve can be placed to occlude a section of the lung in order to block inspiratory air flow from entering the pleural cavity through the fistula while allowing mucus secretions to pass through the valve.

The valve remains closed during inhalation, preventing airflow to the parenchyma causing the air leak and consequently stopping the abnormal communication between the bronchial tree and the pleural space via the fistula. The affected lobe can then expand more fully, allowing apposition of the visceral and parietal pleural surfaces and enabling the lung to heal and seal the fistula.[10]

Zephyr Valves are placed during bronchoscopy under either conscious sedation or general anesthesia. This enables a minimally-invasive solution for patients where more aggressive surgical options are neither desirable nor viable options.

Placing Zephyr Valves



>20,000 patients treated globally for emphysema and airleak

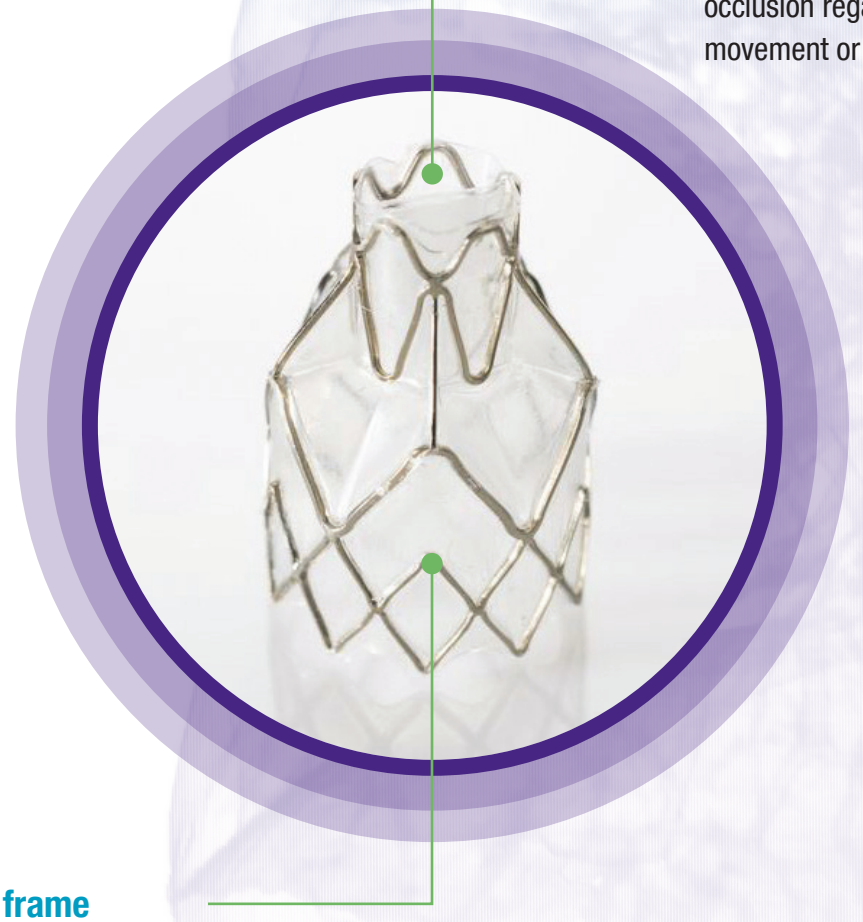
The Innovative Zephyr® Valve Design

The Zephyr Endobronchial Valve is a one-way, silicone, duckbill valve mounted in a self-expanding nitinol/silicon retainer.

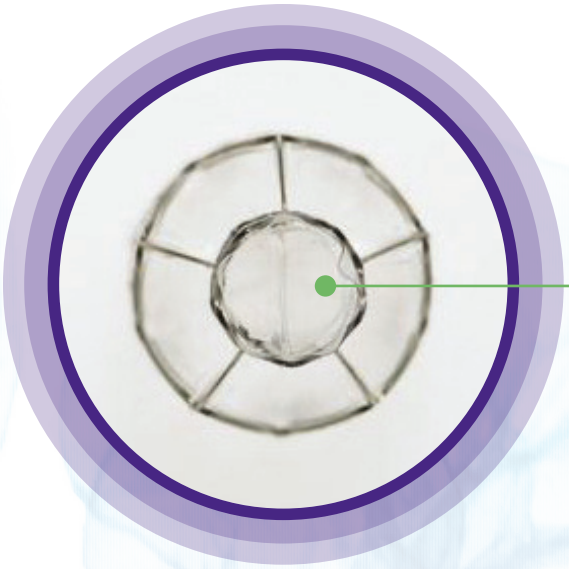
The various valve sizes combined with the innovative flexible retainer housing allows the valve to dynamically conform to a variety of airway shapes and sizes.

Design Features of the Zephyr Valve

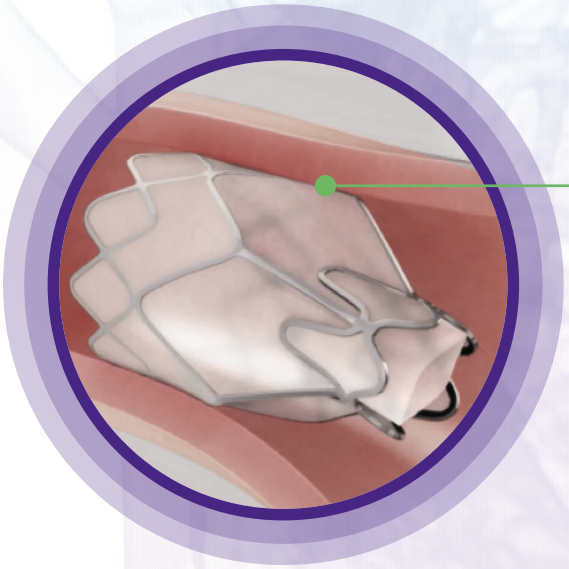
Silicone duck-bill is the first and only valve to function **independently of the airway wall** allowing for effective occlusion regardless of the airway movement or shape



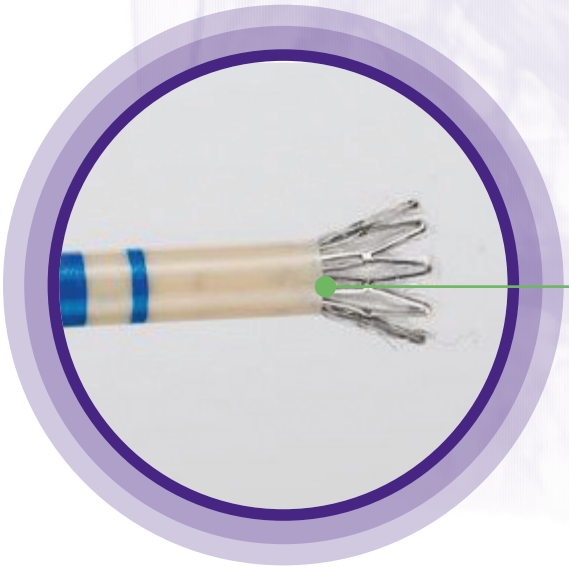
Self-expanding **Nitinol frame** exerts radial force against the airway walls, which allows for **simple sizing and treatment** of a wide range of airways with a single valve diameter size



Fatigue-resistant design to **prevent fractures and fragmentation**



Anchorless Fixation allows for **secure placement** (<1% migration[1]) and **atraumatic removal**



Allows **partial deployment method** for **easy and accurate placement**

Clinical Evidence

The success of Zephyr® Valves to manage persistent air leaks has been reported in multiple case series and case reports.

Travaline J et al.[11]

Case series of 40 patients with persistent air leaks of different etiologies treated with the Zephyr Valve.

- Immediate improvement of the air leak in 93% of patients.
- Complete cessation of the air leak in 48% of the patients.
- There were no Zephyr Valve related adverse events.

Firlinger L et al.[12]

Case series of 16 patients with persistent air leak (>7 days) of various etiologies who had not responded to standard treatment.

- Zephyr Valves placed in 13 patients where source of air leak was clearly identified.
- Significant reduction of the air leak in 77% (10/13) of patients; and
- Immediate mean decrease in air flow from 871±551 ml/min to 61±72 mL/min.
- No adverse events related to the valve implants were reported at follow-up.

Fiorelli A et al. [13]

Case series including five patients with persistent air-leaks refractory to standard treatment (duration 25.8±9.8 days); etiology of the air leaks was pneumothorax or complication of thoracic surgery.

- Air leaks stopped in the first 24 hours after the procedure in 3 patients and at 3 and 5 days later, respectively, in the remaining two.
- The mean time to stopping of air leak was 2.2±1.7 days.

Fiorelli A et al.[14]

Assessed safety and efficacy of Zephyr Valves in the management of persistent air leaks for alveolar pleural fistula in a retrospective, multicenter study of 67 consecutive patients.

Complete resolution of the air leak was achieved in 59 (88%) patients. An additional 6 patients (9%) had a reduction in the air leak and 2 patients (2%) did not experience any benefit.

Comparison of data before and after valve treatment showed significant reduction of the following:

	Before (days)	After (days)
Air leak duration (p<0.0001)	16.2±8.8	5.0±1.7
Chest tube removal (p<0.0001)	16.2±8.8	7.3±2.7
Length of hospital stay (LOS) (p=0.0004)	16.2±8.8	9.7±2.8

- Only one patient presented with hemoptysis that resolved with valve removal.
- The valves were removed in 55/67 (82%) patients after a mean time of 134±83 days from the implant using flexible bronchoscopy.
- No complications or recurrence of air leaks were observed after valve removal.

The Zephyr Valve is also approved for the treatment of hyperinflation associated with severe emphysema. The safety and efficacy of the Zephyr Valves was demonstrated in four randomized clinical trials with significant improvement over patients treated with optimal medical management (standard of care) in lung function, exercise capacity, and quality of life compared with alone.[15–18]

The Zephyr® Valve for PAL Work Flow

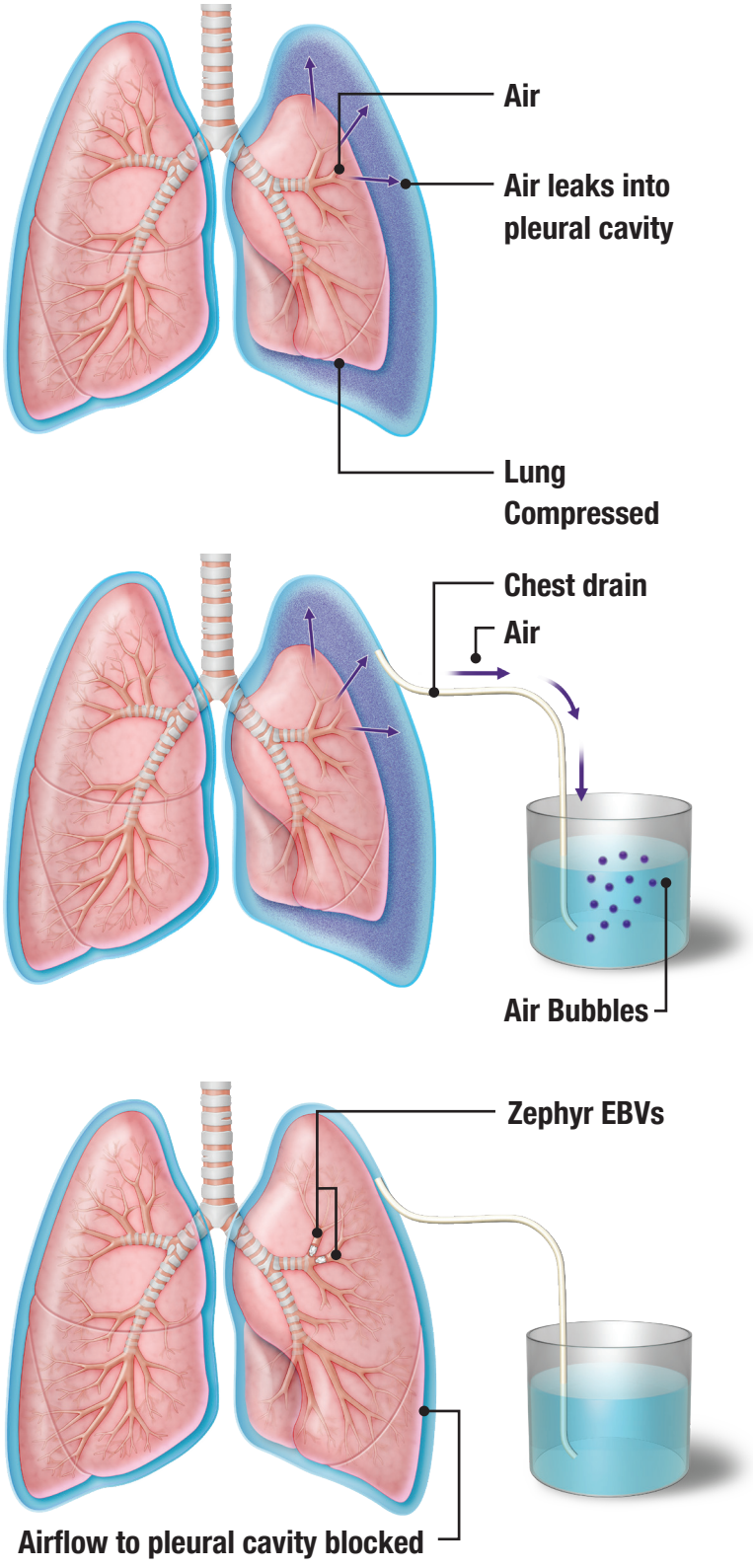
1. Isolate the source of the air leak. The most common method for identifying the target lobe and isolating the leak is sequential balloon occlusion of segmental airways, moving proximally to distally.

2. Place Zephyr Valve(s) in the airway segments identified to reduce the air leak. After placement of the first valve, the chest drain should be observed for four to five ventilatory cycles to assess any changes in the amount of air leak.

3. After completion of Zephyr Valve placement, observe the chest drain to confirm the cessation of the leak.

4. Remove chest drain when cessation of the air leak has been confirmed and chest drain is no longer required.

5. Remove implanted Zephyr Valves based on clinical assessment (if deemed necessary).



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International Brief Statement: The Zephyr® Endobronchial Valve is an implantable bronchial valve intended to control airflow in order to improve lung functions in patients with hyperinflation associated with severe emphysema and/or to reduce air leaks. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; Evidence of active pulmonary infection; Patients with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); Patients with known allergies to silicone; Patients who have not quit smoking. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.

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