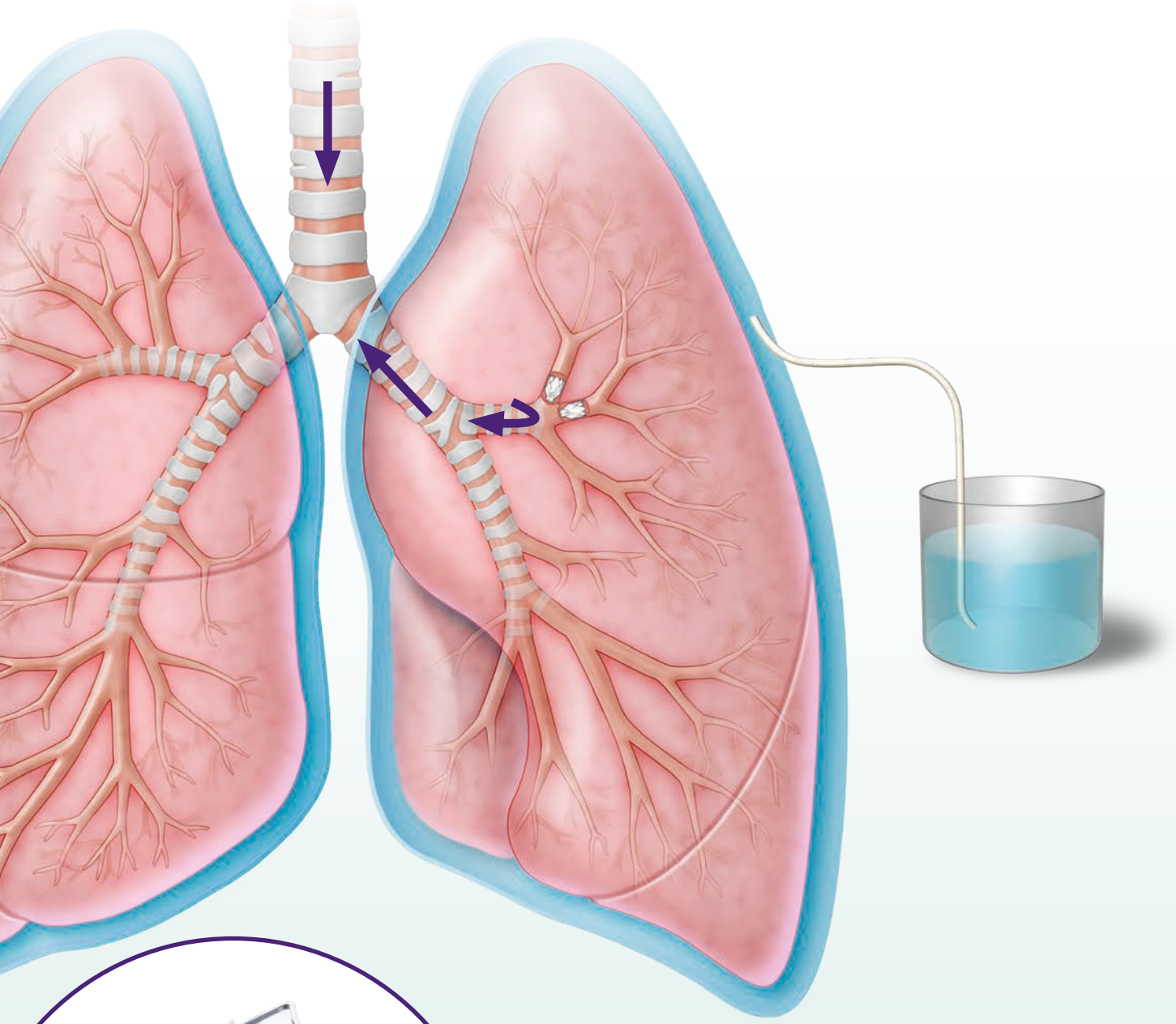
The Zephyr® Valve



Treatment for
Persistent Air Leaks

zephyr®
by pulmonx

Knowledge Page

What is a persistent air leak?

An air leak within the lung is defined as air escaping from the lung into the pleural cavity, also known as a pneumothorax. It is caused by an alveolar-pleural fistula; a communication between the alveoli and the pleural space. This also can occur between a bronchus and the pleura, a broncho-pleural fistula.

If air continues to pass through the fistula and into the pleural space, it can become large enough to inhibit lung expansion, and require treatment with a chest drain.[1]

A persistent air leak is defined as one which lasts for greater than 5 to 7 days.

What conditions cause a persistent air leak?

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.

What is the impact ?

Persistent air leaks are associated with significant morbidity and potentially lengthy hospital stays[2-4] negatively impacting healthcare costs[5,6]. They can also contribute to the development of complications such as pneumonia, atelectasis, empyema, prolonged chest tube duration, hypoventilation, and higher utilization of resources.[5–8]

How are persistent air leaks treated?

At present there are no algorithms or set guidelines in the management of persistent air leaks. There are several techniques which are popular and often are used based on the clinical judgment and experience of the thoracic surgeon.[9] These can be split into conservative, minimally invasive and surgical treatment options.

Conservative

Chest drain insertion: with digital or wall suction, and underwater sealed drain system.

Minimally Invasive

Autologous blood pleurodesis via a bronchoscope or chest drain.
Bronchoscopic insertion of Zephyr® Endobronchial Valves.

Surgical

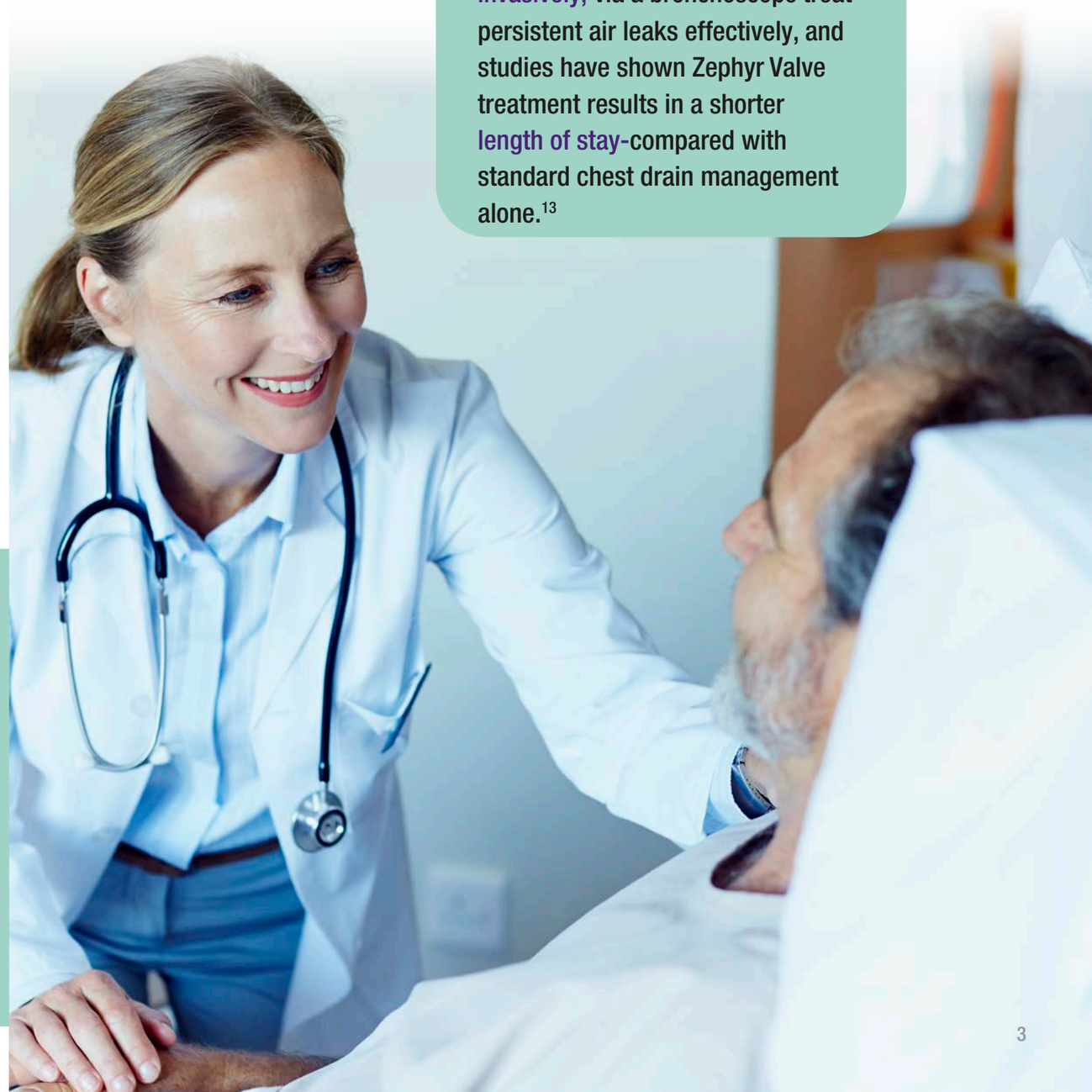
Video assisted thoracoscopic surgery (VATS) stapling with pleurodesis.

Treatment for Persistent Air Leaks

The most commonly reported cause of persistent air leaks is a complication of lung surgery. **It can double the length of stay from 7 to 14 days.**[10] More recently persistent air leaks have been a reported complication in ventilated patients with COVID-19.[11]

Invasive healthcare interventions can negatively impact patients´pain and quality of life post procedure.[12]

Zephyr® Valves, placed minimally invasively, via a bronchoscope treat persistent air leaks effectively, and studies have shown Zephyr Valve treatment results in a shorter length of stay-compared with standard chest drain management alone.[13]

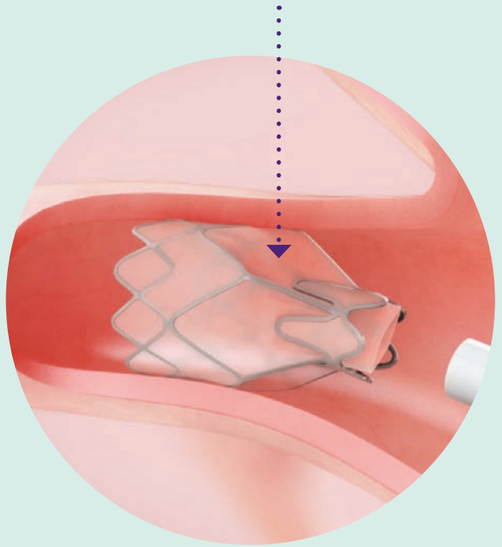


Design Features of the Zephyr® Valve

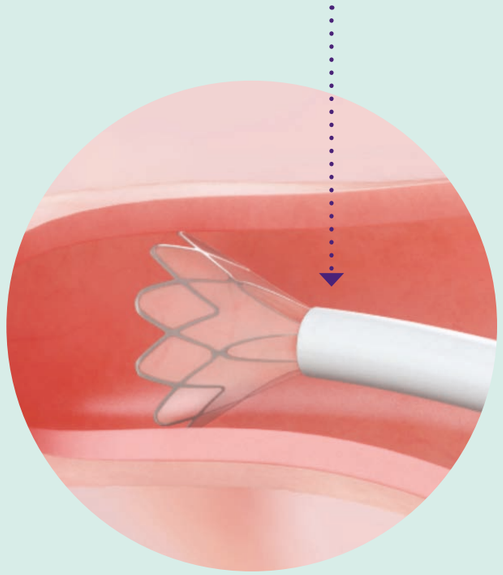
A self expanding **nitinol frame** exerts radial force against the airway walls, which allows for **simple sizing and treatment** of a wide range of airways with a single valve diameters.

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.

Anchorless fixation allows for **secure placement** (<1% migration[14]) and **atraumatic removal**



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

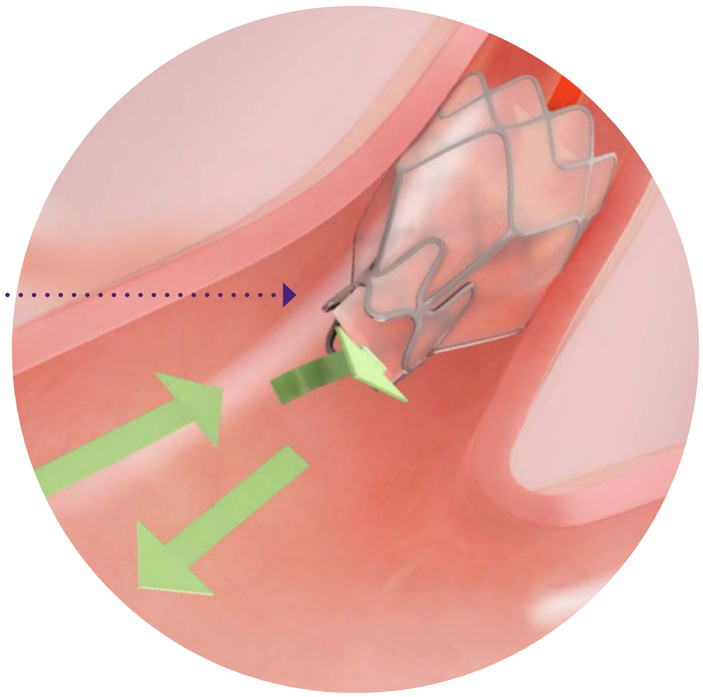


How the Zephyr Valve can treat persistent air leaks:

Zephyr Valves are placed via a bronchoscope under either conscious sedation or general anesthesia.[14]

Positioned at the subsegmental or lobar bronchi **the silicone duckbill valve** blocks the flow of air to the location of the fistula causing the air leak. This allows the fistula to heal and the pneumothorax to resolve.

One-way silicone duckbill valve



Zephyr Valves placed in the lobar or subsegmental bronchi block the flow of air to the leak allowing the pneumothorax to resolve.

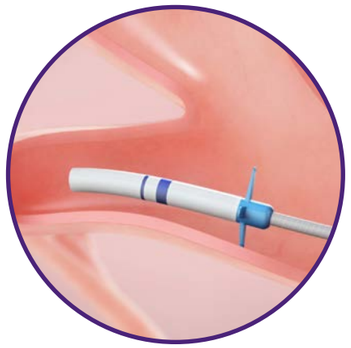
Fiorelli A et al. demonstrated resolution of 88% of the air leaks within 5.0 +/- 1.7 days.

The Procedure

Systematic balloon occlusion — **Sizing** — **Placing the Zephyr Valves** — **Valve placement in all contributing airways** — **Chest drain removal**

Systematic balloon occlusion of segmental airways, moving proximally to distally as described by Mahjan et al (2014)[16]

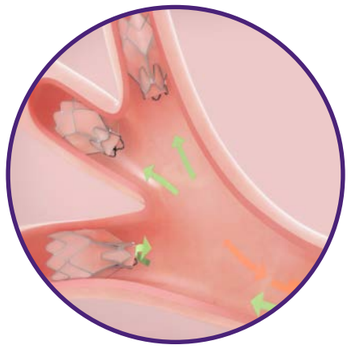
DETAILS IN APPENDIX 1



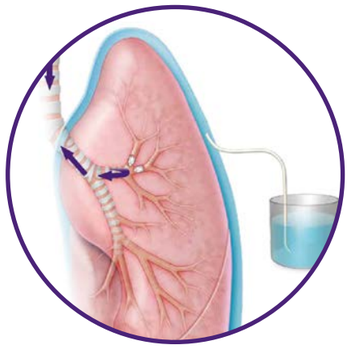
Sizing of the airway to allow for correct valve selection is done using sizing wings on the delivery catheter.

There are four different sizes available. 4 mm to 5.5 mm in diameter.

Zephyr Valves are implanted using a bronchoscope, via a delivery catheter. The Zephyr Valve can be removed and retracted through the bronchoscope if needed.



After the placement of the first valve, observe the flow from the chest drain for 4-5 ventilatory cycles to assess any changes in the amount of air leak. Valves may be needed in additional segments.



Remove chest drain when cessation of the air leak has been confirmed and chest drain is no longer required. Remove implanted valves after air leak has fully resolved. This is usually done at or beyond 6 weeks after cessation of air leak.[15]

Clinical Evidence

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

Ficial et al. 2023[16]

This case series presents the feasibility of endobronchial valve placement in severe parenchymal lung disease with PAL in patients requiring Extracorporeal Membrane Oxygenation (ECMO) for COVID-19 ARDS.

10 ECMO for COVID-19 patients developed PALs, which were successfully treated with bronchoscopic EBV placement.

The average duration of air leaks before EBV deployment was 18 days. **EBV placement resulted in the immediate cessation of air leaks** in all patients with no peri-procedural complications. Weaning of ECMO, successful ventilator recruitment and removal of pleural drains were subsequently possible.

A total of 80% of patients survived to hospital discharge and follow-up. Two patients died from multi-organ failure unrelated to EBV use.

Travaline J et al. Chest 2009[17]

- 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.

Fiorelli A et al. 2018

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.[13]

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

- 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.

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

Firlinger L et al. 2013[18]

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.

Case Studies

A case from Lawrence Okiror, Guy's and St Thomas' Hospital, UK

Post-COVID Air Leak Resolved with Zephyr® Valves

Presentation

- 27-year-old female, 6 weeks postpartum, contracted COVID-19 during late pregnancy requiring emergency C-section
- Significant surgical emphysema, tracheal tear, and bilateral persistent pneumothorax
- Unable to ventilate due to respiratory failure, required ECMO
- Unable to wean off ECMO as pneumothorax continued

Pre-Treatment

Symptoms: Surgical emphysema, tracheal tear, bilateral pneumothorax, respiratory failure worsened post-delivery, on ECMO for 4 weeks

Nature of leak: Persistent air leak, high volume

Management of leak pre-treatment: Drain inserted, ventilation, and ECMO

Duration of air leak prior to valve treatment: 5 weeks

Location where patient managed: Intensive Care Unit

Zephry Valve Treatment

Size of the air leak: 2 liters/min

Treatment details: Chartis® System balloon used to identify location of leak, one Zephyr Valve placed to occlude right middle lobe, 1x Zephyr EBV 5.5-LP

Treatment recovery and complications: Immediate cessation of air leak, no post-procedural complications, repatriated to local treating center after 9 days.

Results

Was the leak stopped?
Yes

Symptoms improvements?
Yes

How long before drain removed?
2 days on achieving complete resolution of air leak

Conclusion

Zephyr Valves successfully stopped a persistent air leak (>5 weeks) in a post-COVID-19 patient with complete resolution and removal of chest tube after 2 days.

Prof. Phan Nguyen, Thoracic Physician - Royal Adelaide Hospital, AUS

Case Studies

Secondary Spontaneous Pneumothorax Persistent 2 l/min

Presentation

- 57-year-old male (history of smoking)
- Admitted to hospital with right sided **secondary spontaneous pneumothorax** on background of severe COPD
- Initially treated with intercostal drain; however, the air leak was persistent and repeat X-ray showed poor re-expansion
- Drain bubbled persistently and patient's respiratory function continued to decline
- Transferred to Cardiothoracic team for surgical intervention but considered poor surgical candidate for video assisted thoracoscopic surgery (VATS); talc pleurodesis via the drain failed
- Endobronchial valves to isolate the air leak was discussed with Thoracic Medicine
- High resolution CT scan performed which confirmed severe bullous disease, collapsed lung, and sub-cutaneous emphysema

Pre-Treatment

Symptoms: Worsening shortness of breath

Nature of leak: Significant persistent air leak, continuous bubbling on drain

Management of leak pre-treatment: Drain inserted, considered for surgical intervention, talc pleurodesis

Duration of air leak prior to valve treatment: 21 days

Location where patient managed: Thoracic Medicine, endobronchial valves inserted in procedure suite

Zephyr Treatment

Size of the air leak: On measurement with the Rocket digital drainage system there was persistent bubbling with flow >2 L/min

Treatment details: Chartis® balloon was used to identify the air leak in the right upper lobe after 1 min of occlusion; in total, three endobronchial valves were inserted in to RB1 (5.5), RB2 (4.0), and RB3 (5.5); all standard lengths

Treatment recovery and complications: None, leak reduced significantly and the drain was removed 48 hours post-procedure with no post-procedural complications

Post-operative management: Follow-up lung function testing showed RV and TLC within normal ranges suggesting Lung Volume Reduction may have been achieved

Results

Was the leak stopped?
Yes

Symptoms improvements?
Yes

How long before drain removed?
2 days post-procedure

Conclusion

Zephyr® Valves successfully stopped a persistent air leak (>3 weeks) in a patient with pneumothorax with complete resolution and removal of chest tube after 2 days.

A case from Mr Aiman Alzetani, Southampton General Hospital, UK

Case Studies

Post-COVID Air Leak Resolution with Zephyr® Valves

Presentation

- 49 Year old male, contracted Covid-19 in January 2021
- Admitted to ICU for respiratory support, but deteriorated and required ventilation
- Ventilator weaning failed, therefore a tracheostomy tube was fitted
- Patient developed a pneumothorax in late February 2021
- Initially treated using an intercostal drain but the air leak was persistent with no re-expansion of the lung and worsening respiratory function
- Not considered for ECMO due to prolonged ventilation. Following a review and CT scan was considered suitable for Zephyr® Valve placement to exclude air leak from the right upper lobe

Pre-Treatment

Symptoms: Worsening respiratory failure

Nature of leak: Persistent air leak, high volume

Management of leak pre-treatment: Drain inserted

Duration of air leak prior to valve treatment: 5 weeks

Location where patient managed: Intensive Care Unit

Zephyr Treatment

Size of the air leak: 2 liters/min

Treatment details: Chartis® System Balloon used to identify location of leak, three Zephyr Valve placed to occlude right middle lobe, 2x Zephyr Valve 5.5 LP, and 1 x Zephyr Valve 5.5 standard

Treatment recovery and complications: Immediate cessation of air leak, no post-procedural complications

Results

Was the leak stopped?
Yes

Symptoms improvements?
Yes

How long before drain removed?
5 days on achieving complete resolution of air leak (and to enable safe transfer back to original hospital)

Conclusion

Zephyr Valves successfully stopped a persistent air leak (>5 weeks) in a post-COVID-19 patient with complete resolution and removal of chest tube after 5 days.

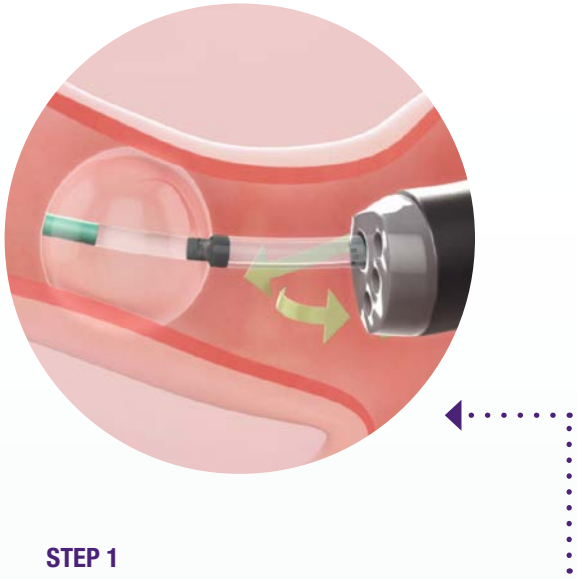
Appendix 1

Systematic Balloon Occlusion

Accurately identifying the airways which lead to the air leak/ fistula is vital to ensure an effective outcome, frequently more than one airway is involved. This is achieved by systematic balloon occlusion of segmental airways, moving proximally to distally.[15]

A summary of the technique described by Mahjan et al (2014)[15] is detailed below.

1. Using a balloon catheter, occlude each main stem bronchus to identify if the leak can be stopped, by observing the chest drain activity. During each occlusion, it is recommended to wait several respiratory cycles (roughly 5 breaths) to determine the effect of airway occlusion on the air leak.
2. Proceed distally and occlude the whole upper lobe. If no change occurs in the degree of the air leak, isolate the lower lobe (and if on the right, the middle lobe at the same time).
3. Once the target lobe is identified, test each individual segment. This approach allows the detection of complex air leaks involving more than one segment and/or more than one lobe.



STEP 1

Systematic Balloon Occlusion

Systematic balloon occlusion of segmental airways, moving proximally to distally as described by Mahjan et al (2014)

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EUR-EN-2180-v1 Persistent Air Leaks Brochure

zephyr®
by pulmonx

Important safety information: 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.