US FDA approves first ever novel device named Zephyr Endobronchial Valve for treating breathing difficulty from severe Emphysema approved on 29th June 2018
About the Pulmonx and Zephyr Endobronchial Valve

The Zephyr® Endobronchial Valve is a lung volume reduction therapy that has been proven to significantly improve lung function, exercise capacity and quality of life for emphysema patients across four randomized, controlled clinical trials and in 12,000 patients worldwide. In combination with its diagnostic companion products, it uniquely offers a prospectively proven method for predicting responders. It is also designed to be removable, preserving future treatment options for patients.

- The UK’s National Institute for Health and Care Excellence (NICE) has updated its guidance for Endobronchial valves and now considers current evidence sufficient to support routine use. The change in NICE guidance is based on safety and efficacy data from multiple randomized clinical trials evaluating the Zephyr EBV, which has demonstrated clinical and quality of life benefits, and long-term safety for eligible patients.
- It significantly **improve the lung function, exercise tolerance and quality of life for patients receiving treatment.**
- The Zephyr Endobronchial Valve is removable, preserving future therapy options.

[https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm612271.htm/](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm612271.htm/)
Zephyr Endobronchial Valve (2)

Product information

- **Adverse Events:** Death, air Leak (pneumothorax), pneumonia, Worsening of emphysema, Coughing up blood, Shortness of breath and Chest pain.
- The Zephyr Valve device is contraindicated for patients with active lung infections; those who are allergic to Nitinol, Nickel, Titanium or Silicone; active smokers.
- **How It works:**
  - Using a standard bronchoscope, Zephyr valves are delivered to target airways using a flexible delivery catheter
  - Once implanted, the one-way valve prevents airflow into the diseased region, while allowing trapped air and fluids to escape
  - Reducing the volume of the diseased region may allow healthier regions to expand and function more efficiently

Mechanism of action

Using a flexible bronchoscope, a doctor places Zephyr Valves, similar in size to pencil erasers, into the diseased areas of the lung airways during a procedure in a hospital setting. Design of the device is intended to prevent air from entering the damaged parts of the lung and allow trapped air and fluids to escape. During inhalation, the valves close, preventing air from entering the damaged part of the lung and during exhalation, the valves open, letting out trapped air, which is intended to relieve pressure.

Source:
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm612271.htm
## Summary of Randomized Clinical Trial

<table>
<thead>
<tr>
<th>RCT</th>
<th>Design</th>
<th>Follow-up period</th>
<th>FEV$_1$% improvement*</th>
<th>6MWT improvement*</th>
<th>SGRQ improvement*</th>
</tr>
</thead>
</table>
| TRANSFORM$^1$ | n = 97  
2:1 RCT  
Valves vs. SoC  
Heterogeneous | 6 months         | 29.3%*              | 79 m*              | -6.5 pts*           |
| IMPACT$^2$     | n = 93  
1:1 RCT  
Valves vs. SoC  
Homogeneous     | 3 months         | 17.0%*              | 40 m*              | -9.6 pts*           |
| STELVIO$^3$   | n = 68  
1:1 RCT  
Valves vs. SoC  
Heterogeneous &  
Homogeneous     | 6 months         | 17.8%*              | 74 m*              | -14.7 pts           |
| BeLieVer-HIFI$^4$ | n = 50  
1:1 RCT  
Valves vs. Sham  
Heterogeneous | 3 months         | 20.9%*              | 33 m*              | -5.1 pts           |
| VENT$^5$ (US+OUS) | n = 492 (122 in subset)  
2:1 RCT  
Valves vs. SoC  
Heterogeneous &  
Homogeneous     | 6 months         | 24.7%               | 28 m               | -8.4 pts           |

* Intention to treat analysis  † Difference between valve and control groups

Emphysema Disease Burden

What is Emphysema?

- Emphysema, including severe emphysema, is a type of chronic obstructive pulmonary disease (COPD) due to damage to the air sacs (alveoli) in the lungs. Lung damage from emphysema is irreversible. The damaged alveoli can cause used air to become trapped in the lungs during exhalation. This can cause the diseased parts of the lung to get larger and put pressure on the healthy part of the lung, which makes it difficult to breathe. As a result, the body may not get the oxygen it needs.

- **Symptoms include:** Shortness of breath, Wheezing or Chronic Cough.

Facts and Figures

The **Global Burden of Disease Study** reports a **prevalence** of 251 million cases **globally in 2016**. **Globally**, it is estimated that 3.17 million deaths were caused by the disease in 2015 (that is, 5% of all deaths **globally in** that year). More than 90% of deaths occur in low and middle income countries. The global emphysema market is expected to grow at a **CAGR** of 6.1% during the forecast period.

Source: [https://www.google.com/search?newwindow=1&safe=active&ei=ojNDW7jQHMvJviA1K4liQbqg&sa=X&ved=2ahUKEwilj9P5s8TlAhWQjWwKHXxODP4QlvwEw0oECAQ&biw=733&bih=975](https://www.google.com/search?newwindow=1&safe=active&ei=ojNDW7jQHMvJviA1K4liQbqg&sa=X&ved=2ahUKEwilj9P5s8TlAhWQjWwKHXxODP4QlvwEw0oECAQ&biw=733&bih=975)
Market Overview – Emphysema Tx

Current Treatment options

- **Lung surgery**: such as lung volume reduction or lung transplants.
- Bronchodilators.
- Corticosteroids.

Top Competitive landscape for Zephyr Endobronchial Valve

- Intrabronchial valve.
- SVS (Spiration Valve System)
  
  Product name: SVS C2 N US

Source:
- https://nursingschoolorsuccess.com/4-common-emphysema-medications-plus-free-cheat-sheet/
- https://www.nexeter.com/company/gwpharm
- https://www.google.com/search?newwindow=1&safe=active&ei=-GVAWS5CXLYLoQGF_YoAg&q=treatment+guidelines+for+epilepsy+in+children&oq=treatment+guidelines+for+epilepsy+in+children&gs_l=psy-ab.3...44426.59007.0.59717.26.25.1.0.0.0.190.3835.0j25.25.0....0...1.1.64.psy-ab.3...44426.59007.0.59717.26.25.1.0.0.190.3835.0j25.25.0....0...1.1.64.psy-ab...0.0.0.0...0.wSQMO,
- https://thorax.bmj.com/content/69/3/280
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