zephyr®
by pulmonx

Patient Selection Guidance

Zephyr Valve Indications for Use[1]

The Pulmonx Zephyr Endobronchial Valves are implantable bronchial valves indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.

Patient Selection Criteria for the Zephyr Valve Based on Multiple RCTs[2-6] and Expert Guidance[7-9]

- Diagnosis of emphysema confirmed by CT
- BMI <35 kg/m^2
- Stable with ≤20 mg prednisone (or equivalent) daily
- RV ≥150% predicted (≥ 200% if homogeneous)
- FEV_1 15-45% predicted
- TLC ≥100% predicted
- 6MWD 100-500 m (150-500 m if homogeneous)
- Not actively smoking (for at least 4 months)
- Target lobe with little to no collateral ventilation (based on fissure completeness on StratX® Platform and/or assessment with Chartis® Pulmonary Assessment System)

Contraindications

The Zephyr Valve is contraindicated for:

- Patients for whom bronchoscopic procedures are contraindicated
- Patients with 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
- Patients with large bullae encompassing greater than 30% of either lung

Warnings

The Zephyr Valve should be used with caution and only after careful consideration in patients with:

- Prior lung transplant, LVRS, median sternotomy, or lobectomy
- Congestive heart failure or recent myocardial infarction
- FEV_1 <15% of predicted value

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Zephyr® Valve Patient Work-Up

☐ Medical history

- ☐ Diagnosis of emphysema
- ☐ BMI <35 kg/m^2
- ☐ Stable with ≤20 mg prednisone (or equivalent) daily
- ☐ Currently non-smoking
- ☐ Collect any available imaging and lung function studies

☐ Pulmonary function tests (post-bronchodilator)

- ☐ Spirometry (FEV_1 15-50% predicted)
- ☐ Body plethysmography (RV ≥150%, TLC ≥100%)

☐ 6MWD (100m-500m)

☐ Imaging

- ☐ High-Resolution CT Inspiration scan (TLC view) with a slice thickness ≤1.5 mm. Ensure all files are in standard .DICOM format.*
- ☐ Upload to StratX® Platform
- ☐ Perfusion Scan (if needed)

☐ Echocardiogram

- ☐ Rule out congestive heart failure, LVEF <45%
- ☐ Rule out uncontrolled pulmonary hypertension sPAP >45 mmHg

*Do not upload Scout scan, Dose Report, or any other study series which has less than 50 .DICOM files. These smaller series scans often contain PHI and will be rejected, requiring the site to re-upload the scans.

United States

Important Safety Information: The Pulmonx Zephyr® Endobronchial Valves are implantable bronchial valves indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; those with evidence of active pulmonary infection; known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); known allergies to silicone; or with large bullae encompassing greater than 30% of either lung; Patients who have not quit smoking. The Zephyr Valve should be used with caution and only after careful consideration in treating patients with: Prior lung transplant, LVRS, median sternotomy, or lobectomy; Congestive heart failure or recent myocardial infarction; FEV_1 <15% of predicted value. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial Valve System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.

Important Safety Information: The Chartis® System is indicated for use by bronchoscopists during a bronchoscopy in adult patients with emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD), in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information. The Chartis System is contraindicated in the presence of active infection or major bleeding diathesis. There are no known interfering substances. Use is restricted to a trained physician. Prior to use, please reference the Chartis System Instructions for Use/ User Manual for more information on indications, contraindications, warnings, all precautions, and adverse events.

Caution: Federal law restricts this device to sale by or on the order of a physician.

References:

1 Zephyr Valve IFU

2 Criner, GJ et al. Am J Resp Crit Care Med. 2018; 198(9): 1151-1164 as DOI: https://doi.org/10.1164/rccm. 201803-0590OC

3 Kemp, SV et al. Am J Resp Crit Care Med. 2017; 196(12): 1535-43.

4 Valipor, A et al. Am J Resp Crit Care Med. 2017; 196(9): 1073-82.

5 Data on file at Pulmonx.

6 Klooster, K et al. N Engl J Med. 2015; 373(24): 2325-35 + Supplementary Appendix.

7 Klooster, K, & Slebos, DJ. CHEST. 2021; 159(5): 1833-1842.

8 Klooster, K et al. J Bronchology Interv Pulmonol. 2021; 1(28): Letter to Editor.

9 Posthuma, R et al: Curr Opin Support Palliat Care. 2023; 17(4): 296–300.

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