zephyr®
valve

Patient Selection Guidance

Zephyr Valve Indications for Use[1]

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.

Patient Selection Criteria for the Zephyr Valve Based on Multiple RCTs[2]

- Diagnosis of emphysema confirmed by CT
- BMI < 35 kg/m^2
- Stable with ≤ 20 mg prednisone (or equivalent) daily
- RV ≥ 175 % predicted (≥ 200 % if homogeneous)
- FEV_1 15 - 45 % predicted
- TLC ≥ 100 % predicted
- 6MWD 100 - 500m (150 - 500m if homogeneous)
- Not actively smoking (for at least 4 months)
- Target lobe with little or no collateral ventilation (as measured by StratX and/or Chartis Assessment)

Patient Exclusion Criteria for the Zephyr Valve Based on Multiple RCTs[2]

- Prior lung transplant, LVRS, median sternotomy or lobectomy
- Congestive heart failure: Left Ventricular Ejection Fraction < 45 %; unstable cardiac arrythmia, myocardial infarction or stroke
- Known allergies to Nitinol, Nickel, Titanium or Silicone
- Large bullae > 30 % of either lung
- Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for the procedure
- Contraindications for bronchoscopy; patient characteristics that
- may carry a high risk for postoperative morbidity and/or mortality
- Severe hypercapnia ($PaCO_2$ ≥ 50 mmHg on room air) and/or
- severe hypoxemia (PaO_2 ≤ 45 mmHg on room air)
- Uncontrolled pulmonary hypertension (sPAP > 45 mmHg)

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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
- ☐ Non-smoking
- ☐ Collect any available imaging and lung function studies

☐ Pulmonary function tests (post-bronchodilator)

- ☐ Spirometry (FEV_1 15 - 45 % predicted)
- ☐ Body plethysmography (RV ≥ 175 %, TLC ≥ 100 %)

☐ Arterial blood gas levels collected on room air

- ☐ Rule out severe hypercapnia $PaCO_2$ ≥ 50 mmHg
- ☐ Rule out severe hypoxemia PaO_2 ≤ 45 mmHg

☐ 6MWD (100 – 500 m)

☐ 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
- ☐ 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.

Brief Statements International
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.

Global Riskstatement
Complications of the Zephyr Endobronchial Valve treatment can include but are not limited to pneumothorax, worsening of COPD symptoms, hemoptysis, pneumonia, dyspnea and, in rare cases death.

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1 Zephyr Valve IFU.

2 Criner et al. Am J Resp Crit Care Med May 2018 as DOI: https://doi.org/10.1164/rccm.201803-05900C, Kemp et al. Am J Resp Crit Care Med 2017: (196)12 1535-1543, Valipour et al. Am J Respir Crit Care Med 2016; Vol 194, Iss. 9 pp 1073-1082 and data on file at Pulmonx, Klooster et al. N Engl J Med. 2015; 373: 2325-2335 + Supplementary Appendix.