zephyr® valve

# Patient Selection Guidance

## Zephyr Valve Indications for Use[1]

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]

- Diagnosis of emphysema confirmed by CT
- BMI <35 kg/m$^2$
- Stable with ≤20mg 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 to 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 mm Hg on room air) and/or severe hypoxemia ($PaO_2$ ≤45 mm Hg on room air)
- Uncontrolled pulmonary hypertension (sPAP >45 mm Hg)

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# Zephyr Valve Patient Work-Up

## ☐ Medical history

- ☐ Diagnosis of emphysema
- ☐ BMI <35 kg/m$^2$
- ☐ Stable with ≤20mg 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 mm Hg
- ☐ Rule out severe hypoxemia $PaO_2$ ≤45 mm Hg

## ☐ 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
- ☐ Perfusion Scan (if needed)

## ☐ Echocardiogram

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

*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 Statement: 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; 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. 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.

Brief Statement: 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.

1 Zephyr Valve IFU

2 Criner et al. Am J Resp Crit Care Med May 2018 as DOI: https://doi.org/10.1164/rccm.201803-0590OC, 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.

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