Lung Report Interpretation



StratX provides a non-invasive radiological assessment to determine a patient's candidacy for Zephyr Valves.

StratX lung reports contain tabulated lobar data on:

- Fissure completeness
- Destruction score
- Volume



Fissure completeness is a demonstrated predictor of Zephyr Valve success.⁴

Fissure completeness key:

- For fissure completeness scores of >80%, fissure integrity should be confirmed using Pulmonx's Chartis® Pulmonary Assessment System to ensure that the target lobe is negative for collateral ventilation
- A fissure completeness score of <80% indicates the presence of collateral ventilation in that lobe and the lobe should not be considered for treatment with **Zephyr Valves**

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.

- file for Zephyr Valve.
- from the IMPACT study. Am J Respir Crit Care Med. 2016: 194(9), 1073-1082 and data on file.
- heterogeneous emphysema (TRANSFORM). Am J Respir Crit Care Med, 2017; 196(12), 1535–1543.
- Eur Respir J. 2012: 39(6), 1334–1342.
- endoscopic lung volume reduction. Respir, 2017;93(2), 138-150.

Destruction Scores^{1–3}

- Lobar Destruction Score values of >50% at -910 HU were inclusion criteria for various Zephyr Valve clinical trials
- Lobar Destruction Score values of <50% at -910 HU are generally not considered as potential targets



spiration Volume

- Inspiration Volume represents the volume of each lobe in milliliters
- Inspiration volume helps identify the most hyperinflated lobe targets

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; 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, <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



While the summary section provides a good quick reference, the actual values in the results table should be reviewed before making a decision on which lobe(s) to target.



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pulmonX

1. Criner, GJ, Sue, R, Wright, S, Dransfield, M, Rivas-Perez H, Wiese, T, Sciurba, FC, Shah, PL, Wahidi, MM, de Oliveira, HG, & Morrissev, B, A multicenter randomized controlled trial of Zephyr endobronchial valve treatment in heterogeneous emphysema (LIBERATE). Am J Respir Crit Care Med, 2018; 198(9), 1151–1164 and data on

2. Valipour, A, Slebos, DJ, Herth, F, Darwiche, K, Wagner, M, Ficker, JH, & Eberhardt, R. Endobronchial valve therapy in patients with homogeneous emphysema. Results

3. Kemp, SV, Slebos, DJ, Kirk, A, Kornaszewska, M, Carron, K, Ek, L, & Briault, A. A multicenter randomized controlled trial of Zephyr endobronchial valve treatment in

4. Herth, FJ, Noppen, M, Valipour, A, Leroy, S, Vergnon, JM, Ficker, JH & Ernst, A. Efficacy predictors of lung volume reduction with Zephyr valves in a European cohort

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

Chartis Console is capital equipment that is reusable and displays the patient

information. The Chartis System is contraindicated in the presence of active

the working channel of a bronchoscope and connects to the Chartis Console. The

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

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

System Instructions for Use/User Manual for more information on indications.

contraindications, warnings, all precautions, and adverse events.

5. Slebos, DJ, Shah, PL, Herth, FJ & Valipour, A. Endobronchial valves for endoscopic lung volume reduction; best practice recommendations from expert panel on

StratX[®] Lung Analysis Platform Treat with Confidence

Patient ID 123456 Scan ID ID-789 CT Scan Date 8/14/20		Upload D Report D Scan Comme	ate 8/15/2 ate 8/15/2 ents	20 20		
SUMMARY				×EY	0% Voxel Densi ss Than -910 HU -70% Voxel Den ss Than -910 HU -60% Voxel Dens ss Than -910 HU 0% Voxel Dens Ss Than -910 HU	ity J sity J sity J ity
RESULTS	RIGHT LUI	NG		— ≥9 — 80 <8	5% Fissure Con -95% Fissure Co 0% Fissure Con LEFT LUNG	mplet
RESULTS % Fissure Completeness	RIGHT LUI RUL 79	NG RUL+RML 90	RML 79	= ≥9 = 80 <8 RLL 90	5% Fissure Con -95% Fissure Co 0% Fissure Co LEFT LUNG LUL 96	nple ompl nple
RESULTS % Fissure Completeness % Voxel Density Less Than -910 HU	RIGHT LUI RUL 79 48	NG RUL+RML 90 52	RML 79 58	= ≥9 = 80 <8 RLL 90 69	5% Fissure Con -95% Fissure Co 0% Fissure Con LEFT LUNG LUL 96 48	nple ompl L
% Fissure Completeness % Yoxel Density Less Than - 910 HU % Yoxel Density Less Than - 950 HU	RIGHT LUL RUL 79 48 23	NG RUL+RML 90 52 30	RML 79 58 33	29 30 30 80 80 80 80 80 80 80 80 80 80 80 80 80	5% Fissure Con -95% Fissure Co 0% Fissure Con LEFT LUNG LUL 96 48 30	nple ompl nple

A cloud-based quantitative CT analysis service that supports Zephyr Valve patient selection and clinical outcome optimization

Zephyr Valve treatment is the most rigorously studied **MINIMALLY-INVASIVE** treatment for severe emphysema and is proven to improve patients' BREATHING FUNCTION, EXERCISE CAPACITY, and **OUALITY OF LIFE.1-**



Target Lobe Selection

StratX provides fissure completeness, emphysema density, and inspiratory volumes to allow identification of target lobes that are good candidates for treatment with Zephyr Valves.



Features a USER-FRIENDLY DESIGN for clear interpretation and ease of use

StratX Features

Lung analysis platform enables you to:

- Screen treatment candidates non-invasively
- Choose between multiple potential treatment targets if applicable
- Enhance case planning and optimize procedure time





De-identify CT Scan — The CT should be de-identified to your institution's standards prior to upload.

(www.pulmonxstratxusa.com) StratX platform.

- Use a Java-enabled browser or Google Chrome or Firefox
- Standard PHI DICOM fields are anonymized during the upload process as a secondary PHI removal step
- Secure 256 bit SSL socket level encryption



Analyze Data + Generate Report — Data is analyzed by validated algorithms and the StratX report is uploaded to the StratX platform within 2-3 working days.



Review Report + Confidently Determine Treatment Options — Access www.pulmonxstratxusa.com to review the report to determine the most suitable treatment option for your patient.

• Post-treatment analysis of Zephyr Valve procedure to ensure optimal valve placement

- Educate referrers about the optimal candidate for Zephyr Valve therapy
- Educate patients using userfriendly reports

Capture CT Scan — Capture a high resolution chest CT scan according to the StratX CT parameters.

Upload CT Scan — Use web browser to upload CT scan to the secure, cloud-based

StratX Post-Treatment Report Benefits

Some patients report loss of benefit or no improvement after treatment. When loss of benefit or no benefit is reported, valve adjustment via re-bronchoscopy is recommended and has demonstrated to improve patient outcomes.⁵

StratX Post Treatment Reports provide non-invasive radiological assessment of Zephyr Valves

Assessment Details RLL StratX Patient ID: POST Inova108 StratX Scan ID: 60.137 CT Scan Date: 26-Feb-2021 Comments: B8, B9 and B10 are treated by a bronchial origin and here I have				a valve in common re marked it as B9.		Lobar Volume Reduction Baseline Volume: Follow-up Volume: TLVR (mL): TLVR %		1602.48 834.97 ↓ 767.51 ↓ 47.9%	
Intermediate Level			Segmental Level			Subsegmental Level			
	Airway	Placed	Valve Status	Airway	Placed	Valve Status	Airway	Placed	Valve Status
				RB6	No	Not Treated	RB6a	Yes-1	Occluded
RLL							RB6b	Yes-1	Possible Leak
							RB6c	No	Airway Not Pres
	RLL Intermediate Bronchus	No	Not Treated	RB7	Yes-1	Occluded	RB7a	No	Occluded by Proximal Valv
							RB7b	No	Occluded by Proximal Valy
				RB8	No	Occluded by Proximal Valve	RB8a	No	Occluded Proximal
							RB8b	No	Occludec Proximal Va
				RB9	Yes-1	Occluded	RB9a	No	Occluded by Proximal Valv
							RB9b	No	Occluded by Proximal Valv
				RB10	No	Occluded by Proximal Valve	RB10a	No	Occluded by Proximal Valv
							RB10b	No	Occluded by Proximal Valv
							RB10c	No	Occluded by Proximal Valy

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Quantitative Assessment of Pre- & Post-volumes of **Treated Lobes**



Radiological Assessment of Valve Presence & Valve **Seal Quality**

