A New Treatment Option for Severe COPD/Emphysema

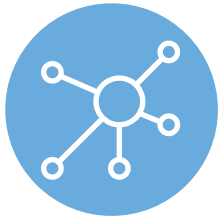
Hospital Name/Logo Here
February 2021

Agenda

Innovative Technology

The Problem of Severe Emphysema & Hyperinflation

A New Treatment Option: The Zephyr® Valve



Review of Key Clinical Data from Multiple Trials

Which Patients are Eligible?

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Review of Key Clinical Data from Multiple Trials

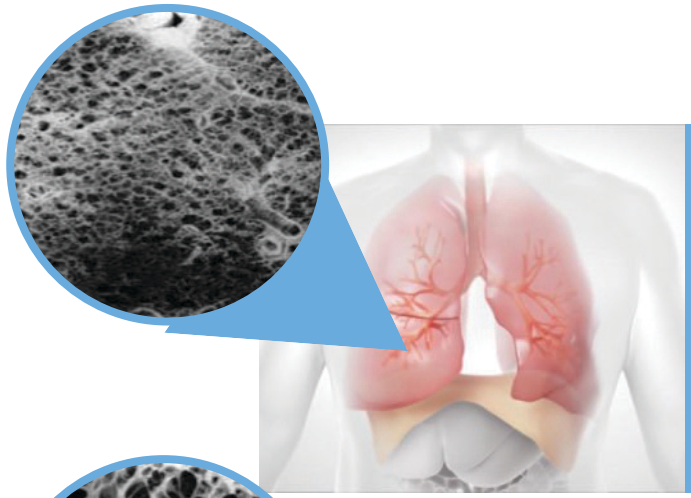
Which Patients are Eligible?

Emphysema

- A severe form of Chronic Obstructive Pulmonary Disease (COPD)
- Progressive disease – destruction of lung tissue
- Air trapping causes persistent breathlessness

Air Trapping and Hyperinflation in Emphysema

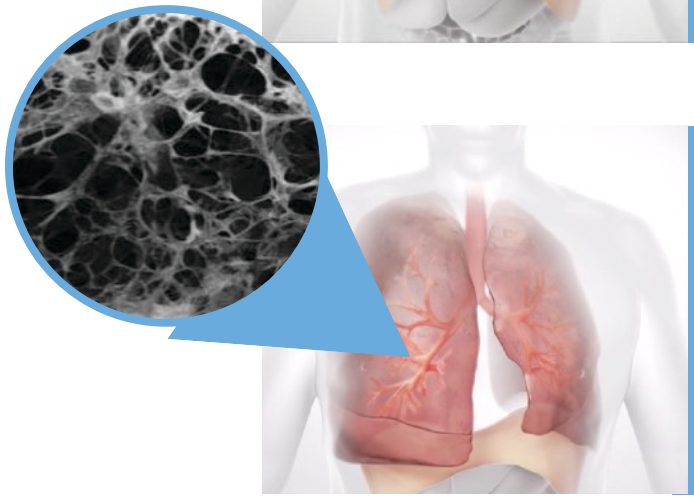
- Among the **leading causes of death** worldwide
- In the US, COPD is expected to be associated with approximately **$49 billion in direct medical costs in 2020**[1]
- Prognosis and quality of life are **worse than patients with lung cancer**



Healthy Lung

Tissue is elastic with large surface area

Breathing is easy; Lung expands and contracts normally



Lung with Emphysema

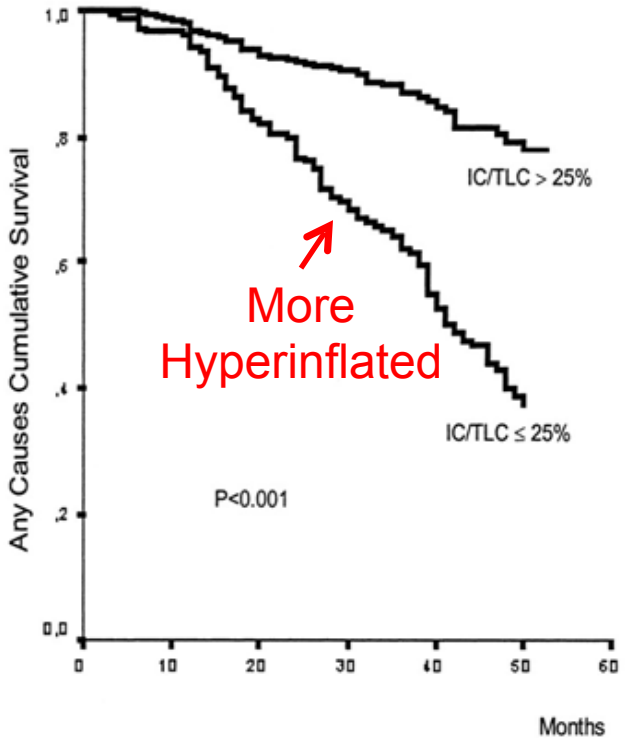
Tissue destruction reduces elasticity and gas exchange

Air is trapped in the diseased portion of the lungs, increasing lung volume and putting pressure on the diaphragm

1. https://journal.chestnet.org/article/S0012-3692(15)30233-6/fulltext

Hyperinflation is a Key Driver of Symptoms & Mortality

Higher Mortality



Worse Quality of Life

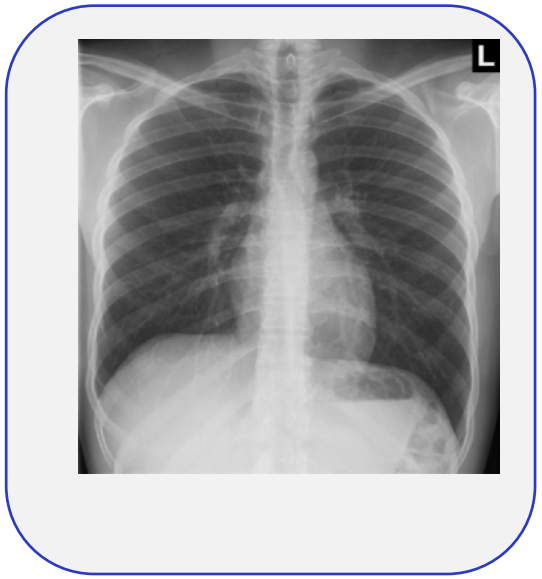
- Higher baseline dyspnea
- Significant intolerance to exercise
- Low peak oxygen uptake
- Lower daily activity levels
- Low BMI and/or muscle strength
- **Reduced cardiac and circulatory function**

Casanova AJRCCM 2001;171:591-597

Dubé et al. COPD Research and Practice (2016) 2:1 DOI 10.1186/s40749-015-0017-7

The lungs of a COPD patient are hyperinflated compared to age & height matched healthy individuals

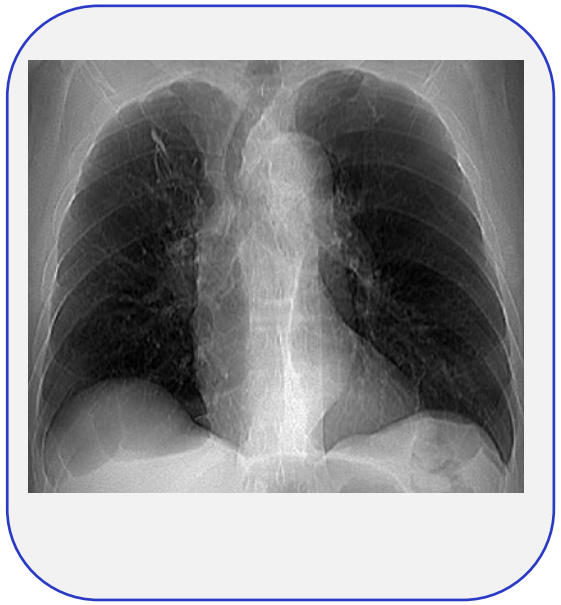
Healthy



IC ~3.3 L

TLC 6.45 L
FRC 4.22 L

COPD

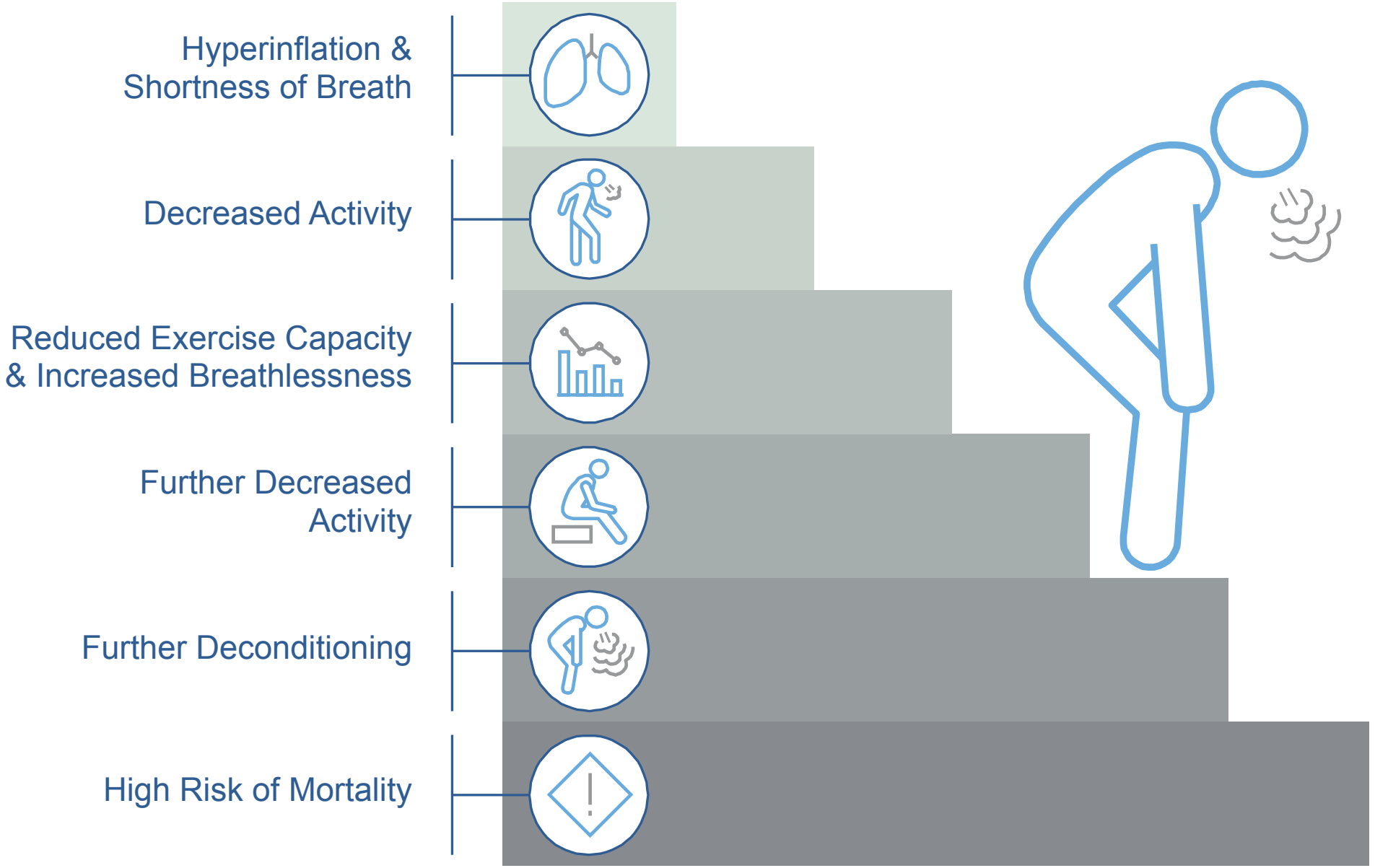


IC ~1.2 L

TLC 9.38 L (146%pr)
FRC 8.22 L (195%pr)

Images used with permission from Prof. Denis O'Donnell, Queen's University and Kingston General Hospital, December 2016

Disease Progression



Adapted from Global initiative for Chronic Obstructive Pulmonary Disease(GOLD) Global Strategy for the Diagnosis, Management and Prevention of COPD.

Agenda

Innovative Technology

- The Problem of Severe Emphysema & Hyperinflation
-  **A New Treatment Option: The Zephyr® Valve**
- Review of Key Clinical Data from Multiple Trials
- Which Patients are Eligible?

Spectrum of Treatment Options

Oxygen Therapy, Corticosteroids, Bronchodilator

Pulmonary Rehabilitation

Lung Volume Reduction Surgery

Lung Transplant

zephyr® valve

The Zephyr Endobronchial Valve

"Breakthrough Technology" Approved by the FDA for Severe Emphysema Patients

- Tiny implantable devices
- Benefits similar to surgery with no cutting
- Precise patient selection
- Proven in clinical trials and included in guidelines
- Fully removable

Spectrum of Treatment Options

< LESS INVASIVE

MORE INVASIVE >

Oxygen Therapy, Corticosteroids, Bronchodilator

Pulmonary Rehabilitation

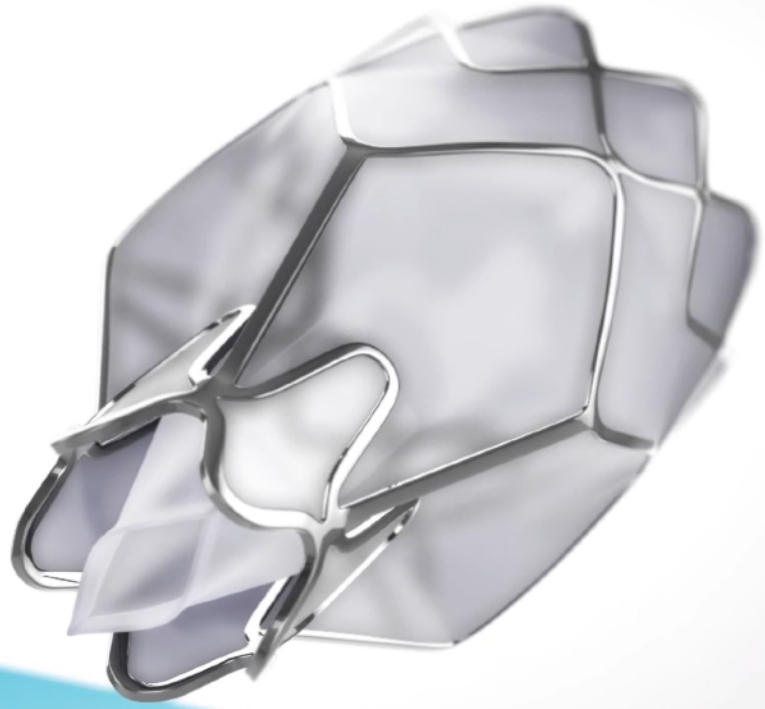
Zephyr® Endobronchial Valves

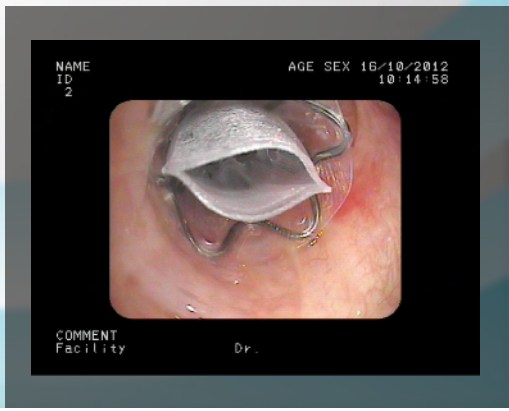
Lung Volume Reduction Surgery

Lung Transplant

How Zephyr Valves Work

Zephyr®
Endobronchial Valve





Criner, G et al, AJRCCM. Am J Respir Crit Care Med, 2018; 198 (9): 1151–1164

Zephyr® Valve Patient Benefits

Improved Health Status
(BODE)

Improved Quality of Life & Exercise
(SGRQ, TDI/BDI, CAT, 6MWD)

Reduced Breathlessness
(mMRC, BORG)

Improved Lung Function
(FEV_1, DLCO, FRC)

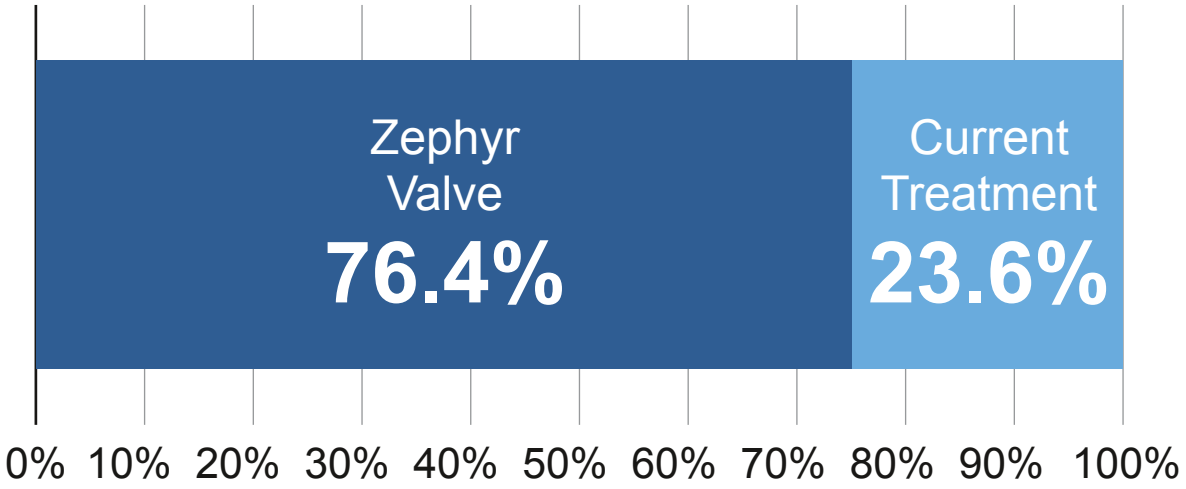
Reduced Gas Trapping
(RV, IC/TLC)

Successful Lobar Occlusion
(TLVR)

Criner, G et al, AJRCCM. AJRCCM. 2018; 198 (9): 1151–1164

Emphysema Patients are Eager for New Options

Preference Share Predications for a Choice Between product like Zephyr® Valve and Medical Management



- Preference study surveyed 294 US patients with severe emphysema
- Found they value access to an interventional treatment that offers benefits above and beyond their current medical management, despite the risks associated with these treatments
- More than 3 in 4 patients would select a treatment with the clinical benefits and risk profile of Zephyr Valves over current treatment

Mansfield, et al, Chronic Obstr Pulm Dis. 2019;6(1):In press. doi: https://doi.org/10.15326/jcopdf.6.1.2018.0147

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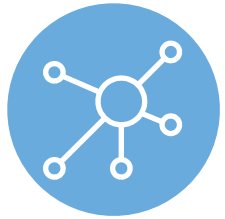
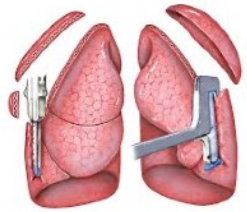


Review of Key Clinical Data from Multiple Trials

Which Patients are Eligible?

The Learning Journey

NETT [1]



- Upper Lobe Treatment

VENT [2]

- Upper & Lower Lobe Treatment

BeLieVeR [3]

- Upper & Lower Lobe treatment

- Fissures identified visually in CT

STELVIO [4]

- Upper & Lower Lobe Treatment

- CV- confirmed by Chartis
- Heterogeneous & Homogeneous

IMPACT [5]

- Upper & Lower Lobe Treatment

- CV- confirmed by Chartis®
- Homogeneous

TRANSFORM [6]

- Upper & Lower Lobe Treatment

- CV- confirmed by Chartis
- Heterogeneous

LIBERATE [7]

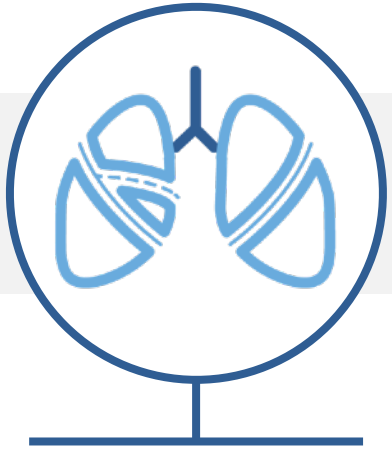
- Upper & Lower Lobe Treatment

- CV- confirmed by Chartis
- Heterogeneous

2001 2010 2013 2015 2016 2017 2018

1. Fishman, A et al. N Engl J Med. 2003; 348:2059–73.
2. Sciurba, FC et al. N Eng J Med. 2010; 363:12331244
3. Davey, et al. Lancet. 2015:386;1066 and Zoumot et al. NIHR Bookshelf 2015.
4. Klooster, K et al. N Engl J Med. 2015; 373(24):2325–2335.
5. Valipour, A et al. AJRCCM. 2016;194(9):1073–1082.
6. Kemp, SV et al, AJRCCM. 2017;196(12):1535–1543.
7: Criner, G et al. AJRCCM. AJRCCM, 2018; 198 (9): 1151–1164

Clinical Benefits for a Diverse Patient Profile



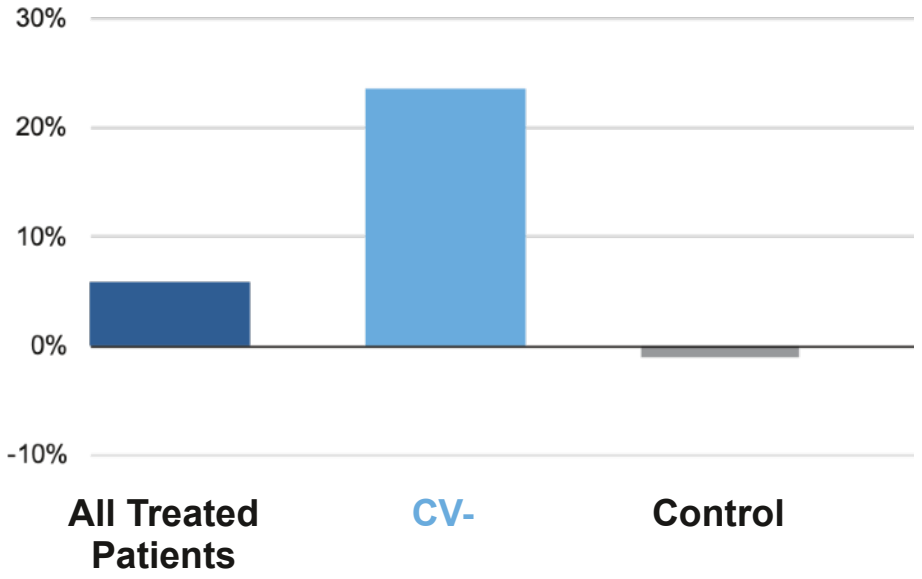
Upper AND Lower Lobe Treatment

Heterogeneous AND Homogeneous emphysema

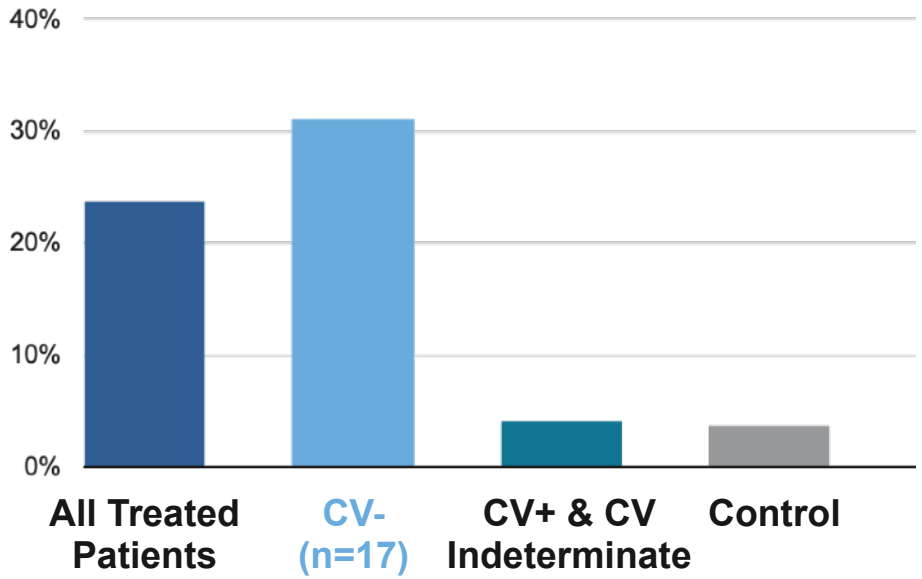
Collateral ventilation status indicated by CT and confirmed by Chartis®

VENT and BeLieVeR Trials

Vent Trial: Mean FEV_1% Change From Baseline



BeLiever Trial: Mean FEV_1% Change From Baseline



* Included CV+ and CV indeterminant lobes
Sciurba, FC et al. N Eng J Med. 2010; 363:1233–1244 (including supplementary appendix)., data on file at Pulmonx
Supplement to: Davey, C et al. Lancet. 2015; 386:1066–1073. doi: 10.1016/S0140-6736(15)60001-0.

Key Learning:

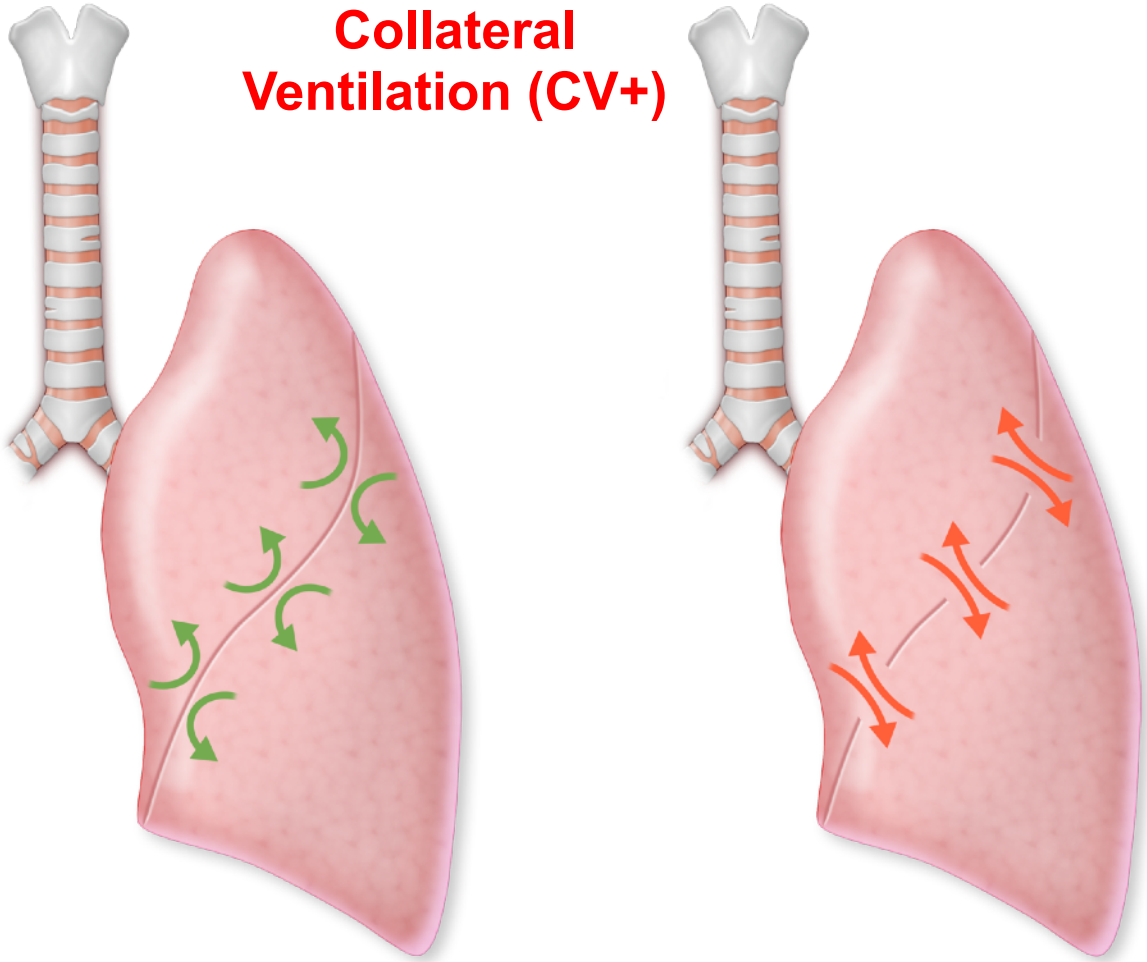
- Patients without collateral ventilation have greater improvement
- Total lobar occlusion is required for improvement

Collateral Ventilation Screening

- **Collateral ventilation is airflow between lobes** “through channels that bypass the normal airways”*
- **Only lobes WITHOUT collateral ventilation should be treated with Zephyr® Valves**

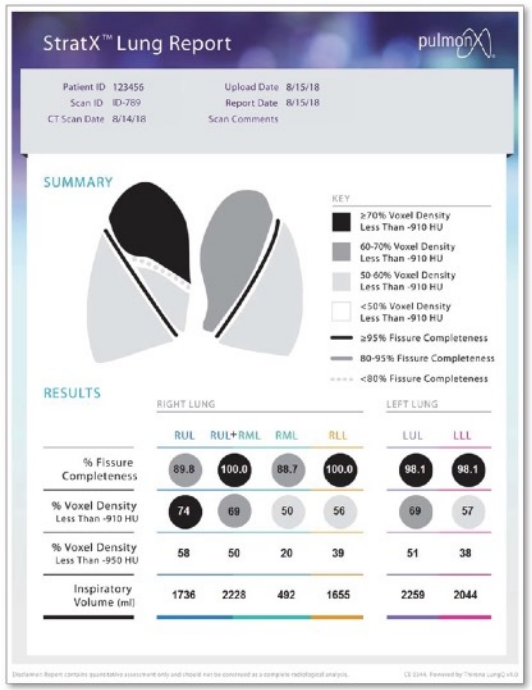
No Collateral Ventilation (CV-)

Collateral Ventilation (CV+)



* E J Cetti, A J Moore, and D M Geddes. Collateral Ventilation. Thorax. 2006; 61(5): 371–373

Pulmonx Tools Enable Precise Patient Selection



Noninvasive: StratX® Analysis Platform

- Quantitative analysis of CT scan
- Cloud-based system
- Identify one or more potential lobes for treatment

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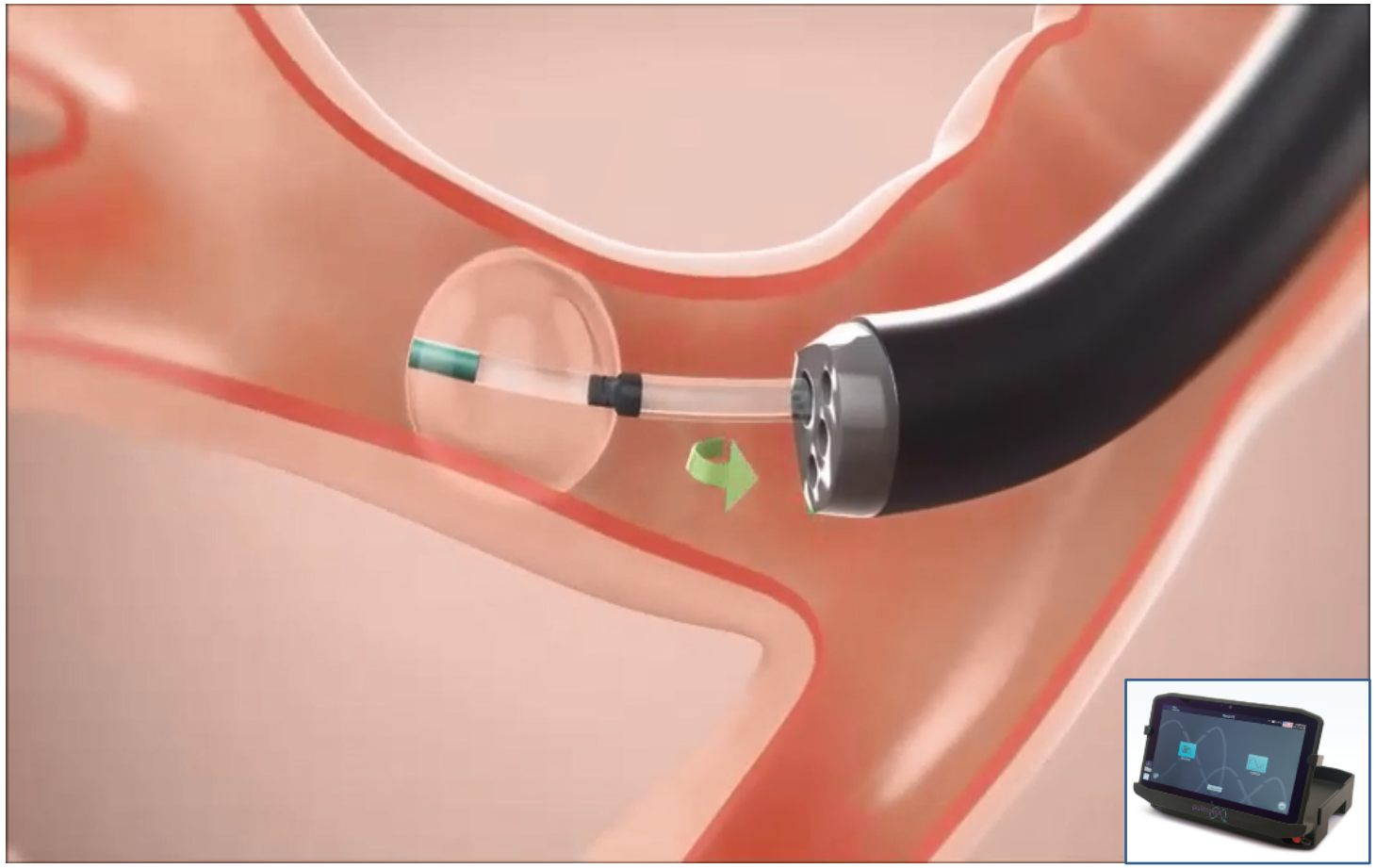
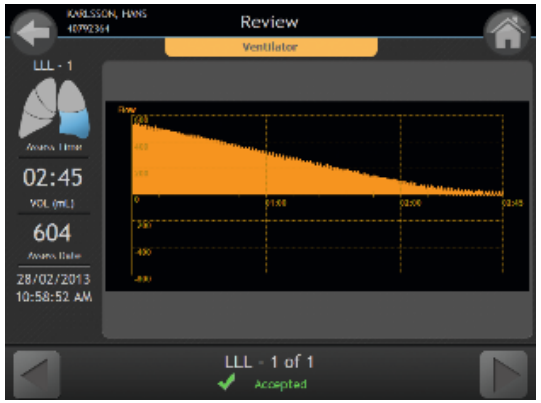
…nula…

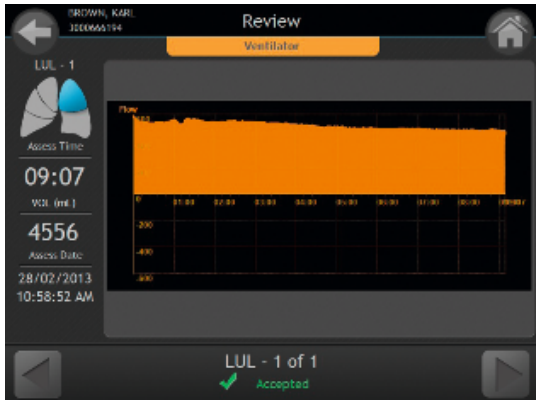
- Meas…

Assessing Collateral Ventilation — Chartis® System



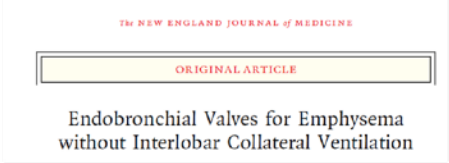


No collaterals, higher likelihood of good treatment response

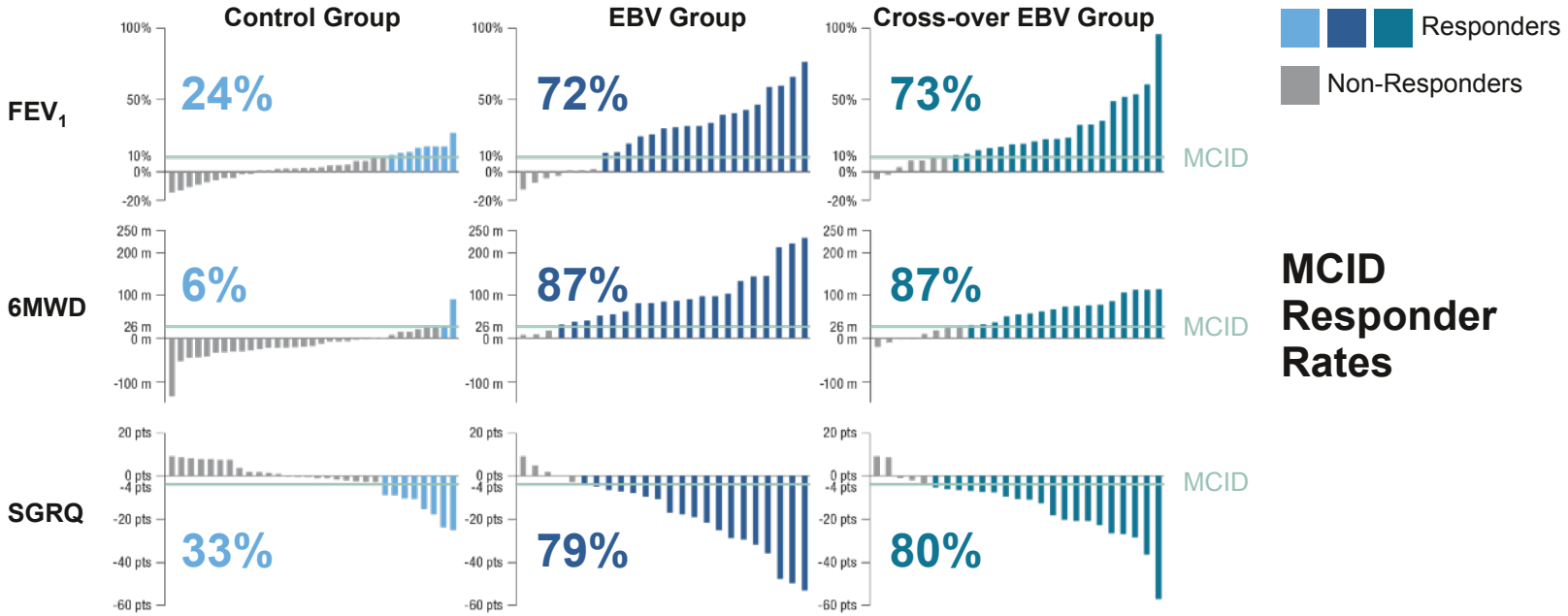


Collaterals, lower likelihood of good treatment response

STELVIO



- 84 patients identified with severe (homogeneous and heterogeneous) emphysema on CT, likely with complete fissures
- 68 patients **confirmed as collateral ventilation negative** with Chartis® System, and likely responders to Zephyr® Valves



Key Learning:

- Confirmation CV- patients have improvement in lung function, exercise capacity, and quality of life
- Excellent outcomes in heterogeneous and homogenous disease

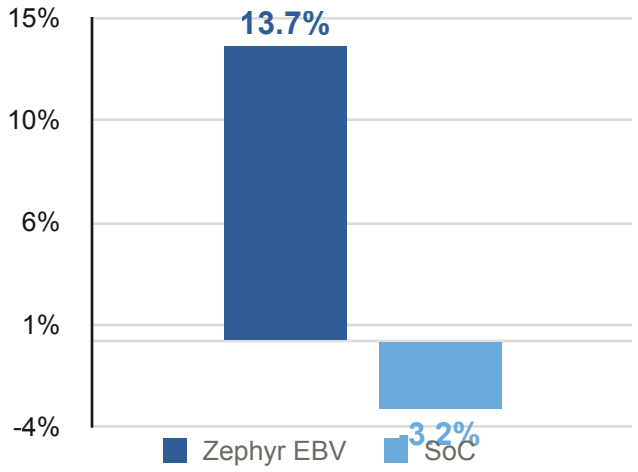
Klooster, et al. NEJM. 2015:373;2325–2335.

IMPACT

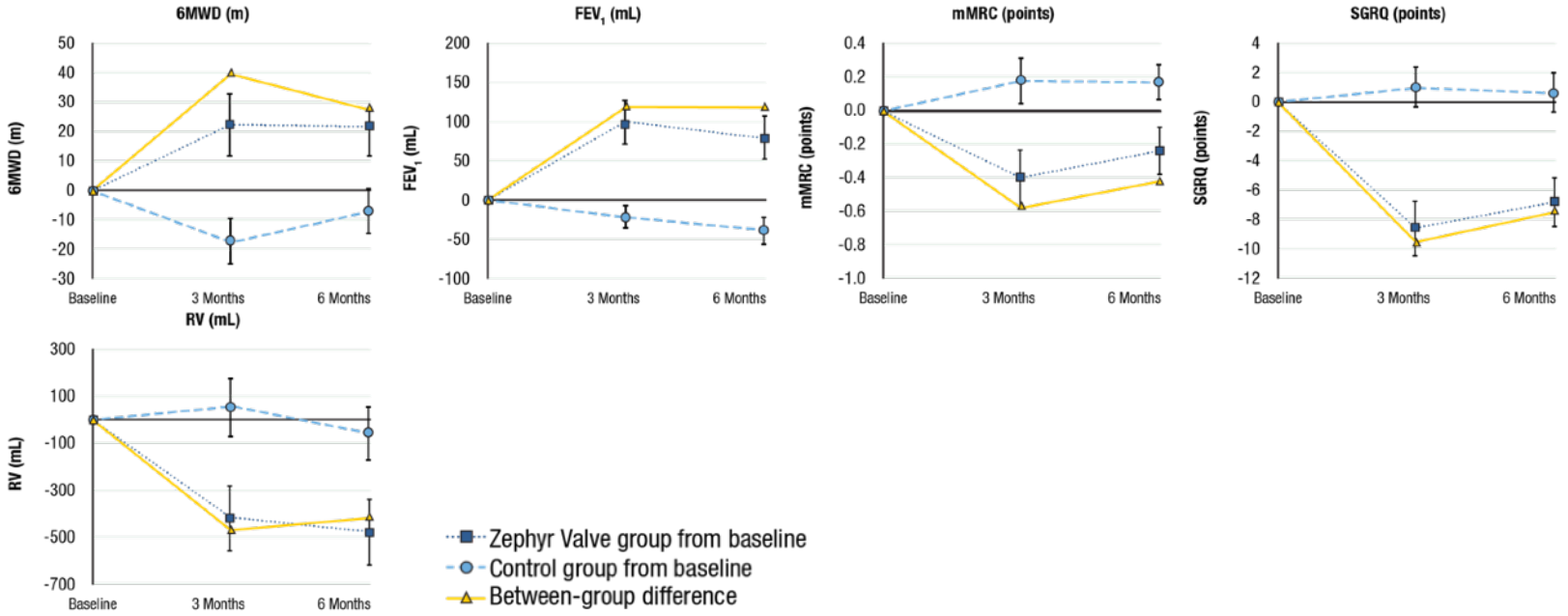
AMERICAN JOURNAL OF Respiratory and Critical Care Medicine
ORIGINAL ARTICLE

- 93 subjects with homogeneous emphysema randomized 1:1 Zephyr® Valve and SoC

Primary Endpoint (ITT)
Mean Change from Baseline in FEV_1 at 3 Months



Secondary Endpoints (ITT) Mean Change from Baseline at 6 Months



Key Learning:

- Confirmation of efficacy across primary and secondary outcome measures in homogeneous emphysema patients

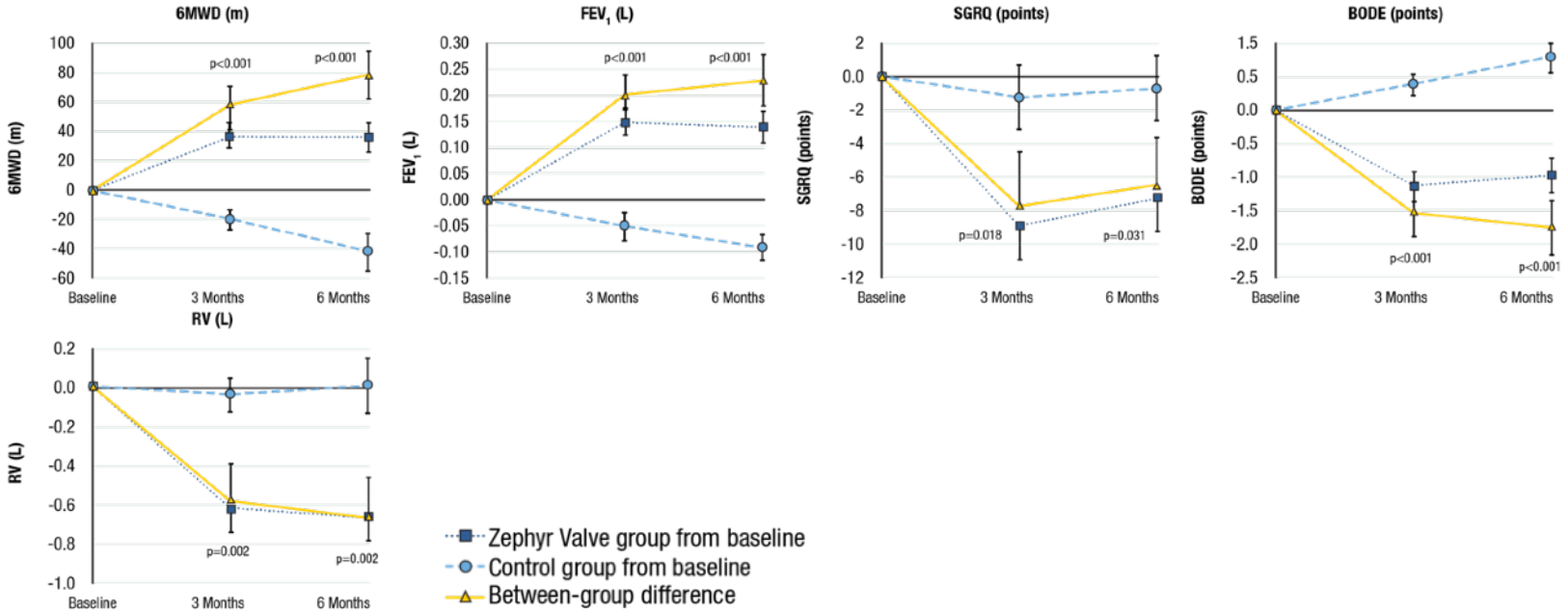
Valipour, A et al, AJRCCM. 2016. 194:1073–1082, Data on file at Pulmonx, Zephyr Valve Instructions for Use.

TRANSFORM

AMERICAN JOURNAL OF Respiratory and Critical Care Medicine
ORIGINAL ARTICLE

- 97 patients with severe heterogeneous emphysema on CT and CV- on Chartis® were randomized 2:1 to Zephyr® Valve and SoC

Secondary Endpoints (ITT) Mean Change from Baseline at 6 Months



Key Learning:

- Confirmation of efficacy across primary and secondary outcome measures in heterogenous emphysema patients

Kemp, SV et al Am J Respir Crit Care Med 2017; 196:1535–1543.

The LIBERATE Study

AMERICAN JOURNAL OF Respiratory and Critical Care Medicine
ORIGINAL ARTICLE

- **Multicenter, international randomized controlled study IDE approval trial**
  - **190 severe heterogeneous emphysema subjects with little to no collateral ventilation**, randomized 2:1 Zephyr® Valve to Standard of Care
  - First and only valve RCT with 12-month follow-up in both treatment and control arms

Baseline Demographics	Zephyr Valve (n=128)	SoC (n=62)
Gender	72 Females (56.3%)	29 Females (46.8%)
Age (years)	64.0 ± 6.85	62.5 ± 7.12
BMI (kg/m²)	24.67 ± 3.90	24.32 ± 4.38
Smoking history (pack years)	50.78 ± 26.88	48.59 ± 28.48
Emphysema score of the target lobe at -910 HU	70.9 ± 8.52	70.9 ± 8.77
Heterogeneity Index between target and ipsilateral lobes	25.5 ± 9.85	26.1 ± 9.81
Post-BD (FEV_1) (L)	0.76 ± 0.25	0.75 ± 0.22
Post-BD (FEV_1) (% predicted)	28.0 ± 7.45	26.2 ± 6.28
DLCO (% predicted)	34.6 ± 11.34	33.1 ± 9.84
Residual Volume (% predicted)	224.5 ± 42.45	224.6 ± 38.86
6 Minute Walk Distance (m)	311 ± 81	302 ± 79
SGRQ Total Score	55.15 ± 14.08	53.10 ± 14.14
mMRC Score	2.4 ± 0.97	2.2 ± 0.83
BODE Index	5.34 ± 1.52	5.32 ± 1.56
Patients on Continuous Oxygen Usage	46 (35.9%)	17 (27.4%)

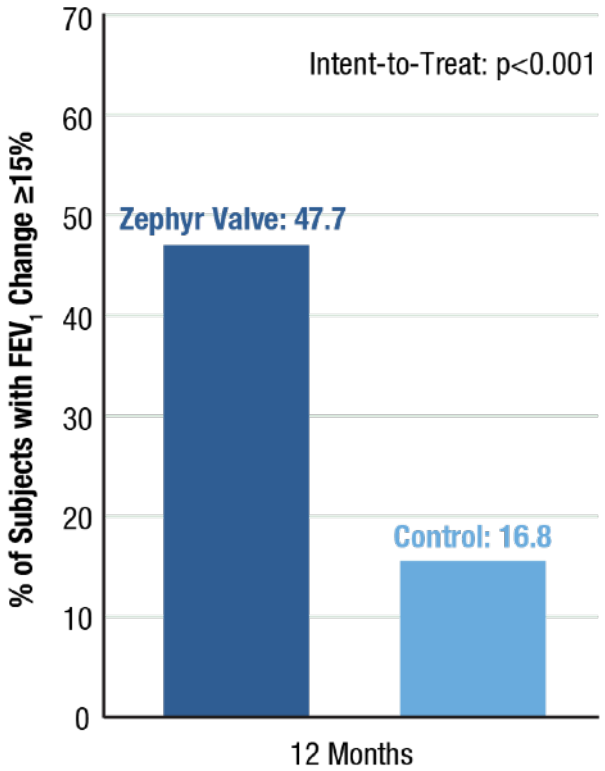
Key Learning:

- Confirmation of efficacy across primary and secondary outcome measures in heterogenous emphysema patients

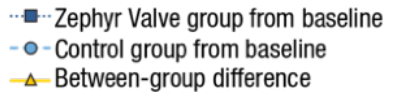
Criner, G et al, AJRCCM. 2018; 198 (9): 1151–1164

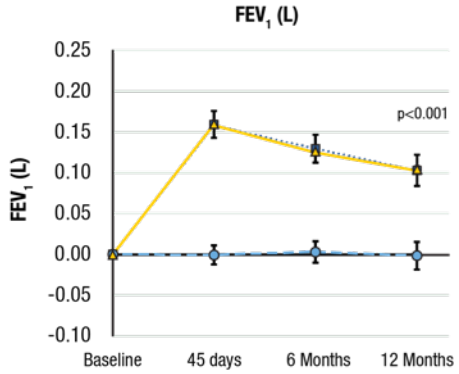
LIBERATE Primary and Secondary Outcomes

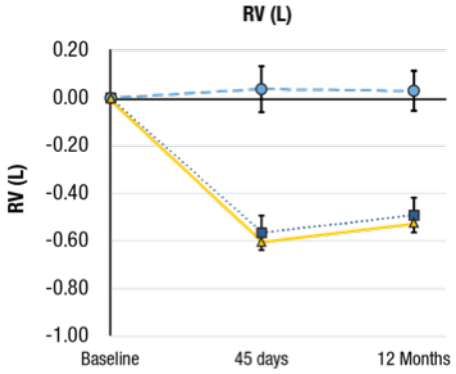
Primary Endpoint
Percent of Subjects with FEV_1 Change from Baseline to 12-months of ≥15%

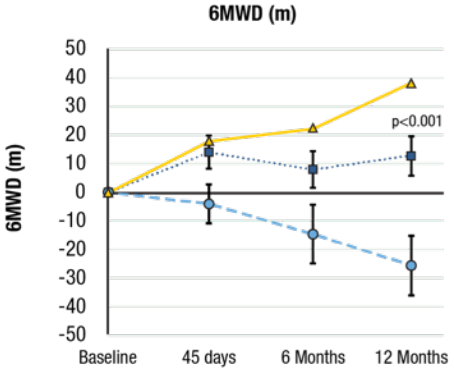


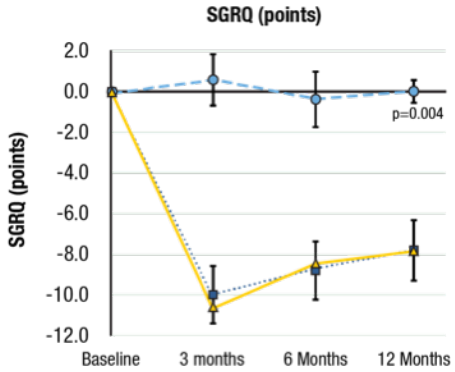
Secondary Endpoints
Change from Baseline to 12 months
FEV_1, RV, BODE, SGRQ, 6MWD, and mMRC

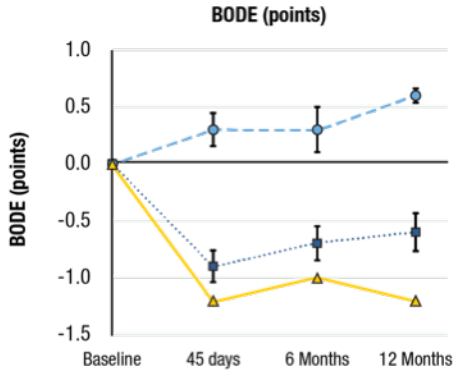


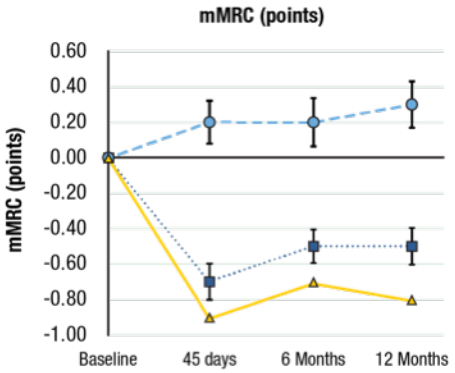








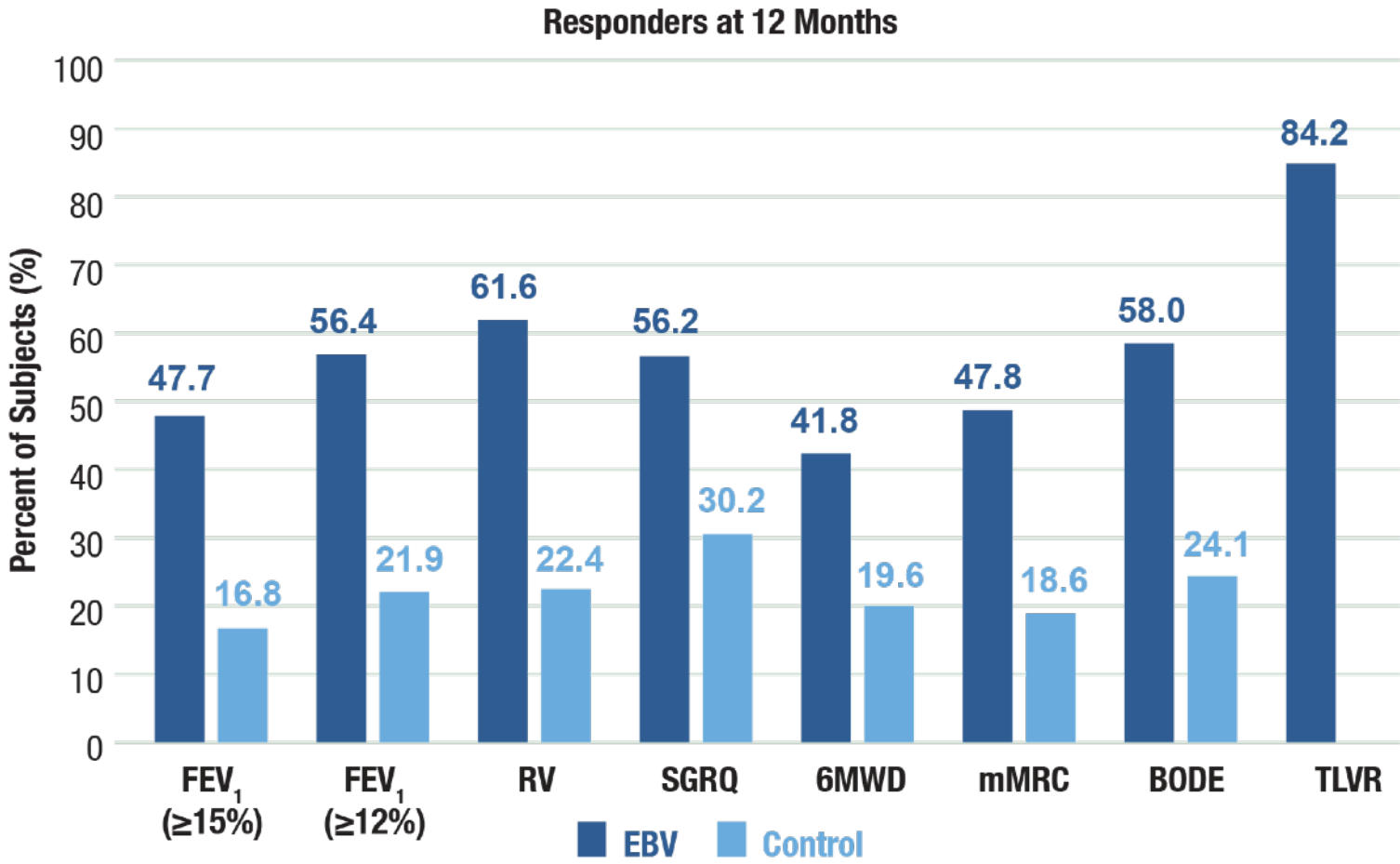




Criner, G et al, AJRCCM. 2018; 198 (9): 1151–1164

Responder Rates for Key Outcomes

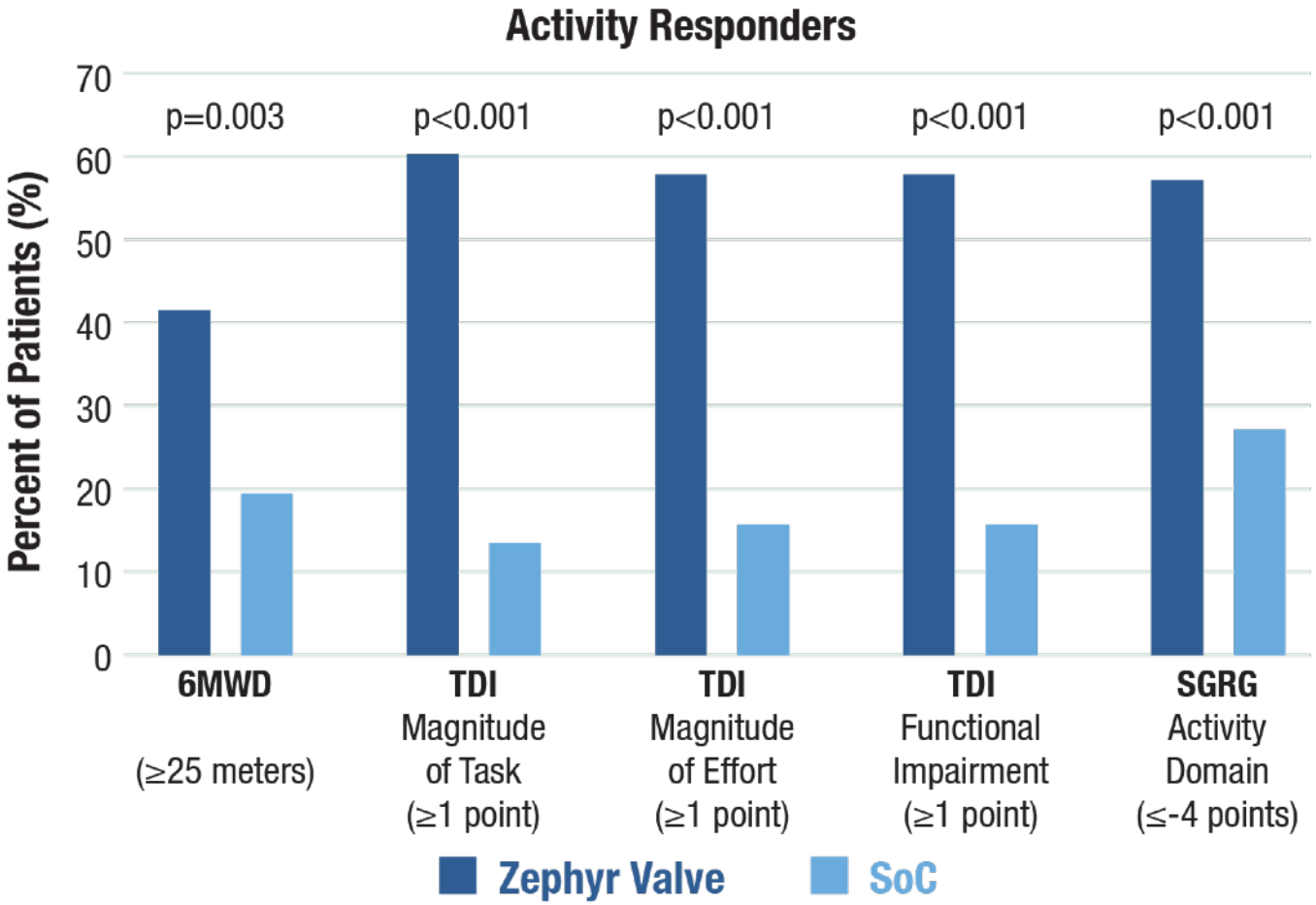
- FEV_1: ≥15% and ≥12% improvement
- SQRQ Score: ≥-4 points improvement
- mMRC: ≥-1 point improvement
- BODE Index: ≥-1 point improvement
- RV: ≥-310 mL improvement
- 6MWD: ≥25-meter improvement
- TLVR: ≥-350 mL improvement



Criner, G et al, AJRCCM. 2018; 198 (9): 1151–1164

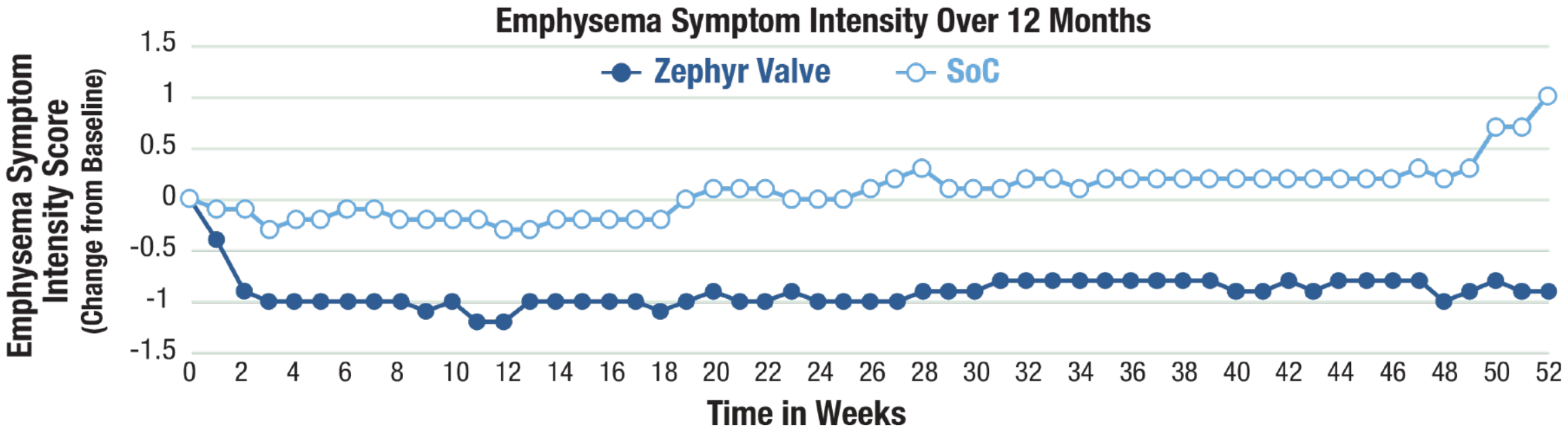
Patient Reported Outcome – LIBERATE

"Multiple measures of activity levels in Zephyr® treated patients showed statistically significant improvements compared to SoC at 12-months, notably TDI measures of effort, task, and functional impairment. These changes in activity levels can be very meaningful for patients.
For example, a 3-point change in TDI focal score implies a return to most work/leisure activities previously impacted, and 54.9% of Zephyr Valve-treated patients achieved this in LIBERATE."



Dransfield MT et. al. Published March 30, 2020 as doi.org/10.1513/AnnalsATS.201909-666OC

Emphysema Symptoms from Daily Diary



Patients reported their daily symptoms in a Daily Diary by responding to the question, “Mark the scale to show the intensity of the emphysema symptoms you had today (scale of 0=none to 10=intolerable; instrument not validated).” Over the year following randomization, control patients perceived worsening of their symptoms, while Zephyr®-treated patients on average perceived an improvement of symptoms within two weeks after the procedure, which persisted out to at least 12 months.

At the individual level, “Zephyr Valve experienced significantly more days that were ‘better’ and fewer days that were ‘worse’ over 12 months.”

Dransfield MT et. al. Published March 30, 2020 as doi.org/10.1513/AnnalsATS.201909-666OC

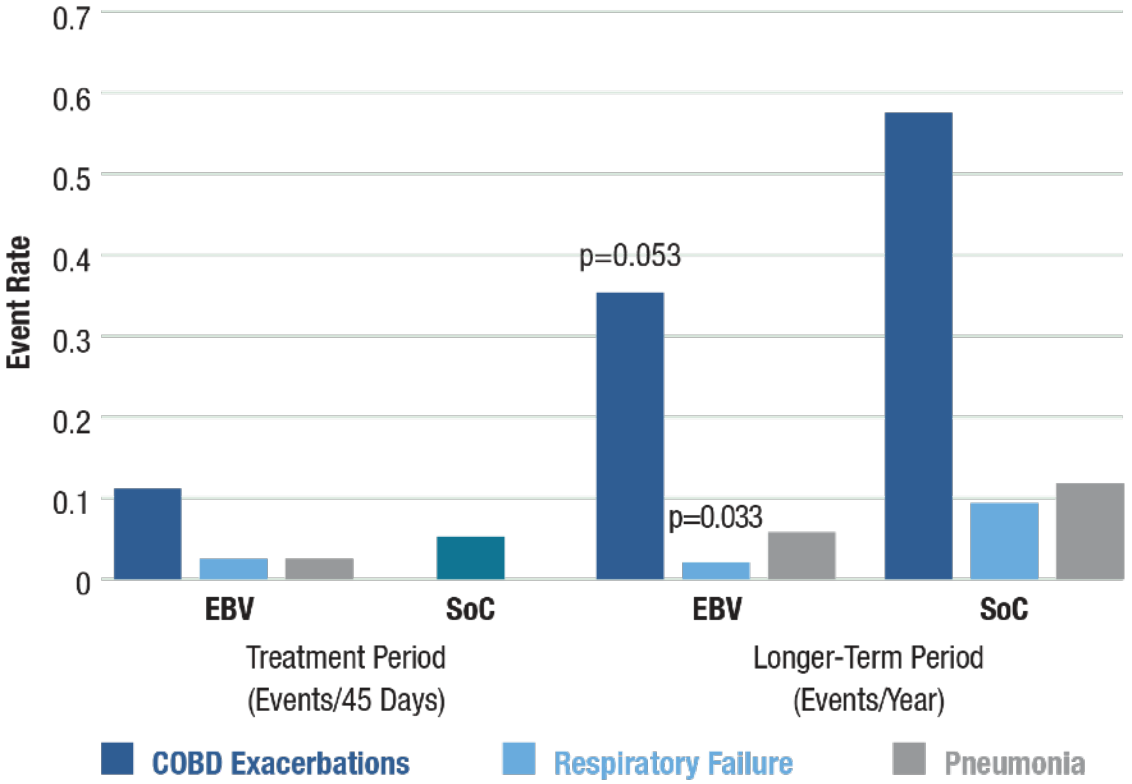
LIBERATE Safety

SAEs Occurring in at Least 3% of Subjects, as Defined by Investigators

* p<0.05

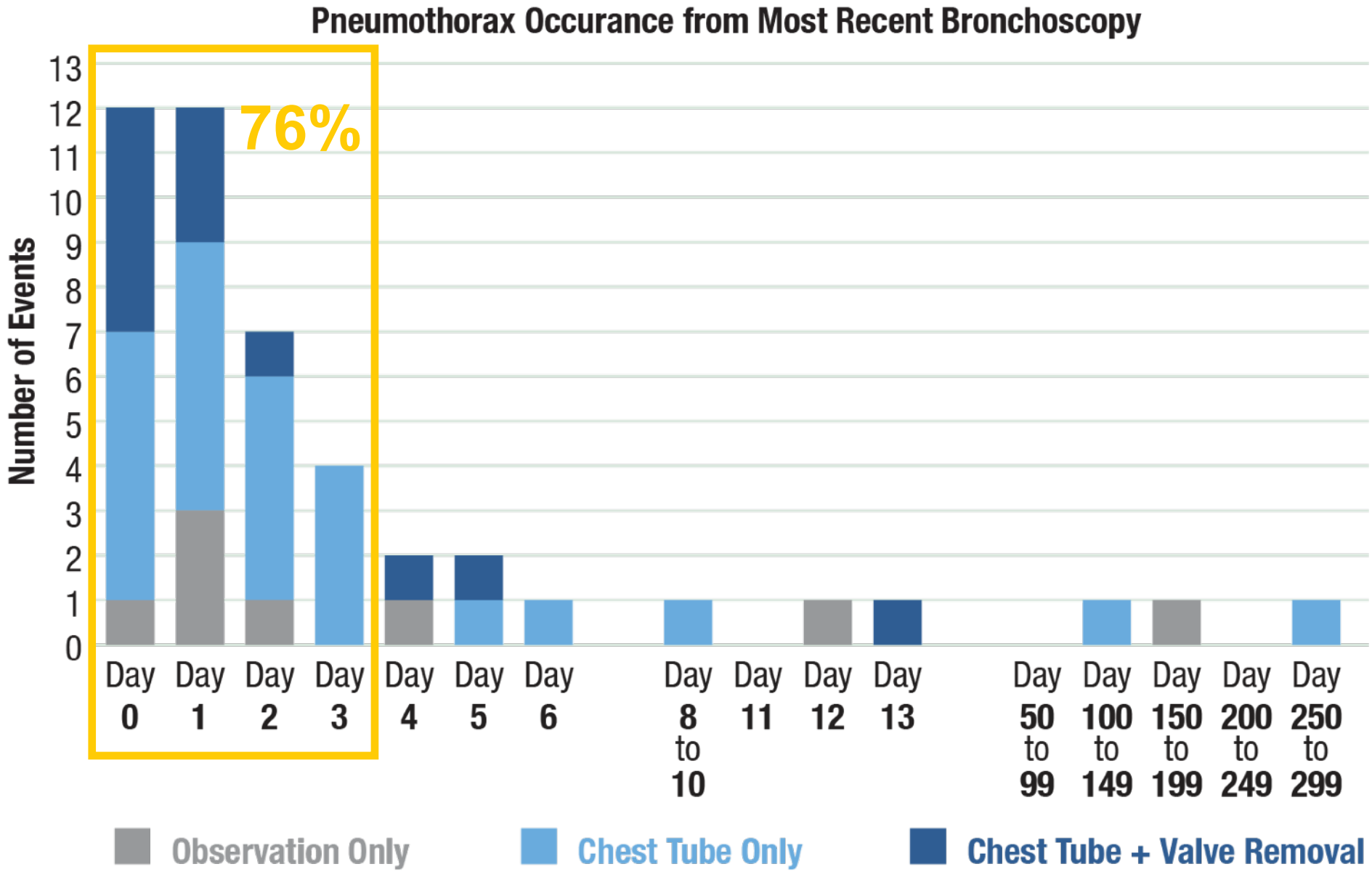
	Treatment Period (Day of Procedure/ Randomization to 45 Days)		Longer-Term Period (45 Days from the Study Procedure/ Randomization until 12-month Visit Date)	
	Zephyr® Valve (N=128)	SoC (N=62)	Zephyr Valve (N=122)	SoC (N=62)
Death	4 (3.1%)	0 (0.0%)	1 (0.8%)	1 (1.6%)
Pneumothorax	34 (26.6%)*	0	8 (6.6%)	0
Severe COPD exacerbation	10 (7.8%)	3 (4.8%)	28 (23.0%)	19 (30.6%)
Pneumonia	1 (0.8%)	0	7 (5.7%)	5 (8.1%)
Respiratory failure	2 (1.6%)	0	1 (0.8%)	2 (3.2%)
Arrhythmia	0	0	1 (0.8%)	2 (3.2%)
Diverticulitis	0	0	1 (0.8%)	2 (3.2%)

SAEs as Adjudicated by CEC



Criner, G et al, AJRCCM. 2018; 198 (9): 1151–1164.

76% of Pneumothoraces within 3 Days of Procedure



Criner, G et al, AJRCCM. 2018; 198 (9): 1151–1164.

76% of Pneumothoraces within 3 Days of Procedure

- All Zephyr Valve procedures are done as in-patient procedures with a 3-night stay
- Zephyr Valve Treating Centers are trained to handle pneumothorax
- Patients are advised of the signs and symptoms of pneumothorax at discharge

Criner, G et al, AJRCCM. 2018; 198 (9): 1151–1164

Summary of Key Measures Across Studies in CV- Patients

				Difference Zephyr Valve vs. Control Groups (ITT)		
RCT	**Design**	**Size & Follow-up period**	**Procedural Success**	Lung Function (FEV_1%) MCID = 10%-15%	Exercise Capacity (6MWD) MCID = 26 m	Quality of Life (SGRQ) MCID = -4 pts
LIBERATE[1]	2:1 Randomization **Heterogeneous only** Multicenter	n=190 12 Mo	**84%**	**18.0%** p<0.001	**39 m** p=0.002	**-7.1 pts** p=0.004
TRANSFORM[2]	2:1 Randomization **Heterogeneous only** Multicenter	n=97 6 Mo	**90%**	29.3% p<0.001	79 m p<0.001	-6.5 pts p=0.031
IMPACT[3]	1:1 Randomization **Homogeneous only** Multicenter	n=93 6 Mo*	**89%**	16.3% p<0.001	28 m p=0.016	-7.5 pts p<0.001
STELVIO[4]	1:1 Randomization **Heterogeneous & Homogeneous** Single Center	n=68 6 Mo	**88%**	17.8% p=0.001	74 m p<0.001	-14.7 pts** p<0.001

**Data on file at PMX (not in publication)* ***Completed cases, all other values listed are ITT population*

1 Criner, et al. Am J Resp Crit Care Med, 2018; 198 (9): 1151–1164 | 2 Kemp, S et al. Am J Resp Crit Care Med, 2017; (196)12:1535–1543 | 3 Valipour, et al. Am J Respir Crit Care Med. 2016; Vol 194, Iss 9, pp 1073–1082 and Data on file at Pulmonx | 4 Klooster, K. et al. N Engl J Med. 2015; 373:2325–2336 + Supplementary Appendix.

Clinically Accepted Globally

Zephyr® Valve treatment of severe emphysema is included in global and national guidance documents, such as those sponsored by:

- Global Initiative for Chronic Obstructive Lung Disease (GOLD) Evidence Level A
- The UK's National Institute for Care and Excellence (NICE)
- German Respiratory Society (DGP)
- National Health Care Institute of the Netherlands (Zorginstituut Nederland)

>20,000
Patients Treated Globally

Agenda

Innovative Technology

The Problem of Severe Emphysema & Hyperinflation

A New Treatment Option: The Zephyr® Valve

Review of Key Clinical Data from Multiple Trials

Which Patients are Eligible?

Zephyr® Valve Indication for Use – United States

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.

Minimum Criteria for Referral

1. **Confirmed diagnosis of COPD**
2. **Non-smoking or willing to quit smoking**
3. **FEV_1 < 50% predicted**
4. **Breathless despite optimal medical management (mMRC≥2)**

Modified MRC Dyspnea Scores	
0	I only get breathless with strenuous exercise
1	I get short of breath when hurrying up the level or walking up a slight hill
2	I walk slower than people of the same age on the level because of breathlessness, or I have to stop for breath when walking at my own pace on the level
3	I stop for breath after walking about 100 meters or after a few minutes on the level
4	I am too breathless to leave the house, or I am breathless when dressing or undressing

How to Send a Referral

Identify Potential Candidates

- Explore Existing Databases*
  - PFT Software (FEV_1 <50%, RV >150%, TLC >100%)
  - Possible ICD-10-CM** Diagnosis Codes (J43, J44)

Make a Connection with Local Treating Center

- Locate on MyLungsMyLife.com website
- Reach out to treating center and schedule a meeting to discuss referrals
- Set up an easy referral process for your patients – use referral form

Follow up with Referral Once Treated

- The treating center will communicate with the patient
  - Patient to report back once seen by physician
- When you get your patient back
  - Report all outcomes back to the treating center

* These are only suggested broad search terms, and as such, not all patients will ultimately qualify for Zephyr® Valves.
**Refer to ICD International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) list here: https://www.cdc.gov/nchs/icd/icd10cm.htm

Typical Work Up for Zephyr® Valve Eligibility

- ❑ 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
- ❑ 6MWD (100m–500m)
- ❑ Pulmonary Function Tests (post-bronchodilator)
  - ❑ Spirometry (FEV_1 15–45% predicted)
  - ❑ Body Plethysmography (RV ≥ 175%, TLC ≥ 100% for Heterogenous emphysema and RV ≥ 200% predicted, TLC ≥ 100% predicted for Homogeneous emphysema)
- ❑ Arterial Blood Gas Levels collected on room air
  - ❑ Rule out severe hypercapnia PaCO2 ≥50 mm Hg
  - ❑ Rule out severe hypoxemia PaO2 ≤45 mm Hg
- ❑ Imaging
  - ❑ High Resolution CT (≤ 1.5mm slice thickness, TLC view)
  - ❑ Upload to StratX®
  - ❑ Perfusion Scan (Highly Recommended)
- ❑ Echocardiogram
  - ❑ Rule out congestive heart failure, LVEF <45%
  - ❑ Rule out uncontrolled pulmonary hypertension, sPAP >45mm Hg

Patient Screening & Treatment Process

Clinical Work Up

Step 1:

- Medical history
- Lung function tests
- CT Scan

StratX®

Step 2:

StratX report to support target lobe selection:

- Lobar volume
- Emphysema destruction score
- Fissure completeness

Chartis®

Step 3:

Chartis procedure

- Confirm target lobe has no collateral ventilation

Zephyr® Valve

Step 4:

Zephyr Valves placed to completely occlude the target lobe

Post-Procedure Management

Step 5:

The patient should remain in the hospital for 3 nights following the procedure for observation

Reimbursement for Zephyr® Valves

- Most patients who qualify for the procedure are able to secure insurance coverage for their Zephyr Valve treatment when the medical criteria are met.
- Many plans cover the Zephyr Valve treatment and most plans that do not yet have a policy are approving prior-authorization requests on a case-by-case basis
- It is recommended that a patient seek prior-authorization approval before the procedure
- **For patients whose doctor has recommended the Zephyr Valve procedure, the Pulmonx Patient Reimbursement Support Program is available to patients and their caregivers as they navigate the insurance process for the Zephyr Valve procedure**

Summary

1. Zephyr® Valves have been **extensively studied clinically** (4 Randomized Controlled Trials)
2. Patients treated with Zephyr Valve had **clinically significant improvement** in lung function, exercise capacity, and quality of life
3. Endobronchial Valve treatment is an established therapy for patients with emphysema included in global guidance of the treatment of COPD. **GOLD: (Evidence Level A)**
4. Most patients who qualify for the Zephyr Valve procedure are able to secure insurance **Coverage** for their treatment.
5. Severe emphysema **patients are searching for additional therapies**

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.

Brief Statements United States
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; FEV1 <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.

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.