

# CONVERT II

## Clinical Trial

A trial to evaluate the safety and effectiveness of AeriSeal® System to block collateral ventilation (CV) and convert a severe emphysema patient from CV+ to CV- status.



CAUTION - Investigational device. Limited by Federal law to investigational use.  
The AeriSeal System is under investigation in the US and its use is limited to this trial.  
AeriSeal System has received CE Mark in Europe and registration from Australian TGA.

This brochure is for physician use only. Not approved by ethics committee for distribution to patients.

 **CONVERT II**  
by pulmonx



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## Participant Eligibility

### KEY INCLUSION CRITERIA

Please consider referring any patient who meets the following criteria:

- Adults (40-80 years of age)
- Severe emphysema
- Stopped smoking (>8 weeks)
- Have at least one clear target lobe with:
  - $\geq 50\%$  destruction at  $-910\text{HU}$ , and
  - incomplete adjacent fissure ( $\geq 80\%$ ), and
  - heterogenous emphysema (defined as  $\geq 15\%$  difference between the target lobe and the ipsilateral lobe)
- Collateral ventilation confirmed by the Chartis<sup>®</sup> System
- 6MWD  $\geq 250\text{m}$  and  $\leq 450\text{m}$
- Pulmonary rehab completed within 6 months of enrollment

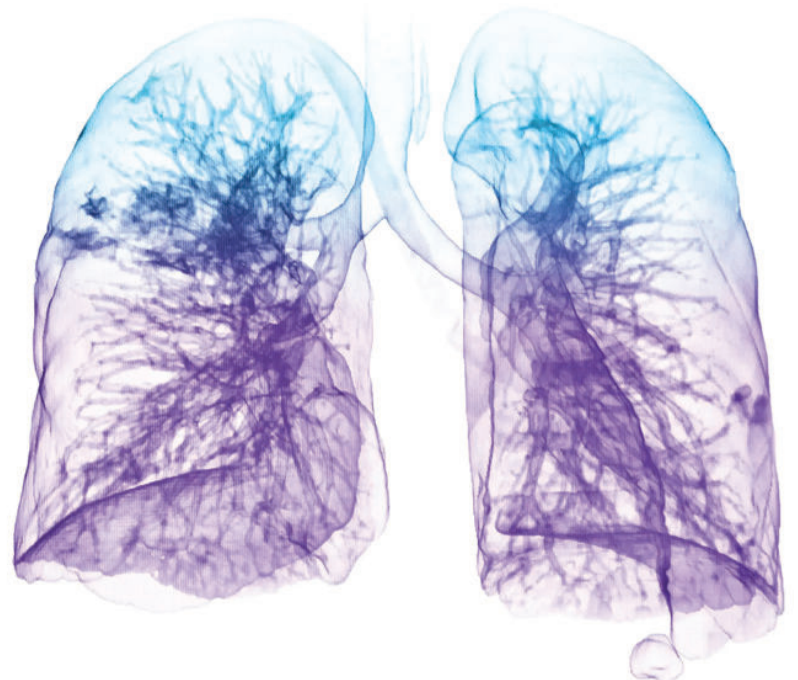
### EXCLUSION CRITERIA

Please note that if your patient presents with any of the following, he or she is not an appropriate candidate for the CONVERT II Trial:

- Prior LVRS, lobectomy or pneumonectomy, lung transplantation
- 3 or more COPD exacerbations requiring hospitalization within the last 12 months
- Asthma or chronic bronchitis as the primary diagnosis
- Ongoing active respiratory infection
- Requires invasive ventilatory support
- Pulmonary hypertension
- Alpha-1-antitrypsin



Please refer to the **CONVERT II** Pocket Guide to help identify appropriate patients.





## Study Overview

### THE GOAL

The objective of the CONVERT II Pivotal Trial is to establish the safety and effectiveness of using the AeriSeal<sup>®</sup> System to target and treat the fissural defects that cause collateral ventilation between lung lobes, which preclude some severe COPD/emphysema patients from benefiting from minimally invasive bronchoscopic lung volume reduction (BLVR) treatment with Zephyr<sup>®</sup> Valves.

The CONVERT II Trial will complement the results gained in the CONVERT Trial. (ClinicalTrials.gov Identifier: NCT04559464).

**You likely have patients who could be eligible for and benefit from participating in the CONVERT II trial. →**

### METHODS

The CONVERT II Trial (NCT06035120) is a multicenter, prospective, single-arm, pivotal study conducted by Pulmonx Corporation.

**200** PATIENTS WILL BE ENROLLED

**30** STUDY CENTERS ACROSS THE US, EU AND AUSTRALIA

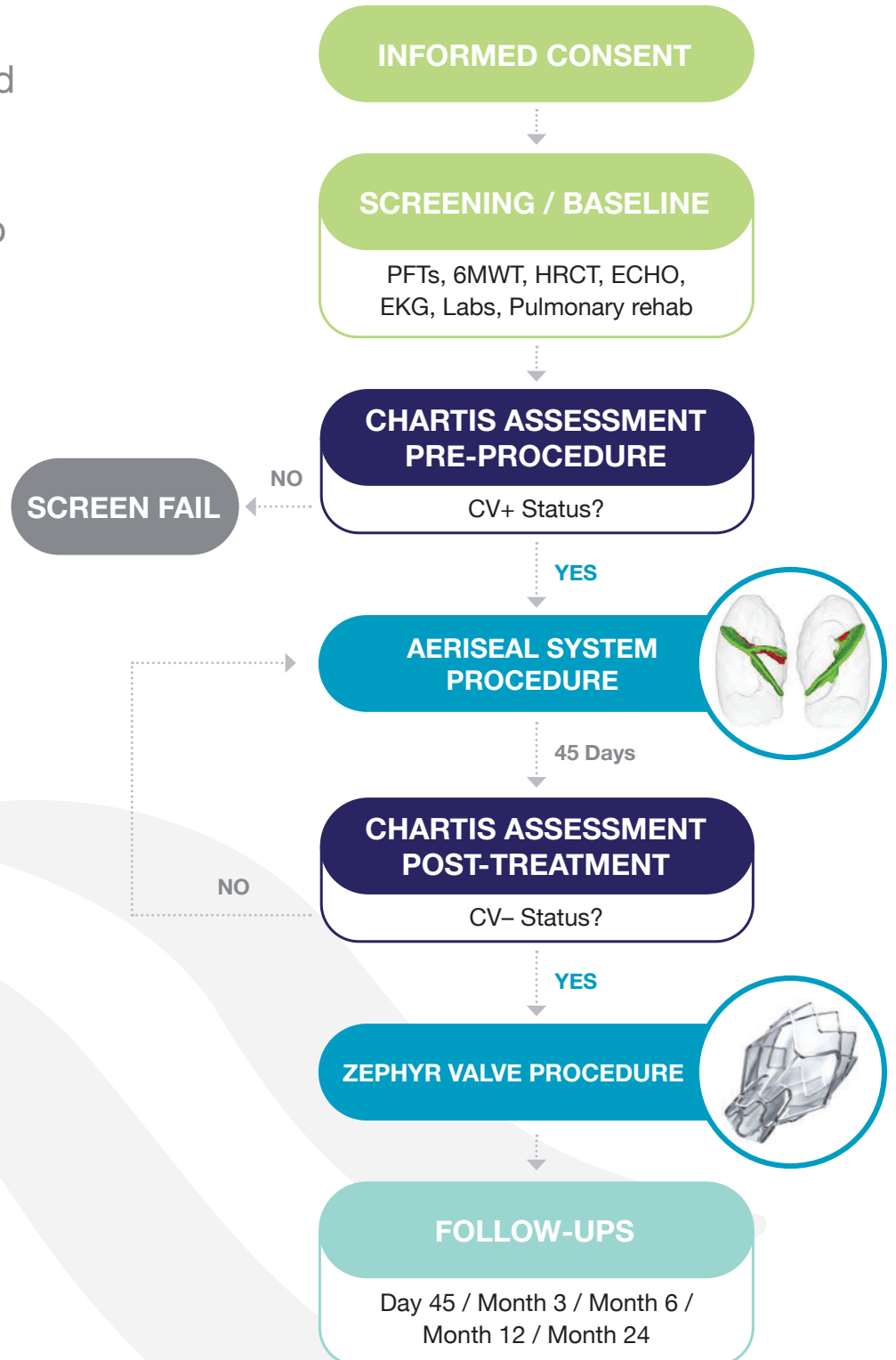
**2** YEAR FOLLOW-UP

**AeriSeal System**  
INVESTIGATIONAL DEVICE IN THE US

# CONVERT II Trial

## STUDY DESIGN

Participants will be evaluated at 14 visits (9 in clinic and 5 via phone) over 2½ years. In addition, pulmonary rehab must be completed within 6 months of enrollment and following treatment with Zephyr Valves.



## Initial CONVERT Trial<sup>1</sup>

### ABOUT

A multicenter, prospective, single-arm study is being conducted at 14 clinical centers across Europe and Australia to evaluate AeriSeal System to occlude collateral channels to convert a CV+ lung lobe to having little to no CV-.

A secondary objective is Zephyr Valve treatment in the CV- converted patients and assessment of clinical outcomes.

Enrollment has been completed and patients are being followed through 1 year post-Zephyr Valve Treatment.



### INTERIM RESULTS

CONVERT Trial (NCT04559464)

**101** PATIENTS  
ENROLLED AT  
14 OUS SITES

**77%** CONVERSION  
RATE (75/97)

**89%** TLVR MCID -350ML  
45 DAYS POST-ZV  
(62/70)

#### SAE REPORTED THROUGH 12 MONTHS, INCLUDED:

Inflammatory response (post-AS)	15.7%
COPD exacerbation	10.8%
Pneumonia	9.8%
Pneumonitis	5.9%
Pneumothorax (post-ZV)	21.1%
Death (9 months post-ZV)	1%

# CONVERT II is currently enrolling patients in sites around the world.



Please visit  
[pulmonx.com/active-clinical-trials/](https://pulmonx.com/active-clinical-trials/)  
to contact a site near you.



Information also available at [clinicaltrials.gov/study/NCT06035120](https://clinicaltrials.gov/study/NCT06035120)

Reference: 1. Bezzi M et al. *Eur Respir J* 2022; 60: Suppl. 66, 1231.

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