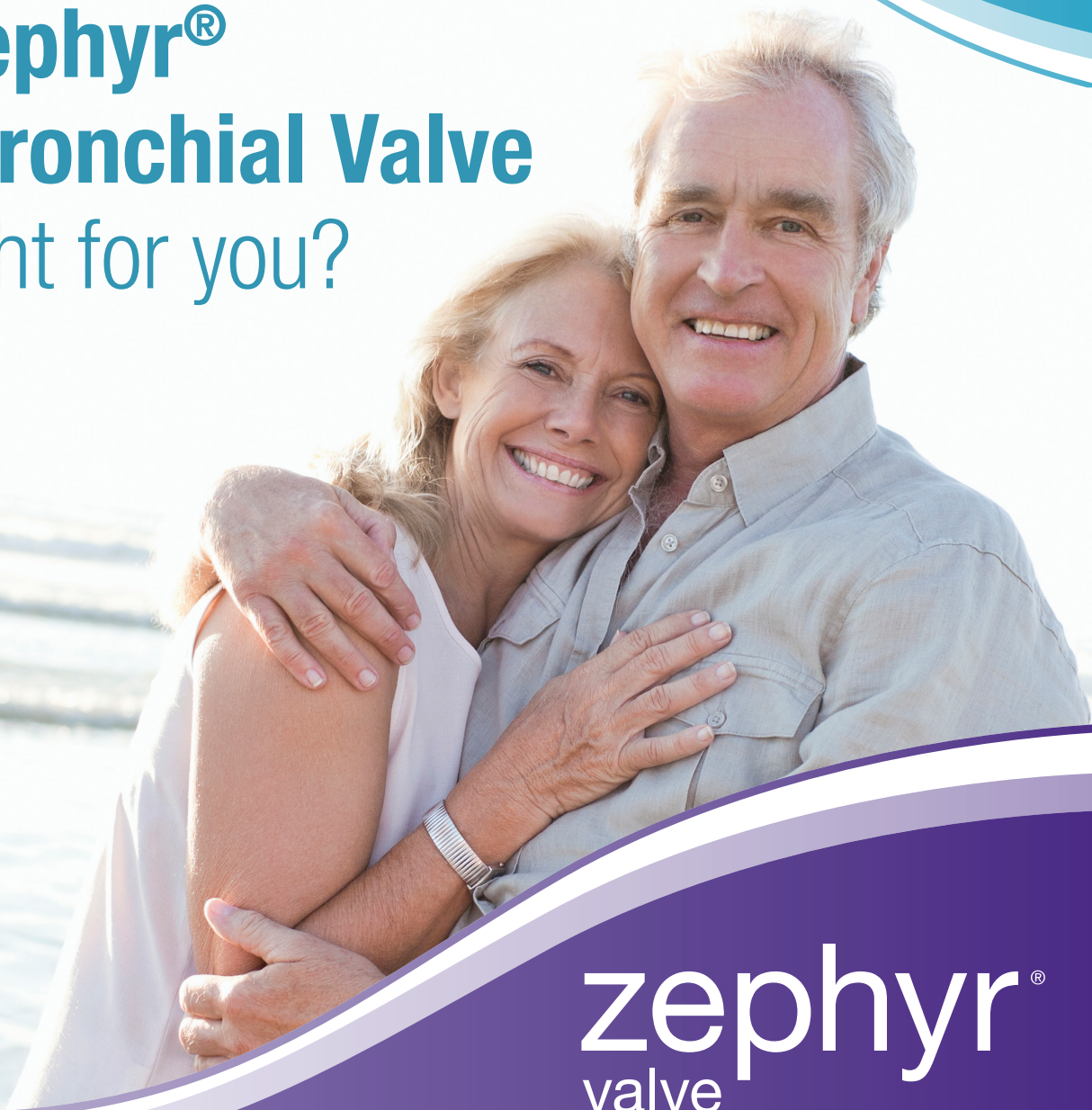


PATIENT EDUCATION

The Zephyr[®] Endobronchial Valve

Is it right for you?



zephyr[®]
valve



Introduction

Zephyr Valves are a breakthrough technology that is clinically proven to help patients breathe easier, be more active, and enjoy a better quality of life.¹

The Zephyr Valve is not another medication or surgery. It is a minimally invasive procedure that uses a bronchoscope to place tiny valves in your airways. The Zephyr Valves allow trapped air from your treated lung to escape while preventing air from entering that lung so hyperinflation in the lung is reduced. This leaves room for the healthier parts of your lungs to expand and take in more air.

Learn More About Zephyr Valve Treatment

If you have severe emphysema, a form of COPD, you may be a candidate for the Zephyr Valve Treatment.

There are several important steps you can take to see if Zephyr Valves could help you breathe easier, do more, and enjoy life. It starts with contacting your treating doctor.



Emphysema is not holding me back anymore...I am back to doing the things I enjoy in life.

– Jim, 76

Steps for Zephyr Treatment



Initial Consultation



Clinical Work-Up



Procedure



Post-Procedure Follow-Up



I felt the difference immediately...I am back to living life.

– Mike, 65



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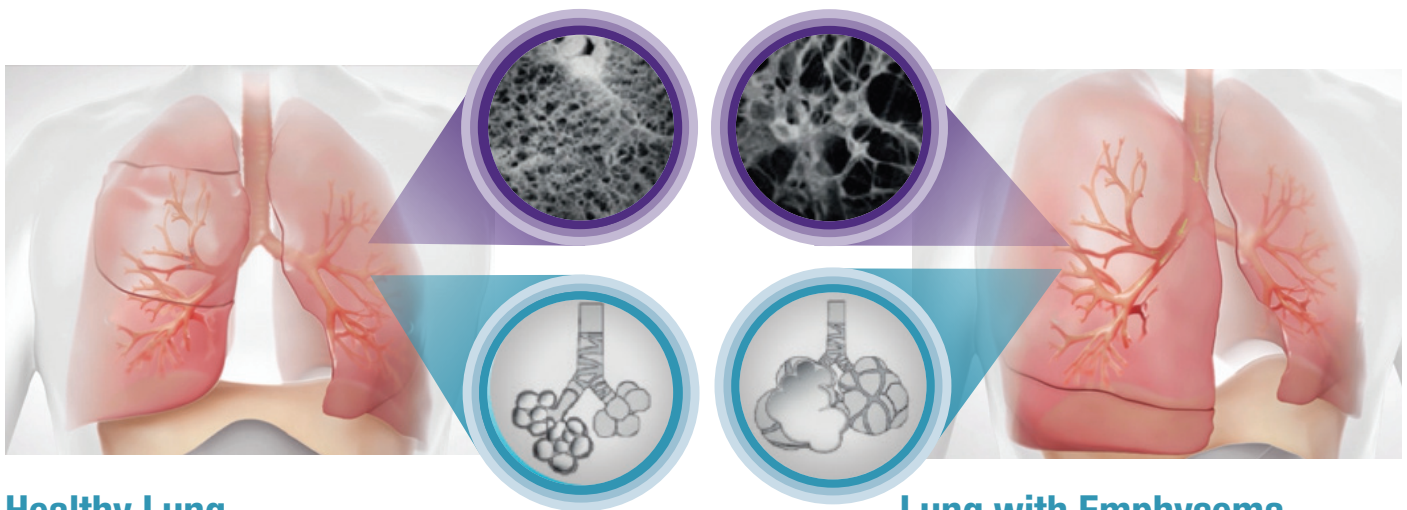
Chapter 1: What is COPD/Emphysema?

COPD stands for Chronic Obstructive Pulmonary Disease. It is a disease that causes persistent airflow limitation in the lungs. The symptoms of COPD include breathing difficulty, cough, mucus production, and wheezing.

Emphysema is a severe form of COPD where the damage to the lung results in creation of large air spaces instead of small ones where air you breathe becomes trapped (like a balloon) and the lung overexpands — this is called **hyperinflation**.

Chronic bronchitis is a form of COPD which involves long-term cough and mucus production (Zephyr Valves do not work in patients with Chronic Bronchitis).

The expansion of the diseased parts of the lung puts pressure on the healthy parts of your lungs and diaphragm. This is what causes you to feel out of breath. (See diagram)



Healthy Lung

Healthy air sacs are small and do not trap air you breathe in

Lung with Emphysema

Damaged air sacs are larger and create more space for the air you breathe in to get trapped

Zephyr Valves work to reduce the hyperinflation associated with severe emphysema by preventing the air you breathe in from getting trapped in the damaged part of the lung.

Homogeneous vs. Heterogeneous Emphysema

Patients with emphysema are classified into two different groups based on the distribution and extent of damage to the lungs — homogeneous and heterogeneous.

Homogeneous emphysema is where damage is uniform throughout the lungs (disease is the same all over). Heterogeneous emphysema is where damage is concentrated in specific areas of the lung.

Below are images of homogeneous and heterogeneous emphysema. Zephyr Valves are proven to be effective in both homogeneous and heterogeneous emphysema.

This is an example of **homogeneous emphysema**, where the disease destruction is similar in all areas of the lungs. Notice the uniform color all over.



This is an example of **heterogeneous emphysema**, where some areas show more disease destruction than other areas. Notice that some sections of the lungs are darker than other sections.



Chapter 2: Understanding the Lungs

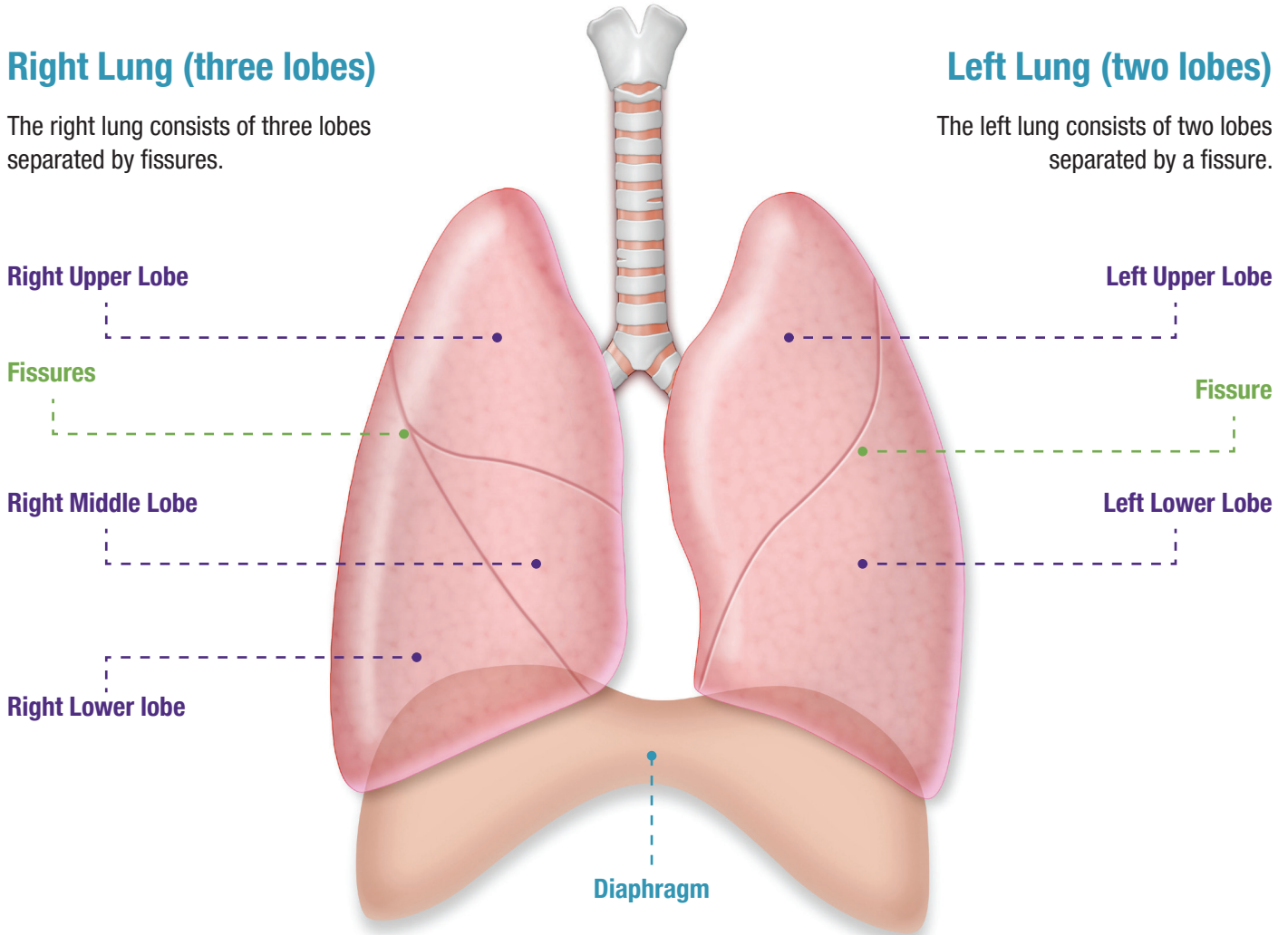
Your lungs are the main organ in your body that continuously supply oxygen (which is good) and remove carbon dioxide (which is bad) from the blood. The primary muscle used to breathe is called the diaphragm and is located directly below the lungs.

Right Lung (three lobes)

The right lung consists of three lobes separated by fissures.

Left Lung (two lobes)

The left lung consists of two lobes separated by a fissure.



What are Fissures and Why They Matter

Lung fissures separate the individual lobes in your lungs.

For the Zephyr Valves to work properly, you must have fissures between the lobes that have no gaps. A complete fissure prevents collateral ventilation between two lobes.

What is Collateral Ventilation?

Collateral ventilation happens when the fissure structure between lobes is not solid and air can pass through from one lobe to another. It is as if the fissures are walls and there is a window in that wall that allows air to pass through from one lobe to the adjacent lobe.

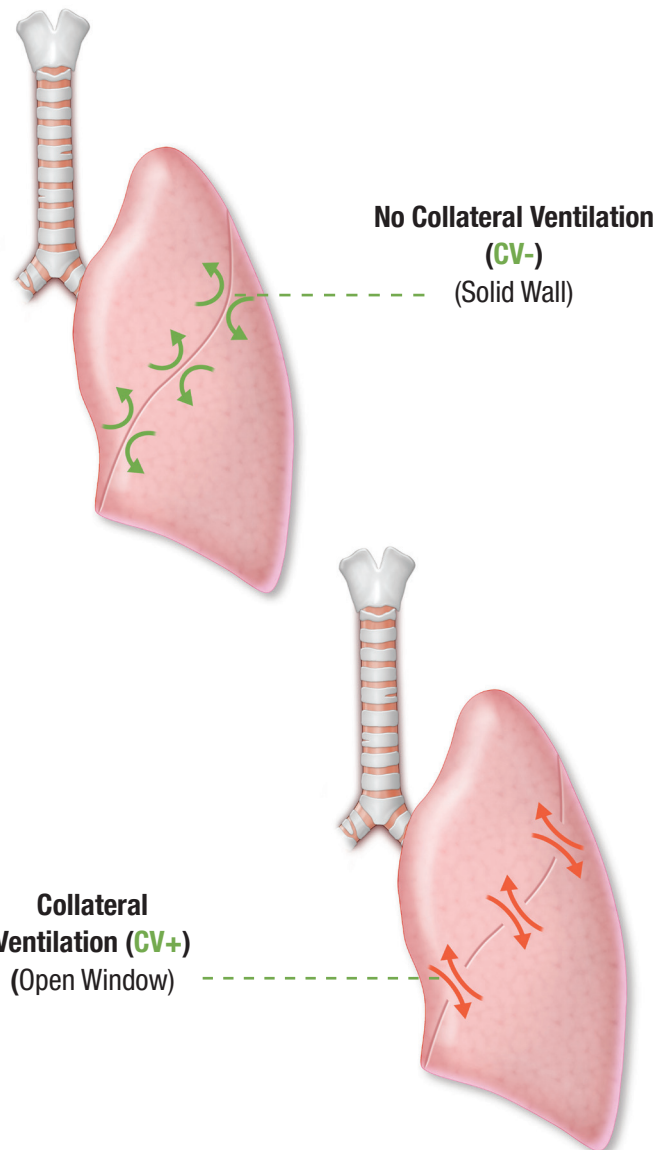
Why Zephyr Valves Will Not Work if There is Collateral Ventilation

Zephyr Valves work by releasing trapped air in the damaged, hyperinflated parts of the lung, preventing air from entering, and not allowing the part of the lung to re-inflate. When there is collateral ventilation, it makes it difficult for the Zephyr Valves to successfully keep the damaged areas from re-inflating.

Testing for Collateral Ventilation

Your Zephyr Valve Treating Doctor will use two tests to look for Collateral Ventilation (CV). The first is a computer-aided analysis of a CT scan, where pictures of your lungs show potential CV status. Then, on the day of your Zephyr Valve procedure, the doctor will check with a different test before placing the valves. Read more about these tests in the next two chapters.

Understanding Collateral Ventilation, the Good and Bad:

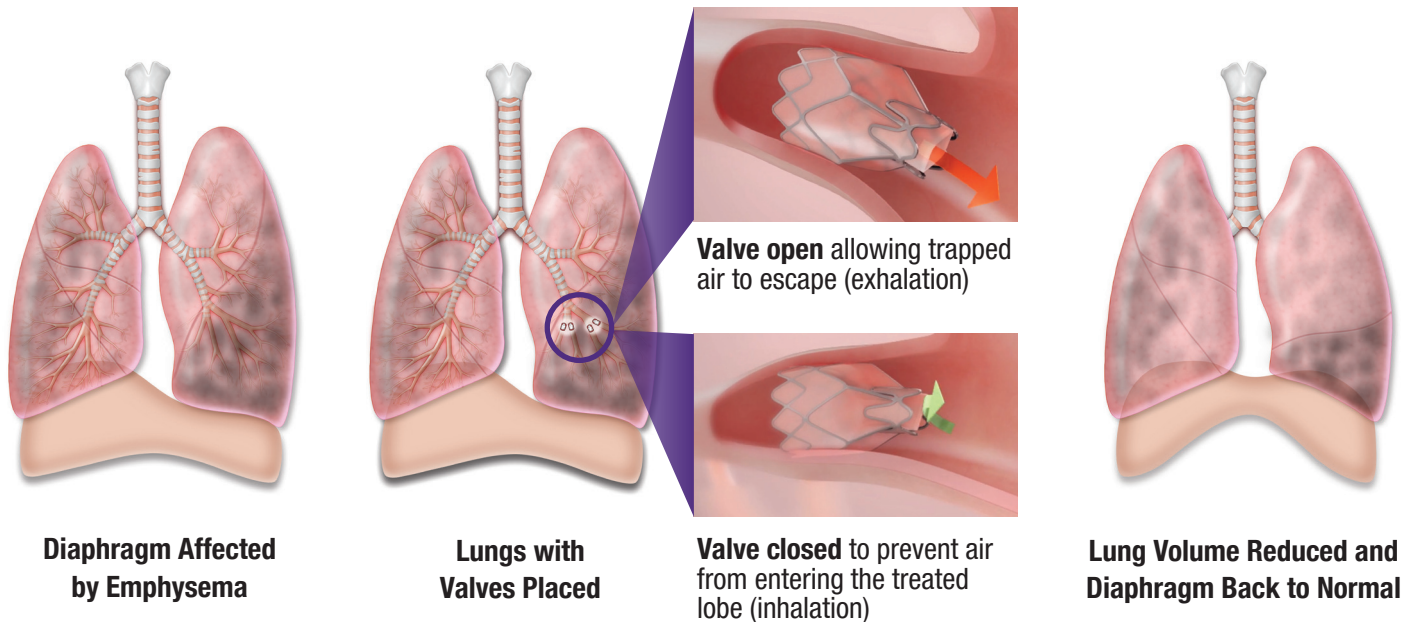


Chapter 3: How Do Zephyr Valves Work?

When Zephyr Valves are placed in a lobe, the one-way valves open when you breathe out (exhalation) allowing trapped air to move out of the treated lobe. They close when you breathe in (inhalation) to prevent air from re-entering the lobe.

Over time, the treated lobe deflates/shrinks (like a balloon losing air). This allows the healthier portions of the lung to take in more air and expand to fill the space created by the shrinking of the treated lobe. This also reduces the pressure on the diaphragm allowing it to return to its normal shape and function.

Zephyr Valves Reduce Hyperinflation



Chapter 4: Testing to Confirm You Have Severe Emphysema

Your doctor will carry out a number of tests to confirm that you have severe emphysema with hyperinflation and to determine if Zephyr Valves may help you. You may already be familiar with some of these tests, but some may be new.

Please refer to the table below for information regarding each of the tests and their purpose. Completion of all required tests can take between 1–8 weeks depending on availability.

The below values are guidelines. The final clinical decision about whether you are a good candidate for this procedure will be made by your treating physician.

TESTS	DESCRIPTION OF TEST	TYPICAL VALUES TO QUALIFY FOR ZEPHYR VALVES
Spirometry	Measures how your lungs work, then your values are compared to normal values based on height, gender, and age	FEV ₁ =15% to 45% of predicted
Body Plethysmography	Determines how much air is trapped in your lungs from emphysema	Residual Volume ≥ 175% Predicted Heterogeneous Residual Volume ≥ 200% Predicted Homogeneous Total Lung Capacity > 100% predicted
High Resolution CT Scan	Determines disease severity and air volume by lobe Also evaluates fissure anatomy that separates the lobes from each other (for collateral ventilation)	Provides information on the degree of damage to different parts of the lung and information on fissure completeness to help target where to place Zephyr Valves
Perfusion Scan	Looks at which parts of your lung receive the most air and blood circulation	Helps to target areas of the lungs that are not functioning as well as others as good targets for treatment
6-Minute Walk Test	Measures how much your emphysema affects your ability to exercise	100 to 500 Metres (Heterogeneous Emphysema) 150 to 500 Metres (Homogeneous Emphysema)
Arterial Blood Gas (ABG)	Measures the amount of oxygen and carbon dioxide in your blood	PaCO ₂ < 50 mm Hg PaO ₂ > 45 mm Hg
Echocardiogram	Measures your heart and lung function	Left Ventricular Ejection Fraction LVRF > 45% sPAP < 45 mm

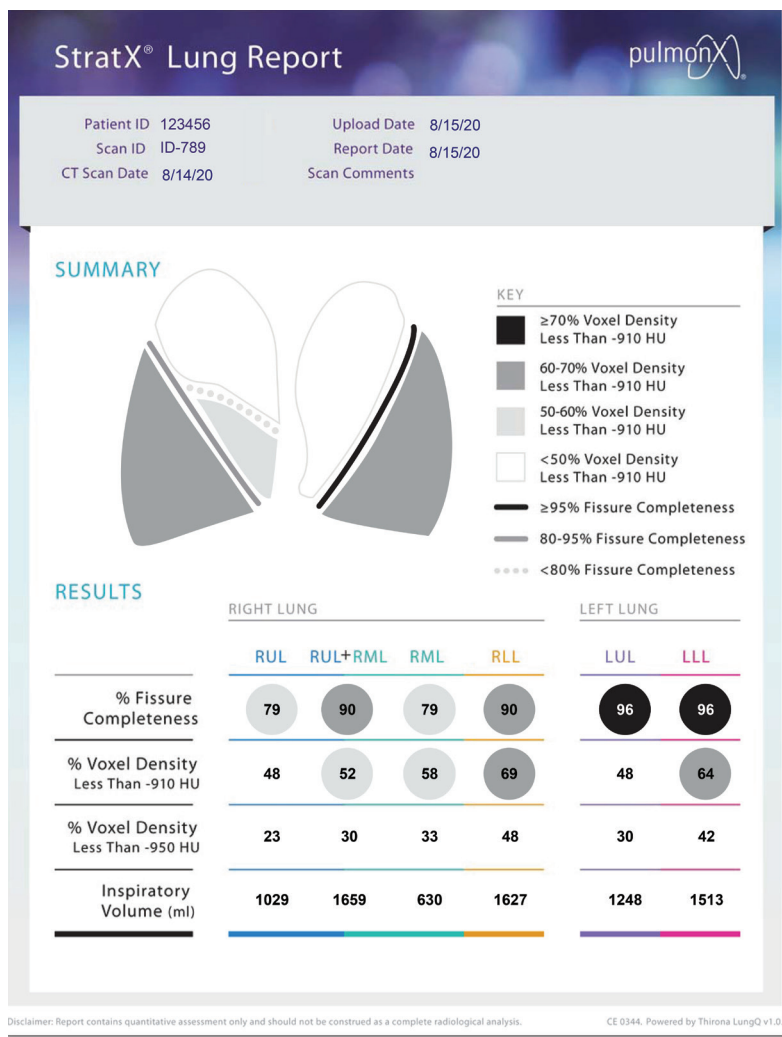
Diagnostic Tests to Confirm if Zephyr Valves May Help You

High-Resolution Computed Tomography (HRCT) Scan — This is a special X-ray procedure that takes very thin slice images of your lungs to create a computer-generated 3D image, which is used by your doctor to evaluate the condition of your lungs. You may have a previous CT scan. However, if the previous scan did not include a sufficient number of images, you may be required to have a new CT scan.

Your doctor will send your HRCT scan to be evaluated through a special software called **StratX®** and will receive a report that has important information about your lung disease that will tell them:

- the amount of emphysema damage to each lobe within your lungs
- whether your fissures are complete or incomplete, and if incomplete, how incomplete
- how much air you have in each lobe

This scan helps to determine if you are a good candidate for Zephyr Valves and if you are, which part of the lung should be treated. It also helps your doctor to look for other medical conditions.



Chapter 5: Pulmonary Rehabilitation – Pre and Post Procedure

Pulmonary Rehabilitation (PR) is a supervised programme focused on helping patients with lung disease by providing education and exercise with the goal of making breathing easier and improving activities of daily living.



These programmes are specific and tailored to you.

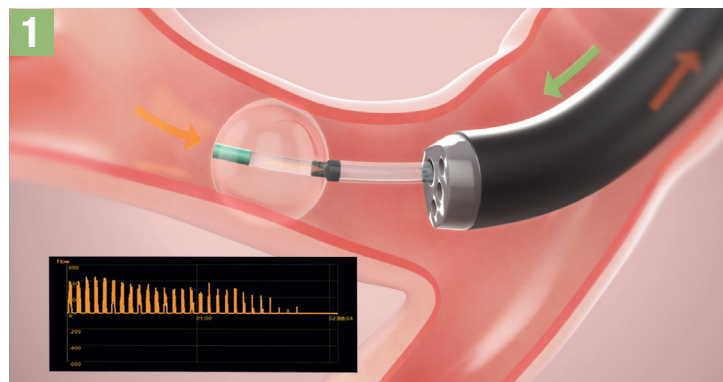
- Programmes are typically around 6–8 weeks long. They include:
 - Breathing exercises
 - Education for the individual and family
 - General exercise
 - Lifestyle modifications
 - Nutritional interventions
 - Psychosocial support
 - Strengthening programmes
- PR is recommended for all Zephyr Valve patients both before and after treatment to help with outcomes
- You usually get referred for PR either by your GP, practice nurse, or respiratory team. They will help identify programmes to complete your PR.

Chapter 6: What to Expect During the Zephyr Valve Procedure

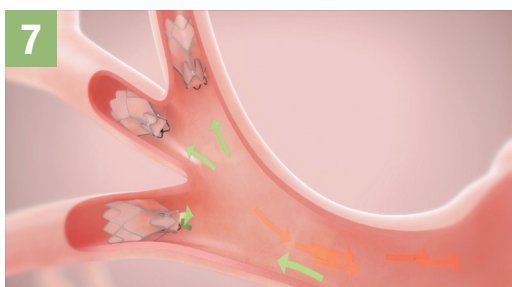
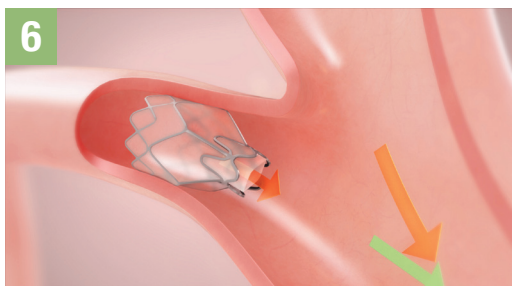
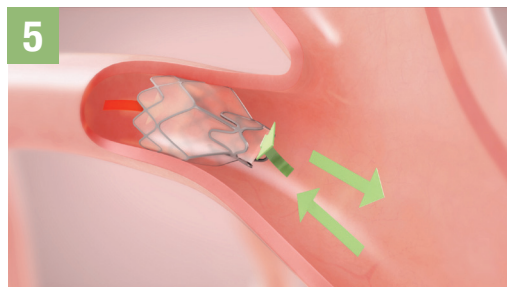
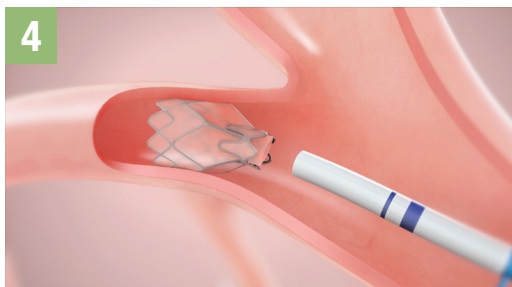
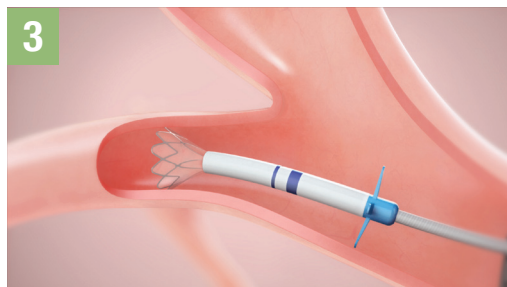
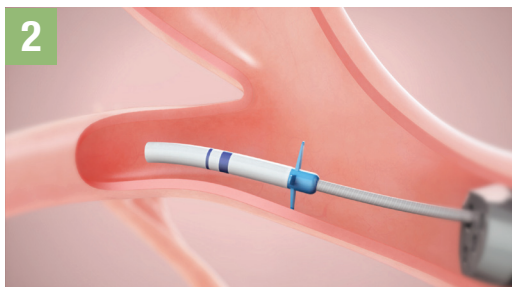
On the Day of the Zephyr Valve Procedure:

- Your doctor will give you medicine for sedation/ anesthesia.
- A long, flexible tube with a camera (called a bronchoscope) will be inserted through your mouth or nose so that the doctor can view your airways.
- Your doctor will use a balloon on a catheter that is inserted through the bronchoscope to simulate the valve placement and test if you have collateral ventilation. This is called the **Chartis®** Pulmonary Assessment. **Step 1.**
- If you have **little or no** collateral ventilation, your doctor will place the Zephyr Valves using the bronchoscope. The number of valves will depend on the shape and size of the airways in your lungs. **Steps 2–7** (see page 14).
- No cutting or incisions will be needed to complete this treatment, and the procedure should last around 60 minutes.
- You will be carefully observed as you wake up and recover.

NOTE: If the Chartis test confirms that you have collateral ventilation, Zephyr Valves will **not** be placed because they will not provide any benefit to your breathing. Please see page 8 for more information on collateral ventilation.



Placing Zephyr Valves



I want to share my story because there are a lot of people who can benefit from these valves.
— Karen, 62

Chapter 7: What to Expect After the Zephyr Valve Procedure

After your Zephyr Valves are placed, you will be monitored closely by your doctor and the medical team.

Immediately Post-Procedure

You will remain in the hospital for at least three (3) nights in order for the medical team to watch for any side effects.

One side effect that can happen in up to one in three procedures is a **pneumothorax**, which is a tear in the lung that causes the air to leak from your lungs into your chest space.

This is usually treated by putting a small tube in your chest to let out the air from the tear. It can take from a few hours to a few days for the air leak to stop at which time the tube can be removed. If this happens your doctor may need you to stay in the hospital up to a week or longer for the tissue to heal.

Hospital Discharge

At the time of discharge from the hospital, your doctor or medical team will explain what to do if you experience certain symptoms such as:

- Sudden shortness of breath
- Sudden sharp pain in the chest
- Rapid breathing or coughing
- Rapid heart rate
- Sudden dizziness

*Patients who had a pneumothorax experienced long-term benefits from Zephyr Valves just like the patients who did not have a pneumothorax.**

If you experience any of the symptoms described (above), if you cough up any blood or there is blood in your sputum, or if you are having any other symptoms not related to your breathing, you should call your doctor or go to the nearest emergency department.

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

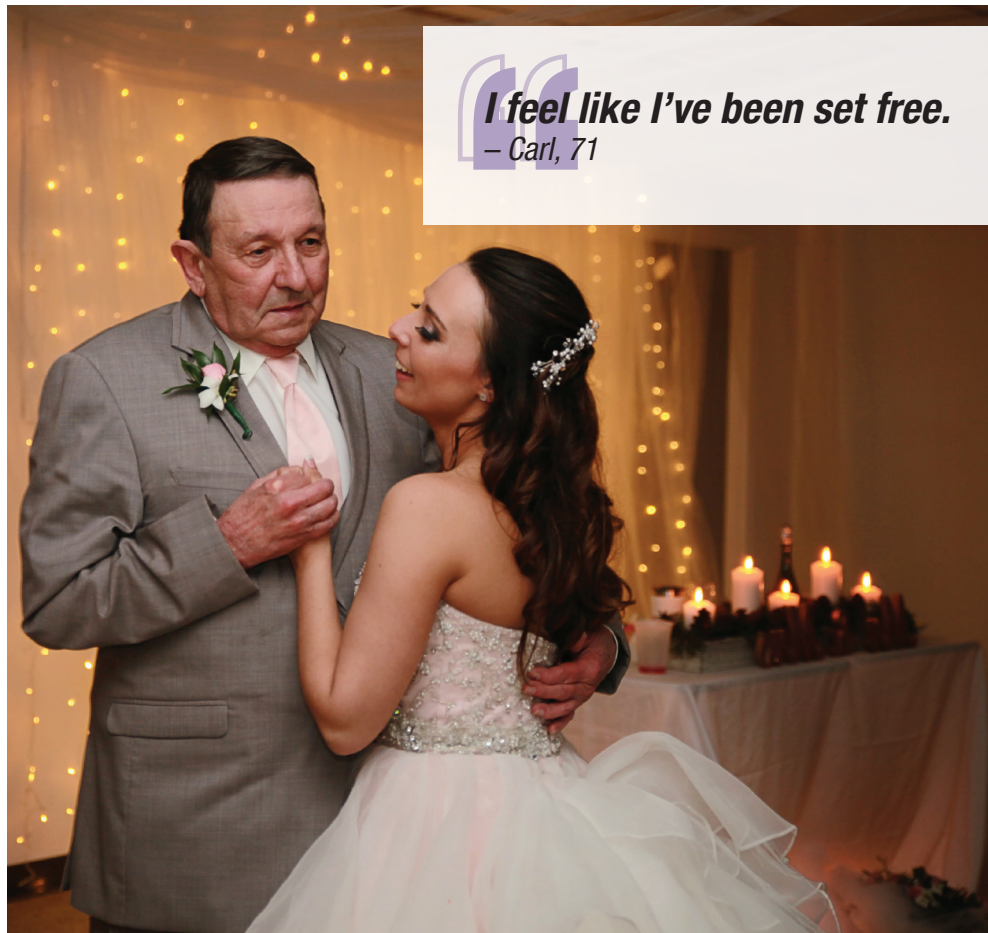
Your doctor may prescribe a course of antibiotics or steroid medication for you after your procedure.

You will be given a wallet-sized patient information card (patient ID card) stating that you have one or more Zephyr Valve implants in your lung, and it will have the contact information of your doctor. Always keep this card with you and show it to anyone who gives you medical care, including any emergency room medical staff, or to anyone who plans to perform an MRI scan. Patients with Zephyr Valves can safely undergo MRI scans with the instructions provided on your patient ID card.

Patients with Zephyr Valves can safely pass through metal detectors or X-ray machines at airports or other facilities where security checks are performed for entry.

Your doctor will schedule follow-up evaluations in the doctor's office after your airways recover from the treatment.

You will continue to use the medicines that your doctor has prescribed for your severe emphysema.



I feel like I've been set free.
– Carl, 71

Chapter 8: The Benefits and Risks of Zephyr Valves

In clinical trials, patients treated with Zephyr Valves were compared to patients on standard medical care (COPD medications plus pulmonary rehabilitation and oxygen, if required).

Zephyr Valve Treated Patients Were Found to:¹

- Breathe easier and have improved lung function
- Be able to do more exercise and walk further
- Be able to do more daily life activities, such as walking, bathing, and gardening
- Enjoy a better quality of life with more energy
- Feel more confident leaving their home

Complications of endobronchial valve treatment can include, but are not limited to, pneumothorax, worsening of COPD symptoms, pneumonia, dyspnea, and, in rare cases, death.



Chapter 9: Frequently Asked Questions



***I have a positive attitude
and look at what I can
do now.***

– Nancy, 69

General Questions:

Are the Zephyr Valves widely used?

In the past 10 years, more than 25,000 patients around the world have received Zephyr Valves.

Are Zephyr Valves available on the NHS?

Yes, Zephyr Valve treatment is recommended by The National Institute for Health and Care Excellence (NICE) and available on the NHS.

After the procedure will I still have to take my regular medications?

Yes, you will continue to take your medications as prescribed by your doctor for your condition.

After the procedure will I still need my supplemental oxygen?

In our LIBERATE¹ study - conducted for Zephyr Valve approval in the US — at 12 months more patients treated with the Zephyr Valves used less oxygen compared to untreated patients (15.7% vs. 6.9%, respectively). At the same time, more untreated patients reported increased oxygen use.

What are Zephyr Valves made of?

Zephyr Valves are made of **Nitinol** (nickel-titanium) and Silicone. Zephyr Valves are contraindicated in patients with known

allergies to nitinol and silicone.

General Questions (continued):

Who cannot have the Zephyr Valve treatment?

Patients who:

- Are unable to have a bronchoscopic procedure
- Have an active lung infection
- Have an allergy to Nitinol, nickel, titanium, or silicone
- Have not stopped smoking
- Have an air pocket (bullae) that is greater than 1/3 of the size of the lung

Zephyr Valves are unlikely to work in patients who:

- Have passages or channels in their lungs that bypass the normal airways (collateral ventilation)
- Have chronic bronchitis
- Have IPF or lung scarring
- Have active uncontrolled exacerbations

Before having the Zephyr Valve Treatment, patients should tell their doctor if they:

- Have had a lung transplant, lung volume reduction surgery, or any other major procedure in the lungs
- Have heart disease or had a recent heart attack

Is there an age limit?

The procedure is for adult patients (18 years and older). A Zephyr Valve trained physician will determine if you are a candidate but there is no strict upper age limit.

When will I feel the benefits?

While a majority of patients experience the benefit early after placement of valves, a number of patients appear to take longer to feel the benefits. Every patient is different. However, your physician will schedule follow-up visits at 45 days, six months, and a year post-procedure to monitor your progress following treatment. If it is determined during the follow-up evaluations that you have not experienced any benefit, you may be evaluated to make sure all the valves are appropriately located. If needed, you may undergo another procedure to replace or add one or more valves to help improve your condition.

What are the success rates?

The carefully conducted clinical trials of the Zephyr Valve procedure show that over 75% of the treated patients had meaningful benefit in one or more of the outcomes of improved lung function, improved ability to exercise, and improved quality of life.¹ As with any medical product, individual patient outcomes from the use of Zephyr Valves outside of these clinical studies may vary.

Can the valves come out?

The Zephyr Valves are designed to be permanent, but they are



Patient Checklist

General Information:

Treatment Centre: _____

Phone Number: _____

First Appointment: _____

Tests to Get:

(Your doctor will determine the tests you need, as not all are required):

- Pulmonary Function Tests (PFTs) _____
 - Spirometry _____
 - Body Plethysmography _____
 - Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO) _____
- Arterial Blood Gas (ABG) _____
- 6-minute walk test (6MWD) _____
- HRCT Scan _____
- VQ Lung Scan/Perfusion Scan (if recommended by your doctor) _____
- Echocardiogram (Echo) _____
- Confirm Vaccinations (flu & pneumococcal) _____
- Other _____

Doctor: _____

Address: _____

Pulmonary Rehab:

Start Date: _____

End Date: _____

Procedure Information

Treatment Date: _____

Follow-up Appointments:

- Plan appointment _____

Glossary of Terms

6-minute walk test (6MWD) — Test to measure your ability to tolerate physical activity. During this test, you walk as far as you can for six minutes at a normal pace.

Alveoli — Tiny air sacs in your lungs that deliver oxygen to your bloodstream and remove the carbon dioxide. Alveoli are damaged in people with emphysema.

Arterial Blood Gas (ABG) — Measures the amount of oxygen and carbon dioxide in your blood.

Body Plethysmography — A test to measure how much air your lungs can hold after you take in a deep breath (called Total Lung Capacity or TLC), and how much air is left in your lungs after breathing out as much as you can (called Residual Volume or RV). Also called a body-box.

Bronchoscope — A flexible tube with a camera (called a bronchoscope) which is inserted into your lungs through the nose or mouth.

Chartis — A procedure to test for collateral ventilation. A small balloon attached to a catheter is inserted through a bronchoscope into your lungs to temporarily close an airway in a part of the lung and look to see if air is entering the blocked lobe through collateral ventilation.

Chronic Bronchitis — One form of COPD in which your lungs produce a lot of mucus which causes a long-term cough. Zephyr Valves cannot be used to treat chronic bronchitis.

Collateral Ventilation — When air passes between the lobes of your lungs, like passing through an open window between the lobes. You could be CV+, meaning the air is flowing between the lobes or CV-, meaning it is not. People who are CV+ are not eligible to receive Zephyr Valve treatment. Your doctor can perform a test on the day of your procedure to determine if you are CV+ or CV-.

COPD — A chronic inflammatory lung disease that causes obstruction of airflow from the lungs. Symptoms include breathing difficulty, cough, mucus (sputum) production, and wheezing. Emphysema is one form of COPD.

Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO) — A measure of how well your lungs can exchange oxygen to your bloodstream from the air that you breathe into your lungs.

Echocardiogram (Echo) — A test that uses sound waves to create pictures of your heart. It will provide your doctor information on whether the condition of your heart is stable enough to undergo a bronchoscopic procedure.

Emphysema — A lung condition that causes shortness of breath. In people with emphysema, the air sacs in the lungs (alveoli) are damaged. Over time, the inner walls of the air sacs weaken and rupture — creating larger air spaces instead of many small ones.

Fissures — A boundary that separates lobes within your lungs from each other.

Glossary of Terms (continued)

Homogeneous and heterogeneous emphysema —

These terms are used to describe the level of damage throughout your lungs. Heterogeneous emphysema refers to more damage in some areas of the lung compared to others. Homogeneous emphysema refers to damage that is evenly distributed throughout your lungs. Some other treatments are not able to treat both kinds of emphysema. Zephyr Valve treatment has been proven effective in clinical studies for both kinds of severe emphysema.

HRCT or CT Scan — Special X-ray procedure that combines many X-ray images with the help of a computer to generate views through your lungs that allows your doctor to evaluate the condition of your lungs.

Hyperinflation — Air becomes trapped in your lungs and they overexpand, putting pressure on healthy parts of your lungs and your diaphragm, causing you to feel out of breath.

Lobes — Your lungs are divided into five separate lobes, three in the right lung and two in the left lung.

Minimally invasive procedure — Any procedure that requires little or no cutting or incisions. Zephyr Valve treatment is performed without any incisions, as the valves are placed in your lungs using a bronchoscope, which is inserted through your nose or mouth.

Nitinol — Nitinol is a metal alloy made from Nickel and Titanium.

Pneumothorax — A tear in the lung that causes the air to leak from your lungs into your chest space. This is usually treated by putting a small tube in your chest to let out the air from the tear. It can take from a few hours to a few days for the air leak to stop at which time the tube can be removed, and you can go home. If this happens your doctor may need you to stay in the hospital up to a week or longer for the tissue to heal.

Pulmonary Function Tests (PFTs) — Breathing tests to measure how well you move air in and out of your lungs and how well oxygen enters your bloodstream.

Pulmonary Rehabilitation — A programme of education and exercise to increase awareness about your lungs and your disease and exercises to improve your breathing. Exercising your lungs and your muscles helps you be more active. You may do pulmonary rehabilitation before your procedure to get your lungs as healthy as possible and it is also recommended after your procedure to recondition your lungs and improve your overall breathing.

Spirometry — A common test to measure how much air you can breathe into your lungs and how much air you can quickly blow out of your lungs.

StratX Lung Assessment — This test evaluates how much damage you have in your lungs and the likelihood that you could benefit from Zephyr Valves treatment. The results help your doctor to identify which lobes could be treated with Zephyr Valves.

Glossary of Terms (continued)

VQ Lung Scan or Ventilation Perfusion Scan — This test measures the distribution of air and blood flow in all areas of the lung and helps your doctor determine which lobes are functioning well and which lobes are functioning poorly.

Zephyr Valve Treatment — The Zephyr Valve procedure is minimally invasive and does not require cutting or incisions. A doctor uses a bronchoscope to position a long, flexible catheter into your lungs and place tiny valves into your airways. Once the valves are placed, trapped air in your lungs can escape. The valves also prevent fresh air from entering the part of the lung that has been treated. This causes the treated lobe to collapse and creates room for the healthier parts of your lungs to expand and take in more air.

Additional Notes

Get more information about the Zephyr® Valve treatment for severe emphysema.

www.getcopdhelp.co.uk

Email: info@getcopdhelp.co.uk

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.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

Brief Statement: 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 with little to no collateral ventilation, 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.

1. Criner, GJ, Sue, R, Wright, S, Dransfield, M, Rivas-Perez, H, Wiese, T & Morrissey, 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.

zephyr®
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