

Zephyr® Endobronchial Valve – A New Treatment for Severe Emphysema



This brochure describes a new procedure for treating severe emphysema in adults.
Caution: Federal law restricts this device to sale by or on the order of a physician.

zephyr®
valve



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What is Severe Emphysema?

Emphysema is a form of chronic obstructive pulmonary disease or COPD. In severe emphysema, parts of the lungs are damaged, which traps air in your lungs. This causes the diseased parts of the lung to get larger and put pressure on the healthy parts of your lungs and diaphragm. As a result, you may find it difficult to breathe properly and take full, deep breaths.

This constant shortness of breath can make it difficult to do everyday activities and to enjoy many aspects of your life – such as walking, bathing, dressing, gardening, preparing meals, and going out with family or friends – without stopping for air, resting or requiring help.



Healthy Lung



Lung with Emphysema

Zephyr® Endobronchial Valve –

A New Treatment Option for Severe Emphysema

Your doctor offers a new procedure to help you with severe emphysema. It is called the Zephyr® Valve treatment. The Zephyr Valve treatment is a procedure that allows a doctor to place one or more small valves in your airways, which release trapped pockets of air to improve your ability to breathe. It is not a medicine and it is not surgery.

Other Treatment Options

Emphysema cannot be cured; however, treatment may help reduce symptoms, improve quality of life, and slow progression of the disease.

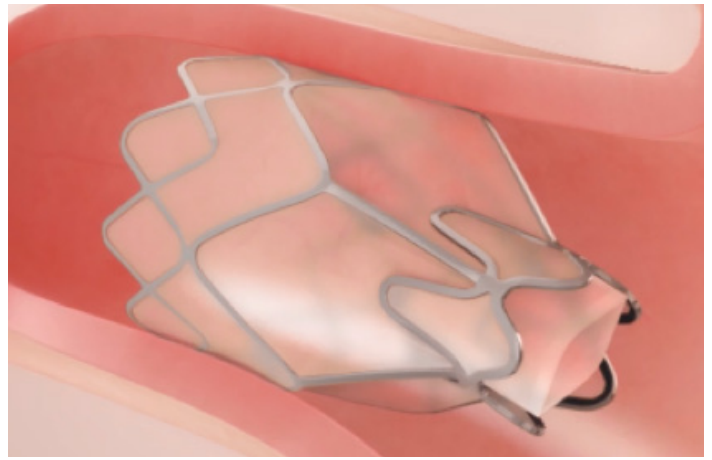
Current Emphysema Treatment Options:

- Stop smoking
- Medication
- Long term oxygen therapy
- Pulmonary rehabilitation
- Surgical lung volume reduction
- Lung transplant

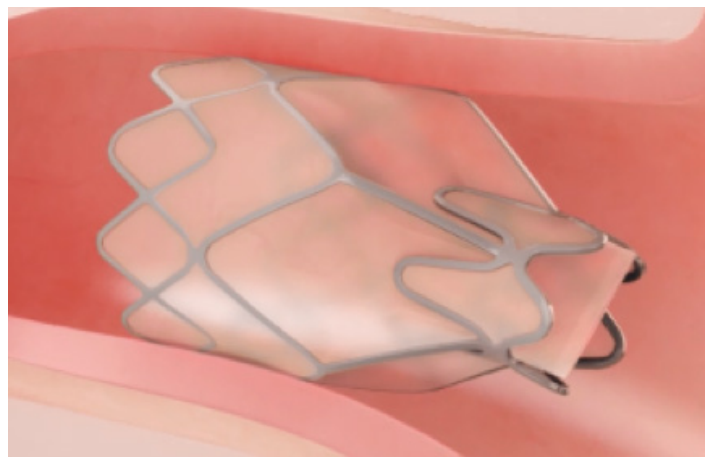


What is the Zephyr Valve?

Zephyr Valves are tiny valves placed in the airways to occlude or block a diseased part of the lungs and reduce hyperinflation. This helps the healthier parts of the lungs to expand and lifts pressure off the diaphragm, thereby decreasing shortness of breath and making breathing easier.



When the Zephyr Valve is placed in the airway, the valve opens to allow trapped air to escape until lung volume of the treated lobe is reduced

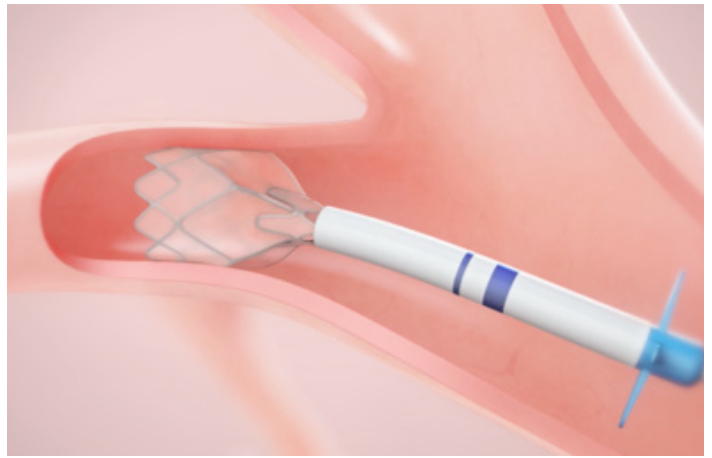


The Zephyr Valve closes to block air from entering the damaged part of the lung to allow the healthier lobes to expand.

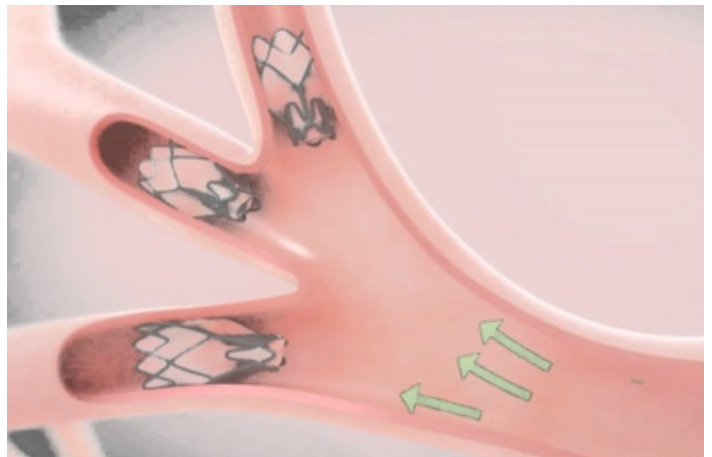
What is the Zephyr Valve treatment?

If your doctor agrees that you are good candidate, you will be sent to a specialist to decide if you qualify for treatment. The 30 to 60 minute Zephyr Valve procedure is performed in a hospital. The doctor will give you medicine to make you sleepy and insert a small tube with a camera (called a bronchoscope) into your lungs through your nose or mouth. The doctor will use the same tube to place between 3 to 5 Zephyr Valves in the airways in the part of the lung being treated. After the procedure, you will continue to use the medicines that your doctor has prescribed for your condition.

You can go home after 3 to 5 days unless you have side effects such as a small tear in the lung tissue, which can happen in up to 1 in 3 procedures. If this happens your doctor may put a small tube in your chest to let out the air from the tear, and you may need to stay in the hospital up to a week longer for the tissue to heal.



Placement of Zephyr Valve



Multiples Zephyr Valves in Place

Who can have the Zephyr Valve treatment?

The Zephyr Valve is used to treat patients whose lungs are increased in size by trapped air due to severe emphysema. Before you are treated, your doctor will give you a test to check that the blocked part(s) of your lung cannot refill with air from side passages from other parts of your lung.

Who cannot have the Zephyr Valve treatment?

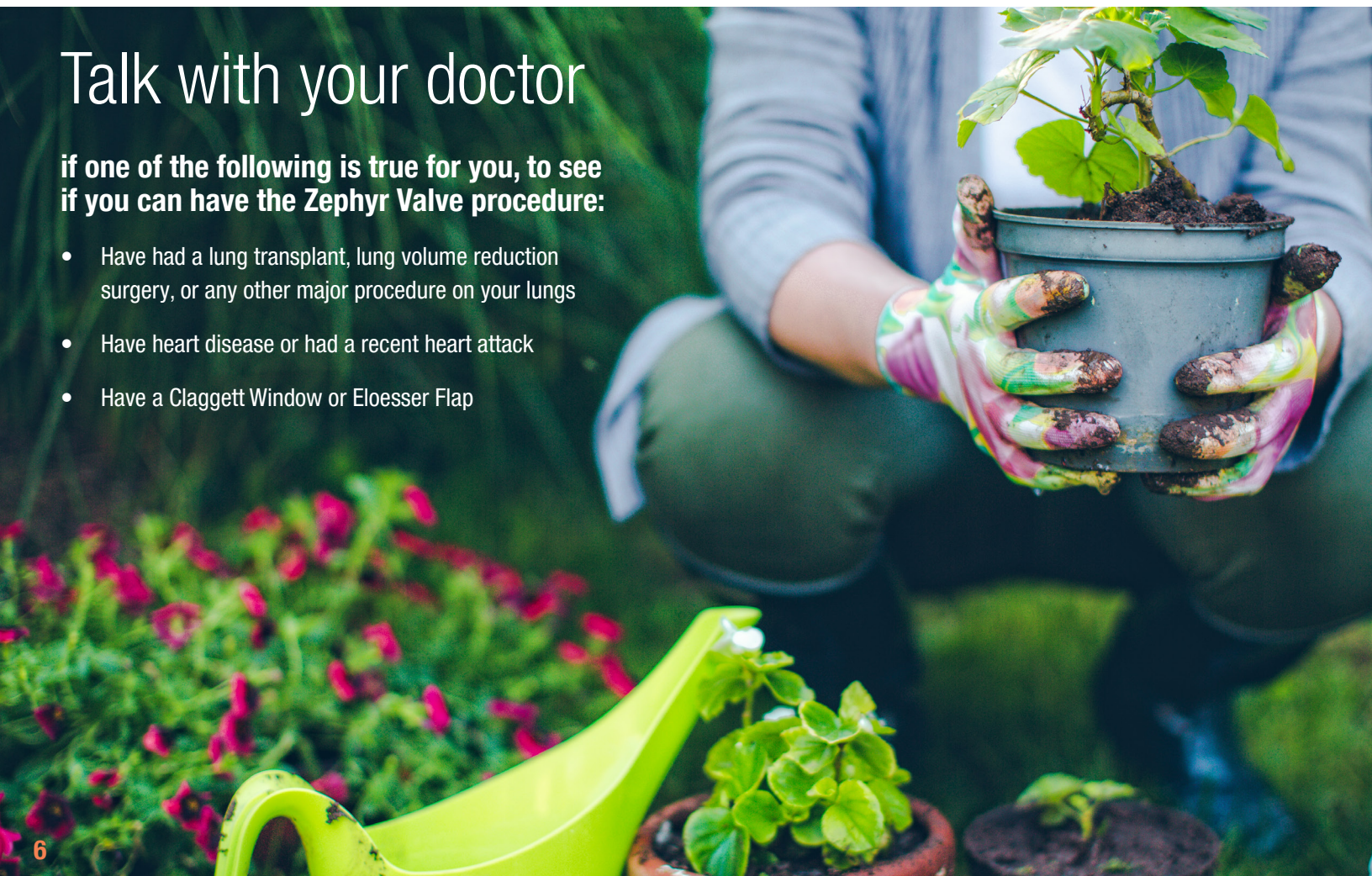
You cannot have this treatment if you:

- 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

Talk with your doctor

if one of the following is true for you, to see if you can have the Zephyr Valve procedure:

- Have had a lung transplant, lung volume reduction surgery, or any other major procedure on your lungs
- Have heart disease or had a recent heart attack
- Have a Claggett Window or Eloesser Flap



Zephyr Valve Clinical Studies Results

The Zephyr Valve has been studied in multiple clinical trials with patients in the United States, Europe, and Brazil. In these clinical trials, the Zephyr Valve was placed in over 1,000 patients with severe emphysema. In these studies, patients who had Zephyr Valves and were taking their normal emphysema medicines were able to breathe better, could do more exercise and had better quality of life than patients who did not have the Zephyr Valves.



Risks

What are the side effects of Zephyr Valve treatment?

In the most recent LIBERATE clinical trial, patients receiving Zephyr Valves had an increased risk of the following side effects in the first 45 days (in order of severity):

- Death
- Air Leak, also known as Pneumothorax (tear in the lung)
- Pneumonia
- Worsening of Emphysema Symptoms
- Coughing up Blood
- Shortness of Breath
- Chest Pain or Chest Discomfort
- Cough

This list does not include all the side effects that were seen in the clinical trials. You should talk with your doctor for more information regarding the Zephyr Valve procedure.

After the first 45 days, the LIBERATE patients who received the Zephyr Valve did not have an increased risk of side effects. About 1 in 5 patients in LIBERATE had a second bronchoscope procedure to adjust the valves position or to manage side effects.

Benefits

Zephyr Valves provide significantly more benefit than medicine alone

In the LIBERATE clinical trial, at 1-year, the patients who received the Zephyr Valve experienced the following benefits compared to patients on medications alone.

- Increased exercise capacity - they could walk further
- Could do more daily life activities, such as walking, gardening, and getting ready in the morning, with less shortness of breath
- Increased lung function, as measured by FEV1
- Better quality of life

What happens before and during treatment?

- Your doctor will do an examination and perform lung function tests to determine if you are a good candidate.
- At the time of your procedure, your doctor will give you medicine that will make you sleepy and insert a flexible tube with a camera (called a bronchoscope) into your lungs through your nose or mouth.
- Your doctor will place the Zephyr Valves using the bronchoscope. The number of valves will be dependent on the structure of your lungs.
- The procedure should last between 30 to 60 minutes.
- After the procedure the bronchoscope is removed from your nose or mouth.
- You will be carefully observed as you wake up and recover.

What happens after treatment?

- You will be monitored closely by your doctor.
- You can go home after 3 to 5 days unless you have side effects like a tear in the lung tissue, which can happen up to 1 in 3 procedures. If this happens your doctor may put a small tube in your chest to let out the air from the tear and may need to stay in the hospital up to a week longer for the tissue to heal.
- Your doctor may recommend that you take antibiotics or steroid medicines after your Zephyr Valve procedure.
- You will be given a wallet-sized patient information card (patient ID card) that says you have one or more Zephyr Valve implants in your lung. It will also have the contact information of your doctor. Please keep this card with you at all times and show it to anyone who gives you medical care, including any emergency room medical staff. Please show your patient ID card to anyone who plans to perform an MRI scan.
- You will continue to use the medicines that your doctor has prescribed for your severe emphysema.
- After your airways recover from treatment, you will go back to your doctor for a checkup.


About 1 in 5 patients require an adjustment procedure. Zephyr Valves are removable. If you should require an adjustment procedure, one or more valves that have been previously placed are removed and replaced. During this procedure, your doctor may also place more valves as necessary to treat your lungs.

When should you seek medical help?

It is especially important to pay attention to symptoms within the first 2 weeks after any procedure.

- The risk of a tear in the lung (pneumothorax) is increased during the initial period post-procedure. This is a serious condition and requires (or may require) immediate emergency treatment. You should report to your local medical facility if you experience sudden chest pain, shortness of breath, rapid breathing or coughing, rapid heart rate, or sudden dizziness.
- If you cough up any blood or there is blood in your sputum, you should immediately go to your local medical facility or your doctor's office to be checked.
- Tell your doctor if you are having breathing symptoms or any other symptoms whether or not they are related to your breathing.





Get more information about the Zephyr Endobronchial Valve treatment for your emphysema.

Talk to your doctor

www.MyLungsMyLife.com

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zephyr[®]
valve

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