



## PATIENT INFORMATION GUIDE

### **A Clinical Trial for People with Emphysema**

This brochure describes a clinical trial using an investigational device for the treatment of emphysema. You and your doctor can determine if participation may be right for you.

# Clinical Trial to Evaluate a Non-Surgical Treatment for Emphysema

EMPROVE is a clinical trial to evaluate the IBV® Valve System. This is a treatment for patients with emphysema who have shortness of breath, but can still walk.



## Patients with Emphysema

With every breath, lungs deliver oxygen to the rest of the body to perform essential life functions. Lungs are made up of tiny air sacs which absorb the oxygen in the air you breathe. In patients with emphysema, these air sacs are gradually destroyed and lose their elastic strength, which makes it difficult for air to exit the air sacs. This allows air to become trapped in the most diseased areas of the lungs. The trapped air interferes with the function of the healthier areas of the lung, which adds to difficulty in breathing.

## Treatment Choices

Doctors now treat emphysema with drugs, oxygen, or in some cases, surgery. Surgery may not be appropriate for some patients, depending on their health status. Only your doctor can advise you on the appropriate therapy.



# The IBV<sup>®</sup> Valve Procedure

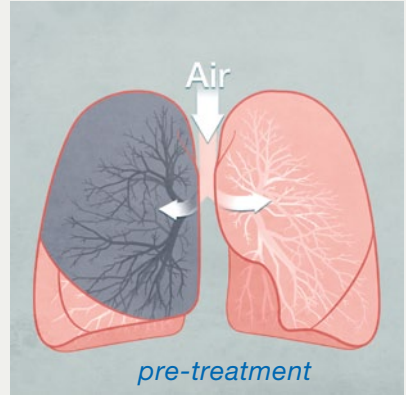
The IBV Valve is a small, umbrella-shaped, one-way valve that is placed inside the airways of a lung. It is used to redirect air from the less healthy to the more healthy parts of the lung.

This helps to reduce over-inflation while letting trapped air and fluids escape. The volume of the treated part of the lung is reduced, allowing healthier parts of the lung to expand and function more normally. This helps to reduce over-inflation and may improve overall lung function and quality of life for people living with emphysema.

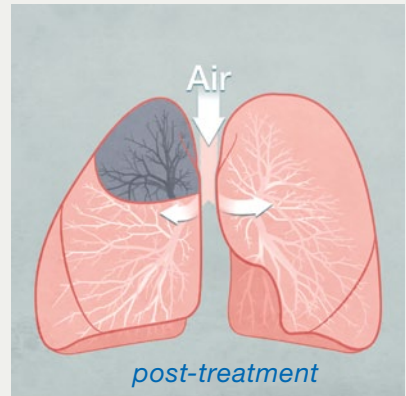
After the procedure, your trial doctor will require you to stay in the hospital for a minimum of one night.

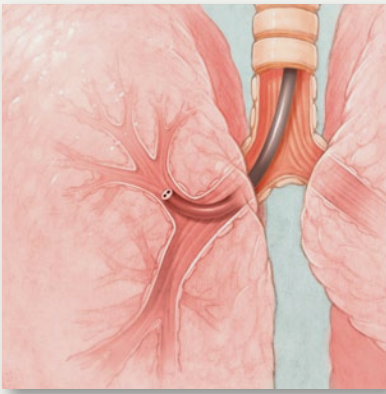
Although the valves are meant to be permanent, they are designed to be removable.

## Over-Inflated Lung



## Diseased Parts Reduce, Healthier Parts Expand

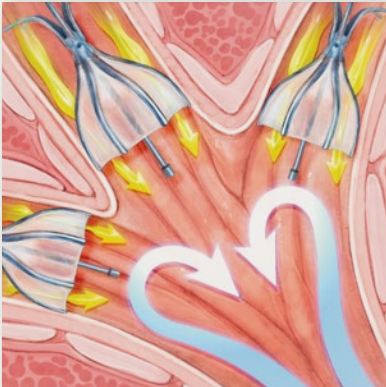




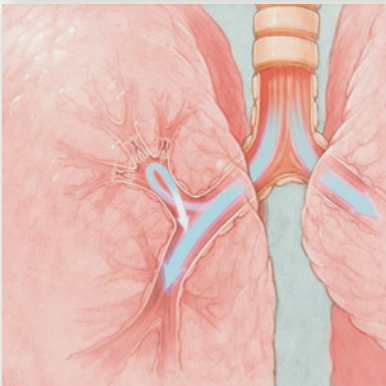
Surgery is not needed to place valves in the airways of the lung. The IBV Valves are placed using a tool called a bronchoscope, which is a flexible tube with a camera at the end.



The valve is placed in the airway using a catheter that goes down the bronchoscope. Once the valve is in the airway, it expands and contracts with breathing.



More than one valve will be placed. The valve allows trapped air and fluids to flow past it, but blocks air from entering the diseased part of the lung.



The valve redirects air to healthier parts of the lung and reduces over-inflation.

# How the Clinical Trial Works

There are two groups in the clinical trial. The Treatment Group will have valves placed in their lung. The Control Group will not have valves placed in their lung, but will be taken care of by the trial doctor.

The groups are assigned randomly and you and your doctor will not have a choice regarding which group you will be in. For every three people enrolled in the trial, two people will go into the Treatment Group and one person will go into the Control Group.

All testing, doctor visits and the procedure are provided at no cost to you.

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## **The following is provided to trial participants at no cost:**

- Be under the care of a trial doctor, who is a lung specialist, for the entire time you are in the trial.
- Receive regular check-ups and health assessments throughout the 6 month trial.
- Receive annual check-ups for 5 years for the Treatment Group and 2 years for the Control Group.

## **Potential Risks of Participating in this Clinical Trial**

Not all patients will benefit from the procedure and there are some significant risks.

Potential benefits and risks will be reviewed with all eligible patients by the trial doctor and a member of the trial support team.

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## Are You a Candidate?

You may be eligible to be part of this trial if you:

- Have severe emphysema
- Have had pulmonary rehabilitation
- Can complete a walking exercise test
- Can commit to multiple visits with the trial doctor for an initial health assessment and follow-up testing
- Have stopped smoking for at least four months and will not smoke while in the trial

**Your doctor will discuss the full list of criteria for participating in the trial with you.**



**For More Information Contact:**

CAUTION – Investigational device. Limited by Federal (or United States) law to investigational use.

**Spiration, Inc., of Redmond, Washington,  
is the sponsor of the EMPROVE Clinical Trial.**

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