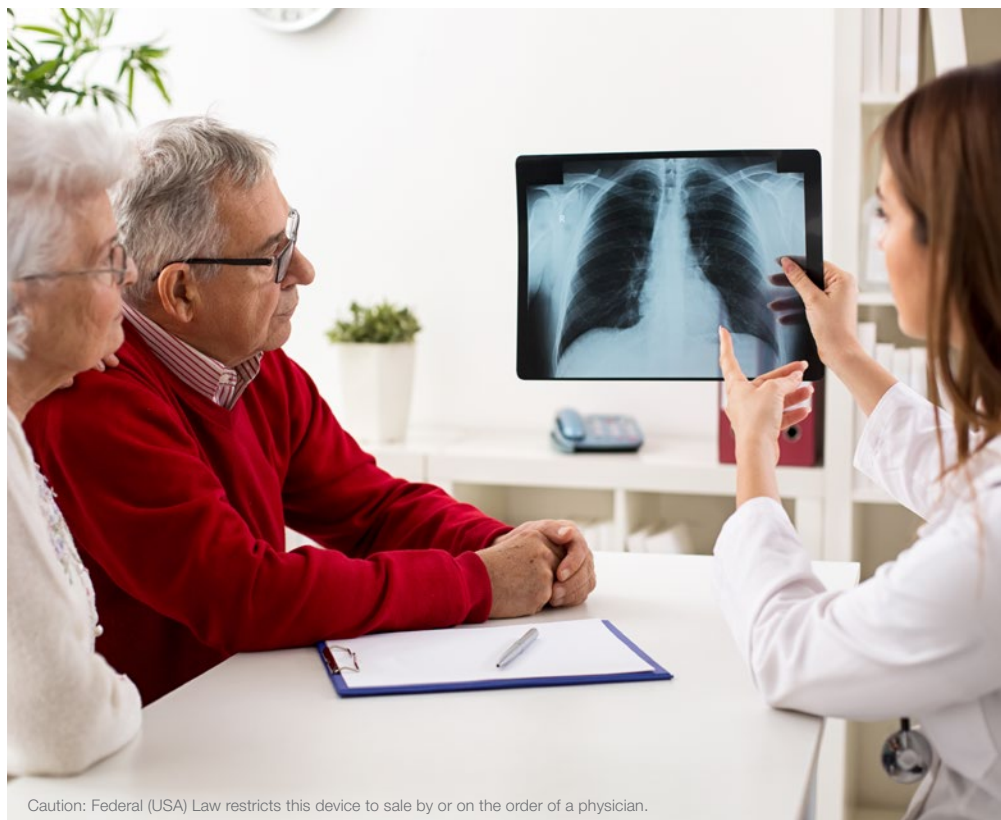

Valve Therapy

for Treatment of Severe Emphysema

Patient Reference Guide



Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

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CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) AND EMPHYSEMA

If you are reading this booklet then it's most likely that you or a loved one has been diagnosed with *COPD*. COPD is an umbrella term used to describe progressive lung diseases including *emphysema*, *chronic bronchitis*, refractory (non-reversible) *asthma*, and some forms of *bronchiectasis*.

Every affected person's experience is different. The characteristic symptoms of COPD include frequent coughing, wheezing, shortness of breath, feeling tired — especially when doing daily activities and exercise — a tight feeling in the chest, and increased mucus in the lungs.

As the chronic disease progresses, your symptoms will tend to get worse as more damage occurs in the lungs.

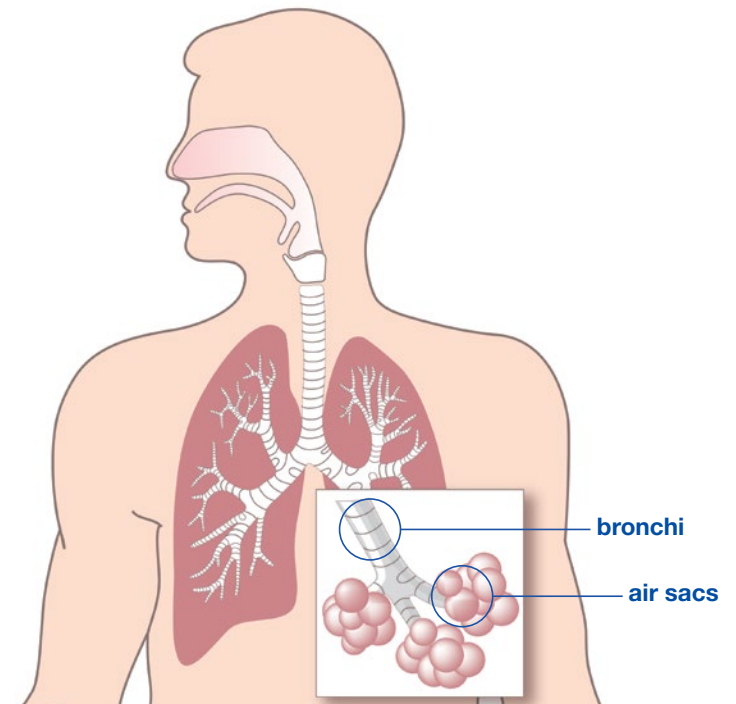


Figure 1.

Emphysema

A consequence of *chronic* inflammation of lung tissue is pulmonary emphysema. *Emphysema* is one of the Chronic Obstructive Pulmonary Diseases.

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 (Figure 2) called alveoli. 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. Air then becomes trapped in the most diseased areas of the lungs, causing over-inflated lungs. The trapped air interferes with the function of the healthier areas of the lung, which adds to difficulty in breathing.

Every affected person's experience is different, but the characteristic symptoms include chronic coughing, shortness of breath, chest infections, a tight feeling in the chest, and increased mucus in the lungs.

The symptoms usually develop slowly over many years. As a result, most patients only consult a doctor when they suffer breathlessness—even when exerting themselves only a little.

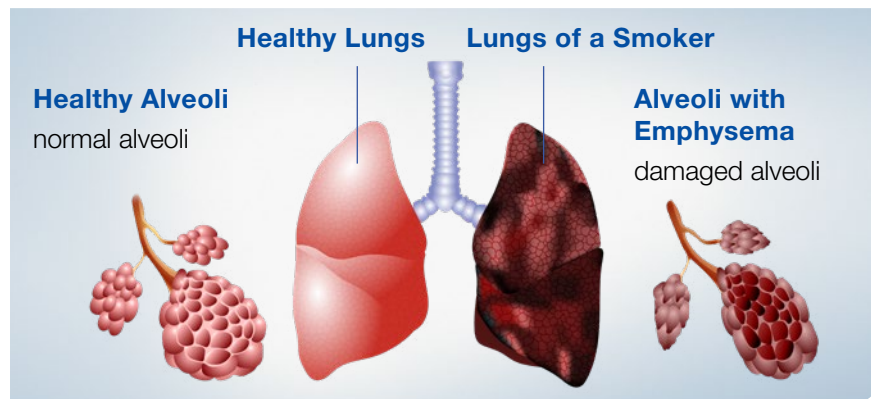


Figure 2.

TREATMENT CHOICES

Treatments for *emphysema* include drugs, oxygen, or in some cases, surgery. Surgery may not be appropriate for some patients, depending on their health status. Doctors advise patients on the appropriate therapy options.

If symptoms are mild, doctors frequently recommend:

- Avoiding smoking and other risk factors
- Having vaccinations against flu and pneumonia
- Short-acting drugs to expand the *bronchi* (*bronchodilators*), taken as needed

In the case of moderate symptoms:

- Long-acting drugs to expand the *bronchi* (*bronchodilators*), taken as a regular medication
- *Pulmonary rehabilitation* with exercise to strengthen the lungs, including power, stamina and relaxation elements, as well as training in correct use of inhalation systems

In the case of severe symptoms:

- Combinations of long-acting drugs
- Oxygen treatment
- Pulmonary rehabilitation with exercise as advised by your physician
- Bronchial valve therapy (Spiration® Valve Procedure)
- Surgery (for example: lung volume reduction or lung transplant)

DEVICE DESCRIPTIONS

The Spiration® Valve System consists of the following parts:

The Valve

The umbrella shaped valve is made of a flexible metal frame (nitinol — composed of titanium and nickel) covered by a thin flexible membrane, (see Figure 3). The valve is designed to fit the shape and size of airways of the lung. The valve is a one-way device, which means that the flexible umbrella blocks air from moving further into your lungs, but allows trapped air to move out of your lungs as you breathe out.

Tiny Anchors

Lightly grasps airway to help stay in place.

Umbrella

The umbrella redirects air you breathe in and allows secretions to escape naturally.

Removal Rod

Allows doctor to remove the valve, if necessary.



Actual size of 7mm valve



Figure 3. Valve design

The Deployment Catheter

The *valve* is loaded into a long narrow tube called the *deployment catheter*. The deployment catheter (see Figure 4) places the valve in your airway.



Figure 4. The Deployment Catheter

Required Accessories:

Balloon Catheter

The doctor will be using a *balloon catheter* to measure the size of the airway that the proper valve size can be used.

Bronchoscope

In this procedure, the doctor will use a *bronchoscope* to see the airways of your lung. The deployment catheter and balloon catheter go through the *bronchoscope* to reach the airways.

The Spiration® Valve System is intended to treat patients with severe *emphysema* and evidence of low *collateral ventilation*, such as *fissure integrity*, by limiting airflow to selected areas of the lung.

INDICATIONS FOR USE

Spiration® Valves are one-way endobronchial valves indicated for adult patients with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung that have evidence of low collateral ventilation.

Am I a candidate for valve therapy?

Valve therapy is suitable primarily for *COPD* (Chronic Obstructive Pulmonary Disease) patients suffering from severe emphysema who are not feeling better — despite drugs, *pulmonary rehabilitation* and oxygen therapy.

Valve therapy will only work in select patients when air can't flow from one *lobe* of the lung to another *lobe*. A doctor will have the patient take several *lung function tests* and a CT scan to see if patients will benefit from *valve therapy*.

Valve therapy is usually not possible in the case of prior lung surgery, *pleural diseases*, cancer, or severe heart disease.

When the Spiration Valve System Should Not Be Used (Contraindications)

Your doctor will not place a Spiration Valve in your lungs if you are unable to have a *bronchoscope* placed through your nose or mouth and into your lungs. If you suspect or know that you are sensitive to or allergic to nickel, let your doctor know, you shouldn't have a Spiration Valve placed in your lungs.

You are not a candidate for valve therapy:

- if you are still smoking
- if you have large bullae (holes) in the lung
- if you have certain types of emphysema
- if you have an active pulmonary infection

POTENTIAL RISKS AND BENEFITS OF SPIRATION® VALVE THERAPY

Potential Risks: Warnings and Precautions

Valve therapy is a minimally invasive procedure that is well tolerated by most patients, but is not without risks. Please discuss these potential risks with your doctor. Call your doctor immediately if you have any discomfort, pain or any other concerns after your procedure.

- The Spiration Valve System should not be used for patients who have active *asthma*, *bronchitis* or clinically significant *bronchiectasis*.
- If you have swelling of airways (active *asthma*), inflammation of lung tissue (*bronchitis*), or airways that have gotten larger and/or infected (*bronchiectasis*), you should not have Spiration Valves placed in your lungs.
- You will be given drugs to make you unaware of pain during the procedure. These will make you sleepy (*sedation*) or unconscious (*anesthesia*). Talk with your doctor about the problems that can occur with *sedation* or *anesthesia*.
- The Spiration Valves are MR-conditional, which means that you can have an MRI procedure (a method for taking pictures of your internal organs) under certain conditions while the valves are implanted in your lungs. You will be given an information card to carry in your wallet. Show this card to a health care professional if you require an MRI.
- Although rare, as with all drugs and devices, it is possible that you may have an allergic reaction to the materials used in the Spiration Valve System.

POTENTIAL COMPLICATIONS

The following may be associated with bronchoscopy and/or valve placement include, but are not limited to:

- Altered arterial blood gas
- *Anesthesia* complications
- *Atelectasis*
- Bronchial injury
- *Bronchitis*
- *Bronchospasm*
- Chest Pain
- Chronic Obstructive Pulmonary Disease (COPD) exacerbation
- Death
- *Dyspnea*
- Empyema/Lung abscess
- *Hemoptysis* (or bleeding)
- *Hemothorax*
- *Hypoxemia*
- Iatrogenic injuries
- Infection
- *Migration* of a valve out of the lung or within the lung
- Persistent cough
- Pleural effusion
- *Pneumonia*
- *Pneumothorax*
- *Respiratory failure*
- Sore throat
- *Thorax pain*
- *Tissue hyperplasia* or other reaction at valve site
- Valve fracture
- Vocal cord injury
- Wheezing
- Other procedure-related complications may occur

POTENTIAL BENEFITS

Spiration® Valves may reduce the volume of diseased parts of the lung, and redirect air to the healthier parts. This may help improve overall lung function and quality of life for people living with *emphysema*.

In a recent clinical trial with the Spiration Valve System, the EMPROVE study, patients treated with medication and the Spiration Valve System were compared to a group of patients treated with medication only. Results of this study showed that the Spiration Valve System treated group experienced the following benefits compared to the medication-only patients:

- **Improved lung function:** The volume of air that can be forced out in one second after taking a deep breath (FEV₁) is an important measure of lung function. The treated group improved their FEV₁ by approximately 100ml over 6-month and 12-month time periods. This represented a 12% improvement in lung function, which indicates a clinically meaningful benefit to patients.
- **Reduction of hyperinflation (air trapped in the diseased portion of the lung):** Hyperinflation is a measurement of air trapped in the diseased portion of the lung. The treated group showed reduced hyperinflation over six months. Reducing hyperinflation helps healthier portions of the lung to work more efficiently and allows improvement in overall lung function.
- **Decreased shortness of breath (dyspnea):** The treated group showed reduced dyspnea over 6-month and 12-month time periods. This means that patients experienced decreased episodes of shortness of breath, which may lead to increased ability to accomplish daily activities.
- **Improved quality of life:** Doctors measure quality of life using a survey called the St. George's Respiratory Questionnaire (SGRQ), and generally agree that improvements over 4 points represent a clinically meaningful benefit to patients. The treated group showed improvement in SGRQ of 13.0 points (over six months) and 9.5 points (over twelve months).

THE PROCEDURE

How to Prepare for the Procedure

Your doctor will review a CT scan to determine which *lobe* to place the valves in, prior to your procedure. Right before the procedure begins your doctor will give you medicine that will make you unaware of pain and will make you sleepy (*sedation*) or unconscious (*anesthesia*). If you know you are allergic to the drugs to make you sleepy or unconscious, it's important to let your doctor know. Your doctor will talk with you about the best type of *sedation* or *anesthesia* for you.

The *balloon catheter* will be used to measure the airways where the valves will be placed.

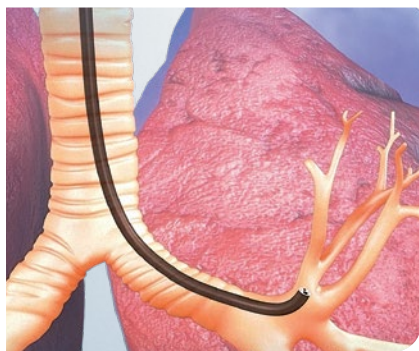


Figure 5a. The bronchoscope will be inserted into the lungs through the mouth or nose and directed to the target airways where valves might be placed.



Figure 5b. A small balloon will be inflated in the airway to check for the size of valve needed for that airway.

The Procedure

The Spiration® Valve is a small, umbrella-shaped, one-way valve that is placed inside the airways of a diseased lung. Placing the valve in the airways will typically result in:

- Air that gets breathed in will be redirected away from the diseased part of the lung to the healthier parts of the lung, and
- Air and any fluids that are trapped in the over-inflated, diseased portion of the lung are allowed to escape.

These actions cause the overall volume of the treated part of the lung to shrink, which then allows the healthier parts of the lung to expand and function more normally.

The goal of valve therapy is to improve overall lung function and quality of life for patients living with *emphysema*.

The patient may be required to stay in the hospital for a minimum of one night after the procedure.

The valves are meant to be permanently implanted in the airways, but they are also designed to be removed if necessary.

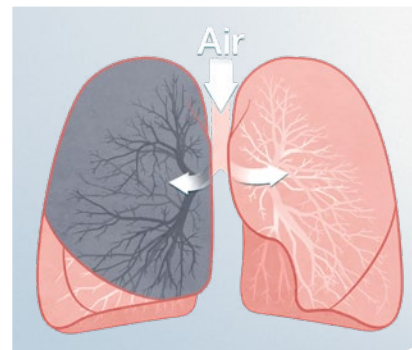


Figure 6a. Over-Inflated Lung

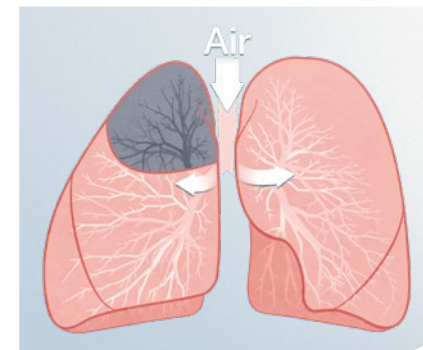


Figure 6b. Diseased Parts Reduce, Healthier Parts Expand

THE PROCEDURE

What to Expect After the Placement Procedure

After the procedure you may be required to stay in the hospital for a minimum of one night.

Your doctor will likely order a chest x-ray to see how your lungs are responding to the valve treatment. They will be watching for any complications, including a *pneumothorax*. A *pneumothorax* is air that becomes trapped between the lung and chest wall. If you have a *pneumothorax* you may need to have a *chest tube* to allow the trapped air to escape, and your doctor might need to remove a valve, which can be replaced at a later date.

Your doctor will give you instructions for your care at home. This will include information on what medicines you should take and follow-up visits.

You will be given a **Patient Information Card** for your wallet (purse) that says you have one or more Spiration® Valves and shows where they are placed (see Figure 11). This card will also have your doctor's contact information. It's important to keep this card with you at all times and to show it to anyone who gives you medical care, especially emergency room staff.

Call your doctor immediately if you have any discomfort, pain, or any other concerns after your procedure.

- If you suddenly have severe chest pain or breathing becomes increasingly difficult, get immediate emergency care, and advise your treating physician.

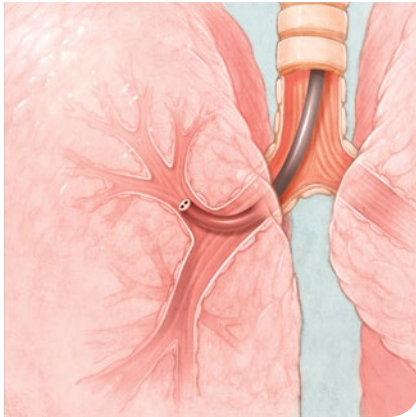


Figure 7. Surgery is not needed to place valves in the airways of the lung. The Spiration® Valves are placed using a bronchoscope.



Figure 8. 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.



Figure 9. 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.

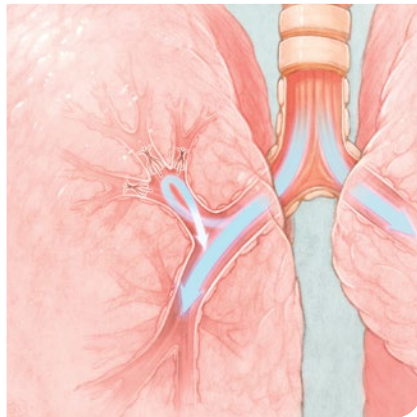


Figure 10. The valve redirects air to healthier parts of the lung and reduces over-inflation.

PATIENT INFORMATION CARD

Spiration® Valve System

INSTRUCTIONS: Please carry this card at all times and show it to any medical personnel who may be treating you. Notify your physician if symptoms fail to improve, worsen, or new symptoms develop.

Patient Name

Patient ID


Physician

Office Phone

Hospital

Address

Procedure Date: / / (MM/DD/YY)

 MR Conditional

MR Information

The Spiration Valve was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

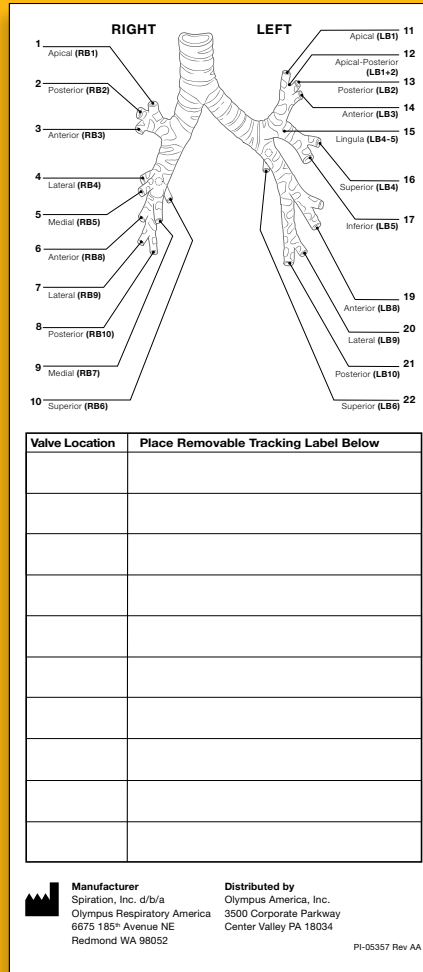
Non-clinical testing demonstrated that the Spiration Valve is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial magnetic gradient field of 720-Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the Spiration Valve produced a temperature rise of less than or equal to 0.5° C at a maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of MR scanning in a 3-Tesla MR system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Spiration Valve. Optimization of MR imaging parameters is recommended.

OLYMPUS



MY CARE REGIMEN

Plan to rest and limit your activities for at least one week following the procedure — give the therapy some time to work.



VALVE REMOVAL

What to Expect if a Spiration® Valve Needs to be Removed

The Spiration Valve is designed to be a permanent, long-term implant. However, if there are any complications, your doctor may decide to remove a valve. Valve removal is a fairly simple, straight-forward procedure.

Like valve placement, the valve removal procedure is done using *sedation or anesthesia*. A *bronchoscope* will be used as it was during *valve placement*.

Forceps will be placed into the *bronchoscope* to grab and remove the valve (see Figure 12a and 12b).

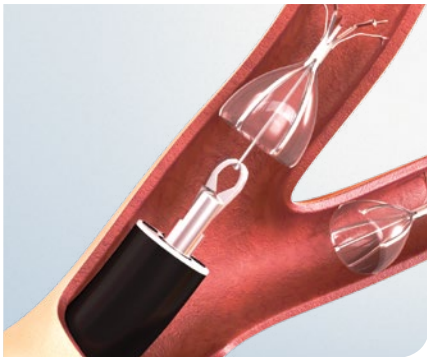


Figure 12a. Forceps placed through the bronchoscope will grab the valve.



Figure 12b. The valve is removed along with the bronchoscope.

FREQUENTLY ASKED QUESTIONS

1. Will I be able to feel the Spiration® Valve in my lung?

No, you will not be able to feel the Spiration Valve after it's been placed in your lung.

2. How long will the procedure take?

The bronchoscopy procedure used to place the Spiration Valve usually takes less than one hour but may take up to two hours.

3. When will I feel better after procedure?

The amount of time that it takes to feel better after your procedure varies from patient to patient. You should discuss how you are feeling regularly with your doctor.

4. Can it be coughed out?

In Spiration Valve clinical trials, no patients have coughed out a Spiration Valve. However, in a rare case, a valve may be coughed out.

5. Will I be able to stop or decrease using my oxygen and other COPD medications?

Although you may feel better after receiving the Spiration Valves, always consult your doctor before you make any changes to using oxygen and *COPD* medications. Valve therapy is not a substitute for treatment of *COPD* by medication or oxygen therapy.

6. How long will it stay implanted in me? Is the procedure reversible?

The Spiration Valve is intended to be permanent, however it's designed to be removed if necessary.

FREQUENTLY ASKED QUESTIONS

(Continued)

7. How many valves will the doctor place in me?

Every person's lungs are different, however on average about 4 Spiration Valves are typically used.

8. Does the doctor ever need to go back to check on them?

Yes. As part of your regular follow-up visits with your doctor (pulmonologist), they will examine the effect of the *valve* therapy. Your doctor may want to inspect your *valves* using a *bronchoscope*.

9. What happens when I go through security at the airport?

The Spiration Valve will not set off the metal detectors used by airport security.

10. What is the expected length of recovery from the procedure?

When can I go back to normal activities?

Although you may feel much better after the procedure, it's very important to allow your lungs to adjust to the recent procedure so that you don't suffer any setbacks. Follow your doctor's post-surgical instructions, and plan to rest and limit your activities for at least one week following the procedure.

GLOSSARY

Airway: The tubes in the lungs that pass air to and from the lung tissue.

Anesthesia: A medical procedure that makes the patient unconscious and makes the body insensitive to pain.

Asthma: Swelling of the airways in the lung, making breathing difficult.

Atelectasis: Collapse of all or part of the lung.

Balloon Catheter: A narrow, flexible tube with a small balloon at the end.

Bronchi: The large air passages that lead from the trachea (windpipe) to the lungs.

Bronchiectasis: A lung condition in which the airways of the lungs get bigger and often get infected.

Bronchitis: An infection that causes inflammation of lung tissue.

Bronchodilators: Drugs which relax the bronchial muscle, causing the airways to dilate and thus alleviate the symptoms of COPD.

Bronchoscope: A narrow, flexible tube, with a camera on the end that is used to see the airways inside the lungs.

Bronchospasm: A tightening of the muscles that line the airways (bronchi) in your lungs. When these muscles tighten, your airways narrow. It causes difficulty in breathing which can be very mild to severe.

CT Scan: A radiographic image taken of a body part.

Carbon dioxide: Result of the chemical reaction between oxygen (from the air breathed in) and carbon (from carbohydrates in the food); replaced in the lung by "fresh" oxygen.

Chest tube: A plastic tube that is inserted through the skin and rib cage and into the chest cavity to allow air and fluids leaking from the lung to exit the body.

Chest X-ray: a picture of the chest that shows your heart, lungs, airway, blood vessels, and lymph nodes.

Chronic: Permanent, long-term.

Collateral Ventilation: The ventilation of alveolar structures through passages or channels that bypass the normal airways.

Contraindication: A specific situation in which the valve therapy procedure should not be used because it may be harmful to the patient.

For more information on the Spiration Valve System, please visit svs.olympusamerica.com/patients-and-family

Deployment Catheter: A narrow, flexible tube used to deliver the Spiration® Valve to target airways of the lung.

Dyspnea: Shortness of breath, often described as an intense tightening in the chest, air hunger or a feeling of suffocation.

Emphysema: A lung condition in which the air sacs of the lungs are damaged and enlarged, causing breathlessness.

Expiration: When a person breaths out.

Fissure Integrity: Lung fissures are divisions from the surface to the interior of the lung tissue which divides it into lobes. Therefore the completeness of separation between the lobes.

Forced expiratory volume in one second (FEV₁): Forced expiratory volume in one second (FEV₁) corresponds to the quantity of air the patient can breathe out within one second after breathing in as deeply as possible.

Forceps: A common tool used in medical procedures to help doctors grab onto tissue and other objects in the body.

Hemoptysis: The coughing up of blood or blood-stained mucus from the bronchi, trachea, or lungs.

Hemothorax: A condition when blood collects between your chest wall and your lungs—in your pleural cavity.

Hypoxemia: A below-normal level of oxygen in the blood. It's a sign of a problem related to breathing or circulation.

Inhaled Corticosteroids (ICS): A type of steroid medication that is inhaled. Corticosteroids are very good at reducing inflammation (swelling) and mucus production in the airways of the lungs. They also help other quick-relief medicines work better.

Lobe: A clear anatomical division of an organ. The right lung is made up of the right upper lobe, right middle lobe and right middle lobe. The left lung is made up of the left upper lobe and the left lower lobe.

Lung Function Test: These include a variety of tests that check how well the lungs work.

Lung Volume Reduction Surgery (LVRS): A surgical treatment for patients with advanced emphysema whose breathlessness is poorly controlled by medical management. LVRS reduces the lung volume by wedge excisions of diseased tissue.

Migration: The movement from one location to another.

Nitinol: A metal made of nickel and titanium distinguished from other materials by its shape memory and super elastic characteristics.

Oxygen therapy: Administration of air with an increased concentration of oxygen to make breathing easier.

Pleural disease: Any type of disease that affects the pleura. The pleura is the membrane that lines the chest cavity and covers the lungs. The pleural space is the area between the lungs and the chest wall.

Pneumonia: A lung infection with symptoms like a cough, fever, and difficulty breathing.

Pneumothorax: A pneumothorax occurs when air leaks into the space between your lung and chest wall. This air pushes on the outside of your lung and makes it collapse.

Pulmonary Rehabilitation: A program of exercise, education and support to help COPD patients to breathe and function at the highest level possible.

Respiratory failure: Is a syndrome in which the respiratory system fails in one or both of its gas exchange functions: oxygenation and carbon dioxide elimination.

Respiratory compromise: Breathing difficulty — causes less oxygen to be available to the body and negatively affects bodily functions.

Sedation: A medical procedure in which medicine is given to the patient to make him or her comfortable and unaware of pain during surgery. It relaxes the central nervous system and can cause sleepiness.

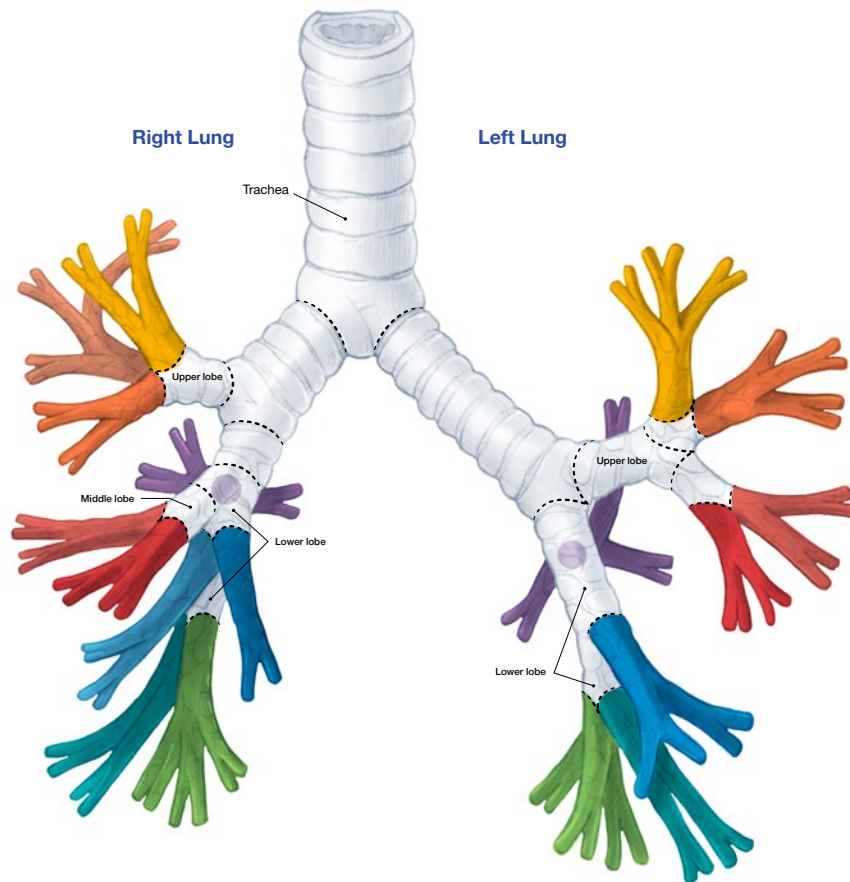
Thorax pain: Chest pain, which has many possible causes — and some of them are serious. It's important to see your doctor about chest pain.

Tissue hyperplasia: An abnormal increase in volume of a tissue or organ (i.e. the lung) caused by the formation and growth of new cells.

Valve: The Spiration® Valve is a small, umbrella-shaped one-way device that is placed inside the airways of the lung that redirects air away from damaged lung tissue.

MY LUNGS

Talk with your doctor about your Spiration® Valve Procedure.
Use this picture to understand where valves could be placed.



MY NOTES

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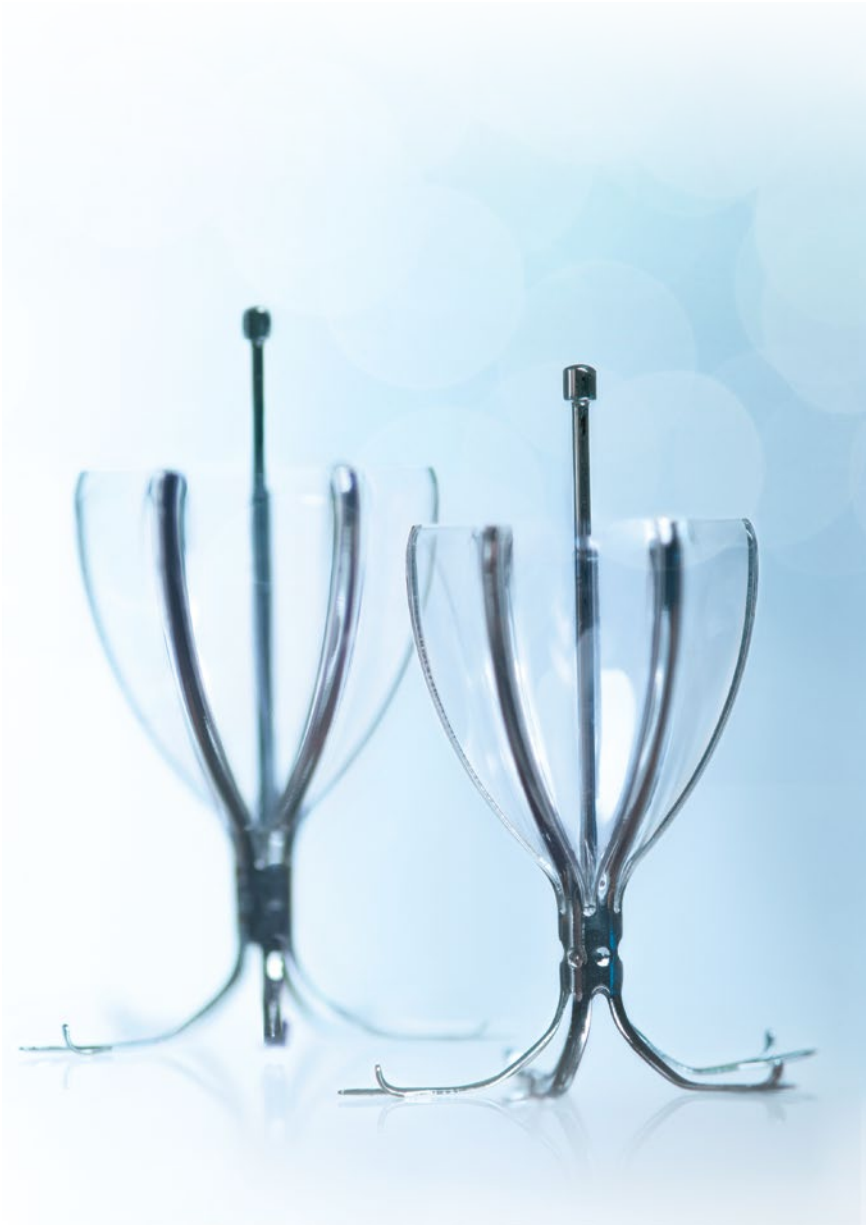
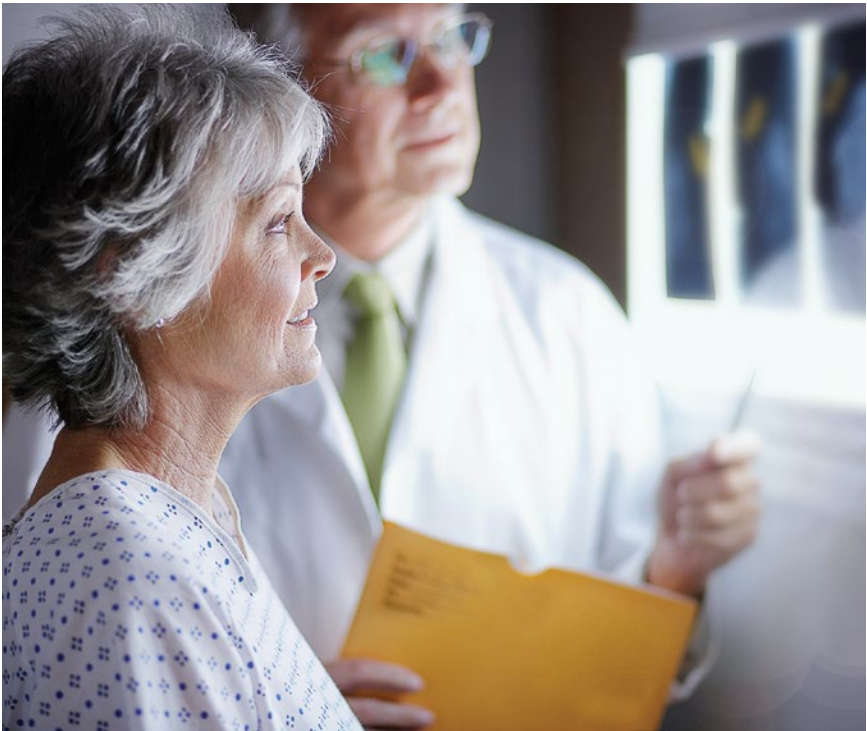
MY PROCEDURE

My Doctor's Name: _____

Hospital: _____

Planned Procedure: _____

Date: _____ Time: _____



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