



**Lung Volume
Reducing Coil System**

WHAT IS PULMONARY EMPHYSDIA?

- **Emphysema, Chronic Obstructive Pulmonary Disease –Is a form of COPD.**
- In patients diagnosed with emphysema, the tissue that keeps the airways open than normal is destroyed and these airways become unable to maintain their shape during exhalation, resulting in airway blockage. This situation makes it difficult for the patient with emphysema to completely exhaust the air that is in the lungs. When they exhale, these airways close and the old air stays inside, preventing the entry of clean, oxygen-rich air. This "air retention", combined with damaged alveoli and worse oxygen delivery, results in a feeling of breathlessness and a slow loss of lung function. Getting your emphysema diagnosed early gives you the best chance of preventing lung damage from progressing.
- However, treatments are available to help people feel better and live a more active life at different stages of emphysema.



WHAT ARE THE CAUSES OF EMPHYSEMA?

Emphysema has many causes. Major factors that increase a person's possibility of developing emphysema include:

- Smoking
- Breathing cigarette smoke
- Occupational hazards such as exposure to chemical vapor, smoke or dust
- Long-term exposure to lung irritants such as air pollution

- While some patients develop emphysema, some patients do not, there is little information about this condition. In some patients, emphysema can be caused by genetic factors or the body's inability to produce enough amount of a specific protein that protects the lungs and liver.



What are the symptoms and findings of emphysema?

The symptoms of emphysema are what physicians seek to identify emphysema and its severity in a patient. The onset of emphysema is usually slow and progresses over time. Emphysema symptoms include:

- * Gradual extension of the chest
- * Rounding of the fingertips
- * Low weight, malnutrition
- * Bluish lips due to decreased oxygen levels circulating in the bloodstream

Symptoms of emphysema are those described by a person with emphysema, such as gasping or tightness in the chest. In smokers who develop emphysema, the first symptoms usually begin between the ages of 45 and 60.

Anyone with emphysema will experience gasping, especially after physical fatigue, such as exercise. The feeling of gasping may worsen if the patient continues to smoke.

Patients with emphysema may develop some other common symptoms, such as:

- * Wheezing
- * Cough

Patients with emphysema may develop some other less common symptoms, such as:

- * Loss of appetite and weight loss
- * Depression
- * Poor sleep quality
- * Anxiety in situations of extreme breathlessness



WHAT ARE THE TREATMENT OPTIONS FOR EMPHYSEMA?

Various treatment options are available, depending on the stage of your emphysema:

- * Quit smoking
- * Medical treatment-corticosteroids (CSIs), long acting bronchodilators (LaBD), anticholinergics (ACs)
- * Oxygen supplement
- * Pulmonary Rehabilitation and / or Exercise Maintenance Programs
- * Lung Volume Reduction Surgery or Endobronchial (Lung Volume Reduction) Coils

Advanced interventions for living with COPD may provide new options when medications, oxygen therapy, special exercises and pulmonary rehabilitation fail to relieve symptoms from emphysema.



WHAT ARE ENDOBRONCHIAL COILS?

Endobronchial Coils are super-elastic-shape memory sterile, permanent medical implants made of nitinol, a metal containing nickel and titanium. Nitinol is often used in other medical implants such as cardiac stents and bone anchors. Each helix is formed in the form of a helix (double-loop) with a ball at the end of each wire, with no sharp ends. Coils are available in different sizes to suit airway sizes in different patients.

Treatment with endobronchial coils may be appropriate for patients with severe emphysema and who complain of increased breathlessness despite taking medication. Some preliminary examinations are made before treatment can implementation. These may include lung function tests, exercise capacity testing, imaging procedures (CT scans and optional x-rays), and diagnostic bronchoscopy. You should do the best you can with rehabilitation and maintenance exercise and stop smoking at the same time. Your doctor will discuss with you whether Coils are right for you and the benefits you could see from the treatment.



HOW ENDOBRONCHIAL COILS WORK?

Endobronchial coils are permanently implanted in the damaged airways of the lung. The coils come together and compress damaged lung tissue, increasing elastic recoil, allowing the lung to contract more effectively in the breathing cycle. The unique shape of the coils helps keep small airways open (as a result of tissue damage) that can collapse when the patient exhales. This action reduces air retention and hyperinflation while directing air to healthier parts of the lung.



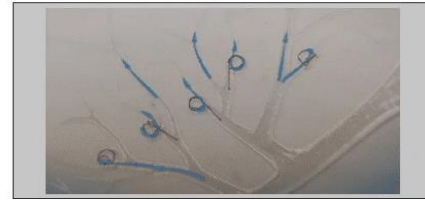
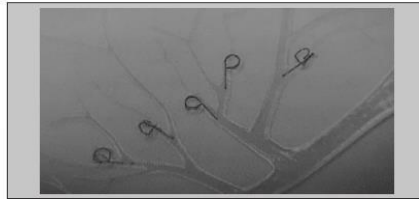
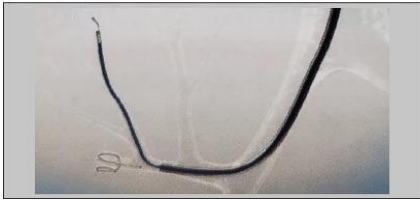
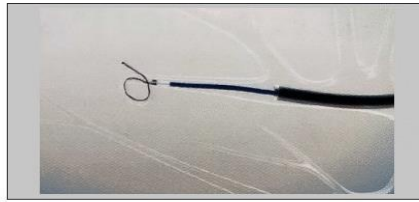
HOW IS THE ENDOBRONCHIAL COILS PROCEDURE?

After careful screening by your doctor and your consent to the procedure, your first endobronchial spiral procedure will be planned. Endobronchial coils treatment is usually carried out by two procedures, one for each lung.

On the day of the procedure, you will enter the hospital's Interventional Bronchoscopy department. Hospital staff will prepare for your Endobronchial coil procedure according to standard hospital practice. General anesthesia will be applied so that the coiling process can take place while you are sleeping.

Each coil is temporarily straightened using specially designed medical tools. Once straightened, it is threaded down your throat using a coiled bronchoscope and catheter. The doctor directs the catheter to the area of your lung with the greatest amount of tissue damage. Your doctor will implant the coils one at a time until enough coils have been implanted. Your doctor will decide on the exact number of coils you will receive during the procedure.





After the procedure is over, you will be taken to an observation area for one to two hours of monitoring until all medications given have gone through enough and you can swallow safely. Usually, an x-ray is taken four hours after the procedure to make sure the coils are not dislodged after implantation. During the observation, your doctor will check to make sure that there is no evidence of collapsed lungs before you leave the hospital. Depending on local protocols, some hospitals may have a few days of observation time.



WHAT TO EXPECT AFTER THE COILS PROCESS?

Some patients may cough up a small amount of dark brown blood one to two days after the procedure. This is expected and should not cause panic.

However, if there is persistent bright red blood in the sputum, contact your implanting doctor immediately. If you experience an increase in body temperature, feeling cold and persistent cough, your implanting doctor should be reported immediately to rule out the possibility of pneumonia, respiratory infection and the onset of a COPD exacerbation.

Instructions for discharge from the hospital should include your medications, activity, smoking cessation, possible pulmonary rehabilitation, and planning the second procedure. Usually the second treatment is carried out 1 -3 months after the first coiling procedure.



WHAT ARE THE RISKS OF THE COIL PROCESS?

As with any medical procedure, there are risks and complications associated with endobronchial coil therapy and the bronchoscopy procedure. Some patients may experience a sore throat, mild cough, wheezing, fever spasm, irregular heartbeat, or shortness of breath for several days after the procedure. In some patients, they may experience temporary chest discomfort while the coils help remodel the lung, or they may produce pink-colored sputum or small amounts of blood when coughing. Some patients had worsened symptoms of COPD, pneumonia or pneumonia-like symptoms, which usually improved with standard medical care. Occasionally, severe problems may occur, such as severe respiratory tract infection, pneumothorax, severe hemoptysis (coughing up more blood or bloody mucus), or respiratory failure that can result in death. As with other medical procedures, if you experience any unusual respiratory symptoms (such as chest pain, difficulty in breathing, coughing blood and swelling of your neck and / or face) after your coil implant procedure, you should contact your doctor.

Your doctor will explain both the risks and the risks of endoscopic treatment with Coils. will tell you about its advantages.



WHAT ARE THE BENEFITS OF COILS?

Coils have been shown to be effective and safe in patients with heterogeneous and / or homogeneous emphysema. Many patients treated with both lung endobronchial coils experienced improvement in quality of life, lung function, and exercise capacity. Your results may differ depending on your condition and the treatment you receive.



VOLUTAM HELIX LUNG VOLUME REDUCER COIL SYSTEM

The Volutam Helix System is intended to improve lung function in patients with emphysema by using a minimally invasive technique to apply Nitinol spring coils to the sub-segmental airways of the lung.

Spiral:

- * Squeezing diseased tissue into reduced volume
- * Providing elastic tension to ensure airway patency and reduce air trapping
- * Designed to adjust lung compliance to shift the preferential filling from diseased tissue to healthy tissue.



COMPRESSING DISEASED TISSUE AND CALIBRATION LUNG ADAPTATION

Before Treatment

Diseased
parenchyma

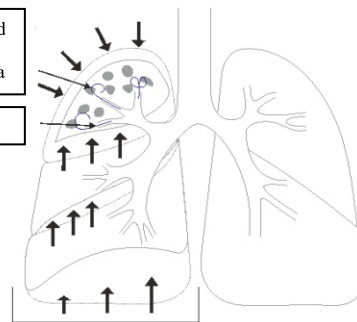


Untreated lungs

After Treatment

Compressed
diseased
parenchyma

Coils

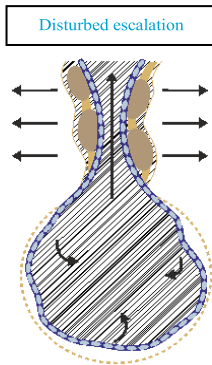


Cured upper lobe



PROTECTING THE AIRLINE CLEARANCE

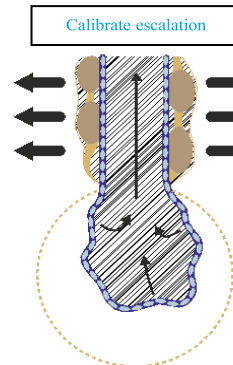
Before Treatment



Loss of elastic recoil results in premature collapse of small airways

Difficult exhalation due to decreased alveolar elastic recoil, narrowed bronchioles and air trapping

After Treatment



Elastic recoil corrected as the Helix spiral keeps the airway open

Improved exhalation due to reduced elastic tension and reduced air trapping



APPLICATION SYSTEM

Catheter

The catheter enters through the working channel of the bronchoscope. Provides a channel to target the airway area for coil application.



Guide Wire

The guide wire guides the catheter to the airway. Facilitates the selection of the appropriate coil length.



Cartridge

Cartridge reinforces coil to allow loading into catheter. Attaches to catheter center.



Forceps

Forceps grasp the proximal end of the coil and are used to apply the coil over the catheter to the target airway or disannex the coil if necessary.



BENEFITS



- * Upper Lobe Heterogeneous Diseased
- * Lower Lobe Heterogeneous Diseased
- * Non-Violent Homogeneous

It is effective in treating emphysema disease. ¹

VOLUTAM Helix provides unique benefits:

- * Minimally Invasive Procedure
- * Applied with a standard 2.8 mm bronchoscope
- * Short operation time ²
- * Limited stay in the hospital ³



VOLUTAM Helix provides unique benefits:







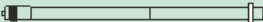
- * PFT and C-Scan based patient selection
- * Highest secure responder rate
 - Residual volume 175% above predicted
 - 6 minutes walking over 140 meters
 - At least one lobe with some structural tissue in the lung being treated

Unique Clinical Result

	FEV1	RV	6MWT	SGRQ
Change in baseline	+17,5%	-11%	28% (+71m)	-16 points
Responder ratio			73% ⁸	82% ⁷



TECHNICAL SPECIFICATIONS

Explanation		Packaging
100 mm Coil		Per part number 5 Coil
125 mm Coil		Per part number 5 Coil
150 mm Coil		Per part number 5 Coil
Application system		Content;
Catheter application		Per part number
Guide wire		* 1 Catheter application
Forceps		* 1 Guide wire
Cartridge		* 1 Forceps * 1 Cartridge



1. Volutam pilot study and feasibility study data
2. Procedure time: average 30-40 minutes
3. 1 day if no complications
4. Based on analysis of first 200 procedures
5. Volutam pilot study - Change in baseline of the second party within 6 months after treatment
6. 73% of patients showed significant improvement in exercise capacity, as defined by an increase of more than 25 meters in 6MWT at 6 months after treatment for the second side.
7. 82% of patients had significant improvement in quality of life, defined by a decrease in the second-party's SGRQ at 6 months post-treatment by more than 4 points.





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