FreeFlow® Coil
LT Device System, Large
Instructions for Use

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Description

The Free Flow Medical ***FreeFlow® Coil System*** is a Bronchoscope delivered Implant System designed specifically to treat patients suffering from Emphysema. The FreeFlow® Coil System consists of a sterile permanent Implant with detachable Delivery Accessory Loading Sleeve, and a separate sterile, disposable, single-patient Delivery System consisting of a Catheter and Guidewire. The Delivery System components are packaged and sold separately.

The FreeFlow® Coil implant is comprised of Nitinol super-elastic metal. The super-elastic FreeFlow® Coil is delivered through a Catheter and Bronchoscope into lung tissue to cause lung volume reduction which improves breathing mechanics and improves quality of life in Emphysema patients. As the FreeFlow® Coil compresses lung tissue, it tensions surrounding tissue which helps restore lung elastic recoil and maintains airway patency. By increasing tension in the lung tissue, airways are better supported to increase expiratory outflow, reduce air trapping and redirect oxygen to healthier portions of the lung to provide better perfusion-ventilation. This therapy is deployed in local diseased regions of the lung and a typical treatment of a lung would require approximately 10 FreeFlow® Coils to achieve adequate effect.

The FreeFlow® Coil, Large is made from a single piece of nitinol wire that is formed into a 3-dimensional shape. The FreeFlow® Coil, Large is provided already attached to a Delivery Accessory that assists to advance and deliver the implant into the lung.

The FreeFlow® Coil is guided into the lung through the Catheter. The Catheter is first advanced through the Bronchoscope and into lung tissue with guidance provided by the Guidewire.

The FreeFlow® Coil may be removed from the patient but it is generally intended to remain a permanent implant. Removal is accomplished by 1) capturing the proximal end of the FreeFlow® Coil with forceps, and 2) withdrawing the FreeFlow® Coil out of the lung tissue and into a Bronchoscope or Catheter.

The procedure is designed to be performed using a therapeutic type Bronchoscope with a 2.8mm working channel and fluoroscopy for visualization beyond the Bronchoscope.

Each FreeFlow® Coil is individually pouched in its own protective packaging. The FreeFlow® Coil with Delivery Accessories is sterilized using electron beam (e-beam) radiation.

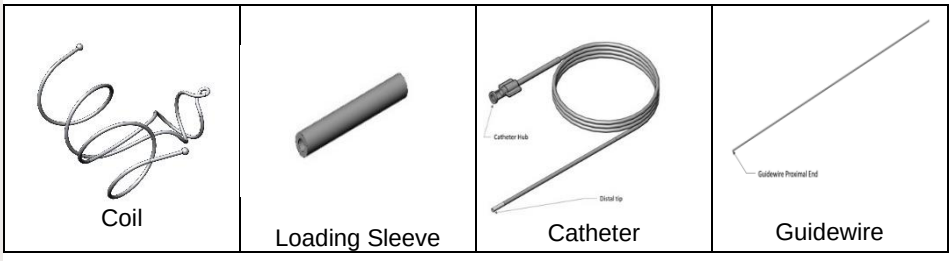


Figure 1. Components of the System

Indication for Use

The FreeFlow® Coil System is intended to improve exercise capacity, lung function and quality of life in patients with both severe heterogeneous and homogeneous Emphysema.

Contraindications

The FreeFlow® Coil System is contraindicated for:

- Patients for whom bronchoscopic procedures are contraindicated
- Patients with evidence of active infection in lungs
- Patients with known allergies to nitinol (nickel-titanium)
- History of recurrent clinically significant respiratory infections
- Patients with clinical relevant pulmonary hypertension
- Hypertension history that has manifested to dilate pulmonary arteries
- Clinically significant bronchiectasis
- Hypercapnea

Warnings

- Do not use the device if the package is damaged as sterility may be compromised.
- Store this product in a dry place.
- Failure to follow the deployment procedure may cause damage to the FreeFlow® Coil. Discard and replace if needed.
- Do not attempt to resterilize any of the FreeFlow® Coil System components. All components are provided sterile and have been designed and tested for single use only. If the surface finish of the FreeFlow® Coil is scratched, nicked or otherwise compromised, re-use could result in functional failure or could possibly cause the implant to break. The product components were not designed to be adequately cleaned and sterilized for re-use, and thus re-use could result in infection or infectious disease. In addition, the FreeFlow® Coil and Delivery System components may not function as intended if re-used after being subjected to re-sterilization that requires elevated temperatures.
- The safety and effectiveness of FreeFlow® Coil therapy has not been established in the following patient populations:
  - Children under the age of 18
  - Pregnant or lactating women
  - FEV1 <20% of predicted value
  - Patients with DLCO ≤ 20% of predicted value
  - Patients with giant bullae
  - Patients with serious bleeding disorders
  - Patients who have had prior lung transplant, LVRS, median sternotomy, or lobectomy
  - Patients with congestive heart failure or recent myocardial infarction
  - Patients with moderate to severe chronic inflammatory autoimmune disorders that have a tendency to cause an overactive immune system response

Caution – The following instructions are provided as a general informational guide for the safe, effective use of the FreeFlow® Coil System. Medical practitioners should always rely on their clinical experience and judgment, including current sterile techniques and surgical practices.

Precautions

Read all labels and instructions prior to use. Ignoring or not fully recognizing or understanding the Instructions for Use may result in procedural difficulties and/or complications.

The FreeFlow® Coil System is intended to be used with a therapeutic bronchoscope with a 2.8 mm minimum inner diameter working channel and a 65 cm maximum working length.

Caution – Use with incompatible bronchoscopes may result in equipment or device damage.

Complications

Potential complications include, but are not limited to, the following:

- Bleeding (local)
- Bronchospasm
- COPD exacerbation
- Cough
- Death
- Hemoptysis
- Hoarseness
- Infection (including pneumonia)
- Pain
- Pneumothorax
- Respiratory acidosis
- Shortness of breath
- Tissue hyperplasia or other localized tissue reaction at implant site
- Tissue perforation/dissection

Directions for Use

Deployment Instructions

1. Insert the Bronchoscope into the patient's bronchus.
2. Identify airways leading to diseased parenchyma and navigate the Bronchoscope to the selected airway.
3. Position the Bronchoscope tip in a segmental airway, near the origin of a sub-segmental airway.
4. Remove the Guidewire and the Catheter from their packaging.
5. Insert the Guidewire into the Catheter, then both into the working channel of the Bronchoscope.
6. Advance the Catheter until it can be seen exiting the Bronchoscope.
7. Advance the Guidewire out of the Catheter 1cm or more. Note: Use fluoroscopy whenever the Guidewire is beyond the visual range of the bronchoscope image.
8. Navigate the Guidewire and Catheter into the distal airway.
9. Using fluoroscopy as guidance, gently navigate the Guidewire into the distal airways until the Guidewire tip is at the pleura or as far distal as it can be advanced safely. A visual indicator that the wire is approaching the pleura is seen as a small radius bend at the wire tip (<1cm radius)
10. While the Guidewire tip is positioned at the pleura or intended distal location, grasp the Guidewire where it exits the proximal end of the Catheter and retract the Guidewire 5cm.
11. Maintain the Guidewire position and advance the Catheter until the Catheter tip is aligned with the tip of the Guidewire. Caution: Do not force the Catheter.
12. Remove the Guidewire from the Catheter while maintaining the Catheter position.
13. Remove the FreeFlow® Coil from the packaging.
14. Attach the Loading Sleeve hub to the Catheter hub.
15. Advance the FreeFlow® Coil into the Catheter by advancing the delivery accessory shaft. Always grasp the delivery accessory shaft no more than 5 cm from the proximal end of the Loading Sleeve to prevent kinking the shaft while advancing.
16. Advance the FreeFlow® Coil through the Catheter until the 1st black marker band on the Delivery Accessory meets the Loading Sleeve proximal end
17. Turn on fluoroscopy to visualize the Coil deployment
18. Resume advancing the FreeFlow® Coil until the distal tip of the FreeFlow® Coil is delivered into lung tissue at the target location; Advance until the 2nd black marker band on the Delivery Accessory meets the Loading Sleeve proximal end
19. Retract the Catheter, Delivery Accessory and optionally the Bronchoscope together, until the distal tissue is tensioned.
20. Retract the Catheter proximally to deploy the proximal end of the FreeFlow® Coil.
21. Observe the FreeFlow® Coil position. If this is not ideal, the FreeFlow® Coil can be recaptured by advancing the Catheter distally while holding the Delivery Accessory position fixed. If the position is ideal, go to step 22.
22. Decouple the Delivery Accessory Shaft from the FreeFlow® Coil and remove it from the Bronchoscope
23. Position the Catheter until it is just inside the distal tip of the Bronchoscope.
24. Reposition the Bronchoscope to the next target airway.
25. Insert the Guidewire into the Catheter.
26. Repeat steps 5-25 until all FreeFlow® Coils are deployed.
27. Remove the Catheter and Bronchoscope from the patient.

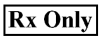
Medically Indicated Removal

Instructions

1. Navigate a 2.8mm working channel Bronchoscope and Guidewire to identify the airway in which the proximal end of the FreeFlow® Coil resides.
2. Remove the Guidewire and Insert a small Forceps (alligator teeth) instrument into the Catheter. Advance the Catheter and small Forceps through the working channel of the Bronchoscope.
3. Manipulate the Forceps to capture a proximal strut of the FreeFlow® Coil proximal end with the jaws of the Forceps.
4. Hold the FreeFlow® Coil with the Forceps and advance the Catheter distally to recapture the FreeFlow® Coil.

Note: Do not reuse the FreeFlow® Coil.

Symbol Key for Product Labels

	Consult Instruction For Use (IFU)
	Lot number
	Catalog number
	Use by date
	Sterilized by Electron Beam irradiation to SAL of 10^{-6}
	By prescription only
	Single patient use only, do not reuse
	Do not use if package or product is damaged
	Keep dry
	Manufacturer
	Authorized Representative in the European Economic Area (EEA)
	Instruction for Use
	Contains one device per box