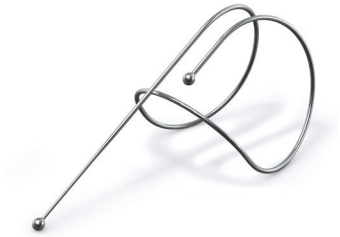
PneumRx

Elevair™ Endobronchial Coil System

INSTRUCTIONS FOR USE



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1.0 Device Description

The PneumRx® Elevair™ Endobronchial Coil System (also referred to as the "ELEVAIR System") consists of two main components: sterile ELEVAIR Endobronchial Coils (also referred to as "ELEVAIR Coils" or "Coils") and a sterile, disposable, single-procedure ELEVAIR Endobronchial Coil Delivery System (also referred to as "ELEVAIR Delivery System" or "Delivery System"). The implantable shape-memory nitinol Coils are designed to improve lung function in patients with homogeneous and/or heterogeneous severe emphysema by restoring airway patency and reducing airway collapse during exhalation and exercise.

The ELEVAIR System is used in conjunction with a 2.8mm working channel therapeutic bronchoscope and fluoroscopic imaging to introduce multiple Coils into the lungs using a minimally invasive approach that requires no incision. When implanted in sub-segmental airways of the lung, each nitinol Coil is designed to gather and compress damaged lung tissue, re-tensioning the airway network to mechanically increase elastic recoil in the emphysematous lung. This action may reduce airway collapse and air trapping, while redirecting air to healthier portions of the lung. The Coils are available in several sizes to accommodate various airway lengths.

The ELEVAIR Delivery System consists of a Guidewire, Cartridge, Catheter, and Forceps. The Guidewire guides the Catheter to the target airway and facilitates the selection of the appropriate Coil length. The Cartridge couples to the Catheter and temporarily straightens the Coil, which facilitates Coil advancement into the Catheter. The Catheter delivers the straightened Coil through the bronchoscope and into the target airway. The Forceps grasp the proximal end of the Coil to deliver the Coil to the target airway through the Catheter, where the Coil recovers to its pre-determined shape upon deployment at the target tissue site. The Catheter and Forceps can also be used to remove and/or re-position the Coil, if necessary. A single Delivery System is used to deliver multiple Coils to the same patient in a single procedure.

The ELEVAIR Coils are provided in three sizes: #1 (100mm length), #2 (125mm length), and #3 (150mm length). Each Coil is individually packaged in a protective packaging shell, which is placed inside of a pouch and carton, and sterilized by Electron Beam (E-Beam) radiation. The Delivery System components are pouched together, placed inside of a carton, and sterilized by Ethylene Oxide (EtO) gas.

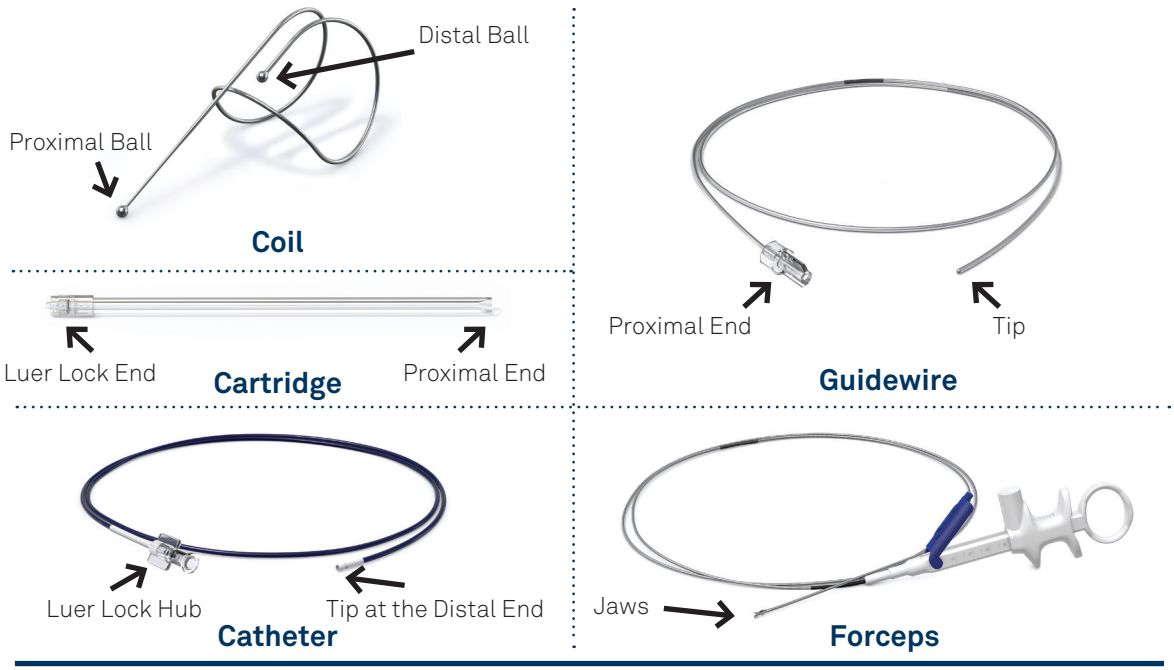

Figure 1: Components of the ELEVAIR System

2.0 Indications for Use

The ELEVAIR Endobronchial Coil System is indicated for use in patients with homogeneous and/or heterogeneous severe emphysema to improve quality of life, lung function, and exercise capacity.

3.0 Contraindications

The ELEVAIR Endobronchial Coil System is contraindicated for use in:

- Patients with a known sensitivity to drugs required for performing bronchoscopy or in whom bronchoscopic procedures are contraindicated
- Patients with evidence of active infection in the lungs
- Patients with hypersensitivity or allergy to nitinol (nickel-titanium) or its constituent metals
- Patients with clinically significant bleeding disorders
- Patients with clinically significant pulmonary fibrosis
- Patients with severe bullous disease (defined by bulla >1/3 of lung volume, or single bullous defect >8cm), or significant paraseptal emphysema (defined by numerous large [>1cm] paraseptal defects in the target lobe comprising >5% of total lung volume).
- Patients with clinically significant, generalized bronchiectasis
- Patients with severe pulmonary hypertension defined by right ventricular systolic pressure >50mmHg (preferably measured by right heart catheterization)

Note: For further guidance, see **Section 4.3.5 – Pulmonary Hypertension**.

- Patients taking immunosuppressive drugs other than steroids (e.g., for the treatment of cancer, rheumatoid arthritis, autoimmune disease, or prevention of tissue or organ rejection)
- Patients taking >20mg prednisone (or equivalent dose of a similar steroid) daily

4.0 Warnings

4.1 Clinician Use Warnings

- The ELEVAIR System should only be used by those physicians skilled in the use of therapeutic bronchoscopes and who have appropriate training by a PneumRx representative. Users should be familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with interventional pulmonology procedures and the ELEVAIR Endobronchial Coil Procedure.

4.2 Coil Removal Warnings

- Bronchoscopic Coil removal **must be medically indicated** (e.g., persistent pleuritic pain). The potential benefit of Coil removal must be weighed against the potential harm including the known risks of bronchoscopy.
- Removing Coils bronchoscopically may become increasingly difficult **after 2 or more months** following implantation, depending on the amount of tissue regrowth present. If bronchoscopic removal is not possible, surgical removal using a thoracoscopic approach can be considered. See **Section 13.0 – Bronchoscopic Coil Removal Following Implantation** for procedural details.
- If Coil removal is required, do not attempt to cut through, bend or break the Coil in any manner. Mishandling of the Coil in this manner can result in corrosion of the device and creation of sharp surfaces that can lead to injury, illness or death of the patient.

Note: Bronchoscopic Coil removal subsequent to the implantation procedure must be performed using a therapeutic bronchoscope with a minimum 2.0mm inner diameter working channel and a 65cm maximum working length.

4.3 Warnings Regarding Patient Pre-Existing Conditions

4.3.1 Hemoptysis and Anticoagulation

- Hemoptysis is a known complication of Coil treatment and of diagnostic and interventional bronchoscopic procedures in general. In infrequent cases, fatal hemoptysis has occurred in patients who have undergone Coil treatment. As such, the use of anticoagulant drugs in patients undergoing Coil treatment should be carefully considered, as it may be associated with an increased bleeding risk.

- To decrease the risk of serious pulmonary bleeding events, use of antiplatelet (e.g., aspirin, clopidogrel) or anticoagulant therapy (e.g., warfarin, NOAC's) should be stopped for seven (7) days prior to and seven (7) days following the Coil implantation procedure, or as recommended by the pharmaceutical manufacturer.
- The benefits and risks of initiation or continuing use of antiplatelet or anticoagulant medications in patients who have undergone Coil treatment should be carefully assessed.

4.3.2 Bronchiectasis and Atelectasis

- To decrease the risk of serious pulmonary bleeding events, Coil implantation should be performed in patients with bronchiectasis only after careful consideration, avoiding any suspect areas of the lung. Do not implant ELEVAIR Coils in any area of the lung exhibiting bronchiectasis or significant atelectasis.

4.3.3 Cancerous Lung Nodules/Other Lung Conditions

- Exercise additional caution when considering implanting ELEVAIR Coils in patients with DLCO <20% of predicted value since the safety and effectiveness of ELEVAIR System therapy has not been evaluated in these patient populations.
- Exercise additional caution when considering treatment of patients with suspicious or confirmed cancerous lung nodules or evidence of other severe disease or lung conditions that may compromise survival of the patient post procedure, in consideration of the patient's likelihood of benefiting from ELEVAIR Coil therapy.

4.3.4 Asthma-predominance

- In patients with asthma COPD overlap, asthma predominant disease should be ruled out by the treating physician. Patients with significant bronchodilator reversibility of FEV_1 (FEV_1 >20% post-bronchodilator) have not been clinically evaluated. See **Section 6.1 – Use in Special Populations** for a list of other patient populations that have not been evaluated in clinical studies.

4.3.5 Pulmonary Hypertension

- Patients with imaging findings indicative of severe pulmonary hypertension (e.g., a segmental artery-to-bronchus ratio greater than 1:1 in three of four pulmonary lobes) should undergo further testing to rule out severe pulmonary hypertension, which is a contraindicated condition.

Note: For additional patient selection considerations, see **Section 6.0 – Individualization of Treatment.**

4.4 ELEVAIR Coil and Delivery System Warnings

- To avoid puncturing the pleura or causing airway trauma, never advance the Guidewire, Catheter, or any other ELEVAIR System component against resistance. If resistance is met, determine the cause and take remedial action before again attempting to advance the ELEVAIR System component.
- Do not attempt to reuse, reprocess, clean or re-sterilize the ELEVAIR System components by any method. Reuse, reprocessing, or re-sterilization using irradiation, steam, ethylene oxide or other chemical sterilants may compromise the structural integrity of the device and/or lead to device failure, and may create the risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Do not use the ELEVAIR System components if the carton is compromised upon receipt. Always inspect the pouch seals prior to opening the pouch. Do not use the ELEVAIR System components if the pouch is open or damaged, as device functionality and/or sterility may be compromised. Use of non-sterile or damaged devices may result in patient harm.

- Do not use the ELEVAIR System components if the tamper-evident seal is broken, the “Use By” (expiration) date specified on the package has lapsed, or the device has been dropped or damaged. Never attempt to repair a damaged device. If damage is found, discard the device and call your PneumRx representative for a replacement.
- Do not use the ELEVAIR System if labeling is incomplete or illegible.
- Refer to the Instructions for Use supplied with any ancillary devices to be used in conjunction with the ELEVAIR System for applicable intended use, contraindications, warnings, precautions, and potential complications.
- After use, dispose of the product and packaging in accordance with hospital, administrative and/ or local government policy.

5.0 Precautions

5.1 General Precautions

- Carefully read all labels and instructions prior to using the ELEVAIR System. Observe all contraindications, warnings, and precautions noted throughout these instructions. Failure to follow the Instructions for Use may result in increased risk of patient harm, procedural difficulties, complications, or device damage.
- The ELEVAIR Endobronchial Coil procedure is a bilateral treatment that should be performed in two separate sessions.
- Do not expose the Delivery System to organic solvents (alcohol), as structural integrity and/ or function of the device may be impaired.

5.2 Procedural Precautions

- Always use a bronchoscope for the procedure. The ELEVAIR System is intended to be used with a therapeutic bronchoscope with a 2.8mm inner diameter working channel and a 65cm maximum working length. Use of the ELEVAIR System with bronchoscopes not meeting these criteria may result in equipment or device damage.
- Do not use a kinked Delivery System or Coil.
- Coils should be placed so that they are not in contact with adjacent Coils in order to avoid metal-on-metal friction.
- Avoid placing two Coils in the same airway.
- Do not advance the Catheter without Guidewire support. When advancing the Catheter, always lead with the Guidewire.
- Grip the Guidewire no more than 5cm from the proximal end of the Catheter to prevent kinking while advancing.
- Use fluoroscopy to visualize the Guidewire when it is beyond the visual range of the bronchoscope. Turn on fluoroscopy when the Guidewire fluoroscopy marker band enters the Catheter hub.
- Do not advance the Guidewire against resistance.
- Forcing the Guidewire past a sudden curve in a distal airway could cause tissue to become pinched within the curved portion of the Guidewire.
- Fluoroscopy should remain on to make sure the Guidewire does not move during Catheter advancement.
- Do not force the Catheter around a sharp bend on the Guidewire.
- If unable to advance the Catheter to the distal end of the Guidewire, pull the Guidewire back to be aligned with the tip of the Catheter. Do not force the Catheter.
- Do not pull the Forceps jaws or the Coil out of the proximal end of the Cartridge while loading a Coil. Pushing the Coil back into the Cartridge may cause damage to the Coil. If this happens, do not use the Coil.
- Do not use the Coil if the Coil is dropped or outside of the packaging shell for any reason.
- Grip the Forceps no more than 5cm from the proximal end of the Cartridge to prevent kinking while advancing.
- Do not advance the ELEVAIR System components beyond the visual range of the bronchoscope unless under fluoroscopic visualization. Turn fluoroscopy on when the black proximal marker band on the Forceps enters the Cartridge.

- Do not move the bronchoscope position during the deployment procedure.
- Do not attempt to deliver Coils without using fluoroscopy.
- The Forceps jaws cannot open if they are within the Catheter. The Forceps jaws must extend at least 1cm beyond the distal tip of the Catheter and the bronchoscope to release the Coil.
- Do not reuse the Coil if Coil removal is performed in a procedure separate from the Coil placement procedure. Coil may be reused if removed and redeployed during original bronchoscopy for Coil placement.

6.0 Individualization of Treatment

The risks and benefits should be considered for each patient before use of the ELEVAIR System. Patient selection factors should be assessed, such as patient comorbidities and important risk factors, including antiplatelet or anticoagulant therapy.

Exercise additional caution when considering treatment of patients with homogeneous emphysema in combination with less severe air trapping. A post-hoc analysis of this subgroup in the RENEW Pivotal Trial showed a deterioration in the median 6-Minute Walk Test, although the change was not statistically significant. [1]

The ELEVAIR System should be used with caution and only after careful consideration, especially in patients with:

- History of frequent recurrent clinically significant respiratory infections
- Hypercapnia
- Uncontrolled or severe congestive heart failure or recent myocardial infarction

6.1 Use in Special Populations

The safety and effectiveness of ELEVAIR System therapy has not been evaluated in the following patient populations:

- Pregnant or lactating women
- Patients who have not quit smoking
- Patients with FEV_1 >45% of predicted value
- Patients who have had Lung Volume Reduction Surgery or lobectomy
- Patients with alpha-1 antitrypsin deficiency
- Patients with Residual Volume (RV) <175% predicted
- Patients with low levels of visible parenchymal structure on CT
- Patients with severe gas exchange abnormalities as defined as PaCO2 >55mm Hg, or PaO2 <45mm Hg on room air (high altitude criterion: PaO2 <30mm Hg)
- Patients with a change in FEV_1 >20% post-bronchodilator (or, for patients with pre-bronchodilator FEV_1 below 1L, a change of >200mL) unless physician confirmed by other means that the patient does not have asthma.

[1]Sciurba FC et al. JAMA 2016; 315:2178-2189

7.0 Potential Adverse Events

Adverse events that may be observed with endobronchial devices, systems for placement of these devices, and related procedures (including diagnostics and bronchoscopy procedures) and use of the ELEVAIR System include, but are not limited to, the events shown below. These events may vary in frequency and severity.

- Allergic Reaction
- Aspiration
- Bleeding or Hemorrhage
- Bronchial Blood Clot
- Bronchial Ulceration
- Bronchospasm
- Cardiac Arrhythmias
- COPD Exacerbation
- Cough
- Death
- Device Dislocation
- Dyspnea
- Emphysema, Subcutaneous
- Hemoptysis, including severe hemoptysis
- Hoarseness
- Hypertension
- Hypotension
- Infection
- Inflammation
- Lung Abscess
- Pain
- Painful Respiration
- Pleural Effusion
- Pleural Fistula
- Pneumonia*
- Pneumonitis
- Pneumothorax
- Procedure-Related Complications (e.g., fever, spasm)
- Pulmonary Embolism
- Respiratory Distress
- Respiratory Failure
- Respiratory Tract Infection
- Sedation-Related Complications (e.g., nausea, vomiting, headache)
- Sepsis
- Tissue Reaction, Localized (a.k.a. Coil Associated Opacity*)
- Tissue Trauma, Procedural (e.g., tissue perforation, dissection)

Note: Additional interventional procedures may be necessary if patients experience some of these potential adverse event(s) following ELEVAIR Coil treatment.

* A recognized, non-infectious localized tissue reaction, also termed Coil Associated Opacity (CAO), may occur in the area of implanted ELEVAIR Coils and is typically diagnosed on imaging (chest X-ray or CT scan). This is believed to be an inflammatory response that presents with pneumonia-like symptoms, including chest or pleuritic pain/discomfort, increased dyspnea, fatigue, and/or haze or infiltrates on chest X-ray, and may be difficult to distinguish from pneumonia. While some degree of CAO has been observed in clinical trials up to 2 months following the Coil procedure, many of these events are asymptomatic or symptomatically mild, resolve with limited intervention, and do not develop into serious adverse events (SAEs). However, CAO can become severe and require prompt and specific intervention. Thus, patients are advised to contact their treating physician immediately for follow-up if they experience pneumonia-like symptoms.

8.0 Clinician Use Information

These Instructions for Use are provided as a general informational guide for the safe, effective use of the ELEVAIR System. Medical practitioners should always rely on their clinical experience and judgment, including current sterile techniques and interventional practices when using the ELEVAIR System.

8.1 Materials Required

The following additional materials are required to perform the ELEVAIR Endobronchial Coil procedure:

- Therapeutic bronchoscope with a 2.8mm inner diameter working channel and a 65cm maximum working length

Note: Bronchoscopic Coil removal subsequent to the implantation procedure must be performed using a therapeutic bronchoscope with a minimum 2.0mm inner diameter working channel and a 65cm maximum working length.

- Fluoroscopic imaging equipment
- Sterile saline
- High-walled tray or large table with rim to maintain coiled Guidewire and Forceps when not in use
- Sufficient space to work with ELEVAIR System components, including space for product and to load Coils into Cartridge

8.2 Peri-procedural Care

After careful evaluation to ensure the patient is an appropriate candidate for use of the ELEVAIR System, schedule the procedure. Computed tomography (CT) or other appropriate method(s) for assessment of emphysematous lung tissue may be used during treatment planning to identify the lung lobes most appropriate for treatment.

A prophylactic regimen of antibiotics should be taken on the day of the procedure and for at least seven (7) days after the procedure. It is recommended that steroids be taken two (2) days before and at least seven (7) days after the procedure.

Perform radiographic procedures and prepare subject for bronchoscopy per standard hospital practice. After the procedure, allow the patient to recover from anesthesia and monitor as per standard hospital practice.

A chest fluoroscopic image/X-ray should be taken post-procedure to verify Coil placement and to ensure no pneumothorax is present. A second chest X-ray should be done before discharge, a minimum of 4 hours following the first chest X-ray.

Provide detailed instructions to the patient on expected side-effects of the Coil procedure, including the potential adverse events listed in **Section 7.0 - Potential Adverse Events**, and instruct the patient to contact their treating physician immediately should any of the potential adverse events be experienced.

It is particularly important that patients be instructed at discharge to contact their implanting physician if they experience symptoms that may be indicative of pneumonia or CAO, to ensure that appropriate treatment is delivered.

After the patient recovers, the following procedure to treat the contralateral lung should typically be scheduled for 1 to 3 months after the first procedure.

9.0 Patient Information

9.1 Patient Implant Card and Patient Brochure

A Patient Implant Card containing specific information about the ELEVAIR Coils is available from PneumRx, Inc. After implantation, please note the number and location of ELEVAIR Coils implanted in the section titled "Location & Number of Coils". Provide the treating facility and physician information in the section titled "Treating Facility Contact Information". Provide the card to the patient prior to discharge. All patients should keep this card in their possession at all times for procedure and Coil identification.

PneumRx has developed a Patient Brochure that includes information specifically designed for patients regarding how the ELEVAIR Coils work and procedural information including potential risks and benefits. Copies of the brochure can be obtained by emailing PneumRx at **pneumrx@pneumrx.com** or by calling **+49 (0) 211 54 22 75 0**. Instruct all patients to obtain and read the Patient Brochure prior to treatment.

9.2 Magnetic Resonance Imaging (MRI) Safety Information

MR Conditional

The ELEVAIR Coil is **MR Conditional** and this information applies to the entire family of ELEVAIR Coils (i.e. all Coil sizes). Non-clinical testing and MRI simulations were performed to identify the worst case conditions that were used to demonstrate that the ELEVAIR Coil is **MR Conditional**. A patient with this device can be scanned safely, immediately (or at any time) after placement under the following conditions:

- Static magnetic field of 1.5- or 3-Tesla, only
- Maximum spatial gradient magnetic field of 5,000-Gauss/cm (extrapolated) or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode of operation for the MR system

MRI-Related Heating

In non-clinical testing, the ELEVAIR Coil produced the following temperature rises during MRI performed for 15 minutes of scanning (i.e., per pulse sequence) in 1.5-Tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems:

	1.5-Tesla	3-Tesla
MR system reported, whole body averaged SAR	2.9-W/kg	2.9-W/kg
Calorimetry measured values, whole body averaged SAR	2.1-W/kg	2.7-W/kg
Highest temperature change	5.4˚C	3.2˚C
Temperature scaled to whole body averaged SAR of 2-W/kg	3.7˚C	2.2˚C

Artifact Information

The maximum artifact size as seen on the gradient echo pulse sequence at 3-Tesla extends approximately 10mm relative to the size of the shape of the ELEVAIR Coil.

10.0 How Supplied and Storage

10.1 Delivery System

The Delivery System (Guidewire, Catheter, Cartridge, and Forceps) is assembled onto a backer card, which is pouched and packaged in a carton. The Delivery System is provided STERILE for use in a single patient.

10.2 Coil

Each individual Coil is contained in a protective packaging shell, which is pouched and packaged in a carton containing either one (1) Coil or five (5) Coils. Each Coil is provided STERILE for single use only.

10.3 Storage

Always store the ELEVAIR System components in a dry place.

11.0 Directions for Use

⚠ ***Caution:*** **Always use a bronchoscope for the procedure. The ELEVAIR System is intended to be used with a therapeutic bronchoscope with a 2.8mm inner diameter working channel and a 65cm maximum working length. Use of the ELEVAIR System with bronchoscopes not meeting these criteria may result in equipment or device damage.**

PREPARE DEVICES FOR USE

1. Remove the Guidewire and Catheter together from the packaging hoop.
2. Remove the Forceps and the Cartridge from the packaging.

⚠***Caution:*** **Do not use a kinked Delivery System or Coil.**

3. Flush the Cartridge with sterile saline (prior to first Coil deployment only).

POSITION DELIVERY SYSTEM

4. Identify the airways leading to the diseased parenchyma.
   a. Treatment should target the most damaged lobe (upper or lower) in each lung identified through pre-procedure assessment method.
   b. Deployment of Coils should start in the segment which presents the most difficult access first, and then progress to less difficult segments.
   c. The recommended treatment strategy is to deploy **10-12 Coils in upper lobes** or **10-14 Coils in lower lobes**. When approaching the upper limit, discontinue deploying additional Coils if increased resistance is felt while advancing the proximal end of the Coil into the lung.
   d. To achieve optimal Coil placement, position Coils in the area between the hilum and the pleura, leaving a "Coil-free zone" approximately 4cm adjacent to the pleura. This placement will result in a "fan-like" distribution of Coils in the sub-segmental airways throughout the treated lobe, as shown in **Figure 2**.

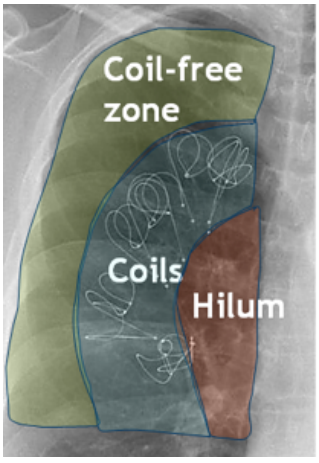

Figure 2: Optimal Coil Placement

⚠***Caution:*** **Coils should be placed so that they are not in contact with adjacent Coils in order to avoid metal on metal friction.**

⚠***Caution:*** **Avoid placing two Coils in the same airway.**

5. Navigate and wedge the bronchoscope into the selected airway (at the ostium leading to sub-segmental airways).
6. Advance the tip of the Guidewire so that approximately 1mm protrudes out from the end of the Catheter (see **Figure 3**).

⚠***Caution:*** **Do not advance the Catheter without Guidewire support. When advancing the Catheter, always lead with the Guidewire.**

Figure 3: Advance Guidewire Slightly Beyond Catheter Tip

7. Insert the Catheter and Guidewire into the working channel of the bronchoscope (see **Figure 4**).

Figure 4: Insert Catheter and Guidewire Together

8. Advance the Catheter and Guidewire to the tip of the bronchoscope.
9. Advance the Guidewire to the end of the targeted airway (see **Figure 5**).

⚠***Caution:*** **Grip the Guidewire no more than 5cm from the proximal end of the Catheter to prevent kinking while advancing.**

⚠***Caution:*** **Use fluoroscopy to visualize the Guidewire when it is beyond the visual range of the bronchoscope. Turn on fluoroscopy when the Guidewire fluoroscopy marker band enters the Catheter hub.**

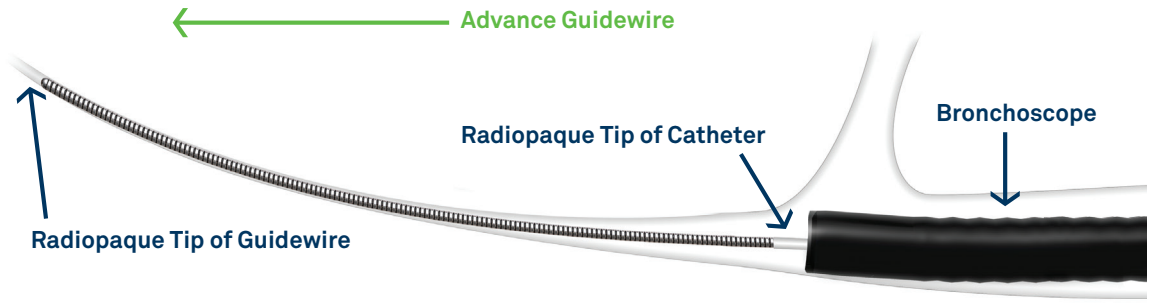

Figure 5: Advancing Guidewire into Targeted Airways

a. Gently navigate the Guidewire into the distal airways under fluoroscopic guidance until the tip reaches the pleura or suddenly curves from a straight path.

⚠ ***Caution:*** **Do not advance the Guidewire against resistance.**

⚠ ***Caution:*** **Forcing the Guidewire past a sudden curve in a distal airway could cause tissue to become pinched within the curved portion of the Guidewire.**

10. Retract the Guidewire tip by grasping the proximal end of the Guidewire, adjacent to the Catheter hub, and withdrawing **4-5cm** (using predetermined measurement reference) from the hub.
11. While holding the Guidewire position fixed relative to the bronchoscope, advance the Catheter distally until it is even with the tip of the Guidewire (see **Figure 6**).

⚠ ***Caution:*** **Fluoroscopy should remain on to make sure the Guidewire does not move during Catheter advancement.**

⚠ ***Caution:*** **Do not force the Catheter around a sharp bend on the Guidewire.**

⚠ ***Caution:*** **If unable to advance the Catheter to the distal end of the Guidewire, pull the Guidewire back to be aligned with the tip of the Catheter. Do not force the Catheter.**

Figure 6: Catheter Tip Aligned with Guidewire Tip

SELECT COIL

12. Select the appropriate Coil size by counting the number of radiopaque markers on the Guidewire visible outside the bronchoscope (see **Figure 7** and **Table 1**).
    a. The markers indicate the minimum recommended Coil size to be used.
    b. Do not count the Guidewire tip as a marker for Coil selection.
13. Remove the Guidewire from the Catheter while maintaining the Catheter position. Turn fluoroscopy off after the Guidewire is removed from the Catheter.

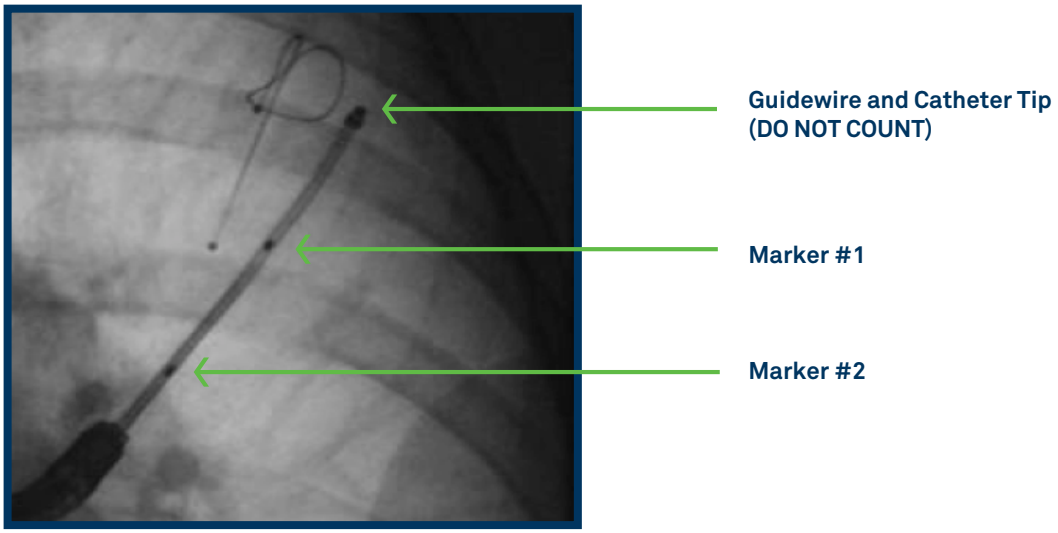

Figure 7: Guidewire Radiopaque Marker Band under Fluoroscopy

Table 1: Coil Size Selection

Number of Radiopaque Markers Visible Outside Bronchoscope	Appropriate Coil Size
0	Determine possibility for Coil #1. While maintaining Catheter position, advance the Guidewire to the end of the airway. If a marker is seen outside of bronchoscope: ⟶ Select Coil #1 If **NO** marker is seen outside of bronchoscope: ⟶ **DO NOT** deploy a Coil
1	Coil #1 or Coil #2
2	Coil #2 or Coil #3
3	Coil #3

Note: Coil #1 = 100mm length; Coil #2 = 125mm length; Coil #3 = 150mm length

LOAD COIL

14. Remove the plastic shell containing the selected Coil from the carton and pouch.
15. Insert the Forceps into and through the Cartridge, making certain that the Forceps exit the Luer lock end of the Cartridge as shown in **Figure 8**.

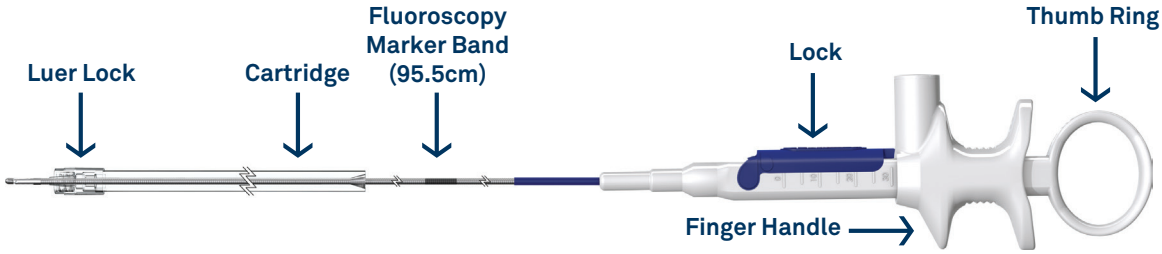

Figure 8: Advancing Forceps through Cartridge

16. Unlock the Forceps by closing the jaws with force and lifting the Lock up (close by squeezing the Finger Handle and Thumb Ring closer together).
17. Open the Forceps jaws by increasing the distance between the Finger Handle and Thumb Ring (see **Figure 9**).

Figure 9: Opening Forceps

18. Grasp the Coil by closing the Forceps jaws around the proximal ball (see **Figure 10**).

Figure 10: Grasp Coil by Closing Forceps Jaws

19. Close and lock the Forceps jaws closed (see **Figure 11** and **Figure 12**). Press the blue locking tab to the handle until an audible clicking sound is heard to prevent releasing the Coil.

Figure 11: Closing Forceps

Figure 12: Locking Forceps

20. Seat the Cartridge into the opening of the plastic protective shell (see **Figure13**).

Figure 13: Seat Cartridge into Shell

21. Slowly pull the Forceps until the Coil is removed from the plastic protective shell and completely inside the Cartridge (see **Figure 14**).

⚠ ***Caution:*** **Do not pull the Forceps jaws or the Coil out of the proximal end of the Cartridge while loading a Coil. Pushing the Coil back into the Cartridge may cause damage to the Coil. If this happens, do not use the Coil.**

⚠ ***Caution:*** **Do not use the Coil if the Coil is dropped or outside of the packaging shell for any reason.**

Figure 14: Pull Coil into Cartridge

22. Connect and lock the Cartridge to the Luer lock hub of the Catheter.
23. Deliver the Coil into the Catheter by advancing the Forceps and Coil (see **Figure 15**).

⚠ ***Caution:*** **Grip the Forceps no more than 5cm from the proximal end of the Cartridge to prevent kinking while advancing.**

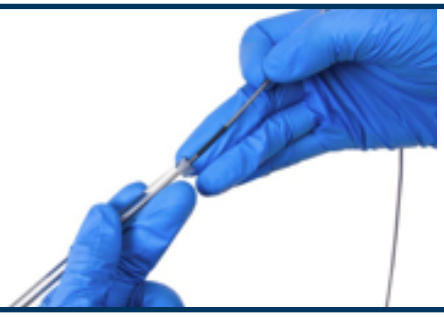

Figure 15: Advance Coil Until Fluoroscopy Marker Band Enters Cartridge

24. Turn on fluoroscopy when the black fluoroscopy marker band (on Forceps shaft) enters the Cartridge.

⚠ ***Caution:*** **Do not advance the ELEVAIR System components beyond the visual range of the bronchoscope unless under fluoroscopic visualization. Turn fluoroscopy on when the black proximal marker band on the Forceps enters the Cartridge.**

25. Advance the Coil distal ball to the distal end of the Catheter and verify the position of the Coil via fluoroscopy.
26. Have the assistant hold the bronchoscope fixed relative to the patient.

⚠ ***Caution:*** **Do not move the bronchoscope position during the deployment procedure.**

DEPLOY COIL

⚠ ***Caution:*** **Do not attempt to deliver Coils without using fluoroscopy.**

WARNING: To avoid puncturing the pleura or causing airway trauma, never advance the Guidewire, Catheter, or any other ELEVAIR System component against resistance. If resistance is met, determine the cause and take remedial action before again attempting to advance the ELEVAIR System component.

27. Deploy the Coil by distally advancing the Forceps. Advance the Coil out of the distal end of the Catheter until the first half-loop is positioned in the target airway (see **Figure 16**).

Note: If the view of the Coil is obstructed, adjust the fluoroscope to allow adequate visualization.

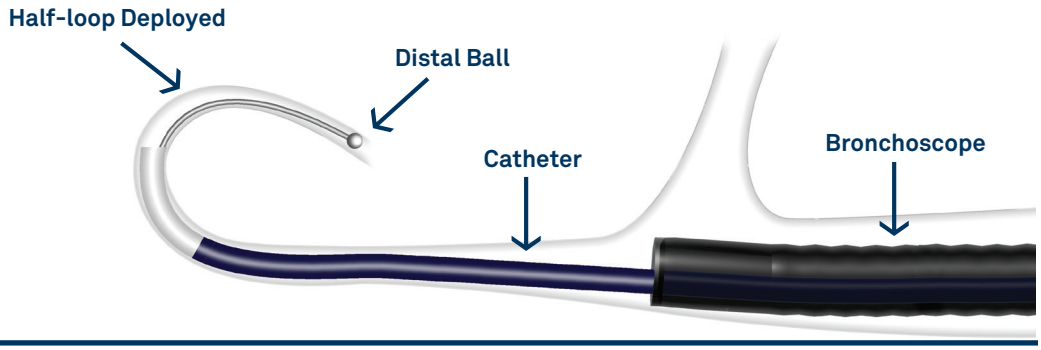

Figure 16: Observing the Partially Deployed Coil

28. Retract the Catheter while maintaining a slight constant pressure to advance the Forceps forward until the Forceps jaws are visible approximately 2cm distal to the end of the bronchoscope. Maintain Forceps position and continue to retract the Catheter into the bronchoscope (see **Figure 17**).

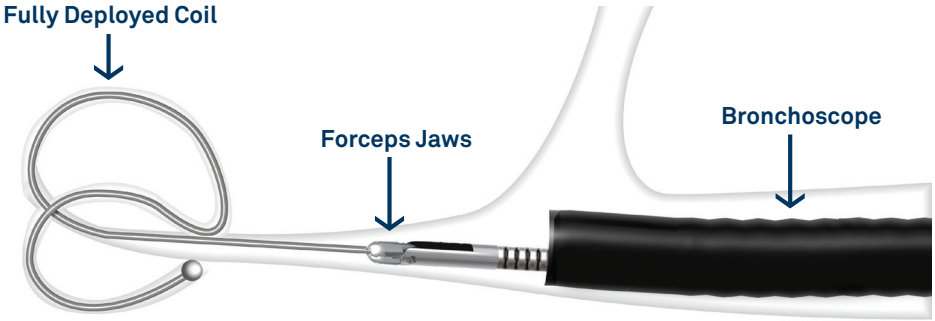

Figure 17: Observing the Completely Deployed Coil

29. Verify the position of the Coil prior to unlocking the Forceps and releasing the Coil.
    a. Ideally the proximal end of the Coil is in the segmental airway or more distal.
    b. If the Coil has been placed proximal to the airway, continue to place Coils and reassess placement after placement of the last Coil. If the proximal end of the Coil is pressing into the tissue as shown in **Figure 18**, reposition or redeploy the Coil.

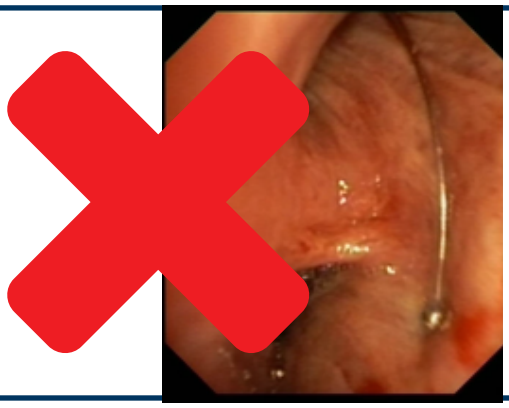

Figure 18: Example of Proximal Placement

c. If Coil position is not ideal (optimal placement shown in **Figure 19**), see **Section 12.0 – Coil Repositioning Following Deployment.**

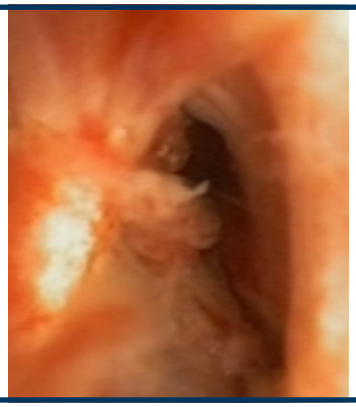

Figure 19: Example of Optimal Coil Placement

DETACH AND REMOVE DELIVERY SYSTEM

30. Gently retract the Forceps approximately 1cm to create slight tension between the Forceps and the Coil. Maintain the tension.
31. Unlock and open the Forceps jaws.

⚠ ***Caution:*** **The Forceps jaws cannot open if they are within the Catheter. The Forceps jaws must extend at least 1cm beyond the distal end of the Catheter and the bronchoscope to release the Coil.**

32. Close and lock the Forceps jaws.
33. Confirm that the proximal ball has been released before turning the fluoroscopy off.
34. Unlock the Cartridge from the Catheter (Luer lock), and remove the Cartridge and Forceps from the Catheter together as a unit.
35. Withdraw the distal tip of the Catheter into the bronchoscope.

Note: The Catheter may remain in the bronchoscope during positioning to the next treatment airway. Repeat Steps 7 to 35 to deploy additional Coils.

12.0 Coil Repositioning Following Deployment

Note: If the Coil is already released from the Forceps but the proximal ball is not in the segmental airway or more distal, it is recommended to deploy all remaining Coils before attempting to reposition. If a Coil placement is still not ideal at the end of the treatment, recapture the proximal ball with the Forceps and reposition as described. If you cannot capture the proximal ball with the Forceps, capture the wire and reposition the Coil proximal end until you can capture the proximal ball.

If proximal ball needs to be advanced 0-1cm

1. Advance the Catheter 2cm past the Forceps jaws, then gently advance the Catheter and Forceps together.
2. Repeat Steps 28 and 29 (See **Section 11.0 – Directions for Use**).

If proximal ball needs to be advanced 1-2cm

1. Hold the Forceps and Coil position fixed relative to the bronchoscope and advance the Catheter distally to resheathe up to half of the Coil.
2. Retract the Catheter while advancing the Forceps more distal than during the previous deployment.

If proximal ball needs to be advanced more than 2cm

Recapture and redeploy the Coil:

1. Resheathe the Coil until it is fully captured in the Catheter.
2. Withdraw the Coil by proximally retracting the Forceps until the Coil is within the Cartridge.
3. Unlock the Luer lock and remove the Cartridge, Coil, and Forceps as a single unit, while leaving the Catheter in place.
4. Introduce the Guidewire into the Catheter and reposition the Catheter so the Coil can be redeployed.

13.0 Bronchoscopic Coil Removal Following Implantation

WARNING: Bronchoscopic Coil removal **must be medically indicated** (e.g., persistent pleuritic pain). The potential benefit of Coil removal must be weighed against the potential harm including the known risks of bronchoscopy.

Note: Coil removal should always be performed using fluoroscopy.

WARNING: Removing Coils bronchoscopically may become increasingly difficult **after 2 or more months** following implantation, depending on the amount of tissue regrowth present. If bronchoscopic removal is not possible, surgical removal using a thoracoscopic approach can be considered.

WARNING: If Coil removal is required, do not attempt to cut through, bend or break the Coil in any manner. Mishandling of the Coil in this manner can result in corrosion of the device and creation of sharp surfaces that can lead to injury, illness or death of the patient.

⚠ ***Caution: Do not reuse the Coil if Coil removal is performed in a procedure separate from the Coil placement procedure. Coil may be reused if removed and redeployed during original bronchoscopy for Coil placement.***

1. To perform bronchoscopic Coil removal subsequent to the implantation procedure, you must have a therapeutic bronchoscope with a minimum 2.0mm inner diameter working channel and a 65cm maximum working length.

2. Use fluoroscopy to determine location of the Coil that needs to be removed.

3. Navigate bronchoscope to the Coil.

4. Insert the Forceps through the bronchoscope channel.

5. Capture the proximal ball with the Forceps. If you cannot capture the proximal ball, capture the wire and reposition the Coil proximal end until you can capture the proximal ball.

6. Lock the Forceps.

7. Advance the bronchoscope (wedge) and retract the Coil into the bronchoscope working channel.

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