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(54) **ELECTRODE MARKERS AND METHODS OF USE**

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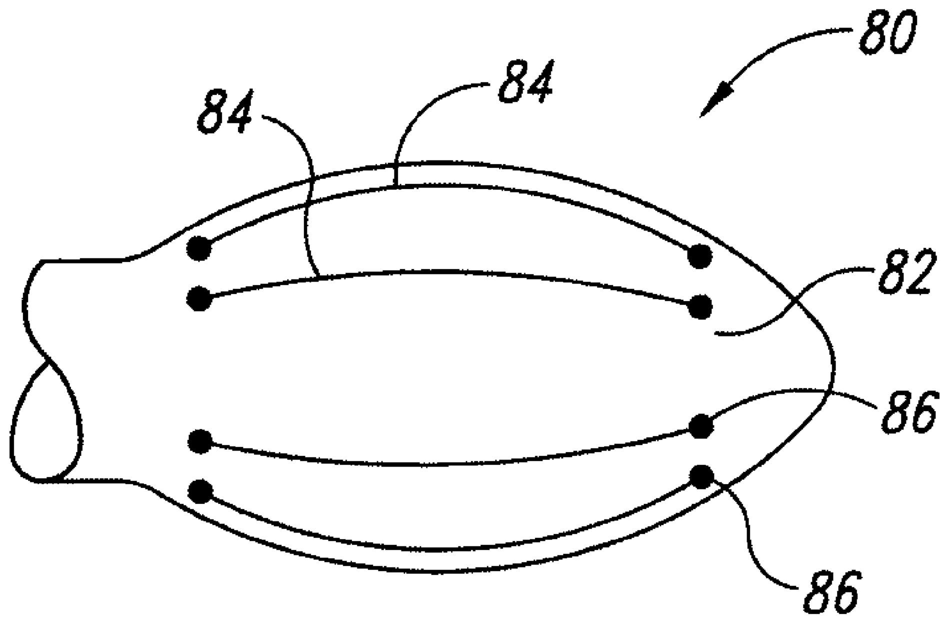
(57) **ABSTRACT**

An energy delivery device for treating tissue regions in a body conduit, such as a lung airway, may utilize one or more markers, rings, bands, or other visual indicators along an outer surface of the device body. The one or more visual indicators facilitate guidance of the device to effectively and efficiently treat the tissue according to a predetermined axial treatment as well as measure extension of a distal portion of the device, tissue length, and/or treatment length. The predetermined axial treatment may be contiguous, overlapping, or intermittently spaced apart as determined by the marker spacing distance.



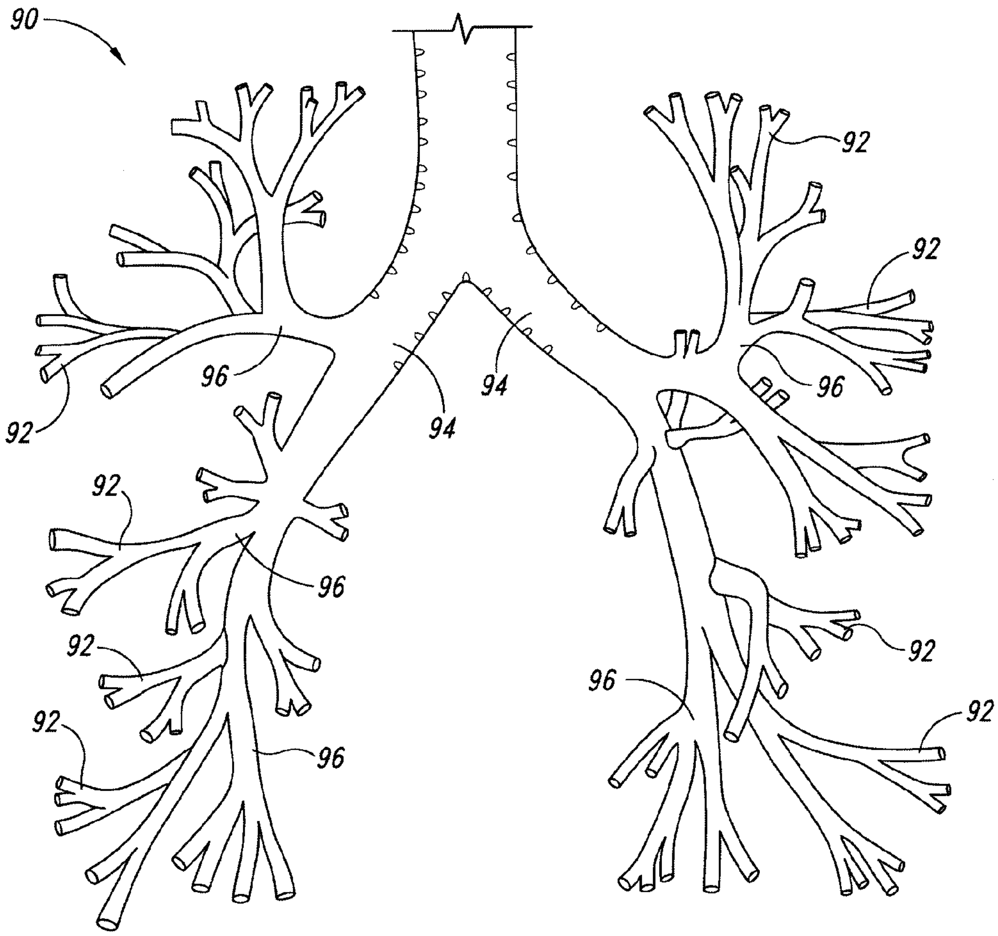
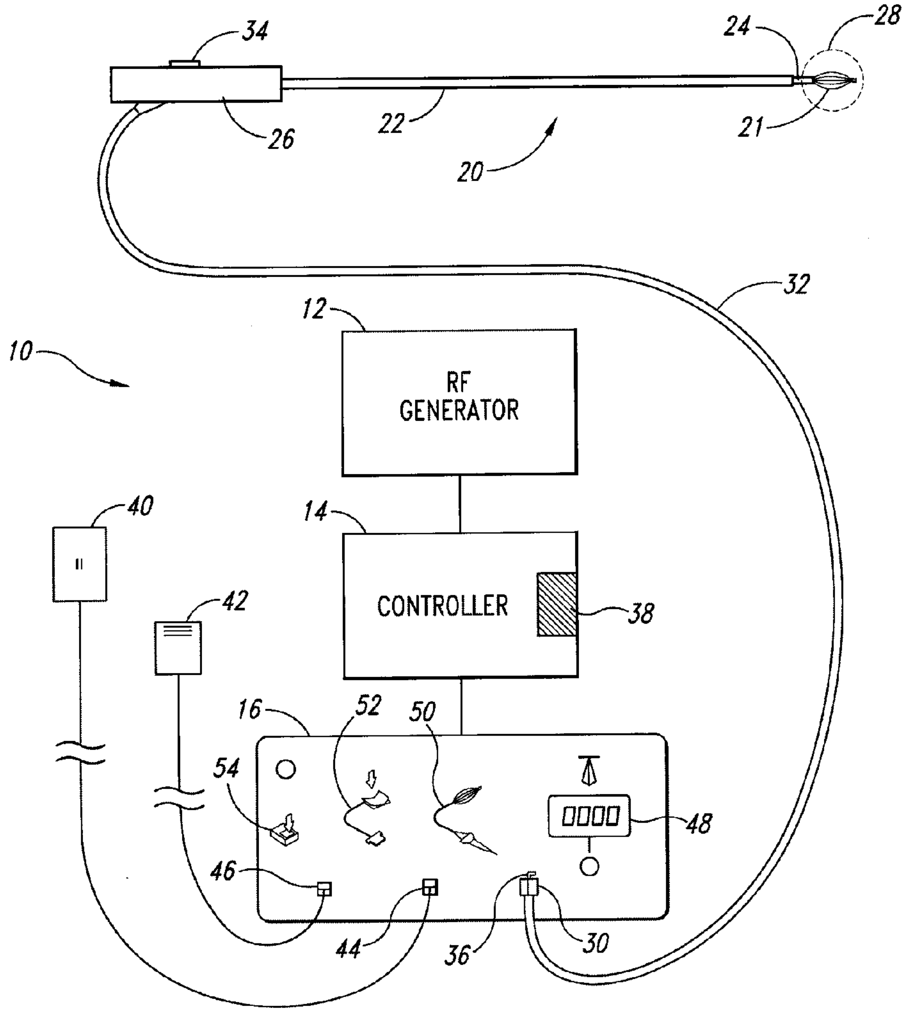


Fig. 1



34
24
28
26
22
21
20
32
12
10
RF GENERATOR
14
40
42
CONTROLLER
38
16
52
50
54
0000
48
46
44
36
30

Fig. 2

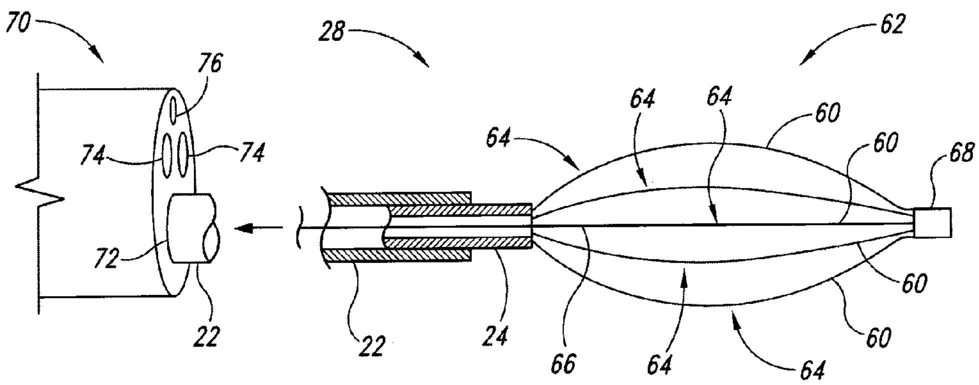

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Fig. 3A

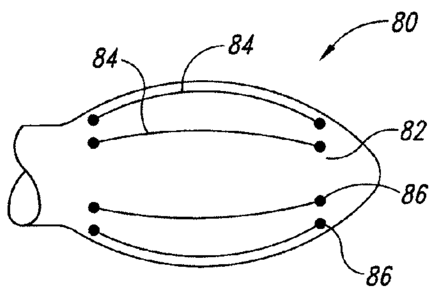
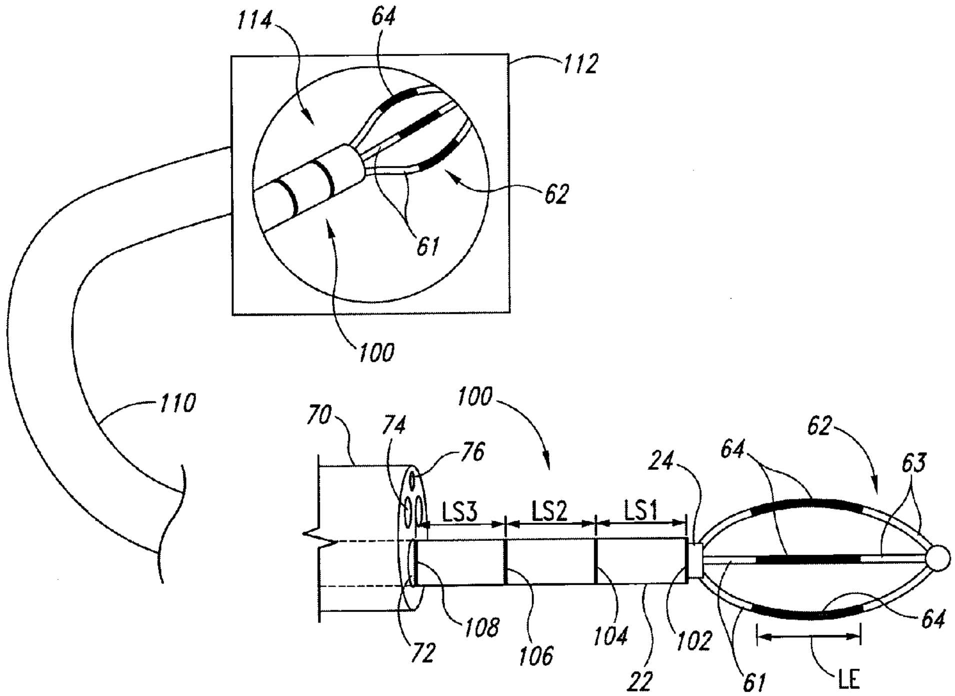

80
84
84
82
86
86

Fig. 3B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110
70
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76
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LS3
LS2
LS1
108
106
104
102
72
22
61
64
LE

Fig. 4

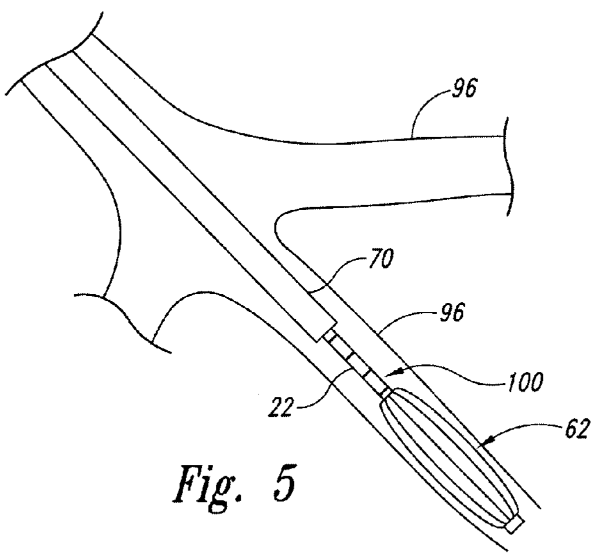
96
70
96
100
22
62

Fig. 5

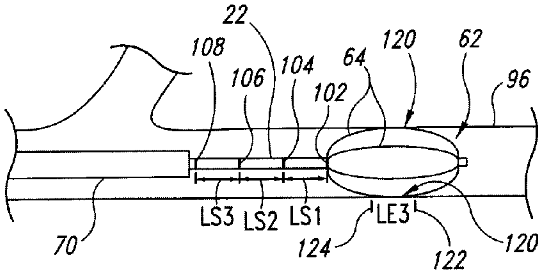

Fig. 6A

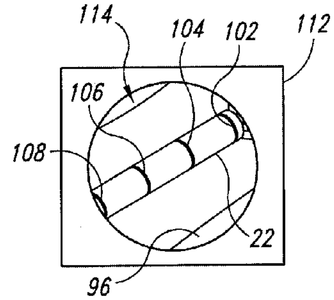

Fig. 6B

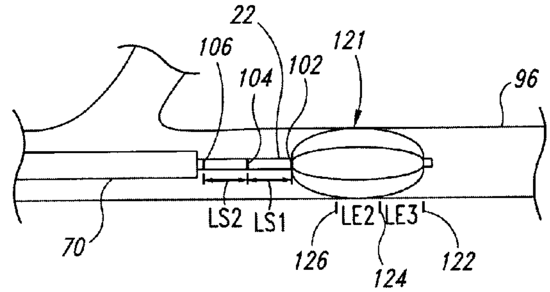

Fig. 7A

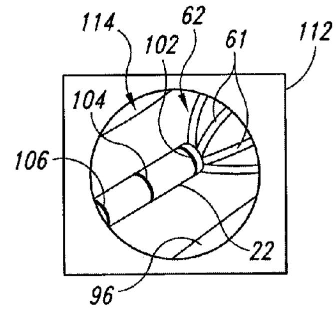

Fig. 7B

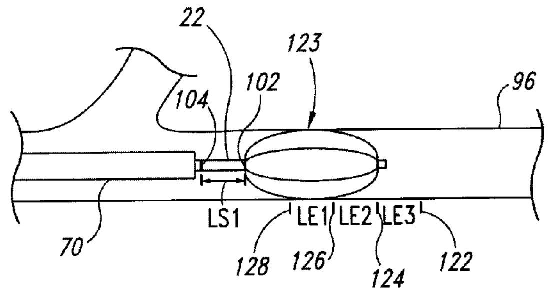

Fig. 8A

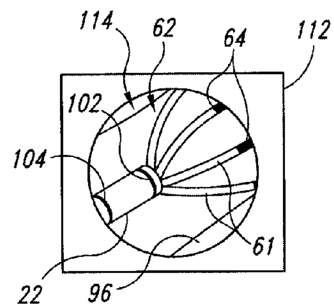

Fig. 8B

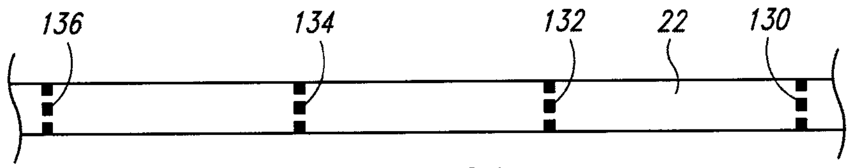

Fig. 9A

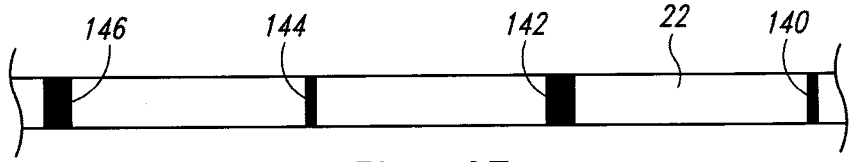

Fig. 9B

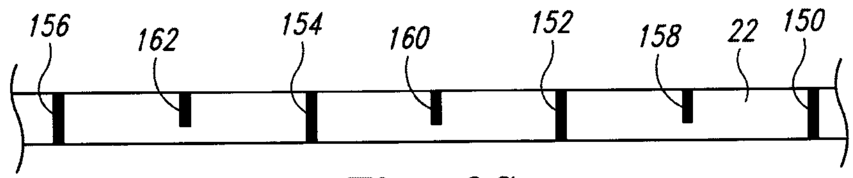

Fig. 9C

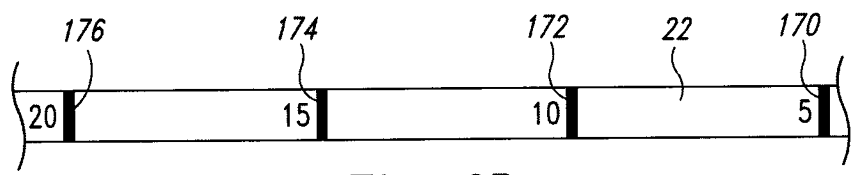

Fig. 9D

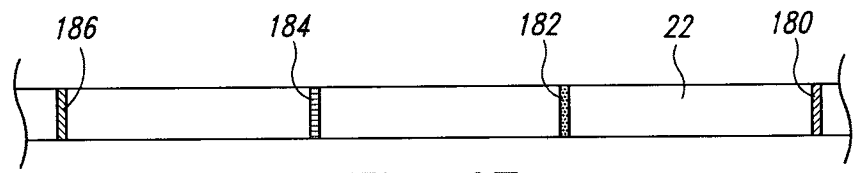

Fig. 9E

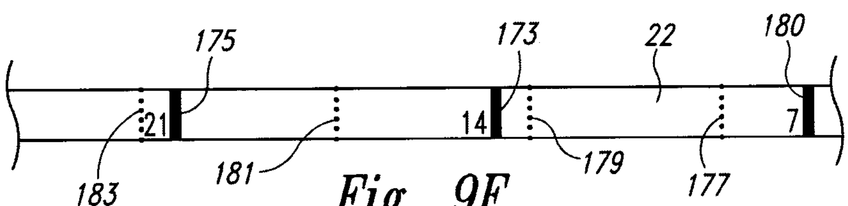

Fig. 9F

ELECTRODE MARKERS AND METHODS OF USE

BACKGROUND OF THE INVENTION

[0001] Asthma is a disease in which bronchoconstriction, excessive mucus production, and inflammation and swelling of airways occur. This causes widespread variable airflow obstruction which makes it difficult for an asthma sufferer to breathe. Asthma is a chronic disorder, primarily characterized by persistent airway inflammation. Asthma is further characterized by acute episodes of additional airway narrowing via contraction of hyper-responsive airway smooth muscle.

[0002] Asthma is traditionally managed pharmacologically by: (1) long term control through use of anti-inflammatories and long-acting bronchodilators and (2) short term management of acute exacerbations through use of short-acting bronchodilators. Both of these approaches require repeated and regular use of prescribed drugs, which often present difficulties in patient compliance. High doses of corticosteroid anti-inflammatory drugs can have serious side effects that require careful management. In addition, some patients are resistant to steroid treatment. The difficulty of avoiding stimulus that triggers asthma is also a common barrier to successful asthma management. As such, current management techniques are neither completely successful nor free from side effects.

[0003] Presently, a new treatment for asthma is showing promise. This treatment comprises the application of energy to the airway tissue. This treatment is described in more detail in commonly assigned U.S. Pat. Nos. 6,411,852; 6,634,363; 7,027,869; 7,104,987 and U.S. Publication No. 2005/0010270, each of which is incorporated herein by reference.

[0004] The application of energy to airway tissue, when performed via insertion of a treatment device into the bronchial passageways, requires navigation through tortuous anatomy as well as the ability to treat a variety of sizes of bronchial passageways. As discussed in the above referenced patents and applications, use of a radio frequency (RF) energy delivery device provides one mechanism for treating tissue within the bronchial passageways.

[0005] FIG. **1** illustrates a bronchial tree **90**. As noted herein, devices treating areas of the lungs desirably have a construction that enables navigation through the tortuous passages. As shown, the various bronchioles **92** decrease in size and have many branching segments **96** as they extend into the right and left bronchi **94**. Accordingly, an efficient treatment utilizes devices that are able to treat airways of varying sizes as well as function properly when repeatedly deployed after navigating through the tortuous anatomy.

[0006] In addition to considerations of navigation and site access, there exists the matter of device orientation at the treatment site. The treatment devices generally make contact or are placed in close proximity to the target tissue. However, in utilizing the treatment devices in a patient, visibility of the energy delivery element, particularly depth perception, within the lung airways may be relatively limited as viewed from an imaging lens of an access device, such as a bronchoscope or endoscope. Limited visibility combined with a variety of other factors, including airway movement due to patient breathing, coughing, and/or wheezing (tidal motion) as well as movement of the access device, may make it difficult to ensure desired axial treatment of the lung airways with the energy delivery device.

[0007] For example, in procedures where a relatively long region of tissue is to be treated (e.g., longer than a length of the energy delivery element), difficulty in ascertaining the amount of tissue being treated may result in over-treatment of the same region or non-treatment of the target region. In particular, as the energy delivery element is translated from a first region to a second region and so on, portions of the target tissue may be over-treated or skipped entirely. Additionally, such conditions may result in slower procedures that increase total procedure time and patient discomfort.

[0008] In view of the above, methods and devices are desired for treating tortuous anatomy such as the bronchial passages which enable a user to effectively and efficiently treat tissue and relocate an energy delivery device along one or more portions of the tissue.

SUMMARY OF THE INVENTION

[0009] In treating tissue regions, such as within the lungs, a treatment device may utilize an elongate sheath or shaft having a plurality of markers, rings, bands, or other visual indicators along an outer surface thereof so as to facilitate guidance of the device to effectively and efficiently treat the tissue according to a predetermined axial treatment. The predetermined axial treatment may be contiguous (adjacent), overlapping, intermittently spaced apart (gapping), or a combination thereof as determined by the marker spacing, and as desired. The visual indicators may also serve as a mechanism for measuring a depth of the treatment device, the tissue length, and/or treatment length, as further described below.

[0010] In one aspect of the present invention, an energy delivery device such as an RF electrode basket may be advanced within a working channel of an access device, such as a bronchoscope or endoscope, until a final proximal marker, e.g., a fourth mark, is extended outside the access device, such that the electrode basket, or at least a proximal insulation thereof, and the markers are visible via an imaging lens in the access device. The electrode basket may be deployed into contact against the tissue to be treated and then activated. The treatment device may then be pulled proximally until the next adjacent mark, e.g., a third mark, is reached. This process of activation and pulling proximally may be repeated until a last mark is reached providing for a contiguous and/or continuous axial treatment length of the tissue.

[0011] In another aspect of the present invention, the treatment device which may be used in a body conduit, cavity, passageway, or lumen, such as a lung airway, may generally comprise an elongate body, an energy delivery element, and one or more visual indicators. The elongate body comprises a proximal portion with a proximal end and a distal portion with a distal end. The energy delivery element may be disposed at the distal end of the elongate body. The one or more visual indicators may be disposed on the distal portion of the elongate body. Significantly, the visual indicators are separated by a predetermined spacing distance so as to provide the desired predetermined axial treatment in the body conduit or cavity.

[0012] In yet another aspect of the prevent invention, the treatment device may comprise a radio frequency energy delivery device for use in a lung airway so as to treat asthma. The device comprises an elongate body having a proximal portion with a proximal end and a distal portion with a distal end. A RF electrode is disposed at the distal end of the elongate body. A plurality of visual indicators are disposed on the distal portion of the elongate body, wherein the visual indicators are separated by a predetermined spacing distance so as to provide a predetermined axial treatment in a lung airway so as to treat asthma.

[0013] In a further aspect of the present invention, one method for using the treatment device to deliver energy may generally comprise positioning the access device having a visualization element within a lung airway so as to access airways that are typically 3 mm (or smaller) to 10 mm (or larger) in diameter, as can be properly viewed with direct real-time visualization. The access device may then be stabilized or anchored. The energy delivery device is advanced within the access device so that at least one visual indicator disposed on a distal portion of the energy delivery device and proximal an energy element delivery element disposed on a distal end of the energy delivery device is positioned outside the access device as verified with the visualization element. The visual indicators in turn will provide the desired predetermined axial treatment in the lung airway with the energy delivery element relative to the access device.

[0014] A further understanding of the nature and advantages of the present invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The following drawings should be read with reference to the detailed description. Like numbers in different drawings refer to like elements. The drawings, which are not necessarily to scale, illustratively depict embodiments of the present invention and are not intended to limit the scope of the invention.

[0016] FIG. **1** is an illustration of the airways within a human lung.

[0017] FIG. **2** illustrates a schematic view of a treatment system for delivering energy to tissue utilizing an expandable electrode basket.

[0018] FIG. **3**A illustrates a side view of the treatment device of FIG. **2** extending distally from a bronchoscope, wherein the device has an active distal end for treating tissue using energy delivery.

[0019] FIG. **3**B illustrates a variation of a treatment device comprising an expandable body, such as a balloon, having one or more electrodes disposed along its surface.

[0020] FIG. **4** illustrates an exemplary schematic view of an expandable electrode basket projecting distally from an elongate sheath having one or more markers delineated along its length and a representative image on a monitor corresponding to an image as viewed from the bronchoscope, wherein the spacing distance between each adjacent marker corresponds to a length of the electrodes located on the treatment device.

[0021] FIG. **5** illustrates the energy delivery device of FIG. **4** advanced into a bronchial airway and positioned for treatment upon the tissue.

[0022] FIGS. **6**A and **6**B illustrates the treatment device advanced distally within an airway lumen for treating the tissue and the corresponding image from a bronchoscope on a monitor showing the markers along the sheath.

[0023] FIGS. **7**A and **7**B illustrate the treatment device pulled proximally along the tissue by a length corresponding to a length between markers along the sheath such that the treatment device is aligned to an adjacent region of tissue to be treated.

[0024] FIGS. **8**A and **8**B illustrate the treatment device pulled further proximally along the tissue by a length corresponding to a length between markers along the sheath such that the treatment device is aligned to another adjacent region of tissue to be treated.

[0025] FIG. **9**A illustrates a variation of the sheath utilizing dashed markers.

[0026] FIG. **9**B illustrates another variation of the sheath utilizing non-uniform markers.

[0027] FIG. **9**C illustrates another variation of the sheath utilizing markers which have a length between adjacent markers which is less than a length of the electrodes on the treatment device such that overlapping regions of tissue may be treated.

[0028] FIG. **9**D illustrates yet another variation of the sheath utilizing markers having graduated measurements therealong to provide a visual indication of tissue or treatment length and/or electrode basket depth.

[0029] FIG. **9**E illustrates yet another variation of the sheath utilizing markers having alternative colors, such as a green marker to indicate treatment device deployment or a red marker to indicate a maximum length of sheath extension.

[0030] FIG. **9**F illustrates still another variation of the sheath utilizing markers which have a length between adjacent markers which is greater than a length of the electrodes on the treatment device such that intermittent regions of tissue may be treated.

DETAILED DESCRIPTION OF THE INVENTION

[0031] It will be appreciated that the examples below discuss uses in the airways of the lungs. However, unless specifically noted, the devices and methods described herein are not limited to use in the bronchial passageways. Instead, such devices and methods may have applicability in various parts of the body, such as the upper respiratory tract, trachea, esophagus, urethra, ureter, digestive tract, cardiovascular system, circulatory system, arthroscopic, brain, liver, etc. Moreover, the present invention may be used in various procedures where the benefits of the device are desired.

[0032] Generally, in treating tissue regions within the lungs, the treatment device may utilize an elongate body, such as tubular sheath, shaft, or catheter, having a plurality of markers, rings, bands, or other visual indicators (e.g., circular or otherwise) along an outer surface thereof. The plurality of visual indicators facilitate guidance of the device to effectively and efficiently treat the tissue according to a predetermined axial treatment. The predetermined axial treatment may be contiguous, overlapping, or intermittently spaced apart treatment of the lung airway walls with the energy delivery element(s). The plurality of visual indicators may also serve as a mechanism to measure a depth of the device, tissue length, airway segment length, and/or treatment length.

[0033] In one example of operation, the treatment device, such as an RF electrode basket assembly, may be advanced within a working channel of an access device, such as a bronchoscope, until a final proximal marker is extended distally from the access device while under direct real-time visualization. With the treatment device and the markers visible through the access device, the electrode basket assembly may be deployed against the tissue to be treated and activated. The treatment device may then be pulled proximally relative to the access device until the next adjacent marker is reached. The treatment device may then be activated to treat the portion of tissue adjacent to the previously treated portion without overlap (i.e., over-treatment of the same region) or separation (i.e., non-treatment of target tissue) between the adjacent portions of treated tissue. This process of activation and pulling proximally may be repeated until the last mark is reached providing for a continuous axial treatment where the target tissue regions are neither over-treated nor skipped.

[0034] Referring now to FIG. **2**, a schematic diagram of one example of a treatment system **10** for delivering therapeutic energy to tissue of a patient is illustrated. The system **10** comprises a power supply having an energy generator **12**, a controller **14** coupled to the energy generator **12**, and a user interface surface **16** in communication with the controller **14**. The system **10** further includes an energy delivery device **20**, a return electrode **40** (if the system **10** employs a mono-polar RF configuration), and foot actuation pedal(s) **42**. It will be appreciated that the above depictions are for illustrative purposes only and do not necessarily reflect the actual shape, size, or dimensions of the system **10** or device **20**. This applies to all depictions hereinafter.

[0035] The system **10** depicted in FIG. **2** shows the user interface portion **16** having one or more connections **36**, **44**, **46** for the device **20**, the return electrode **40** (optional), and the actuation pedal(s) **42** (optional) respectively. The user interface **16** may also include visual prompts **48**, **50**, **52**, **54** for user feedback regarding setup or operation of the system **10**. The user interface **16** may also employ graphical representations of components of the system **10**, audio tone generators, as well as other features to assist the user with system operation.

[0036] The controller **14** may be configured to deliver RF energy in either a mono-polar or bi-polar configuration. In many variations of the system **10**, the controller **14** may include a processor **38** that is generally configured to accept information from the system and system components, and process the information according to various algorithms to produce control signals for controlling the energy generator **12**. The processor **38** may also accept information from the system **10** and system components, process the information according to various algorithms and produce information signals that may be directed to the visual indicators, digital display or audio tone generator of the user interface in order to inform the user of the system status, component status, procedure status or any other useful information that is being monitored by the system. The processor **38** of the controller **14** may be a digital IC processor, analog processor, or any other suitable logic or control system that carries out the control algorithms.

[0037] Detailed descriptions on the processor **38**, user interface **16**, and safety algorithms that are useful for the treatment of asthma as discussed above may be found in commonly assigned U.S. patent application Ser. No. 11/408,688, filed Apr. 21, 2006, entitled CONTROL METHODS AND DEVICES FOR ENERGY DELIVERY, which is incorporated herein by reference.

[0038] It is understood that the device **20** of the present invention may be used with a variety of systems **10**, having the same or different components as described in FIG. **2**. For example, although the device **20** is described with reference to RF energy delivery systems **10**, variations of the device and system may include light energy sources, laser systems, resistive heating systems, infrared heating elements, microwave energy systems, focused ultrasound, cryo-ablation, radiation, electrical stimulation, or any other energy delivery system or configuration.

[0039] The energy delivery device **20** may include a flexible tubular sheath **22**, an elongate shaft **24** (in this example, the shaft **24** extends out from the distal end of the sheath **22**), and a handle or other optional operator interface **26** secured to a proximal end of the sheath **22**. The distal portion of the device **20** includes an energy transfer element **28** for applying energy to the tissue of interest. The energy transfer element **28**, such as an expandable electrode basket, may be advanced into and through the patient body in an atraumatic low profile configuration. Upon reaching the designed tissue region to be treated, the energy transfer element **28** may be expanded or reconfigured into a treatment configuration which facilitates contact of the element **28** against the tissue to be treated. In one example, the energy transfer element **28** may be reconfigured via a pull wire **21** routed proximally through elongate shaft **24** and/or flexible sheath **22** and affixed to a handle **26** and actuated with a slide mechanism **34**.

[0040] Additionally, the device **20** may includes a connector **30** common to such energy delivery devices. The connector **30** may be integral to the end of a cable **32** coupled to the handle **26** or the connector **30** may be fitted to receive a separate cable **32**. In any case, the device **20** is configured for attachment to the power supply via some type of connector or adaptor plug **30**. The elongate shaft **24** and/or flexible sheath **22** may also be configured and sized to permit passage through a working channel of a commercially available bronchoscope or endoscope. However, the device **20** may also be advanced into a body conduit or cavity with or without a steerable catheter, in a minimally invasive procedure, in an open surgical procedure, or with or without the guidance of various vision or imaging systems.

[0041] The devices **20** of the present invention will have a sufficient length and/or diameter and/or flexibility to access the tissue targeted for treatment. For example, treating airways as small as 3 mm in diameter may utilize the flexible sheath **22** and/or elongate shaft **24** which is sufficiently long and sized in diameter to reach deep into the lungs to treat the airways. Generally the device shaft **24** and/or sheath **22** will have a length in range from about 0.5 feet to about 8.0 feet and an expanded basket diameter **28** in a range from about 1 mm to about 25 mm, more preferably from about 3 mm to about 10 mm. However, it is noted that this example is merely illustrative and is not limiting in dimension or flexibility.

[0042] Referring now to FIG. **3**A, an example of an energy transfer device **28** is illustrated as an expandable electrode basket. The device **28** has one or more legs **60** configured in the form of a basket **62** converging to an atraumatic common distal tip **68**. The basket **62** may reconfigure from an atraumatic low profile shape to an expanded or deployed configuration to facilitate contact against the tissue walls of a body conduit, cavity, passageway, or lumen, such as a lung airway wall. Examples of such devices are described in greater detail in commonly assigned U.S. Publication No. 2003/0233099, which is incorporated herein by reference.

[0043] The one or more legs **60** may be configured into the basket shape **62** such that the legs **60** may expand radially during operation to a working diameter as described above that will achieve contact between the legs **60** having active electrode regions **64** and the airway walls. The legs **60** may also include temperature sensors for tissue temperature feedback to the controller **14**. In this configuration, four legs **60** are shown, however any number of legs **60** may be utilized to form the basket **62** (e.g., 2, 3, 4, 5, 6, 7, 8, 9, 10, etc.).

[0044] As illustrated in FIG. **3**A, a pull wire **66** may extend through a lumen of the elongate shaft body **24**, to which the basket **62** may be directly mounted. Pull wire **66** may be utilized to deliver energy to the active electrodes **64** and/or assist basket **62** in expanding into its deployed treatment configuration. The treatment device **62** may optionally be delivered to a treatment site directly through the elongate delivery sheath or sleeve body **22**. In still other embodiments, pull wire **66** may be omitted entirely in which case basket **62** may be expanded or deployed by utilizing one or more legs **60** which are fabricated as elastic, super-elastic, or shape memory alloys (e.g., nickel-titanium alloys) which may self-expand from a compressed configuration when removed from the elongate sheath **22**. In summary, basket **62** may expand upon activation by the user or it may automatically expand when advanced out of a restraining sheath **22** or when the sheath **22** is withdrawn proximally from the basket **62**.

[0045] The energy transfer device **28** is shown in association with a bronchoscope access device **70**. The elongate shaft **24** and flexible sheath **22** are received within a working channel **72** of the bronchoscope **70**. Accordingly, the energy transfer device **28** may be utilized along with an imaging lumen **76** and/or light optical fibers **74** of the bronchoscope **70**. The imaging lumen **76** may utilize visualization elements, such as CCD imaging or a camera lens. The bronchoscope **70** may additionally comprise an aspiration lumen (not shown).

[0046] Referring now to FIG. **3**B, an alternative configuration of the energy transfer device **80** is illustrated. The active member **80** is configured as a body **82** having a set diameter and length. One or more electrodes **84** are shown secured to the body **82** through holes **86** or adhesives or other attachment mechanisms. The electrodes **84** may be oriented axially relative to the body **82** to optimize contact along the tissue walls during treatment. The diameter of active member **80** is set to correspond to that desired for treating a given body lumen or passageway, such as lung airway. Accordingly, body **82** may be configured as an inflatable balloon member, an expandable scaffold member, and the like, where the electrodes **84** will move outward upon body **82** expansion.

[0047] Energy delivery devices **28**, **80** of wire frames and/or basket configurations will generally have its members (e.g., electrodes) symmetrically deployed. This shape may be round, rounded, or polygonal in cross section. These and other configurations, including asymmetrical active member configurations, are described in detail in U.S. patent application Ser. No. 11/255,796, filed Oct. 21, 2005, entitled IMPROVED ENERGY DELIVERY DEVICES AND METHODS and Ser. No. 11/420,438, filed May 25, 2006, entitled MEDICAL DEVICE WITH PROCEDURE IMPROVEMENT FEATURES, each of which is incorporated herein by reference.

[0048] Referring now to FIG. **4**, one variation of an exemplary treatment device is shown which facilitates guidance of the expandable electrode basket **62** so as to effectively and efficiently treat tissue as desired, particularly relatively long portions of tissue (e.g., regions of tissue longer than a length of the electrode **64**). In this embodiment, the basket **62** is disposed at the distal end of the elongate sheath **22** which in turn is shown projecting distally outward from the bronchoscope **70**. One or more visual indicators **100** are disposed along a length of the elongate sheath **22** (or shaft **24**), preferably on a distal portion of the sheath **22** and proximal to the basket **62**. Visual indicators **100** may generally comprise one or more markers, rings, bands, and the like. For example, a first marker **102** may be positioned proximally of basket **62**, a second marker **104** may be positioned proximally of first marker **102**, a third marker **106** may be positioned proximally of second marker **104**, and a fourth marker **108** may be positioned proximally of third marker **106**. In another variation, at least two circular bands or rings may be utilized and in other variations, four circular bands or rings may be utilized. It will be appreciated that any number, type, and/or combination of markers, rings or bands may be utilized in the present invention (e.g., 2, 3, 4, 5, 6, 7, 8, 9, 10, etc.).

[0049] Each marker **102**, **104**, **106**, **108** may be uniformly spaced apart from one another with each spacing matching the length of the active electrodes **64** of basket **62**. Thus, each spacing between markers **102**, **104**, **106**, **108** may be set to correspond to a length of a active electrode **64** located centrally between proximal and distal insulation regions **61**, **63** of the basket leg **60**. For instance, active electrodes **64** having a length of 5 mm along basket **62** may provide for a length of 5 mm between markers **102**, **104**, **106**, **108**. It will be appreciated that the active electrode length **64** and corresponding marker spacing of 5 mm is illustrative and other lengths fewer than 5 mm or greater than 5 mm may also be utilized as desired. For example, the predetermined spacing distance may range anywhere from about 3 mm to about 30 mm, more preferably in a range from about 5 mm to about 15 mm, depending on the active electrode length, basket leg length, electrode array length parallel to a longitudinal axis of the airway lumen, treatment temperature, time, power, current, voltage, and/or energy settings, and/or polarity configuration.

[0050] As mentioned above, in one variation the spacing between these markers **102**, **104**, **106**, **108** may each correspond to a length LE of the active electrodes **64** on basket **62**. For instance, a first marker distance LS**1** between first marker **102** and second marker **104**, a second marker distance LS**2** between second marker **104** and third marker **106**, and a third marker distance LS**3** between third marker **106** and fourth marker **108** may each correspond in length to the length LE of active electrodes **64** on basket **62**. Moreover, although four markers are illustrated in this example, fewer than four or more than four markers, as desired, may be utilized along the length of elongate sheath **22** in alternative variations.

[0051] Bronchoscope **70** may be electrically coupled **110** to a monitor **112** and/or processor configured to display images **114** received from imaging lumen **76**. As represented on monitor **112**, the displayed image corresponds to an image as viewed from the perspective of lumen **76** showing basket **62** projected from the elongate sheath **22**. Also illustrated are the visual markings **100** positioned along the sheath **22**.

[0052] Advantageously, the embodiment of FIG. **4** allows for the amount of tissue being treated by the basket **62** to be easily ascertained with reference to the visual markers **100**. In particular, markers **100** improve visibility and/or navigation of locating and placing the treatment electrodes **64** so as to reliably and uniformly apply predetermined axial treatments (e.g., continuous activation treatments). This in turn may reduce physician effort or fatigue (e.g., less surgical technique sensitive), total treatment procedure time, and/or patient discomfort and improve procedure efficacy.

[0053] Referring now to FIGS. **5** through **8**B, the basket **62** and elongate sheath **22** may be deployed from bronchoscope **70** and positioned distally of bronchoscope **70** along the tissue wall of a bifurcated airway **96**. In one example of use, basket **62** may be deployed from bronchoscope **70** and advanced distally relative to bronchoscope working channel **72**, as shown in FIG. **6**A, while visualizing the passage of markers **102**, **104**, **106**, **108** in monitor **112** directly in real-time, as illustrated in FIG. **6**B. With basket **62** positioned, it may be expanded into contact against the surrounding tissue wall **96** and the active electrodes **64** may be activated to heat the airway tissue **120** along a treatment length LE**3**. The treated tissue length LE**3**, extending between tissue borders **122**, **124**, may correspond in length to third marker spacing distance LS3 on elongate sheath **22**.

[0054] Once the treatment is completed along tissue length LE**3**, basket **62** may be retracted and withdrawn proximally relative to bronchoscope **70** while visualizing on monitor **112** by one marker length until the fourth marker **108** is no longer visible and third marker **106** is verified as visible in the monitor **112**, as shown in FIG. **7**B. Moving elongate sheath **22** by such a distance also translates basket **62** proximally by one marker length LS3 and correspondingly translates the active electrodes **64** to an adjacent tissue region proximal to the previously treated tissue length LE**3**. Once desirably positioned, basket **62** may then again be actuated so as to deploy against the airway wall **96** and activated to heat the airway tissue **121** along a treatment length LE**2** which borders treated tissue length LE**3** contiguously without overlapping or leaving any gap between the two treated tissue lengths, as shown in FIG. **7**A.

[0055] Once the tissue along tissue length LE**2** has been treated, basket **62** may once again be retracted and withdrawn proximally relative to bronchoscope **70** by another marker length such that third marker **106** is no longer visible and second marker **104** is verified as visible on the monitor **112**, as shown in FIG. **8**B. Accordingly, basket **62** is translated proximally by a corresponding distance along the tissue such that the active electrodes **64** are aligned between tissue borders **126** and **128**. The basket **62** may then be activated to treat the tissue region **123** along tissue length LE**1** which borders treated tissue length LE**2**, as illustrated in FIG. **8**A. This process of deploying, activating, retracting, and pulling proximally may be repeated, as desired, until first marker **102** is reached or by pulling the bronchoscope **70** proximally with respect to the sheath markers **100** and following the above steps relative to the stationary bronchoscope **70**. Thus, longer portions of the tissue may be treated as desired.

[0056] The resulting treated tissue may be thus formed into a contiguous length of treated tissue (e.g., LE**1**, LE**2**, LE**3**) which avoids over-treating the tissue by avoiding overlapping regions and avoids the formation of gaps between adjacent tissue lengths. Once the treatment is completed, the basket **62** may be withdrawn proximally into the bronchoscope working channel **72** for withdrawal from the patient or advancement into another region of tissue to be treated. Thus, if the length of the active electrode **64** is 5 mm and the corresponding marker lengths LS**1**, LS**2**, LS**3** are each 5 mm in length, the tissue may be treated in increments of **5**, **10**, **15**, 20 mm or more in a contiguous manner depending upon the desired length of tissue to be treated. The predetermined axial treatment (e.g., LE**1**, LE**2**, LE**3**) may comprise treatment of the lung airways for a length of at least 10 mm, preferably in a range from about 10 mm to about 75 mm, more preferably in a range from about 20 mm to about 30 mm.

[0057] It will be appreciated that there are several ways to use the device of the present invention, and as such is not limited by the above example. In an alternative method of use, elongate sheath **22** may be translated distally relative to bronchoscope **70** such that the initial treatment is initiated when first marker **102** is visualized. Accordingly, subsequent portions of tissue may be treated by advancing the basket **62** distally relative to bronchoscope **70** while viewing advancement of the markers on monitor **112**. In yet another variation, the elongate sheath **22** and basket **62** may be initially advanced distally until the first marker **102**, second marker **104**, or third marker **106** is exposed rather than being fully advanced until the fourth marker **108** is exposed. Thus, shorter portions of the tissue may be treated as desired.

[0058] Referring now to FIGS. **9**A through **9**F, although markers **100** may be identical, it will be appreciated that they may also be varied in any number of configurations. For example, FIG. **9**A illustrates one variation where the markers **130**, **132**, **134**, **136** may be dashed rather than solid. Another variation is shown in FIG. **9**B where the markers may be non-uniform in width, or alternating in width. For instance, markers **140**, **144** may have a first width while alternating markers **142**, **146** may have a second width larger than the first width.

[0059] In yet another variation, the markers **150**, **152**, **154**, **156** may be aligned to correspond to the active electrode length, as described above. Additional half markers **158**, **160**, **162** may be marked at, e.g., intermediate positions between markers **150**, **152**, **154**, **156**, to denote positions where portions of tissue may be treated by overlapping the treatment regions, as shown in FIG. **9**C.

[0060] Another variation is illustrated in FIG. **9**D where markers **170**, **172**, **174**, **176** may be graduated with length measurements, e.g., 5 mm, 10 mm, 15 mm, 20 mm, etc., much like an endoscope to facilitate measurement of basket **62** insertion depth or to facilitate measurement of the tissue region (e.g., length of the lung airway). In this manner, a portion of tissue or the depth in which the treatment device is advanced may be ascertained by directly visualizing the elongate sheath **22** extending from the stationary bronchoscope **70**. Although the measurement values are illustrated in 5 mm increments corresponding to the length of the active electrode **64** on the electrode basket **62**, any number of incremental values may be marked and delineated either in a corresponding or even non-corresponding manner with respect to the active electrodes, if so desired.

[0061] Referring now to FIG. **9**E, an elongate sheath **22** having markers which are in various colors to denote particular features associated with that particular marking is illustrated. Although the markers may be colored in the same color (e.g., black), various colors may be utilized, particularly to indicate predetermined device states. For example, marker **180** may comprise a first color (e.g., green) to indicate that once marker **180** is visible, electrode basket **62** is sufficiently advanced relative to the bronchoscope **70** for expansion and/or activation. Additional markers **182**, **184** may also comprise various colors as well while the proximal marker **186** may also be colored in yet another color (e.g., red) as a visual indication that the elongate sheath **22** should not be advanced any further distal into the airway lung.

[0062] In yet another variation, markers **171**, **173**, **175** (with graduations 7 mm, 14 mm, 21 mm) may have a length between adjacent markers which is greater than a length of the active electrodes **64** of the treatment device so that intermittent regions of tissue may be treated, as shown in. FIG. **9**F. Still further, the sheath may have a second set of markers **177**, **179**, **181**, **183** that have a different spacing distance, e.g., set to the active electrode **64** length, so that a user may utilize a particular marker set based on a particular anatomy section to be treated.

[0063] In these and other variations described herein, each of the markers may be marked on the elongate sheath **22** in various increments and are not limited to just the length of the active electrodes **64**, as described above in detail. Moreover, additional markers may be utilized or as few as a single marker may be utilized depending upon the desired visual indications.

[0064] The markers may also serve as a safety feature to discourage the pre-mature deployment of the electrode basket **62** within the bronchoscope **70**. For example, the first proximal marker may serve this purpose so as to prevent against any electrical discharge from flowing proximally along the sheath **22**, shaft **24** and/or bronchoscope **70**, which could potentially result in injury or harm to the patient or user. Additionally, the final proximal marker, which may be positioned along sheath **22** up to 75 mm or more, more preferably up to 50 mm or 30 mm, from the electrode basket **62**, may also serve as a visual safety feature to ensure against advancing the electrode basket **62** too deep into the patient body (i.e., beyond bronchoscopic vision), which in turn prevents against any patient harm, such as puncturing of the airway wall into the parenchyma, pneumothorax, pneumomediastinum, etc.

[0065] In yet another alternative, at least one of the markers may also be aligned with an anatomical landmark within the lung airway to provide not only for alignment of the device but also to facilitate measurement of the lung airway, if so desired. For example, a marker may be aligned with a particular airway bifurcation, colored tissue, cartilage ring, tissue nodule, and the like, so as to ensure against user disorientation due to tidal motion or movement of the access device.

[0066] Referring back to FIG. **8**B, it will be further appreciated that the markers **102** further allow for user differentiation of the sheath **22** from the insulated electrodes **61**, **63**, particularly the proximal insulation regions of the basket legs **60**. This visualization is important to ensure proper deployment of the basket electrode **62**.

[0067] Although certain exemplary embodiments and methods have been described in some detail, for clarity of understanding and by way of example, it will be apparent from the foregoing disclosure to those skilled in the art that variations, modifications, changes, and adaptations of such embodiments and methods may be made without departing from the true spirit and scope of the invention. For example, the plurality of visual indicators may be located on the device shaft, the energy delivery device may comprise a non-RF source, and/or the expandable energy device may comprise an inflatable balloon member. Still further, the markers of the present invention may be positioned alternatively or additionally on a proximal portion of the sheath or shaft that extends at least partially outside the access device and patient. Proximal makers may also facilitate quicker and more confident introduction of the shaft into the access device by indicating a measurement of the shaft within the access device. Reference to a singular element, includes the possibility that there are plural of the same elements present. More specifically, as used herein and in the appended claims, the singular forms "a," "an," "said," and "the" include plural referents unless the context clearly dictates otherwise. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

1-27. (canceled)

28. A method for treating a lung, comprising:

positioning an energy delivery element at a first location by aligning a first marker with a reference location;

delivering energy to lung tissue at the first location with the energy delivery element;

positioning the energy delivery element at a second location by aligning a second marker with the reference location; and

delivering energy to lung tissue at the second location with the energy delivery element.

29. The method of claim **28**, further including positioning the energy delivery element at a third location by aligning a third marker with the reference location, and delivering energy to the third location with the energy delivery element

30. The method of claim **29**, wherein a spacing between the first and second markers is equal to a spacing between the second and third markers.

31. The method of claim **28**, wherein the energy delivery element is an electrode having an exposed electrically conductive portion having a first length.

32. The method of claim **31**, wherein the first and second markers are spaced apart from one another by the first length.

33. The method of claim **31**, wherein the electrically conductive portion is defined at a proximal end and at a distal end by electrically non-conductive portions.

34. The method of claim **28**, wherein the energy delivery element is disposed at or adjacent to a distal end of an elongate member.

35. The method of claim **34**, wherein the first marker and the second marker are disposed on the elongate member.

36. The method of claim **35**, wherein the first marker and the second marker are disposed proximal to the energy delivery element.

37. The method of claim **36**, wherein positioning the energy delivery element at the second location includes pulling the energy delivery element proximally from the first location.

38. The method of claim **28**, wherein the first marker is proximal to the second marker.

39. The method of claim **28**, wherein aligning the first marker with the reference location includes visualizing an image of the first marker and the reference location.

40. A method for treating a lung, comprising:

delivering energy to lung tissue at a first location with an energy delivery element, the energy delivery element being disposed at or adjacent to a distal end of an elongate member, wherein the elongate member includes a plurality of markers spaced apart from one another;

determining a second location using the plurality of markers; and

delivering energy to lung tissue at the second location with the energy delivery element.

41. The method of claim **40**, wherein the energy delivery element includes an active energy delivery region, and the first location is spaced from the second location by a distance corresponding to a length of the active energy delivery region.

42. The method of claim **41**, wherein the active energy delivery region of the energy delivery element includes an electrically conductive portion defined at a proximal end and at a distal end by electrically non-conductive portions.

43. A method for treating a lung, comprising:

advancing an energy delivery device into the lung, the energy delivery device having an elongate member with a first marker and a second marker distal to the first marker, and an energy delivery element at or adjacent a distal end of the elongate member, wherein the energy delivery device is advanced into the lung until the first marker is aligned with a reference point;

delivering energy to the lung when the first marker is aligned with the reference point;

pulling the energy delivery device proximally until the second marker is aligned with the reference point, the first marker and the second marker being spaced apart from one another by a first distance corresponding to an active region of the energy delivery element; and

delivering energy to the lung when the second marker is aligned with the reference point.

44. The method of claim **43**, wherein the energy delivery device further includes a third marker distal to the second marker, and the method further includes pulling the energy delivery device proximally until the third marker is aligned with the reference point, and delivering energy to the lung when the third marker is aligned with the reference point.

45. The method of claim **44**, wherein the second marker and the third marker are spaced apart from one another by the first distance.

46. The method of claim **43**, wherein the energy delivery element is one of a plurality of energy delivery elements radially spaced apart from one another along a longitudinal axis of the energy delivery device.

47. The method of claim **43**, wherein the energy delivery element is reciprocally movable between a collapsed configuration and an expanded configuration.

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