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(54) **ENERGY DELIVERY AND ILLUMINATION DEVICES AND METHODS**

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(73) Assignee: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

(21) Appl. No.: **15/416,716**

(22) Filed: **Jan. 26, 2017**

Related U.S. Application Data

(63) Continuation of application No. 11/617,512, filed on Dec. 28, 2006, now abandoned, which is a continuation of application No. 11/420,407, filed on May 25, 2006, now Pat. No. 8,920,413, which is a continuation of application No. PCT/US05/41243, filed on Nov. 14, 2005, which is a continuation of application No. 11/255,796, filed on Oct. 21, 2005, now abandoned.

(60) Provisional application No. 60/627,662, filed on Nov. 12, 2004.

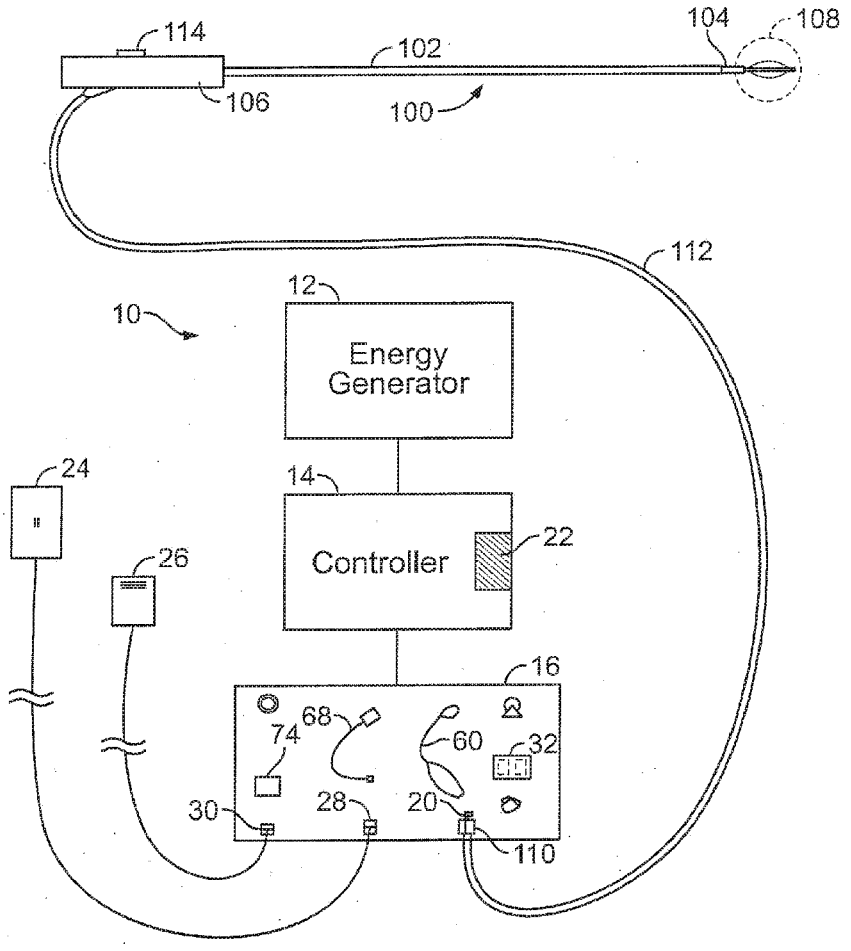
Publication Classification

(51) **Int. Cl.**
A61B 18/14 (2006.01)
A61B 90/30 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 18/1492*** (2013.01); ***A61B 90/30*** (2016.02); *A61B 2018/0022* (2013.01)

(57) **ABSTRACT**

This relates to methods and devices for improving treatment to a wall, a cavity or passageway with a medical device when used in tortuous anatomy.



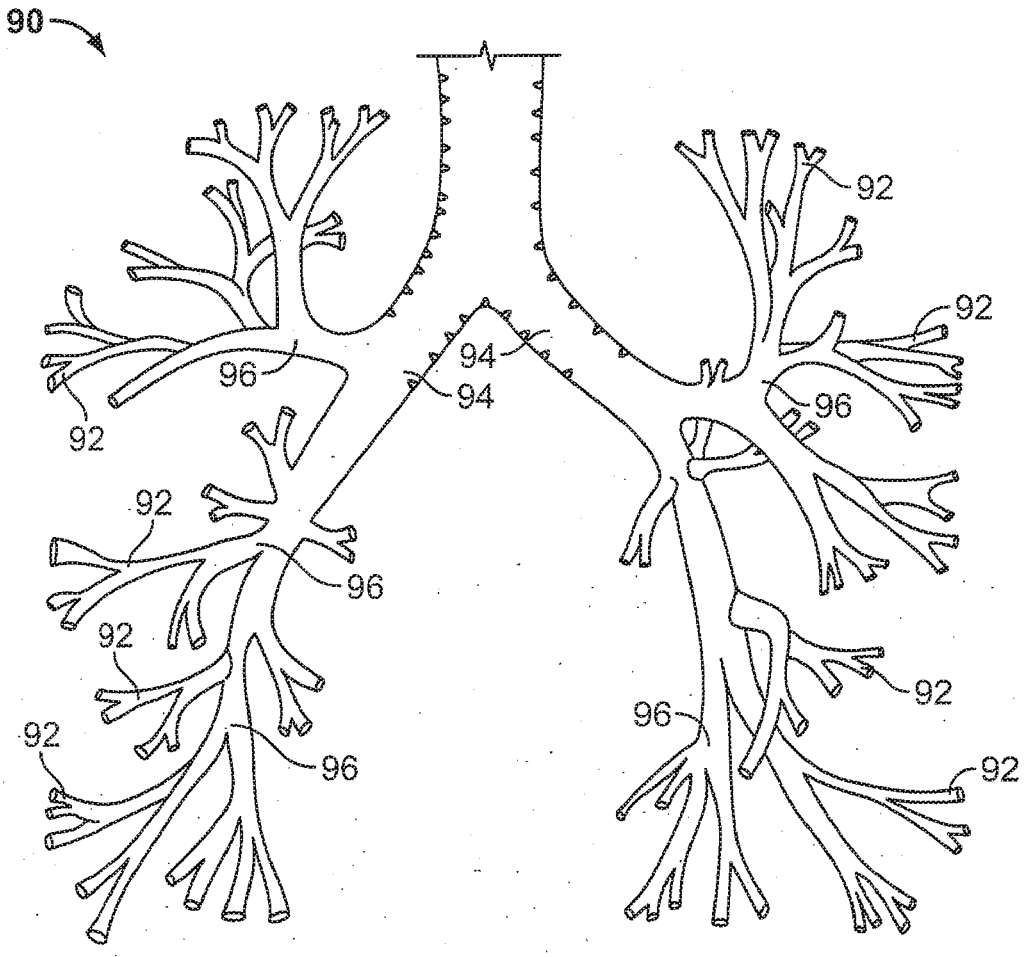


FIG. 1

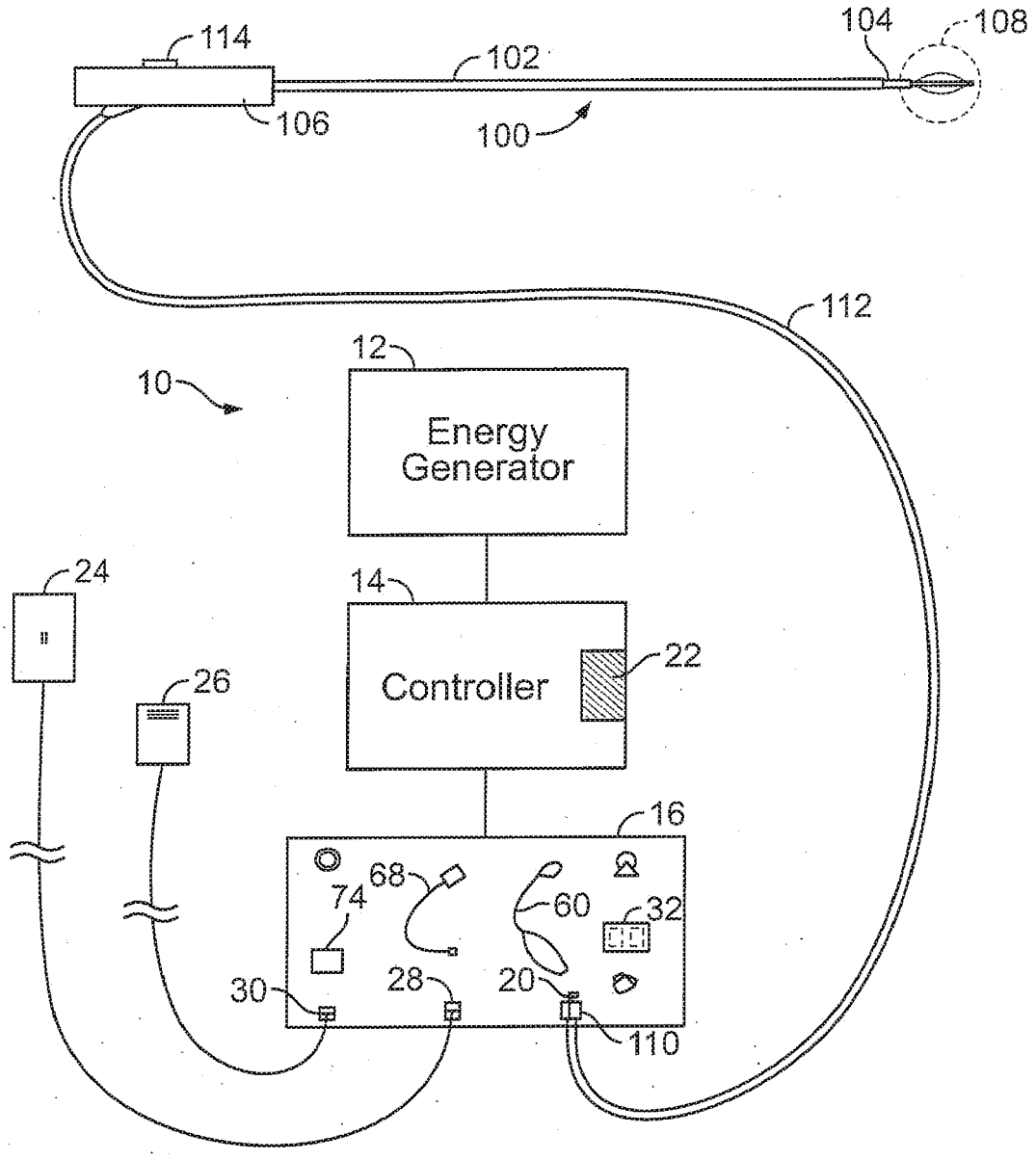

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FIG. 2A

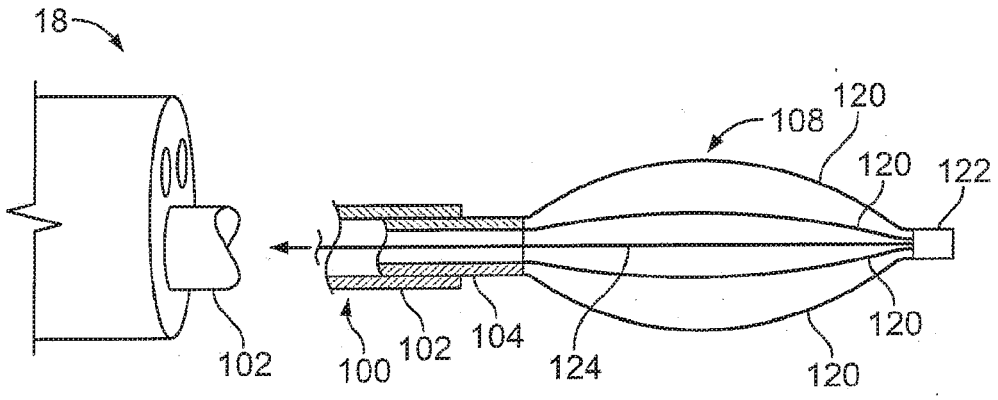


FIG. 2B

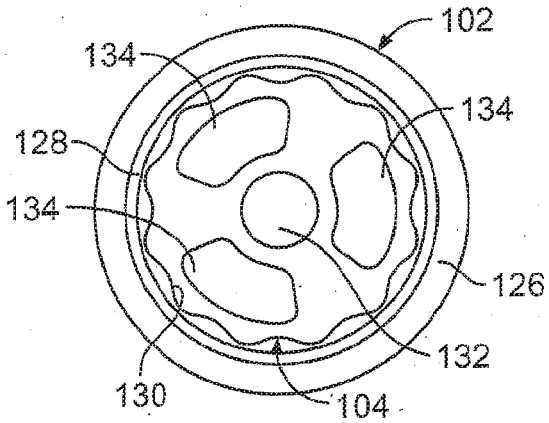


FIG. 3A

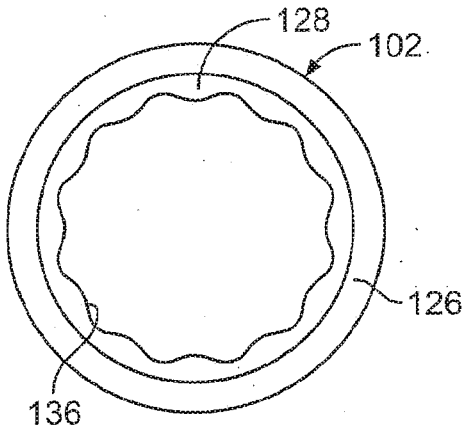


FIG. 3B

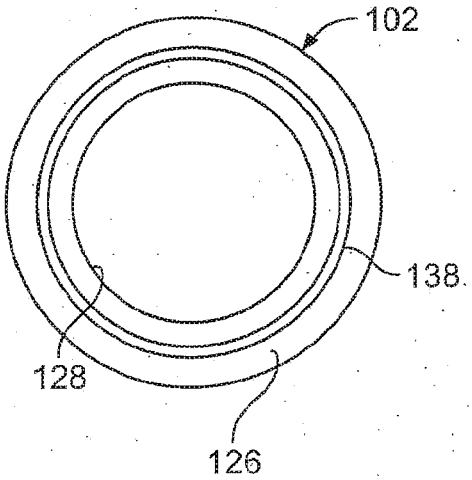


FIG. 3C

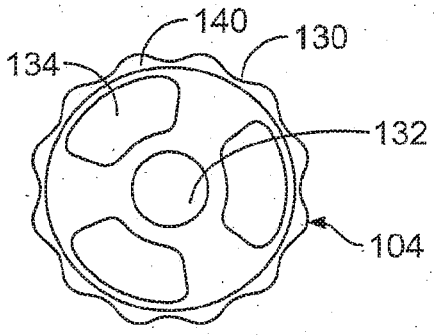


FIG. 3D

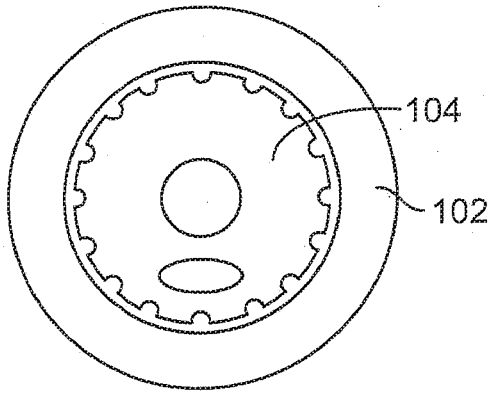


FIG. 3E

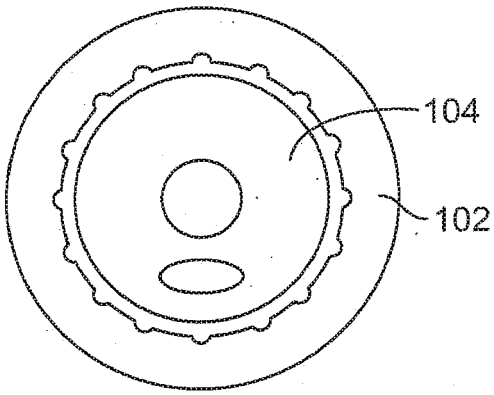


FIG. 3F

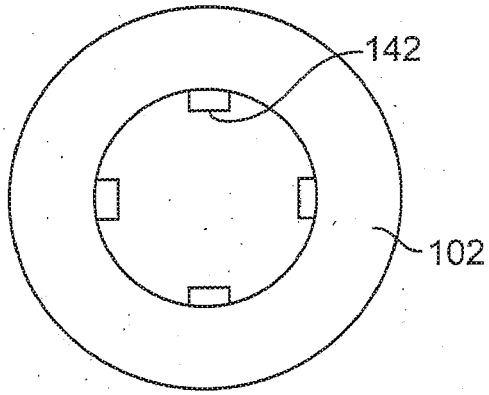


FIG. 3G

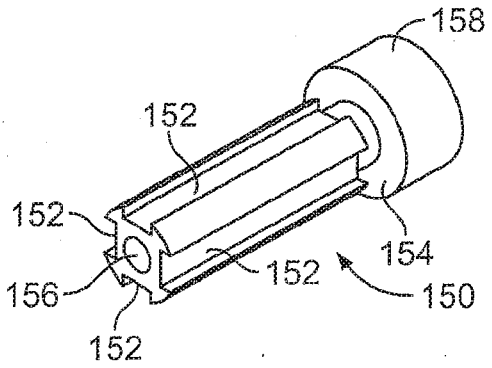


FIG. 4A

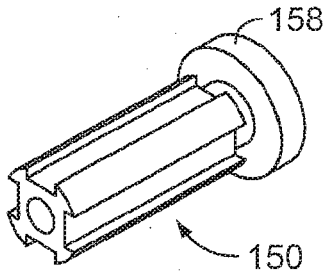


FIG. 4B

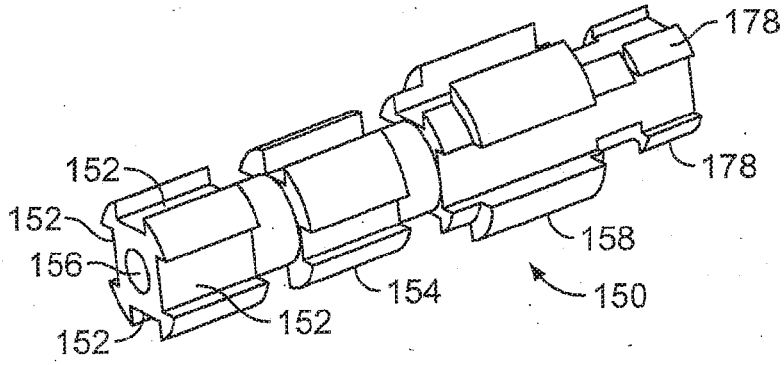


FIG. 4C

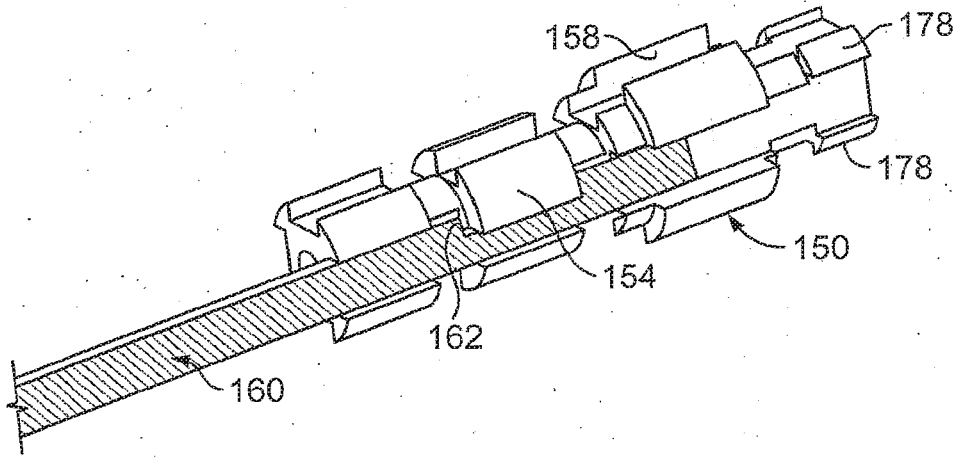
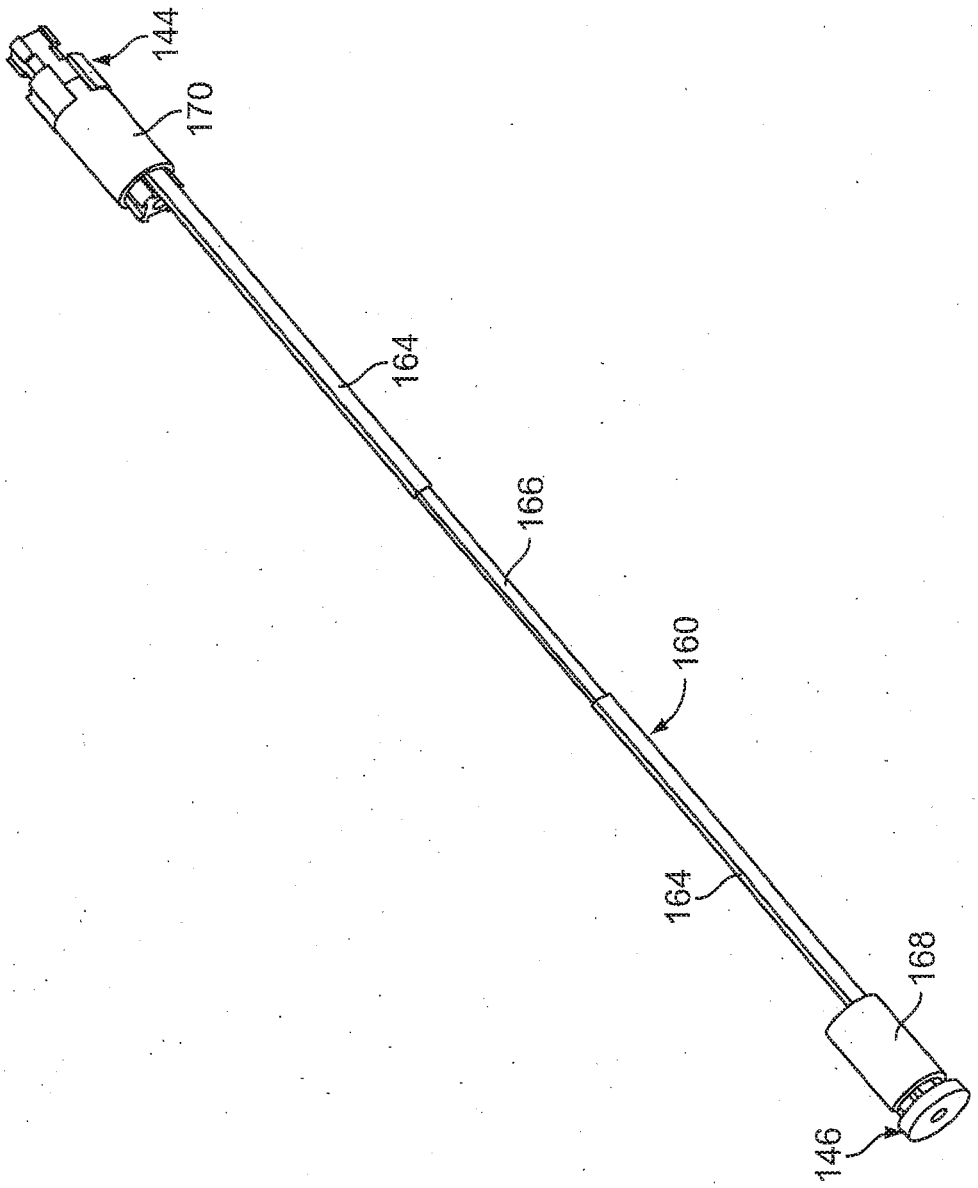


FIG. 4D



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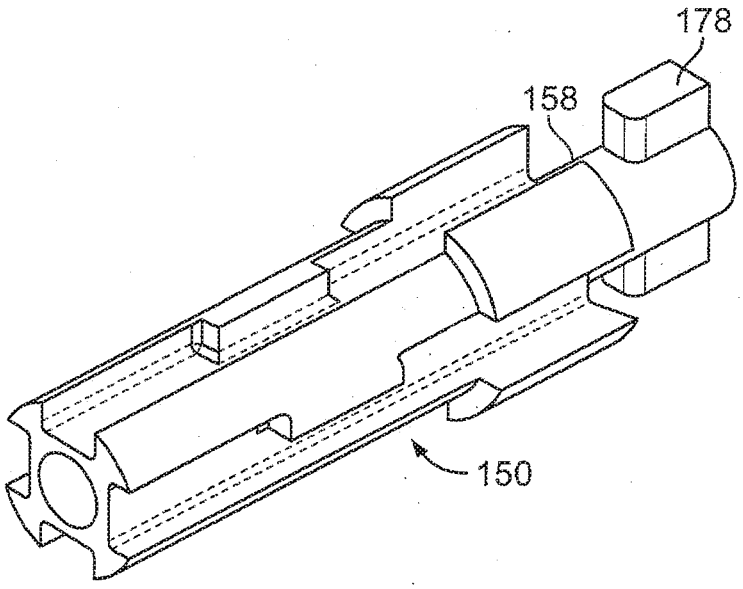

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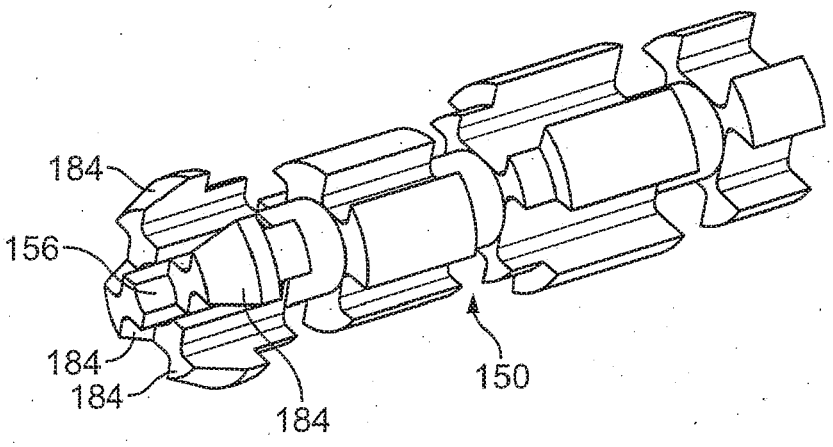

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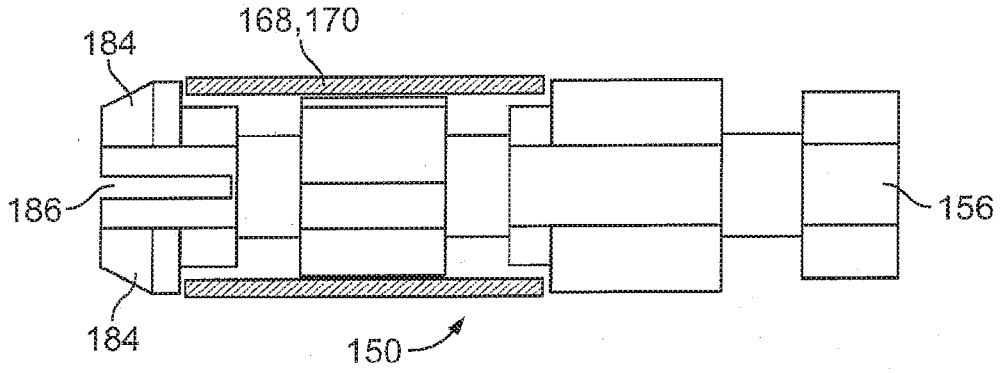


FIG. 4H

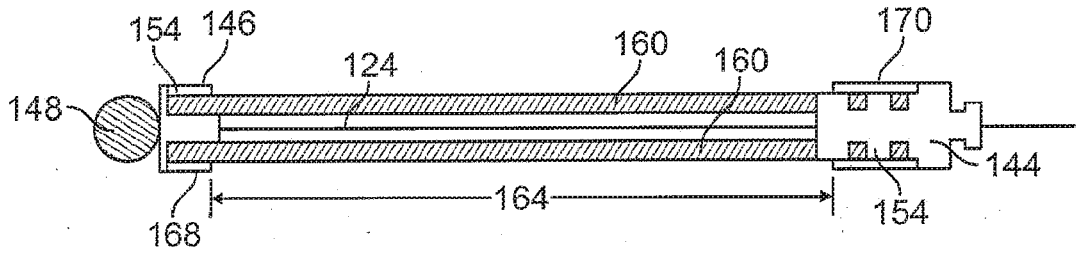


FIG. 5A

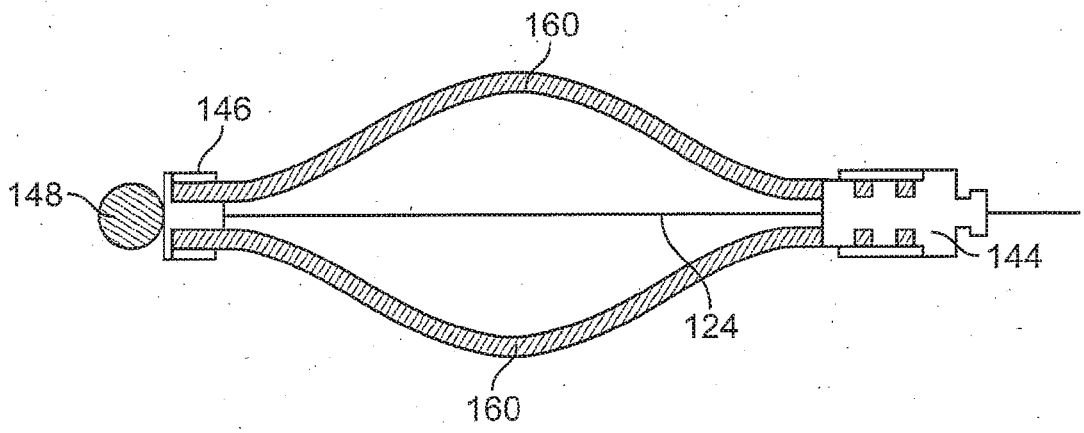
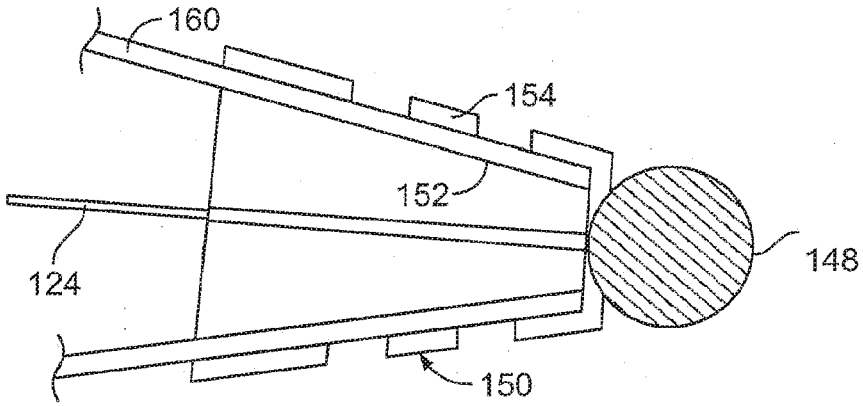


FIG. 5B



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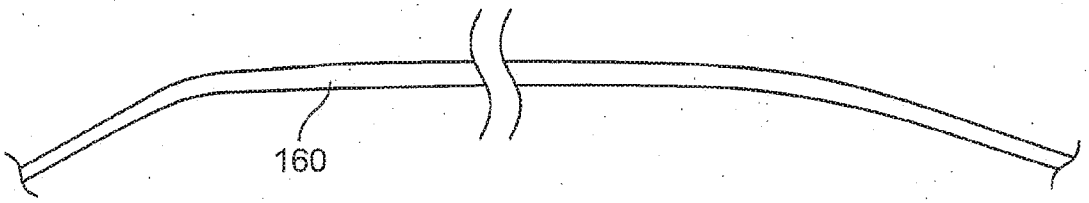


FIG. 5D

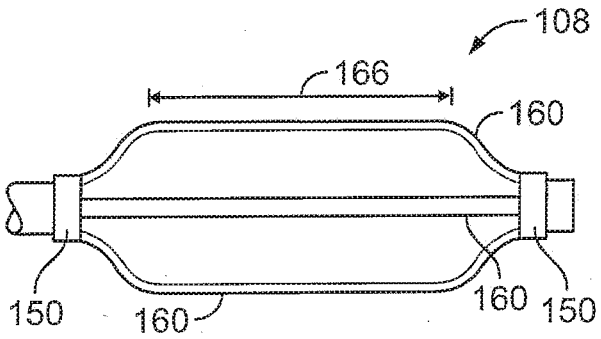


FIG. 6A

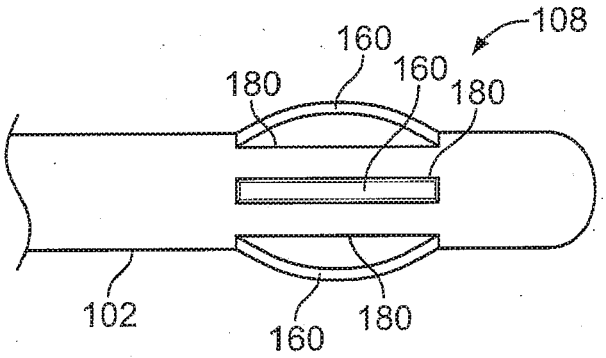
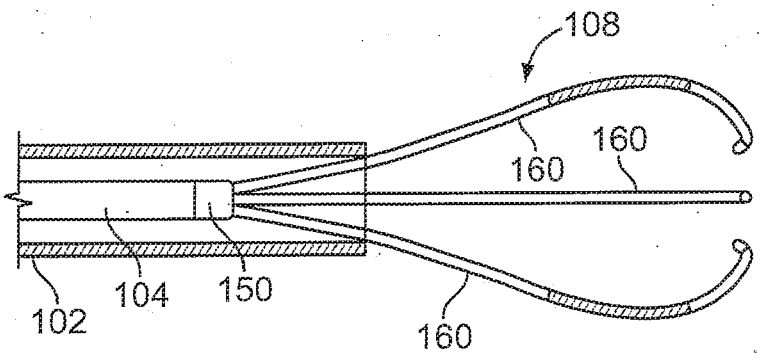


FIG. 6B



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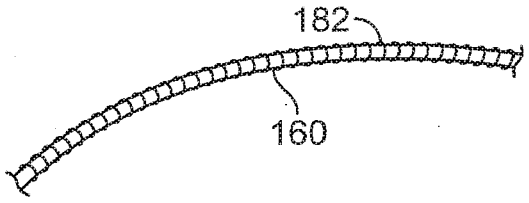


FIG. 7A

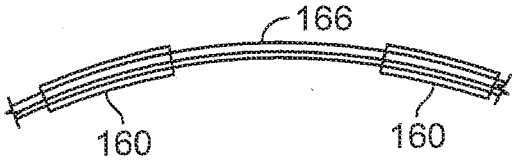


FIG. 7B

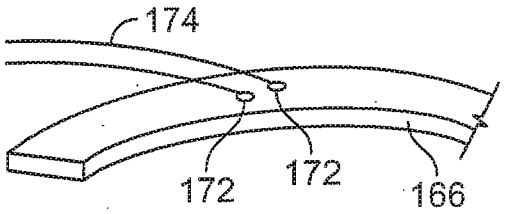


FIG. 7C

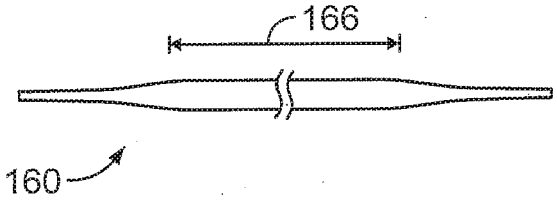


FIG. 7D

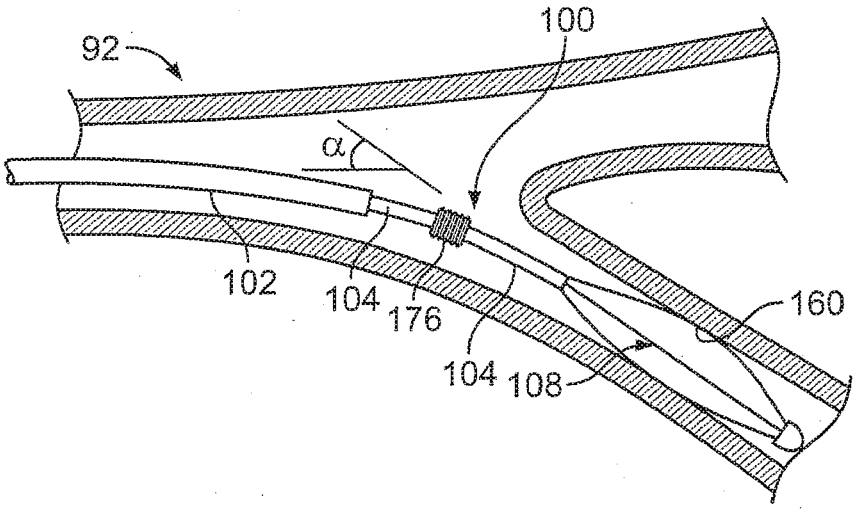


FIG. 8A

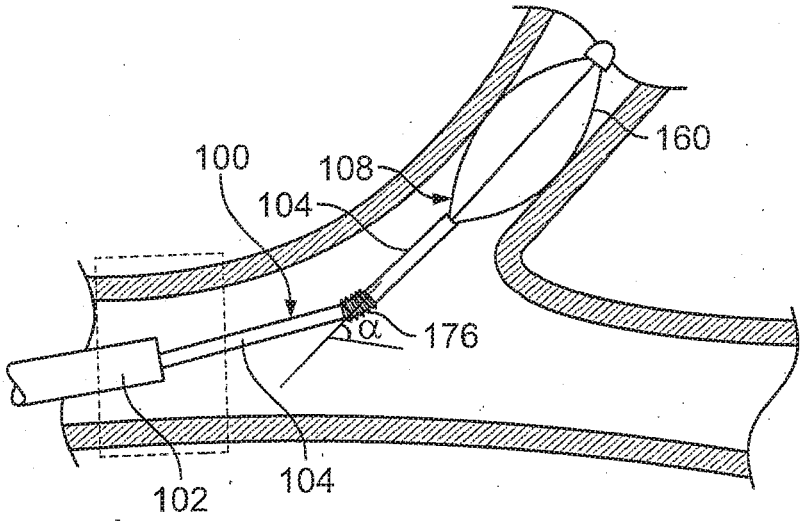
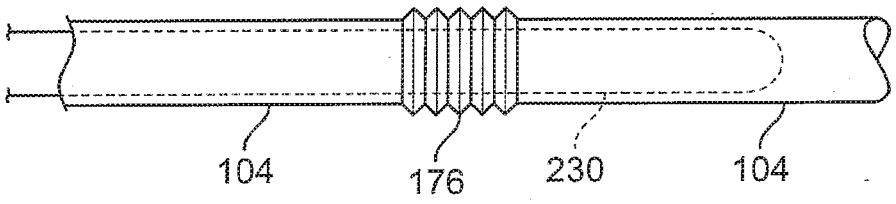


FIG. 8B



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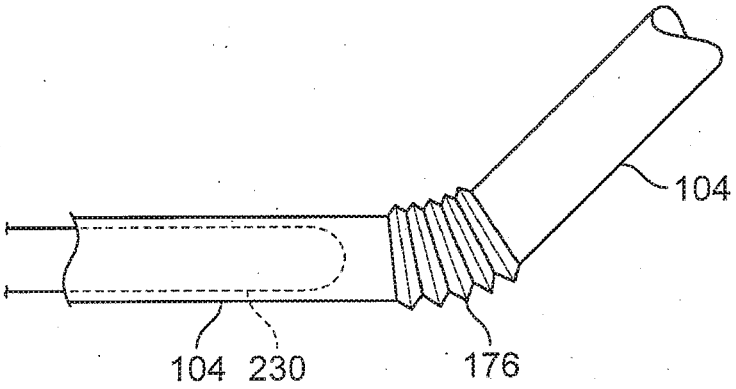

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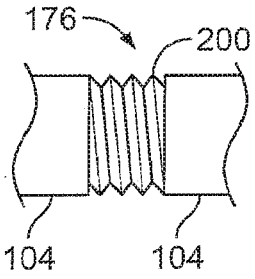


FIG. 9A

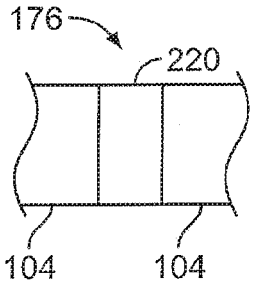
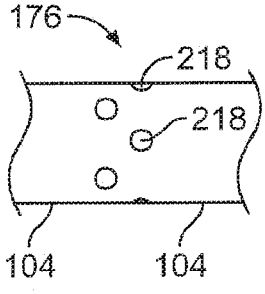


FIG. 9B



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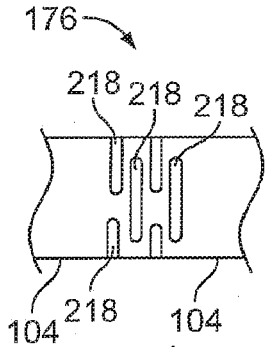

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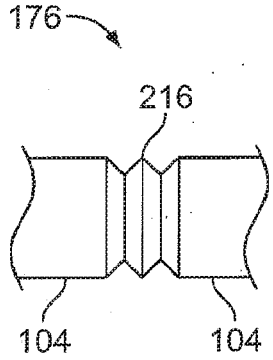

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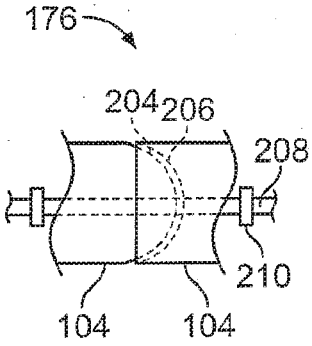

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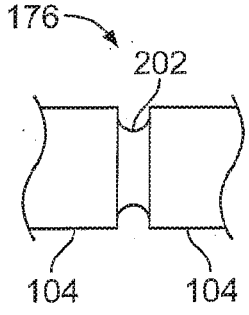

FIG. 9G

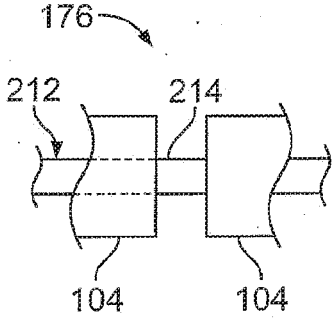

FIG. 9H

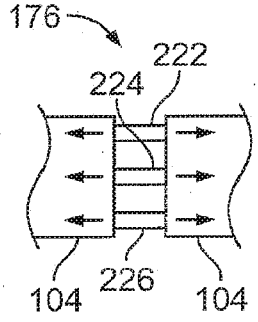

FIG. 9I

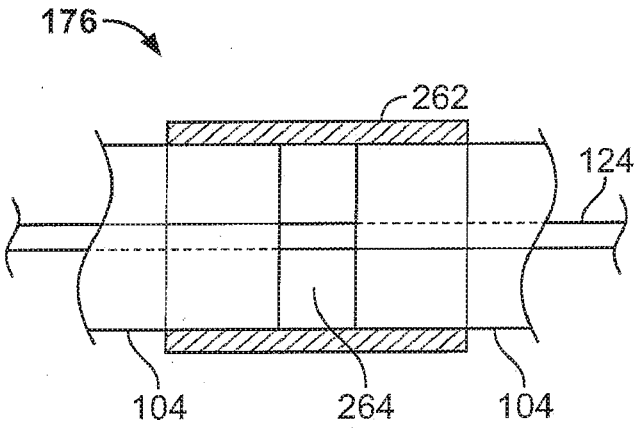

FIG. 9J

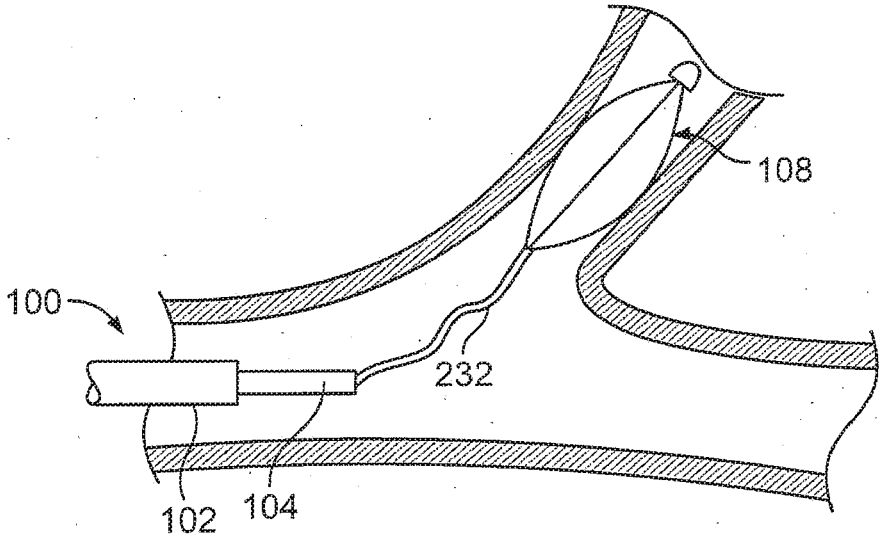

FIG. 10A

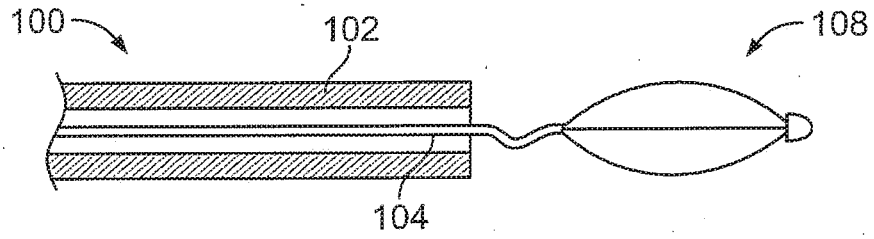

FIG. 10B

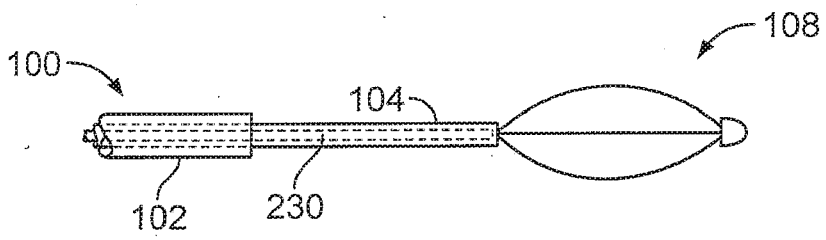

FIG. 10C

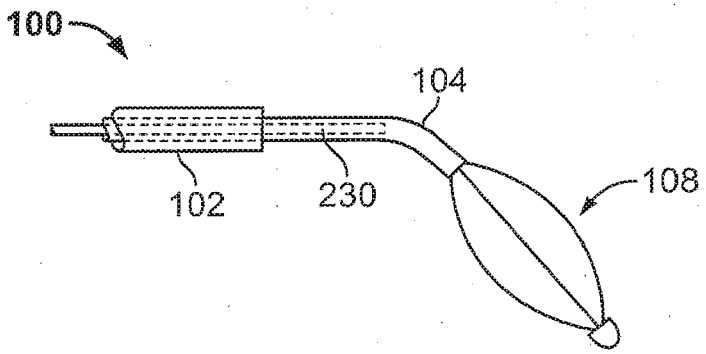

FIG. 10D

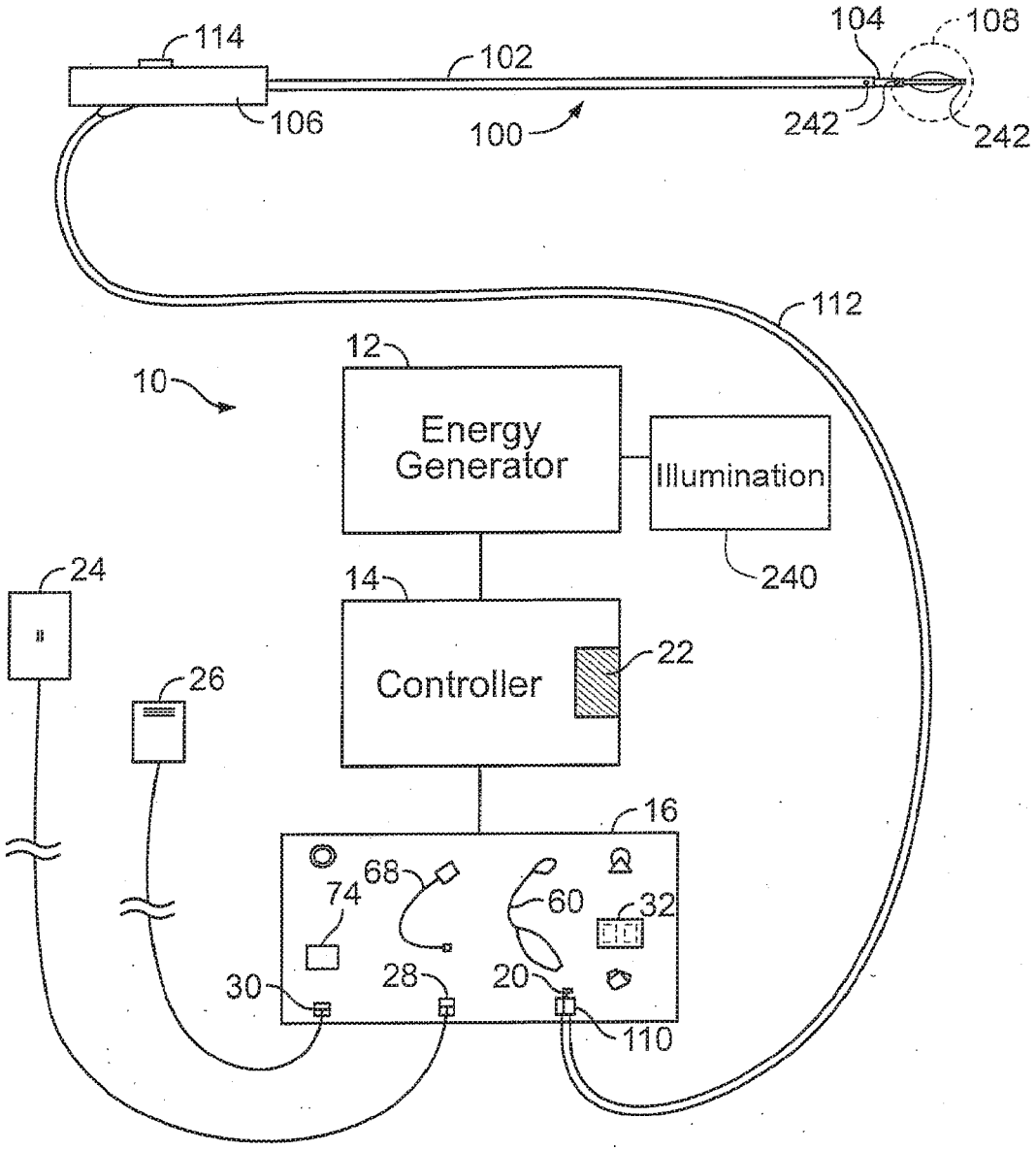
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FIG. 11A

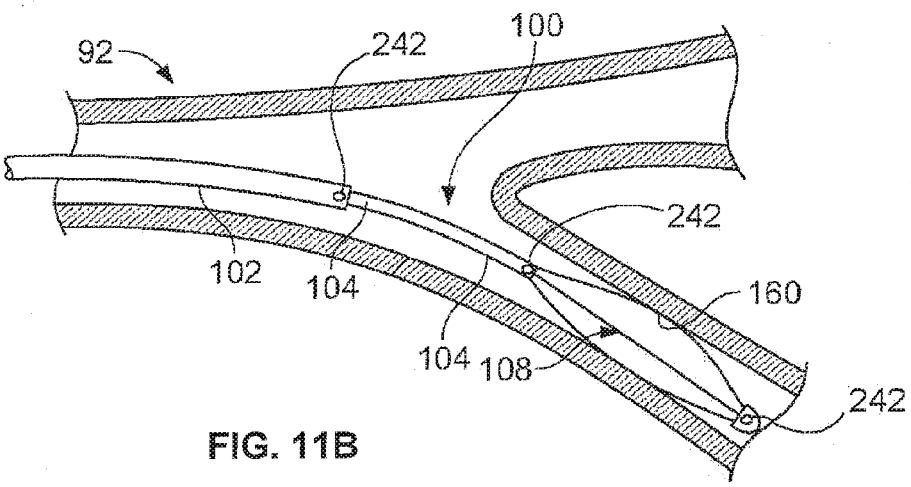


FIG. 11B

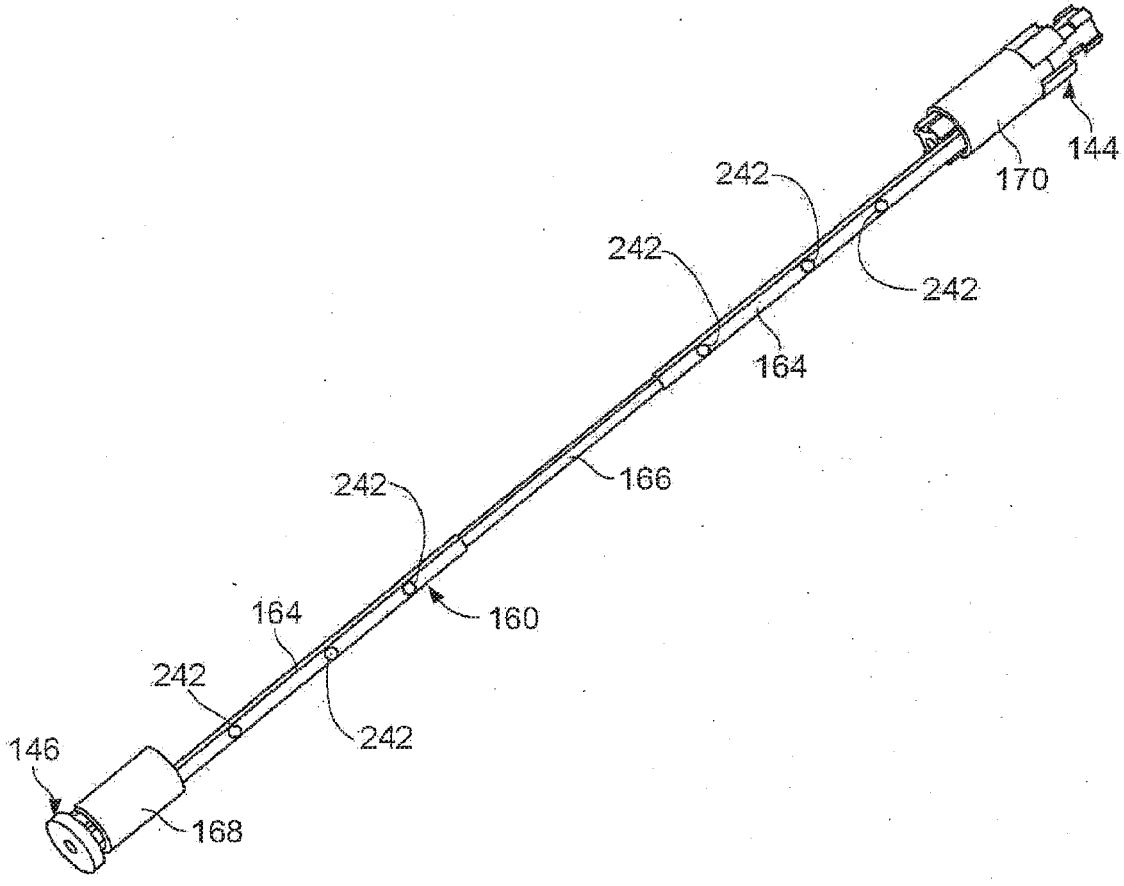


FIG. 11C

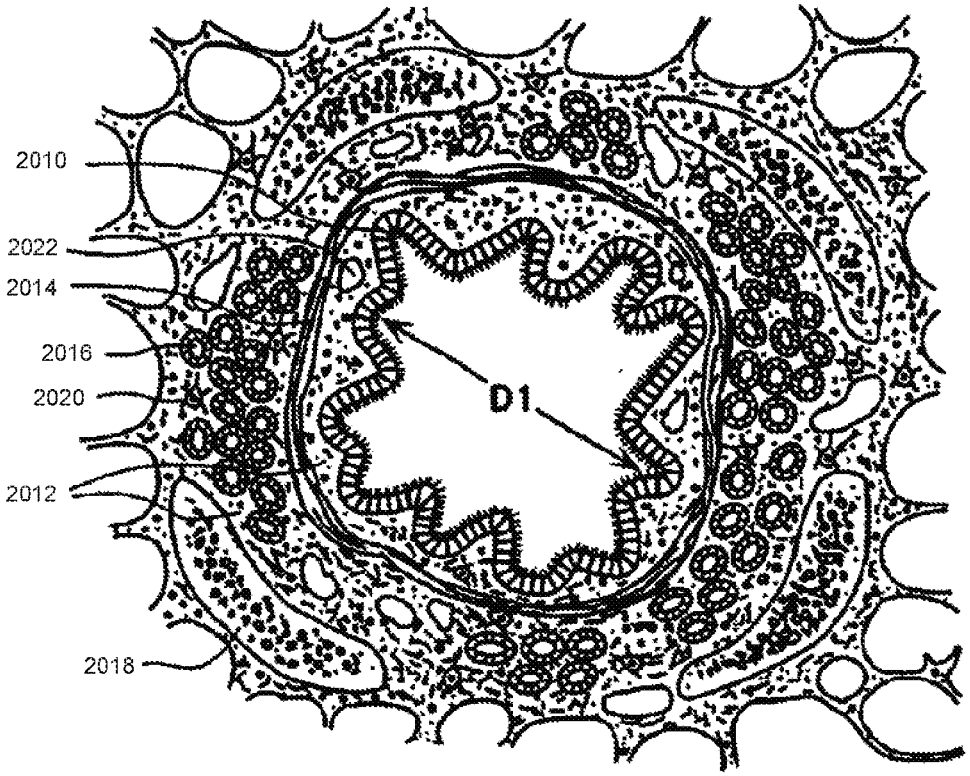


FIG. 12

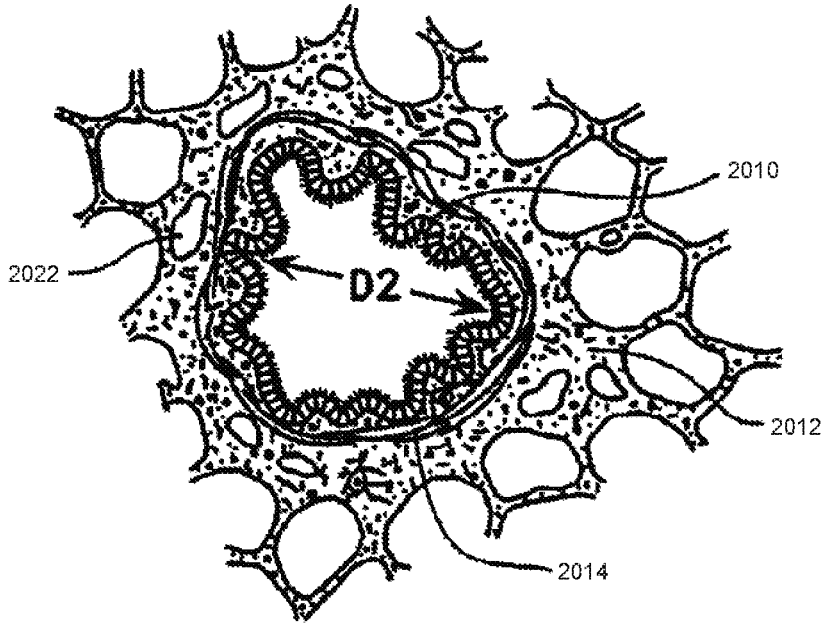
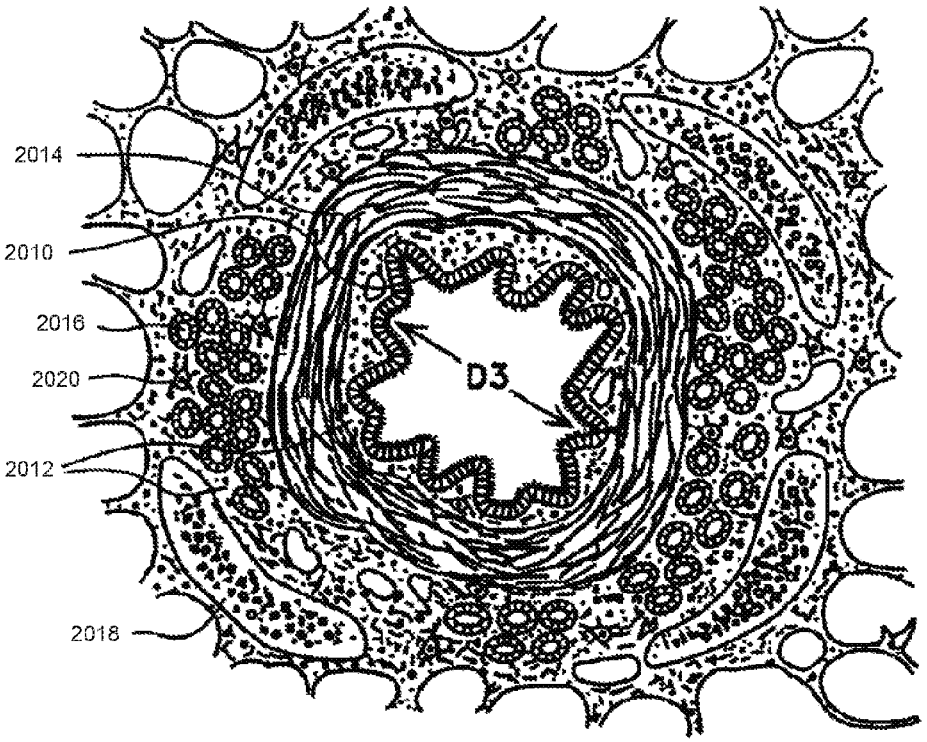


FIG. 13


2014
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D3

FIG. 14

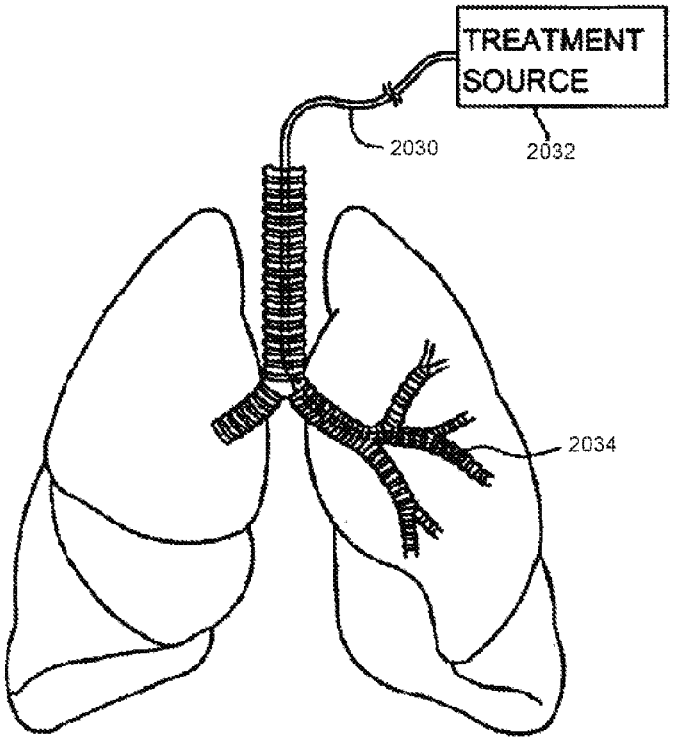
TREATMENT SOURCE
2030
2032
2034

FIG. 15

ENERGY DELIVERY AND ILLUMINATION DEVICES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 11/617,512, filed Dec. 28, 2006, which is a continuation of U.S. patent application Ser. No. 11/420,407, filed May 25, 2006, now U.S. Pat. No. 8,920,413, which is a continuation of PCT Application No. PCT/US2005/041243, filed Nov. 14, 2005, which claims benefit to U.S. Provisional Patent Application No. 60/627,662, filed Nov. 12, 2004 and U.S. patent application Ser. No. 11/255,796, filed Oct. 21, 2005, the contents of each of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

[0002] Asthma is a disease in which (i) bronchoconstriction, (ii) excessive mucus production, and (iii) inflammation and swelling of airways occur, causing widespread but variable airflow obstruction thereby making it difficult for the asthma sufferer to breathe. Asthma is a chronic disorder, primarily characterized by persistent airway inflammation. However, asthma is further characterized by acute episodes of additional airway narrowing via contraction of hyperresponsive airway smooth muscle.

[0003] Asthma is 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 the prescribed drugs. 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 involved in patient compliance with pharmacologic management and the difficulty of avoiding stimulus that triggers asthma are common barriers to successful asthma management.

[0004] Current management techniques are neither completely successful nor free from side effects. Presently, a new treatment for asthma is showing promise. This treatment comprises the application of energy to the airway smooth muscle tissue. Additional information about this treatment may be found in commonly assigned patents and applications in U.S. Pat. Nos. 6,411,852, 6,634,363 and U.S. published application nos. US-2005-0010270-A1 and US-2002-0091379-A1, the entirety of each of which is incorporated by reference.

[0005] The application of energy to airway smooth muscle 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 an RF energy delivery device is one means of treating smooth muscle tissue within the bronchial passageways.

[0006] FIG. **1**A illustrates a bronchial tree **90**. As noted herein, devices treating areas of the lungs must have a construction that enables navigation through the tortuous passages. As shown, the various bronchioles **92** decrease in size and have many branches as they extend into the right and left bronchi **94**. Accordingly, an efficient treatment requires devices that are able to treat airways of varying sizes as well as function properly when repeatedly deployed after navigating through the tortuous anatomy.

[0007] Tortuous anatomy also poses challenges when the treatment device requires mechanical actuation of the treatment portion (e.g., expansion of a treatment element at a remote site). In particular, attempting to actuate a member may be difficult in view of the fact that the force applied at the operator's hand-piece must translate to the distal end of the device. The strain on the operator is further intensified given that the operator must actuate the distal end of the device many times to treat various portions of the anatomy. When a typical device is contorted after being advanced to a remote site in the lungs, the resistance within the device may be amplified given that internal components are forced together.

[0008] It is also noted that the friction of polymers is different from that of metals. Most polymers are viscoelastic and deform to a greater degree under load than metals. Accordingly, when energy or force is applied to move two polymers against each other, a significant part of friction between the polymers is the energy loss through inelastic hysteresis. In addition, adhesion between polymers also plays a significant part in the friction between such polymers.

[0009] In addition to basic considerations of navigation and site access, there exists the matter of device orientation and tissue contact at the treatment site. Many treatment devices make contact or are placed in close proximity to the target tissue. Yet, variances in the construction of the treatment device may hinder proper alignment or orientation of the device. For example, in the case of a device having a basket-type energy transfer element that is deployed intralumenally, the treatment may benefit from uniform contact of basket elements around the perimeter of the lumen. However, in this case, design or manufacturing variances may tend to produce a device where the angle between basket elements is not uniform. This problem tends to be exacerbated after repeated actuation of the device and/or navigating the device through tortuous anatomy when the imperfections of the device become worsened through plastic deformation of the individual components. Experience demonstrates that once a member becomes predisposed to splaying (i.e., not maintaining the desired angular separation from an adjacent element), or inverting (i.e., buckling inward instead of deploying outward), the problem is unlikely to resolve itself without requiring attention by the operator. As a result, the operator is forced to remove the device from the patient, make adjustments, and then restart treatment. This interruption tends to increase the time of the treatment session.

[0010] As one example, commonly assigned U.S. Pat. No. 6,411,852, incorporated by reference herein, describes a treatment for asthma using devices having flexible electrode members that can be expanded to better fill a space (e.g., the lumen of an airway.) However, the tortuous nature of the airways was found to cause significant bending and/or flexure of the distal end of the device. As a result, the spacing of electrode members tended not to be even. In some extreme cases, electrode elements could tend to invert, where instead of expanding an electrode leg would invert behind an opposing leg.

[0011] For many treatment devices, the distortion of the energy transfer elements might cause variability in the treatment effect. For example, many RF devices heat tissue

based on the tissue's resistive properties. Increasing or decreasing the surface contact between the electrode and tissue often increases or decreases the amount of current flowing through the tissue at the point of contact. This directly affects the extent to which the tissue is heated. Similar concerns may also arise with resistive heating elements, devices used to cool the airway wall by removing heat, or any energy transfer device. In any number of cases, variability of the energy transfer/tissue interface causes variability in treatment results. The consequential risks range from an ineffective treatment to the possibility of patient injury.

[0012] Furthermore, most medical practitioners recognize the importance of establishing acceptable contact between the transfer element and tissue. Therefore, distortion of the transfer element or elements increases the procedure time when the practitioner spends an inordinate amount of time adjusting a device to compensate for or avoid such distortion. Such action becomes increasingly problematic in those cases where proper patient management limits the time available for the procedure.

[0013] For example, if a patient requires an increasing amount of medication (e.g., sedatives or anesthesia) to remain under continued control for performance of the procedure, then a medical practitioner may limit the procedure time rather than risk overmedicating the patient. As a result, rather than treating the patient continuously to complete the procedure, the practitioner may plan to break the procedure in two or more sessions. Subsequently, increasing the number of sessions poses additional consequences on the part of the patient in cost, the residual effects of any medication, adverse effects of the non-therapeutic portion of the procedure, etc.

[0014] In addition to the above, because the procedure is generally performed under direct visualization via a scope-type device, it may be desirable for a medical practitioner to directly observe the treatment areas so that the next adjacent area of tissue may be treated while minimizing overlap between treatment areas. Alternatively, or in combination, the medical practitioner may advance a device out of the bronchoscope into distal airways where visualization is difficult because the scope's light source is insufficient or blocked. Accordingly, there remains a need to provide a device that supplements the illumination provided by the scope, or illuminates the airway with a light of a particular wavelength that allows the practitioner to better observe the treatment area.

[0015] In view of the above, the present methods and devices described herein provide an improved means for treating tortuous anatomy such as the bronchial passages. It is noted that the improvements of the present device may be beneficial for use in other parts of the anatomy as well as the lungs.

SUMMARY OF THE INVENTION

[0016] The present invention includes devices configured to treat the airways or other anatomical structures, and may be especially useful in tortuous anatomy. The devices described herein are configured to treat with uniform or predictable contact (or near contact) between an active element and tissue. Typically, the invention allows this result with little or no effort by a physician. Accordingly, aspects of the invention offer increased effectiveness and efficiency in carrying out a medical procedure. The increases in effectiveness and efficiency may be especially apparent in using devices having relatively longer active end members.

[0017] In view of the above, a variation of the invention includes a catheter for use with a power supply, the catheter comprising a flexible elongate shaft coupled to at least one energy transfer element that is adapted to apply energy to the body lumen. The shaft will have a flexibility to accommodate navigation through tortuous anatomy. The energy transfer elements are described below and include basket type design, or other expandable designs that permit reduction in size or profile to aid in advancing the device to a particular treatment site and then may be expanded to properly treat the target site. The basket type designs may be combined with expandable balloon or other similar structures.

[0018] Variations of the device can include an elongate sheath having a near end, a far end adapted for insertion into the body, and having a flexibility to accommodate navigation through tortuous anatomy, the sheath having a passageway extending therethrough, the passageway having a lubricious layer extending from at least a portion of the near end to the far end of the sheath. Where the shaft is slidably located within the passageway of the sheath.

[0019] Variations of devices described herein can include a connector for coupling the energy transfer element to the power supply. The connector may be any type of connector commonly used in such applications. Furthermore, the connector may include a cable that is hard-wired to the catheter and connects to a remote power supply. Alternatively, the connector may be an interface that connects to a cable from the power supply.

[0020] As noted below, variations of the device allow for reduce friction between the shaft and sheath to allow relatively low force advancement of a distal end of the shaft out of the far end of the sheath for advancement the energy transfer element.

[0021] Additional variations of the invention include devices allowing for repeatable deployment of the expandable energy transfer element while maintaining the orientation and/or profile of the components of the energy transfer element. One such example includes an energy transfer basket comprising a plurality of legs, each leg having a distal end and a proximal end, each leg having a flexure length that is less than a full length of the leg. The legs are coupled to near and far alignment components. The near alignment component includes a plurality of near seats extending along an axis of the alignment component. The near alignment component can be secured to the elongate shaft of the device. The far alignment component may have a plurality of far seats extending along an axis of the alignment component, where the plurality of near seats are in alignment with the plurality of far seats. In these variations of the device, each distal end of each leg is nested within a far seat of the far alignment component and each proximal end of each leg is nested within a near seat of the near alignment component such that an angle between adjacent legs is determined by an angle between adjacent near seats and the flexure length of each length is determined by the distance between near and far alignment components.

[0022] One or both of the components may include stops that control flexure length of each leg. Such a design increases the likelihood that the flexure of each leg is uniform.

[0023] An additional variation of the device includes a catheter for use in tortuous anatomy to deliver energy from

a power supply to a body passageway. Such a catheter includes an expandable energy transfer element having a reduced profile for advancement and an expanded profile to contact a surface of the body passageway and an elongate shaft having a near end, a far end adapted for insertion into the body, the expandable energy transfer element coupled to the far end of the shaft, the shaft having a length sufficient to access remote areas in the anatomy. The design of this shaft includes a column strength sufficient to advance the expandable energy transfer element within the anatomy, and a flexibility that permits self-centering of the energy transfer element when expanded to contact the surface of the body passageway.

[0024] In a further variation of the invention, the device and/or system may include an illumination source and/or supply. The illumination source may be configured to provide a single or multiple wavelength of light depending upon the particular application. For example, the device may be configured to provide illumination that is visible light, or white light. The illumination can be a single visible color such as red, green, blue, yellow, or a combination. The illumination may be a non-visible wavelength that is made visible by some type of filter or other such means on the scope or viewing monitor for the scope.

[0025] When tissue, in particular airway wall tissue, is heated as a result of treatment, collagen fibers within the tissue loose their organization. As a result, the ability to polarize transmitted and reflected light is altered. In some cases, depending on temperature, the polarization axis changes. This is a so-called change in birefringence. In certain cases, tissue heated to a sufficiently high temperature may lose the ability to polarize light. Therefore, the illumination may be suited to view areas of heated collagen fibers so as to identify treated tissue (e.g., with the procedures described in the patents discussed above and U.S. Pat. No. 6,634,363, US publication 20020091379A1 both of which are incorporated by reference). Various wavelengths (including but not limited to wavelengths in the infrared, ultraviolet, as well as visible spectrum) of the illumination source and/or filters may be used so that the medical practitioner may identify the treated tissue.

[0026] In addition, certain wavelengths may afford separation from red and orange (e.g., 590 nm, 570 nm, 470 nm or yellow, green, and blue.) These colors may offer better distinction when used in airways.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.

[0028] FIG. **1** is an illustration of the airways within a human lung.

[0029] FIG. **2**A is a schematic view of an exemplary system for delivering energy according to the present invention.

[0030] FIG. **2**B is a side view of a device extending out of an endoscope/bronchoscope, where the device has an active distal end for treating tissue using energy delivery.

[0031] FIGS. **3**A-**3**G show various features of the device allowing for low force deployment of the energy element.

[0032] FIGS. **4**A-**4**C illustrate various alignment components of the device.

[0033] FIGS. **4**D-**4**E demonstrate the alignment components coupled to a leg of the device.

[0034] FIGS. **4**F-**4**H illustrate an additional variation of an alignment component.

[0035] FIGS. **5**A-**5**B is a variation of an energy transfer element according to the present device.

[0036] FIGS. **5**C-**5**D show variations in which the legs of the device are biased to expand outward.

[0037] FIGS. **6**A-**6**C show various basket configurations for the device.

[0038] FIGS. **7**A-**7**D illustrate various features of variations of legs for use with the present devices.

[0039] FIGS. **8**A-**8**D show various junctions for use with the present devices to improve alignment when the device is advanced through tortuous anatomy.

[0040] FIGS. **9**A-**9**J are addition variations of junctions.

[0041] FIGS. **10**A-**10**D shows additional variations of junctions for use in the present devices.

[0042] FIGS. **11**A-**11**C shows additional variations of systems and devices using illumination.

[0043] FIG. **12** is a cross sectional view of an airway in a healthy lung.

[0044] FIG. **13** shows a section through a bronchiole having an airway diameter smaller than that shown in FIG. **12**.

[0045] FIG. **14** illustrates the airway of FIG. **12** in which the smooth muscle **2014** has hypertrophied and increased in thickness causing reduction of the airway diameter.

[0046] FIG. **15** is a schematic side view of the lungs being treated with a treatment device **2030** as described herein.

DETAILED DESCRIPTION

[0047] It is understood that the examples below discuss uses in the airways of the lungs. However, unless specifically noted, the invention is not limited to use in the lung. Instead, the invention may have applicability in various parts of the body. Moreover, the invention may be used in various procedures where the benefits of the device are desired.

[0048] FIG. **2**A shows a schematic diagram of one example of a system **10** for delivering therapeutic energy to tissue of a patient for use with the device described herein. The illustrated variation shows, the system **10** having a power supply (e.g., consisting of an energy generator **12**, a controller **14** coupled to the energy generator, a user interface surface **16** in communication with the controller **14**). It is noted that the device may be used with a variety of systems (having the same or different components). For example, although variations of the device shall be described as RF energy delivery devices, variations of the device may include resistive heating systems, infrared heating elements, microwave energy systems, focused ultrasound, cryo-ablation, or any other energy deliver system. It is noted that the devices described should have sufficient length to access the tissue targeted for treatment. For example, it is presently believed necessary to treat airways as small as 3 mm in diameter to treat enough airways for the patient to benefit from the described treatment (however, it is noted that the invention is not limited to any particular size of airways and airways smaller than 3 mm may be treated). Accordingly, devices for treating the lungs must be sufficiently long to reach deep enough into the lungs to treat these airways. Accordingly, the length of the sheath/shaft of the device that is designed for use in the lungs should preferably be between 1.5-3 ft long in order to reach the targeted airways.

[0049] The particular system **10** depicted in FIG. **2**A is one having a user interface as well as safety algorithms that are useful for the asthma treatment discussed above. Addition information on such a system may be found in U.S. Provisional application No. 60/674,106, filed Apr. 21, 2005 entitled CONTROL METHODS AND DEVICES FOR ENERGY DELIVERY, the entirety of which is incorporated by reference herein.

[0050] Referring again to FIG. **2**A, a variation of a device **100** described herein includes a flexible sheath **102**, an elongate shaft **104** (in this example, the shaft extends out from the distal end of the sheath **102**), and a handle or other operator interface **106** (optional) secured to a proximal end of the sheath **102**. The distal portion of the device **100** includes an energy transfer element **108** (e.g., an electrode, a basket electrode, a resistive heating element, cyroprobe, etc.). Additionally, the device includes a connector **110** common to such energy delivery devices. The connector **110** may be integral to the end of a cable **112** as shown, or the connector **110** may be fitted to receive a separate cable **112**. In any case, the device is configured for attachment to the power supply via some type connector **110**. The elongate portions of the device **102** and **104** may also be configured and sized to permit passage through the working lumen of a commercially available bronchoscope or endoscope. As discussed herein, the device is often used within an endoscope, bronchoscope or similar device. However, the device may also be advanced into the body with or without a steerable catheter, in a minimally invasive procedure or in an open surgical procedure, and with or without the guidance of various vision or imaging systems.

[0051] FIG. **2**A also illustrates additional components used in variations of the system. Although the depicted systems are shown as RF type energy delivery systems, it is noted that the invention is not limited as such. Other energy delivery configurations contemplated may include or not require some of the elements described below. The power supply (usually the user interface portion **16**) shall have connections **20**, **28**, **30** for the device **100**, return electrode **24** (if the system **10** employs a monopolor RF configuration), and actuation pedal(s) **26** (optional). The power supply and controller may also be configured to deliver RF energy to an energy transfer element configured for bipolar RF energy delivery. The user interface **16** may also include visual prompts **32**, **60**, **68**, **74** for user feedback regarding setup or operation of the system. The user interface **16** may also employ graphical representations of components of the system, audio tone generators, as well as other features to assist the user with system use.

[0052] In many variations of the system, the controller **14** includes a processor **22** 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 **22** 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 **22** of the controller **14** may be digital IC processor, analog processor or any other suitable logic or control system that carries out the control algorithms. U.S. Provisional application No. 60/674,106 filed Apr. 21, 2005 entitled CONTROL METHODS AND DEVICES FOR ENERGY DELIVERY the entirety of which is incorporated by reference herein.

[0053] FIG. **2**B illustrates one example of an energy transfer element **108**. In this example the energy transfer element **108** is a "basket-type" configuration that requires actuation for expansion of the basket in diameter. Such a feature is useful when the device is operated intralumenally or in anatomy such as the lungs due to the varying size of the bronchial passageways that may require treatment. As illustrated, the basket contains a number of arms **120** which carry electrodes (not shown). In this variation the arms **120** are attached to the elongated shaft **104** at a proximal end while the distal end of the arms **120** are affixed to a distal tip **122**. To actuate the basket **108** a wire or tether **124** is affixed to the distal tip **122** to enable compression of the arms **120** between the distal tip **122** and elongate sheath **104**.

[0054] FIG. **2**B also illustrates the device **100** as being advanced through a working channel **32** of a bronchoscope **18**. While a bronchoscope **18** may assist in the procedure, the device **100** may be used through direct insertion or other insertion means as well.

[0055] As noted above, some variations of the devices described herein have sufficient lengths to reach remote parts of the body (e.g., bronchial passageways around 3 mm in diameter). FIGS. **3**A-**3**G illustrate various configurations that reduce the force required to actuate the device's basket or other energy transfer element.

[0056] FIG. **3**A illustrates a cross section taken from the sheath **102** and elongate shaft **104**. As shown, the sheath **102** includes an outer layer **126** and an inner lubricious layer **128**. The outer layer **126** may be any commonly known polymer such as Nylon, PTFE, etc. The lubricious layers **128** discussed herein may comprise a lubricious polymer (for example, HDPE, hydrogel, polytetrafluoroethylene). Typically, lubricious layer **128** will be selected for optimal pairing with the shaft **104**. One means to select a pairing of polymers is to maximize the difference in Gibbs surface energy between the two contact layers. Such polymers may also be chose to give the lubricious layer **128** a different modulus of elasticity than the outer layer **126**. For example, the modulus of the lubricious layer **128** may be higher or lower than that of the outer layer **126**.

[0057] Alternatively, or in combination, the lubricious layers may comprise a fluid or liquid (e.g., silicone, petroleum based oils, food based oils, saline, etc.) that is either coated or sprayed on the interface of the shaft **104** and sheath **102**. The coating may be applied at the time of manufacture or at time of use. Moreover, the lubricious layers **128** may even include polymers that are treated such that the surface properties of the polymer changes while the bulk properties of the polymer are unaffected (e.g., via a process of plasma surface modification on polymer, fluoropolymer, and other materials). Another feature of the treatment is to treat the surfaces of the devices with substances that provide antibacterial/antimicrobial properties.

[0058] In one variation of the invention, the shaft **104** and/or sheath **102** will be selected from a material to provide sufficient column strength to advance the expandable energy transfer element within the anatomy. Furthermore, the materials and or design of the shaft/sheath will permit a flexibility that allows the energy transfer element to essentially self-align or self-center when expanded to contact the surface of

the body passageway. For example, when advanced through tortuous anatomy, the flexibility of this variation should be sufficient that when the energy transfer element expands, the shaft and/or sheath deforms to permit self-centering of the energy transfer element. It is noted that the other material selection and/or designs described herein shall aid in providing this feature of the invention.

[0059] FIG. **3**A also depicts a variation of a shaft **104** for use in the present device. In this variation the shaft **104** includes a corrugated surface **130**. It is envisioned that the corrugated surface **130** may include ribbed, textured, scalloped, striated, ribbed, undercut, polygonal, or any similar geometry resulting in a reduced area of surface contact with any adjoining surface(s). The corrugated surface **130** may extend over a portion or the entire length of the shaft **104**. In addition, the shape of the corrugations may change at varying points along the shaft **104**.

[0060] The shaft **104** may also include one or more lumens **132**, **134**. Typically, one lumen will suffice to provide power to the energy transfer elements (as discussed below). However, in the variation show, the shaft may also benefit from additional lumens (such as lumens **134**) to support additional features of the device (e.g., temperature sensing elements, other sensor elements such as pressure or fluid sensors, utilizing different lumens for different sensor leads, and fluid delivery or suctioning, etc.). In addition the lumens may be used to deliver fluids or suction fluid to assist in managing the moisture within the passageway. Such management may optimize the electrical coupling of the electrode to the tissue (by, for example, altering impedance). Since the device is suited for use in tortuous anatomy, a variation of the shaft **104** may have lumens **134** that are symmetrically formed about an axis of the shaft. As shown, the additional lumens **134** are symmetric about the shaft **104**. This construction provides the shaft **104** with a cross sectional symmetry that aid in preventing the shaft **104** from being predisposed to flex or bend in any one particular direction.

[0061] FIG. **3**B illustrates another variation where the sheath **102** includes an outer layer **126** and a lubricious layer **128**. However, in this variation the lubricious layer **128** also includes a corrugated surface **136**. It is noted that any combination of the sheath **102** and shaft **104** may have a corrugated surface.

[0062] FIG. **3**C illustrates yet another aspect of construction of a sheath **102** for use with the present device. In this variation, the sheath **102** includes a multi-layer construction having an outer layer **126**, one or more middle layers **138**. The middle layers **138** may be selected to have properties that transition between the outer layer properties and the lubricious layer properties, and improve the bonding between inner and outer layer. Alternatively, the middle layer **138** may be selected to aid in the column strength of the device. An example of the middle layer includes Plexar PX **306**, **3060**, and/or **3080**.

[0063] FIG. **3**D depicts a variation of a shaft **104** for use with the devices described herein where the shaft outer surface comprises a lubricious layer **140**. As illustrated, the shaft outer surface may also optionally have a corrugated surface **130**. FIGS. **3**E-**3**G illustrate additional variations of corrugated surfaces. As shown in FIGS. **3**E and **3**F, either or both the sheath **102** and the shaft **104** may have corrugated surfaces that are formed by interrupting the surface. Naturally, different shapes and configurations may be otherwise constructed. FIG. **3**G illustrates a variation where the sheath **102** comprises protrusions or spacer **142** to separate the surfaces of the sheath/shaft.

[0064] FIGS. **4**A-**4**D illustrate yet another feature that may be incorporated with any of the subject devices. FIG. **4**A illustrates an example of an alignment component **150**. In this variation, the alignment component **150** includes a plurality of seats **152** that nest electrode arms (not shown). As discussed herein, the seats **152** allow for improved control of the angular spacing of the arms. Moreover, the seats **152** permits design of a device in which the flexure length of each of the arms of a basket type device is uniform (even if the tolerance of each arm varies). Though the alignment component **150** is shown as having four seats **152**, any number of seats may be employed.

[0065] The alignment component **150** also includes a stop **154**. The stop **154** acts as a reference guide for placement of the arms as discussed below. In this variation, the stop **154** is formed from a surface of an end portion **158**. This end portion **158** is typically used to secure the alignment component **150** to (or within) the sheath/shaft of the device. The alignment component **150** may optionally include a through hole or lumen **156**.

[0066] FIG. **4**B illustrates another variation of an alignment component **152**. This variation is similar to the variation shown in FIG. **4**A, with the difference being the length of the end portion **158**. The smaller end portion **158** may optionally be employed when the component **150** is used at the distal end of the device. In such a case, the component **158** may not be attached to the sheath or shaft. In addition, the end portion **158** may optionally be rounded, for example, to minimize tissue trauma that may be caused by the end of the device.

[0067] The alignment components **150** of the present invention may be fabricated from a variety of polymers (such as nylon or any other polymer commonly used in medical devices), either by machining, molding, or by cutting an extruded profile to length. One feature of this design is electrical isolation between the legs, which may also be obtained using a variation of the invention that employs a ceramic material for the alignment component. However, in one variation of the invention, an alignment component may be fabricated from a conductive material (e.g., stainless steel, polymer loaded with conductive material, or metallized ceramic) so that it provides electrical conductivity between adjacent electrode legs. In such a case, a power supply may be coupled to the alignment component, which then electrically couples all of the legs placed in contact with that component. The legs may be attached to the conductive alignment component with conductive adhesive, or by soldering or welding the legs to the alignment component. This does not preclude the legs and alignment component form being formed from one piece of metal.

[0068] Devices of the present invention may have one or more alignment components. Typically the alignment components are of the same size and/or the angular spacing of the seats is the same. However, variations may require alignment components of different sizes and/or different angular spacing. Another variation of the invention is to have the seats at an angle relative to the axis of the device, so as to form a helically shaped energy delivery element.

[0069] FIG. **4**C illustrates another variation of an alignment component **150**. In this variation, the alignment component **150** includes four seats **152**. This variation includes

an alignment stop **154** that protrudes from the surface of the component **150**. In addition, the end portion **158** of the alignment component **150** is also of a cross section that may improve strength of the connection between the component and the sheath/shaft. In this case, the end portion **158** allows for crimping of the sheath/shaft. Optionally as shown, radial protrusions **178** at the right of the end portion **158** may be included to allow heat bonding of the alignment component to the shaft. In this case, the shaft may be a polymer with a melting temperature lower than that of the alignment component. When constrained to be coaxial, heat, and if necessary axial pressure, may be applied to join the two components.

[0070] FIG. **4**D illustrates the protrusion-type stop **154** that retains a notch **162** of the electrode leg **160**. This mode of securing the electrode leg **160** provides a "redundant-type" joint. In one example, the leg **160** is secured to the alignment component **150** using a sleeve (not shown) placed over both the leg **160** and alignment component **150** with or without the use of an adhesive within the sleeve. The notch **162** in the leg **160** is placed around the protrusion-type-stop **154**. As a result, the notch-stop interface prevents the leg from being pulled from the device and is especially useful to prevent the proximal or near ends of the legs from separating from the device. It is noted that this safety feature is especially important when considering that if the proximal/near ends of the legs separate and hook on the anatomical passage, it may be difficult or impossible to remove the device from the passage. Such a failure may require significant medical intervention.

[0071] FIG. **4**E illustrates one example of a leg **160** affixed to near/proximal and far/distal alignment components **144**, **146**. As shown, the leg **160** may have an insulated portion **164** and an exposed portion **166** that form electrodes. The near and far ends of the leg **160** are secured to respective alignment components **144**, **146**. In this example, sleeves **168** and **170** cover the leg and alignment component. As noted above, one or both of the alignment components may be electrically conductive to provide power to the electrodes. Furthermore, adhesive (e.g., cyanoacrylate, UV-cured acrylic, epoxy, or any such adhesive) may also be used to secure the leg to the components.

[0072] Additionally, the alignment components may be designed such that the sleeves may be press or snap fit onto the alignment components, eliminating the need for adhesively bonding the sleeves to the alignment components. FIG. **4**F illustrates a perspective view of an end portion of an alignment component **150** having one or more slots **186** to create end portion segments **184**. The slots **186** permit deflection of the end portion segments **184** to allow sliding of a sleeve or hypotube (either a near or far sleeve **168** or **170**) over the end portion. FIG. **4**G shows a cross sectional view of the component **150** of FIG. **4**F. As shown, once advanced over the end portion segment **184**, the sleeve or hypotube becomes secured to the component **150**. To lock the sleeve in place, an insert or wire member **124** (not shown) is placed in the through hole or lumen **156**. The insert or wire member prevents inward deflection of the end portion segments **184** thereby ensuring that the sleeve or hypotube remains secured to the component **150**.

[0073] FIG. **5**A shows a cross sectional view of two legs **160** attached to alignment components **144**, **146**. The sheath and shaft have been omitted for clarity. The flexure length **164** of the leg **160** is defined as the length between the alignment components **144**, **146** over which the leg may flex when the proximal and distal ends are moved closer to one another. As noted above, the alignment components permit the flexure length **164** of the legs **160** to be uniform even if the leg lengths vary. The flexure length **164** is essentially set by the longest leg, the shorter legs may float between the stops **154** of the alignment components **144**, **146**. As an additional measure to prevent the legs **160** from inverting, the lengths of the sleeves **168** and **170** may be selected to be less than the length of the respective alignment components **144**, **146** (as shown in the figure). The tendency of the leg to deflect outward can be improved by selecting the sleeve length as such. When the legs **160** expand they are supported by their respective seat on the interior side but unsupported on outer side. In yet another variation, the seats can slant to predispose the arms to deflect in a desired direction. For example, as shown in FIG. **5**C, the seats **152** can slant as shown to predispose the legs **160** to outward deflection. Such a construction can be accomplished by machining or by drafting a molded part in the direction of the catheter axis. As shown in FIG. **5**D, the leg can have a slight bend or shape that predisposes the legs to bow outward.

[0074] FIG. **5**B illustrates the variation of FIG. **5**A in an expanded state. As shown, the device may have a wire **124** or other similar member that permits movement of the far alignment component **146** relative to the near alignment component **144**. As noted herein, the wire **124** may be electrically conductive to provide power to electrodes on the device. FIG. **5**B also illustrates a ball tip **148** at the end of the device. The ball tip **148** may serve as a means to secure the wire **124** as well as providing an atraumatic tip for the device.

[0075] Variations of the wire **124** may include a braided or coiled wire. The wire may be polymer coated or otherwise treated to electrically insulate or increase lubricity for easier movement within the device.

[0076] To expand the energy transfer element **108**, the wire **124** may be affixed to a handle **106** and actuated with a slide mechanism **114** (as shown in FIG. **2**A.) In an alternative design, the wire **124** may be affixed between the handle **106** and the distal end of the energy transfer element **108**. In such a case, the slide mechanism **114** may be affixed to the shaft **104**. Movement of the slide mechanism **114** causes expansion of the element **108** as the shaft causes movement of the proximal end of the energy transfer element (being fixed to the shaft) relative to the distal end of the energy transfer element (being fixed to the wire **124**. In an additional variation, movement of the slide **114** may have two outcomes: 1) advancing the energy transfer element out of the sheath; and 2) subsequently expanding the energy transfer element. Such constructions are disclosed in U.S. patent application Ser. No. 09/436,455 filed Nov. 8, 1999 the entirety of which is incorporated by reference herein.

[0077] FIG. **6**A illustrates a variation of an energy transfer element **108** in which the legs **160** have a predetermined shape. This shape may be selected as required for the particular application. As shown, the predetermined shape provides a certain length of the electrode **166** that may be useful for treatment of a long section of tissue.

[0078] FIG. **6**B illustrates another variation of the energy transfer element **108**. In this variation, the legs **160** extend out of openings **180** in the sheath **102** (in other variations, the legs may extend out of openings in the shaft). Accord-

ingly, the alignment components and other parts of the device would be located within the sheath **102**.

[0079] FIG. **6**C illustrates yet another variation of an energy transfer element **108**. In this variation, the basket is connected at a proximal end and opened at a distal end. The electrode legs **160** only have a single alignment component **150**. The conductive member (or wire) may be located within the shaft **104**. In this variation, advancement of the energy transfer element **108** out of the sheath **102** causes expansion of the element. The energy transfer elements may be predisposed or spring loaded to bow outward when advanced from the sheath.

[0080] FIG. **7**A illustrates an example of a leg **160** with an energy element **180** coiled around the leg **160**. In this example, the energy element **182** uses conductive heating and comprises a resistance heating element coiled around the leg **160**. FIG. **7**B illustrates a variation of the invention having an RF electrode attached to the basket leg **160**. The RF electrode may be attached to the basket leg **160** via the use of a fastener. For example, the electrode may be attached via the use of a heat shrink fastener, (e.g., polymeric material such as PET or polyethylene tubing). Alternatively, as discussed above, the entire leg may be a conductive medium where a non-conductive coating insulates the majority of the leg leaving the electrode portion uninsulated. Further examples of energy transfer element configurations include paired bipolar electrodes, where the pairs are leg to leg or within each leg, and large matrices of paired electrodes affixed to a variety of expanding members (balloons, mechanisms, etc.)

[0081] FIG. **7**C illustrates a variation of the invention having thermocouple leads **172** attached to an electrode **166** or leg of the device. The leads may be soldered, welded, or otherwise attached. This variation of the invention shows both leads **172** of the thermocouple **174** attached in electrical communication to a leg **160** at separate joints (or the leads may be separated but the solder on each connection actually flows together). In this case, the temperature sensor is at the surface of the leg. This variation provides a safety measure in case either joint becomes detached, the circuit will be open and the thermocouple **174** stops reading temperature. Such a condition may be monitored via the power supply and allow a safe shutdown of the system.

[0082] By spacing the leads of the thermocouple closely together to minimize temperature gradients in the energy transfer element between the thermocouple leads, thermoelectric voltage generated within the energy transfer element does not compromise the accuracy of the measurement. The leads may be spaced as close together as possible while still maintaining a gap so as to form an intrinsic junction with the energy transfer element. In another variation of the device, the thermocouple leads may be spaced anywhere along the tissue contacting region of the energy transfer element. Alternatively, or in combination, the leads may be spaced along the portion of an electrode that remains substantially straight. The intrinsic junction also provides a more accurate way of measuring surface temperature of the energy transfer element, as it minimizes the conduction error associated with an extrinsic junction adhered to the device.

[0083] The thermocouple leads may be attached to an interior of the leg or electrode. Such a configuration protects the thermocouple as the device expands against tissue and protects the tissue from potential trauma. The device may also include both of the thermocouple leads as having the same joint.

[0084] The devices of the present invention may use a variety of temperature sensing elements (a thermocouple being just one example, others include, infrared sensors, thermistors, resistance temperature detectors (RTDs), or any other component capable of detecting temperatures or changes in temperature). The temperature detecting elements may be placed on a single leg, on multiple legs or on all of the legs.

[0085] The present invention may also incorporate a junction that adjusts for misalignment between the branching airways or other body passages. This junction may be employed in addition to the other features described herein. FIG. **8**A illustrates a device **100** having such a junction **176** allowing alignment of the device to closely match the alignment of the airway. It is noted that the present feature also benefits those cases in which the pathway and target site are offset as opposed to having an angular difference.

[0086] The junction **176** helps to eliminate the need for alignment of the axis of the active element **108** with the remainder of the device in order to provide substantially even tissue contact. The junction may be a joint, a flexure or equivalent means. A non-exhaustive listing of examples is provided below.

[0087] The legs **160** of the energy transfer element may have various shapes. For example, the shapes may be round, rounded or polygonal in cross section. Additionally, each leg may change cross section along its axis, providing for, for example, electrodes that are smaller or larger in cross section that the distal and proximal portions of each leg. This would provide a variety of energy delivery characteristics and bending profiles, allowing the design to be improved such that longer or wider electrode configurations can be employed. For example, as shown in FIG. **7**D, if the cross-sectional thickness of the electrode portion **166** of the leg **160** is greater than the cross-sectional thickness of the distal and proximal portions of the leg, the leg would be predisposed to bow outward in the distal and proximal sections, while remaining flatter in the electrode area of the leg, potentially providing improved tissue contact.

[0088] As for the action the junction enables, it allows the distal end of the device to self-align with the cavity or passageway to be treated, irrespective of the alignment of the access passageway. FIG. **8**A illustrates an example of where the access passageway and passageway to be treated are misaligned by an angle α. In the example shown in FIG. **8**B, the misalignment angle α is greater than the angle illustrated in FIG. **8**A. Yet, the energy transfer element **108** of the treatment device **100** remains substantially aligned with the target area.

[0089] FIGS. **8**C and **8**D illustrate an additional variation of the junction **176**. In this variation the junction **176** may be reinforced with a reinforcing member **230**. The reinforcing member may have some degree of flexibility to navigate the tortuous anatomy, but the flexibility will be less than the junction **176**. As shown in FIG. **8**C, the reinforcing member **230** maintains the device shaft **104** in an aligned position, preferably for insertion, removal, and or navigation of the device. When desired, the reinforcing member **230** may be removed from the junction **176** as illustrated in FIG. **8**D. Accordingly, upon removal, the device is free to flex or orientate as desired. Furthermore, the reinforcing member

may be reinserted within the junction **176** when repositioning or removing the device from the target site. In additional variations, it is contemplated that the reinforcing member may be placed external to the device/junction.

[0090] FIGS. **9**A-**9**I illustrate additional junctions for use in the devices described herein. As for these examples, FIG. **9**A illustrates a junction **176** in the form of a plurality of turns or coils **200** of a spring. The coil offers a flexure with 3-dimensional freedom allowing realignment of the active end of the subject device in any direction. Of course, a simple hinge or universal joint may also be employed.

[0091] The length of the junction (whether a spring junction or some other structure) may vary. Its length may depend on the overall system diameter. It may also depend on the degree of compliance desired. For example, with a longer effective junction length (made by extending the coil with additional turns), the junction becomes less rigid or more "floppy".

[0092] In any case, it may be desired that the junction has substantially the same diameter of the device structure adjacent the junction. In this way, a more atraumatic system can be provided. In this respect, it may also be desired to encapsulate the junction with a sleeve or covering if they include open or openable structures. Junction **176** shown in FIGS. **8**A and **8**B is illustrated as being covered. A covering can help avoid contaminating the joint with body fluid or debris which could compromise junction function.

[0093] Some of the junctions are inherently protected. Junction **176** shown in FIG. **9**B comprises a polymer plug **220** or a section of polymer having a different flexibility or durometer than adjacent sections. When a separate piece of polymer is to be employed, it can be chemically, adhesively, or heat welded to adjacent structure; when the junction is formed integrally, this may be accomplished by selective vulcanizing, or reinforcement (even with a braid or by other means of forming a composite structure). Generally, it is noted that any connection of pieces or construction provided may be produced by methods known by those with skill in the art.

[0094] As for junction **176** shown in FIG. **9**C, it is formed by removing sections of material from the body of the device. Openings **218** formed at the junction may be left empty, covered or filled with a more compliant material. FIG. **9**D also shows a junction **176** in which openings are provided to provide increased flexibility. Here, openings **218** are offset from each other to form a sort of flexible universal joint. In either junction variation shown in FIG. **9**C or **9**D, the size, number shape, etc. of the opening may vary or be tuned as desired.

[0095] FIG. **9**E shows a junction **176** in the form of a bellows comprising plurality of pleats **216**. Here too, the number of pleats, etc. may be varied to achieve desirable performance. Junction **176** in FIG. **9**F shows a true "joint" configuration. In this case, it is a universal joint provided by ball **204** and socket **206**. These elements may be held together by a tie wire **208**, possibly with caps **210**. Other configurations are possible as well.

[0096] FIG. **9**G illustrates a junction **176** in the form of a reduced diameter section **202**. This variation offers greater flexibility by virtue of its decreased moment of inertia at the junction. While section **202** is integrally formed, the related junction **176** in FIG. **9**H is formed from a hypotube or wire **212** having an exposed junction section **214** on the shaft **104**. Variations of the invention will permit a junction having a reduced bending moment of inertia section as compared to the remainder of the device and/or shaft of the device. Reducing the bending moment of inertia may be accomplished in any number of ways. For example, there could be an area of reduced diameter, a section of material having a lower modulus, a section having a different shape, a flexible joint structure, etc. It should be noted that there are many additional ways to reduce the bending moment that will be readily apparent to those skilled in the art viewing the invention disclosed herein.

[0097] Yet another junction example is provided in FIG. **9**I. Here junction **176** comprises a plurality of wires **222**, **224**, **226**. In one variation, the wires simply offer increased flexibility of the junction. In another variation, the wires serve as an "active" or "dynamic" junction. The wires may be adjusted relative to one another to physically steer the distal end of the device. This junction may be manipulated manually with an appropriate user interface—especially one, like a joy-stick, that allows for full 3-dimensional or rotational freedom—or it may be controlled by automation using appropriate hardware and software controls. Of course, other "dynamic" junctions are possible as well.

[0098] FIG. **9**J shows another joint configuration **176** employing an external sleeve **262** between sections of the shaft **104**. A moveable wire **124** to actuate a distal basket or the like is also shown. The space between the wire and sleeve may be left open as shown, or filled in with a flexible polymer **264**, such as low durometer urethane, a visco-elastic material, etc. Though not necessary, providing an internal member may improve system pushability. The sleeve itself will typically be a polymeric sleeve. It may be heat-shrink material such as PET tubing; it may be integrally formed with either catheter body portion and press fit or slip fit and glued over other etc.

[0099] Another variation of the junctions includes junctions variations where the shaft **104** is "floppy" (i.e., without sufficient column strength for the device to be pushable for navigation). In FIG. **10**A, a tether **232** connects energy transfer element **108** to the shaft **104** of the device **100**. The tether may simply comprise a flexible wire or cable, it may comprise a plurality of links, etc. The tether variation of the invention also accommodates relative motion between the device and the body (e.g., tidal motion of breathing, other muscle contractions, etc.) The tether permits the device to move relative to its intended treatment location unless the user desires and uses the tether or the sheath to pull the device back or drive it forward. The tether may have an alignment component (not illustrated) at the near end of the energy transfer element **108**.

[0100] To navigate such a device to a treatment site, the energy transfer element **108** and tether **232** may be next to or within the sheath **102**. In this manner, the column strength provided by the sheath allows for advancement of the active member within the subject anatomy.

[0101] The same action is required to navigate the device shown in FIG. **10**B. What differs in this variation of the invention, however, is that the "tether" is actually a continuation of a highly flexible shaft **104**. In this case, the shaft **104** of the device is shown with a thicker or reinforced wall. In such a device, the shaft carries the compressive loads on the device back to its distal end.

[0102] Like the device in FIG. **10**B, the devices in FIGS. **10**C and **10**D have highly flexible shafts **104**. However, instead of a stiffening external sheath, the device may

employ a stiffening obturator **230** within a lumen of the shaft **104**. As shown in FIG. **10**C, when the obturator **230** fills the lumen, the device is relatively straight or stiff. When the shaft is withdrawn as shown in FIG. **10**D, the distal end of the device is "floppy" or easily conformable to the subject anatomy. With the shaft advanced substantially to the end of the device, it offers ease of navigation; when withdrawn, it offers a compliant section according to an aspect of the present invention.

[0103] FIGS. **11**A-**11**C illustrate yet another aspect of the invention in which a treatment device is equipped with an illumination source **242**. As noted above, the illumination source **242** may be configured to provide additional light when the device is used without a scope or to supplement the illumination of the scope. Variations of the invention may include devices having one or more illumination sources **242** that are coupled to an illumination supply **240** that generates the light energy externally to the device (e.g., via a fiber or other type of light conductor). Alternatively, or in combination, the illumination source **242** may generate the light at the distal portion of the device (e.g., via a light emitting diode, etc). It should be noted that although FIG. **11**, depicts the illumination supply **240** as being separate from the controller and energy generator, the illumination supply **240** may be integrated into the controller or energy generator.

[0104] FIG. **11**A illustrates a variation of a system according to the present invention as shown in FIG. **2**A above, with the addition of an illumination supply **240** and a device with one or more illumination sources **242**. As noted above, a separate illumination supply **240** is optional as the illumination supply **240** may be incorporated with other components of the system (e.g., device controller, generator, or other).

[0105] FIG. **11**B shows a variation of a device as shown in FIG. **8**A. However, in this variation, the device includes an illumination source **242**. As shown, the illumination source **242** may be located on a tip **122** of the device, on the shaft **104**, on the sheath **102**, on the energy transfer element (as shown in FIG. **11**C) or in any combination thereof. Although not illustrated, the illumination source may be placed on or adjacent to a center wire **124** of the basket member **108**. For example, an LED may be placed on the wire, or an optical fiber may be placed adjacent to or wrapped around the wire **124**. Alternatively, a filament or other similar type component may be affixed to the wire in a similar manner, where the filament generates light of a particular wavelength.

[0106] FIG. **11**C illustrates just one example of a basket leg variation as shown in FIG. **4**E above, with the addition of an illumination source **242** that is placed on the leg. In each of the above cases, the illumination source **242** may be an end of a fiber type element that extends through the device and terminates at the illumination source **242** (alternatively or in combination, this variation may include a lens or cover at the termination of the fiber). The illumination source may also comprise a component that emits energy or light (such as a light emitting diode).

[0107] It is further contemplated that the illumination source **242** may be placed on a single side of the device or may be placed such that all walls of the airway are illuminated.

[0108] It is noted that variations of the device may include a single illumination source **242** or multiple illumination sources **242**. The illumination source(s) **242** may be configured to provide a single or multiple wavelength of light depending upon the particular application. For example, the device may be configured to provide illumination that is visible light, or white light. The illumination can be a single visible color such as red, green, blue, yellow, or a combination. The illumination may be a non-visible wavelength that is made visible by some type of filter or other such means on the scope or viewing monitor for the scope.

[0109] Variations of the invention include aiming or positioning the illumination source rearward to aid in light collection by the scope, use of a flex circuit to carry LED and have traces, use of LED lens cap as an atraumatic distal tip.

[0110] In addition, certain wavelengths may afford separation from red and orange (e.g., 590 nm, 570 nm, 470 nm or yellow, green, and blue. These colors may offer better distinction when used in airways. In variations of the invention using light emitting diodes (LEDS), the may be commercially available in surface mount configurations having a size that is suited for a device that must fit in a 2 mm working channel. See for example, www.kingbright-led.com, surface mount LED package, APHH1005.

[0111] At the very least, LED may make it easier for the practitioner to identify treated areas within the airway, such as tissue that is blanched or otherwise marked by the application of energy. In these cases, the reflectance of this tissue may be different than surrounding areas.

[0112] The invention may also be used with polarizing filters or polarizing fibers to differentiate treated from untreated tissue. Use of circularly polarized filters may be preferred in such a case to eliminate the need for rotation of the filters. In yet another approach the illumination supply/source may use coherent sources of light such as solid state or optical lasers. In the case of a solid state laser, the laser source may actually be placed on the distal end of the device rather than being transmitted via a fiber.

[0113] Furthermore, use digital (electronic) filtering of the image from CCD chip mounted at the end of the bronchoscope may permit filtering for desirable wavelengths and/or the image could be amplified to enable discernment. In addition, so long as long the system delivers light containing a broad spectrum of wavelengths, electronic or manual filtering may allow for filtering out any undesirable components. In additional variations, a filter or filters may be placed on the end of the device.

[0114] The invention relates to methods for improving airflow through the airways of a lung having reversible obstructive pulmonary disease. It is intended that the invention is applicable to any aspect of reversible obstructive pulmonary disease, including but not limited to asthma. One way of improving airflow is to decrease the resistance to airflow within the lungs. There are several approaches to reducing this resistance, including but not limited to reducing the ability of the airway to contract, increasing the airway diameter, reducing the inflammation of airway tissues, and/or reducing the amount of mucus plugging of the airway. The present invention includes advancing a treatment device into the lung and treating the lung to at least reduce the ability of the lung to produce at least one symptom of reversible obstructive pulmonary disease. The following is a brief discussion of some causes of increased resistance to airflow within the lungs and the inventive treatment of the invention described herein. As such, the following discussion is not intended to limit the aspects or objective of the inventive method as the inventive method may cause physiological changes not described below but

such changes still contributing to reducing or eliminating at least one of the symptoms of reversible obstructive pulmonary disease.

[0115] Reducing the Ability of the Airway to Contract

[0116] The inventive treatment reduces the ability of the airways to narrow or to reduce in diameter due to airway smooth muscle contraction. The inventive treatment uses a modality of treatments including, but not limited to the following: chemical, radio frequency, radioactivity, heat, ultrasound, radiant, laser, microwave, or mechanical energy (such as in the form of cutting, punching, abrading, rubbing, or dilating). This treatment reduces the ability of the smooth muscle to contract thereby lessening the severity of an asthma attack. The reduction in the ability of the smooth muscle to contract may be achieved by treating the smooth muscle itself or by treating other tissues which in turn influence smooth muscle contraction or the response of the airway to the smooth muscle contraction. Treatment may also reduce airway responsiveness or the tendency of the airway to narrow or to constrict in response to a stimulus.

[0117] The amount of smooth muscle surrounding the airway can be reduced by exposing the smooth muscle to energy which either kills the muscle cells or prevents these cells from replicating. The reduction in smooth muscle reduces the ability of the smooth muscle to contract and to narrow the airway during a spasm. The reduction in smooth muscle and surrounding tissue has the added potential benefit of increasing the caliber or diameter of the airways, this benefit reduces the resistance to airflow through the airways. In addition to the use of debulking smooth muscle tissue to open up the airways, the device used in the present invention may also eliminate smooth muscle altogether by damaging or destroying the muscle. The elimination of the smooth muscle prevents the contraction or spasms of hyper-reactive airways of a patient having reversible obstructive pulmonary disease. By doing so, the elimination of the smooth muscle may reduce some symptoms of reversible obstructive pulmonary disease.

[0118] The ability of the airway to contract can also be altered by treatment of the smooth muscle in particular patterns. The smooth muscle is arranged around the airways in a generally helical pattern with pitch angles ranging from about −30 to about +30 degrees. Thus, the treatment of the smooth muscle in appropriate patterns interrupts or cuts through the helical pattern of the smooth muscle at a proper pitch and prevents the airway from constricting. This procedure of patterned treatment application eliminates contraction of the airways without completely eradicating smooth muscle and other airway tissue. A pattern for treatment may be chosen from a variety of patterns including longitudinal or axial stripes, circumferential bands, helical stripes, and the like as well as spot patterns having rectangular, elliptical, circular or other shapes. The size, number, and spacing of the treatment bands, stripes, or spots are chosen to provide a desired clinical effect of reduced airway responsiveness while limiting insult to the airway to a clinically acceptable level.

[0119] The patterned treatment of the tissues surrounding the airways with energy provides various advantages. The careful selection of the portion of the airway to be treated allows desired results to be achieved while reducing the total healing load. Patterned treatment can also achieve desired results with decreased morbidity, preservation of epithelium, and preservation of a continuous or near continuous ciliated inner surface of the airway for mucociliary clearance. The pattern of treatment may also be chosen to achieve desired results while limiting total treatment area and/or the number of airways treated, thereby improving speed and ease of treatment.

[0120] Application of energy to the tissue surrounding the airways may also cause the DNA of the cells to become cross linked. The treated cells with cross linked DNA are incapable of replicating. Accordingly, over time, as the smooth muscle cells die, the total thickness of smooth muscle decreases because of the inability of the cells to replicate. The programmed cell death causing a reduction in the volume of tissue is called apoptosis. This treatment does not cause an immediate effect but causes shrinking of the smooth muscle and opening of the airway over time and substantially prevents re-growth. The application of energy to the walls of the airway may also be used to cause a cross linking of the DNA of the mucus gland cells thereby preventing them from replicating and reducing excess mucus plugging or production over time.

[0121] The ability of the airways to contract may also be reduced by altering mechanical properties of the airway wall, such as by increasing stiffness of the wall or by increasing parenchymal tethering of the airway wall. Both of these methods increase the strength of the airway wall and further oppose contraction and narrowing of the airway.

[0122] There are several ways to increase the stiffness of the airway wall. One way to increase stiffness is to induce fibrosis or a wound healing response by causing trauma to the airway wall. The trauma can be caused by delivery of therapeutic energy to the tissue in the airway wall, by mechanical insult to the tissue, or by chemically affecting the tissue. The energy is preferably delivered in such a way that it minimizes or limits the intra-luminal thickening that may occur.

[0123] Another way to increase the effective stiffness of the airway wall is to alter the submucosal folding of the airway upon narrowing. The mucosal layer includes the epithelium, its basement membrane, and the lamina propria, a subepithelial collagen layer. The submucosal layer may also play a role in airway folding. As an airway narrows, its perimeter remains relatively constant, with the mucosal layer folding upon itself. As the airway narrows further, the mucosal folds mechanically interfere with each other, effectively stiffening the airway. In asthmatic patients, the number of folds is fewer and the size of the folds is larger, and thus, the airway is free to narrow with less mechanical interference of mucosal folds than in a healthy patient. Thus, asthmatic patients have a decrease in airway stiffness and the airways have less resistance to narrowing.

[0124] The mucosal folding in asthmatic patients can be improved by treatment of the airway in a manner which encourages folding. Preferably, a treatment will increase the number of folds and/or decrease the size of the folds in the mucosal layer. For example, treatment of the airway wall in a pattern such as longitudinal stripes can encourage greater number of smaller mucosal folds and increase airway stiffness.

[0125] The mucosal folding can also be increased by encouraging a greater number of smaller folds by reducing the thickness of the mucosa and/or submucosal layer. The decreased thickness of the mucosa or submucosa may be achieved by application of energy which either reduces the number of cells in the mucosa or submucosal layer or which

prevents replication of the cells in the mucosa or submucosal layer. A thinner mucosa or submucosal layer will have an increased tendency to fold and increased mechanical stiffening caused by the folds.

[0126] Another way to reduce the ability of the airways to contract is to improve parenchymal tethering. The parenchyma surrounds airways and includes the alveolus and tissue connected to and surrounding the outer portion of the airway wall. The parenchyma includes the alveolus and tissue connected to and surrounding the cartilage that supports the larger airways. In a healthy patient, the parenchyma provides a tissue network which connects to and helps to support the airway. Edema or accumulation of fluid in lung tissue in patients with asthma or COPD is believed to decouple the airway from the parenchyma reducing the restraining force of the parenchyma which opposes airway constriction. Energy can be used to treat the parenchyma to reduce edema and/or improve parenchymal tethering.

[0127] In addition, the applied energy may be used to improve connection between the airway smooth muscle and submucosal layer to the surrounding cartilage, and to encourage wound healing, collagen deposition, and/or fibrosis in the tissue surrounding the airway to help support the airway and prevent airway contraction.

[0128] Increasing the Airway Diameter

[0129] Hypertrophy of smooth muscle, chronic inflammation of airway tissues, and general thickening of all parts of the airway wall can reduce the airway diameter in patients with reversible obstructive pulmonary, disease. Increasing the overall airway diameter using a variety of techniques can improve the passage of air through the airways. Application of energy to the airway smooth muscle of an asthmatic patient can debulk or reduce the volume of smooth muscle. This reduced volume of smooth muscle increases the airway diameter for improved air exchange.

[0130] Reducing inflammation and edema of the tissue surrounding the airway can also increase the diameter of an airway. Inflammation and edema (accumulation of fluid) of the airway are chronic features of asthma. The inflammation and edema can be reduced by application of energy to stimulate wound healing and regenerate normal tissue. Healing of the epithelium or sections of the epithelium experiencing ongoing denudation and renewal allows regeneration of healthy epithelium with less associated airway inflammation. The less inflamed airway has an increased airway diameter both at a resting state and in constriction. The wound healing can also deposit collagen which improves parenchymal tethering.

[0131] Inflammatory mediators released by tissue in the airway wall may serve as a stimulus for airway smooth muscle contraction. Therapy that reduces the production and release of inflammatory mediator can reduce smooth muscle contraction, inflammation of the airways, and edema. Examples of inflammatory mediators are cytokines, chemokines, and histamine. The tissues which produce and release inflammatory mediators include airway smooth muscle, epithelium, and mast cells. Treatment of these structures with energy can reduce the ability of the airway structures to produce or release inflammatory mediators. The reduction in released inflammatory mediators will reduce chronic inflammation, thereby increasing the airway inner diameter, and may also reduce hyper-responsiveness of the airway smooth muscle.

[0132] A further process for increasing the airway diameter is by denervation. A resting tone of smooth muscle is nerve regulated by release of catecholamines. Thus, by damaging or eliminating nerve tissue in the airways the resting tone of the smooth muscle is reduced, and the airway diameter is increased. Resting tone may also be reduced by directly affecting the ability of smooth muscle tissue to contract.

[0133] Reducing Plugging of the Airway

[0134] Excess mucus production and mucus plugging are common problems during both acute asthma exacerbation and in chronic asthma management. Excess mucus in the airways increases the resistance to airflow through the airways by physically blocking all or part of the airway. Excess mucus may also contribute to increased numbers of leukocytes found in airways of asthmatic patients by trapping leukocytes. Thus, excess mucus can increase chronic inflammation of the airways.

[0135] One type of asthma therapy involves treatment of the airways with energy to target and reduce the amount of mucus producing cells and glands and to reduce the effectiveness of the remaining mucus producing cells and glands. The treatment can eliminate all or a portion of the mucus producing cells and glands, can prevent the cells from replicating or can inhibit their ability to secrete mucus. This treatment will have both chronic benefits in increasing airflow through the airways and will lessen the severity of acute exacerbation of the symptoms of reversible obstructive pulmonary disease.

[0136] Application of Treatment

[0137] The following illustrations are examples of the invention described herein. It is contemplated that combinations of aspects of specific embodiments or combinations of the specific embodiments themselves are within the scope of this disclosure.

[0138] FIGS. **12** and **13** illustrate cross sections of two different airways in a healthy patient. The airway of FIG. **12** is a medium sized bronchus having an airway diameter D**1** of about 3 mm. FIG. **13** shows a section through a bronchiole having an airway diameter D**2** of about 1.5 mm. Each airway includes a folded inner surface or epithelium **2010** surrounded by stroma **2012** and smooth muscle tissue **2014**. The larger airways including the bronchus shown in FIG. **12** also have mucous glands **2016** and cartilage **2018** surrounding the smooth muscle tissue **2014**. Nerve fibers **2020** and blood vessels **2022** also surround the airway.

[0139] FIG. **14** illustrates the bronchus of FIG. **12** in which the smooth muscle **2014** has hypertrophied and increased in thickness causing the airway diameter to be reduced from the diameter D**1** to a diameter D**3**.

[0140] FIG. **15** is a schematic side view of the lungs being treated with a treatment device **2030**. The treatment device **2030** is an elongated member for treating tissue at a treatment site **2034** within a lung. The treatment device **2030** may use a variety of processes to achieve a desired response. The treatment device **2030** may use a modality of treatments as represented by the treatment source **2032**, including, but not limited to the following: chemical, radio frequency, radioactivity, heat, ultrasound, radiant, laser, microwave, or mechanical energy (such as in the form of cutting, punching, abrading, rubbing, or dilating). Although the invention discusses treatment of tissue at the surface it is also intended that the invention include treatment below an epithelial layer of the lung tissue.

[0141] The treatment of an airway with the treatment device may involve placing a visualization system such as an endoscope or bronchoscope into the airways. The treatment device is then inserted through or next to the bronchoscope or endoscope while visualizing the airways. Alternatively, the visualization system may be built directly into the treatment device using fiber optic imaging and lenses or a CCD and lens arranged at the distal portion of the treatment device. The treatment device may also be positioned using radiographic visualization such as fluoroscopy or other external visualization means. The treatment device which has been positioned with a distal end within an airway to be treated is energized so that energy is applied to the tissue of the airway walls in a desired pattern and intensity. The distal end of the treatment device may be moved through the airway in a uniform painting like motion to expose the entire length of an airway to be treated to the energy. The treatment device may be passed axially along the airway one or more times to achieve adequate treatment. The "painting-like" motion used to exposed the entire length of an airway to the energy may be performed by moving the entire treatment device from the proximal end either manually or by motor. Alternatively, segments, stripes, rings or other treatment patterns may be used.

[0142] According to one variation of the invention, the energy is transferred to or from an airway wall in the opening region of the airway, preferably within a length of approximately two times the airway diameter or less, and to wall regions of airways distal to bifurcations and side branches, preferably within a distance of approximately twice the airway diameter or less. The invention may also be used to treat long segments of un-bifurcated airway.

[0143] The invention includes a method of advancing a treatment device into a lung and treating the lung with the device to, at least, reduce the ability of the lung to produce at least one symptom of reversible obstructive pulmonary disease. It is contemplated that the treatment may reduce all of the symptoms of reversible obstructive disease. Alternatively, the treatment may be selected to address specific symptoms of the disease. It is also intended that the treatment of the lung may sufficiently reduce the symptoms of reversible obstructive pulmonary disease such that the patient is able to function as those free from the disease. Alternatively, the treatment may be such that the symptoms are reduced to allow the patient to more easily manage the disease. It is also intended that the effects of the treatment may be either long term or short term with repeating treatment necessary to suppress the symptoms.

[0144] The methods of the invention described herein may be performed while the lung is experiencing natural symptoms of reversible obstructive pulmonary disease. One such example is where an individual, experiencing an asthma attack, or acute exacerbation of asthma or COPD, undergoes treatment to improve the individual's ability to breath. In such a case, the treatment, called 'rescue,' seeks to provide immediate relief for the patient.

[0145] The method may also include the steps of locating one or more treatment sites within an airway of the lung, selecting one of the treatment sites from the locating step and treating at least one of the selected treatment sites. As mentioned above, these steps may be, but are not necessarily, performed while the lung is experiencing symptoms of reversible obstructive pulmonary disease.

[0146] The invention may further comprise the step of stimulating the lung to produce at least one artificially induced symptom of reversible obstructive pulmonary disease. For example, stimulation of the lung would preferably increase the resistance to airflow within the lung, constrict airways within the lung, inflame/irritate airway tissues, increase edema and/or increase the amount of mucus plugging of the airway. Stimulation of the lung may occur at any point during the procedure or before the procedure. For example, the lung may be stimulated either prior to or after, the step of locating a treatment site. If the lung is stimulated prior to the step of locating a treatment site, the reaction of the stimulated tissue within the lung may be useful in determining which locations are to be selected as treatment sites. The lung tissue or airway tissue within the lung may be stimulated by a variety of methods including but not limited to pharmacological stimulation, (e.g., histamine, methacholine, or other bronchoconstricting agents, etc.), electrical stimulation, mechanical stimulation, or any other stimuli causing obstructive pulmonary symptoms. For example, electrical stimulation may comprise exposing airway tissue to electrical field stimulation. An example of such parameters include 15 VDC, 0.5 ms pulses, 0.5-16 Hz, and 70 VDC, 2-3 ms pulses, 20 HZ.

[0147] The locating step described above may be performed using a non-invasive imaging technique, including but not limited to, a bronchogram, magnetic resonance imaging, computed tomography, radiography (e.g., x-ray), and ventilation perfusion scans.

[0148] The invention further includes the steps of testing the lung for at least one pre-treatment pulmonary function value prior to treating the lung with the device. After the lung is treated, the lung is re-tested for at least one post-treatment pulmonary function value. Naturally, the two pulmonary function values may be compared to estimate the effect of the treatment. The invention may also include treating additional sites in the lung after the re-testing step to at least reduce the effect, of at least one symptom of reversible obstructive pulmonary disease. The invention may also include stimulating the lung to produce at least one artificially induced symptom of reversible obstructive pulmonary disease. As mentioned above, the stimulation of the lung may occur at any point during, or prior to, the procedure. For example, stimulation of the lung may occur prior to the step of testing the lung for pre-treatment pulmonary values. In this case, the values would be determinative of pulmonary function values of a lung experiencing symptoms of reversible obstructive pulmonary disease. Accordingly, the objective is to treat the lung until acceptable pulmonary function values are obtained. One benefit of such a procedure is that the effect of the treatment on the patient is more readily observed as compared to the situation where a patient, having previously been treated, must wait for an attack of reversible obstructive pulmonary disease to determine the efficacy of the treatment.

[0149] Pulmonary function values are well known in the art. The following is an example of pulmonary function values that may be used. Other pulmonary function values, or combinations thereof, are intended to be within the scope of this invention. The values include, but are not limited to, FEV (forced expiratory volume), FVC (forced vital capacity), FEF (forced expiratory flow), Vmax (maximum flow), PEFR (peak expiratory flow rate), FRC (functional residual capacity), RV (residual volume), TLC (total lung capacity).

[0150] FEV measures the volume of air exhaled over a pre-determined period of time by a forced expiration immediately after a full inspiration. FVC measures the total volume of air exhaled immediately after a full inspiration. Forced expiratory flow measures the volume of air exhaled during a FVC divided by the time in seconds. Vmax is the maximum flow measured during FVC. PEFR measures the maximum flow rate during a forced exhale starting from full inspiration. RV is the volume of air remaining in the lungs after a full expiration.

[0151] The locating step described above may also comprise identifying treatment sites within the airway being susceptible to a symptom of reversible obstructive pulmonary disease. For example, symptoms may include, but are not limited to, airway inflammation, airway constriction, excessive mucous secretion, or any other asthmatic symptom. Stimulation of the lung to produce symptoms of reversible obstructive pulmonary disease may assist in identifying ideal treatment sites.

[0152] As noted above, the method of the present invention may include stimulating the lung to produce at least one artificially induced symptom of reversible obstructive pulmonary disease and further include the step of evaluating the result of stimulation of the lung. For example, the evaluating step may include visually evaluating the effect of the stimulating step on the airway using a bronchoscope with a visualization system or by non-invasive imaging techniques, such as those describe herein. The evaluating step may include measuring pressure changes in the airway before and after the stimulating step. Pressure may be measured globally (e.g., within the entire lung), or locally (e.g., within a specific section of the lung such as an airway or alveolar sac.) Also, the evaluating step may comprise measuring the electrical properties of the tissue before and after the stimulating step. The invention may also include evaluating the results of the stimulating step by combining any of the methods previously mentioned. Also, the invention may further comprise the step of selecting at least one treatment parameter based upon the results of the evaluating step. Such treatment parameters may include, but are not limited to, duration of treatment, intensity of treatment, temperature, amount of tissue treated, depth of treatment, etc.

[0153] The method may also include the step of determining the effect of the treatment by visually observing lung, airway or other such tissue for blanching of the tissue. The term "blanching" is intended to include any physical change in tissue that is usually, but not necessarily, accompanied by a change in the color of the tissue. One example of such blanching is where the tissue turns to a whitish color after the treatment of application of energy.

[0154] The invention may also include the step of monitoring impedance across a treated area of tissue within the lung. Measuring impedance may be performed in cases of monopolar or bipolar energy delivery devices. Additionally, impedance may be monitored at more than one site within the lungs. The measuring of impedance may be, but is not necessarily, performed by the same electrodes used to deliver the energy treatment to the tissue. Furthermore, the invention includes adjusting the treatment parameters based upon the monitoring of the change in impedance after the treatment step. For example, as the energy treatment affects the properties of the treated tissue, measuring changes in impedance may provide information useful in adjusting treatment parameters to obtain a desired result.

[0155] Another aspect of the invention includes advancing a treatment device into the lung and treating lung tissue to at least reduce the ability of the lung to produce at least one symptom of reversible obstructive pulmonary disease and further comprising the step of sub-mucosal sensing of the treatment to the lung tissue. The sub-mucosal sensing may be invasive such as when using a probe equipped to monitor temperature, impedance, and/or blood flow. Or, the sub-mucosal sensing may be non-invasive in such cases as infra-red sensing.

[0156] The invention may also include using the treatment device to deposit radioactive substances at select treatment sites within the lung. The radioactive substances, including, but not limited to Iridium (e.g. 192Ir.) either treat the lung tissue over time or provide treatment upon being deposited.

[0157] The invention also includes scraping epithelial tissue from the wall of an airway within the lung prior to advancing a treatment device into the lung to treat the lung tissue. The removal of the epithelial tissue allows the device to treat the walls of an airway more effectively. The invention further comprises the step of depositing a substance on the scraped wall of the airway after the device treats the airway wall. The substance may include epithelial tissue, collagen, growth factors, or any other bio-compatible tissue or substance, which promotes healing, prevent infection, and/or assists in the clearing of mucus. Alternatively, the treatment may comprise the act of scraping epithelial tissue to induce yield the desired response.

[0158] The invention includes using the treating device to pre-treat the lung to at least reduce the ability of the lung to produce at least one symptom of reversible obstructive pulmonary disease prior to the treating step. At least one of the parameters of the pre-treating step may differ than one of the parameters of the treating step. Such parameters may include time, temperature, amount of tissue over which treatment is applied, amount of energy applied, depth of treatment, etc.

[0159] The invention may also include advancing the treatment device into the lung and treating the lung tissue in separate stages. One of the benefits of dividing the treating step into separate stages is that the healing load of the patient is lessened. Dividing of the treating step may be accomplished by treating different regions of the lung at different times. Or, the total number of treatment sites may be divided into a plurality of groups of treatment sites, where each group of treatment sites is treated at a different time. The amount of time between treatments may be chosen such that the healing load placed on the lungs is minimized.

[0160] The invention may also include advancing a treatment device into the lung, treating the lung with the device and sensing movement of the lung to reposition the treatment device in response to the movement. This sensing step accounts for the tidal motion of the lung during breathing cycles or other movement. Taking into account the tidal motion allows improved accuracy in repositioning of the device at a desired target.

[0161] The invention may also include the additional step of reducing or stabilizing the temperature of lung tissue near to a treatment site. This may be accomplished for example, by injecting a cold fluid into lung parenchyma or into the airway being treated, where the airway is proximal, distal, or circumferentially adjacent to the treatment site. The fluid may be sterile normal saline, or any other bio-compatible fluid. The fluid may be injected into treatment regions within

the lung while other regions of the lung normally ventilated by gas. Or, the fluid may be oxygenated to eliminate the need for alternate ventilation of the lung. Upon achieving the desired reduction or stabilization of temperature the fluid may be removed from the lungs. In the case where a gas is used to reduce temperature, the gas may be removed from the lung or allowed to be naturally exhaled. One benefit of reducing or stabilizing the temperature of the lung may be to prevent excessive destruction of the tissue, or to prevent destruction of certain types of tissue such as the epithelium, or to reduce the systemic healing load upon the patient's lung.

[0162] Also contemplated as within the scope of the invention is the additional step of providing therapy to further reduce the effects of reversible obstructive pulmonary disease or which aids the healing process after such treatment. Some examples of therapy include, drug therapy, exercise therapy, and respiratory therapy. The invention further includes providing education on reversible obstructive pulmonary disease management techniques to further reduce the effects of the disease. For example, such techniques may be instruction on lifestyle changes, self-monitoring techniques to assess the state of the disease, and/or medication compliance education.

[0163] There may be occurrences where it is necessary to reverse the effects of the treatment described herein. Accordingly, the invention further includes a method for reversing a treatment to reduce the ability of the lung to produce at least one symptom of reversible obstructive pulmonary disease comprising the step of stimulating re-growth of smooth muscle tissue. The re-stimulation of the muscle may be accomplished by the use of electro-stimulation, exercising of the muscle and/or drug therapy.

[0164] The invention further includes methods of evaluating individuals having reversible obstructive pulmonary disease, or a symptom thereof, as a candidate for a procedure to reduce the ability of the individual's lung to produce at least one symptom of reversible obstructive pulmonary disease. The method comprises the steps of assessing the pulmonary condition of the individual, comparing the pulmonary condition to a corresponding pre-determined state, and evaluate the individual as a candidate based upon the comparison.

[0165] In assessing the pulmonary condition, the method may comprise the steps of performing pulmonary function tests on the individual to obtain a pulmonary function value which is compared to a predetermined value. Examples of pre-determined values are found above.

[0166] The method of evaluating may further include the step of determining how the individual's tissue will react to treatment allowing the treatment to be tailored to the expected tissue response.

[0167] The method of evaluating may further comprises the step of pulmonary function testing using a gas, a mixture of gases, or a composition of several mixtures of gases to ventilate the lung. The difference in properties of the gases may aid in the pulmonary function testing. For example, comparison of one or more pulmonary function test values that are obtained with the patient breathing gas mixtures of varying densities may help to diagnose lung function. Examples of such mixtures include air, at standard atmospheric conditions, and a mixture of helium and oxygen. Additional examples of pulmonary testing include tests that measure capability and evenness of ventilation given diffusion of special gas mixtures. Other examples of gases used in the described tests, include but are not limited to, nitrogen, carbon monoxide, carbon dioxide, and a range of inert gases.

[0168] The invention may also comprise the step of stimulating the lung to produce at least one artificially induced symptom of reversible obstructive pulmonary disease. Stimulating the symptoms of the disease in an individual allows the individual to be evaluated as the individual experiences the symptoms thereby allowing appropriate adjustment of the treatment.

[0169] The method of evaluating may also comprise the step of obtaining clinical information from the individual and accounting for the clinical information for treatment.

[0170] The method may further comprise the selection of a patient for treatment based upon a classification of the subtype of the patient's disease. For example, in asthma there are a number of ways to classify the disease state. One such method is the assessment of the severity of the disease. An example of a classification scheme by severity is found in the NHLBI Expert Panel 2 Guidelines for the Diagnosis and Treatment of Asthma. Another selection method may include selecting a patient by the type of trigger that induces the exacerbation. Such triggers may be classified further by comparing allergic versus non-allergic triggers. For instance, an exercise induced bronchospasm (EIB) is an example of a non-allergenic trigger. The allergic sub-type may be further classified according to specific triggers (e.g., dust mites, animal dander, etc.). Another classification of the allergic sub-type may be according to characteristic features of the immune system response such as levels of IgE (a class of antibodies that function in allergic reactions, also called immunoglobulin). Yet another classification of allergic subtypes may be according to the expression of genes controlling certain interleukins (e.g., IL-4, IL-5, etc.) which have been shown to play a key role in certain types of asthma.

[0171] The invention further comprises methods to determine the completion of the procedure and the effectiveness of the reduction in the lung's ability to produce at least one symptom of reversible obstructive pulmonary disease. This variation of the invention comprises assessing the pulmonary condition of the individual, comparing the pulmonary condition to a corresponding predetermined state, and evaluating the effectiveness of the procedure based on the comparison. The invention may also comprise the steps of performing pulmonary function tests on the individual to obtain at least one pulmonary function value, treating the lung to at least reduce the ability of the lung to produce at least one symptom of reversible obstructive pulmonary disease, performing a post-procedure pulmonary function tests on the individual to obtain at least one post pulmonary function value and comparing the two values.

[0172] This variation of the invention comprises obtaining clinical information, evaluating the clinical information with the results of the test to determine the effectiveness of the procedure. Furthermore, the variation may include stimulating the lung to produce a symptom of reversible obstructive pulmonary disease, assessing the pulmonary condition of the patient, then repeating the stimulation before the post-procedure pulmonary therapy. These steps allow comparison of the lung function when it is experiencing symptoms of reversible obstructive pulmonary disease, before and after

the treatment, thereby allowing for an assessment of the improved efficiency of the lung during an attack of the disease.

[0173] As for other details of the present invention, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts a commonly or logically employed. In addition, though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention.

[0174] Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention.

[0175] It is contemplated that, where possible, combinations of aspects of each embodiment or combinations of the embodiments themselves are within the scope of the invention.

[0176] Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said," and "the" include plural referents unless the context clearly dictates otherwise.

1-28. (canceled)

29. A method of treating a lung, the method comprising:
stimulating tissue surrounding an airway of the lung to constrict the airway, using a medical device including a catheter, a balloon disposed at a distal end of the catheter, and an electrode, by contacting the tissue with a pharmacological agent to induce constriction of the airway;
after stimulating the tissue, measuring a parameter of the airway;
identifying a treatment site based on the measured parameter by selecting the contacted tissue to receive energy from the electrode;
delivering a liquid to the airway to electrically couple the electrode to the contacted tissue;
applying energy to the contacted tissue from the electrode, through the liquid, to damage nerve tissue; and
after applying energy to the contacted tissue, determining an effectiveness of applying energy to the contacted tissue by determining whether the contacted tissue has a reduced ability to respond to a stimulus.

30. The method of claim **29**, wherein measuring the parameter is performed with the medical device.

31. The method of claim **29**, wherein applying energy includes applying RF energy.

32. The method of claim **29**, wherein the medical device includes a plurality of circumferentially spaced electrodes.

33. The method of claim **29**, wherein the pharmacological agent is a bronchoconstricting agent.

34. The method of claim **33**, wherein the bronchoconstricting agent is histamine or methacholine.

35. A method of treating a lung, the method comprising:
delivering a liquid to an airway of the lung, via a medical device including a catheter and an electrode, to electrically couple the electrode to tissue surrounding the airway; and
applying energy from the electrode, through the liquid, to damage the tissue.

36. The method of claim **35**, wherein the medical device further includes an expandable balloon.

37. The method of claim **35**, further including:
stimulating the tissue surrounding the airway in the lung to constrict the airway,
after stimulating the tissue, measuring a parameter of the airway;
identifying a treatment site based on the measured parameter, wherein the energy is applied to the treatment site.

38. The method of claim **37**, wherein:
stimulating the tissue includes contacting the tissue with a pharmacological agent to induce constriction of the airway; and
identifying the treatment site includes selecting the contacted tissue to receive energy from the electrode.

39. The method of claim **37**, wherein stimulating the tissue includes electrically stimulating the tissue, mechanically stimulating the tissue, or stimulating the tissue by delivering a pharmacological agent to the tissue.

40. The method of claim **35**, further including, after applying energy, determining an effectiveness of applying energy by determining whether the lung has a reduced ability to produce at least one symptom of reversible obstructive pulmonary disease.

41. The method of claim **35**, wherein damaging tissue of the lung includes damaging nerve tissue.

42. A method of treating a lung, the method comprising:
contacting tissue surrounding an airway of the lung with an agent to induce constriction of the airway, wherein the medical device includes a catheter, a balloon disposed at a distal end of the catheter, and an electrode;
after contacting the tissue, measuring a parameter of the airway;
identifying a treatment site based on the measured parameter by selecting the contacted tissue to receive energy from the electrode;
delivering an electrically-conductive liquid to the airway;
applying energy to the contacted tissue from the electrode, through the liquid, to damage nerve tissue; and
after applying energy to the contacted tissue, determining an effectiveness of applying energy to the contacted tissue.

43. The method of claim **42**, wherein measuring the parameter is performed with the medical device.

44. The method of claim **42**, wherein applying energy includes applying RF energy.

45. The method of claim **42**, wherein the medical device includes a plurality of circumferentially spaced electrodes.

46. The method of claim **42**, wherein the pharmacological agent is a bronchoconstricting agent.

47. The method of claim **46**, wherein the bronchoconstricting agent is histamine or methacholine.

48. The method of claim **42**, wherein the parameter is constriction of the airway.

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