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application No. 11/420,442, filed on May 25, 2006, now Pat. No. 7,853,331, which is a continuation of application No. PCT/US2005/040378, filed on Nov. 7, 2005.

(60) Provisional application No. 60/625,256, filed on Nov. 5, 2004, provisional application No. 60/650,368, filed on Feb. 4, 2005.

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	CPC	<i>A61B 18/1492</i> (2013.01); <i>A61B 18/18</i> (2013.01)
	USPC	606/33

ABSTRACT

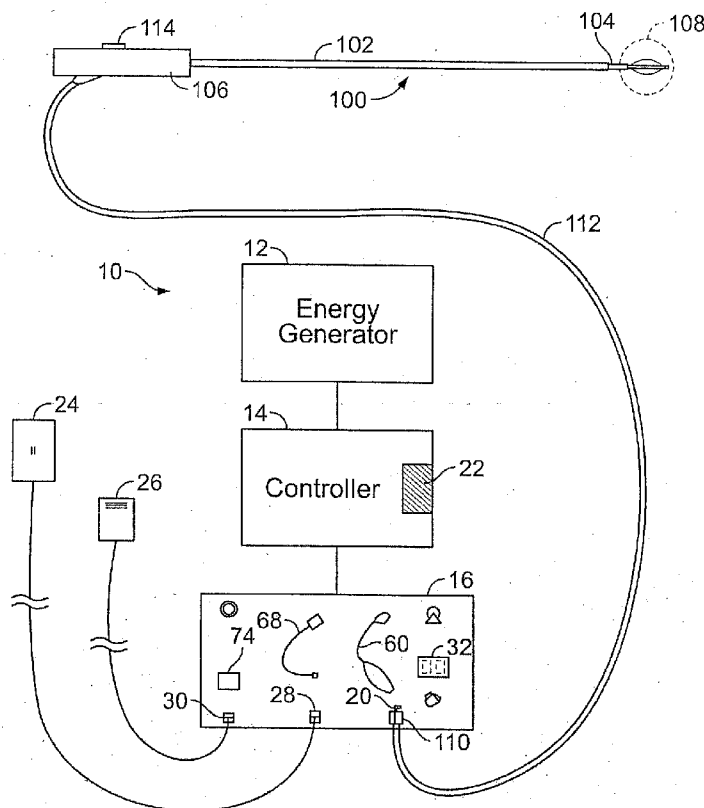
(22) Filed: **Sep. 11, 2013**

Related U.S. Application Data

(63) Continuation of application No. 13/860,216, filed on Apr. 10, 2013, which is a continuation of application No. 13/087,161, filed on Apr. 14, 2011, now abandoned, which is a continuation of application No. 11/618,533, filed on Dec. 29, 2006, now Pat. No. 7,949,407, which is a continuation-in-part of application No. 11/256,295, filed on Oct. 21, 2005, now Pat. No. 7,200,445, which is a continuation-in-part of

(57) **ABSTRACT**

A method of treating an airway includes inserting a treatment device into the airway, wherein the treatment device includes an energy delivery element configured to deliver energy to tissue of the airway, advancing the treatment device to a treatment location in the airway, activating the energy delivery element to deliver energy to tissue at the treatment location, and cooling tissue near the treatment location simultaneously with the activating step.



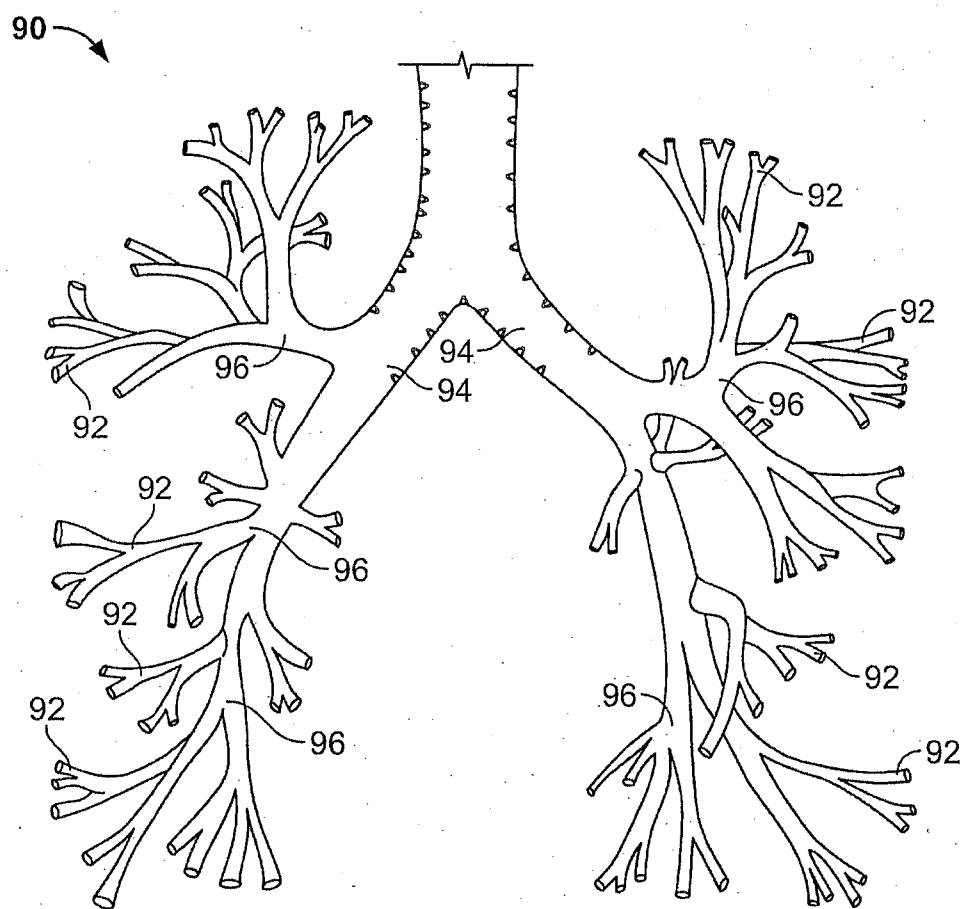


FIG. 1

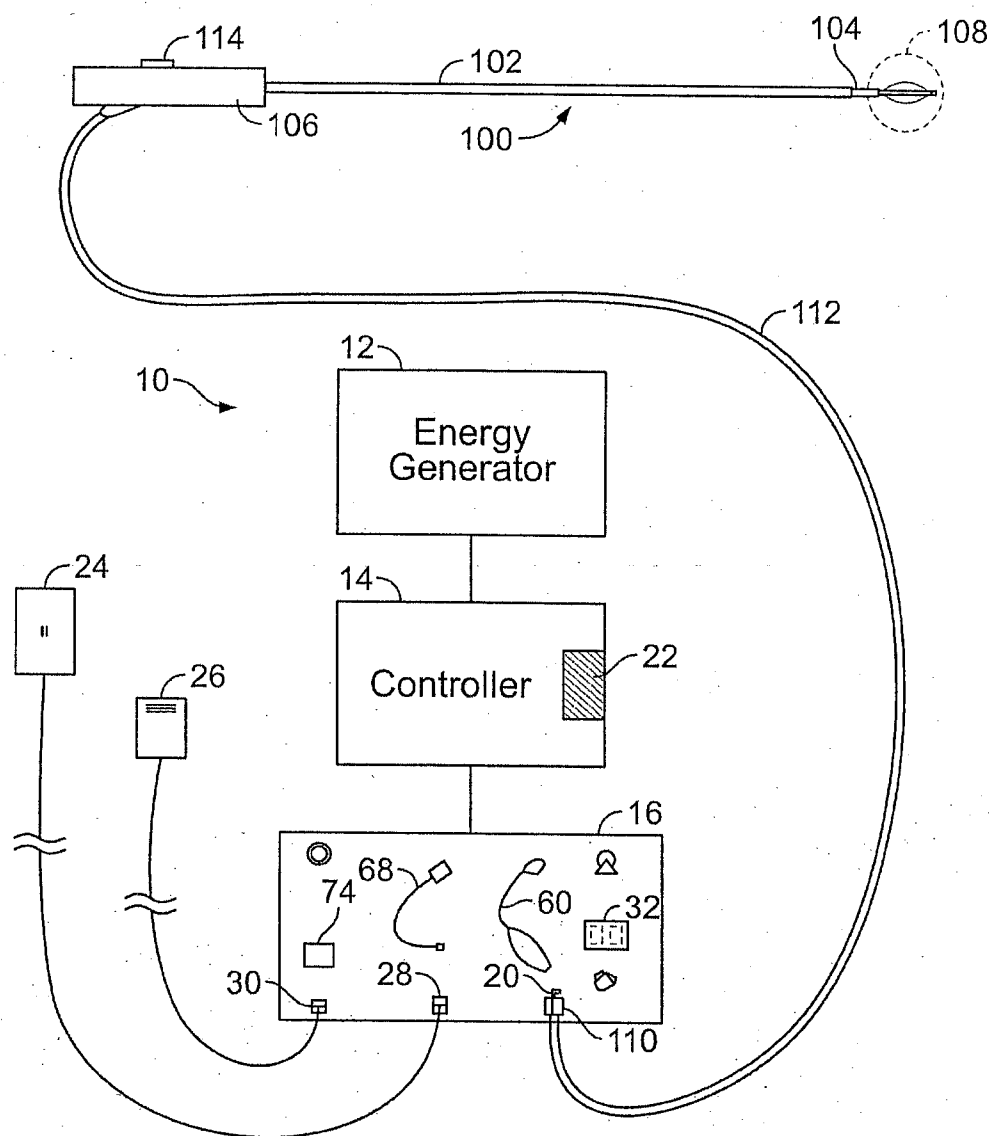


FIG. 2A

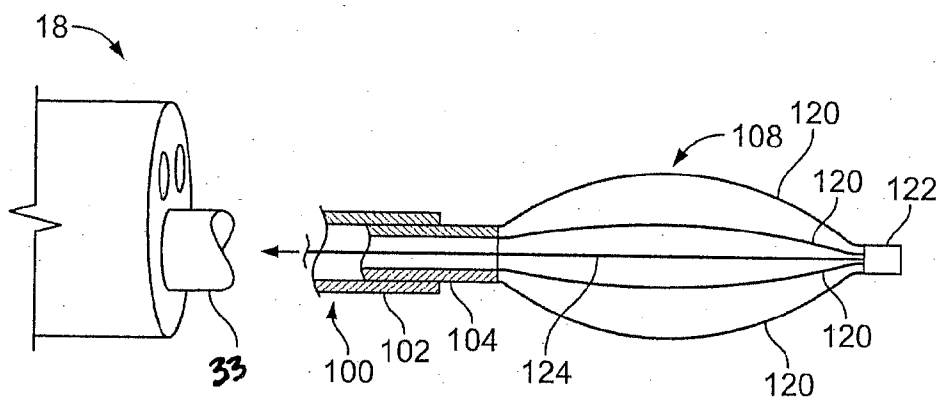


FIG. 2B

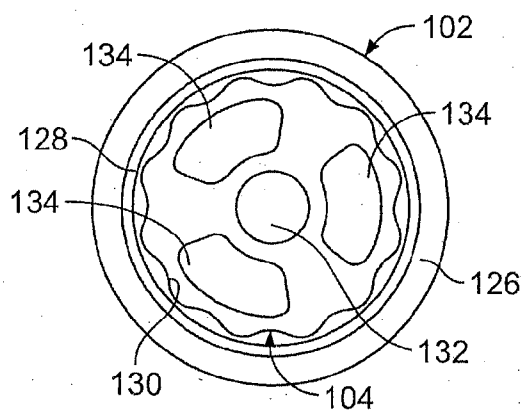


FIG. 3A

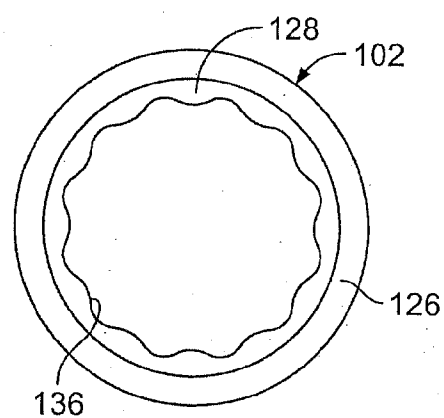


FIG. 3B

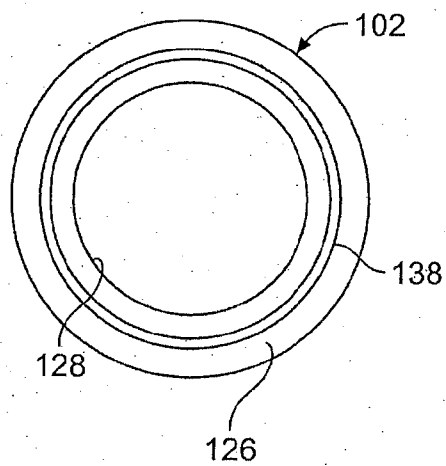


FIG. 3C

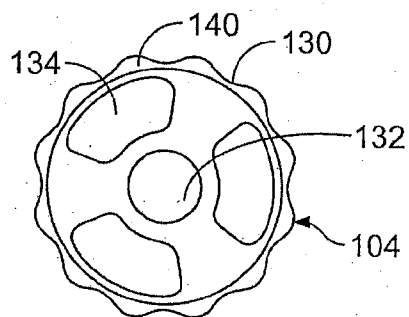


FIG. 3D

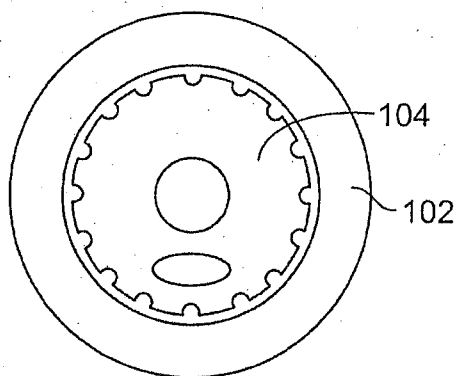


FIG. 3E

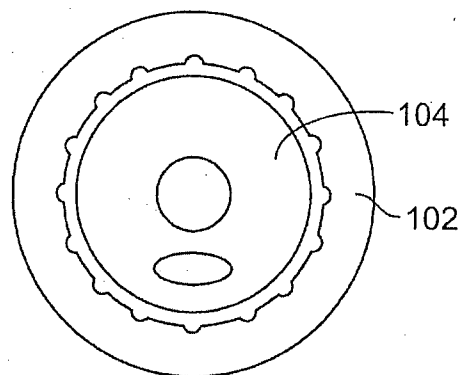


FIG. 3F

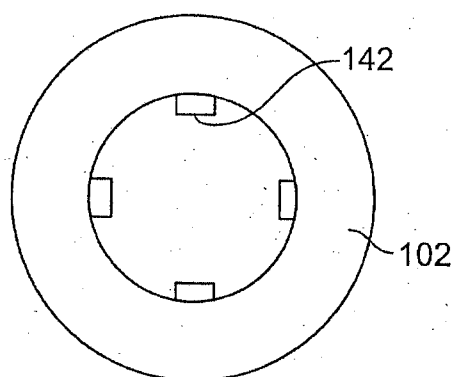


FIG. 3G

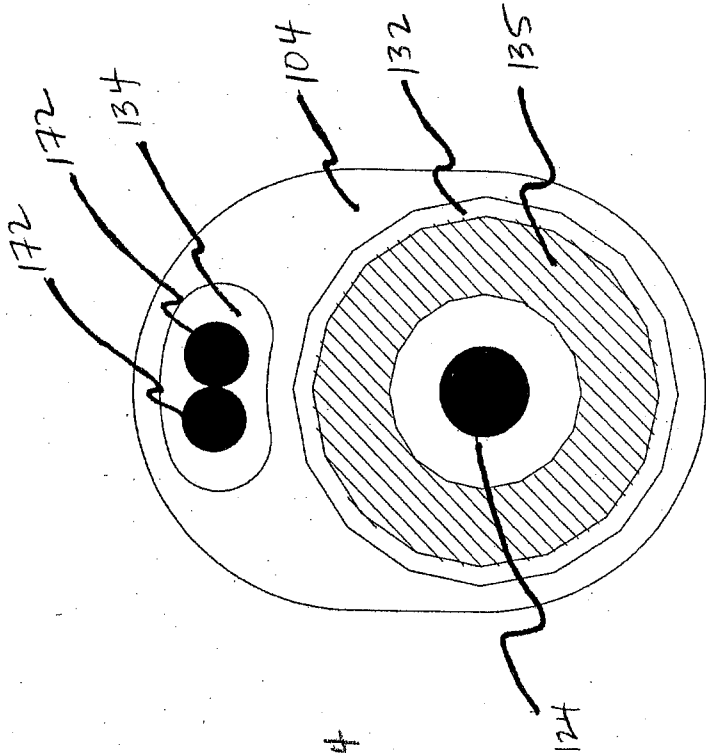


FIG. 3H

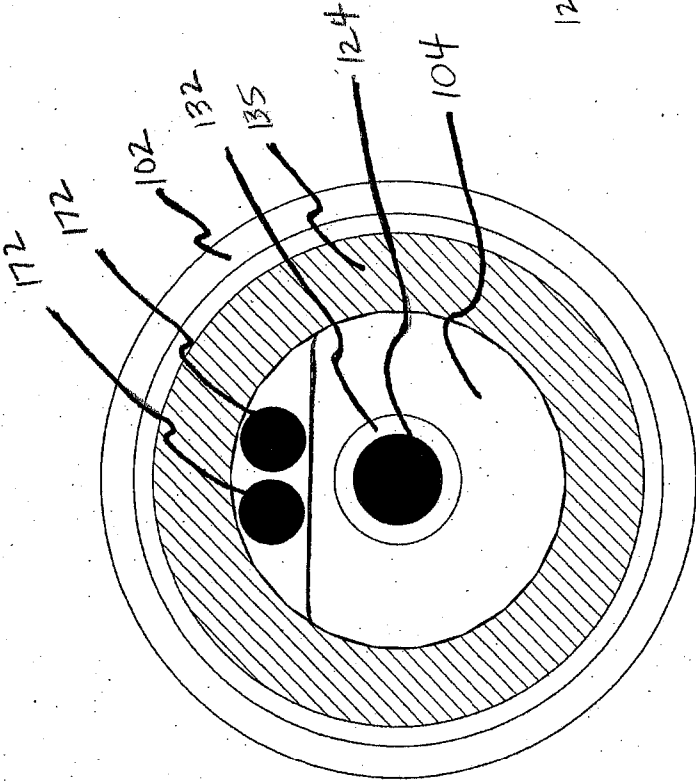


FIG. 3I

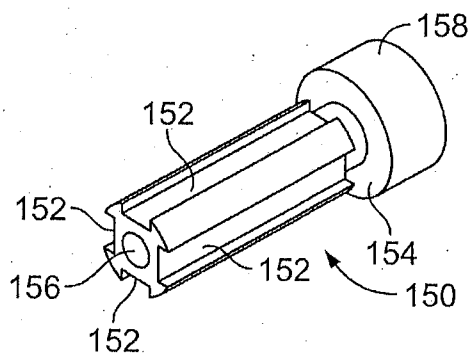


FIG. 4A

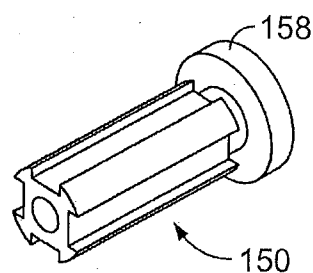


FIG. 4B

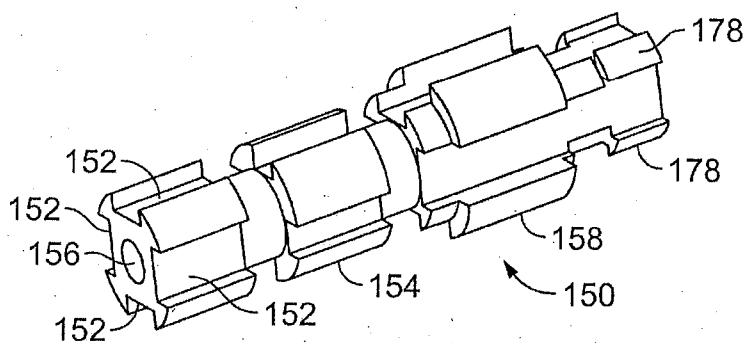


FIG. 4C

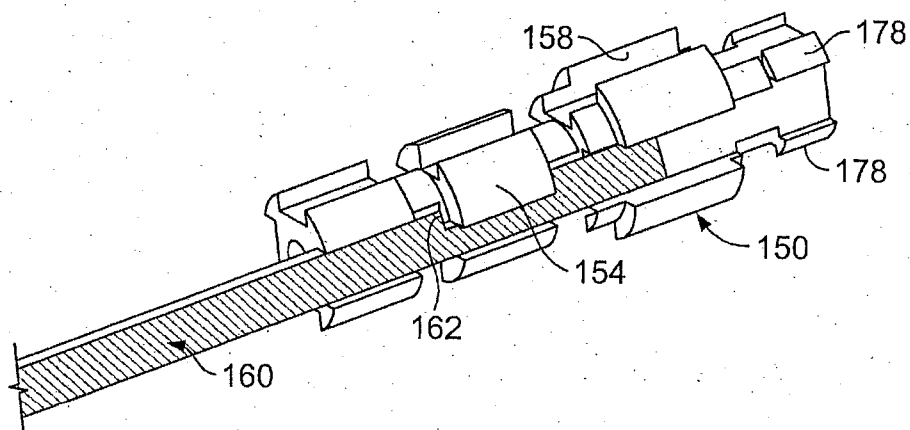


FIG. 4D

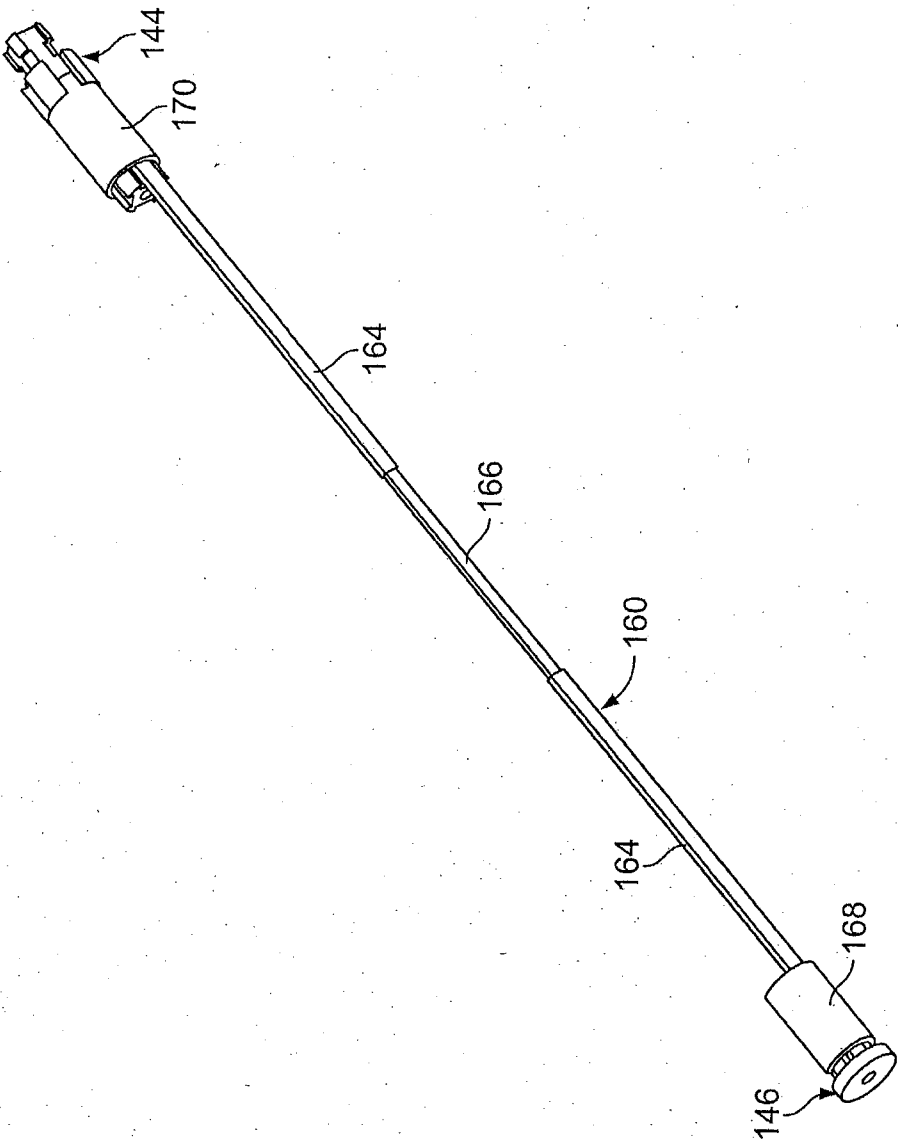


FIG. 4E

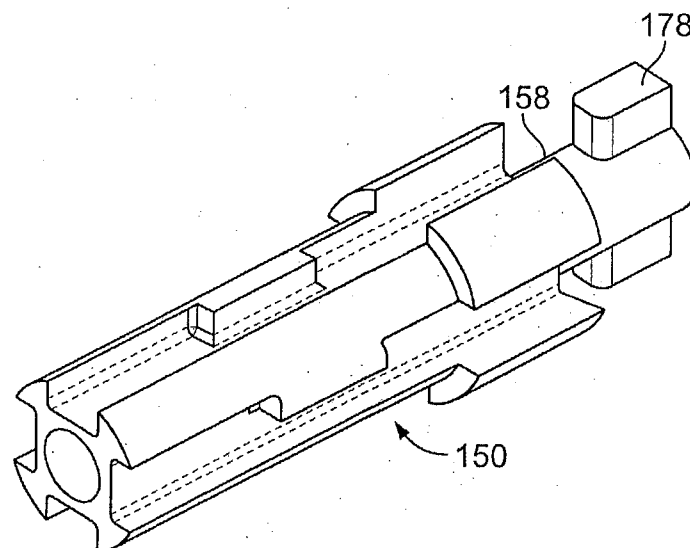


FIG. 4F

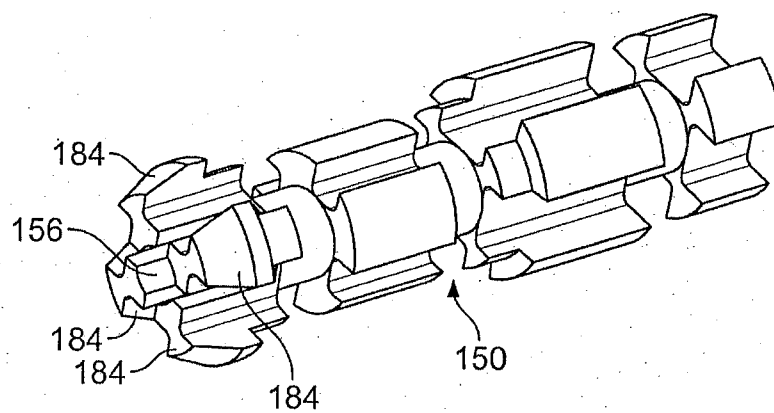


FIG. 4G

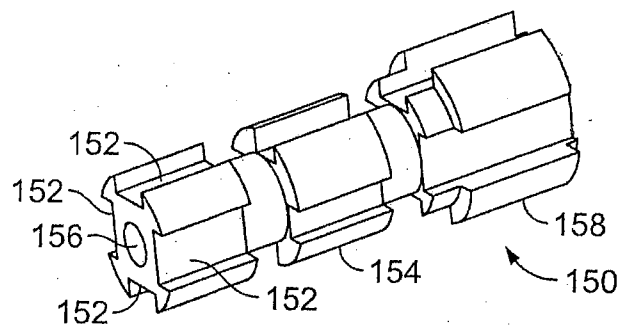


FIG. 4I

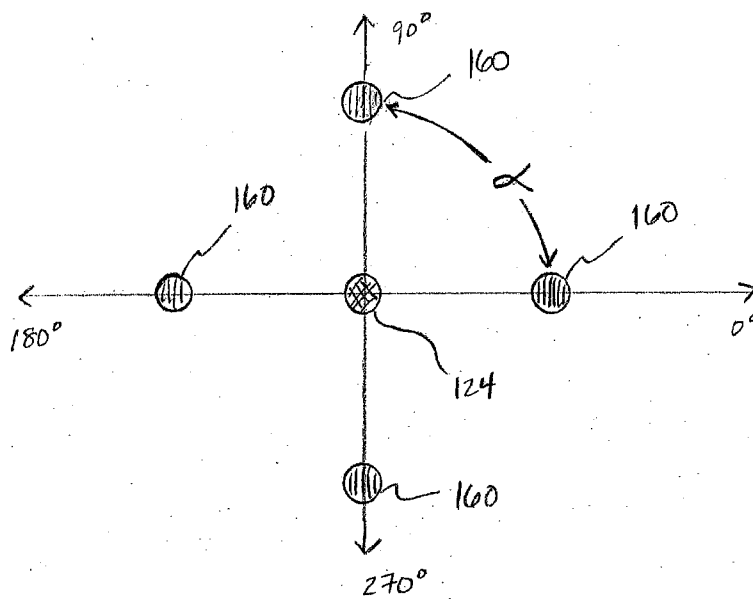


FIG. 4J

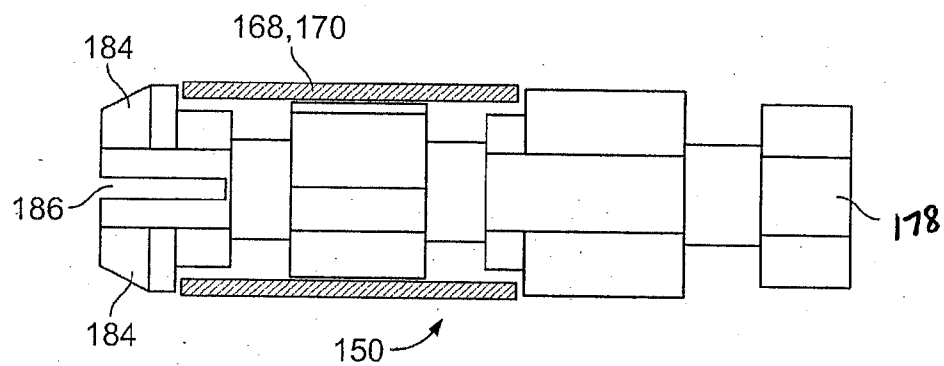


FIG. 4H

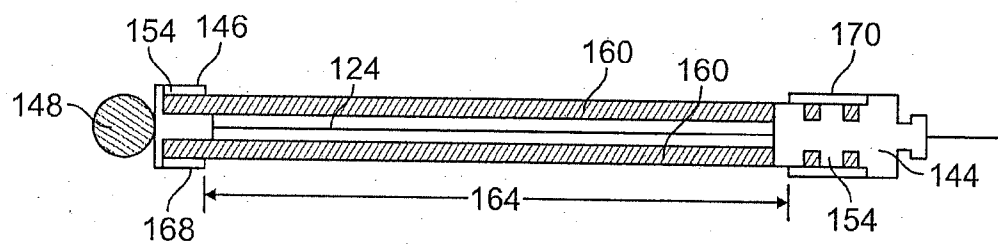


FIG. 5A

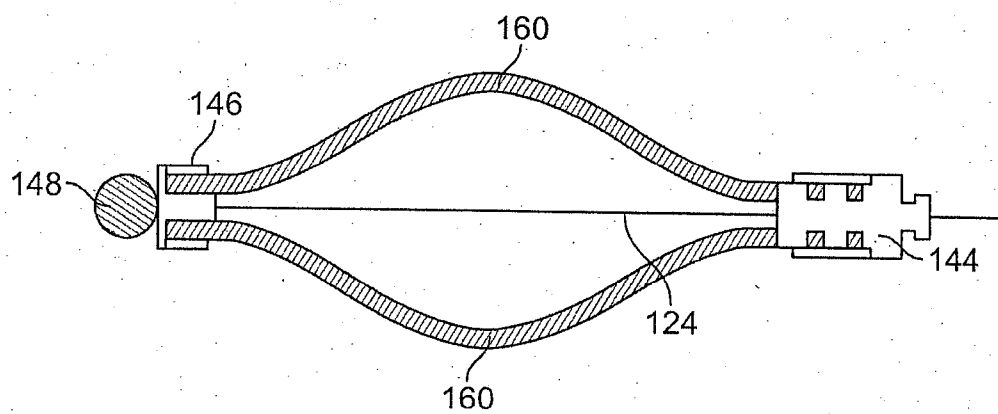


FIG. 5B

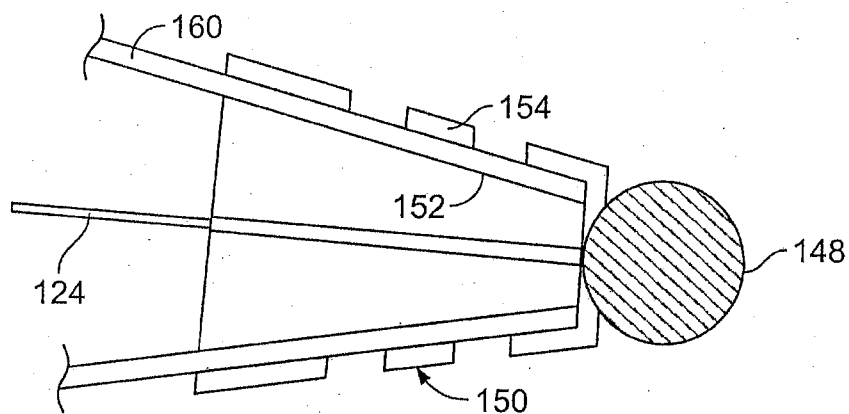


FIG. 5C

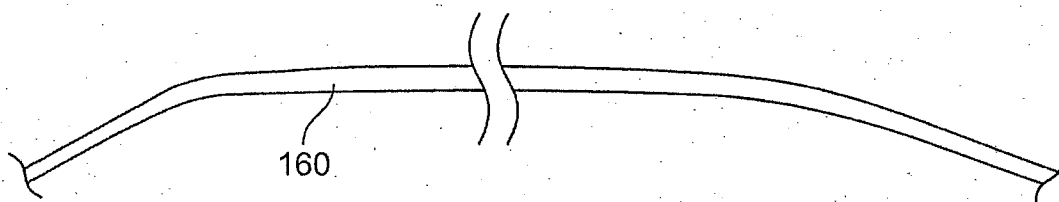


FIG. 5D

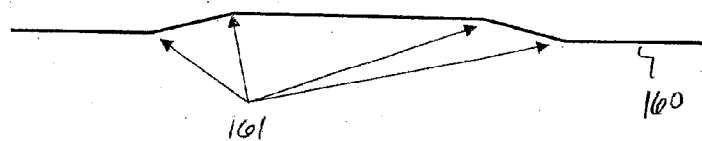


FIG. 5E

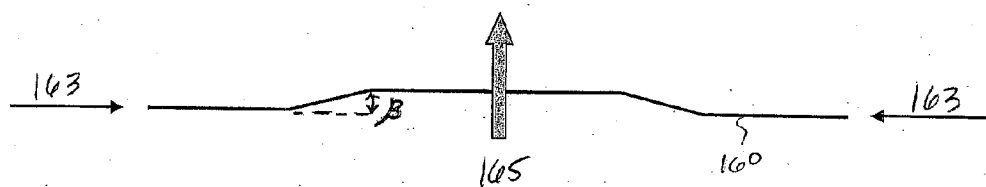


FIG. 5F

FIG. 5G

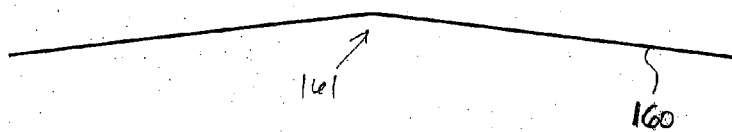


FIG. 5H

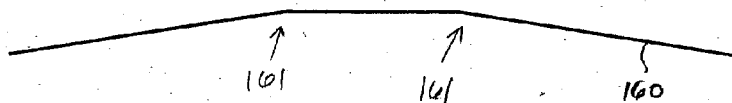
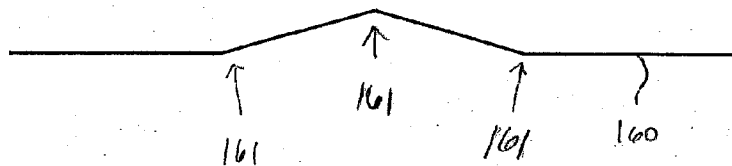
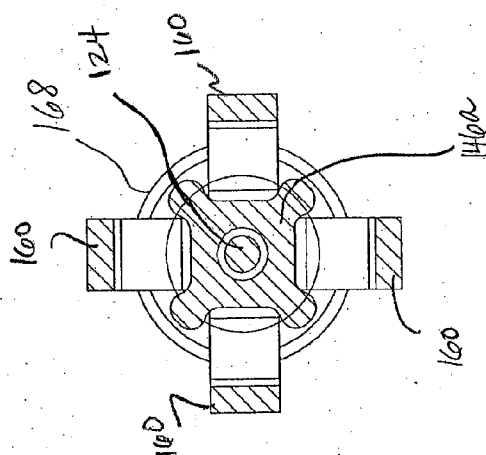
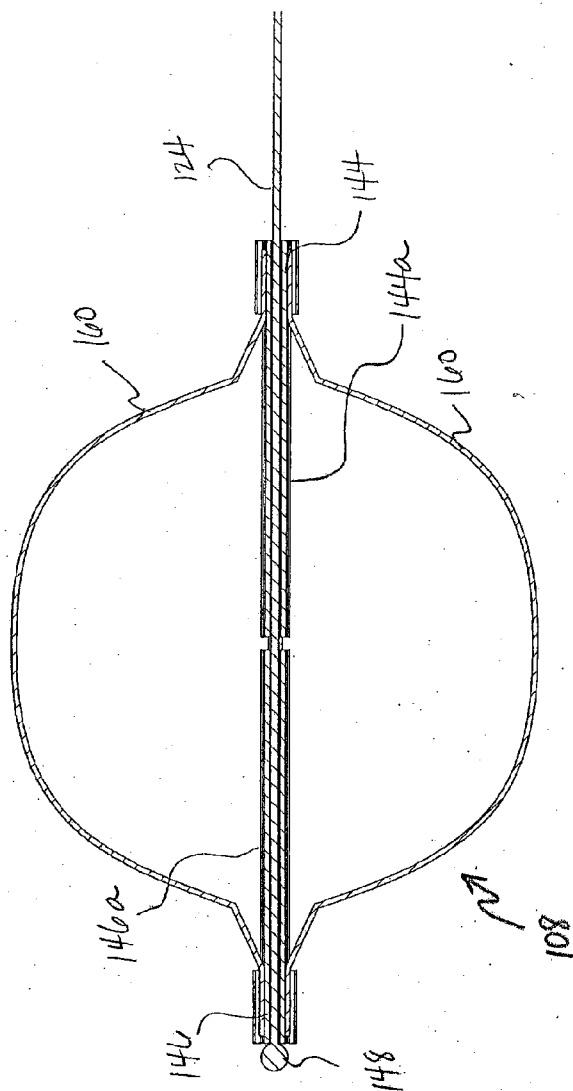
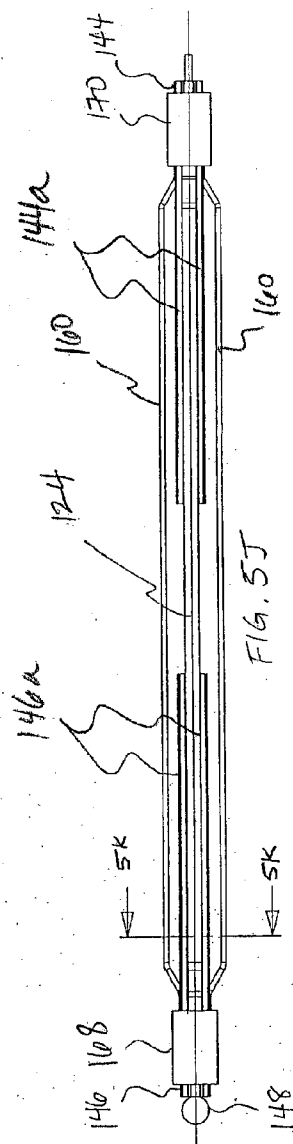


FIG. 5I





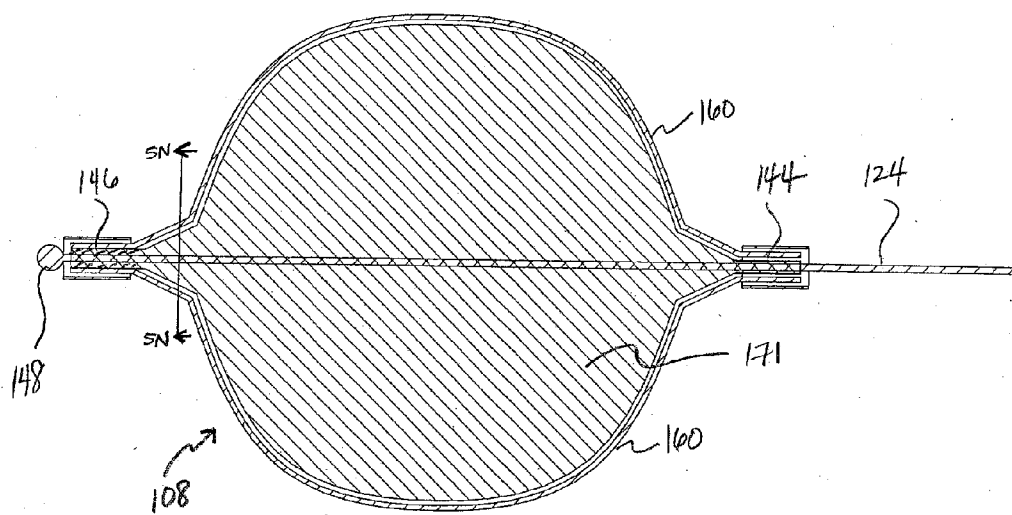


FIG. 5M

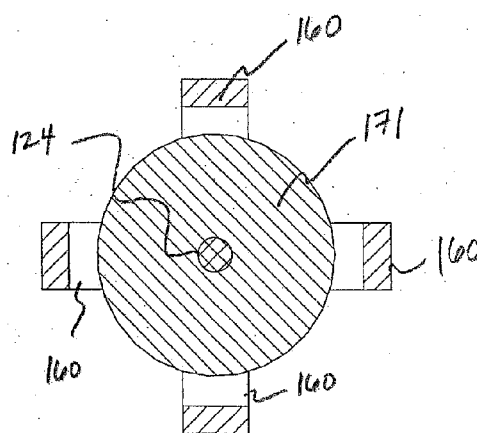


FIG. 5N

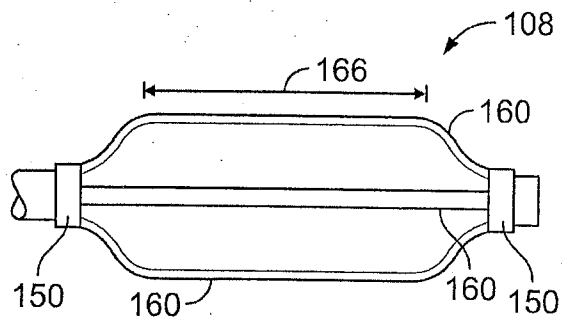


FIG. 6A

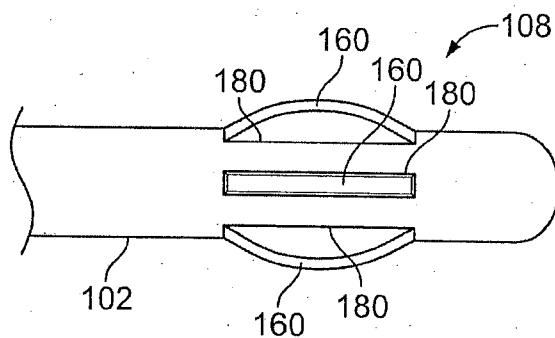


FIG. 6B

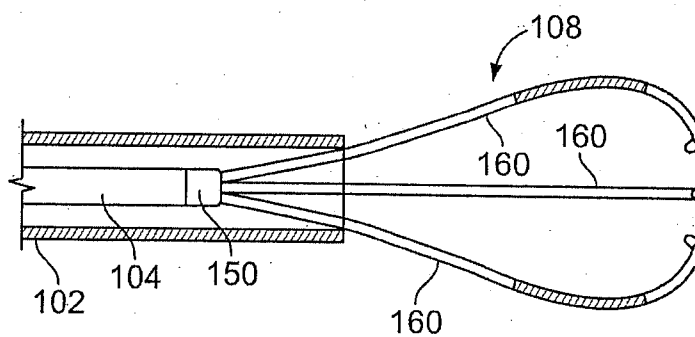


FIG. 6C

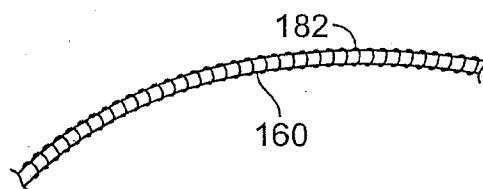


FIG. 7A

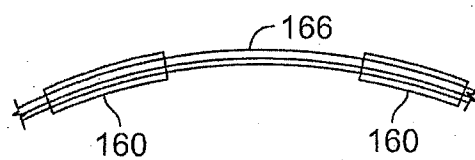


FIG. 7B

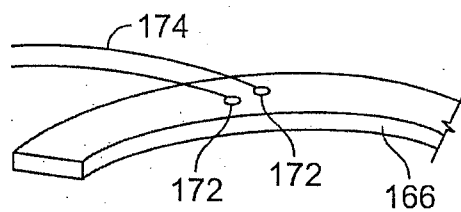


FIG. 7C

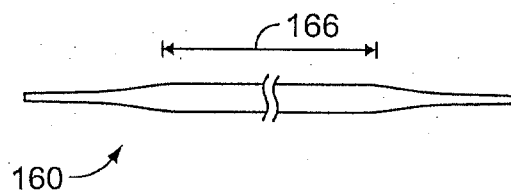


FIG. 7D

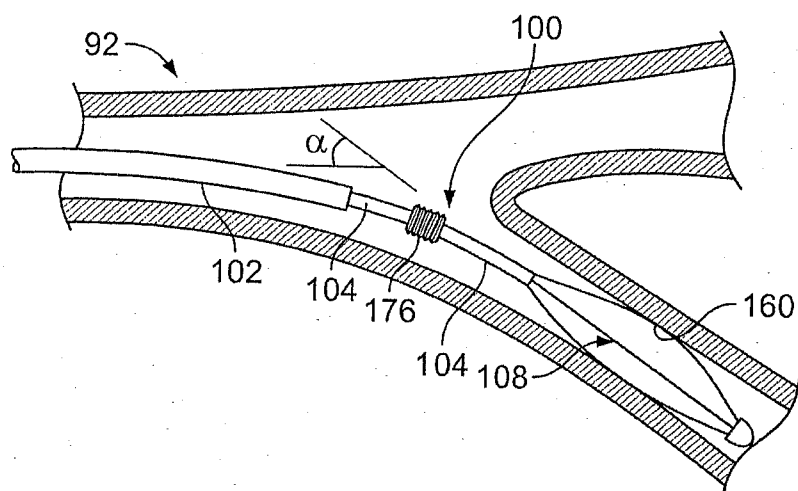


FIG. 8A

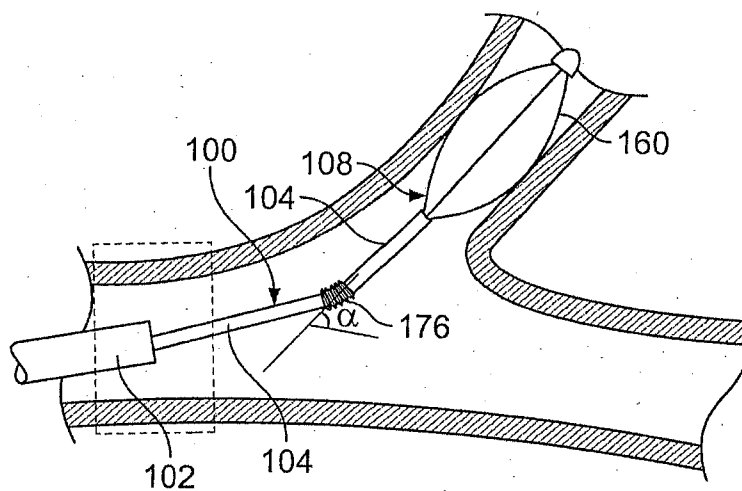


FIG. 8B

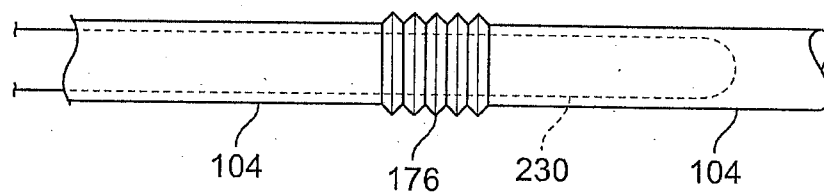


FIG. 8C

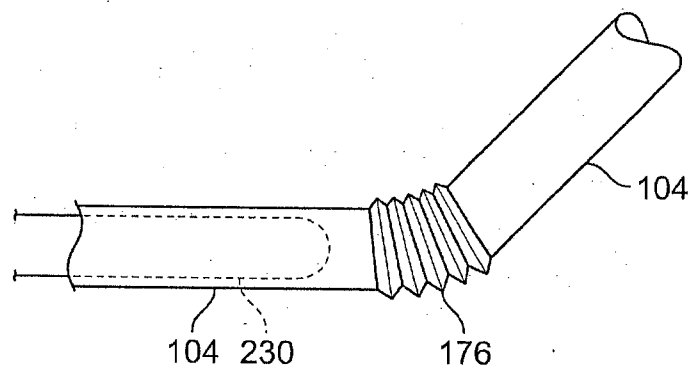


FIG. 8D

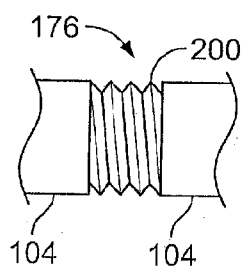


FIG. 9A

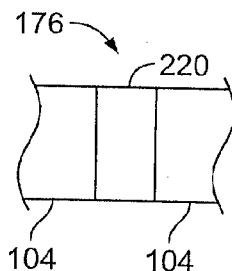


FIG. 9B

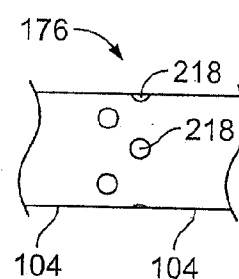


FIG. 9C

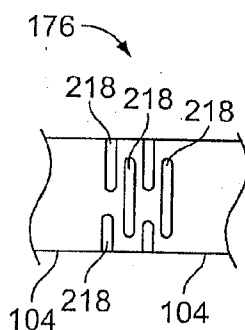


FIG. 9D

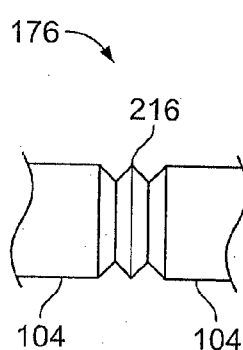


FIG. 9E

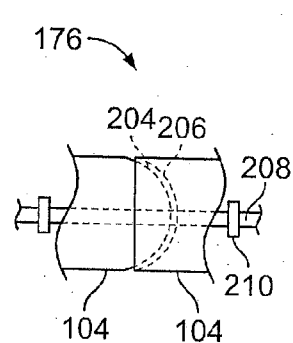


FIG. 9F

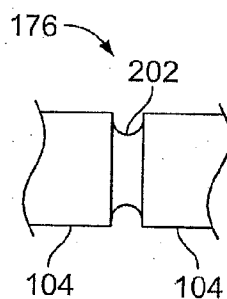


FIG. 9G

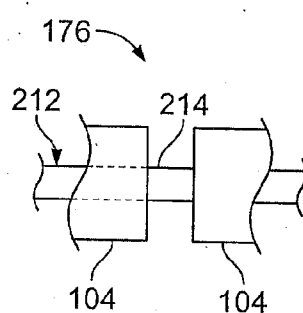


FIG. 9H

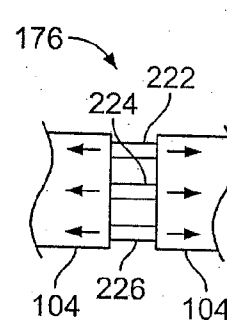


FIG. 9I

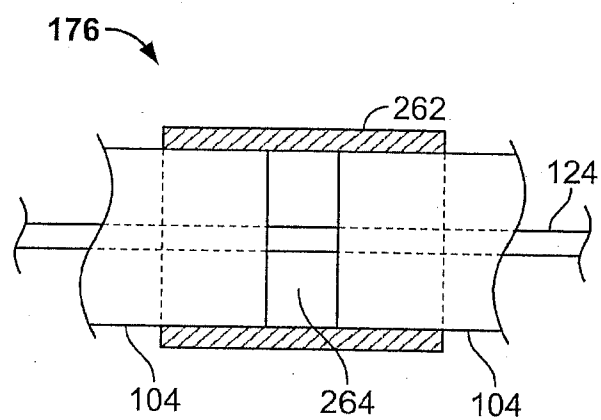


FIG. 9J

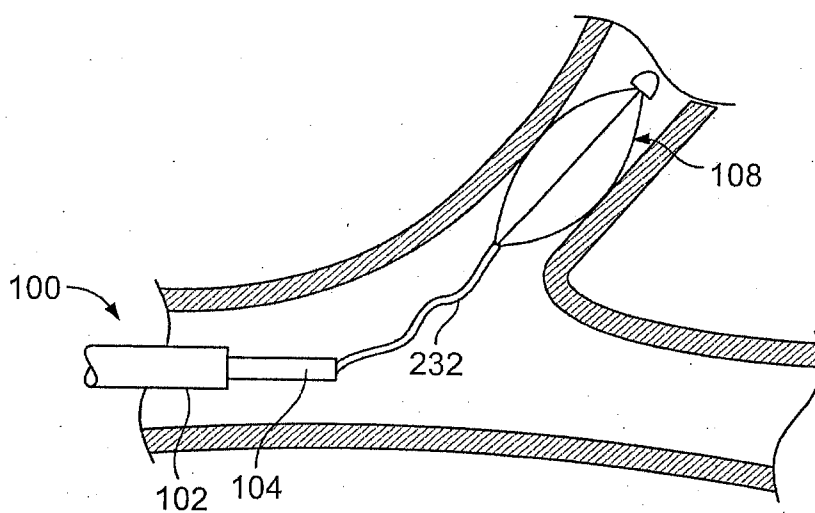


FIG. 10A

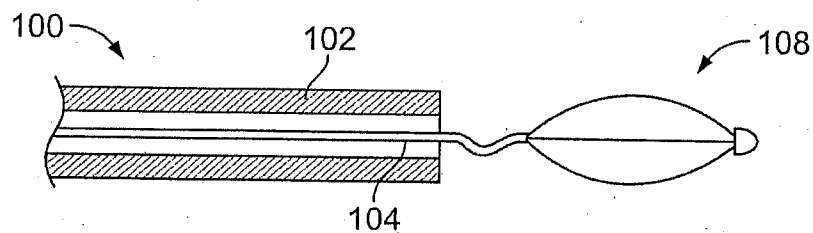


FIG. 10B

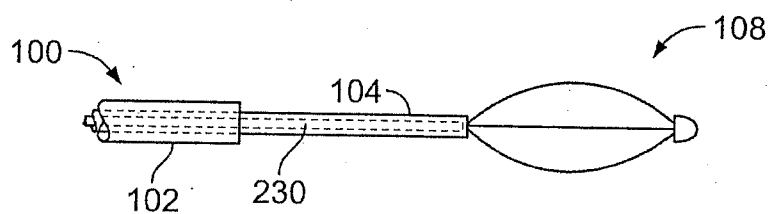


FIG. 10C

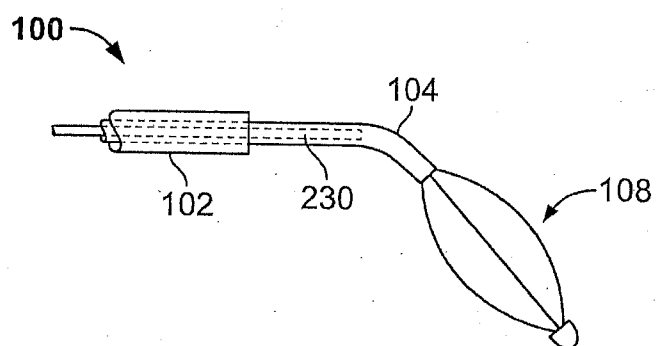


FIG. 10D

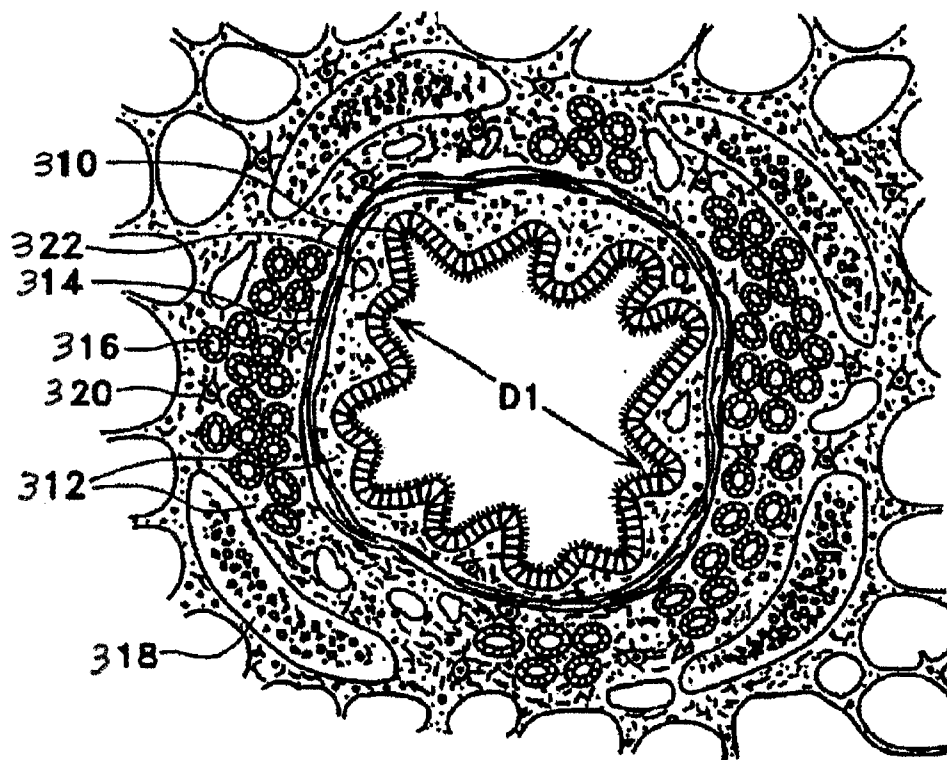


FIG. 11

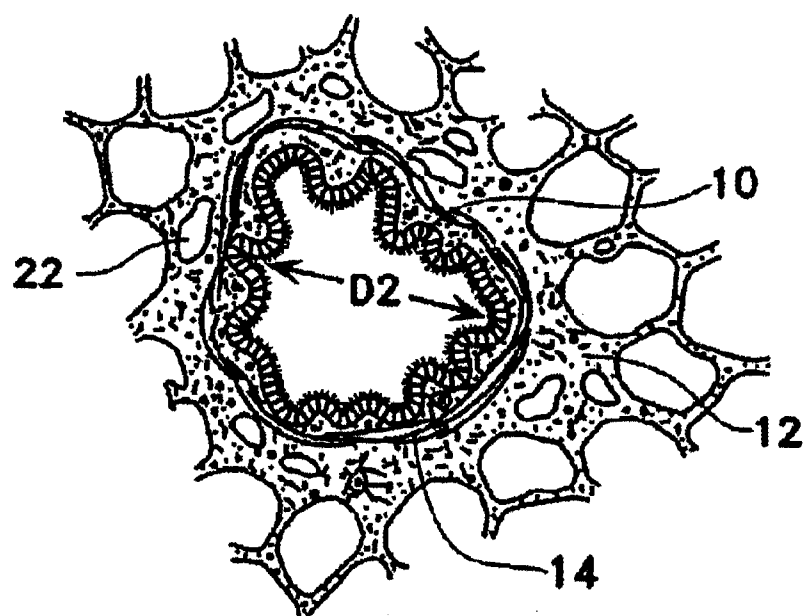


FIG. 12

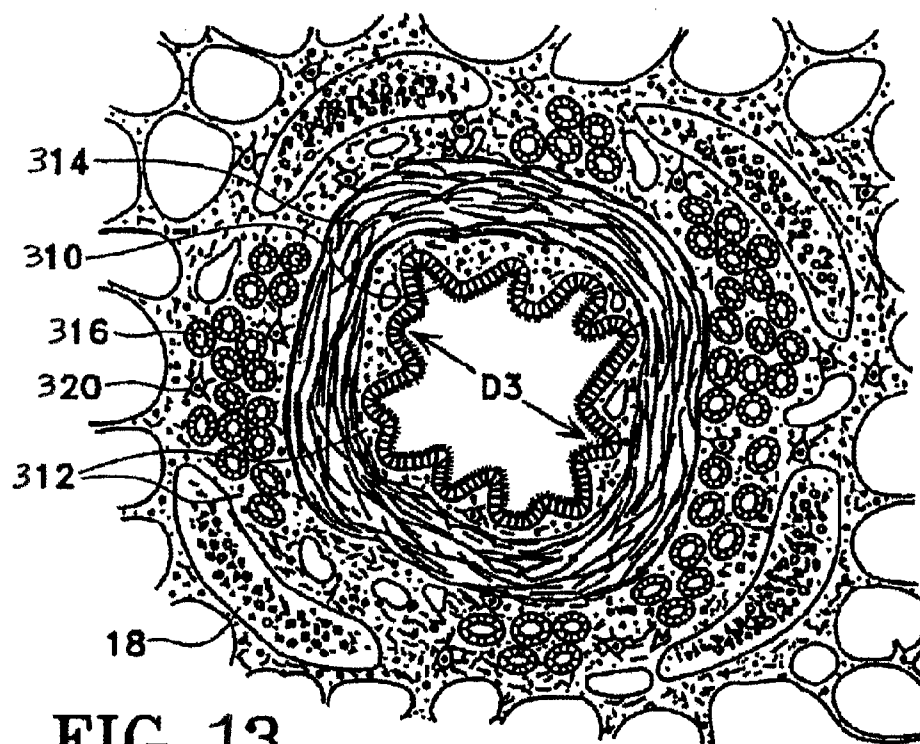


FIG. 13

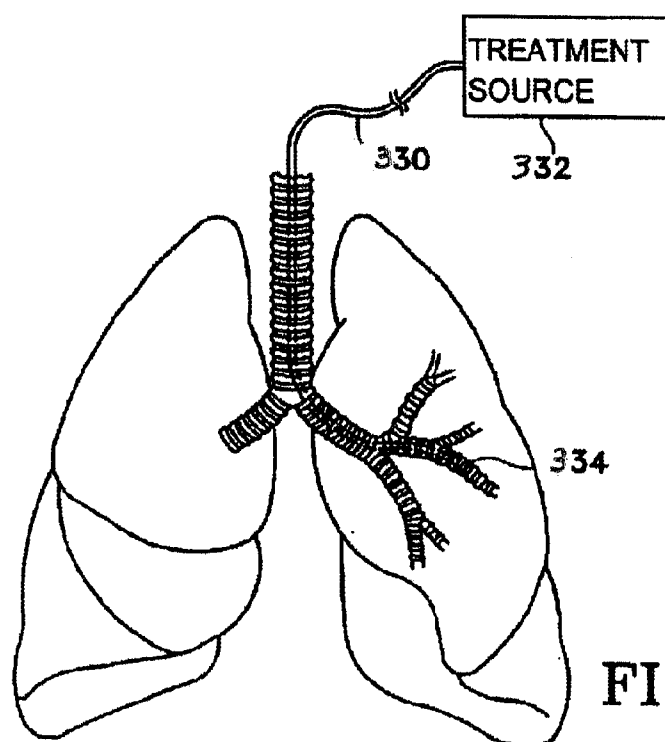


FIG. 14

ENERGY DELIVERY DEVICES AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 13/860,216, filed Apr. 10, 2013, which is a continuation of U.S. patent application Ser. No. 13/087,161, filed Apr. 14, 2011 (now abandoned), which is a continuation of U.S. patent application Ser. No. 11/618,533, filed Dec. 29, 2006 (now U.S. Pat. No. 7,949,407), which is a continuation-in-part of U.S. patent application Ser. No. 11/256,295, filed Oct. 21, 2005 (now U.S. Pat. No. 7,200,445) and U.S. patent application Ser. No. 11/420,442, filed May 25, 2006 (now U.S. Pat. No. 7,853,331), which is a continuation of PCT Application No. PCT/US2005/040378, filed Nov. 7, 2005, which claims the benefit of U.S. Provisional Patent Application Nos. 60/625,256, filed Nov. 5, 2004, and 60/650,368, filed Feb. 4, 2005, the full disclosures of which are incorporated herein by reference.

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 hyper-responsive 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. 1A illustrates a bronchial tree 90. As noted herein, devices treating areas of the lungs must have a con-

struction that enables navigation through the tortuous passages. As shown, the various bronchioles 92 decrease in size and have many branches 96 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, 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 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

[0015] 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.

[0016] 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.

[0017] 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.

[0018] 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.

[0019] 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.

[0020] 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 leg is determined by the distance between near and far alignment components.

[0021] 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.

[0022] 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.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.

[0024] FIG. 1 is an illustration of the airways within a human lung.

[0025] FIG. 2A is a schematic view of an exemplary system for delivering energy according to the present invention.

[0026] FIG. 2B 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.

[0027] FIGS. 3A-3G show various features of the device allowing for low force deployment of the energy element.

[0028] FIG. 3H illustrates a sheathless device having an oblong or oval shaft cross section.

[0029] FIG. 3I illustrates another variation of the device having a D-shaped cross section.

[0030] FIGS. 4A-4C illustrate various alignment components of the device.

[0031] FIGS. 4D-4E demonstrate the alignment components coupled to a leg of the device.

[0032] FIGS. 4F-4H illustrate an additional variation of an alignment component.

[0033] FIG. 4I illustrates yet another variation of an alignment component.

[0034] FIG. 4J illustrates an angle between basket electrode legs.

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

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

[0037] FIGS. 5E-5F illustrate another variation of the leg having a pre-shaped form.

[0038] FIGS. 5G-5I show further variations of the pre-bent legs.

[0039] FIGS. 5J-5L illustrate the pre-shaped legs in a collapsed and expanded configuration, wherein the proximal and distal alignment components extend within the expandable basket.

[0040] FIGS. 5M-5N illustrate the pre-shaped legs in an expanded configuration, wherein a basket support is disposed within the expandable basket.

[0041] FIGS. 6A-6C show various basket configurations for the device.

[0042] FIGS. 7A-7D illustrate various features of variations of legs for use with the present devices.

[0043] FIGS. 8A-8D show various junctions for use with the present devices to improve alignment when the device is advanced through tortuous anatomy.

[0044] FIGS. 9A-9J are addition variations of junctions.

[0045] FIGS. 10A-10D shows additional variations of junctions for use in the present devices.

[0046] FIG. 11 is a cross sectional view of an airway in a healthy lung.

[0047] FIG. 12 shows a section through a bronchiole having an airway diameter smaller than that shown in FIG. 11.

[0048] FIG. 13 illustrates the airway of FIG. 11 in which the smooth muscle 314 has hypertrophied and increased in thickness causing reduction of the airway diameter.

[0049] FIG. 14 is a schematic side view of the lungs being treated with a treatment device 330 as described herein.

DETAILED DESCRIPTION

[0050] 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.

[0051] As described in U.S. Pat. No. 6,634,363, the entirety of which has been incorporated by reference above, 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. Embodiments described herein include 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 treatment described herein. As such, the following discussion is not intended to limit the aspects or objective of the method as the 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.

Reducing the Ability of the Airway to Contract

[0052] In embodiments, the inventive treatment reduces the ability of the airways to narrow or to reduce in diameter due to airway smooth muscle contraction. The 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.

[0053] 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 embodiments of 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.

[0054] 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.

[0055] 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.

[0056] 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.

[0057] 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.

[0058] 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.

[0059] 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.

[0060] 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.

[0061] 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.

[0062] 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.

[0063] 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.

Increasing the Airway Diameter

[0064] 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.

[0065] 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.

[0066] 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.

[0067] 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.

[0068] FIGS. 11 and 12 illustrate cross sections of two different airways in a healthy patient. The airway of FIG. 11 is a medium sized bronchus having an airway diameter D1 of about 3 mm. FIG. 12 shows a section through a bronchiole having an airway diameter D2 of about 1.5 mm. Each airway includes a folded inner surface or epithelium 310 surrounded by stroma 312 and smooth muscle tissue 314. The larger airways including the bronchus shown in FIG. 11 also have mucous glands 316 and cartilage 318 surrounding the smooth muscle tissue 314. Nerve fibers 320 and blood vessels 322 also surround the airway.

[0069] FIG. 13 illustrates the bronchus of FIG. 11 in which the smooth muscle 314 has hypertrophied and increased in thickness causing the airway diameter to be reduced from the diameter D1 to a diameter D3.

[0070] FIG. 14 is a schematic side view of the lungs being treated with a treatment device 330 as described in the references incorporated by reference herein, as set forth below. The treatment device 330 is an elongated member for treating tissue at a treatment site 334 within a lung. The treatment device 330 may use a variety of processes to achieve a desired response. The treatment device 330 may use a modality of treatments as represented by the treatment source 332, 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.

[0071] As described in U.S. patent application Ser. No. 09/436,455 (now U.S. Pat. No. 7,425,212), the entirety of which has been incorporated by reference below, the airways

which are treated with the device according to embodiments of the present invention are preferably 1 mm in diameter or greater, more preferably 3 mm in diameter. The devices are preferably used to treat airways of the second to eighth generation, more preferably airways of the second to sixth generation.

[0072] FIG. 2A 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.

[0073] The particular system 10 depicted in FIG. 2A is one having a user interface as well as safety algorithms that are useful for the asthma treatment discussed above. Additional 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.

[0074] Referring again to FIG. 2A, 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, cryoprobe, 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.

[0075] FIG. 2A 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 monopolar 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.

[0076] 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.

[0077] As described in U.S. Patent Application Publication No. 2002/0091379, the entirety of which has been incorporated by reference above, the power supply can include circuitry for monitoring parameters of energy transfer: (for example, voltage, current, power, impedance, as well as temperature from the temperature sensing element), and use this information to control the amount of energy delivered. In the case of delivering RF energy, typical frequencies of the RF energy or RF power waveform are from 300 to 1750 kHz with 300 to 500 kHz or 450 to 475 being preferred. The RF power-level generally ranges from about 0-30 W but depends upon a number of factors such as the size and number of the electrodes. The controller may also be configured to independently and selectively apply energy to one or more of the basket leg electrodes.

[0078] A power supply may also include control modes for delivering energy safely and effectively. Energy may be delivered in open loop (power held constant) mode for a specific time duration. For example, a power setting of 8 to 30 Watts for up to 10 seconds is suitable and a power setting of 12 to 30 Watts for up to 5 seconds is preferred. For more permanent restructuring of the airways, a power setting of 8 to 15 Watts for 5 to 10 seconds is suitable. For mere temporary relief or enlargement of the airway, a power setting of 10 to 25 Watts for up to 3 seconds is suitable. With higher power settings, correspondingly lower time durations are preferred to limit collateral thermal damage.

[0079] Energy may also be delivered in temperature control mode, with output power varied to maintain a certain temperature-for a specific time duration. For example, energy

may be delivered for up to 20 seconds at a temperature of 55 to 80 degrees C., and more preferably, energy is delivered up to 10 seconds at a temperature in the range of 60 to 70 degrees C. For more permanent restructuring of the airways, energy is delivered for 5 to 10 seconds at a temperature in the range of 60 to 70 degrees C. For mere temporary relief or enlargement of the airway, energy is delivered for up to 5 seconds at a temperature of 55 to 80 degrees C. Additionally, the power supply may operate in impedance control mode.

[0080] FIG. 2B 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 via a slide mechanism 114 on the handle 106. 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.

[0081] FIG. 2B also illustrates the device 100 as being advanced through a working channel 33 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.

[0082] 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. 3A-3G illustrate various configurations that reduce the force required to actuate the device's basket or other energy transfer element.

[0083] FIG. 3A 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.

[0084] Alternatively, or in combination, the lubricious layers 128 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.

[0085] 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. Examples of shaft **104** or sheath **102** materials include nylon, PET, LLDPE, HDPE, Plexar PX, PTFE, teflon and/or any other polymer commonly used in medical devices. As described above, the inner or outer surfaces of the shaft **104** and/or sheath **102** may also comprise lubricant impregnations or coatings, such as silicone fluid, carbon, PTFE, or any of the materials described with reference to lubricious layer **128**. It is noted that the other material selection and/or designs described herein shall aid in providing this feature of the invention.

[0086] FIG. 3A 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**.

[0087] 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 shown, 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 utilizing separate or the same lumen(s) for fluid delivery or suctioning, lumens for blowing gas (e.g., pressurized air, hot air) into the airway to move or desiccate secretions (e.g., mucus) out of the way, etc.). In addition, the lumen(s) may be used to simultaneously or sequentially deliver fluids and/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).

[0088] 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. Further, the shaft **104** may be designed to increase clearance between a center wire **124** that runs through the shaft lumen **132** so as to minimize friction and improve basket **108** deployment in tortuous anatomy. Still further, the shaft **104** may be designed so as to efficiently transmit torque from the handle **106** to the basket array **108** in order to rotate the basket array **108** within the airways so as to enhance device positioning. For example, this may be accomplished by incor-

porating a braided member (e.g., braided wire) into the shaft **104** extrusion or by joining the shaft **104** coaxially with the braided member.

[0089] FIG. 3B 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.

[0090] FIG. 3C 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 LLDPE, Plexar PX 306, 3060, and/or 3080.

[0091] FIG. 3D 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. 3E-3G illustrate additional variations of corrugated surfaces. As shown in FIGS. 3E and 3F, 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. 3G illustrates a variation where the sheath **102** comprises protrusions or spacer **142** to separate the surfaces of the sheath/shaft.

[0092] FIGS. 3H and 3I illustrate further variations of a shaft **104** which may be incorporated within any of the devices described herein. FIG. 3H illustrates a two lumen shaft **104** having an oblong or oval shaped cross section. The first lumen **132** may be utilized to receive the conductive center wire **124** which electrically couples the legs **120** to the energy generator **12**. The second lumen **134** may be utilized to receive temperature detecting leads **172** as described in more detail with reference to FIG. 7C. Further, a coil **135** or other reinforcing element (e.g., polymeric insert, braided member) may be utilized to prevent kinking or collapse of the shaft **104**, which is of particular benefit during basket **108** deployment in tortuous anatomy. In this depiction, the coiled wire **135** is disposed within lumen **132** of the shaft **104** and surrounding the center wire **124**. Referring now to FIG. 3I, a single lumen shaft **104** having a D-shaped cross section is illustrated. The single lumen **132** receives the center wire **124** as in FIG. 3H, but in this embodiment the reinforcing coil **135** is disposed outside the shaft **104** and further encompasses the temperature detecting leads **172**. The coil **135** may also reinforce a tubular sheath **102** which is disposed over the coil **135** and extends along a length of the shaft **104**. The embodiments of FIGS. 3I and 3H also provide an exposed basket **108** configuration (e.g., sheathless) which reduces friction and as such improves basket **108** deployment mechanics.

[0093] These oblong, oval, or D-shaped shaft cross sections advantageously allow for a reduced profile while still axially centering the center wire **124** with respect to the expandable basket **108**. This reduced size profile not only permits passage of the sheathless catheter of FIG. 3H or sheathed catheter of FIG. 3I through the working channel lumen of an access device, such as a bronchoscope, but allows for fluid delivery

or suction through an opening created between the working channel lumen and an outer surface of the catheter. As already described above, alternatively or in the adjunct, additional lumens **134** within the device shaft **104** may be utilized for fluid delivery of cleaning fluids (e.g., saline, bio-compatible fluids), drugs (e.g., lidocaine, tetracaine), cooling fluids (e.g., cooled saline, cooled sterile water, or other fluids for cooling the airway wall), electrically conductive fluids (e.g., saline), thermally conductive fluids, or fluids to increase the viscosity of mucus so it can be more easily suctioned (e.g., saline), or for suctioning of delivered fluids or excretions within the airway (e.g., mucus). Advantageously, suctioning or fluid delivery from or to the airway may be accomplished while the asthma treatment device remains within the airways without requiring the device user to pull the device out of the airway, which in turn reduces procedure time and improves patient manageability. For example, irrigation and/or suctioning may be carried out simultaneously or sequentially with energy delivery to the airway wall while the device is within the airway.

[0094] As described in U.S. Pat. No. 6,634,363, the entirety of which has been incorporated by reference above, embodiments of 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.

[0095] FIGS. 4A-4D illustrate yet another feature that may be incorporated with any of the subject devices. FIG. 4A 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.

[0096] 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**.

[0097] FIG. 4B illustrates another variation of an alignment component **150**. This variation is similar to the variation shown in FIG. 4A, 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.

[0098] The alignment components **150** of the present invention may be fabricated from a variety of polymers (e.g., PEEK, ULTEM, PEI, nylon, PET and/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 and the conductive wire. 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.

[0099] 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.

[0100] FIG. 4C 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.

[0101] FIG. 4D 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.

[0102] FIG. 4E 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 (e.g., loctite), UV-cured acrylic, epoxy, and/or any such adhesive) may also be used to secure the leg and/or sleeves to the components.

[0103] Additionally, the alignment components may be designed such that the sleeves 168, 170 may be press or snap fit onto the alignment components, eliminating the need for adhesively bonding the sleeves to the alignment components. FIG. 4F 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. 4G shows a cross sectional view of the component 150 of FIG. 4F. 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.

[0104] Referring now to FIG. 4I, another variation of the alignment component 150 is shown. This proximal joint 150 is similar to that of FIG. 4C, but has a reduced axial length by omission of the radial protrusions 178. This shortening improves joint flexibility in tortuous airways as a user can translate the shaft 104 and basket assembly 108 with more ease through the sheath 102 which in turn improves basket 108 deployment. In this embodiment, the end portion 158 may be directly coupled to the shaft 104 by utilizing heat shrink (e.g., PET) with a wicking adhesive as described above. This coupling results in a lower proximal joint profile so as to reduce the friction between the sheath 102 and shaft 104 which in turn improves joint 150 flexibility and basket 108 deployment. Further, in this embodiment, a PET shaft 104 may be utilized to provide enhanced pushability of the shaft 104 so as to further aid in basket 108 deployment and to reduce susceptibility to water absorption so as to ensure greater consistency of deployed basket diameter (e.g., >10 mm).

[0105] As discussed herein, the seats 152 allow for improved control of the angular spacing of the legs 160. In particular, the seats 152 of the proximal and distal alignment components 144, 146 are aligned, wherein the angle between adjacent legs 160 is determined by the angle between adjacent seat 152. The seats 152 preferably provide for symmetrical deployment of the arms 160, wherein any angle between adjacent legs varies less than 20 degrees. As shown in cross sectional view of FIG. 4J, in the case of a four leg basket 108, the angle α between adjacent legs is in a range from about 70 degrees to about 110 degrees, preferably 90 degrees. Likewise, in the case of a six leg basket 108, the angle between adjacent legs is in a range from about 45 degrees to

about 75 degrees, preferably 60 degrees so that a variance is less than 15 degrees. Further, in the case of a eight leg basket 108, the angle between adjacent legs is in a range from about 33 degrees to about 57 degrees, preferably 45 degrees so that a variance is less than 12 degrees or for a ten leg basket 108, the angle between adjacent legs is in a range from about 26 degrees to about 46 degrees, preferably 36 degrees so that a variance is less than 10 degrees. Symmetrical deployment ensures proper temperature distribution, which may be important for the treatment of asthma in the lung airways. It will be appreciated that the present invention is not limited to an even number of basket legs 160. For example, five or seven basket legs 160 may be employed as long as the spacing between each leg 160 is equivalent.

[0106] FIG. 5A 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. 5C, 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. 5D, the leg can have a slight bend or shape that predisposes the legs to bow outward.

[0107] FIG. 5B illustrates the variation of FIG. 5A 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. 5B 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.

[0108] 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.

[0109] 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. 2A.) 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 104 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. In a still further variation, movement of the slide 114 may cause the wire 124 to be pulled proximally while the shaft 104 is pushed distally so that energy transfer element remains stationary during deployment.

[0110] Referring now to FIGS. 5E-5N, the electrode legs 160 may be pre-shaped as already described herein. In particular, the electrodes 160 may be pre-shaped so as to control the direction in which the legs deflect upon basket deployment 108 so as to prevent electrode inversion, provide controlled buckling of the basket electrode 108, and improve tissue contact. FIG. 5E illustrates a pre-bent leg 160 having four discrete bends 161. As shown in FIG. 5F, when axial compressive loads 163 are applied to the electrode 160 during deployment, the pre-shaped leg is predisposed to buckle or deflect in a predictable, desired outwards direction 165 to make contact with the airway wall. Hence, the pre-shaped leg 160 provides for preferential buckling in the outward direction 165, which is of particular benefit in tortuous airways where orthogonal or side loads commonly cause leg inversions. As illustrated in the example of FIG. 5F, an angle .beta. of the discrete pre-bends 161 on the proximal and distal ends of the electrode 160 may be at an angle that is in a range from about 10 degrees to about 20 degrees, preferably 15 degrees.

[0111] It will be appreciated that several other pre-shaped variations may be employed to induce buckling in the desired outward direction 165. For example, the pre-bent electrode may comprise a single bend 161 as shown in FIG. 5G, two bends 161 as shown in FIG. 5H, three bends 161 as shown in FIG. 5I, and the like. Further, the angle .beta. of the bend 161 or the positioning of the bend 161 may vary depending on a variety of factors. Still further, the electrode 160 may be pre-shaped to form a continuous curve, as illustrated in FIG. 2B, or a parabolic curve as illustrated below in FIG. 6A, or some other pre-shaped configuration in which a portion of the electrode 160 is out-of-plane from the axially active compressive loads 163.

[0112] Referring now to FIGS. 5J-5L, cross sectional views of the pre-bent legs 160 attached to proximal and distal alignment components 144, 146 are illustrated. The shaft 102 in this depiction has been omitted for clarity. In this particular embodiment, the alignment components extend within the expandable basket 108, as illustrated by reference numerals 144a, 146a. As the basket is deployed, as shown in FIG. 5L, the proximal and distal extrusions or flanges 144a, 146a in the basket 108 further prevent against electrode leg 160 inversions from the desired outward direction 165.

[0113] In addition or alternatively, inward leg buckling or inversions may also be prevented by disposing basket support (s) inside the expandable basket 108. For example, as shown in the cross sectional view of FIGS. 5M and 5N, a balloon member 171 may also be deployed inside the basket 108 and inflated to prevent inward deflection of the electrode legs 160. Further, the balloon member 171 may utilize its inflation lumen to receive cooling fluids so as to cool the electrode 160 and airway wall. Still further, the balloon member 171 may also be utilized to deploy the basket 108 in lieu of the pull wire 124.

[0114] FIG. 6A illustrates a variation of an energy transfer element 108 in which the legs 160 have a pre-determined

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.

[0115] FIG. 6B 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). Accordingly, the alignment components and other parts of the device would be located within the sheath 102.

[0116] FIG. 6C 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.

[0117] FIG. 7A 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. 7B 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.)

[0118] FIG. 7C 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.

[0119] 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 ele-

ment, as it minimizes the conduction error associated with an extrinsic junction adhered to the device.

[0120] 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.

[0121] 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.

[0122] 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. 8A 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.

[0123] 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.

[0124] 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 than 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. 7D, 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.

[0125] 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. 8A 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. 8B, the misalignment angle α is greater than the angle illustrated in FIG. 8A. Yet, the energy transfer element 108 of the treatment device 100 remains substantially aligned with the target area.

[0126] FIGS. 8C and 8D 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. 8C, 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. 8D. 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.

[0127] FIGS. 9A-9I illustrate additional junctions for use in the devices described herein. As for these examples, FIG. 9A 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.

[0128] 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".

[0129] 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. 8A and 8B is illustrated as being covered. A covering can help avoid contaminating the joint with body fluid or debris which could compromise junction function.

[0130] Some of the junctions are inherently protected. Junction 176 shown in FIG. 9B 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.

[0131] As for junction 176 shown in FIG. 9C, 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. 9D 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. 9C or 9D, the size, number shape, etc. of the opening may vary or be tuned as desired.

[0132] FIG. 9E 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.

[0133] Junction 176 in FIG. 9F 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.

[0134] FIG. 9G 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. 9H 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.

[0135] Yet another junction example is provided in FIG. 9I. 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.

[0136] FIG. 9J 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.

[0137] Another variation of the junctions includes junction variations where the shaft 104 is “floppy” (i.e., without sufficient column strength for the device to be pushable for navigation). In FIG. 10A, 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.

[0138] 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.

[0139] The same action is required to navigate the device shown in FIG. 10B. 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.

[0140] Like the device in FIG. 10B, the devices in FIGS. 10C and 10D 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. 10C, when the obturator 230 fills the lumen, the device is relatively straight or stiff. When the shaft is withdrawn as shown in FIG. 10D, 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.

[0141] 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.

[0142] 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. Also, any optional feature of the inventive variations may be set forth and claimed independently, or in combination with any one or more of the features described herein. Accordingly, the invention contemplates combinations of various aspects of the embodiments or of the embodiments themselves, where possible. 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. A method of treating an airway, comprising: inserting a treatment device into the airway, wherein the treatment device includes an energy delivery element configured to deliver energy to tissue of the airway; advancing the treatment device to a treatment location in the airway; activating the energy delivery element to deliver energy to tissue at the treatment location; and cooling tissue near the treatment location simultaneously with the activating step.
2. The method of claim 1, wherein cooling tissue includes preventing destruction of an inner surface of the airway.
3. The method of claim 1, wherein the energy delivery element includes an electrode.
4. The method of claim 1, wherein activating the energy delivery element to deliver energy to tissue at the treatment location includes damaging nerve tissue of the airway.
5. A method of treating an airway, comprising: moving an intraluminal device along a lumen of an airway of a bronchial tree, the intraluminal device comprising an expandable member and an energy emitter; inflating the expandable member with a cooling fluid; and delivering energy from the energy emitter to nerves so as to damage nerves along the airway.
6. The method of claim 5, wherein the expandable member includes a balloon.
7. The method of claim 5, wherein the cooling fluid cools tissue along the airway.

8. The method of claim 7, wherein cooling tissue along the airway and delivering energy from the energy emitter occur simultaneously.

9. The method of claim 7, wherein cooling tissue along the airway and delivering energy from the energy emitter occur sequentially.

10. The method of claim 5, wherein the energy emitter includes an electrode.

11. A device for treating an airway, comprising:

an energy delivery element configured to deliver energy to nerves so as to damage nerves of the airway; and
an expandable member coupled to the energy delivery element and configured to receive a fluid to cool tissue of the airway.

12. The device of claim 11, wherein the energy delivery element includes an electrode.

13. The device of claim 12, wherein the expandable member includes a balloon.

14. The device of claim 13, wherein the electrode is outside of the balloon, and the balloon is coupled to the electrode so that the electrode moves towards tissue of the airway as the balloon is inflated.

15. The device of claim 14, wherein a cooling fluid expands the balloon and cools the electrode and tissue of the airway.

16. The device of claim 13, wherein the energy delivery element includes multiple electrodes spaced about the balloon.

17. The device of claim 11, wherein the device is configured to deliver energy to nerves while the expandable member receives a cooling fluid.

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