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Devices, systems and methods for diagnosing and treating sinusitus and other disorders of the ears, nose and/or throat

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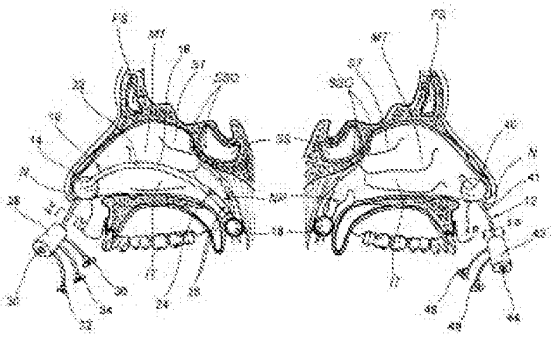
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Sinusitis, enlarged nasal turbinates, tumors, infections, hearing disorders, allergic conditions, facial fractures and other disorders of the ear, nose and throat are diagnosed and/or treated using minimally invasive approaches and, in many cases, flexible catheters as opposed to instruments having rigid shafts. Various diagnostic procedures and devices are used to perform imaging studies, mucus flow studies, air/gas flow studies, anatomic dimension studies, endoscopic studies and transillumination studies. Access and occluder devices may be used to establish fluid tight seals in the anterior or posterior nasal cavities/nasopharynx and to facilitate insertion of working devices (e.g., scopes, guidewires, catheters, tissue cutting or remodeling devices, electrosurgical devices, energy emitting devices, devices for injecting diagnostic or therapeutic agents, devices for implanting devices such as stents, substance eluting devices, substance delivery implants, etc.

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Description of corresponding document: US2005240147 (A1)

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FIELD OF THE INVENTION

[0001] The present invention relates generally to medical devices and methods and more particularly to minimally invasive, catheter based devices, systems and methods for treating sinusitis and other ear, nose & throat disorders.

BACKGROUND

[0002] The human nose is responsible for warming, humidifying and filtering inspired air and for conserving heat and moisture from expired air. The nose is also an important cosmetic feature of the face. The nose is formed mainly of cartilage, bone, mucous membranes and skin. The right and left nostrils lead into right and left nasal cavities on either side of the intranasal septum. The right and left nasal cavities extend back to the soft palate, where they merge to form the posterior choanae. The posterior choanae opens into the nasopharynx. The roof of the nose is formed, in part, by a bone known as the cribriform plate. The cribriform plate contains numerous tiny perforations through which sensory nerve fibers extend to the olfactory bulbs. The sensation of smell occurs when inhaled odors contact a small area of mucosa in the superior region of the nose, stimulating the nerve fibers that lead to the olfactory bulbs.

[0003] The paranasal sinuses are cavities formed within the bones of the face. The

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paranasal sinuses include frontal sinuses, ethmoid sinuses, sphenoidal sinuses and maxillary sinuses. The paranasal sinuses are lined with mucous-producing epithelial tissue. Normally, mucous produced by the linings of the paranasal sinuses slowly drains out of each sinus through an opening known as an ostium, and into the nasopharnyx. Disorders that interfere with drainage of mucous (e.g., occlusion of the sinus ostia) can result in a reduced ability of the paranasal sinuses to function normally. This results in mucosal congestion within the paranasal sinuses. Such mucosal congestion of the sinuses can cause damage to the epithelium that lines the sinus with subsequent decreased oxygen tension and microbial growth (e.g., a sinus infection).

[0004] The nasal turbinates are three (or sometimes four) bony processes that extend inwardly from the lateral walls of the nose and are covered with mucosal tissue. These turbinates serve to increase the interior surface area of the nose and to impart warmth and moisture to air that is inhaled through the nose. The mucosal tissue that covers the turbinates is capable of becoming engorged with blood and swelling or becoming substantially devoid of blood and shrinking, in response to changes in physiologic or environmental conditions. The curved edge of each turbinate defines a passageway known as a meatus. For example, the inferior meatus is a passageway that passes beneath the inferior turbinate. Ducts, known as the nasolacrimal ducts, drain tears from the eyes into the nose through openings located within the inferior meatus. The middle meatus is a passageway that extends inferior to the middle turbinate. The middle meatus contains the semilunar hiatus, with openings or ostia leading into the maxillary, frontal, and anterior ethmoid sinuses. The superior meatus is located between the superior and medial turbinates. Nasal Polyps:

[0005] Nasal polyps are benign masses that grow from the lining of the nose or paranasal sinuses. Nasal polyps often result from chronic allergic rhinitis or other chronic inflammation of the nasal mucosa. Nasal polyps are also common in children who suffer from cystic fibrosis. In cases where nasal polyps develop to a point where they obstruct normal drainage from the paranasal sinuses, they can cause sinusitis. Sinusitis:

[0006] The term "sinusitis" refers generally to any inflammation or infection of the paranasal sinuses. Sinusitis can be caused by bacteria, viruses, fungi (molds), allergies or combinations thereof. It has been estimated that chronic sinusitis (e.g., lasting more than 3 months or so) results in 18 million to 22 million physician office visits per year in the United States.

[0007] Patients who suffer from sinusitis typically experience at least some of the following symptoms:

headaches or facial pain
nasal congestion or post-nasal drainage
difficulty breathing through one or both nostrils
bad breath
pain in the upper teeth
Proposed Mechanism of Sinus Pain & Diagnosis

[0013] The sinuses consist of a series of cavities connected by passageways, ultimately opening into the nasal cavity. As described previously, these passageways and cavities are formed by bone, but covered in mucosa. If the mucosa of one of these passageways becomes inflamed for any reason, the cavities which drain through that

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passageway can become blocked. This trapping of mucous can be periodic (resulting in episodes of pain) or chronic. Chronically blocked passageways are targets of infection. Ultimately, it is the dimensions of the bony passageways and thickness of the overlying mucosa and its chronicity that dictate the duration and severity of sinus symptoms. Thus, the primary target for sinus therapy is the passageway, with the primary goal to regain drainage. Often CT will not reveal these dimensional issues, especially when the patient is not currently experiencing severe symptoms. Therefore there exists a need to dynamically evaluate the sinus passageways under normal conditions, in response to challenging stimuli. As suggested herein, if it would be possible to assess sinus disease and its dynamic component, one might better target therapy for sinusitis and possibly be able to treat patients in a more focused and minimally invasive manner. Such focus on the passageway and the use of flexible instrumentation suggests an entirely new approach to sinus intervention: one utilizing flexible catheters and guidance tools, with passageway and cavity modifying devices capable of being delivered with minimal damage to the surrounding tissues. Deviated Septum:

[0014] The intranasal septum is a cartilaginous anatomical structure that divides one side of the nose from the other. Normally, the septum is relatively straight. A deviated septum is a condition where the cartilage that forms the septum is abnormally curved or bent. A deviated nasal septum may develop as the nose grows or, in some cases, may result from trauma to the nose. A deviated septum can interfere with proper breathing or may obstruct normal drainage of nasal discharge, especially in patient's whose nasal turbinates are swollen or enlarged due to allergy, overuse of decongestant medications, etc. Such interference with drainage of the sinuses can predispose the patient to sinus infections.

[0015] A deviated nasal septum that interferes with proper function of the nose can be surgically corrected by a procedure known as septoplasty. In a typical septoplasty procedure, an endoscope is inserted into the nose and the surgeon makes an incision inside the nose, lifts up the lining of the septum, and removes and straightens the underlying bone and cartilage that is abnormally deviated. Such surgical septoplasty procedures can effectively straighten a deviated septum but, because the nasal cartilage has some memory, the septum may tend to resume its original deviated shape. Reduction/Removal of Nasal Turbinates

[0016] Various surgical techniques, including endoscopic surgery, have been used for reduction and/or removal of the inferior turbinate in patient's whose inferior turbinate is chronically enlarged such that it is obstructing normal breathing and/or normal drainage from the paranasal sinuses. Typically, chronic enlargement of the inferior turbinates is the result of allergies or chronic inflammation. Enlargement of the inferior turbinate can be especially problematic in patient's who also suffer from a deviated septum that crowds or impinges upon the soft tissue of the turbinate. Thus, a septoplasty to straighten the deviated septum is sometimes performed concurrently with a reduction of the inferior turbinates. Sinus Tumors

[0017] Most polyps are benign, but one form of a nasal polyp, known as an inverting papilloma, can develop into a malignancy. Unlike most benign polyps, which typically occur on both sides of the nose, an inverting papilloma is usually found on just one side. Thus, in cases where a unilateral polyp is observed, it is usually biopsied to determine if it is malignant. If an inverting papilloma is detected before it becomes malignant and is removed completely, it will typically not recur. However, using the

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technology that has heretofore been available, it has sometimes been difficult to determine if the papilloma has been entirely removed unless and until regrowth of the polyp is observed on long term post-surgical follow-up.

[0018] Various benign sinus tumors have also been known to occur, but are relatively rare. The most common form of malignant sinus tumor is squamous cell carcinoma. Even with surgery and radiation treatment, squamous cell carcinoma of the paranasal sinus is associated with a relatively poor prognosis. Other types of malignant tumors that invade the paranasal sinuses include adenocarcinoma and, more rarely, lymphoma and even more rarely, melanoma. Facial Fractures

[0019] The most common cause of fractures of the facial bones is auto accidents, but facial fractures are also frequently caused by sports injuries, industrial accidents, falls, assaults and gunshot wounds. Some facial fractures involve bones that are accessible from inside the nasal cavities or paranasal sinuses. Notably, the nose is the most commonly injured facial structure due to its prominent position on the face. Thus, fractures of the nasal bone (with or without resultant deviated septum) are not uncommon. Other facial fractures such as fractures of the orbital floor and/or the ethmoid or frontal sinuses are also accessible from inside the nose or sinuses. A common type of orbital floor fracture is a "blowout" fracture that typically results from blunt trauma to the eye where the force is transmitted downwardly causing the relatively thin bone that forms the floor of the orbit to fracture downwardly. This can cause the periorbital tissues to herniate into the maxillary sinus and sometimes can also create a "trap door" of bone that extends downwardly into the maxillary sinus. Endoscopic Sinus Surgery and Other Current Procedures

[0020] Functional Endoscopic Sinus Surgery

[0021] The most common corrective surgery for chronic sinusitis is functional endoscopic sinus surgery (FESS). In FESS, an endoscope is inserted into the nose and, under visualization through the endoscope, the surgeon may remove diseased or hypertrophic tissue or bone and may enlarge the ostia of the sinuses to restore normal drainage of the sinuses. FESS procedures can be effective in the treatment of sinusitis and for the removal of tumors, polyps and other aberrant growths from the nose. Other endoscopic intranasal procedures have been used to remove pituitary tumors, to treat Graves disease (i.e., a complication of hyperthyroidism which results in protrusion of the eyes) and surgical repair of rare conditions wherein cerebrospinal fluid leaks into the nose (i.e., cerebrospinal fluid rhinorrhea).

[0022] Surgery to reduce the size of the inferior turbinates can be accomplished with endoscopic visualization (with magnification where desired) and is typically performed with the patient under general anesthesia. An incision is typically made in the mucosa that lines the turbinate to expose the underlying bone. Some quantity of the underlying bone may then be removed. If selective removal of some of the mucosa or soft tissue is also desired, such soft tissue can be debulked or removed through by traditional surgical cutting or by the use of other tissue ablation or debulking apparatus such as microdebriders or lasers. Less frequently, chronically enlarged inferior turbinates have been treated by cryotherapy. It is typically desirable to remove only as much tissue as necessary to restore normal breathing and drainage, as removal of too much tissue from the turbinates can impair the ability of the turbinates to perform their physiological functions of warming and humidifying inspired air and conserving warmth and moisture from expired air. Complications associated with inferior turbinate surgery include

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bleeding, crusting, dryness, and scarring.

[0023] In some patients, the middle turbinate is enlarged due to the presence of an invading air cell (concha bullosa), or the middle turbinate may be malformed (paradoxically bent). Severe ethmoid sinusitis or nasal polyps can also result in enlargement or malformation of the middle turbinates. Since a substantial amount of drainage from the sinuses passes through the middle meatus (i.e., the passage that runs alongside middle turbinate) any enlargement or malformation of the middle turbinate can contribute to sinus problems and require surgical correction. Thus, in some FESS procedures carried out to treat sinusitis, the middle meatus is cleared (e.g., the polyps or hypertorophic tissue are removed) thereby improving sinus drainage. However, the middle turbinate can include some of the olfactory nerve endings that contribute to the patient's sense of smell. For this reason, any reduction of the middle turbinate is typically performed in a very conservative manner with care being taken to preserve as much tissue as possible. In patients who suffer from concha bullosa, this may involve removing the bone on one side of an invading air sac. In the cases where the middle turbinate is malformed, just the offending portion(s) of the turbinate may be removed.

[0024] Extended Endoscopic Frontal Sinus Surgery

[0025] Because of its narrow anatomical configuration, inflammation of the frontal sinuses can be particularly persistent, even after surgery and/or medical therapy has resolved the inflammation in the other paranasal sinuses. In cases of persistent inflammation of the frontal sinuses, a surgery known as a trans-septal frontal sinusotomy, or modified Lothrop procedure, is sometimes performed. In this procedure, the surgeon removes a portion of the nasal septum and the bony partition between the sinuses to form one large common drainage channel for draining the frontal sinuses into the nose. This complicated procedure, as well as some other ear, nose and throat surgical procedures, can carry a risk of penetrating the cranial vault and causing leakage of cerebrospinal fluid (CSF). Also, some sinus surgeries as well as other ear, nose and throat procedures are performed close to the optic nerves, the eyes, and the brain and can cause damage to those structures. To minimize the potential for such untoward complications or damage, image-guided surgery systems have been used to perform some complex head and neck procedures. In image guided surgery, integrated anatomical information is supplied through CT-scan images or other anatomical mapping data taken before the operation. Data from a preoperative CT scan or other anatomical mapping procedure is downloaded into a computer and special sensors known as localizers are attached to the surgical instruments. Thus, using the computer, the surgeon can ascertain, in three dimensions, the precise position of each localizer-equipped surgical instrument at any given point in time. This information, coupled with the visual observations made through the standard endoscope, can help the surgeon to carefully position the surgical instruments to avoid creating CSF leaks and to avoid causing damage to nerves or other critical structures.

[0026] Shortcomings of FESS

[0027] Although FESS continues to be the gold standard therapy for severe sinuses, it has several shortfalls. Often patients complain of the post-operative pain and bleeding associated with the procedure, and a significant subset of patients remain symptomatic even after multiple surgeries. Since FESS is considered an option only for the most severe cases (those showing abnormalities under CT scan), a large population of

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patients exist that can neither tolerate the prescribed medications nor be considered candidates for surgery. Further, because the methodologies to assess sinus disease are primarily static measurements (CT, MRI), patients whose symptoms are episodic are often simply offered drug therapy when in fact underlying mechanical factors may play a significant role. To date, there is no mechanical therapy offered for these patients, and even though they may fail pharmaceutical therapies, no other course of action is indicated. This leaves a large population of patients in need of relief, unwilling or afraid to take steroids, but not sick enough to qualify for surgery.

[0028] One of the reasons why FESS and sinus surgery is so bloody and painful relates to the fact that straight instrumentation with rigid shafts are used. Due to the fact that the sinuses are so close to the brain and other important structures, physicians have developed techniques using straight tools and image guidance to reduce the likelihood of penetrating into unwanted areas. In an effort to target deep areas of the anatomy, this reliance on straight instrumentation has resulted in the need to resect and remove or otherwise manipulate any anatomical structures that may lie in the path of the instruments, regardless of whether those anatomical structures are part of the pathology. With the advances in catheter based technology and imaging developed for the cardiovascular system, there exists a significant opportunity to reduce the morbidity of sinus interventional through the use of flexible instrumentation and guidance.

[0029] If flexible tools could be developed such that sinus intervention may be able to be carried out with even less bleeding and post-operative pain, these procedures may be applicable to a larger group of patients. Further, as described here, flexible instrumentation may allow the application of new diagnostic and therapeutic modalities that have never before been possible.

[0030] Laser or Radiofrequency Turbinate Reduction (Soft Tissue Only)

[0031] In cases where it is not necessary to revise the bone that underlies the turbinate, the surgeon may elect to perform a laser or radiofrequency procedure designed to create a coagulative lesion in (or on) the turbinate, which in turn causes the soft tissue of the turbinate to shrink. Also, in some cases, a plasma generator wand may be used create high energy plasma adjacent to the turbinate to cause a reduction in the size of the turbinate.

[0032] One example of a radio frequency procedure that may be used to shrink enlarged inferior turbinates is radiofrequency volumetric tissue reduction (RFVTR) using the Somnoplasty(R) system (Somnus Medical Technologies, Sunnyvale, Calif.). The Somnoplasty(R) system includes a radio frequency generator attached to a probe. The probe is inserted through the mucosa into the underlying soft tissue of the turbinate, usually under direct visualization. Radiofrequency energy is then delivered to heat the submucosal tissue around the probe, thereby creating a submucosal coagulative lesion while allowing the mucosa to remain in tact. As the coagulative lesion heals, the submucosal tissue shrinks thereby reducing the overall size of the turbinate. Radiofrequency volumetric tissue reduction (RFVTR) can be performed as an office procedure with local anesthesia.

[0033] Many of the above-described procedures and techniques may be adaptable to minimaly invasive approaches and/or the use of flexible instrumentation. There exists a need in the art for the development of such minimally invasive procedures and techniques as well as instrumentaion (e.g., flexible instruments or catheters) useable to

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perform such procedures and techniques.

SUMMARY OF THE INVENTION

[0034] In general, the present invention provides methods, devices and systems for diagnosing and/or treating sinusitis or other conditions of the ear, nose or throat.

[0035] In accordance with the present invention, there are provided methods wherein one or more flexible catheters or other flexible elongate devices as described herein are inserted in to the nose, nasopharynx, paranasal sinus, middle ear or associated anatomical passageways to perform an interventional or surgical procedure. Examples of procedures that may be performed using these flexible catheters or other flexible elongate devices include but are not limited to: delivering contrast medium; delivering a therapeutically effective amount of a therapeutic substance; implanting a stent, tissue remodeling device, substance delivery implant or other therapeutic apparatus; cutting, ablating, debulking, cauterizing, heating, freezing, lasing, dilating or otherwise modifying tissue such as nasal polyps, abberant or enlarged tissue, abnormal tissue, etc.; grafting or implanting cells or tissue; reducing, setting, screwing, applying adhesive to, affixing, decompressing or otherwise treating a fracture; delivering a gene or gene therapy preparation; cutting, ablating, debulking, cauterizing, heating, freezing, lasing, forming an osteotomy or trephination in or otherwise modifying bony or cartilaginous tissue within paranasal sinus or elsewhere within the nose; remodeling or changing the shape, size or configuration of a sinus ostium or other anatomical structure that affects drainage from one or more paranasal sinuses; removing puss or aberrant matter from the paranasal sinus or elsewhere within the nose; scraping or otherwise removing cells that line the interior of a paranasal sinus; removing all or a portion of a tumor; removing a polyp; delivering histamine, an allergen or another substance that causes secretion of mucous by tissues within a paranasal sinus to permit assessment of drainage from the sinus; implanting a cochlear implant or indwelling hearing aid or amplification device, etc.

[0036] Further in accordance with the invention, there are provided methods for diagnosing and assessing sinus conditions, including methods for delivering contrast media into cavities, assessing mucosal flow, assessing passageway resistance and cilliary function, exposing certain regions to antigen challenge, etc

[0037] Still further in accordance with the invention, there are provided novel devices for performing some or all of the procedures described herein.

[0038] Further aspects, details and embodiments of the present invention will be understood by those of skill in the art upon reading the following detailed description of the invention and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] FIG. 1A (Prior Art) is a frontal view of a human head showing the locations of the paranasal sinuses.

[0040] FIG. 1B (Prior Art) is a side view of a human head showing the locations of the paranasal sinuses.

[0041] FIG. 2A is a partial sectional view of head of a human patient showing the right

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nasal cavity, the right side of the nasopharynx and the associated paranasal sinuses, with an anterior/posterior occluder & access device of the present invention inserted therein.

[0042] FIG. 2B is a partial sectional view of head of a human patient showing the left nasal cavity, the left side of the nasopharynx and the associated paranasal sinuses, with an anterior occluder & access device of the present invention inserted therein.

[0043] FIG. 2C is a cross sectional view through line C-C of FIG. 2A.

[0044] FIG. 2D is a cross sectional view through line D-D of FIG. 2B.

[0045] FIG. 2E is a perspective view of a posterior occluder/suction/access device of the present invention that is insertable through the oral cavity.

[0046] FIG. 2F is a cross-sectional view through Line 2F-2F of FIG. 2E.

[0047] FIG. 2G is a partial sectional view of head of a human patient showing the right nasal cavity, the right side of the nasopharynx and the associated paranasal sinuses, with an anterior occluder & access device of the present invention inserted in the right nasal cavity and a posterior occluder/suction/access device of FIG. 2E inserted through the oral cavity.

[0048] FIG. 2H is a partial sectional view of head of a human patient showing the left nasal cavity, the left side of the nasopharynx and the associated paranasal sinuses, with an anterior occluder & access device of the present invention inserted in the left nasal cavity and the same posterior occluder/suction/access device that appears in FIG. 2G extending through the oral cavity.

[0049] FIG. 2I is a perspective view of a posterior occluder/suction device of the present invention that is insertable transnasally.

[0050] FIG. 2J is a cross-sectional view through Line 2J-2J of FIG. 21.

[0051] FIG. 2K is a partial sectional view of head of a human patient showing the right nasal cavity, the right side of the nasopharynx and the associated paranasal sinuses, with the posterior occluder/suction device shown in FIG. 21 inserted through the right nasal cavity.

[0052] FIG. 2L is a partial sectional view of head of a human patient showing the left nasal cavity, the left side of the nasopharynx and the associated paranasal sinuses and showing the posterior occluder portion of the device of FIG. 2K residing in and occluding the nasopharynx at a location posterior to the septum and superior to the glottis.

[0053] FIG. 2M is a partial sectional view of head of a human patient showing the right nasal cavity, the right side of the nasopharynx and the associated paranasal sinuses, with an extended posterior occluder/suction device inserted through the right nasal cavity.

[0054] FIG. 2N is a partial sectional view of head of a human patient showing the left nasal cavity, the left side of the nasopharynx and the associated paranasal sinuses and

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showing the posterior occluder and distal tubular extension portions of the device of FIG. 2M residing in the nasopharynx posterior to the septum and superior to the glottis.

[0055] FIG. 2O is a partial sectional view of head of a human patient showing the right nasal cavity, the right side of the nasopharynx and the associated paranasal sinuses, with a posterior occluder/slidable suction device inserted through the right nasal cavity.

[0056] FIG. 2P is a partial sectional view of head of a human patient showing the left nasal cavity, the left side of the nasopharynx and the associated paranasal sinuses and showing the posterior occluder and distal portion of the slidable suction cannula of the device of FIG. 2O residing in the nasopharynx posterior to the septum and superior to the glottis.

[0057] FIG. 2Q is a partial sectional view of head of a human patient showing the right nasal cavity, the right side of the nasopharynx and the associated paranasal sinuses, with another posterior occluder/tapered suction device inserted through the right nasal cavity.

[0058] FIG. 2R is a partial sectional view of head of a human patient showing the left nasal cavity, the left side of the nasopharynx and the associated paranasal sinuses and showing the posterior occluder and distal portion of the tapered suction cannula of the device of FIG. 2Q residing in the nasopharynx posterior to the septum and superior to the glottis.

[0059] FIG. 3A is a partial perspective view of one embodiment of an occluder/suction device of the present invention positioned within an anatomical passageway.

[0060] FIG. 3B is a partial perspective view of another embodiment of an occluder/suction device of the present invention positioned within an anatomical passageway.

[0061] FIG. 3C is a partial perspective view of another embodiment of an occluder/suction device of the present invention positioned within an anatomical passageway.

[0062] FIG. 3C' is a cross sectional view through line 3C'-3C' of FIG. 3C.

[0063] FIG. 3D is a partial perspective view of yet another embodiment of an occluder/suction device of the present invention positioned within an anatomical passageway.

[0064] FIG. 3E', 3E" and 3E"' are partial perspective views of still another embodiment of an occluder/suction device of the present invention showing various steps in a process by which the occluder/suction device is positioned within an anatomical passageway.

[0065] FIG. 3F is a partial perspective view of still another embodiment of an occluder/suction device of the present invention positioned within an anatomical passageway.

[0066] FIGS. 3F', 3F" and 3F"' show alternative constructions of the distal portion of the suction cannula of the occluder/suction device shown in FIG. 3F.

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[0067] FIG. 3G is a partial perspective view of still another embodiment of an occluder/suction device of the present invention positioned within an anatomical passageway.

[0068] FIG. 3H is a partial perspective view of still another embodiment of an occluder/suction device of the present invention positioned within an anatomical passageway.

[0069] FIG. 3I is a partial perspective view of still another embodiment of an occluder/suction device of the present invention positioned within an anatomical passageway.

[0070] FIG. 3J is a partial perspective view of still another embodiment of an occluder/suction device of the present invention positioned within an anatomical passageway.

[0071] FIG. 3K is a partial perspective view of still another embodiment of an occluder/suction device of the present invention positioned within an anatomical passageway.

[0072] FIGS. 3L' and 3L" show partial longitudinal sectional views of another occluder/suction device of the present invention.

[0073] FIGS. 3M' and 3M" show partial perspective views of another occluder/suction device of the present invention positioned within an anatomical passageway.

[0074] FIG. 4 is a longitudinal sectional view of the oropharynx and anterior neck of a human patient having a nasopharyngeal occluder/endotracheal tube device of the present invention inserted through the right nasal cavity and into the trachea.

[0075] FIG. 5A is a partial perspective view of a side cutting or ablation device being used in accordance with the present invention.

[0076] FIG. 5B is a partial perspective view of a device having laterally deployable needles, electrodes or other treatment delivering projections, being used in accordance with the present invention.

[0077] FIG. 5C is a partial perspective view of a drill (e.g., a tissue drill, bone drill, or trephine device) being used in accordance with the present invention.

[0078] FIG. 5D is a partial perspective view of a catheter having a laterally deployed needle or tube for delivering a substance or apparatus to a target location and an optional on-board imaging or guidance apparatus, being used in accordance with the present invention.

[0079] FIG. 5E is a partial perspective view of a balloon catheter being used in accordance with the present invention.

[0080] FIG. 5F is a partial perspective view of a balloon catheter having blades or electrodes thereon, being used in accordance with the present invention.

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[0081] FIG. 5G' is a partial perspective view of a balloon catheter having a stent positioned thereon being inserted into an occluded region within the nose, nasopharynx or paranasal sinus in accordance with the present invention.

[0082] FIG. 5G" shows the balloon catheter and stent of FIG. 3G', with the balloon inflated and the stent expanded so as to open or dilate the occluded region within the nose, nasopharynx or paranasal sinus.

[0083] FIG. 5G"' shows the balloon catheter and stent of FIG. 3G' with the stent implanted, the balloon deflated and the catheter being withdrawn and removed.

[0084] FIG. 5H is a partial perspective view of a tissue shrinking electrode device being used in accordance with the present invention.

[0085] FIG. 5I is a partial perspective view of a cryogenic or plasma state treatment device being used in accordance with the present invention.

[0086] FIG. 5J is a partial perspective view of an expandable tissue expanding device positioned within a passageway in the nose, nasopharynx or paranasal sinus in accordance with the present invention.

[0087] FIG. 5K is a partial sectional view of one embodiment of a forward cutting/suction catheter of the present invention.

[0088] FIG. 5K' shows the device of FIG. 5K being used to remove a nasal polyp or other obstructive mass from an anatomical passage within the nose or paranasal sinus.

[0089] FIG. 5L is a partial sectional view of a forward cutting/suction catheter/endoscope device of the present invention.

[0090] FIG. 5M is a partial sectional view of a side cutting/suction catheter device of the present invention.

[0091] FIG. 5N is a partial sectional view of a side cutting/suction catheter device of the present invention having an optional guidewire lumen and optional endoscopic component(s).

[0092] FIG. 5O is a partial perspective view of the distal end of a guide catheter/endoscope of the present invention.

[0093] FIG. 5P is a partial perspective view of a balloon catheter/pressure-expandable intranasal stent/endoscope device of the present invention.

[0094] FIG. 5Q is a partial perspective view of a delivery catheter/self expanding intranasal stent/endoscope device of the present invention.

[0095] FIG. 5Q' is a cross-sectional view through line 5Q'-5Q' of FIG. 5Q.

[0096] FIG. 5R' shows an example of an optional modified shape of the balloon and stent of FIG. 5P.

[0097] FIG. 5R" shows another example of an optional modified shape of the balloon

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and stent of FIG. 5P.

[0098] FIG. 5S is a partial perspective view of a snare catheter of the present invention with optional endoscopic component(s).

[0099] FIG. 5T is a partial perspective view of a forceps device of the present invention having optional endoscopic component(s).

[0100] FIG. 5U is a partial perspective view of a system of the present invention comprising a guide catheter, endoscope and guidewire.

[0101] FIG. 5U' is a cross-sectional view through line 5T'-5T' of FIG. 5T.

[0102] FIG. 5V is a partial perspective view of a microdebrider catheter of the present invention.

[0103] FIG. 5W is a partial perspective view of a bone remodeling device of the present invention.

[0104] FIGS. 5W' and 5W'' show steps in a method for using the bone remodeling device of FIG. 5W.

[0105] FIGS. 5X'-5X'''' are partial perspective views of alternative designs for bone remodeling devices of the present invention.

[0106] FIGS. 5Y-5Y'''' are perspective views of examples of substance delivering implant devices useable in the present invention.

[0107] FIG. 6A is a perspective view of one embodiment of a sphenoid sinus guide catheter of the present invention.

[0108] FIG. 6B is a perspective view of a frontal sinus guide catheter of the present invention.

[0109] FIG. 6C is a perspective view of one embodiment of a maxillary sinus guide catheter of the present invention.

[0110] FIG. 6D is a perspective view of one embodiment of an ethmoid sinus guide catheter of the present invention.

[0111] FIG. 6E is a perspective view of one embodiment of a plugging guide catheter of the present invention useable for temporarily plugging the opening into a nasolacrimal duct or Eustachian tube.

[0112] FIG. 7A is a sectional view of a paranasal sinus with a catheter introducing an expandable electrode cage into the sinus in accordance with the present invention.

[0113] FIG. 7B is a sectional view of a paranasal sinus that is filled with a diagnostic or therapeutic substance and wherein a plug tipped catheter is being used to plug the ostium of the sinus to retain the substance within the sinus, in accordance with the present invention.

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[0114] FIG. 7C is a sectional view of a paranasal sinus with a catheter introducing a diagnostic or therapeutic substance into contact with the tissue lining the sinus, in accordance with the present invention.

[0115] FIG. 7D is a sectional view of a paranasal sinus with a catheter having emitters and/or sensors for 3 dimensional mapping or navigation, in accordance with the present invention.

[0116] FIG. 7E is a sectional view of a paranasal sinus with a catheter delivering a coil apparatus into the sinus to embolize the sinus and/or to deliver a diagnostic or therapeutic substance into the sinus in accordance with the present invention.

[0117] FIG. 7F is a sectional view of a paranasal sinus with a guide catheter, guide wire and over-the-wire flexible endoscope inserted into the sinus, in accordance with the present invention.

[0118] FIG. 7G shows the guide catheter and endoscope of FIG. 5F with a working device (e.g., a biopsy instrument) inserted through a working channel of the endoscope to perform a procedure within the sinus under endoscopic visualization, in accordance with the present invention.

[0119] FIGS. 8A-8E show steps in a sinus treatment procedure conducted in accordance with the present invention.

[0120] FIGS. 9A-9C show steps in a cochlear implant procedure conducted in accordance with the present invention.

DETAILED DESCRIPTION

[0121] The following detailed description and the accompanying drawings are intended to describe some, but not necessarily all, examples or embodiments of the invention only and does not limit the scope of the invention in any way.

[0122] A number of the drawings in this patent application show anatomical structures of the ear, nose and throat. In general, these anatomical structures are labeled with the following reference letters:

Nasal Cavity NC

Nasopharynx NP

Superior Turbinate ST

Middle Turbinate MT

Inferior Turbinate IT

Frontal Sinus FS

Ethmoid Sinus ES

Sphenoid Sinus SS

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Sphenoid Sinus Ostium SSO

Maxillary Sinus MS

[0123] The human nose has right and left nostrils or nares which lead into separate right and left nasal cavities. The right and left nasal cavities are separated by the intranasal septum, which is formed substantially of cartilage and bone. Posterior to the intranasal septum, the nasal cavities converge into a single nasopharyngeal cavity. The right and left Eustachian tubes (i.e., auditory tubes) extend from the middle ear on each side of the head to openings located on the lateral aspects of the nasopharynx. The nasopharynx extends inferiorly over the uvula and into the pharynx. As shown in FIGS. 1A and 1B, paranasal sinuses are formed in the facial bones on either side of the face. The paranasal sinuses open, through individual openings or ostia, into the nasal cavities. The paranasal sinuses include frontal sinuses FS, ethmoid sinuses ES, sphenoidal sinuses SS and maxillary sinuses MS.

[0124] The present invention provides a comprehensive system of devices and associated methods for diagnosing and treating disorders of the ears, nose and throat in a less invasive fashion than current day approaches. Specifically, examples of which are described below, the invention provides devices that wholly or partially effect a fluid-tight seal of the operative field (e.g., the nasopharynx and/or one or more of the sinus cavities or regional ducts). This fluid-tight sealing of the operative field allows the cavities, ducts and passageways to be imaged using fluid/gas based agents in combination with various imaging modalities without the nsk of aspiration or uncontrolled leakage of fluid from the operative field. Further, this fluid-tight sealing of the operative field permits the retention and collection of any blood or flushing fluids released during the procedure. Another aspect of the invention is a set of methods and devices useable to assess the static and dynamic nature of the paranasal sinuses and to provide for the guidance of specific therapies to particular sinuses or particular target regions (e.g., stenotic sinus ostia, infected tissues within sinuses, tumors, other target structures). Another aspect of the invention is the use of devices and methods which are designed for minimally invasive entry into the sinus passageways or regional ducts under image and/or endoscopic guidance to provide local therapy such as dilation, ablation, resection, injection, implantation, etc. to the region of concern. These devices and methods may be disposable or temporary in their application, or they may be implantable with on-going functionality (such as implantable drug delivery systems, cochlear implants, etc.). In a number of embodiments, the present invention utilizes flexible catheters and various working devices that are mounted on or delivered through elongate flexible members or catheters, to diagnose and treat a wide range or ear, nose and throat disorders including; nasal polyps, sinusitis, enlarged turbinates, deviated septum, tumors, infections, deformities, etc. The following pages describe a number of specific devices and methods that are useable in accordance with this invention. It is to be understood that any component, element, limitation, attribute or step described in relation to any particular device or method described herebelow, may be incorporated in or used with any other device or method of the present invention unless to do so would render the resultant device or method unusable for its intended purpose.

[0125] A. Occluders & Access Port Devices

[0126] Many of the procedures of the present invention require the insertion and

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positioning of one or more flexible catheters or other flexible elongate working devices (examples of which are shown in FIGS. 5A-5Y"" and described herebelow) within the nose, nasopharynx, middle ear or paranasal sinuses. To facilitate the insertion and proper positioning of such catheters and/or other elongate working devices and to prevent undesirable drainage of blood or debris from the operative site, the present invention includes a number of different occluder and/or access port devices, examples of which are shown in FIGS. 2A-2R, that are inserted through the nose and/or oral cavity and function to a) prevent unwanted drainage or escape of fluid (e.g., gas or liquid) and b) facilitate the insertion and positioning of guides and working devices, examples of such working devices being shown in FIGS. 5A-5Y"" and 6A-6E.

[0127] FIGS. 2A-2B show partial sectional views of opposite sides of the head of a human patient having an anterior/posterior occluder & access device 10 inserted through the right nasal cavity and anterior occluder & access device 12 positioned in the anterior region of the left nasal cavity. Specifically, FIG. 2A shows the nasal cavity, the right side of the nasopharynx and the associated paranasal sinuses, with an anterior/posterior occluder & access device 10 of the present invention inserted therein. The anterior/posterior occluder & access device 10 comprises an anterior occluder 14 which occludes the right nasal cavity on the right side of the nasal septum, a posterior occluder 18 that occludes the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis) and a tube 16 that extends between the anterior occluder 14 and posterior occluder 18. Devices for posterior occlusion and anterior occlusion may be used alone or in combination. They may be coaxially deployed or alternatively they may be deployed in a singular fashion, one in each orifice. It should be noted that any combination of these sealing modalities may be employed to achieve one or more of the stated objectives. A cross-section through the tube 16 is shown in FIG. 2C. Other cross-sectional configurations could also be possible, including those that comprise more lumens to permit the passage of multiple devices or fluids (e.g., liquid or gases). In some embodiments, it may be desirable for the device 10 (or any of the other occluder/access devices described herein) to have separate lumens for infusion and aspiration, thereby allowing for concurrent infusion of an irrigation fluid or other fluid and suctioning of the irrigation fluid or other fluid from the operative field. Such continuous turnover of fluid within a sealed operative field may be useful for clearing blood or debris from the operative field to facilitate unobstructed viewing of the anatomical structures using an endoscope or for various other reasons. A port body 28 as attached to the proximal end of the tube 16. A device insertion aperture 30 extends through the port body 28 into working lumen 50 of tube 16. One or more outlet openings 22, 24 are at location(s) in the tube such that a device (e.g., a catheter, fluid injector or other elongate device examples of which are shown in FIGS. 5A-5Y"" and described herebelow) or fluid(s) may be inserted into the device insertion opening 30, advanced through the working lumen 50 and out of a selected one of the outlet openings 22, 24 to a position within the nose, nasopharynx or paranasal sinus. In the particular embodiment shown in FIG. 2A the anterior and posterior occluders 14, 18 comprise balloons, but various other types of occluders could be used in place of balloons, examples of which are shown in FIGS. 3A-3K and described herebelow. Balloon inflation/deflation lumens 52, 56 extends from proximal Luer connectors 32, 36, through the tube 16 and to the anterior occluder 14 and posterior occluder 18, respectively. Thus, a syringe or other fluid expelling and/or withdrawing device may be connected to connector 32 and used to selectively inflate and/or deflate the anterior occluder 14. Another syringe or other fluid expelling and/or withdrawing device may be connected to connector 36 and used to selectively inflate and/or deflate the posterior occluder 18. As may be appreciated from the showing of FIG. 2B, the posterior

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occluder (when fully inflated) may be sized and shaped to occlude the entire posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis), thereby preventing blood or other fluid or debris from draining into the patient's pharynx from either the right or left nasal cavity. When fully inflated, the anterior occluder 14 of the device 10 occludes only the right nasal cavity and serves to prevent blood, other fluid or debris from draining around the tube 16 and out of the right nostril during the operative procedure. A one way valve, such as a flapper valve, duckbill valve, hemostatic valve or other one way valve of the type well known in the art of biomedical device design, may be positioned within the port body 28 to permit a catheter or other elongate device (examples of which are shown in FIGS. 5A-5T and described herebelow) to be advanced in the distal direction though insertion port 30, through the port body 28 and through the working lumen 50 but to prevent blood, other fluid or debris from draining through the working lumen 50 out of the device insertion port 30. In this manner, the device 10 forms a substantially fluid tight anterior seal in the anterior aspect of the right nasal cavity and a substantially fluid tight posterior seal in the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis). Since a substantially fluid tight seal is formed, one or more valves (not shown) may be provided to relieve positive or negative pressure created between the anterior or posterior occluders 14, 18 as a result of the injection of matter (e.g., contrast medium, irrigation solution, medicament, etc.) into the operative field and/or suctioning or removal of matter (e.g., blood, other fluid or debris) from the operative field. Additionally, a suction lumen 54 may extend from suction Luer connector 34, through suction lumen 54 and to suction openings 26 may be formed in the tube 16. A suction pump may be connected to the suction connector 34 to aspirate blood, other fluid and/or debris out of the right nasal operative region defined between anterior occluder 14 and posterior occluder 18. It should be appreciated that, while the occlusion/access devices shown in the drawings and described herein are designed to isolate a relatively large operative field (e.g., one or both nasal cavities, sinus, nasal cavities-nasopharynx, etc.), once a specific problem has been diagnosed and/or once a specific target region has been identified, the occluders 14, 18 may be repositioned and/or other occluder devices may be inserted to isolate and form a fluid tight seal of just a portion of the original operative field (e.g., just one sinus, one nasal cavity, one Eustachian tube, etc.) thereby allowing the procedure to go forward with only the necessary region(s) of the nose, nasopharynx, paranasal sinuses or other structures sealed off and/or instrumented, to minimize trauma and improve patient comfort.

[0128] It should be appreciated that in any embodiment of an anterior/posterior occluder & access device, such as the device 10 shown in FIGS. 2A and 2B, the distance between the anterior occluder 14 and posterior occluder 18 may be adjustable so as to accommodate variations in anatomy and/or specific target regions or isolated operative fields of interest. The anterior and posterior occluders 14, 18 may be separate devices where the anterior occluder may slide or pass through one lumen of the posterior occluder, which may contain several lumens (e.g., inflation, working channel, irrigation, etc.), and may or may not be integrated with the posterior occluder. The posterior occluder may also contain several lumens (e.g., inflation, working channel, irrigation, etc.). Additionally, all lumens for both the anterior and posterior occluders may contain valves so as to prevent leakage or flow of gas, fluid, blood, etc.

[0129] It is to be further appreciated that in embodiments that have anterior and posterior outlet openings 22, 24 (as shown in the example of FIGS. 2A-2B) tools, instrumentation and fluids may be delivered via either of the posterior or anterior access ports 22, 24. In some cases, access via a posterior outlet 24 is desirable to gain

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a better perspective on the target anatomical lumen or lumen (i.e. openings to the ethmoid cells).

[0130] As shown in FIGS. 2B and 2D, in some procedures wherein the anterior/posterior occluder & access device 10 is inserted through one nasal cavity, it may be desirable to position a separate anterior occluder & access device 12 within the opposite nasal cavity to prevent drainage of blood, other fluid or debris from the other nostril and to facilitate insertion of catheters or other elongate devices (examples of which are shown in FIGS. 5A-5T and described herebelow) into the left nasal cavity and the paranasal sinuses or other anatomical structures accessible from the other nasal cavity. As shown, in FIG. 2B, the anterior occluder & access device 12 may comprise a tube 41 having an anterior occluder 40 and a port body 42 attached thereto. A device insertion aperture 44 extends through the port body 42 and through a working lumen 58 of tube 41 to an outlet aperture in the distal end of tube 41. A one way valve (such as the valve described hereabove in connection with the anterior/posterior occluder & access device 10) may optionally be provided within port body 42 to prevent draining of blood, other fluid or debris out of insertion aperture 44. In the particular embodiment shown in FIGS. 2B and 2D, the anterior occluder 40 is a balloon, but such occluder 40 may be of various other constructions, examples of which are shown in FIGS. 3A-3M" and described herebelow. To facilitate inflation and deflation of this balloon type anterior occluder 40, a balloon inflation/deflation lumen 60 extends from Luer connector 48, through tube 41 to the balloon-type anterior occluder 40. A syringe or other fluid expelling and/or withdrawing device may be connected to connector 48 and used to selectively inflate and/or deflate the anterior occluder 40. Optionally, a side tube and Luer connector 46 may be connected to the working lumen 58 of tube 41 to allow blood, other fluid and debris to be suctioned from the left nasal cavity through the working lumen 58 of tube 41. In some embodiments, dedicated suction and/or irrigation lumen(s) with separate suction and/or irrigation ports may be formed in tube 41 in a manner similar to that described hereabove with respect to the anterior/posterior occluder & access device 10.

[0131] FIGS. 2E-2H show an alternative system for occlusion and access, wherein anterior occluder & access device(s) 12 is/are positioned in one or both nostrils or nasal cavities and an orally insertable posterior occluder device 300 is inserted through the patient's oral cavity and positioned so as to occlude the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis). The embodiment of the orally insertable posterior occluder device 300 shown in FIGS. 2E-2G comprises a curved tube 302 having an occluder 304 positioned at or near the distal end thereof. The device 300 is configured such that it may be inserted through the patient's oral cavity to a position where the occluder 304 is located within, and disposed, so as to substantially occlude the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis). The posterior occluder 304 may also be positioned next to the Eustachian tube to block the Eustachian tube, thereby preventing fluid from tracking into the Eustachian tube during the procedure (if access to the Eustachian tube or middle ear or inner ear is not desired). Further, it may be necessary to place specific targeted balloons or occluders in ducts or channels which are not intended to be intervened upon (lacrimal ducts, Eustachian tubes, etc.). In such cases, these extra ductal occluders serve to prevent aberrant fluid/gas loss and/or to maintain the integrity of the lumen, while other nearby structures are being modified. In the particular example shown in FIGS. 2E-2G, the occluder 304 comprises a balloon. However, such occluder 304 may be constructed in various alternative ways, examples of which are shown in FIGS. 3A-3K and described

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herebelow. As may be appreciated from the cross-sectional showing of FIG. 2F, in this example a balloon inflation/deflation lumen 318 may extend from Luer connector 314, through tube 302 to the balloon-type occluder 304. A syringe or other inflation/deflation apparatus may be attached to the Luer connector 314 and used to inflate and deflate the balloon 304. A stopcock or other valve (not shown) may also be provided on balloon inflation tube 318 to maintain inflation of the balloon when desired. In routine use, the occluder 304 is initially deflated and the device 300 is inserted through the oral cavity and advanced to its desired position with the deflated occluder positioned within the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis). Thereafter, the occluder 304 may be expanded (e.g., inflated) such that it occludes or blocks the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis), thereby substantially preventing blood, other fluid or debris from draining into the patient's esophagus or trachea during the procedure. In some cases, as shown in FIGS. 2E-2H, the tube 302 may have one or more lumen(s) 310 that extend(s) through the occluder 304 and open (s) through an opening 310 distal to the balloon. Working devices, such as catheters or other elongate devices examples of which are shown in FIGS. 5A-5Y"" and described herebelow may be advanced through such a lumen 310 and into the patient's nasopharynx, nasal cavities, paranasal sinuses, middle ears, etc. Alternatively, suction may be applied to such a lumen 310 to suction blood, other fluid or debris from the area superior to the occluder 304. In some cases, the lumen 310 shown may be divided into a working lumen and a suction lumen. The suction lumen may terminate in separate suction port(s) (not shown) at the distal end of the tube and a connector (not shown) at the proximal end, such that suction may be applied through a lumen that is separate from the lumen through which the working device(s) is/are passed. A port body 306 may be positioned on the proximal end of the tube 302. A device insertion port 308 may extend through the port body 306 into a lumen 310 of the tube 302. A one way valve, such as a flapper valve, duckbill valve, hemostatic valve or other one way valve of the type well known in the art of biomedical device design, may be positioned within the port body 306 to permit a catheter or other elongate device to be advanced in the distal direction though insertion port 308, through the port body 306 and through a lumen 310 but to prevent blood, other fluid or debris from draining through the lumen 310 and out of the device insertion port 308. In some cases, the orally insertable posterior occluder device 300 may be used without any anterior occluder device(s) positioned in the nostril(s) or nasal cavity(ies). In other cases, it will be desirable to use this orally insertable posterior occluder device 300 in combination with one or two anterior occluder & access devices 12 as shown in the example of FIGS. 2G and 2H. The use of these devices 300, 12 in combination serves to establish a substantially fluid tight operative field between the posterior occluder 304 and the anterior occluder(s) 40 while allowing various catheters and other operative instruments to be inserted into the operative field through optional access ports 44 and/or 308.

[0132] FIGS. 2I-2L show a trans-nasally insertable posterior occluder device 301 that does not include any anterior occluder. This device 301 comprises a curved tube 303 having an occluder 305 positioned at or near the distal end of the tube 303. As shown in FIGS. 2K-2L, this device 301 is inserted through either the right or left nasal cavity and advanced to a position where the occluder 305 substantially occludes the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis). In the particular example shown, this occluder 305 comprises a balloon. However, such occluder 305 may be constructed in various alternative ways, examples of which are shown in FIGS. 3A-3K and described herebelow. As may be appreciated from the cross-sectional showing of FIG. 2J, in this example a balloon inflation/deflation

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lumen 317 may extend from Luer connector 311, through tube 303 to the balloon-type occluder 305. A syringe or other inflation/deflation apparatus may be attached to the Luer connector 311 and used to inflate and deflate the balloon-type occluder 305. A stopcock or other valve (not shown) may also be provided on balloon inflation lumen 317 to maintain inflation of the balloon when desired. In routine use, the occluder 305 is initially deflated and the device 301 is inserted through the right or left nasal cavity and advanced to its desired position where the deflated occluder 305 is positioned within the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis). Thereafter, the occluder 305may be expanded (e.g., inflated) such that it occludes or blocks the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis), thereby substantially preventing blood, other fluid or debris from draining into the patient's esophagus or trachea during the procedure. Optionally, distal suction ports 309 and/or proximal suction ports 307 may open into lumen 315 of the tube 303 and such lumen 315 may be attached to a suction connector 313. In this manner, suction may be applied to remove blood, other fluid or debris from the nasopharynx superior to the occluder 305 and/or from the nasal cavity through which the device 3301 is inserted. As may be appreciated from the showings of FIGS. 2K and 2L, in this example, the trans-nasal posterior occluder device 301 is inserted through the right nasal cavity. A working device WD such as a catheter or other elongate operative apparatus (examples of which are shown in FIGS. 5A-5Y"" and described herebelow) may be advanced into the right nasal cavity adjacent to the tube 303 or through the left nasal cavity which remains open, as no anterior occlusion is provided by this trans-nasal posterior occluder device 301. This arrangement may be particularly suitable for procedures where the physician desires to directly visualize, through the nostril(s), the anatomical structures within the nose, such as the inferior, middle or superior turbinates IT, MT, ST, as shown in FIGS. 2K-2L.

[0133] FIGS. 2M-2N show a modified version of the trans-nasal posterior occluder 301a which includes all of the elements described above with respect to the trans-nasal posterior occluder device 301 shown in FIGS. 2I-2L as well as a distal extension 303a of the tube 303 that extends distal to the occluder 305 and an additional proximal connector 319. A separate lumen (not shown) extends from connector 319 through tube 303 and through distal tube extension 303a, which terminates in a distal end opening 321. Suction may thus be applied to connector 319 to suction matter through distal opening 321, through the distal tube extension 303a and through tube 303. This distal tube extension 303a and additional lumen may be optionally added to any other the other posterior occluder devices described herein in cases where doing so would not render the device unsuitable for its intended application.

[0134] FIGS. 2O-2P show an alternative posterior occluder system 400 that comprises an intranasal catheter 402 that is inserted into a nasal cavity and an occluder catheter 404 that is inserted through the intranasal catheter 402, as shown. A posterior occluder 406 is located at or near the distal end of the occluder catheter 404. In the particular embodiment shown in FIGS. 2O-2P, the occluder 406 is sized and configured to occlude the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis). In the particular example shown, this occluder 406 comprises a balloon. However, such occluder 406 may be constructed in various alternative ways, examples of which are shown in FIGS. 3A-3K and described herebelow. In this example a balloon inflation/deflation lumen may extend from Luer connector 408, through occluder catheter 404 and to the balloon-type proximal occluder 406. A syringe or other inflation/deflation apparatus may be attached to the

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Luer connector 408 and used to inflate and deflate the balloon-type posterior occluder 406. A stopcock or other valve (not shown) may also be provided on the balloon inflation/deflation lumen to maintain inflation of the balloon-type posterior occluder 406, when desired. Optionally, distal tubular extension 412 may extend distally of the posterior occluder 406 and a separate lumen may extend from an optional second connector 410, through distal tubular extension 412 and through an opening 414 such that matter may also be aspirated from the area distal to the posterior occluder 406. A port body 418 is formed on the proximal end of the intranasal tube 402. An insertion port 420 extends through port body 418 into the lumen 422 of the intra nasal tube. A side suction port 416 may also be connected to the lumen 422 of the intranasal tube 402. In routine operation, the intranasal tube 402 is inserted through the nostril into one nasal cavity and advanced to a position where its distal end is within or near the posterior choanae or nasopharynx. With the posterior occluder 406 in a collapsed (e.g., deflated) configuration, the occluder catheter 404 is advanced through the lumen 422 of the intranasal catheter 402 to a position where the posterior occluder is located in the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis). Thereafter, the posterior occluder 406 may be expanded (e.g., inflated) such that it occludes or blocks the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis), thereby substantially preventing blood, other fluid or debris from draining into the patient's esophagus or trachea during the procedure. Thereafter, suction may be applied to suction port 416 to suction blood, other fluid or debris from the area proximal to the posterior occluder 406. During such suctioning, the intranasal tube 402 may be moved back and/or forth as indicated by arrows on FIG. 2O, while the occluder catheter 404 remains stationary. Such ability to move the intranasal catheter 402 during the suctioning process may facilitate complete removal of blood, other fluid and/or debris from the operative field.

[0135] FIGS. 2Q and 2R show a modified posterior occluder system 430 which includes the same elements and components as the posterior occluder system 400 described above, but wherein the distal end 434 of the intranasal tube 402a is tapered and wherein a plurality of side apertures 432 are formed in the intranasal tube 402a such that blood, other fluid or debris may be aspirated into the lumen 422a of the intranasal tube 402a through such side apertures 432.

[0136] B. Variations in Occluder Design and Suction Apparatus:

[0137] Although the above-described examples of occluder/access devices 10, 12, 300, 400 show occluders that are in nature of inflatable balloons, it will be appreciated that these occluders are not limited to balloons and may be of various other designs and types. Further, it is to be understood that various arrangements of access and/or suction tubing/port(s) may be used to facilitate complete removal of blood, fluid or other debris from the areas adjacent to the occluder(s) and/or elsewhere in the operative field or optimal positioning of working devices within the operative field. In fact, certain occluder and/or suction-access tubing/port designs may be more desirable for certain procedures than others depending on a number of factors including the positioning of the patient's head during surgery, whether the patient will be under a general anesthetic, whether an endotracheal tube will be inserted, etc. In some cases, where a posterior occluder is positioned within the posterior choanae, nasopharynx or pharynx posterior to the nasal septum the completeness with which blood, other fluid or debris may be suctioned out of the area adjacent to that posterior occluder may depend on the shape and/or design of the occluder itself as well as the shape and location of the

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suction lumen(s) and port(s) through which the blood, fluid or debris is to be suctioned. Beyond optimized fluid control, the posterior occluder and/or associated access tubing may also serve as an essential guiding element for devices, and alternative shapes and trajectories may be particularly useful to access specific structures. FIGS. 3A-3K show examples of varied occluder types and variations in the arrangements of suction lumen (s) and port(s) through which the blood, fluid or debris may be suctioned from areas adjacent to the occluder or elsewhere within the operative field. The examples shown in FIGS. 3A and 3K may be incorporated into the occluder & access devices shown in FIGS. 2A-2R, when appropriate.

[0138] FIG. 3A shows an occluder 446 mounted on a tube 442, wherein a generally "U" shaped curve is formed in the distal end of the tube such that a distal portion of the tube 442 passes beneath the upper surface 449 of the occluder 446 and curves upwardly such that the distal end of the tube 442 terminates in an opening 444 that is flush with the upper surface 449 of occluder 446. In this manner, any fluid that has accumulated adjacent to the upper surface 449 of occluder 446 may be suctioned into opening 444 and through tube 442. In embodiments where the occluder comprises a balloon, a balloon inflation lumen may extend through the tube and open through an opening 447 into the interior of the balloon, to permit inflation/deflation of the balloon. Optionally, a working device 448, such as a flexible catheter or elongate apparatus examples of which are shown in FIGS. 5A-5T and described herebelow, may also be advanced through the suction lumen of tube 442 and out of opening 444 as indicated on FIG. 3A.

[0139] FIG. 3B shows another alternative wherein an occluder 450 has a depression or well 454 formed in its upper surface. A tube 452 is attached to the occluder by attachment members 456 and the distal end of the tube 452 protrudes into well 454 such that any blood, fluid or debris that collects within the well 454 may be suctioned through the tube 452. In embodiments where the occluder 450 comprises a balloon, the tube 452 may incorporate a balloon inflation/deflation lumen which may extend through an inflation/deflation side tube 458 into the interior of the balloon to facilitate inflation and deflation of the balloon.

[0140] FIGS. 3C and 3C' show another alternative wherein an occluder 460 had a depression or well 462 formed in its upper surface and a tube 464 is attached to the occluder 460, as shown. A lumen of the tube 464 is in communication with the area adjacent the floor of the well to facilitate suctioning of blood, fluid or debris that collects within the well. In embodiments where the occluder 460 comprises a balloon, the tube 464 may incorporate a suction lumen 468 and a balloon inflation/deflation lumen 470. A small curved (e.g., generally "U" shaped) suction tube 466 may be connected in a sealed connection to the distal end of suction lumen 468 and the interior of the well 462 such that blood, other fluid or debris may be suctioned from the well 462, through suction tube 466 and through suction lumen 468.

[0141] FIG. 3D shows a concave occluder 471 that comprises a self expanding concave structure 472 such as a basket formed of a superelastic or resilient mesh material (e.g., nickel titanium alloy wire mesh). The expanding concave structure 472 is covered by a fluid impermeable flexible covering 474 such as a skin formed of flexible polymer (e.g., expanded polytetrafluoroethylene, polyurethane, polyethylene teraphthalate, etc.). When fully expanded the concave occluder 471 occludes the body lumen in which it is positioned (e.g., the nasal cavity, posterior choanae, nasopharynx, pharynx, etc.) and forms a concave well 479. A tube 480 extends into the well 479 of

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the concave occluder 471 and may be used to suction blood, fluid or debris from the well 479. The occluder 471 may be advanced from and withdrawn into a delivery catheter 478. Struts 472 may connect the concave occluder 471 to a delivery member (not shown) within the delivery catheter 478, such delivery member being advanceable to push the occluder 471 out of the delivery catheter 478 and retractable to withdraw the occluder 471 into the delivery catheter 478. When inside the delivery catheter, the occluder 471 may be in a collapsed configuration but when expelled out of the delivery catheter the occluder will resiliently spring or self-expand to its expanded concave configuration, as shown in FIG. 3D. The suction catheter 480 may advance from and/or retract into the delivery catheter 478 concurrently with, or separately from, the occluder 471.

[0142] FIGS. 3E'-3E'" show yet another occluder/suction arrangement wherein the occluder 484 comprises an everting tubular member that is advanceable from a delivery/suction catheter 486. The everting tubular member comprises a frame 488 that is covered with a covering 500. Initially the everting tubular member is in a substantially cylindrical configuration within the lumen of the delivery/suction catheter 486. The frame may be a resilient or superelastic material that is biased to the everted shape shown in FIG. 3E'". Such frame 488 may be formed of mesh material (e.g., nickel titanium alloy wire mesh). The covering 500 may be formed of flexible polymer (e.g., expanded polytetrafluoroethylene, polyurethane, polyethylene teraphthalate, etc.) In operation, the delivery/suction catheter 486 is advanced to the position where it is desired to place the occluder 484. Then, the everting tube is advanced from the distal end opening of the delivery/suction tube 486, as shown in FIGS. 3E' and 3E". As it advances out of the catheter 486, the everting tube member assumes its everted configuration, forming a concave occluder 484 as shown in FIG. 3E'". The occluder 484, when fully everted, occludes the body lumen in which it is positioned (e.g., the nasal cavity, posterior choanae, nasopharynx, pharynx, etc.) and creates a concave well 504. The delivery/suction catheter 486 may be advanced into the concave well 504 such that any blood, fluid or debris that collects within concave well 504 may be suctioned through suction ports 502 and through the distal end of the delivery/suction catheter 486.

[0143] FIG. 3F-3F'" show another embodiment wherein an occluder 510 is positioned on the end of a tube 512. The occluder 510 has an arched upper surface such that a generally "V" shaped annular collection space 518 is created in the region of the coaptation between the occluder 510 and the adjacent wall of the body lumen in which it is positioned (e.g., a nasal cavity, posterior choanae, nasopharynx, pharynx, etc.). A suction tube 516 extends from tube 512 into the annular collection space 518 and blood, other fluid or debris that collects in the annular collection space 518 may be suctioned through suction tube 516 and through a lumen of tube 512, thereby providing for maintenance of a substantially dry environment adjacent to the upper surface of the occluder 510. The occluder 510 may comprise a balloon or any other suitable occlusion member as described herein or known in the art. As shown in FIGS. 3F'-3F'" the suction tube 516 may comprise a simple tube having an open distal end or, alternatively, the device may incorporate a suction tube 516a that has a plurality of side apertures 520 formed near its distal end and/or a suction tube 516 that has a guard member 522, such as a screen, formed over its suction ports or openings to deter solid matter (e.g., blood clots or other debris) from clogging the suction ports or openings.

[0144] FIG. 3G shows an occluder 530 attached to a tube 532 that has a curved (e.g., generally "U" shaped) distal end that does not protrude into the interior of the occluder.

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Suction apertures 536 are formed in the distal portion of the tube 532 to permit blood, fluid or debris that collects adjacent to the upper surface of the occluder 530 to be suctioned through the tube 532. In embodiments where the occluder is a balloon a balloon/inflation lumen may extend through tube 532 and a small balloon inflation tube 538 may extend into the interior of the balloon to permit the balloon to be inflated and deflated. Optionally, in some embodiments, a separate tube 540 may extend through tube 532 and trough occluder 530 to provide access to the area distal to the occluder 530 for purposes of suctioning, introduction of instruments, or other purposes.

[0145] FIG. 3H shows another embodiment wherein the occluder 546 is connected to a tube or elongate member 550 and a suction tube 548 having an expanded (e.g., trumpet shaped) distal end is useable to suction blood, fluid or debris from the area adjacent to the upper surface of the occluder. As can be seen from FIG. 3H, where the upper surface of the occluder is arched and annular collection space may be created around the perimeter of the occluder 546 where the occluder 546 coapts with the wall of the anatomical structure in which it is positioned (e.g., a nasal cavity, posterior choanae, nasopharynx, pharynx, etc.) and the expanded end 552 of the suction tube 548 may be sized and shaped to receive the arched upper surface of the occluder 546 and to suction any blood, fluid or debris from that annular collection space. In embodiments where the occluder is a balloon a balloon/inflation lumen may extend through tube 548 and a small balloon inflation tube may extend into the interior of the balloon to permit the balloon to be inflated and deflated. Optionally, in some embodiments, a separate tube 550 may extend through tube 548 and through occluder 546 to provide access to the area distal to the occluder 546 for purposes of suctioning, introduction of instruments or fluid injectors, or other purposes.

[0146] FIG. 3I shows an embodiment wherein the occluder 570 comprises a mass of absorbent material such as a tampon (e.g., cotton, gauze, hydrogel or other material or composite of materials that will absorb fluid and occlude the desired body lumen). In the particular example shown, the occluder is advanced out of an aperture 578 formed in a tube 572 that has a curved (e.g., generally "U" shaped) tip. Suction apertures 576 are formed in the distal portion of the tube 572 to permit blood, fluid or debris that collects adjacent to the upper surface of the occluder 570 to be suctioned through the tube 572. After the procedure is complete or the occlusion is no longer required, the tube 572 and fluid-soaked occluder 570 may be withdrawn from the body without retraction of the occluder 570 into the tube 572. Optionally, a distal end opening 574 may be formed in tube 572 and such distal end opening may be connected to the same lumen as openings 576 or a separate lumen to the optional distal end opening 574 to be used for suctioning, irrigation or introduction of a working device 580 such those shown in FIGS. 5A-5Y"" and described herebelow.

[0147] FIG. 3J shows an occluder embodiment similar to that of the device shown in FIGS. 2O and 2P and described hereabove. In this embodiment, an occluder 600 is attached to a tube or elongate member 604 and a suction tube 602 is movable back and forth over the tube or elongate member 604 to suction blood, fluid or debris from the area adjacent to the upper surface of the occluder 600 or elsewhere in the body lumen in which the occluder 600 is positioned. In embodiments where the occluder 600 is a balloon, a balloon/inflation lumen may extend through tube or elongate member 604 and into the balloon to permit the balloon to be inflated and deflated. Optionally, in some embodiments, a separate tube 606 may extend trough tube or elongate member 604 and through occluder 600 to provide access to the area distal to the occluder 600 for purposes of suctioning, introduction of instruments, or other purposes.

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[0148] FIG. 3K shows an occluder embodiment similar to that incorporated into the device shown in FIGS. 2Q and 2R and described hereabove. In this embodiment, an occluder 610 is attached to a tube or elongate member 614 and a tapered suction tube 612 having one or more suction apertures 616 formed therein is movable back and forth over the tube or elongate member 614 to suction blood, fluid or debris from the area adjacent to the upper surface of the occluder 610 or elsewhere in the body lumen in which the occluder 600 is positioned. Of course, irrigation solution or other fluids may also be delivered through such apertures 616 or through a separate irrigation/infusion lumen that opens through separate irrigation/infusion aperture(s) (not shown). In embodiments where the occluder 610 is a balloon, a balloon/inflation lumen may extend through tube or elongate member 614 and into the balloon to permit the balloon to be inflated and deflated. Optionally, in some embodiments, a separate tube 618 may extend trough tube or elongate member 614 and through occluder 610 to provide access to the area distal to the occluder 610 for purposes of suctioning, introduction of instruments, or other purposes.

[0149] FIGS. 3L'-3L" show yet another occluder/tubing device 1000 comprising an outer tube 1002 and an inner tube 1004 disposed coaxially within the outer tube 1002. An outwardly bendable region 1006 is formed in the wall of the outer tube 1002 near its distal end. The distal end of the outer tube 1002 is affixed to the inner tube 1004. A passageway 1010 extends between the outer tube 1002 and inner tube 1004 and openings 1008 are formed in the wall of the outer tube 1002. In routine operation, this device 1000 is initially disposed in the configuration shown in FIG. 3L' and is inserted into the desired passageway. Thereafter, the inner tube 1004 is pulled in the proximal direction while the outer tube 1002 is held stationary, thereby causing the outwardly bendable region 1006 to protrude outwardly as shown in FIG. 3L" and resulting in occlusion of the body lumen in which the distal portion of the device 1000 is positioned. Suction may be applied to passageway 1010 to remove blood, fluid or other debris from the area adjacent to the upper surface of 1007 of the outwardly protruding bendable region 1006. In this regard, the openings 1008 may be formed close to and/or even in the upper surface 1007 of the outwardly protruding bendable region 1006.

[0150] FIGS. 3M' and 3M" show another occluder/tubing device 1020 comprising an outer tube 1022 an inner tube 1024. The inner tube 1024 is advanceable out of the distal end of the outer tube 1022 and a distal portion of the inner tube 1024 expands as it emerges from the inner tube, thereby forming an occluder that occludes the body lumen or passageway in which it is positioned, as shown in FIG. 3M". Blood, other fluid or debris may be suctioned from the area adjacent to the upper surface of the occluder through the open distal end of the outer tube 1022 and/or through optional side apertures 1026.

[0151] FIG. 4 shows a nasopharyngeal occluder/endotracheal tube device 620 of the present invention inserted through the right nasal cavity and into the trachea. This device 620 comprises a curved tube 622 having a posterior occluder 626 positioned at or near the distal end of the tube 622 and, optionally an anterior occluder (shown in dotted lines on FIG. 4) formed near the proximal end of the tube 622. An endotracheal tube 624 extends through curved tube 622, through the posterior occluder and into the patient's trachea. Optionally, a cuff 628 may be formed on endotracheal tube 624 to provide a second substantially fluid tight seal within the patient's trachea, inferior to the glottis. A hub 630 is formed on the proximal end of tube 622. A ventilator tube 634 extends from the hub and is connected to endotracheal tube 624 and is attachable to a

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ventilator, anesthesia machine, t-tube, Ambu-bag, etc. In embodiments where the posterior occluder 626 is a balloon, a posterior occluder inflation/deflation connector 632 extends from hub 630 and is connected to an inflation/deflation lumen that extends through tube 622 for inflation/deflation of the posterior occluder 626. A cuff inflation/deflation connector 634 may also extend from hub 630 and through the endotracheal tube 624 for inflation/deflation of the endotracheal tube cuff 628. Optionally, suction and/or device insertion ports may also be formed in hub 630, as described above in connection with other occluder/access devices. In routine operation, this device 620 is inserted to a position where the posterior occluder 626 occludes the posterior choanae, nasopharynx or pharynx posterior to the nasal septum (but typically superior to the glottis) and the endotracheal tube 624 extends into the patient's trachea with the optional cuff positioned in the trachea inferior to the glottis.

[0152] C. Working Devices for Delivering Substances or for Cutting, Ablating, Remodeling or Expanding Bone or Soft Tissue

[0153] The present invention provides a variety of apparatus that may be inserted into the nasal cavity, paranasal sinus, nasopharynx or middle ear to perform diagnostic or therapeutic procedures. These devices may be delivered through or incorporated into flexible catheters or flexible rod-like shafts. Such flexible construction allows these devices to be delivered and positioned to perform the desired diagnostic or therapeutic procedures with minimal trauma to other tissues, as can result from the insertion of rigid scopes and rigid instruments in accordance with the methodology of the prior art. It is within the scope of this approach that these devices may be partially flexible or have rigid portions and flexible portions to facilitate their control and guidance to the appropriate region. Further, they may be used in conjunction or combination with other standard rigid apparatus (scopes, etc.) during some part of the procedure, if desired.

[0154] Also, in some but not necessarily all procedures, these working devices (and/or the catheters used to deliver them) may be inserted through lumens of the occluder & access devices 10, 12, 300, 301, 400, 430, etc. as shown in FIGS. 2A-2R and described above. As stated earlier, it may also be desirable to focus the access and occlusion to an even smaller territory, through stand-alone guide catheters or subselective guide catheters with or without balloons or other occluders.

[0155] Optionally, any of the working devices anmd guide catheters described herein may be configured to receive or be advanced over a guidewire unless to do so would render the device inoperable for its intended purpose. Some of the specific examples described herein include guidewires, but it is to be appreciated that the use of guidewires and the incorporation of guidewire lumens is not limited to only the specific examples in which guidewires or guidewire lumens are shown. The guidewires used in this invention may be constructed and coated as is common in the art of cardiology. This may include the use of coils, tapered or non-tapered core wires, radiopaque tips and/or entire lengths, shaping ribbons, variations of stiffness, PTFE, silicone, hydrophilic coatings, polymer coatings, etc. For the scope of this inventions, these wires may possess dimensions of length between 5 and 75 cm and outer diameter between 0.005" and 0.050".

[0156] Also, some of the working devices shown in FIGS. 5A-5Y"" and described herein incorporate assemblies, components or mechanisms (e.g., rotating cutters, radiofrequency electrodes, electrocautery devics, recepacles for capturing matter, cryosurgical apparatus, balloons, stents, radioactive or substance-eluting coatings,

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snares, electro-anatomical mapping and guidance, optical fibers, lenses and other endoscope apparatus, seals, hemostatic valves, etc. The designs and constructions of such components and assemblies are will known in the art. Non-limiting examples of some such designs and constructions are set forth in U.S. Pat. No. 5,722,984 (Fischell et al.), U.S. Pat. No. 5,775,327 (Randolph et al.), U.S. Pat. No. 5,685,838 (Peters, et al.), U.S. Pat. No. 6,013,019 (Fischell et al.), U.S. Pat. No. 5,356,418 (Shturman), U.S. Pat. No. 5,634,908 (Loomas), U.S. Pat. No. 5,255,679 (Imran), U.S. Pat. No. 6,048,299 (Hoffman), U.S. Pat. No. 6,585,794 (Wright et al.), U.S. Pat. No. 6,503,185 (Waksman), U.S. Pat. No. 6,669,689 (Lehmann et al.), U.S. Pat. No. 6,638,233 (Corvi et al.), U.S. Pat. No. 5,026,384 (Farr et al.), U.S. Pat. No. 4,669,469 (Gifford et al.), U.S. Pat. No. 6,685,648 (Flaherty et al.), U.S. Pat. No. 5,250,059 (Andreas et al.), U.S. Pat. No. 4,708,834 (Tsuno), U.S. Pat. No. 5,171,233 (Amplatz), U.S. Pat. No. 6,468,297 (Williams et al.) and U.S. Pat. No. 4,748,869 (Wardle).

[0157] As shown in the examples of FIGS. 5A-5Y"" these working devices include guide catheters, substance delivery catheters, scopes, injectors, cutters, bone breaking apparatus, balloons and other dilators, laser/thermal delivery devices, braces, implants, stents, snares, biopsy tools, forceps, etc.

[0158] FIG. 5A shows a side suction and/or cutting catheter 70 comprising a flexible catheter body 72 having a side opening 74. The catheter 72 is advanced into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. and positioned so that the opening 74 is adjacent to matter (e.g., a polyp, lesion, piece of debris, tissue, blood clot, etc.) that is to be removed. Suction may be applied through a lumen of the catheter 72 to suction the matter through the opening 74 and into the catheter 72. In some cases, a cutter such as a rotating cutter, linear slicer, pincher, laser beam, electrosurgical cutter, etc. may be incorporated into the catheter 72 to assist in severing or ablating tissue or other matter that has been positioned in the side opening 74. This catheter may incorporate a deflectable tip or a curved distal end which may force the opening of the catheter against the tissue of interest. Further, this device 70 may have an optional stabilizing balloon (similar to that shown in FIG. 5M and described herebelow) incorporated on one side of the catheter 72to press it against the tissue of interest and may also contain one or more on-board imaging modalities such as ultrasound, fiber or digital optics, OCT, RF or electro-magnetic sensors or emitters, etc.

[0159] FIG. 5B shows an injector catheter 76 that comprises a flexible catheter shaft 78 having one or more injector(s) 80 that are advanceable into tissue or other matter that is located in or on the wall of the body lumen in which the catheter 78 is positioned. The catheter 78 is advanced, with the injector(s) retracted into the catheter body, through a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. and positioned adjacent the area to which a diagnostic or therapeutic substance is to be injected. Thereafter, the injector(s) are advanced into the adjacent tissue or matter and the desired substance is injected. Energy, such as laser, RF, thermal or other energy may be delivered through these injectors 80 or energy emitting implants (such as gamma or beta radioactive seeds) may also be delivered through these injectors 80, either alone or in combination with a fluid carrier or other substance such as a diagnostic or therapeutic substance (as defined herein). It will be noted that this device 76 as well as other working devices and methods of the present invention (including the various implantable devices described herein) are useable to deliver diagnostic or therapeutic substances. The term "diagnostic or therapeutic substance" as used herein is to be broadly construed to include any feasible drugs, prodrugs, proteins, gene

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therapy preparations, cells, diagnostic agents, contrast or imaging agents, biologicals, etc. For example, in some applications where it is desired to treat or prevent a microbial infection, the substance delivered may comprise pharmaceutically acceptable salt or dosage form of an antimicrobial agent (e.g., antibiotic, antiviral, antiparacytic, antifungal, etc.).

[0160] Some nonlimiting examples of antimicrobial agents that may be used in this invention include acyclovir, amantadine, aminoglycosides (e.g., amikacin, gentamicin and tobramycin), amoxicillin, amoxicillin/Clavulanate, amphotericin B, ampicillin, ampicillin/sulbactam, atovaquone, azithromycin, cefazolin, cefepime, cefotaxime, cefotetan, cefpodoxime, ceftazidime, ceftizoxime, ceftriaxone, cefuroxime, cefuroxime axetil, cephalexin, chloramphenicol, clotrimazole, ciprofloxacin, clarithromycin, clindamycin, dapsone, dicloxacillin, doxycycline, erythromycin, fluconazole, foscarnet, ganciclovir, atifloxacin, imipenem/cilastatin, isoniazid, itraconazole, ketoconazole, metronidazole, nafcillin, nafcillin, nystatin, penicillin, penicillin G, pentamidine, piperacillin/tazobactam, rifampin, quinupristin-dalfopristin, ticarcillin/clavulanate, trimethoprim/sulfamethoxazole, valacyclovir, vancomycin, mafenide, silver sulfadiazine, mupirocin, nystatin, triamcinolone/nystatin, clotrimazole/betamethasone, clotrimazole, ketoconazole, butoconazole, miconazole, tioconazole, detergent-like chemicals that disrupt or disable microbes (e.g., nonoxynol-9, octoxynol-9, benzalkonium chloride, menfegol, and N-docasanol); chemicals that block microbial attachment to target cells and/or inhibits entry of infectious pathogens (e.g., sulphated and sulponated polymers such as PC-515 (carrageenan), Pro-2000, and Dextrin 2 Sulphate); antiretroviral agents (e.g., PMPA gel) that prevent retroviruses from replicating in the cells; genetically engineered or naturally occurring antibodies that combat pathogens such as anti-viral antibodies genetically engineered from plants known as "plantibodies;" agents which change the condition of the tissue to make it hostile to the pathogen (such as substances which alter mucosal pH (e.g., Buffer Gel and Acidform) or non-pathogenic or "friendly" bacteria or other microbes that cause the production of hydrogen peroxide or other substances that kill or inhibit the growth of pathogenic microbes (e.g., lactobacillus). As may be applied to any of the substances listed previously or below, these substances may be combined with any one or more drug-releasing devices or molecular constructs such as polymers, collagen, gels, implantable osmotic pump devices, etc. to permit their release over an extended period of time once deposited. Further, these substances may also be combined with any of the implantable structural devices described below (stents, expanders, etc.) to reduce infection, encrustation, or encapsulation of the implant itself, or to allow the drug to be deposited in the optimal location mucosally, sub-mucosally or into the bone. Examples of implantable substance delivery devices useable in this invention include those shown in FIGS. 5Y'-5Y''''' and described herebelow.

[0161] Additionally or alternatively, in some applications where it is desired to treat or prevent inflamation the substances delivered in this invention may include various steroids. For example, corticosteroids that have previously administered by intranasal administration may be used, such as beclomethasone (Vancenase(R) or Beconase (R)), flunisolide (Nasalide(R)), fluticasone (Flonase(R)), triamcinolone (Nasacort(R)) and mometasone (Nasonex(R)). Also, other steroids that may be useable in the present invention include but are not limited to aclometasone, desonide, hydrocortisone, betamethasone, clocortolone, desoximetasone, fluocinolone, flurandrenolide, mometasone, prednicarbate; amcinonide, desoximetasone, diflorasone, fluocinolone, fluocinonide, halcinonide, clobetasol, augmented betamethasone, diflorasone, halobetasol, prednasone, dexamethasone and

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methylprednisolone,

[0162] Additionally or alternatively, in some applications, such as those where it is desired to treat or prevent an allergic or immune response, the substances delivered in this invention may include a) various cytokine inhibitors such as humanized anti-cytokine antibodies, anti-cytokine receptor antibodies, recombinant (new cell resulting from genetic recombination) antagonists, or soluble receptors; b) various leucotriene modifiers such as zafirlukast, montelukast and zileuton; c) immunoglobulin E (IgE) inhibitors such as Omalizumab (an anti-IgE monoclonal antibody formerly called rhu Mab-E25) and secretory leukocyte protease inhibitor).

[0163] Additionally or alternatively, in some applications, such as those where it is desired to shrink mucosal tissue, cause decongestion or effect hemostasis, the substances delivered in this invention may include various vasoconstrictors for decongestant and or hemostatic purposes including but not limited to pseudoephedrine, xylometazoline, oxymetazoline, phenylephrine, epinephrine, etc.

[0164] Additionally or alternatively, in some applications, such as those where it is desired to facilitate the flow of mucous, the substances delivered in this invention may include various mucolytics or other agents that modify the viscosity or consistency of mucous or mucoid secretions, including but not limited to acetylcysteine (Mucomyst (TM), Mucosil(TM)) and guaifenesin.

[0165] Additionally or alternatively, in some applications such as those where it is desired to prevent or deter histamine release, the substances delivered in this invention may include various mast cell stabilizers or drugs which prevent the release of histamine such as cromolyn (e.g., Nasal Chrom(R)) and nedocromil.

[0166] Additionally or alternatively, in some applications such as those where it is desired to prevent or inhibit the effect of histamine, the substances delivered in this invention may include various antihistamines such as azelastine (e.g., Astylin(R)), diphenhydramine, loratidine, etc.

[0167] Additionally or alternatively, in some embodiments such as those where it is desired to dissolve, degrade, cut, break or remodel bone or cartilage, the substances delivered in this invention may include substances that weaken or modify bone and/or cartilage to facilitate other procedures of this invention wherein bone or cartilage is remodeled, reshaped, broken or removed. One example of such an agent would be a calcium chelator such as EDTA that could be injected or delivered in a substance delivery implant next to a region of bone that is to be remodeled or modified. Another example would be a preparation consisting or or containing bone degrading cells such as osteoclasts. Other examples would include various enzymes of material that may soften or break down components of bone or cartilage such as collagenase (CGN), trypsin, trypsin/EDTA, hyaluronidase, and tosylilysylchloromethane (TLCM).

[0168] Additionally or alternatively, in some applications, the substances delivered in this invention may include other classes of substances that are used to treat rhinitis, nasal polyps, nasal inflammation, and other disorders of the ear, nose and throat including but not limited to anticolinergic agents that tend to dry up nasal secretions such as ipratropium (Atrovent Nasal(R)), as well as other agents not listed here.

[0169] Additionally or alternatively, in some applications such as those where it is

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desired to draw fluid from polyps or edematous tissue, the substances delivered in this invention may include locally or topically acting diuretics such as furosemide and/or hyperosmolar agents such as sodium chloride gel or other salt preparations that draw water from tissue or substances that directly or indirectly change the osmolar content of the mucous to cause more water to exit the tissue to shrink the polyps directly at their site.

[0170] Additionally or alternatively, in some applications such as those wherein it is desired to treat a tumor or cancerous lesion, the substances delivered in this invention may include antitumor agents (e.g., cancer chemotherapeutic agents, biological response modifiers, vascularization inhibitors, hormone receptor blockers, cryotherapeutic agents or other agents that destroy or inhibit neoplasia or tumorigenesis) such as; alkylating agents or other agents which directly kill cancer cells by attacking their DNA (e.g., cyclophosphamide, isophosphamide), nitrosoureas or other agents which kill cancer cells by inhibiting changes necessary for cellular DNA repair (e.g., carmustine (BCNU) and lomustine (CCNU)), antimetabolites and other agents that block cancer cell growth by interfering with certain cell functions, usually DNA synthesis (e.g., 6 mercaptopurine and 5-fluorouracil (5FU), antitumor antibiotics and other compounds that act by binding or intercalating DNA and preventing RNA synthesis (e.g., doxorubicin, daunorubicin, epirubicin, idarubicin, mitomycin-C and bleomycin) plant (vinca) alkaloids and other anti-tumor agents derived from plants (e.g., vincristine and vinblastine), steroid hormones, hormone inhibitors, hormone receptor antagonists and other agents which affect the growth of hormone-responsive cancers (e.g., tamoxifen, herceptin, aromatase ingibitors such as aminoglutethamide and formestane, trriazole inhibitors such as letrozole and anastrazole, steroidal inhibitors such as exemestane), antiangiogenic proteins, small molecules, gene therapies and/or other agents that inhibit angiogenesis or vascularization of tumors (e.g., meth-1, meth-2, thalidomide), bevacizumab (Avastin), squalamine, endostatin, angiostatin, Angiozyme, AE-941 (Neovastat), CC-5013 (Revimid), medi-522 (Vitaxin), 2-methoxyestradiol (2ME2, Panzem), carboxyamidotriazole (CAI), combretastatin A4 prodrug (CA4P), SU6668, SU11248, BMS-275291, COL-3, EMD 121974, IMC-1C11, IM862, TNP-470, celecoxib (Celebrex), rofecoxib (Vioxx), interferon alpha, interleukin-12 (IL-12) or any of the compounds identified in Science Vol. 289, Pages 1197-1201 (Aug. 17, 2000) which is expressly incorporated herein by reference, biological response modifiers (e.g., interferon, bacillus calmette-guerin (BCG), monoclonal antibodies, interluken 2, granulocyte colony stimulating factor (GCSF), etc.), PGDF receptor antagonists, herceptin, asparaginase, busulphan, carboplatin, cisplatin, carmustine, cchlorambucil, cytarabine, dacarbazine, etoposide, flucarbazine, flurouracil, gemcitabine, hydroxyurea, ifosphamide, irinotecan, lomustine, melphalan, mercaptopurine, methotrexate, thioguanine, thiotepa, tomudex, topotecan, treosulfan, vinblastine, vincristine, mitoazitrone, oxaliplatin, procarbazine, streptocin, taxol, taxotere, analogs/congeners and derivatives of such compounds as well as other antitumor agents not listed here.

[0171] Additionally or alternatively, in some applications such as those where it is desired to grow new cells or to modify existing cells, the substances delivered in this invention may include cells (mucosal cells, fibroblasts, stem cells or genetically engineered cells) as well as genes and gene delivery vehicles like plasmids, adenoviral vectors or naked DNA, mRNA, etc. injected with genes that code for anti-inflammatory substances, etc., and, as mentioned above, osteoclasts that modify or soften bone when so desired.

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[0172] Additionally or alternatively to being combined with a device and/or a substance releasing modality, it may be ideal to position the device in a specific location upstream in the mucous flow path (i.e. frontal sinus or ethmoid cells). This could allow the deposition of fewer drug releasing devices, and permit the "bathing" of all the downstream tissues with the desired drug. This utilization of mucous as a carrier for the drug may be ideal, especially since the concentrations for the drug may be highest in regions where the mucous is retained; whereas non-diseased regions with good mucouse flow will be less affected by the drug. This could be particularly useful in chronic sinusitis, or tumors where bringing the concentration of drug higher at those specific sites may have greater therapeutic benefit. In all such cases, local delivery will permit these drugs to have much less systemic impact. Further, it may be ideal to configure the composition of the drug or delivery system such that it maintains a loose affinity to the mucous permitting it to distribute evenly in the flow. Also, in some applications, rather than a drug, a solute such as a salt or other mucous soluble material may be positioned at a location whereby mucous will contact the substance and a quantity of the substance will become dissolved in the mucous thereby changing some property (e.g., pH, osmolarity, etc) of the mucous. In some cases, this technique may be used to render the mucous hyperosmolar so that the flowing mucous will draw water from polyps, edematous mucosal tissue, etc. thereby providing a desiccating therapeutic effect.

[0173] Additionally or alternatively to substances directed towards local delivery to affect changes within the sinus cavity, the nasal cavities provide unique access to the olfactory system and thus the brain. Any of the devices and methods described herein may also be used to deliver substances to the brain or alter the functioning of the olfactory system. Such examples include, the delivery of energy or the deposition of devices and/or substances and/or substance delivering implant(s) to occlude or alter olfactory perception, to suppress appetite or otherwise treat obesity, epilepsy (e.g., barbiturates such as phenobarbital or mephoobarbital; iminostilbenes such as carbamazepine and oxcarbazepine; succinimides such as ethylsuximide; valproic acid; benzodiazepines such as clonazepam, clorazepate, diazepam and lorazepam, gabapentin, lamotrigine, acetazolamide, felbamate, levetiraceam, tiagabine, topiramate, zonisamide, etc.), personality or mental disorders (e.g., antidepressants, antianxiety agents, antipsychotics, etc.), chronic pain, Parkinson's disease (e.g., dopamine receptor agonists such as bromocriptine, pergolide, ropinitrol and pramipexole; dopamine precursors such as levodopa; COMT inhibitors such as tolcapone and entacapone; selegiline; muscarinic receptor antagonists such as trihexyphenidyl, benztropine and diphenhydramine) and Alzheimer's, Huntington's Disease or other dementias, disorders of cognition or chronic degenerative diseases (e.g. tacrine, donepezil, rivastigmine, galantamine, fluoxetine, carbamazepine, clozapine, clonazepam and proteins or genetic therapies that inhibit the formation of beta-amyloid plaques), etc.

[0174] FIG. 5C shows a device 82 that comprises a rotating shaft 84 having a drill, auger or burr 86 that is useable to drill, bore, grind or cut through tissue, bone, cartilage or other matter. This device 82 may deployed as shown or, alternatively, the device 82 may be inserted through a small mucosal incision to preserve the overlying mucosal lining while removing or boring into the bone or cartilage below the mucosal lining.

[0175] FIG. 5D shows a guided injector catheter device 88 for delivering a diagnostic or therapeutic substance as defined above. This device 88 comprises a flexible catheter 90 having an imaging apparatus 96 thereon and an injector 92 that is advanceable from

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and retractable into the catheter 90. The imaging apparatus 96 is useable to image the target location 94 at which the substance is to be deposited and to enable orientation of the catheter 88 such that, when the injector 92 is advanced from the catheter 88, the injector 92 will travel to the desired target location 94. Examples of such catheter 88 are described in U.S. Pat. No. 6,195,225 (Makower), U.S. Pat. No. 6,544,230 (Flaherty et al.), U.S. Pat. No. 6,375,615 (Flaherty et al.), U.S. Pat. No. 6,302,875 (Makower et al), U.S. Pat. No. 6,190,353 (Makower et al.) and U.S. Pat. No. 6,685,648 (Flaherty et al.), the entireties of which are expressly incorporated herein by reference.

[0176] FIG. 5E shows a balloon catheter device 98 comprising a flexible catheter 100 having a balloon 102 thereon. The catheter device 98 is advanced, with balloon 102 deflated, into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. and positioned with the deflated balloon 102 situated within an ostium, passageway or adjacent to tissue or matter that is to be dilated, expanded or compressed (e.g., to apply pressure for hemostasis, etc.). Thereafter, the balloon 102 may be inflated to dilate, expand or compress the ostium, passageway, tissue or matter. Thereafter the balloon 102 may be deflated and the device 98 may be removed. This balloon 102 may also be coated, impregnated or otherwise provided with a medicament or substance that will elute from the balloon into the adjacent tissue (e.g., bathing the adjacent tissue with drug or radiating the tissue with thermal or other energy to shrink the tissues in contact with the balloon 102). Alternatively, in some embodiments, the balloon may have a plurality of apertures or openings through which a substance may be delivered, sometimes under pressure, to cause the substance to bathe or diffuse into the tissues adjacent to the balloon. Alternatively, in some embodiments, radioactive seeds, threads, ribbons, gas or liquid, etc. may be advanced into the catheter shaft 100 or balloon 102 or a completely separate catheter body for some period of time to expose the adjacent tissue and to achieve a desired diagnostic or therapeutic effect (e.g. tissue shrinkage, etc.).

[0177] FIG. 5F shows a balloon/cutter catheter device 104 comprising a flexible catheter 106 having a balloon 108 with one or more cutter blades 110 formed thereon. The device 104 is advanced, with balloon 108 deflated, into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. and positioned with the deflated balloon 108 situated within an ostium, passageway or adjacent to tissue or matter that is to be dilated, expanded or compressed and in which it is desired to make one or more cuts or scores (e.g. to control the fracturing of tissue during expansion and minimize tissue trauma etc.). Thereafter, the balloon 108 may be inflated balloon to dilate, expand or compress the ostium, passageway, tissue or matter and causing the cutter blade(s) 110 to make cut(s) in the adjacent tissue or matter. Thereafter the balloon 108 may be deflated and the device 104 may be removed. The blade may be energized with mono or bi-polar RF energy or simply be thermally heated to part the tissues in a hemostatic fashion, as well as cause contraction of collagen fibers or other connective tissue proteins, remodeling or softening of cartilage, etc.

[0178] FIGS. 5G'-5G"' show a device 160 and method for delivery of a pressure expandable stent 166. This device 160 comprises a flexible catheter 162 having a balloon 164 thereon. Initially, as shown in FIG. 5G', the balloon 164 is deflated and the stent 166 is radially compressed to a collapsed configuration, around the deflated balloon 164. The catheter 162 with the balloon 164 deflated and the collapsed stent 166 mounted thereon is advanced into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. that is to be stented. Thereafter, the balloon 164 is inflated causing the stent 166 to expand to a size that frictionally engages the

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surrounding tissue so as to hold the stent 166 in place, as shown in FIG. 5G". In some instances the procedure will be performed for the purpose of enlarging a passageway (e.g., an ostium, meatus, etc.) and the stent 166 will be expanded to a diameter that is sufficiently large to cause the desired enlargement of the passageway and the stent will then perform a scaffolding function, maintaining the passageway in such enlarged condition. After the stent 166 has been fully expanded and implanted, the balloon 164 may be deflated and the catheter 162 removed as shown in FIG. 5G'". In some applications, the stent may contain a diagnostic or therapeutic substance as defined herein and such substance may elute from the stent 166 into the surrounding tissue to bring about a desired diagnostic or therapeutic effect. In some cases, the stent 166 may be permanently implanted. In other cases the stent 166 may be temporarily implanted. In cases where the stent 166 is temporarily implanted, it may be removed in a second procedure conducted to retrieve the stent 166 or the stent 166 may be made of bioabsorbable or biodegradable material such that it degrades or is absorbed within a desired period of time after implantation. In some cases, such as when the stent is to be placed within the ostium of a paranasal sinus, the stent and/or the balloon may be specifically shaped to facilitate and/or cause the stent 166 to seat in a desired position and to prevent unwanted slippage of the stent 166. For example, the stent 166 and/or balloon 164 may have an annular groove formed about the middle thereof or may be hourglass or venture shaped, to facilitate seating of the stent 166 within an ostium or orifice without longitudinal slippage of the stent 166. In some cases it may be desirable to leave a tether or suture attached to the stent 166 to allow for simple removal of the stent 166 in the physician's office or other suitable location. In some cases the procedure may be intended to actually break bone (e.g., where the stent is intended to dilate or enlarge a sinus ostium). Thus, the balloon 164 may be made of polymeric material including, but not limited to flexible polyvinyl chloride (PVC), polyethylene terephthalate (PET), cross-linked polyethylene, polyester, polyamide, polyolefin, polyurethane and silicone. Various balloon properties (strength, flexibility, thickness, etc.) may be modified by, but not limited to, blending, layering, mixing, co-extruding, irradiating, and other means of engineering balloon material(s). This allows for the use of compliant balloons that can conform to the surrounding structure or non-compliant balloons that can deform or break the surrounding structures (e.g., bone).

[0179] FIG. 5H shows an electrosurgical device 208 comprising a flexible shaft 210 (e.g., a catheter or solid shaft) having arched strut members 214 attached thereto. Electrodes 216 are located on the strut members 214. In some cases, the strut members may be of fixed configuration and in other cases the strut members 214 may be collapsible and expandable. In operation, the device 208 is advanced into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. Thereafter, current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated. The electrodes 216 may be bipolar, monopolar or facilitated by any other suitable form of energy such as a gas or plasma arc. Additionally, sensing elements may also be attached to the catheter and/or strut members to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.). In instances where monopolar electrodes are used, a separate antenna electrode (not shown) will be applied to the patient's body in accordance with processes and techniques that are well known in the art.

[0180] FIG. 5I shows a device 218 that delivers a flow 222 of material (e.g., cryogenic material, diagnostic or therapeutic agent, etc.) or energy (laser light, infrared light, etc.) to the tissues adjacent to the passage or body cavity in which the device 218 is positioned. This device comprises a flexible catheter 220 with an outlet aperture or lens

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at or near its distal end, through which the flow of material or energy is delivered. This device may be used to cryogenically freeze polyps or other tissues or to deliver laser energy to turbinates or other tissues for the purpose of ablating the tissue or to heat the tissue to a temperature that results in shrinking of the tissue.

[0181] FIG. 5J shows an implantable pressure exerting device 224 that is implantable within a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. to exert pressure on bone, cartilage, soft tissue, etc. Examples of situations where it is desirable to apply such pressure to an anatomical structure include those wherein it is desired to splint or maintain approximation of a broken bone or those wherein it is desired to cause remodeling or gradual repositioning or reshaping of bone, cartilage, soft tissue or other structures. This implanatble device 224 comprises a pressure exerting member 228 and two or more plate members 226. The device 224 is initially constrained in a collapsed configuration wherein the pressure exerting member 228 is compressed or collapsed and the device 224 is advanced into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. where it is desired to apply pressure to an anatomical structure. When the device 224 is in the desired position, the pressure exerting member 228 is expanded or elongated to exert outward pressure on the plate members 226 and onto the anatomical structures against which the plate members 226 are positioned. In some embodiments, the pressure exerting member may comprise a spring. In other embodiments, the pressure exerting member may comprise a ratchet, hydraulic cylinder or other mechanical apparatus that may be adjusted to create a desired amount of pressure on the plate members 226. In some applications, the pressure exerting member 228 may be adjustable in situ (i.e., with the device implanted in the body) so as to allow the operator to periodically change the amount of pressure being applied to the anatomical structures of interest (e.g., the operator may change to position of a ratchet or add fluid to a hydraulic cylinder) thereby bringing about gradual remodeling or movement of an anatomical structure in a manner similar to that achieved during dental orthodontia. Thus, this pressure exerting device 224 has broad applicability in a variety of procedures including those intended to enlarge a sinus ostium or to straighten an intranasal septum.

[0182] FIGS. 5K-5K' and 5L show a forward rotary cutting catheter device 700 that comprises a flexible outer tube 702 and a flexible inner tube 704 disposed coaxially and rotatably mounted within the outer tube 702. One or more bearings 708 (e.g., a helical bearing or a series of individual cylindrical bearings) may be disposed between the outer tube 702 and inner tube 704, as shown. Alternatively, one or both apposing tube surfaces may be made of, lined with, or be coated by etc. a lubricious material such as silicone or PTFE to facilitate movement. A rotating cutter 706 is positioned on the distal end of the inner tube 704. In operation, as shown in FIG. 5K', the device 700 is advanced through a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. to a position where the distal end of the device 700 is positioned just behind some obstructive matter, such as a polyp P. The inner tube 704 and its cutter 706 are rotated as the device is advanced into the obstructive matter P and/or suction is applied through the lumen of the inner tube 704 and/or through the lumen of the outer tube 702 to draw the obstructive matter P into contact with the rotating cutter 706. It is to be appreciated that, although this embodiment shows a rotating cutter 706, various other types of cutters such as lasers, radiofrequency cutters and other mechanical cutters, etc. may be used instead. As the obstructive matter P is severed by the rotating cutter 706 the obstructive matter P or pieces thereof may be suctioned through the lumen of the inner tube 704 and/or through the lumen of the outer tube 702. In some applications, as shown in FIG. 5L, a scope or guidewire 710 may extend

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through the lumen of the inner tube to facilitate advancement and positioning of the device 700 prior to the removal of the obstructive matter P.

[0183] FIGS. 5M and 5N show a side rotary cutting device 714 comprising a flexible outer tube 718and a flexible inner tube 722 that is disposed coaxially and rotatably mounted within the outer tube 718. One or more bearings 730 (e.g., a helical bearing or a series of individual cylindrical bearings) may be disposed between the outer tube 718 and inner tube 722, as shown. Alternatively, one or both apposing tube surfaces may be made of, lined with, or be coated by etc. a lubricious material such as silicone or PTFE to facilitate movement. A rotating cutter 724 is positioned on the distal end of the inner tube 722. A side opening 720 is formed in the outer tube 718 and the cutter 724 is positioned proximal to the side opening 720. A pull member 728 extends through the inner tube 722 and is attached to a retractor head 726. In operation, the device 714 is advanced and/or torqued to a position where the side opening 720 is near a polyp, tissue or other obstructive matter to be removed. The inner tube 722 and its cutter 724 are rotated. In some applications, suction may be applied through the inner tube 722 and/or through the lumen of the outer tube 718 to draw the obstructive matter into the side opening 720. The pull member 728 is pulled in the proximal direction, causing the retractor head 726 to retract or pull the obstructive matter into contact with the rotating cutter 724. As the obstructive matter is severed by the rotating cutter, the severed obstructive matter or pieces thereof may be suctioned through the lumen of the inner tube 722 and/or through the lumen of the outer tube 718. The pull member 728 may then be advanced in the distal direction to return the retractor head 726 to its original position as shown in FIGS. 5M and 5N. An optional balloon 719 or other laterally extendable member may be located on the side of the catheter 718 opposite the side opening 720 to push the side opening 720 against a lumen wall or into the direction of a polyp or other tissue to be removed. Alternatively, the catheter may incorporate a deflectable tip or a curved distal end that may force the side opening of the catheter against a lumen wall or into the direction of a polyp or other tissue to be removed. With specific reference to FIG. 5N, there is shown a side rotary cutting device 714a that includes all of the elements of the device 714 shown in FIG. 5M, but includes a side lumen 731. A scope may be permanently positioned within this side lumen 731 or a scope may be temporarily inserted into (or through) the side lumen 731 to enable the operator to view the area near the side opening 720 and to facilitate the advancement and positioning of the device 714A. Also, the side lumen 731 may function as a guidewire lumen to allow the device 714A to be advanced over a guidewire.

[0184] It is to be understood that any of the devices described within this document may be further modified to include any one of the following devices within its structure: electromagnetic positioning sensor/detector (Biosense/JNJ, Surgical Navigation Technologies/Medtronic, Calypso Medical), RF sensor/transmitter, magnetic direction localizer (Stereotaxis, Inc.), thermal sensor, radiopaque composition, radioactive detection emitter/sensor, ultrasonic scanner/transmitter/receiver, Doppler scanner, electrical stimulator, fiber optic, digital optic, local diagnostic chip containing elements responsive to the presence or absence of certain substances and therefore having the ability to diagnose the presence of fungus, microbes, viruses, blood, abnormal mucous content, cancer cells, drugs of abuse, genetic abnormalities, metabolic bi-products, etc.

[0185] It is to be further understood that any and all of the devices described in this patent application may incorporate, or may be used in conjunction with, endoscopes. Such endoscopes will typically include light transmitting optical fibers for casting light in the area to be viewed by the scope and image transmitting optical fibers for carrying an

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image received by the scope to an eyepiece or monitor device located outside the patient's body. In some embodiments a scope, such as a disposable and/or flexible scope, may be affixed to the working device. Examples of such endoscopes that are suitable for incorporation into the working devices of this invention include that described in U.S. Pat. Nos. 4,708,434; 4,919,112; 5,127,393; 5,519,532; 5,171,233, 5,549,542, 6,551,239 and 6,572,538 as well as published U.S. Patent Application No. 2001/0029317A1, the entireties of which are expressly incorporated herein by reference.

[0186] It is to be further understood that any catheters or elongate flexible devices of this invention may include design elements that impact performance features which include, but are not limited to, durability, flexibility, stiffness, length, profile, lubricity, trackability, steerability, torqueability, deflectability, guidance, and radiopacity. Design elements can include, but are not limited to, use of various polymers and metals, use of varying durometer materials to establish a desired flexibility gradient along the device, blending/mixing/layering/co-extruding etc. various materials, using bearings or lubricious coatings or lubricious materials (e.g., silicone, PTFE, parylene, polyethene, etc.) where two or more surfaces will move relative to each other (e.g., guidewire or instrument lumen, deflecting tendon in lumen, etc.), use of braiding or springs to increase torque control over the device, using materials (e.g. barium, tantalum, etc.) to increase polymer radiopacity, and use of elements to predictably deflect various sections of the catheter (e.g., tension straps or wires, shape memory alloys such as nitinol, etc.).

[0187] It is to be further understood that any of the catheters, scopes, elongate working devices or other devices disclosed in this patent application may be rendered steerable or volitionally bendable, unless to do so would make such device inoperative for its intended purpose. Steerable catheters and scopes are well known in the art and may utilize mechanical steering assemblies (e.g., pull wires, hinges, etc.) or shape memory materials (e.g., nickel titanium alloys, shape memory polymers, etc.) to induce the device to undergo the desired bending or curvature after it has been inserted into the body. Examples of apparatus and construction that may be used to render these devices steerable or volitionally bendable include but are not limited to those described in U.S. Pat. No. 5,507,725 (Savage et al.), U.S. Pat. No. 5,656,030 (Hunjan et al.), U.S. Pat. No. 6,183,464 (Webster), U.S. Pat. No. 5,251,092 (Qin et al.), U.S. Pat. No. 6,500,130 (Kinsella et al.), U.S. Pat. No. 6,571,131 (Nguyen), U.S. Pat. No. 5,415,633 (Lazarus et al.), U.S. Pat. No. 4,998,916 (Hammerslag et al.), U.S. Pat. No. 4,898,577 (Badger et al.), U.S. Pat. No. 4,815,478 (Buchbinder et al.) and publised U.S. Patent Applications No. 2003/0181827A1 (Hojeibane et al.) and 2003/0130598A1 (Manning et al.), the entirities of which are expressly incorporated herein by reference.

[0188] FIG. 5O shows a flexible catheter 733 having a working lumen 734 that extends though the catheter 732 and terminates in a distal end opening. Optionally, a second lumen 736 may also extend though the catheter 732 and terminate in a distal end opening, as shown. An endoscope 738 may be permanently positioned within this lumen 736 or such endoscope 738 may be temporarily inserted into (or through) the lumen 736 to enable the operator to view the area distal to the catheter 732. Additionally or alternatively, a side scope or lumen 740 may be located on the catheter 732 and an endoscope may be permanently embodied by or positioned in or temporarily inserted into (or through) such side scope or lumen 740 to enable the operator to view the area distal to the catheter 732 and, in at least some cases, the distal end of the catheter 732 itself. In any devices which incorporate such optional side

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scope or lumen 740, the side scope or lumen 740 may be of any suitable length and may terminate distally at any suitable location and such side scope or lumen 740 is not limited to the specific positioning and the specific distal end location shown in the drawings. Also, in embodiments that incorporate a side scope or lumen 740 such side lumen may be employed as a guidewire or working lumen to permit the catheter to be advanced over a guidewire or for other working devices to be inserted therethrough.

[0189] FIG. 5P shows a balloon catheter and pressure expandable stent system 744 which includes all of the elements of the balloon expandable stent system shown in FIGS. 5G'-5G"' and, in addition, may incorporate an endoscope or side lumen. Specifically, referring to FIG. 5P, there is shown a balloon catheter and pressure expandable stent system 744 that comprises a flexible catheter 746 having a balloon 750 and pressure expandable stent 748 thereon. A side lumen 756 may be located on the catheter 746 and an endoscope may be permanently positioned in or temporarily inserted into (or through) such side lumen 756 to enable the operator to view the balloon 750 and stent 748 and to advance the catheter 749 to its desired position. Also, in embodiments that incorporate a side lumen 756 such side lumen may be employed as a guidewire lumen to permit the catheter 746 to be advanced over a guidewire. Optionally, a lumen may extend through the catheter 746 and through an opening 752 in the distal end of the catheter 749 and a straight, curved, bendable, deflectable or steerable scope and/or stent 754 may be passed through or received in that lumen to facilitate over the wire and/or scope assisted and/or guided and/or manipulated advancement of the catheter 749 to an intended location. In routine use, the balloon 750 is initially deflated and the stent 748 is radially compressed to a collapsed configuration, around the deflated balloon 750. The catheter 746 with the balloon 750 deflated and the collapsed stent 748 mounted thereon is advanced, under endoscopic guidance or over a guidewire, to a position within a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. that is to be stented. Thereafter, the balloon 750 is inflated causing the stent 748 to expand to a size that frictionally engages the surrounding tissue so as to hold the stent 748 in place. In some instances the procedure will be performed for the purpose of enlarging a passageway (e.g., an ostium, meatus, etc.) and the stent 748 will be expanded to a diameter that is sufficiently large to cause the desired enlargement of the passageway and the stent 748 will then perform a scaffolding function, maintaining the passageway in such enlarged condition. After the stent 748 has been fully expanded and implanted, the balloon 750 may be deflated and the catheter 748 removed. In some applications, the stent 748 may contain a diagnostic or therapeutic substance as defined herein and such substance may elute from the stent 748 into the surrounding tissue to bring about a desired diagnostic or therapeutic effect. In some cases, the stent 748 may be permanently implanted. In other cases the stent 748 may be temporarily implanted. In cases where the stent 748 is temporarily implanted, it may be removed in a second procedure conducted to retrieve the stent 748 or the stent 748 may be made of bioabsorbable or biodegradable material such that it degrades or is absorbed within a desired period of time after implantation. As shown in the examples of FIGS. 5R' and 5R", in some cases, such as when a stent is to be placed within the ostium of a paranasal sinus, the stent and/or the balloon may be specifically shaped to facilitate and/or cause the stent to seat in a desired position and to prevent unwanted slippage of the stent. For example, FIG. 5R' shows a device 1040 comprising a catheter 1042 having a balloon 1044 and stent 1046 mounted thereon as described above. However, in this embodiment, the balloon 1044 and stent 1046 are of a configuration where one end of the balloon 1044 and stent 1046 is larger in diameter than the other end. As described above in connection with other embodiments such as those shown in FIGS.

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5P and 5Q, a side scope or side lumen 1048 may optionally be formed on the catheter 1042 and/or a scope or guidewire 1050 may optionally be passed through a lumen of the catheter 1042 and out of its distal end. FIG. 5R" shows another device 1052 comprising a catheter 1054 having a balloon 1056 and stent 1058 mounted thereon as described above. However, in this embodiment, the balloon 1056 and stent 1058 are of a configuration where both ends of the balloon 1056 and stent 1058 are larger in diameter than the middle of the balloon 1056 and stent 1058. As a result, the stent 1058 has an annular groove or indentation formed circumferentially or about the mid-portion thereof or may be hourglass or venture shaped, to facilitate seating of the stent 1058 within an ostium or orifice without longitudinal slippage of the stent 1058. Again, as described above in connection with other embodiments such as those shown in FIGS. 5P and 5Q, a side scope or side lumen 1060 may optionally be formed on the catheter 1052 and/or a scope or guidewire 1062 may optionally be passed through a lumen of the catheter 1054 and out of its distal end. In cases where the procedure is intended to actually break bone (e.g., where the stent 1046, 1058 is intended to dilate or enlarge a sinus ostium) the specially shaped balloon 1044, 1056 may be made of strong polymeric material as described hereabove to enable it to exert bone-breaking pressure on the adjacent or surrounding bone as it is inflated.

[0190] FIGS. 5Q and 5Q' show a self expanding stent and delivery system 760 comprising a flexible outer sheath 762, a flexible inner tube 764 and a stent 768. This stent differs from the stent 748 of FIG. 5P only in that it is resilient and self-expanding rather than pressure expandable. The stent 768 is biased to an expanded configuration. Initially, it is compressed to a radially collapsed configuration on the outer surface of the inner tube 764 and the outer sheath 762 is advanced over the stent 768 to constrain the stent 768 in its collapsed configuration, as can be seen in the cross-sectional showing of FIG. 5Q'. A scope and/or guidewire 770 may be inserted through the lumen of the inner tube 764. Additionally or alternatively, a side lumen 772 may be located on the outer sheath 762 and an endoscope may be permanently positioned in or temporarily inserted into (or through) such side lumen 772 to enable the operator to view the distal portion of the system 760 and the area ahead of the distal end of the sheath 762 as the system is advanced. Also, in embodiments that incorporate a side lumen 772 such side lumen 772 may be employed as a guidewire lumen to permit the system 760 to be advanced over a guidewire. In routine operation the system 760, with its sheath 762 in a distally advanced position such that it surrounds and constrains the collapsed stent 768, is advanced, under endoscopic guidance and/or over a guidewire, to a position within a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. that is to be stented. Thereafter, when the stent 768 is positioned at the location to be stented, the sheath 762 is withdrawn, allowing the self-expanding stent 768 to spring or self expand to a radially expanded configuration in which it frictionally engages the surrounding anatomical structure. Thereafter, the remainder of the system 760 is removed, leaving the stent 768 implanted in the body. The stent 768 may perform dilation and scaffolding and/or substance delivery function (s) as described hereabove with respect to the pressure expandable stent 748 of FIG. 5P.

[0191] FIG. 5S shows a snare apparatus 780 comprising a flexible catheter 782 having a lumen 784 extending therethrough. A snare 786 having a general loop shape is advanceable out of the lumen 784 of the device 780. In some embodiments, the snare 786 may optionally be charged with electrical current or otherwise heated so that it performs a cauterization function as it cuts through tissue. Additionally or alternatively, in some embodiments, the snare 786 may be of variable diameter (e.g., a noose that

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may be tightened or loosened by the operator). Also, optionally, a scope or side lumen 788 may be located on the catheter 782 and a stationary or moveable endoscope may be permanently embodied in or temporarily inserted into (or through) such side lumen 788 to enable the operator to view the distal portion of the device 780 and the area of the snare 786. Also, in embodiments where the scope or side lumen 780 comprises a side lumen, such side lumen 788 may be employed as a guidewire lumen to permit the device 780 to be advanced over a guidewire. Alternatively, multiple lumens may run through catheter 782 such that they can accommodate a snare, a guidewire and/or an endoscope. In routine operation, the snare 786 is initially retracted within lumen 784 and the device 780 is advanced under endoscopic guidance and/or over a guidewire, to a position within a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. where a polyp or other matter to be snared or cut away is located. The snare 786 is advanced out of lumen 784 and positioned around the polyp or other matter and, thereafter, the snare may be pulled or moved, heated (if equipped for heating) and/or tightened (if equipped for tightening) so as to sever or cut the polyp or other matter. In some cases, the severed polyp or other matter bay be suctioned through the lumen 784. In other cases, a separate catheter or device may be introduced to retrieve the severed polyp or other matter. After completion of the procedure, the snare 786 may be retracted into lumen 784 and the device 780 may be removed. Also, in some embodiments, the snare 786 may be replaced by a basket, bag or other retrieval receptacle that is useable to capture and retrieve tissue or other matter and to withdraw it into the lumen of the catheter 782.

[0192] FIG. 5T shows a forceps device 790 which comprises a flexible shaft 792 having jaws or forceps 794 thereon. The jaws or forceps 794 may be volitionally opened and closed by the operator. A scope or side lumen 796 may be located on the flexible shaft 792, as shown. In embodiments where the scope or side lumen 792 comprises a scope, such scope may be fixed or moveable and may be used to observe or view the advancement of the device 790 and/or the use of the forceps 794. In embodiments where the scope or side lumen 796 comprises a side lumen, a stationary or moveable endoscope may be permanently embodied in or temporarily inserted into (or through) such side lumen 796 to enable the operator to view the distal portion of the device 790 and the area of the forceps 794. Also, in embodiments where the scope or side lumen 796 comprises a side lumen, such side lumen 796 may be employed as a guidewire lumen to permit the device 790 to be advanced over a guidewire. In routine operation, the device 790 is advanced, either alone or through the lumen of a catheter, and possibly under endoscopic guidance and/or over a guidewire, to a position within a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. where matter is to be grasped by the forceps. Thereafter, under optional endoscopic guidance and observation, the forceps 794 are used to grasp the intended matter. In some embodiments, a distal portion of the flexible shaft 792 may be bendable or steerable as indicated by doted lines on the example of FIG. 5T. In some embodiments, the jaws of the forceps 794 may be designed to sever and retain a specimen of tissue for biopsy or other tissue sampling applications or the forceps 794 may comprise scissors for cutting tissue, cartilage, bone, etc. Alternatively, a lumen may pass through flexible shaft 792 and exit through or next to the forceps 794 and allow the passage of a guidewire or endoscope through such lumen.

[0193] FIGS. 5U and 5U' show a telescoping system 800 comprising a flexible catheter 802, a flexible scope 804 and a guidewire 806. The flexible scope 804 comprises a plurality of light transmitting pathways 808 (e.g., optical fibers) that transmit light in the distal direction from a light source (not shown) and out of the distal end of the scope

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804 such that the light is cast onto the object or anatomical structure to be viewed. Also, the scope comprises an image transmitting pathway 810 (e.g., optical fiber and lens) that carries reflected light from distal end of the scope to an eyepiece or monitor on which the image may be viewed. The scope also has a guidewire lumen 805 extending therethrough and opening through its distal end. The scope 804 is advanceable through the flexible catheter 802 and a guidewire 806 that is advanceable through a guidewire lumen 805 of the scope, as shown. In routine operation, the telescoping system 800 may be inserted into the nose and the scope 804 may be utilized to view an anatomical structure, such as the ostium of a paranasal sinus, and facilitate advancement of the guidewire into that anatomical structure. Thereafter, the scope may be advanced over the guidewire and into the anatomical structure (e.g., though the ostium and into the interior of the paranasal sinus). The scope may then be used to examine the anatomical structure (e.g., to view the condition of the mucosa lining the paranasal sinus and to look for signs of infection, tumors, etc.) The catheter 802 may then be advanced over the scope 804 and into the anatomical structure (e.g., the catheter tip may be advanced through the ostium and into the paranasal sinus). Thereafter, the scope 804 may be removed and a diagnostic or therapeutic substance as defined hereabove may be infused through the catheter 802 and/or another working device, including but not limited to the working devices shown in FIGS. 5A-5T and 5V-5Y"", may be advanced through the catheter 802 and into the anatomical structure where it is used to perform a diagnostic or therapeutic function.

[0194] FIG. 5V shows a side port suction/cutting device 820 which comprises a flexible outer tube 822, a flexible inner tube 830 is disposed coaxially and rotatably mounted within the outer tube 822. One or more bearings 834 (e.g., a helical bearing or a series of individual cylindrical bearings) may be disposed between the outer tube 822 and inner tube 830, as shown. Alternatively, one or both apposing tube surfaces may be made of, lined with, or be coated by etc. a lubricious material such as silicone or PTFE to facilitate movement. A rotating cutter 832 is positioned on the distal end of the inner tube 830. A side opening 828 is formed in the outer tube 822 and the cutter 832 is positioned proximal to the side opening 828. Optionally, a tapered atraumatic distal tip 824 may be formed on the distal end of the outer tube 822 and the side opening 828 may be configured to form a ramp or chute through which matter may pass into the area immediately distal to the cutter 832. Also optionally, an opening may be formed in the distal end of the distal tip such that a guidewire or scope 826 may pass through the lumen of the inner tube 830 and out of the opening in the distal tip, as shown. In operation, the device 820 is advanced to a position where the side opening 828 is near a polyp, tissue or other obstructive matter to be removed. The inner tube 830 and cutter 832 are rotated. Suction may be applied through the lumen of the inner tube 830 and/or through the lumen of the outer tube 822 to draw the obstructive matter into the side opening 828 and into contact with the rotating cutter 832. As the obstructive matter is severed by the rotating cutter 832, the severed obstructive matter or pieces thereof may be suctioned through the lumen of the inner tube 830 and/or through the lumen of the outer tube 822. Of course, as in any of the working devices described in this patent application, a scope or side lumen of any size or length, into which a scope may be inserted (not shown in FIG. 5U but shown in various other figures such as FIGS. 50, 5P, 5Q, 5R, 5S and 5T) may be attached to the outer tube 822 at a position which allows a scope to be used to view the side opening 828 and matter entering the side opening 828. Alternatively, the catheter may incorporate a deflectable tip or a curved distal end which may force the side opening of the catheter against a lumen wall or into the direction of a polyp or other tissue to be removed.

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[0195] In some applications of the invention, it may be desirable to break bone, such as the thin bone that forms the periphery of a sinus ostium. FIGS. 5W-5X"" show devices that may be used to break bones at specific locations. For example, FIGS. 5W-5W" show a device 840 that comprises a flexible catheter 842 having a rigid cylindrical member 847 located on the distal end thereof. An advanceable and retractable member 846 extends through the catheter 842 and is connected to a distal tip member 844. The distal tip member 844 has a cylindrical proximal end 849 that is sized to be received within the cylindrical member 847. As shown in FIGS. 5W' and 5W", in routine operation, the advanceable and retractable member 846 is advanced to separate the distal tip member 844 from the rigid cylindrical member 847. The device 840 is advanced to a position adjacent to a bony structure, such as a structure formed by bone B covered with mucosal tissue M. The device is positioned such that the bony structure is between the cylindrical proximal end 849 of the distal tip member 844 and the cylindrical member 847. The advanceable and retractable member 846 is then retracted, pulling the distal tip member 844 in the proximal direction and capturing the bony structure between the cylindrical proximal end 849 of the distal tip member 844 and the cylindrical member 847, thereby breaking the bone B. The shape or configuration of the distal tip member 844 and/or cylindrical member 847 may be varied depending on the shape and pattern of break desired to be made in the bone B. In this regard, FIGS. 5X-5X"" show alternative constructions or configurations that may be used to produce different shapes and patterns of bone breaks. FIG. 5X' shows an assembly 850 comprising a distal tip member 852 that has three (3) projections on its proximal side and a proximal member 854 that has three (3) notches in its distal surface, such notches being configured to receive the three projections of the distal tip member 852 when the distal tip member 852 is retracted. FIG. 5W" shows an assembly 860 comprising a distal tip member that forms a pincher for breaking bone. FIG. 5X"' shows an assembly 870 comprising a collapsible distal tip member 872 and a cylindrical proximal member 874. The distal tip member 872 may be initially deployed in a collapsed configuration that allows it to be advanced through an opening such as the ostium of a sinus. Then, it may be expanded to a size that is too large in diameter to pass through that opening, thereby causing it to strike the periphery of the opening as it is retracted in the proximal direction. In this manner, the assembly 5X"' may be used to break bone B all the way around an ostium or aperture. FIG. 5X"" shows another assembly 880 comprising a distal tip 882 that has two projections on its proximal side and a proximal member 884 that has one projection on its distal side. The projection on the distal side of the proximal member 884 is received between the projections formed on the proximal side of the distal member 882 when the distal member 882 is retracted in the proximal direction.

[0196] FIGS. 5Y'-5Y""" show various substance delivery implants that may be implanted into the nasal cavities, paranasal sinuses, middle or inner ear, nasopharynx, etc. to deliver a diagnostic or therapeutic substance as defined herein. These devices may be formed of permanent or bio-absorbable material. In many instances, these devices will be formed of a polymer (e.g., Hydron, hydrogel, collagen, etc.) within which the diagnostic or therapeutic substance is contained or a polymer or metal that is coated with or otherwise contains the substance. FIG. 5Y' shows an implant 1070 that comprises a bead or pellet. FIG. 5Y" shows an implant 1072 that comprises a wafer. FIG. 5Y"' shows an implant 1074 that comprises a brad or staple. FIG. 5Y"" shows an implant 1076 that comprises a screw or helical coil. FIG. 5Y""' shows an implant 1078 that comprises a strand or coil, another example of which is shown in FIG. 7E and described herebelow.

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[0197] D. Pre-Shaped Guide Catheters

[0198] FIGS. 6A-6E show various guide catheters that may be used in the methods of the present invention.

[0199] FIG. 6A shows a sphenoid sinus guide catheter 120 that incorporates three preformed curves 122, 124, 126. The three dimensional shape of the catheter 120 is such that, when advanced through a nasal cavity, the distal end of the catheter 120 will tend to enter the ostium of the sphenoid sinus.

[0200] FIG. 6B shows a frontal sinus guide catheter 128 that incorporates two preformed curves 130, 133. The shape of the catheter 128 is such that, when advanced through a nasal cavity, the distal end of the catheter 128 will tend to enter the ostium of the frontal sinus.

[0201] FIG. 6C shows a maxillary sinus guide catheter 136 that incorporates three preformed curves 138, 140, 142. The three dimensional shape of the catheter 136 is such that, when advanced through a nasal cavity, the distal end of the catheter 136 will tend to enter the ostium of the maxillary sinus.

[0202] FIG. 6D shows an ethmoid sinus guide catheter 144that incorporates two preformed curves 146, 148. The three dimensional shape of the catheter 144 is such that, when advanced through a nasal cavity, the distal end of the catheter 144 will tend to enter the ostium of the ethmoid sinus.

[0203] In some of the methods of the invention, it will be desirable to plug the ostium of a sinus or another opening such as the nasolacrimal duct or the nasopharyngeal opening into the Eustachian tube. Thus, any of the above-described guide catheters 120, 128, 136, 144 may be equipped with a plug on its distal tip such that when its distal end enters the sinus ostium it will plug the sinus thereby preventing fluid from exiting the sinus through the ostium. An example of one such procedure is shown in FIG. 7B and described herebelow.

[0204] FIG. 6E shows a plug guide catheter 149 that is useable for temporarily plugging the opening into a nasolacrimal duct. This plug guide catheter 149 has two preformed curves 150, 152 and a plug 154 at its distal tip. The three dimensional configuration of this catheter 149 is such that, when advanced through a nasal cavity the distal tip plug 154 will tend to enter the opening into the nasolacrimal duct. The plug may consist of, but is not limited to, a semi-rigid plug or a balloon on the end of the catheter. It will be appreciated that a different shaped plug guide catheter (not shown) may be used to plug the Eustachian tube.

[0205] E. Devices and Methods for Treatment Within Paranasal Sinuses:

[0206] FIGS. 7A-7G provide examples of devices and methods for performing diagnostic or therapeutic procedures within the paranasal sinuses. In the methods of the prior art, rigid or flexible scopes are sometimes used to visualize the ostia of sinuses but, typically, such scopes have not actually been advanced into the interior of the sinuses. As described hereabove, the present invention does provide devices and methods for placing endoscopes inside the paranasal sinuses and such methods may or may not be used in conjunction with any of the diagnostic or therapeutic devices and methods shown in FIGS. 7A-7G.

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[0207] FIG. 7A shows an electrode network delivery device 168 being used to deliver radiofrequency or electrical current to the lining of the sphenoid sinus SS. This device 168 comprises a flexible catheter 168 that has been inserted through the sphenoidal sinus ostium SSO. An expandable electrode network such as a cage 170 is advanced out of the distal end of the catheter 169. Electrodes 172 are positioned at spaced apart locations on the cage. As the cage 170 expands, it places the electrodes in contact with the lining of the sinus SS. Current is delivered to the electrodes 172 to ablate all mucous producing tissue within the sinus in preparation for the sinus to be functionally isolated or embolized, or to ablate tumors or polyps located within the sinus.

[0208] FIG. 7B shows a procedure where a flowable substance, such as a diagnostic or therapeutic substance as defined above, is introduced into the sphenoid sinus SS and the ostium SSO has been plugged by a sphenoid sinus plug guide catheter device 174. This device 174 comprises a flexible catheter 176 having the shape shown in FIG. 6A and described above and a plug member 178 at its distal tip. The fluid is maintained in the sphenoid sinus SS until the plug catheter device 174 is removed, allowing the fluid to then drain through the sphenoid sinus ostium SSO. This procedure may be particularly useful when it is desired to fill a sinus with radiographic contrast agent to visualize the entire sinus or to apply a therapeutic agent to the entire lining of the sinus by entirely filling the sinus with the agent and maintaining such fully filled state for a desired period of time to allow the agent to act on the entire lining of the sinus. Imaging materials may be mixed with visous agents so that they simulate mucous or if simple structural imaging is desired it may be preferable to have substances of lower viscosity. It may be also desirable to use imaging agents which bind with the surface of the mucosa to minimize the amount of injected contrast.

[0209] FIG. 7C shows a balloon catheter device 180 which comprises a flexible catheter 182 having a balloon 184 that is positioned in the sphenoid sinus ostium SSO and inflated to hold the catheter 182 in position while a quantity of a diagnostic or therapeutic substance 186 (as defined above) is introduced into the interior of the sinus SS. This therapeutic substance may be one or more of any of the drug delivery materials and drugs selected from the previous list, or may additionally include a sclerotic agent such as alcohol to uniformly kill all the tissues within the cavity. Other materials such as capasian or other neuro-toxic substances may be considered to eliminate the pain and other sensation within the caity.

[0210] FIG. 7D shows a sensor equipped catheter device 190 that comprises a flexible catheter 192 having a sensor 194 thereon for 3 dimensional mapping or navigation. This procedure may be used to map the precise configuration of the interior of the sphenoid sinus SS. Examples of the construction and use of such sensor 194 and associated systems/computers are found in U.S. Pat. Nos. 5,647,361; 5,820,568; 5,730,128; 5,722,401; 5,578,007; 5,558,073; 5,465,717; 5,568,809; 5,694,945; 5,713,946; 5,729,129; 5,752,513; 5,833,608; 5,935,061; 5,931,818; 6,171,303; 5,931,818; 5,343,865; 5,425,370; 5,669,388; 6,015,414; 6,148,823 and 6,176,829, the entirities of which are expressly incorporated herein by reference.

[0211] FIG. 7E shows an implant delivery device 196 which comprises a flexible catheter 198 that is inserted through the sphenoid sinus ostium SSO and into the sphenoid sinus SS and is being used to implant a coil 200 within the sphenoid sinus. Such coil 200 may comprise an elongate fiber or other elongate member that may contain a diagnostic or therapeutic substance as defined herein. This coil 200 may be

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constructed to embolize the sinus for the purpose of to permanently close off the sinus and to prevent any further mucous production, trapping of secretions or infection and/or to deliver a diagnostic or therapeutic substance to the tissues lining the sinus. For example, a coil for sustained delivery of an antimicrobial agent may be implanted in a sinus to treat an acute or chronic infection of that sinus. In some cases, the coil may be bioabsorbable.

[0212] FIG. 7F shows an over-the-wire endoscopic system 240 being used to view the interior of the sphenoid sinus SS. A flexible catheter 242 is positioned in or near the sphenoid sinus ostium SSO and a guidewire 248 is advanced through the sphenoid sinus ostium SSO and into the sphenoid sinus SS. An over-the-wire endoscope 246 (such as a 2.2 mm over-the-wire scope available commercially as Model # AF-28C from Olympus America, Melville, N.Y.) is advanced over the guidewire 248 and is used to examine the interior of the sphenoid sinus SS.

[0213] FIG. 7G shows a biopsy system 250 being used to obtain a biopsy specimen from a lesion L within the sphenoid sinus SS. A flexible catheter 242 is positioned in or near the sphenoid sinus ostium SSO and an endoscope 246 is advanced through the catheter 242 and into the interior of the sinus SS. A biopsy instrument 252 is inserted through a working channel of the endoscope 246 and is used, under endoscopic visualization and guidance, to obtain a specimen of the lesion L.

[0214] F. General Examples Of Interventions Using the Occluder & Access Devices and/or Working Devices

[0215] FIGS. 8A-8D show two of many possible examples of methods wherein the occluder & access devices 10, 12 of FIGS. 2A and 2B and/or various working devices such as those shown in FIGS. 5A-5Y" " are used to perform diagnostic and/or therapeutic procedures within the nose, nasopharynx or paranasal sinuses.

[0216] In general, diagnostic interventions in accordance with this invention may include: a) anatomic studies where obstructions, sizes, parameters or abnormalities in anatomy are visualized and/or identified, b) dynamic studies where gas, mucous or fluid is introduced into the nose, sinus, nasal cavity, nasopharynx, Eustachian tube, inner or middle ear, etc and the movement of such materials is monitored to asses drainage or gas flow issues and c) perturbation studies where an agent (e.g., an allergen, irritant, agent that induces mucous production, etc.) is introduced into the nose, sinus, nasal cavity, nasopharynx, Eustachian tube, inner or middle ear, etc., and the patient's response and/or flow of the endogenously produced mucous or other secretions is assessed. Examples of procedures that may be used to perform these types of diagnostic interventions include, but are not limited to, the following:

[0217] 1. Gaining Access To Sinus: Access to one of more of the paranasal sinuses is gained by advancement of catheter(s) into the sinus or sinuses of interest. A guidewire may be inserted into the sinus first and the catheter may then be advanced over the guidewire and into the sinus. In some cases, a sinus ostium guide catheter of the type shown in FIGS. 6A-6E may be inserted into the ostium of the sinus and a smaller catheter may be advanced through the guide catheter. One or more scopes may be used to visualize the sinus ostium and to guide the guidewire and/or catheter into the sinus ostium. In some cases, a steerable guidewire, catheter and/or scope may be used to gain entry into the sinus. In some cases, occlusion & access device(s) such as those shown in FIGS. 2A-2R, may be inserted and the guidewire(s), catheter(s) and/or

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scope(s) used to access the sinus may be inserted through a device insertion port on the occluder & access device.

[0218] 2. Mucous Flow Study: Optionally, after catheter access to the sinus has been gained, an imageable contrast substance or radioactive material such as microbeads or a flowable contrast medium (e.g., an iodinated contrast solution with or without a thickening agent to adjust its viscosity to that of mucous) that may have a consistency similar to that of mucous may be injected into the sinus. An imaging or scanning technique (e.g., X-ray, fluoroscopy, CT scan, ultrasound, MRI, radiation detector, gamma camera, etc.) may then be used to observe the flow of the contrast medium through and out of the sinus. In some cases a fluoroscope with a C-arm may be used in a fashion similar to that used in coronary artery catheterization and angiography procedures to allow the clinician to view the movement of the contrast medium from different vantage points or angles. To facilitate flow of the contrast medium from the sinus, the previously inserted catheter(s) and/or guidewires and/or scope(s) may be backed out of the sinus and ostium or removed completely, to allow normal flow to occur. The patient's head and/or other body parts may be repositioned to observe different postural drainage effects. In this manner, the clinician may specifically locate and identify which anatomical structures are obstructing or interfering with normal mucous flow from the sinus.

[0219] 3. Air Flow Study: Optionally, after access to the sinus has been gained as described in No. 1 above, an imageable or traceable gas, such as a radiolabled gas, radiopaque gas or a gas with imageable or radioactive microbeads therein, may be injected through a catheter and into the sinus. An imaging device or tracing device (e.g., radiation detector, gamma camera, X-ray, fluoroscopy, CT scan, ultrasound, MRI) may then be used to observe subsequent movement or dissipation of the gas as it passes out of the sinus and/or equilibrates with other sinus cavities. In this manner, the clinician may determine whether normal gas exchange in the sinus is occurring and may locate and identify any anatomical structures or irregularities that are obstructing or interfering with normal gas flow and/or gas exchange.

[0220] 4. Anatomic Dimension Study: An entire paranasal sinus or other anatomical passageway or structure may be filled with an imageable substance or otherwise measured to determine its actual dimensions and/or configuration. In some such studies, access to a paranasal sinus will be gained as described in No.1 above and the sinus may be filled with an imageable substance (e.g., contrast medium). A suitable imaging technique (e.g., X-ray, fluoroscopy, CT scan, ultrasound, MRI, radiation detector, gamma camera, etc.) may then be used to determine the size and shape of the sinus. Again, in such procedure, a moveable imaging apparatus such as a fluoroscope with a C-arm may be used to view and measure the contrast filled sinus from different vantage points or angles. One example of such a procedure is shown in FIG. 7B and described hereabove.

[0221] 5. Endoscopic Study: A flexible and/or steerable endoscope, as described above, may be inserted into the nose, sinus, nasal cavity, nasopharynx, Eustachian tube, inner or middle ear, etc and used to visually examine the anatomy and/or to observe a treatment and/or to assess the efficacy or completeness of a previously rendered treatment. In cases where it is desired to view the interior of a paranasal sinus, access to the sinus may be gained as described in No. 1 above and the endoscope may be advanced into the interior of the sinus either directly or over a guidewire.

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[0222] 6. Transillumination Study: A flexible light emitting instrument (e.g., a catheter having a powerful light emitting apparatus at its distal end) may be advanced into the nose, paranasal sinus, nasal cavity, nasopharynx, Eustachian tube, inner or middle ear, etc and used to illuminate anatomical structures. Direct or endoscopic observation may then be made from outside the body and/or from other locations within the nose, sinus, nasal cavity, nasopharynx, Eustachian tube, inner or middle ear, orbit, cranial vault, etc. to observe anatomical structures and/or to detect aberrant openings or leaks through which the light passes. In cases where the light emitter and/or the viewing instrument (e.g., endoscope) is/are positioned within paranasal sinus(es) access to the sinus(es) may be gained as described in No. 1 above and the light emitter and/or viewing instrument may then be advanced into the sinus(es) either directly or over guidewire(s).

[0223] 7. Other Imaging Studies: Other imaging techniques such as MRI, CT, etc. in combination with any of the modalities set forth in Nos. 1-6 above and modifications may be made to any of those techniques to adjust for sinus anatomy or other pathology.

[0224] After any or all of the elected diagnostic studies have been completed, one or more working devices, such as the flexible devices described herein and shown in FIGS. 5A-5Y"", may be inserted and used to perform therapeutic procedure(s).

[0225] As shown in the example of FIG. 8A, an anterior/posterior occluder & access device 10 is inserted through the right nasal cavity NC. The device's anterior occluder 14 is positioned to occlude the nostril on the right side while its posterior occluder (not seen in FIGS. 8A-8E) occludes the posterior choanae or nasopharynx. An anterior occluder & access device 12 is inserted into the left nasal cavity and its occluder 40 occludes the left nostril. In this manner, a sealed operative field is established between the posterior occluder positioned in the posterior choanae or nasopharynx and the anterior occluders 14, 40 positioned in the right and left nostrils or anterior nasal cavities.

[0226] FIGS. 8B-8C show an example of a method for performing a diagnostic and/or therapeutic procedure in the right frontal sinus FS in the patient in whom the occluder & access devices 10, 14 have been inserted. In FIG. 8B, a frontal sinus guide catheter 128 is inserted into the working device insertion port 30 and advanced through tube 16 and out of outlet aperture 22. The guide catheter 128 is then advanced to a position where its distal end is in the right frontal sinus ostium.

[0227] In FIG. 8C, a working device 202 is inserted through the guide catheter 128 and into the frontal sinus FS. This working device 202 may comprise any of the devices shown in FIGS. 5A-5Y"" or 7A-7G. In some procedures, it may be desired to initially introduce a contrast agent into the frontal sinus FS and pull back the guide catheter 128 to allow the contrast agent to drain from the sinus. Imaging of the draining contrast agent may be used to diagnose drainage impairment and to identify the specific anatomical structures that are causing the impairment of drainage. Thereafter, the guide catheter may be reinserted into the frontal sinus ostium and the working device (s) 202 may be used to modify the structures that have been identified and impairments to drainage. Thereafter, the contrast injection and imaging steps may be repeated to assess whether the procedure(s) performed have overcome or corrected the drainage problem that had been initially diagnosed. A suction device 206 is connected by way of suction line 204 to port 36 to suction blood, other fluid or debris from the operative field

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during the procedure.

[0228] FIGS. 8D and 8E show an example of a treatment rendered to the left maxillary sinus MS, in the same patient in whom the occluder & access devices 10, 14 have been inserted. In FIG. 8D, a guide catheter 136 is inserted into device insertion aperture 44 and advanced through tube 41 to a position where the distal end of the guide catheter 136 is positioned in the ostium of the maxillary sinus MS.

[0229] Thereafter, as shown in FIG. 8E, a working device 202 is inserted through the guide catheter 136 and into the maxillary sinus MS. This working device 202 may comprise any of the devices shown in FIGS. 5A-Y"" or 7A-7G. In some procedures, it may be desired to initially introduce a contrast agent into the maxillary sinus MS by the same procedure described above in reference to FIGS. 8B and 8C.

[0230] After all of the desired procedures have been completed, the anterior occluders 14, 40 and posterior occluder (not shown on FIGS. 8A-8E) are collapsed (e.g., deflated) and the occluder & access devices as well as the guide catheters and working devices are removed (except for implants such as stents, embolic coils, substance delivery implants, etc.).

[0231] G. Cochlear Implant Procedure

[0232] FIGS. 9A-9C show a procedure for installation of a cochlear implant in accordance with the present invention. In this procedure, the nasopharyngeal opening into the Eustachian tube ET is located and a guidewire is initially advanced into the Eustachian tube ET. A catheter 900 is advanced over the guidewire to a location where the distal end of the catheter 900 is in or near the tympanic cavity TC of the middle ear. Thereafter, if deemed necessary, a forceps device 790 and/or other devices are advanced through the catheter 900 and used to remove the small bones of the sear (i.e., the malleus, incus and stirrup) as shown in FIG. 9A. This optional removal of the bones of the middle ear may be done under endoscopic visualization using an endoscope equipped device such as the endoscope equipped forceps device 790 shown in FIG. 5T and described above. As shown in FIG. 9B, a cochlear guide catheter 904 having a "J" shaped distal tip 905 is advanced through the catheter 900 to a position where the tip 905 of the cochlear guide catheter 904 is directed into or inserted into the cochlea C. In some applications, the cochlear guide catheter 904 may be configured to advance into the round window of the cochlea and through the secondary tympanic membrane that covers the round window. If necessary, a penetrator such as a needle, drill or cutter may be advanced through or formed or positioned on the distal end of the cochlear guide catheter 904 to penetrate through the secondary tympanic membrane. In other applications, the cochlear guide catheter 904 may be positioned adjacent to the cochlea and a cochleostomy device (e.g., a penetrator such as a drill, needle or cutter) may be advanced through or formed or positioned on the distal end of the cochlear guide catheter 904 and used to form a cochleostomy through which the distal end of the guide catheter 904 is advanced into the cochlea C. Thereafter, a cochlear electrode array 906 is advanced through the cochlear guide catheter 904 and into the cochlea, as seen in FIG. 9B. One example of a commercially available cochlear electrode array is the Nucleus 24 Countour device manufactured by Cochlear Corporation.

[0233] Thereafter, a sound receiving device or transducer 908 is advanced through the catheter 900 and positioned in the tympanic cavity TC. The sound receiving device or

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transducer 908 may be of any type that is a) sufficiently small to pass through the Eustachian tube ET and into the tympanic cavity TC and b) useable to perform the desired function of converting sound waves to electrical impulses and delivering such electrical impulses to the cochlear electrode array 906. A microphone/power/electronics device 910 may be positioned in the outer ear canal, as shown in FIG. 9C or may be implanted subcutaneously or in any other way that is acceptable. Certain non-limiting examples of devices 906, 908, 910 that may be useable for this procedure are set forth in PCT International Patent Publication No. WO 2004/018980 A2 designating the United States, the entirety of which is expressly incorporated herein by reference.

[0234] It is to be appreciated that the invention has been described hereabove with reference to certain examples or embodiments of the invention but that various additions, deletions, alterations and modifications may be made to those examples and embodiemnts without departing from the intended spirit and scope of the invention. For example, any element or attribute of one embodiment or example may be incorporated into or used with another embodiment or example, unless to do so would render the embodiment or example unsuitable for its intended use. All reasonable additions, deletions, modifications and alterations are to be considered equivalents of the described examples and embodiments and are to be included within the scope of the following claims.

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Espacenet

Claims: JP2007537784 (A) — 2007-12-27

Devices, systems and methods for diagnosing and treating sinusitus and other disorders of the ears, nose and/or throat

Claims not available for JP2007537784 (A)
Claims of corresponding document: US2005240147 (A1)

A high quality text as facsimile in your desired language may be available amongst the following family members:

AU2005249376 (B2) CA2563711 (A1) EP1744708 (A2) ES2591282 (T3) US2005240147 (A1) WO2005117755 (A2) EP2638871 (A1) US2008097295 (A1) US2008154250 (A1) US2008275483 (A1) US2010100181 (A1) US2010210901 (A1) US2017071625 (A1) US2017164965 (A1) US2019388113 (A1) US2020022717 (A1) US2021007762 (A1)

- Original claims
- Claims tree

The EPO does not accept any responsibility for the accuracy of data and information originating from other authorities than the EPO; in particular, the EPO does not guarantee that they are complete, up-to-date or fit for specific purposes.

1. A method for diagnosing and/or treating sinusitis or another disorder affecting the nose, paranasal sinuses or other anatomical structures of the ear, nose or throat, said method comprising the steps of:
(A) placing a port device in the nostril or nasal cavity on at least one side of the intranasal septum, said port device comprising a device insertion port and a valve that is operative to allow a working device to be inserted through said device insertion port while preventing blood or other fluid from backflowing out of the device insertion port at least when no working device is inserted therethrough;
(B) advancing at least one working device through the port device to a location within the nose, nasopharynx or paranasal sinus; and
(C) using the working device to perform a diagnostic or therapeutic procedure

2. A method according to claim 1 wherein the working device is used to perform a procedure selected from the group consisting of:
i) delivering an imageable or traceable substance;
ii) delivering a therapeutically effective amount of a therapeutic substance;
iii) implanting a stent, tissue remodeling device, substance delivery implant or other therapeutic apparatus;
iv) cutting, ablating, debulking, cauterizing, heating, lasing, dilating or otherwise modifying tissue;
v) grafting or implanting cells or tissue;

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vi) reducing, setting, screwing, applying adhesive to, affixing, decompressing or otherwise treating a fracture;
vii) delivering a gene or gene therapy preparation;
viii) cutting, ablating, debulking, cauterizing, heating, lasing, forming an osteotomy in or otherwise modifying bony or cartilaginous tissue within paranasal sinus or elsewhere within the nose;
ix) remodeling or changing the shape, size or configuration of a sinus ostium or other anatomical structure that affects drainage from one or more paranasal sinuses;
x) removing puss or aberrant matter from the paranasal sinus or elsewhere within the nose; and
xi) scraping or otherwise removing cells that line the interior of a paranasal sinus;
xii) removing all or a portion of a tumor;
xiii) removing a polyp; and
xiv) delivering histamine, an allergen or another substance that causes secretion of mucous by tissues within a paranasal sinus to permit assessment of drainage from the sinus.

3. A method according to claim 1 wherein a port device positioned in Step A comprises an anterior nasal occluder and access device that comprises an occluder and a working device insertion port.

4. A method according to claim 3 wherein Step A further comprises deploying the anterior nasal occluder and access device such that its occluder occludes the nostril or nasal cavity on one side of the nasal septum and wherein Step B comprises inserting the working device through the working device insertion opening and advancing the working device to a location within the nose, nasopharynx or paranasal sinus.

5. A method according to claim 4 wherein a first anterior nasal occluder and access device is positioned on one side of the nasal septum and a second anterior nasal occluder and access device is positioned on the other side of the nasal septum.

6. A method according to claim 1 comprising the steps of:
providing a posterior occluder device that is configured to occlude the posterior choanae, nasopharynx or pharynx at a location that is posterior to the intranasal septum and superior to the glotis; and
positioning the posterior occluder device such that it does occlude the posterior choanae, nasopharynx or pharynx posterior to the intranasal septum and superior to the glottis, thereby deterring fluid from draining into the patient's esophagus or trachea during the performance of the method.

7. A method according to claim 1 comprising the steps of:
providing an anterior/posterior nasal occluder and access device that comprises an anterior occluder member, a working device insertion port and a posterior occluder member; and
deploying the anterior/posterior nasal occluder and access such that; its anterior occluder occludes a nostril or nasal cavity on one side of the nasal septum and its posterior occluder occludes the posterior choanae, nasopharynx or pharynx posterior to the intranasal septum and superior to the glottis; and
wherein Step B comprises:
inserting the working device through the working device insertion opening and advancing the working device to a location within the nose, nasopharynx, middle ear or paranasal sinus.

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8. A method according to claim 7 further comprising the step of:
providing an anterior nasal occluder device; and
and positioning the anterior nasal occluder device such that it occludes the other nostril or nasal cavity on the other side of the nasal septum.

9. A method according to claim 7 further comprising the step of:
providing an anterior nasal occluder and access device that comprises an occluder member and a working device insertion port; and
positioning the anterior nasal occluder and access device such that its occluder occludes the other nostril or nasal cavity on the other side of the nasal septum.

10. A method according to claim 9 further comprising the step of:
inserting a working device through the working device insertion port of the on the anterior nasal occluder and access device and advancing that working device to a location within the nose, nasopharynx or paranasal sinus.

11. A method according to claim 7 wherein the anterior/posterior occlusion and access device comprises 1) a tube having an anterior end, a posterior end and at least one lumen; ii) an anterior occluder at a first location on the tube; iii) a posterior occluder at a second location on the tube, said second location being posterior to said first location; iv) a working device insertion opening located anterior to the anterior occluder; and v) a working device exit opening located between the anterior occluder and the posterior occluder and placing said anterior/posterior nasal occlusion and access device such that its anterior occluder occludes the nostril or nasal cavity on one side of the intranasal septum and its posterior occluder occludes the nasopharynx at a location posterior to the intranasal septum and superior to the glottis.

12. A method according to claim 11 wherein Step B comprises inserting a working device through the working device insertion opening and advancing the working device out of the working device exit opening to a location within the nose, nasopharynx or paranasal sinus.

13. A method according to claim 1 further comprising the step of:
suctioning fluid from the nose, nasopharynx or paranasal sinus.

14. A method according to claim 11 wherein the anterior/posterior nasal occlusion and access device comprises a suction lumen and a suction opening formed in said tube between the anterior occluder and the posterior occluder and wherein the method further comprises the step of:
applying suction to the suction lumen to suction matter through the suction opening and through the suction lumen.

15. A method according to claim 1 wherein Step B comprises:
inserting a guide catheter; and, thereafter,
inserting another working device through the guide catheter.

16. A method according to claim 1 wherein:
Step B comprises advancing a tube through the port device to a location within a paranasal sinus; and
Step C comprises delivering a flowable contrast agent into a paranasal sinus through the tube and subsequently imaging the flowable contrast agent to assess the manner in

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which the flowable contrast agent drains from the paranasal sinus.

17. A method according to claim 16 wherein the flowable contrast agent has a viscosity similar to the viscosity of mucous.

18. A method according to claim 16 wherein the imaging is carried out using an imaging apparatus that is moveable and wherein the imaging apparatus is moved to different positions to different vantage points relative to the patient's anatomy.

19. A method according to any of claim 1 wherein Step B comprises inserting a scope into the nose or paranasal sinus and wherein Step C comprises using the scope to visualize structures within the nose and/or paranasal sinuses.

20. A method according to claim 19 wherein the scope is used to guide, facilitate or verify positioning of another working device.

21. A method according to claim 19 wherein the scope is used to guide, facilitate or verify positioning of a guide catheter and wherein another working apparatus is then advanced through the guide catheter after the guide catheter has been positioned.

22. A method according to claim 1 wherein Step C comprises implanting a stent.

23. A method according to claim 22 wherein the stent is positioned at least partially within the ostium of a paranasal sinus.

24. A method according to claim 22 wherein the stent comprises a substance eluting stent.

25. A method according to claim 24 wherein the substance eluting stent elutes a therapeutically effective amount of at least one substance selected from the group consisting of:
an antibiotic;
an antifungal;
an antiparacytic;
an antimicrobial;
a steroid;
a vasoconstrictor;
a leukotriene inhibitor;
an IgE inhibitor;
an anti-inflammatory;
a mast cell stabilizer;
an antihistamine;
an imunomodulator;
a chemotherapeutic agent;
an antineoplastic agent;
a mucolytic agent;
an agent that thins or otherwise changes the viscosity of mucous;
a substance that facilitates remodeling of soft tissue and/or bone and/or cartilage.

26. A method according to claim 1 wherein Step C comprises implanting a device that will change the size, shape, configuration or position of soft tissue, bone or cartilage.

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27. A method according to claim 26 wherein the implanted device can be adjusted one or more times after implantation and wherein the method further comprises the step of adjusting the implanted device at least one time subsequent to implantation.

28. A method according to claims 1 wherein Step C comprises enlarging or modifying a sinus ostium, nasal meatus, or other passage way within the nose or nasopharynx.

29. A method according to claim 1 wherein Step C comprises introducing a diagnostically or therapeutically effective amount of a diagnostic or therapeutic substance to a location within the nose, nasopharynx or paranasal sinus.

30. A method according to claim 29 wherein the substance is contained in a substance delivery implant and wherein Step C comprises implanting the substance delivery implant at a location within the nose, nasopharynx or paranasal sinus.

31. A method according to claim 29 wherein Step C comprises injecting the substance at a location within the nose, nasopharynx or paranasal sinus.

32. A method according to claim 29 wherein the substance is selected from the group consisting of:
an imageable contrast agent;
a diagnostic indicator agent;
an antibiotic;
an antifungal;
an antiparacytic;
an antimicrobial;
a steroid;
a vasoconstrictor;
a leukotriene inhibitor;
an IgE inhibitor;
an anti-inflammatory;
a mast cell stabilizer;
an antihistamine;
an imunomodulator;
a chemotherapeutic agent;
an antineoplastic agent;
a mucolytic agent;
an agent that thins or otherwise changes the viscosity of mucous; and
a substance that facilitates remodeling of soft tissue and/or bone and/or cartilage.

33. An anterior/posterior occlusion and access device for use in the diagnosis and/or treatment of sinusitis or a disorder of the ear, nose or throat, said device comprising:
a tube having an anterior end, a posterior end and at least one lumen;
an anterior occluder at a first location on the tube;
a posterior occluder at a second location on the tube, said second location being posterior to said first location;
a working device insertion opening located anterior to the anterior occluder; and
a working device exit opening located between the anterior occluder and the posterior occluder; and
at least one additional element selected from the group consisting of a) a valve that is operative to allow a working device to be inserted through said device insertion port while preventing blood or other fluid from backflowing out of the device insertion port at

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least when no working device is inserted therethrough, b) at least one moveable suction port for suctioning blood, fluid or debris from a plurality of locations between the anterior occluder and posterior occluder and/or c) separate infusion and suction lumens such that fluid may be infused into a location between the anterior and posterior occluders at the same time that fluid is being suctioned from a location between the anterior and posterior occluders.
said nasal access and occlusion device being deployable such that i) the anterior occluder occludes the nostril or nasal cavity on one side of the intranasal septum ii) the posterior occluder occludes the nasopharynx at a location posterior to the intranasal septum and iii) a working device may be inserted through the working device insertion opening and advanced out of the working device exit opening to a location within the nose, nasopharynx or paranasal sinus.

34. A device according to claim 33 wherein the anterior occluder comprises a balloon.

35. A device according to claim 33 wherein the posterior occluder comprises a balloon.

36. A device according to claim 33 which includes at least first and second working device exit openings such that a working device may be selectively advanced out of either the first or second working device exit opening.

37. A system that comprises a nasal access and occlusion device according to claim 33 in combination with at least one working device selected from the group consisting of:
a guidewire;
a guide catheter;
a guide catheter shaped to advance into the ostium of a paranasal sinus;
a balloon catheter,
apparatus for delivery of a stent;
apparatus for delivery of a substance-eluting stent;
implantable apparatus for exerting pressure on bone or soft tissue to cause reshaping of the bone or soft tissue;
apparatus for cutting tissue;
apparatus for ablating tissue;
apparatus for debulking tissue;
apparatus for cauterizing tissue;
apparatus for dilating a passageway;
apparatus for delivering a cryogen;
apparatus for delivering a radiographic contrast agent,
apparatus for delivering a diagnostic or therapeutic substance;
a cannula;
an endoscope;
a sensor;
a light;
a diagnostic device;
a therapeutic device.

38. A device according to claim 33 further comprising at least one suction port located on the tube between the anterior occluder and the posterior occluder such that fluid or debris may be aspirated though the aspiration port and through a lumen of the tube.

39. A system comprising a device according to claim 33 in combination with an anterior

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nasal occlusion and access device that is positionable on the other side of the nasal septum, said anterior nasal occlusion and access device comprising:
an anterior occluder for occluding the nostril or nasal cavity on one side of the nasal septum; and
a working device insertion opening through which a working device may be inserted and advanced past the anterior occluder to a location within the nose, nasopharynx or paranasal sinus.

40. A system according to claim 39 wherein the anterior occluder of the anterior nasal occlusion and access device comprises a balloon.

41. A device according to claim 33 further comprising a valve associated with the working device insertion opening, said valve being configured to prevent backflow out of the working device opening when no working device is inserted through said working device insertion opening.

42. A system according to claim 39 further comprising a valve associated with the working device insertion opening of the anterior nasal occlusion and access device that is positionable on the other side of the nasal septum, said valve being configured to prevent backflow out of the working device opening when no working device is inserted through said working device insertion opening.

43. A nasal access and anterior occlusion device for use in the diagnosis and/or treatment of sinusitis or a disorder of the ear, nose or throat, said device comprising:
an anterior occluder for occluding the nostril or nasal cavity on one side of the nasal septum; and
a working device insertion port through which a working device may be inserted and advanced past the anterior occluder to a location within the nose, nasopharynx or paranasal sinus; and
at least one valve that allows a working device to be inserted through said working device insertion port and prevents blood or other fluid from backflowing out of the working device insertion port, at least when no working device is inserted therethrough.

44. A device according to claim 43 wherein the anterior occluder comprises a balloon.

45. A system that comprises an anterior nasal occlusion and access and access device according to claim 43 in combination with at least one working device selected from the group consisting of:
a guidewire;
a guide catheter;
a guide catheter shaped to advance into the ostium of a paranasal sinus;
a balloon catheter,
apparatus for delivery of a stent;
apparatus for delivery of a substance-eluting stent;
implantable apparatus for exerting pressure on bone or soft tissue to cause reshaping of the bone or soft tissue;
apparatus for cutting tissue;
apparatus for ablating tissue;
apparatus for debulking tissue;
apparatus for cauterizing tissue;
apparatus for dilating a passageway;
apparatus for delivering a cryogen;

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apparatus for delivering a radiographic contrast agent,
apparatus for delivering a diagnostic or therapeutic substance;
a cannula;
an endoscope;
a sensor;
a light;
a diagnostic device;
a therapeutic device.

46. A device according to claim 43 further comprising a valve associated with the working device insertion opening, said valve being configured to prevent backflow out of the working device opening when no working device is inserted through said working device insertion opening.

47. A method for diagnosing or locating an obstruction that impedes drainage from a paranasal sinus or for assessing the efficacy of previously rendered treatment intended to improve or modify drainage from a paranasal sinus, said method comprising the steps of:
A. introducing a flowable medium into the paranasal sinus; and,
B. monitoring the flow or diffusion of the flowable medium from the paranasal sinus.

48. A method according to claim 47 further comprising the step of occluding the nasopharynx posterior to the nasal septum but superior to the glottis so as to deter drainage of the flowable medium into the esophagus or trachea.

49. A method according to claim 47 further comprising the step of occluding the nostril or nasal cavity on at least one side of the intranasal septum to deter drainage of the flowable medium out of the nostril.

50. A method according to claim 47 wherein Step A comprises inserting a catheter into the paranasal sinus and infusing the flowable medium through the catheter and into the paranasal sinus.

51. A method according to claim 47 further comprising the steps of:
providing an anterior nasal occlusion and access device that comprises an anterior occluder and a device insertion passageway;
positioning the anterior nasal occlusion and access device such that its occluder occludes the nostril or nasal cavity on one side of the intranasal septum; and
wherein Step A comprises inserting a catheter through the device insertion passageway, advancing the catheter to or through the ostium of the paranasal sinus and infusing the contrast medium through the catheter and into the paranasal sinus.

52. A method according to claim 51 wherein the anterior nasal occlusion and access device comprises an anterior occluder for occluding the nostril or nasal cavity on one side of the nasal septum and a working device insertion port through which a working device may be inserted and wherein:
Step A comprises i) inserting a catheter through the working device insertion port, ii) advancing the catheter to or through the ostium of the paranasal sinus and iii) infusing the contrast medium through the catheter and into the paranasal sinus.

53. A method according to claim 47 further comprising the steps of:
providing an anterior/posterior nasal occlusion and access device that comprises an

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anterior occluder, a posterior occluder and a device insertion passageway; and positioning the anterior/posterior nasal occlusion and access device such that its anterior occluder occludes the nostril or nasal cavity on one side of the intranasal septum and its posterior occluder occludes the nasopharynx posterior to the intranasal septum and superior to the glottis; and
wherein Step A comprises advancing a catheter through the device insertion passageway to or through the ostium of the paranasal sinus and infusing the contrast medium through the catheter and into the paranasal sinus.

54. A method according to claim 47 wherein the flowable medium is an imageable contrast medium and wherein Step B of the method comprises imaging the imageable contrast medium.

55. A method according to claim 47 wherein Step B is carried out using a moveable imaging device and comprises obtaining images from a plurality of vantage points.

56. A method according to claim 55 wherein the movable imaging device comprises a radiographic imaging device and a C-arm and wherein Step B comprises moving the C-arm to obtain images from a plurality of vantage points.

57. A method according to claim 47 wherein the flowable medium is a radioactive or radiolabled fluid and wherein Step B of the method comprises tracing the radioactive or radiolabled fluid using a device that detects radioactivity.

58. A method for diagnosing or locating an obstruction that impedes drainage from a paranasal sinus or for assessing the efficacy of previously rendered treatment intended to improve or modify drainage from a paranasal sinus, said method comprising the steps of:
(A) introducing into the paranasal sinus a substance that causes tissues lining the paranasal sinus to secrete mucous or other secretions; and,
(B) monitoring the flow of the mucous or other secretions from the paranasal sinus.

59. A method according to claim 58 wherein the substance introduced in Step A comprises histamine.

60. A method according to claim 58 wherein the substance introduced in Step A comprises an allergen to which the patient is allergic.

61. A method according to claim 58 wherein the drainage of the mucous or other secretions is assessed visually using an endoscope.

62. A method according to claim 58 wherein Step A further comprises causing a contrast agent to be combined with the mucous or other secretions and wherein the drainage of mucous or other secretions is assessed by imaging the contrast agent.

63. A device for removing polyps or other tissue from the nose, nasopharynx or paranasal sinus, said device comprising:
a flexible catheter having a distal end and a lumen;
a flexible tube having an open distal end and a lumen extending therethrough, said flexible tube being rotatably disposed within a lumen of the catheter such that the flexible tube may rotate while the catheter does not rotate;
a rotating cutter on the distal end of the flexible tube; and

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an opening formed in the catheter such that matter may be received through the opening and cut by the rotating cutter.

64. A device according to claim 63, further comprising a connector for connecting the lumen of the flexible tube to a source of negative pressure such that matter that is cut by the rotating cutter will be suctioned though the open distal end and through the lumen of the flexible tube.

65. A device according to claim 63 wherein the opening in the catheter is an opening in the distal end of the catheter.

66. A device according to claim 63 wherein the opening in the catheter is a side opening formed in a side of the catheter.

67. A device according to claim 63 wherein there is at least one bearing disposed between the catheter and the flexible tube.

68. A device according to claim 63 further comprising a scope which is useable to view the distal end of the catheter while the device is inserted in the body of a patient.

69. A device according to claim 68 wherein the scope extends through the lumen of the flexible tube.

70. A device according to claim 68 wherein the scope is attached to the exterior of the catheter.

71. A device according to claim 70 wherein the scope is disposed in a lumen on one side of the catheter.

72. A device according to claim 70 further comprising a side lumen on the catheter.

73. A system comprising a device according to claim 72 in combination with a scope positioned in the side lumen.

74. A system comprising a device according to claim 72 in combination with a guidewire positioned in the side lumen.

75. A device according to claim 66 further comprising moveable retractor apparatus that is operative to retract matter that has entered the opening into contact with the rotating cutter.

76. A device according to claim 75 wherein the moveable retractor apparatus comprises an elongate member having a retractor head, said elongate member being advanceable in a distal direction to move the retractor head to a location distal to the side opening and retractable in the proximal direction to move the retractor head in the proximal direction such that the retractor head will propel matter that has entered the opening into contact with the rotating cutter.

77. A device according to claim 66 wherein the catheter has a closed distal tip.

78. A device according to claim 77 further comprising a lumen that extends through the flexible tube and through an opening formed in the distal tip of the catheter.

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79. A system comprising a device according to claim 78 in combination with a scope positioned within the lumen that extends through the flexible tube and through an opening formed in the distal tip of the catheter.

80. A system comprising a device according to claim 78 in combination with a guidewire positioned within the lumen that extends through the flexible tube and through an opening formed in the distal tip of the catheter.

81. A method for treating deafness or hearing impairment in a human or veterinary patient having a Eustachian tube, a cochlea, a tympanic cavity and an outer ear, said method comprising the steps of:
(A) inserting a flexible catheter through the patient's nose and into the Eustachian tube;
(B) providing a cochlear implant system comprising a cochlear electrode array, a transducer and a power source;
(C) advancing the cochlear electrode array through the catheter that is inserted in the Eustachian tube and into the cochlea; and
(D) communicating the cochlear electrode array to the transducer and power source such that the cochlear implant system delivers sound-associated electrical impulses to the cochlea.

81. A method according to claim 81 wherein Step A comprises using a scope to visualize the Eustachian tube and guiding said catheter into the Eustachian tube.

83. A method according to claim 81 wherein Step C comprises inserting a cochlear guide through the catheter that is positioned in the Eustachian tube and advancing the electrode array over or through the cochlear guide and into the cochlea.

84. A method according to claim 81 wherein Step C comprises advancing the cochlear electrode array through the round window of the cochlea.

85. A method according to claim 81 wherein Step C further comprises penetrating the secondary tympanic membrane.

86. A method according to claim 81 wherein Step C comprises creating a cochleostomy and advancing the cochlear electrode through the cochleostomy.

87. A method according to claim 81 further comprising the step of passing the transducer through the Eustachian tube and implanting the transducer in the tympanic cavity.

88. A method according to claim 87 wherein the method further comprises the step of removing bones from the tympanic cavity prior to implantation of the transducer in the tympanic cavity.

89. A method according to claim 81 further comprising the step of placing the power supply in the outer ear canal.

90. A method according to claim 7 further comprising the step of adjusting the distance between the anterior occluder member and the posterior occluder member.

91. An anterior/posterior occlusion and access device according to claim 33 wherein

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the distance between the anterior occluder and posterior occluder is adjustable.

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DEVICES FOR THERAPEUTIC NASAL NEUROMODULATION AND ASSOCIATED METHODS AND SYSTEMS

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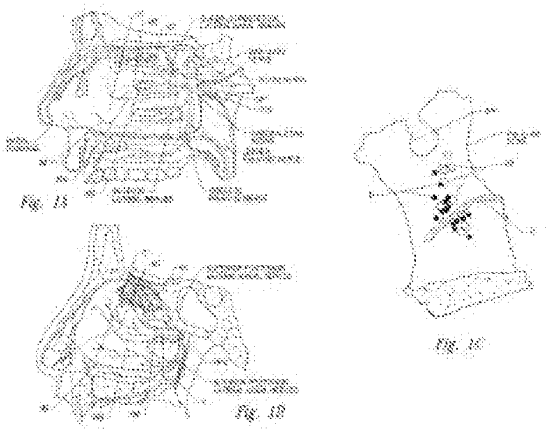
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Devices for therapeutic nasal neuromodulation and associated systems and methods are disclosed herein. A system for therapeutic neuromodulation in a nasal region configured in accordance with embodiments of the present technology can include, for example, a shaft and a therapeutic element at a distal portion of the shaft. The shaft can locate the distal portion intraluminally at a target site inferior to a patient's sphenopalatine foramen. The therapeutic element can include an energy delivery element configured to therapeutically modulate postganglionic parasympathetic nerves at microforamina of a palatine bone of the human patient for the treatment of rhinitis or other indications. In other embodiments, the therapeutic element can be configured to therapeutically modulate nerves that innervate the frontal, ethmoidal, sphenoidal, and maxillary sinuses for the treatment of chronic sinusitis.



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DESCRIPTION JP2018515314A

Devices and related methods and systems for therapeutic nasal nerve modulation

[0001]

[Cross Reference to Related Applications] This application claims priority to U.S. Provisional Patent Application No. 62/160,289, filed May 12, 2015, which is incorporated herein by reference in its entirety. do.

[0002]

TECHNICAL FIELD The present technology generally relates to devices, systems, and methods for therapeutic modulation of nerves within or associated with the nasal region of a patient

Specifically, various embodiments of the present technology relate to therapeutic neuromodulation systems and methods for treating rhinitis and other indications.

[0003]

Rhinosinusitis is characterized as inflammation of the mucous membranes of the nose and refers to a group of conditions including allergic rhinitis, non-allergic rhinitis, chronic rhinitis, chronic sinusitis, and medically resistant rhinitis.

Symptoms of rhinosinusitis include nasal congestion, obstruction, congestion, nasal discharge (eg, rhinorrhea and/or postnasal drip), facial pain, facial pressure, and/or reduced or loss of sense of smell. Allergic rhinitis can include additional symptoms such as sneezing, watery rhinorrhea, itchy nose, and itchy or watery eyes. Severe rhinitis can lead to associated asthma flare-ups, sleep disturbances, and reduced daily activities. Depending on the interval and type of system, rhinosinusitis can include acute rhinosinusitis, recurrent rhinosinusitis, and chronic rhinosinusitis with nasal polyps (i e., soft, non-cancerous growths inside the nostrils or sinuses). It can be included in four subtypes of rhinosinusitis and chronic rhinosinusitis without nasal polyps. Acute rhinosinusitis refers to symptoms lasting less than 12 weeks, whereas chronic rhinosinusitis (with or without nasal polyps) refers to symptoms lasting longer than 12 weeks. Recurrent rhinosinusitis refers to four episodes of acute rhinosinusitis within a 12-month period with resolution of symptoms between each episode.

[0004]

There are numerous environmental and biological causes of rhinosinusitis.

For example, non-allergic rhinosinusitis can be caused by environmental irritants (e.g., exhaust steam, cleaning fluids, latex, fragrances, dust, etc.), drugs (e.g., NSAIDs, oral contraceptives, blood pressure medications including ACE inhibitors, depressants, etc.), foods (eg, alcoholic beverages, spicy foods, etc.), hormonal changes (eg, pregnancy and menstruation), and/or a deviated nasal septum. Triggers for allergic rhinitis include seasonal allergens (e.g., exposure to environmental

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allergens that occur at similar times each year), perennial allergens that occur throughout the year (e.g., dust mites, animal dander, mold, etc.); Exposure to/or occupational allergens (e.g., certain chemicals, grains, latex, etc.) may be mentioned.

[0005]

Treatment of rhinosinusitis may include general avoidance of rhinitis triggers, nasal irrigation with saline solutions, and/or drug therapy.

Medications prescribed for rhinosinusitis include, for example, oral H1 antihistamines, topical nasal H1 antihistamines, topical intranasal corticosteroids, systemic glucocorticoids, injectable corticosteroids, and antileukotrienes. drugs, nasal or oral decongestants, topical anticholinergics, cromoglycate, and/or anti-immunoglobulin E therapy. However, these medications have limited efficacy (e.g., 17% greater or less than placebo), as well as sedation, irritation, taste disturbances, pharyngeal congestion, nasal dryness, epistaxis (i.e., epistaxis), and/or or have undesirable side effects such as headaches. Immunotherapy, including sublingual immunotherapy ("SLIT"), is also used to treat allergic rhinitis by desensitizing patients to specific allergens through repeated administration of allergen extracts. ing. However, immunotherapy requires an extended administration period (e.g., 3 to 5 years for SLIT) and can cause pain and swelling at the site of injection, skin itching (i.e., urticaria), angioedema, asthma, and It can result in a number of side effects including anaphylaxis.

[0006]

Surgical intervention has also been used in attempts to treat patients with severe rhinitis symptoms that are resistant to drug therapy.

From the 1960s to the 1980s, surgical procedures were performed to reduce parasympathetic tone in the nasal mucosa by cutting parasympathetic nerve fibers within the alar canals. More recent attempts at vidian neurotomy have been found to be 50-88% effective in treating rhinorrhea, with other attendant benefits including improvement of symptoms of sneezing and nasal obstruction. Improvement in these symptoms was also correlated with histological mucosal changes due to reductions in interstitial edema, eosinophilic cell infiltration, mast cell levels, and histamine concentrations in the denervated mucosa. However, despite the clinical and histological efficacy of vidian nerve transection, vidian nerve resection is primarily due to the mortality associated with its lack of anatomical and autonomic selectivity. , failed to gain widespread support. For example, the site of neurotomy involves preganglionic secretagogue fibers to the lacrimal gland, and therefore neurotomy often results in loss of lachrymal reflex, or epiphora, which in severe cases May cause loss of vision. Due to such irreversible complications, this technique was quickly abandoned. Furthermore, because of the passage of postganglionic pterygopalatine fibers through the retroorbital plexus, the location of the vidian neurotomy relative to the target end organ (i.e., the nasal mucosa) may interfere with the autonomic plexus and the otic ganglion process, which proceed with the accessory meningeal artery. can lead to reinnervation through

[0007]

Complications associated with vidian nerve transection are generally due to nonspecific sites of autonomic nerve denervation.

As a result, surgeons have recently shifted the site of neurotomy to postganglionic parasympathetic branches, which can have the same physiological effects as vidian neurotomy, while avoiding secondary injury to the lacrimal gland and sympathetic nerve fibers. are doing. For example, Japanese surgeons have performed transnasal inferior turbinate submucosal resection along with resection of the posterior nasal nerve ("PNN"), a postganglionic nerve pathway further downstream of the vidian nerve. (Kobayashi T, Hyodo M, Nakamura K, Komobuchi H, Honda N, Resection of peripheral branch of the posterior nasal nerve compared to conventional posterior neurectomy in severe allergic rhinitis. Auris Nasus Larynx. See February 15, 2012; 39:593-596.) PNN nerve transection is performed at the sphenopalatine foramen where the PNN is thought to enter the nasal region. These nerve transections are very complex and cumbersome due to the lack of good surgical markers to identify the desired posterior nasal nerve, and even once the desired nerve location has been determined. Nerve resection is extremely difficult because the nerve must be separated from the surrounding vasculature (eg, the sphenopalatine artery).

[0008]

Many aspects of the present technology may be better understood with reference to the following drawings.

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The components in the drawings are not necessarily to scale. Instead, the emphasis is on clearly illustrating the principles of the technology. For ease of reference, the same reference numbers may be used throughout this disclosure to identify the same or at least generally similar or similar components or features.

[0009]

FIG. 2 is a cutaway side view illustrating the anatomy of the side wall of the nose.

[0010]

FIG. 1B is an enlarged side view of the nerve on the side wall of the nose of FIG. 1A.

[0011]

FIG. 3 is a front view of the left palatine bone illustrating the geometry of the micropores within the left palatine bone.

[0012]

1 is a partial schematic diagram of a therapeutic neuromodulation system for therapeutically modulating nerves within the nasal region in accordance with an embodiment of the present technology; FIG.

[0013]

FIG. 3 is a partially cutaway side view illustrating various approaches for delivering a distal portion of a therapeutic neuromodulation device to a target site within the nasal region according to embodiments of the present technology.

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FIG. 3 is a partially cutaway side view illustrating various approaches for delivering a distal portion of a therapeutic neuromodulation device to a target site within the nasal region according to embodiments of the present technology.

[0014]

FIG. 3 is an isometric view of a distal portion of a therapeutic neuromodulation device constructed in accordance with an embodiment of the present technology

[0015]

1 is an isometric view of an electrode configuration of a therapeutic neuromodulation device for therapeutic neuromodulation according to an embodiment of the present technology; FIG.

1 is an isometric view of an electrode configuration of a therapeutic neuromodulation device for therapeutic neuromodulation according to an embodiment of the present technology; FIG.

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1 is an isometric view of an electrode configuration of a therapeutic neuromodulation device for therapeutic neuromodulation according to an embodiment of the present technology; FIG. 1 is an isometric view of an electrode configuration of a therapeutic neuromodulation device for therapeutic neuromodulation according to an embodiment of the present technology; FIG. 1 is an isometric view of an electrode configuration of a therapeutic neuromodulation device for therapeutic neuromodulation according to an embodiment of the present technology; FIG. 1 is an isometric view of an electrode configuration of a therapeutic neuromodulation device for therapeutic neuromodulation according to an embodiment of the present technology; FIG.

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[0016]

1 is a partial schematic diagram illustrating an electrode configuration in a distal portion of a therapeutic neuromodulation device for neural sensing constructed in accordance with embodiments of the present technology; FIG.

1 is a partial schematic diagram illustrating an electrode configuration in a distal portion of a therapeutic neuromodulation device for neural sensing constructed in accordance with embodiments of the present technology; FIG.

[0017]

2 is a graph illustrating threshold levels of nasal tissue electrical conductivity with respect to temperature.

[0018]

FIG. 3 is an isometric view of a distal portion of a therapeutic neuromodulation device constructed in accordance with an embodiment of the present technology.

FIG. 3 is an isometric view of a distal portion of a therapeutic neuromodulation device constructed in accordance with an embodiment of the present technology.

[0019]

FIG. 6 is an isometric view of a distal portion of a therapeutic neuromodulation device constructed in accordance with another embodiment of the present technology

10A is an isometric view illustrating the therapeutic neuromodulation device of FIG. 10A at a treatment site. FIG.

[0020]

FIG. 7 is an isometric view illustrating a distal portion of a therapeutic neuromodulation device constructed in accordance with yet another embodiment of the present technology.

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FIG. 7 is an isometric view illustrating a distal portion of a therapeutic neuromodulation device constructed in accordance with yet another embodiment of the present technology. FIG. 7 is an isometric view illustrating a distal portion of a therapeutic neuromodulation device constructed in accordance with yet another embodiment of the present technology.

[0021]

FIG. 7 is a side view of a distal portion of a therapeutic neuromodulation device constructed in accordance with a further embodiment of the present technology.

[0022]

FIG. 7 is a side view of a distal portion of a therapeutic neuromodulation device constructed in accordance with yet a further embodiment of the present technology.

[0023]

FIG. 7 is an isometric side view of a distal portion of a therapeutic neuromodulation device constructed in accordance with additional embodiments of the present technology.

[0024]

FIG. 7 is an isometric side view of a distal portion of a therapeutic neuromodulation device constructed in accordance with additional embodiments of the present technology.

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[0025]

FIG. 7 is a side cross-sectional view of a distal portion of a therapeutic neuromodulation device constructed in accordance with additional embodiments of the present technology.

[0026]

FIG. 7 is a side cross-sectional view of a distal portion of a therapeutic neuromodulation device constructed in accordance with additional embodiments of the present technology.

[0027]

FIG. 7 is a side cross-sectional view of a distal portion of a therapeutic neuromodulation device constructed in accordance with additional embodiments of the present technology.

[0028]

FIG. 7 is a side view of a distal portion of a therapeutic neuromodulation device constructed in accordance with additional embodiments of the present technology.

[0029]

FIG. 3 is a partially cutaway side view illustrating a target site proximal to a nasal sinus ostium for a therapeutic neuromodulation device constructed in accordance with an embodiment of the present technology.

[0030]

The present technology generally relates to devices and related systems and methods for therapeutic nasal neuromodulation.

The disclosed device is configured to provide precise, localized, non-invasive energy application to disrupt parasympathetic kinesthetic function within the nasal region.

Specific details of some embodiments of the present technology are described herein with reference to FIGS. 1A-20.

Although many of the embodiments are described with respect to devices, systems, and methods for therapeutically modulating nerves within the nasal region for the treatment of rhinitis, in addition to those described herein: Other applications and other embodiments are within the scope of the present technology.

For example, at least some embodiments of the present technology may be useful in treating chronic sinusitis and other indications, such as treating epistaxis.

It should be noted that other embodiments, in addition to those described herein, are within the scope of the technology.

Additionally, embodiments of the technology may have different configurations, components, and/or procedures than those illustrated or described herein.

Additionally, those skilled in the art will appreciate that embodiments of the present technology may have features, components, and/or procedures in addition to those illustrated or described herein, and that these and other embodiments may include It will be understood that some of the structures, components, and/or procedures illustrated or described herein may be omitted without departing from the present technology.

[0031]

With respect to the terms "distal" and "proximal" within this description, unless otherwise specified, these terms refer to the therapeutic neuromodulation device and/or associated delivery to the operator and/or intranasal location. May refer to the location of parts of the device.

For example, with respect to delivery catheters suitable for delivering and positioning the various prosthetic valve devices described herein, "proximal" refers to a location closer to the point of access of the operator of the device or the entry point of

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the patient's nares. , and "distal" can refer to a location farther from the operator of the device or farther from the point of access of the patient's nostril entrance.

Additionally, posterior, anterior, inferior, and superior are used according to standard medical terminology.

[0032]

As used herein, the terms "therapeutic modulation" and "therapeutic neuromodulation" of a nerve include partial or complete ablation of the nerve, partial or complete disabling or other refers to the effective disruption of

For example, therapeutic neuromodulation can include partially or completely inhibiting, reducing, and/or blocking nerve transmission along nerve fibers.

[0033]

Nasal Cavity Anatomy FIG. 1A is a cutaway side view illustrating the anatomy of the nasal lateral wall, and FIG. 1B is an enlarged side view of the nerves of the nasal lateral wall of FIG. 1A.

The sphenopalatine foramen ("SPF", FIG. 1A) is an opening or conduit defined by the palatine and sphenoid bones through which the sphenopalatine vessels and posterior superior nasal nerve pass into the nasal cavity.

More specifically, the orbital and sphenoid processes of the vertical plate of the palatine bone define the sphenopalatine notch, which is transformed into the SPF by articulation with the surface of the sphenoid body.

[0034]

The location of the SPF is highly variable within the posterior region of the lateral nasal cavity, which makes it difficult to visually determine the location of the SPF.

Typically, the SPF is placed within the middle meatus ("MM", Figure 1A), however, anatomical variations may also occur within the superior meatus ("SM", Figure 1A) or in the upper nasal meatus ("SM", Figure 1A), and SPF placed at the transition of the middle meatus.

In certain individuals, for example, the inferior border of the SPF is approximately 13 mm above the horizontal lamina of the inferior nasal turbinate ("IT", Figure 1A) of the horizontal lamina of the palatine bone (i.e., the nasal floor). The average distance from the nasal floor to the SPF is approximately 64.4 mm, resulting in an angle of approach from the nasal floor to the SPA of approximately 11.4°. However, studies to measure the exact location of SPF have limited practical application due to the high variability of its location.

[0035]

Anatomical variations in SPF are predicted to correspond to changes in the autonomic nerve and vascular pathways traversing into the nasal cavity.

Generally, the posterior nasal nerve (also referred to as the lateral posterior superior nasal nerve) branches from the pterygopalatine ganglion ("PPG", also referred to as the sphenopalatine ganglion, Figure 1A) and passes through the SPF to the nasal cavity of the nasal cavity. The sphenopalatine artery is thought to pass from the pterygopalatine fossa to the SPF on the lateral wall of the nose. The sphenopalatine artery branches into two main parts: the posterolateral nasal branch and the posteroseptal branch. A major branch of the posterolateral nasal artery courses inferiorly into the inferior turbinate IT (e.g., approximately 1.0 mm to 1.5 mm from the posterior end of the inferior turbinate IT), and another branch extends into the middle turbinate IT. It enters the MT and branches anteriorly and posteriorly.

[0036]

Beyond the SPF, studies have shown that over 30% of human patients have one or more accessory foramina that also carry arteries and nerves into the nasal cavity.

The minor foramena is typically smaller than the SPF and positioned below the SPF. For example, there may be one, two, three or more branches of the posterior nasal artery and nerve extending through the corresponding accessory foramen. Variations in location, size, and volume associated with the accessory foramen and the associated branch arteries and nerves that pass

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through it create a great deal of uncertainty regarding the location of the vasculature and nerves in the sphenopalatine region. Additionally, the neural anatomy extending from the SPF often includes deep inferior and/or superior grooves that carry neural and arterial pathways, making it difficult to determine the location of arterial and nerve branches. For example, the groove may extend more than 5 mm long, more than 2 mm wide, and more than 1 mm deep, thereby creating a passageway sufficient to carry both arteries and nerves. Variations caused by the grooves and accessory foramina within the sphenopalatine region make it extremely difficult for the surgeon to locate and access the artery and nerve (located posterior to the artery).

[0037]

Recent microanatomical dissections of the pterygopalatine fossa (PPF) have further demonstrated the highly variable anatomy of the surrounding region of the SPF, which projects from the pterygopalatine ganglion ("PPG", Figure 1). The large number of efferent branches of the cerebrovascular system indicate that they innervate the orbital and nasal mucosa via multiple groups of small nerve bundles rather than individual postganglionic autonomic nerves (eg, the posterior nasal nerve).

Studies have shown that at least 87% of humans have micropores and microbranches within their palatal bones. For example, FIG. 1C is a front view of the left palatine bone illustrating the geometry of the micropores and microbranches within the left palatine bone. In Figure 1C, filled areas represent nerves that traverse directly through the palatine bone, and open circles represent nerves that were associated with individual micropores. Indeed, FIG. 1C illustrates that the central portion of the palatine bone may contain at least 25 accessory posterolateral nerves.

[0038]

The respiratory part of the nasal mucosa consists of a type of ciliated multicolumn columnar epithelium with a basement membrane.

Nasal secretions (eg, mucus) are secreted by exudates from germ cells, submucosal glands, and plasma. The mixed glands and blood vessels of the nose are highly regulated by parasympathetic innervation derived from the vidian and other nerves. Parasympathetic (cholinergic) stimulation through acetylcholine and vasoactive intestinal peptide generally results in mucus production. Therefore, parasympathetic innervation of the mucosa is primarily responsible for activation/hyperactivation of the submucosal glands, venous congestion (eg, congestion), and increased blood flow to the vessels lining the nose. Therefore, severing or modulating the parasympathetic pathways that innervate the mucosa would be predicted to reduce or eliminate the overactivation of submucosal glands and vascular hyperemia that causes symptoms associated with rhinosinusitis and other signs. Ru

[0039]

As mentioned above, the postganglionic parasympathetic fibers (ie, the posterior superior nasal nerve) innervating the nasal mucosa were thought to course through the SPF exclusively as a sphenopalatine neurovascular bundle.

The posterior nasal nerve innervates the nasal cavity through numerous smaller medial and collateral branches that extend through the mucosa of the superior and middle turbinates ST and MT (i.e., the nasal chonchea) to the nasal septum. It is a branch of the maxillary nerve. The nasopalatine nerve is generally the largest of the medial posterior superior nasal nerves. It passes anteroinferiorly into the supravomer groove to the floor of the nasal cavity. From here, it passes through the incisor fossa of the hard palate and communicates with the larger palatine nerve, supplying the mucosa of the hard palate. The posterior superior nasal nerve passes without coaptation through the pterygopalatine ganglion PPG and over the maxillary nerve via its ganglionic branches.

[0040]

Based on the understanding that the posterior nasal nerve exclusively traverses the SPF to innervate the nasal mucosa, surgeries have been performed to selectively sever the posterior nasal nerve as it exits the SPF.

However, as mentioned above, the parasympathetic pathway of the sinuses actually has multiple small nerve bundles (i.e., rather than a single branch that projects from the pterygopalatine ganglion (PPG) and extends through the SPF) Contains individual branches that innervate the nasal mucosa via the accessory posterolateral nerve). These branches communicate through multiple fissures, accessory foramina, and microforamina throughout the palatine bone and may demonstrate an anastomotic ring with both the SPF and other accessory nerves. Therefore, if only the parasympathetic nerves that traverse the

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SPF are severed, nearly all patients (e.g., >90% of patients) retain intact parasecretagogue fibers to the posterolateral mucosa, which Nerve transection would result in the continuation of the symptoms it was intended to believe.

[0041]

Accordingly, embodiments of the present technique provide precise, focused treatment sites (e.g., target area T shown in FIG.) is configured to therapeutically modulate nerves.

In certain embodiments, the targeted nerve is a postganglionic parasympathetic nerve that goes on to innervate the nasal mucosa. This selective neurotherapy also allows the clinician to progressively increase the degree of anterior denervation through careful avoidance of the orbital branches (rami orbitonasalis), thereby reducing postoperative nasal eschar formation and it is expected to reduce the rate of drying. Additionally, embodiments of the present technology also reduce at least some sympathetic tone by preserving some of the sympathetic contribution from the deep petrosal nerve and internal maxillary peripheral plexus. It is also predicted to maintain the nasal obstruction and lead to improved outcomes regarding nasal obstruction. In addition, embodiments of the present technique provide complete resection of all anastomotic rings, thereby providing numerous parasympathetic entry points into the nasal region to reduce the rate of long-term reinnervation. (e.g., subpores, cracks, and micropores).

[0042]

Selected Embodiments of Systems for Therapeutic Nasal Nerve Modulation and Neural Mapping FIG. 2 shows a therapeutic neuromodulation system 200 ("system 200") is a partial schematic diagram.

System 200 includes a therapeutic neuromodulation catheter or device 202, a console 204, and a cable 206 extending therebetween. Therapeutic neuromodulation device 202 includes a shaft 208 having a proximal portion 208a, a distal portion 208b, a handle 210 at the proximal portion 208a of the shaft 208, and a therapeutic assembly or element 212 at the distal portion 208b of the shaft 208. including. Shaft 208 is configured to intraluminally position distal portion 208b at a treatment or target site within the nasal region proximal to the postganglionic parasympathetic nerves that innervate the nasal mucosa. The target site may be a region, volume, or area where the target nerve is located, and may be of different size and shape depending on the patient's anatomy. For example, the target site may be an area of 3 cm below the SPF. In other embodiments, the targeting site may be larger, smaller, and/or placed elsewhere within the nasal cavity to target the desired nerve fibers. Therapeutic assembly 212 may include at least one energy delivery element 214 configured to therapeutically modulate postganglionic parasympathetic nerves. In certain embodiments, for example, the therapeutic assembly 212 branches from the pterygopalatine ganglion, such as the parasympathetic nerve (e.g., the posterior nasal nerve) that traverses the SPF, accessory foramen, and microforamen of the palatine bone, and the nasal region. and postganglionic parasympathetic nerves that innervate the nasal mucosa.

[0043]

As shown in FIG. 2, therapeutic assembly 212 includes at least one energy delivery element 214 configured to provide therapeutic neuromodulation to a target site.

In certain embodiments, for example, energy delivery element 214 may include one or more electrodes configured to apply electromagnetic neuromodulation energy (eg, RF energy) to a target site. In other embodiments, the energy delivery element 214 includes, for example, cryotherapeutic cooling, ultrasound energy (e.g., high-intensity focused ultrasound ("HIFU") energy), microwave energy (e.g., via a microwave antenna). A variety of other modalities can be configured to provide therapeutic neuromodulation, such as direct heating, high and/or low power laser energy, mechanical vibration, and/or optical power. In further embodiments, therapeutic assembly 212 may be configured to deliver chemicals or drugs to the target site to chemically ablate or occlude the target nerve. For example, the therapeutic assembly 212 may include a needle applicator extending through the access portion of the shaft 208 and/or a separate introducer, the needle applicator extending through the access portion of the shaft 208 and/or a separate introducer to therapeutically modulate the target nerve. For example, it may be configured to inject chemicals into the target site, such as Botox, alcohol, guanethidine, ethanol, phenol, neurotoxins, or another suitable agent that alters, damages, or disrupts nerves.

[0044]

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In certain embodiments, therapeutic assembly 212 includes one or more sensors (not shown), such as, for example, one or more temperature sensors (e.g., thermocouples, thermistors, etc.), impedance sensors, and/or other sensors.) may be included.

The sensor(s) and/or energy delivery element 214 is connected to the shaft for transmitting signals to and/or from the sensor(s) and/or conveying energy to the energy delivery element 214. 208 may be connected to one or more wires (not shown, eg, copper wires) extending through 208.

[0045]

Therapeutic neuromodulation device 202 may be operatively coupled to console 204 via a wired connection (eg, via cable 206) and/or a wireless connection.

Console 204 may be configured to control, monitor, supply, and/or otherwise support the operation of therapeutic neuromodulation device 202. Console 204 may be further configured to generate a selected form and/or magnitude of energy for delivery to tissue or nerves at a target site via therapeutic assembly 212, and thus console 204 may be configured to. The therapeutic neuromodulation device 202 may have different configurations depending on the treatment modality. For example, when therapeutic neuromodulation device 202 is configured for electrode-based, thermal element-based, and/or transducer-based therapy, console 204 may be configured to use RF energy (e.g., unipolar, bipolar, or multipolar RF energy), pulsed electrical energy, microwave energy, optical energy, ultrasound energy (e.g., intracavitary ultrasound and/or HIFU), direct thermal energy, radiation (e.g., infrared, visible, and An energy generator 216 configured to generate gamma rays and/or another suitable type of energy may be included. When therapeutic neuromodulation device 202 is configured for cryotherapy treatment, console 204 may include a coolant reservoir (not shown) and is configured to supply coolant to therapeutic neuromodulation device 202. can be done. Similarly, if the therapeutic neuromodulating device 202 is configured for chemical-based therapy (e.g., drug infusion), the console 204 may include a chemical reservoir (not shown) and the therapeutic neuromodulating device 202 may include a chemical reservoir (not shown). may be configured to supply one or more chemicals to the patient.

[0046]

As further shown in FIG. 2, system 200 may further include a controller 218 communicatively coupled to therapeutic neuromodulation device 202.

In the illustrated embodiment, controller 218 is housed within console 204 . In other embodiments, the controller 218 may be carried by the handle 210 of the therapeutic neuromodulation device 202, the cable 206, a separate component, and/or another part of the system 200. Controller 218 is configured to initiate, terminate, and/or regulate operation of one or more components (e.g., energy delivery element 214) of therapeutic neuromodulation device 202, directly and/or via console 204. may be configured. Controller 218 may be configured to execute automatic control algorithms and/or receive control instructions from an operator (eg, a clinician). For example, controller 218 and/or other components of console 204 (e.g., memory) may include a computer-readable medium having instructions that, when executed by controller 218, cause the therapeutic assembly 202 to perform a specific function (eg, apply energy in a specific manner, detect impedance, detect temperature, detect nerve location or anatomical structure, etc.). Memory includes one or more of a variety of hardware devices for volatile and nonvolatile storage, and may include both read-only and writable memory. For example, memory can include random access memory (RAM), CPU registers, read-only memory (ROM), and writable memory such as flash memory, hard drives, floppy disks, CDs, DVDs, magnetic storage devices, tape drives, device buffers, etc. May include non-volatile memory. Memory does not carry signals that are separate from the underlying hardware, and therefore memory is non-transitory.

[0047]

Further, the console 204 may be configured to provide feedback to the operator before, during, and/or after a therapeutic procedure via an evaluation/feedback algorithm 220.

For example, the assessment/feedback algorithm 220 may be configured to provide information associated with the temperature of tissue at the treatment site, the location of nerves at the treatment site, and/or the effects of therapeutic neuromodulation on nerves at the treatment site. In certain embodiments, evaluation/feedback algorithm 220 may include features to confirm effectiveness of treatment and/or enhance desired performance of system 200. For example, the evaluation/feedback algorithm 220, in conjunction with the controller 218, monitors the temperature of the treatment site during therapy so that the temperature reaches a predetermined maximum value (e.g., upon application of RF energy) or a predetermined minimum value (e.g., when

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RF energy is applied). , during the application of cryotherapy). In other embodiments, the evaluation/feedback algorithm 220, in conjunction with the controller 218, provides a predetermined maximum impedance elevation of the targeted tissue (i.e., compared to a baseline impedance measurement) for a predetermined maximum time. The treatment may be configured to automatically terminate the treatment after a predetermined maximum impedance of the visualized tissue) and/or other threshold of a biomarker associated with autonomic function. This and other information associated with the operation of system 200 may be provided via display 222 (e.g., a monitor or touch screen) on console 204 and/or a separate display (not shown) communicatively coupled to console 204. may be communicated to the operator.

[0048]

In various embodiments, the treatment assembly 212 and/or other portions of the system 200 detect various parameters of the heterogeneous tissue at the target site to determine the anatomy at the target site (e.g., tissue type, tissue location, vasculature, bony structures, foramina, sinuses, etc.), determine the location of nerves and/or other structures, and enable neural mapping.

For example, treatment assembly 212 may be configured to detect impedance, dielectric properties, temperature, and/or other properties indicative of the presence of nerve fibers within the target area. As shown in FIG. 2, the console 204 includes a neuromonitoring assembly 221 (shown schematically) that receives detected electrical and/or thermal measurements of tissue at the target site obtained by the treatment assembly 212. and may process this information to identify the presence of nerves, nerve location, and/or neural activity at the target site. This information may then be communicated to the operator via a high resolution spatial grid (eg, on display 222) and/or other types of displays. Neuromonitoring assembly 221 is connected to energy delivery element 214 and/or other features of therapeutic assembly 212 via signal wires (e.g., copper wires) that extend through cable 206 and through the length of shaft 208. may be operably linked. In other embodiments, treatment assembly 212 may be communicatively coupled to neuromonitoring assembly 221 using other suitable communication means

[0049]

Neuromonitoring assembly 221 determines the location and activity of the nerve prior to therapeutic neuromodulation to determine the precise treatment area corresponding to the desired nerve location, and determines the effectiveness of the therapeutic neuromodulation during treatment. and/or assess after treatment whether the therapeutic neuromodulation has treated the target nerve to a desired extent.

This information can be used to make various decisions regarding the nerves proximal to the target site, such as whether the target site is suitable for neuromodulation. In addition, the neural monitoring assembly 221 also compares the detected neural location and/or activity before and after therapeutic neuromodulation, and compares changes in neural activity to predetermined thresholds to It can be assessed whether the application of the adjustment was effective across the treatment area. For example, neuromonitoring assembly 221 may determine neuroelectrogram (ENG) signals based on recordings of neuron electrical activity obtained by therapeutic assembly 212 before and after therapeutic neuromodulation. A statistically significant (eg, measurable or significant) decrease in the ENG signal(s) obtained after neuromodulation can serve as an indicator that the nerve has been sufficiently ablated.

[0050]

System 200 may further include a channel 224 extending along and communicating with at least a portion of shaft 208 and port 226 in shaft distal portion 208b.

In certain embodiments, channel 224 is a fluid pathway for delivering fluid to distal portion 208b of shaft 208 via port 226. For example, channel 224 may deliver a saline solution or other fluid to rinse the intraluminal nasal passageway during delivery of therapeutic assembly 212 to the target site prior to application of therapeutic neuromodulation to the target site. Fluid may be delivered to the target site during flushing and/or energy delivery to reduce heating or cooling of tissue adjacent energy delivery element 214. In other embodiments, channel 224 allows delivery of drugs to the treatment site. For example, a needle (not shown) can take and protrude port 226 to inject or otherwise deliver nerve blocks, local anesthetics, and/or other pharmacological agents into tissue at the target site. obtain.

[0051]

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Therapeutic neuromodulation device 202 provides access to target sites deep within the nasal region, such as at the peripheral entrance of parasympathetic nerve fibers into the nasal cavity, to therapeutically modulate autonomic nerve activity within the nasal cavity. provide.

In certain embodiments, for example, the therapeutic neuromodulation device 202 may position the therapeutic assembly 212 below the SPF at the site of the access foramen and/or micropores (e.g., FIG. 1B and 1C). By manipulating the proximal portion 208a of the shaft 208 from outside the nasal inlet, the clinician can advance the shaft 208 through the intricate intraluminal passages and through the nasal cavity to extend the distal portion of the shaft 208 through the handle 210. Portion 208b may be remotely manipulated to position therapeutic assembly 212 at a target site. In certain embodiments, the shaft 208 has a small bend radius (e.g., 5 mm bend radius, 4 mm bend radius, 3 mm bend radius, or (e.g., a steerable catheter). The steerable shaft may be further configured to articulate in at least two different directions. For example, the steerable shaft 208 has dual pull wiring that allows the clinician to shape the distal portion 208b of the shaft 208 into an "S" shape to accommodate the anatomy of the nasal region. may include. In other embodiments, the articulation shaft 208 is made from a substantially rigid material (e.g., a metallic material) that resists deflection but still has a small bend radius (e.g., a 5 mm bend radius, a 4 mm bend radius, 3 mm bend radius, or less) in the distal portion 208b of the shaft 208. In further embodiments, steerable shaft 208 may be a laser cut tube made from metal and/or other suitable materials. One or more laser-cut tubes are operated by the clinician to enable the clinician to deflect the distal portion 208b of the shaft 208 to navigate the intricate nasal anatomy to the target site. may include a pull wire.

[0052]

In various embodiments, the distal portion 208b of the shaft 208 is configured to guide the appropriate target site via a guidewire (not shown) using over-the-wire (OTW) or rapid exchange (RX) techniques. guided to the position.

For example, the distal end of treatment assembly 212 may include a channel that engages a guidewire. Intracavitary delivery of therapeutic assembly 212 involves inserting a guidewire into an orifice that communicates with the nasal cavity (e.g., the nostril or mouth) and moving the guidewire through the shaft until the therapeutic assembly 212 reaches the target site (e.g., below the SPF). 208 and/or treatment assembly 212 along the guidewire

[0053]

In further embodiments, therapeutic neuromodulation device 202 may be configured for delivery via a guide catheter or introducer sheath (not shown) with or without the use of a guidewire.

First, an introducer sheath may be inserted intraluminally at a target site within the nasal region, and then distal portion 208b of shaft 208 may be inserted through the introducer sheath. At the target site, the therapeutic assembly 212 may be deployed through the distal end opening of the introducer sheath or the side port of the introducer sheath. In certain embodiments, the introducer sheath has a straight portion and a fixed curvature (e.g., 5 mm curvature, 4 mm curvature, 3 mm curvature, etc.) that may be deployed within the cavity to access the target site. and a pre-shaped portion. In this embodiment, the introducer sheath may have a side port proximal to or along a pre-shaped curved portion through which the therapeutic assembly 212 may be deployed. In other embodiments, the introducer sheath may be made from a rigid material, such as a metallic material coated with an insulating or dielectric material. In this embodiment, the introducer sheath is substantially straight and delivers the therapeutic assembly 212 to the target site via a substantially straight path, such as through the middle meatus MM (FIG. 1A). may be used for

[0054]

Image guidance may be used to assist the clinician in positioning and manipulating the distal portion 208b of the shaft 208 and the treatment assembly 212.

For example, as described in further detail below with respect to FIGS. 3A-3E, an endoscope (not shown) may be used to locate a target site, position the therapeutic assembly 212 at the target site, and/or perform treatment during therapeutic neuromodulation. assembly 212 can be positioned to visualize it. In certain embodiments, the distal portion 208b of the shaft 208 is delivered through a working channel that extends through the endoscope, such that the endoscope is in direct contact with the target site and the treatment assembly 212. May provide serial visualization. In other embodiments, an endoscope is incorporated with the treatment assembly 212 and/or the distal portion 208b of the shaft 208 to provide in-line visualization of the assembly 212 and/or surrounding nasal anatomy. In still further embodiments, image guidance includes image filtering within the infrared (IR) spectrum, computed tomography (CT), fluoroscopy, It may be provided with various other guidance

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modalities such as acoustic waves, optical coherence tomography (OCT), and/or combinations thereof. Additionally, in some embodiments, image guidance components may be integrated with therapeutic neuromodulation device 202 to provide image guidance during positioning of therapeutic assembly 212.

[0055]

Once located at the target site, therapeutic modulation is applied to precise, localized tissue areas via energy delivery element 214 and/or other features of therapeutic assembly 212 to stimulate parasympathetic motor sensory function. One or more desired therapeutic neuromodulatory effects may be induced.

The therapeutic assembly 212 may selectively target postganglionic parasympathetic nerve fibers that innervate the nasal mucosa proximal to or at the target or treatment site proximal to the entrance into the nasal region. For example, therapeutic assembly 212 may be positioned to apply therapeutic neuromodulation at least proximal to the SPF (FIG. 1A) to therapeutically modulate nerves that enter the nasal region through the SPF. Therapeutic assembly 212 also applies therapeutic neuromodulation energy across the accessory foramina and microforamina (e.g., within the palatine bone) through which the smaller medial and collateral branches of the posterosuperior lateral nasal nerve enter the nasal region. As such, it can be positioned below the SPF. Purposeful energy application at the target site can achieve therapeutic neuromodulation along all or at least a portion of the posterior nasal nerve fibers that enter the nasal region. Therapeutic neuromodulatory effects are generally a function, at least in part, of power, time, and contact between the energy delivery element and adjacent tissue. For example, in certain embodiments, therapeutic neuromodulation of autonomic nerve fibers involves applying RF energy at a power of about 2 to 20 W (e.g., 5 W, 7 W, 10 W, etc.) for about 1 to 20 seconds (e.g., 5 to 10 seconds, 8-10 seconds, 10-12 seconds, etc.). Therapeutic neuromodulatory effects may include partial or complete denervation via thermal ablation and/or non-ablative thermal alteration or damage (e.g., via prolonged heating and/or resistive heating) . The desired thermal heating effect is to raise the temperature of the target nerve fiber above a desired threshold to achieve non-ablative thermal alteration or above a higher temperature to achieve ablative thermal alteration. May include. For example, the target temperature may be above body temperature (e.g., approximately 37°C) but below about 90°C (e.g., 70-75°C) for non-ablative thermal alterations, or the target temperature may be Regarding thermal alteration, the temperature may be about 100°C or higher (for example, 110° C, 120°C, etc.). Desired non-thermal neuromodulation effects may include altering electrical signals transmitted within the nerve.

[0056]

A hypothermic effect may also provide neuromodulation.

As described in more detail below, for example, therapeutically effective direct cell injury (e.g., necrosis), vascular injury (e.g., deprivation of nutrients and starvation of cells by damaging supply vessels); A cryotherapy applicator may be used to cool tissue at the target site to provide sublethal hypothermia with subsequent apoptosis. Exposure to cryotherapeutic cooling can cause acute cell death (eg, immediately after exposure) and/or delayed cell death (eg, during tissue thawing and subsequent hyperperfusion). Embodiments of the present technology may include cooling structures positioned at or near tissue such that the tissue is effectively cooled to a depth where the targeted postganglionic parasympathetic nerves reside. For example, the cooling structure is cooled to an extent that causes therapeutically effective cryogenic posterior nasal neuromodulation.

[0057]

In certain embodiments, the system 200 may determine the location of nerves, accessory foramina, and/or microforamina prior to therapy so that therapeutic neuromodulation may be applied to the precise area containing parasympathetic nerve fibers. .

For example, system 200 may identify a target site having a length and/or width approximately 3 mm below the SPF, and therapeutic assembly 212 may identify a target site through one or more applications of therapeutic neuromodulation. Therapeutic neuromodulation can be applied to targeted areas. In other embodiments, the target site may be smaller or larger (eg, a 3 cm long target area) based on the location of the detected nerve fibers and foramena. This anatomical mapping of the nerves allows the system 200 to accurately detect and therapeutically modulate the postganglionic parasympathetic nerve fibers that innervate the mucosa at the entry points of multiple nerves into the nasal cavity. Furthermore, because there are no obvious anatomical markers to indicate the location of SPF, accessory foramina, and microforamina, nerve mapping does not allow the operator to identify nerves that would otherwise not be located without complex mucosal dissection. , allowing for therapeutic modulation. In addition, anatomical mapping may also allow the operator to identify particular structures (eg, particular arteries) that the operator may wish to avoid during therapeutic neuromodulation.

[0058]

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Sufficient modulation of at least a portion of the parasympathetic nerves is predicted to slow or potentially block the conduction of autonomic signals to the nasal mucosa, producing a long-term or permanent reduction in nasal parasympathetic nerve activity. Ru.

This is expected to reduce or eliminate activation or overactivation of submucosal glands and venous congestion, thereby reducing or eliminating symptoms of rhinosinusitis. Furthermore, because the system 200 applies therapeutic neuromodulation to multiple branches of the posterior nasal nerve, rather than a single large branch of the posterior nasal nerve branch that enters the nasal cavity at SPF, the system 200 it affects the nasal mucosa and provides a more complete disruption of the parasympathetic pathways resulting in rhinosinusitis. Accordingly, system 200 is expected to have enhanced therapeutic efficacy for the treatment of rhinosinusitis and reduced reinnervation of the treated mucosa.

[0059]

In other embodiments, system 200 may be configured to therapeutically modulate nerves and/or other structures to treat different indications.

As discussed in further detail below, for example, system 200 can determine the location of nerves that innervate sinuses and/or therapeutically modulate them to treat chronic sinusitis. can be used. In further embodiments, the systems 200 and devices disclosed herein therapeutically modulate the vasculature within the nasal anatomy to prevent other problems such as epistaxis (i.e., excessive bleeding from the nose). may be configured to treat symptoms of. For example, the system 200 and therapeutic neuromodulation devices described herein can be applied to arteries (e.g., the sphenopalatine artery and its branches) that enter the nasal cavity (e.g., via the SPF, collateral foramina, etc.). Sometimes the application of therapeutically effective energy can be used to partially or completely coagulate or ligate an artery. In other embodiments, system 200 may be configured to partially or completely coagulate or ligate veins and/or other blood vessels. For such embodiments in which the therapeutic assembly 212 ligates or coagulates the vasculature, the system 200 has significantly higher power (e.g., about 100 W) than would be required for therapeutic neuromodulation and/or It may be modified to deliver energy for long periods of time (eg, one minute or more). In various embodiments, the system 100 uses methods described herein to determine the location of or detect the targeted vasculature and surrounding anatomy before, during, and/or after treatment. The disclosed anatomical mapping techniques may be applied.

[0060]

3A-3E are side views with partial cutaways illustrating various approaches for delivering the distal portion of the therapeutic neuromodulation device 202 of FIG. 2 to a target site within the nasal region according to embodiments of the present technology be.

As shown in FIG. 3A, in various embodiments, the distal portion 208b of the shaft 208 enters the nasal passage NP, passes through the inferior meatus IM between the inferior turbinate IT and the nasal floor NS, and passes through the inferior nasal passage IM between the inferior turbinate IT and the nasal floor NS. Extending around to the posterior portion of the IT, where the treatment assembly 212 is deployed at the treatment site. As shown in Figure 3A, the treatment site is a postganglionic parasympathetic nerve entry point(s) into the nasal cavity (e.g., a branch of the posterior nasal nerve and/or other parasympathetic nerve fibers innervating the nasal mucosa). may be placed proximal to the. In other embodiments, the target site may be elsewhere within the nasal cavity depending on the location of the target nerve. The endoscope 330 and/or other visualization device is positioned proximal to the target site by extending through the nasal passage NP and through the middle meatus MM between the inferior turbinate IT and middle turbinate MT. delivered to. From a visualization location within the middle meatus MM, endoscope 330 may be used to visualize the treatment site, the surrounding area of the nasal anatomy, and treatment assembly 212.

[0061]

As further shown in FIG. 3A, the shaft 208 of the therapeutic neuromodulation device 202 can include a therapeutic assembly 212 and a positioning member 332 positioned proximal to the target site.

In the illustrated embodiment, the positioning member 332 is expanded within the opening (e.g., one of the nasal passages) against an opposing structure (e.g., between the nasal turbinates) to extend the distal portion of the shaft 208. 208b is a balloon that consistently maintains the desired location relative to the target site to provide stability for deployment of the therapeutic

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assembly 212. In other embodiments, positioning member 332 may include other expandable structures (eg, mesh baskets) or fixation features that can be deployed to maintain shaft 208 in a desired position within the nasal cavity. In further embodiments, positioning member 332 may be positioned distal to treatment assembly 212 and expanded within a region distal to treatment assembly 212 and the treatment site. In still further embodiments, the positioning member 332 provides an introduction through which the shaft 208 and/or other devices (e g., fluid lines for saline or local anesthetic delivery, endoscopes, sensors, etc.) may pass. Positioned on a sheath (not shown). Positioning member 332 may be positioned proximal to the target site (eg, similar to the position shown in FIG. 3A) or distal to the treatment site. When positioned distally, the introducer sheath may include a side exit port through which the therapeutic assembly 212 and other features may be deployed at the target site. When positioning member 332 is positioned on the introducer sheath, positioning member 332 may provide stability for delivery and deployment of distal portion 208b of shaft 208 and therapeutic assembly 212. Positioning member 332 may be incorporated onto shaft 208, an associated introducer sheath, and/or other delivery features of system 200 (FIG. 2) when therapeutic assembly 212 is delivered through different intraluminal passageways. obtain.

[0062]

FIG. 3B shows that the distal portion 208b of the shaft 208 has entered the nasal passage NP and passed through the middle meatus MM between the inferior nasal turbinate IT and the middle nasal turbinate after the treatment assembly 212 is deployed at the treatment site. 3 illustrates different embodiments extending in the direction.

In this embodiment, endoscope 330 and/or other visualization device is delivered parallel to shaft 208 through the same intraluminal pathway as treatment assembly 212. A route through the middle meatus MM may provide generally straight access to the target site, depending on the particular region of interest and anatomical variations of the patient. Accordingly, approaches through the middle meatus MM may require less maneuvering and/or articulation of shaft 208 and endoscope 330. Additionally, because the distal portion 208b of the shaft 208 and the endoscope 330 travel along the same delivery path, the endoscopes may provide serial or parallel visualization of the therapeutic assembly 212.

[0063]

Similar to the embodiment shown in FIG. 3B, FIG. 3C shows that endoscope 330 provides serial or parallel visualization of distal portion 208b of shaft 208, treatment assembly 212, and/or nasal anatomy. 3 illustrates another intraluminal path in which the distal portion 208b of the shaft 208 and the endoscope 330 are advanced side by side to obtain the results.

However, in the embodiment shown in FIG. 3C, the intraluminal pathway extends through the inferior meatus IM to the treatment site posteriorly.

[0064]

As shown in FIG. 3D, in other embodiments, the distal portion 208b of the shaft 208 extends through the middle meatus MM to the treatment site and the endoscope 330 extends through the inferior meatus IM to target the treatment site. Extends to a proximal location of the site.

In this embodiment, the endoscope 330 is articulated or steerable to orient the endoscope 330 upwardly to visualize the nasal anatomy and treatment assembly 332 at the target site. , or may have a curved distal end. For example, the distal end portion of endoscope 330 can be configured to bend at least 30 degrees to visualize the treatment site.

[0065]

As shown in FIG. 3E, in a further embodiment, the distal portion 208b of the shaft 208 may be delivered to the treatment site via the mouth.

In this embodiment, therapeutic neuromodulation may be applied to a treatment site posterior to the nasal cavity (eg, posterior to the SPF). An endoscope 330 (not shown) may enter the nasal passage NP and extend through the middle meatus MM or the inferior meatus IM to a location proximal to the treatment site. Alternatively, endoscope 330 (not shown) may follow the same path as shaft 208.

[0066]

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FIG. 4 is an isometric view of a distal portion of a therapeutic neuromodulation device 402 constructed in accordance with an embodiment of the present technology.

Therapeutic neuromodulation device 402 may be used in conjunction with system 200 described above with respect to FIGS. 2-3E. As shown in FIG. 4, therapeutic neuromodulation device 402 can include a shaft 408 having a proximal portion (not shown) and a distal portion 408b, and a therapeutic assembly 412 at distal portion 408b of shaft 408. . The therapeutic assembly 412 is deformable between a low profile delivery state to facilitate intracavitary delivery of the therapeutic assembly 412 to a treatment site within the nasal region and an expanded state (shown in FIG. 4). . Treatment assembly 412 includes a plurality of struts 440 that are spaced apart from each other to form a frame or basket 442 when treatment assembly 412 is in an expanded state. Strut 440 may carry one or more energy delivery elements, such as a plurality of electrodes 444. In the expanded state, the strut 440 may position at least two of the electrodes 444 against tissue at a target site within the nasal region (eg, proximal to the palatine bone below the SPF). Electrodes 444 may apply bipolar or multipolar radio frequency (RF) energy to the target site to therapeutically modulate postganglionic parasympathetic nerves that innervate the nasal mucosa proximal to the target site. In various embodiments, the electrode 444 is configured to apply pulsed RF energy with a desired duty cycle (e g., 1 second on/0.5 second off) to modulate the temperature increase in the target tissue. may be configured.

[0067]

In the embodiment illustrated in FIG. 4, the basket 442 includes eight branches 446 that are radially spaced from each other to form at least a generally spherical structure, each of the branches 446 being positioned adjacent to each other. Includes two struts 440.

However, in other embodiments, the basket 442 may include fewer than eight branches 446 (eg, 2, 3, 4, 5, 6, or 7 branches) or more than eight branches 446. In further embodiments, each branch 446 of the basket 442 may include a single strut 440, more than two struts 440, and/or the number of struts 440 per branch may vary. In still further embodiments, branches 446 and struts 440 may form a basket or frame having other suitable shapes for positioning electrode 444 in contact with tissue at a target site. For example, in the expanded state, struts 440 may form an oval shape, a hemispherical shape, a cylindrical structure, a pyramidal structure, and/or other suitable shape.

[0068]

As shown in FIG. 4, the treatment assembly 412 may further include an internal or inner support member 448 extending distally from the distal portion 408b of the shaft 408

A distal end portion 450 of support member 448 may support a distal end portion of strut 440 to form a desired basket shape. For example, as shown in FIG. 4, strut 440 may extend distally from distal position 408b of shaft 408, with a distal end portion of strut 440 extending from distal position 408b of support member 448. It can be attached to section 450. In certain embodiments, support member 448 includes an internal channel (not shown) through which electrical connectors (e.g., wires) coupled to electrodes 444 and/or other electrical features of therapeutic element 412 may run.) may be included. In various embodiments, internal support member 448 may also carry electrodes (not shown) at distal end portion 450 and/or along the length of support member 448.

[0069]

Basket 442 can be expanded from a low profile delivery state by manipulating a handle (e.g., handle 210 in FIG. 2) and/or other features operably coupled to basket 442 on a proximal portion of shaft 408. state (FIG. 4).

For example, to move basket 442 from the expanded state to the delivered state, the operator can push support member 448 distally to bring struts 440 inwardly toward support member 448. An introducer or guide sheath (not shown) is positioned over the low profile therapeutic assembly 412 to facilitate intraluminal delivery or removal of the therapeutic assembly 412 from or to the target site. obtain. In other embodiments, therapeutic assembly 412 is transformed between the delivered and expanded states using other suitable means.

[0070]

Individual struts 440 may be made from a resilient material, such as a shape memory material (eg, Nitinol) that allows the struts 440 to self-expand into the desired basket 442 shape when in the expanded state.

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In other embodiments, struts 440 may be made from other suitable materials and/or treatment assembly 412 may be expanded mechanically via a balloon or by proximal movement of support member 448. may be done. Basket 442 and associated struts 440 may have sufficient rigidity to support electrode 444 and position or press electrode 444 against tissue at a target site. In addition, the expanded basket 442 may be pressed against the proximal surrounding anatomical structures of the target site (e g., nasal turbinates, palatine bones, etc.), and the individual struts 440 may be pressed against adjacent anatomical structures. may at least partially conform to the shape of the treatment element 412 to secure the treatment element 412 at the treatment site during energy delivery. In addition, the expansion and conformability of struts 440 may facilitate positioning electrodes 444 in contact with surrounding tissue at the target site.

[0071]

At least one electrode 444 is disposed on each post 440.

In the illustrated embodiment, two electrodes 444 are positioned along the length of each post 440. In other embodiments, the number of electrodes 444 on an individual post 440 may be only one, more than two, zero, and/or the number of electrodes 444 on different posts 440 may be varied. Good too. Electrode 444 is made of platinum, indium, gold, silver, stainless steel, platinum-iridium, cobalt chromium, iridium oxide, polyethylenedioxythiophene ("PEDOT"), titanium, titanium nitride, carbon, carbon nanotubes, platinum gray, Fort Wayne. , Drawn Filled Tubing ("DFT") with a silver core from Fort Wayne Metals of Indiana, and/or other materials suitable for delivery of RF energy to target tissues.

[0072]

In certain embodiments, each electrode 444 may be operated independently of other electrodes 444.

For example, each electrode may be activated individually, and the polarity and amplitude of each electrode may be selected by an operator or a control algorithm (eg, executed by controller 218 of FIG. 2). Various embodiments of such independently controlled electrodes 444 are described in further detail below with reference to FIGS. 5A-5G. Selective independent control of electrodes 444 allows treatment assembly 412 to deliver RF energy to highly customized areas. For example, selected portions of electrodes 444 may be activated to target nerve fibers within a particular region while other electrodes 444 remain inactive. In certain embodiments, for example, electrodes 444 may be activated over the portion of basket 442 adjacent to tissue at the target site, and electrodes 444 that are not proximal to the target tissue may be activated for application of energy to non-target tissue. may remain inactive to avoid Such a configuration facilitates selective therapeutic modulation of nerves on the sidewall of the nose within one nostril without applying energy to structures within other parts of the nasal cavity.

[0073]

Electrode 444 may be electrically coupled to an RF generator (eg, generator 216 of FIG. 2) via a wire (not shown) that extends from electrode 444 through shaft 408 to the RF generator.

When each electrode 444 is independently controlled, each electrode 444 couples to a corresponding wire extending through shaft 408. In other embodiments, multiple electrodes 444 may be controlled together, such that multiple electrodes 444 may be electrically coupled to the same wire extending through shaft 408. The RF generator and/or a component operably coupled thereto (eg, a control module) may include a custom algorithm to control activation of electrode 444. For example, the RF generator delivers approximately 200-300 W of RF power to the electrodes 444 in a predetermined pattern selected based on the location of the treatment element 412 relative to the treatment site and/or the identified location of the target nerve. This may be done while activating electrode 444. In other embodiments, the RF generator delivers power at lower levels (eg, less than 15 W, 15-50 W, 50-150 W, etc.) and/or higher power levels.

[0074]

As shown in FIG. 4, the treatment assembly 412 includes one or more sensors disposed on the strut 440 and/or other portions of the treatment assembly 412 and configured to detect temperature adjacent the temperature sensor 452. The temperature sensor 452 may further include a temperature sensor 452 .

Temperature sensor 452 may be electrically coupled to a console (eg, console 204 of FIG. 2) via a wire (not shown) extending through shaft 408. In various embodiments, temperature sensor 452 may be positioned proximal to electrode 444 to detect the temperature of the interface between tissue and electrode 444 at the target site. In other embodiments, temperature sensor 452 may penetrate tissue at a target site (eg, a penetrating thermocouple) to detect temperature at a depth within the tissue.

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Temperature measurements may provide feedback to the operator or system regarding the effects of therapeutic neuromodulation on the tissue. For example, in certain embodiments, the operator may desire to prevent or reduce damage to tissue at the treatment site (e.g., nasal mucosa), and thus the temperature sensor 452 indicates that the temperature of the tissue is It can be used to determine whether a predetermined threshold for damage is reached. Once a threshold is reached, application of therapeutic neuromodulatory energy may be terminated such that the tissue may remain intact. In certain embodiments, energy delivery is performed using an evaluation/feedback algorithm (e.g., evaluation/feedback algorithm 220 of FIG. 2) stored on a console (e.g., console 204 of FIG. 2) operably coupled to temperature sensor 452.) may be automatically terminated

[0075]

5A-5G illustrate therapeutic neuromodulation devices (individually identified as first through fourth therapeutic neuromodulation devices 502a-502d, respectively, and collectively) for therapeutic neuromodulation according to embodiments of the present technology. 5 is an isometric view of an example electrode configuration for a therapeutic neuromodulation device (referred to as a therapeutic neuromodulation device 502); FIG.

Therapeutic neuromodulation device 502 of FIGS. 5A-5G may include features generally similar to those of therapeutic neuromodulation device 402 of FIG. 4. For example, therapeutic neurormodulation device 502 includes a plurality of struts 440 that form a basket 442 when in an expanded state, and a plurality of electrodes 444 disposed on one or more of the struts 440. In the illustrated embodiment, the first to third therapeutic neuromodulation devices 502a-c shown in FIGS. 5A-5E include a single strut 440 corresponding to each branch 446 of the basket 442, and A fourth therapeutic neuromodulation device 502d shown in 5G includes two adjacent struts 440 within each branch 446 of basket 442. However, in other embodiments, the branches 446 of the therapeutic neuromodulation device 502 have different amounts of struts 440 and transmit RF energy in the same manner as described below with reference to FIGS. 5A-5G. May be applied. As shown in FIGS. 5A-5G, electrodes 444 can be independently controlled and activated via commands from a controller (e.g., controller 218 of FIG. 2) or a generator (e.g., generator 216 of FIG. 2). may be applied to apply RF energy over selected regions or segments of treatment assembly 412.

[0076]

In the embodiment shown in FIG. 5A, two electrodes 444 of therapeutic assembly 412 are activated within first therapeutic neuromodulation device 502a.

More specifically, a first electrode 444a on a first post 440a is activated with positive polarity and a second electrode on a second post 440b is radially spaced apart from the first post 440a. 444b is activated with negative polarity. The remainder of electrode 444 remains inactive. Thus, as indicated by the arrows, electrical current may flow through the target tissue from the first electrode 444a to the second electrode 444b over the circumference or peripheral segment of the treatment assembly 412. This configuration can be used to therapeutically modulate nerves located proximally to peripheral segments. In other embodiments, different or additional electrodes 444 may be activated with selected polarities to apply therapeutic neuromodulation over selected regions of therapeutic assembly 412 in a predetermined manner. .

[0077]

In the embodiment shown in FIG. 5B, the first therapeutic neuromodulation device 502a is configured with three selectively active electrodes 444.

The first electrode 444a on the first pillar 440a is activated with positive polarity, and the second and third electrodes 444b and 444c on the corresponding second and third pillars 440b and 440c are activated with negative polarity. activated The remainder of electrode 444 remains inactive. As indicated by the arrows, current flows through the tissue across the segments of the treatment assembly 412 from the first electrode 444a to the second and third electrodes 444b and 444c, thus positioned proximal to the peripheral segment. Can therapeutically modulate nerves. In the illustrated embodiment, the second and third activated electrodes 444b and 444c are radially spaced from, but adjacent to, the first post 440a carrying the first active electrode 444a. Positioned on struts 440b, 440c. However, in other embodiments, electrodes positioned on post 440 are located further from first post 440a to apply energy over a larger and/or wider segment of treatment assembly 412 444.

[0078]

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In the embodiment shown in FIG. 5C, all of the electrodes 444 in the first hemispherical region 501a of the treatment assembly 412 are activated and the electrodes 444 in the second hemispherical region 501b are not activated.

The first electrode on the first pillar 440a is selectively activated with positive polarity, and the plurality of electrodes 444 (each individually second to fifth electrodes 444b to 444e) in the first hemispherical region 501a are activated with positive polarity.) is selectively activated with negative polarity such that RF energy is applied over the first hemispherical region 501a. This electrode activation configuration may be used to apply RF energy across one side of the basket 442 to therapeutically modulate nerves on the sidewall of the nose within one nostril. When the treatment assembly 412 is positioned within the other nostril, different sets of electrodes 444 may be activated over the hemispherical region of the treatment assembly 412 based on the orientation of the basket 442 relative to the sidewall of the nose. Additionally, because the basket 442 has a generally symmetrical shape (e.g., circular, oval, etc.) and because the electrodes 444 can be selectively activated, the orientation of the basket 442 relative to the target site on the sidewall of the nose may be a problem. isn't it. Alternatively, the operator may deploy treatment assembly 412 at the target site without regard to orientation and selectively activate electrodes 444 in the desired alignment to apply RF energy across the target site.

[0079]

In the embodiment shown in FIG. 5D, the second therapeutic neuromodulation device 502b selectively controls the polarity of the plurality of electrodes 444 over at least a portion of the therapeutic assembly 412 to make the RF energy sesquipolar. (i.e., continuous or temporary bipolar pairing of electrodes).

In the illustrated embodiment, the first electrode 444a is biased with positive polarity and the second through seventh electrodes 444b-444g are controlled to have negative polarity. The second through seventh electrodes 444b-444g are spaced substantially equal distances from the first electrode 444a such that the electrodes 444 are dimensionally prepositioned for multiplexing in sequence. During operation, the first through seventh electrodes 444a-444g are activated simultaneously. However, rather than all of the negative electrodes 444 simultaneously pairing or multiplexing with the positive first electrode 444a, the first electrodes 444a separate the individual electrodes in a sequential manner based on the path of least resistance. It will pair with negative electrode 444. This path of least resistance is determined by the natural anatomy of the treatment site in contact with electrode 444. For example, based on the anatomy at the target site, the first electrode 444a may be initially paired with the second electrode 444b. After this initial pairing preference disappears, a second pairing (eg, with third electrode 444c) will occur based on the path of least resistance. The first electrode 444a is activated in a similar manner as the remaining activated negative electrodes until a threshold is reached and the electrodes 444 are in a state of equilibrium where there is a homogeneous current between all of the electrode pairs. They will continue to pair up continuously. With each successive pairing, therapeutic assembly 412 increases the size of the ablation zone (ie, the area to which therapeutic neuromodulatory energy is applied). As indicated by numbers 1-6 in FIG. 5D, this successive pairing of electrodes 444 occurs in a circular direction (e.g., counterclockwise or clockwise direction) based on impedance changes between electrodes 444. You may. In other embodiments, sequential pairing of electrodes 444 may occur in different patterns based on the surrounding anatomical context and/or positioning of electrodes 444. For example, in the illustrated embodiment, activated electrodes 444 are positioned within quadrants of therapeutic element 412 with equal radial distances between individual electrode pairs. In other embodiments, activated electrodes 444 may be positioned over a larger or smaller area of treatment element 412 to apply energy over a larger or smaller treatment area.

[0080]

Sesquipolar application of RF energy allows therapeutic assembly 412 to intelligently apply RF energy across a target site to therapeutically modulate nerves proximal to the treatment site.

For example, when in equidistant radial relationship to one another, naturally occurring impedance changes between electrode pairs cause therapeutic assembly 412 to radially increase the compartment of energy application with each pairing. In other embodiments, the electrodes 444 are sequentially connected to each other in a manner such that the parcellation of energy application increases in a lateral and/or longitudinal manner based on naturally occurring impedance changes between the electrodes 444. They may be configured in pairs. Additionally, successive impedance-based pairings of electrodes 444 can provide sesquipolar alignment of therapeutic assembly 412, since if the impedance exceeds a threshold in one electrode pairing, the next electrode pairing occurs at a lower impedance. can inherently limit the energy applied to tissue at the target site. In other embodiments, a controller (e.g., controller 218 of FIG. 2) provides instructions (e.g., software) may be included.

[0081]

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In further embodiments, a portion of the strut 440 itself may define the electrode 444.

In this embodiment, struts 440 are made from a conductive material and coated with an insulating material (eg, a polyxylene polymer including Paralyene C). https://en wikipedia.org/wiki/Xylylenehttps://en wikipedia.org/wiki/Polymers A portion of post 440 may be left uncovered to define electrode 444. The location of the uncovered portions of struts 440 (ie, electrodes 444) may be selected to provide the desired neuromodulation pattern. For example, the uncovered portions can be placed equally spaced from the central electrode 444 to enable sesquipolar RF applications. In this embodiment, the conductive struts 440 serve as electrical connectors, so the therapeutic assembly 412 does not require as many wires as if the electrodes 444 were separate elements positioned on the struts 440. do not.

[0082]

In the embodiment shown in FIG. 5E, the third therapeutic neuromodulation device 502c includes a return electrode 503 at the distal end portion 450 of the support member 448 to provide radial multiplexing of the electrode 444; and selective polarity control of individual electrodes 444 on struts 440.

Return electrode 503 has negative polarity, and other electrode 444 has positive polarity. In the illustrated embodiment, all of the electrodes 444 are activated, but in other embodiments, the electrodes 444 may be selectively activated based on the desired energy application zone. As indicated by the arrow, this configuration applies RF energy over the distal hemispherical region of the basket 442. In other embodiments, return electrode 503 may be positioned elsewhere on treatment assembly 412 and electrodes 444, 503 may be used to apply RF energy over different areas of basket 442. In further embodiments, the return electrode 503 may be activated in conjunction with two or more of the electrodes 444 on the post to apply RF energy in a sesquipolar manner.

[0083]

In the embodiment shown in FIG. 5F, the fourth therapeutic neuromodulation device 502d includes a branch 446 with two adjacent struts 440, where the electrodes 444 on the adjacent struts are longitudinally spaced apart from each other and individually selectively activated to apply energy radially across sections of the .

For example, the first electrode 444a on the first strut 440a of the first branch 446a may be selectively activated to have a first polarity, and the first electrode 444a on the first strut 440a of the first branch 446a may be selectively activated to have a The second electrode 444b on the post 440b may be selectively activated to have a second polarity opposite the first polarity. As indicated by the arrows in FIG. 5F, first and second electrodes 444a and 444b may then apply bipolar RF energy radially within specific regions of treatment assembly 412.

[0084]

As further shown in FIG. 5F, an individual strut 440 may include a plurality of electrodes 444 disposed thereon, and adjacent struts 440 within the same branch 446 may be arranged along distinct regions of the branch 446. It may have a corresponding amount of electrodes 444 to allow bipolar coupling of each of the electrode pairs.

In certain embodiments, the electrodes of one strut 440 may all have the same polarity (e g., first wire connected, not shown), and the electrodes of adjacent struts 440 within the same branch 446 444 can all have opposite polarities (eg, coupled to a second wire, not shown). In other embodiments, the electrodes 444 on individual struts 440 may be independently controlled to have the desired polarity.

[0085]

In various embodiments, the electrode pairing configuration shown in FIG. 5F may be used to detect impedance across selected regions of treatment assembly 412 defined by bipolar electrode pairs.

Impedance measurements can then be used to identify the presence of nerve fibers within the selected region. If a nerve is detected within one or more specific regions associated with the electrode pair, the same electrode pair is used to apply RF energy to that region and therapeutically modulate the nerve within that region. can be done.

[0086]

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In the embodiment shown in FIG. 5G, the fourth therapeutic neuromodulation device 502d selectively controls the polarity of the plurality of electrodes 444 across at least a portion of the therapeutic assembly 412 to provide a multipolar and configured to apply RF energy in a fashion.

As shown in FIG. 5G, the electrode 444 of one branch 446 may be activated to have a negative polarity, and the electrode 444 of another branch 446 may be activated to have a positive polarity. The arrangement of electrodes 444 and the variable distance between electrodes 444 can be different so that the energy application zones have different shapes or patterns. In other embodiments, positive and negative electrodes 444 are spaced apart from each other by a variable distance. The changes in impedance resulting from the surrounding anatomy cause the electrodes to pair with each other in a continuous manner, thereby continuously creating a section or area where energy is applied in a radial and generally spiral manner. increase.

[0087]

Generally, the further the positive and negative electrode pairs are spaced apart from each other, the deeper the energy will travel into the adjacent target tissue.

Therefore, the depth of impact of therapeutic neuromodulatory energy is expected to increase as the coupled electrode pairs are placed further apart from each other on the basket 442. In the embodiment illustrated in FIG. 5G, for example, electrode pairs in the distal and proximal regions of basket 442 deliver energy to a shallower depth within the target tissue than electrode pairs located in the central region of basket 442. Apply. Therefore, electrode pairs placed closer together may therapeutically modulate nerves at a shallower depth than electrode pairs placed further apart from each other. As shown in the illustrated embodiment, some of the electrodes 444 and/or the entire branch 446 of the basket 442 may be inert to achieve the desired depth of energy application and/or neuromodulation pattern. It can remain as it is. Selected embodiments of neural detection and mapping

[0088]

Various embodiments of the present technology measure bioelectrical, dielectric, and/or other properties of heterogeneous tissue at target sites within the nasal region to determine the presence, location, and/or activity of nerve fibers. and optionally may include features mapping the location of the detected nerve.

The features described below can be incorporated into any of the systems and/or devices disclosed herein to provide accurate delineation of nerves at a target site.

[0089]

Nerve detection may be performed prior to application of therapeutic neuromodulation energy to (a) determine the presence or location of nerves at the target site and/or record baseline levels of neural activity; (b) at the treatment site. (c) during therapeutic neuromodulation to determine the effect of energy application on nerve fibers in the targeted nerve; and/or (c) after therapeutic neuromodulation to confirm the effectiveness of the treatment in the targeted nerve. can occur.

Because of the anatomical variation in the number and location of parasympathetic nerve fibers that innervate the nasal cavity and the numerous points of access through which they enter the nasal cavity (e.g., SPF, paraforamina, and microforamina), such nerve fibers Detection and mapping may provide an accurate representation of the neural structure to appropriately treat the parasympathetic nerve as well as one or two major branches of the posterior nasal nerve that traverse the SPF.

[0090]

In certain embodiments, the systems disclosed herein use bioelectrical measurements such as, for example, impedance, resistance, voltage, current density, and/or other parameters (e.g., temperature) to measure the target site. can determine the biological structure, specifically the neural structure, of the brain.

Next, the location of the neural structures determines which treatment site(s) should involve various anatomical structures for therapeutically effective neuromodulation of the targeted parasympathetic nasal nerve. can be used for. For example, the information may be used to determine treatment site(s) with respect to the location of the nasal turbinates or nasal passages.

[0091]

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Bioelectrical properties can be detected via electrodes (eg, electrode 444 of therapeutic neuromodulation devices 402-502d of FIGS. 4-5G).

Electrode pairing on the device (e.g., therapeutic assembly 412 described with respect to FIGS. 4-5G) is selected to acquire bioelectrical data in a particular compartment or region at a particular depth of the targeted region. can be done. For example, FIGS. 6A and 6B are partial schematic diagrams illustrating the configuration of electrodes 644 for neural sensing configured in accordance with embodiments of the present technology. As shown in FIG. 6A, the further apart the electrodes 644 are from each other, the deeper the current flows into the tissue. Accordingly, electrode 644 may be selectively activated based on the depth at which the desired measurement is to be made. As shown in FIG. 6B, the spacing between electrodes 644 along a plane (eg, the surface of a tissue) can affect the area in which measurements are taken. Accordingly, electrode 644 can be selectively activated to obtain information (eg, impedance) over a desired area at a desired depth. In other embodiments, bioelectrical properties may be detected using optical coherent tomography (OCT), ultrasound, and/or other suitable detection modalities.

[0092]

Measurement of bioelectrical properties may provide information associated with identifying not only the location of nerve fibers, but also the overall anatomy (e.g., nasal turbinates, nasal passages, bones, etc.), which may be useful for system delivery and it can be used to facilitate identification of target nerves relative to the gross anatomy.

For example, global target identification may be determined by evaluating the incident electromagnetic field on soft and hard tissues within the nasal region, which depends on the local geometry and dielectric properties of those features. For example, due to the layered structure of the nasal cavity anatomy (e.g., nasal mucosa, submucosa, periosteum, and bony plate), there are large differences in the relative conductivity of soft and hard tissues, which can be used to distinguish the "deeper" mucosal tissue of the nasal turbinates from the "shallower" tissue external to the nasal turbinates.

[0093]

In certain embodiments, measurements for neural mapping include applying a constant current to the electrodes and measuring the voltage difference between adjacent pairs of electrodes to create a spectral profile or to measure tissue at the target site. It can be obtained by mapping.

Impedance data may be acquired while applying high, medium, and/or low frequencies to the target tissue. At high frequencies, the current passes directly through the cell membrane and the resulting measurements are indicative of tissue and fluid both outside and inside the cell. At low frequencies, cell membranes impede electrical current and provide different defining characteristics of the tissue. Accordingly, bioimpedance can be used to measure targeted geometric or electrical properties of tissues and/or other structures of the nasal cavity. In addition, complex neural mapping may be performed using frequency difference reconstruction, which requires measurement data (eg, impedance) at two different frequencies.

[0094]

When detecting nerve location and activity through bioelectrical properties, the spatial orientation, direction, and activity of the detected nerve bundles can be used to further identify and characterize the nerve.

For example, the measured bioelectrical properties include axons that terminate (i.e., enter the sensing region but do not exit from it), axons that branch (i.e., enter the sensing region, and increase in number as they exit the sensing region).), migrating axons (i.e., entering and exiting the detection region without geometric or numerical changes), and/or other properties of the nerve may be distinguished. In addition, the orientation of the axons relative to the electrode array can be determined by the nerve fibers being parallel (X direction), perpendicular (Y direction), penetrating depth (Z direction), and/or arbitrary for these parameters. It may be specified to indicate the relative position or angle at which it extends. This information can then be used to selectively treat specific nerve fibers. For example, a selected electrode configuration may be applied to treat a particular area, and/or the treatment assembly may be moved or manipulated to treat nerves from a different orientation or location.

[0095]

In certain embodiments, temperature measurements may be obtained to determine the effects of therapeutic neuromodulation on nasal tissue.

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For example, FIG. 7 is a graph illustrating threshold levels of nasal tissue electrical conductivity versus temperature. A first curve 701 depicts tissue electrical conductivity (σ) in response to temperature and shows that a temperature of about 70° C. corresponds to a first threshold of irreversible change in tissue impedance. The second curve 703 shows a permanent significant increase in tissue electrical conductivity (i.e., a decrease in impedance) after the tissue is exposed to a temperature of 70°C, as can occur during therapeutic neuromodulation. Show that. If the therapeutic neuromodulation is stopped when the tissue temperature is detected to be about 70°C, without reaching a stage where the tissue is structurally altered or damaged (e.g., by evaporation, desiccation, etc.) It is expected that there will be a permanently measurable change in tissue conductivity. However, if tissue is exposed to temperatures above a second thermal threshold of approximately 90°C, the tissue will undergo a high degree of tissue desiccation and therefore a significant decrease in electrical conductivity (i.e., higher levels of electrical impedance). receive. The third curve 705 illustrates this lower tissue electrical conductivity after exposure to temperatures above 90°C. Accordingly, in various embodiments, the systems disclosed herein cease neuromodulation when the temperature reaches about 70°C (e.g., 70-80°C) to prevent structural changes to the mucosa or it can be configured to provide what is expected to be therapeutically effective neuromodulation while avoiding damage.

[0096]

Neural detection and mapping may provide pre-treatment assessment of neural structure, in-procedure assessment and feedback on temporal changes in tissue during neuromodulation, and/or post-treatment assessment of neural activity as a validation check.

In various embodiments, bioelectrical measurements taken before, during, and after treatment may be taken multiple times during each stage of treatment to assess and confirm findings. Pre-procedure assessment evaluates the bioelectrical properties of the native/host tissue to identify the original biological trace for subsequent action and to identify anatomical targets of interest (e.g. nerves, micropores, etc.) can be used to determine the baseline as a reference guide for the This information can be determined by placing a multi-electrode array in a known spatial configuration and detecting and then mapping electroanatomical properties (eg, variations in impedance of different tissue types) The resulting anatomical mapping may include the construction of multiple (dense) activation sequences in multiple planes with impedance variations to identify different tissue types and structures. During the procedure, impedance measurements can be used to confirm that the electrode maintains good contact with the tissue at the target site. During and after the procedure, the data can be used to determine whether spectra recorded during or after the procedure have a shape consistent with the expected tissue type. After treatment, the information can be used to determine whether the targeted nerve has been therapeutically treated.

[0097]

In other embodiments, nerve fiber action potentials may be detected via electrodes and/or other contacts to dynamically map nerve location and/or activity within a target area.

For example, recorded action potentials can be used to numerically measure, map, and/or image fast neuronal depolarizations to generate an accurate picture of neural activity. Generally, depolarization of a neuron membrane can cause a drop in voltage of about 110 μV, has a duration of about 2 ms, and has an impedance/resistance of 1000 Ωcm to 25 Ωcm. In further embodiments, metabolic recovery processes associated with action potential activity (i.e., to restore ion gradients to normal) may also be detected and used to dynamically map nerves at a target site. Detection of bioelectrical properties associated with these features has the advantage that the changes are much larger (eg, approximately 1000 times larger) and therefore easier to measure.

[0098]

In various embodiments, non-therapeutic stimulation (eg, RF energy) may be applied to the tissue in the detection area via two or more electrodes of the electrode array to enhance action potential recording.

Application of stimulating energy can temporarily activate nerve fibers and the resulting action potentials can be recorded For example, two or more electrodes of the therapeutic assembly may deliver stimulatory pulses of energy, and other two or more electrodes may be configured to detect the resulting action potentials. Stimulatory energy pulses are expected to strengthen the action potential signal and make recording easier. Selected embodiments of therapeutic neuromodulation devices

[0099]

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8 and 9 are isometric views of a distal portion of a therapeutic neuromodulation device 802 ("device 802") constructed in accordance with an embodiment of the present technology.

Device 802 may include various features generally similar to those of therapeutic neuromodulation devices 402 and 502a-d described above with reference to FIGS. 4-5G. For example, device 802 includes a therapeutic assembly 812 at distal portion 408b of shaft 408. The treatment assembly 812 includes a plurality of struts 440 forming a branch 446 and defining an expandable frame or basket 442, and one or more electrodes 444 disposed on one or more of the struts 440. including. As shown in FIGS. 8 and 9, device 902 may further include an expandable member 856 (eg, a balloon) carried by support member 448 and expandable within basket 442. As shown in FIGS. Expandable member 856 may include a plurality of electrodes 858 disposed on an outer surface of expandable member 856. Electrode 858 is capable of detecting bioelectrical characteristics (e.g., impedance) to enable mapping of neural structures at the target site before, during, and/or after therapeutic neuromodulation via other electrodes 444. can be used for In other embodiments, electrode 858 may be configured to apply energy for therapeutic neuromodulation.

[0100]

As shown in FIGS. 8 and 9, electrodes 858 may be positioned on expandable member 856 in a substantially symmetrical manner and uniform distribution.

This provides an expandable array by which impedance and/or other properties may be detected across the tissue, thus providing a more detailed mapping of the tissue and nerves at the treatment site. In other embodiments, electrodes 858 may be grouped toward a central portion of expandable member 856 and/or around different portions of expandable member 856. In certain embodiments, the electrodes 858 may be selectively activated with a particular polarity such that the electrode array is configured in a variety of static configurations and dynamically changes the order (e.g., depending on the sesquipolarity of the current). application), which may be advantageous for mapping functions.

[0101]

In operation, expandable member 856 may be inflated or otherwise expanded (FIG. 9) to place at least a portion of electrode 858 in contact with tissue at a target site.

Electrodes 858 may measure various bioelectrical properties of tissue (eg, impedance, action potentials, etc.) to detect, locate, and/or map nerves at the treatment site. In certain embodiments, electrodes 444 on struts 440 and/or portions of electrodes 858 on expandable member 856 may apply stimulatory pulses of RF energy, and electrodes 858 may generate a resulting neural response. Can be detected. After mapping, expandable member 856 can be deflated or collapsed (FIG. 8) and electrodes 444 on struts 440 can apply therapeutically effective neuromodulatory energy to the target site. For example, the ablation pattern of electrode 444 may be based on nerve location identified via information detected from sensing electrode 858 on expandable member 856. In other embodiments, the expandable member 856 may remain expanded during neuromodulation, the electrode 858 may detect neural activity during the neuromodulation procedure, or the electrode 858 may itself may be configured to apply neuromodulatory energy to the treatment area. After application of neuromodulation energy, electrodes 858 on expandable member 856 can be placed in contact with tissue again at the target site and used to record bioelectrical properties (eg, impedance). Detected characteristics (eg, impedance) obtained before, during, and/or after neuromodulation can be compared to each other to determine whether the neuromodulation was therapeutically effective. Otherwise, the electrodes 444 may again apply therapeutic neuromodulatory energy to the same treatment site, or the configuration of active electrodes 444 may be changed to apply therapeutic neuromodulatory energy in a different pattern or order. The treatment assembly 812 may be changed and/or moved to a different treatment site.

[0102]

FIG. 10A is an isometric view of a distal portion of a therapeutic neuromodulation device 1002 ("device 1002") configured in accordance with another embodiment of the present technology, and FIG. 10 is an isometric view illustrating a neuromodulation device 1002. FIG.

Device 1002 may include various features generally similar to those of therapeutic neuromodulation devices 402, 502a-d, and 802 described above with reference to FIGS. 4-5G, 8, and 9. For example, device 1002 includes a shaft 1008 and a treatment assembly 1012 at a distal portion 1008b of shaft 1008. The treatment assembly 1012 includes a plurality of struts 1040 forming a branch 1046 and defining an expandable frame or basket 1042, and one or more electrodes 1044 disposed on one or more of the struts 1040. including. As shown in FIG. 10A, device 1002 may further include a secondary or return electrode 1060

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disposed along a distal portion of shaft 1008. In the illustrated embodiment, return electrode 1060 is a ring electrode having a ring-like shape, although in other embodiments return electrode 1060 may have other shapes or configurations.

[0103]

Return electrode 1060 may be biased with negative polarity, and at least a portion of electrode 1044 on post 1040 and/or other portions of treatment assembly 1012 may be biased with positive polarity.

As indicated by the arrows in FIG. 10A, bipolar RF energy may flow over an area extending from the treatment assembly 1012 to the return electrode 1060 on this distal portion 1008b of the shaft 1008. In various embodiments, RF energy may be applied in a sesquipolar manner (ie, unbalanced bipolar energy).

[0104]

As shown in FIG. 10B, the treatment assembly 1012 can be positioned below the SPF and above at least a portion of the microforamen MF and nerve N that traverse the inferior turbinate IT and palatine bone.

A return electrode 1060 may be positioned below the inferior turbinate IT and at least a portion of the microforamen MF and nerve N that traverses the palatine bone. RF energy may then be applied over a wide area extending from treatment assembly 1012 to return electrode 1060. As shown in FIG. 10B, for example, the device 1002 may apply energy across the top and bottom of the inferior nasal turbinate where a high density of micropores is present.

[0105]

11A-11D are isometric illustrations of distal portions of a therapeutic neuromodulation device 1102 (individually referred to as a first device 1102a and a second device 1102b) configured in accordance with further embodiments of the present technology. It is a diagram.

The first device 1102a includes various features generally similar to those of the therapeutic neuromodulation devices 402, 502a-d, 802, and 1002 described above with reference to FIGS. 4-5G and 8-10B. obtain. For example, first device 1102a includes a shaft 1108 and a treatment assembly 1112 at a distal portion 1108b of shaft 1108. Therapeutic assembly 1112 includes a flexible membrane 1162 that carries a plurality of electrodes 1144 and/or other energy delivery elements arranged in an array across the flexible membrane 1162.

[0106]

As shown in FIGS. 11A-11C, the flexible membrane 1162 deforms from a low profile delivery state (FIG. 11A) to an expanded state (FIG. 11B) via self-expansion or mechanical expansion means to remove the device from the nasal cavity. For removal, it may be configured to return to a low profile delivery or retrieval state (FIG. 11C).

In the expanded state shown in FIG. 11B, the flexible membrane is configured to enhance the contact area between the flexible membrane 1162 (and the electrode 1144 disposed thereon) and the non-planar anatomy. , may conform to the uneven anatomy of the nasal spaces (eg, turbinates, sinuses, and/or other paranasal areas). Flexible membrane 1162 may be made of a flexible, dynamic material that supports electrode 1144. For example, in certain embodiments, flexible membrane 1162 may include polymer filaments and/or other materials that add support and structure to flexible membrane 1162. In various embodiments, flexible membrane 1162 may have a preset geometry to maintain a predetermined shape. For example, the flexible membrane 1162 and/or the electrode array on the flexible membrane 1162 may maintain a spherical curvature (eg, as shown in FIG. 11A).

[0107]

In various embodiments, shaft 1108 may be movable relative to flexible membrane 1162 to allow deployment and recapture of flexible membrane 1162.

For example, flexible membrane 1162 may be rolled or otherwise folded into a circular shape when in the delivery state (FIG. 11A). To move to the expanded state (FIG. 11B), the components of shaft 1108 are rotated and/or moved axially relative to flexible membrane 1162 such that flexible membrane 1162 at least partially opens; Flexible membrane 1162 may be unwound or otherwise expanded to conform to the configuration of the surrounding anatomy and place electrode 1144 in contact with

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tissue at the target site. To recapture the device in the retracted state (FIG. 11C), the shaft 1108 can be moved again in an axial or rotational manner to wrap or otherwise fold the flexible membrane 1162 closer together.

[0108]

As shown in FIGS. 11A-11C, the electrodes 1144 are interconnected through a plurality of connectors 1164, such as, for example, nanoribbons, nanowires, direct inking, multidirectional printing/deposition, and/or other suitable electrical connectors. Good too.

In various embodiments, interconnects 1164 between electrodes 1144 may include periodic wavy conduits or lines having a "U", "S", or elliptical shape. These undulating connectors 1164 form multidimensional springs within the flexible membrane 1162 and/or facilitate apposition of the flexible membrane 1162 against tissue at the target site to improve energy conductivity/transfer. The shape of the flexible membrane 1162 may be given to the flexible membrane 1162.

[0109]

Electrodes 1144 may be surface mounted on flexible membrane 1162 or embedded within the multilayer composite structure of flexible membrane 1162.

In various embodiments, electrode 1144 may be relatively small in size, with a diameter ranging from 50 to 2,000 microns. Electrodes 1144 may be configured to deliver energy in a unipolar, bipolar, or multipolar manner. For example, multipolar electrodes may be used in bipolar and quadripolar arrays to facilitate linear and angular (diagonal) energy connectivity between electrodes 1144.

[0110]

Electrode 1144 may be connected to a connection pad contained within shaft 1108 and/or to a feature connected to a proximal portion of shaft 1108, such as a handle or console.

Electrodes 1144 can be connected to connection pads through conductive connector cables (eg, metal cables, polymer cables, and/or combinations thereof)

[0111]

In certain embodiments, flexible membrane 1162 may also house a feedback system (not shown) to control the delivery of RF energy and maintain predefined treatment parameters

For example, the electronic circuitry of the flexible membrane 1162 may include a thermal sensor that provides temperature feedback to control energy dissipation and penetration depth of the RF energy. The electronic circuitry features of the flexible membrane 1162 may also measure resistance and temperature at the treatment site to determine the effectiveness of therapeutic energy application. This information may be used to adjust energy application and avoid secondary damage to host tissue. For example, energy delivery via electrode 1144 may be automatically terminated if the detected temperature and/or resistance reaches a predetermined threshold maximum (e.g., a threshold temperature associated with tissue damage). . Energy delivery via electrode 1144 is automatically or manually performed when the detected temperature and/or resistance is below a predetermined threshold range indicative of parameters associated with therapeutically effective modulation of the parasympathetic nasal nerve. may be adjusted to in other embodiments, the feedback system may be incorporated into components communicatively coupled to electrodes 1144 on flexible membrane 1162 and any additional sensors. For example, the feedback system may be stored on console 204 of FIG. 2 and executed by controller 218 (FIG. 2).

[0112]

In the embodiment shown in FIG. 11D, the second device 1102b may include various features generally similar to the features of the first device 1102a described above with reference to FIGS. 11A-11C.

For example, device 1102b of FIG. 11D includes a flexible membrane 1162 that includes a plurality of electrodes 1144 disposed on or embedded within the flexible membrane 1162. It carries associated electrical connectors 1164. Device 1102b further includes an expandable frame 1166 carrying a flexible membrane 1162. Frame 1166 may have a U-shape and may be made

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from a shape memory material (eg, Nitinol). In other embodiments, the frame may have a different shape and/or be made from a different material suitable for supporting the flexible membrane 1162.

[0113]

In operation, frame 1166 facilitates deployment of flexible membrane 1162 against the anatomy of the nasal cavity and provides support for flexible membrane 1162 and associated array of electrodes 1144.

U-shaped frame 1166 may enhance the ability of flexible membrane 1162 to contact non-planar anatomy at the target site. In various embodiments, for example, the frame 1166 functions as a cantilever spring to establish positive apposition of the membrane 1162 to the target surface tissue and improve energy conductivity/transfer from the electrode 1144 to the target tissue. You may.

[0114]

FIG. 12 is a side view of a distal portion of a therapeutic neuromodulation device 1202 ("device 1202") constructed in accordance with a further embodiment of the present technology.

Device 1202 includes various features generally similar to those of therapeutic neuromodulation devices 402, 502a-d, 802, 1002, and 1102 described above with reference to FIGS. 4-5G and 8-11. . For example, device 1202 includes a shaft 1208 and a treatment assembly 1212 that includes a plurality of energy delivery elements, such as electrodes 1244, at a distal portion 1208b of shaft 1208. In the illustrated embodiment, treatment assembly 1212 includes four electrodes 1244 arranged along a spiral/helical section 1268 in distal portion 1208b of shaft 1208. In other embodiments, however, the therapeutic assembly 1212 may include one, two, three, or more than four electrodes 1244 and/or may include different energy delivery elements. Therapeutic assembly 1212 also detects various characteristics at the treatment site before, during, and/or after application of therapeutic neuromodulatory energy and provides feedback that can be used to control operation of the therapeutic assembly 1212. A temperature sensor 1252 (e.g., a thermocouple) and/or other types of sensors may be included for the purpose. Such sensors may be incorporated into any of the other embodiments of therapeutic assemblies disclosed herein.

[0115]

During delivery of the therapeutic assembly 1212, the spiral/helical section 1168 of the shaft 1208 may be substantially narrowed or narrowed within the introducer sheath and/or via mechanical components associated with the shaft 1208. It can be positioned in a flattened, low profile delivery state.

At the target site, the operator may deform the spiral/helical section 1268 to an expanded state (shown in FIG. 12) to place one or more of the electrodes 1244 in contact with the target tissue. One or more of the electrodes 1244 then apply RF energy (e.g., monopolar and/or bipolar RF energy) to tissue at the target site within the nasal region to treat nerves proximal to the treatment site. can be selectively activated for specific regulation. In other embodiments, the distal section of shaft 1208 may have other suitable shapes, sizes, and/or configurations that facilitate placement of electrode 1244 in contact with tissue at the target site. For example, in further embodiments, the distal portion 1208b of the shaft 1208 may have a semicircular, curved, bent, or straight shape, and/or the treatment assembly 1212 may include one of the electrodes 1244. The support member may include a plurality of support members configured to carry more than one support member.

[0116]

FIG. 13 is a side view of a distal portion of a therapeutic neuromodulation device 1302 ("device 1302") constructed in accordance with yet a further embodiment of the present technology.

Device 1302 includes various features generally similar to those of therapeutic neuromodulation devices 402, 502a-d, 802, 1002, 1102, and 1202 described above with reference to FIGS. 4-5G and 8-12. Contains Contains. For example, device 1302 includes a shaft 1308 and a therapeutic assembly 1312 that includes a plurality of energy delivery elements, such as an array of electrodes 1344, at a distal portion 1308b of shaft 1308. In the embodiment illustrated in FIG. 13, treatment assembly 1312 includes a balloon 1370 carrying electrodes 1344. Support member 1372 extends through the length of balloon 1370 to support balloon 1370 and optionally includes a guidewire (not shown) to facilitate delivery of therapeutic assembly 1312 to the target site. It may include a channel that may extend therethrough. In other embodiments, support member 1372 may be omitted.

[0117]

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Electrodes 1344 may be made from conductive ink printed, sprayed, and/or otherwise disposed on the surface of balloon 1370.

Such conductive ink electrodes facilitate the use of complex electrode configurations. Additionally, thermocouples (not shown) may also be incorporated onto the surface of balloon 1370 using conductive ink and/or other suitable methods. In other embodiments, electrodes 1344 can be made from foil and adhered to the surface of balloon 1370. In further embodiments, electrodes 1344 may be made from other suitable materials that may be disposed on the surface of balloon 1370 and/or embedded within the material of balloon 1370.

[0118]

Balloon 1370 can be made from a variety of different materials and have a variety of different shapes.

For example, as shown in FIG. 13, balloon 1370 may have an oval shape when in the expanded state, which is expected to improve adaptation to anatomical variations at target sites within the nasal cavity. In other embodiments, the balloon 1370 may have a circular shape, a spherical shape, an irregular shape, and/or other suitable shape for expansion within the nasal anatomy. Balloon 1370 may be made from a flexible material (eg, a urethane material) that allows balloon 1370 to accommodate anatomical differences when expanded within the nasal region. In other embodiments, the balloon is made of a non-flexible material (e.g., polyethylene, terephthalate, etc.) that allows the balloon 1370 to have a defined shape when expanded and facilitates attachment of the electrode 1344 to the balloon surface. , nylon, etc.). In a further embodiment, balloon 1370 may be dip coated to form a spherical tip at the distal end of shaft 1308.

[0119]

Balloon 1370 may be inflated with fluid through an opening or port 1374 in support member 1372 and/or an opening in shaft 1308 that is in fluid communication with the interior of balloon 1370.

For example, support member 1372 and/or shaft 1308 may include a channel extending along the length of shaft 1308 and connected to a fluid supply in a proximal portion of shaft 1308 so that fluid may be delivered to balloon 1370. may be included. Balloon 1370 may be inflated against the nasal anatomy at the target site to place electrode 1344 in contact with tissue at the target site.

[0120]

At the target site, electrodes 1344 deliver RF energy to tissue to therapeutically modulate nerves at the treatment site.

In certain embodiments, an array of electrodes 1344 can be arranged on the balloon 1370 and/or selectively activated to apply lateral bipolar RF energy over a radial region of the balloon 1370. (i.e., extending around the circumferential portion of balloon 1370). In other embodiments, an array of electrodes 1344 may be arranged on the balloon 1370 and/or selectively activated to apply longitudinal bipolar RF energy over a longitudinal region of the balloon 1370. (i.e., extending between the proximal and distal portions of balloon 1370).

[0121]

In various embodiments, treatment assembly 1312 may include features that facilitate positioning of balloon 1370 within the nasal anatomy and proper placement of electrodes 1344 at the treatment site.

For example, as shown in FIG. 13, endoscope 1371 may be positioned on the surface of balloon 1370 to provide direct in-line visualization of balloon 1370 and the target site during placement at the target site. good. Treatment assembly 1312 may also include graded markings 1373 along the surface of support member 1372 and/or balloon 1370 to indicate spatial orientation and/or depth positioning of treatment assembly 1312.

[0122]

In certain embodiments, balloon 1370 may be configured to allow slow perfusion of fluid through the balloon wall and cool electrode 1344 while energy is applied to the target tissue.

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For example, such a "weep" balloon 1370 may include laser-drilled holes and/or other holes along at least a portion of the balloon 1370 to allow low-velocity perfusion of fluid (e.g., saline solution) through the balloon wall. may contain small openings or pores. When the balloon perfuses the saline solution, the saline solution is expected to improve the electrical conductivity between the electrode 1344 and the target tissue, which may enhance the effects of the RF energy on the nerve at the target site. In other embodiments, cooled fluid may be circulated through balloon 1470 during activation of electrode 1444 to cool electrode 1444 and surrounding tissue during energy delivery.

[0123]

FIG. 14 is a side view of a distal portion of a therapeutic neuromodulation device 1402 ("device 1402") configured in accordance with additional embodiments of the present technology.

Device 1402 includes various features generally similar to those of therapeutic neuromodulation device 1302 described above with reference to FIG. 13. For example, device 1402 includes a shaft 1408 and a treatment assembly 1412 at a distal portion 1408b of shaft 1408. Treatment assembly 1412 includes a balloon 1470, a support member 1472 supporting balloon 1470, and a plurality of energy delivery elements, such as an array of electrodes 1444 disposed on balloon 1470. In the embodiment illustrated in FIG. 14, electrode 1444 is part of a flex circuit 1476 adhered to the surface of balloon 1470. Flex circuit 1476 facilitates the creation of complex electrode arrays that can create highly customizable neuromodulation patterns. In certain embodiments, for example, flex circuit 1476 includes a conductive return electrode along the surface of balloon 1470 and a conductive return electrode on a proximal or distal portion of balloon 1470 (e.g., a conical end portion of balloon 1470), and a plurality of electrodes. In addition, flex circuit 1476 may incorporate thermocouples and/or thermistors into circuits on the surface of balloon 1470 to detect temperature at the treatment site before, during, and/or after energy application.

[0124]

FIG. 15 is an isometric side view of a distal portion of a therapeutic neuromodulation device 1502 ("device 1502") constructed in accordance with additional embodiments of the present technology.

Device 1502 includes various features generally similar to those of therapeutic neuromodulation devices 1302 and 1402 described above with reference to FIGS. 13 and 14. For example, device 1502 includes a shaft 1508 and a treatment assembly 1512 at a distal portion 1508b of shaft 1508. Treatment assembly 1512 includes a plurality of balloons 1578 positioned about inner support member 1580 and a plurality of energy delivery elements, such as electrodes 1544 disposed on one or more of balloons 1578. In certain embodiments, balloon 1578 is independently inflatable. This allows for asymmetric and variable inflation of the balloon 1578, thereby enhancing the ability of the treatment assembly 1512 to conform to the uneven geometry of the nasal region at the target site and the electrodes relative to the tissue at the target site. Promote 1544 juxtaposition.

[0125]

In the illustrated embodiment, four independently inflated balloons 1578 are positioned around the outer circumference of inner support member 1580.

However, in other embodiments, the device 1502 may include fewer than four balloons 1578 or more than four balloons 1578 arranged around the inner support member 1580. In further embodiments, balloons 1578 may have different sizes and/or shapes and may be positioned along various portions of inner support member 1580. In yet a further embodiment, the balloon 1578 is attached at an end portion to an inner support member 1580 and when inflated (e.g., in a manner similar to struts 440 of therapeutic neuromodulation device 402 of FIG. 4) It is configured as a strut extending outwardly from support member 1580.

[0126]

During energy delivery, electrodes 1544 may be configured to apply bipolar RF energy across electrodes 1544 on different balloons 1578 and/or between electrodes 1544 on the same balloon 1578.

In other embodiments, electrode 1544 applies energy in a sesquipolar manner. For example, inner support member 1580 may include a return electrode (not shown) and electrodes 1544 on two or more of balloons 1578 may be activated for sesquipolar RF energy delivery.

[0127]

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FIG. 16 is a side cross-sectional view of a distal portion of a therapeutic neuromodulation device 1602 ("device 1602") constructed in accordance with additional embodiments of the present technology.

Device 1602 includes various features generally similar to those of the therapeutic neuromodulation devices described above. For example, device 1602 includes a shaft 1608 and a treatment assembly 1612 at a distal portion 1608b of shaft 1608. In the embodiment illustrated in FIG. 16, therapeutic assembly 1612 is configured to apply cryotherapeutic cooling to therapeutically modulate nerves at a target site. As shown in FIG. 16, the cryotherapy assembly 1612 includes an expansion chamber 1682 (e.g., a balloon, inflatable body, etc.). A supply lumen 1682 extends along at least a portion of the shaft 1608 and may be configured to transport coolant in at least a partially liquid state to a distal portion 1608b of the shaft 1608. An exhaust tube or lumen 1689 (e.g., defined by a portion of the shaft 1608) provides fluid communication with the interior of the expansion chamber 1682 via an outlet 1688 such that the exhaust lumen 1689 can return coolant to the proximal portion of the shaft 1608. may be placed in communication. For example, in one embodiment, a vacuum (not shown) in the proximal portion of shaft 1608 may be used to evacuate coolant from expansion chamber 1682 via evacuation lumen 1689. In other embodiments, coolant may be delivered to the proximal portion of shaft 1608 using other suitable mechanisms known to those skilled in the art.

[0128]

During cryotherapy, the opening 1686 in the supply lumen 1684 restricts the flow of coolant and provides a high pressure differential between the supply lumen 1684 and the expansion chamber 1682, thereby reducing the flow of coolant within the expansion chamber 1682. expansion into the gas phase.

The pressure drop as the liquid coolant passes through the opening 1682 causes the coolant to expand into a gas, reducing the temperature to a therapeutically effective temperature that may modulate nerve fibers proximal to the treatment site within the nasal cavity. do. In the illustrated embodiment, the expansion chamber 1682 contacts the tissue at the target site and cools it at a rate sufficient to cause cryotherapeutic neuromodulation of postganglionic parasympathetic nerve fibers innervating the nasal mucosa. Includes thermal section 1691. For example, the treatment assembly 1602 may operate at a temperature of -40<0>C, -60<0>C, -80<0>C, or less. In other embodiments, the therapeutic assembly 1602 may be operated at higher cryotherapeutic temperatures (eg, 5°C and -15°C, -20°C, etc.).

[0129]

Coolants used for cryogenic cooling in device 1602 may include, for example, nitrous oxide (N₂O), carbon dioxide (CO₂), hydrofluorocarbons (e.g., manufactured by EI du Pont de Nemours and Company of Wilmington, DE). FREON) and/or other suitable fluids that can be stored at sufficiently high pressures to be at least substantially liquid at about ambient temperature. It can be a compressed or condensed gas.

For example, the non-azeotropic but azeotropic R-410A, which is a close mixture, can be at least substantially in a liquid phase at about ambient temperature when contained at a pressure of about 1.45 MPa (210 psi). Under appropriate conditions, these coolants can achieve cryotherapeutic temperatures at or near their respective standard boiling points (e.g., approximately -88°C for nitrous oxide) to provide therapeutic neuromodulation. can be reached.

[0130]

In other embodiments, the treatment assembly 1612 may include a cryotherapy applicator rather than the expansion chamber 1682 of FIG. 16.

Such cryotherapy applicators can be used for highly targeted treatments of nerves.

[0131]

As further shown in FIG. 16, device 1602 may also include a support member 1690 that extends through expansion chamber 1682 and is configured to carry a distal portion of expansion chamber 1682.

Support member 1690 also includes a channel extending along its length and an opening in a distal end portion of support member 1690 to facilitate delivery of treatment assembly 1612 to a treatment site via guidewire GW. 1692 may also be included.

[0132]

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FIG. 17 is a side cross-sectional view of a distal portion of a therapeutic neuromodulation device 1702 ("device 1702") constructed in accordance with additional embodiments of the present technology.

Device 1702 includes various features generally similar to those of the therapeutic neuromodulation devices described above. For example, device 1702 includes a shaft 1708 and a treatment assembly 1712 at a distal portion 1708b of shaft 1708. In the embodiment illustrated in FIG. 17, therapeutic assembly 1712 is configured to apply direct conduction heating to thermally therapeutically modulate nerves at a target site. As shown in FIG. 17, treatment assembly 1712 includes a balloon 1770 in fluid communication with a supply tube or lumen 1794 (e.g., defined by a portion of shaft 1708) via an outlet in a distal portion of supply lumen 1794. obtain. A supply lumen 1794 extends along at least a portion of the shaft 1708 and can be insulated to transport heated fluid (e.g., heated saline) to the balloon 1770 in the distal portion 1708b of the shaft 1708. . A discharge or return tube or lumen 1796 (e.g., defined by a portion of shaft 1708) allows return lumen 1796 to direct fluid to a proximal portion of shaft 1708 (e.g., using a vacuum in the proximal portion of shaft 1708). It may be placed in fluid communication with the interior of the balloon 1770 via the outlet for evacuation.

[0133]

During thermal therapeutic neuromodulation, supply lumen 1794 may supply heated fluid to balloon 1770 and evacuation lumen 1796 may be used to expel fluid from balloon 1770 so that it is heated. The fluid is circulated through balloon 1770 (eg, as indicated by the arrow).

The heated fluid causes time-dependent thermal damage (e.g., determined using the Arrhenius equation) to the target tissue at the treatment site within the nasal cavity, causing damage within or near the heated target tissue. can be heated to a therapeutically effective temperature that modulates nerve fibers in the body. In the illustrated embodiment, for example, the wall of balloon 1770 and/or a portion thereof may contact tissue at the target site, cause thermal damage to the target tissue, and induce postganglionic parasympathetic nerve fibers innervating the nasal mucosa. Tissue can be heated at a rate and time sufficient to provide therapeutic neuromodulation.

[0134]

As shown in FIG. 17, device 1702 may also include a support member 1790 that extends through balloon 1770 and is configured to carry a distal portion of balloon 1770.

Support member 1790 also has a channel extending along its length and a distal end of support member 1790 that can be used to facilitate delivery of treatment assembly 1712 to a treatment site via guidewire GW. It may also include an opening 1792 in the section.

[0135]

FIG. 18 is a side cross-sectional view of a distal portion of a therapeutic neuromodulation device 1802 ("device 1802") constructed in accordance with additional embodiments of the present technology.

Device 1802 includes various features generally similar to those of the therapeutic neuromodulation devices described above. For example, device 1802 includes a shaft 1808 and a treatment assembly 1812 at a distal portion 1808b of shaft 1808. Treatment assembly 1812 may include an inflatable balloon 1870 and a support member 1890 extending through balloon 1870. Support member 1890 may also include a channel with an opening 1892 that allows guidewire delivery of treatment assembly 1812 to a treatment site.

[0136]

Similar to therapeutic assembly 1712 of FIG. 17, therapeutic assembly 1812 applies therapeutically effective heating to tissue at a target site to generate time-dependent thermal tissue damage (e.g., using the Arrhenius equation).) and modulate nerve fibers within or near the heated target tissue.

However, in the embodiment illustrated in FIG. 18, heating is provided via a heating element 1898 positioned within balloon 1880 and carried by support member 1890 and/or another feature of treatment assembly 1812. Heating element 1898 may be a plate or other structure that is heated using resistive heating (via a generator) and/or other suitable heating mechanism. In operation, heat from heating element 1898 may be transferred from heating element 1898 to fluid within balloon 1870 and then through the wall of balloon 1870 to adjacent tissue at the treatment site. The fluid heated by the heating element 1898 is heated

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to a therapeutically effective temperature that causes thermal damage to the target tissue at the treatment site within the nasal cavity and modulates nerve fibers within or proximal to the heated target tissue. can be heated to In certain embodiments, balloon 1870 can include conductive features (eg, metal panels) on its surface to focus the heating effect on targeted areas of balloon 1870.

[0137]

In other embodiments, the balloon 1870 is configured to reach a therapeutically effective temperature that causes thermal damage to the target tissue at the treatment site within the nasal cavity and modulates nerve fibers within or near the heated target tissue. can be heated through capacitive coupling.

For example, balloon 1870 may be inflated using an isotonic solution, and balloon 1870 may be ionically agitated at high frequency to allow capacitive energy to be released across the membrane of balloon 1870 into the target tissue.

[0138]

FIG 19 is a side view of a distal portion of a therapeutic neuromodulation device 1902 ("device 1902") configured in accordance with additional embodiments of the present technology.

Device 1902 includes various features generally similar to those of the therapeutic neuromodulation devices described above. For example, device 1902 includes a shaft 1908 and a treatment assembly 1912 at a distal portion 1908b of shaft 1908. In the embodiment illustrated in FIG. 19, therapeutic assembly 1912 is configured to apply plasma or laser ablation to therapeutically modulate nerves at a target site. As shown in FIG. 19, treatment assembly 1912 can include an ablation element 1999 (eg, an electrode) on a distal end portion of shaft 1908. Ablation element 1999 may apply a high energy laser pulse to ionize molecules within a small portion at the beginning of the pulse. This process leads to plasma bubbles or fields (eg, 100-200 μm) that can be used to desiccate or otherwise destroy tissue and nerves at the target site. Cutting element 1999 may operate at temperatures below 100° C to limit thermal effects on surrounding tissue.

[0139]

In other embodiments, ablation element 1999 may perform laser ablation of the nerve at the target site.

For example, a nerve tracer, such as indocyanine green (ICG), can be injected into the target site to stain the nerves at the target site. Ablation element 1999 can be a laser tuned to absorb a spectrum of nerve tracers, thereby ablating stained nerves at the target site.

[0140]

Selected Embodiments of Therapeutic Neuromodulation for Treatment of Chronic Sinusitis FIG. FIG. 2 is a partially cutaway side view illustrating a target site.

Any of the therapeutic modulation devices and systems described above may be used to therapeutically modulate the nerves innervating the sinuses to treat chronic sinusitis and/or similar conditions . Referring to FIG. 20, the sinuses include the frontal sinus FS, sphenoid sinus SS, maxillary sinus ("MS", not shown), as well as posterior ethmoid cells ("PEC"), middle ethmoid cells (" ``MEC"), and the ethmoid sinus or ethmoid cell (not shown), including the anterior ethmoid cell (``AEC"). Each sinus opens into the nasal cavity at one or more individual ostia. FIG. 20 illustrates the general location of the frontal, sphenoid, and maxillary sinus ostia as well as the posterior, middle, and anterior ethmoid cell ostia.

[0141]

Parasympathetic nerves innervate the sinus mucosa and stimulate mucus production within the sinuses.

Overactivity of the parasympathetic nerves that innervate the sinuses can cause overproduction of mucus and congestion of soft tissues. Inflammation of the soft tissues proximal to the sinus can cause occlusion of the conduit between the sinus and the nasal cavity and block the ostium to the sinus. In addition, overactive mucosa and/or ostial blockage can cause retention of mucosal secretions within the sinus due to lack of drainage from the sinus. This can lead to infection and ultimately a condition of chronic sinusitis.

[0142]

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Therapeutic modulation of the parasympathetic nerves that control sinus autonomic function is expected to reduce and eliminate overactive mucosal secretions and soft tissue congestion, thereby treating chronic sinusitis or related symptoms.

Any of the therapeutic neuromodulation devices described above provides therapeutically effective neuromodulation in or proximal to the ostia of the affected sphenoid, maxillary, frontal, and/or ethmoid sinuses. Energy can be applied to modulate sinus autonomic function. For example, the therapeutic neuromodulation device may include RF energy, microwave energy, ultrasound energy, cryotherapeutic cooling, therapeutic heating, plasma ablation, and/or laser therapy to the treatment site at or around the sinus ostium. Can be used to apply ablation. Similar to the devices described above, therapeutic neuromodulation devices may be routed through the nares to access the desired sinus ostium(s), the upper nasal meatus, the middle nasal meatus, and/or the lower nasal meatus. can be delivered intraluminally through the tract. In various embodiments, neural mapping techniques similar to those described above with respect to FIGS. 6A-9 may be used to locate or detect parasympathetic nerves innervating the ostium before, during, and/or after treatment. can be used for Application of therapeutic neuromodulation at a target site proximal to the sinus ostium can disrupt parasympathetic signals to the sinus tissue, leading to opening of the ostium and the ability to drain fluid. Additional Examples 1. A system for therapeutic neuromodulation in the nasal region of a human patient, the shaft having a proximal portion and a distal portion, the distal portion being connected to a target site below the sphenopalatine foramen of the human patient. a shaft configured for intraluminal positioning; and a therapeutic assembly at the distal portion of the shaft, the postganglionic parasympathetic member innervating the nasal mucosa in a microforamen of a palatal bone of the human patient. a therapeutic assembly comprising an energy delivery element configured to therapeutically modulate nerves. 2. The energy delivery element is configured to deliver at least one of ultrasound energy, microwave energy, laser energy, or radio frequency (RF) energy to therapeutically modulate the postganglionic parasympathetic nerve. The system of Example 1. 3. The system of Example 1 or 2, wherein the therapeutic assembly is configured to dispense a drug to chemically modulate the postganglionic parasympathetic nerve. 4. The shaft includes a drug delivery channel having an outlet in the distal portion of the shaft, the drug delivery channel configured to deliver at least one of a local anesthetic or a nerve block to the target site. The system of any one of Examples 1 to 3.

5. The shaft includes a fluid channel having an outlet in the distal portion of the shaft, the fluid channel configured to deliver saline to the target site to rinse the treatment area with saline. The system of any one of Examples 1-4. 6. further comprising an introducer having a rigid metal portion, the rigid metal portion sized and shaped to extend through the nasal passage to the target site to deliver the therapeutic assembly to the target site. The system of any one of Examples 1 to 5. 7. 7. The system of any one of Examples 1-6, wherein the shaft is a steerable catheter shaft and the distal portion of the shaft has a bend radius of 3 mm or less. 8. 7. The system of any one of Examples 1-6, wherein the distal portion of the shaft comprises an articulation region having rigid links sized and shaped to have a bending radius of 3 mm or less. 9. further comprising a fixation member along the shaft, the fixation member expanding within the cavity of the nasal region to cause the distal portion of the shaft to deploy the therapeutic assembly at the target site. 9. The system of any one of Examples 1-8, comprising a balloon configured to hold the balloon in a fixed position. 10. The system of any one of Examples 1-9, wherein the energy delivery element of the therapeutic assembly comprises a plurality of electrodes configured to apply RF energy to therapeutically modulate postganglionic parasympathetic nerves. . 11. Examples 1-10, wherein the therapeutic assembly comprises a plurality of sensing electrodes configured to detect at least one neural activity before, during, or after therapeutic neuromodulation. Any one system. 12. The therapeutic assembly comprises: a basket deformable between a low profile delivery state and an expanded state, the basket including a plurality of struts radially spaced apart from each other when the basket is in the expanded state; a plurality of electrodes disposed on the struts, the plurality of struts configured to position at least two of the electrodes at the target site when the basket is in the expanded state; a plurality of electrodes configured to apply radio frequency (RF) energy to the target site for therapeutically modulating parasympathetic nerves proximal to the target site. The system of any one of Examples 1 to 11. 13. The therapeutic assembly includes: a flexible membrane deformable between a low profile delivery state and an expanded state; and a plurality of electrodes disposed on the flexible membrane, the electrodes comprising. a flexible membrane deformable between a low profile delivery state and an expanded state; 12. The system of any one of Examples 1-11 configured to apply radio frequency (RF) energy to a target site for therapeutically modulating parasympathetic nerves proximal to the target site.

14. The system of Example 13, wherein the treatment assembly further comprises a frame supporting the flexible membrane. 15. the distal portion of the shaft is deformable between a low profile delivery state and an expanded state; when the distal portion of the shaft is in the expanded state; having a spiral/helical shape, the energy delivery element is disposed on the distal portion of the shaft, and the energy delivery element is disposed on the distal portion of the shaft and has a wireless connection to the target site for therapeutically modulating parasympathetic nerves proximal to the target site. a plurality of electrodes configured to deliver frequency (RF) energy, the distal portion of the shaft being configured to deliver at least one of the electrodes when the distal portion of the shaft is in the expanded state; 12. The system of any one of Examples 1-11,

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wherein the system is configured to place one in contact with tissue at the target site. 16. The therapeutic assembly includes: a balloon deformable between a low profile delivery state and an expanded state; and a plurality of electrodes disposed on the balloon, the therapeutic assembly comprising: a balloon deformable between a low profile delivery state and an expanded state; 12. The system of any one of Examples 1-11, comprising a plurality of electrodes configured to deliver radio frequency (RF) energy for therapeutically modulating parasympathetic nerves. 17. The system of Example 16, wherein the balloon comprises a plurality of holes configured to allow perfusion of fluid through the balloon when the balloon is in the expanded state. 18. an implementation further comprising: a support extending through the balloon; and a plurality of graduated markings on at least one of the support or the balloon to identify spatial positioning of the balloon Example 16 system. 19. The therapeutic assembly comprises: a balloon deformable between a low profile delivery state and an expanded state, the balloon comprising a proximal cone portion; a return electrode on the balloon; and the proximal cone portion. a flex circuit above, wherein the return electrode and the flex circuit deliver radio frequency (RF) energy to the target site for therapeutically modulating parasympathetic nerves proximal to the target site. 12. The system of any one of Examples 1-11, comprising: a flex circuit configured. 20. The treatment assembly includes: a plurality of balloons extending distally from the distal portion of the shaft, the balloons being independently expandable; and at least one electrode on each of the balloons. and an electrode configured to deliver radio frequency (RF) energy to the target site for therapeutically modulating parasympathetic nerves proximal to the target site. Any one of 11 systems.

21. The system of Example 20, further comprising an internal support member extending through a region between the balloons and configured to carry the balloons, the internal support member including a return electrode. 22. Any one of Examples 1-9, wherein the therapeutic assembly comprises a cryotherapy balloon configured to apply cryogenic cooling to tissue at the target site to therapeutically modulate autonomic nerve activity. one system. 23. The therapeutic assembly includes a balloon sized and shaped to contact tissue in a targeted state when expanded, the balloon circulating a fluid heated to at least 60° C. to stimulate autonomic nerve activity. 10. The system of any one of Examples 1-9, configured to thermally modulate. 24. The therapeutic assembly includes: a balloon configured to be expanded with a fluid, the balloon being sized and shaped to contact tissue in the target condition when expanded; 10. The system of any one of Examples 1-9, comprising a heating member configured to heat the fluid within the balloon to thermally modulate autonomic nerve activity. 25. 10 The system of any one of Examples 1-9, wherein the treatment assembly comprises a plasma ablation probe. 26. A system for therapeutic neuromodulation in the nasal region of a human patient, comprising: a shaft having a proximal portion and a distal portion, the distal portion being configured for intraluminal positioning at a target site; a shaft, wherein the target site is at least one of proximal to the sphenopalatine foramen or below the sphenopalatine foramen of a human patient; and the distal portion of the shaft is in a low profile delivery state and an expanded state. a therapeutic assembly comprising a plurality of struts and a plurality of electrodes disposed on the struts, the plurality of struts being deformable between the therapeutic assembly when the therapeutic assembly is in the expanded state; a therapeutic assembly forming a basket for positioning at least two of the electrodes at the target site below the sphenopalatine foramen of the human patient; A system configured to apply radio frequency (RF) energy to therapeutically modulate parasympathetic nerves proximal to a site. 27. the plurality of struts comprising at least three struts radially spaced from each other in the expanded state to define the basket, each of the three struts including at least one of the electrodes; System of Example 26.

28. the basket comprises at least three branches radially spaced from each other in the expanded state to form the basket, each branch comprising at least two struts positioned adjacent to each other, each strut The system of Example 26 or 27, wherein the system comprises at least one of the electrodes. 29. further comprising a thermocouple positioned at least proximally to one of the electrodes, the thermocouple being in contact with the electrode and tissue adjacent the electrode when the treatment assembly is in the expanded state. 29. The system of any one of Examples 26-28, configured to sense temperature at an interface between. 30. Examples 26-26, wherein each of the electrodes is configured to be independently activated and independently assigned a selective polarity to apply therapeutic neuromodulation over a selected region of the basket. Any one of 29 systems. 31. the basket has a spherical or oval shape, and the electrodes are selectively activated to apply RF energy over at least one of a segment, quadrant, or hemisphere of the basket; The system of any one of Examples 26-30, configured. 32. The plurality of electrodes includes first to third electrodes disposed on corresponding first to third posts, and the system further includes a controller operably coupled to the plurality of electrodes. and the control device has a computer readable medium carrying instructions, which, when executed by the control device, control the first to third electrodes of the plurality of electrodes. an electrode has a positive polarity, the second and third electrodes have a negative polarity, and the electrode is activated to apply RF energy in a sesquipolar manner over a selected peripheral area of the basket. The system of any one of Examples 26-31. 33. the basket includes an internal support member having a distal end portion extending through a region between the plurality of struts and supporting distal end portions of the plurality of struts; , comprising at least a first column and a second column, and the plurality of electrodes include a first electrode disposed on the first column and a second electrode disposed on the second column. an electrode, and a third electrode disposed on the distal end portion of the internal support member, the system further comprising a controller operably coupled to the plurality of electrodes, the system

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further comprising: a controller operably coupled to the plurality of electrodes; The apparatus has a computer readable medium carrying instructions, which, when executed by the controller, control the first to third electrodes of the plurality of electrodes. has a positive polarity, the third electrode has a negative polarity, and the electrode is activated to apply RF energy across a distal region of the basket. one system.

３４． the basket comprises at least two branches that are radially spaced apart from each other when the treatment assembly is in the expanded state, each branch including at least a first strut and a second strut positioned adjacent to each other; a strut, the first strut having a first electrode disposed thereon, the second strut having a second electrode disposed thereon, and the second strut having a second electrode disposed thereon; 32, wherein the first and second electrodes have opposite polarities and are configured to apply RF energy between the first and second electrodes. system. ３５． the basket comprises at least two branches that are radially spaced apart from each other when the treatment assembly is in the expanded state, each branch including at least a first strut and a second strut positioned adjacent to each other; a strut, the first strut having a first electrode disposed thereon, the second strut having a second electrode disposed thereon, and the second strut having a second electrode disposed thereon; the first and second electrodes of one branch are configured to have positive polarity; the first and second electrodes of the second branch are configured to have negative polarity; The system of any one of Examples 26-31, wherein the treatment assembly is configured to deliver RF energy between the first branch and the second branch over a peripheral portion of the basket. ． ３６． further comprising a return electrode disposed on the distal portion of the shaft positioned proximal to the treatment assembly, the electrode on the post configured to have positive polarity; The system of any one of Examples 26-31, wherein the system is configured such that has negative polarity. ３７． 37. The system of any one of Examples 26-36, wherein at least a portion of the electrode is configured to detect impedance at the target site to determine nerve location at the target site. ３８． the plurality of electrodes on the strut are a first plurality of electrodes; the treatment assembly includes: an expandable balloon disposed within the strut, and a second plurality of electrodes on the expandable balloon. electrodes, and when in the expanded state, the expandable balloon positions at least a portion of the second plurality of electrodes in contact with tissue at the target site to induce neural stimulation at the target site. 38. The system of any one of Examples 26-37 for detecting activity. ３９． further comprising an RF generator operably connected to the treatment assembly, the RF generator including a controller having a computer readable medium carrying instructions, the instructions being executed by the controller; 39. The system of any one of Examples 26-38, wherein the therapeutic assembly detects at least one of impedance or temperature at least proximal to the target site.

４０． further comprising an RF generator operably connected to the treatment assembly, the RF generator including a controller having a computer readable medium carrying instructions, the instructions being executed by the controller; The system of any one of Examples 26-39, wherein the therapeutic assembly applies RF energy in a predetermined pattern to the target site. ４１． A system for neural mapping and therapeutic neuromodulation in the nasal region of a human patient, comprising: a shaft having a proximal portion and a distal portion, the distal portion being positioned proximal to the sphenopalatine foramen of the human patient; a shaft configured for intraluminal positioning at a target site; and a plurality of electrodes at the distal portion of the shaft configured to detect the location of the parasympathetic nerve at the target site. an electrode, and a therapeutic assembly in the distal portion of the shaft, the energy delivery element configured to therapeutically modulate postganglionic parasympathetic nerves innervating nasal mucosa at the target site. A system comprising: a treatment assembly; ４２． 42. The system of Example 41, wherein the electrode defines the energy delivery element and is configured to apply radio frequency (RF) energy to the target site. ４３． 43. The system of Example 41 or 42, wherein the electrode is configured to detect dielectric properties of heterogeneous tissue at the target site to localize parasympathetic nerves. ４４． 44. The system of any one of Examples 41-43, wherein the electrode is configured to detect heterogeneous tissue impedance characteristics at the target site to localize parasympathetic nerves. ４５． A method of therapeutically modulating nerves in a nasal region of a human patient, the method comprising: intraluminally advancing a therapeutic assembly in a distal portion of a shaft of a therapeutic device to a target site within the nasal region. , the target site is proximal to a parasympathetic nerve extending across at least one of the proximal accessory or microforamina of the sphenopalatine foramen; applying energy to the site to therapeutically modulate autonomic nerve activity in at least one of the nasal cavity, nasopharynx, or sinuses. ４６． 46. The method of Example 45, wherein intraluminally advancing the therapeutic assembly to the target site includes positioning the therapeutic assembly in the palatine bone of the human patient below the sphenopalatine foramen. ４７．

Intraluminally advancing the therapeutic assembly to the target site includes advancing the therapeutic assembly intraluminally through the human patient's nasal entrance, through the inferior nasal meatus, and to the target site. The method of Example 45 or 46, comprising: ４８． Intraluminally advancing the therapeutic assembly to the target site includes advancing the therapeutic assembly intraluminally through the human patient's nasal entrance, through the middle nasal meatus, and to the target site. The method of Example 45 or 46, comprising ４９． Examples 45-48 further comprising advancing an endoscope intraluminally through the nasal entrance and through the middle nasal meatus of the human patient to visualize the therapeutic assembly at the target site. Any one of these methods. ５０． Examples 45-48 further comprising advancing an endoscope

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intraluminally through the nasal entrance and through the inferior nasal meatus of the human patient to visualize the therapeutic assembly at the target site. Any one of these methods. 5 1 . Intraluminally advancing the therapeutic assembly to the target site includes advancing the therapeutic assembly intraluminally through the human patient's nasal entrance, through the inferior nasal meatus, and to the target site. The method comprises: advancing an endoscope intraluminally through the entrance of the nose of the human patient and through the inferior nasal meatus to visualize the therapeutic assembly at the target site. The method of Example 45 or 46, further comprising: 5 2 . Intraluminally advancing the therapeutic assembly to the target site includes advancing the therapeutic assembly intraluminally through the human patient's nasal entrance, through the middle nasal meatus, and to the target site. advancing an endoscope intraluminally through the entrance of the nose of the human patient and through the middle meatus to visualize the therapeutic assembly at the target site. The method of Example 45 or 46, further comprising: 5 3 . further comprising advancing an endoscope intraluminally through the nasal entrance of the human patient, through one of the inferior nasal meatus or the middle nasal meatus, to a region at least proximal to the target site. , advancing the therapeutic assembly intraluminally to the target site; advancing the distal portion of the shaft through a channel of the endoscope and beyond the target site; and 47. The method of Example 45 or 46, comprising advancing the assembly out of an opening in a distal portion of the endoscope. 5 4 . Example 45, wherein intraluminally advancing the therapeutic assembly to the target site includes advancing the distal portion of the shaft through the mouth and oropharynx of the human patient to the target site. Or 46 methods.

5 5 . 55. The method of any one of Examples 45-54, further comprising imaging the target site via infrared (IR) spectroscopy to visualize the vasculature at least proximal to the target site. 5 6 . further comprising expanding a fixation member positioned along the distal portion of the shaft within a cavity of the nasal region, the fixation member directing the distal portion of the shaft to the target site. 56. The method of any one of Examples 45-55 for holding the therapeutic assembly in position for deployment. 5 7 . the target site is a first target site, applying energy to the target site includes applying energy to the first target site, and the method includes: repositioning a second target site within the region; and using the therapeutic assembly to therapeutically modulate parasympathetic nerves proximal to the second target site. 57. The method of any one of Examples 45-56, further comprising: applying energy of . 5 8 . Any of Examples 45-57, wherein applying energy comprises applying pulsed radio frequency (RF) energy to the target site via a plurality of electrodes of the thereapeutic element. Or one method. 5 9 . Any of Examples 45-58, further comprising detecting impedance at the target site to locate parasympathetic nerves extending across at least one of the accessory foramina or microforamina proximal to the sphenopalatine foramen. Or one method. 6 0 . Example 59, wherein applying energy to the target site comprises applying energy to discrete regions of the therapeutic assembly that correspond to the location of the parasympathetic nerve identified via impedance measurements. Method. 6 1 . The treatment assembly includes a plurality of electrodes, and applying energy to the target site includes independently activating each of the electrodes and selecting the polarity of each of the electrodes to effect the treatment. applying therapeutic neuromodulation over selective areas of the assembly. 6 2 . Applying energy to the target site further includes applying energy within a first hemispherical portion of the treatment assembly, wherein the treatment assembly includes a second hemispherical portion of the treatment assembly. The method of Example 61 without applying energy. 6 3 . The treatment assembly comprises an expandable basket having a plurality of struts, the plurality of struts having a plurality of electrodes disposed on the struts, and applying energy to the target site. activating a first electrode of the plurality of electrodes to have positive polarity; and activating at least a second electrode and a third electrode of the plurality of electrodes to have negative polarity. the first, second, and third electrodes are activated simultaneously, and the second and third electrodes are sequentially paired with the first electrode based on a path of least resistance. 63. The method of any one of Examples 45-62, comprising activating, sequentially applying therapeutic neuromodulation across the region of the basket.

6 4 . The treatment assembly comprises an expandable basket having a plurality of struts, the plurality of struts having a plurality of electrodes disposed on the struts, and applying energy to the target site. activating a first electrode of the plurality of electrodes to have positive polarity; and activating at least second to sixth electrodes of the plurality of electrodes to have negative polarity , first to sixth electrodes are activated simultaneously, and the second to sixth electrodes are sequentially paired with the first electrode based on a path of least resistance to form a hemisphere of the basket. 63. The method of any one of Examples 45-62, comprising activating, sequentially applying therapeutic neuromodulation over the region. 6 5 . The treatment assembly includes a plurality of struts, a plurality of struts with a plurality of electrodes disposed on the struts, and an inner support member returning to a distal end portion of the inner support member. an expandable basket having an internal support member comprising an electrode; applying energy to the target site; activating the electrode on the strut to have a positive polarity, activating an electrode to have negative polarity, the electrode comprising applying RF energy across a distal region of the basket. Or one method. 6 6 . The treatment assembly comprises an expandable basket having a plurality of branches radially spaced apart from each other when the treatment assembly is in an expanded state, each branch having at least two adjacent struts; comprising a strut with an electrode positioned on each strut, applying energy to the target region comprises: displacing the electrode on an adjacent strut of at least one of the branches, the electrode having an opposite polarity; and applying RF energy between the electrodes on the adjacent struts. 6 7 . The therapeutic assembly includes a

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plurality of electrodes, and applying energy to the target site includes: activating the electrodes of the therapeutic assembly to have a positive polarity; activating a return electrode disposed on the distal portion of the shaft, the return electrode having a negative polarity, the electrode and the return electrode having a negative polarity; 63. The method of any one of Examples 45-62, wherein activating the electrode applies RF energy across the nasal turbinates of the human patient.

6 8 . detecting neural activity at the target site via a plurality of sensing electrodes prior to applying energy to the target site to therapeutically modulate autonomic nerve activity; and based on the detected neural activity. mapping the location of a nerve at the target region, applying energy to the target region selectively applying energy to a region based on the location of the detected nerve The method of any one of Examples 45-67, comprising: 6 9 . 69. The method of Example 68, further comprising applying non-therapeutic neural stimulation to the target site prior to detecting neural activity. 7 0 . further comprising detecting neural activity via the plurality of sensing electrodes after applying energy to the target site to determine whether the application of energy therapeutically modulated nerves at the target site, Method of Example 68. 7 1 . The treatment assembly comprises a flexible membrane carrying a plurality of electrodes, and prior to applying energy, the method expands the flexible membrane at the target site to displace at least a portion of the electrodes. placing in contact with tissue at the target site, and applying energy to the target site comprises applying RF energy to the target site via the electrode One method. 7 2 . transforming the distal portion of the shaft from a low profile delivery state to an expanded state such that a plurality of electrodes disposed on the distal portion of the shaft are placed in contact with tissue at the target site; the distal portion of the shaft has a spiral/helical shape in the expanded state, further comprising: deforming the distal portion of the shaft to have a spiral/helical shape in the expanded state; 63. The method of any one of Examples 45-62, comprising applying RF energy to the site. 7 3 . The treatment assembly includes a balloon carrying a plurality of electrodes, and prior to applying energy, the method includes expanding the balloon at the target site to engage at least a portion of the electrodes with tissue at the target site. The method of any one of Examples 45-62, further comprising placing in contact, and applying energy to the target site comprises applying RF energy to the target site via the electrode. . 7 4 . 74 The method of Example 73, wherein applying energy to the target site further comprises selectively activating the electrodes to apply electrical current radially across a circumferential segment of the balloon.

7 5 . 74 The method of Example 73, wherein applying energy to the target site further comprises selectively activating the electrodes to apply electrical current longitudinally across a longitudinal region of the balloon. 7 6 . The method of Example 73, wherein expanding the balloon includes filling the balloon with a fluid, the balloon comprising a plurality of holes that allow perfusion of the fluid through the balloon during energy application. . 7 7 . 74. The method of Example 73, wherein expanding the balloon includes circulating a fluid through the balloon, the fluid cooling the electrode during energy application. 7 8 . The treatment assembly includes a plurality of balloons extending distally from the distal portion of the shaft, prior to applying energy, the method includes independently expanding the balloons at the target site; placing at least a portion of the electrode in contact with tissue at the target site, and applying energy to the target site includes applying RF energy to the target site via the electrode. , the method of any one of Examples 45-62. 7 9 . Applying energy to the target site includes: activating a return electrode on an internal support member extending through the plurality of balloons; and activating at least a portion of the electrodes on the balloons. 79. The method of Example 78, further comprising . 8 0 . 80. The method of any one of Examples 45-79, further comprising: measuring the temperature of tissue at the target site during energy application; and terminating energy application when a threshold maximum temperature is reached. 8 1 . 81. The method of any one of Examples 45-80, further comprising terminating energy application after a predetermined maximum period of time. 8 2 . 82. The method of any one of Examples 45-81, further comprising: detecting tissue impedance at the target site during energy application; and terminating energy application when a threshold impedance value is reached. 8 3 . detecting the impedance of tissue at the target site prior to energy application to define a baseline impedance; detecting the impedance of tissue at the target site during energy application; and determining the impedance from the baseline impedance. 83. The method of any one of Examples 45-82, further comprising terminating energy application when a threshold change is reached.

8 4 . Applying energy to the target site applies therapeutic cryogenic cooling to tissue at the target site to therapeutically modulate autonomic nerve activity within the nasal cavity, the nasopharynx, and/or the paranasal sinuses. The method of any one of Examples 45-57, comprising: 8 5 . Applying energy to the target site circulates heated fluid within the balloon such that the outer surface of the balloon contacts tissue at the target site, heating the tissue and heating the tissue at the target site. 58. The method of any one of Examples 45-57, comprising thermally modulating autonomic nerve activity in. 8 6 . Applying energy to the target site comprises: expanding a balloon so that an outer surface of the balloon contacts tissue at the target site; and heating a heating member within the balloon. , heat from the heating member is transferred to the fluid and to the tissue adjacent the balloon to thermally modulate autonomic nerve activity. Any one of these methods. 8 7 . 58. The method of any one of Examples 45-57, wherein applying energy to the target site includes generating a plasma field to therapeutically modulate nerves at the target site. 8 8 . 88. The method of any one of Examples 45-87, wherein applying energy to the target site therapeutically modulates cholinergic pathways that signal submucosal glands. 8 9 . Intraluminally advancing the

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therapeutic assembly to the target site includes moving the therapeutic assembly into the accessory foramen and at least one of the superior meatus, middle meatus, inferior meatus, or pterygopalatine fossa. 89. The method of any one of Examples 45-88, comprising advancing intraluminally through a micropore to a parasympathetic point of entry into said nasal region. 9 0 . A method of therapeutically modulating nerves in the nasal region, the method comprising: intraluminally advancing a therapeutic assembly in a distal portion of a shaft of a therapeutic device to a target site within the nasal region; is proximal to the parasympathetic nerve proximal to the sphenopalatine foramen; detecting a location of the parasympathetic nerve at the target site; and based on the detected location of the parasympathetic nerve. , applying energy to the target site using the therapeutic assembly, wherein applying the energy therapeutically modulates autonomic nerve activity in at least one of the nasal cavity, nasopharynx, or sinuses. A method comprising adjusting and applying.

9 1 . Detecting the location of the parasympathetic nerve at the target site detects the dielectric properties of heterogeneous tissue within at least one of the nasal cavity, the nasopharynx, and/or the paranasal sinuses on a high-resolution spatial grid. The method of Example 90, comprising measuring. 9 2 . Detecting the location of the parasympathetic nerve at the target site includes measuring dipole characteristics of heterogeneous tissue within the nasal cavity, the nasopharynx, and/or the paranasal sinuses on a high-resolution spatial grid. , the method of Example 90 or 92. 9 3 . Detecting the location of the parasympathetic nerve at the target site comprises detecting the impedance of heterogeneous tissue within at least one of the nasal cavity, the nasopharynx, or the paranasal sinuses on a high-resolution spatial grid. The method of any one of Examples 90-92. 9 4 . A device for therapeutic neuromodulation in the nasal region of a human patient, comprising: a delivery catheter having a distal portion configured to position the distal portion at a target site within the nasal region. a delivery catheter; a flexible support at the distal portion of the delivery catheter; and a plurality of electrodes carried by the flexible support, the flexible support at the target site. configured to conform to local anatomical irregularities to provide local compliance and interlocking for electrical activation of at least a portion of the electrode, the electrode being directly or indirectly connected to the electrode; A device that therapeutically modulates parasympathetic nerves in contacting mucosal and submucosal structures. 9 5 . The device of Example 94, further comprising a controllable recapture mechanism configured to recapture the flexible support after energy delivery to enable withdrawal of the flexible support from the nasal cavity. . 9 6 . The device of Example 94 or 94, wherein the target site is the sphenopalatine foramen. 9 7 . Any one of Examples 94-46, wherein the electrode is configured to be selectively activated to control the direction and associated dissipation of energy for precise and localized energy delivery. One device 98. A method of therapeutically modulating nerves in a nasal region of a human patient, the method comprising: intraluminally advancing a therapeutic assembly in a distal portion of a shaft of a therapeutic device to a target site within the nasal region. , the target site is at least proximal to an ostium of at least one of the frontal sinus, ethmoid sinus, sphenoid sinus, or maxillary sinus of the human patient; and advancing the therapeutic assembly. applying energy to the target site to therapeutically modulate parasympathetic nerves at the target site using the method to treat chronic sinusitis.

9 9 . Intraluminally advancing the therapeutic assembly to the target site includes positioning the therapeutic assembly proximal to the ostium of the frontal sinus; applying energy to the target site; applying energy to at least one of the supraorbital nerve, the supratrochlear nerve, a branch of the supraorbital nerve, a branch of the supratrochlear nerve, or other parasympathetic nerve fibers innervating the mucosa of the frontal sinus; 99. The method of claim 98, comprising: 1 0 0 . Intraluminally advancing the treatment assembly to the target site includes positioning the treatment assembly proximal to the ostium of the ethmoid sinus, and applying energy to the target site. , an anterior ethmoid branch of the nasociliary nerve, a posterior ethmoid branch of the nasociliary nerve, a maxillary nerve, a branch of the nasociliary nerve, a branch of the maxillary nerve, or the mucous membrane of the ethmoid sinus. 99. The method of claim 98, comprising applying energy to at least one of the other parasympathetic nerve fibers that innervate the. 1 0 1 . Intraluminally advancing the treatment assembly to the target site includes positioning the treatment assembly proximal to the stoma of the maxillary sinus; applying energy to the target site; 99. The method of claim 98, comprising applying energy to at least one of the infraorbital branch of the maxillary nerve, the alveolar branch of the maxillary nerve, or other parasympathetic nerve fibers innervating the mucosa of the maxillary sinus. . 1 0 2 . Intraluminally advancing the therapeutic assembly to the target site includes positioning the therapeutic assembly proximal to the ostium of the sphenoid sinus, and applying energy to the target site. to at least one of the posterior ethmoid branch of the optic nerve, the maxillary nerve, a branch of the optic nerve, a branch of the maxillary nerve, or other parasympathetic nerve fibers innervating the mucosa of the sphenoid sinus. 99. The method of claim 98, comprising applying energy. 1 0 3 . A system for therapeutic neuromodulation in the nasal region of a human patient for the treatment of chronic sinusitis, comprising: a shaft having a proximal portion and a distal portion, the distal portion being a target region; wherein the target site is at least proximal to a foramen of at least one of the frontal sinus, ethmoid sinus, sphenoid sinus, or maxillary sinus of the human patient; a shaft; and a therapeutic assembly in the distal portion of the shaft, the parasympathetic nerve innervating the mucosa of at least one of the frontal sinus, the ethmoid sinus, the sphenoid sinus, or the maxillary sinus. a therapeutic assembly comprising an energy delivery element configured to therapeutically modulate the energy delivery element.

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[0143]

Conclusion This disclosure is not intended to be exhaustive or to limit the technology to the precise form disclosed herein.

Although particular embodiments are disclosed herein for illustrative purposes, those skilled in the relevant art will recognize that various equivalent modifications are possible without departing from the present technology. be. In other instances, well-known structures and functions have not been shown and/or described in detail to avoid unnecessarily obscuring the description of embodiments of the present technology. Although the steps of the method may be presented herein in a specific order, in alternative embodiments the steps may have another suitable order. Similarly, certain aspects of the technology disclosed in the context of particular embodiments may be combined or excluded in other embodiments. Furthermore, although advantages associated with particular embodiments may be disclosed in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments may be It is not necessary to indicate such or other advantages disclosed herein to fall within the scope of the present technology. Accordingly, the present disclosure and related technology may encompass other embodiments not expressly shown and/or described herein.

[0144]

Throughout this disclosure, the singular terms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

Similarly, the word "or" in a list of two or more items is not expressly limited to mean only a single item to the exclusion of other items; Use should be construed as including (a) any single item in the list, (b) all items in the list, or (c) any combination of items in the list. In addition, terms such as "comprising" refer to at least the described feature(s) in a greater number of the same feature(s) and/or of one or more additional types. Used throughout this disclosure to mean including, rather than excluding, features. Directional terms such as "upper," "lower," "front," "rear," "vertical," and "horizontal" are used herein to indicate relationships between various elements and for clarity. can be used in books. It should be understood that such terms do not indicate absolute orientation. References herein to "one embodiment," "an embodiment," or similar phrases refer to the specific features, structure, operation, or characteristic may be included in at least one embodiment of the present technology. Therefore, the appearances of such phrases or phrases in the specification are not necessarily all referring to the same embodiment. Moreover, the various specific features, structures, operations, or characteristics may be combined in any suitable manner in one or more embodiments.

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CLAIMS JP2018515314A

1.

A system for therapeutic neuromodulation in the nasal region of a human patient, comprising: a shaft having a proximal portion and a distal portion, the distal portion being positioned at a target site below the sphenopalatine foramen of the human patient; a shaft configured for intraluminal positioning; and a therapeutic assembly in the distal portion of the shaft, the postganglionic assembly innervating the nasal mucosa in a microforamen of the palatal bone of the human patient. a therapeutic assembly comprising an energy delivery element configured to therapeutically modulate parasympathetic nerves.

2.

The energy delivery element is configured to deliver at least one of ultrasound energy, microwave energy, laser energy, or radio frequency (RF) energy to therapeutically modulate the postganglionic parasympathetic nerve. 2. The system of claim 1, wherein:

3.

2. The system of claim 1, wherein the therapeutic assembly is configured to dispense a drug to chemically modulate the postganglionic parasympathetic nerves.

4.

The shaft includes a drug delivery channel having an outlet in the distal portion of the shaft, the drug delivery channel configured to deliver at least one of a local anesthetic or a nerve block to the target site. 2. The system of claim 1, wherein:

5.

The shaft includes a fluid channel having an outlet in the distal portion of the shaft, the fluid channel configured to deliver saline to the target site to rinse the treatment area with saline. 2. The system of claim 1, wherein:

6.

further comprising an introducer having a rigid metal portion, the rigid metal portion sized and shaped to extend through the nasal passageway to the target site to deliver the therapeutic assembly to the target site. 2. The system of claim 1.

7.

2. The system of claim 1, wherein the shaft is a steerable catheter shaft and the distal portion of the shaft has a bend radius of 3 mm or less.

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8.

2. The system of claim 1, wherein the distal portion of the shaft comprises an articulation region having rigid links sized and shaped to have a bend radius of 3 mm or less.

9.

further comprising a fixation member along the shaft, the fixation member expanding within the cavity of the nasal region to allow the distal portion of the shaft to deploy the therapeutic assembly at the target site. 2. The system of claim 1, including a balloon configured to hold the balloon in position.

10.

2. The system of claim 1, wherein the energy delivery element of the therapeutic assembly comprises a plurality of electrodes configured to apply RF energy to therapeutically modulate postganglionic parasympathetic nerves.

11.

2. The therapeutic assembly comprises a plurality of sensing electrodes configured to detect at least one neural activity before, during, or after therapeutic neuromodulation. system.

12.

The therapeutic assembly comprises: a basket deformable between a low profile delivery state and an expanded state, the basket comprising a plurality of struts radially spaced from each other when the basket is in the expanded state; a plurality of electrodes disposed on the struts, the plurality of struts configured to position at least two of the electrodes at the target site when the basket is in the expanded state; a plurality of electrodes configured to apply radio frequency (RF) energy to the target site for therapeutically modulating parasympathetic nerves proximal to the target site. 2. The system of claim 1, wherein:

13.

The therapeutic assembly comprises: a flexible membrane deformable between a low profile delivery state and an expanded state; and a plurality of electrodes disposed on the flexible membrane, the electrodes comprising: 2. The system of claim 1, configured to apply radio frequency (RF) energy to a target site for therapeutically modulating parasympathetic nerves proximal to the target site.

14.

The system of claim 13, wherein the treatment assembly further comprises a frame supporting the flexible membrane.

15.

the distal portion of the shaft is deformable between a low profile delivery state and an expanded state; the distal portion of the shaft is in the expanded state; having a spiral/helical shape, the energy delivery element being disposed on the distal portion of the shaft and transmitting a wireless signal to the target site for therapeutically modulating parasympathetic nerves proximal to the target site. a plurality of electrodes configured to deliver frequency (RF) energy, the distal portion of the shaft being in the expanded state, at least one of the electrodes; 2. The system of claim 1, wherein the system is configured to place one in contact with tissue at the target site.

16.

The therapeutic assembly includes: a balloon deformable between a low profile delivery state and an expanded state; and a plurality of electrodes disposed on the balloon, the therapeutic assembly comprising: a balloon deformable between a low profile delivery state and an expanded state; 2. The system of claim 1, comprising a plurality of electrodes configured to deliver radio frequency (RF) energy for therapeutically modulating parasympathetic nerves.

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17.

The system of claim 16, wherein the balloon comprises a plurality of holes configured to allow perfusion of fluid through the balloon when the balloon is in the expanded state.

18.

5. A support extending through the balloon, and a plurality of graduated markings on at least one of the support or the balloon for identifying spatial positioning of the balloon. The system according to item 16.

19.

The therapeutic assembly comprises: a balloon deformable between a low profile delivery state and an expanded state, the balloon comprising a proximal cone portion; a return electrode on the balloon, and the proximal cone portion. and a flex circuit, the return electrode and the flex circuit configured to deliver radio frequency (RF) energy to the target site for therapeutically modulating parasympathetic nerves proximal to the target site. The system of claim 1, wherein the system is configured to

20.

The treatment assembly includes: a plurality of balloons extending distally from the distal portion of the shaft, the plurality of balloons being independently expandable; and at least one balloon on each of the plurality of balloons. an electrode configured to deliver radio frequency (RF) energy to the target site for therapeutically modulating parasympathetic nerves proximal to the target site. , the system of claim 1.

21.

The internal support member of claim 20, further comprising an internal support member extending through a region between the plurality of balloons and configured to carry the plurality of balloons, the internal support member including a return electrode. System described.

22.

2. The system of claim 1, wherein the therapeutic assembly comprises a cryotherapy balloon configured to apply cryogenic cooling to tissue at the target site to therapeutically modulate autonomic nerve activity.

23.

The therapeutic assembly includes a balloon sized and shaped to contact tissue at the target site when expanded, the balloon circulating a fluid heated to at least 60° C. to stimulate the autonomic nervous system. 2. The system of claim 1, configured to thermally modulate activity.

24.

The therapeutic assembly includes: a balloon configured to be expanded by a fluid, the balloon being sized and shaped to contact tissue at the target site when expanded; 2. The system of claim 1, comprising a heating member configured to heat the fluid within the balloon to thermally modulate autonomic nerve activity.

25.

The system of claim 1, wherein the treatment assembly comprises a plasma ablation probe.

26.

A system for therapeutic neuromodulation in the nasal region of a human patient, comprising: a shaft having a proximal portion and a distal portion, the distal portion being configured to intraluminally position the distal portion at a target site; a shaft,

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wherein the target site is at least one of proximal to the sphenopalatine foramen or inferior to the sphenopalatine foramen of a human patient; and the distal portion of the shaft is in a low profile delivery state and an expanded state. a therapeutic assembly comprising a plurality of struts and a plurality of electrodes disposed on the struts, the plurality of struts being deformable between , a therapeutic assembly forming a basket for positioning at least two of the electrodes at the target site proximal to or below the sphenopalatine foramen of the human patient, the electrodes at the target site; A system configured to apply radio frequency (RF) energy to therapeutically modulate parasympathetic nerves proximal to the target site.

27.

the plurality of struts comprising at least three struts radially spaced from each other in the expanded state to define the basket, each of the three struts including at least one of the electrodes; 27. The system of claim 26.

28.

the basket comprises at least three branches radially spaced from each other in the expanded state to form the basket, each branch comprising at least two struts positioned adjacent to each other, each strut 27. The system of claim 26, wherein includes at least one of the electrodes.

29.

further comprising a thermocouple positioned at least proximal to one of the electrodes, the thermocouple being in contact with the electrode and tissue adjacent the electrode when the treatment assembly is in the expanded state. 27. The system of claim 26, configured to sense temperature at an interface between

30.

26. Each of the electrodes is configured to be independently activated and independently assigned a selective polarity to apply therapeutic neuromodulation over a selected region of the basket. system described in.

31.

The basket has a spherical or oval shape, and the electrodes are selectively activated to apply RF energy over at least one of a segment, quadrant, or hemisphere of the basket. 27. The system of claim 26, wherein the system is configured.

32.

The plurality of electrodes includes first to third electrodes disposed on corresponding first to third posts, and the system further includes a control device operably coupled to the plurality of electrodes. The control device has a computer-readable medium carrying instructions, and the instructions, when executed by the control device, control the first to third electrodes of the plurality of electrodes. one electrode has a positive polarity, the second and third electrodes have a negative polarity, and the electrodes transmit RF energy in a sesquipolar manner over selected peripheral areas of the basket. 27. The system of claim 26, applying and activating.

33.

the basket includes an internal support member having a distal end portion extending through a region between the plurality of struts and supporting distal end portions of the plurality of struts; , comprising at least a first column and a second column, and the plurality of electrodes include a first electrode disposed on the first column and a second electrode disposed on the second column. an electrode, and a third electrode disposed on the distal end portion of the internal support member, the system further comprising a controller operably coupled to the plurality of electrodes, the system further comprising: a controller operably coupled to the plurality of electrodes; The apparatus includes a computer-readable medium carrying instructions, which, when executed by the controller, control the first to third electrodes of the plurality of electrodes to the first and second electrodes. 27. The third electrode has a positive polarity; and the third electrode has a negative polarity, and the electrode is activated to apply RF energy across a distal region of the basket. System described.

34.

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the basket comprises at least two branches that are radially spaced apart from each other when the treatment assembly is in the expanded state, each branch having at least a first strut and a second strut positioned adjacent to each other, a strut, the first strut having a first electrode disposed thereon, the second strut having a second electrode disposed thereon, and the second strut having a second electrode disposed thereon; 27. The system of claim 26, wherein the first and second electrodes have opposite polarities and are configured to apply RF energy between the first and second electrodes.

35.

the basket comprises at least two branches that are radially spaced apart from each other when the treatment assembly is in the expanded state, each branch having at least a first strut and a second strut positioned adjacent to each other; a strut, the first strut having a first electrode disposed thereon, and the second strut having a second strut disposed thereon, the first and second electrodes of one branch are configured to have positive polarity, the first and second electrodes of the second branch are configured to have negative polarity, and the treatment 27. The system of claim 26, wherein the assembly is configured to deliver RF energy between the first branch and the second branch over a peripheral portion of the basket.

36.

further comprising a return electrode disposed on the distal portion of the shaft positioned proximal to the treatment assembly, the electrode on the strut configured to have positive polarity; 27. The system of claim 26, wherein is configured to have negative polarity.

37.

27. The system of claim 26, wherein at least a portion of the electrodes are configured to detect impedance at the target site to determine nerve location at the target site.

38.

the plurality of electrodes on the strut are a first plurality of electrodes; the treatment assembly includes: an expandable balloon disposed within the strut; and a second plurality of electrodes on the expandable balloon. electrodes, wherein when in the expanded state, the expandable balloon positions at least a portion of the second plurality of electrodes in contact with tissue at the target site, 27. The system of claim 26, wherein the system detects neural activity in.

39.

further comprising an RF generator operably connected to the treatment assembly, the RF generator including a controller having a computer readable medium carrying instructions, the instructions being executed by the controller; 27. The system of claim 26, wherein the therapeutic assembly detects at least one of impedance or temperature at least proximal to the target site.

40.

further comprising an RF generator operably connected to the treatment assembly, the RF generator including a controller having a computer readable medium carrying instructions, the instructions being executed by the controller; 27. The system of claim 26, further comprising. causing the treatment assembly to apply RF energy to the target site in a predetermined pattern.

41.

A system for neural mapping and therapeutic neuromodulation in the nasal region of a human patient, comprising: a shaft having a proximal portion and a distal portion, the distal portion being positioned proximal to the sphenopalatine foramen of the human patient; a shaft configured for intraluminal positioning at a target site; a plurality of electrodes at the distal portion of the shaft, the plurality of electrodes configured to detect the location of the parasympathetic nerve at the target site; an electrode configured; and an energy delivery element configured to therapeutically modulate postganglionic parasympathetic nerves innervating nasal mucosa at the target site. A system comprising: a therapeutic assembly;

42.

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The system of claim 41, wherein the electrode defines the energy delivery element and is configured to apply radio frequency (RF) energy to the target site.

43.

42. The system of claim 41, wherein the electrode is configured to detect dielectric properties of heterogeneous tissue at the target site to localize parasympathetic nerves.

44.

42. The system of claim 41, wherein the electrodes are configured to detect heterogeneous tissue impedance characteristics at the target site to localize parasympathetic nerves.

45.

A method of therapeutically modulating nerves in a nasal region of a human patient, the method comprising: advancing a therapeutic assembly in a distal portion of a shaft of a therapeutic device intraluminally to a target site within said nasal region. the target site is proximal to the parasympathetic nerve extending across at least one of the proximal accessory or microforamina of the sphenopalatine foramen; and using the therapeutic assembly to advance the target site; applying energy to the site to therapeutically modulate autonomic nerve activity in at least one of the nasal cavity, nasopharynx, or sinuses.

46.

The method of claim 45, wherein intraluminally advancing the treatment assembly to the target site includes positioning the treatment assembly in the human patient's palatine bone below the sphenopalatine foramen.

47.

intraluminally advancing the therapeutic assembly to the target site, the step of intraluminally advancing the therapeutic assembly through the human patient's nasal entrance, through the inferior nasal meatus, and toward the target site; 46. The method of claim 45, comprising the steps of:

48.

intraluminally advancing the therapeutic assembly to the target site, wherein the therapeutic assembly is intraluminally advanced through the human patient's nasal entrance, through the middle nasal meatus, and to the target site; 46. The method of claim 45, comprising:

49.

46. The method of claim 45, further comprising advancing an endoscope intraluminally through the human patient's nasal entrance and through the middle nasal meatus to visualize the therapeutic assembly at the target site. the method of.

50.

46. The method of claim 45, further comprising advancing an endoscope intraluminally through the human patient's nasal entrance and through the inferior nasal meatus to visualize the therapeutic assembly at the target site. the method of.

51.

intraluminally advancing the therapeutic assembly to the target site, the step of intraluminally advancing the therapeutic assembly through the human patient's nasal entrance, through the inferior nasal meatus, and toward the target site; The method includes advancing an endoscope intraluminally through the entrance of the nose of the human patient and through the inferior nasal meatus to visualize the therapeutic assembly at the target site. 46. The method of claim 45, further comprising the step of:

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52.

Intraluminally advancing the therapeutic assembly to the target site, the step of intraluminally advancing the therapeutic assembly through the human patient's nasal entrance, through the middle nasal meatus, and into the target site. The method comprises: advancing an endoscope intraluminally through the entrance of the nose of the human patient and through the middle meatus to visualize the therapeutic assembly at the target site. 46. The method of claim 45, further comprising the step of:

53.

further comprising advancing an endoscope intraluminally through the human patient's nasal entrance, through one of the inferior nasal meatus or the middle nasal meatus, to a region at least proximal to the target site. , advancing the therapeutic assembly intraluminally to the target site; advancing the distal portion of the shaft through a channel of the endoscope; and advancing the therapeutic assembly intraluminally to the target site. 46. The method of claim 45, comprising advancing the endoscope out of an opening in a distal portion thereof.

54.

10. The step of intraluminally advancing the therapeutic assembly to the target site includes advancing the distal portion of the shaft through the human patient's mouth and oropharynx to the target site. 45.

55.

46. The method of claim 45, further comprising imaging the target site via infrared (IR) spectroscopy to visualize the vasculature at least proximal to the target site.

56.

further comprising expanding a fixation member positioned along the distal portion of the shaft within a cavity of the nasal region, the fixation member directing the distal portion of the shaft to the target site. 46. The method of claim 45, wherein the treatment assembly is held in position for deployment.

57.

the target site is a first target site, applying energy to the target site includes applying energy to the first target site, and the method includes: repositioning a second target site within the region; and using the therapeutic assembly to therapeutically modulate parasympathetic nerves proximal to the second target site. 46. The method of claim 45, further comprising: applying energy of.

58.

46. The method of claim 45, wherein applying energy comprises applying pulsed radio frequency (RF) energy to the target site via a plurality of electrodes of a treatment element.

59.

46. The method of claim 45, further comprising detecting impedance at the target site to locate parasympathetic nerves extending across at least one of the proximal accessory or microforamina of the sphenopalatine foramen.

60.

Claim 59, wherein applying energy to the target region comprises applying energy to discrete areas of the therapeutic assembly corresponding to the location of the parasympathetic nerve identified via impedance measurements. Method described.

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The treatment assembly includes a plurality of electrodes, and applying energy to the target site includes independently activating each of the electrodes and selecting the polarity of each of the electrodes to effect the treatment. 46. The method of claim 45, comprising applying therapeutic neuromodulation over selective areas of the assembly.

62.

Applying energy to the target region further includes applying energy in a first hemispherical portion of the treatment assembly, and the treatment assembly includes a second hemispherical portion of the treatment assembly. 62. The method of claim 61, wherein no energy is applied.

63.

the treatment assembly comprises an expandable basket having a plurality of struts with a plurality of electrodes disposed on the struts, and applying energy to the target region comprises: a step of activating a first electrode of the electrodes to have positive polarity; a step of activating at least a second electrode and a third electrode of the plurality of electrodes to have negative polarity; a first, second, and third electrode are activated simultaneously, and the second and third electrodes are sequentially paired with the first electrode based on a path of least resistance. 46. The method of claim 45, wherein the therapeutic neuromodulation is applied sequentially over an area of the basket.

64.

the treatment assembly comprises an expandable basket having a plurality of struts with a plurality of electrodes disposed on the struts, and applying energy to the target region comprises: activating a first electrode of the plurality of electrodes to have positive polarity; and activating at least second to sixth electrodes of the plurality of electrodes to have negative polarity. , first to sixth electrodes are activated simultaneously, and said second to sixth electrodes are sequentially paired with said first electrode based on a path of least resistance to form one of said baskets. 46. The method of claim 45, wherein therapeutic neuromodulation is applied sequentially over hemispheric regions.

65.

The treatment assembly includes a plurality of struts with a plurality of electrodes disposed on the struts, and an inner support member with a return electrode at a distal end portion of the inner support member. an expandable basket having an internal support member; applying energy to the target site; activating the electrode on the post to have a positive polarity; 46. The method of claim 45, comprising activating the electrode to have a negative polarity, and applying RF energy over a distal region of the basket.

66.

The treatment assembly comprises an expandable basket having a plurality of branches that are radially spaced apart from each other when the treatment assembly is in an expanded state, each branch having at least two adjacent struts, each of which comprising a strut with an electrode positioned on the strut, and applying energy to the target site comprises connecting the electrode on an adjacent strut of at least one of the branches such that the electrode has an opposite polarity. and applying RF energy between the electrodes on the adjacent struts.

67.

the therapeutic assembly includes a plurality of electrodes, and applying energy to the target region includes activating the electrodes of the therapeutic assembly to have a positive polarity; activating a return electrode disposed on the distal portion of the shaft, the return electrode having a negative polarity, the electrode and the return electrode 46. The method of claim 45, wherein activating applies RF energy across the nasal turbinates of the human patient.

68.

detecting neural activity at the target site via a plurality of sensing electrodes prior to applying energy to therapeutically modulate autonomic nerve activity at the target site; and based on the detected neural activity. mapping the location of nerves at the

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target region, wherein applying energy to the target region includes selectively applying energy to regions based on the detected nerve locations. 46. The method of claim 45, comprising:

69.

The method of claim 68, further comprising applying non-therapeutic neural stimulation to the target site prior to detecting neural activity.

70.

further comprising detecting neural activity via the plurality of sensing electrodes after applying energy to the target site to determine whether the application of energy therapeutically modulated nerves at the target site. 69. The method of claim 68.

71.

The treatment assembly comprises a flexible membrane carrying a plurality of electrodes, and prior to applying energy, the method expands the flexible membrane at the target site to dislodge at least a portion of the electrodes. 46. The method of claim 45, comprising placing in contact with tissue at the target site, and applying energy to the target site comprises applying RF energy to the target site via the electrode. Method.

72.

transforming the distal portion of the shaft from a low profile delivery state to an expanded state such that a plurality of electrodes disposed on the distal portion of the shaft are placed in contact with tissue at the target site; the step further comprises deforming the distal portion of the shaft to have a spiral/helical shape in the expanded state, and applying energy to the target region via the electrodes. 46. The method of claim 45, comprising applying RF energy to.

73.

The treatment assembly includes a balloon carrying a plurality of electrodes, and prior to applying energy, the method includes expanding the balloon at the target site to engage at least a portion of the electrodes with tissue at the target site. 46. The method of claim 45, further comprising: contacting and placing; and applying energy to the target site includes applying RF energy to the target site via the electrode.

74.

The method of claim 73, wherein applying energy to the target site further comprises: selectively activating the electrodes to apply electrical current radially across a circumferential segment of the balloon.

75.

74. The method of claim 73, wherein applying energy to the target site further comprises: selectively activating the electrodes to apply electrical current longitudinally across a longitudinal region of the balloon.

76.

74. The balloon of claim 73, wherein expanding the balloon includes filling the balloon with fluid, and wherein the balloon comprises a plurality of holes that allow perfusion of the fluid through the balloon during energy application. the method of.

77.

74. The method of claim 73, wherein expanding the balloon includes circulating a fluid through the balloon, the fluid cooling the electrode during energy application.

78.

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the treatment assembly comprises a plurality of balloons extending distally from the distal portion of the shaft and a plurality of electrodes disposed on the plurality of balloons, and prior to applying energy; The method further comprises independently expanding the plurality of balloons at the target site to place at least a portion of the electrode in contact with tissue at the target site, and applying energy to the target site. 46. The method of claim 45, wherein step comprises applying RF energy to the target site via the electrode.

78.

Applying energy to the target site includes: activating a return electrode on an internal support member extending through the plurality of balloons; and activating at least a portion of the electrodes on the plurality of balloons. 79. The method of claim 78, further comprising the steps of:

80.

46. The method of claim 45, further comprising: measuring tissue temperature at the target site during energy application; and terminating energy application when a threshold maximum temperature is reached.

81.

46. The method of claim 45, further comprising terminating energy application after a predetermined maximum period of time.

82.

46. The method of claim 45, further comprising: detecting tissue impedance at the target site during energy application; and terminating energy application when a threshold impedance value is reached.

83.

detecting the impedance of tissue at the target site prior to energy application to define a baseline impedance; detecting the impedance of tissue at the target site during energy application; and determining the impedance from the baseline impedance. 46. The method of claim 45, further comprising terminating energy application when a threshold change is reached.

84.

Applying energy to the target site applies therapeutic cryogenic cooling to tissue at the target site to therapeutically modulate autonomic nerve activity within the nasal cavity, the nasopharynx, and/or the paranasal sinuses. 46. The method of claim 45, comprising the step of:

85.

Applying energy to the target site includes circulating heated fluid within a balloon such that an outer surface of the balloon contacts tissue at the target site, heating the tissue and causing the target site to 46. The method of claim 45, comprising the step of thermally modulating autonomic nerve activity at.

86.

Applying energy to the target site includes: expanding a balloon so that an outer surface of the balloon contacts tissue at the target site; and heating a heating member within the balloon. 46. The method of claim 45, comprising: heat from the heating member is transferred to the fluid and to the tissue adjacent the balloon to thermally modulate autonomic nerve activity.

87.

46. The method of claim 45, wherein applying energy to the target site includes generating a plasma field to therapeutically modulate nerves at the target site.

88.

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46. The method of claim 45, wherein applying energy to the target site therapeutically modulates cholinergic pathways that signal submucosal glands.

89.

intraluminally advancing the treatment assembly to the target site, the step of intraluminally advancing the treatment assembly to the target site, the treatment assembly being inserted into the accessory foramen in at least one of the superior meatus, the middle meatus, the inferior meatus, or the pterygopalatine fossa. 46. The method of claim 45, comprising advancing intraluminally through a micropore and/or a parasympathetic point of entry into the nasal region.

90.

A method of therapeutically modulating nerves in the nasal region, the method comprising: advancing a therapeutic assembly in a distal portion of a shaft of a therapeutic device intraluminally to a target site within the nasal region, the method comprising: advancing the site is proximal to the parasympathetic nerve proximal to the sphenopalatine foramen; detecting the location of the parasympathetic nerve at the target site; and based on the detected location of the parasympathetic nerve at the target site; applying energy to the target site using the therapeutic assembly, the applying energy therapeutically modulating autonomic nerve activity within at least one of the nasal cavity, nasopharynx, or sinuses; , including a method.

91.

Detecting the location of the parasympathetic nerve at the target site comprises detecting the dielectric properties of heterogeneous tissue within at least one of the nasal cavity, the nasopharynx and/or the paranasal sinuses on a high-resolution spatial grid. 91. The method of claim 90, comprising the step of measuring.

92.

Detecting the location of the parasympathetic nerves at the target site comprises measuring dipole characteristics of heterogeneous tissue within the nasal cavity, the nasopharynx and/or the paranasal sinuses on a high-resolution spatial grid. 91. The method of claim 90.

93.

Detecting the location of the parasympathetic nerves at the target site includes detecting the impedance of heterogeneous tissue within at least one of the nasal cavity, the nasopharynx, or the paranasal sinuses on a high-resolution spatial grid. 91. The method of claim 90, comprising:

94.

A device for therapeutic neuromodulation in the nasal region of a human patient, comprising: a delivery catheter having a distal portion configured to position the distal portion at a target site within the nasal region. a delivery catheter; a flexible support at the distal portion of the delivery catheter; and a plurality of electrodes carried by the flexible support, the flexible support at the target site. configured to conform to local anatomical irregularities to provide local compliance and interlocking for electrical activation of at least a portion of the electrode, the electrode being directly or indirectly connected to the electrode; A device configured to therapeutically modulate parasympathetic nerves of contacting mucosal and submucosal structures.

95.

Claim 94, further comprising a controllable recapture mechanism configured to recapture the flexible support after energy delivery to enable withdrawal of the flexible support from the nasal cavity. device.

96.

95. The device of claim 94, wherein the target site is the sphenopalatine foramen

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97.

95. The device of claim 94, wherein the electrodes are configured to be selectively activated to control direction and associated dissipation of energy for precise and localized energy delivery.

98.

A method of therapeutically modulating nerves in the nasal region of a human patient, the method comprising: advancing a therapeutic assembly in a distal portion of a shaft of a therapeutic device intraluminally to a target site within the nasal region. the therapeutic assembly, wherein the target site is at least proximal to an ostium of at least one of the frontal, ethmoid, sphenoid, or maxillary sinuses of the human patient, applying energy to the target site to therapeutically modulate parasympathetic nerves at the target site using a method of treating chronic sinusitis.

99.

intraluminally advancing the treatment assembly to the target site, comprising positioning the treatment assembly proximal to the ostium of the frontal sinus; and applying energy to the target site. , applying energy to at least one of the supraorbital nerve, the supratrochlear nerve, a branch of the supraorbital nerve, a branch of the supratrochlear nerve, or other parasympathetic nerve fibers innervating the mucosa of the frontal sinus. 99. The method of claim 98, comprising the step of:

100.

intraluminally advancing the treatment assembly to the target site, comprising positioning the treatment assembly proximal to the ostium of the ethmoid sinus; and applying energy to the target site. is the anterior ethmoid branch of the nasociliary nerve, the posterior ethmoid branch of the nasociliary nerve, the maxillary nerve, a branch of the nasociliary nerve, a branch of the maxillary nerve, or the ethmoid sinus. 99. The method of claim 98, comprising applying energy to at least one of the other parasympathetic nerve fibers innervating the mucosa.

101.

intraluminally advancing the treatment assembly to the target site, comprising positioning the treatment assembly proximal to the ostium of the maxillary sinus; and applying energy to the target site. , an infraorbital branch of the maxillary nerve, an alveolar branch of the maxillary nerve, or other parasympathetic nerve fibers innervating the mucosa of the maxillary sinus. Method described.

102.

intraluminally advancing the treatment assembly to the target site, including positioning the treatment assembly proximal to the ostium of the sphenoid sinus; and applying energy to the target site. the step is at least one of the posterior ethmoid branch of the optic nerve, the maxillary nerve, a branch of the optic nerve, a branch of the maxillary nerve, or other parasympathetic nerve fibers innervating the mucosa of the sphenoid sinus. 99. The method of claim 98, comprising applying energy to.

103.

A system for therapeutic neuromodulation in the nasal region of a human patient for the treatment of chronic sinusitis, comprising: a shaft having a proximal portion and a distal portion, the distal portion being directed to a target site; a shaft configured for placement within a cavity, the target site being at least proximal to an ostium of at least one of a frontal sinus, an ethmoid sinus, a sphenoid sinus, or a maxillary sinus of the human patient; , a therapeutic assembly in the distal portion of the shaft, the parasympathetic nerves innervating the mucosa of at least one of the frontal sinus, the ethmoid sinus, the sphenoid sinus, or the maxillary sinus; a therapeutic assembly comprising an energy delivery element configured to adjust to.

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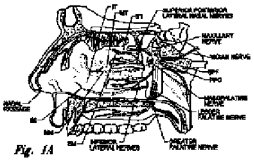
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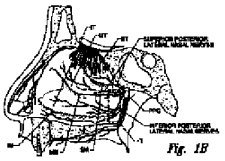
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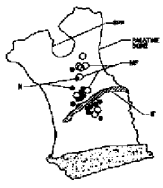
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(54)【発明の名称】治療的鼻神経調節のためのデバイスならびに関連する方法及びシステム

(57)【要約】
治療的鼻神経調節のためのデバイスならびに関連するシステム及び方法が、本明細書に開示される。本技術の実施形態に従って構成される鼻領域における治療的神経調節のためのシステムは、例えば、シャフトと、シャフトの遠位部分における治療用要素とを含み得る。シャフトは、遠位部分を、患者の蝶口蓋孔の下方の標的部位に腔内に配置し得る。治療用要素は、鼻炎または他の兆候の治療のために、ヒト患者の口蓋骨のミクロ孔において節後副交感神経を治療的に調節するように構成されたエネルギー送達要素を含み得る。他の実施形態では、治療用要素は、慢性副鼻腔炎の治療のために、前頭洞、篩骨洞、蝶形骨洞、及び上顎洞を神経支配する神経を治療的に調節するように構成され得る。


Fig. 1A


Fig. 1B


Fig. 1C

【特許請求の範囲】
【請求項１】
ヒト患者の鼻領域における治療的神経調節のためのシステムであって、
近位部分及び遠位部分を有するシャフトであって、前記遠位部分を、前記ヒト患者の蝶口蓋孔の下方の標的部位に、腔内に配置するように構成されている、シャフトと、
前記シャフトの前記遠位部分における治療用アセンブリであって、前記ヒト患者の口蓋骨のミクロ孔において鼻粘膜を神経支配する節後副交感神経を治療的に調節するように構成されたエネルギー送達要素を備える、治療用アセンブリと、を備える、システム。
【請求項２】
前記エネルギー送達要素が、前記節後副交感神経を治療的に調節するために、超音波エネルギー、マイクロ波エネルギー、レーザーエネルギー、または無線周波数（ＲＦ）エネルギーのうちの少なくとも１つを送達するように構成されている、請求項１に記載のシステム。
【請求項３】
前記治療用アセンブリが、前記節後副交感神経を化学的に調節するために、薬物を分注するように構成されている、請求項１に記載のシステム。
【請求項４】
前記シャフトが、前記シャフトの前記遠位部分に出口を有する薬物送達チャネルを備え、前記薬物送達チャネルが、局所麻酔薬または神経ブロックのうちの少なくとも１つを前記標的部位に送達するように構成されている、請求項１に記載のシステム。
【請求項５】
前記シャフトが、前記シャフトの前記遠位部分に出口を有する流体チャネルを備え、前記流体チャネルが、前記標的部位に生理食塩水を送達して、前記治療エリアを生理食塩水で濯ぐように構成されている、請求項１に記載のシステム。
【請求項６】
剛性金属部分を有する導入器をさらに備え、前記剛性金属部分が、前記標的部位に前記治療用アセンブリを送達するために、鼻道を通って前記標的部位に延在するようにサイズ決定及び成形される、請求項１に記載のシステム。
【請求項７】
前記シャフトが、操縦可能なカテーテルシャフトであり、前記シャフトの前記遠位部分が、３ｍｍ以下の曲げ半径を有する、請求項１に記載のシステム。
【請求項８】
前記シャフトの前記遠位部分が、３ｍｍ以下の曲げ半径を有するようにサイズ決定及び成形された剛性リンクを有する関節運動領域を備える、請求項１に記載のシステム。
【請求項９】
前記シャフトに沿って固定部材をさらに備え、前記固定部材が、前記鼻領域の腔内で拡張して、前記シャフトの前記遠位部分を、前記標的部位に前記治療用アセンブリを展開するのに適切な位置に保持するように構成されたバルーンを含む、請求項１に記載のシステム。
【請求項１０】
前記治療用アセンブリの前記エネルギー送達要素が、節後副交感神経を治療的に調節するためのＲＦエネルギーを適用するように構成された複数の電極を備える、請求項１に記載のシステム。
【請求項１１】
前記治療用アセンブリが、治療的調節前、治療的調節中、または治療的神経調節後のうちの少なくとも１つの神経活動を検出するように構成された複数の感知電極を備える、請求項１に記載のシステム。
【請求項１２】
前記治療用アセンブリが、
低プロファイル送達状態と拡張状態との間で変形可能なバスケットであって、前記バス

ケットが前記拡張状態にあるときに互いに半径方向に離間される複数の支柱を含む、バスケットと、
前記支柱上に配設された複数の電極であって、前記複数の支柱が、前記バスケットが前記拡張状態にあるときに、前記電極のうちの少なくとも２つを前記標的部位に位置付けるように構成された、複数の電極と、を備え、
前記電極が、前記標的部位に、前記標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを適用するように構成されている、請求項１に記載のシステム。
【請求項１３】
前記治療用アセンブリが、
低プロファイル送達状態と拡張状態との間で変形可能な可撓性膜と、
前記可撓性膜上に配設された複数の電極と、を備え、
前記電極が、前記標的部位に、前記標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを適用するように構成されている、請求項１に記載のシステム。
【請求項１４】
前記治療用アセンブリが、前記可撓性膜を支持するフレームをさらに備える、請求項１３に記載のシステム。
【請求項１５】
前記シャフトの前記遠位部分が、低プロファイル送達状態と拡張状態との間で変形可能であり、
前記シャフトの前記遠位部分が、前記シャフトの前記遠位部分が前記拡張状態にあるときに、渦巻き／螺旋形状を有し、
前記エネルギー送達要素が、前記シャフトの前記遠位部分上に配設され、前記標的部位に、前記標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを送達するように構成された複数の電極を備え、
前記シャフトの前記遠位部分が、前記シャフトの前記遠位部分が前記拡張状態にあるときに、前記電極のうちの少なくとも１つを前記標的部位において組織と接触して定置するように構成されている、請求項１に記載のシステム。
【請求項１６】
前記治療用アセンブリが、
低プロファイル送達状態と拡張状態との間で変形可能なバルーンと、
前記バルーン上に配設された複数の電極であって、前記標的部位に、前記標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを送達するように構成された、複数の電極と、を備える、請求項１に記載のシステム。
【請求項１７】
前記バルーンが、前記バルーンが前記拡張状態にあるときに、前記バルーンを通る流体の灌流を可能にするように構成された複数の穴を備える、請求項１６に記載のシステム。
【請求項１８】
前記バルーンを通って延在する支持体と、
前記バルーンの空間的位置付けを特定するための、前記支持体または前記バルーンのうちの少なくとも１つの上の複数の段階的マーキングと、をさらに備える、請求項１６に記載のシステム。
【請求項１９】
前記治療用アセンブリが、
低プロファイル送達状態と拡張状態との間で変形可能なバルーンであって、近位錐体部分を備える、バルーンと、
前記バルーン上の戻り電極と、
前記近位錐体部分上のフレックス回路と、
を備え、

前記戻り電極及び前記フレックス回路は、前記標的部位に、前記標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを送達するように構成されている、請求項１に記載のシステム。

【請求項２０】

前記治療用アセンブリが、

前記シャフトの前記遠位部分から遠位に延在する複数のバルーンであって、独立して拡張可能である、複数のバルーンと、

前記複数のバルーンの各々の上の少なくとも１つの電極であって、前記標的部位に、前記標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを送達するように構成されている、電極と、を備える、請求項１に記載のシステム。

【請求項２１】

前記複数のバルーンの間の領域を通って延在し、前記複数のバルーンを担持するように構成された内部支持部材であって、戻り電極を含む、内部支持部材をさらに備える、請求項２０に記載のシステム。

【請求項２２】

前記治療用アセンブリが、前記標的部位において組織に極低温冷却を適用して、自律神経活動を治療的に調節するように構成された凍結治療用バルーンを備える、請求項１に記載のシステム。

【請求項２３】

前記治療用アセンブリが、拡張されるときに前記標的部位において組織と接触するようにサイズ決定及び成形されたバルーンを備え、前記バルーンが、少なくとも６０℃に加熱された流体を循環させて、自律神経活動を熱的に調節するように構成されている、請求項１に記載のシステム。

【請求項２４】

前記治療用アセンブリが、

流体によって拡張されるように構成されたバルーンであって、拡張されるときに前記標的部位において組織と接触するようにサイズ決定及び成形された、バルーンと、

前記バルーン内の加熱部材であって、前記バルーン内で前記流体を加熱して、自律神経活動を熱的に調節するように構成された加熱部材と、を備える、請求項１に記載のシステム。

【請求項２５】

前記治療用アセンブリが、プラズマ切除プローブを備える、請求項１に記載のシステム。

【請求項２６】

ヒト患者の鼻領域における治療的神経調節のためのシステムであって、

近位部分及び遠位部分を有するシャフトであって、前記遠位部分を標的部位に腔内に配置するように構成され、前記標的部位が、ヒト患者の蝶口蓋孔の近位または蝶口蓋孔の下方のうちの少なくとも１つである、シャフトと、

前記シャフトの前記遠位部分にあり、低プロファイル送達状態と拡張状態との間で変形可能である治療用アセンブリであって、複数の支柱及び前記支柱上に配設された複数の電極を備え、前記複数の支柱が、前記治療用アセンブリが前記拡張状態にあるときに、前記電極のうちの少なくとも２つを前記ヒト患者の蝶口蓋孔の近位または下方の前記標的部位に位置付けるバスケットを形成する、治療用アセンブリと、を備え、

前記電極が、前記標的部位に、前記標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを適用するように構成されている、システム。

【請求項２７】

前記複数の支柱が、前記拡張状態において互いに半径方向に離間されて、前記バスケットを画定するような少なくとも３つの支柱を備え、

前記３つの支柱の各々が、前記電極うちの少なくとも１つを含む、請求項２６に記載のシステム。

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【請求項２８】
前記バスケットが、前記拡張状態において互いに半径方向に離間されて、前記バスケットを形成するような少なくとも３つの分岐を備え、
各分岐が、互いに隣接して位置付けられた少なくとも２つの支柱を備え、
各支柱が、前記電極のうちの少なくとも１つを含む、請求項２６に記載のシステム。
【請求項２９】
前記電極のうちの１つに少なくとも近位に位置付けられた熱電対をさらに備え、前記熱電対が、前記治療用アセンブリが前記拡張状態にあるときに、前記電極と前記電極に隣接した組織との間の境界面にて温度を検出するように構成されている、請求項２６に記載のシステム。
【請求項３０】
前記電極の各々が、独立して活性化され、独立して選択的な極性に割り当てられて、前記バスケットの選択された領域にわたって治療的神経調節を適用するように構成されている、請求項２６に記載のシステム。
【請求項３１】
前記バスケットが、球体または卵形形状を有し、前記電極が、選択的に活性化されて、前記バスケットのセグメント、四分円、または半球のうちの少なくとも１つにわたってＲＦエネルギーを適用するように構成されている、請求項２６に記載のシステム。
【請求項３２】
前記複数の電極が、対応する第１～第３の支柱上に配設された第１～第３の電極を備え、
前記システムが、前記複数の電極に動作可能に連結された制御装置をさらに備え、前記制御装置が、命令を保有するコンピュータ可読媒体を有し、該命令は、前記制御装置によって実行されるときに、前記複数の電極のうちの第１～第３の電極を、
前記第１の電極が、正極性を有し、
前記第２及び第３の電極が、負極性を有し、
前記電極が、前記バスケットの選択された周辺領域にわたってＲＦエネルギーをセスキ極性（ｓｅｓｑｕｉｐｏｌａｒ）様式で適用する、ように活性化する、請求項２６に記載のシステム。
【請求項３３】
前記バスケットが、前記複数の支柱の間の領域を通って延在し、前記複数の支柱の遠位端部部分を支持する遠位端部部分を有する内部支持部材を備え、
前記複数の支柱が、少なくとも第１の支柱及び第２の支柱を備え、
前記複数の電極は、前記第１の支柱上に配設された第１の電極、前記第２の支柱上に配設された第２の電極、及び前記内部支持部材の前記遠位端部部分上に配設された第３の電極を備え、
前記システムが、前記複数の電極に動作可能に連結された制御装置をさらに備え、前記制御装置が、命令を保有するコンピュータ可読媒体を有し、該命令は、前記制御装置によって実行されるときに、前記複数の電極のうちの第１～第３の電極を、
前記第１及び第２の電極が、正極性を有し、
前記第３の電極が、負極性を有し、
前記電極が、前記バスケットの遠位領域にわたってＲＦエネルギーを適用する、ように活性化する、請求項２６に記載のシステム。
【請求項３４】
前記バスケットが、前記治療用アセンブリが前記拡張状態にあるときに互いに半径方向に離間される少なくとも２つの分岐を備え、
各分岐が、互いに隣接して位置付けられた少なくとも第１の支柱及び第２の支柱を備え、前記第１の支柱が、その上に配設された第１の電極を有し、前記第２の支柱が、その上に配設された第２の電極を有し、前記第１及び第２の電極が、反対の極性を有し、前記第１の電極と第２の電極との間にＲＦエネルギーを適用するように構成される、請求項２６

に記載のシステム。
【請求項３５】
前記バスケットが、前記治療用アセンブリが前記拡張状態にあるときに互いに半径方向に離間される少なくとも２つの分岐を備え、
各分岐が、互いに隣接して位置付けられた少なくとも第１の支柱及び第２の支柱を備え、前記第１の支柱が、その上に配設された第１の電極を有し、前記第２の支柱が、その上に配設された第２の支柱を有し、
前記第１の分岐の前記第１及び第２の電極が、正極性を有するように構成され、
前記第２の分岐の前記第１及び第２の電極が、負極性を有するように構成され、
前記治療用アセンブリが、前記バスケットの周辺部分にわたって前記第１の分岐と第２の分岐との間にＲＦエネルギーを送達するように構成される、請求項２６に記載のシステム。
【請求項３６】
前記治療用アセンブリの近位に位置付けられた前記シャフトの前記遠位部分上に配設された戻り電極をさらに備え、
前記支柱上の前記電極が、正極性を有するように構成され、前記戻り電極が、負極性を有するように構成される、請求項２６に記載のシステム。
【請求項３７】
前記電極の少なくとも一部分が、前記標的部位においてインピーダンスを検出して、前記標的部位における神経の場所を決定するように構成される、請求項２６に記載のシステム。
【請求項３８】
前記支柱上の前記複数の電極が、第１の複数の電極であり、
前記治療用アセンブリが、
前記支柱内に配設された拡張可能なバルーンと、
前記拡張可能なバルーン上の第２の複数の電極と、をさらに備え、
前記拡張状態にあるときに、前記拡張可能なバルーンが、前記第２の複数の電極の少なくとも一部分を前記標的部位において組織と接触して定置して、前記標的部位における神経活動を検出する、請求項２６に記載のシステム。
【請求項３９】
前記治療用アセンブリに動作可能に接続されたＲＦ生成器をさらに備え、前記ＲＦ生成器が、命令を保有するコンピュータ可読媒体を有する制御装置を含み、該命令は、前記制御装置によって実行されるときに、前記治療用アセンブリに、前記標的部位に少なくとも近位のインピーダンスまたは温度のうちの少なくとも１つを検出させる、請求項２６に記載のシステム。
【請求項４０】
前記治療用アセンブリに動作可能に接続されたＲＦ生成器をさらに備え、前記ＲＦ生成器が、命令を保有するコンピュータ可読媒体を有する制御装置を含み、該命令は、前記制御装置によって実行されるときに、前記治療用アセンブリに、前記標的部位に所定のパターンでＲＦエネルギーを適用させる、請求項２６に記載のシステム。
【請求項４１】
ヒト患者の鼻領域における神経マッピング及び治療的神経調節のためのシステムであって、
近位部分及び遠位部分を有するシャフトであって、前記遠位部分を、前記ヒト患者の蝶口蓋孔の近位の標的部位に、腔内に配置するように構成されている、シャフトと、
前記シャフトの前記遠位部分における複数の電極であって、前記標的部位において前記副交感神経の場所を検出するように構成された、電極と、
前記シャフトの前記遠位部分における治療用アセンブリであって、前記標的部位において鼻粘膜を神経支配する節後副交感神経を治療的に調節するように構成されたエネルギー送達要素を備える、治療用アセンブリと、を備える、システム。

【請求項４２】
前記電極が、前記エネルギー送達要素を画定し、前記標的部位に無線周波数（ＲＦ）エネルギーを適用するように構成されている、請求項４１に記載のシステム。
【請求項４３】
前記電極が、前記標的部位における不均一組織の誘電特性を検出して、副交感神経の場所を特定するように構成されている、請求項４１に記載のシステム。
【請求項４４】
前記電極が、前記標的部位における不均一組織のインピーダンス特性を検出して、副交感神経の場所を特定するように構成されている、請求項４１に記載のシステム。
【請求項４５】
ヒト患者の鼻領域における神経を治療的に調節する方法であって、
治療用デバイスのシャフトの遠位部分における治療用アセンブリを、前記鼻領域内の標的部位への腔内で前進させる工程であって、前記標的部位が、蝶口蓋孔の近位の副孔またはミクロ孔のうちの少なくとも１つにわたって広がる副交感神経の近位である、前進させる工程と、
前記治療用アセンブリを用いて、前記標的部位に、鼻腔、鼻咽頭、または副鼻腔のうちの少なくとも１つの中の自律神経活動を治療的に調節するためのエネルギーを適用する工程と、を含む、方法。
【請求項４６】
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、前記治療用アセンブリを、蝶口蓋孔の下方の前記ヒト患者の口蓋骨に位置付ける工程を含む、請求項４５に記載の方法。
【請求項４７】
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、前記治療用アセンブリを、前記ヒト患者の鼻の入口を通り、下鼻道を通って前記標的部位へと腔内で前進させる工程を含む、請求項４５に記載の方法。
【請求項４８】
前記治療用アセンブリを前記標的部位に腔内で前進させる工程が、前記治療用アセンブリを、前記ヒト患者の鼻の入口を通り、中鼻道を通って前記標的部位へと腔内で前進させる工程を含む、請求項４５に記載の方法。
【請求項４９】
内視鏡を、前記ヒト患者の鼻の入口を通り、中鼻道を通って腔内で前進させて、前記標的部位において前記治療用アセンブリを視覚化する工程をさらに含む、請求項４５に記載の方法。
【請求項５０】
内視鏡を、前記ヒト患者の鼻の入口を通り、下鼻道を通って腔内で前進させて、前記標的部位において前記治療用アセンブリを視覚化する工程をさらに含む、請求項４５に記載の方法。
【請求項５１】
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、前記治療用アセンブリを、前記ヒト患者の鼻の入口を通り、下鼻道を通って前記標的部位へと腔内で前進させる工程を含み、
前記方法が、内視鏡を、前記ヒト患者の前記鼻の前記入口を通り、前記下鼻道を通って腔内で前進させて、前記標的部位において前記治療用アセンブリを視覚化する工程をさらに含む、請求項４５に記載の方法。
【請求項５２】
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、前記治療用アセンブリを、前記ヒト患者の鼻の入口を通り、中鼻道を通って前記標的部位へと腔内で前進させる工程を含み、
前記方法が、内視鏡を、前記ヒト患者の前記鼻の前記入口を通り、前記中鼻道を通って

腔内で前進させて、前記標的部位において前記治療用アセンブリを視覚化する工程をさらに含む、請求項４５に記載の方法。
【請求項５３】
内視鏡を、前記ヒト患者の鼻の入口を通り、下鼻道または中鼻道のうちの１つを通って、前記標的部位に少なくとも近位の領域に腔内で前進させる工程をさらに含み、
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、
前記シャフトの前記遠位部分を、前記内視鏡のチャネルを通り、向こう側へ前進させる工程と、
前記治療用アセンブリを、前記内視鏡の遠位部分における開口から外へ前進させる工程と、を含む、請求項４５に記載の方法。
【請求項５４】
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、前記シャフトの前記遠位部分を、前記ヒト患者の口及び中咽頭を通り、前記標的部位へ前進させる工程を含む、請求項４５に記載の方法。
【請求項５５】
赤外線（ＩＲ）分光法を介して前記標的部位を撮像して、前記標的部位に少なくとも近位の脈管系を視覚化する工程をさらに含む、請求項４５に記載の方法。
【請求項５６】
前記シャフトの前記遠位部分に沿って位置付けられた固定部材を、前記鼻領域の腔内で拡張する工程をさらに含み、前記固定部材が、前記シャフトの前記遠位部分を、前記標的部位に前記治療用アセンブリを展開するのに適切な位置に保持する、請求項４５に記載の方法。
【請求項５７】
前記標的部位が、第１の標的部位であり、エネルギーを前記標的部位に適用する工程が、エネルギーを前記第１の標的部位に適用する工程を含み、前記方法が、
前記治療用アセンブリを前記鼻領域内の第２の標的部位に再位置付けする工程と、
前記治療用アセンブリを用いて、前記第２の標的部位に、前記第２の標的部位の近位の副交感神経を治療的に調節するためのエネルギーを適用する工程と、をさらに含む、請求項４５に記載の方法。
【請求項５８】
エネルギーを適用する工程が、治療要素の複数の電極を介して、パルス状の無線周波数（ＲＦ）エネルギーを前記標的部位に適用する工程を含む、請求項４５に記載の方法。
【請求項５９】
前記標的部位においてインピーダンスを検出して、蝶口蓋孔の近位の副孔またはミクロ孔のうちの少なくとも１つにわたって広がる副交感神経の位置を特定する工程をさらに含む、請求項４５に記載の方法。
【請求項６０】
前記標的部位にエネルギーを適用する工程が、インピーダンス測定を介して特定された前記副交感神経の前記位置に対応する前記治療用アセンブリの個別の領域に、エネルギーを適用する工程を含む、請求項５９に記載の方法。
【請求項６１】
前記治療用アセンブリが、複数の電極を備え、前記標的部位にエネルギーを適用する工程が、個々の前記電極を独立して活性化する工程と、個々の前記電極の極性を選択して、前記治療用アセンブリの選択的領域にわたって治療的神経調節を適用する工程と、を含む、請求項４５に記載の方法。
【請求項６２】
前記標的部位にエネルギーを適用する工程が、前記治療用アセンブリの第１の半球部分内にエネルギーを適用する工程をさらに含み、前記治療用アセンブリが、前記治療用アセンブリの第２の半球部分にはエネルギーを適用しない、請求項６１に記載の方法。
【請求項６３】

前記治療用アセンブリが、複数の支柱であって前記支柱上に配設された複数電極を伴う複数の支柱、を有する拡張可能なバスケットを備え、
前記標的部位にエネルギーを適用する工程が、
前記複数の電極の第１の電極を、正極性を有するように活性化する工程と、
前記複数の電極の少なくとも第２の電極及び第３の電極を、負極性を有するように活性化する工程と、を含み、
第１、第２、及び第３の電極が、同時に活性化され、前記第２及び第３の電極が、最小抵抗の通路に基づいて前記第１の電極と連続的に対になって、前記バスケットの一領域にわたって治療的神経調節を連続的に適用する、請求項４５に記載の方法。
【請求項６４】
前記治療用アセンブリが、複数の支柱であって前記支柱上に配設された複数電極を伴う複数の支柱、を有する拡張可能なバスケットを備え、
前記標的部位にエネルギーを適用する工程が、
前記複数の電極の第１の電極を、正極性を有するように活性化する工程と、
前記複数の電極の少なくとも第２～第６の電極を、負極性を有するように活性化する工程と、を含み、
第１～第６の電極が、同時に活性化され、前記第２～第６の電極が、最小抵抗の通路に基づいて前記第１の電極と連続的に対になって、前記バスケットの一半球領域にわたって治療的神経調節を連続的に適用する、請求項４５に記載の方法。
【請求項６５】
前記治療用アセンブリが、複数の支柱であって前記支柱上に配設された複数電極を伴う複数の支柱と、内部支持部材であって前記内部支持部材の遠位端部部分に戻り電極を備える内部支持部材と、を有する拡張可能なバスケットを備え、
前記標的部位にエネルギーを適用する工程が、
前記支柱上の前記電極を、正極性を有するように活性化する工程と、
前記戻り電極を、負極性を有するように活性化する工程と、を含み、
前記電極が、前記バスケットの遠位領域にわたってＲＦエネルギーを適用する、請求項４５に記載の方法。
【請求項６６】
前記治療用アセンブリが、前記治療用アセンブリが拡張状態にあるときに互いに半径方向に離間される複数の分岐を有する拡張可能なバスケットを備え、
各分岐が、少なくとも２つの隣接した支柱であって各支柱上に位置付けられた電極を伴う支柱を備え、
前記標的部位にエネルギーを適用する工程が、
前記分岐のうちの少なくとも１つの隣接した支柱上の前記電極を、前記電極が反対の極性を有するように活性化する工程と、
前記隣接した支柱上の前記電極間にＲＦエネルギーを適用する工程と、を含む、請求項４５に記載の方法。
【請求項６７】
前記治療用アセンブリが、複数の電極を備え、
前記標的部位にエネルギーを適用する工程が、
前記治療用アセンブリの前記電極を、正極性を有するように活性化する工程と、
前記治療用アセンブリの近位の前記シャフトの前記遠位部分上に配設された戻り電極を活性化する工程であって、前記戻り電極が負極性を有する、活性化する工程と、を含み、
前記電極及び前記戻り電極を活性化する工程が、前記ヒト患者の鼻甲介にわたってＲＦエネルギーを適用する、請求項４５に記載の方法。
【請求項６８】
前記標的部位に自律神経活動を治療的に調節するためのエネルギーを適用する前に、複数の感知電極を介して、前記標的部位における神経活動を検出する工程と、
前記検出された神経活動に基づいて、前記標的部位における神経の場所をマッピングす

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る工程と、をさらに含み、
前記標的部位にエネルギーを適用する工程が、前記検出された神経の場所に基づく領域にエネルギーを選択的に適用する工程を含む、請求項４５に記載の方法。
【請求項６９】
神経活動を検出する前に、前記標的部位に非治療的神経性刺激を適用する工程をさらに含む、請求項６８に記載の方法。
【請求項７０】
前記標的部位にエネルギーを適用した後に、前記複数の感知電極を介して神経活動を検出して、前記エネルギーの適用が前記標的部位において神経を治療的に調節したかを判定する工程をさらに含む、請求項６８に記載の方法。
【請求項７１】
前記治療用アセンブリが、複数の電極を担持する可撓性膜を備え、
エネルギーを適用する前に、前記方法が、前記可撓性膜を前記標的部位において拡張して、前記電極の少なくとも一部分を前記標的部位において組織と接触して定置する工程を含み、
前記標的部位にエネルギーを適用する工程が、前記電極を介して前記標的部位にＲＦエネルギーを適用する工程を含む、請求項４５に記載の方法。
【請求項７２】
前記シャフトの前記遠位部分上に配設された複数の電極が前記標的部位において組織と接触して定置されるように、前記シャフトの前記遠位部分を低プロファイル送達状態から拡張状態に変形させる工程であって、前記シャフトの前記遠位部分が前記拡張状態において渦巻き／螺旋形状を有する、変形させる工程をさらに含み、
前記標的部位にエネルギーを適用する工程が、前記電極を介して前記標的部位にＲＦエネルギーを適用する工程を含む、請求項４５に記載の方法。
【請求項７３】
前記治療用アセンブリが、複数の電極を担持するバルーンを備え、
エネルギーを適用する前に、前記方法が、前記バルーンを前記標的部位において拡張して、前記電極の少なくとも一部分を前記標的部位において組織と接触して定置する工程をさらに含み、
前記標的部位にエネルギーを適用する工程が、前記電極を介して前記標的部位にＲＦエネルギーを適用する工程を含む、請求項４５に記載の方法。
【請求項７４】
前記標的部位にエネルギーを適用する工程が、
前記電極を選択的に活性化して、前記バルーンの周方向セグメントにわたって半径方向に電流を適用する工程をさらに含む、請求項７３に記載の方法。
【請求項７５】
前記標的部位にエネルギーを適用する工程が、
前記電極を選択的に活性化して、前記バルーンの長手方向領域にわたって長手方向に電流を適用する工程をさらに含む、請求項７３に記載の方法。
【請求項７６】
前記バルーンを拡張する工程が、前記バルーンを流体で充填する工程を含み、
前記バルーンが、エネルギー適用中に前記バルーンを通る前記流体の灌流を可能にする複数の穴を備える、請求項７３に記載の方法。
【請求項７７】
前記バルーンを拡張する工程が、前記バルーンを通して流体を循環させる工程を含み、
前記流体が、エネルギー適用中に前記電極を冷却する、請求項７３に記載の方法。
【請求項７８】
前記治療用アセンブリが、前記シャフトの前記遠位部分から遠位に延在する複数のバルーンと、前記複数のバルーン上に配設された複数の電極と、を備え、
エネルギーを適用する前に、前記方法が、前記複数のバルーンを前記標的部位において

独立して拡張して、前記電極の少なくとも一部分を前記標的部位において組織と接触して定置する工程をさらに含み、
前記標的部位にエネルギーを適用する工程が、前記電極を介して前記標的部位にＲＦエネルギーを適用する工程を含む、請求項４５に記載の方法。
【請求項７９】
前記標的部位にエネルギーを適用する工程が、
前記複数のバルーンを通って延在する内部支持部材上の戻り電極を活性化する工程と、
前記複数のバルーン上の前記電極の少なくとも一部分を活性化する工程と、をさらに含む、請求項７８に記載の方法。
【請求項８０】
エネルギー適用中に前記標的部位において組織の温度を測定する工程と、
閾値最大温度に到達したときに、エネルギー適用を終了させる工程と、をさらに含む、請求項４５に記載の方法。
【請求項８１】
所定の最大期間の後にエネルギー適用を終了させる工程をさらに含む、請求項４５に記載の方法。
【請求項８２】
エネルギー適用中に前記標的部位における組織のインピーダンスを検出する工程と、
閾値インピーダンス値に到達したときに、エネルギー適用を終了させる工程と、をさらに含む、請求項４５に記載の方法。
【請求項８３】
エネルギー適用前に前記標的部位における組織のインピーダンスを検出して、ベースラインインピーダンスを定義する工程と、
エネルギー適用中に前記標的部位における組織のインピーダンスを検出する工程と、
前記ベースラインインピーダンスからのインピーダンスの閾値変化に到達したときに、エネルギー適用を終了させる工程と、をさらに含む、請求項４５に記載の方法。
【請求項８４】
前記標的部位にエネルギーを適用する工程が、前記標的部位における組織に治療的極低温冷却を適用して、前記鼻腔、前記鼻咽頭、及び／または前記副鼻腔内の自律神経活動を治療的に調節する工程を含む、請求項４５に記載の方法。
【請求項８５】
前記標的部位にエネルギーを適用する工程が、
加熱された流体をバルーン内で循環させ、その結果、前記バルーンの外側表面が前記標的部位において組織と接触し、前記組織を加熱して、前記標的部位において自律神経活動を熱的に調節する工程を含む、請求項４５に記載の方法。
【請求項８６】
前記標的部位にエネルギーを適用する工程が、
バルーンを拡張して、その結果、前記バルーンの外側表面が前記標的部位において組織と接触する工程と、
前記バルーン内の加熱部材を加熱する工程と、を含み、
前記加熱部材からの熱が、前記流体へ及び前記バルーンに隣接した前記組織へと移動して、自律神経活動を熱的に調節する、請求項４５に記載の方法。
【請求項８７】
前記標的部位にエネルギーを適用する工程が、プラズマ場を生成して、前記標的部位における神経を治療的に調節する工程を含む、請求項４５に記載の方法。
【請求項８８】
前記標的部位にエネルギーを適用する工程が、粘膜下腺に信号を送るコリン作動性経路を治療的に調節する、請求項４５に記載の方法。
【請求項８９】
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、前記治療用アセン

ブリを、上鼻道、中鼻道、下鼻道、または翼口蓋窩のうちの少なくとも１つの中の副孔及び／またはミクロ孔を介して、前記鼻領域内への入口の副交感神経点へと腔内で前進させる工程を含む、請求項４５に記載の方法。

【請求項９０】

鼻領域における神経を治療的に調節する方法であって、

治療用デバイスのシャフトの遠位部分における治療用アセンブリを、鼻領域内の標的部位へと腔内で前進させる工程であって、前記標的部位が蝶口蓋孔の近位の副交感神経の近位である、前進させる工程と、

前記標的部位における前記副交感神経の場所を検出する工程と、

前記副交感神経の前記検出された場所に基づいて、前記治療用アセンブリを用いて前記標的部位にエネルギーを適用する工程であって、鼻腔、鼻咽頭、または副鼻腔のうちの少なくとも１つの中の自律神経活動を治療的に調節する、適用する工程と、を含む、方法。

【請求項９１】

前記標的部位における前記副交感神経の場所を検出する工程が、高解像度空間格子上で、前記鼻腔、前記鼻咽頭及び／または前記副鼻腔のうちの少なくとも１つの中の、不均一組織の誘電特性を測定する工程を含む、請求項９０に記載の方法。

【請求項９２】

前記標的部位における前記副交感神経の場所を検出する工程が、高解像度空間格子上で、前記鼻腔、前記鼻咽頭及び／または前記副鼻腔の中の、不均一組織のダイポール特性を測定する工程を含む、請求項９０に記載の方法。

【請求項９３】

前記標的部位における前記副交感神経の場所を検出する工程が、高解像度空間格子上で、前記鼻腔、前記鼻咽頭または前記副鼻腔のうちの少なくとも１つの中の、不均一組織のインピーダンスを検出する工程を含む、請求項９０に記載の方法。

【請求項９４】

ヒト患者の鼻領域における治療的神経調節のためのデバイスであって、

遠位部分を有する送達カテーテルであって、前記鼻領域内の標的部位に前記遠位部分を配置するように構成された、送達カテーテルと、

前記送達カテーテルの前記遠位部分における可撓性支持体と、

前記可撓性支持体によって担持される複数の電極と、を備え、

前記可撓性支持体が、前記標的部位における局所的生体構造の凹凸に適合して、前記電極の少なくとも一部分の電気的活性化のための局部的コンプライアンス及び連動を提供するように構成され、

前記電極が、前記電極と直接的または間接的に接触する粘膜及び粘膜下構造の副交感神経を治療的に調節するように構成されている、デバイス。

【請求項９５】

エネルギー送達後に前記可撓性支持体を再捕捉して、鼻腔から前記可撓性支持体を引き抜くことを可能にするように構成された制御可能な再捕捉機構をさらに備える、請求項９４に記載のデバイス。

【請求項９６】

前記標的部位が、蝶口蓋孔である、請求項９４に記載のデバイス。

【請求項９７】

前記電極が、正確で局在的なエネルギー送達のために、エネルギーの方向及び関連する消散を制御するように選択的に活性化されるように構成される、請求項９４に記載のデバイス。

【請求項９８】

ヒト患者の鼻領域における神経を治療的に調節する方法であって、

治療用デバイスのシャフトの遠位部分における治療用アセンブリを、前記鼻領域内の標的部位へと腔内で前進させる工程であって、前記標的部位が、前記ヒト患者の前頭洞、篩骨洞、蝶形骨洞、または上顎洞のうちの少なくとも１つの小孔に少なくとも近位である、

前進させる工程と、
前記治療用アセンブリを用いて、前記標的部位に、前記標的部位における副交感神経を治療的に調節するためのエネルギーを適用して、慢性副鼻腔炎を治療する工程と、を含む、方法。
【請求項９９】
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、前記治療用アセンブリを、前記前頭洞の前記小孔の近位に位置付ける工程を含み、
前記標的部位にエネルギーを適用する工程が、眼窩上神経、滑車上神経、前記眼窩上神経の分枝、前記滑車上神経の分枝、または前記前頭洞の粘膜を神経支配する他の副交感神経線維のうちの少なくとも１つにエネルギーを適用する工程を含む、請求項９８に記載の方法。
【請求項１００】
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、前記治療用アセンブリを、前記篩骨洞の前記小孔の近位に位置付ける工程を含み、
前記標的部位にエネルギーを適用する工程が、鼻毛様体神経の前篩骨分枝、前記鼻毛様体神経の後篩骨分枝、上顎神経、前記鼻毛様体神経の分枝、前記上顎神経の分枝、または前記篩骨洞の粘膜を神経支配する他の副交感神経線維のうちの少なくとも１つにエネルギーを適用する工程を含む、請求項９８に記載の方法。
【請求項１０１】
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、前記治療用アセンブリを、前記上顎洞の前記小孔の近位に位置付ける工程を含み、
前記標的部位にエネルギーを適用する工程が、上顎神経の眼窩下分枝、前記上顎神経の歯槽枝、または前記上顎洞の粘膜を神経支配する他の副交感神経線維のうちの少なくとも１つにエネルギーを適用する工程を含む、請求項９８に記載の方法。
【請求項１０２】
前記治療用アセンブリを前記標的部位へと腔内で前進させる工程が、前記治療用アセンブリを、前記蝶形骨洞の前記小孔の近位に位置付ける工程を含み、
前記標的部位にエネルギーを適用する工程が、視神経の後篩骨分枝、上顎神経、前記視神経の分枝、前記上顎神経の分枝、または前記蝶形骨洞の粘膜を神経支配する他の副交感神経線維のうちの少なくとも１つにエネルギーを適用する工程を含む、請求項９８に記載の方法。
【請求項１０３】
慢性副鼻腔炎の治療のための、ヒト患者の鼻領域における治療的神経調節のためのシステムであって、
近位部分及び遠位部分を有するシャフトであって、前記遠位部分を標的部位へと腔内に配置するように構成され、前記標的部位が前記ヒト患者の前頭洞、篩骨洞、蝶形骨洞または上顎洞のうちの少なくとも１つの小孔に少なくとも近位である、シャフトと、
前記シャフトの前記遠位部分における治療用アセンブリであって、前記前頭洞、前記篩骨洞、前記蝶形骨洞または前記上顎洞のうちの少なくとも１つの粘膜を神経支配する副交感神経を治療的に調節するように構成されたエネルギー送達要素を備える、治療用アセンブリと、を備える、システム。
【発明の詳細な説明】
【技術分野】
【０００１】
[関連出願の相互参照]
本出願は、その全体が本明細書に参照によって援用される、２０１５年５月１２日に出願された米国仮特許出願第６２／１６０，２８９号に対する優先権を主張する。
【０００２】
[技術分野]
本技術は、概して、患者の鼻領域内の、または患者の鼻領域に関連付けられる神経を治

療的調節するためのデバイス、システム、及び方法に関する。具体的には、本技術の種々の実施形態は、鼻炎及び他の兆候を治療するための治療的神経調節システム及び方法に関する。

【背景技術】

【０００３】

鼻副鼻腔炎は、鼻の粘膜の炎症として特徴付けられ、アレルギー性鼻炎、非アレルギー性鼻炎、慢性鼻炎、慢性副鼻腔炎、及び医学的耐性鼻炎を含む一群の状態を指す。鼻副鼻腔炎の症状としては、鼻詰まり、閉塞、鬱血、鼻汁（例えば、鼻漏及び／または後鼻漏）、顔面痛、顔面圧迫感、及び／または嗅覚の低減もしくは損失が挙げられる。アレルギー性鼻炎は、くしゃみ、水様性鼻漏、鼻の痒み、及び目の痒みまたは涙目等のさらなる症状を含み得る。重度の鼻炎は、合併する喘息の再燃、睡眠障害、及び日常活動の低下につながり得る。システムの間隔及び種類に応じて、鼻副鼻腔炎は、急性鼻副鼻腔炎、再発性鼻副鼻腔炎、鼻ポリープ（すなわち、鼻孔または洞の内側の軟らかい非癌性の増殖）を有する慢性鼻副鼻腔炎、及び鼻ポリープを伴わない慢性鼻副鼻腔炎の４つの亜型に含まれ得る。急性鼻副鼻腔炎とは、１２週間未満続く症状を指し、一方、慢性鼻副鼻腔炎（鼻ポリープを伴うまたは伴わない）とは、１２週間より長く続く症状を指す。再発性鼻副鼻腔炎とは、各エピソードの間に症状の消散を伴う、１２カ月の期間以内の４つの急性鼻副鼻腔炎のエピソードを指す。

【０００４】

鼻副鼻腔炎の多数の環境的及び生物学的原因が存在する。例えば、非アレルギー性鼻副鼻腔炎は、環境的刺激物（例えば、排蒸気、洗浄液、ラテックス、香料、埃等）、薬物（例えば、ＮＳＡＩＤ、経口避妊薬、ＡＣＥ阻害剤を含む血圧薬、抗鬱剤等）、食品（例えば、アルコール飲料、香辛料の入った食品等）、ホルモンの変化（例えば、妊娠及び月経）、及び／または鼻中隔湾曲によって引き起こされ得る。アレルギー性鼻炎の誘因としては、季節性アレルゲン（例えば、毎年同様の時期に起こる環境性アレルゲンへの曝露）、一年中発生する通年性アレルゲン（例えば、イエダニ、動物の鱗屑、黴等）、及び／または職業性アレルゲン（例えば、特定の化学物質、穀物、ラテックス等）への曝露が挙げられ得る。

【０００５】

鼻副鼻腔炎の治療は、鼻炎の誘因の全般的な回避、生理食塩水溶液による鼻洗浄、及び／または薬物療法を含み得る。鼻副鼻腔炎に処方される医薬品としては、例えば、経口Ｈ１抗ヒスタミン薬、局所用経鼻Ｈ１抗ヒスタミン薬、局所用鼻腔内コルチコステロイド、全身用グルココルチコイド、注射用コルチコステロイド、抗ロイコトリエン薬、経鼻もしくは経口充血緩和剤、局所用抗コリン薬、クロモグリカート、及び／または抗免疫グロブリンＥ療法が挙げられる。しかしながら、これらの医薬品は、限定された有効性（例えば、プラセボより１７％高いかそれ未満）、ならびに鎮静、刺激、味覚障害、咽頭通、鼻の乾燥、鼻出血（すなわち、鼻血）、及び／または頭痛等の望ましくない副作用を有する。舌下免疫療法（「ＳＬＩＴ」）を含む免疫療法もまた、患者を、アレルゲン抽出物の反復的投与によって特定のアレルゲンに対して脱感作させることによって、アレルギー性鼻炎を治療するために使用されている。しかしながら、免疫療法は、延長された投与期間（例えば、ＳＬＩＴでは３～５年間）を必要とし、注射の部位における痛み及び腫れ、皮膚の掻痒（すなわち、蕁麻疹）、血管性浮腫、喘息、ならびにアナフィラキシーを含む多数の副作用をもたらし得る。

【０００６】

外科的介入もまた、薬物療法耐性を持つ重度の鼻炎症状を有する患者を治療する試みにおいて用いられてきた。１９６０年代～１９８０年代には、翼状管内の副交感神経線維を切断して、鼻粘膜における副交感神経の緊張を減少させるために、外科手術が実施された。ビディアン神経切断術におけるより最近の試みは、くしゃみ及び鼻閉塞の症状の改善を含む他の付随的な利益を伴って、鼻漏の治療に５０～８８％有効であることが見出された。これらの症状の改善はまた、間質浮腫、好酸球性細胞浸潤、マスト細胞レベル、及び除

神経粘膜におけるヒスタミン濃度の低減による組織学的な粘膜の変化と相関していた。しかしながら、ビディアン神経切断術の臨床的及び組織学的有効性にも関わらず、ヴィディアン神経の切除は、主にその解剖学的及び自律神経的な選択性の欠失に関連付けられる死亡率のため、幅広い支持を得ることができなかった。例えば、神経切断術の部位は、涙腺への節前分泌促進性線維を含み、したがって、神経切断術はしばしば、涙の反射、すなわち流涙の損失をもたらしており、これは、重度の症例では視覚の損失を引き起こし得る。かかる不可逆的合併症のため、この技法は、早々に断念された。さらに、眼窩後方叢を通る節後翼口蓋線維の通路のため、標的末端器官（すなわち、鼻粘膜）に対するビディアン神経切断術の位置は、副髄膜動脈と共に進む自律神経叢及び耳神経節突起を介して再神経支配をもたらし得る。

【０００７】

ビディアン神経切断術に関連付けられる合併症は、概して自律神経除神経の非特異的な部位に起因する。その結果、外科医は近年、涙腺及び交感神経線維への二次的な傷害を回避しながら、神経切断術の部位をビディアン神経切断術と同じ生理学的効果を有し得る節後副交感神経枝に移行している。例えば、日本の外科医は、ヴィディアン神経のさらに下流にある節後神経経路である後鼻神経（「ＰＮＮ」）の切除と共に、経鼻的下鼻甲介粘膜下切除を実施している。（Ｋｏｂａｙａｓｈｉ Ｔ，Ｈｙｏｄｏ Ｍ，Ｎａｋａｍｕｒａ Ｋ，Ｋｏｍｏｂｕｃｈｉ Ｈ，Ｈｏｎｄａ Ｎ，Ｒｅｓｅｃｔｉｏｎ ｏｆ ｐｅｒｉｐｈｅｒａｌ ｂｒａｎｃｈ ｏｆ ｔｈｅ ｐｏｓｔｅｒｉｏｒ ｎａｓａｌ ｎｅｒｖｅ ｃｏｍｐａｒｅｄ ｔｏ ｃｏｎｖｅｎｔｉｏｎａｌ ｐｏｓｔｅｒｉｏｒ ｎｅｕｒｅｃｔｏｍｙ ｉｎ ｓｅｖｅｒｅ ａｌｌｅｒｇｉｃ ｒｈｉｎｉｔｉｓ．Ａｕｒｉｓ Ｎａｓｕｓ Ｌａｒｙｎｘ．２０１２年２月１５日；３９：５９３－５９６を参照。）ＰＮＮ神経切断術は、ＰＮＮが鼻領域に入ると考えられる蝶口蓋孔において実施される。これらの神経切断術は、所望の後鼻神経を特定するための優れた外科用マーカーがないため、非常に複雑で面倒であり、また所望の神経の場所が決定された場合であっても、神経は、周囲の脈管系（例えば、蝶口蓋動脈）から分離されなければならないため、神経の切除は、極めて困難である。

【０００８】

本技術の多数の態様は、以下の図面を参照してより良く理解され得る。図面内の構成要素は、必ずしも縮尺通りではない。その代わり、本技術の原理を明確に例証することに重点が置かれている。参照を容易にするために、本開示全体を通して、同一の参照番号は、同一または少なくとも概して類似もしくは相似の構成要素または特徴を特定するために使用され得る。

【図面の簡単な説明】

【０００９】

【図１Ａ】鼻の側壁の生体構造を例証する切り欠き側面図である。

【００１０】

【図１Ｂ】図１Ａの鼻の側壁の神経の拡大側面図である。

【００１１】

【図１Ｃ】左口蓋骨内のミクロ孔の幾何学を例証する左口蓋骨の正面図である。

【００１２】

【図２】本技術の実施形態に従って鼻領域内の神経を治療的に調節するための治療的神経調節システムの部分概略図である。

【００１３】

【図３Ａ】本技術の実施形態に従って治療的神経調節デバイスの遠位部分を鼻領域内の標的部位に送達するための種々のアプローチを例証する部分切り欠き側面図である。

【図３Ｂ】本技術の実施形態に従って治療的神経調節デバイスの遠位部分を鼻領域内の標的部位に送達するための種々のアプローチを例証する部分切り欠き側面図である。

【図３Ｃ】本技術の実施形態に従って治療的神経調節デバイスの遠位部分を鼻領域内の標的部位に送達するための種々のアプローチを例証する部分切り欠き側面図である。

【図３Ｄ】本技術の実施形態に従って治療的神経調節デバイスの遠位部分を鼻領域内の標的部位に送達するための種々のアプローチを例証する部分切り欠き側面図である。
【図３Ｅ】本技術の実施形態に従って治療的神経調節デバイスの遠位部分を鼻領域内の標的部位に送達するための種々のアプローチを例証する部分切り欠き側面図である。
【００１４】
【図４】本技術の実施形態に従って構成された治療的神経調節デバイスの遠位部分の等角図である。
【００１５】
【図５Ａ】本技術の実施形態に従う治療的神経調節のための治療的神経調節デバイスの電極構成の等角図である。
【図５Ｂ】本技術の実施形態に従う治療的神経調節のための治療的神経調節デバイスの電極構成の等角図である。
【図５Ｃ】本技術の実施形態に従う治療的神経調節のための治療的神経調節デバイスの電極構成の等角図である。
【図５Ｄ】本技術の実施形態に従う治療的神経調節のための治療的神経調節デバイスの電極構成の等角図である。
【図５Ｅ】本技術の実施形態に従う治療的神経調節のための治療的神経調節デバイスの電極構成の等角図である。
【図５Ｆ】本技術の実施形態に従う治療的神経調節のための治療的神経調節デバイスの電極構成の等角図である。
【図５Ｇ】本技術の実施形態に従う治療的神経調節のための治療的神経調節デバイスの電極構成の等角図である。
【００１６】
【図６Ａ】本技術の実施形態に従って構成された神経検出のための治療的神経調節デバイスの遠位部分における電極構成を例証する部分概略図である。
【図６Ｂ】本技術の実施形態に従って構成された神経検出のための治療的神経調節デバイスの遠位部分における電極構成を例証する部分概略図である。
【００１７】
【図７】温度に関する鼻組織の電気伝導率の閾値レベルを例証するグラフである。
【００１８】
【図８】本技術の実施形態に従って構成された治療的神経調節デバイスの遠位部分の等角図である。
【図９】本技術の実施形態に従って構成された治療的神経調節デバイスの遠位部分の等角図である。
【００１９】
【図１０Ａ】本技術の別の実施形態に従って構成された治療的神経調節デバイスの遠位部分の等角図である。
【図１０Ｂ】治療部位における図１０Ａの治療的神経調節デバイスを例証する等角図である。
【００２０】
【図１１Ａ】本技術のまた別の実施形態に従って構成された治療的神経調節デバイスの遠位部分を例証する等角図である。
【図１１Ｂ】本技術のまた別の実施形態に従って構成された治療的神経調節デバイスの遠位部分を例証する等角図である。
【図１１Ｃ】本技術のまた別の実施形態に従って構成された治療的神経調節デバイスの遠位部分を例証する等角図である。
【図１１Ｄ】本技術のまた別の実施形態に従って構成された治療的神経調節デバイスの遠位部分を例証する等角図である。
【００２１】
【図１２】本技術のさらなる実施形態に従って構成された治療的神経調節デバイスの遠位

部分の側面図である。
【００２２】
【図１３】本技術のまたさらなる実施形態に従って構成された治療的神経調節デバイスの遠位部分の側面図である。
【００２３】
【図１４】本技術の追加的実施形態に従って構成された治療的神経調節デバイスの遠位部分の等角側面図である。
【００２４】
【図１５】本技術の追加的実施形態に従って構成された治療的神経調節デバイスの遠位部分の等角側面図である。
【００２５】
【図１６】本技術の追加的実施形態に従って構成された治療的神経調節デバイスの遠位部分の側面断面図である。
【００２６】
【図１７】本技術の追加的実施形態に従って構成された治療的神経調節デバイスの遠位部分の側面断面図である。
【００２７】
【図１８】本技術の追加的実施形態に従って構成された治療的神経調節デバイスの遠位部分の側面断面図である。
【００２８】
【図１９】本技術の追加的実施形態に従って構成された治療的神経調節デバイスの遠位部分の側面図である。
【００２９】
【図２０】本技術の実施形態に従って構成された治療的神経調節デバイスのための、鼻洞の小孔の近位の標的部位を例証する部分切り欠き側面図である。
【発明を実施するための形態】
【００３０】
本技術は、概して、治療的鼻神経調節のためのデバイスならびに関連するシステム及び方法に関する。開示されるデバイスは、正確で局在的な非侵襲的なエネルギー適用を提供して、鼻領域内の副交感神経の運動感覚機能を乱すように構成される。本技術のいくつかの実施形態の特定の詳細が、図１Ａ～２０を参照して本明細書に説明される。実施形態の多くは、鼻炎の治療のために鼻領域内の神経を治療的に調節するためのデバイス、システム、及び方法に関して説明されているが、本明細書に説明されるものに加えて、他の用途及び他の実施形態が、本技術の範囲内である。例えば、本技術の少なくともいくつかの実施形態は、慢性副鼻腔炎及び鼻出血の治療等の他の兆候の治療に有用であり得る。本明細書に説明されるものに加えて、他の実施形態が本技術の範囲内であることに留意されるべきである。さらに、本技術の実施形態は、本明細書に図示または説明されるもの以外の異なる構成、構成要素、及び／または手順を有し得る。さらに、当業者は、本技術の実施形態は、本明細書に図示または説明されるものに加えて構成、構成要素、及び／または手順を有し得ること、またこれら及び他の実施形態は、本技術から逸脱することなく、本明細書に図示または説明される構成、構成要素、及び／または手順のうちのいくつかを伴わなくてもよいことを理解するであろう。
【００３１】
この説明内の「遠位」及び「近位」という用語に関して、別段に指定のない限り、これらの用語は、操作者及び／または鼻腔内の場所に対する治療的神経調節デバイス及び／または関連する送達デバイスの部分の位置に言及し得る。例えば、本明細書に説明される種々の人口弁デバイスを送達する及び位置付けるのに好適な送達カテーテルに関して、「近位」は、デバイスの操作者または患者の鼻孔の入口点の接近点により近い位置を指すことができ、「遠位」は、デバイスの操作者からより離れた、または患者の鼻孔の入口の接近点からより遠い位置を指すことができる。それに加えて、後、前、下、及び上は、標準的

な医学用語に従って使用される。

【００３２】

本明細書で使用されるとき、神経の「治療的調節」及び「治療的神経調節」という用語は、神経の部分的または完全な切除を含む、神経活動の部分的または完全な無能化または他の効果的な混乱を指す。例えば、療的神経調節は、神経線維に沿って神経の伝達を部分的または完全に阻害、低減、及び／または遮断することを含み得る。

【００３３】

鼻腔の生体構造

図１Ａは、鼻の側壁の生体構造を例証する切り欠き側面図であり、図１Ｂは、図１Ａの鼻の側壁の神経の拡大側面図である。蝶口蓋孔（「ＳＰＦ」、図１Ａ）は、口蓋骨及び蝶形骨によって画定される開口または導管であり、それを通って蝶口蓋血管及び後上鼻神経が鼻腔内に進む。より具体的には、口蓋骨の垂直板の眼窩及び蝶形骨突起は、蝶口蓋切痕を画定し、これは、蝶形骨体の表面との関節によってＳＰＦに変換される。

【００３４】

ＳＰＦの場所は、側方鼻腔の後領域内で極めて変動的であり、これは、ＳＰＦの場所を視覚的に決定することを困難にする。典型的には、ＳＰＦは中鼻道（「ＭＭ」、図１Ａ）内に配置されるが、しかしながら、解剖学的変異はまた、上鼻道（「ＳＭ」、図１Ａ）内または上鼻道及び中鼻道の遷移部に配置されたＳＰＦをもたらす。特定の個体では、例えば、ＳＰＦの下縁は、下鼻甲介（「ＩＴ」、図１Ａ）の水平薄板の約１３ｍｍ上にある口蓋骨の水平板（すなわち、鼻底（ｎａｓａｌ　ｓｉｌｌ））の約１９ｍｍ上にあると測定されており、鼻底からＳＰＦまでの平均距離は、約６４．４ｍｍであり、その結果、鼻底からＳＰＡまでのアプローチの角度は約１１．４°となる。しかしながら、ＳＰＦの正確な場所を測定するための研究は、その場所の高い変動により、実践的用途が限定されている。

【００３５】

ＳＰＦの解剖学的変異は、鼻腔内へ横断する自律神経及び血管経路の変化に対応すると予測される。概して、後鼻神経（外側後上鼻神経とも称される）は、翼口蓋神経節（「ＰＰＧ」、蝶口蓋神経節とも称される、図１Ａ）から分岐し、ＳＰＦを通って鼻腔の鼻の側壁に入り、蝶口蓋動脈は、翼口蓋窩から鼻の側壁上のＳＰＦを通ると考えられる。蝶口蓋動脈は、後外側鼻枝及び後中隔枝の２つの主要部分に分岐する。後外側鼻動脈の主要な分枝は、下鼻甲介ＩＴ内へ下方に（例えば、下鼻甲介ＩＴの後端から約１．０ｍｍ～１．５ｍｍ）進み、別の分枝は、中鼻甲介ＭＴに入り、前方及び後方に分岐する。

【００３６】

ＳＰＦの先では、ヒト患者の３０％超が、鼻腔内への動脈及び神経も運ぶ１つ以上の副孔を有することが研究によって示されている。副フォラメナ（ｆｏｒａｍｅｎａ）は、典型的にはＳＰＦより小さく、ＳＰＦの下方に位置付けられる。例えば、対応する副孔を通って延在する後鼻動脈及び後鼻神経の１、２、３つ以上の分枝が存在し得る。副孔ならびに副孔を通って進む関連する分岐動脈及び神経に関連付けられる場所、サイズ、及び量の変動は、蝶口蓋領域の脈管系及び神経の位置に関する多大の不確実さを生じさせる。さらに、ＳＰＦから延在する神経の生体構造は、神経及び動脈経路を運ぶ深い下及び／または上溝を含むことが多く、これは、動脈及び神経分枝の場所を決定することを困難にする。例えば、溝は、５ｍｍ超の長さ、２ｍｍ超の幅、及び１ｍｍ超の深さに延在し、それによって、動脈及び神経の両方を運ぶのに十分な通路を作成し得る。蝶口蓋領域内の溝及び副孔によって引き起こされる変動は、外科医にとって、動脈及び（動脈の後方に位置する）神経の場所を決定し、それらへ接近することを極めて困難にする。

【００３７】

近年の翼口蓋窩（ＰＰＦ）の微小解剖学的切開は、ＳＰＦの周囲の領域の非常に変動的な生体構造をさらに証明しており、翼口蓋神経節（「ＰＰＧ」、図１）から突出する多数の遠心性枝が、個々の節後自律神経（例えば、後鼻神経）というよりもむしろ多数の小神経束群を介して眼窩及び鼻粘膜を神経支配することを示している。研究は、ヒトの少なく

とも８７％が口蓋骨内にミクロ孔及びミクロ枝を有することを示している。例えば、図１Ｃは、左口蓋骨内のミクロ孔及びミクロ枝の幾何学を例証する左口蓋骨の正面図である。図１Ｃでは、塗りつぶされた領域は、口蓋骨を直接通って横断する神経を表し、白丸は、個別のミクロ孔に関連付けられていた神経を表す。実際、図１Ｃは、口蓋骨の中央部分が少なくとも２５の副後外側神経を含み得ることを例証している。

【００３８】

鼻腔粘膜の呼吸部分は、基底膜を有する線毛多列円柱上皮の一種からなる。鼻分泌物（例えば、粘液）は、胚細胞、粘膜下腺、及び血漿からの浸出液によって分泌される。鼻の混合腺及び血管は、ビディアン神経及び他の神経に由来する副交感神経支配によって高度に調整される。アセチルコリン及び血管作動性腸管ペプチドを通じた副交感神経（コリン作動性）刺激は、概して、粘液の産生をもたらす。したがって、粘膜の副交感神経支配は、粘膜下腺の活性化／過剰活性化、静脈充血（例えば、鬱血）、及び鼻の内側の血管への増加された血流に主に関与する。したがって、粘膜を神経支配する副交感神経経路の切断または調節は、鼻副鼻腔炎及び他の兆候に関連付けられる症状を引き起こす粘膜下腺の過剰活性化及び血管の充血を低減または排除することが予測される。

【００３９】

上述の通り、鼻粘膜を神経支配する節後副交感神経線維（すなわち、後上鼻神経）は、専ら、蝶口蓋神経血管束としてＳＰＦを通って進むと考えられた。後鼻神経は、上鼻甲介ＳＴ及び中鼻甲介ＭＴ（すなわち、鼻甲介（ｎａｓａｌ　ｃｈｏｎｃｈｅａ））の粘膜を通り鼻中隔へ延在する多数のより小さい内側枝及び側枝を介して鼻腔を神経支配する、上顎神経の分枝である。鼻口蓋神経は概して、内側後上鼻神経の最大のものである。それは、鋤骨上の溝内を鼻腔の底部へと前下方に通過する。ここから、それは、硬口蓋の切歯窩を通過し、より大きい口蓋神経と連絡して、硬口蓋の粘膜を供給する。後上鼻神経は、接合することなく翼口蓋神経節ＰＰＧを通り、上顎神経上をその神経節枝を介して通過する。

【００４０】

後鼻神経は専らＳＰＦを横断して鼻粘膜を神経支配するという理解に基づき、外科手術は、後鼻神経を、それがＳＰＦから出るときに選択的に切断するように実施されてきた。しかしながら、上述の通り、副鼻腔の副交感神経経路は、実際には、翼口蓋神経節（ＰＰＧ）から突出し、ＳＰＦを通って延在する単一の分枝ではなく複数の小神経束（すなわち、副後外側神経）を介して鼻粘膜を神経支配する個々の枝を含む。これらの枝は、口蓋骨全体の複数の亀裂、副孔、及びミクロ孔を通じて伝達され、ＳＰＦ及び他の副神経の両方を伴う吻合輪を実証し得る。したがって、ＳＰＦを横断する副交感神経のみが切断される場合、ほぼ全ての患者（例えば、９０％以上の患者）が、後外側粘膜に対して無傷の副分泌促進性線維を保持し、これは、神経切断術が信じるように意図されていた症状の持続をもたらすことになる。

【００４１】

したがって、本技術の実施形態は、口蓋骨全体の亀裂、副孔、及びミクロ孔を通って延在する枝の部位に対応する正確で集中した治療部位（例えば、図１Ｂに示される標的領域Ｔ）において、神経を治療的に調節するように構成される。特定の実施形態では、標的化される神経は、鼻粘膜を神経支配するように進む節後副交感神経である。この選択的な神経治療はまた、臨床医が、眼窩枝（ｒａｍｉ　ｏｒｂｉｔｏｎａｓａｌｉｓ）の慎重な回避を通じて前部の除神経の程度を漸増することを可能にするため、術後の鼻の痂皮形成及び乾燥の率を減少させることが予測される。さらに、本技術の実施形態はまた、深錐体神経及び内部上顎細動脈周囲叢（ｉｎｔｅｒｎａｌ　ｍａｘｉｌｌａｒｙ　ｐｅｒｉａｒｔｅｒｉｏｌａｒ　ｐｌｅｘｉ）からの交感神経の寄与の一部を保存することによって、少なくともいくつかの交感神経の緊張を維持し、鼻閉塞に関する改善された結果を導くことも予測される。それに加えて、本技術の実施形態は、全ての吻合輪の完全な切除を提供し、それによって長期的な再神経支配の速度を低減するために、多数の副交感神経の鼻領域への進入場所（例えば、副孔、亀裂、及びミクロ孔）を標的化するように構成される。

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【００４２】
治療的鼻神経調節及び神経マッピングのためのシステムの選択された実施形態
図２は、本技術の実施形態に従って鼻領域内の神経を治療的に調節するための治療的神経調節システム２００（「システム２００」）の部分概略図である。システム２００は、治療的神経調節カテーテルまたはデバイス２０２、コンソール２０４、及びそれらの間に延在するケーブル２０６を含む。治療的神経調節デバイス２０２は、近位部分２０８ａ、遠位部分２０８ｂを有するシャフト２０８と、シャフト２０８の近位部分２０８ａにおけるハンドル２１０と、シャフト２０８の遠位部分２０８ｂにおける治療用アセンブリまたは要素２１２とを含む。シャフト２０８は、鼻粘膜を神経支配する節後副交感神経の近位の鼻領域内の治療または標的部位に、遠位部分２０８ｂを腔内に配置するように構成される。標的部位は、標的神経が配置される領域、体積、または面積であってもよく、患者の生体構造に応じて異なるサイズ及び形状であってもよい。例えば、標的部位は、ＳＰＦの下方の３ｃｍの面積であってもよい。他の実施形態では、標的部位は、所望の神経線維を標的化するために、より大きくても、より小さくても、及び／または鼻腔内の他の場所に配置されてもよい。治療用アセンブリ２１２は、節後副交感神経を治療的に調節するように構成された少なくとも１つのエネルギー送達要素２１４を含み得る。特定の実施形態では、例えば、治療用アセンブリ２１２は、口蓋骨のＳＰＦ、副孔、及びミクロ孔を横断する副交感神経（例えば、後鼻神経）等の、翼口蓋神経節から分岐し、鼻領域及び鼻粘膜を神経支配する節後副交感神経を治療的に調節し得る。
【００４３】
図２に示される通り、治療用アセンブリ２１２は、標的部位に治療的神経調節を提供するように構成された少なくとも１つのエネルギー送達要素２１４を含む。特定の実施形態では、例えば、エネルギー送達要素２１４は、電磁気神経調節エネルギー（例えば、ＲＦエネルギー）を標的部位に適用するように構成された１つ以上の電極を含み得る。他の実施形態では、エネルギー送達要素２１４は、例えば、凍結治療的冷却、超音波エネルギー（例えば、高強度焦点式超音波（「ＨＩＦＵ」）エネルギー）、マイクロ波エネルギー（例えば、マイクロ波アンテナを介して）、直接加熱、高及び／もしくは低出力レーザーエネルギー、機械的振動、ならびに／または光パワー等の種々の他のモダリティーを使用して、治療的神経調節を提供するように構成され得る。さらなる実施形態では、治療用アセンブリ２１２は、標的部位に化学物質または薬物を送達して、標的神経を化学的に切除または閉塞するように構成され得る。例えば、治療用アセンブリ２１２は、シャフト２０８の接近部分及び／または別個の導入器を通って延在する針アプリケータを含み得、該針アプリケータは、標的神経を治療的に調節するために、例えば、ボトックス、アルコール、グアネチジン、エタノール、フェノール、神経毒、または神経を変質させる、損傷する、または乱す別の好適な薬剤等の化学物質を標的部位に注入するように構成され得る。
【００４４】
特定の実施形態では、治療用アセンブリ２１２は、例えば、１つ以上の温度センサ（例えば、熱電対、サーミスタ等）、インピーダンスセンサ、及び／または他のセンサ等の１つ以上のセンサ（図示せず）を含み得る。センサ（複数可）及び／またはエネルギー送達要素２１４は、信号をセンサ（複数可）に、及び／もしくはセンサ（複数可）から送信する、ならびに／またはエネルギー送達要素２１４にエネルギーを伝えるために、シャフト２０８を通って延在する１つ以上のワイヤ（図示せず、例えば、銅線）に接続され得る。
【００４５】
治療的神経調節デバイス２０２は、有線接続（例えば、ケーブル２０６を介して）及び／または無線接続を介してコンソール２０４に動作的に連結され得る。コンソール２０４は、治療的神経調節デバイス２０２の動作を制御、監視、供給、及び／または別の方法で支持するように構成され得る。コンソール２０４は、治療用アセンブリ２１２を介した標的部位における組織または神経への送達のために、選択された形態及び／または規模のエネルギーを生成するようにさらに構成され得、したがって、コンソール２０４は、治療的神経調節デバイス２０２の治療モダリティに応じて異なる構成を有してもよい。例えば、

治療的神経調節デバイス２０２が、電極ベース、熱要素ベース、及び／またはトンランスデューサベース治療用に構成されるとき、コンソール２０４は、ＲＦエネルギー（例えば、単極性、双極性、または多極性ＲＦエネルギー）、パルス状電気エネルギー、マイクロ波エネルギー、光エネルギー、超音波エネルギー（例えば、腔内に送達される超音波及び／またはＨＩＦＵ）、直接熱エネルギー、放射線（例えば、赤外線、可視線、及び／またはガンマ線、及び／または別の好適な種類のエネルギーを生成するように構成されたエネルギー生成器２１６を含み得る。治療的神経調節デバイス２０２が凍結治療的治療用に構成される場合、コンソール２０４は、冷却剤貯留容器（図示せず）を含み得、治療的神経調節デバイス２０２に冷却剤を供給するように構成され得る。同様に、治療的神経調節デバイス２０２が化学物質ベース治療（例えば、薬物注入）用に構成される場合、コンソール２０４は、化学物質貯留容器（図示せず）を含み得、治療的神経調節デバイス２０２に１つ以上の化学物質を供給するように構成され得る。

【００４６】

図２にさらに示される通り、システム２００は、治療的神経調節デバイス２０２に通信可能に連結された制御装置２１８をさらに含み得る。例証される実施形態では、制御装置２１８は、コンソール２０４内に収容される。他の実施形態では、制御装置２１８は、治療的神経調節デバイス２０２のハンドル２１０、ケーブル２０６、独立した構成要素、及び／またはシステム２００の別の部分によって担持され得る。制御装置２１８は、治療的神経調節デバイス２０２の１つ以上の構成要素（例えば、エネルギー送達要素２１４）の動作を、直接及び／またはコンソール２０４を介して、開始、終了、及び／または調整するように構成され得る。制御装置２１８は、自動制御アルゴリズムを実行する、及び／または操作者（例えば、臨床医）からの制御命令を受信するように構成され得る。例えば、制御装置２１８及び／またはコンソール２０４の他の構成要素（例えば、メモリ）は、命令を保有するコンピュータ可読媒体を含み得、該命令は、制御装置２１８によって実行されるときに、治療用アセンブリ２０２に、特定の機能を実施させる（例えば、特定の様式でエネルギーを適用する、インピーダンスを検出する、温度を検出する、神経の場所または解剖学的構造を検出する等）。メモリは、揮発性及び不揮発性記憶装置用の種々のハードウェアデバイスのうちの１つ以上を含み、読み取り専用メモリ及び書き込み可能メモリの両方を含み得る。例えば、メモリは、ランダムアクセスメモリ（ＲＡＭ）、ＣＰＵレジスタ、読み取り専用メモリ（ＲＯＭ）、及びフラッシュメモリ、ハードドライブ、フロッピーディスク、ＣＤ、ＤＶＤ、磁気記憶デバイス、テープドライブ、デバイスバッファ等の書き込み可能な不揮発性メモリを含み得る。メモリは、基礎的なハードウェアから分離される信号を伝搬しておらず、したがって、メモリは非一時的である。

【００４７】

さらに、コンソール２０４は、評価／フィードバックアルゴリズム２２０を介して、治療処置の前、間、及び／または後に操作者にフィードバックを提供するように構成され得る。例えば、評価／フィードバックアルゴリズム２２０は、治療部位における組織の温度、治療部位における神経の場所、及び／または治療部位における神経に対する治療的神経調節の効果に関連付けられる情報を提供するように構成され得る。特定の実施形態では、評価／フィードバックアルゴリズム２２０は、治療の有効性を確認する、及び／またはシステム２００の所望の性能を強化するための特徴を含み得る。例えば、評価／フィードバックアルゴリズム２２０は、制御装置２１８と併せて、療法中の治療部位の温度を監視して、温度が所定の最大値（例えば、ＲＦエネルギーの適用時）または所定の最小値（例えば、凍結療法の適用時）に到達したときに、エネルギー送達を自動的に止めるように構成され得る。他の実施形態では、評価／フィードバックアルゴリズム２２０は、制御装置２１８と併せて、所定の最大時間、標的化された組織の所定の最大インピーダンス上昇（すなわち、ベースラインインピーダンス測定と比較して）、標的化された組織の所定の最大インピーダンス）、及び／または自律神経機能に関連付けられるバイオマーカーの他の閾値の後に、治療を自動的に終了させるように構成され得る。システム２００の動作に関連付けられるこの及び他の情報は、コンソール２０４上のディスプレイ２２２（例えば、モ

ニタまたはタッチスクリーン）及び／またはコンソール２０４に通信可能に連結された別個のディスプレイ（図示せず）を介して、操作者に通信され得る。

【００４８】

種々の実施形態では、治療用アセンブリ２１２及び／またはシステム２００の他の部分は、標的部位における不均一組織の種々のパラメータを検出して、標的部位における生体構造（例えば、組織の種類、組織の場所、脈管系、骨構造、孔、洞等）を決定し、神経及び／または他の構造の場所を決定し、神経マッピングを可能にするように構成され得る。例えば、治療用アセンブリ２１２は、インピーダンス、誘電特性、温度、及び／または標的領域内の神経線維の存在を示唆する他の特性を検出するように構成され得る。図２に示される通り、コンソール２０４は、治療用アセンブリ２１２によって取得される標的部位における組織の検出された電気的及び／または熱的測定を受信する神経監視アセンブリ２２１（概略的に示される）を含み、この情報を処理して、標的部位における神経の存在、神経の場所、及び／または神経活動を特定し得る。この情報は次に、（例えば、ディスプレイ２２２上の）高解像度空間格子及び／または他の種類のディスプレイを介して操作者に通信され得る。神経監視アセンブリ２２１は、ケーブル２０６を通り、シャフト２０８の長さを通って延在する信号ワイヤ（例えば、銅線）を介して、エネルギー送達要素２１４及び／または治療用アセンブリ２１２の他の特徴に動作可能に連結され得る。他の実施形態では、治療用アセンブリ２１２は、他の好適な通信手段を使用して神経監視アセンブリ２２１に通信可能に連結され得る。

【００４９】

神経監視アセンブリ２２１は、治療的神経調節の前に神経の場所及び活性を決定して、所望の神経の位置に対応する正確な治療領域を決定する、治療中に治療的神経調節の効果を決定する、ならびに／または治療後に治療的神経調節が標的神経を所望の程度に治療したかを評価することができる。この情報は、標的部位が神経調節に好適であるか等、標的部位に近位の神経に関する種々の決定を行うために使用され得る。それに加えて、神経監視アセンブリ２２１はまた、治療的神経調節の前及び後の検出された神経の場所及び／または活性を比較し、神経活動の変化を所定の閾値と比較して、治療的神経調節の適用が治療部位にわたって有効であったかを評定し得る。例えば、神経監視アセンブリ２２１は、治療的神経調節の前及び後に治療用アセンブリ２１２によって取得されるニューロンの電気的活性の記録に基づいて、神経電気記録図（ＥＮＧ）信号を決定し得る。神経調節後に取得される統計的に有意な（例えば、測定可能なまたは顕著な）ＥＮＧ信号（複数可）の減少は、神経が十分に切除されたことの指標の役割を果たし得る。

【００５０】

システム２００は、シャフト２０８の少なくとも一部分とシャフトの遠位部分２０８ｂにおけるポート２２６とに沿って延在し、ポート２２６と連通するチャネル２２４をさらに含み得る。特定の実施形態では、チャネル２２４は、ポート２２６を介してシャフト２０８の遠位部分２０８ｂに流体を送達するための流体経路である。例えば、チャネル２２４は、生理食塩水溶液または他の流体を送達して、治療用アセンブリ２１２の送達中に腔内の鼻経路を濯ぐ、標的部位への治療的神経調節の適用前に標的部位を洗い流す、及び／またはエネルギー送達中に流体を標的部位に送達して、エネルギー送達要素２１４に隣接した組織の加熱もしくは冷却を低減することができる。他の実施形態では、チャネル２２４は、治療部位への薬物の送達を可能にする。例えば、針（図示せず）は、神経ブロック、局所麻酔薬、及び／または他の薬理学的薬剤を標的部位における組織に注入するか、さもなくば送達するために、ポート２２６を取って突出し得る。

【００５１】

治療的神経調節デバイス２０２は、鼻腔内の自律神経活動を治療的に調節するために、例えば、鼻腔内への副交感神経線維の周辺入口等において、鼻領域内の奥深くの標的部位への接近を提供する。特定の実施形態では、例えば、治療的神経調節デバイス２０２は、治療用アセンブリ２１２を、接近用の孔（ａｃｃｅｓｓ　ｆｏｒａｍｅｎ）及び／またはミクロ孔の部位においてＳＰＦの下方に位置付け得る（例えば、図１Ｂ及び１Ｃに示され

る通り）。鼻の入口の外側からシャフト２０８の近位部分２０８ａを操作することによって、臨床医は、シャフト２０８を、入り組んだ腔内路を通し、鼻腔を通して前進させて、ハンドル２１０を介してシャフト２０８の遠位部分２０８ｂを遠隔操作して、治療用アセンブリ２１２を標的部位に位置付けてもよい。特定の実施形態では、シャフト２０８は、臨床医が入り組んだ鼻の生体構造を通って進むことを可能にする小さい曲げ半径（例えば、５ｍｍの曲げ半径、４ｍｍの曲げ半径、３ｍｍの曲げ半径、またはそれ未満）有する操縦可能なデバイス（例えば、操縦可能なカテーテル）であり得る。操縦可能なシャフトは、少なくとも２つの異なる方向に関節運動するようにさらに構成され得る。例えば、操縦可能なシャフト２０８は、臨床医が、シャフト２０８の遠位部分２０８ｂを鼻領域の生体構造に対応するように「Ｓ」字型に形成することを可能にする、二重の引きワイヤリングを含み得る。他の実施形態では、関節運動シャフト２０８は、実質的に剛性の材料（例えば、金属材料）から作製され、偏向に耐えるが、依然小さい曲げ半径（例えば、５ｍｍの曲げ半径、４ｍｍの曲げ半径、３ｍｍ曲げ半径、またはそれ未満）を可能にするシャフト２０８の遠位部分２０８ｂにおける剛性リンクを含み得る。さらなる実施形態では、操縦可能なシャフト２０８は、金属及び／または他の好適な材料から作製されるレーザー切断された管であってもよい。レーザー切断された管は、臨床医が、入り組んだ鼻の生体構造を標的部位まで進むようにシャフト２０８の遠位部分２０８ｂを偏向させることを可能するために、臨床医によって動作される１つ以上の引きワイヤを含み得る。

【００５２】

種々の実施形態では、シャフト２０８の遠位部分２０８ｂは、オーバー・ザ・ワイヤ（ＯＴＷ）または迅速交換（ＲＸ）技法を使用して、ガイドワイヤ（図示せず）を介して標的部位における適切な位置に誘導される。例えば、治療用アセンブリ２１２の遠位端部は、ガイドワイヤに係合するチャネルを含み得る。治療用アセンブリ２１２の腔内送達は、ガイドワイヤを鼻腔と連通するｏｒｉｆｉｃｅ（例えば、鼻孔または口）に挿入することと、治療用アセンブリ２１２が標的部位（例えば、ＳＰＦの下方）に到達するまでシャフト２０８及び／または治療用アセンブリ２１２をガイドワイヤに沿って移動させることとを含み得る。

【００５３】

さらなる実施形態では、治療的神経調節デバイス２０２は、ガイドワイヤの使用を伴うまたは伴わない、ガイドカテーテルまたは導入器鞘（図示せず）を介した送達のために構成され得る。まず、導入器鞘が、鼻領域内の標的部位に腔内に挿入され得、次に、シャフト２０８の遠位部分２０８ｂが、導入器鞘を通して挿入され得る。標的部位において、治療用アセンブリ２１２は、導入器鞘の遠位端部開口または導入器鞘の側部ポートを通して展開され得る。特定の実施形態では、導入器鞘は、真っ直ぐな部分と、腔内で展開されて、標的部位に接近し得る固定の湾曲（例えば、５ｍｍの湾曲、４ｍｍの湾曲、３ｍｍの湾曲等）を有する予め成形された部分とを含み得る。この実施形態では、導入器鞘は、それを通して治療用アセンブリ２１２が展開され得る予め成形された湾曲部分の近位に、またはそれに沿って、側部ポートを有してもよい。他の実施形態では、導入器鞘は、絶縁性または誘電性材料で被覆された金属材料等の剛性材料から作製されてもよい。この実施形態では、導入器鞘は、実質的に真っ直ぐであり、例えば、中鼻道ＭＭ（図１Ａ）を通る等、実質的に真っ直ぐな経路を介して標的部位に治療用アセンブリ２１２を送達するために使用されてもよい。

【００５４】

臨床医がシャフト２０８の遠位部分２０８ｂ及び治療用アセンブリ２１２を位置付ける及び操作するのを助けるために、画像誘導が使用されてもよい。例えば、図３Ａ～３Ｅに関して下記にさらに詳細に説明される通り、内視鏡（図示せず）が、標的部位、標的部位における治療用アセンブリ２１２の位置付け、及び／または治療的神経調節中の治療用アセンブリ２１２を視覚化するために位置付けられ得る。特定の実施形態では、シャフト２０８の遠位部分２０８ｂは、内視鏡を通って延在する作業チャネルを介して送達され、したがって、内視鏡は、標的部位及び治療用アセンブリ２１２の直接的な直列の視覚化を提

供し得る。他の実施形態では、内視鏡は、治療用アセンブリ２１２及び／またはシャフト２０８の遠位部分２０８ｂと共に組み込まれて、アセンブリ２１２及び／または周囲の鼻の生体構造の直列の視覚化を提供する。またさらなる実施形態では、画像誘導は、脈管系及び／もしくは他の解剖学的構造を視覚化するための赤外線（ＩＲ）スペクトル内の画像フィルタリング、コンピュータ断層撮影（ＣＴ）、蛍光透視法、超音波、光コヒーレンス断層撮影（ＯＣＴ）、ならびに／またはそれらの組み合わせ等の種々の他の誘導モダリティと共に提供され得る。さらに、いくつかの実施形態では、画像誘導構成要素は、治療的神経調節デバイス２０２と一体化されて、治療用アセンブリ２１２の位置付け中の画像誘導を提供してもよい。

【００５５】

標的部位に位置付けられた後、治療的調節は、エネルギー送達要素２１４及び／または治療用アセンブリ２１２の他の特徴を介して正確で局在的な組織領域に適用されて、副交感神経運動感覚機能を乱すような１つ以上の所望の治療的神経調節効果を誘発し得る。治療用アセンブリ２１２は、鼻領域内への入口の近位の、または鼻領域内への入口における標的または治療部位における鼻粘膜を神経支配する節後副交感神経線維を、選択的に標的化し得る。例えば、治療用アセンブリ２１２は、ＳＰＦ（図１Ａ）の少なくとも近位に治療的神経調節を適用して、ＳＰＦを介して鼻領域に入る神経を治療的に調節するように位置付けられ得る。治療用アセンブリ２１２はまた、後上外側鼻神経のより小さい内側枝及び側枝がそれを通って鼻領域に入る（例えば、口蓋骨内の）副孔及びミクロ孔にわたって治療的神経調節エネルギーを適用するように、ＳＰＦの下方に位置付けられ得る。標的部位における目的のあるエネルギー適用は、鼻領域に入る後鼻神経線維の全部または少なくとも一部分に沿って、治療的神経調節を達成し得る。治療的神経調節効果は概して、少なくとも部分的に、出力、時間、及びエネルギー送達要素と隣接した組織との間の接触の関数である。例えば、特定の実施形態では、自律神経線維の治療的神経調節は、ＲＦエネルギーを、約２～２０Ｗ（例えば、５Ｗ、７Ｗ、１０Ｗ等）の出力で約１～２０秒間（例えば、５～１０秒間、８～１０秒間、１０～１２秒間等）の期間適用することによって生み出される。治療的神経調節効果は、熱的切除及び／または非切除熱変質もしくは損傷を介した（例えば、長時間の加熱及び／または抵抗加熱を介した）、部分的または完全な除神経を含んでもよい。所望の熱的加熱効果は、標的神経線維の温度を、非切除熱変質を達成するための所望の閾値より上か、または切除熱変質を達成するためのより高い温度より上に上昇させることを含んでもよい。例えば、標的温度は、非切除熱変質に関しては、体温（例えば、およそ３７℃）より上であるが約９０℃未満（例えば、７０～７５℃）であってもよく、または標的温度は、切除熱変質に関しては、約１００℃以上（例えば、１１０℃、１２０℃等）であってもよい。所望の非熱的神経調節効果は、神経内に送信される電気信号を変化させることを含んでもよい。

【００５６】

体温低下効果もまた、神経調節を提供し得る。下記にさらに詳細に説明される通り、例えば、治療的に有効な直接的な細胞傷害（例えば、ネクローシス）、血管傷害（例えば、供給血管を損傷することによって栄養を断ち、細胞を餓死させる）、及びその後のアポトーシスを伴う亜致死低体温を提供するために、標的部位における組織を冷却するために凍結治療用アプリケータが使用されてもよい。凍結治療的冷却への曝露は、急性細胞死（例えば、曝露の直後）及び／または遅発性細胞死（例えば、組織の解凍及びその後の過剰灌流中）を引き起こし得る。本技術の実施形態は、標的化された節後副交感神経が存在する深さまで組織が有効に冷却されるように、組織に、またはその付近に位置付けられた構造を冷却することを含み得る。例えば、冷却構造は、治療的に有効な極低温の後鼻神経調節を引き起こす程度にまで冷却される。

【００５７】

特定の実施形態では、システム２００は、治療的神経調節が副交感神経線維を含む正確な領域に適用され得るように、神経、副孔、及び／またはミクロ孔の場所を療法の前に決定し得る。例えば、システム２００は、ＳＰＦの約３ｍｍ下方の長さ及び／または幅を有

する標的部位を特定してもよく、治療用アセンブリ２１２は、治療的神経調節の１つ以上の適用を介して特定された標的部位に治療的神経調節を適用し得る。他の実施形態では、標的部位は、検出された神経線維及びフォラメナ（ｆｏｒａｍｅｎａ）の場所に基づいて、より小さいまたはより大きくてもよい（例えば、３ｃｍ長さの標的領域）。この神経の解剖学的マッピングは、システム２００が、鼻腔内への多数の神経の入口点において粘膜を神経支配する節後副交感神経線維正確に検出し、治療的に調節することを可能にする。さらに、ＳＰＦ、副孔、及びミクロ孔の場所を示す明白な解剖学的マーカーが存在しないため、神経マッピングは、操作者が、さもなくば複雑な粘膜の切開なしには特定できない神経を特定し、治療的に調節することを可能にする。それに加えて、解剖学的マッピングはまた、操作者が、治療的神経性調節中に操作者が回避したいと望み得る特定の構造（例えば、特定の動脈）を特定することを可能にし得る。

【００５８】

副交感神経の少なくとも一部分の十分な調節は、鼻粘膜への自律神経信号の伝導を減速させるか、または潜在的に遮断して、鼻副交感神経活動の長期のまたは恒久的な低減を生み出すと予測される。これは、粘膜下腺及び静脈充血の活性化または過剰活性化を低減または排除し、それによって、鼻副鼻腔炎の症状を低減または排除すると予測される。さらに、システム２００は、ＳＰＦにおいて鼻腔内に入る後鼻神経分岐の単一の大きい分枝というよりもむしろ、後鼻神経の多数の分枝に治療的神経調節を適用するため、システム２００は、鼻粘膜に影響を及ぼし、鼻副鼻腔炎をもたらす副交感神経経路のより完全な混乱を提供する。したがって、システム２００は、鼻副鼻腔炎の治療に関する強化された治療効果、及び治療される粘膜の低減された再神経支配を有すると予測される。

【００５９】

他の実施形態では、システム２００は、異なる兆候を治療するために、神経及び／または他の構造を治療的に調節するように構成され得る。下記にさらに詳細に述べられる通り、例えば、システム２００は、副鼻洞を神経支配する神経の場所を決定する、及び／またはそれらを治療的に調節して、慢性副鼻腔炎を治療するために使用され得る。さらなる実施形態では、本明細書に開示されるシステム２００及びデバイスは、鼻の生体構造内の脈管系を治療的に調節して、鼻出血（すなわち、鼻からの過剰な出血）等の他の兆候を治療するように構成され得る。例えば、本明細書に説明されるシステム２００及び治療的神経調節デバイスは、動脈（例えば、蝶口蓋動脈及びその分枝）に、それらが（例えば、ＳＰＦ、副孔等を介して）鼻腔に入るときに治療的に有効なエネルギーを適用して、動脈を部分的または完全に凝固させるまたは結紮するために使用され得る。他の実施形態では、システム２００は、静脈及び／または他の血管を部分的または完全に凝固させるまたは結紮するように構成され得る。治療用アセンブリ２１２が脈管系を結紮するまたは凝固させるかかる実施形態に関して、システム２００は、治療的神経調節に必要とされるであろうものよりも著しく高い出力（例えば、約１００Ｗ）及び／または長い時間（例えば、１分間以上）、エネルギーを送達するように修正されるであろう。種々の実施形態では、システム１００は、治療の前、間、及び／後に、標的化された脈管系及び周囲の生体構造の場所を決定する、またはそれを検出するために、本明細書に開示される解剖学的マッピング技法を適用し得る。

【００６０】

図３Ａ～３Ｅは、本技術の実施形態に従って図２の治療的神経調節デバイス２０２の遠位部分を鼻領域内の標的部位に送達するための種々のアプローチを例証する、部分切り欠き側面図である。図３Ａに示される通り、種々の実施形態では、シャフト２０８の遠位部分２０８ｂは、鼻孔ＮＰ内へ入り、下鼻甲介ＩＴと鼻底ＮＳとの間の下鼻道ＩＭを通り、下鼻甲介ＩＴの後部分へ回って延在し、ここで、治療用アセンブリ２１２は治療部位において展開される。図３Ａに示される通り、治療部位は、鼻腔内への節後副交感神経の接近点（複数可）（例えば、後鼻神経及び／または鼻粘膜を神経支配する他の副交感神経線維の分枝）の近位に配置され得る。他の実施形態では、標的部位は、標的神経の場所に応じて、鼻腔内の他の場所であってもよい。内視鏡３３０及び／または他の視覚化デバイスは

、鼻孔ＮＰを通り、下鼻甲介ＩＴと中鼻甲介ＭＴとの間の中鼻道ＭＭを通って延在することによって、標的部位の近位に送達される。中鼻道ＭＭ内の視覚化の場所から、内視鏡３３０は、治療部位、鼻の生体構造の周囲領域、及び治療用アセンブリ２１２を視覚化するために使用され得る。

【００６１】

図３Ａにさらに示される通り、治療的神経調節デバイス２０２のシャフト２０８は、治療用アセンブリ２１２及び標的部位の近位に位置付けられた位置付け部材３３２を含み得る。例証される実施形態では、位置付け部材３３２は、対向する構造（例えば、鼻甲介の間）に接して開口（例えば、鼻道のうちの１つ）内で拡張されて、シャフト２０８の遠位部分２０８ｂを、標的部位に対して所望の部分に一貫して保持して、治療用アセンブリ２１２の展開のための安定性を提供するバルーンである。他の実施形態では、位置付け部材３３２は、鼻腔内でシャフト２０８を所望の位置に維持するように展開され得る他の拡張可能な構造（例えば、メッシュバスケット）または固定特徴を含んでもよい。さらなる実施形態では、位置付け部材３３２は、治療用アセンブリ２１２の遠位に位置付けられ、治療用アセンブリ２１２及び治療部位の遠位の領域内で拡張され得る。またさらなる実施形態では、位置付け部材３３２は、シャフト２０８及び／または他のデバイス（例えば、生理食塩水または局所麻酔薬の送達用の流体線、内視鏡、センサ等）がそれを通過し得る導入器鞘（図示せず）上に位置付けられる。位置付け部材３３２は、標的部位の近位（例えば、図３Ａに示される位置に類似）または治療部位の遠位に位置付けられ得る。遠位に位置付けられる場合、導入器鞘は、治療用アセンブリ２１２及び他の特徴がそれを通って標的部位において展開され得る側部出口ポートを含み得る。位置付け部材３３２が導入器鞘上に位置付けられる場合、位置付け部材３３２は、シャフト２０８の遠位部分２０８ｂ及び治療用アセンブリ２１２の送達及び展開のための安定性を提供し得る。位置付け部材３３２は、治療用アセンブリ２１２が異なる腔内通路を通って送達されるときに、シャフト２０８、関連する導入器鞘、及び／またはシステム２００（図２）の他の送達特徴上に組み込まれ得る。

【００６２】

図３Ｂは、シャフト２０８の遠位部分２０８ｂが、鼻孔ＮＰ内に入り、下鼻甲介ＩＴと中鼻甲介との間の中鼻道ＭＭを通り、治療用アセンブリ２１２が治療部位において展開される後方向に延在する、異なる実施形態を例証する。この実施形態では、内視鏡３３０及び／または他の視覚化デバイスは、治療用アセンブリ２１２と同一の腔内経路を通ってシャフト２０８と並行に送達される。中鼻道ＭＭを通る経路は、特定の関心の領域及び患者の解剖学的変異に応じて、標的部位への概して真っ直ぐな接近を提供し得る。したがって、中鼻道ＭＭを通るアプローチは、シャフト２０８及び内視鏡３３０のより少ない操縦及び／または関節運動を必要とし得る。さらに、シャフト２０８の遠位部分２０８ｂ及び内視鏡３３０は同一の送達路に沿って進むため、内視鏡は、治療用アセンブリ２１２の直列または並列の視覚化を提供し得る。

【００６３】

図３Ｂに示される実施形態と同様に、図３Ｃは、内視鏡３３０がシャフト２０８の遠位部分２０８ｂ、治療用アセンブリ２１２、及び／または鼻の生体構造の直列または並列の視覚化を提供し得るように、シャフト２０８の遠位部分２０８ｂ及び内視鏡３３０が隣り合って進む別の腔内経路を例証する。しかしながら、図３Ｃに示される実施形態では、腔内経路は、下鼻道ＩＭを通って後方の治療部位に延在する。

【００６４】

図３Ｄに示される通り、他の実施形態では、シャフト２０８の遠位部分２０８ｂは、中鼻道ＭＭを介して治療部位に延在し、内視鏡３３０は、下鼻道ＩＭを通って標的部位の近位の位置に延在する。この実施形態では、内視鏡３３０は、内視鏡３３０を上方に方向付けて、標的部位において鼻の生体構造及び治療用アセンブリ３３２を視覚化する、関節運動をするか、操縦可能であるか、または湾曲した遠位端部を有してもよい。例えば、内視鏡３３０の遠位端部部分は、治療部位を視覚化するために、少なくとも３０°曲がるよう

に構成され得る。

【００６５】

図３Ｅに示される通り、さらなる実施形態では、シャフト２０８の遠位部分２０８ｂは、口を介して治療部位に送達され得る。この実施形態では、治療的神経調節は、鼻腔の後方（例えば、ＳＰＦの後方）の治療部位に適用され得る。内視鏡３３０（図示せず）は、鼻孔ＮＰ内に入り、中鼻道ＭＭまたは下鼻道ＩＭを通り、治療部位の近位の位置に延在し得る。代替的に、内視鏡３３０（図示せず）は、シャフト２０８と同一の経路に沿って進んでもよい。

【００６６】

図４は、本技術の実施形態に従って構成された治療的神経調節デバイス４０２の遠位部分の等角図である。治療的神経調節デバイス４０２は、図２～３Ｅに関して上記に説明されるシステム２００と併せて使用され得る。図４に示される通り、治療的神経調節デバイス４０２は、近位部分（図示せず）及び遠位部分４０８ｂを有するシャフト４０８と、シャフト４０８の遠位部分４０８ｂにおける治療用アセンブリ４１２とを含み得る。治療用アセンブリ４１２は、鼻領域内の治療部位への治療用アセンブリ４１２の腔内送達を促進するための低プロファイル送達状態と、拡張状態（図４に示される）との間で変形可能である。治療用アセンブリ４１２は、治療用アセンブリ４１２が拡張状態にあるときに互いに離間されて、フレームまたはバスケット４４２を形成する複数の支柱４４０を含む。支柱４４０は、複数の電極４４４等の１つ以上のエネルギー送達要素を担持し得る。拡張状態では、支柱４４０は、電極４４４のうちの少なくとも２つを、鼻領域内の標的部位（例えば、ＳＰＦの下方の口蓋骨の近位）において組織に接して位置付け得る。電極４４４は、標的部位に、標的部位の近位の鼻粘膜を神経支配する節後副交感神経を治療的に調節するための双極性または多極性無線周波数（ＲＦ）エネルギーを適用し得る。種々の実施形態では、電極４４４は、標的組織の温度増加を調整するために、所望の負荷サイクル（例えば、１秒間作動／０．５秒間停止）を用いてパルス状のＲＦエネルギーを適用するように構成され得る。

【００６７】

図４に例証される実施形態では、バスケット４４２は、互いに半径方向に離間されて、少なくとも略球体の構造を形成する８つの分岐４４６を含み、分岐４４６の各々は、互いに隣接して位置付けられた２つの支柱４４０を含む。しかしながら、他の実施形態では、バスケット４４２は、８つよりも少ない分岐４４６（例えば、２、３、４、５、６、または７つの分岐）または８つを超える分岐４４６を含み得る。さらなる実施形態では、バスケット４４２の各分岐４４６は、単一の支柱４４０、２つ超の支柱４４０を含んでもよく、及び／または分岐毎の支柱４４０の数は、変動してもよい。またさらなる実施形態では、分岐４４６及び支柱４４０は、電極４４４を標的部位において組織と接触して定置するための他の好適な形状を有するバスケットまたはフレームを形成し得る。例えば、拡張状態において、支柱４４０は、卵形形状、半球形状、円筒構造、ピラミッド構造、及び／または他の好適な形状を形成し得る。

【００６８】

図４に示される通り、治療用アセンブリ４１２は、シャフト４０８の遠位部分４０８ｂから遠位に延在する内部または内側支持部材４４８をさらに含み得る。支持部材４４８の遠位端部部分４５０は、支柱４４０の遠位端部部分を支持して、所望のバスケット形状を形成し得る。例えば、図４に示される通り、支柱４４０は、シャフト４０８の遠位ポション（ｐｏｔｉｏｎ）４０８ｂから遠位に延在し得、支柱４４０の遠位端部部分は、支持部材４４８の遠位端部部分４５０に取着し得る。特定の実施形態では、支持部材４４８は、電極４４４及び／または治療用要素４１２の他の電気的特徴に連結された電気コネクタ（例えば、ワイヤ）がそれを通って走り得る内部チャネル（図示せず）を含み得る。種々の実施形態では、内部支持部材４４８はまた、遠位端部部分４５０において、及び／または支持部材４４８の長さに沿って、電極（図示せず）を担持し得る。

【００６９】

バスケット４４２は、シャフト４０８の近位部分にある、バスケット４４２に動作可能に連結されたハンドル（例えば、図２のハンドル２１０）及び／または他の特徴を操作することによって、低プロファイル送達状態から拡張状態（図４）に変形し得る。例えば、バスケット４４２を拡張状態から送達状態に移動させるために、操作者は、支持部材４４８を遠位に押して、支柱４４０を支持部材４４８に向かって内向きに持ってくることができる。導入器またはガイド鞘（図示せず）は、標的部位からの、または標的部位への治療用アセンブリ４１２の腔内送達または除去を促進するように、低プロファイルの治療用アセンブリ４１２の上に位置付けられ得る。他の実施形態では、治療用アセンブリ４１２は、他の好適な手段を使用して、送達状態と拡張状態との間で変形される。

【００７０】

個々の支柱４４０は、拡張状態にあるときに支柱４４０が所望のバスケット４４２形状に自己拡張することを可能にする形状記憶材料（例えば、ニチノール）等の、弾性材料から作製され得る。他の実施形態では、支柱４４０は、他の好適な材料から作製されてもよく、及び／または治療用アセンブリ４１２は、バルーンを介してか、もしくは支持部材４４８の近位移動によって機械的に拡張されてもよい。バスケット４４２及び関連する支柱４４０は、電極４４４を支持し、電極４４４を標的部位における組織に接して位置付けるまたは押し付けるのに十分な剛性を有し得る。それに加えて、拡張されたバスケット４４２は、標的部位の近位の周囲の解剖学的構造（例えば、鼻甲介、口蓋骨等）に押し付けられ得、個々の支柱４４０は、隣接した解剖学的構造の形状に少なくとも部分的に適合して、エネルギー送達中に治療用要素４１２を治療部位において固定し得る。それに加えて、支柱４４０の拡張及び適合性は、電極４４４を標的部位において周囲の組織と接触して定置することを促進し得る。

【００７１】

少なくとも１つの電極４４４は、個々の支柱４４０上に配設される。例証される実施形態では、２つの電極４４４は、各支柱４４０の長さに沿って位置付けられる。他の実施形態では、個々の支柱４４０上の電極４４４の数は、１つのみ、２つ超、ゼロであってもよく、及び／または異なる支柱４４０上の電極４４４の数は、変動してもよい。電極４４４は、白金、イリジウム、金、銀、ステンレス鋼、白金－イリジウム、コバルトクロム、酸化イリジウム、ポリエチレンジオキシチオフェン（「ＰＥＤＯＴ」）、チタン、窒化チタン、炭素、カーボンナノチューブ、白金グレイ、Ｆｏｒｔ　Ｗａｙｎｅ、ＩｎｄｉａｎａのＦｏｒｔ　Ｗａｙｎｅ　Ｍｅｔａｌｓ製の銀芯を有するＤｒａｗｎ　Ｆｉｌｌｅｄ　Ｔｕｂｉｎｇ（「ＤＦＴ」）、及び／または標的組織のＲＦエネルギーの送達に好適な他の材料から作製され得る。

【００７２】

特定の実施形態では、各電極４４４は、他の電極４４４と独立して動作され得る。例えば、各電極は、個々に活性化され得、各電極の極性及び振幅は、操作者または制御アルゴリズム（例えば、図２の制御装置２１８によって実行される）によって選択され得る。かかる独立して制御される電極４４４の種々の実施形態は、図５Ａ～５Ｇを参照して下記にさらに詳細に説明される。電極４４４の選択的な独立した制御は、治療用アセンブリ４１２が、ＲＦエネルギーを高度にカスタマイズされた領域に送達することを可能にする。例えば、電極４４４の選択された部分は、他の電極４４４は不活性のまま、特定の領域内の神経線維を標的化するように活性化され得る。特定の実施形態では、例えば、電極４４４は、標的部位において組織に隣接したバスケット４４２の部分にわたって活性化されてもよく、標的組織の近位にない電極４４４は、非標的組織へのエネルギーの適用を回避するために不活性のままであり得る。かかる構成は、鼻腔の他の部分内の構造にエネルギーを適用することなく、１つの鼻孔内の鼻の側壁上の神経の選択的な治療的調節を促進する。

【００７３】

電極４４４は、電極４４４からシャフト４０８を通ってＲＦ生成器に延在するワイヤ（図示せず）を介して、ＲＦ生成器（例えば、図２の生成器２１６）に電気的に連結され得る。電極４４４の各々が独立して制御されるとき、各電極４４４は、シャフト４０８を通

って延在する対応するワイヤに連結する。他の実施形態では、複数の電極４４４は、一緒に制御され得、したがって、複数の電極４４４は、シャフト４０８を通って延在する同一のワイヤに電気的に連結され得る。ＲＦ生成器、及び／またはそれに動作可能に連結された構成要素（例えば、制御モジュール）は、電極４４４の活性化を制御するためのカスタムアルゴリズムを含み得る。例えば、ＲＦ生成器は、約２００～３００ＷのＲＦ出力を電極４４４に送達し、治療部位及び／または標的神経の特定された場所に対する治療用要素４１２の位置に基づいて選択された所定のパターンで電極４４４を活性化しながら、そのようにし得る。他の実施形態では、ＲＦ生成器は、より低いレベル（例えば、１５Ｗ未満、１５～５０Ｗ、５０～１５０Ｗ等）及び／またはより高き出力レベルで出力を送達する。

【００７４】

図４に示される通り、治療用アセンブリ４１２は、支柱４４０及び／または治療用アセンブリ４１２の他の部分上に配設され、温度センサ４５２に隣接した温度を検出するように構成された１つ以上の温度センサ４５２をさらに含み得る。温度センサ４５２は、シャフト４０８を通って延在するワイヤ（図示せず）を介して、コンソール（例えば、図２のコンソール２０４）に電気的に連結され得る。種々の実施形態では、温度センサ４５２は、標的部位における組織と電極４４４との間の境界面の温度を検出するために、電極４４４の近位に位置付けられ得る。他の実施形態では、温度センサ４５２は、組織内のある深さの温度を検出するために、標的部位における組織を貫通し得る（例えば、貫通熱電対）。温度測定は、操作者またはシステムに、組織に対する治療的神経調節の効果に関するフィードバックを提供し得る。例えば、特定の実施形態では、操作者は、治療部位（例えば、鼻粘膜）における組織への損傷を防止または低減したいと望む場合があり、したがって温度センサ４５２は、組織の温度が不可逆的な組織損傷に関する所定の閾値に到達するかを決定するために使用され得る。閾値が到達されると、治療的神経調節エネルギーの適用は、組織が無傷のままであり得るように終了され得る。特定の実施形態では、エネルギー送達は、温度センサ４５２に動作可能に連結されたコンソール（例えば、図２のコンソール２０４）上に保存された評価／フィードバックアルゴリズム（例えば、図２の評価／フィードバックアルゴリズム２２０）に基づいて、自動的に終了し得る。

【００７５】

図５Ａ～５Ｇは、本技術の実施形態に従う治療的神経調節のための治療的神経調節デバイス（それぞれ、個々に第１～第４の治療的神経調節デバイス５０２ａ～５０２ｄと特定され、集合的に治療的神経調節デバイス５０２と称される）の電極構成の例の等角図である。図５Ａ～５Ｇの治療的神経調節デバイス５０２は、図４の治療的神経調節デバイス４０２の特徴に概して類似の特徴を含み得る。例えば、治療的神経調節デバイス５０２は、拡張状態にあるときにバスケット４４２を形成する複数の支柱４４０と、支柱４４０のうちの１つ以上の上に配設された複数の電極４４４とを含む。例証される実施形態では、図５Ａ～５Ｅに示される第１～第３の治療的神経調節デバイス５０２ａ～ｃは、バスケット４４２の各分岐４４６に対応する単一の支柱４４０を含み、図５Ｆ及び５Ｇに示される第４の治療的神経調節デバイス５０２ｄは、バスケット４４２の各分岐４４６内に２つの隣接した支柱４４０を含む。しかしながら、他の実施形態では、治療的神経調節デバイス５０２の分岐４４６は、異なる量の支柱４４０を有し、図５Ａ～５Ｇを参照して下記に説明されるものと同一の様式でＲＦエネルギーを適用してもよい。図５Ａ～５Ｇに示される通り、電極４４４は、制御装置（例えば、図２の制御装置２１８）または生成器（例えば、図２の生成器２１６）からの命令を介して独立して制御及び活性化されて、治療用アセンブリ４１２の選択された領域またはセグメントにわたってＲＦエネルギーを適用し得る。

【００７６】

図５Ａに示される実施形態では、治療用アセンブリ４１２の２つの電極４４４が、第１の治療的神経調節デバイス５０２ａ内で活性化される。より具体的には、第１の支柱４４０ａ上の第１の電極４４４ａは、正極性で活性化され、第１の支柱４４０ａから半径方向に離間された第２の支柱４４０ｂ上の第２の電極４４４ｂは、負極性で活性化される。電

極４４４の残りは、不活性のままである。したがって、矢印によって示される通り、電流は、治療用アセンブリ４１２の円周または周辺セグメントにわたって、第１の電極４４４ａから第２の電極４４４ｂへと標的組織を通して流れ得る。この構成は、周辺セグメントの近位に位置付けられた神経を治療的に調節するために使用され得る。他の実施形態では、異なるまたは追加的な電極４４４が、選択された極性を有するように活性化されて、所定の様式で治療用アセンブリ４１２の選択された領域にわたって治療的神経調節を適用し得る。

【００７７】

図５Ｂに示される実施形態では、第１の治療的神経調節デバイス５０２ａは、３つの選択的に活性な電極４４４を有するように構成される。第１の支柱４４０ａ上の第１の電極４４４ａは、正極性で活性化され、対応する第２及び第３の支柱４４０ｂ及び４４０ｃ上の第２及び第３の電極４４４ｂ及び４４４ｃは、負極性で活性化される。電極４４４の残りは、不活性のままである。矢印によって示される通り、電流は、治療用アセンブリ４１２のセグメントにわたって、第１の電極４４４ａから第２及び第３の電極４４４ｂ及び４４４ｃへと組織を通して流れ、したがって、周辺セグメントの近位に位置付けられた神経を治療的に調節し得る。例証される実施形態では、第２及び第３の活性化された電極４４４ｂ及び４４４ｃは、第１の活性電極４４４ａを担持する第１の支柱４４０ａから半径方向に離間されているが、それに隣接した支柱４４０ｂ、４４０ｃ上に位置付けられる。しかしながら、他の実施形態では、治療用アセンブリ４１２のより大きい及び／またはより広いセグメントにわたってエネルギーを適用するために、第１の支柱４４０ａからさらに遠くに置かれた、支柱４４０上に位置付けられた電極４４４。

【００７８】

図５Ｃに示される実施形態では、治療用アセンブリ４１２の第１の半球領域５０１ａ内の電極４４４の全てが活性化され、第２の半球領域５０１ｂの電極４４４は活性化されない。第１の支柱４４０ａ上の第１の電極は、正極性で選択的に活性化され、第１の半球領域５０１ａ内の複数の電極４４４（それぞれ、個々に第２～第５の電極４４４ｂ～４４４ｅと特定される）は、ＲＦエネルギーが第１の半球領域５０１ａにわたって適用されるように、負極性で選択的に活性化される。この電極活性化構成は、１つの鼻孔内の鼻の側壁上の神経を治療的に調節するために、バスケット４４２の片側にわたってＲＦエネルギーを適用するために使用され得る。治療用アセンブリ４１２が他の鼻孔内に位置付けられる場合、電極４４４の異なるセットが、鼻の側壁に対するバスケット４４２の配向に基づいて治療用アセンブリ４１２の半球領域にわたって活性化され得る。さらに、バスケット４４２は略対称な形状（例えば、円形、長円形等）を有するため、また電極４４４は選択的に活性化され得るため、鼻の側壁上の標的部位に対するバスケット４４２の配向は、問題ではない。代わりに、操作者は、治療用アセンブリ４１２を標的部位において配向に関係なく展開し、電極４４４を所望の配列で選択的に活性化して、標的部位にわたってＲＦエネルギーを適用し得る。

【００７９】

図５Ｄに示される実施形態では、第２の治療的神経調節デバイス５０２ｂは、治療用アセンブリ４１２の少なくとも一部分にわたって複数の電極４４４の極性を選択的に制御して、ＲＦエネルギーをセスキ極性（ｓｅｓｑｕｉｐｏｌａｒ）方式（すなわち、連続的または一時的な電極の双極性対形成）で適用するように構成される。例証される実施形態では、第１の電極４４４ａは、正極性でバイアスされ、第２～第７の電極４４４ｂ～４４４ｇは、負極性を有するように制御される。第２～第７の電極４４４ｂ～４４４ｇは、電極４４４が、順に多重送信するように寸法的に予め配設されるように、第１の電極４４４ａから実質的に等しい距離に離れて置かれる。動作中、第１～第７の電極４４４ａ～４４４ｇは、同時に活性化される。しかしながら、負の電極４４４の全てが正の第１の電極４４４ａと同時に対形成または多重送信するというよりもむしろ、第１の電極４４４ａは、最小抵抗の通路に基づいて連続的な様式で個々の負の電極４４４と対になるであろう。この最小抵抗の通路は、電極４４４と接触している治療部位の天然の生体構造によって決定

される。例えば、標的部位における生体構造に基づき、第１の電極４４４ａは、第２の電極４４４ｂと最初に対になってもよい。この最初の対形成選好が消失した後、第２の対形成（例えば、第３の電極４４４ｃとの）が、最小抵抗の通路に基づいて発生するであろう。第１の電極４４４ａは、閾値が到達され、電極４４４が、電極対の全ての間に均質な電流が存在する平衡の状態になるまで、残りの活性化された負の電極と同様の様式で連続的に対になり続けるであろう。各連続的な対形成によって、治療用アセンブリ４１２は、切除区画（すなわち、治療的神経調節エネルギーが適用される領域）のサイズを増加させる。図５Ｄ内の番号１～６によって示される通り、この電極４４４の連続的な対形成は、電極４４４間のインピーダンス変化に基づいて、円形方向（例えば、反時計回りまたは時計回りの方向）に発生してもよい。他の実施形態では、電極４４４の連続的な対形成は、周囲の解剖学的状況及び／または電極４４４の位置付けに基づいて、異なるパターンで発生してもよい。例えば、例証される実施形態では、活性化された電極４４４は、個々の電極対間に等しい半径方向距離を有して、治療用要素４１２の四分円内に位置付けられる。他の実施形態では、活性化された電極４４４は、より大きいまたはより小さい治療領域にわたってエネルギーを適用するために、治療用要素４１２のより大きいまたはより小さい領域にわたって位置付けられ得る。

【００８０】

ＲＦエネルギーのセスキ極性適用は、治療用アセンブリ４１２が、治療部位の近位の神経を治療的に調節するために、標的部位にわたってＲＦエネルギーを知的に適用することを可能にする。例えば、互いに等距離の半径方向関係にあるとき、電極対間の自然に発生するインピーダンスの変化は、治療用アセンブリ４１２に、各対形成を有するエネルギー適用の区画を半径方向に増加させる。他の実施形態では、電極４４４は、エネルギー適用の区画が、電極４４４間の自然に発生するインピーダンスの変化に基づいて横方向及び／または長手方向様式で増加するような様式で、連続的に互いに対になるように構成され得る。さらに、１つの電極対形成においてインピーダンスが閾値を超過すると、次の電極対形成はより低いインピーダンスで発生するため、電極４４４の連続的なインピーダンスに基づく対形成によって、療用アセンブリ４１２のセスキ極性配列は、標的部位における組織に適用されるエネルギーを本質的に制限し得る。他の実施形態では、制御装置（例えば、図２の制御装置２１８）は、半径方向、横方向、長手方向、及び／または渦巻き様式の電極の連続的な対形成を提供する命令（例えば、ソフトウェア）を含み得る。

【００８１】

さらなる実施形態では、支柱４４０自体の一部分が、電極４４４を画定し得る。この実施形態では、支柱４４０は、導電性材料から作製され、絶縁性材料（例えば、パラリエン（Ｐａｒａｌｙｅｎｅ）Ｃを含むポリキシレンポリマー）で被覆される。https://en.wikipedia.org/wiki/Xylylenehttps://en.wikipedia.org/wiki/Polymers支柱４４０の一部分は、電極４４４を画定するために、被覆されないままであり得る。支柱４４０の被覆されていない部分（すなわち、電極４４４）の場所は、所望の神経調節パターンを提供するように選択され得る。例えば、被覆されていない部分は、セスキ極性ＲＦ適用を可能にするために、中央の電極４４４から等しく離れて置かれ得る。この実施形態では、伝導性の支柱４４０は、電気コネクタの役割を果たし、したがって治療用アセンブリ４１２は、電極４４４が支柱４４０上に位置付けられた別個の要素である場合程に多くのワイヤを必要としない。

【００８２】

図５Ｅに示される実施形態では、第３の治療的神経調節デバイス５０２ｃは、電極４４４の半径方向の多重送信を提供するように、支持部材４４８の遠位端部部分４５０における戻り電極５０３と、支柱４４０上の個々の電極４４４の選択的な極性制御とを含む。戻り電極５０３は、負極性を有し、他の電極４４４は、正極性を有する。例証される実施形態では、電極４４４の全てが活性化されるが、他の実施形態では、電極４４４は、所望のエネルギー適用区画に基づいて選択的に活性化され得る。矢印によって示される通り、この構成は、バスケット４４２の遠位半球領域にわたってＲＦエネルギーを適用する。他の

実施形態では、戻り電極５０３は、治療用アセンブリ４１２上の他の場所に位置付けられ得、電極４４４、５０３は、バスケット４４２の異なる領域にわたってＲＦエネルギーを適用するために使用され得る。さらなる実施形態では、戻り電極５０３は、セスキ極性様式でＲＦエネルギーを適用するために、支柱上の電極４４４のうちの２つ以上と共に活性化され得る。

【００８３】

図５Ｆに示される実施形態では、第４の治療的神経調節デバイス５０２ｄは、２つの隣接した支柱４４０を有する分岐４４６を含み、隣接した支柱上の電極４４４は、長手方向に互いに離間され、個別の区画にわたって半径方向にエネルギーを適用するように選択的に活性化される。例えば、第１の分岐４４６ａの第１の支柱４４０ａ上の第１の電極４４４ａは、第１の極性を有するように選択的に活性化されてもよく、第１の分岐４４６ａの隣接した第２の支柱４４０ｂ上の第２の電極４４４ｂは、第１の極性とは反対の第２の極性を有するように選択的に活性化されてもよい。図５Ｆ内に矢印によって示される通り、第１及び第２の電極４４４ａ及び４４４ｂは次に、治療用アセンブリ４１２の特定の領域内に半径方向に双極性ＲＦエネルギーを適用し得る。

【００８４】

図５Ｆにさらに示される通り、個々の支柱４４０は、その上に配設された複数の電極４４４を含み得、同一の分岐４４６内の隣接した支柱４４０は、分岐４４６の個別の領域に沿った電極対の各々の双極性連結を可能にするように、対応する量の電極４４４を有し得る。特定の実施形態では、１つの支柱４４０の電極は、全て同一の極性を有し得（例えば、第１のワイヤ連結される、図示せず）、同一の分岐４４６内の隣接した支柱４４０の電極４４４は、全て反対の極性を有し得る（例えば、第２のワイヤに連結される、図示せず）。他の実施形態では、個々の支柱４４０上の電極４４４は、所望の極性を有するように独立して制御され得る。

【００８５】

種々の実施形態では、図５Ｆに示される電極対形成構成は、双極性電極対によって画定される治療用アセンブリ４１２の選択される領域にわたってインピーダンスを検出するために使用され得る。インピーダンス測定は次に、選択される領域内の神経線維の存在を特定するために使用され得る。電極対に関連付けられる１つ以上の特定の領域内に神経が検出される場合、同一の電極対は、その領域にＲＦエネルギーを適用し、その領域内の神経を治療的に調節するために使用され得る。

【００８６】

図５Ｇに示される実施形態では、第４の治療的神経調節デバイス５０２ｄは、治療用アセンブリ４１２の少なくとも一部分にわたって複数の電極４４４の極性を選択的に制御して、円形または渦巻きパターンで、多極性様式でＲＦエネルギーを適用するように構成される。図５Ｇに示される通り、ある分岐４４６の電極４４４は、負極性を有するように活性化され得、別の分岐４４６の電極４４４は、正極性を有するように活性化され得る。電極４４４の配列及び電極４４４間の可変的な距離は、エネルギー適用区画が異なる形状またはパターンを有するように、異なり得る。他の実施形態では、正及び負の電極４４４は、可変的な距離で互いに離間される。周囲の解剖学的構造からもたらされるインピーダンスの変化は、電極を連続的な様式で互いに対にさせ、それによって、エネルギーが半径方向に及び略渦巻き様式で適用される区画または領域を、継続的に増加させる。

【００８７】

エネルギーは概して、正及び負の電極対が互いに遠くに離間されればされる程、隣接した標的組織内により深く伝わる。したがって、治療的神経調節エネルギーの影響の深さは、連結された電極対がバスケット４４２上で互いにより離れて置かれるのに伴い、増加すると予測される。図５Ｇに例証される実施形態では、例えば、バスケット４４２の遠位及び近位領域における電極対は、バスケット４４２の中央領域に位置付けられた電極対よりも、標的組織内で浅い深さにエネルギーを適用する。したがって、より近くに一緒に位置付けられた電極対は、互いにより離れて置かれた電極対よりも、より浅い深さにおいて神

経を治療的に調節し得る。例証される実施形態に示される通り、電極４４４のうちのいくつか及び／またはバスケット４４２の分岐４４６全体は、所望の深さのエネルギー適用及び／または神経調節パターンを達成するために、不活性のままであり得る。

神経検出及びマッピングの選択される実施形態

【００８８】

本技術の種々の実施形態は、鼻領域内の標的部位における不均一な組織の生体電気の、誘電性の、及びまたは他の特性を測定して、神経線維の存在、場所、及び／または活性を決定し、任意に、検出された神経の場所をマッピングする特徴を含み得る。下記に述べられる特徴は、標的部位における神経の正確な描写を提供するために、本明細書に開示されるシステム及び／またはデバイスのいずれにも組み込まれ得る。

【００８９】

神経検出は、（ａ）標的部位における神経の存在もしくは場所を決定する、及び／または神経活動のベースラインレベルを記録するために、治療的神経調節エネルギーの適用の前に、（ｂ）治療部位における神経線維に対するエネルギー適用の効果を決定するために、治療的神経調節中に、ならびに／あるいは（ｃ）標的化された神経における治療の有効性を確認するために、治療的神経調節の後に、生じ得る。鼻腔を神経支配する副交感神経線維の数及び場所の解剖学的変異、ならびにそれを通ってそれらが鼻腔内に入る多数の接近点（例えば、ＳＰＦ、副孔、及びミクロ孔）のため、かかる神経検出及びマッピングは、ＳＰＦを横断する後鼻神経の１つまたは２つの主要分岐のみでなく副交感神経を適切に治療するための、神経構造の正確な表現を提供し得る。

【００９０】

特定の実施形態では、本明細書に開示されるシステムは、例えば、インピーダンス、抵抗、電圧、電流密度、及び／または他のパラメータ（例えば、温度）等の生体電気測定を使用して、標的部位における生体構造、具体的には神経構造を決定し得る。次に、神経構造の場所は、治療部位（複数可）が、標的化された副交感性鼻神経の治療的に有効な神経調節のための種々の解剖学的構造に関わるべきかを決定するために使用され得る。例えば、情報は、鼻甲介または鼻道の場所に関して治療部位（複数可）を決定するために使用され得る。

【００９１】

生体電気特性は、電極（例えば、図４～５Ｇの治療的神経調節デバイス４０２～５０２ｄの電極４４４）を介して検出され得る。デバイス（例えば、図４～５Ｇに関して説明される治療用アセンブリ４１２）上の電極対形成は、標的化された領域の特定の深さにおける特定の区画または領域において生体電気データを取得するように選択され得る。例えば、図６Ａ及び６Ｂは、本技術の実施形態に従って構成された神経検出のための電極６４４の構成を例証する部分概略図である。図６Ａに示される通り、電極６４４が互いにより離れれば離れるほど、電流は組織内へより深く流れる。したがって、電極６４４は、所望の測定が行われるべき深さに基づいて選択的に活性化され得る。図６Ｂに示される通り、平面（例えば、組織の表面）に沿った電極６４４間の間隔は、測定が行われる領域に影響を及ぼし得る。したがって、電極６４４は、所望の深さにおいて、所望の領域にわたって情報（例えば、インピーダンス）を取得するように、選択的に活性化され得る。他の実施形態では、生体電気特性は、光コヒーレント断層撮影（ＯＣＴ）、超音波、及び／または他の好適な検出モダリティを使用して検出され得る。

【００９２】

生体電気特性の測定は、神経線維の場所のみでなく、全体的な生体構造（例えば、鼻甲介、鼻道、骨等）の特定に関連付けられる情報を提供し得、これは、システムの送達及び全体的な生体構造に対する標的神経の特定を促進するために使用され得る。例えば、全体的な標的特定は、鼻領域内の軟及び硬組織上の入射電磁場を評価することによって決定され得、これは、それらの特徴の局所幾何学及び誘電特性に依存する。例えば、鼻腔の生体構造の層状構造（例えば、鼻粘膜、粘膜下層、骨膜、及び骨板）のため、軟及び硬組織の相対的な伝導度には大きな差異があり、これは、鼻甲介上の「より深い」粘膜組織を鼻甲

介の外部の「浅い」組織と区別するために使用され得る。

【００９３】

特定の実施形態では、神経マッピングのための測定は、一定の電流を電極に適用し、隣接する電極の対間の電圧差を測定して、スペクトルプロファイルを作成するか、または標的部位において組織をマッピングすることによって取得され得る。インピーダンスデータは、標的組織に高、中、及び／または低周波数を適用しながら取得され得る。高周波数では、電流は、細胞膜を直接通過し、結果として得られる測定は、細胞の外側及び内側の両方の組織及び液体を示す。低周波数では、細胞膜は、電流を妨げ、組織の異なる定義的特性を提供する。したがって、生体インピーダンスは、組織及び／または鼻腔の他の構造の標的化された形状または電気的特性を測定するために使用され得る。それに加えて、複雑な神経マッピングは、２つの異なる周波数での測定データ（例えば、インピーダンス）を必要とする周波数差再構成を使用して実施され得る。

【００９４】

生体電気特性を介して神経の場所及び活性を検出するとき、検出される神経束の空間的配向、方向、及び活性は、神経をさらに特定及び特性化するために使用され得る。例えば、測定される生体電気特性は、終了する軸索（すなわち、検出領域に入るが、そこから出ない）、分岐する軸索（すなわち、検出領域に入り、検出領域から出るときに数が増加する）、移動する軸索（すなわち、幾何学または数値の変化を伴うことなく検出領域に入り、そこから出る）、及び／または神経の他の特性を区別し得る。それに加えて、電極アレイに対する軸索の配向は、神経線維が、平行（Ｘ方向）に、垂直（Ｙ方向）に、貫通する深さ（Ｚ方向）に、及び／またはこれらのパラメータに対する任意の相対的位置もしくは角度に延在するかを示すために特定され得る。この情報は次に、特定の神経線維を選択的に治療するために使用され得る。例えば、選択される電極構成が、特定の領域を治療するために適用され得、及び／または治療用アセンブリは、異なる配向もしくは場所から神経を治療するために移動もしくは操作され得る。

【００９５】

特定の実施形態では、温度測定は、鼻組織に対する治療的神経調節の効果を決定するために取得され得る。例えば、図７は、温度に対する鼻組織の電気伝導率の閾値レベルを例証するグラフである。第１の曲線７０１は、温度に応答した組織の電気伝導率（σ）を描いており、約７０℃の温度が、組織のインピーダンスの不可逆的変化の第１の閾値に対応することを示す。第２の曲線７０３は、治療的神経調節中に起こり得るように、組織が７０℃の温度に曝露された後に、組織の電気伝導率が恒久的に著しく増加する（すなわち、インピーダンスが減少する）ことを示す。組織温度が約７０℃であると検出されたときに治療的神経調節が停止される場合、組織が構造的に変化または損傷される（例えば、蒸発、乾燥等によって）段階に到達することなく、組織の伝導率の恒久的に測定可能な変化があると予測される。しかしながら、組織が約９０℃の第２の熱閾値を上回る温度に曝露される場合、組織は、高度の組織乾燥を受け、したがって電気伝導率の著しい減少（すなわち、より高レベルの電気インピーダンス）を受ける。第３の曲線７０５は、９０℃を上回る温度への曝露後の、このより低い組織の電気伝導率を例証する。したがって、種々の実施形態では、本明細書に開示されるシステムは、温度が約７０℃（例えば、７０～８０℃）に到達したときに神経調節を停止して、粘膜への構造的変化または損傷を回避ながらも、治療的に有効な神経調節であるために期待されるものを提供するように構成され得る。

【００９６】

神経検出及びマッピングは、神経構造の処置前評定、神経調節中の組織の一時的変化に対する処置中評定及びフィードバック、ならびに／または有効性の確認としての神経活動の処置後評定を提供し得る。種々の実施形態では、処置前、処置中、及び処置後に行われる生体電気測定は、所見を評定及び確認するために、処置の各段階中に複数回行われ得る。処置前評定は、天然／宿主組織の生体電気特性を評価して、その後の行為に関する、また関心の解剖学的標的（例えば、神経、ミクロ孔等）を特定するための元の生物学的痕跡に対する参照ガイドとしてのベースラインを決定するために使用され得る。この情報は、

既知の空間的構成内に多電極アレイを置き、電気解剖学的特性（例えば、異なる組織の種類のインピーダンスの変動）を検出した後、マッピングすることによって決定され得る。結果として得られる解剖学的マッピングは、異なる組織の種類及び構造を特定するための、インピーダンスの変動による複数の平面における複数（高密度）の活性化順序の構成を含み得る。処置の間、インピーダンス測定は、電極が標的部位における組織との良好な接触を維持しているかを確認するために使用され得る。処置の間及び後、データは、処置中または処置後に記録されたスペクトルが、予測される組織の種類と一致した形状を有するかを決定するために使用され得る。処置後、情報は、標的化された神経が治療的に治療されたかを決定するために使用され得る。

【００９７】

他の実施形態では、神経線維の活動電位は、標的領域内の神経の場所及び／または活性を動的にマッピングするために、電極及びまたは他の接点を介して検出され得る。例えば、記録された活動電位は、高速のニューロン脱分極を数的に測定する、マッピングする、及び／またはその画像を作製して、神経活動の正確な絵を生成するために使用され得る。概して、ニューロン膜の脱分極は、約１１０μＶの電圧における降下を引き起こし得、約２ｍｓを有し、１０００Ωｃｍ～２５Ωｃｍのインピーダンス／抵抗を有する。さらなる実施形態では、活動電位活性に関連付けられる（すなわち、イオン勾配を正常に戻すための）代謝回復プロセスも、標的部位における神経を動的にマッピングするために検出及び使用され得る。これらの特徴に関連付けられる生体電気特性の検出は、変化が遥かに大きく（例えば、およそ１０００倍大きい）、したがって測定がより容易であるという利点を有する。

【００９８】

種々の実施形態では、活動電位の記録を強化するために、非治療的刺激（例えば、ＲＦエネルギー）が、電極アレイのうちの２つ以上の電極を介して検出領域における組織に適用され得る。刺激性エネルギーの適用は、神経線維を一時的に活性化し得、結果として得られる活動電位は、記録され得る。例えば、治療用アセンブリの２つ以上の電極は、エネルギーの刺激性パルスを送達し得、他の２つ以上の電極は、結果として得られる活動電位を検出するように構成され得る。刺激性エネルギーパルスは、活動電位信号を強化し、記録をより容易にすると予測される。

治療的神経調節デバイスの選択される実施形態

【００９９】

図８及び９は、本技術の実施形態に従って構成された治療的神経調節デバイス８０２（「デバイス８０２」）の遠位部分の等角図である。デバイス８０２は、図４～５Ｇを参照して上記に説明される治療的神経調節デバイス４０２及び５０２ａ～ｄの特徴に概して類似の種々の特徴を含み得る。例えば、デバイス８０２は、シャフト４０８の遠位部分４０８ｂにおける治療用アセンブリ８１２を含む。治療用アセンブリ８１２は、分岐４４６を形成し、拡張可能なフレームまたはバスケット４４２を画定する複数の支柱４４０と、支柱４４０のうちの１つ以上の上に配設された１つ以上の電極４４４とを含む。図８及び９に示される通り、デバイス９０２は、支持部材４４８によって担持され、バスケット４４２内で拡張可能である拡張可能な部材８５６（例えば、バルーン）をさらに含み得る。拡張可能な部材８５６は、拡張可能な部材８５６の外側表面上に配設された複数の電極８５８を含み得る。電極８５８は、他の電極４４４を介した治療的神経調節の前、間、及び／または後の標的部位における神経構造のマッピングを可能にするために、生体電気特徴（例えば、インピーダンス）の検出のために使用され得る。他の実施形態では、電極８５８は、治療的神経調節のためのエネルギーを適用するように構成され得る。

【０１００】

図８及び９に示される通り、電極８５８は、実質的に対称な様式及び均一な分布で拡張可能な部材８５６上に位置付けられ得る。これは、それによってインピーダンス及び／または他の特性が組織にわたって検出され得、したがって、治療部位における組織及び神経のより詳細なマッピングを提供する場合がある拡張性アレイを提供する。他の実施形態で

は、電極８５８は、拡張可能な部材８５６の中央部分に向かって、及び／または拡張可能な部材８５６の異なる部分の周りで群化され得る。特定の実施形態では、電極８５８は、特定の極性で選択的に活性化され得、したがって電極アレイは、多様な静的構成で構成され、順序を動的に変化させる（例えば、電流のセスキ極性適用）ことができ、これは、マッピング機能に有利であり得る。

【０１０１】

動作中、拡張可能な部材８５６は、膨張されるか、さもなくば拡張されて（図９）、電極８５８の少なくとも一部分を標的部位において組織と接触して定置し得る。電極８５８は、治療部位における神経を検出する、その場所を決定する、及び／またはそれをマッピングするための組織の種々の生体電気特性（例えば、インピーダンス、活動電位等）を測定し得る。特定の実施形態では、支柱４４０上の電極４４４及び／または拡張可能な部材８５６上の電極８５８の部分は、ＲＦエネルギーの刺激性パルスを適用し得、電極８５８は、結果として得られる神経応答を検出し得る。マッピング後、拡張可能な部材８５６は、収縮されるか、または折り畳まれることができ（図８）、支柱４４０上の電極４４４は、治療的に有効な神経調節エネルギーを標的部位に適用し得る。例えば、電極４４４の切除パターンは、拡張可能な部材８５６上の感知電極８５８から検出された情報を介して特定される神経の場所に基づき得る。他の実施形態では、拡張可能な部材８５６は、神経調節中は拡張されたままであってもよく、電極８５８は、神経調節処置中に神経活動を検出し得るか、または電極８５８は、それ自体が治療部位に神経調節エネルギーを適用するように構成され得る。神経調節エネルギーの適用後、拡張可能な部材８５６上の電極８５８は、再び標的部位において組織と接触して定置され、生体電気特性（例えば、インピーダンス）を記録するために使用され得る。神経調節の前、間、及び／または後に取得される、検出される特性（例えば、インピーダンス）は、神経調節が治療的に有効であったかを決定するために互いに比較され得る。そうではない場合、電極４４４は、同一の治療部位に再び治療的神経調節エネルギーを適用し得るか、または、異なるパターンもしくは順序で治療的神経調節エネルギーを適用するために、活性電極４４４の構成が変化され得るか、及び／または、治療用アセンブリ８１２が、異なる治療部位に移動され得る。

【０１０２】

図１０Ａは、本技術の別の実施形態に従って構成された治療的神経調節デバイス１００２（「デバイス１００２」）の遠位部分の等角図であり、図１０Ｂは、治療部位における図１０Ａの治療的神経調節デバイス１００２を例証する等角図である。デバイス１００２は、図４～５Ｇ、８、及び９を参照して上記に説明される治療的神経調節デバイス４０２、５０２ａ～ｄ、及び８０２の特徴に概して類似の種々の特徴を含み得る。例えば、デバイス１００２は、シャフト１００８と、シャフト１００８の遠位部分１００８ｂにおける治療用アセンブリ１０１２とを含む。治療用アセンブリ１０１２は、分岐１０４６を形成し、拡張可能なフレームまたはバスケット１０４２を画定する複数の支柱１０４０と、支柱１０４０のうちの１つ以上の上に配設された１つ以上の電極１０４４とを含む。図１０Ａに示される通り、デバイス１００２は、シャフト１００８の遠位部分に沿って配設された二次的なまたは戻り電極１０６０をさらに含み得る。例証される実施形態では、戻り電極１０６０は、リング様形状を有するリング電極であるが、他の実施形態では、戻り電極１０６０は、他の形状または構成を有してもよい。

【０１０３】

戻り電極１０６０は、負極性でバイアスされてもよく、支柱１０４０上の電極１０４４の少なくとも一部分は及び／または治療用アセンブリ１０１２の他の部分は、正極性でバイアスされてもよい。図１０Ａ内に矢印によって示される通り、双極性ＲＦエネルギーは、治療用アセンブリ１０１２からシャフト１００８のこの遠位部分１００８ｂ上の戻り電極１０６０に及ぶ領域にわたって、流れ得る。種々の実施形態では、ＲＦエネルギーは、セスキ極性様式で適用され得る（すなわち、不均衡な双極性エネルギー）。

【０１０４】

図１０Ｂに示される通り、治療用アセンブリ１０１２は、ＳＰＦの下方、かつ下鼻甲介

ＩＴならびに口蓋骨を横断するミクロ孔ＭＦ及び神経Ｎの少なくとも一部分の上方に位置付けられ得る。戻り電極１０６０は、下鼻甲介ＩＴならびに口蓋骨を横断するミクロ孔ＭＦ及び神経Ｎの少なくとも一部分の下方に位置付けられ得る。ＲＦエネルギーは次に、治療用アセンブリ１０１２から戻り電極１０６０に及ぶ広い領域にわたって適用され得る。図１０Ｂに示される通り、例えば、デバイス１００２は、高密度のミクロ孔が存在する下鼻甲介の上部及び底部にわたってエネルギーを適用し得る。

【０１０５】

図１１Ａ～１１Ｄは、本技術のさらなる実施形態に従って構成された治療的神経調節デバイス１１０２（個々に第１のデバイス１１０２ａ及び第２のデバイス１１０２ｂと称される）の遠位部分を例証する等角図である。第１のデバイス１１０２ａは、図４～５Ｇ及び８～１０Ｂを参照して上記に説明される治療的神経調節デバイス４０２、５０２ａ～ｄ、８０２、及び１００２の特徴に概して類似の種々の特徴を含み得る。例えば、第１のデバイス１１０２ａは、シャフト１１０８と、シャフト１１０８の遠位部分１１０８ｂにおける治療用アセンブリ１１１２とを含む。治療用アセンブリ１１１２は、可撓性膜１１６２を含み、該可撓性膜１１６２は、可撓性膜１１６２にわたってアレイ内に配列された複数の電極１１４４及び／または他のエネルギー送達要素を担持する。

【０１０６】

図１１Ａ～１１Ｃに示される通り、可撓性膜１１６２は、低プロファイル送達状態（図１１Ａ）から拡張状態（図１１Ｂ）へと自己拡張または機械的拡張手段を介して変形し、鼻腔からデバイスを除去するために、低プロファイル送達または回収状態（図１１Ｃ）に戻るように構成され得る。図１１Ｂに示される拡張状態では、可撓性膜は、可撓性膜１１６２（及びその上に配設された電極１１４４）と非平面的な生体構との間の接触面積を強化するように、鼻の空間（例えば、鼻甲介、洞、及び／または他の鼻傍）の凹凸のある生体構造に適合し得る。可撓性膜１１６２は、電極１１４４を支持するような可撓性で動的な材料から作製され得る。例えば、特定の実施形態では、可撓性膜１１６２は、ポリマーフィラメントならびに／または可撓性膜１１６２に支持及び構造を付加する他の材料を含み得る。種々の実施形態では、可撓性膜１１６２は、所定の形状を保持するために予め設定された幾何学を有し得る。例えば、可撓性膜１１６２及び／または可撓性膜１１６２上の電極アレイは、球面曲率を保持し得る（例えば、図１１Ａに示される通り）。

【０１０７】

種々の実施形態では、シャフト１１０８は、可撓性膜１１６２の展開及び再捕捉を可能にするように、可撓性膜１１６２に対して移動可能であり得る。例えば、可撓性膜１１６２は、送達状態（図１１Ａ）にあるときに、丸められるか、さもなくば円形形状に折り畳まれてもよい。拡張状態（図１１Ｂ）に移動するために、シャフト１１０８の構成要素は、可撓性膜１１６２に対して軸方向に回転及び／または移動されて、可撓性膜１１６２が少なくとも部分的に開き、周囲の生体構造の構造に適合して、電極１１４４を標的部位において組織と接触して定置するように、可撓性膜１１６２をほどくか、さもなくば拡張し得る。撤回された状態（図１１Ｃ）にデバイスを再捕捉するために、シャフト１１０８は、可撓性膜１１６２を近くへ巻くか、さもなくば折り畳むように、軸方向または回転様式で再び移動され得る。

【０１０８】

図１１Ａ～１１Ｃに示される通り、電極１１４４は、例えば、ナノリボン、ナノワイヤ、直接インキング、多方向印刷／沈着、及び／または他の好適な電気コネクタ等の複数のコネクタ１１６４を通じて、相互接続されてもよい。種々の実施形態では、電極１１４４間の相互接続１１６４は、「Ｕ」、「Ｓ」、または楕円形形状を有する周期的な波状の導管または線を含み得る。これらの波状コネクタ１１６４は、可撓性膜１１６２内に多次元ばねを形成する、及び／または標的部位における組織に対する可撓性膜１１６２の並置を促進して、エネルギー伝導率／移動を改善する所定の形状を可撓性膜１１６２に付与してもよい。

【０１０９】

電極１１４４は、可撓性膜１１６２上に表面取り付けされるか、または可撓性膜１１６２の多層の複合構造内に埋め込まれてもよい。種々の実施形態では、電極１１４４は、比較的小さいサイズであってもよく、５０～２，０００ミクロンの範囲の直径を有する。電極１１４４は、単極性、双極性、または多極性様式でエネルギーを送達するように構成されてもよい。例えば、多極性電極は、電極１１４４間の線形及び角度付き（斜め方向）のエネルギー接続性を促進するために、双極性配列及び４極性配列で使用され得る。

【０１１０】

電極１１４４は、シャフト１１０８内に収容された接続パッド、及び／またはハンドルもしくはコンソール等のシャフト１１０８の近位部分に接続された特徴に接続され得る。電極１１４４は、伝導性コネクタケーブル（例えば、金属製ケーブル、ポリマーケーブル、及び／またはそれらの組み合わせ）を通じて接続パッドに接続され得る。

【０１１１】

特定の実施形態では、可撓性膜１１６２はまた、ＲＦエネルギーの送達を制御し、予め定義された治療パラメータを維持するためのフィードバックシステム（図示せず）を収容してもよい。例えば、可撓性膜１１６２の電子回路は、ＲＦエネルギーのエネルギー消散及び貫通深さを制御するための温度フィードバックを提供する熱センサを含んでもよい。可撓性膜１１６２の電子回路の特徴はまた、治療的エネルギー適用の効果を決定するために、治療部位における抵抗及び温度を測定してもよい。この情報は、エネルギー適用を調整し、宿主組織への二次的損傷を回避するために使用されてもよい。例えば、電極１１４４を介したエネルギー送達は、検出される温度及び／または抵抗が所定の閾値最大値（例えば、組織損傷に関連付けられる閾値温度）に到達した場合に、自動的に終了されてもよい。電極１１４４を介したエネルギー送達は、検出される温度及び／または抵抗が、副交感性鼻神経の治療的に有効な調節に関連付けられるパラメータを示す所定の閾値範囲を下回る場合に、自動的または手動的に調整されてもよい。他の実施形態では、フィードバックシステムは、可撓性膜１１６２上の電極１１４４及び任意の追加的なセンサに通信可能に連結された構成要素に組み込まれ得る。例えば、フィードバックシステムは、図２のコンソール２０４上に保存され、制御装置２１８（図２）によって実行され得る。

【０１１２】

図１１Ｄに示される実施形態では、第２のデバイス１１０２ｂは、図１１Ａ～１１Ｃを参照して上記に説明される第１のデバイス１１０２ａの特徴に概して類似の種々の特徴を含み得る。例えば、図１１Ｄのデバイス１１０２ｂは、可撓性膜１１６２を含み、該可撓性膜１１６２は、可撓性膜１１６２上に配設されるか、またはその中に埋め込まれた複数の電極１１４４及び関連する電気コネクタ１１６４を担持する。デバイス１１０２ｂは、可撓性膜１１６２を担持する拡張可能なフレーム１１６６をさらに含む。フレーム１１６６は、Ｕ字形状を有してもよく、形状記憶材料（例えば、ニチノール）から作製され得る。他の実施形態では、フレームは、異なる形状を有してもよく、及び／または可撓性膜１１６２を支持するのに好適な異なる材料から作製されてもよい。

【０１１３】

動作中、フレーム１１６６は、鼻腔の生体構造に対する可撓性膜１１６２の展開を促進し、可撓性膜１１６２及び関連する電極１１４４のアレイのための支持を提供する。Ｕ字型フレーム１１６６は、標的部位において非平面的な生体構造に接触する可撓性膜１１６２の能力を強化し得る。種々の実施形態では、例えば、フレーム１１６６は、標的の表面組織に対する膜１１６２の正方向の並置を確立し、電極１１４４から標的組織へのエネルギー伝導率／移動を改善するための片持ちばねとして機能してもよい。

【０１１４】

図１２は、本技術のさらなる実施形態に従って構成された治療的神経調節デバイス１２０２（「デバイス１２０２」）の遠位部分の側面図である。デバイス１２０２は、図４～５Ｇ及び８～１１を参照して上記に説明される治療的神経調節デバイス４０２、５０２ａ～ｄ、８０２、１００２、及び１１０２の特徴に概して類似の種々の特徴を含む含む。例えば、デバイス１２０２は、シャフト１２０８と、シャフト１２０８の遠位部分１２０８

ｂにおける、電極１２４４等の複数のエネルギー送達要素を含む治療用アセンブリ１２１２とを含む。例証される実施形態では、治療用アセンブリ１２１２は、シャフト１２０８の遠位部分１２０８ｂにおいて渦巻き／螺旋形セクション１２６８に沿って配列された４つの電極１２４４を含む。他の実施形態では、しかしながら、治療用アセンブリ１２１２は、１、２、３、もしくは４つを超える電極１２４４を含んでもよく、及び／または異なるエネルギー送達要素を含んでもよい。治療用アセンブリ１２１２はまた、治療的神経調節エネルギーの適用の前、間、及び／または後に治療部位における種々の特性を検出し、治療用アセンブリ１２１２の動作を制御するために使用され得るフィードバックを提供するための温度センサ１２５２（例えば、熱電対）及び／または他の種類のセンサを含み得る。かかるセンサは、本明細書に開示される治療用アセンブリの他の実施形態のいずれかに組み込まれ得る。

【０１１５】

治療用アセンブリ１２１２の送達中、シャフト１２０８の渦巻き／螺旋形セクション１１６８は、セクション１２６８が、導入器鞘内に及び／またはシャフト１２０８に関連付けられる機械的構成要素を介して実質的に狭められるかまたは平坦にされる、低プロファイル送達状態に位置付けられ得る。標的部位において、操作者は、渦巻き／螺旋形セクション１２６８を拡張状態（図１２に示される）に変形させて、電極１２４４のうちの１つ以上を標的組織と接触して定置し得る。電極１２４４のうちの１つ以上は次に、ＲＦエネルギー（例えば、単極性及び／または双極性ＲＦエネルギー）を鼻領域内の標的部位における組織に適用して、治療部位の近位の神経を治療的に調節するために、選択的に活性化され得る。他の実施形態では、シャフト１２０８の遠位セクションは、標的部位において組織と接触した電極１２４４の定置を促進する他の好適な形状、サイズ、及び／または構成を有し得る。例えば、さらなる実施形態では、シャフト１２０８の遠位部分１２０８ｂは、半円形の、湾曲した、曲がった、もしくは直線の形状を有し得、及び／または治療用アセンブリ１２１２は、電極１２４４のうちの１つ以上を担持するように構成された複数の支持部材を含み得る。

【０１１６】

図１３は、本技術のまたさらなる実施形態に従って構成された治療的神経調節デバイス１３０２（「デバイス１３０２」）の遠位部分の側面図である。デバイス１３０２は、図４～５Ｇ及び８～１２を参照して上記に説明される治療的神経調節デバイス４０２、５０２ａ～ｄ、８０２、１００２、１１０２、及び１２０２の特徴に概して類似の種々の特徴を含む含む。例えば、デバイス１３０２は、シャフト１３０８と、シャフト１３０８の遠位部分１３０８ｂにおける、電極１３４４のアレイ等の複数のエネルギー送達要素を含む治療用アセンブリ１３１２とを含む。図１３に例証される実施形態では、治療用アセンブリ１３１２は、電極１３４４を担持するバルーン１３７０を含む。支持部材１３７２は、バルーン１３７０を支持するようにバルーン１３７０の長さを通って延在し、任意に、標的部位への治療用アセンブリ１３１２の送達を促進するようにガイドワイヤ（図示せず）がそれを通って延在し得るチャネルを含み得る。他の実施形態では、支持部材１３７２は、省略されてもよい。

【０１１７】

電極１３４４は、バルーン１３７０の表面上に印刷された、噴霧された、及び／または別の方法で配設された伝導性インクから作製され得る。かかる伝導性インク電極は、複雑な電極構成の使用を促進する。それに加えて、熱電対（図示せず）もまた、伝導性インク及び／または他の好適な方法を使用して、バルーン１３７０の表面上に組み込まれ得る。他の実施形態では、電極１３４４は、箔から作製され、バルーン１３７０の表面に接着され得る。さらなる実施形態では、電極１３４４は、バルーン１３７０の表面上に配設されてもよい、及び／またはバルーン１３７０の材料内に埋め込まれてもよい、他の好適な材料から作製され得る。

【０１１８】

バルーン１３７０は、種々の異なる材料から作製され、種々の異なる形状を有し得る。

例えば、図１３に示される通り、バルーン１３７０は、拡張状態にあるときに卵形形状を有し得、これは、鼻腔内の標的部位における解剖学的変異への適合を改善すると予測される。他の実施形態では、バルーン１３７０は、円形形状、球体形状、不規則な形状、及び／または鼻の生体構造内で拡張のための他の好適な形状を有し得る。バルーン１３７０は、バルーン１３７０が鼻領域内で拡張されるときに、解剖学的相違に適合することを可能にする柔軟性材料（例えば、ウレタン材料）から作製され得る。他の実施形態では、バルーンは、バルーン１３７０が拡張されるときに定義された形状を有することを可能にし、バルーン表面への電極１３４４の取着を促進する非柔軟性材料（例えば、ポリエチレン、テレフタレート、ナイロン等）から作製されてもよい。さらなる実施形態では、バルーン１３７０は、浸漬被覆され、シャフト１３０８の遠位端部に球形の先端を形成してもよい。

【０１１９】

バルーン１３７０は、支持部材１３７２内の開口もしくはポート１３７４及び／またはバルーン１３７０の内側と流体連通しているシャフト１３０８内の開口を介して、流体によって膨張されてもよい。例えば、支持部材１３７２及び／またはシャフト１３０８は、流体がバルーン１３７０に送達され得るように、シャフト１３０８の長さに沿って延在し、シャフト１３０８の近位部分における流体供給に接続されたチャネルを含み得る。バルーン１３７０は、標的部位における鼻の生体構造に接して膨張して、電極１３４４を標的部位において組織と接触して定置し得る。

【０１２０】

標的部位において、電極１３４４は、ＲＦエネルギーを組織に送達して、治療部位における神経を治療的に調節する。特定の実施形態では、電極１３４４のアレイは、バルーン１３７０の半径方向領域にわたって横方向の双極性ＲＦエネルギーを適用するように、バルーン１３７０上に配列される、及び／または選択的に活性化され得る（すなわち、バルーン１３７０の円周部分の周りを延在する）。他の実施形態では、電極１３４４のアレイは、バルーン１３７０の長手方向領域にわたって長手方向の双極性ＲＦエネルギーを適用するように、バルーン１３７０上に配列される、及び／または選択的に活性化され得る（すなわち、バルーン１３７０の近位部分と遠位部分との間に延在する）。

【０１２１】

種々の実施形態では、治療用アセンブリ１３１２は、鼻の生体構造内でのバルーン１３７０の位置付け及び治療部位における電極１３４４の適切な定置を促進する特徴を含んでもよい。例えば、図１３に示される通り、内視鏡１３７１は、標的部位における定置中にバルーン１３７０及び標的部位の直接的な直列の視覚化を提供するように、バルーン１３７０の表面上に位置付けられてもよい。治療用アセンブリ１３１２はまた、治療用アセンブリ１３１２の空間的配向及び／または深さ位置付けを示すための、支持部材１３７２及び／またはバルーン１３７０の表面に沿った段階的マーキング１３７３も含み得る。

【０１２２】

特定の実施形態では、バルーン１３７０は、バルーン壁を通る流体の低速灌流を可能にし、エネルギーが標的組織に適用される間に電極１３４４を冷却するように構成され得る。例えば、かかる「浸出」バルーン１３７０は、バルーン壁を通る流体（例えば、生理食塩水溶液）の低速灌流を可能にするために、バルーン１３７０の少なくとも一部分に沿って、レーザー穴明け機穴及び／または他の小さい開口もしくは孔を含み得る。バルーンが生理食塩水溶液を灌流させるとき、生理食塩水溶液は、電極１３４４と標的組織との間の電気伝導率を改善すると予測され、標的部位における神経に対するＲＦエネルギーの効果を強化し得る。他の実施形態では、冷却された流体は、電極１４４４の活性化中にバルーン１４７０を通して循環されて、エネルギー送達中に電極１４４４及び周囲の組織を冷却し得る。

【０１２３】

図１４は、本技術の追加的実施形態に従って構成された治療的神経調節デバイス１４０２（「デバイス１４０２」）の遠位部分の側面図である。デバイス１４０２は、図１３を

参照して上記に説明される治療的神経調節デバイス１３０２の特徴に概して類似の種々の特徴を含む含む。例えば、デバイス１４０２は、シャフト１４０８と、シャフト１４０８の遠位部分１４０８ｂにおける治療用アセンブリ１４１２とを含む。治療用アセンブリ１４１２は、バルーン１４７０と、バルーン１４７０を支持する支持部材１４７２と、バルーン１４７０上に配設された電極１４４４のアレイ等の複数のエネルギー送達要素とを含む。図１４に例証される実施形態では、電極１４４４は、バルーン１４７０の表面に接着されたフレックス回路１４７６の一部である。フレックス回路１４７６は、高度にカスタマイズ可能な神経調節パターンを作成し得る複雑な電極アレイの作成を促進する。特定の実施形態では、例えば、フレックス回路１４７６は、バルーン１４７０の表面に沿った伝導性の戻り電極と、バルーン１４７０の近位または遠位部分（例えば、バルーン１４７０の円錐形端部部分）上の複数の電極とを含み得る。それに加えて、フレックス回路１４７６は、エネルギー適用の前、間、及び／または後に治療部位における温度を検出するために、熱電対及び／またはサーミスタを、バルーン１４７０の表面上の回路に組み込み得る。

【０１２４】

図１５は、本技術の追加的実施形態に従って構成された治療的神経調節デバイス１５０２（「デバイス１５０２」）の遠位部分の等角側面図である。デバイス１５０２は、図１３及び１４を参照して上記に説明される治療的神経調節デバイス１３０２及び１４０２の特徴に概して類似の種々の特徴を含む含む。例えば、デバイス１５０２は、シャフト１５０８と、シャフト１５０８の遠位部分１５０８ｂにおける治療用アセンブリ１５１２とを含む。治療用アセンブリ１５１２は、内側支持部材１５８０の周りに位置付けられた複数のバルーン１５７８と、バルーン１５７８のうちの１つ以上の上に配設された電極１５４４等の複数のエネルギー送達要素とを含む。特定の実施形態では、バルーン１５７８は、独立して膨張可能である。これは、バルーン１５７８の非対称で可変的な膨張を可能にし、それによって、治療用アセンブリ１５１２の、標的部位における鼻領域の凹凸のある幾何学に適合する能力を強化し、標的部位における組織に対する電極１５４４の並置を促進する。

【０１２５】

例証される実施形態では、４つの独立して膨張されるバルーン１５７８が、内側支持部材１５８０の外周の周りに位置付けられる。しかしながら、他の実施形態では、デバイス１５０２は、内側支持部材１５８０の周りに配列された４つ未満のバルーン１５７８または４つ超のバルーン１５７８を含み得る。さらなる実施形態では、バルーン１５７８は、異なるサイズ及び／または形状を有し得、内側支持部材１５８０の種々の部分に沿って位置付けられ得る。またさらなる実施形態では、バルーン１５７８は、端部部分において内側支持部材１５８０に取着され、膨張される（例えば、図４の治療的神経調節デバイス４０２の支柱４４０に類似の様式で）ときに内側支持部材１５８０から外向きに延在する支柱として構成される。

【０１２６】

エネルギー送達中、電極１５４４は、異なるバルーン１５７８上の電極１５４４にわたって、及び／または同一のバルーン１５７８上の電極１５４４間に双極性ＲＦエネルギーを適用するように構成され得る。他の実施形態では、電極１５４４は、セスキ極性様式でエネルギーを適用する。例えば、内側支持部材１５８０は、戻り電極（図示せず）を含み得、バルーン１５７８のうちの２つ以上の上の電極１５４４が、セスキ極性ＲＦエネルギー送達のために活性化されてもよい。

【０１２７】

図１６は、本技術の追加的実施形態に従って構成された治療的神経調節デバイス１６０２（「デバイス１６０２」）の遠位部分の側面断面図である。デバイス１６０２は、上記に説明される治療的神経調節デバイスの特徴に概して類似の種々の特徴を含む。例えば、デバイス１６０２は、シャフト１６０８と、シャフト１６０８の遠位部分１６０８ｂにおける治療用アセンブリ１６１２とを含む。図１６に例証される実施形態では、治療用アセ

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ンブリ１６１２は、凍結治療的冷却を適用して、標的部位における神経を治療的に調節するように構成される。図１６に示される通り、凍結治療用アセンブリ１６１２は、供給ルーメン１６８４内の対応する開口部１６８６を介して１つ以上の供給管またはルーメン１６８４と流体連通する拡張チャンバ１６８２（例えば、バルーン、膨張可能な本体等）を含み得る。供給ルーメン１６８２は、シャフト１６０８の少なくとも一部分に沿って延在し、少なくとも部分的に液体状態の冷却材をシャフト１６０８の遠位部分１６０８ｂに輸送するように構成され得る。排出管またはルーメン１６８９（例えば、シャフト１６０８の一部分によって画定される）は、排出ルーメン１６８９が冷却剤をシャフト１６０８の近位部分に戻し得るように、出口１６８８を介して拡張チャンバ１６８２の内側と流体連通して定置され得る。例えば、一実施形態では、排出ルーメン１６８９を介して拡張チャンバ１６８２から冷却剤を排出するために、シャフト１６０８の近位部分における真空（図示せず）が使用されてもよい。他の実施形態では、冷却剤は、当業者に既知の他の好適な機構を使用してシャフト１６０８の近位部分に輸送されてもよい。

【０１２８】

凍結療法中、供給ルーメン１６８４の開口部１６８６は、冷却剤の流れを制限し、供給ルーメン１６８４と拡張チャンバ１６８２との間に高い圧力差を提供し、それによって、拡張チャンバ１６８２内での冷却剤の気相への拡張を促進し得る。液体冷却剤が開口部１６８２を通過する際の圧力降下は、冷却剤を気体に拡張させ、温度を、鼻腔内の治療部位の近位の神経線維を調節し得る治療的に有効な温度に低減する。例証される実施形態では、拡張チャンバ１６８２は、標的部位において組織と接触し、鼻粘膜を神経支配する節後副交感神経線維の凍結治療的神経調節を引き起こすのに十分な速度でそれを冷却する伝熱部分１６９１を含む。例えば、治療用アセンブリ１６０２は、－４０℃、－６０℃、－８０℃以下の温度で動作し得る。他の実施形態では、治療用アセンブリ１６０２は、より高い凍結治療的温度（例えば、５℃及び－１５℃、－２０℃等）で動作され得る。

【０１２９】

デバイス１６０２における極低温冷却に使用される冷却剤は、例えば、亜酸化窒素（N_2O）、二酸化炭素（CO_2）、ハイドロフルオロカーボン（例えば、Ｗｉｌｍｉｎｇｔｏｎ、ＤＥのＥ．Ｉ．ｄｕ　Ｐｏｎｔ　ｄｅ　Ｎｅｍｏｕｒｓ　ａｎｄ　Ｃｏｍｐａｎｙによって製造され、入手可能であるＦＲＥＯＮ）、及び／または概ね周囲温度において少なくとも実質的に液相であるのに十分に高い圧力で保管され得る他の好適な流体等の、少なくとも実質的に液相で保管される圧縮または凝縮された気体であり得る。例えば、ジフルオロメタン（CH_2F_2、ＨＦＣ－３２またはＲ－３２としても知られる）及びペンタフルオロエタン（CHF_2CF_3、ＨＦＣ－１２５またはＲ－１２５としても知られる）の非共沸性であるが共沸性に近い混合物であるＲ－４１０Ａは、約１．４５ＭＰａ（２１０ｐｓｉ）の圧力で含有されるとき、概ね周囲温度において少なくとも実質的に液相であり得る。適切な条件下で、これらの冷却剤は、治療的神経調節をもたらすために、それらのそれぞれの標準沸点（例えば、亜酸化窒素に関してはおよそ－８８℃）において、またはその付近で凍結治療的温度に到達し得る。

【０１３０】

他の実施形態では、治療用アセンブリ１６１２は、図１６の拡張チャンバ１６８２というよりもむしろ、凍結治療用アプリケータを含み得る。かかる凍結治療用アプリケータは、神経の非常に標的化された治療のために使用され得る。

【０１３１】

図１６にさらに示される通り、デバイス１６０２はまた、拡張チャンバ１６８２を通って延在し、拡張チャンバ１６８２の遠位部分を担持するように構成された支持部材１６９０も含み得る。支持部材１６９０はまた、ガイドワイヤＧＷを介した治療部位への治療用アセンブリ１６１２の送達を促進するために、その長さに沿って延在するチャネルと支持部材１６９０の遠位端部部分における開口１６９２とも含み得る。

【０１３２】

図１７は、本技術の追加的実施形態に従って構成された治療的神経調節デバイス１７０

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２（「デバイス１７０２」）の遠位部分の側面断面図である。デバイス１７０２は、上記に説明される治療的神経調節デバイスの特徴に概して類似の種々の特徴を含む。例えば、デバイス１７０２は、シャフト１７０８と、シャフト１７０８の遠位部分１７０８ｂにおける治療用アセンブリ１７１２とを含む。図１７に例証される実施形態では、治療用アセンブリ１７１２は、標的部位における神経を熱的に治療的に調節するために、直接伝導加熱を適用するように構成される。図１７に示される通り、治療用アセンブリ１７１２は、供給ルーメン１７９４の遠位部分における出口を介して供給管またはルーメン１７９４（例えば、シャフト１７０８の一部分によって画定される）と流体連通するバルーン１７７０を含み得る。供給ルーメン１７９４は、シャフト１７０８の少なくとも一部分に沿って延在し、加熱された流体（例えば、加熱された生理食塩水）をシャフト１７０８の遠位部分１７０８ｂにおけるバルーン１７７０に輸送するように断熱され得る。排出または戻り管またはルーメン１７９６（例えば、シャフト１７０８の一部分によって画定される）は、戻りルーメン１７９６が（例えば、シャフト１７０８の近位部分における真空を使用して）流体をシャフト１７０８の近位部分に排出し得るように、出口を介してバルーン１７７０の内側と流体連通して定置され得る。

【０１３３】

熱的な治療的神経性調節中、供給ルーメン１７９４は、加熱された流体をバルーン１７７０に供給し得、排出ルーメン１７９６は、流体をバルーン１７７０から排出するために使用され得、その結果、加熱された流体は（例えば、矢印によって示される通り）バルーン１７７０を通って循環する。加熱された流体は、鼻腔内の治療部位における標的組織に対して時間依存性の熱損傷（例えば、アレニウスの式を使用して決定される）を引き起こし、加熱された標的組織の内部またはその近位の神経線維を調節する、治療的に有効な温度に加熱され得る。例証される実施形態では、例えば、バルーン１７７０の壁及び／またはその一部分は、標的部位において組織と接触し、標的組織に対して熱損傷を引き起こし、鼻粘膜を神経支配する節後副交感神経線維の治療的神経調節を提供するのに十分な速度及び時間で組織を加熱し得る。

【０１３４】

図１７に示される通り、デバイス１７０２はまた、バルーン１７７０を通って延在し、バルーン１７７０の遠位部分を担持するように構成された支持部材１７９０も含み得る。支持部材１７９０はまた、その長さに沿って延在するチャネルと、ガイドワイヤＧＷを介した治療部位への治療用アセンブリ１７１２の送達を促進するために使用され得る、支持部材１７９０の遠位端部部分における開口１７９２とも含み得る。

【０１３５】

図１８は、本技術の追加的実施形態に従って構成された治療的神経調節デバイス１８０２（「デバイス１８０２」）の遠位部分の側面断面図である。デバイス１８０２は、上記に説明される治療的神経調節デバイスの特徴に概して類似の種々の特徴を含む。例えば、デバイス１８０２は、シャフト１８０８と、シャフト１８０８の遠位部分１８０８ｂにおける治療用アセンブリ１８１２とを含む。治療用アセンブリ１８１２は、膨張可能なバルーン１８７０と、バルーン１８７０を通って延在する支持部材１８９０とを含み得る。支持部材１８９０はまた、治療部位への治療用アセンブリ１８１２のガイドワイヤ送達を可能にする開口１８９２を有するチャネルを含んでもよい。

【０１３６】

図１７の治療用アセンブリ１７１２と同様に、治療用アセンブリ１８１２は、標的部位における組織に治療的に有効な加熱を適用して、時間依存性の熱的組織損傷（例えば、アレニウスの式を使用して決定される）を引き起こし、加熱された標的組織の内部またはその近くの神経線維を調節し得る。しかしながら、図１８に例証される実施形態では、加熱は、バルーン１８８０内に位置付けられ、支持部材１８９０及び／または治療用アセンブリ１８１２の別の特徴によって担持される加熱要素１８９８を介して供給される。加熱要素１８９８は、抵抗加熱（生成器を介する）及び／または他の好適な加熱機構を使用して加熱されるプレートまたは他の構造であってもよい。動作中、加熱要素１８９８からの熱

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は加熱要素１８９８からバルーン１８７０内の流体に、次にバルーン１８７０の壁を通して、治療部位における隣接した組織に移動し得る。加熱要素１８９８によって加熱された流体は、鼻腔内の治療部位における標的組織に対して熱損傷を引き起こし、加熱された標的組織の内部またはその近位の神経線維を調節する、治療的に有効な温度に加熱され得る。特定の実施形態では、バルーン１８７０は、加熱効果をバルーン１８７０の標的化された領域に集中させるために、その表面上に伝導性特徴（例えば、金属製パネル）を含み得る。

【０１３７】

他の実施形態では、バルーン１８７０は、鼻腔内の治療部位における標的組織に対する熱損傷を引き起こし、加熱された標的組織の内部またはその近くの神経線維を調節する治療的に有効な温度に到達するように、容量結合を介して加熱され得る。例えば、バルーン１８７０は、等張液を用いて膨張され得、バルーン１８７０は、高周波数でイオン的に撹拌されて、容量エネルギーがバルーン１８７０の膜にわたって標的組織へと放出することを可能にし得る。

【０１３８】

図１９は、本技術の追加的実施形態に従って構成された治療的神経調節デバイス１９０２（「デバイス１９０２」）の遠位部分の側面図である。デバイス１９０２は、上記に説明される治療的神経調節デバイスの特徴に概して類似した種々の特徴を含む。例えば、デバイス１９０２は、シャフト１９０８と、シャフト１９０８の遠位部分１９０８ｂにおける治療用アセンブリ１９１２とを含む。図１９に例証される実施形態では、治療用アセンブリ１９１２は、標的部位における神経を治療的に調節するために、プラズマまたはレーザー切除を適用するように構成される。図１９に示される通り、治療用アセンブリ１９１２は、シャフト１９０８の遠位端部部分上に切除要素１９９９（例えば、電極）を含み得る。切除要素１９９９は、高エネルギーレーザーパルスを適用して、パルスの初めの少量の部分内の分子をイオン化し得る。このプロセスは、標的部位における組織及び神経を乾燥させるか、さもなくば破壊するために使用され得るプラズマの小泡または場（例えば、１００～２００μｍ）を導く。切除要素１９９９は、１００℃未満の温度で動作し得、周囲の組織に対する熱的効果を制限し得る。

【０１３９】

他の実施形態では、切除要素１９９９は、標的部位における神経のレーザー切除を実施し得る。例えば、神経トレーサー（例えば、インドシアニングリーン（ＩＣＧ））が、標的部位における神経を染色するために標的部位に注入され得る。切除要素１９９９は、神経トレーサーのスペクトルを吸収するように調整され、それによって標的部位において染色された神経を切除するレーザーであり得る。

【０１４０】

慢性副鼻腔炎の治療のための治療的神経調節の選択された実施形態

図２０は、本技術の実施形態に従って構成された治療的神経調節デバイスのための、鼻洞の小孔の近位の標的部位を例証する部分切り欠き側面図である。上記に説明される治療的調節デバイス及びシステムのいずれも、慢性副鼻腔炎及び／または類似の兆候を治療するために、副鼻洞を神経支配する神経を治療的に調節するために使用され得る。図２０を参照すると、副鼻洞は、前頭洞ＦＳ、蝶形骨洞ＳＳ、上顎洞（「ＭＳ」、図示せず）、ならびに後篩骨細胞（「ＰＥＣ」）、中篩骨細胞（「ＭＥＣ」）、及び前篩骨細胞（「ＡＥＣ」）を含む篩骨洞または篩骨細胞（図示せず）を含む。各洞は、１つ以上の個別の小孔において鼻腔に対して開いている。図２０は、前頭洞、蝶形骨洞、上顎洞の小孔、ならびに後、中、及び前篩骨細胞の小孔の一般的な場所を例証する。

【０１４１】

副交感神経は、洞の粘膜を神経支配し、洞内の粘液の産生を刺激する。洞を神経支配する副交感神経の過剰活性は、粘液の過剰産生及び軟組織の鬱血を引き起こし得る。洞の近位の軟組織の炎症は、引き起こし得、洞と鼻腔との間の導管を塞ぎ、洞への小孔を遮断し得る。それに加えて、過活動粘膜及び／または小孔の詰まりは、洞からの排出の不足に起

因して生じる洞内の粘膜分泌物の滞留を引き起こし得る。これは、感染を導き、最終的には慢性副鼻腔炎の状態を導き得る。

【０１４２】

洞の自律神経機能を制御する副交感神経の治療的調節は、過活動粘膜分泌及び軟組織の鬱血を低減及び排除し、それによって慢性副鼻腔炎または関連する兆候を治療することが期待される。上記に説明される治療的神経調節デバイスのいずれも、罹患した蝶形骨洞、上顎洞、前頭洞、及び／または篩骨洞の小孔において、またはその近位に治療的に有効な神経調節エネルギーを適用して、洞の自律神経機能を調節するために使用され得る。例えば、治療的神経調節デバイスは、洞の小孔における、またはその周りの治療部位に、ＲＦエネルギー、マイクロ波エネルギー、超音波エネルギー、凍結治療的冷却、治療的加熱、プラズマ切除、及び／またはレーザー切除を適用するために使用され得る。上記に説明されるデバイスと同様に、治療的神経調節デバイスは、所望の洞の小孔（複数可）に接近するために、鼻孔を介し、上鼻道、中鼻道、及び／または下鼻道を通って腔内に送達され得る。種々の実施形態では、図６Ａ～９に関して上記に説明されるものに類似の神経マッピング技法が、治療の前、間、及び／または後に、小孔を神経支配する副交感神経の場所決定または検出のために使用され得る。洞の小孔の近位の標的部位における治療的神経調節の適用は、洞組織への副交感神経信号を乱し、小孔の開放及び流体を排出する能力を導き得る。

追加的な実施例

１．ヒト患者の鼻領域における治療的神経調節のためのシステムであって、

近位部分及び遠位部分を有するシャフトであって、該遠位部分を、該ヒト患者の蝶口蓋孔の下方の標的部位に、腔内に配置するように構成される、シャフトと、

該シャフトの該遠位部分における治療用アセンブリであって、該ヒト患者の口蓋骨のミクロ孔において鼻粘膜を神経支配する節後副交感神経を治療的に調節するように構成されたエネルギー送達要素を備える、治療用アセンブリと、を備える、システム。

２．該エネルギー送達要素が、該節後副交感神経を治療的に調節するために、超音波エネルギー、マイクロ波エネルギー、レーザーエネルギー、または無線周波数（ＲＦ）エネルギーのうちの少なくとも１つを送達するように構成される、実施例１のシステム。

３．該治療用アセンブリが、該節後副交感神経を化学的に調節するために、薬物を分注するように構成される、実施例１または２のシステム。

４．該シャフトが、該シャフトの該遠位部分に出口を有する薬物送達チャネルを備え、該薬物送達チャネルが、局所麻酔薬または神経ブロックのうちの少なくとも１つを該標的部位に送達するように構成される、実施例１～３のいずれか１つのシステム。

５．該シャフトが、該シャフトの該遠位部分に出口を有する流体チャネルを備え、該流体チャネルが、該標的部位に生理食塩水を送達して、該治療エリアを生理食塩水で濯ぐように構成される、実施例１～４のいずれか１つのシステム。

６．剛性金属部分を有する導入器をさらに備え、該剛性金属部分が、該標的部位に該治療用アセンブリを送達するために、鼻道を通って該標的部位に延在するようにサイズ決定及び成形される、実施例１～５のいずれか１つのシステム。

７．該シャフトが、操縦可能なカテーテルシャフトであり、該シャフトの該遠位部分が、３ｍｍ以下の曲げ半径を有する、実施例１～６のいずれか１つのシステム。

８．該シャフトの該遠位部分が、３ｍｍ以下の曲げ半径を有するようにサイズ決定及び成形された剛性リンクを有する関節運動領域を備える、実施例１～６のいずれか１つのシステム。

９．該シャフトに沿って固定部材をさらに備え、該固定部材が、該鼻領域の腔内で拡張して、該シャフトの該遠位部分を、該標的部位に該治療用アセンブリを展開するのに適切な位置に保持するように構成されたバルーンを含む、実施例１～８のいずれか１つのシステム。

１０．該治療用アセンブリの該エネルギー送達要素が、節後副交感神経を治療的に調節するためのＲＦエネルギーを適用するように構成された複数の電極を備える、実施例１～９

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のいずれか１つのシステム。
１１．該治療用アセンブリが、治療的調節前、治療的調節中、または治療的神経調節後のうちの少なくとも１つの神経活動を検出するように構成された複数の感知電極を備える、実施例１～１０のいずれか１つのシステム。
１２．該治療用アセンブリが、
低プロファイル送達状態と拡張状態との間で変形可能なバスケットであって、該バスケットが該拡張状態にあるときに互いに半径方向に離間される複数の支柱を含む、バスケットと、
該支柱上に配設された複数の電極であって、該複数の支柱が、該バスケットが該拡張状態にあるときに、該電極のうちの少なくとも２つを該標的部位に位置付けるように構成された、複数の電極と、を備え、
該電極が、該標的部位に、該標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを適用するように構成される、実施例１～１１のいずれか１つのシステム。
１３．該治療用アセンブリが、
低プロファイル送達状態と拡張状態との間で変形可能な可撓性膜と、
該可撓性膜上に配設された複数の電極と、を備え、
該電極が、該標的部位に、該標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを適用するように構成される、実施例１～１１のいずれか１つのシステム。
１４．該治療用アセンブリが、該可撓性膜を支持するフレームをさらに備える、実施例１３のシステム。
１５．該シャフトの該遠位部分が、低プロファイル送達状態と拡張状態との間で変形可能であり、
該シャフトの該遠位部分が、該シャフトの該遠位部分が該拡張状態にあるときに、渦巻き／螺旋形状を有し、
該エネルギー送達要素が、該シャフトの該遠位部分上に配設され、該標的部位に、該標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを送達するように構成された複数の電極を備え、
該シャフトの該遠位部分が、該シャフトの該遠位部分が該拡張状態にあるときに、該電極のうちの少なくとも１つを該標的部位において組織と接触して定置するように構成される、実施例１～１１のいずれか１つのシステム。
１６．該治療用アセンブリが、
低プロファイル送達状態と拡張状態との間で変形可能なバルーンと、
該バルーン上に配設された複数の電極であって、該標的部位に、該標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを送達するように構成された、複数の電極と、を備える、実施例１～１１のいずれか１つのシステム。
１７．該バルーンが、該バルーンが該拡張状態にあるときに、該バルーンを通る流体の灌流を可能にするように構成された複数の穴を備える、実施例１６のシステム。
１８．該バルーンを通って延在する支持体と、
該バルーンの空間的位置付けを特定するための、該支持体または該バルーンのうちの少なくとも１つの上の複数の段階的マーキングと、をさらに備える、実施例１６のシステム。
１９．該治療用アセンブリが、
低プロファイル送達状態と拡張状態との間で変形可能なバルーンであって、近位錐体部分を備える、バルーンと、
該バルーン上の戻り電極と、
該近位錐体部分上のフレックス回路であって、該戻り電極及び該フレックス回路が、該標的部位に、該標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを送達するように構成される、フレックス回路と、を備える、実施例１～１

１のいずれか１つのシステム。
２０．該治療用アセンブリが、
該シャフトの該遠位部分から遠位に延在する複数のバルーンであって、独立して拡張可能である、バルーンと、
該バルーンの各々の上の少なくとも１つの電極であって、該標的部位に、該標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを送達するように構成された、電極と、を備える、実施例１～１１のいずれか１つのシステム。
２１．該バルーンの間の領域を通って延在し、該バルーンを担持するように構成された内部支持部材であって、戻り電極を含む、内部支持部材をさらに備える、実施例２０のシステム。
２２．該治療用アセンブリが、該標的部位において組織に極低温冷却を適用して、自律神経活動を治療的に調節するように構成された凍結治療用バルーンを備える、実施例１～９のいずれか１つのシステム。
２３．該治療用アセンブリが、拡張されるときに標的状態において組織と接触するようにサイズ決定及び成形されたバルーンを備え、該バルーンが、少なくとも６０℃に加熱された流体を循環させて、自律神経活動を熱的に調節するように構成される、実施例１～９のいずれか１つのシステム。
２４．該治療用アセンブリが、
流体と共に拡張されるように構成されたバルーンであって、拡張されるときに該標的状態において組織と接触するようにサイズ決定及び成形された、バルーンと、
該バルーン内の加熱部材であって、該バルーン内で該流体を加熱して、自律神経活動を熱的に調節するように構成された加熱部材と、を備える、実施例１～９のいずれか１つのシステム。
２５．該治療用アセンブリが、プラズマ切除プローブを備える、実施例１～９のいずれか１つのシステム。
２６．ヒト患者の鼻領域における治療的神経調節のためのシステムであって、
近位部分及び遠位部分を有するシャフトであって、該遠位部分を標的部位に腔内に配置するように構成され、該標的部位が、ヒト患者の蝶口蓋孔の近位または該蝶口蓋孔の下方のうちの少なくとも１つである、シャフトと、
該シャフトの該遠位部分にあり、低プロファイル送達状態と拡張状態との間で変形可能である治療用アセンブリであって、複数の支柱及び該支柱上に配設された複数の電極を備え、該複数の支柱が、該治療用アセンブリが該拡張状態にあるときに、該電極のうちの少なくとも２つを該ヒト患者の蝶口蓋孔の下方の該標的部位に位置付けるバスケットを形成する、治療用アセンブリと、を備え、
該電極が、該標的部位に、該標的部位の近位の副交感神経を治療的に調節するための無線周波数（ＲＦ）エネルギーを適用するように構成される、システム。
２７．該複数の支柱が、該拡張状態において互いに半径方向に離間されて、該バスケットを画定するような少なくとも３つの支柱を備え、
該３つの支柱の各々が、該電極うちの少なくとも１つを含む、実施例２６のシステム。
２８．該バスケットが、該拡張状態において互いに半径方向に離間されて、該バスケットを形成するような少なくとも３つの分岐を備え、
各分岐が、互いに隣接して位置付けられた少なくとも２つの支柱を備え、
各支柱が、該電極のうちの少なくとも１つを含む、実施例２６または２７のシステム。
２９．該電極のうちの１つに少なくとも近位に位置付けられた熱電対をさらに備え、該熱電対が、該治療用アセンブリが該拡張状態にあるときに、該電極と該電極に隣接した組織との間の境界面にて温度を検出するように構成される、実施例２６～２８のいずれか１つのシステム。
３０．該電極の各々が、独立して活性化され、独立して選択的な極性に割り当てられて、該バスケットの選択された領域にわたって治療的神経調節を適用するように構成される、実施例２６～２９のいずれか１つのシステム。

３１．該バスケットが、球体または卵形形状を有し、該電極が、選択的に活性化されて、該バスケットのセグメント、四分円、または半球のうちの少なくとも１つにわたってＲＦエネルギーを適用するように構成される、実施例２６～３０のいずれか１つのシステム。
３２．該複数の電極が、対応する第１～第３の支柱上に配設された第１～第３の電極を備え、
該システムが、該複数の電極に動作可能に連結された制御装置をさらに備え、該制御装置が、命令を保有するコンピュータ可読媒体を有し、該命令は、該制御装置によって実行されるときに、該複数の電極の第１～第３の電極を、
該第１の電極が、正極性を有し、
該第２及び第３の電極が、負極性を有し、
該電極が、該バスケットの選択された周辺領域にわたってＲＦエネルギーをセスキ極性様式で適用するように活性化する、実施例２６～３１のいずれか１つのシステム。
３３．該バスケットが、該複数の支柱の間の領域を通って延在し、該複数の支柱の遠位端部部分を支持する遠位端部部分を有する内部支持部材を備え、
該複数の支柱が、少なくとも第１の支柱及び第２の支柱を備え、
該複数の電極は、該第１の支柱上に配設された第１の電極、該第２の支柱上に配設された第２の電極、及び該内部支持部材の該遠位端部部分上に配設された第３の電極を備え、
該システムが、該複数の電極に動作可能に連結された制御装置をさらに備え、該制御装置が、命令を保有するコンピュータ可読媒体を有し、該命令は、該制御装置によって実行されるときに、該複数の電極の第１～第３の電極を、
該第１及び第２の電極が正極性を有し、
該第３の電極が負極性を有し、
該電極が、該バスケットの遠位領域にわたってＲＦエネルギーを適用するように活性化する、実施例２６～３１のいずれか１つのシステム。
３４．該バスケットが、該治療用アセンブリが該拡張状態にあるときに互いに半径方向に離間される少なくとも２つの分岐を備え、
各分岐が、互いに隣接して位置付けられた少なくとも第１の支柱及び第２の支柱を備え、該第１の支柱が、その上に配設された第１の電極を有し、該第２の支柱が、その上に配設された第２の電極を有し、該第１及び第２の電極が、反対の極性を有し、該第１の電極と第２の電極との間にＲＦエネルギーを適用するように構成される、実施例２６～３１のいずれか１つのシステム。
３５．該バスケットが、該治療用アセンブリが該拡張状態にあるときに互いに半径方向に離間される少なくとも２つの分岐を備え、
各分岐が、互いに隣接して位置付けられた少なくとも第１の支柱及び第２の支柱を備え、該第１の支柱が、その上に配設された第１の電極を有し、該第２の支柱が、その上に配設された第２の電極を有し、
該第１の分岐の該第１及び第２の電極が、正極性を有するように構成され、
該第２の分岐の該第１及び第２の電極が、負極性を有するように構成され、及び適用し、
該治療用アセンブリが、該バスケットの周辺部分にわたって該第１の分岐と第２の分岐との間にＲＦエネルギーを送達するように構成される、実施例２６～３１のいずれか１つのシステム。
３６．該治療用アセンブリの近位に位置付けられた該シャフトの該遠位部分上に配設された戻り電極をさらに備え、
該支柱上の該電極が、正極性を有するように構成され、該戻り電極が、負極性を有するように構成される、実施例２６～３１のいずれか１つのシステム。
３７．該電極の少なくとも一部分が、該標的部位においてインピーダンスを検出して、該標的部位における神経の場所を決定するように構成される、実施例２６～３６のいずれか１つのシステム。
３８．該支柱上の該複数の電極が、第１の複数の電極であり、

該治療用アセンブリが、
該支柱内に配設された拡張可能なバルーンと、
該拡張可能なバルーン上の第２の複数の電極とを備え、
該拡張状態にあるときに、該拡張可能なバルーンが、該第２の複数の電極の少なくとも一部分を該標的部位において組織と接触して定置して、該標的部位における神経活動を検出する、実施例２６～３７のいずれか１つのシステム。
３９．該治療用アセンブリに動作可能に接続されたＲＦ生成器をさらに備え、該ＲＦ生成器が、命令を保有するコンピュータ可読媒体を有する制御装置を含み、該命令は、該制御装置によって実行されるときに、該治療用アセンブリに、該標的部位に少なくとも近位のインピーダンスまたは温度のうちの少なくとも１つを検出させる、実施例２６～３８のいずれか１つのシステム。
４０．該治療用アセンブリに動作可能に接続されたＲＦ生成器をさらに備え、該ＲＦ生成器が、命令を保有するコンピュータ可読媒体を有する制御装置を含み、該命令は、該制御装置によって実行されるときに、該治療用アセンブリに、該標的部位に所定のパターンでＲＦエネルギーを適用させる、実施例２６～３９のいずれか１つのシステム。
４１．ヒト患者の鼻領域における神経マッピング及び治療的神経調節のためのシステムであって、
近位部分及び遠位部分を有するシャフトであって、該遠位部分を、該ヒト患者の蝶口蓋孔の近位の標的部位に、腔内に配置するように構成される、シャフトと、
該シャフトの該遠位部分における複数の電極であって、該標的部位において該副交感神経の場所を検出するように構成された、電極と、
該シャフトの該遠位部分における治療用アセンブリであって、該標的部位において鼻粘膜を神経支配する節後副交感神経を治療的に調節するように構成されたエネルギー送達要素を備える、治療用アセンブリと、を備える、システム。
４２．該電極が、該エネルギー送達要素を画定し、該標的部位に無線周波数（ＲＦ）エネルギーを適用するように構成される、実施例４１のシステム。
４３．該電極が、該標的部位における不均一組織の誘電特性を検出して、副交感神経の場所を特定するように構成される、実施例４１または４２のシステム。
４４．該電極が、該標的部位における不均一組織のインピーダンス特性を検出して、副交感神経の場所を特定するように構成される、実施例４１～４３のいずれか１つのシステム。
４５．ヒト患者の鼻領域における神経を治療的に調節する方法であって、
治療用デバイスのシャフトの遠位部分における治療用アセンブリを、該鼻領域内の標的部位に腔内で前進させることであって、該標的部位が、該蝶口蓋孔の近位の副孔またはミクロ孔のうちの少なくとも１つにわたって広がる副交感神経の近位である、前進させることと、
該治療用アセンブリを用いて、該標的部位に、鼻腔、鼻咽頭、または副鼻腔のうちの少なくとも１つの中の自律神経活動を治療的に調節するためのエネルギーを適用することと、を含む、方法。
４６．該治療用アセンブリを該標的部位に腔内で前進させることが、該治療用アセンブリを、該蝶口蓋孔の下方の該ヒト患者の口蓋骨に位置付けることを含む、実施例４５の方法。
４７．該治療用アセンブリを該標的部位に腔内で前進させることが、該治療用アセンブリを、該ヒト患者の鼻の入口を通り、下鼻道を通って該標的部位に腔内で前進させることを含む、実施例４５または４６の方法。
４８．該治療用アセンブリを該標的部位に腔内で前進させることが、該治療用アセンブリを、該ヒト患者の鼻の入口を通り、中鼻道を通って該標的部位に腔内で前進させることを含む、実施例４５または４６の方法。
４９．内視鏡を、該ヒト患者の鼻の入口を通り、中鼻道を通って腔内で前進させて、該標的部位において該治療用アセンブリを視覚化することをさらに含む、実施例４５～４８の

いずれか１つの方法。
５０．内視鏡を、該ヒト患者の鼻の入口を通り、下鼻道を通って腔内で前進させて、該標的部位において該治療用アセンブリを視覚化することをさらに含む、実施例４５～４８のいずれか１つの方法。
５１．該治療用アセンブリを該標的部位に腔内で前進させることが、該治療用アセンブリを、該ヒト患者の鼻の入口を通り、下鼻道を通って該標的部位に腔内で前進させることを含み、
該方法が、内視鏡を、該ヒト患者の該鼻の該入口を通り、該下鼻道を通って腔内で前進させて、該標的部位において該治療用アセンブリを視覚化することをさらに含む、実施例４５または４６の方法。
５２．該治療用アセンブリを該標的部位に腔内で前進させることが、該治療用アセンブリを、該ヒト患者の鼻の入口を通り、中鼻道を通って該標的部位に腔内で前進させることを含み、
該方法が、内視鏡を、該ヒト患者の該鼻の該入口を通り、該中鼻道を通って腔内で前進させて、該標的部位において該治療用アセンブリを視覚化することをさらに含む、実施例４５または４６の方法。
５３．内視鏡を、該ヒト患者の鼻の入口を通り、下鼻道または中鼻道のうちの１つを通って、該標的部位に少なくとも近位の領域に腔内で前進させることをさらに含み、
該治療用アセンブリを該標的部位に腔内で前進させることが、
該シャフトの該遠位部分を、該内視鏡のチャネルを通って該標的部位を超えて前進させることと、
該治療用アセンブリを、該内視鏡の遠位部分における開口から外へ前進させることと、を含む、実施例４５または４６の方法。
５４．該治療用アセンブリを該標的部位に腔内で前進させることが、該シャフトの該遠位部分を、該ヒト患者の口及び中咽頭を通り、該標的部位へ前進させることを含む、実施例４５または４６の方法。
５５．赤外線（ＩＲ）分光法を介して該標的部位を撮像して、該標的部位に少なくとも近位の脈管系を視覚化することをさらに含む、実施例４５～５４のいずれか１つの方法。
５６．該シャフトの該遠位部分に沿って位置付けられた固定部材を、該鼻領域の腔内で拡張することをさらに含み、該固定部材が、該シャフトの該遠位部分を、該標的部位に該治療用アセンブリを展開するのに適切な位置に保持する、実施例４５～５５のいずれか１つの方法。
５７．該標的部位が、第１の標的部位であり、エネルギーを該標的部位に適用することが、エネルギーを該第１の標的部位に適用することを含み、該方法が、
該治療用アセンブリを該鼻領域内の第２の標的部位に再位置付けすることと、
該治療用アセンブリを用いて、該第２の標的部位に、該第２の標的部位の近位の副交感神経を治療的に調節するためのエネルギーを適用することと、をさらに含む、実施例４５～５６のいずれか１つの方法。
５８．エネルギーを適用することが、該セレアピューティック（ｔｈｅｒｅａｐｅｕｔｉｃ）要素の複数の電極を介して、パルス状の無線周波数（ＲＦ）エネルギーを該標的部位に適用することを含む、実施例４５～５７のいずれか１つの方法。
５９．該標的部位においてインピーダンスを検出して、該蝶口蓋孔の近位の副孔またはミクロ孔のうちの少なくとも１つにわたって広がる副交感神経の位置を特定することをさらに含む、実施例４５～５８のいずれか１つの方法。
６０．該標的部位にエネルギーを適用することが、インピーダンス測定を介して特定された該副交感神経の該位置に対応する該治療用アセンブリの個別の領域に、エネルギーを適用することを含む、実施例５９の方法。
６１．該治療用アセンブリが、複数の電極を備え、該標的部位にエネルギーを適用することが、個々の該電極を独立して活性化することと、個々の該電極の極性を選択して、該治療用アセンブリの選択的領域にわたって治療的神経調節を適用することとを含む、実施例

４５～６０のいずれか１つの方法。
６２．該標的部位にエネルギーを適用することが、該治療用アセンブリの第１の半球部分内にエネルギーを適用することをさらに含み、該治療用アセンブリが、該治療用アセンブリの第２の半球部分にはエネルギーを適用しない、実施例６１の方法。
６３．該治療用アセンブリが、複数の支柱であって、該支柱上に配設された複数電極を伴う、複数の支柱を有する拡張可能なバスケットを備え、該標的部位にエネルギーを適用することが、
該複数の電極の第１の電極を、正極性を有するように活性化することと、
該複数の電極の少なくとも第２の電極及び第３の電極を、負極性を有するように活性化することであって、第１、第２、及び第３の電極が、同時に活性化され、該第２及び第３の電極が、最小抵抗の通路に基づいて該第１の電極と連続的に対になって、該バスケットの領域にわたって治療的神経調節を連続的に適用する、活性化することと、を含む、実施例４５～６２のいずれか１つの方法。
６４．該治療用アセンブリが、複数の支柱であって、該支柱上に配設された複数電極を伴う、複数の支柱を有する拡張可能なバスケットを備え、該標的部位にエネルギーを適用することが、
該複数の電極の第１の電極を、正極性を有するように活性化することと、
該複数の電極の少なくとも第２～第６の電極を、負極性を有するように活性化することであって、第１～第６の電極が、同時に活性化され、該第２～第６の電極が、最小抵抗の通路に基づいて該第１の電極と連続的に対になって、該バスケットの半球領域にわたって治療的神経調節を連続的に適用する、活性化することと、を含む、実施例４５～６２のいずれか１つの方法。
６５．該治療用アセンブリが、複数の支柱であって、該支柱上に配設された複数電極を伴う、複数の支柱と、内部支持部材であって、該内部支持部材の遠位端部部分に戻り電極を備える、内部支持部材とを有する拡張可能なバスケットを備え、該標的部位にエネルギーを適用することが、
該支柱上の該電極を、正極性を有するように活性化することと、
該戻り電極を、負極性を有するように活性化することであって、該電極が、該バスケットの遠位領域にわたってＲＦエネルギーを適用する、活性化することと、を含む、実施例４５～６２のいずれか１つの方法。
６６．該治療用アセンブリが、該治療用アセンブリが拡張状態にあるときに互いに半径方向に離間される複数の分岐を有する拡張可能なバスケットを備え、各分岐が、少なくとも２つの隣接した支柱であって、各支柱上に位置付けられた電極を伴う、支柱を備え、該標的部位にエネルギーを適用することが、
該分岐のうちの少なくとも１つの隣接した支柱上の該電極を、該電極が反対の極性を有するように活性化することと、
該隣接した支柱上の該電極間にＲＦエネルギーを適用することと、を含む、実施例４５～６２のいずれか１つの方法。
６７．該治療用アセンブリが、複数の電極を備え、該標的部位にエネルギーを適用することが、
該治療用アセンブリの該電極を、正極性を有するように活性化することと、
該治療用アセンブリの近位の該シャフトの該遠位部分上に配設された戻り電極を活性化することであって、該戻り電極が、負極性を有する、活性化することと、を含み、
該電極及び該戻り電極を活性化することが、該ヒト患者の鼻甲介にわたってＲＦエネルギーを適用する、実施例４５～６２のいずれか１つの方法。
６８．該標的部位に、自律神経活動を治療的に調節するためのエネルギーを適用する前に、複数の感知電極を介して該標的部位における神経活動を検出することと、
該検出された神経活動に基づいて、該標的部位における神経の場所をマッピングすることと、をさらに含み、
該標的部位にエネルギーを適用することが、検出された神経の該場所に基づいて領域に

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エネルギーを選択的に適用することを含む、実施例４５～６７のいずれか１つの方法。
６９．神経活動を検出する前に、該標的部位に非治療的神経性刺激を適用することをさらに含む、実施例６８の方法。
７０．該標的部位にエネルギーを適用した後に、該複数の感知電極を介して神経活動を検出して、該エネルギーの適用が該標的部位において神経を治療的に調節したかを判定することをさらに含む、実施例６８の方法。
７１．該治療用アセンブリが、複数の電極を担持する可撓性膜を備え、
エネルギーを適用する前に、該方法が、該可撓性膜を該標的部位において拡張して、該電極の少なくとも一部分を該標的部位において組織と接触して定置することを含み、
該標的部位にエネルギーを適用することが、該電極を介して該標的部位にＲＦエネルギーを適用することを含む、実施例４５～６２のいずれか１つの方法。
７２．該シャフトの該遠位部分上に配設された複数の電極が該標的部位において組織と接触して定置されるように、該シャフトの該遠位部分を低プロファイル送達状態から拡張状態に変形させることであって、該シャフトの該遠位部分が、該拡張状態において渦巻き／螺旋形状を有する、変形させることをさらに含み、
該標的部位においてエネルギーを適用することが、該電極を介して該標的部位にＲＦエネルギーを適用することを含む、実施例４５～６２のいずれか１つの方法。
７３．該治療用アセンブリが、複数の電極を担持するバルーンを備え、
エネルギーを適用する前に、該方法が、該バルーンを該標的部位において拡張して、該電極の少なくとも一部分を該標的部位において組織と接触して定置することをさらに含み、
該標的部位にエネルギーを適用することが、該電極を介して該標的部位にＲＦエネルギーを適用することを含む、実施例４５～６２のいずれか１つの方法。
７４．該標的部位にエネルギーを適用することが、
該電極を選択的に活性化して、該バルーンの円周セグメントにわたって半径方向に電流を適用することをさらに含む、実施例７３の方法。
７５．該標的部位にエネルギーを適用することが、
該電極を選択的に活性化して、該バルーンの長手方向領域にわたって長手方向に電流を適用することをさらに含む、実施例７３の方法。
７６．該バルーンを拡張することが、該バルーンを流体で充填することを含み、該バルーンが、エネルギー適用中に該バルーンを通る該流体の灌流を可能にする複数の穴を備える、実施例７３の方法。
７７．該バルーンを拡張することが、該バルーンを通して流体を循環させることを含み、該流体が、エネルギー適用中に該電極を冷却する、実施例７３の方法。
７８．該治療用アセンブリが、該シャフトの該遠位部分から遠位に延在する複数のバルーンと、
エネルギーを適用する前に、該方法が、該バルーンを該標的部位において独立して拡張して、該電極の少なくとも一部分を該標的部位において組織と接触して定置することをさらに含み、
該標的部位にエネルギーを適用することが、該電極を介して該標的部位にＲＦエネルギーを適用することを含む、実施例４５～６２のいずれか１つの方法。
７９．該標的部位にエネルギーを適用することが、
該複数のバルーンを通って延在する内部支持部材上の戻り電極を活性化することと、
該バルーン上の該電極の少なくとも一部分を活性化することと、をさらに含む、実施例７８の方法。
８０．エネルギー適用中に該標的部位において組織の温度を測定することと、
閾値最大温度に到達したときに、エネルギー適用を終了させることと、をさらに含む、実施例４５～７９のいずれか１つの方法。
８１．所定の最大期間の後にエネルギー適用を終了させることをさらに含む、実施例４５～８０のいずれか１つの方法。

８２．エネルギー適用中に該標的部位における組織のインピーダンスを検出することと、
閾値インピーダンス値に到達したときに、エネルギー適用を終了させることと、をさらに含む、実施例４５～８１のいずれか１つの方法。
８３．エネルギー適用前に該標的部位における組織のインピーダンスを検出して、ベースラインインピーダンスを定義することと、
エネルギー適用中に該標的部位における組織のインピーダンスを検出することと、
該ベースラインインピーダンスからのインピーダンスの閾値変化に到達したときに、エネルギー適用を終了させることと、をさらに含む、実施例４５～８２のいずれか１つの方法。
８４．該標的部位にエネルギーを適用することが、該標的部位における組織に治療的極低温冷却を適用して、該鼻腔、該鼻咽頭、及び／または該副鼻腔内の自律神経活動を治療的に調節することを含む、実施例４５～５７のいずれか１つの方法。
８５．該標的部位にエネルギーを適用することが、
バルーン内で加熱された流体を循環させ、その結果、該バルーンの外側表面が該標的部位において組織と接触し、該組織を加熱して、該標的部位において自律神経活動を熱的に調節することを含む、実施例４５～５７のいずれか１つの方法。
８６．該標的部位にエネルギーを適用することが、
バルーンを拡張して、その結果、該バルーンの外側表面が該標的部位において組織と接触することと、
該バルーン内の加熱部材を加熱することであって、該加熱部材からの熱が、該流体へ、及び該バルーンに隣接した該組織へと移動して、自律神経活動を熱的に調節する、加熱することと、を含む、実施例４５～５７のいずれか１つの方法。
８７．該標的部位にエネルギーを適用することが、プラズマ場を生成して、該標的部位における神経を治療的に調節することを含む、実施例４５～５７のいずれか１つの方法。
８８．該標的部位にエネルギーを適用することが、粘膜下腺に信号を送るコリン作動性経路を治療的に調節する、実施例４５～８７のいずれか１つの方法。
８９．該治療用アセンブリを該標的部位に腔内で前進させることが、該治療用アセンブリを、上鼻道、中鼻道、下鼻道、または翼口蓋窩のうちの少なくとも１つの中の副孔及び／またはミクロ孔を介して、該鼻領域内への入口の副交感神経点へ腔内で前進させることを含む、実施例４５～８８のいずれか１つの方法。
９０．鼻領域における神経を治療的に調節する方法であって、
治療用デバイスのシャフトの遠位部分における治療用アセンブリを、鼻領域内の標的部位に腔内で前進させることであって、該標的部位が、該蝶口蓋孔の近位の副交感神経の近位である、前進させることと、
該標的部位における該副交感神経の場所を検出することと、
該副交感神経の該検出された場所に基づいて、該治療用アセンブリを用いて該標的部位にエネルギーを適用することであって、エネルギーを適用することが、鼻腔、鼻咽頭、または副鼻腔のうちの少なくとも１つの中の自律神経活動を治療的に調節する、適用することと、を含む、方法。
９１．該標的部位における該副交感神経の場所を検出することが、高解像度空間格子上で、該鼻腔、該鼻咽頭、及び／または該副鼻腔のうちの少なくとも１つの中の不均一組織の誘電特性を測定することを含む、実施例９０の方法。
９２．該標的部位における該副交感神経の場所を検出することが、高解像度空間格子上で、該鼻腔、該鼻咽頭、及び／または該副鼻腔の中の不均一組織のダイポール特性を測定することを含む、実施例９０または９２の方法。
９３．該標的部位における該副交感神経の場所を検出することが、高解像度空間格子上で、該鼻腔、該鼻咽頭、または該副鼻腔のうちの少なくとも１つの中の不均一組織のインピーダンスを検出することを含む、実施例９０～９２のいずれか１つの方法。
９４．ヒト患者の鼻領域における治療的神経調節のためのデバイスであって、
遠位部分を有する送達カテーテルであって、該鼻領域内の標的部位に該遠位部分を配置

するように構成された、送達カテーテルと、
該送達カテーテルの該遠位部分における可撓性支持体と、
該可撓性支持体によって担持される複数の電極と、を備え、
該可撓性支持体が、該標的部位における局所的生体構造の凹凸に適合して、該電極の少なくとも一部分の電気的活性化のための局部的コンプライアンス及び連動を提供するように構成され、
該電極が、該電極と直接的または間接的に接触する粘膜及び粘膜下構造の副交感神経を治療的に調節する、デバイス。
９５．エネルギー送達後に該可撓性支持体を再捕捉して、鼻腔から該可撓性支持体を引き抜くことを可能にするように構成された制御可能な再捕捉機構をさらに備える、実施例９４のデバイス。
９６．該標的部位が、蝶口蓋孔である、実施例９４または９４のデバイス。
９７．該電極が、正確で局在的なエネルギー送達のために、エネルギーの方向及び関連する消散を制御するように選択的に活性化されるように構成される、実施例９４～４６のいずれか１つのデバイス
９８．ヒト患者の鼻領域における神経を治療的に調節する方法であって、
治療用デバイスのシャフトの遠位部分における治療用アセンブリを、該鼻領域内の標的部位に腔内で前進させることであって、該標的部位が、該ヒト患者の前頭洞、篩骨洞、蝶形骨洞、または上顎洞のうちの少なくとも１つの小孔に少なくとも近位である、前進させることと、
該治療用アセンブリを用いて、該標的部位に、該標的部位における副交感神経を治療的に調節するためのエネルギーを適用して、慢性副鼻腔炎を治療することと、を含む、方法。
９９．該治療用アセンブリを該標的部位に腔内で前進させることが、該治療用アセンブリを、該前頭洞の該小孔の近位に位置付けることを含み、
該標的部位にエネルギーを適用することが、眼窩上神経、滑車上神経、該眼窩上神経の分枝、該滑車上神経の分枝、または該前頭洞の粘膜を神経支配する他の副交感神経線維のうちの少なくとも１つにエネルギーを適用することを含む、請求項９８の方法。
１００．該治療用アセンブリを該標的部位に腔内で前進させることが、該治療用アセンブリを、該篩骨洞の該小孔の近位に位置付けることを含み、
該標的部位にエネルギーを適用することが、鼻毛様体神経の前篩骨分枝、該鼻毛様体神経の後篩骨分枝、上顎神経、該鼻毛様体神経の分枝、該上顎神経の分枝、または該篩骨洞の粘膜を神経支配する他の副交感神経線維のうちの少なくとも１つにエネルギーを適用することを含む、請求項９８の方法。
１０１．該治療用アセンブリを該標的部位に腔内で前進させることが、該治療用アセンブリを、該上顎洞の該小孔の近位に位置付けることを含み、
該標的部位にエネルギーを適用することが、上顎神経の眼窩下分枝、該上顎神経の歯槽枝、または該上顎洞の粘膜を神経支配する他の副交感神経線維のうちの少なくとも１つにエネルギーを適用することを含む、請求項９８の方法。
１０２．該治療用アセンブリを該標的部位に腔内で前進させることが、該治療用アセンブリを、該蝶形骨洞の該小孔の近位に位置付けることを含み、
該標的部位にエネルギーを適用することが、視神経の後篩骨分枝、上顎神経、該視神経の分枝、該上顎神経の分枝、または該蝶形骨洞の粘膜を神経支配する他の副交感神経線維のうちの少なくとも１つにエネルギーを適用することを含む、請求項９８の方法。
１０３．慢性副鼻腔炎の治療のための、ヒト患者の鼻領域における治療的神経調節のためのシステムであって、
近位部分及び遠位部分を有するシャフトであって、該遠位部分を、標的部位に腔内に配置するように構成され、該標的部位が、該ヒト患者の前頭洞、篩骨洞、蝶形骨洞、または上顎洞のうちの少なくとも１つの小孔に少なくとも近位である、シャフトと、
該シャフトの該遠位部分における治療用アセンブリであって、該前頭洞、該篩骨洞、該

蝶形骨洞、または該上顎洞のうちの少なくとも１つの粘膜を神経支配する副交感神経を治療的に調節するように構成されたエネルギー送達要素を備える、治療用アセンブリと、を備える、システム。

【０１４３】

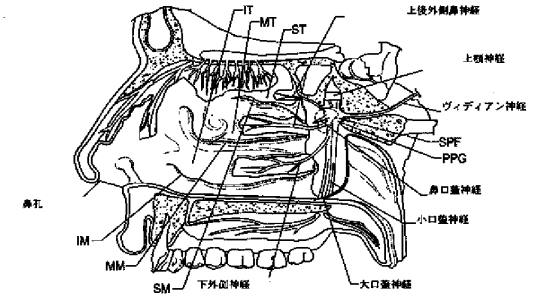
結論

本開示は、徹底的であること、または本技術を本明細書に開示される精密な形態に限定することを意図されない。特定の実施形態が例証の目的のために本明細書に開示されているが、関連技術の当業者が認識するであろう通り、種々の同等な修正が、本技術から逸脱することなく可能である。場合により、周知の構造及び機能は、本技術の実施形態の説明を不必要に曖昧にするのを避けるために、詳細に図示及び／または説明されていない。方法のステップは具体的な順序で本明細書に提示され得るが、代替的実施形態では、ステップは別の好適な順序を有してもよい。同様に、具体的な実施形態の文脈において開示される本技術の特定の態様は、他の実施形態では組み合わせられ得るか、または排除され得る。さらに、特定の実施形態に関連付けられる利点は、それらの実施形態の文脈において開示されている場合もあるが、他の実施形態もまた、かかる利点を示すことができ、必ずしも全ての実施形態が、かかる利点または本明細書に開示される他の利点を本技術の範囲に含まれるように示す必要はない。したがって、本開示及び関連する技術は、本明細書に明白に図示及び／または説明されていない他の実施形態を包含し得る。

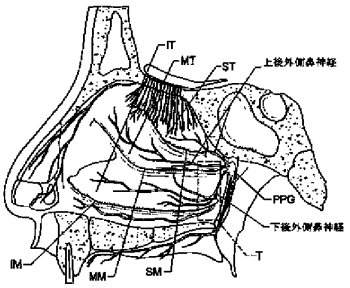
【０１４４】

本開示全体を通して、単数形の用語「ａ」、「ａｎ」、及び「ｔｈｅ」は、文脈が明確にそうではないと示さない限り、複数の指示対象を含む。同様に、「または」という語は、２つ以上の項目のリストに関して他の項目を排して単一の項目のみを意味するように明白に限定されていない限り、かかるリストにおける「または」の使用は、（ａ）リスト内の任意の単一の項目、（ｂ）リスト内の全ての項目、または（ｃ）リスト内の項目の任意の組み合わせを含むものとして解釈されるべきである。それに加えて、「含む（ｃｏｍｐｒｉｓｉｎｇ）」等の用語は、少なくともその記載される特徴（複数可）を、より多くの数の同一の特徴（複数可）及び／または１つ以上の追加の種類の特徴が除外されないように含むことを意味するように、本開示全体を通して使用される。「上側」、「下側」、「前側」、「後ろ側」、「垂直」、及び「水平」等の方向に関する用語は、種々の要素間の関係性を表し、明確にするために本明細書において使用され得る。かかる用語は、絶対的な配向を示すものではないことが理解されるべきである。本明細書における「一実施形態（ｏｎｅ　ｅｍｂｏｄｉｍｅｎｔ）」、「実施形態（ａｎ　ｅｍｂｏｄｉｍｅｎｔ）」、または類似の語句への言及は、その実施形態に関連して説明される特定の特徴、構造、動作、または特性が、本技術の少なくとも１つの実施形態に含まれ得ることを意味する。したがって、本明細書内のかかる句または語句の出現は、必ずしも全て同一の実施形態について言及しているわけではない。さらに、種々の特定の特徴、構造、動作、または特性は、１つ以上の実施形態において任意の好適な様式で組み合わせられてもよい。

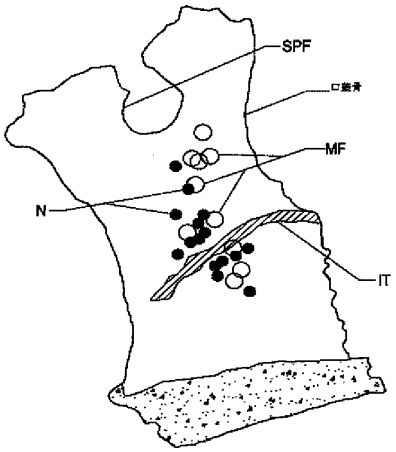
【 図１ Ａ 】



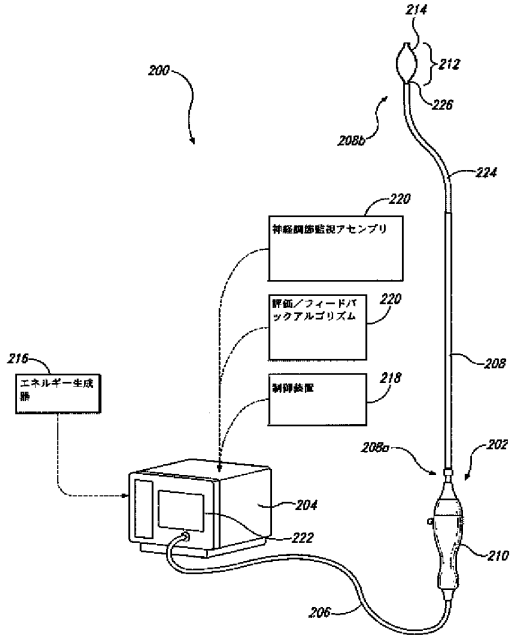
【 図１ Ｂ 】



【 図１ Ｃ 】



【 図２ 】



【 図３ Ａ 】

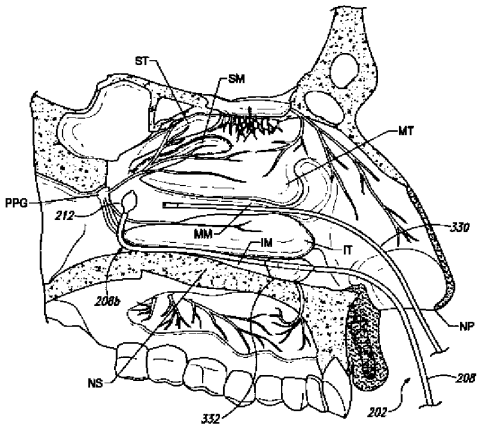


Fig. 3A

【 図 3 B 】

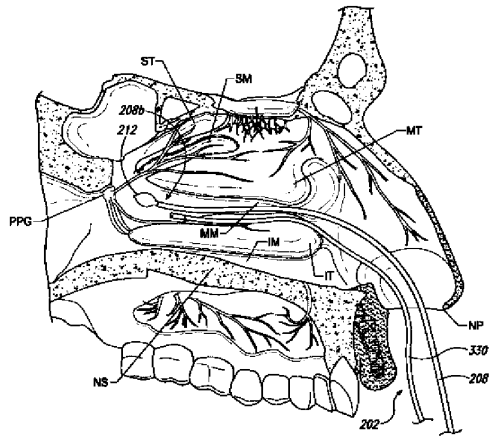


Fig. 3B

【 図 3 C 】

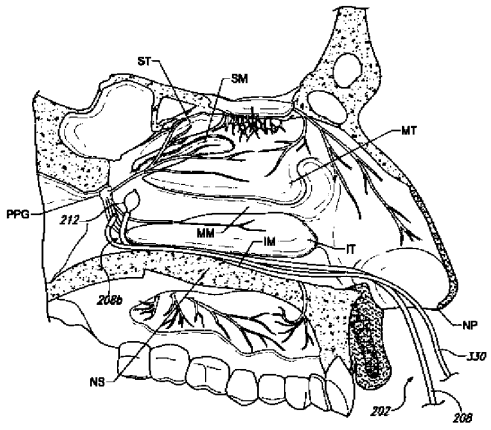


Fig. 3C

【 図 3 D 】

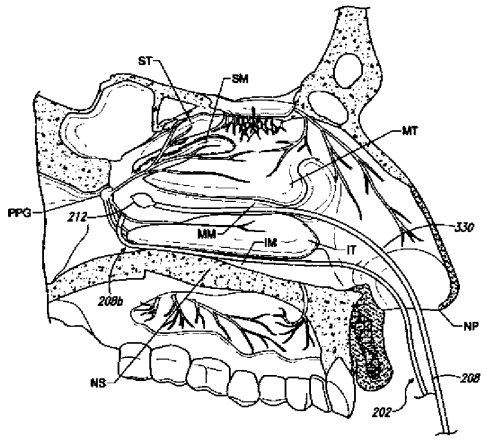


Fig. 3D

【 図 3 E 】

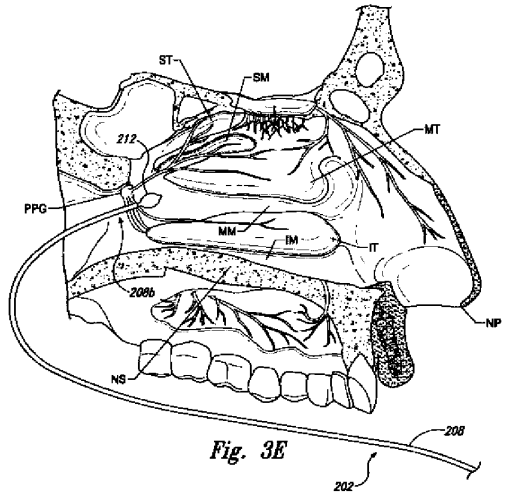


Fig. 3E

【 図 4 】

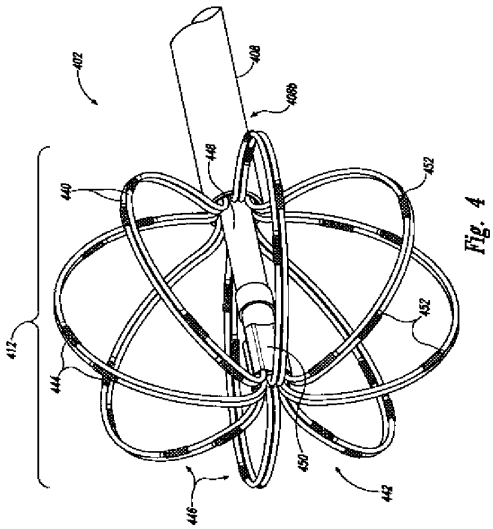


Fig. 4

【 図 5 A 】

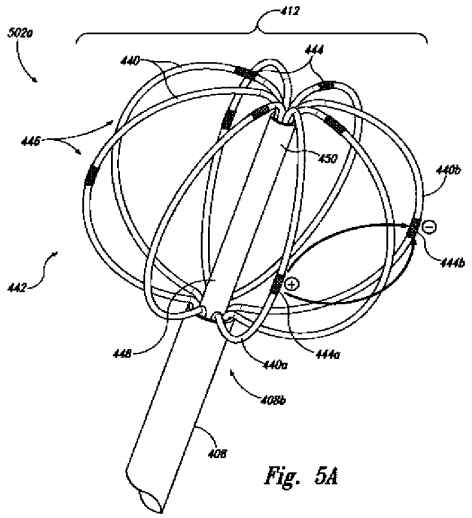


Fig. 5A

【 図 5 B 】

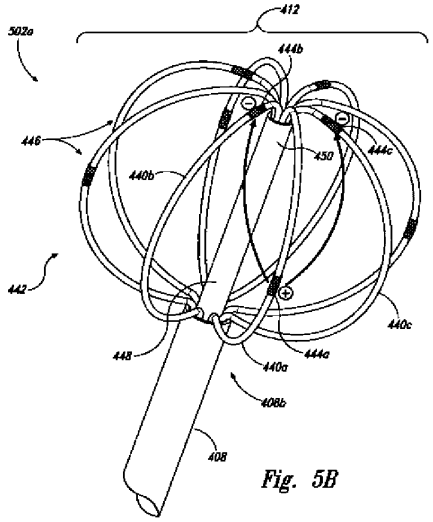


Fig. 5B

【 図 5 C 】

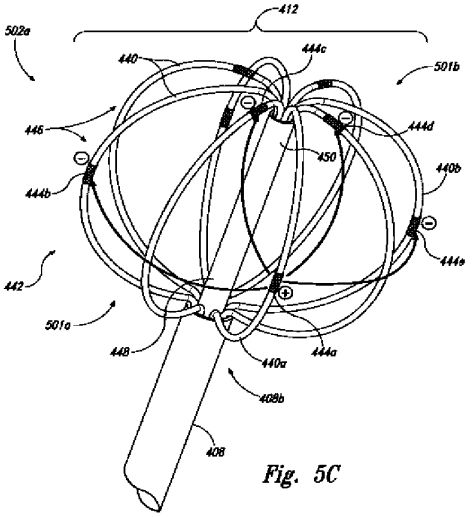


Fig. 5C

【 図 5 D 】

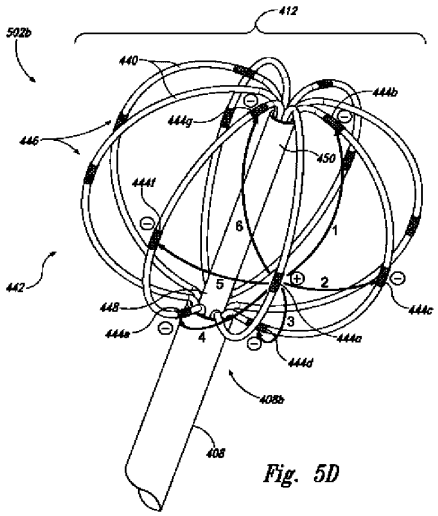


Fig. 5D

【 図 5 E 】

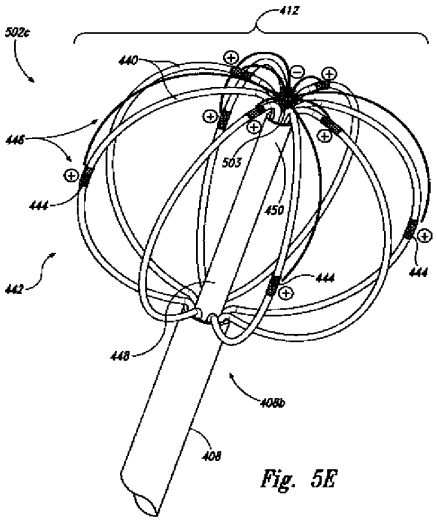


Fig. 5E

【 図 5 F 】

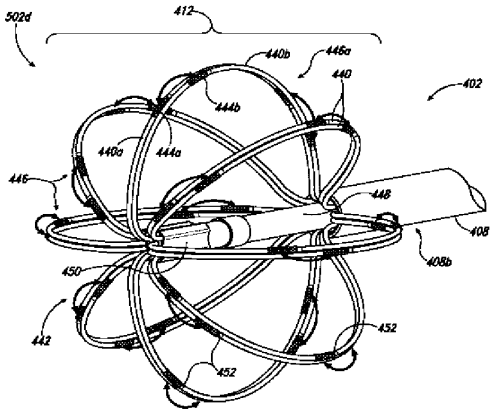


Fig. 5F

【 図 5 G 】

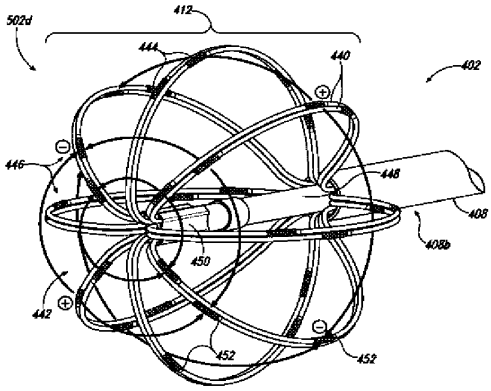
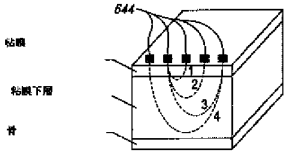
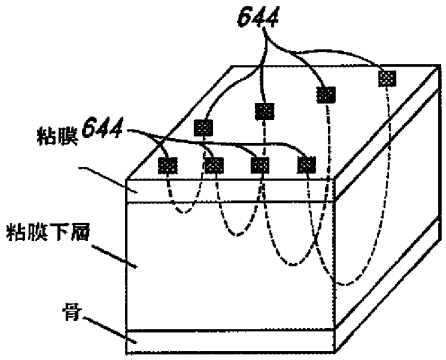


Fig. 5G

【 図 6 A 】



【 図６ Ｂ 】



【 図７ 】

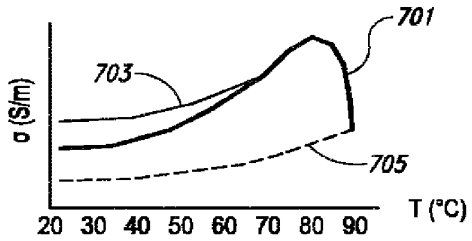


Fig. 7

【 図８ 】

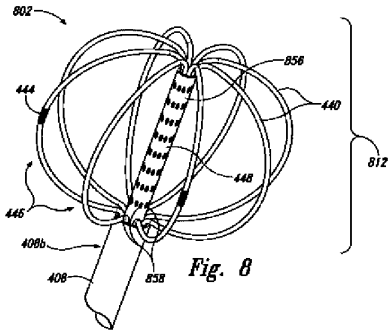


Fig. 8

【 図９ 】

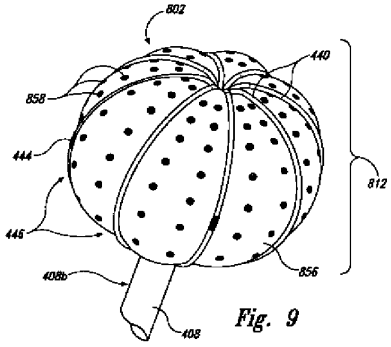


Fig. 9

【 図１０Ａ 】

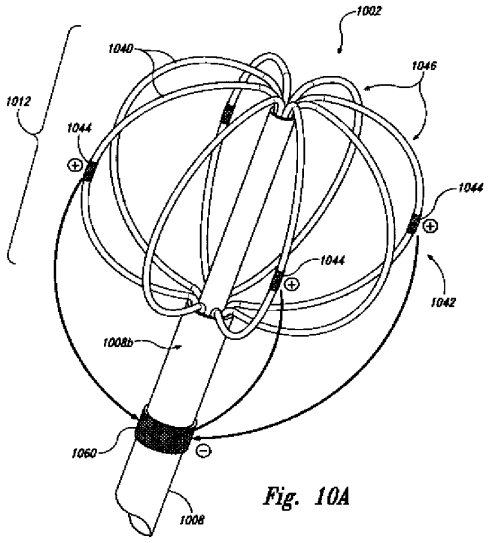
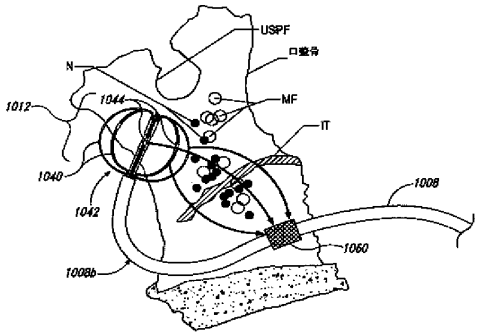


Fig. 10A

【 図１ ０ Ｂ 】



【 図１ １ Ａ 】

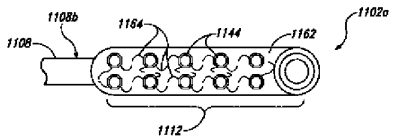


Fig. 11A

【 図１ １ Ｂ 】

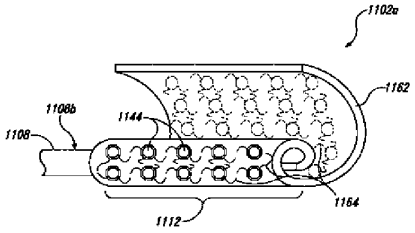


Fig. 11B

【 図１ １ Ｃ 】

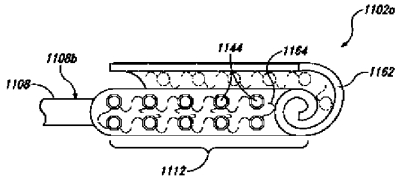


Fig. 11C

【 図１ １ Ｄ 】

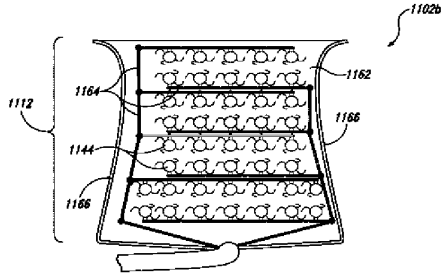


Fig. 11D

【 図１ ２ 】

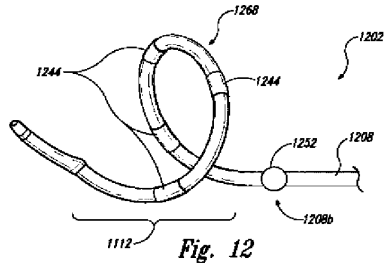


Fig. 12

【 図１ ３ 】

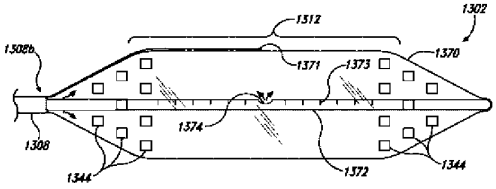


Fig. 13

【 図１ ４ 】

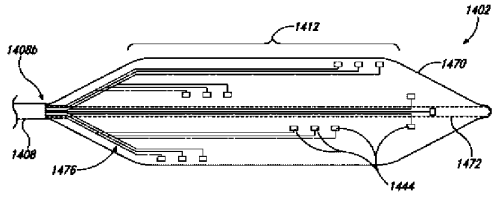


Fig. 14

【 図１５ 】

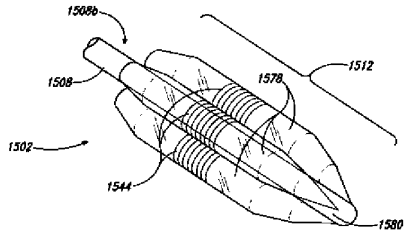


Fig. 15

【 図１６ 】

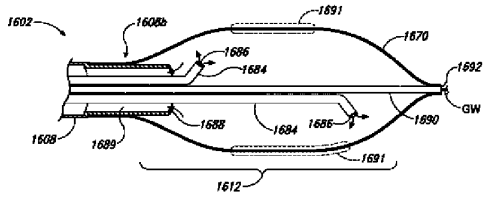


Fig. 16

【 図１７ 】

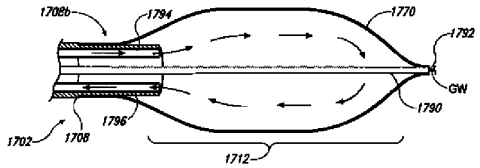


Fig. 17

【 図１８ 】

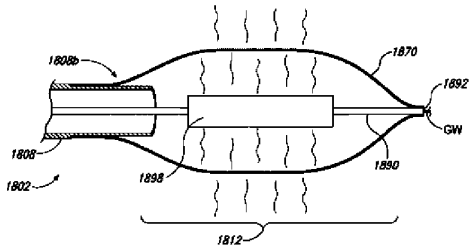


Fig. 18

【 図１９ 】

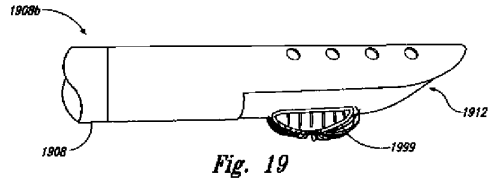
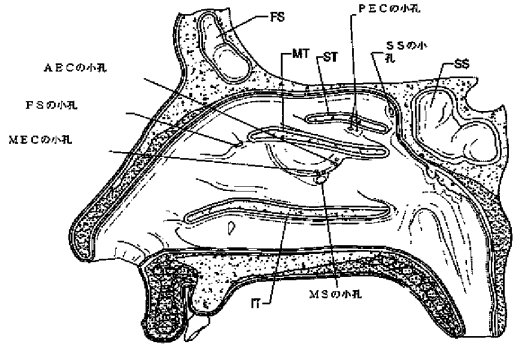


Fig. 19

【 図２０ 】



【 国際調査報告 】

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/032132

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/32 A61N1/18 A61B18/00 A61B18/02 A61B18/18
A61N1/36 A61N1/05 A61B18/04
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/031341 A1 (DIMAURO THOMAS M [US] ET AL) 8 February 2007 (2007-02-08) abstract; figures 1-12C paragraphs [0028] - [0163]	1-3,6-8, 103
X	US 2012/323214 A1 (SHANTHA TOTADA R [US]) 20 December 2012 (2012-12-20) abstract; figures 1-26 paragraphs [0059] - [0458]	1-9,103
X	WO 2015/013252 A1 (WEDGE THERAPEUTICS LLC [US]) 29 January 2015 (2015-01-29) abstract; figures 1-30 pages 3-44	1-9,103

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 November 2016	14/11/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Lins, Stephanie

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Aerin Medical Inc. v. Neurent Medical Ltd.
IPR2025-01125

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/032132

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/078377 A1 (GONZALES DONALD A [US] ET AL) 29 March 2012 (2012-03-29) abstract; figures 1-31B paragraphs [0016] - [0298]	1-8,103
X	US 2014/114233 A1 (DEEM MARK E [US] ET AL) 24 April 2014 (2014-04-24) abstract; figures 1-32 paragraphs [0059] - [0141]	26
X	US 2005/288730 A1 (DEEM MARK [US] ET AL) 29 December 2005 (2005-12-29) abstract; figures 1-22 paragraphs [0077] - [0144]	10,12, 15,16, 18-29, 37,39,40
X	US 2007/129760 A1 (DEMARAIS DENISE [US] ET AL) 7 June 2007 (2007-06-07) abstract; figures 1-10 paragraphs [0021] - [0074]	13,14, 19, 23-26, 30-33, 36-40
X	US 2014/025069 A1 (WILLARD MARTIN R [US] ET AL) 23 January 2014 (2014-01-23) abstract; figures 1-9 paragraphs [0026] - [0098]	26,34,35
X	US 2010/204560 A1 (SALAHIEH AMR [US] ET AL) 12 August 2010 (2010-08-12) abstract; figures 1-40 paragraphs [0074] - [0222]	17
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3

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/032132

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 45-93, 98-102
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)

International Application No. PCT/ US2016/ 032132

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-9, 103

Device for chemical neuromodulation in a nasal region.

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2. claims: 10, 12-40

Therapeutic assembly with RF electrodes and expandable structure

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3. claims: 11, 41-44

System for neural mapping and neuromodulation

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4. claims: 94-97

Device for therapeutic neuromodulation with flexible support.

INTERNATIONAL SEARCH REPORT

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International application No
PCT/US2016/032132

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4C167 AA09　BB26　BB27　BB41　BB42　CC15　EE05

Espacenet

Bibliographic data: EP2929852 (A1) — 2015-10-14

SYSTEM FOR PULMONARY TREATMENT

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Classification: **- international:** ***A61B18/12; A61B18/18;*** *A61B18/00; A61B19/00*
- cooperative: **A61B18/1815 (EP);** A61B18/1492 (EP); A61B2018/00017 (EP); A61B2018/00023 (EP); A61B2018/0022 (EP); A61B2018/00434 (EP); A61B2018/00541 (EP); A61B2018/147 (EP); A61B2018/162 (EP); A61B2018/1861 (EP); A61B2090/0481 (EP)

Application number: EP20150164212 20110406 Global Dossier

Priority number(s): US20100321346P 20100406 ; EP20110714906 20110406

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Abstract of EP2929852 (A1)

An apparatus and method for pulmonary treatment by denervation is provided. The apparatus includes an elongate member configured for insertion into the trachea to a positions adjacent a pulmonary plexus. The apparatus further includes at least one energy delivery element disposed on the elongate member. The energy delivery element is positionable to target at least one nerve in the tracheal wall when the elongate member is positioned in the trachea. Energy from the energy delivery element is delivered to the at least one nerve to treat pulmonary

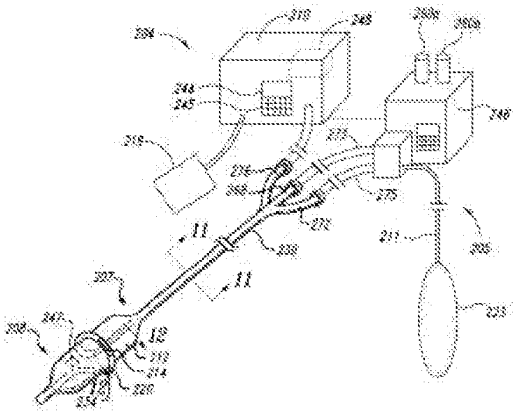


FIG. 10

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symptoms, conditions, and/or diseases, such as asthma, COPD, obstructive lung diseases, or other pulmonary diseases.

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(19) Europäisches Patentamt
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A61B 18/18 *(2006.01)* ***A61B 18/12*** *(2006.01)*
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Remarks:
This application was filed on 20-04-2015 as a divisional application to the application mentioned under INID code 62.

(54) SYSTEM FOR PULMONARY TREATMENT

(57) An apparatus and method for pulmonary treatment by denervation is provided. The apparatus includes an elongate member configured for insertion into the trachea to a positions adjacent a pulmonary plexus. The apparatus further includes at least one energy delivery element disposed on the elongate member. The energy delivery element is positionable to target at least one nerve in the tracheal wall when the elongate member is positioned in the trachea. Energy from the energy delivery element is delivered to the at least one nerve to treat pulmonary symptoms, conditions, and/or diseases, such as asthma, COPD, obstructive lung diseases, or other pulmonary diseases.

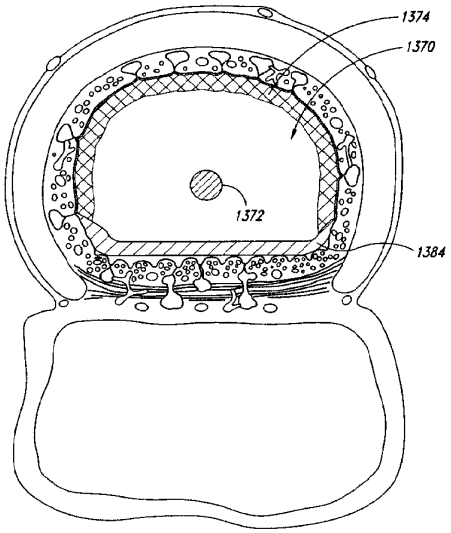


FIG. 53

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Description

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application No. 61/321,346 filed April 6, 2010. This provisional application is incorporated herein by reference in its entirety.

BACKGROUND

Technical Field

[0002] The present invention generally relates to the field of pulmonary treatments.

Description of the Related Art

[0003] One treatment for asthma which was performed in the 1930's to 1950's, prior to the advent of effective asthma medications, was surgical sympathectomy of the posterior pulmonary nerve plexus. Although the surgery was very morbid, typically requiring severing large muscle groups and manipulating the ribs, pleura and lungs, it was in some cases effective. As an alternative for patients for whom medications and other conventional treatments are ineffective, it would be desirable to achieve the benefits of a pulmonary sympathectomy, but without the high morbidity rates typically associated with such a procedure in the past.

[0004] There exists, in addition to the posterior pulmonary nerve plexus, an anterior pulmonary nerve plexus. The anterior pulmonary nerve plexus was never approached surgically due to its proximity to the heart and the great vessels. It is possible that these nerves also are involved in airway constriction associated with asthma and other pulmonary diseases.

[0005] There are several complicating factors to performing a denervation of these nerves from within the body. The nerves of interest run along the outside of the anterior trachea and bronchi, and the posterior plexus runs along the posterior, along and within the junction between the trachea and the esophagus. As a result of such difficulties there has been minimal interest in such approaches to the treatment of asthma.

BRIEF SUMMARY

[0006] At least some embodiments include a treatment system that can be used to perform pulmonary treatments to address a wide range of pulmonary symptoms, conditions, and/or diseases, including, without limitation, asthma, chronic obstructive pulmonary disease ("COPD"), obstructive lung diseases, or other diseases that lead to an unwanted (e.g., increased) resistance to airflow in the lungs.

[0007] In some embodiments, an apparatus for pulmonary treatment by select denervation includes an elongate member configured for insertion into the trachea to a position adjacent target nerve tissue, such as a pulmonary plexus. The apparatus further includes at least one energy delivery element disposed on the elongate member in a position corresponding to the anatomical location of at least one nerve in or adjacent the tracheal wall when the elongate member is positioned in the trachea. In certain embodiments, energy from a single energy delivery element ablates the at least one nerve. In other embodiments, a plurality of energy delivery elements cooperate to ablate or otherwise alter the nerve or other targeted tissue.

[0008] A pulmonary treatment method, in some embodiments, includes positioning at least one energy delivery element in a trachea or airway of the bronchial tree adjacent a nerve site to be treated. In some embodiments, energy from the element is delivered to a portion of the circumference of the trachea at the treatment site. Tissue adjacent the treatment site is cooled to prevent tissue damage outside the treatment site.

[0009] To cool the tissue, a cooling medium can be delivered through a device positioned along a lumen of the esophagus. The device can have one or more cooling balloons configured to contact the wall of the esophagus to absorb heat, thereby cooling non-targeted tissue. Additionally or alternatively, an apparatus in the trachea combined with or separate from the at least one energy delivery element can include one or more cooling devices (*e.g.,* cooling balloons).

[0010] Some embodiments include an apparatus and method for targeting one or more target sites positioned between the lumens of the trachea and the esophagus. In certain embodiments, one or more devices are placed on the lumens of the trachea and/or esophagus to deliver energy so as to damage or otherwise alter one or more target sites located between the lumens of the trachea and the esophagus. The target sites can include nerve tissue. Preferably, such target sites are damaged while tissue closer to the lumens of the trachea and/or esophagus are protected from damage.

[0011] In some embodiments, a system for pulmonary treatment includes a pulmonary treatment device and a protection device. The pulmonary treatment device has one or more energy delivery elements positionable through at least

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a portion of a trachea into in an airway. The one or more energy delivery elements are configured to deliver energy to a wall of the airway to alter nerve tissue located in or proximate to the wall of the airway. The protection device has a protection member positionable in an esophagus even when the pulmonary treatment device is positioned in the airway. The protection member is configured to absorb heat from a wall of the esophagus to inhibit damage to esophageal tissue. In some procedures, the system is used to ablate nerve tissue of nerve trunks travelling along the airway. Additionally or alternatively, nerve tissue within the airway wall can be ablated.

[0012] A cooling apparatus can be associated with the energy delivery element to limit tissue damage adjacent select denervation sites. The cooling apparatus can include one or more pumps, blowers, conduits, facemasks, valves, or the like. Media from the cooling apparatus can flow through the subject to cool internal tissue. In some embodiments, the cooling apparatus includes a pump that delivers chilled air through a conduit into a lumen of the esophagus. The chilled air circulates within the lumen to cool the esophageal tissue.

[0013] A method for pulmonary treatment includes positioning at least one energy delivery element through at least a portion of the trachea into an airway adjacent a treatment site to be treated. In certain procedures, the airway is part of the trachea. In other procedures, the at least one energy delivery element is delivered through and out of the trachea and into the bronchial tree.

[0014] The method can further include delivering energy from the element to a portion of the circumference of the airway. The temperature of tissues can be adjusted to prevent or limited damaged to non-target tissue. In some procedures, tissues of an esophagus are cooled to prevent damage of the esophageal tissues while the energy is delivered. The esophageal tissues can also be cooled before and/or after delivering the energy.

[0015] The energy delivery element can be repositioned any number of times. In certain embodiments, the energy delivery element can be positioned in close proximity to the previous position. Energy is delivered to an adjacent treatment site. The adjacent site can barely overlap with the previous site. Alternatively, a small gap can be between the two treatment sites. The apparatus can be moved (*e.g.,* rotated, translated, or both) to reposition the energy delivery element to provide a slight overlap or a slight gap circumferentially with respect to an already treated site.

[0016] In some embodiments, a pulmonary treatment apparatus includes an elongate member and a microwave antenna. The elongate member is insertable through at least a portion of a trachea into an airway. The microwave antenna is coupled to the elongate member and positionable in the airway at a treatment location proximate nerve tissue in a wall thereof. The microwave antenna is configured to deliver microwave energy so as to alter the nerve tissue in a manner which disrupts transmission of nerve signals therein while non-target tissue (*e.g.,* tissue disposed between the microwave antenna and the nerve tissue) is not permanently injured. An active electrode can be non-inflatably (*e.g.,* balloonlessly) expandable from a contracted configuration to an expanded configuration. Thus, the activate electrode can be moved without the use of a balloon or other type of expansion device.

[0017] A system for pulmonary treatment can include at least one pulmonary treatment device capable of damaging nerve tissue such that the destroyed nerve tissue impedes or stops the transmission of nervous system signals to nerves more distal along the bronchial tree. The nerve tissue can be temporarily or permanently damaged by delivering different types of energy to the nerve tissue. For example, the nerve tissue can be thermally damaged by increasing a temperature of the nerve tissue to a first temperature (*e.g.,* an ablation temperature) while the wall of the airway is at a second temperature that is less than the first temperature. In some embodiments, a portion of the airway wall positioned radially inward from the nerve tissue can be at the first temperature so as to prevent permanent damage to the portion of the airway wall. The first temperature can be sufficiently high to cause permanent destruction of the nerve tissue. In some embodiments, the nerve tissue is part of a nerve trunk located in connective tissue outside of the airway wall. The smooth muscle and nerve tissue in the airway wall can remain functional to maintain a desired level of smooth muscle tone. The airway can constrict/dilate in response to stimulation (*e.g.,* stimulation caused by inhaled irritants, the local nervous system, or systemic hormones). In other embodiments, the nerve tissue is part of a nerve branch or nerve fibers in the airway wall. In yet other embodiments, both nerve tissue of the nerve trunk and nerve tissue of nerve branches/fibers are simultaneously or sequentially damaged. Various types of activatable elements, such as ablation elements in the form of microwave antenna, RF electrodes, heating elements, or the like, can be utilized to output the energy.

[0018] At least some methods of pulmonary treatment include positioning an elongate member through at least a portion of the trachea. The elongate member has a treatment element and a sensor coupled thereto. A first tissue characteristic is sensed using the sensor with the treatment element at a first airway location. The first tissue characteristic is compared to a reference value to evaluate the location of the treatment element in the airway. The treatment element is activated to treat an airway.

[0019] In certain embodiments, an apparatus for pulmonary treatment includes an elongate member insertable through a trachea into an airway and an active electrode coupled to the elongate member. The active electrode is configured to deliver energy to target tissue in a wall of the airway. A return electrode is positionable in the airway or the esophagus and configured to receive the energy from the target tissue. A protection member is configured to cool non-target tissue proximate to the target tissue. The non-target tissue can be surrounded or can be spaced apart from the target tissue.

[0020] The active electrode is expandable from a contracted configuration to an expanded configuration without the

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use of a balloon. The device can be self-expanding. For example, the device can include a self-expanding basket, a cage, a wire mesh, or other type of component capable of assuming a helical, spiral, corkscrew, or similar configuration. As such the active electrode can be non-inflatably expanded or actuated.

[0021] A method of pulmonary treatment includes delivering energy at a first power level from an active portion of an energy delivery element to create a first lesion covering a first portion of a circumference of an airway. Energy is delivered at a second power level from the active portion of the energy delivery element to create a second lesion covering a second portion of the circumference of the airway displaced from the first portion. The first power level is substantially greater than the second power level. In certain embodiments, the second portion is circumferentially or axially displaced from the first portion relative to a lumen of the airway. For example, the second portion can be both circumferentially displaced and axially displaced from the first portion.

[0022] Another method of pulmonary treatment includes delivering a first amount of energy from an energy delivery device to a first portion of a wall of an airway and delivering a second amount of energy from the energy delivery device to a second portion of the airway wall. The first portion of the wall and the second portion of the wall are spaced apart from one another or can partially overlap one another. For example, most of the first and second portions by area or volume can overlap one another.

[0023] A method of pulmonary treatment includes positioning an energy delivery element in an airway of a subject. The energy delivery element is non-inflatably actuated. The energy delivery element can be moved into engagement with a wall of the airway without using a balloon or other type of inflation device. The energy delivery element can be self-expanding. For example, the energy delivery element can be a self-expandable cage. The non-inflatably expandable cage can move one or more electrodes proximate to or in contact with the airway wall.

[0024] Energy can be delivered from the energy delivery element to the wall of the airway to alter target nerve tissue therein or proximate thereto. A cooling medium is passed into the airway into direct contact with the wall to absorb heat from the wall while delivering the energy. Alternatively, a protection device can be used to cool the airway wall.

[0025] The energy delivery element can comprise a first electrode. The first electrode is positioned within a first space between a first pair of adjacent cartilage rings of the airway. A second electrode is placed in a second space between a second pair of adjacent cartilage rings of the airway. The electrode can be part of a helical or corkscrew shaped device.

[0026] A protection device can be positioned in the esophagus to absorb heat from esophageal tissue while delivering the energy. Energy can be received by the protection device with or delivering energy from a second electrode coupled to the protection device.

[0027] A surface layer of tissue of the wall (*e.g.*, a wall of the trachea, a wall of the esophagus, etc.) can be protected from permanent injury while a lesion of permanently injured tissue is created at a depth below the surface layer. The surface layer is at least about 2 mm in thickness. At least a portion of the lesion contains nerve tissue. In certain procedures, the nerve tissue is altered sufficiently to reduce airway constriction in the subject.

[0028] The cooling medium can include one or more gas or other type of media. The energy delivery element is coupled to an elongate member such that the cooling medium is introduced into the airway through a channel in the elongate member. The cooling medium flows through a channel in the energy delivery element to absorb heat therefrom.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0029] For the purpose of illustrating the invention, the drawings show aspects of one or more embodiments of the invention. However, it should be understood that the present invention is not limited to the precise arrangements and instrumentalities shown in the drawings, wherein:

Figure 1 shows a cross section of the trachea and esophagus, and approximate locations of the anterior and posterior plexus nerves.

Figure 2 shows the cartilaginous rings of the trachea. The connective tissue sheath is shown cut away.

Figure 3 shows the trachea in cross section, illustrating a target region in the pulmonary plexus for treatment in embodiments of the present invention.

Figure 4 is a lateral view illustrating the length of a potential target region corresponding to the cross section in Figure 3.

Figure 4A is an anatomical drawing showing details of the posterior pulmonary plexus.

Figure 5 is a lateral view of a treatment system positioned in the trachea and the esophagus.

Figure 6 is a detailed view of a treatment device in the trachea and an esophageal device in the esophagus.

Figure 7 is cutaway view of a trachea and a distal tip of the treatment device.

Figure 8A is a cross-sectional view of the trachea and isotherms in tissue of the trachea and the esophagus.

Figure 8B is a cross-sectional view of the trachea and isotherms in tissue of the trachea and the esophagus.

Figure 9 illustrates a tracheal treatment device and an esophageal treatment device.

Figure 10 is an isometric view of a treatment system.

Figure 11 is a cross-sectional view of a tracheal catheter taken along a line 11-11.

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Figure 12 is a cross-sectional view of the tracheal catheter taken along a line 12-12.
Figure 13 is an isometric view of an electrode assembly.
Figure 14 is a cross-sectional view of the electrode assembly of Figure 13 taken along a line 14-14.
Figure 15 is a partial cross-sectional view of a treatment system with a catheter extending out of a delivery apparatus.
Figure 16 is a side elevational view of a deployed energy delivery assembly with fluid flowing through an energy emitter assembly.
Figure 17 is a cross-sectional view of the deployed energy delivery assembly with fluid flowing through an expandable member.
Figure 18 is a cross-sectional view of the energy delivery assembly with fluid flowing into the expandable member.
Figure 19 is an elevational view of the ablation assembly with fluid flowing through the energy emitter assembly.
Figure 20 is a side elevational view of an electrode adjacent a cartilaginous ring.
Figure 21 is a side elevational view of electrodes positioned between cartilaginous rings.
Figure 22 is an isometric view of an ablation assembly with a pair of electrodes.
Figure 23 is an isometric view of an ablation assembly with three electrodes.
Figure 24A is a schematic view of a treatment system employing monopolar electrodes for pulmonary treatment and an esophageal device in a subject.
Figure 24B is a schematic view of an embodiment of the present invention employing monopolar electrodes for treatment.
Figure 25A is a schematic view of a tracheal device and an esophageal device in a subject.
Figure 25B is a schematic view of an embodiment employing trachea-to-esophagus circumferential bipolar electrodes.
Figure 26 illustrates a circumferential bipolar energy distribution possible with the embodiment of Figures 25A and 25B.
Figure 27 is a schematic view of an embodiment employing trachea-to-esophagus bipolar, anterior esophageal return electrodes.
Figure 28 illustrates a bipolar energy density distribution possible with the embodiment of Figure 27.
Figure 29 is a schematic view of an embodiment of the present invention employing trachea-to-esophagus bipolar, posterior isolated electrodes.
Figure 30 illustrates a bipolar energy distribution possible with the embodiment of Figure 29.
Figures 31A and 32B are schematic views of an embodiment of the present invention employing trachea-to-esophagus bipolar electrodes with no balloon support.
Figure 32 is an elevational view of an exemplary basket embodiment according to the present invention.
Figures 33A and 33B are schematic views of an embodiment employing a bipolar wire cage with circumferential electrode bands.
Figures 34A and 34B are schematic views of an embodiment of the present invention employing bipolar balloons with circumferential electrode bands.
Figure 35 is a schematic view of an embodiment of the present invention employing tracheal bipolar electrodes with a single tracheal protection zone.
Figure 36A is a schematic view of an embodiment of the present invention in an airway and employing tracheal bipolar electrodes with a dual tracheal protection zone.
Figure 36B is a schematic view of the tracheal device of Figure 36A.
Figure 36C is a top plan view of the tracheal device of Figure 36A.
Figures 37A-37C are schematic views of an embodiment of the present invention employing inter-cartilage electrodes in a stacked ring configuration.
Figures 38A and 38B are schematic views of an embodiment of the present invention employing inter-cartilage electrodes in a coiled configuration.
Figures 39A and 39B are schematic views of an embodiment of the present invention employing inter-cartilage electrodes with a winding adjustment element.
Figures 40A and 40B are schematic views of an embodiment of the present invention employing inter-cartilage electrodes with adjustable D-shaped rings in a bipolar configuration.
Figures 41A and 41B are schematic views of an embodiment of the present invention employing inter-cartilage electrodes with adjustable D-shaped rings in a bipolar configuration with cooling means.
Figure 42 is a schematic view of an embodiment of the present invention employing an esophageal protection device.
Figure 43 is a schematic view of an embodiment of the present invention employing esophageal protection with conductive elements.
Figure 44 is a schematic view of an embodiment of the present invention employing a distal occlusion device with a gas protectant.
Figure 45 is a schematic view of an embodiment of the present invention employing a distal occlusion device with

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a gas protectant and conductive elements.
Figure 46 is a schematic view of an embodiment of the present invention employing a distal occlusion device with a gas protectant and conductive elements showing the protective gas flow.
Figure 47 is a schematic view of an embodiment of the present invention employing a multi-slot coaxial microwave antenna.
Figure 48A is a schematic side view of a tracheal device employing a single antenna microwave system.
Figure 48B is a schematic view of the tracheal device of Figure 48A.
Figure 49 is a side view of a tracheal device.
Figure 50A is a schematic side view of a tracheal device with a dual antenna microwave system.
Figure 50B is a schematic front view of the tracheal device of Figure 53A.
Figure 51A is a schematic side view of a tracheal device with a dual antenna microwave system and an esophageal reflector/protector.
Figure 51B is a schematic front view of the tracheal device and esophageal reflector/protector device of Figure 51A.
Figure 52A is a schematic side view of a tracheal device with a microwave device with a cooling or coupling jacket.
Figure 52B is a schematic front view of the tracheal device of Figure 55A.
Figure 53 is a cross-sectional view of a tracheal device positioned within the trachea.
Figure 54A is a schematic view of an alternative embodiment of the present invention employing a microwave device with a cooling/coupling element.
Figure 54B illustrates a specific absorption rate profile generated by the treatment system of Figure 54A.
Figure 54C is a graph of an axial profile along a specific absorption rate observation line.

DETAILED DESCRIPTION

[0030] Throughout this disclosure, the words disrupt, ablate, modulate, denervate will be used. It should be understood that these globally refer to any manipulation of the nerve that changes the action of that nerve. This can be a total cessation of signals, as in ablation or severing, or it can be a modulation, as is done by partial or temporary disruption, pacing, etc.

[0031] Similarly, trachea is often used to describe a segment wherein the devices and methods will be used. It should be understood that this is shorthand and can be meant to encompass the trachea itself, as well as the right and left main bronchi and other portions of the pulmonary tree as necessary.

[0032] It should be noted that the pulmonary nerves referred to in the disclosure not only include nerves that innervate the pulmonary system but also any neural structures that can influence pulmonary behavior. For example, elements of the cardiac plexus, or the nerves that innervate the esophagus, also interact with the airways and may contribute to asthmatic conditions. The nerves can include nerve trunks along the outer walls of hollow vessels, nerve fibers within the walls of hollow vessels (*e.g.,* the wall of the trachea and/or esophagus), nerves within a bridge between the trachea and esophagus, or at other locations. The left and right vagus nerves originate in the brainstem, pass through the neck, and descend through the chest on either side of the trachea. These nerves can be targeted. The vagus nerves spread out into nerve trunks that include the anterior and posterior pulmonary plexuses that wrap around the trachea, the left main bronchus, and the right main bronchus. The nerve trunks also extend along and outside of the branching airways of the bronchial tree. Nerve trunks are the main stem of a nerve comprising a bundle of nerve fibers bound together by a tough sheath of connective tissue. The vagus nerves, including their nerve trunks, along the trachea or other nerve tissue along, proximate to, or in the bronchial tree can be targeted. A treatment device in the form of a tracheal device can be positioned at different locations within an airway (*e.g.,* the trachea, one of the main stem bronchi, or other structures of the bronchial tree).

[0033] The pulmonary branches of the vagus nerve along the left and right main stem bronchus intermedius are particularly preferred targets. The nerve trunks of the pulmonary branches extend along and outside of the left and right main stem bronchus and distal airways of the bronchial tree. Nerve trunks of the main stem nerve comprise a bundle of nerve fibers bound together by a tough sheath of connective tissue. Any number of procedures can be performed on one or more nerve trunks to affect the portion of the lung associated with those nerve trunks. Because some of the nerve tissue in the network of nerve trunks coalesce into other nerves (*e.g.,* nerves connected to the esophagus, nerves though the chest and into the abdomen, and the like), specific sites can be targeted to minimize, limit, or substantially eliminate unwanted damage of those other nerves.

[0034] Some fibers of anterior and posterior pulmonary plexuses coalesce into small nerve trunks which extend along the outer surfaces of the trachea and the branching bronchi and bronchioles as they travel outward into the lungs. Along the branching bronchi, these small nerve trunks continually ramify with each other and send fibers into the walls of the airways. Any of those nerve trunks or nerve tissue in walls can be targeted. Various procedures that may be performed with at least some of the devices and methods of embodiments of the present invention are described in copending application Serial No. 12/463,304 filed on May 8, 2009, which is incorporated herein by reference in its entirety.

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[0035] As illustrated in Figure 1, the C-shaped structure 10 that separates the inner elements of the airway-the smooth muscle 12, goblet cells 16, mucosa, anterior plexus nerves 22, posterior plexus nerves 23, epithelium 24, nerves 25, arteries 26, etc.,-from the nerves are thick bands of cartilage 10. These bands 10 cover the majority of the circumference of the trachea and larger bronchi, with a discontinuity only along the posterior segment where the trachea and esophagus are coincident. As further shown in Figure 2, these bands 10a, 10b, 10c (collectively "10") are discrete elements, arranged longitudinally along the length of the trachea 18 and large bronchi, with thinner areas of connective tissue between them. The anterior plexus runs outside of these bands. So it can be seen that any modality designed to sever or disrupt these nerves will be heavily guarded against by these rings.

[0036] A different complication exists along the posterior border where the discontinuity in the cartilage bands exists. Here, the trachea and esophagus are coincident, connected to one another by an area of connective tissue. Here the problem is the opposite of that on the posterior side. The esophagus can be easily damaged by devices operating from within the lung to disrupt or modulate the nerves running between the two lumens. A rare but fatal complication of cardiac ablation for the treatment of atrial fibrillation occurs when ablations performed within the heart create a weakness along the esophagus (the posterior left atrium is also adjacent the esophagus). In some cases, this weakness turns into a fistula, causing atrial rupture, massive hemorrhage and death. So it is critical to protect these ancillary structures or to direct the means for disruption or modulation away from them.

[0037] It can be seen from these descriptions of the anatomy of the trachea 18 and esophagus 30 that (as shown in Figure 3) energy or treatment means directed at or through the posterior wall 31 of the trachea 18, or the anterior wall 32 of the esophagus 30, would have direct access to the posterior pulmonary plexus 23.

[0038] A potential region of interest for pulmonary nerve therapy is further described with reference to Figure 4A. Nerves which supply the pulmonary plexus arise from multiple levels of the thoracic spine 38 as well as multiple levels of the vagus nerve. Treatment and/or therapy delivery may occur anywhere within this potential target region 40, as a single treatment or as a plurality of treatments, administered in a single treatment session or staged over multiple sessions.

[0039] To modulate or disable the pulmonary nerves, it can be seen from the above anatomical descriptions that protection and or therapy can be delivered via the trachea 18, main stem bronchii or other airways further distally in the bronchial tree, the esophagus 30, or combinations of these. Following are brief descriptions of a number of different embodiments wherein energy is delivered to the targeted nerves through combinations of devices, or in some embodiments, through a single device. The targeted nerves can run along the trachea 18 and the esophagus 30, between the trachea 18 and the esophagus 30, or other suitable locations. For example, nerve tissue within walls of the trachea 18 and/or the esophagus 30 can be destroyed or otherwise altered. Alternatively or additionally, nerve trunks running along the outer wall of the trachea 18 and/or the esophagus 30 can be altered or destroyed.

[0040] In addition to the potential access to the pulmonary plexus 23 from the area of the trachea 18 and the correlated area in the esophagus 30, it can be seen from Figure 4A that a good number of branches from the thoracic ganglia 40 converge in the area of the carina, and the areas of the upper right bronchi 42 and upper left bronchi 44. Thus, the esophagus 30 may still need to be protected if tissue modification is to be done in the area of the carina, but as the target area moves more distally down the right and left bronchi, the need for esophageal protection diminishes.

[0041] Another reason that it may be beneficial to focus the treatment area more towards the individual right and left bronchi 42, 44 is that the recurrent laryngeal nerve may in some cases be collocated with nerves supplying the pulmonary plexus as they travel down the tracheal/esophageal interface to the lower areas of the plexus. Damage to the laryngeal nerve was shown in the surgical literature for pulmonary sympathectomy to be associated with complications of speech and swallowing, so preserving its function is critical.

[0042] Of note, as the treatment zone is located farther down the bronchial tree, past the carina and away from the trachea, the cartilaginous rings become completely circumferential-the area of non-coverage which was available for exploitation by a treatment device is no longer present. With this in mind, devices targeting regions of full cartilaginous coverage may have the requirement that they need to traverse and deliver therapy around, between or through these rings in order to reach the target nerves.

[0043] According to certain embodiments of the invention, devices may be configured for the delivery of radio frequency energy to modulate or disable the pulmonary plexus. While embodiments shown are configured for delivery of RF energy, many of the configurations can also be adapted to accommodate a catheter based microwave antenna, high energy pulse electroporation, or similar energy modalities.

[0044] The RF energy can be delivered in a traditional conductive mode RF, where the energy is directly applied to the tissue through a direct contact electrode, or it can be delivered through the use of capacitive coupling to the tissue. In capacitive coupling, a slightly higher frequency signal is typically used compared to traditional RF, and the energy is delivered to the tissue across a dielectric, which is often a cooling element. In one example of capacitive coupling, energy may be delivered across a cooling plate that keeps the surface of tissue contacted from being harmed as energy is delivered deeper into the target tissue.

[0045] The RF energy can be delivered to different target regions, which can include, without limitation, nerve tissue (*e.g.,* tissue of the vagus nerves, nerve trunks, etc.), fibrous tissue, diseased or abnormal tissues (*e.g.,* cancerous tissue,

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inflamed tissue, and the like), cardiac tissue, muscle tissue, blood, blood vessels, anatomical features (*e.g.,* membranes, glands, cilia, and the like), or other sites of interest. In RF ablation, heat is generated due to the tissue resistance as RF electrical current travels through the tissue. The tissue resistance results in power dissipation that is equal to the current flow squared times the tissue resistance. To ablate deep tissues, tissue between an RF electrode and the deep tissue can become heated if active cooling is not employed using a cooling device, such as a cooling plate or cooling balloon. The cooling device can be used to keep tissue near the electrode below a temperature that results in cell death or damage, thereby protecting tissue. For example, cooling can prevent or limit overheating at the electrode-tissue interface. Overheating (*e.g.,* tissue at temperatures above 95°C to about 110°C) can lead to the formation of coagulum, tissue desiccation, tissue charring, and explosive outgassing of steam. These effects can result in increased tissue resistance and reduced RF energy transfer into the tissue, thereby limiting the effective RF ablation lesion depth. Active cooling can be used to produce significantly deeper tissue lesions. The temperature of coolant for active cooling can be about 0°C to about 24°C. In some embodiments, the coolant and electrode produce a lesion at a therapeutic depth of at least about 3 mm while protecting tissue at shallower depths from lethal injury. In some embodiments, the lesions can be formed at a depth of about 3 mm to about 5 mm to damage nerve tissue. Other temperatures and depths can be achieved.

[0046] Figure 5 shows a system 204 including a pulmonary treatment device in the form of a tracheal catheter 207 positioned in the trachea 18 and a protection device 205, or temperature control device, positioned in the esophagus 30. An energy delivery assembly 208 is positioned to deliver energy to ablate targeted tissue between the trachea 18 and esophagus 30 while protecting non-targeted tissue. The temperature control device 205 includes a protection member 212 that absorbs heat to cool and protect tissue of the esophagus 30, thereby inhibiting damage to esophageal tissue. The tracheal catheter 207 can deliver a sufficient amount of energy to the trachea wall to heat and damage target tissue while the temperature control device 205 absorbs a sufficient amount of heat from the esophagus wall to inhibit damage to esophageal tissue while the target tissue is damaged. The tracheal device 204 and the temperature control device 205 can cooperate to ablate or otherwise alter targeted tissue, such as the pulmonary plexus 32.

[0047] It will be understood that, with regard to any of the embodiments described herein, while described here for use in the trachea, the devices and methods of the invention may be used for treatment in more distal airways including the mainstem bronchii, broncus intermedius, and more distal branches of the bronchial tree. Thus the terms "tracheal device" and the like are not intended to be limited to devices used in the trachea and may be interpreted to mean devices for use in any location in the trachea or bronchial tree where nerve tissue may be targeted to treat asthma and other pulmonary diseases using the techniques described herein.

[0048] Referring to Figures 6 and 7, if the energy delivery assembly 208 includes an energy delivery element in the form of an RF electrode 214, the electrode 214 can be brought into contact with or proximate to an inner surface of the trachea 18. The RF electrode 214 can output RF energy which travels through the tissue and is converted into heat. The heat causes formation of a lesion. The RF energy can be directed radially outward towards the targeted tissue without causing appreciable damage to non-targeted tissue (*e.g.,* tissue of the esophagus 30, inner tissue of the trachea 18, anterior tissue of the trachea 18) using coolant (represented by arrows 201). A wide range of different procedures, such as, for example, denervation of a portion of the trachea 18, an entire circumference of the trachea 18, target nerve trunks travelling to one lung or both lungs, or the like. Nerve tissue is damaged to relax the muscle tissue in the bronchial tree to dilate the airway to reduce air flow resistance in one or both lungs, thereby allowing more air to reach the alveolar sacs for the gas exchange process. Decreases in airway resistance may indicate that passageways of airways are opening, for example in response to attenuation of nervous system input to those airways. The balloon 212 can absorb heat to cool the anterior region 203 (shown removed in Figure 7) of the trachea 18. Emitter assembly 220 wraps around the balloon 212 to contact the posterior region 202 of the trachea 18, as shown in Figure 6. The emitter assembly 220 extends along the balloon 212 to a distal tip 197.

[0049] A physician can select and ablate or otherwise alter appropriate nerve tissue to achieve a desired decrease in airway resistance, which can be measured at a subject's mouth, a bronchial branch that is proximate to the treatment site, a trachea, or any other suitable location. The airway resistance can be measured before performing the therapy, during the therapy, and/or after the therapy. In some embodiments, airway resistance is measured at a location within the bronchial tree by, for example, using a vented treatment system that allows for respiration from areas that are more distal to the treatment site. Any number of procedures can be used to treat asthma, COPD, and other diseases, conditions, or symptoms.

[0050] The temperature control device 205 of Figure 6 includes an elongate member 211 connected to the inflatable member 223. Media, such as chilled saline, flows through an input lumen 213 and circulates through a chamber 215. The media absorbs heat and exits the chamber 215 through an outlet 217. The media flows proximally through an output tube 216. The longitudinal length of the inflatable member 223 can be longer than a longitudinal length of the energy delivery assembly 208 to ensure that a longitudinal section of tissue extending distally and proximally of the targeted tissue is cooled to avoid unwanted tissue alteration, for example, tissue damage.

[0051] Figures 8A and 8B show isotherms. By adjusting the rate of power delivery to an electrode 214, the rate at which media is passed into the energy delivery assembly 208, the rate at which media is passed into the inflatable

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member 212, the temperatures of the media, the sizes and configuration of energy delivery assembly 208/inflatable member 212, and the exact contour and temperature of the individual isotherms can be modified. An energy distribution can be produced which results in isotherm A being warmest and, moving radially outward from isotherm A, each successive isotherm becomes cooler, with isotherm F being coolest. At minimum, the temperature at isotherm A will be high enough to produce cell death in the target tissue. In at least some preferred embodiments, isotherm A will be in a range of about 50°C to about 90°C, more preferably about 60°C to about 85°C, and most preferably about 70°C to about 80°C. Isotherm F will be at or around body temperature, and the intervening isotherms will be at intervals between body temperature and the temperature at isotherm A. For example, by selecting the proper temperature and flow rate of saline and the rate of power delivery to the electrode, it is possible to achieve temperatures in which isotherm A = 70°C, B = 55°C, C = 50°C, D = 45°C, E = 40°C, and F = 37°C. In some tissues, a lethal temperature may be greater than or equal to about 70°C. For example, the A isotherm can be about 75°C to about 80°C to form lesions in nerve tissue. Different isotherms and temperature profiles can be generated for different types of tissue because different types of tissue can be affected at different temperatures. Further adjustments make it possible to achieve temperatures where isotherm A = 50°C, B = 47.5°C, C = 45°C, D = 42.5°C, E = 40°C, and F = 37°C. Alternative adjustments make it possible to achieve temperatures where isotherm A is equal to or greater than 90°C, B = 80°C, C = 70°C, D = 60°C, E = 50°C, and F = 40°C. Only those areas contained within the A and B isotherms will be heated enough to induce cell death for certain types of tissue. Other temperature ranges are also possible depending on the lethal temperature of the target tissue. In some procedures, tissue at a depth of about 2 mm to about 8 mm in the airway wall can be ablated while other non-targeted tissues at a depth of less than 2 mm in the airway wall are kept at a temperature below a temperature that would cause cell death. The isotherms of Figure 8A can be generated without cooling using the temperature control device 205. By cooling tissue using the temperature control device 205, the isotherms generate bands, as illustrated in Figure 8B. Advantageously, the interior tissues of the trachea 18 and the esophagus 30 can be undamaged while deep tissue, including nerve tissue 23, is damaged.

[0052] The RF electrode 214 can be positioned at other locations. Figure 9 shows the RF electrode 214 positioned to target the right anterior plexus 22. After each application of energy, the energy delivery assembly 208 can be angularly rotated to treat a different section of the trachea wall. In some procedures, an entire circumference of the trachea wall 18 can be treated. In other embodiments, circumferential segments of the trachea wall 18 are treated to target specific tissue while minimizing tissue damage of adjacent sections of the trachea wall. Throughout the procedure, the temperature control device 205 can cool the esophageal tissue.

[0053] Different amounts of energy can be delivered to different sections of the trachea 18. Energy delivered at a first power level from the electrode 214 can create a first lesion covering a first portion of a circumference of the airway. Energy delivered at a second power level from the electrode 214 can create a second lesion covering a second portion of the circumference of the airway displaced from the first portion. The first power level is substantially different (*e.g.,* greater) than the second power level. For example, the second power level can be about 40% to about 90% of the first power level, more preferably about 50%-80% of the first power level. The second power level can be selected to avoid permanent injury to non-target tissue proximate to the treatment site. The second portion can be circumferentially or axially displaced from the first portion relative to lumen of the airway. The first portion of the circumference can be on an anterior aspect of the airway, and the second portion can be on a posterior aspect of the airway.

[0054] Because the anterior region of the trachea 18 is spaced well apart from the esophagus 30, a higher amount of energy can be used to ablate the pulmonary plexus 22. As the electrode 214 is rotated towards the esophagus 30, the amount of emitted energy can be reduced. This can help minimize, limit, or substantially eliminate tissue damage to the esophageal tissue. Different amounts of energy can be delivered to different regions (*e.g.,* circumferential locations) of the trachea 18. A relatively high amount of energy can be delivered to the anterior region of the trachea 18 as compared to the amount of energy delivered to the posterior region of trachea 18. A lower amount of energy can be delivered to the posterior tissue of the trachea 18 to avoid damage to esophagus tissue. In some protocols, about 20 watts of energy is delivered to electrode 214 to ablate tissue located at the anterior region of the trachea 18. The electrode 214 can emit no more than about 15 watts of energy when it is positioned to contact the posterior region of the trachea 18. In various procedures, the amount of energy delivered to the electrode 214 can be at least about 40% but less than 90% of the energy delivered to the electrode 214 at a different region of the trachea 18. In certain embodiments, the amount of energy emitted by the electrode 214 positioned along the posterior portion of the trachea 18 is in a range of about 50% to about 80% of the energy delivered to the electrode 214 positioned at the anterior portion of the trachea 18. In other embodiments, the amount of energy emitted by the electrode 214 positioned along the posterior portion of the trachea 18 is in a range of about 60% to about 90% of the energy delivered to the electrode 214 positioned at the anterior portion of the trachea 18. Other relative percentages are also possible.

[0055] As the mainstem bronchi pass from the lung root at the main carina out towards the lungs, a variety of external structures lie in close proximity to their outer surfaces. Anteriorly, these external structures are the pulmonary arteries and veins, aorta and superior vena cava; medially they are the soft tissues of the mediastinum and the heart; laterally the external structure is the lung parenchyma; posteriorly on the right it is again lung parenchyma; proximally on the left

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it is the esophagus; and distally it is the lung. Additionally, the continuation of the left main vagus nerve as it passes inferiorly to innervate the abdomen and pelvis is interposed between the esophagus and the left main bronchi.

[0056] Due to the high rate of blood flow through the blood vessels and the heart, these structures are effective heat sinks and much of the heat generated during treatment is removed from their walls during treatment. Thus, the walls of the blood vessels and of the heart are relatively unaffected by the treatment. The mediastinal soft tissues and the lung lack the heat sinking effect seen in the blood vessels and heart, but they may tolerate thermal injury without untoward clinical consequences. However, the esophagus and interposed vagus nerve lack significant blood flow and may be susceptible to thermal injury during treatment in the left mainstem bronchus.

[0057] In one procedure, the treatment site to which RF energy is applied is the most distal centimeter of the left mainstem bronchus. Because the esophagus 30 runs along the posterior aspect of the proximal potion of the left mainstem bronchus, at this most distal aspect of the bronchus, the posterior wall is in contact with lung parenchyma only. Thus, the RF energy can be delivered to the most distal centimeter of the left mainstem bronchus to avoid injury to the esophagus 30. Other types of energy can also be delivered to this location.

[0058] In another procedure, the posterior wall of the left mainstem bronchus is either not treated or is treated with a lower dose of energy, while the remainder of the airway's circumference is treated with a higher dose of energy. When the balloon 212 of Figures 5 and 6 has a longitudinal length of about 8 mm to about 12 mm, the electrode 214 can be cooled with either room temperature water or iced water coolant passing through the electrode 214 and balloon 212. In certain procedures, the rate of flow of the water or coolant through the balloon 212 and the electrode 214 can be maintained at about 100 ml per minute for a treatment duration of about 120 seconds, while power levels are maintained at less than 15 W applied on the posterior wall of the mainstem bronchus to cause substantially no injury to the esophagus 30 or the interposed vagus nerve. Other combinations of electrode size, coolant, coolant temperature, coolant flow, treatment duration and power could be used to achieve the same results.

[0059] Referring to Figure 10, the treatment system 204 includes a media delivery system 246 and a control module 210 coupled to an elongate member in the form of a shaft 230 of the catheter 207. The temperature control device 205 is coupled to the media delivery system 246. An electrode pad 219 for placement against the patient is connected to the control module 210. Energy delivery assembly 208 comprises an emitter assembly 220 extending from the elongate shaft 230 and wrapping around a balloon 212. The balloon 212 can be inflated from a collapsed state (see Figure 15) to the expanded state shown in Figure 10. As the balloon 212 inflates, the electrode 214 can be moved towards the airway wall. The fully inflated balloon 212 can hold the electrode 214 near (*e.g.,* proximate or in contact with) tissue through which energy is delivered. The coolant can absorb thermal energy to cool the balloon 212 or the energy emitter assembly 220, or both. This in turn cools the outer surface of the airway wall.

[0060] The control module 210 can include, without limitation, one or more computers, processors, microprocessors, digital signal processors (DSPs), field programmable gate arrays (FPGA), computing devices, and/or application-specific integrated circuits (ASICs), memory devices, buses, power sources, and the like. For example, the control module 210 can include a processor in communication with one or more memory devices. Buses can link an internal or external power supply to the processor. The memories may take a variety of forms, including, for example, one or more buffers, registers, random access memories (RAMs), and/or read-only memories (ROMs). Programs, databases, values, or other information can be stored in memory. For example, in some embodiments, the control module 210 includes information associated with tissue characteristics. A comparison can be performed between sensed tissue characteristics and stored tissue characteristics. Operation of the catheter 207 can be adjusted based, at least in part, on the comparison. Different types of reference values (*e.g.,* reference values for non-treated tissue, reference values for treated tissues, impedance values, etc.) corresponding to tissue characteristics can be utilized in such a protocol. The control module 210 may also include a display 244, such as a screen, and an input device 245. The input device 245 can include one or more dials, knobs, touchpads, or a keyboard and can be operated by a user to control the catheter 207. Optionally, the input device 245 can also be used to control operation of the temperature control device 205.

[0061] The control module 210 can store different programs. A user can select a program that accounts for the characteristics of the tissue and desired target region. For example, an air-filled lung can have relatively high impedance, lymph nodes have medium impedance, and blood vessels have relatively low impedance. The control module 210 can determine an appropriate program based on the impedance. A differential cooling program can be executed to deliver different temperature coolants through the balloon 212 and the emitter assembly 220. The temperature difference can be at least 10°C. Performance can be optimized based on feedback from sensors that detect temperatures, tissue impedance, or the like. For example, operation of the energy delivery assembly 208 can be controlled based on a surface temperature of the tissue to which energy is delivered. If the surface temperature becomes excessively high, cooling can be increased and/or electrode power decreased in order to produce deep lesions while protecting surface tissues.

[0062] The control module 210 can function as an energy generator, such as a radio frequency (RF) electrical generator. RF energy can be outputted at a desired frequency. Example frequencies include, without limitation, frequencies in a range of about 50 KHZ to about 1,000 MHZ. When the RF energy is directed into tissue, the energy is converted within the tissue into heat causing the temperature of the tissue to be in the range of about 40°C to about 99°C. The RF energy

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can be applied for about 1 second to about 120 seconds. In some embodiments, the RF generator has a single channel and delivers approximately 1 to 25 watts of RF energy and possesses continuous flow capability. Other ranges of frequencies, time intervals, and power outputs can also be used. An internal power supply 248 can be an energy storage device, such as one or more batteries. Electrical energy can be delivered to the energy emitter assembly 220, which converts the electrical energy to RF energy or another suitable form of energy. Other forms of energy that may be delivered include, without limitation, microwave, ultrasound, direct current, or laser energy. Alternatively, cryogenic ablation may be utilized wherein a fluid at cryogenic temperatures is delivered through the shaft 230 to cool a cryogenic heat exchanger on the assembly 208.

[0063] Referring again to Figures 5 and 10, the control module 210 can have one or more communication devices to wirelessly, optically, or otherwise communicate with the media delivery system 246. Pumps of the media delivery system 246 can be operated based on the signals. In other embodiments, the control module 210 can include the media delivery system 246. A single unit can therefore control operation of the catheter 207 and the temperature control device 205.

[0064] The media delivery system 246 can pump cooling media through the pulmonary treatment device 207 and the temperature control device 205 and includes a media container 260a coupled to a supply line 268 and a media container 260b coupled to a return line 272. Luer connectors or other types of connectors can couple the lines 268, 272 to lines 273, 275. The media container 260a can include a container (*e.g.,* a bottle, a canister, a tank, a bag, or other type of vessel for holding fluid or other media). In pressurizable embodiments, the media container 260a includes one or more pressurization devices *(e.g.,* one or more pumps, compressors, or the like) that pressurize coolant. Temperature control devices (*e.g.,* Peltier devices, heat exchangers, or the like) can cool or recondition the fluid. The media can be a coolant including saline, deionized water, refrigerant, cryogenic fluid, gas, mixtures thereof, or the like.

[0065] In other embodiments, the media container 260a can be an insulated container that holds and delivers a chilled coolant to the supply line 268. In embodiments, the media container 260a is bag, such as an IV type bag, configured to be held on a pole.

[0066] The balloon 212 optionally has a sensor 247 (illustrated in dashed line in Figure 10) that is communicatively coupled to the control module 210. The control module 210 can command the catheter 207 based on signals from the sensor 247 (*e.g.,* a pressure sensor, a temperature sensor, a thermocouple, a pressure sensor, a contact sensor, an impedance sensor, or the like). Sensors can also be positioned on energy emitter assembly 220, along the elongate shaft 230, or at any other location. In a closed loop system, the electrical energy is delivered to the electrode 214 based upon feedback signals from one or more sensors configured to transmit (or send) one or more signals indicative of one or more tissue characteristics, energy distribution, tissue temperatures, or any other measurable parameters of interest. Based on those readings, the control module 210 adjusts operation of the electrode 214. Alternatively, in an open loop system, the operation of the electrode 214 is set by user input. For example, the user can observe tissue temperature or impedance readings and manually adjust the power level delivered to the electrode 214. Alternatively, the power can be set to a fixed power mode. In yet other embodiments, a user can repeatedly switch between a closed loop system and an open loop system.

[0067] In certain procedures, the sensor 247 can sense one or more tissue characteristics. The control module 210 can analyze the sensed tissue characteristics. For example, the control module 210 compares at least one sensed tissue characteristic to at least one stored reference value to, for example, evaluate the location of the electrode 214 relative to the airway. The evaluation can include, without limitation, determining the position of the electrode 214 relative to a reference location. The control unit 210 can estimate the location of at least one non-target structure or tissue based on impedance and/or other measurable characteristic. After estimating the location of the non-target structure or tissue, the electrode 214 can be repositioned before delivering energy so as to avoid injury to the non-target structures or tissue. Previously treated tissue can be detected based on impedance and/or other measurable characteristics. The electrode 214 can be activated to treat the airway when it is determined that the electrode 214 is located in the desired position.

[0068] Media flowing through the conduit 234 cools the electrode 214. Alternatively, flow diverters within the balloon 212 can direct some or all of the coolant in the balloon 212 towards the electrode 214 or a balloon sidewall and may provide a separate cooling channel for the electrode 214. In some embodiments, one or more cooling channels extend through the electrode 214 (*e.g.,* electrode 214 may be tubular so that coolant can flow through it). In other embodiments, the coolant flows around or adjacent the electrode 214. For example, an outer member, illustrated as the conduit 234 in Figure 10, can surround the electrode 214 such that fluid can flow between the electrode 214 and the conduit 234. Additionally or alternatively, the energy delivery assembly 208 can be actively cooled or heated using one or more thermal devices (*e.g.,* Peltier devices), cooling/heating channels, or the like.

[0069] Referring to Figures 10 and 11, the elongate shaft 230 extends from the control module 210 to the energy delivery assembly 208 and includes a power line lumen 320, a delivery lumen 324, and a return lumen 326. A power line 280 extends through the power line lumen 320 and couples the control module 210 to the electrode 214. The delivery lumen 324 provides fluid communication between the media container 260a and the energy emitter assembly 220 and balloon 212. The return lumen 326 provides fluid communication between the balloon 212 and/or electrode 214 and the fluid receptacle 260b. The elongate shaft 230 can be made, in whole or in part, of one or more metals, alloys (*e.g.,* steel

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alloys such as stainless steel), plastics, polymers, and combinations thereof, as well as other biocompatible materials, and can be flexible to pass conveniently along highly branched airways. Sensors can be embedded in the elongate shaft 230 to detect the temperature of the fluids flowing therethrough.

[0070] Figure 12 shows the electrode 214 positioned in a channel 330 of the conduit 234 and includes a coolant channel 340. The electrode main body 350 can be a rigid tube made, in whole or in part, of metal (*e.g.,* titanium, stainless steel, or the like). In some embodiments, conduit 234 does not extend over the entire electrode 214, leaving a central portion of the tubular electrode exposed for direct contact with the airway wall. In other embodiments, the electrode main body 350 is made, in whole or in part, of a shape memory material. Shape memory materials include, for example, shape memory metals or alloys (*e.g.,* Nitinol), shape memory polymers, ferromagnetic materials, combinations thereof, and the like. These materials can assume predefined shapes when released from a constrained condition or different configurations when activated with heat. In some embodiments, the shape memory material can be transformed from a first preset configuration to a second preset configuration when activated (*e.g.,* thermally activated).

[0071] As shown in Figures 13 and 14, sensors 360a, 360b (collectively "360") are coupled to the electrode main body 350. A pair of lines 370a, 370b (collectively "370") pass through the channel 340 and are coupled to the sensors 360a, 360b, respectively. In some embodiments, the sensor 360a is a contact sensor, and the sensor 360b is a temperature sensor, impedance sensor, and/or a pressure sensor. The number, positions, and types of sensors can be selected based on the treatment to be performed.

[0072] In multilayer embodiments, the electrode main body 350 can include at least one tube (*e.g.,* a non-metal tube, a plastic tube, etc.) with one or more films or coatings. The films or coatings can be made of metal, conductive polymers, or other suitable materials formed by a deposition process *(e.g.,* a metal deposition process), coating process, etc., and can comprise, in whole or in part, silver ink, silver epoxy, combinations thereof, or the like.

[0073] Radio-opaque markers or other types of visualization features can be used to position the main body 350. To increase visibility of the electrode 214 itself, the electrode 214 may be made, in whole or in part, of radiographically opaque material.

[0074] Figures 15-17 show one exemplary method of using a treatment system 200. A physician can visually inspect the airway 100 using a delivery apparatus 206 to locate and evaluate the treatment site(s) and non-targeted tissues before, during, and/or after performing a therapy. The airway 100 can be part of the trachea, main stem bronchi, or any other airway of the bronchial tree. A delivery apparatus 206 can be a bronchoscope, a guide tube, a delivery sheath, or an endoscope and can include one or more viewing devices, such as optical viewing devices (*e.g.,* cameras), optical trains (*e.g.,* a set of lenses), and the like. For example, the delivery apparatus 206 can be a bronchoscope having one or more lights for illumination and optical fibers for transmitting images. The catheter 207 may be adapted to be delivered over a guidewire (not shown) that passes between the balloon 212 and the energy emitter assembly 220. This provides for rapid exchange capabilities.

[0075] When the delivery apparatus 206 of Figure 15 is moved along a body lumen 101 (*e.g.,* an airway), the collapsed energy delivery assembly 208 is held within a working channel 386 of the delivery apparatus 206. The conduit 234 can form a loop 221 such that the electrode 214 is almost parallel to a long axis 373 when the catheter 207 is in a substantially straight configuration. In the illustrated embodiment of Figure 15, an angle β is defined between the direction of the long axis 373 of the catheter 207 and a long axis 374 of the electrode 214. The angle β can be in a range of about 0 degrees to about 30 degrees. In some embodiments, the angle β is in a range of about 0 degrees to about 20 degrees. The electrode 214, being curved, can also nest with and partially encircle the elongate shaft 230. In certain embodiments, at least a portion of the elongate shaft 230 is disposed within an arc of the electrode 214 for a further reduced profile. As such, the shaft 230 can be positioned between the ends of the electrode 214. Electrode 214 may have various lengths, depending on the desired length of the lesion to be created in each electrode position. In preferred embodiments, electrode 214 has a length of at least about 1 mm to about 4 mm. In certain embodiments, the length of the electrode 214 is about 2 mm up to about 3 mm. The electrode can have a width (or diameter if cylindrical) no larger than the width of the spaces between the cartilage rings, in some embodiments being about 0.1 mm to about 3 mm.

[0076] With continued reference to Figure 15, the diameter D_L of the working channel 386 can be less than about 8 mm. The diameter D_B of the deflated balloon 212 can be relatively small. For example, a minimum diameter $D_{B\ min}$ can be in a range of about 2 mm to about 3 mm, and a maximum diameter $D_{B\ max}$ in a range of about 5 mm to about 6 mm when the balloon 212 is fully collapsed. If the electrode 214 is collapsible, the diameter D_{max} of the assembly 208 can be less than about 3 mm. In ultra low-profile configurations, the maximum diameter D_{max} can be less than about 2.8 mm.

[0077] The balloon 212 can be inflated to move the energy emitter assembly 220 near (*e.g.,* proximate to or in contact with) the airway 100. The angle P can be increased between 70 degrees and about 110 degrees when the balloon 212 is fully inflated. Figure 16 shows the energy delivery assembly 208 deployed, wherein the electrode 214 can be about perpendicular to the long axis 373. There can be play between the energy emitter assembly 220 and the balloon 212 such that the angle β is in a range of about 60 degrees to about 120 degrees in order to accommodate variations of anatomical structures, misalignment (*e.g.,* misalignment of the catheter shaft 230), or the like. In some embodiments, the electrode 214 moves towards a circumferentially extending orientation as it moves from a delivery orientation to the

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deployed orientation. The electrode 214 in the deployed orientation extends substantially circumferentially along the wall of the airway 100. In certain embodiments, the electrode 214 will be configured to be positioned entirely within the spaces 375 between cartilage rings 376 along the airway wall when the energy delivery assembly 208 is in the fully deployed configuration.

[0078] Figures 16 and 17 show the energy emitter assembly 220 fluidically coupled to both the elongate shaft 230 and the balloon 212. Generally, coolant cools the tissue-contacting portion of the energy emitter assembly 220. The cooling section 209 of the energy delivery assembly 208 contacts the airway wall 100 so as to cool tissue adjacent to the tissue-contacting portion while energy is outputted by the electrode 214. The cooling section 209 can be formed by the portions of the energy emitting assembly 220 and the balloon 212 that contact the airway wall 100. If the electrode 214 faces an anterior region of the trachea 18, the assembly 208 can seat between cartilage rings 376 to avoid or limit movement of the electrode 214 along the length of the airway 100. If the energy delivery assembly 208 is positioned in the bronchial tree, especially in the main stem bronchi, the electrode 214 can be seated between spaced apart cartilage rings 376.

[0079] As the balloon 212 inflates, the electrode 214 moves (*e.g.,* pivots, rotates, displaces, etc.) from a first orientation of Figure 15 in which the electrode 214 extends axially along the airway 100 and a second orientation of Figure 16 in which the entire electrode 214 is disposed in a space 375 between adjacent cartilage rings 376a, 376b. The balloon 212 can both cool the airway 100 and cause the electrode 214 to seat in the space 375.

[0080] Figure 16 shows the energy emitter assembly 220 positioned to locate the electrode 214 in the space 375. In certain embodiments, the electrode 214, in the first orientation, extends a distance with respect to a longitudinal axis 373 (see Figure 15) that can be greater than the distance the electrode 214, in the second orientation, extends with respect to the longitudinal axis 373.

[0081] To deploy the energy emitting assembly 208, coolant from the elongate shaft 230 flows through the energy emitter assembly 220 and into the balloon 212. The electrode 214 can output a sufficient amount of energy to ablate a target region. The electrode 214 can be at a position corresponding to the anatomical location of at least one nerve in or proximate to the airway wall 100. The electrode 214 outputs energy to ablate the targeted nerve tissue. The coolant absorbs thermal energy from electrode 214 and the airway wall 100.

[0082] To treat tissue along the trachea, the diameter D_E of the electrode 214 and conduit 234 can be in a range of about 1.5 cm to about 2 cm when pressurized with coolant. In some embodiments, the diameter D_E of the electrode 214 and conduit 234 can be in a range of about 2 cm to about 2.5 cm to treat an average sized adult human. To treat tissue along one of the main stem bronchi, the diameter D_E can be in a range of about 1.5 mm to about 2.5 mm. Such embodiments are well suited to treat tissue outside the lung along the main bronchi. In certain embodiments, the diameter D_E is about 2 mm. In yet other embodiments, the diameter D_E can be in a range of about 0.1 mm to about 3 mm. The diameter D_E of the deflated conduit 234 and electrode 214 can be about 0.1 mm to about 1 mm. For example, to treat a bronchial tree of a human, the diameter of the inflated balloon 212 can be in a range of about 12 mm to about 18 mm. For enhanced treatment flexibility of the bronchial tree, the inflated balloon diameter may be in a range of about 7 mm to about 25 mm. Of course, the balloon 212 can be other sizes to treat other organs or tissue of other animals.

[0083] The energy delivery assembly 208 provides differential cooling because the coolant in the energy emitter assembly 220 is at a lower temperature and a higher velocity than the coolant in the balloon 212. Coolant, represented by arrows, flows out of the elongate shaft 230 and into the energy emitter assembly 220. The coolant proceeds through the energy emitter assembly 220 and the coolant channel 340 (Figure 14) of the electrode 214. The coolant absorbs thermal energy from the electrode 214. The heated coolant flows into the tip 240 and proceeds proximally through a lumen 400, as shown in Figure 18. The coolant flows through a valve 420 (*e.g.,* a throttle) and passes through a port 424. The valve 420 is disposed along a fluid path connecting the energy emitting assembly 220 and the portion of the balloon 212 defining the cooling section 209. The coolant circulates in a chamber 426 and absorbs heat from the tissue. This helps keep shallow tissue below a temperature that would cause cell death or tissue damage.

[0084] The coolant flows through a port 430, a lumen 432, and a throttle 434. The throttles 420, 434 can cooperate to maintain a desired pressure. The throttle 420 is configured to maintain a first flow rate of the coolant through the energy emitting assembly 220 and a second flow rate of the coolant through the cooling section 209. The first flow rate can be significantly different from the second flow rate.

[0085] The conduit 324 can assume a preset shape when pressurized. The valves 420, 434 can cooperate to maintain the desired pressure within the balloon 212 within a range of about 5 psig to about 15 psig. Such pressures are well suited to help push the electrode 214 between cartilaginous rings. Other pressures can be selected based on the treatment to be performed. The valves 420, 434 can be throttle valves, butterfly valves, check valves, duck bill valves, one-way valves, or other suitable valves.

[0086] When RF energy is transmitted to the electrode 214, the electrode 214 outputs RF energy that travels through tissue. The RF energy can heat tissue (*e.g.,* superficial and deep tissue) of the airway wall while the coolant cools the tissue (*e.g.,* superficial tissues). The net effect of this superficial and deep heating by RF energy and superficial cooling by the circulating coolant is the concentration of heat in the outer layers of the airway wall 100. Tissue structures can

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vary between different types of airways. In the bronchial tree, the temperature of the connective tissue can be higher than the temperatures of the epithelium, stroma, and/or smooth muscle. By example, the temperature of the connective tissue can be sufficiently high to cause damage to the nerve trunk tissue or other deep tissue while other non-targeted tissues of the airway are kept at a lower temperature to prevent or limit damage to the non-targeted tissues.

[0087] Heat can be concentrated in one or more of the internal layers (*e.g.,* the stroma) of the airway wall or in the inner lining (*e.g.,* the epithelium) of the airway wall. Furthermore, one or more of the vessels (*e.g.,* vessels of the bronchial artery) may be within the lesion. The heat generated using the electrode 214 can be controlled such that blood flowing through the bronchial artery branches protects those branches from thermal injury while nerve trunk tissue is damaged, even if the nerve tissue is next to the artery branches. The catheter 207 can produce relatively small regions of cell death. For example, a 2 mm to 3 mm section of tissue in the middle of the airway wall 100, along the outer surface of the airway wall 100, or between the airway wall 100 and other body tissue (*e.g.,* tissue of the esophagus) can be destroyed. By the appropriate application of power and the appropriate cooling, lesions can be created at any desired depth.

[0088] A circumferential lesion can be formed around all or most of the circumference of the airway wall 100 by ablating tissue while slowly rotating the energy delivery assembly 208 or by positioning the energy delivery assembly 208 in a series of rotational positions at each of which energy is delivered for a desired time period. Some procedures form adjacent lesions that become contiguous and form a circumferential band all the way around the airway wall 100. In some embodiments, the entire loop 221 (Figure 16) can be an electrode. The loop 221 can be coated with a conductive material and can carry the electrode. A single procedure can produce a circumferential lesion. After forming the lesion, coolant flowing into the balloon 212 can be stopped. The balloon 212 is deflated causing the energy emitter assembly 220 to recoil away from the airway wall 100. The catheter 207 may be repositioned to treat other locations or removed from the subject entirely.

[0089] If the user wants the coolant in the balloon 212 to be at a lower temperature than the coolant in the energy emitter assembly 220, chilled coolant can be delivered into the balloon 212 and then into the energy emitter assembly 220. Figures 18 and 19 show such a coolant flow. Low temperature coolant flowing through the elongate body 230 passes through the valve 434 and the port 430. The coolant circulates in the chamber 426 and absorbs heat. The heated coolant flows through the valve 420 and proceeds through the energy emitter assembly 220 to cool the electrode 214.

[0090] Airway cartilage rings or cartilage layers typically have a significantly larger electrical resistance than airway soft tissue (*e.g.,* smooth muscle or connective tissue). Airway cartilage impedes energy flow (*e.g.,* electrical radio frequency current flow) and makes the formation of therapeutic lesions with radio frequency electrical energy to affect airway nerve trunk(s) challenging when the electrode is next to cartilage.

[0091] Positioners can facilitate positioning of the electrodes. Such positioners include, without limitation, bumps, bulges, protrusions, ribs or other features that help preferentially seat the electrode 214 at a desired location, thus making it easy to perform the treatment or to verify correct positioning. Figures 20 and 21 show the energy emitter assembly capable of serving as an intercartilaginous positioner. When the balloon 212 presses against the airway 100, the loop 221 moves along the balloon 212 to preferentially position the electrodes 214 between cartilage rings 452a, 452b. The loop 221 protrudes outwardly from the balloon 212 a sufficient distance to ensure that the energy delivery assembly 208 applies sufficient pressure to the airway wall to cause self-seating. The catheter 207 can be moved back and forth to help position the electrodes 214 next to soft compliant tissue 453 in the space 453. The energy emitter assembly 220 can be configured to displace a distance D_o (*e.g.,* measured along a long axis 310), which is at least half of the distance D between the cartilage rings 452a, 452b. This ensures that the electrodes 214 can be positioned generally midway between the cartilage rings 452a, 452b.

[0092] The plurality of electrodes 214 can reduce both treatment time and procedure complexity as compared to a catheter with a single electrode. This is because the multi-electrode catheter may have to be positioned a smaller number of times within a bronchial tree (or other hollow organ) as compared to single electrode catheters to produce a number of lesions of a desired therapeutic size. Multi-electrode catheters can thus precisely and accurately treat a user's respiratory system.

[0093] Figure 22 shows an energy emitter assembly 500 that includes two energy delivery elements including electrodes 510a, 510b spaced apart from one another about a circumference of a balloon 520. The electrodes 510a, 510b can be about 45 degrees to 210 degrees from another with respect to a long axis 511 of an ablation assembly 501. Other electrode positions are possible. Figure 23 shows an energy emitter assembly 530 with three energy delivery elements 540a, 540b, 540c positioned about 60 degrees from one another. In these embodiments, each electrode may be coupled to separate power lines to allow for independent control of each, or all electrodes may be coupled to the same power line so as to be operated together. Further, a pair of electrodes may be operated in a bipolar manner, wherein one electrode is positive and the other negative, with RF power being transmitted from one to the other through the tissue.

[0094] Figures 24A and 24B illustrate a portion of a treatment apparatus in the form of a tracheal device 639 in a delivered configuration for treating the trachea 18 in a monopolar fashion. The tracheal device 639 includes a basket 638 with a positioning member 640 and electrode members 642a, 642b, 642c (collectively "642"). The electrode members

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642 can cooperate to treat the posterior plexus nerves 23. In this instance, an active device is placed in the trachea, with a ground pad placed on the patient's skin, typically in the thigh area. In order to prevent damage to the esophagus 30, a cooling or protection device is inserted into the esophagus 30. This device can be inserted through the mouth, or preferably, trans-nasally. The trans-nasal placement keeps the device separated from the manipulations of the device, to be placed in the trachea.

[0095] The basket 638 can be a cage or other type of self-expanding device. Advantageously, the basket 638 can be moved from a low profile (or collapsed configuration) to deployed state (or an expanded configuration) without the use of a balloon. Such non-inflatably expandable embodiments can be made of one or more shape memory materials (*e.g.,* Nitinol) capable of assuming different configurations. Additionally or alternatively, the basket 638 can be actuated using one or more pull wires or similar components.

[0096] A protection device in the form of a catheter 643 has a cooling balloon 644. In order for such an embodiment to efficiently circulate cooling media, the protection catheter 643 can include an inlet and an outlet to allow circulation of media (e.g., cooling media) through the balloon 644. The protective or cooling media is introduced through one lumen, allowed to inflate and circulate within the balloon 644, and exit through a second lumen. Additionally, the cooling media can be either gas or liquid, and can be chosen from a number of different varieties of either. Example gasses include room temperature or cooled air, nitrogen, cryogenic media, or the like. Example liquids include room temperature or cooled water, saline, ringer's solution, glucose solutions or the like.

[0097] Whereas Figures 24A, 24B referred to above describe a monopolar device with esophageal protection, Figures 25A and 25B illustrate one of a group of embodiments which will be called the trachea-to-esophagus, or T:E devices. In these embodiments, devices 666, 662 are inserted into the trachea 18 and esophagus 30, respectively. The devices 666, 662 cooperate to form a therapy and protection system encompassing the use of both devices to send and receive energy to the targeted tissue, and to protect the non-target tissue as well, as desired and required.

[0098] The protection or cooling media in the two different devices 666, 662 can be set up to maintain the same level of protection in both devices and both structures, or they may be set to provide differential cooling to one structure over another. For example, it may be desirable to cool the esophagus 30 more than the trachea 18, in order to provide greater protection to the esophagus 30, and in order to locate the lesion within the tissue bridge between the structures biased toward the trachea side of the bridge. This might better target the neural plexus specifically, while providing greater safety to the esophagus 30.

[0099] In Figures 25A and 25B, two devices 666, 662, which may be essentially the same in design, are inserted into each of the lumens (trachea and esophagus). The devices 666, 662 have an optional central lumen for guide wire guidance, a balloon with inflation lumens, and optionally, a second lumen for circulation of protective cooling media, and outer electrodes 667, 668. In the embodiments of Figures 25A and 25B, the outer electrodes 667, 668 are comprised of a cage of wires surrounding balloons 676, 678. Each cage can be deployed by the respective balloon 676, 678 directly, or they can be made of a suitable shape memory alloy to allow them to expand to contact the tissue independent of balloon action. The electrodes 667, 668 can be comprised of any suitable conductive material, including stainless steel, chromium cobalt, nickel titanium, metal-loaded conductive polymers, or the like. One of the devices can be attached to the energy delivery aspect of a delivery control box, and one acts as the return electrode. Depending on the specific energy density desired, the active device can placed in either the trachea 18 or the esophagus 30, and the return in the other. A cooled fluid may be circulated through balloons 676, 678 to absorb heat from energy delivery elements including electrodes 667, 668 and from the tissue of the esophageal and tracheal wall. During treatment, the balloons 676, 678 can be inflated to physically contact the inner surfaces of the trachea 18 and esophagus 30, respectively. The balloons 676, 678 have a generally circular shape as viewed along the lumen of the trachea 18, similar to the embodiments shown in Figure 24B. The balloons 676, 678 can have transverse cross-sections that are substantially circular, elliptical, polygonal, or combinations thereof and can have a smoother exterior surface, roughened exterior surface, undulating or wavy exterior surface, or the like. The electrodes 667, 668 deliver energy directly to the tissue. In other treatments, the balloons 676, 678 can be smaller than the lumens of the trachea 18 and the esophagus 30.

[0100] Figure 26 shows the energy distribution around the esophagus 30 and trachea 18 as may be produced by a system as described in Figures 25A and 25B. An area of high energy density 680 (shown hatched) exists in the tissue bridge 682 between the two structures, with relatively lower energy density 684, 686 (shown non-hatched) in other tissues around the perimeter of each of the individual structures. Without cooling, the tissue of the high energy density region 680 is ablated or otherwise altered (*e.g.,* damaged, destroyed, etc.) and preferably includes the posterior plexus nerves 23. In certain treatments, all of the posterior plexus nerves 23 between lumens of the trachea 18 and the esophagus 30 are damaged. In other treatments, targeted posterior plexus nerves 23 are damaged. If cooling media is circulated through one or both balloons, 676, 678, the tissue near the inner surface of the tracheal wall, as well as the tissue of the esophagus, can be protected from injury, while ablating target nerve tissues. Energy delivery and cooling may be adjusted to produce the isotherms of Figures 8A and 8B which are well suited for targeting damage to the interior tissue, such as the posterior plexus nerves 23, without damaging other tissue of the trachea 18, esophagus 30, and bridge 682.

[0101] An embodiment designed to optimize energy density around the trachea 18 is shown in Figure 27. In this

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embodiment, the active electrodes 700 of a device 702 are arranged around the entire circumference in the trachea 18, and the return electrodes 714 are disposed only on the anterior aspect of the esophageal device 712. In this case, the anteriorly oriented support electrodes 714 are conductive, while the posterior and optionally the posterior-lateral elements 716 are non-conductive. To render them non-conductive, they could simply be insulated from the return leads at the points of connection at the distal and proximal ends of the balloon, insulated over the length of the members via insulating shrink tubing, polymer coextrusion or coating, or made of completely non-conductive materials, such as an extruded polymer.

[0102] Figure 28 illustrates a resultant energy density distribution that may be created by the system of Figure 27. A relatively high energy density 720 (shown hatched) develops between the trachea 18 and esophagus 30, in the area of the posterior plexus 23, with a slightly lower density 721 developing around the lateral and anterior aspects of the trachea 18 (still sufficient to ablate the anterior plexus), and almost no field develops around the majority of the circumference of the esophagus 30. By circulating cooling media through the balloon of the esophageal device, the tissue of the esophagus may be protected from injury. Further, by circulating cooling fluid through the balloon of the tracheal device, the surface tissue on the inner wall of the trachea may be protected.

[0103] A further localization of the energy field may be achieved through alternative embodiments, for example, as shown in Figure 29. In this embodiment, the active electrodes 730, 732 are confined to the posterior aspect of the tracheal device 740 and the anterior aspect of the esophageal device 742. The opposing arms 750, 752 of the devices 740, 742 can be passive (*e.g.,* ground electrodes). All of the aforementioned alternatives for achieving this electrode localization apply, as well as those describing the potential differential cooling/protection options.

[0104] Figure 30 illustrates an energy density localization as may be achieved by the embodiment of Figure 29. Such embodiments localize the energy density in the region 760 between the trachea 18 and the esophagus 30, and target more specifically the posterior plexus. Again, esophageal cooling may be applied to minimize damage to esophageal tissue.

[0105] It should also be appreciated that any of the above balloon supported embodiments (Figures 25A through 30) can be made with the electrode and support elements only without the use of balloons, and can be made to create the same ablation patterns seen in all of the above balloon supported embodiments. For example, Figures 31A and 31B illustrate an alternative embodiment similar to the embodiment described in connection with Figures 29 and 30, but in a non-balloon-supported embodiment. An energy density distribution pattern such as shown in Figure 30 also may be produced by the embodiment of Figures 31A and 31B.

[0106] Figure 32 illustrates an embodiment of the present invention in side elevation that may correspond to the types of device described in the previous embodiments. Note that in Figure 32, the device 799 includes a balloon 800 shown in conjunction with the basket electrode array 810. In some embodiments, as described, the balloon 800 is eliminated and the basket array 810 is carried directly on a central shaft 820. The basket array 810 includes a plurality of flexible, resilient, elongated electrode struts 813 oriented in a longitudinal direction and arranged around the circumference of shaft 820. Electrode struts 813 bow outwardly into an expanded, arcuate shape either under the expansion force of balloon 800, or by pulling on the distal ends thereof in a proximal direction, whereby electrode struts 813 bow outwardly under compression. The device 799 includes in inflow conduit 822 and an outflow conduit 824 used to circulate media through the balloon 800.

[0107] Other variations of the embodiments described so far are shown in Figures 33A and 33B. In Figures 33A and 33B, a tracheal device 840 includes a support cage 844 which carries on its periphery a circumferential band 845 that can be selectively insulated and energized to create any of a variety of energy density patterns, including those shown in Figures 26, 28 or 30. The band 845 can be a conductive flexible member that is in the form of a conductive strip, tubular band, or the like. The band may have one or more discontinuities or a sinusoidal or other shape to allow it to expand circumferentially. The band 845 can be movable from a contracted configuration to an expanded configuration. Spaced apart struts of the support cage 844 extend radially outward to the circumferential band 845. Any number of bands of different sizes and configurations can be carried by the cage 844.

[0108] The esophageal device 850 includes a support cage 854 that may also carry on its periphery a circumferential band 855 that can be selectively insulated and energized to create any of the energy density patterns shown in Figures 26, 28 or 30 or a variety of other patterns. Similarly, the support structures 844, 854 for the circumferential band of Figures 33A and 33B could be replaced by a balloon 846, as shown in Figure 34A and 34B. Figure 34B also show one possible energy density pattern, including high energy density region 849 (shown hatched), achieved by the embodiments in either Figures 33A-33B or Figures 34A-34B.

[0109] A tracheal device 862 of Figures 34A and 34B can include a band 864 with an active electrode. In some embodiments, the entire band 864 is an electrode. In other embodiments, one or more portions of the band 864 can be electrodes while other portions are insulated. A device 872 includes a band 874 with an active portion 876 and a passive portion 878. The active portion 876 can be an electrode that cooperates with the band 864 to target the posterior pulmonary plexus or other target region. The bands 864, 874 can be portions of a balloon or other type of inflatable or expandable member. In some embodiments, the walls of the balloons include electrodes mounted or adhered thereto.

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The balloon (wire basket or cage) can be an actuable device movable between a delivery configuration and a deployed configuration to move the band 874.

[0110] Eliminating the balloon in the longitudinal support structure embodiments described above may require different means for providing cooling or protection. Further description of such alternative embodiments are provided later in the present disclosure.

[0111] Embodiments described to this point have either shown monopolar devices within the trachea, or bipolar devices which energize from trachea to esophagus, or vice versa. Figure 35 illustrates a further embodiment whereby bipolar energy can be delivered from within the trachea 18 alone, in order to concentrate the energy density around the circumference of the trachea 18 and target both the anterior plexus 22 and posterior plexus 23, with potentially higher energy density than would be achievable by monopolar energy alone.

[0112] In the embodiment of Figure 35, a device 900 includes an electrode array 902 that is divided into two distinct sections, wherein one section serves as the active electrodes 910 and the other section serves as return electrodes 912 (*e.g.,* ground electrodes). In this way energy may be delivered from active electrodes 910 to return electrodes 912 via the tissue in the tracheal wall to produce the desired energy density pattern. Other aspects of electrode design and material selection previously described apply to this embodiment as well.

[0113] Figures 36A-36C show a variation of the bipolar system in Figure 35. The system includes a basket-type electrode array as described in previous embodiments having a plurality of electrode bands. The electrode array is disposed around a balloon 922. The balloon 922 is divided into different sections by a septum 925 within the balloon 922. The septum 925 divides chambers 927, 929. Fluid at different temperatures can be delivered to the chambers 927, 929 to provide differential cooling between opposing surfaces of the balloon 922. In a further alternative, there would be a dual balloon system having one balloon facing the anterior and one balloon facing the posterior portion of the trachea 18. Different temperatures or different flow rates of media can be introduced into the different cooling/protection zones in order to provide greater protection for one area than the other. This differential in temperature profiles can also be used to direct the area of ablation more deeply into the wall of the trachea 18, directing it more towards the nerves. For example, if the nerves 23 on the posterior side are more deeply embedded in the bridge tissue between the trachea 18 and esophagus 30, more cooling might be desired here than on the anterior side. Another scenario is one in which the user only wants to protect the superficial mucosa on the anterior side, and so a comparatively low level of protection is required. On the posterior side, on the other hand, more protection may be required to preserve the integrity and function of the esophagus 30, and to prevent fistulas from occurring. A wide range of different types of split or multi-chambered inflatable members can be used.

[0114] It can also be appreciated that embodiments disclosed herein, such as the embodiment of Figures 36A-36C, which occlude the lung during treatment, can be deployed and retracted in order to allow for ventilation. Alternatively (not shown), any of these occlusive devices can be designed with a lumen or lumens which provide flow through the devices, allowing for ventilation of the lung distal to the occlusion site. Room air, oxygen or the like can be supplied to the distal lung.

[0115] The following family of designs shares a common attribute in that they take advantage of the cartilaginous rings which surround the upper airways to actually locate the delivery portions between the insulating rings, directing the energy directly into the only weakness in the wall of the airway from which the energy can reach the nerves on the anterior side.

[0116] Figures 37A-37C illustrate an embodiment with a device 1000 that includes a stack of a plurality of ring electrodes 1002 attached to a central or offset shaft 1010 which lends support and provides electrical connection to the control box of the system. The illustrated ring electrodes 1002 extend circumferentially about the inner wall of the trachea. The shaft 1010 extends vertically from the rings along a lumen of the trachea. The diameter and width of the ring material is chosen such that it fits entirely or substantially within the gap between two adjacent cartilaginous rings.

[0117] The diameter of the rings 1002 can be set to slightly oversize or to roughly match the diameter of the airway 1016, as shown in Figure 37A. The rings 1002 themselves may be resilient and expandable similar to a self-expanding vascular stent such that, regardless of airway diameter, they expand to fill the airway circumference. Various designs and methods to vary the diameter of the rings 1002 can be employed in these designs. For example, one end of a given ring may be fixed to the longitudinal spine of the device, and the other formed to engage another longitudinal element which winds the ring down into a smaller diameter for more distal placement (not shown).

[0118] The impedance sensors 1003 (shown in dashed line) of Figure 37B detect the impedance of the tissue of the airway wall and any external structures that may be in contact with the airway wall, such as the pulmonary artery or esophagus. Each of the various tissues and fluids in and surrounding the airway, such as smooth muscle, cartilage, nerves, blood vessels, mucous, air, and blood, has a different impedance. Moreover, previously treated (ablated) tissue will have different impedance than untreated tissue. Thus, the longitudinal and rotational position of the sensor (and hence the electrode) may be detected by measuring the impedance at the location and comparing it to a reference value or to the impedance of tissue at other locations. In this way, the power level or degree of cooling or both may selected based upon the location of the electrode to ensure target nerve structures are ablated without damaging other critical

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structures such as the esophagus. In addition, the presence of previously created lesions may be detected so that overlapping such lesions and over-treating tissue can be avoided.

[0119] Impedance sensors 1003 may be adapted to be manually activated by the user at any particular electrode location. Alternatively, the system may be configured to run the sensors continuously or automatically trigger them prior to or simultaneous with energy delivery through the electrode at each treatment location. Prior to energy delivery, the system may provide an indication of the impedance to the user so that power or coolant delivery may be adjusted, or the system may automatically adjust the power delivered through the electrode based on the measured impedance.

[0120] Impedance may also be detected using the electrodes themselves without a separate sensor. The RF generator may be equipped with an impedance detection system which calculates the impedance seen by the electrode when power is delivered. In this way prior to lesion creation at any particular location a very low power signal may be delivered from the electrode and impedance then calculated to ensure proper positioning and power settings.

[0121] In use, the rings 1002 are deployed within the desired treatment area. They can be delivered within a sheath or tubular cannula in a compressed state and released when in position to expand into contact with the airway wall. Once deployed, the system is withdrawn proximally, or pushed distally by a small amount. Tactile feedback lets the physician know when the rings have slipped into place. In some embodiments, an active electrode is configured to fit between a first pair of adjacent cartilage rings of the airway in the expanded configuration. Return electrodes arc configured to fit between a second pair of adjacent cartilage rings of the airway while the active electrode is positioned between the first pair of adjacent cartilage rings. Alternatively, tissue impedance can be measured, with lower impedance signaling the electrodes are between rings, and in position to access the nerves.

[0122] As an alternative to the stacked ring design, a coil could be formed to provide the same inter-cartilaginous locking functionality as the stacked ring design. Figure 38A shows a device 1040 that includes a coiled or corkscrew-shaped ring 1044. The pitch of the coils 1044 is set such that adjacent turns of the coil lock into separate neighboring inter-cartilaginous regions. In one version of the coiled ring design, a length of resilient coil is provided straightened out inside of a delivery catheter or capture sheath. When the distal tip of the capture sheath is in place at the distal end of the treatment region, a distal tip 1045 and the coils 1044 are delivered to the distal end of the treatment region. The capture sheath is withdrawn until the entire treatment area of interest is covered by the coiled elements. Again, tactile feedback confirms that the rings are locked into place, or impedance is measured. A shaft 1046 extends from the coiled ring 1044 along the lumen of the trachea.

[0123] Figures 39A and 39B show another embodiment of the coiled ring system 1060 wherein the distal and proximal ends of the coils are both attached to longitudinal members. Coil diameter can be varied by twisting the two elements relative to one another in order to tighten or loosen the diameter of the coils. The coils can seat between the cartilage rings. The system 1060 includes a winding arm 1061 and a proximal electrode 1063.

[0124] The locking ring electrode concept can be incorporated into a number of the previously described tracheal-esophageal embodiments in order to recreate the energy density distributions shown in Figures 26, 28, and 30. A ring-type device in the lung could be used in combination with any of the previously described esophageal devices to provide esophageal cooling, or to provide esophageal electrodes for a bipolar delivery system.

[0125] Another variation of the locking ring embodiment is shown in Figures 40A and 40B. In this case, a device 1070 includes an anterior portion 1072 defined by a resilient member 1074 formed into a roughly "D" or kidney-shaped or rabbit ear-shaped member or ring. The ends of member 1074 may be wrapped around two independently rotatable longitudinal members 1075a, 1075b, so that the size and shape of the "D" can be modified by rotating the longitudinal members 1075a, 1075b to wrap or unwrap the resilient member. For example, rotating the left longitudinal member 1075a counterclockwise and the right one 1075b clockwise in Figure 40B would result in the D ring reducing in size (as shown by the dashed lines).

[0126] A plurality of these D-rings can be attached above or below one another in a configuration similar to the one shown in Figure 37A, and if desired can all be made expandable and contractible as described above. If a bipolar energy pattern is desired, a second set of D-rings can be positioned to contact the posterior wall of the trachea as well (not shown). The anterior and posterior rings can be alternated, or interleaved, such that each subsequent ring faces the opposite direction, or a series of rings can face one direction, and then a separate series of rings faces the opposite direction. The latter configuration provides longitudinal separation of the active and return electrode as well as the anterior/posterior separation provided by the interleaved design.

[0127] Alternatively, as shown in Figures 40A and 40B, a non-ring electrode 1082 can be used along the posterior aspect of the trachea 18. Since there are no cartilaginous rings on the posterior aspect, an electrode 1082 can be in the form of a mesh electrode, arrays of longitudinal spine electrodes, or any other suitable electrode design can be used in conjunction with the ring or D-ring electrodes described above to allow bipolar energy delivery.

[0128] Figures 41A and 41B illustrate a further alternative device 1090 that includes holes or vents for introduction of cooling media, and a plurality of spaced apart ring electrodes 1092a, 1092b. Cooling vents may be disposed in the shaft 1095 to which the electrodes 1092a, 1092b are attached. Through these vents cooling or protectant media (represented by arrows) can be directly applied to the electrodes and/or to the tissue adjacent to the electrodes. The media can be

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any of the aforementioned media. Alternatively, any of the vented designs described in this disclosure can use a liquefied gas wherein the gas flows into the system liquefied and cools via an endothermic phase transition.

[0129] In another exemplary embodiment, shown in Figure 42, the esophagus is protected by an esophageal device 1100 in the situation where the tracheal device (not shown) alone is involved in the modification or ablation of the nerves. The tracheal device can be monopolar RF, bipolar RF with both leads in the trachea, or microwave.

[0130] The embodiment of Figure 42 is shown to cover a substantial portion of the entire zone of the esophagus 1141 which could potentially suffer tissue damage from a delivery device positioned within the trachea. This affords protection of the entire exposed esophageal territory with a single device placement. Alternatively, the esophageal device could be made shorter, and moved either in concert with, or at appropriate intervals to the movement of the tracheal device. Such an embodiment may include features such as an elongate shaft to insert the balloon and circulate cooling fluid through a balloon 1142, multiple lumens to effectively circulate protectant, and/or an optional guide wire lumen to aid in placement of the device.

[0131] Although there is an area of the trachea shown in crosshatch Figure 42 as the treatment area of the trachea, it should be noted in this and all figures that show exemplary treatment areas that this area is not the only potential treatment area. It is shown merely to point out that in some embodiments the esophageal device covers substantially the entire potential intended treatment zone.

[0132] A catheter shaft 1113 of Figure 42 is connected to a generator/pump unit and can be a multi-lumen shaft to allow bidirectional fluid flow. In certain embodiments, the catheter shaft 1113 has two lumens coupled to side holes. Fluid can be delivered into a proximal balloon end 1142 through one lumen. Media can be circulated within the balloon 1142 to cool the tissue surrounding the esophagus. The media can flow out of the balloon 1142 using the other lumen.

[0133] The catheter shaft 1113 can have a sealed tip 1130. A fluid can be delivered through the chamber of the balloon 1142 and returned via the body 1110. One or more conductive elements 1140 can be positioned to be adjacent to or to contact the potential ablative zone. During ablation, the conductive element can help conduct heat between the tissue and the cooling media circulating within the expandable balloon 1142 covering the potential ablative zone 1141.

[0134] The exemplary embodiment illustrated in Figure 43 is a variation of the embodiment of Figure 42, in which conductive means are added to the basic protection system to allow for bipolar trachea-to-esophagus treatment options. All of the previously mentioned features and benefits apply the embodiment of Figure 43 as well. While Figure 43 shows a circumferential conductive zone, such as a wire mesh 1160 on the device, it should be appreciated that any of the conductive elements described herein (wire cages, ring electrodes, etc.) could be configured onto the protective device 1100. In the case where the protective device is long enough to cover substantially all of the potential treatment area, the conductive elements of the protective device will also cover substantially the entire potential treatment zone.

[0135] Figure 44 illustrates another alternative embodiment including means for protecting the esophagus during nerve modification. In this case, a relatively short occlusion device 1180 is delivered to the esophagus distal to the most likely termination of the potential treatment zone. Behind this occlusion device 1180, protectant media is circulated freely in the esophagus. In this embodiment, cooled gasses are most likely to be used. Room air, nitrogen, oxygen, etc., may be used. Forced media (*e.g.,* forced cool air) can be circulated above the occlusion device 1180 illustrated as a balloon. A wide range of different types of sources 1181 with one or more pumps (*e.g.,* piston pumps, positive displacement pumps, roller pumps, etc.) or blowers can pass media through a conduit 1183. The illustrated conduit 1183 is positioned in the lumen of the esophagus 30 to circulate the media in the lumen of the esophagus 30. The media can flow at a relatively high flow rate to protect the trachea and/or esophagus. The occlusion device 1180 prevents media from distending the stomach and/or the gastrointestinal tract.

[0136] As shown in the exemplary embodiment of Figure 44, the occlusion device 1180 is a balloon, but other devices which provide substantial blockage to the passage of gas can be used. Additionally, Figure 44 shows the protectant being introduced via the nose or the mouth directly. Custom nose plugs or facemasks can be designed to effect this delivery. For example, a pump or blower can deliver chilled media to the airway or esophagus of the patient via a facemask. Alternatively (not shown), side holes in the shaft of the occlusion device can be used for introduction of protectant. In this case, liquefied gas that is allowed to warm in the catheter shaft and exit the catheter as a gas can be used. The degree of protection, as with all of the protective devices, can be varied through temperature of the protective media, or through the flow rate of the protective media.

[0137] Figures 45 and 46 show further alternative embodiments of a distal occlusion protective device wherein a conductive element is incorporated into the system. This enables bipolar trachea-to-esophagus treatment. The conductive element may be attached to the same shaft as the occlusion device, such that the entire system is introduced at once. Alternatively, the conductive elements could be a separate device which is placed alongside of or over top of the occlusion device, and which is insertable and operable separately from the occlusion device. The conductive element may be constructed similarly to any of the esophageal devices described herein, such as a basket electrode array 1190 having a plurality of electrode bands.

[0138] Figure 46 shows the embodiment of Figure 45 with protectant circulating around and through the elements of the conductive system. As with prior embodiments, the protectant can be introduced through the nose or mouth, through

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the central shafts of the devices, or through the conductive elements themselves. Introduction through the conductive elements themselves provides the added bonus of cooling those elements and preventing tissue charring during thermal ablation. Charring on the electrodes greatly increases the impedance of the system and decreases or eliminates the effectiveness of the ablation.

[0139] Microwave energy has found increasing uses over the past few years and may be used in embodiments of the present invention as an alternative energy system. Principally, microwave energy is delivered through an antenna. There are a number of different types of microwave antennae. With suitable modifications based on the teachings of the instant disclosure, some the basic microwave antenna forms may be incorporated into devices designed for modulating or modifying pulmonary nerves as described herein. Of particular use for the application of catheter based microwave energy within the trachea-to-esophagus region is the family of antenna based upon coaxial wire leads. There are a number of different designs using the coaxial leads. These types of antennae come in many different configurations-monopole, dipole, slot, capped, choked, cap-choke, sleeved, etc. Each antenna variation is intended to either shift the field orientation, to improve the efficiency of energy delivery, or both. Wave guide antennae are another known antennae for microwave applications. Wave guide antennae are typically a metal jacketed dielectric, which is fed with a coaxial cable inserted into a side hole in the device.

[0140] Examples of basic configurations for microwave antennae that may be modified and configured for use with embodiments of the present invention by persons of ordinary skill in the art may be found in the following publications: Microwave Catheter Design; Robert D. Nevels, G. Dickey Arndt, George W. Raffoul, James R. Carl, and Antonio Pacifico. IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, VOL. 45, NO. 7, JULY 1998, and A Review of Coaxial-Based Interstitial Antennas for Hepatic Microwave Ablation, John M. Bertram, Deshan Yang, Mark C. Converse, John G. Webster, & David M. Mahvi; Critical Reviews™ in Biomedical Engineering, 34(3):187-213 (2006). Both of these publications are incorporated by reference in their entirety. Among the reasons that such antennae designs cannot be directly incorporated into embodiments of the present invention is their unsuitability for pulmonary devices without modification. Among the parameters that must be reconfigured for deployment in the pulmonary tree according to embodiments of the present invention are the size, stiffness and general deliverability.

[0141] In pulmonary applications, the devices need to be introduced through or in conjunction with bronchoscopes, and manipulated down tortuous paths into the area of the lung to be treated. This necessitates the translation of conventional microwave antenna designs into application specific embodiments, such as the exemplary embodiments shown in Figures 51A-54C. One generally common aspect for these pulmonary devices is flexibility, although in some cases a flexible body member is coupled to more rigid segments in the area of the slots, caps, and chokes. Other aspects that must be specially considered for pulmonary applications are features to provide tissue coupling, maintain positioning relative to the target tissue, cool non-target tissue, etc.

[0142] In one exemplary embodiment, an antenna that may be particularly effective in pulmonary applications for microwave energy delivery is a multi-slot coaxial design such as shown Figure 47. In this embodiment, in addition to a slot near the tip, a plurality of additional slots are positioned at appropriate distances down the shaft of the device, with the distances being determined by wavelengths of operation, desired specific absorption rate (SAR) pattern, etc. Specific absorption rate, or SAR, is a proxy for energy delivery to the tissue, or heating profiles of the tissue, and are the standard way in which antenna designs are evaluated and optimized.

[0143] In many microwave antenna applications in medicine, the desire is to provide the largest effective area of energy delivery to tissue, with the area of treatment extending from the edge of the antenna or applicator to the periphery of the largest area possible. However, in the case of pulmonary nerve modulation, protection of the structures immediately adjacent the applicator is preferred. Ideally, the energy would pass through a cooling or protective layer, heat tissue within a few millimeters of a zone, and then drop off in intensity in order not to harm critical non-target tissues such as the esophagus and alveoli. This is not possible in any of the antenna designs shown from the prior art. Embodiments to achieve these ends are shown and described in detail below in Figures 58A-53.

[0144] In microwave terms, the more "lossy" a material is, the higher the propensity of that material to heat up. Lossy materials in the body are typically those with higher water content. This is due to the fact that microwaves heat dipole molecules by causing rotation of the dipole molecule under the oscillations of the wave. Water is a strong dipole molecule, and heats extremely well under microwaves.

[0145] The tables below show various electrical properties of different tissues at two different commonly used medical microwave frequencies, 915 MHz and 2.45 GHz. One aspect that is apparent from these data is that as microwave frequency increases, depth of penetration decreases-so lesions are made more shallowly. For this reason, it is likely that the preferred frequency for pulmonary nerve modulation will be 2.45 GHz or higher. At least one microwave system designed by Micrōsulis Inc. operates at frequencies in the 9 GHz region. The frequency can be selected so that the microwave energy penetrates the tissue to a depth of the target tissue with an intensity sufficient to alter the target tissue while having insufficient intensity in non-target tissue, such as non-target tissue beyond the nerve tissue.

[0146] Frequency alone does not determine depth and character of penetration and tissue modification. It is known that standing waves can develop in microwave fields, and specific systems must be modeled with FEA systems to

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determine the most likely resultant SAR patterns within a given tissue system.

[0147] For example, the permittivities of most of the tissue types listed below are roughly in a similar range, indicating that they will heat similarly. However, there are a couple of exceptions-the esophagus may heat more easily than other tissues, and so may require the protection that has been discussed throughout this disclosure. Also, it is of particular interest that the permittivity of the lung differs significantly as between the inflated and deflated states.

Tissue name	Frequency [Hz]	Conductivity [S/m]	Relative permittivity	Loss tangent	Wavelength [m]	Penetration depth [m]
Cartilage	915000000	0.7892	42.6	0.36394	0.049412	0.044603
Cartilage	2450000000	1.7559	38.77	0.33228	0.019393	0.019077
Tissue name	**Frequency [Hz]**	**Conductivity [S/m]**	**Relative permittivity**	**Loss tangent**	**Wavelength [m]**	**Penetration depth [m]**
LungInflated	915000000	0.45926	21.972	0.41063	0.068523	0.05527
LungInflated	2450000000	0.80416	20.477	0.28813	0.02677	0.030175
Tissue name	**Frequency [Hz]**	**Conductivity [S/m]**	**Relative permittivity**	**Loss tangent**	**Wavelength [m]**	**Penetration depth [m]**
Mucous Membrane	915000000	0.85015	46.021	0.36291	0.047545	0.043032
Mucous Membrane	2450000000	1.5919	42.853	0.27255	0.018524	0.022029
Tissue name	**Frequency [Hz]**	**Conductivity [S/m]**	**Relative permittivity**	**Loss tangent**	**Wavelength [m]**	**Penetration depth [m]**
Nerve	915000000	0.57759	32.486	0.34929	0.056652	0.053157
Nerve	2450000000	1.0886	30.145	0.26494	0.022097	0.027006
Tissue name	**Frequency [Hz]**	**Conductivity [S/m]**	**Relative permittivity**	**Loss tangent**	**Wavelength [m]**	**Penetration depth [m]**
Oesophagus	915000000	1.1932	65.02	0.36053	0.040007	0.036435
Oesophagus	2450000000	2.2105	62.158	0.26092	0.015392	0.019092
Tissue name	**Frequency [Hz]**	**Conductivity [S/m]**	**Relative permittivity**	**Loss tangent**	**Wavelength [m]**	**Penetration depth [m]**
Trachea	915000000	0.7757	41.971	0.36308	0.049785	0.04504
Trachea	2450000000	1.4488	39.733	0.26753	0.019244	0.023299

[0148] The significance of the change in permittivity of the lung upon inspiration may be of particular interest in a case where the nerve modulation is to be conducted at or below the area of the carina. Once into the right and left bronchi, tissue surrounding the bronchi is increasingly alveolar tissues-highly compliant, and highly air-filled. It is this air that is likely responsible for the decrease in permittivity of filled lungs. The permittivity of air is 1-it does not heat in any significant way in the presence of microwaves.

[0149] One significance of this fact for the subject applications is that it may be beneficial to tie the application of microwave energy to the inspiration cycle of respiration, when the lung is filled with air. Alternatively, the method of treatment could include a breath-hold or a ventilatory hold induced by a ventilator machine in order to ensure air-filled tissue surrounding the bronchi supporting the nerves to be treated.

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[0150] Microwaves encountering materials of different permittivities can also act in unusual ways. Reflections can be created at tissue interfaces or air/tissue interfaces which can be exploited to focus ablative or modulatory energy more specifically on the tissues to be treated.

[0151] Figures 48A and 48B show embodiments of microwave systems. The pulmonary treatment apparatus 1201 includes an elongate member 1203 and a microwave antenna 1210 coupled the elongate member 1203. The microwave antenna 1210 is positioned at treatment location proximate a target site in or proximate to the airway. The microwave antenna 1210 delivers microwave energy so as to alter nerve tissue in a manner which disrupts transmission of nerve signals while non-target tissue disposed between the microwave antenna 1210 and the nerve tissue is not permanently injured.

[0152] Expandable or deployable supporting elements 1200 are provided which ensure solid coupling of the antenna 1210 to the tissue. The supporting elements 1200 are movable from a contracted position (shown in dashed line in Figure 48A) to the illustrated expanded position. These elements can be wires, balloons, fingers, or the like. The supporting elements 1200 of Figures 48A and 48B are illustrated as a pair of elongate members 1210 configured to bow outwardly to engage the anterior wall of the airway. Optionally, shielding 1220 can be provided on one or more sides of the device to further focus the microwave energy into the tissue and/or to protect non-target tissues. Shielding 1220 can be metallic foil, metal loaded polymer, metallic mesh with mesh opening of an appropriate fraction of the wavelength in use so as to block transmission of the waves therethrough, or any known microwave shielding material. Not shown in Figures 48A and 48B is an optional esophageal protection system. This system can take any of the forms previously disclosed.

[0153] Also noted in Figure 48B is a tissue plane discontinuity between the esophagus and the trachea. If therapy is to be delivered at this level rather than down in the bronchi below the carina, it is possible that the differences in tissue properties will cause reflection, or that the air in the esophagus, or the protectant system in the esophagus, will cause reflection of the microwaves. Reflection of waves can result in cancellation, summation, or additive power of the waves, or it can result in standing waves. Cancellation would tend to negate clinical effectiveness and must be avoided in the system design. Summation or standing waves can be beneficial, and may be designed into the system to provide higher effective energy levels at the target tissue than the level of energy delivered by the system alone. Figure 49 shows emitted waves.

[0154] Figures 50A and 50B illustrate a further alternative embodiment of the present invention including a dual antenna system 1300 built on the same basic principles as described in connection with the embodiments disclosed above. A shield of dielectric material 1311 can be mechanically coupled to antennae 1302a, 1302b. Support structures 1310a, 1310b can help hold the antennae 1302a, 1302b proximate or against the posterior tissue of the trachea 18. The support structures 1310a, 1310b can be elongate arms, ribs, inflatable members, or the like. The antennae 1302a, 1302b can cooperate to form standing waves in a desired configuration. Optionally, a protective device can be used to protect tissue of the esophagus 30 or any other bridging tissue proximate or adjacent to the trachea 18 and/or the esophagus 30. Note that while two antennae 1302a, 1302b are shown in this embodiment, any number of antennae can be included without departing from the teachings of the present invention. The antennae may be bound edge-to-edge down the longitudinal axis of the catheters, or they may be separated by an appropriate dielectric material. The antennae 1302a, 1302b can be fired simultaneously, in sequence, alternating or in various other patterns to modify or optimize the SAR distribution to the desired tissue.

[0155] Figures 51A and 51B illustrates yet another embodiment of the microwave therapy system wherein an esophageal device 1340 is included to modify or optimize the microwave SAR pattern in the target tissues. The esophageal device 1340 shown here is a reflector 1342. The reflector 1342 includes a balloon filled with inflation media chosen for specific dielectric properties that alter the SAR pattern in the tissue therebetween. This alteration of the SAR pattern acts to reflect microwave energy back toward the delivering device in order to sum the wave energies or to create a standing wave within the tissue. It could alternatively be used to provide negation of oncoming waves, or it could be used to absorb microwave energy in order to draw the energy deeper into the tissue and then negate it at the device. The balloon 1342 can be connected to the media source. The media source can be the media delivery system 246 discussed in connection with Figure 10.

[0156] While a balloon is shown in the embodiment of Figures 51A and 51B, persons of ordinary skill in the art will recognize based on the teachings herein that other devices may be used whose materials, design, use or any combination of these factors provide an alteration to the SAR pattern created by the matched microwave antenna when used in concert with that antenna. Other types of reflectors may include, without limitation, one or more balloons, plates, or the like. Also note that although the microwave embodiment in Figure 51B is a dual antenna design, any contemplated antenna design could be substituted in this system. Although the use of the dielectric SAR altering device is described with that device in the esophagus and the microwave antenna in the trachea or bronchi, the devices could be placed in the reverse arrangement as desired.

[0157] In another alternative embodiment, as shown in Figures 52A and 52B, microwave systems such as those shown in Figures 48A-50B can be outfitted with a cooling device in the form of an outer jacket 1356 through which media can be introduced or circulated. A plurality of channels can extend through a main body 1357. This media can serve as a

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cooling agent via temperature control or flow control of the media, or a combination of the two. The media may be chosen for dielectric properties which provide better coupling between the antenna and the tissue. The outer jacket 1356 may also include shielding 1360.

[0158] Figure 53 illustrates another alternative embodiment including cooling or coupling media in a chamber 1370 to surround an antenna 1372. In this embodiment, a cooling device includes an outer member 1374 (illustrated as a balloon wall) of the device that surrounds the antenna 1372 and couples with substantially the entire circumference of the trachea or bronchi. The outer member 1374 cools at least a portion of the non-target tissue while the microwave antenna 1372 delivers the microwave energy. Thus, the wall of the outer member 1374 is positioned between the microwave antenna 1372 and the wall of the airway. The microwave energy can pass through the outer member 1374 and penetrates the airway wall to a depth of the target tissue with an intensity sufficient to alter the tissue. Optionally, shielding 1384 may be built into the device to block transmission on a portion of the circumference to protect that portion from treatment as explained below. In other embodiments, the shielding 1384 can absorb the microwave energy. This shielding could be used to protect the esophagus, for example.

[0159] Alternatively, the embodiment of Figure 53 could be used in a method of treatment for which multiple embodiments throughout this disclosure may be used. To use the device in Figure 53 with shielding, as an example of a method of treatment according to one embodiment of the present invention, the device would be introduced to a point along the desired treatment zone of the airway. Energy is delivered to a portion of the circumference of the airway which is less than 360 degrees. The device is then advanced or withdrawn so that the next treatment zone either barely overlaps, or allows a small gap between it and the last treatment zone. Additionally, the device is rotated such that there is either a slight overlap or a slight gap circumferentially as compared to the prior treatment site. By repositioning the device both longitudinally and circumferentially, in two or more treatments the entire circumference of the airway could be treated, but not contiguously. In effect, there is a spiral treatment area created, with the proximal and distal ends of the spiral approximately matched or overlapped when compared circumferentially, but which are separated longitudinally.

[0160] This spiral or displaced treatment pattern would allow modulation or ablation of the nerves surrounding an airway, without risking the creation of a circumferential zone of treatment which could cause unwanted wall effects such as hyperproliferation of cells during healing, scarring, stenosis or the like.

[0161] Another embodiment that would provide the spiral treatment pattern desired would be a multi-slotted antennae 800 as was described in connection with Figure 47. In addition to the extra slots 811 a, 811b, 811c, and hence extra treatment zones spaced longitudinally down a catheter shaft 820, the spiral design may have partial-circumferential shielding (device not shown). Figure 47 also shows a SAR pattern. The position of the shielding would vary by position along the length of the catheter. For example, a multi-slot design providing four treatment areas longitudinally could be shielded from 12-3 o'clock in longitudinal segment 1, 3-6 o'clock in longitudinal segment 2, 6-9 o'clock in longitudinal segment 3, and 9-12 o'clock in the final longitudinal segment. Thus, it is possible with a single energy application that the entire spiral-shaped energy deposition is made.

[0162] Figure 54A shows a further alternative embodiment for a microwave antenna intended to create as large an area of ablation as possible for a given insertion into the body. While the bifurcated shape of the antenna in Figures 54A and 54B are interesting for lung applications, several issues make it infeasible to use for this application as shown. Given the rigidity of coaxial cable used in antennae such as that shown in Figures 54A and 54B, it may require specific device designs to achieve delivery of such a split tip design to the lung. Pull wires 1402, 1404 attached to the tips 1412, 1414 could be added to deflect the tips 1412, 1414 actively as desired. Memory materials could be built into the shafts of the split segments to bias them outward, and an outer sheath provided to hold them together for delivery. Given the stiffness of some coaxial wire, a wedge-shaped element 1415 (illustrated in dashed line) can be added between legs 1416, 1417 of the split tip 1419, which when retracted via pull wires 1402, 1404 or the like, the legs 1416, 1417 are forced outward and apart.

[0163] Additionally, the actual SAR pattern of the antenna shown is not applicable in the pulmonary indication. Note the "tail" of the SAR pattern which extends downward between the legs 1416, 1417 of the device shown in Figure 54B. This energy deposition would occur in non-target tissues if used in the lung as designed-most probably, the heart.

[0164] Significant redesign of the system shown can be performed for pulmonary applications. One embodiment which would provide both the deployment of the legs 1416, 1417 of the split antenna device as well as creating a more desirable SAR pattern would be to provide a sliding wedge element 1415to separate the legs 1416, 1417, but the material of which is a dielectric material selected to modify the SAR pattern to more closely follow the legs 1416, 1417 of the antennae, without the unwanted "tail" energy directed towards the heart.

[0165] High intensity ultrasound (HIFU) is another energy modality that can be employed to provide pulmonary nerve modulation. In HIFU, ultrasound transducers are shaped, or in some cases multiple transducers are electronically beam-formed to a focal point. At the focal point, relatively low intensity ultrasound departs the ultrasound transducer(s) and converges at the focal point designed into the transducer to create a zone of heating and tissue ablation.

[0166] A jacketed esophageal HIFU device appears in "US2007/0027445 Method and Apparatus for Noninvasively Treating Patent Foramen Ovale Using High Intensity Focused Ultrasound" by the present inventors, which disclosure

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is incorporated herein by reference in its entirety. This device is a transesophageal HIFU device coupled to the target tissue with a cooling jacket or balloon surrounding the HIFU elements. This device was initially designed to treat atrial fibrillation by targeting the posterior wall of the heart from the esophagus. However, the same or similar device could be adapted for use in the currently disclosed methods for pulmonary treatment.

[0167] HIFU devices are to be used to fire energy into structures which are either tissue or fluid. While reflections of ultrasound may occur at transitions between different tissue types, all of the structures are essentially acoustic conductors. Air, however, will not conduct ultrasound. So in the unique case of pulmonary neuromodulation, HIFU fired from either the airway or esophagus will encounter an air barrier just beyond the target tissue, and become attenuated, or reflect to form a standing wave within the target tissues.

[0168] In order to maximize the desired effects, a device similar to the one shown in Figures 54A and 54B may be employed wherein the microwave device would be replaced with a HIFU transducer. For HIFU, the dielectric properties of the fluid in the balloon 1342 would be replaced by specific acoustic properties, to either enhance the absorption or reflection of the applied acoustic power.

[0169] Different types of modifications can be made to treat tissue with different types of energy. Energy can be used to damage target regions. As used herein, the term "energy" is broadly construed to include, without limitation, thermal energy, cryogenic energy (*e.g.,* cooling energy), electrical energy, acoustic energy (*e.g.,* ultrasonic energy), HIFU energy, RF energy, pulsed high voltage energy, mechanical energy, ionizing radiation, optical energy (*e.g.,* light energy), microwave energy, and combinations thereof, as well as other types of energy suitable for treating tissue. In some embodiments, the catheter system, devices, or apparatus disclosed herein delivers energy and one or more substances (*e.g.,* radioactive seeds, radioactive materials, etc.), treatment agents, and the like. For example, the assembly 208 of Figures 5 and 6 can include one or more ports through which a treatment agent is delivered. Exemplary non-limiting treatment agents include, without limitation, one or more antibiotics, antiinflammatory agents, pharmaceutically active substances, bronchoconstrictors, bronchodilators (*e.g.,* beta-adrenergic agonists, anticholinergics, etc.), nerve blocking drugs, photoreactive agents, or combinations thereof. For example, long acting or short acting nerve blocking drugs (*e.g.,* anticholinergics) can be delivered to the nerve tissue to temporarily or permanently attenuate signal transmission. Substances can also be delivered to chemically damage the nerve tissue. The electrodes, antenna, or other energy emitting components can be replaced with other types of components based on the desired type of energy to be used for treatment.

[0170] The various embodiments described above can be combined to provide further embodiments. These and other changes can be made to the embodiments in light of the above-detailed description. The embodiments, features, systems, devices, materials, methods and techniques described herein may, in some embodiments, be similar to any one or more of the embodiments, features, systems, devices, materials, methods and techniques described in U.S. Provisional Patent Application No. 61/321,346 filed April 6, 2010; U.S. Application No. 12/463,304 filed on May 8, 2009; U.S. Application No. 12/913,702 filed on October 27, 2010; PCT Application No. PCT/US2010/056424 filed November 11, 2010; U.S. Application No. 12/944,666 filed November 11, 2010; and PCT Patent Application No. PCT/US2010/56425 filed November 11, 2010. Each of these applications is incorporated herein by reference in its entirety. In addition, the embodiments, features, systems, devices, materials, methods and techniques described herein may, in certain embodiments, be applied to or used in connection with any one or more of the embodiments, features, systems, devices, materials, methods and techniques disclosed in the above-mentioned U.S. Application No. 12/463,304 filed on May 8, 2009; U.S. Application No. 12/913,702 filed on October 27, 2010; PCT Application No. PCT/US2010/056424 filed November 11, 2010; U.S. Application No. 12/944,666 filed November 11, 2010; and PCT Patent Application No. PCT/US2010/56425 filed November 11, 2010. For example, the apparatuses of disclosed in U.S. Application No. 12/463,304 may incorporate the electrodes or other features, such as the protection devices, disclosed herein. All of the U.S. patents, U.S. patent application publications, U.S. patent application, foreign patents, foreign patent application and non-patent publications referred to in this specification and/or listed in the Application Data Sheetare incorporated herein by reference, in their entirety. Aspects of the embodiments can be modified, if necessary to employ concepts of the various patents, application and publications to provide yet further embodiments.

[0171] These and other changes can be made to the embodiments in light of the above-detailed description. In general, in the following claims, the terms used should not be construed to limit the claims to the specific embodiments disclosed in the specification and the claims, but should be construed to include all possible embodiments along with the full scope of equivalents to which such claims are entitled. Accordingly, the claims are not limited by the disclosure.

[0172] Further preferred embodiments of the invention are as follows:

1. A system for pulmonary treatment, comprising: a pulmonary treatment device having an energy delivery element positionable through at least a portion of a trachea into an airway and configured to deliver energy to a wall of the airway to alter nerve tissue located in or proximate to the wall of the airway; and
a protection device having a protection member positionable in an esophagus while the pulmonary treatment device is positioned in the airway, the protection member being configured to absorb heat from a wall of the esophagus to inhibit damage to esophageal tissue.

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2. The system of embodiment 1 wherein the pulmonary treatment device is configured to deliver a sufficient amount of energy to the wall of the airway to heat and damage the nerve tissue, wherein the protection device is configured to absorb a sufficient amount of heat from the wall of the esophagus to inhibit damage to esophageal tissue while the nerve tissue is damaged.

3. The system of embodiment 1, further comprising a media delivery system fluidically coupled to the pulmonary treatment device and the protection device, the media delivery system being configured to deliver cooling media through the pulmonary treatment device to cool the energy delivery element and configured to deliver cooling media through the protection device to cool the protection member.

4. The system of embodiment 1 wherein the airway treatment device comprises a first elongate member configured for insertion through the airway, and the at least one energy delivery element is disposed on the first elongate member in a position corresponding to the anatomical location of at least one nerve in or proximate to the airway wall when said first elongate member is positioned therein.

5. The system of embodiment 4 wherein the protection device comprises a second elongate member configured for insertion in the esophagus, the protection member being disposed on the second elongate member in a position generally aligned with the position of the at least one energy delivery element when the airway treatment device is positioned in the airway and the second elongate member is positioned in the esophagus.

6. The system of embodiment 1, further comprising cooling means associated with said at least one energy delivery element to limit tissue damage adjacent select denervation sites.

7. The system of embodiment 1 wherein said protection member comprises an expandable member configured for insertion into the esophagus.

8. The system of embodiment 7 wherein said expandable member comprises an inflatable balloon configured to circulate a cooling medium therein.

9. The system of embodiment 7 wherein said expandable member comprises a balloon configured to occlude the esophagus and said cooling means further comprises means for circulating a cooling fluid within the occluded esophagus.

10. The system of embodiment 1 wherein said airway treatment device comprises an inflatable balloon.

11. The system of embodiment 10 wherein said inflatable balloon is configured for circulation of cooling fluid therein.

12. The system of embodiment 1 wherein the active electrode is balloonlessly expandable from a contracted configuration to an expanded configuration.

13. The apparatus of embodiment 12 wherein the active electrode is configured to fit between adjacent cartilage rings of the airway in the expanded configuration.

14. The system of embodiment 1 wherein said airway treatment device comprises a helical or ring-shaped member that includes the energy delivery element.

15. The system of embodiment 1 wherein said pulmonary treatment device comprises an energy delivery device configured to be positioned in the airway to locate the energy delivery element into an intercartilaginous region.

16. The system of embodiment 1 wherein said at least one energy delivery element comprises an RF electrode.

17. The system of embodiment 16 wherein said energy delivery element further comprises a return electrode, said electrodes being configured for bipolar energy delivery.

18. The system of embodiment 1 wherein said at least one energy delivery element comprises a microwave antenna.

19. The system of embodiment 1 wherein said protection device comprises at least one electrode configured to be operatively coupled with the energy delivery element of the airway treatment device.

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20. A method for pulmonary treatment, comprising: positioning at least one energy delivery element through at least a portion of the trachea into an airway adjacent a treatment site to be treated;
delivering energy from said at least one element to a portion of the circumference of the airway at said treatment site; and
cooling tissues of an esophagus to prevent damage of the tissues of the esophagus while the energy is delivered.

21. The method of embodiment 20 wherein said cooling comprises delivering a cooling medium into the esophagus.

22. The method of embodiment 20 wherein said portion of the circumference of the trachea of the subject is less than 360 degrees around the trachea.

23. The method of embodiment 20, further comprising:

repositioning the at least one energy delivery element in close proximity to the previous position;
and
delivering energy in an adjacent treatment site wherein said adjacent site barely overlaps or allows a small gap with the previous treatment site.

24. The method of embodiment 20, further comprising rotating the at least one energy delivery element to provide a slight overlap or a slight gap circumferentially with respect to the previous treatment site.

25. The method of embodiment 20 wherein said delivering comprises delivering RF energy.

26. The method of embodiment 20 wherein said delivering further comprises bipolar delivery of RF energy.

27. The method of embodiment 20 wherein said delivering comprises delivering microwave energy.

28. The method of embodiment 20, further comprising positioning at least one esophageal energy delivery element in the esophagus and delivering or receiving energy to or from said esophageally positioned element.

29. The method of embodiment 20 wherein the energy delivery element comprises a first electrode, the first electrode being positioned within a first space between a first pair of adjacent cartilage rings of the airway.

30. The method of embodiment 29, further comprising placing a second electrode in a second space between a second pair of adjacent cartilage rings of the airway.

31. The method of embodiment 30, further comprising delivering energy between the first and second electrodes to alter target tissue in a wall of the airway longitudinally displaced from the first and second spaces.

32. A pulmonary treatment apparatus comprising:

an elongate member insertable through at least a portion of a trachea into an airway; and

a microwave antenna coupled to the elongate member and positionable in the airway at a treatment location proximate nerve tissue in a wall thereof, the microwave antenna being configured to deliver microwave energy so as to alter the nerve tissue in a manner which disrupts transmission of nerve signals therein while non-target tissue disposed between the microwave antenna and the nerve tissue is not permanently injured.

33. The pulmonary treatment apparatus of embodiment 32, further comprising a cooling device coupled to the elongate member configured to cool at least a portion of the non-target tissue while the microwave antenna delivers the microwave energy.

34. The pulmonary treatment apparatus of embodiment 32 wherein the cooling device comprises a jacket surrounding the microwave antenna.

35. The pulmonary treatment apparatus of embodiment 32 wherein the cooling device comprises an inflatable balloon having a chamber, the microwave antenna being disposed in the chamber.

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36. The pulmonary treatment apparatus of embodiment 32 wherein at least a portion of the cooling device is disposed between the antenna and the wall of the airway when the antenna is positioned at the treatment location.

37. The pulmonary treatment apparatus of embodiment 32 wherein the microwave antenna is configured to heat the nerve tissue to a lethal nerve temperature while the non-target tissue is maintained at a temperature below a lethal tissue temperature.

38. The pulmonary treatment apparatus of embodiment 32 wherein the microwave antenna is configured to alter the nerve tissue while non-target tissue disposed beyond the nerve tissue is not permanently injured.

39. The pulmonary treatment apparatus of embodiment 32 wherein the microwave antenna operates at a frequency selected so that the microwave energy penetrates the airway wall to a depth of the nerve tissue with an intensity sufficient to alter the nerve tissue while having insufficient intensity in non-target tissue beyond the nerve tissue to cause permanent injury.

40. The pulmonary treatment apparatus of embodiment 32, further comprising at least one supporting element movable from a contracted position to an expanded position and configured to engage the wall of the airway to position the microwave antenna.

41. The pulmonary treatment apparatus of embodiment 32 wherein the antenna comprises a plurality of longitudinally spaced slots.

42. The pulmonary treatment apparatus of embodiment 32 wherein the microwave antenna comprises a dual antenna system configured to produce a standing wave at a location corresponding to the nerve tissue when the microwave antenna is at the treatment location.

43. The pulmonary treatment apparatus of embodiment 32, further comprising a shield positioned and configured to block or attenuate the microwave energy emitted in a selected direction from the microwave antenna.

44. The pulmonary treatment apparatus of embodiment 32, further comprising a reflector positionable at a location spaced apart from the microwave antenna and configured to reflect the microwave energy delivered therefrom.

45. The pulmonary treatment apparatus of embodiment 44 wherein the reflector is positionable in an esophagus.

46. The pulmonary treatment apparatus of embodiment 45 wherein the reflector comprises an inflatable member connected to a source of inflation fluid.

47. The pulmonary treatment apparatus of embodiment 32, further comprising a protection member positionable in an esophagus.

48. The pulmonary treatment apparatus of embodiment 47 wherein the protection member comprises an expandable member configured to engage esophageal tissue and absorb heat therefrom.

49. The pulmonary treatment apparatus of embodiment 47 wherein the protection member is configured to absorb microwave energy delivered from the microwave antenna.

50. The pulmonary treatment apparatus of embodiment 32 wherein the microwave antenna is positionable through a bronchoscope to the treatment location.

51. A method of pulmonary treatment comprising:

positioning an elongate member through at least a portion of the trachea into an airway, the elongate member having a treatment element and an sensor coupled thereto;

sensing a first tissue characteristic using the sensor with the treatment element at a first airway location;

comparing the first tissue characteristic to a reference value to evaluate the location of the treatment element in the airway; and

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activating the treatment element to treat the airway.

52. The method of embodiment 51 wherein the sensor comprises at least one impedance sensor configured to sense tissue impedance.

53. The method of embodiment 51 wherein the treatment element is activated at a second airway location between two adjacent cartilage rings of the airway.

54. The method of embodiment 53 wherein the first airway location is at least partially surrounded by one of the cartilage rings, further comprising re-positioning the treatment element to the second airway location before activating the treatment element.

55. The method of embodiment 51 , further comprising estimating the location of a non-target structure relative to the treatment element based on the first impedance.

56. The method of embodiment 55, further comprising, after estimating the location of the non-target structure, repositioning the treatment element before actuation thereof so as to avoid injury to the non-target structures.

57. The method of embodiment 51 wherein the non-target structure comprises the esophagus.

58. The method of embodiment 51 , further comprising detecting previously treated tissue based on the first impedance.

59. The method of embodiment 58, further comprising, after detecting the previously treated tissue, repositioning the treatment element before actuation thereof to avoid re-treatment of the previously treated tissue.

60. The method of embodiment 51 wherein activating the treatment element comprises delivering energy therefrom to tissue in a wall of the airway.

61. The method of embodiment 60 wherein the energy alters nerve tissue in the wall of the airway to disrupt transmission of nerve signals therein.

62. The method of embodiment 61, further comprising protecting non-target tissue between the treatment element and the nerve tissue from permanent injury.

63. An apparatus for pulmonary treatment comprising: an elongate member insertable through a trachea into an airway;
an active electrode coupled to the elongate member and configured to deliver energy to target tissue in a wall of the airway.
a return electrode positionable in the airway or the esophagus and configured to receive the energy from the target tissue; and
a protection member configured to cool non-target tissue proximate to the target tissue.

64. The apparatus of embodiment 63 wherein the return electrode is coupled to the elongate member so as to be positionable in the airway adjacent to the active electrode.

65. The apparatus of embodiment 63 wherein the active electrode is configured to engage a posterior aspect of the airway and the return electrode is configured to engage an anterior aspect of the airway.

66. The apparatus of embodiment 63 wherein the active electrode comprises a plurality of conductive bands movable from a contracted configuration to an expanded configuration.

67. The apparatus of embodiment 66 wherein the return electrode comprises at least one additional conductive band coupled to the conductive bands of the active electrode and electrically isolated therefrom, the return electrode being movable with the active electrode from a contracted configuration to an expanded configuration.

68. The apparatus of embodiment 63 wherein the active electrode is disposed on the exterior of an expandable balloon coupled to the elongate member.

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69. The apparatus of embodiment 68 wherein the balloon is connected to source of coolant, the protection member comprising a cooled portion of the balloon.

70. The apparatus of embodiment 63 wherein the active electrode is expandable from a contracted configuration to an expanded configuration without the use of a balloon.

71. The apparatus of embodiment 70 wherein the active electrode is configured to fit between a first pair of adjacent cartilage rings of the airway in the expanded configuration.

72. The apparatus of embodiment 70 wherein the return electrode is configured to fit between a second pair of adjacent cartilage rings of the airway while the active electrode is positioned between the first pair of adjacent cartilage rings.

73. The apparatus of embodiment 63 wherein the active electrode is carried by an actuable device movable between a delivery configuration and a deployed configuration, the actuable device is coupled to the elongate member.

74. The apparatus of embodiment 73 wherein the actuable device defines a plurality of spaced apart rings configured to preferentially seat in one or more intercartilaginous spaces.

75. The apparatus of embodiment 74 wherein the actuable device has a helical or ring-shape in the deployed configuration.

76. The apparatus of embodiment 63 wherein the active electrode comprises a cooling channel fluidly coupled to a source of coolant.

77. The apparatus of embodiment 63 wherein the return electrode is coupled to an elongate shaft positionable in the esophagus.

78. The apparatus of embodiment 63 wherein the protection member is positionable in the esophagus while the elongate member and active electrode are positioned in the airway.

79. The apparatus of embodiment 78 wherein the protection member comprises an expandable member configured to engage esophageal tissue.

80. The apparatus of embodiment 79 wherein the return electrode is coupled to the expandable member.

81. A method of pulmonary treatment comprising:

inserting an elongate member through at least a portion of a trachea such that an energy delivery element coupled to the elongate member is positioned at a treatment site in an airway;

delivering energy at a first power level from an active portion of the energy delivery element to create a first lesion covering a first portion of a

circumference of the airway;

moving the energy delivery element; and

delivering energy at a second power level from the active portion of the energy delivery element to create a second lesion covering a second portion of the circumference of the airway displaced from the first portion;

wherein the first power level is substantially greater than the second power level.

82. The method of embodiment 81 wherein the second portion is circumferentially or axially displaced from the first portion relative to lumen of the airway.

83. The method of embodiment 81 wherein the first portion of the circumference is on an anterior aspect of the airway.

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84. The method of embodiment 81 wherein the second portion is on a posterior aspect of the airway.

85. The method of embodiment 81 wherein the second power level is about 50% to about 80% of the first power level.

86. The method of embodiment 81 wherein the second power level is selected to avoid permanent injury to non-target tissue proximate to the treatment site.

87. The method of embodiment 86 wherein the first power level would permanently injure the non-target tissues if delivered to the second portion of the circumference.

88. The method of embodiment 87 wherein the non-target tissue comprises tissue of the esophagus.

89. The method of embodiment 81 wherein the airway comprises the left main bronchus.

90. The method of embodiment 81 wherein the first and second lesions are created at a depth in the airway wall without permanently injuring non-target tissue of the airway wall between the energy delivery element and the first and second lesions.

91. The method of embodiment 90, further comprising cooling tissue of the airway wall during the creation of the first and second lesions.

92. The method of embodiment 81 wherein at least one of the first and second lesions are created so as to alter nerve tissue in or proximate to the airway wall to disrupt signal transmission along the airway.

93. The method of embodiment 81 wherein moving the energy delivery element includes rotating the energy delivery element about a longitudinal axis of the airway.

94. A method of pulmonary treatment comprising:

delivering a first amount of energy from an energy delivery device to a first portion of a wall of an airway; and

delivering a second amount of energy from the energy delivery device to a second portion of the wall of the airway, the first portion of the wall and the second portion of the wall are spaced apart from one another or partially overlap one another, and the second amount of energy is different from the first amount of energy.

95. The method of embodiment 94, further comprising moving an elongate body and the energy delivery device coupled to the elongated body relative to the wall of the airway after delivering the first amount of energy and prior to delivering the second amount of energy.

96. The method of embodiment 94 wherein the first portion of the airway is located at an anterior region of the airway, and the first amount of energy is greater than the second amount of energy.

97. The method of embodiment 94 wherein delivering the first amount of energy comprises delivering energy at a first power level from an active portion of the energy delivery device, and delivering the second amount of energy comprises delivering energy at a second power level from the active portion of the energy delivery device.

98. The method of embodiment 94, further comprising ablating substantially all of the nerve trunks travelling along the wall of the airway using energy delivered from the energy delivery device.

99. A method of pulmonary treatment comprising:

positioning an energy delivery element in an airway of a subject;

non-inflatably moving the energy delivery element into engagement with a wall of the airway;

delivering energy from the energy delivery element to the wall of the airway to alter target nerve tissue therein or proximate thereto; and

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introducing a cooling medium into the airway into direct contact with the wall to absorb heat from the wall while delivering the energy.

100. The method of embodiment 99 wherein the energy delivery element comprises a first electrode, the first electrode being positioned within a first space between a first pair of adjacent cartilage rings of the airway.

101. The method of embodiment 100, further comprising placing a second electrode in a second space between a second pair of adjacent cartilage rings of the airway.

102. The method of embodiment 100, further comprising delivering energy between the first and second electrodes to alter target tissue in a wall of the airway longitudinally displaced from the first and second spaces.

103. The method of embodiment 99, further comprising positioning a protection device in the esophagus to absorb heat from esophageal tissue while delivering the energy.

104. The method of embodiment 103, further comprising receiving energy with or delivering energy from a second electrode coupled to the protection device.

105. The method of embodiment 99 wherein a surface layer of tissue of the wall is protected from permanent injury while a lesion of permanently injured tissue is created at a depth below the surface layer.

106. The method of embodiment 105 wherein the surface layer is at least about 2 mm in thickness.

107. The method of embodiment 105 wherein the lesion contains the nerve tissue.

108. The method of embodiment 105 wherein the nerve tissue is altered sufficiently to reduce airway constriction in the subject.

109. The method of embodiment 99 wherein the cooling medium is a gas.

110. The method of embodiment 99 wherein the energy delivery element is coupled to an elongate member, and the cooling medium is introduced into the airway through a channel in the elongate member.

111. The method of embodiment 110 wherein the cooling medium flows through a channel in the energy delivery element to absorb heat therefrom.

Claims

1. A pulmonary treatment apparatus comprising:

   an elongate member insertable through at least a portion of a trachea into a first airway;
   a microwave antenna coupled to the elongate member and positionable in the first airway at a treatment location proximate nerve tissue of a nerve trunk in or around an airway wall thereof; and
   a cooling device having an outer member surrounding the microwave antenna and configured to contact the airway wall, the cooling device including a cooling chamber configured to contain coolant so as to cool the outer member,
   wherein the microwave antenna is configured to deliver microwave energy through the outer member and the airway wall to a depth of the nerve tissue so as to alter the nerve tissue in a manner which reduces airway resistance in a second airway of higher generation than the first airway, and
   wherein the cooling device is configured to absorb sufficient heat from non-target tissue disposed between the outer member and the nerve tissue during delivery of the microwave energy such that the non-target tissue is not permanently injured.

2. The pulmonary treatment apparatus of claim 1, wherein the cooling device comprises a jacket surrounding the microwave antenna.

3. The pulmonary treatment apparatus of claim 1 or 2, wherein the cooling device comprises an inflatable balloon

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having a chamber, the microwave antenna being disposed in the chamber.

4. The pulmonary treatment apparatus of any of the preceding claims, wherein at least a portion of the cooling device is disposed between the antenna and the wall of the airway when the antenna is positioned at the treatment location.

5. The pulmonary treatment apparatus of any of the preceding claims, wherein the microwave antenna operates at a frequency selected so that the microwave energy penetrates the airway wall to a depth of the nerve tissue with an intensity sufficient to alter the nerve tissue while having insufficient intensity in non-target tissue beyond the nerve tissue to cause permanent injury.

6. The pulmonary treatment apparatus of any of the preceding claims, further comprising at least one supporting element movable from a contracted position to an expanded position and configured to engage the wall of the airway to position the microwave antenna.

7. The pulmonary treatment apparatus of any of the preceding claims, wherein the antenna comprises a plurality of longitudinally spaced slots.

8. The pulmonary treatment apparatus of any of the preceding claims, wherein the microwave antenna comprises a dual antenna system configured to produce a standing wave at a location corresponding to the nerve tissue when the microwave antenna is at the treatment location.

9. The pulmonary treatment apparatus of any of the preceding claims, further comprising a shield positioned and configured to block or attenuate the microwave energy emitted in a selected direction from the microwave antenna.

10. The pulmonary treatment apparatus of any of the preceding claims, further comprising a reflector positionable at a location spaced apart from the microwave antenna and configured to reflect the microwave energy delivered therefrom.

11. The pulmonary treatment apparatus of claim 10, wherein the reflector is positionable in an esophagus and preferably comprises an inflatable member connected to a source of inflation fluid.

12. The pulmonary treatment apparatus of any of the preceding claims, further comprising a protection member positionable in an esophagus.

13. The pulmonary treatment apparatus of claim 12, wherein the protection member comprises an expandable member configured to engage esophageal tissue and absorb heat therefrom.

14. The pulmonary treatment apparatus of claim 12, wherein the protection member is configured to absorb microwave energy delivered from the microwave antenna.

15. The pulmonary treatment apparatus of any of the preceding claims, wherein the microwave antenna is positionable through a bronchoscope to the treatment location.

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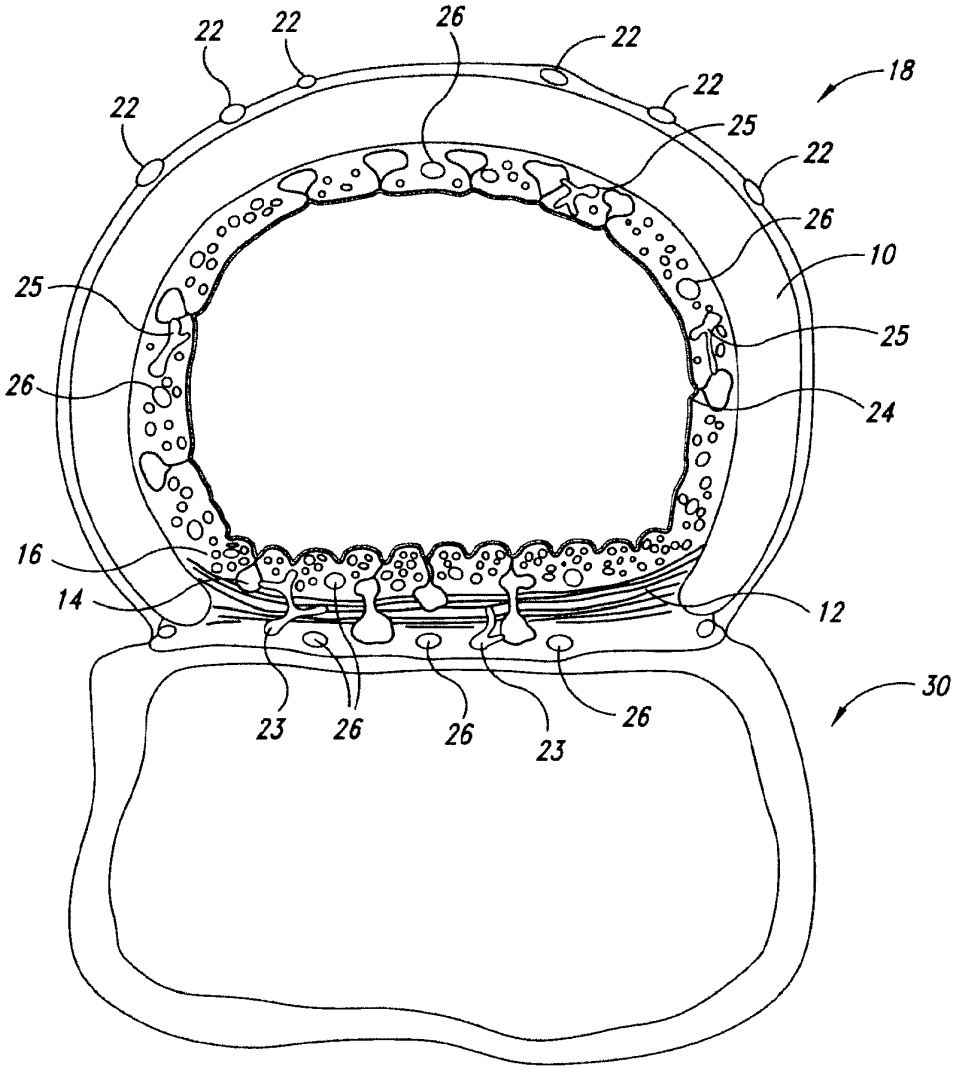


FIG. 1

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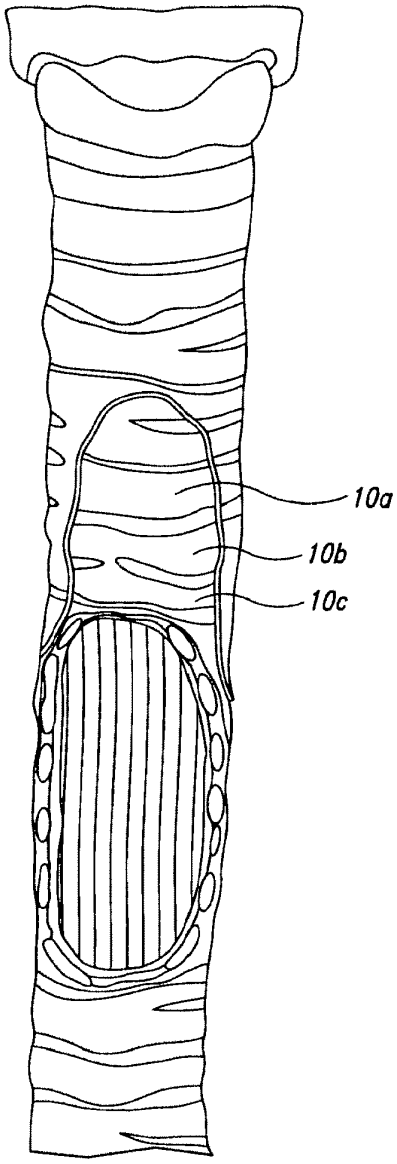


FIG. 2

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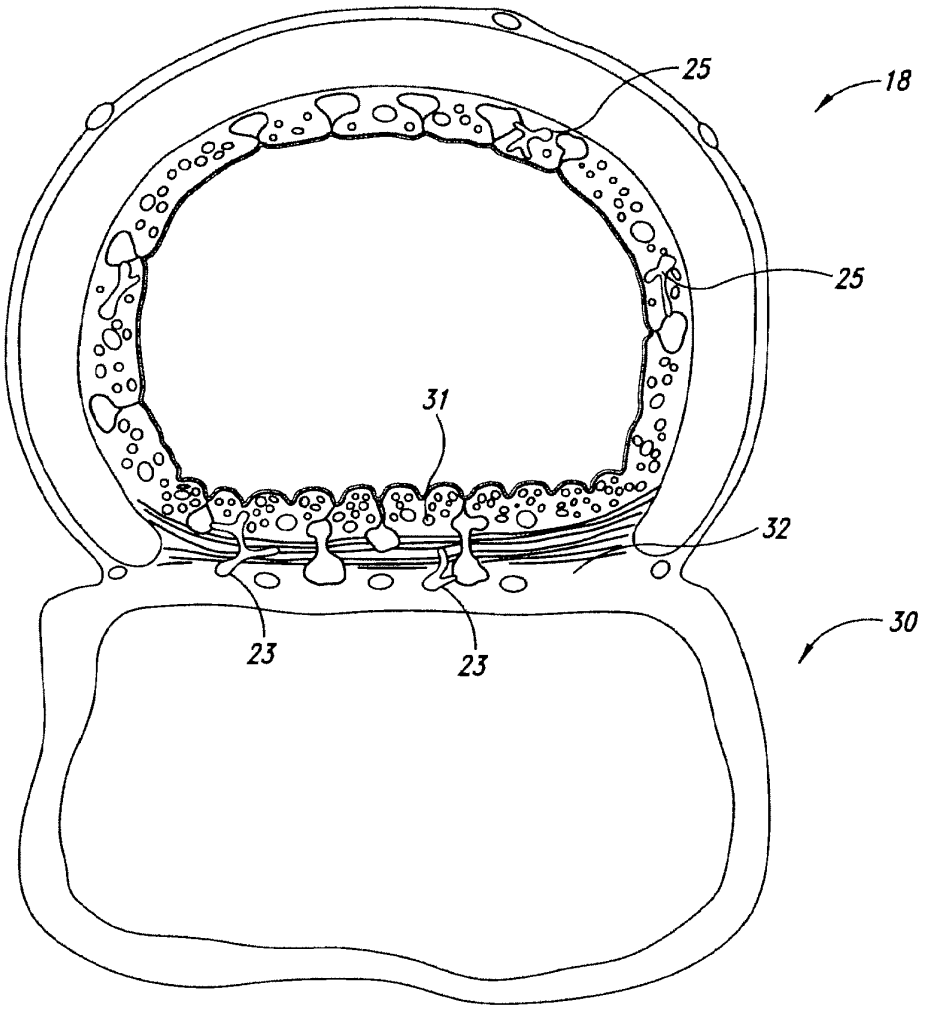


FIG. 3

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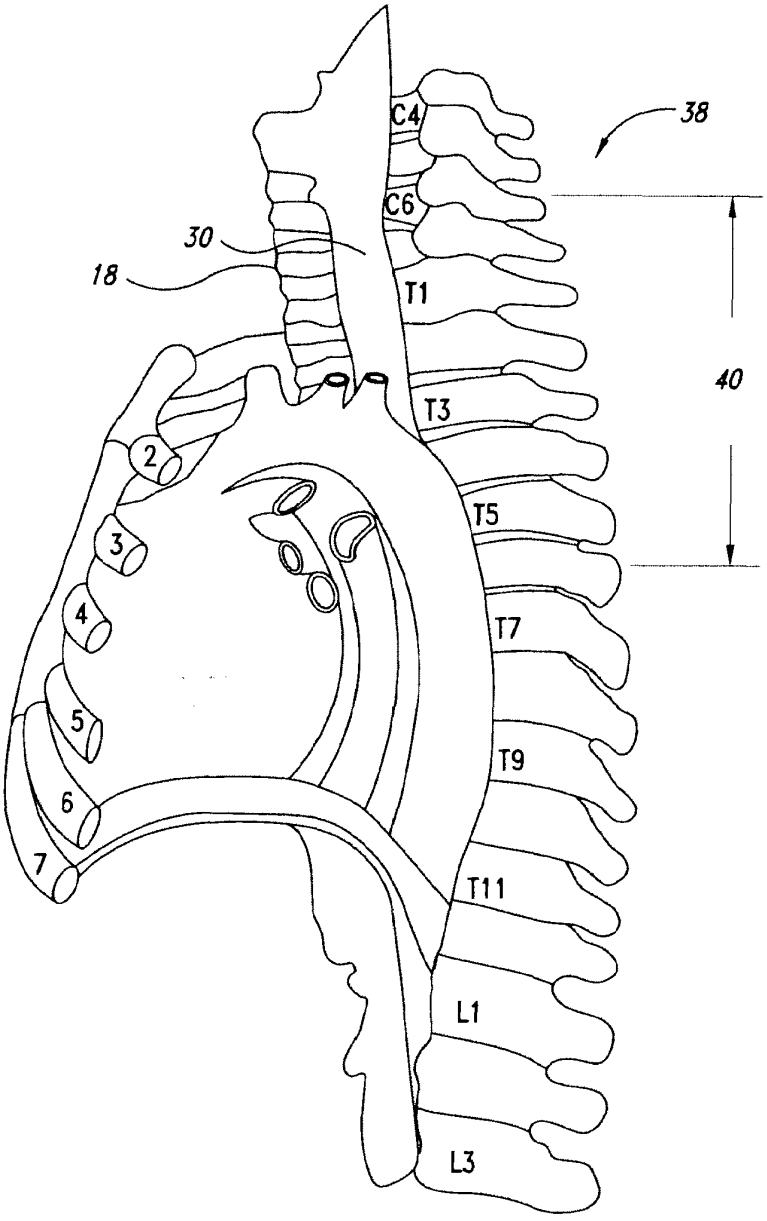


FIG. 4

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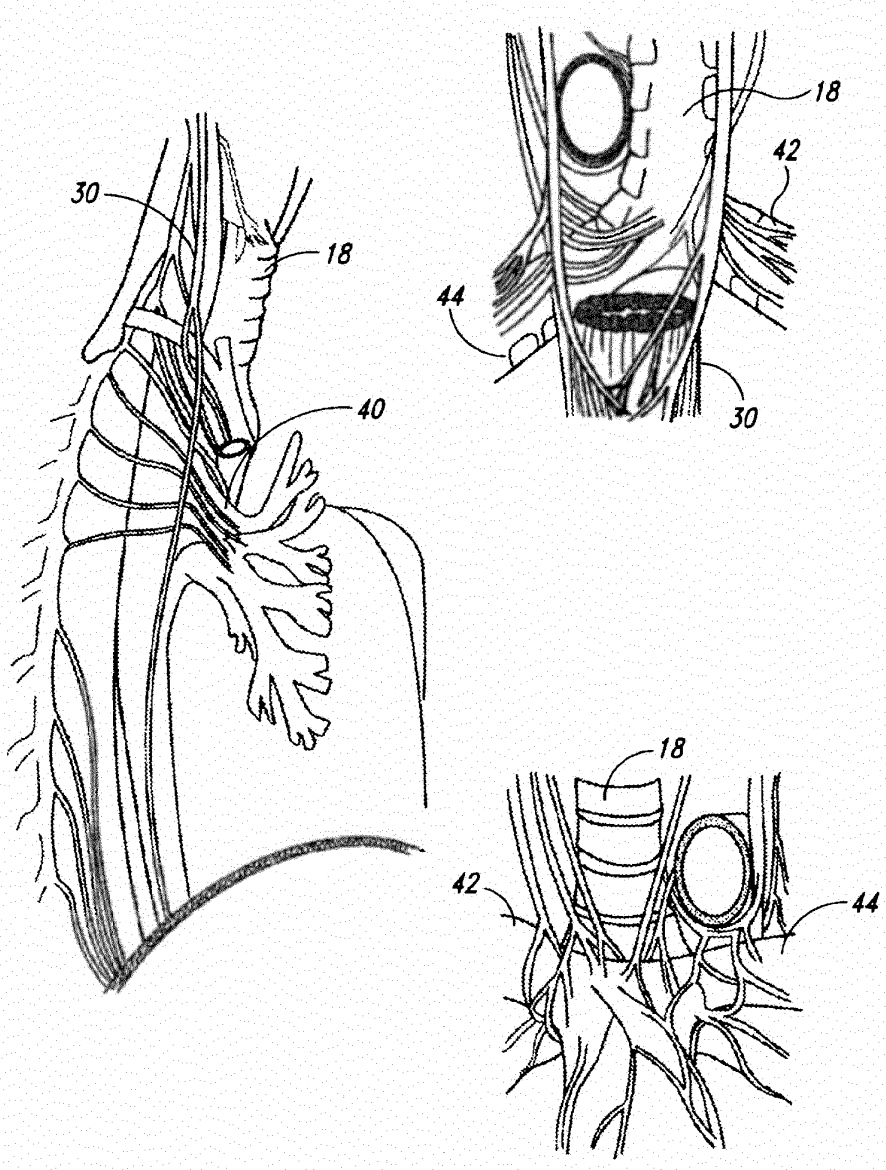


FIG. 4A

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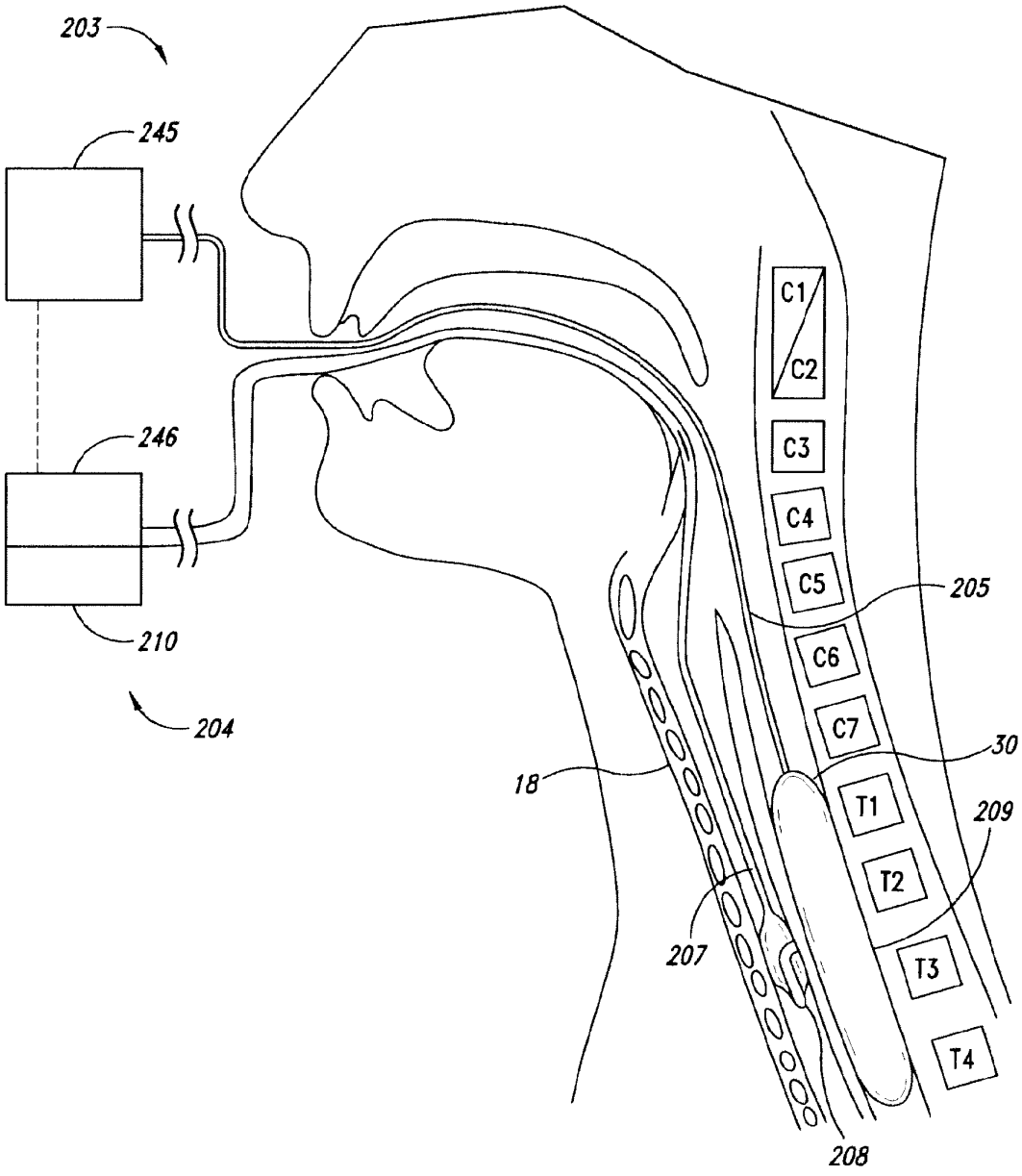


FIG. 5

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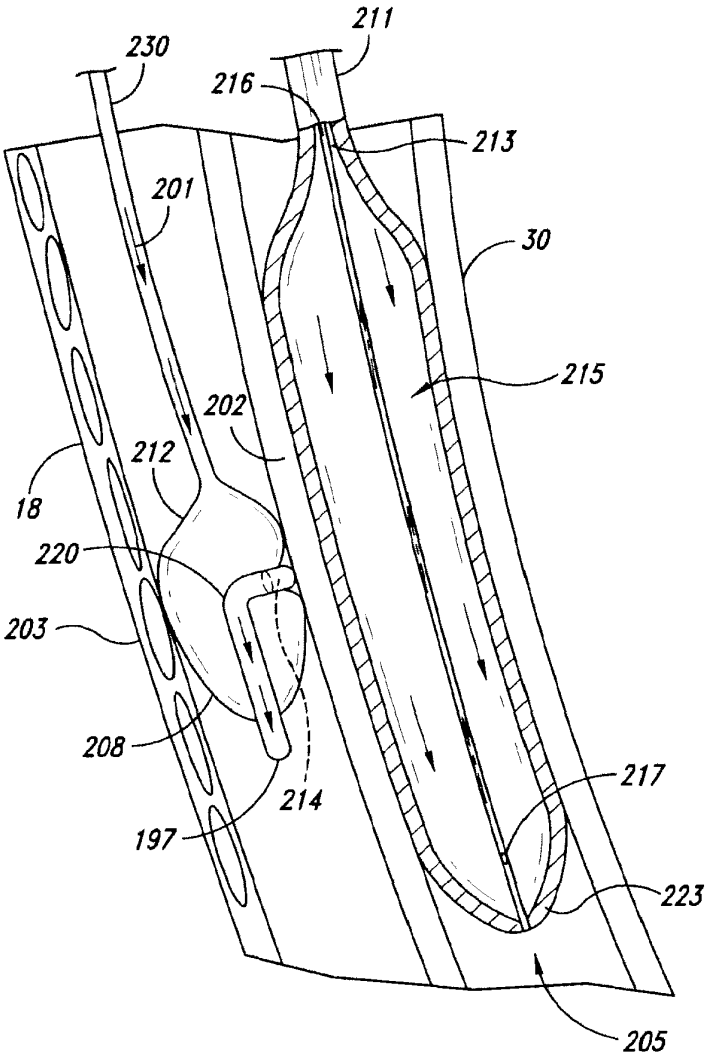


FIG. 6

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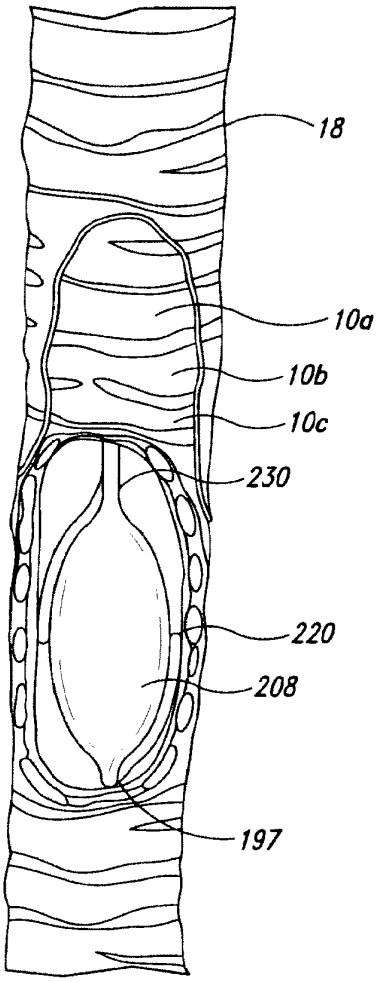


FIG. 7

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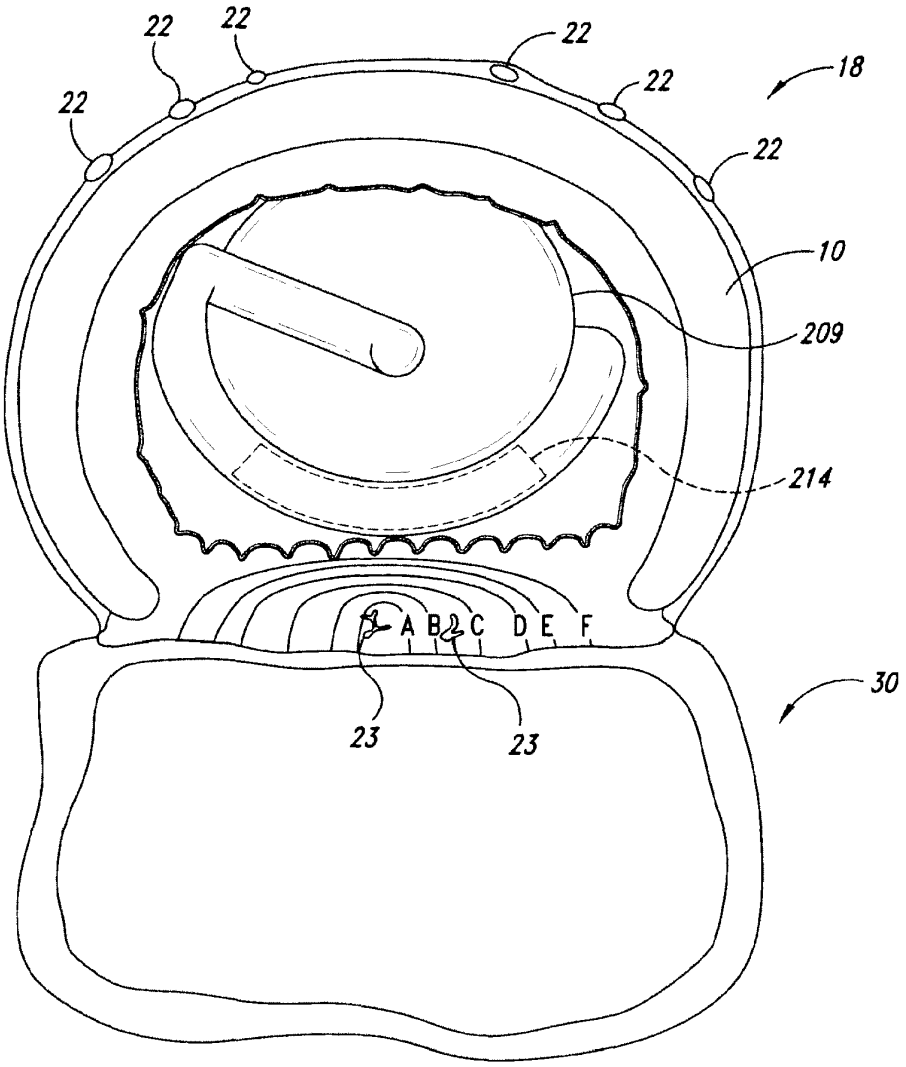


FIG. 8A

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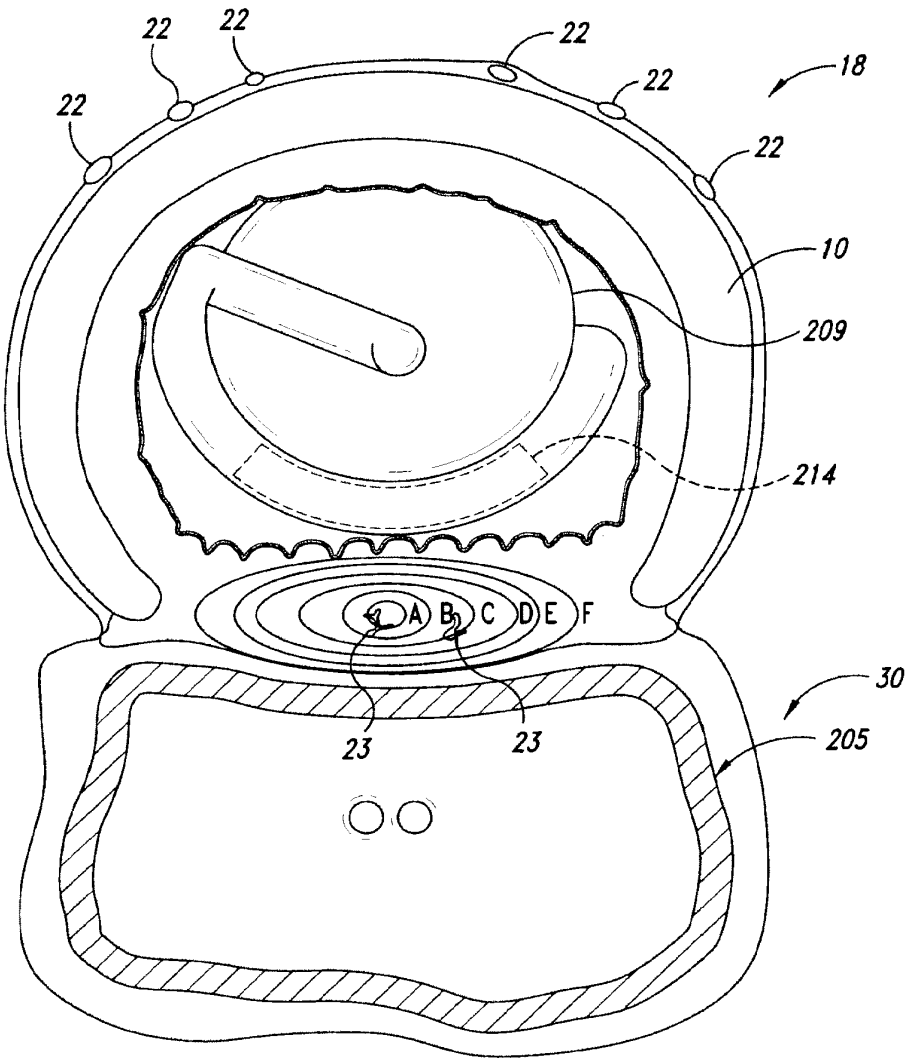


FIG. 8B

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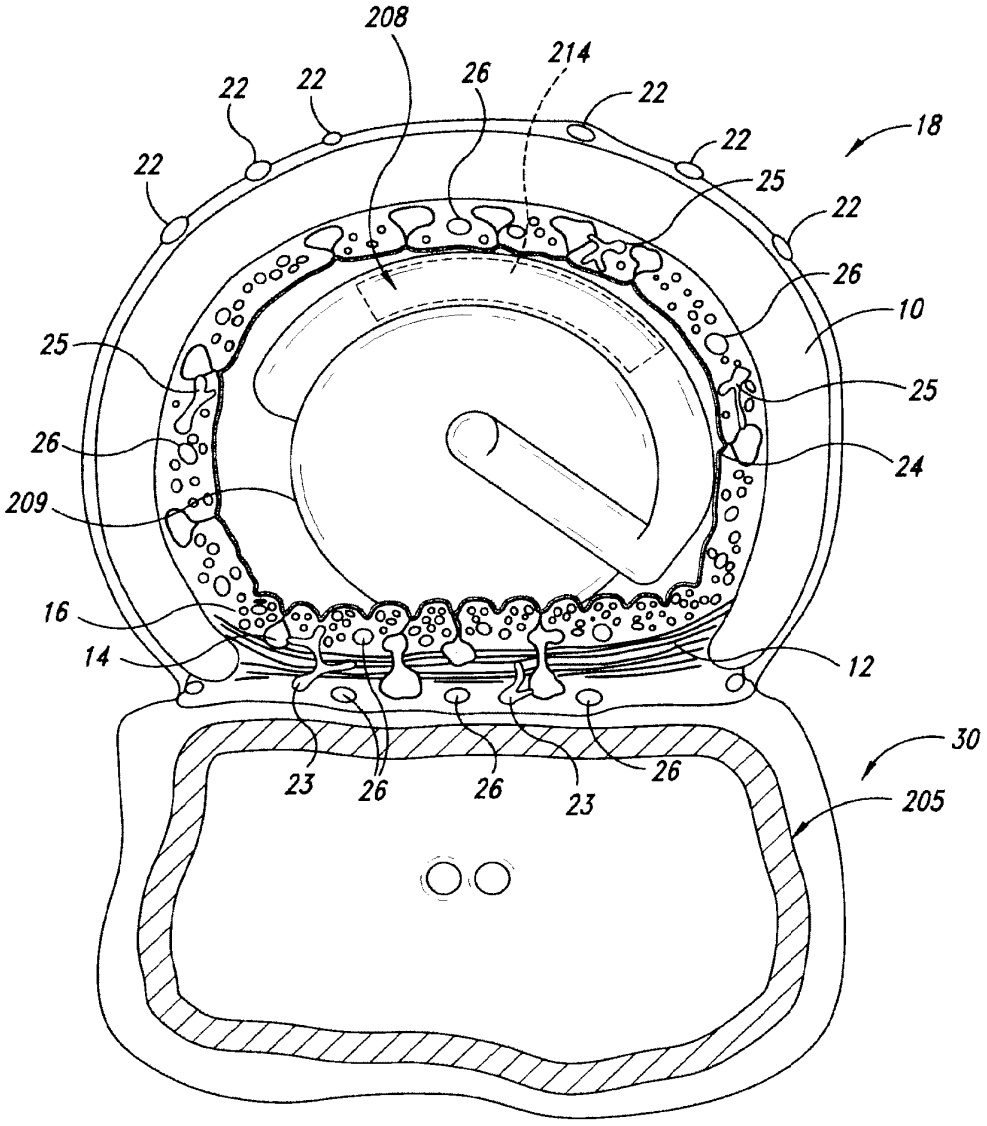


FIG. 9

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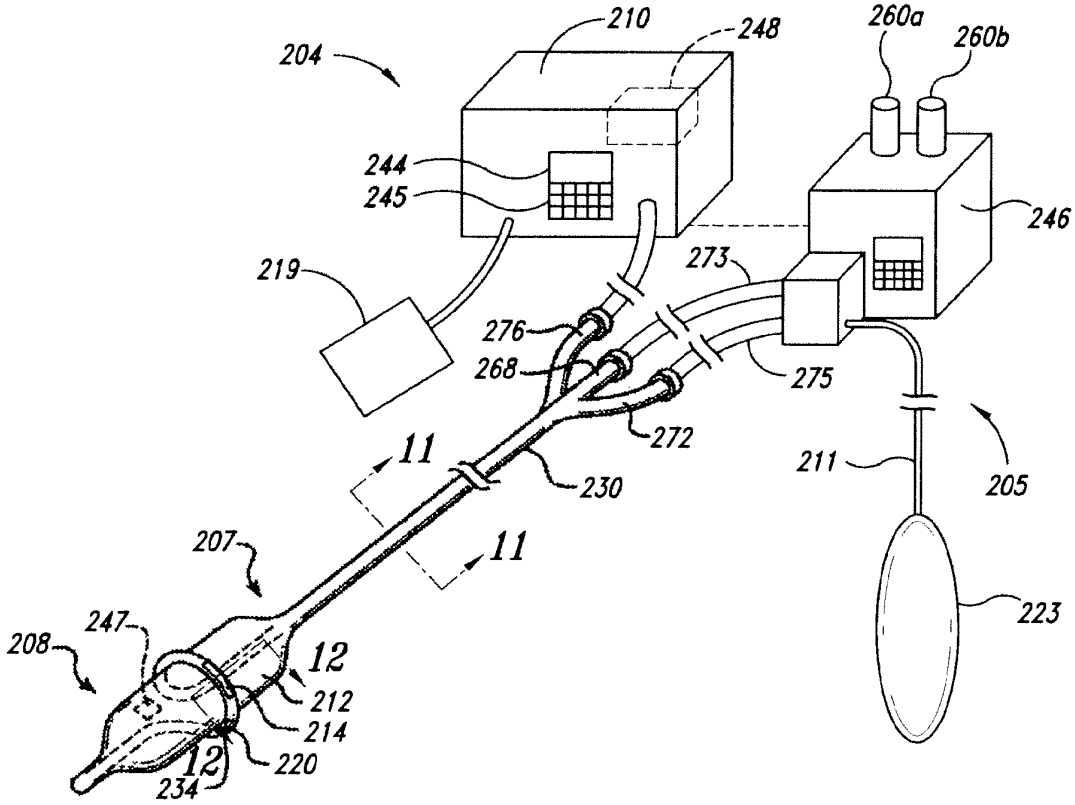


FIG. 10

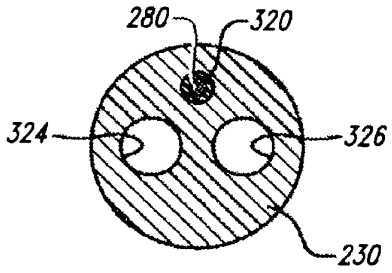


FIG. 11

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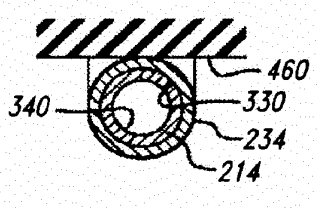


FIG. 12

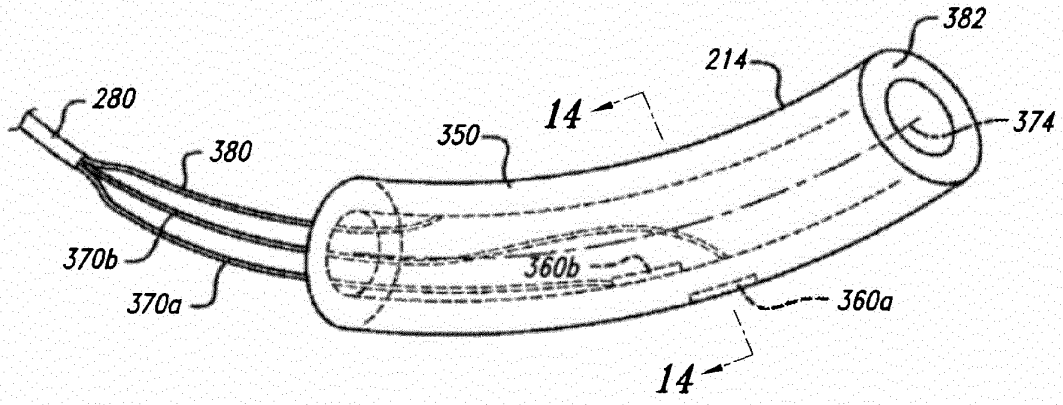


FIG. 13

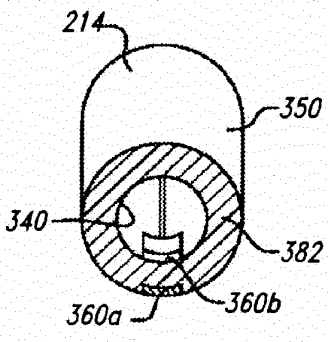


FIG. 14

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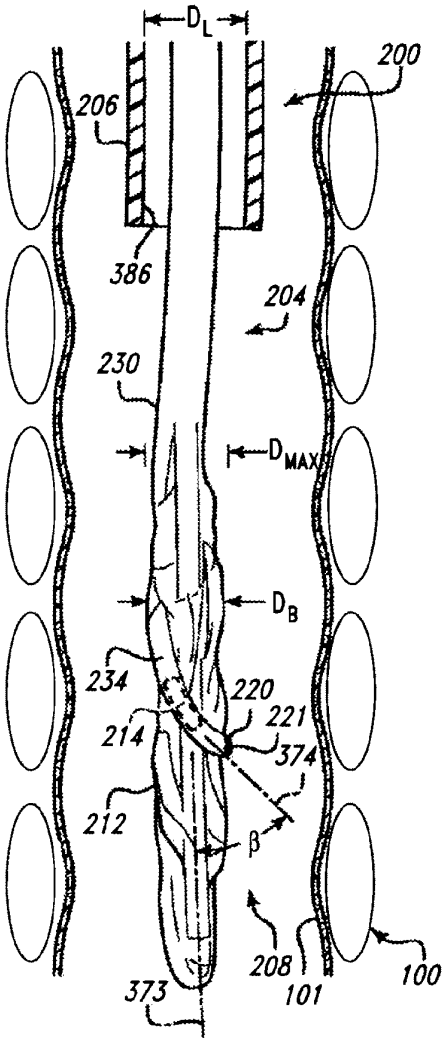


FIG. 15

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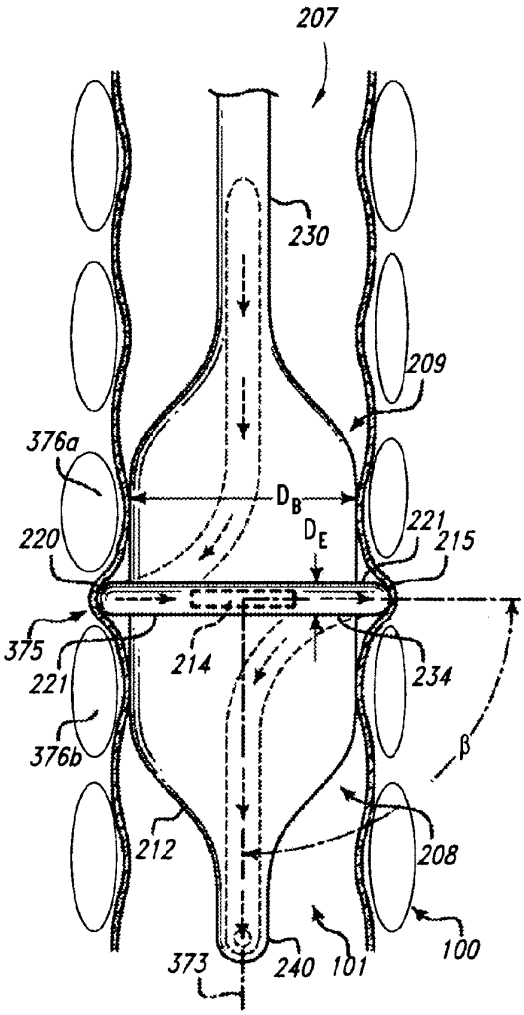


FIG. 16

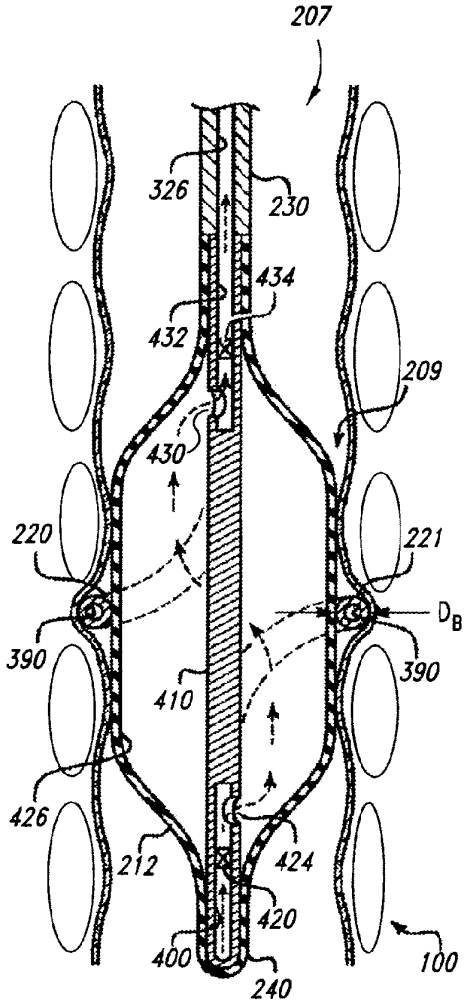


FIG. 17

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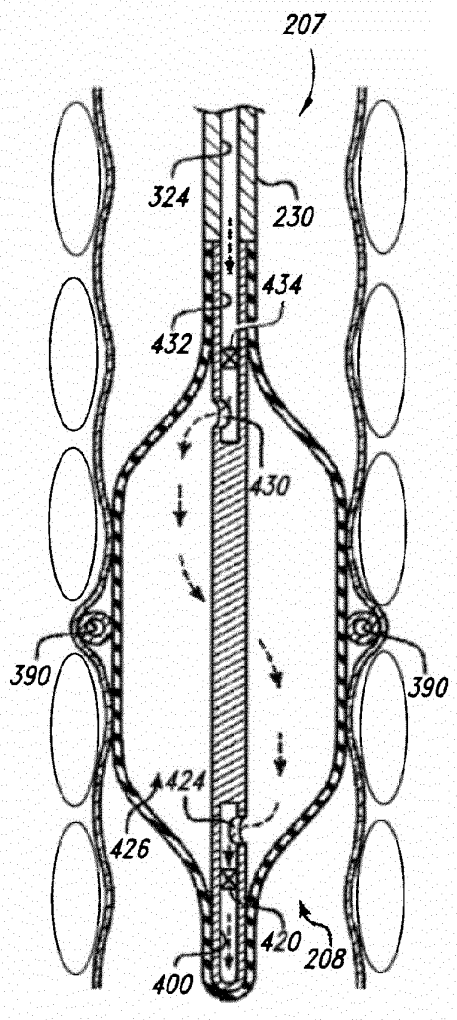


FIG. 18

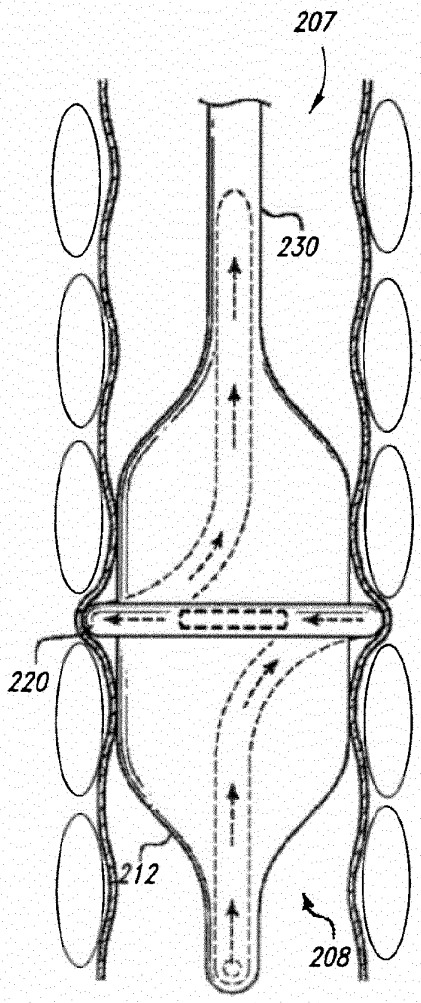


FIG. 19

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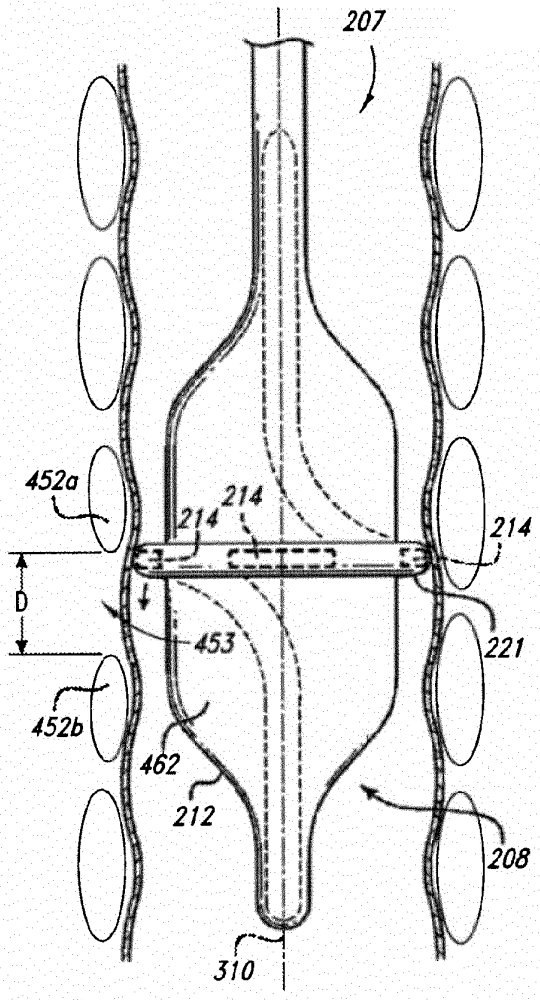


FIG. 20

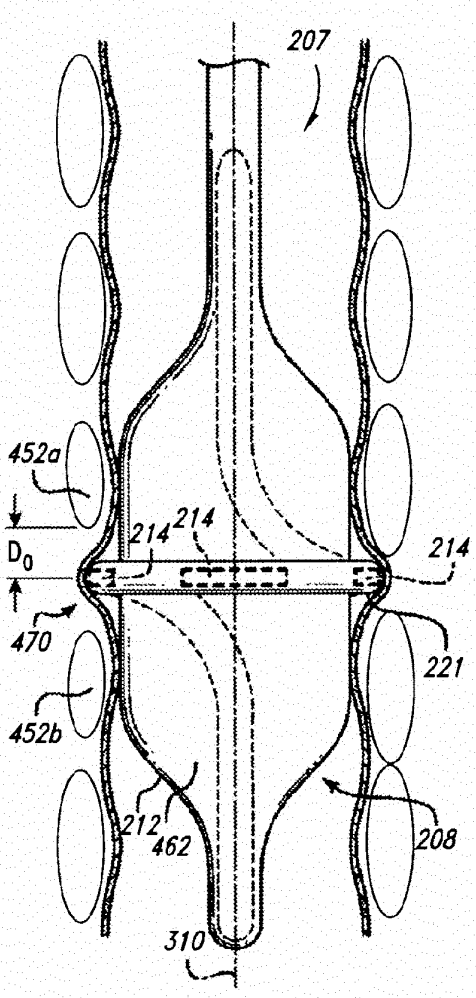


FIG. 21

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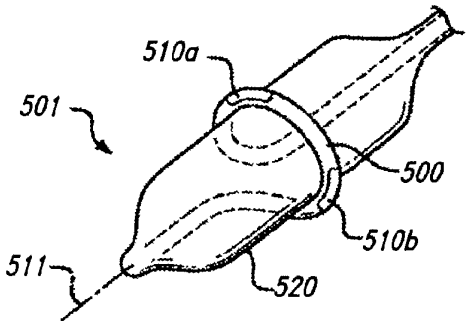


FIG. 22

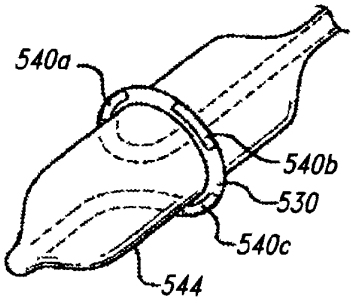


FIG. 23

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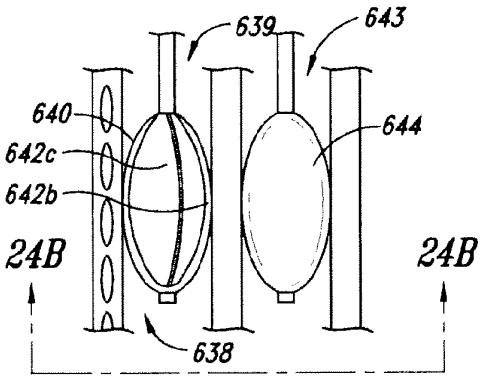


FIG. 24A

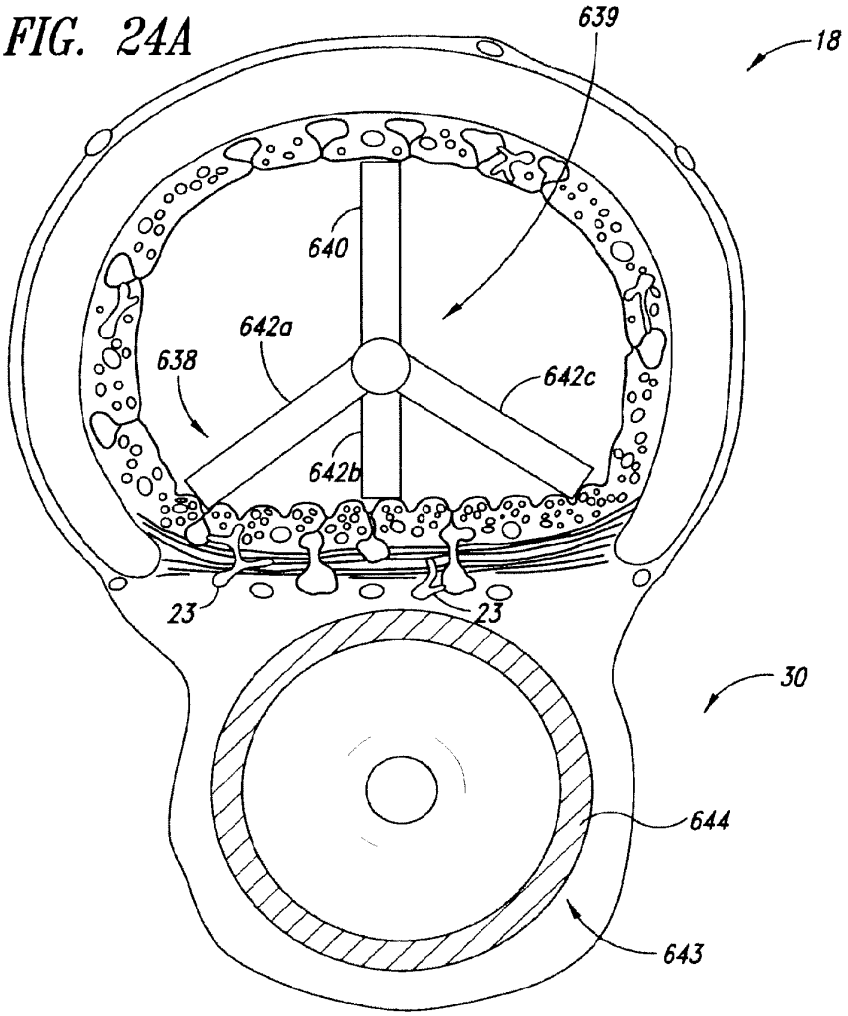


FIG. 24B

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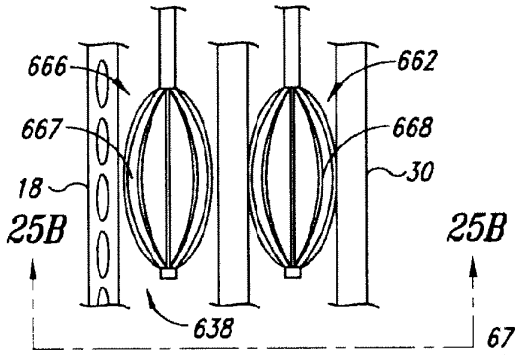


FIG. 25A

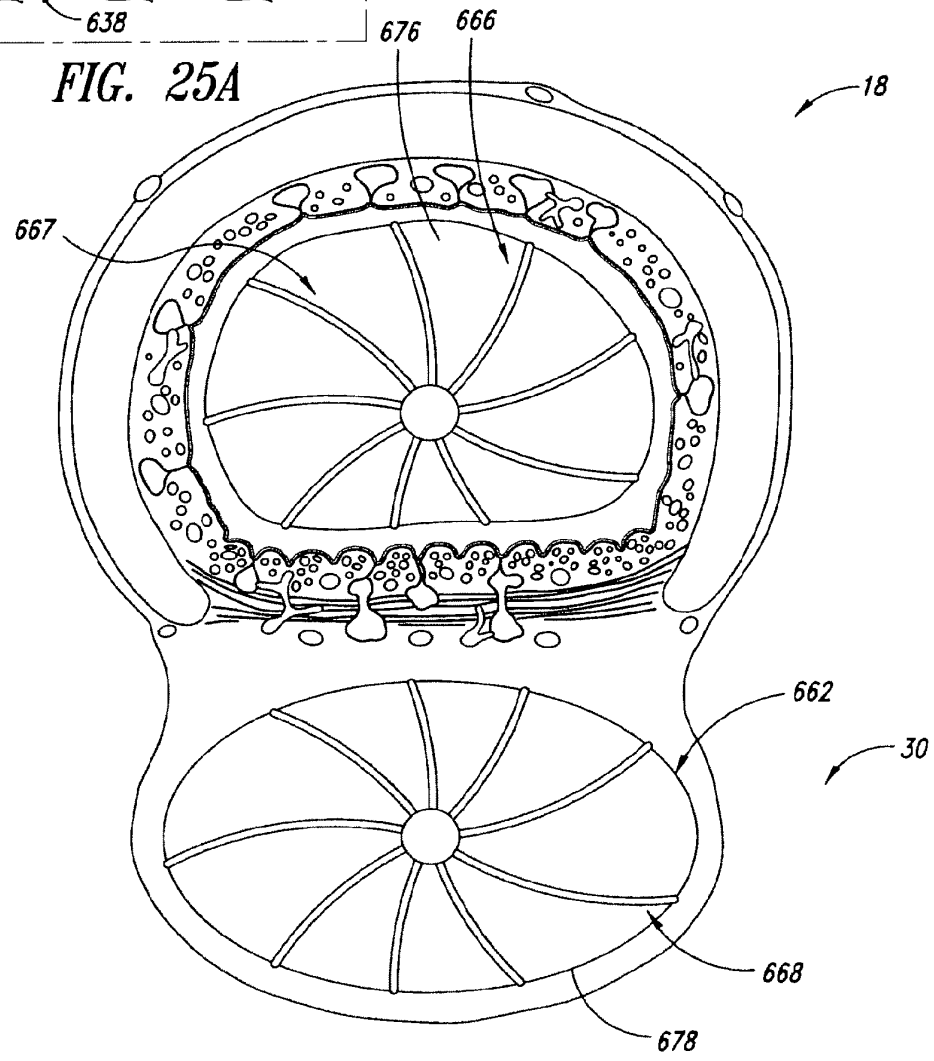


FIG. 25B

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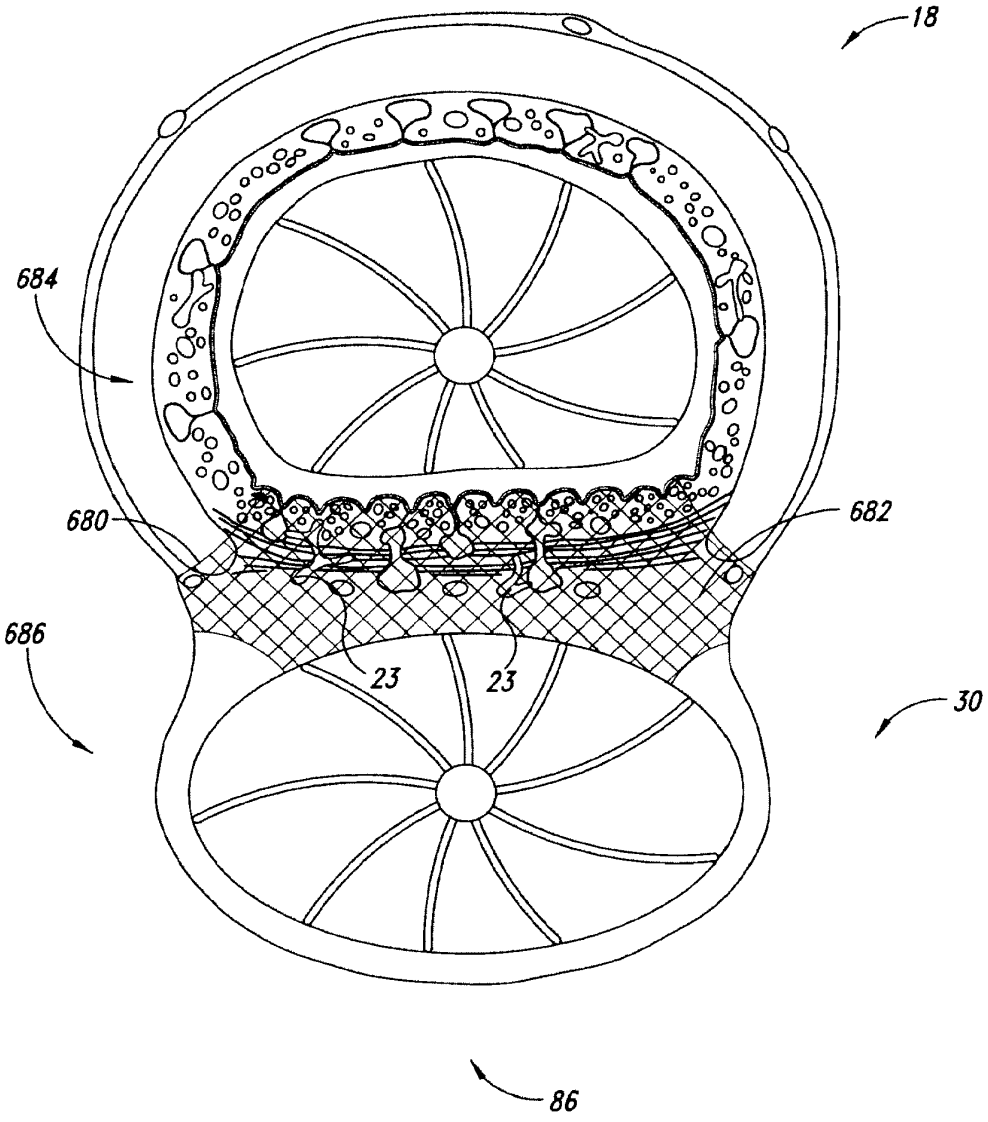


FIG. 26

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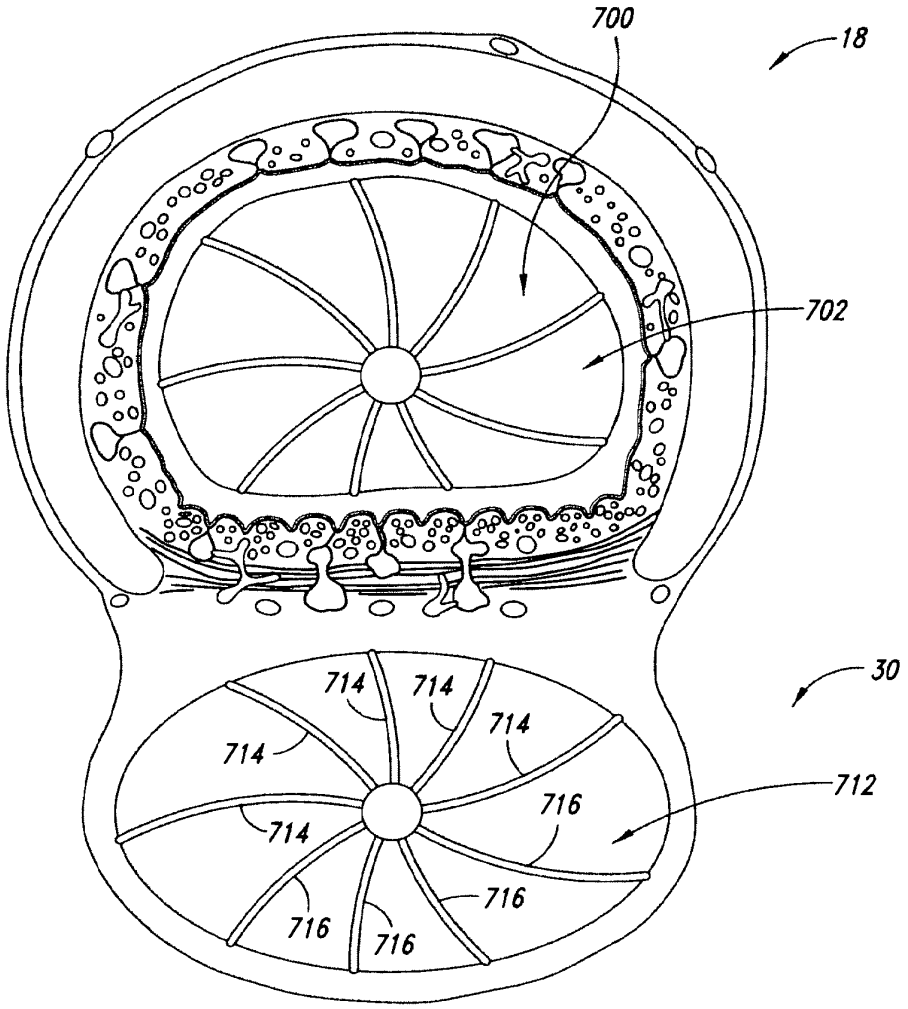


FIG. 27

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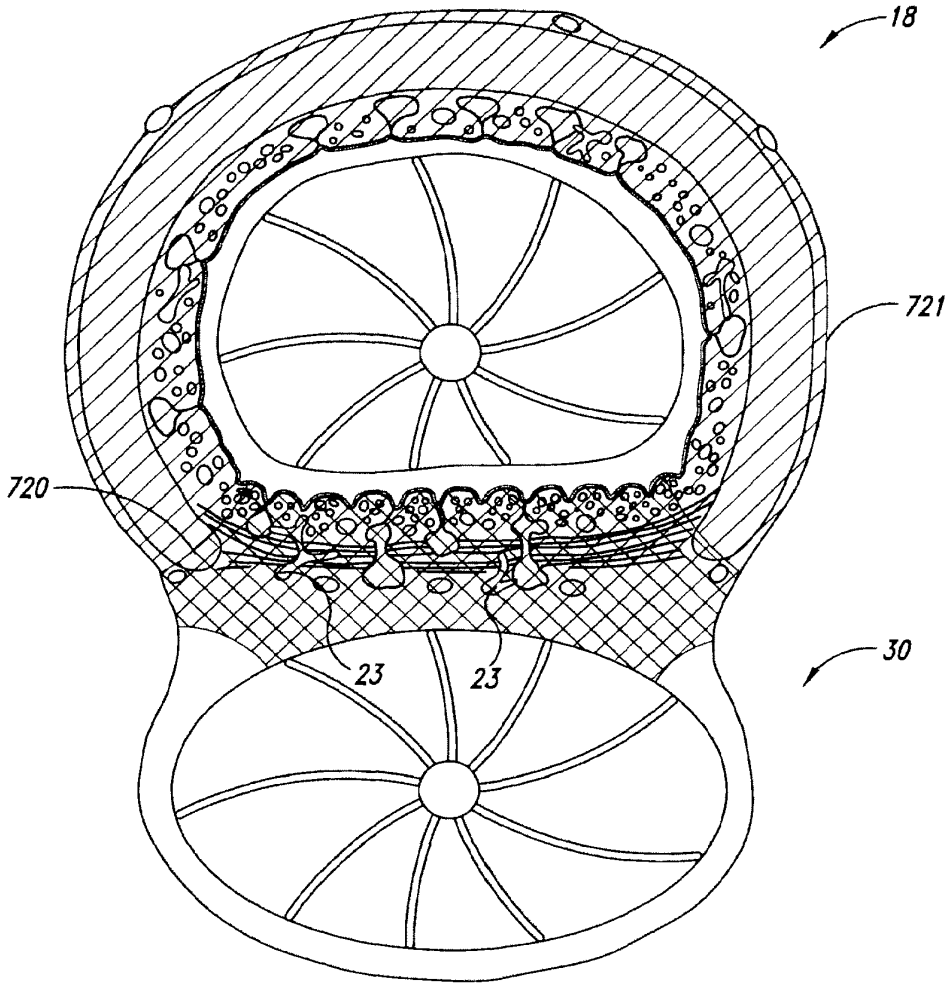


FIG. 28

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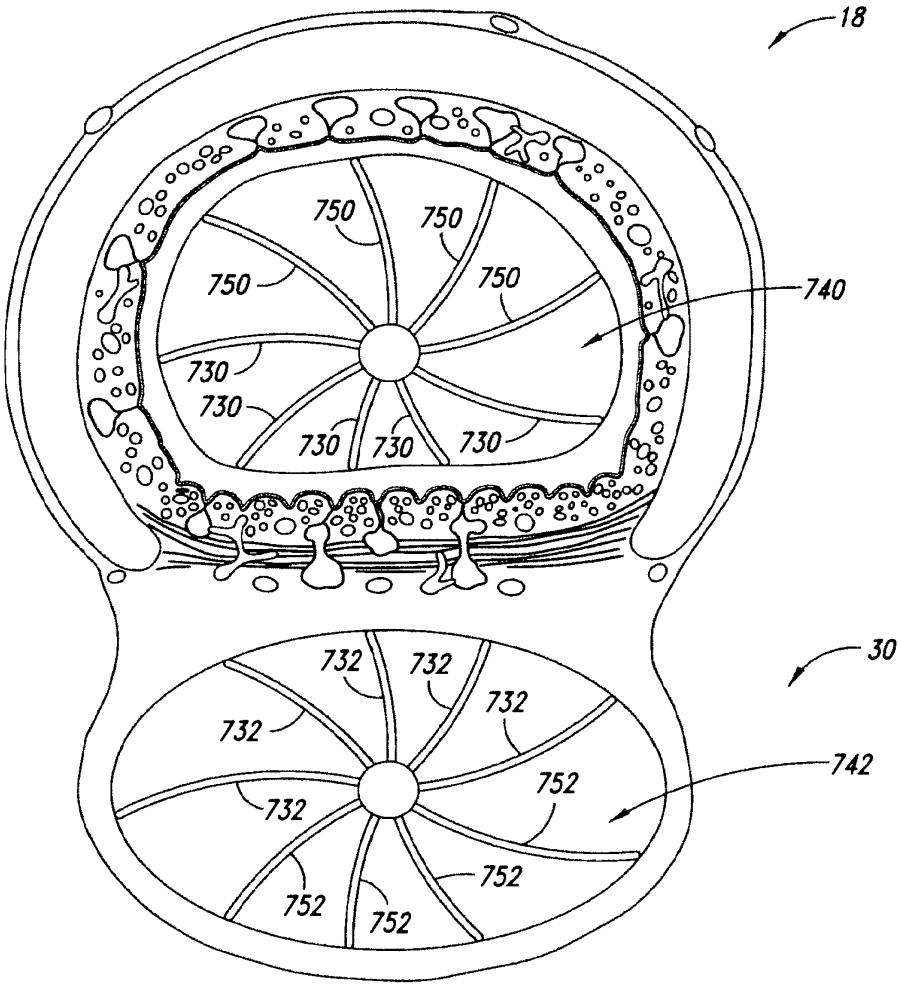


FIG. 29

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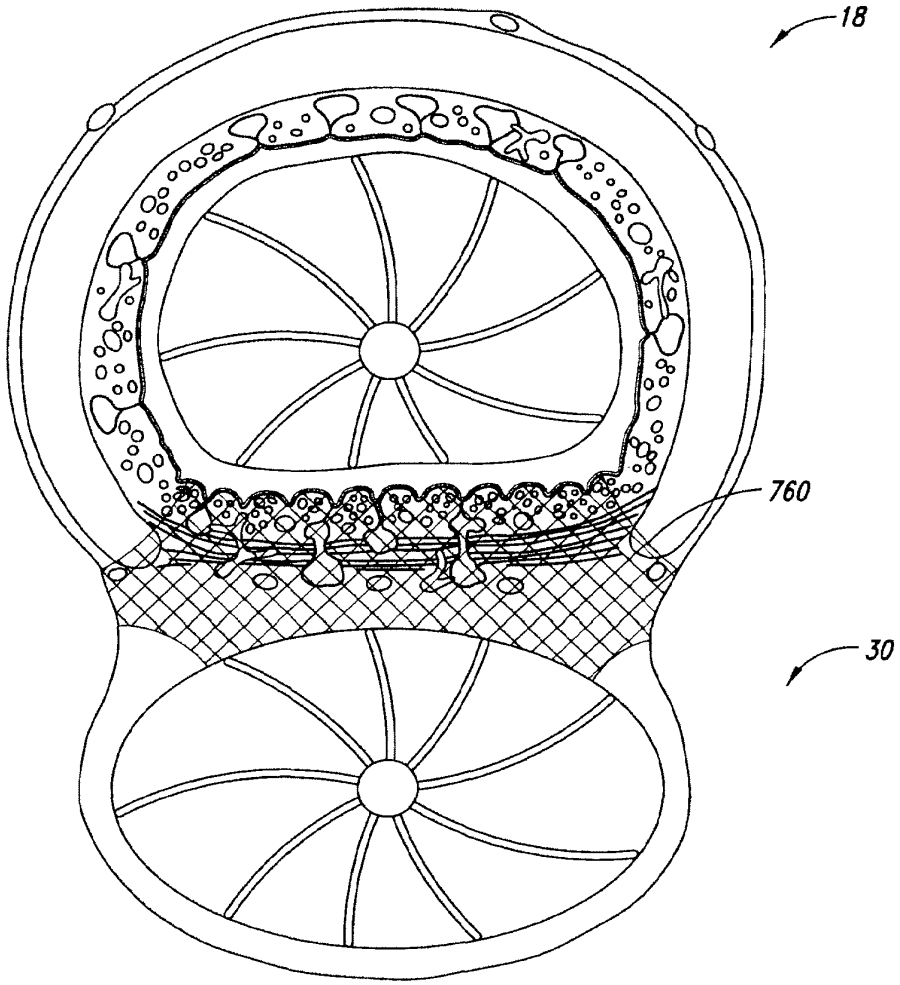


FIG. 30

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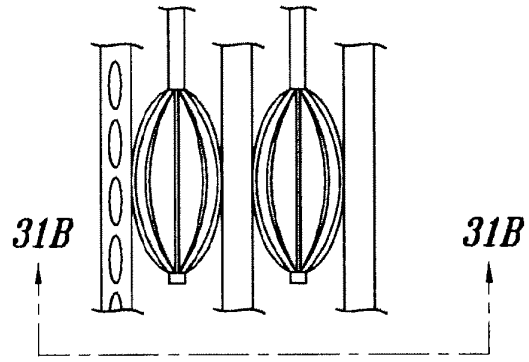


FIG. 31A

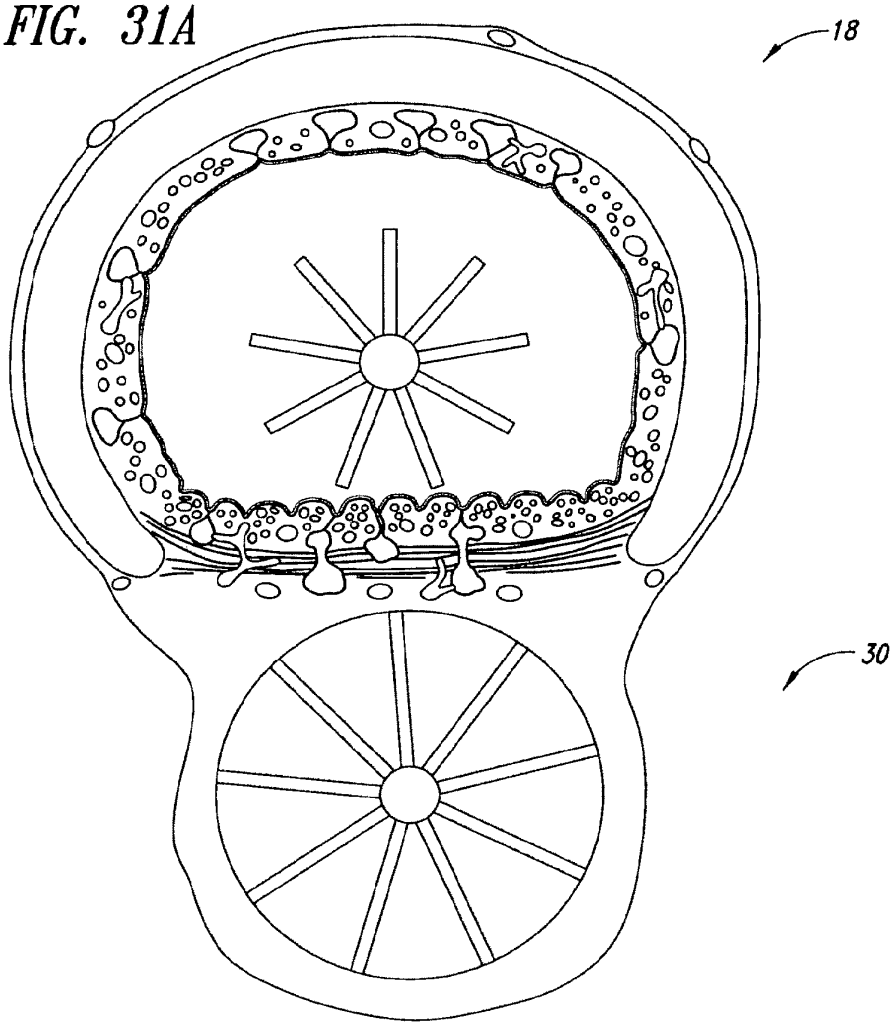


FIG. 31B

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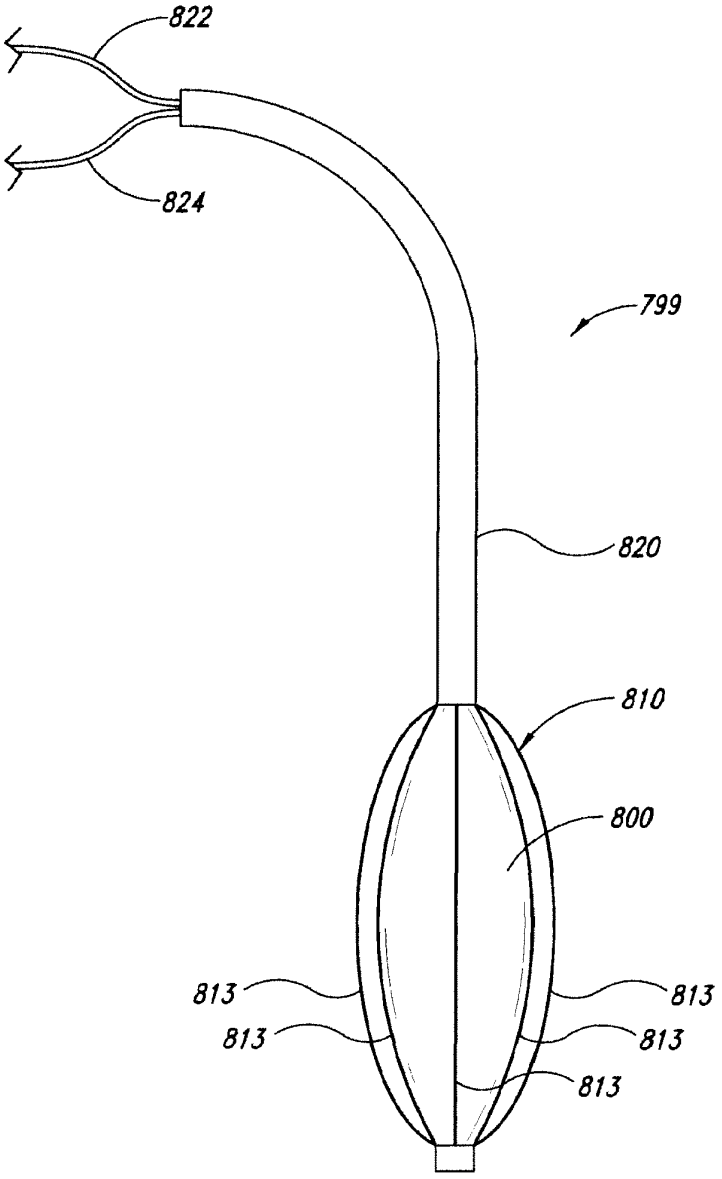


FIG. 32

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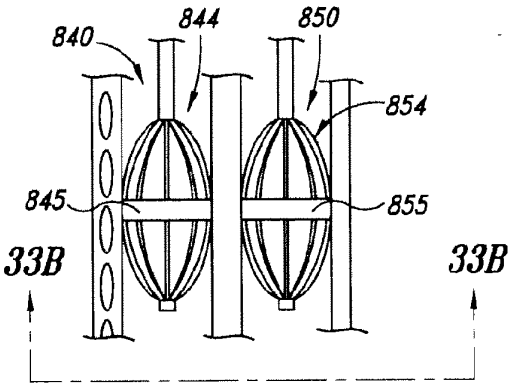


FIG. 33A

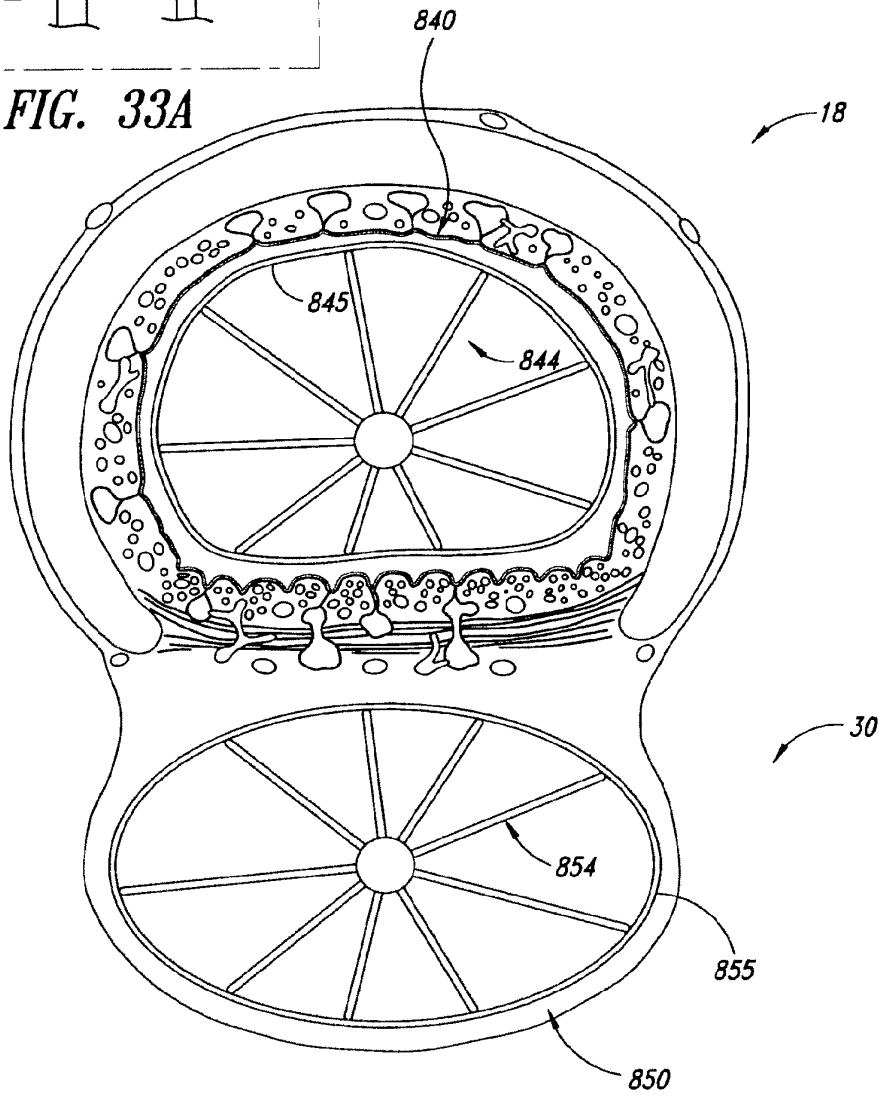


FIG. 33B

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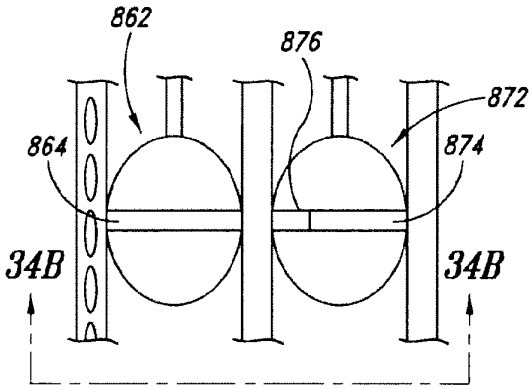


FIG. 34A

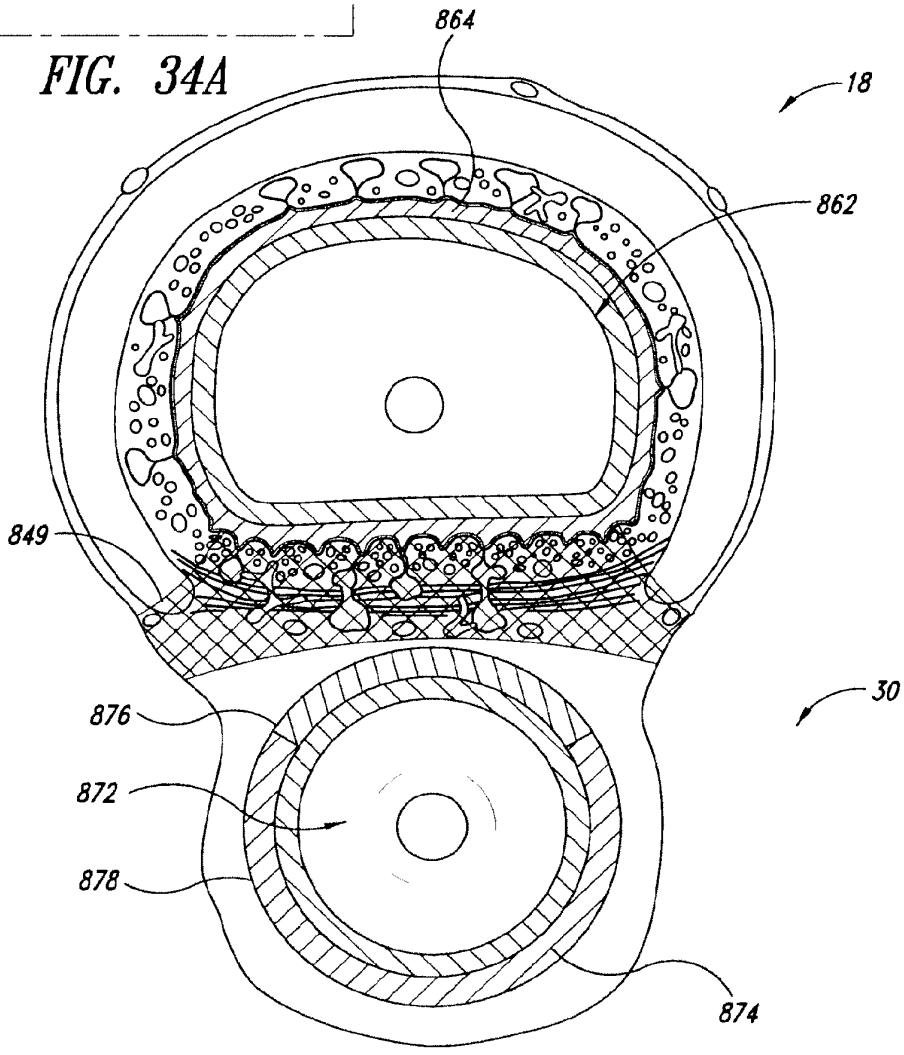


FIG. 34B

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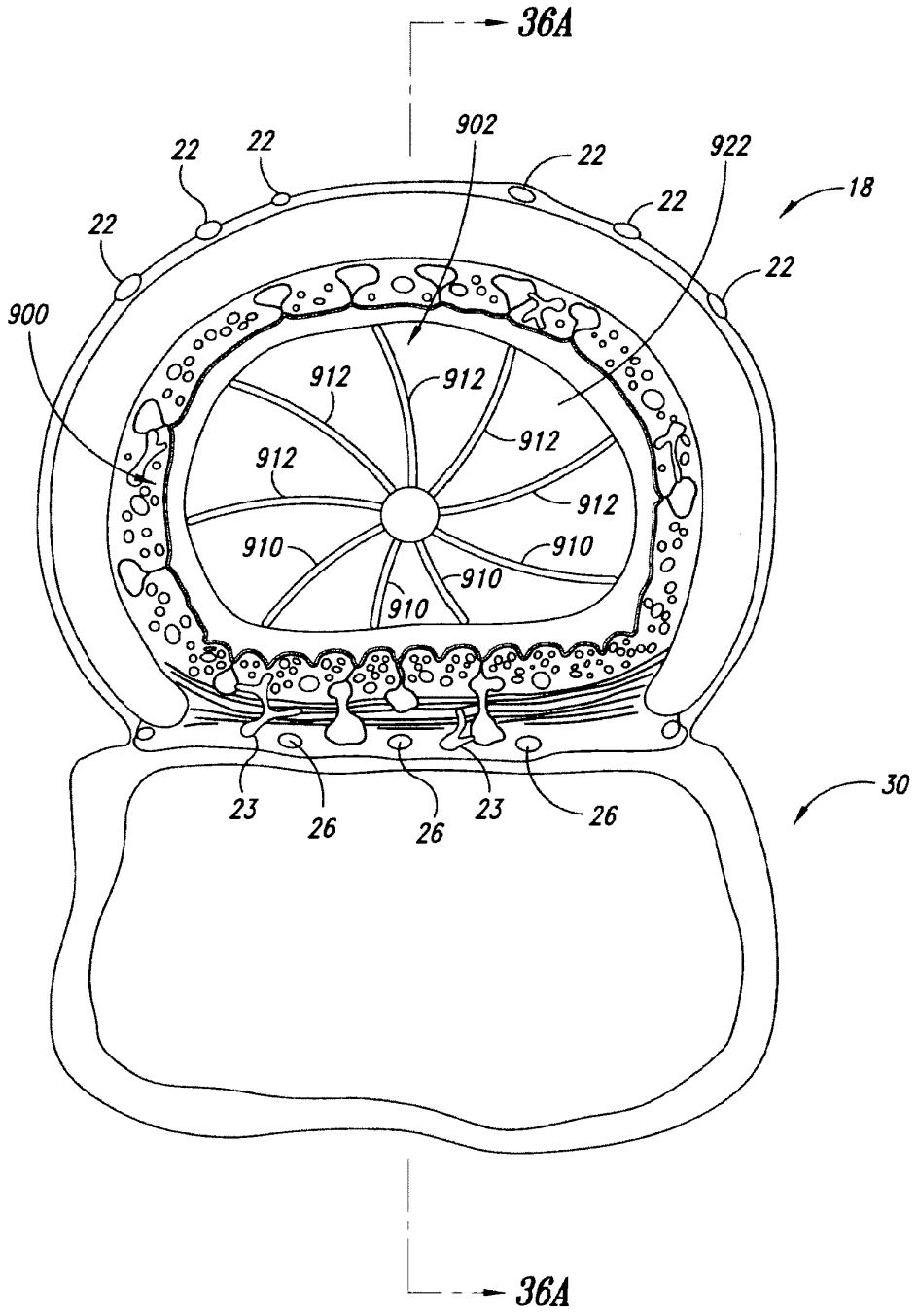


FIG. 35

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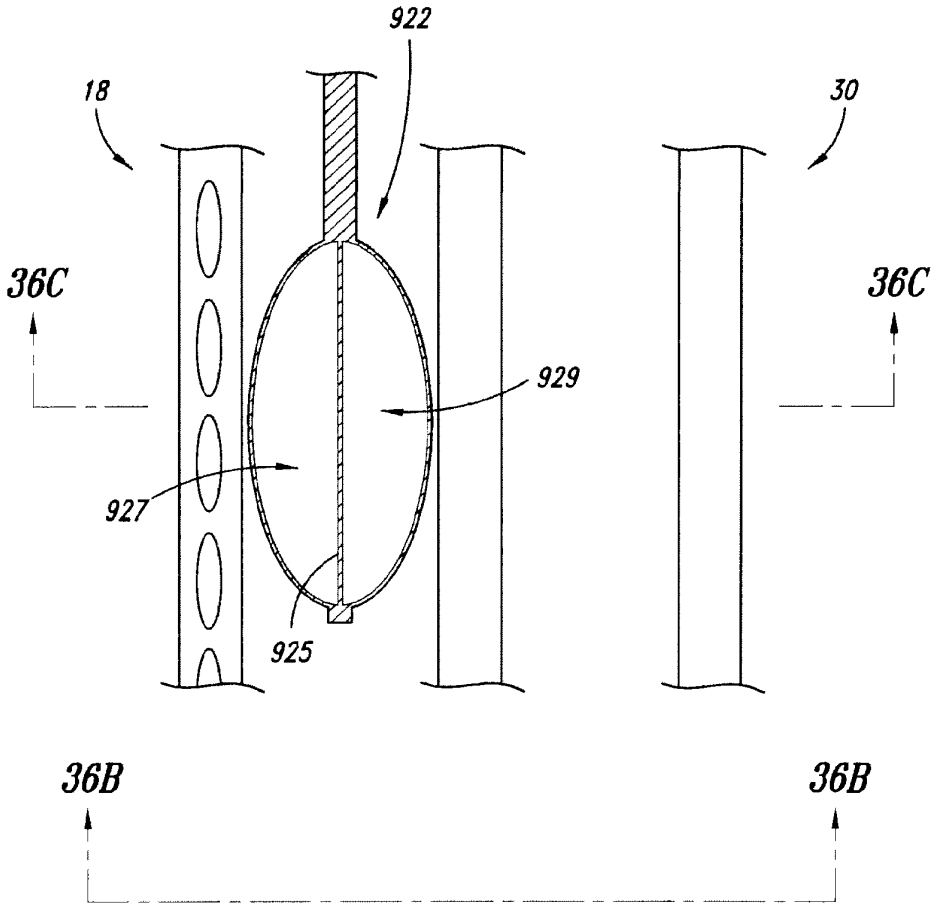


FIG. 36A

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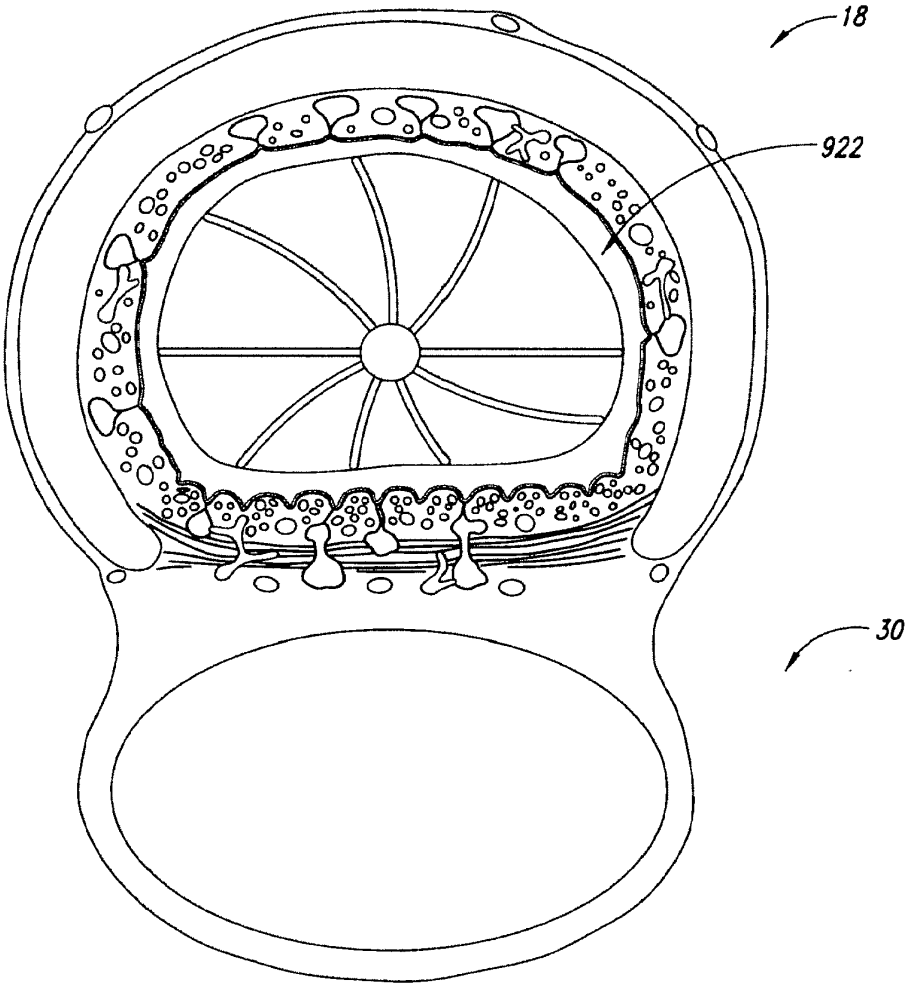


FIG. 36B

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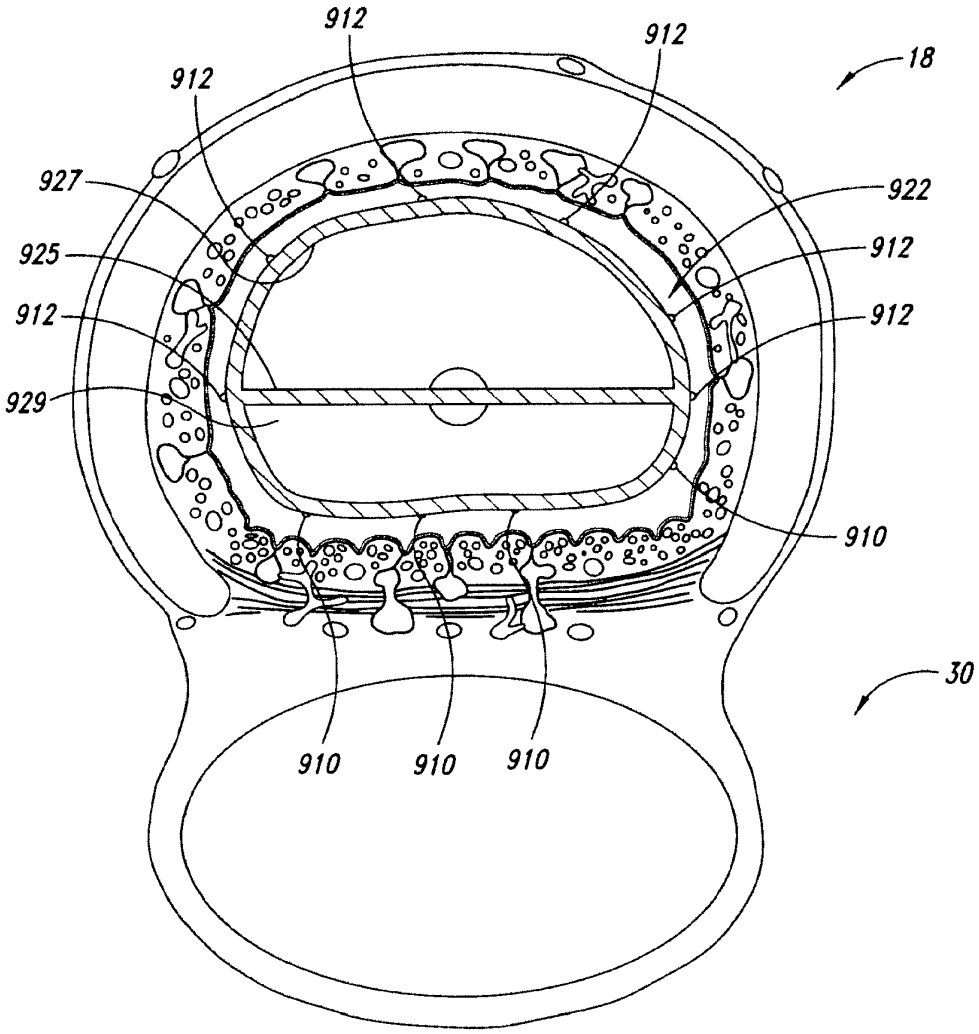


FIG. 36C

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IPR2025-01125

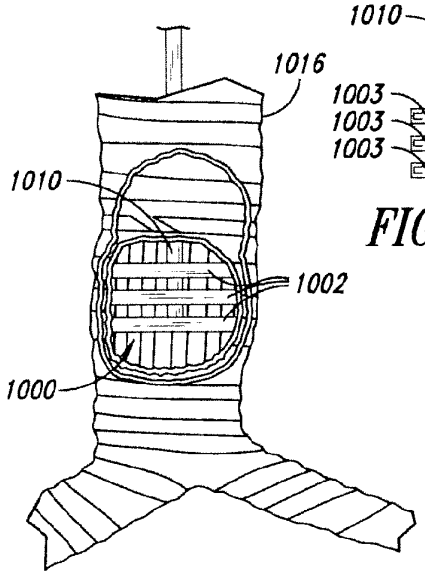


FIG. 37A

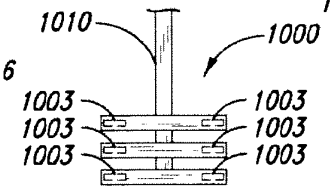


FIG. 37B

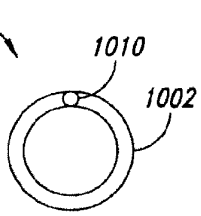


FIG. 37C

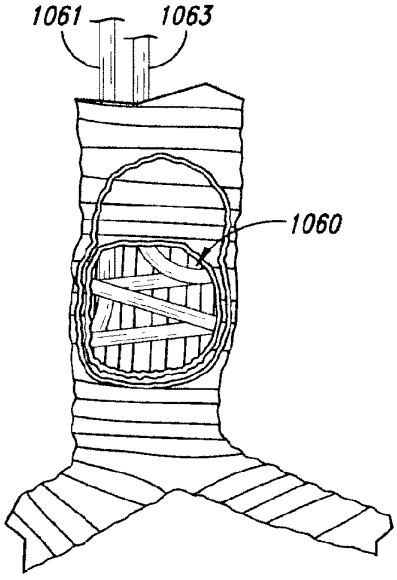


FIG. 39A

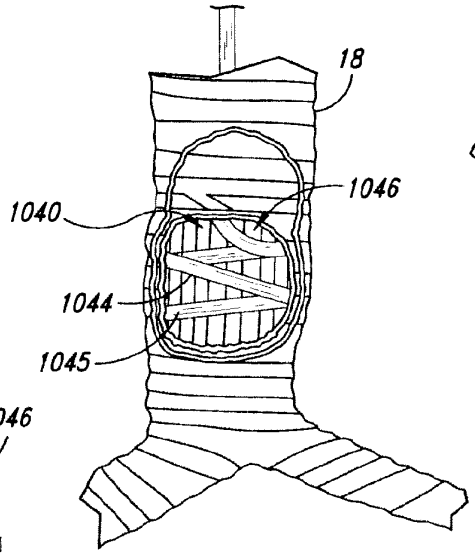


FIG. 38A

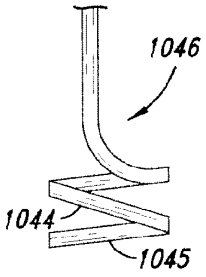


FIG. 38B

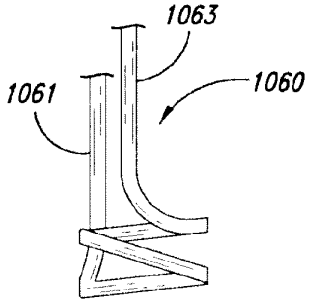


FIG. 39B

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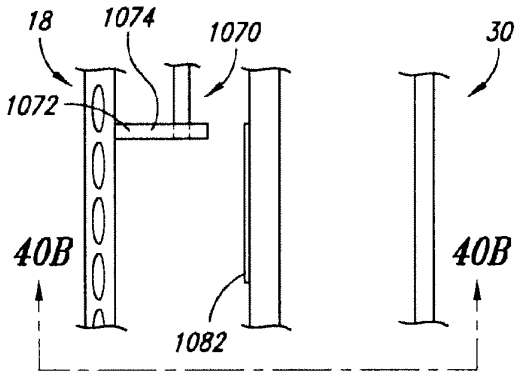


FIG. 40A

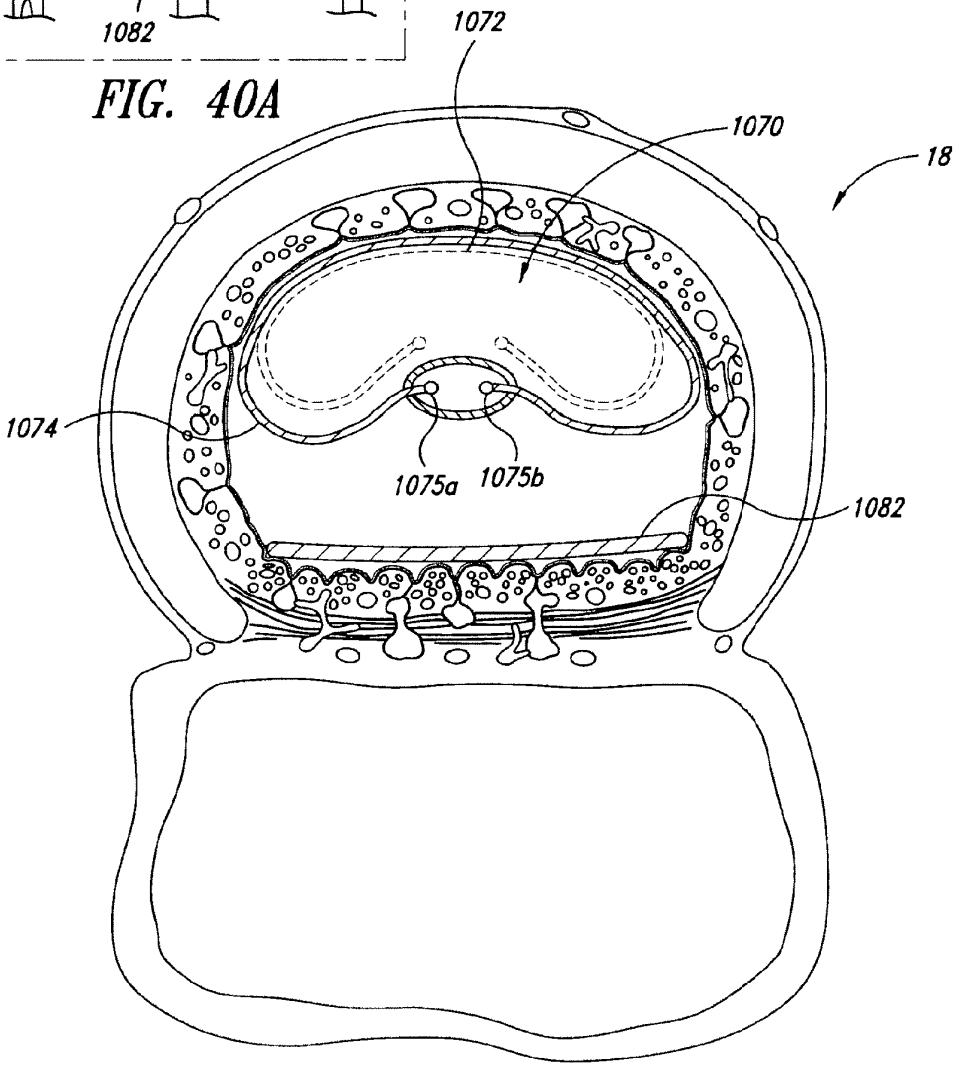


FIG. 40B

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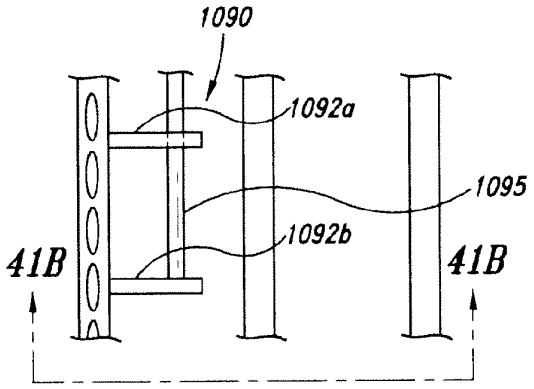


FIG. 41A

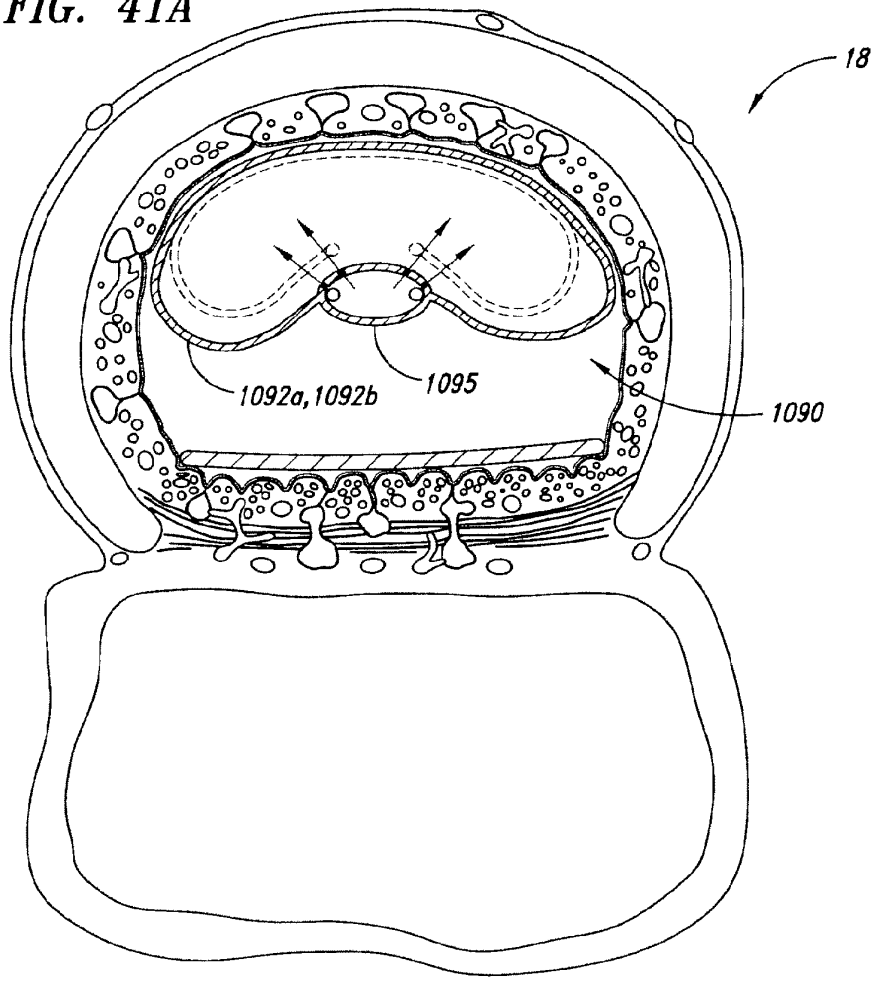


FIG. 41B

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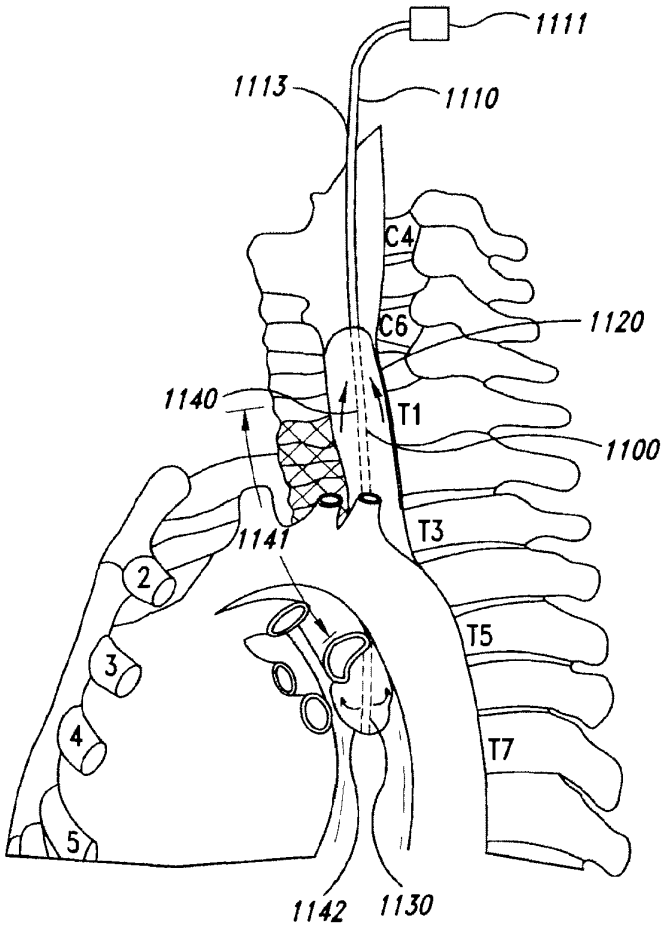


FIG. 42

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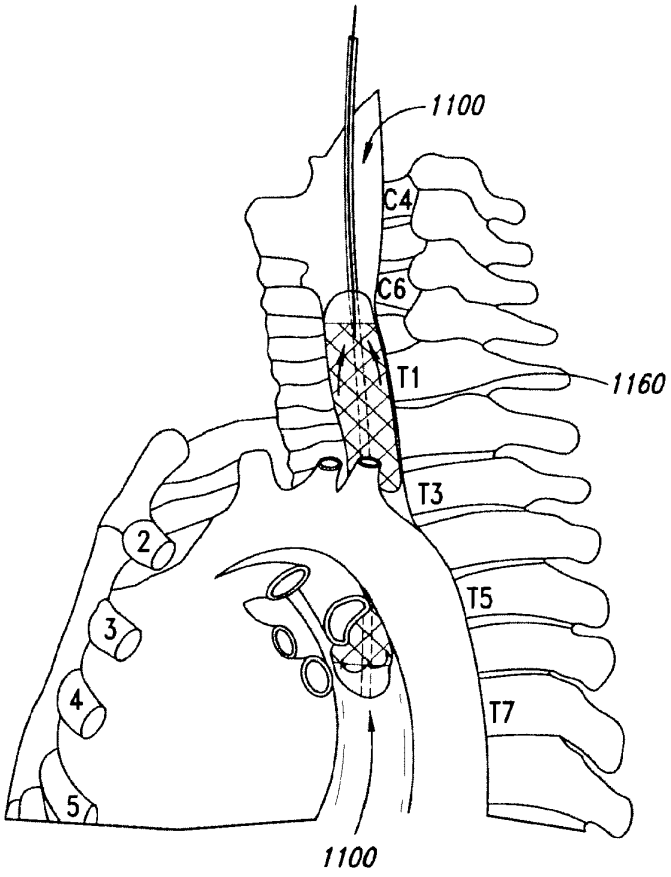


FIG. 43

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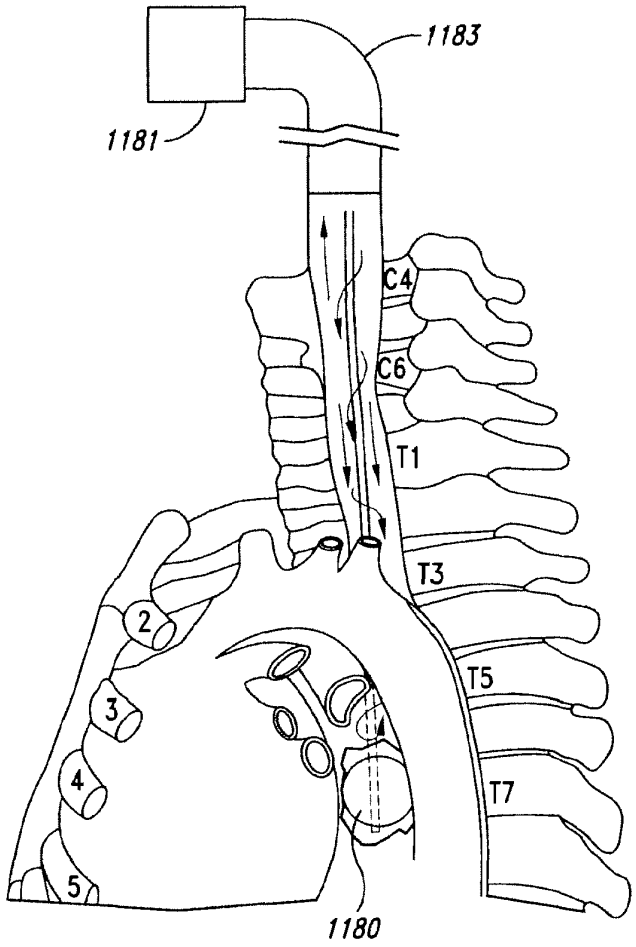


FIG. 44

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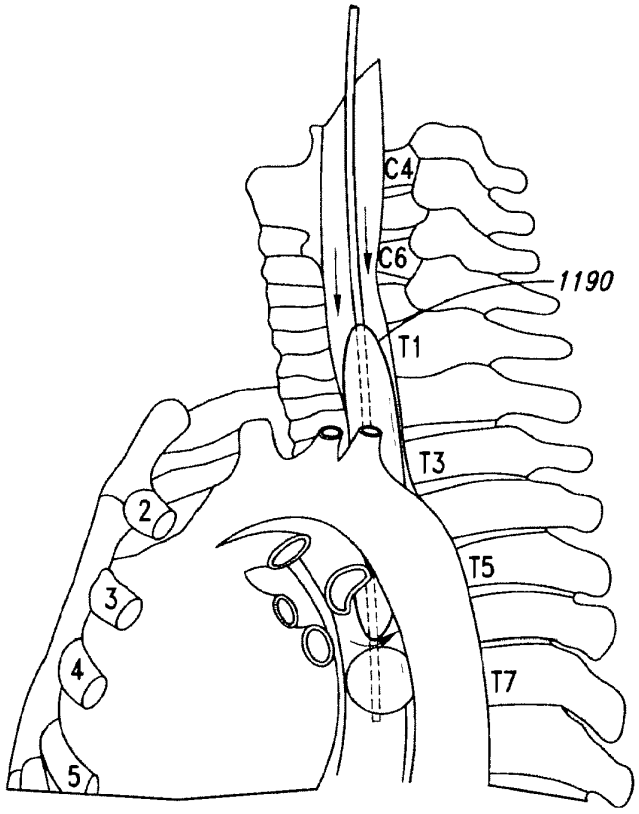


FIG. 45

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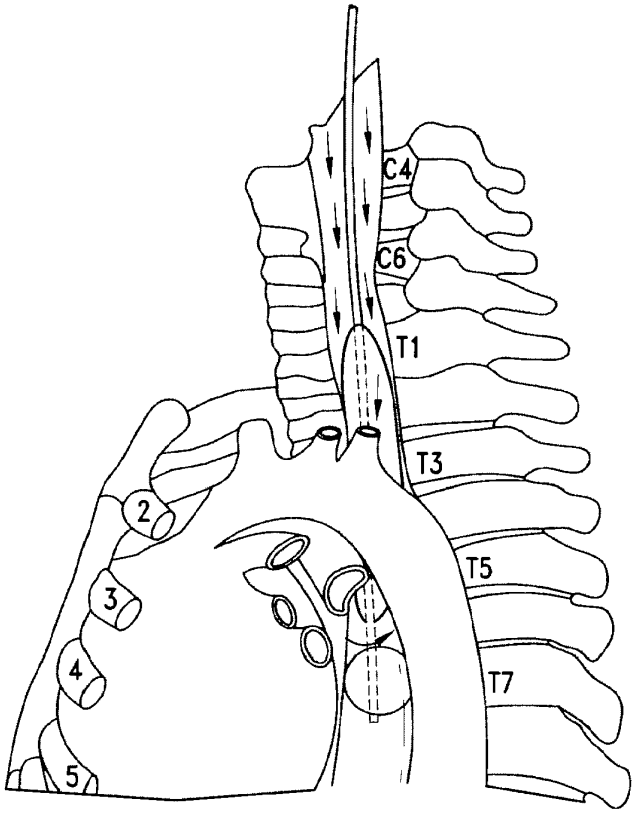


FIG. 46

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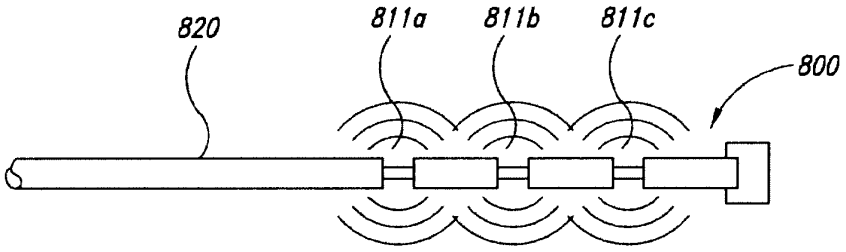


FIG. 47

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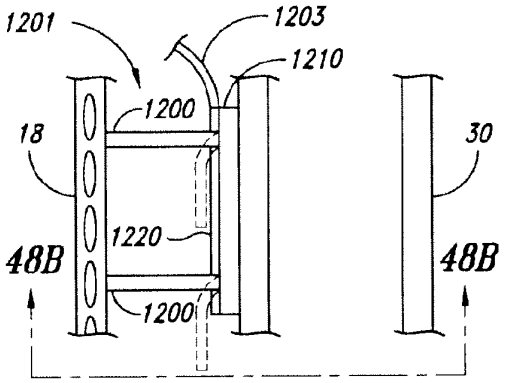


FIG. 48A

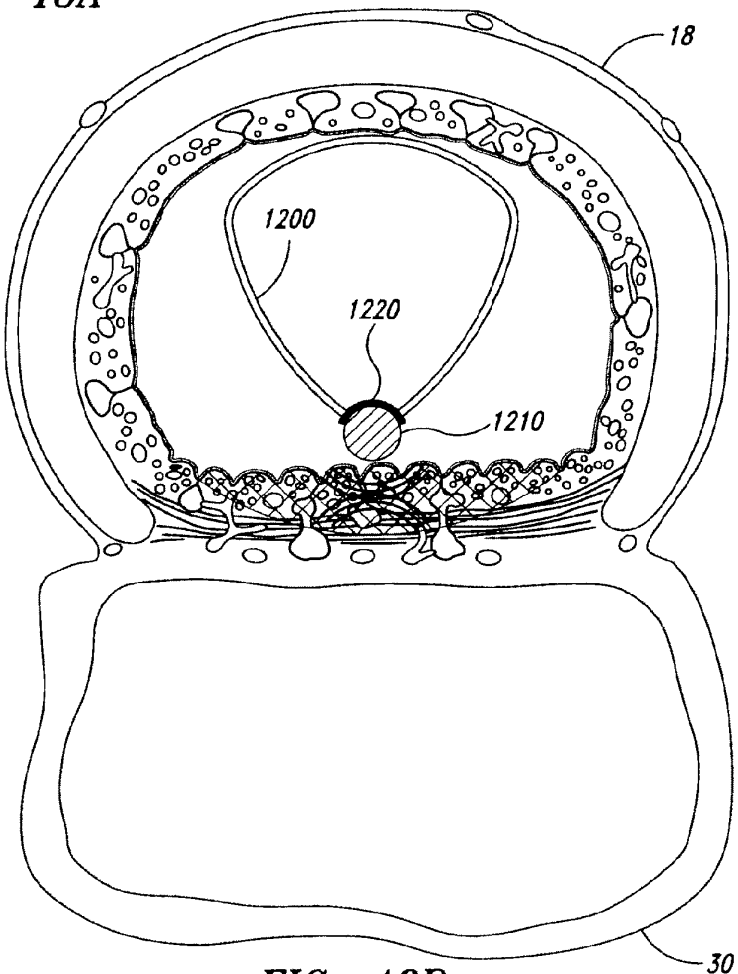


FIG. 48B

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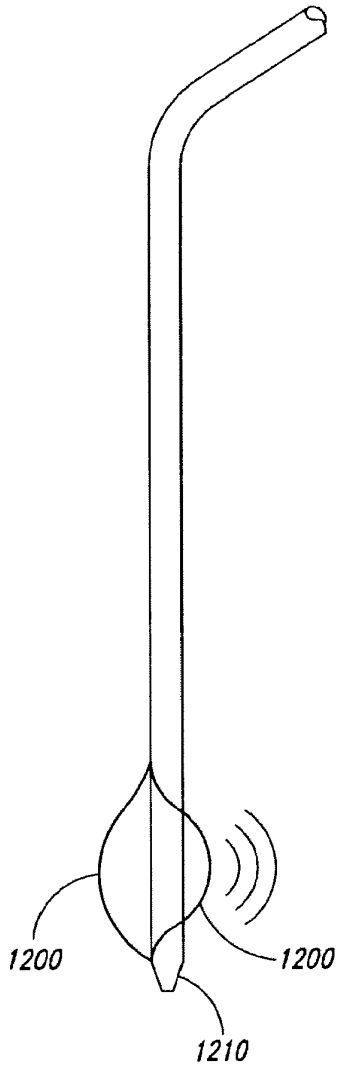


FIG. 49

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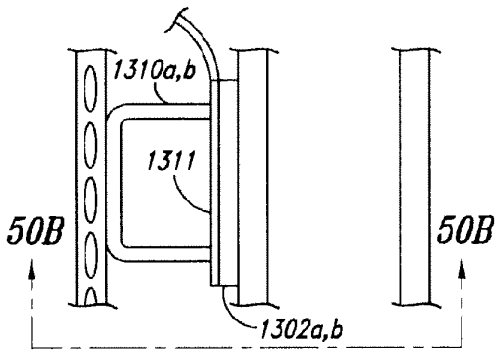


FIG. 50A

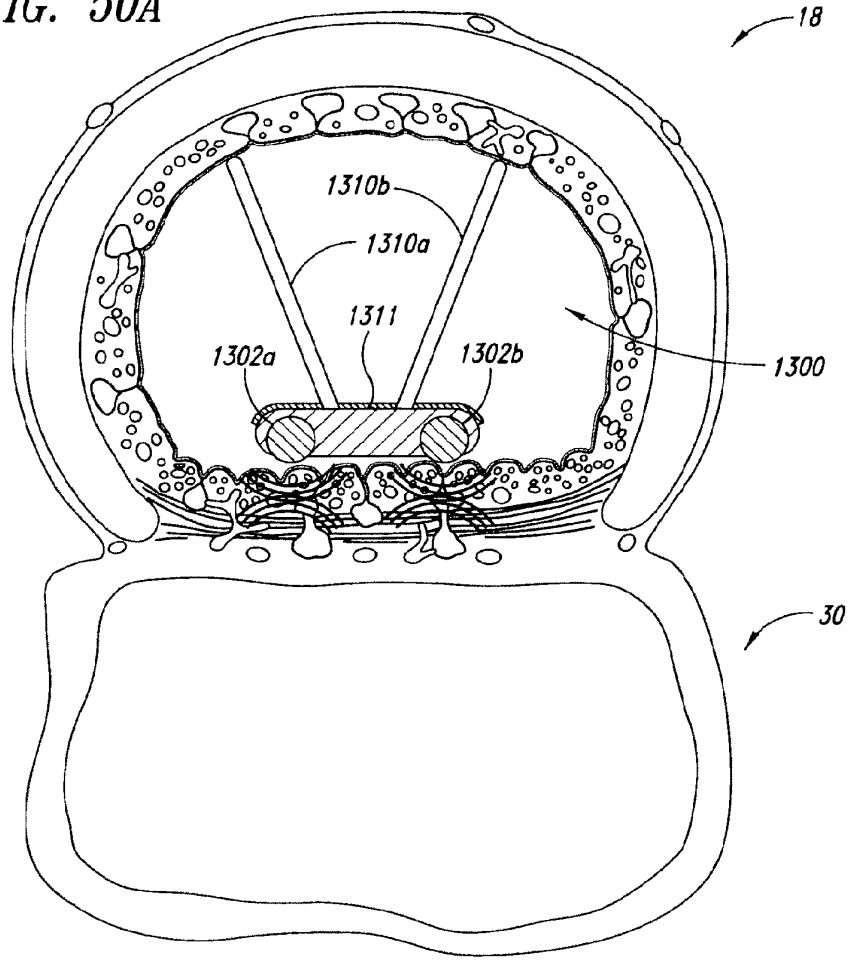


FIG. 50B

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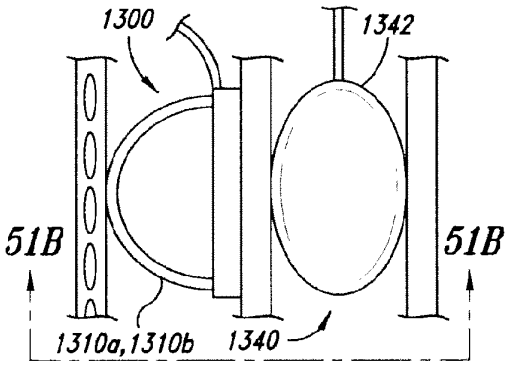


FIG. 51A

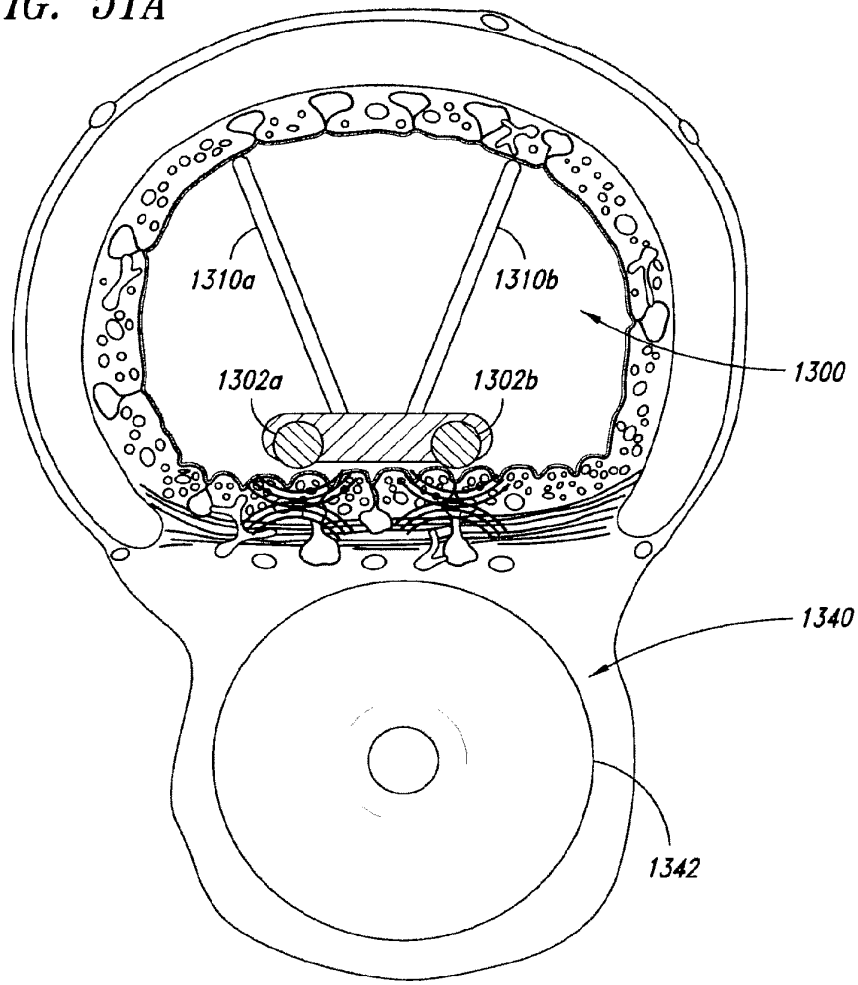


FIG. 51B

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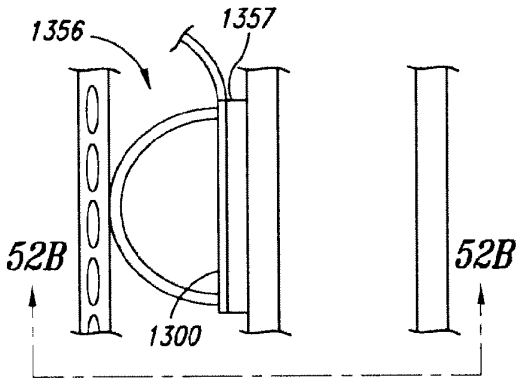


FIG. 52A

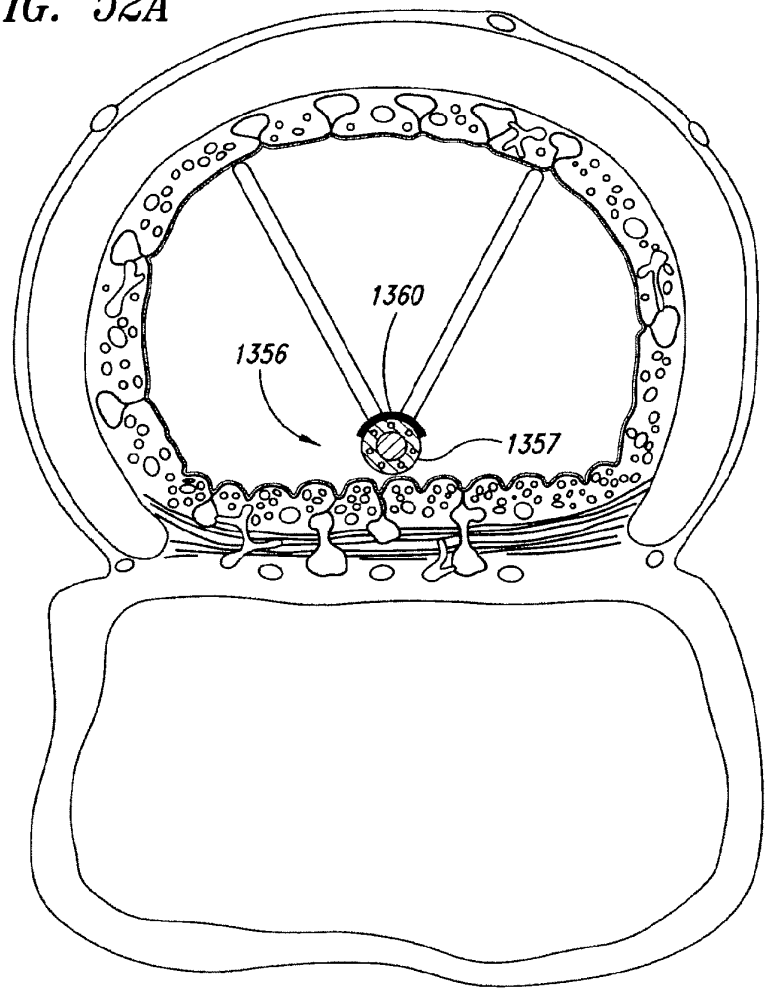


FIG. 52B

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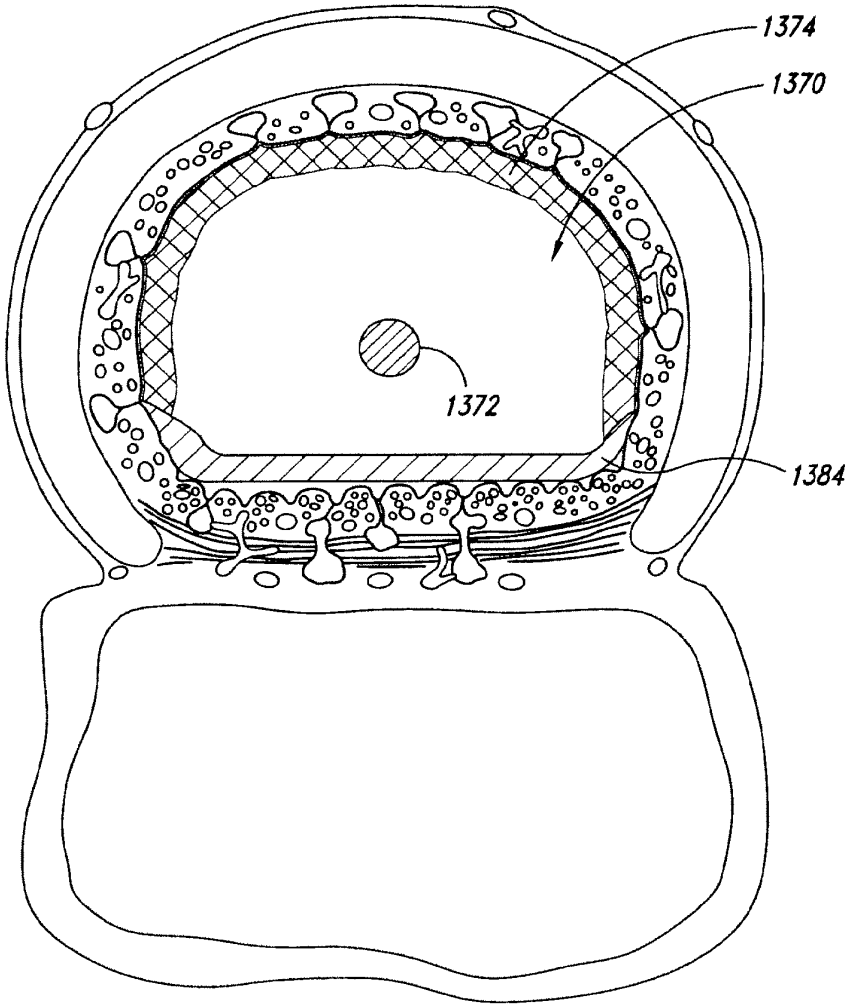


FIG. 53

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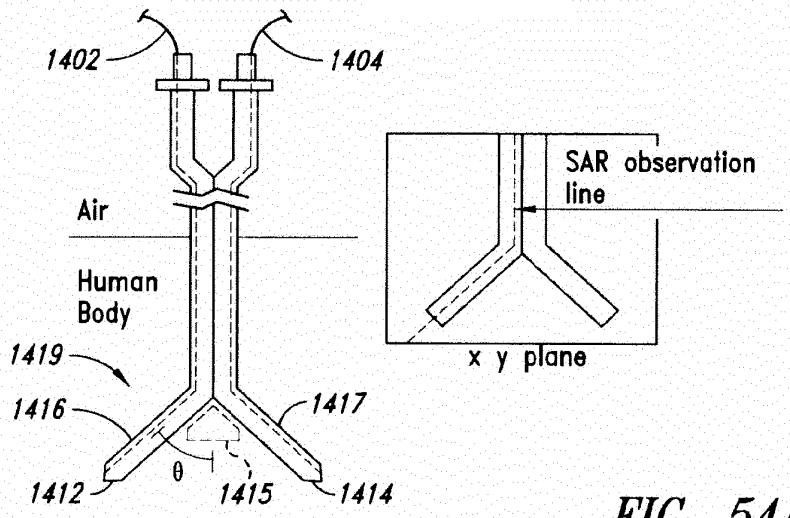


FIG. 54A

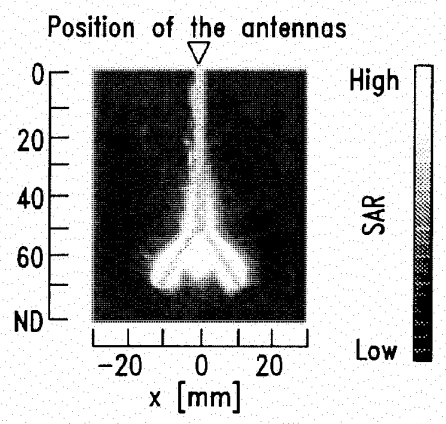


FIG. 54B

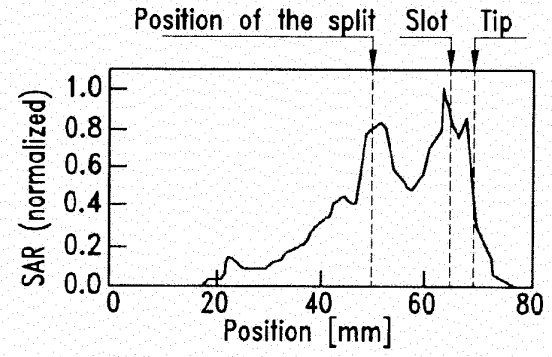


FIG. 54C

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IPR2025-01125

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EUROPEAN SEARCH REPORT

Application Number
EP 15 16 4212

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X Y	US 2009/043301 A1 (JARRARD JERRY [US] ET AL) 12 February 2009 (2009-02-12) * paragraph [0023] * * paragraph [0024] * * paragraph [0002] * * paragraph [0027] * * paragraph [0035] * * paragraph [0036] * * paragraph [0037] * * paragraph [0038] * * paragraph [0046]; claims 22,29; figure 4A *	1-11,14 12-14	INV. A61B18/18 A61B18/12 ADD. A61B18/00 A61B19/00
Y	US 2009/306644 A1 (MAYSE MARTIN L [US] ET AL) 10 December 2009 (2009-12-10) * paragraph [0025] * * paragraph [0026] * * paragraph [0027] * * paragraph [0031] * * paragraph [0143] * * paragraph [0144] * * paragraph [0100] * * paragraph [0134] * * paragraph [0135] * * paragraph [0136] * * paragraph [0159] * * paragraph [0160] *	1-15	TECHNICAL FIELDS SEARCHED (IPC) A61B
Y	US 2007/100390 A1 (DANAEK CHRISTOPHER J [US] ET AL) 3 May 2007 (2007-05-03) * figure 11 * * paragraph [0119] * * paragraph [0145] * * paragraph [0176] *	1-15	

-/--

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	20 July 2015	Rodríguez Cosío, J

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EUROPEAN SEARCH REPORT

Application Number
EP 15 16 4212

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
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Y	US 2008/243112 A1 (DE NEVE WERNER FRANCOIS [BE]) 2 October 2008 (2008-10-02) * paragraph [0011] * * paragraph [0035] * * paragraph [0052] * * paragraph [0072] * * paragraph [0073] * * paragraph [0089] * -----	12-14	TECHNICAL FIELDS SEARCHED (IPC)
Y	US 2008/161890 A1 (LAFONTAINE DANIEL M [US]) 3 July 2008 (2008-07-03) * figures 1-2 * * paragraph [0034] * * paragraph [0040] * * paragraph [0043] * -----	12-14	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	20 July 2015	Rodríguez Cosío, J

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IPR2025-01125

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 15 16 4212

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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20-07-2015

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REFERENCES CITED IN THE DESCRIPTION

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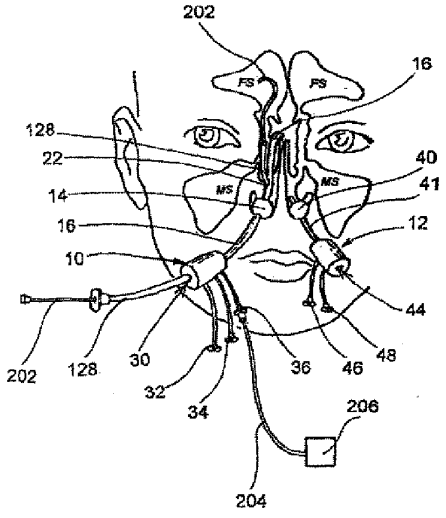
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(54)【発明の名称】副鼻腔炎および耳、鼻、および／または、喉の各種疾病を診断および治療する装置、システム、および、その方法

(57)【要約】
【課題】副鼻腔炎、鼻介骨肥大、腫瘍、感染症、難聴、アレルギー症、顔面骨折、および、それ以外の耳、鼻、喉の障害を診断および／または治療するにあたり、観血を最小限に抑えた取り組みを採用する。
【解決手段】多くの場合、剛性シャフトを設けた器具を使用するのとは対照的に、可撓性のカテーテルを使用する。画像化調査、粘液流調査、空気流／気体流調査、解剖学的寸法調査、内視鏡調査、および、透視調査を実施するのに、多様な診断装置と診断装置が使用される。接近閉塞装置を使って、前後いずれかの鼻腔／鼻咽頭に流体封鎖シールを確立し、作業装置を容易に挿入することができるようにする。作業装置の具体例としては、例えば、視認用機器、ガイドワイヤ、カテーテル、組織切除装置または組織改造装置、電気外科手術装置、エネルギー発射装置、診断薬または治療薬を注入する装置、ステントのような装置を移植する装置、物質溶離装置、物質搬送移植片などが挙げられる。
【選択図】図８Ｃ



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【特許請求の範囲】
【請求項1】
副鼻腔炎または鼻、副鼻腔、もしくは、それ以外の耳、鼻、喉などの解剖学的構造に影響を及ぼす別な疾病を診断および／または治療する方法であって、該方法は、
（Ａ）鼻中隔の少なくとも一方側の鼻孔または鼻腔にポート装置を設置する工程であって、ポート装置が装置挿入ポートおよび弁を有しており、弁は、装置挿入ポートを通して作業装置を挿入することができるようにすると同時に、その間、少なくとも作業装置が装置挿入ポートに挿入されている際には、ポートから外に血液またはそれ以外の流体が逆流するのを阻止するように作動する工程と、
（Ｂ）ポート装置を通して鼻、鼻咽頭、または、副鼻腔の内部の位置に少なくとも１個の作業装置を進入させる工程と、
（Ｃ）作業装置を使って、診断処置または治療処置を実施する工程とを含んでいる、診断および／または治療方法。
【請求項2】
前記作業装置を使って、１群の処置から選択された１処置を実施し、該１群の処置は、
ｉ）画像化物質または追跡標識物質を搬送する処置と、
ii）治療有効量の治療物質を搬送する処置と、
iii）ステント、組織改造装置、物質搬送移植片、それ以外の治療装置などを移植する処置と、
iv）組織を切除し、融除し、嵩減らしし、焼灼し、加熱し、レーザー処理し、拡張し、または、それ以外の修正を施す処置と、
ｖ）細胞または組織を移植または埋設する処置と、
vi）骨折を整復し、整骨し、ネジ留めし、粘着剤を塗布し、固定し、減圧し、または、それ以外の方法で治療する処置と、
vii）遺伝子または遺伝子治療試料を搬送する処置と、
viii）副鼻腔内または鼻の内側のどこか他の部位内の硬骨組織または軟骨組織を切除し、融除し、嵩減らしし、焼灼し、加熱し、レーザー処理し、中に截骨部を設け、または、それ以外の方法で修復する処置と、
ix）副鼻腔の洞口または副鼻腔の１個以上の洞からの排液に影響を及ぼす解剖学的構造の形状、寸法、または、輪郭を改修または変更する処置と、
ｘ）副鼻腔または鼻の内部のどこか他の部位から膿または異所迷入物質を除去する処置と、
xi）副鼻腔の内部の内層を成している細胞を掻き落し、または、それ以外の方法で除去する処置と、
xii）腫瘍の全部または一部を除去する処置と、
xiii）ポリープを除去する処置と、
xiv）ヒスタミン、アレルゲン、または、それ以外の、副鼻腔の内部の組織によって粘膜の分泌の原因となる物質を搬送して、副鼻腔からの排液を査定できるようにする処置からなる、請求項１に記載の方法。
【請求項3】
前記工程（Ａ）で設置されるポート装置は、閉塞部材および作業装置挿入ポートを有している前鼻閉塞接近装置を備えている、請求項１に記載の方法。
【請求項4】
前記工程（Ａ）は前鼻閉塞接近装置を配備して、閉塞部材が鼻中隔の一方側の鼻孔または鼻孔を閉鎖する工程を更に含んでおり、また、前記工程（Ｂ）は作業装置挿入開口を通して前記作業装置を挿入して、鼻、鼻咽頭、副鼻腔などの内部の位置に作業装置を進入させる工程とを含んでいる、請求項３に記載の方法。
【請求項5】
第１の前鼻閉塞部接近装置が鼻中隔の一方側に設置され、第１の前鼻閉塞接近装置が鼻

中隔の他方側に設置される、請求項４に記載の方法。
【請求項6】
鼻中隔の後ろの声門の上の位置で後鼻孔、鼻咽頭、または、咽頭を閉塞するような形状の後閉塞部材を設ける工程と、
鼻中隔の後ろの声門の上の位置で後鼻孔、鼻咽頭、または、咽頭を閉塞するように後閉塞装置を設置することにより、前記方法を実施している間、患者の食道または気管に流体が排出されるのを阻止する工程とを含んでいる、請求項１に記載の方法。
【請求項7】
前閉塞部材、作業装置挿入ポート、および、後閉塞部材を有している前後鼻閉塞接近装置を設ける工程と、
前閉塞部材が鼻中隔の一方側の鼻孔または鼻腔を閉鎖し、かつ、後閉塞部材が鼻中隔の後ろの声門より上の位置で後鼻孔、鼻咽頭、または、咽頭を閉鎖するように前後鼻閉塞接近装置を配備する工程とを含んでおり、
前記工程（Ｂ）は、
作業装置挿入開口を通して前記作業装置を挿入して、鼻、鼻咽頭、中耳、副鼻腔などの内部の位置に作業装置を進入させる工程を含んでいる、請求項１に記載の方法。
【請求項8】
前鼻閉塞装置を設ける工程と、
鼻中隔の残りの側の残りの鼻孔または鼻腔を閉塞するように前鼻閉塞装置を設置する工程とを更に含んでいる、請求項７に記載の方法。
【請求項9】
閉塞部材および作業装置挿入ポートを有している前鼻閉塞接近装置を設ける工程と、
閉塞部材が鼻中隔の残りの側の残りの鼻孔または鼻腔を閉鎖するように前鼻閉塞接近装置を設置する工程とを更に含んでいる、請求項７に記載の方法。
【請求項10】
前記前鼻閉塞接近装置上に設けられた前記作業装置挿入ポートを通して前記作業装置を挿入して、鼻、鼻咽頭、副鼻腔などの内部の位置まで作業装置を進入させる工程を更に含んでいる、請求項９に記載の方法。
【請求項11】
前記前後閉塞接近装置は、ｉ）前端、後端、および、少なくとも１本の管腔が設けられた管と、ii）管材上の第１位置の前閉塞部材と、iii）管材上の第２位置の後閉塞部材であって、第２位置が第１位置より後ろにある後閉塞部材と、iv）前閉塞部材の前に設置された作業装置挿入開口と、ｖ）前閉塞部材と後閉塞部材の間に配置されており、かつ、前閉塞部材が鼻中隔の一方側の鼻孔または鼻腔を閉鎖するように、また、後閉塞部材が鼻中隔の後ろの声門の上の位置で鼻咽頭を閉塞するように前後鼻閉塞接近装置を位置決めする作業装置出口開口とを備えている、請求項７に記載の方法。
【請求項12】
前記工程（Ｂ）は、前記作業装置挿入開口を通して作業装置を挿入し、作業装置出口開口から外へ作業装置を前進させて、鼻、鼻咽頭、副鼻腔などの内部の位置まで前進させる工程を含んでいる、請求項１１に記載の方法。
【請求項13】
鼻、鼻咽頭、副鼻腔などからの流体を吸引する工程を更に含んでいる、請求項１に記載の方法。
【請求項14】
前記前後鼻閉塞接近装置には吸引管腔と、前記前閉塞部材と前記後閉塞部材の間で前記管材に形成された吸引開口とが設けられており、前記方法は、
吸引管腔に吸引を施して、吸引開口を通してから、更に吸引管腔を通して物体を吸引するようにした工程を更に含んでいる、請求項１１に記載の方法。
【請求項15】
前記工程（Ｂ）は、

ガイドカテーテルを挿入し、その後で、
ガイドカテーテルを通してまた別な作業装置を挿入する工程を含んでいる、請求項１に記載の方法。
【請求項16】
前記工程（Ｂ）は、前記ポート装置を通して管材を前進させて副鼻腔の内部の位置まで進入させる工程を含んでおり、
前記工程（Ｃ）は、管材を通して副鼻腔に流動可能な造影剤を搬入し、その後で、流入可能な造影剤を画像化して、流動可能な造影剤が副鼻腔から排出される態様を査定する工程を含んでいる、請求項１に記載の方法。
【請求項17】
前記流動可能な造影剤は粘性が粘液のものと同じぐらいである、請求項１６に記載の方法。
【請求項18】
前記画像化は、移動可能な画像化装置を使って実行され、画像化装置は異なる位置まで移動させられ、患者の解剖学的構造に対して異なる視点まで移動させられる、請求項１６に記載の方法。
【請求項19】
前記工程（Ｂ）は、鼻または副鼻腔に視認用機器を挿入する工程を含んでおり、工程（Ｃ）は、視認用機器を使って、鼻および／または副鼻腔の内部の構造体を視認する工程を含んでいる、請求項１に記載の方法。
【請求項20】
前記視認用機器を使って、また別な作業装置の設置を支援し、容易にし、または、検証する、請求項１９に記載の方法。
【請求項21】
前記視認用機器を使って、ガイドカテーテルの設置を支援し、容易にし、または、検証し、ガイドカテーテルが設置されてしまってから、ガイドカテーテルを通して別な作業装置を前進させる、請求項１９に記載の方法。
【請求項22】
前記工程（Ｃ）はステントを移植する工程を含んでいる、請求項１に記載の方法。
【請求項23】
前記ステントは副鼻腔の小口の内側に少なくとも一部が位置決めされる、請求項２２に記載の方法。
【請求項24】
前記ステントとしては物質溶離ステントがある、請求項２２に記載の方法。
【請求項25】
前記物質溶離ステントは治療有効量の少なくとも１種類の、次のグループから選択された物質を溶離し、該グループは、

抗生物質、
抗菌剤、
アンチパラサイト剤、
抗真菌剤、
ステロイド、
血管収縮神経剤、
ロイコトリエン阻害剤、
免疫グロブリンＥ（IgE）阻害剤、
抗炎症剤、
肥満細胞安定化薬、
抗ヒスタミン薬、
免疫変調剤、
化学治療薬、

抗腫瘍薬、
ムコ多糖類加水分解薬、
粘液の粘性を薄め、または、それ以外の多様で変化させる薬剤、
柔組織および／または硬骨および／または軟骨の改造を促進する物質
から構成されている、請求項２４に記載の方法。

【請求項26】
前記工程（Ｃ）は、柔組織、硬骨、軟骨などの寸法、形状、輪郭、位置などを変える装置を移植する工程を含んでいる、請求項１に記載の方法。

【請求項27】
前記装置は、移植後は、１回以上調節することができ、前記方法は、移植後は装置を少なくとも１回は調節する工程を更に含んでいる、請求項２６に記載の方法。

【請求項28】
前記工程（Ｃ）は、副鼻腔の洞口、鼻道、鼻または鼻咽頭の内部の上記以外の通路を拡大または修正する工程を含んでいる、請求項１に記載の方法。

【請求項29】
前記工程（Ｃ）は、鼻、鼻咽頭、副鼻腔などの内部の位置に診断有効量の診断用物質または治療有効量の治療物質を導入する工程を含んでいる、請求項１に記載の方法。

【請求項30】
前記物質は物質搬送移植片に含有されており、前記工程（Ｃ）は鼻、鼻咽頭、または、副鼻腔の内部の位置に物質搬送移植片を移植する工程を含んでいる、請求項２９に記載の方法。

【請求項31】
前記工程（Ｃ）は、鼻、鼻咽頭、または、副鼻腔の内部の位置に物質を注入する工程を含んでいる、請求項２９に記載の方法。

【請求項32】
前記物質は次のグループから選択され、該グループは、
画像化造影剤、
診断用標識剤、
抗生物質、
抗菌剤、
アンチパラサイト剤、
抗真菌剤、
ステロイド、
血管収縮神経剤、
ロイコトリエン阻害剤、
免疫グロブリンＥ（IgE）阻害剤、
抗炎症剤、
肥満細胞安定化薬、
抗ヒスタミン薬、
免疫変調剤、
化学治療薬、
抗腫瘍薬、
ムコ多糖類加水分解薬、
粘液の粘性を薄め、または、それ以外の多様で変化させる薬剤、
柔組織および／または硬骨および／または軟骨の改造を促進する物質
から構成されている、請求項２９に記載の方法。

【請求項33】
副鼻腔炎または耳、鼻、喉などの疾病を診断および／または治療する用途の前後鼻閉塞接近装置であって、該装置は、
前端、後端、および、少なくとも１本の管腔が設けられた管と、

管材上の第１位置の前閉塞部材と、
管材上の第２位置の後閉塞部材であって、第２位置が第１位置より後ろにある後閉塞部材と、
前閉塞部材の前に設置された作業装置挿入開口と、
前閉塞部材と後閉塞部材の間に配置されている作業装置出口開口と、
次のグループから選択される少なくとも１個のまた別な構成要素とを備えており、該グループは、ａ）装置挿入ポートを通して作業装置を挿入することができるようにすると同時に、その間、少なくとも作業装置が装置挿入ポートに挿入されている際には、ポートから外に血液またはそれ以外の流体が逆流するのを阻止するように作動する弁と、ｂ）前閉塞部材と後閉塞部材の間の複数の位置から血液、流体、堆積物などを吸引する、少なくとも１個の可動吸引ポート、および／または、ｃ）流体が前閉塞部材と後閉塞部材の間の位置から吸引されるのと同時に、前閉塞部材と後閉塞部材の間の位置に流体を注入することができるようにした、別個の注入管腔および吸引管腔から構成されており、
前後鼻閉塞接近装置は、ｉ）前閉塞部材が鼻中隔の一方側の鼻孔または鼻腔を閉鎖するように、ii）後閉塞部材が鼻中隔の後ろの位置で鼻咽頭を閉鎖するように、iii）作業装置が作業装置挿入開口を通して挿入され、作業装置出口開口から外へ出されて、鼻、鼻咽頭、副鼻腔などの内部の位置まで進入させられるように配備することができる、前後鼻閉塞接近装置。
【請求項34】
前記前閉塞部材としては、バルーンがある、請求項３３に記載の装置。
【請求項35】
前記後閉塞部材としては、バルーンがある、請求項３３に記載の装置。
【請求項36】
少なくとも第１作業装置出口開口および第２作業装置出口開口を備えており、作業装置が第１作業装置出口開口および第２作業装置出口開口のいずれかから選択的に外へでて前進させられるようにした、請求項３３に記載の装置。
【請求項37】
次のグループから選択された少なくとも１個の作業装置と組合わせられる、請求項３３に記載の前後鼻閉塞接近装置を備えているシステムであって、該グループは、
ガイドワイヤ、
ガイドカテーテル、
副鼻腔の小口へ進入するような形状のガイドカテーテル、
バルーンカテーテル、
ステント搬送用の装置、
物質溶離ステントの搬送装置、
骨または柔組織に圧力を加えて、骨または柔組織を成形しなおすための、移植可能な装置、
組織切断装置、
組織融除装置、
組織の嵩減らし装置、
組織焼灼装置、
通路を拡張する装置、
起寒剤を搬送する装置、
放射線不透過性の造影剤を搬送する装置、
診断用物質または治療用物質を搬送する装置、
カニューレ、
内視鏡、
センサー、
光、
診断用装置、

治療用装置
から構成されている、システム。
【請求項38】
前閉塞部材と後閉塞部材の間で管材上に配置された少なくとも１個の吸引ポートを更に備えており、流体または堆積物が吸引ポートを通ってから、更に管材の管腔を通って吸引されるようにした、請求項３３に記載の装置。
【請求項39】
鼻中隔の残りの側に設置することができる前鼻閉塞接近装置と組み合わされる、請求項３３に記載の装置を備えているシステムであって、前鼻閉塞接近装置は、
鼻中隔の一方側の鼻孔または鼻腔を閉塞する前閉塞部材と、
中に作業装置を挿入して、前閉塞部材を越えて前進させ、鼻、鼻咽頭、副鼻腔などの内部の位置まで進入させる、作業装置挿入開口とを備えている、システム。
【請求項40】
前記前鼻閉塞接近装置の前記前閉塞部材としては、バルーンがある、請求項３９に記載のシステム。
【請求項41】
前記作業装置挿入開口に付随している弁を更に備えており、弁は、作業装置挿入開口を通して作業装置が挿入されていない時には、作業装置挿入開口から外へ向かう逆流を阻止するような形状に設定されている、請求項３３に記載の装置。
【請求項42】
鼻中隔の残りの側に設置することができる前記前鼻閉塞接近装置の作業装置挿入開口に付随している弁を更に備えており、弁は、作業装置挿入開口を通して作業装置が挿入されていない時には、作業装置挿入開口から外へ向かう逆流を阻止するような形状に設定されている、請求項３９に記載の装置。
【請求項43】
副鼻腔炎または耳、鼻、喉などの疾病を診断および／または治療する用途の前鼻閉塞接近装置であって、該装置は、
鼻中隔の一方側の鼻孔または鼻腔を閉鎖するための前閉塞部材と、
中に作業装置を挿入してから、前閉塞部材を越えて前進させ、鼻、鼻咽頭、副鼻腔などの内部の位置まで進ませる作業装置挿入ポートと、
作業装置挿入ポートを通して作業装置を挿入して、作業装置挿入ポートを通して作業装置が挿入されていない時だけでも、作業装置挿入ポートから外へ血液またはそれ以外の流体が逆流するのを阻止することができるようにした、少なくとも１個の弁とを備えている、前鼻閉塞接近装置。
【請求項44】
前記前閉塞部材としては、バルーンがある、請求項４３に記載の装置。
【請求項45】
次のグループから選択された少なくとも１個の作業装置と組合わされる、請求項４３に記載の前鼻閉塞接近装置を備えているシステムであって、該グループは、
ガイドワイヤ、
ガイドカテーテル、
副鼻腔の小口へ進入するような形状のガイドカテーテル、
バルーンカテーテル、
ステント搬送用の装置、
物質溶離ステントの搬送装置、
骨または柔組織に圧力を加えて、骨または柔組織を成形しなおすための、移植可能な装置、
組織切断装置、
組織融除装置、
組織の嵩減らし装置、

組織焼灼装置、
通路を拡張する装置、
起寒剤を搬送する装置、
放射線不透過性の造影剤を搬送する装置、
診断用物質または治療用物質を搬送する装置、
カニューレ、
内視鏡、
センサー、
光、
診断用装置、
治療用装置、
から構成されている、システム。

【請求項46】
前記作業装置挿入開口に付随している弁を更に備えており、弁は、作業装置挿入開口を通して作業装置が挿入されていない時には、作業装置挿入開口から外へ向かう逆流を阻止するような形状に設定されている、請求項４３に記載の装置。

【請求項47】
副鼻腔からの排液を阻害する障害を診断し、または、その位置を探し、或いは、副鼻腔からの排液を改善または修正することを意図して先に施された治療の効能を査定する方法であって、該方法は、
Ａ．流動可能な媒体を副鼻腔に導入する工程と、
Ｂ．副鼻腔からの流動可能な媒体が流れるのを、または拡散するのを監視する工程とを含んでいる、方法。

【請求項48】
鼻中隔の後ろの声門の上の位置で鼻咽頭を閉塞して、食道または気管に流動可能な媒体が排出されるのを阻止する工程を更に含んでいる、請求項４７に記載の方法。

【請求項49】
鼻中隔の少なくとも一方側の鼻孔または鼻腔を閉鎖して、鼻孔から外へ流動可能な媒体が排出されるのを阻止する工程を更に含んでいる、請求項４７に記載の方法。

【請求項50】
前記工程Ａは、副鼻腔にカテーテルを挿入して、カテーテルを通して流動可能な媒体を注入して、副鼻腔に入れる工程を含んでいる、請求項４７に記載の方法。

【請求項51】
前閉塞部材および装置挿入通路を備えている前鼻閉塞接近装置を設ける工程と、
閉塞装置が鼻中隔の一方の鼻孔または鼻腔を閉鎖するように、前鼻閉鎖接近装置を設置する工程とを更に含んでおり、
前記工程Ａは、装置挿入数路を通してカテーテルを挿入し、副鼻腔の小口に、または、そこを通してカテーテルを進入させ、更に、カテーテルを通して造影媒体を注入して、副鼻腔に入れる工程を含んでいる、請求項４７に記載の方法。

【請求項52】
前記前鼻閉塞接近装置は、鼻中隔の一方側の鼻孔または鼻腔を閉鎖するための前閉塞部材と、中に作業装置が挿入される作業装置挿入ポートとを備えており、
前記工程Ａは、ｉ）作業装置挿入ポートを通してカテーテルを挿入する工程と、ii）副鼻腔の小口に、または、そこを通してカテーテルを進入させる工程と、iii）カテーテルを通して造影媒体を注入し、副鼻腔に入れる工程とを含んでいる、請求項５１に記載の方法。

【請求項53】
前閉塞部材、後閉塞部材、および、装置挿入通路を備えている前後鼻閉塞接近装置を設ける工程と、
前閉塞部材が鼻中隔の一方側の鼻孔または鼻腔を閉鎖するように、また、後閉塞部材が

鼻中隔の後ろの声門の上の位置で鼻咽頭を閉鎖するように、前後鼻閉鎖接近装置を設置する工程とを更に含んでおり、
　前記工程Ａは、装置挿入通路を通してカテーテルを前進させ、副鼻腔の小口に入れ、または、そこを通し、カテーテルを通して造影倍端を注入して、副鼻腔に入れる工程を含んでいる、請求項４７に記載の方法。
【請求項54】
　前記流動可能な媒体は画像化造影媒体であり、前記方法の前記工程Ｂは画像化造影媒体を画像化する工程を含んでいる、請求項４７に記載の方法。
【請求項55】
　前記工程Ｂは、可動画像化装置を使用して実行され、複数の視点から画像を得る工程を含んでいる、請求項４７に記載の方法。
【請求項56】
　前記可動画像化装置はＸ線撮影画像化装置とＣ字型アームを備えており、前記工程ＢはＣ字型アームを移動させて、複数の視点から画像を得るようにしている、請求項５５に記載の方法。
【請求項57】
　前記流動可能な媒体は放射能液または放射性標識液であり、前記方法の前記工程Ｂは、放射能を検出する装置を使用して、放射能液または放射性標識液を追跡する工程を含んでいる、請求項４７に記載の方法。
【請求項58】
　副鼻腔からの排液を阻害する障害を診断し、または、その位置を探し、或いは、副鼻腔からの排液を改善または修正することを意図して先に施された治療の効能を査定する方法であって、該方法は、
　（Ａ）副鼻腔の内層を形成している組織に粘液またはそれ以外の分泌物を分泌させる物質を副鼻腔に導入する工程と、
　（Ｂ）副鼻腔から粘液またはそれ以外の分泌液が流れるのを監視する工程とを含んでいる、方法。
【請求項59】
　前記工程（Ａ）で導入された物質としては、ヒスタミンがある、請求項５８に記載の方法。
【請求項60】
　前記工程（Ａ）で導入された物質としては、患者のアレルギーを誘発するアレルゲンがある、請求項５８に記載の方法。
【請求項61】
　粘液またはそれ以外の分泌物の排出は、内視鏡を使って視覚的に査定される、請求項５８に記載の方法。
【請求項62】
　前記工程（Ａ）は、粘液またはそれ以外の分泌物と造影剤を結合させる工程を更に含んでおり、また、粘液またはそれ以外の分泌物の排出は、造影剤の画像化により査定される、請求項５８に記載の方法。
【請求項63】
　鼻、鼻咽頭、副鼻腔などからポリープまたはそれ以外の組織を除去する装置であって、該装置は、
　遠位端および管腔が設けられた可撓性のカテーテルと、
　開いた遠位端を有しているとともに、管腔が中を通って延びている可撓性の管材であって、可撓性の管材はカテーテルの管腔の内側に回転自在に配置されており、可撓性の管材が回転することのできる間は、カテーテルが回転しないようにした、可撓性の管材と、
　可撓性の管材の遠位端に設けられた回転式カッターと、
　カテーテルに形成された開口であって、そこを通して物体が回収されてから回転式カッターによって切除されるようにした、開口とを備えている、装置。

【請求項64】
可撓性の管材の管腔を負圧源に接続して、回転式カッターによって切除された物体が開放遠位端を通して吸引されてから、更に可撓性の管材の管腔を通して吸引されるようにしたコネクタを更に備えている、請求項６３に記載の装置。
【請求項65】
カテーテルに設けられた前記開口はカテーテルの遠位端の開口である、請求項６３に記載の装置。
【請求項66】
カテーテルに設けられた前記開口はカテーテルの側面に形成された側面開口である、請求項６３に記載の装置。
【請求項67】
少なくとも１個のベアリングが前記カテーテルと前記可撓性の管材との間に存在する、請求項６３に記載の装置。
【請求項68】
前記装置が患者の体内に挿入されている間に、前記カテーテルの前記遠位端を視認するために使うことができる視認用機器を更に備えている、請求項６３に記載の装置。
【請求項69】
前記視認用機器は前記可撓性の管材の前記管腔を通して延びる、請求項６８に記載の装置。
【請求項70】
前記視認用機器は前記カテーテルの外部に取り付けられている、請求項６８に記載の装置。
【請求項71】
前記視認用機器は前記カテーテルの一方側の管腔の中に配置されている、請求項７０に記載の装置。
【請求項72】
前記カテーテルに設けられた副次管腔を更に備えている、請求項７０に記載の装置。
【請求項73】
前記副次管腔内に設置された視認用機器と組合わされた、請求項７２に記載の装置を備えているシステム。
【請求項74】
前記副次管腔内に設置されたガイドワイヤと組合わされた、請求項７２に記載の装置を備えているシステム。
【請求項75】
前記開口の中に入って前記回転式カッターと接触する物体を後退させるように作動する可動牽引装置を更に備えている、請求項６６に記載の装置。
【請求項76】
前記可動牽引装置は、牽引ヘッドが設けられた長手の部材を備えており、長手の部材は遠位方向に前進して牽引ヘッドを側面開口より遠位の位置に移動させることができるとともに、近位方向に後退して牽引ヘッドを近位方向に移動させることで、牽引ヘッドに開口に入った物体を押させて前記回転式カッターと接触状態にさせることができる、請求項７５に記載の装置。
【請求項77】
前記カテーテルは閉じた遠位先端部が設けられている、請求項６６に記載の装置。
【請求項78】
前記可撓性の管材を通って延びてから、更に前記の前記遠位先端部に形成されている開口を通って延びる管腔を更に備えている、請求項７７に記載の装置。
【請求項79】
前記可撓性の管材を通って延びてから、更に前記カテーテルの前記遠位先端に形成された開口を通って延びる管腔内に設置された視認用機器と組合わされて、請求項７８に記載

の装置を備えているシステム。
【請求項80】
前記可撓性の管材を通って延びてから、更に前記カテーテルの前記遠位先端に形成された開口を通って延びる管腔内に設置されたガイドワイヤと組合わされて、請求項７８に記載の装置を備えているシステム。
【請求項81】
人間またはエウスタキオ管、内耳蝸牛、鼓室、および、外耳を有している多様な患者の難聴または聴覚障害を治療する方法であって、該方法は、
（Ａ）患者の鼻を通して可撓性のカテーテルを挿入して、エウスタキオ管の中に入れる工程と、
（Ｂ）蝸牛電極配列、トランスデューサー、および、電源を有している移植蝸牛刺激システムを設ける工程と、
（Ｃ）エウスタキオ管に挿入されてから、更に内耳蝸牛に入るカテーテルを通して、蝸牛電極配列を進入させる工程と、
（Ｄ）蝸牛電極配列をトランスデューサーおよび電源に導通させて、移植蝸牛刺激システムに音に関連する電気衝撃を内耳蝸牛に伝搬させる工程とを含んでいる、治療方法。
【請求項82】
前記工程（Ａ）は、視認用機器を使ってエウスタキオ管を視認し、前記カテーテルを誘導してエウスタキオ管の中に入れる工程を含んでいる、請求項８１に記載の方法。
【請求項83】
前記工程（Ｃ）は、エウスタキオ管内に設置されているカテーテルを通して蝸牛ガイドを挿入し、蝸牛ガイドの上を伝って、または、その中を通して電極配列を前進させ、内耳蝸牛の中に入れる工程を含んでいる、請求項８１に記載の方法。
【請求項84】
前記工程（Ｃ）は、内耳蝸牛の丸窓を通して蝸牛電極配列を進入させる工程を含んでいる、請求項８１に記載の方法。
【請求項85】
前記工程（Ｃ）は、二次鼓膜を刺し通す工程を更に含んでいる、請求項８１に記載の方法。
【請求項86】
前記工程（Ｃ）は、蝸牛瘻を設け、蝸牛瘻を通して蝸牛電極を進入させる工程を含んでいる、請求項８１に記載の方法。
【請求項87】
エウスタキオ管を通してトランスデューサーを渡し、鼓室にトランスデューサーを移植する工程を更に含んでいる、請求項８１に記載の方法。
【請求項88】
前記方法は、鼓室の中にトランスデューサーを移植する前に、鼓室から骨を除去する工程を更に含んでいる、請求項８７に記載の方法。
【請求項89】
外耳管に電源を設置する工程を更に含んでいる、請求項８１に記載の方法。
【請求項90】
前記前閉塞部材と後閉塞部材の間の距離を調節する工程を更に含んでいる、請求項７に記載の方法。
【請求項91】
前記前閉塞部材と前記後閉塞部材の間の距離は調節できる、請求項３３に記載の前後閉塞接近装置。

【発明の詳細な説明】
【技術分野】
【0001】
本発明は、広義には、副鼻腔炎および耳、鼻、および、喉の各種疾病を治療するための医療装置および医療法に関するものであり、特に、そのような治療のための、観血を最小

限に抑えたカテーテルベースの装置、システム、および、その方法に関連している。
【背景技術】
【0002】
人間の鼻は吸気を暖め、湿らせ、更に、沪過するとともに、吐息の熱と水分を一定に保つ役割がある。鼻は顔面の美容上の特徴部としても重要である。鼻は主として軟骨、硬骨、粘膜、および、皮膚から形成されている。左右の鼻孔は鼻中隔の両側の左右鼻腔に通じている。左右の鼻腔は奥へ延びて軟口蓋に至り、この部位で鼻腔が合流して後鼻孔を形成している。後鼻孔は鼻咽頭内に向けて開いている。鼻の天蓋は、部分的に、篩板として周知の骨によって形成されている。篩板は無数の小さな孔を有しており、これらの孔を通して知覚神経繊維が嗅球まで延びている。吸い込んだ臭いが鼻の上位領域の粘膜の小領域に接触すると、嗅球まで通じている神経線維を刺激して、臭いの感覚が生じる。
【0003】
副鼻腔は、顔面の骨の内側に形成された空洞である。副鼻腔には前頭洞、篩骨洞、蝶形骨洞、および、上顎洞などがある。副鼻腔は粘液生成上皮組織の並ぶ垣ができている。通例、副鼻腔の内層によって作られている粘液は口（アスティア）として周知の開口部を通して個々の副鼻腔から外にゆっくりと排出され、鼻咽頭に入る。粘液の排出を阻害する疾病（例えば、鼻洞口の閉塞症など）の結果として、副鼻腔が正常に効能する能力減退が生じることがある。この結果、副鼻腔の内部の粘液滞留を生じることになる。鼻洞のこのような粘液滞留は、鼻洞沿いに並ぶ上皮に損傷を与え、二次的な酸素減圧や細菌増殖（例えば、鼻洞感染症）を伴うことがある。
【0004】
鼻介骨は、鼻の左右両横壁から内向きに延びて粘膜組織で覆われている３個（たまに４個）の骨突起である。これら鼻介骨は鼻の内部表面領域を広げる働きがあるとともに、鼻を通して吸い込まれた空気に温度と湿度を与える働きがある。鼻介骨を覆っている粘膜組織は、生理学的状態または環境条件の変動に応じて、充血して膨張状態になるか、または、実質的に無血で収縮状態になることができる。鼻介骨は各々の湾曲端縁が、鼻道として周知の通路の外郭を画定している。例えば、下位鼻道は、下位鼻介骨の下を通っている通路である。鼻涙管として周知の管は目から来た涙を下位鼻道の内部に位置する複数開口部を通して鼻の中に排出する。中位鼻道は下位鼻介骨から中位鼻介骨まで延びる通路である。中位鼻道は半月裂孔を有しており、複数の開口または小孔が上顎篩骨洞、前篩骨洞、後篩骨洞に通じている。上位鼻道は上位鼻介骨と中位鼻介骨の間に位置している。
【0005】
＜鼻ポリープ＞
鼻ポリープは、鼻または副鼻腔の内層から成長する良性腫瘤である。鼻ポリープは慢性アレルギー性鼻炎、または、鼻粘膜のアレルギー性鼻炎以外の慢性的炎症が原因で生じることが多い。鼻ポリープはまた、膵嚢胞性線維症に罹患している子供にはよく見られる。鼻ポリープが発達して、副鼻腔からの正常な排液を遮るまでになった場合には、副鼻腔炎を引き起こす恐れがある。
【0006】
＜副鼻腔炎＞
「副鼻腔炎」という語は、一般に、副鼻腔の炎症または感染症を意味する。副鼻腔炎はバクテリア、ウイルス、菌類（カビ）、アレルギー、または、これらの組合せが原因で起こることがある。慢性副鼻腔炎（例えば、３ヶ月程度以上も継続する）の結果として、米国では年間の病医院診療件数が1800万ないし2200万件と推定されている。
【0007】
副鼻腔炎に罹っている患者は、通例、次のような症候のうちの少なくとも幾つかを経験している。

- 頭痛または顔面痛
- 鼻腔鬱血または後鼻漏
- 一方または両方の鼻孔の呼吸困難

・　口臭
・　上顎の歯痛

【0008】

＜鼻洞痛のメカニズムと診断＞

鼻洞は、一連の空洞が通路でつながり、最終的には鼻腔へと通じているものから構成されている。前述のとおり、このような通路と空洞は骨でできているが、粘膜で被覆されている。このような通路のうちの１つの粘膜が何らかの理由で炎症を起こすと、通路を通して排液をしている空洞は遮断状態となる。粘液がこのように滞留するのは周期的である場合もあれば（その結果、痛みの症状が発現する）、慢性的である場合もある。慢性的に遮断された通路は感染症の治療対象となる。最終的に、鼻洞の諸症候の持続期間と酷さを物語るのは、骨性通路の広がりと、その上に位置する粘膜の厚みと、その慢性状態である。従って、鼻洞治療の主たる目標は通路であり、主たる達成目標点は排液を再開することである。CTではこのような空間的問題を明らかにすることができないことが多く、とりわけ、患者が目下のところ酷い症候を見せていない場合には、そのことが言える。よって、興味のある刺激に反応して、正常な状態にある鼻洞通路をダイナミックに評価する必要がある。本件で提案されているように、鼻洞疾患およびそのダイナミックな成分を査定することができるのであれば、副鼻腔炎の治療を目標に決めて、より集中的かつ観血を最小限に押さえた様式で患者治療にあたることができるかもしれない。このように通路に注目して、可撓性に富む器具を使用することで、鼻洞介在処置に全く新しい取組みを提案することができるが、すなわち、可撓性に富むカテーテルおよびガイド器具を利用し、それらを、周囲組織に対して最小限の損傷で搬送することのできる通路および空洞の修正装置と併用するという取組みである。

【0009】

＜鼻中隔＞

鼻中隔は、鼻の一方側を他方側と分割する軟骨性の解剖学的構造である。通例、この鼻中隔は比較的真っ直ぐである。偏向鼻中隔は、隔壁を形成している軟骨が以上に湾曲または屈曲している状態である。偏向した鼻中隔は鼻をかむと発生することがあり、或いは、場合によっては、鼻に外傷が生じた結果として発生することがある。偏向鼻中隔は適切な呼吸を妨害し、鼻汁の正常な排液の障害となることがあり、特に、アレルギー、鬱血緩和剤の濫用などが原因で鼻介骨が膨張または拡張している患者についてはありがちである。鼻洞の排液がこのように阻害されることで、患者は鼻洞感染症に罹りやすくなる。

【0010】

鼻が適切に機能するのを阻害する鼻腔の偏向鼻中隔は、鼻中隔形成術として周知の処置により、外科手術で矯正することができる。典型的な鼻中隔形成処置では、内視鏡を鼻に挿入して、医者が鼻の内部に切開部を設け、鼻中隔の内層を持ち上げて、その下に位置する、異常に偏向した硬骨および軟骨を除去して真っ直ぐにする。そのような外科手術による鼻中隔形成処置は偏向鼻中隔を効果的に真っ直ぐにすることができるが、鼻の軟骨にはある種の形状記憶があり、鼻中隔はその元の偏向形状に戻ろうとする傾向がある。

【0011】

＜鼻介骨の削減／除去＞

内視鏡外科手術を含む多様な外科手術技術を利用して、下位鼻介骨が慢性的に拡張しているせいで正常な呼吸や副鼻腔からの正常な排液が阻害されている患者の下位鼻介骨の削減および／または除去をすることは既に実施されている。通例、下位鼻介骨の慢性的拡張はアレルギーや慢性的炎症の結果である。下位鼻介骨の肥大は、鼻介骨の柔組織を押しやり、または、そこに衝突する偏向鼻中隔を患っている患者にとっては特に問題となる。従って、偏向鼻中隔を真っ直ぐにするための鼻中隔形成術は、しばしば、下位鼻介骨の削減と同時に実施される。

【0012】

＜鼻洞腫瘍＞

大抵のポリープは良性であるが、転位乳頭腫として周知の鼻ポリープの一形態は悪性腫

瘍として発生することがある。鼻の両側に発生するのが通例である大抵の良性ポリープとは異なり、転位乳頭腫は一方側だけに見られるのが普通である。従って、片側のみのポリープが見られるような場合は、生検に付して悪性であるか否かを判定するのが普通である。転位乳頭腫は、悪性になる前に見つかって完全に除去されてしまえば、通例は再発することがない。しかし、これまでのところ利用できた技術を利用した場合、長期に亘る術後追跡調査でポリープの再生が見られない限り、また、ポリープ再生が見つかるまでは、乳頭腫が完全に除去されたか否かを判定することが難しい場合があった。

【0013】

多様な良性の鼻洞腫瘍の発生がこれまでに分かるようになってきたが、現在では比較的稀有である。悪性の鼻洞腫瘍の最もありふれた形態は増殖上皮細胞癌である。外科手術や放射線治療やったとしても、副鼻腔の増殖上皮細胞癌は比較的悲観的な予後を伴う。副鼻腔を侵す、上記以外の悪性腫瘍としては腺癌があり、それよりは稀なものとしてリンパ腺腫があり、更に稀なものとして黒色腫がある。

【0014】

＜顔面骨折＞

顔面の骨折の最もありふれた原因は自動車事故であるが、顔面骨折はまた、スポーツ傷害、産業事故、落下、暴行、銃撃による負傷などを原因とすることが多い。顔面骨折の或るものは、鼻腔または副鼻腔の内部から接近できる骨に関与している。注目すべきことに、鼻は顔の中で突出した位置にあるため、顔面構造部の中でも最も負傷しやすい部位である。従って、鼻の骨折は（その結果として偏向鼻中隔を伴う場合も、伴わない場合も）稀有なことではない。眼窩床および／または篩骨洞や前頭洞の骨折などの、上記以外の顔面骨折も鼻または鼻洞の内側から接近できる。よくあるタイプの眼窩床骨折が「破裂」骨折であり、これは通例、目に加えられた鈍い外傷が原因であり、力が下向きに伝達されて、眼窩床を形成している比較的薄い骨が下方向に砕けるというものである。これにより、眼窩周辺組織は上顎洞の中に脱漏し、しばしば、下方向に延びて上顎洞に入り込む、骨の「捕獲穴」を作ってしまうこともある。

【0015】

＜内視鏡による鼻洞外科手術とそれ以外の現在の処置＞

<<機能的内視鏡鼻洞外科手術>>

慢性副鼻腔炎のもっともありふれた矯正外科手術は機能的内視鏡鼻腔外科手術（FESS）である。FESSでは、内視鏡が鼻に挿入され、内視鏡を介して視認しながら、医者は罹患組織または罹患骨、または、肥大組織または肥厚骨を除去し、鼻腔の小口を拡大して、鼻腔の正常な排液を回復させる。FESS処置は副鼻腔炎の治療と腫瘍除去、ポリープ除去、および、それ以外の異常増殖の除去に効果を有する。上記以外の内視鏡による鼻腔内処置を採用して、脳下垂体腫瘍を除去し、グレーヴズ病（すなわち、甲状腺亢進症の合併症で、眼球の突出を生じる）の治療、および、鼻に脳脊髄液が漏出する（すなわち、脳脊髄液鼻漏）稀有な症状の外科手術による修復を図っている。

【0016】

下位鼻介骨の寸法を低減する外科手術は、内視鏡により視認しながら（所望部位を拡大しながら）達成されるが、通例は、患者に全身麻酔を施した状態で実施される。切開部は、通例、鼻介骨の垣となる粘膜中に設けられ、その下に位置する骨を露出させる。下に位置する骨のうち或る分量が除去される。粘膜と柔組織のうち幾らかを選択的に除去することが望ましい場合でも、そのような柔組織は嵩減らしや除去を行えるが、その場合の手段として、従来の外科手術切除処置を利用したり、マイクロ創面切除装置やレーザーなどのような組織融除装置または組織の嵩減らし装置を使用することができる。それほど頻繁ではないが、慢性肥大状態の下位鼻介骨が寒冷治療法により処置されている。正常な呼吸や正常な鼻汁排出を回復するのに必要な量だけを除去するのが普通は望ましいが、それは、過剰な組織を鼻介骨から除去することで、吸気を暖めて湿り気を与えたり吐息から温度と水分が逃げないようにするという鼻介骨本来の生理学的機能を鼻介骨が実施する能力を損なう恐れがあるからである。下位鼻介骨外科手術に付随する合併症としては、出血、硬皮

成長、脱水、および、傷痕残留などがある。

【0017】

患者によっては、中位鼻介骨は侵入含気蜂巣細胞（水疱性甲介）が存在するせいで肥大し、或いは、中位鼻介骨は形成異常（奇異屈曲）を呈することがある。酷い篩骨洞炎や鼻ポリープも、中位鼻介骨の肥大または形成異常を生じることがある。副鼻腔からのかなりの量の鼻汁排出は中位鼻道（すなわち、中位鼻介骨に沿って延びる通路）を通過するため、中位鼻介骨の如何なる肥大、如何なる形成異常も鼻腔で生じる問題の原因となり、外科手術による矯正が必要である。従って、副鼻腔炎を治療するために実施する或るFESS処置では、中位鼻道が空いた状態にされる（例えば、ポリープまたは肥厚組織が除去される）ことで、鼻腔排液の改善を図っている。しかし、中位鼻介骨は、患者の嗅覚に寄与する嗅神経末端のうちの幾らかを含むことがある。このため、中位鼻介骨の削減は、通例は、できる限り多くの組織を残すように配慮しながら、極めて保存志向的態様で実施される。水疱性甲介に罹患している患者では、これは、侵入含気嚢の一方側にある骨を除去することを含む。中位鼻介骨が形成異常である場合には、鼻介骨の邪魔になる部分だけが除去される。

【0018】

<<拡張内視鏡前頭洞外科手術>>

前頭洞の炎症は、同部位の狭い解剖学的形状のせいで、それ以外の副鼻腔各部の炎症を外科手術および／または医学的治療が解消した後ですら、特に持続する恐れがある。前頭洞の炎症が宿存する場合、中隔横断前頭洞切開術として周知の外科手術、または、修正ロスロップ処置がしばしば実施される。この処置では、医者は鼻中隔の一部や洞と洞の間の骨隔壁を除去し、１つの大きな共通排液路を形成することで、前頭洞の排液を鼻に流すよう図る。この複雑な処置は、何か他の、耳、鼻、喉の外科手術処置と同様に、頭蓋を刺し通して脳脊髄液（CSF）を漏出させてしまう危険を担う恐れがある。また、或る鼻腔外科手術は、それ以外の耳、鼻、喉の処置手順と同様に、視神経、眼球、脳に近接して実施されるため、そのような構造体に損傷を生じる恐れがある。そのような厄介な合併症や損傷の潜在的可能性を最小限に抑えるために、画像支援外科手術システムを利用して、複雑な頭部および頚部の処置を実施してきた。画像支援外科手術では、統合的解剖学情報が術前に取得されたCTスキャン画像またはそれ以外の解剖学的マッピングデータにより供給される。術前CTスキャンまたはそれ以外の解剖学的マッピング処置に由来するデータはコンピュータに読み込まれ、ローカライザとして周知の特殊センサーが外科手術器具に装着される。斯様にして、コンピュータを使用し、ローカライザ装備の外科手術器具の各々がどの点にあっても、その厳密な位置を適時に医者は確認することができる。この情報は、標準内視鏡により行われた目視観察記録と連動させられて、医者が外科手術器具を注意深く設置して、CSF漏出を生じるのを防止し、神経またはその他の重要な構造体に損傷を与えるのを回避するのを助ける。

【0019】

<<FESSの短所>>

FESSは今も尚、酷い副鼻腔炎の一等級治療であるが、いくつかの欠点がある。患者が処置に付随する術後の痛みや出血を訴えることが多く、多数の外科手術を受けた後でさえ、相当な患者集団が依然として症候が残ったままである。FESSは極めて深刻な事例（CTスキャンで異常が確認されているもの等のような）についてのみの選択肢であると考えられているので、処方された治療薬に我慢ができずに外科手術を志願したいと考えるている患者はかなり大勢存在する。更に、副鼻腔炎を査定する方法論が主として静止測定（CT、MRI）であるため、症候が慢性的ではない患者は、実際に潜伏する瑣末要因が重要な役割を演じる場合には、クスリ治療を提供されるだけである場合が多い。これまで、このような患者に提供される瑣末治療というものは存在せず、薬剤治療を見限っても、それ以外に取るべき道は明確ではない。これにより、救済を必要とするかなりの数の患者がステロイド服用を望まない、または、その服用に懸念を抱いたままであるが、外科手術を施すのに適格といえるほどの重病でもない。

【0020】
FESSと鼻洞外科手術の観血性が高いうえに痛みを伴う理由の１つは、剛性シャフトを設けた直状の器具類が使用されるという事実に関連している。副鼻腔の各洞は脳やその他の重要構造体の至近に位置しているという事実のせいで、医者は直状の器具と画像支援を利用して望ましくない領域へ刺し通してしまう恐れを低減する技術を開発してきた。解剖学的構造の深層領域を標的にしようと努力するうちに、直状の器具類に上記のように依存した結果として、器具類の経路に存在している解剖学的構造体を部分切除して取除き、或いは、それ以外の方法で対処する必要が生じたが、その場合、その解剖学的構造体が罹患部の一部であるか否かとは無関係であった。カテーテルベースの技術と心臓血管系のために開発された画像化の進歩に伴い、可撓性の器具および支援装置を利用することで、副鼻腔介入措置が罹患状態を緩和する機会は相当に増えている。
【0021】
副鼻腔介入措置を実施するにあたり、観血と術後の痛みを以前よりも抑えることができるように可撓性の器具を開発することができるのであれば、このような処置はより多数の患者に適用できるようにすることができるだろう。更に、本件に記載されているように、可撓性の器具類は、以前には決してできなかった新しい診断様式や治療法の適用ができるようにする。
【0022】
<<レーザーまたは高周波数による鼻介骨削減>>
鼻介骨の下に位置する骨を改造する必要が無い場合には、医者は鼻介骨内（または、その上）の凝血異常部を生じさせるように、延いては、鼻介骨の柔組織を収縮させるように設計されたレーザ処置または高周波処置を実施することを選ぶことがある。また、場合によっては、プラズマ発生装置ワンドを利用して、鼻介骨に隣接して高エネルギープラズマを生じさせ、鼻介骨の寸法を削減させることもある。
【0023】
肥大した下位鼻介骨を収縮させるために利用できる高周波数処置の一例が、米国カリフォルニア州サニーヴェイルのソムナス・メディカル・テクノロジーズ（Somnus Medical Technologies）のソムノプラスティー（Somnoplasty：登録商標）システム高周波組織容積削減法（RFVTR）である。ソムノプラスティーシステムは探針に高周波発生装置が装着されている。探針は粘膜を通して、その下に位置する鼻介骨柔組織に挿入されるが、これは通常、直接視認環境で実施される。次いで、高周波エネルギーが伝搬され、探針の周囲の粘膜下組織を加熱することで、粘膜を無傷のまま残存させながら粘膜下の凝血異常部を生じさせる。凝血異常部が治癒するにつれて、粘膜下組織が収縮することで、鼻介骨の全体的寸法を低減する。高周波組織体積削減法（RFVTR）は、局所麻酔を利用した小規模病院内処置として実施することができる。
【発明の開示】
【発明が解決しようとする課題】
【0024】
上述の処置および技術の大半が、観血を最小限に抑えたアプローチおよび／または可撓性器具類の使用に対して適用することができる。当該技術では、このような観血を最小限に抑えた処置および技術と、そのような処置および技術を実施するために使用することができる器具類（例えば、可撓性器具または可撓性カテーテルなど）も開発する必要がある。
【課題を解決するための手段】
【0025】
一般に、本発明は副鼻腔炎またはそれ以外の、耳、鼻、喉の諸症状を診断および／または治療する方法、装置、および、システムを提供する。
【0026】
本発明によれば、本件で先に述べたような１本以上の可撓性のカテーテルまたはそれ以外の可撓性の長手装置を鼻、鼻咽頭、副鼻腔、中耳、または、これらに付随する解剖学的

経路に挿入し、介入措置または外科手術処置を実施する方法が提示される。このような可撓性カテーテルまたはそれ以外の可撓性の長手装置を使用しながら実施することができる処置の具体例として次のものが挙げられるが、それらに限定される訳ではない。すなわち、造影剤を搬送する工程、治療有効量の治療物質を搬送する工程、ステント、組織改造装置、物質搬送移植片、または、上記以外の治療装置を移植する工程、鼻ポリープ、異常組織、肥大組織、奇形組織などの組織を切除し、融除し、嵩減らしし、焼灼し、加熱し、凍結させ、レーザ処理し、拡張させ、或いは、上記以外の修正を施す工程と、細胞または組織を補綴または移植し、骨折を緩和し、据付け、ネジ留めし、粘着剤を塗布し、固定し、減圧し、または、上記以外の治療を施す工程と、遺伝子または遺伝子治療試料を搬送し、副鼻腔内またはそれ以外の鼻の内部の硬骨性組織または軟骨性組織を切除し、融除し、嵩減らしし、焼灼し、加熱し、凍結させ、レーザー処理し、截骨領域または穿孔を設け、または、上記以外の修正を施す工程と、副鼻腔の１個以上の洞からの排液に影響する副鼻腔小口またはそれ以外の解剖学的構造の形状、寸法、または、構造を修復または変更する工程と、副鼻腔またはそれ以外の鼻の内部に由来する膿または異所迷入物質を除去する工程と、副鼻腔の内部に沿って存在する細胞を掻き落し、または、他の態様で除去する工程と、腫瘍の全部または一部を除去する工程と、ポリープを除去する工程と、ヒスタミン、アレルゲン、または、それ以外の、副鼻腔の内部の組織によって粘膜の分泌の原因となる物質を搬送して副鼻腔からの排液を査定できるようにする工程と、移植蝸牛刺激装置、体内留置式の補聴装置または音増幅装置などを移植する工程とを含んでいる。

【0027】

更に本発明によれば、副鼻腔の諸症状を診断および査定する方法が提示されるが、その具体例として、空洞に造影剤を搬送する方法、粘膜液を査定する方法、通路抵抗と繊毛機能を査定する方法と、或る領域に抗原投与する方法などを含んでいる。

【0028】

更に本発明によれば、本件記載の処置のうちの幾つかまたは全部を実施する新規な装置が提示される。

【0029】

上記以外の本発明の局面、詳細、および、実施形態は、本発明の後段の詳細な説明と添付図面とを見れば、当業者なら理解することができる。

【発明を実施するための最良の形態】

【0030】

後段の詳細な説明と添付図面は、本発明の具体例すなわち実施形態の幾つかを説明したにすぎず、必ずしも全部を説明したものではないと解釈するべきであり、本発明の範囲を限定するものではない。

【0031】

本特許出願の図面の多くが耳、鼻、および、喉の解剖学的構造を例示している。一般に、このような解剖学的構造は次のような参照符号で表示されている。

鼻腔	NC
鼻咽頭	NP
上位鼻介骨	ST
中位鼻介骨	MT
下位鼻介骨	IT
前頭洞	FS
篩骨洞	ES
蝶形骨洞	SS
蝶形骨洞小口	SSO
上顎洞	MS

【0032】

人間の鼻には左右の鼻孔または外鼻孔があり、これらは左右別個の鼻孔に通じている。左右の鼻孔は鼻中隔によって分離されており、鼻中隔は実質的に軟骨と硬骨から形成され

ている。鼻中隔の後ろでは、複数の鼻腔が集束して鼻咽喉になっている。左右のエウスタキオ管（すなわち、耳管）は頭部の両側で中耳から、鼻咽頭の左右両側に位置する開口部まで延びている。鼻咽頭は口蓋垂を越えて下位側に延びて咽頭に入る。図１Ａおよび図１Ｂに例示されているように、顔面の両側の顔面骨に副鼻腔が形成されている。副鼻腔は個々の開口部すなわち小口を通して鼻腔の中へ開いている。副鼻腔は、前頭洞FS、篩骨洞ES、蝶形骨洞SS、および、上顎洞MSからなる。

【0033】

本発明は、現行の取組みよりも観血を少なくした態様で、耳、鼻、および、喉の疾病を診断および治療する各種装置とそれらに付随する各種方法からなる包括的システムを提供するものである。詳細に述べると、後段で具体的に説明されるが、本発明は、手術場（例えば、鼻咽頭および／または１個以上の鼻腔または局所の管など）の液体封鎖を全体的または部分的に実施する装置を提供する。このような手術場の液体封鎖により、多様な画像化様式と組合わせた流体ベースまたは気体ベースの薬剤を利用して鼻腔、管、通路を画像化することができるようになると同時に、手術場から液体を吸引する危険や、かかる液体の漏出を抑制できなくなる危険を回避することができる。更に、手術場をこのように液体封鎖することで、処置途中に放出された血液または洗浄液の保持と収集を行えるようになる。本発明のまた別な局面は、副鼻腔の静的性質と動的性質を査定するとともに、特定の副鼻腔または特定の標的領域（例えば、狭窄した鼻腔小口、鼻腔内の感染組織、腫瘍、その他の標的構造体など）に対する特殊治療を支援するためにも利用することができる、１組の方法および装置である。本発明のまた別な局面は、画像支援および／または内視鏡支援を受けながら、鼻腔通路または局所の管への観血を最小限に抑えた進入に適するように設計されることで、問題の領域に対して拡張、融除、部分切除、注入、移植などのような局所治療を施すようにした各種の装置および方法の用途である。このような装置および方法は使い捨て可能であり、或いは、一時的に適用するだけで済むか、或いは、進行中の機能部材（移植可能な薬物搬送システム、蝸牛移植片など）と一緒に移植することができる。多数の実施形態で、本発明は、可撓性のカテーテルと、細長い可撓性部材またはカテーテルに搭載されるか、それらを通して搬送される多様な作業装置を活用し、広範な鼻疾病および喉疾病を診断および治療することを含み、これら疾病として、鼻ポリープ、副鼻腔炎、肥大鼻介骨、偏向鼻中隔、腫瘍、感染、変形などがある。後段には、本発明に従って使用することができる、多数の特殊装置および方法が記載されている。後段に記載されている特定の装置または方法のいずれかと関連づけて説明されている構成要素、素子、制約、属性、または、工程はいずれも、本発明の他の装置または方法のいずれかに組み込まれ、或いは、それらのいずれかと併用することができるが、但し、そうすることで結果として得られた装置または方法が利用するにあたって個々に意図された目的に適っている場合に限られるものと理解するべきである。

【0034】

Ａ．　閉塞接近ポート装置

本発明の処置の大半は、鼻、鼻咽頭、中耳、または、副鼻腔の内部に１本以上の可撓性カテーテルまたはそれ以外の可撓性の細長い作業装置（その具体例は、図５Ａから図５Ｙ’’’’’に例示されており、後段で説明される）を挿入して設置することを要件としている。このようなカテーテルおよび／またはそれ以外の細長い作業装置を容易に挿入できるようにして適切に設置するために、また、血液または堆積物が手術部位から排出されるという望ましくない出来事を防止するために、本発明は、多数の異なる閉塞部材および／または接近ポート装置を含んでいるが、それらの具体例が図２Ａから図２Ｒに例示されており、これらは、鼻および／または口腔を通して挿入されて、ａ）液体（例えば、ガスまたは液体など）が排出されたり漏出するという望ましくない出来事を防止し、ｂ）ガイドや作業装置の挿入と設置を容易にするが、ガイドおよび作業装置の具体例は図５Ａから図５Ｙ’’’’’と図６Ａから図６Ｅに例示されている。

【0035】

図２Ａないし図２Ｂは、前後閉塞接近装置１０が右鼻腔を通して挿入されているととも

に前閉塞接近装置１２が左鼻腔の前領域に設置されている、人間患者の頭部の両側の部分断面図である。詳細には、図２Ａは、鼻腔、鼻咽頭の右側、および、これらに付随する副鼻腔と、これらの部位に本発明の前後閉塞接近装置１０が挿入されているのとを例示している。前後閉塞接近装置１０は、鼻中隔の右側の右鼻腔を閉鎖する前閉塞部材１４と、鼻中隔の背後で（しかし、通例は、声門の上で）後鼻孔、鼻咽頭、または、咽頭を閉鎖する後閉塞部材１８と、前閉塞部材１５と後閉塞部材１８の間で延在している管材１６とを備えている。後閉鎖の装置と前閉鎖の装置は単独で使用されてもよいし、組合わせて使用されてもよい。これらは同軸に配備されてもよいが、代替例として、一開口部ごとに１個、単独様式で配備されてもよい。これら閉鎖様式のどのような組合せを採用しても１つ以上の上述の目的を達成することができる点に、注目するべきである。管１６の横断面が図２Ｃに例示されている。これ以外の断面形状も可能であり、例えば、多数の装置または複数の流体（具体的には、液体と気体）が通過することができるようにした、より多くの管腔を備えているものが挙げられる。或る実施形態では、装置１０（または、それ以外の、本件に記載されている閉塞接近装置のいずれか）が注入用と吸引用に別個の管腔を有していることにより、潅注液またはそれ以外の流体の注入と、潅注液またはそれ以外の手術場に由来する流体の吸引とを同時に行うことができるようにするのが望ましい場合がある。このように、封鎖された手術場の内側で流体が連続して方向転換することは、手術場から血液または堆積物を洗浄し、内視鏡を利用する場合やそれ以外の様々な理由から、解剖学的構造を支障なく容易に視認できるようにするのに有用となる。ポート本体部２８は管１６の近位端に取り付けられる。装置挿入開口３０はポート本体部２８を通って延び、管１６の作業管腔に入る。１個以上の出口開口２２、２４が管の各部に置かれて、装置（例えば、カテーテル、流体注入装置、または、それ以外の、図５Ａないし図５Ｙ’’’’’に例示されているとともに後段で説明されている長手の装置例など）が装置入口開口３０に挿入されて作業管腔５０を通って前進させられ、出口開口２２、２４のうちの選択された一方から外に出て、鼻、鼻咽頭、または、副鼻腔内の一点へ至るようにする。図２Ａに例示されている特定の実施形態では、前閉塞部材１４および後閉塞部材１８はバルーンを有しているが、これら以外の多種多様な閉塞部材がバルーンの代用にされてもよいが、その具体例は図３Ａないし図３Ｋに例示されているとともに後段で説明される。バルーン膨張／収縮管腔５２、５６は近位ルアーコネクタ３２、２６から管１６を通り、前閉塞部材１４および後閉塞部材１８へとそれぞれに延びている。従って、注射器またはそれ以外の流体放出／回収装置をコネクタ３２に接続して、前閉塞部材１４を選択的に膨張および／または収縮させることができる。また別な注射器またはそれ以外の流体放出／回収装置をコネクタ３６に接続して、後閉塞部材１８を選択的に膨張および／または収縮させるようにしてもよい。図２Ｂの例示から明らかになるように、後閉塞部材は（十分に膨張すると）鼻中隔の後ろの（但し、通例は、声門の上の）後鼻孔、鼻咽頭、または、咽頭を完全に閉塞するような寸法および形状になるため、血液またはそれ以外の液体や堆積物が患者の右鼻腔または左鼻腔のいずれかから咽頭に排出されるのを阻止することができる。装置１０の前閉塞部材１４は、十分に膨張すると、右鼻腔のみを閉塞し、手術処置中に血液またはそれ以外の液体や堆積物が管１６の周囲で排出されて右鼻孔から外に漏れるのを阻止するように働く。フラッパーバルブ、ダックビルバルブ、止血バルブのような逆止弁、または、それ以外のバイオ医療装置設計の分野で従来公知のタイプの逆止弁がポート本体部２８の内側に設置されて、カテーテルまたはそれ以外の長手装置（その具体例は図５Ａないし図５Ｔに例示されているとともに後段で説明される）に挿入ポート３０を通して遠位方向に前進させ、ポート本体部２８を通り抜けてから作業管腔５０を通過させながらも、血液またはそれ以外の液体や堆積物が作業管腔５０を通して排出されて装置挿入ポート３０から外へ漏れるのを阻止することができる。このような態様で、装置１０は右鼻腔の前面では実質的に液体封鎖式の前シールを形成し、鼻中隔の後ろの（但し、通例は、声門の上の）後鼻孔、鼻咽頭、または、咽頭では実質的に液体封鎖式の後シールを形成している。実質的に液体封鎖式のシールが形成されるため、１個以上のバルブ（図示せず）が設けられて、術場へ物質（例えば、造影剤、潅注溶液、薬剤など）を注入した結果として、かつ／または

、術場から物質（例えば、血液、それ以外の液体、堆積物など）を吸引または排除した結果として、前閉塞部材１４と後閉塞部材１８の間に生成された正圧または負圧を緩和することができる。更に、吸引管腔５４は吸引ルアーコネクタ３４から延びて、作業管腔５０を通って、管１６に形成された吸引開口２６に至る。吸引ポンプが吸引コネクタ３４に接続されて、血液、それ以外の液体、および／または、堆積物を吸引して、前閉塞部材１４と後閉塞部材１８の間に画定されている右鼻手術領域から外へ排出される。図面に例示されているとともに本件で説明されている閉塞接近装置は比較的広い術場（例えば、鼻腔と副鼻腔のうち一方または両方、鼻腔から鼻咽頭までなど）を隔絶するように設計されているが、特殊な問題が診断されてしまうと、かつ／または、特殊な標的領域が識別されてしまうと、閉塞部材１４、１８は別の場所に移され、かつ／または、また別な閉塞装置をそうニュして元の術場の一部のみ（例えば、１個の鼻腔のみ、１個の副鼻腔のみ、１個のエウスタキオ管のみなど）を隔絶して液体封鎖式のシールを形成することができるため、鼻、鼻咽頭、副鼻腔、または、それ以外の封鎖され、かつ／または、器具設置された構造体の必要な領域（単数および複数）のみについて処置を進めることができるようになり、外傷を最小限に抑えるとともに患者の快適さを増すことができることが分かる。

【0036】

図２Ａおよび図２Ｂに例示されている装置１０のような前後閉塞接近装置の実施形態のどれについても、前閉塞部材１４と後閉塞部材１８の間の距離は、解剖学的構造および／または特殊な標的領域もしくは興味の対象である隔絶された術場の変化に適応するように調節可能であることが分かる。前閉塞部材１４および後閉塞部材１８は分離可能な装置であり、前閉塞部材は、複数の管腔（例えば、膨張用管腔、作業チャネル用管腔、潅注用管腔など）を設けることのできる後閉塞部材の一本の管腔を通って滑動または通過することができ、また、前閉塞部材は後閉塞部材と一体型にしてもよいし、そうでなくてもよい。後閉塞部材はまた、複数の管腔（例えば、膨張用管腔、作業チャネル用管腔、潅注用管腔など）を設けるようにしてもよい。更に、前閉塞部材と後閉塞部材の両方について全ての管腔に弁が設けられて、気体、液体、血液などの漏出または流動を阻止することができる。

【0037】

前出口開口２２と後出口開口２４を設けた実施形態では（図２Ａから図２Ｂの実施例に示されているように）、器具、器具類、および、流体は前出口開口２２と後出口開口２４のいずれかを介して搬送することができることが更に分かる。或る事例では、標的の解剖学的管腔または篩骨細胞に至る開口部などの管腔をより良好に視認できるようにするためには、後出口開口２４を通って接近することが望ましい。

【0038】

図２Ｂおよび図２Ｄに例示されているように、前後閉塞接近装置１０が一方の鼻腔を通して挿入される処置では、両方の鼻腔の内部に別個の前後閉塞接近装置１２を設置して、血液、それ以外の流体、または、堆積物が残りの鼻孔から排出されるのを阻止するとともに、カテーテルまたはそれ以外の長手装置（その具体例は図５Ａないし図５Ｔに例示されているとともに後段で説明される）を左鼻腔および副鼻腔から、または、それ以外の、残りの鼻腔から接近することのできる解剖学的構造に容易に挿入することができるようにするのが望ましいことがある。図２Ｂに例示されているように、前閉塞接近装置１２には、前閉塞部材４０およびポート本体部４２が取り付けられた管材４１が設けられている。装置挿入開口４４はポート本体部４２を通り、更に、管材４１の作業管腔５８を通って延び、管材４１の遠位端の出口開口に至る。逆止弁（例えば、前後閉塞接近装置１０と関連づけて前段で説明された弁など）が任意でポート本体部４２の内部に設けられ、血液、それ以外の流体、または、堆積物が挿入開口４４から排出されるのを阻止することができる。図２Ｂおよび図２Ｄに例示されている特定の実施形態では、前閉塞部材４０はバルーンであるが、そのような閉塞具４０はそれ以外にも多様な構造からなっていてもよく、その具体例が図３Ａないし図３Ｍ’’に例示されているとともに、後段で説明される。バルーン型の前閉塞部材４０を膨張および収縮させるために、バルーン膨張／収縮管腔６０はルアー

コネクタ４８から管材４１を通って延び、バルーン型の前閉塞部材４０に至る。注射器またはそれ以外の流体放出／吸引装置がコネクタ４８に接続され、前閉塞部材４０を選択的に膨張および／または収縮させるために使用される。任意で、サイドチューブおよびルアーコネクタ４６が管材４１の作業管腔５８に接続されて、血液、それ以外の流体、および、堆積物を左鼻腔から管材４１の作業管腔５８を通して吸引することができるようにしている。或る実施形態では、専用の吸引管腔／灌注管腔に別個の吸引ポートと灌注ポートを設けたものが管材４１に形成されており、その態様は、前後閉塞接近装置１０に関して先に説明したものに類似している。

【0039】

図２Ｅないし図２Ｈは閉塞接近用の代替のシステムを例示しているが、この場合、前閉塞接近装置（単数または複数）１２が鼻孔または鼻腔の一方または両方に設置され、口腔に挿入可能な後閉塞装置３００が患者の口腔を通して挿入されてから、鼻中隔の後ろの（但し、通例は、声門の上の）後鼻孔、鼻咽頭、または、咽頭を閉塞するように設置される。図２Ｅないし図２Ｇに例示されている口腔に挿入可能な後閉塞装置３００の実施形態には、閉塞部材３０４が遠位端またはその付近に設置された湾曲管３０２が設けられている。装置３００の形状は、患者の口腔を通して挿入されてから、閉塞部材３０４が内部に配置されている位置へ至り、鼻中隔の後ろの（但し、通例は声門の上の）後鼻孔、鼻咽頭、または、咽頭を実質的に閉塞することができるように設定されている。後閉塞部材３０４はまた、エウスタキオ管の隣に設置されてエウスタキオ管を遮断することで、処置途中で（エウスタキオ管または中耳もしくは内耳への接近が望ましくない場合は）流体がエウスタキオ管を辿って入り込むのを阻止することもできる。更に、（涙管、エウスタキオ管など）で介在させたくない管または経路に特殊な標的バルーンまたは閉塞部材を設置することが必要になることがある。このような場合には、このような予備の管閉塞部材の働きで流体／気体の異所迷入喪失を防止し、かつ／または、管腔の保全を保ち、その間に、近隣の構造体の修復が実施される。図２Ｅから図２Ｇに例示されている特定の具体例では、閉塞部材３０４はバルーンを有している。しかしながら、このような閉塞部材３０４は多様な代替の方法で構築することができ、その具体例が図３Ａないし図３Ｋに例示されているとともに後段で説明されている。図２Ｆの断面図から分かるように、この具体例では、バルーン膨張／収縮管腔３１８はルアーコネクタ３１４から管材３０２を通ってバルーン型の閉塞部材３０４まで延びている。注射器またはそれ以外の膨張／収縮装置がルアーコネクタ３１４に取り付けられて、バルーン３０４を膨張および収縮させるために使用される。止め栓またはそれ以外の弁（図示せず）をバルーン膨張管材３１８の上に設けて、所望される時にバルーンの膨張を維持するようにしてもよい。定常使用では、閉塞部材３０４がまず収縮されてから、鼻中隔の後ろの（但し、通例は声門の上の）後鼻孔、鼻咽頭、または、咽頭の内部に収縮された閉塞部材が設置された状態で、装置３００が口腔を通して挿入され、所望の位置まで前進させられる。その後、閉塞部材３０４は拡張され（例えば、膨張状態になる）、鼻中隔の後ろの（但し、通例は声門の上の）後鼻孔、鼻咽頭、または、咽頭を閉塞または遮断することができるため、処置中に血液、それ以外の液体、または、堆積物が患者の食道または気管に排出されるのを実質的に阻止することができるようにしている。場合によっては、図２Ｅないし図２Ｈに例示されているように、管材３０２は閉塞部材３０４を通って延びている１本以上の管腔３１０を有しているとともに、バルーンより遠位に位置する開口部３１０を通して開放している。カテーテル、または、それ以外の長手装置のような（その具体例は図５Ａないし図５Ｙ''''’に例示されているとともに後段で説明されている）作業装置は、上述のような管腔３１０を通して前進させられて、患者の鼻咽頭、鼻腔、副鼻腔、中耳などに入る。これに代わる例として、上述のような管腔３１０に吸引が施され、血液、それ以外の流体、または、堆積物を閉塞部材より上位の領域から吸引するようにしてもよい。或る事例では、例示の管腔３１０は作業管腔と吸引管腔に分割されてもよい。吸引管腔は管材の遠位端の別個の吸引ポート（単数または複数、図示せず）および近位端のコネクタ（図示せず）で終端しており、作業装置（単数または複数）が中を通される管腔とは別個の管腔を通して、吸引が施されるようにしても

よい。ポート本体部３０６は管材３０２の近位端に設置することができる。装置挿入ポート３０８はポート本体部３０６を通って延びて、管材３０２の管腔３１０に入る。フラッパーバルブ、ダックビルバルブ、止血バルブのような逆止弁か、または、それ以外の、バイオ医学装置設計の分野で従来公知のタイプの逆止弁がポート本体部３０６の内部に設置されて、カテーテルまたはそれ以外の長手装置を挿入ポート３０８を通して遠位方向へ前進させたのち、ポート本体部３０６を通ってから管腔３１０を通過させることができるようにしながらも、血液、それ以外の流体、または、堆積物が管腔３１０を通って装置挿入ポート３０８から外へ排出されるのを阻止することができる。或る事例では、口腔に挿入可能な後閉塞装置３００を使用するにあたり、前閉塞装置（単数または複数）を鼻孔（一方または両方）または鼻腔（単数または複数）に設置せずに済む。また別な事例では、このような口腔に挿入可能な後閉塞装置３００を図２Ｇおよび図２Ｈの具体例に例示されているような１個または２個の前閉塞接近装置１２と組合わせて使用するのが望ましいことがある。このような装置３００および装置１２を組合わせて使用することで、後閉塞部材３０４と前閉塞部材（単数または複数）４０の間に実質的に液体封鎖式の術場を確立する働きがあると同時に、多様なカテーテルやそれ以外の手術器具を任意の接近ポート４４および／またはポート３０８を通して術場に挿入することができるようになる。

【0040】

図２Ｉから図２Ｌは、前閉塞部材を全く備えていない、経鼻挿入可能な後閉塞装置３０１を例示している。装置３０１は、閉塞部材３０５が管材の遠位端またはその付近に設置された湾曲管材３０３を有している。図２Ｋから図２Ｌに例示されているように、この装置３０１は右鼻腔または左鼻腔のいずれかを通して挿入されてから、閉塞部材３０５が鼻中隔の後ろの（但し、通例は声門の上の）後鼻孔、鼻咽頭、または、咽頭を実質的に閉塞する位置まで前進させられる。例示の特定の具体例では、この閉塞部材３０５はバルーンを有している。しかしながら、このような閉塞部材３０５は多様な代替の方法で構築することができ、その具体例が図３Ａないし図３Ｋに例示されているとともに後段で説明されている。図２Ｊの断面図から分かるように、この具体例では、バルーン膨張／収縮管腔３１７はルアーコネクタ３１１から延びて管材３０３を通り、バルーン型の閉塞部材３０５に至る。注射器またはそれ以外の膨張／収縮装置がルアーコネクタ３１１に取り付けられ、バルーン型の閉塞部材３０５を膨張および収縮させるために使用される。止め栓またはそれ以外の弁（図示せず）がバルーン膨張管腔３１７上に設けられて、所望されれば、バルーンの膨張を維持するもできる。定常使用では、閉塞部材３０５がまず収縮されてから、装置３０１が右鼻腔または左鼻腔を通して挿入され、更に、収縮状態の閉塞部材３０５が鼻中隔の後ろの（但し、通例は声門の上の）後鼻孔、鼻咽頭、または、咽頭の内部に設置される所望の位置まで前進させられる。その後、閉塞部材３０５が拡張され（例えば、膨張状態になる）、鼻中隔の後ろの（但し、通例は声門の上の）後鼻孔、鼻咽頭、または、咽頭を閉塞またはブロックすることができるようにすることで、血液、それ以外の流体、または、堆積物が処置中に患者の食道または気管に排出されるのを実質的に阻止することができる。任意で、遠位吸引ポート３０９および／または近位吸引ポート３０７が管材３０３の管腔内へと開放され、このような管腔３１５が吸引コネクタ３１３に取り付けられるようにしてもよい。このような態様では、閉塞部材３０５の上の鼻咽頭から、かつ／または、装置３０１が中に挿入される鼻腔から、血液、それ以外の流体、または、堆積物を除去するために吸引が施される。図２Ｋおよび図２Ｌの例示から分かるように、この具体例では、経鼻後閉塞装置３０１は右鼻腔を通して挿入される。カテーテルまたはそれ以外の長手の手術装置（その具体例は図５Ａないし図５Ｙ’’’’’に例示されているとともに後段で説明される）のような作業装置ＷＤは管材３０３に隣接している右鼻腔に進入させられ、或いは、経鼻後閉塞装置３０１によって前閉塞が施されないせいで開いたままになっている左鼻腔を通して進入させられる。このような構成は、図２Ｋないし図２Ｌに例示されているような上位鼻介骨IT、中位鼻介骨MT、下位鼻介骨STのような鼻の内部の解剖学的構造を鼻孔（一方または両方）を介して直接視認化するのを医者が望んでいるような処置について、特に好適であるかもしれない。

【0041】
図２Ｍないし図２Ｎは、図２Ｉないし図２Ｌに例示されている経鼻後閉塞装置３０１に関連して説明された先に説明された構成要素を全部備えている経鼻後閉塞部材３０１ａのみならず、閉塞部材３０５より遠位まで延びている管材３０３の遠位拡張部３０３ａと付加的な近位コネクタ３１９の修正版を例示している。別個の管腔（図示せず）がコネクタ３１９から管材３０３を通して延びているとともに、遠位管材拡張部３０３ａを更に通過しており、この遠位管材拡張部は遠位端開口３２１で終端している。斯くして、コネクタ３１９に吸引が施されて、遠位開口部３２１を通し、遠位管材拡張部３０３ａを通し、更に、管材３０３を通して物質を吸引する。このような遠位管材拡張部３０３ａと付加的な管腔は、上述のとおりにやっても装置を意図した応用例に適合させることができないような場合に、本件で説明されているような他の後閉塞装置に任意で追加することができる。
【0042】
図２Ｏから図２Ｐは鼻孔に挿入される鼻腔内カテーテル４０２と、例示のように、鼻腔内カテーテル４０２を通して挿入される閉塞部材カテーテル４０４とを備えている。後閉塞部材４０６は閉塞部材カテーテル４０４の遠位端またはその付近に配置される。図２Ｏないし図２Ｐに例示されている特定の実施形態では、閉塞部材４０６は鼻中隔の後ろの（但し、通例は声門の上の）後鼻孔、鼻咽頭、または、咽頭を閉塞するような寸法および形状に設定されている。例示されている特定の具体例では、この閉塞部材４０６はバルーンを備えている。しかしながら、このような閉塞部材４０６は多様な代替の方法で構築されていてもよいが、その具体例が図３Ａないし図３Ｋに例示されているとともに後段で説明されている。この具体例では、バルーン膨張／収縮管腔はルアーコネクタ４０８から延びて閉塞部材カテーテル４０４を通り、バルーン型の近位閉塞部材４０６に至る。注射器またはそれ以外の膨張／収縮装置はルアーコネクタ４０８に取り付けられて、バルーン型の後閉塞部材４０６を膨張および収縮させるために使用される。止め栓またはそれ以外の弁（図示せず）がバルーン膨張／収縮管腔上に設けられて、所望された場合には、バルーン型の後閉塞部材４０６の膨張を維持することもできる。任意で、遠位管状拡張部４１２が後閉塞部材４０６より遠位に延びて、別個の管腔が任意の第２コネクタ４１０から遠位管状拡張部４１２を通って延び、更に、開口部４１４を通過することで、物質が後閉塞部材４０６より遠位の領域から吸引されるようにしてもよい。ポート本体部４１８が鼻腔内管材４０２の近位端に形成されている。挿入ポート４２０はポート本体部４１８を通って延びて、鼻腔内管材の管腔４２２に入り込む。側部吸引ポート４１６が鼻腔内管材４０２の管腔に接続されていてもよい。定常動作では、鼻腔内管材４０２は鼻孔を通して鼻腔に挿入されてから、遠位端が後鼻孔または鼻咽頭内またはその付近に存在する位置まで進入させられる。後閉塞部材４０６が折り畳まれた（例えば、収縮状態の）形状を呈している場合には、閉塞部材カテーテル４０４は鼻腔内カテーテル４０２の管腔４２２を通って前進させられて、後閉塞部材が鼻中隔の後ろの（但し、通例は声門の上の）後鼻孔、鼻咽頭、または、咽頭に配置されている位置に至る。その後、後閉塞部材４０６が拡張させられ（例えば、膨張状態となる）、鼻中隔の後ろの（但し、通例は声門の上の）後鼻孔、鼻咽頭、または、咽頭を閉塞または遮断するようにしたことで、処置の途中で患者の食道または気管に血液、それ以外の流体、または、堆積物が排出されるのを阻止することができる。その後、吸引ポート４１６に吸引が施され、後閉塞部材４０６より近位の領域から血液、それ以外の流体、または、堆積物を吸引することができる。このような吸引作業中に、鼻腔内管材４０２が図２Ｏの矢印で示されるように前および／または後ろに移動させられ、その間、閉塞部材カテーテル４０４は静止したままである。吸引プロセスの最中に鼻腔内カテーテル４０２を移動させることのできる上述のような能力は、術場から血液、それ以外の流体、および／または、堆積物を完全に除去するのを容易にすることができる。
【0043】
図２Ｑおよび図２Ｒは、上述の後閉塞システム４００と同じ素子や同じ構成要素を備えている修正された後閉塞システム４３０を例示しているが、ここでは、鼻腔内管材４０２ａの遠位端４３４は先細り状にされ、また、複数の側部開口４３２が鼻腔内管材４０２ａ

に形成されて、血液、それ以外の流体、または、堆積物が上述のような側部開口４３２を通して鼻腔内管材４０２ａの管腔４２２ａに吸引されるようにすることができる。

【0044】

Ｂ．　閉塞部材設計と吸引装置の変形例

閉塞接近装置１０、１２、３００、４００の上述の具体例は本質的に膨張可能なバルーンである閉塞部材を例示しているが、このような閉塞部材はバルーンに限定されず、また、これ以外の多様な設計や種類であってもよいことが分かる。更に、接近吸引管、接近吸引ポートの多様な構成を利用して、血液、それ以外の流体、または、堆積物を閉塞部材（単数または複数）に隣接している領域から、かつ／または、術場のどこか他の部位から完全に除去するのを容易にすることができるとともに、術場の内部に作業装置を最適設置するのを容易にすることができるものと理解することができる。事実、或る閉塞部材設計および／または吸引接近管設計や吸引接近ポート設計は、外科手術中に患者の頭部の位置決め処理や、患者が全身麻酔を受けるのか否か、気管内管材が挿入されるのか否かなどを含む多数の要因次第で、或る処置については他の処置よりは望ましいことがある。或る事例では、後閉塞部材が鼻中隔の後ろの後鼻孔、鼻咽頭、または、咽頭の内部に設置されている場合は、後閉塞部材に隣接している領域から外へ血液、それ以外の流体、または、堆積物が吸引される完璧さの度合いは、閉塞部材そのものの形状および／または設計で決まるほかに、血液、流体、または、堆積物が中を通って吸引されることになる吸引管腔（単数または複数）やポート（単数または複数）の形状および位置で決まる。最適化された流体制御のほかにも、後閉塞部材および／または付随する接近管材も装置の不可欠な案内部材として機能し、特殊な構造体に接近するには代替の形状および軌跡が特に有用となることがある。図３Ａないし図３Ｋは、多様な閉塞部材の種類の変形例と、閉塞部材に隣接している領域から、または、術場内のどこか他の部位から血液、流体、または、堆積物が中を通って吸引される吸引管腔（単数または複数）および吸引ポート（単数または複数）の配置の変形例の具体例を例示している。図３Ａおよび図３Ｋに例示されている具体例は、適当ならば、図２Ａないし図２Ｒに例示されている閉塞接近装置に組み込むことができる。

【0045】

図３Ａは管材４４２に搭載されている閉塞部材４４６を例示しているが、ここでは、概ねＵ字型の湾曲部が管材の遠位端に形成されており、管材４４２の遠位部が閉塞部材４４６の上面４４９の下を通ってから上方向に湾曲し、管材４４２の遠位端が閉塞部材４４６の上面４４９と同一平面上にある開口部４４４で終端するようになっている。この態様で、閉塞部材４４６の上面４４９に隣接して蓄積された流体はいずれも、開口部４４４に吸引されて管材４４２を通される。閉塞部材がバルーンを有している実施形態では、バルーン膨張管腔は管材を通って延びてから、開口部４４７を通ってバルーンの内部に向かって開放され、バルーンの膨張／収縮を行えるようにすることができる。任意で、可撓性カテーテルまたは長手の装置（その具体例は図５Ａないし図５Ｔに例示されているとともに後段で説明される）のような作業装置４４８は管材の吸引管腔を通して前進させられてから、図３Ａに示されているような開口４４４から外へ出る。

【0046】

図３Ｂはまた別な代替例を示しており、この場合、閉塞部材４５０には上面に陥凹部またはウエル４５４が形成されている。管材４５２は、取付け部材４５６により閉塞部材に取り付けられ、管材４５２の遠位端はウエル４５４の中に突出しているため、ウエル４５４の内部に集まる血液、流体、または、堆積物はいずれも、管材４５２を通して吸引される。閉塞部材４５０がバルーンを備えている実施形態では、管材４５２は、膨張／収縮副次管材４５８を通ってバルーンの中まで延ばすことができるバルーン膨張／収縮管腔を組み入れて、バルーンの膨張および収縮を容易にするようにしてもよい。

【0047】

図３Ｃおよび図３Ｃ’はまた別な実施形態を例示しており、この場合、閉塞部材４６０の上面に陥凹部またはウエル４６２が形成されており、図示のように管材４６４が閉塞部材４６０に取り付けられている。管材４６４の管腔はウエルの床に隣接している領域と連

絡状態になっており、ウエルの内部に集まった血液、流体、または、堆積物の吸引を容易にしている。閉塞部材４６０がバルーンを有している実施形態では、管材４６４は吸引管腔４６８とバルーン膨張／収縮管腔４７０を組み入れることができる。小型の湾曲した（例えば、略U字型の）吸引管材４６６は吸引管腔４６８の遠位端およびウエル４６２の内部に封鎖接続状態で連結されており、血液、それ以外の流体、または、堆積物がウエル４６２から吸引管材４６６を通して、更に、吸引管腔４６８を通して吸引されるようにすることができる。

【0048】

図３Ｄは、超伸縮性または弾性のメッシュ材（例えば、ニッケルチタン合金のワイヤメッシュなど）から形成されたバスケットのような自己拡張型の陥凹構造体４７２を備えている凹状の閉塞部材４７１を例示している。拡張型の凹状構造体４７２は可撓性のポリマー（例えば、発泡ポリテトラフルオロエチレン、ポリウレタン、ポリエチレン、テレフタレートなど）から形成されたスキンのような流体不透過性の可撓性被覆材４７４で覆われている。凹状の閉塞部材４７１は、十分に拡張されると、設置部位である肉体管腔（例えば、鼻腔、後鼻孔、鼻咽頭、咽頭など）を閉塞し、凹状のウエル４７９を形成する。管材４８０は凹状の閉塞部材４７１のウエルの中まで延びて、ウエル４７９から血液、流体、または、堆積物を吸引するために使用される。閉塞部材４７１は搬送カテーテル４７８から前進させられ、また、同カテーテル内に引き込まれる。支柱４７２は凹状の閉塞部材４７１を搬送カテーテル４７８の内部の搬送部材（図示せず）に連結することができるが、このとき同時に、搬送部材は搬送カテーテル４７８から外へ閉塞部材４７１を押し出すように前進させることができるとともに、搬送カテーテル４７８の中へ塞栓部材４７１を引き込むように後退させることができる。閉塞部材４７１は、搬送カテーテルの内側にある時には、収縮した形状を呈しているが、閉塞部材は、搬送カテーテルから外へ放出されてしまうと、弾性的に弾けて、図３Ｄに例示されているような拡張した凹状の形状になるまで自己拡張する。吸引カテーテル４８０は、閉塞部材４７１と同時に、或いは、閉塞部材４７１とは別々に、搬送カテーテル４７８から前進し、かつ／または、搬送カテーテルの中へ後退する。

【0049】

図３Ｅ'ないし図３Ｅ'''は更にまた別な閉塞吸引構成を例示しており、閉塞部材４８４は、搬送吸引カテーテル４８６から前進させることのできる外翻型の管状部材を備えている。外翻型の管状部材は被覆材５００で被覆されている枠４８８を有している。初期的に、外翻型の管状部材は、搬送吸引カテーテル４８６の管腔内では、実質的に円筒状の形状を呈している。枠は弾性または超伸縮性の素材であり、図３Ｅ'''に例示されている外翻された形状まで偏倚される。このようなフレーム４８８メッシュ材（例えば、ニッケルチタン合金のワイヤメッシュなど）から形成される。被覆材５００は可撓性のポリマー（例えば、発泡ポリテトラフルオロエチレン、ポリウレタン、ポリエチレン、テレフタレートなど）から形成することができる。動作中は、搬送吸引カテーテル４８６は、閉塞部材４８４を設置するのに望ましい位置まで前進させられる。続いて、外翻型の管材が、図３Ｅ'および図３Ｅ''に例示されているように、搬送吸引管材４８６の遠位端開口部から前進させられる。外翻型の管材は、カテーテル４８６から外へ出て前進するにつれて、外翻形状を呈するようになり、図３Ｅ'''に例示されているような凹状の閉塞部材４８４を形成する。閉塞部材４８４は、十分に外翻されると、設置部位である肉体管腔（例えば、鼻腔、後鼻孔、鼻咽頭、咽頭など）を閉塞し、凹状のウエル５０４を形成する。搬送吸引カテーテル４８６が凹状のウエル５０４の中に前進させられた結果、凹状のウエル５０４の内部に集まった血液、流体、または、堆積物は吸引ポート５０２を通して吸引され、更に、搬送吸引カテーテル４８６の遠位端を通して吸引される。

【0050】

図３Ｆないし図３Ｆ'''はまた別な実施形態を例示しており、この場合、閉塞部材５１０は管材５１２の端部に設置されている。閉塞部材５１０には弧状の上面が設けられており、閉塞部材５１０と、閉塞部材の設置部位である肉体管腔（例えば、鼻腔、後鼻孔、鼻

咽頭、咽頭など）の隣接壁との間の領域に、略Ｖ字状の環状収集空間５１８が設けられる。吸引管材５１６は管材５１２から環状の収集空間５１８の中まで延びて、環状の収集空間５１８に集まった血液、それ以外の流体、または、堆積物が吸引管材５１６を通して吸引され、更に、管材５１２の管腔を通して吸引されることで、閉塞部材５１０の上面に隣接して実質的に乾いた環境を維持する。閉塞部材５１０はバルーン、または、それ以外の、本件で説明されたような、または、当該技術で周知の好適な閉塞部材を備えていてもよい。図３Ｆ'ないし図３Ｆ'''に例示されているように、吸引管材５１６は、開放遠位端を設けた簡単な管材を備えていることもあれば、その代替例として、装置は、複数の側部開口５２０が遠位端に形成されている吸引管材５１６ａを組み入れ、かつ／または、吸引ポートまたは開口を覆う位置にスクリーンのような保護部材５２２が形成された吸引管５１６ｂを組み入れて、固形物質（例えば、血餅やそれ以外の堆積物など）が吸引ポートまたは開口を詰まらせることが無いようにしてもよい。

【0051】

図３Ｇは管材５３２に取り付けられた閉塞部材５３０を例示しており、この管材は閉塞部材の内部には突出していない湾曲した（例えば、略Ｕ字形の）遠位端が設けられている。管材５３２の遠位部には吸引開口５３６が形成されており、閉塞部材５３０の上面に隣接して集まる血液、流体、または、堆積物が管材５３２を通して吸引されるように図っている。閉塞部材がバルーンである実施形態では、バルーン／膨張管腔は管材５３２を通って延び、小型のバルーン膨張管材５３８がバルーンの内部に延びて入り、バルーンを膨張および収縮させることができる。任意で、或る実施形態では、別個の管材５４０が管材５３２を通って延び、更に、閉塞部材５３０を通過することで、閉塞部材５３０より遠位の領域に接近して、吸引、器具類の導入、或いは、それ以外の目的を達成する。

【0052】

図３Ｈはまた別な実施形態を例示しており、この場合、閉塞部材５４６は管材または長手の部材５５０に接続されており、拡張型の（例えば、トランペット型などの）遠位端を設けた吸引管材５４８が、閉塞部材の上面に隣接している領域から血液、流体、または、堆積物を吸引するために利用することができる。図３Ｈで分かるように、同図では、閉塞部材の上面が弧状であるとともに環状の収集空間が閉塞部材５４６の周囲を廻って設けられており、この場合、閉塞部材５４６は設置部位である解剖学的構造（例えば、鼻腔、後鼻孔、鼻咽頭、咽頭など）の壁と接合し、また、吸引管材５４８の拡張端５５２の寸法と形状は、閉塞部材５４６の弧状の上面を受容するとともに、環状の収集空間から血液、流体、または、堆積物を吸引するように設定されている。閉塞部材がバルーンである実施形態では、バルーン／膨張管腔は管材５４８を通って延び、小型のバルーン膨張管材はバルーンの内部へ延びて入り、バルーンを膨張および収縮させることができる。任意で、或る実施形態では、別個の管材５５０が管材５４８を通って延び、更に、閉塞部材５４６を通過して、閉塞部材５４６より遠位の領域に接近することができるようにすることで、吸引、器具類や液体注入装置の導入、或いは、それ以外の目的を達成する。

【0053】

図３Ｉは、閉塞部材５７０がタンポン（例えば、綿、ガーゼ、ヒドロゲル、または、それ以外の流体を吸収して所望の肉体管腔を閉塞する単一素材または複数素材の複合材など）のような吸収剤の塊を包含しているのを例示している。例示された特定の具体例では、閉塞部材は、湾曲した（例えば、略Ｕ字型の）先端部を設けた管材５７２に形成された開口５７８から外へ前進させられる。吸引開口５７６が管材５７２の遠位部に形成されて、閉塞部材５７０の上面に隣接して集まる血液、流体、または、堆積物が管材５７２を通して吸引されるようにしている。この処置が完了した後、または、閉塞がもはや不要となった後で、管材５７２および流体で濡れた閉塞部材５７０が体内から引き出されるが、このとき、閉塞部材５７０を管材５７２の中に後退させることはしない。任意で、遠位端開口部５７４が管材５７２に形成されてもよく、また、そのような遠位端開口部は開口部５７６と同じ管腔に接続されてもよいし、或いは、任意の遠位端開口部５７４に至る別個の管腔に接続されて、吸引、灌注、図５Ａないし図５Ｙ'''''に例示されているとともに後段

で説明されるもののような作業装置５８０の導入を図るように利用されてもよい。

【0054】

図３Ｊは、図２Ｏおよび図２Ｐに例示されているとともに後段で説明される装置の閉塞部材に類似している閉塞部材の実施形態を例示している。この実施形態では、閉塞部材６００は管材または長手の部材６０４に取り付けられており、また、吸引管材６０２は管材または長手部材６０４の上を前後に移動して、閉塞部材６００の上面に隣接している領域から、または、閉塞部材６００が設置されている肉体管腔のどこか別な部位から、血液、流体、または、堆積物を吸引することができる。閉塞部材６００がバルーンである実施形態では、バルーン／膨張管腔は管材または長手部材６０４を通って延びてバルーンに入り込み、バルーンを膨張および収縮させることができる。任意で、或る実施形態では、別個の管材６０６は管材または長手部材６０４を通って延びてから、更に閉塞部材６００を通過して、閉塞部材６００より遠位の領域に接近することで、吸引、器具類の導入、または、それ以外の目的を達成する。

【0055】

図３Ｋは、図２Ｑおよび図２Ｒに例示されているとともに後段で説明される装置に組み込まれた閉塞部材に類似している閉塞部材の実施形態を例示している。この実施形態では、閉塞部材６１０は管材または長手部材６１４に取り付けられており、１個以上の吸引開口６１６が形成された先細り状の吸引管材６１２が管材または長手部材６１４の上を前後に移動して、閉塞部材６１０の上面に隣接している領域から、または、閉塞部材６００が設置されている肉体管腔のどこか別な部位から、血液、流体、または、堆積物を吸引することができる。勿論、潅注溶液またはそれ以外の流体を上述のような開口６１６を介して搬送してもよいし、或いは、別個の潅注／膨張開口（単数または複数、図示せず）を通って開放している別個の潅注／膨張管腔を介して搬送してもよい。閉塞部材６１０がバルーンである実施形態では、バルーン／膨張管腔は管材または長手部材６１４を通って延びてバルーンの中に入り込み、バルーンを膨張および収縮させるようにしてもよい。任意で、或る実施形態では、別個の管材６１８は管材または長手部材６１４を通って延びてから、更に閉塞部材６１０を通過して、閉塞部材６１０より遠位の領域に接近することができるようにすることで、吸引、器具類の導入、または、それ以外の目的を達成する。

【0056】

図３Ｌ'ないし図３Ｌ''はまた別な閉塞管状装置１０００を例示しており、かかる装置は、外側管材１００２と、外側管材１００２の内部に同軸配置された内側管材１００４とを備えている。外方向に屈曲自在な領域１００６が外側管材１００２の壁の遠位端の付近に形成されている。外側管材１００２の遠位端は内側管材１００４に固着されている。通路１０１０は外側管材１００２と内側管材１００４の間に延在しており、開口１００８が外側管材１００２の壁に形成されている。定常動作では、この装置１０００は、初期的に図３Ｌ'に例示されている形状で配置されてから、所望の通路に挿入される。その後、外側管材１００２は静止状態のままで、内側管材１００４が近位方向に引き込まれることで、外向きに屈曲自在な領域１００６を図３Ｌ''に例示されているように外向きに突出させ、その結果、装置１０００の遠位部が設置されている肉体管腔を閉塞させる。通路１０１０に吸引を施すことで、外向きに突出した屈曲自在領域１００６の上面１００７に隣接している領域から血液、流体、または、それ以外の堆積物を除去することができる。この点で、開口１００８は外向きに突出した屈曲自在な領域１００６の上面１００７に近接して形成してもよいし、かつ／または、上面１００７に形成してもよい。

【0057】

図３Ｍ'および図３Ｍ''は、外側管材１０２２および内側管材１０２４を備えているまた別な閉塞管状装置１０２０を例示している、内側管材１０２４は外側管材１０２２の遠位端から外へ前進することができ、内側管材１０２４の遠位部は、内側管材から外へ出た際に拡張されて、図３Ｍ''に例示されているように、設置部位である肉体管腔または肉体通路を閉鎖する閉塞部材を形成する。血液、それ以外の流体、または、堆積物は外側管材１０２２の開放遠位端を通して、かつ／または、任意の側部開口１０２６を介して、閉塞

部材の上面に隣接している領域から吸引される。

【0058】

図４は、本発明の鼻咽頭閉塞気管内管材装置６２０が右鼻腔を通して気管に挿入されているの例示している。装置６２０は湾曲した管材６２２を備えているが、後閉塞部材６２６が管材６２２の遠位端またはその付近に設置されており、装置はまた、任意で、管材６２２の近位端付近に前閉塞部材（図４に点線で例示されている）が形成されている。気管内管材６２４は湾曲管材６２２を通って延び、更に後閉塞部材を通過して患者の気管に入る。任意で、帯部材６２８を気管内管材６２４に形成して、患者の気管内で正門の上の位置に第２の実質的に流体封鎖シールを設けるようにしてもよい。ハブ６３０が管材６２２の近位端に形成される。換気管材６３４がハブから延びて、気管内管材６２４に接続されるとともに、換気装置、麻酔装置、ｔ字型チューブ、救急車用バッグなどに装着することができる。後閉塞部材６２６がバルーンである実施形態では、後閉塞膨張／収縮コネクタ６３２はハブ６３０から延びており、また、後閉塞部材６２６の膨張／収縮を目的としえ管材６２２を通って延びる膨張／収縮管腔に接続されている。帯状の膨張／収縮コネクタ６３４もハブ６３０から延びて気管内管材６２４を通り、気管内管材帯部材６２８の膨張／収縮を達成する。任意で、吸引ポートおよび／または装置挿入用ポートがハブ６３０に形成されていれもよいが、これは、他の閉塞接近装置と関連して先に説明されたとおりである。定常動作では、この装置６２０は、後閉塞部材６２６が鼻中隔の後ろの（但し、通例は声門の上の）後鼻孔、鼻咽頭、または、咽頭を閉塞する位置まで挿入され、気管内管材６２４は、任意の帯部材が声門の上の位置で気管に設置された状態で、患者の気管の中に入り込む。

【0059】

Ｃ．　物質搬送用の作業装置、または、骨もしくは柔組織の切断用、削除用、改造用または拡張用の作業装置

本発明は、鼻腔、副鼻腔、鼻咽頭、または、中耳に挿入されて診断書地または治療処置を施すことができる多様な装置を提供する。このような装置は可撓性カテーテルまたは可撓性の棒状シャフトを通して搬送され、或いは、それらカテーテルやシャフトに組み込むことができる。このような可撓性の構造のおかげで、装置を搬送および設置して所望の診断処置または治療処置を施しながら、同時に、先行技術の方法論によれば剛性の視認用機器および剛性の器具類が原因で生じる恐れのあった他の組織への外傷を最小限に抑えることができる。このような装置が部分的に可撓性に富んでいる、或いは、装置に剛性部分と可撓性部分が設けられて、適切な領域まで制御および案内するのを容易にすることは、この取組みの範囲に入る。更に、処置の或る部分で、所望に応じて、このような装置を他の標準的な剛性装置（例えば、視認用機器など）と関連して、または、結合させて使用してもよい。

【0060】

また、全ての処置ではないにしても幾つかの処置では、このような作業装置（および／または、作業装置を搬送するために使用されるカテーテル）は、図２Ａないし図２Ｒに例示されているとともに先に説明されたような閉塞接近装置１０、１２、３００、３０１、４００、４３０の管腔を通して挿入することができる。上述のとおり、独立型ガイドカテーテルを通して、或いは、バルーンまたはそれ以外の閉塞部材を備えた、または、備えていない二次選択的なガイドカテーテルを通して、接近および閉塞をもっと小規模な領域に収束させるのが望ましいこともある。

【0061】

任意で、本件に記載されている作業装置およびガイドカテーテルのいずれもが、ガイドワイヤ上を伝って受容し、前進させられるような形状になっているが、これは、そうすることで装置が意図された目的達成のために作動させることができる場合に限られる。本件に記載されている特殊な具体例のうちの或るものはガイドワイヤを備えているが、ガイドワイヤを使用し、更に、ガイドワイヤ管腔を組み入れることは、ガイドワイヤまたはガイドワイヤ管腔が例示されている特殊な具体例のみに限定されるわけではないことが分かる

。本発明で使用されるガイドワイヤは、心臓病学の分野でよく知られているとおりに構築され、被覆される。これは、コイル、先細り状コアワイヤまたは非先細り状コアワイヤ、放射線不透過性先端部および／または放射線不透過性全長部、成形リボン、多様な硬度、PTFE（ポリテトラフルオロエチレン）、シリコーン、親水性皮膜、ポリマー皮膜などを使用することを含んでいる。本発明の範囲については、このようなワイヤは5センチから75センチの長さと0.005インチから0.050インチの外径という寸法を有している。

【0062】

また、図５Ａないし図５Ｙ’’’’’に例示されているとともにここに説明されている作業装置の幾つかは各種の組立体、構成要素、または、機構（例えば、回転式カッター、高周波電極、電気焼灼装置、物を回収する容器、寒冷外科手術装置、バルーン、ステント、放射性皮膜または物質溶離性皮膜、係蹄、電気解剖学的マッピング支援、光ファイバー、レンズおよびそれ以外の内視鏡装置、シール、止血弁など）を組み入れている。このような各種の構成要素および組立体の設計および構造は当該技術で従来公知である。このような設計および構成の無制限な具体例が次の米国特許に明示されている。すなわち、米国特許第5,722,984号（フィッシェルほか）、第5,775,327号（ランドルフほか）、第5,685,838号（ピータースほか）、第6,013,019号（フィッシェルほか）、第5,356,418号（シュツルマン）、第5,634,908号（ルーマス）、第5,255,679号（イムラン）、第6,048,299号（ホフマン）、第6,585,794号（ライトほか）、第6,503,185号（バクスマン）、第6,669,689号（レーマンほか）、第6,638,233号（コルヴィほか）、第5,026,384号（ファールほか）、第4,669,469号（ジフォードほか）、第6,685,648号（フラハーティほか）、第5,250,059号（アンドレアスほか）、第4,708,834号（ツノ）、第5,171,233号（アンプラッツ）、第6,468,297号（ウイリアムスほか）、および、第4,748,869号（ウオードル）に明示されている。

【0063】

図５Ａないし図５Ｙ’’’’’の具体例に示されているように、このような作業装置としては、各種のガイドカテーテル、物質搬送カテーテル、視認用機器類、注入装置、カッター、骨破壊装置、バルーンおよびそれ以外の拡張装置、レーザー／熱の搬送装置、固定具類、移植片、ステント、係蹄、生検器具、鉗子などが挙げられる。

【0064】

図５Ａは、可撓性のカテーテル本体部７２に側部開口７４が設けられた側部吸引切除カテーテル７０を例示している。カテーテル７２は、鼻孔、鼻腔、開口、小口、鼻腔の内部などの通路の中を前進させられてから、除去するべき物質（例えば、ポリープ、病巣、堆積物片、組織、血餅など）に隣接した位置に開口７４がくるように設置される。カテーテル７２の管腔を介して吸引が施され、開口７４を通してカテーテル７２の中へ物質を吸引することができる。或る事例では、回転式カッター、直線スライサー、ピンチャー、レーザービーム、電気外科手術用カッターなどのようなカッターをカテーテル７２の中に組み込んで、側部開口７４の中に置かれた組織または物質を剪断または離除するのを助けることができる。このカテーテルは、興味の対象である組織に対してカテーテルの開口部を押し付けることのできる偏向自在な先端部、または、湾曲した遠位端を組み入れていてもよい。更に、この装置７０では、任意の安定化バルーン（図５Ｍに例示されているとともに後段で説明されるものに類似している）がカテーテル７２の一方側に組み込まれて、興味の対象である組織に対して装置を押し付けることができるようにしてもよいし、また、超音波、ファイバーまたはディジタル光学系、光干渉断層撮像法（OCT）、高周波（RF）、電磁センサー、エミッターなどのような１個以上の実装画像化機能を備えていてもよい。

【0065】

図５Ｂは、１個以上の注入装置８０を有している可撓性カテーテルシャフト７８を設けた注入カテーテル７６を例示しており、この注入装置は、カテーテル７８の設置部位である肉体管腔の壁の中、または、壁の上に置かれた組織または物質の中へ進入させることができる。カテーテル７８は、注入装置をカテーテル本体部の中に後退させたままで、鼻孔、鼻腔、開口、小口、鼻腔の内部などのような通路を通して前進させられてから、診断物

質または治療物資が注入されるべき領域に隣接して設置される。その後、注入装置（単数または複数）が隣接組織または隣接物質の中に進入させられて、所望の物質が注入される。レーザー、ＲＦ、熱のようなエネルギーか、または、それ以外のエネルギーがこのような注入装置８０を通して搬送され、或いは、エネルギー放射移植片（ガンマ放射線種またはベータ放射線種など）もこのような注入装置８０を介して搬送されるが、その場合、移植片単独で搬送されるか、または、流体担体か、或いは、それ以外の、診断用物質または治療用物質（本件で規定されているような）などの物質と結合させて搬送されるか、いずれかである。この装置７６ばかりか、それ以外の作業装置や本発明の方法（本件で説明されている多様な移植可能な装置）が診断用物質または治療用物質を搬送するために利用することが出来る点は、注目に値する。本件で使用されるような「診断用物質または治療用物質」という語は広く解釈することにより、好適であればどのような薬剤、プロドラッグ、遺伝子治療試料、細胞、診断薬、造影剤または画像化用薬剤、生物製剤などでも含むものとする。例えば、細菌感染を治療または予防するのが望ましい応用例では、搬送される物質は薬学的に容認できる塩または抗細菌剤（例えば、抗生物質、抗ウイルス剤、アンチパラサイト剤、抗真菌剤など）の投与形式を含む。

【0066】

本発明で使用することのできる抗細菌剤の無制限な具体例として、アシクロビル、アマンタジン、アミノグリコシド（例えば、アミカシン、ゲンタマイシン、トブラマイシンなど）、アモキシシリン、アモキシシリン／クラブラン酸、アンフォテリシンＢ、アンピシリン、アンピシリン／スルバクタム、アトヴァクオーネ、アジスロマイシン、セファゾリン、セフェパイム、セフォタキシム、セフォテタン、セフォドキシム、セファタジディン、セフチゾキシム、セフトリアクソン、セフロキシム、セフロキシムアキセチル、セファレキシン、クロランフェニコル、クロトリマゾール、シプロフロキサシン、クラリスロマイシン、クリンダマイシン、ダプゾン、ジクロキサシリン、ドキシサイクリン、エリスロマイシン、フルコナゾール、フォスカルネット、ガンシクロビル、ガチフロキサシン、イミペネム／シラスタチン、イソニアジド、イトラコナゾール、ケトコナゾール、メトロニダゾール、ナフシリン、ニスタチン、ペニシリン、ペニシリンＧ、ペンタミジン、ピペラシリン／タゾバクタム、リファンピン、キヌプリスチン・ダルホプリスチン、チカルシリン／クラブラン酸、トリメトプリム／スルファメトキサゾール、バラシクロビル、バンコマイシン、マフェナイド、スルファジアジン銀、ムピロシン、ナイスタチン、トリアムシノロン／ナイスタチン、クロトリマゾール／ベタメタゾン、クロトリマゾール、ケトコナゾール、ブトコナゾール、ミコナゾール、チオコナゾール、微生物を破滅させる、または、微生物を無能にする界面活性剤様の化学物質（例えば、ノンオキシノル9、オクトキシル9、塩化ベンザルコニウム、メンフェゴール、N-ドコサノールなど）、標的細胞に微生物が付着するのを阻止し、かつ／または、感染症病原体の侵入を阻止する化学物質（例えば、PC-515（カラギーナン）、Pro-2000、および、デキストリン2サルフェートのような硫酸塩ポリマーまたはスルホン酸塩ポリマーなど）、細胞内でレトロウイルスが複製を行うのを阻止する抗レトロウイルス剤（例えば、PMPAゲルなど）、「植物性抗体」として周知の、植物から遺伝子工学的に生成される抗ウイルス性抗体のような病原体と闘う、遺伝子工学的に生成された抗体または自然発生する抗体、組織の状態を変化させて組織を病原体と敵対させる物質（上述のような病原体としては、粘膜pHを変える物質（例えば、緩衝ゲルや酸形成物質など）、非病原性バクテリアすなわち「役に立つ」バクテリア、または、それ以外の、過酸化水素またはそれ以外の病原性細菌（例えば、乳酸桿菌など）を殺傷またはその成長を抑止する物質を生成する微生物）などがある。この前後にリストに挙がった物質のいずれかに適用することができるように、このような物質は、各種の薬物放出装置、各種のポリマー、コラーゲン、ゲルのような分子構造物、移植可能な浸透性ポンプ装置などのうちのいずれか１個または複数個と組合わせて使うことで、一度設置されれば、より長期間にわたって物質を放出しつづけることができる。更に、このような物質はまた、後段で説明される移植可能な構造装置（ステント、拡張装置など）のいずれかと組合されて、移植片それ自体が感染し、堆積物で覆われ、または、封じ込められることがない

ようにし、或いは、粘膜中または粘膜下組織中の最適位置や骨の中に薬物を投与することができるようにする。本発明で使用することのできる移植可能な物質の搬送装置の具体例としては、図５Ｙ’ないし図５Ｙ’’’’’に例示されているとともに後段で説明されているものがある。

【0067】

これに加えて、または、これに代わる例として、炎症を治療し、または、炎症を防止することが望ましい応用例では、本発明で搬送される物質は多様なステロイドを含む。例えば、鼻腔内投与によって既に投薬されているコルチコステロイドを利用することができるが、その具体例としては、ベクロメタゾン（バンセナーゼ（Vancenase登録商標）またはベコナーゼ（Beconase登録商標））、フルニソリド（ネイザリド（Nasalide登録商標））、フルチカゾン（フロナーゼ（Flonase登録商標））、トリアムシノロン（ナザコート（Nasacort登録商標））、モメタゾン（ナゾネクス（Nasonex登録商標））などがある。また、これら以外の、本発明で利用することのできるステロイドとしてはアクロメタゾン、デソニド、ヒドロコルチゾン、ベタメタゾン、クロコルトロン、デソキシメタゾン、フルオシノロン、フルランドレノリド、モメタゾン、プレドニカルベート、アムシノニド、デソキシメタゾン、ジフロラゾン、フルオシノロン、フルオシノニド、ハルシノニド、クロベタゾル、増強ベタメタゾン、ジフロラゾン、ハロベータゾル、プレドニゾン、デキサメタゾン、メチルプレドニソロンなどが挙げられるが、これらに限定されない。

【0068】

これに加えて、または、これに代わる例として、アレルギー反応または免疫反応を治療または阻止するのが望ましいような応用例の或るものでは、本発明で搬送される物質は、ａ）人体に適応するように改良された抗サイトカイン抗体、抗サイトカイン受容体抗体、組換え型の（遺伝子組換えの結果として得られた新細胞）拮抗薬、または、可溶性レセプタのような多様なサイトカイン阻害剤、ｂ）ザフィルルカスト、モンテルカスト、ザイリュートンなどのような多様なリューコトリエン変更因子、ｃ）オマリズマブ（以前はrhuMab-E25と呼ばれていた抗免疫グロブリンＥ単クローン性抗体）などの免疫グロブリンＥ（IgE）阻害剤や、分泌性白血球プロテアーゼ抑制剤などが挙げられる。

【0069】

これに加えて、または、これに代わる例として、粘膜組織を収縮させること、鬱血を緩和すること、または、止血を実施することが望ましいような応用例の或るものについては、本発明で搬送される物質としては、鬱血除去または止血を目的とした多様な血管収縮神経薬を含み、その具体例としては、偽性エフェドリン、キシロメタゾリン、オキシメタゾリン、フェニレフリン、エピネフリンなどが挙げられるが、これらに限定されない。

【0070】

これに加えて、または、これに代わる例として、粘液の流れを促進するのが望ましいような応用例の或るものでは、本発明で搬送される物質としては、粘液または類粘分泌液の粘性または粘稠度を修正する多様な粘液溶解薬またはそれ以外の薬剤を含み、その具体例としては、アセチルシステイン（ミューコマイスト（Mucomyst商標）、ミューコシル（Mucosil商標）など）とグアイフェネシンなどが挙げられるが、これらに限定されない。

【0071】

これに加えて、または、これに代わる例として、ヒスタミン放出を阻止または抑止するのが望ましいような応用例の或るものでは、本発明で搬送される物質としては、多様なマスト細胞安定剤、または、ヒスタミンの放出を阻止する薬剤を含み、例えば、クロモリン（例えば、ネイザルクロム（Nasal Chrom登録商標）やネドクロミルなどがある。

【0072】

これに加えて、または、これに代わる例として、ヒスタミンの効果を阻止または抑制するのが望ましいような応用例の或るものでは、本発明で搬送される物質としては多様な抗ヒスタミン剤を含んでおり、例えば、アゼラスチン（例えば、アスチリン（Astylin登録商標））、ジフェニドラミン、ロラタジンなどがある。

【0073】

これに加えて、または、これに代わる例として、硬骨または軟骨を溶解し、分解し、切断し、破断し、または、改造するのが望ましいような実施形態の或るものでは、本発明で搬送される物質としては、硬骨および／または軟骨を弱化または変化させることで、硬骨または軟骨の改造、再成形、破断、または、除去を行う本発明の他の処置を容易にする物質が含まれる。このような薬剤の一例を挙げるならば、例えばEDTAなどのような、改造または変形されるべき骨の領域の隣に注入することができる、または、かかる領域の隣に物質搬送移植片で搬送することのできるカルシウムキレート剤がある。また別な例として挙げるならば、骨分解細胞を構成要素に含む、または、骨分解細胞を含有する、オステオクラストなどのような製剤がある。これ以外の具体例としては、骨または軟骨を軟化させ、または、その成分を破壊することのできる多様な酵素または物資が含まれるが、例えば、コラゲナーゼ（CGN）、トリプシン、トリプシン／EDTA、ヒアルロニダーゼ、トシルリシルクロロメタン（TLCM）などがある。

【0074】

これに加えて、または、これに代わる例として、或る応用例では、本発明で搬送される物質としては、鼻炎、鼻ポリープ、鼻の炎症、それ以外の耳、鼻、喉の疾患を治療するために使用される、上記以外の分類の物質を含み、その具体例には、鼻汁を脱水させる傾向にある抗コリン作用薬で、例えば、イプラトロピウム（アトロヴェント・ネイザル（Atrovent Nasal登録商標）などのほかに、これ以外の本件に挙げられない多数の薬剤があるが、これらに限定されない。

【0075】

これに加えて、または、これに代わる例として、ポリープまたは浮腫組織から流体を抜き取るのが望ましいような応用例の或るものでは、本発明で搬送される物質としては、フロセミドのような局在作用性または局所作用性の利尿剤、および／または、塩化ナトリウムゲルまたはそれ以外の、組織から水分を抜き取る塩製剤のような超浸透性薬剤、或いは、粘液の浸透性含有物を直接的または間接的に変化させてより多くの水分を組織から外に出すことでポリープをその部位で直接的に収縮させてしまう物質が挙げられる。

【0076】

これに加えて、または、これに代わる例として、腫瘍または癌病巣を治療するのが望ましいような応用例の或るものでは、本発明で搬送される物質としては、抗腫瘍薬（例えば、癌化学療法薬、生物学的反応変更剤、血管新生抑止剤、ホルモン受容体遮断薬、寒冷治療剤、または、それ以外の、新生組織形成または腫瘍形成を破壊または阻害する薬剤など）があるが、その具体例には、アルキル化薬またはそれ以外の、癌細胞のDNAを攻撃することにより癌細胞を直接死滅させる薬剤（例えば、シクロフォスファミド、イソホスファミドなど）、ナイトロソーリアス（nitrosoureas）またはそれ以外の、細胞のDNA修復に必要な変化を阻害することにより癌細胞を死滅させる薬剤（例えば、カルムスチン（BCNU）、ロムスチン（CCNU）など）、代謝拮抗薬およびそれ以外の、或る細胞機能（通常はDNA合成）に干渉することにより癌細胞の成長を遮断する薬剤（例えば、6メルカプトプリン、5フルオロウラシル（5FU）など）、抗腫瘍抗生物質およびそれ以外の、DNAを結合するか介在させるかして、RNA合成を阻害することにより作用する化合物（例えば、ドクソルビシン、ダウノルビシン、エピルビシン、イダルビシン、ミトマイシンＣ、ブレオマイシンなど）、植物（ツルニチソウ属ヴィンカ）アルカロイドおよびそれ以外の植物由来の抗腫瘍薬（例えば、ビンクリスチン、ビンブラスチンなど）、ステロイドホルモン、ホルモン阻害薬、ホルモン受容体拮抗薬およびそれ以外の、ホルモン反応性癌の成長に影響を与える薬剤（例えば、タモキシフェン、ヘルセプチン、アミノグルテサミド（aminoglutethamide）およびホルメスタンのようなアロマターゼ阻害薬、レトロゾールおよびアナストラゾールのようなトリアゾール阻害薬、エクセメスタンのようなステロイド阻害剤など）、抗血管新生性タンパク質、小型分子の遺伝子治療薬、および／または、それ以外の、腫瘍の血管新生または血管形成を阻害する薬剤（例えば、メチル１、メチル２、サリドマイドなど）、ベバシズマブ（アヴァスチン）、スクアラミン、エンドスタチン、アンジオスタチン、アンジオザイム、AE-941（ネオバスタット）、CC-5013（レビミド）、medi-522

（ヴィタクシン）、2-メトキシエストラジオール（2ME2、パンゼム）、カルボキシアミドトリアゾール（CAI）、コンブレタスタチンA4プロドラッグ（CA4P）、SU6668、SU11248、BMS-275291、COL3、EMD121974、IMC-1C11、IM862、TNP-470、セレコキシブ（セレブレックス）、ロフェコキシブ（ヴィオックス）、インターフェロンアルファ、インタールーキン-12（IL-12）または引例に挙げることで本件に組み込まれているのが明らかであるサイエンス（Science）第289巻の1197頁から1201頁（2000年8月17日刊行）で識別される化合物のうちのいずれか、生物学的反応変更剤（例えば、インターフェロン、カルメッテ・ゲリンのバチルス培養菌（BCG）、モノクロナル抗体、インタールーケン-2、顆粒白血球培養群刺激因子（GCSF）など）、PGDF受容体拮抗剤、ヘルセプチン、アスパラギナーゼ、ブスルファン、カルボプラチン、シスプラチン、カルムスチン、クロランブシル、シタラビン、ダカルバジン、エトポシド、フルカルバジン（flucarbazine）、フルオロウラシル、ゲムシタビン、ハイドロオキシウレア、イホスファミド、イリノテカン、ロムスチン、メルファラン、メルカプトプリン、メソトレキセート、チオグアニン、チオテパ、トミュデックス、トポテカン、トレオスルファン、ビンブラスチン、ビンクリスチン、ミトアジトロン（mitoazitrone）、オキサリプラチン、プロカルバジン、ストレプトシン、タクソル、タキソテール、上記のような化合物の類似物／同種物および派生物、これらに加えて、ここに挙がっていない上記以外の抗腫瘍薬などがある。

【0077】

これに加えて、または、これに代わる例として、新しい細胞を成長させるか、または、既存の細胞を改変するのが望ましいような応用例の或るものでは、本発明で搬送される物質としては、各種の細胞（粘膜細胞、線維芽細胞、幹細胞、遺伝子工学により生成された細胞など）のほかに、遺伝子、プラスミドやアデノウイルスベクターのような遺伝子担体、遺伝子と一緒に注入されて抗炎症物質の遺伝子コードを指定する裸のDNAやmRNAなどと、上述のように、望ましい場合には骨を改変または軟化させる破骨細胞が含まれる。

【0078】

装置および／または物質放出機能と組合わせることに加えて、または、それに代わる例として、粘液の流動経路（すなわち、前頭洞または篩骨細胞）の上流側の特殊な部位に装置を設置するのが理想的である場合がある。これにより、配置する薬物放出装置の個数が少なく済ませることができるとともに、下流側の組織全体に所望の薬物を「浴びさせる」ことができる。粘液を薬物の担体としてこのように利用するのが理想的であるが、特に、粘液が保持される領域で薬物の濃度を最高にすることができる一方で、粘液の流動が良好な非罹患領域が薬物の影響をそれほど受けなくて済むからである。これは、慢性副鼻腔炎や腫瘍など、そのような特殊な部位により高い濃度の薬剤を運ぶことで治療の恩恵が高まるような場合には特に有用となる。このような事例では全て、局所搬送することにより、薬物が全身に与える衝撃の度合いを遥かに軽減することができる。更に、薬物の組成や搬送システムの構成を設定するにあたり、その組成や構成が粘液に対する親和性をあまり堅牢でないように保つことで、組成や構成が流動中にむらなく分配されるようにするのが理想的である場合もある。また、或る応用例では、薬剤ではなくむしろ、塩のような溶質やそれ以外の粘液性可溶物質を或る部位に置くことで、粘液が物質に接触し、或る量の物質が粘液中に溶解することで、粘液の或る特性（例えば、pH、浸透性など）を変化させることができる。或る事例では、この技術を利用して粘液を超浸透的にすることで、流動する粘液がポリープや浮腫粘膜組織などから水分を抜き取り、脱水治療効果を供与することができる。

【0079】

局所搬送を目的として副鼻腔内の変化に影響を及ぼす物質に加えて、または、それに代わる例として、鼻腔が嗅覚神経系への特殊な接近路となり、延いては、脳への特殊な接近路となる。本件に記載されている装置および方法のいずれかを利用して、脳に物質を搬送したり、嗅覚神経系の機能を変えることができる。このような具体例として、エネルギーの搬送、装置および／または物質の配置、物質搬送移植片の設置により、嗅覚を妨げ、または、嗅覚を変化させ、食欲を抑え、或いは、別な方法で肥満治療を実施し、癲癇を抑え

（例えば、フェノバルビタールまたはメフォバルビタールのようなバルビツール剤、カルバマゼピンやオクスカルバゼピンなどのイミノスチルベン、エチルスクシミドなどのサクシンイミド、バルプロイック酸、クロナゼパン、クロラゼペート、ジアゼパン、ロラゼパン、ガバペンジン、ラモトリジン、アセタゾラミド、フェルバメート、レベチラセタム、チアガビン、トピラメート、ゾニサミドなどのベンゾジアゼピン）、性格または心的障害を治療し（例えば、抗うつ剤、抗不安剤、抗精神病薬など）、慢性的な痛みを抑え、パーキンソン氏病を治療し（例えば、ブロモクリプチン、ペルゴリド、ロピニロール、プラミペキソールなどのドーパミン受容体作用薬、レボドーパのようなドーパミン前駆物質、トルカポンやエンタカポンなどのCOMT阻害剤、セレギリン、トリヘキシフェニジル、ベンズトロピン、ジフェンヒドラミンなどのムスカリン受容体拮抗剤）、アルツハイマー病、ハンティントン病、または、それ以外の痴呆症、認知障害を、慢性成人病を治療する（例えば、タクリン、ドネペジル、リバスチグミン、ガランタミン、フルオキセチン、カルバマゼピン、クロザピン、クロナゼパン、および、ベータアミロイドや血小板などの形成を阻害するタンパク質または遺伝子治療薬）ものが挙げられる。

【0080】

図５Ｃは、組織、硬骨、軟骨、または、それ以外の物体を貫いて掘削し、孔を穿ち、研削し、または、切除するためのドリル、螺旋錐、または、バリ８６を設けた回転式シャフト８４を備えている装置８２を例示している。この装置８２は図示のように配備されてもよいし、或いはその代わりに、装置８２は小さい粘膜切開部を通して挿入されて、粘膜内層の下の硬骨または軟骨を除去し、あるいは、そこに穿孔を設ける間、上に位置する粘膜内層を保護することができる。

【0081】

図５Ｄは、上述のような診断用物質または治療用物質を搬送するための支援式注入カテーテル装置８８を例示している。この装置８８は可撓性のカテーテル９０を備えており、カテーテルには画像化装置９６が搭載されているとともに、カテーテル９０から前進させることができるとともにカテーテルのカテーテルの中に後退させることができる注入装置９２が設けられている。この画像化装置９６を利用することで、物質を置くべき標的部位９４を画像化することができるとともに、注入装置９２がカテーテル８８から進み出た際に、注入装置が所望の標的部位９４まで移動してゆけるようにカテーテル８８を配向させることができる。このようなカテーテル８８の具体例は米国特許第6,195 ,225号（マッカウアー）、第6,544,230号（フラハーティーほか）、第6,375,615号（フラハーティーほか）、第6,302,875号（マッカウアーほか）、第6,190,353号（マッカウアーほか）、および、第6,685,648号（フラハーティーほか）に記載されており、これら特許の全体的内容は引例に挙げることにより本件の一部をなすことは明らかである。

【0082】

図５Ｅは、バルーン１０２を搭載した可撓性カテーテル１００を備えているカテーテル装置９８を例示している。カテーテル装置９８は、バルーン１０２を収縮させたままで、鼻孔、鼻腔、鼻道、小口、副鼻腔の内部などの通路の中へ進入させられてから位置決めされ、収縮状態のバルーン１０２を小口内、通路内、組織または物体に隣接した位置に据え置くが、それらの部位をバルーンが後ほど拡張させ、膨張させ、或いは、与圧する（例えば、止血を目的として圧迫力を付与するために）ことになる。その後、バルーン１０２を膨張させて、上述の小口、通路、組織、または、物体を拡張させ、膨張させ、或いは、圧迫する。その後、バルーン１０２は収縮されて、装置９８が取り出される。このバルーン１０２にはまた、薬剤または物質が皮膜され、含浸され、それ以外の態様で備えられるが、このような薬剤や物質はバルーンから溶出して隣接組織に入る（例えば、隣接組織を薬剤に浸し、或いは、組織に熱エネルギーまたはその他のエネルギーを放射して、バルーン１０２と接触している組織を収縮させるため）。これに代わる例として、或る実施形態では、バルーン１０２には複数の開口または穴が設けられて、これらの開口または穴を通して物質を搬送し、時には圧力下で搬送することで、バルーンに隣接している組織に物質を浴びせ、或いは、組織内に物質を拡散させることができる。この代替例として、或る実施

形態では、放射性線種、ネジ、リボン、気体、液体などをカテーテルシャフト１００、バルーン１０２、または、完全に別個のカテーテル本体部の中へ或る期間にわたって進入させて、隣接組織を被爆させ、所望の診断効果または所望の治療効果（例えば、組織収縮など）を達成することができる。

【0083】

図５Ｆは、１個以上のカッター刃１１０が搭載されたバルーン１０８を有している可撓性カテーテル１０６を備えているバルーン／カッターカテーテル装置１０４を例示している。装置１０４は、バルーン１０８を収縮させたままで、鼻孔、鼻腔、鼻道、小口、副鼻腔の内部などの通路に進入させられてから位置決めされ、収縮状態のバルーン１０８を小口内、通路内、組織または物体に隣接した位置に据え置くが、それらの部位をバルーンが後ほど拡張させ、膨張させ、或いは、与圧することになり、また、そのような部位には１個以上の切り口または切り込みが設けられる（例えば、バルーン拡張中に組織の破壊を抑制する、組織外傷を最小限に抑える等の目的で）のが望ましい。その後、バルーン１０８を膨張させて、上述の小口、通路、組織、または、物体を拡張させ、膨張させ、或いは、圧迫し、組織または物体に隣接した部位にカッター刃（単数または複数）１１０に切り口をつけさせる。その後、バルーン１０８は収縮されて、装置１０４が取り出される。このような刃にはまた、モノポーラまたはバイポーラの高周波エネルギーが投入され、或いは、単に熱加熱されることで組織を止血状態のまま切断することができるようにするうえに、膠原線維またはその他の接続組織タンパク質を収縮させ、或いは、軟骨を改造または軟化させるなどの目的を達成することができるようにする。

【0084】

図５Ｇ’ないし図５Ｇ’’’は、圧力により拡張自在となるステント１６６の搬送装置１６０および搬送方法を例示している。この装置１６０は、バルーン１６４が搭載された可撓性のカテーテル１６２を備えている。初期状態では、図５Ｇ’に例示されているように、バルーン１６４は収縮状態にあり、ステント１６６は放射方向に与圧されて収縮したバルーン１６４の周囲で折り畳まれた形状を呈している。カテーテル１６２は、バルーン１６４を収縮させたままで、また、折り畳まれたステント１６６を搭載したままで、鼻孔、鼻腔、鼻道、小口、副鼻腔の内部のような、後でステント移植されることになる部位などの通路に進入させられる。その後、バルーン１６４は膨張させられてステントを拡張させて周囲組織に摩擦係合する寸法にし、図５Ｇ’’に例示されているように適所にステント１６６を保持する。或る事例では、この処置は通路（例えば、鼻の小口、鼻道など）を拡大する目的で実施され、更に、ステント１６６は通路を所望どおりに拡大させるのに十分なだけの直径まで拡張させられたうえに、更に、ステントが足場機能を果たして、通路を上述のような拡大状態のまま維持する。ステント１６６が十分に拡張されて移植されてしまってから、バルーン１６４が収縮させられて、図５Ｇ’’’に例示されているようにカテーテル１６２が取り出される。或る応用例では、ステントは本件で規定されているような診断物質または治療物質を含有していてもよく、更に、そのような物質はステント１６６から溶離して周囲組織に浸透し、所望の診断効果または治療効果をもたらすようにしてもよい。或る事例では、ステント１６６は恒久移植される。その他の事例では、ステントは暫定移植される。ステント１６６が恒久移植される事例では、ステント１６６はその回収が行われる第２回目の処置で取り出すことができ、或いは、ステント１６６は、移植後所望の期間のうちに分解したり吸収されてしまうような、生体吸収可能な物質または生体分解性物質から作成されてもよい。副鼻腔の小口の内部にステントを設置しなければならないような或る事例では、ステントおよび／またはバルーンは特殊な形状に設定されることで、ステント１６６を所望の位置に据え付けるのを容易にし、かつ／または、そのように据え付けさせて、ステント１６６が滑落するという望ましくない事態を防止することができる。例えば、ステント１６６および／またはバルーン１６４は、その中間付近に環状の溝が形成されていてもよいし、或いは、砂時計またはヴェンチユリ計のような形状にされて、ステント１６６が長軸線方向に滑落することなく、小口または開口の内側にステント１６６を容易に載置させることができるようにしてもよい。場合によっては、繋留紐または縫

合糸をステント１６６に取り付けたままにして、開業医の診察室やそれ以外の好適な施設でステント１６６を簡単に取り外せるようにするのが望ましいこともある。場合によっては、処置によって意図的に実際に骨を砕くこともある（例えば、ステントに副鼻腔の小口を拡張または拡大させたい場合など）。従って、バルーン１６４はポリマー材から作成することができるが、その具体例としては、可撓性の塩化ポリビニル（PVC）、ポリエチレンテレフタレート（PET）、架橋結合型ポリエチレン、ポリエステル、ポリアミド、ポリオレフィン、ポリウレタン、シリコーンなどがあるが、但し、これらに限定されない。多様なバルーン特性（強度、可撓性、厚みなど）を修正する手段として、ブレンディング、皮膜積層、ミキシング、同時押出成形、線照射、その他のバルーン材（一種類または複数種類）を工学的に加工成形する手段が挙げられるが、これらに限定されない。これは、周囲の解剖学的構造に一致させることができる伸展性の高いバルーンを使用することを斟酌したものであり、或いは、周囲の構造（例えば、骨など）を変形させたり破壊することができる非伸展性バルーンの使用を斟酌している。

【0085】

図５Ｈは、弧状の支柱部材２１４が装着された可撓性シャフト２１０（例えば、カテーテルまたは中実シャフトなど）を備えている電気外科手術装置２０８を例示している。電極２１６が支柱部材２１４に設置されている。或る事例では、支柱部材２１４は一定の形状を呈しており、また別な事例では、支柱部材２１４は折り畳み自在で拡張自在である。動作中は、装置２０８が鼻孔、鼻腔、鼻道、小口、副鼻腔の内部などの通路に進入させられる。その後、電極２１６に電流が印加されて、支柱２１４に隣接している組織が焼灼または加熱される。電極２１６はバイポーラ、モノポーラ、または、ガスアークまたはプラズマアークのような上記以外の好適なエネルギー形態で励起される。これに加えて、検知素子をカテーテルおよび／または支柱部材に装着して、カテーテルおよび／または周囲組織の多様なパラメータ（例えば、温度など）を監視することもできる。モノポーラ電極が使用されている場合は、当該技術で周知のプロセスおよび技術に従って、別個のアンテナ電極（図示せず）が患者の肉体に付与される。

【0086】

図５Ｉは装置２１８を例示しており、この装置は、後でその設置部位となる通路または肉体空洞に隣接している組織に向けて、物質（例えば、低温物質、診断薬、または、治療薬など）の流れ２２２またはエネルギー（例えば、レーザー光、赤外線光など）の流れ２２２を伝搬する。この装置は可撓性のカテーテル２２０を備えており、カテーテルの遠位端またはその付近には出口開口またはレンズが設けられて、このカテーテルの中を通して物質やエネルギーの流れが伝搬される。このような装置を使って、ポリープまたはそれ以外の組織を低温凍結したり、鼻介骨またはそれ以外の組織にレーザーエネルギーを伝搬して組織を融除したり、組織を収縮させることになる温度まで組織を加熱することができる。

【0087】

図５Ｊは、鼻孔、鼻腔、鼻道、小口、副鼻腔の内部などのような通路の内部に移植することができて、硬骨、軟骨、柔組織などの圧力を加えるようにした移植可能な加圧装置２２４を例示している。解剖学的構造に圧力を加えるのが望ましい状況の具体例としては、骨折部に添え木を施したり、骨折部を接合するのが望ましい場合、硬骨、軟骨、柔組織、または、それ以外の解剖学低構造体を改造したり、徐々に元の位置に戻したり、整形するのが望ましい場合などがある。このような移植可能な装置２２４は加圧部材２２８と２個以上のプレート部材２２６から構成されている。装置２２４は初期状態では折り畳まれた形状に拘束されて、この場合、加圧部材２２８は圧縮状態または折畳み状態を呈したまま、与圧するのが望ましい解剖学的構造が存在する鼻孔、鼻腔、鼻道、小口、副鼻腔の内部などのような通路に装置２２４が進入させられる。装置２２４が所望の位置に至ると、加圧部材２２８が拡張または拡大させられて、プレート部材２２６に外向きの圧力を与えるとともに、プレート部材２２６の設置により押圧される解剖学的構造にも圧力が及ぼされる。或る実施形態では、加圧部材はバネを備えている。これ以外の実施形態では、加圧部

材はラチェット、油圧シリンダー、または、それ以外の機械装置であって、プレート部材２２６に所望量の圧力を生じるように調節することができるものを備えているようにしてもよい。或る応用例では、加圧部材２２８の調節は正常位置（すなわち、装置が体内に移植された状態）で行うことができ、操作者は関心のある解剖学的構造に与える圧力の量を周期的に変動させることで（例えば、操作者がラチェットの位置を変えたり、油圧シリンダーに流体を付加すること等）、歯科矯正術中に行われるのと同じ態様で、解剖学的構造を徐々に改造したり、移動させたりすることができる。従って、この加圧部材２２４は、副鼻腔の小口を拡大したり、鼻中隔を真っ直ぐにするという意図の下で行われる処置を含め、多様な処置について広範な適用可能性を示すものである。

【0088】

図５Ｋないし図５Ｋ’および図５Ｌは、可撓性の外側管材７０２と外側管材の内側に同軸かつ回転自在に取り付けられた可撓性の内側管材７０４とを有している前方回転式切断カテーテル装置７００を例示している。１個以上のベアリング７０８（例えば、螺旋状のベアリングまたは一連の個別の円筒状ベアリングなど）が、図示のように、外側管材７０２と内側管材７０４の間に配置されている。これに代わる例として、互いに向かい合う管面の一方または両方が、シリコーンまたはPTFEのような潤滑性物質から作成され、かかる物質で内面を覆われ、または、かかる物質で皮膜されるなどして、容易に運動できるようにしている。回転式カッター７０６が内側管材７０４の遠位端に設置される。動作中は、図５Ｋ’に例示されているように、装置７００は鼻孔、鼻腔、鼻道、小口、副鼻腔の内部などのような通路に通されて、装置７００の遠位端の設置位置である、ポリープＰのような何らかの障害物の真後ろの位置まで進入させられる。装置が障害物Ｐの中へ進入させられ、かつ／または、内側管材７０４の管腔を通して、かつ／または、外側管材７０２の管腔を通して吸引が施されて、障害物Ｐを回転式カッター７０６と接触状態になるまで引き寄せると、内側管材７０４とそのカッター７０６が回転させられる。この実施形態は回転式カッター７０６を例示しているが、これ以外に、レーザー、高周波カッター、機械カッターなどのような、多様な種類のカッターを代用とすることができるのが分かる。障害物Ｐが回転式カッター７０６によって剪断されると、障害物Ｐまたはその細片が内側管材７０４の管腔を通して吸引され、かつ／または、外側管腔７０２の管腔を通して吸引される。或る適用例では、図５Ｌに例示されているように、視認用機器またはガイドワイヤ７１０が内側管材の管腔を通って延びて、障害物Ｐを取り出す前段階における装置７００の進入と位置決めを容易にすることができる。

【0089】

図５Ｍおよび図５Ｎは、可撓性の外側管材７１８と、外側管材の内側にこれと同軸かつ回転自在に載置された可撓性の内側管材７２２とを備えている側部回転式切断装置７１４を例示している。１個以上のベアリング７３０（例えば、螺旋状ベアリングまたは一連の個別の円筒状ベアリングなど）が、図示のように、外側管材７１８と内側管材７２２の間に配置される。これに代わる例として、互いに向かい合う管材面の一方または両方がシリコーンまたはPTFEのような潤滑性物質から作成され、かかる物質で内面を覆われ、または、かかる物質で皮膜されるなどして、容易に運動できるようにしている。回転式カッター７２４が内側管材７２２の遠位端に設置される。側面開口７２０が外側管材７１８に形成され、カッター７２４は側面開口７２０より近位に設置される。引張り部材７２８が内側管材７２２を通って延びて、牽引ヘッド７２６に装着されている。動作中は、側面開口７２０がポリープ、組織、または、それ以外の除去されるべき障害物の傍にくる位置まで、装置７１４が進入させられ、かつ／または、トルクを付与される。内側管材７２２とそのカッター７２４が回転させられる。或る応用例では、内側管材７２２を通して、かつ／または、外側管材７１８の管腔を通して吸引が施され、側面開口７２０の中に障害物を引き寄せる。引張り部材７２８が近位方向に引張られ、牽引ヘッド７２６を後退させ、すなわち、障害物を引き寄せさせて回転カッター７２４と接触させる。障害物が回転式カッターによって剪断されると、剪断された障害物またはその細片が内側管材７２２の管腔を通して吸引され、かつ／または、外側管腔７１８の管腔を通して吸引される。次いで、引張り

部材７２８は遠位方向に前進させられて、図５Ｍおよび図５Ｎに例示されているように、牽引ヘッド７２６を元の位置へ戻す。任意のバルーン７１９またはそれ以外の左右横方向に拡張可能な部材がカテーテル７１８の側面の側面開口７２０とは反対側に配置され、側面開口７２０を管腔壁に押し付け、すなわち、除去されるべきポリープまたはそれ以外の組織の方に押しやる。これに代わる例として、偏向自在な先端部または湾曲して、カテーテルの側面開口を管腔壁に押し付けたり、除去されるべきポリープまたはそれ以外の組織の法に押しやることのできる遠位端をカテーテルが組込んでいるようにしてもよい。図５Ｎを仔細に見ると、図５Ｍに例示されている装置７１４の構成要素を全て有していて、しかも、副次管腔７３１を備えている側部回転式切断装置７１４ａが例示されている。視認用機器は副次管腔７３１の内部に恒久設置されるか、或いは、副次管腔７３１の中に（または、そこを通して）暫定挿入されて、操作者が側面開口７２０の付近の領域を視認できるようにするとともに、装置７１４ａの進入および設置を容易にするようにしてもよい。また、副次管腔７３１はガイドワイヤ管腔として機能して、ガイドワイヤの上を伝って装置７１４ａを前進させることができるようにしてもよい。

【0090】

本明細書中に記載されている装置のいずれも、その構造内に次に挙げる装置のいずれか１つを備えるように更に変更を加えることができるものと理解するべきである。すなわち、その装置とは、電磁測位センサー／検出装置（バイオセンス／JNJ、サージカル・ナビゲーション・テクノロジーズ／メドトロニック、カリプソ・メディカル）、高周波センサー／送信機、磁気方位定位装置（ステレオアクシス・インコーポレーティッド）、熱センサー、放射線不透過性成分、放射能検出エミッタ／センサー、超音波スキャナー／送信機／受信機、ドップラースキャナー、電気刺激装置、光ファイバー、ディジタル光学系、或る物質の在・不在に反応し、よって、菌類、微生物、ウイルス、血液、異常粘液内容物、癌細胞、過剰摂取した薬物、遺伝子異常、代謝副産物などの存在を診断する能力を有している局所診断チップ含有素子などである。

【0091】

本件特許出願に記載されている装置のいずれかまたは全部が内視鏡を組込んでいてもよいし、或いは、内視鏡と関連して使用されてもよい。このような内視鏡は、通例、視認用機器によって視認されるべき領域に光を投じるための光伝達用の光ファイバーと、視認用機器によって受信された画像を患者の体外に設置された接眼装置または監視装置に伝搬するための画像伝達用の光ファイバーを備えているものと、更に理解するべきである。このような、本発明の作業装置に組込むのに好適な内視鏡の具体例としては、米国特許第4,708,434号、第4,919,112号、第5,127,393号、第5,519,532号、第5,171,233号、第5,549,542号、第6,551,239号、および、第6,572,538号に記載されているもののほかに、米国特許出願公開第2001/0029317A1号に記載されているものがあり、これら特許および特許出願の内容全体は、引例に挙げることにより本件の一部をなしているのは明らかである。

【0092】

本発明のカテーテルまたは長手の可撓性装置のいずれも、耐性、可撓性、硬度、長さ、プロファイル、潤滑性、追従自在性、操舵自在性、回転性能、偏向性能、誘導性能、放射線不透過性などの（これらに限定されないが）性能特性に大きな影響を及ぼす各種の設計要素を含んでいてもよいものと、更に理解するべきである。設計要素には、多様なポリマーおよび金属を使用すること、多様な硬度計測可能素材を使用して装置に沿って所望の可撓性勾配を確立すること、多様な素材を混和させ、混合し、皮膜積層し、同時押出成形処理に付すこと等、２つ以上の表面が相関的に運動する場合に（例えば、ガイドワイヤまたは器具管腔、管腔内の屈撓腱など）ベアリングまたは潤滑皮膜もしくは潤滑剤（例えば、シリコーン、PTFE、パリレン、ポリエチレンなど）を使用すること、編組またはバネを使用して装置のトルク制御を高めること、各種素材（例えば、バリウム、タンタルなど）を使用してポリマーの放射線不透過性を増大させること、各種構成要素（例えば、張力ストラップ、張力ワイヤ、ニチノールなどの形状記憶合金）を使用してカテーテルの多様な区分を予想どおりに偏向させることができるようにすることなどが挙げられるが、これらに

限定されない。

【0093】

カテーテル、視認用機器、長手の作業装置、本特許出願に開示されている上記以外の装置のいずれも、操舵自在にされ、或いは、意図的に屈撓自在にされるが、そうすることで意図した目的に適うように装置を作動させることができる場合に限られるものと、更に理解するべきである。操舵自在なカテーテルおよび視認用機器は当該技術で周知であり、機械的な操舵組立体（例えば、引張りワイヤ、蝶番など）または形状記憶素材（例えば、ニッケルチタン合金、形状記憶ポリマーなど）を活用して、装置が体内への挿入後に所望の曲げを受け、或いは、所望の湾曲を受けるように誘導してもよい。このような装置を操舵自在はたま意図的に屈撓自在にするために使用することのできる装置と構造の具体例として、次に挙げる特許および特許出願に記載されているものがあるが、それらに限定されない。すなわち、米国特許第5,507,725号（サヴェッジほか）、第5,656,030号（ハンヤンほか）、第6,182,464号（ウエブスター）、第5,251,092号（クインほか）、第6,500,130号（キンセラほか）、第6,571,131号（ニュグイェン）、第5,415,633号（ラザルスほか）、第4,998,916号（ハマースラグほか）、第4,898,577号（バッジャほか）、第4,815,478号（バクビンダほか）、および、米国特許出願公開第2003/0181827A1号（ホエイベンほか）、第2003/0130598A1号（マニングほか）があり、これら特許および特許出願の内容全体は引例に挙げることにより本件の一部をなすことは明らかである。

【0094】

図５Ｏは、作業管腔７３４がカテーテル７３２を通って延びて遠位端開口で終端している、可撓性のカテーテル７３３を例示している。任意で、第２の管腔７３６もまた、カテーテル７３２を通って延びて、図示のように、遠位端開口で終端している。内視鏡７３８は管腔７３６の内側に恒久設置され、或いは、内視鏡７３８は管腔７３６に（または、そこを通して）暫定挿入され、カテーテル７３２より遠位の領域を操作者が視認できるようにしている。これに加えて、または、これに代わる例として、副次視認用機器または副次管腔７４０がカテーテル７３２に設置されてもよく、また、カテーテル７３２より遠位の領域を操作者が視認することができるようにするのに、また、少なくとも或る事例では、カテーテル７３２そのものの遠位端を視認することができるようにするのに、内視鏡がそのような副次視認用機器または副次管腔７４０によって具現化されてもよいし、または、その中に恒久設置されてもよいし、或いは、そこに（または、そこを介して）暫定的に挿入されてもよい。上述のおうな任意の副次視認用機器または管腔７４０を組み入れている装置はいずれも、副次視認用機器または管腔７４０は好適な長さであればよく、また、遠位方向の好適な位置で終端していればよく、このような副次視認用機器または管腔７４０は図面に例示されているような特別な定位に限定されず、また、特別な遠位端位置に限定されない。また、副次視認用機器または管腔７４０を組み入れている実施形態では、そのような副次管腔はガイドワイヤまたは作業管腔として採用されることで、ガイドワイヤ上を伝ってカテーテルが前進することができるようにしたり、別な作業装置を中に挿入することができるようにしてもよい。

【0095】

図５Ｐは、図５Ｇ'ないし図５Ｇ'''に例示されているバルーンにより拡張自在なステントシステムの構成要素の全部を備えているのに加えて、内視鏡または副次管腔を組み入れることのできるバルーンカテーテルと圧力により膨張自在なステントのシステム７４４を例示している。詳細には、図５Ｐを参照すると、バルーン７５０とバルーンの上に載置された圧力膨張自在ステント７４８とを有している可撓性のカテーテル７４６を備えている、バルーンカテーテルーと圧力により膨張自在なステントのシステム７４４が例示されている。副次管腔７５６はカテーテル７４６に配置され、内視鏡はそのような副次管腔７５６の中に恒久設置され、或いは、その中に（または、そこを通して）暫定挿入されて、バルーン７５０およびステント７４８を操作者が視認しながら、カテーテル７４９を所望位置まで前進させることができるようにしている。また、副次管腔７５６を組み入れた実施形態では、上述のような副次管腔はガイドワイヤ管腔として採用されることで、ガイドワ

イヤ上を伝ってカテーテル７４６を前進させることができるようにしている。任意で、管腔はカテーテル７４６を通って延びてから、更にカテーテル７４９の遠位端の開口７５２を通過するようにしてもよく、また、直状、湾曲状、屈曲自在、偏向自在、または、操舵自在な視認用機器および／またはステント７５４がその管腔の中を通され、または、その中に受容されて、意図した位置までカテーテル７４９が容易にワイヤ上を伝って、かつ／または、視認用機器に支援されて、かつ／または、案内されて、かつ／または、操作されながら前進することができるように図ってもよい。定常使用では、バルーン７５０は初期状態では収縮しており、ステント７４８は放射方向に圧縮されて折畳まれた形状で収縮したバルーンの周囲に置かれる。カテーテル７４６は、バルーン７５０を収縮させたままで、また、折畳まれたステント７４８を搭載したままで、内視鏡支援下で、または、ガイドワイヤ上を伝って前進させられて、ステント設置されるべき鼻孔、鼻腔、鼻道、小口、副鼻腔の内部などのような通路の内部の位置に至る。その後、バルーン７５０が膨張させられてステント７４８を拡張させて、周囲の組織に摩擦係合することでステント７４８を適所に保持することのできる寸法にする。或る事例では、このような処置を実施する目的は、通路（例えば、小口、耳道など）を拡大することであるが、ステント７４８は通路を望みどおりに拡大させるのに十分な大きさの直径まで拡張させられ、また、ステント７４８は支柱機能を果たして、通路を上述のような拡大状態に維持する。ステント７４８が十分に拡張されて移植された後、バルーン７５０が収縮させられてから、カテーテル７４８が取り出される。或る応用例では、ステント７４８は本件で規定されているような診断用物質または治療用物質を含有しており、そのような物質がステント７４８から溶離して周囲組織に浸透し、所望の診断効果または治療効果をもたらすことができる。或る事例では、ステント７４８は恒久移植することができる。それ以外の事例では、ステント７４８は暫定移植することができる。ステント７４８が暫定移植される事例では、ステント７４８は、それを回収するために遂行される第２回目の処置で取り出すことができ、或いは、ステント７４８は生体吸収可能な素材または生体分解性の素材から作成されて、移植後所望期間のうちに分解し、または、吸収される。図５Ｒ'および図５Ｒ''の具体例に例示されているように、副鼻腔の小口の内部にステントが設置されなければならないような或る事例では、ステントおよび／またはバルーンは、ステントを所望位置に載置してステントが滑落するという望ましくない事態を防止するのを容易にし、かつ／または、それを達成するような特殊な形状に設定される。例えば、図５Ｒ'は、上述のようにバルーン１０４４およびその上に搭載されたステント１０４６を有しているカテーテル１０４２を備えている装置１０４０を例示している。しかし、この実施形態では、バルーン１０４４およびステント１０４６は、バルーン１０４４およびステント１０４６の直径が一方端では他方端よりも大きいような形状を呈している。図５Ｐおよび図５Ｑに例示されているもののような別な実施形態に関連して先に説明されているように、副次視認用機器または副次管腔１０４８が任意でカテーテル１０４２の上に形成されてもよいし、かつ／または、視認用機器またはガイドワイヤ１０５０が任意でカテーテル１０４２の管腔を通されてから遠位端の外へ出るようにしてもよい。図５Ｒ''は、上述のように、バルーン１０５６およびそこに搭載されたステント１０５８を有しているカテーテル１０５４を備えている、また別な装置１０５２を例示している。しかしながら、この実施形態では、バルーン１０５６およびステント１０５８は、バルーン１０５６およびステント１０５８は直径がそれぞれの両端ではそれぞれの中間部分よりも大きいような形状を呈している。その結果、ステント１０５８は環状の溝または陥凹部がその中央部分の周方向または周囲を廻って形成されており、或いは、砂時計またはヴェンチュリ計のような形状にされて、ステント１０５８が長軸線方向に滑落すること無く、小口または開口の内部にステント１０５８を載置するのを容易にしている。ここでもまた、図５Ｐおよび図５Ｑに例示されているもののような別な実施形態と関連して先に説明されているように、副次視認用機器または副次管腔１０６０が任意でカテーテル１０５２の上に形成されてもよいし、かつ／または、視認用機器またはガイドワイヤ１０６２が任意でカテーテル１０５４の管腔を通されて、その遠位端から外に出されるようにしてもよい。この処置が実際に骨を破砕することを意図している場合（

例えば、ステント１０４６、１０５８が副鼻腔の小口を拡大または拡張するよう意図されている場合）、特殊な形状のバルーン１０４４、１０５６が既に説明されたような強靭なポリマー素材から作成されて、膨張時に隣接する骨または周囲の骨にバルーンが骨破砕圧を及ぼすことができるようにしてもよい。

【0096】

図５Ｑおよび図５Ｑ’は、可撓性の外側鞘部材７６２、可撓性の内側管材６４、および、ステント７６８を備えている自己拡張型ステント搬送システム７６０を例示している。このステントが図５Ｐのステント７４８と異なっているのは、圧力により拡張可能となるのではなくむしろ、弾性に富んでおり自己拡張するという点だけである。ステント７６８は偏倚により拡張した形状になる。初期状態では、ステントは与圧により放射方向に折畳まれて内側管材７６４の外面上に押し付けられた状態になっており、その後、外側鞘部材７６２がステント７６８の上を伝って前進させられて、ステントを折畳まれた状態のまま拘束するが、これは図５Ｑ’の断面図で分かるとおりである。視認用機器および／またはガイドワイヤ７７０が内側管材７６４の管腔を通して挿入される。これに加えて、または、これに代わる例として、副次管腔７７２は外側鞘部材７６２の上に設置され、内視鏡がそのような副次管腔７７２の内部に恒久設置され、または、その中に（または、それを通して）暫定挿入されて、システム７６０の進入時に、システムの遠位部と鞘部材７６２の遠位端より前方の領域を操作者が視認することができるようにしてもよい。また、副次管腔７７２を組み入れている実施形態では、副次管腔７７２がガイドワイヤ管腔として採用されて、ガイドワイヤの上を伝ってシステムを前進させることができる。定常動作では、鞘部材７６２が遠位方向に進んだ位置にきて折畳まれたステント７６８を包囲および拘禁した状態のままで、システム７６０が内視鏡支援下で、かつ／または、ガイドワイヤ上を伝って前進させられ、ステント設置されるべき鼻孔、鼻腔、耳道、小口、副鼻腔の内部などのような通路の内部の位置に至る。その後、ステント７６８がステント設置されるべき位置に設置されると、鞘部材が引き出され、自己拡張型ステント７６８が弾けて、すなわち、自己拡張して放射方向に拡張した形状になり、その形状で、ステントは周囲の解剖学的構造と摩擦係合する。その後、システム６０の残余の部分が取り出され、ステント７６８を体内に移植されたままにする。ステント７６８は、図５Ｐの圧力により拡張することができるステント７４８に関して先に説明したように、拡張し、支柱機能を果たし、かつ／または、物質搬送機能を果たす。

【0097】

図５Ｓは、可撓性カテーテル７８２の内部に管腔７８４が延在している係蹄装置７８０を例示している。係蹄７８６は、概ねループ状であり、装置７８０の管腔７８４から外へ前進させることができる。或る実施形態では、係蹄７８６は任意で電流が投入され、或いは、そうでなければ加熱されて、組織を剪断する際に焼灼機能を果たす。これに加えて、または、これに代わる例として、或る実施形態では、係蹄７８６は径を変動させることができるようにしてもよい（例えば、操作者により締めたり緩めたりすることができる輪など）。また、任意で、視認用機器または副次管腔７８８がカテーテル７８２に配置されてもよいし、更に、静止内視鏡または可動内視鏡が副次管腔７８８の中に（または、そこを通して）恒久埋設され、或いは、暫定挿入され、装置７８０の遠位部と係蹄７８６の領域を操作者が視認できるようにしてもよい。また、視認用機器または副次管腔が更に副次管腔を備えているような実施形態では、かかる副次管腔７８８がガイドワイヤ管腔として採用されて、ガイドワイヤ上を伝って装置７８０を前進させることができるようにしてもよい。その代替例として、多数管腔がカテーテル７８２を通って延び、これら管腔が係蹄、ガイドワイヤ、および／または、内視鏡を収容するようにしてもよい。定常動作では、係蹄７８６は初期的には管腔７８４の内部に後退させられており、装置７８０は内視鏡支援下で、かつ／または、ガイドワイヤ上を伝って前進させられて、係蹄設置されるべき、すなわち、切除されるべきポリープまたはそれ以外の物体の存在位置である鼻孔、鼻腔、耳道、小口、副鼻腔の内部などのような通路の中の位置に至る。係蹄７８６は管腔７８４から外へ前進させられてからポリープまたはそれ以外の物体を取り巻いて設置され、その後

、係蹄が引張られ、または、動かされ、加熱され（加熱用の装備がある場合は）、かつ／または、締め付けられて（締め付け用の装備がある場合は）、ポリープまたはそれ以外の物体を剪断または切除することができる。場合によっては、剪断されたポリープまたはそれ以外の物体は管腔７８４を通して吸引されてもよい。別な場合には、別個のカテーテルまたは別個の装置が導入されて、剪断されたポリープまたはそれ以外の物体を回収するようにしてもよい。処置完了後、係蹄７８６は管腔７８４の中に後退させられ、装置７８０が取り出される。また、或る実施形態では、組織およびそれ以外の物体を捕獲して回収し、カテーテル７８２の管腔内に引き出すために使うことができる籠、嚢、または、それ以外の回収物容器と係蹄７８６を置換えてもよい。

【0098】

図５Ｔは、可撓性のシャフト７９２に顎鉄または鉗子７９４が搭載されている鉗子装置７９０を例示している。顎鉄または鉗子７９４は操作者によって意図的に開閉することができる。視認用機器または副次管腔７９６は、図示のように、可撓性のシャフト７９２に配置される。視認用機器または副次管腔７９２がスコープを備えている実施形態では、スコープは固定式または可動式のいずれでもよく、装置７９０の前進および／または鉗子７９４の使用を観察または視認するために使うことができる。視認用機器または副次管腔７９６が補助内腔を備えている実施形態では、静止内視鏡または可動内視鏡がそのような補助内腔７９６の中に恒久埋設され、または、その中に（または、そこを通して）暫定挿入されて、装置７９０の遠位部および鉗子７９４の領域を操作者が視認することができるようにしてもよい。また、視認用機器または副次管腔７９６が補助内腔を備えている実施形態では、かかる補助内腔がガイドワイヤ管腔として採用されて、ガイドワイヤ上を伝って装置７９０を前進させることができるようにしてもよい。定常動作では、装置７９０は単独で前進させられるか、または、カテーテルの管腔を通して前進させられるかのいずれかであり、また、内視鏡支援下で、かつ／または、ガイドワイヤ上を伝って前進させられることも大いにありうるが、鉗子で把持するべき物体が存在する鼻孔、鼻腔、鼻道、小口、副鼻腔の内部などのような通路の内部の位置へ至る。その後、任意の内視鏡支援下で観察しながら、鉗子７９４を使って意図した物体を把持する。或る実施形態では、図５Ｔの具体例について点線で示されているように、可撓性のシャフト７９２の遠位部は屈曲自在または操舵自在であってもよい。或る実施形態では、鉗子７９４の顎鉄は生検用の組織標本を剪断して保持するように設計されていてもよいし、或いは、それ以外の、鉗子７９４の組織サンプル採取の応用例が組織、軟骨、硬骨などの切断用の鉄を備えていてもよい。その代替例として、管腔が可撓性シャフト７９２の中を通過してから鉗子７９４を通ってから外に出るか、または、鉗子の脇で外にでて、ガイドワイヤまたは内視鏡にそのような管腔を通すことができるようにしてもよい。

【0099】

図５Ｕおよび図５Ｕ’は、可撓性のカテーテル８０２、可撓性の視認用機器８０４、および、ガイドワイヤ８０６を備えている入れ子式システム８００を例示している。可撓性の視認用機器８０４は複数の光伝達経路８０８（例えば、光ファイバーなど）を備えており、この経路は、光源（図示せず）から遠位方向に視認用機器８０４の遠位端の外へ光を伝達して、光が視認されるべき目標構造または解剖学的構造に投射されるようにする。また、視認用機器には画像伝達経路８１０（例えば、光ファイバーとレンズ）が設けられており、この経路は、視認用機器の遠位端から画像を見ることができる接眼レンズまたは監視装置へと反射光を伝搬する。視認用機器はまた、ガイドワイヤ管腔８０５が中を通って延びて、その遠位端を通り抜けたところで開放している。図示のとおり、視認用機器８０４は可撓性カテーテル８０２を通って前進させることができ、また、ガイドワイヤ８０６は視認用機器のガイドワイヤ管腔８０５を通って前進させることができる。定常動作では、入れ子式システム８００は鼻に挿入され、視認用機器８０４を利用して副鼻腔の小口のような解剖学的構造を視認することができるとともに、解剖学的構造内にガイドワイヤを進入させるのを容易にすることができる。その後、視認用機器を使って、解剖学的構造を精査することができる（例えば、副鼻腔の内側を覆っている粘膜の状態を視認したり、感

染、腫瘍などの兆候を探す等）。次いで、カテーテル８０２が視認用機器８０４の上を伝って前進させられて、解剖学的構造の中に入る（例えば、カテーテル先端部は小口を通って前進させられて、副鼻腔の中に入る）。その後、視認用機器８０４が取り出されて、既に規定されたような診断用物質または治療用物質がカテーテル８０２を通して注入され、かつ／または、図５Ａから図５Ｔおよび図５Ｖから図５Ｙ’’’’’に例示されているような作業装置（それらに限定される訳ではないが）がカテーテル８０２を通して前進させられて、診断機能または治療機能を果たす目的で作業装置が使用される場所である解剖学的の中に入る。

【0100】

図５Ｖは副次ポート吸引切断装置８２０を例示しているが、この装置は、可撓性の外側管材８２２と、外側管材の内部に同軸かつ回転自在に配置された可撓性の内側管材８３０とを備えている。１個以上のベアリング８３４（例えば、螺旋状ベアリングまたは一連の個別の円筒状ベアリング）が、図示のように、外側管材８２２と内側管材８３０の間に配置されている。その代替例としては、互いに向かい合う管材の面の一方または両方がシリコーンまたはPTFEのような潤滑性物質から作成され、かかる物質で内面を覆われ、または、かかる物質で皮膜されるなどして、容易に運動できるようにしている。回転式カッター８３２が内側管材８３０の遠位端に設置される。側面開口８２８が外側管材８２２に形成されており、カッター８３２が側面開口８２８より近位に設置される。任意で、先細りの非外傷性遠位先端部８２４が外側管材８２２の遠位端に形成されてもよく、側面開口８２８は斜路またはシュートを形成するような形状になっており、この斜路またはシュートを通して物体がカッター８３２の直ぐ遠位にある領域に渡される。また、任意で、遠位先端部の遠位端に開口が形成されて、ガイドワイヤまたは視認用機器８２６が内側管材８３０の管腔を通過してから、図示のように、遠位先端部に設けられたこの開口から外へ出るようにしてもよい。動作中は、ポリープ、組織、または、それ以外の除去されるべき障害物の直ぐ傍に側面開口８２８がくる位置まで、装置８２０が前進させられる。内側管材８３０とカッター８３２は回転させられる。内側管材８３０の管腔を通して、かつ／または、外側管材８２２の管腔を通して吸引が施され、障害物を側面開口８２８の中に引き込んで、回転しているカッター８３２と接触させる。障害物が回転カッター８３２によって剪断されると、剪断された障害物またはその細片が内側管材８３０の管腔を通して吸引され、かつ／または、外側管材８２２の管腔を通して吸引される。勿論、この特許出願に記載されている作業装置のどれについても言えることであるが、視認用機器と、この視認用機器を挿入する寸法または長さを有する副次管腔（図５Ｕには例示されていないが、図５Ｏ、図５Ｐ、図５Ｑ、図５Ｒ、図５Ｓ、および、図５Ｔのような他の多様な図には例示されている）が外側管材８２２に取り付けられるが、取り付け位置は、視認用機器を使って側面開口８２８と側面開口に入ってくる物体とを視認することができるような位置である。その代替例として、カテーテルは偏向自在な先端部または湾曲した遠位端を組込んで、その先端部または遠位端が強制的にカテーテルの側面開口を管腔壁に押し付け、または、除去されるポリープまたはそれ以外の組織の方向へ押しやるようにしてもよい。

【0101】

本発明の或る実施形態では、副鼻腔の小口の周辺部を形成している薄い骨のような骨を破砕するのが望ましいことがある。図５Ｗないし図５Ｘ’’’’は、特殊な位置の骨を破砕するために使用することができる装置を例示している。例えば、図５Ｗないし図５Ｗ’’は、剛性の円筒状部材８４７が遠位端に配置された可撓性のカテーテル８４２を備えている装置８４０を例示している。前進と後退を自在に行える部材８４６がカテーテル８４２を通って延びて、遠位先端部材８４４に接続される。遠位先端部材８４４には、円筒状部材８４７の内部に受容されるような寸法に設定された円筒状の近位端８４９が設けられている。図５Ｗ’および図５Ｗ’’に例示されているように、定常動作では、前進および後退を自在に行える部材８４６を前進させて、遠位先端部材８４４を剛性の円筒状部材８４７から分離させる。装置８４０は、粘膜組織Ｍで被覆されている骨Ｂによって形成されている構造のような骨構造に隣接している位置まで前進させられる。遠位先端部材８４４の円筒状

の近位端８４９と円筒状部材８４７の間に骨構造が位置するように、装置が設置される。次に、前進と後退を自在に行える部材８４６を後退させて、近位方向に遠位先端部材８４４を引張るとともに遠位先端部材８４４の円筒状近位端８４９と円筒状部材８４７の間の骨構造体を捕獲し、それにより、骨Ｂを破砕する。遠位先端部材８４４および／または円筒状部材８４７の形状または構成は、骨Ｂに施すのが望ましい破砕の形状とパターン次第で変動させることができる。この点で、図５Ｘないし図５Ｘ''''は、異なる形状と異なるパターンの骨破砕を生じるために利用することができる代替の構造または構成を例示している。図５Ｘ'は、近位側に３個の突起が設けられている遠位先端部材８５２と遠位面に３個の切欠きが設けられている近位部材８５４とを備えている組立体８５０を例示しているが、遠位先端部材８５２が後退させられると、このような切欠きは遠位先端部材８５２の３個の突起を受容するような形状になっている。図５Ｘ'''は、折畳み可能な遠位先端部材８７２と円筒状近位部材８７４を備えている組立体８７０を例示している。遠位先端部材８７２は、初期状態では、副鼻腔の小口のような開口を通して前進することができるような折り畳み形状に配備されている。次に、遠位先端部は、上述のような開口を通過するには直径が大きすぎるような寸法まで拡張することにより、近位方向に後退した際に、開口の周辺部に打ち当たる。このような態様で、図５Ｘ'''の組立体を使用して、小口または開口を廻る全周にわたって骨Ｂを破砕することができる。図５Ｘ''''は、近位側に２個の突起が設けられている遠位先端部８８２と遠位側に１個の突起が設けられている近位部材８８４とを備えている別な組立体８８０を例示している。遠位部材８８２を近位方向に後退させると、近位部材８８４の遠位側の突起は、遠位部材８８２の近位側に形成されている２個の突起の間に受容される。

【0102】

図５Ｙ'ないし図５Ｙ'''''は、鼻腔、副鼻腔、中耳または内耳、鼻咽頭などに移植されて、本件に規定されているような診断用物質または治療用物質を搬送することができる、多様な物質搬送移植片を例示している。このような装置は耐久性素材または生体吸収可能な素材のいずれから形成されていてもよい。多くの事例で、このような装置は、中に診断用物質または治療用物質が含有されているポリマー（例えば、ハイドロン、ヒドロゲル、コラーゲンなど）から形成されるか、または、診断用物質または治療用物質で皮膜されているか別な方法で該物質を含有しているポリマーまたは金属から形成される。図５Ｙ'は、ヘッドまたはペレットを有している移植片１０７０を例示している。図５Ｙ''は、ウエーハを有している移植片１０７２を例示している。図５Ｙ'''は、無頭釘またはまた釘を有している移植片１０７４を例示している。図５Ｙ''''は、ネジまたは螺旋状コイルを有している移植片１０７６を例示している。図５Ｙ'''''は、スタンドまたはコイルを有している移植片１０７８を例示しており、その別な具体例が図７Ｅに例示されているとともに後段で説明される。

【0103】

Ｄ．　予備成形されたガイドカテーテル

図６Ａないし図６Ｅは、本発明の方法で使用することができる多様なガイドカテーテルを例示している。

【0104】

図６Ａは、３個の予備成形された湾曲部１２２、１２４、１２６を組み入れた蝶形骨洞ガイドカテーテル１２０を例示している。カテーテル１２０の３次元形状は、カテーテル１２０の遠位端が鼻腔を通して前進させられると蝶形骨洞の小口に入る傾向を示すように設定される。

【0105】

図６Ｂは、２個の予備成形された湾曲部１３０、１３３を組込んだ前頭洞ガイドカテーテル１２８を例示している。カテーテル１２８の形状は、カテーテル１２８の遠位端が鼻腔を通して前進させられると前頭洞の小口に入る傾向を示すように設定されている。

【0106】

図６Ｃは、３個の予備成形された湾曲部１３８、１４０、１４２を組込んだ上顎洞ガイ

ドカテーテル１３６を例示している。カテーテル１３６の３次元形状は、カテーテル１３６の遠位端が鼻腔を通して前進させられると上顎洞の小口に入る傾向を示すように設定されている。

【0107】

図６Ｄは、２個の予備形成された湾曲部１４６、１４８を組込んだ篩骨洞カテーテル１４４を例示している。カテーテル１４４の３次元形状は、カテーテル１４４の遠位癌が鼻腔を通して前進させられると篩骨洞の小口に入る傾向を示すように設定されている。

【0108】

本発明の方法の或るものでは、副鼻腔の小口や、または、それ以外の、エウスタキオ管に導通している鼻涙管または鼻咽喉開口のような開口を塞栓するのが望ましい。従って、上述のガイドカテーテル１２０、１２８、１３６、１４４のいずれの遠位先端部も栓子部材を装備しており、遠位端が副鼻腔の小口に入ると副鼻腔を塞栓し、上述の小口を通して流体が副鼻腔から出るのを阻止することができる。そのような処置の一例が図７部に例示されているとともに後段で説明される。

【0109】

図６Ｅは、鼻涙管に導通している開口を一時的に栓止めするのに利用することができる詮子ガイドカテーテル１４９を例示している。この栓子ガイドカテーテル１４９は２個の予備成形された湾曲部１５０、１５２と遠位先端部に設けられた栓子１５４から構成されている。このカテーテル１４９の３次元形状は、遠位先端栓子１５４が鼻腔を通して前進させられると鼻涙管導通している開口に入る傾向を示すように設定されている。この栓子は、カテーテルの端部に取り付けられた半剛性栓子またはバルーンから構成することができるが、これらに限定されない。異なる形状の栓子ガイドカテーテル（図示せず）を使ってエウスタキオ管を閉塞することができることも分かる。

【0110】

Ｅ．　副鼻腔内部の治療装置および治療方法

図７Ａから図７Ｇは、副鼻腔内で診断処置または治療処置を実施する装置および方法の具体例を提示している。先行技術の方法では、剛性または可撓性の視認用機器を使って副鼻腔の小口を視認化することがあるが、通例、現実にはそのような視認用機器を副鼻腔の内部に進入させていた訳ではない。上述のように、本発明は副鼻腔の内側に内視鏡を設置する装置および方法を提供するものではないが、副鼻腔の内側に内視鏡を設置する方法を利用するのに、図７Ａないし図７Ｇに例示されている診断装置または治療装置および診断方法または治療方法のいずれかと関連づけてもよいし、また、そうでなくてもよい。

【0111】

図７Ａは、電極ネットワーク搬送装置１６８が使用されて蝶形骨洞SSの内層に高周波または電流を搬送しているのを例示している。この装置１６８は、蝶形骨洞口SSOを通して挿入される可撓性カテーテル１６９を備えている。ケージ１７０のような拡張自在な電極ネットワークが前進させられて、カテーテル１６９の遠位端から外へ出る。電極１７２はケージ内の互いから離隔した位置に設置されている。ケージ１７０は、拡張すると、電極を蝶形骨洞SSの内層に接触させる。電流が電極１７２に搬送されて、洞内の粘膜生成組織を全部融除し、蝶形骨洞が機能的に隔絶される、すなわち、塞栓される準備ができた状態になり、或いは、蝶形骨洞の内部にできた腫瘍またはポリープを融除する準備ができた状態になる。

【0112】

図７Ｂは、前段で規定されているような診断用物質または治療用物質のような流動性物質を蝶形骨洞SSに導入し、蝶形骨洞栓子ガイドカテーテル装置１７４によって蝶形骨洞口SSOを塞栓する処置を例示している。この装置１７４は図６Ａに例示されているとともに先に説明された形状を呈する可撓性カテーテル１７６とその遠位先端部の栓子部材１７８とを備えている。栓子カテーテル装置１７４が取り出されるまで、流体は蝶形骨洞SSの中に保持され、カテーテル装置の取り出し後、蝶形骨洞口SSOを通して流体を排出することができるようにする。この処置は、放射線不透過性造影剤で蝶形骨洞を充満させる場合に、

洞全体を視認化し、或いは、洞の内層全体に治療薬を投与するのに特に有用となるが、その手段として、蝶形骨洞を薬剤で完全に満たしてから、完全な充満状態を所望の期間に亘って維持することで、洞の内層全体に薬剤を作用させることができるようにする。画像化剤は粘性剤と混合されて、粘膜を刺激し、或いは、簡単な構造の画像化が所望される場合には、粘性の低い物質を用いるのが好ましい場合もある。注入される造影剤の量を最小限に抑えるために、粘膜の表面と決着する画像化剤を使用するのが望ましい場合もある。

【0113】

図７Ｃは、バルーン１８４を搭載した可撓性カテーテル１８２を備えているバルーンカテーテル装置１８０を例示しており、バルーンは蝶形骨洞口SSOに設置されてから膨張されてカテーテル１８２を適所に保持するが、それと同時に、或る量の診断用物質または治療用物質１８６（前段で規定されているような）が蝶形骨洞SSの内部に導入される。このような治療用物質は薬物搬送素材や前述のリストから選択された薬剤のうちのいずれか１種類以上であってもよいし、または、アルコールのような硬化症治療薬を追加して、洞内の組織を全てむらなく殺傷するようにしてもよい。カプシアン（capasian）またはそれ以外の神経毒性物質のような他の物質が痛みやその他の洞内感覚を緩和するものと思われる。

【0114】

図７Ｄは、３次元マッピングまたは操舵を目的としてセンサーが搭載された可撓性のカテーテル１９２を備えているセンサー装備式のカテーテル装置１９０を例示している。このような処置を利用して、蝶形骨洞SSの内部の厳密な形状をマッピングすることができる。このようなセンサー１９４およびそれに付随するシステム／コンピュータの構造の用途の具体例が次の米国特許に見られる。すなわち、米国特許第5,647,361号、第5,820,568号、第5,730,128号、第5,722,401号、第5,578,007号、第5,558,073号、第5,465,717号、第5,568,809号、第5,694,945号、第5,713,946号、第5,729,129号、第5,752,513号、第5,833,608号、第5,935,061号、第5,931,818号、第6,171,303号、第5,931,818号、第5,343,865号、第5,425,370号、第5,669,388号、第6,015,414号、第6,148,823号、第6,176,829号に開示されており、これら特許の内容全体は引例に挙げることにより本件の一部をなすことは明らかである。

【0115】

図７Ｅは可撓性カテーテル１９８を備えている移植片搬送装置１９６を例示しており、このカテーテルは蝶形骨洞口SSOを通して挿入されて蝶形骨洞に入り、また、蝶形骨洞の内部ではコイル２００を移植するために使用される。このようなコイル２００は細長いファイバーか、または、それ以外の、本件で規定されているような診断用物質または治療用物質を含有している細長い部材を含んでいる。このコイル２００は蝶形骨洞を塞栓するような構成になっており、その目的は、洞を恒久閉鎖すること、これ以上の粘液生成、分泌液の滞留、または、感染を阻止すること、および／または、洞の内層を覆っている組織に診断用物質または治療用物質を搬送することである。例えば、抗菌剤を持続的に搬送するためのコイルが蝶形骨洞に移植され、洞の急性感染症または慢性感染症を治療するようにしてもよい。或る事例では、コイルは生体吸収性であってもよい。

【0116】

図７Ｆは、ワイヤ上を伝って導入する内視鏡システム２４０を利用して蝶形骨洞SSの内部を視認しているのが例示されている。可撓性のカテーテル２４２は蝶形骨洞口SSO内またはその付近に設置され、ガイドワイヤ２４８は蝶形骨洞口SSOを通して前進させられて、蝶形骨洞SSに入る。ワイヤ上を伝う内視鏡２４６（米国ニューヨーク州メルヴィルに居所を置くオリンパス・アメリカからモデル番号AF-28Cとして購入可能な2.2 mmのオーヴァーザワイヤ・スコープなど）がガイドワイヤ２４８上を伝って前進させられ、蝶形骨洞SSの内部を精査するために使用される。

【0117】

図７Ｇは、生検システム２５０が使用されて蝶形骨洞SS内の病巣Lから生検試料を得ているところを例示している。可撓性のカテーテル２４２が蝶形骨洞口SSOの中またはその付

近に設置されて、内視鏡２４６がカテーテル２４２を通って前進させられて、蝶形骨洞SSの中に入る。生検器具２５２は内視鏡２４６の作業チャネルを通して挿入されて、内視鏡視認化と内視鏡支援のもとで使用されて、病巣Lの試料を得る。

【0118】

Ｆ．　閉塞接近装置および／または作業装置を用いた介在処置の大まかな具体例

図８Aないし図８Dは、図２Aおよび図２Bの閉塞接近装置１０、１２および／または図５Aないし図５Y''''に例示されているもののような多様な作業装置が使用されて鼻、鼻咽頭、または、副鼻腔の内部で診断処置および／または治療処置を実施しているのを例示している。

【0119】

一般に、本発明による診断のための介入措置としては、ａ）解剖学的構造の閉塞部、寸法、特質、または、異常部位を視認および／または識別する構造上の調査、ｂ）気体、粘液、または、流体を鼻、副鼻腔、鼻王、鼻咽頭、エウスタキオ管、内耳または中耳などに導入し、そのような物体を監視して漏出すなわち気体流の流出を査定する力学的調査、ｃ）薬剤（例えば、アレルゲン、刺激原、粘液生成を誘発する薬剤など）を鼻、副鼻腔、鼻腔、鼻咽頭、エウスタキオ管、内耳または中耳などに導入し、患者の反応および／または内生粘液またはそれ以外の分泌液の流動を査定する心配原因の調査などがある。このような種類の診断介入を実施するために利用することのできる処置の具体例には次に挙げるようなものがあるが、それらに限定されない。

【0120】

１．副鼻腔への接近

副鼻腔の１個以上の洞に接近する手段として、興味の対象である洞（単数または複数）にカテーテルを進入させる方法がある。まず、ガイドワイヤを副鼻腔に挿入してから、ガイドワイヤ上を伝ってカテーテルを前進させて、洞に入る。或る事例では、図６Ａないし図６Ｅに例示されている類の洞口ガイドカテーテルは副鼻腔の小口に挿入され、より小型のカテーテルがガイドカテーテルを通しえ前進させられる。１個以上の視認用危機を使って副鼻腔の小口を視認するとともに、ガイドワイヤおよび／またはカテーテルを洞口の中へ誘導することができる。或る事例では、操舵自在なガイドワイヤ、カテーテル、および／または、視認用機器を使って、副鼻腔へ入ることができる。或る事例では、図２Ａから図２Ｒに例示されているもののような閉塞接近装置が挿入され、副鼻腔に接近するために使用されたガイドワイヤ（単数または複数）、カテーテル（単数または複数）、および／または、視認用機器（単数または複数）が閉塞接近装置に設けられた装置挿入ポートを通して挿入される。

【0121】

２．粘液流の調査

任意で、副鼻腔へのカテーテル接近を達成した後で、マイクロビーズまたは流動性造影媒体（例えば、ヨウ素標識造影溶液に濃化剤を添加したり、添加せずに済ましたりして、対粘液の粘度を調節したものなど）のような、粘稠度が粘液のものに類似している、画像化できる造影物質または放射性物質を副鼻腔に注入する。次に、画像化技術または走査技術（例えば、Ｘ線、放射線透視法、CTスキャン、超音波、MRI、放射線検出装置、ガンマカメラなど）を使って、副鼻腔を通ってからその外へ出る造影媒体の流れを観察することができる。或る事例では、冠動脈カテーテル挿入処置や血管形成処置で採用されるのとよく似た様式で、Ｃ字型アームを備えている放射線透視装置を使い、異なる複数の視点または角度から造影媒体の運動を視認することができる。副鼻腔から造影媒体が容易に流出することができるようにするために、先に挿入されたカテーテル（単数または複数）および／またはガイドワイヤ（単数または複数）および／または視認用機器（単数または複数）を副鼻腔とその洞口から外へ逆戻りさせ、或いは、完全に取り出して、正常な流れが生じるようにしてもよい。患者の頭部および／またはそれ以外の肉体部分の位置を整えて、異なる姿勢の排出効果を観察するようにしてもよい。この態様で臨床医は、解剖学的構造が副鼻腔から流出する正常な粘液の流れを閉塞している、または、妨害している位置を探し

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て特定し、識別することができる。

【0122】

３．空気流の調査

任意で、上述の項目１に記載されているように副鼻腔への接近を果たした後、例えば、放射性標識ガス、放射線不透過性ガス、または、画像化マイクロビーズまたは放射性マイクロビーズを含有する気体などのような画像化ガスすなわち追跡標識ガスをカテーテルを通して注入し、副鼻腔の中に入れる。次に、画像化装置または追跡装置（後江波、放射線検出装置、ガンマカメラ、Ｘ線、放射線透視装置、CTスキャン、超音波、MRIなど）を使って、その後、気体が副鼻腔から外に出て、かつ／または、副鼻腔の他の洞との平衡を保つようになった時の気体の運動または散逸を観察する。この態様で、副鼻腔の洞で正常な気体交換が行われているか否かを臨床医は判断できるうえに、正常な気体流および／または正常な気体交換を遮断している、または、妨害している解剖学的構造または不整の部位を探して同定することができる。

【0123】

４．解剖学上の寸法の調査

副鼻腔、それ以外の解剖学的通路、または、解剖学的構造の全体を画像化物質で充満させ、或いは、それ以外の方法で測定することにより、実際の寸法および／または形状を判定する。そのような調査の或る事例では、上の項目１に記載されているように副鼻腔への接近を果たして、副鼻腔の洞を画像化物質（例えば、造影媒体など）で充満させることができる。次に、好適な画像化技術（例えば、Ｘ線、放射線透視装置、CTスキャン、超音波、MRI、放射線検出装置、ガンマカメラなど）を利用して、洞の寸法と形状を判定する。ここでもまた、そのような処置では、Ｃ字型アームを使って、それぞれ異なる複数の視点または角度から、造影剤を充満させた副鼻腔の洞を視認して測定することができる。そのような処置の一例は図７Ｂに例示されているとともに、前段で説明されている。

【0124】

５．内視鏡調査

上述のように、可撓性の内視鏡および／または操舵自在な内視鏡を鼻、副鼻腔、鼻腔、鼻咽頭、エウスタキオ管、内耳または中耳などに挿入し、そのような内視鏡を使って、解剖学的構造を目で精査し、かつ／または、治療を観察し、かつ／または、先に施した治療の効能または完全さを査定することができる。副鼻腔の内部を視認するのが望ましい事例では、上段の項目１に記載されているように副鼻腔に接近して、直接またはガイドワイヤ上を伝わせて内視鏡を副鼻腔の内部に進入させる。

【0125】

６．透視研究

可撓性の発光器具（例えば、遠位端に強力発光装置を搭載したカテーテルなど）を鼻、副鼻腔、鼻腔、鼻咽頭、エウスタキオ管、内耳または中耳などに進入させ、そのような発光器具を使って解剖学的構造を照射する。体外から、かつ／または、それ以外の、鼻、副鼻腔、鼻腔、鼻咽頭、エウスタキオ管、内耳または中耳、眼窩、頭蓋冠などの内部の位置から直接観察または内視鏡観察を行い、解剖学的構造を観察し、かつ／または、光が入る迷入口または異常漏出口を検出することができる。発光装置および／または視認用機器（例えば、内視鏡）が副鼻腔の洞（単数または複数）の内部に設置される場合は、前段の項目１に記載されているような副鼻腔の洞（単数または複数）へ接近して、発光装置および／または視認用器具を直接またはガイドワイヤ上を伝わせて副鼻腔の洞（単数または複数）の中に進入させることができる。

【0126】

７．それ以外の画像化調査

上記以外の、MRIやCTなどの画像化技術を前段の項目１から項目６に明示されている様相のいずれかと組合わせたものを実施して、そのような技術を修正することで、副鼻腔解剖学またはそれ以外の病理学ごとに調整を行うことができる。

【0127】

選り抜かれた診断調査のうちいずれか、または、全部を完了してから、本件に記載されているとともに図５Ａから図５’’’’’に例示されている可撓性装置のような１個以上の作業装置を挿入し、それを使って治療処置（１種類または多種類）を実施する。

【0128】

図８Ａの具体例に示されているように、前後閉塞接近装置１０を右鼻腔ＮＣを通して挿入する。装置の前閉塞部材１４を設置して、右側の鼻孔を閉鎖すると同時に、後閉塞部材（図８Ａから図８Ｅには図示されていない）で後鼻孔または鼻咽頭を閉鎖する。前閉塞接近装置１２を左鼻孔に挿入し、同装置の閉塞部材４０で左鼻孔を閉鎖する。このような態様で、後鼻孔または鼻咽頭に設置された後閉塞部材と左右両鼻孔または前鼻腔に設置された前閉塞部材１４、４０との間に封鎖された術場を確立する。

【0129】

図８Ｂから図８Ｃは、体内に閉塞接近装置１０、１４が既に挿入されている患者の右前頭洞FSで診断処置および／または治療処置を実施する方法の一例を示している。図８Ｂでは、前頭洞ガイドカテーテル１２８を作業装置挿入ポート３０に挿入して、管材１６を通して進入させ、出口開口２２から外へ出す。次に、ガイドカテーテル１２８を前進させて、カテーテルの遠位端が右前頭洞口に達した位置まで進入させる。

【0130】

図８Ｃでは、作業装置２０２をガイドカテーテル１２８を通して挿入し、前頭洞FSに入れる。この作業装置２０２は、図５Ａないし図５Ｙ’’’’’または図７Ａないし図７Ｇに例示されている装置のいずれかを備えている。或る処置では、初期的に前頭洞FSに造影剤を導入してからガイドカテーテル１２８を引き戻し、前頭洞から造影剤を排出させることができるようにするのが望ましい場合がある。流れ出る造影剤の画像化を利用して、排液障害を診断し、排液障害の原因となっている特殊な解剖学的構造を識別することができる。その後、ガイドカテーテルを前頭洞口に挿入し直してから、作業装置（単数または複数）２０２を使って、既に識別済みの構造と排液障害を修復することができる。その後、造影剤注入工程と画像化工程を反復して、実施された処置が初期診断された排液欠陥を克服したか否か、すなわち、矯正することができたか否かを査定することができる。吸引ライン２０４により、吸引装置２０６をポート３６に接続し、処置中に血液、それ以外の流体、または、堆積物を術場から吸引する。

【0131】

図８Ｄおよび図８Ｅは、閉塞接近装置１０、１４が既に挿入された同じ患者の左上顎洞MSに施された治療の一例を示している。図８Ｄでは、ガイドカテーテル１３６を装置挿入開口４４に挿入し、管材４１を通して前進させて、ガイドカテーテル１３６の遠位端が上顎洞MSの小口に達している位置まで進入させる。

【0132】

その後、図８Ｅに例示されているように、作業装置２０２をガイドカテーテル１３６を通して挿入し、上顎洞MSに入れる。この作業装置２０２は、図５Ａから図５Ｙ’’’’’または図７Ａから図７Ｇに例示されている装置のずれかを備えていてもよい。或る処置では、図８Ｂおよび図８Ｃを参照しながら前段に記載されたのと同じ処置により、初期的に上顎洞MSに造影剤を導入するのが望ましい場合がある。

【0133】

所望の処置を全部完了した後で、前閉塞部材１４、４０と後閉塞部材（図８Ａから図８Ｅには例示されていない）を折畳み（例えば、収縮させ）、閉塞接近装置のみならずガイドカテーテルや作業装置を一緒に取り出す（ステント、塞栓コイル、物質搬送移植片などを除く）。

【0134】

Ｇ．　蝸牛移植処置

図９Ａから図９Ｃは、本発明による移植蝸牛刺激装置の取付け処置を例示している。この処置では、エウスタキオ管ETに導通する鼻咽喉口の位置を探査し、初期的にガイドワイヤをエウスタキオ管ETに進入させる。ガイドワイヤ上を伝わせてカテーテル９００を前進

させて、カテーテル９００の遠位端が中耳の鼓室TCまたはその付近に達している位置まで進入させる。その後、必要と思われるのであれば、カテーテル９００を通して鉗子装置および／またはそれ以外の装置を前進させて、それら装置を使って、図９Ａに例示されているように、耳の小型の骨（すなわち、槌骨、砧骨、鐙骨）を取り除く。中耳の骨をこのように任意で除去する処置は、図５Ｔに例示されているとともに前段に記載されている内視鏡を装備した鉗子装置７９０のような内視鏡装備装置を使った内視鏡視認下で遂行される。図９Ｂに例示されているように、Ｊ字型の遠位先端部９０５を設けた蝸牛ガイドカテーテル９０４をカテーテル９００を通して前進させて、蝸牛ガイドカテーテル９０４の先端部９０５の蝸牛Ｃ内での目標地点、すなわち、蝸牛Ｃ内の挿入位置まで進入させる。或る応用例では、蝸牛ガイドカテーテル９０４は、蝸牛の丸窓の中に丸窓を覆っている二次鼓膜を通して進入することができるような構成になっていてもよい。必要ならば、ニードル、ドリル、または、カッターのような刺し通し装置が蝸牛ガイドカテーテル９０４の遠位端を通して前進させられ、整列させられ、または、位置決めされてから、刺し通しにより二次鼓膜を貫くことができる。また別な応用例では、蝸牛ガイドカテーテルを蝸牛に隣接させて置くようにしてもよいし、蝸牛瘻造設装置（例えば、ドリル、ニードル、カッターなどの刺し通し装置）が蝸牛ガイドカテーテル９０４の遠位端を通して前進させられ、整列させられ、または、位置決めされてから、その装置を使うことで、蝸牛Ｃの内部に進入させるのにガイドカテーテル９０４の遠位端を通す蝸牛瘻を形成することができる。その後、蝸牛ガイドカテーテル９０４を通して蝸牛電極配列９０６を前進させ、図９Ｂで分かるように、蝸牛に進入させる。購入可能な蝸牛電極配列の一例は、コウクリア・コーポレーション（Cochlear Corporation）が製造しているニュークレウス24カウントゥアー（Nucleus 24 Countour）装置である。

【0135】

その後、カテーテル９００を通して集音装置またはトランスデューサー９０８を前進させ、鼓室TCに設置する。集音装置またはトランスデューサー９０８は次のどのタイプのものであってもよい。すなわち、ａ）エウスタキオ管ETを通して鼓室TCに入れるのに十分な小型であり、ｂ）音波を電気衝撃に変換してそのような電気衝撃を蝸牛電極配列９０６に伝搬するという所望の機能を果たす目的で利用することができる。マイクロフォン／動力源／電子装置９１０を図９Ｃに例示されているように外耳に設置してもよいし、或いは、皮下移植またはそれ以外の容認できる方法で移植してもよい。このような処置のために使うことができる装置９０６、９０８、９１０の或る無制限な例が、指定国を合衆国としたPCT国際特許公開番号WO 2004/018980 A2に明示されており、その内容全体は引例に挙げることにより本件の一部をなすのは明らかである。

【0136】

これまで、本発明の具体例すなわち実施形態に言及しながら発明を説明してきたが、本発明の意図した真髄および範囲から逸脱せずにそのような具体例や実施形態に様々な付加、削除、変更、および、修正を施すことができるのが分かる。例えば、一実施形態または一実施例の要素または属性を別な実施形態または実施例に組み入れたり併用することも、そうすることで、その実施形態または実施例を意図した用途にうまく適合させることができる限りにおいては、容認できる。理に適った付加、削除、修正、および、変更は、上述の実施例や実施形態の均等物であると解釈されるべきであり、添付の特許請求の範囲の各請求項の範囲に入れることができる。

【図面の簡単な説明】

【0137】

【図1A】先行技術に関連して副鼻腔の位置を示す、人体頭部の正面図である。

【図1B】先行技術に関連して副鼻腔の位置を示す、人体頭部の側面図である。

【図2A】右鼻腔、鼻咽頭の右側、および、これらに付随する副鼻腔と、そこに本発明の前後それぞれの閉塞接近装置が挿入されているのを例示した、人間患者の頭部の部分断面図である。

【図2B】左鼻腔、鼻咽頭の左側、および、これらに付随する副鼻腔と、そこに本発明の前

閉塞接近装置が挿入されているのを例示した、人間患者の頭部の部分断面図である。
【図2C】図２Aの線C－Cに沿って破断された断面図である。
【図2D】図２Bの線D－Dに沿って破断された断面図である。
【図2E】口腔を通して挿入可能な本発明の後閉塞吸引接近装置の斜視図である。
【図2F】図２Eの線２F－２Fに沿って破断された断面図である。
【図2G】右鼻腔、鼻咽頭の右側、および、これらに付随する副鼻腔と、本発明の前閉塞接近装置が右鼻腔に挿入され、かつ、図２Eの後閉塞吸引接近装置が口腔を通して挿入されているのとを例示した、人間患者の頭部の部分断面図である。
【図2H】左鼻腔、鼻咽頭の左側、および、これらに付随する副鼻腔と、本発明の前閉塞接近装置が左鼻腔に挿入され、かつ、図２Gに描かれたのと同じ後閉塞吸引接近装置が口腔を通して挿入されているのとを例示した、人間患者の頭部の部分断面図である。
【図2I】経鼻挿入可能な本発明の後閉塞吸引装置の斜視図である。
【図2J】図２Iの線２J－２Jに沿って破断された断面図である。
【図2K】右鼻腔、鼻咽頭の右側、および、これらに付随する副鼻腔と、図２Iに描かれた後閉塞吸引装置が右鼻腔を通して挿入されているのとを例示した、人間患者の頭部の部分断面図である。
【図2L】左鼻腔、鼻咽頭の左側、および、これらに付随する副鼻腔と、図２Kの装置の後閉塞部材が鼻中隔の後ろで声門の上の位置において鼻咽頭に載置されて閉塞しているのとを例示した、人間患者の頭部の部分断面図である。
【図2M】右鼻腔、鼻咽頭の右側、および、これらに付随する副鼻腔と、延長した後閉塞吸引装置が右鼻腔を通して挿入されているのとを例示した、人間患者の頭部の部分断面図である。
【図2N】左鼻腔、鼻咽頭の左側、および、これらに付随する副鼻腔と、図２Mの装置の後閉塞部材と遠位管状延長部材が鼻中隔の後ろで声門の上の位置で鼻咽頭に載置されているのを例示した、人間患者の頭部の部分断面図である。
【図2O】右鼻腔、鼻咽頭の右側、および、これらに付随する副鼻腔と、後閉塞滑動自在吸引装置が右鼻腔を通して挿入されているのとを例示した、人間患者の頭部の部分断面図である。
【図2P】左鼻腔、鼻咽頭の左側、および、これらに付随する副鼻腔と、図２Oの装置の後閉塞部材および滑動自在カニューレの遠位部が鼻中隔の後ろで声門の上の位置で鼻咽頭に載置されているのとを例示した、人間患者の頭部の部分断面図である。
【図2Q】右鼻腔、鼻咽頭の右側、および、これらに付随する副鼻腔と、また別な閉塞先細吸引装置が右鼻腔を通して挿入されているのとを例示した、人間患者の頭部の部分断面図である。
【図2R】左鼻腔、鼻咽頭の左側、および、これらに付随する副鼻腔を例示しているとともに、図２Qの装置の後閉塞部材および先細吸引カニューレの遠位部が鼻中隔の後ろで声門の上の位置で鼻咽頭に載置されているのを例示した、人間患者の頭部の部分断面図である。
【図3A】本発明の閉塞吸引装置の一実施形態が解剖学的通路の内部に設置されているのを例示した部分斜視図である。
【図3B】本発明の閉塞吸引装置の別な実施形態が解剖学的通路の内部に設置されているのを例示した部分斜視図である。
【図3C】本発明の閉塞吸引装置のまた別な実施形態が解剖学的通路の内部に設置されているのを例示した部分斜視図である。図３C'は、図３Cの線３C'－３C'に沿って破断された断面図である。
【図3D】本発明の閉塞吸引装置の更に別な実施形態が解剖学的通路の内部に設置されているのを例示した、部分斜視図である。
【図3E】図3E'は、本発明の閉塞吸引装置のまた別な実施形態であって、閉塞吸引装置が解剖学的通路に設置されるプロセスの多様な工程の１つを例示した図である。図３E''は、閉塞吸引装置が解剖学的通路の内部に設置されるプロセスの多様な工程の１つを例示し

た図である。図３E’’’は、閉塞吸引装置が解剖学的通路の内部に設置されるプロセスの多様な工程の１つを例示した図である。
【図3F】図3Fは、本発明の閉塞吸引装置のまた別な実施形態が解剖学的通路の内部に設置されているのを例示した部分斜視図である。図３F’～図3F’’’は、図３Fに例示されている閉塞吸引装置の吸引カニューレの遠位部の代替の構造を例示した図である。
【図3G】本発明の閉塞吸引装置のまた別な実施形態が解剖学的通路の内部に設置されているのを例示した部分斜視図である。
【図3H】本発明の閉塞吸引装置の更に別な実施系形態が解剖学的通路の内部に設置されているのを例示した部分斜視図である。
【図3I】本発明の閉塞吸引装置のまた別な実施形態が解剖学的通路の内部に設置されているのを例示した部分斜視図である。
【図3J】本発明の閉塞吸引装置の更に別な実施形態が解剖学的通路の内部に設置されているのを例示した部分斜視図である。
【図3K】本発明の閉塞吸引装置のまた別な実施形態が解剖学的通路の内部に設置されているのを例示した部分斜視図である。
【図3L】図3L’、図3L’’は、本発明のまた別な閉塞吸引装置を例示した部分長軸線方向断面図である。
【図3M】図3M’、図３M’’は、本発明のまた別な閉塞吸引装置が解剖学的通路の内部に設置されているのを例示した部分斜視図である。
【図4】本発明の鼻咽頭閉塞気管内管状装置が右鼻腔を通って気管に挿入されている人間患者の口腔咽頭と前頸部の長軸線方向断面図である。
【図5A】側部切除または融除用装置が本発明に従って使用されているのを例示した部分斜視図である。
【図5B】左右方向に配備可能なニードル、電極、または、それ以外の治療搬送突起部材が本発明に従って使用されているのを例示した部分斜視図である。
【図5C】ドリル（例えば、組織ドリル、骨ドリル、または、穿孔装置）が本発明に従って使用されているのを例示した部分斜視図である。
【図5D】左右方向に配備することができる、標的部位への物質搬送用または装置搬送用のニードルまたは管と、任意の積載型画像化装置または支援装置とを設けたカテーテルが本発明に従って使用されているのを例示した部分斜視図である。
【図5E】バルーンカテーテルが本発明に従って使用されているのを例示した部分斜視図である。
【図5F】刃または電極が搭載されたバルーンカテーテルが本発明に従って使用されているのを例示した部分斜視図である。
【図5G】図5G’は、ステントが載置されたバルーンカテーテルが本発明に従って鼻、鼻咽頭、または、副鼻腔の内部の閉塞領域に挿入されているのを例示した部分斜視図である。図５G’’は、図３G’のバルーンカテーテルおよびステントの、バルーンが膨張してステントが拡張し、鼻、鼻咽頭、または、副鼻腔の内部の閉塞領域を開く、すなわち、拡張するようにしているのを例示した図である。図５G’’’は、図３G’のバルーンカテーテルおよびステントの、ステントが移植され、バルーンが収縮され、カテーテルが引き出されて取り出されているのを例示した図である。
【図5H】組織収縮電極装置が本発明に従って使用されているのを例示した部分斜視図である。
【図5I】低温状態治療装置またはプラズマ状態治療装置が本発明に従って使用されているのを例示した部分斜視図である。
【図5J】膨張可能な組織拡張装置が本発明に従って鼻、鼻咽頭、または、副鼻腔の通路の内部に設置されているのを例示した部分斜視図である。
【図5K】図5Kは、本発明の前方切除吸引カテーテルの一実施形態を例示した部分断面図である。図５K’は、図５Kの装置が使用されて、鼻または副鼻腔の内部の解剖学的通路から鼻ポリープまたはそれ以外の障害となる塊を除去しているのを例示した図である。

【図5L】本発明の前方切除吸引カテーテル内視鏡装置を例示した部分断面図である。
【図5M】本発明の側部切除吸引カテーテル装置を例示した部分断面図である。
【図5N】本発明の側部切除吸引カテーテル装置に任意のガイドワイヤ管腔および任意の内視鏡構成要素（単数または複数）が設けられているのを例示した部分断面図である。
【図5O】本発明のガイドカテーテル内視鏡の遠位端を例示した部分斜視図である。
【図5P】本発明のバルーンカテーテル圧力膨張式鼻腔内ステント内視鏡装置を例示した部分斜視図である。
【図5Q】図5Qは、本発明の搬送カテーテル自己膨張式鼻腔内ステント内視鏡装置を例示した部分斜視図である。図５Q'は、図５Qの線５Q'－５Q'に沿って破断された断面図である。
【図5R】図5R'は、図５Pのバルーンおよびステントの任意の修正された形状の一例を示した図である。図５R''は、図５Pのバルーンおよびステントの任意の修正された形状の別な一例を示した図である。
【図5S】本発明の、任意の内視鏡構成要素（単数または複数）を設けた係蹄カテーテルを例示した部分斜視図である。
【図5T】本発明の鉗子装置に任意の内視鏡構成要素（単数または複数）が設けられているのを例示した部分斜視図である。
【図5U】図5Uは、本発明のシステムにガイドカテーテル、内視鏡、および、ガイドワイヤが設けられているのを例示した部分斜視図である。図５U'は、図５Tの線５T'－５T'に沿って破断された断面図である。
【図5V】本発明のマイクロ創面切除カテーテルを例示した部分斜視図である。
【図5W】図5Wは、本発明の骨改造装置の部分斜視図である。図5W'、図5W''は、図５Wの骨改造装置を利用する方法の一工程を例示した図である。
【図5X】図5X'～５X''''は、本発明の骨改造装置の代替の設計を例示した部分斜視図である。
【図5Y】図5Y'～図５Y'''''は、本発明の骨改造装置の代替の設計を例示した部分斜視図である。
【図6A】本発明の蝶形骨洞ガイドカテーテルの一実施形態を例示した斜視図である。
【図6B】本発明の前頭洞ガイドカテーテルを例示した斜視図である。
【図6C】本発明の上顎洞ガイドカテーテルの一実施形態を例示した斜視図である。
【図6D】本発明の篩骨洞ガイドカテーテルの一実施形態を例示した斜視図である。
【図6E】暫定的に開口部を鼻涙管またはエウスタキオ管に接続するために使用することができる、本発明のプラグガイドカテーテルの一実施形態を例示した斜視図である。
【図7A】カテーテルが本発明に従って膨張自在な電極ケージを副鼻腔に導入しているのを例示した、副鼻腔の断面図である。
【図7B】診断用物質または治療用物質が充満された副鼻腔で、プラグが先端に付いたカテーテルが本発明に従って使用され、副鼻腔の小口を栓止して副鼻腔の内部に物質を保持するようにしているのを例示した断面図である。
【図7C】カテーテルが本発明に従って診断用物質または治療用物質を導入して副鼻腔沿いに位置する組織と接触させているのを例示した、副鼻腔の断面図である。
【図7D】カテーテルが本発明に従って３次元マッピングまたは航行のためのエミッタおよび／またはセンサーを有しているのを例示した、副鼻腔の断面図である。
【図7E】カテーテルが本発明に従ってコイル装置を副鼻腔に搬入し、副鼻腔を閉塞し、かつ／または、診断用物質または治療用物質を副鼻腔に搬入しているのを例示した、副鼻腔の断面図である。
【図7F】ガイドカテーテル、ガイドワイヤ、および、ワイヤ上を伝って案内される可撓性の内視鏡が本発明に従って副鼻腔に挿入されているのを例示した、副鼻腔の断面図である。
【図7G】図５Fのガイドカテーテルおよび内視鏡で、作業装置（例えば、生検器具など）が本発明に従って内視鏡の作業チャネルを通して挿入されて、内視鏡で視認しながら副鼻

腔の内部で処置を実施しているのを例示した図である。
【図8A】副鼻腔治療処置において、本発明に従って遂行される一工程を例示した図である
。
【図8B】副鼻腔治療処置において、本発明に従って遂行される一工程を例示した図である
。
【図8C】副鼻腔治療処置において、本発明に従って遂行される一工程を例示した図である
。
【図8D】副鼻腔治療処置において、本発明に従って遂行される一工程を例示した図である
。
【図8E】副鼻腔治療処置において、本発明に従って遂行される一工程を例示した図である
。
【図9A】蝸牛移植片処置において、本発明に従って遂行される一工程を例示した図である
。
【図9B】蝸牛移植片処置において、本発明に従って遂行される一工程を例示した図である
。
【図9C】蝸牛移植片処置において、本発明に従って遂行される一工程を例示した図である
。

【図1A】

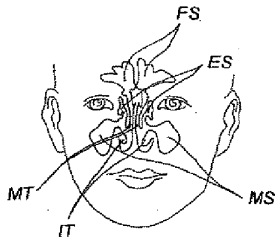


Fig. 1A (Prior art)

【図1B】

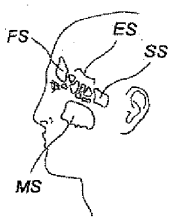


Fig. 1B (Prior art)

【図2A】

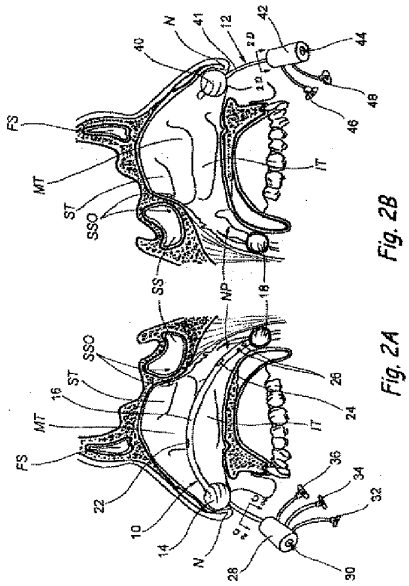


Fig. 2B

Fig. 2A

【図2B】

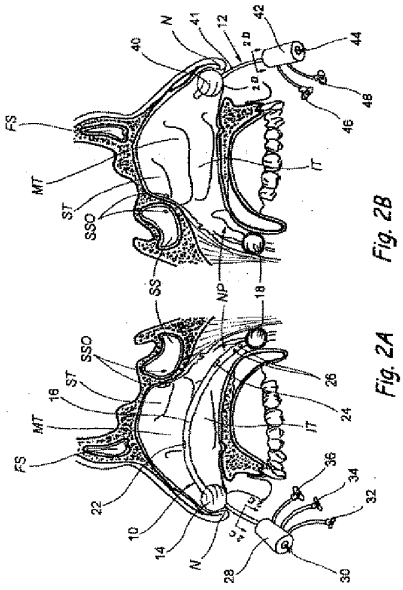


Fig. 2A

Fig. 2B

【図2C】

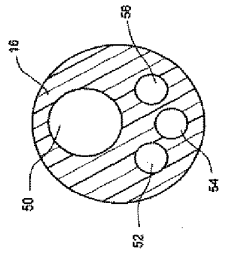


Fig. 2C

【図2D】

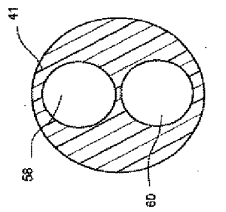


Fig. 2D

【図2E】

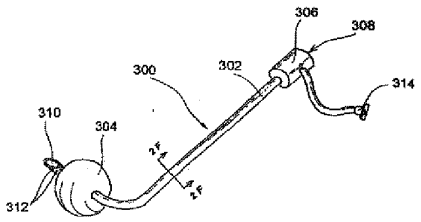


Fig. 2E

【図2F】

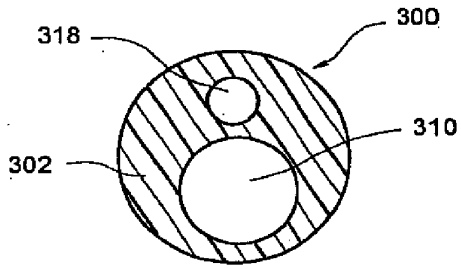


Fig. 2F

【図2G】

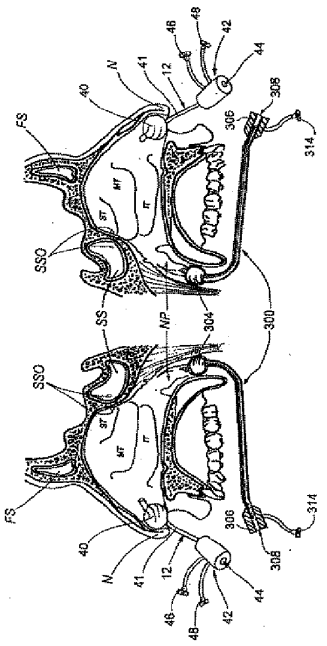


Fig. 2G

【図2H】

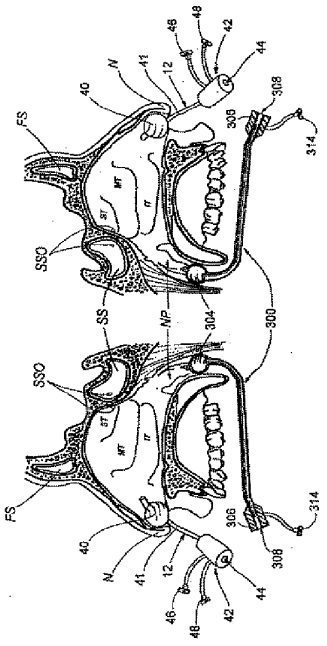


Fig. 2H

【図2I】

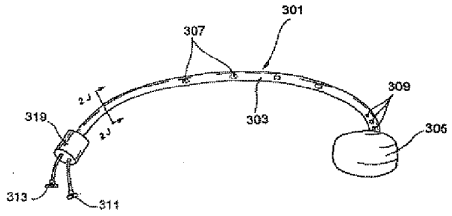


Fig. 2I

【図2J】

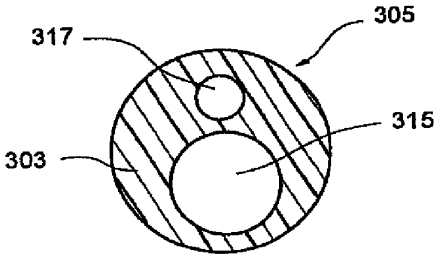
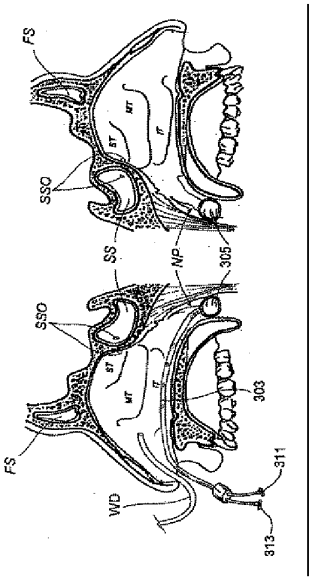


Fig. 2J

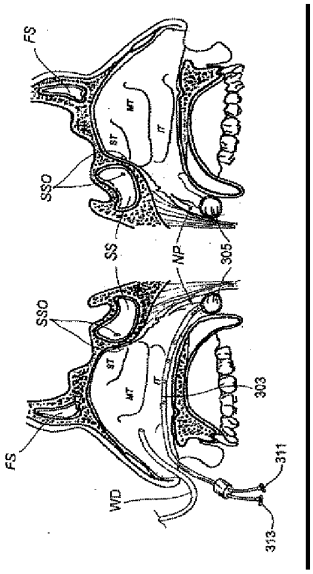
【図2K】

Fig. 2K



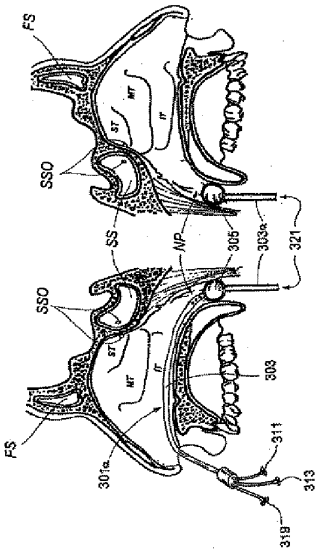
【図2L】

Fig. 2L



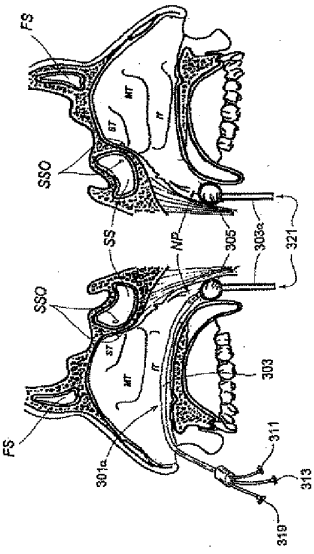
【図2M】

Fig. 2M



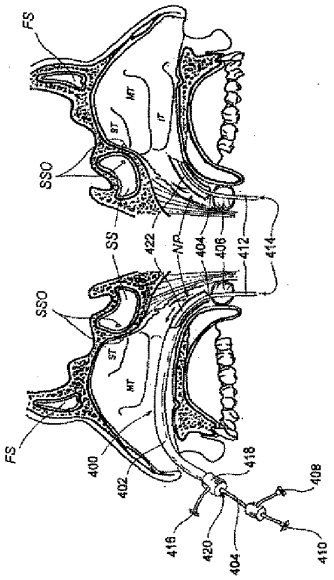
【図2N】

Fig. 2N



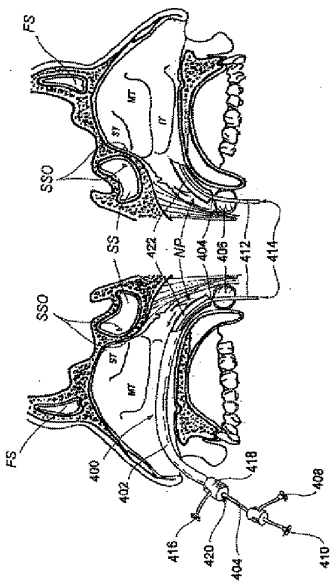
【図20】

Fig. 2O



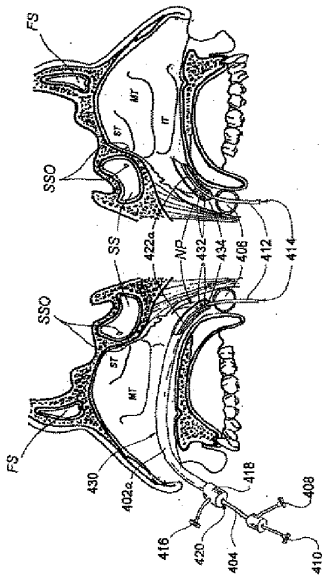
【図2P】

Fig. 2P



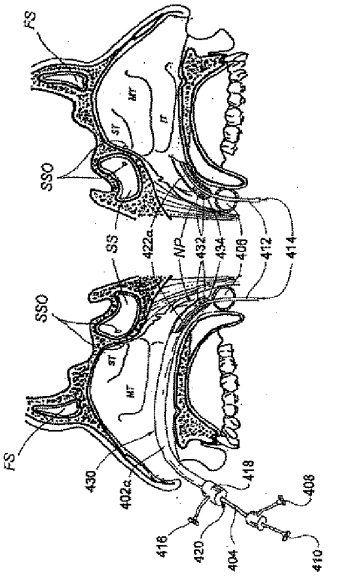
【図2Q】

Fig. 2Q



【図2R】

Fig. 2R



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【図3A】

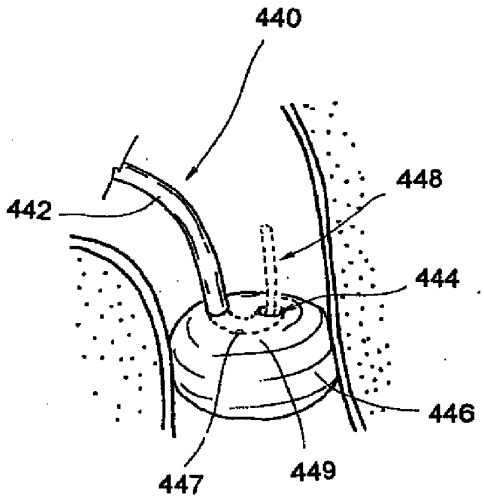


Fig. 3A

【図3B】

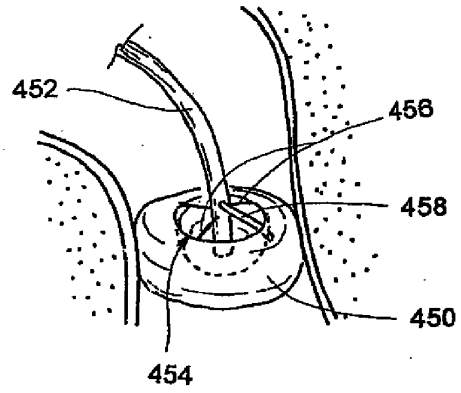


Fig. 3B

【図3C】

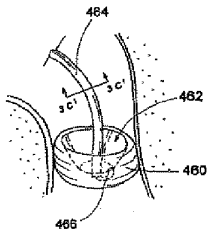


Fig. 3C

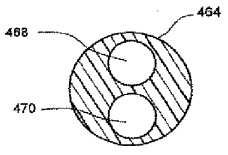


Fig. 3C'

【図3D】

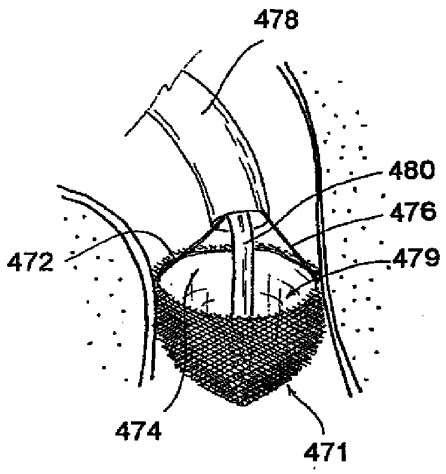


Fig. 3D

【図3E】

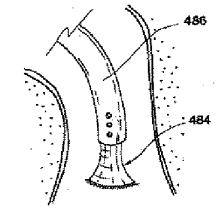


Fig. 3E^{I}

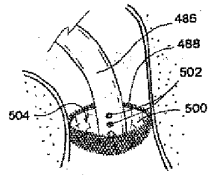


Fig. 3E^{II}

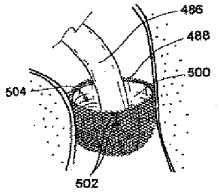


Fig. 3E^{III}

【図3F】

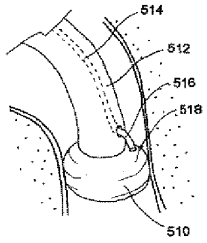


Fig. 3F

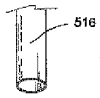


Fig. 3F^{I}

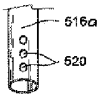


Fig. 3F^{II}

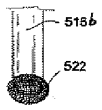


Fig. 3F^{III}

【図3G】

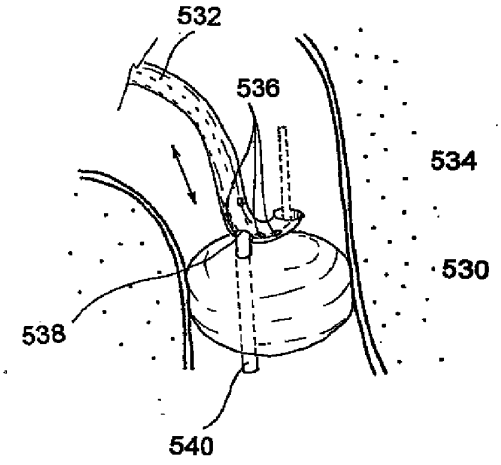


Fig. 3G

【図3H】

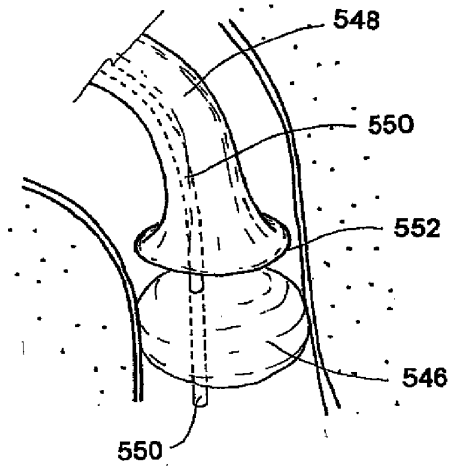


Fig. 3H

【図3I】

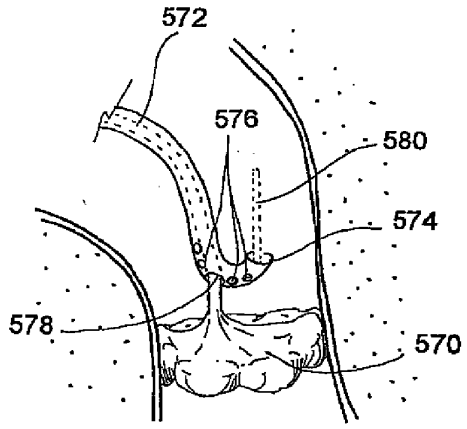


Fig. 3I

【図3J】

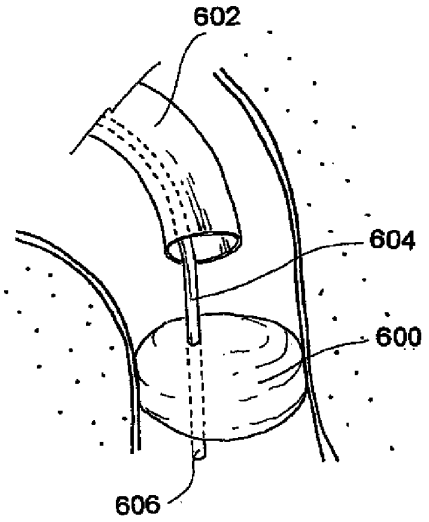


Fig. 3J

【図3K】

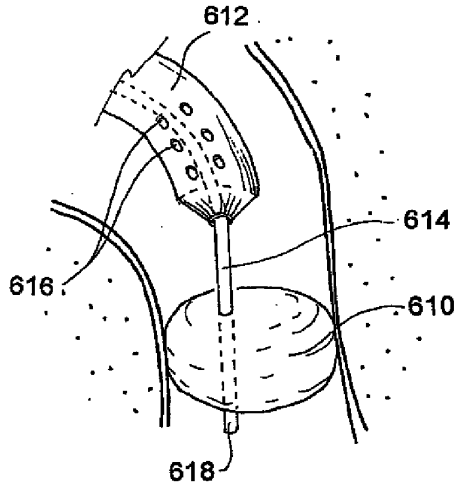


Fig. 3K

【図3L】

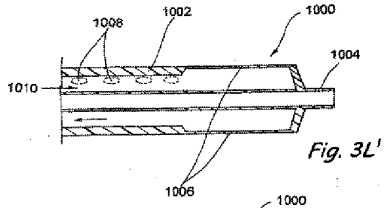


Fig. 3L'

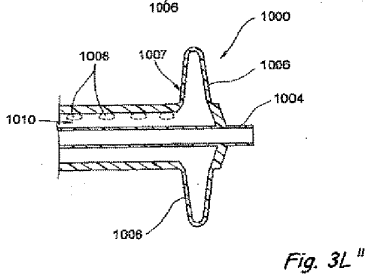


Fig. 3L''

【図3M】

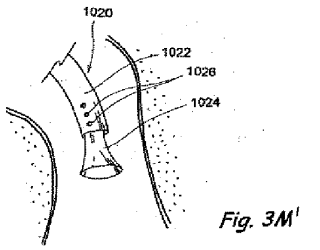


Fig. 3M'

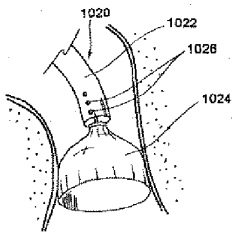


Fig. 3M''

【図4】

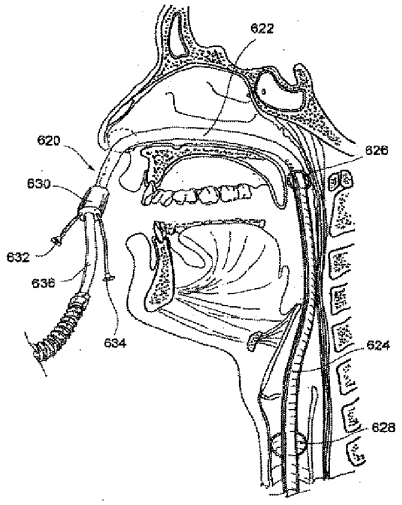


Fig. 4

【図5A】

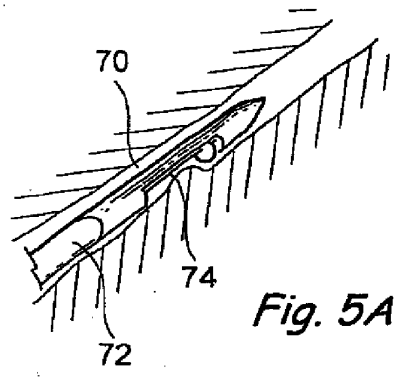


Fig. 5A

【図5B】

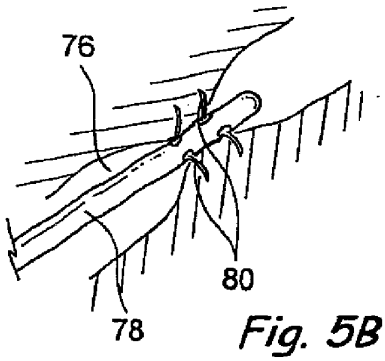


Fig. 5B

【図5C】

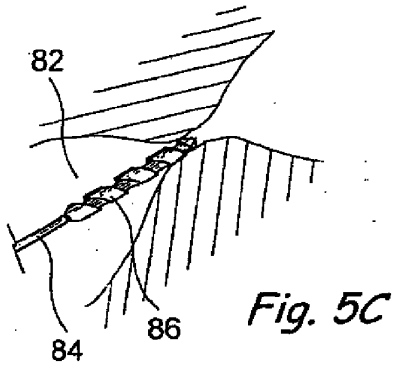


Fig. 5C

【図5D】

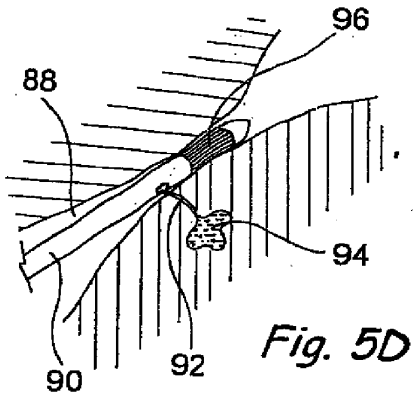


Fig. 5D

【図5E】

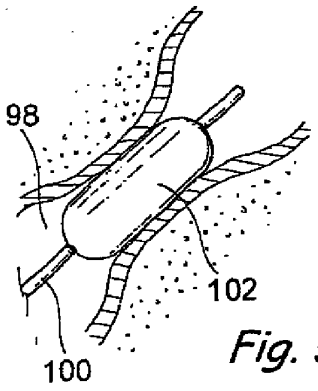


Fig. 5E

【図5F】

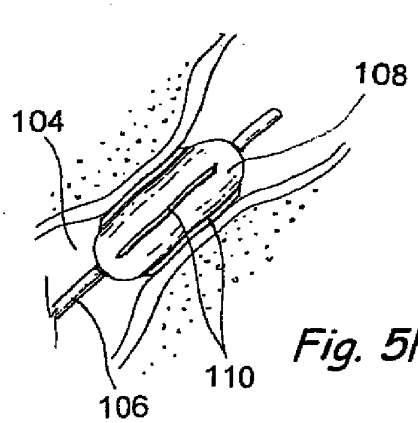
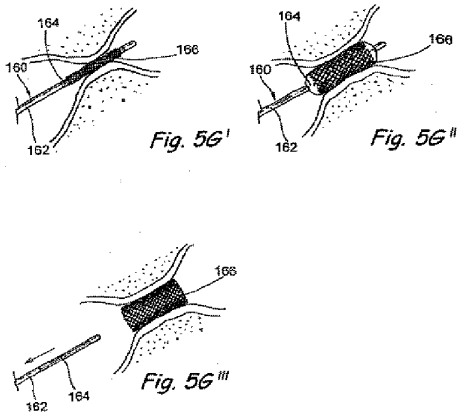
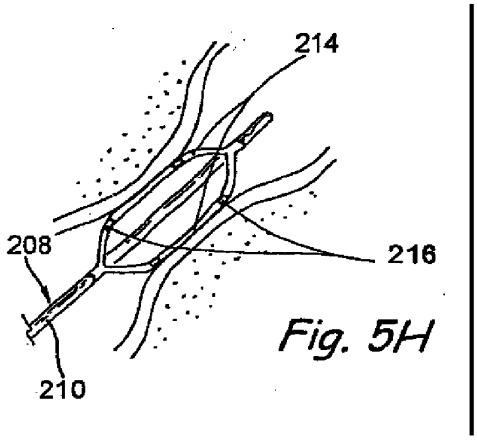


Fig. 5F

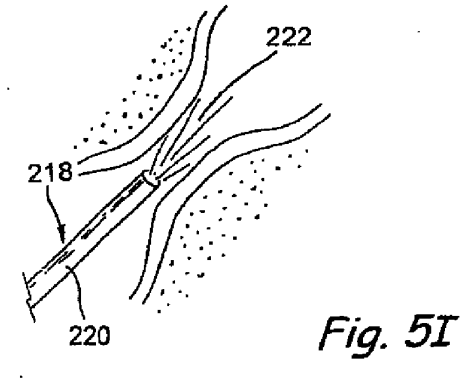
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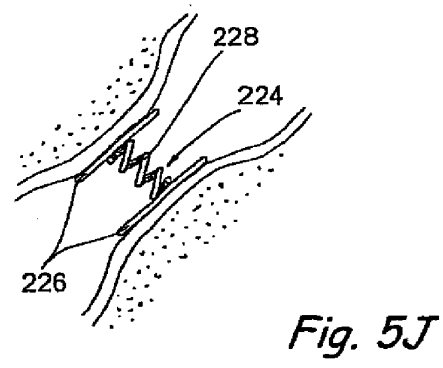
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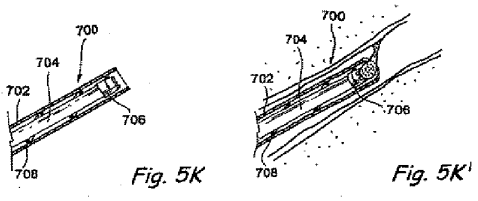
【図5I】



【図5J】



【図5K】



【図5L】

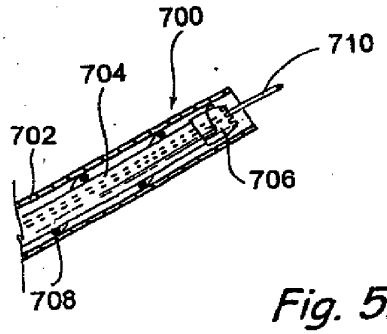


Fig. 5L

【図5M】

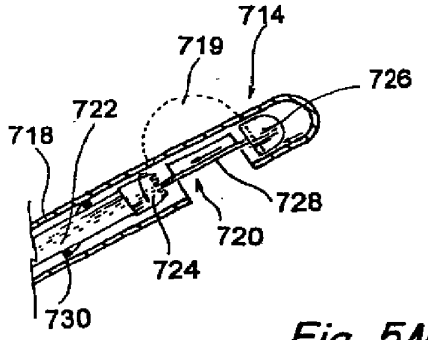


Fig. 5M

【図5N】

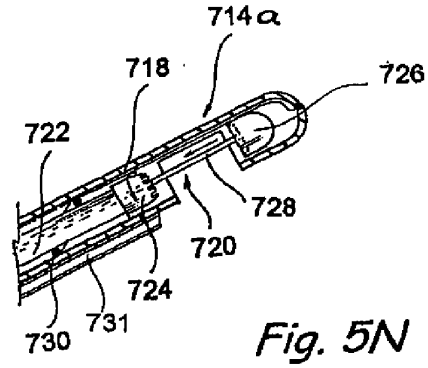


Fig. 5N

【図5P】

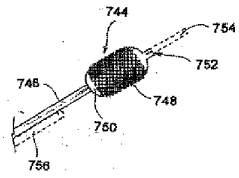


Fig. 5P

【図5Q】

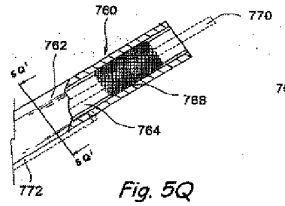


Fig. 5Q

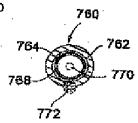


Fig. 5Q'

【図5O】

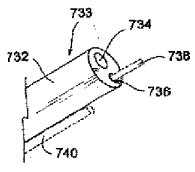


Fig. 5O

【図5R】

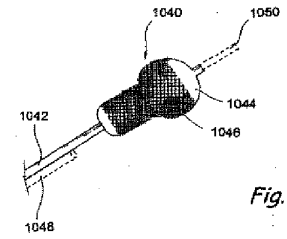


Fig. 5R'

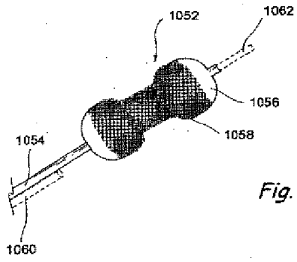


Fig. 5R''

【図5S】

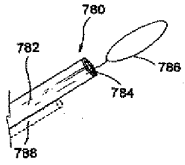


Fig. 5S

【図5T】

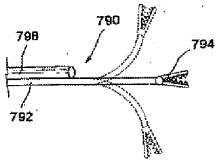


Fig. 5T

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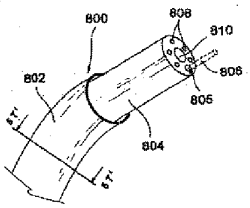


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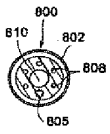


Fig. 5U'

【図5V】

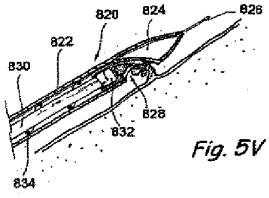


Fig. 5V

【図5W】

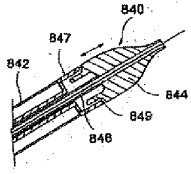


Fig. 5W

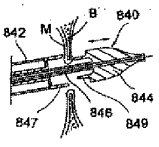


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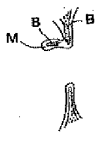


Fig. 5W''

【図5X】

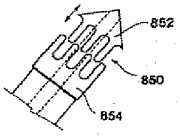


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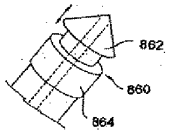


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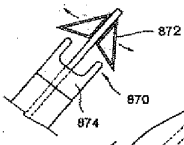


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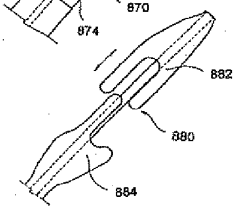
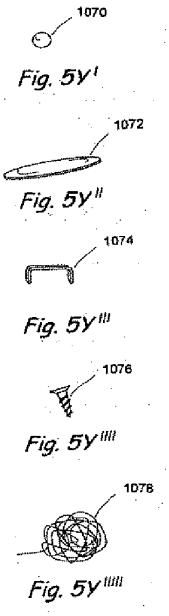


Fig. 5X''''

【図5y】



【図6A】

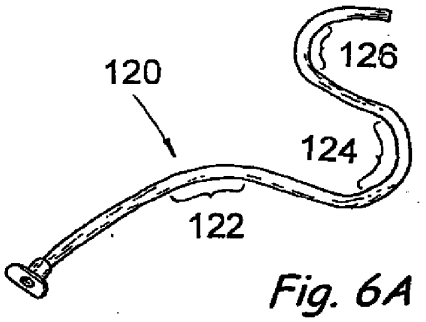


Fig. 6A

【図6B】

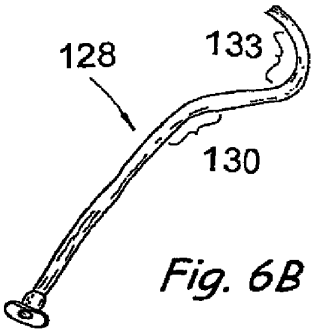


Fig. 6B

【図6C】

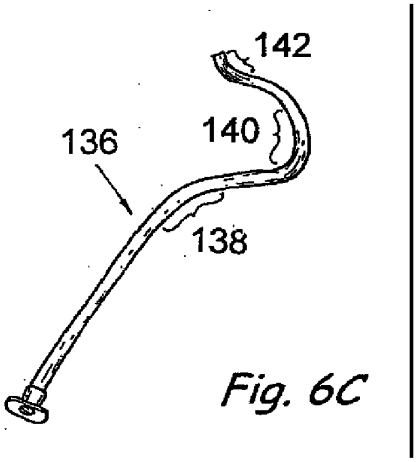


Fig. 6C

【図6D】

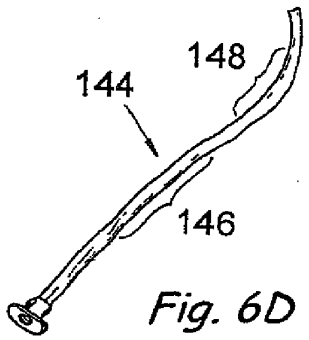


Fig. 6D

【図6E】

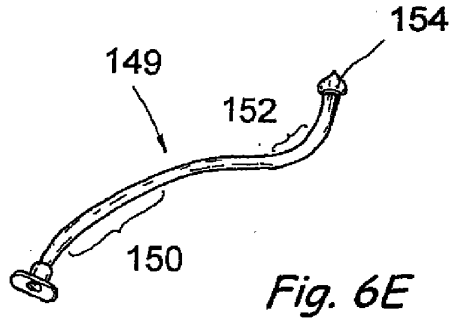


Fig. 6E

【図7A】

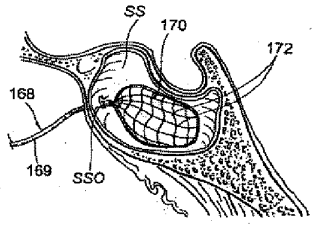


Fig. 7A

【図7B】

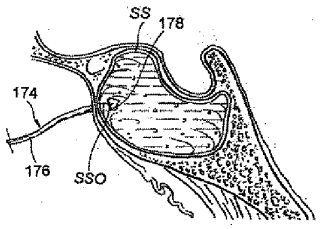


Fig. 7B

【図7C】

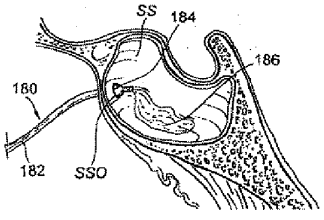


Fig. 7C

【図7D】

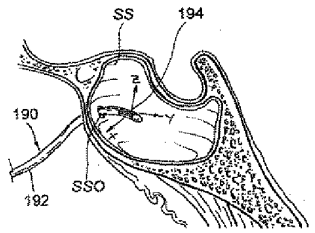


Fig. 7D

【図7E】

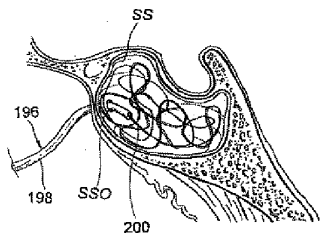


Fig. 7E

【図7F】

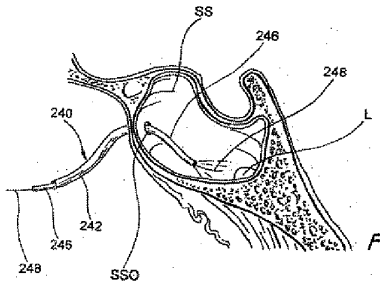


Fig. 7F

【図7G】

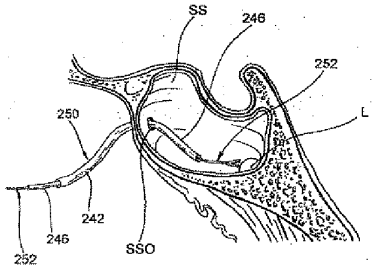


Fig. 7G

【図8A】

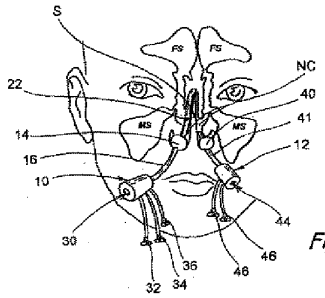


Fig. 8A

【図8B】

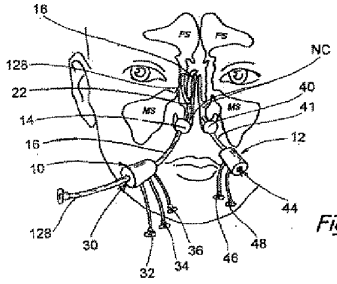


Fig. 8B

【図8C】

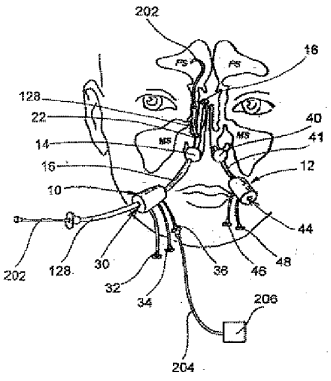


Fig. 8C

【図8D】

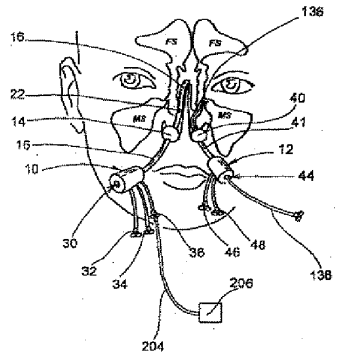


Fig. 8D

【図8E】

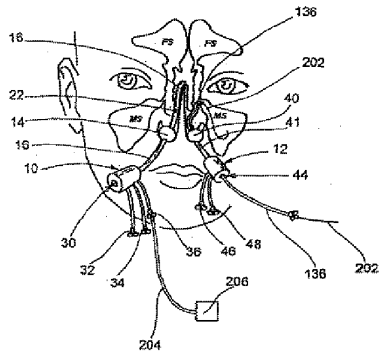


Fig. 8E

【図9A】

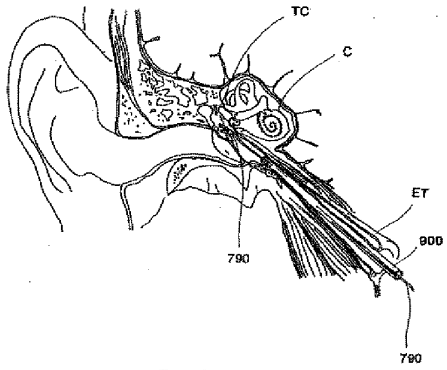


Fig. 9A

【図9B】

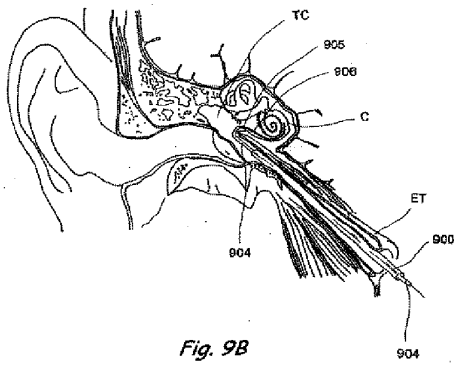


Fig. 9B

【図9C】

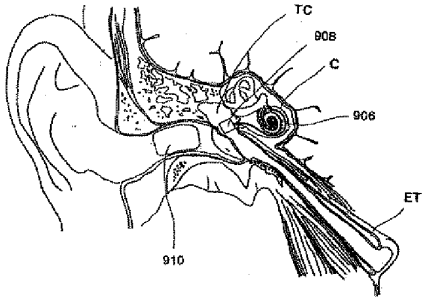


Fig. 9C

(51)Int.Cl.			FI		テーマコード（参考）
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Ａ６１Ｍ	25/01	(2006.01)	Ａ６１Ｍ	25/00	４５０Ｂ
Ａ６１Ｆ	2/82	(2006.01)	Ａ６１Ｍ	29/00	
Ａ６１Ｍ	25/00	(2006.01)	Ａ６１Ｍ	25/00	４１０Ｚ
Ａ６１Ｆ	11/00	(2006.01)	Ａ６１Ｆ	11/00	３５０
Ａ６１Ｂ	18/20	(2006.01)	Ａ６１Ｂ	17/36	３５０
Ａ６１Ｍ	31/00	(2006.01)	Ａ６１Ｍ	31/00	
			Ａ６１Ｆ	11/00	３１５

(81)指定国　AP(BW,GH,GM,KE,LS,MW,MZ,NA,SD,SL,SZ,TZ,UG,ZM,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(AT,BE,BG,CH,CY,CZ,DE,DK,EE,ES,FI,FR,GB,GR,HU,IE,IS,IT,LT,LU,MC,NL,PL,PT,RO,SE,SI,SK,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BW,BY,BZ,CA,CH,CN,CO,CR,CU,CZ,DE,DK,DM,DZ,EC,EE,EG,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KM,KP,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,MZ,NA,NI,NO,NZ,OM,PG,PH,PL,PT,RO,RU,SC,SD,SE,SG,SK,SL,SM,SY,TJ,TM,TN,TR,TT,TZ,UA,UG,US,UZ,VC,VN,YU,ZA,ZM,ZW

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4C097 AA29 BB01 BB04 CC04 MM10
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HH08

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SYSTEMS AND APPARATUS FOR FACILITATING INTRANASAL TREATMENT OF A PATIENT

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Systems are disclosed for facilitating intranasal treatment of a patient's sphenopalatine/pterygopalatine recess. Likewise the instant system is effective for addressing acute pain conditions, and is refined enough to be performed by physician's assistants, nurses, and other well-trained practitioners. Apparatus involved includes a sheath hub, a catheter hub, an arresting element, and an engagement element in embodiments. Engagement between the arresting element and the engagement element prevents rotation of the sheath hub with respect to the catheter hub.

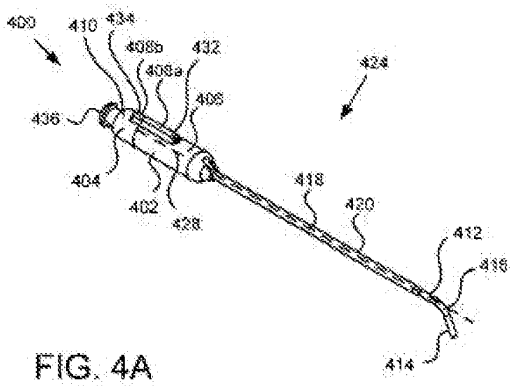


FIG. 4A

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DESCRIPTION JP2015507964A

Systems and devices to facilitate intranasal treatment of patients

[0001]

This subject relates to autonomy and nociceptive nerve blockade, and more specifically to blockage of the sphenopalatine / pterygopalatine ganglion. Specifically, the subject presents systems and devices that reduce, relieve, and ameliorate pain due to numerous indications during use.

[0002]

Autonomic neuralgia is a type of neuralgia caused by abnormalities in the function of the autonomic nervous system. With autonomic neuralgia, abnormalities in nerve groups called ganglia cause pain in organs or areas within the body. To treat autonomic intervening pain, the physician can block the ganglia by injection or application of a drug to a specific area of the body. To treat acute pain therapeutically, doctors inject or apply local anesthetics to the affected ganglion. This type of treatment can be called a nerve block.

[0003]

In 1908, Dr. Greenfield Sluder published a paper entitled "The roll of the sphere ganglion in natural headaches" in the New York Medical Journal.

He insisted on injecting cocaine into the pterygopalatine ganglion (SPG) and using a long needle through the sides of the face to treat some severe relapsed headaches. For more than a century of medicine, the basic premise of Sluder, where sphenopalatine ganglion blockade (SPGB) is a useful tool in headache management, has been established. However, prior to this teaching, there is a lack of tools in the treatment.

[0004]

SPG is a collection of nerve cells that rests just below the thin tissue that lines the back of the nasal cavity.

Due to the neural connections that pass through it, SPG plays an essential role in various types of headaches. Temporary interruptions in impulse conduction through the SPG can often interrupt headaches and sometimes provide long-term relief for headache patients.

[0005]

Other symptoms shown in the published literature to respond to SPGB are discussed herein and, as claimed below, among several indications, trigeminal neuralgia, toothache, includes postpartum cervical and back pain, complex local pain syndrome, herpes zoster (shingles), temporomandibular joint (TMJ) pain, and primary hyperhidrosis.

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[0006]

Aside from the personal pain suffered by those who experience severe recurrent headaches, the enormous financial costs to society are difficult to estimate or grasp.

With only 30 million migraine patients in the United States, annual direct health care costs are estimated to exceed $ 12 billion, with an additional $ 12 billion in productivity losses that burden employers.

These figures do not include the other 24 types of headache found in other parts of the world or in the World Health Organization headache classification scheme.

[0007]

An estimated 4-5% of the population suffers from chronic daily headaches that, by definition, affect an individual's ability to function for at least 3 months and at least 15 days a month.

Of these patients, 30% are managed with relatively inexpensive medications, 17% require pharmacological dosing plans in excess of $ 500 / month, and more than half fail in the de facto of modern medicine. I continue to suffer.

[0008]

Any intervention that reduces the onset or duration of headache has the potential to dramatically reduce individual distress and save large amounts of money for patients, companies, and governments.

The SphenoCath TM brand of catheter systems provides simple, safe, and inexpensive interventions, described throughout and as claimed below.

[0009]

The SPG / pterygopalatine ganglion is a neural structure located primarily in the center of the head within the pterygopalatine fossa posterior to the middle turbinate.

The SPG / pterygopalatine ganglion comprises the largest collection of sympathetic neurons within the outer head of the brain. The SPG / pterygopalatine ganglion interacts with nerve impulses and directs most of the autonomic or parasympathetic pathways of the head. Therefore, any abnormality or damage to this structure can cause severe pain. Nerve blocks in the SPG / pterygopalatine ganglion can relieve a variety of pain symptoms ranging from headache to low back pain. In addition, SPG / pterygopalatine ganglion and peripheral structure blockage of local anesthesia and / or other pharmacological enhancements or mechanical modifications suppress or suppress other disease processes such as headache disorders and other neurological symptoms. Can be improved.

[0010]

Unfortunately, due to the anatomical location of the SPG / pterygopalatine ganglion, the structure is very difficult to block with a local anesthetic solution.

The anatomical location of the SPG / pterygopalatine ganglion is dangerously close to many vital and delicate midbrain structures. Direct needle placement can be employed under fluoroscopy guidance to administer the anesthetic to the SPG / pterygopalatine ganglion, but most practitioners are at the extreme risk of technical difficulty and abnormal needle placement. Will not try to perform the procedure.

[0011]

Accessing the SPG / pterygopalatine ganglion to treat the SPG / pterygopalatine ganglion with a conventional device is the curvature for the conventional device to typically access the sphenopalatine / pterygopalatine recess. It is difficult in that it does not include

In addition, even if the conventional needle is curved to access the sphenopalatine / pterygopalatine recess, once the curved needle is inserted into the patient's nasal cavity, a doctor or other healthcare professional will tell the needle. The direction of the curve will not be discernible. In the absence of fluoroscopy induction, the insertion end of the needle can contact and / or

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damage vital and delicate midbrain structures. To date, this limitation has limited significant involvement of both service providers and patients.

[0012]

From the above discussion, we hope that it can be done safely in due course, that is, by non-medical professionals who can count on one hand at the top level, who can make it successful. It should become clear that there is a need for equipment and systems to facilitate intranasal treatment of patients.

Beneficially, such devices and systems would administer the drug directly to the sphenopalatine / pterygopalatine ganglion.

[0013]

This subject has been developed according to current state-of-the-art techniques, specifically according to problems and needs that have not yet been fully resolved by currently available intranasal treatment devices, systems, and methods. ing.

Accordingly, the subject has been developed to provide devices and systems for intranasal treatment of patients that overcome many or all of the above drawbacks in the art.

[0014]

Devices that facilitate intranasal treatment of a patient's SPG / pterygopalatine depression include, in certain embodiments, a sheath hub, a catheter hub, a deterrent element, and an engagement element.

The sheath hub has an outer surface facing the inner surface.

The inner surface defines the catheter hub receiving space.

The catheter hub is slidably received within the catheter hub receiving space and can be positioned along the longitudinal axis of the sheath hub.

The deterrent element is located on one of the catheter hub and the sheath hub, and the engaging element is located on the other of the catheter hub and the sheath hub

The restraining element continuously engages the engaging element when the catheter hub is positioned along the longitudinal axis of the sheath hub.

The engagement between the restraining element and the engaging element prevents the sheath hub from rotating with respect to the catheter hub

[0015]

The device, in one embodiment, includes a catheter and a rotational orientation indicator.

The catheter is connected to a catheter hub and at least a portion of the catheter contains an internal bend.

The rotational orientation indicator identifies the rotational orientation of the internal bend of the catheter.

In certain embodiments, the rotational orientation indicator comprises a ridge extending longitudinally along at least one of a sheath hub and a catheter hub.

In other embodiments, the rotational orientation indicator provides only a visual indication of the rotational orientation of the internal bend of the catheter.

[0016]

According to embodiments, the catheter comprises an insertion end and a connecting end.

In such embodiments, the insertion end may include an internal bend with respect to the longitudinal axis of the catheter and a rotational orientation indicator identifies the rotational orientation of the internal bend of the catheter.

[0017]

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In certain embodiments, the device comprises a sheath coupled to a sheath hub and a catheter coupled to the catheter hub and received within the sheath.

The catheter comprises an insertion end and a connecting end, which has an internal bend with respect to the longitudinal axis of the catheter.

In such an embodiment, the catheter hub can be positioned between the insertion and expansion positions.

When the catheter hub is positioned in the extended position, the sheath straightens the internal bend of the catheter.

[0018]

The catheter, in some embodiments, comprises an insertion end having a tip that is curved so that the tip is rounded.

The sheath includes an introductory end with an outermost edge that slopes to the apex.

In such an embodiment, when the catheter hub is positioned in the dilated position, the apex is aligned with the onset of curvature of the rounded tip of the catheter.

In one embodiment, the transition between the apex and the onset of curvature of the rounded tip of the catheter is continuous when the catheter hub is positioned in the extended position.

In one embodiment, the tip of the insertion end of the catheter is spherical.

[0019]

The deterrent element is, in one embodiment, a flange that is connected to or extends vertically from either the outer surface of the catheter hub or the inner surface of the sheath hub.

In such an embodiment, the engaging element is a recess extending longitudinally along the other side of the inner surface of the sheath hub or the outer surface of the catheter hub.

The flange is positioned and moves along the recess when the catheter hub is rearranged along the longitudinal axis of the sheath hub.

[0020]

In certain embodiments, the device comprises a stop element coupled to either a catheter hub or a sheath hub.

The stop element is configured to engage the deterrent element to stop the catheter hub from being removed from the catheter hub receiving space.

In one embodiment, the stop element is configured to align the apex of the sheath with the start of curvature of the rounded tip of the catheter when the catheter hub is positioned in the dilated position.

[0021]

In certain embodiments, the device includes a sheath hub, a catheter hub, a restraining element, an engaging element, and a rotational orientation indicator.

The sheath hub has an outer surface facing the inner surface.

The inner surface defines the catheter hub receiving space.

The catheter hub is slidably received within the catheter hub receiving space and can be positioned along the longitudinal axis of the sheath hub.

The deterrent element is connected to or positioned on either the catheter hub or the sheath hub.

The engaging element is connected to or positioned on the other of the catheter hub and sheath hub.

The restraining element continuously engages the engaging element when the catheter hub is rearranged along the longitudinal axis of the sheath hub.

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The engagement between the restraining element and the engaging element prevents the sheath hub from rotating with respect to the catheter hub.

The rotational orientation indicator identifies the rotational orientation of at least one of the sheath hub and the catheter hub.

[0022]

In certain embodiments, the reorientation indicator is a ridge extending longitudinally along at least one of a sheath hub and a catheter hub.

The ridge identifies the rotational orientation of at least one of the sheath hub and catheter hub both visually and tactilely.

[0023]

According to embodiments, the device comprises a catheter coupled to a catheter hub.

The catheter has an insertion end and a connecting end, the insertion end having an internal bend with respect to the longitudinal axis of the catheter.

In such an embodiment, the rotational orientation indicator identifies the orientation of the internal bend of the catheter.

[0024]

The deterrent element, in one embodiment, includes a flange that is connected to or extends vertically from either the outer surface of the catheter hub or the inner surface of the sheath hub.

In such embodiments, the engaging element comprises a recess extending longitudinally along the other of the inner surface of the sheath hub and the outer surface of the catheter hub.

The restraining element flange is positioned and moves along the recess of the engaging element when the catheter hub is rearranged along the longitudinal axis of the sheath hub.

[0025]

In certain embodiments, the device further comprises a sheath connected to a sheath hub, the catheter hub being positionable between the insertion and expansion positions.

In the extended position, the sheath straightens the internal bend of the catheter.

In one embodiment, the tip of the insertion end of the catheter is curved so that the tip is rounded.

In such an embodiment, the sheath includes an introduction end and a connection end.

The outermost edge of the introduction end is tilted to the apex, which coincides with the onset of curvature of the rounded tip of the catheter when the catheter hub is repositioned in the extended position within the sheath hub.

[0026]

Also disclosed are devices for facilitating intranasal treatment of a patient's SPG / pterygopalatine depression, including a sheath hub, a catheter hub, a deterrent element, an engaging element, a sheath, and a catheter.

The sheath hub has an outer surface facing the inner surface.

The inner surface defines the catheter hub receiving space, and the catheter hub is slidably received within the catheter hub receiving space.

The catheter hub can be positioned along the longitudinal axis of the sheath hub.

The deterrent element is placed on either the catheter hub or the sheath hub.

The engaging element is located on or in the catheter hub or the other of the sheath hubs.

The restraining element continuously engages the engaging element when the catheter hub is rearranged along the longitudinal axis of the sheath hub between the insertion and expansion positions.

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The sheath includes an introduction end that is connected to a sheath hub and has an outermost edge.

The catheter is received within the sheath and connected to the catheter hub.

The catheter comprises an insertion end having a tip that is curved so that the tip is rounded.

The outermost edge of the sheath coincides with the onset of curvature of the rounded tip of the catheter when the catheter hub is positioned in the extended position.

[0027]

In one embodiment, the outermost edge of the introduction end of the sheath slopes to the apex.

In such an embodiment, the apex is aligned with the onset of curvature of the rounded tip of the catheter when the catheter is positioned in the dilated position.

In one embodiment, the transition between the apex and the onset of curvature of the rounded tip of the catheter is continuous when the catheter hub is positioned in the dilated position.

In another embodiment, the tip of the insertion end of the catheter is spherical.

In such embodiments, the spherical tip of the insertion end of the catheter may protect the sheath from catching on delicate tissue within the patient's nasal cavity.

[0028]

According to embodiments, systems and devices for coping with acute pain are disclosed and the indications are head and neck cancer, complex local pain syndrome, reflex sympathetic dystrophy, vasomotor rhinitis, oral cavity. Preoperative and postoperative desensitization, swarm headache, headache, cervical spasm, any level of disc disease or hernia, lumbar pain, lumbosacral spasm, pear muscle spasm syndrome, spasticity (convulsive) in maxillofacial surgery.) Oblique neck, SPG nerve pain (Sulder syndrome), trigeminal nerve pain (painful tick), post-herpes zoster nerve pain, autonomic nerve pain, atypical facial pain, bulging disc, lumbosacral disc, causalgia, reflex sympathetic Distrophy (RSD), cervical spondylosis, migraine, sinus headache, cerebrospinal fluid leak headache, chronic sinusitis, tension headache, myofascial pain syndrome , Pinched nerve, sciatic nerve pain, slipped disc, sinus pain, jaw joint syndrome (TMJ), whipping, allergic rhinitis, vasomotor rhinitis, asthma, bell palsy (Facial nerve palsy), bone pain, cancer pain, bronchial spasm, chronic bronchitis, menstrual difficulty, endometriosis, fibromyalgia, multiple sclerosis with convulsions, peripheral neuropathy (neuropathy pain), Reynaud phenomenon, rheumatoid arthritis (redness), herpes zoster (herpes zoster), spinal cord stenosis, chronic fatigue syndrome, chronic regurgitation, diabetic neuropathy, hypertension, hypotension headache, phantom limb / toothache, sensory abnormalities, repetitive it is present for at least one of sexual stress injury and ear ringing (low frequency).

[0029]

According to embodiments, a kit is disclosed that includes instructions and an improved system disclosed herein and claimed below.

[0030]

All references to features, advantages, and similar terms throughout this specification should be within any single embodiment of the subject, or all of the features and advantages that may be realized in the subject. Does not suggest that there is.

Rather, the term referring to a feature and an advantage is understood to mean that a particular feature, advantage, or characteristic described in connection with an embodiment is included in at least one embodiment of the subject.

Thus, the discussion of features and benefits, as well as similar terms, may, but may not necessarily, refer to the same embodiment throughout the specification.

[0031]

In addition, the described features, advantages, and properties of the subject may be combined in any suitable manner in one or more embodiments.

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One of ordinary skill in the art will recognize that the subject may be practiced without one or more of the particular features or advantages of a particular embodiment.

In other cases, additional features and advantages that may not be present in all embodiments of the subject may be recognized in certain embodiments.

[0032]

These features and advantages of the subject matter may be more fully apparent from the following description and claims, or may be learned by the practice of the subject matter described below.

[0033]

For easy understanding of the advantages of this subject, reference to the specific embodiments illustrated in the accompanying drawings will provide a more specific description of the subject as briefly described above. Let's do it.

Understanding that these drawings depict only typical embodiments of the subject and are therefore not considered to limit their scope, the subject is an additional peculiarity through the use of the accompanying drawings. It will be described and explained with sex and details.

[0034]

FIG. 1 is a cross-sectional view illustrating an embodiment of a patient's facial biostructure in which the apparatus, system, and method of the present invention may be employed.

FIG. 2 is a cross-sectional view illustrating a prior art method of treating headache.

FIG. 3 is a cross-sectional view illustrating a prior art method of treating headache.

FIG. 4A is for facilitating intranasal treatment of a patient's sphenopalatine / pterygopalatine depression, according to the subject, where the catheter hub is positioned at the insertion site within the sheath hub (ready for drug delivery). It is a perspective view which illustrates one Embodiment of the apparatus.

FIG. 4B, according to the subject, facilitates intranasal treatment of a patient's sphenopalatine / pterygopalatine depression in which the catheter hub is positioned in an extended position within the sheath hub (ready for device insertion). It is a perspective view which illustrates one Embodiment of the apparatus.

FIG. 5A, according to the subject, facilitates intranasal treatment of a patient's sphenopalatine / pterygopalatine depression in which the catheter hub is positioned in an extended position within the sheath hub (ready for device insertion). It is a top view which illustrates one Embodiment of the apparatus.

FIG. 5B, according to the subject, facilitates intranasal treatment of a patient's sphenopalatine / pterygopalatine depression in which the catheter hub is positioned in an extended position within the sheath hub (ready for device insertion). It is a side sectional view illustrating one embodiment of the apparatus.

FIG. 6A is for facilitating intranasal treatment of a patient's sphenopalatine / pterygopalatine depression, according to the subject, where the catheter hub is positioned at the insertion site within the sheath hub (ready for drug delivery). It is a top view which shows one Embodiment of the apparatus.

FIG. 6B is for facilitating intranasal treatment of a patient's sphenopalatine / pterygopalatine depression, according to the subject, where the catheter hub is positioned at the insertion site within the sheath hub (ready for drug delivery). It is a side sectional view illustrating one embodiment of the apparatus.

FIG. 7 is a perspective view illustrating an embodiment of a catheter hub according to the subject.

FIG. 8A is a top view illustrating an embodiment of a catheter hub according to the subject.

FIG. 8B is a side sectional view illustrating an embodiment of a catheter hub and catheter according to the subject.

FIG. 9A is an end view illustrating an embodiment of a catheter hub obtained in the direction of the treatment receiving end of the catheter hub according to the subject.

FIG. 9B is an end view illustrating an embodiment of a catheter hub obtained in the direction of the therapeutic delivery end of the catheter hub according to the subject.

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FIG. 10A is a top view illustrating an embodiment of a sheath hub and sheath according to the subject.

FIG. 10B is a side sectional view illustrating an embodiment of a sheath hub and a sheath according to the present subject.

FIG. 11 is an enlarged view of the region of the sheath hub including the stop element according to the subject.

FIG. 12 is an end view illustrating an embodiment of a sheath hub obtained in the direction of the sheath receiving end of the sheath hub according to the present subject.

FIG. 13A is a cross-sectional view illustrating an embodiment of a sheath introduction end and a catheter insertion end where the apex of the sheath coincides with the initiation of curvature of the catheter insertion end.

FIG. 13B is a cross-sectional view illustrating an embodiment of a sheath introduction end and a catheter insertion end where the apex of the sheath is inconsistent with the initiation of curvature of the catheter insertion end.

FIG. 13C is a cross-sectional view illustrating an embodiment of a sheath introduction end and a catheter insertion end where the apex of the sheath is inconsistent with the initiation of curvature of the catheter insertion end.

[0035]

The inventors of the present invention have a higher success rate than expected for non-licensed physicians (trained and surgically untrained practitioners by licensed medical professionals) due to the enhanced system. I found that it was possible to deal with the problem.

[0036]

The SphenoCath TM branded medical device, when used as designed, is the direction needed to safely and painlessly deliver the right dose of drug to the SPG in a clinic environment without needles, analgesics, or anesthetics. Bring control to any practitioner.

[0037]

References to "one embodiment," "embodiment," or similar term throughout the specification have a particular feature, structure, or property described in connection with the embodiment, but at least one of the subject matter. Means to be included in one embodiment.

Thus, the appearance of the phrase "in one embodiment", "in an embodiment", or similar terms throughout the specification can all refer to the same embodiment, but is not always the case.

[0038]

In addition, the described features, structures, or properties of the subject may be combined in any suitable manner in one or more embodiments.

In the following description, a number of specific details are provided for a thorough understanding of the embodiments of this subject.

However, one of ordinary skill in the art will recognize that the subject may be practiced without one or more of the specific details or with other methods, components, materials, etc. Let's do it.

In other cases, well-known structures, materials, or behaviors are not shown or described in detail to avoid obscuring aspects of the subject.

[0039]

FIG. 1 is an explanatory diagram of one environment in which the device and the system operate.

Specifically, FIG. 1 depicts a cross-sectional view of the anatomical features of a typical human nasal cavity.

Those skilled in the art will recognize that certain anatomical features and structures of the human nasal cavity are omitted to avoid obscuring the structures associated with the practice of this subject.

The mouth 106 is illustrated along with the teeth 108 and the tongue 110 to help guide the reader in the correct direction.

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Anatomical structures related to one practice of the subject include a palatal 100 that separates the oral cavity 102 from the nasal cavity 104, an inferior turbinate 112, a middle turbinate 114, and a superior turbinate 116, and a nasal bone 122.

The middle turbinate 114 and the superior turbinate 116 define the sphenopalatine / pterygopalatine recess 118.

The sphenopalatine / pterygopalatine ganglion 120 is located deep in the sphenopalatine / pterygopalatine recess 118 and at the rear 124 of the sphenopalatine / pterygopalatine recess 118.

[0040]

Those of skill in the art will recognize that the medical community is not unified in terms of the sphenopalatine or pterygopalatine ganglion.

Some practitioners use the sphenopalatine, while others use the pterygopalatine.

Therefore, in this description, the ganglion labeled with 120 is referred to as SPG / pterygopalatine ganglion 120.

Similarly, the recess labeled 118 would be referred to as the SPG / pterygopalatine recess 118.

However, this term is not limited in any way in the structure intended for this subject.

If the practitioner or scientist distinguishes between the butterfly and pterygopalatine ganglia, the present disclosure will be understood to apply either structure.

[0041]

The sphenopalatine / pterygopalatine ganglion 120 is a neural structure located primarily in the center of the head within the pterygopalatine fossa behind the middle turbinate 114.

The sphenopalatine / pterygopalatine ganglion 120 comprises the largest collection of sympathetic neurons within the outer head of the brain.

The sphenopalatine / pterygopalatine ganglion 120 interacts with nerve impulses and directs most of the autonomic or parasympathetic pathways of the head.

Therefore, any abnormality or damage to this structure can cause severe pain.

Nerve blocks in the pterygopalatine / pterygopalatine ganglion 120 may be effective in alleviating a variety of pain symptoms ranging from headache to low back pain.

In addition, by local anesthesia blockade of the butterfly palatal / pterygopalatine ganglion 120 and surrounding structures, and / or other pharmacological enhancements or mechanical modifications, other disease processes such as headache disorders and other neurological symptoms Can be deterred or improved.

[0042]

Unfortunately, due to the anatomical location of the sphenopalatine / pterygopalatine ganglion 120, the structure is very difficult to block with a local anesthetic solution using some commonly practiced techniques. obtain.

The anatomical location of the sphenopalatine / pterygopalatine ganglion 120 is dangerously close to many vital and delicate midbrain structures.

Direct needle placement can be employed under fluoroscopy guidance to administer the anesthetic to the sphenopalatine / pterygopalatine ganglion 120, but most practitioners have the extreme technical difficulty and abnormal needle placement. Due to the danger, he will not try to perform the procedure.

[0043]

As shown in the illustration of the prior art depicted in FIG. 2, the sphenopalatine / pterygopalatine ganglion 120 is located deep in the sphenopalatine / pterygopalatine recess 118.

Conventional methods undertaken by pain specialists, neurologists, and neurosurgeons include the use of an 8-inch cotton swab 200 saturated with a local anesthetic.

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Since the cotton swab 200 is used, this procedure is called a "cotton swab (Q-tip)" procedure.

The swab 200 is immersed in a vial of concentrated local anesthetic.

In certain embodiments, the anesthetic solution is lidocaine, cocaine, etidocaine, or prilocaine, or other non-specific local anesthetic.

The swab 200 is then advanced into the nostril 202 and through the nasal cavity 104.

To reach the sphenopalatine / pterygopalatine ganglion 120 in the sphenopalatine / pterygopalatine recess 118, the cotton rod 200 enters the nasal cavity 104, past the turbinate 114, and the sphenopalatine / pterygopalatine depression. Must be advanced into the recess 118

[0044]

FIG. 3 illustrates a meandering path that a prior art cotton swab 200 must traverse to reach the sphenopalatine / pterygopalatine recess 118.

To perform the procedure, the patient is placed in the supine position.

The swab 200 is immersed in a vial of concentrated local anesthetic or other pharmacological agent.

The doctor then inserts a swab 200 into the patient's nostril 202 and through the nasal cavity 104.

The swab 200 must be inserted almost parallel to the patient's face so that it passes through the anterior ridge 302 of the middle turbinate 114, thus advancing the straight rigid swab 200 into the sphenopalatine / pterygopalatine recess 118. That can be difficult and painful for the patient.

The swab 200 must then bend approximately 90 degrees to avoid the lower surface 304 of the nasal bone 122 and access the sphenopalatine / pterygopalatine recess 118.

The cotton swab 200 allows the diffusion of local anesthetics or other pharmacological agents through the sinus mucosa to modulate the sphenopalatine / pterygopalatine ganglion 120, temporarily blocking or permanently blocking nerve transmission. It is left in the patient's sphenopalatine / pterygopalatine recess 118 for about 20 minutes to be removed.

[0045]

The use of a straight rigid cotton swab 200, which has to make some fairly serpentine diversions around some very sensitive, vascularized, fragile, highly innervated structures The procedure is so complicated that many practitioners will not try it.

Known complications include complications associated with epistaxis, including extreme patient discomfort, epistaxis, and venous irritation, arterial bleeding, aspiration, bloody stools, or even death.

Other complications include local anesthetic toxicity, seizures, iatrogenic foreign bodies such as broken cotton swabs 200, sinus mucosal lacerations, and infections.

[0046]

Anesthesia blockade of any neural structure requires a direct physical interaction between the anesthetic solution and the target tissue.

Therefore, in order to function, the swab 200 must deliver the anesthetic solution directly to the sphenopalatine / pterygopalatine ganglion 120

The correct placement of the swab 200 is technically difficult, and many practitioners simply remove the desired structure, the sphenopalatine / pterygopalatine ganglion 120, when attempting the procedure.

To help perform the complex flexion required to reach the sphenopalatine / pterygopalatine recess 118, many practitioners soak the top 2 inches of the swab 200 and the patient is less irritated. Instead, the handle will be manipulated to make it flexible so that the risk of bleeding is reduced.

Even with the flexible cotton swab 200, the procedure is difficult.

Common placement failures include the lower surface 304 of the nasal bone 122 and the anterior ridge 302 of the middle turbinate 114.

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When the swab 200 is misplaced, a "squeeze" effect can occur, where the anesthetic is squeezed out of the swab before it is delivered to the sphenopalatine / pterygopalatine ganglion 120, resulting in an ineffective procedure.

Moreover, as discussed above, the abundant vascular and neural structure of the nasal cavity 104 makes any misplacement of the swab 200 dangerous and painful.

[0047]

FIG. 4A depicts a perspective view of an embodiment of the device 400 for facilitating intranasal treatment of a patient's sphenopalatine / pterygopalatine depression 118.

In one embodiment, the device 400 includes a sheath hub 402, a catheter hub 404, a catheter 412, and a sheath 420.

The device 400 of FIG. 4A is depicted with a catheter hub 404 located at insertion position 424 within the sheath hub 402.

FIG. 4B illustrates a perspective view of an embodiment of device 400 of FIG. 4A, in which the catheter hub 404 is located at the extended position 426 within the sheath hub 402.

[0048]

The sheath hub 402 includes an outer surface 406 facing the inner surface 502 (FIG. 5B).

The inner surface 502 of the catheter hub 404 defines the catheter hub receiving space 504 (FIG. 5B).

At least a portion 422 of the catheter hub 404 is received within the catheter hub receiving space 504, and the catheter hub 404 is repositionable along the longitudinal axis 428 of the sheath hub 402.

In certain embodiments, the catheter hub 404 is repositionable between the insertion position 424 as shown in FIG. 4A and the expansion position 426 as shown in FIG. 4B.

[0049]

In one embodiment, the catheter hub 404 comprises a stop surface 425.

When the catheter hub 404 is fully inserted into the catheter hub receiving space 504, the stop surface 425 of the catheter hub 404 contacts the sheath hub 402 to prevent further insertion of the catheter hub 404 within the catheter hub receiving space 504. ..

When the catheter hub 404 is fully positioned within the catheter hub receiving space 504 until the stop surface 425 contacts the sheath hub 402, the catheter hub 404 provides an internal catheter fully extended beyond the distal tip of the sheath. Concomitantly, it may be considered to be positioned at the full insertion position 424.

As the catheter hub 404 is withdrawn from within the catheter hub receiving space 504 in the direction indicated by arrow 407, the catheter hub 404 may be considered positioned at the fully expanded position 426.

[0050]

In the illustrated embodiment, the outer shape of the sheath hub 402 and the outer shape of the catheter hub 404 are substantially circular.

In other embodiments, the sheath hub 402 and the catheter hub 406 have an outer shape having a triangular outer shape, a square outer shape, a rectangular outer shape, a polygonal outer shape, an elliptical outer shape, or any other geometric shape. You may.

[0051]

The catheter 412 is connected to the catheter hub 404 at the connecting end 506 of the catheter 412 (see FIG. 5B).

The insertion end (distal tip) 414 of the catheter 412 includes an internal bend 416 with respect to the longitudinal axis 418 of the catheter 412.

The insertion end 414 of the catheter 412 is located opposite the connecting end 506 of the catheter 412.

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The partial curvature 416 of the insertion end 414 of the catheter 412 bends the insertion end 414 of the catheter 412 when advanced beyond the distal tip of the sheath 420.

When the device 400 is inserted into the patient's nasal cavity 104, a doctor or other healthcare professional will use a catheter beyond the distal tip of the sheath 420 of the patient without contacting the delicate peripheral structure of the patient's nasal cavity 104. The internal bend 416 of the insertion end 414 is retracted into the sheath 420 until it is advanced directly into the space above the sphenopalatine / pterygopalatine recess 118.

[0052]

When the catheter 412 is first inserted into the patient's nasal cavity 104, the catheter 412 is relatively straight past the anterior ridge 302 of the middle turbinate 114 to access the patient's sphenopalatine / pterygopalatine recess 118. You have to travel by the route of.

Therefore, when inserted into the patient's nasal cavity, the catheter 412 should be relatively straight.

In order to straighten the internal bend 416 of the insertion end 414 of the catheter 412, the catheter 412 has sufficient structural rigidity to straighten the internal bend 416 of the insertion end 414 of the catheter 412, within the sheath 420. Accepted at.

The sheath 420 is connected to the sheath hub 402 and the catheter 412 is received within the sheath 420.

[0053]

Since the catheter 412 is connected to the catheter hub 404 and the sheath 420 is connected to the sheath hub 402, the catheter 412 is retracted into the sheath 420 as shown in FIG. 4B when the catheter hub 404 is positioned at the expansion position 426. is done.

When the catheter 412 is pulled into the sheath 420, the structural rigidity of the sheath 420 straightens the internal bend 416 of the insertion end 414 of the catheter 412, and a doctor or other medical professional can tell the anterior ridge 302 of the middle turbinate 114. Allows the insertion end 414 of the catheter 412 to be manipulated past.

[0054]

Once the insertion end 414 of the catheter 412 passes through the anterior ridge 302 of the middle turbinate 114, the physician or other medical professional can advance the catheter hub 404 to the insertion position 424.

When the catheter hub 404 is rearranged at the insertion position 424, the internal bend 416 of the insertion end 414 of the catheter 412 is not positioned within the sheath 420 and is therefore not straightened by the sheath 420.

The internal bend 416 of the insertion end 414 of the catheter 412 bends the insertion end 414 of the catheter 412.

Flexion of the catheter 412 allows the physician or other medical professional to orient the insertion end 414 of the catheter 412 into the patient's pterygopalatine / pterygopalatine recess 118, where the physician or other medical professional The home can deliver the treatment to the patient's butterfly / pterygopalatine ganglion 120.

[0055]

This discussion will cover access to the sphenopalatine / pterygopalatine recess 118 for treating the sphenopalatine / pterygopalatine ganglion 120, but to those skilled in the art, in other embodiments, other areas of the patient. You will recognize that device 400 may be used to access.

For example, device 400 is used by a physician or other medical professional to position the insertion end 414 of the catheter 412, which is placed with reference to the entry point, within any region on the non-linear patient. May be good.

Examples of such areas may include the patient's ear cavity, veins, arteries, and the like.

[0056]

In certain embodiments, the treatment delivered may be dispensing of a neuroleptic agent into the sphenopalatine / pterygopalatine ganglion 120 through a catheter 412.

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In another embodiment, the catheter 412 may include electrodes configured to deliver electrical stimulation to the sphenopalatine / pterygopalatine ganglion 120.

Those skilled in the art will recognize that other medical procedures may be delivered to the sphenopalatine / pterygopalatine ganglion 120.

[0057]

When a doctor or other healthcare professional inserts the insertion end of the catheter 412 into the patient's nasal cavity, the view of the physician or other healthcare professional at the insertion end 414 of the catheter 412 is obstructed by the peripheral structure of the patient's nose. obtain.

In addition, the physician or other healthcare professional will determine if the internal bend 416 is oriented to advance the insertion end 414 of the catheter 412 into the patient's sphenopalatine / pterygopalatine recess 118. Therefore, the orientation of the internal bend 416 or the insertion end 414 of the catheter 412 cannot be seen.

To assist a physician or other healthcare professional in advancing the insertion end 414 of the catheter 412 into the patient's sphenopalatine / pterygopalatine recess 118, in one embodiment, the device 400 is a rotational orientation indicator 408. including.

In one embodiment, the rotational orientation indicator 408 identifies the rotational orientation of the internal bend 416 of the catheter 412 to assist the physician or other medical professional in determining the orientation of the insertion end 414 of the catheter.

In certain embodiments, the rotational orientation indicator 408 may be a visual indication, such as a line, point, or other indication, located on the outer surface 406 of the sheath hub 402, the outer surface 410 of the catheter hub 404, or both. ..

[0058]

In the embodiments illustrated in FIGS. 4A and 4B, the rotational orientation indicator 408 has a first rotational orientation indicator 408a located on the outer surface 406 of the sheath hub 402 and a second rotation located on the outer surface 410 of the catheter hub 404. Includes orientation indicator 408b and.

In other embodiments, only one of the sheath hub 402 or the catheter hub 404 comprises a rotational orientation indicator 408.

[0059]

In one embodiment, the rotational orientation indicator 408a on the sheath hub 402 is a ridge 432 extending longitudinally along at least a portion of the sheath hub 402.

The ridge 432 extends substantially vertically from the outer surface 406 of the sheath hub 402 to provide tactile feedback regarding the orientation of the internal bend 416 of the catheter 412 to the physician or other medical professional.

Thus, when a physician or other healthcare professional advances the insertion end 414 of the catheter 412 into the patient's nasal cavity 104, the physician or other healthcare professional will discuss the depth of the catheter 412 within the patient's nasal cavity 104, etc. Visual attention can be focused on other factors that can affect the procedure.

[0060]

In certain embodiments, the rotational orientation indicator 408b on the catheter hub 404 may also be a ridge 434.

In such an embodiment, the ridge 434 extends longitudinally along at least a portion of the catheter hub 404.

The ridge 432 extends substantially vertically from the outer surface 410 of the catheter hub 404 to provide tactile feedback regarding the orientation of the internal bend 416 of the catheter 412 to the physician or other medical professional.

In embodiments, the physician or other medical professional has any component (catheter hub 404 or sheath hub 402) in which both the sheath hub 402 and the catheter hub 404 include ridges 432 and 434 that serve as rotational orientation indicators 408. The orientation of the internal bend 416 of the catheter 412 can be determined regardless of whether it is operated by a physician or other medical professional.

[0061]

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In certain embodiments, the ridges 432 and 434 on the sheath hub 402 and catheter hub 404 are aligned along the same axis.

In other embodiments, the ridge 432 on the sheath hub 402 may be offset from the ridge 434 on the catheter hub 404.

In yet another embodiment, as discussed above, only one of the sheath hub 402 or catheter hub 404 comprises a rotational orientation indicator 408.

In such an embodiment, the device 400 may include either a ridge 432 on the outer surface 406 of the sheath hub 402 or a ridge 434 on the outer surface 410 of the catheter hub 404.

[0062]

In one embodiment, the device 400 comprises a therapy receiving port 436 to receive drug therapy.

For example, in one embodiment, the treatment receiving port 436 can be linked to a syringe or other drug delivery device.

The treatment receiving port 436 is in fluid communication with the catheter 412 so that the drug can be delivered to the sphenopalatine / pterygopalatine ganglion 120 through the catheter 412.

[0063]

In other embodiments, other treatment delivery devices may be coupled to the treatment receiving port 436.

For example, in one embodiment, the therapeutic delivery device may include an electrical stimulation device configured to transmit an electric current to the device 400.

In such an embodiment, the catheter 412 may include an electrical conduit that conducts current from the treatment receiving port 436 to the insertion end 414 of the catheter 412.

An electrode located above the insertion end 414 of the catheter 412 delivers an electric current to the patient.

[0064]

FIG. 5A depicts a top view of an embodiment of the device 400 for facilitating intranasal treatment of a patient's sphenopalatine / pterygopalatine depression 118.

In the embodiment depicted in FIG. 5A, the catheter hub 404 is located at extended position 426.

In one embodiment, the sheath 420 is tilted to the apex 508 so that the entire sheath 420 introduction end 505 forms a smooth slope without any edges that catch on the tissue of the patient's nasal cavity 104. Includes 505.

[0065]

In one embodiment, the insertion end 414 of the catheter 412 is curved so that the tip 510 of the insertion end 414 of the catheter 412 is rounded.

By including a rounded tip 510 over the insertion end 414 of the catheter 412, a physician or other healthcare professional will capture or hook the delicate tissue of the patient's nasal cavity 104 at the insertion end 414 of the catheter 412. It is unlikely

As further described below, in certain embodiments, when the catheter hub 404 is positioned at the extended position 426, the apex 508 at the introduction end 505 of the sheath 420 is the transition 512 between the catheter 412 and the sheath 420. Consistent with the initiation of the curvature of the rounded tip 510 of the catheter 412 so that it is continuous, smooth, and substantially free of edges.

The smooth transition 512 between the catheter 412 and the sheath 420 helps to avoid capturing tissue within the patient's nasal cavity 104.

[0066]

In certain embodiments, the treatment receiving port 436 comprises a connecting member 514 for connecting the device 400 to a treatment delivery device.

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For example, in one embodiment, the connecting member 514 may be a plurality of threads arranged around the circumference of the treatment receiving port 436.

The threads of the coupling member 514 engage the threads on the syringe or other treatment delivery device to connect the treatment delivery device to the treatment receiving port 436.

[0067]

FIG. 5B depicts a side sectional view of an embodiment of the device 400 for facilitating intranasal treatment of a patient's sphenopalatine / pterygopalatine depression 118.

In the embodiment depicted in FIG. 5B, the catheter hub 404 is located at extended position 426.

The embodiment depicted in FIG. 5B is obtained along line AA of FIG. 5A and more clearly illustrates one embodiment of the inner surface 502 of the sheath hub 402 and the catheter hub receiving space 504.

[0068]

In one embodiment, the sheath hub 402 has an outer surface 406 facing an inner surface 502.

The inner surface 502 of the sheath hub 402 defines the catheter hub receiving space 504.

Part 422 of the catheter hub 404 has a reduced diameter so that the catheter hub 404 can be placed longitudinally along the longitudinal axis 428 of the sheath hub 402 (see FIGS. 4A and 4B). Slidably received within 504.

[0069]

In certain embodiments, the device 400 comprises a deterrent element 516 on either the catheter hub 404 or the sheath hub 402.

In the embodiment illustrated in FIG. 5B, the deterrent element 516 is a flange connected to and vertically extending from the outer surface 518 of the reduced diameter portion 422 of the catheter hub 404.

[0070]

In one embodiment, the device 400 also comprises an engaging element 520 on either the catheter hub 404 or the sheath hub 402.

In the embodiment illustrated in FIG. 5B, the engaging element 520 is a recess extending longitudinally along the inner surface 502 of the sheath hub 402.

The flange of the restraining element 516 is positioned and moves along the recess of the engaging element 520 when the catheter hub 404 is rearranged along the longitudinal axis 428 of the sheath hub 402.

The coordination between the restraining element 516 and the engaging element 520 allows the catheter hub 404 to be slidably received within the catheter hub receiving space 504 while limiting the rotation of the catheter hub 404 with respect to the sheath hub 402. do.

Thus, in one embodiment, the flange of the restraining element 516 is continuously engaged within the recess of the engaging element 520 when the catheter hub 404 is rearranged along the longitudinal axis 428 of the sheath hub 402. Be done.

The engagement between the restraining element 516 and the engaging element 520 prevents rotation of the sheath hub 402 with respect to the catheter hub 404.

[0071]

By limiting the rotation of the catheter hub 404 with respect to the sheath hub 402, the physician or other medical professional can determine the orientation of the internal bend 414 of the catheter 412 by the position of the rotational orientation indicator 408a on the catheter hub 404. Yes, the rotational orientation indicator 408b on the sheath hub 402 may be unnecessary.

[0072]

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In certain embodiments, the device 400 also includes a stop element 522 attached to either the catheter hub 404 or the sheath hub 402.

The stop element 522 is configured to engage the deterrent element 516 to stop the catheter hub 404 from being removed from the catheter hub receiving space 504.

In the embodiment illustrated in FIG. 5B, the stop element 522 is a substantially rigid wall that engages the deterrent element 516 to stop the catheter hub 404 from being removed from the catheter hub receiving space 504.

In one embodiment, the stop element 522 also has a continuous, smooth, and substantially edge of the transition 512 between the catheter 412 and the sheath 420 when the catheter hub 404 is positioned at the dilated position 426. Also facilitates alignment of apex 508 at the introduction end 505 of the sheath 420 with the initiation of curvature of the rounded tip 510 of the catheter 412 so as not to include.

[0073]

Of course, one of ordinary skill in the art will recognize that in certain embodiments, the positions of the deterrent element 516, the engaging element 520, and the stopping element 522 may be reversed.

For example, in one embodiment, the restraining element 516 may be coupled to the inner surface 502 of the sheath hub 402, and the recess of the engaging element 520 may be positioned within the outer surface 518 of the reduced diameter portion 506 of the catheter hub 404. good.

Similarly, in one embodiment, the stop element 522 is coupled to the reduced diameter portion 506 of the catheter hub 404 so as to limit the removal of the catheter hub 404 from within the catheter hub receiving space 504 within the sheath hub 402. May be.

[0074]

FIG. 6A depicts a top view of an embodiment of the device 400 for facilitating intranasal treatment of a patient's sphenopalatine / pterygopalatine depression 118.

In the embodiment illustrated in FIG. 6A, the catheter hub 404 is positioned at the insertion position 424.

[0075]

FIG. 6B is a side sectional view of an embodiment of an embodiment of a device for facilitating intranasal treatment of a patient's sphenopalatine / pterygopalatine depression 118.

In the embodiment depicted in FIG. 6B, the catheter hub 404 is positioned at insertion position 424.

The embodiment depicted in FIG. 6B is obtained along line BB of FIG. 6A.

[0076]

In one embodiment, when the catheter hub 404 is fully inserted into the catheter hub receiving space 504, the stop surface 425 of the catheter hub 404 prevents further insertion of the catheter hub 404 within the catheter hub receiving space 504. Contact the end 602 of the sheath hub 402.

In another embodiment, the end 604 of the reduced diameter portion 422 of the catheter hub 404 contacts the inner wall 606 within the catheter hub receiving space 504 to prevent further insertion of the catheter hub 404 within the catheter hub receiving space 504. do.

If the catheter hub 404 is fully positioned within the catheter hub receiving space 504 to the point where the stop surface 425 contacts the sheath hub 402, the catheter hub 404 may be considered positioned at the complete insertion position 424.

[0077]

FIG. 7A illustrates a perspective view of an embodiment of the catheter hub 404 according to the present disclosure.

In the embodiment illustrated in FIG. 7A, the sheath hub 402 and the catheter 412 are omitted to better illustrate the catheter hub 404.

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[0078]

In one embodiment, the catheter hub 404 comprises a treatment receiving end 702 located opposite the treatment delivery end 704.

In one embodiment, the catheter hub 404 includes an operating portion 706, an insertion portion 708, and a connecting portion 710.

In the illustrated embodiment, the operating portion 706, the insertion portion 708, and the connecting portion 710 are substantially cylindrical.

In other embodiments, the operating portion 706, the insertion portion 708, and / or the connecting portion 710 is a triangular outline, a square outline, a rectangular outline, a polygonal outline, an elliptical outline, or any other geometry. It may have an outer shape having a geometric shape.

[0079]

In one embodiment, the insertion portion 708 of the catheter hub 404 comprises a reduced diameter portion 422 of the catheter hub 404.

The insertion portion 708, in one embodiment, begins at the stop surface 425 of the catheter hub 404 and extends to the therapeutic delivery end 704 of the catheter hub 404.

[0080]

The connecting portion 710 of the catheter hub 404 is located opposite the insertion portion 708 and includes a treatment receiving port 436.

An anesthetic, drug, current, or any other treatment is received at the treatment receiving port 436 and from the treatment receiving end 702 to the treatment delivery end 704 through the lumen 712 located through the catheter hub 404 to the treatment delivery end 704. Will be delivered.

When the catheter 412 is positioned within the lumen 712, the catheter receives treatment and delivers it to the desired area, such as the patient's sphenopalatine / pterygopalatine recess 118.

[0081]

The operating portion 706 of the catheter hub 404, in certain embodiments, has an increased diameter relative to the insertion portion 708 and is positioned between the connecting portion 710 and the insertion portion 708.

The increased diameter of the operating portion 706 of the catheter hub 404 facilitates the operation of the catheter hub 404 by a physician or other medical professional.

[0082]

The deterrent element 516 is connected to the outer surface 518 of the insertion portion 708 of the catheter hub 404 and extends substantially vertically from there.

The deterrent element 516 includes, in one embodiment, an inclined surface 715.

For example, in one embodiment, the end 711 of the deterrent element 516 adjacent to the treatment delivery end 704 of the catheter hub 404 is substantially smaller than the end 714 of the deterrent element 516 closer to the treatment receiving end 702 of the catheter hub 404. At a distance, it extends from the outer surface 518 of the insertion portion 708 of the catheter hub 404.

The slanted surface 715 of the restraint element 516 allows the flange of the restraint element 516 to be inserted past the stop element 522 into the recess of the engagement element 520.

The posterior surface 716 of the restraint element 516 extends substantially vertically from the outer surface 518 of the reduced diameter portion 422 of the catheter hub 404.

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When the catheter hub 404 is withdrawn from within the catheter hub receiving space 504, the posterior surface 716 of the deterrent element 516 engages the stopping element 522 to stop the catheter hub 404 from being removed from within the catheter hub receiving space 504. ..

In one embodiment, the interaction between the posterior surface of the deterrent element 516 and the stop element 522 is such that the apex 508 at the introduction end 505 of the sheath 420 coincides with the initiation of the curvature of the rounded tip 510 of the catheter 412. Position the catheter 412 within the sheath 420.

At this position, the transition 512 between the catheter 412 and the sheath 420 is continuous, smooth and substantially free of edges.

[0083]

FIG. 8A illustrates a side view of an embodiment of the catheter hub 404 and catheter 412 according to the present invention.

In the embodiment illustrated in FIG. 8A, the threads of the connecting member 514 are more clearly illustrated.

In another embodiment, the connecting member 514 is a snap-fitting attachment, a peripheral edge for chemically adhering the therapeutic delivery device, or any other attachment or attachment to the catheter hub 404 for the therapeutic delivery device. It may be the means of.

[0084]

In one embodiment, the catheter hub 404 comprises a plurality of depth indicators 806 arranged along the insertion portion 708 of the catheter hub 404 at regular intervals.

In the embodiment illustrated in FIG. 8A, the depth indicator 806 is a line positioned around the circumference of the insertion portion 708 of the catheter hub 404.

In other embodiments, the depth indicator 806 may include other shapes such as points, squares, circles, triangles, or any other visual indicator.

In one embodiment, the depth indicator 806 may also include a numerical indication of the depth of the catheter hub 404 within the catheter hub receiving space 504.

[0085]

To perform the initial nerve block, the catheter hub 404 is positioned in the dilated position 426 and the physician or other medical professional advances the sheath 420 and catheter 412 into the patient's nasal cavity 104.

Once the catheter insertion end 414 passes through the anterior ridge 302 of the middle turbinate 114, physicians or other medical professionals advance the catheter hub 404 deeper into the catheter hub receiving space 504 to advance the catheter hub 404 to the introduction end 505 of the sheath 420. To advance the insertion end 414 of the catheter 412 past.

Once the insertion end 414 of the catheter 412 is advanced to a position where the sheath 420 no longer contains the internal bend 416 of the catheter 412, the catheter 412 bends.

The doctor or other medical professional knows the direction in which the catheter 412 is flexed by the orientation of the rotational orientation indicator 408, so that the doctor or other medical professional can perform nerve block or other treatment with the pterygopalatine / wing. The insertion end 414 of the catheter 412 can be oriented into the pterygopalatine / pterygopalatine recess 118 for delivery to the palatal ganglion 120.

[0086]

As will be apparent to those skilled in the art, the anatomy of a patient's nasal cavity 104 will vary from individual to individual.

Therefore, one patient will have a deeper sphenopalatine / pterygopalatine recess 118 than another.

The depth indicator 806 on the insertion portion 708 of the catheter hub 404 is provided by a physician or other medical professional to the catheter 412 when the insertion end 414 of the catheter 412 is positioned within the patient's sphenopalatine / pterygopalatine recess 118. It makes it possible to determine the depth of the insertion end 414.

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In one embodiment, during the initial treatment of the sphenopalatine / pterygopalatine ganglion 120 of a particular patient, the physician or other healthcare professional may record the depth of the patient's sphenopalatine / pterygopalatine recess 118. ..

In subsequent treatment of the patient's sphenopalatine / pterygopalatine ganglion 120, the physician or other healthcare professional can use the recorded depth as a guide.

[0087]

FIG. 8B illustrates a cross-sectional view of an embodiment of the catheter hub 404 according to the present disclosure.

The embodiment depicted in FIG. 8B is obtained along lines CC of FIG. 8A.

[0088]

In one embodiment, the catheter 412 is located within the lumen 712 within the catheter hub 404 and at least partially extends into the lumen 712.

In another embodiment, the catheter 412 may be attached to the end face 802 at the therapeutic delivery end 704 of the catheter 412.

In either embodiment, the catheter 412 fluidly communicates with the lumen 712 so as to deliver a drug, anesthetic, or other chemical to the insertion end 414 of the catheter 412 that can be dispensed to the patient. Can be communicated with.

[0089]

In another embodiment, an electrical conduit such as a wire is positioned through lumen 712 in catheter 412 and through lumen 804 in catheter.

In such embodiments, the electrical conduit may be coupled to a power source to deliver current to an electrode located at the insertion end 414 of the catheter 412.

The electrodes are configured to deliver an electric current to the patient.

[0090]

FIG. 9A is an end view illustrating an embodiment of the catheter hub 404 according to the present disclosure.

The embodiment illustrated in FIG. 9A is obtained in the direction of the treatment receiving end 702 of the catheter hub 404.

[0091]

In one embodiment, the catheter hub 404 comprises one or more connecting flanges 902a and 902b located on the inner circumference 904 of the treatment receiving port 436.

In such an embodiment, the connecting flange 902 is configured to connect a syringe or other therapeutic delivery device to the catheter hub.

[0092]

FIG. 9B is an end view illustrating an embodiment of the catheter hub 404 according to the present disclosure.

The embodiment illustrated in FIG. 9A is obtained in the direction of the therapeutic delivery end 704 of the catheter hub 404.

[0093]

FIG. 10A is a top view of an embodiment of the sheath hub 402 connected to the sheath 420 according to the present disclosure.

In one embodiment, the sheath hub 402 includes a catheter hub receiving end 1002 and a sheath receiving end 1004.

In the embodiment illustrated in FIG. 10A, the sheath 420 is coupled to the sheath receiving end 1004 of the sheath hub 402.

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[0094]

In one embodiment, the sheath hub 406 comprises a substantially cylindrical portion 1006 and a tapered portion 1008.

A catheter hub receiving space 504 is arranged within the cylindrical portion 1006.

In one embodiment, the catheter hub receiving space 504 is also a substantially cylindrical void within the sheath hub 406.

In such an embodiment, the insertion portion 708 of the catheter hub 404 is also cylindrical so that the insertion portion 708 of the catheter hub 404 can be received within the catheter hub receiving space.

In other embodiments, the outer surface 406 of the sheath hub 402 has an outer surface 406 of the sheath hub 402, while the shape of the insertion portion 708 of the catheter hub 404 and the shape of the void in the catheter hub receiving space 504 may be any other geometric shape. It remains cylindrical.

Of course, in one embodiment, the opposite may be true.

That is, in one embodiment, the outer surface 406 of the sheath hub 402 may have a shape other than the cylindrical shape, while the shape of the insertion portion 708 of the catheter hub 404 and the shape of the void in the catheter hub receiving space 504 are cylindrical. Is.

[0095]

The tapered portion 1008 of the sheath hub 402 extends from the cylindrical portion 1006 to the sheath receiving end 1004 of the sheath hub 402.

The diameter of the sheath hub 402 at the sheath receiving end 1004 is such that the diameter of the sheath hub 402 at the interface 1010 between the cylindrical portion 1006 and the tapered portion 1008 so that the tapered portion 1008 of the sheath hub 402 inclines toward the tapered portion 1008 of the sheath hub 402. Substantially smaller than the diameter.

[0096]

In certain embodiments, the sheath 420 may include a plurality of depth indicators 1016 arranged along at least a portion of the outer surface 1018 of the sheath 420 at regular intervals.

In the embodiment illustrated in FIG. 10A, the depth indicator 1016 is a line located on the outer surface 1018 of the sheath 420.

In other embodiments, the depth indicator 1016 may include other shapes such as points, squares, circles, triangles, or any other visual indicator.

In one embodiment, the depth indicator 1016 may include a numerical indication of the depth of the sheath 420 when the sheath 420 is positioned within the patient's nasal cavity 104.

[0097]

As discussed above, the anatomy of a patient's nasal cavity 104 varies from individual to individual.

Therefore, the depth of the anterior ridge 302 of the middle turbinate 114 varies from patient to patient.

During initial treatment, the physician or other medical professional may use the depth indicator 1016 on the sheath 420 to record the depth of the anterior ridge 302 of the middle turbinate 114 of a particular patient.

In certain embodiments, the physician or other medical professional may also record the depth of the lower surface 304 of the patient's nasal bone 122.

For subsequent treatment, the physician or other health care professional can refer to the recorded depth to avoid contact or damage to the delicate tissue within the patient's nasal cavity 104.

[0098]

In one embodiment, for initial treatment, the physician or other healthcare professional describes the average depth of the anterior ridge 302 of the middle turbinate 114 of the patient and the average depth of the lower surface 304 of the nasal bone 122 according to certain characteristics of the patient. You may refer to the table (not shown).

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For example, in one embodiment, the table may describe the average depth of the anterior ridge 302 of the middle turbinate 114 of a given age group and the average depth of the lower surface 304 of the nasal bone 122.

The table may also list the average depth of the sphenopalatine / pterygopalatine recess 118 for a given age group.

In certain embodiments, the table may be further subdivided into gender classifications.

In another embodiment, the table may describe the average depth according to the measurements obtained on the patient's external nasal biostructure.

[0099]

FIG. 10B illustrates a cross-sectional view of an embodiment of the sheath hub 402 coupled to the sheath 420 according to the present disclosure.

The embodiment depicted in FIG. 10B is obtained along lines DD of FIG. 10A.

[0100]

In certain embodiments, the tapered portion comprises a cavity 1012 extending through the tapered portion from the catheter hub receiving space 504 in the sheath hub 402 to the sheath receiving end 1004 of the sheath hub 402.

The sheath 420 is received in the cavity 1012 to connect the sheath to the sheath hub 402.

[0101]

In the embodiment illustrated in FIG. 10B, the engaging element 520 is more clearly shown as a recess extending longitudinally along the inner surface 502 of the sheath hub 402.

In one embodiment, the recess of the engaging element 520 is located only within the cylindrical portion 1006 of the sheath hub 402.

In such an embodiment, the recess of the engaging element 520 may extend from the stop element 522 to the interface 1010 between the cylindrical portion 1006 and the tapered portion 1008.

In other embodiments, such as the embodiment illustrated in FIG. 10B, the recess of the engaging element 520 may extend through the tapered portion 1008 of the sheath hub 402.

[0102]

FIG. 11 illustrates an enlarged view of region 1014 of the sheath hub 402 including the stop element 522 according to one embodiment of the present disclosure.

In one embodiment, the stop element 522 includes an inclined surface 1102 located adjacent to the catheter hub receiving end 1002 of the sheath hub 402.

Even if the inclined surface 1102 of the stop element 522 is engaged by the inclined surface 715 of the flange of the restraining element 516 so as to facilitate the easy insertion of the insertion portion 708 of the catheter hub 404 into the catheter hub receiving space 504. good.

In certain embodiments, the stop element 522, the flange of the deterrent element 516, or both are flexible or semi-flexible to facilitate easy insertion of the insertion portion 708 of the catheter hub 404 into the catheter hub receiving space 504. It may be made of a material.

In other embodiments, the entire catheter hub 402, the entire sheath hub 402, or both may be made of a flexible or semi-flexible material.

[0103]

The stop surface 1104 of the stop element 522 extends substantially vertically from the inner surface 502 of the sheath hub 402.

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When the catheter hub 404 is withdrawn from within the catheter hub receiving space 504 to the extended position 426, the stopping surface 1104 of the stopping element 522 stops further withdrawal of the catheter hub 404 from within the catheter hub receiving space 504. Engage with the rear surface 716 of the 516.

[0104]

FIG. 12 illustrates an end view of an embodiment of the sheath hub 402 according to the present disclosure.

The embodiment illustrated in FIG. 12 is obtained in the direction of the sheath receiving end 1004 of the sheath hub 402, with the sheath 420 removed for clarity.

[0105]

In the embodiment illustrated in FIG. 12, the recess of the engaging element 520 extends through the tapered portion 1008 of the sheath hub 402 to the sheath receiving end 1004.

In one embodiment, the recess of the engaging element 520 is aligned with the longitudinal axis of the sheath hub 402 in the same rotational orientation as the rotational orientation indicator 408b.

In another embodiment, the recess of the engaging element 520 may be offset from the rotational orientation indicator 408b.

[0106]

FIG. 13A illustrates a cross-sectional view of an embodiment of the introduction end 505 of the sheath 420 and the insertion end 414 of the catheter 412.

In the embodiment illustrated in FIG. 13A, the introduction end 505 of the sheath 420 and the insertion end 414 of the catheter 412 are the introduction end 505 of the sheath 420 and the insertion end 414 of the sheath 420 when the catheter hub 404 (not shown) is positioned at the extension position 426. It is positioned at the position where the insertion end 414 of the catheter 412 is located.

[0107]

In one embodiment, the tip 510 of the insertion end 414 of the catheter 412 is 1306 with the tip 510 curved so that the tip 510 is rounded.

The outermost edge 1302 at the introduction end 505 of the sheath 420 is inclined to the apex 508.

In one embodiment, when the catheter hub 404 is positioned at the extension position 426, the apex 508 at the introduction end 505 of the sheath 420 is aligned with the start 1304 of the curvature 1306 of the rounded tip 510 of the catheter 412.

In such an embodiment, the transition 512 between the catheter 412 and the sheath 420 is continuous, smooth and substantially free of edges.

In one embodiment, the fit between the catheter 412 and the sheath 420 is tight.

That is, in one embodiment, there is substantially no gap between the catheter 412 and the sheath 420.

In one embodiment, the lack of a gap between the catheter 412 and the sheath 420 is such that the apex 508 at the introduction end 505 of the sheath 420 is caught in delicate tissue within the patient's nasal cavity 104 or otherwise damaged. Reduce the chances of it happening.

[0108]

FIG. 13B illustrates a cross-sectional view of an embodiment of the introduction end 505 of the sheath 420 and the insertion end 414 of the catheter 412.

In the embodiment illustrated in FIG. 13B, the outer diameter 1308 of the catheter 412 is substantially smaller than the inner diameter 1310 of the sheath 1420.

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In such an embodiment, the transition 512 between the catheter 412 and the sheath 420 is not smooth and the apex 508 on the introduction end 505 of the sheath 420 is caught in delicate tissue within the patient's nasal cavity 104, or Sharp edges may be formed that can be otherwise damaged.

Therefore, in certain embodiments, the catheter 412 and sheath 420 may be designed such that the fit between the catheter 412 and the sheath 420 is tight so as to avoid sharp edges.

[0109]

FIG. 13C illustrates a cross-sectional view of another embodiment of the introduction end 505 of the sheath 420 and the insertion end 414 of the catheter 412.

In the embodiment illustrated in FIG. 13C, the catheter 412 is positioned within the sheath 420 at a position extending the apex 508 of the sheath 420 beyond the start 1304 of the curvature 1306 at the insertion end 414 of the catheter 412.

In such an embodiment, the transition 512 between the catheter 412 and the sheath 420 is not smooth and the apex 508 on the introduction end 505 of the sheath 420 is caught in delicate tissue within the patient's nasal cavity 104, or Sharp edges may be formed that can be otherwise damaged.

Thus, in one embodiment, the stop element 522 is from within the catheter hub receiving space 504 at a position that aligns the apex 508 on the introduction end 505 of the sheath 420 with the start 1304 of the curvature 1306 at the insertion end 414 of the catheter 412. Stop withdrawing the catheter hub 404.

[0110]

Unexpectedly, with patient consent, advanced prototype catheters are being effectively used to relieve headaches.

The results of these procedures have been recorded and are promising.

After 74 procedures, only 4 patients evaluated the procedure's tolerability as either "poor" or "reasonable."

Of the remaining patients, 24 rated tolerability as "good" and 46 as "excellent".

This tolerability improved when the patient was pretreated with an intranasal anesthetic, as summarized in Table 1 below

[0111]

Of the 74 treatments recorded, no adverse events required intervention.

In 5 cases, attention was paid to the slight bleeding of blood into the nasal mucosa, but no obvious epistaxis occurred.

Two procedures resulted in exacerbation of headache, but both patients returned to baseline headache the next day without further onset.

Except for these two patients, all patients replied that they would undergo the procedure again if necessary.

[0112]

On the day of SPGB, 58% of patients left the office with complete relief of headache, while 74% had significant clinical improvement as assessed by the Visual Analog Scale (VAS). Experienced.

Although some patients had failed follow-up, a significant improvement in headache severity persisted in one-third of patients per month.

These results violate expectations, both in terms of clinical outcome and expected efficacy of both devices and procedures.

Similarly, the direct patient acceptance and tolerability of the procedure is also unexpected.

Given the nature of the procedure and the outcome of patient satisfaction, the performance of this procedure by anyone other than the most skilled and experienced skilled surgeon is suggested to be a neurosurgeon or neurosurgeon in this case, one of ordinary skill in the art. Will constitute scientific advances and useful techniques based on an unexpected series of results.

[0114]

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BC suffered a head injury in a snowmobile accident nearly 10 years ago and hasn't been able to remember a day without headaches ever since.

No cure, standard medication, or even anesthetic could give him relief.

Every day ended with an 8/10 headache.

He has experienced 100% headache relief after SPGB and has remained headache-free for over a year.

[0115]

Highway patrol policeman AD suffered an 8/10 headache virtually every day for years.

He remained headache-free for two months after SPGB.

Recalling how good life could be without a headache in the last two months, he tearfully demanded a re-procedure when the headache recurred.

Currently, he undergoes a short painless bimonthly procedure and lives without headaches.

[0116]

Similarly, certain types of headaches are the result of neurological dysfunction, and disruption of dysfunctional circuits can serve as a reset, allowing normal neural function to return.

For this reason, the benefits of SPGB can persist over an uncertain period, well beyond the effects of local anesthetics.

Therefore, it has been found that many patients experience increased benefit when the procedure is repeated.

[0117]

Conventional teaching cannot suggest such a result.

For example, a randomized, double-blind, controlled trial presented at the Journal of the American Medical Association in 1996 found that 55% of patients with headaches had rapid migraine headaches when topical lidocaine was infused into the nose. Explained mitigation.

Of the responding patients, 42% usually experienced a recurrence of headache within 1 hour.

It should be noted that they excluded patients who had "headaches lasting longer than 3 days or had severe headaches more than once a week".

[0118]

Our patients suffered from chronic routine headaches, and many had exactly the type of headache excluded by this study.

Because of the good scientific theory behind SPGB for several types of headache, and because the potential adverse effects of the procedure are very small and very mild, we are much more comprehensive in the use of SPGB. We have taken the approach of being and are experiencing better results than expected.

[0119]

A retrospective chart review at Thomas Jefferson University in 2006 included 41 patients with 12 patients with daily persistent headaches and 16 with "other headache diagnoses". We examined a more similar refractory chronic headache population in our patients.

They reported that "25.4% had a complete response, 57.1% had a partial response, 3.2% had deteriorated, and 14.3% had no change."

However, their lidocaine dosing regimen was intravenous lidocaine in a cardiac surveillance unit for 2 to 15 days.

[0120]

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It is believed that SphenoCath TM branded medical devices may surpass most, if not all, published research results simply because they deliver the drug to the desired location more precisely and consistently.

Direct fluorescence fluoroscopy demonstrates the ability of SphenoCath TM branded medical devices to deliver infusions to targets.

In addition, the SphenoCath TM branded medical device expands SPGB opportunities and exponentially increases patient access to the procedure, from a small number of pain specialists to clinic practitioners.

[0121]

In one embodiment, the apex 508 at the introduction end 505 of the sheath 420 is protected from delicate tissue within the patient's nasal cavity 104 by the rounded side wall 1314 of the spherical tip region 1310.

In another embodiment, the outer diameter 1316 of the sheath 420 is such that the spherical tip region protects the introduction end 505 of the sheath 420 from potential caiching or other damage to delicate tissue within the patient's nasal cavity 104. , Can be substantially smaller than the outer diameter 1318 of the spherical tip region 1310.

In such an embodiment, the introduction end 505 may be cornered or rounded rather than tilted, as illustrated in the illustrated embodiment.

[0122]

For those skilled in the art, head and neck cancer, complex regional pain syndrome, reflex sympathetic dystrophy, vasomotor rhinitis, preoperative and postoperative desensitization in oral and maxillofacial surgery, cluster headache, headache, Cervical spasm, any level of intervertebral disc disease or hernia, lower back pain, lumbosacral spasm, pear muscle spasm syndrome, spastic (convulsive) oblique neck, SPG neuralgia (Sulder syndrome), trigeminal neuralgia (painful tick), zonal Post-vesicular nerve pain, autonomic nerve pain, atypical facial pain, disc bulge, lumbosacral disc, causalgia, reflex sympathetic dystrophy (RSD), cervical spondylosis, migraine, trigeminal neuralgia, cerebrospinal fluid (CSF) leakage Headache, chronic trigeminal neuralgia, tension headache, myofascial pain syndrome, compression nerve, sciatic nerve pain, disc prolapse, trigeminal neuralgia, jaw joint syndrome (TMJ), whipping, allergic rhinitis, vasomotor rhinitis, asthma , Bell palsy (facial neuralgia), bone pain, cancer pain, bronchial spasm, chronic bronchitis, menstrual difficulty, endometriosis, fibromyalgia, multiple sclerosis with spasm, peripheral neuropathy (neuropathy) Sexual pain), Reynaud phenomenon, rheumatoid arthritis (redness), herpes zoster (herpes zoster), spinal cord stenosis, chronic fatigue syndrome, chronic regurgitation, diabetic neuropathy, hypersweat, hypotension headache, phantom limb / toothache, It will be easy to understand the use of the invention for indications, which are at least one of sensory abnormalities, recurrent stress injury, and ear ringing (low frequency).

[0123]

The subject may be embodied in other concrete forms without departing from its spiritual or essential traits.

The embodiments described are considered in all respects to be merely exemplary rather than restrictive.

Therefore, the scope of the subject matter is set forth in the appended claims rather than the aforementioned description.

Any changes that fall within the meaning and scope of the equivalent of the claims are within those scopes

[0124]

Although the methods and devices have been described with respect to what is currently considered to be the most practical, it should be understood that the present disclosure need not be limited to the disclosed implementations.

It is intended to cover various modifications and similar sequences contained within the spirit and scope of the claims, the scope of which should be broadly interpreted to include all such modifications and similar structures. Is.

The disclosure also includes any implementation of the following claims.

[0125]

It should also be understood that various changes may be made without departing from the essence of the present disclosure.

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Such changes are also implied in the description.

They are still within the scope of this disclosure.

It is to be understood that the present disclosure is intended to provide patents that cover many aspects of the invention, both independently and as an overall system, both in method and in device mode.

[0126]

Moreover, each of the various elements of the present disclosure and claims may also be achieved in different ways.

It is understood that the present disclosure includes variants, methods or process implementations of any implementation of any device implementation, or even variations of any element of these, respectively. Should be.

[0127]

Specifically, as the present disclosure relates to the elements of the invention, the term for each element may be expressed in terms of equivalent device or method, even if only the function or result is the same. I want you to understand.

[0128]

Such equivalent, broader, or more general terms should be considered to be included in the description of each element or measure.

Such terms can be substituted where it is desired to express an implicitly broad range that the invention can enjoy.

[0129]

It should be understood that all measures may be expressed as a means to take such measures or as an element causing the measures.

[0130]

Similarly, each physical element disclosed should be understood to include disclosure of the measures promoted by that physical element.

[0131]

Any patents, publications, or other references described herein for patent purposes are incorporated herein by reference

In addition, for each term used, the general dictionary definition should be understood to be incorporated for each term, as long as its use in this application does not contradict such an interpretation, by an expert. All definitions, alternative terms, and synonyms such as those contained in at least one of the recognized Standards Dictionary and the latest version of Random House Webster's United Dictionary are incorporated herein by reference. Please understand that.

[0132]

Finally, all references described in the Information Disclosure Statement or other informational documents filed with the present application are incorporated herein by reference, but with respect to each of the above, by reference. As long as such information or documents may be considered inconsistent with the invention / patents of these inventions, such documents are not expressly considered produced by the applicant.

[0133]

In this regard, it is understood that Applicants are only presenting claims with the first dependent claim to avoid adding potentially hundreds of claims for practical reasons. sea bream.

[0134]

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To the extent that inadequate substitutions are made, and otherwise applicable, to the extent that Applicants have not actually drafted any claims to literally include any particular exemplary implementation. To a degree, the Applicant may have simply not been able to predict all contingencies, and the Applicant intended or in fact abandoned such scope in any way. It should not be understood that it was done.

One of ordinary skill in the art should not reasonably expect to have drafted a claim that would literally include such an alternative exemplary implementation

[0135]

Moreover, the use of the transitional phrase "comprising" is used herein to maintain the "unconstrained" claim, according to the conventional interpretation of the claim

Thus, unless the context otherwise requires, the term "comprise", or variants such as "comprises" or "comprising", may be any other element or step or it should be understood that it is intended to imply the inclusion of the described element or step or element or group of steps, not the exclusion of the element or group of steps.

[0136]

Such terms should be construed in their most expansive form so as to give the applicant the broadest legally permissible range.

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CLAIMS JP2015507964A

1.

A device that facilitates intranasal treatment of a patient's butterfly / wing palatal depression, a sheath hub having an outer surface facing the inner surface, wherein the inner surface defines a catheter hub receiving space, the sheath hub and said. A catheter hub that is slidably received within a catheter hub receiving space, wherein the catheter hub can be positioned along the longitudinal axis of the sheath hub, the catheter hub, the catheter hub, and the sheath hub. A deterrent element on one and an engaging element on the other of the catheter hub and the sheath hub, wherein the catheter hub is rearranged along the longitudinal axis of the sheath hub. When so, the engagement element is continuously engaged with the engagement element, and the engagement between the restraining element and the engagement element prevents the sheath hub from rotating with respect to the catheter hub. A device provided in combination.

2.

The device of claim 1, further comprising a catheter and a rotational orientation indicator, wherein the catheter is coupled to the catheter hub, at least a portion of the catheter includes an internal bend, the rotational orientation indicator is , A device for identifying the rotational orientation of the internal bend of the catheter.

3.

The device of claim 2, wherein the rotational orientation indicator comprises a ridge extending longitudinally along at least one of the sheath hub and the catheter hub.

4.

The device of claim 2, further comprising a catheter coupled to the catheter hub, wherein the catheter comprises an insertion end and a connection end, the insertion end being an internal bend with respect to the longitudinal axis of the catheter. The rotational orientation indicator is a device that identifies the orientation of the internal bend of the catheter.

5.

The device according to claim 1, further comprising a sheath connected to the sheath hub and a catheter connected to the catheter hub, wherein the catheter is received within the sheath and the catheter is with an insertion end. The insertion end has an internal bend with respect to the longitudinal axis of the catheter, the catheter hub can be positioned between the insertion position and the extension position, and the sheath is When the catheter hub is positioned in the dilated position, the internal bend of the catheter is straightened and the catheter hub indicates the position of the insertion end of the catheter with respect to the introduction end of the sheath, at least 1. A device that includes two depth indicators.

6.

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The device according to claim 1, further comprising a catheter connected to the catheter hub and a sheath connected to the sheath hub, wherein the catheter is received in the sheath and the catheter hub is in an insertion position. Can be positioned between and the dilated position, the catheter has an insertion end with a tip curved to round the tip, and the sheath has an outermost edge inclined to the apex, introduced. A device comprising an end, wherein the apex is aligned with the initiation of curvature of the rounded tip of the catheter when the catheter hub is positioned in the dilated position.

7.

6. The sixth aspect of claim 6, wherein the transition between the apex and the initiation of the curvature of the rounded tip of the catheter is continuous when the catheter hub is positioned in the dilated position. Device.

8.

The device of claim 1, further comprising a catheter coupled to the catheter hub, wherein the catheter comprises an insertion end and a connection end, the insertion end being internally bent with respect to the longitudinal axis of the catheter. A device having a portion, wherein the tip of the insertion end of the catheter is spherical.

9.

The restraining element comprises a flange connected to one of the outer surface of the catheter hub and the inner surface of the sheath hub and extending vertically from it, the engaging element being the inner surface of the sheath hub and the catheter hub. It comprises a longitudinally extending recess along the other of the outer surfaces, the flange being in the recess as the catheter hub is rearranged along the longitudinal axis of the sheath hub. The device of claim 1, which is positioned and moves along it.

10.

The apparatus of claim 1, further comprising a stop element coupled to the catheter hub and one of the sheath hubs, wherein the catheter hub is the longitudinal length of the sheath hub between an insertion position and an expansion position. A device that can be positioned along an axis of direction and the stopping element is configured to engage the deterrent element to stop the catheter hub from being removed from the catheter hub receiving space.

11.

A system for coping with an acute pain condition, a sheath hub having an outer surface facing the inner surface, wherein the inner surface slides in the sheath hub and the catheter hub receiving space, which defines the catheter hub receiving space. A possibly accepted catheter hub, wherein the catheter hub can be positioned along the longitudinal axis of the sheath hub, with the catheter hub and a deterrent element on one of the catheter hub and the sheath hub. , The engaging element on the other of the catheter hub and the sheath hub, wherein the restraining element is the engaging when the catheter hub is rearranged along the longitudinal axis of the sheath hub. Of the engaging element and the sheath hub and the catheter hub, which continuously engages the element and the engagement between the restraining element and the engaging element prevents rotation of the sheath hub with respect to the catheter hub. A system comprising a rotational orientation indicator, which identifies at least one rotational orientation.

12.

The rotational orientation indicator comprises a ridge extending longitudinally along at least one of the sheath hub and the catheter hub, wherein the ridge is at least one of the sheath hub and the catheter hub. 11. The system of claim 11, wherein the rotational orientation is visually and tactilely identified.

13.

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11. The system of claim 11, further comprising a catheter coupled to the catheter hub, wherein the catheter comprises an insertion end and a connection end, the insertion end being an internal bend with respect to the longitudinal axis of the catheter. The system, wherein the rotational orientation indicator identifies the orientation of the internal bend of the catheter.

14.

The restraining element comprises a flange connected to one of the outer surface of the catheter hub and the inner surface of the sheath hub and extending vertically from it, the engaging element being the inner surface of the sheath hub and the catheter hub. It comprises a longitudinally extending recess along the other of the outer surfaces, the flange being in the recess as the catheter hub is rearranged along the longitudinal axis of the sheath hub. 11. The system of claim 11, which is positioned and moves along it.

15.

11. The system of claim 11, further comprising a sheath coupled to the sheath hub, wherein the catheter hub can be positioned between an insertion position and an expansion position, the sheath in which the catheter hub is the expansion. A system that straightens the internal bend of the catheter when positioned in position.

16.

The tip of the insertion end of the catheter is curved so that the tip is rounded, the sheath comprises an introduction end and a connection end, and the outermost edge of the introduction end is inclined to the apex. The apex coincides with the initiation of curvature of the rounded tip of the catheter when the catheter hub is rearranged in the sheath hub to the dilated position, and the catheter hub is the introduction of the sheath. 15. The system of claim 15, comprising at least one depth indicator indicating the location of the insertion end of the catheter with respect to the end.

17.

The catheters are used for head and neck cancer, complex regional pain syndrome, reflex sympathetic dystrophy, vasomotor rhinitis, preoperative and postoperative desensitization in oral and maxillofacial surgery, cluster headache, headache, cervical region. Convulsions, any level of disc disease or hernia, lower back pain, lumbosacral spasm, pear muscle spasm syndrome, spastic (convulsive) oblique neck, SPG neuralgia (Sulder syndrome), trigeminal neuralgia (painful tick), post-shed Neuralgia, autonomic neuralgia, atypical facial pain, bulging intervertebral disc, lumbosacral disc, causalgia, reflex sympathetic dystrophy (RSD), cervical spondylosis, migraine, trigeminal neuralgia, cerebrospinal fluid (CSF) leaking headache, Chronic trigeminal neuralgia, tension headache, myofascular pain syndrome, compression nerve, sciatic nerve pain, disc prolapse, trigeminal neuralgia, jaw joint syndrome (TMJ), whipping, allergic rhinitis, vasomotor rhinitis, asthma, bell Paralysis (facial neuralgia), bone pain, cancer pain, bronchial spasm, chronic bronchitis, menstrual difficulty, endometriosis, fibromyalgia, multiple sclerosis with spasm, peripheral neuropathy (neuropathy pain)), Reynaud phenomenon, rheumatoid arthritis (redness), herpes zoster (herpes zoster), spinal cord stenosis, chronic fatigue syndrome, chronic regurgitation, diabetic neuropathy, hyperperspiration, hypotension headache, phantom limbs / toothache, sensory abnormalities The system of claim 16, which is designed to address applications for at least one of, repetitive stress injury, and ear ringing (low frequency).

18.

17. The system of claim 17, wherein the system is designed to be performed by a medical professional selected from a group of nurse practitioners, physician assistants, surgeons, neurologists, and intervention physicians.

19.

A system for facilitating intranasal treatment of a patient's butterfly / wing palatal depression, with a combination of removable tools defined by a sheath hub, catheter hub, deterrent element, and engagement element, in use. In addition, the system is advanced into an anatomically constrained space in the patient's nasal cavity, whereby during use, the system is at least a target tissue site within the butterfly palatal / wing palate recess. At least one medical treatment selected from the group adjacent to and selected from the group consisting of pharmacy, biology, electrical / electronic stimulation, sonic, mechanical and others consisting essentially of pulsed or streamed energies. A system delivered to the target tissue site.

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20.

17. A system for facilitating intranasal treatment of a sphenopalatine / pterygopalatine depression in a patient, wherein the system is used by a neurologist, a neurosurgeon, an intervention physician, a surgeon, a nurse. A system performed by at least one medical professional selected from a group consisting essentially of a practitioner, and a physician's assistant.

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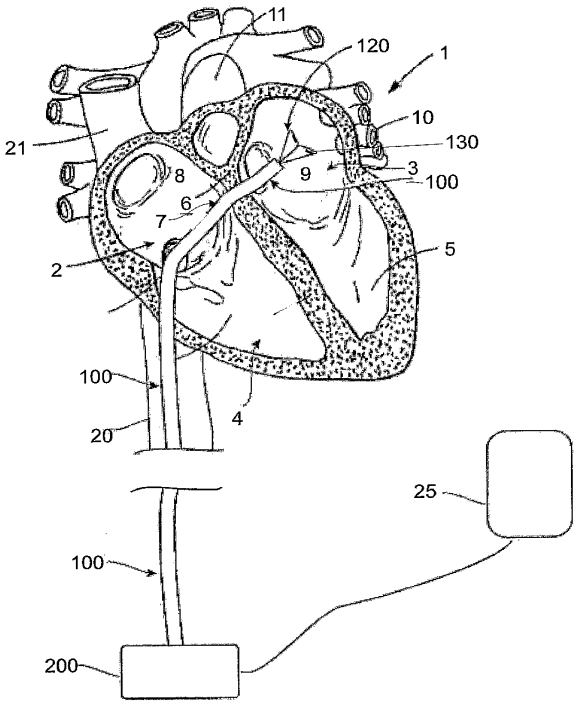
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[Continued on next page]

(54) Title: LOW POWER TISSUE ABLATION SYSTEM



(57) Abstract: Devices, systems and methods are disclosed for the ablation of tissue. Embodiments include an ablation catheter that has an array of ablation elements attached to a deployable carrier assembly. The carrier assembly can be constrained within the lumen of a catheter, and deployed to take on an expanded condition. The carrier assembly includes multiple electrodes that are configured to ablate tissue at low power. Additional embodiments include a system that includes an interface unit for delivering one or more forms of energy to the ablation catheter.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

LOW POWER TISSUE ABLATION SYSTEM

DESCRIPTION OF THE INVENTION

Statement of Related Application

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 60/698,355, filed July 11, 2005, entitled "Low Power Tissue Ablation System", which is incorporated by reference in its entirety herein.

Field of the Invention

[0002] The present invention relates generally to systems, catheters and methods for performing targeted tissue ablation in a subject. In particular, the present invention provides devices comprising one or more elements designed to efficiently deliver energy to tissue with precise control of the tissue to be ablated.

BACKGROUND OF THE INVENTION

[0003] Tissue ablation is used in numerous medical procedures to treat a patient. Ablation can be performed to remove undesired tissue such as cancer cells. Ablation procedures may also involve the modification of the tissue without removal, such as to stop electrical propagation through the tissue in patients with an arrhythmia. Often the ablation is performed by passing energy, such as electrical energy, through one or more electrodes causing the tissue in contact with the electrodes to heat up to an ablative temperature. Ablation procedures can be performed on patients with atrial fibrillation by ablating tissue in the heart.

[0004] Mammalian organ function typically occurs through the transmission of

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electrical impulses from one tissue to another. A disturbance of such electrical transmission may lead to organ malfunction. One particular area where electrical impulse transmission is critical for proper organ function is in the heart. Normal sinus rhythm of the heart begins with the sinus node generating an electrical impulse that is propagated uniformly across the right and left atria to the atrioventricular node. Atrial contraction leads to the pumping of blood into the ventricles in a manner synchronous with the pulse.

[0005] Atrial fibrillation refers to a type of cardiac arrhythmia where there is disorganized electrical conduction in the atria causing rapid uncoordinated contractions that result in ineffective pumping of blood into the ventricle and a lack of synchrony. During atrial fibrillation, the atrioventricular node receives electrical impulses from numerous locations throughout the atria instead of only from the sinus node. This condition overwhelms the atrioventricular node into producing an irregular and rapid heartbeat. As a result, blood pools in the atria and increases the risk of blood clot formation. The major risk factors for atrial fibrillation include age, coronary artery disease, rheumatic heart disease, hypertension, diabetes, and thyrotoxicosis. Atrial fibrillation affects 7% of the population over age 65.

[0006] Atrial fibrillation treatment options are limited. Three known treatments, lifestyle change, medical therapy and electrical cardioversion all have significant limitations. Lifestyle change only assists individuals with lifestyle-related atrial fibrillation. Medication therapy assists only in the management of atrial fibrillation symptoms, may present side effects more dangerous than atrial fibrillation, and fail to cure atrial fibrillation. Electrical cardioversion attempts to restore sinus rhythm but has a high recurrence rate. In addition, if there is a blood clot in the atria, cardioversion may

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cause the clot to leave the heart and travel to the brain or to some other part of the body, which may lead to stroke. What are needed are new methods for treating atrial fibrillation and other conditions involving disorganized electrical conduction.

[0007] Various ablation techniques have been proposed to treat atrial fibrillation, including the Cox-Maze procedure, linear ablation of various regions of the atrium, and circumferential ablation of pulmonary vein ostia. The Cox-Maze procedure and linear ablation procedures are unrefined, unnecessarily complex, and imprecise, with unpredictable and inconsistent results and an unacceptable level of unsuccessful procedures. These procedures are also tedious and time-consuming, taking several hours to accomplish. Pulmonary vein ostial ablation is proving to be difficult to do, and has led to rapid stenosis and potential occlusion of the pulmonary veins. There is therefore a need for improved atrial ablation products and techniques.

SUMMARY OF THE INVENTION

[0008] According to a first aspect of the invention, an ablation system used by an operator to treat a patient is disclosed. The system comprises an ablation catheter that has a flexible shaft with a proximal end and a distal end, and includes at least one ablation element for delivering energy to tissue. The system further comprises an interface unit that provides energy to the ablation catheter. The at least one ablation element is configured to rapidly transition from a first temperature to a second temperature. The first temperature approaches tissue ablation temperature, preferably 60° C, and the second temperature approaches body temperature, typically 37° C. In a preferred embodiment, the at least one ablation element has a majority of surface area in contact with circulating blood when energy is being delivered to the tissue. The majority of this blood exposed

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surface area is at least 60%, preferably more than 75% and potentially greater than 85% of the total surface area of the electrode. Numerous electrode configurations are described including three segment ("triangle"), semicircular and crescent cross sections, cross sections with curvilinear, serpentine and zigzag segments; cross sections with segments with projecting fins, and cross sections that include an energy delivery portion and a non-energy delivery portion. The electrodes of the present invention are configured to rapidly cool, during energy delivery such as in bipolar energy delivery that follows monopolar energy delivery; and when no energy is being delivered. The electrodes of the present invention are configured to transition from ablation temperature to body temperature in less than 20 seconds, preferably less than 10 seconds. These electrodes are also configured to transition from body temperature to ablation temperature in less than 5 seconds.

[0009] According to a second aspect of the invention, an ablation system used by an operator to treat a patient is disclosed. The system comprises an ablation catheter that has a flexible shaft with a proximal end and a distal end, and includes at least one ablation element for delivering energy to tissue. The system further comprises an interface unit that provides energy to the ablation catheter. The at least one ablation element is configured such that a majority of its external surface area is in contact with tissue when energy is delivered to that tissue. The electrode is configured such that at least 60% of the total surface area is in tissue contact, preferably 70% or more. Numerous electrode configurations are described including three segment ("triangle"), semicircular and crescent cross sections, cross sections with curvilinear, serpentine and zigzag segments; cross sections with segments with projecting fins, and cross sections that include an

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energy delivery portion and a non-energy delivery portion. The electrodes of the present invention are configured to maximize the amount of energy transferred to the tissue, thus minimizing the amount of energy delivered to the blood, such as undesired energy which may cause a blood clot.

[0010] According to a third aspect of the invention, an ablation system used by an operator to treat a patient is disclosed. The system comprises a first ablation catheter that has a flexible shaft with a proximal end and a distal end, and includes at least one ablation element for delivering energy to tissue; and a second ablation catheter that has a flexible shaft with a proximal end and a distal end, and includes at least one ablation element for delivering energy to tissue. The system further comprises an interface unit that provides energy to the ablation catheter. The energy delivered by the system is limited by a threshold that is a first value when the first ablation catheter is in use and a different value when the second ablation catheter is in use. The first and second ablation catheters preferably include one or more different functional elements, such as different ablation elements and/or patterns of ablation elements. Ablation elements can be varied in size and cross sectional geometry, cooling and heating properties, type of energy delivered, and other electrode parameters.

[0011] According to a fourth aspect of the invention, an ablation system used by an operator to treat a patient is disclosed. The system comprises an ablation catheter that has a flexible shaft with a proximal end and a distal end, and includes at least one ablation element for delivering energy to tissue. The system further comprises an interface unit that provides energy to the ablation catheter. The energy delivered by the interface unit is configured to (1) achieve a target energy level t a target tissue depth; and (2) pulse energy

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such that the tissue surrounding the electrode does not exceed a threshold temperature. In a preferred embodiment, the energy delivered is RF energy, and the system is configured to automatically transition between bipolar and monopolar RF delivery. Energy delivery is adjusted based on a value selected from the group consisting of: temperature of tissue; rate of change of temperature of tissue; temperature of the at least one ablation element; rate of change of temperature of the at least one ablation element; EKG; tissue thickness; tissue location; cardiac flow rate; and combinations thereof. Automatic adjustments are made to minimize depth of the lesion, minimize the width of the lesion, or both. In a preferred embodiment, the energy delivery is adjusted to achieve a target depth of the lesion. Temperature information is preferably provided by one or more temperature sensors, such as sensors mounted in, on or near an ablation element.

[0012] According to a fifth aspect of the invention, an ablation system used by an operator to treat a patient is disclosed. The system comprises an ablation catheter that has a flexible shaft with a proximal end and a distal end, and includes at least one ablation element for delivering energy to tissue. The system further comprises an interface unit that provides energy to the ablation catheter. The interface unit monitors one or more parameters of the system, and prevents the energy delivered from exceeding a threshold. The value of the threshold is determined by the at least one ablation element. The system parameters are preferably selected from the group consisting of: temperature such as temperature from a temperature sensor; a value of measured current; a value of measured voltage; a flow measurement value; a force measurement value such as a measurement of strain; a pressure measurement value; and combinations thereof. The threshold is preferably an energy delivery threshold selected from the group consisting of: peak

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energy such as peak energy below 10 Watts; average energy such as average energy below 5 Watts; and cumulative energy such as a value below 500 Watt-seconds or less than 300 Watt-seconds; and combinations thereof. In another preferred embodiment, the interface unit includes a threshold comparator for comparing a measured, calculated or otherwise determined value to the threshold. In another preferred embodiment, the threshold changes over time. In yet another preferred embodiment, the system is configured to deliver a low level energy delivery followed by a higher level energy delivery. During or immediately following the low level energy delivery, a threshold value is determined which is utilized in the subsequent higher level energy delivery.

[0013] According to a sixth aspect of the invention, an ablation catheter device is disclosed. The ablation catheter comprises an elongated, flexible, tubular body member having a proximal end, a distal end, and a lumen extending therebetween. A control shaft is coaxially disposed and is slidingly received within the lumen of the tubular body member. The catheter further comprises a flexible carrier assembly which includes at least two arms, each arm including at least one ablation element used to deliver energy to tissue. Each ablation element includes a relatively uniform triangle cross-section along its length, with a continuous or discontinuous perimeter or path. The cross section is preferably an isosceles triangle wherein the common base is opposite two sides that determine a vertex angle. This vertex angle is configured, based on the number of carrier arms of the particular carrier assembly, to allow a number of electrodes to be constrained into a volumetrically efficient circle or "pie" shape, the sum of all the vertex angles approximating 360 degrees, such that:

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$$\text{Vertex Angle} = \frac{360 \text{ degrees}}{\text{Number of Carrier Arms}}$$

[0014] In an alternative embodiment, at least one cross section is dissimilar, and/or the cross sections do not include only isosceles triangle geometries. In these configurations, the relevant (vertex) angles are configured such that their sum approaches 360 degrees in total, similarly providing efficiently constrainable volumes when maintained within the lumen of carrier assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate various embodiments of the present invention, and, together with the description, serve to explain the principles of the invention. In the drawings:

[0016] Fig. 1 illustrates the treatment to be accomplished with the devices and methods described below.

[0017] Fig. 2a illustrates a perspective view of an ablation catheter consistent with the present invention in which the carrier element has four carrier arms, each including two ablation elements.

[0018] Fig. 2b is a sectional view of a finned electrode of Fig. 2a.

[0019] Fig. 3a is a sectional view of an ablation element consistent with the present invention.

[0020] Fig. 3b is a sectional view of multiple ablation elements of Fig. 3a shown constrained in the distal end of an ablation catheter of the present invention.

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[0021] Fig. 3c is a perspective, partial cutaway view of the ablation catheter of Fig. 3b.

[0022] Fig. 4 illustrates a perspective, partial cutaway view of a preferred embodiment of an ablation catheter consistent with the present invention in which the carrier element has three carrier arms each including two ablation elements.

[0023] Fig 4a is a sectional view of a distal portion of the ablation catheter of Fig. 4.

[0024] Figs. 5a, 5b, 5c, 5d, 5e, and 5f are sectional end views of ablation elements consistent with the present invention, shown in associated contact with tissue during energy delivery.

[0025] Figs. 6a and 6b are sectional end views of ablation elements consistent with the present invention.

[0026] Fig. 6c is a side view of an ablation element consistent with the present invention.

DESCRIPTION OF THE EMBODIMENTS

[0027] Reference will now be made in detail to the present embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0028] The present invention utilizes ablation therapy. Tissue ablation is often used in treating several medical conditions, including abnormal heart rhythms. Ablation can be performed both surgically and non-surgically. Non-surgical ablation is typically performed in a special lab called the electrophysiology (EP) laboratory. During this non-surgical procedure a catheter is inserted into a vessel such as a vein, and guided into the

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heart using fluoroscopy for visualization. Subsequently, an energy delivery apparatus is used to supply energy to the heart muscle. This energy either "disconnects" or "isolates" the pathway of the abnormal rhythm. It can also be used to disconnect the conductive pathway between the upper chambers (atria) and the lower chambers (ventricles) of the heart. For individuals requiring heart surgery, ablation can be performed during coronary artery bypass or valve surgery.

[0029] The present invention provides catheters for performing targeted tissue ablation in a subject. In preferred embodiments, the catheters comprise a tubular body member having a proximal end and distal end and preferably a lumen extending therebetween. The catheter is preferably of the type used for performing intracardiac procedures, typically being introduced from the femoral vein in a patient's leg or a vein in the patient's neck. The catheter is preferably introducible through a sheath with a steerable tip that allows positioning of the distal portion to be used, for example, when the distal end of the catheter is within a heart chamber. The catheters include ablation elements mounted on a carrier assembly. The carrier assembly is preferably attached to a coupler, which in turn is connected to a control shaft that is coaxially disposed and slidingly received within the lumen of the tubular body member. The carrier assembly is deployable from the distal end of the tubular body member by advancing the control shaft, such as to engage one or more ablation elements against cardiac tissue, which is typically atrial wall tissue or other endocardial tissue. Retraction of the control shaft causes the carrier assembly to be constrained within the lumen of the tubular body member.

[0030] Arrays of ablation elements, preferably electrode arrays, may be configured in

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a wide variety of ways and patterns. In particular, the present invention provides devices with electrode arrays that provide electrical energy, such as radiofrequency (RF) energy, in monopolar (unipolar), bipolar or combined monopolar-bipolar fashion, as well as methods for treating conditions (e.g., atrial fibrillation, supra ventricular tachycardia, atrial tachycardia, ventricular tachycardia, ventricular fibrillation, and the like) with these devices. Alternative to or in combination with ablation elements that deliver electrical energy to tissue, other forms and types of energy can be delivered including but not limited to: sound energy such as acoustic energy and ultrasound energy; electromagnetic energy such as electrical, magnetic, microwave and radiofrequency energies; thermal energy such as heat and cryogenic energies; chemical energy such as energy generated by delivery of a drug; light energy such as infrared and visible light energies; mechanical and physical energy; radiation; and combinations thereof.

[0031] As described above, the normal functioning of the heart relies on proper electrical impulse generation and transmission. In certain heart diseases (e.g., atrial fibrillation) proper electrical generation and transmission are disrupted or are otherwise abnormal. In order to prevent improper impulse generation and transmission from causing an undesired condition, the ablation catheters of the present invention may be employed.

[0032] One current method of treating cardiac arrhythmias is with catheter ablation therapy, which, to date, has been difficult and impractical to employ. In catheter ablation therapy, physicians make use of catheters to gain access into interior regions of the body. Catheters with attached electrode arrays or other ablating devices are used to create lesions that disrupt electrical pathways in cardiac tissue. In the treatment of cardiac

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arrhythmias, a specific area of cardiac tissue having aberrant conductive pathways, such as atrial rotors, emitting or conducting erratic electrical impulses, is initially localized. A user (e.g., a physician such as an electrophysiologist) directs a catheter through a main vein or artery into the interior region of the heart that is to be treated. The ablating element is next placed near the targeted cardiac tissue that is to be ablated. The physician directs energy, provided by a source external to the patient, from one ore more ablation elements to ablate the neighboring tissue and form a lesion. In general, the goal of catheter ablation therapy is to disrupt the electrical pathways in cardiac tissue to stop the emission of and/or prevent the propagation of erratic electric impulses, thereby curing the heart of the disorder. For treatment of atrial fibrillation, currently available methods and devices have shown only limited success and/or employ devices that are extremely difficult to use or otherwise impractical.

[0033] The ablation catheters of the present invention allow the generation of lesions of appropriate size and shape to treat conditions involving disorganized electrical conduction (e.g., atrial fibrillation). The ablation catheters of the present invention are also practical in terms of ease-of-use and limiting risk to the patient, as well as significantly reducing procedure times. The present invention accomplishes these goals by, for example, the use of spiral shaped and radial arm shaped (also called umbrella shaped) carrier assemblies whose ablation elements create spiral, radial, or other simple or complex shaped patterns of lesions in the endocardial surface of the atria by delivery of energy to tissue or other means. The lesions created by the ablation catheters are suitable for inhibiting the propagation of inappropriate electrical impulses in the heart for prevention of reentrant arrhythmias.

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[0034] Definitions. To facilitate an understanding of the invention, a number of terms are defined below.

[0035] As used herein, the terms "subject" and "patient" refer to any animal, such as a mammal like livestock, pets, and preferably a human. Specific examples of "subjects" and "patients" include, but are not limited, to individuals requiring medical assistance, and in particular, requiring atrial fibrillation catheter ablation treatment.

[0036] As used herein, the terms "catheter ablation" or "ablation procedures" or "ablation therapy," and like terms, refer to what is generally known as tissue destruction procedures.

[0037] As used herein, the term "ablation element" refers to an energy delivery element, such as an electrode for delivering electrical energy. Ablation elements can be configured to deliver multiple types of energy, such as ultrasound energy and cryogenic energy, either simultaneously or serially. Electrodes can be constructed of a conductive plate, wire coil, or other means of conducting electrical energy through contacting tissue. In monopolar energy delivery, the energy is conducted from the electrode, through the tissue to a ground pad, such as a conductive pad attached to the back of the patient. The high concentration of energy at the electrode site causes localized tissue ablation. In bipolar energy delivery, the energy is conducted from a first electrode to one or more separate electrodes, relatively local to the first electrode, through the tissue between the associated electrodes. Bipolar energy delivery results in more precise, shallow lesions while monopolar delivery results in deeper lesions. Both monopolar and bipolar delivery provide advantages, and the combination of their use is a preferred embodiment of this application. Energy can also be delivered using pulse width modulated drive signals, well

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known to those of skill in the art. Energy can also be delivered in a closed loop fashion, such as a system with temperature feedback wherein the temperature modifies the type, frequency and or magnitude of the energy delivered.

[0038] As used herein, the term "carrier assembly" refers to a flexible carrier, on which one or more ablation elements are disposed. Carrier assemblies are not limited to any particular size, or shape, and can be configured to be constrained within an appropriately sized lumen.

[0039] As used herein, the term "spiral tip" refers to a carrier assembly configured in its fully expanded state into the shape of a spiral. The spiral tip is not limited in the number of spirals it may contain. Examples include, but are not limited to, a wire tip body with one spiral, two spirals, ten spirals, and a half of a spiral. The spirals can lie in a relatively single plane, or in multiple planes. A spiral tip may be configured for energy delivery during an ablation procedure.

[0040] As used herein the term "umbrella tip" refers to a carrier assembly with a geometric center which lies at a point along the axis of the distal portion of the tubular body member, with one or more bendable or hinged carrier arms extending from the geometric center, in an umbrella configuration. Each carrier arm may include one or more ablation elements. Each carrier arm of an umbrella tip includes a proximal arm segment and a distal arm segment, the distal arm segment more distal than the proximal arm segment when the carrier assembly is in a fully expanded condition. One or more additional carrier arms can be included which include no ablation elements, such as carrier arms used to provide support or cause a particular deflection. An umbrella tip

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body is not limited to any particular size. An umbrella tip may be configured for energy delivery during an ablation procedure.

[0041] As used herein, the term "lesion," or "ablation lesion," and like terms, refers to tissue that has received ablation therapy. Examples include, but are not limited to, scars, scabs, dead tissue, burned tissue and tissue with conductive pathways that have been made highly resistive or disconnected.

[0042] As used herein, the term "spiral lesion" refers to an ablation lesion delivered through a spiral tip ablation catheter. Examples include, but are not limited to, lesions in the shape of a wide spiral, and a narrow spiral, a continuous spiral and a discontinuous spiral.

[0043] As used herein, the term "umbrella lesion" or "radial lesion," and like terms, refers to an ablation lesion delivered through an umbrella tip ablation catheter. Examples include, but are not limited to, lesions with five equilateral prongs extending from center point, lesions with four equilateral prongs extending from center point, lesions with three equilateral prongs extending from center point, and lesions with three to five non-equilateral prongs extending from center point.

[0044] As used herein, the term "coupler" refers to an element that connects the carrier assembly to the control shaft. Multiple shafts, or ends of the carrier assembly may connect to the coupler. Multiple carrier arms can have one or more of their ends attached to the coupler. The coupler may include anti-rotation means that work in combination with mating means in the tubular body member. Couplers may be constructed of one or more materials such as polyurethane, steel, titanium, and polyethylene.

[0045] As used herein, the term "carrier arm" refers to a wire-like shaft capable of

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interfacing with electrodes and the coupler. A carrier arm is not limited to any size or measurement. Examples include, but are not limited to: stainless steel shafts; Nitinol shafts; titanium shafts; polyurethane shafts; nylon shafts; and steel shafts. Carrier arms can be entirely flexible, or may include flexible and rigid segments.

[0046] As used herein, the term "carrier arm bend point" refers to a joint (e.g., junction, flexion point) located on a carrier arm. The degree of flexion for a carrier arm bend point may range from 0 to 360 degrees. The bend portion can be manufactured such that when the carrier assembly is fully expanded, the bend point is positioned in a relatively straight configuration, a curved configuration, or in a discrete transition from a first direction to a second direction, such as a 45 degree bend transition. The bend portion can include one or more flexing means such as a spring, a reduced diameter segment, or a segment of increased flexibility.

[0047] The present invention provides structures that embody aspects of the ablation catheter. The present invention also provides tissue ablation systems and methods for using such ablation systems. The illustrated and various embodiments of the present invention present these structures and techniques in the context of catheter-based cardiac ablation. These structures, systems, and techniques are well suited for use in the field of cardiac ablation.

[0048] However, it should be appreciated that the present invention is also applicable for use in other tissue ablation applications such as tumor ablation procedures. For example, the various aspects of the invention have application in procedures for ablating tissue in the prostrate, brain, gall bladder, uterus, and other regions of the body,

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preferably regions with an accessible wall or flat tissue surface, using systems that are not necessarily catheter-based.

[0049] The multifunctional catheters of the present invention have numerous advantages over previous prior art devices. The present invention achieves efficiency in tissue ablation by maximizing contact between electrodes and tissue, such as the atrial walls, while also achieving rapid and/or efficient transfer of heat from the electrode into the circulating blood ("cooling"), such as by maximizing electrode surface area in contact with circulating blood. To achieve this result, in a preferred embodiment the electrode has a projecting fin that is configured to act as a heat sink that provides rapid and efficient cooling of the electrode. In another preferred embodiment the electrode comprises two components such that one component, the electrode conductive portion, contracts tissue and the other component, the nonconductive portion, remains thermally conductive. The present invention includes electrodes with improved and miniaturized cross sectional geometries and carrier assemblies that "fold-up" efficiently to allow a smaller ablation catheter to be employed. These improved electrodes are preferably triangularly shaped as described in detail in reference to subsequent figures below. Because these triangular electrodes fold up efficiently, and can have either a "base" to contact tissue or a "point" to contact tissue, greater efficiency and versatility are achieved. The devices and systems are configured to minimize the amount of tissue ablated while still achieving the desired therapeutic benefit of the ablation therapy. Ablated lesions are created with a target depth, and minimal widths. System components monitor energy delivered, parameters associated with energy delivered and other system parameters. Energy delivered is prevented from achieving one or more threshold values.

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[0050] Figs. 1-12 show various embodiments of the multifunctional catheters of the present invention. The present invention is not limited to these particular configurations.

[0051] Fig. 1 illustrates the treatment to be accomplished with the devices and methods described herebelow. Fig. 1 shows a cutaway view of the human heart 1 showing the major structures of the heart including the right atrium 2, the left atrium 3, the right ventricle 4, and the left ventricle 5. The atrial septum 6 separates the left and right atria. The fossa ovalis 7 is a small depression in the atrial septum that may be used as an access pathway to the left atrium from the right atrium. The fossa ovalis 7 can be punctured, and easily reseals and heals after procedure completion. In a patient suffering from atrial fibrillation, aberrant electrically conducive tissue may be found in the atrial walls 8 and 9, as well as in the pulmonary veins 10 and the pulmonary arteries 11. Ablation of these areas, referred to arrhythmogenic foci (also referred to as drivers or rotors), is an effective treatment for atrial fibrillation. Though circumferential ablation of the pulmonary vein usually cures the arrhythmia that originates in the pulmonary veins, as a sole therapy it is usually associated with lesions that have high risk of the eventual stenosis of these pulmonary veins, a very undesirable condition. The catheters of the present invention provide means of creating lesions remote from these pulmonary veins and their ostia while easily being deployed to ablate the driver and rotor tissue.

[0052] To accomplish this, catheter 100 is inserted into the right atrium 2, preferably through the inferior vena cava 20, as shown in the illustration, or through the superior vena cava 21. Catheter 100 may include an integral sheath, such as a tip deflecting sheath, or may work in combination with a separate sheath. When passing into the left atrium, the catheter passes through or penetrates the fossa ovalis 7, such as over a guide

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wire placed by a trans-septal puncture device. The catheter 100 carries a structure carrying multiple ablation elements such as RF electrodes, carrier assembly 120, into the left atrium. Carrier assembly 120, which includes multiple electrodes 130, can be advanced and retracted out of distal end of catheter 100. Carrier assembly 120 is adapted to be deformable such that pressing carrier assembly 120 into left atrial wall 9 will cause one or more, and preferably all of electrodes 130 to make contact with tissue to be analyzed and/or ablated. Each of the electrodes 130 is attached via connecting wires to an energy delivery apparatus, RF delivery unit 200, which is also attached to patch electrode 25, preferably a conductive pad attached to the back of the patient.

[0053] RF delivery unit 200 is configured to deliver RF energy in monopolar, bipolar or combination monopolar-bipolar energy delivery modes. In a preferred embodiment, monopolar energy delivery is followed by bipolar energy delivery. In an alternative embodiment, the bipolar energy is then followed by a period without energy delivery; such as a sequence in which the three steps are have equal durations. In another preferred embodiment, RF delivery unit 200 is configured to also provide electrical mapping of the tissue that is contacted by one or more electrodes integral to carrier assembly 120. Electrodes 130, preferably with a triangular cross section, can also be configured to be mapping electrodes and/or additional electrodes can be integral to carrier assembly 120 to provide a mapping function. Carrier assembly 120 is configured to be engaged over an endocardial surface to map and/or ablate tissue on the surface. RF energy is delivered after a proper location of the electrodes 130 is confirmed with a mapping procedure. If the position is determined to be inadequate, carrier assembly 120 is repositioned through various manipulations at the proximal end of the ablation catheter 100. In another

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preferred embodiment, RF delivery unit 200 is configured to deliver both RF energy and ultrasound energy through identical or different electrodes 130. In another preferred embodiment, RF delivery unit 200 is configured to accept a signal from one or more sensors integral to ablation catheter 100, not shown, such that the energy delivered can be modified via an algorithm which processes the information received from the one or more sensors. The improved electrodes and other catheter and system components of the present invention typically require only 3 to 5 watts of RF energy to adequately ablate the tissue. The minimal power requirements results in reduced procedure time as well as greatly enhanced safety of the overall procedure.

[0054] Figures 2a and 2b illustrate an exemplary embodiment of the ablation catheter 100 of the present invention. These ablation catheters have triangular electrodes 130, each with fin 133 configured to provide rapid and efficient cooling of electrode 130. The cooling efficiency prevents over-heating of the electrode and neighboring tissue during ablation, as well as a short transition time from an ablation temperature, preferably 60° C, to body temperature, typically 37° C after an ablation cycle has ceased. This rapid transition is typically less than 20 seconds, even when the electrode remains in contact with recently ablated tissue. Other benefits of the rapid and efficient cooling electrode configuration include reducing the risk of blood clotting.

[0055] The ablation elements of the present invention include RF energy delivery electrodes 130 of Figs. 2a and 2b, as well as other elements capable of delivering one or more forms of energy, described in detail hereabove, the electrodes and other system components configured in a manner sufficient to controllably ablate tissue. Electrodes 130 include conductive materials, such as a metal or metal-coated material. Metals and

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combinations of metals are appropriate such as: platinum, iridium, gold, stainless steel and aluminum. Conductive polymers are also appropriate materials. Conductive surfaces may be painted, coated or plated surfaces, such as gold plated over a copper base. Electrode materials may also include foils such as aluminum or gold foils attached to a base. Electrodes 130 deliver RF energy in monopolar or bipolar mode as has been described in reference to Fig. 1. Electrodes 130 are designed to have small surface area, typically less than 2.5mm^2 and preferably approximating 0.56mm^2. Electrodes 130 are designed to have small volume, typically less than 3.0mm^3 and preferably approximating 1.3mm^3. Electrodes 130 are designed to have small mass, typically less than 0.05 grams, and preferably approximating 0.03 grams. These miniaturized electrodes, especially those with a triangular cross section, provide numerous advantages such as high ratio of energy to surface area (energy density) during ablation, as well as efficiently compact volume of carrier assembly 120 when constrained within the lumen of the ablation catheter in the retracted, undeployed state.

[0056] Figure 2a shows the structures of the ablation carrier assembly 120 and other portions of ablation catheter 100. The ablation carrier assembly 120 shown includes carrier arms 123 that extend radially out from the central axis of the distal end of catheter shaft 101, the carrier arms 123 positioned in a symmetric configuration with equal angles (ninety degrees in a four arm configuration between each arm). Carrier assembly 120 is shown with four carrier arms 123, however any number can be used, and each arm can carry one or more mapping or ablating electrodes 130, or be void of electrodes. Carrier arms 123 are resiliently biased, preferably constructed of a wire such as a ribbon wire, and may have segments with different levels of flexibility. Carrier arms 123 are shown

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with multiple electrodes 130 fixedly mounted (such as with glues, soldering, welding, crimping or other attachment means) to its distal arm segment 127. In an alternative embodiment, different patterns of electrodes are employed, and one or more arms may be void of electrodes such as where carrier arm 123 provides support only. In a preferred embodiment, different types of ablation elements are mounted to one or more carrier arms 123, such as electrodes with different geometries, or ablation elements that deliver different forms of energy. Carrier arms 123 may also include mapping electrodes, thermal sensors or other sensors, with or without the inclusion of ablation elements. In a preferred embodiment, each carrier arm 123 includes at least one ablation element. In alternative embodiments, three or more arms can be separated by non-equal angles.

[0057] Each carrier arm 123 includes proximal arm segment 125 and distal arm segment 127. Electrodes 130 are mounted onto distal arm segment 127. During the ablation procedure, an operator presses distal arm segment 127 into tissue prior to and during energy delivery. Carrier assembly 120 is configured with specific rigidity such that the operator can exert a nominal force to cause the appropriate electrodes 130 to press and slightly "bury" into the tissue, without perforating or otherwise damaging the neighboring tissue. In a preferred embodiment, the distal arm segments contain thermocouples such as sensors embedded in the electrodes 130, or sensors mounted equidistant between two electrodes 130. Proximal arm segment 125 and distal arm segment 127 connect at a bendable joint, carrier arm bend point 121. In a preferred embodiment, proximal arm segment 125, distal arm segment 127 and bend point 121 are a continuous resiliently flexible wire. Each distal arm segment 127 bends radially inward from the bend point 121 toward the longitudinal axis of catheter shaft 101. The distal arm

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segments 127 are shown also to tend proximally, to establish an acute angle with the proximal arm segment 125 from which it extends, and the angle is small such that the distal end of the distal arm segment 127 is proximal to the carrier arm bend point 121. Bend point 121 allows "folding out" of carrier assembly 120 during retraction, acting as a hinge in providing the means for rotably joining the distal arm segment 127 to the proximal arm segment 125. The proximal arm segment 125 of the carrier arm 123 may include temperature sensors, not shown, such as thermocouples to measure temperature of blood. In the configuration shown, the proximal arm segment 125 will not contact tissue during the ablation procedure. In an alternative embodiment, proximal arm segment 125 includes one or more electrodes, for ablation and/or for mapping, such that the opposite side of carrier assembly 120 can be used to map or ablate tissue and is configured to contact tissue, such as when carrier assembly 120 is deployed and catheter shaft 101 is in tension such as when pulled back by an operator.

[0058] Each distal arm segment 127 connects, at its end opposite bend point 121, to connection point 124, a mechanical joint such as a soldered, crimped or welded connection that stabilizes each distal arm segment 127 relative to the others. In a preferred embodiment, two continuous wires or ribbons are used to create the four distal arm segments 127. Each wire or ribbon comprises the pair of distal arm segments 127 that are linearly aligned, and the two wires are connected at their midpoint at connection point 124. These wires or ribbons are preferably constructed of Nitinol, but other materials such as stainless steel or a plastic may be used. In an alternative embodiment, the two connection wires are resiliently biased to deploy in the configuration shown in

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Fig. 2a, but do not include connection point 124 such that the center portion of the two continuous wires can move relative to each other.

[0059] Referring to the ablation catheter 100 structures, Fig. 2a shows a tubular body member that is an elongated, flexible, hollow tube, catheter shaft 101, which connects at its proximal end to handle 110. The material used for the construction of the catheter shaft 101 and each component which resides or is configured to be inserted through a lumen integral to catheter shaft 101, are selected to provide the suitable flexibility, column strength and steerability to allow percutaneous introduction of ablation catheter 100 through the vasculature of the patient, entering the right atrium 2 through the septum 6 and into the left atrium 3. Catheter shaft 101 and other tubular conduits of ablation catheter 100 are constructed of materials such as Pebax, urethanes, nylons, thermoplastic elastomers, and polyimides. The shafts may be reinforced with wire or plastic braids and/or may include coil springs. Catheter shaft 101 is typically between 4 to 12 French and typically 6 to 8 French. In a preferred embodiment, catheter shaft 101 is introduced through a deflectable sheath where the sheath mechanism is already in place in left atrium 3. In an alternative embodiment, catheter 100 is inserted directly without the use of an outer sheath, and catheter 100 includes a deflectable tip assembly and deflection controls.

[0060] Handle 110 on the ablation catheter includes controls to operate the carrier assembly 120. Handle 110 is constructed of a rigid or semi-rigid material such as Delrin or polycarbonate, and includes button 116 that is connected to switch means, not shown, for starting and/or stopping the delivery of energy to one or more of electrodes 130. Handle 110 may include other controls, not shown, to perform numerous functions such

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as change energy delivery settings. Handle 110 may include a retraction mechanism, not shown, to advance and retreat carrier assembly 120. In an alternative embodiment, handle 110 is attached to an inner shaft slidingly received within catheter shaft 101 such that retraction of the handle 110 causes the carrier assembly 120 to collapse and be constrained within the lumen at end of catheter shaft 101. Carrier arm 123 is resiliently biased in shown position so that it can be collapsed and withdrawn within lumen of catheter shaft 101 through manipulation of handle 110 on proximal end of catheter 100.

[0061] Handle 110 includes a plug 118 that attaches to an interface unit of the present invention, such as an RF energy generator that also includes mapping functions and display. Plug 118 is connected to electrical wires that extend distally with a lumen integral to catheter shaft 101 of carrier assembly 120, terminating at each of the electrodes 130.

[0062] Fig. 2b illustrates the cross section, preferably a uniform cross section, of one or more electrodes 130 mounted to distal arm segment 127 of Fig. 2a. A projecting member, fin 133, assists in the rapid and efficient cooling of electrode 130 during and after ablation energy application, acting as a heat sink and efficiently transferring heat energy to the neighboring blood, such as blood circulating in the left atrium 3 or the right atrium 2 depending upon where the carrier assembly 120 has been placed by the operator. The size, surface area and mass of fin 133 are chosen to effectively transfer the heat energy while allowing carrier assembly 120 to achieve a sufficiently compact configuration when constrained within the lumen of the ablation catheter. In a preferred embodiment, fin 133 is sized such that the portion of the surface area of electrode 130 that is in contact with circulating blood is at least 60%, and preferably 70% of the total

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surface area of electrode 130. Fin 133 may change laminar and/or other non-turbulent flows to turbulent flow, such that heat is more efficiently transmitted away from electrode 130. In an alternative embodiment, illustrated and described in reference to Figs. 5c and 5d, fin 133 may be electrically isolated from the remainder of electrode 130, such that fin 133 does not deliver energy to the circulating blood. In another alternative embodiment, illustrated and described in reference to Fig. 6b, electrode 130 may include multiple fins.

[0063] First wire 134 is an energy delivery conduit that connects to electrode 130 to transfer ablation energy and preferably to also send and/or receive signals to map the tissue of the heart. Second wire 135 depicts an exemplary wire that connects to electrode 130, and may act as the return wire to first wire 134, for return of ablation energy and/or mapping signals. Wire 134 and wire 135 are typically 30 awg wire including a 0.003" polyamide insulating outer jacket, each parameter chosen to carry sufficient ablation currents and prevent voltage breakdown between neighboring wires. The efficiency of the electrodes of the present invention, as well as the efficient configuration of the other components of the system, allow greatly reduced wire gauge and insulation thickness, correlating to smaller diameter and more flexible ablation catheters.

[0064] Surface 136 is the base of the electrode that is the part of the structure that contacts tissue during ablation. In a preferred embodiment, surface 136 is a small surface area so that energy delivered per square area is maximized. Fin 133 projects from the apex opposite surface 136, and provides sufficient surface area such that the majority of the surface area of electrode 130 resides in the circulating blood when surface 136 is in contact with tissue and energy is being delivered. Within the triangular cross section of

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electrode 130 passes each wire 134 and 135, as well as distal arm segment 127, to which electrode 130 is fixedly mounted.

[0065] Referring now to Figs. 3a through 3c, another preferred embodiment of the ablation catheter and components of the ablation system of the present invention is illustrated. Electrodes 130 have a triangular cross section with a continuous perimeter or path, preferably an isosceles triangle wherein the common base is opposite two sides that determine a vertex angle. This vertex angle is configured, based on the number of carrier arms of the particular carrier assembly, to allow a number of electrodes to be constrained into a volumetrically efficient circle or "pie" shape, the sum of all the vertex angles approximating 360 degrees, such that:

$$\text{Vertex Angle} = \frac{360 \text{ degrees}}{\text{Number of Carrier Arms}}$$

[0066] In an alternative embodiment, the cross sections are dissimilar, and/or the cross sections do not include only isosceles geometries, however the individual vertex angles are configured such that their sum approaches 360 degrees in total, providing efficient constrained volume of the carrier assembly. In addition to allowing compact constrained volume, and overall small surface area, volume and mass of electrodes 130, the electrodes of the present invention provide maximum flexibility in performing ablation procedures, such as by: minimizing energy delivered to blood; avoiding energy delivered to non-targeted tissue and/or minimizing tissue area receiving energy during ablation; maximizing energy density delivered to tissue; reducing procedure time, and other advantages. In a preferred embodiment, the ablation catheter and system of the

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present invention includes multiple dissimilar electrodes, fixedly mounted to a single ablation catheter or mounted to multiple ablation catheters used sequentially or simultaneously in a single ablation procedure for a patient.

[0067] Referring specifically to Fig. 3a, electrode 130a is configured to deliver RF energy to tissue via surface 136. Electrode 130a of Fig. 3a is similar to electrode 130 of Fig. 2b with a smaller projecting fin 133, sized to allow a more compact constrained configuration of the carrier assembly while still increasing the surface area of electrode 130a in the circulating blood during ablation. Electrode 130a is fixedly mounted to distal arm segment 127 which comprises a Nitinol wire or ribbon but alternatively a non-conductive material such as nylon or other non-metal which does not require electrode 130a from being electrically isolated from distal arm segment 27, isolation means not shown. Electrode 130a includes within its triangular cross section wire 134 and wire 135 that are electrically connected to electrode 140a and travel proximally to an electrical connection point that attaches to an interface unit of the present invention. Wire 134 and 135 provide supply and return of RF power and potentially supply and return of mapping drive and record signals. Additional wires and other energy delivery or other conduits, not shown, may pass through the triangular cross section of electrode 130a, such as energy and/or signal delivery conduits that connect to sensors such as thermocouples, or other ablation or mapping elements. In a preferred embodiment, electrode 130a includes an embedded thermocouple, not shown but preferably a bimetallic thermocouple consisting of copper and alloy 11 or Constantan alloy. Each thermocouple is attached to 40 awg wire with a 0.001" insulating jacket, the wires traveling proximally and attaching to the interface unit of the present invention for converting signals to temperature values.

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[0068] Referring to Fig. 3b, a partial cutaway view of the ablation catheter of the present invention is illustrated, including the multiple electrodes 130a of Fig. 3a constrained with a lumen of catheter shaft 101 of ablation catheter 100. Ablation catheter 100 may be configured to be inserted through a deflectable guide catheter, or include distal tip deflection means, not shown. Electrodes 130a are fixedly mounted to distal arm segments 127 which are attached to proximal arm segments via a bendable portion (both proximal arm segments and bendable portion not shown but described in detail in reference to Fig. 2a). The ablation element carrier assembly has been folded into the retracted state shown, by retraction of handle 110 and/or activation of a control of handle 110, not shown but preferably a sliding knob or lever on handle 110. Handle 110 includes connector 118 for electrical attachment to an energy delivery apparatus such as an RF generator and/or electrophysiology mapping unit, and further includes button 116 used by the operator to initiate an energy delivery event. Handle 110 may additionally include other functional components and assemblies such as other control or activation means, as well as audio and/or tactile transducers to alert the operator of alert conditions.

[0069] Referring additionally to Fig. 3c, the carrier assembly of Figs. 3b and 3c includes five electrodes 130a and five distal arm segments 127 that have been placed in a constrained condition within a lumen of catheter shaft 101 such that at least a portion of each of the triangle cross section of the five electrodes 130a lie in a single plane. Each electrode 130a has a similar isosceles triangle shaped cross section such that the vertex angle A approximates 75 degrees allowing the compact 360 circular or pie shaped configuration. In the constrained configuration shown, each vertex angle A is aligned radially outward from the central axis of shaft 101 such that the tissue contacting surface

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136 of each electrode 130a is in relative contact with the inner wall of shaft 101. These triangle cross sections and relatively small projecting fins 133 are sized and configured to allow a compact constrained configuration that includes coupler 140 at its center. Coupler 140, described in detail in reference to Fig. 4, couples the carrier arms of the carrier assembly to a slidable shaft, not shown but operably attached to handle 110 and advanced and retracted by an operator to position the carrier assembly in its deployed (expanded) and constrained configurations respectively.

[0070] While the carrier assembly configuration of Figs. 3b and 3c illustrate a five carrier arm configuration that correlates to an electrode 130a cross section triangular vertex angle approximating 75 degrees, it can be easily derived from the equation above that a vertex angle of 120 degrees would correspond to three arm carrier assembly configurations and a vertex angle of 90 degrees would correspond to four arm configurations. It also should be easily understood that in embodiments in which electrode 130a cross sections are dissimilar, the sum of the vertex angles of the appropriate cross sections, those cross sections that are linearly aligned within the lumen of catheter shaft 101 in the retracted position, should approximate 360 degrees to minimize the overall constrained cross sectional area.X

[0071] Referring now to Figs. 4 and 4a, another preferred embodiment of ablation catheter 100 and ablation system of the present invention is illustrated. Catheter 100 includes carrier assembly 120 configured in another umbrella tip configuration. Carrier assembly 120 includes three carrier arms 123, each separated by 120 degrees from the neighboring arm when in the deployed condition, and each of which includes two ablation elements, electrodes 130. In an alternative embodiment, different patterns of electrodes

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are employed, and one or more arms may be void of electrodes. Electrodes can take on one or more various forms, such as those described in detail in reference to Figs. 5a through 5f and Figs. 6a through 6c. The six electrodes 130 shown may have similar or dissimilar characteristics. They may be chosen to maximize cooling or maximize energy delivery to tissue. Each electrode 130 may be energized with one or more forms of energy such as RF energy in a sequence of monopolar and bipolar energy delivery. Referring back to Fig. 4, carrier arms 123 extend radially out from the central axis of the distal end of catheter shaft 101. Each carrier arm 123 includes proximal arm segment 125 and distal arm segment 127, these segments connected at a bendable joint, bend point 121. In a preferred embodiment, proximal arm segment 125 and distal arm segment 127 and bend point 121 are a continuous resiliently flexible wire, such as a "trained" Nitinol wire that creates the umbrella tip. Each electrode 130 is mounted to an insulator, insulating band 131 such that the electrode is electrically isolated from the wire segments of carrier assembly 120. Each electrode 130 is connected to wires that extend along shafts of carrier assembly 120, toward a lumen of catheter shaft 101, and proximally to handle 110. These wires, not shown but described in detail hereabove, include insulation to electrically isolate one wire from another. One end of each distal arm segment 127 is attached to a cylinder, coupler 140, which is sized to be slidably received within a lumen of catheter shaft 101.

[0072] Coupler 140 can be flexible or rigid, and may contain both rigid and flexible portions along its length. Coupler 140 may provide electrical connection means to connect wires extending from the handle to wires from carrier assembly 120 electrodes. The ends of the distal arm segments 127 and the ends of the proximal arm segments 125

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can be attached to the outside of coupler 140, the inside of coupler 140 or both. Coupler 140 includes along its outer surface, a projection, projection 142, which has a cross section profile which mates with a recess, groove 106 of catheter shaft 101 which prevents undesired rotation of carrier assembly 120. In an alternative embodiment, catheter shaft 101 includes a projection, and coupler 140 includes a groove to accomplish a similar prevention of rotation. In another alternative embodiment, control shaft 150, which is slidingly received within a lumen of shaft 101, additionally or alternatively includes a projection or other means to mate with shaft 101 to prevent undesired rotation of carrier assembly 120. As depicted in Fig. 4a, control shaft 140 includes a thru lumen, lumen 152, such that ablation catheter 101 can be inserted over a guidewire (guidewire exit on handle 110 not shown). Additionally or alternatively, lumen 152 may include one or more wires or other filamentous conduits extending from proximal handle 110 a point more distal.

[0073] Control shaft 150 is mechanically attached to coupler 140. Control shaft 150 extends proximally to handle 110 and is operably connected to knob 115 such that rotation of knob 115 from a deployed position to a withdrawn position causes carrier assembly 120 to be constrained within a lumen of catheter shaft 101, and rotation of knob 115 from a withdrawn position to a deployed position causes carrier assembly 120 to extend beyond the distal end of catheter shaft 101 to be in an expanded condition. In a preferred embodiment, knob 115 is operably connected to control shaft 150 via a cam, or set of gears, not shown, to provide a mechanical advantage in the distance traveled by control shaft 150.

[0074] Catheter shaft 101 is preferably part of a steerable sheath, steering

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mechanism not shown, and includes flush port 170, which is configured to be attachable to a flushing syringe, used to flush blood and other debris or contaminants from the lumen of an empty catheter shaft 101 (wherein control shaft 150, coupler 140 and carrier assembly 120 have been removed) or for flushing the space between control shaft 150 and the inner wall of catheter shaft 101. Catheter shaft 101 is not connected to handle 110, such that handle 110 can be withdrawn, removing control shaft 150, coupler 140 and carrier assembly 120 from catheter shaft 101. This configuration is useful when these components are provided in a kit form, including combinations of different versions of these components, the different combinations made available to treat multiple patients, or a single patient requiring multiple electrode patterns or other varied electrode properties such as tissue contact surface area, electrode cooling properties and temperature sensor location. A preferred example of a kit would include the catheter shaft 101 and flush port 170 of Fig. 6 acting as a sheath; kitted with the insertable shaft assembly comprising handle 110, control shaft 150, coupler 140 and umbrella tipped carrier assembly 120 of Fig. 6 as well as a second insertable shaft assembly. The second insertable shaft assembly preferably includes a different carrier assembly of ablation elements such as a different pattern of electrodes or electrodes with different properties that the first insertable shaft assembly. Electrode or other ablation element variations include but are not limited to: type of energy delivered; size; cross sectional geometry; cooling properties; heating properties; and combinations thereof. In another preferred embodiment of the kit, a catheter configured for creating lesions at or near the pulmonary veins of the left atrium is included.

[0075] Also depicted in Fig. 4 is a system of the present invention, including in

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addition to ablation catheter 100, RF delivery unit 200, an interface unit of the present invention which connects to handle 110 with a multi-conductor cable 202 at RF attachment port 181. RF delivery unit 200 includes user interface 201, such as a user interface including data input devices like touch screens, buttons, switches, keypads, magnetic readers and other input devices; and also including data output devices like data and image screens, lights, audible transducers, tactile transducers and other output devices. User interface 201 is used to perform numerous functions including but not limited to: selecting electrodes to receive energy (electrodes 130 of carrier assembly 120); setting power levels, types (bipolar and monopolar) and durations; setting catheter and other system threshold levels; setting mapping and other system parameters; initiating and ceasing power delivery; deactivating an alarm condition; and performing other functions common to electronic medical devices. User interface 201 also provides information to the operator including but not limited to: system parameter information including threshold information; mapping and ablation information including ablation element temperature and cooling information; and other data common to ablation therapy and other electronic medical devices and procedures. In a preferred embodiment, RF delivery unit 200 attaches to a temperature probe, such as an esophageal temperature probe, determines the temperature from one or more sensors integral to the probe, and further interprets and/or displays the temperature information on user interface 201. In another preferred embodiment, RF delivery unit 200 also includes cardiac mapping means, such that mapping attachment port 182 can be attached to RF delivery unit 200 avoiding the need for a separate piece of equipment in the system. In another preferred embodiment, RF delivery unit 200 can also deliver ultrasound and/or another form of energy, such

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energy delivered by one or more additional ablation elements integral to carrier assembly 120, additional ablation elements not shown. Applicable types of energy include but are not limited to: sound energy such as acoustic energy and ultrasound energy; electromagnetic energy such as electrical, magnetic, microwave and radiofrequency energies; thermal energy such as heat and cryogenic energies; chemical energy; light energy such as infrared and visible light energies; mechanical energy; radiation; and combinations thereof.

[0076] In a preferred embodiment, ablation catheter 100 includes an embedded identifier (ID), an uploadable electronic or other code, which can be used by RF delivery unit 200 to confirm compatibility and other acceptability of the specific catheter 100 with the specific RF delivery unit 200. The electronic code can be a bar code, not shown, on handle 110 which is read by RF delivery unit 200, an electronic code which is transferred to RF delivery unit 200 via a wired or wireless connection, not shown, or other identifying means, such as an RF tag embedded in handle 110. In another preferred embodiment, RF delivery unit 200 also includes an embedded ID, such as an ID that can be downloaded to catheter 100 for a second or alternative acceptability check. The embedded ID can also be used to automatically set certain parameters or certain parameter ranges, and can be used to increase safety by preventing inadvertent settings outside of an acceptable range for the specific catheter 100.

[0077] Handle 110 includes two push buttons, first button 116 and second button 117. These buttons can be used to perform one or more functions, and can work in cooperation with user input components of user interface 201 such that commands entered into user interface 201 set the action taken when either or both button 116 and

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button 117 are pressed. In a preferred embodiment, both button 116 and button 117 must be pressed simultaneously to deliver energy to one or more ablation elements of catheter 100. At the distal end of catheter shaft 101 is a circumferential band, band 104. Band 104 is preferably a visualization marker, such as a radiographic marker, ultrasound marker, electromagnetic marker, magnetic marker and combinations thereof. In an alternative embodiment, band 104 transmits or receives energy, such as when the marker is used as a ground or other electrode during an ablation. In another alternative embodiment, band 104 is an antenna used to determine the position of the distal end of catheter shaft 101 or the location of another component in relation to band 104. In another preferred embodiment, band 104 is used to store energy, such as capacitively stored energy that can be used to generate a magnetic field or to deliver ablation energy.

[0078] While the ablation catheter of Figs. 4 and 4a is shown with an umbrella tip geometry, it should be appreciated that numerous configurations of carrier arms, such as spiral, zigzag, and other patterns could be employed. These carrier assemblies are configured to provide sufficient forces to maximally engage the appropriate ablation element with the tissue to be ablated, without adversely impacting neighboring structures and other tissues. While the carrier assembly 120 of Fig. 4 "folds in" during retraction of shaft 150, other collapsing configurations can be employed such as the "fold out" configuration of the catheter of Fig. 2a, or configuration in which the carrier assembly transforms from a spiral, zigzag, or other curvilinear shape to a relatively straight or linear configuration as it is retracted and captured by the lumen of catheter shaft 101. Electrodes 130 of carrier assembly of Fig. 4 are shown facing out from the distal end of shaft 101 such that advancement or "pushing" of carrier assembly 120 engages electrodes

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130 with tissue. In an alternative embodiment, electrodes are positioned, alternatively or additionally, to face toward the distal end of shaft 101. These electrodes may be mounted to proximal arm segment 125 such that retraction or "pulling" of carrier assembly 120, once deployed, engages these rear facing electrodes with tissue.

[0079] Ablation catheter 100 and RF delivery unit 200 are configured to ablate tissue with minimal power and precise control. RF Power levels are preferably less than 10 watts per electrode, and preferably 3 to 5 watts. Electrodes 130 are powered to reach an ablation temperature of approximately 60° C. The electrode geometries of the present invention, described in detail in reference to Figs. 5a through 5f and Figs. 6a through 6c, provide numerous and varied benefits including enhanced cooling properties. Electrodes of the present invention are configured to transition from an ablation temperature of 60° C to body temperature of 37° C in less than 20 seconds and preferably less than ten seconds. These electrodes are further configured to increase from body temperature to ablation temperature in less than 5 seconds. In a preferred embodiment, bipolar RF energy is delivered subsequent to monopolar delivery. The electrodes and power delivery subsystems of the present invention are configured to allow the electrode and neighboring tissue to decrease in temperature during the bipolar RF energy delivery following the monopolar delivery. This bimodal, sequential power delivery reduces procedure time, allows precise control of lesion depth and width, and reduces large swings in ablation temperatures. In another preferred embodiment, the temperature in the tissue in proximity to the electrode actually continues to increase as the electrode temperature decreases, such as during the bipolar delivery following monopolar delivery. In an alternative embodiment, the monopolar delivery cycle, the bipolar delivery cycle, or both,

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are followed by a period of time in which no RF energy is delivered. During this "off" time period, no energy may be delivered or an alternative energy may be delivered such as cryogenic energy that actually decreases the temperature of the tissue in order to ablate.

[0080] In a preferred embodiment, parameters associated with the bipolar and monopolar energy delivery are adjusted during the procedure, automatically by the system and/or manually by the operator. The energy delivery parameters are adjusted by measured, calculated or otherwise determined values include those relating to: energy delivered measurements such as voltage or current delivered to an electrode; force or pressure measurement such as the force exerted by the carrier assembly as measured by an integral strain gauge; other ablation catheter or ablation system parameter; temperature of tissue; rate of change of temperature of tissue; temperature of an electrode or other ablation element; rate of change of temperature of an electrode or other ablation element; EKG; tissue thickness; tissue location; cardiac flow-rate; other patient physiologic and other patient parameters; and combinations thereof. The energy delivery drive parameters may be adjusted by a combination of these determined values. In order to automatically modify an energy delivery parameter, or to notify an operator of a condition, these determined values are compared to a threshold, such as via a threshold comparator integral to the interface unit of the present invention. Threshold values can be calculated by the system or can be entered by the operator into a user interface of the system.

[0081] Energy delivered measurements, such as current, voltage and power measurements, which may be compared to a threshold value, include average energy; instantaneous energy; peak energy; cumulative or integrated energy amounts; and

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combinations thereof. In the catheter and system of the present invention, average power is approximately 5 Watts and less, cumulative energy for a cycle of bipolar and monopolar delivery is typically less than 500 Watt-seconds and preferably less than 300 Watt-seconds (5 watts for 60 seconds). Each threshold value may change over time and may be adjustable by an operator such as via a password enabled user interface. Cumulative determined values, such as cumulative energy delivered and "time at temperature" values may be able to be reset, such as automatically by the system and/or manually by an operator. Automatic resets may occur at specific events such as each time an ablation element is repositioned on tissue or each time energy delivered changes states, including the switching of electrodes receiving energy or the completion of a monopolar-bipolar delivery cycle.

[0082] Determined values such as temperature measurements may be made from single or multiple sensors, such as multiple temperature sensors during a single ablation cycle. In a preferred embodiment, multiple sensors are used and the more extreme (e.g. a higher temperature) value is compared to a threshold. When the threshold comparator determines a particular threshold has been reached, the system can adjust or otherwise react in various ways. In a preferred embodiment, the system enters an alarm or alert state. In another preferred embodiment, the energy delivery transmitted to an ablation element is modified; such as to cease or reduce the amount of RF energy delivered to an electrode. Numerous energy delivery parameters can be modified including but not limited to: current level; voltage level; frequency (usually fixed at 500 KHz); bipolar delivery "on" times; monopolar delivery "on" times; no energy delivery "on" times; electrode selected such as bipolar return electrode selected; and combinations thereof.

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[0083] The automatic and manual adjustments of the present invention are triggered by comparing a measured, calculated or otherwise determined value to a threshold. These adjustments improve numerous outcomes of the proposed ablation therapy including those associated with improved efficacy and reduced adverse events. Specific benefits include precision controlled depth and width of lesions through a combination of bipolar and monopolar sequential duty cycles. The system is adjustable by the operator to modify intended lesion geometry to safely avoid structures like pulmonary vein lumens and the esophagus, as well as work in portions of the atrial wall that require deep lesions to effectively interrupt aberrant pathways.

[0084] Referring now to Figs. 5a through 5f, multiple preferred embodiments of electrode-type ablation element of the present invention are illustrated. These electrodes are shown in sectional view in contact with tissue 30 just prior to or during delivery of energy to tissue 30 via the electrode. Each of the electrodes of Figs. 5a through 5f are intended to maximize cooling, minimize energy delivered to non-targeted tissue (e.g. blood), or both. Certain electrodes are configured to minimize "low flow" areas for blood, such blood more likely to absorb enough energy to clot during an energy delivery cycle. The electrode cross sections assume various geometries such as triangular, semi-circular and crescent shaped, and are all preferably relatively uniform along their length such as to simplify their manufacturing. Cross sectional geometries are configured to create lesions of specific widths and depths, and to otherwise minimize trauma to neighboring tissue such as when force is applied to press the electrode "into" the tissue to be ablated. In a preferred embodiment, each of the electrodes of Figs 5a through 5f

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includes one or more temperature sensors, such as a thermocouple in a non-energy delivery portion.

[0085] Referring specifically to Fig. 5a, electrode 130b is displayed including a triangular cross section and configured to be placed by an operator with base 136 in contact with tissue 30. Electrode 130b includes an isosceles triangle cross section, with two equal sides, sides 137 and 138, each positioned in circulating blood when ablation energy, such as RF energy, is being delivered via wires 134 and 135. Electrode 130b is fixedly mounted to distal arm segment 127, as has been described in detail in reference to previous figures. Distal arm segment 127 is sufficiently rigid to allow the operator to apply a force to electrode 130b such that electrode 130b can be pressed, as shown, into tissue 30. The transition point from base 136 to side 137 and from base 136 to side 138 each are rounded such that although electrode 130b is slightly depressed into tissue 30, low blood flow area 31 (an area where blood will tend to heat up at a faster rate) is minimized as well as tension in the neighboring tissue. The surface area of sides 137 and 138 are sufficiently large (i.e. the combined lengths of sides 137 and 138 is sufficiently long) such that their combined surface area is greater than 60% of the overall total surface area of electrode 130b, preferably greater than 75% of the total. This high percentage of surface area in the circulating blood provides rapid and efficient cooling of electrode 130b.

[0086] Referring specifically to Fig. 5b, electrode 130c is displayed including a triangular cross section and configured to be placed by an operator with the majority of sides 137and 138 in contact with tissue 30. Electrode 130c includes an isosceles triangle cross section and base 136 positioned in circulating blood when ablation energy, such as

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RF energy, is being delivered via wires 134 and 135. Electrode 130c is fixedly mounted to distal arm segment 127, as has been described in detail in reference to previous figures. Distal arm segment 127 is sufficiently rigid to allow the operator to apply a force to electrode 130c such that electrode 130c can be pressed, as shown, into tissue 30. The surface area of sides 137 and 138 are sufficiently large such that their combined surface area is greater than 60% of the overall total surface area of electrode 130c, preferably greater than 70% of the total. This high percentage of surface area in contact with tissue minimizes the amount of energy delivered by electrode 130c into the neighboring blood. The energy delivery parameters are chosen such as to prevent the blood residing in or near low flow area 31 from clotting.

[0087] Referring specifically to Fig. 5c, electrode 130d is displayed including a laminate construction with a triangular cross section and configured to be placed by an operator with the majority of sides 137and 138 in contact with tissue 30. Electrode 130d is configured to both improve cooling, and maximize energy delivered to tissue versus blood. Electrode 130d includes an isosceles triangle cross section, with base 136 positioned in circulating blood when ablation energy, such as RF energy, is being delivered via wires 134 and 135. Electrode 130d is fixedly mounted to distal arm segment 127, as has been described in detail in reference to previous figures. Distal arm segment 127 is sufficiently rigid to allow the operator to apply a force to electrode 130d such that electrode 130d can be pressed, as shown, into tissue 30. Electrode 130d has a laminate construction that includes a first portion that receives and delivers energy to tissue, electrical portion 132, a segment preferably constructed of standard RF electrode materials described hereabove. Electrical portion 132 makes up the majority of sides 137

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and 138 and is sized such that all or nearly all of its surface area is in contact with tissue 30 during delivery of energy. Electrode 130d has a second portion that is thermally conductive, thermal portion 139. Thermal portion 139 is either electrically non-conductive, minimally electrically conductive, and/or electrically isolated from electrical portion 132 such that thermal portion 139 does not deliver energy when energy is applied to and delivered by electrical portion 132. Thermal portion 139 may be constructed of standard electrode materials but be electrically isolated from electrical portion 132 such as with insulating glue 146. In this configuration and in an additional embodiment, thermal portion 139 may also (in addition to electrical portion 132) independently be used to map or deliver energy with different drive wires not shown. Alternatively, thermal portion 139 may be a plastic with high thermal conductivity such as a Konduit™ thermally conductive thermoplastic compound manufactured by LNP Engineering Plastics of Exton, Pa. Thermal portion 139 makes up a small portion of each of side 137 and side 138, and the entirety of base 136 such that when electrode 130d is positioned 'into" tissue by the operator, most of thermal portion 139 is in the circulating blood, dissipating heat from electrical portion 132 and the neighboring tissue. Thermal portion 139 is sized such that no significant energy is delivered to low flow area 31, greatly reducing any chance of clot formation. Electrode 130d is configured to apply the great majority of the energy it receives into tissue and not blood, as well as provide enhanced cooling by having a thermal portion with significant surface area and/or efficient thermal mass that resides in the circulating blood during energy delivery. In an alternative embodiment, thermal portion 139 further includes a projecting fin to increase the transfer of heat from electrode 130d into the blood stream as has been described in reference to

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Fig. 2b hereabove. In an alternative embodiment, not shown, electrode 130d is fixedly attached to distal arm segment 127 in the opposite (mirrored) orientation such that base 136 is in contact with tissue 30 during ablation, similar to the attachment configuration of electrode 130b of Fig. 5a. In this particular preferred embodiment, electrical portion 132 makes up the majority of base 136, and thermal portion 139 makes up both sides 137 and 138 as well as two small end portions of base 136, such that all of the energy delivered from base 136 is transferred to tissue 30, and a greatly increased surface area comprising sides 137 and 138 is in contact with circulating blood to cool electrode 130d.

[0088] Referring specifically to Fig. 5d, electrode 130e is displayed including a similar construction to electrode 130d of Fig. 5c with a semi-circular cross section instead of a triangular cross section and a portion which does not deliver energy but acts as a heat sink. The crescent shaped cross section of electrode 130e causes less tissue deflection per unit force than the triangular cross section of electrode 130d of Fig. 5c, and may be preferable for ablating a wider lesion, ablating in areas of thin or weakened tissue, or for other operator preferences or patient requirements. Electrode 130e is configured to be placed by an operator with a central portion of rounded side 137 in contact with tissue 30. Electrode 130e is configured to both improve cooling, and maximize energy delivered to tissue versus blood. Base 136 is positioned in circulating blood when ablation energy, such as RF energy, is being delivered via wires 134 and 135. Electrode 130e is fixedly mounted to distal arm segment 127, as has been described in detail in reference to previous figures. Distal arm segment 127 is sufficiently rigid to allow the operator to apply a force to electrode 130e such that electrode 130e can be pressed, as shown, into tissue 30. Electrode 130e has a laminate construction that includes a first portion that

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receives and delivers energy to tissue, electrical portion 132, a segment preferably constructed of standard RF electrode materials described hereabove. Electrical portion 132 is sized such that all or nearly all of its surface area is in contact with tissue 30 during delivery of energy. Electrode 130e has a second portion that is thermally conductive, thermal portion 139. Thermal portion 139 is either electrically non-conductive or electrically isolated from electrical portion 132 such that thermal portion 139 does not deliver energy when energy is applied to and delivered by electrical portion 132. Thermal portion 139 is a plastic with high thermal conductivity such as a Konduit™ thermally conductive thermoplastic compound manufactured by LNP Engineering Plastics of Exton, Pa and is attached to electrical portion 132 at joint 147. Alternatively, thermal portion 139 may be constructed of standard electrode materials and be electrically isolated from electrical portion 132 such as with insulating glue, not shown. Thermal portion 139 is appropriately sized such that when the operator positions electrode 130d into tissue, most of thermal portion 139 is in the circulating blood, efficiently dissipating heat from electrical portion 132 and the neighboring tissue. Thermal portion 139 is sized such that no significant energy is delivered to low flow area 31, greatly reducing any chance of clot formation. Electrode 130e is configured to apply the great majority of the energy it receives into tissue and not blood, as well as provide enhanced cooling by having a thermal portion with significant surface area and/or efficient thermal mass that resides in the circulating blood during energy delivery. In an alternative embodiment, thermal portion 139 further includes a fin to increase the transfer of heat from electrode 130e into the blood stream.

[0089] Referring specifically to Fig. 5e, electrode 130f is displayed including a

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crescent shaped cross section and configured to be placed by an operator with side 137 in contact with tissue 30. The crescent shaped cross section of electrode 130f causes less tissue deflection per unit force than the triangular cross section of electrode 130d of Fig. 5c, and may be preferable for ablating a wider lesion, ablating in areas of thin or weakened tissue, or for other operator preferences or patient requirements. The surface area of base 136, positioned in circulating blood when ablation energy is being delivered via wires 134 and 135, is less that the surface area of side 137, which causes the majority of energy delivered to electrode 130f to be delivered to tissue versus blood. The crescent shape of electrode 130f is chosen to minimize trauma as electrode 130f is being pressed into the tissue. Electrode 130f is fixedly mounted to distal arm segment 127, as has been described in detail in reference to previous figures. Distal arm segment 127 is sufficiently rigid to allow the operator to apply a force to electrode 130f such that electrode 130f can be pressed, as shown, into tissue 30. The crescent shape greatly reduces the volume of low flow area 31, minimizing the chance of blood clotting.

[0090] Referring specifically to Fig. 5f, electrode 130g is displayed including a crescent shaped cross section and configured to be placed by an operator with side 137 in contact with tissue 30. The crescent shaped cross section of electrode 130g causes less tissue deflection per unit force than the triangular cross section of electrode 130d of Fig. 5c, and may be preferable for ablating a wider lesion, ablating in areas of thin or weakened tissue, or for other operator preferences or patient requirements. As compared to electrode 130f of Fig. 5e, side 137 has a serpentine segment that greatly increases the surface area of side 137. In should be appreciated that numerous other configurations can be used to increase the length of side 137 and the resultant surface area, such as zigzag

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segments and combinations of straight and non-straight line segments. The surface area of base 136, positioned in circulating blood when ablation energy is being delivered via wires 134 and 135, is much less that the surface area of side 137, which causes a great majority of energy delivered to electrode 130g to be delivered to tissue versus blood. The crescent shape of electrode 130g is chosen to minimize trauma as electrode 130f is being pressed into the tissue. Electrode 130g is fixedly mounted to distal arm segment 127, as has been described in detail in reference to previous figures. Distal arm segment 127 is sufficiently rigid to allow the operator to apply a force to electrode 130g such that electrode 130g can be pressed, as shown, into tissue 30. The crescent shape greatly reduces the volume of low flow area 31, minimizing the chance of blood clotting. In an alternative embodiment, electrode 130g is fixedly mounted to distal arm segment 127 in the opposite (mirrored) orientation such that the large surface area serpentine side 137 is in the circulating blood during ablation, providing a highly efficient cooling electrode configuration.

[0091] Referring now to Figs. 6a through 6cf, multiple preferred embodiments of electrode-type ablation element of the present invention are illustrated. Each of the electrodes of Figs. 6a through 6c are intended to maximize cooling, minimize energy delivered to non-targeted tissue (e.g. blood), or both. Certain electrodes are configured to minimize "low flow" areas for blood, such blood more likely to absorb enough energy to clot during an energy delivery cycle. The electrodes cross sections assume various geometries and are all preferably relatively uniform along their length such as to simplify their manufacturing. Cross sectional geometries are configured to create lesions of specific widths and depths, and to otherwise minimize trauma to neighboring tissue such

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as when force is applied to press the electrode "into" the tissue to be ablated. In a preferred embodiment, each of the electrodes of Figs 6a through 6c includes one or more temperature sensors, such as a thermocouple in a non-energy delivery portion.

[0092] Referring specifically to Fig. 6a, electrode 130h, displayed in a sectional view, has a triangular cross section and is configured to be placed by an operator with base 136 in contact with tissue to be ablated. Electrode 130h includes an isosceles triangle cross section, with two equal sides, sides 137 and 138, each positioned in circulating blood when ablation energy, such as RF energy, is being delivered via wires 134 and 135. Electrode 130h is fixedly mounted to distal arm segment 127, as has been described in detail in reference to previous figures. Distal arm segment 127 is sufficiently rigid to allow the operator to apply a force to electrode 130h such that electrode 130h can be pressed into the tissue to be ablated. The transition point from base 136 to side 137 and from base 136 to side 138 each are rounded to reduce tissue trauma and low blood flow areas during ablation. The thickness of sides 137 and 138 as well as base 136 are chosen to have sufficient mass to effectively deliver energy to tissue without overheating, while minimizing a large thermal mass that would be difficult to cool. In a preferred embodiment, sides 137 and 138 have a smaller wall thickness than base 136, differentiation in thickness not illustrated. Side 137 and side 138 are not connected, leaving opening 148 opposite side 136, to provide enhanced cooling such as by increasing the effective surface area (allowing circulating blood to pass by the interior surfaces of sides 137 and 138 and potentially base 136). The surface area of sides 137 and 138 are sufficiently large (i.e. the combined lengths of sides 137 and 138 is sufficiently long) such that their combined surface area is greater than 60% of the overall total surface area of

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electrode 130h, preferably greater than 75% of the total. In alternative embodiments, side 137 and/or side 138 comprises a non-straight segment such as a curved segment, serpentine segment, zigzag segment, or combinations of straight and non-straight segments. The high percentage of surface area in the circulating blood, in addition to the advantages provided by opening 148, provide rapid and efficient cooling of electrode 130h.

[0093] Referring specifically to Fig. 6b, electrode 130i, displayed in a sectional view, has a triangular cross section and is configured to be placed by an operator with base 136 in contact with tissue to be ablated. Electrode 130i includes an isosceles triangle cross section, with two equal sides, sides 137 and 138, each positioned in circulating blood when ablation energy, such as RF energy, is being delivered via wires 134 and 135. Electrode 130i is fixedly mounted to distal arm segment 127, as has been described in detail in reference to previous figures. Distal arm segment 127 is sufficiently rigid to allow the operator to apply a force to electrode 130i such that electrode 130i can be pressed into the tissue to be ablated. The transition point from base 136 to side 137 and from base 136 to side 138 each are rounded to reduce tissue trauma and low blood flow areas during ablation. The thickness of sides 137 and 138 as well as base 136 are chosen to have sufficient mass to effectively deliver energy to tissue without overheating, while minimizing a large thermal mass that would be difficult to cool. In a preferred embodiment, sides 137 and 138 have a smaller wall thickness than base 136, differentiation in thickness not illustrated. Side 137 and side 138 are not connected, leaving opening 148 opposite side 136, to provide enhanced cooling such as by increasing the effective surface area (allowing circulating blood to pass by the interior surfaces of

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sides 137 and 138 and potentially base 136). Included on each of side 137 and side 138 is a projecting fin, fin 133a and 133b respectively, which increase the surface areas of sides 137 and 138. The surface areas of sides 137 and 138 are sufficiently large (i.e. the combined lengths of sides 137 and 138 is sufficiently long) such that their combined surface area is greater than 60% of the overall total surface area of electrode 130i, preferably greater than 75% of the total. The high percentage of surface area in the circulating blood provides rapid and efficient cooling of electrode 130i.

[0094] Referring specifically to Fig. 6c, electrode 130j, displayed in a side view, is configured to be placed by an operator with base 136 in contact with tissue to be ablated. Electrode 130j includes a rectangular cross-section, not illustrated, with four projecting fins 133a, 133b, 133c and 133d extending from a top surface 149. Top surface 149 and each projecting fin are each positioned in circulating blood when ablation energy, such as RF energy, is being delivered via wires 134 and 135. Electrode 130j is fixedly mounted to distal arm segment 127, as has been described in detail in reference to previous figures. Distal arm segment 127 is sufficiently rigid to allow the operator to apply a force to electrode 130j such that electrode 130j can be pressed into the tissue to be ablated. The thickness of base 136, top surface 149 and projections 133a, 133b, 133c and 133d are chosen to have sufficient mass to effectively deliver energy to tissue without overheating, while minimizing a large thermal mass that would be difficult to cool. In a preferred embodiment, top surface 149 and fins 133a, 133b, 133c, and 133d have a smaller wall thickness than base 136, differentiation in thickness not illustrated. The surface areas of top surface 149 and fins 133a, 133b, 133c and 133d are sufficiently large such that their combined surface area is typically greater than 60% of the overall total surface area of

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electrode 130i, preferably greater than 85% of the total. The high percentage of surface area in the circulating blood provides rapid and efficient cooling of electrode 130j.

[0095] It should be understood that numerous other configurations of the systems, devices and methods described herein may be employed without departing from the spirit or scope of this application. The ablation catheter includes one or more ablation elements such as the electrodes described in reference to Figs. 5a through 5f and Figs. 6a through 6c. These electrodes include various cross-sectional geometries, projecting fins, energy delivering portions and non-energy delivering portions, and other features described in reference to these drawings. It should be appreciated that one or more features described in reference to one specific electrode can be combined with one or more features described in reference to a different electrode, in whole or in part, in any combination, without departing from the spirit and scope of this application. The electrodes can be configured to maximize tissue contact of the energy delivering portion(s), maximize cooling, or both. Clinician preferences, broad patient population requirements, and other treatment goals are likely to require catheters with different performance parameters, as are described in detail throughout this application, to both safely and effectively block an aberrant conductive pathway. The systems, catheters and ablation elements of the present invention are designed to achieve specific depths and widths of lesions, while preventing overheating that may damage more tissue than necessary and/or create dangerous embolus such as blood clots or fragmented tissue. The systems of the present invention are configured to automatically, semi-automatically or manually adjust the energy applied to the ablation elements such as by adjusting one or more of the following: the level or amount of energy delivered; type of energy delivered; drive signal supplied such as

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monopolar and bipolar; phasing, timing or other time derived parameter of the applied energy; and combinations thereof.

[0096] The ablation elements of the present invention are attached to energy delivery conduits that carry the energy to the electrode that is supplied by the interface unit. RF electrodes are connected to wires, preferably in a configuration with individual wires to at least two electrodes to allow independent drive of the electrodes including sequential and simultaneous delivery of energy from multiple electrodes. Alternative or additional energy delivery conduits may be employed, such as fiber optic cables for carrying light energy such as laser energy; tubes that carry cryogenic fluid for cryogenic ablation or saline for saline mediated electrical energy ablation; conduits for carrying sound energy; other energy delivery conduits; and combinations thereof.

[0097] The system includes multiple functional components, such as the ablation catheter, and the interface unit. The interface unit preferably energy supply means and a user interface, as well as calculating means for interpreting data such as mapping data and data received from one or more sensors, as well as means of comparing measured, calculated or otherwise determined values to one or more thresholds. In a preferred embodiment, a low level energy delivery is performed prior to a higher level energy delivery. During or after the low energy delivery, one or more parameters are measured, calculated or otherwise determined that are used to determine a threshold for the second energy delivery, such as a second delivery of energy to the same relative tissue location.

[0098] The interface unit further includes means of adjusting one or more system parameters, such as the amount type, or configuration of energy being delivered, when a particular threshold is met. The ablation catheter includes at least one ablation element

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for delivering energy to tissue such as cardiac tissue. Cardiac tissue applicable for ablation includes left and right atrial walls, as well as other tissues including the septum and ventricular tissue. The ablation catheter of the present invention includes a flexible shaft with a proximal end, a distal end, and a deployable carrier assembly with at least one, and preferably multiple ablation elements. The flexible shafts may include one or more lumens, such as thru lumens or blind lumens. A thru lumen may be configured to allow over-the-wire delivery of the catheter or probe. Alternatively the catheter may include a rapid exchange sidecar at or near its distal end, consisting of a small projection with a guidewire lumen therethrough. A lumen may be used to slidingly receive a control shaft with a carrier assembly on its distal end, the carrier assembly deployable to exit either the distal end or a side hole of the flexible shaft. The advancement of the carrier assembly, such as through a side hole, via controls on the proximal end of the device, allows specific displacement of any functional elements, such as electrodes, mounted on the carrier assembly. Other shafts may be incorporated which act as a rotational linkage as well as shafts that retract, advance or rotate one or more components. A lumen may be used as an inflation lumen, which permits a balloon mounted on a portion of the exterior wall of the flexible shaft to be controllably inflated and deflated. The balloon may be concentric or eccentric with the central axis of the shaft, it may be a perfusion balloon, and may include an in-line pressure sensor to avoid over-pressurizing. A lumen may be used to receive a rotating linkage, such as a linkage used to provide high-speed rotation of an array of ultrasound transducers mounted near the distal end of the linkage. Each device included in a lumen of the flexible shafts may be removable or configured to prevent removal.

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[0099] The ablation catheter of the present invention may include one or more functional elements, such as one or more location elements, sensors, transducers, antennas, or other functional components. Functional elements can be used to deliver energy such as electrodes delivering energy for tissue ablation, cardiac pacing or cardiac defibrillation. Functional elements can be used to sense a parameter such as tissue temperature; cardiac signals or other physiologic parameters; contact with a surface such as the esophageal or atrial walls of a patient; an energy parameter transmitted from another functional element such as amplitude, frequency; phase; direction; or wavelength parameters; and other parameters. In a preferred embodiment of the present invention, the ablation catheter includes multiple functional elements. In another preferred embodiment, the ablation catheter includes a deflectable distal end; such as a deflected end that causes one or more functional elements to make contact with tissue. Deflection means may include one or more of: a pull wire; an expandable cage such as an eccentric cage; an expandable balloon such as an eccentric balloon; an expandable cuff; a deflecting arm such as an arm which exits the flexible catheter shaft in a lateral direction; and a suction port.

[00100] The ablation catheter of the present invention preferably includes a handle on their proximal end. The handle may be attached to an outer sheath, allowing one or more inner shafts or tubes to be controlled with controls integral to the handle such as sliding and rotating knobs that are operable attached to those shafts or tubes. Alternatively, the handle may be attached to a shaft that is slidingly received by an outer sheath, such that an operator can advance and retract the shaft by advancing and retracting the handle and

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holding the sheath in a relatively fixed position. The handle may include one or more attachment ports, such as attachment ports which electrically connect to one or more wires; ports which provide connection to optical fibers providing laser or other light energies; ports which fluidly connect to one or more conduits such as an endoflator for expanding a balloon with saline or a source of cooling fluids; and combinations thereof. Other controls may be integrated into the handle such as deflecting tip controls, buttons that complete a circuit or otherwise initiate an event such as the start of energy delivery to an ablation element. In addition, the handle may include other functional components including but not limited to: transducers such as a sound transducer which is activated to alert an operator of a change is status; a visual alert component such as an LED, a power supply such as a battery; a lock which prevents inadvertent activation of an event such as energy delivery; input and output devices that send and receive signals from the interface unit of the present invention; and combinations thereof.

[0100] The interface unit of the present invention provides energy to the ablation elements of the ablation catheter. In preferred embodiments, one or more ablation elements are electrodes configured to deliver RF energy. Other forms of energy, alternative or in addition to RF, may be delivered, including but not limited to: acoustic energy and ultrasound energy; electromagnetic energy such as electrical, magnetic, microwave and radiofrequency energies; thermal energy such as heat and cryogenic energies; chemical energy; light energy such as infrared and visible light energies; mechanical energy; radiation; and combinations thereof. The ablation elements can deliver energy individually, in combination with or in serial fashion with other ablation elements. The ablation elements can be electrically connected in parallel, in series,

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individually, or combinations thereof. The ablation catheter may include cooling means to prevent undesired tissue damage and/or blood clotting. The ablation elements may be constructed of various materials, such as plates of metal and coils of wire for RF or other electromagnetic energy delivery. The electrodes can take on various shapes including shapes used to focus energy such as a horn shape to focus sound energy, and shapes to assist in cooling such as a geometry providing large surface area. Electrodes can vary within a single carrier assembly, such as a spiral array of electrodes or an umbrella tip configuration wherein electrodes farthest from the central axis of the catheter have the largest major axis. Wires and other flexible energy delivery conduits are attached to the ablation elements, such as electrical energy carrying wires for RF electrodes or ultrasound crystals, fiber optic cables for transmission of light energy, and tubes for cryogenic fluid delivery.

[0101] The ablation elements requiring electrical energy to ablate require wired connections to an electrical energy power source such as an RF power source. In configurations with large numbers of electrodes, individual pairs of wires for each electrode may be bulky and compromise the cross-sectional profile of the ablation catheter. In an alternative embodiment, one or more electrodes are connected in serial fashion such that a reduced number of wires, such as two wires, can be attached to two or more electrodes and switching or multiplexing circuitry are included to individually connect one or more electrodes to the ablative energy source. Switching means may be a thermal switch, such that as a first electrodes heats up, a single pole double throw switch change state disconnecting power from that electrode and attaching power to the next electrode in the serial connection. This integral temperature switch may have a first

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temperature to disconnect the electrode, and a second temperature to reconnect the electrode wherein the second temperature is lower than the first temperature, such as a second temperature below body temperature. In an alternative embodiment, each electrode is constructed of materials in their conductive path such that as when the temperature increased and reached a predetermined threshold, the resistance abruptly decreased to near zero, such that power dissipation, or heat, generated by the electrode was also near zero, and more power could be delivered to the next electrode incorporating the above switching means

[0102] The interface unit of the present invention includes a user interface including components including but not limited to: an ultrasound monitor such as an ultrasound monitor in communication with one or more ultrasound crystals near a temperature sensor of an esophageal probe or ultrasound crystals within an electrode carrier assembly of the ablation catheter; an x-ray monitor such as a fluoroscope monitor used to measure the distance between two or more location elements; other user output components such as lights and audio transducers; input components such as touch screens, buttons and knobs; and combinations thereof. In a preferred embodiment, the interface unit provides functions in addition to providing the energy to the ablation catheter including but not limited to: providing a cardiac mapping function; providing cardiac defibrillation energy and control; providing cardiac pacing energy and control; providing a system diagnostic such as a diagnostic confirming proper device connection; providing the calculating function of the present invention; providing a signal processing function such as interpreting signals received from one or more sensors of a probe, such as an esophageal probe, and/or the ablation catheter; providing drive signals and/or energy to one or more

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functional elements of the ablation catheter; providing a second energy type to the ablation elements of the ablation catheter; and combinations thereof.

[0103] In a preferred embodiment, the interface unit provides an analysis function to determine one or more system parameters that correlate to ablation settings, the parameters including but not limited to: an energy delivery amount; an energy delivery frequency; an energy delivery voltage; an energy delivery current; an *energy delivery temperature; an energy delivery rate; an energy delivery duration; an energy delivery modulation parameter; an energy threshold; another energy delivery parameter; a temperature threshold; an alarm threshold; another alarm parameter; and combinations thereof. The analysis function compares a measured, calculated or otherwise determined function to a threshold value, such as a threshold value settable by an operator of the system. In a preferred embodiment, the interface unit receives temperature information from multiple sensors of the ablation catheter and/or other body inserted devices, and the highest reading received is compared to a temperature threshold such as a temperature threshold determined by the location of tissue being ablated. The analysis function includes one or more algorithms that mathematically process information such as signals received from sensors of the ablation catheter or other device; information entered into the user interface of the interface unit by the operator; embedded electronic information uploaded from the ablation catheter or other device such as information determined during the manufacture of the catheter or device; and combinations thereof. In a preferred embodiment, the ablation setting determined by the analysis function is provided to the operator via a display or other user interface output component.

[0104] The interface unit of the present invention performs one or more

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mathematical functions, signal processing functions; signal transmission functions; and combinations thereof, to determine a system performance (e.g. during ablation) or other system parameter. A calculation may include a function performed by an operator of the system such as a distance value that is entered into the interface unit after a measurement is performed such as a measurement made from an IVUS monitor or a fluoroscopy screen. In a preferred embodiment, energy delivered , such as a maximum cumulative energy, maximum peak energy or maximum average energy is limited by a threshold. In a preferred embodiment, when a temperature reaches a threshold, one or more system parameters are modified. These modifications include but are not limited to: a threshold parameter such as an increased temperature threshold; an alarm or alert parameter such as an audible alarm "on" state; an energy parameter such as a parameter changing energy type or modifying energy delivery such as switching from RF energy to cryogenic energy or stopping energy delivery; a sensor parameter such as a parameter which activates one or more additional sensors; cooling apparatus parameter such as a parameter activating a cooling apparatus; a parameter that changes the polarity of energy delivery or the modulation of energy delivery such as a parameter that switches from monopolar to bipolar delivery or phased monopolar-bipolar to bipolar; and combinations thereof.

[0105] The system of the present invention preferably includes multiple functional elements integral to the ablation catheter and/or other system component. These functional elements may be mounted on the outer wall of the flexible shaft of the device. Alternatively or additionally, one or more functional elements may be mounted to a balloon, such as a perfusion balloon, eccentric balloon or concentric balloon and/or elements may be mounted to a carrier assembly such as a carrier assembly than exits the

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distal end or a side hole of the flexible shaft. These functional elements may be covered with a membrane and multiple elements may be configured in an array such as an array that is rotated within a lumen of the flexible shaft. Functional elements may be placed on the patient's chest, such as EKG electrodes, pacing electrodes or defibrillation electrodes. Functional elements include but are not limited to: sensors such as temperature sensors; transmitters such as energy transmitting electrodes, antennas and electro-magnetic transmitters; imaging transducers; signal transmitters such as drive signal transmitters.

[0106] Functional elements may include sensing functions such a sensor to detect a physiologic parameter. In a preferred embodiment, one or more functional elements are configured as sensors to receive signals that are indicative of one or more cardiac functions of the patient. Sensors may include but are not limited to: an electrical signal sensor such as a cardiac electrode; a temperature sensor such as a thermocouple; an imaging transducer such as an array of ultrasound crystals; a pressure sensor; a pH sensor; a blood sensor, a respiratory sensor; an EEG sensor, a pulse oximetry sensor; a blood glucose sensor; an impedance sensor; a contact sensor; a strain gauge; an acoustic sensor such as a microphone; a photodetector such as an infrared photodetector; and combinations thereof. Functional elements alternatively or additionally include one or more transducers. The transducer may be a location element; a transmitter such as a transmitting antenna, an RF electrode, a sound transmitter; a photodiode, a pacing electrode, a defibrillation electrode, a visible or infrared light emitting diode and a laser diode; a visualization transducer such as an ultrasound crystal; and combinations thereof.

[0107] Numerous kit configurations are also to be considered within the scope of this

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application. An ablation catheter is provided with multiple carrier assemblies. These carrier assemblies can be removed for the tubular body member of the catheter, or may include multiple tubular body members in the kit. The multiple carrier assemblies can have different patterns, different types or amounts of electrodes, and have numerous other configurations including compatibility with different forms of energy. Multiple sensors, such as EKG skin electrodes may be included, such as electrodes that attach to the interface unit of the present invention. A kit may include one or more catheters, such as an ultrasound catheter, which are configured to enter and extend distally in a lumen of the ablation catheter. One or more esophageal probes may be included such as probes with different tip or sensor configurations.

[0108] Though the ablation device has been described in terms of its preferred endocardial and percutaneous method of use, the array may be used on the heart during open-heart surgery, open-chest surgery, or minimally invasive thoracic surgery. Thus, during open-chest surgery, a short catheter or cannula carrying the carrier assembly and its electrodes may be inserted into the heart, such as through the left atrial appendage or an incision in the atrium wall, to apply the electrodes to the tissue to be ablated. Also, the carrier assembly and its electrodes may be applied to the epicardial surface of the atrium or other areas of the heart to detect and/or ablate arrhythmogenic foci from outside the heart.

[0109] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims. In

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addition, where this application has listed the steps of a method or procedure in a specific order, it may be possible, or even expedient in certain circumstances, to change the order in which some steps are performed, and it is intended that the particular steps of the method or procedure claim set forth herebelow not be construed as being order-specific unless such order specificity is expressly stated in the claim.

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We Claim:

1. An ablation system for an operator to treat a patient, said system comprising:

an ablation catheter including at least one ablation element for delivering energy to tissue, said catheter comprising a flexible shaft with a proximal end and a distal end;

and

an interface unit for providing energy to the ablation catheter;

wherein the at least one ablation element is configured to rapidly transition from a first temperature to a second temperature wherein said first temp approaches a tissue ablation temperature and said second temp approaches body temperature.

2. The system of claim 1 wherein the at least one ablation element includes an outer surface and at least 60% of said surface is in contact with the patient's circulating blood when the energy is delivered.

3. The system of claim 1 wherein the at least one ablation element includes an outer surface and at least 75% of said surface is in contact with the patient's circulating blood when the energy is delivered.

4. The system of claim 1 wherein the at least one ablation element includes an outer surface and at least 85% of said surface is in contact with the patient's circulating blood when the energy is delivered.

5. The system of claim 1 wherein the ablation element includes a relatively uniform cross-section along its length.

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6. The system of claim 5 wherein said cross-section has a first portion and a second portion, and wherein the first portion is relatively straight and the second portion is longer than said first portion.

7. The system of claim 6 wherein said cross-section has a triangular shape.

8. The system of claim 7 wherein the first portion comprises a base of the triangle and the second portion comprises the two opposing sides.

9. The system of claim 7 wherein the two opposing sides are not connected.

10. The system of claim 6 wherein said cross-section has a crescent shape.

11. The system of claim 6 wherein the second portion of the cross-section is semicircular.

12. The system of claim 6 wherein the second portion comprises a series of segments selected from the group consisting of: straight segments; curved segments; serpentine segments; zigzag segments; and combinations thereof.

13. The system of claim 6 wherein when the energy is being delivered to the tissue, the first portion of said cross-section is in contact with circulating blood and the second portion of said cross-section is in contact with the patient's tissue.

14. The system of claim 6 wherein the portion of said cross-section in contact with circulating blood when energy is being delivered to the tissue further comprises at least one projecting fin.

15. The system of claim 1 wherein the at least one ablation element causes the patient's blood flow to change from laminar flow to turbulent flow.

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16. The system of claim 1 wherein the at least one ablation element has a mass of less than 0.05 grams.

17. The system of claim 16 wherein said ablation element includes an outer surface and at least 50% of said surface is in contact with the patient's blood when the energy is delivered.

18. The system of claim 1 wherein the first temperature approaches 60° C.

19. The system of claim 1 wherein the ablation element transitions from said first temperature to said second temperature in less than 20 seconds.

20. The system of claim 19 wherein the ablation element transitions from said first temperature to said second temperature in less than 10 seconds.

21. The system of claim 19 wherein the first temperature is approximately 60° C.

22. The system of claim 1 wherein the at least one ablation element subsequently transitions from said second temperature to a third temperature, wherein said third temperature approaches the tissue ablation temperature.

23. The system of claim 22 wherein the at least one ablation element transitions from said second temperature to said third temperature in less than 5 seconds.

24. The system of claim 1 wherein bipolar radiofrequency energy is delivered to the at least one ablation element when said ablation element transitions from the first temperature to the second temperature.

25. The system of claim 1 wherein at least a portion of tissue neighboring the at least one ablation element increases in temperature as said ablation element transitions from the first temperature to the second temperature.

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26. The system of claim 1 wherein zero radiofrequency energy is delivered when the ablation element transitions from the first temperature to the second temperature.

27. The system of claim 26 wherein non-radiofrequency energy is delivered when the ablation element transitions from the first temperature to the second temperature.

28. The system of claim 27 wherein the non-radiofrequency energy delivered is selected from the group consisting of: ultrasound energy; cryogenic energy; and combinations thereof.

29. An ablation system for an operator to treat a patient, said system comprising:

an ablation catheter including at least one ablation element with an external surface area, said ablation element for delivering energy to tissue, and said catheter comprising a flexible shaft with a proximal end and a distal end;

and;

an interface unit for providing energy to the ablation catheter;

wherein a majority of the external surface area of said at least one ablation element is in contact with the tissue when energy is delivered to said tissue.

30. The system of claim 29 wherein the at least one ablation element includes an outer surface and at least 60% of said surface is in contact with the patient's tissue when the energy is delivered.

31. The system of claim 30 wherein at least 70% of said surface is in contact with

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the patient's tissue when the energy is delivered.

32. The system of claim 29 wherein the ablation element includes a relatively uniform cross-section along its length.

33. The system of claim 32 wherein said cross-section has a first portion and a second portion, and wherein the first portion is relatively straight and the second portion is longer than said first portion.

34. The system of claim 33 wherein said cross-section has a triangular shape.

35. The system of claim 34 wherein the first portion comprises a base of the triangle and the second portion comprises the two opposing sides.

36. The system of claim 34 wherein the two opposing sides are not connected.

37. The system of claim 33 wherein said cross-section has a crescent shape.

38. The system of claim 37 wherein the second portion of the cross-section is semicircular.

39. The system of claim 33 wherein the second portion comprises a series of segments selected from the group consisting of: straight segments; curved segments; serpentine segments; zigzag segments; and combinations thereof.

40. The system of claim 33 wherein when the energy is being delivered to the tissue, the second portion of said cross-section is in contact with circulating blood and the first portion of said cross-section is in contact with the patient's tissue.

41. The system of claim 33 wherein the portion of said cross-section in contact

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with circulating blood when energy is being delivered to the tissue further comprises at least one projecting fin.

42. The system of claim 29 wherein said majority of surface area is for minimizing amount of energy to ablate tissue.

43. The system of claim 29 wherein said majority of surface area is for minimizing the amount of energy delivered to the patient's blood.

44. The system of claim 29 further comprising a carrier assembly including the at least one electrode, said carrier assembly configured to maximize engagement with the tissue receiving the energy.

45. An ablation system for an operator to treat a patient with arrhythmia comprising:

a first ablation catheter including at least one ablation element for delivering energy to cardiac tissue, said catheter comprising a flexible shaft with a proximal end and a distal end;

a second ablation catheter including at least one ablation element for delivering energy to cardiac tissue, said catheter comprising a flexible shaft with a proximal end and a distal end;

and;

an interface unit for providing energy to the ablation catheter;

wherein the energy delivered does not exceed a threshold, said threshold set to a different value for said first ablation catheter and said second ablation catheter.

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46. The system of claim 45 wherein the first ablation catheter has a different pattern of ablation elements than the second ablation catheter.

47. The system of claim 45 wherein the first ablation catheter delivers at least one form of energy not delivered by the second ablation catheter.

48. The system of claim 45 wherein the at least one ablation element of the first ablation catheter has a different surface area than the at least one ablation element of the second ablation catheter.

49. The system of claim 45 wherein the at least one ablation element of the first ablation catheter has a different cross-sectional geometry than the at least one ablation element of the second ablation catheter.

50. The system of claim 45 wherein the at least one ablation element of the first ablation catheter has different cooling properties than the at least one ablation element of the second ablation catheter.

51. The system of claim 45 wherein the at least one ablation element of the first ablation catheter has different heating properties than the at least one ablation element of the second ablation catheter.

52. An ablation system for an operator to treat a patient, said system comprising:

an ablation catheter including at least one ablation element for delivering energy to tissue, said catheter comprising a flexible shaft with a proximal end and a distal end;

and;

an interface unit for providing energy to the ablation catheter;

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wherein the energy provided by the interface unit is configured to (1) achieve a target energy level at a target tissue depth; and (2) pulse energy such that the tissue surrounding the electrode does not exceed a threshold temperature.

53. The system of claim 52 wherein the energy delivered is radiofrequency energy.

54. The system of claim 53 wherein bipolar and monopolar energy are delivered.

55. The system of claim 53 wherein the interface unit automatically modifies the duration of one or more of: monopolar energy delivery time; bipolar energy delivery time; and time periods wherein zero energy is delivered.

56. The system of claim 52 wherein the interface unit adjusts an energy delivery parameter based on a value selected from the group consisting of: temperature of tissue; rate of change of temperature of tissue; temperature of the at least one ablation element; rate of change of temperature of the at least one ablation element; EKG; tissue thickness; tissue location; cardiac flow rate; and combinations thereof.

57. The system of claim 56 wherein the energy delivered is electrical energy.

58. The system of claim 57 wherein the energy delivery parameter adjusted is frequency.

59. The system of claim 57 wherein the energy delivery parameter adjusted is monopolar duty cycle.

60. The system of claim 57 wherein the energy delivery parameter adjusted is bipolar duty cycle.

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61. The system of claim 57 wherein the energy delivery parameter adjusted is cumulative amount of energy delivered.

62. The system of claim 52 wherein the threshold is selected to minimize depth of the lesion created by delivering the energy to the tissue.

63. The system of claim 52 wherein the threshold is selected to minimize the width of the lesion created by delivering the energy to the tissue.

64. The system of claim 52 wherein the threshold is selected to minimize both the width and the depth of the lesion created by delivering energy to the tissue.

65. The system of claim 52 wherein the threshold is selected to achieve a desired depth of the lesion created by delivering energy to the tissue.

66. The system of claim 65 wherein said desired depth is dependent on the thickness of the tissue at the ablation location.

67. The system of claim 52 further comprising a temperature sensor configured to provide information regarding said tissue temperature.

68. The system of claim 67 wherein the temperature sensor is placed in a chamber of the heart.

69. The system of claim 67 wherein the temperature sensor is mounted on or near the at least one ablation element.

70. The system of claim 67 wherein the temperature sensor is placed in the esophagus of the patient.

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71. The system of claim 67 further comprising a second temperature sensor configured to provide information regarding said tissue temperature.

72. An ablation system for an operator to treat a patient, said system comprising:

an ablation catheter including at least one ablation element for delivering energy to tissue, said catheter comprising a flexible shaft with a proximal end and a distal end;

and;

an interface unit for providing energy to the ablation catheter;

wherein the interface unit monitors at least one parameter of the system to prevent energy delivered from exceeding a threshold value, said threshold value determined by the at least one ablation element delivering energy.

73. The system of claim 72 wherein the ablation catheter further comprises a second ablation element for delivering energy to tissue.

74. The system of claim 73 wherein the ablation catheter is configured to monitor the temperature of the firs ablation element and the second ablation element.

75. The system of claim 74 wherein the higher of the first ablation element temperature and the second ablation element temperature is said at least one parameter monitored to prevent the energy delivered from exceeding said threshold value.

76. The system of claim 72 Wherein the monitored parameter is selected from the group consisting of: temperature such as temperature from a temperature sensor; a value of measured current; a value of measured voltage; a flow

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measurement value; a force measurement value such as a measurement of strain; a pressure measurement value; and combinations thereof.

77. The system of claim 72 wherein the energy delivery threshold is a peak energy delivered threshold.

78. The system of claim 77 wherein the threshold is 10 Watts.

79. The system of claim 72 wherein the energy delivery threshold is an average energy delivered threshold.

80. The system of claim 79 wherein the threshold is 4 Watts.

81. The system of claim 72 wherein the energy delivery threshold is a cumulative energy delivered threshold.

82. The system of claim 81 wherein the threshold is 500 Watt-seconds.

83. The system of claim 81 wherein the threshold is 300 Watt-seconds.

84. The system of claim 72 further comprising a threshold comparator configured to compare a determined value to a threshold.

85. The system of claim 84 wherein said determined value represents an instantaneous amount of energy delivered to tissue.

86. The system of claim 84 wherein said determined value represents an integration of the amount of energy delivered to tissue.

87. The system of claim 86 wherein the determined value can be reset.

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88. The system of claim 87 wherein the determined value is reset each time energy delivered to the at least one ablation element is switched from off to on states.

89. The system of claim 87 wherein the determined value is reset each time the at least one ablation element is repositioned by the operator.

90. The system of claim 84 wherein said determined value represents an average of the amount of energy delivered to tissue.

91. The system of claim 84 wherein the threshold comparator is further configured to compared a second determined value to a second threshold.

92. The system of claim 72 wherein said threshold value changes over time.

93. The system of claim 72 wherein said system is configured to deliver a first energy level followed by a second energy level, said first energy level of lesser magnitude than said second energy level.

94. The system of claim 94 wherein said threshold is modified after said first energy level is delivered.

95. The system of claim 1 or 29 or 45 or 52 or 72 wherein the patient is a human being.

96. The system of claim 1 or 29 or 45 or 52 or 72 wherein the ablation catheter further comprises a deployable carrier assembly fixedly attached to a control shaft, said carrier assembly including at least one ablation element.

97. The system of claim 96 wherein the carrier assembly is flexible.

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98. The system of claim 97 wherein the carrier assembly is configured to conform with an endocardial surface of the heart.

99. The system of claim 96 wherein the ablation catheter further comprises a handle on its proximal end, said handle including means of deploying the catheter assembly.

100. The system of claim 96 wherein the carrier assembly is configured in an umbrella geometry.

101. The system of claim 96 wherein the carrier assembly is configured in a spiral geometry.

102. The system of claim 1 or 29 or 45 or 52 or 72 wherein the ablation catheter further comprises an integral functional element is selected from the group consisting of: a sensor; a transmitter; an imaging element; and combinations thereof.

103. The system of claim 102 wherein the functional element is a sensor selected from the group consisting of: an electrical signal sensor such as a cardiac electrode; a temperature sensor such as a thermocouple; an imaging transducer such as an array of ultrasound crystals; a pressure sensor; a pH sensor; a physiologic sensor such as a blood sensor; a respiratory sensor; an EEG sensor; a pulse oximetry sensor; a blood glucose sensor; an impedance sensor; a contact sensor; a strain gauge; an acoustic sensor; and combinations thereof.

104. The system of claim 1 or 29 or 45 or 52 or 72 wherein the at least one ablation element is an electrode.

105. The system of claim 104 wherein said electrode is constructed of materials

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selected from the group consisting of: platinum; iridium; gold; and combinations thereof.

106. The system of claim 1 or 29 or 45 or 52 or 72 wherein the at least one ablation element comprises a thermally conductive energy delivery portion and a thermally conductive non-energy delivery portion.

107. The system of claim 106 wherein the energy deliver portion is electrically conductive and the non-energy delivery portion is not electrically conductive.

108. The system of claim 106 wherein energy delivery portion and the non-energy delivery portion are separated by an insulator.

109. The system of claim 106 wherein the energy delivery portion includes a temperature sensor.

110. The system of claim 106 wherein the non-energy delivery portion includes a temperature sensor.

111. The system of claim 1 or 29 or 45 or 52 or 72 wherein the at least one ablation element has a surface area less than 2.5 mm^2.

112. The system of claim 111 wherein the at least one ablation element is configured to ablate tissue when energized with less than 10 watts of energy.

113. The system of claim 111 wherein the at least one ablation element is configured to ablate tissue when energized with less than 5 watts of energy.

114. The system of claim 111 wherein the at least one ablation element has a surface area less than 0.75 mm^2.

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115. The system of claim 114 wherein the at least one ablation element is configured to ablate tissue when energized with less than 10 watts of energy.

116. The system of claim 114 wherein the at least one ablation element is configured to ablate tissue when energized with less than 5 watts of energy.

117. The system of claim 1 or 29 or 45 or 52 or 72 wherein the at least one ablation element has a mass of less than 0.05 grams.

118. The system of claim 117 wherein the at least one ablation element is configured to ablate tissue when energized with less than 10 watts of energy.

119. The system of claim 117 wherein the at least one ablation element is configured to ablate tissue when energized with less than 5 watts of energy.

120. The system of claim 1 or 29 or 45 or 52 or 72 wherein the at least one ablation element has a volume of less than 3.0 mm^3.

121. The system of claim 120 wherein the at least one ablation element is configured to ablate tissue when energized with less than 10 watts of energy.

122. The system of claim 120 wherein the at least one ablation element is configured to ablate tissue when energized with less than 5 watts of energy.

123. The system of claim 1 or 29 or 45 or 52 or 72 wherein the at least one ablation element comprises a thermally conductive portion configured to reside in or near circulating blood during the delivering of energy to tissue.

124. The system of claim 123 wherein said at least one ablation element has a majority of its surface area in contact with circulating blood during the delivery of energy to tissue.

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125. The system of claim 123 wherein said thermally conductive portion comprises a projecting fin.

126. The system of claim 125 wherein the projecting fin is electrically isolated from the remainder of the at least one ablation element.

127. The system of claim 123 wherein said thermally conductive portion comprises multiple projecting fins.

128. The system of claim 123 wherein said thermally conductive portion is configured to modify blood flow during the delivery of energy to tissue.

129. The system of claim 128 wherein said thermally conductive portion is configured to change non-turbulent blood flow to turbulent blood flow.

130. The system of claim 129 wherein a majority of said thermally conductive portion does not deliver energy.

131. The system of claim 1 or 29 or 45 or 52 or 72 wherein the ablation catheter further comprises two or more ablation elements.

132. The system of claim 131 wherein the ablation catheter includes a first energy delivery conduit and a second energy delivery conduit, each energy delivery conduit configured to independently deliver energy to a first ablation element and a second ablation element.

133. The system of claim 132 wherein the ablation catheter includes at least three ablation elements, and at least two ablation elements receive energy from the first energy delivery conduit.

134. The system of claim 131 wherein a first ablation element has a different

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cross-sectional profile than a second ablation element.

135. The system of claim 131 wherein a first ablation element has a larger surface area contacting tissue during energy delivery than a second ablation element.

136. The system of claim 131 wherein a first ablation element has a larger percentage of its overall surface area in contact with tissue during energy delivery than a second ablation element.

137. The system of claim 1 or 29 or 45 or 52 or 72 wherein the at least one ablation element includes a temperature sensor.

138. The system of claim 137 wherein the temperature sensor is a thermocouple.

139. The system of claim 1 or 29 or 45 or 52 or 72 wherein the ablation catheter is configured to deliver multiple forms of energy.

140. The system of claim 139 wherein the at least one ablation element comprises an electrode and an ultrasound crystal.

141. The system of claim 139 wherein the catheter is configured to deliver a first energy that causes tissue to increase in temperature and a second energy that causes tissue to decrease in temperature.

142. The system of claim 1 or 29 or 45 or 52 or 72 wherein the ablation catheter includes an energy delivery conduit which transmits the energy to the at least one ablation element.

143. The system of claim 142 wherein the energy delivery conduit is a wire.

144. The system of claim 142 wherein the energy delivery conduit is a fiber optic

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cable.

145. The system of claim 144 wherein the energy delivered is laser energy.

146. The system of claim 142 wherein the energy delivery conduit is a hollow tube.

147. The system of claim 145 wherein the hollow tube is configured to carry a flowing fluid during the delivery of energy to tissue.

148. The system of claim 147 wherein the fluid is nitrogen.

149. The system of claim 147 wherein the fluid is saline and the energy delivered is electrical energy.

150. The system of claim 142 wherein the ablation catheter further comprises a second energy delivery conduit, said second energy delivery conduit transmitting energy to said at least one ablation element.

151. The system of claim 150 wherein the second energy delivery conduit transmits a different form of energy than the first energy delivery conduit.

152. The system of claim 1 or 29 or 45 or 52 or 72 wherein the delivered energy is selected from the group consisting of: sound energy such as acoustic energy and ultrasound energy; electromagnetic energy such as electrical, magnetic, microwave and radiofrequency energies; thermal energy such as heat and cryogenic energies; chemical energy; light energy such as infrared and visible light energies; mechanical energy; radiation; and combinations thereof.

153. The system of claim 152 wherein multiple forms of energy are delivered.

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154. The system of claim 152 wherein radiofrequency and ultrasound energy are delivered.

155. The system of claim 152 wherein radiofrequency energy is delivered.

156. The system of claim 155 wherein monopolar and bipolar radiofrequency energy are delivered.

157. The system of claim 156 wherein monopolar and bipolar energy are delivered sequentially.

158. The system of claim 156 wherein the power delivered to the at least one ablation element is less than ten watts.

159. The system of claim 1 or 29 or 45 or 52 or 72 wherein the tissue is cardiac tissue.

160. The system of claim 1 or 29 or 45 or 52 or 72 wherein the tissue is selected from the group consisting of: prostate; brain; gall bladder; uterus; tumor; and combinations thereof.

161. The system of claim 1 or 29 or 45 or 52 or 72 wherein the ablation catheter further comprises a second ablation element and the interface unit provides and directs energy to the first ablation element and the second ablation element independently.

162. The system of claim 161 wherein the interface unit provides energy to the first ablation element and the second ablation element simultaneously or sequentially.

163. The system of claim 1 or 29 or 45 or 52 or 72 wherein the interface unit is

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configured to provide information relating to the temperature of the at least one ablation element.

164. The system of claim 163 wherein the information is rate of cooling information.

165. The system of claim 1 or 29 or 45 or 52 or 72 wherein the interface unit is configured to compare the temperature of the at least one ablation element to a threshold.

166. The system of claim 165 wherein the threshold is calculated by the system.

167. The system of claim 165 wherein the threshold is adjustable by the operator.

168. The system of claim 165 wherein an ablation parameter is modified when said threshold is reached.

169. The system of claim 168 wherein the ablation parameter results in a modification to the energy delivered to the at least one ablation element.

170. The system of claim 168 wherein the ablation parameter results in the activation of an alarm.

171. The system of claim 1 or 29 or 45 or 52 or 72 further comprising a thermal monitoring circuit.

172. The system of claim 171 wherein the thermal monitoring circuit includes a thermal sensor on or near the at least one ablation element.

173. The system of claim 171 wherein the thermal sensor is integral to the at least one ablation element.

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174. The system of claim 171 wherein the thermal sensor is mounted to a distal portion of the ablation catheter at a location remote from the at least one ablation element.

175. The system of claim 174 wherein the ablation catheter further comprises a second ablation element and the thermal sensor is in between said first ablation element and said second ablation element.

176. The system of claim 171 wherein the thermal sensor provides a temperature information signal to the interface unit.

177. The system of claim 171 wherein the thermal monitoring circuit comprises multiple thermal sensors.

178. An ablation catheter device, comprising:

(a) an elongated, flexible, tubular body member having a proximal end, a distal end and a lumen extending therebetween;

(b) a control shaft coaxially disposed and slidingly received within the lumen of the tubular body member;

and;

(c) a flexible carrier assembly which includes at least two arms, each arm including at least one ablation element used to deliver energy to tissue;

wherein each ablation element includes a relatively uniform triangle shaped cross-section along its length.

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179. The device of claim 178 wherein the triangular cross-section comprises a continuous path.

180. The device of claim 178 wherein the triangular cross-section comprises a discontinuous path.

181. The device of claim 180 wherein the discontinuity is at the junction of two sides of the triangular cross-section.

182. The device of claim 178 wherein retraction of the control shaft causes the carrier assembly to be constrained within the lumen of the tubular body member;

and;

wherein advancement of the control shaft causes the carrier assembly to extend beyond the distal end of the tubular body member.

183. The device of claim 178 wherein retraction of the control shaft causes the distal end of the carrier assembly to enter the lumen of the tubular body member prior to the mid-point of the carrier assembly to enter said lumen.

184. The device of claim 178 wherein retraction of the control shaft causes the mid-point of the carrier assembly to enter the lumen of the tubular body member prior to the distal end of the carrier assembly entering said lumen.

185. The device of claim 178 wherein the carrier assembly includes three arms, and each ablation element triangle shaped cross-section includes two sides defining an angle of approximately 120 degrees.

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186. The device of claim 178 wherein the carrier assembly includes four arms, and each ablation element triangle shaped cross-section includes two sides defining an angle of approximately 90 degrees.

187. The device of claim 178 wherein the carrier assembly includes five arms, and each ablation element triangle shaped cross-section includes two sides defining an angle of approximately 75 degrees.

188. The device of claim 178 wherein the carrier assembly includes three or more arms, and each ablation element triangle shaped cross-section includes two sides defining an angle of x degrees, wherein x is approximately 360 divided by the number of arms.

189. A method of using any of the systems or devices of claims 1 through 188.

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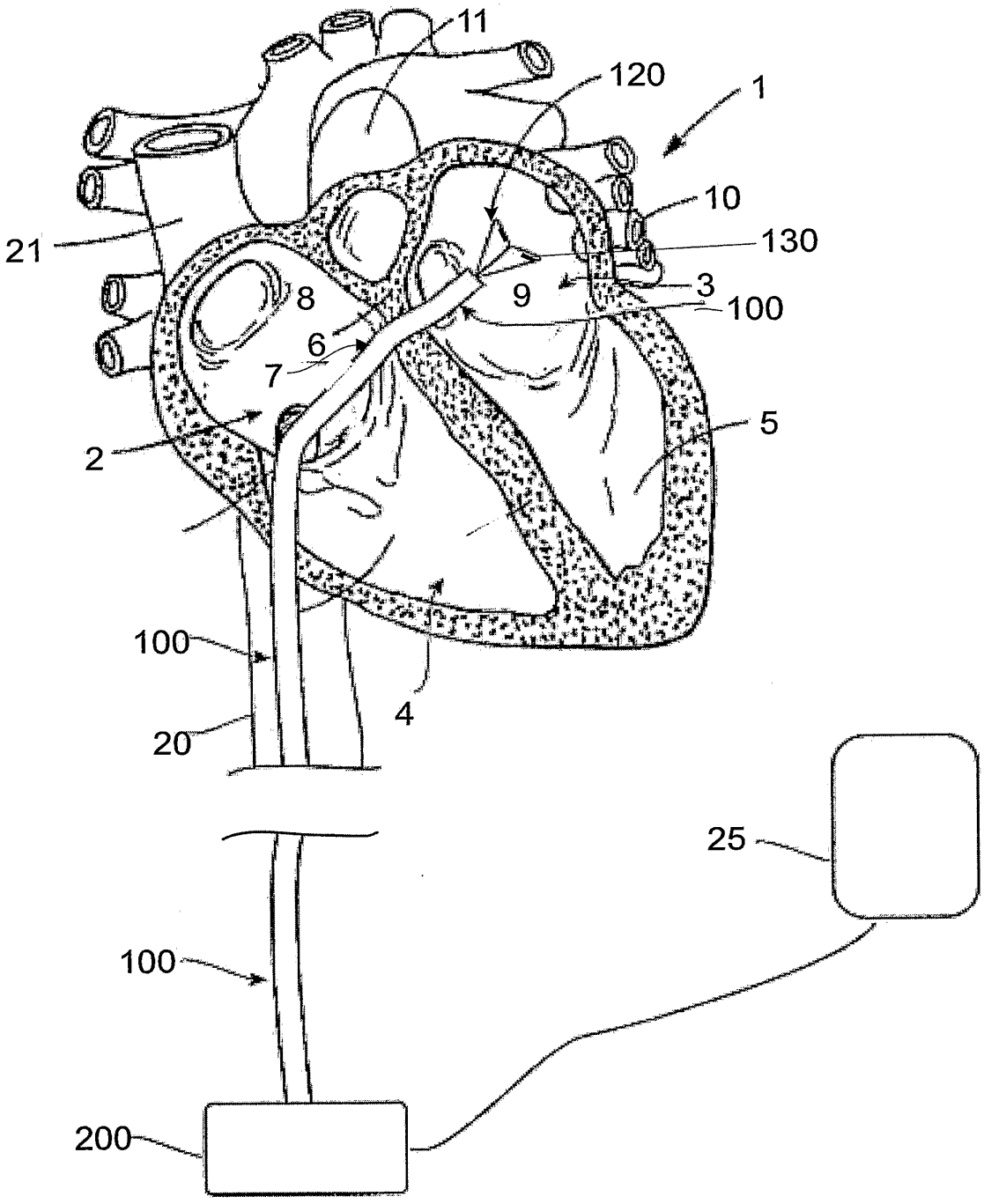


Figure 1

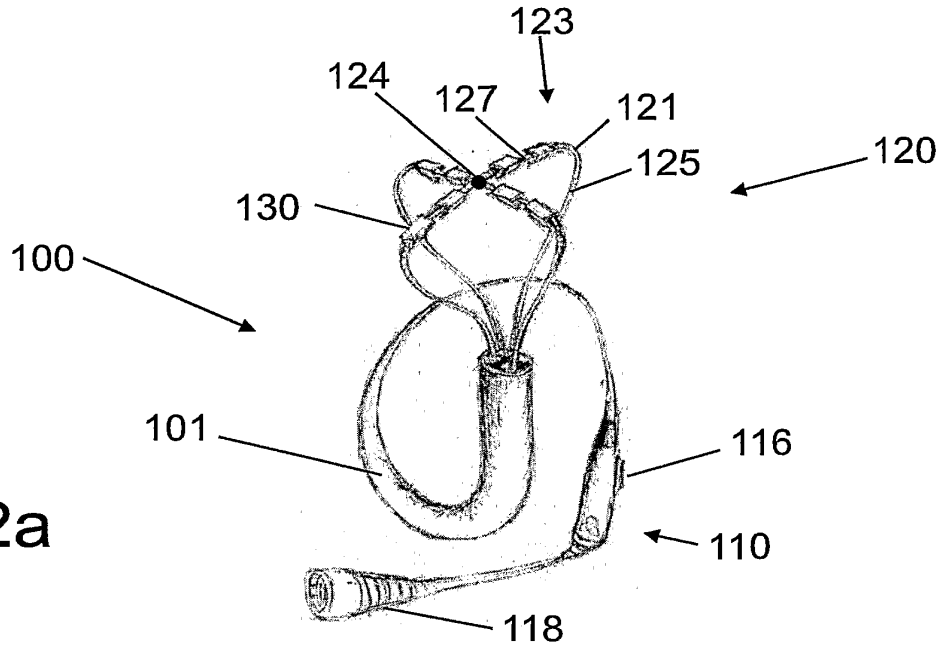


Figure 2a

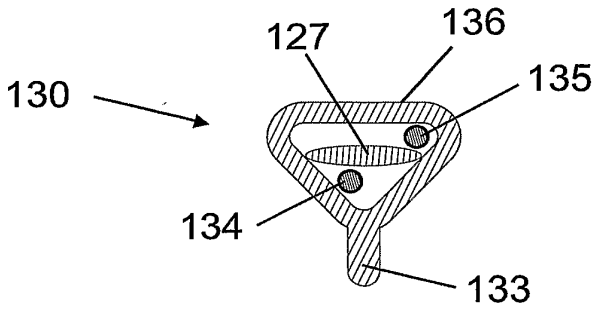


Figure 2b

Figure 3a

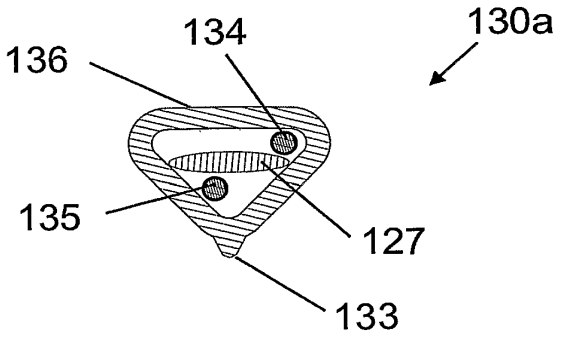


Figure 3b

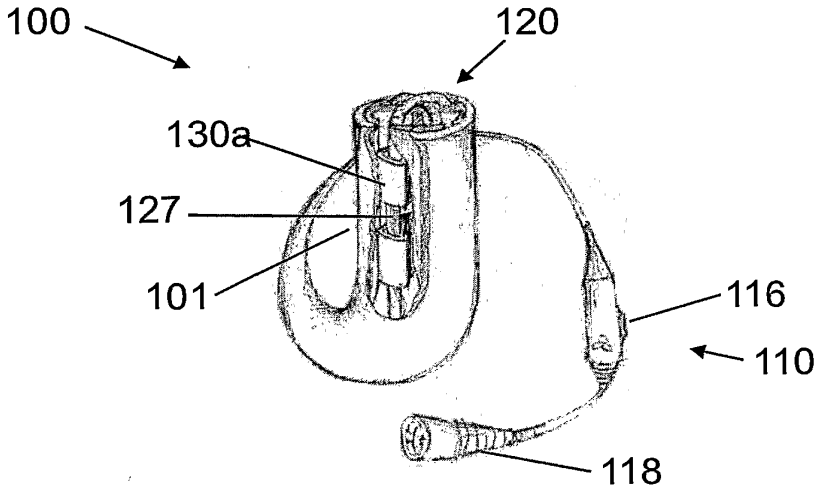
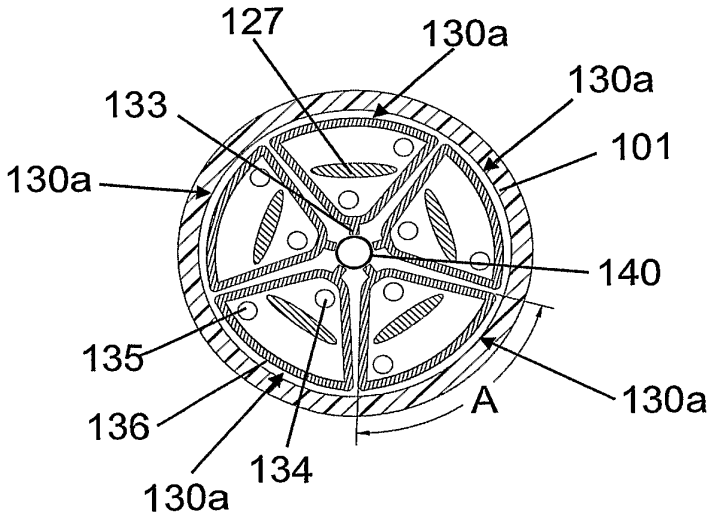


Figure 3c



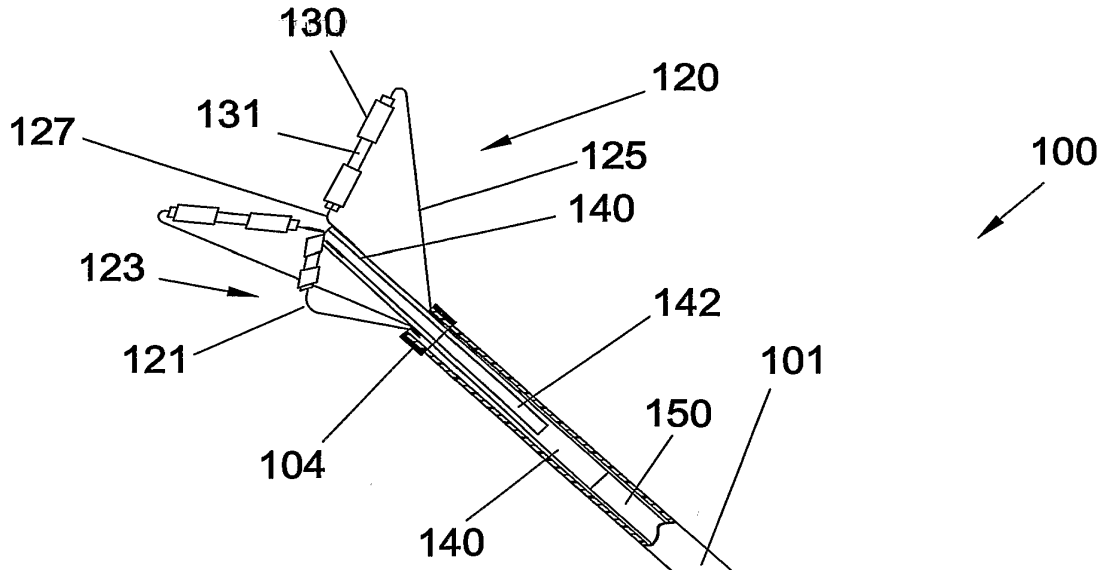
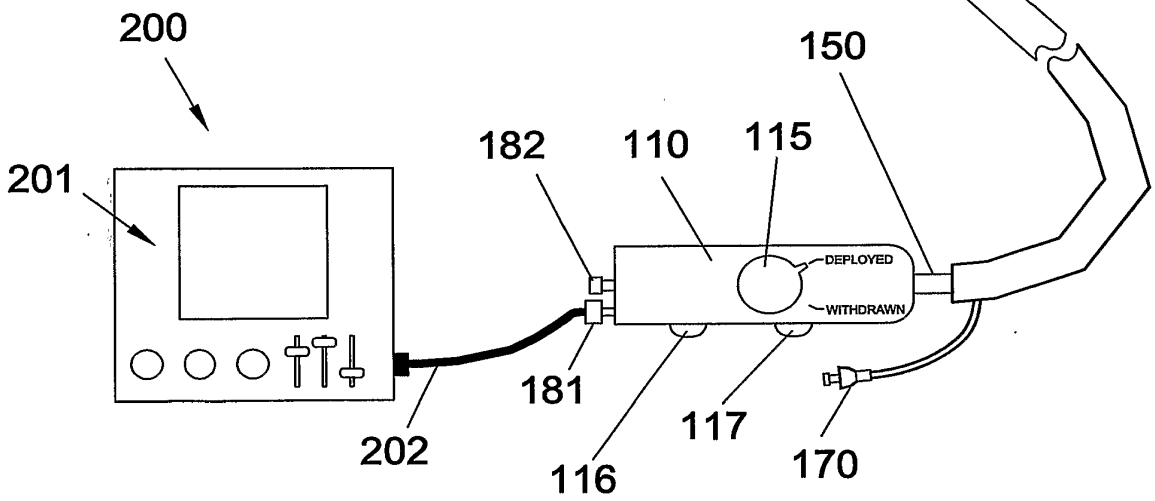

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Fig. 4


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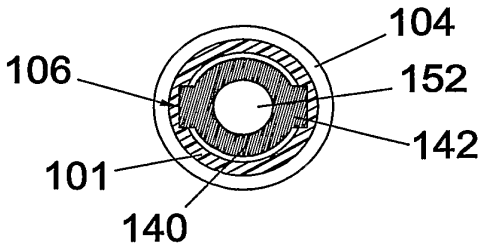

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Fig. 4a

Fig. 5a

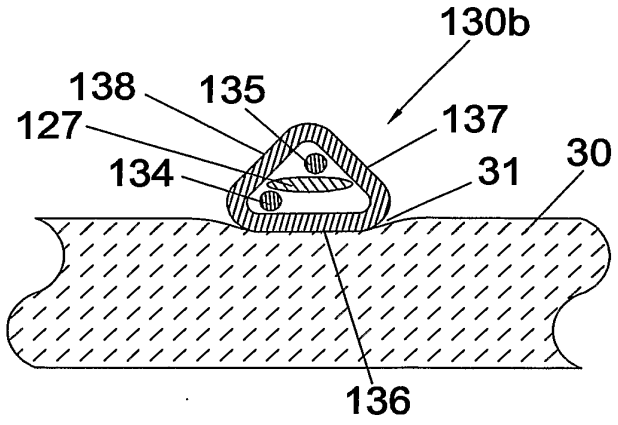


Fig. 5b

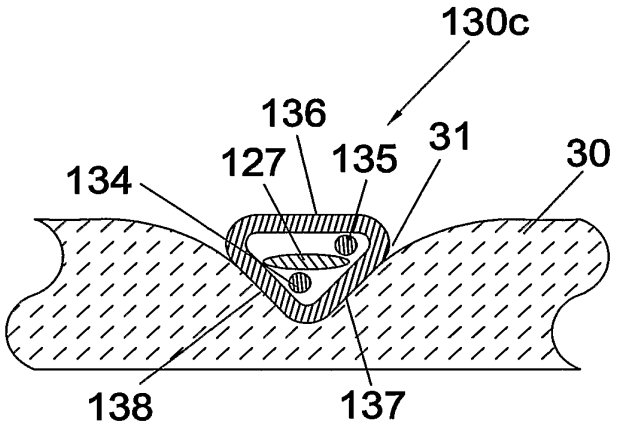


Fig. 5c

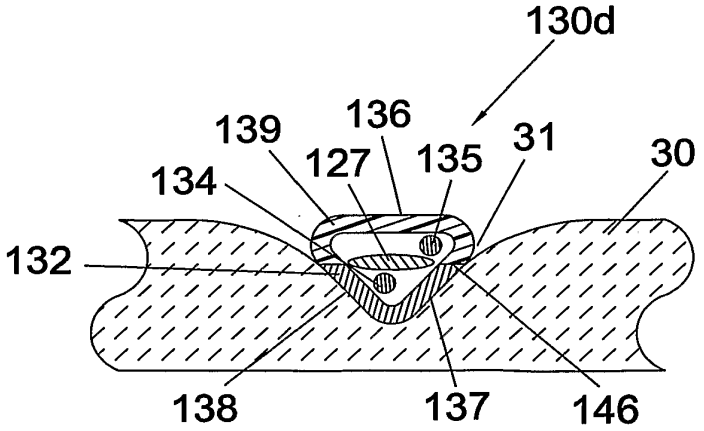


Fig. 5d

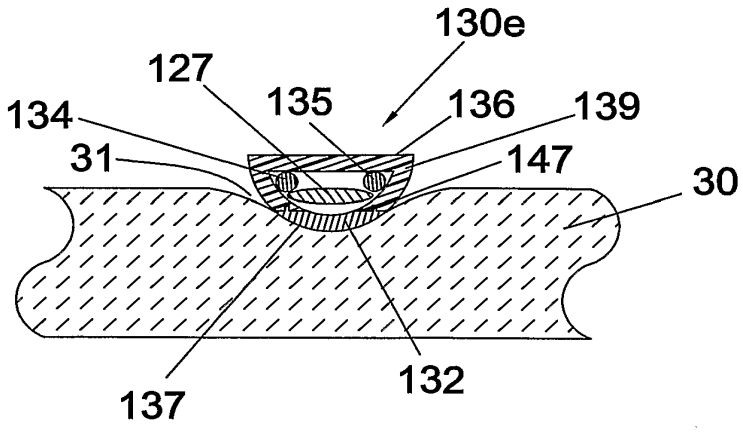


Fig. 5e

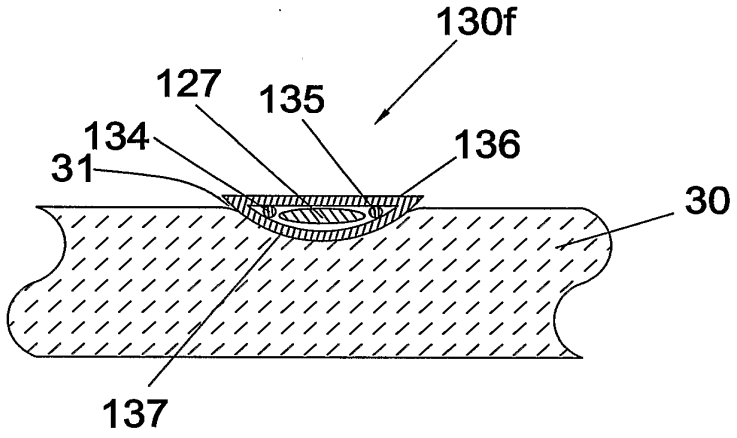


Fig. 5f

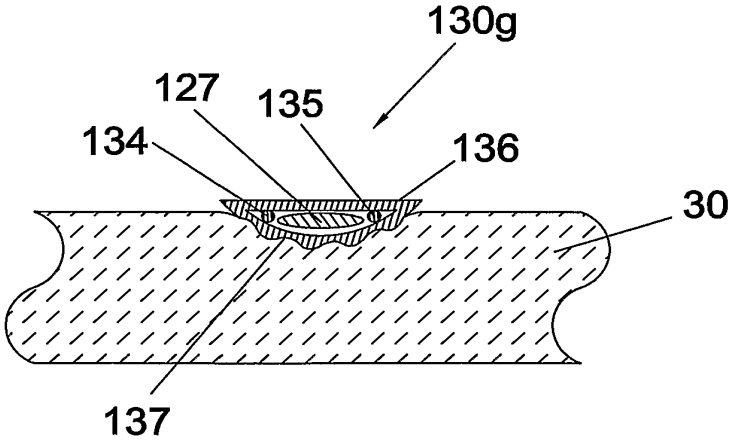


Fig. 6a

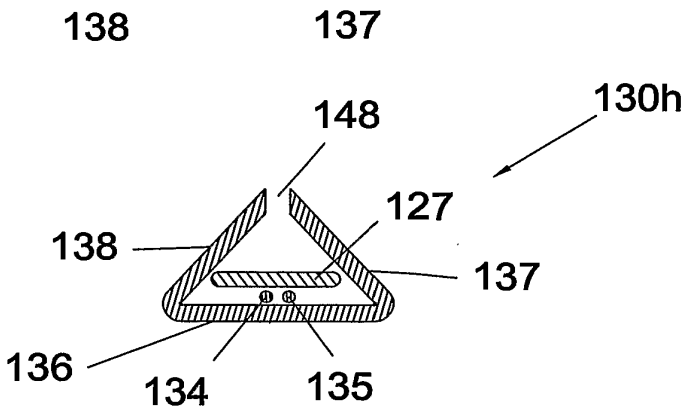


Fig. 6b

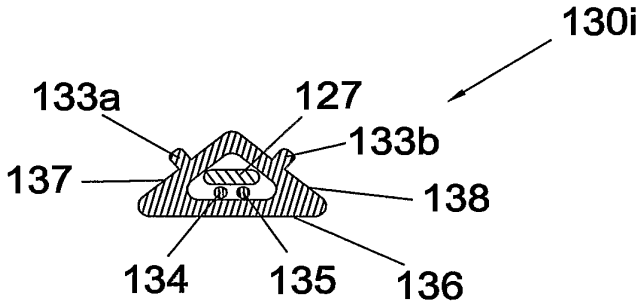
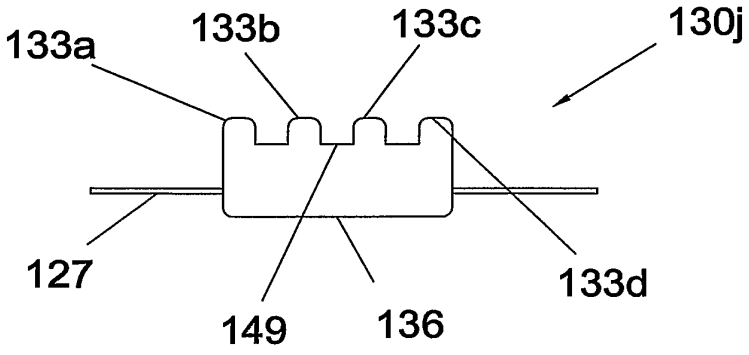


Fig. 6c



PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
1205338001WO00		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2016/032132	12 May 2016 (12-05-2016)	12 May 2015 (12-05-2015)
Applicant		
NATIONAL UNIVERSITY OF IRELAND, GALWAY		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 8 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [X] **Certain claims were found unsearchable** (See Box No. II)

3. [X] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      [X] as suggested by the applicant
      [ ] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 45-93, 98-102
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/032132

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/32 A61N1/18 A61B18/00 A61B18/02 A61B18/18
A61N1/36 A61N1/05 A61B18/04
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/031341 A1 (DIMAURO THOMAS M [US] ET AL) 8 February 2007 (2007-02-08) abstract; figures 1-12C paragraphs [0028] - [0163]	1-3,6-8, 103
X	US 2012/323214 A1 (SHANTHA TOTADA R [US]) 20 December 2012 (2012-12-20) abstract; figures 1-26 paragraphs [0059] - [0458]	1-9,103
X	WO 2015/013252 A1 (WEDGE THERAPEUTICS LLC [US]) 29 January 2015 (2015-01-29) abstract; figures 1-30 pages 3-44	1-9,103

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 November 2016	14/11/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Lins, Stephanie

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Form PCT/ISA/210 (second sheet) (April 2005)

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IPR2025-01125

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/032132

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/078377 A1 (GONZALES DONALD A [US] ET AL) 29 March 2012 (2012-03-29) abstract; figures 1-31B paragraphs [0016] - [0298]	1-8,103
X	US 2014/114233 A1 (DEEM MARK E [US] ET AL) 24 April 2014 (2014-04-24) abstract; figures 1-32 paragraphs [0059] - [0141]	26
X	US 2005/288730 A1 (DEEM MARK [US] ET AL) 29 December 2005 (2005-12-29) abstract; figures 1-22 paragraphs [0077] - [0144]	10,12, 15,16, 18-29, 37,39,40
X	US 2007/129760 A1 (DEMARAIS DENISE [US] ET AL) 7 June 2007 (2007-06-07) abstract; figures 1-10 paragraphs [0021] - [0074]	13,14, 19, 23-26, 30-33, 36-40
X	US 2014/025069 A1 (WILLARD MARTIN R [US] ET AL) 23 January 2014 (2014-01-23) abstract; figures 1-9 paragraphs [0026] - [0098]	26,34,35
X	US 2010/204560 A1 (SALAHIEH AMR [US] ET AL) 12 August 2010 (2010-08-12) abstract; figures 1-40 paragraphs [0074] - [0222]	17
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X	US 2015/018818 A1 (WILLARD MARTIN R [US] ET AL) 15 January 2015 (2015-01-15) abstract; figures 1-7 paragraphs [0019] - [0100]	94-97
X	US 2013/165916 A1 (MATHUR PRABODH [US] ET AL) 27 June 2013 (2013-06-27) abstract; figures 1-49 paragraphs [0286] - [0462]	94-97

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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2016/032132

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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Aerin Medical Inc. v. Neurent Medical Ltd.
IPR2025-01125

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IPR2025-01125

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2016/032132

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-9, 103

   Device for chemical neuromodulation in a nasal region.

   ---

2. claims: 10, 12-40

   Therapeutic assembly with RF electrodes and expandable structure

   ---

3. claims: 11, 41-44

   System for neural mapping and neuromodulation

   ---

4. claims: 94-97

   Device for therapeutic neuromodulation with flexible support.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2016/032132	12.05.2016	12.05.2015

International Patent Classification (IPC) or both national classification and IPC
INV. A61N1/32 A61N1/18 A61B18/00 A61B18/02 A61B18/18 A61N1/36 A61N1/05 A61B18/04

Applicant
NATIONAL UNIVERSITY OF IRELAND, GALWAY

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Lins, Stephanie Telephone No. +49 89 2399-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 45-93, 98-102

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 45-93, 98-102

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☒ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-103

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	19, 23-25, 37, 39, 40
	No:	Claims	1-18, 20-22, 26-36, 38, 41-44, 94-97, 103
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-44, 94-97, 103
Industrial applicability (IA)	Yes:	Claims	1-44, 94-97, 103
	No:	Claims	

2. Citations and explanations

   see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Aerin Exhibit 1011, Page 2028 of 2183
Aerin Medical Inc. v. Neurent Medical Ltd.
IPR2025-01125

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 45 to 89, 90 to 93 and 98 to 102 relate to a subject-matter mentioned in Rule 39.1 (iv) PCT and in Rule 67.1 (iv) PCT, in particular to a method of treatment of the human body by therapy.

The subject-matter of claims 45 to 89, 90 to 93 and 98 to 102 defines a method of therapeutically modulating nerves in a nasal region of a human patient. The method comprises the step of applying energy, with a therapeutic assembly, to the target site to therapeutically modulate nerves to therapeutically modulate autonomic activity. Therefore the subject-matter of these claims defines a method of treatment of the human body by therapy.

Under terms of Art.17(2)(a)(i) an International Search Authority is not required to carry out a search of such claims.

Furthermore, under terms of Art.34(4)(a)(i) an International Preliminary Examining Authority is not required to carry out examination of such claims.

Re Item IV

Lack of unity of invention

The application does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

1 This Authority considers that there are 4 inventions covered by the claims. The separate groups of inventions are as follows:

I: Claims : 1-9, 103

II: Claims : 10, 12-40

III: Claims : 11, 41-44

IV: Claims : 94-97

2 The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 and 13.2 PCT, are as follows:

Aerin Exhibit 1011, Page 2029 of 2183
Aerin Medical Inc. v. Neurent Medical Ltd.
IPR2025-01125

The features common to all independent apparatus claims 1, 26, 41, 94 and 103 are:

a flexible shaft configured to locate the distal portion at a target site within the nasal region.

Such a device is known from document US2007031341 (fig.2C, par.[0062]).

Since the technical feature in common to all independent apparatus claims is known, there is no common contribution over the cited prior art. Therefore, claims 1, 26, 41, 94 and 103 can not define a common inventive concept as required by Rules 13.1 and 13.2 PCT, therefore the requirement of unity of the invention is not fulfilled.

3 The following technical features of the independent apparatus claims make a contribution over this prior art and can be considered as special technical features within the meaning of Rule 13.2 PCT:

Group I: No further contribution over the prior art.

Group II: Therapeutic assembly transformable between a low-profile delivery state and an expanded state, including electrodes to apply RF energy.

Group III: Plurality of sensing electrodes at the distal portion of the shaft

Group IV: Flexible support at the distal portion of the shaft.

These features are obviously not the same.

4 The problem solved by theses special technical features can therefore be construed as:

Group I: No further problem solved.

Group II: To facilitate delivery of the therapeutic assembly through narrow passageways.

Group III: Allow the mapping and detection of the nerve location.

Group IV: Allow the shaft to conform to irregularities of local anatomy at the target site.

This shows lack of corresponding effects as well.

5 Consequently neither the objective problem underlying the subject of the claimed inventions, nor their solutions defined by the special technical features allow for a relationship to be established between the said inventions, which involves a single general inventive concept.

The application, hence does not meet the requirement of unity of invention as defined in Rules 13.1. and 13.2 PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 US 2007/031341 A1 (DIMAURO THOMAS M [US] ET AL) 8 February 2007 (2007-02-08)

D2 US 2012/323214 A1 (SHANTHA TOTADA R [US]) 20 December 2012 (2012-12-20)

D3 WO 2015/013252 A1 (WEDGE THERAPEUTICS LLC [US]) 29 January 2015 (2015-01-29)

D4 US 2012/078377 A1 (GONZALES DONALD A [US] ET AL) 29 March 2012 (2012-03-29)

D5 US 2014/114233 A1 (DEEM MARK E [US] ET AL) 24 April 2014 (2014-04-24)

D6 US 2005/288730 A1 (DEEM MARK [US] ET AL) 29 December 2005 (2005-12-29)

D7 US 2007/129760 A1 (DEMARAIS DENISE [US] ET AL) 7 June 2007 (2007-06-07)

D8 US 2014/025069 A1 (WILLARD MARTIN R [US] ET AL) 23 January 2014 (2014-01-23)

D9 US 2010/204560 A1 (SALAHIEH AMR [US] ET AL) 12 August 2010 (2010-08-12)

D10 US 2015/066006 A1 (SRIVASTAVA NISHANT R [US]) 5 March 2015 (2015-03-05)

D11 US 2015/018818 A1 (WILLARD MARTIN R [US] ET AL) 15 January 2015 (2015-01-15)

D12 US 2013/165916 A1 (MATHUR PRABODH [US] ET AL) 27 June 2013 (2013-06-27)

FIRST INVENTION

6 INDEPENDENT CLAIMS 1 AND 103

6.1 The definition of "*an energy delivery element configured to therapeutically modulate parasympathetic nerves that innervate mucosa"* of present claims 1 and 103 is considered to be unclear and therefore does not meet the requirements of Article 6 PCT. The subject-matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result (e.g. waveform, type of stimulation, etc.). In terms of technical features, the above lines merely define an energy delivery element as such.

6.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 103 is not new in the sense of Article 33(2) PCT.

6.2.1 The document D1 discloses (the references in parentheses applying to this document):

A system (fig.2C, abstract) for therapeutic neuromodulation in a nasal region of a human patient, the system comprising:
a shaft (fig.2C, par.[0062]) having a proximal portion and a distal portion, wherein the shaft is configured to locate the distal portion intraluminally at a target site inferior to a sphenopalatine foramen of the human patient; and
a therapeutic assembly (fig.2C, par.[0062]) at the distal portion of the

shaft, wherein the therapeutic assembly comprises an energy delivery element configured to therapeutically modulate (par.[0162]) postganglionic parasympathetic nerves innervating nasal mucosa at microforamina of a palatine bone of the human patient.

Therefore the subject-matter of claim 1 is not new.

6.2.2 The document D1 discloses (the references in parentheses applying to this document):

A system (fig.2C, abstract) for therapeutic neuromodulation in a nasal region of a human patient for treatment of chronic sinusitis, the system comprising:
a shaft (fig.2C, par.[0062]) having a proximal portion and a distal portion, wherein the shaft is configured to locate the distal portion intraluminally at a target site, wherein the target site is at least proximate to an ostium of at least one of a frontal sinus, an ethmoidal sinus, a sphenoidal sinus, or a maxillary sinus of the human patient; and
a therapeutic assembly (fig.2C, par.[0062]) at the distal portion of the shaft, wherein the therapeutic assembly is comprises an energy delivery element configured to therapeutically modulate (par.[0162]) parasympathetic nerves that innervate mucosa of at least one of the frontal sinus, the ethmoidal sinus, the sphenoidal sinus, or the maxillary sinus.

Therefore the subject-matter of claim 103 is not new.

6.2.3 Furthermore, the subject-matter of claims 1 and 103 is also not new compared to each of the following documents:

D2: abstract, fig.9, par.[0177], par.[0178].

D3: abstract, fig.2, fig.28, par.[0111].

D4: abstract, fig.1A, fig.2A, par.[0275]-[0281].

7 DEPENDENT CLAIMS 2-9

Dependent claims 2 to 9 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty Article 33(2) PCT and/or inventive step Article 33(3) PCT.

7.1 The additional features being disclosed as follows:

Aerin Exhibit 1011, Page 2033 of 2183
Aerin Medical Inc. v. Neurent Medical Ltd.
IPR2025-01125

Claim 2:	D4: par.[0088].
Claim 3:	D1: abstract, par.[0162].
Claims 4, 5:	D2: par.[0179], fig.9 (529).
Claim 6:	D2: fig.7, metal being considered an obvious choice of material, cf. D4 par. [0266]
Claims 7, 8:	D4: fig.11F, fig.14E, 14F.
Claim 9:	D2: Fig.7, par.[0089].

SECOND INVENTION

8 INDEPENDENT CLAIM 26

8.1 The definition of "*radiofrequency (RF) energy applied to the target site to therapeutically modulate parasympathetic nerves proximate to the target site*" of present claim 26 is considered to be unclear and therefore does not meet the requirements of Article 6 PCT. The subject-matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result (e.g. waveform, type of stimulation, etc.). In terms of technical features, the above lines merely define an energy delivery element as such.

8.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 26 is not new in the sense of Article 33(2) PCT.

The document D5 discloses (the references in parentheses applying to this document):

A system for therapeutic neuromodulation in a nasal region of a human patient (abstract, fig.25, fig.5A, par.[0085]), the system comprising:
a shaft having a proximal portion and a distal portion (fig.5), wherein the shaft is configured to locate the distal portion intraluminally at a target site (fig.32), wherein the target site is at least one of proximate to the sphenopalatine foramen of a human patient or inferior to the

sphenopalatine foramen (not a technical feature of the device, system of D5 is considered suitable for such application); and
a therapeutic assembly (fig.32 (113)) at the distal portion of the shaft and transformable between a low-profile delivery state and an expanded state, wherein the therapeutic assembly comprises a plurality of struts and a plurality of electrodes disposed on the struts, and wherein the plurality of struts form a basket (fig.32 (113), par.[0112]) that positions at least two of the electrodes at the target site inferior to a sphenopalatine foramen of the human patient when the therapeutic assembly is in the expanded state, and
wherein the electrodes are configured to apply radiofrequency (RF) energy (par.[0065]) to the target site to therapeutically modulate parasympathetic nerves proximate to the target site.

Therefore the subject-matter of claim 26 is not new.

Furthermore the subject-matter of claim 26 is also not new compared to each of the following documents:

D6: abstract, fig.8, fig.9, par.[0095]-[0101];

D7: abstract, fig.5A - fig.6B, par.[0053]-[0056];

D8: abstract, fig.9, par.[0084]-[0088].

The systems disclosed in D6, D7 and D8 are considered to be suitable to be introduced into the nasal region.

9 DEPENDENT CLAIMS 10,12-25 AND 27-40

Dependent claims 10,12-25 and 27-40 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty Article 33(2) PCT and/or inventive step Article 33(3) PCT.

9.1 The additional features being disclosed as follows:

Claims 10, 12:	D6: fig.8, fig.9 par.[0088].
Claims 13, 14:	D7: fig.4B, fig.5B, par.[0025], par.[0050]-[0055].
Claim 15:	D6: fig.5, par.[0088].
Claim 16:	D6: fig.6, par.[0089].

Claim 17:	D9: par.[0123].
Claim 18:	D6: par.[0109].
Claims 20-22:	D6: fig.22, par.[0120]-[0128], D7, fig.6A.
Claims 27-28:	D6: fig.8, fig.9 par.[0088].
Claim 29:	D6: par.[0142].
Claim 30:	D7: par.[0041].
Claims 31-33, 36:	D7: fig.4B, fig.5B, par.[0025], par.[0050]-[0055].
Claims 34, 35:	D8: fig.9, par.[0085], par.[0088].
Claim 38:	D7: fig.6B.

9.2 The feature of claims 19, 23-25, 37, 39 and 40 is well known in the art and therefore is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

THIRD INVENTION

10 INDEPENDENT CLAIM 41

10.1 The definition of *"an energy delivery element configured to therapeutically modulate postganglionic parasympathetic nerves innervating a nasal mucosa at the target site"* of present claim 41 is considered to be unclear and therefore does not meet the requirements of Article 6 PCT. The subject-matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result (e.g. waveform, type of stimulation, etc.). In terms of technical features, the above lines merely define an energy delivery element as such.

10.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 41 is not new in the sense of Article 33(2) PCT.

The document D10 discloses (the references in parentheses applying to this document):

A system for neural mapping (fig.3A, claim 23) and therapeutic neuromodulation in a nasal region of a human patient (not a technical feature), the system comprising:
a shaft (claim 23) having a proximal portion and a distal portion, wherein the shaft is configured to locate the distal portion intraluminally at a target site (claim 23) proximate to a sphenopalatine foramen of the human patient;
a plurality of electrodes (claim 23) at the distal portion of the shaft, wherein the electrodes are configured to detect locations of the parasympathetic nerves at the target site; and
a therapeutic assembly at the distal portion (claim 23) of the shaft, wherein the therapeutic assembly is comprises an energy delivery element configured to therapeutically modulate postganglionic parasympathetic nerves innervating a nasal mucosa at the target site.

Therefore the subject-matter of claim 41 is not new.

11 DEPENDENT CLAIMS 11 AND 42-44

Dependent claims 11 and 42-44 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty Article 33(2) PCT and/or inventive step Article 33(3) PCT.

11.1 The additional features being disclosed as follows:

Claim 11 : D10: claim 23, par.[0051].

Claims 42-44 : D10: par.[0051].

FOURTH INVENTION

12 INDEPENDENT CLAIM 94

12.1 The definition of *"wherein the electrodes are configured to therapeutically modulate parasympathetic nerves of mucosal and sub-mucosal structures in direct or in-direct contact with the electrodes"* of present claim 94 is considered to be unclear and therefore does not meet the requirements of

Article 6 PCT. The subject-matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result (e.g. waveform, type of stimulation, etc.). In terms of technical features, the above lines merely define an energy delivery element as such.

12.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 94 is not new in the sense of Article 33(2) PCT.

The document D11 discloses (the references in parentheses applying to this document):

> *A device for therapeutic neuromodulation (abstract) in a nasal region of a human patient, the system comprising:*
> *a delivery catheter having a distal portion, wherein the delivery catheter is configured to locate the distal portion at a target site (par.[0030]) within the nasal region;*
> *a flexible support (fig.2B, par.[0036]) at the distal portion of the delivery catheter; and*
> *a plurality of electrodes carried by the flexible (fig.2B, par.[0037]) support,*
> *wherein the flexible support is configured to conform to irregularities of local anatomy at the target site (par.[0033], par.[0035]) to provide topographical compliance and a linkage for electrical activation of at least a portion of the electrodes, and*
> *wherein the electrodes are configured to therapeutically modulate parasympathetic nerves (par.[0036]) of mucosal and sub-mucosal structures in direct or in-direct contact with the electrodes.*

Therefore the subject-matter of claim 94 is not new.

Furthermore, the subject-matter of claim 94 is also not new compared to

D12: abstract, fig.1A, 1B, par.[0134]-[0137].

13 DEPENDENT CLAIMS 95 TO 97

Dependent claims 95 to 97 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of

the PCT in respect of novelty Article 33(2) PCT and/or inventive step Article 33(3) PCT.

13.1 The additional features being disclosed as follows:

Claim 95:	D11: par.[0035].
Claim 96 :	The target site is not a technical feature of the device. D12: par[0134] defines an outer diameter of 4mm, which is considered suitable for nasal application.
Claim 87:	D12: par.[0140].

Re Item VII

Certain defects in the international application

1 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D4 is not mentioned in the description, nor are these documents identified therein.

3 The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT.

UNITED STATES
PATENT AND TRADEMARK OFFICE

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www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/411,476	**03/19/2024 01:58:24 PM Z ET**	**NEURE-008/03US 35242/151**

Title of Invention

SYSTEMS AND METHODS FOR IMPROVING SLEEP WITH THERAPEUTIC NASAL TREATMENT

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8746	FILED BY	Kelley Warren
PATENT CENTER #	64706099	FILING DATE	01/12/2024
CUSTOMER #	21710	FIRST NAMED INVENTOR	David Townley
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew York

Documents

TOTAL DOCUMENTS: 58

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
35242_8US - EP2929852A1-FOR.pdf	87	Foreign Reference	4587 KB
35242_27US - JP2001120565A-FOR.pdf	17	Foreign Reference	624 KB
35242_99US - Translation of JP2001526077A-FOR.pdf	26	Foreign Reference	357 KB
35242_11US - JP2007537784A-FOR.pdf	71	Foreign Reference	3459 KB
35242_11US - Translation of JP2007537784A-FOR.pdf	61	Foreign Reference	622 KB
35242_10US - JP2009538641A-FOR.pdf	42	Foreign Reference	797 KB

35242_10US - Translation of JP2009538641A-FOR.pdf	34	Foreign Reference	455 KB
35242_10US - JP2012143573A-FOR.pdf	34	Foreign Reference	1637 KB
35242_10US - Translation of JP2012143573A-FOR.pdf	35	Foreign Reference	469 KB
35242_10US - JP2015507964A-FOR.pdf	36	Foreign Reference	1489 KB
35242_10US - Translation of JP2015507964A-FOR.pdf	33	Foreign Reference	458 KB
35242_99US - JP2018515314A-FOR.pdf	123	Foreign Reference	3701 KB
35242_85WO - WO0117450A1-FOR.pdf	39	Foreign Reference	1261 KB
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35242_80WO - WO2009154456A1-FOR.pdf	31	Foreign Reference	1275 KB
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35242_8US - WO2018087601A1-FOR.pdf	89	Foreign Reference	4449 KB
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35242_31US - Annotated Perfler Figure-NPL.pdf	1	Drawings-only black and white line drawings	20 KB
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35242_37US - Arora - 1980-NPL.pdf	3	Non Patent Literature	445 KB
35242_151US - Chen Translation-NPL.pdf	10	Non Patent Literature	3769 KB
35242_151US - Fang Translation-NPL.pdf	32	Non Patent Literature	17688 KB
35242_10US - Horesh-2006-NPL.pdf	266	Non Patent Literature	20002 KB
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35242_8US - International Search Report and Written	15	Non Patent Literature	498 KB

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35242_26US - KAYANA-2009-NPL.pdf	4	Non Patent Literature	1420 KB
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35242_151US - Liang Translation-NPL.pdf	8	Non Patent Literature	994 KB
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35242_57US - Neubauer-2022-NPL.pdf	8	Non Patent Literature	750 KB
35242_37US - Ozenberger - Cryosurgery in chronic rhinitis-NPL.pdf	12	Non Patent Literature	541 KB
35242_37US - Ozenberger - Cryosurgery for the treatment of chronic rhinitis-NPL.pdf	9	Non Patent Literature	534 KB
35242_10US - Paterno-2009-NPL.pdf	10	Non Patent Literature	1248 KB
35242_10US - Yang-2014-NPL.pdf	143	Non Patent Literature	9135 KB
35242_151_Information_Disclosure_Statement_Fillable_PDF.pdf	35	Information Disclosure Statement (IDS) Form (SB08)	1243 KB

Digest

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35242_80WO - Flexible electronics - Wikipedia-NPL.pdf	6324066A3BDC2CFEA8202E6BF8670143E993E906E3753146A EC713A83C9EBF27F82CA15FABE086F8AE86841F60DF6537B D200D0B826F92A033A92511DD925510
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35242_8US - International Search Report and Written Opinion for PCTIB2017001541-NPL.pdf	AB4858B3FC3C1538ECBC815811D656A2FDE3A24B219B239E3B3254A15740B96336749CD0C458D28E1A58D5CE58DDD3EFF47833A70AB9FAAFCBE3E138253E5889
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If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.