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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	P244690US02 (494912-15)
First Named Inventor	Scott J. WOLF
Title	POST NASAL DRIP TREATMENT
Express Mail Label No.	efs

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [✓] **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. [✓] **Applicant asserts small entity status.** See 37 CFR 1.27
3. [ ] **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. [✓] **Specification** [*Total Pages* 50] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. [✓] **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* 29]
6. **Inventor's Oath or Declaration** [*Total Pages* 0] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. [ ] Newly executed (original or copy)
   b. [ ] A copy from a prior application (37 CFR 1.63(d))
7. [✓] **Application Data Sheet** ** See note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
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ACCOMPANYING APPLICATION PAPERS

10. [✓] **Assignment Papers** (cover sheet & document(s)) Name of Assignee AERIN MEDICAL, INC.
11. [ ] **37 CFR 3.73(c) Statement** (*when there is an assignee*) [✓] **Power of Attorney**
12. [ ] **English Translation Document** (*if applicable*)
13. [ ] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [ ] Copies of citations attached
14. [ ] **Preliminary Amendment**
15. [ ] **Return Receipt Postcard** (*MPEP § 503*) (*Should be specifically itemized*)
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17. [ ] **Nonpublication Request** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. [ ] **Other:**

***Note**: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

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P244690US02
(494912-15)

POST NASAL DRIP TREATMENT

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Andrew FRAZIER

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application No. 61/974,534, entitled Post Nasal Drip Treatment, filed April 3, 2014.

[0002] This application is also a continuation-in-part of pending U.S. Patent Application Serial No. 14/319,087, entitled Methods and Devices to Treat Nasal Airways, filed June 30, 2014, (U.S. Publication No. 2014/0316396), which is a continuation-in-part of U.S. Application No. 13/495,844, which issued on January 20, 2015, as U.S. Patent No. 8,936,594; which claims priority to U.S. Provisional Patent Application No. 61/603,864, filed February 27, 2012 and U.S. Provisional Patent Application No. 61/496,930, filed June 14, 2011. The disclosures of all the above-referenced patent applications are hereby incorporated by reference in their entireties herein.

FIELD

[0003] This application relates generally to the field of medical devices and treatments. More specifically, the application relates to systems, devices and methods for treating structures within the upper airway to reduce and/or prevent overproduction and/or flow of mucus to alleviate the discomfort of post nasal drip symptoms.

BACKGROUND

[0004] In a healthy human body, glands in the lining of the nose, throat and airways produce about 1 to 1.5 liters daily of a thick, wet substance called mucus. The purpose of mucus is to help trap and destroy harmful bacteria and viruses in the airways before they can enter the body. Mucus produced in the nose is transported toward the throat and into the digestive system. This process is called mucociliary clearance and generally goes unnoticed, similar to breathing or blinking. However, viruses, infections, and the inhalation of airborne irritants, particles and micro-organisms can trigger an overproduction of mucus and/or thicker-than-usual mucus. This

increased/thickened mucus causes irritation, which is known as post nasal drip syndrome (PNDS) or upper airway cough syndrome (UACS).

[0005] Nasal mucus is produced by the nasal mucosa and mucosal tissues lining airways (trachea, bronchus, bronchioles). Mucosal tissues include specialized airway epithelial cells (goblet cells) and submucosal glands. Goblet cells are situated in the epithelium of the conducting airways, often with their apical surfaces protruding into the lumen, a location which allows them to aid in a rapid response to inhaled airway insults. Goblet cells may have a much greater potential for mucus secretion than do the submucosal glands. Thus, goblet cells may represent the principal front-line defender of the airway.

[0006] New information demonstrates that goblet cells can discharge vast quantities of mucus in fractions of a second, a property integral to airway defense against acute insult. Goblet cells can also increase in number in response to continued airway insult. The increase in goblet cells, and hence mucus production, may be a result of hyperplasia (involving cell division) and/or metaplasia (involving cell differentiation). Preventing metaplasia may be achieved by eliminating goblet cell metaplasia inducing components, such as Interleukin (IL)-13. This gene encodes an immunoregulatory cytokine produced primarily by activated Th2 cells. This cytokine is involved in several stages of B-cell maturation and differentiation.

[0007] While the overproduction of nasal mucus can be a result of anatomical causes like deviated nasal septum and turbinate hypertrophy, non-anatomical causes, such as allergies, have also been known to trigger PNDS. These patients may have overactive immune systems, leading to an overproduction of mucus. The most straightforward method of treating the allergy problem is to take a test to diagnose the causes of allergies and making lifestyle changes to stay away from these causes. Medications like antihistamines are often prescribed to block allergy mediators. However, antihistamines may thicken mucus secretions and can worsen bacterial rhinitis or sinusitis. A specific antihistamine may lose its effectiveness over time, requiring more or alternative antihistamines to reduce systemic reaction. In addition, antihistamines may come with side effects such as headache, dry mouth, and dry nose.

[0008] Nasal-spray corticosteroids (commonly called steroids) are considered the most effective drugs for controlling the symptoms of moderate-to-severe allergic rhinitis. However,

side effects may include dryness, burning, stinging in the nasal passage, sneezing, headaches and nosebleed. There may also be long term complications caused by hormone suppression, such as lower resistance to infection, effects on growth in children, nervousness, acne, etc. Cromolyn and leukotriene antagonists may have lesser side effects, but are not as effective as nasal corticosteroids. The major hazard with nasal-delivery decongestants, particularly long-acting forms, is a cycle of dependency and rebound effects. For oral decongestants, side effects such as insomnia, irritability, nervousness, and heart palpitations may be observed.

[0009] Immunotherapy (commonly referred to as "allergy shots") is a safe and effective treatment for patients with allergies. The major downside to immunotherapy is that it requires a prolonged course of weekly injections. This makes the treatment process laborious and patients often fail to comply with the regimens, limiting the end results of the therapy.

[0010] Therefore, a need exists for a long lasting, single-treatment or low frequency treatment for PNDS caused by allergies, anatomical causes or other causes. Ideally, such a treatment would alleviate PNDS symptoms, without producing severe and/or chronic side effects.

BRIEF SUMMARY

[0011] Certain implementations of the systems and methods disclosed herein address the above mentioned needs by delivering a therapy in an upper airway to treat PNDS and/or UACS. The therapy delivered may involve delivering energy to, removing energy from (e.g., cryotherapy) and/or delivering a substance to mucosal tissue and/or a tissue underlying mucosal tissue in the upper airway. The therapy delivery may have any of a number of different effects on the treated tissue. For example, the therapy may decrease the absolute number and/or the mucus producing ability of mucus producing cells and/or mucus glands, such as by inactivating, retarding and/or replacing the cells. In other embodiments, the therapy may ablate or otherwise deactivate nerve tissue underlying mucosal tissue and thus ameliorate PNDS and/or UACS symptoms. In various embodiments, treatment may be applied during early stages of PNDS and/or UACS symptoms, before hyperplasia and metaplasia occur. Such early stage intervention may involve inactivating or modifying goblet cells and/or any other mucus producing cells and/or glands via the application of energy.

[0012] Embodiments of the present application are directed to devices, systems and methods for treating upper airways. Such embodiments may be used to treat PNDS by reducing the production of mucus in the upper airways, thus preventing the mucus from causing PNDS. For example, the devices, systems and methods described herein may be used to change the properties of the tissue of the nose and throat, including but not limited to skin, muscle, mucosa, submucosa and nasal turbinate.

[0013] According to one embodiment, a device for treating PNDS includes an elongate shaft having a proximal end and a distal end. In one embodiment, the device includes an treatment portion, such as an energy delivery member, sized to be inserted into a nose and/or throat or delivered external to a nose and/or throat. The energy delivery member is configured to deliver energy to tissues within the nose and/or throat and change the properties of a region of the nose and/or throat to minimize mucus production and prevent mucus from causing PNDS. The device may further include a handle at the proximal end of the elongate shaft. The devices described herein may be configured to be positioned internally or externally within the nose, throat and/or mouth. Certain embodiments are configured to be delivered into one or both nostrils, and other embodiments are configured to be delivered into the throat.

[0014] Other embodiments of the devices for treating a patient's PNDS include devices that apply other types of treatment. For example, a treatment device may apply energy of form selected from a group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, cryogenic and laser. The treatment device may also be configured to inject a polymerizing liquid or to deliver cauterizing agent to the upper airway. Other embodiments are described below.

[0015] In some embodiments, the device may comprise a treatment element having a shaped surface conformed to the region of the nose or throat to be treated. For embodiments using an energy delivery element, the treatment element may be a separate element from the energy delivery element, or the energy delivery element and the treatment element may be part of the same element. The energy delivery element and/or treatment element in one embodiment may have a concave surface to cover the treatment region as much as possible.

[0016] In embodiments using energy delivery, a handle may be provided comprising a button or other input control to activate one or more electrodes. Electrodes may comprise one or more

monopolar needles, one or more monopolar plates, or one or more bipolar electrode pairs (which may also comprise one or more needles or plates). These electrodes may be located in various locations, for example, inside the nasal passageway, inside the throat or external to both nose and throat. For example, when using a bipolar electrode pairs, a first electrode surface may be positioned internal to the nose and a second electrode surface may be positioned external to the nose, so that the two electrode surface are positioned on opposite sides of the nasal tissue. In certain implementations, electrodes may be surface acting, transdermal or subdermal (e.g., by access via an incision) or a combination thereof.

[0017] The device of one energy delivery embodiment may comprise an adaptor configured to be connected to an energy source, such as a RF energy source. The device may also comprise a control system configured to control the characteristics of the energy applied to the tissue.

[0018] A thermocouple or other sensor may be provided to measure a temperature near the tissue or other tissue or device parameter. Sensor(s) to monitor tissue properties such as impedance, resistance, moisture level may also be provided.

[0019] In another aspect, a system is provided comprising a device as described above and further below in combination with one or more other components. One such component may be a control system for controlling the energy source and/or treatment device. In another embodiment, the system may comprise a cooling mechanism to cool desired tissue locations while treatment is being applied. In monopolar electrode embodiments, a grounding pad may also be provided as part of the system. Another system includes a positioning and/or other parameters for using the device to treat the feeling and effects of PNDS.

[0020] According to another aspect, a method of treating a patient's PNDS is provided. In one embodiment, the method includes altering the tissue properties of the nasal inferior turbinate by applying a treatment sufficient to alter the tissue properties to reduce mucus production.

[0021] According to one embodiment, a method of treating a patient's PNDS comprises positioning a treatment element within the upper airway tissue to be treated. The treatment element comprises one or more electrodes, such as described above in further detail below.

[0022] In certain implementations, the method may further comprise altering the properties of the nasal or throat tissue by pressing a surface of the treatment element against the upper airway

tissue to be treated. In certain implementations, the method may further comprise delivering radiofrequency (RF) energy to the one or more electrodes to locally heat the tissue to be treated, wherein delivering RF energy while altering the properties of the tissue causes less mucus production in the treatment area. The method may also comprise removing the treatment element from the upper airway.

[0023] In one aspect, a method for reducing mucus secretion in an upper airway of a patient to treat post nasal drip and/or chronic cough may involve: advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient; contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and delivering a treatment from the treatment delivery portion to the mucosal tissue and/or another tissue underlying the mucosal tissue to modify a property the tissue and thus treat at least one of post nasal drip or chronic cough in the patient.

[0024] In some embodiments, the treatment may be delivered without forming an incision in the mucosal tissue and without delivering an implant. In some embodiments, delivering the treatment involves delivering energy from the delivery treatment portion in the form of ultrasound, microwave, heat, radiofrequency, electrical, light or laser energy.

[0025] In some embodiments, delivering the treatment comprises delivering radiofrequency energy from a first electrode on a tissue contact surface of the treatment portion across a convex portion of the tissue contact surface to a second electrode on the tissue contact surface. In some embodiments, contacting the mucosal tissue comprises contacting multiple non-piercing bumps on the tissue contact surface with the mucosal tissue. In some embodiments, the at least one tissue comprises nerve tissue underlying the mucosal tissue, and delivering the energy comprises ablating the nerve tissue. Some embodiments may further comprise measuring an amount of delivered energy using a thermocouple on the treatment portion. Some embodiments may further comprise adjusting the amount of delivered energy by adjusting a setting of the treatment delivery portion.

[0026] In some embodiments, delivering the treatment comprises removing energy, and the treatment delivery portion comprises a cryotherapy device. In some embodiments, the at least one tissue comprises nerve tissue underlying the mucosal tissue, and removing energy comprises

ablating the nerve tissue using the cryotherapy device. In some embodiments, applying a treatment comprises injecting a polymerizing liquid.

[0027] In some embodiments, delivering the treatment comprises injuring the at least one tissue. In some embodiments, delivering the treatment comprises injuring goblet cells that are part of the mucosal tissue. In some embodiments, the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves, submucosal tissue, muscle, ligaments, cartilage, tendon, and skin. In some embodiments, delivering the treatment comprises simultaneously mechanically altering the mucosal tissue and delivering energy to the at least one tissue. In some embodiments, delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue. In some embodiments, delivering the treatment comprises delivering a cauterizing agent to tissue to be treated. In some embodiments, delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway. In some embodiments, the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate.

[0028] In another aspect, a device for reducing mucus secretion in an upper airway of a patient to treat post nasal drip and/or chronic cough may include: an elongate, malleable shaft having a proximal end and a distal end; a handle at the proximal end of the elongate shaft; and a treatment portion at the distal end of the elongate shaft. The treatment portion may include a treatment surface, which may include at least two energy delivery members extending longitudinally along the treatment surface and a concave trough extending longitudinally along the treatment surface and separating the at least two energy delivery members.

[0029] In some embodiments, the at least two energy delivery members comprise at least one positive electrode on one side of the concave trough and at least one negative electrode on an opposite side of the concave trough. In some embodiments, the at least one positive electrode comprises a row of positive electrodes, and the at least on negative electrode comprises a row of negative electrodes. In some embodiments, the electrodes (which may be blunt-tipped electrodes) protrude from the treatment surface. Some embodiments further comprise a thermocouple disposed within the concave trough.

[0030] In another aspect, a method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough may involve: bending a malleable shaft of a treatment device into a desired configuration; advancing a treatment portion of the treatment device into a nostril of the patient to contact a treatment surface of the treatment portion with mucosal tissue of the upper airway, without piercing the mucosal tissue; and delivering radiofrequency energy from a first electrode on the treatment surface across a concave trough in the treatment surface to a second electrode on the treatment surface, to treat mucosal tissue and/or another tissue underlying the mucosal tissue to modify a property of the tissue and thus treat post nasal drip and/or chronic cough in the patient. The method also involves measuring an amount of the radiofrequency energy delivered, using a thermocouple disposed in the concave trough, and removing the treatment portion from the upper airway without leaving an implant in the upper airway.

[0031] Some embodiments further comprise performing a test to determine whether a desired contact between the treatment surface and the mucosal tissue has been achieved. In some embodiments, delivering and measuring steps comprise delivering a first amount of the radiofrequency energy from the first electrode to the second electrode; measuring a temperature of the mucosal tissue using the thermocouple; and delivering a second amount of the radiofrequency energy from the first electrode to the second electrode, wherein the second amount of radiofrequency energy is based at least in part on the measured temperature.

[0032] In some embodiments, the mucosal tissue comprises tissue located on at least one nasal turbinate of the upper airway. In some embodiments, the mucosal tissue comprises tissue located on a posterior aspect of an inferior turbinate. In some embodiments, delivering the radiofrequency energy comprises delivering the radiofrequency energy in an amount that deactivates mucus producing cells by impairing at least one of mucus production ability or cell differentiation ability of the mucus producing cells. In some embodiments, delivering the radiofrequency energy comprises delivering the radiofrequency energy in an amount that causes one or more mucus paths of the upper airway to divert. Some embodiments comprise repeating the bending, advancing, and delivery steps.

[0033] These and other aspects and embodiments will be described in further detail below, in reference to the attached drawing figures.

BRIEF DESCRIPTION OF DRAWINGS

[0034] FIG. 1 is a side-view diagram of a mucus producing cell in the lining of a nasal epithelium.

[0035] FIG. 2 is a diagram of a process of exocytosis.

[0036] FIG. 3 is a diagram of a Ca2+ filled vesicle fusing with a membrane and opening up to an extracellular space containing Na+ and Cl-.

[0037] FIGS. 4A–4C are diagrams of a membrane-vesicle fusion process.

[0038] FIG. 5 is a side-view diagram of respiratory epithelium, illustrating a process of squamous metaplasia of columnar cells to squamous cells.

[0039] FIG. 6 is a top-view illustration of a mucus reduction treatment device, according to one embodiment.

[0040] FIG. 7 is a perspective view of a treatment portion shape for a treatment portion of a mucus reduction treatment device, according to one embodiment.

[0041] FIG. 8 is a perspective view of a treatment portion of a mucus reduction treatment device, according to an alternative embodiment.

[0042] FIG. 9 is a perspective view of a treatment portion of a mucus reduction treatment device, according to another alternative embodiment.

[0043] FIG. 10 is a cross-sectional view of a distal end of a treatment portion of a treatment device, showing microneedles puncturing tissue in order to apply treatment at a desired tissue depth, according to one embodiment.

[0044] FIG. 11 is a perspective view of an energy delivery balloon being inserted into a nose, according to one embodiment.

[0045] FIGS. 12A–12E are cross-sectional views of various electrode arrangements for applying energy to the treatment tissue in the nose or throat according to various embodiments.

[0046] FIG. 13 is a perspective view of an electrode arrangement of a treatment element according to one embodiment.

[0047] FIG. 14 is a perspective view of an electrode arrangement of a treatment element according to one embodiment.

[0048] FIGS. 15A–15C are cross-sectional views of various electrode arrangements for applying energy to the treatment tissue in the nose or throat according to various embodiments.

[0049] FIGS. 16A–16I are cross-sectional views of various permutations of electrodes-thermocouples combinations for a multi-channel configuration according to various embodiments.

[0050] FIG. 17 is a perspective view of a device for applying energy to upper airway tissues using monopolar electrodes according to one embodiment.

[0051] FIG. 18 is a perspective view of a device for applying energy to upper airway tissues using monopolar electrodes according to one embodiment.

[0052] FIG. 19A is a perspective view of a device for applying energy to the upper airway tissues using a bipolar electrode according to one embodiment.

[0053] FIG. 19B is an enlarged perspective view of the treatment member of the device of FIG. 19A.

[0054] FIG. 20 is a flow diagram of an example method of use of various devices.

[0055] FIGS. 21A–21B are perspective views of a device for applying energy to the upper airway tissues using a bipolar electrode and a positioning element according to one embodiment.

[0056] FIG. 22A is a perspective view of a clamp-like device for applying energy to the upper airway tissues using a bipolar electrode according to one embodiment.

[0057] FIG. 22B is a perspective view of a one-prong device for applying energy to the upper airway tissues using a monopolar electrode according to one embodiment.

[0058] FIG. 23 is a perspective view of a device with concave head, for applying energy to the upper airway tissues using a bipolar electrode according to one embodiment.

[0059] FIG. 24 is a perspective view of a device with grounding probes, for applying energy to the upper airway tissues using a monopolar electrode according to one embodiment.

[0060] FIG. 25 is a perspective view of a treatment element with flexible wings according to one embodiment.

[0061] FIGS. 26A–26F are perspective views of a treatment element with electrodes of adjustable heights according to certain embodiments.

[0062] FIG. 27 is a perspective view of a treatment element with an extendable component according to one embodiment.

[0063] FIGS. 28A–28E are side-cutaway views of treatment elements according to certain embodiments.

[0064] FIG. 29A is a side-cutaway view of nasal skin in cross section, including mucosa, cartilage, dermis and epidermis and a treatment device having an external component according to one embodiment.

[0065] FIG. 29B is a perspective view of a treatment of an applied external component according to one embodiment.

DETAILED DESCRIPTION

[0066] The following disclosure provides embodiments of systems and methods for treating PNDS and/or UACS, which may be generally referred to herein as "post-nasal drip" or "PND." Certain embodiments include methods and devices for reshaping, remodeling, strengthening, and/or changing a property and/or type of tissue of the nose and/or upper airway, including but not limited to the epithelial layer, skin, muscle, mucosa, submucosa, and cartilage in the upper airway. Certain embodiments may be used to decrease or eliminate mucus production in the upper airway. While some embodiments may change a property of a tissue, such as an ability of a tissue to produce mucus, other embodiments may change a tissue from one type to another type. One example of this latter change is changing goblet cells to scar tissue. Various embodiments may be used to reduce movement of mucus, reduce amount of mucus produced, reduce frequency of mucus production, change the mucus viscosity/consistency, and/or change the path of mucus flow.

[0067] Remodeling or changing the properties of the tissues in the upper airway linings can improve the condition of PND caused by mucus hypersecretion. Methods and devices described herein may be used to treat upper airways without the need for more invasive procedures (e.g., ablation or surgery).

[0068] PND symptoms may be alleviated by decreasing mucus production in the upper airways. In certain implementations, mucus production may be decreased by modifying the properties of mucus producing cells in the upper airway epithelium. In some implementations, modifying the properties of the mucus producing cells may include reducing the rate at which cells produce mucus. In some implementations, modifying the properties of mucus producing cells may include deactivating some or all mucus producing cells in a region. Modifying these cells can be performed alone or together with other procedures (e.g., surgical procedures), such as those described above. Such methods and devices may alleviate PND symptoms.

[0069] Mucus hypersecretion often occurs when a mucus producing cell displays rapid mucus secretion behavior. To prevent this, properties of the cell can be modified to inactivate or retard the cell so as to halt or impede the release of mucins into the airway.

[0070] FIGS. 1-5 are provided for background. FIG. 1 is a side-view diagram of a mucus producing cell in the lining of a nasal epithelium. Mucin granules tightly packed in the mucus producing cell (e.g. a goblet cell) before and after release. Before release, mucus condensation is achieved by the granules containing high concentrations of Ca2+, which acts as a "shielding" cation to nullify the repulsive forces within the molecule.

[0071] FIG. 2 is a diagram of a process of exocytosis. As illustrated, an intracellular vesicle (membrane bounded sphere) containing mucins (substance) moves to the plasma membrane and subsequent fusion of the vesicular membrane and plasma membrane ensues.

[0072] FIG. 3 is a diagram of a Ca2+ filled vesicle fusing with a membrane and opening up to an extracellular space containing Na+ and Cl-. The opening of the pore between intragranular space and extracellular space permits water, sodium (and other monovalent cations) to enter the vesicle and Ca2+ exit. Loss of charge-shielding allows electrostatic repulsion to rapidly expand the mucin polymer network, which facilitates hydration with the incoming water, and the resultant vastly expanded network erupts from the cell in the fashion of a "jack-in-the-box." The

mucin expands from the vesicle into the extracellular space at a very rapid rate. This process of mucin granules in mucus producing cells escaping and forming mucus in the airway is known as exocytosis.

[0073] FIGS. 4A–C are diagrams of a membrane-vesicle fusion process. In FIG. 4A, the participants of the vesicle-membrane fusion are a vesicle with a receptor, a Rab protein, and a membrane with a receptor. The Rab family of proteins is a member of the Ras superfamily of monomeric G proteins. Only the active form of Rab GTPases is able to regulate membrane fusion.

[0074] In FIG. 4B, when the vesicle receptor is compatible with the Rab protein, the Rab protein docks onto the vesicle receptor and transports it towards the membrane acceptor. If the membrane acceptor is compatible with the Rab protein, docking occurs as shown.

[0075] In FIG. 4C, the Rab protein releases the vesicle to allow it to fuse with the membrane, thus kick-starting the exocytosis process illustrated in FIG. 3.

[0076] FIG. 5 is a side-view diagram of respiratory epithelium, illustrating a process of squamous metaplasia of columnar cells to squamous cells. The mucus producing cells are inactivated by undergoing cell metaplasia, the switching of cells from one type to another. In the presence of stimulants, the mucus producing cells, which are columnar cells, may switch to squamous cells to better protect themselves against these stimulants. When squamous metaplasia occurs, mucus is no longer produced due to the absence of mucus producing cells.

[0077] The measurement of secretion of mucins by mucus producing cells is made indirectly. Radiolabelled precursors of mucin are often used to quantify secretion *in vitro* and *in vivo*. Lectin staining, antibodies to mucus, staining with "mucus" stains (in particular Alcian blue and PAS), or usation of endogenous markers for mucus (for example fucose) may each be used to quantify the magnitude of mucus cell secretion. In some embodiments, it may be desirable to measure the secretion of mucins by mucus producing cells prior to, during and/or after a procedure.

[0078] PND occurs when mucus production is excessive and this excess mucus runs down the back of the throat, causing irritation. Modifying properties of the participants of the vesicle-membrane fusion and/or introducing stimulants to encourage squamous metaplasia decreases the likelihood of successful mucus production.

[0079] Some embodiments below provide apparatus and methods for reducing the amount of mucus production from each mucus-secreting cell by modifying the properties of the participants of the vesicle-membrane fusion. Other embodiments below provide apparatus and methods for deactivating mucus producing cells by impairing some or all of their mucus production and cell differentiation abilities, thus reducing the numbers of active mucus producing cells. Still other embodiments combine the two approaches of modifying and inactivating mucus producing cells.

[0080] In some embodiments, the amount of mucus production of each cell can be decreased by: a device or treatment limiting the number of mucins formed in the cell, a device or treatment modifying the mucin receptors such that the receptors are not highly compatible with Rab proteins, a device or treatment limiting the number of active form of Rab GTPases proteins available, and/or a device or treatment modifying the membrane acceptors such that the acceptors are not highly compatible with the Rab protein.

[0081] In some embodiments, the mucus producing cells can be deactivated by: a device or treatment destroying mucins in the cell, a device or treatment destroying mucin receptors such that they cannot receive Rab proteins, a device or treatment destroying the active form of Rab GTPases proteins, a device or treatment destroying membrane acceptors such that the acceptors cannot receive the Rab protein, and/or a device or treatment that causes metaplasia of the mucus producing cells into a non-mucus producing cell type.

[0082] In any one or more of the above mentioned embodiments, such modification and/or inactivation of mucus producing cells may include the application of energy by devices. In some embodiments, energy may be applied in the form of heat, radiofrequency (RF), laser, light, ultrasound (e.g. high intensity focused ultrasound), microwave energy, electromechanical, mechanical force, cooling, alternating or direct electrical current (DC current), chemical, electrochemical, cryogenic or others.

[0083] Any one or more of the above energy-application mechanisms may be used to re-shape, remodel, or change mechanical or physiologic properties of structures of a participant of the vesicle-membrane fusion. The modification results in a tightening, shrinking or enlarging of these participants, resulting in a change of shape, which impedes the exocytosis process.

[0084] In certain implementations, the energy-application mechanisms may be used to re-shape, remodel, or change the mechanical or physiologic properties of structures in order to cause mucus to divert. For example, one or more mucus paths may be diverted so mucus is moved to the lateral walls of the pharynx in addition to or instead of the posterior aspect of the pharynx. In certain implementations, diverting one or more mucus paths may be achieved by selectively treating certain areas of the upper airway.

[0085] In alternative embodiments, conformation changes (i.e., re-shaping) of participants of the vesicle-membrane fusion to impede the exocytosis process may include the healing process. For example, in some embodiments energy may be applied to a participant of the vesicle-membrane fusion in such a way that the healing process causes a change to the shape of the receptors, Rab, and acceptors.

[0086] In some embodiments, energy may be delivered into the cartilage tissue to cause a conformational change and/or a change in the physical properties of the cartilage. For example, in certain embodiments, the physical properties of the cartilage may be changed to divert or otherwise redirect the flow of mucus within the upper airway. Energy delivery may be accomplished by transferring the energy through the tissue covering the cartilage such as the epithelium, mucosa, sub-mucosa, muscle, ligaments, tendon and/or skin. In some embodiments, energy may also be delivered to the cartilage using needles, probes or microneedles that pass through the epithelium, mucosa, submucosa, muscle, ligaments, tendon and/or skin.

[0087] In some embodiments, energy may be delivered into the submucosal tissue to cause a conformational change and/or a change in the physical properties and/or type of the submucosal tissue. Energy delivery may be accomplished by transferring the energy through the tissue covering the submucosa such as the epithelium, mucosa, muscle, ligaments, cartilage, tendon and/or skin. In some embodiments, energy may also be delivered to the submucosa using needles, probes, microneedles, micro blades, or other non-round needles that pass through the epithelium, mucosa, muscle, ligaments, tendon and/or skin. In certain embodiments, the energy may be delivered through a combination of means. In certain embodiments, the energy may be delivered through one or both of surgical and non-surgical access.

[0088] In some embodiments, energy may be delivered to various tissues in order to achieve desired therapeutic results. The tissue may include, but is not limited to: cilia, goblet cells, nerves (such as the sphenopalatine ganglion), submucosal tissue, and other tissue. For example, in certain implementations, energy may be delivered to nerve tissue that controls the behavior of mucus producing cells or tissue.

[0089] FIG. 6 is a top-view schematic illustration of a mucus reduction treatment device 30, according to one embodiment. The device 30 comprises a treatment element 32 which may be configured to be placed inside the nasal cavity, nasal passage, nasal airway and/or throat to deliver the desired treatment. In some embodiments, the device 30 may further comprise a handle section 34 which may be sized and configured for easy handheld operation by a clinician. In some embodiments, a display 36 may be provided for displaying information to a clinician during treatment.

[0090] In some embodiments, the information provided on the display 36 may include treatment delivery information (e.g. quantitative information describing the energy being delivered to the treatment element) and/or feedback information from sensors within the device and/or within the treatment element. In some embodiments, the display may provide information on physician selected parameters of treatment, including time, power level, temperature, electric impedance, electric current, depth of treatment and/or other selectable parameters.

[0091] In some embodiments, the handle section 34 may also comprise input controls 38, such as buttons, knobs, dials, touchpad, joystick, etc. In some embodiments, controls may be incorporated into the display, such as by the use of a touch screen. In further embodiments, controls may be located on an auxiliary device which may be configured to communicate with the treatment device 30 via analog or digital signals sent over a cable 40 or wirelessly, such as via BLUETOOTH, WI-FI (or other 802.11 standard wireless protocol), infrared or any other wired or wireless communication method.

[0092] In some embodiments the treatment system may comprise an electronic control system 42 configured to control the timing, location, intensity and/or other properties and characteristics of energy or other treatment applied to targeted regions of a nasal passageway. In some embodiments, a control system 42 may be integrally incorporated into the handle section 34.

Alternatively, the control system 42 may be located in an external device which may be configured to communicate with electronics within the handle section 34. A control system may include a closed-loop control system having any number of sensors, such as thermocouples, electric resistance or impedance sensors, ultrasound transducers, or any other sensors configured to detect treatment variables or other control parameters.

[0093] The treatment system may also comprise a power supply 44. In some embodiments, the power supply 44 may be integrally incorporated within the handle section 34. In alternative embodiments, the power supply 44 may be external to the handle section 34. An external power supply 44 may be configured to deliver power to the handle section 34 and/or the treatment element 32 by a cable or other suitable connection. In some embodiments, the power supply 44 may include a battery or other electrical energy storage or energy generation device. In other embodiments, the power supply 44 may be configured to draw electrical power from a standard wall outlet. In some embodiments, a power supply 44 may also include a system configured for driving a specific energy delivery technology in the treatment element 32. For example, the power supply 44 may be configured to deliver a radio frequency alternating current signal to an RF energy delivery element.

[0094] Alternatively, the power supply 44 may be configured to deliver a signal suitable for delivering ultrasound or microwave energy via suitable transducers. In further alternative embodiments, the power supply 44 may be configured to deliver a high-temperature or low-temperature fluid (e.g. air, water, steam, saline, or other gas or liquid) to the treatment element 32 by way of a fluid conduit.

[0095] In some embodiments, the treatment element 32 may have a substantially rigid or minimally elastic shape sized and shaped such that it substantially conforms to an ideal shape and size of a patient's nasal passageway and/or upper airway. In some embodiments, the treatment element 32 may have a curved shape, either concave or convex with respect to the interior of the lateral wall of the nasal passage and/or upper airway.

[0096] In some embodiments, the treatment element 32 may be configured to deliver energy (e.g. heat, RF, ultrasound, microwave) or cryo-therapy uniformly over an entire outer surface of the treatment element, thereby treating all nasal and/or upper airway tissues in contact with the

treatment element 32. Alternatively, the treatment element 32 may be configured to deliver energy at only selective locations on the outer surface of the treatment element 32 in order to treat selected regions of upper airway tissues. In such embodiments, the treatment element 32 may be configured so that energy being delivered to selected regions of the treatment element 32 can be individually controlled. In some embodiments, portions of the treatment element 32 are inert and do not deliver energy to the tissue. In further alternative embodiments, the treatment element 32 may be configured with energy-delivery (or removal) elements distributed over an entire outer surface of the treatment element 32. The control system 42 may be configured to engage such distributed elements individually or in selected groups so as to treat only targeted areas of the upper airway passageway.

[0097] In some embodiments, the treatment element 32 may be configured to deliver heat energy to the upper airway tissues. In such embodiments, the treatment element 32 may comprise any suitable heating element available to the skilled artisan. For example, the treatment element 32 may comprise electrical resistance heating elements. In alternative embodiments, the heating element may comprise conduits for delivering high-temperature fluids (e.g. hot water or steam) onto the tissue. In some embodiments, a high-temperature fluid heating element may comprise flow channels which place high-temperature fluids into conductive contact with tissues (e.g. through a membrane wall) without injecting such fluids into the patient's nose. In further embodiments, any other suitable heating element may be provided. In further embodiments, the treatment element 32 may comprise elements for delivering energy in other forms such as light, laser, RF, microwave, cryogenic cooling, DC current and/or ultrasound in addition to or in place of heating elements. In alternative embodiments, similar effects can be achieved through the use of energy removal devices, such as cryogenic therapies configured to transfer heat energy out of selected tissues, thereby lowering the temperature of targeted tissues until a desired level of tissue modification is achieved.

[0098] In some embodiments, the treatment element 32 may be an inflatable balloon with energy delivery elements that deliver heat by circulating a fluid of elevated temperature though the inflated balloon during treatment. The balloon can also deliver cryotherapy (e.g. by circulating a low-temperature liquid such as liquid nitrogen) while it is enlarged to increase the surface area of contact between the treated tissue and treatment element 32.

[0099] Several embodiments may be employed for delivering energy treatment over a desired target area. For example, in some embodiments, a laser treatment system may treat a large surface area by scanning a desired treatment pattern over an area to be treated. In the case of microwave or ultrasound, suitably configured transducers may be positioned adjacent to a target area and desired transducer elements may be activated under suitable depth focus and power controls to treat a desired tissue depth and region. In some embodiments, ultrasound and/or microwave treatment devices may also make use of lenses or other beam shaping of focusing devices or controls. In some embodiments, one or more electrical resistance heating elements may be positioned adjacent to a target region, and activated at a desired power level for a therapeutically effective duration. In some embodiments, such heating elements may be operated in a cyclical fashion to repeatedly heat and cool a target tissue. In other embodiments, RF electrodes may be positioned adjacent to and in contact with a targeted tissue region. The RF electrodes may then be activated at some frequency and power level therapeutically effective duration. In some embodiments, the depth of treatment may be controlled by controlling a spacing between electrodes. In alternative embodiments, RF electrodes may include needles which may puncture a nasal or upper airway tissue to a desired depth (as shown for example in FIG. 10 and in other embodiments below).

[0100] In some embodiments, the treatment element 32 and control system 42 may be configured to deliver treatment energy or cryotherapy to a selected tissue depth in order to target treatment at specific tissues. For example, in some embodiments, treatments may be targeted at completely inactivating mucus producing cells. In other embodiments, treatments may be targeted at modifying the mucus production capacity of these cells.

[0101] In some embodiments, the treatment element 32 and control system 42 may be configured to deliver treatment energy to create specific localized tissue damage or ablation, stimulating the body's healing response to create desired conformational or structural changes that reduces the mucus producing ability of the mucus producing cells.

[0102] In some embodiments, the treatment element 32 and control system 42 may be configured to create specific localized tissue damage or ablation without the application of energy. For example the treatment element 32 may be configured to chemically cauterize tissue

in an upper airway passage by delivering a cauterizing agent (e.g., silver nitrate, trichloroacetic acid, cantharidin, etc.) to the tissue. The treatment element 32 may comprise apertures configured to permit the cauterizing agent pass through to the upper airway. In some embodiment, the treatment element 32 may aerosolize the cauterizing agent. Other delivery methods are also contemplated. The treatment element 32 may comprise a lumen through which the cauterizing agent passes. The lumen may be fluidly connected to a reservoir or container holding the cauterizing agent. The device may comprise an input control (e.g., a button or switch) configured to control the delivery of the cauterizing agent. In some embodiments, the treatment element 32 comprises an applicator that can be coated in a cauterizing agent (e.g., dipped in a reservoir of cauterizing agent, swabbed with cauterizing agent, etc.) and the coated treatment element applicator may be applied to tissue to be treated. In some embodiments, the treatment element 32 may be configured to apply cauterizing agent to the patient over a prolonged period of time (e.g., 30 seconds, 1 minute, 2 minutes, etc.). In some embodiment, the treatment element 32 comprises shields configured to protect tissue surrounding the tissue to be treated from coming into contact with the cauterizing agent. In some embodiments, a separate element is used to shield tissue surrounding the tissue to be treated from coming into contact with the cauterizing agent. While such treatments may be performed without the application of energy, in some embodiments, they are performed in conjunction with energy treatments.

[0103] In some embodiments, the treatment device 30 is configured to position tissue to be treated. In some embodiments, the device 30 comprises features and mechanisms to pull, push or position the upper airway tissue into a placing such that it is accessible to the device 30. For example, suction, counter traction, or compression between two parts of the device 30 may be used.

[0104] In some embodiments, the treatment device 30 comprises one, two, three, four, or more molds configured to position tissue. The mold or positioning element may be fixed in size or may vary in size. The mold may also be fixed in shape or may vary in shape. For example, the size or shape of the element may be varied or adjusted to better conform to an upper airway passage of a patient. Adjustability may be accomplished using a variety of means, including, for example, mechanically moving the mold by way of joints, arms, guidewires, balloons, screws,

stents, and scissoring arms, among other means. The mold may be adjusted manually or automatically.

[0105] In some embodiments, the treatment device 30 may be configured to heat specific tissue while maintaining a relatively lower temperature in other adjacent tissue. It may be beneficial to confine heat energy applied to mainly the tissue to be treated. Adjacent tissues such as a basement membrane and skin may be maintained at different temperatures. Limiting unwanted heating of non-target tissues may allow trauma and pain to be reduced, may reduce scarring, may preserve tissue function, and may also decrease healing time. Combinations of heat transfer and/or heat isolation may allow directed treatment of specific tissue such as cells, while excluding another tissue, such as skin, without surgical dissection.

[0106] In some embodiments, the mold or positioning element comprises a separate or integrated energy delivery or treatment element 32 (e.g., an electrode such as those described below with respect to FIGS. 12A–E). The treatment element 32 may be fixed or adjustable in size.

[0107] For example, the treatment element 32 may be adjusted to better conform to the upper airway passage of a patient. In the case of a separate positioning element and treatment element 32, a distance between the two elements may either be fixed or adjustable. Adjustability may be accomplished using a variety of means, including, for example, mechanically moving the mold by way of joints, arms, guidewires, balloons, screws, stents, and scissoring arms, among other means. In some embodiments, the mold or another part of the device 30 is configured to deliver cooling (discussed in more detail below). In some embodiments, the mold or repositioning element comprises a balloon configured to reposition and/or modify tissue. A balloon may also be configured to deliver energy such as heat using hot liquid or gas.

[0108] In some embodiments (e.g., as shown in FIG. 6) the treatment element 32 may comprise a substantially cylindrical central portion with a semi-spherical or semi-ellipsoid or another shaped end-cap section at proximal and/or distal ends of the treatment element 32. In alternative embodiments, the treatment element may comprise a substantially ellipsoid shape as shown, for example in FIGS. 7–10.

[0109] FIG. 7 is a perspective diagram of a treatment portion shape for a treatment portion 46 of a mucus reduction treatment device, according to one embodiment. In some embodiments, the treatment portion 46 may be an ellipsoid balloon having an asymmetrical shape. In alternative embodiments, the treatment portion 46 may have an asymmetrical "egg-shape" with a large-diameter proximal end and a smaller diameter distal end. Any suitable solid or expandable medical balloon material and construction available to the skilled artisan may be used.

[0110] FIG. 8 is a perspective illustration of a treatment portion 48 of a mucus reduction treatment device, according to an alternative embodiment. The treatment portion 48 may be configured to deliver energy to an interior of an upper airway. In some embodiments, the treatment element 48 may include an expandable balloon.

[0111] FIG. 9 is a perspective illustration of a bifurcated treatment element 70 of a mucus reduction treatment device, according to another alternative embodiment. The bifurcated treatment element 70 may have a pair of semi-ellipsoid elements 72, 74 sized and configured to be inserted into the nose with one element 72, 74 on either side of the septum. The elements may each have a medial surface 75a and 75b, which may be substantially flat, curved or otherwise shaped and configured to lie adjacent to (and possibly in contact with) the nasal septum. In some embodiments, the elements 72, 74 may include expandable balloons with independent inflation lumens 76, 78. In alternative embodiments, the elements 72, 74 have substantially fixed non-expandable shapes. In still further embodiments, the elements 72, 74 may include substantially self-expandable sections. In some embodiments, the bifurcated treatment element halves 72, 74 may also carry energy delivery structures as described elsewhere herein. In some embodiments, the shape of the elements 72, 74 may be modified by the operator to impart an optimal configuration to the treated tissue.

[0112] Some embodiments of treatment elements may comprise one or more inflatable or expandable sections configured to expand from a collapsed configuration for insertion into the nasal passageway and/or throat, to an expanded configuration in which some portion of the treatment element contacts and engages an internal surface of an upper airway. In some embodiments, an expandable treatment element may comprise an inflation lumen configured to facilitate injection of an inflation medium into an expandable portion of the treatment element. In

alternative embodiments, an expandable treatment element may comprise one or more segments comprising a shape-memory alloy material which may be configured to expand to a desired size and shape in response to a change of temperature past a transition temperature. In some embodiments, such a temperature change may be brought about by activating an energy-delivery (or removal) element in the treatment element.

[0113] In some embodiments, the treatment element may expand with various locations on the element expanding to different configurations or not expanding at all to achieve a desired shape of the treatment element. In some embodiments, such expandable treatment elements or sections may be elastic, inelastic, or pre-shaped. In some embodiments, expandable treatment elements or sections thereof may be made from shape-memory metals such as nickel-cobalt or nickel-titanium, shape memory polymers, biodegradable polymers or other metals or polymers. Expandable balloon elements may be made of any elastic or inelastic expandable balloon material.

[0114] FIG. 10 is a cross-sectional view of a distal end 80 of a treatment portion 82 of a treatment device, showing microneedles 84 puncturing tissue 86 in order to apply treatment at a desired tissue depth, according to one embodiment.

[0115] Treatment elements may be generally configured to be used once and removed from a patient's upper airway once a treatment is delivered. In some embodiments, treatments may further involve placing longer term treatment elements, such as stents, molds, external strips, etc. for a period of time after treatment.

[0116] FIG. 11 is a perspective view of an energy delivery balloon 92, including a needle portion 94 being inserted into a nose 90, according to one embodiment.

Examples of Various Electrode Arrangements

[0117] Described below are embodiments of various treatment devices and, more particularly, electrode arrangements that may be used for applying energy to the upper airway. These electrodes may, for example, deliver RF energy to modify properties of mucus producing cells and/or glands to reduce mucus production. In some embodiments, one or more electrodes may be used alone or in combination with a tissue positioning device or mold.

[0118] In other embodiments, one or more electrodes may be integrally formed with a tissue positioning device or mold, so that the electrodes themselves hold the position of the tissue. In some embodiments, the energy delivery devices may use alternating current. In some embodiments, the energy delivery devices may use direct current. In certain such embodiments, the energy delivery device may comprise a configuration using a grounding pad.

[0119] In some embodiments, the term "electrode" refers to any conductive or semi-conductive element that may be used to treat the tissue. This includes, but is not limited to metallic plates, needles, and various intermediate shapes such as dimpled plates, rods, domed plates, blades, etc. Electrodes may also be configured to provide tissue deformation in addition to energy delivery. Unless specified otherwise, electrodes described can be monopolar (e.g., used in conjunction with a grounding pad) or bipolar (e.g., alternate polarities within the electrode body, used in conjunction with other tissue-applied electrodes). In some embodiments, "counter-traction" refers to applying a force opposite the electrode's primary force on the tissue to increase stability, adjustability, or for positioning tissue.

[0120] FIGS. 12A–E are cross-sectional views of various electrode arrangements for applying energy to the treatment tissue in the nose or throat according to various embodiments. As shown in FIG. 12A, in some embodiments, bipolar electrodes may be used to deliver energy, with one electrode 202 placed internally in the nose or throat, and one electrode 204 placed externally on the outside of the nose or throat. This embodiment may advantageously provide direct current flow through the tissue with no physical trauma from needles (as shown in some embodiments below).

[0121] As shown in FIG. 12B, in some embodiments, bipolar electrodes may be used to deliver energy, with both electrodes 210, 212 placed internally. An insulating spacer 214 may be placed between them. This embodiment may be simple and may advantageously minimize current flow through the skin layer.

[0122] FIG. 12C illustrates certain embodiments wherein bipolar electrodes 220, 222 may be both placed externally and may be connected to a passive positioning element 224 placed inside the nose or throat, adjacent to tissue to be treated. This embodiment may advantageously minimize the potential for mucosal damage. In some embodiments, electrodes placed internally

may be shaped to function as a positioning element or may comprise an additional structure that may function as a positioning element.

[0123] FIG. 12D illustrates certain embodiments wherein a monopolar electrode 230 may be used to deliver energy. The electrode 230 may be placed internally and may be connected to an external, remote grounding pad 232. The grounding pad 232 may, for example, be placed on the abdomen of a patient or in other desired locations. This embodiment may advantageously be simple to manufacture and may minimize current flow through the skin. In some embodiments, a monopolar electrode may be placed externally and may be connected to a positioning element placed inside the nose or throat as well as a remote grounding pad. This embodiment may also advantageously be simple to manufacture, may minimize mucosal current flow, and may also be simple to position. In some embodiments, electrodes placed internally may be shaped to function as a positioning element or may comprise an additional structure that may function as a positioning element.

[0124] FIG. 12E illustrates certain embodiments wherein monopolar transmucosal needle electrodes 240 may be used to deliver energy. The needle electrodes 240 may be placed internally and penetrate through the mucosa to the cartilage. A remote grounding pad 242 or element may be placed externally. In some embodiments, monopolar transmucosal needles may be used in conjunction with one or more positioning elements which may be disposed on or around the needles. In some embodiments, monopolar transdermal needles may be used to deliver energy. In other embodiments (not shown), the needles may be placed external to the nose or throat, and penetrate through to tissue to be treated. Needle configurations may advantageously target the upper airway tissue to be treated specifically. The monopolar transdermal needles may be used in conjunction with an internal positioning device (not shown).

[0125] In some embodiments, bipolar transmucosal needles may be used to deliver energy to tissue to be treated. The needles may be placed internally, with an insulating spacer between them and may penetrate through cell membrane to the mucins and/or Rab and/or other exocytosis components to be treated. In some embodiments, the bipolar transmucosal needles may be used in combination with one or more internal positioning elements. The one or more positioning elements may be placed on or near the needles. In some embodiments, bipolar transdermal

needles may be used to deliver energy. In other embodiments, the transdermal needles may be placed externally and penetrate through to tissue to be treated. Needle configurations may advantageously target the mucus producing cells to be treated specifically. The transdermal bipolar needles may be used in conjunction with an internal positioning element.

[0126] FIG. 13 is a perspective view of an electrode arrangement of a treatment element 250 according to one embodiment. An array of electrodes comprising one, two, or many pairs of bipolar needles 252 may be located on the treatment element 250 and be configured to be placed into contact with the mucus producing cells. An insulator 254 may be disposed between the bipolar needles 252. An insulator may also be used on part of the needle's length to allow energy to be delivered only to certain tissue structures, such as mucus producing cells. The electrodes may be placed either internally or transmucosally or they may be placed externally or transdermally. In some embodiments, the insulator 254 may also function as a positioning element. In other embodiments (not shown), the array of electrodes may be used in conjunction with a separate tissue positioning element.

[0127] FIG. 14 is a perspective view of an electrode arrangement of a treatment element 256 according to one embodiment. The treatment element 256 may comprise one, two or many pairs of bipolar electrodes 258. An insulator 260 may be disposed between the bipolar electrodes 260. As opposed to the electrode arrangement shown in FIG. 13, where the pairs of electrodes are arranged side-by-side, the embodiment of FIG. 14 arranges the pairs of electrodes 258 along the length of the treatment element 256. In some embodiments, the electrodes may be non-penetrating, in contrast to the needles 252 of FIG. 13. The electrodes 258 may be placed against either the skin, externally, or the mucosa, internally as a means of delivering energy to target tissue such as mucus producing cells.

[0128] In some embodiments of treatment devices comprising an array or multiple pairs of electrodes, each pair of electrodes (bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. For example, in some embodiments, needles or needle pairs may be individually controlled to produce an optimal treatment effect. For another example, in some embodiments, separate electrodes (e.g. those of FIGS. 12B and 12C) may be individually

controlled to produce an optimal treatment effect. Other examples are also contemplated. The channels may also comprise separate or integrated feedback. This may advantageously allow for more accurate temperature control and more precise targeting of tissue. Separate control may also allow energy to be focused and/or intensified on a desired region of the treatment element in cases where the anatomy of the upper airway tissue/structures does not allow the entire electrode region of the treatment element to engage the tissue. In such embodiments, the upper airway tissue that is in contact with the treatment element may receive sufficient energy to treat the tissue.

[0129] FIGS. 15A–C are cross-sectional views of various electrode arrangements for applying energy to the treatment tissue in the nose or throat according to various embodiments. Combinations of the described electrode configurations may be used to deliver energy to tissue to be treated. For example, FIG. 15A illustrates internally-placed transmucosal needles 264 penetrating through to tissue to be treated and an external electrode 266 according to one embodiment. This embodiment may advantageously target the mucus producing and/or controlling cells specifically and be biased for mucosal preservation.

[0130] FIG. 15B illustrates externally-placed transdermal needles 268 and an internally-placed electrode 270 according to one embodiment. This embodiment may advantageously target the mucus producing and/or controlling cells specifically and be biased towards skin preservation.

[0131] FIG. 15C illustrates bipolar needle electrodes 272, 274 be placed both transdermally or externally and transmucosally or internally according to one embodiment. This embodiment may advantageously target the mucus producing cells specifically. Some embodiments of treatment elements may include inert areas which do not delivery energy to the tissue. Other combinations of electrode configuration are also possible.

Multi-channel configuration

[0132] During treatment, each pair of electrodes may have varying degrees of contact with the tissue, depending on the skills and habits of the device user. For a configuration in which all pairs of electrodes are controlled by one main electrical channel, this can lead to varying magnitudes of treatment energy passing through each electrode pair.

[0133] The pair/pairs of electrode that has/have a higher degree of contact with the tissue, will experience higher magnitudes of impedance in their/its individual circuit. Since treatment energy takes the path of least resistance, this can lead to treatment energy being diverted to the other pair/pairs of electrodes that experiences/experience a relatively lower magnitude of impedance due to relatively lower degrees of tissue contact.

[0134] This creates a situation in which the treatment energy flowing through each pair of electrodes is not repeatable due to the electrodes-tissue contact being user dependent. To ensure a greater degree of control and accuracy over the treatment energy through each electrode, each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. Each electrode pair may also be paired up with its own thermocouple.

[0135] An intermittent electrode-tissue contact may also result in coagulum forming due to fluctuating waveform. When electrode-tissue contact is intermittent, the impedance value fluctuates and the power delivered also has to adapt rapidly in order to reach or maintain set temperature. This may be conducive for coagulum to form on the electrode, causing impedance to rise. This starts a cycle of escalating power delivered and impedance increment with coagulum build up on the electrodes, causing the treatment process to be less effective. Hence, there is a need for a system set up which ensures repeatable and controllable delivery of treatment energy to each electrode pair in order to achieve the desired surgery outcome. The system may comprise one or more thermocouples and an RF output channel assigned to each electrode pair for feedback.

[0136] FIGS. 16A–I are cross-sectional views of various permutations of electrodes-thermocouples combinations for a multi-channel configuration according to various embodiments. FIG. 16A illustrates a cross-sectional view of an electrode arrangement according to one embodiment, including a row of positive electrodes spaced from a row of negative electrodes and a row of thermocouples, including electrode 363 and electrode 364. A pair of electrodes 363, 364 may have its own individual subsystem 360 of controlled RF output channel 361 and thermocouple 362 to allow for independent adjustments. The thermocouple 362 act as a feedback-control to ensure that proper temperature is maintained at the site of surgery.

[0137] In certain implementations, the nasal treatment device may include one or more thermocouples 362 and an RF output channel 361 assigned to each electrode pair for feedback. An electrode pair may include a positive electrode 363 and a negative electrode 364. In some embodiments, the positive electrode 363 and the negative electrode 364 may be positioned opposite to one another. Each electrode pair may have its own individual subsystem 360. The individual subsystem 360 may include a controlled RF output channel 361 and a thermocouple 362 to allow for independent adjustments. The thermocouple 362 may act as a feedback control to ensure that proper temperature is maintained at the site of treatment.

[0138] FIG. 16B illustrates a cross-sectional view of an electrode arrangement according to one embodiment that provides a means to allow pairing of any of the positive electrode to any of the negative electrode to form a complete circuit. A positive electrode 363 may be paired with the opposite negative electrode (e.g., as shown in FIG. 16A) or to any of the other negative electrodes (e.g. negative electrode 364) regardless of its location in the device. The device may include a plurality of thermocouples 362 and an RF output channel 361 assigned to each pair of electrodes for feedback. Temperature readings from two adjacent thermocouples 362 may be averaged to obtain a temperature reading for the region in which the circuit is located. In some embodiments, the two thermocouples 362 may be the thermocouples in the closest proximity to the positive electrode 363 and the negative electrode 364.

[0139] FIG. 16C illustrates a cross-sectional view of an electrode arrangement according to one embodiment. In certain embodiments, the electrode array may be arranged such that each electrode pair of the array of electrodes may have its own individual subsystem 370. An electrode pair may include a positive electrode 373 and a negative electrode 374. Each individual subsystem 370 may include controlled RF channels 371, a first thermocouple 372a, and a second thermocouple 372b to allow for independent temperature readings and/or individual temperature adjustments. In certain implementations, the temperature input signals sensed from neighboring thermocouples 372a and 372b are electronically subtracted from each other and act as a feedback-control to ensure that proper temperature is maintained at the treatment site. In certain implementations, a temperature reading for an individual subsystem 370 may be obtained from the average temperature input signals of the neighboring thermocouples 372a and 372b. The

temperature reading may act as a feedback control to ensure that proper temperature is maintained at the treatment site.

[0140] FIGS. 16D and 16E illustrate a cross-sectional view of an electrode arrangement according to various embodiments. In certain implementations, a device may include multiplexed configurations by providing functionality to allow pairing of any of the positive electrodes 373 to any of the negative electrodes 374 to form a complete circuit. A positive electrode 373 may be paired with the opposite negative electrode 374, or to any of the other negative electrodes 374 regardless of its location in the device. FIG. 16D shows one example where temperature readings may be the average of three adjacent thermocouples 372a, 372b, and 372c. FIG. 16E shows one example where temperature reading may be the average of four adjacent thermocouples 372a, 372b, 372c, and 372d. It will be appreciated that the average of any number of thermocouples may be used to obtain a temperature reading.

[0141] FIG. 16F illustrates a cross-sectional view of an electrode arrangement according to one embodiment. In certain implementations, the positive electrodes 383 may be configured to share a common negative electrode 384. While the negative electrode 384 is common, each positive electrode 383 may be independently controlled to achieve desired treatment. In some embodiments, a temperature reading may be obtained from temperature input signals sensed from one or more thermocouple 382. In certain implementations, each RF output channel may comprise a positive electrode and the negative electrode.

[0142] FIG. 16G illustrates a cross-sectional view of an electrode arrangement according to one embodiment. In certain implementations, all the positive electrodes 393 may share a common negative electrode 394.

[0143] FIG. 16H illustrates a cross-sectional view of an electrode arrangement according to one embodiment. In some embodiments, the positive electrodes 393 of the array of electrodes may share a common negative electrode 394. Each RF output channel may include a positive electrode 393 and the negative electrode 394. While the negative electrode 394 is common, each positive electrode 393 may be independently controlled to achieve the desired treatment. In some embodiments, a temperature reading may be obtained from temperature input signals sensed from one or more thermocouples 392.

[0144] FIG. 16I illustrates a cross-sectional view of an electrode arrangement according to one embodiment. In this configuration there are two rows with the same polarity and a third row with a different polarity. For example, as shown in FIG. 16I, the outer rows of electrodes 397 have a positive polarity and the inner row of electrodes 398 has a negative polarity. Interspersed between the rows are a first and second row of thermocouples 396. This configuration may affect a larger area than other configurations.

Examples of Treatment Devices Including Electrodes

[0145] Embodiments of treatment devices incorporating treatment elements such as the electrodes described above are illustrated in FIGS. 17–19B. The designs described in these embodiments may be used in various devices, for example the device 30, described above. In certain embodiments, the devices provide tissue modification via energy delivery. Applying energy to the upper airway may require properly positioning the electrode(s) at the region to be treated, and delivering or applying energy consistently prior to device removal. Embodiments described herein may advantageously provide adjustability, visualization of effect, ease of use, ease of manufacturability and component cost.

[0146] FIG. 17 is a perspective view of a device 300 for applying energy to upper airway tissues using monopolar electrodes according to one embodiment. The device 300 may comprise a single inter-nasal monopolar electrode 301 located at the end of a shaft 302. A handle 303 may be attached to the shaft. In certain implementations, the electrode configuration may be similar to that described with respect to FIG. 12D.

[0147] FIG. 18 is a perspective view of a device 304 for applying energy to upper airway tissues using monopolar electrodes according to one embodiment. In certain implementations, the device 304 may comprise a single inter-nasal, monopolar electrode 305. The electrode 305 is located at the distal end of a shaft 306, which is attached to a handle 307. The handle 309 comprises a power button 308 that may be used to activate and deactivate the electrode. As stated above, the device 304 may either comprise a generator or be connected to a remote generator. The electrode 305 may be provided on an enlarged, distal end of the shaft 306.

[0148] FIG. 19A is a perspective view of a device 347 for applying energy to the upper airway tissues using a bipolar electrode according to one embodiment. FIG. 19B illustrates an

enlarged perspective view focusing on the treatment portion 350 of the device 347. In certain implementations, the device 347 may include a handle 348, a shaft 349, a treatment portion 350, radiofrequency electrodes 352 (such as bi-polar electrodes), a trough 354, and a thermocouple 356.

[0149] The handle 348 may be an area by which the device 347 may be held. The proximal end of the shaft 349 may be connected to the distal end of the handle 348.

[0150] The shaft 349 may be an elongate member extending from the handle 348. In certain implementations, the shaft 349 may be adjustable or otherwise malleable. For example, in certain implementations, the shaft 349 may be malleable or otherwise able to be formed into a particular shape and substantially retain the shape. The adjustability of the shaft 349 may enable a clinician to re-shape the shaft 349 to improve the ability of the device 347 to navigate nasal or other anatomy. The adjustability may also enable the electrodes 352 to be positioned to contact tissues to be treated.

[0151] The treatment portion 350 has tissue contact surface (or "treatment surface"), which is the surface of the treatment portion 350 that includes the multiple features for addressing and treating tissue, such as mucosal tissue. The treatment surface of the treatment portion 350 includes the concave-shaped trough 354 and two rows of electrodes 352 separated by the thermocouple 356, which is disposed within the trough 354. The electrodes 352 and the thermocouple 356 are both raised off of the treatment surface in this embodiment. However, other configurations are also possible (see, e.g., FIGS. 16A–I for other configurations of electrodes and thermocouples). In certain implementations, the treatment portion 350 may also be adjustable. For instance, the treatment portion 350 may be capable of being bent, twisted, rotated, flexed, or otherwise articulated to facilitate treatment.

[0152] In various alternative embodiments, the electrodes 352 may be replaced with any other suitable treatment delivery members. In various embodiments, for example, other forms of energy may be delivered by alternative energy delivery members. Such energy forms may include, but are not limited to, ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy. In another alternative embodiment, energy may be removed from tissue by the treatment portion 350, via one or more cryotherapy members on the tissue contact surface. In yet

other embodiments, the treatment portion 350 may include one or more substance delivery members. In certain implementations, the treatment portion 350 may be flush with the shaft 349, be an area of increased diameter of the shaft 349, or a combination thereof. In certain implementations, the treatment portion 350 may extend laterally from the distal end of the shaft 349.

[0153] The electrodes 352 may be recessed from, flush with, and/or protrude from the treatment portion 350. The electrodes 352 may extend substantially perpendicularly from the treatment portion 350 and/or may extend at a non-perpendicular angle. The rows of electrodes 352 may, but need not, extend parallel to each other. In certain implementations, one or more electrodes 352 may be designed to avoid puncturing tissue (e.g. by having blunt, rounded, or otherwise atraumatic tips). In certain other implementations, one or more electrodes 352 may be designed to puncture tissue.

[0154] The trough 354 may be an elongate, concave channel that runs substantially along the length of the treatment portion 350. In certain implementations, the trough 354 may be sized to or otherwise configured to match the size and/or shape of a nasal turbinate, such as the inferior nasal concha.

[0155] The thermocouple 356 may be one or more sensors configured to gather one or more temperature readings of tissue during operation of the device 347. In certain implementations, the thermocouple 356 may rest substantially flush with the trough 354. In certain other implementations, the thermocouple 356 may protrude from the trough 354. In certain embodiments, the protrusion may be slight, such that the thermocouple 356 remains within the trough 354, in other embodiments, the thermocouple 356 may extend out of the trough 354.

[0156] The electrodes 352 and the thermocouple 356 may be connected with a device control system connected integrated with or attached to the device 347. For example, the device 347 may comprise a generator or a means for connecting to a remote generator. This connection may be established through wires extending the length of the shaft 349 to a connection within a handle of the device 347.

[0157] FIG. 20 is a flow diagram of an example method 500 of use of various devices, including the device 347. In certain implementations, the method 500 may include preparing the

device 502, advancing a portion of the device to a treatment site 504, delivering therapy to the treatment site 506, and removing the treatment device 508.

[0158] In certain implementations, the method 500 may start at the step of preparing the device 502. Preparing the device 502 may include removing the device from sterile packaging, assembling one or more components of the device, sterilizing the device, attaching the device to an energy source, and/or other preparatory work. In certain implementations, this step may include customizing the device to suit the particular needs of the patient and the clinician. This may include articulating, manipulating, or otherwise changing one or more components of the device. For example, a clinician may articulate or bend the shaft 349 and/or the treatment portion 350 to place the device in a first, desired configuration. The first, desired configuration may be selected to facilitate navigation of the nasal anatomy of the particular patient to reach the desired treatment site.

[0159] In certain circumstances, preparing the device 502 may follow removing the treatment device 508. For example, the clinician may determine that the device is not suitable in its current state, remove the device, and then reconfigure the device in a more suitable format (e.g. a second configuration).

[0160] Advancing a portion of the device to a treatment site 504 may follow the preparation of the device 502. For example, the clinician may navigate the patient's nasal anatomy with the device 347 in the first configuration. Specifically, the clinician may advance a treatment portion of the treatment device into a nostril of the patient to contact a treatment surface of the treatment portion with mucosal tissue of the upper airway. This step 504 may be performed without piercing the mucosal tissue. The goal of the navigation may be to place the treatment element in contact with the treatment site.

[0161] In certain circumstances, advancing a portion of the device to a treatment site 504 may follow the removal of the treatment device 508. In this circumstance, this step may include the clinician wholly or partially re-navigating the device through the nasal anatomy to improve, for example, contact between the treatment portion 350 and the treatment site.

[0162] During navigation, the clinician may perform one or more tests to determine whether proper contact with the treatment site has been made. For example, the clinician may activate

one or more pairs of the electrodes (such as electrodes 352). Based on measured results, the clinician may determine that proper contact has not been achieved because an energy pathway could not be made between one or more pairs of electrodes and/or that one or more measured electrical parameters (e.g., impedance, voltage, current, etc.) is outside of a desired range. As another example, the clinician may attempt to apply pressure to the treatment site with the treatment portion 350 and determine by feel whether proper contact has been made. As yet another example, the clinician may take a reading using a thermocouple (such as thermocouple 356) to determine whether proper contact has been made.

[0163] Based on the one or more tests, the clinician may determine that proper contact has been made between the treatment portion and the treatment site. In this situation, the flow may move to the step of delivering therapy to the treatment site 506. In certain circumstances, the clinician may determine that proper contact has not been made or that the device is otherwise unsuitable in its current state. In this situation, the flow may move to the step of removing the treatment device 508.

[0164] Delivering therapy to the treatment site 506 may follow advancing a portion of the device to a treatment site 504. In this step, the clinician may cause the device to apply energy to the treatment site. For example, in certain implementations, a clinician may use the device to apply energy to the posterior aspect of the inferior turbinate. For this treatment, it may be desirable to press the treatment portion against the tissue of the posterior aspect of the inferior turbinate such that the tissue substantially conforms to the shape of the treatment element.

[0165] For instance, a concave shape may be formed on the tissue turbinate against the convex shape of the treatment portion 350 of device 347. The electrodes 352 may create indentations within the tissue. A portion of the tissue may be enter and conform to the shape of the trough 354 and contact the thermocouple 356. While the tissue is in this configuration, the clinician may activate one or more pairs of electrodes 352 to deliver therapy to the treatment site. In certain implementations, delivering therapy to the treatment site 506 may include delivering radiofrequency energy from a first electrode on the treatment portion 350 across the trough 354 of the treatment portion 350 to a second electrode on the treatment portion 350, to treat at least one tissue selected from the group of the mucosal tissue and another tissue underlying the

mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.

[0166] The step of removing the treatment device 508 may follow from the step of advancing a portion of the device to a treatment site 504 and/or delivering therapy to the treatment site 506. In certain circumstances, the clinician may remove part or all of the device from the nasal anatomy of the patient. The clinician may determine that one or more further adjustments may improve contact between the treatment portion and the treatment site or otherwise achieve improved therapeutic results. In such circumstances, the flow may move to the step of preparing the device 502. For example, the clinician may articulate one or more components of the device to place the device in a second configuration. The clinician may then navigate the nasal anatomy again and deliver therapy to the treatment site.

[0167] When the step of removing the treatment device 508 follows from delivering therapy to the treatment site 506, the clinician may simply remove the device from the patient and end the procedure. In certain other circumstances, the clinician may partially or wholly remove the device and repeat one or more of the steps of the method 500 in order to more fully treat the treatment site and/or treat other treatment sites. In certain circumstances, the method 500 may end after step 508. While this method 500 has been described with reference to device 347, the method 500 may be used with some or all of the other devices and methods disclosed herein.

[0168] FIGS. 21A–B are perspective views of a device 310 for applying energy to the upper airway tissues using bipolar electrodes and a positioning element according to one embodiment. FIG. 21A depicts the device 310 comprising bipolar electrodes 312 located at the end of a shaft 316. The shaft 316 may be attached to a handle 314. Also attached to the handle 314 may be a grounding member 318. The shaft 316 and the grounding member 318 may be attached to the handle 314, such that one or both of the shaft 316 and the grounding member 318 may be moved relative to each other. In certain implementations, the grounding member 318 may be an external mold. The grounding probe 318 may be moved such that tissue to be treated is compressed between the grounding probe 318 and the electrode 312. In certain implementations, the grounding probe 318 may be a needle. The device 310 may be connected to a remote generator,

or may comprise a generator. A power button on the handle 316 may be used to activate and deactivate the electrodes.

[0169] FIG. 21B illustrates the device 310 being used at an inferior turbinate. Specifically, the grounding member 318 pierces the tissue of the inferior turbinate and the bipolar electrodes 312 press against the tissue. When activated, current flows from one or more of the electrodes 312 to the grounding member 318.

[0170] FIG. 22A is a perspective view of a clamp-like device 320 for applying energy to the upper airway tissues using a bipolar electrode according to one embodiment. In certain implementations, the device 320 may comprise two prongs 322, 324. The prongs 322, 324 may be flexible such that they move towards each other when compressed by an external force, and upon removal of this force, they spring back to their original positions. Bipolar electrodes 326 may be located at the end of prong 322 while prong 324 acts as an external positioning element. Prongs 322 and 324 may be moved such that tissue to be treated is compressed between the prong 324 and the electrode 326. The device 320 may be connected to a remote generator, or the device may comprise a generator. A power button on one of the prongs 322, 324 or the junction between both prongs 322, 324 may be used to activate and deactivate the electrodes 326.

[0171] FIG. 22B is a perspective view of a one-prong device 328 for applying energy to the upper airway tissues using a monopolar electrode according to one embodiment. In certain implementations, the device 328 may comprise a single prong 330. Monopolar electrodes 332 may be located at the end of the prong 330. The prong 330 is inserted into the upper airway and electrodes 332 are placed on the tissue to be treated. A grounding pad 329 may be placed on the patient's body, usually the back. The device 328 may be connected to a remote generator, or it may comprise a generator, with a power button on the prong 330 that may be used to activate and deactivate the electrodes.

[0172] FIG. 23 is a perspective view of a device 334 with concave head for applying energy to the upper airway tissues using a bipolar electrode according to one embodiment. In certain implementations, the device 334 may comprise bipolar electrodes located at the end of a shaft 336. The positive electrodes may be located on a concave surface 338 at the end of the shaft 336. A grounding ring 340 may be formed around the rim of the concave surface 338. The device 334

may be used to treat convex tissues with the tissues nestled within and compressed against the concave surface 338. The device 334 may be connected to a remote generator, or the device 334 may comprise a generator. A power button on shaft 336 may be used to activate and deactivate the electrodes. In certain implementations, the device 334 may be formed with a dome shape and have current passing from a top region to a bottom region. This may enable a maximum surface area of current flow.

[0173] FIG. 24 is a perspective view of a device 340 with grounding probes, for applying energy to the upper airway tissues using a monopolar electrode according to one embodiment. In certain implementations, the device 340 may comprise monopolar electrodes 342 located at the end of a shaft 344. The grounding probe 346 may be a needle or needles inserted into the tissue to be treated. The electrodes 342 may be compressed against the tissue to be treated. The device 340 may be connected to a remote generator, or it may comprise a generator, with a power button on shaft 344 that may be used to activate and deactivate the electrodes. It will be appreciated that any combination of electrode configurations, molds, handles, connection between handles, and the like may be used to treat the upper airway.

Profile of treatment element

[0174] The sizes and shapes of anatomies to be treated may vary at different treatment stages and also among different patients. To ensure best possible electrode-tissue contact, the treatment element 32 can be designed to be adjustable depending on the anatomy to be treated. Possible designs are mentioned below, it is also possible to have designs which are combinations of the ones mentioned. In certain implementations, the head may be designed with flexible wings, with electrodes of adjustable heights, and/or with one or more extensions.

[0175] FIG. 25 is a perspective view of a treatment device 400 with flexible wings according to one embodiment. Electrodes may be positioned on the interior or exterior or both. In the case of a convex anatomy, the wings can be adjusted to wrap around the targeted anatomy, using the electrodes on the interior. In the case of a concave anatomy, the wings can be adjusted to fit into the anatomy, using the electrodes on the exterior.

[0176] In certain implementations, the device 400 may include a treatment element 401 positioned on a head section 402 of the device 400, which may be configured to be placed inside

the nasal cavity, nasal passage, nasal airway, and/or other anatomy to deliver the desired treatment. The treatment element 401 may be positioned on an interior portion 404 and/or an exterior portion 405 of the head section 402. In some embodiments, the device 400 may further comprise a shaft section 403, which may be sized and configured for easy handheld operation by a clinician. In some embodiments, the head section 402 may be adjustable. It may be advantageous to use an adjustable head section 402 to treat anatomy that may vary in shape and size. The shape of the head section 402 or parts of the head section 402 may be actively or passively adjusted to affect the engagement to the tissue or the effect on the tissue. In some embodiments, the adjustment of the head section 402 may result in a change in shape and/or size of the interior portion 404 and/or the exterior portion 405.

[0177] The head section 402 may be implemented using flexible sections configured to be adjusted depending on the anatomy to be treated. Electrodes (not shown) may be positioned on the interior or the exterior of the flexible sections. In some embodiments, electrodes may be positioned on both the interior 404 and the exterior 405 of the flexible sections. For example, in the case of a convex anatomy, the flexible sections may be adjusted to wrap around the anatomy using electrodes on the interior 404 of the flexible sections. In the case of a concave anatomy, the flexible sections may be adjusted to fit into the anatomy using electrodes on the exterior 405 of the flexible sections. In some embodiments, the head section 402 may include functionality to inflate and deflate the flexible sections to adjust the size of a treatment surface of the device 400 in a radial direction. In some embodiments, the head section 402 may include functionality to rotate the head section 402 in any direction to allow the head section 402 to be angled in a desired position.

[0178] FIGS. 26A–F are perspective views of embodiments of the treatment device 400 with an electrode array 410 having adjustable heights. In some implementations, one or more electrodes of the electrode array 410 may have adjustable heights. For example, each electrode may extend or retract to a preset height, achieving a combination which forms the required treatment surface profile. The surface profile may be in any combination of electrode heights.

[0179] In certain implementations, the electrode array 410 may include numerous electrodes positioned on a surface of a treatment element 401 of the device 400. In some embodiments, the

electrodes may be arranged in a grid pattern. The electrodes may be arranged in any pattern. One or more of the electrodes may be extended or retracted to a preset height. It may be advantageous to manipulate the heights of the electrodes of the electrode array 410 to achieve a combination that forms a required treatment surface profile 411. The treatment surface profile 411 may include any combination of electrode numbers and heights. For example, the electrodes may be arranged and manipulated to achieve a generally concave treatment surface profile, a generally convex treatment surface profile (see, e.g., FIG. 26F and FIG. 26C), a generally flat treatment surface profile (See, e.g., FIG. 26E and FIG. 26B), and/or a generally concave treatment surface profile (see, e.g., FIG. 26D and FIG. 26A).

[0180] FIG. 27 is a perspective view of an embodiment of the treatment device 400 with an extendable component 422. The expandable component 422 may be used to adjust the size of the treatment surface of the treatment device 400. The extendable component 422 may be moved in any direction, not limited to the direction shown in FIG. 27. The number of extendable components 422 need not be limited to one.

[0181] In certain implementations, an embodiment of a nasal valve treatment device 400, comprising a first treatment element 401 and a second treatment element 421. The first treatment element 401 may be positioned on a first side of a head section 402. The first treatment element 401 may include a first electrode array 410. In some embodiments, the head section 402 may be implemented with an extendable component 422. It may be advantageous to provide an extendable component 422 to allow the size of the treatment surface 423 to be adjustable. The extendable component 422 may include a second treatment element 421, including a second electrode array 420. In some embodiments, the extendable component 422 may be positioned on a second side of the head section 402 such that it is behind the first treatment element 401. The extendable component 422 may include functionality to move such that it may be shifted from behind the first treatment element 401 of the head section 402 to adjacent to the first treatment element 401 of the head section 402. This shift may expose the second electrode array 420, thereby extending the treatment surface 423. The extendable component 422 may be moved in any direction, and the direction depicted in FIG. 27 is merely an example of one direction in which it may be moved. All adjustments can be applied before and also during treatments so as to cater to anatomy changes during treatments.

[0182] FIGS. 28A–E are side-cutaway views of treatment elements according to certain embodiments. The treatment elements may be configured to maintain different temperatures in adjacent tissues. Differential cooling mechanisms may be applied to a cross-section of tissue.

[0183] As shown in FIG. 28A, in some embodiments, the differential cooling mechanism comprises two elements: a first element 708 and a second element 710. The two elements are on either side of the thickness of the nasal tissue. In one embodiment, the mechanism is configured to maintain normal temperatures in the cartilage 704 while cooling the mucosa 702 and the skin706. In such an embodiment, the first and second elements 708, 710 comprise a cooling apparatus such as those described above (e.g., heat sink, coolant lines, etc.). In some embodiments, the mucosa 702 and the skin 706 are heated while normal temperatures are maintained in the cartilaginous middle layer 704. The cartilage 704 may be somewhat warmed, in such embodiments, but may be cooler than the mucosa 702 and the skin 706. In such embodiments, the first and second elements 708, 710 comprise a heating apparatus, such as radio frequency electrodes or resistive heating elements. Depending on the treatment target, the temperature of different layers or regions of tissue may be controlled. For example, in some embodiments, the mucosa 702 is heated, the skin 706 is cooled, and normal temperatures are maintained in the cartilage 704. In such embodiments, the first element 708 comprises a heating apparatus and the second element 710 comprises a cooling apparatus. As another example, in some embodiments, the skin 706 is heated, the mucosa 702 is cooled, and normal temperatures are maintained in the cartilage 704. In such embodiments, the first element 708 comprises a cooling apparatus and the second element 710 comprises a heating apparatus. As another example, submucosa and associated cells are heated while normal temperatures are maintained elsewhere.

[0184] FIG. 28B shows an example of one of the embodiments described with respect to FIG. 28A. The first element 730 is on the mucosal surface 702. The second element 732 is an energy delivery element and is positioned on the skin side 706 of the tissue thickness. The first element 730 comprises a cooling apparatus and the second element 732 comprises an energy delivery element (e.g., an RF electrode). The mucosal layer 702 is cooled while the skin 706 and cartilaginous areas 704 are heated. In other embodiments, the first element 730 can be positioned

on the skin 706 and the second element 732 can be positioned on the mucosa 702. In such embodiments, the skin 706 is cooled while the mucosa 702 and the cartilage 704 are heated.

[0185] As shown in FIG. 28C, in some embodiments, the differential cooling mechanism comprises a first element 720 and a second element 722. Both elements 720, 722 are on the mucosa 702 side of the tissue thickness. In some embodiments, the mucosal layer 702 is cooled while higher temperatures are maintained in the middle cartilaginous layer 704. In such embodiments, the first element 720 comprises a cooling apparatus, and the second element 722 comprises an energy delivery apparatus (e.g., a monopolar radiofrequency electrode). In some embodiments, the first element 720 is sufficiently efficient to maintain cool temperatures at the mucosa 702 despite the energy provided by the second element 722. In other embodiments, the first and second elements 720, 722 are both positioned on the skin side 706 of the tissue thickness. In such embodiments, the skin 706 is cooled while higher temperatures are maintained in the middle cartilaginous layer.

[0186] As shown in FIG. 28D, in some embodiments, the differential cooling mechanism comprises a first surface element 740 and a second surface element 742 on either side of the tissue thickness. A third subsurface element 744 is engaged through the mucosa 702 and into the cartilage area 704. In some embodiments, the mucosa 702 and the skin 706 are cooled while the middle cartilaginous layer 704 is heated. In such embodiments, the first and second elements 740, 742 comprise cooling apparatus while the third element 744 comprises a heating element (e.g., RF monopolar electrode, RF bipolar needles, etc.). In other embodiments, the third subsurface element 744 may be engaged through the skin 706 and into the cartilage area 704.

[0187] As shown in FIG. 28E, in some embodiments, the differential cooling mechanism comprises a first surface element 750 and a second surface element 752 on either side of the tissue thickness. The differential cooling mechanism further comprises a third surface element 754 and a fourth surface element 756 on either side of the tissue thickness. In some embodiments, the cartilage layer 704 is heated while the mucosa 702 and the skin 706 are cooled. In such embodiments, the first and second elements 750, 752 comprise cooling apparatus and the third and fourth elements 754, 756 comprise energy delivery apparatuses (e.g., bipolar plate electrodes). In some embodiments, the cartilage 704 and mucosal 702 layers are heated

while the skin 706 is cooled. In such embodiments, the first element 750 comprises a heating apparatus; the second element 752 comprises a cooling apparatus; and the third and fourth elements 754, 756 comprise energy delivery apparatuses. It will be appreciated that different differential temperature effects can be achieved by reconfiguring and adding or subtracting to the described configuration of elements.

[0188] FIGS. 29A–B illustrate certain implementations of a system for treating a nasal airway including one or more sensors. Such sensors may be used to sense any of a number of relevant tissue properties, such as temperature, impedance and the like. The sensors may be located on a treatment device in some embodiments, or alternatively they may be separate from the treatment device and positioned at or near the device during treatment. In some embodiments, the sensor(s) may provide feedback directly to the treatment device. For example if a particular tissue temperature threshold is reached, a sensor (or sensors) may send a signal to a power generator to shut down or decrease power delivered to a treatment device. In alternative embodiment, the sensor(s) may instead provide feedback to a physician or other user, so that the physician or other user can make treatment adjustments. For example, sensors may provide a warning signal when a particular tissue temperature or impedance is reached, which will help a physician know when to turn off or decrease power delivery to a treatment device. Additionally, sensor(s) may be used to sense one or more tissue properties in any suitable tissue or multiple tissues, such as but not limited to mucosa, cartilage, dermis, epidermis and other types of body soft tissue.

[0189] FIG. 29A is a side-cutaway view of nasal skin in cross section, including mucosa, cartilage, dermis and epidermis and a treatment device having an external component according to one embodiment. In certain implementations, a sensor device 920 may include an epidermal sensor 922 that is coupled to the epidermis via an adhesive 924. Any suitable sensor 922 (temperature, impedance, etc.) and any suitable adhesive 924 may be used. This embodiment of the sensor device 920 is also illustrated on a patient's face in FIG. 29B.

[0190] In an alternative embodiment, a sensor device 930 may include a transdermal needle sensor 932. In another alternative embodiment, a sensor device 942 may be attached directly to a treatment device 940. As illustrated by these various embodiments, sensors 922, 932 and 942 may be positioned either at or near a treatment location during a treatment. In some

embodiments, for example, a sensor 922, 932 may be placed on or in epidermis while a treatment is being performed on mucosa. Alternatively, a sensor 942 may be placed directly on mucosa during a treatment of mucosa. Additionally, in any given embodiment, multiple sensors may be placed at multiple different locations in and/or on tissue. As mentioned above, the sensor devices 920, 930 and 940 may, in various embodiments, provide any of a number of different types of feedback, such as feedback to a user, feedback to a power generator, or both.

[0191] Although this invention has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

CLAIMS

What is claimed is:

1. A method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the method comprising:

advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient;

contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and

delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.

2. The method of claim 1, wherein the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant.

3. The method of claim 1, wherein delivering the treatment comprises delivering energy from the delivery treatment portion in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy.

4. The method of claim 3, wherein delivering the treatment comprises delivering radiofrequency energy from a first electrode on a tissue contact surface of the treatment portion across a convex portion of the tissue contact surface to a second electrode on the tissue contact surface.

5. The method of claim 4, wherein contacting the mucosal tissue comprises contacting multiple non-piercing bumps on the tissue contact surface with the mucosal tissue.

6. The method of claim 3, wherein the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein delivering the energy comprises ablating the nerve tissue.

7. The method of claim 3, further comprising measuring an amount of delivered energy using a thermocouple on the treatment portion.

8. The method of claim 7, further comprising adjusting the amount of delivered energy by adjusting a setting of the treatment delivery portion.

9. The method of claim 1, wherein delivering the treatment comprises removing energy, and wherein the treatment delivery portion comprises a cryotherapy device.

10. The method of claim 9, wherein the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein removing energy comprises ablating the nerve tissue using the cryotherapy device.

11. The method of claim 1, wherein applying a treatment comprises injecting a polymerizing liquid.

12. The method of claim 1, wherein delivering the treatment comprises injuring the at least one tissue.

13. The method of claim 12, wherein delivering the treatment comprises injuring goblet cells that are part of the mucosal tissue.

14. The method of claim 12, wherein the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves, submucosal tissue, muscle, ligaments, cartilage, tendon, and skin.

15. The method of claim 1, wherein delivering the treatment comprises simultaneously mechanically altering the mucosal tissue and delivering energy to the at least one tissue.

16. The method of claim 1, wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue.

17. The method of claim 1, wherein delivering the treatment comprises delivering a cauterizing agent to tissue to be treated.

18. The method of claim 1, wherein delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway.

19. The method of claim 18, wherein the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate.

20. A device for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the device comprising:

an elongate, malleable shaft having a proximal end and a distal end;

a handle at the proximal end of the elongate shaft; and

a treatment portion at the distal end of the elongate shaft, the treatment portion comprising a treatment surface, the treatment surface comprising:

at least two energy delivery members extending longitudinally along the treatment surface; and

a concave trough extending longitudinally along the treatment surface and separating the at least two energy delivery members.

21. The device of claim 20, wherein the at least two energy delivery members comprise at least one positive electrode on one side of the concave trough and at least one negative electrode on an opposite side of the concave trough.

22. The device of claim 21, wherein the at least one positive electrode comprises a row of positive electrodes, and wherein the at least on negative electrode comprises a row of negative electrodes.

23. The device of claim 22, wherein the electrodes protrude from the treatment surface.

24. The device of claim 23, wherein the electrodes are blunt-tipped electrodes.

25. The device of claim 20, further comprising a thermocouple disposed within the concave trough.

26. A method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the method comprising:

bending a malleable shaft of a treatment device into a desired configuration;

advancing a treatment portion of the treatment device into a nostril of the patient to contact a treatment surface of the treatment portion with mucosal tissue of the upper airway, without piercing the mucosal tissue;

delivering radiofrequency energy from a first electrode on the treatment surface across a concave trough in the treatment surface to a second electrode on the treatment surface, to treat at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient;

measuring an amount of the radiofrequency energy delivered, using a thermocouple disposed in the concave trough; and

removing the treatment portion from the upper airway without leaving an implant in the upper airway.

27. The method of claim 26, further comprising performing a test to determine whether a desired contact between the treatment surface and the mucosal tissue has been achieved.

28. The method of claim 26, wherein the delivering and measuring steps comprise:

delivering a first amount of the radiofrequency energy from the first electrode to the second electrode;

measuring a temperature of the mucosal tissue using the thermocouple; and

delivering a second amount of the radiofrequency energy from the first electrode to the second electrode, wherein the second amount of radiofrequency energy is based at least in part on the measured temperature.

29. The method of claim 26, wherein the mucosal tissue comprises tissue located on at least one nasal turbinate of the upper airway.

30. The method of claim 29, wherein the mucosal tissue comprises tissue located on a posterior aspect of an inferior turbinate.

31. The method of claim 26, wherein delivering the radiofrequency energy comprises delivering the radiofrequency energy in an amount that deactivates mucus producing

cells by impairing at least one of mucus production ability or cell differentiation ability of the mucus producing cells.

32. The method of claim 26, wherein delivering the radiofrequency energy comprises delivering the radiofrequency energy in an amount that causes one or more mucus paths of the upper airway to divert.

33. The method of claim 26, further comprising repeating the bending, advancing, and delivery steps.

ABSTRACT

Systems and methods for treating a patient's mucus hypersecretion condition are disclosed herein. Certain implementations may involve a method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough. The method may include advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient. The treatment delivery portion may contact mucosal tissue of the upper airway without piercing the mucosal tissue. The treatment delivery portion may deliver treatment to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Filer:	Scott Michael Smith/Laura Lee Mosier
Attorney Docket Number:	P244690US02 (494912-15)

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	70	70
Utility Search Fee	2111	1	300	300
Utility Examination Fee	2311	1	360	360
Pages:				
Claims:				
Claims in excess of 20	2202	13	40	520
Miscellaneous-Filing:				
Late Filing Fee for Oath or Declaration	2051	1	70	70

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1320**

Electronic Acknowledgement Receipt

EFS ID:	21935639
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	31-MAR-2015
Filing Date:	
Time Stamp:	22:43:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1320
RAM confirmation Number	7441
Deposit Account	502319
Authorized User	

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	P244690US02_ADS.pdf	114972 34a5183969ec7d10976337a422c14353bb095e1a	no	6
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
2	Power of Attorney	Aerin_signed_POA.pdf	137089 9e2a81ca4f1838b5e0a7b4d211d0f5c6c68d7871	no	1
Warnings:					
Information:					
3	Drawings-only black and white line drawings	P244690US02_drawings.pdf	3256629 6ce9971564e0190c9aa85aaf0e1c8c20ff205bac	no	29
Warnings:					
Information:					
4	Transmittal of New Application	P244690US02_Application_Transmittal.pdf	238190 df6afe43bd6557ebef33044b09cde1f0b4f2dd95	no	2
Warnings:					
Information:					
5		P244690US02_Specification.pdf	237769 650dfda459bf1610691675bdba0b394114233227	yes	50

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	44
Claims	45	49
Abstract	50	50

Warnings:

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6	Fee Worksheet (SB06)	fee-info.pdf	38070 15af3aa833747af69d6b5d2761ab519393b3b1fc	no	2

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Total Files Size (in bytes):	4022719

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If a new application is being filed and the application includes the necessary components for a 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
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244690US02 (494912-15)
	Application Number	
Title of Invention	POST NASAL DRIP TREATMENT	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Scott	J.	WOLF	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Menlo Park	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	319 Trenton Way		
Address 2			
City	Menlo Park	State/Province	CA
Postal Code	94025	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		FRAZIER	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Sunnyvale	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	517 Fern Ridge Court		
Address 2			
City	Sunnyvale	State/Province	CA
Postal Code	94087	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244690US02 (494912-15)
	Application Number	
Title of Invention	POST NASAL DRIP TREATMENT	

☐ An Address is being provided for the correspondence Information of this application.			
Customer Number	75149		
Email Address	docketingdept-sf@dorsey.com	Add Email	Remove Email

Application Information:

Title of the Invention	POST NASAL DRIP TREATMENT		
Attorney Docket Number	P244690US02 (494912-15)	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	29	**Suggested Figure for Publication (if any)**	19A

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	75149		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	non provisional of	61974534	2014-04-03
Prior Application Status	Pending		Remove

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244690US02 (494912-15)
	Application Number	
Title of Invention	POST NASAL DRIP TREATMENT	

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation in part of	14319087	2014-06-30
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14319087	Continuation in part of	13495844	2012-06-13	8936594	2015-01-20
Prior Application Status	Expired			Remove	

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13495844	non provisional of	61603864	2012-02-27
Prior Application Status	Expired		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13495844	non provisional of	61496930	2011-06-14

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244690US02 (494912-15)
	Application Number	
Title of Invention	POST NASAL DRIP TREATMENT	

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☒ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date o f filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244690US02 (494912-15)
	Application Number	
Title of Invention	POST NASAL DRIP TREATMENT	

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☒

Organization Name	AERIN MEDICAL INC.

Mailing Address Information For Applicant:

Address 1	690 W. Fremont Avenue		
Address 2	Unit 3		
City	Sunnyvale	**State/Province**	CA
Country	US	Postal Code	94087
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee is an Organization check here. ☐

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244690US02 (494912-15)
	Application Number	
Title of Invention	POST NASAL DRIP TREATMENT	

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Non-Applicant Assignee:

Address 1	
Address 2	

City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Signature	/Scott M. Smith, Reg. No. 48,268/			Date (YYYY-MM-DD)	2015-03-31
First Name	Scott M.	Last Name	SMITH	Registration Number	48268

Additional Signature may be generated within this form by selecting the Add button.

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PTO/AIA/80 (07-12)
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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

■ Practitioners associated with Customer Number: 75149

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

■ The address associated with Customer Number: 75149

OR

☐

Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

Assignee Name and Address: Aerin Medical, Inc.
650 Page Mill Road
Menlo Park, CA 94304

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be Filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of The practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature	S Wolf	Date	10 / 09 / 2013
Name	Scott Wolf	Telephone	650-605-3579
Title	CEO		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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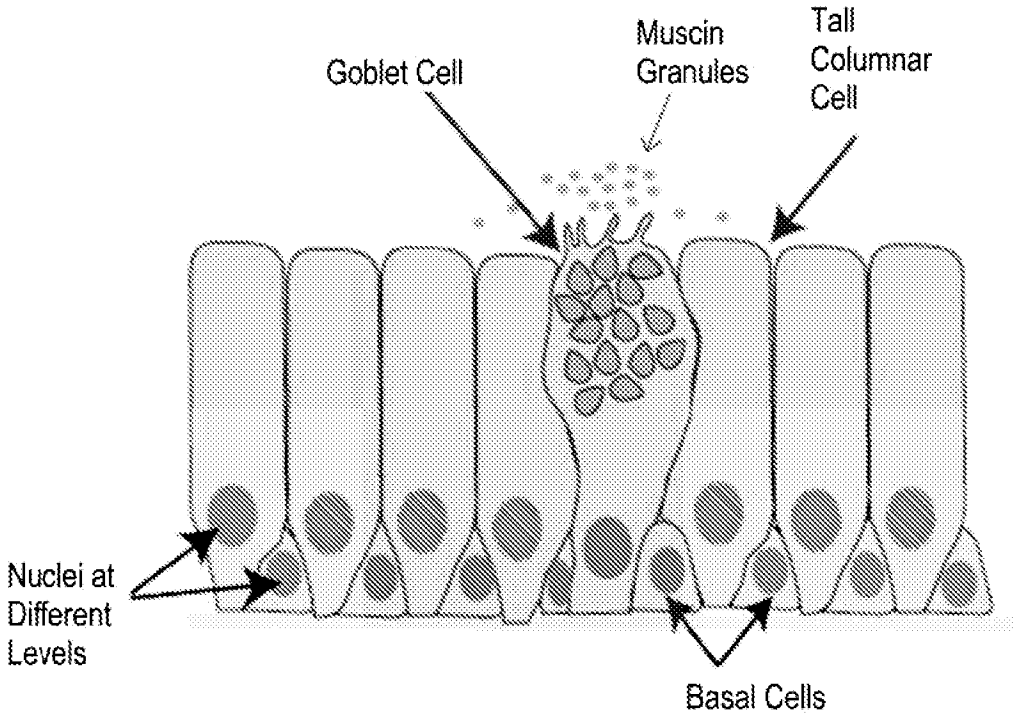

Goblet Cell
Muscin Granules
Tall Columnar Cell
Nuclei at Different Levels
Basal Cells

FIG. 1

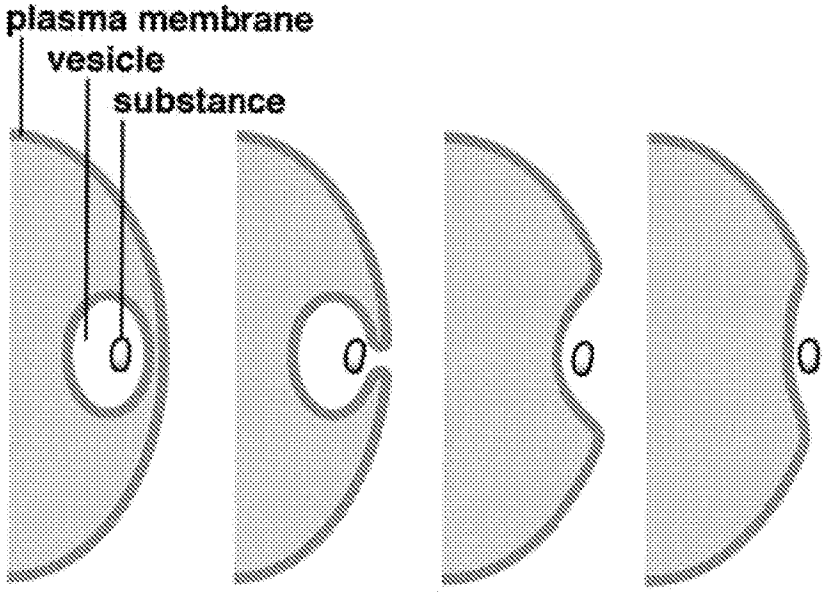

plasma membrane
vesicle
substance

FIG. 2

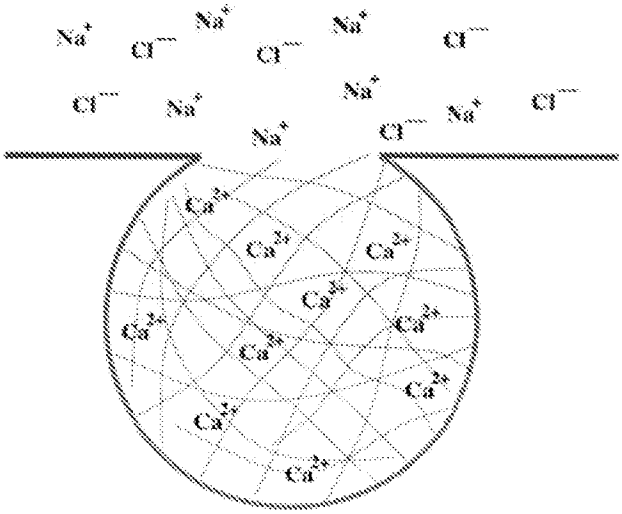

Na+
Cl−
Na+
Cl−
Na+
Cl−
Cl−
Na+
Na+
Cl−
Na+
Cl−
Na+
Cl−
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+

FIG. 3

FIG. 4A

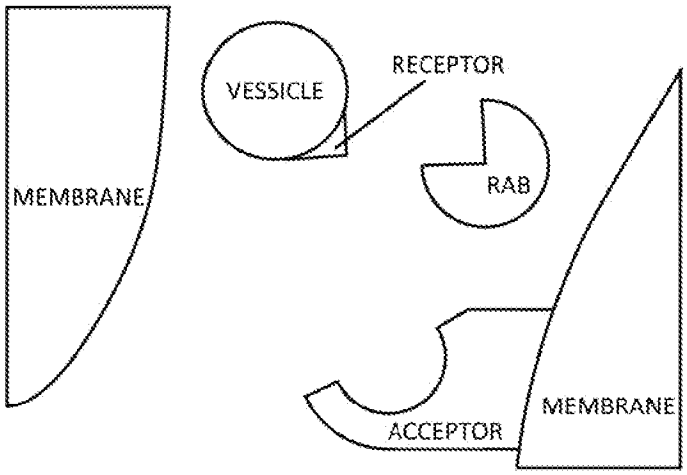


FIG. 4B

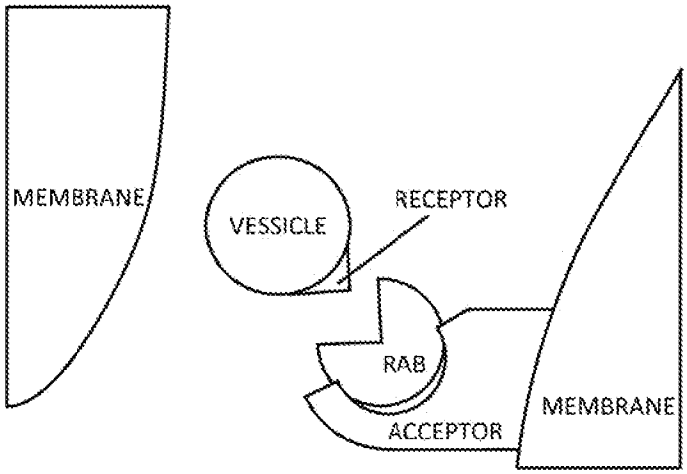
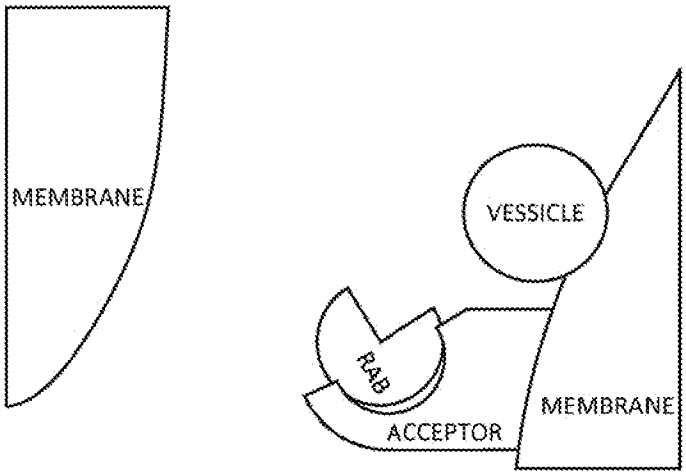


FIG. 4C



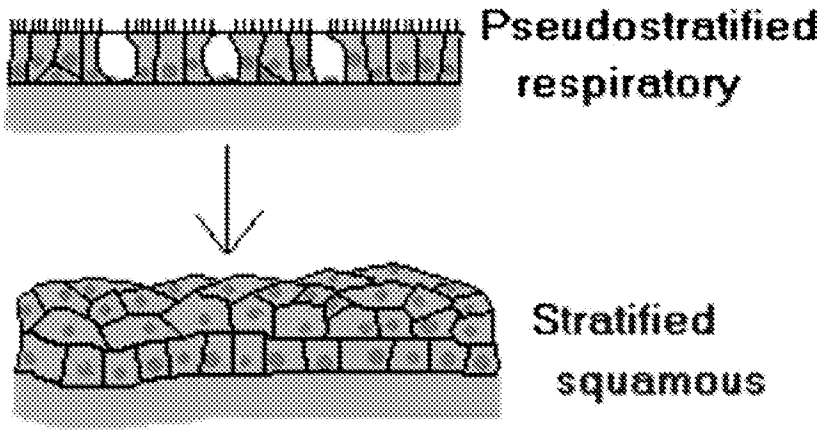

Pseudostratified
respiratory
Stratified
squamous

FIG. 5

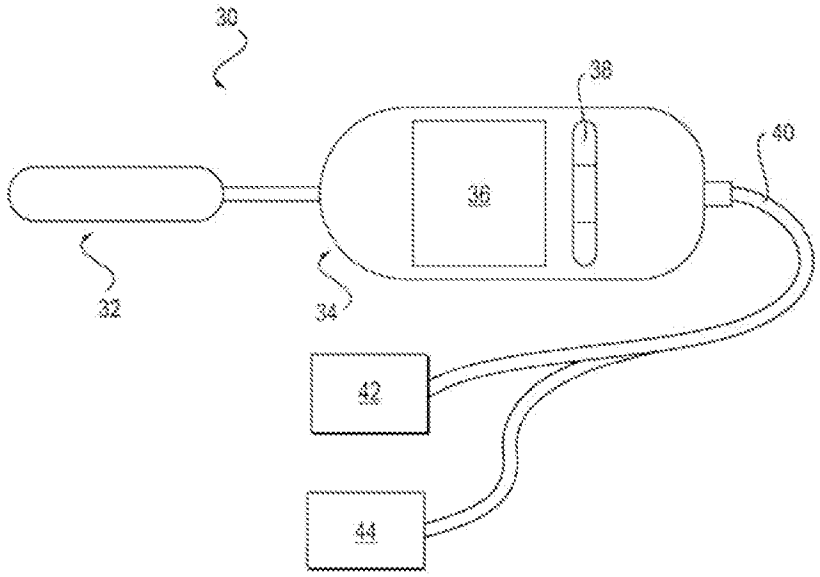

30
38
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36
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42
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FIG. 6

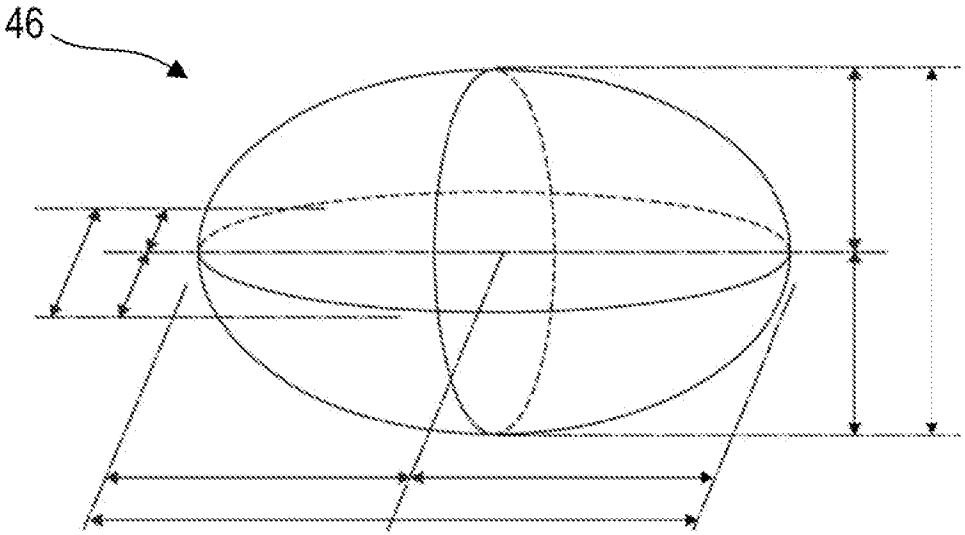


FIG. 7

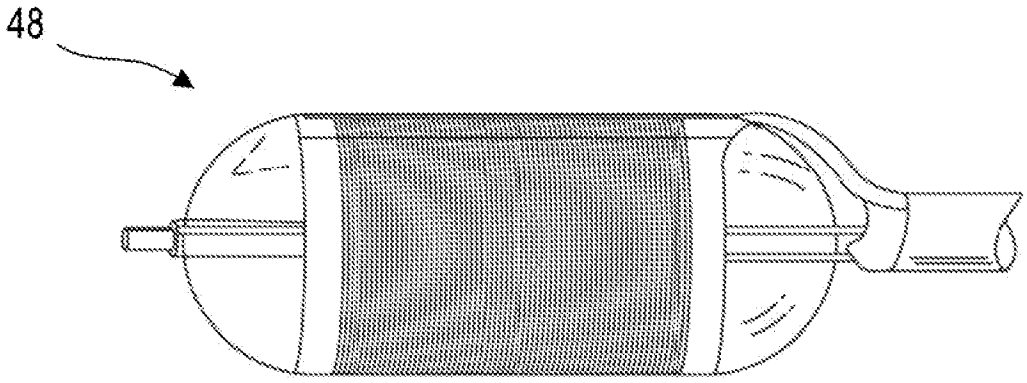


FIG. 8

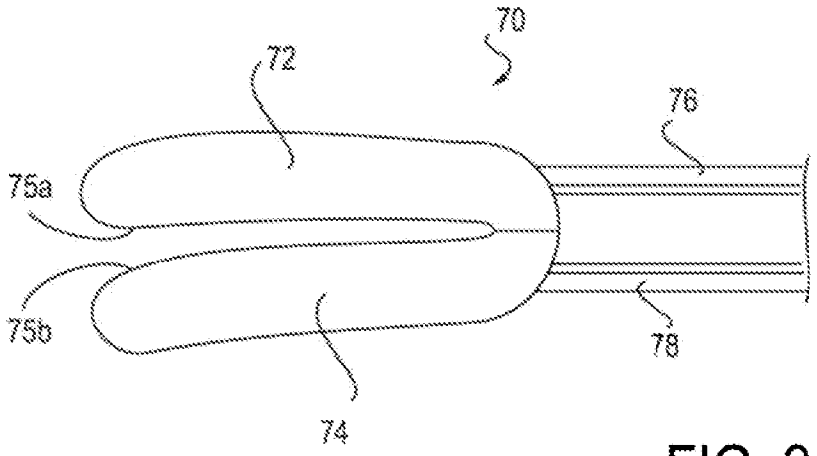


FIG. 9

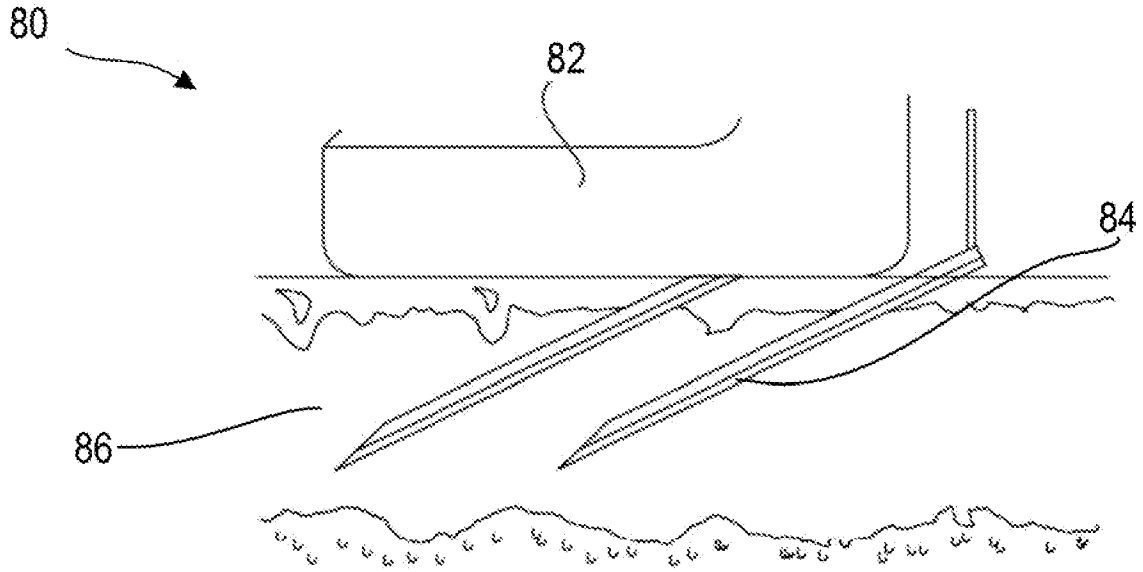


FIG. 10

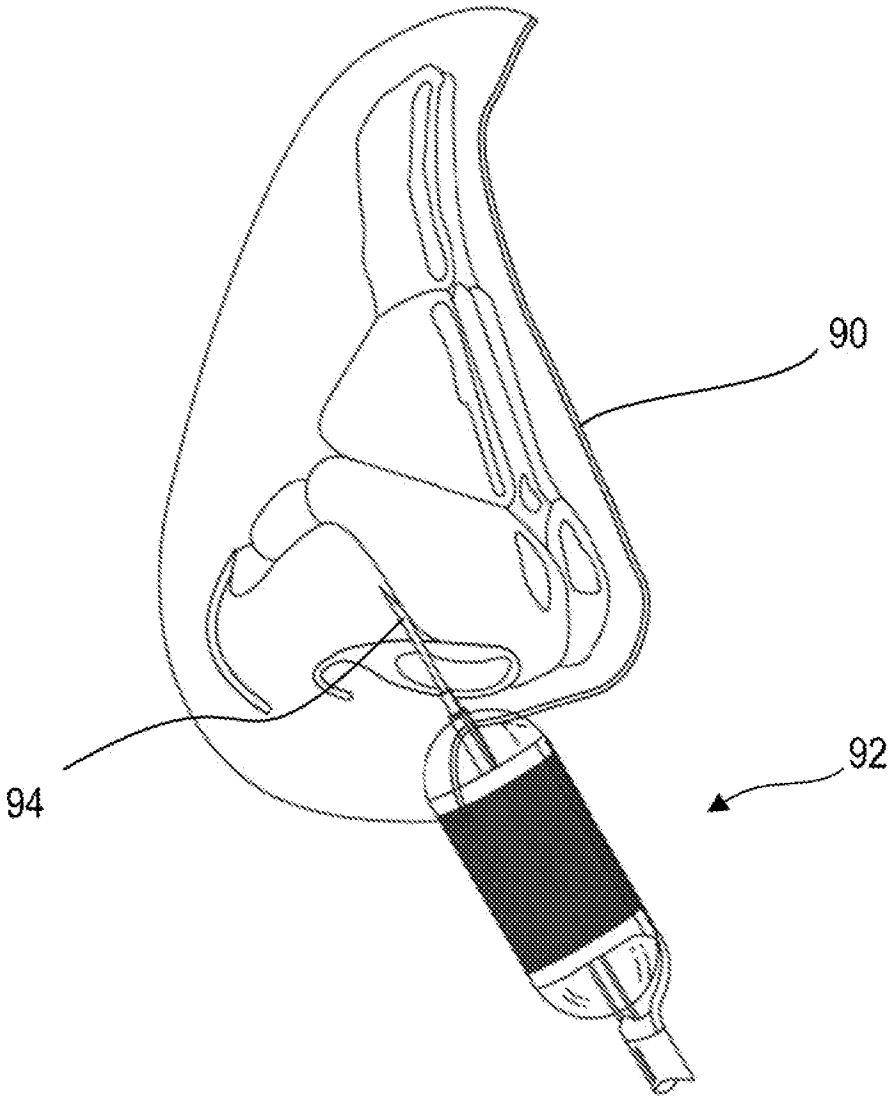


FIG. 11

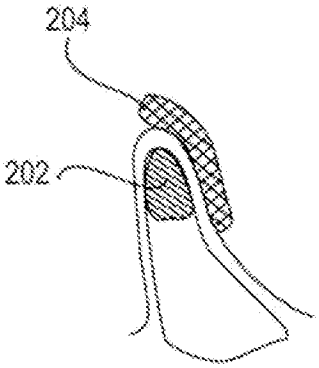


FIG. 12A

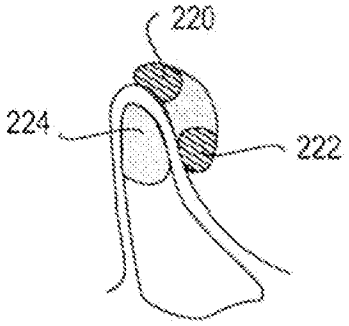


FIG. 12C

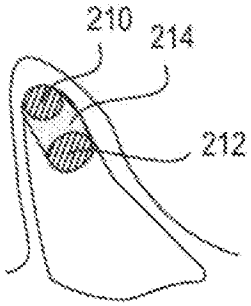


FIG. 12B

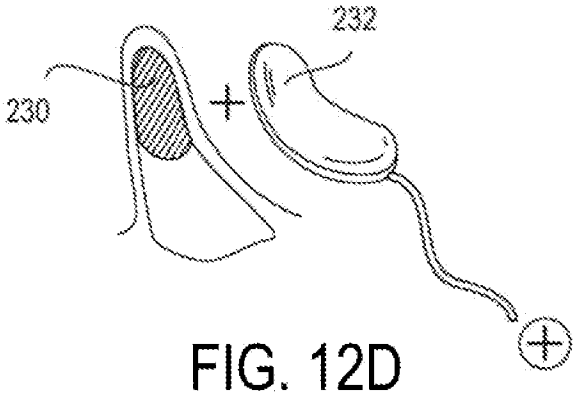


FIG. 12D

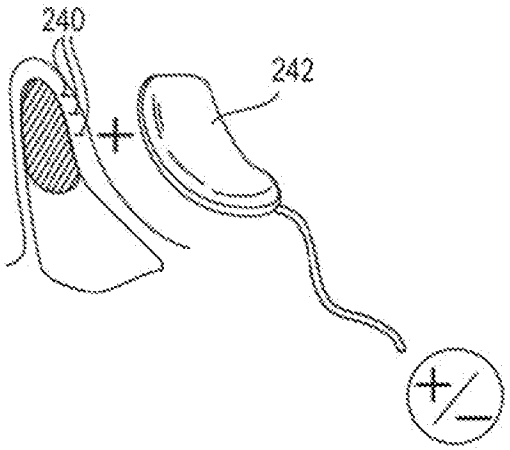


FIG. 12E

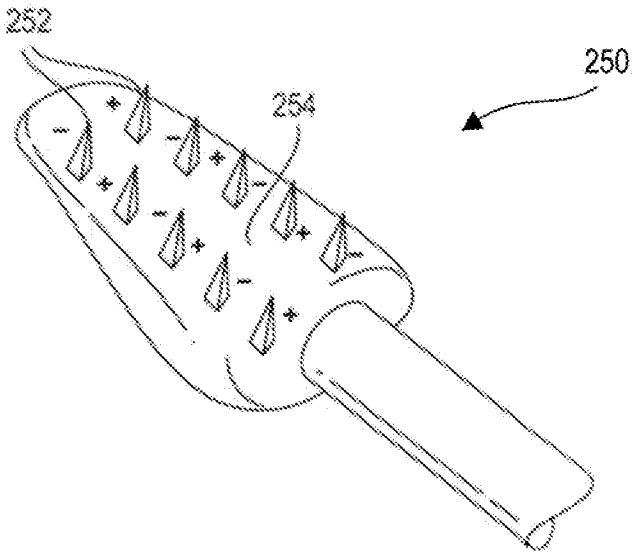


FIG. 13

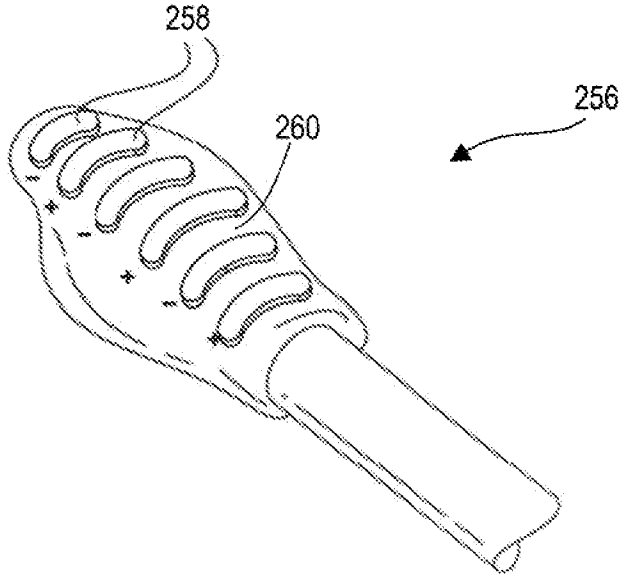


FIG. 14

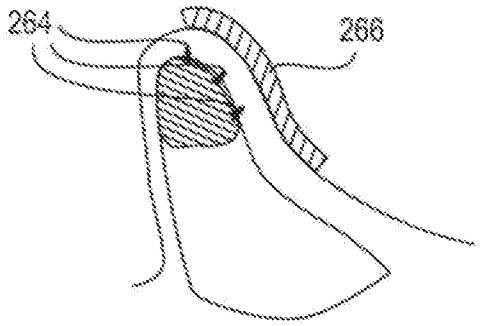


FIG. 15A

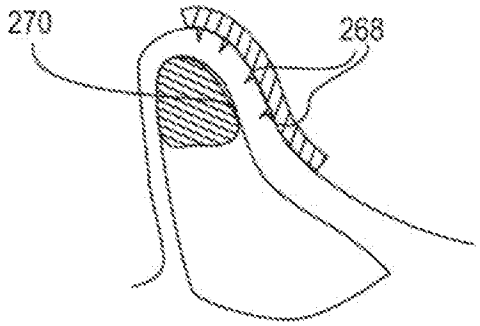


FIG. 15B

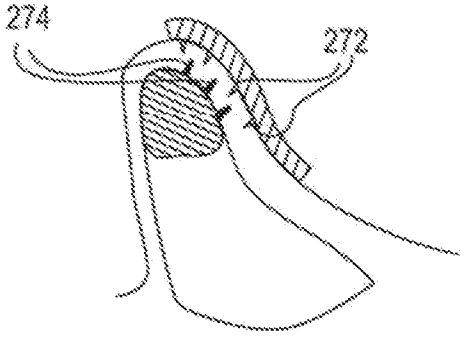


FIG. 15C

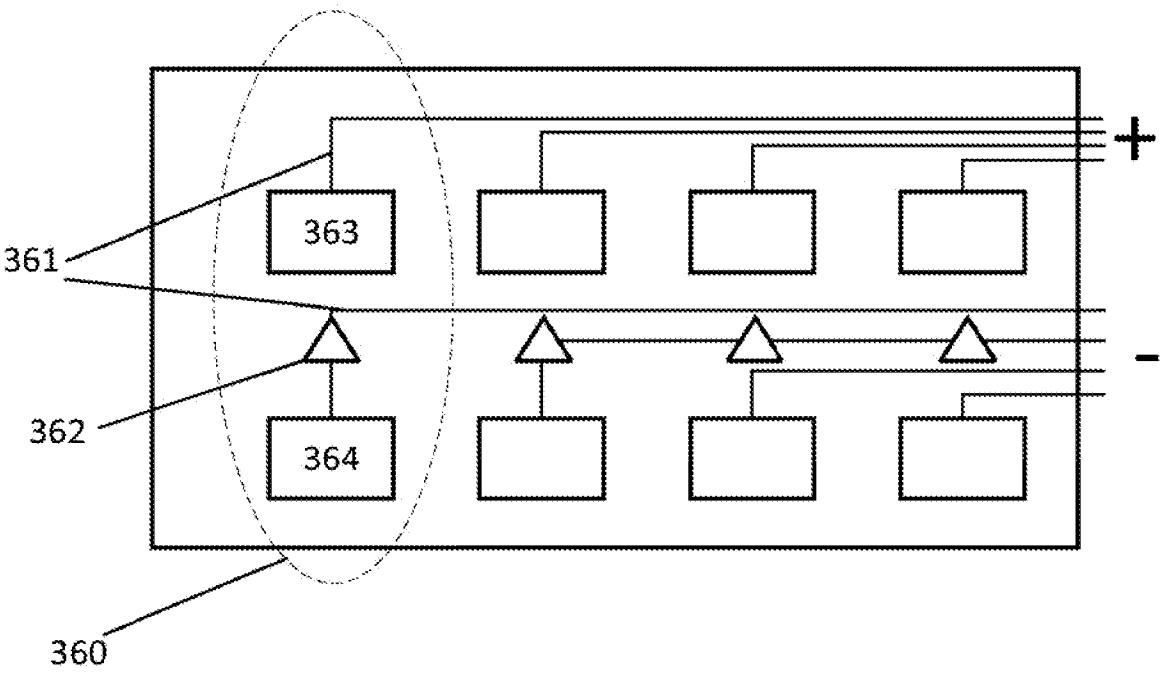


FIG. 16A

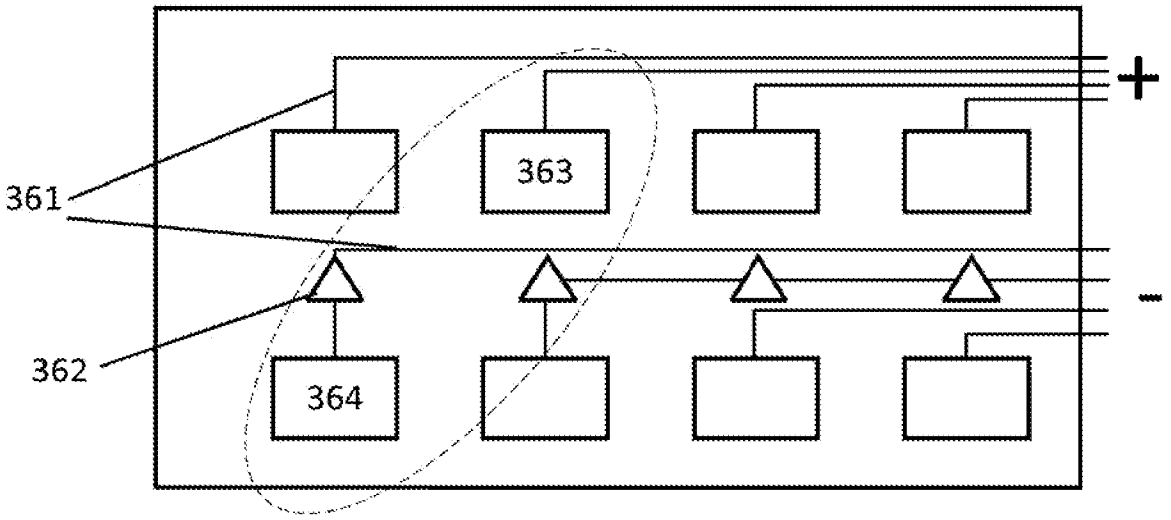


FIG. 16B

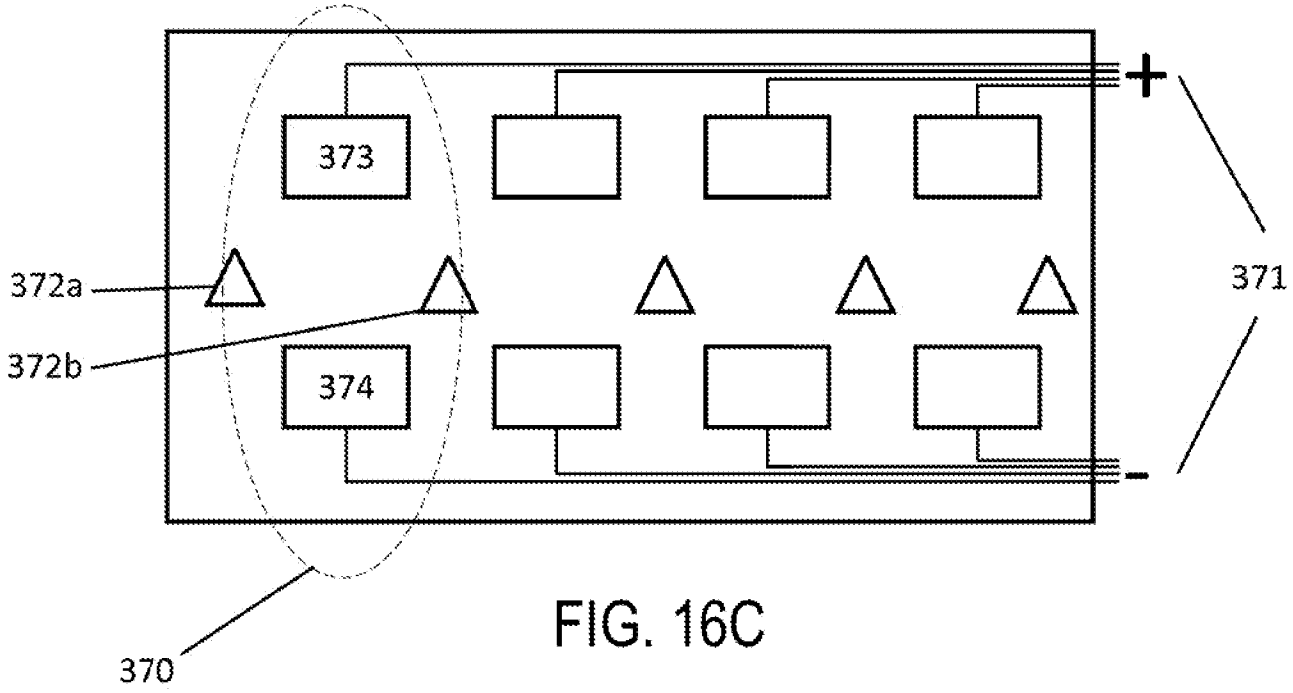


FIG. 16C

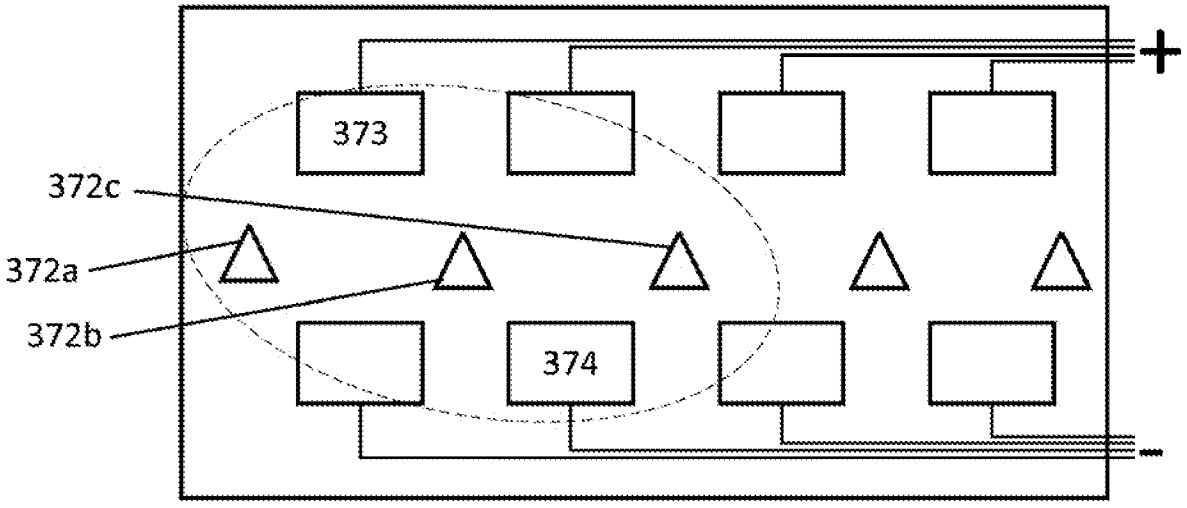


FIG. 16D

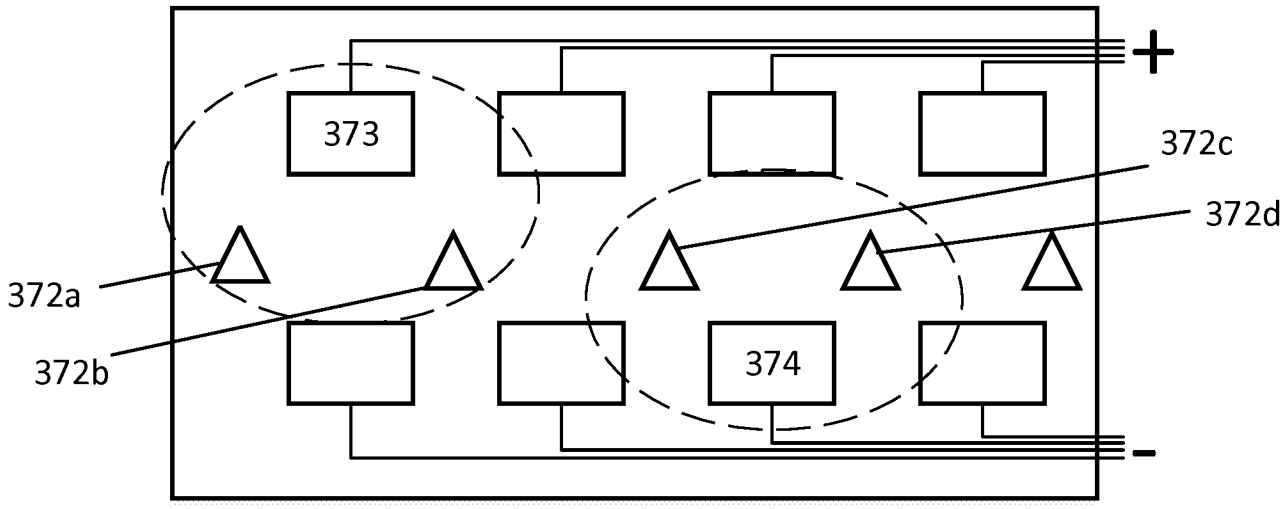


FIG. 16E

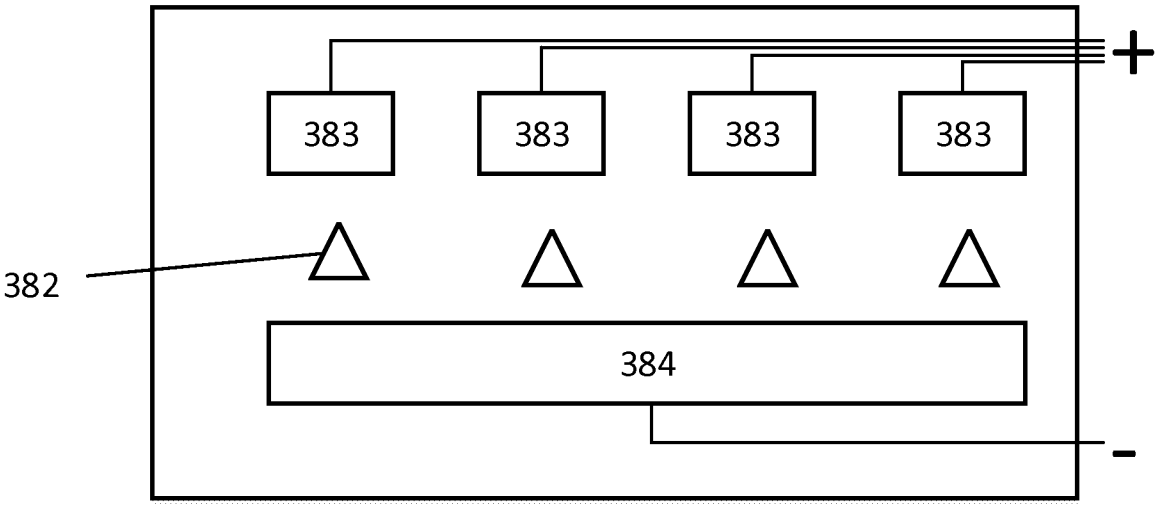


FIG. 16F

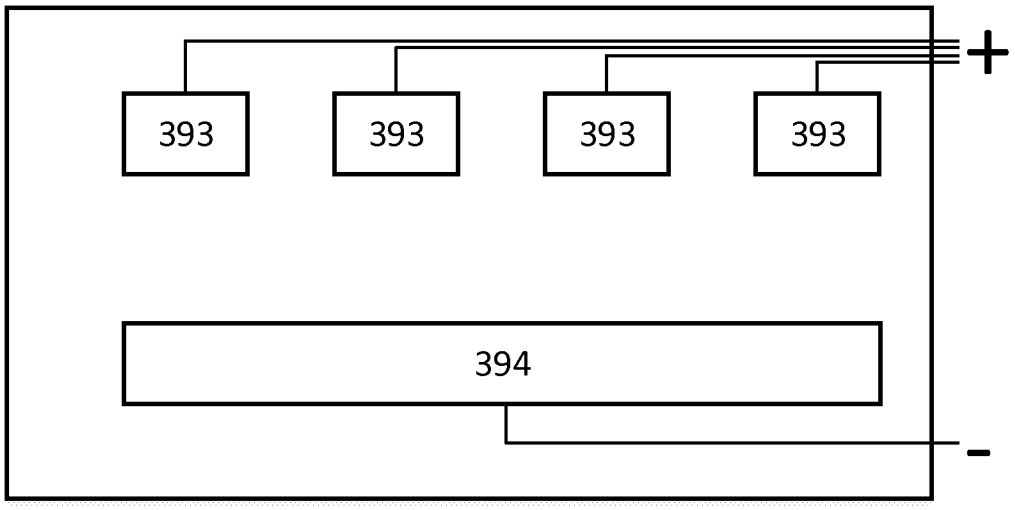


FIG. 16G

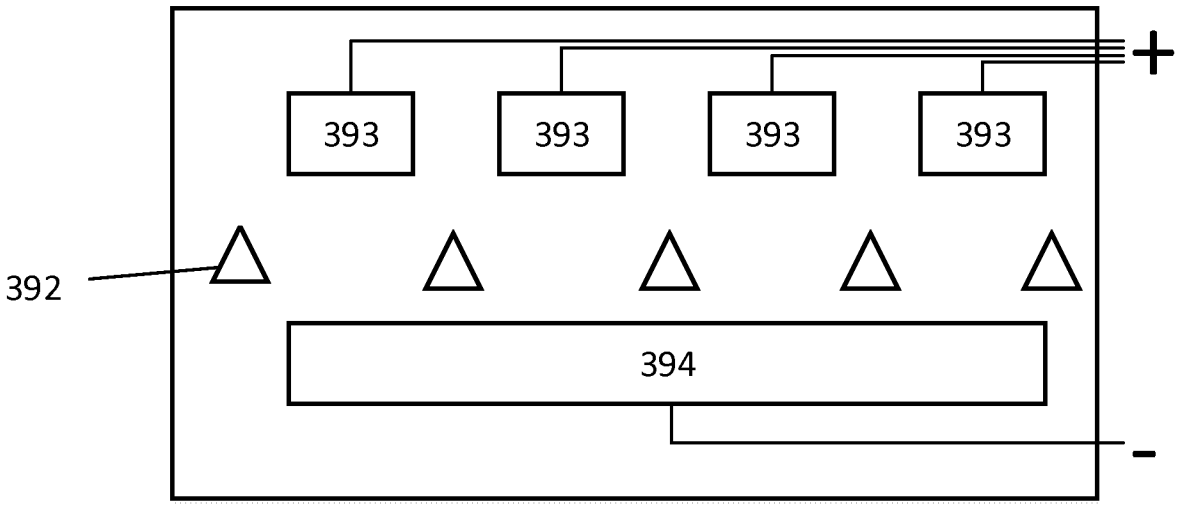


FIG. 16H

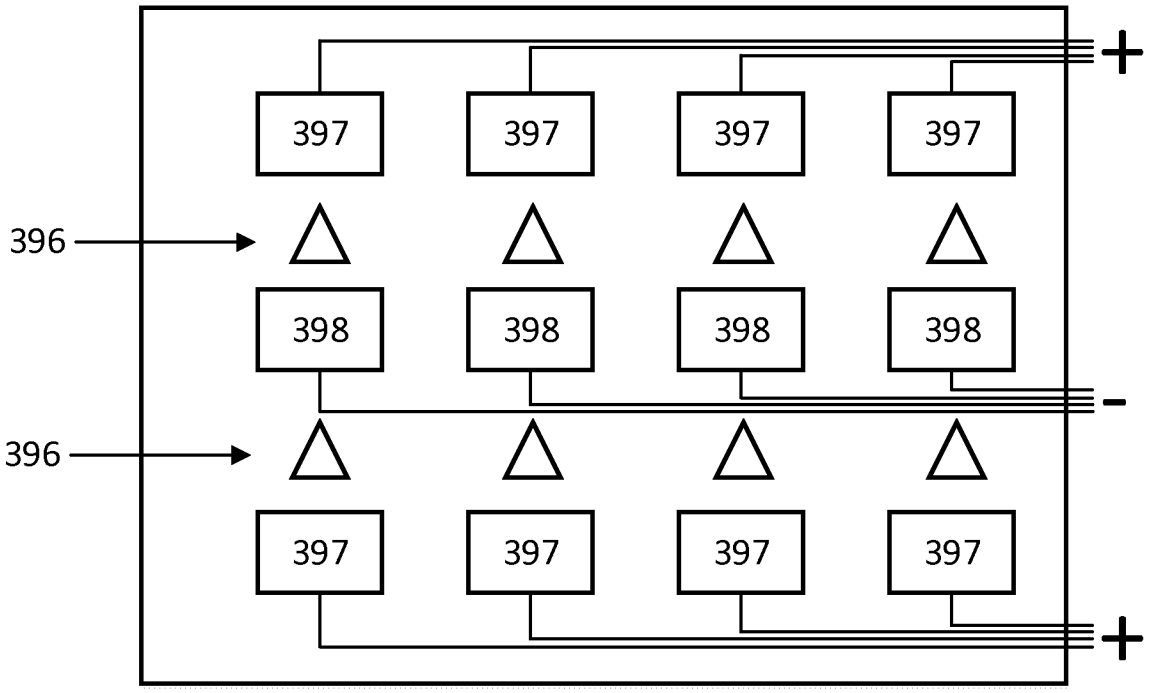


FIG. 16I

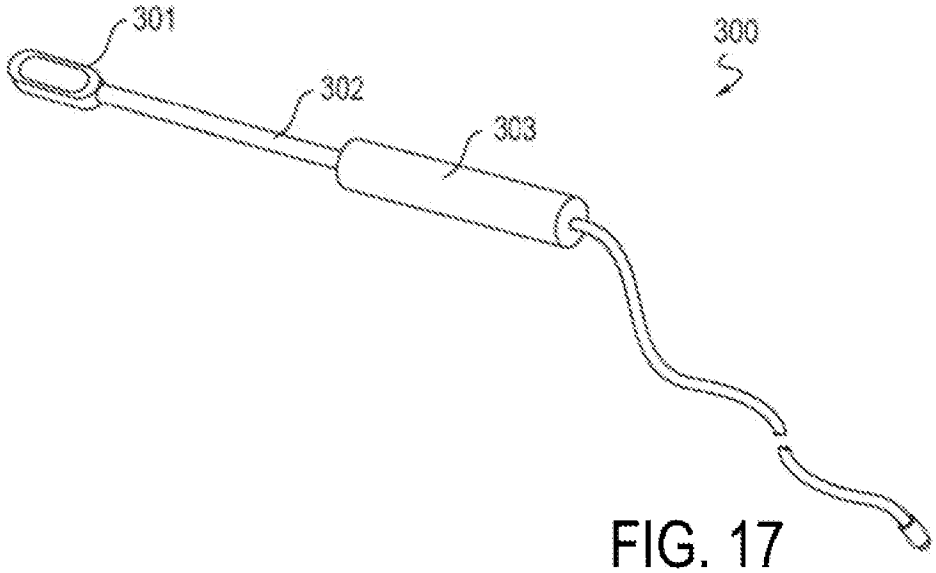


FIG. 17

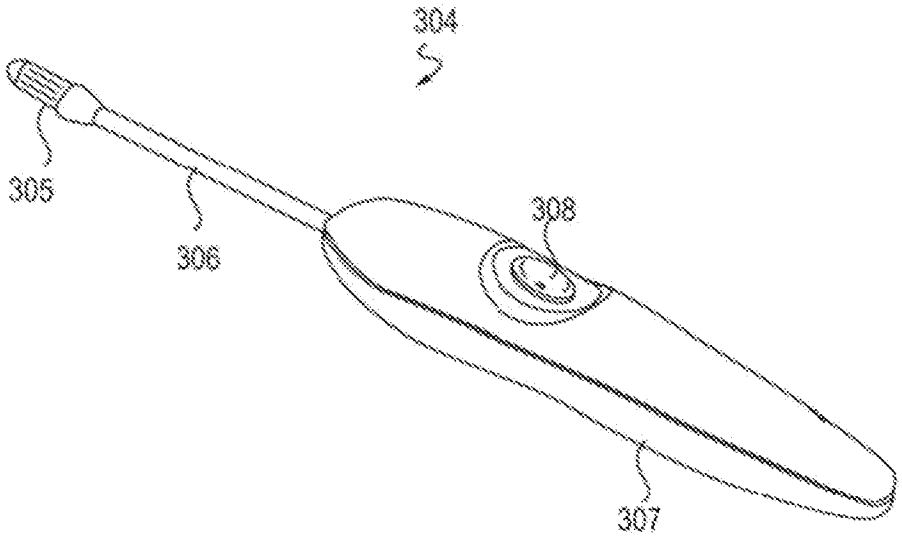


FIG. 18

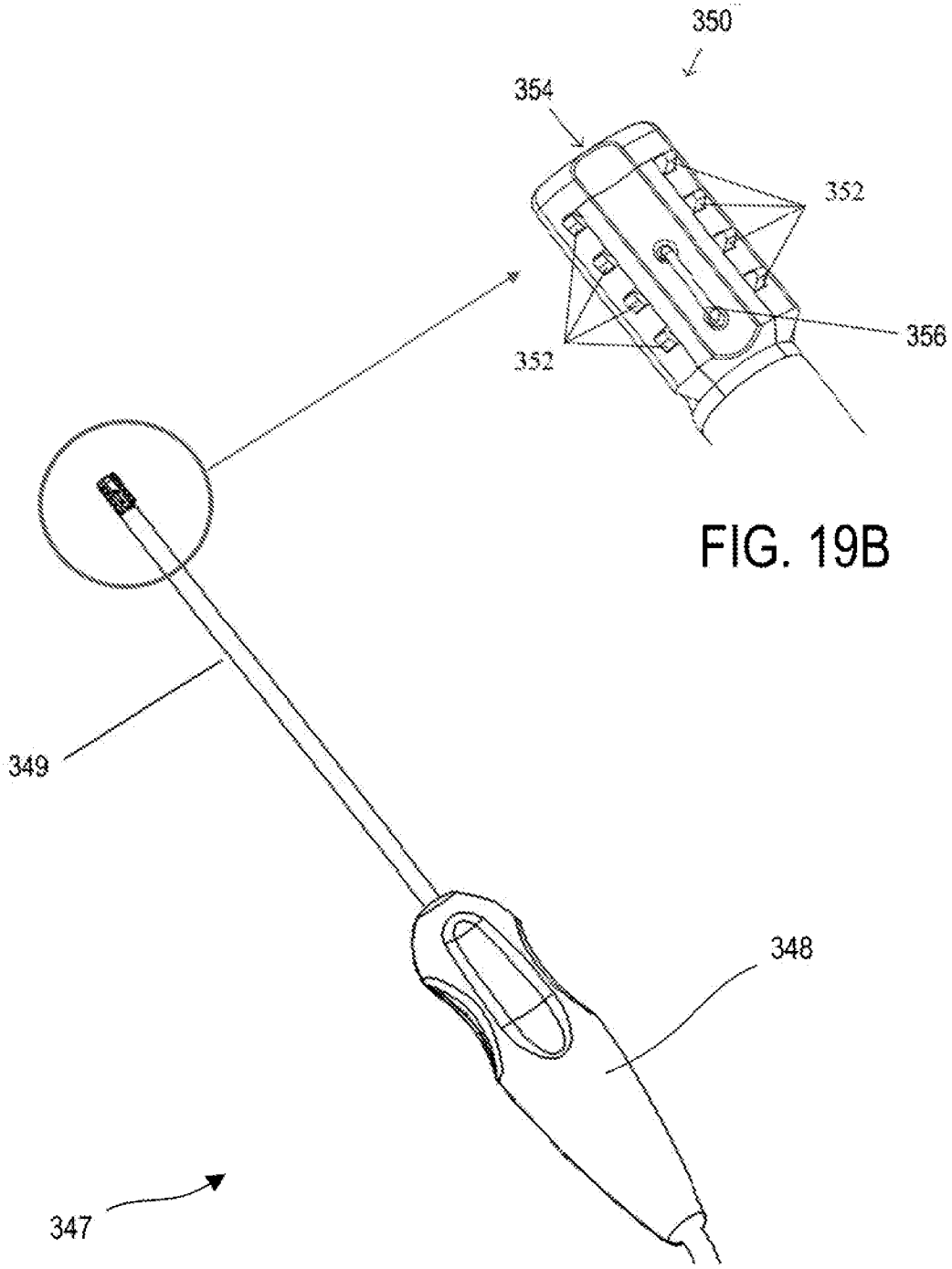


FIG. 19B

FIG. 19A

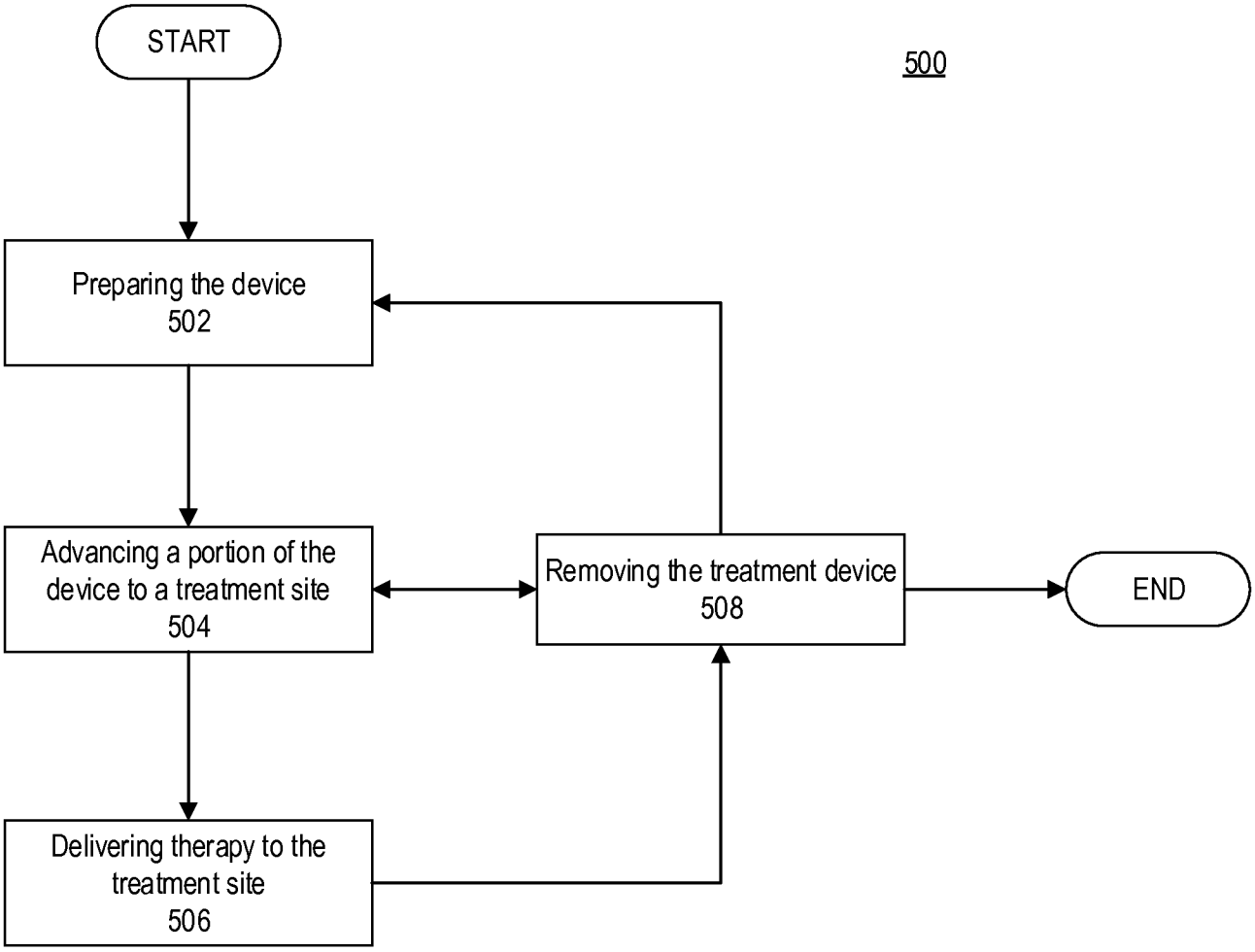

START
500
Preparing the device
502
Advancing a portion of the device to a treatment site
504
Delivering therapy to the treatment site
506
Removing the treatment device
508
END

FIG. 20

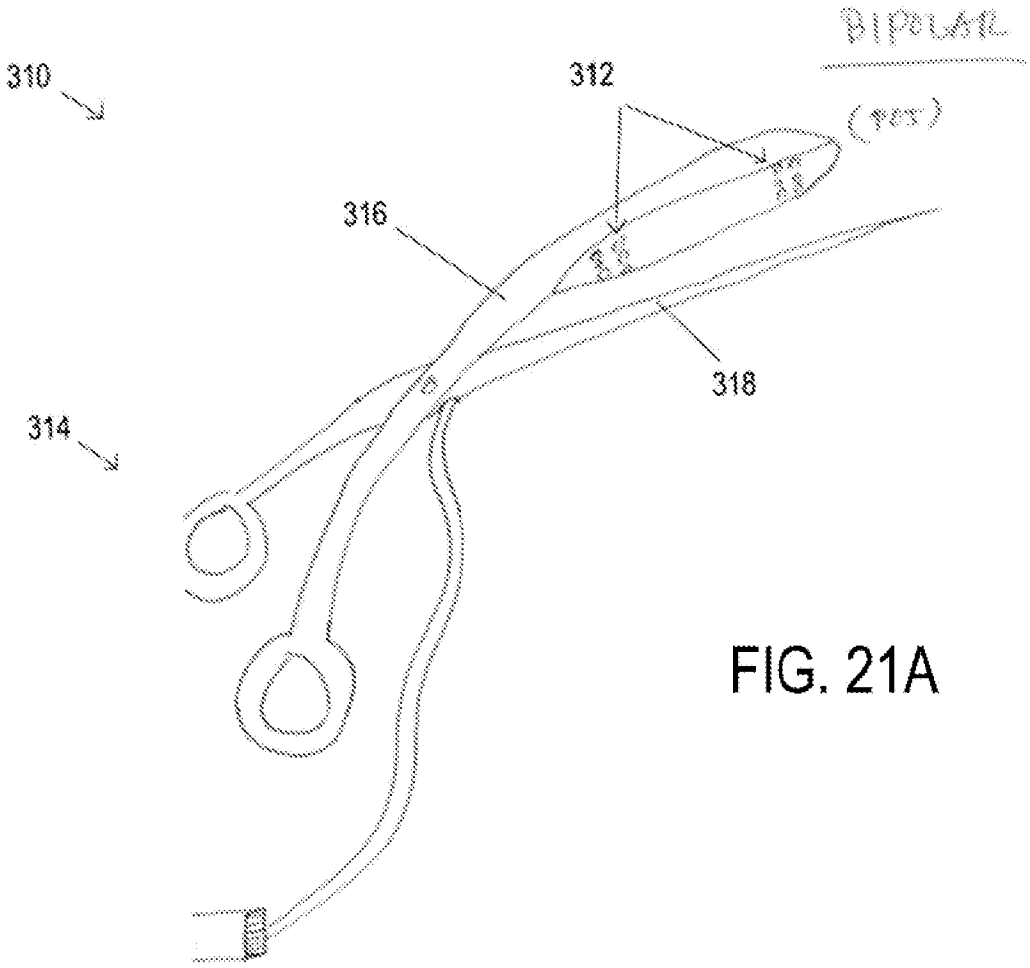


FIG. 21A

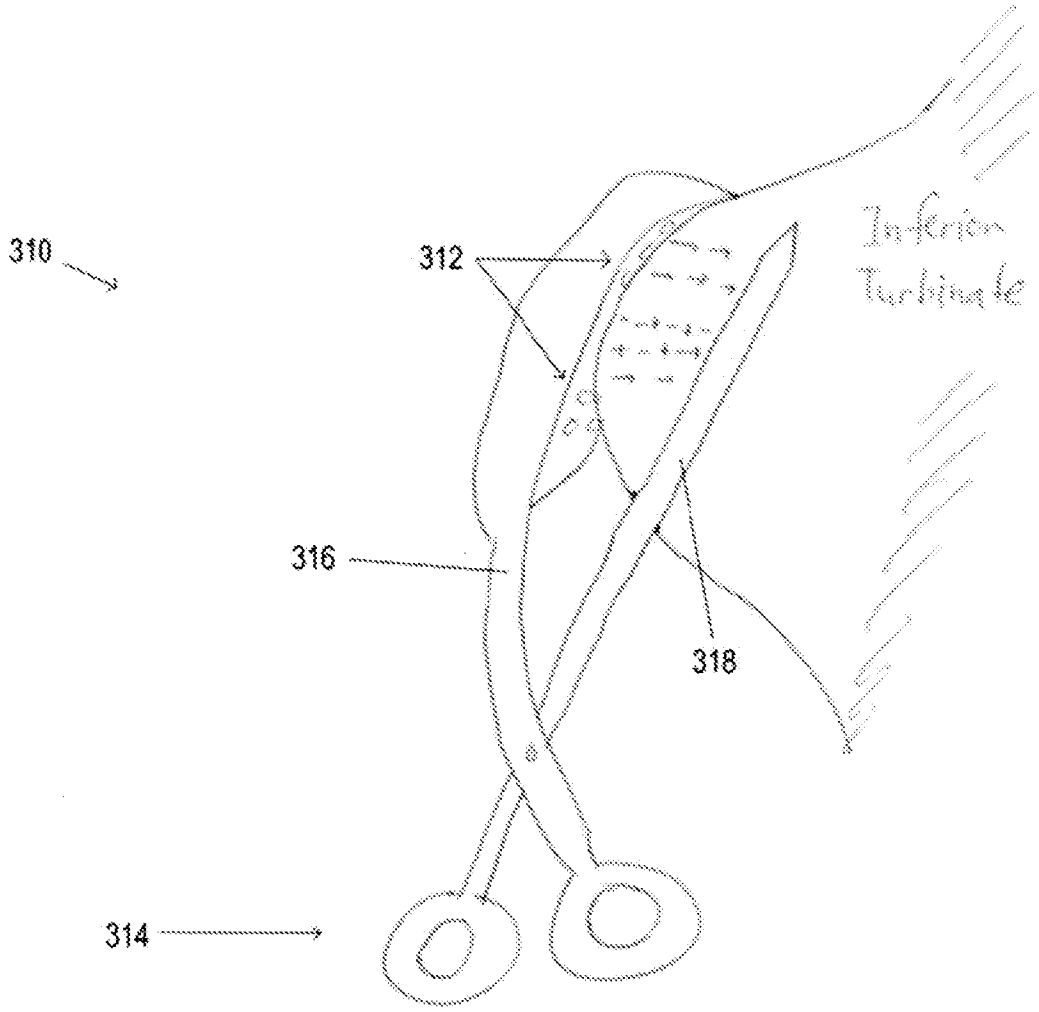


FIG. 21B

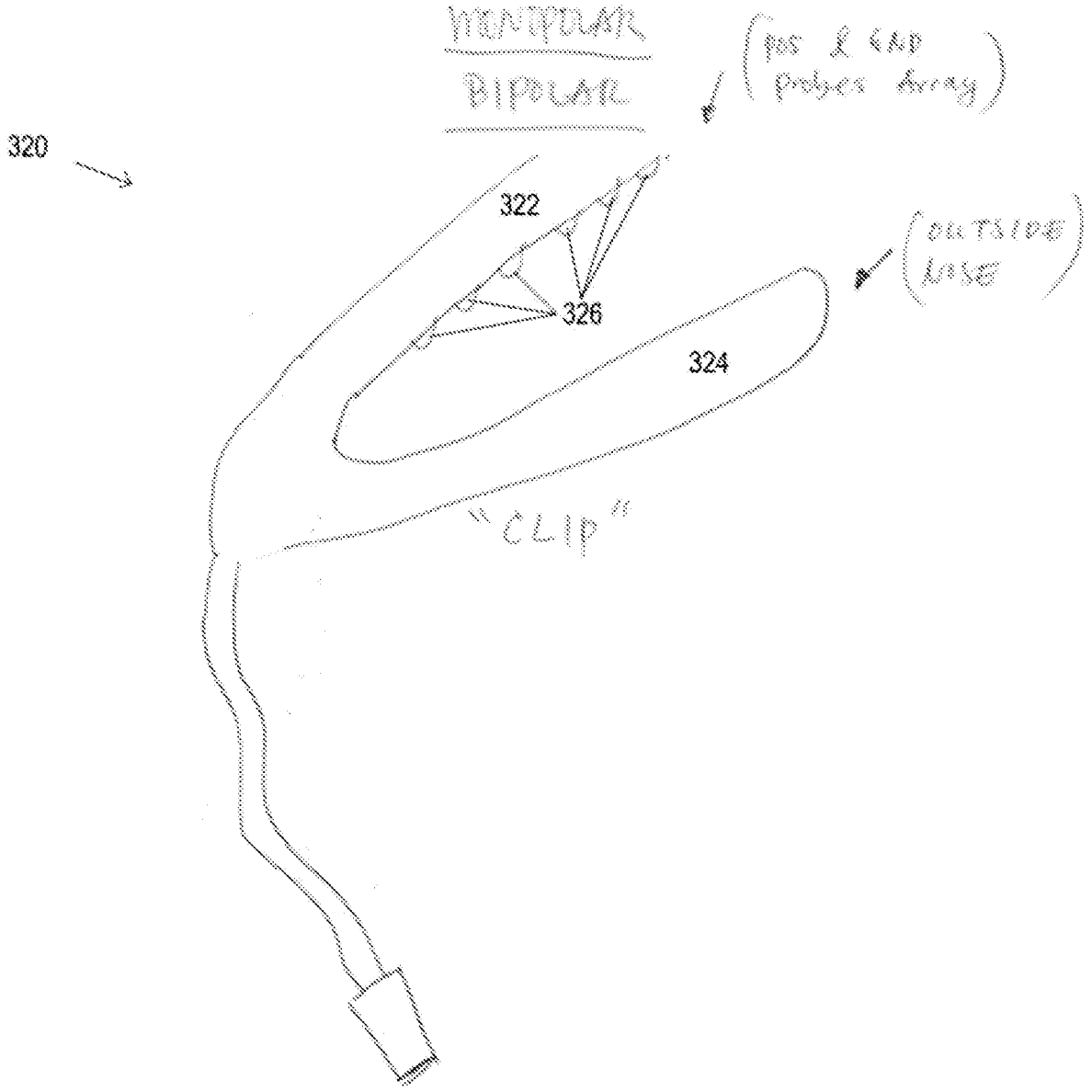


FIG. 22A

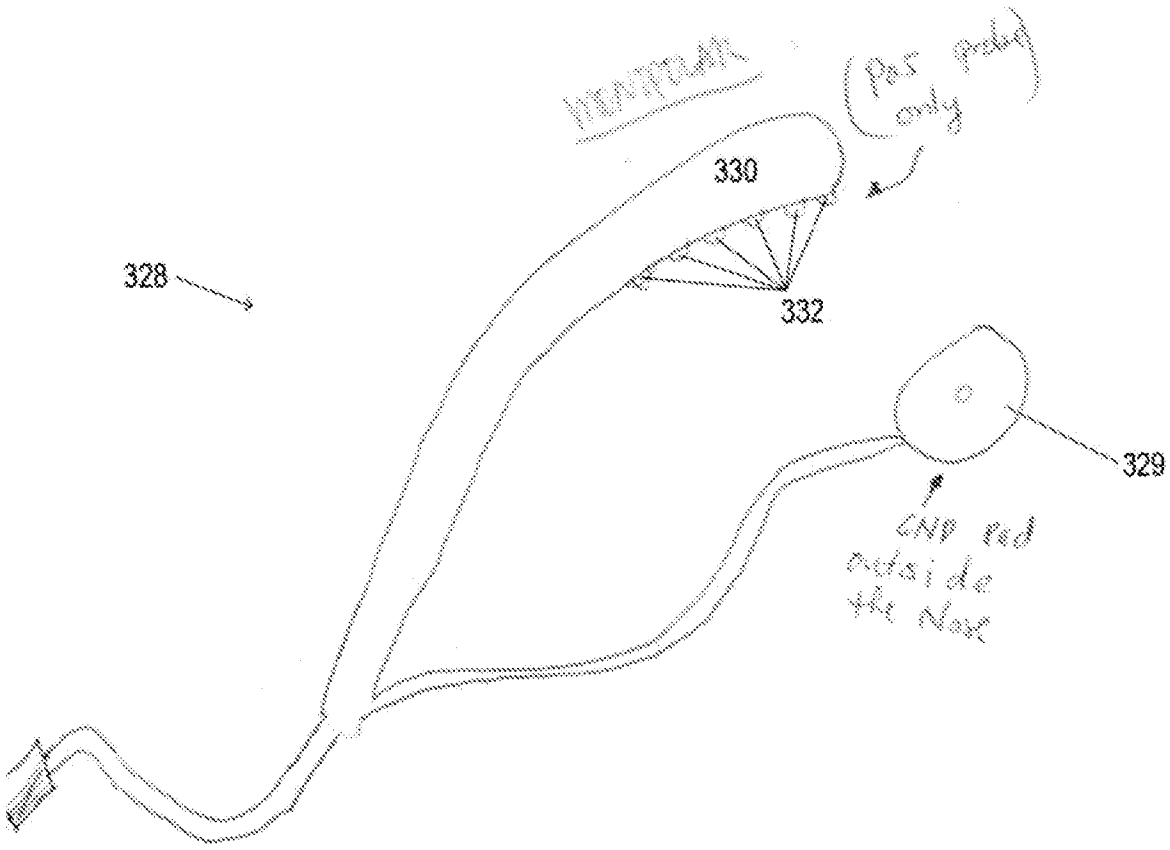


FIG. 22B

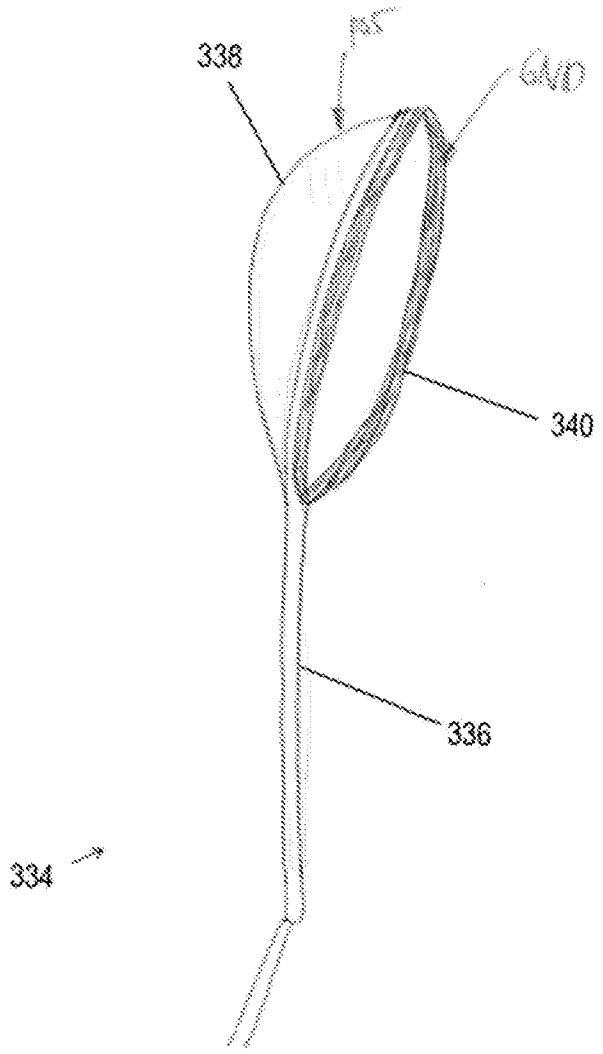


FIG. 23

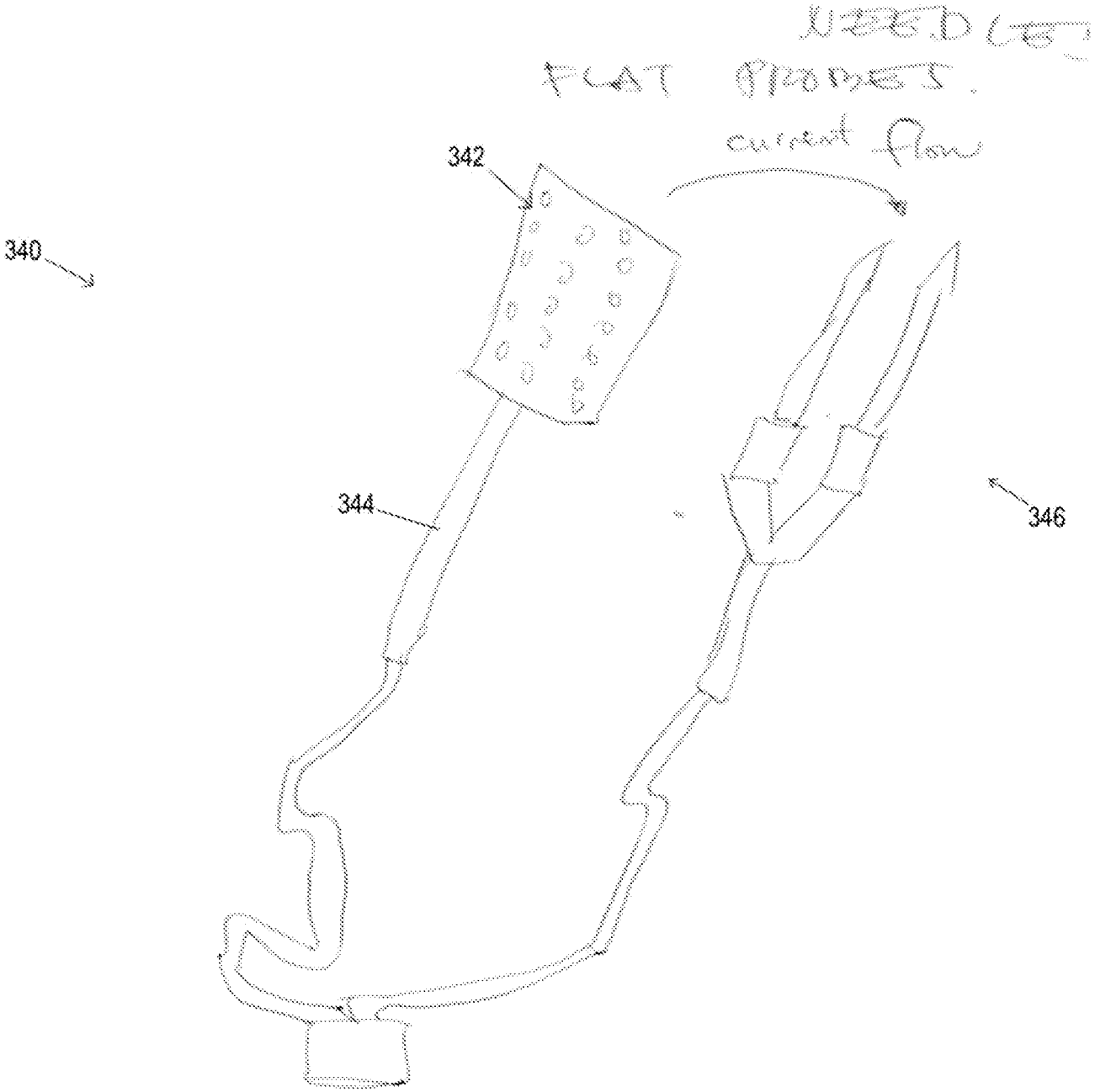


FIG. 24

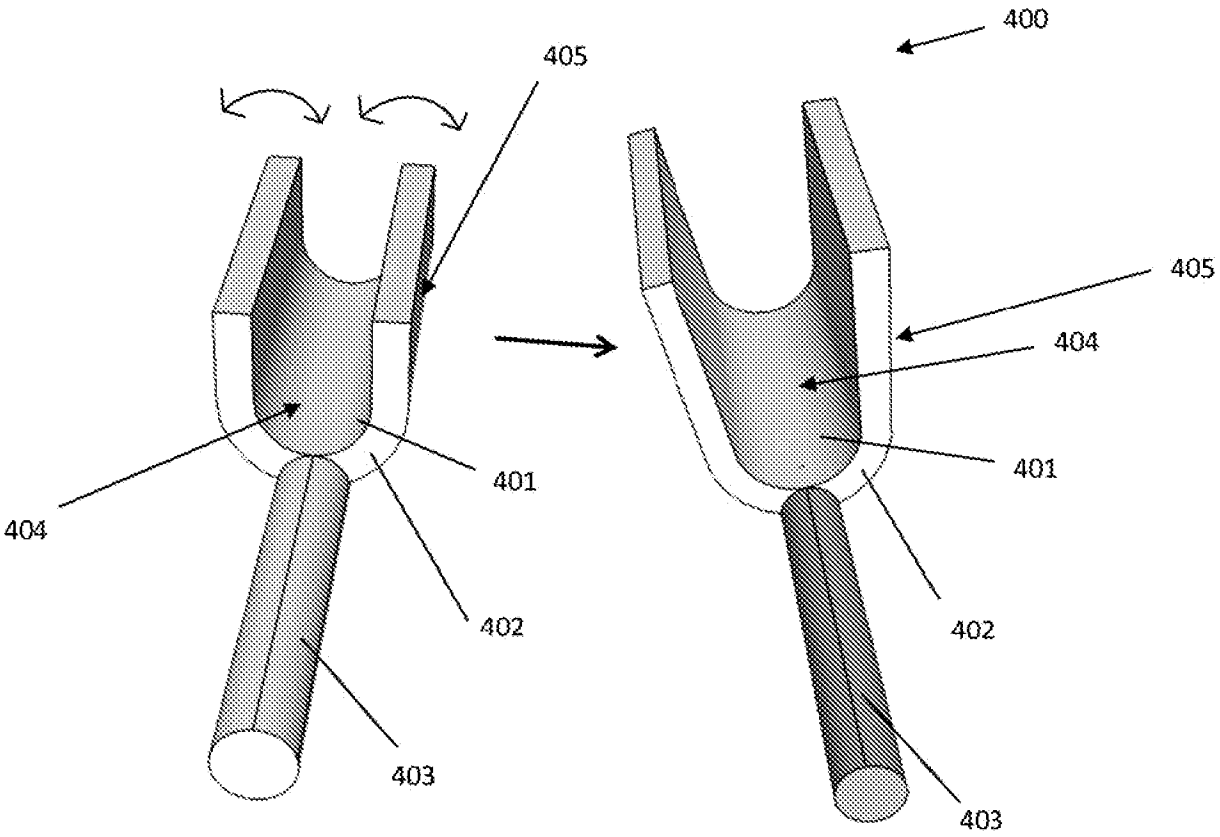


FIG. 25

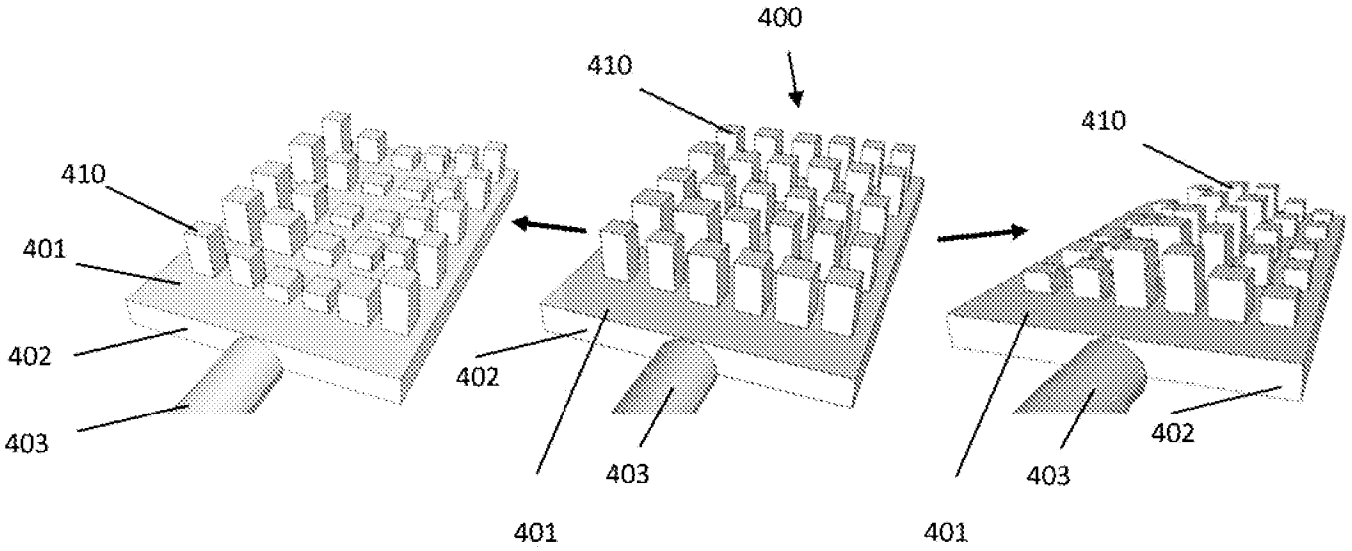


FIG. 26A FIG. 26B FIG. 26C

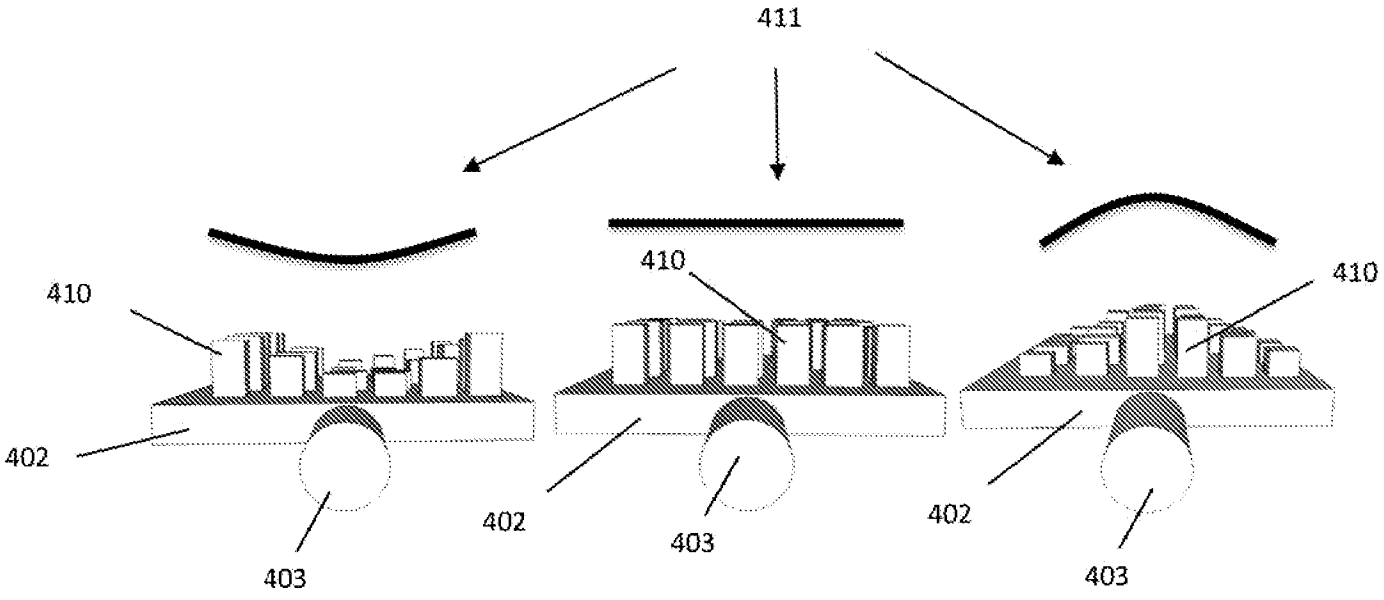


FIG. 26D FIG. 26E FIG. 26F

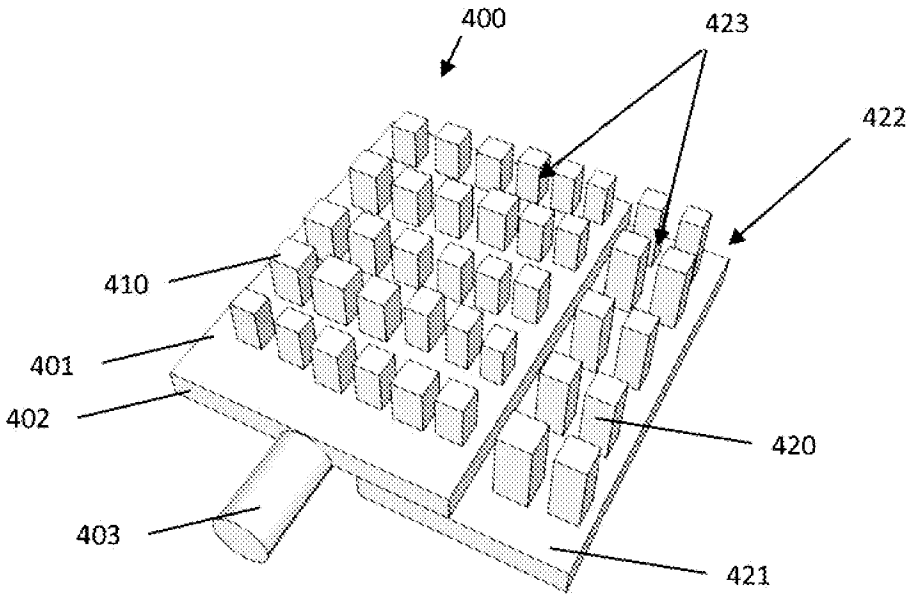


FIG. 27

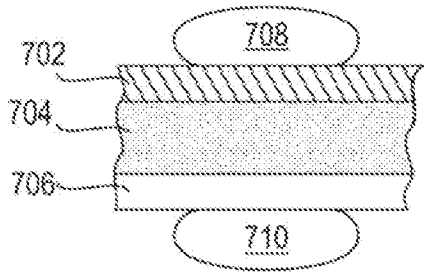


FIG. 28A

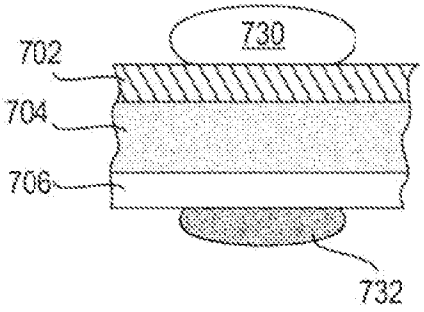


FIG. 28B

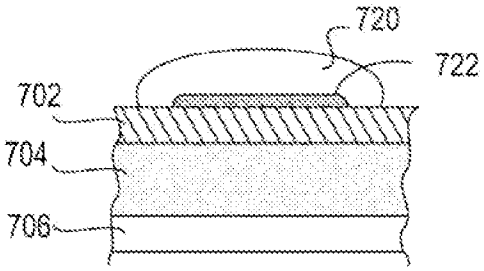


FIG. 28C

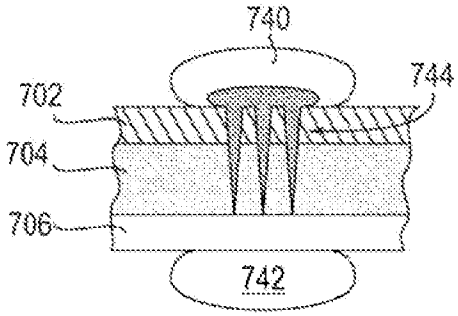


FIG. 28D

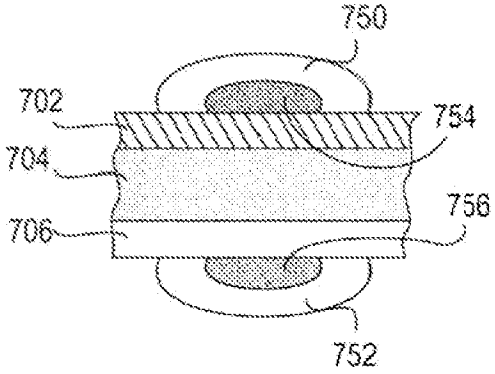


FIG. 28E

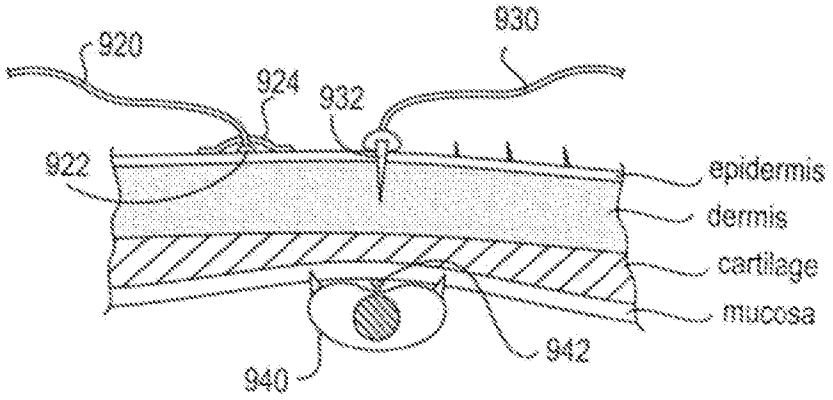


FIG. 29A

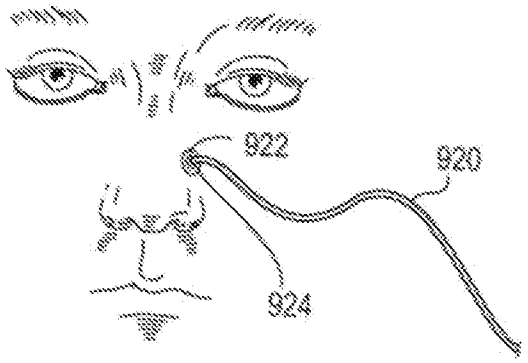


FIG. 29B

DocCode - SCORE

SCORE Placeholder Sheet for IFW Content

Application Number: 14675689 Document Date: 03/31/2015

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/675,689	03/31/2015	Scott J. WOLF	P244690US02 (494912-15)

CONFIRMATION NO. 9467

75149
Dorsey & Whitney LLP - PA
Intellectual Property Department
Columbia Center
701 Fifth Avenue, Suite 6100
Seattle, WA 98104-7043

NOTICE



Date Mailed: 04/14/2015

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Scott J. WOLF
  Andrew FRAZIER

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/675,689	03/31/2015	1615	1320	P244690US02 (494912-15)	33	3

CONFIRMATION NO. 9467

75149
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FILING RECEIPT



Date Mailed: 04/14/2015

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Scott J. WOLF, Menlo Park, CA;
Andrew FRAZIER, Sunnyvale, CA;

Applicant(s)

AERIN MEDICAL INC., Sunnyvale, CA

Assignment For Published Patent Application

AERIN MEDICAL, INC.

Power of Attorney: The patent practitioners associated with Customer Number 75149

Domestic Priority data as claimed by applicant

This appln claims benefit of 61/974,534 04/03/2014
and is a CIP of 14/319,087 06/30/2014
which is a CIP of 13/495,844 06/13/2012 PAT 8936594
which claims benefit of 61/603,864 02/27/2012
and claims benefit of 61/496,930 06/14/2011

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 04/13/2015

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/675,689**

Projected Publication Date: 07/23/2015

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

POST NASAL DRIP TREATMENT

Preliminary Class

424

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: Yes

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number
14/675,689

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	33 minus 20 =	* 13	x 40 =	520	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1250		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	POST NASAL DRIP TREATMENT

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ☒ United States application or PCT international application number 14/675,689 filed on March 31, 2015.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Andrew FRAZIER Date (Optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014 OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	POST NASAL DRIP TREATMENT

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ☒ United States application or PCT international application number 14/675,689 filed on March 31, 2015.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

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LEGAL NAME OF INVENTOR

Inventor: Scott J. WOLF Date (Optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	22115517
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	20-APR-2015
Filing Date:	31-MAR-2015
Time Stamp:	19:14:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	P244690US02_Frazier_Declaration.pdf	1298087 aa06f5509e9ba2c744b1e3f9c5e3053bd8875ca5	no	1

Warnings:	
Information:	

2	Oath or Declaration filed	P244690US02_Wolf_Declaration.pdf	1356196 fbe50d1eaa809dd4225f15bfa419502a92496249	no	1

Warnings:	
Information:	
Total Files Size (in bytes):	2654283

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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.

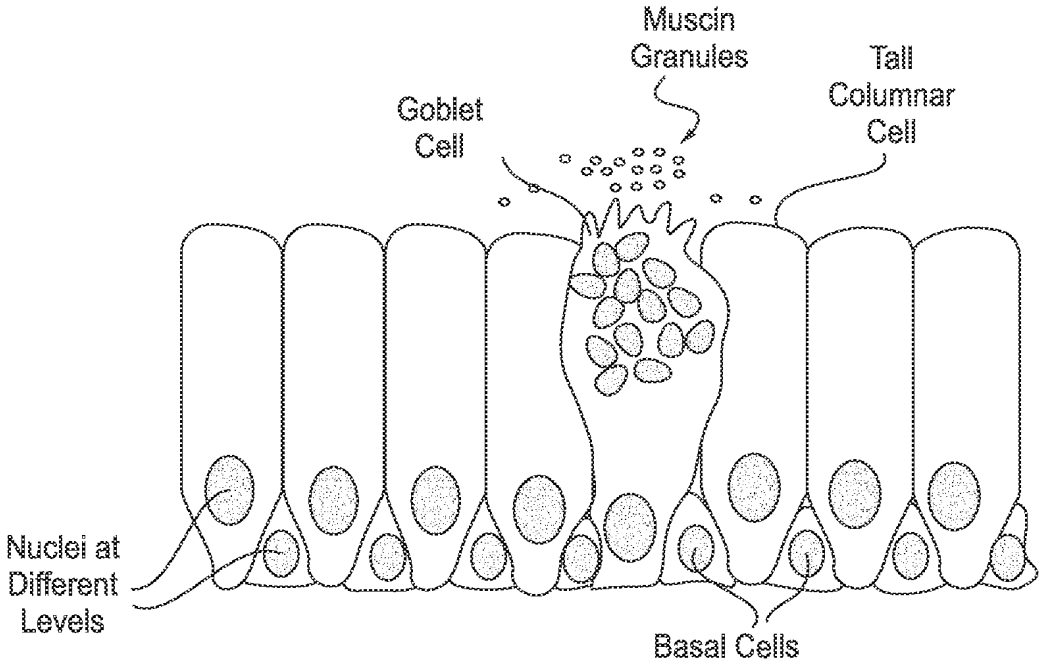

Muscin
Granules
Tall
Columnar
Cell
Goblet
Cell
Nuclei at
Different
Levels
Basal Cells

FIG. 1

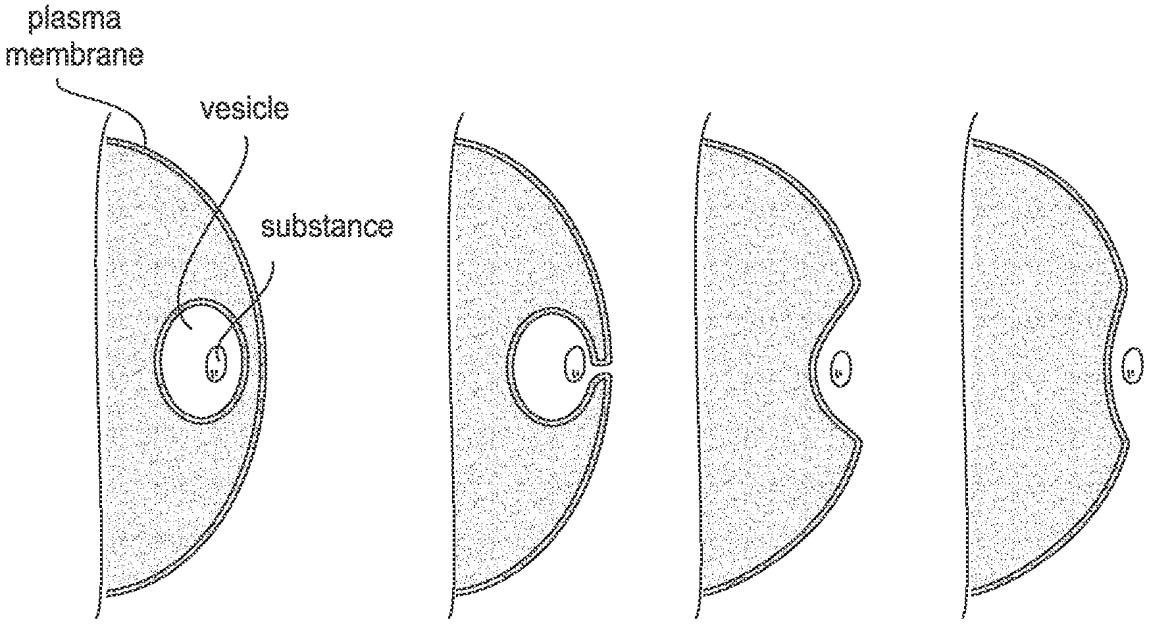

plasma
membrane
vesicle
substance

FIG. 2

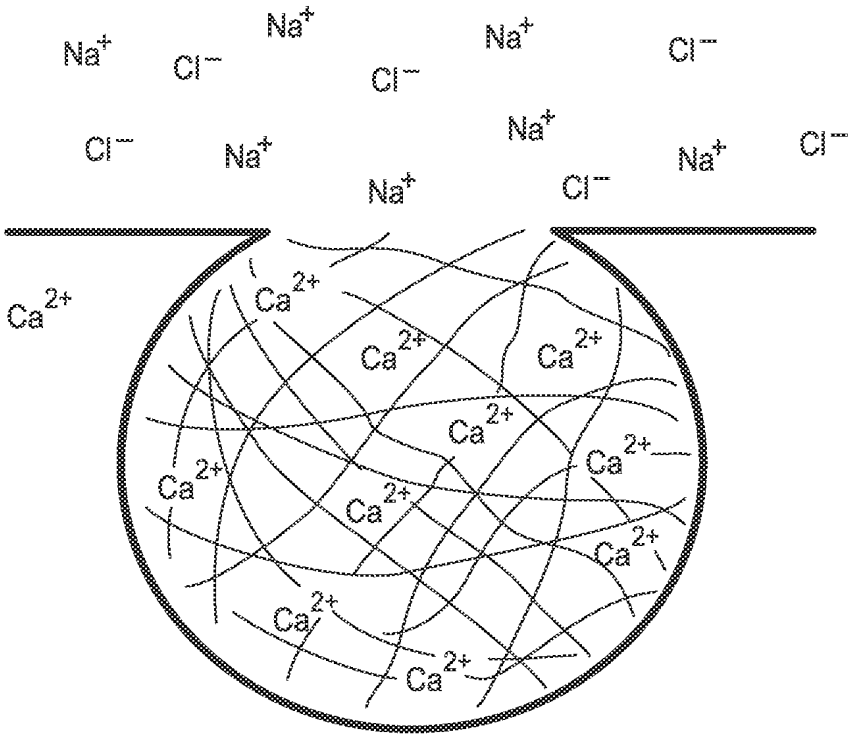

Na+
Cl−
Na+
Na+
Cl−
Cl−
Na+
Cl−
Na+
Cl−
Na+
Na+
Cl−
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+
Ca2+

FIG. 3

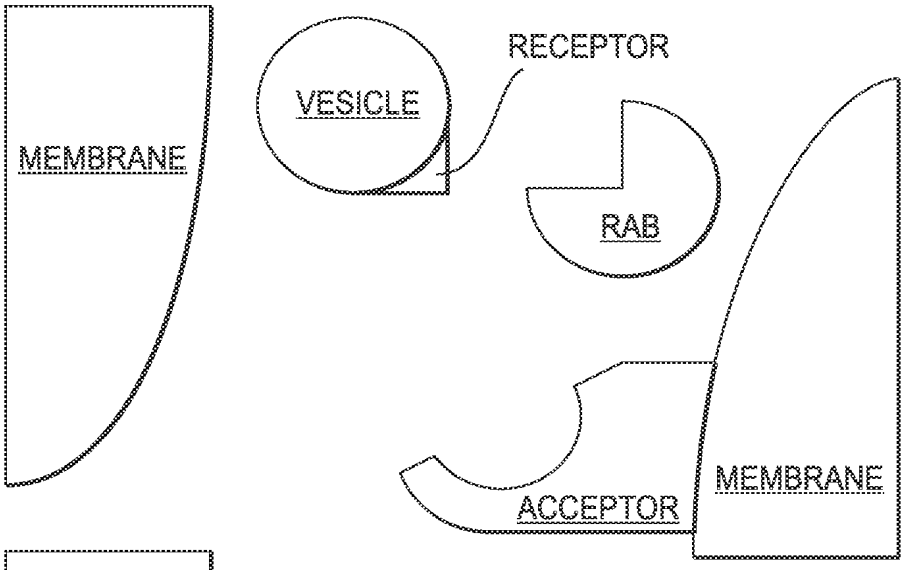


FIG. 4A

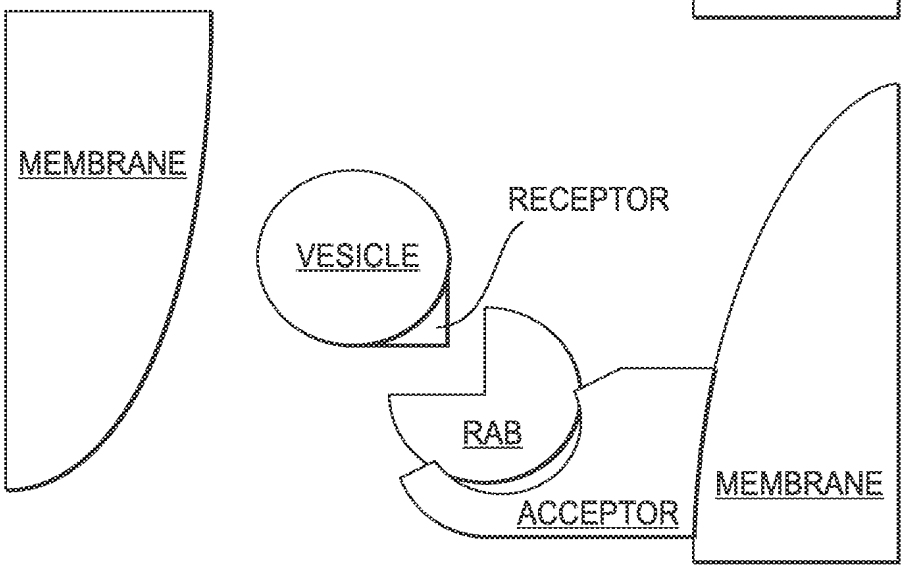


FIG. 4B

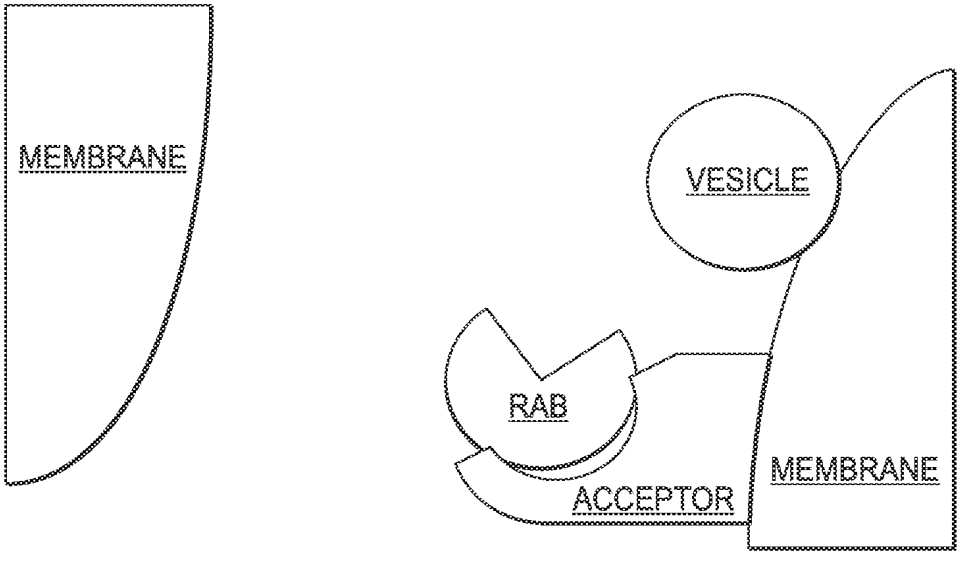


FIG. 4c

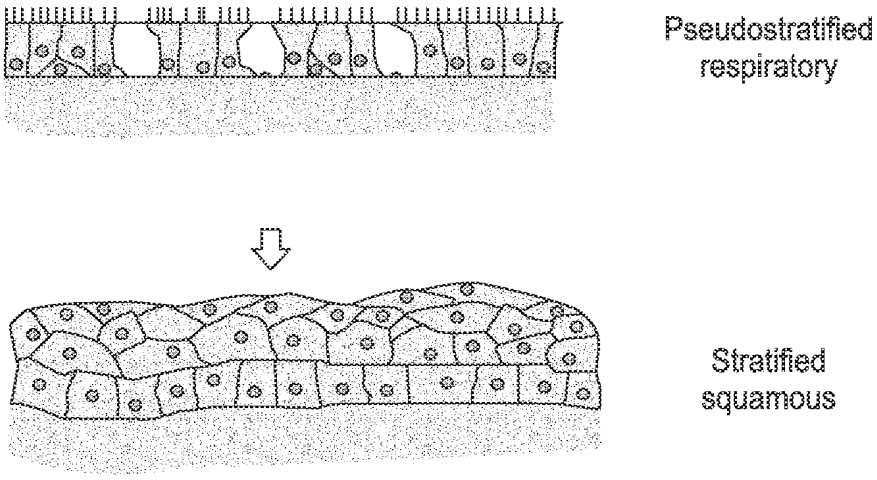

Pseudostratified
respiratory
Stratified
squamous

FIG. 5

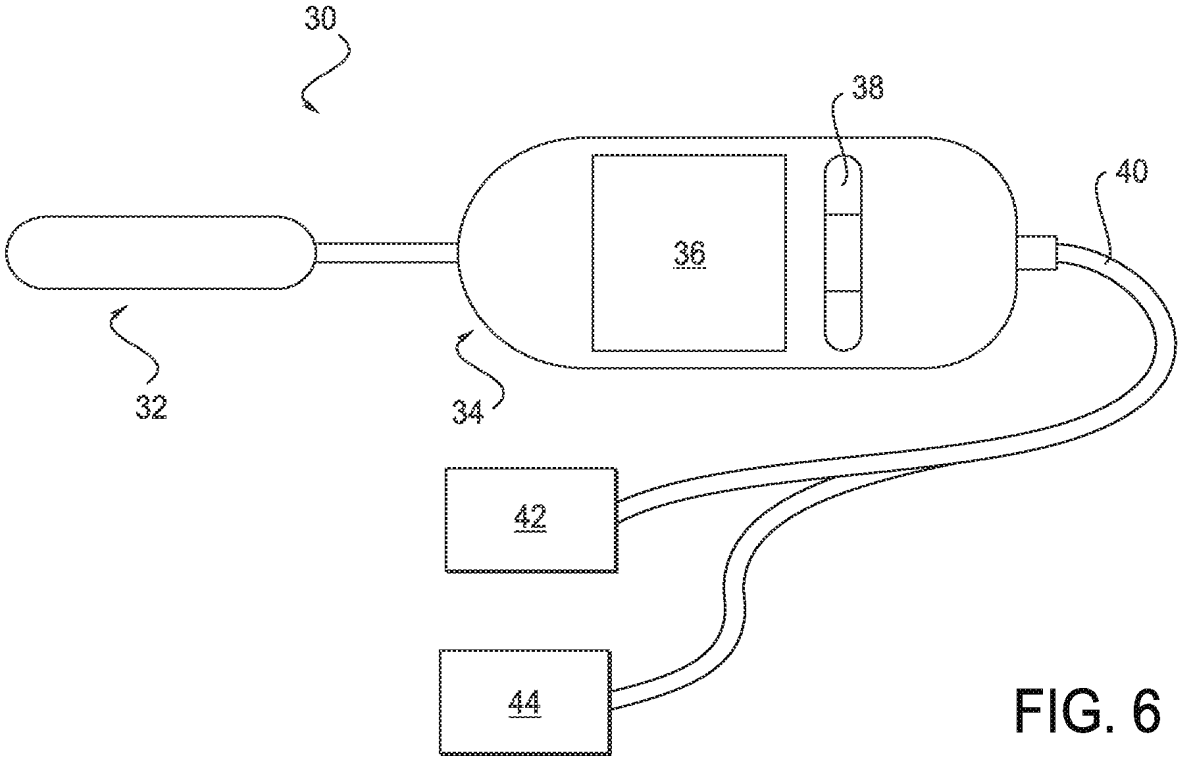

30
38
40
36
32
34
42
44

FIG. 6

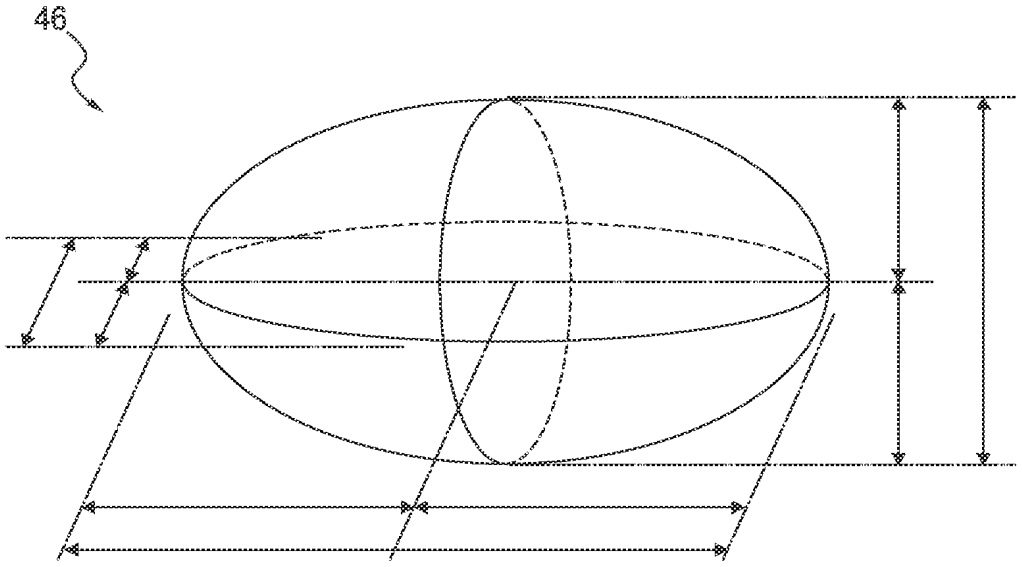


FIG. 7

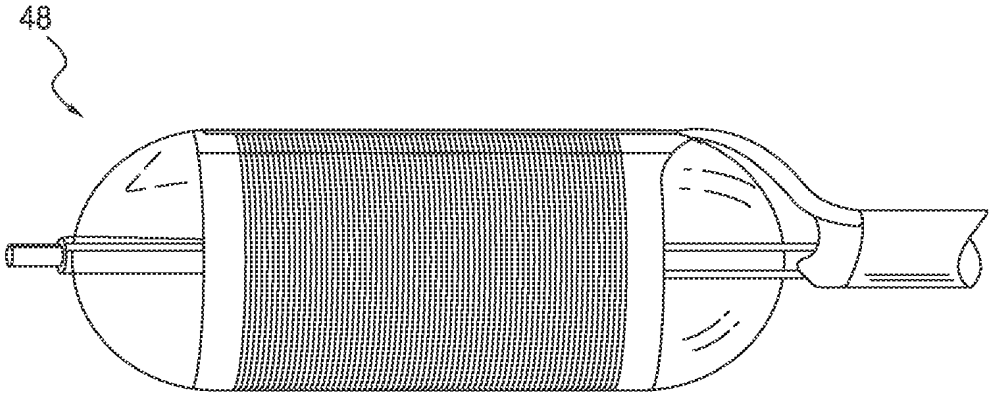


FIG. 8

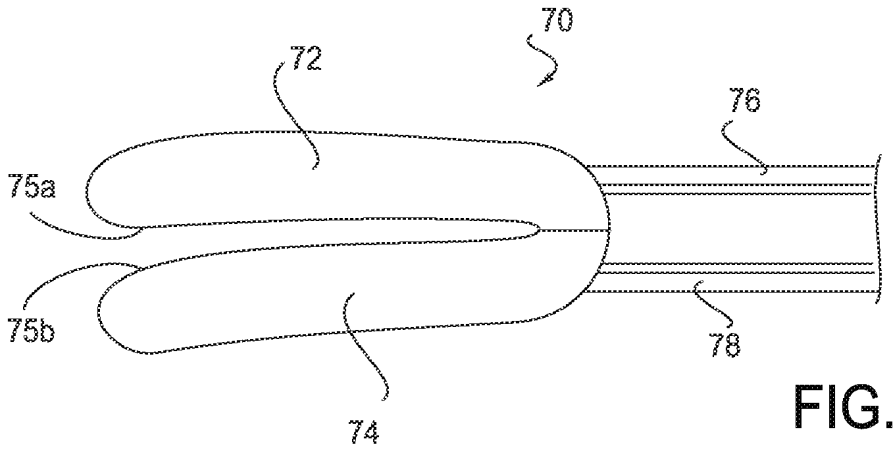


FIG. 9

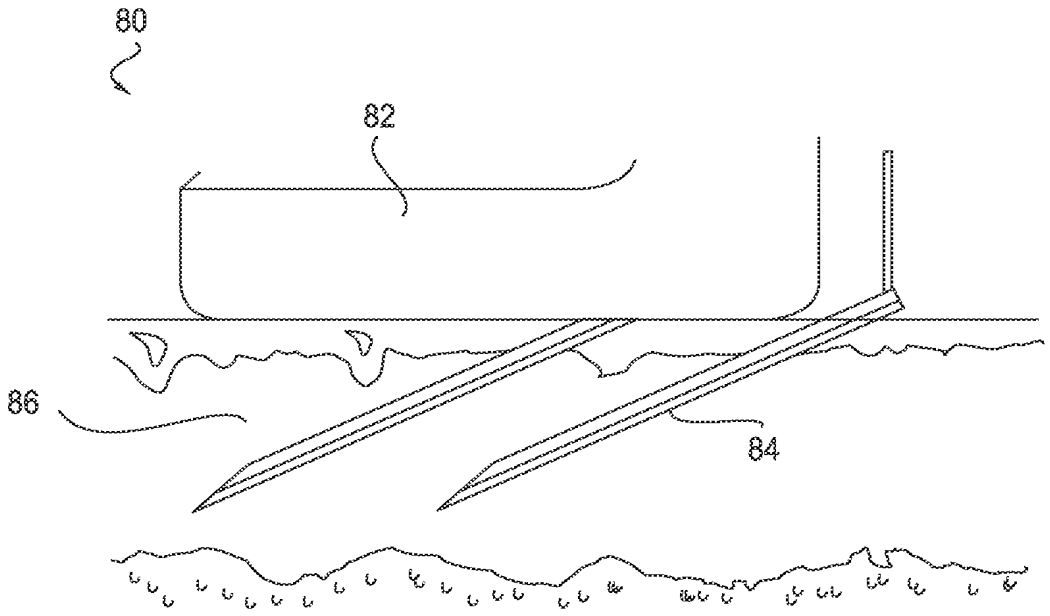


FIG. 10

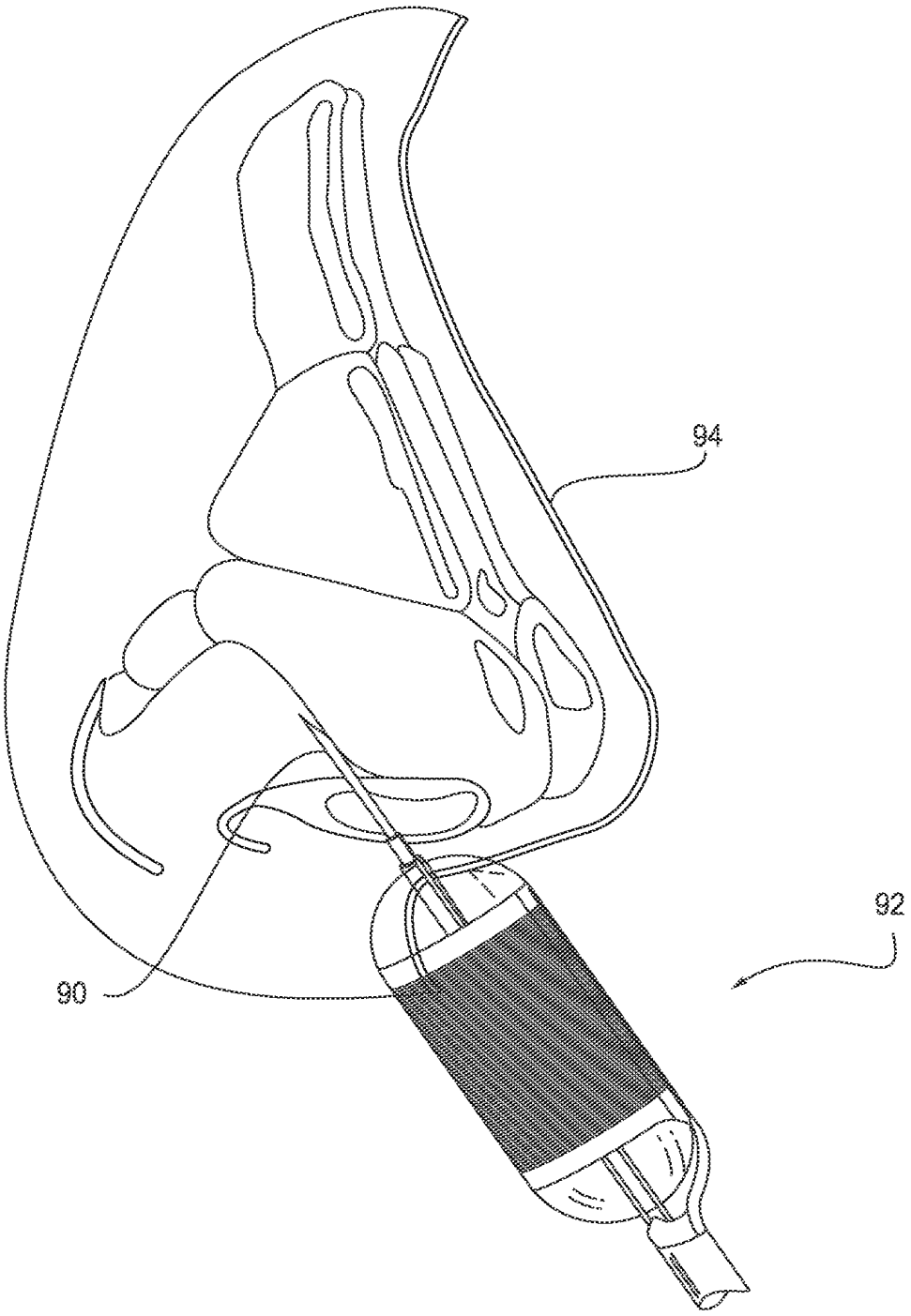


FIG. 11

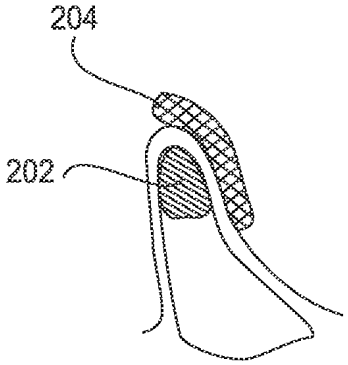


FIG. 12A

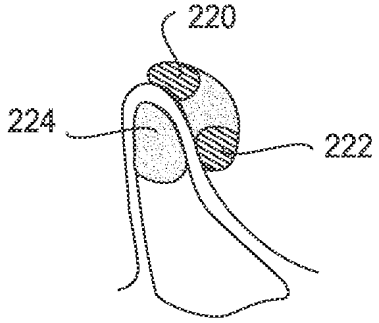


FIG. 12C

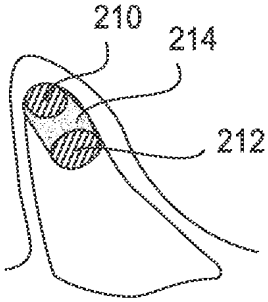


FIG. 12B

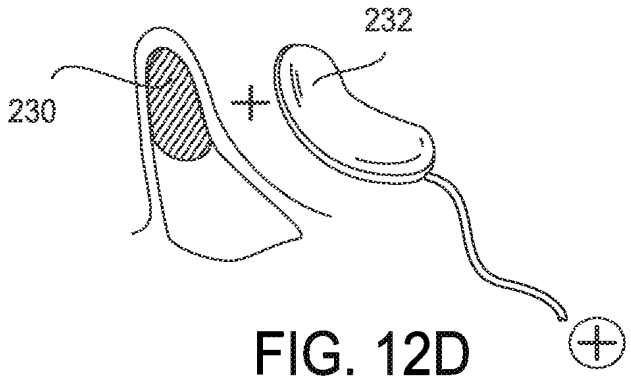


FIG. 12D

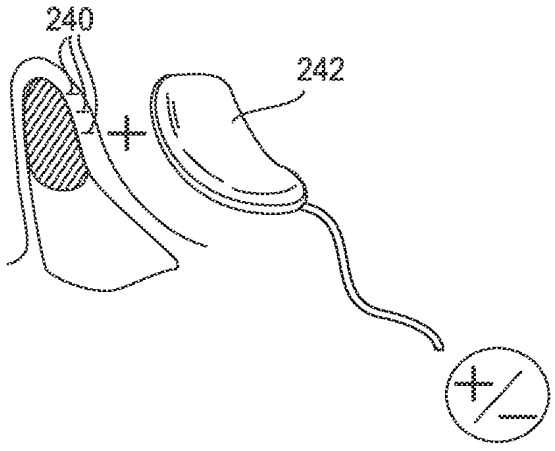


FIG. 12E

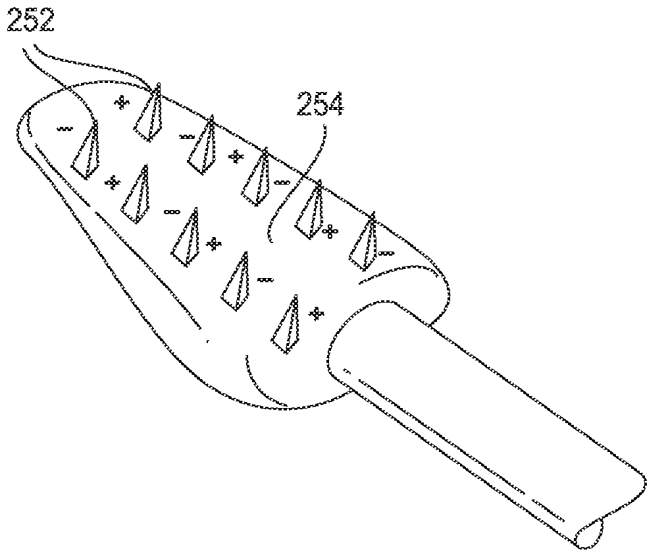


FIG. 13

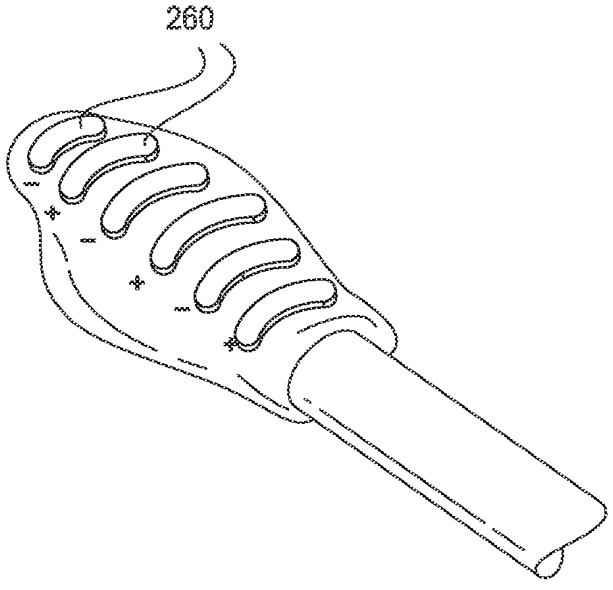


FIG. 14

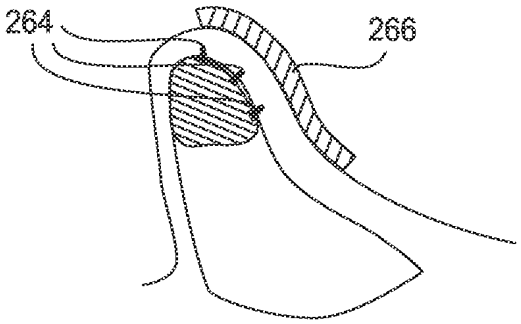


FIG. 15A

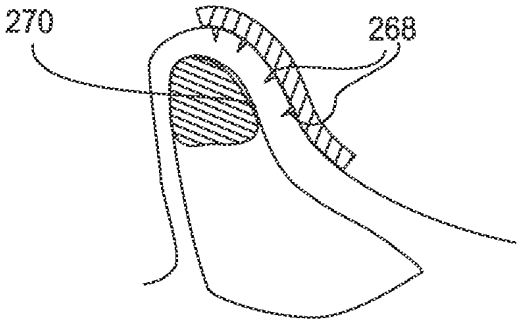


FIG. 15B

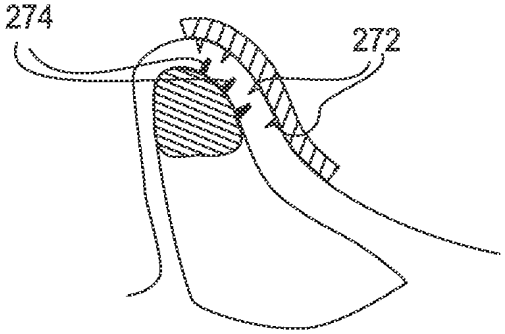


FIG. 15C

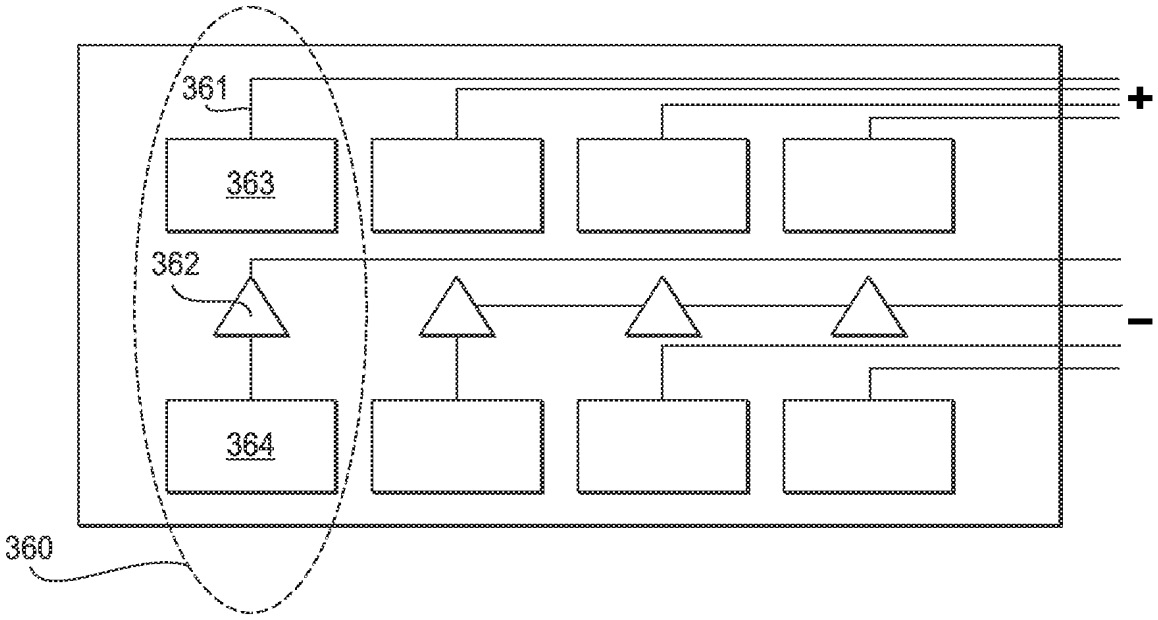


FIG. 16A

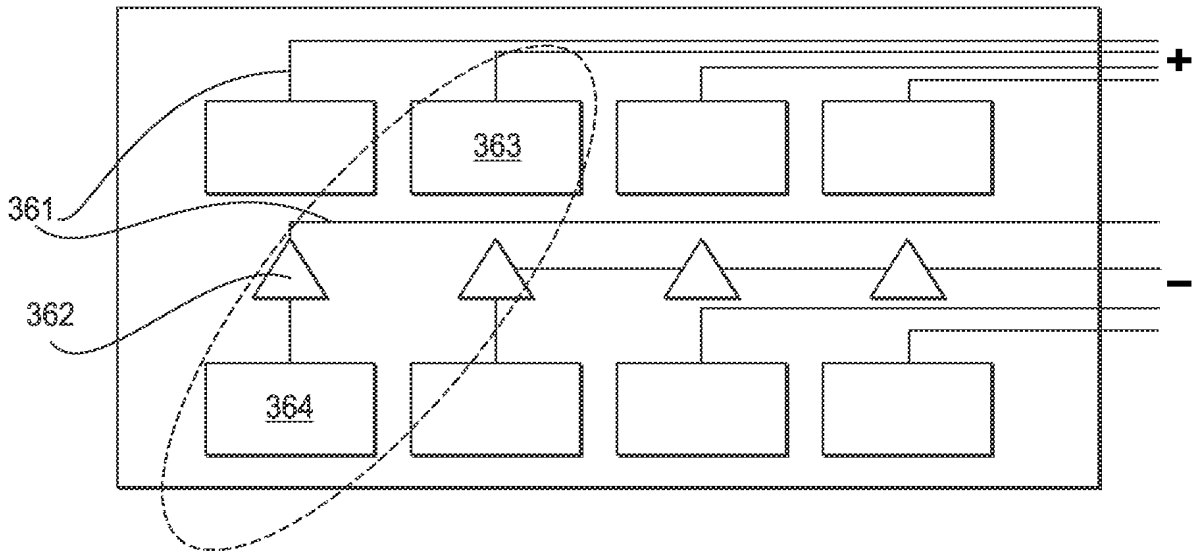


FIG. 16B

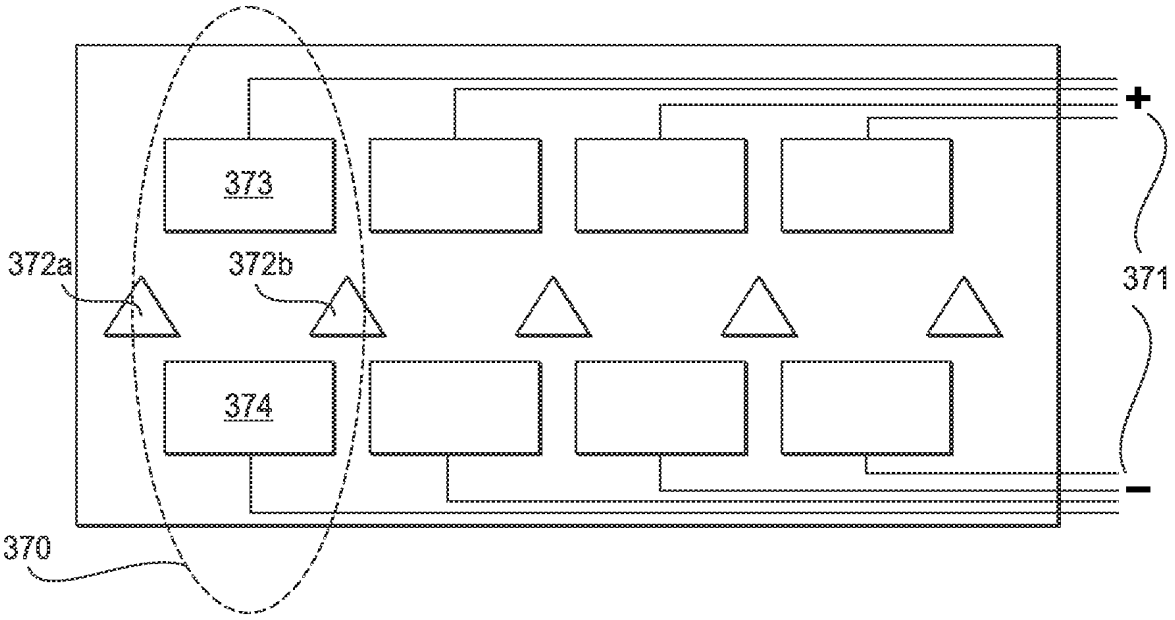


FIG. 16C

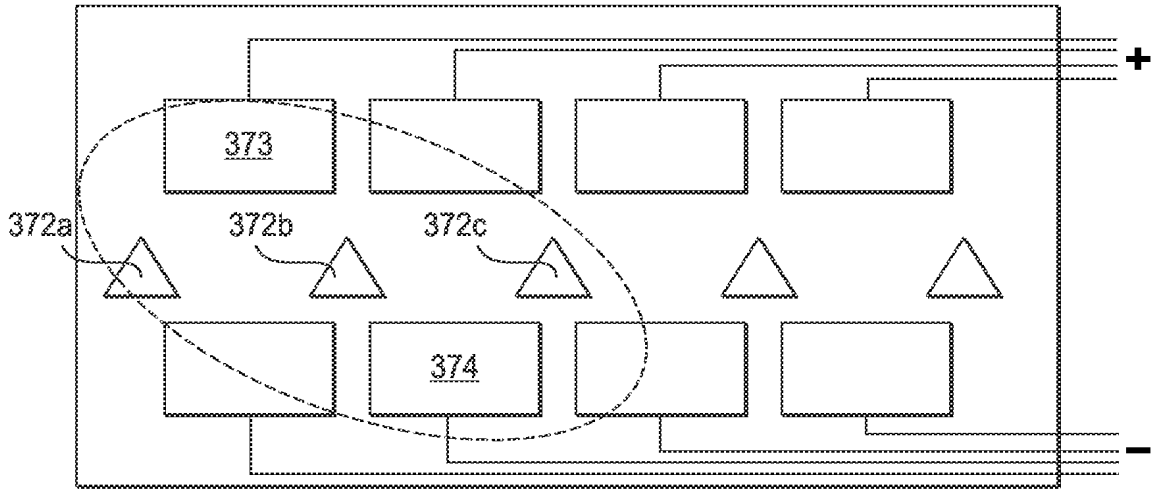


FIG. 16D

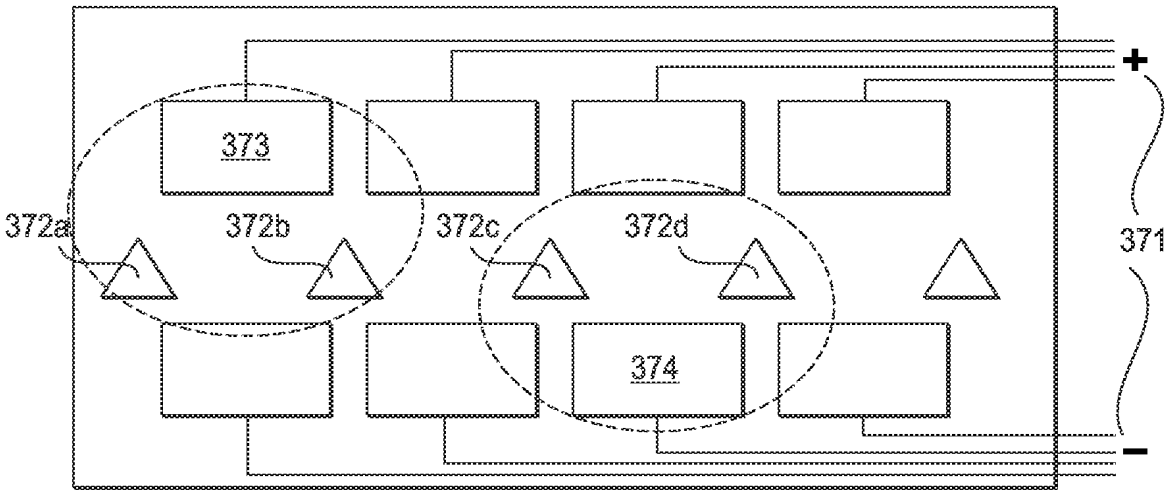


FIG. 16E

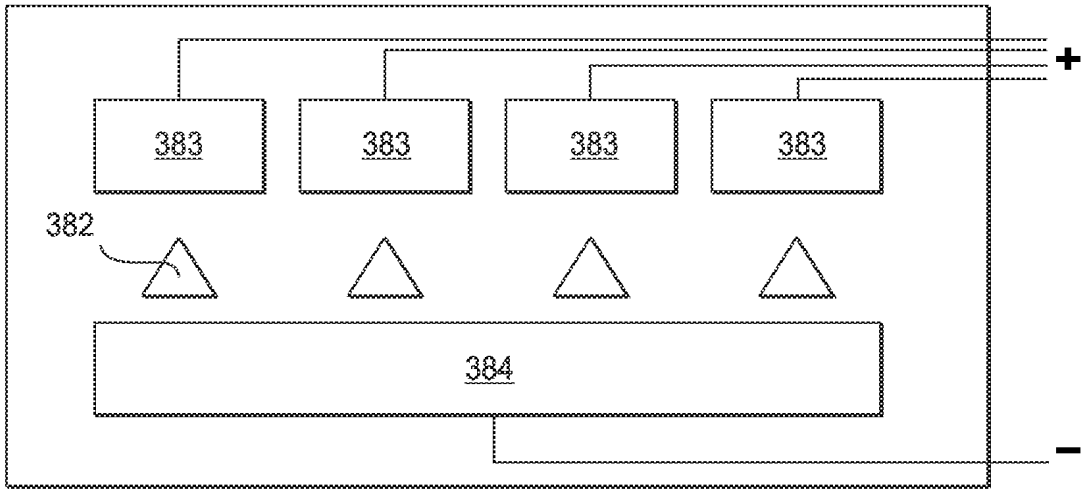


FIG. 16F

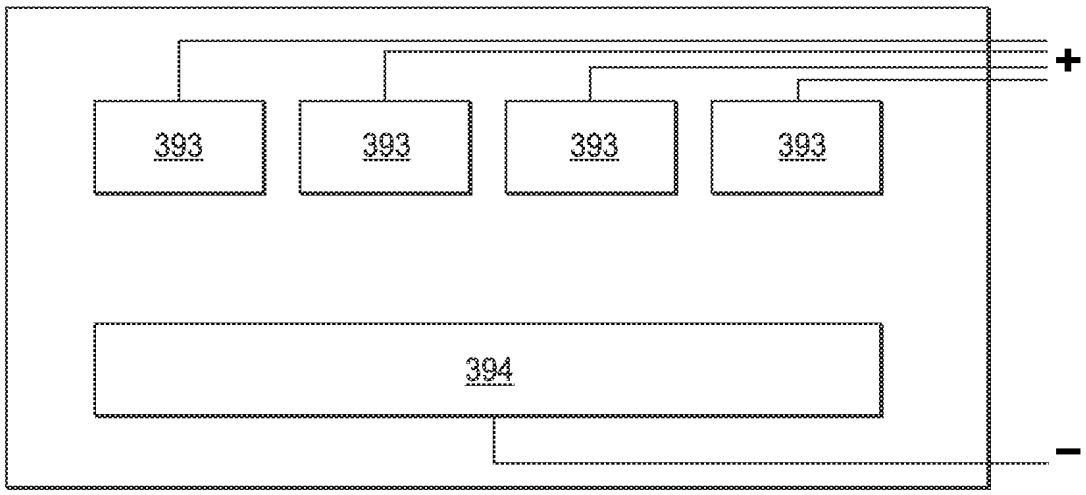


FIG. 16G

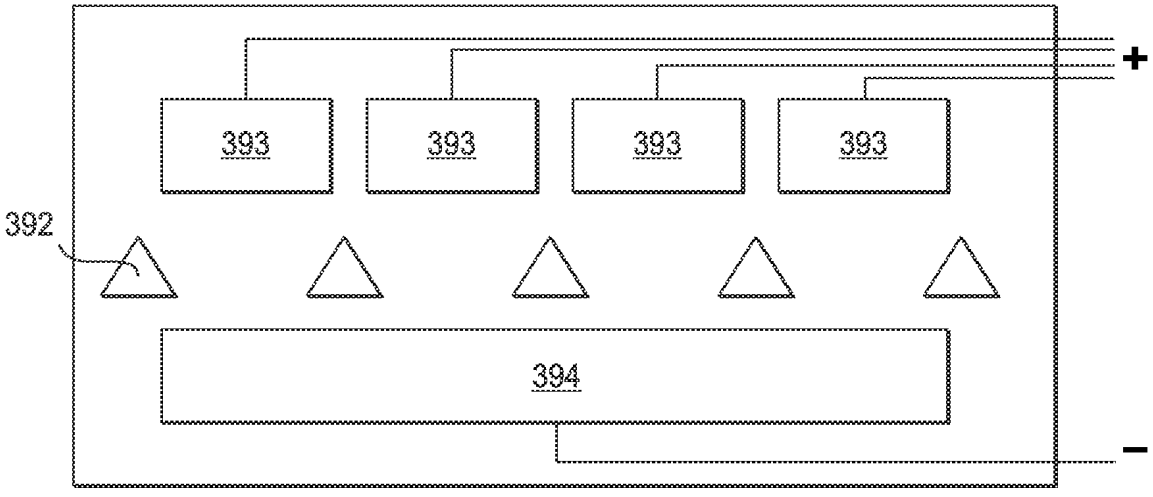


FIG. 16H

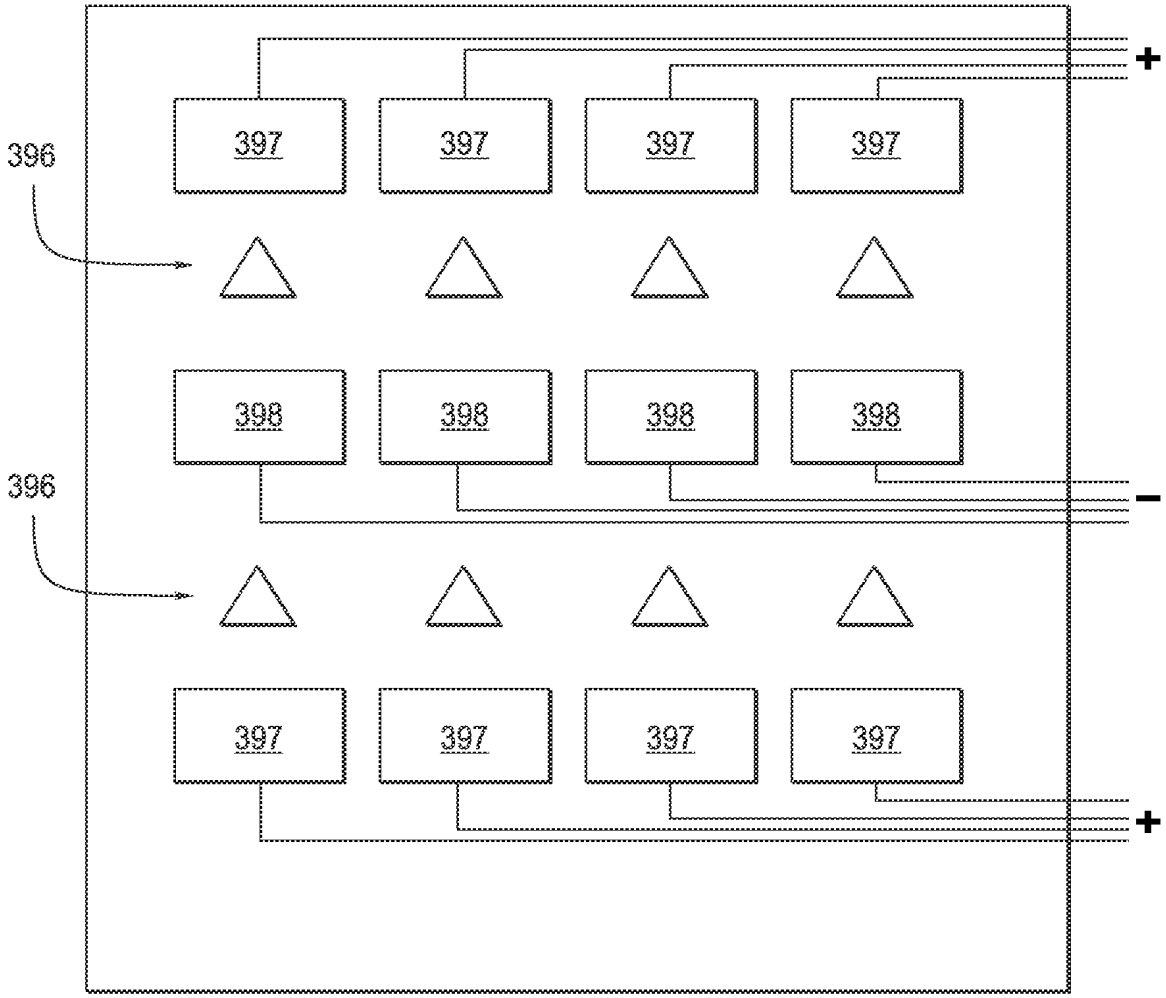


FIG. 16I

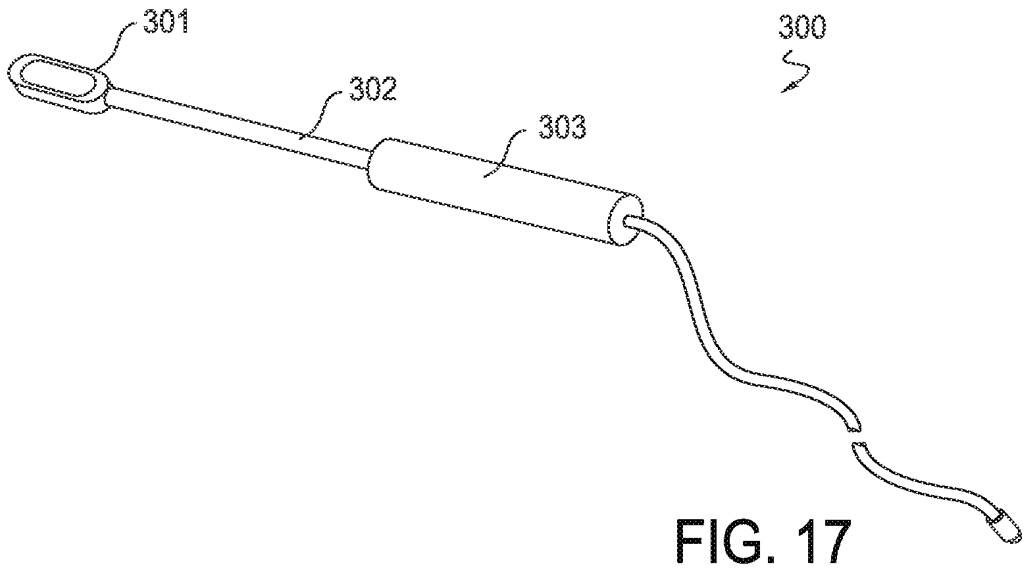


FIG. 17

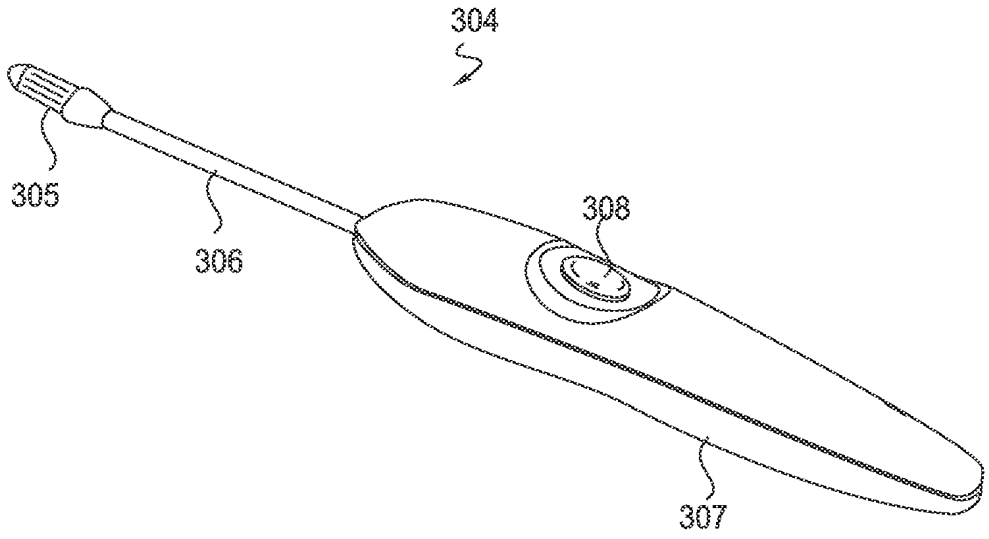


FIG. 18

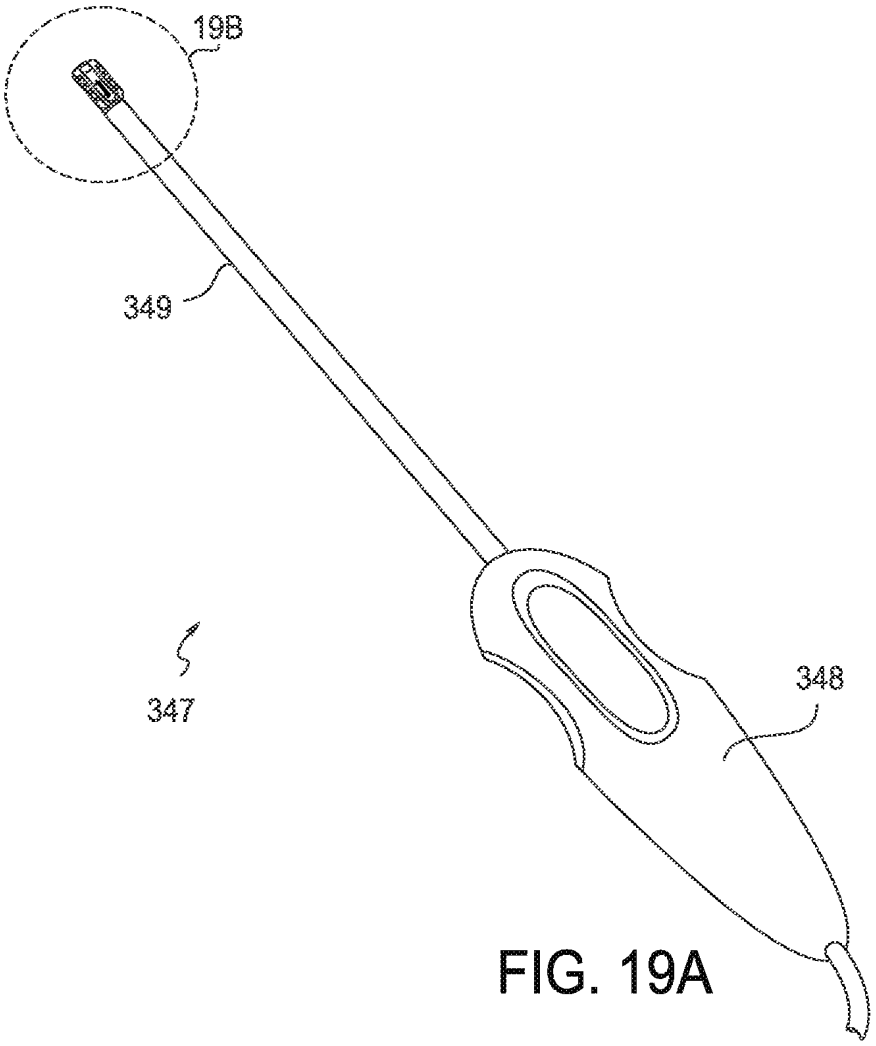


FIG. 19A

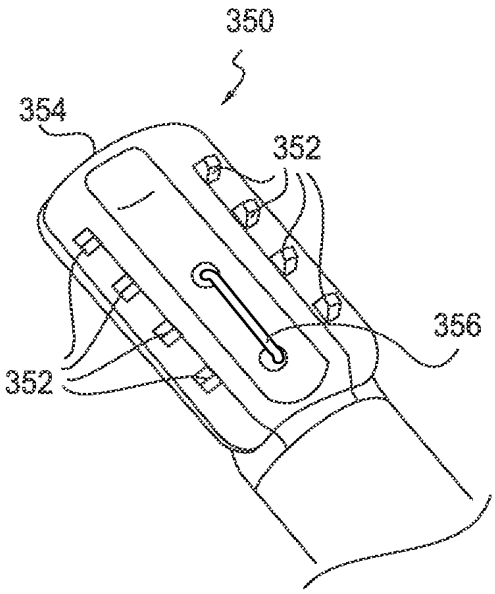


FIG. 19B

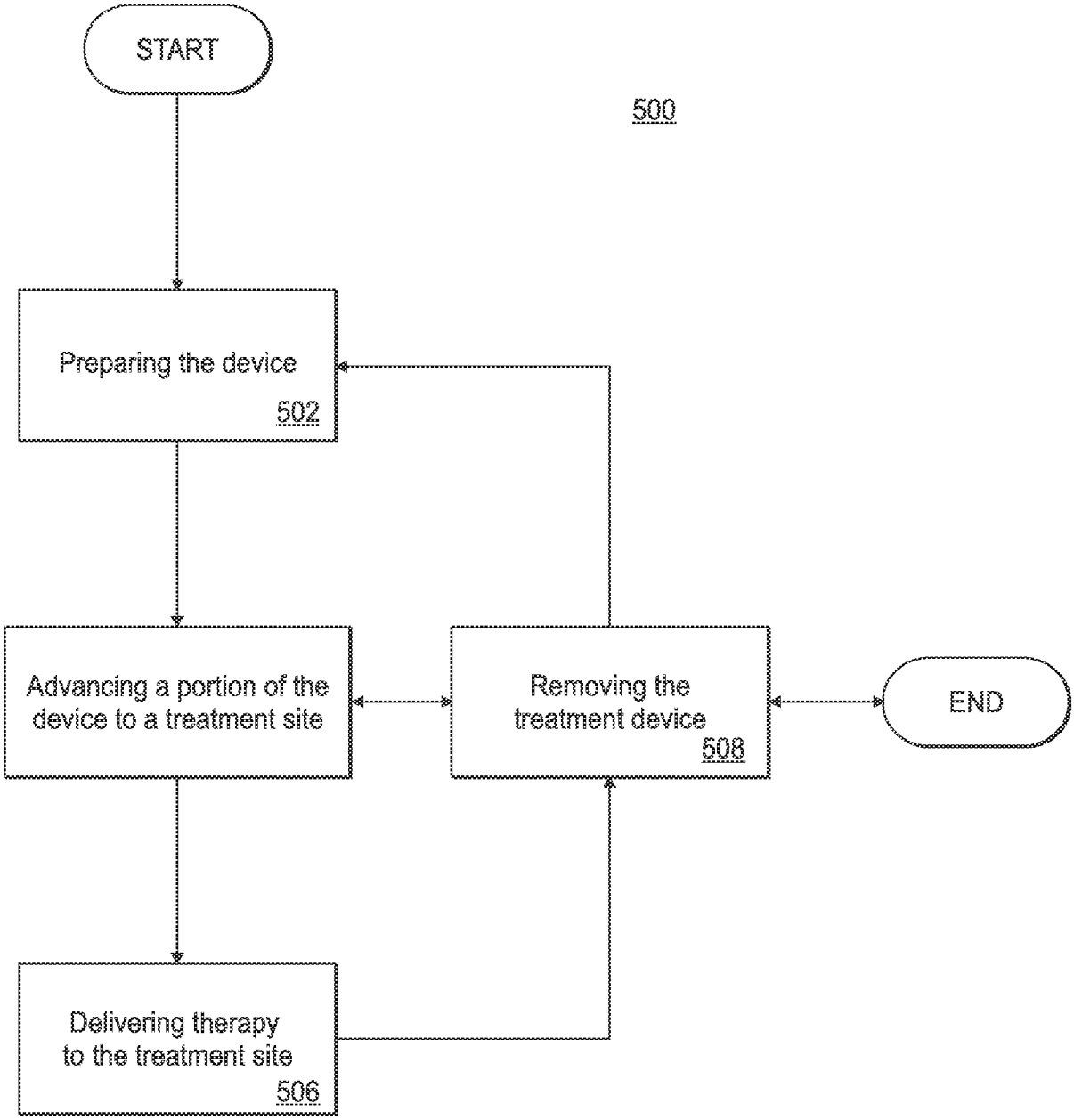

START
500
Preparing the device
502
Advancing a portion of the device to a treatment site
Removing the treatment device
508
END
Delivering therapy to the treatment site
506

FIG. 20

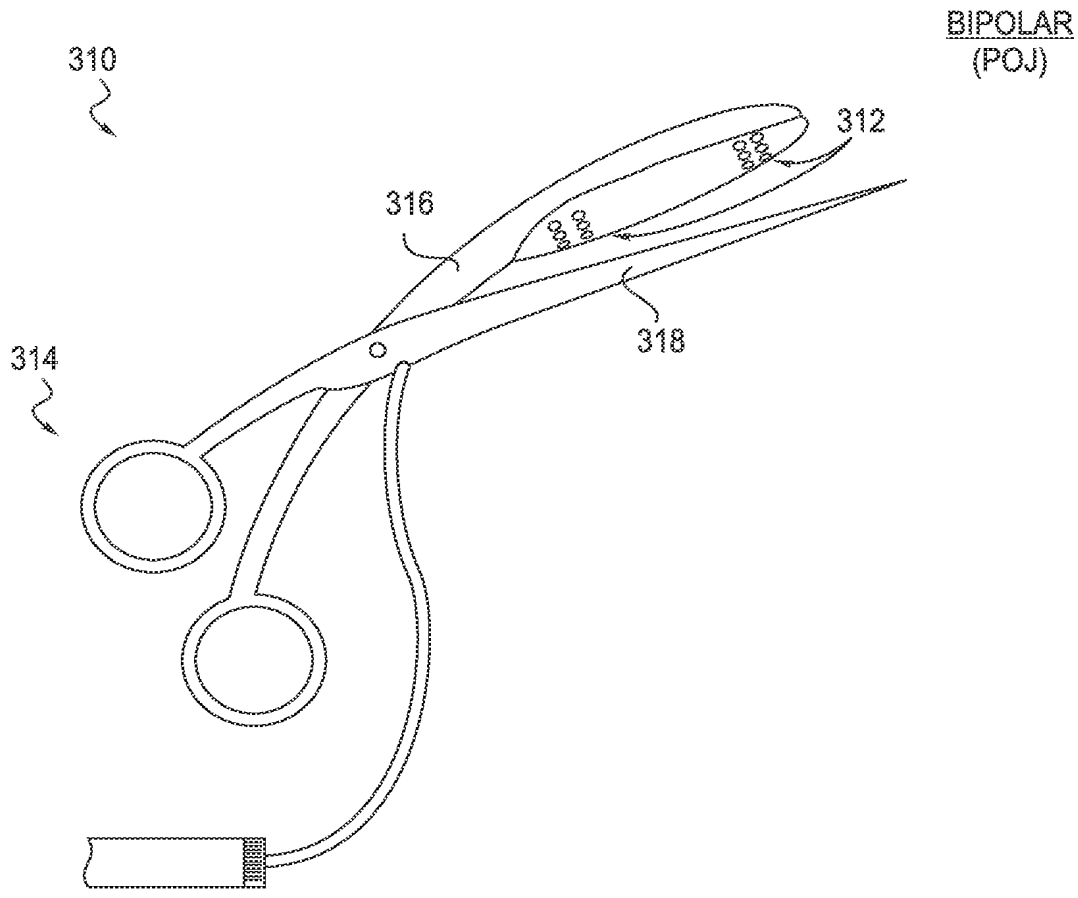


FIG. 21A

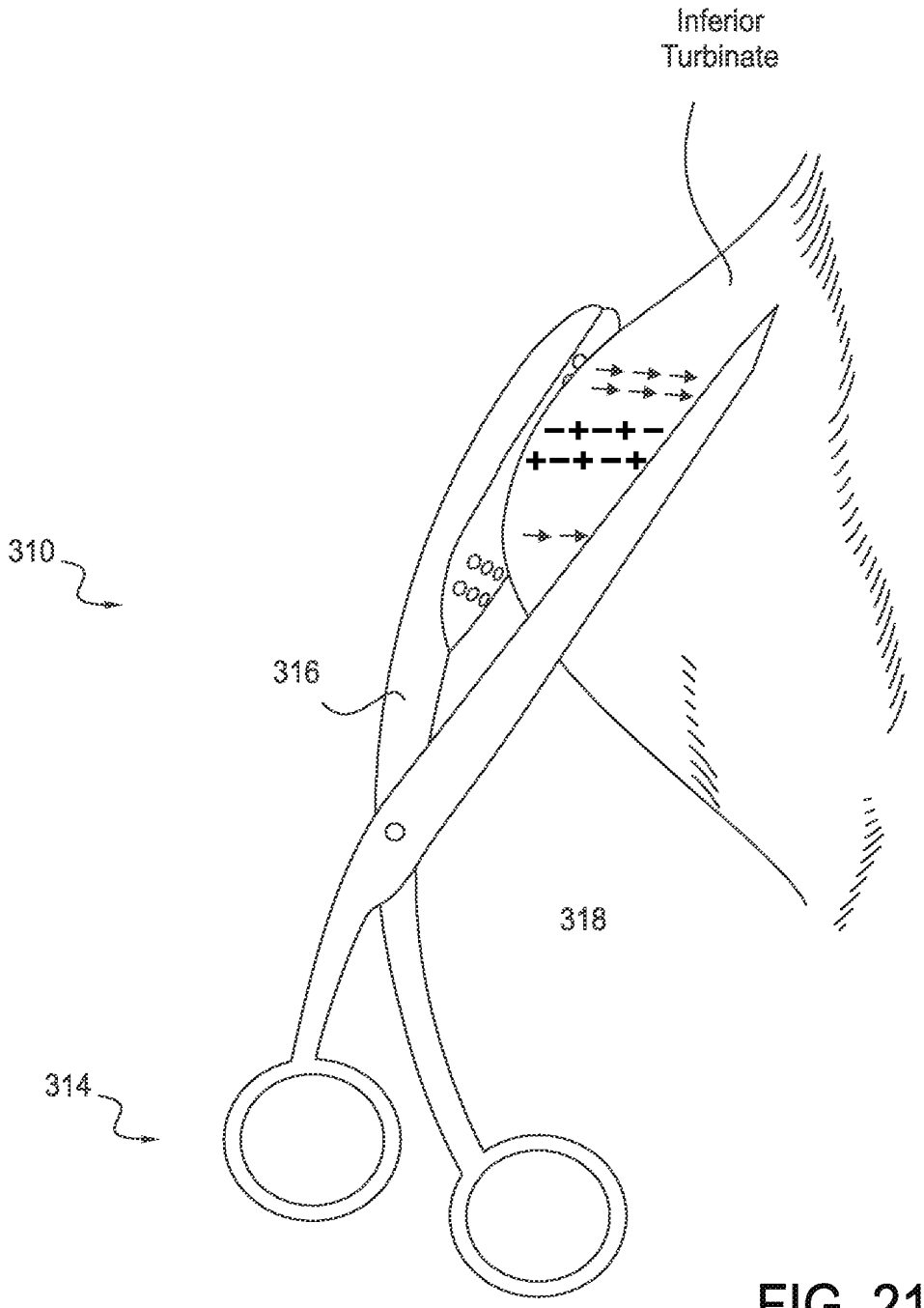


FIG. 21B

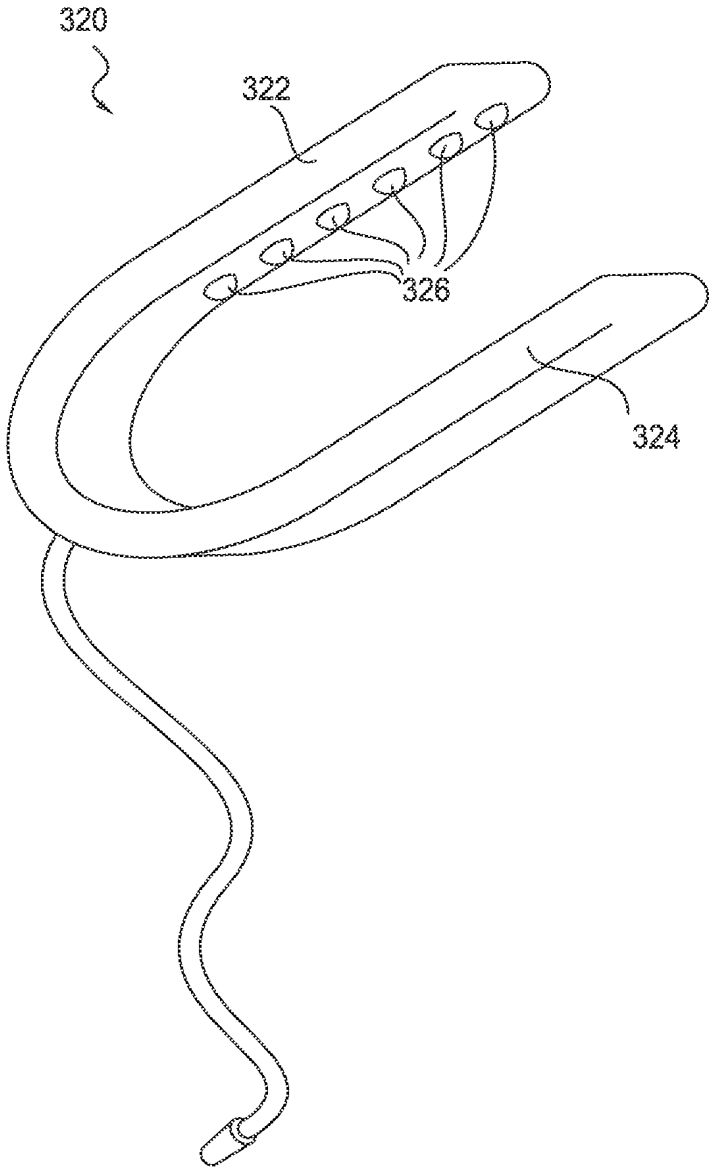


FIG. 22A

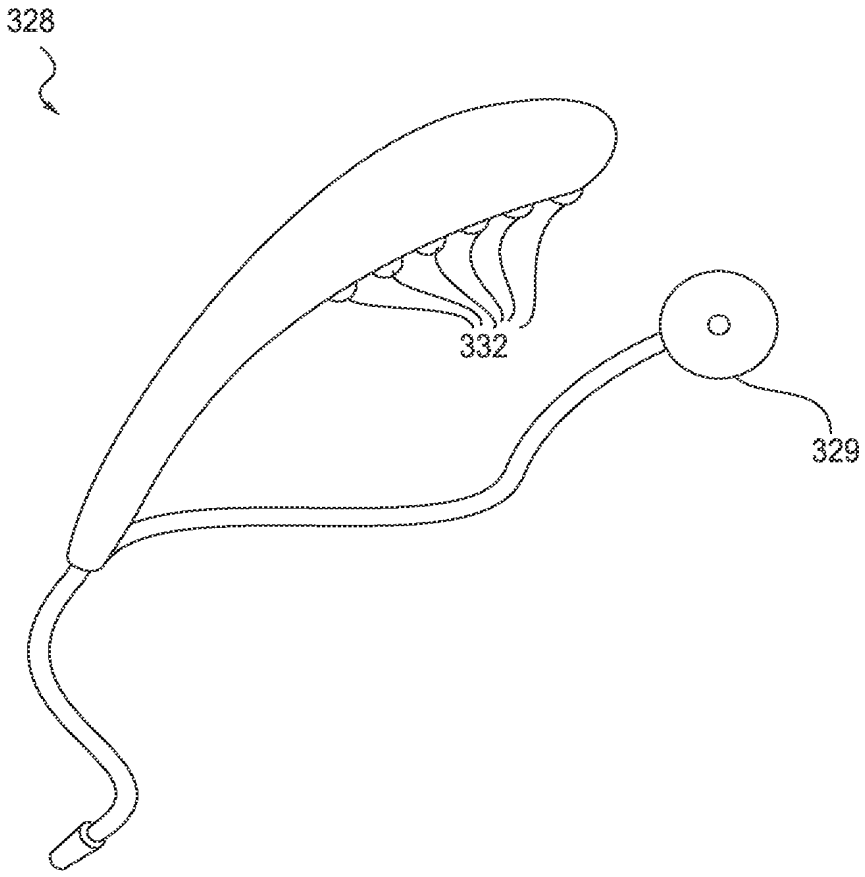


FIG. 22B

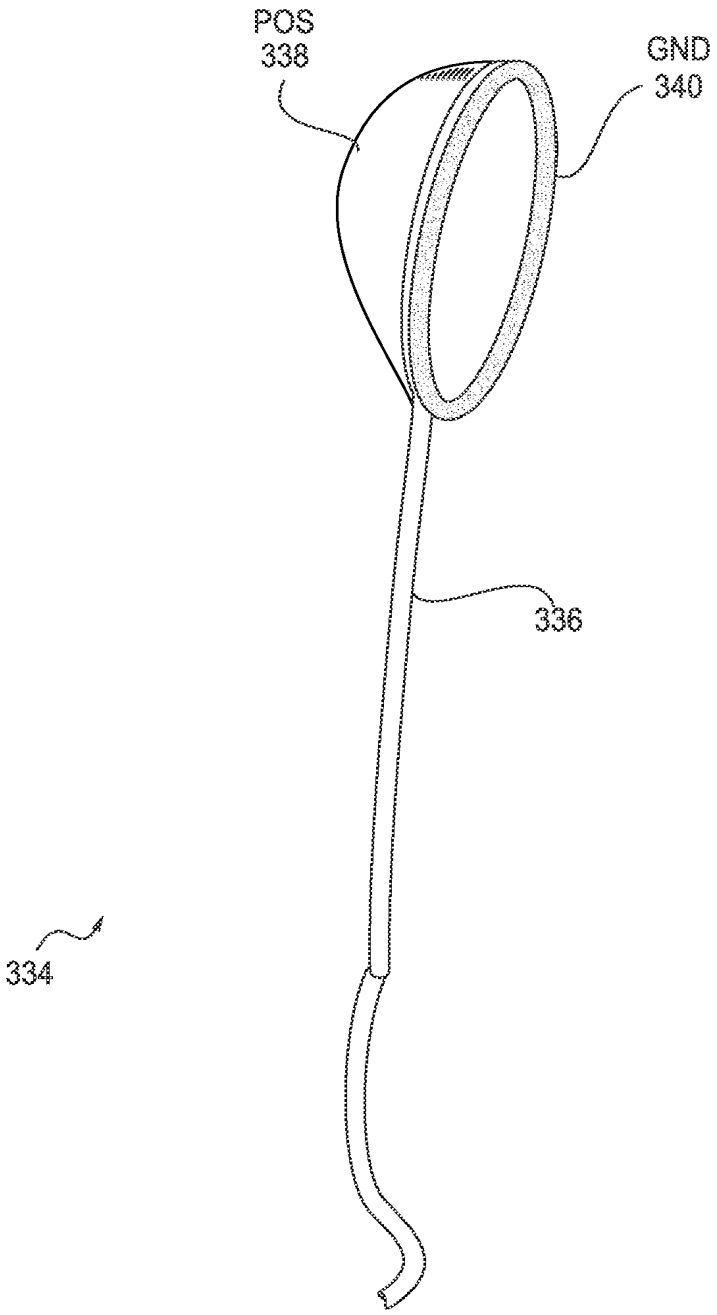


FIG. 23

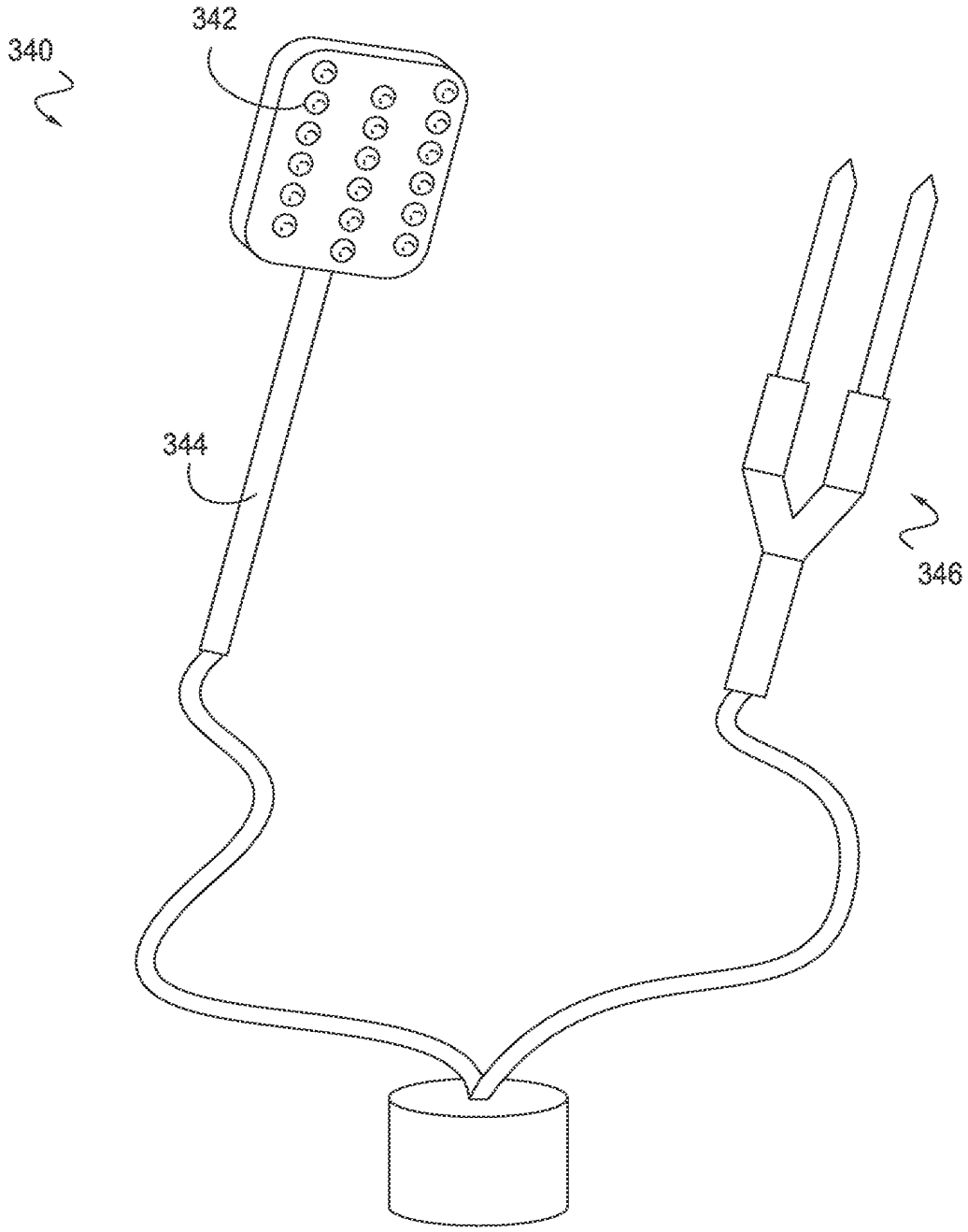


FIG. 24

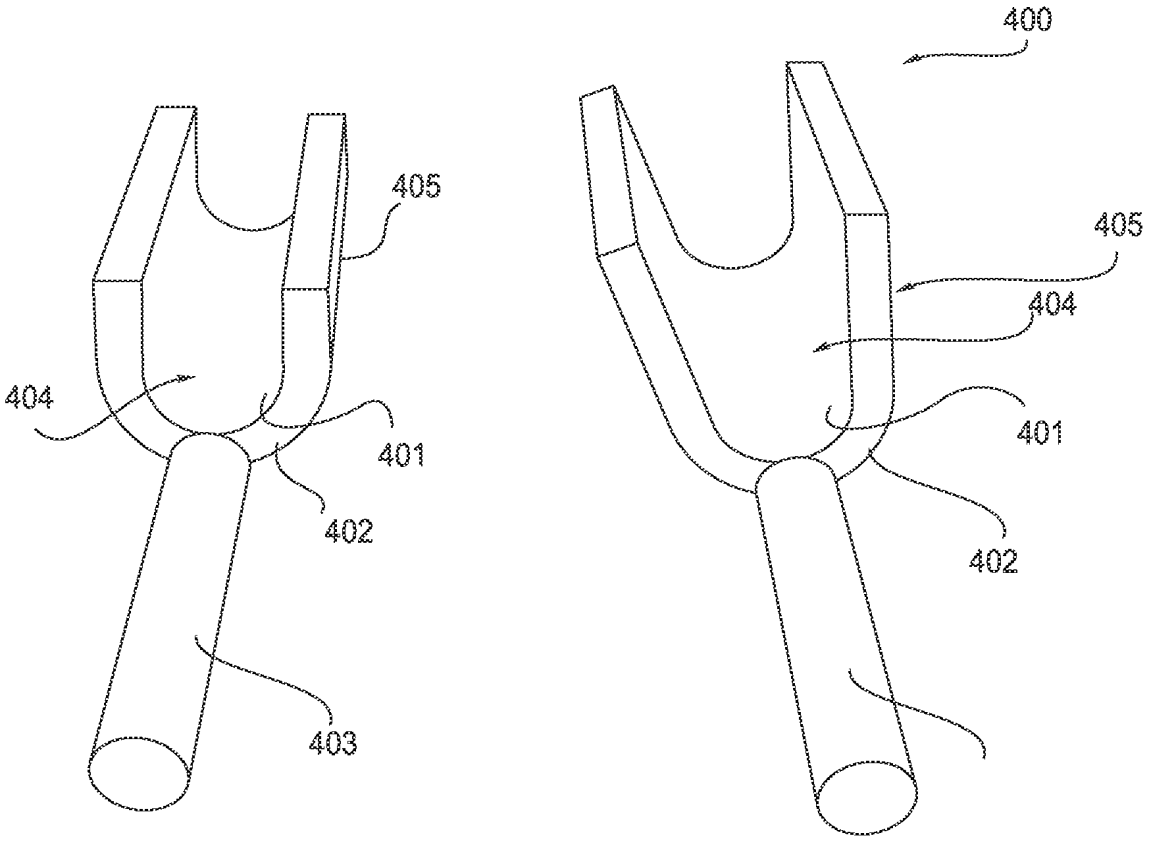


FIG. 25

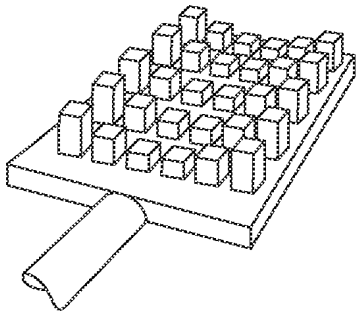


FIG. 26A

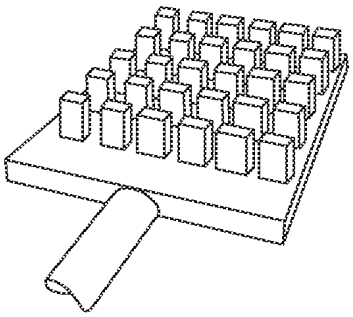


FIG. 26B

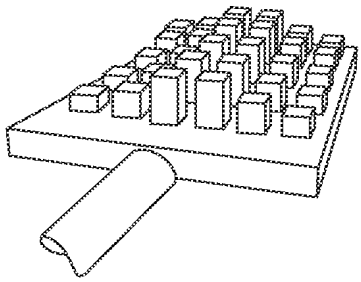


FIG. 26C

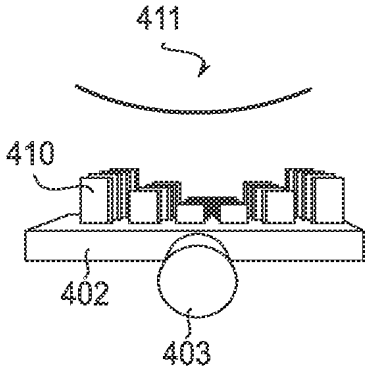


FIG. 26D

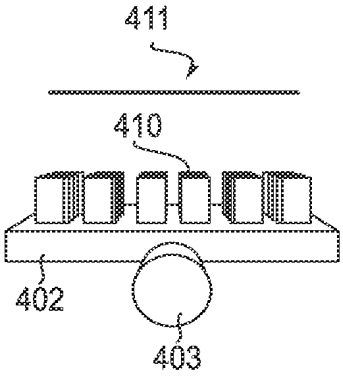


FIG. 26E

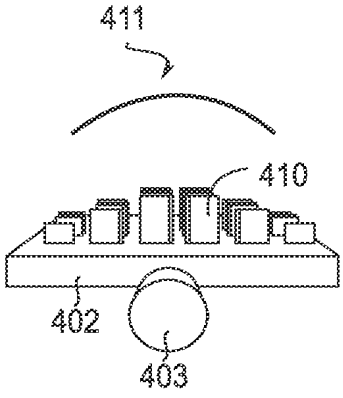


FIG. 26F

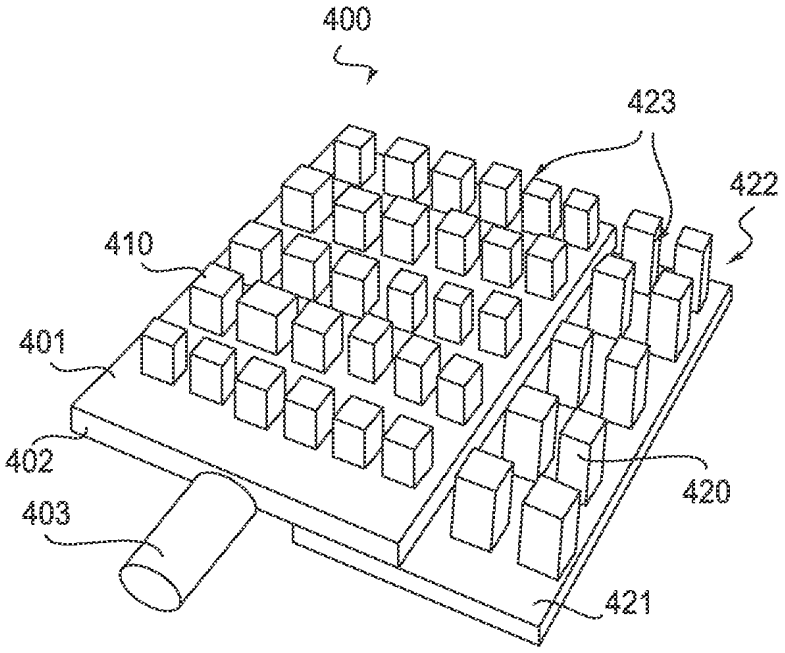


FIG. 27

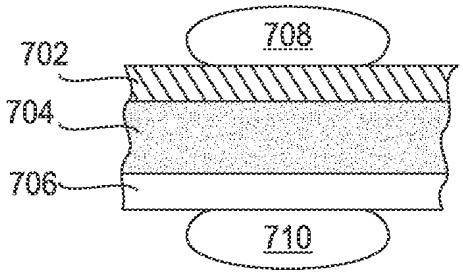


FIG. 28A

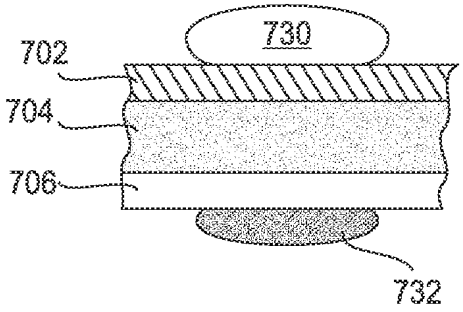


FIG. 28B

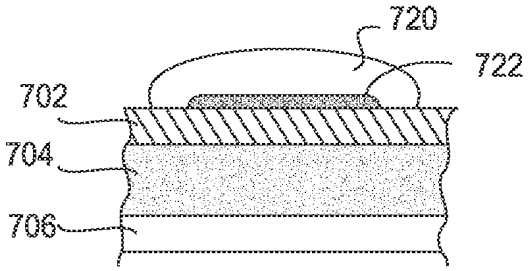


FIG. 28C

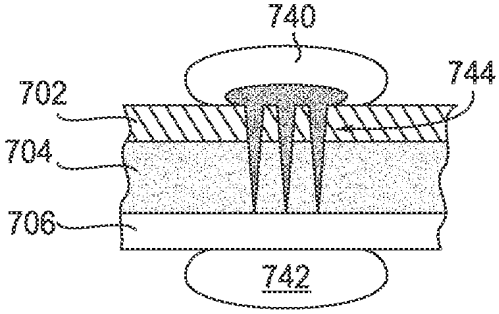


FIG. 28D

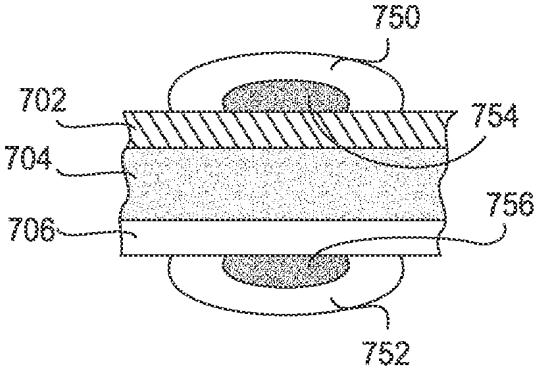


FIG. 28E

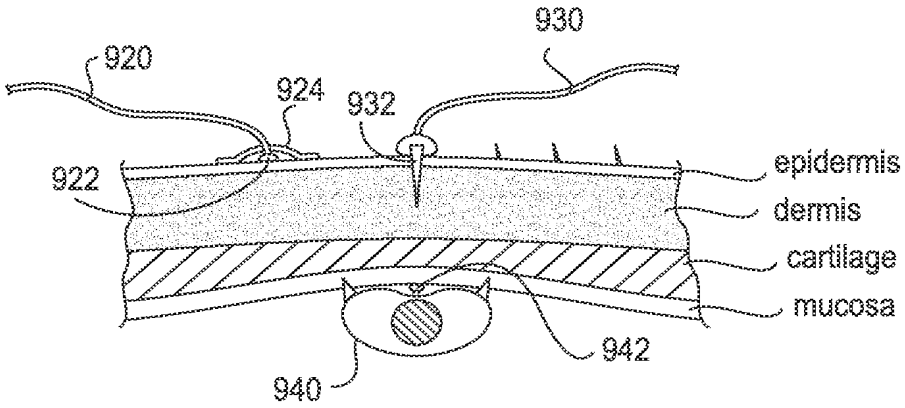


FIG. 32A

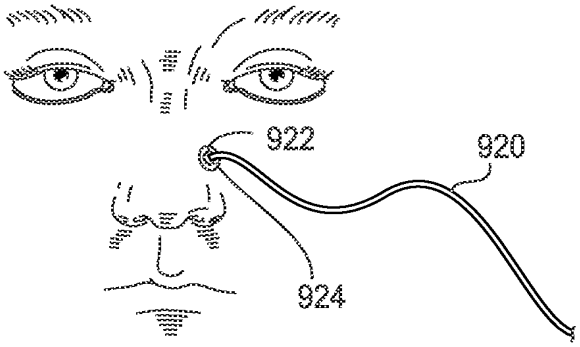


FIG. 32B

Electronic Acknowledgement Receipt

EFS ID:	22692007
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	20-JUN-2015
Filing Date:	31-MAR-2015
Time Stamp:	17:09:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Drawings-only black and white line drawings	P244690WO01_Formal_Drawings.pdf	871978 1b876d57638d29e036dd713eabe2c763628469c6	no	29

Warnings:	
Information:	

Total Files Size (in bytes):	871978

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/675,689
	Filing Date	March 31, 2015
	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	To be assigned
	Attorney Docket Number	P244690US02 (494912-15)

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		5,348,008		1994-09-20	BORNN, *et al.*	
		5,533,499		1996-07-09	JOHNSON	
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		5,827,277		1998-10-27	EDWARDS	
		5,843,021		1998-12-01	EDWARDS, *et al.*	
		5,843,077		1998-12-01	EDWARDS	

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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	Application Number	14/675,689
	Filing Date	March 31, 2015
	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	To be assigned
	Attorney Docket Number	P244690US02 (494912-15)

		5,846,235		1998-12-08	PASRICHA, *et al.*	
		5,879,349		1999-03-09	EDWARDS	
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		6,126,657		2000-10-03	EDWARDS, *et al.*	
		6,131,579		2013-10-17	THORSON, *et al.*	
		6,139,546		2000-10-31	KOENIG, *et al.*	
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	First Named Inventor	Scott J. WOLF
	Art Unit	3762
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	Attorney Docket Number	P244690US02 (494912-15)

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	July 9, 2015
Name/Print	Scott Michael Smith	Registration Number	48268

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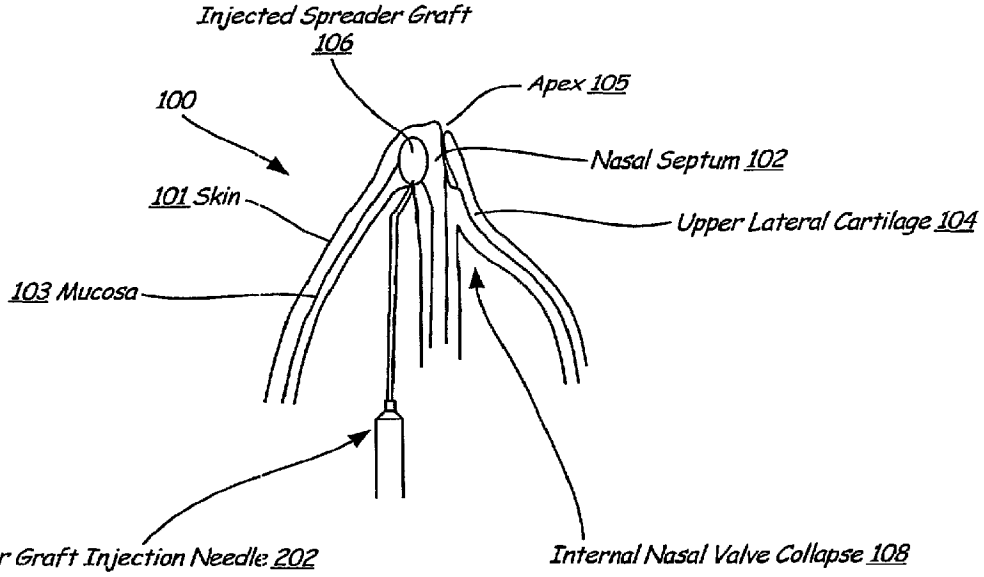
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(54) Title: METHOD AND SYSTEM FOR TREATMENT OF INTERNAL NASAL VALVES



(57) Abstract: Internal nasal valve involves injecting a biomaterial filler into the internal nasal valve of the patient. The injected biomaterial filler in the internal nasal valve increases an internal nasal valve angle.

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METHOD AND SYSTEM FOR TREATMENT OF INTERNAL NASAL VALVES

FIELD OF THE INVENTION

[001] The invention relates to methods for non-surgically introducing an injectable material into the nasal valve of a patient. The invention further relates to providing a non-surgical system for treatment of nasal valve collapse.

BACKGROUND OF THE INVENTION

[002] The internal nasal valve is the narrowest point in the nasal airway and is the controlling point that regulates inspiration flow. A large percentage of inspiratory resistance is attributable to internal nasal valve function. Collapse of one or both internal nasal valves is a common cause of nasal airway obstruction, because of its narrowness, and may lead to difficulty in respiration and snoring. Internal nasal valve collapse can be a consequence of previous surgery, trauma, aging, or primary weakness of the upper lateral cartilage and is often symptomatic and debilitating.

[003] Methods of correcting internal nasal valve collapse are typically focused on repositioning the upper lateral cartilage or adding structural grafts to support the lateral wall of the nose. The most frequent methods used surgically correct internal nasal valve collapse and involve the use of spreader grafts placed between the upper lateral cartilage and septum. Spreader grafts function by repositioning the upper lateral cartilage in a lateralized position, and by adding width to the middle nasal vault.

[004] Spreader grafts are designed to lateralize the upper lateral cartilage by the width of the graft, thereby increasing the cross-sectional area of the nasal valve. Commonly, septal cartilage is harvested and shaped into spreader grafts. If the septum is unavailable, conchal cartilage or Medpor may be used. The grafts are placed in a sub-mucosal pocket between the septum and the upper lateral cartilage. However, spreader graft techniques are associated with complications because the nasal mucosa may be disrupted leading to web formation and further valve stenosis. In addition, surgery may be prolonged in order to perform final trimming to remove any sharp edges that may be visible or palpable resulting in added trauma to a patient's implant area.

[005] Other surgical rhinoplasty techniques of internal nasal valve repair include suture-suspension and flaring techniques, butterfly grafts, and alar batten grafts, as well as septoplasty, turbinoplasty, and aperture widening. Each of the techniques are invasive surgical techniques that are costly and involve a degree of morbidity. In addition, the invasive surgical techniques may require hospital stays and involve long recoveries.

[006] Methods and systems for repairing internal nasal valves including internal nasal valve collapse are desirable that eliminate invasive surgical techniques in order to reduce morbidity, eliminate hospital stays, and shorten recovery periods.

BRIEF SUMMARY OF THE INVENTION

[007] Objects of the present invention include providing a method and system for treating internal nasal valve collapse. According to the present invention, this is achieved by non-surgical treatment. Treatment of the internal nasal valve includes injecting a biomaterial filler into the internal nasal valve of the patient. The injected biomaterial filler in the internal nasal valve, according to the invention, causes an increase in an internal nasal valve angle.

[008] In certain embodiments, the increase in internal nasal valve angle is effected by the biomaterial filler displacing the upper lateral cartilage portion laterally away from the septal cartilage portion of the internal nasal valve.

[009] In another embodiment, the biomaterial filler is injected into a junction of an upper lateral cartilage portion and a septum cartilage portion of the internal nasal valve. The biomaterial filler may be a gel cartilage matrix, for example.

[010] In another embodiment, the treatment method includes inserting an injection device to an end point of the internal nasal valve and injecting the biomaterial filler at the end point and along an injection device withdrawing path up to a point of injection external to the patient.

[011] In one embodiment, treatment includes injecting at least one 0.05 ml aliquot of biomaterial filler. Alternatively, a plurality of 0.05 ml aliquots of biomaterial filler at a plurality of positions of the internal nasal valve.

[012] In one embodiment, the treatment method may include increasing a patient's internal nasal valve angle so that the treatment results in a 10-15 degree internal nasal valve angle.

[013] The treatment method, according to embodiments of the invention, may be used to treat, nasal snoring, sleep apnea, and/or internal nasal valve collapse.

[014] In another embodiment, a system for non-surgically treating an internal nasal valve of a patient includes a control syringe; and a 2-inch, 25 gauge thin-thin wall short bevel needle. The needle including a 10-20 degree bend at the terminal portion of the needle about 0.25 inches from the terminal end; and a hub for fluidly coupling to the control syringe.

[015] In another embodiment, the control syringe is a 1.0 cc control syringe. Alternatively, the control syringe is a 0.3 cc control syringe.

[016] The needle, according to an embodiment of the invention includes a 15 degree bend at the terminal portion of the needle about 0.25 inches from the terminal end. According to a further embodiment, the needle may include a straight needle fluidly coupled to a hub, the straight needle capable of fluidly coupling to the 2-inch needle, and the hub capable of fluidly coupling to the control syringe. According to certain embodiments of the invention, the needle may be stainless steel or polypropylene.

[017] In another embodiment the system for treating internal nasal valves includes a pre-loaded syringe with a biomaterial filler. In one embodiment, the biomaterial filler is a gel cartilage matrix. In another embodiment, the biomaterial filler is a calcium hydroxylapatite gel.

BRIEF DESCRIPTION OF THE DRAWINGS

[018] The invention will now be described by way of describing exemplary embodiments, including preferred embodiments, with reference to the accompanying Figures.

[019] Fig. 1 depicts a cross-sectional view of the internal nasal valve portion of the nose in which embodiments of the present invention may be performed.

[020] Fig. 2 depicts an intranasal injection system for treating internal nasal valve collapse in accordance with an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[021] Methods and systems for non-surgically treating a patient's internal nasal valve are disclosed. The internal nasal valve is made up of the junction of the upper lateral cartilage and dorsal septum which forms an angle typically considered normal in the range of 9-15 degrees. An internal nasal valve angle of approximately 10 degrees or less may be a factor contributing to nasal snoring or sleep apnea in a patient. Sleep apnea is occurs when a person stops breathing during sleep. Apnea is common among people who snore and/or in people who have anatomical abnormalities such as internal nasal valve collapse due to increased nasal resistance. Treating a patient's internal nasal valve non-surgically involves injecting a material along a patient's internal nasal valve in order to reverse collapse of the patient's internal nasal valve. The treatment thereby allowing opening of one or both nasal passages of a patient and/or reducing or eliminating snoring in a patient.

[022] Methods and systems of the present invention include the use of biomaterial fillers in the nose as an effective injectable spreader graft to treat internal nose valve collapse. Biomaterial fillers may include a gel cartilage matrix or calcium hydroxylapatite (CaHA) filler material . CaHA material includes Radiesse manufactured by Bioform, Inc., which is a sterile, latex-free, cohesive material composed of CaHA microspheres having similar constituents as bone and teeth. Biomaterial used in embodiments of the present invention are injectable through a needle.

[023] According to one embodiment, CaHA gel may be injected into a bilateral internal nose valve-collapsed patient's sub-mucoperichondrial plane at the junction of the patient's upper lateral cartilage and septum. In another embodiment, a gel cartilage matrix may be injected into one or both sides of an internal nasal valve collapsed patient's sub-mucosal plane at the junction of the patient's upper lateral cartilage and septum, and at locations posterior to the junction as needed.

[024] Fig. 1 depicts a cross-sectional view of the internal nasal valve portion of the nose 100 in which embodiments of the present invention may be performed. Cross-sectional view of nose 100 includes skin 101, septum cartilage 102, mucosa 103, upper lateral cartilage 104,

and an internal nasal valve apex 105. According to an embodiment of the invention, gel cartilage matrix is injected at the apex 105 of the internal nasal valve and at points just under it (posterior) using spreader graft injection needle 202. Injection of the gel cartilage matrix at the apex 105 moves upper lateral cartilage 104 laterally away from septum cartilage 102. The amount of gel cartilage matrix injected into nose 101 is determined by the collapsed internal nasal valve angle before treatment and the desired internal nasal valve angle. Treatment of nasal valve collapse may further include injecting biomaterial back to the nasal bone (not shown).

[025] The right side of nose 100 in Fig. 1 depicts a cross-sectional pre-treatment view, and the left side of nose 100 depicts a post-treatment view using a treatment method according to an embodiment of the invention. On the right side of nose 100 the upper lateral cartilage 104 is seen curving inward toward the nasal septum 102. The arrow on the right side of nose 100 indicates the apex 105 of the right side of the patient's nose where injection of biomaterial filler may take place, using a methods according to embodiments of the invention. For example, apex 105 may correspond with the junction between the septum and the upper lateral cartilage. The left side of nose 100 is shown with injected biomaterial filler serving as an injected spreader graft 106. The biomaterial filler serving as an injected spreader graft 106 moves upper lateral cartilage 104 laterally away from septum 102 resulting in a an increased internal nasal valve angle and a stiffening of upper lateral cartilage 202. In some embodiments, the post-treatment internal nasal valve angle is 10-15 degrees. However, small increases in internal nasal valve angle will decrease nasal valve resistance, and in some cases dramatically.

[026] In another embodiment of the present invention, biomaterial filler, such as CaHA gel, is injected in small aliquots, e.g., 0.05 ml aliquots, at points along the upper lateral cartilage and septum junction in order to produce a stiff scaffolding effect similar to surgically placed septal or conchal cartilage grafting. The injections may be performed three times along the junction between the dorsal septum and upper lateral cartilage, for example. After each of the three 0.05cc CaHA injections, which may be performed on one or both sides of the internal nasal valve, the upper lateral cartilage may move laterally away from the nasal septum and become less flaccid, resulting in a wider valve angle and an improvement in airflow corresponding to the increased internal nose valve angle.

[027] In another embodiment of the present invention, the end point for CaHA injection into an internal nasal valve is upon the cantilever effect of the CAHA graft resulting in the stiffening of the upper lateral cartilage sufficient to produce minimal collapse of the internal nasal valve during inspiration with manual contralateral nostril occlusion.

[028] Internal nasal valve collapse treatment procedures may be performed under local or topical anesthetic in a non-surgical setting. For example, a topical anesthetic on a cotton ball may be applied to a patient's nose for 10 minutes before injection of the biomaterial filler. This allows local or topical anesthetics to be titrated to effect applying or injecting only what is needed for symptomatic relief of nasal obstruction.

[029] In another embodiment of the present invention, a system for treating internal nasal valve collapse involves providing CaHA in a single, sterile, pre-filled, 0.3-cc syringe. Alternatively, the system may include a 1.0-cc syringe. Such syringes may be obtained through Bioform Inc. A speculum may be used in order to displace the ala and superior medial aspect of the upper lateral cartilage away from the dorsal septum. Once the junction is exposed, CaHA may be injected with a 25 gauge needle. For example the injection may include introducing three 0.05ml aliquots (totaling 0.15cc) into the sub-mucoperichondrial plane at the junction between the dorsal septum and upper lateral cartilage. Alternatively, small aliquots of biomaterial filler may be injected into the sub-mucosal plane. The injection device used for the injection of biomaterial filler, according to embodiments of the invention, may include any type of control syringe capable of holding biomaterial filler, and may include any type of needle suitable for introducing biomaterial filler into the internal nasal valve of the nose, such as a 23 gauge 1.5" needle, in order to increase the internal nasal valve angle.

[030] In yet another embodiment of the present invention, and in accordance with Fig. 2, an intranasal injection system 200 for treating internal nasal valve collapse in accordance with an embodiment of the invention is depicted. The system 200 includes a 1.0 cc control syringe 201, a 2-inch, 25 gauge thin wall short bevel needle having about a 15 degree upward curve at the terminal end 202 (2-inch needle). An intranasal injection system 200 may be used as a spreader graft injection system where the 1.0 cc control syringe is pre-loaded with biomaterial filler, such as CaHA, and the 2-inch needle 202 being configured for injecting into the junction between the upper lateral cartilage and the septum. The 2-inch needle may

be, 25 gauge thin wall 204 needle having a short bevel 205. The thin wall needle may include an inner diameter of 0.012", and an outer diameter of 0.020". A 1.75 inch portion 206 of the needle extends straight from a needle hub 207. Hub 207 may be metal or polypropylene. At the end of the 1.75 inch portion 206 nearest the short bevel point 205, the needle is curved or bent at about a 15 degree angle such that the 0.25 inch terminal portion 208 of the needle points at about a 15 degree angle with respect to the 1.75 inch portion. The terminal end of the needle includes the short bevel facing upwards, such that when the 1.75 inch portion of the needle is horizontal, the 15 degree angle 0.25 inch portion of the needle is pointed upward, and the bevel facing inward. The slight curve to the needle enables easier access to internal valve over different points of the upper lateral cartilage-septal junction of the nose. The curve may provide for precise localization of the apex and points posterior at the junction of the upper lateral cartilage and septum. In addition to the 2 inch curved needle, a straight needle having a hub (not shown) may be inserted into the hub of the 2-inch needle thereby providing fluid coupling between the two needles. The hub of the second needle may also be fluidly coupled to the injection device, such as 1 cc control syringe 201. The straight needle may include a metal or polypropylene hub.

[031] Methods using the system depicted in Fig. 2 include, for example, advancing the 2-inch needle 202 toward the osseocartilaginous junction from the apex and injecting CaHA while withdrawing the needle making the upper lateral cartilage more rigid at the septal junction. The final injection placed at the apex of the internal nasal valve, results in the upper lateral cartilage being displaced laterally away from the septum, causing a widening of the valve angle, and improving patency. In another embodiment of the invention, a series of two 0.05 cc CaHA aliquots may be injected to provide internal nasal valve patency. Compared to surgical placement of spreader grafts that extend from the osseocartilaginous junction to the internal nasal valve, some injectable spreader grafts may be shortened and injected at the apex of the internal nasal valve junction where the cantilever effect appears to be maximized, thereby improving nasal airway patency with a shorter injectable spreader graft.

[032] Treatment of internal nasal valve collapse using the methods described above can provide long-term relief from nasal obstruction due to internal nasal valve collapse. In some instances the method may result in relief for at least 8 months. However, the example of 8 months of relief from nasal obstruction is not limiting, and treatment of internal nasal valve collapse may be effective for more than 8 months.

[033] Methods and systems described above may result in significantly buttressing the upper lateral cartilage and stabilize valve patency. This is because biomaterial filler such as CaHA injected into the internal nasal valve acts as a buttress and stiffens the valve, thereby preventing collapse with inspiration, especially in people with inherently weak cartilages.

[034] In the foregoing description, embodiments of the invention, including preferred embodiments, have been presented for the purpose of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiments were chosen and described to provide the best illustration of the principals of the invention and its practical application, and to enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth they are fairly, legally, and equitably entitled.

CLAIMS

1. A method for non-surgically treating an internal nasal valve of a patient comprising, injecting a biomaterial filler into the internal nasal valve of the patient, wherein the injected biomaterial filler in the internal nasal valve increases an internal nasal valve angle.

2. The method of claim 1, wherein the increase in internal nasal valve angle results in a 10-15 degree internal nasal valve angle.

3. The method of claim 1, wherein the biomaterial filler is injected into a junction of an upper lateral cartilage portion and a septum cartilage portion of the internal nasal valve.

4. The method of claim 3, wherein the increase in internal nasal valve angle is effected by the biomaterial filler displacing the upper lateral cartilage portion laterally away from the septal cartilage portion of the internal nasal valve.

5. The method of claim 1, wherein injecting biomaterial filler is for treatment of internal nasal valve collapse.

6. The method of claim 1, wherein injecting biomaterial filler is for treatment of sleep apnea.

7. The method of claim 1, wherein injecting biomaterial filler is for treatment of nasal snoring.

8. The method of claim 1, wherein injecting comprises injecting at least one 0.05 ml aliquot of biomaterial filler.

9. The method of claim 1, wherein injecting comprises injecting a plurality of 0.05 ml aliquots of biomaterial filler at a plurality of positions of the internal nasal valve.

10. The method of claim 1, wherein injecting comprises inserting an injection device to an end point of the internal nasal valve and injecting the biomaterial filler at the end point and along an injection device withdrawing path up to a point of injection external to the patient.

11. The method of claim 1, wherein the biomaterial filler is a gel cartilage matrix.

12. A system for non-surgically treating an internal nasal valve of a patient comprising:
a control syringe; and
a 2-inch, 25 gauge thin-thin wall short bevel needle, wherein the needle comprises:
a 10-20 degree bend at the terminal portion of the needle about 0.25 inches from the terminal end; and
a hub for fluidly coupling to the control syringe.

13. The system of claim 12, wherein the control syringe is a 1.0 cc control syringe.

14. The system of claim 12, wherein the control syringe is a 0.3 cc control syringe.

15. The system of claim 12, wherein the needle comprises a 15 degree bend at the terminal portion of the needle about 0.25 inches from the terminal end.

16. The system of claim 12, further comprising a straight needle fluidly coupled to a hub, the straight needle capable of fluidly coupling to the 2-inch needle, and the hub capable of fluidly coupling to the control syringe.

17. The system of claim 12, wherein the needle is stainless steel.

18. The system of claim 12, wherein the hub is stainless steel.

19. The system of claim 12, wherein the control syringe is pre-loaded with a biomaterial filler.

20. The system of claim 19, wherein the biomaterial filler is a gel cartilage matrix.

21. The system of claim 19, wherein the biomaterial filler is a calcium hydroxylapatite gel.

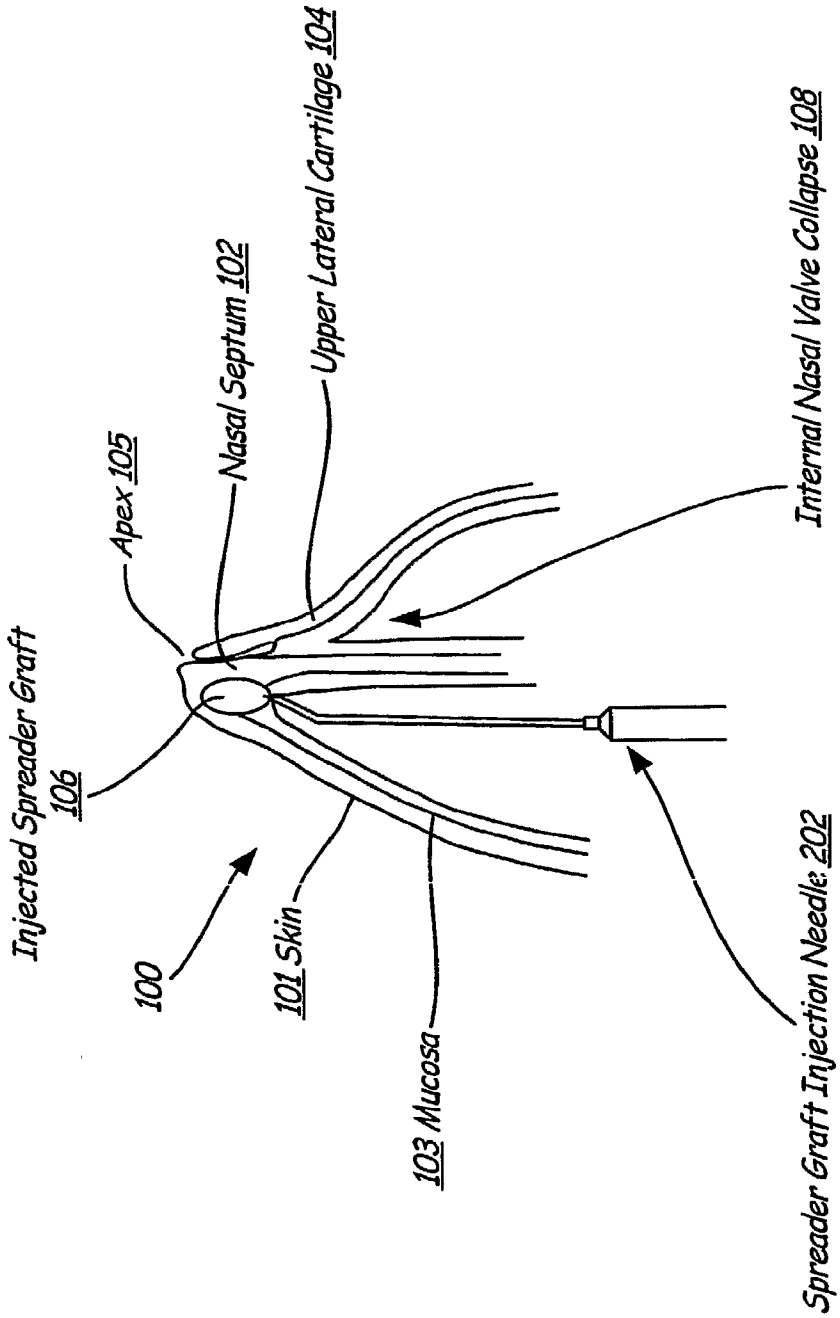

Injected Spreader Graft 106
Apex 105
Nasal Septum 102
Upper Lateral Cartilage 104
Internal Nasal Valve Collapse 108
100
101 Skin
103 Mucosa
Spreader Graft Injection Needle 202

FIG. 1

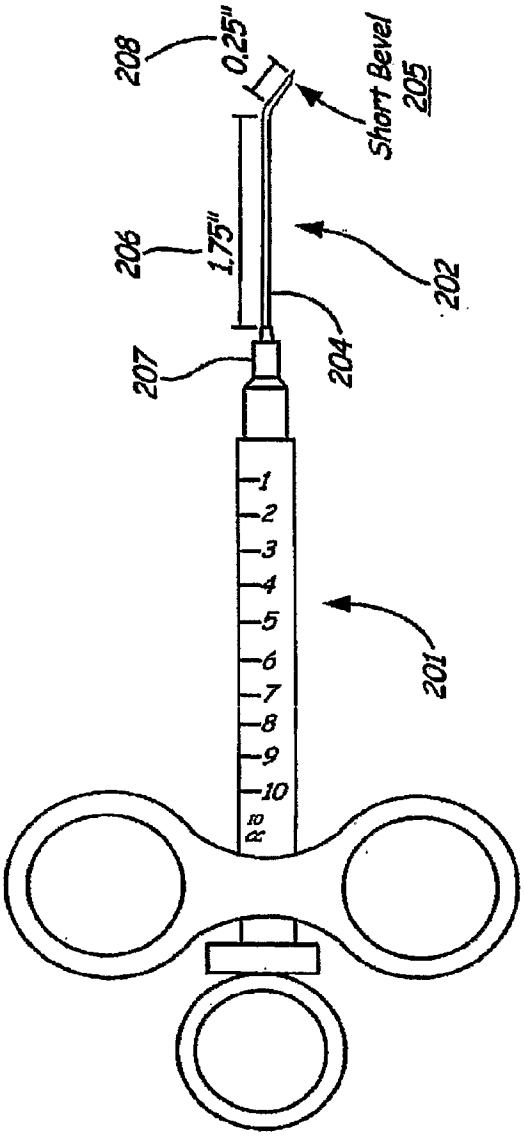


FIG. 2

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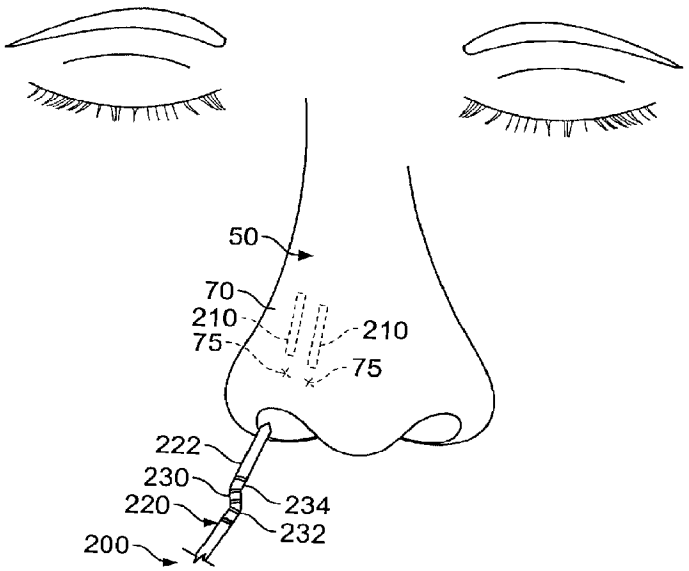
Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

[Continued on next page]

(54) Title: DEVICES AND METHODS TO TREAT NASAL PASSAGES



(57) Abstract: Some embodiments of a nasal implant delivery system may provide minimally invasive insertion of one or more implants in suitable tissue planes of the nasal rim, the lateral nasal wall, or both. Such a delivery system may be minimally invasive in that it does not require a surgical intervention or an incision that cuts a portion of the nasal tissue. Rather, in some embodiments, the nasal implant delivery system may include a needle or other cannula device having a curvature at the distal portion adapted to penetrate into a targeted tissue plane in the nasal rim, the lateral nasal wall, the nasal septum, or the columella. Also, some embodiments of a delivery system can be used to apply a nasal rigidity supplement to internal or external portions of the nasal rim, the lateral nasal wall, or other nasal structures.

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Devices and Methods to Treat Nasal Passages

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Patent Application No. 60/800,573 filed on May 15, 2006 and entitled "Delivery of Nasal Implants," the entire contents of which is incorporated herein by reference.

TECHNICAL FIELD

This document relates to delivering materials or devices for treatment of nasal tissue.

BACKGROUND

Upper airway obstruction (e.g., snoring, sleep apnea, nasal breathing disorders, and the like) may occur as a result of obstructive anatomic elements located in the oral cavity, oropharynx, nasal cavity, nasopharynx, hypopharynx, or larynx. Common sites of obstruction include the tongue, the soft palate, and the nasal cavity. Snoring may result from vibrations of any one of a number of surfaces or structures of the pharynx, such as the soft palate, tongue base, or pharyngeal walls. Sleep apnea may result from partial or complete collapse of the upper airway and pharyngeal walls during sleep. Both snoring and obstructive sleep apnea may be exacerbated by a variety of anatomical findings in the nasal cavity.

Upper airway obstruction has been treated with a number of different therapies, such as the implantation of stiffening devices into the soft palate to improve airflow through the pharynx. These stiffening implants may act to change airflow patterns and alleviate some airway obstructions. Other techniques have focused on the tongue base in an effort to stiffen it or to reduce its size. A multitude of surgical techniques are available for the treatment of nasal obstruction, and there are a limited few minimally invasive techniques for the treatment of nasal obstruction.

Nasal obstruction most commonly occurs in isolation, but may also be associated with snoring and sleep apnea. The vast majority of techniques available for the treatment of nasal obstruction include surgical procedures in which a scalpel is used to incise the patient's nasal tissue for access to the nose. Subsequently, strengthening techniques

through tissue rearrangement and suture reinforcement may be used to improve a patient's nasal airflow. Additional techniques are available in which an incision is made and implants of various materials are placed to help strengthen the walls of the nose. After a nasal implant is inserted, the surgical incision may be closed in a standard fashion. Many techniques for improving nasal obstruction involve surgical intervention in the form of septoplasty, septorhinoplasty, nasal reconstruction, nasal vestibular stenosis repair, nasal valve collapse repair, or other surgeries which require incisions. Surgically placed implants may fail when the implant is improperly positioned or if the body rejects the material. For example, when the implant device is not placed in a suitable tissue plane, the implant may either extrude through the mucosal membrane surface (functional failure) or be visible on the dermal surface (cosmetic failure).

SUMMARY

Some embodiments of a nasal implant delivery system may provide minimally invasive insertion of one or more implants in suitable tissue planes of the nasal rim, the lateral nasal wall, the nasal septum, the columella, or all of these areas. Such a delivery system may be minimally invasive in that it does not require a surgical intervention or a scalpel incision that cuts a portion of the nasal tissue. Rather, in some embodiments, the nasal implant delivery system may include a needle or other cannula device having a curvature at the distal portion adapted to penetrate into a targeted tissue plane in the nasal rim, the lateral nasal wall, the nasal septum, or the columella.

In some embodiments, a nasal implant delivery system may include a delivery cannula having a distal portion, a proximal portion, and a lumen extending therebetween. The delivery system may also include a handle member coupled with the delivery cannula. The handle member may extend at least partially downward from the proximal portion of delivery cannula. The delivery system may also include an actuation member movably disposed in the lumen. The actuation member can include a distal surface to at least partially engage an implant device when the implant device is disposed in the lumen. The distal portion of the delivery cannula may include a curved section extending at least partially upward and generally away from the handle member that extends at least partially downward.

In one aspect, the curved section of the distal portion of the delivery cannula may be penetrable into a tissue plane of a nasal rim. For example, the curved section of the delivery cannula may extend in a generally arcuate shape toward the upward direction.

In another aspect, the curved section of the distal portion of the delivery cannula may be penetrable into a tissue plane of a lateral nasal wall. For example, the curved section of the delivery cannula may include a first curve that extends at least partially upward and a second curve that extends in a generally longitudinal direction toward a distal tip of the delivery cannula.

In particular embodiments, a nasal implant delivery system may include a delivery cannula including a distal portion, a proximal portion, and a lumen extending therebetween. At least a section of the proximal portion may extend in longitudinal direction along a central axis. The distal portion of the delivery cannula may include a curved section that extends in an at least partially lateral direction away from the central axis and may include a port to deliver a nasal implant. The system may further include an actuation member movable disposed in the lumen. The actuation member may include a distal surface to at least partially engage the nasal implant when the implant is disposed in the lumen. Also, the system may include a handle member coupled with the delivery cannula to manipulate the position of the distal portion relative to a targeted site. The handle member may be coupled to a hand-adjustable switch to cause the actuation member to move in the lumen.

In other embodiments, a nasal implant delivery system may include a delivery cannula having a distal portion, a proximal portion, and at least one lumen extending therebetween. At least a section of the proximal portion may extend in longitudinal direction along a central axis. The distal portion of the delivery cannula may include a curved section that extends in an at least partially lateral direction away from the central axis and may also include a port in communication with the at least one lumen to deploy a nasal implant material. The system may further include a fluid reservoir in fluid communication with the at least one lumen. The fluid reservoir may contain a polymer material in a generally non-rigid state. The system may also include an actuation member to deploy the polymer material from the distal portion of the delivery cannula and to a

targeted nasal tissue plane. The polymer material can transition to a resilient state when deployed from the distal portion.

In some embodiments, a delivery system for a nasal rigidity supplement may include a delivery instrument having a distal portion and a proximal portion. The proximal portion may extend in longitudinal direction along a central axis, and the distal portion of the delivery instrument may include an applicator to contact a targeted nasal tissue site. The delivery system may also include a rigidity supplement material arranged on the applicator of the delivery instrument. The rigidity supplement material may be in a generally non-rigid state when arranged on the applicator, and the rigidity supplement material can transition to a resilient state when deployed from the applicator to the targeted nasal tissue site.

These and other embodiments may provide one or more of the following advantages. First, the delivery system may be used without a surgical incision that cuts a portion of the nasal tissue, thereby providing minimally invasive insertion of one or more implants in suitable tissue planes of the nasal rim, the lateral nasal wall, the nasal septum, the columella, or all of these areas. Second, the delivery system may deliver implants to the nasal rim, the lateral nasal wall, the septum, or the columella to treat conditions or defects in the nasal anatomy, which may not be adequately treated by procedures on the soft palate. Third, the delivery system may include a distal tip portion that is curved in a manner to provide ready access to the nasal rim or the lateral nasal wall, thereby permitting a practitioner to operate the delivery system from an effective and efficient position relative to the patient. Fourth, the distal tip portion of the delivery system may access the nasal anatomy along an insertion path that positions the implant in a targeted tissue plane, which can reduce the likelihood of functional failure (e.g., the implant extruding through the mucosal membrane surface) and cosmetic failure (e.g., the implant being visible on the dermal surface). Fifth, implant device may comprise a biocompatible material (e.g., Dacron or the like) that is flexible enough to pass through the curved section of the delivery system and is rigid enough to at least partially stiffen the surrounding nasal anatomy, which can change the nasal airflow patterns and can alleviate certain airway obstructions.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. 1 is a perspective view of a portion of a delivery system and implant devices disposed in nasal rims, in accordance with some embodiments.

FIG. 2 is a perspective view of the implant devices of FIG. 1 when in a non-flexed condition.

FIG. 3 is a perspective view of a portion of a delivery system and implant devices disposed in a nasal lateral wall, in accordance with another embodiment.

FIG. 4 is a perspective view of the implant devices of FIG. 4 when in a non-flexed condition.

FIG. 5 is a side view of a delivery system for implanting nasal implants, in accordance with some embodiments.

FIG. 6 is a cross-sectional view of an embodiment of a tip of the delivery system of FIG. 5.

FIG. 7 is a cross-sectional view of another embodiment of a tip of the delivery system of FIG. 5.

FIG. 8 is a perspective view of a portion of the delivery system of FIG. 5 penetrating into a nasal rim, in accordance with some embodiments.

FIG. 9 is a cross-sectional view of the nasal implant disposed in the nasal rim of FIG. 8.

FIG. 10 is another cross-sectional view of the nasal implant of FIG. 9.

FIG. 11 is a side view of a delivery system for implanting nasal implants, in accordance with some embodiments.

FIG. 12 is a cross-sectional view of an embodiment of a tip of the delivery system of FIG. 11.

FIG. 13 is a cross-sectional view of another embodiment of a tip of the delivery system of FIG. 11.

FIG. 14 is a perspective view of a portion of the delivery system of FIG. 11 penetrating into a nasal lateral wall, in accordance with some embodiments.

FIG. 15 is a cross-sectional view of the nasal implant disposed in the nasal rim of FIG. 14.

FIG. 16 is another cross-sectional view of the nasal implant of FIG. 15.

FIG. 17 is a perspective view of a delivery system for implanting nasal implants, in accordance with some embodiments.

FIG. 18 is a top view of the delivery system of FIG. 17.

FIG. 19 a perspective view of a portion of a delivery system and implants disposed in the nasal rims, in accordance with some embodiments.

FIG. 20 is a cross-sectional view of an embodiment of a tip of a delivery system, in accordance with some embodiments.

FIG. 21 is a perspective view of a portion of a delivery system and implants disposed in a nasal lateral wall, in accordance with another embodiment.

FIG. 22 a perspective view of a portion of a delivery system and nasal rigidity supplements disposed on the nasal rims, in accordance with some embodiments.

FIG. 23 is a perspective view of a portion of a delivery system and nasal rigidity supplements disposed on the nasal lateral walls, in accordance with another embodiment.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

A nasal implant delivery system can provide nonsurgical insertion path for one or more implants in targeted tissue planes of the nasal rim, the lateral nasal wall, or both. In some embodiments, the nasal implant delivery system may include a needle or other cannula device having a curvature at the distal portion adapted to penetrate into the targeted tissue plane in the nasal rim or in the nasal lateral wall. The nasal implants delivered into the nasal tissue may be used to treat conditions such as snoring, sleep apnea, nasal breathing disorders, and the like. For example, weakened cartilaginous support in the nose (e.g., septum, upper lateral wall, columella, or other part of the nasal anatomy) can cause nasal obstruction and altered nasal shape. The nasal implants described herein may be disposed in the nasal rim of each nostril, the lateral walls on

each side of the nose, or both so as to at least partially support the surrounding nasal tissue and change the nasal airflow patterns. Moreover, the delivery system described herein can position the implant devices in a targeted tissue plane to reduce the likelihood of functional failure (e.g., extruding through the mucosal membrane surface) and cosmetic failure (e.g., be visible on the dermal surface).

Referring to FIG. 1, a delivery system 100 may be inserted into nasal tissue proximate to the nostril rim 60 of a nose 50 to position a nasal implant device 110 therein. The delivery system 100 may include a delivery needle 120 or other cannula device (e.g., a specially configured hypotube, a polymer cannula, or the like) having sufficient rigidity to penetrate into the nasal tissue. The delivery needle 120 includes a distal tip portion 122, a proximal portion 124 (not shown in FIG. 1), and a lumen 125 extending therebetween (not shown in FIG. 1). As described in more detail below in connection with FIG. 5, the delivery system 100 may also include a handle member at a proximal portion coupled with the delivery needle 120. Also described in more detail below, an actuation member can be movably adjusted in the lumen of the delivery needle 120 to force the implant device 110 out from the distal tip portion 122 when the distal tip portion 122 is disposed in a targeted tissue plane of the nasal rim 60.

The distal tip portion 122 of the delivery needle 120 may include a curved section 130 extending at least partially in a lateral direction (e.g., a generally upward direction as shown, for example, in FIG. 5). Such a curved orientation may facilitate delivery of the implant device 110 into the targeted tissue plane of the nasal rim 60. For example, the curved section 130 of the delivery needle 120 may include a generally arcuate shape that curls in the lateral direction (e.g., toward the upward direction as shown, for example, in FIG. 5) so as to provide an effective implantation path into the nasal rim 60. In this embodiment, the distal tip portion 122 can penetrate an insertion site 65 in the mucosal surface at the base of the nostril and moved along an implantation path 66 towards the tip 55 of the nose 50 along the nasal rim 60. The practitioner may then drawback the distal tip portion 222 as the implant device 210 is deployed in the nasal rim 60. In another embodiment, the distal tip portion 122 can be inserted at the base of the nostril on the dermal side and moved towards the tip 55 of the nose 50 in a dorsal to ventral path. As such, the curved shape of the section 130 may generally correspond to a portion of the

nasal rim curvature, thereby facilitating delivery of the nasal implant device 110 and, in some circumstances, permitting a practitioner to operate the delivery system 100 from an effective position relative to the patient. As described in more detail below, the length of the distal tip portion 122 and the shape of the curved section 130 may be selected by the practitioner depending upon the patient's nasal anatomy (e.g., nose size, rim curvature, tissue thickness, and the like).

Referring to FIG. 2, the nasal implant device 110 may comprise a biocompatible material that is sufficiently flexible to pass through the curved section 130 of the delivery needle 120 (FIG. 1) yet is rigid enough to at least partially support the surrounding nasal tissue. For example, the implant device may comprise Dacron (polyethylene terephthalate), PTFE, silicone, or the like. In this embodiment, the nasal implant device 110 includes a generally flat, thin, and long body and a generally rectangular cross-sectional geometric profile. Such a body shape may serve to stiffen the tissue in the nasal rim. In some embodiments, the nasal implant device 110 may have a length 112 of about 1.0 cm to about 3.8 cm, about 1.5 cm to about 3.5 cm, about 1.8 cm to about 2.8 cm, and about 2.0 cm to about 2.5 cm; may have a thickness 114 of about 0.3 mm to about 3.5 mm, about 0.5 mm to about 3.2 mm, about 1.0 mm to about 3.0 mm, and about 1.2 mm to about 2.0 mm; and may have a width 116 about 0.3 mm to about 3.5 mm, about 0.5 mm to about 3.2 mm, about 1.0 mm to about 3.0 mm, and about 1.2 mm to about 2.0 mm. In this embodiment, the width 116 is greater than the thickness 114, thereby providing the generally rectangular cross-sectional profile. As described in more detail below, the nasal implant device 110 may be trimmed by the practitioner before the implantation procedure so as to customize the length, thickness, or width. In other embodiments, the nasal implant device 110 may comprise a body having a cross-sectional geometric profile that is not rectangular, such as a circular profile, a square profile, an elliptical profile, a hexagonal profile, or the like. In addition, in some embodiments, the nasal implant device 110 may comprise a body having a cross-sectional geometric profile that transitions from a first shape to a second shape, for example, transitions from a rectangular cross-sectional profile to an elliptical cross-sectional profile.

In this embodiment, the nasal implant device 110 may comprise Dacron material that is wound, molded, or otherwise formed to the desired length. For example, implant

device 110 may be formed from a braid of Dacron fibers. The Dacron material can be woven into a tight nonresorbable mesh, which allows a slight amount of tissue ingrowth to maintain the implant position in the nasal tissue. In these embodiments, the multifilament arrangement promotes securement between the implant device 110 and the adjacent nasal tissue, which facilitates the position of the implant device 110 immediately after its release from the distal tip portion (FIG. 1). The Dacron material is an example of a polymer material that provides sufficient flexibility to pass through the curved section 130 of the delivery needle 120 and that provides rigidity and resiliency to stiffen the nasal rim 60 (FIG. 1). In addition, the Dacron material may provide a soft feel that causes the implant device 110 to be more discrete when implanted in the nasal tissue (e.g., less detectable by skin palpation or visual inspection of the nose 50).

Referring now to FIG. 3, another embodiment of a delivery system 200 may be inserted into nasal tissue proximate to the nasal lateral wall 70 of a nose 50 to position one or more nasal implant devices 210 therein. Similar to the previously described embodiments, the delivery system 200 may include a delivery needle 220 or other cannula device (e.g., a specially configured hypotube, a polymer cannula, or the like) having sufficient rigidity to penetrate into the nasal tissue. The delivery needle 220 includes a distal tip portion 222, a proximal portion 224 (not shown in FIG. 3), and a lumen 225 extending therebetween (not shown in FIG. 3). As described in more detail below in connection with FIG. 11, the delivery system 200 may also include a handle member at a proximal portion coupled with the delivery needle 120 and an actuation member to force the implant device 210 out from the distal tip portion 222.

The distal tip portion 222 of the delivery needle 220 may include a curved section 230 having at least one curve extending at least partially in a lateral direction (e.g., a generally upward direction as shown, for example, in FIG. 11). For example, the curved section 230 of the delivery needle 120 may include a first curve 232 that extends at least partially in the lateral direction and a second curve 234 that extends in a generally longitudinal direction toward the distal tip so as to provide an effective implantation path into the nasal lateral wall 70. Such a curved orientation may facilitate delivery of the implant device 210 into the targeted tissue plane of the nasal lateral wall 70. In this embodiment, the distal tip portion 222 can penetrate an insertion site 75 in the mucosal

surface near the end of the nostril and advanced in a cephalo-caudal path into the lateral wall 70. The needle 220 may be inserted into the lateral wall 70 until the distal tip portion 222 reaches the nasal bone (e.g., palpated by the practitioner or visualized on the dermal surface or by tactile feedback when the needle hits the bone). The practitioner may then drawback the distal tip portion 222 as the implant device 210 is deployed. In another embodiment, the distal tip portion 222 can be inserted near the end of the nostril on the dermal side and advanced in a cephalo-caudal path. As such, the curved shape of the curved section 230 may generally correspond to an implantation path in a portion of the nasal lateral wall 70, thereby permitting a practitioner to operate the delivery system 200 from an effective position relative to the patient. As described in more detail below, the length of the distal tip portion 222 and the shape of the curved section 230 may be selected by the practitioner depending upon the patient's nasal anatomy (e.g., nose size, lateral wall length, tissue thickness, and the like).

Referring to FIG. 4, the nasal implant device 210 may comprise a biocompatible material that is sufficiently flexible to pass through the curved section 230 of the delivery needle 220 (FIG. 1) yet is rigid enough to at least partially support the surrounding nasal tissue. For example, the implant device may comprise Dacron (polyethylene terephthalate), PTFE, silicone, or the like. Similar to the previously described embodiments, the nasal implant device 210 includes a generally flat, thin, and long body and a generally rectangular cross-sectional geometric profile. Such a body shape may serve to stiffen the tissue in the nasal lateral wall 70. In some embodiments, the nasal implant device 210 may have a length 212 of about 0.7 cm to about 2.7 cm, about 1.0 cm to about 2.0 cm, and about 1.2 cm to about 1.8 cm; may have a thickness 214 of about 0.2 mm to about 2.5 mm, about 0.5 mm to about 2.0 mm, and about 0.7 mm to about 1.5 mm; and may have a width 216 about 0.2 mm to about 2.5 mm, about 0.5 mm to about 2.0 mm, and about 0.7 mm to about 1.5 mm. In this embodiment, the width 216 is greater than the thickness 214, thereby providing the generally rectangular cross-sectional profile. As previously described, the nasal implant device 210 may comprise a body having a cross-sectional geometric profile that is not rectangular, such as a circular profile, a square profile, an elliptical profile, a hexagonal profile, or the like. In addition, in some embodiments, the nasal implant device 210 may comprise a body having a cross-

sectional geometric profile that transitions from a first shape to a second shape, for example, transitions from a rectangular cross-sectional profile to an elliptical cross-sectional profile.

Similar to the previously described embodiments, the nasal implant device 210 may comprise Dacron material that is wound, molded, or otherwise formed to the desired length. For example, implant device 210 may be formed from a braid of Dacron fibers that are woven into a tight nonresorbable mesh. The Dacron material is an example of a polymer material that provides sufficient flexibility to pass through the curved section 230 of the delivery needle 220 and that provides rigidity and resiliency to stiffen the nasal lateral wall (FIG. 3). Also, the Dacron material may have a soft feel that causes the implant device 210 to be more discrete (e.g., less detectable by skin palpation or visual inspection of the nose 50).

Returning now to the embodiments of the delivery system 100 described in connection with FIGS. 1-2, an exemplary embodiment of the delivery system 100 is shown in FIG. 5. As previously described, the delivery needle 120 includes a proximal portion 124 that may be coupled to a handle member 140. In this embodiment, the handle member 140 includes a grasping portion 145 that extends in an at least partially downward direction 146 from the axis of the delivery needle 120 (from the perspective shown in FIG. 5). The curved section 130 of the distal tip portion 122 extends in an at least partially upward direction 126 (from the perspective shown in FIG. 5). As such, the curved section 130 of the distal tip portion 122 extends generally away from the grasping portion 145 of the handle member 140 so that a user may readily grasp the handle member 140 (with the grasping section 145 extending at least partially downward 146 as shown in FIG. 5) while the distal tip portion 122 curves at least partially upward 126 (as shown in FIG. 5). Such a curved orientation of the delivery needle 120 can facilitate delivery of the implant device 110 into the targeted tissue plane of the nasal rim or other nasal anatomy.

Still referring to FIG. 5, the curved section 130 of the delivery needle 120 may include a generally arcuate shape that extends in a lateral direction (e.g., toward the upward direction 126 as shown, for example, in FIG. 5). This arcuate curvature may be selected to substantially correspond to an approximate curvature of at least a portion of

the patient's nasal rim 60 (FIG. 1), thereby providing a desirable implantation path into the nasal rim. It should be understood from the description herein that the curved section 130 may include another curvature, such as a transitional curvature that transitions from a first radius of curvature to a second radius of curvature. In some embodiments, the delivery needle 120 may be releasably coupled to the handle member 140 so that a practitioner may select one delivery needle 120 from a plurality of connectable delivery needles 120 (e.g., provided in a kit with the handle member 140) having a variety of curvatures in the curved section 130. Thus, the practitioner may releasably couple the selected delivery needle 120 with the handle member 140 depending upon the nasal anatomy of the patient. For example, a delivery needle 120 having a relatively short radius of curvature may be selected for a patient having a smaller nasal rim circumference. In another example, a delivery needle 120 having a transitional curvature may be selected for a patient having a nasal rim shape that does not correspond to a generally arcuate shape. In addition, the practitioner may be provided with more than one handle member 140 having different sizes (e.g., the kit may include a plurality of delivery needles 120 that are individually connectable with a plurality of handle members 140). In some embodiments, each of the delivery needles 120 in the kit may be preloaded with an implant device 110 (e.g., retained in the needle lumen 125 near the distal tip opening). Alternatively, the user may insert the implant device into the delivery needle 120 before the implantation procedure.

In this embodiment, the delivery needle 120 is releasably coupled with the handle member 140 by an adaptor 128 connected to the needle 120 that mates with a connector 149 of the handle member 140. For example, the adaptor 128 may include a flange portion 129 that can be inserted into a mating condition with a rim connector 149 of the handle member 140. Then, the adaptor may be partially rotated so that the delivery needle locks into position when the curve section 130 extends at least partially in the lateral direction (e.g., the generally upward direction 126 as shown, for example, in FIG. 5). Such a releasably coupling permits the practitioner to select a desirable delivery needle 120 for attachment to the handle member 140.

In some embodiments, the distal tip portion 122 may comprise a malleable material that permits a practitioner to at least partially modify the curved section 130 of

the needle 120. For example, the distal tip portion 122 may comprise a ductile aluminum material that can be bent using a hand tool so as to modify the curved section 130. In another example, the distal tip portion 122 may comprise a Beta III titanium alloy (e.g., a titanium alloy including Ti, Mb, Zr, and Sn) that is capable of undergoing plastic flow to take a set shape when subjected to a strain of greater than the set threshold strain. In these examples, the practitioner may select a delivery needle 120 that is suitable for the intended nasal anatomy and may slightly modify the curved section 130 to fine tune the curvature to fit the patient's nasal anatomy.

In some embodiments, the delivery needle 120 may include one or more markings 135 to indicate the depth of tissue penetration during the implantation procedure. For example, the distal tip portion 122 may include a plurality of markings 135 that indicate to a practitioner the depth of needle tip penetration into the nasal rim tissue. Such markings 135 may assist the practitioner in determining the proper deployment position in which the implant device 110 can be arranged. The markings can be positioned on the curved section 130 (as shown in FIG. 5), on the generally noncurved portions of the needle 120, or both.

Still referring to FIG. 5, the handle member 140 may include a trigger mechanism 142 to movably adjust the actuation member 150 in the lumen of the delivery needle 120 (described in more detail below in connection with FIGS. 6-7). By applying a force 143 to the trigger mechanism 142, the practitioner may cause the actuation member 150 to apply a deployment force 123 (FIG. 6) to the implant device 110. In this embodiment, the trigger mechanism 142 may include a lever 144 that is pivotably engaged with the grasping section 145 of the handle member 140. As such, the user may hold the grasping section 145 and squeeze the lever 144 towards the grasping section 145, thereby applying a force 143 to deploy the implant device 110. In other embodiments, the trigger mechanism 142 may be a thumb switch along the grasping section 145 that can receive a force from the user's thumb, may be a push rod device extending from the base of the handle member 140, may be an electromechanical device that is activated by a button pressed by the user's thumb or index finger, or the like. In alternative embodiments, the handle member may be grasped like a pencil or the like so that the user's finger can adjust a finger switch (described below in connection with FIGS. 17-18).

As shown in FIG. 5, an actuation indicator 147 may be disposed on the handle member 140. The actuation indicator 147 may inform the user of the length that the actuation member 150 (FIG. 6) has traveled from its nondeployed position. For example, the delivery needle 120 may be inserted in to the nasal tissue while the actuation member 150 is in the nondeployed position (e.g., when the implant device 110 is retained in the lumen 125 of the needle 120 near the distal tip opening). When the delivery needle 120 is positioned in the targeted tissue plane of the nasal rim, the user may apply a force 143 (FIG. 5) to the trigger mechanism 142 that causes the actuation member 150 to deploy the implanted device 110 (FIG. 6). The actuation indicator 147 may display the length of travel of the actuation member 150 in the needle lumen 125 so that the user may know when the implant device 110 is fully deployed. For example, if the implant device 110 has a length 112 (FIG. 2) of 1.8 cm, the user may continue to apply a force 143 to the trigger mechanism 142 and partially withdraw the distal tip portion 122 until the actuation indicator 147 displays a travel length of at least 1.8 cm. Then, the user may fully withdraw the delivery needle 120 from the nasal tissue while the implant device 110 remains deployed in the nasal rim. In this embodiment, the actuation indicator 147 includes one or more markings 148 that indicate the travel length based upon the motion of the trigger mechanism 142 and its interaction with the actuation member 150. In other embodiments, the actuation indicator 148 may include a digital display that shows the travel length based upon one or more sensors disposed in the handle member 140.

Referring to FIG. 6, the actuation member 150 may include at least one surface 152 that engages the implant device 110. In this embodiment, the actuation member 150 may serve as a push rod device that is movably adjusted in response to movement of the trigger mechanism 142 (FIG. 5). As previously described, the user may apply a force 143 to the trigger mechanism 142 that causes the actuation member 150 to travel in a distal direction. When the actuation member 150 travels in the distal direction through the lumen 125, the surface 152 applies a deployment force 123 to the implant device 110.

In some embodiments, the distal tip portion 122 (and possibly the entire delivery needle 120) may include a generally rectangular cross-sectional profile with a generally rectangular lumen 125 extending through the distal tip portion 122. As such, the lumen 125 may receive the implant device 110 having a generally rectangular profile. It should

be understood that, in those embodiments in which the implant device has a nonrectangular profile, the distal tip portion 122 and the lumen 125 extending therethrough may also have a non-rectangular profile. Also, in other embodiments, the distal tip portion 122 and the lumen 125 extending therethrough may have a generally circular cross-sectional shape to receive implant devices 110 having a rectangular profile or having different cross-sectional profiles.

Still referring to FIG. 6, the distal tip potion 122 of the delivery needle 120 may include a light source 160 that can be viewed while the distal tip potion 122 is disposed under the dermal surface. For example, the light source 160 may comprise a luminescent coating applied to part of the distal tip portion 122 so that the practitioner can maintain an appropriate tissue depth while advancing the needle 120. The light source 160 may appear brighter to the practitioner as distal tip portion 122 is advanced too close to the dermal surface. In another example, the light source may comprise a miniature LED device disposed on the distal tip portion 122.

Referring to FIG. 7, the distal tip portion 122 may include an adjustable opening 127 that expands when the implant device 110 is deployed from the needle 120. In this embodiment, the distal tip portion 122 may include a distal opening 127 having a closed position (shown in FIG. 7) when the implant device 110 is retained further into the lumen 125. For example, the closed position may provide a more pointed needle tip that facilitates penetration into the nasal tissue. The adjustable opening 127 may be at least partially defined by opposing tip walls that can outwardly flex from the closed position to an open position, as shown by the directional arrows in FIG. 7. As such, when the implant device 110 is forced distally from the needle 120, the opposing tip walls flex outwardly to permit the passage of the implant device 110. In such embodiments, the opposing tip walls that at least partially defined adjustable opening 127 may comprise a biocompatible polymer material or a shape memory material that exhibits superelastic characteristics at or above normal human body temperature (e.g., nitonol material or the like).

Referring now to FIGS. 8-10, the delivery system 100 may be operated by the practitioner to delivery the implant device 110 to a targeted tissue plane in the nasal rim 60. Implantation into a proper tissue plane can reduce the likelihood of functional failure

(e.g., extruding the implant device through the mucosal membrane surface) and cosmetic failure (e.g., the implant device being noticeably viewable on the dermal surface). In the embodiment depicted in FIG. 8, the distal tip portion 122 can penetrate an insertion site 65 in the mucosal surface at the base of the nostril and can be advanced along an implantation path towards the tip 55 of the nose 50 along the nasal rim 60. As shown in FIG. 8, the implant device 110 may be disposed in the lumen of the distal tip portion 122 as the distal tip portion is inserted into the nasal tissue. As previously described, the length of the distal tip portion 122 and the shape of the curved section 130 can be selected by the practitioner depending upon the patient's nasal anatomy (e.g., nose size, rim curvature, tissue thickness, and the like). In this embodiment, the curved shape of the section 130 may substantially correspond to a curved portion of the nasal rim curvature, which can facilitate placement of the implanted device into a targeted tissue plane. Also, the curved shape of the section 130 may permit the practitioner to operate the delivery system 100 from an effective position relative to the patient (e.g., the patient may be resting on his or her back in a reclining chair or on a table surface while the practitioner approaches the patient's nose 50 from a comfortable position in front of the patient or standing over the patient). As previously described, an alternative approach may be employed in which the distal tip portion 122 is inserted at the base of the nostril on the dermal side and moved towards the tip 55 of the nose 50 in a dorsal to ventral path.

As shown in FIGS. 9-10, in some embodiments, the targeted tissue plane in the nasal rim 60 for the implant device 110 may be under the dermal layer 61 and between the SMAS layer 62 (superficial muscle and aponeurotic tissue) and the mucosa layer 64. (It should be understood that the tissue layers 61, 62, and 64 and the implant device 110 are shown for illustrative purposes and are not necessarily shown in scale.) After the distal tip portion 122 has penetrated into the nasal rim and has advanced along the targeted tissue plane, the practitioner may then drawback the distal tip portion 122 while the implant device 110 is deployed in the targeted tissue plane (refer also, for example, to FIG. 1). Accordingly, the delivery system 100 can provide a nonsurgical insertion path the implant device 110 in the targeted tissue plane of the nasal rim 60. The distal tip portion 122 of the delivery needle 120 includes a curved section 130 adapted to penetrate into the targeted tissue plane in the nasal rim and subsequently maintain its position in the

targeted tissue plane as it is advanced along the nasal rim 60. In these embodiments, the delivery system 100 can position the implant device 110 in the targeted tissue plane to reduce the likelihood of functional failure and cosmetic failure.

Referring again to the embodiments of the delivery system 200 described in connection with FIGS. 3-4, an exemplary embodiment of the delivery system 200 is shown in FIG. 11. As previously described, the delivery needle 220 includes a proximal portion 224 that may be coupled to a handle member 240. Similar to the previous embodiments, the handle member 240 includes a grasping portion 245 that extends in an at least partially downward direction 246 from the axis of the delivery needle 220 (from the perspective shown in FIG. 11). The curved section 230 of the may include a first curve 232 that extends at least partially in a lateral direction 226a (e.g., a partially upward direction as shown in FIG. 11) and a second curve 234 that extends in a generally longitudinal direction 226b. As such, at least the first curve 232 of the curved section 230 extends generally away from the grasping portion 245 of the handle member 240. Thus, in this embodiment, a user may readily grasp the handle member 240 (with the grasping section 245 extending at least partially downward 246 as shown in FIG. 11) while the distal tip portion 222 curves at least partially upward 226a (as shown in FIG. 11). Such a curved orientation of the delivery needle 220 can facilitate delivery of the implant device 210 into the targeted tissue plane of the nasal lateral wall 70 or other nasal anatomy.

Still referring to FIG. 11, the two curves 232 and 234 of the curved section 230 may provide a distal tip portion 222 that extends longitudinally after a lateral curve, which might be referred to as a "bayonet" shape. This compound curvature may be selected to substantially correspond to an implantation path in a portion of the nasal lateral wall 70, thereby permitting a practitioner to operate the delivery system 200 from an effective position relative to the patient. Also, such a compound curvature may provide the practitioner with a direct line of sight to the implantation site as the distal tip portion 222 approaches the implantation site.

In some embodiments, a guide flange 238 may be coupled to the delivery needle 220 so that the distal tip portion 222 is advanced into the nasal lateral wall 70 at the proper tissue depth. As such, the guide flange 238 may direct the distal tip portion 222 to the targeted tissue plane in the nasal lateral wall 70. Further, the guide flange 238 may

reduce the likelihood of the needle tip departing from the targeted tissue plane during advancement (e.g., reduces the likelihood of being advanced too deep or to shallow during insertion). In some embodiments, the guide flange 238 may be fixedly mounted to the delivery needle 220. Alternatively, the guide flange 238 may be releasably engaged with the delivery needle 220 so that the practitioner may elect to use the guide flange 238 in those circumstances where it is most helpful.

Similar to previously described embodiments, the delivery needle 220 may be releasably coupled with the handle member 240 so that a practitioner may select one delivery needle 220 from a plurality of connectable delivery needles 220 (e.g., provided in a kit with the handle member 240) having a variety of curvatures in the curved section 230. Thus, the practitioner may releasably couple a particular delivery needle 220 with the handle member 240 depending upon the nasal anatomy of the patient. In addition, the practitioner may be provided with more than one handle member 240 having different sizes (e.g., the kit may include a plurality of delivery needles 220 that are individually connectable with a plurality of handle members 240). In some embodiments, each of the delivery needles 220 in the kit may be preloaded with an implant device 210 (e.g., retained in the needle lumen 225 near the distal tip opening). Alternatively, the user may insert the implant device into the delivery needle 220 before the implantation procedure. In this embodiment, the adaptor 228 may include a flange portion 229 that can be inserted into a mating condition with a rim connector 249 of the handle member 240. Then, the adaptor 228 may be partially rotated so that the delivery needle 220 locks into position when the curve section 230 extends in the at least partially upward direction 226a (as shown in FIG. 11). Such a releasably coupling permits the practitioner to select a desirable delivery needle 220 for attachment to the handle member 240.

In some embodiments, the distal tip portion 222 may comprise a malleable material that permits a practitioner to at least partially modify the curved section 230 of the needle 220. For example, the distal tip portion 222 may comprise a ductile aluminum material that can be bent using a hand tool so as to modify the curved section 230. In another example, the distal tip portion 222 may comprise a Beta III titanium alloy (e.g., a titanium alloy including Ti, Mb, Zr, and Sn) that is capable of undergoing plastic flow to take a set shape when subjected to a strain of greater than the set threshold strain. In

these examples, the practitioner may select a delivery needle 220 that is suitable for the intended nasal anatomy and may slightly modify the curved section 230 to fine tune the curvature to fit the patient's nasal anatomy.

Similar to previously described embodiments, the delivery needle 220 may include one or more markings 235 to indicate the depth of tissue penetration during the implantation procedure. For example, the distal tip portion 222 may include a plurality of markings 235 that indicate to a practitioner the depth of needle tip penetration into the nasal lateral wall tissue. Such markings 235 may assist the practitioner in determining the proper deployment position in which the implant device 210 can be arranged. The markings can be positioned on the curved section 230 (as shown in FIG. 11), on the generally noncurved portions of the needle 220, or both.

Still referring to FIG. 11, similar to previously described embodiments, the handle member 240 may include a trigger mechanism 242 to movably adjust the actuation member 250 in the lumen of the delivery needle 220. By applying a force 243 to the trigger mechanism 242, the practitioner may cause the actuation member 250 to apply a deployment force 223 (FIG. 12) to the implant device 210. In this embodiment, the trigger mechanism 242 includes a lever 244 that is pivotably engaged with the grasping section 245 of the handle member 240. In other embodiments, the trigger mechanism 242 may be a thumb switch along the grasping section 245 that can receive a force from the user's thumb, may be a push rod device extending from the base of the handle member 240, may be an electromechanical device that is activated by a button pressed by the user's thumb or index finger, or the like. In alternative embodiments, the handle member may be grasped like a pencil or the like so that the user's finger can adjust a finger switch (described below in connection with FIGS. 17-18).

Similar to previously described embodiments, an actuation indicator 247 may be disposed on the handle member 240. The actuation indicator 247 may display the length of travel of the actuation member 250 (FIG. 12) in the needle lumen 225 so that the user may know when the implant device 210 is fully deployed. For example, if the implant device 210 has a length 212 (FIG. 4) of 1.2 cm, the user may continue to apply a force 243 to the trigger mechanism 242 and partially withdraw the distal tip portion 222 until the actuation indicator 247 displays a travel length of at least 1.2 cm. Then, the user may

fully withdraw the delivery needle 220 from the nasal tissue while the implant device 210 remains deployed in the nasal lateral wall 70. In this embodiment, the actuation indicator 247 includes one or more markings 248 that indicate the travel length based upon the motion of the trigger mechanism 242 and its interaction with the actuation member 250. In other embodiments, the actuation indicator 248 may include a digital display that shows the travel length based upon one or more sensors disposed in the handle member 240.

Referring to FIG. 12, the actuation member 250 may include at least one surface 252 that engages the implant device 210. In this embodiment, the actuation member 250 may serve as a push rod device that is movably adjusted in response to movement of the trigger mechanism 242 (FIG. 11). When the actuation member 250 travels in the distal direction through the lumen 225, the surface 252 applies a deployment force 223 to the implant device 210. Similar to previously described embodiments, the distal tip potion 222 of the delivery needle 220 may include a light source 260 that can be viewed while the distal tip potion 222 is disposed under the dermal surface. For example, the light source 260 may comprise a luminescent coating applied to part of the distal tip portion 222 or may comprise a miniature LED device disposed on the distal tip portion 222.

As previously described, the guide flange 238 may be coupled to the delivery needle 220 so that the distal tip portion 222 is advanced into the nasal lateral wall 70 at the proper tissue depth. The guide flange 238 may be axially spaced apart from the distal tip portion 222 by a clearance space 239 so as to permit a certain amount of nasal tissue therebetween. Accordingly, the guide flange 238 may facilitate advancement of the distal tip portion 222 at the approximate tissue depth to find the targeted tissue plane (refer also to FIGS. 15-16).

Referring to FIG. 13, the distal tip portion 222 may include an adjustable opening 227 that expands when the implant device 210 is deployed from the needle 220, as described in previous embodiments. For example, the distal tip portion 222 may include a distal opening 227 having a closed position (shown in FIG. 13) that provides a more pointed needle tip. When the implant device 210 is forced distally from the needle 220, the opposing tip walls flex outwardly to permit the passage of the implant device 210.

Referring now to FIGS. 14-16, the delivery system 200 may be operated by the practitioner to delivery the implant device 210 to a targeted tissue plane in the nasal lateral wall 70. As previously described, implantation into a proper tissue plane can reduce the likelihood of functional failure (e.g., extruding the implant device through the mucosal membrane surface) and cosmetic failure (e.g., the implant device being noticeably viewable on the dermal surface). In the embodiment depicted in FIG. 14, the distal tip portion 222 can penetrate an insertion site 75 in the mucosal surface near the end of the nostril and can be advanced in a cephalo-caudal path into the lateral wall 70. The needle 220 may be advanced into the lateral wall 70 until the distal tip portion 222 reaches the nasal bone (e.g., palpated by the practitioner or visualized on the dermal surface or by tactile feedback when the needle hits the bone). As shown in FIG. 14, the implant device 210 may be disposed in the lumen of the distal tip portion 222 as the distal tip portion 222 is inserted into the nasal tissue. As previously described, the length of the distal tip portion 222 and the shape of the curved section 230 can be selected by the practitioner depending upon the patient's nasal anatomy (e.g., nose size, tissue thickness, and the like). As such, the curved shape of the section 230 may generally correspond to an implantation path in a portion of the nasal lateral wall 70, thereby permitting a practitioner to operate the delivery system 200 from an effective position relative to the patient (e.g., the patient may be resting on his or her back in a reclining chair or on a table surface while the practitioner approaches the patient's nose 50 from a comfortable position in front of the patient or standing over the patient). As previously described, an alternative approach may be employed in which the distal tip portion 222 in inserted near the end of the nostril on the dermal side and advanced in a cephalo-caudal path.

As shown in FIGS. 15-16, in some embodiments, the targeted tissue plane in the nasal lateral wall 70 for the implant device 210 may be under the dermal layer 71 and between the SMAS layer 72 (superficial muscle and aponeurotic tissue) and the cartilage layers 73, which are above the mucosa layer 74. (It should be understood that the tissue layers 71, 72, 73, and 74 and the implant device 210 are shown for illustrative purposes and are not necessarily shown in scale.) After the distal tip portion 222 has penetrated into the nasal lateral wall and has advanced along the targeted tissue plane, the practitioner may then drawback the distal tip portion 222 while the implant device 210 is

deployed in the targeted tissue plane (refer also, for example, to FIG. 3). Accordingly, the delivery system 200 can provide a nonsurgical insertion path the implant device 210 in the targeted tissue plane of the nasal lateral wall 70. The distal tip portion 222 of the delivery needle 220 includes a curved section 230 adapted to penetrate into the targeted tissue plane in the nasal lateral wall 70 and subsequently maintain its position in the targeted tissue plane as it is advanced along the lateral wall 70. In these embodiments, the delivery system 200 can position the implant device 210 in the targeted tissue plane to reduce the likelihood of functional failure and cosmetic failure.

It will be understood that various modifications may be implemented to the delivery system. For example, in some embodiments, a guide flange (similar to flange 238 shown in FIG. 11) may be coupled to the delivery needle 120 (described in connection with FIG. 5). In these embodiments, the guide flange may include an upward curvature similar to the curved section 130. In another example, the delivery system 100 described in connection with FIGS. 4-10 may also be employed to deliver an implant device 210 into the nasal lateral wall 70 (similar to the embodiment shown in FIG. 3). In such embodiments, the distal tip portion 122 (FIG. 5) may penetrate the dermal side of the nasal lateral wall 70 and then be advanced in a cephalo-caudal path into the lateral wall 70.

Furthermore, it should be understood that the embodiments described herein are not limited to the particular examples illustrated in FIGS. 1-16. For example, in some embodiments, a delivery system may have a handle member that is different from those previously illustrated in FIGS. 5 and 11.

Referring to FIGS. 17-18, some embodiments of a delivery system 300 may include a handle member 340 that can be grasped like a pencil or the like so that the user's finger can adjust a finger switch 342. Such a handle member 340 can be engaged primarily by the practitioner's fingers and is capable of providing a high degree of dexterity and control when manipulating the delivery needle 320. The handle member 340 includes a grasping portion 245 that extends in a generally longitudinal direction 346 along the axis of the delivery needle 320 (from the perspective shown in FIGS. 17-18). Similar to previously described embodiments, the delivery needle 320 includes a proximal portion 324 that is coupled to a handle member 340 and a distal tip portion 322

having a curved section 330. The curved section includes a first curve 332 that extends at least partially in a lateral direction 326a (e.g., a partially upward direction as shown in FIG. 17) and a second curve 334 that extends in a generally longitudinal direction 326b. These two curves 332 and 334 of the curved section 330 may provide a distal tip portion 322 that extends longitudinally after a lateral curve, which might be referred to as a "bayonet" shape. This compound curvature may be selected to substantially correspond to an implantation path in a portion of the nasal lateral wall 70, thereby permitting a practitioner to operate the delivery system 300 from an effective position relative to the patient. Also, such a compound curvature may provide the practitioner with a direct line of sight to the implantation site as the distal tip portion 322 approaches the implantation site. Accordingly, in this embodiment, a user may readily grasp the handle member 340 in a manner similar to that of grasping a pencil while the distal tip portion 222 curves at least partially upward 226a (as shown in FIG. 17), which can facilitate delivery of the implant device (e.g., device 210 as described in connection with FIGS. 3-4) into the targeted tissue plane of the nasal lateral wall 70 or other nasal anatomy.

In other embodiments, the delivery system 300 may employ a delivery cannula other than the "bayonet" shape delivery needle 320. For example, in some embodiments, the delivery system 300 may include a delivery needle have a distal tip portion similar to that of the delivery needle 120 described in connection with FIGS. 5-10. In such circumstances, the delivery needle configured to delivery a nasal implant into the nasal rim is coupled to the handle member 340. Thus, a user may readily grasp the handle member 340 in a manner similar to that of grasping a pencil while the distal tip portion curls at least partially in a lateral direction to facilitate the implant delivery to the nasal rim (refer, for example, to FIG. 8).

Similar to the embodiments previously described in connection with FIGS. 1-16, the delivery needle 320 may be coupled with a guide flange 338 so that the distal tip portion 322 is advanced into the nasal lateral wall 70 at the proper tissue depth. The distal tip portion 322 may include an adjustable opening that expands when the implant device (e.g., implant device 210) is deployed from the needle 320 (described in connection with FIGS. 6-7 and 12-13). Also, similar to previously described embodiments, the delivery needle 320 may be releasably coupled with the handle

member 340 so that a practitioner may select one delivery needle 320 from a plurality of connectable delivery needles 320 (e.g., provided in a kit with the handle member 340) having a variety of curvatures in the curved section 330. Furthermore, in some embodiments, the distal tip portion 322 may comprise a malleable material that permits a practitioner to at least partially modify the curved section 330 of the needle 320 (described in connection with FIG. 11). Similar to previously described embodiments, the delivery needle 320 may include one or more markings 335 (FIG. 8) to indicate the depth of tissue penetration during the implantation procedure. Finally, similar to previously described embodiments, the distal tip potion 322 of the delivery needle 320 may include a light source that can be viewed while the distal tip potion 322 is disposed under the dermal surface.

Still referring to FIGS. 17-18, the handle member 340 includes a trigger mechanism 342 to movably adjust the actuation member in the lumen of the delivery needle 320. By applying a force 243 to the trigger mechanism 242 (as shown in FIG. 17), the practitioner may cause the actuation member to apply a deployment force to the implant device. In this embodiment, the trigger mechanism 342 includes a finger-actuated switch that is slidable within a guide slot 343 (FIG. 18) of the handle member 340. Similar to previously described embodiments, an actuation indicator 347 may be disposed on the handle member 340. The actuation indicator 347 may display the length of travel of the actuation member in the needle lumen so that the user may know when the implant device is fully deployed. In this embodiment, the actuation indicator 347 includes one or more markings 348 that indicate the travel length based upon the motion of the trigger mechanism 342 and its interaction with the actuation member. As previously described in connection with FIGS. 14-16, the delivery system 300 may be operated by the practitioner to delivery the implant device (e.g., implant device 210) to a targeted tissue plane in the nasal lateral wall 70. Implantation into a proper tissue plane can reduce the likelihood of functional failure (e.g., extruding the implant device through the mucosal membrane surface) and cosmetic failure (e.g., the implant device being noticeably viewable on the dermal surface).

Referring now to FIGS. 19-20, some embodiments of a delivery system 400 may be configured to deliver a nasal implant material in a non-rigid state, which stiffens after

to a more rigid or resilient state after deployment to the nasal tissue. As shown in FIG. 19, the delivery system 400 may be inserted into nasal tissue proximate to the nostril rim 60 of a nose 50 in a manner similar to the embodiments previously described in connection with FIGS. 1 and 8-10. The delivery system 400 includes a delivery needle 420 or other cannula device (e.g., a specially configured hypotube, a polymer cannula, or the like) having sufficient rigidity to penetrate into the nasal tissue. The delivery needle 420 includes a distal tip portion 422, a proximal portion (not shown in FIG. 19), and one or more lumens 425 extending therebetween (refer to FIG. 20). Similar to previously described embodiments, the delivery system 400 may also include a handle member at a proximal portion coupled with the delivery needle 420 (refer, for example, to FIGS. 5, 11, and 17-18).

Also, as previously described in connection with FIGS. 1 and 8-10, the distal tip portion 422 of the delivery needle 420 may include a curved section 430 extending at least partially in a lateral direction. Such a curved orientation may facilitate delivery of the implant 410 into the targeted tissue plane of the nasal rim 60. For example, the curved section 430 of the delivery needle 420 may include a generally arcuate shape that curls in the lateral direction so as to provide an effective implantation path into the nasal rim 60. In this embodiment, the distal tip portion 422 can penetrate an insertion site 65 in the mucosal surface at the base of the nostril and moved along an implantation path towards the tip 55 of the nose 50 along the nasal rim 60. The practitioner may then drawback the distal tip portion 422 as the implant 410 is deployed in the nasal rim 60. The length of the distal tip portion 422 and the shape of the curved section 430 may be selected by the practitioner depending upon the patient's nasal anatomy (e.g., nose size, rim curvature, tissue thickness, and the like).

In use, the one or more lumens of the delivery needle 420 may be in fluid communication with one or more fluid reservoirs arranged in the handle member (not shown in FIG. 19). For example, a syringe-type reservoir may be arranged in the handle member so that a trigger mechanism can be actuated to forwardly advance a plunger of the syringe-type reservoir. Thus, the reservoir can be used to advance at least a first agent 410a through the delivery needle 420 (described below), which also provides the actuation force 423 to deploy the nasal implant 410 from the delivery needle 420.

Referring to FIG. 20, the nasal implant device 410 may comprise one or more biocompatible materials that are advanced through the delivery needle 422 in a generally non-rigid state and thereafter stiffen to form a resilient implant 410 that is rigid enough to at least partially support the surrounding nasal tissue. For example, the implant 410 may comprise a first agent 410 that is advanced through a first lumen of the delivery needle 422 toward the distal port. The first agent 410a may comprise a material that reacts with a second agent 410b to form a resilient material for the deployed implant 410.

For example, the first agent 410a may comprise a polymer resin in a non-rigid, fluid state that can be combined with a second polymer resin 410b (passing through a second lumen of the delivery needle 420) during deployment. When the first and second resins 410a and 410b are combined, the resulting material polymerizes or sets into a more rigid and resilient product. This resulting material can be forced from the delivery needle 420 by an actuation force 423 and into the targeted nasal tissue where it serves as the nasal implant 410.

In another example, the first agent 410a may comprise a polymer material in a non-rigid state (e.g., heated to an elevated temperature) that reacts with or is cooled by a second agent 410b, such as air, water, or saline, during deployment. The polymer material 410a can be fully or partially stiffening as it is deployed from the port of the delivery needle 420. As such, the polymer material may form a resilient nasal implant 410 that is deployed into the targeted tissue plane.

In other embodiments, the delivery system may employ a delivery cannula other than the arcuate curved delivery needle 420. For example, as shown in FIG. 21, the delivery system 500 may include a delivery needle 520 having a distal tip portion 522 capable of delivering one or more nasal implants to the nasal lateral walls. Similar to the embodiments described in connection with FIGS. 19-20, the delivery system 500 is configured to deliver a nasal implant material in a non-rigid state, which stiffens after to a more rigid or resilient state after deployment to the nasal tissue the delivery needle includes one or more lumens.

The distal tip portion 522 of the delivery needle 520 may include a curved section 530 having at least one curve extending at least partially in a lateral direction. For example, the curved section 530 of the delivery needle 520 may include a first curve 532

that extends at least partially in the lateral direction and a second curve 534 that extends in a generally longitudinal direction toward the distal tip so as to provide an effective implantation path into the nasal lateral wall 70. Such a curved orientation may facilitate delivery of the nasal implant 510 into the targeted tissue plane of the nasal lateral wall 70. In this embodiment, the distal tip portion 522 can penetrate an insertion site 75 in the mucosal surface near the end of the nostril and advanced in a cephalo-caudal path into the lateral wall 70. The needle 520 may be inserted into the lateral wall 70 until the distal tip portion 522 reaches the nasal bone (e.g., palpated by the practitioner or visualized on the dermal surface or by tactile feedback when the needle hits the bone). The practitioner may then drawback the distal tip portion 522 as the implant device 210 is deployed. In another embodiment, the distal tip portion 522 can be inserted near the end of the nostril on the dermal side and advanced in a cephalo-caudal path. As such, the curved shape of the curved section 530 may generally correspond to an implantation path in a portion of the nasal lateral wall 70, thereby permitting a practitioner to operate the delivery system 500 from an effective position relative to the patient. As previously described, the length of the distal tip portion 522 and the shape of the curved section 530 may be selected by the practitioner depending upon the patient's nasal anatomy (e.g., nose size, lateral wall length, tissue thickness, and the like).

In use, the one or more lumens of the delivery needle 520 may be in fluid communication with one or more fluid reservoirs arranged in the handle member (not shown in FIG. 21). In one example, a syringe-type reservoir may be arranged in the handle member so that a trigger mechanism can be actuated to forwardly advance a plunger of the syringe-type reservoir. Accordingly, the reservoir can be used to advance at least a first agent through the delivery needle 520, which also provides the actuation force to deploy the nasal implant 510 from the delivery needle 520. Similar to the embodiments previously describe din connection with FIG. 20, the nasal implant 510 may comprise one or more biocompatible materials that are advanced through the delivery needle 522 in a generally non-rigid state and thereafter stiffen to form a resilient implant 510 that is rigid enough to at least partially support the surrounding nasal tissue. For example, the first agent may comprise a material that reacts with a second agent to form a resilient material for the deployed implant 410.

Referring now to FIGS. 22-23, some embodiments of a delivery system 600 or 700 may include a delivery instrument 620 or 720 configured to apply a rigidity supplement material to a targeted region of nasal tissue. As shown in FIG. 22, the delivery system 600 may be adapted to apply the rigidity supplement material to an internal portion or external portion of the nasal rim 60. As shown in FIG. 23, the delivery system 700 may be adapted to apply the rigidity supplement material to an internal portion or external portion of the lateral nasal wall 70 or across the bridge of the nose along the lateral nasal walls 70.

In some embodiments, the rigidity supplement material may comprise a substantially translucent or transparent polymer that is applied in a non-rigid, generally liquid state. The polymer material is selected to be biocompatible with the outer dermal layers and the mucous membranes. In this embodiment, the polymer can provide elastic properties after it has transitioned from the non-rigid state to a resilient state. For example, after the polymer material is applied to the nasal skin or the mucous membranes, it may partially dry and thereafter contract to provide a stiffening effect on the nasal structure to which it was applied. In some embodiments, the polymer may react via air after being applied to the targeted nasal tissue. Alternatively, the polymer may be applied as two or more resins that react and set to form a resilient product when applied to the nasal tissue. After a particular duration of use, the polymer material may be removed from the nasal tissue either by peeling away from the tissue or by washing with a solvent. Accordingly, the delivery systems 600 and 700 can provide a non-surgical treatment option that can be comfortably used during both day and night. In particular, the rigidity supplement material can be applied to either the internal or external portions of the nose 50 without being noticeably visible on the dermal surface.

Referring to FIG. 22, the delivery system 600 includes a delivery instrument 620 having sufficient rigidity to press an applicator 635 to the targeted tissue. The delivery instrument 620 includes a distal tip portion 622 and a proximal portion (not shown in FIG. 22). Similar to previously described embodiments, the delivery system 600 may also include a handle member at a proximal portion coupled with the delivery instrument 620 (refer, for example, to FIGS. 5, 11, and 17-18). Also, as previously described in connection with FIGS. 1, 5 and 8, the distal tip portion 622 of the delivery instrument 620

may include a curved section 630 extending at least partially in a lateral direction. Such a curved orientation may facilitate application of the rigidity supplement material 610a onto the internal portion of the nasal rim 60. For example, the curved section 630 of the delivery instrument 620 may include a generally arcuate shape that curls in the lateral direction so as to provide an effective application path to the nasal rim 60. In addition, such a curved orientation may facilitate application of the rigidity supplement material 610b onto the external portion of the nasal rim 60. The length of the distal tip portion 622 and the shape of the curved section 630 may be selected by the practitioner depending upon the patient's nasal anatomy (e.g., nose size, rim curvature, tissue thickness, and the like).

The delivery instrument 620 includes an applicator 635 that contacts the targeted nasal tissue and deposits one or more layers of the rigidity supplement material 610a and 610b. In this embodiment, the applicator 635 comprises a miniature roller 636 that receives the previously described polymer material in the non-rigid, generally liquid state. In other embodiments, the applicator 635 may comprise a miniature brush having bristles that receive the polymer material in the non-rigid, generally liquid state. The delivery instrument 620 can be manipulated by the user (e.g., using the handle member) so that the applicator 635 is brought into contact with the targeted nasal tissue and the polymer material is deposited thereon. Thereafter, the polymer can partially dry or otherwise stiffen to provide supplemental rigidity to the nasal structure to which it was applied.

Referring to FIG. 23, the delivery system 700 includes a delivery instrument 720 having sufficient rigidity to press an applicator 735 to the targeted tissue. The delivery instrument 720 includes a distal tip portion 722 and a proximal portion (not shown in FIG. 23). Similar to previously described embodiments, the delivery system 700 may also include a handle member at a proximal portion coupled with the delivery instrument 720 (refer, for example, to FIGS. 5, 11, and 17-18). Also, as previously described in connection with FIGS. 3, 11, and 14, the distal tip portion 722 of the delivery instrument 720 may include a curved section 730 extending at least partially in a lateral direction. For example, the curved section 730 of the delivery instrument 720 may include a first curve 732 that extends at least partially in the lateral direction and a second curve 734

that extends in a generally longitudinal direction toward the distal tip so as to provide an effective application path to the nasal lateral wall 70. Such a curved orientation may facilitate application of the rigidity supplement material 710a onto the internal portion of the nasal lateral wall 70. In addition, such a curved orientation may facilitate application of the rigidity supplement material 710b onto the external portion of the nasal lateral wall 70. The delivery instrument 720 may also be used to apply the rigidity supplement material 710c onto an external portion of the nasal bridge along both nasal lateral walls 70. The length of the distal tip portion 722 and the shape of the curved section 730 may be selected by the practitioner depending upon the patient's nasal anatomy (e.g., nose size, rim curvature, tissue thickness, and the like).

The delivery instrument 720 includes an applicator 735 that contacts the targeted nasal tissue and deposits one or more layers of the rigidity supplement material 710a, 710b, and 710c. Similar to the embodiments previously described in connection with FIG. 22, the applicator 735 comprises a miniature roller 736 that receives the previously described polymer material in the non-rigid, generally liquid state. In other embodiments, the applicator 735 may comprise a miniature brush having bristles that receive the polymer material in the non-rigid, generally liquid state. The delivery instrument7 can be manipulated by the user (e.g., using the handle member) so that the applicator 735 is brought into contact with the targeted nasal tissue and the polymer material is deposited thereon. Thereafter, the polymer can partially dry or otherwise stiffen to provide supplemental rigidity to the nasal structure to which it was applied.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A nasal implant delivery system comprising:

a delivery cannula including a distal portion, a proximal portion, and a lumen extending therebetween, at least a section of the proximal portion extending in longitudinal direction along a central axis, the distal portion of the delivery cannula including a curved section that extends in an at least partially lateral direction away from the central axis and including a port to deliver a nasal implant;

an actuation member movable disposed in the lumen, the actuation member including a distal surface to at least partially engage the nasal implant when the implant is disposed in the lumen; and

a handle member coupled with the delivery cannula to manipulate the position of the distal portion relative to a targeted site, the handle member being coupled to a hand-adjustable switch to cause the actuation member to move in the lumen.

2. The nasal implant delivery system of claim 1, wherein the curved section of the distal portion of the delivery cannula is penetrable into a tissue plane of a nasal rim.

3. The nasal implant delivery system of claim 2, wherein the curved section of the delivery cannula curls in a generally arcuate shape away from the central axis.

4. The nasal implant delivery system of claim 3, wherein the generally arcuate shape of the curved section is substantially congruent to an anatomical curvature to at least a portion of a nasal rim.

5. The nasal implant delivery system of claim 1, wherein the curved section of the distal portion of the delivery cannula is penetrable into a tissue plane of a lateral nasal wall.

6. The nasal implant delivery system of claim 5, wherein the curved section of the delivery cannula includes a first curve that extends in the at least partially lateral direction away from the central axis and a second curve that extends in a longitudinal

direction generally parallel to the central axis toward a distal tip of the delivery cannula.

7. The nasal implant delivery system of claim 6, wherein the distal tip is insertable into a mucosal surface and advanceable in a cephalo-caudal direction toward the targeted tissue plane.

8. The nasal implant delivery system of claim 1, further comprising a guide flange offset from and extending generally parallel to at least a part of the distal portion of the delivery cannula.

9. The nasal implant delivery system of claim 1, wherein at least the distal portion of the delivery cannula comprises a needle.

10. The nasal implant delivery system of claim 1, further comprising a nasal implant arranged in the distal portion of the delivery cannula.

11. The nasal implant delivery system of claim 10, wherein the nasal implant comprises a resilient elongate structure that is deliverable to a targeted nasal tissue plane.

12. A nasal implant delivery system, comprising:

a delivery cannula including a distal portion, a proximal portion, and at least one lumen extending therebetween, at least a section of the proximal portion extending in longitudinal direction along a central axis, the distal portion of the delivery cannula including a curved section that extends in an at least partially lateral direction away from the central axis and including a port in communication with the at least one lumen to deploy a nasal implant material;

a fluid reservoir in fluid communication with the at least one lumen, the fluid reservoir containing a polymer material in a generally non-rigid state; and

an actuation member to deploy the polymer material from the distal portion of the delivery cannula and to a targeted nasal tissue plane, the polymer material transitioning to a resilient state when deployed from the distal portion.

13. The nasal implant delivery system of claim 12, wherein the curved section of the distal portion of the delivery cannula is penetrable into a tissue plane of a nasal rim.

14. The nasal implant delivery system of claim 13, wherein the curved section of the delivery cannula curls in a generally arcuate shape away from the central axis.

15. The nasal implant delivery system of claim 14, wherein the generally arcuate shape of the curved section is substantially congruent to an anatomical curvature to at least a portion of a nasal rim.

16. The nasal implant delivery system of claim 12, wherein the curved section of the distal portion of the delivery cannula is penetrable into a tissue plane of a lateral nasal wall.

17. The nasal implant delivery system of claim 16, wherein the curved section of the delivery cannula includes a first curve that extends in the at least partially lateral direction away from the central axis and a second curve that extends in a longitudinal direction generally parallel to the central axis toward a distal tip of the delivery cannula.

18. The nasal implant delivery system of claim 17, wherein the distal tip is insertable into a mucosal surface and advanceable in a cephalo-caudal direction toward the targeted tissue plane.

19. The nasal implant delivery system of claim 12, further comprising a guide flange offset from and extending generally parallel to at least a part of the distal portion of the delivery cannula.

20. The nasal implant delivery system of claim 12, wherein at least the distal portion of the delivery cannula comprises a needle.

21. A delivery system for a nasal rigidity supplement, comprising:

a delivery instrument including a distal portion and a proximal portion, the proximal portion extending in longitudinal direction along a central axis, the distal portion of the delivery instrument including an applicator to contact a targeted nasal tissue site; and

a rigidity supplement material arranged on the applicator of the delivery instrument, the rigidity supplement material being in a generally non-rigid state when arranged on the applicator,

wherein the rigidity supplement material transitions to a resilient state when deployed from the applicator to the targeted nasal tissue site.

22. The delivery system of claim 21, wherein the rigidity supplement material reacts with air to transition to the resilient state.

23. The delivery system of claim 21, wherein the rigidity supplement material comprises a substantially translucent or transparent material transitions when in the resilient state.

24. The delivery system of claim 21, wherein the applicator comprises a brush device.

25. The delivery system of claim 21, wherein the applicator comprises a roller device.

26. The delivery system of claim 21, the rigidity supplement material comprises a generally elastic laminate material transitions when in the resilient state.

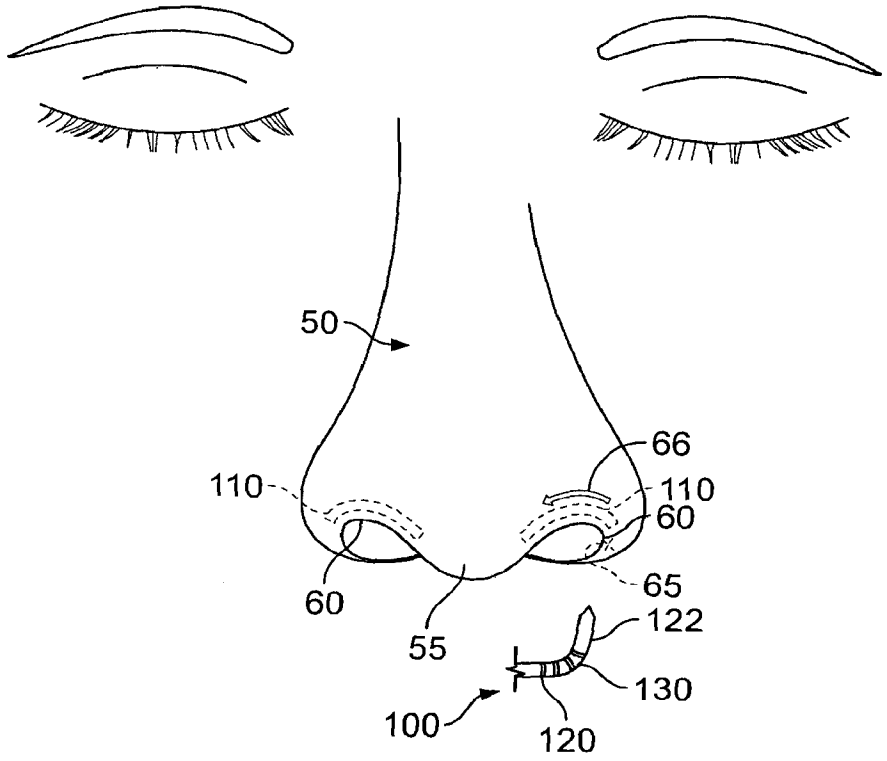


FIG. 1

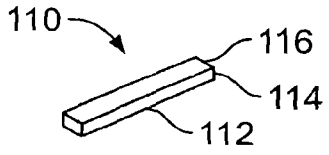


FIG. 2

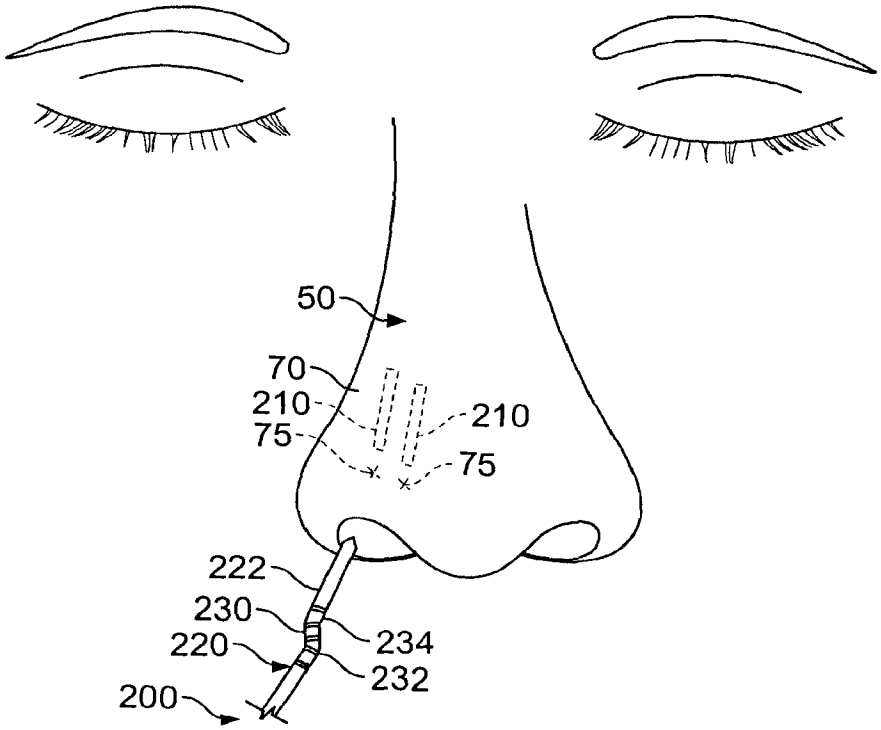


FIG. 3

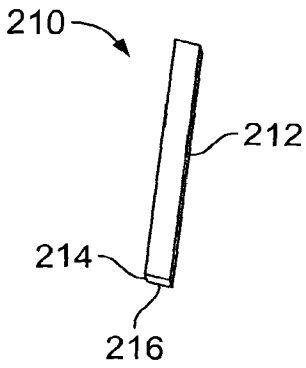


FIG. 4

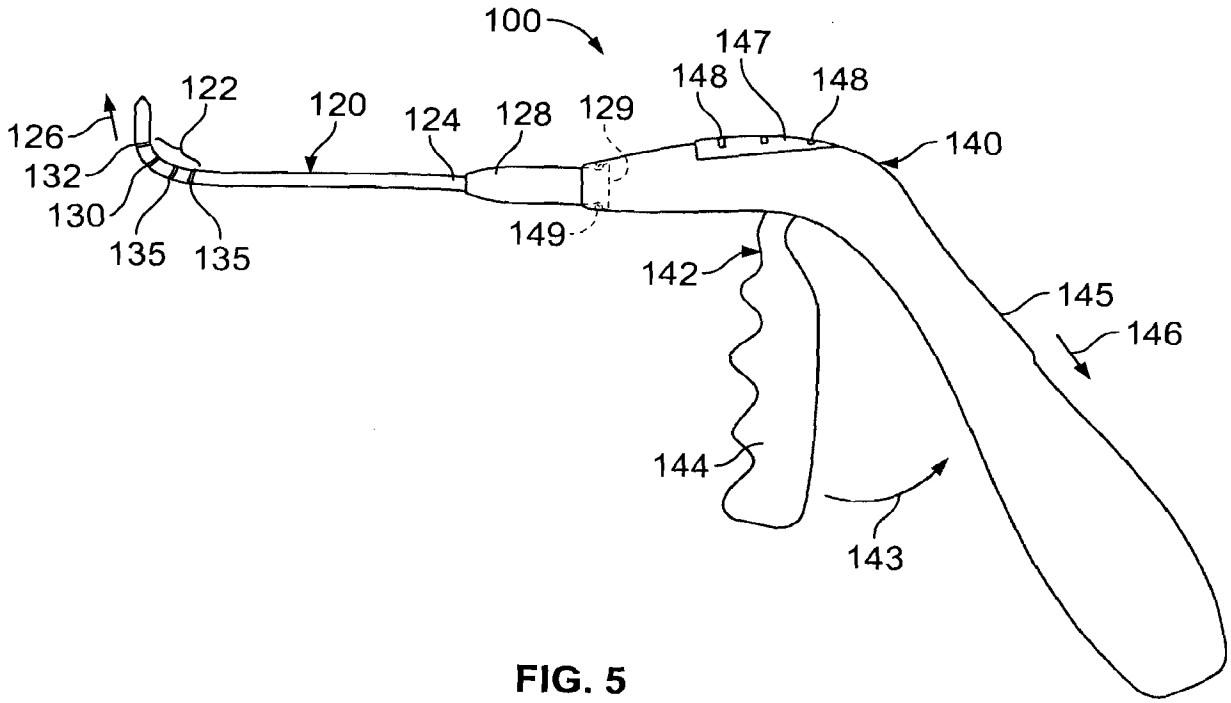


FIG. 5

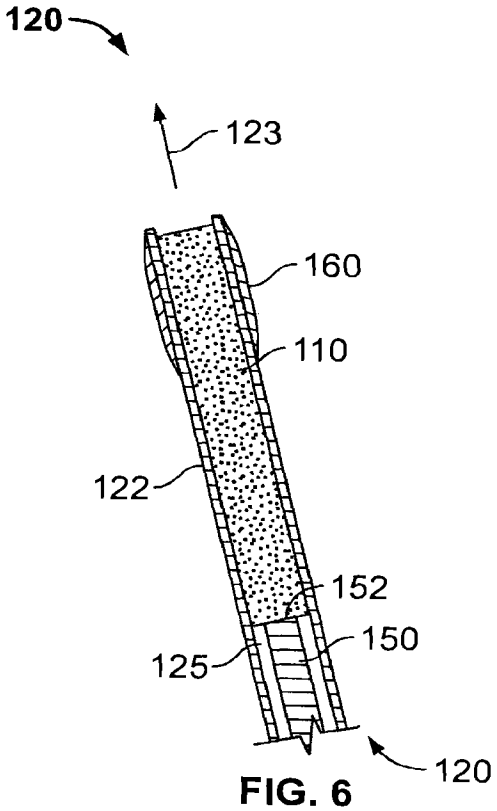


FIG. 6

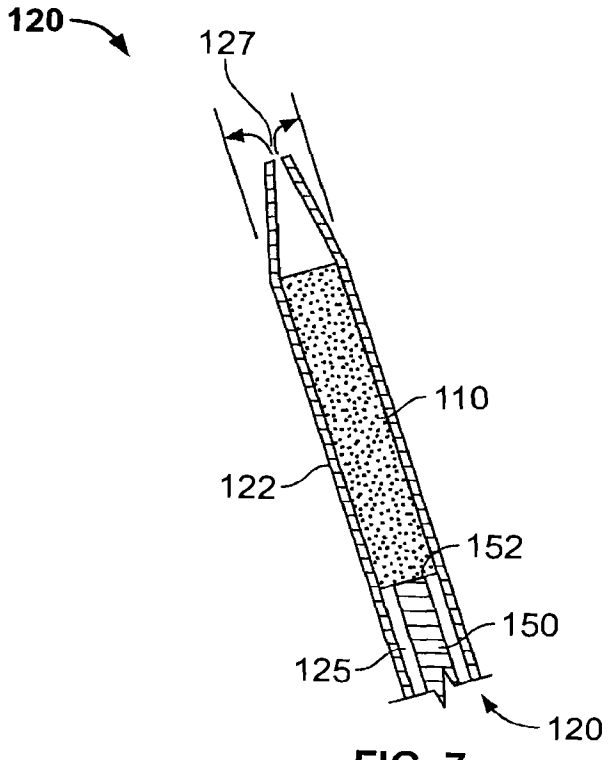


FIG. 7

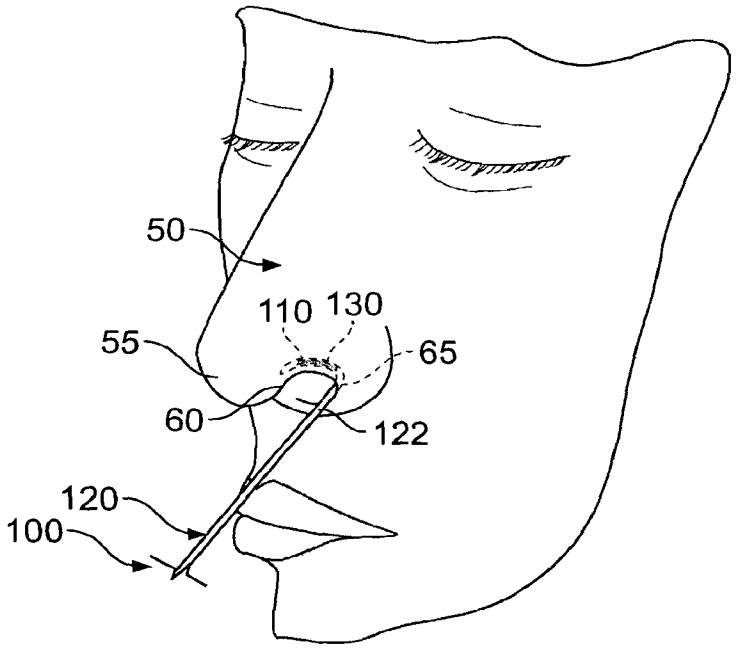


FIG. 8

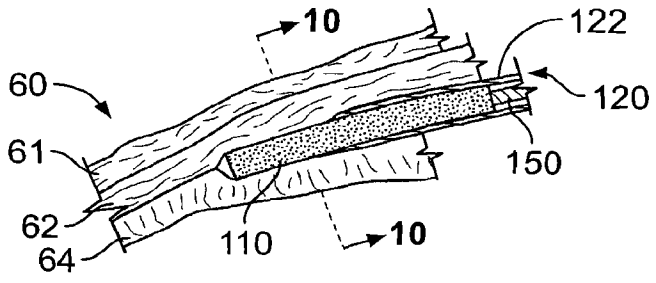


FIG. 9

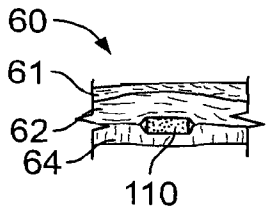


FIG. 10

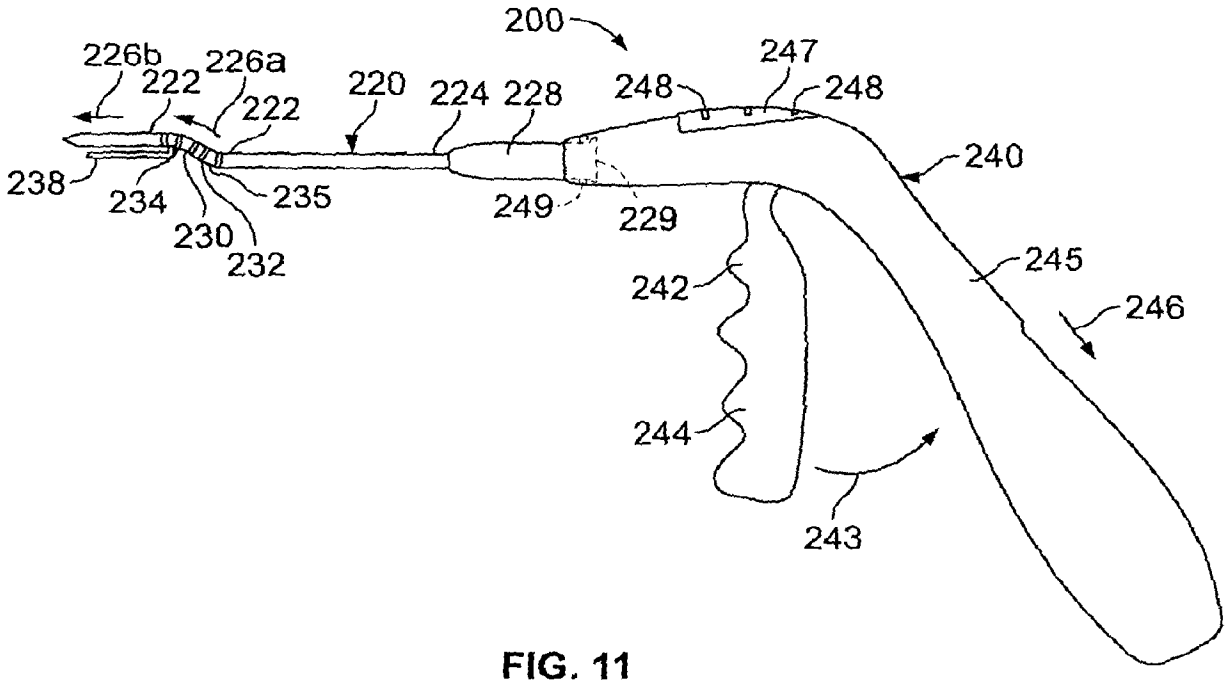


FIG. 11

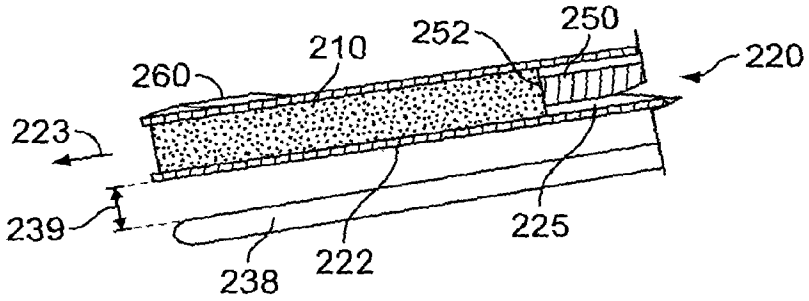


FIG. 12

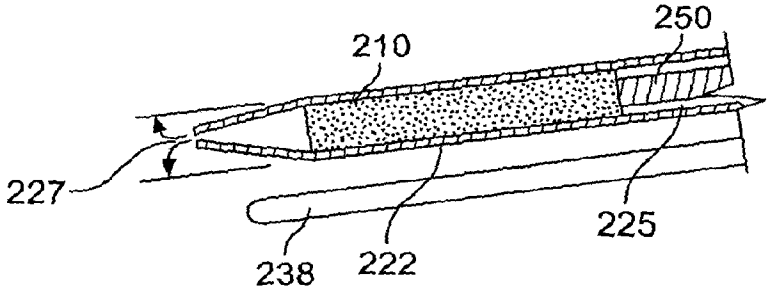


FIG. 13

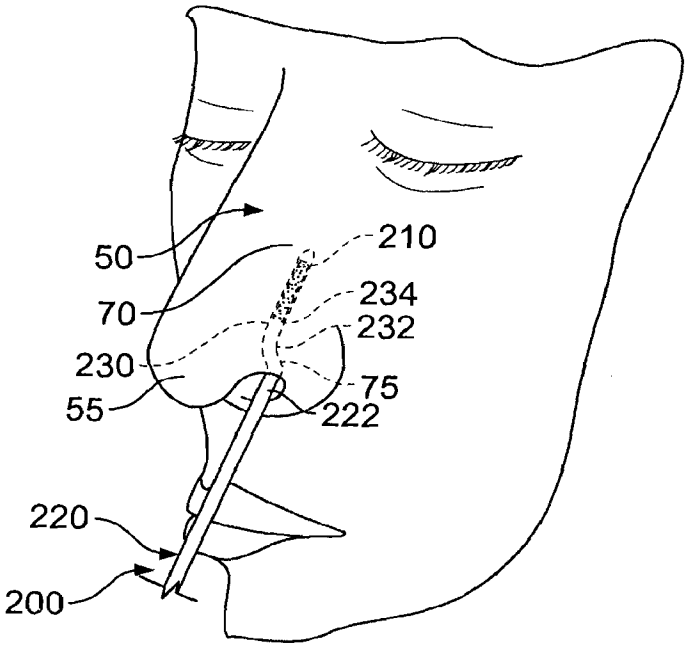


FIG. 14

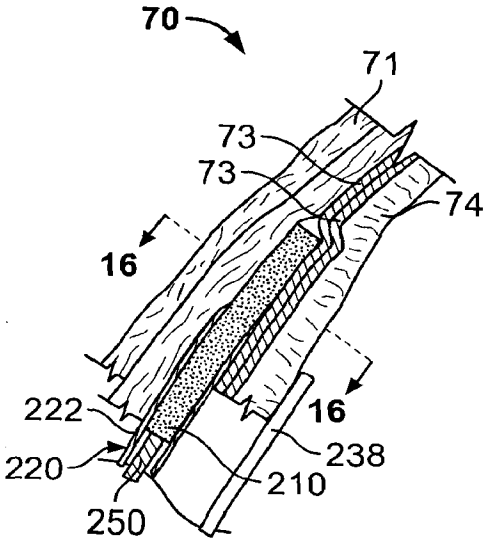


FIG. 15

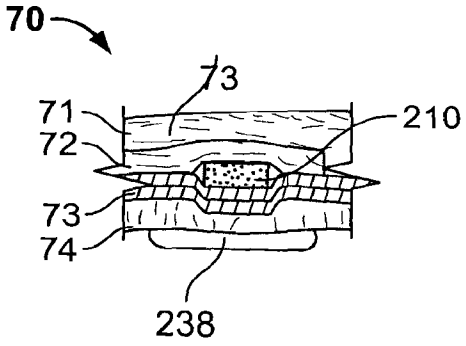


FIG. 16

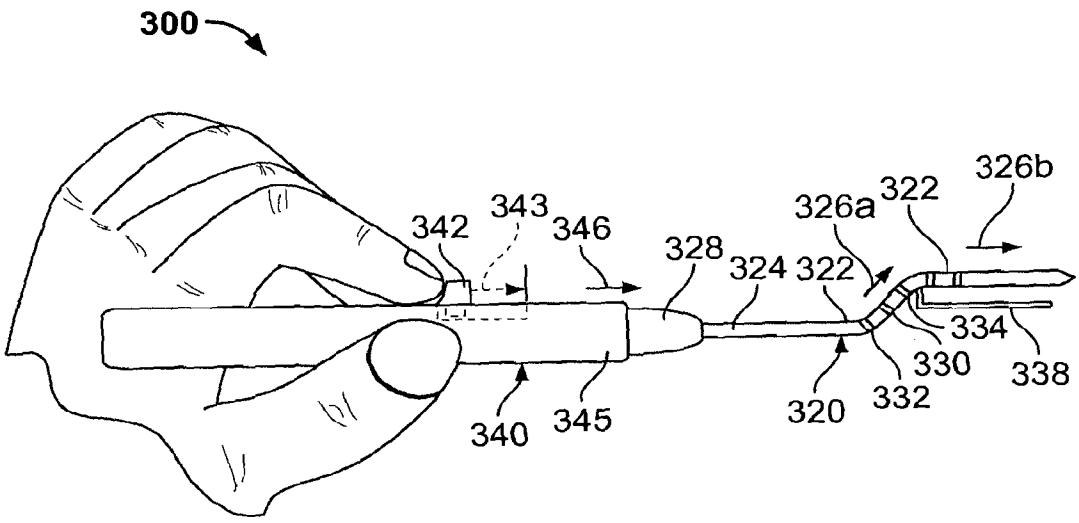

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326a
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326b
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FIG. 17

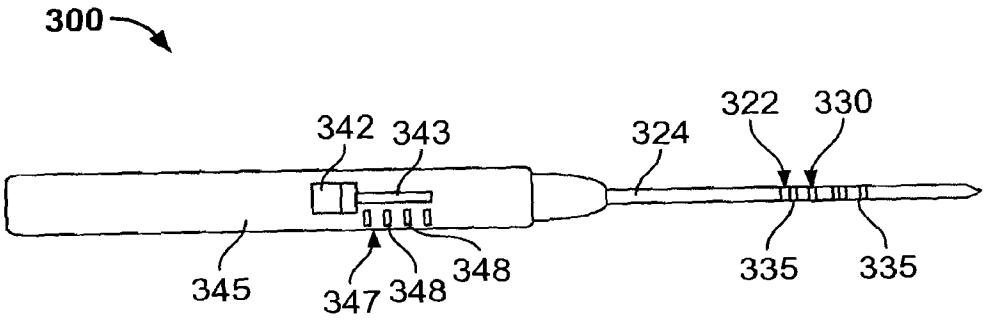

300
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FIG. 18

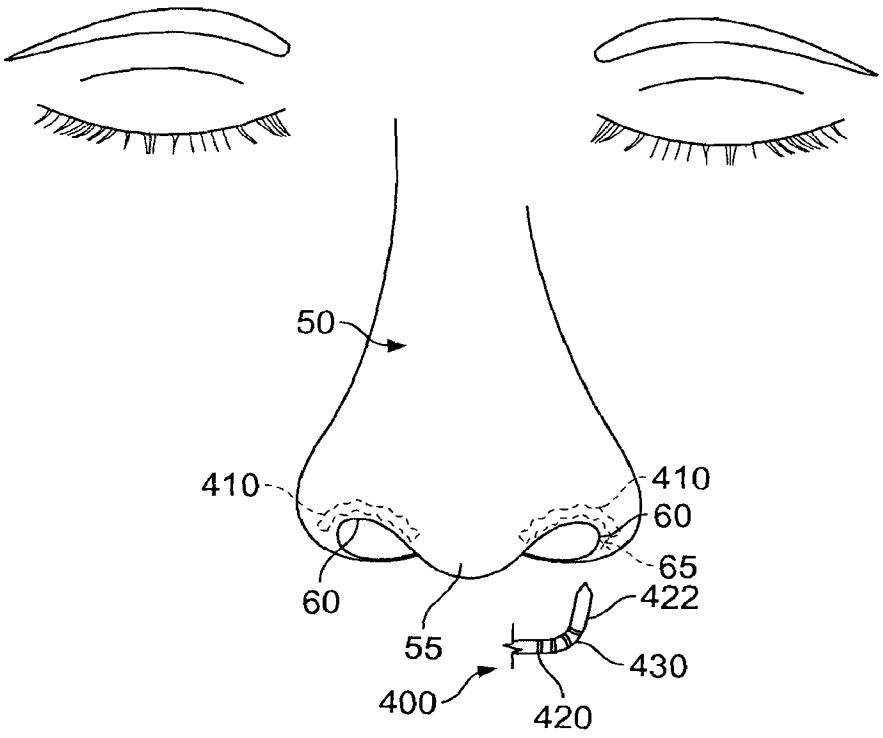

50
410
410
60
65
60
422
55
430
400
420

FIG. 19

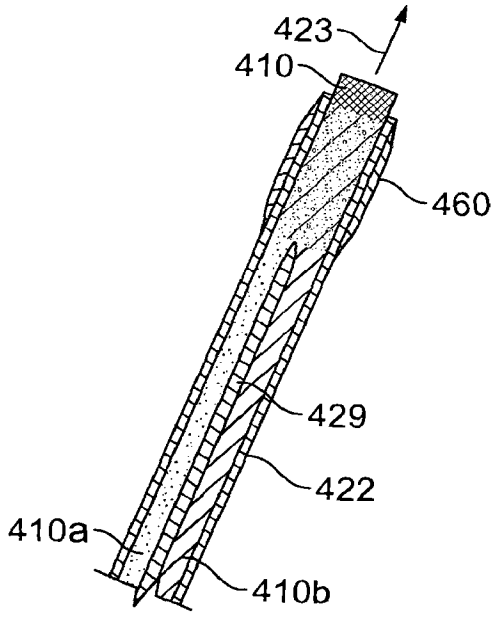

423
410
460
429
422
410a
410b

FIG. 20

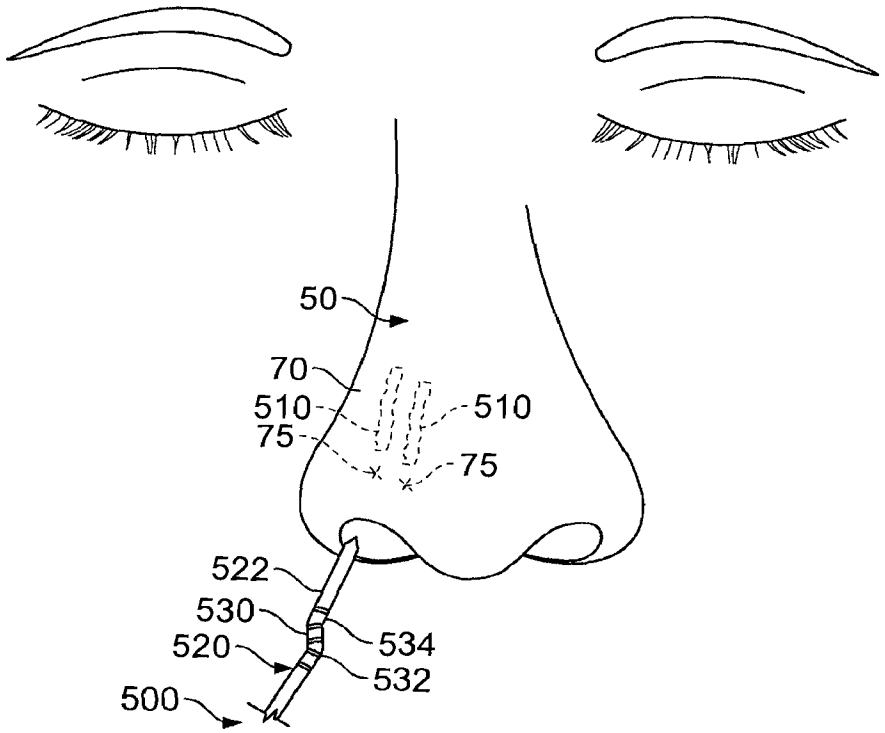


FIG. 21

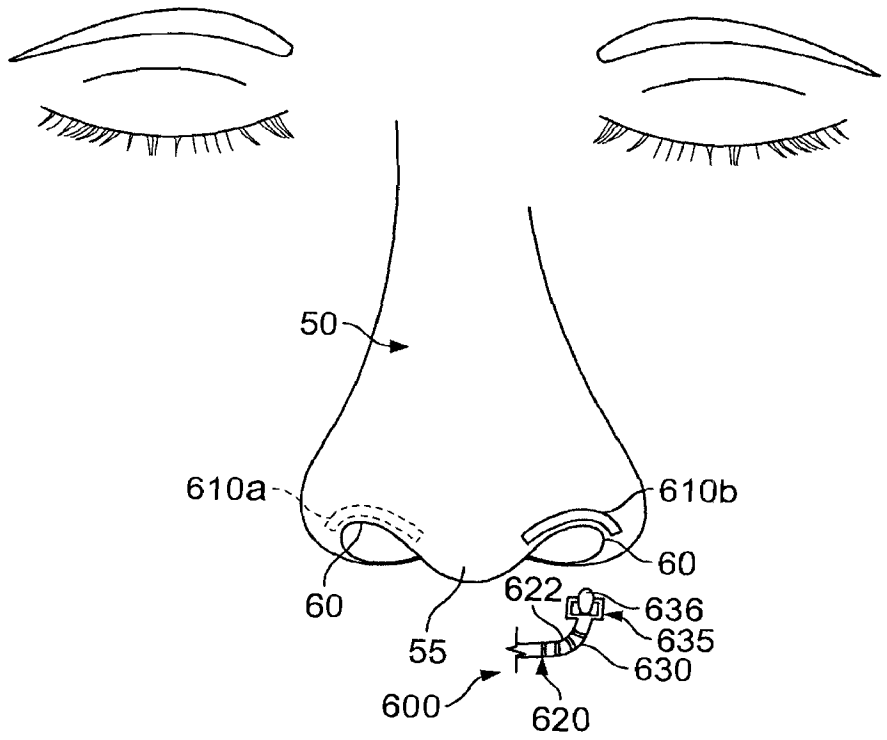


FIG. 22

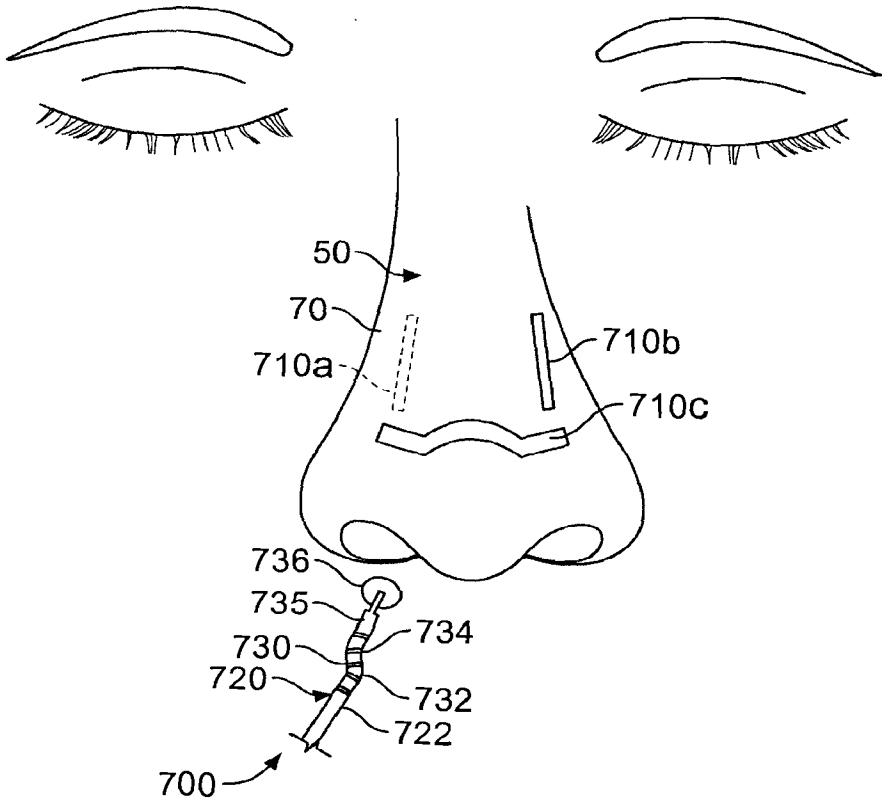


FIG. 23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/068370

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/18(2006.01)i

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)
IPC 8: A61F, A61B, A61K, A61N

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)
eKIPASS(KIPO internal), Delphion, Pubmed (implant, delivery, cannula, lumen, nasal, and similar terms)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6936052B2 (BOSTON SCIENTIFIC SCIMED, INC.) 30 AUG. 2005 See Abstract, Figures 1 & 23, and Claims 1-12.	1-26
A	US 6875219B2 (ARRAMON, Y.P. & MCINTYRE, S.H.) 05 APR. 2005 See Abstract, Figures 12 & 13.	1-26
A	US 6395007B1 (AMERICAN OSTEOMEDIX, INC.) 28 MAY 2002 See Abstract, and Figures 1, 4, & 11.	1-26
A	US 6512958B1 (MEDTRONIC, INC.) 28 JAN. 2003 See Abstract, and Figure 1.	1-26

☐ Further documents are listed in the continuation of Box C.

☒ 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
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INTERNATIONAL SEARCH REPORT

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

[Continued on next page]

(54) Title: SINUS WALL IMPLANT

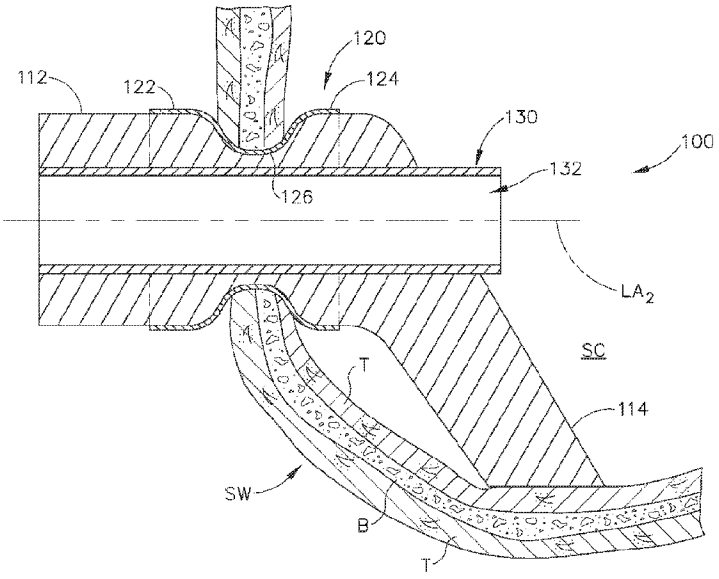


Fig.10

(57) Abstract: An apparatus comprises an absorbent body, a non-permeable feature, and a port feature. The absorbent body comprises a wicking feature. The non-permeable feature is coupled with the absorbent body. The non-permeable feature and at least a portion of the absorbent body are configured to fit in an opening in a paranasal sinus wall. The port feature extends through the absorbent body. The port feature defines a lumen. The wicking feature extends outwardly relative to the port lumen. During installation of the apparatus, the non-permeable feature is positioned in an opening in the paranasal sinus wall. The absorbent body is oriented such that the wicking feature is in contact with mucosal tissue in a sinus cavity defined by the paranasal sinus wall. A proximal portion of the absorbent body is positioned outside the paranasal sinus wall.

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SINUS WALL IMPLANT

PRIORITY

[0001] This application claims priority to U.S. Provisional Pat. App. No. 61/883,234, entitled "Sinus Wall Implant," filed September 27, 2013, the disclosure of which is incorporated by reference herein.

BACKGROUND

[0002] In some instances, it may be desirable to implant a device within or adjacent to a wall of a patient's paranasal sinus. Paranasal sinuses include ostia for providing fluid communication to and from the sinus and the nasal cavity. In particular, such ostia may provide paths for communication of mucus from the sinus to the nasal cavity; and of air/medication/etc. from the nasal cavity to the sinus. In some instances, it may be desirable to provide an implant that promotes or enhances the communication of mucus from the sinus to the nasal cavity, that promotes or enhances the communication of air from the nasal cavity to the sinus, and/or that promotes or enhances the communication of medication or other substances from the nasal cavity to the sinus.

[0003] If a naturally occurring ostium is blocked, functionally closed due to mucosal thickening, or otherwise not sufficiently open, the ostium may be dilated before deploying an implant in the ostium. One method of dilating an ostium includes using a guidewire and catheter to position an inflatable balloon within the anatomical passageway, then inflating the balloon with a fluid (e.g., saline) to dilate the anatomical passageway. For instance, the expandable balloon may be positioned within an ostium at a paranasal sinus and then be inflated, to thereby dilate the ostium by remodeling the bone adjacent to the ostium, without requiring incision of the mucosa or removal of any bone. Examples of such dilation systems are disclosed in U.S. Pub. No. 2011/0004057, entitled "Systems and Methods for Transnasal Dilation of Passageways in the Ear, Nose

or Throat," published January 6, 2011, the disclosure of which is incorporated by reference herein. Another example of such a system is the Relieva® Spin Balloon Sinuplasty™ System by Acclarent, Inc. of Menlo Park, California. Exemplary balloon dilator catheters include the Relieva Ultirra™ Sinus Balloon Catheter and the, both by Acclarent, Inc. of Menlo Park, California. An exemplary guide catheter that may be used to position a balloon catheter is the Relieva Flex™ Sinus Guide Catheter by Acclarent, Inc. of Menlo Park, California. Examples of devices that may be used to inflate a balloon of a dilation catheter are disclosed in U.S. Patent App. No. 14/020,924, titled "Inflator for Dilation of Anatomical Passageway," filed September 9, 2013, the disclosure of which is incorporated by reference herein.

[0004] In some instances, it may be desirable to create an ostium in a sinus. This may be done with a cutting device that is operable to cut through bone and tissue or otherwise form an opening in a sinus wall. Examples of such devices are disclosed in U.S. Patent App. No. 14/038,867, entitled "Apparatus and Method for Treatment of Ethmoid Sinusitis," filed on September 27, 2013, the disclosure of which is incorporated by reference herein. When an ostium is formed using a cutting device, the ostium may be further enlarged by a balloon dilation device or using other devices/techniques.

[0005] A variable direction view endoscope may be used to provide visualization within the nasal cavity to position a dilation catheter, a cutting device, and/or an implant at a desired location. A variable direction view endoscope may enable viewing along a variety of transverse viewing angles without having to flex the shaft of the endoscope within the nasal cavity. Such an endoscope that may be provided in accordance with the teachings of U.S. Pub. No. 2010/0030031, entitled "Swing Prism Endoscope," published February 4, 2010, the disclosure of which is incorporated by reference herein. An example of such an endoscope is the Acclarent Cyclops™ Multi-Angle Endoscope by Acclarent, Inc. of Menlo Park, California. In some instances where a balloon dilation catheter is used, an illuminating guidewire may also be used to provide confirmation of the proper positioning of the catheter before inflating the balloon. Such a guidewire may

be positioned within the target area and then illuminated, with light projecting from the distal end of the guidewire. This light may illuminate the adjacent tissue and thus be visible to the naked eye from outside the patient through transcutaneous illumination. For instance, when the distal end is positioned in the maxillary sinus, the light may be visible through the patient's cheek. Using such external visualization to confirm the position of the guidewire, the balloon may then be advanced distally along the guidewire into position at the dilation site. Such an illuminating guidewire may be provided in accordance with the teachings of U.S. Pub. No. 2012/0078118, entitled "Sinus Illumination Lightwire Device," published March 29, 2012, the disclosure of which is incorporated by reference herein. An example of such an illuminating guidewire is the Relieva Luma Sentry™ Sinus Illumination System by Acclarent, Inc. of Menlo Park, California.

[0006] While several instruments and procedures have been made and used for treatment of anatomical passageways in a patient, it is believed that no one prior to the inventors has made or used the invention described in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] While the specification concludes with claims which particularly point out and distinctly claim the invention, it is believed the present invention will be better understood from the following description of certain examples taken in conjunction with the accompanying drawings, in which like reference numerals identify the same elements and in which:

[0008] FIG. 1 depicts a left sagittal cross-sectional view of a portion of a human head, showing paranasal sinus structures;

[0009] FIG. 2 depicts an anterior coronal cross-sectional view of a portion of a human head, showing paranasal sinus structures;

[00010] FIG. 3 depicts a superior axial cross-sectional view of a portion of a human head,

showing paranasal sinus structures;

[00011] FIG. 4 depicts an enlarged left sagittal cross-sectional view of a portion of a human head, showing an implant positioned in the ethmoid bulla;

[00012] FIG. 5 depicts an enlarged anterior coronal cross-sectional view of a portion of a human head, showing the implant of FIG. 4 positioned in the ethmoid bulla;

[00013] FIG. 6A depicts a side elevational view of the implant of FIG. 4, with a portion of the ethmoid bulla in cross-section, and with the implant in a relaxed state;

[00014] FIG. 6B depicts a side elevational view of the implant of FIG. 4, with a portion of the ethmoid bulla in cross-section, and with the implant in an actuated state;

[00015] FIG. 7 depicts a perspective view of another exemplary sinus implant;

[00016] FIG. 8 depicts another perspective view of the implant of FIG. 7;

[00017] FIG. 9 depicts a side elevational view of the implant of FIG. 7;

[00018] FIG. 10 depicts a cross-sectional view of the implant of FIG. 7 positioned in a sinus wall;

[00019] FIG. 11 depicts a perspective view of another exemplary sinus implant;

[00020] FIG. 12 depicts a cross-sectional view of the implant of FIG. 11;

[00021] FIG. 13 depicts a perspective view of another exemplary sinus implant;

[00022] FIG. 14 depicts an enlarged anterior coronal cross-sectional view of a portion of a human head, showing the implant of FIG. 13 positioned in the middle meatus with dendrites extending into the frontal recess, the maxillary sinus, and the anterior middle meatus;

[00023] FIG. 15 depicts an enlarged superior axial cross-sectional view of a portion of a

human head, showing the implant of FIG. 13 positioned in the middle meatus with dendrites extending into the frontal recess, the maxillary sinus, and the anterior middle meatus, with an anchor member positioned in the ethmoid bulla;

[00024] FIG. 16 depicts a rear elevational view of an exemplary implantable sinus port;

[00025] FIG. 17A depicts a cross-sectional view of the port of FIG. 16, taken along line 17-17 of FIG. 16, implanted in a sinus wall with the port in a relaxed state; and

[00026] FIG. 17B depicts a cross-sectional view of the port of FIG. 16, taken along line 17-17 of FIG. 16, with retention features of the port being actuated to release the port from the sinus wall.

[00027] The drawings are not intended to be limiting in any way, and it is contemplated that various embodiments of the invention may be carried out in a variety of other ways, including those not necessarily depicted in the drawings. The accompanying drawings incorporated in and forming a part of the specification illustrate several aspects of the present invention, and together with the description serve to explain the principles of the invention; it being understood, however, that this invention is not limited to the precise arrangements shown.

DETAILED DESCRIPTION

[00028] The following description of certain examples of the technology should not be used to limit its scope. Other examples, features, aspects, embodiments, and advantages of the technology will become apparent to those skilled in the art from the following description, which is by way of illustration, one of the best modes contemplated for carrying out the technology. As will be realized, the technology described herein is capable of other different and obvious aspects, all without departing from the technology. Accordingly, the drawings and descriptions should be regarded as illustrative in nature and not restrictive.

[00029] It will be appreciated that the terms "proximal" and "distal" are used herein with

reference to a clinician gripping a handpiece assembly. Thus, an end effector is distal with respect to the more proximal handpiece assembly. It will be further appreciated that, for convenience and clarity, spatial terms such as "top" and "bottom" also are used herein with respect to the clinician gripping the handpiece assembly. However, surgical instruments are used in many orientations and positions, and these terms are not intended to be limiting and absolute.

[00030] It is further understood that any one or more of the teachings, expressions, versions, examples, etc. described herein may be combined with any one or more of the other teachings, expressions, versions, examples, etc. that are described herein. The following-described teachings, expressions, versions, examples, etc. should therefore not be viewed in isolation relative to each other. Various suitable ways in which the teachings herein may be combined will be readily apparent to those of ordinary skill in the art in view of the teachings herein. Such modifications and variations are intended to be included within the scope of the claims.

[00031] I. Overview of Sinus System

[00032] FIGS. 1-3 show views of various sinus structures in a portion of a human head. In particular, FIG. 1 shows a left sagittal cross-sectional view of a portion of a human head. FIG. 2 shows a coronal cross-sectional view of the human head, looking posteriorly from an anterior perspective. FIG. 3 shows an axial cross-sectional view of the human head, looking inferiorly from a superior perspective. As best seen in FIG. 1, the human head includes a sphenoid sinus (SS), ethmoid sinus (ES), frontal sinus (FS), middle turbinate (MT), middle turbinate horizontal basal lamella (MThBL), middle turbinate vertical basal lamella (MTvBL), inferior turbinate (IT), uncinate process (UP), and lateral nasal wall (LNW). As best seen in FIG. 2, the human head also includes a frontal recess (FR), an ethmoid infundibulum (EI), a maxillary sinus (MS), a middle meatus (MM), and a nasal septum (NS). The frontal recess (FR) is inferior to the frontal sinus (FS). The ethmoid infundibulum (EI) is defined by the ethmoid bulla (EB) and the uncinate process (UP). The ethmoid infundibulum (EI) leads to the maxillary sinus (MS). The middle meatus

(MM) is a passageway defined as the space lateral to the middle turbinate (MT).

[00033] The ethmoid sinus (ES) comprises a set of sinus cells (EAC) that may be categorized as anterior ethmoid sinus (AES) cells and posterior ethmoid sinus (PES) cells. The ethmoid bulla (EB), which is the primary anterior ethmoid air cell (EAC), is generally inferior and anterior to the other anterior ethmoid sinus (AES) cells (EACs) and posterior ethmoid sinus (PES) cells (EACs). The posterior wall of the ethmoid bulla (EB) and the middle turbinate vertical basal lamella (MTvBL) together define a retrobullar space (RBS). It should be understood that anatomical variation in the human is such that this retrobullar space (RBS) may or may not be present in a given individual.

[00034] The ethmoid sinus (ES) includes ostia (not shown) for providing fluid communication to and from the cells of the ethmoid sinus (ES) and the nasal cavity. For instance, ostia may provide fluid paths for cells (EACs) within the anterior ethmoid sinus (AES), cells (EACs) within the posterior ethmoid sinus (PES), and the ethmoid bulla (EB). In some instances, suprabullar cells (EACs) of the ethmoid sinus (ES) drain into the ethmoid bulla (EB) cell (EAC). Some suprabullar cells (EACs) may drain directly into thc rctrobullar spacc (RBS). Thc cthmoid bulla (EB) may itsclf providc fluid communication with the nasal cavity via one or more ostia, such that the ethmoid bulla (EB) may provide a fluid communication path between the other ethmoid sinus (ES) cells (EACs) (that drain into the ethmoid bulla (EB) cell (EAC)) and the nasal cavity. For instance, the ethmoid bulla (EB) may provide fluid communication through an ostium at the retrobullar space (RBS). The fluid communication paths provided by ostia may allow the entry of air and liquids (e.g., medications); while also allowing drainage of mucus. In some instances, the ostia may become blocked, may become functionally closed due to mucosal thickening, or may otherwise not provide sufficient fluid communication. In addition or in the alternative, the configuration of the retrobullar space (RBS) may impede flow through the ostium of the ethmoid bulla (EB).

[00035] The following examples of fluid delivery implants and port implants are described mainly in the context of the ethmoid bulla (EB). However, it should be understood that

this context is merely illustrative, and that the below teachings are not limited to the ethmoid bulla (EB) sinus wall. The various fluid delivery implants and port implants described below may alternatively be implanted in other sinus walls, as will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00036] II. Exemplary Fluid Delivery Implants for Sinus Walls

[00037] In some clinical contexts, it may be desirable to deploy a wick or other type of fluid delivery implant in the ethmoid bulla (EB) and/or in other sinus cavities. A fluid delivery implant may promote communication of medical fluids to the mucosa of the ethmoid bulla (EB) through a capillary action. This capillary action may be enhanced by maximizing contact between the wick material and the mucosa in the ethmoid bulla (EB) or other sinus cavity. At least part of the fluid delivery implant may be bioabsorbable and may itself be formed in part by a therapeutic material. The degree to which material used in the implant is hydrophilic or hydrophobic may be manipulated to provide a desired type of fluid transport. By way of example only, fluids that may be communicated by a fluid delivery implant may include saline, a combination of saline and a surfactant, an anti-inflammatory (e.g., mometasone, etc.), an antibiotic, an anti-fungal, anti-microbial, surfactants, and/or various other kinds of fluids/medications, including combinations thereof. Various examples of intrasinus and intersinus fluid delivery implants will be described in greater detail below, while other examples will be apparent to those of ordinary skill in the art in view of the teachings herein. Similarly, various kinds of fluids that may be delivered using the implants described below will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00038] It should be understood that the various fluid delivery implants described below may be deployed in a naturally occurring ostium, in an enlarged natural ostium, and/or in a created ostium. By way of example only, the fluid delivery implants described herein may be deployed in a naturally occurring ostium that has been enlarged in accordance with at least some of the teachings of U.S. Pub. No. 2011/0004057, the disclosure of which is incorporated by reference herein. As another merely illustrative example, the

fluid delivery implants described herein may be deployed in an ostium that has been created in accordance with at least some of the teachings of U.S. Patent App. No. 14/038,867, entitled "Apparatus and Method for Treatment of Ethmoid Sinusitis," filed on September 27, 2013, the disclosure of which is incorporated by reference herein. Furthermore, the fluid delivery implants described herein may be deployed in an ostium that has been first created in accordance with at least some of the teachings of S. Patent App. No. 14/038,867, entitled "Apparatus and Method for Treatment of Ethmoid Sinusitis," filed on September 27, 2013, the disclosure of which is incorporated by reference herein; then enlarged in accordance with at least some of the teachings of U.S. Pub. No. 2011/0004057, the disclosure of which is incorporated by reference herein. Other settings in which the below described fluid delivery implants may be deployed will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00039] A. Exemplary Sinus Wall Implant with Paddle

[00040] FIGS. 4-6B show an exemplary fluid delivery implant (10) positioned in an ethmoid bulla (EB). Implant (10) of this example comprises a retainer body (12), a first flange (14), a second flange (16), a foam member (20), a brace (22), a compression member (24), and a paddle (26). In the present example, body (12) is substantially cylindraceous, while flanges (14, 16) and compression member (24) are disc-shaped. Alternatively, any other suitable configurations may be used. Body (12) defines a passageway (30) extending through the full length of body (12). While a single large passageway (30) is shown, it should be understood that body (12) may instead define several smaller passageways. Body (12) is configured to fit in an opening of the ethmoid bulla (EB), with flanges (14, 16) cooperating to retain body (12) in the opening like a grommet. In the present example, flange (14) is flexible enough to enable flange (14) to pass through the opening without widening the opening; yet rigid enough to substantially maintain the position of body (12) in the opening. Various suitable materials and configurations that may be used to form flange (14) will be apparent to those of ordinary skill in the art in view of the teachings herein. Furthermore, various suitable ways in

which body (12) may be inserted into the opening in the ethmoid bulla (EB) will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00041] Foam member (20) comprises an open cell material that is configured to hold a fluid such as any of the various fluids referred to herein and/or any other suitable fluid as will be apparent to those of ordinary skill in the art in view of the teachings herein. Passageway (30) of body (12) is in fluid communication with foam member (20). Brace (22) extends through foam member (20) and couples compression member (24) with flange (16). Brace (22) divides foam member (20) into an anterior portion (20a) and a posterior portion (20b). In the present example, posterior portion (20b) is covered with a fluid impermeable skin (27), while anterior portion (20a) lacks a skin such that the open cells of anterior portion (20a) are exposed. Brace (22) is flexible and includes several fenestrations (not shown) formed therethrough, allowing fluid to be transferred within foam member (20) across brace (22). Paddle (26) projects from compression member (24). In some variations, brace (22) is substantially rigid but is joined with flange (16) by a living hinge or other flexible feature. Paddle (26) and compression member (24) are both substantially rigid. Brace (22) is resiliently biased to assume a substantially straight configuration, whereby body (12), flanges (14, 16), brace (22), compression member (24), and paddle (26) are aligned along a longitudinal axis (LA_1) as shown in FIG. 6A.

[00042] Implant (10) is implanted at an orientation where inspired air (30) will impose against paddle (26), as shown in FIG. 6B. In particular, paddle (26) presents a broad face that is normal to the main vector of inspiratory air flow, such that inspired air (30) urges paddle (26) posteriorly, deflecting paddle (26) away from the longitudinal axis (LA_1), which causes brace (22) to flex. As brace (22) flexes, compression member (24) compresses a posterior region of foam member (20) against flange (16). This compression of foam member (20) urges fluid out of foam member (20) and through passageway (30) into the cell (EAC) of the ethmoid bulla (EB). Such transport of fluid is provided because posterior portion (20b) is covered in impermeable skin (27) and because posterior portion (20b) is compressed while anterior portion (20a) is expanded.

[00043] In some versions, expired air urges paddle (26) anteriorly, deflecting paddle (26) away from the longitudinal axis (LA_1) in the direction opposite to that shown in FIG. 6B. This may cause compression member (24) to compress an anterior region of foam member (20) against flange (16). This compression of foam member (20) may also urge fluid out of foam member (20). In some other versions, expired air simply urges paddle (26) back to the position shown in FIG. 6A.

[00044] In some variations, foam member (20) is substituted or supplemented with a pump feature that is actuated by deflection of paddle (26) away from the longitudinal axis (LA_1). For instance, repeated deflection of paddle (26) may drive a ratcheting feature that progressively compresses a bellows reservoir, a diaphragm pump, and/or some other kind of pumping feature. Various suitable kinds of pumping features that may be driven by paddle (26) will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00045] It should be understood that implant (10) may be implanted with or without fluid already in foam member (20). Regardless, the physician or patient may add fluid to foam member (20) after implantation using any suitable known nasal fluid administration device or technique (e.g., aerosolized spray, non-aerosolized flush, etc.). Fluids delivered in such a fashion may readily reach foam member (20) and thereby be absorbed by foam member (20) via anterior portion (20a). In some such instances, foam member (20) may need to be replenished with fluid on a periodic basis.

[00046] B. Exemplary Sinus Wall Implant with Port and Wicking Feature

[00047] FIGS. 7-10 show another exemplary implant (100) that may be implanted in a sinus wall (SW). Sinus wall (SW) comprises a thin layer of bone (B) interposed between two layers of tissue (T). To the extent that other depictions of sinus walls in the present drawings do not include depictions of tissue layers, it should be understood that those sinus walls may still in fact include tissue layers surrounding a layer of bone just as depicted in FIG. 10. Implant (100) of this example comprises a porous foam body (110), a non-permeable feature (120), and a port tube (130). Foam body (110) comprises a

proximal portion (112) and a distal wick feature (114). Port tube (130) defines a lumen (132). Non-permeable feature (120) and port tube (130) are coaxially aligned with each other along a common longitudinal axis (LA_2), while wick feature (114) extends obliquely relative to longitudinal axis (LA_2).

[00048] In the present example, foam body (110) is formed of polyvinyl alcohol (PVA) foam. Alternatively, any other suitable materials or combinations of materials may be used. It should also be understood that pores may be formed in foam body (110) using a variety of techniques. By way of example only, pores may be formed through the use of sacrificial material that is dissolved or otherwise removed following the forming of the material of body (110). As another merely illustrative example, pores may be formed by infusing gas into the material of body (110) as it is formed, or by including chemical components that combine in a gas-forming reaction as the material of body (110) is formed. Other suitable ways in which pores may be formed will be apparent to those of ordinary skill in the art in view of the teachings herein. It should also be understood that body (110) may include capillaries and/or microcapillaries.

[00049] Body (110) and non-permeable feature (120) are configured to fit in an opening of a sinus wall (SW) (e.g., the antero-inferior wall of the ethmoid bulla (EB)). FIGS. 7-10 show non-permeable feature (120) as defining an enlarged proximal region (122), an enlarged distal region (124), and a recess (126) positioned longitudinally between regions (122, 124). In some versions, non-permeable feature (120) is preformed to have this configuration, such that enlarged regions (122, 124) cooperate to retain body (110) and non-permeable feature (120) in the opening. Non-permeable feature (120) may thus be configured as a resilient grommet. In the present example, non-permeable feature (120) is flexible enough to enable non-permeable feature (120) to pass through the opening without widening the opening; yet rigid enough to substantially maintain the position of body (110) and non-permeable feature (120) in the opening.

[00050] In some other versions, non-permeable feature (120), is fully compliant, has a generally cylindraceous preformed configuration, or has some other preformed

configuration; and non-permeable feature (120) assumes the configuration shown in FIGS. 7-10 after implant (100) is positioned in an opening formed in a sinus wall (SW). In other words, the edge of the sinus wall (SW) that defines the opening in which implant is inserted (100) may cause non-permeable feature (120) to deform to assume the shape shown in FIGS. 7-10. As another merely illustrative example, non-permeable feature (120) may simply comprise a fully compliant sleeve, such that an outward resilient bias of body (110) effectively creates enlarged regions (122, 124) when implant (100) is positioned in an opening of a sinus wall (SW) that has a diameter smaller than an expanded diameter of body (110). A relatively smaller diameter of an opening formed in the sinus wall (SW) may thus deform non-permeable feature (120) and body (110) to the configuration shown in FIGS. 7-10, such that an outward bias of body (110) creates friction to hold implant (100) in place in the sinus wall (SW). In addition or in the alternative, distal wick feature (114) may provide retention of body (110) relative to the sinus wall (SW). Other suitable ways in which implant (100) may be retained in the sinus wall (SW) will be apparent to those of ordinary skill in the art in view of the teachings herein. Furthermore, various suitable ways in which body (110), non-permeable feature (120), and distal wick feature (114) may be inserted into the opening in the sinus wall (SW) will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00051] It should be understood that non-permeable feature (120) is formed of a material that is fluid impermeable, such that fluid does not pass from body (110) to the sinus wall (SW) at (or immediately adjacent to) the opening formed in the sinus wall (SW). Various suitable materials and configurations that may be used to form non-permeable feature (120) will be apparent to those of ordinary skill in the art in view of the teachings herein. By way of example only, non-permeable feature (120) may comprise a non-permeable sleeve disposed about body (110), a non-permeable skin or film deposited on body (110), a non-permeable coating provided on body (110), a region of body (110) where pores are closed or filled to render that region of body (110) impermeable by fluid, etc. In some variations, body (110) includes additional non-permeable features that prevent the

communication of fluid out of body (110) along certain regions of the length of body (110). Such additional non-permeable features may be positioned distal to and/or proximal to non-permeable feature (120). Even when additional non-permeable features are included, the distal end of wicking feature (114) remains exposed such that body (110) may emit fluid at the distal end of wicking feature (114). Other suitable ways in which non-permeable feature (120) may be formed will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00052] As shown in FIG. 10, implant (100) is implanted such that the sinus wall (SW) is positioned in recess (126) of non-permeable feature (120) and such that wick feature (114) is in contact with a layer of mucosal tissue (T) in the sinus cavity (SC). The oblique orientation of wick feature (114) may promote contact between wick feature (114) and the mucosal tissue (T), reducing chances of wick feature (114) being impeded by internal partitions within the sinus cavity (SC). It should be understood that contact between wick feature (114) and the mucosal tissue (T) of sinus cavity (SC) may promote a capillary action through body (110) such that fluid reaching proximal end (112) of body (110) is wicked through body (110), thereby reaching the mucosal tissue (T) of sinus cavity (SC) via wick feature (114). It should also be understood that the non-permeability of non-permeable feature (120) will prevent the fluid from being communicated directly to tissue (T) at (or adjacent to) the opening formed in the sinus wall (SW). Non-permeable feature (120) thus prevents the formation of a fluid short circuit between tissue (T) and body (110) upstream of wick feature (114). Proximal end (112) of body (110) is positioned exterior to the sinus wall (SW) and sinus cavity (SC). Proximal end (112) of body (110) is thus exposed within the nasal cavity, such that proximal end (112) may receive fluid by a physician or the patient using any suitable known nasal fluid administration device or technique (e.g., aerosolized spray, non-aerosolized flush, etc.). The physician or patient may administer fluid to body (110) to at least a point where body (110) becomes fully saturated. In some instances, the physician or patient continues to deliver fluid to body (110) after body (110) has become saturated,

to further ensure further delivery of the fluid to the mucosal tissue (T) of sinus cavity (SC) via wick feature (114).

[00053] Port tube (130) may be formed of a bioresorbable material or a non-bioresorbable material. By way of example only, port tube (130) may comprise polydimethylsiloxane, polyurethane, polydiaxanone, polylactic acid, polyglycolic acid, other biocompatible materials, or combinations thereof. Lumen (132) of port tube (130) is configured to provide ventilation of sinus cavity (SC) and to provide a pathway for drainage of fluid (e.g., excess mucus) from sinus cavity (SC). It should therefore be understood that implant (100) of this example provides a combination of fluid delivery (through wicking feature (114)), ventilation (through lumen (132)), and drainage (through lumen (132)) for a sinus cavity (SC). It should also be understood that drainage via lumen (132) may be encouraged by gravity (e.g., when the patient is lying down) and/or mucociliary transport.

[00054] FIGS. 11-12 show an exemplary variation of implant (100). In particular, FIGS. 11-12 show an exemplary implant (200) that comprises a porous foam body (210), an outer non-permeable feature (220), and a port tube (230). Non-permeable feature (220) and port tube (230) are substantially identical to non-permeable feature (120) and port tube (130) described above. Body (210) is substantially similar to body (110) described above, except that body (210) of this example include three wick features (214). Wick features (214) all extend obliquely relative to a longitudinal axis (LA_3) shared by non-permeable feature (120) and port tube (130). Wick features (214) are also equidistantly spaced about longitudinal axis (LA_3). It should be understood that having a plurality of wick features (214) may further enhance the communication of fluid from body (210) to the mucosal tissue (T) of sinus cavity (SC) by providing additional routes for capillary action. It should also be understood that any other suitable number of wick features (214) may be provided. Still other suitable variations of implants (100, 200) will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00055] C. Exemplary Sinus Wall Implant with Dendrites

[00056] FIGS. 13-15 show an exemplary implant (300) that comprises a porous foam body (310), an anchor feature (320), a first dendrite (330), a second dendrite (340), and a third dendrite (350). Anchor feature (320) includes a body (322) and a retention flange (324). Body (322) is configured to fit in an opening of the ethmoid bulla (EB), with flange (324) being configured to retain body (322) in the opening. Body (322) includes a non-permeable material such that fluid does not leak through the exterior of body. In the present example, flange (324) is flexible enough to enable flange (324) to pass through the opening without widening the opening; yet rigid enough to substantially maintain the position of body (322) in the opening. Various suitable materials and configurations that may be used to form (324) will be apparent to those of ordinary skill in the art in view of the teachings herein. Furthermore, various suitable ways in which body (324) may be inserted into the opening in the ethmoid bulla (EB) will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00057] Body (310) and dendrites (330, 340, 350) are formed of an open cellular porous material, such as polyvinyl alcohol (PVA) foam. Each dendrite (330, 340, 350) includes a respective free end (332, 342, 352) and a non-permeable skin (334, 344, 354) extending along part of the length of dendrite (330, 340, 350). When body (310) and dendrites (330, 340, 350) are saturated with fluid, skin (334, 344, 354) prevents dendrites (330, 340, 350) from emitting the fluid along the regions that are covered by skins (334, 344, 354). However, free ends (332, 342, 352) are exposed relative to skins (334, 344, 354), such that dendrites (330, 340, 350) are able to emit fluid at free ends (332, 342, 352). Body (310) is also exposed relative to skins (334, 344, 354), such that body (310) is capable of absorbing incident fluids. In particular, body (310) serves as a fluid hub in the present example, with fluid that is absorbed at body (310) being delivered to tissue through free ends (332, 342, 352) of dendrites (330, 340, 350).

[00058] In an exemplary use, body (310) is implanted in the middle meatus (MM), as shown in FIGS. 14-15. Anchor feature (320) is secured to the ethmoid bulla (EB). First dendrite (330) is positioned such that free end (332) is located in the frontal recess (FR), contacting tissue therein. Second dendrite (340) is routed through the ethmoid

infundibulum (EI) and maxillary ostium such that free end (342) is located in the maxillary sinus (MS), contacting tissue therein. Third dendrite (350) is positioned such that free end (352) is located in the anterior middle meatus (MM). It should be understood that dendrites (330, 340, 360) may be positioned in any suitable order using any suitable instruments and techniques. It should also be understood that anchor feature (320) may be secured to the ethmoid bulla (EB) before or after any or all of dendrites (330, 340, 360) are positioned. Moreover, implant (300) may be anchored in place in some other fashion.

[00059] Once implant (300) is positioned, the physician or patient may administer fluid within the nasal cavity using any suitable known nasal fluid administration device or technique (e.g., aerosolized spray, non-aerosolized flush, etc.). The fluid will eventually reach body (310) which will absorb the fluid. As body (310) becomes saturated, the fluid will wick through dendrites (330, 340, 360) and reach the frontal recess (FR), maxillary sinus (MS), and anterior middle meatus (MM) through capillary action as described above. When saturated, free ends (332, 342, 352) may expand to increase surface area contact with adjacent mucosal tissue. In some instances, dendrite (350) serves as a fluid input for implant (300), such that fluid introduced to the nasal cavity is first incident on free end (352), where it is drawn in and eventually wicked through body (310) and the other dendrites (340, 350) to reach the frontal recess (FR) and maxillary sinus (MS). Thus, in some alternative versions, body (310) is covered with a skin such that free ends (332, 342, 352) are the only portions of the porous material that are exposed. Still other variations of implant (300) will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00060] III. Exemplary Removable Port Implant for Sinus Wall

[00061] As noted above, naturally occurring and/or surgically formed ostia may provide a path for fluid communication between a sinus cavity and the nasal cavity, allowing air and liquids (e.g., medications, etc.) to enter the sinus cavity; and mucus to exit the sinus cavity. In some instances, the ostia may become blocked, may become functionally

closed due to mucosal thickening, or may otherwise not provide sufficient fluid communication. A port may be implanted in order to maintain patency through an ostium. Some examples of sinus ostium ports are described above. Additional examples of sinus ostium ports are described in U.S. Patent App. No. 14/038,867, entitled "Apparatus and Method for Treatment of Ethmoid Sinusitis," filed on September 27, 2013, the disclosure of which is incorporated by reference herein. In some instances, it may be desirable to provide one or more features that enable a sinus ostium port to the removed from the patient with relative ease, without imposing trauma on the sinus wall or adjacent structures. One merely illustrative example of such a port feature will be described in greater detail below, while other examples will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00062] FIGS. 16-17B show an exemplary port (400) that includes a cylindraceous body (402), an annular flange (404), and a pair of retention wings (410). Flange (404) is resiliently biased to extend along a plane that is perpendicular to the longitudinal axis of cylindraceous body (402). Each retention wing (410) includes a strut portion (412) pivotally coupled with flange (404) by a respective living hinge (420). The material used to form living hinges (420) may have a lower flexural modulus (and be fused or otherwise molded into the remaining structure that is formed from a material of a higher flexural modulus); or may have a thinner wall and/or narrower width than strut portions (412). Port (400) defines a lumen (430) extending along the length of body (402). Each retention wing (410) includes a release element (414) extending through lumen (430). Release elements (414) extend proximal to annular flange (404), such that release elements (414) may be readily grasped from a position proximal to annular flange (404). While only two retention wings (410) are shown in the present example, it should be understood that any other suitable number of retention wings (410) may be used.

[00063] As shown in FIG. 17, port (400) may be implanted in an ostium formed in a sinus wall (SW). The ostium may be a naturally occurring ostium, a naturally occurring ostium that has been enlarged (e.g., using a balloon dilation device, etc.), or an ostium formed by an instrument. Port (400) is positioned such that retention wings (410) are located in the

sinus cavity while flange (404) is located in the nasal cavity, outside the sinus cavity. Various suitable ways in which port (400) may be implanted at such positioning will be apparent to those of ordinary skill in the art in view of the teachings herein. Living hinges (420) are resiliently biased to hold retention wings (410) in the position shown in FIG. 17A. In this grommet-like configuration, wings (410) and flange (414) cooperate to hold port (400) in place in the sinus wall (SW). In particular, flange (414) prevents port (400) from migrating into the sinus cavity while retention wings (410) prevent port (400) from migrating into the nasal cavity. Lumen (430) maintains patency through the ostium in the sinus wall (SW). It should be understood that the deformability of living hinges (420), retention wings (410) and/or other features of port (400) may be varied based on wall thickness, member width, member material, and/or other factors, including combinations thereof.

[00064] In order to remove port (400) from the sinus wall (SW), the operator may simply grasp release elements (414) (e.g., using forceps, etc.), then pull release elements (414) proximally. The rigidity of strut portions (412) and the flexibility of living hinges cause retention wings (410) to pivot inwardly in response to proximal pulling on release elements (414), as shown in FIG. 17B. When pivoted inwardly, retention wings (410) are substantially aligned with (or deflected inwardly relative to) the wall of body (402), such that the distance between the outermost surfaces of strut portions (412) is less than the diameter of the ostium in the sinus wall (SW). At this stage, the operator may thus pull further proximally on port (400) to remove port from the sinus wall (SW). In some instances, this may entail simply pulling further proximally on release elements (414).

[00065] In the present example, port (400) is formed from a non-bioresorbable material (e.g., silicone, etc.). Thus, port (400) will remain in the sinus wall (SW) until it is removed. In some other versions, at least a portion of port (400) may be formed of a bioresorbable or biodegradable material, such that port (400) may eventually dislodge or disappear from the sinus wall (SW) even if it is not actively removed.

[00066] IV. Exemplary Combinations

[00067] The following examples relate to various non-exhaustive ways in which the teachings herein may be combined or applied. It should be understood that the following examples are not intended to restrict the coverage of any claims that may be presented at any time in this application or in subsequent filings of this application. No disclaimer is intended. The following examples are being provided for nothing more than merely illustrative purposes. It is contemplated that the various teachings herein may be arranged and applied in numerous other ways. It is also contemplated that some variations may omit certain features referred to in the below examples. Therefore, none of the aspects or features referred to below should be deemed critical unless otherwise explicitly indicated as such at a later date by the inventors or by a successor in interest to the inventors. If any claims are presented in this application or in subsequent filings related to this application that include additional features beyond those referred to below, those additional features shall not be presumed to have been added for any reason relating to patentability.

[00068] Example 1

[00069] An apparatus, comprising: (a) a retainer body, wherein the retainer body is configured to fit in an opening in a sinus wall; (b) an absorbent member; (c) a compression feature coupled with the body, wherein the compression feature is configured to selectively compress at least a portion of the absorbent member to thereby drive fluid from the absorbent member.

[00070] Example 2

[00071] The apparatus of Example 1, wherein the retainer body includes a first flange and a second flange.

[00072] Example 3

[00073] The apparatus of Example 2, wherein the first flange and the second flange are spaced to receive the sinus wall between the first flange and the second flange.

[00074] Example 4

[00075] The apparatus of any of the preceding Examples 1 through 3, wherein the retainer body has a cylindraceous configuration.

[00076] Example 5

[00077] The apparatus of any of the preceding examples 1 through 4, wherein the retainer body defines a fluid passageway.

[00078] Example 6

[00079] The apparatus of Example 5, wherein the compression feature is configured to selectively compress at least a portion of the absorbent member to thereby drive fluid from the absorbent member through the fluid passageway of the body.

[00080] Example 7

[00081] The apparatus of any of the preceding Examples 1 through 6, wherein the compression feature has a disc shape.

[00082] Example 8

[00083] The apparatus of any of the preceding Examples 1 through 7, wherein the absorbent member is captured between the compression feature and the retainer body.

[00084] Example 9

[00085] The apparatus of any of the preceding Examples 1 through 8, further comprising a brace coupling the compression feature with the retainer body.

[00086] Example 10

[00087] The apparatus of Example 9, wherein the brace is flexible, such that the brace enables deflection of the compression feature away from a longitudinal axis extending along a center of the retainer body.

[00088] Example 11

[00089] The apparatus of any of the preceding Examples 1 through 10, further comprising an extension projecting away from the compression feature, wherein the extension is configured to drive the compression feature away from a longitudinal axis extending along a center of the retainer body in response to a lateral force exerted on the extension.

[00090] Example 12

[00091] The apparatus of Example 11, wherein the extension comprises a paddle.

[00092] Example 13

[00093] The apparatus of Example 12, wherein the extension is configured to drive the compression feature away from a longitudinal axis extending along a center of the retainer body in response to inspired air impinging against an anterior face of the extension.

[00094] Example 14

[00095] The apparatus of any of the preceding Examples 1 through 13, wherein absorbent member comprises a foam structure.

[00096] Example 15

[00097] The apparatus of any of the preceding Examples 1 through 14, wherein the absorbent member comprises an exposed portion and a covered portion.

[00098] Example 16

[00099] The apparatus of Example 15, further comprising a non-permeable skin covering the covered portion of the absorbent member.

[000100] Example 17

[000101] The apparatus of Example 15, wherein the exposed portion is associated with an anterior side of the absorbent member.

[000102] Example 18

[000103] The apparatus of Example 15, wherein the covered portion is associated with a posterior side of the absorbent member.

[000104] Example 19

[000105] The apparatus of any of the preceding Examples 1 through 18, wherein the absorbent member is saturated with a medical liquid.

[000106] Example 20

[000107] A method of treating a sinus using an implant, wherein the implant includes a retainer body, an absorbent member, and a compression feature, wherein the compression feature is configured to selectively compress at least a portion of the absorbent member to thereby drive fluid from the absorbent member, wherein the compression feature comprises an impingement face, the method comprising: (a) positioning the retainer body in an opening in a sinus wall; and (b) orienting the retainer body such that the impingement face is facing anteriorly such that inspired air will impinge against the impingement face, wherein the compression feature is configured to drive fluid from the absorbent member in response to inspired air impinging against the impingement face.

[000108] Example 21

[000109] The method of Example 20, wherein the sinus wall comprises an ethmoid bulla sinus wall.

[000110] Example 22

[000111] The method of any of the preceding Examples 20 through 21, wherein the opening comprises a naturally occurring opening in the sinus wall.

[000112] Example 23

[000113] The method of Example 22, further comprising enlarging the naturally occurring opening in the sinus wall.

[000114] Example 24

[000115] The method of Example 23, wherein the act of enlarging comprises inflating a dilator in the naturally occurring opening.

[000116] Example 25

[000117] The method of Example 20, further comprising forming the opening in the sinus wall.

[000118] Example 26

[000119] An apparatus, comprising: (a) an absorbent body, wherein the absorbent body comprises a wicking feature; (b) a non-permeable feature coupled with the absorbent body, wherein the non-permeable feature and at least a portion of the absorbent body are configured to fit in an opening in a sinus wall; and (c) a port feature extending through the absorbent body, wherein the port feature defines a lumen.

[000120] Example 27

[000121] The apparatus of Example 26, wherein the port feature comprises a tubular structure.

[000122] Example 28

[000123] The apparatus of Example 27, wherein the tubular structure defines a longitudinal axis.

[000124] Example 29

[000125] The apparatus of Example 28, wherein the wicking feature extends obliquely relative to the longitudinal axis.

[000126] Example 30

[000127] The apparatus of any of the preceding Examples 26 through 29, wherein the wicking feature is configured to contact tissue inside a sinus cavity while the non-permeable feature is positioned in an opening formed in the wall of the sinus cavity.

[000128] Example 31

[000129] The apparatus of any of the preceding Examples 26 through 30, wherein the non-permeable feature has a grommet configuration.

[000130] Example 32

[000131] The apparatus of any of the preceding Examples 26 through 31, wherein the non-permeable feature and the port feature are coaxially aligned with each other.

[000132] Example 33

[000133] The apparatus of any of the preceding Examples 26 through 32, wherein the absorbent body further comprises a plurality of wicking features.

[000134] Example 34

[000135] The apparatus of Example 33, wherein the wicking features extend outwardly.

[000136] Example 35

[000137] The apparatus of any of the preceding Examples 26 through 34, wherein the absorbent body comprises polyvinyl alcohol foam.

[000138] Example 36

[000139] The apparatus of any of the preceding Examples 26 through 35, wherein the absorbent body passes through the non-permeable feature.

[000140] Example 37

[000141] The apparatus of Example 36, wherein the non-permeable feature comprises a sleeve, skin, film, or coating positioned about the absorbent body.

[000142] Example 38

[000143] The apparatus of any of the preceding Examples 26 through 37, wherein the absorbent body is configured to deliver fluid from a location in the nasal cavity to

mucosal tissue in a sinus cavity defined by the sinus wall, through a capillary action provided by the wicking feature.

[000144] Example 39

[000145] The apparatus of any of the preceding Examples 26 through 38, wherein the lumen of the port feature is configured to provide a path for ingress of air into a sinus cavity defined by the sinus wall and egress of mucus from the sinus cavity defined by the sinus wall.

[000146] Example 40

[000147] A method of treating a sinus using an implant, wherein the implant includes an absorbent body, a non-permeable feature, and a port feature, wherein the absorbent body comprises a wicking feature, wherein the wicking feature extends obliquely relative to the port feature, the method comprising: (a) positioning the non-permeable feature in an opening in a sinus wall; and (b) orienting the absorbent body such that the wicking feature is in contact with mucosal tissue in a sinus cavity defined by the sinus wall, wherein a proximal portion of the absorbent body is positioned outside the sinus wall.

[000148] Example 41

[000149] The method of Example 40, wherein the sinus wall comprises an ethmoid bulla sinus wall.

[000150] Example 42

[000151] The method of any of the preceding Examples 40 through 41, wherein the opening comprises a naturally occurring opening in the sinus wall.

[000152] Example 43

[000153] The method of Example 42, further comprising enlarging the naturally occurring opening in the sinus wall.

[000154] Example 44

[000155] The method of Example 43, wherein the act of enlarging comprises inflating a dilator in the naturally occurring opening.

[000156] Example 45

[000157] The method of any of the preceding Examples 40 through 41, further comprising forming the opening in the sinus wall.

[000158] Example 46

[000159] The method of any of the preceding Examples 40 through 45, further comprising administering a fluid to the proximal portion of the absorbent body, wherein the wicking feature is configured to communicate the administered fluid to the mucosal tissue through a capillary action.

[000160] Example 47

[000161] An apparatus, comprising (a) an absorbent body; (b) a non-permeable feature coupled with the absorbent body, wherein the non-permeable feature is configured to fit in an opening in a sinus wall; and (c) a plurality of extensions extending outwardly from the absorbent body, wherein the extensions are configured to wick fluid from the absorbent body along the lengths of the extensions.

[000162] Example 48

[000163] The apparatus of Example 47, wherein each extension includes a respective covered portion and exposed portion.

[000164] Example 49

[000165] The apparatus of Example 48, further comprising one or more skins covering the covered portions of the extensions.

[000166] Example 50

[000167] The apparatus of Example 49, wherein the one or more skins are formed of a non permeable material.

[000168] Example 51

[000169] The apparatus of any one of the preceding Examples 48 through 50, wherein the exposed portions are located at free ends of the extensions.

[000170] Example 52

[000171] The apparatus of any one of the preceding Examples 47 through 51, wherein absorbent body is sized and configured to fit in a middle meatus of a nasal cavity.

[000172] Example 53

[000173] The apparatus of Example 52, wherein a first extension of the plurality of extensions has a free end and a length, wherein the length is configured to enable placement of the free end in a frontal recess of the nasal cavity while the absorbent body is positioned in the middle meatus of the nasal cavity.

[000174] Example 54

[000175] The apparatus of Example 52, wherein a first extension of the plurality of extensions has a free end and a length, wherein the length is configured to enable placement of the free end in a maxillary sinus while the absorbent body is positioned in the middle meatus of the nasal cavity.

[000176] Example 55

[000177] The apparatus of Example 52, wherein a first extension of the plurality of extensions has a free end and a length, wherein the length is configured to enable placement of the free end in an anterior region of the middle meatus while the absorbent body is positioned in the middle meatus of the nasal cavity.

[000178] Example 56

[000179] The apparatus of any one of the preceding Examples 47 through 55, wherein the retention feature comprises a cylindraceous body.

[000180] Example 57

[000181] The apparatus of any one of the preceding Examples 47 through 56, wherein the retention feature comprises a flange configured to fit in a sinus cavity.

[000182] Example 58

[000183] A method of treating a sinus using an implant, wherein the implant includes an absorbent body, a retention feature, and a plurality of extensions extending outwardly from the absorbent body, wherein the extensions are configured to wick fluid from the absorbent body along the lengths of the extensions, the method comprising: (a) positioning the absorbent body in a first region of the nasal cavity; (b) positioning a first extension of the plurality of extensions in a second region of the nasal cavity; and (c) orienting a second extension of the plurality of extensions in a third region of the nasal cavity.

[000184] Example 59

[000185] The method of Example 58, wherein the first region comprises a middle meatus.

[000186] Example 60

[000187] The method of Example 59, further comprising positioning a third extension of the plurality of extensions in an anterior region of the middle meatus.

[000188] Example 61

[000189] The method of Example 60, further comprising administering a fluid to the third extension, wherein the first and second extensions are configured to communicate the administered fluid to mucosal tissue in the second and third region of the nasal cavity through a capillary action.

[000190] Example 62

[000179] The apparatus of any one of the preceding Examples 47 through 55, wherein the retention feature comprises a cylindraceous body.

[000180] Example 57

[000181] The apparatus of any one of the preceding Examples 47 through 56, wherein the retention feature comprises a flange configured to fit in a sinus cavity.

[000182] Example 58

[000183] A method of treating a sinus using an implant, wherein the implant includes an absorbent body, a retention feature, and a plurality of extensions extending outwardly from the absorbent body, wherein the extensions are configured to wick fluid from the absorbent body along the lengths of the extensions, the method comprising: (a) positioning the absorbent body in a first region of the nasal cavity; (b) positioning a first extension of the plurality of extensions in a second region of the nasal cavity; and (c) orienting a second extension of the plurality of extensions in a third region of the nasal cavity.

[000184] Example 59

[000185] The method of Example 58, wherein the first region comprises a middle meatus.

[000186] Example 60

[000187] The method of Example 59, further comprising positioning a third extension of the plurality of extensions in an anterior region of the middle meatus.

[000188] Example 61

[000189] The method of Example 60, further comprising administering a fluid to the third extension, wherein the first and second extensions are configured to communicate the administered fluid to mucosal tissue in the second and third region of the nasal cavity through a capillary action.

[000190] Example 62

[000191] The method of any one of the preceding Examples 58 through 61, wherein the second region comprises a frontal recess.

[000192] Example 63

[000193] The method of any one of the preceding Examples 58 through 62, wherein the third region comprises a maxillary sinus.

[000194] Example 64

[000195] The method of any one of the preceding Examples 58 through 63, further comprising securing the retention feature to a region of the ethmoid bulla.

[000196] Example 65

[000197] An apparatus, comprising: (a) a port body defining a longitudinal axis and a lumen, wherein the port body is configured to fit in an opening formed through a sinus wall; (b) a first retaining feature located at a proximal end of the port body; (c) a second retaining feature located at a distal end of the port body; and (d) a release feature operable to selectively deflect the second retaining feature inwardly toward the longitudinal axis defined by the port body.

[000198] Example 66

[000199] The apparatus of Example 65, wherein the lumen extends along the longitudinal axis.

[000200] Example 67

[000201] The apparatus of any of the preceding Examples 65 through 66, wherein the first retaining feature comprises an outwardly extending flange.

[000202] Example 68

[000203] The apparatus of any of the preceding Examples 65 through 67, wherein the second retaining feature comprises at least two wings.

[000204] Example 69

[000205] The apparatus of any of the preceding Examples 65 through 68, wherein the second retaining feature is coupled with the port body by one or more living hinges.

[000206] Example 70

[000207] The apparatus of any of the preceding Examples 65 through 69, wherein the second retaining feature is resiliently biased to extend outwardly relative to the longitudinal axis defined by the port body.

[000208] Example 71

[000209] The apparatus of any of the preceding Examples 65 through 70, wherein the release feature extends through the lumen of the port body.

[000210] Example 72

[000211] The apparatus of any of the preceding Examples 65 through 71, wherein the release feature is accessible from a location proximal to the first retaining feature.

[000212] Example 73

[000213] The apparatus of any of the preceding Examples 65 through 72, wherein the release feature is operable to deflect the second retaining feature inwardly in response to proximal movement of the release feature relative to the port body.

[000214] Example 74

[000215] A method of treating a sinus using an apparatus comprising a port body, a first retaining feature, a second retaining feature, and a release feature, wherein the port body defines a longitudinal axis and a lumen, wherein the first retaining feature is located at a proximal end of the body, wherein the second retaining feature is located at a distal end of the port body, wherein the release feature is feature operable to selectively deflect the second retaining feature inwardly toward the longitudinal axis defined by the port body, the method comprising: (a) passing the second retaining feature through an opening

formed in a sinus wall; and (b) positioning the port body in the opening formed through the sinus wall such that the sinus wall is positioned between the first and second retaining features.

[000216] Example 75

[000217] The method of Example 74, wherein the sinus wall comprises an ethmoid bulla sinus wall.

[000218] Example 76

[000219] The method of any of the preceding Examples 74 through 75, wherein the opening comprises a naturally occurring opening in the sinus wall.

[000220] Example 77

[000221] The method of Example 76, further comprising enlarging the naturally occurring opening in the sinus wall.

[000222] Example 78

[000223] The method of Example 77, wherein the act of enlarging comprises inflating a dilator in the naturally occurring opening.

[000224] Example 79

[000225] The method of any of the preceding Examples 74 through 75, further comprising forming the opening in the sinus wall.

[000226] Example 80

[000227] The method of any of the preceding Examples 74 through 79, wherein the act of passing the second retaining feature through an opening formed in a sinus wall comprises deflecting the second retaining feature inwardly toward the longitudinal axis defined by the port body.

[000228] Example 81

[000229] The method of Example 80, further comprising releasing the second retaining feature to enable the second retaining feature to deflect away from the longitudinal axis defined by the port body.

[000230] Example 82

[000231] The method of any of the preceding Examples 74 through 81, further comprising pulling proximally on the release feature to deflect the second retaining feature toward the longitudinal axis defined by the port body.

[000232] Example 83

[000233] The method of Example 82, wherein the second retaining feature is substantially aligned with the port body in response to the act of pulling proximally on the release feature.

[000234] V. Miscellaneous

[000235] The various devices described herein may be used in various anatomical locations in addition to or in lieu of those locations described herein. By way of example only, the devices described herein may be used in an opening that is surgically formed in a paranasal sinus wall, a naturally occurring opening in a paranasal sinus wall, a naturally occurring opening that has been surgically altered in a paranasal sinus wall, other kinds of drainage passageways or outflow tracts of the various paranasal sinuses, and/or other locations. Various suitable locations in which the devices described herein may be used will be apparent to those of ordinary skill in the art in view of the teachings herein. Similarly, various clinical contexts in which the devices described herein may be used will be apparent to those of ordinary skill in the art in view of the teachings herein.

[000236] It should be understood that any of the examples described herein may include various other features in addition to or in lieu of those described above. By way of example only, any of the examples described herein may also include one or more of the various features disclosed in any of the various references that are incorporated by reference herein.

[000237] It should be understood that any one or more of the teachings, expressions, embodiments, examples, etc. described herein may be combined with any one or more of the other teachings, expressions, embodiments, examples, etc. that are described herein. The above-described teachings, expressions, embodiments, examples, etc. should thcrcforc not bc vicwcd in isolation rclativc to cach othcr. Various suitablc ways in which the teachings herein may be combined will be readily apparent to those of ordinary skill in the art in view of the teachings herein. Such modifications and variations are intended to be included within the scope of the claims.

[000238] It should be appreciated that any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated material does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to thc cxtcnt ncccssary, thc disclosurc as cxplicitly sct forth hcrcin supcrscdcs any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

[000239] Versions described above may be designed to be disposed of after a single use, or they can be designed to be used multiple times. Versions may, in either or both cases, be reconditioned for reuse after at least one use. Reconditioning may include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, some versions of the device may be disassembled, and any number of the particular pieces or parts of the device may be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, some versions of the device may be reassembled for subsequent use either at a reconditioning facility, or by a user immediately prior to a procedure. Those skilled in the art will appreciate that reconditioning of a device may utilize a variety of techniques for disassembly,

cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[000240] By way of example only, versions described herein may be sterilized before and/or after a procedure. In one sterilization technique, the device is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and device may then be placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation may kill bacteria on the device and in the container. The sterilized device may then be stored in the sterile container for later use. A device may also be sterilized using any other technique known in the art, including but not limited to beta or gamma radiation, ethylene oxide, or steam.

[000241] Having shown and described various embodiments of the present invention, further adaptations of the methods and systems described herein may be accomplished by appropriate modifications by one of ordinary skill in the art without departing from the scope of the present invention. Several of such potential modifications have been mentioned, and others will be apparent to those skilled in the art. For instance, the examples, embodiments, geometrics, materials, dimensions, ratios, steps, and the like discussed above are illustrative and are not required. Accordingly, the scope of the present invention should be considered in terms of the following claims and is understood not to be limited to the details of structure and operation shown and described in the specification and drawings.

I/we claim:

1. An apparatus, comprising:
   (a) an absorbent body, wherein the absorbent body comprises a wicking feature;
   (b) a non-permeable feature coupled with the absorbent body, wherein the non-permeable feature and at least a portion of the absorbent body are configured to fit in an opening in a paranasal sinus wall; and
   (c) a port feature extending through the absorbent body, wherein the port feature defines an open lumen, wherein the wicking feature extends outwardly relative to the port feature.

2. The apparatus of claim 1, wherein the port feature comprises a tubular structure.

3. The apparatus of claim 2, wherein the tubular structure defines a longitudinal axis.

4. The apparatus of claim 3, wherein the wicking feature extends obliquely relative to the longitudinal axis.

5. The apparatus of claim 1, wherein the wicking feature is configured and oriented to contact tissue inside a sinus cavity while the non-permeable feature is positioned in an opening formed in the wall of the sinus cavity.

6. The apparatus of claim 1, wherein the non-permeable feature has a grommet configuration.

7. The apparatus of claim 1, wherein the non-permeable feature and the port feature are coaxially aligned with each other.

8. The apparatus of claim 1, wherein the absorbent body further comprises a plurality of wicking features.

9. The apparatus of claim 8, wherein the wicking features extend outwardly.

10. The apparatus of claim 8, wherein the absorbent body comprises:

(i) a proximal region,

(ii) a distal region, and

(iii) an intermediate region between the proximal and distal regions,

wherein the non-permeable feature is located in the intermediate region,

wherein the wicking features are located at the distal region.

11. The apparatus of claim 1, wherein the absorbent body comprises polyvinyl alcohol foam.

12. The apparatus of claim 1, wherein the absorbent body passes through the non-permeable feature such that the non-permeable feature is positioned outside the absorbent body.

13. The apparatus of claim 1, wherein the non-permeable feature comprises a sleeve, skin, film, or coating positioned about the absorbent body.

14. The apparatus of claim 1, wherein the absorbent body is configured to deliver fluid from a location in the nasal cavity to mucosal tissue in a paranasal sinus cavity defined by the paranasal sinus wall, through a capillary action provided by the wicking feature.

15. The apparatus of claim 1, wherein the lumen of the port feature is configured to provide a path for ingress of air into a paranasal sinus cavity defined by the paranasal sinus wall and egress of mucus from the paranasal sinus cavity defined by the paranasal sinus wall.

16. An apparatus, comprising:

(a) an absorbent body, wherein the absorbent body comprises:

(i) a proximal region,

(ii) a distal region,

(iii) an intermediate region located between the proximal region and the distal region, and

(iv) a wicking feature, wherein the wicking feature extends outwardly from the distal region;

(b) a non-permeable feature coupled with the absorbent body, wherein the non-permeable feature is positioned at the intermediate region of the absorbent body, wherein the non-permeable feature and at least a portion of the absorbent body are configured to fit in an opening in a paranasal sinus wall; and

(c) a port feature extending through the absorbent body, wherein the port feature defines a lumen.

17. A method of treating a sinus using an implant, wherein the implant includes an absorbent body, a non-permeable feature, and a port feature, wherein the absorbent body comprises a wicking feature, wherein the wicking feature extends obliquely relative to the port feature, the method comprising:

(a) positioning the non-permeable feature in an opening in a paranasal sinus wall; and

(b) orienting the absorbent body such that the wicking feature is in contact with mucosal tissue in a sinus cavity defined by the paranasal sinus wall, wherein a proximal portion of the absorbent body is positioned outside the paranasal sinus wall.

18. The method of claim 17, wherein the paranasal sinus wall comprises an ethmoid bulla sinus wall.

19. The method of claim 17, further comprising forming or enlarging the opening in the paranasal sinus wall.

20. The method of claim 17, further comprising administering a fluid to the proximal portion of the absorbent body, wherein the wicking feature is configured to communicate the administered fluid to the mucosal tissue through a capillary action.

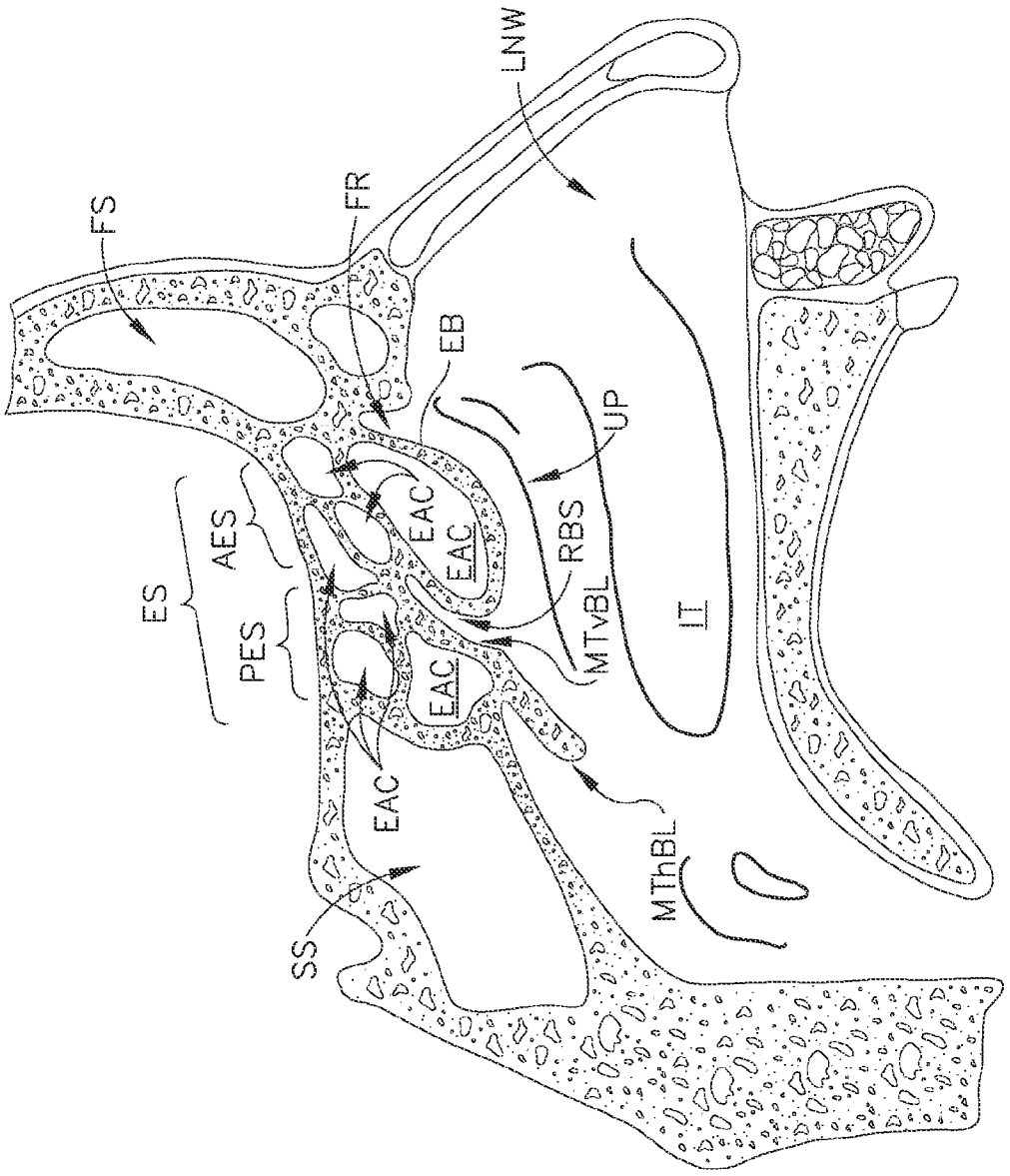


Fig. 1

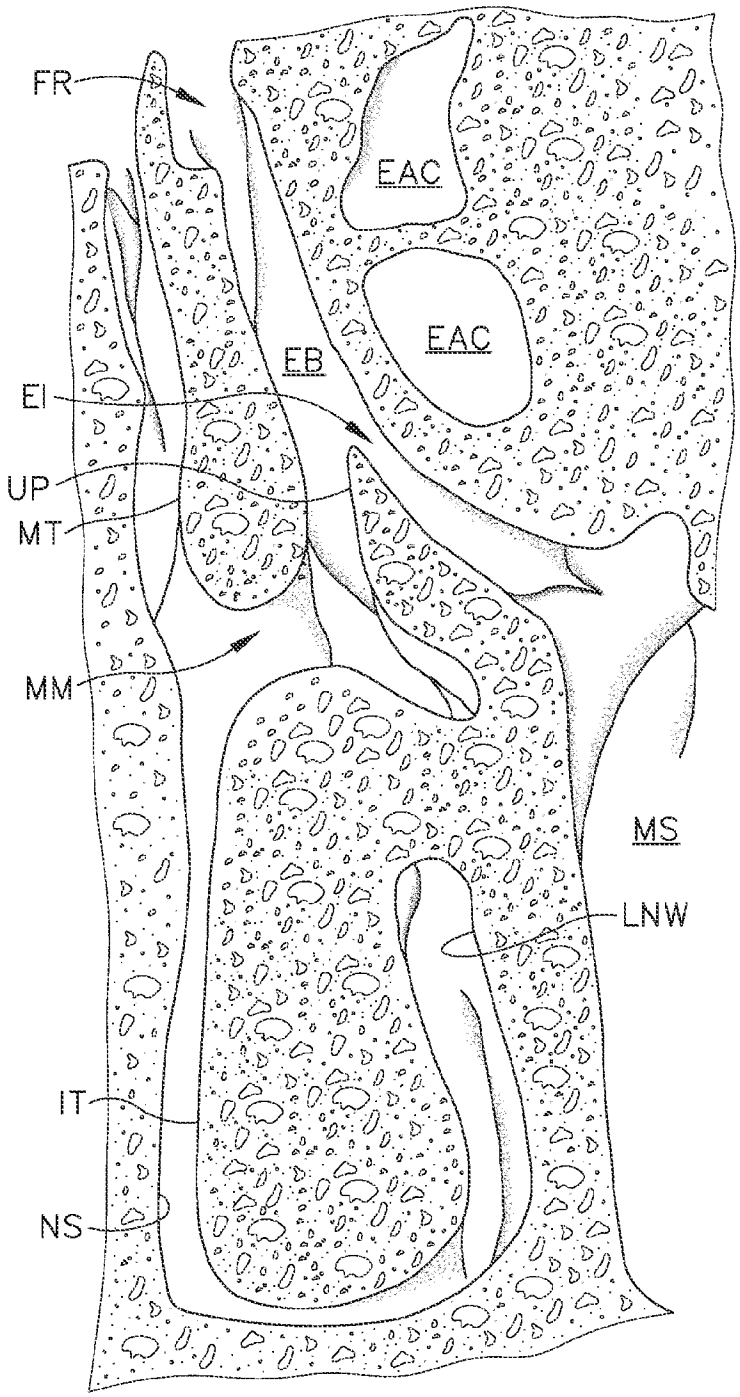


Fig.2

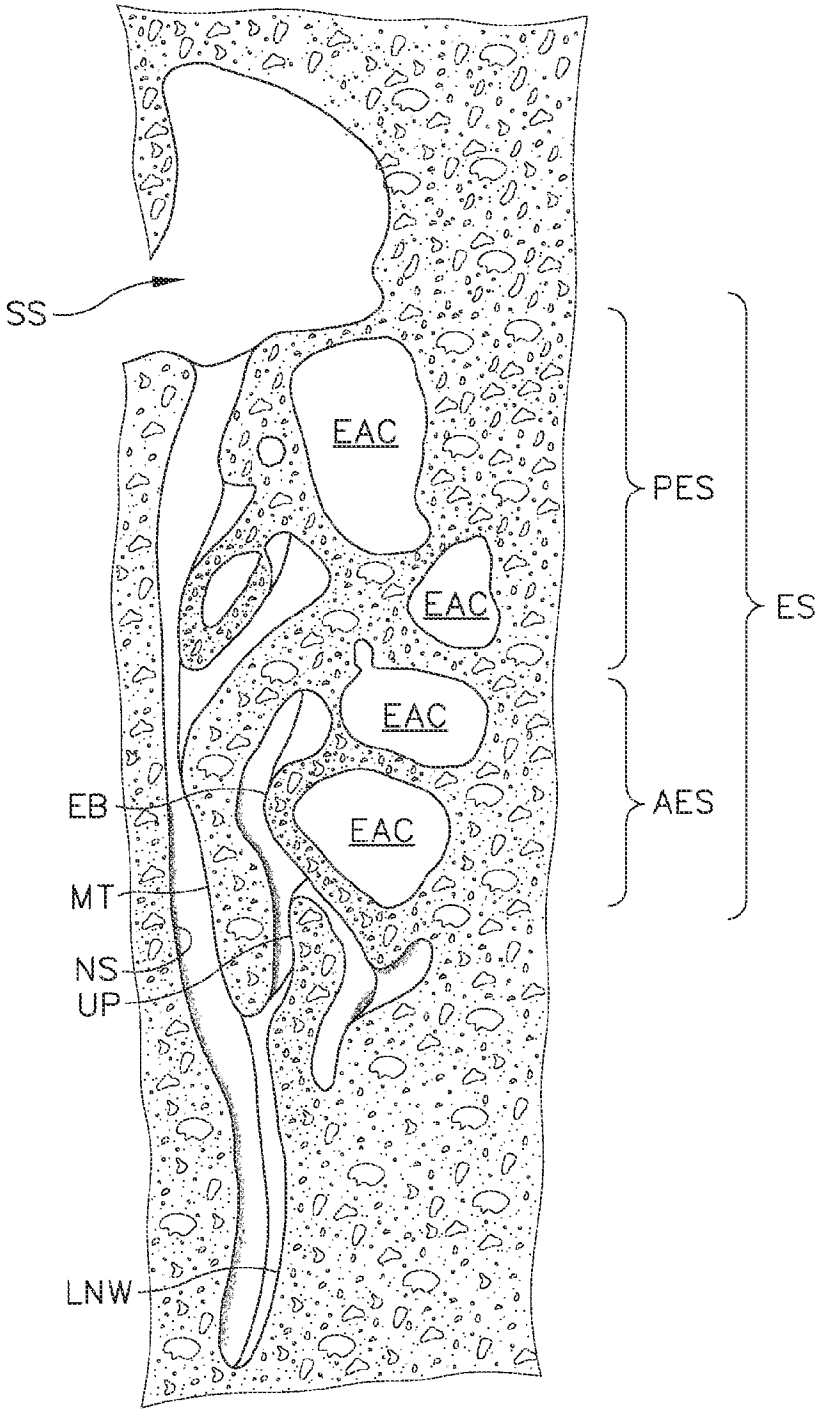


Fig.3

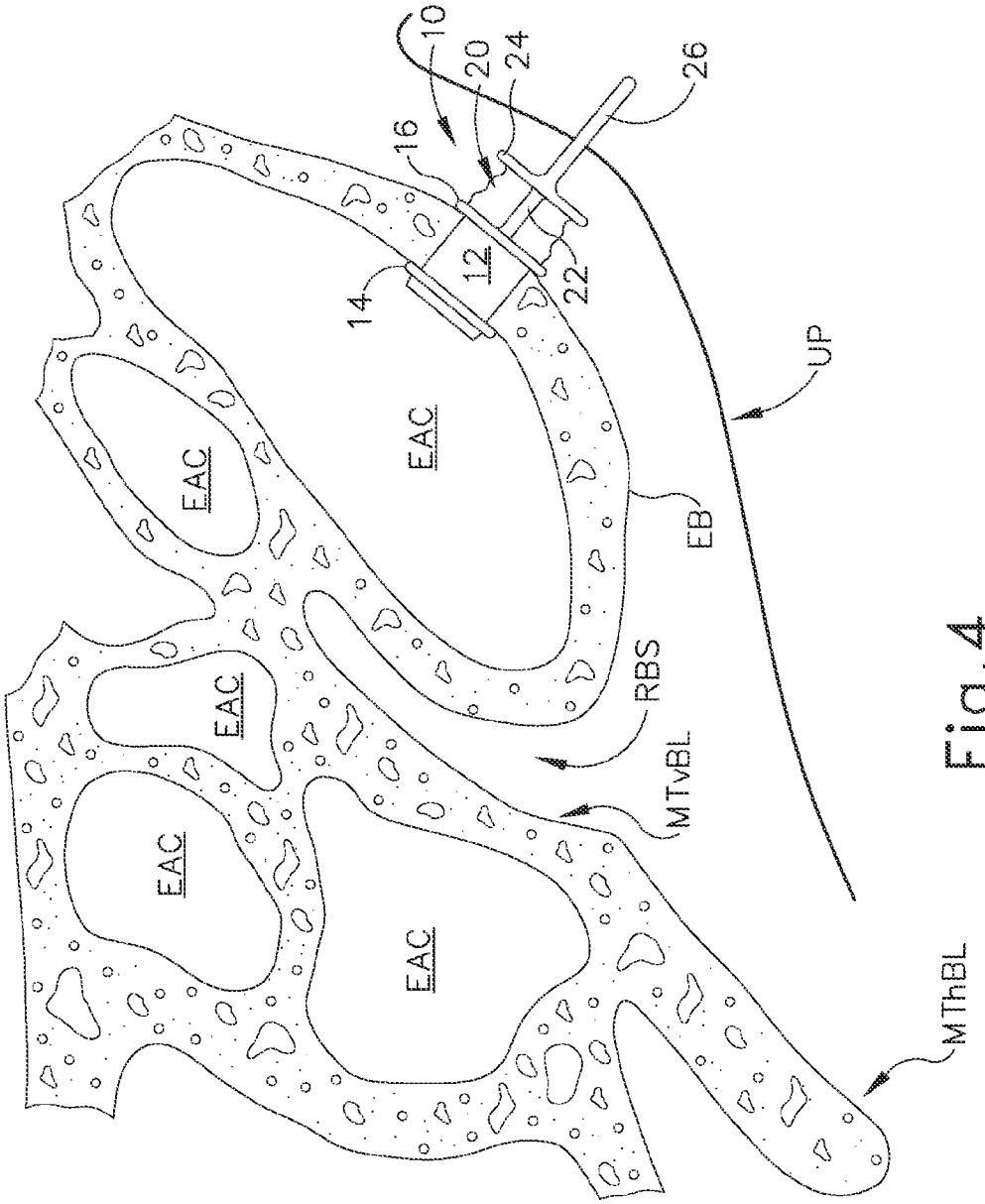


Fig.4

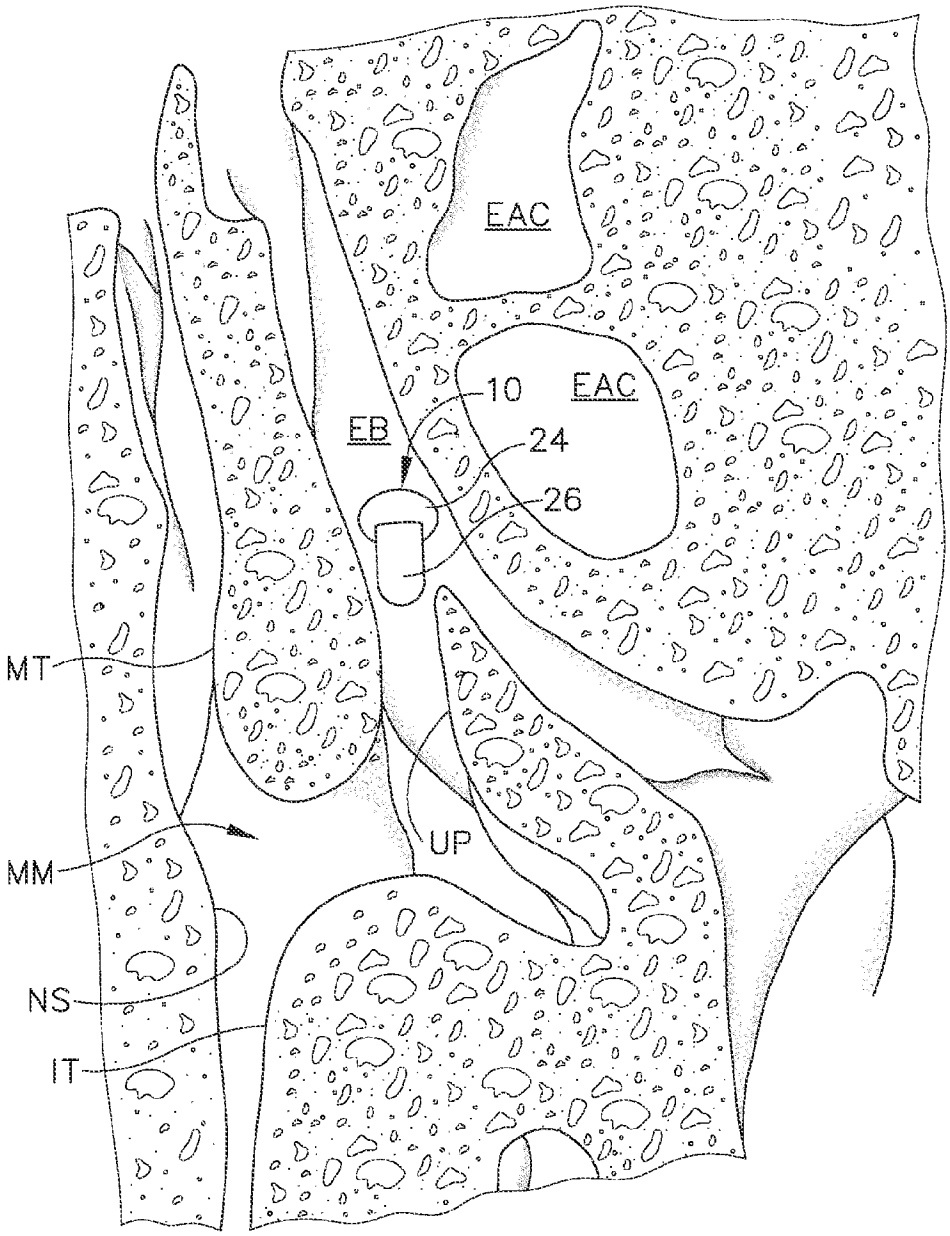


Fig.5

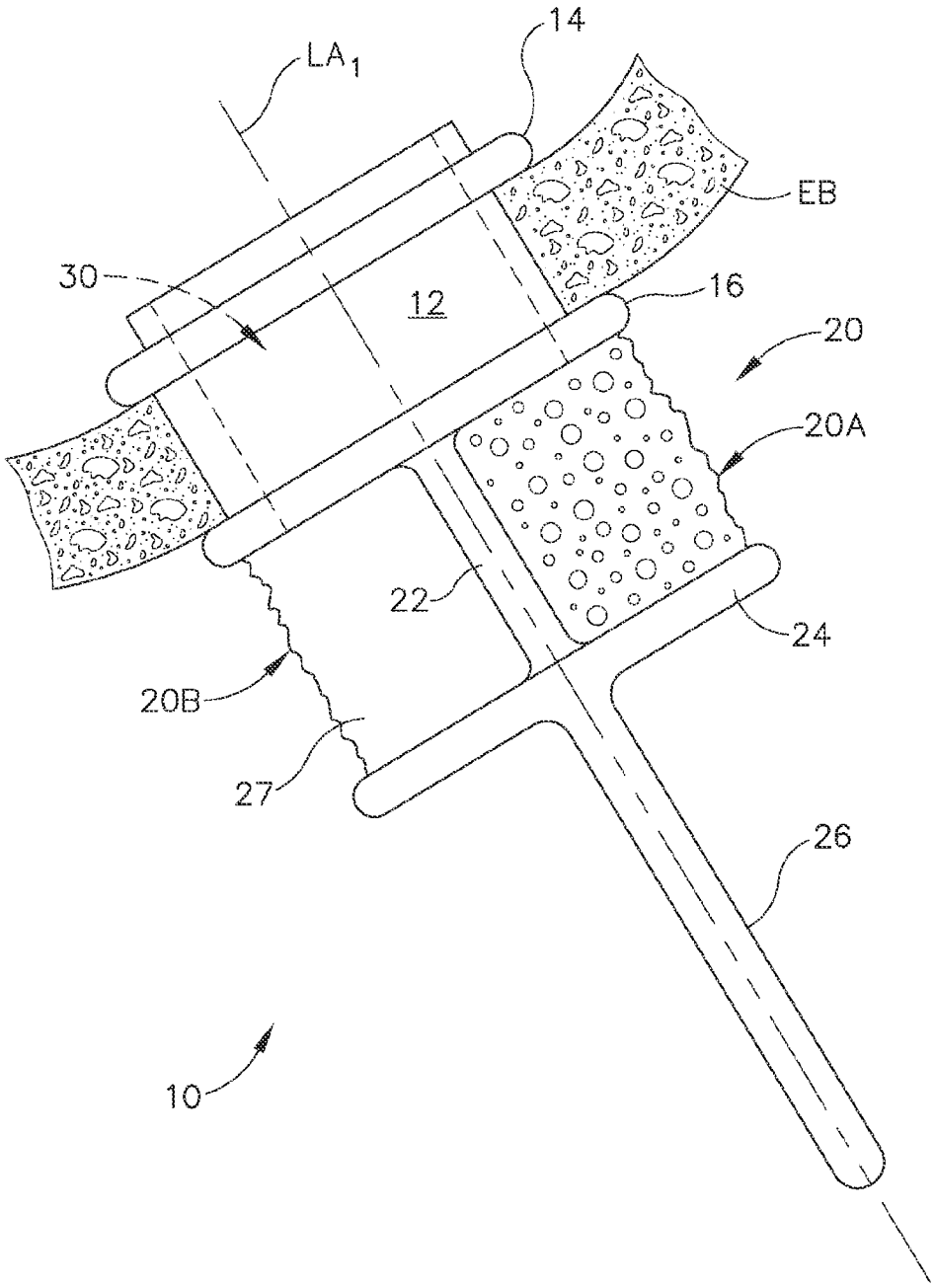


Fig.6A

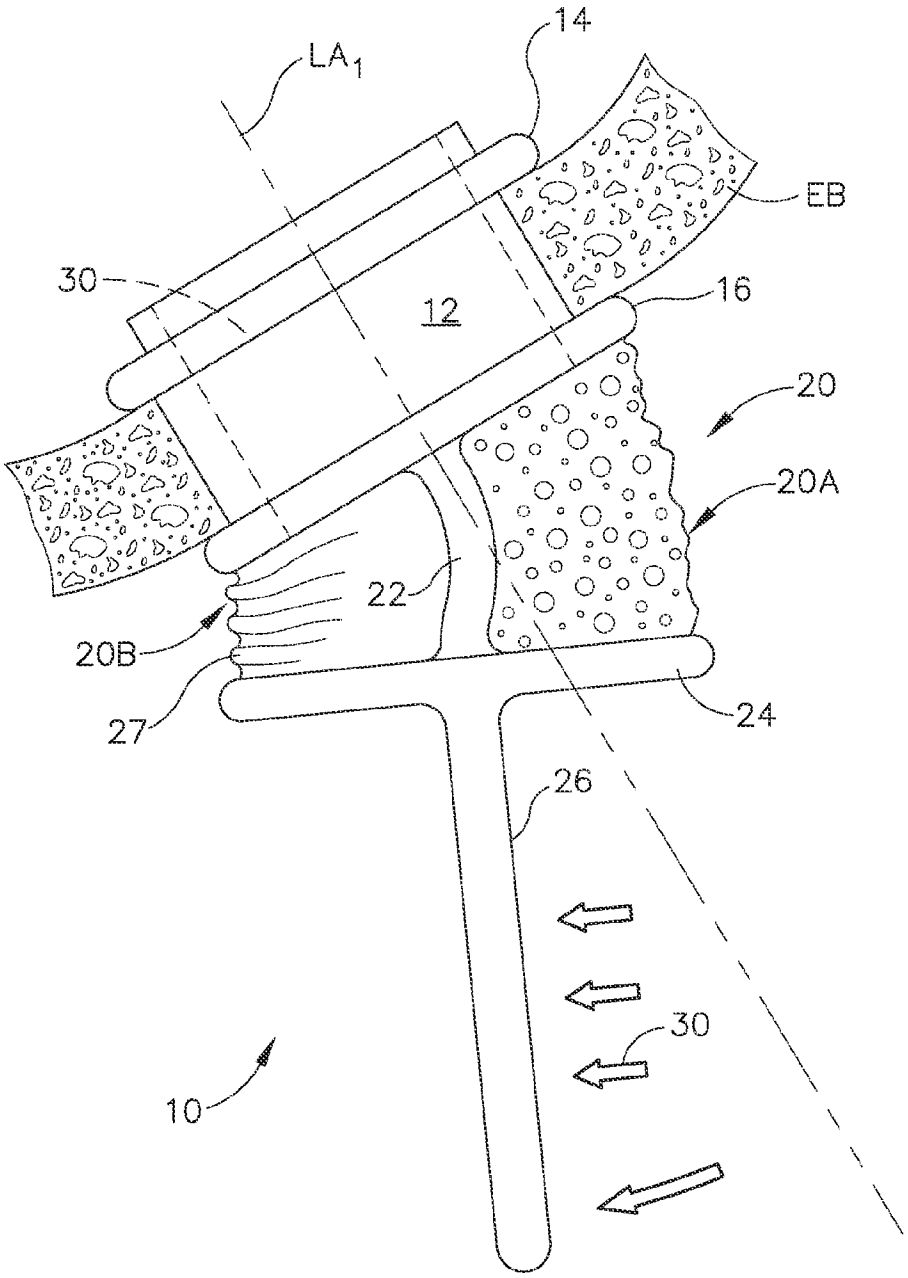


Fig.6B

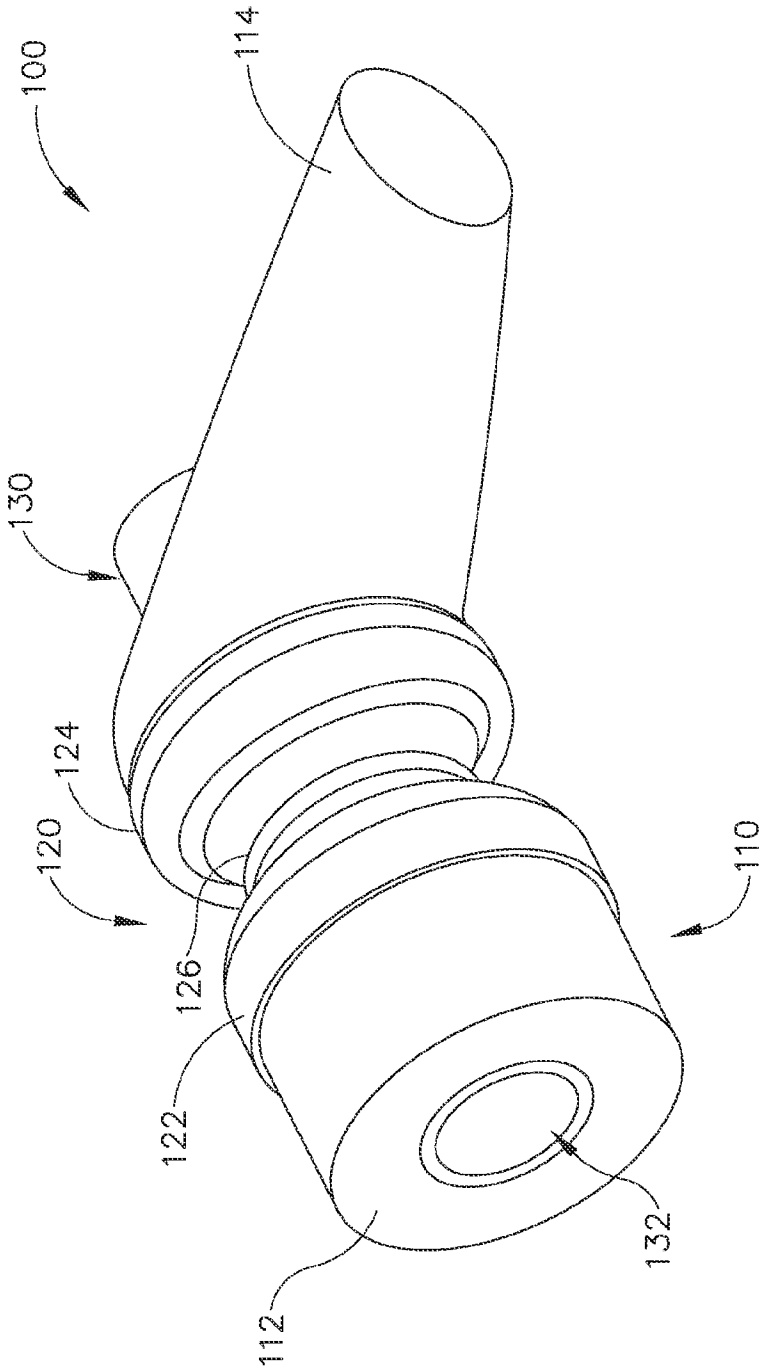


Fig. 7

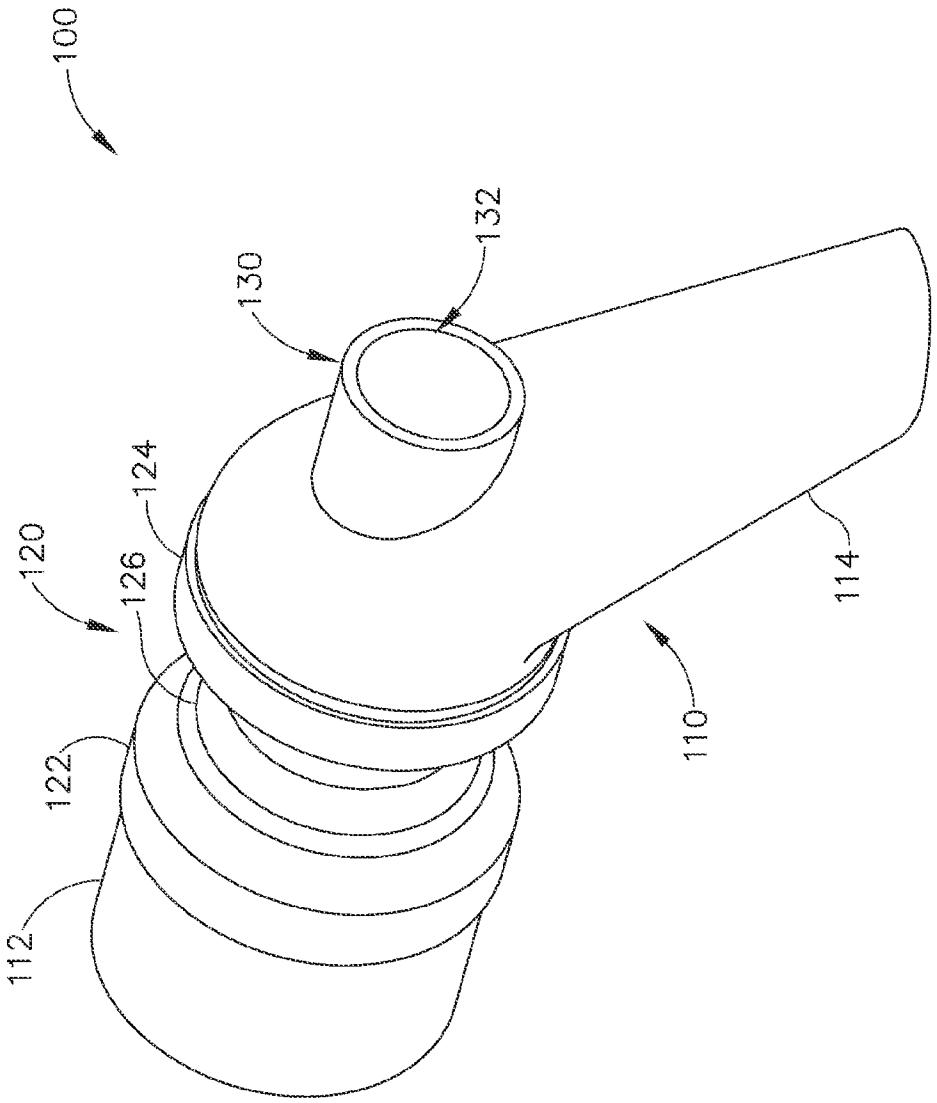


Fig.8

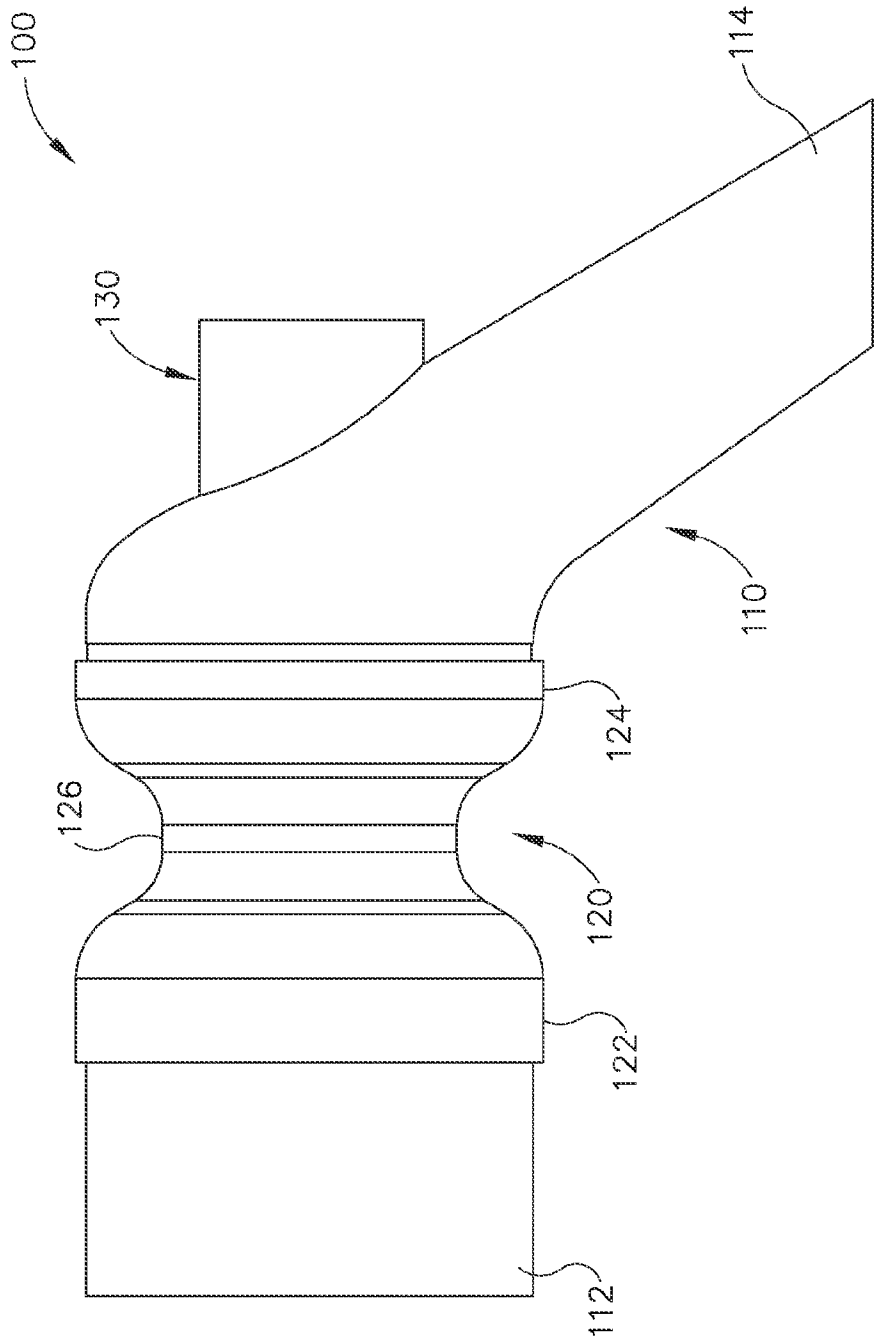


Fig.9

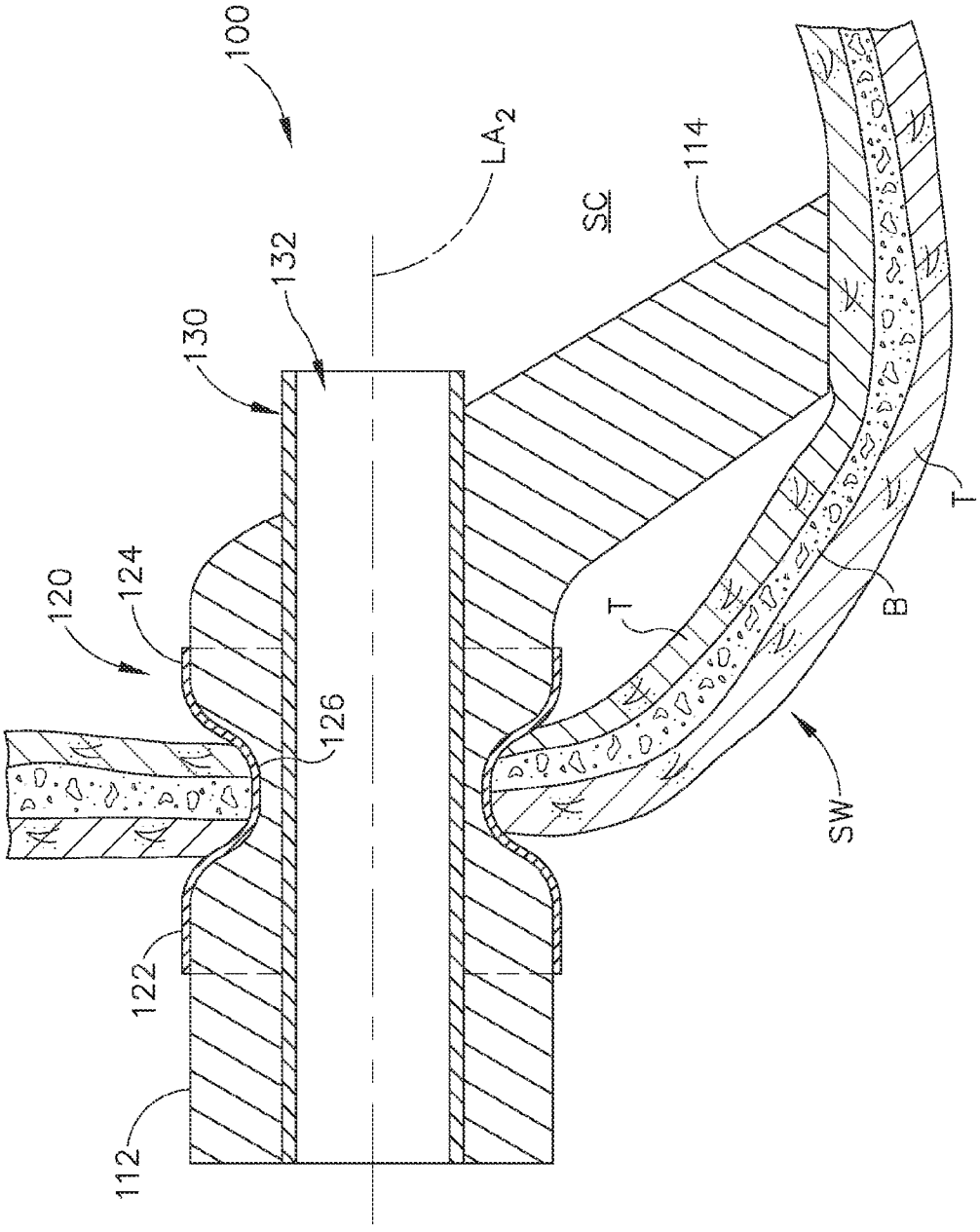


Fig. 10

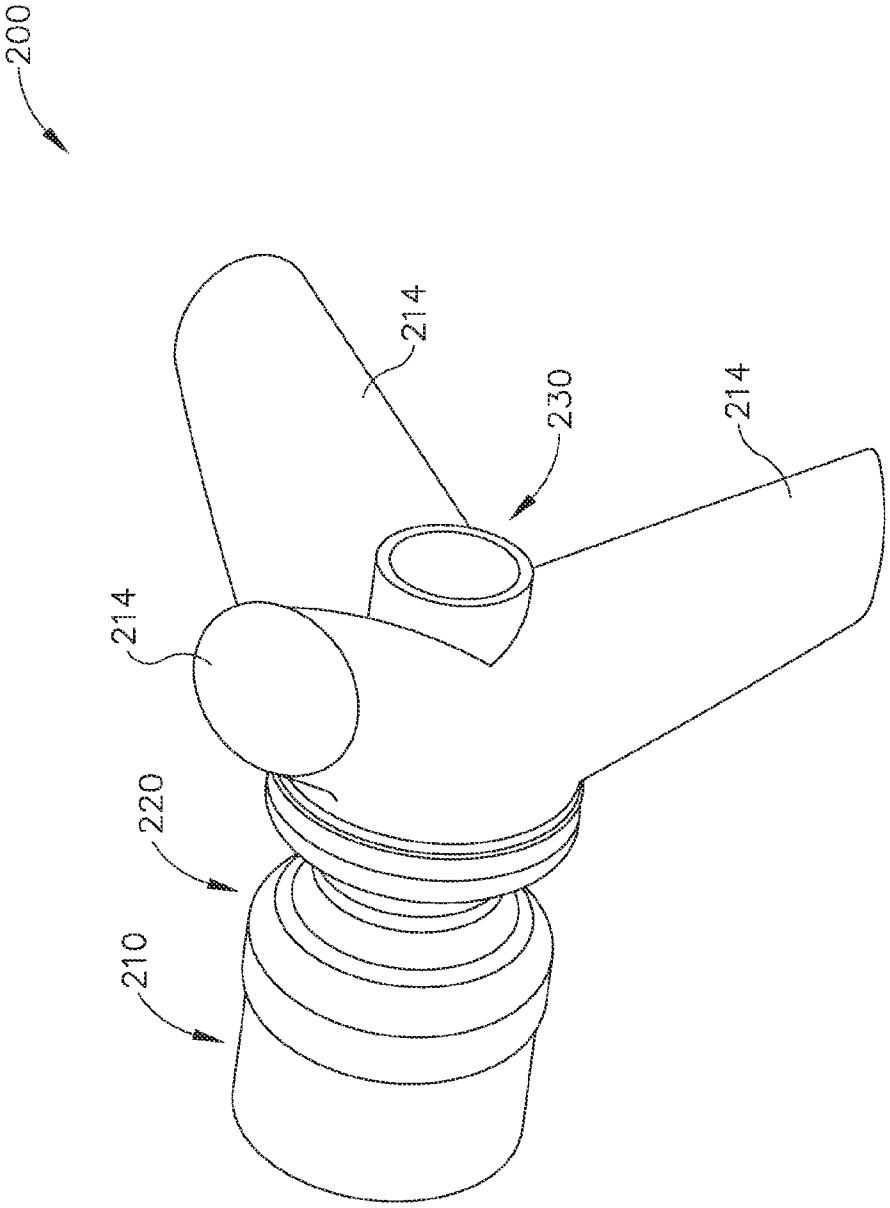


Fig. 11

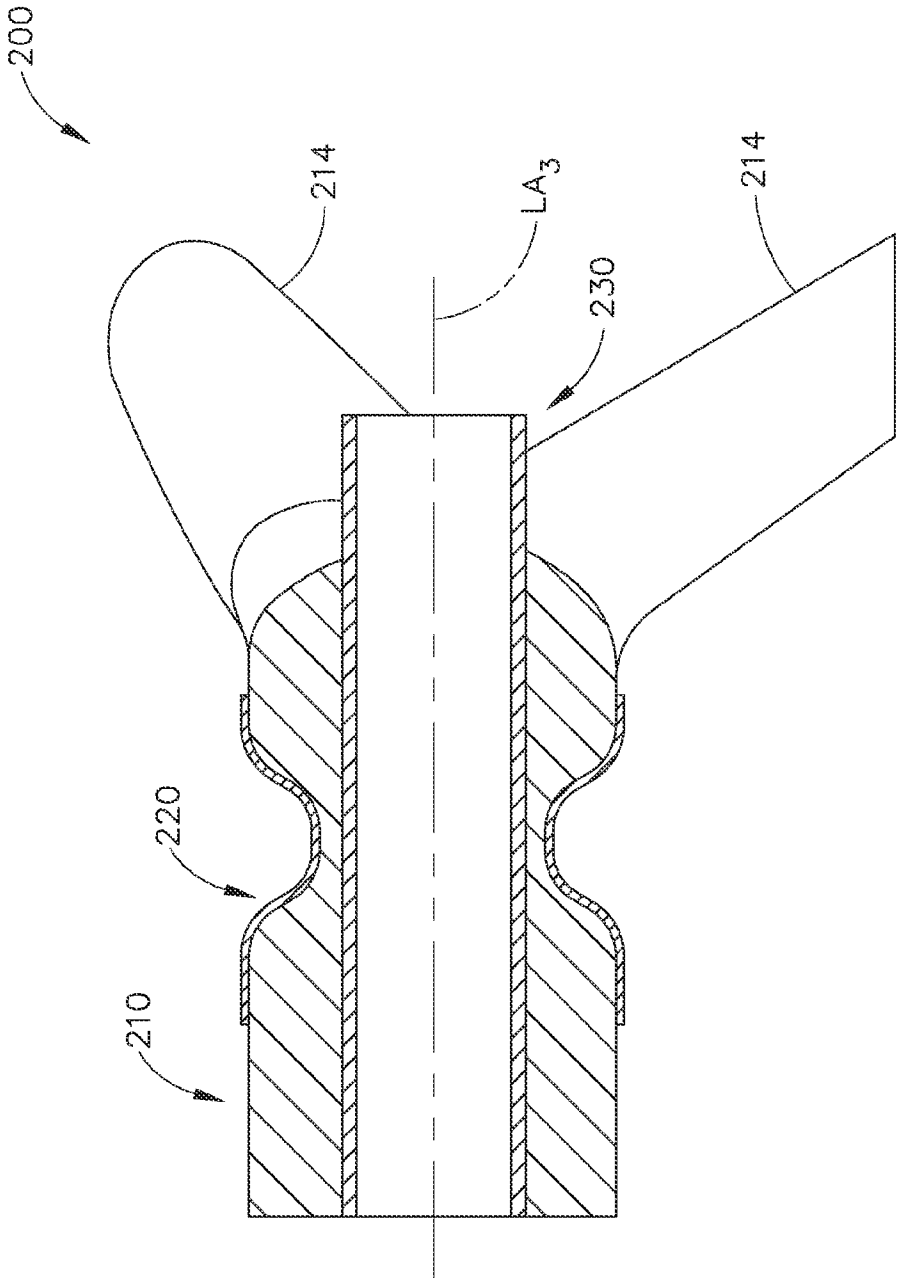


Fig. 12

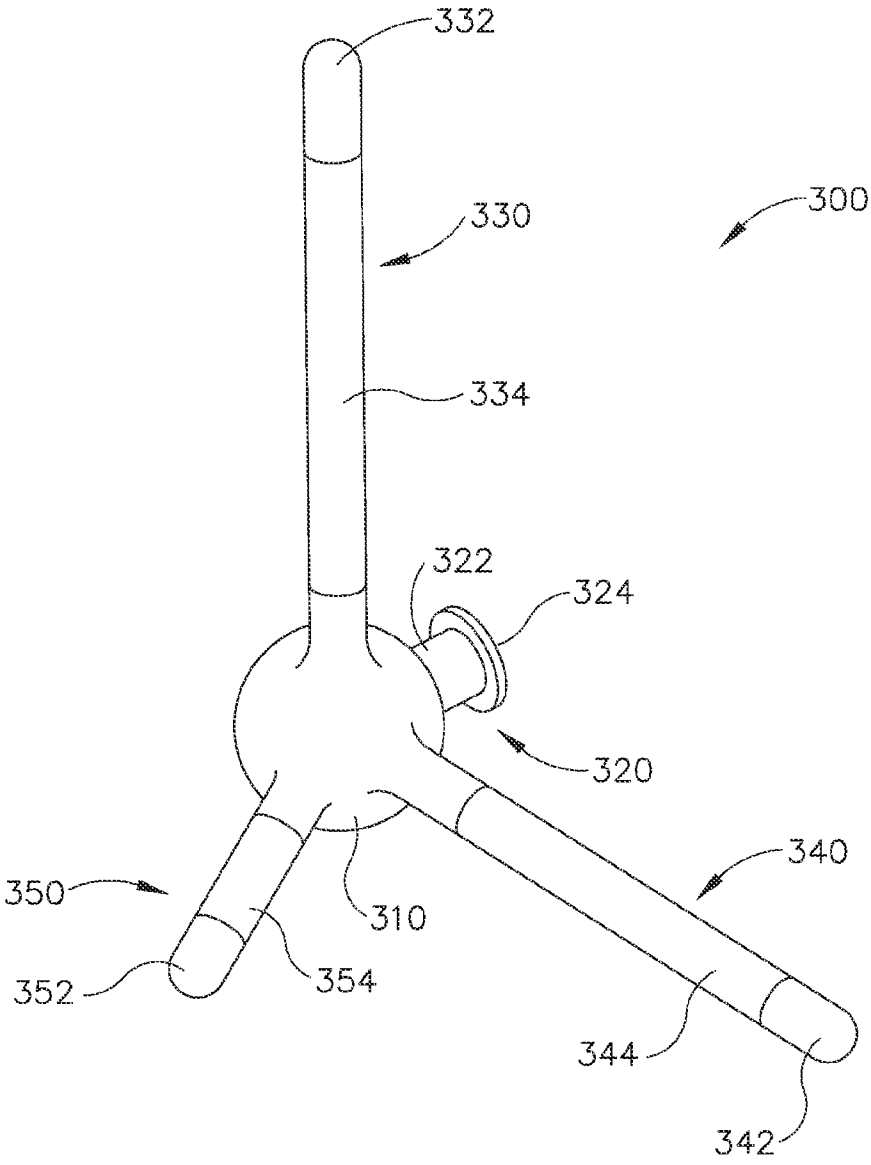


Fig.13

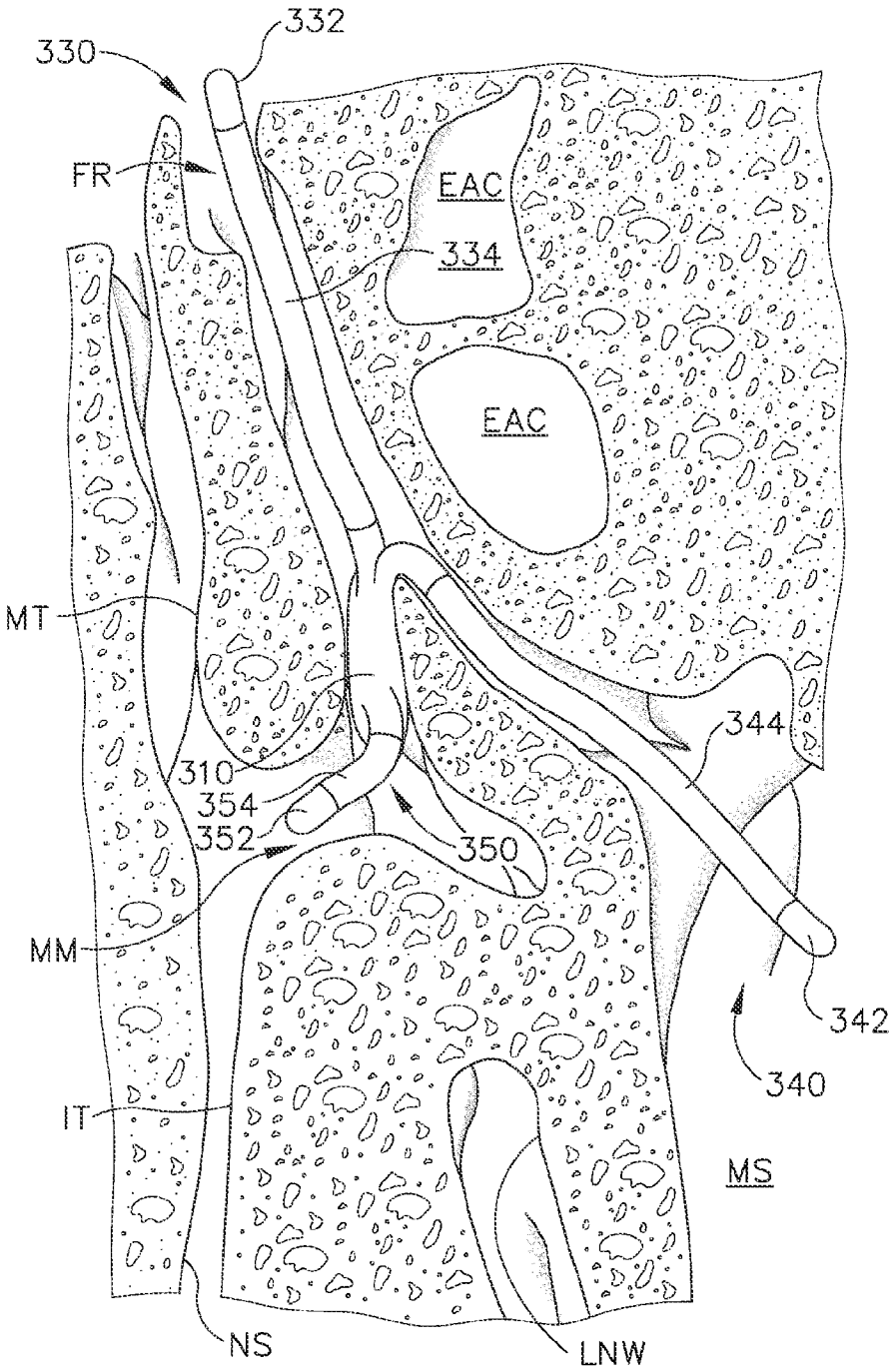

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Fig. 14

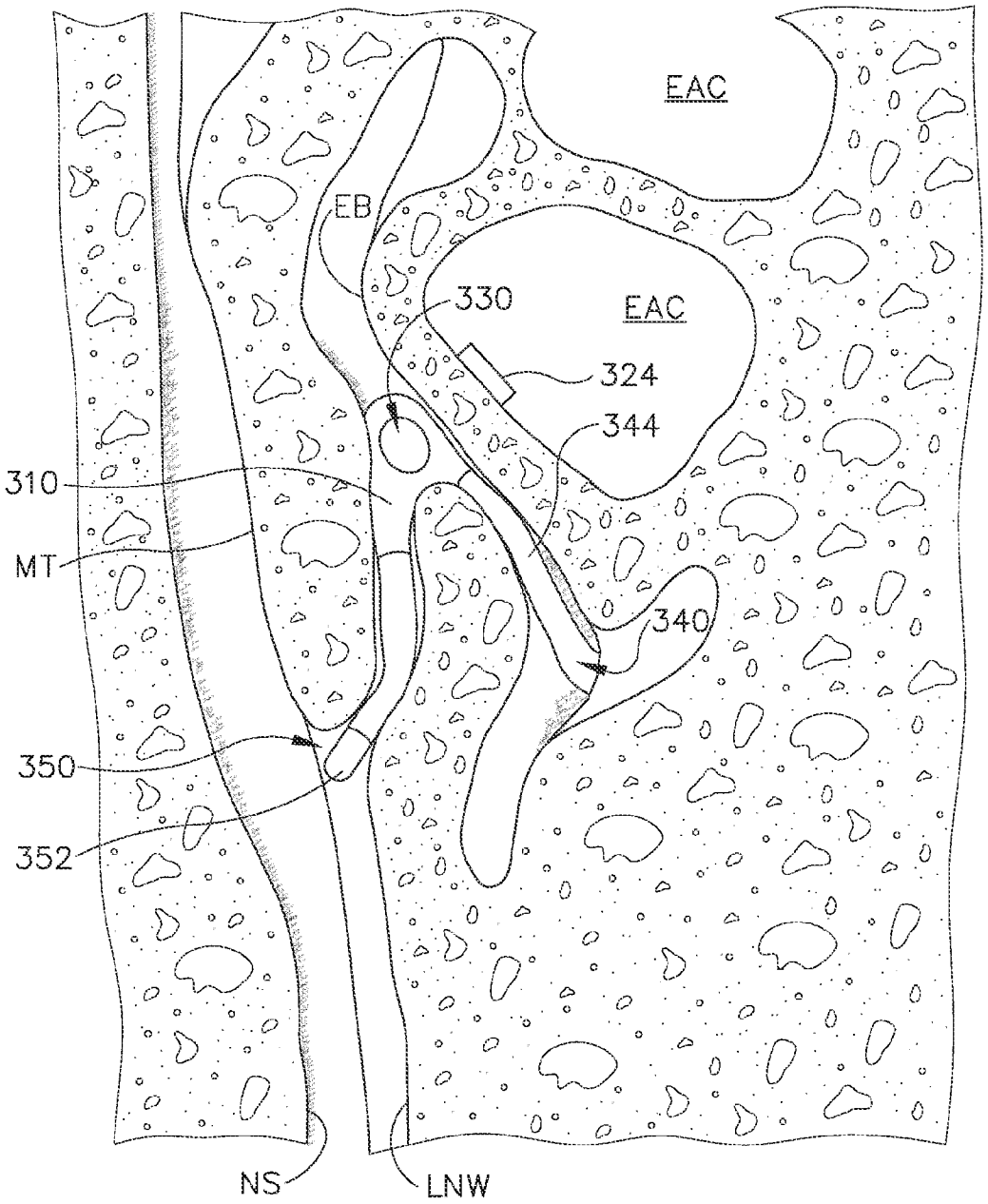


Fig.15

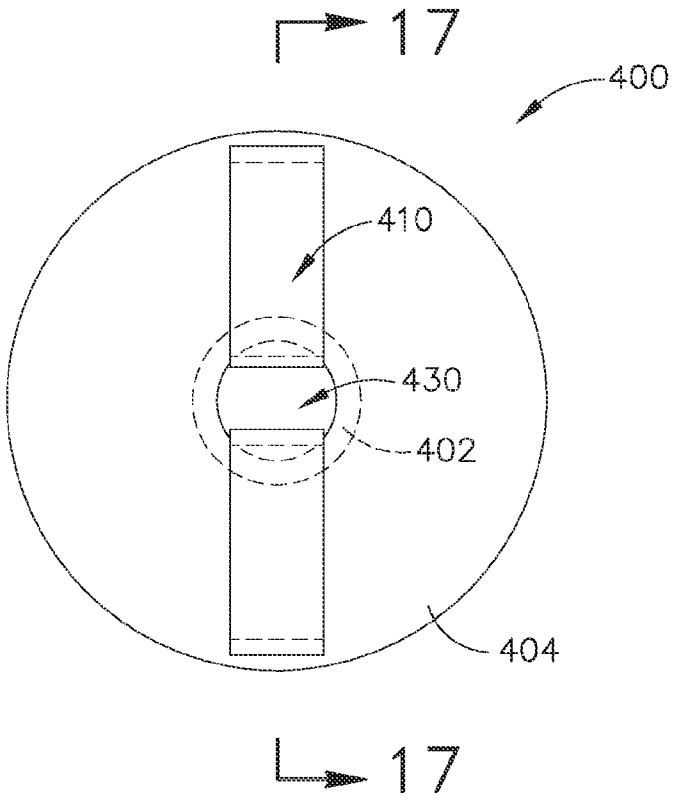


Fig.16

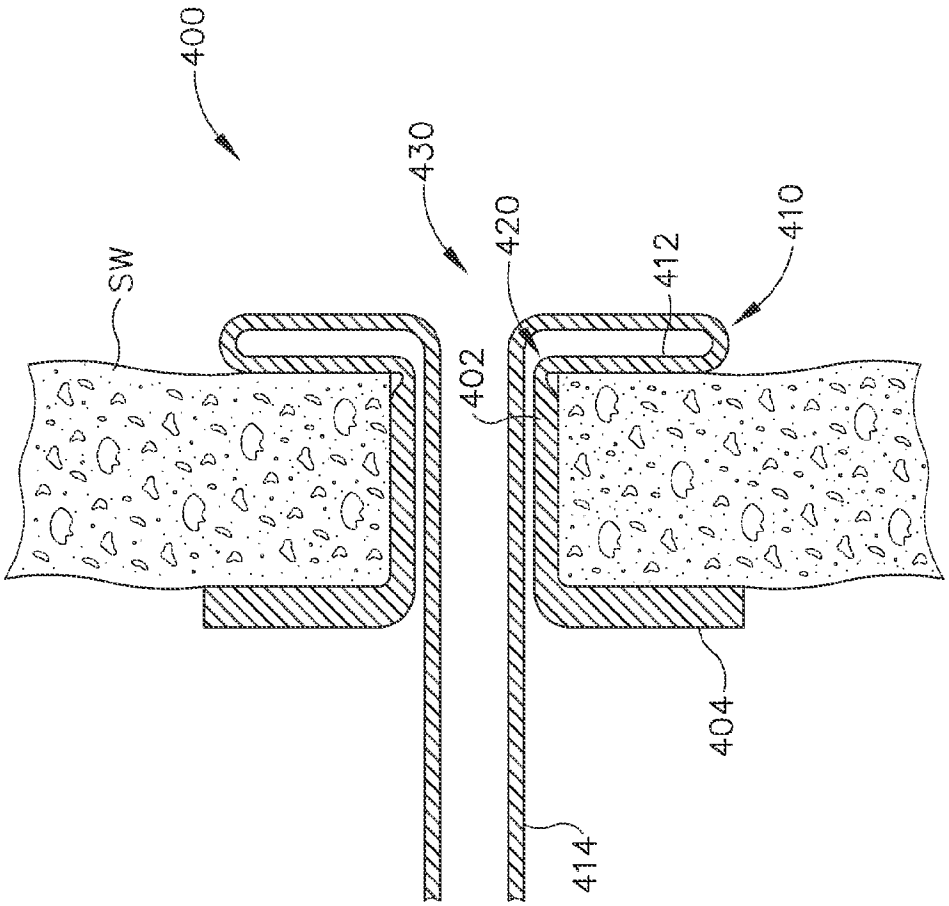


Fig. 17A

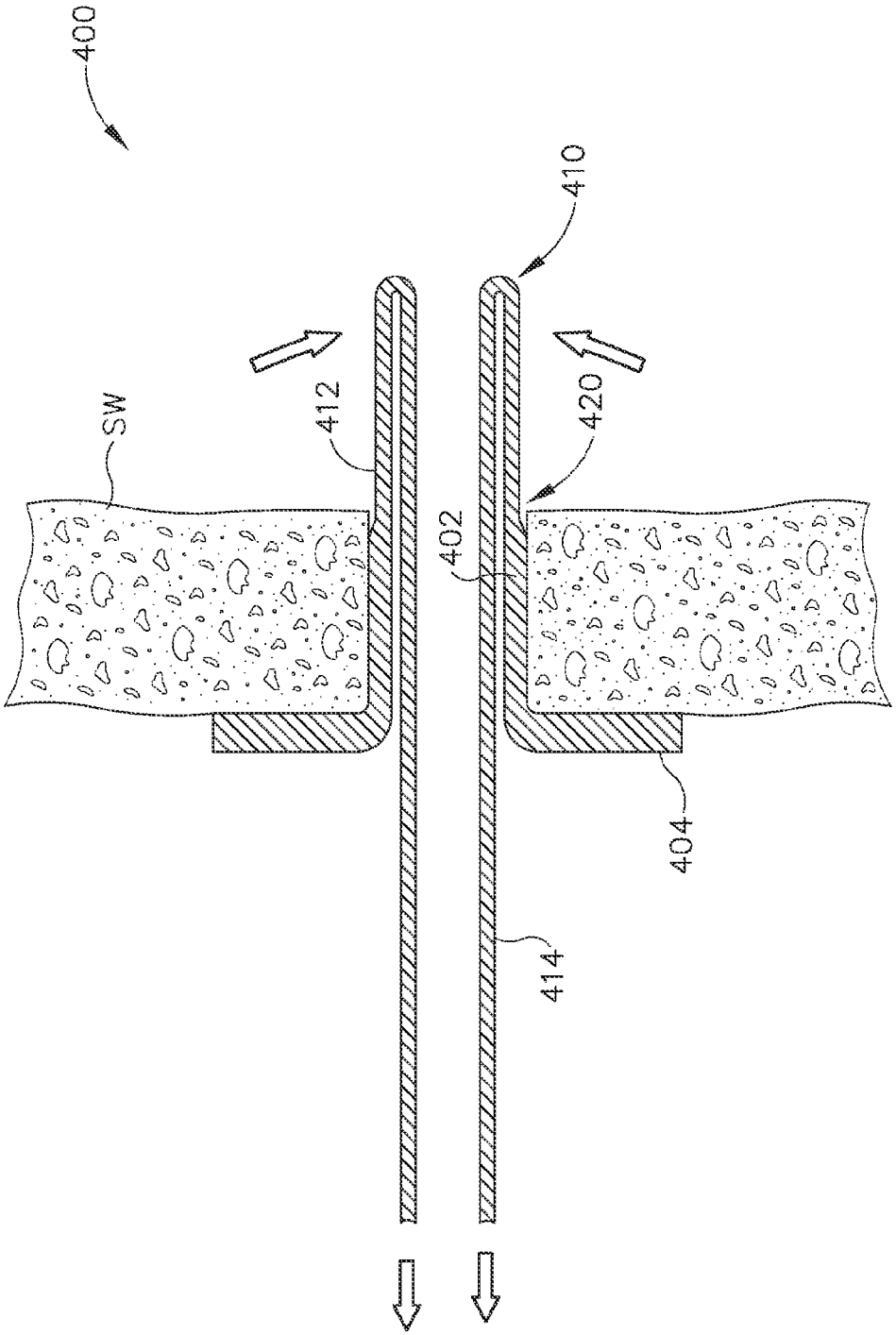


Fig. 17B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/056265

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M27/00 A61M31/00
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)
A61M

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	EP 0 605 974 A1 (SMITH & NEPHEW RICHARDS INC) 13 July 1994 (1994-07-13) column 5, lines 43-53; figure 8	1-3,5,7, 11-15
X	EP 0 467 516 A1 (SQUIBB BRISTOL MYERS CO) 22 January 1992 (1992-01-22) column 3, lines 1-10; figure 6	1
X	US 4 233 025 A (LARSON WILLIAM A ET AL) 11 November 1980 (1980-11-11) column 3, lines 4-20; figure 1	1
X	US 5 203 699 A (MCGUIRE JIMMIE L) 20 April 1993 (1993-04-20) column 4, lines 1-19; figure 6	1
X	US 5 827 224 A (SHIPPERT RONALD D) 27 October 1998 (1998-10-27) column 9, lines 3-10; figure 10	1

☐ Further documents are listed in the continuation of Box C.

☒ 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
17 December 2014	05/01/2015

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	Segerberg, Tomas

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/056265

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.: 17-20
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 17-20 relate to subject-matter concerning methods for treatment of the human body by therapy, Rule 67.1(iv) PCT. The method is a treatment by definition in the first line of claim 17, and further includes positioning, orienting and contact.

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:

1. [ ] 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.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/056265

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0605974 A1	13-07-1994	AU 674711 B2	09-01-1997
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		US 6123697 A	26-09-2000

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
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2 April 2015 (02.04.2015)

WIPO | PCT

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30 September 2014 (30.09.2014)

(25) Filing Language: English

(26) Publication Language: English

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62/015,468 22 June 2014 (22.06.2014) US

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

[Continued on next page]

(54) Title: APPARATUS AND METHODS FOR TREATING RHINITIS

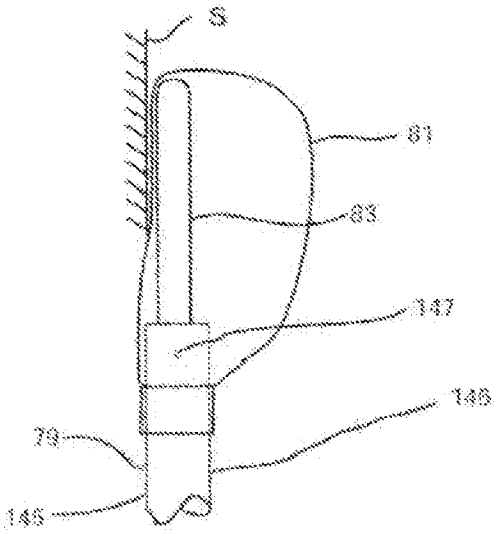


Figure 6H

(57) Abstract: Apparatus and methods for treating conditions such as rhinitis are disclosed herein where a distal end of a probe shaft is introduced through the nasal cavity where the distal end has an end effector with a first configuration having a low-profile which is shaped to manipulate tissue within the nasal cavity. The distal end may be positioned into proximity of a tissue region having a post nasal nerve associated with a middle or inferior nasal turbinate. Once suitably positioned, the distal end may be reconfigured from the first configuration to a second configuration which is shaped to contact and follow the tissue region and the post nasal nerve may then be ablated via the distal end. Ablation may be performed using various mechanisms, such as cryotherapy, and optionally under direct visualization.

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APPARATUS AND METHODS FOR TREATING RHINITIS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application No. 61/884,547 filed September 30, 2013 and 62/015,468 filed June 22, 2014, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention is related to devices and methods for ablating regions of tissue. More particularly, the present invention is related to devices and methods for ablating regions of tissue such as through cryogenic ablation of tissue regions within the nasal cavity for treating conditions such as rhinitis.

BACKGROUND OF THE INVENTION

[0003] The human nose is responsible for warming, humidifying and filtering inspired air. The nose is mainly formed of cartilage, bone, mucous membranes and skin. 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 for 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.

[0004] The nasal turbinates are three 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 passage way known as a meatus. For example, the inferior meatus is a passageway that passes beneath the inferior turbinate. Ducts, knows 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.

[0005] The turbinates are autonomically innervated by nerves arising from the Vidian nerve which contains sympathetic and parasympathetic afferents that can modulate the function of the turbinates to either increase (parasympathetic) or decrease (sympathetic) activity of the submucosal layer. The pterygoid canal carries both parasympathetic and sympathetic fibers, namely the vidian nerve, to the sphenopalatine ganglion. Exclusive of the sphenopalatine foramen (SPF) contents, additional posterolateral neurovascular rami project from the sphinopaletine ganglion via multiple individual postganglionic rami to supply the nasal mucosa . The most common locations for these rami are within 1 cm posterosuperior to the horizontal attachment of the inferior turbinate, within 5 mm anteroinferior to this attachment, and the palatine bone via a foramen distinct from the SPF. Also, Blier, et.al showed that interfascicle anastomotic loops in some cases, are associated with at least 3 accessory nerves. Based on Blier et.al work each accessory nerve could be proximally traced directly to the PPG or greater palatine nerve.

[0006] Rhinitis is defined as inflammation of the membranes lining the nose, characterized by nasal symptoms, including itching, rhinorrhea, and/or nasal congestion. Chronic Rhinitis affects tens of millions of people in the US and is a leading cause for patients to seek medical care. Medical treatment has been shown to have limited effects for chronic rhinitis sufferers and requires daily medication use or onerous allergy treatments and up to 20% of patients may be refractory.

[0007] In addition to the medications turbinate reduction surgery (RF and micro-debridement) both have temporary duration of effect of 1-2 years and can result in complications including mucosal sloughing, acute pain and swelling, overtreatment and bone damage. Additionally, turbinate reduction does not treat the symptom of rhinorrhea. It is thought that parasympathetic effect of the vidian nerve predominates so that, on transecting it, the result is decreased rhinitis and congestion. This pathophysiology has been confirmed as surgical treatment of the vidian nerve has been tried with great success; however, the procedure is invasive, time consuming and potentially can result in dry eyes due to autonomic fibers in the vidian nerve that supply the lacrimal glands.

[0008] Golding-Wood, who recommended cutting the parasympathetic nerve fibers in the vidian canal to decrease the parasympathetic tone to the nasal mucosa, introduced a different approach for the treatment of hypersecretion in 1961. Various approaches to the

vidian canal were subsequently developed, and the method was widely employed in the 1970s. However, the original technique was abandoned at the beginning of the 1980s because of its irreversible complications such as dry eyes.

[0009] Recent studies have shown that selectively interrupting the Post Nasal Nerves (PNN) in patients with chronic rhinitis improves their symptoms while avoiding the morbidities associated with vidian neurectomy.[1] The study by Ikeda et.al suggests that the effect of an anticholinergic drug on nasal symptoms resembled that of PNN resection in patients with chronic rhinitis. Based on his study the glandular mucosal acinar cells were significantly reduced after the PNN resection. The reduction in glandular cells may be explained by decreased secretion of the nerve growth factor or epidermal growth factor regulated by acetylcholine, a major neurotransmitter of parasympathetic systems.

[0010] Posterior nasal neurectomy, initially developed by Kikawada in 1998 and later modified by Kawamura and Kubo, is an alternative method in which neural bundles are selectively cut or cauterized from the sphenopalatine foramen. Autonomic and sensory nerve fibers that pass through the foramen anatomically branch into the middle and inferior turbinate and are distributed around the mucosal layer of the nose. Therefore, selective neurectomy at this point enables physicians to theoretically avoid surgical complications such as inhibition of lacrimal secretion.

SUMMARY OF THE INVENTION

[0011] The Posterior Nasal Nerves (PNN) innervate, inferior, middle, and inferior turbinates. Ablating these nerves leads to a decrease in or interruption of parasympathetic nerve signals that contribute to congestion and rhinorrhea in patients with chronic rhinitis (allergic or vasomotor). The devices and methods described herein are configured to be used for ablating one or more of these branches to reduce or eliminate rhinitis, e.g., ablating the Posterior Nasal Nerves (PNN).

[0012] Generally, several various apparatus and methods may be used to ablate the PNN as described below. One method for treating the tissue region within a nasal cavity in proximity to the PNN may be comprised of introducing a distal end of a probe shaft through the nasal cavity, wherein the distal end has an end effector with a first configuration having a low-profile which is shaped to manipulate tissue within the nasal cavity. The distal end may be positioned into proximity of the tissue region having the PNN associated with a middle or inferior nasal turbinate. Once suitably positioned, the distal end may be reconfigured from the first configuration to a second configuration,

which is shaped to contact and follow the tissue region. The distal end may then be used to ablate the PNN within the tissue region utilizing a number of different tissue treatment mechanisms, e.g., cryotherapy, as described herein.

[0013] In treating the tissue region in one variation, the distal end may be positioned specifically into proximity of the tissue region which is surrounded by the middle nasal turbinate, inferior nasal turbinate, and lateral wall forming a cul-de-sac and having the PNN associated with the middle or inferior nasal turbinate. The distal end may be reconfigured to treat the tissue region accordingly.

[0014] Various configurations for the distal end may be utilized in treating the tissue region so long as the distal end is configured for placement within the narrowed confines of the nasal cavity and more specifically within the confines of the cul-de-sac defined by the tissue region surrounding the middle nasal turbinate, inferior nasal turbinate, and lateral nasal tissue wall.

[0015] One example of a surgical probe configured for ablating the tissue region within such narrowed confines includes a surgical probe apparatus having a surgical probe shaft comprising an elongated structure with a distal end and a proximal end, an expandable structure attached to the distal end of the probe shaft, the expandable structure having a deflated configuration and an expanded configuration. A lumen may be defined through the shaft in fluid communication with an interior of the expandable structure. A member may be attached to the distal end and extend within the expandable structure which encloses the member such that the member is unattached to the interior of the expandable structure. Moreover, the member may define an atraumatic shape, which is sized for pressing against and manipulating through the expandable structure the lateral nasal wall or other tissue proximate to the PNN.

[0016] An example of utilizing such a structure in treating the tissue region may generally comprise advancing the distal end of the surgical probe shaft through the nasal cavity and into proximity of the tissue region having PNN associated with a middle or inferior nasal turbinate and introducing a cryogenic fluid into the expandable structure attached to the distal end of the probe shaft such that the expandable structure inflates from a deflated configuration into an expanded configuration against the tissue region.

[0017] As described above, a position of the member relative to the tissue region may be adjusted where the member is attached to the distal end of the probe shaft and extends within the expandable structure, which encloses the member such that the member is unattached to an interior of the expandable structure. The practitioner may apply a

pressure against the distal end such that the member is pressed against the interior of the expandable structure which in turn is pressed against the tissue region having the PNN, wherein the member defines an atraumatic shape which is sized for pressing against and manipulating the tissue region. The member may be maintained against the interior of the expandable structure and the tissue region until the tissue region is cryogenically ablated.

[0018] Any of the ablation devices herein can be used to ablate a single nerve branch or multiple nerve branches.

[0019] One aspect of this invention is a surgical probe configured for ablating the posterior nasal nerve associated with a nasal turbinate. The surgical probe, in one example, comprises a surgical shaft with a proximal end and a distal end, a surgical hand piece disposed on the proximal end, and a coiled spring-like structure disposed on the distal end. The coiled spring-like structure is a hollow structure comprising a closely pitched wire coil forming a central lumen, and an outer surface. The surgical hand piece comprises a pressurized liquid cryogen reservoir and a user actuated liquid cryogen flow control valve. There is at least one liquid cryogen path through the probe shaft in fluidic communication with the liquid flow control valve within the hand piece, and the spring-like coiled structure.

[0020] The pressurized cryogen liquid reservoir contains a liquid cryogen, e.g., nitrous oxide, but may also be another cryogenic liquid such as liquid carbon dioxide, or a liquid chlorofluorocarbon compound, etc. The distal spring-like structure may be configured as a liquid cryogen evaporator, either as a closed liquid cryogen evaporator, or as an open liquid cryogen evaporator.

[0021] In the closed evaporator configuration the inner central lumen of the spring-like structure is lined with a polymeric liner. Liquid cryogen is introduced into the central lumen through liquid cryogen supply line that is connected to the liquid cryogen reservoir in the handle, and runs coaxially through the probe shaft. The evaporated liquid cryogen may be vented to the room, e.g., through the probe shaft to a vent port in the hand piece, or in the vicinity of the proximal end of the probe shaft. No liquid or gas cryogen is introduced into the patient's nasal cavity.

[0022] In the open liquid cryogen evaporator configuration, the evaporated cryogen may exit the central lumen of the spring-like structure between the wire coils, and into the nasal cavity of the patient. Precautions to prevent the patient from inhaling the cryogen gas may be taken. As an example, a distal occlusion balloon may be used to occlude the distal nasal passageway.

[0023] The surgical probe may be configured so that the surgeon can press the distal spring like structure against the lateral nasal wall proximate to the target posterior nasal nerve. The spring-like structure is configured to conform to the morphology of the lateral nasal wall and to evenly engage the lateral nasal wall with a substantially uniform contact pressure. The probe shaft may have a length between, e.g., approximately 4 cm and 10 cm, and a diameter between, e.g., approximately 1 mm and 4 mm. The distal spring-like structure may have an outer diameter that approximates the diameter of the probe shaft, or may be larger or smaller in diameter. The extended length of the spring-like structure may be between, e.g., approximately 0.5 cm and 1.5 cm.

[0024] The surgical probe may be supplied with the distal spring-like structure configured straight and coaxial with the probe shaft. In another embodiment, the distal spring like structure is supplied with a lateral curve with the proximal end of the spring-like structure in a tangential relationship with the distal end of the probe shaft. In another embodiment, the surgical probe may be supplied with the distal spring-like structure in a loop configuration where both ends of the spring-like structure are in a substantially tangential relationship with the distal end of the probe shaft.

[0025] The distal spring-like structure is substantially flexible along its axis; however, the structure may also be at least partly malleable and configured for form shaping by the user. Form shaping of the spring-like structure may be done manually by the surgeon, or alternatively the surgical probe may be supplied with the distal spring like structure in various predetermined/factory configurations. Various lengths, shapes, and diameters of the spring-like structure of the surgical probe may be produced and supplied to the end user.

[0026] In one embodiment, the distal spring-like structure is configured as a cryogenic liquid evaporator, where cryogenic liquid is delivered to the central lumen of the distal spring like structure. The liquid then evaporates at a low temperature, which causes the outer surface of the spring-like structure to reach a temperature that is sufficiently cold to ablate surrounding tissue and the function of the target posterior nasal nerve. The surgical probe may be configured so that the temperature of the outer surface of the spring-like structure is between -20 Deg. C. and -50 Deg. C. during liquid cryogen evaporation.

[0027] The surgical hand piece may comprise a factory filled liquid cryogen reservoir, and a user actuated cryogen flow control valve. The surgical hand piece may be configured so that it is held by the user like a pistol having a pistol grip where the cryogen flow valve actuator is configured like a pistol trigger. In an alternate embodiment, the

surgical hand piece is configured for the surgeon to grip it substantially like a writing utensil, with a button located in the vicinity of the index finger configured to actuate the cryogen flow control valve. In a third embodiment, the surgical hand piece may be configured to be held by the surgeon substantially like a pistol or a writing utensil, with a pistol like trigger configured to actuate a cryogen flow control valve, and a button in the vicinity of the index finger configured to actuate the same or a second cryogen control valve.

[0028] In another embodiment of this invention, the distal spring-like structure is encompassed by an expandable membranous structure. The expandable membranous structure may be a hollow bulbous structure with a single ostium configured for pressure tight bonding to the distal end of the probe shaft. The expandable membranous structure may be configured as a liquid cryogen evaporation chamber. Liquid cryogen is introduced into the expandable membranous structure from the encompassed spring-like structure.

[0029] The evaporated cryogen may be exhausted into the room through the probe shaft to a vent port in the hand piece, or in the vicinity of the proximal end of the probe shaft. The surgical probe is configured so that the expandable membranous structure expands to a predetermined shape in response to liquid cryogen evaporation. The pressure within the expandable membranous structure during cryogen evaporation may be regulated. The regulation means may comprise a pressure relief valve disposed in the gas exhaust path. The expandable membranous structure may be formed from an elastomeric material such as silicone rubber, or a urethane rubber. Alternatively, the expandable membranous structure may be formed from a substantially non-elastomeric material such as polyurethane or PET. The expandable membranous structure is configured so the shape and the size of the structure matches the shape and the size of the cul-de-sac of the lateral nasal wall defined by the tail of the middle turbinate, lateral nasal wall and the inferior turbinate, which is the target location for the ablation of the posterior nasal nerves for the treatment of rhinitis. Matching the size and shape of the expandable membranous structure to the size and shape of the target anatomy facilitates optimal tissue freezing and ablation of posterior nasal nerves. The expandable membranous structure may have an expanded diameter between approximately 3 mm and 12 mm in one radial axis, and may be configured such that the expanded diameter in one radial axis is different than another radial axis.

[0030] The probe shaft may be straight and rigid, or alternatively may be substantially malleable and configured for form shaping by the user. The probe shaft may be straight and rigid in the proximal region, and substantially malleable in the distal region

and configured for form shaping by the user.

[0031] The surgical probe may be configured with a camera and a light source disposed in the vicinity of the distal end of the probe shaft. The camera and light source may be configured to provide the surgeon with images of the nasal anatomy in order to identify anatomical landmarks for guiding the surgical placement of the distal spring-like structure against the lateral nasal wall proximate to the target posterior nasal nerve. The camera and light source may be further configured to image tissue freezing to provide the surgeon with visual feedback on the progress of a cryo-ablation of the nasal tissue innervated by posterior nasal nerves.

[0032] The surgical probe may also be configured with at least one temperature sensor disposed in the vicinity of the distal end. The temperature sensor may be configured to sense a temperature indicative of cryogen evaporation temperature, or a temperature indicative of a tissue temperature of surgical interest. Signals from the at least one temperature sensor may be used to servo-control the flow of cryogen in order to control a tissue temperature or to control the evaporation temperature. A temperature sensor may also be used in an informational display, or for system alarms or interlocks.

[0033] The surgical probe may be configured to automatically adjust the flow rate of liquid cryogen in response to one or more of the following parameters: evaporator temperature, evaporator pressure, tissue temperature, evaporator exhaust gas temperature, or elapsed cryogen flow time. The flow rate may be adjusted in a continuous analog manner, or by an alternating on/off flow modulation.

[0034] Another aspect of this invention is a method for treating rhinitis by ablating posterior nasal nerves associated with a middle or inferior nasal turbinate. The method may comprise inserting the distal end of a surgical probe configured for cryoneurolysis into a nostril of a patient with the surgical probe comprising a hollow probe shaft that is, e.g., substantially rigid. The surgical hand piece disposed on the proximal end of the probe shaft may comprise a liquid cryogen reservoir and, e.g., a user actuated liquid cryogen flow control valve. A cryogen liquid evaporator comprising, e.g., a spring-like structure configured as a liquid cryogen evaporator, may be disposed on the distal end of the probe shaft. The distal spring-like structure may be positioned against the lateral nasal wall proximate to a target posterior nasal nerve and then a flow of liquid cryogen to the spring-like structure may be activated for a period of time sufficient to cryo-ablate a target area in the nose containing posterior nasal nerves.

[0035] The method may further involve the targeting of at least one additional

posterior nasal nerve, either within the ipsilateral nasal cavity, or a posterior nasal nerve in a contralateral nasal cavity.

[0036] The method may comprise the use of a surgical probe which has an expandable membranous or non-membranous structure that encompasses the distal spring-like structure and which is configured as an expandable liquid cryogen evaporation chamber. The expandable membranous structure may be configured to be a predetermined size and shape that matches the size and shape of the nasal wall anatomy proximate to the target posterior nasal nerve. The surgical probe may be configured so the expandable membranous structure expands to its predetermined size and shape in response to liquid cryogen evaporation within.

[0037] The method may comprise controlling the flow of the liquid cryogen into the evaporation chamber based on at least one predetermined parameter, which may comprise one or more of the following parameters: cryogenic liquid flow rate, cryogenic liquid flow elapsed time, cryogenic liquid evaporation pressure, cryogenic liquid evaporation temperature, cryogenic gas exhaust temperature, visual determination of tissue freezing, ultrasonic determination of tissue freezing, or the volume of cryogenic liquid supplied by the cryogenic liquid reservoir.

[0038] The method may comprise determining the location of the target posterior nasal nerve, which may involve one or more of the following targeting techniques: endoscopic determination based on the nasal anatomical landmarks, electrical neuro-stimulation of the target posterior nasal nerve while observing the physiological response to the stimulation, electrical neuro-blockade, while observing the physiological response to the blockade, or identification of the artery associated with the target posterior nasal nerve using, e.g., ultrasonic or optical doppler flow techniques.

[0039] Yet another aspect comprises an embodiment of a surgical probe which is configured for ablation where the surgical probe comprises a surgical probe shaft comprising an elongated structure with a distal end and a proximal end, an expandable structure attached to the distal end of the probe shaft, the expandable structure having a deflated configuration and an expanded configuration, a member attached to the distal end and extending within the expandable structure such that the member is unattached to an interior of the expandable structure, wherein the member defines a flattened shape which is sized for placement against a lateral nasal wall proximate to a posterior nasal nerve, and a lumen in fluid communication with the interior of the expandable structure.

[0040] In use, such a surgical probe may be used for treating a tissue region within

a nasal cavity, generally comprising advancing a distal end of a surgical probe shaft through the nasal cavity and into proximity of the tissue region having a posterior nasal nerve associated with a middle or inferior nasal turbinate, introducing a cryogenic liquid into an expandable structure attached to the distal end of the probe shaft such that the expandable structure inflates from a deflated configuration into an expanded configuration against the tissue region, positioning a member relative to the tissue region, wherein the member is attached to the distal end of the probe shaft and extends within the expandable structure such that the member is unattached to an interior of the expandable structure, and wherein the member defines a flattened shape which is sized for placement against the tissue region proximate to the posterior nasal nerve, and maintaining the member against the tissue region until the posterior nasal nerve is cryogenically ablated.

[0041] One aspect of the invention is a cryo-surgical probe apparatus for ablation of PNN function comprising a handle at the proximal end, a probe shaft with a spatula shaped cryo-ablation element mounted in vicinity of the distal end of the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo-ablation element, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of nasal mucosa containing PNN according to the surgical methods disclosed here within.

[0042] One embodiment of this invention is a cryo-surgical probe apparatus for ablation of nasal mucosa innervated by PNN comprise a handle at the proximal end, a probe shaft with a bullet shaped cryo-ablation element mounted in vicinity of the distal end of the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo-ablation element, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of PNN according to the surgical methods disclosed here within.

[0043] Another embodiment of this invention is a cryo-surgical probe apparatus for ablation of PNN function comprising a handle at the proximal end, a probe shaft with a bullet shaped cryo-ablation element mounted in vicinity of the distal end of the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo-ablation element, wherein the probe shaft is configured with user operable deflectable distal segment, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of PNN according to the surgical methods disclosed here within.

[0044] Another embodiment of this invention is a cryo-surgical probe apparatus for

ablation of PNN comprising a handle at the proximal end, a probe shaft with a cylindrically shaped cryo-ablation element mounted in vicinity of the distal end of the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo-ablation element, wherein the cryo-ablation element comprises a linear segmented cryo-ablation element, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of PNN according to the surgical methods disclosed here within.

[0045] Another embodiment of this invention is a cryo-surgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a cylindrically shaped cryo-ablation element mounted in vicinity of the distal end of the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo-ablation element, wherein the cryo-ablation element comprises a semi-circular cryo-ablation element, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of target tissue containing PNN according to the surgical methods disclosed here within.

[0046] Another embodiment of this invention is a cryo-surgical probe apparatus for ablation of PNN function comprising a handle at the proximal end, a probe shaft with a cylindrically shaped cryo-ablation element mounted in vicinity of the distal end of the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo-ablation element, wherein the cryo-ablation element comprises a spiraled cryo-ablation element, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of target nasal tissue containing PNN according to the surgical methods disclosed here within.

[0047] Another embodiment of this invention is a cryo-surgical probe apparatus for ablation of PNN comprising a proximal end, a probe shaft with a cryo-ablation element comprising a balloon mounted in vicinity of the distal end of the shaft, whereby the proximal end is configured for receiving a cryogen from a cryogen source with the cryogen source comprising a means controlling the flow of the cryogen to the cryo-ablation element, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of PNN according to the surgical methods disclosed here within.

[0048] Another embodiment of this invention is a cryo-surgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a cylindrically shaped cryo-ablation element comprising a balloon mounted in vicinity of the distal end of

the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo- ablation element, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of target nasal tissue containing PNN according to the surgical methods disclosed here within.

[0049] Another embodiment of this invention is a cryo-surgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a cylindrically shaped cryo-ablation element mounted comprising a balloon with two lateral chambers disposed in the vicinity of the distal end of the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo-ablation element, wherein one chamber of the balloon is configured as a cryogen expansion chamber, and the second chamber is configured as a thermal insulation chamber, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of PNN according to the surgical methods disclosed here within.

[0050] Another embodiment of this invention is a cryo-surgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a "T" shaped cryo-ablation element comprising a balloon mounted in vicinity of the distal end of the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo-ablation element, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of PNN according to the surgical methods disclosed here within.

[0051] Another embodiment of this invention is a cryo-surgical probe apparatus for ablation of PNN function comprising a handle at the proximal end, a probe shaft with a "I" shaped cryo-ablation element comprising a balloon mounted in vicinity of the distal end of the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo-ablation element, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of PNN according to the surgical methods disclosed here within.

[0052] Another embodiment of this invention is a cryo-surgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a cryo-ablation element mounted in vicinity of the distal end of the shaft, whereby the handle is configured for housing a cryogen source, and controlling the flow of the cryogen to the cryo-ablation element, wherein a suction means associated with the cryo-ablation element is configured for stabilizing the position of the cryo-ablation element against the target

tissue, and the geometric parameters of the probe shaft and cryo-ablation element are optimally configured for cryo-ablation of PNN according to the surgical methods disclosed here within.

[0053] One aspect of this is a method for cryo-surgical ablation of PNN comprising placing a film of oil or gel on the surface of a cryo-ablation element, then pressing the cryo-ablation element against the lateral wall of a nasal cavity adjacent to a PNN, then ablating the function of the PNN with the cryo-ablation element, whereby the oil or gel prevents frozen nasal tissue from adhering to the cryo-ablation element.

[0054] In another aspect of this invention is an electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector in the vicinity of the handle configured to connect the RF ablation element to a source of radiofrequency energy, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN function according to the surgical methods disclosed here within.

[0055] One embodiment of this invention is an electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector disposed in the vicinity of the handle configured to connect the RF ablation element to a source of radiofrequency energy, and a fluid connector disposed in the vicinity of the handle to connect at least one fluid port associated with the RF ablation element with a source of pressurized liquid, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within.

[0056] Another embodiment of this invention is an electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector disposed in the vicinity of the handle configured to connect the RF ablation element to a source of radiofrequency energy, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within, wherein the RF ablation element comprises a

monopolar electrosurgical configuration comprising one or more electrodes.

[0057] Another embodiment of this invention is an electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector disposed in the vicinity of the handle configured to connect the RF ablation element to a source of radiofrequency energy, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within, wherein the RF ablation element comprises a bi-polar electrosurgical configuration comprising two or more electrodes.

[0058] Another embodiment of this invention is an electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector disposed in the vicinity of the handle configured to connect the RF ablation element to a source of radiofrequency energy, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within, wherein the RF ablation element is disposed in the vicinity of the distal end of the shaft on a cylindrical, "J" shaped, "U" shaped or "T" shaped structure.

[0059] Another embodiment of this invention is an electrosurgical probe apparatus for ablation of PNN function comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector disposed in the vicinity of the handle configured to connect the RF ablation element to a source of radiofrequency energy, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within, wherein the RF ablation element is configured in a lateral or radial arrangement.

[0060] Another embodiment of this invention is n electrosurgical probe apparatus for ablation of PNN function comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector disposed in the vicinity of the handle configured to connect the RF ablation element to a

source of radiofrequency energy, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within, wherein the RF ablation element comprises a circular array of domed electrodes disposed on a flat electrically insulative surface, with the domed electrodes optionally associated with a fluid irrigation port.

[0061] Another embodiment of this invention is an electrosurgical probe for ablation of PNN function comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector disposed in the vicinity of the handle configured to connect the RF ablation element to a source of radiofrequency energy, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within, wherein the RF ablation element comprises a linear array of domed electrodes disposed on a flat electrically insulative surface, with the domed electrodes optionally associated with a fluid irrigation port, and a needle configured for injecting a liquid into a sub-mucosal space.

[0062] Another embodiment of this invention is an electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector disposed in the vicinity of the handle configured to connect the RF ablation element to a source of radiofrequency energy, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within, wherein the RF ablation element comprises at least one needle configured for interstitial RF ablation.

[0063] Another embodiment of this invention is an electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft comprising a distal and proximal end, and an integrated circuit comprising an RF generator disposed in the vicinity of the handle and an RF ablation element disposed in the vicinity of the distal end of the shaft, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within.

[0064] In another aspect of this invention is an ultrasonic energy emitting probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with

an ultrasonic energy ablation element comprising at least one ultrasonic energy emitter mounted in the vicinity of the distal end of the shaft, an electrical connector in the vicinity of the handle configured to connect the ultrasonic energy emitter to an ultrasonic energy generator, whereby the geometric parameters of the probe shaft and ultrasonic energy emitter are optimally configured for ultrasonic energy ablation of PNN according to the surgical methods disclosed here within.

[0065] In another embodiment of this invention is an ultrasonic energy emitting probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with an ultrasonic energy ablation element comprising at least one ultrasonic energy emitter mounted in the vicinity of the distal end of the shaft, an electrical connector in the vicinity of the handle configured to connect the ultrasonic energy emitter to an ultrasonic energy generator, at least one fluid path in communication between at least one fluid connector in the vicinity of the handle and the ultrasonic energy emitter configured to cool the ultrasonic energy emitter during ultrasonic energy emission, whereby the geometric parameters of the probe shaft and ultrasonic energy emitter are optimally configured for ultrasonic energy ablation of PNN according to the surgical methods disclosed here within.

BRIEF DESCRIPTION OF THE DRAWINGS

[0066] Figure 1 is an internal lateral view of the nasal canal showing the relevant nasal anatomy and the targeted region of the lateral nasal wall for cryo-ablation of posterior nasal nerve function.

[0067] Figure 2 is a schematic illustration of a surgical probe configured for cryo-ablation of posterior nasal nerve function for the treatment of rhinitis.

[0068] Figure 3A is a view of the distal end of a surgical probe shaft with the spring-like structure coaxial to the surgical probe shaft.

[0069] Figure 3B is a view of the distal end of a surgical probe shaft with the spring-like structure comprising a lateral curve in a tangential relationship with the surgical probe shaft.

[0070] Figure 3C is a view of the distal end of a surgical probe shaft with the spring-like structure comprising a loop or a continuous structure.

[0071] Figure 4A is a side view of the distal end of the surgical probe shaft with the spring-like structure coaxial to the surgical probe shaft encompassed by an expandable membranous structure in an unexpanded state.

[0072] Figure 4B is a view of the distal end of the surgical probe shaft with the

spring-like structure coaxial to the surgical probe shaft encompassed by an expandable membranous structure in an expanded state.

[0073] Figure 5A is a side view of the distal end of a surgical probe shaft with the spring-like structure comprising a lateral curve in a tangential relationship with the surgical probe shaft encompassed by an expandable membranous structure in an unexpanded state.

[0074] Figure 5B is a view of the distal end of the surgical probe shaft with the spring-like structure comprising a lateral curve in a tangential relationship with the surgical probe shaft encompassed by an expandable membranous structure in an expanded state.

[0075] Figure 5C is a side view that is 90 degrees from the first side view of Figure 5A.

[0076] Figure 5D is a view that is 90 degrees from the first side view of Figure 5B.

[0077] Figure 6A is a view of the distal end of a surgical probe shaft with the spring-like structure comprising a loop encompassed by an expandable membranous structure in an unexpanded state.

[0078] Figure 6B is a view of the distal end of the surgical probe shaft with the spring-like structure comprising a loop encompassed by an expandable membranous structure in an expanded state.

[0079] Figure 6C is a view that is 90 degrees from the first side view of Figure 6A.

[0080] Figure 6D is a view that is 90 degrees from the first side view of Figure 6B.

[0081] Figure 6E is a view of the distal end of a surgical probe shaft with the structure comprising a continuous member encompassed by a non-distensible structure.

[0082] Figure 6F is a view that is 90 degrees from the first side view of Figure 6E.

[0083] Figure 6G is a view of the embodiment of Figure 6E when pressed longitudinally against a tissue region for treatment.

[0084] Figure 6H is a view of the embodiment of Figure 6E when pressed laterally against a tissue region for treatment.

[0085] Figure 7 is a cross sectional schematic view of the distal end of a surgical probe where the spring-like structure is configured as a closed cryogenic liquid evaporator.

[0086] Figure 8 is a cross sectional schematic view of the distal end of a surgical probe where the spring-like structure is encompassed by an expandable membranous structure with the membranous structure configured as a liquid cryogen evaporation chamber.

[0087] Figure 9 is an internal lateral view of the nasal canal showing a surgical probe with the spring-like structure pressed against a lateral nasal wall in position for a

cryo-ablation of a posterior nasal nerve function.

[0088] Figure 10A is a front view illustration the distal end of a paddle balloon ablation probe with its expandable structure in its un-expanded state. Figure 10B is a side view illustration of Figure 10A. Figure 10C is a front view illustration of the distal end of a paddle balloon ablation probe with its expandable structure in its expanded state. Figure 10D is a side view illustration of Figure 10C.

[0089] Figure 11A is a front view illustration of the distal end of a paddle porous balloon ablation probe. Figure 11B is a side view illustration of Figure 11A.

[0090] Figure 12A is a front view illustration the distal end of a paddle double balloon ablation probe with its expandable structure in its un-expanded state. Figure 12B is a side view illustration of Figure 12A. Figure 12C is a front view illustration of the distal end of a paddle double balloon ablation probe with its expandable structure in its expanded state. Figure 12D is a side view illustration of Figure 12C.

[0091] Figure 13A through 13D are schematic sectional coronal illustrations of a nasal cavity depicting the surgical access to a middle meatus and cryogenic ablation of a sphenopalatine brand and foramen.

[0092] Figure 14A is an internal lateral view of the nasal cavity showing an anatomical target for ablation of parasympathetic nervous function of the middle turbinate. Figure 14B is an internal lateral view of the nasal cavity showing an anatomical target for ablation of posterior nasal nerves. Figure 14C is an internal lateral view of the nasal cavity showing an anatomical target for ablation of posterior nasal nerves using an intermittent line of ablation. Figure 14D is an internal lateral view of the nasal cavity showing an anatomical target for ablation of posterior nasal nerves.

[0093] Figure 15A is a schematic illustration of a cryosurgical probe configured for cryo-ablation of posterior nasal nerves comprising a spatula shaped cryosurgical tip. Figure 15B defines a section view of the cryosurgical probe's cryosurgical tip. Figure 15C is a cross sectional view of the cryosurgical probe's tip.

[0094] Figure 16A is a schematic illustration of the distal end of an alternative embodiment of the cryosurgical probe comprising a bullet shaped cryo-ablation element at the distal end of an angled shaft. Figure 16B is a schematic illustration of the distal end of an alternative embodiment of the cryosurgical probe comprising a bullet shaped cryo-ablation element at the distal end of a user deflectable probe shaft. Figure 16C is a schematic illustration of the distal end of an alternative embodiment of the cryosurgical probe where the cryo-ablation element is configured for producing multiple discrete cryo-

ablations simultaneously.

[0095] Figure 17A is a schematic illustration of the distal end of an alternative embodiment of the cryosurgical probe comprising a semi-circular cryo-ablation element. Figure 17B is a schematic illustration of the ablation morphology resulting from use of the semi-circular cryo-ablation element. Figure 17C is a schematic illustration of the distal end of an alternative embodiment of the cryosurgical probe comprising a spiraled cryo-ablation element.

[0096] Figure 18A is a schematic illustration of cryo-ablation balloon probe configured for cryo-ablation of posterior nasal nerves. Figure 18B is a schematic illustration of the distal end of the cryo-ablation balloon probe detailing the geometry of the cryo-ablation balloon. Figure 18C is a schematic illustration of an alternate embodiment of the cryo-ablation balloon probe comprising an insulating chamber within the cryo balloon structure. Figure 18D is a schematic illustration of the distal end of an alternative embodiment of the cryo-ablation balloon probe comprising a tee shaped cryo-ablation balloon. Figure 18E is a schematic illustration of the distal end of an alternative embodiment of the cryo-ablation balloon probe comprising a "J" shaped cryo-ablation balloon.

[0097] Figure 19A is a schematic illustration of the distal end of an alternate embodiment a cryo-ablation probe comprising a cryo-ablation element with suction stabilization. Figure 19B is a cross sectional view of the distal end of the alternative embodiment showing the configuration of the cryo-ablation element and the suction stabilization means.

[0098] Figure 20A is a schematic illustration of a radiofrequency (RF) ablation probe configured for ablation of the posterior nasal nerves with a bi-polar ring electrode ablation element on an "J" shaped distal probe shaft. Figure 20B is a schematic illustration of the distal end of an alternative embodiment of an RF ablation probe comprising a bi-polar ring electrode ablation element on an "J" shaped distal probe shaft. Figure 20C is a schematic illustration of an alternative embodiment of the distal end of an RF ablation probe comprising a bi-polar electrode ablation element on an "J" shaped distal probe shaft with the electrodes disposed in a lateral array. Figure 20D is a schematic illustration of an alternative embodiment of the distal end of an RF ablation probe comprising a bi-polar electrode ablation element on a "U" shaped distal probe shaft with the electrodes disposed in a lateral array. Figure 20E is a schematic illustration of the distal end of an alternative embodiment of an RF ablation probe comprising a bi-polar electrode ablation element on a

user deployable "T" shaped structure.

[0099] Figure 21A is a schematic illustration of an RF ablation probe configured for ablation of posterior nasal nerves comprising an array of RF ablation electrodes disposed on a planar surface and a fluid irrigation means associated with the electrodes. Figure 21B is a schematic illustration of the distal end of the RF ablation probe showing the arrangement of the ablation electrodes and the associated fluid irrigation means.

[0100] Figure 22A is a schematic illustration of an alternative RF ablation probe comprising an electrode array disposed on a planar surface; a fluid irrigation means associated electrodes, and a deployable needle configured for injecting a liquid into a sub-mucosal space. Figure 22B is a schematic illustration of the distal end of the alternative embodiment RF ablation probe showing the arrangement of the ablation electrodes and the associated fluid irrigation means. Figure 22C is a schematic illustration of the distal end of the alternative embodiment RF ablation probe showing the arrangement of the ablation electrodes and the associated fluid irrigation means with the needle deployed.

[0101] Figure 23A is a schematic illustration of an RF interstitial needle ablation probe configured for interstitial ablation of the parasympathetic nervous function of a nasal turbinate(s). Figure 23B is a schematic illustration of the distal end of the RF interstitial needle ablation probe.

[0102] Figure 24A is a cross sectional view of the distal end of an RF interstitial needle ablation comprising a deployable and retractable array of RF ablation needles configured for lateral deployment showing the needle array retracted. Figure 24B is a cross sectional view of the distal end of an RF interstitial needle ablation comprising a deployable and retractable array of RF ablation needles configured for lateral deployment showing the needle array deployed. Figure 24C is a cross sectional view of the distal end of an RF interstitial needle ablation comprising a deployable and retractable array of RF ablation needles configured for axial deployment showing the needle array retracted. Figure 24D is a cross sectional view of the distal end of an RF interstitial needle ablation comprising a deployable and retractable array of RF ablation needles configured for axial deployment showing the needle array deployed.

[0103] Figure 25A is a schematic illustration of an integrated flexible circuit configured for use with an RF ablation probe comprising an RF energy source and control circuits at one end, and an RF ablation electrode array at the opposite end. Figure 25B is a schematic illustration of the RF ablation electrode array of the flexible circuit mounted on the distal shaft of an RF ablation probe that is configured for ablation of posterior nasal

nerves.

[0104] Figure 26A is an in situ schematic illustration of the RF ablation probe depicted in Figures 22A through 22C showing the needle injecting an anesthetic into the sub-mucosal space prior to an RF ablation of posterior nasal nerves. Figure 26B is an in situ schematic illustration of the resulting ablation.

[0105] Figure 27 is an in situ schematic illustration of an ablation of posterior nasal nerves using the RF interstitial needle ablation probe depicted in Figures 23A and 23B.

[0106] Figure 28 is an in situ illustration of the ablation of the posterior nasal nerves at the ablation target depicted in Figure 14D.

[0107] Figure 29 is an in situ illustration of the ablation of the posterior nasal nerves at the ablation target depicted in Figure 24A.

[0108] Figure 30 is an in situ illustration of the ablation of the posterior nasal nerves at the ablation target area depicted in Figure 14B.

[0109] Figure 31A is a schematic illustration of the ablation probe and an insulated probe guide configured to protect the nasal septum from thermal injury during an ablation of the posterior nasal nerves. Figure 31B is an in situ illustration of an ablation probe configured for ablation of the posterior nasal nerves which comprises an insulating structure configured to protect the nasal septum. Figure 31C is an in situ illustration of an ablation probe configured for ablation of the parasympathetic nervous function of posterior nasal nerves which comprises a space creating structure configured to protect the nasal septum.

DETAILED DESCRIPTION OF THE INVENTION

[0110] Figure 1 is an internal view of the nasal cavity showing the relevant nasal anatomy. Shown for orientation is the lateral nasal cavity wall 4, the nose 1, nostril 2, and the upper lip 3. The superior turbinate 5, middle turbinate 6, and inferior turbinate 7 are depicted along with the associated nerves relevant to this invention shown in dashed lines. The posterior nasal nerves 10,11 and 12 are responsible for the parasympathetic control of the nasal mucosa including turbinates. These posterior nasal nerves (PNNs) originate from the sphenopalatine ganglion. At times other accessory posterior nasal nerves (APNNs) may originate from the greater palatine nerve or from the bony plate underneath the mucosa.

[0111] Figure 2 is a schematic illustration of surgical probe 29, which is configured for cryo-ablation of posterior nasal nerve function for the treatment of rhinitis. Surgical probe 29 comprises: probe shaft 20, with shaft distal end 21 and shaft proximal end 27; surgical hand piece 23, e.g., with pistol grip 24, finger grip 25, pistol trigger flow control

valve actuator 26, button flow control flow valve actuator 22, finger grip barrel 28, cryogen reservoir housing 29; and distal end effector 30 (e.g., spring-like structure) with end effector proximal end 31, and end effector distal end 32. Surgical probe shaft 20 is between, e.g., approximately 1 mm and 4 mm in diameter, and between, e.g., approximately 4 cm and 10 cm in length. Surgical probe shaft 20 may be fabricated from various biocompatible materials such as a surgical grade stainless steel hypodermic tube, or may alternatively be fabricated from a polymeric extrusion. Surgical probe shaft 20 comprises at least one liquid cryogen delivery channel between shaft distal end 21 and shaft proximal end 27. Probe shaft 20 is substantially rigid in one variation, and may also be configured to be malleable and shape formable by the user. The distal end effector 30 is shown having multiple variations described herein and may be optionally interchanged depending upon which particular embodiment is utilized by a practitioner.

[0112] Although probe shaft 20 is depicted to be straight, it is well within the scope of this invention probe shaft 20 may be manufactured with at least one curved segment. Surgical hand piece 23 is disposed on the proximal end 22 of probe shaft 20. Surgical hand piece 23 comprises a liquid cryogen reservoir, not shown, that may be conventionally supplied with liquid cryogen and configured for a single patient use. Alternatively, surgical hand piece 23 may be configured for use with a user replaceable liquid cryogen reservoir in the form of a cartridge. Liquid cryogen cartridges are readily commercially available from many sources. In yet another alternative, a reservoir separate from the device may be fluidly coupled to the hand piece 23. Surgical hand piece 23 may further comprise a liquid cryogen flow control valve, not shown, that may be disposed in fluidic communication with the liquid cryogen reservoir and the liquid cryogen channel in probe shaft 20.

[0113] Surgical device 29 may be configured to be held like a pistol by the surgeon or practitioner using pistol grip 24, or the surgeon or practitioner may hold surgical device 29 like a writing utensil using finger grips 25, with finger grip barrel 28 residing between the thumb and index finger of the surgeon. Surgical device 29 may be configured with, e.g., two or more liquid cryogen flow control valve actuators comprising pistol trigger liquid cryogen flow control actuator 26, which may be used to control the flow of liquid cryogen when the surgeon holds surgical device 29 using pistol grip 24. Liquid cryogen flow control actuator button 22 may be used to control the flow of liquid cryogen when the surgeon holds surgical device 29 by finger grips 25. Probe shaft 20 may be configured to be rotatably coupled to the surgical device 29 to facilitate positioning of distal end effector 30 (e.g., spring-like structure) without having to rotate the surgical device 29 excessively.

Distal end effector 30 (e.g., spring–like structure) , with end effector proximal end 31, and end effector distal end 32 is disposed on the distal end 21 of probe shaft 20 as shown. Distal end effector 30 (e.g., spring–like structure) is configured as a liquid cryogen evaporator, and is configured to be pressed against the lateral nasal wall within the cul-de-sac described above for cryo-ablation of at least one posterior nasal nerve. The construction and the function of distal end effector 30 (e.g., spring–like structure) , and alternative embodiments are described in detail below.

[0114] Surgical device 29 may be configured as a simple mechanical device that is void of electronics as shown. Alternatively, surgical device 29 may be configured with at least one electronic function. In one embodiment, a temperature sensor may be disposed in the vicinity of distal end effector 30 (e.g., spring–like structure) and used to measure, display, or control a temperature of surgical interest. A temperature sensor may be configured to sense the temperature of evaporating cryogen within distal end effector 30 (e.g., spring–like structure) . A temperature sensor may also be configured to sense the temperature of a tissue of surgical interest. The liquid cryogen control valve 22 may also optionally comprise a servo mechanism configured to respond to a sensed temperature to modulate the flow of cryogen in order to control a desired surgical parameter.

[0115] In addition to a temperature sensing capability, surgical device 29 may be configured with a camera and/or a light source disposed in the vicinity of distal end 21 of probe shaft 20. The camera and light source may be used, e.g., to identify nasal anatomical landmarks, and may be used to guide the placement of distal end effector 30 (e.g., spring–like structure) against the lateral nasal wall for a cryo-ablation of the function of a target posterior nasal nerve. An ultrasonic or optical doppler flow sensor may also be disposed in the vicinity of distal end 21 of probe shaft 20 and be used, e.g., to locate the major artery associated with the target posterior nasal nerve, as a means for locating the target posterior nasal nerve. In addition, one or more electrodes may be disposed in the vicinity of distal end 21 of probe shaft 20, which may be used for electrical stimulation or electrical blockade of the function of a target posterior nasal nerve using the observed physiological response to the stimulation or blockade to confirm correct surgical positioning of distal end effector 30 (e.g., spring–like structure) prior to a cryo-ablation, and/or to confirm effectiveness of a cryo-ablation by the determination of a change in the physiological response from before and after a cryo-ablation.

[0116] Any number of temperature sensing, endoscopic instruments, servo controlled cryogen control valves, ultrasonic or optical doppler flow detection, and/or

electrical nervous stimulation and blockade mechanisms may be optionally incorporated into the devices described herein. Also, providing a surgical probe as described here with a liquid cryogen reservoir that is external to the probe hand piece is also within the scope of this invention.

[0117] Figure 3A is a schematic illustration of an alternative end effector embodiment, which comprises spring-like structure 39 which is configured in a coaxial arrangement with probe shaft 20. Figure 3B is a schematic illustration of the distal end of an alternative embodiment surgical probe 43 which comprises spring-like structure 44, which is configured with a lateral curve as shown with proximal end 46 in a tangential relationship with the distal end 21 of probe shaft 20. Figure 3C is a schematic illustration of the distal end of an alternative embodiment surgical probe 48, with spring-like structure 49 configured as a loop structure as shown, with both ends of spring-like structure 49 in a substantially tangential relationship with distal end 21 of probe shaft 20. The three alternate spring-like structure embodiments 39, 44, and 49 depicted in Figures 3A, 3B, and 3C are configured as liquid cryogen evaporators, where the outer surface of each spring-like structure may achieve a temperature between, e.g., approximately -20 Deg. C to -90 Deg. C., in response to liquid cryogen evaporation within. As previously described, the end effector described here may be optionally replaced by any of the other end effector embodiments described herein.

[0118] Spring-like structures 39, 44, and 49 are substantially flexible and are configured to conform to the morphology of a lateral nasal wall proximate to a target posterior nasal nerve with a substantially uniform contact pressure. Spring-like structures 39, 44, and 49 may be configured to be partially malleable and form shapeable by the user, while retaining a spring-like resilience during use. Spring-like structures 39 and 44 comprise distal end 40 and 45 respectively, and proximal end 41 and 46 respectively. Spring-like structures 39 and 44 comprise end cap 38, which functions as a pressure bulkhead defining the distal end of the liquid cryogen evaporator that resides within, which is described in detail below. Spring-like structures 39, 44, and 49 comprise a tightly coiled wire that forms a central chamber, and an outer surface. A thin polymeric liner is disposed on the inner surface of the central chamber and functions to contain the evaporating cryogen within the central chamber. Cryogen is introduced into the central chamber through a liquid cryogen supply line, which runs through probe shaft 20, and is in fluidic communication with the liquid cryogen flow control valve and the liquid cryogen reservoir previously described. Evaporated cryogen gas may be vented into the room out of the

central chamber, through probe shaft 20, then out of a vent port disposed in the vicinity of proximal end 22 of probe shaft 20, not shown, or disposed in the surgical hand piece, also not shown. The construction and function of the disclosed embodiments of the spring-like structures is described in detail below.

[0119] Figure 4A is a schematic illustration of a side view of the distal end of alternative embodiment surgical probe 55 comprising expandable membranous structure 58 encompassing spring-like structure 57 in an un-expanded state. Figure 4B is a schematic illustration of a side view of the distal end of surgical probe 55 with expandable structure or expandable membranous structure in an expanded state. In the depicted embodiment, expandable membranous structure 58 is configured as a liquid cryogen evaporation chamber. Liquid cryogen is introduced into the interior of expandable membranous structure 58 from spring-like structure 57. Surgical probe 55 is configured so expandable membranous structure 58 expands to a predetermined size and shape in response to liquid cryogen evaporation within. While structure 58 may be expandable to a predetermined size and shape, the structure 58 may be comprised of a non-distensible material while in other variations, structure 58 may alternatively be comprised of a distensible material which allows for the expanded size and shape to vary depending upon the volume of cryogen introduced. Surgical probe 55 is configured such that the outer surface of expandable membranous structure 58 will be between approximately -20 Deg. C to -90 Deg. C. during cryogen evaporation within. The expanded size or shape of expendable membranous structure 58 is configured to substantially contact the surface of the cul-de-sac (element 13 in Figure 1 which indicates the region of tissue region defined and surrounded by the middle nasal turbinate, inferior nasal turbinate, and lateral wall) when pressed against the lateral nasal wall be the surgeon. Expandable membranous structure 58 may be configured to form a hollow bulbous structure in its expanded state, and comprises a single ostium 59 configured for adhesive bonding to distal end 62 of probe shaft 56 using adhesive bond 60. Cryogen exhaust vent 61 comprises at least one fenestration in distal end 62 of probe shaft 40, which is in fluidic communication with a proximal vent port, not shown, and the room. A pressure relief valve, not shown, may be disposed in the fluid path between the interior of expandable membranous structure 58 and the room to control the pressure within expandable membranous structure 58, and the degree of expansion during liquid cryogen evaporation. The construction and functionality of surgical probe embodiments comprising an expandable membranous structure are described in detail below.

[0120] Figure 5A is a schematic illustration of a side view of the distal end of

alternate embodiment of surgical probe 68 comprising expandable membranous structure 69 encompassing spring-like structure 70. Spring-like structure 70 is configured with a lateral bend as depicted. Expandable membranous structure 69 is depicted in its un-expanded state. Figure 5B is a schematic illustration of the same side view in Figure 5A of alternate embodiment surgical probe 68 with expandable membranous structure 69 in its expandable state. Figure 5C is a schematic side view illustration taken at view A-A from Figure 5A. Figure 5D is a schematic side view illustration taken at view B-B from Figure 5B. Surgical probe 68 is configured with expandable membranous structure 69 functioning as a liquid cryogen evaporation chamber as depicted in Figures 4A and 4B. Liquid cryogen enters the interior of expandable membranous structure 69 from encompassed spring-like structure 70. Evaporated cryogen gas exits the interior of expandable membranous structure 69 through fenestration(s) 144 in distal end 143 of probe shaft 141 and exits surgical probe 68 proximally into the room. Spring-like structure 70 is configured to pre-tension membranous structure 69 in one radial axis to a greater extent than a second radial axis in a manner that causes expansion to be constrained in the radial axis with greatest pre-tensioning. In Figure 5A and 5B, spring-like structure 70 is configured to pre-tension expandable membranous structure 69 to a greater extent in the radial axis that is normal to the view axis. In Figure 5C and 5D, spring-like structure 70 is configured to pre-tension expandable membranous structure 69 to a greater extent in the radial axis that is parallel to the view axis. Figure 5A and Figure 5C depict surgical probe 68 with expandable membranous structure 69 in its un-expanded state. Figure 5B and 5D depict surgical probe 68 with expandable membranous structure 69 in its expanded state. Pre-tensioning of expandable membranous structure 69 provides a means for achieving a predetermined expanded shape for optimal matching of the morphology of the target area of the lateral nasal wall.

[0121] Figure 6A is a schematic illustration of a side view of the distal end of alternate embodiment of surgical probe 79 comprising expandable membranous structure 80 encompassing spring-like structure 82. Spring-like structure 82 is configured as a loop structure as depicted. Expandable membranous structure 80 is depicted in its un-expanded state. Figure 6B is a schematic illustration of the same side view in Figure 6A of alternate embodiment surgical probe 79 with its expandable membranous structure 80 in its expandable state. Figure 6C is a schematic side view illustration taken at view C-C from Figure 6A. Figure 6D is a schematic side view illustration taken at view D-D from Figure 6B. Surgical probe 79 is configured with expandable membranous structure 80 functioning

as a liquid cryogen evaporation chamber as depicted in Figures 4A and 4B. Liquid cryogen enters the interior of expandable membranous structure 80 from encompassed spring-like structure 82. Evaporated cryogen gas exits the interior of expandable membranous structure 69 through fenestration(s) 147 in distal end 146 of probe shaft 145 and exits surgical probe 79 proximally into the room. Spring-like structure 82 is configured to pre-tension expandable membranous structure 80 in one radial axis to a greater extent than a second radial axis in a manner that causes expansion to be constrained in the radial axis with greatest pre-tensioning. In Figure 6A and 6B, spring-like structure 82 is configured to pre-tension membranous structure 80 to a greater extent in the radial axis that is normal to the view axis. In Figure 6C and 6D, spring-like structure 82 is configured to pre-tension expandable membranous structure 80 to a greater extent in the radial axis that is parallel to the view axis. Figure 6A and Figure 6C depict surgical probe 79 with expandable membranous structure 80 in its un-expanded state. Figure 6B and 6D depict surgical probe 79 with expandable membranous structure 80 in its expanded state. Pre-tensioning of expandable membranous structure 80 provides a means for achieving a predetermined expanded shape for optimal matching of the morphology of the target area of the lateral nasal wall.

[0122] Another alternative embodiment is illustrated in the side view of Figure 6E which shows a structure or member 83 which is formed into a looped and elongated structure having arcuate edges for presenting an atraumatic surface. Rather than being formed as a spring like structure, the structure 83 may be formed of a relatively rigid wire or member instead which maintains its configuration when pressed against a tissue surface. Structure 83 may form a continuous structure which defines an opening there through such as a looped or elongated and looped member which is open through the loop. The structure 83 may be contained entirely within the expandable structure 81 which may be formed to have a predefined shape which is distensible or non-distensible when inflated by the cryogen. Moreover, the expandable structure 81 may be formed to surround the structure 83 entirely without being supported by or attached to the structure 83 itself. Such a structure 83 may provide a configuration which presents a low-profile as the device is advanced into and through the nasal cavity and between the nasal turbinate tissues. Yet because of the relatively flattened shape and rigidity and integrity of the structure 83, the structure 83 may be used to manipulate, move, or otherwise part the tissues of the nasal cavity without having to rely upon the expandable structure 81. Additionally, the low-profile enables the structure 83 to be positioned desirably within the narrowed confines of

e.g., the cul-de-sac in proximity to the posterior nasal nerves (as shown by cul-de-sac 13 shown in Figure 1). When the expandable structure 81 is in its deflated state, it may form a flattened shape and when inflated, the expandable structure 81 may inflate into a configuration which remains unsupported by or attached to the structure 83. Because the structure 83 may be formed of a member which solid along its length, the cryogen may be introduced directly into the expandable structure 81 through a distal opening defined in the probe shaft 145.

[0123] Alternatively, structure 83 may be formed of a hollow tubular member which itself is formed into the continuous or looped shape. In such an embodiment, the cryogen may be optionally introduced through the hollow tubular member and dispersed within the interior of the expandable structure 81 through one or more openings which may be defined along the tubular member. In yet another alternative, the structure 83 may be formed into a flattened shape rather than a looped shape. In this configuration, the structure may be either solid or hollow such that that cryogen may be introduced through the structure and into the interior of the expandable structure 81 via one or more openings defined along the structure.

[0124] The structure 83 may extend and remain attached to the probe shaft 145, but the remainder of the structure 83 which extends within the expandable structure 81 may remain unattached or unconnected to any portion of the expandable structure 81. Hence, once the expandable structure 81 is inflated by the cryogen, the structure 83 may be adjusted in position or moved via manipulating the probe shaft 145 relative to the interior of the expandable structure 81 to enable the targeted positioning and cooling of the tissue region when in contact against the outer surface of the expandable structure 81. For instance, the structure 83 may press laterally upon a particular region of the underlying tissue to stretch or thin out the contacted tissue region to facilitate the cryogenic treatment. When the structure 83 is adjusted in position relative to the expandable structure 81, the expandable structure 81 may remain in a static position against a contacted tissue region allowing for limited repositioning of the structure 83 within.

[0125] Alternatively in other variations, the structure 83 may be attached along the interior of the expandable structure 81 partially at particular portions of the structure 83 or along the entirety of the structure 83. For instance, structure 83 may be attached, adhered, or otherwise coupled over its entirety to expandable structure 81 while in other variations, a distal portion of structure 83 may be attached, adhered, or otherwise coupled to a distal portion of the expandable structure 81 while in yet other variations, portions of the

structure 83 may be attached, adhered, or otherwise coupled to the expandable structure 81 along its side portions. Any of these variations may be optionally utilized depending upon the desired interaction and treatment between the structure 83, expandable structure 81, and underlying tissue region to be treated.

[0126] In yet another alternative variation, the lumen 84 for introducing the cryogen into the interior of the expandable structure 81 may be extended past the distal end of the probe shaft such that the cryogen is released within the interior at a more distal location. As shown, the cryogen lumen 84 may be supported along the structure 83, e.g., via a bar or member 85 which extends across the structure 83. This particular variation may allow for the cryogen to be introduced into the distal portion of the interior of the expandable member 81. Either this variation or the variation where the cryogen is released from an opening of the probe shaft may be utilized as desired.

[0127] Figure 6F shows a side view of the embodiment of Figure 6E illustrating how the structure 83 can be formed from a relatively flattened configuration relative to the inflated expandable structure 81. Because of the structural integrity of structure 83 and its relatively flattened profile, the structure 83 may provide for targeted treatment of the tissue when contacted by the device. Figure 6G shows the side view of the inflated expandable structure 81 when pressed in a longitudinal direction by its distal tip against the underlying tissue surface S. The relative strength of the structure 83 provides for the ability to press the device against the tissue surface such that the remainder of the expandable structure 81 may maintain its inflated configuration to potentially insulate the other surrounding tissue regions. Figure 6H likewise shows the device when the structure 83 is pressed laterally along its side against the tissue surface S such that the structure 83 lies flat. The contacted tissue region may be treated while the remainder of the surrounding tissue is potentially insulated by the expanded structure 81.

[0128] While the treatment end effector is designed for application along the tissue region defined by the cul-de-sac, the same end effector may be used in other regions of the nasal cavity as well. For instance, once the ablation is performed along the cul-de-sac, the end effector may then be moved to an adjacent tissue region, e.g., region immediately inferior to the cul-de-sac, and ablation treatment may be effected again. Additionally and/or alternatively, the end effector may also be used to further treat additional tissue regions, e.g., posterior aspect of the superior, middle, and/or inferior turbinates (any one, two, or all three regions). In either case, once the cul-de-sac has been ablated, the end effector may remain in place until the tissue region has thawed partially or completely

before the end effector is moved to the adjacent tissue region for further treatment.

[0129] Once the treatment is completed, or during treatment itself, the tissue region may be assessed utilizing any number of mechanisms. For instance, the tissue region may be visually assessed utilizing an imager during and/or after ablation.

[0130] As described herein, the device may be utilized with a temperature sensor, e.g., thermistor, thermocouple, etc., which may be mounted along the shaft, within or along the expandable structure 81, along the structure 83, etc., to monitor the temperature not only of the cryogen but also a temperature of the tissue region as well under treatment.

[0131] Additionally and/or alternatively, the expandable structure 81 may also be vibrated while maintaining the structure 83 against the interior of the expandable structure 81 and the tissue region utilizing any number of vibrational actuators which may be mounted anywhere along the device as appropriate. The vibrations may be applied directly against the tissue region or, e.g., through a layer of gel to facilitate the vibrational contact with the tissue.

[0132] Additionally and/or alternatively, other biocompatible agents may be used in combination with the cryogenic treatment. For instance, in one variation, an anesthetic may be applied to the tissue region to be treated prior to or during the cryogenic treatment. This and other alternative features described may be utilized not only with the variation shown and described in Figures 6E and 6F but with any other embodiments described herein.

[0133] Figure 7 is a cross sectional schematic illustration of the distal end of a generic surgical probe 89, which represents the construction and functionality of previously described surgical probe end effectors described above. Depicted is the distal end of probe shaft 90, liquid cryogen supply line 91, wire coil 92, inner liner 93, end cap 94, metering orifices 95, liquid cryogen 96, liquid cryogen evaporation chamber 97, and cryogen exhaust path 98. Liquid cryogen evaporation chamber is defined by central channel 134 and inner liner 93 of wire coil 92, end cap 94 at its distal end, probe shaft 90 at its proximal end. Wire coil 92 may be welded to end cap 94 and probe shaft 90 as shown. Alternatively, adhesive may be used for assembly. Probe shaft 90 may be formed from a surgical grade stainless steel hypodermic tube with an outside diameter between, e.g., approximately 1 mm and 4 mm. Wire coil 92 comprises a tightly coiled flat wire with a coil pitch that approximates the axial thickness 136 of wire 135 as shown. Wire 135 may be a stainless steel wire, or may alternatively be a nickel titanium super elastic alloy wire. Wire 135 has an axial thickness 136 between, e.g., approximately 0.5 mm and 1.5 mm, and a radial

thickness 137 between, e.g., approximately 0.1 mm and 0.5 mm. Wire 135 may alternatively be a round wire with a diameter between, e.g., approximately 0.25 mm and 1.0 mm.

[0134] Inner liner 93 is depicted being disposed on the inner wall of wire coil 92. Inner liner 93 is configured to provide a fluid tight seal of wire coil 92. Inner liner 93 may be a polymeric material such as polyethylene, or PTFE. Alternatively a polymeric line may be disposed on the outer surface 133 to provide a fluid tight seal of wire coil 92. Cryogen supply line 91 in fluidic communication with the supply of liquid cryogen in the liquid cryogen reservoir and liquid cryogen flow control valve in the surgical hand piece, not shown. Cryogen supply line 91 may be made from a thin walled tube with a high pressure rating such as a polyimide tube. Cryogen supply line 91 delivers liquid cryogen 96 into liquid cryogen evaporation chamber 97 through metering orifice(s) 95. Liquid cryogen supply line 91 has an inner diameter between, e.g., approximately 0.2 mm and 0.8 mm, and a wall thickness between, e.g., approximately 0.05 mm and 0.5 mm.

[0135] Metering orifices 95 are configured to comprise a distribution of fenestrations in the distal end of liquid cryogen supply line 91 as shown, and are configured to distribute liquid cryogen 96 into liquid cryogen evaporation chamber 97 in a substantially uniform manner. The diameter and number of metering orifices 95 are configured such that the flow of liquid cryogen 96 into liquid cryogen evaporation chamber 97 is sufficient to lower the temperature of outer surface 133 to between, e.g., approximately - 20 Deg. C., and -50 Deg. C. during liquid cryogen evaporation in order to effect a cryo-ablation, while limiting the flow of liquid cryogen 96 into liquid cryogen evaporation chamber 97 so that substantially all liquid cryogen evaporates within liquid cryogen evaporation chamber 97. As depicted, liquid cryogen evaporation chamber 97 is an empty space. Alternatively, liquid cryogen evaporation chamber 97 may comprise a porous material configured to absorb the liquid cryogen 96 and prevent the liquid cryogen from leaving liquid cryogen evaporation chamber 97 while in a liquid state. Cryogenic gas leaves liquid cryogen evaporation chamber 97 through central channel 139, and is vented into the room.

[0136] Figure 8 is a cross sectional schematic illustration of the distal end of generic surgical probe 104 representing the construction and functionality of surgical probe embodiments 55, 68, and 79 previously described and depicted in Figures 4A and 4B, Figures 5A through 5D, and Figures 6A through 6D, respectively. Depicted is the distal end of probe shaft 105, wire coil structure 106, end cap 107, liquid cryogen supply line

108, expandable membranous structure 109, in its expanded state, ostium 110, adhesive bond 111 between ostium 110 and probe shaft 105, cryogen gas exhaust vent 112, exhaust gas flow path 113, pressure bulkhead 114, liquid cryogen evaporation chamber 115, and liquid cryogen 116. Wire coil 106, probe shaft 105, end cap 107, and cryogen supply line 108 are substantially similar to corresponding elements described in detail and depicted in Figure 7, therefore, no further description is warranted. Expandable membranous structure 109, ostium 110, adhesive bond 111, cryogen gas exhaust vent 112, and exhaust gas flow path 113 are substantially similar to corresponding elements described in detail and depicted in Figure 4A, 4B, 5A through 5D, and 6A through 6D, therefore no further description is warranted. Liquid cryogen chamber 139 is defined by spring coil 106, end cap 107, and pressure bulkhead 114. Liquid cryogen 116 enters liquid cryogen chamber 139 through liquid cryogen supply line 108, and through liquid cryogen ports 137. Wire coil 106 is configured to meter liquid cryogen 116 from liquid cryogen chamber 139 into liquid cryogen evaporation chamber 115 in a manner that sprays liquid cryogen 116 in the direction of interior surface 141 of expandable membranous structure 109 so that the liquid cryogen rapidly evaporates upon contact with inner surface 141. A perforated polymeric liner, not shown, disposed upon wire coil 106 may be used to provide proper metering and spatial distribution of liquid cryogen 116.

[0137] Figure 9 is an internal view of the nasal cavity showing surgical probe 148 comprising an expandable membranous structure 123, configured as a liquid cryogen evaporator in position for a cryo-ablation of at least one posterior nasal nerve associated with middle nasal turbinate 129, or inferior nasal turbinate 128. Probe shaft 122 is associated with a surgical hand piece, not shown. Endoscope 126, proximal end not shown, with field of view 127 is positioned to guide the correct surgical placement of spring-like structure 125, and expandable membranous structure 123 against lateral nasal wall 130 at region 124 posterior to the middle turbinate as shown. Expandable membranous structure 123 is depicted in an expanded state. Alternatively, an endoscopic imaging means may be incorporated into the surgical probe 148, along its shaft, which may comprise a CCD or CMOS imager

[0138] Figures 10A thru 10D are schematic illustrations of the distal end 151 of alternative embodiment paddle balloon probe 150. Depicted is probe shaft 154, expandable structure 153, and paddle structure 152. Figure 10A is a front view illustration of distal end 151 with expandable structure 153 in an un-expanded state. Expandable structure 153 is maintained in its un-expanded state during introduction to, and removal from the target region of the

nasal anatomy. Suction may be applied by a suction means to maintain expandable structure 153 in its un-expanded state. Figure 10B is a side view illustration of the distal end 151 of paddle balloon probe 150 with expandable structure 153 in its un-expanded state. Figure 10C is a front view illustration of the distal end 151 of paddle balloon probe 150 with expandable structure 153 in its expanded or inflated state. Figure 10D is a side view illustration of the distal end of paddle balloon probe 150 with expandable structure 153 in its expanded or inflated state. Paddle 152 is configured for access to middle meatus of the lateral nasal wall by means of insertion between the middle nasal turbinate and the inferior nasal turbinate, as illustrated in figures 13A thru 13D below. Paddle structure 152 is a rounded rectangular shape as shown with a major dimension between approximately, e.g. 8mm and 16mm, and a minor dimension between approximately, e.g. 4mm and 10mm. The thickness of paddle structure 152 is between approximately, e.g. 1mm and 3mm. Paddle structure 152 is sufficiently rigid to access the middle meatus between the middle nasal turbinate and the inferior nasal turbinate, and is sufficiently flexible to avoid trauma to the nasal anatomy during use. Expandable structure 153 comprises a membrane that is bonded to paddle structure 152 in a manner that forms a air tight bladder as shown. Paddle balloon probe 150 is configured for introduction of a liquid cryogen into the bladder formed by paddle structure 152 and expandable structure 153, as well as to removed evaporated cryogen from the bladder with an exit to the room. The bladder formed by paddle structure 152 and expandable structure 153 is configured as cryogenic evaporation chamber, and the outer surface of expandable structure 153 is configured as a cryo-ablation surface. Expandable structure 153 is configured apply a force against the middle meatus of the lateral nasal wall between approximately, e.g. 20 grams and 200 grams. Expandable structure 153 is configured for expansion in reaction cryogen evaporation within. Liquid cryogen is introduced into the bladder through probe shaft 154, and evaporated cryogen gas is removed from the bladder and vented to the room trough probe shaft 154. The cryogenic ablation mechanisms and other features are similar to cryo-ablation probe embodiments described above and below.

[0139] Figures 11A and 11 B are schematic illustrations of the distal end 166 of paddle porous balloon probe 163, which is an alternative embodiment of paddle balloon probe 150. Figure 11 A is front view illustration, and Figure 11B is a side view illustration. Paddle porous balloon probe 163 comprises probe shaft 167, porous expandable structure 165, and paddle structure 164. Porous expandable structure 165 is similar to expandable structure 153, described above, comprising a porous membrane versus an air tight

membrane. Porous expandable structure 165 is configured for the venting of evaporated cryogen gas through the pores168 from within the bladder formed by porous expandable structure 165 and paddle structure 164 into the patient's nostril in the immediate vicinity of the surface of the lateral nasal wall that is targeted for cryo-ablation. Venting the cold gas in the vicinity of the targeted lateral nasal wall enhances cooling effectiveness, while precluding the need to vent the evaporated cryogen gas through probe shaft 167, allowing the probe shaft to be smaller in caliber, and therefore less traumatic. The cryogenic ablation mechanisms and other features are similar to cryo-ablation probe embodiments described above and below.

[0140] Figures 12A thru 12D are schematic illustrations of the distal end 179 of double balloon paddle probe 178. Figure 12A is a front view illustration of double balloon paddle probe 178 with expandable structure 181 in its un-expanded state. Figure 12 B is a side view illustration of double balloon paddle probe 178 with expandable structure in its un-expanded state. Figure 12C is a front view illustration of double balloon paddle probe 178 with expandable structure 181 in its expanded state. Figure 12 D is a side view illustration of double balloon paddle probe 178 with its expandable structure 181 in its expanded state. Double balloon paddle probe 178 comprises probe shaft 180, expandable structure 181, paddle structure 182, liquid cryogen port 183, and cryogen gas exhaust port 184. In this embodiment, expandable structure 181 encompasses paddle structure 182 and comprises a single ostium 185, and an adhesive bond 186 which forms an air tight seal of for expandable structure 181. The configuration and function of this embodiment substantially similar to the embodiment depicted in Figures 6A to 6H, with the difference being in this embodiment a paddle structure 182 is encompassed by expandable structure 181, versus a spring-like structure or a formed wire structure encompassed by an expandable structure as depicted in Figures 6A to 6H. Optionally, the distal inner edge of paddle structure 182 and be bonded to the interior of expandable structure 181 by adhesive bond 187.

[0141] Figures 13A through 13D are schematic sectional coronal illustrations of the nasal cavity depicting ablation probe 201 access to the middle meatus 198 between the middle nasal turbinate 6 and inferior nasal turbinate 7. Ablation probe 201 is a generic representation any of the ablation probes disclosed here within that utilize and expandable structure. Figure 13A depicts the thin edge of the distal end of ablation probe 201 being inserted into the thin gap between middle nasal turbinate 6 and inferior nasal turbinate 7. Figure 13B depicts the distal structure of ablation probe 201 behind middle turbinate against the middle meatus 198 in position for an ablation. Figure 13C depicts the initiation

of ablation by activation of the flow of cryogenic liquid into the expandable structure 203 resulting in the inflation of the expandable structure 203 as shown. Please note, as depicted, the expandable structure is most similar to that depicted in Figures 10 and 11, but is not intended imply a preference for those embodiments over the other embodiments disclosed here within. Figure 13D depicts the ablation zone 204 resulting from the application of a cryo-ablation of between approximately, e.g. 20 to 300 seconds. Following ablation, the probe may be removed following a thawing period that may be between approximately, e.g. 20 to 30 seconds. As depicted the sphenopalatine branch, comprising the sphenopalatine artery, sphenopalatine vein, and sphenopalatine nerve, and the sphenopalatine foramen are substantially encompassed by the zone of ablation 204. As previously described, and further described below, the targeted tissue may comprise other locations, including the proximity of accessory posterolateral nerves bounded by a sphenopalatine foramen superiorly, an inferior edge of an inferior turbinate inferiorly, a Eustachian tube posteriorly, or a posterior third of the middle and inferior turbinates anteriorly. Other anatomical targets may include the pterygomaxillary fossa, sphenopalatine ganglion, or vidian nerve.

[0142] Figure 14A is an internal lateral view of the nasal cavity showing target 228 for ablation of the parasympathetic nervous function of middle turbinate 6. Ablation target 228 is directly over the posterior superior lateral nasal branches 11 which innervate middle turbinate 6. Ablation target 228 may be circular as shown or non-circular, with a zone of ablative effect between 1 mm and 4 mm deep. Figure 14B is an internal lateral view of the nasal cavity showing target 246 for ablation of parasympathetic nervous function of superior turbinate 5, middle turbinate 6, and inferior turbinate 7. Ablation target 246 is linier as shown and is directly over posterior inferior lateral nasal branch 10, which innervates inferior turbinate 7, posterior superior lateral nasal branch 11 which innervates middle turbinate 6, and superior lateral nasal branch 12 which innervates superior turbinate 5. The depth of ablative effect is ideally between 1mm and 4mm deep. Figure 14C is an internal lateral view of the nasal cavity showing target 247 for ablation of parasympathetic nervous function of superior turbinate 5, middle turbinate 6, and inferior turbinate 7. Ablation target 246 is linier and segmented as shown with ablation segments directly over posterior inferior lateral nasal branch 10, which innervates inferior turbinate 7, posterior superior lateral nasal branch 11 which innervates middle turbinate 6, and superior lateral nasal branch 12 which innervates superior turbinate 5. The depth of ablative effect is ideally between 1mm and 4mm deep. Figure 2D is an internal lateral view of the nasal

cavity showing target 248 for ablation of the parasympathetic nervous function of middle turbinate 6. Ablation target 228 is directly over the posterior superior lateral nasal branches 11 which innervate middle turbinate 6. Ablation target 248 is oblong as shown and positioned between middle turbinate 6 and inferior turbinate 7 as shown, with a zone of ablative effect between 1 mm and 4 mm deep.

[0143] Figure 15A is a schematic illustration of cryosurgical probe 234 configured for cryo-ablation of parasympathetic nervous function of a nasal turbinate(s) comprising a spatula shaped cryosurgical tip 236. Cryosurgical probe 234 comprises handle 235, probe shaft 237 cryosurgical tip 236 refrigerant cartridge cover 239, and refrigerant control push button 238. Handle 235 may comprise a receptacle, not shown, for receiving a refrigerant filled cartridge, not shown, which may comprise liquid carbon dioxide, which is used for evaporative cryogenic cooling within cryosurgical probe tip 236. Alternatively, the cartridge may comprise a compressed cryogenic gas which may comprise argon or nitrous oxide which is used for Joule-Thompson effect cryogenic cooling within cryosurgical probe tip 236. Those skilled in the art cryosurgical instrumentation are familiar with means for configuring cryosurgical probe 234 for evaporative cryogenic cooling or Joule-Thompson effect cryogenic cooling according to this invention, therefore, further detailed description relating to cryosurgical techniques are not warranted. Refrigerant control push button 238 is in mechanical communication with a valve which is configured to open when push button 238 is depressed by the operator causing the cryogen within the cartridge to flow into cryosurgical probe tip 236 through a conduit within probe shaft 237. Handle 235 further comprises a venting means, not shown for exhausting the expanded cryogen into the atmosphere. Probe shaft 237 is between approximately 2mm and 6mm in diameter, with a length between approximately 4 cm and 10 cm. Figure 15B defines a section view of the cryosurgical probe 234 cryosurgical tip 236. Figure 15C is a cross sectional view of the cryosurgical probe 234 distal end comprising probe shaft 237, refrigerant delivery tube 253, and probe tip 236. Cryogen delivery tube 253 traverses the length of probe shaft 237 in a coaxial relationship and is in fluidic communication with the cryogen cartridge in handle 235 through the cryogen control valve previously described. At the distal end of cryogen delivery tube 253 there is at least one lateral fenestration configured to direct the release of the pressurized cryogen 256 from cryogen delivery tube 253 into expansion chamber 251 of cryosurgical tip 236 in the direction of cryo-ablation surface 249 of cryosurgical tip 236. Cryo-ablation surface 249 is substantially flat. The opposing surface 250 to ablation surface 249 may be cylindrical as shown. By directing the release of

cryogen towards ablation surface 249, ablation surface 249 achieves cryo-ablation temperatures between approximately -20 to -200 degrees centigrade, and opposing surface 250 remains warmer. The expanded cryogen 255 exits expansion chamber 251 through probe shaft 252 and is vented to atmosphere through handle 235 as previously described. Probe shaft 237, cryogen delivery tube 253, and cryosurgical tip 236 may fabricated from a stainless steel as is typical with cryosurgical probes, or may be fabricated with alternative materials as is familiar to those skilled in the art of cryosurgical probes. Probe shaft 237 may configured as shown with curvatures configured for nasal anatomy, or alternatively may be configured as described below.

[0144] Figure 16A is a schematic illustration of the distal end of an alternative embodiment 262 of the cryosurgical probe comprising a bullet shaped cryo-ablation element 263 at the distal end of angled probe shaft 268. In this embodiment pressurized cryogen is released through an orifice in an axial direction into the expansion chamber in the direction cryo-ablation surface 264. The diameter of shaft 265 is between approximately 2mm and 6mm, and the angle of shaft 265 is between approximately 30 and 60 degrees, and the point of bend is between 1 cm and 3 cm from the distal end of ablation element 263. Figure 16B is a schematic illustration of the distal end of an alternative embodiment 266 of the cryosurgical probe comprising a bullet shaped cryo-ablation element 263 at the distal end of a user deflectable probe shaft 267. Deflectable probe shaft 267 comprises distal deflectable segment 268 and a substantially rigid non-deflectable proximal segment 269. Probe shaft 267 diameter is between approximately 2 mm and 6 mm. The border between deflectable distal segment 268 and proximal non-deflectable segment is between approximately 1 cm and 3 cm from the distal end of ablation element 263. The angle of deflection may be between approximately 60 to 120 degrees and may be configured for deflection in one direction, or in two directions as shown. The deflection means comprises at least one pull wire housed within probe shaft 267 and a deflection actuator disposed in the vicinity of the proximal end of probe 266. Those skilled in the art deflectable tipped surgical probes are familiar means for creating a deflectable tipped cryosurgical probe according to this invention. Figure 4C and 4D are schematic illustrations of the distal end of an alternative embodiment 270 of the cryosurgical probe where the cryo-ablation element 274 is configured for producing multiple discrete cryo-ablations simultaneously. Cryo ablation element 274 comprises an expansion chamber, not shown, discrete lateral cryo-ablation surfaces 272, surrounded by thermal insulation 273. Ablation element 274 comprises a hollow bullet shaped metallic structure with lateral protrusions in the surface

forming cryo-ablation surfaces 272, with a thermal insulating material covering all remaining external surfaces of ablation element 274 as shown. As with cryo-surgical probe 234, cryogen is released from cryogen delivery tube in a lateral direction towards cryo-ablation surfaces 272.

[0145] Figure 17A is a schematic illustration of the distal end of an alternative embodiment 280 of the cryosurgical probe comprising a semi-circular cryo-ablation element 282. Cryo-ablation element 282 comprises a continuation of probe shaft 281 formed in a semi-circle as shown. Within the semi-circular section cryogen delivery tube 283 comprises an array of lateral fenestration in the one axial direction relative to semi-circular form, making the corresponding surface of the ablation element 282 the cryo-ablation surface. Figure 17B is a schematic illustration of the ablation 284 morphology in the nasal mucosa 288 resulting from use of the semi-circular ablation element 282. The gap 286 in the ablation provides blood perfusion to the mucosa encompassed by the ablation providing a reduction in tissue sloughing as the result of the ablation, as well as a reduction in the chance of infection, and a reduction of patient discomfort. Figure 17C is a schematic illustration of the distal end of an alternative embodiment 287 of the cryosurgical probe comprising a spiraled cryo-ablation element.

[0146] Figure 18A is a schematic illustration of cryo-ablation balloon probe 294 configured for cryo-ablation of parasympathetic nervous function of a nasal turbinate(s). Cryo-ablation balloon probe 294 comprises balloon 295, probe shaft 296, cryogen delivery tube 297, with lateral fenestrations 298 disposed on the distal end of cryogen delivery tube 297 within balloon 295 as shown. Cryo-ablation balloon probe 294 further comprises proximal hub 299 with cryogen exhaust port 299, cryogen supply port 301. Probe shaft 296 may be rigid or flexible. Balloon 295 functions as a cryogen expansion chamber for either a cryogenic evaporation cooling process or a Joules-Thompson effect cooling process. Pressurized cryogen 256 is delivered to the interior of balloon 295 through cryogen delivery tube 297 under pressure. Cryogen 256 exits cryogen delivery tube 297 through lateral fenestrations 298 as shown, in the radial direction towards the wall of balloon 295. The radial wall of balloon 295 is the cryo-ablation surface. Expanded cryogen 255 exits balloon 295 through probe shaft 296, and is vented to atmosphere through exhaust port 300. Exhaust port 300 may comprise a pressure relief valve, which creates a back pressure to inflate balloon 295 at a predetermined pressure. Cryogen supply port 301 is configured to connect cryogen supply tube 297 to a source of cryogen. Proximal hub 299 may be configured as a handle, and comprise a cryogen control valve. Figure 18B is a schematic

illustration of the distal end of the cryo-ablation balloon probe detailing the geometry of the cryo-ablation balloon. The length 302 of balloon 295 is between approximately 3 mm and 20 mm, and the diameter 303 of balloon 295 is between 1 mm and 5 mm. Figure 18C is a schematic illustration of an alternate embodiment 304 of the cryo-ablation balloon probe 294 comprising an insulating chamber 307 within the cryo balloon 305 structure. Insulating chamber 307 is formed by membrane 306 as shown. Fenestration 308 is a small opening in communication between expansion chamber 311 and insulating chamber 307, which allows insulation chamber to inflate with expanded cryogen gas 255 in a substantially static manner providing thermal insulation to the surface of balloon 305 adjacent to insulation chamber 307. Lateral fenestrations 310 direct pressurized cryogen 301 towards the wall of balloon 305 opposite of insulation chamber 307 forming cryo-ablation surface 312. The length 302 of balloon 305 is between approximately 3 mm and 20 mm, and the diameter of balloon 305 is between approximately 1 mm and 6 mm. Figure 18D is a schematic illustration of the distal end of an alternative embodiment 313 of the cryo-ablation balloon probe 294 comprising a tee shaped cryo-ablation balloon 314. The length 302 of balloon 314 is between approximately 3 mm to 20 mm, and the diameter of balloon 303 is between approximately 1 mm and 6 mm. Cryogen delivery tube 315 is configured to direct pressurized cryogen down the horns 316 of balloon 314 as shown. Figure 18E is a schematic illustration of the distal end of an alternative embodiment 317 of the cryo-ablation balloon probe 294 comprising a "J" shaped cryo-ablation balloon 318. The length 302 of balloon 318 is between approximately 3 mm and 20 mm, and the diameter 303 of balloon 318 is between approximately 1 mm and 6 mm. Cryogen delivery tube 319 is configured to direct pressurized cryogen 256 laterally into the "J" as shown.

[0147] Figure 19A is a schematic illustration of the distal end of an alternate embodiment 325 of cryo-ablation probe 294 comprising a cryo-ablation element 326 with suction stabilization. Figure 19B is a cross sectional view of the distal end of the alternative embodiment 325 showing the configuration of the cryo-ablation element 326 and the suction stabilization means.

[0148] Ablation element 326 is surrounded by suction chamber 329 as shown. Suction chamber 329 is in fluidic communication with a suction source, not shown, by suction tube 331. Suction ports 330 are oriented in the same direction as cryo-ablation surface 332 and are configured to provide suction attachment to the tissue when cryo-ablation surface 332 is placed into contact with the nasal mucosa in the ablation target zone. Probe shaft 325,

cryogen delivery tube 327, and lateral fenestrations 328 have similar function those previously described.

[0149] Figure 20A is a schematic illustration of radiofrequency (RF) ablation probe 338 configured for ablation of the parasympathetic nervous function of a nasal turbinate(s) with a bi-polar ring electrode ablation element 342 on an "J" shaped distal probe tip 341. RF ablation probe 338 comprises handle 339, probe shaft 340, "J" shaped probe tip 341, bipolar ring electrode pair 342, RF activation switch 345, electrical connector 343, and fluid connector 344. Those skilled in the art of RF ablation probes are familiar with the many possible configurations and construction techniques for RF electrodes and probes that are within the scope of this invention, therefore detailed description of the illustrated electrode configurations described below, and their construction techniques is not warranted. Electrical connector 343 is configured for connection to a radiofrequency energy generator, for which there are many commercially available. Fluid connector 344 is configured for connection to source of liquid irrigant. Fluid connector 344 may be in fluidic communication with at least one fluid irrigation port located the vicinity of the RF ablation electrode, and is embodiment specific. RF activation switch 345 allows the user to activate the RF ablation and terminate the RF ablation. Probe shaft 340 is between approximately 2 mm to 6 mm in diameter, and between approximately 4 cm and 10 cm long, but could be longer. The length of "J" tip 341 is between approximately 0.5 cm and 1.5 cm. Ring the spacing between RF electrode pair 342 is between approximately 2 mm and 6 mm. Figure 20B is a schematic illustration of the distal end of an alternative embodiment 346 of RF ablation probe 338 comprising a bi-polar segmented ring electrode ablation element on an "J" shaped distal probe shaft. The gap 348 shown in the ring electrode is on the side opposite of the side configured for RF ablation. The gap 348 in the ring electrodes protect the nasal septum during RF ensuring that RF energy is only applied to the lateral nasal wall at the ablation target. Figure 20C is a schematic illustration of alternative embodiment 349 of the distal end of RF ablation probe 338 comprising a bi-polar electrode ablation element 350 on a "J" shaped distal probe shaft with the electrodes disposed in a lateral array. Figure 20D is a schematic illustration of alternative embodiment 351 of the distal end of RF ablation probe 338 comprising a bi-polar electrode ablation element 352 on a "U" shaped distal probe shaft 353 with the electrodes disposed in a lateral array. Figure 20E is a schematic illustration of the distal end of alternative embodiment 354 of RF ablation probe 338 comprising a bi-polar electrode ablation element 355 on a user deployable "T" shaped structure356. Element 356 is comprised of two halves which can

alternately be collapsed and deployed as in Figure 20E. The two halves of the electrode structure 356 are pivoted to allow them to move laterally relative to the catheter shaft 354. Electrodes 355 can operate in a mono polar, bipolar or multipolar fashion as known in the art.

[0150] Figure 21A is a schematic illustration of alternative embodiment 362 to RF ablation probe 338 configured for ablation of the parasympathetic nervous function of a nasal turbinate(s) comprising an array of RF ablation electrodes 363 disposed on a planar surface with a fluid irrigation means associated with the electrodes. Figure 21B is a schematic illustration of the distal end of the RF ablation probe 362 showing the arrangement of the ablation electrode array 363 and the associated fluid irrigation means. Alternative embodiment 362 comprises distal probe tip 119, probe shaft 369, handle 339, fluid connector 344, and electrical connector 343. Electrode array 363 comprises two or more dome shaped electrodes 365, that are electrically configured into a bipolar pair, meaning that if there are 4 electrodes 365, then two of the electrodes are connectable to one pole of an RF generator, and the second two electrodes are connectable to the opposite pole of the RF generator, etc. Electrodes 365 are dome shaped and protrude from planar surface 366. A fluid port 364 is associated with each electrode 365. All fluid ports are in fluidic communication with fluid connector 344. Fluid ports 364 are configured to irrigate the surface of the nasal mucosa that is contact with electrodes 365 to provide cooling of the mucosa and the electrodes 365, to minimize thermal injury to the surface of the mucosa, and to prevent sticking of the electrodes to the surface of the mucosa. Probe tip 371 is between approximately 4 mm and 8 mm in diameter, and between approximately 3 mm to 8 mm thick. The number of electrodes 365 of electrode array 363 may be between 2 and approximately 10.

[0151] Figure 22A is a schematic illustration of an alternative embodiment 377 of RF ablation probe 362 comprising a linear electrode array 378 disposed on a planar surface; a fluid irrigation ports 387 associated electrodes 379, and a deployable needle 380 configured for injecting a liquid into a sub-mucosal space. Figure 22B is a schematic illustration of the distal end of the alternative embodiment 377 RF ablation probe showing the arrangement of the ablation electrodes 379 and the associated fluid irrigation ports 387. Figure 22C is a schematic illustration of the distal end of the alternative embodiment 377 RF ablation probe showing the arrangement of the ablation electrodes 379 and the associated fluid irrigation ports 387 with the needle 380 deployed. The function, of domed electrodes 379, fluid ports 387, electrical connector 343, fluid connector 344, RF activation

switch 345, handle 382, and shaft 384 all function in essentially the same manner as described for prior embodiment 362. This embodiment has a linear electrode array 378, and a deployable needle configured for injecting a liquid into the sub-mucosal space where the liquid may comprise an anesthetic. Needle actuator 383 provides the user a means actuating needle 380. Fluid connector 389 is in fluidic communication with needle 380, through needle shaft 385, and is configured with a female luer connector for mating with a syringe, not shown. Shaft 384 contains needle shaft 385, electrical cable 386, and provides a conduit for irrigation fluid, not shown.

[0152] Figure 23A is a schematic illustration of an RF interstitial needle ablation probe 395 configured for interstitial ablation of a posterior nasal nerve. Figure 23B is a schematic illustration of the distal end 396 of the RF interstitial needle ablation probe 395. RF interstitial needle probe 395 comprises distal tip 396, probe shaft 398, handle 399, electrical connector 400, fluid connector 401, RF activation switch 402. Distal tip 396 comprises interstitial needle electrode array 397, which comprises more than one interstitial needle 464 Handle, 399, RF activation switch 402, electrical connector 400, and probe shaft 398 function in a manner previously described. Fluid port 401 is in fluidic communication with at least one RF ablation needle 464, with the at least one RF ablation needle 464 being hollow and configured for injecting a liquid into the nasal sub-mucosal space. Each RF ablation needle 464 has a proximal electrically insulating coating 405, and a distal electrically insulating coating 404, forming RF electrode surface 403. Proximal insulator 405, and distal insulator 404 are configured for limiting the ablation effects to the sub-mucosal space, which will be described in further detail below. Interstitial needle electrode array 397 may be configured as a mono-polar electrode array, or a bipolar electrode array. Interstitial needle electrode array 397 may be configured as a linear array, a circular array, a triangular array, or any other geometric form. Interstitial needle electrode array 397 may comprise two or more RF ablation needles 464. RF ablation needles 464 are between approximately 18 and 28 gauge, and between approximately 3 mm and 10 mm long.

[0153] Figure 24A is a cross sectional view of the distal end of an alternative embodiment 411 to RF interstitial needle ablation probe 395 comprising a deployable and retractable array of RF ablation needles 412 configured for lateral deployment showing the needle array retracted. Figure 24B is a cross sectional view of the distal end of an alternative embodiment 411 of RF interstitial needle ablation probe 395 comprising a deployable and retractable array of RF ablation needles configured for lateral deployment showing the

needle array deployed. Interstitial needle array 412 is housed in a hollow sheath with a "J" tip 413 as shown. Linear actuator shaft 414 is in mechanical communication with a user actuator lever at the proximal end not shown. Linear actuator shaft 414 is moved in the distal direction to deploy needle array 412, and moved in the proximal direction to retract needle array 412 as shown. Figure 24C is a cross sectional view of the distal end of an alternative embodiment 415 of RF interstitial needle ablation probe 395 comprising a deployable and retractable array of RF ablation needles configured for axial deployment showing the needle array retracted. Figure 24D is a cross sectional view of the distal end of an alternative embodiment 415 of RF interstitial needle ablation probe 395 comprising a deployable and retractable array of RF ablation needles configured for axial deployment showing the needle array deployed.

[0154] Figure 25A is a schematic illustration of an integrated flexible circuit 421 configured for use with an RF ablation probe comprising an RF energy source and control circuits 422 at one end, and an RF ablation electrode array 423 at the opposite end, connected by electrical conduits 426. Figure 25B is a schematic illustration of the RF ablation electrode array 423 of the flexible circuit mounted on the distal shaft of an RF ablation probe that is configured for ablation of the parasympathetic nervous function of a nasal turbinate. Also shown are optional fluid ports associated with the RF ablation electrode array as shown, with irrigation fluid 427 supplied to irrigation ports 425 through distal shaft 424.

[0155] Figure 26A is an in situ schematic illustration of the RF ablation probe 377 depicted in Figures 10 through 10C showing needle 380 injecting an anesthetic into the sub-mucosal space 433 prior to an RF ablation of the posterior nasal nerve 434. Figure 26B is an in situ schematic illustration of the resulting RF ablation 436 showing the ablation zone 436 encompassing posterior nasal nerve 434, and residing below the mucosal surface 437 due to the cooling effect of liquid irrigant 435.

[0156] Figure 27 is an in situ schematic illustration of an RF ablation of the parasympathetic nerve of a posterior nasal nerve 434 using the RF interstitial needle ablation probe 395 depicted in Figures 11A and 11B showing ablation zone 436 encompassing posterior nasal nerve434 and residing below the mucosal surface 437 due to the arrangement of needle electrode surface(s) 403 and needle insulation zones 404 & 405.

[0157] Figure 28 is an in situ illustration of the ablation of the posterior nasal nervedepicted in Figure 14D. Generic ablation device 441 is shown with cylindrical ablation element 442, which could be a cryo ablation element, an RF ablation element, or

some other type of thermal ablation element. Also shown is endoscope 443, which provides the surgeon an image for positioning ablation element 442 at the target location, and a means for monitoring the ablation.

[0158] Figure 29 is an in situ illustration of the ablation of the posterior nasal nerveof a nasal turbinate at the ablation target depicted in Figure 14B. Generic ablation device 441 is shown with cylindrical ablation element 442, which could be a cryo ablation element, an RF ablation element, or some other type of thermal ablation element. Also shown is endoscope 443, which provides the surgeon an image for positioning ablation element 442 at the target location, and a means for monitoring the ablation.

[0159] Figure 30 is an in situ illustration of the ablation of the posterior nasal nerve using a generic "T" tipped ablation device 448. Generic "T" tipped ablation device 448 is shown with ablation elements 449, which could be cryo ablation elements, RF ablation elements, or some other type of thermal ablation elements. Also shown is endoscope 443, which provides the surgeon an image for positioning ablation element 442 at the target location, and a means for monitoring the ablation.

[0160] Figure 31A is a schematic illustration of generic ablation probe 455 and an insulated probe guide 457 configured to protect the nasal septum from thermal injury during an ablation of the parasympathetic nervous function of a nasal turbinate(s). Probe guide 457 is configured to press ablation element 456 of probe 455 against the lateral wall of a nasal cavity 458 and create a thermally insulative space between the lateral wall of the nasal cavity 458 and the nasal septum 459 as shown in Figures 31B and 31C. Probe guide 457 may be fabricated from foam material, or any other suitable thermally insulative material. Figure 31B is an in situ illustration of generic ablation probe 437 configured for ablation of the posterior nasal nerve which comprises an insulating structure 460 configured to protect the nasal septum 459 from thermal injury. Structure 460 may comprise an inflatable balloon. Figure 31C is an in situ illustration of generic ablation probe 455 configured for ablation of the parasympathetic nervous function of a nasal turbinate(s) which comprises a space creating structure 461 configured to protect the nasal septum 459 from thermal injury. Structure 461 may comprise a deployable wire structure or surgical basket structure.

CLAIMS

What is claimed is:

1. A method for treating a tissue region within a nasal cavity, comprising:

introducing a distal end of a probe shaft through the nasal cavity, wherein the distal end has an end effector with a first configuration having a low-profile which is shaped to manipulate tissue within the nasal cavity;

positioning the distal end into proximity of a tissue region having at least one posterior nasal nerve;

reconfiguring the distal end from the first configuration to a second configuration which is shaped to contact and follow the tissue region; and

ablating the at least one posterior nasal nerve within the tissue region via the distal end.

2. The method of claim 1 wherein ablating the at least one posterior nasal nerve comprises ablating the posterior nasal nerve such that symptoms of rhinitis are reduced.

3. The method of claim 1 wherein introducing a distal end comprises introducing the distal end through a nostril and into the nasal cavity.

4. The method of claim 1 wherein positioning the distal end comprises positioning the distal end at least 2 cm beyond an anterior entrance to a middle meatus.

5. The method of claim 1 wherein positioning the distal end comprises:

advancing the distal end along an upper surface of the inferior nasal turbinate to a mid-portion of the middle nasal turbinate;

advancing the distal end into a middle meatus; and

further advancing the distal end posteriorly up into a cul-de-sac.

6. The method of claim 1 wherein positioning the distal end comprises positioning the distal end between the middle and inferior nasal turbinate.

7. The method of claim 1 wherein positioning the distal end comprises

positioning the distal end relative to the tissue region surrounded by the middle nasal turbinate, inferior nasal turbinate, and lateral wall forming a cul-de-sac.

8. The method on claim 1 wherein positioning the distal end positioning the distal end to contact a lateral nasal wall defined by a tail of a nasal turbinate, lateral wall, and an inferior turbinate.

9. The method of claim 1 wherein positioning the distal end comprises positioning the distal end into proximity of the Pterygomaxillary fossa, sphenopalatine ganglion, sphenopalatine ganglion, or vidian nerve.

10. The method of claim 1 wherein positioning the distal end comprises positioning the distal end into proximity of accessory posterolateral nerves bounded by an sphenopalatine foramen superiorly, an inferior edge of an inferior turbinate inferiorly, a Eustachian tube posteriorly, or a posterior third of the middle and inferior turbinates anteriorly.

11. The method of claim 1 wherein reconfiguring the distal end comprises inflating an expandable structure projecting from the probe shaft into contact against the tissue region.

12. The method of claim 11 further comprising positioning a member extending within the expandable structure, wherein the expandable structure encloses the member such that the member is unattached to the interior of the expandable structure, into contact against the tissue region through the expandable structure.

13. The method of claim 1 wherein ablating the at least one posterior nasal nerve comprises introducing a cryogenic fluid into or through the distal end.

14. The method of claim 1 wherein ablating the at least one posterior nasal nerve comprises cryogenically ablating the tissue region between approximately 20 seconds to 300 seconds.

15. The method of claim 1 wherein ablating the at least one posterior nasal

nerve comprises cryogenically ablating the tissue region between approximately 20 seconds to 120 seconds.

16. The method of claim 1 further comprising introducing an imaging device in proximity to the distal end.

17. The method of claim 1 further comprising visualizing the tissue region while advancing the distal end of the probe shaft through the nasal cavity.

18. The method of claim 17 wherein visualizing comprises visualizing via a CCD or CMOS imager positioned along the surgical probe shaft.

19. The method of claim 17 wherein visualizing comprises visualizing infrared wavelengths.

20. The method of claim 17 wherein visualizing comprises visualizing via a nasal endoscope.

21. The method of claim 20 wherein visualizing comprises advancing the nasal endoscope with the surgical probe shaft.

22. The method of claim 1 further comprising introducing a temperature sensor in proximity to the distal end of the surgical probe shaft.

23. The method of claim 1 further comprising applying a pressure to the tissue region via the distal end with a force of 20 to 200 grams.

24. The method of claim 1 further comprising waiting 10 to 20 seconds after ablating the at least one posterior nasal nerve prior to removing the distal end from the tissue region.

25. The method of claim 1 wherein ablating the at least one posterior nasal nerve comprises ablating the tissue region through a layer of gel.

26. The method of claim 1 further comprising assessing the tissue region during and/or after ablation.

27. The method of claim 26 wherein assessing comprises inspecting the tissue region visually or via ultrasound.

28. The method of claim 26 wherein assessing comprises detecting or a temperature of the tissue region.

29. The method of claim 1 further comprising vibrating the distal end while maintaining the distal end against the tissue region.

30. The method of claim 1 further comprising applying an anesthetic to the tissue region to be treated prior to ablating the post nasal nerve.

31. A method for treating rhinitis, comprising:

introducing a distal end of a probe shaft through the nasal cavity, wherein the distal end has an end effector with a first configuration having a low-profile which is shaped to manipulate tissue within the nasal cavity;

positioning the distal end into proximity of a tissue region surrounded by the middle nasal turbinate, inferior nasal turbinate, and lateral wall forming a cul-de-sac;

reconfiguring the distal end from the first configuration to a second configuration which is shaped to contact and follow the tissue region; and

ablating the at least one posterior nasal nerve within the tissue region via the distal end.

32. The method of claim 31 wherein ablating the at least one posterior nasal nerve comprises ablating the posterior nasal nerves such that symptoms of rhinitis are reduced.

33. The method of claim 31 wherein introducing a distal end comprises introducing the distal end through a nostril and into the nasal cavity.

34. The method of claim 31 wherein positioning the distal end comprises

positioning the distal end at least 2 cm beyond an anterior entrance to a middle meatus.

35. The method of claim 31 wherein positioning the distal end comprises:

advancing the distal end along an upper surface of the inferior nasal turbinate to a mid-portion of the middle nasal turbinate;

advancing the distal end into a middle meatus; and

further advancing the distal end posteriorly up into a cul-de-sac.

36. The method of claim 31 wherein positioning the distal end comprises positioning the distal end between the middle and inferior nasal turbinate.

37. The method on claim 31 wherein positioning the distal end positioning the distal end to contact a lateral nasal wall defined by a tail of a nasal turbinate, lateral wall, and an inferior turbinate.

38. The method of claim 31 wherein positioning the distal end comprises positioning the distal end into proximity of the Pterygomaxillary fossa, sphenopalatine ganglion, sphenopalatine ganglion, or vidian nerve.

39. The method of claim 31 wherein positioning the distal end comprises positioning the distal end into proximity of accessory posterolateral nerves bounded by an sphenopalatine foramen superiorly, an inferior edge of an inferior turbinate inferiorly, a Eustachian tube posteriorly, or a posterior third of the middle and inferior turbinates anteriorly.

40. The method of claim 31 wherein reconfiguring the distal end comprises inflating an expandable structure projecting from the probe shaft into contact against the tissue region.

41. The method of claim 40 further comprising positioning a member extending within the expandable structure, wherein the expandable structure encloses the member such that the member is unattached to the interior of the expandable structure, into contact against the tissue region through the expandable structure.

42. The method of claim 31 wherein ablating the at least one posterior nasal nerve comprises introducing a cryogenic fluid into or through the distal end.

43. The method of claim 31 wherein ablating the at least one posterior nasal nerve comprises cryogenically ablating the tissue region between approximately 20 seconds to 300 seconds.

44. The method of claim 31 wherein ablating the at least one posterior nasal nerve comprises cryogenically ablating the tissue region between approximately 20 seconds to 120 seconds.

45. The method of claim 31 further comprising introducing an imaging device in proximity to the distal end.

46. The method of claim 31 further comprising visualizing the tissue region while advancing the distal end of the probe shaft through the nasal cavity.

47. The method of claim 46 wherein visualizing comprises visualizing via a CCD or CMOS imager positioned along the surgical probe shaft.

48. The method of claim 46 wherein visualizing comprises visualizing infrared wavelengths.

49. The method of claim 46 wherein visualizing comprises visualizing via a nasal endoscope.

50. The method of claim 49 wherein visualizing comprises advancing the nasal endoscope with the surgical probe shaft.

51. The method of claim 31 further comprising introducing a temperature sensor in proximity to the distal end of the surgical probe shaft.

52. The method of claim 31 further comprising applying a pressure to the tissue region via the distal end with a force of 20 to 200 grams.

53. The method of claim 31 further comprising waiting 10 to 20 seconds after ablating the posterior nasal nerves prior to removing the distal end from the tissue region.

54. The method of claim 31 wherein ablating the at least one posterior nasal nerve comprises ablating the tissue region through a layer of gel.

55. The method of claim 31 further comprising assessing the tissue region during and/or after ablation.

56. The method of claim 55 wherein assessing comprises inspecting the tissue region visually or via ultrasound.

57. The method of claim 55 wherein assessing comprises detecting or a temperature of the tissue region.

58. The method of claim 31 further comprising vibrating the distal end while maintaining the distal end against the tissue region.

59. The method of claim 31 further comprising applying an anesthetic to the tissue region to be treated prior to ablating the posterior nasal nerves.

60. A surgical probe configured for ablation, comprising:

a surgical probe shaft comprising an elongated structure with a distal end and a proximal end;

an expandable structure attached to the distal end of the probe shaft, the expandable structure having a deflated configuration and an expanded configuration;

a lumen in fluid communication with an interior of the expandable structure; and

a member attached to the distal end and extending within the expandable structure which encloses the member such that the member is unattached to the interior of the expandable structure,

wherein the member defines an atraumatic shape which is sized for pressing against and manipulating through the expandable structure a lateral nasal wall proximate to at least one posterior nasal nerve.

61. The surgical probe of claim 60 wherein the surgical probe shaft is between 1 mm and 4 mm in diameter and between approximately 4 cm and 10 cm in length.

62. The surgical probe of claim 60 wherein the lumen is defined through the probe shaft.

63. The surgical probe of claim 60 wherein surgical probe shaft is malleable and is configured for shape forming by the user.

64. The surgical probe of claim 60 further comprising a surgical hand piece attached to the proximal end, where the surgical hand piece is configured to be held like writing utensil or like a pistol.

65. The surgical probe of claim 64 wherein the surgical hand piece comprises a flow control valve actuator.

66. The surgical probe of claim 60 further comprising a pressurized reservoir in fluid communication with interior of the expandable structure through the lumen.

67. The surgical probe of claim 66 wherein the reservoir contains a liquid cryogen.

68. The surgical probe of claim 60 wherein the member comprises a looped structure defining an opening therethrough.

69. The surgical probe of claim 60 wherein the member comprises a coiled spring-like structure.

70. The surgical probe of claim 69 wherein the coiled spring-like structure is curved and tangent to the distal end of the surgical probe shaft.

71. The surgical probe of claim 69 wherein the coiled spring-like structure is at least partially malleable and is configured for shape forming by the user.

72. The surgical probe of claim 69 wherein the coiled spring-like structure comprises a tightly coiled metal wire defining a central lumen and an outer surface.

73. The surgical probe of claim 72 wherein the central lumen is in fluidic communication with the lumen.

74. The surgical probe of claim 72 wherein the central lumen comprises a polymeric liner.

75. The surgical probe of claim 60 wherein the expandable structure comprises a distensible or non-distensible material.

76. The surgical probe of claim 60 wherein the expandable structure is configured as a hollow bulbous structure with an ostium configured for fluid tight bonding to the distal end of the surgical probe shaft.

77. The surgical probe of claim 60 wherein the expandable structure is configured to expand to a greater extent in a first radial axis than a second radial axis.

78. The surgical probe of claim 60 further comprising an imaging device in proximity to the distal end of the surgical probe shaft.

79. The surgical probe of claim 60 further comprising a temperature sensor in proximity to the distal end of the surgical probe shaft.

80. The surgical probe of claim 60 further comprising an indicator or marker along the shaft.

81. A method for treating a tissue region within a nasal cavity, comprising:

advancing a distal end of a surgical probe shaft through the nasal cavity and into proximity of the tissue region having at least one posterior nasal nerve;

introducing a cryogenic fluid into an expandable structure attached to the distal end of the probe shaft such that the expandable structure inflates from a deflated configuration

into an expanded configuration against the tissue region;

adjusting a position of a member relative to the tissue region, wherein the member is attached to the distal end of the probe shaft and extends within the expandable structure which encloses the member such that the member is unattached to an interior of the expandable structure;

applying a pressure against the tissue region having the at least one posterior nasal nerve via the member pressing against the interior of the expandable structure, wherein the member defines an atraumatic shape which is sized for pressing against and manipulating the tissue region through the expandable structure; and

maintaining the member against the interior of the expandable structure and the tissue region until the tissue region is cryogenically ablated.

82. The method of claim 81 wherein maintaining the member further comprises cryogenically ablating the at least one posterior nasal nerve such until symptoms of rhinitis are reduced.

83. The method of claim 81 wherein advancing a distal end comprises advancing the distal end through a nostril and into the nasal cavity.

84. The method of claim 81 wherein advancing a distal end comprises advancing the distal end at least 2 cm beyond an anterior entrance to a middle meatus.

85. The method of claim 81 wherein advancing a distal end comprises:

advancing the distal end along an upper surface of the inferior nasal turbinate to a mid-portion of the middle nasal turbinate;

advancing the distal end into a middle meatus; and

further advancing the distal end posteriorly up into a cul-de-sac.

86. The method of claim 81 wherein advancing a distal end comprises positioning the member between the middle and inferior nasal turbinate.

87. The method of claim 81 wherein advancing a distal end comprises positioning the member relative to the tissue region surrounded by the middle nasal turbinate, inferior nasal turbinate, and lateral wall forming a cul-de-sac.

88. The method of claim 81 wherein advancing a distal end comprises positioning the member into proximity of the Pterygomaxillary fossa, sphenopalatine ganglion, sphenopalatine ganglion, or vidian nerve.

89. The method of claim 81 wherein advancing a distal end comprises positioning the member into proximity of accessory posterolateral nerves bounded by an sphenopalatine foramen superiorly, an inferior edge of an inferior turbinate inferiorly, a Eustachian tube posteriorly, or a posterior third of the middle and inferior turbinates anteriorly.

90. The method of claim 81 wherein introducing a cryogenic fluid comprises evaporating the cryogenic fluid within the expandable structure.

91. The method of claim 81 wherein the expandable structure is inflated in response to evaporation of the cryogenic fluid within the interior.

92. The method of claim 81 wherein introducing a cryogenic fluid further comprises expanding the expandable structure to a greater extent in one radial axis compared to a second radial axis.

93. The method on claim 81 wherein adjusting a position of a member further comprises positioning the member to contact a lateral nasal wall defined by a tail of a nasal turbinate, lateral wall, and an inferior turbinate.

94. The method of claim 81 wherein introducing a cryogenic fluid further comprises flowing the cryogenic fluid into the interior between approximately 20 seconds to 300 seconds.

95. The method of claim 81 wherein introducing a cryogenic fluid further comprises flowing the cryogenic fluid into the interior between approximately 20 seconds to 120 seconds.

96. The method of claim 81 wherein the cryogenic fluid comprises nitrous

oxide, liquid nitrogen, or carbon dioxide.

97. The method of claim 81 further comprising introducing an imaging device in proximity to the distal end.

98. The method of claim 81 further comprising visualizing the tissue region while advancing the distal end of the surgical probe through the nasal cavity.

99. The method of claim 98 wherein visualizing comprises visualizing via a CCD or CMOS imager positioned along the surgical probe shaft.

100. The method of claim 98 wherein visualizing comprises visualizing infrared wavelengths.

101. The method of claim 98 wherein visualizing comprises visualizing via a nasal endoscope.

102. The method of claim 101 wherein visualizing comprises advancing the nasal endoscope with the surgical probe shaft.

103. The method of claim 81 further comprising introducing a temperature sensor in proximity to the distal end of the surgical probe shaft.

104. The method of claim 81 wherein advancing a distal end comprises positioning the surgical probe shaft into proximity of an anterior region of middle or inferior nasal turbinate.

105. The method of claim 81 wherein applying a pressure comprises applying a force of 20 to 200 grams via the member pressing against the interior of the expandable structure.

106. The method of claim 81 further comprising stopping the cryogenic fluid and waiting 10 to 20 seconds prior to removing the distal end of the surgical probe shaft from the tissue region.

107. The method of claim 81 wherein maintaining the member comprises ablating the tissue region through a layer of gel.

108. The method of claim 81 further comprising assessing the tissue region during and/or after ablation.

109. The method of claim 108 wherein assessing comprises inspecting the tissue region visually or via ultrasound.

110. The method of claim 81 wherein assessing comprises detecting or a temperature of the tissue region.

111. The method of claim 81 further comprising vibrating the expandable structure while maintaining the member against the interior of the expandable structure and the tissue region.

112. The method of claim 81 further comprising applying an anesthetic to the tissue region to be treated prior to applying a pressure against the tissue region.

113. A method for treating rhinitis, comprising:

advancing a distal end of a surgical probe shaft through the nasal cavity and into proximity of a tissue region surrounded by the middle nasal turbinate, inferior nasal turbinate, and lateral wall forming a cul-de-sac and having at least one posterior nasal nerve;

introducing a cryogenic fluid into an expandable structure attached to the distal end of the probe shaft such that the expandable structure inflates from a deflated configuration into an expanded configuration against the tissue region, wherein the distal end has an attached member which extends within the expandable structure such that the member is unattached to the interior of the expandable structure;

applying a pressure against the tissue region via the member pressing against the interior of the expandable structure, wherein the member defines an atraumatic shape and is unattached to the interior of the expandable structure; and

maintaining the member against the interior of the expandable structure and the

tissue region until the tissue region is cryogenically ablated.

114. The method of claim 113 wherein advancing a distal end comprises advancing the distal end at least 2 cm beyond an anterior entrance to a middle meatus.

115. The method of claim 113 wherein advancing a distal end comprises:

advancing the distal end along an upper surface of the inferior nasal turbinate to a mid-portion of the middle nasal turbinate;

advancing the distal end into a middle meatus; and

further advancing the distal end posteriorly up into a cul-de-sac.

116. The method of claim 113 wherein advancing a distal end comprises positioning the member between the middle and inferior nasal turbinate.

117. The method of claim 113 wherein advancing a distal end comprises positioning the member into proximity of the Pterygomaxillary fossa, sphenopalatine ganglion, sphenopalatine ganglion, or vidian nerve.

118. The method of claim 113 wherein advancing a distal end comprises positioning the member into proximity of accessory posterolateral nerves bounded by an sphenopalatine foramen superiorly, an inferior edge of an inferior turbinate inferiorly, a Eustachian tube posteriorly, or a posterior third of the middle and inferior turbinates anteriorly.

119. The method of claim 113 wherein introducing a cryogenic fluid comprises evaporating the cryogenic fluid within the expandable structure.

120. The method of claim 113 wherein the expandable structure is inflated in response to evaporation of the cryogenic fluid within the interior.

121. The method on claim 113 wherein advancing a distal end further comprises positioning the member to contact a lateral nasal wall defined by a tail of a nasal turbinate, lateral wall, and an inferior turbinate.

122. The method of claim 113 wherein introducing a cryogenic fluid comprises flowing the cryogenic fluid into the interior between approximately 20 seconds to 300 seconds.

123. The method of claim 113 wherein introducing a cryogenic fluid further comprises flowing the cryogenic fluid into the interior between approximately 20 seconds to 120 seconds.

124. The method of claim 113 wherein the cryogenic fluid comprises nitrous oxide, liquid nitrogen, or carbon dioxide.

125. The method of claim 113 further comprising introducing an imaging device in proximity to the distal end.

126. The method of claim 113 further comprising visualizing the tissue region while advancing the distal end of the surgical probe through the nasal cavity.

127. The method of claim 126 wherein visualizing comprises visualizing via a CCD or CMOS imager positioned along the surgical probe shaft.

128. The method of claim 126 wherein visualizing comprises visualizing infrared wavelengths.

129. The method of claim 126 wherein visualizing comprises visualizing via a nasal endoscope.

130. The method of claim 129 wherein visualizing comprises advancing the nasal endoscope with the surgical probe shaft.

131. The method of claim 113 further comprising introducing a temperature sensor in proximity to the distal end of the surgical probe shaft.

132. The method of claim 113 wherein applying a pressure comprises applying a force of 20 to 200 grams via the member pressing against the interior of the expandable

structure.

133. The method of claim 113 further comprising stopping the cryogenic fluid and waiting 10 to 20 seconds prior to removing the distal end of the surgical probe shaft from the tissue region.

134. The method of claim 113 wherein maintaining the member comprises ablating the tissue region through a layer of gel.

135. The method of claim 113 further comprising assessing the tissue region during and/or after ablation.

136. The method of claim 135 wherein assessing comprises inspecting the tissue region visually or via ultrasound.

137. The method of claim 113 wherein assessing comprises detecting or a temperature of the tissue region.

138. The method of claim 113 further comprising vibrating the expandable structure while maintaining the member against the interior of the expandable structure and the tissue region.

139. The method of claim 113 further comprising applying an anesthetic to the tissue region to be treated prior to applying a pressure against the tissue region.

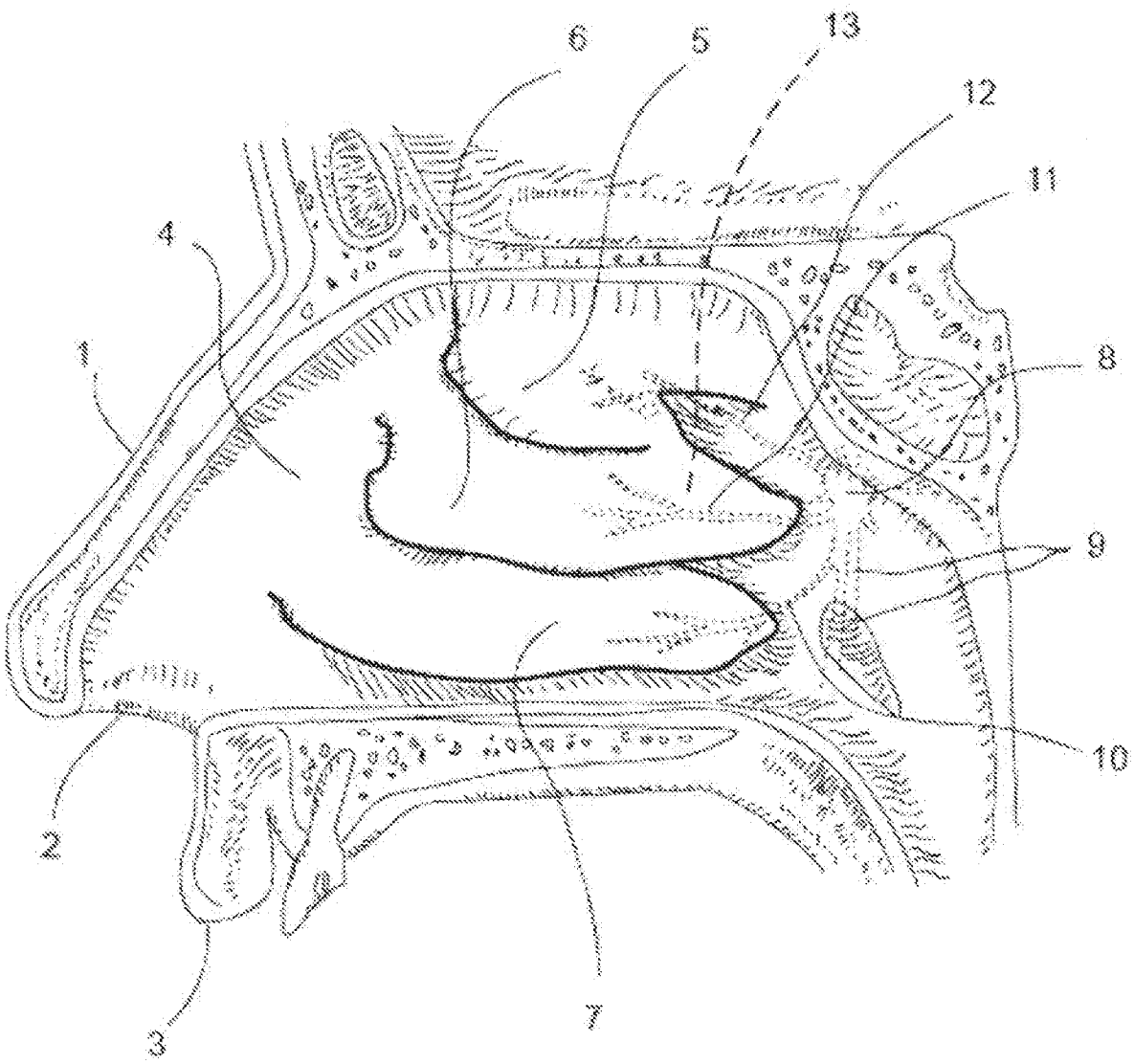


Figure 1

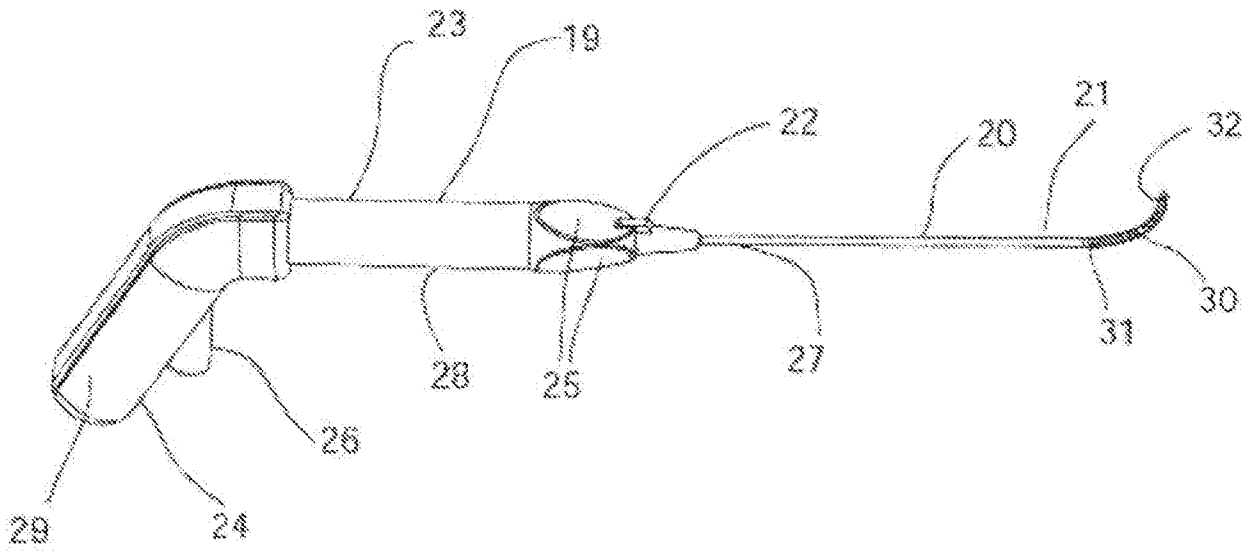


Figure 2

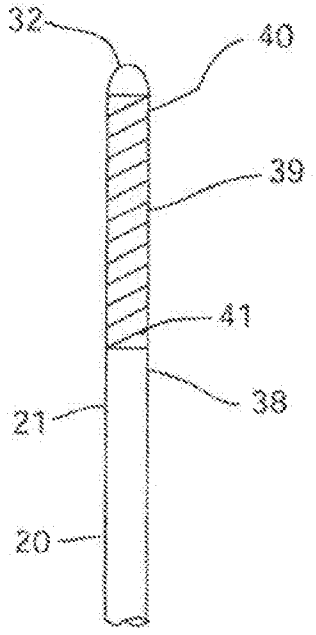


Figure 3A

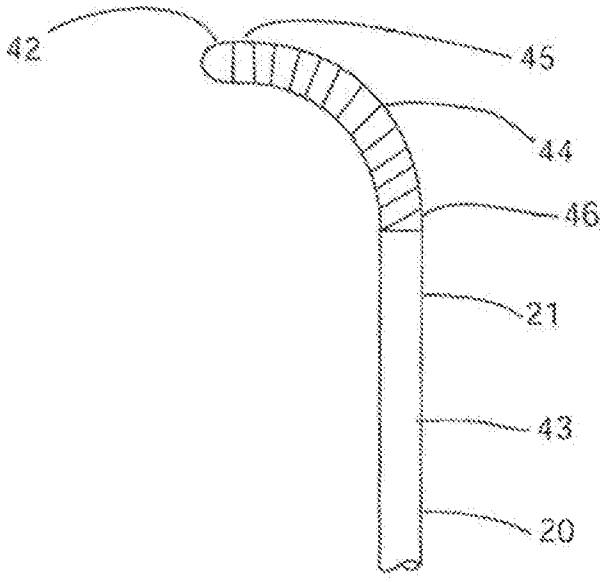


Figure 3B

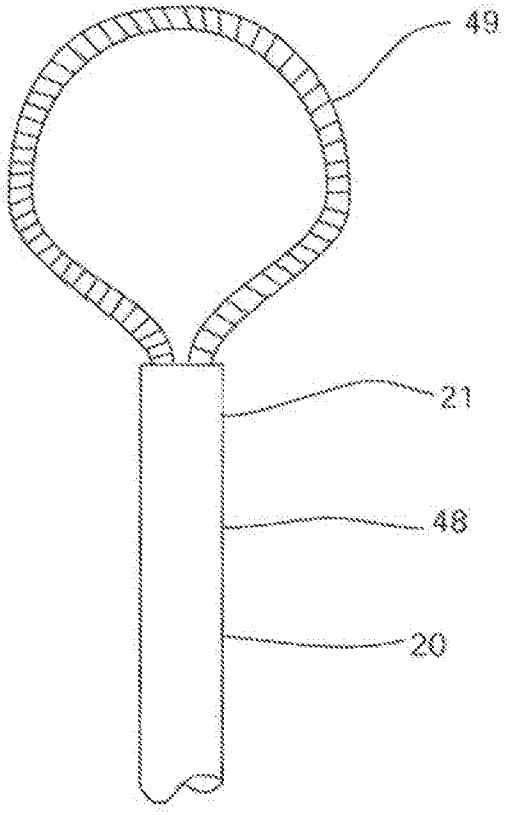


Figure 3C

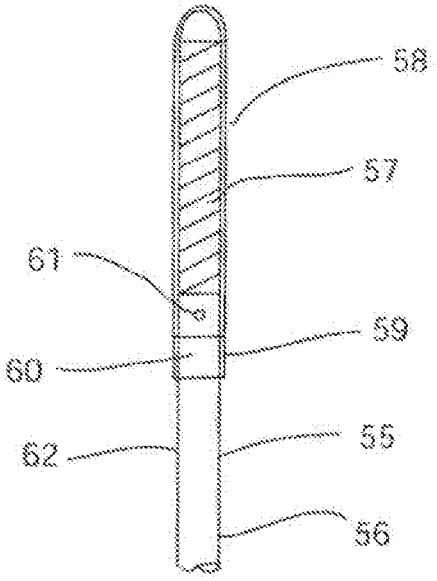


Figure 4A

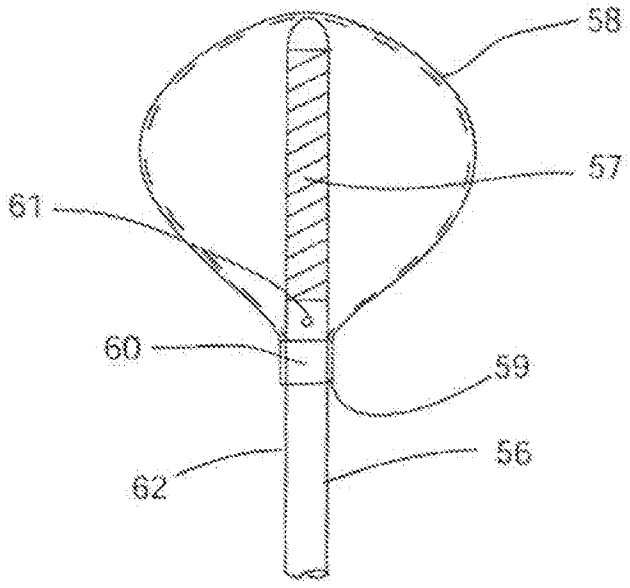


Figure 4B

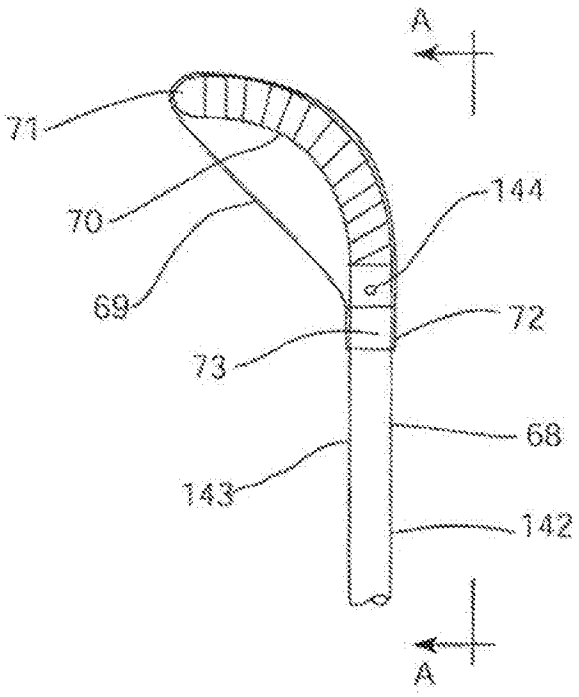


Figure 5A

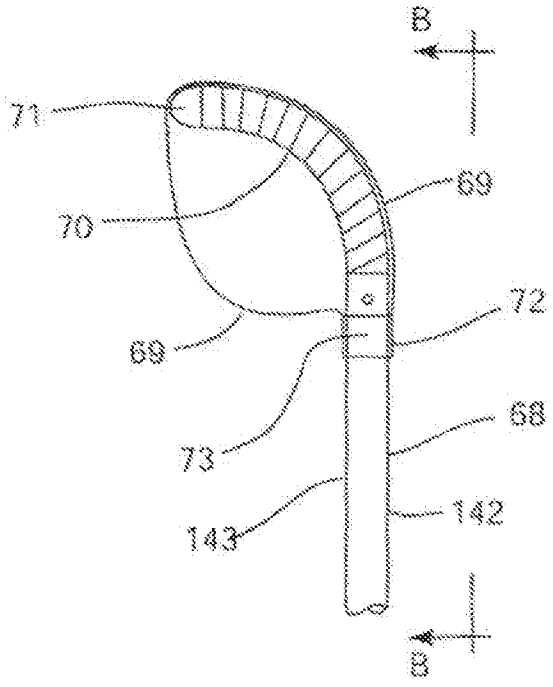
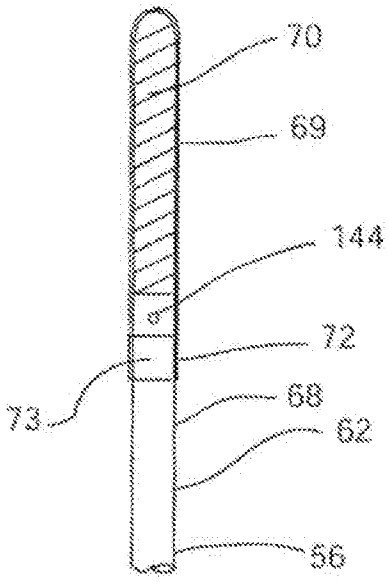
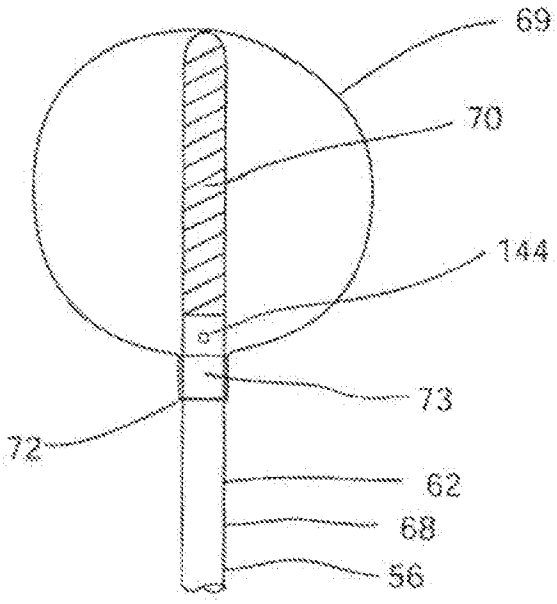


Figure 5B



View A-A

Figure 5C



View B-B

Figure 5D

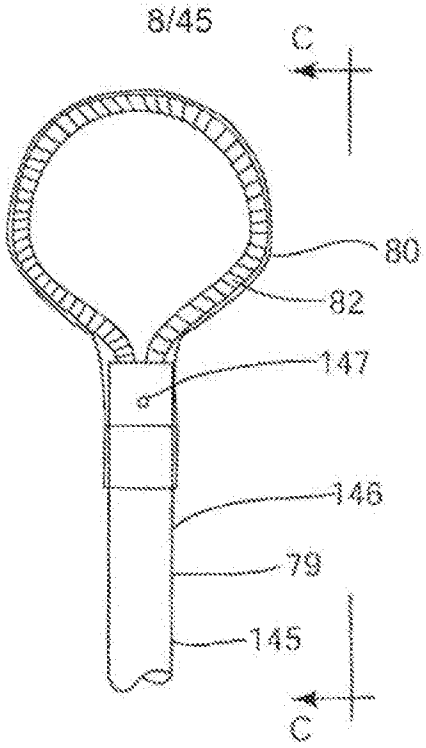


Figure 6A

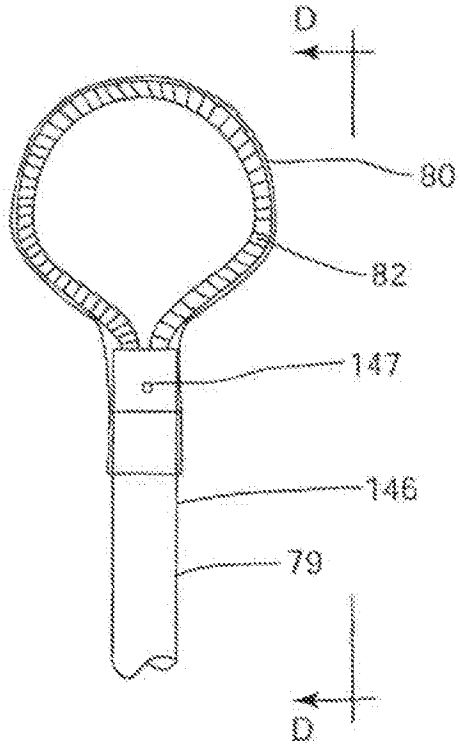
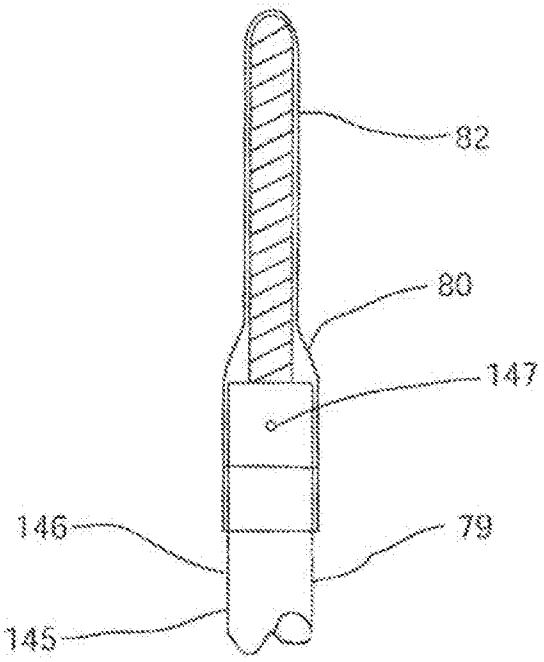
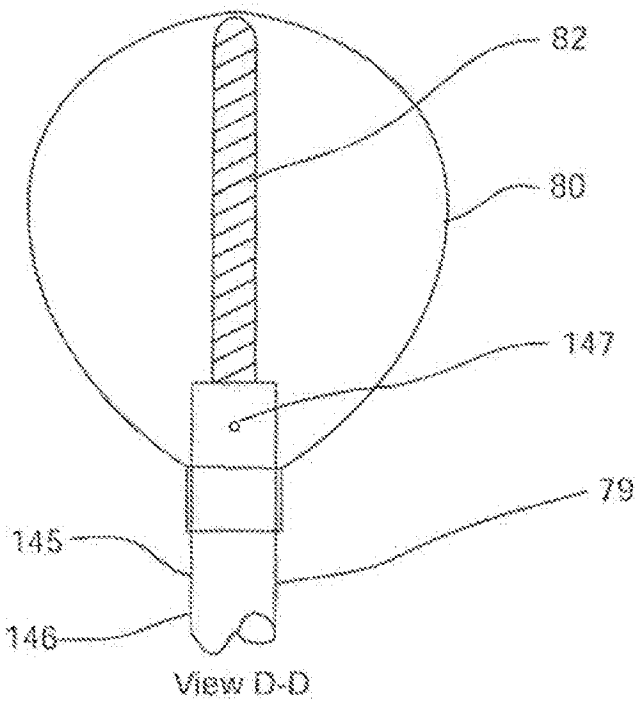


Figure 6B



View C-C

Figure 6C



View D-D

Figure 6D

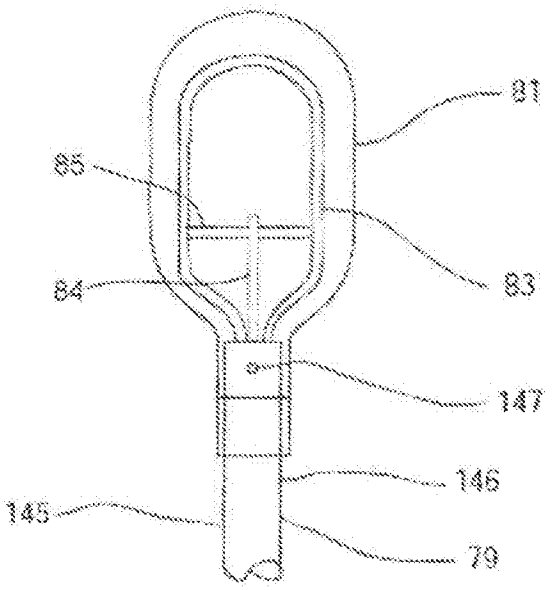


Figure 6E

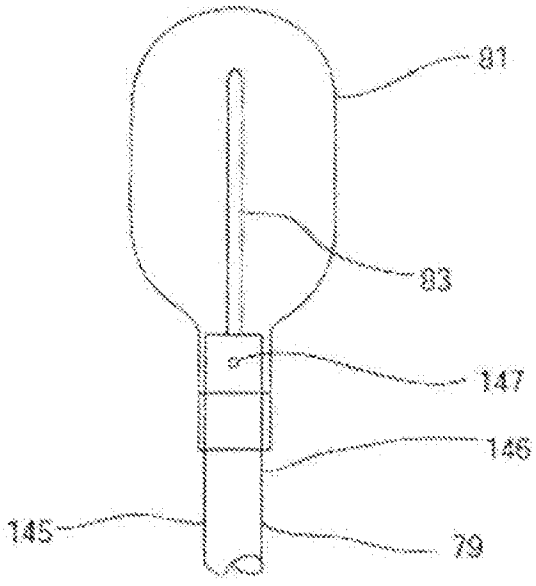


Figure 6F

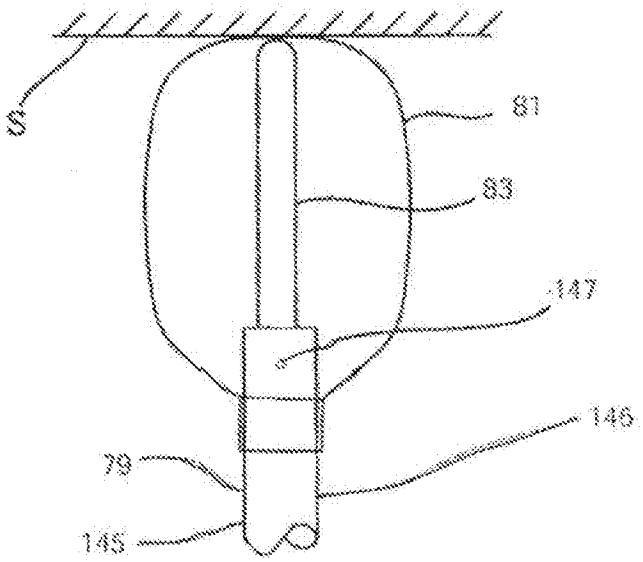


Figure 6G

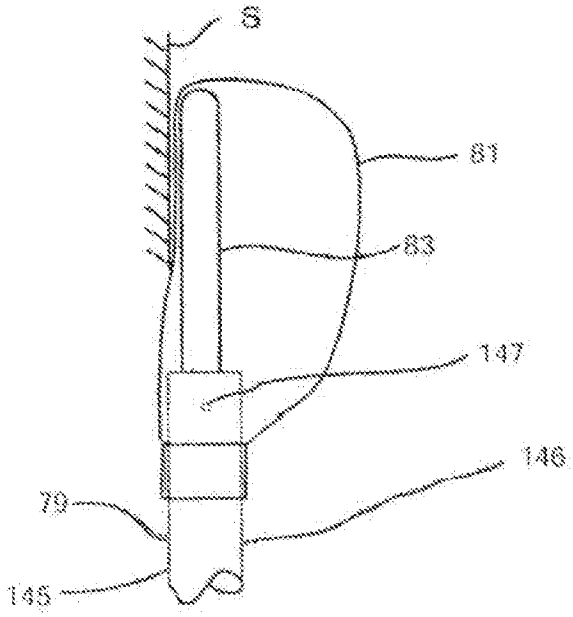


Figure 6H

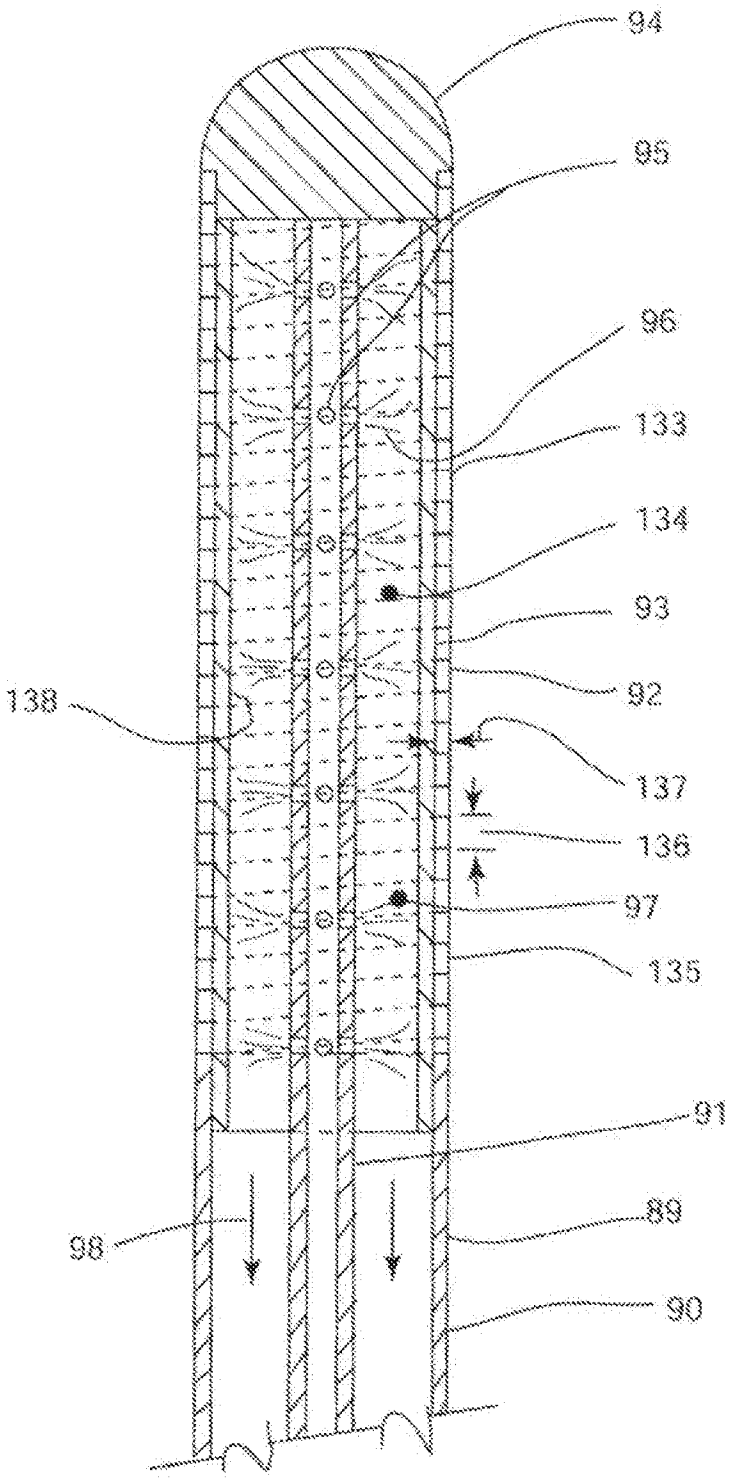


Figure 7

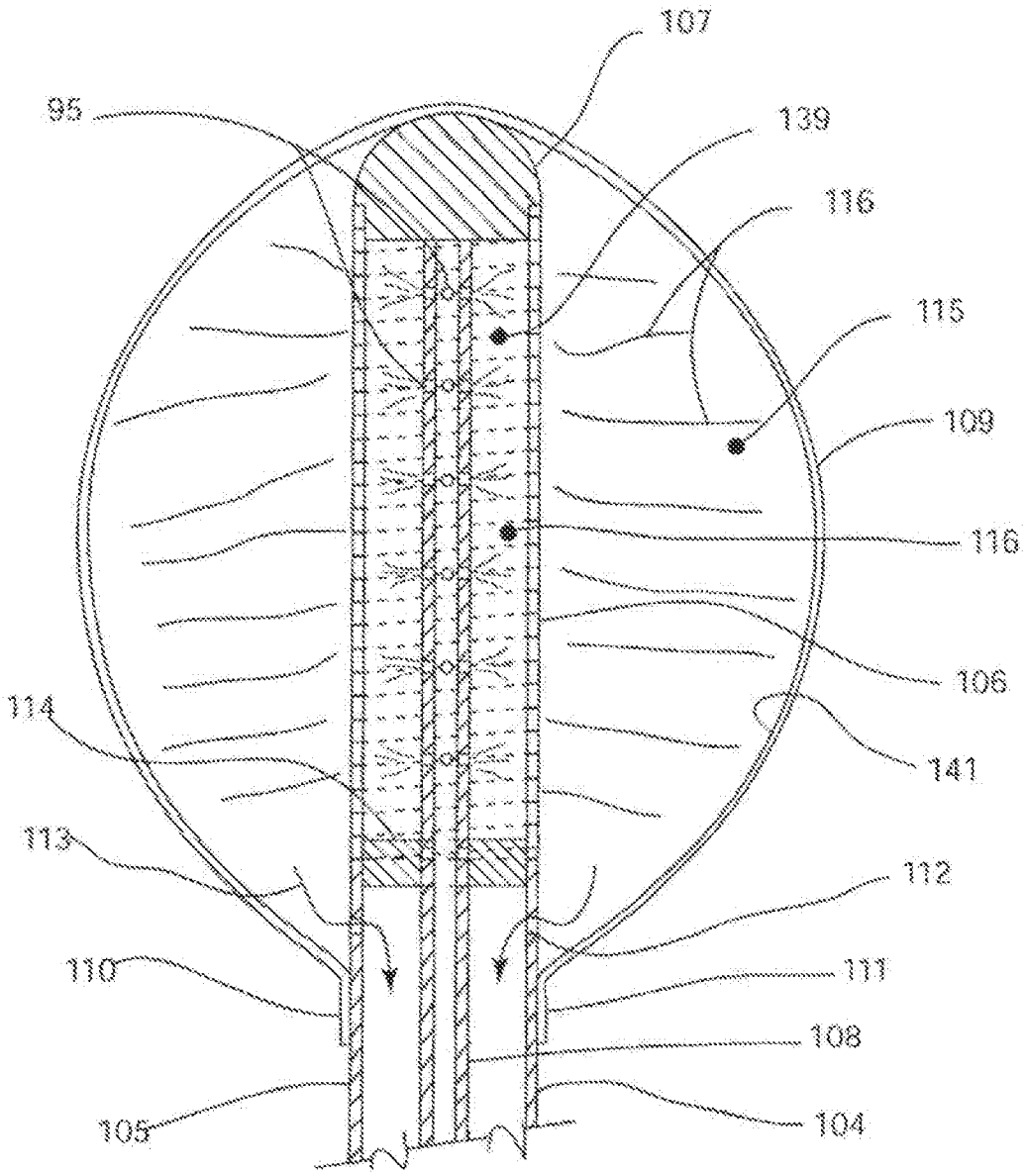

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Figure 8

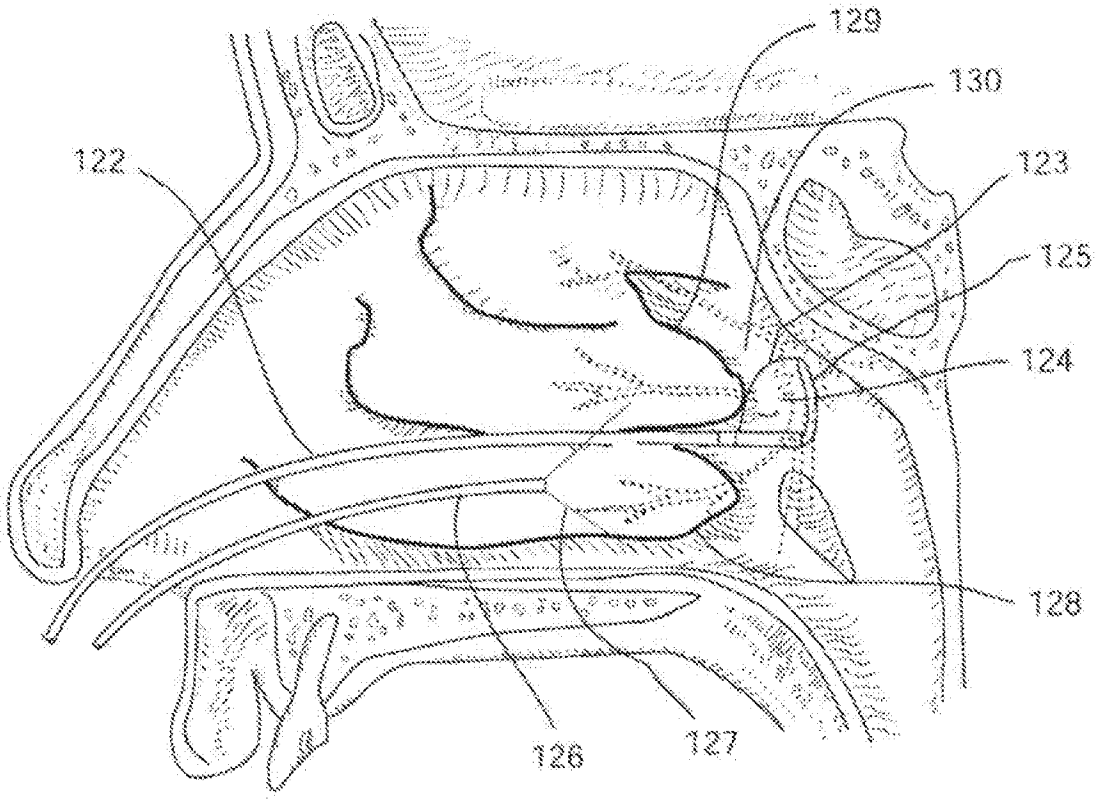


Figure 9

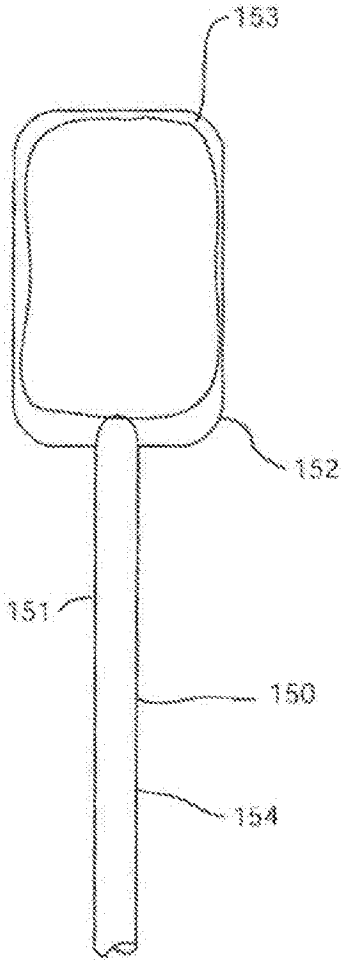


Figure 10A

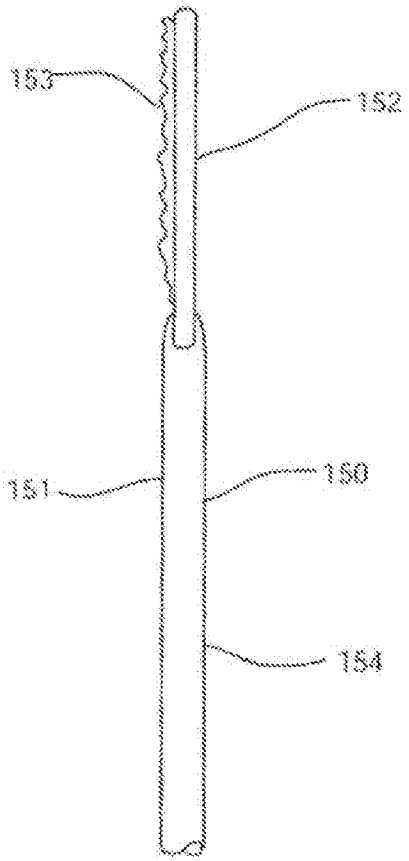


Figure 10B

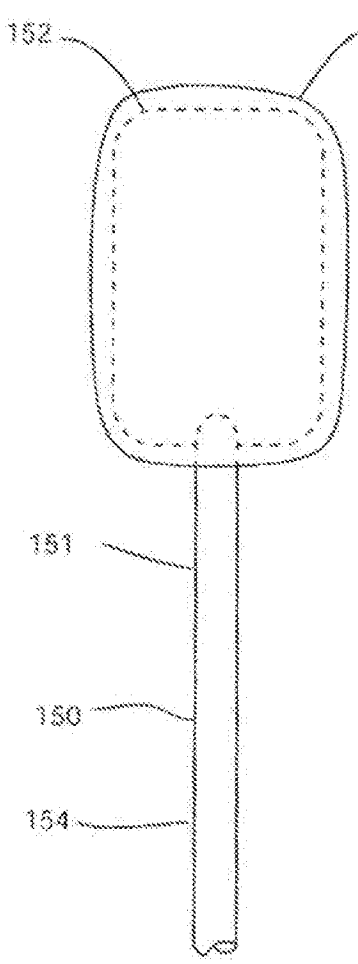


Figure 10C

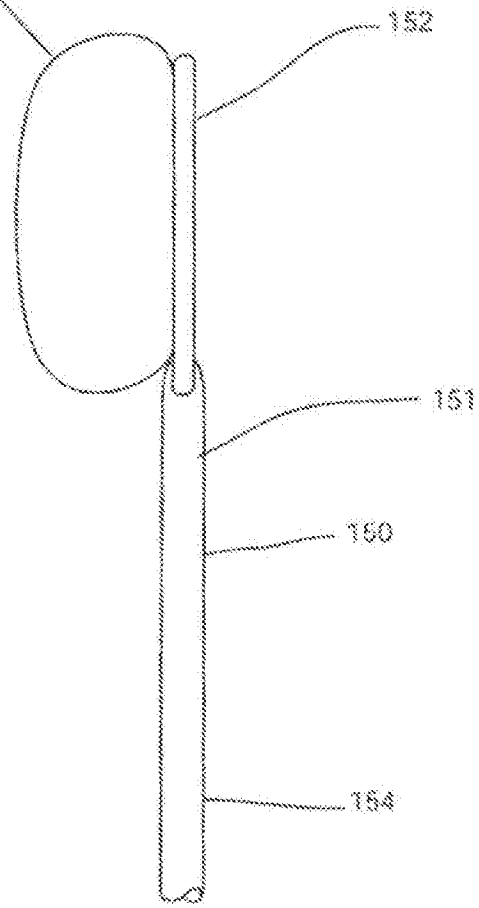


Figure 10D

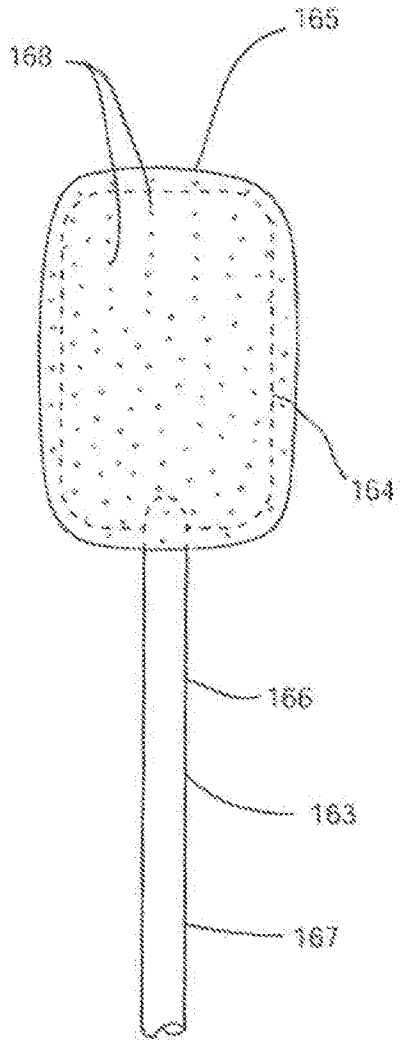


Figure 11A

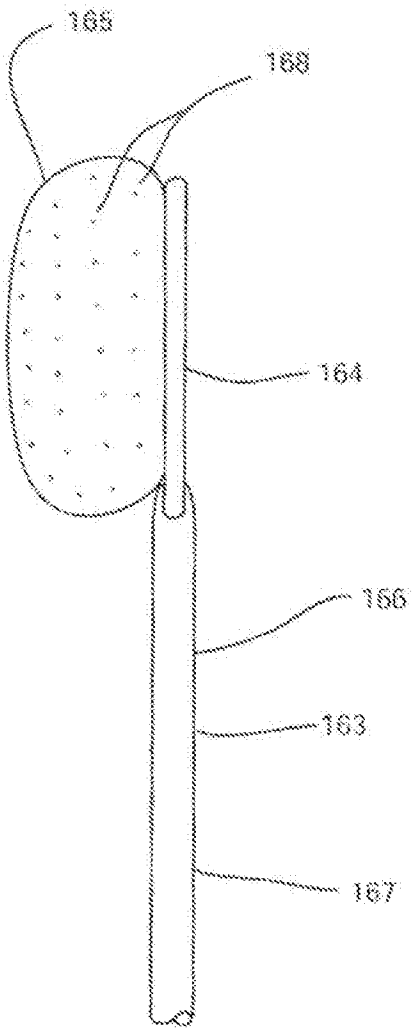


Figure 11B

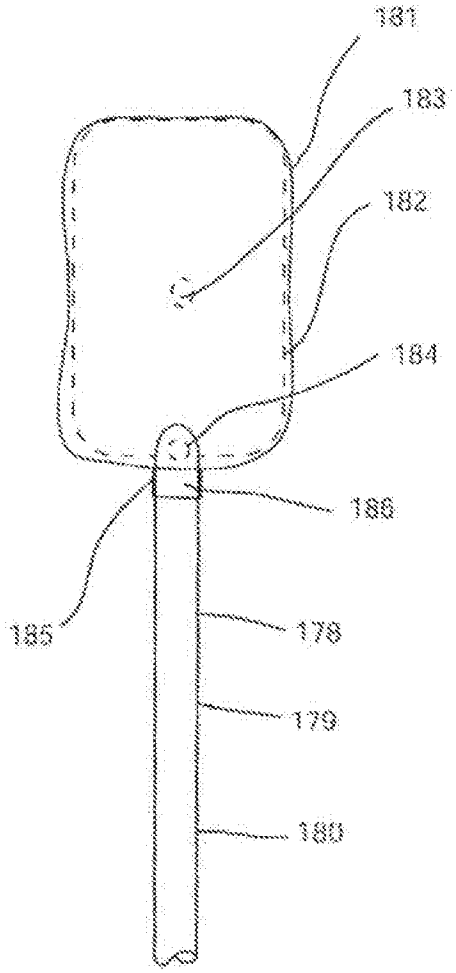


Figure 12A

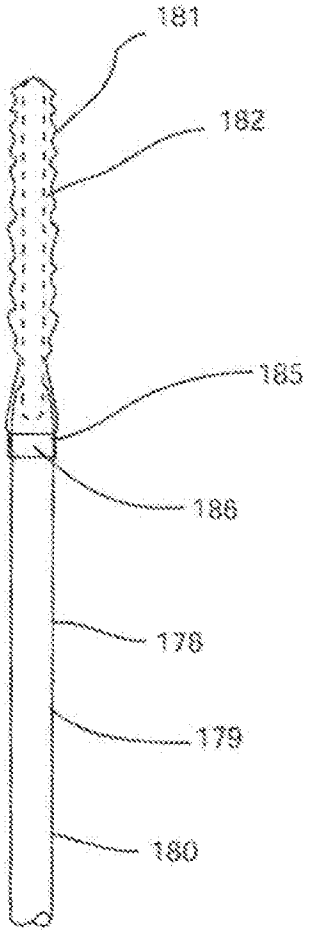


Figure 12B

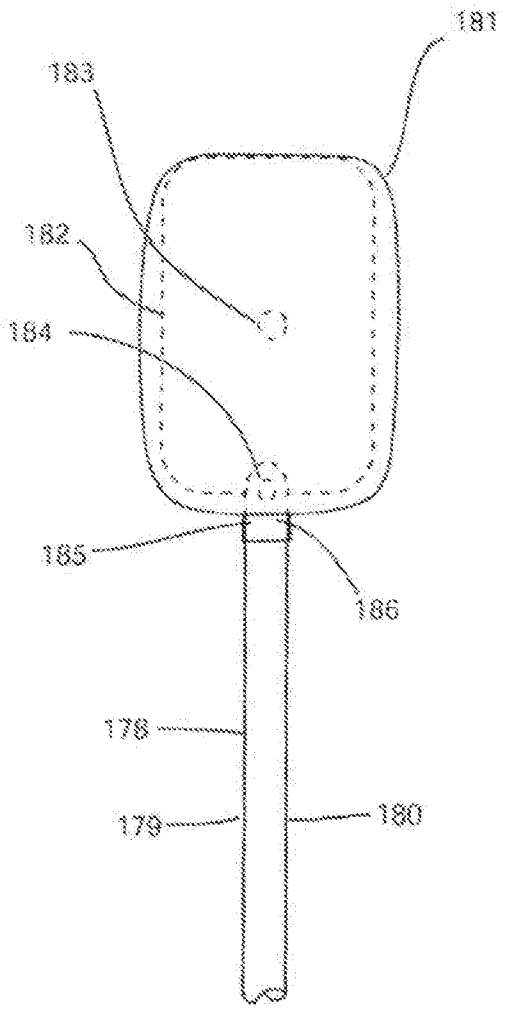


Figure 12C

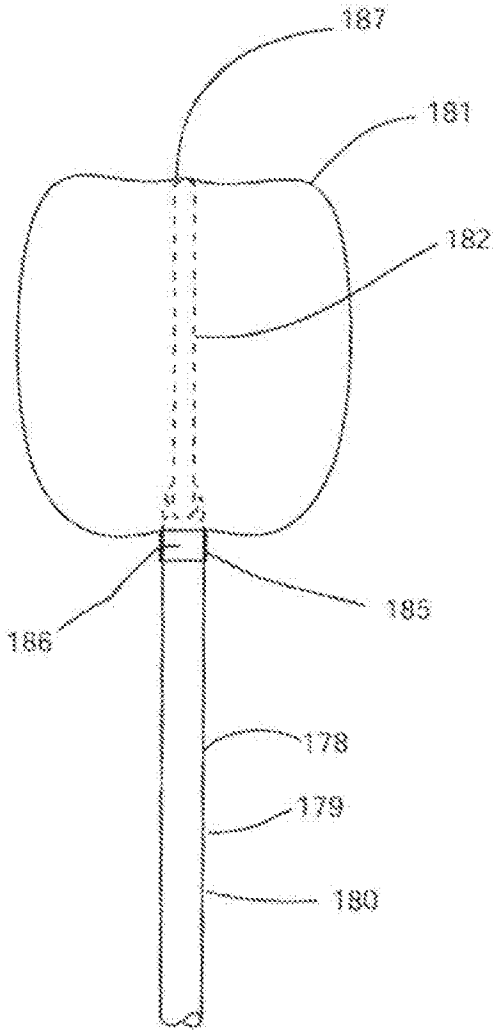


Figure 12D

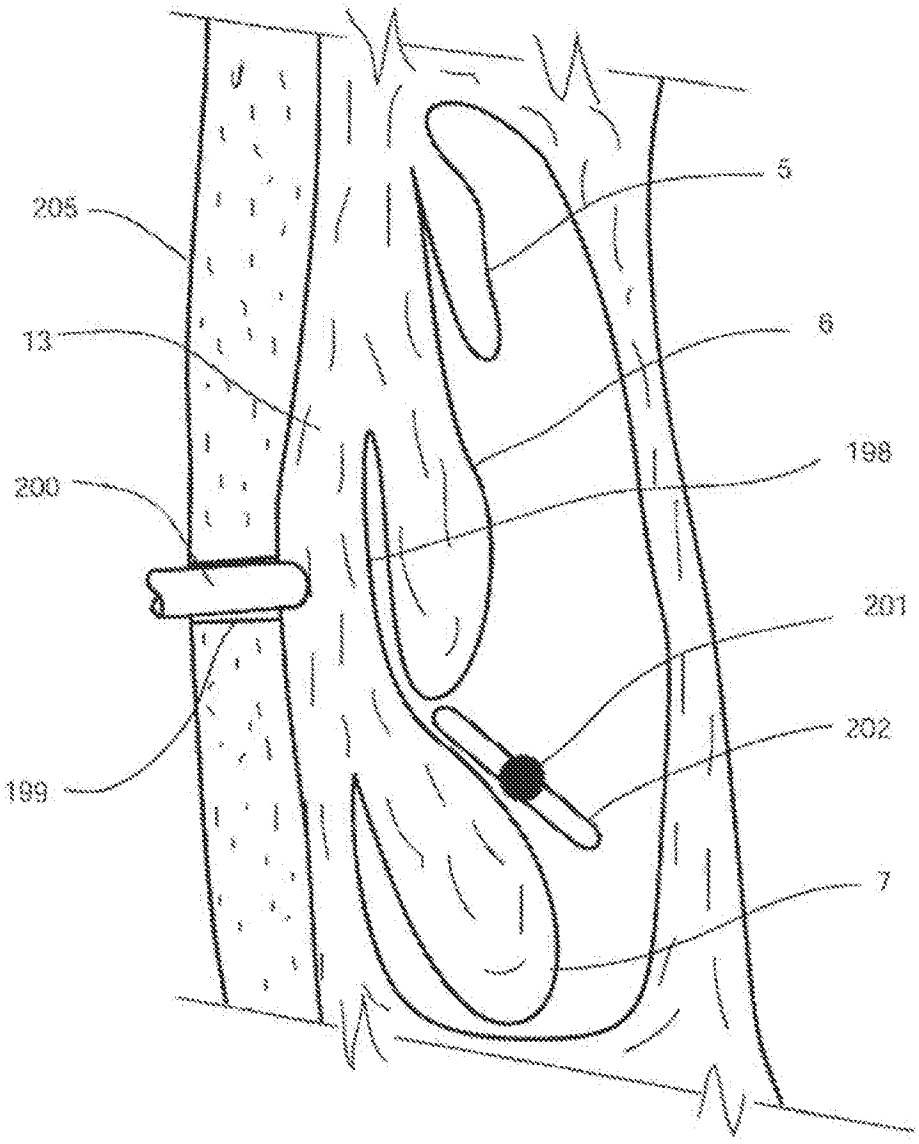


Figure 13A

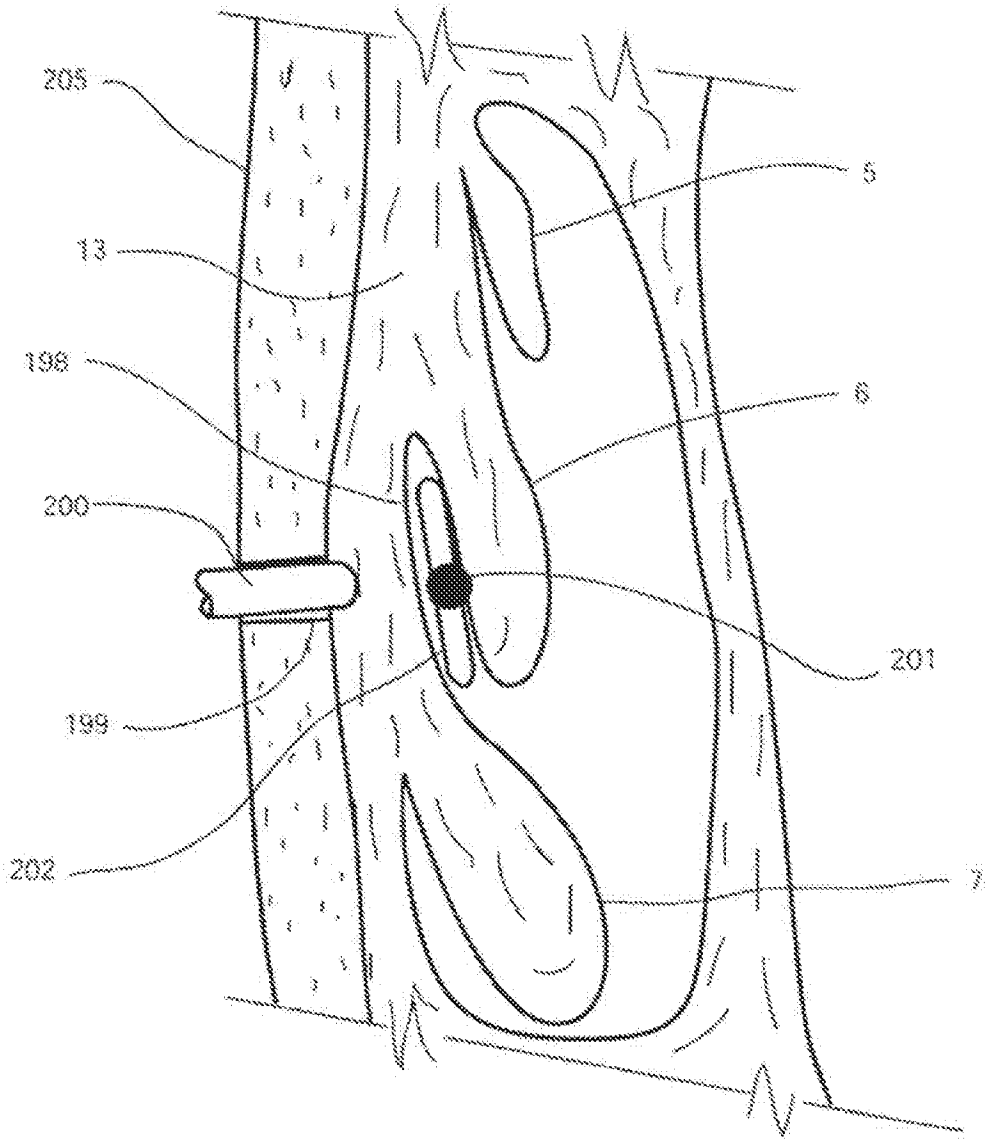


Figure 13B

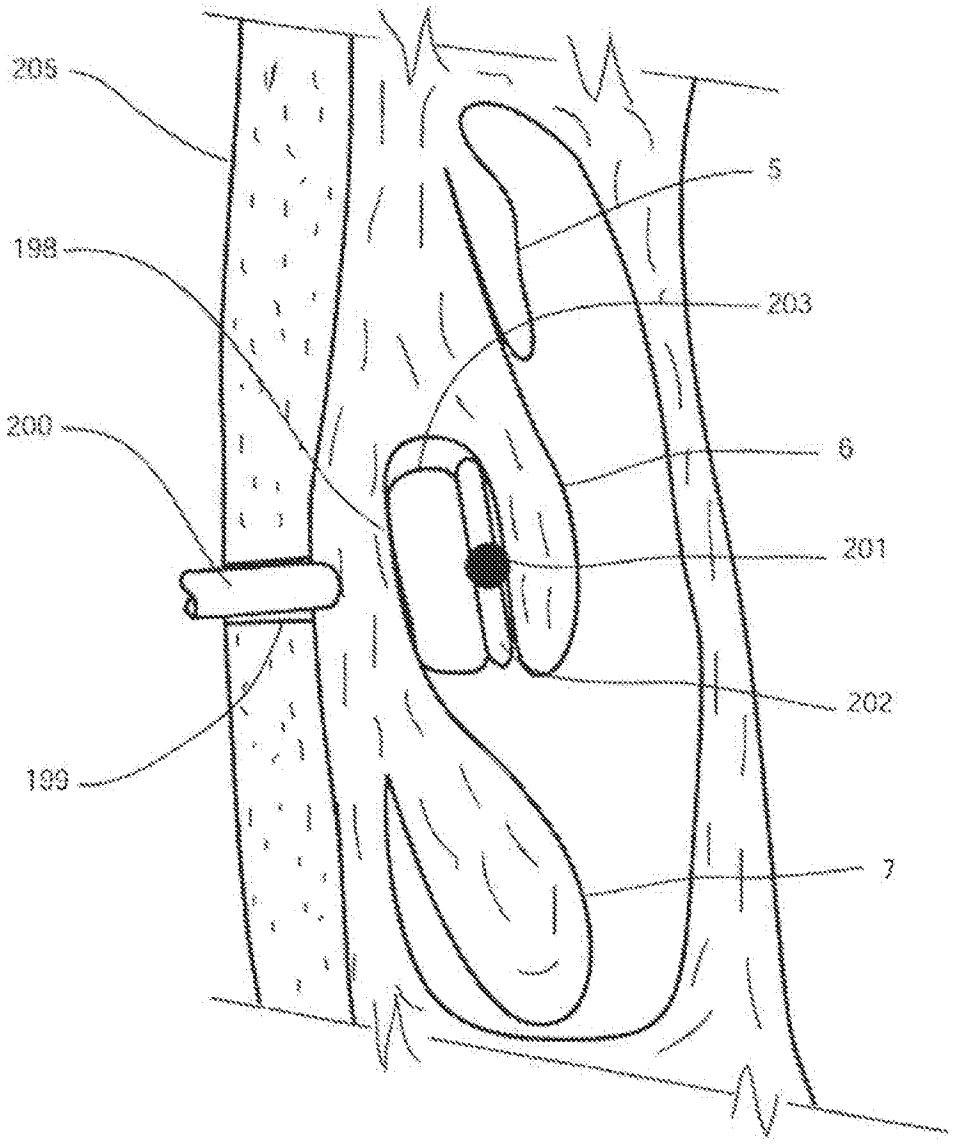


Figure 13C

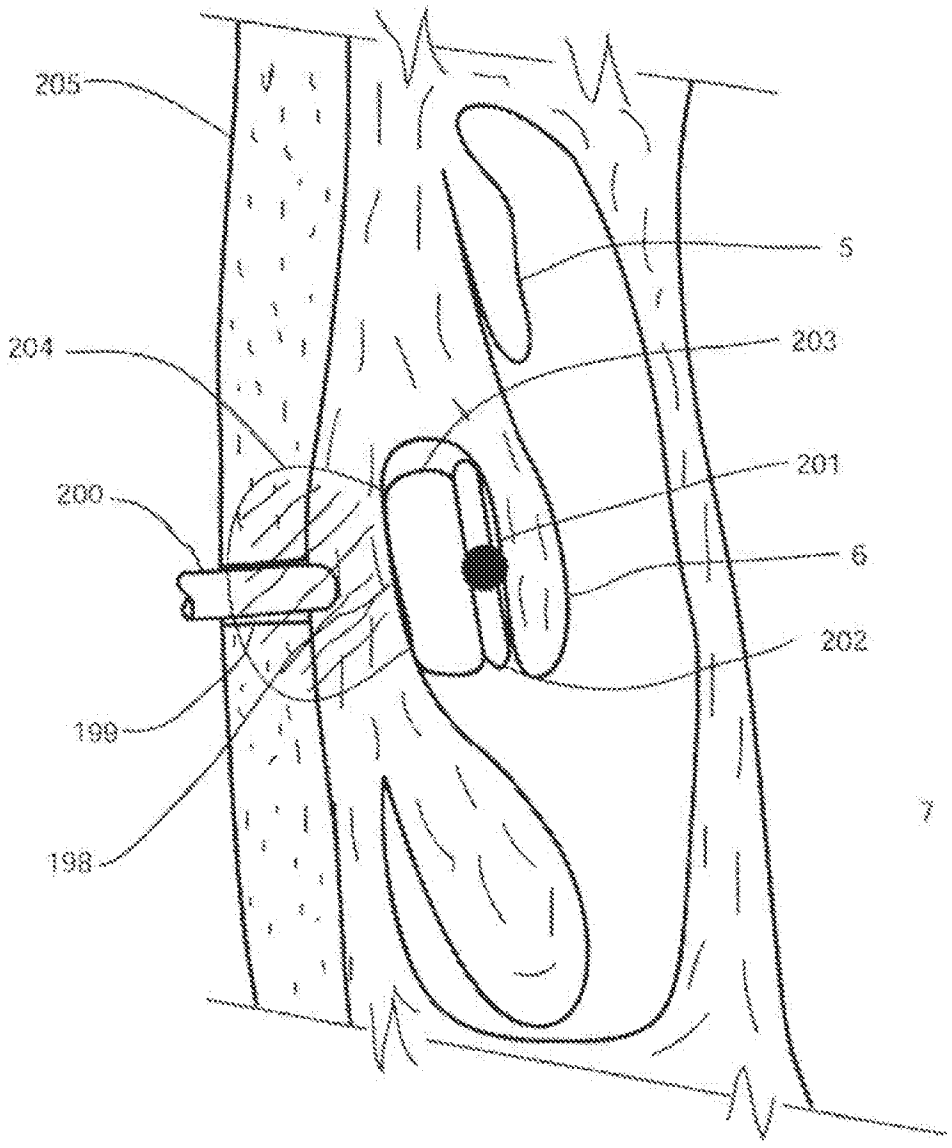


Figure 13D

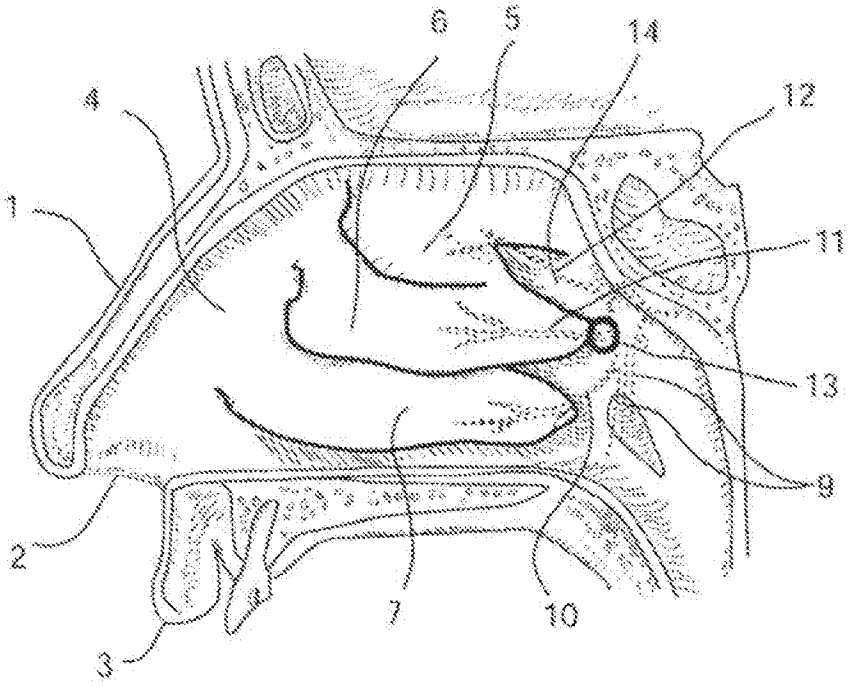


Figure 14A

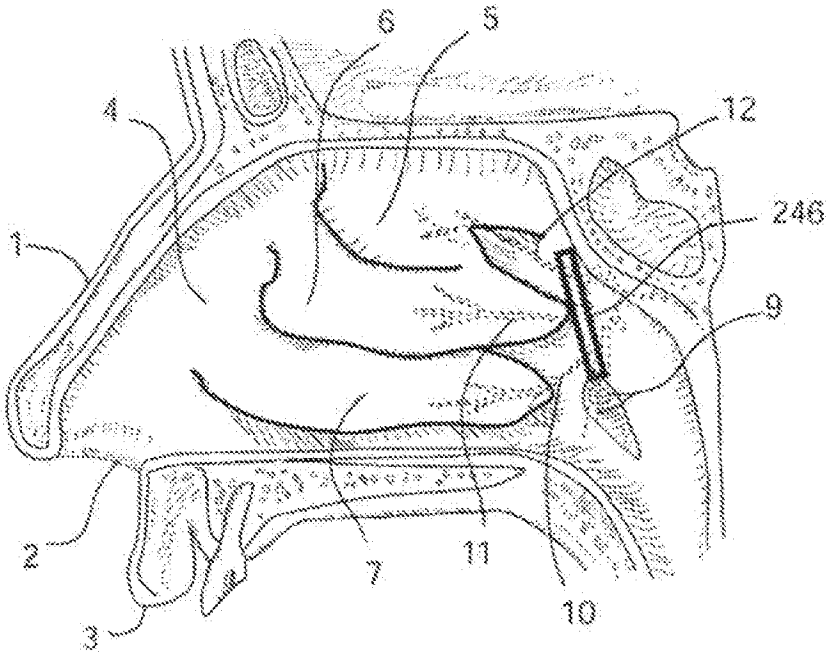


Figure 14B

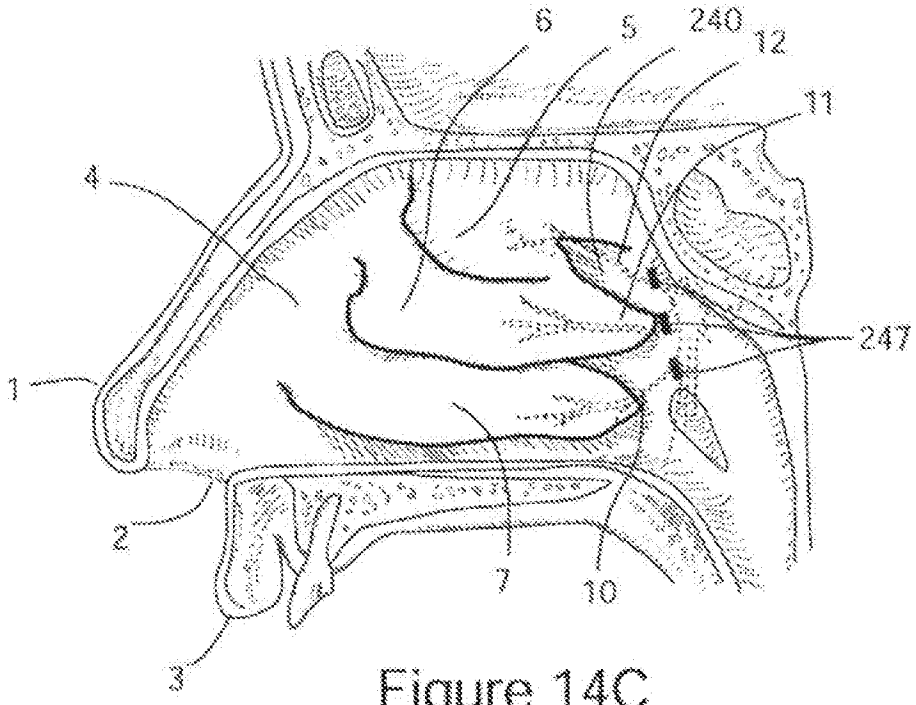


Figure 14C

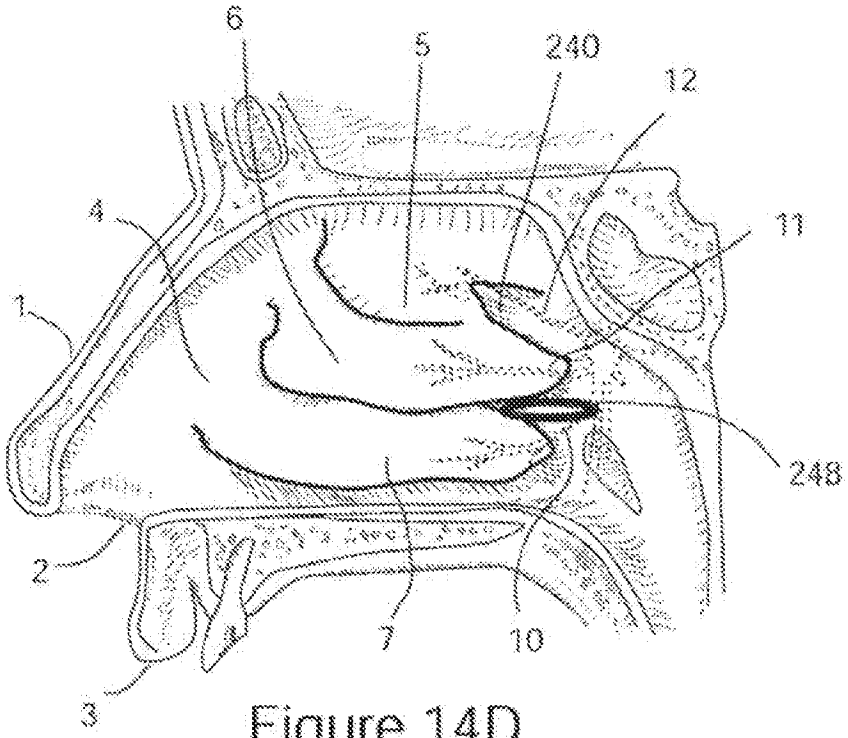


Figure 14D

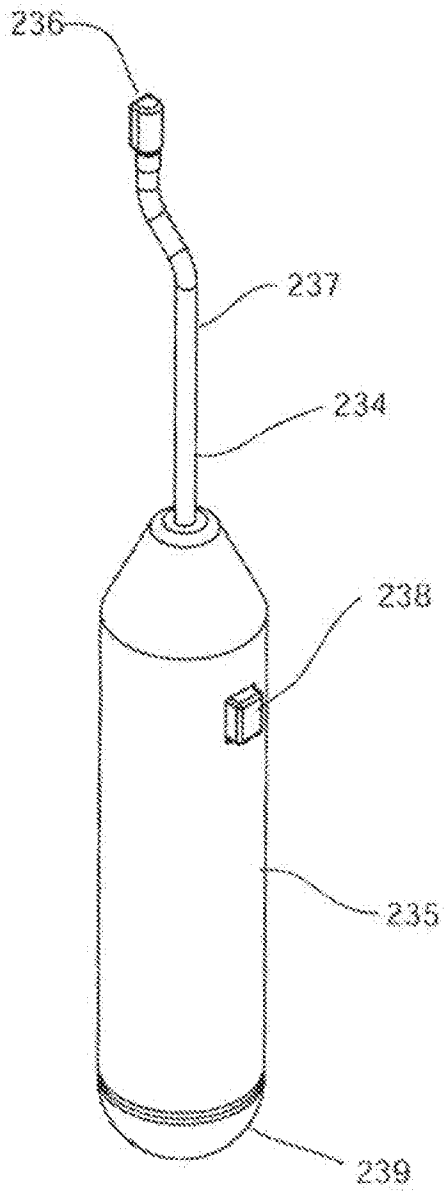


Figure 15A

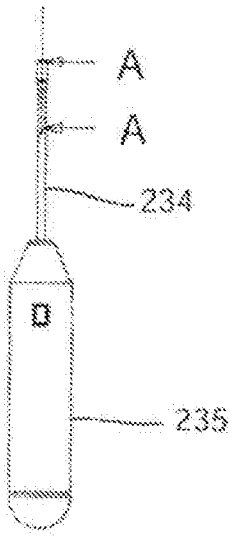
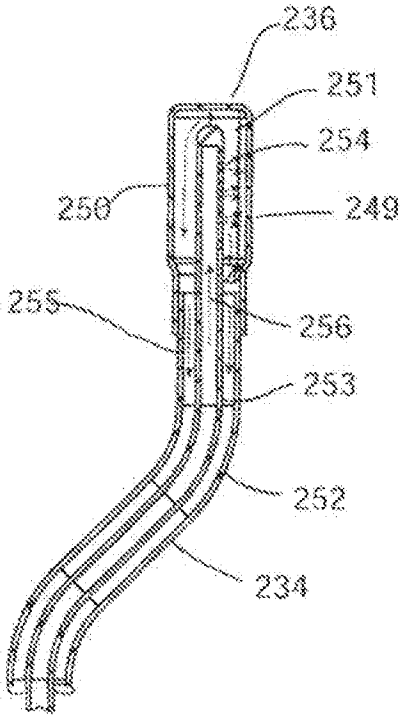


Figure 15B



Section A-A

Figure 15C

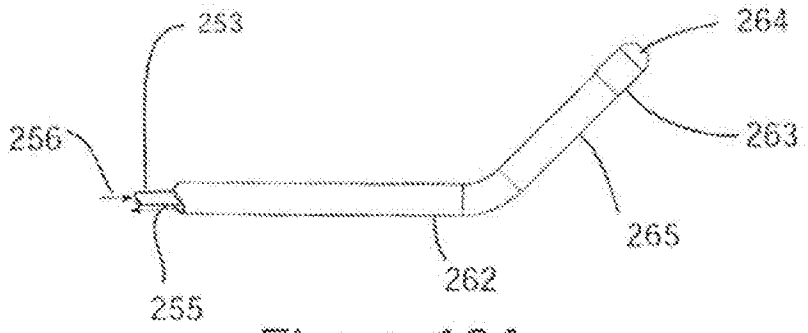


Figure 16A

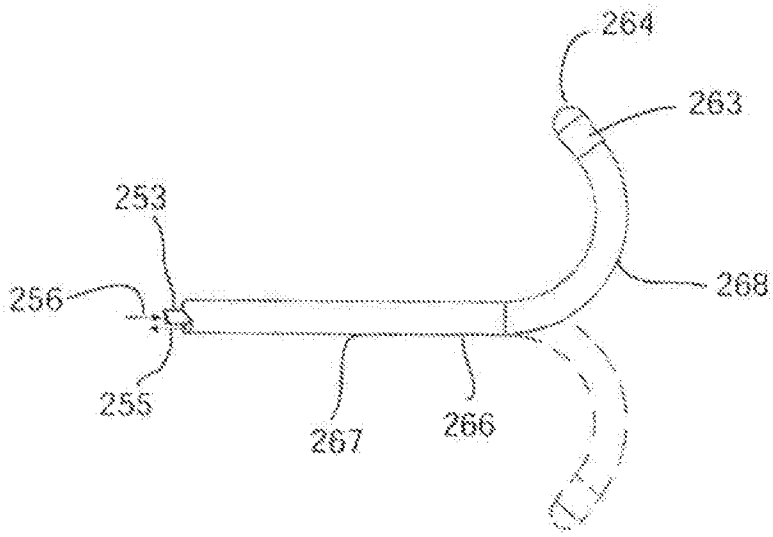


Figure 16B

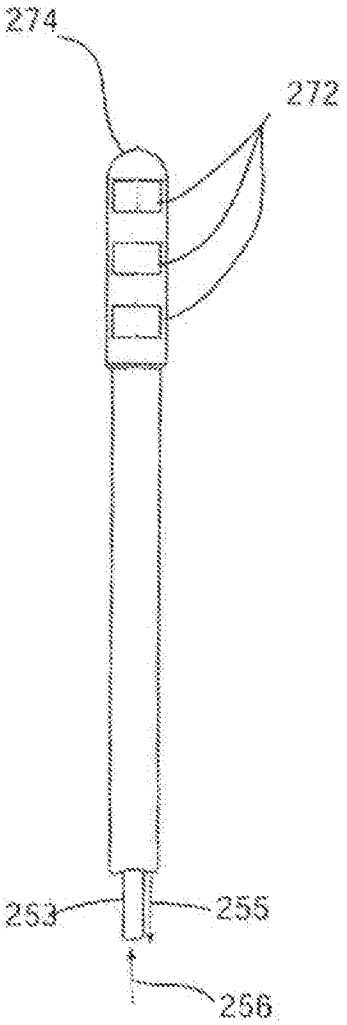


Figure 16C

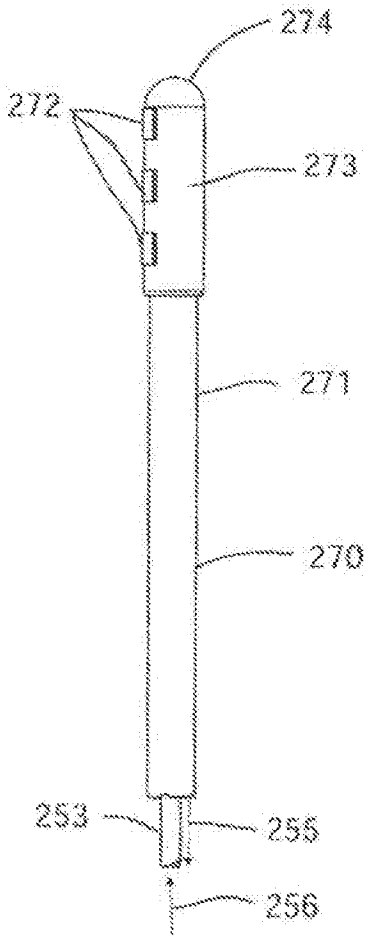


Figure 16D

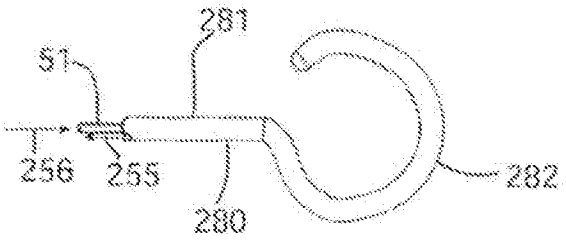


Figure 17A

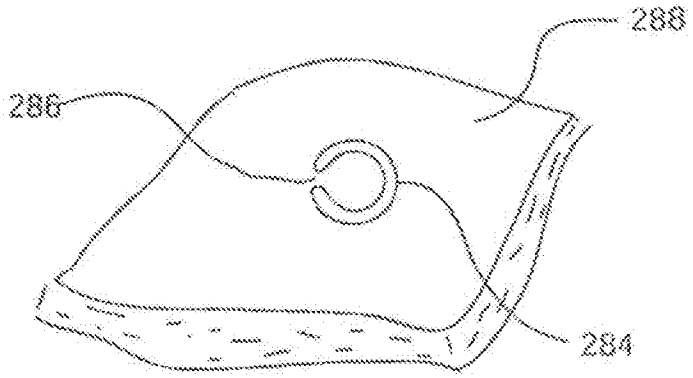


Figure 17B

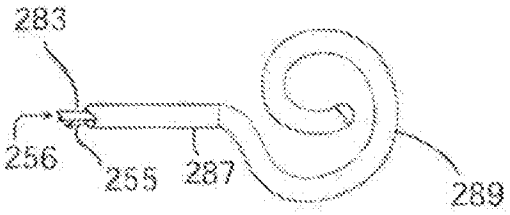


Figure 17C

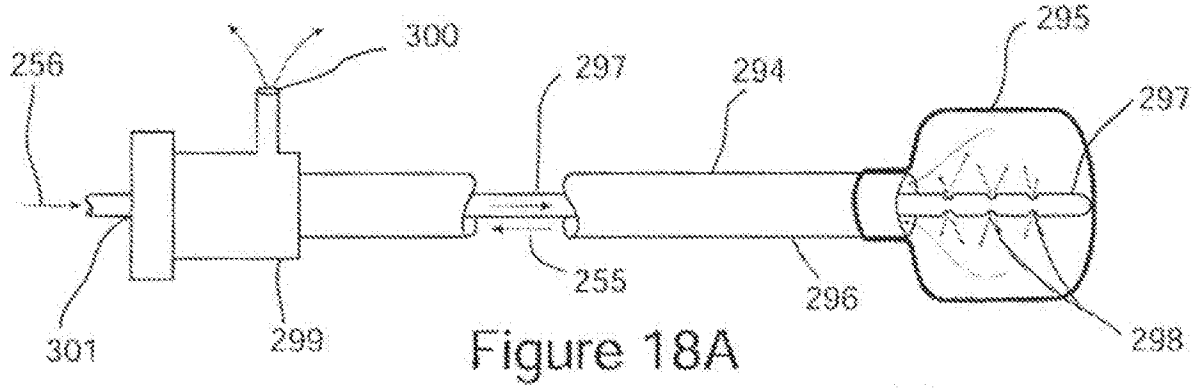


Figure 18A

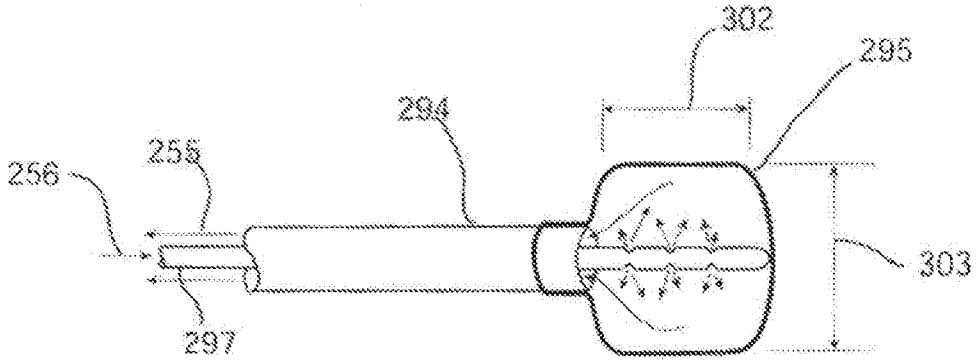


Figure 18B

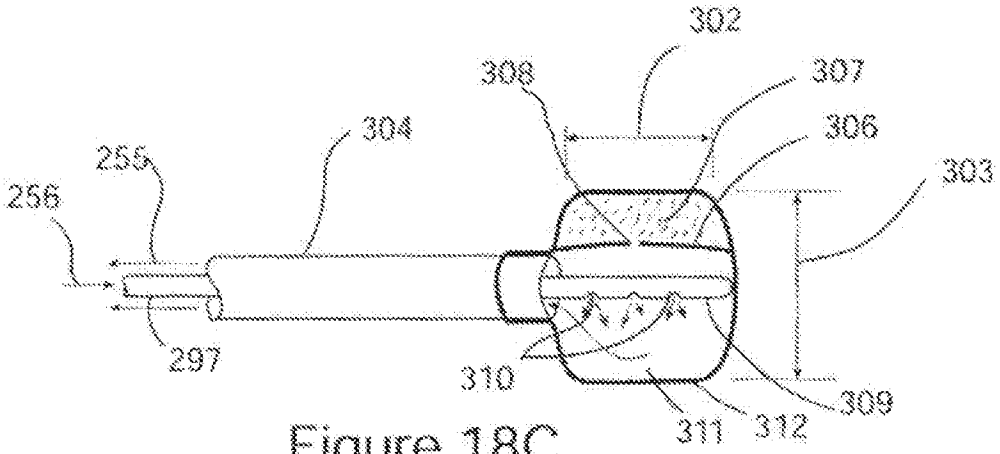


Figure 18C

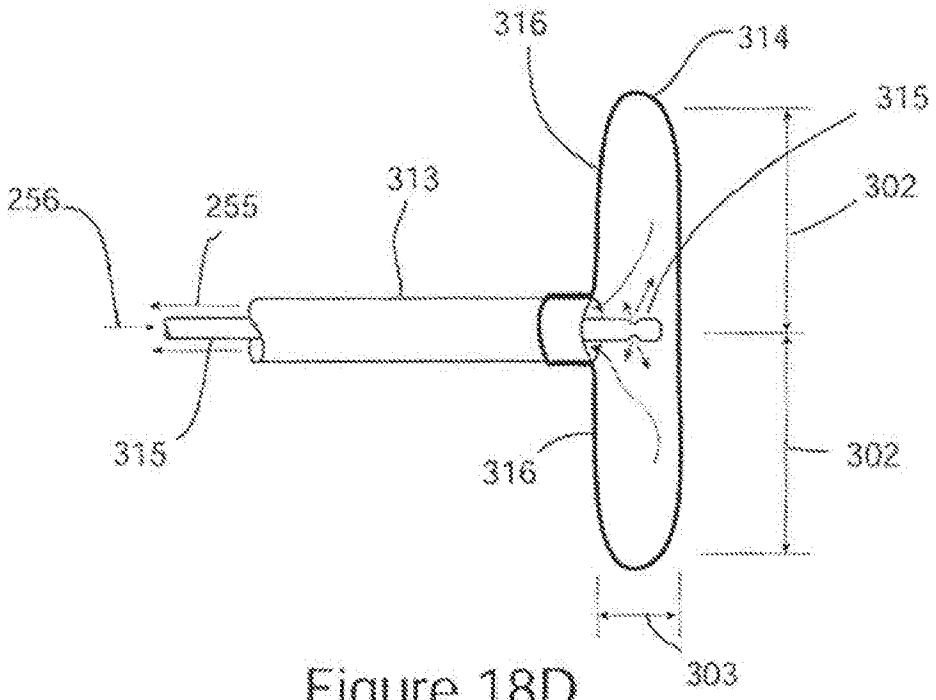


Figure 18D

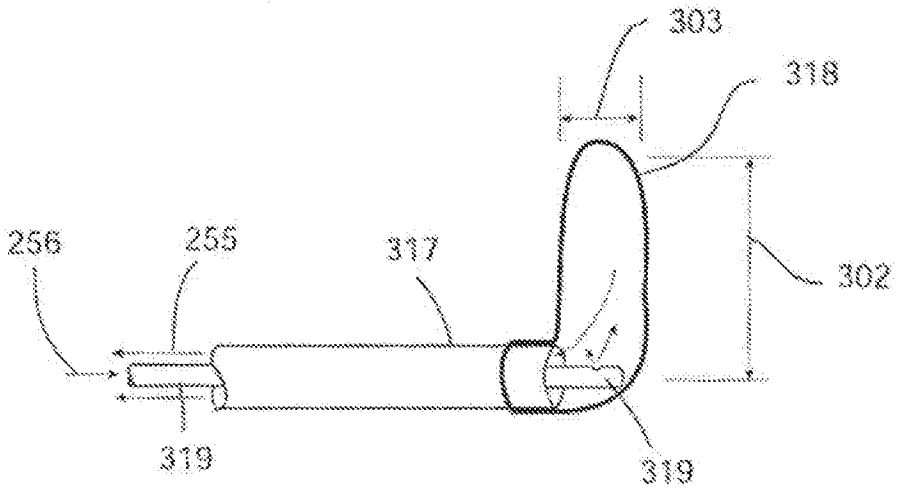


Figure 18E

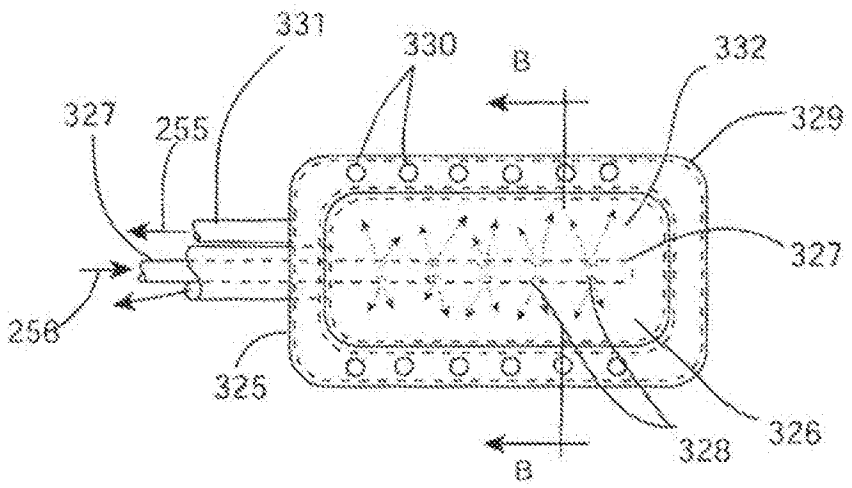
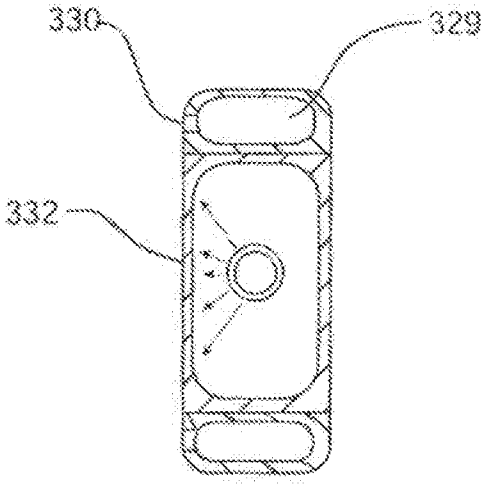


Figure 19A



Section B-B

Figure 19B

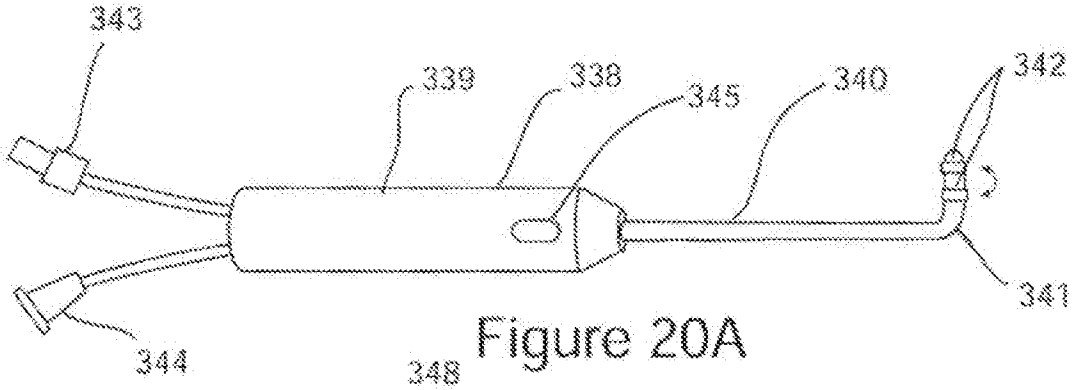


Figure 20A

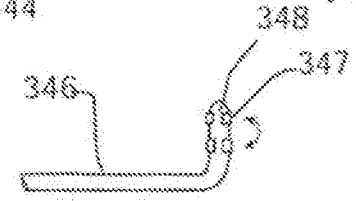


Figure 20B

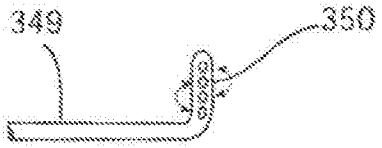


Figure 20C

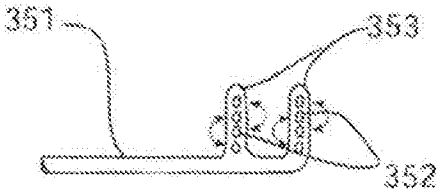


Figure 20D

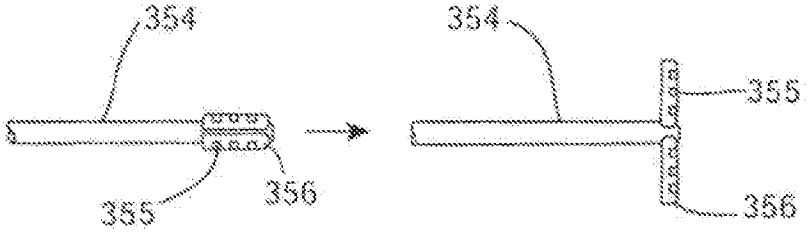


Figure 20E

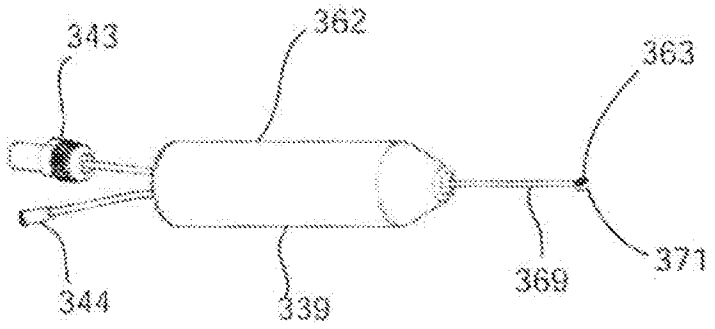


Figure 21A

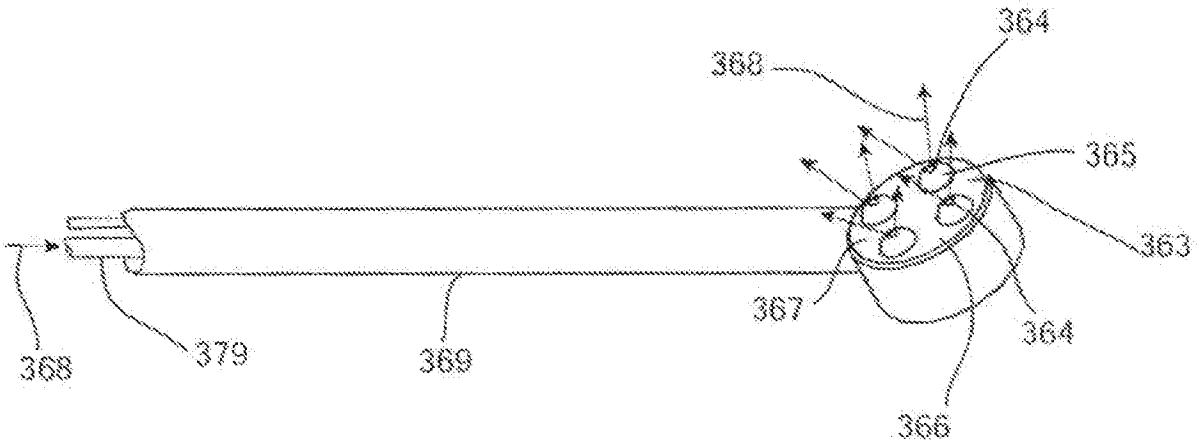


Figure 21B

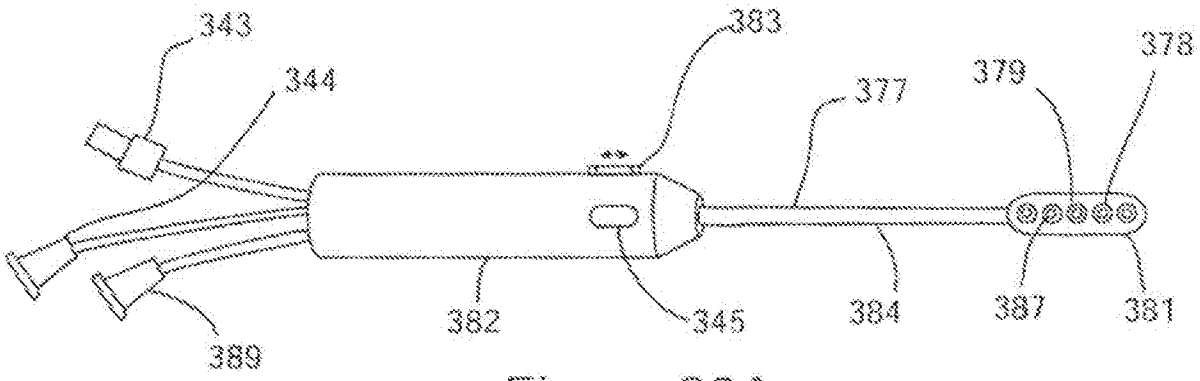


Figure 22A

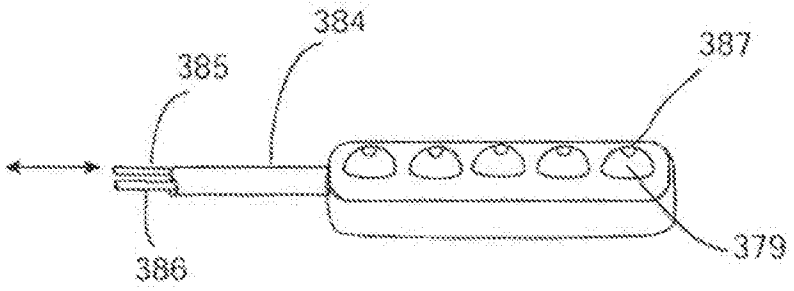


Figure 22B

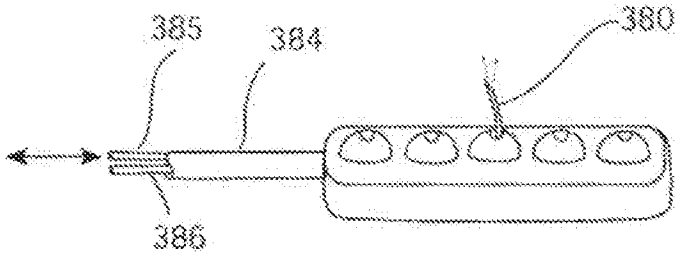


Figure 22C

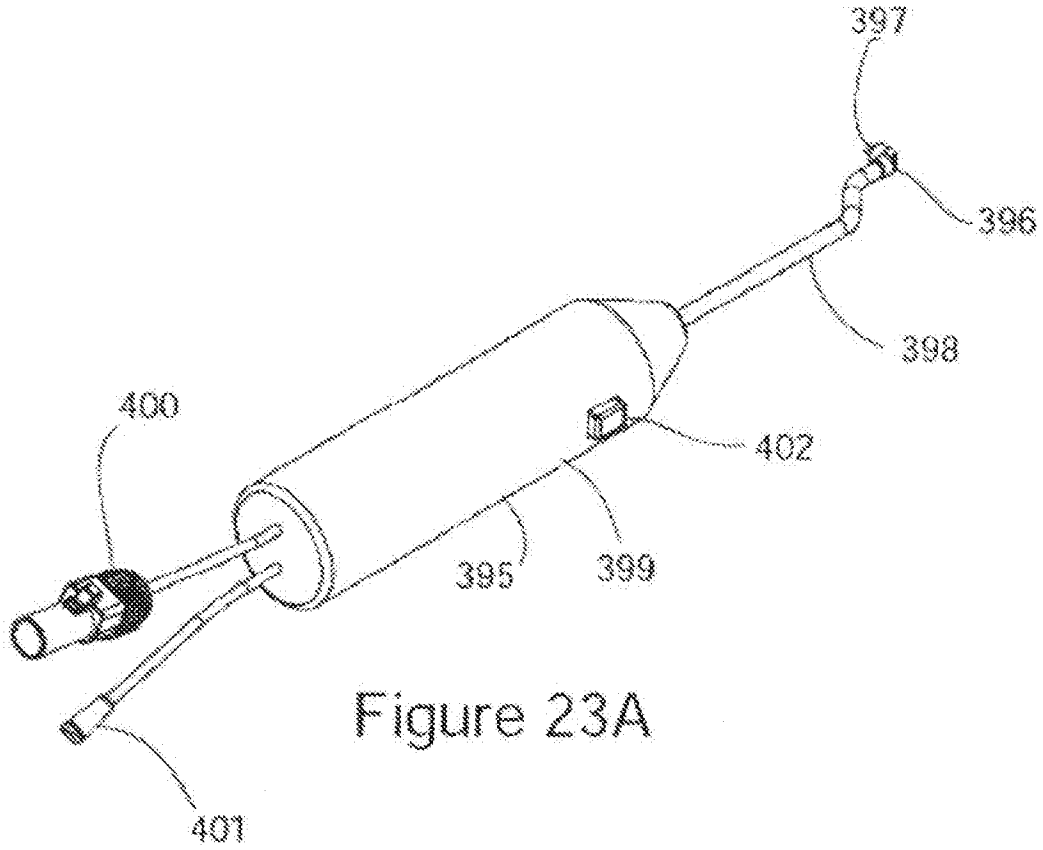


Figure 23A

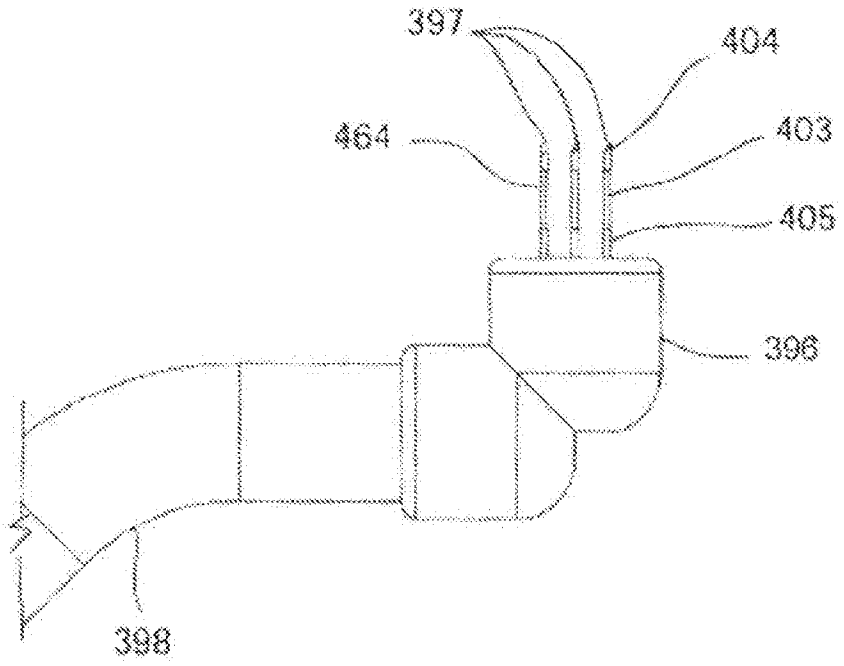


Figure 23B

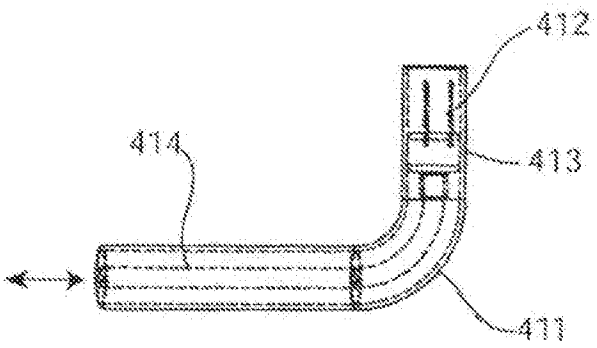


Figure 24A

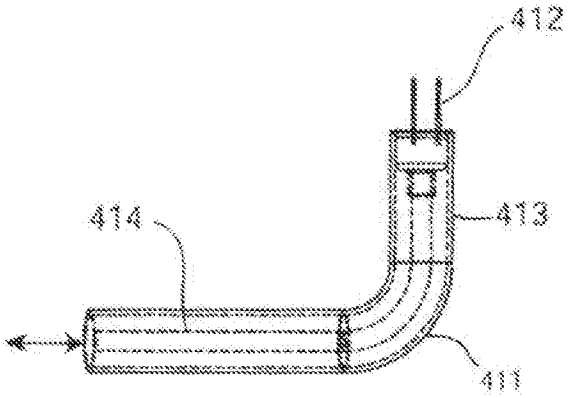


Figure 24B

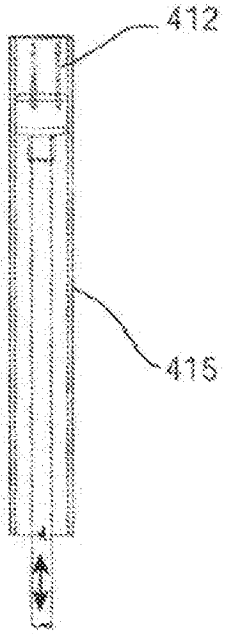


Figure 24C

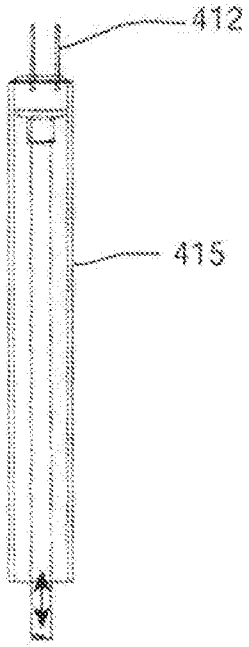


Figure 24D

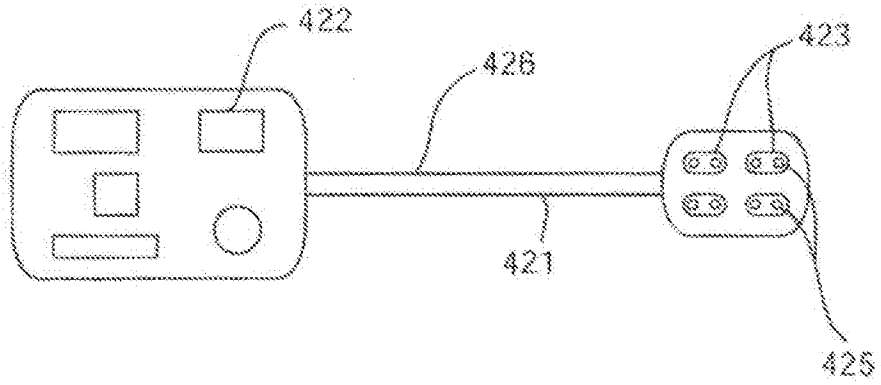


Figure 25A

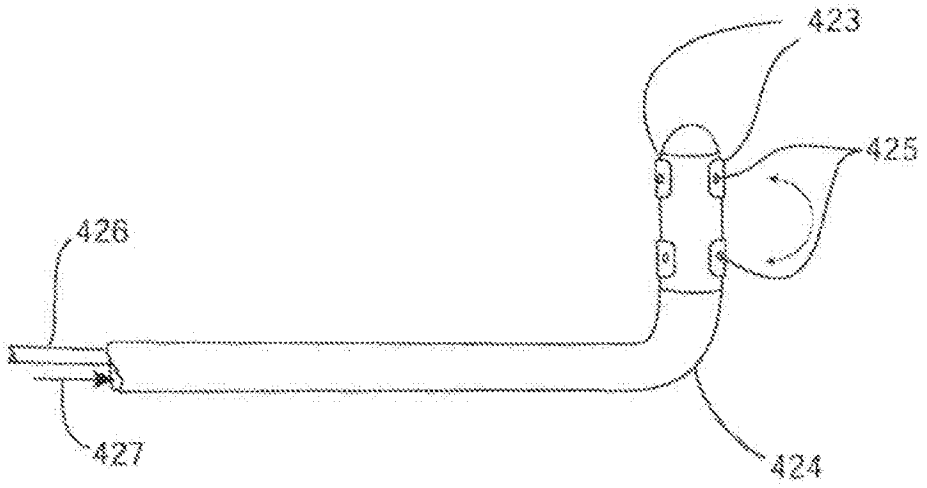


Figure 25B

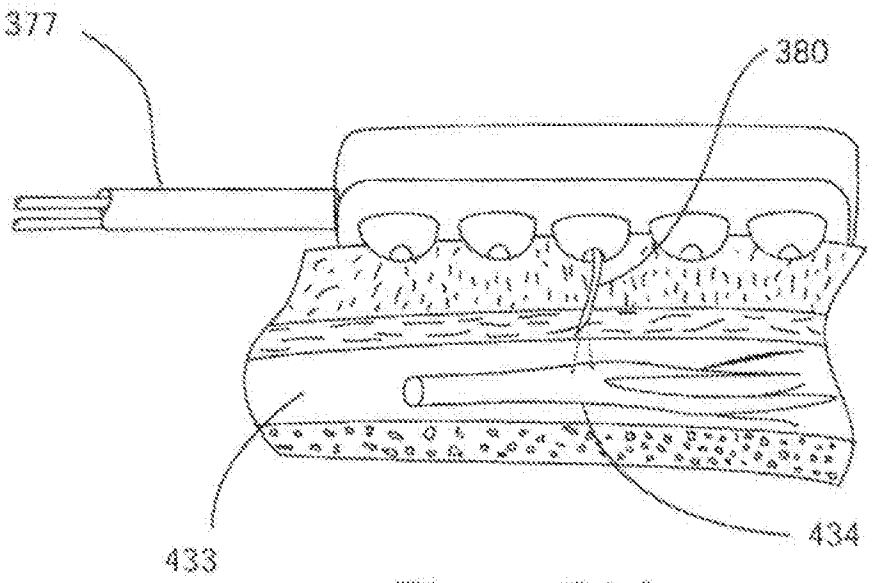


Figure 26A

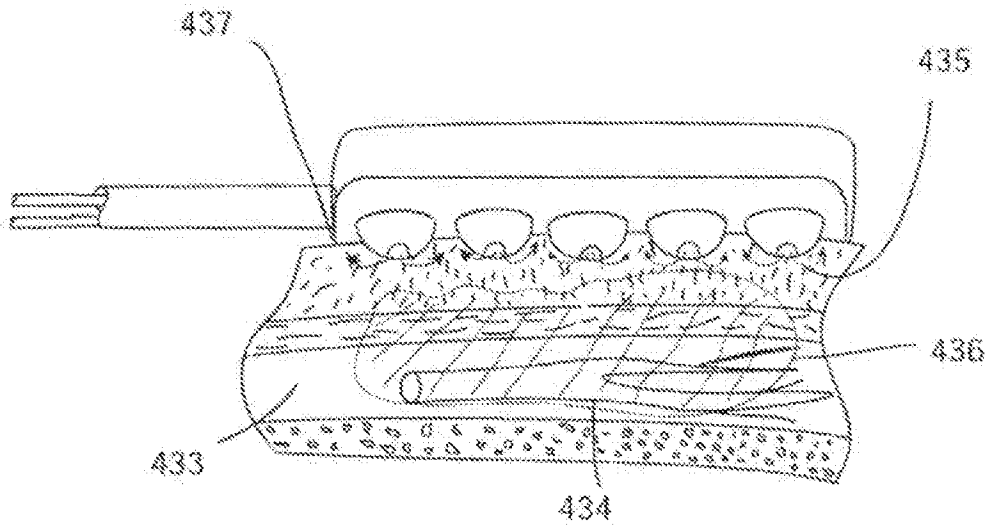


Figure 26B

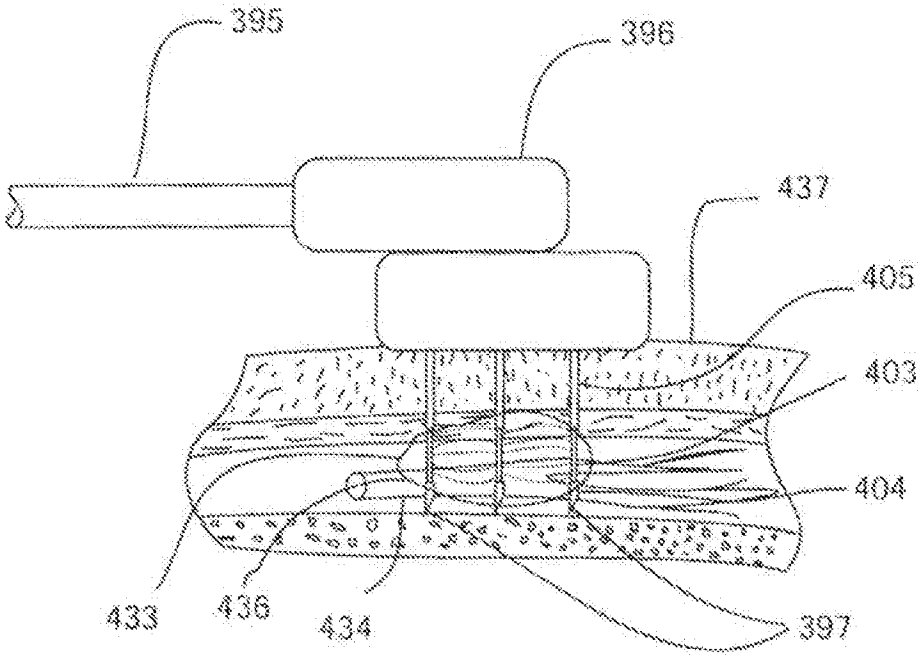


Figure 27

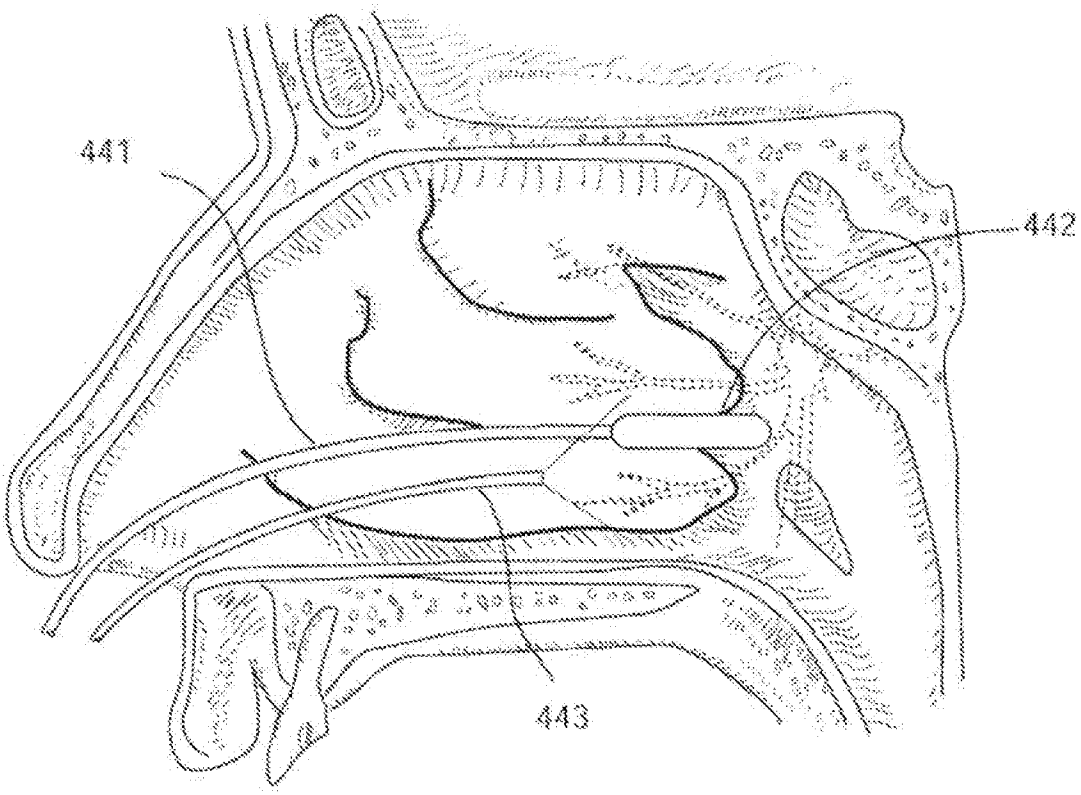


Figure 28

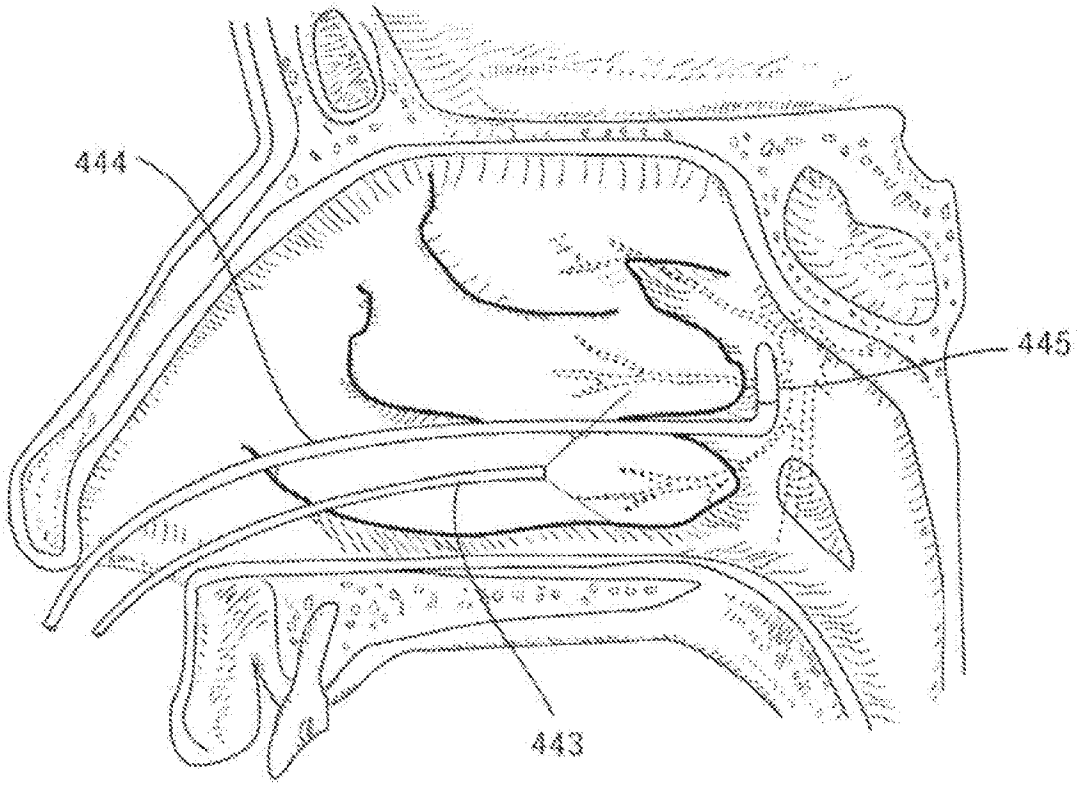


Figure 29

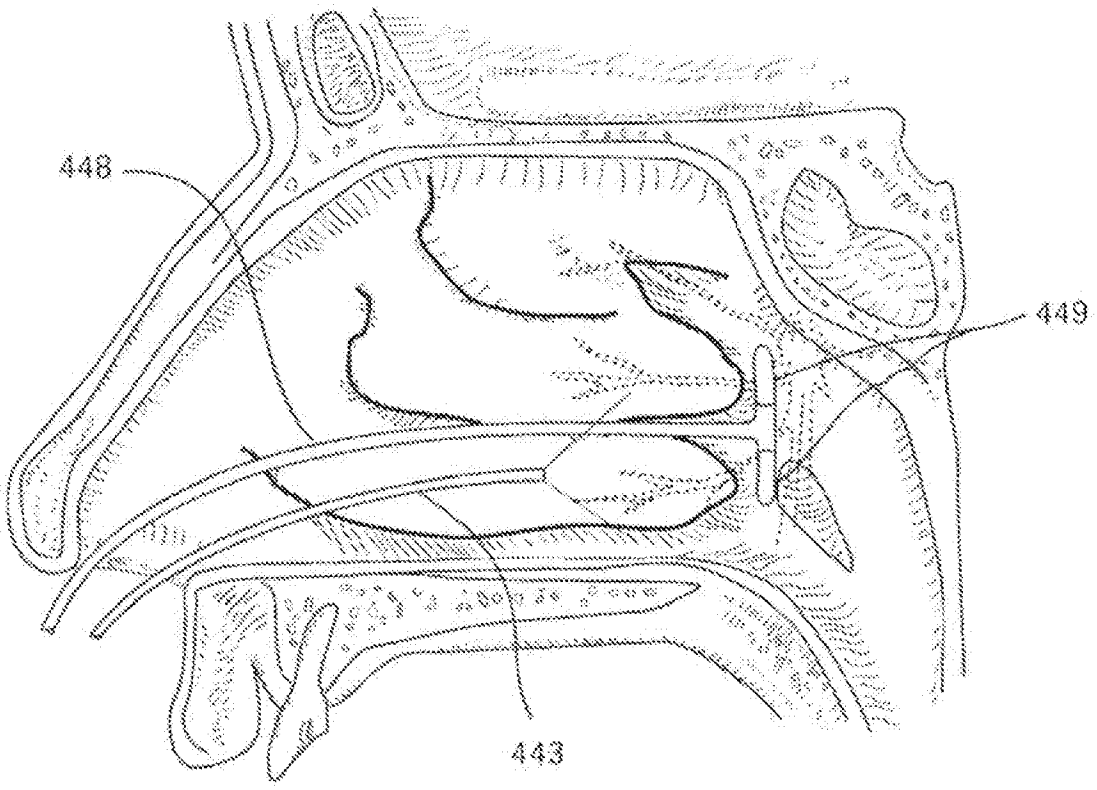


Figure 30

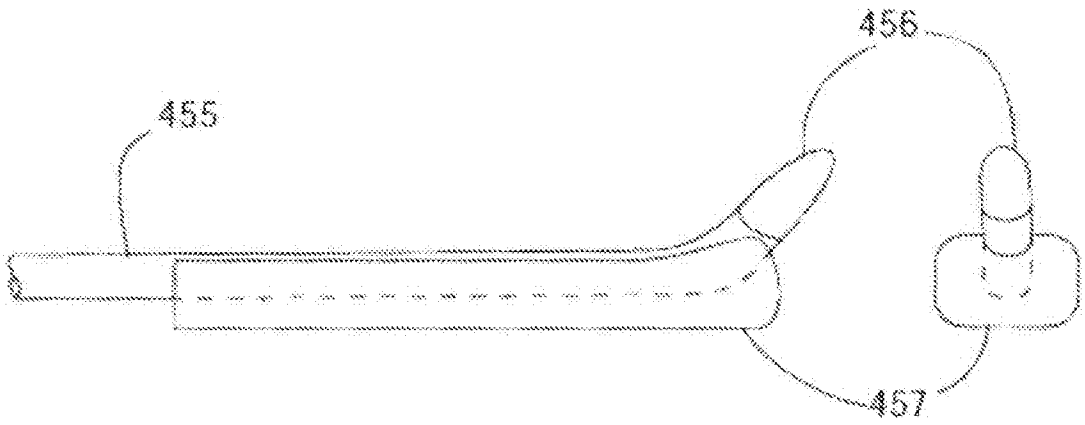


Figure 31A

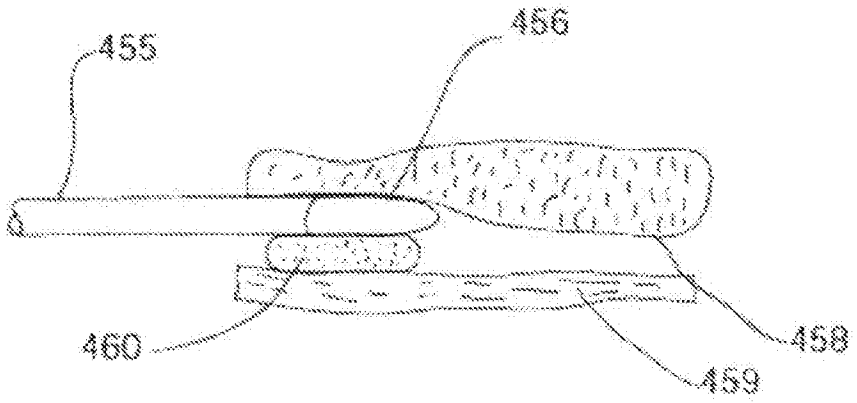


Figure 31B

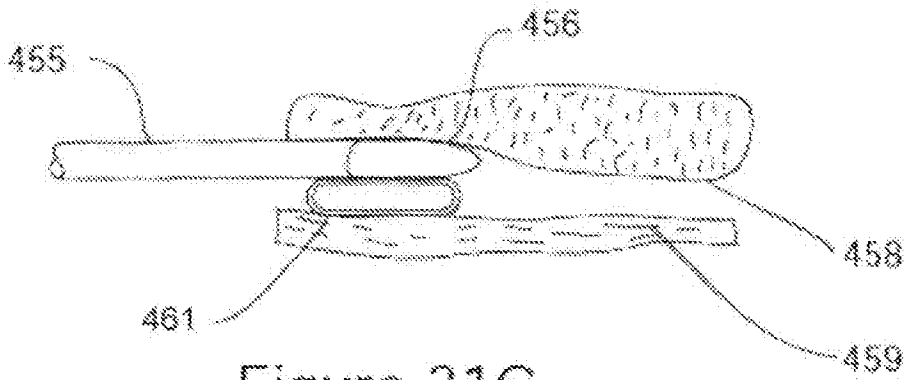


Figure 31C

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/US2012/042316	13.06.2012	14.06.2011

International Patent Classification (IPC) or both national classification and IPC
INV. A61B18/12 A61B18/14 ADD. A61B18/00 A61B18/16

Applicant
AERIN MEDICAL, INC.

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.

3. For further details, see notes to 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	Smit, Jos Telephone No. +49 89 2399-0

Form PCT/ISA/237 (Cover Sheet) (July 2009)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2012/042316

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 43bis.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 filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

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 in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2012/042316

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. 22-39

because:

☒ the said international application, or the said claims Nos. 22-39 relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ 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. 22-39

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper 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 a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form 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 a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☒ See Supplemental Box for further details

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2012/042316

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	5
	No:	Claims	1-4, 6-21
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-21
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

see form 210

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

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 22-39 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) / 67.1(iv) PCT - Method for treatment of the human or animal body by surgery. In particular, claims 22-39 comprise the step of delivering energy to tissues within the nose to reshape a region of the nose to a new conformation.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 US 2003/225403 A1 (WOLOSZKO JEAN [US] ET AL) 4 December 2003 (2003-12-04)

D2 US 2002/016588 A1 (WONG BRIAN J F [US] ET AL) 7 February 2002 (2002-02-07)

2 INDEPENDENT CLAIM 1

2.1 Notwithstanding the lack of clarity mentioned under Item VIII, the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT, the reason being as follows:

2.2 Document D1 discloses (the references in parentheses applying to this document):

A device for treating a patient's nasal airway (fig. 1 (5) (reference sign not shown in figure); par. [0180]), the apparatus comprising:

an energy delivery element sized to be inserted into a nose or to be delivered external to a nose and configured to deliver energy to tissues within the nose to reshape a region of the nose to a new conformation (figs. 1 (20), 15 (490); pars. [0144]-[0145], [0224]).

2.3 Claim 1 is also not new in view of document D2 (cf. pars. [0035]-[0036]; par. [0027]: "for applications such as reconstruction of the [...] nasal ala") (Articles 33(1) and (2) PCT).

3 DEPENDENT CLAIMS 2-4, 6-21

3.1 Notwithstanding the lack of clarity mentioned under Item VIII, dependent claims 2-4, 6-21 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Articles 33(1) and (2) PCT), the reasons being as follows:

3.2 Document D1 discloses (the references applying to this document):

Claim 2: fig. 15 (490); par. [0224];

Claim 3: par. [0172];

Claim 4: fig. 2 (100, 204, 103, 104); pars. [0147], [0150], [0175];

Claims 6-9: pars. [0168]-[0172], [0015]; needless to specify electrode geometry (needle, plate) or electrode polarity (monopolar, bipolar), or to claim the presence of a grounding pad for an electrosurgery device;

Claim 12: fig. 1 (34);

Claim 13: pars. [0153], [0178]; fig. 1 (38); par. [0180];

Claim 20: fig. 1 (10); and

Claim 21: par. [0014].

3.3 Document D2 discloses (the references applying to this document):

Claims 9-11: pars. [0035]-[0036]; par. [0027]: "for applications such as reconstruction of the [...] nasal ala";

Claim 14: pars. [0045], [0060]; and

Claims 15-19: par. [0035]: "The RF electrodes may vary in size and shape, as required for the desired reshaping, and appropriate for the cartilage size and shape"; par. [0036]: "A further embodiment of the present invention is where the electrodes themselves are part of the jig, clamps or scissors, not only heating, but also serving to clamp and/or shape the tissue. The electrodes may also be designed to function as molds, presses and mandrills."; par. [0027]: "for applications such as reconstruction of the [...] nasal ala".

4 DEPENDENT CLAIM 5

4.1 Notwithstanding the lack of clarity mentioned under Item VIII, dependent claim 5 does not appear to contain any additional features which, in combination with the features of any claim to which it refers, meet the requirements of the PCT in respect of inventive step (Articles 33(1) and (3) PCT), the reasons being as follows:

4.2 Claim 5 deals with the problem of activating the electrode of an electrosurgery device. The solution selected in claim 5 (i.e. incorporating an activation button in the handle) 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.

Re Item VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
US 2012/078377 A1	2012-03-29		

The validity of the priority claim has not been considered, because the ISA does not have in its possession a copy of the priority application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1 PCT) is the claimed priority date. Should the priority claim appear to be not valid, document US 2012/078377 A1 would form part of the state of the art in the sense of rule 33.1 PCT. It is pointed out to the applicant that in this case this document would also question the novelty and inventive step of the present claims.

Re Item VII

Certain defects in the international application

1 The application does not meet the requirements of Rule 6 PCT, the reasons being as follows:

1.1 Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (i.e. documents D1-D2) being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

1.2 Claim 20 comprises all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).

1.3 The features of claims 1-21 are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

1.4 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in documents D1-D2 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

1 The application does not meet the requirements of Article 6 PCT, the reasons being as follows:

1.1 Claims 1 and 15 do not meet the requirements of Article 6 PCT because the matter for which protection is sought is not clearly defined. This particularly pertains to the phrases "configured to deliver energy to tissues within the nose to reshape a region of the nose to a new conformation" in claim 1 and "having a shape configured to alter a conformation of a region of the nose to a new conformation" in claim 15. 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.

1.2 Claims 1 and 15 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The functional statements "configured to deliver energy to tissues within the nose to reshape a region of the nose to a new conformation" in claim 1 and "having a shape configured to alter a conformation of a region of the nose to a new conformation" in claim 15 do not enable the skilled person to determine which technical features are necessary to perform the stated function.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT). If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003

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.
AERIN-001WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2012/042316	13/06/2012	14/06/2011
Applicant		
AERIN MEDICAL, INC.		

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 6 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. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [ ] the text is approved as submitted by the applicant
   [X] the text has been established by this Authority to read as follows:

   DEVICES FOR TREATING NASAL AIRWAYS

5. With regard to the **abstract,**
   [ ] the text is approved as submitted by the applicant
   [X] 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. 23A
      [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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/042316

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.: 22-39
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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:

1. [ ] 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.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/042316

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/12 A61B18/14
ADD. A61B18/00 A61B18/16

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)
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 2003/225403 A1 (WOLOSZKO JEAN [US] ET AL) 4 December 2003 (2003-12-04) paragraphs [0014] - [0015], [0143] - [0182], [0222] - [0224]; figures 1-2, 14-15	1-9,12, 13,20,21
X	US 2002/016588 A1 (WONG BRIAN J F [US] ET AL) 7 February 2002 (2002-02-07) paragraphs [0025] - [0027], [0034] - [0037], [0044] - [0045], [0060] - [0061]; figures 3A, 3B	1,9-11, 14-19
X,P	US 2012/078377 A1 (GONZALES DONALD A [US] ET AL) 29 March 2012 (2012-03-29) the whole document	1-21
A	US 6 096 033 A (TU HOSHENG [US] ET AL) 1 August 2000 (2000-08-01) the whole document	1-21

☐ Further documents are listed in the continuation of Box C.

☒ 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
9 August 2012	24/08/2012

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	Smit, Jos

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/042316

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003225403 A1	04-12-2003	AU 2003215263 A1	04-09-2003
		EP 1474203 A2	10-11-2004
		US 2003225403 A1	04-12-2003
		WO 03068311 A2	21-08-2003
US 2002016588 A1	07-02-2002	NONE	
US 2012078377 A1	29-03-2012	US 2012078377 A1	29-03-2012
		WO 2012040557 A2	29-03-2012
US 6096033 A	01-08-2000	NONE	

International Application No. PCT/ US2012/ 042316

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 22-39

Claims 22-39 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) / 67.1(iv) PCT - Method for treatment of the human or animal body by surgery. In particular, claims 22-39 comprise the step of delivering energy to tissues within the nose to reshape a region of the nose to a new conformation.

International application No.
PCT/US2012/042316

INTERNATIONAL SEARCH REPORT

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

Devices for treating nasal airways are provided. Such devices may improve airflow through an internal and/or external nasal valve, and are configured to facilitate the use of mechanical re-shaping, energy application and other treatments to modify the shape, structure, and/or air flow characteristics of an internal nasal valve, an external nasal valve or other nasal airways.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/042316

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.: 22-39
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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:

1. [ ] 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.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/042316

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/12 A61B18/14
ADD. A61B18/00 A61B18/16

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)
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 2003/225403 A1 (WOLOSZKO JEAN [US] ET AL) 4 December 2003 (2003-12-04) paragraphs [0014] - [0015], [0143] - [0182], [0222] - [0224]; figures 1-2, 14-15	1-9,12, 13,20,21
X	US 2002/016588 A1 (WONG BRIAN J F [US] ET AL) 7 February 2002 (2002-02-07) paragraphs [0025] - [0027], [0034] - [0037], [0044] - [0045], [0060] - [0061]; figures 3A, 3B	1,9-11, 14-19
X,P	US 2012/078377 A1 (GONZALES DONALD A [US] ET AL) 29 March 2012 (2012-03-29) the whole document	1-21
A	US 6 096 033 A (TU HOSHENG [US] ET AL) 1 August 2000 (2000-08-01) the whole document	1-21

☐ Further documents are listed in the continuation of Box C. ☒ 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
9 August 2012	24/08/2012

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	Smit, Jos

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/042316

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003225403 A1	04-12-2003	AU 2003215263 A1	04-09-2003
		EP 1474203 A2	10-11-2004
		US 2003225403 A1	04-12-2003
		WO 03068311 A2	21-08-2003
US 2002016588 A1	07-02-2002	NONE	
US 2012078377 A1	29-03-2012	US 2012078377 A1	29-03-2012
		WO 2012040557 A2	29-03-2012
US 6096033 A	01-08-2000	NONE	

International Application No. PCT/ US2012/ 042316

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 22-39

Claims 22-39 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) / 67.1(iv) PCT - Method for treatment of the human or animal body by surgery. In particular, claims 22-39 comprise the step of delivering energy to tissues within the nose to reshape a region of the nose to a new conformation.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: SCOTT M. SMITH
DORSEY & WHITNEY LLP
COLUMBIA CENTER
701 FIFTH AVENUE, SUITE 6100
SEATTLE, WA 98104-7043

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	29 JUN 2015
Applicant's or agent's file reference P244690WO01 (494912-16)	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 15/23742	31 March 2015 (31.03.2015)	03 April 2014 (03.04.2014)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 5/08 (2015.01)
CPC - A61B 2018/143

Applicant AERIN MEDICAL INC.

1. This opinion contains indications relating to the following items:

- [x] 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
- [x] 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
- [ ] 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 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 notified 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 th IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Fom 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/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	04 June 2015 (04.06.2015)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (January 2015)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 15/23742

Box No. I Basis of this 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:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 15/23742

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)	Claims	1-6	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-6	NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-6 lack an inventive step under PCT Article 33(3) as being obvious over US 2014/0088463 A1 to Wolf et al. (hereinafter 'Wolf').

As per claim 1, Wolf discloses a device for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough (Fig. 23A-G), the device comprising:
an elongate, malleable shaft (shaft 558, para [0188]) having a proximal end and a distal end (Fig. 23D; para [0187]);
a handle at the proximal end of the elongate shaft (handle 560, Fig. 23D); and
a treatment portion at the distal end of the elongate shaft (treatment element 552), the treatment portion comprising a treatment surface (front face of treatment element 552), the treatment surface comprising:
at least two energy delivery members extending longitudinally along the treatment surface (array of bipolar electrode needles 554, para [0191]);
and in a separate embodiment, a concave trough extending longitudinally along the treatment surface and separating the at least two energy delivery members (See para [0121], suggesting a treatment element with concave shape to conform to the shape of the nasal features and passage - as modified by this embodiment, some bipolar needles 554 would be located on each side of the concave trough). Accordingly, it would be obvious to one of ordinary skill in the art to combine the two embodiments of Wolf, thereby providing a concave trough longitudinally along the treatment element separating the electrode needles.

As per claim 2, Wolf discloses the device of claim 1, wherein the at least two energy delivery members comprise at least one positive electrode on one side of the concave trough and at least one negative electrode on an opposite side of the concave trough (para [0121] and [0191]).

As per claim 3, Wolf discloses the device of claim 2, wherein the at least one positive electrode comprises a row of positive electrodes, and wherein the at least on negative electrode comprises a row of negative electrodes (horizontally arranged needle pairs 554 of electrode array, para [0191]; See also para [0044] and for better illustration, Fig. 8F, which is a similar embodiment as per para [0187]).

As per claim 4, Wolf discloses the device of claim 3, wherein the electrodes protrude from the treatment surface (Fig. 23G, para [0044]).

As per claim 5. Wolf discloses the device of claim 4, and in a further embodiment, discloses wherein the electrodes are blunt-tipped electrodes (non-penetrating electrodes, para [0173]; for illustration, see Fig. 18, which is a similar embodiment as per para [0187]). Accordingly, it would be obvious to one of ordinary skill in the art to have combined the embodiments of Wolf, thereby employing blunt-tipped electrodes in order to have provided an atraumatic contacting surface allowing for surface contact with the nasal tissue without penetrating it.

As per claim 6, Wolf discloses the device of claim 1, further comprising a thermocouple (555, Fig. 23D; para [0192]) disposed within the concave trough (as modified, the thermocouple would be located within the concave trough of the treatment element 552).

Claims 1-6 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P244690WO01 (494912-16)	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 15/23742	International filing date *(day/month/year)* 31 March 2015 (31.03.2015)	(Earliest) Priority Date *(day/month/year)* 03 April 2014 (03.04.2014)
Applicant AERIN MEDICAL INC.		

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 2 sheets.

☐ 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:

☒ 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. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ 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**,

☒ 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. 19A,B

☒ 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.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/23742

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 5/08 (2015.01)
CPC - A61B 2018/143
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)
CPC: A61B 2018/143; IPC(8): A61F 5/08 (2015.01); USPC: 606/29

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC: A61B 18/1485, A61B 2018/1861, A61B 2018/00577, A61B 2018/00327, A61B 2018/00821, A61B 2018/00005, A61B 2018/00922, A61N 5/0603, A61N 1/403, A61F 5/08; IPC(8): A61B 18/18, A61B 18/14, A61 N1/40 (2015.01); USPC: 606/41, 606/199, 606/1, 606/167

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google (Web, Patent, Scholar) Search Terms Used: Nose post nasal drip chronic cough mucus secretion treatment therapy device shaft rod handle grip energy delivery electrode row array needle blunt blunt-tipped thermocouple concave trough indent* slot groove

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0088463 A1 (Wolf et al.), 27 March 2014 (27.03.2014), entire document, especially Fig. 8F, 18 and 23A-G; para [0044], [0121] and [0187]-[0192]	1-6
A	US 2012/0323232 A1 (Wolf et al.), 20 December 2012 (20.12.2012), entire document	1-6
A	US 6,391,028 B1 (Fanton et al.), 21 May 2002 (21.05.2002), entire document	1-6
A	US 7,442,191 B2 (Hovda et al.), 28 October 2008 (28.10.2008), entire document	1-6
A	US 6,416,491 B1 (Edwards et al.), 09 July 2002 (09.07.2002), entire document	1-6
A	US 6,589,235 B2 (Wong et al.), 08 July 2003 (08.07.2003), entire document	1-6

☐ Further documents are listed in the continuation of Box C. ☐

* 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
04 June 2015 (04.06.2015)	29 JUN 2015
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: SCOTT M. SMITH
DORSEY & WHITNEY LLP
COLUMBIA CENTER
701 FIFTH AVENUE, SUITE 6100
SEATTLE, WA 98104-7043

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	23 DEC 2014
Applicant's or agent's file reference P240109WO01	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2014/054726	09 September 2014	13 September 2013

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B18/04 (2014.01)
CPC - A61B18/04 (2014.11)

Applicant AERIN MEDICAL INC.

1. This opinion contains indications relating to the following items:

- [x] 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
- [x] 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
- [ ] 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 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 notified 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/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	02 December 2014	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (July 2011)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2014/054726

Box No. I Basis of this 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 filed or furnished:
   a. (means)
      - ☐ on paper
      - ☐ in electronic form

   b. (time)
      - ☐ in the international application as filed
      - ☐ together with the international application in electronic form
      - ☐ subsequently to this Authority for the purposes of search

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 in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2014/054726

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)	Claims	None	YES
	Claims	1-9	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-9	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-9 lack novelty under PCT Article 33(2) as being anticipated by Wolf et al. (hereinafter Wolf).

Referring to Claim 1, Wolf discloses a device for treating a patient's nasal airway by modifying at least one property of at least one tissue of or near a nasal valve of the airway (Abstract), without using a surgical incision or an implant, to decrease airflow resistance or perceived airflow resistance in a nasal airway (Abstract), the device (30 in Fig. 3) comprising: an energy delivery member sized to be inserted into a nose and configured to deliver energy to tissues within the nose to modify the at least one property of the at least one tissue (32 in Fig. 3, Para. [0098]); a shaft extending from the energy delivery member (Fig. 3 shows a shaft extending from the energy delivery member); and a handle attached to the shaft at an opposite end from the energy delivery member (34 in Fig. 3), wherein the handle includes a housing to hold a power source for providing energy to the energy delivery member (Para. [0102]).

Referring to Claim 2, the device as in claim 1 as disclosed by Wolf, Wolf discloses wherein the energy delivery member has a contact surface with convex shape configured to at least temporarily create a concavity in nasal tissue (Para. [0025]).

Referring to Claim 3, the device as in claim 1 as disclosed by Wolf, Wolf discloses wherein the energy delivery member has a contact surface with flat shape (Para. [0180]).

Referring to Claim 4, the device as in claim 1 as disclosed by Wolf, Wolf discloses wherein the energy delivery member comprises multiple protruding electrodes configured to at least temporarily deform nasal tissue (Para. [0137]).

Referring to Claim 5, the device as in claim 4 as disclosed by Wolf, Wolf discloses wherein the protruding electrodes comprise two rows of electrodes, wherein the energy delivery member comprises a bipolar radio frequency delivery member, and wherein radio frequency energy travels from one row of electrodes to the other row of electrodes (Fig. 8F shows two rows of electrodes with alternating +ve and –ve electrodes which will travel from one side to other).

Referring to Claim 6, the device as in claim 4 as disclosed by Wolf, Wolf discloses wherein the housing is configured to hold at least one battery (Para. [0102] explains the handle housing incorporating the power supply which can be a battery).

Referring to Claim 7, the device as in claim 4 as disclosed by Wolf, Wolf discloses further comprising at least one sensor configured to sense at least one of temperature or impedance in nasal tissue (Para. [0101]).

Referring to Claim 8, the device as in claim 4 as disclosed by Wolf, Wolf discloses wherein the at least one sensor is attached to the device on or near the energy delivery member (Para. [0177] explains the thermocouple used to monitor the temperature of the electrode).

Referring to Claim 9, the device as in claim 4 as disclosed by Wolf, Wolf discloses further comprising a tissue cooling member attached to the device at or near the energy delivery member (Para. [0028]).

Claims 1-9 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

PCT/US2014/054726 23.12.2014

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P240109WO01	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2014/054726	International filing date *(day/month/year)* 09 September 2014	(Earliest) Priority Date *(day/month/year)* 13 September 2013
Applicant AERIN MEDICAL INC.		

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 2 sheets.

☐ 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:

☒ 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. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ 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**,

☒ 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. 22B

☒ 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.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/054726

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B18/04 (2014.01)
CPC - A61B18/04 (2014.11)
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)
IPC(8) - A61B 18/00, 18/04, 18/08, 18/10, 18/12, 18/14 (2014.01)
CPC - A61B 18/00, 18/04, 18/08, 18/082, 18/10, 18/12, 18/1485 (2014.11) (keyword delimited)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 606/1, 13, 14, 27, 29, 30, 31, 41, 44, 48, 50

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase, Google Patents, Google.
Search terms used: nose, ablation, electrode, needle, bipolar, radio frequency

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0323227 A1 (WOLF et al) 20 December 2012 (20.12.2012) entire document	1-9
A	US 2012/0316557 A1 (SARTOR et al) 13 December 2012 (13.12.2012) entire document	1-9
A	US 2007/0219600 A1 (GERTNER et al) 20 September 2007 (20.09.2007) entire document	1-9

☐ Further documents are listed in the continuation of Box C. ☐

* 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
02 December 2014	23 DEC 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

Electronic Acknowledgement Receipt

EFS ID:	22877058
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	09-JUL-2015
Filing Date:	31-MAR-2015
Time Stamp:	19:43:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P244690US02_IDS_14675689.pdf	202886 a7eed87ec46163dd11fe4b3fdb87bd07d77a8ea5	no	7

Warnings:	
Information:	

This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	WO_2007-037895.pdf	589637 73e4fb567467732a0e1411b0db0d48c15f053feb	no	13
Warnings:					
Information:					
3	Foreign Reference	WO_2007-134005.pdf	2163556 bbc0abd75cd37887ffb5eea8b0a0fa2436a93998	no	49
Warnings:					
Information:					
4	Foreign Reference	WO2015-047863_1-15_compressed.pdf	15889316 5403bf5513bf25a610d7b9ec61b9c96f2a9534d8	no	15
Warnings:					
Information:					
5	Foreign Reference	WO2015-047863_16-30_super_compressed.pdf	1903317 5e66b0aaf126169c5199316032a070ea10212d7	no	16
Warnings:					
Information:					
6	Foreign Reference	WO2015-047863_31-end_compressed.pdf	21931286 1d6dd63ab5671d1fccdf9533d7c0537681ee03ad	no	33
Warnings:					
Information:					
7	Foreign Reference	WO2015-048806.pdf	12661153 cf211ebd7c69c065376ac50f7e40ff3ed9744682	no	107
Warnings:					
Information:					
8	Non Patent Literature	COLE_Biophysics_Nasal_Airflow.pdf	986681 992e7543fc048e496c9fa5d43d1d30f3016b93a6	no	7
Warnings:					
Information:					
9	Non Patent Literature	COLE_Four_Components_of_Nasal_Value.pdf	472613 5cbb6928354681b6ef09c34c52e625801bd8923b	no	6
Warnings:					
Information:					
10	Non Patent Literature	Kjaergaard_Nasal_Cavity_Dimensions.pdf	824336 b4690ae8d5be318cd56742176ec061d53b5c2283	no	6

Warnings:					
Information:					
11	Non Patent Literature	Stupak_Perspective_on_the_Nasal_Valve.pdf	3054629 2c831d0979055ded2f2c318466112ae585d76d68	no	9
Warnings:					
Information:					
12	Non Patent Literature	Stupak_Endonasal_Repositioning_Upper_Lateral_Cartilage.pdf	1203911 96ec89748e5f3ad4da379a029e9b96ac94b0b0e1	no	7
Warnings:					
Information:					
13	Other Reference-Patent/App/Search documents	WO_08-24-2012_PCTUS2012042316.pdf	498091 778692b507a9b8c11fc728881fa5e8c87352df8a	no	10
Warnings:					
Information:					
14	Other Reference-Patent/App/Search documents	ISR_08-24-2012_PCTUS2012042316.pdf	388478 4b922f2c384bfceafa03fb6a70d90ef03e0ec710	no	10
Warnings:					
Information:					
15	Other Reference-Patent/App/Search documents	SGSearchReport.pdf	19489217 e7d952f3b32232fd537c2ddc8df958f552bd5d0f	no	27
Warnings:					
Information:					
16	Other Reference-Patent/App/Search documents	P244690WO01_6-29-2015_Written_Opinion.pdf	3137831 e46b1ea53a6aea4a0923b089aec92b0ecb8bd14d	no	3
Warnings:					
Information:					
17	Other Reference-Patent/App/Search documents	P244690WO01_6-29-2015_ISR.pdf	2331987 c2821be6125a72746a38c7ad807216415e9f2d59	no	2
Warnings:					
Information:					
18	Other Reference-Patent/App/Search documents	P240109WO01_12-23-14_WO_WO2015038523.pdf	134056 f5a5f1b6aa584598363ede71b70be779c52ae459	no	3
Warnings:					
Information:					
19	Other Reference-Patent/App/Search documents	P240109WO01_12-23-14_ISR_WO2015038523.pdf	92852 14e0af62a31884f0fedebd5287489607eba3a585	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	87955833

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/675,689	03/31/2015	Scott J. WOLF	P244690US02 (494912-15)

CONFIRMATION NO. 9467

75149
Dorsey & Whitney LLP - PA
Intellectual Property Department
Columbia Center
701 Fifth Avenue, Suite 6100
Seattle, WA 98104-7043

PUBLICATION NOTICE



Title:POST NASAL DRIP TREATMENT

Publication No.US-2015-0202003-A1
Publication Date:07/23/2015

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to first Official Action		
	Application Number	14/675,689
	Filing Date	March 31, 2015
	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	To be Assigned
	Attorney Docket Number	P244690US02 (494912-15)

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		8,986,301		2015-03-24	WOLF, *et al.*	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2002/0128641		2002-09-12	UNDERWOOD, *et al.*	

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to first Official Action		
	Application Number	14/675,689
	Filing Date	March 31, 2015
	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	To be Assigned
	Attorney Docket Number	P244690US02 (494912-15)

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	August 25, 2015
Name/Print	Scott Michael Smith	Registration Number	48268

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Acknowledgement Receipt

EFS ID:	23309622
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	25-AUG-2015
Filing Date:	31-MAR-2015
Time Stamp:	18:13:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P244690US02_Supplemental_IDS_14675689.pdf	157019 743ea0d9748dd5e10a5f05addb756742f1bf3d5f	no	2

Warnings:	
Information:	

This is not an USPTO supplied IDS fillable form	
Total Files Size (in bytes):	157019

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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

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Application Number	14675689
Filing Date	2015-03-31
First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	WIELAND, ROBERT N
Attorney Docket Number	P244690US02 (494912-15)

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	1	101325919	CN	A	2008-12-17	Starion Instruments Corp.		☒

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	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	WIELAND, ROBERT N
	Attorney Docket Number	P244690US02 (494912-15)

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Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	2015-10-30
Name/Print	Scott M. Smith	Registration Number	48268

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Bibliographic data: CN101325919 (A) — 2008-12-17

Resistive heating device and method for turbinate ablation

Inventor(s):

Applicant(s): STARION INSTRUMENTS CORP [US] + (STARION INSTR CORP)

Classification: **- international:** ***A61B18/08***
- cooperative: **A61B18/082**

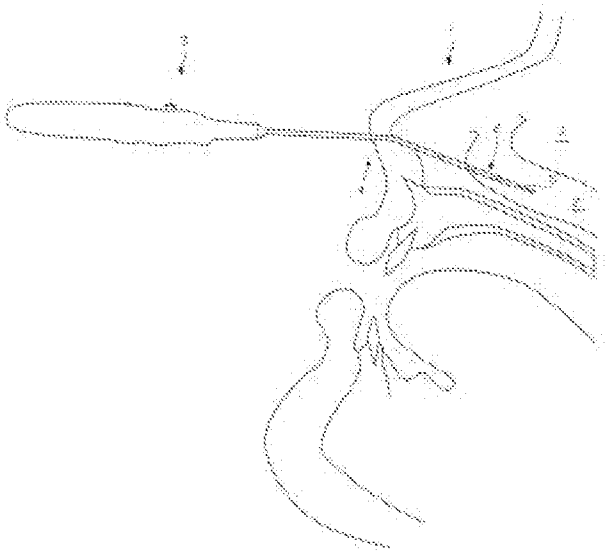
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Abstract of CN101325919 (A)

Devices and methods for thermal ablation of hypertrophied tissue, such as turbinates, with a resistive heating element adapted for insertion into the tissue. The device uses DC current to heat the resistive heating element, and is operated at relatively low voltage levels and low current levels. The device is easy to operate, and may be applied for predetermined time periods without feedback control, using a timing circuit or computerized control system. The resistive heating element is covered with a thin, non-stick, coating that is thermally conductive, such as Xylan TM , Teflon TM or other fluoropolymer or suitable material.



[19] 中华人民共和国国家知识产权局

[51] Int. Cl.
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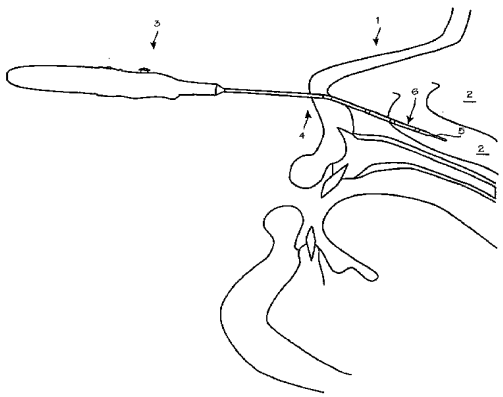
权利要求书 2 页 说明书 4 页 附图 2 页

[54] 发明名称

电阻加热装置和用于鼻甲骨消融的方法

[57] 摘要

本发明涉及一种电阻加热装置和用于鼻甲骨消融的方法，尤其涉及一种用于肥大组织(比如鼻甲骨)热消融的装置和方法，其具有适合于插入组织的电阻加热元件。该装置使用 DC 电流来加热电阻加热元件，并且以相对低的电压水平和低的电流水平操作。该装置易于操作，并且可利用定时电路或计算机化控制系统在没有反馈控制之下施加预定的时间。电阻加热元件由导热的非粘性薄覆层覆盖，比如 Xylan®、Teflon® 或其它含氟聚合物或适合材料。



1. 一种用于执行身体组织热消融的装置，所述装置包括：

适合于插入身体的细长插入部分，所述插入部分具有适合于冷穿透身体组织的远端；

布置在插入部分的远端上、沿着插入部分的远端纵向地延伸的细长电阻加热段，所述电阻加热元件具有电绝缘覆层；

可操作地连接至电阻加热段的电源，所述电源可操作来将电能供应至电阻加热段以引起电阻加热段加热至组织消融的温度。

2. 根据权利要求 1 的装置，其中电阻加热段包括管状电阻加热元件。

3. 根据权利要求 1 的装置，其中加热段包括：

管状电阻加热元件；以及

布置在管状电阻加热元件内的电阻丝。

4. 根据权利要求 3 的装置，其中加热段还包括尖锐远端，所述尖锐远端布置在管状加热元件的远端和电阻丝的远端上并且用来电连接所述管状电阻加热元件和电阻丝。

5. 根据权利要求 1 的装置，其中加热段具有小于大约 0.25 欧姆的电阻并且电源可操作来提供小于大约 3.5 安培的恒定电流。

6. 根据权利要求 1 的装置，还包括适合于对加热段施加预定时间的恒定电流的控制装置。

7. 根据权利要求 5 的装置，还包括适合于对加热段施加大约 60 秒的预定时间的恒定电流的控制装置。

8. 一种对患者执行鼻甲骨消融的方法，所述方法包括：

提供适合于穿入鼻甲骨的粘膜下层组织的细长电阻加热段；

将细长电阻加热段插入鼻甲骨的粘膜下层组织；

将直流电施加至电阻加热段以给加热元件加热，从而加热鼻甲骨的粘膜下层组织以在没有电流穿过粘膜下层组织的情况下引起热消融。

9. 根据权利要求 7 的方法，还包括：

给电阻加热元件施加预定时间的直流电。

10. 根据权利要求 7 的方法还包括：

提供细长电阻加热元件，其呈管状电阻加热元件的形式，并且电阻丝布置在电阻加热元件内并且与之串联，所述电阻加热段具有 0.1 至 0.25 欧姆的电阻，

将 3.0 至 3.5 安培的直流电施加至电阻加热元件至少 30 秒的预定时间。

电阻加热装置和用于鼻甲骨消融的方法

技术领域

下述发明涉及组织消融以及鼻甲骨缩减领域。

背景技术

慢性鼻阻塞通常是鼻甲骨增大的结果，鼻甲骨是覆盖有粘膜的鼻腔的卷状骨质突起。这些粘膜正好位于鼻子内侧，并且它们承受导致慢性充血、窦感染、睡眠障碍和其它慢性状况的慢性膨胀和肥大。最近，鼻甲骨的射频消融，称为射频消融（somnplasty），已经采用为用于鼻甲骨增大的治疗。在这个技术中，细长的射频探针插入鼻甲骨的粘膜下层组织，并且射频能量穿过粘膜下层组织以加热和破坏（消融）这个组织的一小部分。在损坏的组织愈合并且由身体再吸收时，粘膜下层组织收缩并且减轻阻塞。愈合过程需用几个星期。

类似的射频消融过程还能用来收缩上颚中的肥大组织（以治疗打鼾和睡眠呼吸暂停）、脊椎盘中的肥大组织（以治疗椎间盘突出）、或者用于在大脑、肝脏、衰竭等中的各种肿瘤消融以及各种美容外科手术（眼皮下垂）。

由于射频装置使电流穿过身体，必须要警惕以避免过度的电流流动以及有害的电流流动至远离装置的区域。射频消融装置依靠于热反馈或阻抗监视以控制所施加的射频能量以获得实现消融所需要的温度（60－100℃）。这种反馈系统是要确保装置不会将过度的能量传送入身体并损坏附近身体。射频消融装置还会引起不必要的神经刺激，并且必须小心使用以避免与心脏交互作用。射频消融装置会在附近组织结构中和远离施加点的区域中引起意外的组织损坏。

发明内容

下述装置和方法用于肥大组织（比如鼻甲骨）的热消融（thermal

ablation），其具有适合于插入组织的电阻加热元件。该装置使用 DC 电流来加热电阻加热元件，并且以相对低的电压水平和低的电流水平操作。该装置易于操作，并且可利用定时电路或计算机化控制系统在没有反馈控制的情况下施加预定的时间。电阻加热元件由导热的非粘性薄覆层覆盖，比如 Xylan®、Teflon®或其它含氟聚合物或适合材料。

附图说明

图 1 示出了将由热消融装置完成的典型鼻甲骨消融过程。

图 2 示出了适合于图 1 所示过程的热消融装置。

图 3 是图 2 所示热消融装置的远端的细节图。

具体实施方式

图 1 示出了具有增大鼻甲骨 2 的患者 1 的典型鼻甲骨消融过程。为了完成鼻甲骨热消融，医生将消融探针 3 的远端插入穿过鼻孔 4 并且进入窦腔以到达鼻甲骨。医生将安装在远端 6 上的加热段 5 推入鼻甲骨，并且使远端前进进入粘膜下层组织，之后沿着鼻甲骨前进并且位于期望远的粘膜组织内。在对探针尖端的位置满意时，医生将开始探针远端处的加热段的加热，按照需要反复进行以使鼻甲骨消融至由医生所观察的状况所指示的程度。装置被设计来提供预定时间段的加热，通过比如定时电路、计算机控制系统或植入微处理器之类的装置，其中时间段由定时电路的参数或控制系统/微处理器的编程来预先确定，通过电路和/或控制系统允许医生在任何时间关闭装置。

图 2 示出了适合于图 1 所示过程的热消融系统。该系统包括探针 3，其包括把手部分 11 和插入部分 12 以及 DC 电源 13（电池或由家用电流供给的 DC 电源）。手柄部分包括操作按钮 14 和指示灯 15、电源线 16 以及定时装置，无论其是简单的定时电路或板上计算机化控制系统或微处理器。插入部分包括细长海波管（slender hypotube）17，其在靠近加热段 5 大约 2 至 3 英寸（50-80mm）处弯曲大约 15°度至 20°的轻微角度。插入部分标记有标识 18，其指示探针远端至每个标记的长度，以使得医生能易于确定加热段的深度。操作按钮可包括任何适

当的开关，并且可操作为拨动开关或双位置开关。指示灯可连接至电源、开关和定时装置以使得其在电流施加至加热段时发光。

图 3 是图 2 所示热消融装置的远端 6 的细节图。远端包括加热段 5，其包括与电阻丝形式的第二电阻元件 22 串联的管状电阻加热元件 21，它们同轴地布置在管式电阻器内。加热段沿着插入部分的远端纵向地延伸，产生适合于针刺进入柔软身体组织的细长加热段。两个电阻加热元件沿着长度与绝缘材料 23 电绝缘。绝缘材料可包括陶瓷，比如氧化镁、氧化铝或其它具有适合热传导性的陶瓷。两个电阻器 21 和 22 在各自的远端电连接，最便利地通过金属尖端 24，其是尖锐的以便于在探针尖端冷却时加热元件穿透入身体组织。电能通过导体 25 和 26 供应至加热元件，导体 25 和 26 连接至管状电阻加热元件和第二电阻元件的近端。加热元件覆盖有热传导覆盖物或涂层 27，其还可是非粘性、低摩擦、电绝缘的材料，比如 ePTFE 或 Xylan®。加热元件被安装在具有较短长度的热和电绝缘管路 28 的插入部分的海波管 17 上，管路 28 在其内腔内接收加热元件的近端，并且其近端又由海波管接收。陶瓷比如锆硬化矾土（ZTA）、聚合物比如 PEEK（聚醚醚酮）或其它适合的高温塑料或 Torlon®聚酰氨酰亚胺树脂是用于安装管的适合材料，不过也可使用任何适合的材料。

在适合于鼻甲骨消融的实施例中，选择装置部件来提供期望的加热特征以及提供便于安全插入的机械性质。管状电阻加热元件（由标号 21 表示）的外部直径是 0.029 英寸（0.74mm），并且电阻加热元件包括 inconel 625 合金（一种不锈钢）。加热段包覆或覆有非粘性电绝缘材料（ePTFE、Xylan® 等）的薄层（0.001``（0.025mm）），该薄层具有足够的导热性以允许通过包覆层加热。延伸到安装管之外的电阻加热元件大约是 0.345``（9mm）长（管式电阻器的总长度大约为 0.46``（12mm））。加热元件的总电阻是 0.1 至 0.25 欧姆，优选地大约 0.15 欧姆。当以大约 3 至 3.5 安培，优选地大约 3.2 安培的恒定电流施加 DC 电流时，加热段将沿着加热段延伸到海波管和安装管之外的全部长度在大约 60 秒的时间内逐渐地加热鼻甲骨组织至 80 至 100℃。加热以相对慢的速度发生，起始以每五秒间隔大约 20 至 25℃的速度，

并且在施加电流一分钟的过程中减速至每五秒间隔 1 至 5℃的速度。控制装置操作来给加热段施加预定时间的电流。预定时间为至少大约 30 秒（优选为大约 60 秒）适合于鼻甲骨消融。预定时间可在制造中设置，或者可由医生在使用该装置之前改变。电阻加热元件的构造也可改变以提供更慢或更快的加热特征，以使装置适合各种治疗。施加至加热元件的电流和/或电压可改变以获得更慢或更快的加热特征，如由要执行的具体消融治疗所指示的。直流电优选地用于这种应用中，部分地由于其不会与附近的神经交互作用，并且非常少（如果有的话）的电流泄漏入身体（身体比电源线和电阻加热元件的铬镍铁合金的阻抗更大）。尽管直流电是优选的，不过电阻加热也可通过将射频电流或交流电供应至加热段来提供，因为电绝缘材料的覆层将阻止泄漏。

这个实施例中的海波管具有 0.065 英寸（1.7mm）的外部直径和 0.057 英寸（1.4mm）的内部直径（0.008``或 0.2mm 的壁厚），并且大约 4 英寸（100mm）长，并且具有距离装置远端大约 2.25 英寸（大约 60mm）的 18°弯曲。海波管的耐压强度（在其弯扣处的负载）在弯曲点处低于加热段的耐压强度。这个实施例中的海波管将在大约 0.7 至 0.9 磅，优选地大约 0.75 磅的压力负载下扭折或塌陷。这个特点确保了，如果医生将加热元件插入鼻甲骨中并且遇到过度的阻力并且试图用可能损坏加热元件的压力插入加热段时，替代地海波管将皱折。在海波管皱折时，医生能撤回探针并用新的探针重新开始这个过程。

虽然在鼻甲骨消融的环境中进行了描述，但是上述装置和方法可用于柔软上颚消融和通常在脊椎盘减少、肿瘤消融（尤其在大脑中）以及其它目前用射频消融来完成的外科手术的射频消融。因此，虽然装置和方法的优选实施例已经参照其开发环境进行了描述，但是它们仅仅是本发明原理的说明。其它实施例和构造可在不脱离本发明精神和所附权利要求范围之下设计。

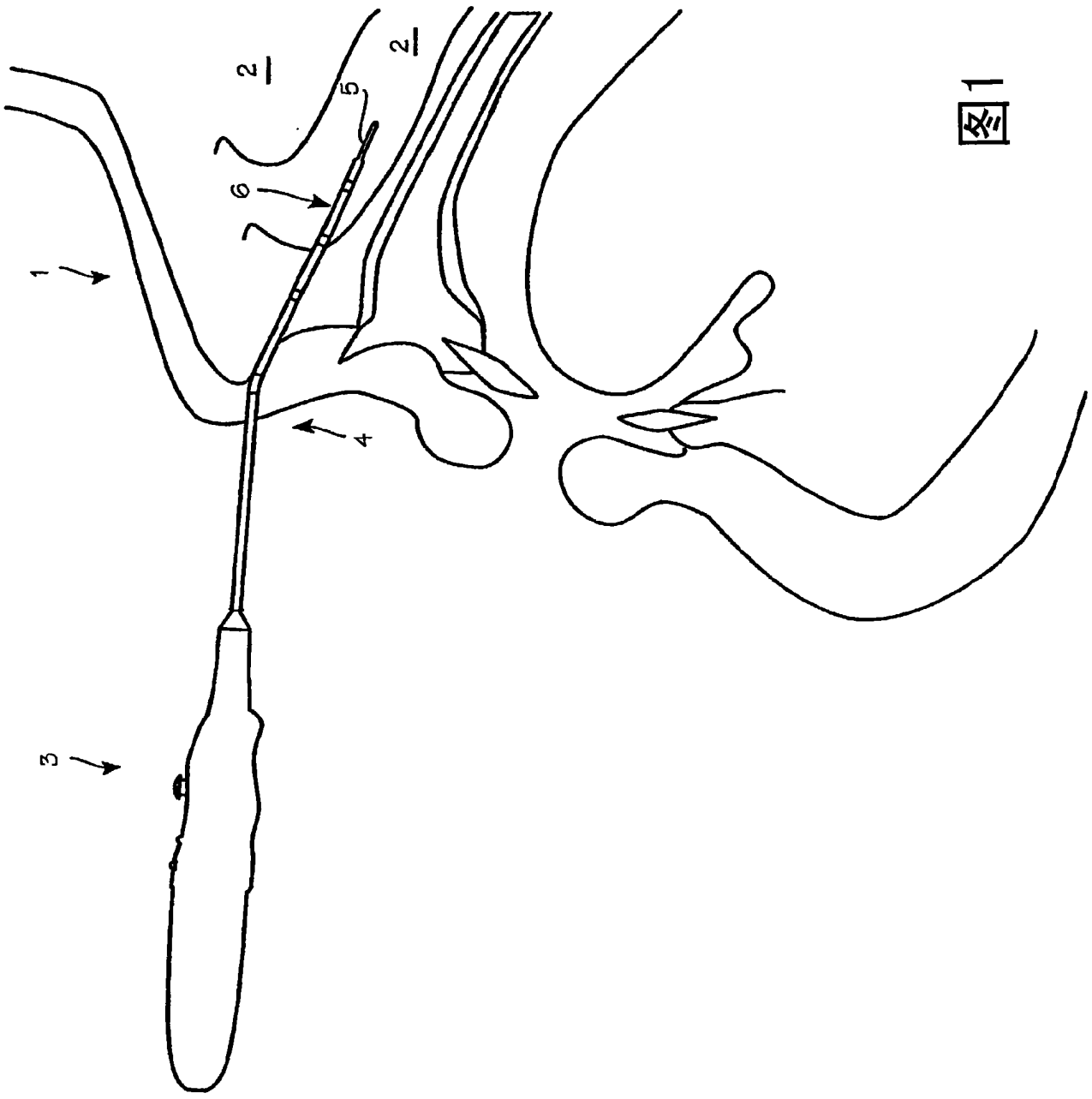


图1

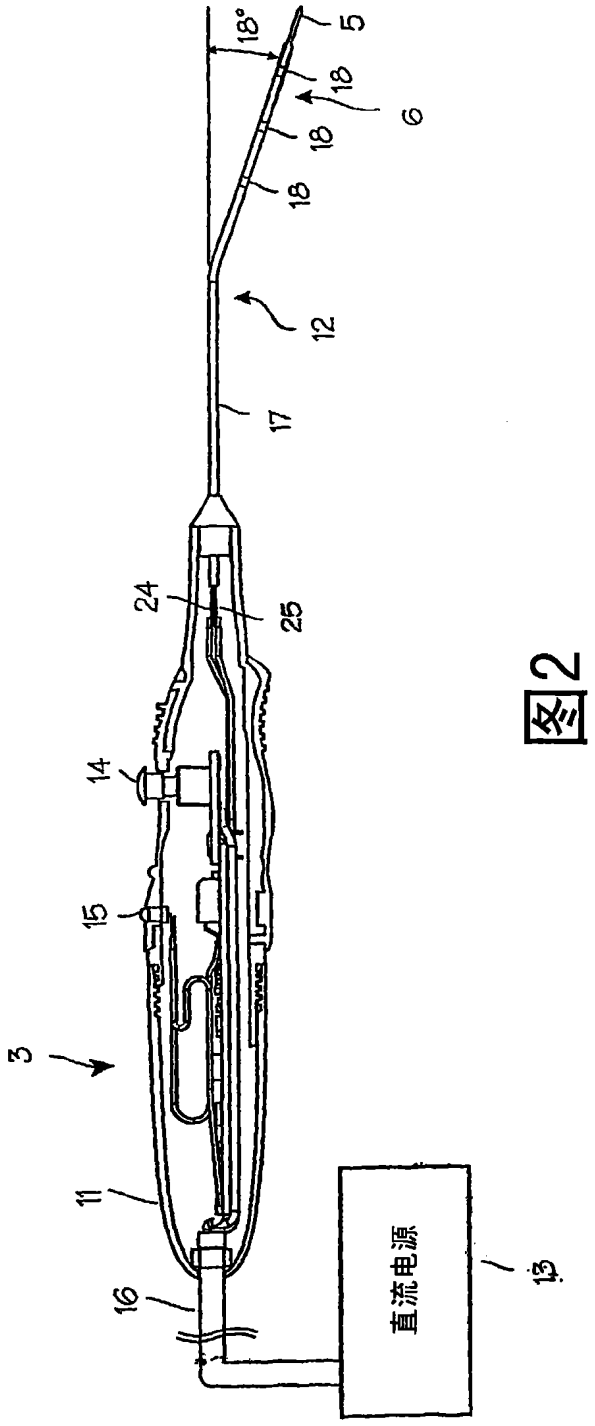

18°
5
6
18
18
18
12
17
24
25
14
15
3
11
16
直流电源
13

图2

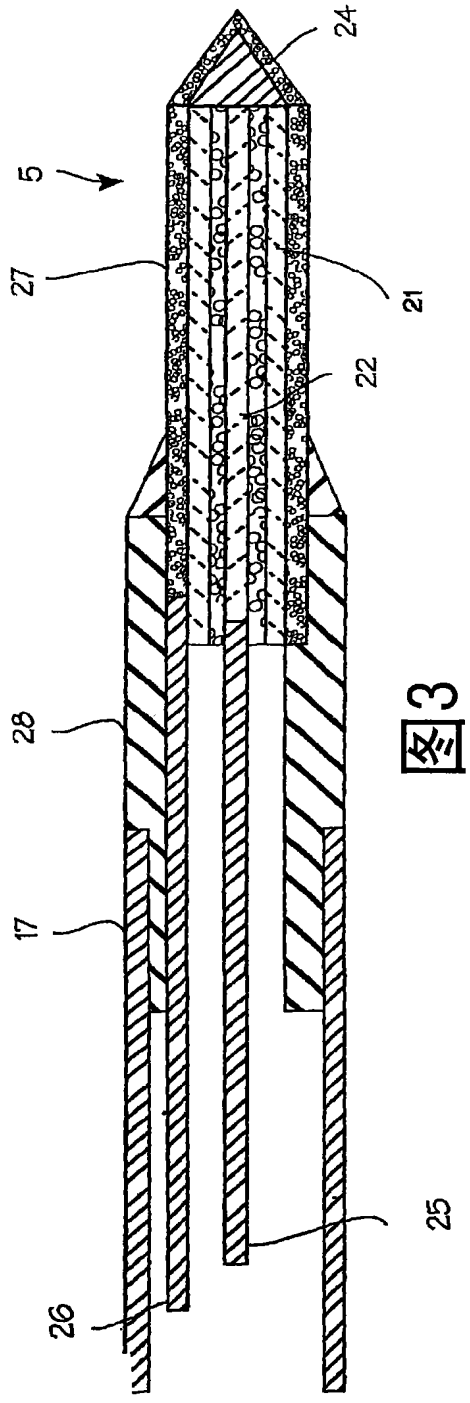

24
5
27
21
22
28
17
26
25

图3

Electronic Acknowledgement Receipt

EFS ID:	23948944
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Julie Wang
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	30-OCT-2015
Filing Date:	31-MAR-2015
Time Stamp:	16:59:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	244690US02-SuppIDS.pdf	1035207 3f2a2773d4a0ae70b2cd88050e93e2c95cd737b6	no	4

Warnings:	
Information:	

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

2	Foreign Reference	NPLCN101325919A.pdf	513472 1d2ef8977dd41e07f72572e7077615fde4048655	no	10

Warnings:

Information:

Total Files Size (in bytes):	1548679

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/675,689	03/31/2015	Scott J. WOLF	P244690US02 (494912-15)	9467

75149 7590 11/03/2015

Dorsey & Whitney LLP - PA
Intellectual Property Department
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402-1498

EXAMINER
WIELAND, ROBERT N

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
11/03/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip.docket@dorsey.com

Office Action Summary	Application No. 14/675,689	Applicant(s) WOLF ET AL.	
	Examiner Robert N. Wieland, Esq.	Art Unit 3762	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/19/2015*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-33* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-4,20 and 26* is/are rejected.

8)☒ Claim(s) *5-19, 21-25 and 27-33* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

1. This Action is in response to documents filed 08/19/2015.

2. Claims 1-33 are pending.

Notice of Pre-AIA or AIA Status

3. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted as listed on the accompanying PTO-326 was/were filed before the mailing date of the present office action. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

IMPORTANT: PLEASE USE THE eTerminal Disclaimer FOR EASE OF USE AND PROMPT, AUTOMATED PROCESSING.

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission.

For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

6. Claims 1-4, 20 and 26 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 9 and 10 of U.S. Patent No. 8,936,594. Once the applicant has received a patent for a species or a more specific

embodiment, he is not entitled to a patent for the generic or broader invention (see *In* re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)). Although the claims at issue are not identical, they are not patentably distinct from each other because both sets of claims are directed to obvious variations of treating a patient's nasal airway using a treatment device to modify a property of the at least one tissue without piercing the mucosal tissue, and another tissue underlying the mucosal tissue is an obvious tissue to treat.

Pertinent Prior Art

7. The following prior art made of record and not relied upon is considered pertinent to Applicant's claims. Applicant is encouraged to consider the disclosures, including potential combinations thereof, beyond the example highlighted portions noted below.

Edwards et al. U.S. Patent No. 6,416,491.

Allowable Subject Matter

8. Claims 5-19, 21-25 and 27-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT N. WIELAND, Esq. whose telephone number is (571) 270-7399. The examiner can normally be reached on Monday-Thursday, 8:00-6:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number directly to Examiner Wieland is 571-270-8399.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert N. Wieland, Esq./
Primary Examiner, A.U. 3762

Notice of References Cited	Application/Control No. 14/675,689	Applicant(s)/Patent Under Reexamination WOLF ET AL.	
	Examiner Robert N. Wieland, Esq.	Art Unit 3762	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-6,416,491 B1	07-2002	Edwards; Stuart D.	A61B18/1206	604/22
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14675689	WOLF ET AL.
	Examiner	**Art Unit**
	ROBERT N WIELAND	3762

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/29/2015								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	O								
	6	O								
	7	O								
	8	O								
	9	O								
	10	O								
	11	O								
	12	O								
	13	O								
	14	O								
	15	O								
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	18	O								
	19	O								
	20	✓								
	21	O								
	22	O								
	23	O								
	24	O								
	25	O								
	26	✓								
	27	O								
	28	O								
	29	O								
	30	O								
	31	O								
	32	O								
	33	O								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14675689	WOLF ET AL.
	Examiner	Art Unit
	ROBERT N WIELAND	3762

CPC- SEARCHED		
Symbol	Date	Examiner
A61B18/1492 or A61B18/1442 or A61B18/1485 or A61F5/08	10/29/2015	/RNW/

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Searched inventor and assignee names; also for obviousness double patenting	10/29/2015	/RNW/
Text-searched selected CPC Class codes; also searched generally	10/29/2015	/RNW/
Placed copy of search report in the record	10/29/2015	/RNW/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	803	electrode SAME (positive or anode) SAME (negative or cathode) SAME (concave or recess$4 or groove or depression) near9 (separat$4 or between) near6 electrode AND (@ad<"20110614" or @RLAD<"20110614")	US-PGPUB; USPAT	ADJ	ON	2015/10/29 13:33
L2	85	electrode SAME (positive or anode) SAME (negative or cathode) SAME (concave or recess$4 or groove or depression) near9 (separat$4 or between) near6 electrode AND (external$4 or exterior or (tissue or skin)) near6 surface SAME (electrode or stimul$5) AND (@ad<"20110614" or @RLAD<"20110614")	US-PGPUB; USPAT	ADJ	ON	2015/10/29 13:35
L3	25	electrode SAME (positive or anode) SAME (negative or cathode) SAME (concave or recess$4 or groove or depression) near9 (separat$4 or between) near6 electrode AND (external$4 or exterior or (tissue or skin)) near6 surface SAME (electrode or stimul$5) AND electrical adj4 stimul$5 AND (@ad<"20110614" or @RLAD<"20110614")	US-PGPUB; USPAT	ADJ	ON	2015/10/29 13:36
L4	8	electrode SAME (positive or anode) SAME (negative or cathode) near9 (concave or recess$4 or groove or depression) AND (external$4 or exterior or (tissue or skin)) near6 surface SAME (electrode or stimul$5) AND electrical adj4 stimul$5 AND (@ad<"20110614" or @RLAD<"20110614") NOT L3	US-PGPUB; USPAT	ADJ	ON	2015/10/29 13:41
L5	1	"6,416,491".pn.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 13:49
L6	2	13/495844.app.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 14:00
L7	1	"8,936,594".pn.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 14:02
L9	4	((AERIN MEDICAL).aanm. or wolf.in.) AND (mucosal tissue).clm. AND energy.clm. AND concave.clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 14:48
L10	1	14/675689.app.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 14:48
L11	4	(L9 or L10) AND device.clm. AND concave.clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 14:48
S1	1	((AERIN MEDICAL).aanm. or wolf.in.) AND (post nasal drip).clm.	US-PGPUB;	ADJ	ON	2015/10/29 11:33

			USPAT			
S2	1	((AERIN MEDICAL).aanm. or wolf.in.) AND (mucus secretion).clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:33
S3	4	((AERIN MEDICAL).aanm. or wolf.in.) AND (mucosal tissue).clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:34
S4	4	((AERIN MEDICAL).aanm. or wolf.in.) AND (mucosal tissue).clm. AND energy.clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:34
S5	4	((AERIN MEDICAL).aanm. or wolf.in.) AND (mucosal tissue).clm. AND energy.clm. AND concave.clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:35
S6	1	14/675689.app.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:38

10/29/2015 3:46:04 PM
C:\Users\rwieland\Documents\EAST\Workspaces\14675689.wsp

Receipt date: 07/09/2015 14675689 - GAU: 3762

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/675,689
	Filing Date	March 31, 2015
	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	To be assigned
	Attorney Docket Number	P244690US02 (494912-15)

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4,887,605		1989-12-19	ANGELSE, *et al.*	
		5,348,008		1994-09-20	BORNN, *et al.*	
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		5,823,197		1997-10-20	EDWARDS	
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		5,843,021		1998-12-01	EDWARDS, *et al.*	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

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	Attorney Docket Number	P244690US02 (494912-15)

		5,846,235		1998-12-08	PASRICHA, *et al.*	
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	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	To be assigned
	Attorney Docket Number	P244690US02 (494912-15)

		6,575,969		2003-06-10	RITTMAN, III, *et al.*	
		6,589,235	B2	2003-07-08	WONG, *et al.*	
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

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	Attorney Docket Number	P244690US02 (494912-15)

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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns, Lines where Relevant Passages or Relevant Figures Appear	T[5]
		2007/037895	WO		2007-04-05	NYTE		
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		2015/048806	WO		2015-04-02	LANE		

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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		STUPAK, *A Perspective on the Nasal Valve*, Power Point Presentation, Department of Otorhinolaryngology, Albert Einstein College of Medicine, Nov. 6, 2009, pp. 1-9	
		STUPAK, *Endonasal Repositioning of the Upper Lateral Cartilage and the Internal Nasal Valve*, Annals of Otology, Rhinology & Laryngology, Annals Publishing Company, Vol. 120(2), 2011, pp. 88-94	

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	Examiner Name	To be assigned
	Attorney Docket Number	P244690US02 (494912-15)

		International Search Report, Issued by the International Searching Authority for corresponding PCT Application No. PCT/US2012/042316, (08/24/2012) pp. 1-11	
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		International Search Report, Issued by the International Searching Authority for corresponding PCT Patent Application No. PCT/US15/023742, Our File No. P244690WO01 (06/29/2015) pp 1-2	
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		Singapore Search Report for Application No. 201309238-2 (June 9, 2014) 27 pages	

EXAMINER SIGNATURE

Examiner Signature	/Robert N. Wieland/	Date Considered	10/29/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

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	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	To be assigned
	Attorney Docket Number	P244690US02 (494912-15)

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	July 9, 2015
Name/Print	Scott Michael Smith	Registration Number	48268

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

4837-5620-3301

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Receipt date: 08/25/2015 14675689 - GAU: 3762

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	Examiner Name	To be Assigned
	Attorney Docket Number	P244690US02 (494912-15)

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2002/0128641		2002-09-12	UNDERWOOD, *et al.*	

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

EXAMINER SIGNATURE

Examiner Signature	/Robert N. Wieland/	Date Considered	10/29/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Receipt date: 08/25/2015 14675689 - GAU: 3762

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	Attorney Docket Number	P244690US02 (494912-15)

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[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	August 25, 2015
Name/Print	Scott Michael Smith	Registration Number	48268

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14675689
Filing Date	2015-03-31
First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	Wieland, Robert N.
Attorney Docket Number	P244690US02 (494912-15)

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6109268	A	2000-08-29	THAPLIYAL, Hira V.	
	2	9179967	B2	2015-11-10	WOLF, Scott J.	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060235377	A1	2006-10-19	EARLEY, Christopher	

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14675689
	Filing Date	2015-03-31
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	Wieland, Robert N.
	Attorney Docket Number	P244690US02 (494912-15)

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14675689
	Filing Date	2015-03-31
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	Wieland, Robert N.
	Attorney Docket Number	P244690US02 (494912-15)

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	2015-12-29
Name/Print	Scott M. Smith	Registration Number	48268

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	24482000
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Julie Wang
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	29-DEC-2015
Filing Date:	31-MAR-2015
Time Stamp:	16:07:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P244690US02-SuppIDS.pdf	1035163 aef136208652fce590fc298dbcb1f2e8a74dcdca	no	4

Warnings:	
Information:	

Total Files Size (in bytes):	1035163

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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.

Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	14675689
Filing Date	31-Mar-2015
First Named Inventor	Scott WOLF
Attorney Docket Number	P244690US02 (494912-15)
Title of Invention	POST NASAL DRIP TREATMENT

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
AERIN MEDICAL, INC.	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

8936594

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.
Applicant claims the following fee status: ◉ Small Entity ○ Micro Entity ○ Regular Undiscounted I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number 48268 ○ A sole inventor ○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ○ A joint inventor; all of whom are signing this request

Signature	/Scott M. Smith/
Name	Scott M. Smith

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	14675689
Filing Date:	31-Mar-2015
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Filer:	Scott Michael Smith/Katherine Benton
Attorney Docket Number:	P244690US02 (494912-15)

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Statutory or Terminal Disclaimer	2814	1	160	160
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**160**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 14675689

Filing Date: 31-Mar-2015

Applicant/Patent under Reexamination: WOLF et al.

Electronic Terminal Disclaimer filed on December 30, 2015

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	24488323
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Katherine Benton
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	30-DEC-2015
Filing Date:	31-MAR-2015
Time Stamp:	10:13:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$160
RAM confirmation Number	12700
Deposit Account	041420
Authorized User	BENTON, KATIE R.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 CFR 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 CFR 1.19 (Document supply fees)

Charge any Additional Fees required under 37 CFR 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Electronic Terminal Disclaimer-Filed	eTerminal-Disclaimer.pdf	33462 0c9c2ba7e8ccef4ad6620b2f2cd700b49bc9adaf	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30412 1422a897ff76774ed37e647ff495a6dd3f602922	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	63874		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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.

Docket: P244690US02 (494912-15)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE			
First Named Inventor:	Scott J. Wolf		
Appln. No.:	14/675,689	Confirmation No.:	9467
Filing Date:	March 31, 2015	Examiner:	Wieland, Robert N.
Title:	Post Nasal Drip Treatment	Group Art Unit:	3762

AMENDMENT AND RESPONSE TO OFFICE ACTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

To the Commissioner:

In response to the Office Action of November 3, 2015, please amend the above-identified application as follows:

A **Listing of Claims** begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Original) A method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the method comprising:

advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient;

contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and

delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient.

2. (Original) The method of claim 1, wherein the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant.

3. (Original) The method of claim 1, wherein delivering the treatment comprises delivering energy from the delivery treatment portion in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy.

4. (Original) The method of claim 3, wherein delivering the treatment comprises delivering radiofrequency energy from a first electrode on a tissue contact surface of the treatment portion across a convex portion of the tissue contact surface to a second electrode on the tissue contact surface.

5. (Original) The method of claim 4, wherein contacting the mucosal tissue comprises contacting multiple non-piercing bumps on the tissue contact surface with the mucosal tissue.

6. (Original) The method of claim 3, wherein the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein delivering the energy comprises ablating the nerve tissue.

7. (Original) The method of claim 3, further comprising measuring an amount of delivered energy using a thermocouple on the treatment portion.

8. (Original) The method of claim 7, further comprising adjusting the amount of delivered energy by adjusting a setting of the treatment delivery portion.

9. (Original) The method of claim 1, wherein delivering the treatment comprises removing energy, and wherein the treatment delivery portion comprises a cryotherapy device.

10. (Original) The method of claim 9, wherein the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein removing energy comprises ablating the nerve tissue using the cryotherapy device.

11. (Original) The method of claim 1, wherein applying a treatment comprises injecting a polymerizing liquid.

12. (Original) The method of claim 1, wherein delivering the treatment comprises injuring the at least one tissue.

13. (Original) The method of claim 12, wherein delivering the treatment comprises injuring goblet cells that are part of the mucosal tissue.

14. (Original) The method of claim 12, wherein the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves, submucosal tissue, muscle, ligaments, cartilage, tendon, and skin.

15. (Original) The method of claim 1, wherein delivering the treatment comprises simultaneously mechanically altering the mucosal tissue and delivering energy to the at least one tissue.

16. (Original) The method of claim 1, wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue.

17. (Original) The method of claim 1, wherein delivering the treatment comprises delivering a cauterizing agent to tissue to be treated.

18. (Original) The method of claim 1, wherein delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway.

19. (Original) The method of claim 18, wherein the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate.

20. (Original) A device for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the device comprising:

an elongate, malleable shaft having a proximal end and a distal end;

a handle at the proximal end of the elongate shaft; and

a treatment portion at the distal end of the elongate shaft, the treatment portion comprising a treatment surface, the treatment surface comprising:

at least two energy delivery members extending longitudinally along the treatment surface; and

a concave trough extending longitudinally along the treatment surface and separating the at least two energy delivery members.

21. (Original) The device of claim 20, wherein the at least two energy delivery members comprise at least one positive electrode on one side of the concave trough and at least one negative electrode on an opposite side of the concave trough.

22. (Original) The device of claim 21, wherein the at least one positive electrode comprises a row of positive electrodes, and wherein the at least on negative electrode comprises a row of negative electrodes.

23. (Original) The device of claim 22, wherein the electrodes protrude from the treatment surface.

24. (Original) The device of claim 23, wherein the electrodes are blunt-tipped electrodes.

25. (Original) The device of claim 20, further comprising a thermocouple disposed within the concave trough.

26. (Original) A method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the method comprising:

bending a malleable shaft of a treatment device into a desired configuration;

advancing a treatment portion of the treatment device into a nostril of the patient to contact a treatment surface of the treatment portion with mucosal tissue of the upper airway, without piercing the mucosal tissue;

delivering radiofrequency energy from a first electrode on the treatment surface across a concave trough in the treatment surface to a second electrode on the treatment surface, to treat at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient;

measuring an amount of the radiofrequency energy delivered, using a thermocouple disposed in the concave trough; and

removing the treatment portion from the upper airway without leaving an implant in the upper airway.

27. (Original) The method of claim 26, further comprising performing a test to determine whether a desired contact between the treatment surface and the mucosal tissue has been achieved.

28. (Original) The method of claim 26, wherein the delivering and measuring steps comprise:

delivering a first amount of the radiofrequency energy from the first electrode to the second electrode;

measuring a temperature of the mucosal tissue using the thermocouple; and

delivering a second amount of the radiofrequency energy from the first electrode to the second electrode, wherein the second amount of radiofrequency energy is based at least in part on the measured temperature.

29. (Original) The method of claim 26, wherein the mucosal tissue comprises tissue located on at least one nasal turbinate of the upper airway.

30. (Original) The method of claim 29, wherein the mucosal tissue comprises tissue located on a posterior aspect of an inferior turbinate.

31. (Original) The method of claim 26, wherein delivering the radiofrequency energy comprises delivering the radiofrequency energy in an amount that deactivates mucus producing cells by impairing at least one of mucus production ability or cell differentiation ability of the mucus producing cells.

32. (Original) The method of claim 26, wherein delivering the radiofrequency energy comprises delivering the radiofrequency energy in an amount that causes one or more mucus paths of the upper airway to divert.

33. (Original) The method of claim 26, further comprising repeating the bending, advancing, and delivery steps.

REMARKS/ARGUMENTS

This communication responds to the Office Action of November 3, 2015, in which claims 1–33 are pending. With this response, no claims are amended, canceled, or added.

The Office Action rejected claims 1–4, 20, and 26 on the ground of nonstatutory double patenting as being unpatentable over claims 1–3, 9 and 10 of U.S. Patent No. 8,936,594. A terminal disclaimer, in compliance with 37 C.F.R. § 1.321 has been submitted. Accordingly, the double patenting rejection has been overcome, and such claims are now allowable.

Claims 5–19, 21–25 and 27–33 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. With this response, the rejection of claims 1–4, 20, and 26 is traversed. Accordingly, claims 5–19, 21–25 and 27–33 are no longer dependent on a rejected base claim. Applicant respectfully requests withdrawal of the objection.

This response is being submitted on or before February 3, 2016, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Each and every claim of this application now stands in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

DORSEY & WHITNEY LLP
Customer Number 75149

Date: December 30, 2015

by: /Scott M. Smith/
Scott M. Smith, Reg. No. 48,268
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498
Tel: (612) 492-6714

Electronic Acknowledgement Receipt

EFS ID:	24489049
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Katherine Benton
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	30-DEC-2015
Filing Date:	31-MAR-2015
Time Stamp:	11:45:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P244690US02_NFOA_Response.pdf	482712 a1f2c968b7da871a80c3e12f7b8f7ff40eeec100	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	7

Warnings:	
Information:	
Total Files Size (in bytes):	482712

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a 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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/675,689	Filing Date 03/31/2015	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)		
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	**140**
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	33 minus 20 =	* 13	x $40 =	**520**
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	* 0	x $210 =	**0**
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	**660**

APPLICATION AS AMENDED – PART II

AMENDMENT	12/30/2015	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 33	Minus	** 33	= 0	x $40 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	x $210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**0**

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/JESSICA GAYNOR/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/675,689
	Filing Date	2015-03-31
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	WIELAND, Robert N.
	Attorney Docket Number	P244690US02 (494012-15)

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		8,137,345		2012-03-20	McNALL, *et al.*	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2006/0253117		2006-11-09	HOVDA, *et al.*	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/675,689
	Filing Date	2015-03-31
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	WIELAND, Robert N.
	Attorney Docket Number	P244690US02 (494012-15)

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17(p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott Michael Smith/	Date (YYYY-MM-DD)	2016-02-09
Name/Print	Scott Michael Smith	Registration Number	48268

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

4811-2009-1693

Electronic Acknowledgement Receipt

EFS ID:	24864960
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Julie Wang
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	09-FEB-2016
Filing Date:	31-MAR-2015
Time Stamp:	14:19:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P244690US02-SuppIDS.pdf	167943 d89a371cc842850a99f1f056c69fecfa0e17748c	no	2

Warnings:	
Information:	

This is not an USPTO supplied IDS fillable form	
Total Files Size (in bytes):	167943

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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.

Docket: P244690US02 (494912-15)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Scott J. Wolf		
Appln. No.:	14/675,689	Confirmation No.:	9467
Filing Date:	March 31, 2015	Examiner:	Wieland, Robert N.
Title:	Post Nasal Drip Treatment	Group Art Unit:	3762

SUPPLEMENTAL AMENDMENT

Mail Stop - Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Examiner Wieland:

As a supplemental amendment and response to the Office Action of November 3, 2015, please amend the above-identified application as follows:

Amendments to the Drawings begin on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

AMENDMENTS TO THE DRAWINGS

Please replace figure sheet 29 with the corresponding replacement figure sheet 29, attached to this Supplemental Amendment. Annotated figure sheet 29, showing changes, is also attached herewith.

REMARKS

This response is submitted as a Supplemental Amendment and Response to the Amendment and Response filed on December 30, 2015, which was submitted in reply to the Non-Final Office Action of November 3, 2015. No amendments to the claims are presented with this amendment. Upon entry of the amendment filed on December 30, 2015, claims 1-33 will be pending and are presented for reexamination and reconsideration.

Amendments to the Drawings

In a voicemail message of March 23, 2016, the Examiner indicated that a typographical error was present on figure sheet 29, in which figure numbers 32A and 32B were mislabeled. Instead, figure numbers 32A and 32B should read FIG. 29A and FIG. 29B respectively. Applicant submits herewith replacement figure sheet 29, in which the figure numbers have been corrected to reflect the appropriate figure numbers corresponding with the specification.

Conclusion

It is believed that no fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

DORSEY & WHITNEY LLP
Customer Number 75149

Date: March 23, 2016

by: /Scott M. Smith/
Scott M. Smith, Reg. No. 48,268
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498
Tel: (612) 492-6714

ANNOTATED SHEET
29/29

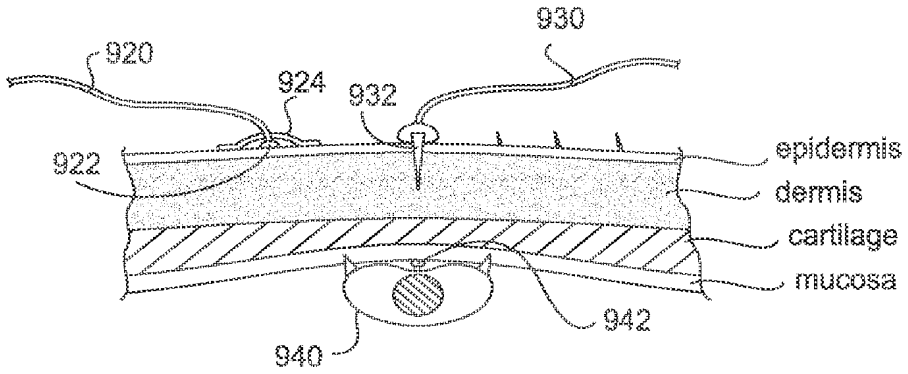


FIG. ~~32A~~ 29A

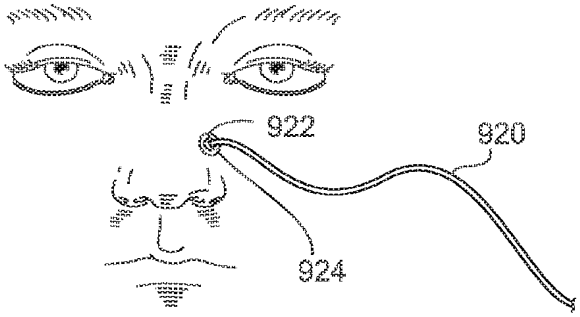


FIG. ~~32B~~ 29A

REPLACEMENT SHEET

29/29

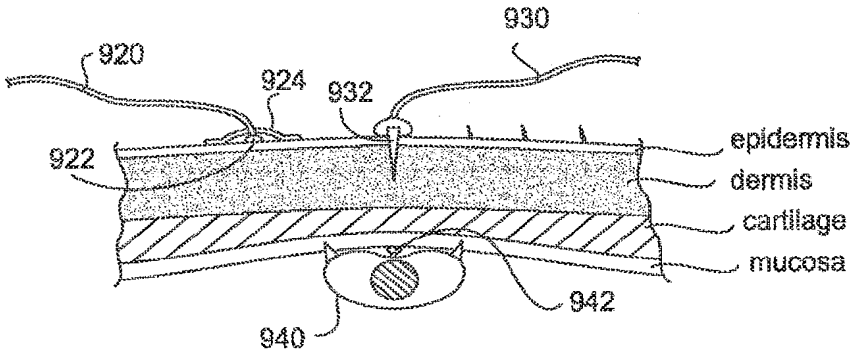


FIG.29A

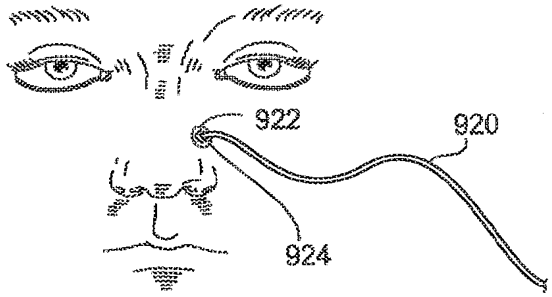


FIG.29B

Electronic Acknowledgement Receipt

EFS ID:	25287025
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Katherine Benton
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	23-MAR-2016
Filing Date:	31-MAR-2015
Time Stamp:	17:30:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P244690US02_Supplemental_Amendment.pdf	476643 5a7de54c0625892fdbe484b75cf670275747d72e	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Supplemental Response or Supplemental Amendment	1	1
	Drawings-only black and white line drawings	2	2
	Applicant Arguments/Remarks Made in an Amendment	3	3

Warnings:					
Information:					
2	Drawings-only black and white line drawings	P244690US02_Annotated_Figure_Sheet.pdf	443718 ba33a3ea05c682ad8009f2d2ec80a4d5d4d8a52a	no	1
Warnings:					
Information:					
3	Drawings-only black and white line drawings	P244690US02_REPLACEMENT_Figure_Sheet.pdf	455775 581994e9e407eee11dce9559b9c1099dc869e851	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	1376136		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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

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New International Application Filed with the USPTO as a Receiving Office

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

75149 7590 04/13/2016

Dorsey & Whitney LLP - PA
Intellectual Property Department
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402-1498

EXAMINER
WIELAND, ROBERT N

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/13/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/675,689	03/31/2015	Scott J. WOLF	P244690US02 (494912-15)	9467

TITLE OF INVENTION: POST NASAL DRIP TREATMENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	07/13/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

75149 7590 04/13/2016
Dorsey & Whitney LLP - PA
Intellectual Property Department
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402-1498

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/675,689	03/31/2015	Scott J. WOLF	P244690US02 (494912-15)	9467

TITLE OF INVENTION: POST NASAL DRIP TREATMENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	07/13/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
WIELAND, ROBERT N	3762	606-041000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/675,689	03/31/2015	Scott J. WOLF	P244690US02 (494912-15)	9467

75149 7590 04/13/2016

Dorsey & Whitney LLP - PA
Intellectual Property Department
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402-1498

EXAMINER	
WIELAND, ROBERT N	
ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/13/2016

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/675,689	Applicant(s) WOLF ET AL.	
	Examiner Robert N. Wieland, Esq.	Art Unit 3762	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *documents received 02/09/2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-33*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Robert N. Wieland, Esq./
Primary Examiner, Art Unit 3762

DETAILED ACTION

1. This Action is in response to the documents filed 03/23/2016.

2. The amendment to figure sheet 29 is acceptable.

3. The Terminal Disclaimer filed on 12/30/2015 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 8,936,594 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Information Disclosure Statement

4. The information disclosure statement(s) referenced on the accompanying PTO-37 was/were filed before the mailing date of the present office action. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Allowable Subject Matter

5. Claims 1-33 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT N. WIELAND, Esq. whose telephone number is (571) 270-7399. The examiner can normally be reached on Monday-Thursday, 8:00-6:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number directly to Examiner Wieland is 571-270-8399.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert N. Wieland, Esq./
Primary Examiner, A.U. 3762

Receipt date: 10/30/2015 14675689 - GAU: 3762
Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed
PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14675689
Filing Date	2015-03-31
First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	WIELAND, ROBERT N
Attorney Docket Number	P244690US02 (494912-15)

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	101325919	CN	A	2008-12-17	Starion Instruments Corp.		☒

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

Receipt date: 10/30/2015 14675689 - GAU: 3762

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14675689
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First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	WIELAND, ROBERT N
Attorney Docket Number	P244690US02 (494912-15)

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Robert N. Wieland/	Date Considered	03/17/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

Receipt date: 10/30/2015 14675689 - GAU: 3762

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14675689
Filing Date	2015-03-31
First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	WIELAND, ROBERT N
Attorney Docket Number	P244690US02 (494912-15)

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	2015-10-30
Name/Print	Scott M. Smith	Registration Number	48268

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

Receipt date: 10/30/2015 14675689 - GAU: 3762

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	14/675689.app.	US-PGPUB; USPAT	ADJ	ON	2016/03/17 16:05
S1	1	((AERIN MEDICAL).aanm. or wolf.in.) AND (post nasal drip).clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:33
S2	1	((AERIN MEDICAL).aanm. or wolf.in.) AND (mucus secretion).clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:33
S3	4	((AERIN MEDICAL).aanm. or wolf.in.) AND (mucosal tissue).clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:34
S4	4	((AERIN MEDICAL).aanm. or wolf.in.) AND (mucosal tissue).clm. AND energy.clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:34
S5	4	((AERIN MEDICAL).aanm. or wolf.in.) AND (mucosal tissue).clm. AND energy.clm. AND concave.clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:35
S6	1	14/675689.app.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 11:38
S7	803	electrode SAME (positive or anode) SAME (negative or cathode) SAME (concave or recess$4 or groove or depression) near9 (separat$4 or between) near6 electrode AND (@ad<"20110614" or @RLAD<"20110614")	US-PGPUB; USPAT	ADJ	ON	2015/10/29 13:33
S8	85	electrode SAME (positive or anode) SAME (negative or cathode) SAME (concave or recess$4 or groove or depression) near9 (separat$4 or between) near6 electrode AND (external$4 or exterior or (tissue or skin)) near6 surface SAME (electrode or stimul$5) AND (@ad<"20110614" or @RLAD<"20110614")	US-PGPUB; USPAT	ADJ	ON	2015/10/29 13:35
S9	25	electrode SAME (positive or anode) SAME (negative or cathode) SAME (concave or recess$4 or groove or depression) near9 (separat$4 or between) near6 electrode AND (external$4 or exterior or (tissue or skin)) near6 surface SAME (electrode or stimul$5) AND electrical adj4 stimul$5 AND (@ad<"20110614" or @RLAD<"20110614")	US-PGPUB; USPAT	ADJ	ON	2015/10/29 13:36
S10	8	electrode SAME (positive or anode) SAME (negative or cathode) near9 (concave or recess$4 or groove or depression) AND (external$4 or exterior or (tissue or skin)) near6 surface SAME (electrode or stimul$5) AND electrical adj4 stimul$5 AND (@ad<"20110614" or @RLAD<"20110614")	US-PGPUB; USPAT	ADJ	ON	2015/10/29 13:41

		NOT S9				
S11	1	"6,416,491".pn.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 13:49
S12	2	13/495844.app.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 14:00
S13	1	"8,936,594".pn.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 14:02
S14	4	((AERIN MEDICAL).aanm. or wolf.in.) AND (mucosal tissue).clm. AND energy.clm. AND concave.clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 14:48
S15	1	14/675689.app.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 14:48
S16	4	(S14 or S15) AND device.clm. AND concave.clm.	US-PGPUB; USPAT	ADJ	ON	2015/10/29 14:48

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	0	(A device for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the device comprising: an elongate, malleable shaft having a proximal end and a distal end, a handle at the proximal end of the elongate shaft, and a treatment portion at the distal end of the elongate shaft, the treatment portion comprising a treatment surface, the treatment surface comprising: at least two energy delivery members extending longitudinally along the treatment surface, and a concave trough extending longitudinally along the treatment surface and separating the at least two energy delivery members).clm.	USPAT	ADJ	ON	2016/03/17 16:11

3/17/2016 4:12:37 PM
C:\Users\rwieland\Documents\EAST\Workspaces\14675689.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14675689	WOLF ET AL.
	Examiner	Art Unit
	ROBERT N WIELAND	3762

CPC- SEARCHED		
Symbol	Date	Examiner
A61B18/1492 or A61B18/1442 or A61B18/1485 or A61F5/08	10/29/2015	/RNW/

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Searched inventor and assignee names; also for obviousness double patenting	10/29/2015	/RNW/
Text-searched selected CPC Class codes; also searched generally	10/29/2015	/RNW/
Placed copy of search report in the record	10/29/2015	/RNW/
Search extended	03/17/2016	/RNW/
Placed copy of interference search report in the record	03/17/2016	/RNW/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
606	41	03/31/2015	/RNW/

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 9467

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/675,689	03/31/2015	606	3762	P244690US02 (494912-15)

APPLICANTS

AERIN MEDICAL INC., Sunnyvale, CA;

INVENTORS

Scott J. WOLF, Menlo Park, CA;
Andrew FRAZIER, Sunnyvale, CA;

**** CONTINUING DATA ***************************

This appln claims benefit of 61/974,534 04/03/2014
and is a CIP of 14/319,087 06/30/2014 PAT 9072597
which is a CIP of 13/495,844 06/13/2012 PAT 8936594
which claims benefit of 61/603,864 02/27/2012
and claims benefit of 61/496,930 06/14/2011

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
04/13/2015

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ROBERT N WIELAND/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	29	33	3

ADDRESS

Dorsey & Whitney LLP - PA
Intellectual Property Department
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402-1498
UNITED STATES

TITLE

POST NASAL DRIP TREATMENT

FILING FEE RECEIVED		
1320	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Receipt date: 02/09/2016 14675689 - GAU: 3762

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/675,689
	Filing Date	2015-03-31
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	WIELAND, Robert N.
	Attorney Docket Number	P244690US02 (494012-15)

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		8,137,345		2012-03-20	McNALL, *et al.*	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2006/0253117		2006-11-09	HOVDA, *et al.*	

EXAMINER SIGNATURE

Examiner Signature	/Robert N. Wieland/	Date Considered	03/17/2016

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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OR

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17(p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott Michael Smith/	Date (YYYY-MM-DD)	2016-02-09
Name/Print	Scott Michael Smith	Registration Number	48268

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

4811-2009-1693

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14675689	WOLF ET AL.
	Examiner	**Art Unit**
	ROBERT N WIELAND	3762

CPC						
Symbol					**Type**	**Version**
A61M		25	/	10	F	2013-01-01
A61B		18	/	02	I	2013-01-01
A61B		2018	/	0293	A	2013-01-01
A61B		2018	/	00994	A	2013-01-01
A61B		2018	/	00577	A	2013-01-01
A61B		2018	/	00595	A	2013-01-01
A61B		2018	/	0022	A	2013-01-01
A61M		2025	/	105	A	2013-01-01
A61F		5	/	08	I	2013-01-01
A61B		18	/	1442	I	2013-01-01
A61B		18	/	1485	I	2013-01-01
A61B		18	/	16	A	2013-01-01
A61B		2018	/	00005	A	2013-01-01
A61B		2018	/	00023	A	2013-01-01
A61B		2018	/	00327	A	2013-01-01
A61B		2018	/	00702	A	2013-01-01
A61B		2018	/	00821	A	2013-01-01
A61B		2018	/	00922	A	2013-01-01
A61B		2018	/	0225	A	2013-01-01
A61B		2018	/	143	A	2013-01-01
A61B		2018	/	1425	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	33	
/ROBERT N WIELAND/ Primary Examiner.Art Unit 3762	03/17/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	11

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14675689	WOLF ET AL.
	Examiner	**Art Unit**
	ROBERT N WIELAND	3762

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
606	41	A	6	1	B	18 / 18 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	33	
/ROBERT N WIELAND/ Primary Examiner.Art Unit 3762	03/17/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	11

Issue Classification	**Application/Control No.**	**Applicant(s)/Patent Under Reexamination**
	14675689	WOLF ET AL.
	Examiner	**Art Unit**
	ROBERT N WIELAND	3762

☒ **Claims renumbered in the same order as presented by applicant** ☐ **CPA** ☒ **T.D.** ☐ **R.1.47**

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17		33										
	2		18												
	3		19												
	4		20												
	5		21												
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	12		28												
	13		29												
	14		30												
	15		31												
	16		32												

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	33	
/ROBERT N WIELAND/ Primary Examiner.Art Unit 3762	03/17/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	11

Receipt date: 12/29/2015 14675689 - GAU: 3762
Doc code: IDS
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PTO/SB/08a (03-15)
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Application Number	14675689
Filing Date	2015-03-31
First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	Wieland, Robert N.
Attorney Docket Number	P244690US02 (494912-15)

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6109268	A	2000-08-29	THAPLIYAL, Hira V.	
	2	9179967	B2	2015-11-10	WOLF, Scott J.	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060235377	A1	2006-10-19	EARLEY, Christopher	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

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Receipt date: 12/29/2015 14675689 - GAU: 3762

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First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	Wieland, Robert N.
Attorney Docket Number	P244690US02 (494912-15)

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

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EXAMINER SIGNATURE

Examiner Signature	/Robert N. Wieland/	Date Considered	03/17/2016

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Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	2015-12-29
Name/Print	Scott M. Smith	Registration Number	48268

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Receipt date: 12/29/2015 14675689 - GAU: 3762

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Doc description: Information Disclosure Statement (IDS) Filed

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	Application Number	14/675,689
	Filing Date	Mar 31, 2015
	First Named Inventor	Scott Wolf
	Art Unit	3762
	Examiner Name	Robert N. Wieland
	Attorney Docket Number	P244690.US.02 (494912-15)

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		9072597	B2	2016-07-07	Wolf et al.	

U.S.PATENT APPLICATION PUBLICATIONS

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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	Attorney Docket Number	P244690.US.02 (494912-15)

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Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	2016-07-07
Name/Print	Scott M. Smith	Registration Number	48268

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Electronic Patent Application Fee Transmittal

Application Number:	14675689
Filing Date:	31-Mar-2015
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Filer:	Scott Michael Smith/Katherine Benton
Attorney Docket Number:	P244690US02 (494912-15)

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
		Total in USD ($)		**90**

Electronic Acknowledgement Receipt

EFS ID:	26284279
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Katherine Benton
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	07-JUL-2016
Filing Date:	31-MAR-2015
Time Stamp:	15:18:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$90
RAM confirmation Number	070816INTEFSW15191900
Deposit Account	1004
Authorized User	Katherine BEnton

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P244690US02_Supplemental_IDS.pdf	490700 ab1ea843f86d62f15135cfbe95a1e12b47fa623f	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Fee Worksheet (SB06)	fee-info.pdf	30583 11cf3076cbae4042aeb442389d01142ee1b8856c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	521283		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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.

Electronic Acknowledgement Receipt

EFS ID:	26284279
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Katherine Benton
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	07-JUL-2016
Filing Date:	31-MAR-2015
Time Stamp:	15:18:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$90
RAM confirmation Number	070816INTEFSW15191900
Deposit Account	041420
Authorized User	Katherine BEnton

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P244690US02_Supplemental_IDS.pdf	490700 ab1ea843f86d62f15135cfbe95a1e12b47fa623f	no	2
Warnings:					
This is not an USPTO supplied IDS fillable form					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30583 11cf3076cbae4042aeb442389d01142ee1b8856c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	521283		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

75149 7590 04/13/2016
Dorsey & Whitney LLP - PA
Intellectual Property Department
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402-1498

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/675,689	03/31/2015	Scott J. WOLF	P244690US02 (494912-15)	9467

TITLE OF INVENTION: POST NASAL DRIP TREATMENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	07/13/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
WIELAND, ROBERT N	3762	606-041000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Dorsey & Whitney LLP
2 Scott M. Smith
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: AERIN MEDICAL INC.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): SUNNYVALE, CALIFORNIA

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Scott M. Smith/ Date July 12, 2016
Typed or printed name Scott M. Smith Registration No. 48,268

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PTO/SB/47 (09-06)
Approved for use through 04/30/2009. OMB 0651-0016
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

"FEE ADDRESS" INDICATION FORM

Address to:
Mail Stop M Correspondence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

- OR -

Fax to:
571-273-6500

INSTRUCTIONS: The issue fee must have been paid for application(s) listed on this form. In addition, only an address represented by a Customer Number can be established as the fee address for maintenance fee purposes (hereafter, fee address). A fee address should be established when correspondence related to maintenance fees should be mailed to a different address than the correspondence address for the application. **When to check the first box below:** If you have a Customer Number to represent the fee address. **When to check the second box below:** If you have no Customer Number representing the desired fee address, in which case a completed Request for Customer Number (PTO/SB/125) must be attached to this form. For more information on Customer Numbers, see the Manual of Patent Examining Procedure (MPEP) § 403.

For the following listed application(s), please recognize as the "Fee Address" under the provisions of 37 CFR 1.363 the address associated with:

☑ Customer Number: 000197

OR

☐ The attached Request for Customer Number (PTO/SB/125) form.

PATENT NUMBER (if known)	APPLICATION NUMBER
	14/675,689

Completed by (check one):

☐ Applicant/Inventor — /Scott M. Smith/ (Signature)

☑ Attorney or Agent of record 48,268 (Reg. No.) — Scott M. Smith (Typed or printed name)

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) — (612) 492-6714 (Requester's telephone number)

☐ Assignee recorded at Reel _____ Frame _____ — July 12, 2016 (Date)

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more that one signature is required, see below*.

☑ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.363. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 5 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND COMPLETED FORMS TO THIS ADDRESS.
SEND TO: Mail Stop M Correspondence, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	14675689
Filing Date:	31-Mar-2015
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Filer:	Scott Michael Smith/Katherine Benton
Attorney Docket Number:	P244690US02 (494912-15)

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	2501	1	480	480

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**480**

Electronic Acknowledgement Receipt

EFS ID:	26324602
Application Number:	14675689
International Application Number:	
Confirmation Number:	9467
Title of Invention:	POST NASAL DRIP TREATMENT
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Katherine Benton
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244690US02 (494912-15)
Receipt Date:	12-JUL-2016
Filing Date:	31-MAR-2015
Time Stamp:	14:22:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$480
RAM confirmation Number	071316INTEFSW14241000
Deposit Account	1004
Authorized User	Katherine BEnton

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	P244690US02_Issue_Fee_Payment.pdf	1992819 6a219392c2736aba4cafc009eb8d7c823c1ab818	no	1
Warnings:					
Information:					
2	Maintenance Fee Address Change	P244690US02_Fee_Address_CPA.pdf	494075 8379efbd3e71b4713f63b45caeaed52ab6135530	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30594 7f69bc1267356d52bd080314be9107e17d081ee9	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2517488		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/675,689	03/31/2015	Scott J. WOLF	P244690US02 (494912-15)	9467

75149 7590 07/14/2016

Dorsey & Whitney LLP - PA
Intellectual Property Department
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402-1498

EXAMINER
WIELAND, ROBERT N

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
07/14/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip.docket@dorsey.com

Corrected Notice of Allowability	**Application No.** 14/675,689	**Applicant(s)** WOLF ET AL.	
	Examiner Robert N. Wieland, Esq.	**Art Unit** 3762	**AIA (First Inventor to File) Status** Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *IDS received 07/07/2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-33*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Robert N. Wieland, Esq./
Primary Examiner, Art Unit 3762

DETAILED ACTION

1. Receipt is acknowledged of an information disclosure statement (IDS) submitted on 07/07/2016. The submission is in compliance with the provisions of 37 CFR 1.97. The information disclosure statement (IDS) has been considered by the examiner.

Allowable Subject Matter

2. Claims 1-33 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT N. WIELAND, Esq. whose telephone number is (571) 270-7399. The examiner can normally be reached on Monday-Thursday, 8:00-6:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number directly to Examiner Wieland is 571-270-8399.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert N. Wieland, Esq./
Primary Examiner, A.U. 3762

Receipt date: 07/07/2016 14675689 - GAU: 3762

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14/675,689
	Filing Date	Mar 31, 2015
	First Named Inventor	Scott Wolf
	Art Unit	3762
	Examiner Name	Robert N. Wieland
	Attorney Docket Number	P244690.US.02 (494912-15)

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		9072597	B2	2016-07-07	Wolf et al.	

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

EXAMINER SIGNATURE

Examiner Signature	/Robert N. Wieland/	Date Considered	07/09/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

Receipt date: 07/07/2016 14675689 - GAU: 3762

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14/675,689
	Filing Date	Mar 31, 2015
	First Named Inventor	Scott Wolf
	Art Unit	3762
	Examiner Name	Robert N. Wieland
	Attorney Docket Number	P244690.US.02 (494912-15)

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	2016-07-07
Name/Print	Scott M. Smith	Registration Number	48268

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RNW/

Receipt date: 07/09/2015 14675689 - GAU: 3762

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed
PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/675,689
	Filing Date	March 31, 2015
	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	To be assigned
	Attorney Docket Number	P244690US02 (494912-15)

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Receipt date: 07/09/2015 14675689 - GAU: 3762

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed
PTO/SB/08a (01-10)
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	Examiner Name	To be assigned
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	Examiner Name	To be assigned
	Attorney Docket Number	P244690US02 (494912-15)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14/675,689
	Filing Date	Mar 31, 2015
	First Named Inventor	Scott Wolf
	Art Unit	3762
	Examiner Name	Robert N. Wieland
	Attorney Docket Number	P244690.US.02 (494912-15)

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

EXAMINER SIGNATURE

Examiner Signature	/Robert N. Wieland/	Date Considered	07/09/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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75149 7590 07/27/2016

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Minneapolis, MN 55402-1498

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Scott J. WOLF, Menlo Park, CA;
AERIN MEDICAL INC., Sunnyvale, CA;
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