PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. 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 contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US11
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

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	State/Province	Country of Residence
Menlo Park	CA	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	State/Province	Country of Residence
Sunnyvale	CA	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).

NEURENT 1034

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US11
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	23552		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		
Attorney Docket Number	17713.0001US11	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	61	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

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	23552		

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US11
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim 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.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
	Continuation of	15272007	2016-09-21	
Prior Application Status	Patented			Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15272007	Continuation of	14754087	2015-06-29	9452010	2016-09-27

Prior Application Status	Patented			Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14754087	Continuation of	14319087	2014-06-30	9072597	2016-07-07

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 or 371(c) Date (YYYY-MM-DD)	
13495844	Claims benefit of provisional	61603864	2012-02-27	
Prior Application Status	Expired			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
13495844	Claims benefit of provisional	61496930	2011-06-14	

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

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US11
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

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. 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(i)(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).

Remove

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

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US11
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is 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 State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US11
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

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.

Applicant 1 — Remove

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	232 EAST CARIBBEAN DRIVE		
Address 2			
City	SUNNYVALE	**State/Province**	CA
Country	US	Postal Code	94089
Phone Number		Fax Number	
Email Address			

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

Assignee Information including Non-Applicant Assignee 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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US11
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

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.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

Organization Name	AERIN MEDICAL, INC.

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	232 EAST CARIBBEAN DRIVE		
Address 2			
City	SUNNYVALE	**State/Province**	CA
Country i	US	Postal Code	94089
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Christopher P. Ziolkowski/			Date (YYYY-MM-DD)	2017-08-25
First Name	Christopher P.	Last Name	Ziolkowski	Registration Number	73729

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US11
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

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.**

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 records.

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 CooperationTreaty.

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.

ABSTRACT

Methods and devices for treating nasal airways are provided. Such devices and methods may improve airflow through an internal and/or external nasal valve, and comprise 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.

CLAIMS

What is claimed is:

1. A method of treating a patient's airway, the method comprising:

advancing a non-expandable, elongate treatment element of a treatment device through a nostril and into the patient's airway, wherein the elongate treatment element includes a tissue-contact surface having a shape;

contacting a pair of bipolar, radiofrequency electrodes protruding from the tissue-contact surface with tissue in the airway;

applying force against the tissue with the shape of the tissue-contact surface to at least temporarily deform the tissue to a desired shape;

delivering radiofrequency energy between the electrodes, to at least one of reshape, remodel, strengthen or change a property of the tissue; and

removing the treatment element from the airway.

2. A method as in claim 1, further comprising forming an incision in mucosal tissue of the patient's airway, wherein the tissue to which the radiofrequency energy is delivered comprises submucosal tissue.

3. A method as in claim 2, wherein the incision is formed using a cutting member on the treatment device.

4. A method as in claim 2, wherein the submucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

5. A method as in claim 1, wherein the shape of the tissue-contact surface comprises a shape selected from the group consisting of a flat shape, a convex shape, and a concave shape.

6. A method of treating a patient's airway, the method comprising:

advancing a treatment element of a treatment device through a nostril of a patient and into the patient's airway, the treatment device having a radiofrequency electrode needle extending from the treatment element;

inserting the radiofrequency electrode needle into tissue of the patient's airway to reach submucosal tissue to be treated;

delivering radiofrequency energy using the inserted radiofrequency electrode needle to at least one of reshape, remodel, strengthen or change a property of the submucosal tissue to be treated; and

removing the treatment element from the airway.

7. The method of claim 6, wherein the radiofrequency electrode needle is a first radiofrequency electrode needle of a pair of bipolar radiofrequency needles, and wherein delivering radiofrequency energy using the inserted radiofrequency electrode needle comprises delivering radiofrequency energy between the pair of bipolar radiofrequency needles.

8. The method of claim 6, wherein the radiofrequency electrode needle is a first radiofrequency electrode needle of multiple radiofrequency electrode needles extending from the treatment element, and wherein delivering radiofrequency energy using the inserted radiofrequency electrode needle comprises selectively delivering energy between one or more sets of the radiofrequency electrode needles or all of the radiofrequency electrode needles.

9. The method of claim 6, further comprising applying a grounding pad to the patient, and wherein delivering radiofrequency energy using the inserted radiofrequency electrode needle comprises delivering radiofrequency energy between the radiofrequency electrode needle and the grounding pad.

10. The method of claim 6, wherein the radiofrequency electrode needle comprises an insulator on part of the radiofrequency electrode needle, and wherein delivering radiofrequency energy using the inserted radiofrequency electrode needle comprises protecting non-target tissue from the delivered radiofrequency energy using the insulator.

11. The method of claim 6, further comprising using a mold to shape, configure, or deflect tissue.

12. The method of claim 6, wherein the submucosal tissue to be treated includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Inventors: Scott J. WOLF
Andrew FRAZIER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 15/272,007, filed September 21, 2016, entitled "METHODS AND DEVICES TO TREAT AIRWAYS," which is a continuation of U.S. Patent Application No. 14/754,087, now U.S. Patent No. 9,452,010 filed June 29, 2015 which is a continuation of U.S. Patent Application No. 14/319,087, now U.S. Patent No. 9,072,597, filed June 30, 2014, which is a continuation-in-part of U.S. Patent Application No. 13/495,844, now U.S. Patent No. 8,936,594, filed June 13, 2012, which claims priority to U.S. Provisional Patent Application Serial Nos. 61/603,864, filed on February 27, 2012 and 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.

[0002] This application is related to Applicant's U.S. Patent Nos. 8,986,301, issued March 24, 2015 and 9,237,924, issued January 19, 2016, the entireties of both of which are hereby incorporated by reference in their entireties herein.

BACKGROUND

[0003] This application relates generally to the field of medical devices and treatments, and in particular to systems, devices and methods for treating structures within the nose and upper airway to reduce resistance to airflow and/or change the pressure level in the nose, nasal cavities, and/or and nasal passages and improve airflow and/or the feeling and effects of nasal obstruction during breathing.

DESCRIPTION OF THE RELATED ART

[0004] During respiration, the anatomy, shape, tissue composition and properties of the human airway produce airflow resistance. The nose is responsible for almost two thirds of this resistance. Most of this resistance occurs in the anterior part of the nose, known as the internal

nasal valve, which acts as a flow limiter. The external nasal valve structure also causes resistance to nasal airflow. Effective physiological normal respiration occurs within a range of airflow resistance. However, excessive resistance to airflow can result in abnormalities of respiration, which can significantly affect a patient's quality of life.

[0005] Inadequate nasal airflow can result from a number of conditions causing an inadequate cross sectional area of the nasal airway in the absence of any collapse or movement of the cartilages and soft tissues of the nasal airway. These include deviation of the nasal septum, turbinate enlargement, mucosal swelling, excessive mucous production, and nasal valve insufficiency, narrowing or collapse. No matter what the cause of inadequate nasal airflow, the nasal valve area is still a site of significant nasal airflow resistance. Increased nasal valve resistance can be due to static narrowing or movement or collapse of the nasal valve area often due to weakness or malformation of cartilage structures of the nose. In more extreme cases, nasal valve dysfunction is a serious medical condition.

[0006] Cartilage is an avascular tissue composed of a specialized matrix of collagens, proteoglycans, and non-collagen proteins, in which chondrocytes constitute the unique cellular component. Cartilage is specialized connective tissue found in various locations throughout the body. Cartilage basically consists of two components: water and a framework of structural macromolecules (matrix) that give the tissue its form and function. The matrix is highly organized and composed of collagens, proteoglycans and noncollagenous proteins.

[0007] The interaction of water and the macromolecular framework give the tissue its mechanical properties and thus its function. Up to 65%-80% of the wet weight of cartilage consists of water, while the rest is matrix, mainly collagens and proteoglycans. Chondrocytes are specialized cells that produce and maintain the extracellular matrix (ECM) of cartilage. The ECM makes up most of the tissue, where dense, covalently-linked heterotypic collagen fibrils interact with a number of other specialized matrix components.

[0008] The nasal valve was originally described by Mink in 1903. It is divided into external and internal portions. The external nasal valve is the external nasal opening formed by the columella at the base of the septum, the nasal floor, and the nasal rim (the lower region of the nasal wall, also known as the caudal border of the lower lateral cartilage). The nasalis muscle dilates the external nasal valve portion during inspiration.

[0009] The internal nasal valve, which accounts for the larger part of the nasal resistance, is located in the area of transition between the skin and respiratory epithelium. The internal nasal valve area is formed by the nasal septum, the caudal border of the upper lateral cartilage (ULC), the head of the inferior turbinate, and the pyriform aperture and the tissues that surround it.

[0010] The angle formed between the caudal border of the ULC and the nasal septum is normally between about 10 degrees-15 degrees as illustrated in FIG. 1. The internal nasal valve is usually the narrowest part of the nasal airway and is responsible for more than two thirds of the resistance produced by the nose.

[0011] In 1894, Franke performed nasal-flow experiments in models and cadavers and found that whirl formation occurred near the head of the turbinate during calm breathing. Mink in 1903 developed this concept further in 1920, suggesting that the greatest area of resistance was in the limen nasi or the union of the lobular cartilage and ULCs. In 1940, Uddstromer found that 70% of the resistance of the nose was produced in the internal nasal valve area and the remaining 30% was due to the nasal fossa. Van Dishoeck further investigated the mechanisms of the nasal valve in 1942, and in 1970, Bridger and Proctor wrote about a "flow-limiting segment" that included the limen nasi and the pyriform aperture. In 1972, Bachman and Legler found the pyriform aperture to have the smallest cross-sectional area of the nasal airway. In 1983, Haight and Cole continued the study of Bridger and Proctor and demonstrated that the maximal nasal resistance was localized near the pyriform aperture and depended on engorgement of the head of the inferior turbinate. A description of the nasal valve and its functions are more fully described in Cole, "The Four Components of the Nasal Valve", American Journal of Rhinology, Vol. 17, No. 2, pp. 107-110 (2003). See also, Cole, "Biophysics of Nasal Air Flow: A Review", American Journal of Rhinology, Vol. 14, No. 4, pp. 245-249 (2000).

[0012] Because ventilation involves pressure changes, the nasal airways must be stable both at rest and under the negative pressures created during quiet and forced inspiration. Proper airflow through the nasal airway depends on satisfactory structural stability (and/or resistance to conformational change resulting from pressure changes) of the upper and lower lateral cartilages and soft tissues respectively. Satisfactory skeletal stability is present when the upper and lower lateral cartilages have sufficient structural stability to resist conformational changes resulting from air pressure changes. When either the skeletal or the soft tissue component is congenitally

deficient or has been compromised by surgery or trauma, the patient experiences a conformation change of the valves during inspiration, with resultant change in the airflow and/or pressure in the nasal airway. Normally, the upper lateral cartilages move, change shape, partially collapse and/or change nasal airway pressure with all ventilatory flow rates. Thus, even normal nasal valves are affected by respiration. However, a patient with dynamic nasal valve dysfunction may have a nasal airway walls that inadequately resist the pressure changes and restrict airflow even during normal nasal breathing.

[0013] Inadequate nasal valve structural strength, stiffness or conformation can be a consequence of previous surgery, trauma, aging, or primary weakness of the upper lateral cartilage and is often symptomatic and debilitating. As many as 13% of the patients with chronic nasal obstruction have some degree of nasal valve collapse. Of these patients, 88% have unilateral collapse.

[0014] Poor nasal breathing and/or nasal congestion has profound effects on a person's health and quality of life, which can be measured by validated questionnaires such as the NOSE score, as described in Stewart M G, Witsell D L, Smith T L, Weaver E M, Yueh B, Hannley M T. Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale. Otolaryngol Head Neck Surg 2004; 130:157-63.

[0015] Causes of inadequate nasal airflow and the structure of the nasal valve inadequacy can be clinically detected by direct visualization (preferably with minimal disturbance so as not to alter the structure by visualizing) or endoscopic examination. Alternatively, CT, MRI, ultrasound or other non-invasive imaging technologies may be employed. One method of evaluating the potential improvement in nasal airflow from widening the nasal valve area nasal valve obstruction is the cottle test, which involves gently pulling the skin of a patient's cheek laterally away from the nose with two fingers, thereby opening the internal nasal valve.

[0016] Existing methods of correcting nasal valve inadequacy include surgically repositioning the upper lateral cartilage or adding structural grafts to support the lateral wall of the nose. Surgical structural enhancement of the valve can include the use of cartilage grafts and grafts made from a number of materials. The most frequent methods surgically correct internal nasal valve collapse and involve the use of spreader grafts placed between the upper lateral cartilage

and septum. Alternately, stents, spreaders or other devices may be implanted to reposition the ULC. Invasive surgical and implant solutions carry substantial risk and discomfort.

[0017] External (non-implanted) nasal dilators which are placed temporarily and removed by the patient are also available. Such external devices are possibly placed on the outside surface of the nose such as the "Breathe Right" strips as shown for example in U.S. Pat. No. 5,533,499 to Johnson or similar devices taught by U.S. Pat. No. 7,114,495 to Lockwood. Other devices may be temporarily placed in the nasal cavity (but not implanted in the nose), such as those taught in U.S. Pat. No. 7,055,523 to Brown, and U.S. Pat. No. 6,978,781 to Jordan. However, such devices can be uncomfortable, unsightly, and require the patient to remove and replace the device on a periodic basis. These devices can cause skin irritation.

[0018] Poor nasal airflow can also occur in people with a structurally normal nasal and/or nasal valve anatomy, as well as a normal nasal passage cross-sectional area. The strength, structure and resistance to collapse of the nasal passage can also be normal in people with poor nasal airflow. People can have poor nasal airflow from other causes, including deviated septum, allergic rhinitis, non-allergic rhinitis, turbinate hyperplasia, nasal tip ptosis, and nasal polyposis. Whatever the cause, the tissues of the nasal valves are intimately involved in nasal airflow and nasal airflow inadequacy. Thus, there remains an unmet need in the art for non-invasive and minimally invasive methods and devices to improve nasal airflow.

SUMMARY

[0019] Embodiments of the present application are directed to devices, systems and methods for treating nasal airways. Such embodiments may be utilized to improve breathing by decreasing airflow resistance and/or improving nasal airflow or perceived airflow resistance in the nasal airways. For example, the devices, systems and methods described herein may be utilized to reshape, remodel, strengthen, or change the properties of the tissues of the nose, including, but not limited to the skin, muscle, mucosa, submucosa and cartilage in the area of the nasal valves.

[0020] According to one aspect, a device for treating a patient's nasal airway is provided. In one embodiment, the device comprises an energy delivery element sized to be inserted into a nose or to be delivered external to a nose. The energy delivery element is configured to deliver energy to tissues within the nose and to reshape a region of the nose to a new conformation.

[0021] According to one embodiment, a device for treating a patient's nasal airway comprises an elongate shaft having a proximal end and a distal end. The device further comprises a handle at the proximal end of the elongate shaft. The device also comprises a treatment element at the distal end of the elongate shaft. The treatment element is sized to be inserted into the nasal airway or to be delivered external to a nose. The treatment element is configured to reshape a region of the nose to a new conformation and comprises an electrode configured to deliver radiofrequency (RF) energy to the nasal tissue.

[0022] Other embodiments of devices for treating a patient's nasal airway include devices that apply other types of treatment. For example, a treatment device may apply energy in the form selected from the group consisting of ultrasound, quantic molecular resonance, microwave, heat, cold, radiofrequency, electrical, light and laser. The treatment device may also be configured to inject a polymerizing liquid or to deliver a cauterizing agent to nasal tissue. Other embodiments are described below.

[0023] The devices described herein may be configured to be positioned internally within the nose, external to the nose, or both. Certain embodiments are configured to be delivered into one nostril, and other embodiments are configured to be delivered into both nostrils. In some embodiments the device may comprise a reshaping element having a shape configured to alter a conformation of a region of the nose to a new conformation. For embodiments utilizing an energy delivery element, the reshaping element may be a separate element from the energy delivery element, or the energy delivery element and the reshaping element may be part of the same element. The energy delivery element and/or reshaping element in one embodiment may have a convex shape to create a concavity in nasal tissue.

[0024] In embodiments utilizing energy delivery, a handle may be provided comprising a button or other input control to active 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, external to the nose or both. For example, when using 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 surfaces are positioned on opposite sides of nasal tissue.

[0025] Furthermore, in embodiments utilizing energy delivery, the reshaping element may incorporate features designed to assist location of the device in the nose as well as protection of tissue around the treatment area.

[0026] The device of one energy delivery embodiment may comprise an adaptor configured to be connected to an energy source, such as an RF energy source. The device may also comprise a control system configured to control the characteristics of energy applied to tissue. A thermocouple or other sensor may be provided to measure a temperature near tissue or other tissue or device parameter.

[0027] 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 an energy source, such as an RF energy source. Another component may be a control system for controlling the energy source and/or treatment device. In another embodiment, the device or 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 device that may be used pre-treatment to determine the optimal device and positioning and/or other parameters for using the device to be treat to the nasal airway.

[0028] According to another aspect, a method of treating a patient's nasal airway is provided. In one embodiment, the method comprises alerting a structure, shape or conformation of one or more nasal structures in an area of a nasal valve by applying a treatment sufficient to modify, by reshaping, tissue at or adjacent to the nasal valve.

[0029] According to one embodiment, a method of treating a patient's nasal airway comprises positioning a treatment element within the nasal airway adjacent to nasal tissue to be treated. The treatment element comprises one or more electrodes, such as described above and in further detail below. The method further comprises deforming the nasal tissue into a desired shape by pressing a surface of the treatment element against the nasal tissue to be treated. The method further comprises delivering radiofrequency (RF) energy to the one or more electrodes to locally heat the nasal tissue, wherein delivering RF energy while deforming the nasal tissue causes the nasal tissue to change shape. The method also comprises removing the treatment element from the nasal airway.

[0030] The methods, devices and systems described herein may be used to reshape tissue without a surgical incision or implant. In certain embodiments, the reshaping of tissue may be accomplished by ablating tissue. In other embodiments, the reshaping of tissue is accomplished without ablation of tissue. In one embodiment, a treatment element is positioned within a nasal passageway. The treatment element may be used to simultaneously mechanically alter the shape of the internal or external nasal valve and apply treatment to tissue of the nose. The treatment applied may comprise modifying a nasal structure in a manner that increases a volumetric airflow rate of air flowing from an exterior of the patient's body into the patient's nasopharynx without changing a shape of an internal nasal valve, said modifying comprising modifying a mechanical property of at least one nasal valve. A positioning element may be used to determine a desired position of a treatment element before the treatment element is delivered to the nasal tissue.

[0031] The treatment may involve delivering energy in the form selected from the group selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser. The nasal tissue to be treated may be cooled prior to, during or after delivering energy. Delivering energy may comprise measuring a temperature near nasal tissue to be treated, and adjusting a level of energy delivered to the tissue. When RF or other types of energy are used, the energy may be delivered to at least one of the nasal valve, tissue near the nasal valve, or the upper lateral cartilage of tissue. For example, RF energy or other energy may be delivered to the one or more electrodes for about 15 seconds to about 1 minute. RF energy or other energy may be delivered to heat an area of tissue to a temperature of about 50 degrees C. to about 70 degrees C.

[0032] Other methods not utilizing energy delivery include injecting a polymerizing liquid, delivering a cauterizing agent, or other embodiments described below.

[0033] Energy or treatment may be delivered for a sufficient period of time or in a sufficient quantity to cause a desired effect. For example, the treatment may cause stress relaxation in the nasal tissue without weakening the tissue. The treatment may also be applied to injure a tissue to be re-shaped.

[0034] In another aspect, a method of treating a patient's nasal airway may involve: advancing a treatment element of a treatment device into an incision in mucosal tissue of the nasal airway to

contact submucosal tissue of the nasal airway, delivering an energy based therapy to the submucosal tissue through the treatment element to reshape, remodel, strengthen and/or change a property of the submucosal tissue; and removing the treatment element from the nasal airway. Optionally, the method may also involve forming the incision in the mucosal tissue, using the treatment device. For example, forming the incision may involve cutting the mucosal tissue with a cutting edge of the treatment device. Alternatively, the incision may be formed during another procedure or may be formed by a separate cutting device as part of the same procedure.

[0035] In various embodiments, the energy delivered may be ultrasound, microwave, heat, radiofrequency, electrical, light, laser or quantic molecular resonance energy. In one alternative embodiment, energy may be removed from tissues using cryotherapy. Various submucosal tissues that may be treated include upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and/or swell bodies on a floor of the nasal cavity.

[0036] Optionally, the method may further include applying force to the submucosal tissue with the treatment element before, during and/or after delivering the energy based therapy to deform the submucosal tissue. In some embodiments, a tissue contacting surface of the treatment element has a shape convex, concave or flat shape.

[0037] In another aspect, a method of treating a patient's nasal airway may involve: adjusting a shape of a nasal airway treatment device; contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway; delivering an energy based therapy to the mucosal tissue and/or an underlying tissue beneath the mucosal tissue, using the treatment element; and removing the treatment element from the nasal airway. Adjusting the shape may involve shaping the treatment element to have a convex treatment surface, a concave treatment surface or a flat surface, or adjusting a height of at least one electrode on a treatment surface of the treatment element. In some embodiments, adjusting the height involves adjusting multiple heights of multiple electrodes to form a treatment surface profile.

[0038] In other embodiments, adjusting the shape may involve manipulating a secondary component of the treatment element to increase a surface area of the treatment element. In yet another embodiment, adjusting the shape may involve inflating the treatment element to increase

a surface area of the treatment element. In yet another embodiment, adjusting the shape may involve forming at least one bend in a shaft of the treatment device. In some embodiments, adjusting the shape involves rotating the treatment element relative to a shaft of the treatment device.

[0039] In various embodiments, the treated mucosal tissue may be located in the nasal valve and/or a part of the nasal airway other than an internal nasal valve of the airway, such as the tissues listed above. The method may further involve applying force to the mucosal tissue with the treatment element before, during and/or after delivering the energy based therapy to deform the mucosal tissue. In some embodiments, delivering the energy based therapy may modifies at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue. The treated underlying tissue may include, for example, cartilage, submucosa, muscle, ligament and/or tendon. Optionally, the method may also include cooling the mucosal tissue and/or another tissue in the nasal airway.

[0040] In another aspect, a method of treating a nasal valve of a nose, without using a surgical incision or an implant, to decrease airflow resistance or perceived airflow resistance in a nasal airway, may involve: contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway; delivering an energy based therapy to at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; sensing at least one temperature of at least one of the mucosal tissue or the underlying tissue, using a sensing element on the treatment device; adjusting the delivery of the energy based therapy, based on the temperature; and removing the treatment element from the nasal airway.

[0041] In some embodiments, sensing the temperature involves sensing multiple temperatures with multiple thermocouples located at or near multiple electrode pairs on the treatment element, where each of the multiple thermocouples is located at or near one of the multiple electrode pairs. The method may also include determining an average temperature of at least two of the multiple temperatures, wherein the delivery of the energy based therapy is adjusted based on the average temperature. In some embodiments, adjusting the delivery may involve adjusting delivery to at least one of the electrode pairs separately from at least one other of the electrode pairs.

[0042] In another aspect, a device for modifying at least one property of at least one tissue in a nasal airway may include: a head portion configured for passing through an incision in mucosal tissue to a location between the mucosal tissue and submucosal tissue; a shaft extending from the head portion; and a handle attached to the shaft at an opposite end from the head portion. The head portion may include an energy based therapy delivery member and an incision forming member. The handle may include a housing to hold a power source for providing energy to the energy delivery member.

[0043] In some embodiments, the energy delivery member may include a contact surface with a convex shape configured to at least temporarily create a concavity in the at least one tissue. In some embodiments, the energy delivery member may have a contact surface with flat shape. In some embodiments, the energy delivery member may include multiple flexible sections configured to be manipulated. For example, the flexible sections may include multiple protruding electrodes configured to at least temporarily deform nasal tissue. Such protruding electrodes may include two rows of electrodes, where the energy delivery member comprises a bipolar radio frequency delivery member, and where radio frequency energy travels from one row of electrodes to the other row of electrodes.

[0044] In some embodiments, the housing is configured to hold at least one battery. Some embodiments may include at least one sensor configured to sense at least one of temperature or impedance in nasal tissue. In some embodiments, the sensor(s) may be attached to the device on or near the energy delivery member. The device may also further include a tissue cooling member attached to the device at or near the energy delivery member.

[0045] In one embodiment, the energy delivery member may include at least one electrode pair configured to apply energy to the at least one tissue. The device may also further include at least one thermocouple configured to sense temperature at each electrode pair. Some embodiments may further include a processor to determine an average temperature from multiple temperatures sensed by more the thermocouples. In some embodiments, each of the electrode pairs is adjustable separately from adjustment of any other of the electrode pairs.

[0046] In some embodiments, the energy delivery member is designed to be inserted into the nasal valve angle to apply energy to a swell body. The energy is intended to shrink the size of the swell body. The energy delivery member can be designed to hold a position in the nasal valve

angle to position the electrodes to only treat the area of the swell body located on the medial wall of the nasal valve. The energy delivery member can be designed with the electrodes positioned in such a way as to direct the energy into the submucosa, while minimizing damage to the mucosal tissue and underlying cartilage. The energy delivery member can also be designed to direct the energy into the underlying cartilage to induce a shape change.

BRIEF DESCRIPTION OF DRAWINGS

[0047] Certain preferred embodiments and modifications thereof will become apparent to those skilled in the art from the detailed description below having reference to the figures that follow.

[0048] FIG. 1 depicts an illustration of bone and cartilage structures of a human nose.

[0049] FIG. 2A illustrates a cross-sectional view illustrating tissues and structures of a human nose.

[0050] FIG. 2B shows a detailed cross-sectional view illustrating a detailed section of the structures of FIG. 2A.

[0051] FIG. 2C illustrates a view of the nostrils illustrating tissues and structures of a human nose.

[0052] FIG. 3 depicts a schematic illustration of a nasal valve re-shaping treatment device.

[0053] FIG. 4A is a perspective illustration of an embodiment of a treatment element shape.

[0054] FIG. 4B depicts a perspective illustration of another embodiment of a treatment element shape.

[0055] FIG. 4C shows a perspective illustration of another embodiment of a treatment element shape.

[0056] FIG. 4D depicts a cross-sectional view of a treatment device comprising a plurality of microneedles puncturing tissue in order to apply treatment at a desired tissue depth.

[0057] FIG. 5A illustrates one embodiment of a clamp-type nasal valve treatment device.

[0058] FIG. 5B illustrates another embodiment of a clamp-type nasal valve treatment device.

[0059] FIG. 6 depicts a partially-transparent perspective view showing a stent implanted in a nose.

[0060] FIG. 7 depicts a perspective view illustrating an energy delivery balloon being inserted into a nose.

[0061] FIGS. 8A-8J depict embodiments of various electrode arrangements for applying energy to the nasal valve area.

[0062] FIGS. 9A and 9B illustrate embodiments of devices for applying energy to the nasal valve area using a monopolar electrode.

[0063] FIGS. 10A and 10B illustrate an embodiment of a device for applying energy to the nasal valve area using a monopolar electrode and an external mold.

[0064] FIGS. 11A and 11B illustrate embodiments of devices for applying energy to the nasal valve area using electrode(s) and a counter-traction element.

[0065] FIGS. 12A and 12B illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously.

[0066] FIGS. 13A-13E illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously, having a mold or counter-traction element for engaging the nose externally.

[0067] FIGS. 14A and 14B illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously, having separate external molds.

[0068] FIGS. 15A-15C illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously, having separate counter-traction elements.

[0069] FIG. 16 shows an embodiment of a system comprising a device for applying energy to the nasal valve area with an external electrode and a separate internal mold.

[0070] FIGS. 17A and 17B illustrate an embodiment of a device for applying energy to the nasal valve area comprising an external electrode and an internal mold.

[0071] FIG. 18 shows an embodiment of a device for applying energy to the nasal valve area comprising an array of non-penetrating electrodes.

[0072] FIGS. 19A and 19B illustrate an embodiment of a device for applying energy to the nasal valve area configured for use in only one nostril.

[0073] FIGS. 20A and 20B illustrate an embodiment of a device for applying energy to the nasal valve area configured for use in either nostril.

[0074] FIGS. 21A and 21B illustrate an embodiment of a device for applying energy to the nasal valve area having a symmetrical shape.

[0075] FIGS. 22A-22G illustrate an embodiment of a device for applying energy to the nasal valve area using a monopolar electrode.

[0076] FIGS. 23A-23G illustrate an embodiment of a device for applying energy to the nasal valve area using an array of needle electrodes.

[0077] FIG. 24A depicts a cross-section of tissue at the nasal valve.

[0078] FIG. 24B depicts heat effects of RF treatment of tissue at the nasal valve.

[0079] FIGS. 25A and 25B illustrate embodiments of devices for applying energy to the nasal valve area incorporating cooling systems.

[0080] FIG. 26 shows an embodiment of a device for applying energy to the nasal valve area incorporating a heat pipe.

[0081] FIG. 27 depicts an embodiment of a device for applying energy to the nasal valve area incorporating heat pipes.

[0082] FIGS. 28A-28E depict embodiments of differential cooling mechanisms.

[0083] FIG. 29 shows an embodiment of a system comprising a device for applying energy to the nasal valve area with electrode needles and a separate cooling mechanism.

[0084] FIG. 30A-30D shows an embodiment of a method for applying energy to the nasal valve area using.

[0085] FIG. 31 illustrates an embodiment of a nasal valve treatment device.

[0086] FIG. 32A illustrates an embodiment of a nasal valve treatment device comprising an electrode array.

[0087] FIG. 32B illustrates an embodiment of a nasal valve treatment device comprising an electrode array arranged in a number of surface profiles.

[0088] FIG. 33 illustrates an embodiment of a nasal valve treatment device comprising a first treatment element and a second treatment element.

[0089] FIG. 34 illustrates an embodiment of a nasal valve treatment device comprising a head section that is offset relative to a shaft section of the device.

[0090] FIG. 35 illustrates an embodiment of a nasal valve treatment device comprising a head section adapted to be at an angle relative to a shaft section of the device.

[0091] FIG. 36 depicts a cross-section of tissue at the nasal valve.

[0092] FIG. 37 is a diagram illustrating a cross-section of tissue at the nasal valve showing a number of target anatomies.

[0093] FIGS. 38A and 38B are frontal see-through and sagittal cross-section illustrations, respectively, of a human head, illustrating nasal and upper airway anatomy, includingthe superior turbinate, the middle turbinate, and the inferior turbinate.

[0094] FIG. 39 is a block diagram depicting an array of electrodes of a nasal treatment device arranged in a multi-channel configuration.

[0095] FIG. 40 is a block diagram depicting an electrode array arranged in a multiplexed configuration allowing pairing of any of the positive electrodes to any of the negative electrodes to form a complete circuit.

[0096] FIG. 41 is a block diagram depicting an electrode array arranged such that each electrode pair of the array of electrodes may have its own individual subsystem.

[0097] FIG. 42A is a block diagram depicting an electrode array in which temperature readings may be the average of three adjacent thermocouples.

[0098] FIG. 42B is a block diagram depicting an electrode array in which temperature reading may be the average of four adjacent thermocouples.

[0099] FIG. 43 is a block diagram depicting an array of electrodes of a nasal treatment device as depicted in FIG. 39, in which the positive electrodes may share a common negative electrode.

[0100] FIG. 44 is a block diagram depicting an array of electrodes of a nasal treatment device as depicted in FIG. 40, in which the positive electrodes may share a common negative electrode.

[0101] FIG. 45 illustrates an embodiment of a device for applying energy into an incision in the nasal valve area using an array of electrodes.

[0102] FIG. 46A illustrates an embodiment of a device for applying energy into an incision in the nasal valve area directly over a target tissue using an array of electrodes.

[0103] FIG. 46B illustrates an embodiment of a device for applying energy into an incision in the nasal valve area offset from a target tissue using an array of electrodes.

[0104] FIG. 47 illustrates an embodiment of a device for creating an incision in the nasal valve area and applying energy into the incision using an array of electrodes.

DETAILED DESCRIPTION

[0105] The following disclosure provides embodiments of systems and methods for improving breathing by decreasing airflow resistance or perceived airflow resistance at or near a site of an internal or external nasal valve. Such embodiments may include methods and devices for reshaping, remodeling, strengthening, or changing the properties of the tissues of the nose, including, but not limited to the skin, muscle, mucosa, submucosa, and cartilage in the area of the nasal valves.

[0106] While, in some instances, nasal dysfunction can lead to poor airflow, nasal breathing can also be improved in people with normal breathing and/or normal nasal anatomy by decreasing nasal airflow resistance in the nasal valve and associated nasal anatomy. Remodeling or changing the structure of the nasal valve can improve nasal airflow in people with inadequate nasal airflow resulting from causes other than nasal valve dysfunction, such as deviated septum, enlarged turbinates, mucosal swelling, and/or mucous production. The methods and devices described above are generally invasive methods or unsightly devices that a person with normal breathing and/or anatomy may not necessarily be inclined to use or undergo. Thus, there remains an unmet need in the art for non-invasive and minimally invasive methods and devices to decrease nasal airflow resistance or perceived nasal airflow resistance and/or to improve nasal

airflow or perceived nasal airflow and the resulting symptoms or sequella of poor nasal airflow including but not limited to snoring, sleep disordered breathing, perceived nasal congestion and poor quality of life through the change of structures within the nose that form the passageways for airflow. Methods and devices described herein may be used to treat nasal airways without the need for more invasive procedures (e.g., ablation, surgery).

[0107] Nasal breathing can be improved in people with normal breathing and/or normal nasal anatomy by decreasing nasal airflow resistance or perceived nasal airflow resistance in the nasal valve and associated nasal anatomy. Restructuring the shape, conformation, angle, strength, and cross sectional area of the nasal valve may improve nasal airflow. Changing the nasal valve can be performed alone or together with other procedures (e.g., surgical procedures), such as those described above. Such methods and devices can lead to improved nasal airflow, increased volume of nasal airflow in patients with normal or reduced nasal airflow.

[0108] The internal nasal valve area is the narrowest portion of the nasal passage and thus functions as the primary regulator of airflow and resistance. The cross-sectional area of the internal nasal valve area is normally about 55-83 mm.sup.2. As described by the Poiseuille law, airflow through the nose is proportional to the fourth power of the radius of the narrowest portion of the nasal passageway. Thus, changes as small as 1 mm in the size of the nasal valve have an exponential effect on airflow and resistance through the nasal cavity and the entire respiratory system.

[0109] FIGS. 1 and 2A-C illustrate anatomical elements of a human nose. The lower lateral cartilage (LLC) includes an external component referred to as the lateral crus and an internal component referred to as the medial crus. The medial crus and septal nasal cartilage create a nasal septum that separates the left and right nostrils. Upper lateral cartilage lies between the lower lateral cartilages and the nasal bone. The left ULC is separated from the right ULC by the septal cartilage extending down the bridge of the nose. The opposing edges of the LLC and ULC may move relative to one another. Disposed between the opposing edges is an accessory nasal cartilage. The septal nasal cartilage and the ULC form an angle (.THETA.) called the nasal valve angle.

[0110] FIG. 2B illustrates a detailed cross-section of a segment of nose tissue in the area of the intersection of the ULC and the LLC. As shown in the detailed view of FIG. 2A, both inner

and outer surfaces of the nasal cartilage are covered with soft tissue including mucosa, sub-mucosa and skin.

[0111] FIG. 2C illustrates a view of the nose as seen from the nostrils. FIG. 2 depicts the nasal valve 1 shown between the septum 2 and the Upper Lateral Cartilage 3. FIG. 2A also depicts the position of the turbinate 4.

[0112] The internal nasal valve area of the nasal airway passage can be visualized prior to and/or during any treatment by any suitable method, including but not limited to direct visualization, endoscopic visualization, visualization by the use of a speculum, transillumination, ultrasound, MRI, x-ray or any other method. In some embodiments, treatments of the nasal valve area as described herein may be performed in conjunction with or following another procedure (e.g., a surgical procedure such as surgically repairing a deviated septum). In such embodiments, the nasal valve area may be visualized and accessed during surgery. In some embodiments, it may be desirable to visualize the internal nasal valve with minimum disturbance, so as to avoid incorrect assessments due to altering the shape of the nasal valve during visualization. In some embodiments, visualization elements may be incorporated into or combined with treatment devices configured for treating internal and/or external nasal valves.

[0113] Airflow through the nasal passage can be measured prior to and/or during any treatment by any suitable method, including, but not limited to, a nasal cannula connected to a pressure measurement system, rhinomanometry, and rhino-hygrometer. Nasal airflow and resistance can also be evaluated by subjective evaluation before and after a manipulation to increase the cross-sectional area of the nasal passage, such as the Cottle maneuver. In some embodiments, it may be desirable to measure nasal airflow and/or resistance prior to, during and/or after a procedure.

[0114] The internal nasal valve area of the nasal airway passage can be accessed through the nares. In some embodiments, one or more devices may be used to pull the tip of the nose caudally and increase the diameter of the nares in order to further facilitate access to the internal nasal valve for treatment. Such devices may include speculum type devices and retractors. In other embodiments, access to the internal nasal valve may also be achieved endoscopically via the nares, or via the mouth and throat. In some embodiments, visualization devices may be incorporated or combined with treatment devices for treating internal and/or external nasal

valves. These and any other access and/or visualization devices may be used with any of the methods and devices below.

[0115] During inhalation, airflow through the nostrils creates an inward pressure at the junction between the upper and lower cartilages. This pressure may be expressed as a function of nasal resistance which may be estimated as 10 centimeters of water per one liter per second in congested patients (see "The Four Components of the Nasal Valve" by Cole, published in the American Journal of Rhinology, pages 107-110, 2003). In response to these low pressures relative to the environment outside the nose, a normal, weakened and/or structurally inadequate nasal valve may move inwardly with the junction between the upper and lower cartilages acting as a hinge point for the inward deflection. Furthermore, a small increase in area through which air flows can greatly decrease the pressure differential in these structures resulting in less inward movement of the internal nasal valve structures. Increasing the cross sectional area of the nasal valve area thus has the beneficial effects of decreasing nasal airflow resistance and decreasing the amount and likelihood of inward movement of the nasal valve structures during inspiration.

[0116] Some embodiments below provide apparatus and methods for increasing the area of the opening at the nasal valve and/or treating nasal valve insufficiency by modifying the structure and/or structural properties of tissues at or adjacent to the internal and/or external nasal valve. Other embodiments below provide apparatus and methods for treating nasal valve insufficiency and/or increasing the area of the opening at nasal valve by re-shaping structures within and/or adjacent to an internal and/or external nasal valve to achieve a more optimum shape and minimize or remove airflow obstructions. Still other embodiments combine the two approaches of re-shaping and modifying tissue and structures of and adjacent to the internal and/or external nasal valves. Still other embodiments provide apparatus and methods for increasing the area of the opening at the nasal valve and treating nasal obstruction resulting from causes other than nasal valve restriction or insufficiency by improving the structure or function of the nasal valve tissue to increase airflow. Still other embodiments below provide apparatus and methods for decreasing airflow resistance in a structurally normal nasal valve and/or increasing the area of the opening at nasal valve by re-shaping structures within and/or adjacent to an internal and/or external nasal valve to achieve a more optimum shape and minimize or remove airflow obstructions. For example, patients having a normal nasal valve anatomy may

still benefit from the devices and treatments described herein, as improvement in the nasal valve structure and/or increasing the area of the opening at the nasal valve may improve breathing problems caused by other conditions. Still other embodiments provide for structural changes in the nasal cavity and airway that improve the relative positions of the structures of the nasal cavity to improve nasal breathing.

[0117] In some embodiments, airflow restrictions to the internal nasal valve may be the result of a smaller-than-optimal internal nasal valve angle, shown as .theta. in FIG. 2. An internal nasal valve angle (i.e. the angle formed between the caudal border of the ULC and the nasal septum) of less than the normally optimal range of between about 10 degrees-15 degrees can result in airflow restrictions. Thus, in some embodiments, treatments may be designed to re-shape structures at or adjacent to the internal nasal valve in order to increase the internal nasal valve angle sufficiently that after such treatments, the nasal valve angle falls within the optimal range of 10-15 degrees. In some embodiments, the internal valve angle may also be increased to be greater than 15 degrees.

[0118] In some embodiments, airflow restrictions to the internal nasal valve may be the result of a smaller-than-optimal area of the internal nasal valve. An internal nasal valve with a less than optimal area can result in airflow restrictions. Thus, in some embodiments, treatments may be designed to re-shape structures at or adjacent to the internal nasal valve in order to increase the internal nasal valve angle sufficiently that after such treatments, the area of the nasal valve falls within an optimal range. In some embodiments, increasing the area of the opening at the nasal valve without increasing the angle of the nasal valve may improve airflow. In some embodiments, increasing the angle of the nasal valve without increasing the area of the opening at the nasal valve may improve airflow. In some embodiments, both the opening at the area of the nasal valve and the angle of the nasal valve may be increased to improve airflow.

[0119] In some embodiments, nasal airflow can be increased in the presence of normal nasal valve anatomy and/or normal or enlarged nasal valve angle or area.

[0120] With reference to FIG. 2A, in some embodiments, the internal valve angle .theta. or area may be increased by mechanically pressing laterally outwards against the internal lateral nasal wall. In some embodiments, this outward pressing may be performed by an inflatable balloon (such as those discussed below with reference to FIGS. 4A-4B) which may be positioned

between the upper portion of the nasal septum 20 and the outer lateral wall 22 and then inflated, pressing against the lateral nasal wall until the nasal valve angle reaches a desired size. Similarly, other mechanical devices such as spreaders or retractors (such as those discussed below with reference to FIGS. 5A & 5B) or molds may be used. In alternative embodiments, short-term removable implants may be used to re-shape the nasal valve. Some examples of short-term implants may include stents, molds or plugs. In further alternative embodiments, external re-shaping elements, such as adhesive strips or face masks may be used to modify the shape of a nasal valve. In some embodiments, energy application or other treatments as described below may be applied to substantially fix the re-shaped tissue in a desired conformational shape before, during or after applying a mechanical re-shaping force (e.g., with the balloon, mechanical devices, molds, short-term implants, or external re-shaping elements described above or any of the mechanical devices described below).

[0121]] In another embodiment, a re-shaping device may be used to expand the diameter of the nasal passage at the site of the internal or external nasal valve. The expansion device can be a balloon, user controlled mechanical device, self expanding mechanical device, fixed shape device or any combination thereof. The expansion can increase the diameter over the normal range in order for the diameter to remain expanded after removal of the device and healing of the tissue.

[0122] In some embodiments, a re-shaping device may be used to conformationally change the structure of the internal or external nasal valve anatomy to allow greater airflow without necessarily expanding the diameter of the nasal passage.

[0123] In some embodiments, a re-shaping or remodeling device can be used to conformationally change the structure of areas of the internal nasal valve other than the nasal valve that causes the cross sectional or three dimensional structure of the nasal airway to assume a shape less restrictive to airflow without widening the nasal valve angle.

[0124] In some embodiments, the tissue of the internal and/or external nasal valve and/or surrounding tissues may be strengthened or otherwise modified to resist a conformational change in response to the negative pressure of inspiration. In some embodiments, this strengthening may be performed by applying treatments selected to change mechanical or structural properties of

the treated tissue. In some embodiments, such treatments may include the application of energy to selected regions of nasal valve and/or surrounding tissues.

[0125] 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, or others. In alternative embodiments, the nasal valve and/or surrounding tissues may be strengthened through the application of cryogenic therapy, or through the injection or application of bulking agents, glues, polymers, collagen and/or other allogenic or autogenic tissues, or growth agents.

[0126] Any one or more of the above energy-application mechanisms may also be used to re-shape, remodel, or change mechanical or physiologic properties of structures of a nasal valve or surrounding tissues. For example, in some embodiments, energy may be applied to a targeted region of tissue adjacent a nasal valve such that the tissue modification results in a tightening, shrinking or enlarging of such targeted tissues resulting in a change of shape. In some such embodiments, re-shaping of a nasal valve section may be achieved by applying energy without necessarily applying a mechanical re-shaping force. For example energy can be used to selectively shrink tissue in specific locations of the nasal airway that will lead to a controlled conformational change.

[0127] In alternative embodiments, strengthening and/or conformation change (i.e., re-shaping) of nasal valve tissue to reduce negative pressure during inspiration may include modification of tissue growth and/or the healing and fibrogenic process. For example, in some embodiments energy may be applied to a targeted tissue in the region of the internal nasal valve in such a way that the healing process causes a change to the shape of the nasal valve and/or a change in the structural properties of the tissue. In some embodiments, such targeted energy application and subsequent healing may be further controlled through the use of temporary implants or re-shaping devices (e.g. internal stents or molds, or external adhesive strips).

[0128] 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. 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 (as illustrated for example in FIG. 4D).

[0129] In some embodiments, energy may be delivered into the submucosal tissue to cause a conformational change and/or a change in the physical properties 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.

[0130] FIG. 3 illustrates an embodiment of a nasal valve treatment device 30. The device 30 comprises a treatment element 32 which may be configured to be placed inside the nasal cavity, nasal passage, and/or nasal airway 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.

[0131] 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.

[0132] 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, WiFi (or other 802.11 standard wireless protocol), infrared or any other wired or wireless communication method.

[0133] 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.

[0134] The treatment system may also comprise a power supply 44. In some embodiments, a power supply may be integrally incorporated within the handle section 34. In alternative embodiments, a 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, a power supply 44 may include a battery or other electrical energy storage or energy generation device. In other embodiments, a power supply 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. Alternatively, the power supply 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.

[0135] 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, including the internal and external nasal valves. 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. In some embodiments, the shape of

a fixed-shape treatment element may be substantially in a shape to be imparted to the cartilage or other structures of the internal or external nasal valve area.

[0136] In some embodiments, as shown for example in FIG. 3, 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. 4A-4D. In some embodiments, an ellipsoid balloon as shown in FIG. 4A may have an asymmetrical shape. In alternative embodiments, the treatment element 32 may have an asymmetrical "egg-shape" with a large-diameter proximal end and a smaller-diameter distal end. In some embodiments, the element 32 can be shaped so as to impart a shape to the tissue treated that is conducive to optimal nasal airflow. Any suitable solid or expandable medical balloon material and construction available to the skilled artisan may be used.

[0137] FIG. 4B illustrates an embodiment of a treatment element configured to deliver energy to an interior of a nasal valve. In some embodiments, the treatment element of FIG. 4B also includes an expandable balloon.

[0138] FIG. 4C illustrates an embodiment of a bifurcated treatment element 70 having 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 & 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. The shape modification of elements 72, 74 can be accomplished pre-procedure or during the procedure and can be either fixed after modification or capable of continuous modification.

[0139] In some embodiments, a nasal valve treatment system may also comprise a re-shaping device configured to mechanically alter a shape of soft tissue and/or cartilage in a region of a nasal valve in order to impart a desired shape and mechanical properties to the tissue of the walls of the nasal airway. In some embodiments the re-shaping device may be configured to re-shape the internal and/or external nasal valve into a shape that improves the patency of one or both nasal valve sections at rest and during inspiration and/or expiration. In some embodiments, the reshaping device may comprise balloons, stents, mechanical devices, molds, external nasal strips, spreader forceps or any other suitable structure. In some embodiments, a re-shaping device may be integrally formed with the treatment element 32. In alternative embodiments, a re-shaping device may be provided as a separate device which may be used independently of the treatment element 32. As described in more detail below, such re-shaping may be performed before, during or after treatment of the nose tissue with energy, injectable compositions or cryo-therapy.

[0140] With reference to FIGS. 4A-4C, some embodiments of treatment elements 32 may comprise one or more inflatable or expandable sections configured to expand from a collapsed configuration for insertion into the nasal passageway, to an expanded configuration in which some portion of the treatment element 32 contacts and engages an internal surface of a nasal passageway. 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 32.

[0141] In some embodiments, the treatment element 32 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 there of 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.

[0142] In alternative embodiments, the treatment element 32 can act to change the properties of the internal soft tissue of the nasal airway in conjunction with an external treatment device of fixed or variable shape to provide additional force to change the shape of the internal and/or external nasal valve. In some embodiments, an external mold element can be combined with an internal element.

[0143] FIGS. 5A and 5B illustrate re-shaping treatment devices 80 and 90, respectively. The treatment devices 80 and 90 are structured as clamp devices configured to engage a targeted section of the nasal valve with either a clamping force or a spreading force. In some embodiments, the treatment devices of FIGS. 5A and 5B may include energy delivery elements (of any type described herein) which may be powered by a fluid lumen or cable 86.

[0144] The treatment device of FIG. 5A includes an outer clamp member 82 and an inner clamp member 84 joined at a hinge point 85. In some embodiments, the outer clamp member 82 may include an outwardly-bent section 86 sized and configured to extend around the bulk of a patient's nose when the inner clamp member may be positioned inside the patient's nose. The inner and outer tissue-engaging tips at the distal ends of the inner and outer clamp members may be configured to impart a desired shape to the internal and/or external nasal valve. In some embodiments, the tissue-engaging tips may be removable to allow for sterilization and/or to allow for tips of a wide range of shapes and sizes to be used with a single clamp handle.

[0145] The treatment device of FIG. 5B includes an outer clamp member 92 and an inner clamp member 94 joined at a hinge point 95. The inner and outer tissue-engaging tips at the distal ends of the inner and outer clamp members may be configured to impart a desired shape to the internal and/or external nasal valve. In the illustrated embodiment, the outer clamp member 92 includes a concave inner surface, and the inner clamp member includes a mating convex inner surface. The shape and dimensions of the mating surfaces may be designed to impart a desired shape to the structures of a patient's nose. In some embodiments, the shape of the mating surfaces may be modified by the operator to impart an optimal configuration to the treated tissue. The shape modification of the mating surfaces can be accomplished pre-procedure or during the procedure and can be either fixed after modification or capable of continuous modification.

[0146] In some embodiments, the tissue-engaging tips may be removable to allow for sterilization and/or to allow for tips of a wide range of shapes and sizes to be used with a single clamp handle.

[0147] In alternative embodiments, the devices of FIGS. 5A and 5B may be used as spreader devices by placing both clamp tips in one nasal valve and separating the handles, thereby separating the distal tips. In alternative embodiments, the handles may be configured to expand in response to a squeezing force. The shapes of the distal tips may be designed to impart a desired shape when used as a spreading device.

[0148] The re-shaping elements of FIGS. 3-5B are generally configured to be used once and removed from a patient's nose 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. An example of such a stent placed within a patient's nose after treatment is shown in FIG. 6. In some embodiments, the stent may be configured to be removed after a therapeutically effective period of time following the treatment. In some embodiments, such a therapeutically effective period of time may be on the order of days, weeks or more.

[0149] In some embodiments, the treatment element 32 may be configured to deliver heat energy to the nasal valve. In such embodiments, the treatment element 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 nasal tissue. In some embodiments, a high-temperature fluid heating element may comprise flow channels which place high-temperature fluids into conductive contact with nasal tissues (e.g. through a membrane wall) without injecting such fluids into the patients 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.

[0150] U.S. Pat. No. 6,551,310 describes embodiments of endoscopic treatment devices configured to ablate tissue at a controlled depth from within a body lumen by applying radio

frequency spectrum energy, non-ionizing ultraviolet radiation, warm fluid or microwave radiation. U.S. Pat. No. 6,451,013 and related applications referenced therein describe devices for ablating tissue at a targeted depth from within a body lumen. Embodiments of laser-treatment elements are described for example in U.S. Pat. No. 4,887,605 among others. U.S. Pat. No. 6,589,235 teaches methods and device for cartilage reshaping by radiofrequency heating. U.S. Pat. No. 7,416,550 also teaches methods and devices for controlling and monitoring shape change in tissues, such as cartilage. The devices described in these and other patents and publications available to the skilled artisan may be adapted for use in treating portions of a nasal valve or adjacent tissue as described herein. U.S. Pat. Nos. 7,416,550, 6,589,235, 6,551,310, 6,451,013 and 4,887,605 are hereby incorporated by reference in their entireties.

[0151] 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. Examples of suitable cryogenic therapy delivery elements are shown and described for example in U.S. Pat. Nos. 6,383,181 and 5,846,235, the entirety of each of which is hereby incorporated by reference.

[0152] 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 32, thereby treating all nasal 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 nasal tissues. In such embodiments, the treatment element 32 may be configured so that energy being delivered to selected regions of the treatment element 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 nasal passageway.

[0153] In some embodiments, the treatment element 32 may be a balloon with energy delivery elements positioned at locations where energy transfer is sufficient or optimal to effect

change in breathing. Such a balloon may be configured to deliver energy while the balloon is in an inflated state, thereby providing a dual effect of repositioning tissue and delivering energy to effect a change the nasal valve. In other embodiments, a balloon may also deliver heat by circulating a fluid of elevated temperature though the balloon during treatment. The balloon can also delivery cryotherapy (e.g. by circulating a low-temperature liquid such as liquid nitrogen) while it is enlarged to increase the nasal valve diameter or otherwise alter the shape of a nasal valve. FIG. 7 illustrates an example of an energy-delivery balloon being inserted into a patient's nose for treatment. 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 valve tissue to a desired depth (as shown for example in FIG. 4D and in other embodiments below).

[0154] 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 tightening sections of the epithelium of the inner surface of the nasal valve. In other embodiments, treatments may be targeted at strengthening soft tissues underlying the epithelium. In further embodiments, treatments may be targeted at strengthening cartilage in the area of the

upper lateral cartilage. In still further embodiments, treatments may be targeted at stimulating or modifying the tissue of muscles of the nose or face in order to dilate the nasal valve.

[0155] 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 in the nasal valve tissue.

[0156] 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 around a nasal valve 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 nose. 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 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.

[0157] In some embodiments, a treatment element may be configured to treat a patient's nasal valve by applying treatment (energy, cryotherapy, or other treatments) from a position outside the patient's nose. For example, in some embodiments, the devices of FIGS. 5A and 5B may be

configured to apply energy from an element positioned outside a patient's nose, such as on the skin. In another embodiment, a device may be placed on the external surface of the nose that would pull skin to effect a change in the nasal airway. Treatment may then be applied to the internal or external nasal tissue to achieve a desired nasal valve function.

[0158] In some embodiments, the device is configured to position tissue to be re-shaped. In some embodiments, the device comprises features and mechanisms to pull, push or position the nasal tissue into a mold for re-shaping. For example, suction, counter traction, or compression between two parts of the device may be used.

[0159] In some embodiments, the treatment device comprises one, two, three, four, or more molds configured to re-shape tissue. The mold or re-shaping 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 a nasal valve 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. The mold is configured to impart a shape to the tissues of the nasal valve area to improve airflow or perceived airflow. The mold is configured to act near the apex of the nasal valve angle, the point at which the upper lateral cartilage meets the cartilage of the nasal septum. It may be desirable to treat in an area near, but not at, the nasal valve so as to avoid post procedure scarring and/or adhesions. This may be accomplished by focusing treatment on the lateral part of the nasal valve angle.

[0160] In some embodiments, the mold or re-shaping element comprises a separate or integrated energy delivery or treatment element (e.g., an electrode such as those described below with respect to FIGS. 8A-8J). The treatment element may be fixed or adjustable in size. For example, the treatment element may be adjusted to better conform to the nasal valve of a patient. In the case of a separate re-shaping element and treatment element, 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 is configured to deliver cooling (discussed in more detail below). In some embodiments, the mold or re-shaping element comprises a balloon configured to reshape and/or deform tissue. A balloon may also be configured to deliver energy such as heat using hot liquid or gas.

Examples of Various Electrode Arrangements

[0161] Described below are embodiments of various treatment devices and, more particularly, electrode arrangements that may be used for applying energy to the nasal valve area. These electrodes may, for example, deliver RF energy to preferentially shape the tissue to provide improved nasal breathing. In some embodiments, one or more electrodes may be used alone or in combination with a tissue shaping device or mold. In other embodiments, one or more electrodes may be integrally formed with a tissue shaping device or mold, so that the electrodes themselves create the shape for the tissue. In some embodiments, the energy delivery devices may utilize alternating current. In some embodiments, the energy delivery devices may utilize direct current. In certain such embodiments, the energy delivery device may comprise a configuration utilizing a grounding pad.

[0162] 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, 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).

[0163] In some embodiments, "mold", "tissue shaper", "re-shaping element" and the like refer to any electrode or non-electrode surface or structure used to shape, configure or deflect tissue during treatment.

[0164] 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 creating a specific shape.

[0165] As shown in FIG. 8A, in some embodiments, bipolar electrodes may be used to deliver energy, with one electrode 202 placed internally in the nasal valve, for example against the upper lateral cartilage, and one electrode 204 placed externally on the outside of the nose. This embodiment may advantageously provide direct current flow through the tissue with no physical trauma from needles (as shown in some embodiments below). As shown in FIG. 8B, 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. In some embodiments, bipolar electrodes 220, 222 may be both placed externally and may be connected to a passive molding element 224 placed inside the nasal valve adjacent to tissue to be treated, as shown in FIG. 8C. This embodiment may advantageously minimize the potential for mucosal damage. In some embodiments, electrodes placed internally may be shaped to function as a mold or may comprise an additional structure that may function as a mold.

[0166] In some embodiments, a monopolar electrode may be used to deliver energy. As shown in FIG. 8D, 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 molding element placed inside the nasal valve 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 mold or may comprise an additional structure that may function as a mold.

[0167] In some embodiments, monopolar transmucosal needles may be used to deliver energy. The needle electrodes 240 may be placed internally, as shown in FIG. 8E penetrating through the mucosa to the cartilage, and 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 molding 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, and penetrate through

to tissue to be treated. Needle configurations may advantageously target the cartilage tissue to be treated specifically. The monopolar transdermal needles may be used in conjunction with an internal molding device (not shown).

[0168] 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 the mucosa to the cartilage to be treated. In some embodiments, the bipolar transmucosal needles may be used in combination with one or more internal molding elements. The one or more molding 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 cartilage tissue to be treated specifically. The transdermal bipolar needles may be utilized in conjunction with an internal molding element.

[0169] As shown in FIG. 8F, in some embodiments, an array of electrodes comprising one, two, or many pairs of bipolar needles 252 are located on a treatment element configured to be placed into contact with the cartilage. An insulator 254 may be disposed between the bipolar needles 252. An insulator may also be utilized on part of the needle's length to allow energy to be delivered only to certain tissue structures, such as cartilage. The electrodes may be placed either internally or transmucosally or they may be placed externally or transdermally. In the embodiment illustrated in FIG. 8F, the insulator 254 may also function as a mold or molding element. In other embodiments (not shown), the array of electrodes is used in conjunction with a separate tissue re-shaping element.

[0170] FIG. 8G illustrates another embodiment of a treatment element comprises one, two or many pairs of bipolar electrodes 260. As opposed to FIG. 8F, where the pairs of electrodes are arranged side-by-side, the embodiment of FIG. 8G arranges the pairs of electrodes along the length of the treatment element. The electrodes of FIG. 8G are also non-penetrating, in contrast to the needles of FIG. 8F. The electrodes 260 may be placed against either the skin, externally, or the mucosa, internally as a means of delivering energy to target tissue such as cartilage.

[0171] 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, the needles or needle pairs of FIG. 8F may be individually controlled to produce an optimal treatment effect. For another example, the separate electrodes of FIGS. 8B and 8C 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 nasal tissue/structures does not allow the entire electrode region of the treatment element to engage the tissue. In such embodiments, the nasal tissue that is in contact with the treatment element may receive sufficient energy to treat the tissue.

[0172] Combinations of the described electrode configurations may also be utilized to deliver energy to tissue to be treated (e.g., by being reshaped). For example, transmucosal needles 264 may be placed internally, penetrating through to the tissue to be treated, and an electrode 266 may be placed externally, as shown in FIG. 8H. This embodiment may advantageously target the cartilage tissue specifically and be biased for mucosal preservation. For another example, transdermal needles 268 may be placed externally and an electrode 270 may be placed internally, as shown in FIG. 8I. This embodiment may advantageously target the cartilage tissue specifically and be biased towards skin preservation. For another example bipolar needle electrodes 272, 274 can be placed both transdermally or externally and transmucosally or internally, as shown in FIG. 8J. This embodiment may advantageously target the cartilage tissue 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.

Examples of Treatment Devices Including Electrodes

[0173] Embodiments of treatment devices incorporating treatment elements such as the electrodes described above are illustrated in FIGS. 9A-21B. The instrument designs described in these embodiments may be used in a device such as the device 30, described above, and in the system of FIG. 3. In some embodiments, the devices provide tissue re-shaping or molding in addition to energy delivery. Applying energy to the nasal valve may require properly positioning the electrode(s) at the nasal valve, deflecting or deforming the tissue into a more functional

shape, 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. Molding and reshaping of the tissues of the nasal valve may allow for non-surgical nasal breathing improvement without the use of implants.

[0174] FIG. 9A depicts a device 300 comprising a single inter-nasal monopolar electrode 301 located at the end of a shaft 302. The shaft is attached to a handle 303. The electrode configuration may be similar to that described with respect to FIG. 8D. FIG. 9B depicts another device 304 comprising 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 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, and in the embodiment illustrated has a convex shape configured to press against and create a concavity in the nasal valve cartilage.

[0175] FIG. 10A depicts a side view of a device 310 comprising a single inter-nasal electrode 312 located at the end of a shaft 314. The shaft is attached to a handle 316. An external mold 318 is attached to the handle 316 and can be moved relative to the electrode shaft 314. The external mold 318 has a curved shape with an inner concave surface that may be moved in order to press against an external surface of a patient's nose to compress tissue between the external mold 318 and the electrode 312. FIG. 10B provides a front view of the device 310.

[0176] FIG. 11A depicts a device 320 comprising a single inter-nasal electrode 322 attached to the end of a shaft 324. The shaft 324 is attached to a handle 326. An internal shaft 328 comprising a tissue-contacting surface is attached to the handle 326. The internal shaft 328 can be moved relative to the electrode shaft 324 and may provide counter-traction and/or positioning. For example, when the electrode 322 is placed against a patient's upper lateral cartilage, the counter-traction element 328 may be pressed against the patient's nasal septum.

[0177] FIG. 11B depicts a device 450 similar to device 320 of FIG. 11A comprising an inter-nasal electrode 451 located at a distal end of a shaft 452 connected to a handle 454. The device 450 further comprises a counter-traction element 456 connected to a handle 458. Like the device 320 depicted in FIG. 11A, the connection 460 between the two handles 454, 458 is such that

squeezing the two handles 454, 458 together causes the electrode 451 and the counter-traction element 456 to move away from each other, spreading the tissue they are contacting.

[0178] FIG. 12A depicts a device 330 comprising a single inter-nasal electrode 332 located at the end of a shaft 334. The shaft 334 is attached to a handle 336. The device 330 comprises another single inter-nasal electrode 338 attached to the end of a shaft 340. The shaft 340 is attached to a handle 342. The device comprises a connection 344 between the two handles 340, 342 that allows simultaneous deformation and treatment of both nostrils.

[0179] FIG. 12B depicts a device 470 similar to device 330 of FIG. 12A comprising a first inter-nasal electrode 472 located at a distal end of a shaft 474 connected to a handle 476. The device 470 comprises a second inter-nasal electrode 478 located at a distal end of a second shaft 480 connected to a second handle 482. The connection 484 between the two handles 476, 482 is such that squeezing the handles 476, 482 together causes the electrodes 472, 478 to move away from one another, spreading any tissue they may be in contact with. The device 470 comprises a ratcheting mechanism 475 between the two handles 476, 482 that allows the relative positions of the electrodes 472, 478 to be locked during treatment.

[0180] FIG. 13A depicts a side view of a device 350 also used for treating two nostrils comprising an inter-nasal electrode 352 attached to the end of a shaft 354. The shaft 354 is attached to a handle 356. As seen in the front view provided in FIG. 13B, the device 350 comprises a second inter-nasal electrode 358. The second inter-nasal electrode 358 is attached to the end of a shaft which is attached to a handle. A connection between the two handles allows simultaneous deformation and treatment of the nostrils. An external mold 366 is attached to the handles. The mold 366 may be moved relative to the electrode shafts 354, 360 and may provide counter-traction (e.g., against the bridge of the nose) and positioning.

[0181] FIGS. 13C-E depicts a device 490 similar to the device 350 shown in FIG. 13A and FIG. 13B. FIGS. 13C and 13D depict side and top views of a device 490 comprising a handle 492. The handle 492 bifurcates into a first shaft 494 with a first inter-nasal electrode 496 located at a distal end of the shaft 494 and a second shaft 498 with a second inter-nasal electrode 500 located at a distal end of the shaft 498. The device 490 comprises a mold 502 configured to provide counter-traction or compression of the bridge of the nose. The mold 502 comprises a handle 504. The connection 506 between the handles 492, 504 is such that squeezing the two

handles 492, 504 causes the electrodes 496, 600 and the mold 502 to be compressed together. FIG. 13E depicts the device 490 being used on a patient. The arrows indicate the directions in which the handles 492, 504 are configured to be squeezed.

[0182] FIG. 14A depicts a front view of a device 370 comprising an inter-nasal electrode 372 attached to the end of a shaft 374 (shown in top view of FIG. 14B). The shaft 374 is attached to a handle 376. The device 370 comprises a second inter-nasal electrode 378 attached to the end of a second shaft 380. The second shaft 380 is attached to a second handle 382. A connection 384 between the two handles 376, 382 may allow simultaneous deformation and treatment of the nostrils. External molds 386, 388 are attached to the handles and can be moved relative to each electrode shaft 374, 380. The molds 386, 388 may provide counter-traction, compression of tissue, positioning, and external tissue deformation.

[0183] FIG. 15A depicts a front view of device 390 comprising a first inter-nasal electrode 392 and a second inter-nasal electrode 398. As shown in the side view of FIG. 15B, the device 390 comprises a first inter-nasal electrode 392 attached to the end of a shaft 394. The shaft is attached to a handle 396. A second inter-nasal electrode 398 is attached to the end of a second shaft 400, as shown in the top view of FIG. 15C. The second shaft 400 is attached to a second handle 402. A connection 404 between the two handles 396, 402 may allow simultaneous deformation and treatment of the nostrils. Additional internal shafts 406, 408 comprise tissue-contacting surfaces and are attached to the handles 396,402. The internal shafts 406, 408 may be moved relative to each electrode shaft 394, 400 (shown in FIG. 15B) and may provide counter-traction and positioning.

[0184] FIG. 16 depicts a system 410 comprising a first device having an extra-nasal electrode 412 along a concave surface configured to positioned against an external surface of a patient's nose, the electrode 412 being attached to the end of a shaft 414. The shaft 414 is attached to a handle 416. A separate device 417 comprising an internal tissue mold 418 is attached to a shaft 420. The internal tissue mold is configured to be positioned inside the patient's nasal valve. The shaft 420 is attached to a handle 422. Each handle 422, 416 may be manipulated individually and may apply energy and deformation to create a desired tissue effect.

[0185] FIG. 17A depicts a side view of a device 430 comprising an extra-nasal electrode 431 attached to the end of a shaft 432. The shaft 432 is attached to a handle 434. The device 430 also

comprises an internal tissue mold 436 attached to a shaft 438 which is attached to a handle 440. The handles 434, 440 are attached together and may be moved relative to each other to simultaneously deliver energy and deform tissue. FIG. 17B depicts a front view of the device 430.

[0186] FIG. 18 depicts a device 390 comprising pairs of bipolar electrodes 392 located at the distal end of a shaft 394. The electrodes may be similar to the electrodes described with respect to the electrode configuration of FIG. 8G in that they are non-penetrating. The shaft 394 is connected to a handle 398 which comprises a button configured to activate and deactivate the electrodes. As stated above, the device 380 may either comprise a generator or be connected to a remote generator.

[0187] FIG. 19A depicts the treatment element 502 of a treatment device (e.g., device 30). The treatment element 502 of the device comprises a monopolar electrode 504. A cross-section of the treatment element 502 is shown in FIG. 19B. It comprises an asymmetrical shape and has a convex surface where the electrode is positioned configured to conform to only one of a patient's nostrils (for example, a patient's right nostril). More specifically, the convex surface is configured such that when inserted into the particular nostril, the convex surface would be located adjacent the upper lateral cartilage of the nasal valve of that nostril. The treatment element 502 further comprises a light 506 configured to illuminate the treatment area. For example an LED or a visible laser may be used. The visible laser may experience less diffusion in the tissue. Furthermore, the light 506 can be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The user can then use the light to properly position the device in the desired location. Because the electrode 504 is not centered on the treatment element 502 of the device, a separate device having a mirror-image configuration may be required to treat the other nostril.

[0188] FIG. 20A depicts the treatment element 512 of a treatment device (e.g., device 30). The treatment element 512 of the device comprises two monopolar electrodes 514, 516 provided side-by-side on a convex surface of the treatment element. The cross section of the treatment element 512, shown in FIG. 20B, is configured to conform to the shape either nostril, depending on which side of the device (and accordingly, which of electrode 514 or 516) is placed in contact with the patient's nasal valve. Comprising two monopolar electrodes 514, 516 may allow the

same treatment element 512 to be used for treatment in both nostrils, and each electrode may be activated separately depending on which side needs to be utilized. The treatment element 512 also comprises two lights 518, 520 (e.g., LEDs, lasers) configured to illuminate the treatment area for both nostrils. One or both of the lights 518, 520 can also be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The user can then use the light to properly position the device in the desired location.

[0189] FIG. 21A depicts a treatment element 522 of a treatment device (e.g., device 30). The tip 522 of the device comprises a monopolar electrode 524. The tip 522 comprises a symmetrical cross-section as shown in FIG. 21B. The tip 522 comprises a light 526 (e.g., LED) configured to illuminate the treatment area. The light 526 can also be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The symmetrical tip allows the user to treat either left or right nostril. The user can then use the light to properly position the device in the desired location.

[0190] FIGS. 22A-G depict a treatment device 530 similar to the embodiments of FIGS. 8D, 9A, and 9B. FIGS. 22A and 22F provide perspective views of the device 530. The device 530 comprises a treatment element 532 at its distal tip 534. The treatment element 532 comprises an electrode 535. The body of the treatment element 532, itself, may comprise an insulating material. The treatment element 532 may be provided on an enlarged distal tip 534 of an elongate shaft 536, and as in the embodiment illustrated, may have a convex shape configured to press against and create a concavity in the nasal valve cartilage (e.g., in the upper lateral cartilage near the nasal valve). The distal tip 534 is located at the distal end of shaft 536. The shaft is attached at its proximal end to a handle 538. The handle 538 comprises an input control such as a power button 540 on its front side that may be used to activate and deactivate the electrode. The power button 540 may be positioned in a recess of the handle to allow for finger stability when activating and deactivating the electrode. In other embodiments, the input control is in the form of a switch or dial. Other configurations are also possible as described above.

[0191] The device 530 comprises a flexible wire or cable 542 electrically connected to an adaptor 544. The adaptor 544 can be used to connect the device 530 to a remote generator (not shown). The adaptor 544 may allow transmission of treatment energy between a remote generator and the device 530. The adaptor may also allow transmission of any sensor signals

between the device 530 and a generator or control unit. The device 530 may either comprise an integrated generator or be connected to a remote generator. The treatment device 530 may be provided in a system or kit also including the remote generator. The system or kit (with or without the remote generator) may also include a grounding device and/or a cooling device as described above and further below. In some embodiments, the kit includes a positioning element (e.g., a "cottle" device) configured to help a user locate the optimal treatment area.

[0192] FIGS. 22B and 22C depict front and back views of the device. As shown in FIGS. 22B and 22C, the handle 538 of the device generally as a rounded elongate shape. Other shapes are also possible. For example the device 530 may have a square shaped cross section. In some embodiments, a circumference (or width or cross-sectional area) of the handle 538 may increase distally along the length of the handle 538.

[0193] FIGS. 22D and 22E depict side views of the device. As shown in FIGS. 22D and 22E, the handle 538 of the device 530 may comprise an indentation or recess around the middle of the handle 538. This may allow for enhanced grip and control when a user is holding the device. The indentation or recess may be near the input control or power button 540 to allow a user to easily activate and deactivate the device while holding it in a comfortable position.

[0194] In some embodiments, the shaft has a width or diameter of about 0.125 inches to about 0.25 inches. In some embodiments, the shaft is about 1.5 inches to about 4 inches long. In some embodiments, the shaft comprises a polymer such as polycarbonate or PEEK. In other embodiments, the shaft comprises stainless steel or other metals. The metals may be coated with an external and/or internal insulating coating (e.g., polyester, polyolefin, etc.). The handle may comprise the same material as the shaft, in some embodiments. In some embodiments, the shaft is rigid. This may allow a user of the device increased control over the deformation of nasal tissue. In some embodiments, the shaft comprises some amount of flexibility. This flexibility may allow a user adjust an angle of the distal tip by bending the distal end of the shaft.

[0195] FIG. 22G depicts a larger view of the distal tip 534 of the device 530. As shown best in FIG. 22G, the treatment element 532 comprises a generally elongate shape. The front of the treatment element 532 comprises a shallow, curved surface, providing a convex shape configured to deform the nasal tissue and create a concavity therein. In some embodiments, the front of the treatment element comprises a concave shape. The shape of the front surface of the treatment

element may be selected to conform to the nasal tissue. The back of the treatment element 532 also comprises a shallow curved surface. As best seen in FIGS. 22D and 22E, the back surface varies in width along the length of the back surface of the treatment element 532. The back surface widens, moving distally along the tip until it is nearly in line with the proximal end of the electrode plate 532. The back surface then narrows towards the distal tip of the treatment element 532. This shape may maximize visualization of the area to be treated, while, at the same time, providing sufficient rigidity for treatment. Other shapes are also possible. For example, the treatment element may comprise a generally spherical or cylindrical shape. In some embodiments, the treatment element comprises an angular shape (e.g., triangular, conical) which may allow for close conformation to the tissue structures. The treatment element 532 comprises a monopolar electrode plate 532. The monopolar electrode plate 532 can be in the shape of a rectangle having a curved or convex tissue-facing surface. Other shapes are also possible (e.g., square, circular, ovular, etc.). The electrode 532 may protrude slightly from the treatment element 535. This may allow the electrode to itself provide a convex shape configured to create a concavity in tissue to be treated.

[0196] In some embodiments, the treatment element has a width or diameter of about 0.25 inches to about 0.45 inches. In some embodiments, the treatment element is about 0.4 inches to about 0.5 inches long. The treatment element can, in some embodiments, comprise a ceramic material (e.g., zirconium, alumina, silicon glass). Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the treatment element comprises polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the treatment element comprises thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the treatment element comprises thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the treatment element comprises glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0197] In some embodiments, the electrode has a width of about 0.15 inches to about 0.25 inches. In some embodiments, the electrode is about 0.2 inches to about 0.5 inches long. In some

embodiments, the treatment element comprises steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0198] As shown in the embodiment of FIG. 22G, the treatment element 532 further comprises a pin-shaped structure comprising a thermocouple 533 within an insulating bushing extending through a middle portion of the plate 532. In some embodiments, different heat sensors (e.g., thermistors) may be used. In some embodiments, the thermocouple 533 is configured to measure a temperature of the surface or subsurface of tissue to be treated or tissue near the tissue to be treated. A pin-shape having a sharp point may allow the structure to penetrate the tissue to obtain temperature readings from below the surface. The thermocouple can also be configured to measure a temperature of the treatment element 532 itself. The temperature measurements taken by the thermocouple can be routed as feedback signals to a control unit (e.g., the control unit 42 described with respect to FIG. 3) and the control unit can use the temperature measurements to adjust the intensity of energy being delivered through the electrode. In some embodiments, thermocouples or other sensing devices may be used to measure multiple tissue and device parameters. For example, multiple thermocouples or thermistors may be used to measure a temperature at different locations along the treatment element. In some embodiments, one of the sensors may be configured to penetrate deeper into the tissue to take a measurement of a more interior section of tissue. For example, a device may have multiple sensors configured to measure a temperature at the mucosa, the cartilage, and/or the treatment element itself. As described above, in some embodiments, the sensors described herein are configured to take a measurement of a different parameter. For example, tissue

impedance can be measured. These measurements can be used to adjust the intensity and/or duration of energy being delivered through the treatment element. This type of feedback may be useful from both an efficacy and a safety perspective.

[0199] As shown in FIG. 22G, in some embodiments the thermocouple is within a pin shaped protrusion on the surface of the electrode 532. In other embodiments, the thermocouple can simply be on the surface of the electrode. In other embodiments, the thermocouple can protrude from the surface of the electrode in a rounded fashion. Rounded structures may be pressed into the tissue to obtain subsurface temperature readings. Other configurations and locations for the thermocouple are also possible. The use of thermocouples or temperature sensors may be applied not only to the embodiment of FIG. 22G, but also to any of the other embodiments described herein.

[0200] FIGS. 23A-G depict a treatment device 550 similar to the embodiments of FIGS. 8F and 18. FIGS. 23A and 23F are perspective views of the device 550 and show the device 550 comprising a treatment element 552 at the distal tip 556 of the device 550. The treatment element 552 may be provided on an enlarged distal tip 556 of an elongate shaft 558, and as in the embodiment illustrated, may have a convex shape configured to press against and create a concavity in the nasal valve cartilage (e.g., in upper lateral cartilage of the nasal valve). The distal tip 556 is located at a distal end of shaft 558. The shaft is attached at its proximal end to a handle 560. The handle 560 comprises an input control, such as a power button 562, on its front side that may be used to activate and deactivate the electrode. The power button may be positioned in a recess of the handle to allow for finger stability when activating and deactivating the electrode. In other embodiments, the input control is in the form of a switch or dial. Other configurations are also possible as described above. The device 550 may either comprise a generator or be connected to a remote generator. The device 550 may comprise a flexible wire or cable 564 that connects to an adaptor 566 that is configured to be plugged into a remote generator (not shown). The adaptor 566 may allow transmission of treatment energy between a remote generator and the device 550. The adaptor 566 may also allow transmission of any sensor signals between the device 550 and a generator or control unit. The treatment device 550 may be provided in a system or kit also including the remote generator. The system or kit (with or without the remote generator) may also include a grounding device and/or a cooling device as

described above and further below. In some embodiments, the kit includes a positioning element (e.g., a "cottle" device) configured to help a user locate the optimal treatment area.

[0201] In some embodiments, the shaft has a width or diameter or about 0.235 inches to about 0.25 inches. In some embodiments, the shaft is about 1.5 inches to about 4 inches long. In some embodiments, the shaft and/or handle comprises a polymer such as polycarbonate or PEEK. In other embodiments, the shaft comprises stainless steel or other metals. The metals may be coated with an external and/or internal insulating coating (e.g., polyester, polyolefin, etc.). The handle may comprise the same material as the shaft, in some embodiments. In some embodiments, the shaft is rigid. This may allow a user of the device increased control over the deformation of nasal tissue. In some embodiments, the shaft comprises some amount of flexibility. This flexibility may allow a user adjust an angle of the distal tip by bending the distal end of the shaft.

[0202] FIGS. 23B and 23C depict side views of the device. As shown in FIGS. 23B and 23C, the handle 560 of the device 550 may comprise an indentation or recess around the middle of the handle 560. This may allow for enhanced grip and control when a user is holding the device. The indentation or recess may be near the input control or power button 562 to allow a user to easily activate and deactivate the device while holding it in a comfortable position.

[0203] FIGS. 23D and 23E depict front and back views of the device. As shown in FIGS. 23D and 23E, the handle 560 of the device generally comprises a rounded elongate shape. Other shapes are also possible. For example the device 550 may have a square shaped cross section. In some embodiments, a circumference (or width or cross-sectional area) of the handle 560 may increase distally along the length of the handle 560.

[0204] FIG. 23G depicts a larger view of the distal tip 556 of the device 550. As shown best in FIG. 23G, the treatment element 552 comprises a generally elongate shape. The front of the treatment element 552 comprises a shallow curved surface, providing a convex shape configured to deform the nasal tissue and create a concavity therein. In some embodiments, the front of the treatment element comprises a concave shape. The shape of the front surface of the treatment element may be selected to conform to the nasal tissue. The back surface of the treatment element 552 comprises a shallow curved surface along most of its length. As best seen in FIGS. 23B and 23C, the back surface narrows distally along the length of the element 552 from approximately the distal end of the needle electrodes to the distal tip of the treatment element

552. This shape may maximize visualization of the area to be treated, while, at the same time, providing sufficient rigidity for treatment. Other shapes are also possible. For example, the treatment element may comprise a generally spherical or cylindrical shape. In some embodiments, the treatment element comprises an angular shape (e.g., triangular, conical) which may allow for close conformation to the tissue structures. The treatment element 552 comprises a monopolar or bipolar needle array comprising multiple needles 554. In some embodiments, the needles 554 are energized in between select needles to deliver bipolar energy. In other embodiments, the energy is delivered between the needles (554) and a remote grounding pad (not shown). In some embodiments, the electrode needle pairs are arranged horizontally across the treatment element 552. In some embodiments, the electrode needle pairs are arranged vertically across the treatment element 552, or along the direction of the shaft 558 and handle 560. Other configurations are also possible. For example, the needle pairs may be arranged diagonally across the treatment element 552. The treatment element 552 may be placed either internally, with the needle pairs 554 positioned transmucosally or the treatment element 552 may be placed externally with the needle pairs 554 positioned transdermally. The distal tip 556 of the device 550 may also function as a mold or molding element. In a monopolar embodiment, the energy may be selectively delivered between certain sets of needles, all needles, or even individual needles to optimize the treatment effect.

[0205] The treatment element 552 of the device 550 further comprises a pin-shaped structure comprising a thermocouple 555 within an insulating bushing extending through a middle portion of the front surface of the treatment element 552. In some embodiments, different heat sensors (e.g., thermistors) may be used. As described above, in some embodiments, the thermocouple 555 is configured to measure a temperature of the surface or subsurface of tissue to be treated or tissue near the tissue to be treated. A pin-shape having a sharp point may allow the structure to penetrate the tissue to obtain temperature readings from below the surface. The thermocouple can also be configured to measure a temperature of the treatment element 552 itself. The temperature measurements taken by the thermocouple can be routed as feedback signals to a control unit (e.g., the control unit 42 described with respect to FIG. 3) and the control unit can use the temperature measurements to adjust the intensity of energy being delivered through the electrode. In some embodiments, thermocouples or other sensing devices may be used to measure multiple tissue and device parameters. For example, multiple thermocouples or

thermistors may be used to measure a temperature at different locations along the treatment element. In some embodiments, one of the sensors may be configured to penetrate deeper into the tissue to take a measurement of a more interior section of tissue. For example, a device may have multiple sensors configured to measure a temperature at the mucosa, the cartilage, and/or the treatment element itself. As described above, in some embodiments, the sensors described herein are configured to take a measurement of a different parameter. For example, tissue impedance can be measured. These measurements can be used to adjust the intensity and/or duration of energy being delivered through the treatment element. This type of feedback may be useful from both an efficacy and a safety perspective.

[0206] In some embodiments, the treatment element has a width or diameter of about 0.25 inches to about 0.45 inches. In some embodiments, the treatment element is about 0.4 inches to about 0.5 inches long. The treatment element can, in some embodiments, comprise a ceramic material (e.g., zirconium, alumina, silicon glass). Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the treatment element comprises polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the treatment element comprises thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the treatment element comprises thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the treatment element comprises glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0207] In some embodiments, the electrodes have a width or diameter of about 0.15 inches to about 0.25 inches. In some embodiments, the electrode is about 0.2 inches to about 0.5 inches long. In some embodiments, the treatment element comprises steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may

advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0208] Energy applied to the tissue to be treated using any combination of the embodiments described in this application may be controlled by a variety of methods. In some embodiments, temperature or a combination of temperature and time may be used to control the amount of energy applied to the tissue. Tissue is particularly sensitive to temperature; so providing just enough energy to reach the target tissue may provide a specific tissue effect while minimizing damage resulting from energy causing excessive temperature readings. For example, a maximum temperature may be used to control the energy. In some embodiments, time at a specified maximum temperature may be used to control the energy. In some embodiments, thermocouples, such as those described above, are provided to monitor the temperature at the electrode and provide feedback to a control unit (e.g., control system 42 described with respect to FIG. 3). In some embodiments, tissue impedance may be used to control the energy. Impedance of tissue changes as it is affected by energy delivery. By determining the impedance reached when a tissue effect has been achieved, a maximum tissue impedance can be used to control energy applied.

[0209] In the embodiments described herein, energy may be produced and controlled via a generator that is either integrated into the electrode handpiece or as part of a separate assembly that delivers energy or control signals to the handpiece via a cable or other connection. In some embodiments, the generator is an RF energy source configured to communicate RF energy to the treatment element. For example, the generator may comprise a 460 KHz sinusoid wave generator. In some embodiments, the generator is configured to run between about 1 and 100 watts. In some embodiments, the generator is configured to run between about 5 and about 75 watts. In some embodiments, the generator is configured to run between about 10 and 50 watts.

[0210] In some embodiments, the energy delivery element comprises a monopolar electrode (e.g., electrode 535 of FIG. 22G). Monopolar electrodes are used in conjunction with a

grounding pad. The grounding pad may be a rectangular, flat, metal pad. Other shapes are also possible. The grounding pad may comprise wires configured to electrically connect the grounding pad to an energy source (e.g., an RF energy source).

[0211] In some embodiments, the energy delivery element such as the electrodes described above can be flat. Other shapes are also possible. For example, the energy delivery element can be curved or comprise a complex shape. For example, a curved shape may be used to place pressure or deform the tissue to be treated. The energy delivery element may comprise needles or microneedles. The needles or microneedles may be partially or fully insulated. Such needles or microneedles may be configured to deliver energy or heat to specific tissues while avoiding tissues that should not receive energy delivery.

[0212] In some embodiments, the electrodes or energy delivery elements described herein comprise steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0213] In some embodiments, the treatment elements (e.g., non-electrode portion of treatment element) of the devices described herein, including but not limited to FIGS. 8A-J, 9A-B, 10A-b, 11A-B, 12A-B, 13A-E, 14A-B, 15A-C, 16, 17A-B, 18, 22A-G, 19A-B, 20A-B, 21A-B, 22A-G, 23A-G, 25A-B, 26, 27, 28A-E, and 29, comprise an insulating material such as a ceramic material (e.g., zirconium, alumina, silicon glass). In some embodiments, the treatment elements comprise an insulating material interposed between multiple electrodes or electrode section. These insulating sections may provide an inert portion of the treatment element that does not delivery energy to the tissue. Such ceramics may advantageously possess high dielectric strength

and high temperature resistance. In some embodiments, the insulators described herein comprise polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the insulators described herein comprise thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the insulators described herein comprise thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the insulators described herein comprise glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0214] In some embodiments, the handle and/or shaft of the devices comprise the same materials as those described with respect to the insulators. In some embodiments, the handle and/or shaft of the device comprises a metal, such as stainless steel. In other embodiments, the handle and/or shaft of the device comprises a polymer, such as polycarbonate. Other metals and polymers are also contemplated.

[0215] In some embodiments, the device may be used in conjunction with a positioning element that can be used to aid in positioning of the device. The positioning element may be integrated into the device itself or can be separate. The positioning element may be used to determine the optimal placement of the device to achieve maximal increase in efficacy. In some embodiments, a positioning element is configured to be inserted and manipulated within the nose until the patient reports a desired improvement in breathing. The treatment device may then be used to treat while the positioning element is holding the nose in the desired configuration. In some embodiments, molds described herein may be used for the same purpose.

[0216] In some embodiments, a positioning element comprises a shaft comprising measurement marks indicating depth. For example, a physician may insert this element into the nose to manipulate the tissue to find the depth of treatment at which the patient reports the best breathing experience. The positioning element may comprise marks around the base of the shaft indicating which point of rotation of the device within the nostril provides the best breathing experience. The positioning element may also comprise marks indicating angle of insertion. The physician may then use the measurement marks to guide insertion of the treatment element to the same spot.

[0217] It will be appreciated that any combination of electrode configurations, molds, handles, connection between handles, and the like may be used to treat the nasal valve.

Cooling Systems

[0218] Embodiments of devices configured to heat specific tissue while maintaining lower temperatures in other adjacent tissue are provided. These devices may be incorporated into any of the treatment apparatuses and methods described herein. The nasal valve is an example of a tissue complex that includes adjacent tissues that may benefit from being maintained at different temperatures. Other examples include the skin, which comprises the epidermis, dermis, and subcutaneous fat, the tonsils, which comprise mucosa, glandular tissue, and vessels. Treatment of other tissue complexes is also possible. For example, in some embodiments, the internal structures of the nasal valve may be heated while maintaining a lower temperature in the mucosal lining of the nose and/or skin. In other embodiments, the mucosa may be heated, while maintaining lower temperatures in the skin. 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 cartilage, while excluding another tissue, such as mucosa, without surgical dissection.

[0219] Generally, when using a device 570 with an electrode 572 (e.g., monopolar RF electrode) to heat nasal cartilage, the electrode 572 must be in contact with the mucosa. FIG. 24A shows a cross-section of tissue at the nasal valve. The cross-section shows that the nasal cartilage 704 sits in between a layer of mucosa (internal) 702 and a layer of skin (external) 706. When the electrode 572 is activated, both the mucosa and the cartilage are heated by the current flowing from the electrode to the return (e.g., ground pad), as shown in FIG. 24B. The tissue closest to the electrode 572 receives the highest current density, and thus, the highest heat. A surface cooling mechanism may allow the temperature of the electrode surface to be reduced. Such a cooling mechanism may maintain a lower temperature at the mucosa even though current flow will continue to heat the cartilage.

[0220] FIG. 25A depicts a device 580 configured to treat the nasal valve using an electrode while maintaining a reduced temperature at the mucosa. The device comprises a treatment element 582 comprising an electrode 584 at the distal tip of the device 580. The treatment

element 582 is attached to a distal end of a shaft 586, which is attached to the distal end of a handle 588. Input and output coolant lines 590, 592 are attached to a pump and reservoir 594 and extend into the handle 588, through the distal end of the treatment element 582 to the electrode 582 and return back through the shaft 586 and handle 588 to the pump and reservoir 594. The coolant may be remotely cooled in the reservoir and may comprise a fluid or gas. The coolant flowing through the electrode 582 may allow the treatment element 582 to be maintained at a reduced temperature while still allowing current flow to heat the cartilage. Examples of coolant include air, saline, water, refrigerants, and the like. Water may advantageously provide moderate heat capacity and be non reactive. Refrigerants may advantageously be able to transfer significant amounts of heat through phase change. The coolant may flow through internal or external cavities of the electrode or wand tip. For example, FIG. 25B depicts an embodiment of a device 600 comprising a treatment element 602 with an electrode 604 at the distal tip of the device 600. The treatment element 602 is attached to the distal end of a shaft 606 which is attached to the distal end of a handle 608. The handle may be attached to a cable comprises a lumen or channel 611 through which gas or fluid may flow. The lumen 611 may diverge, near the treatment element 602, into separate external channels flowing over the electrode 604. The lumen 611 and channels 610 or cavities may be attached to a fan or fluid pump 612. In some embodiments, the fan or fluid pump may remotely cool the gas or fluid.

[0221] FIG. 26 depicts another embodiment of a device 620 configured to treat the nasal valve using an electrode 624 while maintaining a reduced temperature at the mucosa and/or skin. The device comprises a treatment element 622 comprising an electrode 624 at its distal end. The treatment element 622 is connected to the distal end of a shaft 626 which is connected to the distal end of a handle 628. The device 620 comprises a heat pipe 630 attached to the electrode 624 or treatment element 622. The heat pipe 630 is configured to transfer heat to a remote heat sink 632. As shown in FIG. 26, the heat sink 632 may be placed in the handle of the device. In some embodiments, the heat sink may be placed remotely. The heat pipe 630 may comprise a sealed tube (e.g., a copper tube) filled with a material that evaporates at a given temperature. When one end of the heat pipe 630 is heated, the fluid may evaporate and flow to the opposite end where it may condense and subsequently transfer heat to the heat sink 632. Using a material such as copper for the heat pipe 630 and/or heat sink 632 may advantageously provide high heat and electrical conductivity.

[0222] FIG. 27 depicts another embodiment of a device 640 configured to treat the nasal valve using a bipolar electrode pair while maintaining a reduced temperature at the skin. The device 640 comprises a first treatment element 642 comprising a first electrode 644 of a bipolar electrode pair at the distal end of a shaft 646. The treatment element 642 comprises a thermocouple pin 650 like that described with respect to FIG. 22G. The shaft 646 is connected to the distal end of a handle 648. The handle 648 is connected to another handle 652 comprising a shaft 654 with a treatment element 656 at its distal tip. The treatment element 656 comprises a second electrode 657 of the bipolar electrode pair. The first and second treatment elements 642, 656 can be placed on either side of nasal tissue. For example, the first treatment element 642 may be in contact with the mucosa and the second treatment element 656 may be in contact with the skin. Similar to the device depicted in FIG. 26, the device of FIG. 27 comprises a heat pipe within both shafts 654, 646. Thus heat from the tissue is transferred from the treatment elements 642, 656 and is transported down the shafts 654, 646 into an integrated or a remote heat sink (not shown). This heat transfer may keep the skin and the mucosa relatively cool while still delivering sufficient treatment energy to the cartilage. The connection 658 and spring 647 between the two handles 648, 652 is configured to bias the two shafts 646, 654 and treatment elements 642, 656 towards a collapsed state. Squeezing the handles 648, 652 may separate the two shafts 646, 654 and treatment elements 642, 656. Thus, the handles 648, 652 can be squeezed to properly position the device 640 at the nasal tissue to be treated. Releasing the handles 648, 652 can cause the treatment element 642 and the cooling element 656 to contact the tissue. In some embodiments, the device 640 may only comprise one heat pipe. In some embodiments, the device 640 may comprise a treatment element with a monopolar electrode on one shaft and a molding element on the other shaft. Multiple configurations are contemplated. For example, the device may comprise one heat pipe and a bipolar electrode pair. For another example, the device may comprise one heat pipe and a monopolar electrode. For another example, the device may comprise two heat pipes and a monopolar electrode. Other device configurations are also possible.

[0223] The embodiments described with respect to FIGS. 25A-27 employ specific differential cooling mechanisms to maintain different and particular temperatures in adjacent tissues. FIGS. 28A-28E depicts various examples of more general mechanisms configured to maintain different temperatures in adjacent tissues. FIGS. 28A-28E depict examples of differential cooling

mechanisms as applied to a cross-section of tissue at the nasal valve, like that shown in FIG. 24A.

[0224] 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 skin 706. In such an embodiment, the first and second elements 708, 710 comprise a cooling apparatus such as those described above (e.g., heatsink, 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. 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. For example, the device 580, described with respect to FIG. 27, may use such a mechanism. 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. Again, the device 580, described with respect to FIG. 27, is an example of a device that may use such a mechanism.

[0225] 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.

[0226] 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.

[0227] 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.

[0228] 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.

[0229] Cooling occurring before, during, or after treatment may effect reduced temperature of the skin and/or mucosa. In some embodiments, attaching passive fins or other structures to the electrode or wand tip may allow for heat dissipation to the surrounding air. In some embodiments, the device may be configured to spray a cool material such as liquid nitrogen before, during, or after treatment. Using a material such as copper for the passive fins or other structure may advantageously provide high heat and electrical conductivity. In some embodiments, using metals with a high heat capacity in the device (e.g., in the energy delivery element, the re-shaping element, or both) may advantageously provide the ability to resist temperature change during energy delivery. In some embodiments, pre-cooling the electrode (e.g., by refrigeration, submersion, spraying with a cool substance like liquid nitrogen, etc.) may maintain a reduced temperature at the mucosa. Any combination of the cooling methods described herein may be used in conjunction with any of the energy delivery methods described herein (e.g., bipolar RF electrodes, arrays needles, plates, etc.). For example, FIG. 29 depicts an embodiment of a device 800 comprising a treatment element 802 comprising electrode needles 804 at its distal tip. The device 800 may be used in conjunction with a separate cooling device 810 which may comprise channels 812 or cavities to circulate air or fluid. The independent cooling device 810 may, in other embodiments, employ a different cooling mechanism.

[0230] In embodiments using laser energy to heat cartilage, it is possible to use a combination of two or more lasers whose beams converge at a location within the target tissue. This convergence may cause more heat at that junction as compared to locations where only a single beam is acting. The junction may be controlled manually or via computer control. Specific treatment may be provided.

[0231] In some embodiments, insulating material may be used to protect non-target tissue during energy delivery. For example, an electrode needle may be preferentially insulated on a portion of the needle that is in contact with non-target tissue. For another example, flat electrode blades may be insulated on a portion of the blade that is in contact with non-target tissue. Other configurations for heat isolation are also possible.

[0232] Any of the cooling mechanisms or combinations of the cooling mechanisms described herein may be used in conjunction with any of the devices or combinations of devices described herein, or the like.

Examples of Methods of Treatment

[0233] Embodiments of methods for treating nasal airways are now described. Such methods may treat nasal airways by decreasing the airflow resistance or the perceived airflow resistance at the site of an internal or external nasal valve. Such treatments may also address related conditions, such as snoring.

[0234] In one embodiment, a method of decreasing airflow resistance in a nasal valve comprises the steps of inserting an energy-delivery or cryo-therapy device into a nasal passageway, and applying energy or cryo-therapy to a targeted region or tissue of the nasal passageway. For example, in some embodiments, the method may include delivering energy or cryo-therapy to a section of internal nasal valve cartilage in the area of the upper lateral cartilage, or in the area of intersection of the upper and lower lateral cartilage. In alternative embodiments, the method may deliver energy to the epithelium, or underlying soft tissue adjacent to the upper lateral cartilage and/or the intersection of the ULC and the LLC.

[0235] In another embodiment, a method comprises heating a section of nasal valve cartilage to be re-shaped, applying a mechanical re-shaping force, and then removing the heat. In some embodiments, the step of applying a mechanical re-shaping force may occur before, during or after the step of applying heat.

[0236] In some embodiments, the method may further include the step of inserting a re-shaping device into the nasal passageway after applying an energy or cryo-therapy treatment. In such embodiments, a re-shaping device such as an external adhesive nasal strip (such as those described for example in U.S. Pat. No. 5,533,499 to Johnson or U.S. Pat. No. 7,114,495 to Lockwood, the entirety of each of which is hereby incorporated by reference) may be applied to the exterior of the nose after the treatment in order to allow for long-term re-shaping of nasal valve structures as the treated tissues heal over time. In alternative embodiments, a temporary internal re-shaping device (such as those taught in U.S. Pat. No. 7,055,523 to Brown or U.S. Pat. No. 6,978,781 to Jordan, the entirety of each of which is hereby incorporated by reference) may be placed in the nasal passageway after treatment in order to allow for long-term re-shaping of

nasal valve structures as the treated tissues heal over time. In some embodiments, the dilating nasal strips can be worn externally until healing occurs.

[0237] In alternative embodiments, internal and/or external re-shaping devices may be used to re-shape a nasal valve section prior to the step of applying energy or cryo-therapy treatments to targeted sections of the epithelial, soft tissue, mucosa, submucosa and/or cartilage of the nose. In some embodiments, the energy or cryo-therapy treatment may be configured to change the properties of treated tissues such that the tissues will retain the modified shape within a very short time of the treatment. In alternative embodiments, the treatment may be configured to re-shape nasal valve structures over time as the tissue heals.

[0238] In some embodiments, a portion of the nose, the nasal valve and/or the soft tissue and cartilage of the nasal valve may be reshaped using a re-shaping device and then fixed into place. In some embodiments, such fixation may be achieved by injecting a substance such as a glue, adhesive, bulking agent or a curable polymer into a region of the nasal tissue adjacent the target area. Alternatively, such a fixation substance may be applied to an external or internal surface of the nose.

[0239] In some embodiments, an injectable polymer may be injected into a region of the nose, either below the skin on the exterior of the nose, or under the epithelium of the interior of the nose. In some embodiments, an injectable polymer may include a two-part mixture configured to polymerize and solidify through a purely chemical process. One example of a suitable injectable two-part polymer material is described in US Patent Application Publication 2010/0144996, the entirety of which is hereby incorporated by reference. In other embodiments, an injectable polymer may require application of energy in order to cure, polymerize or solidify. A re-shaping device may be used to modify the shape of the nasal valve before or after or during injection of a polymer. In embodiments employing an energy-curable polymer, a re-shaping device may include energy-delivery elements configured to deliver energy suitable for curing the polymer to a desired degree of rigidity.

[0240] In another embodiment, the soft tissue of the upper lip under the nares may be debulked or reshaped to reduce airflow resistance. In some embodiments, such re-shaping of the upper lip soft tissue may be achieved by applying energy and/or cryotherapy from an external and/or internal treatment element. In some embodiments, the tissue of the upper lip under the

nares may be compressed by an internal or external device prior to or during application of the energy or cryo-therapy. For example, devices such as those shown in FIGS. 5A and 5B may be adapted for this purpose by providing tissue-engaging clamp tips shaped for the purpose.

[0241] In another embodiment, the muscles of the nose and/or face are stimulated to dilate the nasal valve area prior to or during application of other treatments such as energy/cryo application or fixation treatments. In such embodiments, the muscles to be treated may include the nasal dilator muscles (nasalis) the levetator labii, or other facial muscles affecting the internal and/or external nasal valves. In some embodiments, the targeted muscles may be stimulated by applying an electric current to contract the muscles, mentally by the patient, or manually by the clinician.

[0242] In some embodiments, the muscles of the nose and/or face may also be selectively deactivated through chemical, ablative, stimulatory, or mechanical means. For example, muscles may be deactivated by temporarily or permanently paralyzing or otherwise preventing the normal contraction of the muscle tissue. Chemical compounds for deactivating muscle tissues may include botulinum toxin (aka "botox"), or others. Ablative mechanisms for deactivating muscle tissue may include RF ablation, laser ablation or others. Mechanical means of deactivating muscle tissues may include one or more surgical incisions to sever targeted muscle tissue.

[0243] In another embodiment, the tissue of the nasal valve may be reshaped by applying energy to the internal and external walls of the nasal valve using a clamp like device as illustrated for example in FIGS. 5A and 5B. One arm of the clamp may provide inward pressure to the external, skin side tissue covering the nasal valve and the other side of the clamp may provide outward pressure to the mucosal tissue on the lateral wall of the nasal airway above the ULC and LLC or both.

[0244] In some embodiments, energy may be applied to the skin of the nose to effect a shrinkage of the skin, epidermis, dermis, subdermal, subcutaneous, tendon, ligament, muscle, cartilage and/or cartilage tissue. The tissue shrinkage is intended to result in a change of forces acting on the tissues of the nasal valve to improve airflow through the nasal airway.

[0245] In another embodiment, the nasal valve tissue may be damaged or stimulated by energy application, incisions, injections, compression, or other mechanical or chemical actions. Following such damage, a device may be used on the tissue to mold or shape the tissue of the valve during healing. In some embodiments, such a re-shaping device may be temporarily placed

or implanted inside or outside the patient's nose to hold a desired shape while the patient's healing process progresses.

[0246] In another embodiment, the aesthetic appearance of the nose may be adjusted by varying the device design and/or treatment procedure. The predicted post-procedure appearance of the nose may be shown to the patient through manipulating the nasal tissue to give a post procedure appearance approximation. The patient may then decide if the predicted post procedure appearance of the face and nose is acceptable or if the physician needs to change parameters of the device or procedure to produce an appearance more acceptable to the patient.

[0247] In another embodiment, reduction of the negative pressure in the nasal airway can be effected to reduce collapse of the structures of the nasal airway on inspiration without changing a shape of the nasal valve. For example, this may be accomplished by creating an air passage that allows flow of air directly into the site of negative pressure. One example of this is creating a hole through the lateral wall of the nose allowing airflow from the exterior of the nose through the nasal wall and into the nasal airway.

[0248] In another embodiment, energy, mechanical or chemical therapy may be applied to the tissue of the nasal airway with the express purpose of changing the properties of the extracellular matrix components to achieve a desired effect without damaging the chondrocytes or other cells of the nasal airway tissue.

[0249] In some embodiments, devices (e.g., devices like those described with respect to FIGS. 9A-21B) may be used to provide tissue re-shaping/molding and to impart energy to the nasal valve. The electrode may be placed in contact with the target nasal valve tissue. The electrodes and molds may be moved to shape the tissue as necessary to achieve improvement in nasal airway. The electrodes may be activated while the tissue is deformed in the new shape to treat the tissue. The electrode may then be deactivated and the device may be removed from the nasal valve area.

[0250] FIGS. 30A-30D depict a method for using a device 900 similar to those devices described above, including but not limited to FIGS. 8A, 9B, 18, 22A-G, and 23A-G, to provide tissue re-shaping/molding and to impart energy to tissue near the nasal valve.

[0251] The method may include identifying a patient who desires to improve the airflow through their nasal passageways and/or who may benefit from an increase in a cross-sectional area of the opening of the nasal valve. The patient may be positioned either in an upright position (e.g., seated or standing) or be lying down. Local anesthesia may be applied to an area near or surrounding the tissue to be treated. General anesthesia may also be used.

[0252] Optionally, a positioning element, like that described herein, may be used to measure a desired depth or angle of treatment. As described above, the positioning element may be inserted to the desired depth of treatment and rotated to a desired angle of treatment. Marks along the positioning element can indicate the desired depth. Marks along the base of the shaft of the positioning element can indicate the desired angle. The physician or other medical professional administering the treatment can then insert the treatment device to the desired location. The physician may also assess any other characteristics relevant to the treatment of the patient's nose that may influence the manner of treatment. In some embodiments, a re-shaping element may be used to manipulate the nasal tissue into a configuration allowing improved airflow; and treatment may be performed while such a re-shaping element is maintaining the desired configuration of the nasal tissue.

[0253] If the treatment device comprises a monopolar electrode or electrode needles, a ground pad may be attached to the patient. The ground pad may be attached at the patient's torso, for example the shoulder or abdomen. Other locations are also possible, such as the patient's buttocks. Preferably, the point of attachment is a large, fleshy area. After being attached, the ground pad may be plugged into a power source. If the device is powered by a remote generator (e.g., RF generator), the device may then be plugged into the generator.

[0254] FIG. 30A depicts the nose of a patient prior to insertion of the device. As shown in FIG. 30B, the device is then inserted into a nostril of the patient. The treatment element 802 of the device 800 may be positioned within the nasal airway, adjacent to nasal tissue (e.g., upper lateral cartilage) to be treated. The treatment element 802 may be positioned so that the electrode is in contact with the tissue to be treated. The device 800 (as shown in FIG. 30C) comprises multiple needle electrodes 804. The needle electrodes 804 may be inserted so that they are penetrating or engaging tissue to be treated.

[0255] The treatment element 802 may be used to deform the nasal tissue into a desired shape by pressing a convex surface of the treatment element 802 against the nasal tissue to be treated. FIG. 30C shows an internal view, from the nares, of the treatment element 802 pushing against the upper lateral cartilage 806 of the nose, deforming the upper lateral cartilage 806 and increasing the area of the opening of the nasal valve 808. FIG. 30D depicts an external view of the treatment element 802 deforming the upper lateral cartilage 806. Even from the outside, the nose appears to be bulging near the area to be treated. In some embodiments, the deformation required to treat the nose is not visually detectable. A control input such as button 814 may be used to activate the electrode and deliver energy (e.g., RF energy) to the tissue to be treated.

[0256] In some embodiments, temperature of the area around the electrode during treating is from about 30 degrees C. to about 90 degrees C. In some embodiments, temperature of the area around the electrode during treating is from about 40 degrees C. to about 80 degrees C. In some embodiments, temperature of the area around the electrode during treating is from about 50 degrees C. to about 70 degrees C. In some embodiments, temperature of the area around the electrode during treating is about 60 degrees C. In some embodiments, for example during cryo-therapy, temperature of the area around the electrode may be lower.

[0257] In some embodiments, treating the target tissue comprises treatment for about 1 s to about 3 minutes. In some embodiments, treating the target tissue comprises treatment for about 10 s to about 2 minutes. In some embodiments, treating the target tissue comprises treatment for about 15 s to about 1 minute. In some embodiments, treating the target tissue comprises treatment for about 20 s to about 45 s. In some embodiments, treating the target tissue comprises treatment for about 30 s.

[0258] In some embodiments, treating the target tissue comprises delivering between about 1 and about 100 watts to the tissue. In some embodiments, treating the target tissue comprises delivering between about 5 and about 75 watts to the tissue. In some embodiments, treating the target tissue comprises delivering between about 10 and about 50 watts to the tissue.

[0259] As shown in FIGS. 30B and 30D, a thermocouple 812 may be provided on the electrode (e.g., as described with reference to FIGS. 22G and 27). In some embodiments, more than one thermocouple may be provided. For example, in embodiments comprising more than one electrode or electrode pair, each electrode or electrode pair may comprise a thermocouple.

The thermocouple 812 may monitor temperature of the electrode and provide feedback to a control unit (e.g., control system 42 described with respect to FIG. 3). The control unit may use the data from the thermocouple 812 to regulate temperature and auto-shutoff once treatment has been achieved or in the case of an overly high temperature.

[0260] After treating the tissue, the device 800 may be removed from the nostril. If a grounding pad is used, the grounding pad may be detached from the patient.

[0261] In some embodiments, differential cooling mechanisms may be used to treat the nasal valve using electrodes or other energy delivery elements while maintaining a reduced temperature at the skin and/or mucosa. For example, devices like those described with respect to FIGS. 25A-27 or devices employing the differential cooling mechanisms described with respect to FIGS. 28A-28E may be used. The cooling system may be activated. The device may then be inserted into the nose and placed in contact with the nasal vale. The device may then be activated. Activation of the device may cause an increase in the cartilage temperature while minimizing the temperature increase in the skin and/or mucosa. The device may then be deactivated and removed from the nose.

[0262] In some embodiments, devices may be used in which insulating material is used to protect non-target tissue during energy delivery. In an embodiment, a device comprises an electrode needle preferentially insulated on a portion of the needle. The needle may be inserted into the cartilage so that the insulated portion is in contact with the mucosa and/or the skin and the non-insulated portion is in contact with the cartilage. The device may be activated, causing an increase in the cartilage temperature while minimizing temperature increase in the skin and/or mucosa. The device may be deactivated and removed from the nose.

[0263] FIG. 31 illustrates an embodiment of a nasal valve treatment device 900. The device 900 may include a treatment element 901 positioned on a head section 902 of the device 900, which may be configured to be placed inside the nasal cavity, nasal passage, and/or nasal airway to deliver the desired treatment. The treatment element 901 may be positioned on an interior portion 904 and/or an exterior portion 905 of the head section 902. In some embodiments, the device 900 may further comprise a shaft section 903, which may be sized and configured for easy handheld operation by a clinician. In some embodiments, the head section 902 may be adjustable. It may be advantageous to use an adjustable head section 902 to treat anatomy that

may vary in shape and size. The shape of the head section 902 or parts of the head section 902 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 902 may result in a change in shape and/or size of the interior portion 904 and/or the exterior portion 905.

[0264] The head section 902 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 904 and the exterior 905 of the flexible sections. For example, in the case of a convex anatomy, the flexible sections may be adjusted to wrap around the anatomy utilizing electrodes on the interior 904 of the flexible sections. In the case of a concave anatomy, the flexible sections may be adjusted to fit into the anatomy utilizing electrodes on the exterior 905 of the flexible sections. In some embodiments, the head section 902 may include functionality to inflate and deflate the flexible sections to adjust the size of a treatment surface of the device 900 in a radial direction. In some embodiments, the head section 902 may include functionality to rotate the head section 902 in any direction to allow the head section 902 to be angled in a desired position.

[0265] FIG. 32A and FIG. 32B illustrate an embodiment of a nasal valve treatment device 900 comprising an electrode array 910. The electrode array 910 may include numerous electrodes positioned on a surface of a treatment element 901 of the device 900. 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 910 to achieve a combination that forms a required treatment surface profile 911. The treatment surface profile 911 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, and/or a generally flat treatment surface profile (See FIG. 32B).

[0266] FIG. 33 illustrates an embodiment of a nasal valve treatment device 900, comprising a first treatment element 901 and a second treatment element 921. The first treatment element 901 may be positioned on a first side of a head section 902. The first treatment element 901 may

include a first electrode array 910. In some embodiments, the head section 902 may be implemented with an extendable component 922. It may be advantageous to provide an extendable component 922 to allow the size of the treatment surface 923 to be adjustable. The extendable component 922 may include a second treatment element 921, including a second electrode array 920. In some embodiments, the extendable component 922 may be positioned on a second side of the head section 902 such that it is behind the first treatment element 901. The extendable component 922 may include functionality to move such that it may be shifted from behind the first treatment element 901 of the head section 902 to adjacent to the first treatment element 901 of the head section 902. This shift may expose the second electrode array 920, thereby extending the treatment surface 923. The extendable component 922 may be moved in any direction, and the direction depicted in FIG. 33 is merely an example of one direction in which it may be moved.

[0267] FIG. 34 illustrates an embodiment of a nasal valve treatment device 900 comprising a head section 902 that is offset relative to a shaft section 903 of the device 900. In some embodiments, the shaft section 903 may be coupled to an offsetting element 930 configured to offset the head section 902 of the device 900 from the shaft section 903. It may be advantageous to offset the shaft section 903 and the head section 902 to provide better access to a target anatomy, for example when the target anatomy is out of a field of view. The offsetting element 930 may include functionality allowing it to be extended or contracted depending on the position of the target anatomy. By adjusting the offsetting element 930, the target anatomy may be contacted by a treatment element 901 incorporated within the head section 902 to apply treatment to the target anatomy.

[0268] FIG. 35 illustrates an embodiment of a nasal valve treatment device 900 comprising a head section 902 adapted to be at an angle 935 relative to a shaft section 903 of the device. In some embodiments, the shaft section 903 may be coupled to an angularly deflecting element, such as a hinge, flexible portion, or the like, including functionality to adjust the angle 935 of the head section 902 relative to the shaft section 903. In some embodiments, the head section 902 may be coupled directly to the shaft section 903 at a predefined angle 935. It may be advantageous to angle the head section 902 relative to the shaft section 903 to provide better access to a target anatomy, for example when the target anatomy is at an angle relative to the

insertion point of the device. By angling the head section 902 relative to the shaft section 903, the target anatomy may be contacted by a treatment element 901 incorporated within the head section 902 to apply treatment to the target anatomy.

[0269] Most of the description above focuses on treatment of tissues in and around the nasal valve. More specifically, much of the discussion above focuses on treating the lateral portion of the nasal valve. In some cases, however, it may possible and even desirable to treat (1) the medial portion of the nasal valve (e.g., nasal septum) and/or (2) one or more airway tissues that are separate from and distanced away from the nasal valve. Such a treatment of tissue(s) may be in addition to, or as an alternative to, treating the lateral portion of the nasal valve, according to various different embodiments. In short, the devices and methods described herein may be applied to any tissue or combination of tissues, according to various embodiments, in an effort to improve breathing, decrease airflow resistance, increase patient comfort and/or the like. Such tissues may be internal, within the airway, and/or external, such as on or through the skin of the nose, sinuses or the like.

[0270] Various anatomical areas may be particularly amenable to treatment for nasal valve disorders or other breathing or nasal issues. For example, in some embodiments, the devices and methods described herein may be used to treat a nasal septum, either as part of a surgical septoplasty procedure or as a stand-alone procedure. At least a portion of the nasal septum—the upper portion—lies within what is usually considered to make up the nasal valve. Thus, treating this part of the septum may be advantageous. Various other areas of the nasal septum for possible treatment using the devices and methods described herein include, but are not limited to, swell bodies located on the septum, the septal turbinate, a high deviated septum and the nasal scroll. A high deviated septum is typically defined by the junction of the inferior and superior lateral cartilage plates. Additionally, the floor of the nasal cavity, part of which may help make up the nasal valve, and which is sometimes referred to as the piriform area, may be treated in some embodiments. Swell bodies may also occur on the floor of the nasal cavity and may be amenable to treatment. In general, the devices and method described herein may be used in a variety of treatments in a variety of anatomical locations in the upper airway and/or external to the airway.

[0271] The nasal swell body (NSB) is a widened region of the septum located superior to the inferior turbinates and anterior to the middle turbinates, and of importance to the airflow-regulating nasal valve. The NSB is composed of septal cartilage. Septal cartilage is thicker here than the other parts of nasal septum. The mucosal covering of septal body is thicker than the other portions of nasal septum. This body is in intimate relationship to the internal nasal valve. It is suspected to play a role in the maintenance of nasal resistance.

[0272] The NSB is a highly glandular structure of the anterior-superior septum, with a moderate proportion of venous sinusoids. Located at the distal valve segment, the NSB appears structured for secretory function and vasoactive airflow regulation. In some embodiments, the energy delivery member is designed to be inserted into the nasal valve angle to apply energy to a swell body. The energy is intended to shrink the size of the swell body. The energy delivery member can be designed to hold a position in the nasal valve angle to position the electrodes to only treat the area of the swell body located on the medial wall of the nasal valve. The energy delivery member can be designed with the electrodes positioned in such a way as to direct the energy into the submucosa while minimizing damage to the mucosal tissue and underlying cartilage. The energy delivery member can also be designed to direct the energy into the underlying cartilage to induce a shape change.

[0273] Impairment of nasal airflow can be caused by the strength, shape or size of any of the components of the nasal valve. The positions of the components relative to each other also determine the volume, speed and pressure of nasal airflow. The three angles of the nasal valve area are between the nasal septum and the ULC, the ULC and the pyriform aperture and the pyriform aperture and the nasal septum. All of these tissues and angles can be treated to increase the size of the nasal valve area to improve nasal airflow.

[0274] The upper portion of the nasal septum near the angle between the ULC and nasal septum is sometimes curved inward or bulging towards the ULC, reducing the angle between them and impairing nasal airflow. This can be caused by a deviated septum, swell body or septal turbinate. All of these causes can be treated to enlarge the nasal valve area and/or improve nasal airflow.

[0275] High septal deviations are another cause of narrowing of the nasal valve. These deviations are difficult to treat surgically because removal of cartilage in this area can cause destabilization of the nose and cerebrospinal fluid leakage.

[0276] Any of the devices and systems described herein may be used to treat any of the anatomical locations or structures described herein, either alone or in combination. Certain embodiments of the devices and systems may be particularly advantageous for certain anatomical structures. For example, an energy delivery device with a flat-shaped head may be advantageous for use in treating a high nasal septum deviation. However, none of the embodiments are limited to treatment of any particular tissue or anatomy.

[0277] FIG. 36 depicts a cross-section of a nose in the area of the nasal valve, and FIG. 37 is a diagram illustrating a nasal valve area in cross-section. These cross-sectional illustrations show that the nasal valve is bordered by the caudal end of the upper lateral cartilages (ULC) 940 and the septum 941. The angle formed between the ULC 940 and the septum 941 may be referred to as the nasal valve angle. Treatment may be performed on a number of surfaces within the nasal valve, including a first lateral surface 942, a second lateral surface 943, the apex 944 of the nasal valve angle, or combinations thereof. As shown in FIG. 36, the surfaces within the nasal valve may be shaped in a non-uniform manner that may pose challenges when a uniform treatment across the surfaces is desired. Adjustable treatment surface features, such as those described above, may help facilitate treatment in these anatomical areas. FIGS. 38A and 38B are frontal/partial see-through and sagittal cross-sectional views, respectively, of a human head, illustrating the upper airway. These figures illustrate the superior turbinate, the middle turbinate, and the inferior turbinate. The turbinates may vary in size and position. The inferior turbinate is often the largest turbinate, and it may extend horizontally along the lateral wall of the nasal cavity. The medial surface of the inferior turbinate may be convex, and the lateral surface may be concave. The middle turbinate may be smaller than the inferior turbinate, and may project downwards over the opening of the maxillary and anterior and middle ethmoid sinuses. The superior turbinate may be a smaller structure connected to the middle turbinate by nerve-endings. Treatment of the turbinates may require a device capable of adjustable treatment surface areas in order to treat the different shapes and sizes of different parts of the turbinates.

[0278] FIG. 39 is a block diagram depicting an array of electrodes of a nasal treatment device arranged in a multi-channel configuration. As described above, different target anatomies may have treatment surface areas of varying size and shape. Additionally, users operating a nasal treatment device may vary in skill, dexterity, and habits. Due to these variabilities, each electrode pair of the device may have varying degrees of contact with tissue of the target anatomy. For a configuration in which all pairs of electrodes are controlled by one main electrical channel, this may lead to varying magnitudes of treatment energy passing through each electrode pair. The pair(s) of electrodes that have a higher degree of contract with the tissue may experience higher magnitudes of impedance in their individual circuit. Since treatment energy takes the path of least resistance, this may lead to treatment energy being diverted to pairs of electrodes that experience a relatively lower magnitude of impedance due to a relatively lower degree of tissue contact. Thus, it may be advantageous to control the treatment energy through each electrode to ensure repeatable treatments.

[0279] In some embodiments, each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. In some embodiments, each electrode pair may be paired with its own thermocouple. By controlling the treatment energy flowing through each pair of electrodes using parameters including, but not limited to, temperature, a greater degree of control and accuracy over the treatment energy may be obtained, such that treatments may be repeatable.

[0280] As shown in FIG. 39, the nasal treatment device may include one or more thermocouples 962 and an RF output channel 961 assigned to each electrode pair for feedback. An electrode pair may include a positive electrode 963 and a negative electrode 964. In some embodiments, the positive electrode 963 and the negative electrode 964 may be positioned opposite to one another. Each electrode pair may have its own individual subsystem 960. The individual subsystem 960 may include a controlled RF output channel 961 and a thermocouple 962 to allow for independent adjustments. The thermocouple 962 may act as a feedback control to ensure that proper temperature is maintained at the site of treatment.

[0281] FIG. 40 is a block diagram depicting an electrode array arranged in a multiplexed configuration allowing pairing of any of the positive electrodes 963 to any of the negative electrodes 964 to form a complete circuit. A positive electrode 963 may be paired with the

opposite negative electrode 964 or to any of the other negative electrodes 964 regardless of its location in the device. The device may include a plurality of thermocouples 962 and an RF output channel 961 assigned to each pair of electrodes for feedback. Temperature readings from two adjacent thermocouples 962 may be averaged to obtain a temperature reading for the region in which the circuit is located. In some embodiments, the two thermocouples 962 may be the thermocouples in the closest proximity to the positive electrode 963 and the negative electrode 964.

[0282] FIG. 41 is a block diagram depicting an electrode array arranged such that each electrode pair of the array of electrodes may have its own individual subsystem 970. An electrode pair may include a positive electrode 973 and a negative electrode 974. Each individual subsystem 970 may include controlled RF channels 971, a first thermocouple 972a, and a second thermocouple 972b to allow for independent temperature readings. In some embodiments, a temperature reading for an individual subsystem 970 may be obtained from the average temperature input signals of the neighboring thermocouples 972a and 972b. The temperature reading may act as a feedback control to ensure that proper temperature is maintained at the site of treatment.

[0283] FIG. 42A and 42B are block diagrams depicting an array of electrodes of a nasal treatment device. In some embodiments, the device may include a multiplexed configuration by providing functionality to allow pairing of any of the positive electrodes 973 to any of the negative electrodes 974 to form a complete circuit. A positive electrode 973 may be paired with the opposite negative electrode 974, or to any of the other negative electrodes 974 regardless of its location in the device. FIG. 42A shows one example where temperature readings may be the average of three adjacent thermocouples 972a, 972b, and 972c. FIG. 42B shows one example where temperature reading may be the average of four adjacent thermocouples 972a, 972b, 972c, and 972d. It will be appreciated that the average of any number of thermocouples may be used to obtain a temperature reading.

[0284] FIG. 43 is a block diagram depicting an array of electrodes of a nasal treatment device as depicted in FIG. 39. In some embodiments, positive electrodes 983 of the array of electrodes may share a common negative electrode 984. Each RF output channel may include a positive electrode 983 and the negative electrode 984. While the negative electrode 984 is common, each

positive electrode 983 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 982.

[0285] FIG. 44 is a block diagram depicting an array of electrodes of a nasal treatment device as depicted in FIG. 40. In some embodiments, positive electrodes 993 of the array of electrodes may share a common negative electrode 994. Each RF output channel may include a positive electrode 993 and the negative electrode 994. While the negative electrode 994 is common, each positive electrode 993 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 992.

[0286] Most, if not all, of the devices and methods have been described above for use without making an incision in tissue. These incision-free devices and methods may be highly advantageous for a number of reasons, one being that no incision is required. On the other hand, there may be cases in which one of the embodiments described above may be used in a procedure involving an incision. For example, if another surgical procedure is being performed in the airway, and that procedure involves making an incision in mucosa, in some embodiments, one of the devices described above may be inserted into the incision to access and treat submucosa, cartilage and/or other tissues below the mucosa. In other embodiments, such as those described immediately below, an incision may be formed exclusively for the treatment using one of the devices described herein. In alternative embodiments, the incision may be formed by the treatment device or by a separate device. Therefore, in general, any of the methods and devices described herein may be used for either incision-less procedures or for procedures that include an incision.

[0287] FIG. 45 illustrates an embodiment of a device 1000 and method for applying energy to submucosal tissues where the treatment device 1000 is advanced through an incision in the mucosa. Such a device 1000 and method may be used in the nasal valve area or any other suitable anatomy in the upper airway. In some embodiments, an incision 1004 may be created to apply treatment energy to a submucosal target tissue, for example the submucosa 1001, which is generally located between the mucosa 1002 and the cartilage 1007 in the nasal valve. The incision 1004 may be created by the treatment device 1000 or, alternatively, by a separate device,

such as a scalpel or any other cutting device. In some embodiments, the incision may extend to a portion of the submucosa 1001 to provide access to a target portion of the submucosa 1001. In some embodiments, a head portion 1009 of the device 1000 may be inserted through the incision 1004, such that electrodes 1003 of the head portion 1009 are in contact with the submucosa 1001. In some embodiments, the head portion 1009 may be in contact with the cartilage 1007 and/or the dermis 1008. A shaft portion 1005 of the device 1000 may be coupled to the head portion 1009 and extend to a handle portion 1006 of the device 1000, so that a user may hold the handle portion 1006 while energy is being applied to the target tissue. In some embodiments, the device 1000 may be coupled to an RF generator 1010 for providing a treatment energy. The treatment energy may include a continuous, intermittent, and/or any other pattern of treatment energy. In alternative embodiments, any other type of energy may be used. In fact, any of the embodiments or features of various embodiments described above may alternatively or additionally be used in performing an incision-based method, such as the one illustrated in FIG. 45.

[0288] FIG. 46A illustrates another embodiment of a method for applying energy to tissue through an incision 1011, for example in the nasal valve area of the upper airway. In this embodiment, the incision 1011 is made directly over a target tissue. The incision may be sized to accommodate the head portion 1009 of the device 1000. In some embodiments, the incision 1011 may be expanded by the head portion 1009 upon insertion of the head portion into the incision 1011. The head portion 1009 may include a relatively narrow portion at its tip that allows it to enter into the incision 1011. The incision 1011 may temporarily or permanently expand as a relatively wider part of the head portion 1009 passes through the incision 1011 during insertion of the device. Electrodes of the head portion 1009 may be positioned to come in contact with the target tissue upon insertion of the device 1000 into the incision 1011. For example, an array of electrodes may be positioned at the tip of the head portion 1009 to come into contact with a target tissue when the device 1000 is inserted through an incision opening 1011 that is directly over the target tissue. Upon coming into contact with the target tissue, the device 1000 may be used to apply energy to the target tissue using the array of electrodes.

[0289] FIG. 46B illustrates another alternative embodiment of a method for applying energy to tissues through an incision 1011 in the nasal valve area. In this embodiment, the incision 1011

is offset from a target tissue. The target tissue may be accessed by dissection or tunneling from the incision 1011 to the target tissue. It may be advantageous to create an offset incision 1011 to be closer to the opening of the nose or to reduce the chance of the incision 1011 reopening post-procedure. The use of an offset incision 1011 may mitigate a risk of creating an ulcer. The head portion 1009 of the device 1000 may be inserted through the offset incision 1011, which allows the device 1000 to pass through the mucosa 1002 to contact the submucosa 1001. The device 1000 may be tunneled through the submucosa 1001 to a target tissue. The target tissue may be adjacent to cartilage 1007 or the mucosa 1002, or it may be a region of tissue within the submucosa 1001. Electrodes of the head portion 1009 may be positioned to be in contact with the target tissue upon insertion of the device through the incision 1011 and dissection through the submucosa 1001. For example, an array of electrodes may be positioned around the circumference of the head portion 1009 to come into contact with the target tissue when the device 1000 is inserted through an incision. Upon coming into contact with the target tissue, the device 1000 may apply energy to the target tissue using the array of electrodes.

[0290] FIG. 47 illustrates an embodiment of a device 1020 for creating an incision in upper airway mucosa and treating one or more submucosal tissues. The device 1020 may include a blade 1013 for creating an incision in the nasal valve area or other portion of the upper airway. In some embodiments, the blade 1013 may be removable and/or retractable. The blade 1013 may create an incision directly over a target tissue or may create an incision offset from the target tissue. When the incision is offset from the target tissue, the blade 1013 may be used to dissect a path from the incision to the target tissue to contact the target tissue with an electrode array 1012 of the head portion 1009 of the device 1020. When the electrode array 1012 is contacted with the target tissue, the device 1020 may be used to apply energy through the electrode array 1012 to the target tissue.

[0291] In alternative embodiments, the blade 1013 may be replaced by any other suitable cutting member(s), such as but not limited to an electrode for cutting and optionally cauterizing tissue. As mentioned above, other incision-based treatment devices may include no cutting member, and whatever incision is used for a procedure may be formed with a separate cutting device.

[0292] Although various embodiments are described herein, the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and modifications and equivalents thereof. Thus, the scope of the present invention should not be limited by the disclosed embodiments, but should be determined only by a fair reading of the claims that follow.

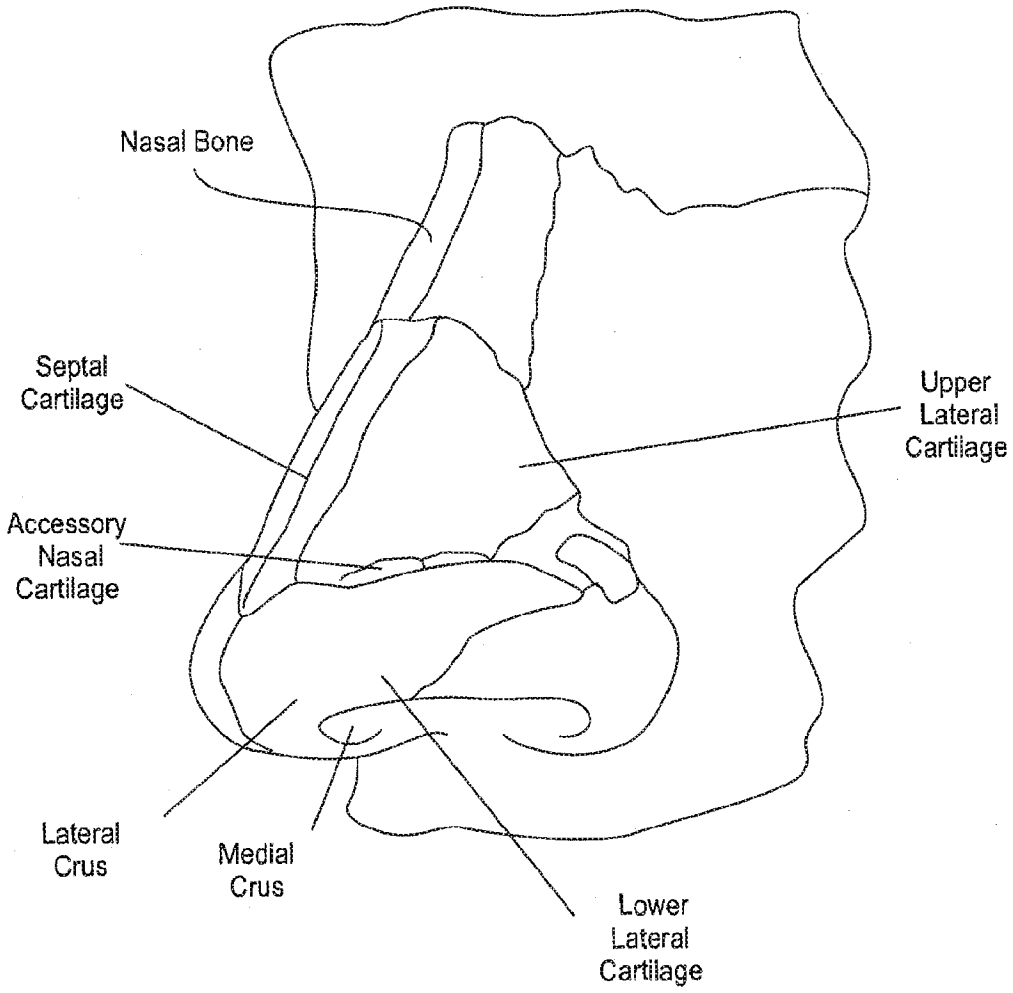

Nasal Bone
Septal Cartilage
Upper Lateral Cartilage
Accessory Nasal Cartilage
Lateral Crus
Medial Crus
Lower Lateral Cartilage

FIG. 1

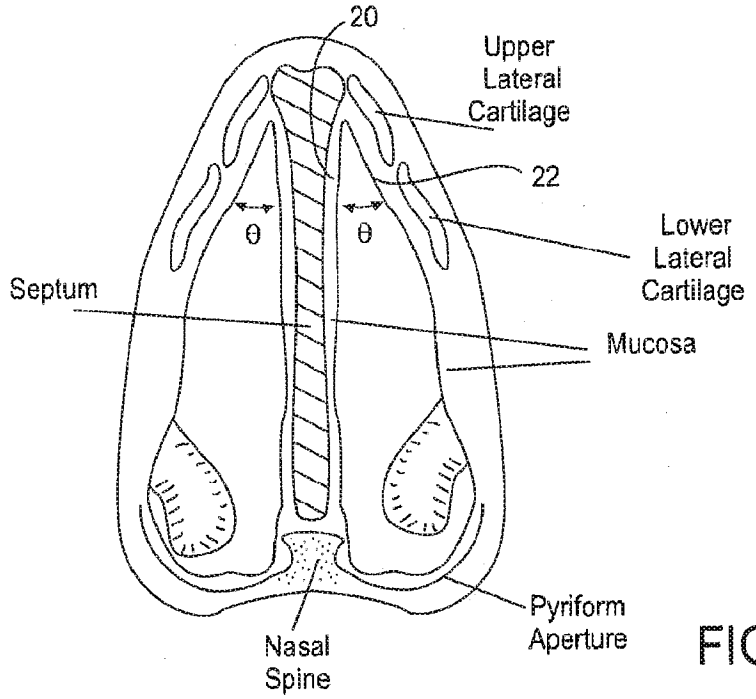

20
Upper
Lateral
Cartilage
22
θ
θ
Lower
Lateral
Cartilage
Septum
Mucosa
Pyriform
Aperture
Nasal
Spine

FIG. 2A

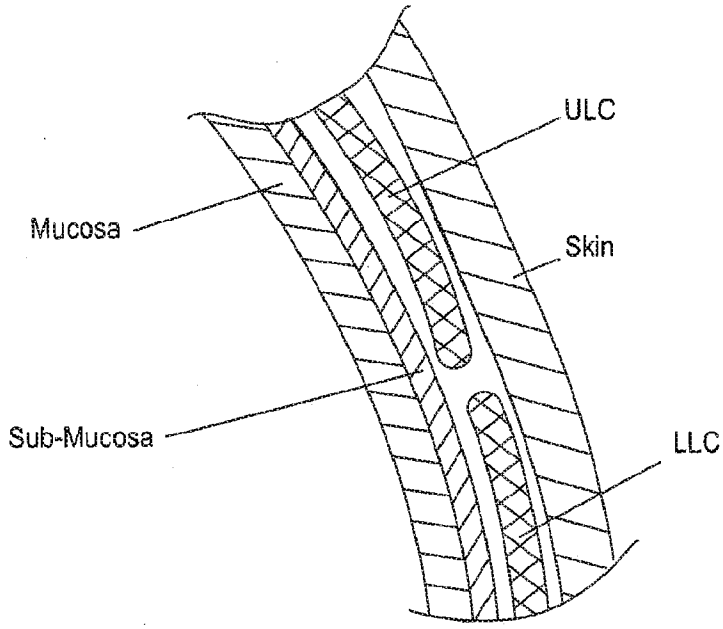

ULC
Mucosa
Skin
Sub-Mucosa
LLC

FIG. 2B

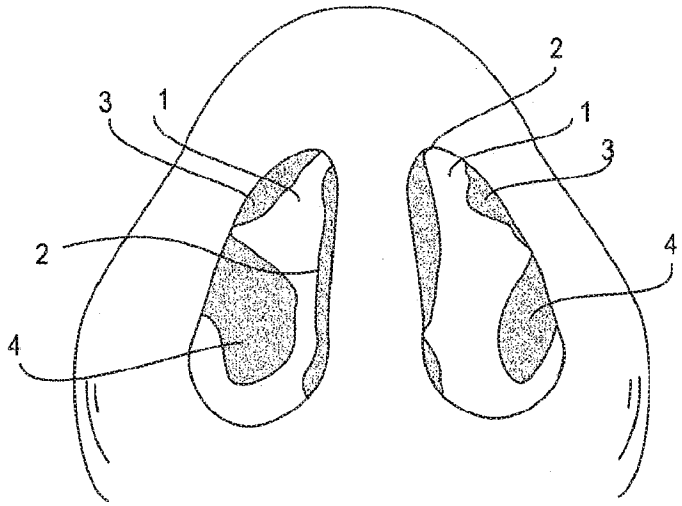


FIG. 2C

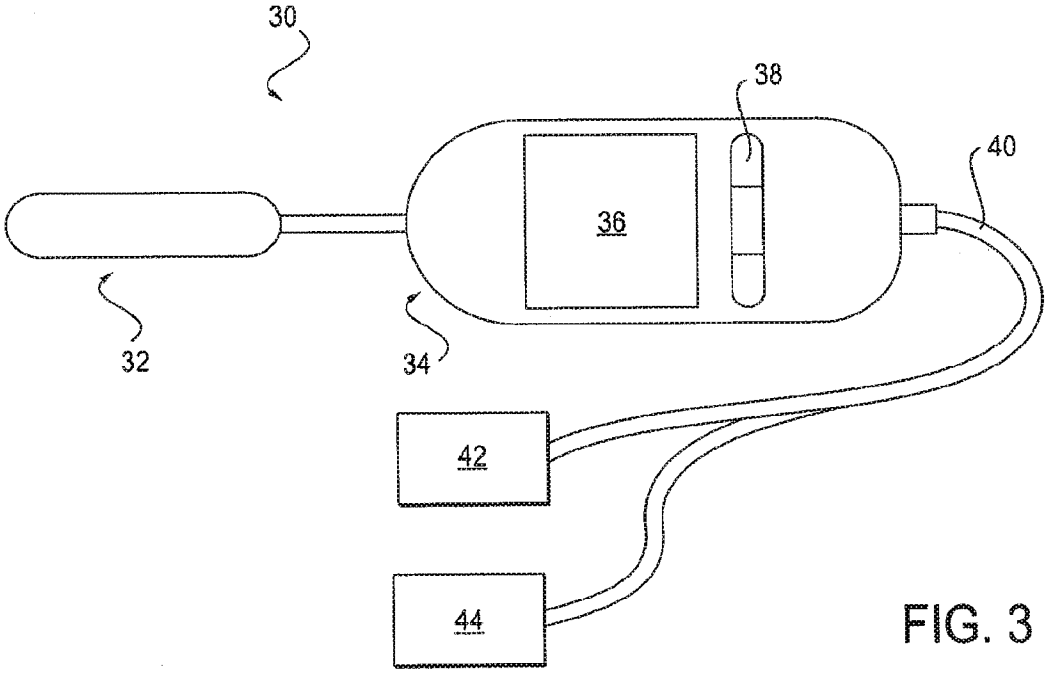


FIG. 3

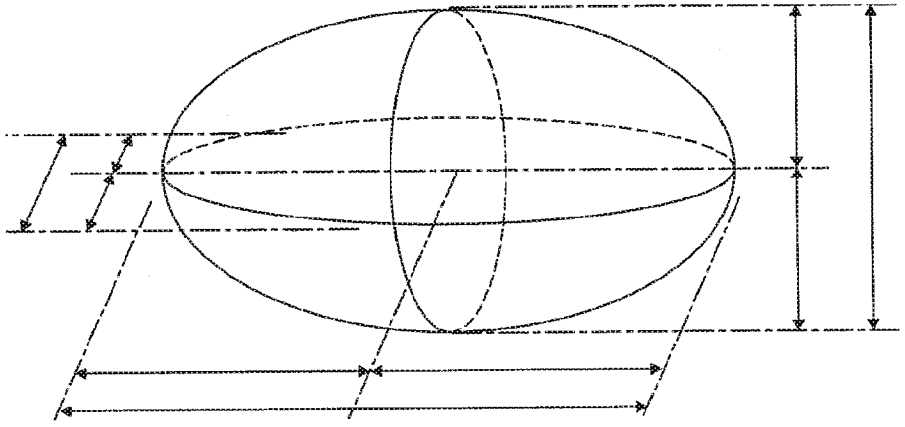


FIG. 4A

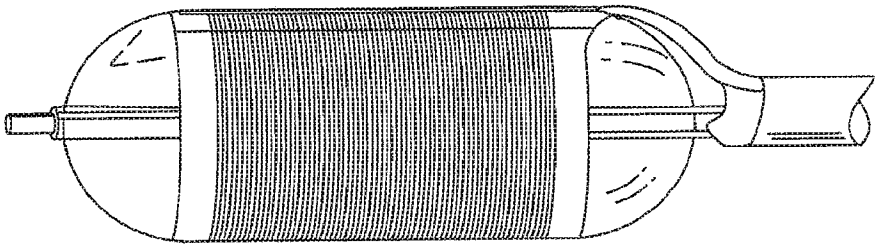


FIG. 4B

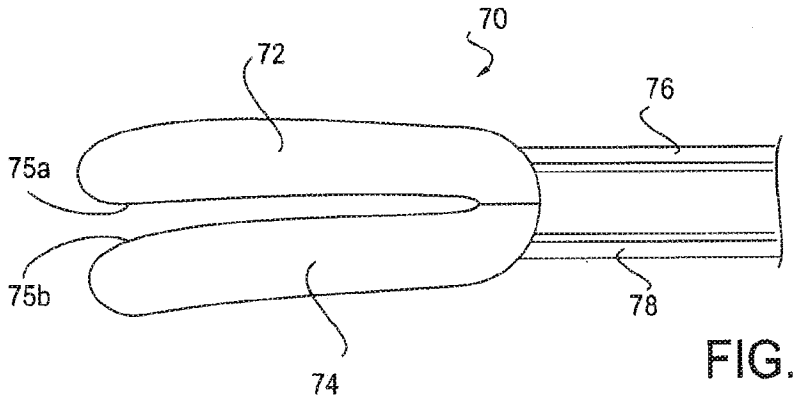


FIG. 4C

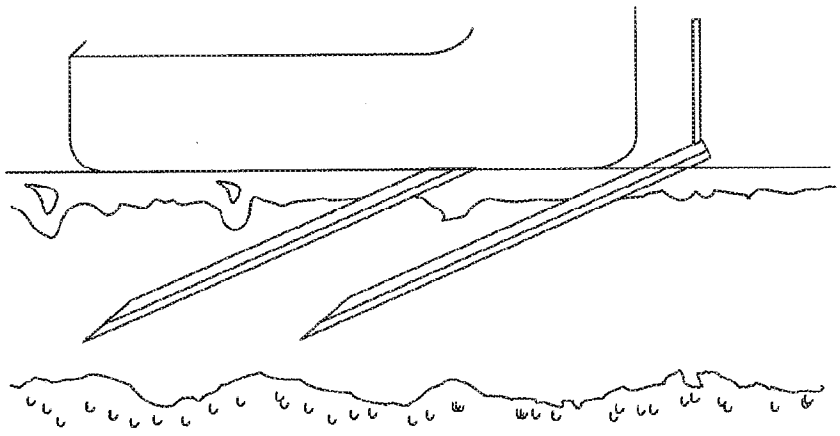


FIG. 4D

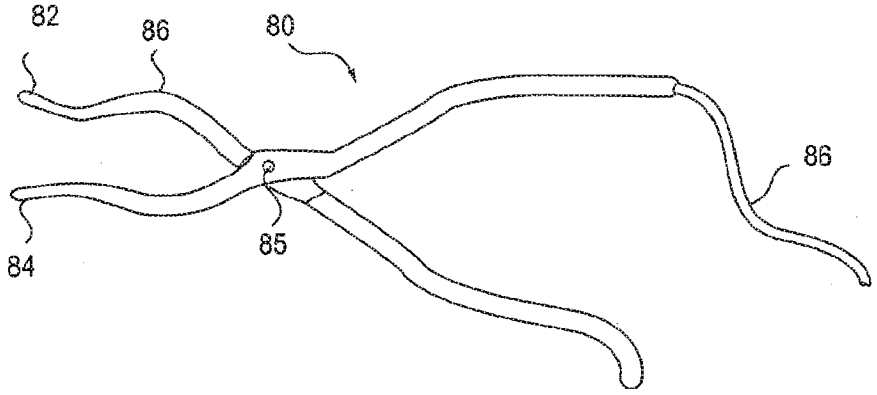


FIG. 5A

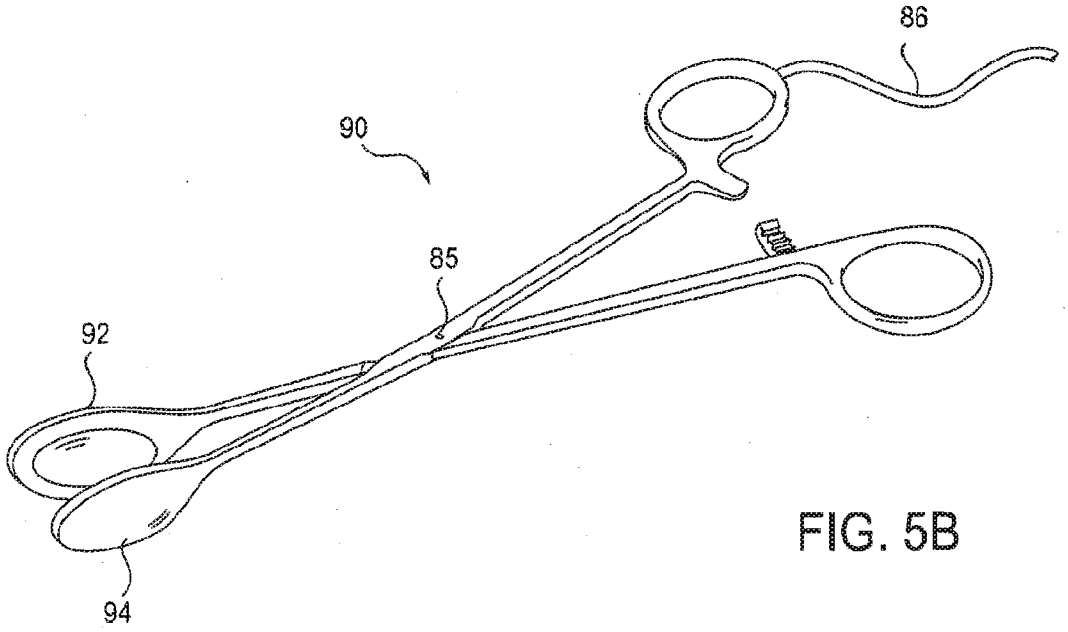


FIG. 5B

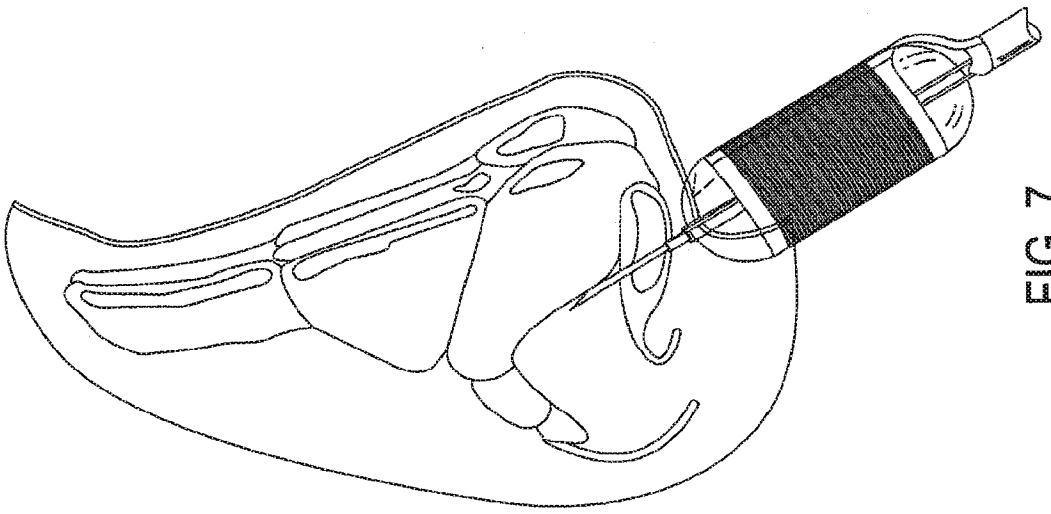


FIG. 7

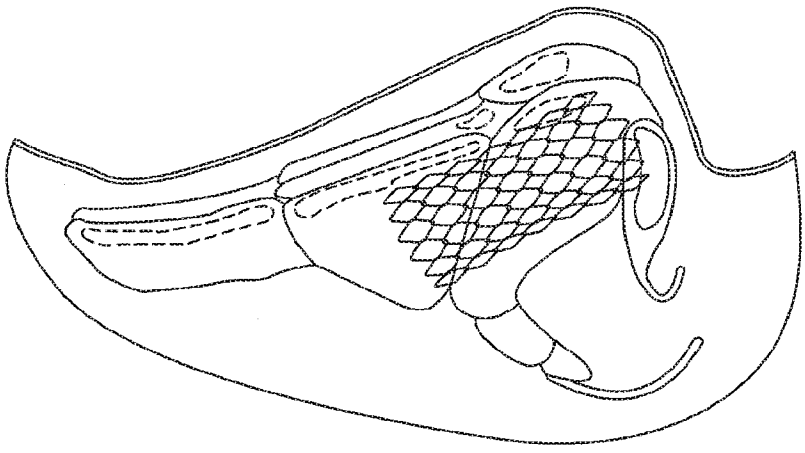


FIG. 6

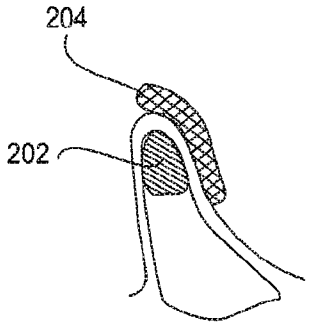


FIG. 8A

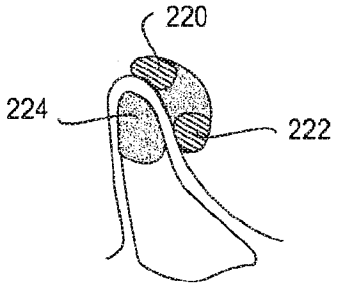


FIG. 8C

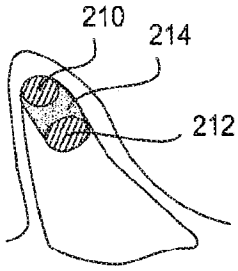


FIG. 8B

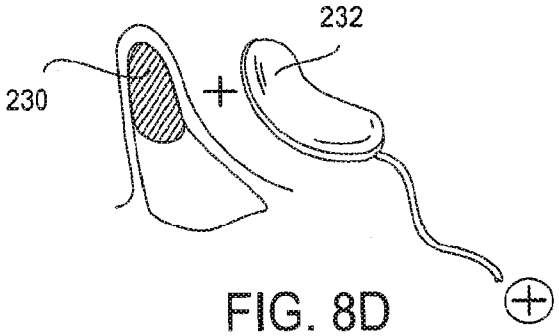


FIG. 8D

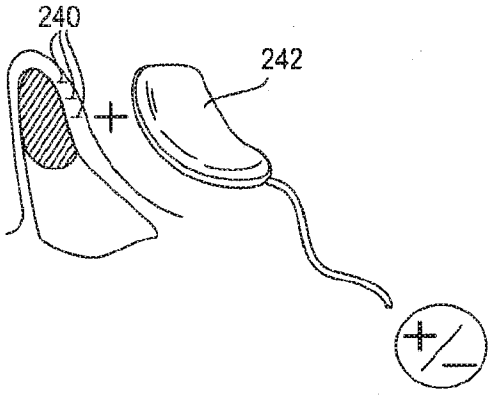


FIG. 8E

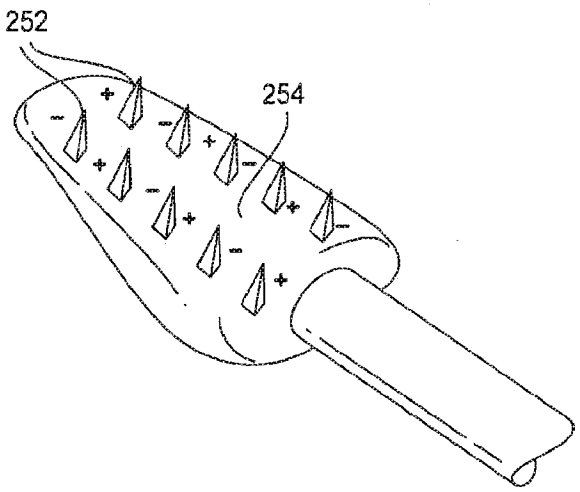


FIG. 8F

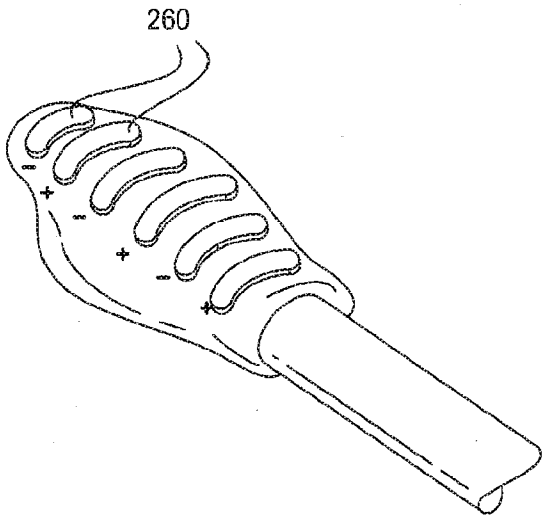


FIG. 8G

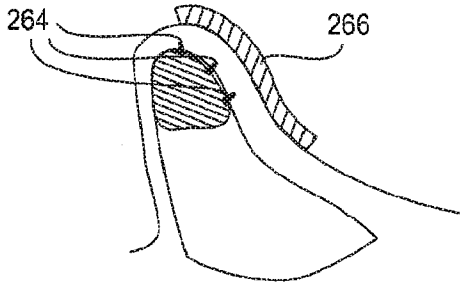


FIG. 8H

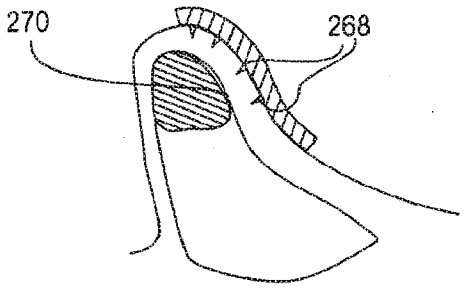


FIG. 8I

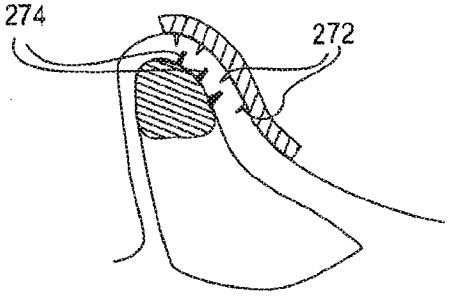


FIG. 8J

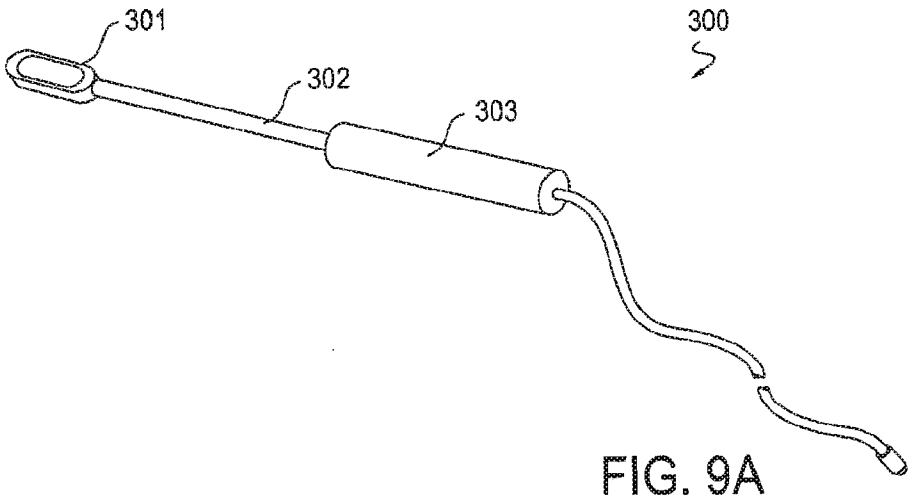


FIG. 9A

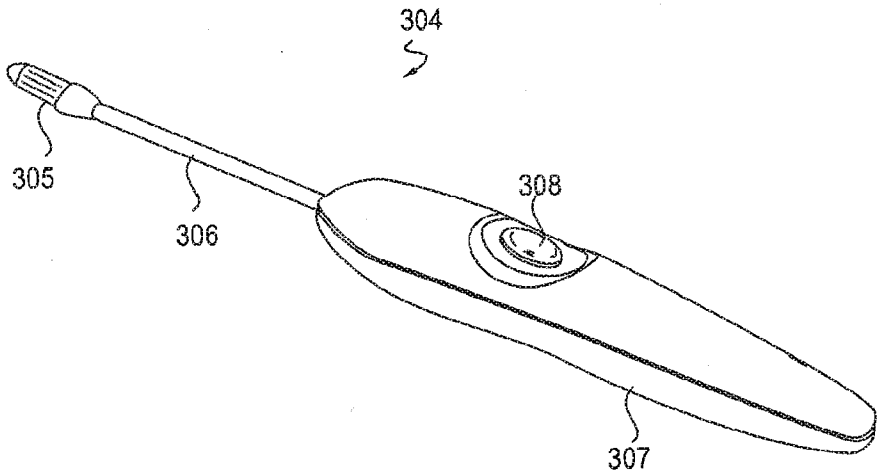


FIG. 9B

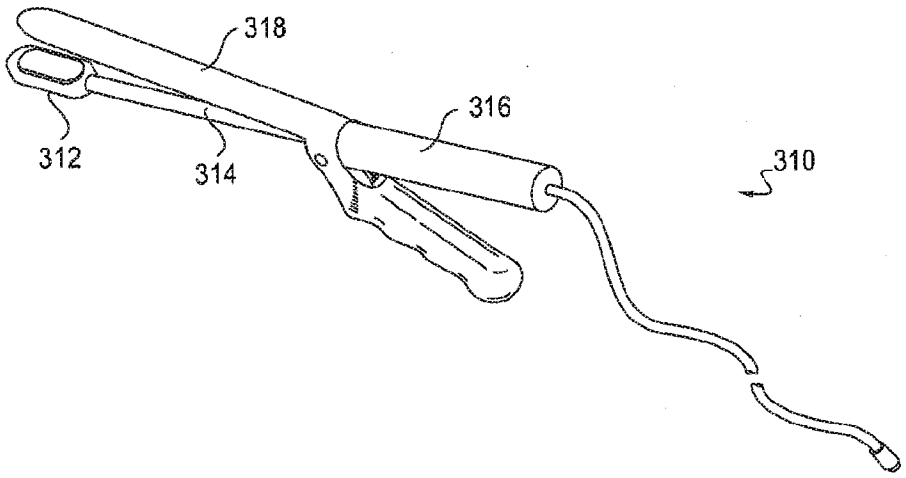


FIG. 10A

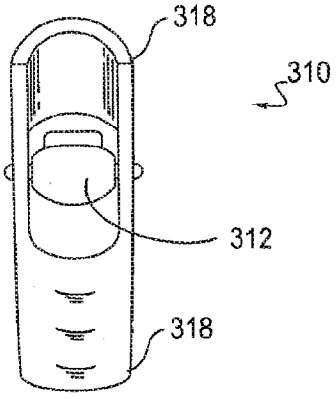


FIG. 10B

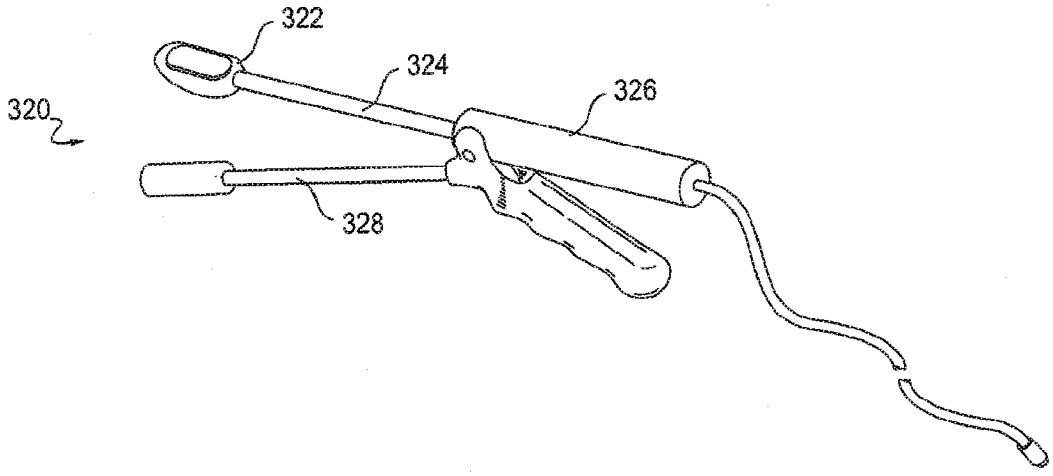


FIG. 11A

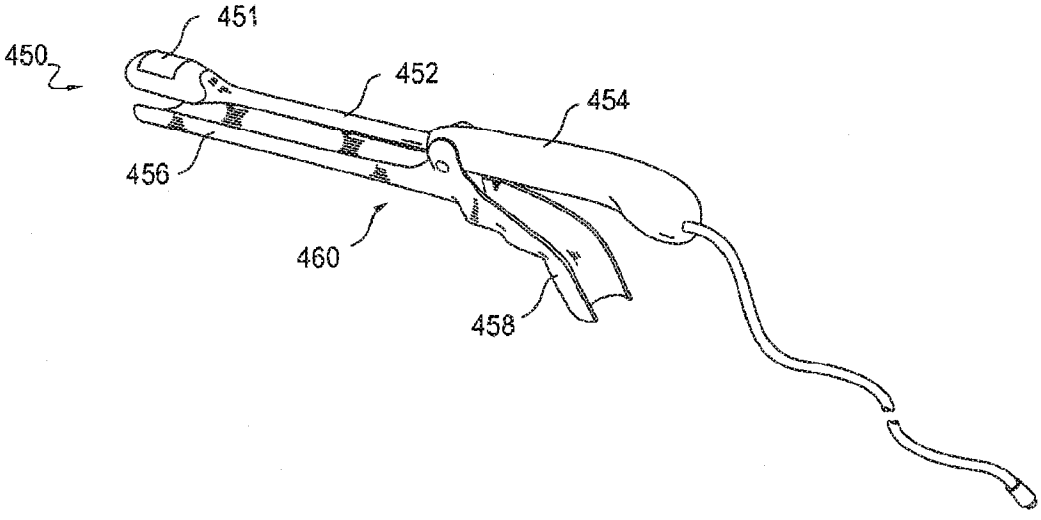


FIG. 11B

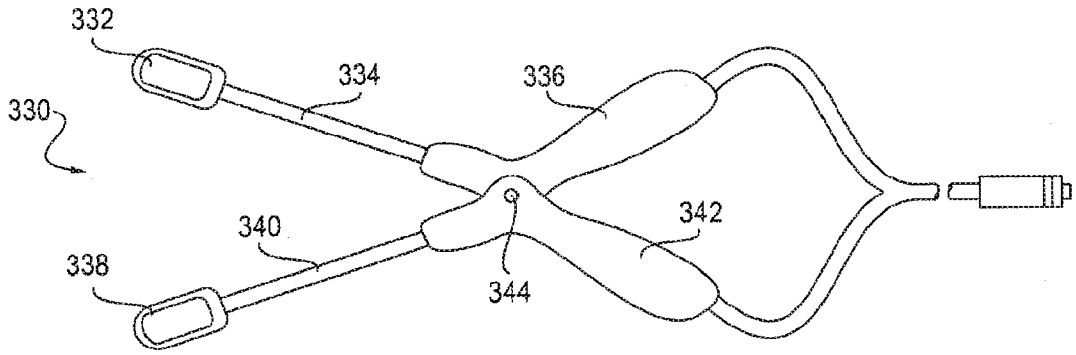


FIG. 12A

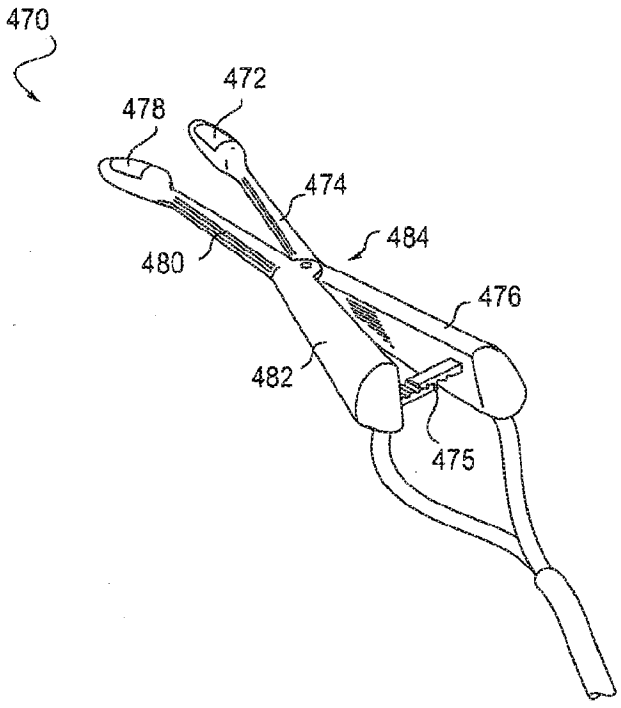


FIG. 12B

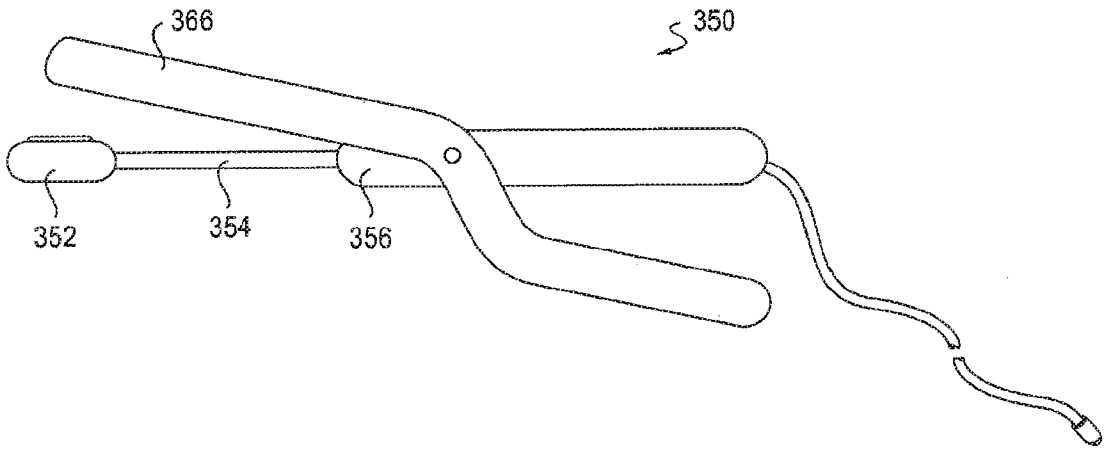


FIG. 13A

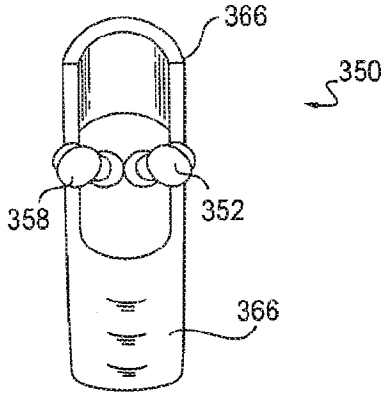


FIG. 13B

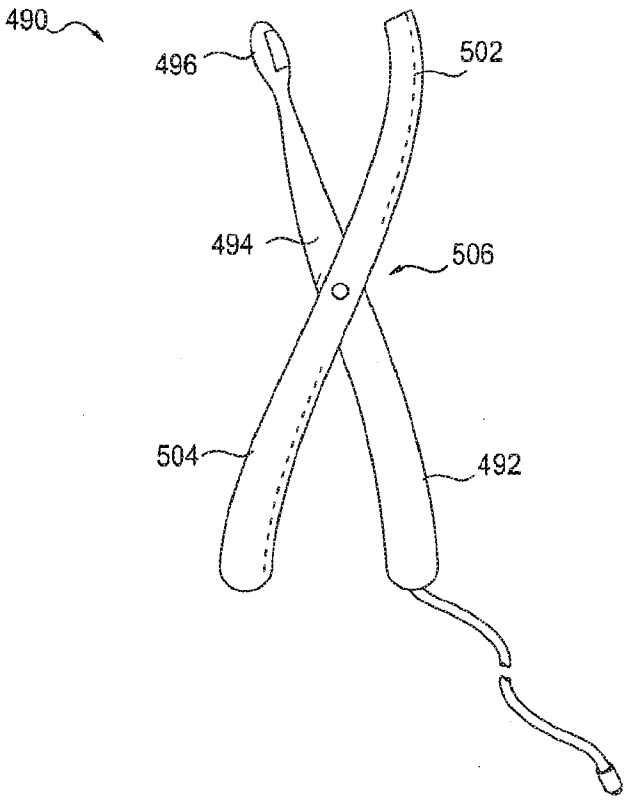


FIG. 13C

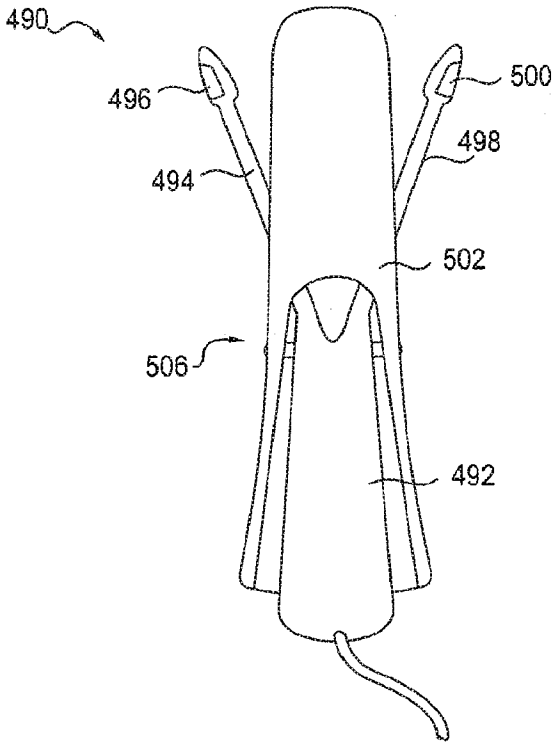


FIG. 13D

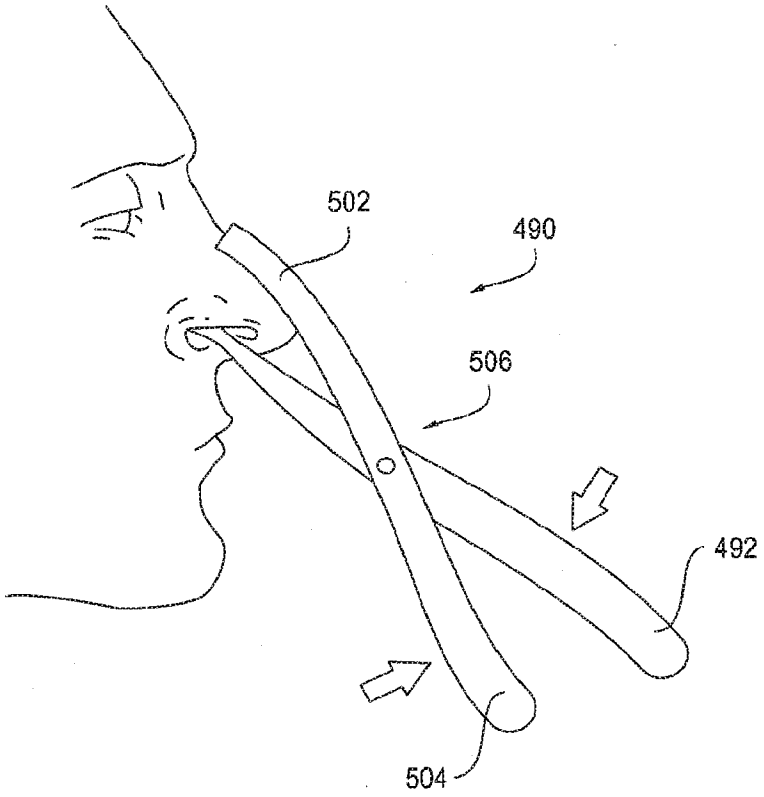


FIG. 13E

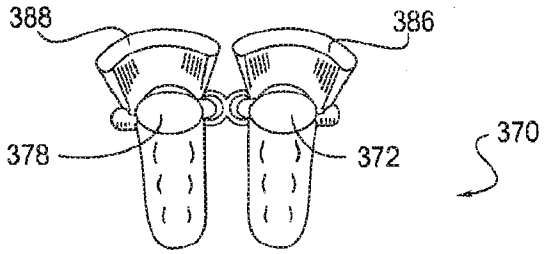


FIG. 14B

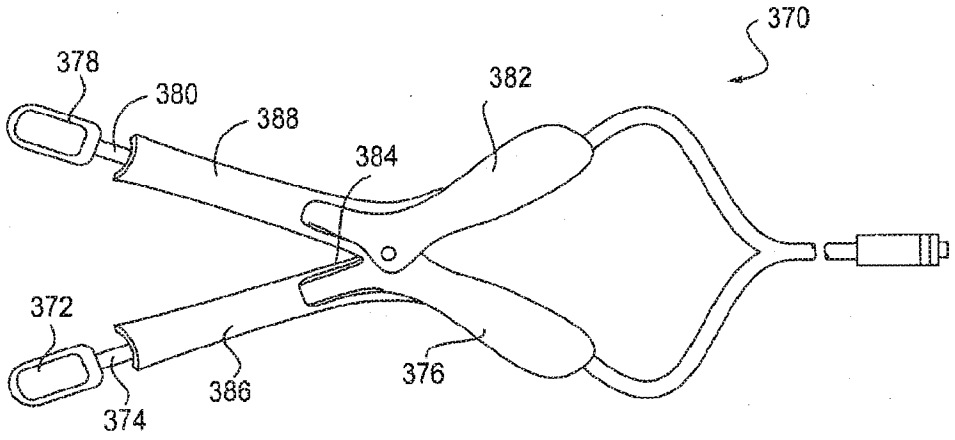


FIG. 14A

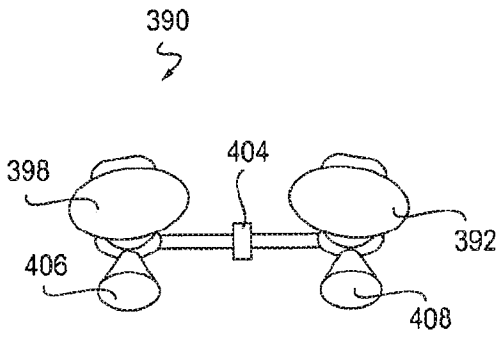


FIG. 15A

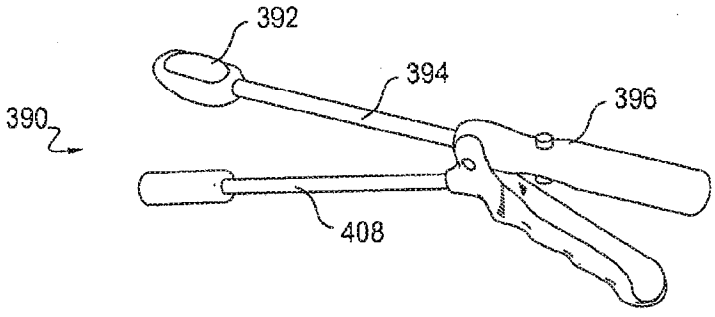


FIG. 15B

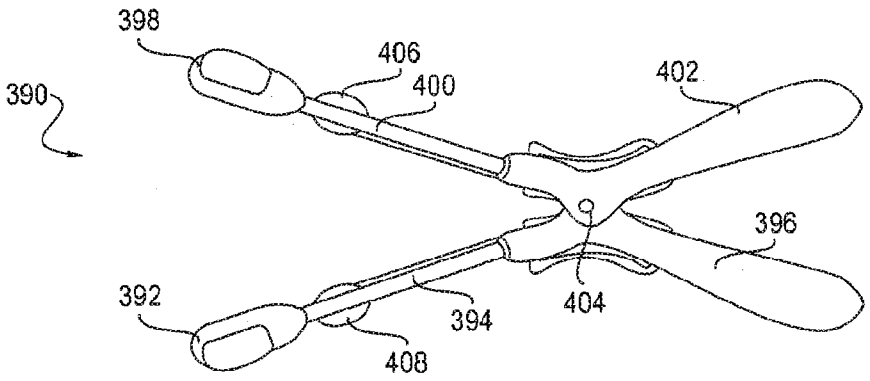


FIG. 15C

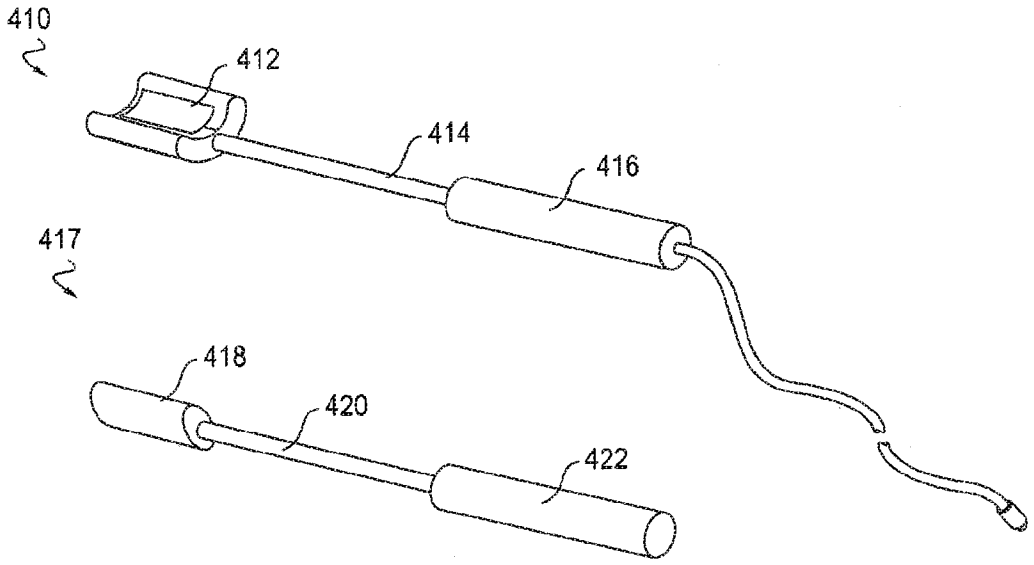


FIG. 16

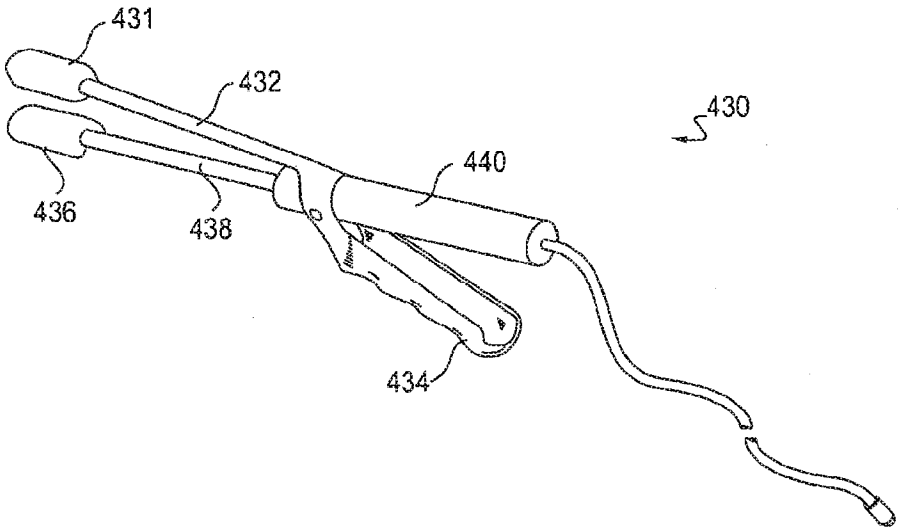


FIG. 17A

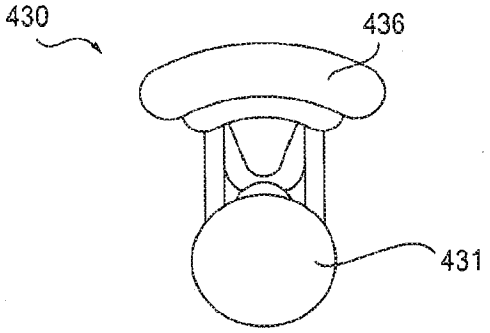


FIG. 17B

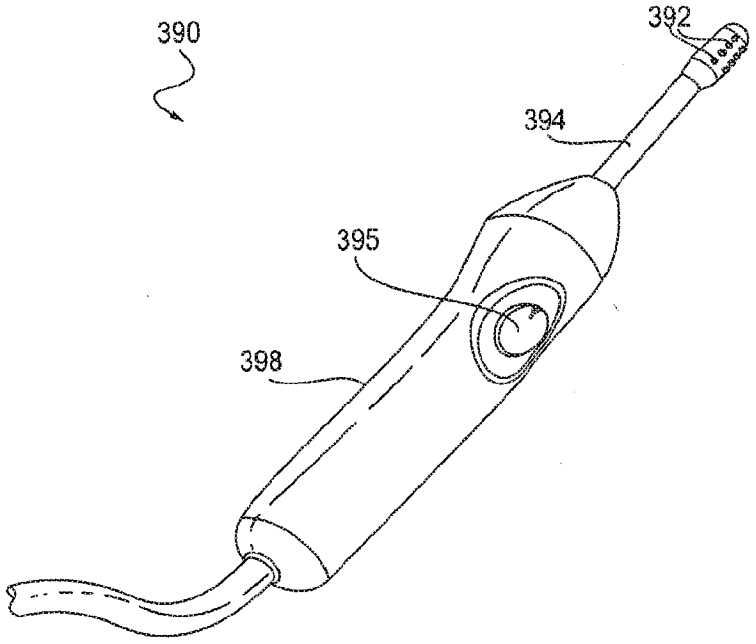


FIG. 18

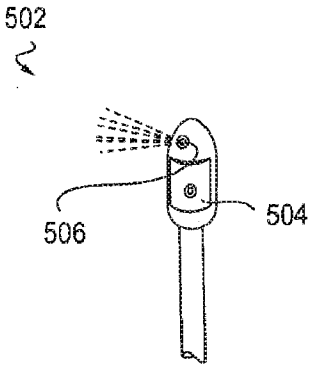


FIG. 19A

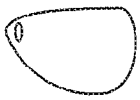


FIG. 19B

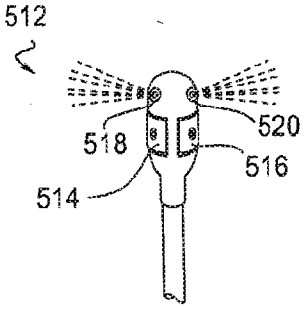


FIG. 20A



FIG. 20B

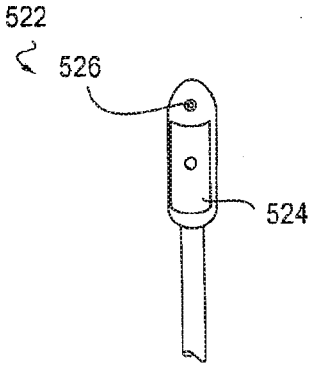


FIG. 21A

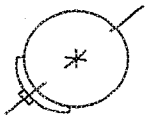


FIG. 21B

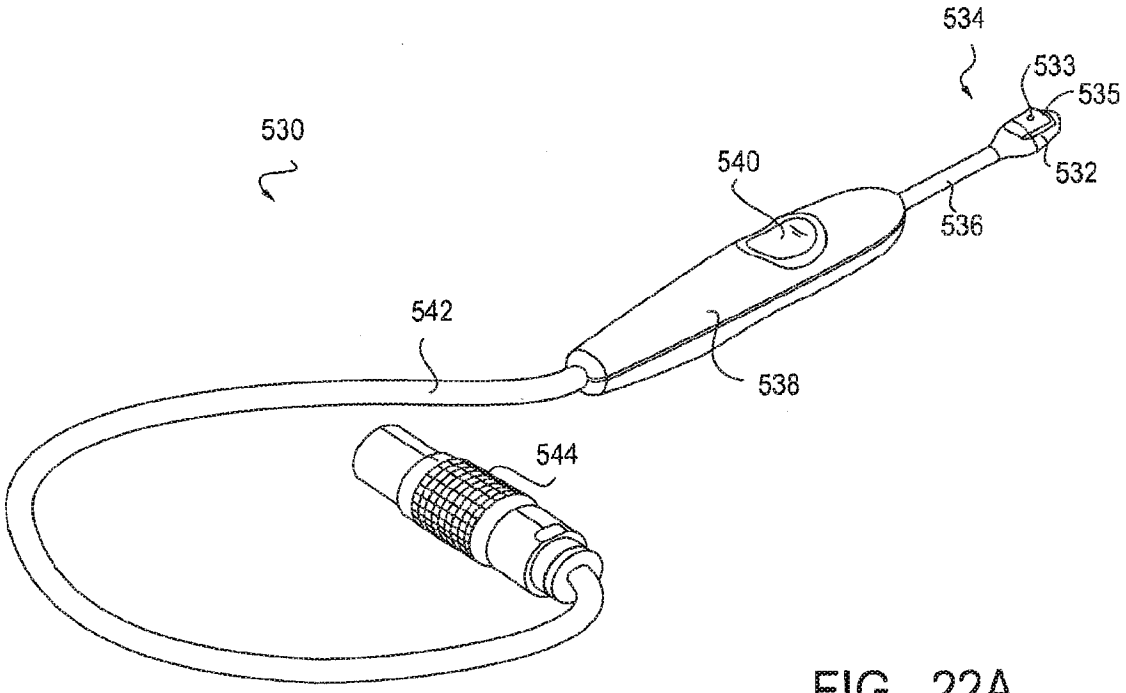


FIG. 22A

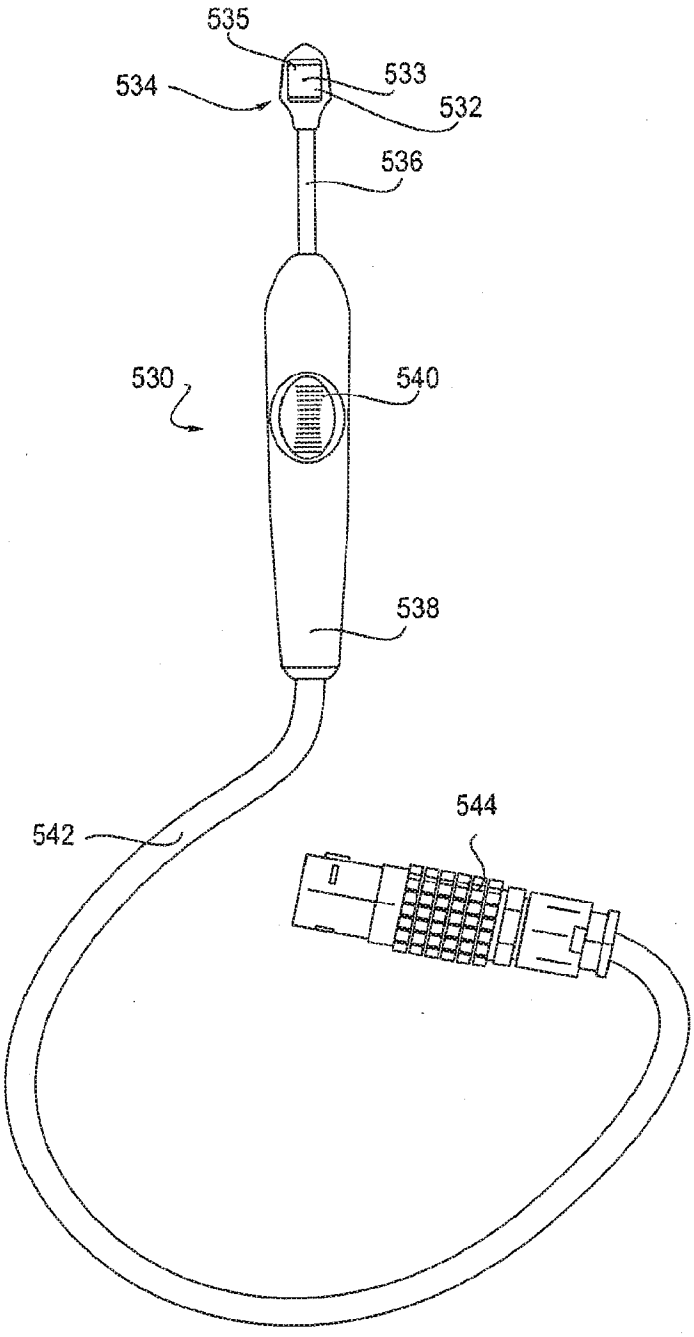


FIG. 22B

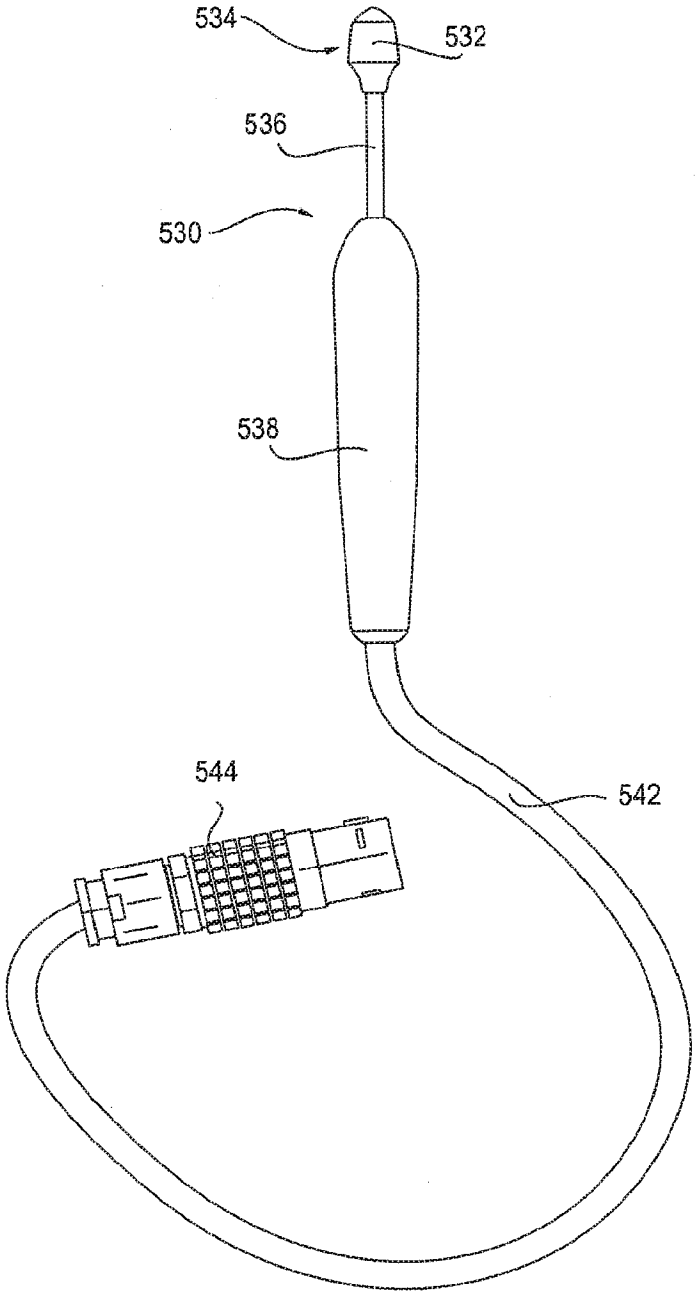


FIG. 22C

FIG. 22D

FIG. 22E

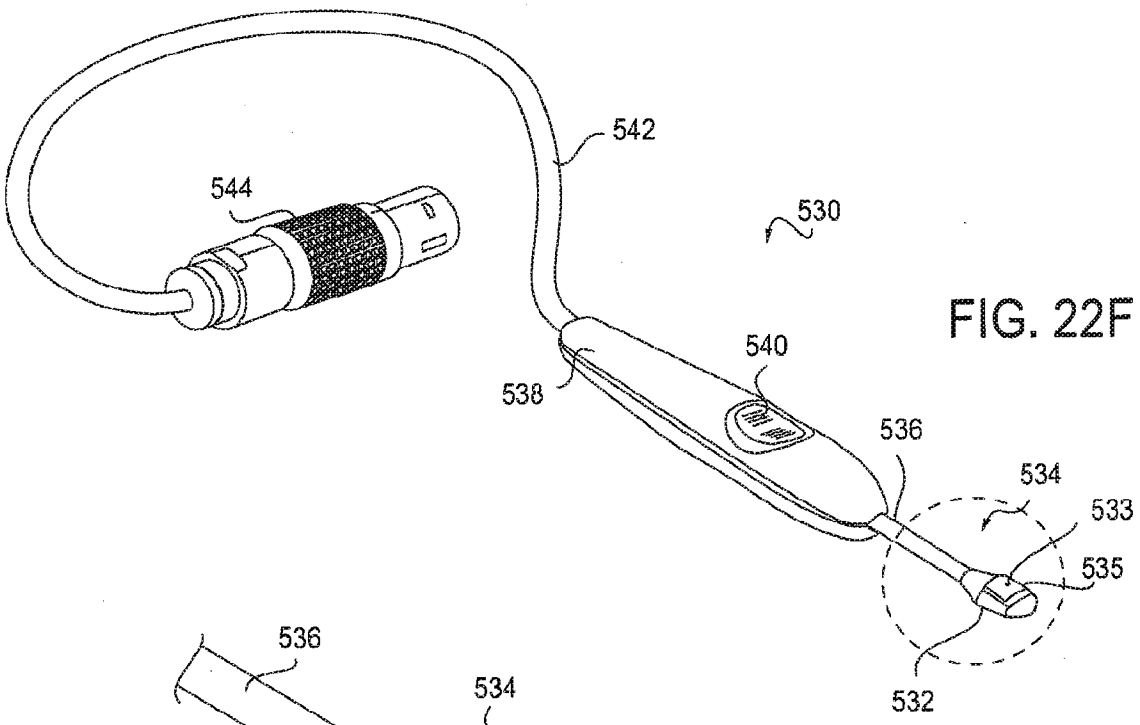


FIG. 22F

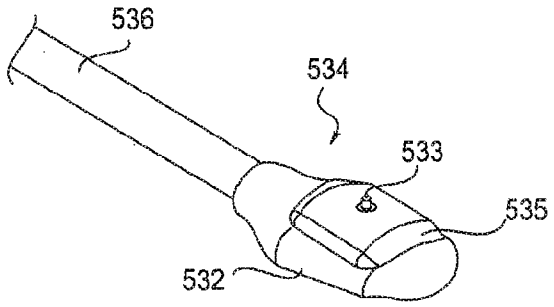


FIG. 22G

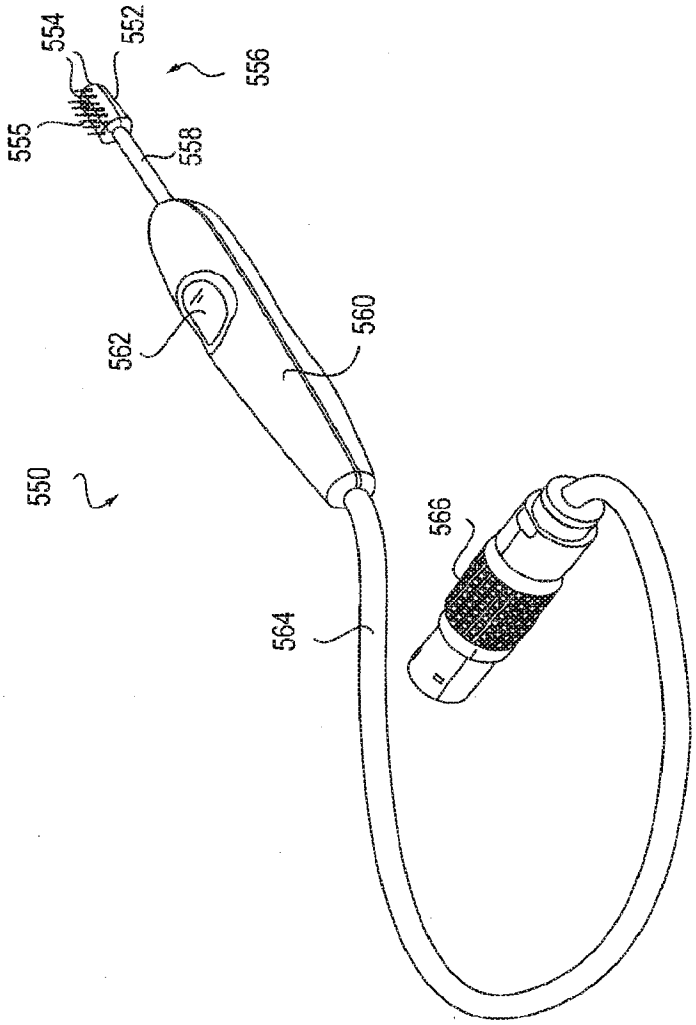


FIG. 23A

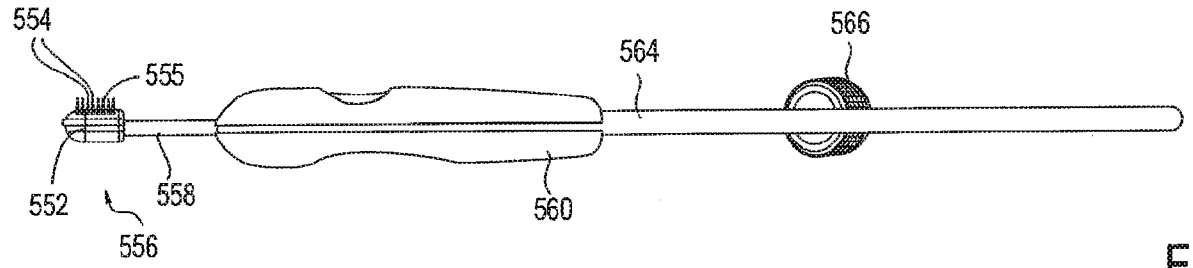


FIG. 23B

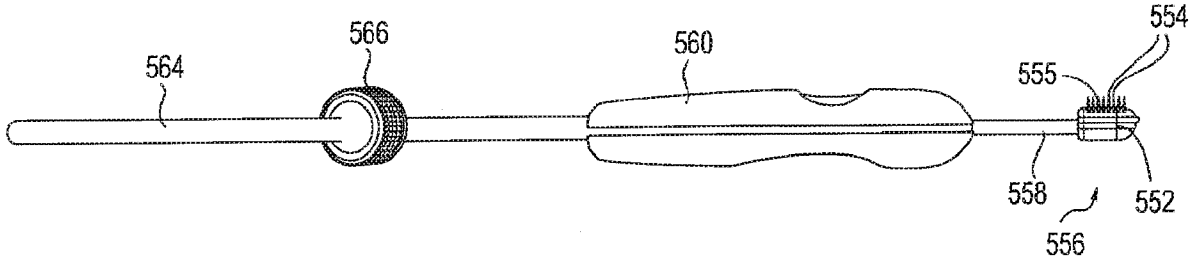


FIG. 23C

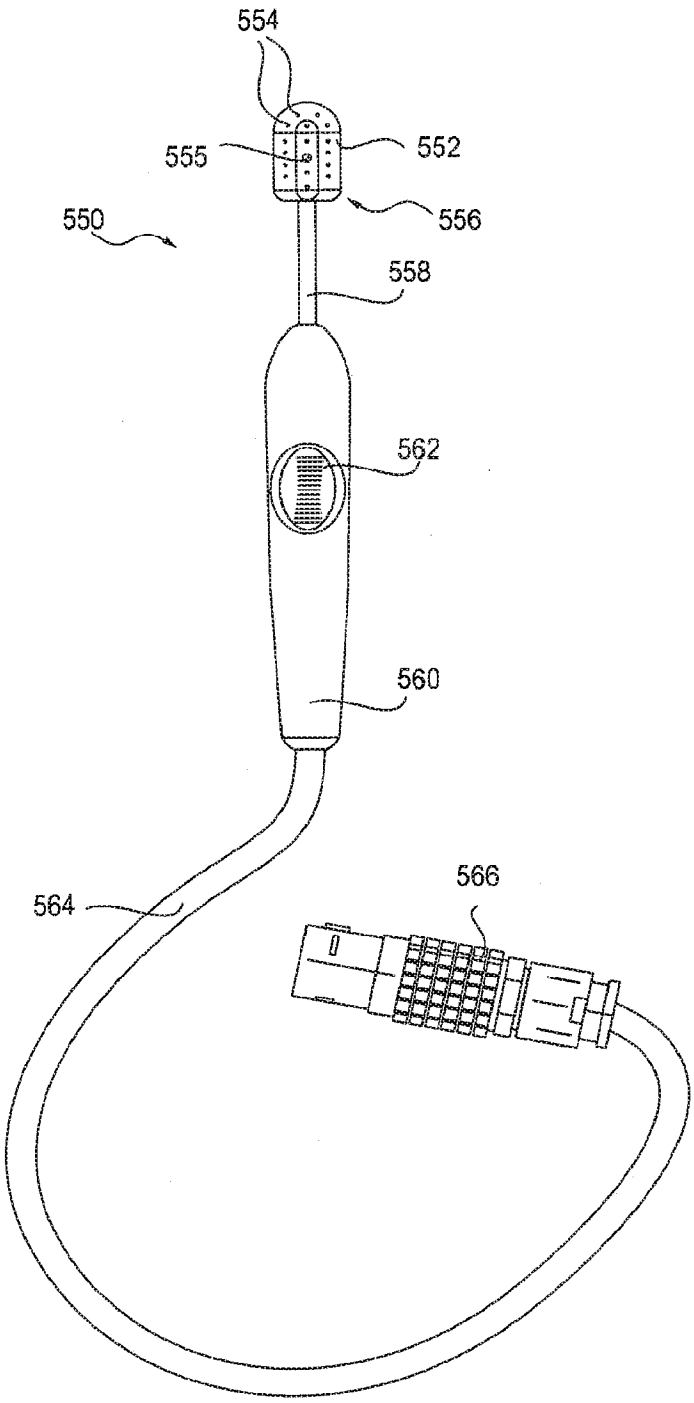


FIG. 23D

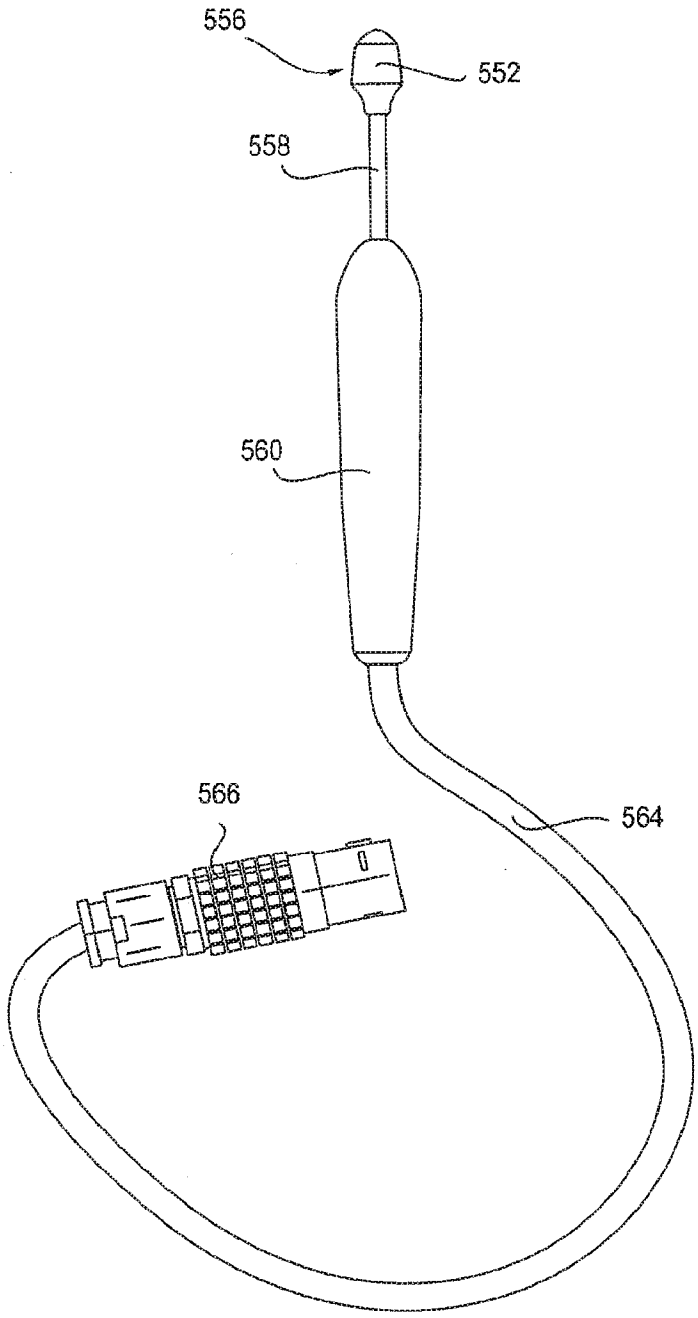


FIG. 23E

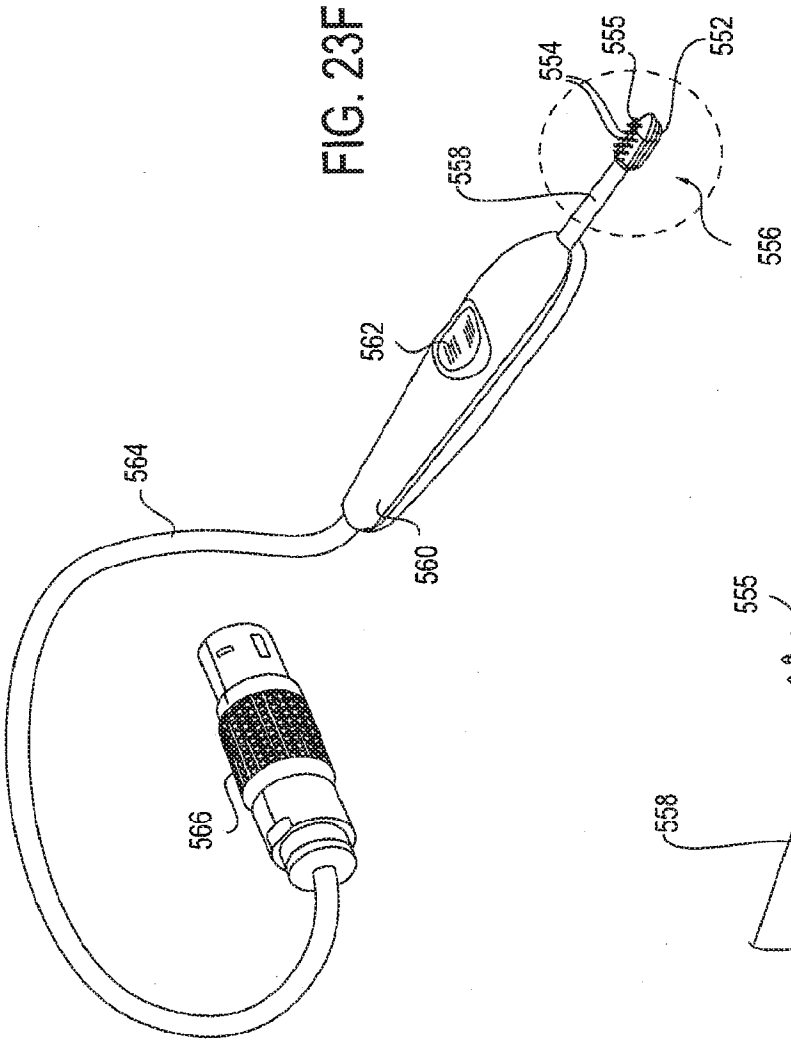


FIG. 23F

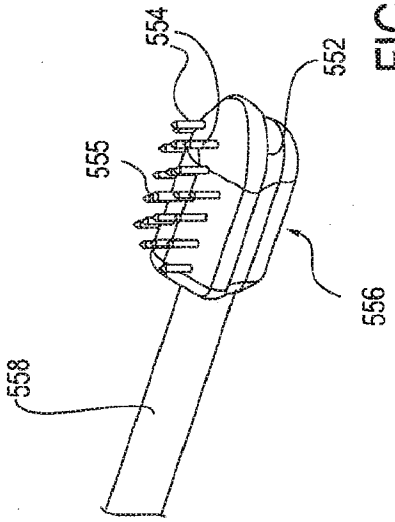


FIG. 23G

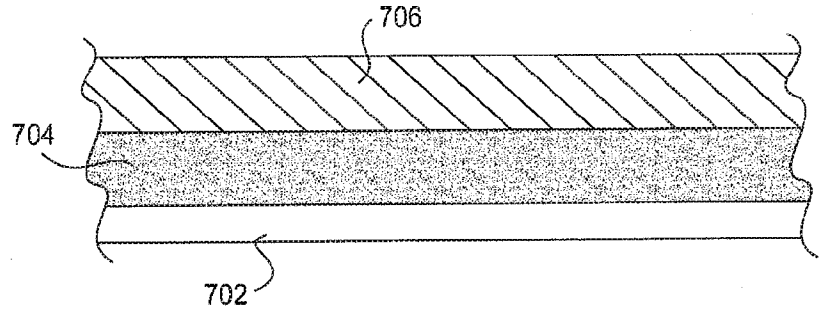


FIG. 24A

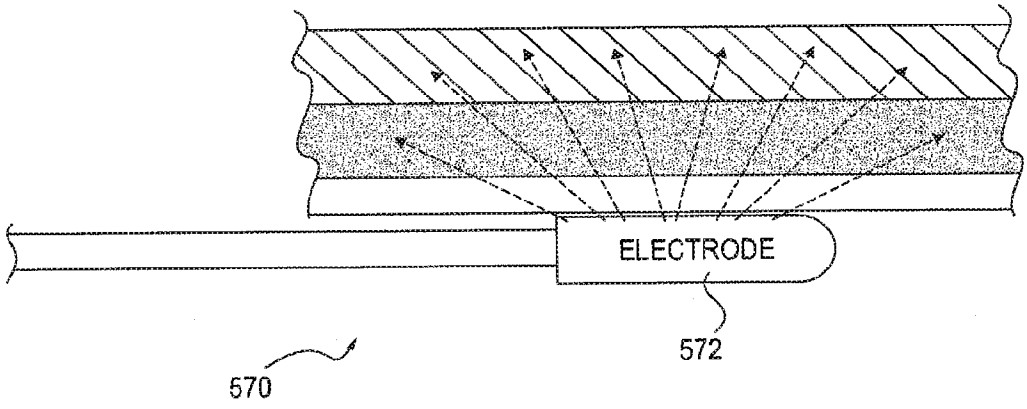


FIG. 24B

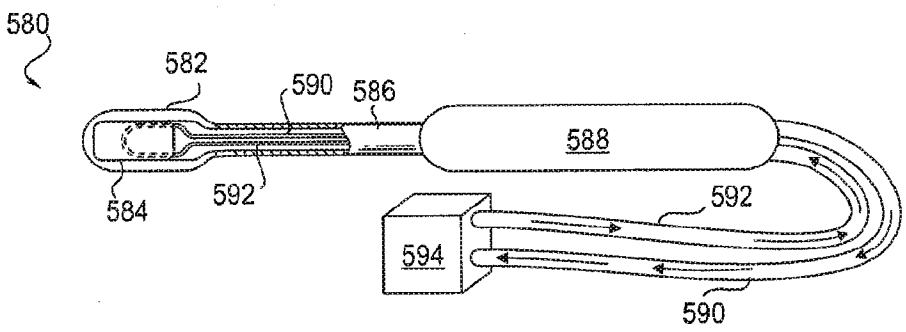


FIG. 25A

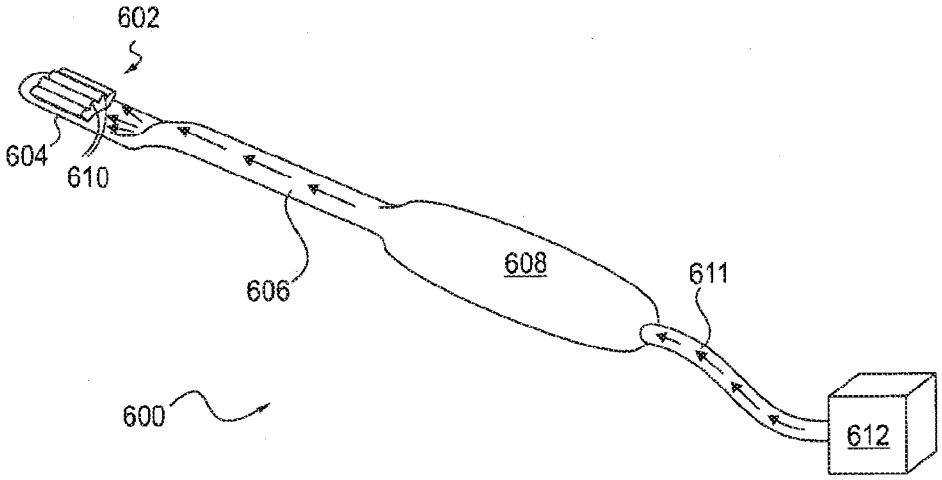


FIG. 25B

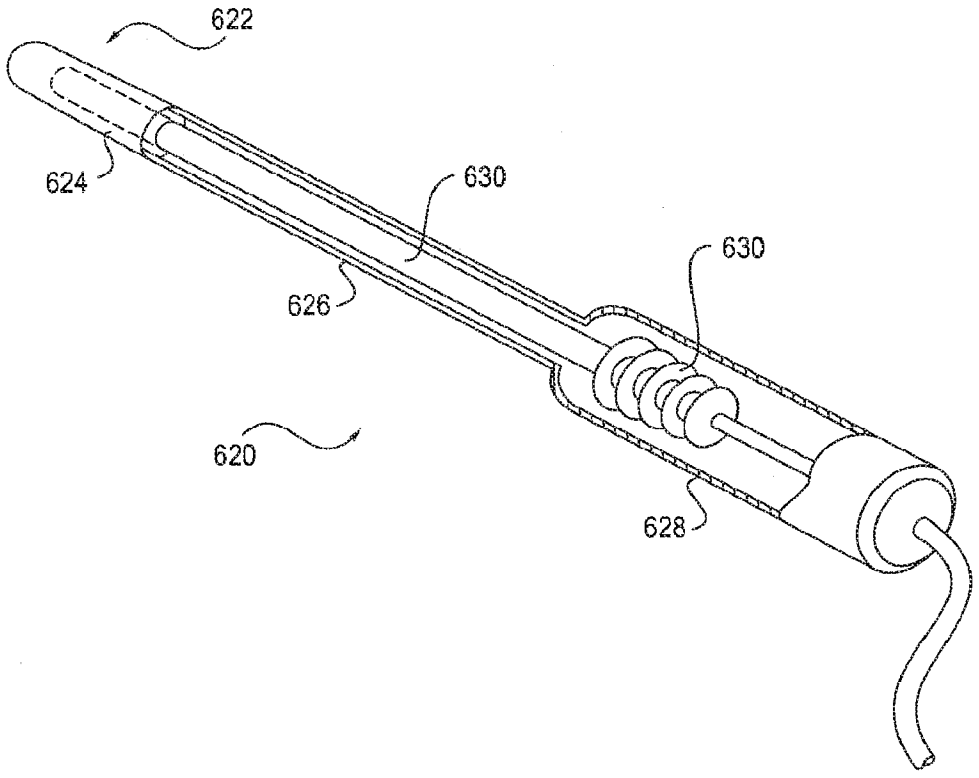


FIG. 26

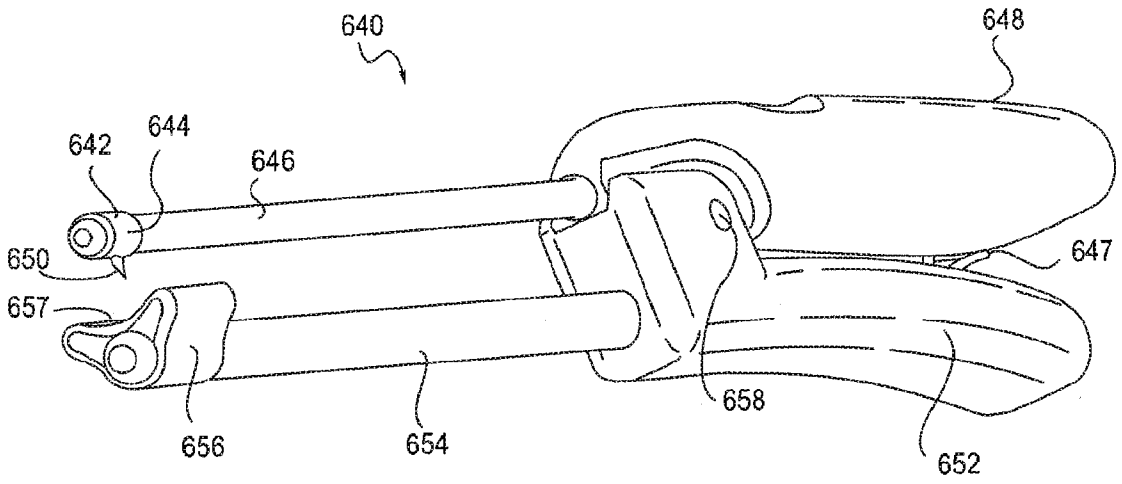


FIG. 27

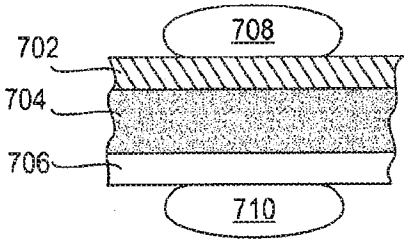


FIG. 28A

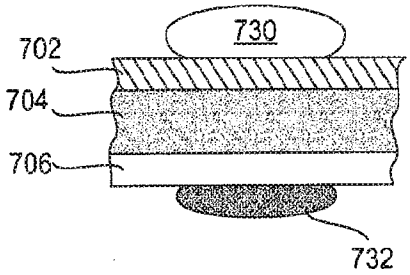


FIG. 28B

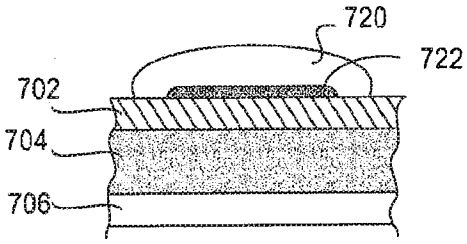


FIG. 28C

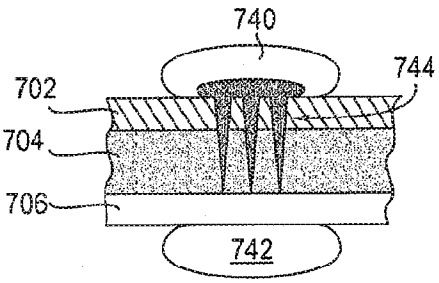


FIG. 28D

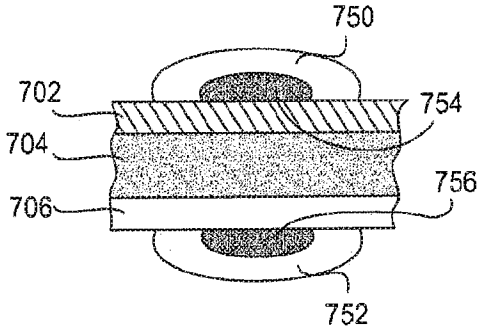


FIG. 28E

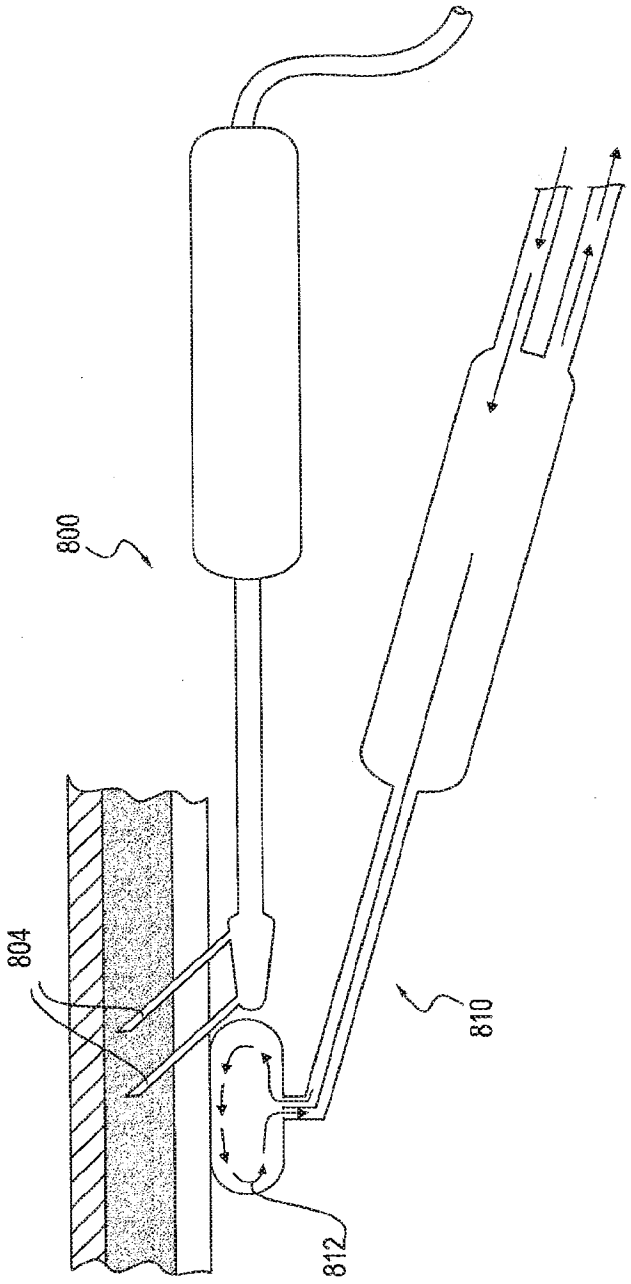


FIG. 29



FIG. 30A

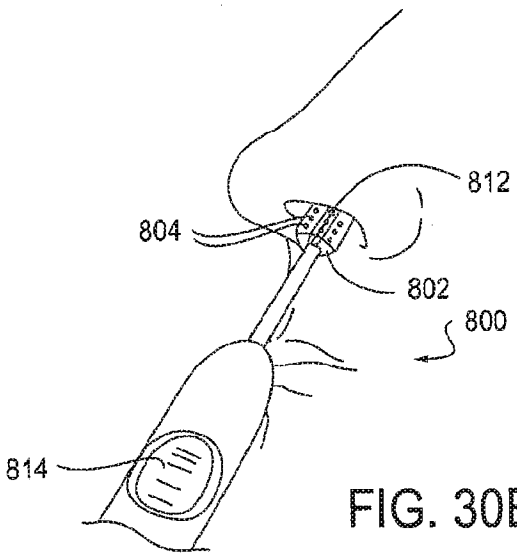


FIG. 30B

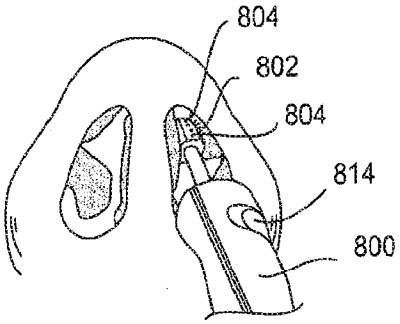


FIG. 30C

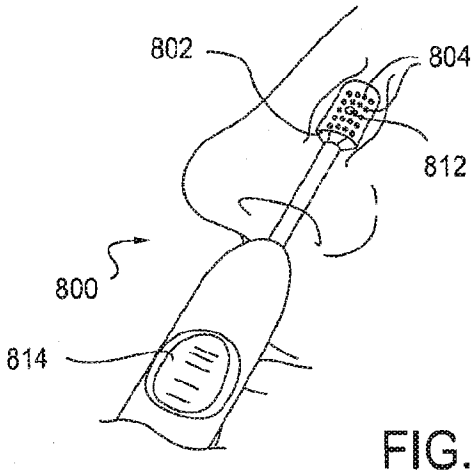


FIG. 30D

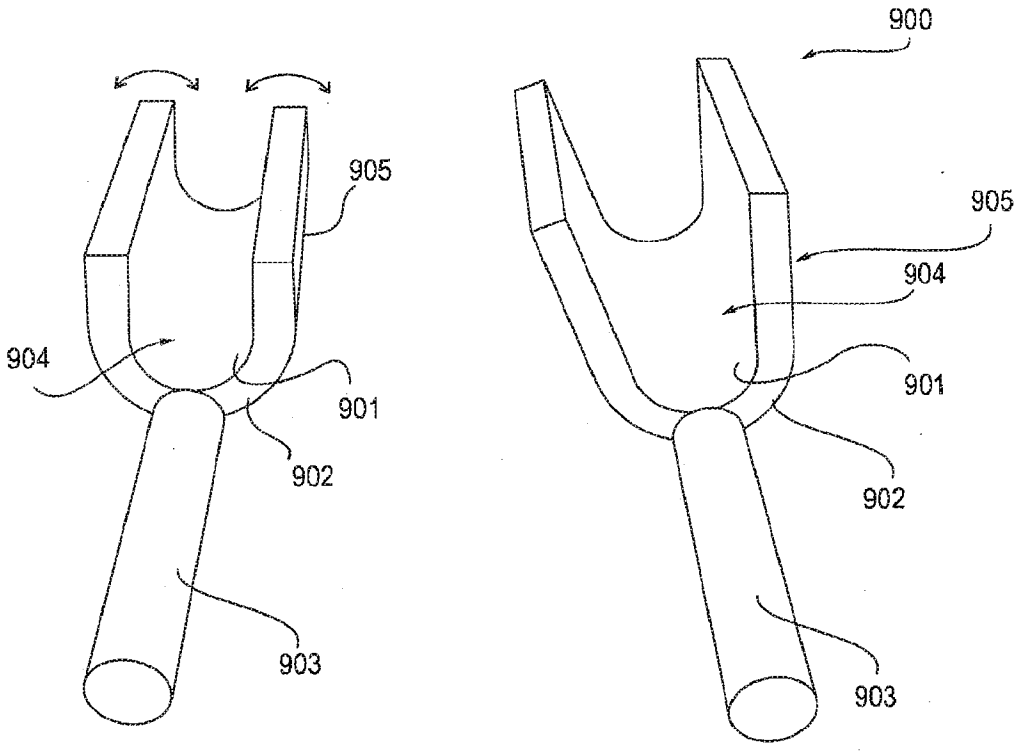


FIG. 31

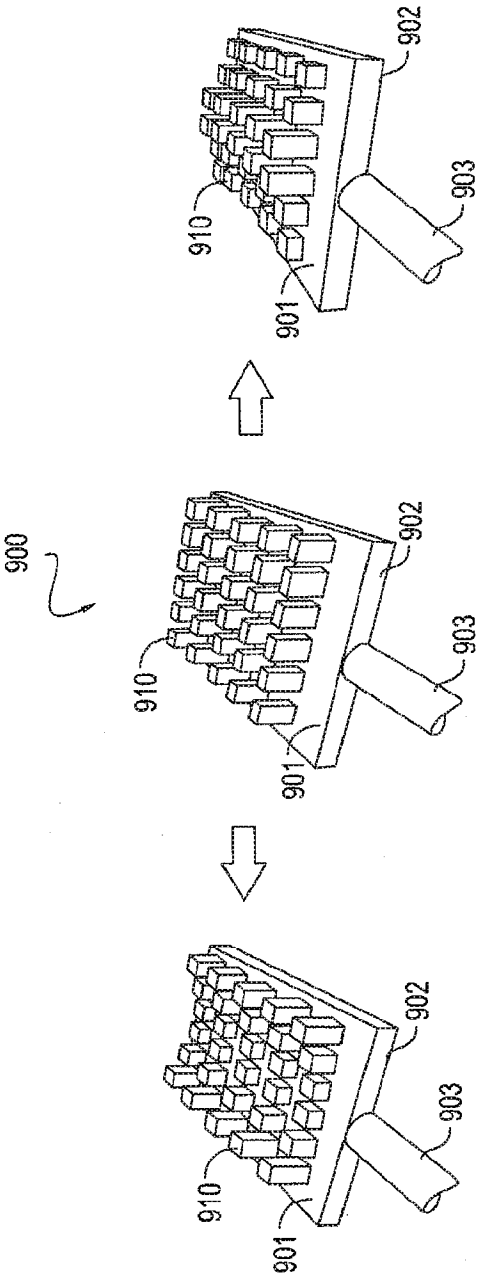


FIG. 32A

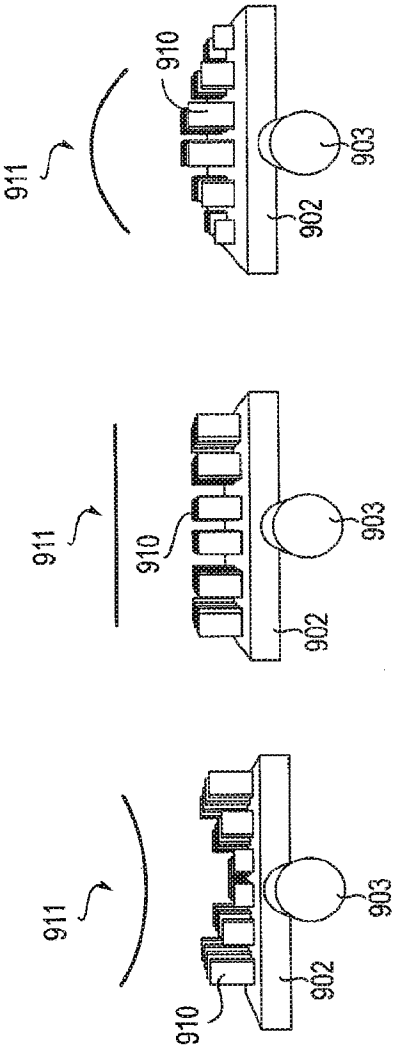


FIG. 32B

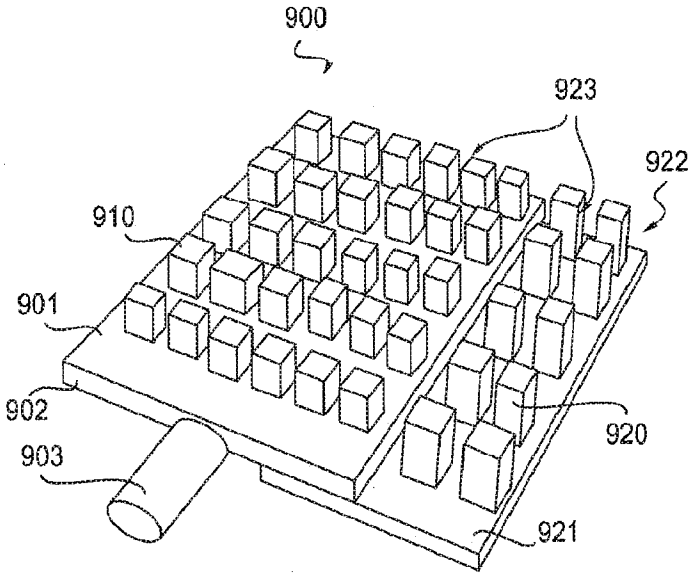


FIG. 33

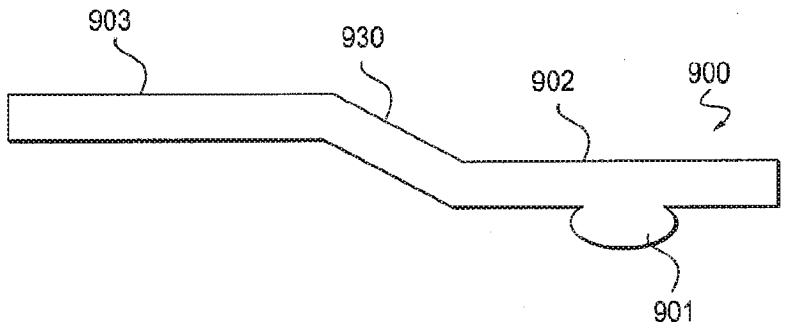


FIG. 34

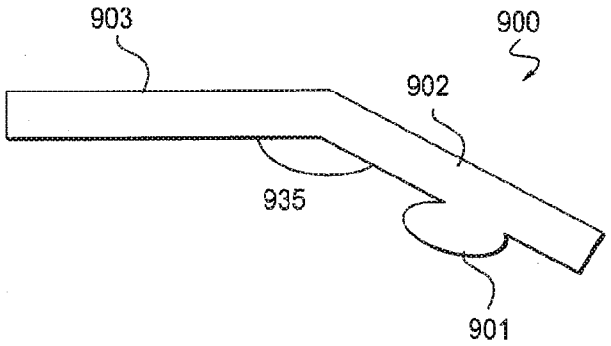


FIG. 35

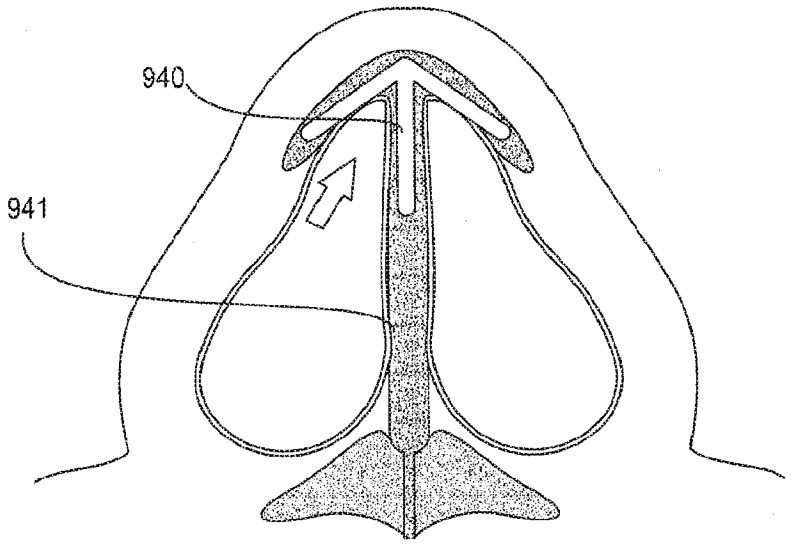


FIG. 36

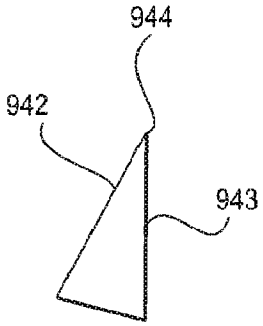


FIG. 37

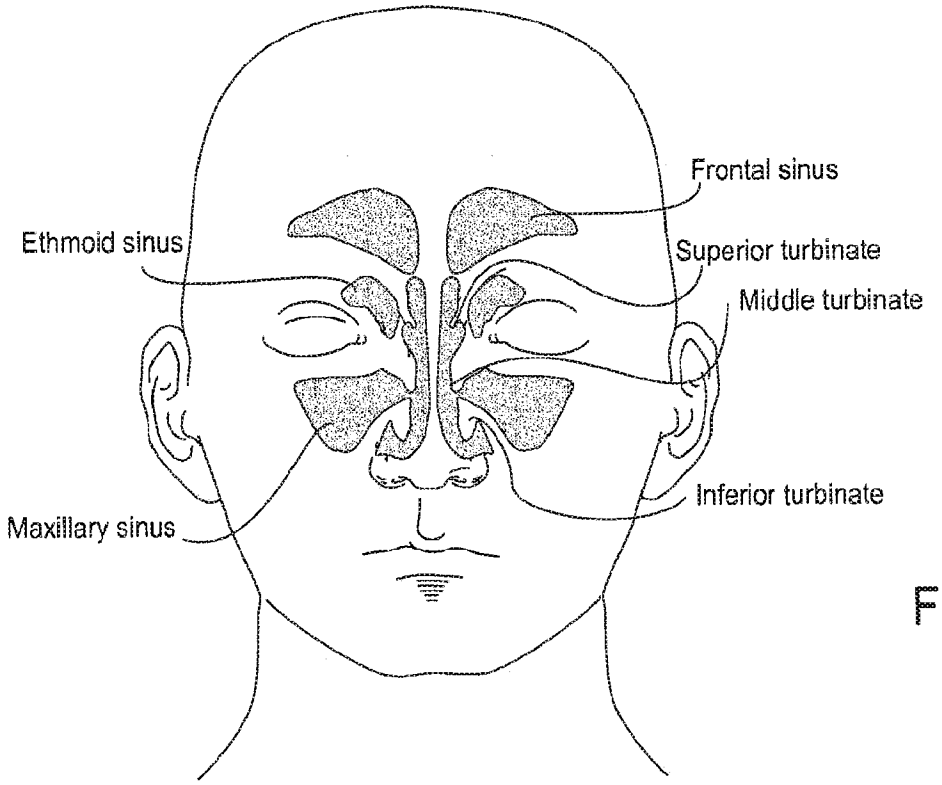


FIG. 38A

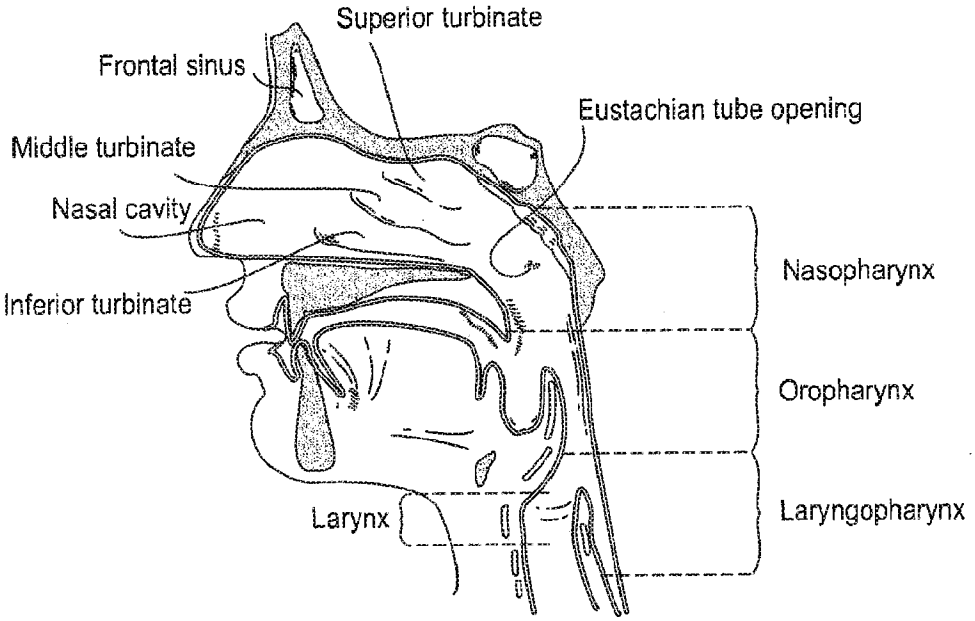


FIG. 38B

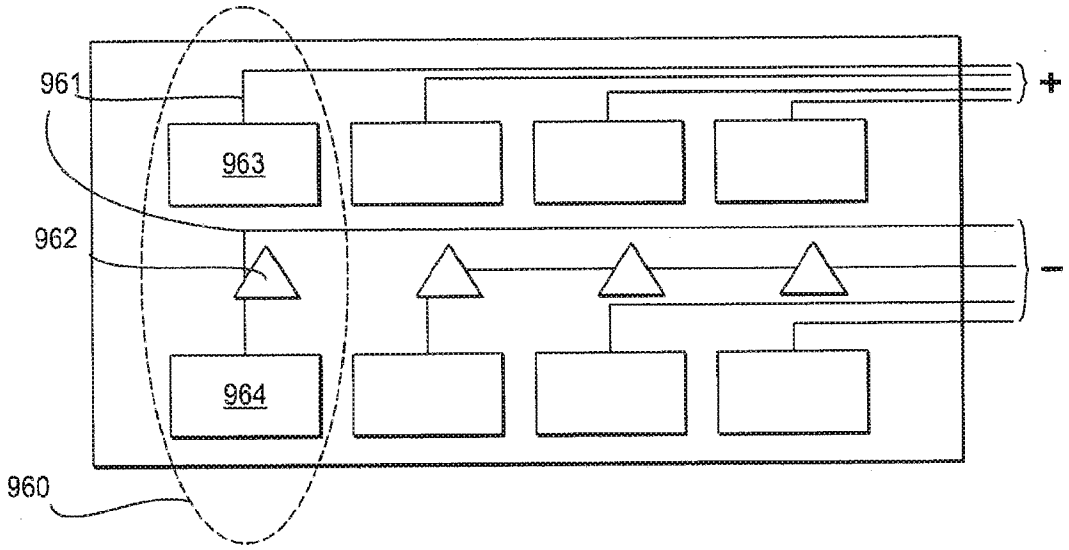


FIG. 39

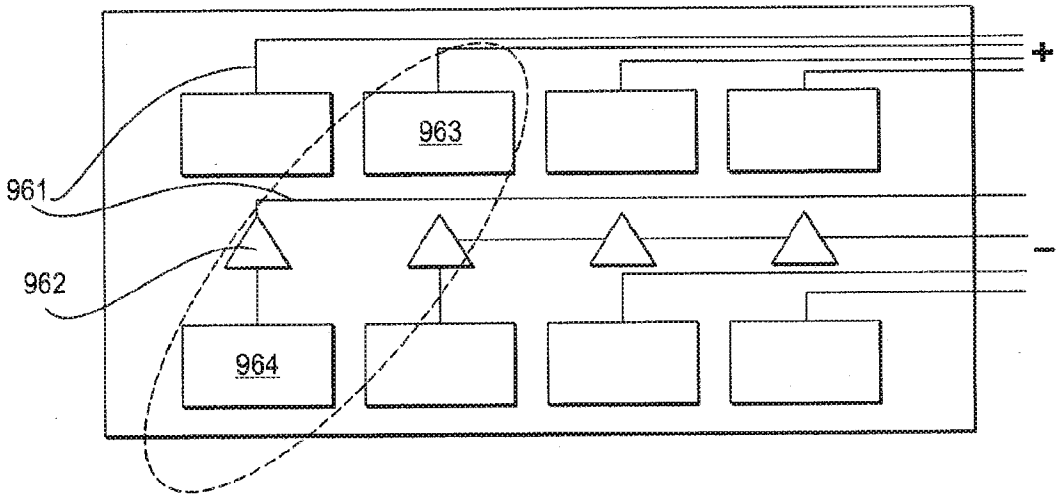


FIG. 40

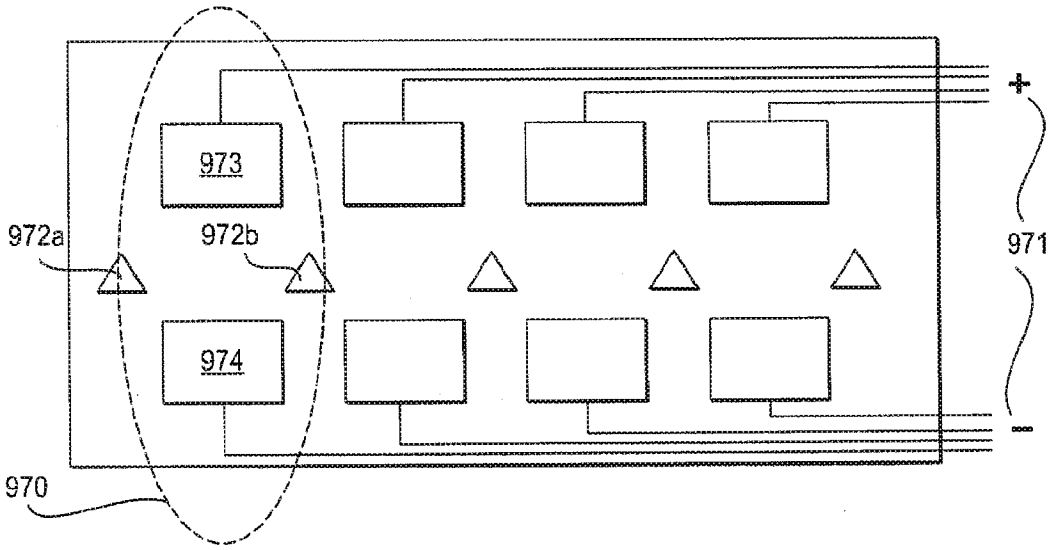


FIG. 41

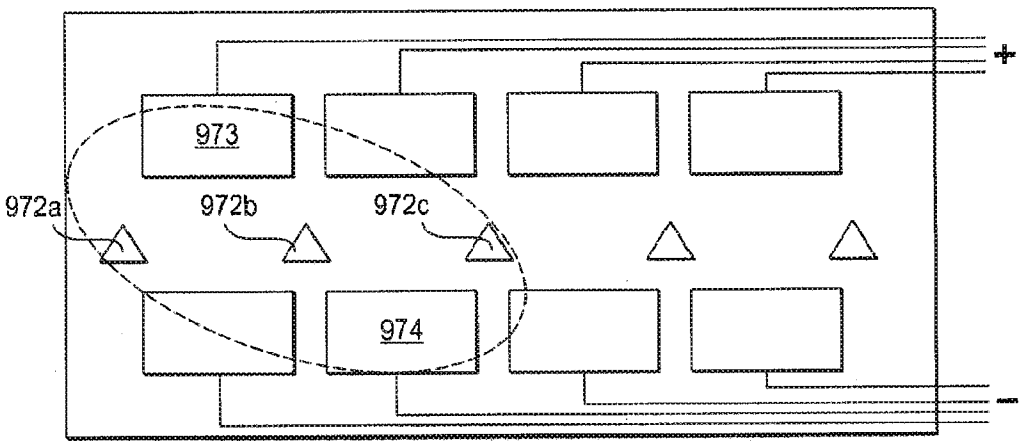


FIG. 42A

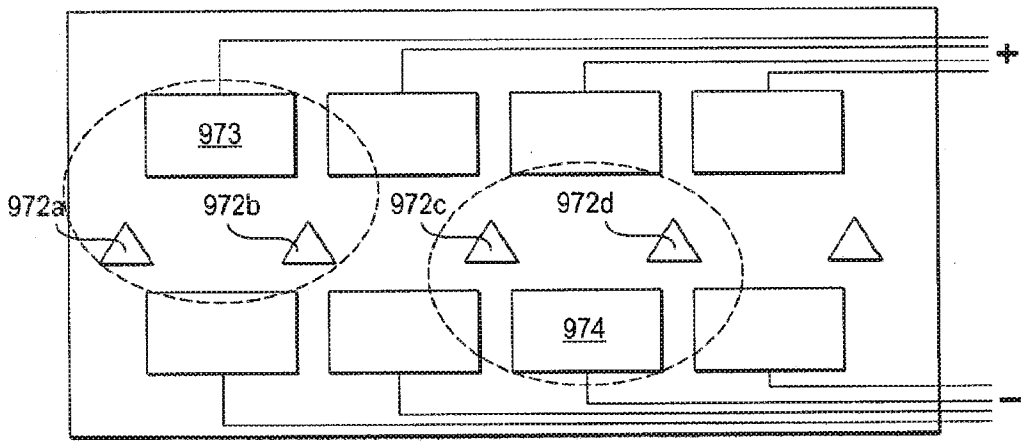


FIG. 42B

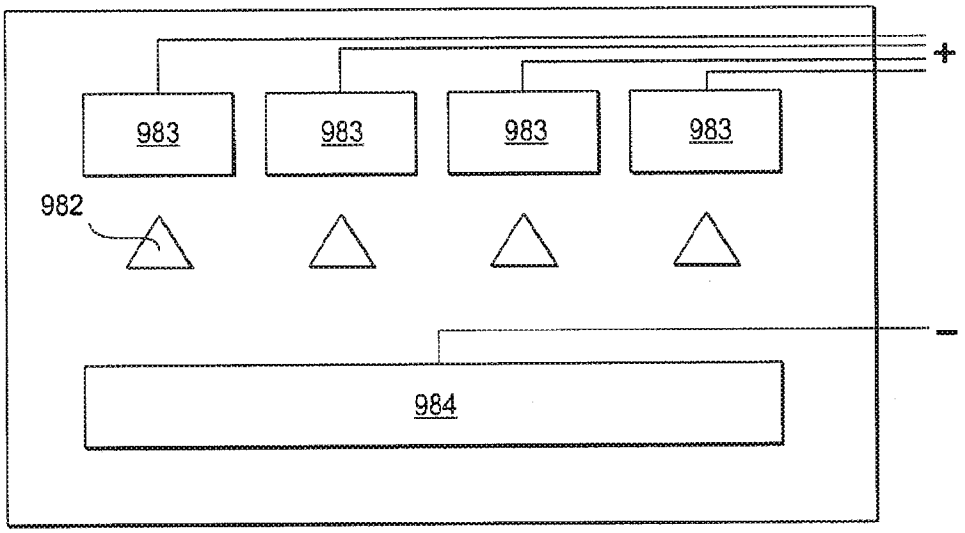


FIG. 43

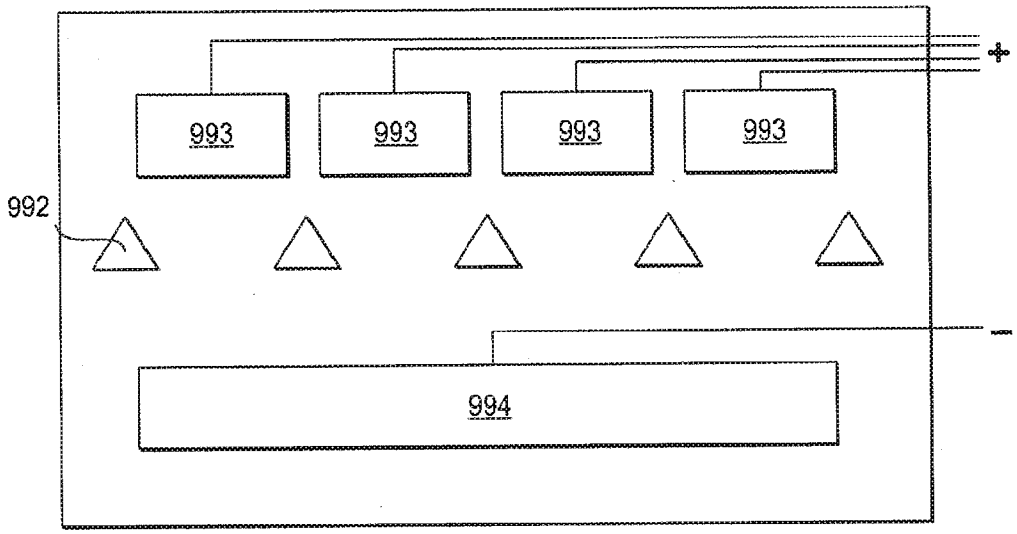


FIG. 44

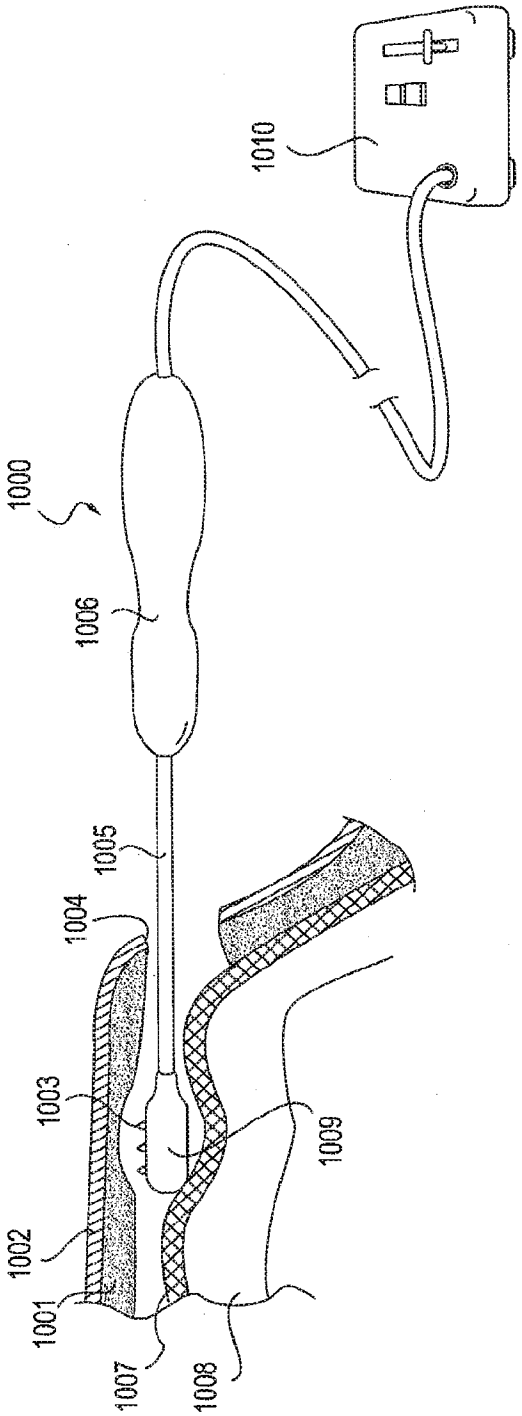


FIG. 45

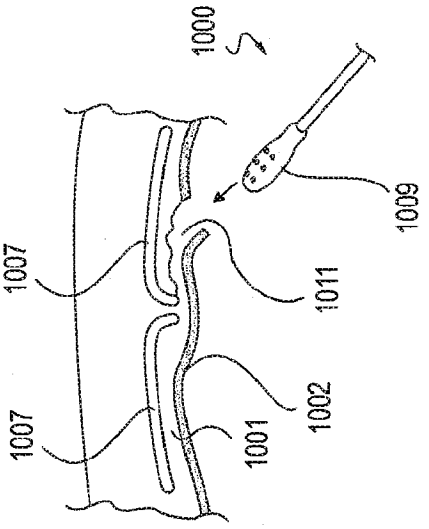


FIG. 46B

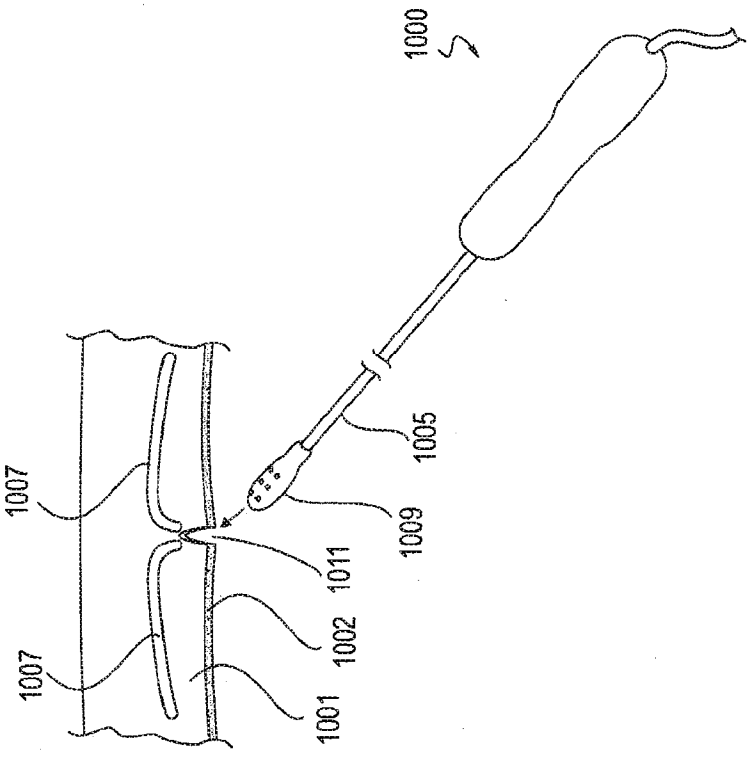


FIG. 46A

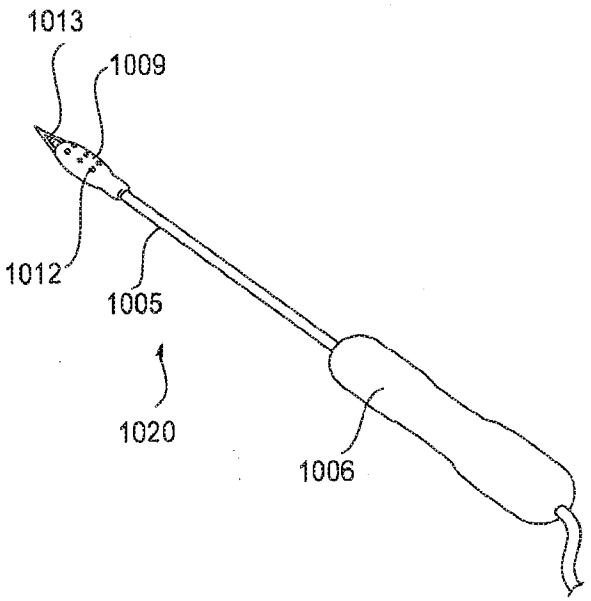


FIG. 47

PTO/AIA/01 (05-12)
Approved for use through 01/31/2014. 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.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Methods and Devices to Treat Nasal Airways

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 14/319,087

filed on June 30, 2014.

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
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.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [ ] The attached application, or
- [X] United States application or PCT international application number 14/319,087 filed on June 30, 2014.

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: 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 Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Attorney Docket Number:	17713.0001US11

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:				
UTILITY APPL SIZE FEE PER 50 SHEETS >100	2081	1	200	200
Claims:				
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**930**

Electronic Acknowledgement Receipt

EFS ID:	30182229
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US11
Receipt Date:	25-AUG-2017
Filing Date:	
Time Stamp:	10:41:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$930
RAM confirmation Number	082517INTEFSW10433200
Deposit Account	132725
Authorized User	Juliana Hoffman

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	Application Data Sheet	2017-08-25_ADS_17713-0001US11.PDF	1823526 c82841e9b2ba604d6eb1f655291b45dd8b31c8ef	no	9
Warnings:					
Information:					
2		2014-08-25_Specification_17713-0001US11.PDF	1230491 0c6ef2b68eb148e5c8fddadcc8e9d6e01f7f8d44	yes	79

Multipart Description/PDF files in .zip description

Document Description	Start	End
Abstract	79	79
Claims	76	78
Specification	1	75

Warnings:					
Information:					
3	Drawings-only black and white line drawings	2017-08-25_Drawings_17713-0001US11.PDF	1126424 eb276312b9c0e9da0c2bb48f9fa050f11857942c	no	61
Warnings:					
Information:					
4	Oath or Declaration filed	2017-08-25_Declarations_17713-0001US11.PDF	218996 1899c29aecd0f12a27717489846 0aae1fdcb7aed	no	2
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	37173 024ae4202b46ea3b2775900eca8cd69dc2eebd90	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	4436610

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/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	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. Wolf
Art Unit	
Examiner Name	
Attorney Docket Number	17713.0001US11

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	4887605		1989-12-19	Angelsen et al.	
	2	5348008		1994-09-20	Bomn et al.	
	3	5533499		1996-07-09	Johnson	
	4	5624439		1997-04-29	Edwards et al.	
	5	5674191		1997-10-07	Edwards et al.	
	6	5707349		1998-01-13	Edwards	
	7	5718702		1998-02-17	Edwards	
	8	5728094		1998-03-17	Edwards	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	9	5730719		1998-03-24	Edwards	
	10	5738114		1998-04-14	Edwards	
	11	5743870		1998-04-28	Edwards	
	12	5743904		1998-04-28	Edwards	
	13	5746224		1998-05-05	Edwards	
	14	5800429		1998-09-01	Edwards	
	15	5807306		1998-09-15	Shapland et al.	
	16	5816095		1998-10-06	Nordell, II et al.	
	17	5817049		1998-10-06	Edwards	
	18	5820580		1998-10-13	Edwards et al.	
	19	5823197		1998-10-20	Edwards	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	20	5827277		1998-10-27	Edwards	
	21	5843021		1998-12-01	Edwards et al.	
	22	5843077		1998-12-01	Edwards	
	23	5846235		1998-12-08	Pasricha et al.	
	24	5879349		1999-03-09	Edwards	
	25	6045549		2000-04-04	Smethers et al.	
	26	6096033		2000-08-01	Tu et al.	
	27	6102907		2000-08-15	Smethers et al.	
	28	6109268		2000-08-29	Thapliyal et al.	
	29	6126657		2000-10-03	Edwards et al.	
	30	6131579		2000-10-17	Thorson et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	31	6139546		2000-10-31	Koenig et al.	
	32	6152143		2000-11-28	Edwards	
	33	6165173		2000-12-26	Kamdar et al.	
	34	6179803		2001-01-30	Edwards et al.	
	35	6210355		2001-04-03	Edwards et al.	
	36	6228079		2001-05-08	Koenig	
	37	6231569		2001-05-15	Bek et al.	
	38	6293941		2001-09-25	Strul et al.	
	39	6309386		2001-10-30	Bek	
	40	6371926		2002-04-16	Thorson et al.	
	41	6383181		2002-05-07	Johnston et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	42	6391028		2002-05-21	Fanton et al.	
	43	6416491		2002-07-09	Edwards et al.	
	44	6425151		2002-07-30	Barnett	
	45	6431174		2002-08-13	Knudson et al.	
	46	6451013		2002-09-17	Bays et al.	
	47	6551310		2003-04-22	Ganz et al.	
	48	6562036		2003-05-13	Ellman et al.	
	49	6575969		2003-06-10	Rittman et al.	
	50	6589235		2003-07-08	Wong et al.	
	51	6659106		2003-12-09	Hovda et al.	
	52	6911027		2005-06-28	Edwards et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	53	6978781		2005-12-27	Jordan	
	54	7055523		2006-06-06	Brown	
	55	7114495		2006-10-03	Lockwood, Jr.	
	56	7322993		2008-01-29	Metzger et al.	
	57	7416550		2008-08-26	Protsenko et al.	
	58	7442191		2008-10-28	Hovda et al.	
	59	7780730		2010-08-24	Saidi	
	60	7824394		2010-11-02	Manstein	
	61	7850683		2010-12-14	Elkins et al.	
	62	8137345		2012-03-20	McNall, III et al.	
	63	8317781		2012-11-27	Owens et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	64	8317782		2012-11-27	Ellman et al.	
	65	8936594		2015-01-20	Wolf et al.	
	66	8986301		2015-03-24	Wolf et al.	
	67	9072597		2015-07-07	Wolf et al.	
	68	9179964		2015-11-10	Wolf et al.	
	69	9179967		2015-11-10	Wolf et al.	
	70	9237924		2016-01-19	Wolf et al.	
	71	9415194		2016-08-16	Wolf et al.	
	72	9433463		2016-09-06	Wolf et al.	
	73	9452010		2016-09-27	Wolf et al.	
	74	9452087		2016-01-27	Holm et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	75	9486278		2016-11-08	Wolf et al.	
	76	9526571		2016-12-27	Wolf et al.	
	77	5938659		1999-08-17	Tu	
	78	6502574		2003-01-07	Stevens	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20020016588		2002-02-07	Wong et al.	
	2	20020128641		2002-09-12	Underwood et al.	
	3	20030144659		2003-07-31	Edwards	
	4	20030208194		2003-11-06	Hovda et al.	
	5	20030225403		2003-12-04	Woloszko et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	6	20040220644		2004-11-04	Shalev et al.	
	7	20050119643		2005-06-02	Sobol et al.	
	8	20050222565		2005-10-06	Manstein	
	9	20060235377		2006-10-19	Earley	
	10	20060253117		2006-11-09	Hovda et al.	
	11	20060276817		2006-12-07	Vassallo et al.	
	12	20070066944		2007-03-22	Nyte	
	13	20070073282		2007-03-29	McGarrigan et al.	
	14	20070219600		2007-09-20	Gertner et al.	
	15	20080027480		2008-01-31	van der Burg et al.	
	16	20080082090		2008-04-03	Manstein	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	17	20090018485		2009-01-15	Krespi et al.	
	18	20090143821		2009-06-04	Stupak	
	19	20090292358		2009-11-26	Saidi	
	20	20100144996		2010-06-10	Kennedy et al.	
	21	20100152730		2010-06-17	Makower et al.	
	22	20110009737		2011-01-13	Manstein	
	23	20110282268		2011-11-17	Baker et al.	
	24	20120039954		2012-02-16	Cupit et al.	
	25	20120078377		2012-03-29	Gonzales et al.	
	26	20120316557		2012-12-13	Sartor et al.	
	27	20120323227		2012-12-20	Wolf et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	28	20120323232		2012-12-20	Wolf et al.	
	29	20130218158		2013-08-22	Danek et al.	
	30	20140088463		2014-03-27	Wolf et al.	
	31	20140114233		2014-04-24	Deem et al.	
	32	20150202003		2015-07-23	Wolf et al.	
	33	20160287315		2016-10-06	Wolf et al.	
	34	20160361112		2016-12-15	Wolf et al.	
	35	20170007316		2017-01-12	Wolf et al.	
	36	20170014258		2017-01-19	Wolf et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	1	101325919	CN		2008-12-17			
	2	2007037895	WO		2007-04-05			
	3	2007134005	WO		2007-11-22			
	4	2015047863	WO		2015-04-02			
	5	2015048806	WO		2015-04-02			

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.	T5
	1	Cole, "Biophysics of nasal airflow: a review," Am J Rhinol., 14(4):245-249, Jul-Aug. 2000.	
	2	Cole, "The four components of the nasal valve," Am J Rhinol., 17(2):107-110, Mar-Apr. 2003.	
	3	International Search Report and Written Opinion for PCT/US15/023742, mailed June 29, 2015, 5 pages.	
	4	International Search Report and Written Opinion for PCT/US2012/042316, mailed Aug. 24, 2012, 15 pages.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	5	International Search Report and Written Opinion for PCT/US2014/054726, mailed December 23, 2014, 5 pages.
	6	Kjaergaard et al., "Relation of nasal air flow to nasal cavity dimensions," Arch Otolaryngol Head Neck Surg., 135 (6):565-570, Jun 2009.
	7	Singapore Search Report for Application Serial No. 201309238-2, Jun. 9, 2014 for pp. 1-27.
	8	Stupak, "Endonasal repositioning of the upper lateral cartilage and the internal nasal valve," Ann Otol Rhinol Laryngol., 120(2):88-94, Feb. 2011.
	9	Buckley et al., "High-resolution spatial mapping of shear properties in cartilage," J Biomech., 2010 Mar 3;43 (4):796-800, Epub Nov. 5, 2009.
	10	Buckley et al., "Mapping the depth dependence of shear properties in articular cartilage," J Biomech., 41 (11):2430-2437, Epub Jul. 10, 2008.
	11	Griffin et al., "Effects of enzymatic treatments on the depth-dependent viscoelastic shear properties of articular cartilage," J Orthop Res., 32(12):1652-1657, Epub Sep. 5, 2014.
	12	Silverberg et al., "Structure-function relations and rigidity percolation in the shear properties of articular cartilage," Biophys J., 107(7):1721-1730, Oct. 7, 2014.
	13	Stewart et al., "Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale," Otolaryngol Head Neck Surg., 130(2):157-163, Feb. 2004.
	14	Stupak, "A Perspective on the Nasal Valve," Dept. of Otorhinolaryngology, Albert Einstein College of Medicine, Nov. 6, 2009.

If you wish to add additional non-patent literature document citation information please click the Add button Add

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

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	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2017-08-25
Name/Print	Christopher P. Ziolkowski/	Registration Number	73,729

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.

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.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. 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 displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: AERIN MEDICAL, INC.

Application No./Patent No.: 15/686,265 Filed/Issue Date: August 25, 2017

Titled: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

AERIN MEDICAL, INC., a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☑ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 043310, Frame 0606, or for which a copy thereof is attached.

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

   The document was recorded in the United States Patent and Trademark Office at

   Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

   The document was recorded in the United States Patent and Trademark Office at

   Reel _____, Frame _____, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). 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 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.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Christopher P. Ziolkowski/	2017-08-25
Signature	Date
Christopher P. Ziolkowski	73,729
Printed or Typed Name	Title or Registration 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.

PATENT ASSIGNMENT

WHEREAS WE, Scott J. WOLF and Andrew FRAZIER (hereinafter the "Assignor"), residing at 319 Trenton Way in Menlo Park, California 94025 and 517 Fern Ridge Court in Sunnyvale, California 94087 respectively, are joint inventors of certain new and useful systems, devices, and methods disclosed and described in certain patent applications ("Patent Assets") as specifically set forth in the attached Exhibit A; and

WHEREAS, Assignor desires to assign any and all right, title and interest to said Patent Assets set forth in Exhibit A, and including any provisional, non-provisional, continuation, continuation-in-part, divisional, international, foreign, regional and convention applications corresponding thereto, and any and all Letters Patent of the United States and countries and regions foreign thereto which may grant or have granted thereto or be lodged in relation thereto, any reissue or reexamination thereof or to be obtained therefor, any renewals, or substitutes thereof, and in and to any and all priority rights or priority claims, International Convention rights, any and all rights to collect past damages for infringement of any and all Letters Patent of the United States and countries and regions foreign thereto which may be published, which may grant, or have granted thereto or be lodged in relation thereto, and other benefits accruing to or to accrue to Assignor with respect to the filing of applications for patents or securing of patents in the United States and countries foreign thereto (the "Patent Rights");

WHEREAS, AERIN MEDICAL INC., a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 650 Page Mill Road, Palo Alto, California 94304, (the "Assignee"), desires to acquire any and all, right, title, and interest of Assignor in and to the Patent Assets, the Patent Rights, and in, to, and under any and all Letters Patent to be obtained therefor;

NOW THEREFORE, for the sum of $1.00 and other good and valuable consideration to me in hand paid, the receipt and sufficiency of which are hereby acknowledged, Assignor has sold, assigned, and transferred, and by these presents does hereby sell, assign and transfer to the said Assignee, and said Assignee's legal representatives, successors and assigns, any and all of the entire right, title and interest in and to the Patent Assets, Patent Rights, and any and all Letters Patent to be obtained therefor;

UPON SAID CONSIDERATION, the Assignor hereby covenants and agrees with the said Assignee that it will not execute any writing or do any act whatsoever conflicting with these

presents, and that it will, at any time upon request, without further or additional consideration, but at the expense of the said Assignee, execute such additional assignments and other writings and do such additional acts as said Assignee may deem necessary or desirable to perfect the Assignee's enjoyment of this grant, and render all necessary assistance in making application for and obtaining original, provisionals, non-provisionals, continuations, continuations-in-part, continuing prosecutions, divisionals, renewals, reissues, reexamined or extended Letters Patent of the United States, or of any and all foreign countries, on said Patent Rights, and execute confirmatory assignments or acknowledgments of this assignment as necessary for full enjoyment of the Patent Rights and for recording in foreign patent offices, and in enforcing any rights or choses in action accruing as a result of such Patent Rights, by giving testimony in any proceedings or transactions involving such Patent Rights, and by executing preliminary statements and other affidavits, it being understood that the foregoing covenant and agreement shall bind, and inure to the benefit of, the assigns and legal representatives of both parties;

UPON SAID CONSIDERATION, Assignor represents and warrants that Assignor has the right, title, and authority to execute this Assignment and to convey any and all right, title, and interest in the Patent Assets and the Patent Rights, and that Assignor has not conveyed nor will convey hereafter all or part of the Patent Assets or Patent Rights to a third party;

ASSIGNOR HEREBY AUTHORIZES said Assignee, its successors, and assigns, or anyone it may properly designate, to apply for Letters Patent in the U.S. and any and all foreign countries and regions, in its own name if desired, and additionally to claim priority to the filing date of the Utility Application and otherwise take advantage of the provisions of any international conventions.

ASSIGNOR HEREBY AUTHORIZES Assignee, its successors and assigns, or anyone it may properly designate, to insert in this instrument the application number, filing date, and title of the Utility Application once known.

IN WITNESS WHEREOF, the Assignor hereunto has executed this Assignment upon the date indicated below.

Date: 10 / 09 / 2013 By: S Wolf
Scott J. WOLF

Date: _____ By: _____
Andrew FRAZIER

presents, and that it will, at any time upon request, without further or additional consideration, but at the expense of the said Assignee, execute such additional assignments and other writings and do such additional acts as said Assignee may deem necessary or desirable to perfect the Assignee's enjoyment of this grant, and render all necessary assistance in making application for and obtaining original, provisionals, non-provisionals, continuations, continuations-in-part, continuing prosecutions, divisionals, renewals, reissues, reexamined or extended Letters Patent of the United States, or of any and all foreign countries, on said Patent Rights, and execute confirmatory assignments or acknowledgments of this assignment as necessary for full enjoyment of the Patent Rights and for recording in foreign patent offices, and in enforcing any rights or choses in action accruing as a result of such Patent Rights, by giving testimony in any proceedings or transactions involving such Patent Rights, and by executing preliminary statements and other affidavits, it being understood that the foregoing covenant and agreement shall bind, and inure to the benefit of, the assigns and legal representatives of both parties;

UPON SAID CONSIDERATION, Assignor represents and warrants that Assignor has the right, title, and authority to execute this Assignment and to convey any and all right, title, and interest in the Patent Assets and the Patent Rights, and that Assignor has not conveyed nor will convey hereafter all or part of the Patent Assets or Patent Rights to a third party;

ASSIGNOR HEREBY AUTHORIZES said Assignee, its successors, and assigns, or anyone it may properly designate, to apply for Letters Patent in the U.S. and any and all foreign countries and regions, in its own name if desired, and additionally to claim priority to the filing date of the Utility Application and otherwise take advantage of the provisions of any international conventions.

ASSIGNOR HEREBY AUTHORIZES Assignee, its successors and assigns, or anyone it may properly designate, to insert in this instrument the application number, filing date, and title of the Utility Application once known.

IN WITNESS WHEREOF, the Assignor hereunto has executed this Assignment upon the date indicated below.

Date: _____ By: _____
Scott J. WOLF

Date: June 11th, 2013 By: _____
Andrew FRAZIER

Exhibit A

Application No.	Filing Date	Atty. Docket No.	Title
13/495,879	June 13, 2012	P239600.US.01	Methods and Devices to Treat Nasal Airways
13/495,844	June 13, 2012	P239600.US.02	Methods and Devices to Treat Nasal Airways
PCT/US2012/042316	June 13, 2012	P239600.WO.01	Methods and Devices to Treat Nasal Airways

CONFIRMATORY ASSIGNMENT [Large Entity]	Attorney Docket No.: P244992US02 (494912-17); P244992US01 (494912-9); P244690US02 (494912-15)	Page 1 of 2
	First Named Inventor: Scott J. Wolf	
	Title: METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

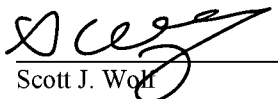
WHEREAS we, Scott J. Wolf, residing at 319 Trenton Way, Menlo Park, CA 94025, and Andrew Frazier, residing at 517 Fern Ridge Court, Sunnyvale, CA 94087, have invented certain new and useful improvements as described in the patents and patent applications identified in Schedule A;

WHEREAS, Aerin Medical, Inc. a corporation organized and existing under the laws of the State of California, and having offices at 690 W. Fremont Ave #3, Sunnyvale, CA 94087 ("Assignee"), is desirous of acquiring the entire right, title and interest in and to the invention, the application, and any and all Letters Patent or similar legal protection, foreign or domestic, to be obtained therefor.

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, I transfer to Assignee, its successors and assigns, my entire right, title, and interest in and to the invention, the above-identified patent application, corresponding domestic applications (including provisionals, non-provisionals, divisionals, continuations, and continuations-in-part), corresponding foreign applications, all Letters Patent or similar legal protection issuing thereon, and all rights and benefits under any applicable treaty or convention; and I authorize the Commissioner of Patents and Trademarks of the United States or foreign equivalent thereof to issue the Letters Patent or similar legal protection to the Assignee.

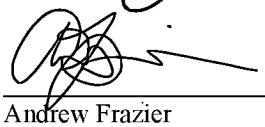
If the application number and filing date are unknown at the time of preparing this Assignment, I authorize the Assignee, its successors and assigns, to insert this instrument the filing date and application number of the application when ascertained. I authorize the Assignee, its successors and assigns, or anyone it may properly designate, to apply for Letters Patent or similar legal protection, in its own name if desired, in any and all foreign countries.

I represent to the Assignee, its successors and assigns, that I have not and shall not execute any writing or do any act whatsoever conflicting with this Assignment. I, my executors or administrators, will at any time upon request, without additional consideration, but at the expense of the Assignee, its successors and assigns, execute such additional writings and do such additional acts as the Assignee, its successors and assigns, may deem desirable to perfect its enjoyment of this grant, and render all assistance in making application for and obtaining, maintaining, and enforcing the Letters Patent or similar legal protection on the invention in any and all countries.



12/29/15

Scott J. Wolf (date)



29DEC2015

Andrew Frazier (date)

SCHEDULE A

TITLE	FIRST NAMED INVENTOR	COUNTRY	APPLICATION NO.	PATENT NO.
METHODS AND DEVICES TO TREAT NASAL AIRWAYS	Scott J. Wolf	U.S.	14/319,087	9,072,597
METHODS AND DEVICES TO TREAT NASAL AIRWAYS	Scott J. Wolf	U.S.	14/754,087	--
POST NASAL DRIP TREATMENT	Scott J. Wolf	U.S.	14/675,689	--

PTO/SB/80 (11-08)
Approved for use through 11/30/2011. OMB 0651-0035
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.

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(b).

I hereby appoint:

☑ Practitioners associated with the Customer Number: 23552

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 assignment documents attached to this form in accordance with 37 CFR 3.73(b).

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

☑ The address associated with Customer Number: 23552

OR

☐ Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

Assignee Name and Address:

Aerin Medical, Inc.
232 East Caribbean Drive
Sunnyvale, California 94089

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, 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		Date	08NOV2016
Name	Fred Dinger	Telephone	(408) 542-9805
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.**

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

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.

Electronic Acknowledgement Receipt

EFS ID:	30182591
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US11
Receipt Date:	25-AUG-2017
Filing Date:	
Time Stamp:	11:03:45
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)	2017-08-25_IDS_17713-0001US11.PDF	634455 db51654d3098a301201b4900657c121d2c334b6d	no	16

Warnings:

Information:					
2	Assignee showing of ownership per 37 CFR 3.73	2017-08-25_37CFR373C_17713-0001US11.PDF	370460 e1cb693154870ab7790c07d5c7c485eacb38b701	no	9
Warnings:					
Information:					
3	Power of Attorney	2017-08-25_POA-AERIN_17713-0001US11.PDF	621543 69d14e13ccb6b0d81b69e966349d4ff5af47c3bb	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1626458		

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/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	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. Wolf
Art Unit	
Examiner Name	
Attorney Docket Number	17713.0001US11

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	5542916		1996-08-06	Hirsch et al.	
	2	7678069		2010-03-16	Baker et al.	
	3	9125677		2015-09-08	Sobol	
	4	9687288		2017-06-27	Saadat	
	5	9687296		2017-06-27	Wolf et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20170095288		2017-04-06	Wolf et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	2	20170209199		2017-07-27	Wolf et al.	
	3	20170231651		2017-08-17	Dinger et al.	
	4	20020049464		2002-04-25	Donofrio et al.	
	5	20050020901		2005-01-27	Belson	
	6	20120316473		2012-12-13	Bonutti et al.	
	7	20170252089		2017-09-07	Hester	
	8	20170252100		2017-09-07	Wolf et al.	
	9	20170245924		2017-08-31	Wolf et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]
	1	2001043653	WO		2001-06-21			

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	2	2015153696	WO		2015-10-08			

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]
	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

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	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2017-09-12
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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.

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.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 June 2001 (21.06.2001)

PCT

(10) International Publication Number
WO 01/43653 A1

(51) International Patent Classification[7]: A61B 18/04, 18/18

(21) International Application Number: PCT/US00/34092

(22) International Filing Date:
15 December 2000 (15.12.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/171,021 15 December 1999 (15.12.1999) US

(71) Applicants and
(72) Inventors: **EDWARDS, Stuart, D.** [US/US]; 658 Westridge Drive, Portola Valley, CA 94028 (US). **MCLAUGHLIN, Robet, B., Jr.** [US/US]; 2025 Morse Avenue, Sacramento, CA 95825 (US).

(74) Agent: **Michael A. Glenn**; Glenn Patent Group, 3475 Edison Way #2, Menlo Park, CA 94025 (US).

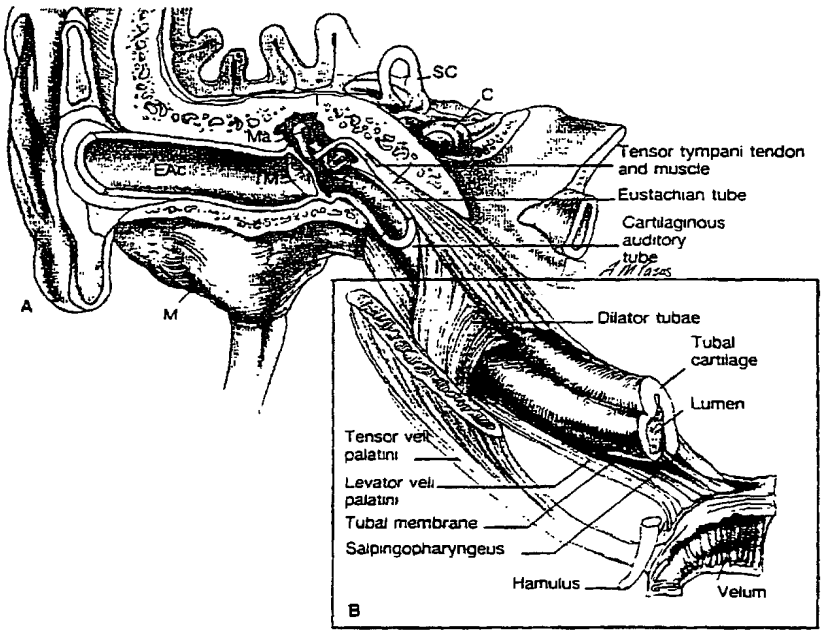
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: TREATMENT OF EUSTACHIAN TUBE DYSFUNCTION BY APPLICATION OF RADIOFREQUENCY ENERGY



(57) Abstract: An orally or nasally insertable apparatus for identifying and treting specific tissues proximate to a human ear eustachian tube. The apparatus incorporates pressure differential feedback elements, a temperature sensor, and RF electrodes capable of heating targeted areas to 70 degrees Celsius.

WO 01/43653 A1

Treatment of Eustachian Tube Dysfunction by Application of Radiofrequency Energy

RELATED APPLICATION

This application is a continuation-in-part of United States Provisional Patent Application Serial No. 60/171,021, filed December 15, 1999, and entitled "Treatment of Eustachian Tube Dysfunction by Application of Radiofrequency Energy," which is incorporated in its entirety herein by reference.

FIELD OF THE INVENTION

This invention relates to treatment of Eustachian tube dysfunction.

BACKGROUND OF THE INVENTION

Diseases of the middle ear, such as otitis media, mastoiditis, cholesteatoma, tympanic membrane perforation, atelectasis and other related disorders are common manifestations of Eustachian tube dysfunction. In many instances, the ventilatory function of the Eustachian tube is impaired because the tube is collapsed or occluded. In other cases, the drainage and clearance functions of the Eustachian tube are impaired because the tube is hypercompliant.

Treatment for many of these diseases is commonly at directed problems caused by hypercompliance or collapse of the Eustachian tube, rather than the dysfunction of the tube. These treatments include pharmaceutical treatments (used both curatively and as a chemoprophylactic measure) and surgical treatments such

as myringotomy, adenoidectomy and placement of tubes.

These remedies are imperfect at best. The benefits derived from surgical treatment are transient: on average, problems recur after twelve months. This recurrence leads to further treatment and increased risk of complications.

Eustachian tube dysfunction is the most important factor in the pathogenesis of middle ear disease. Otitis Media is the second most common disease of childhood. Two thirds of children have at least one episode of otitis media by age three years. After an episode of acute otitis media, 10% of children have middle ear effusion lasting three months or more. See Figure 1,2. Prolonged middle ear effusion associated with hearing loss may interfere with speech and language development. The annual reports of Vital and Health statistics published for 1993 by the National Center for Health Statistics of the Centers for Disease Control and Prevention estimated 27.845 million cases of acute ear infection in the United States. 14.751 million occurred in children younger that 5 years of age, and 7.501 million occurred in children between the ages of 5- 17 years of age. The remaining 6 million occurred in adults 18 years of age and older. The AHCPR panel estimates that 25-35% of the total cases represented otitis media with effusion.

The management of otitis media is initially medical, with surgical therapy reserved for medical failures or complications. Failure of medical and surgical therapy has been associated with persistent Eustachian tube dysfunction. Complications include hearing loss, speech delay, tympanic membrane perforations, atelectasis, retraction pockets, cholesteatoma, mastoiditis as well as less common life threatening intracranial extensions of infection.

The current surgical standard of care, myringotomy and tubes, fails to address the underlying pathophysiology of Eustachian tube dysfunction, resulting in temporary benefit (average 12 months) and the need for repeat procedures (40%). The following document outlines the clinically relevant anatomy and physiology of Eustachian tube dysfunction and explores the potential market opportunity for treatment of this disorder.

A unique technological device is proposed. In light of the large target population, in addition to growth in general otolaryngology, the proposed device would serve as a catalyst for future growth into Otology and Pediatric Otolaryngology. Additional devices could then be developed based to complement the otology and pediatric otolaryngology suites.

Accordingly, it would be advantageous to provide an improved technique for treating Eustachian tube dysfunction. This advantage is achieved by a method and system whereby the Eustachian tube dysfunction is treated by manipulating the adjacent structures so as to strengthen, support and decrease tissue bulk in the Eustachian tube vault.

SUMMARY OF THE INVENTION

The invention provides a method and system for treatment Eustachian tube.

In a first aspect of the invention, the device includes a component that identifies and targets specific tissues proximate to the Eustachian tube. Tissues that can be manipulated in a manner so as to enhance the structural integrity of the Eustachian tube are targeted. This targeting may involve stimulation of muscles or nerves. These tissues may include the tensor veli palatini, the salpinopharyngeal and the levator veli palatini. In some patients, the tensor tympani may also be targeted.

In a second aspect of the invention, the device includes a feedback element that measures the pressure differential across the middle ear. This feedback is used to determine the end point of treatment. In a preferred embodiment, feedback will be obtained with an intact tympanic membrane. However, in other embodiments, myringotomy may be necessary to achieve sufficient feedback. Since this treatment is relative noninvasively and does not require sedation, additional feedback may be obtained by asking the patient how they feel at various points during a treatment.

In a third aspect of the invention, very low levels of RF energy are applied using either a bipolar or monopolar electrode to muscles that determine the structural integrity of the Eustachian tube. Targeted areas are heated to a temperature between 60 and 70 degrees Celsius. Application of this energy shrinks collagenaeous, fibers and shortens tendons, This indirectly decreases the compliance of the midportion of the cartilaginous Eustachian tube and biases it in favor of opening.

In a preferred embodiment, the RF electrodes are inserted orally and treatment is directed through the palate. However, in alternate embodiments, the electrodes may be inserted transnasally, using endoscopic visualization.

Features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended Claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1 to 6 illustrate the problems and solutions that the invention addresses.

The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined

in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following description of the invention is described with regard to preferred process steps and structures. Those skilled in the art would recognize, after perusal of this application, that embodiments of the invention can be implemented using circuitry or other structures adapted to particular process steps and structures, and that implementation of the process steps and structures described herein would not require undue experimentation or further invention.

I. Anatomy of the Eustachian Tube:

The Tube: The lumen is wider at both the proximal(nasopharyngeal) and distal (middle ear) ends than the mid portion (isthmus) where it is narrowest. The Eustachian tube (ET) is longer in the adult (31- 38 mm) than in the infant and young child. By 6 years of age, the ET has generally attained adult proportions. Tubal cartilage increases in mass from birth to puberty and this development has physiologic implications. In the adult, the posterior third is osseous; and the anterior two-thirds is cartilaginous. The healthy osseous portion is open at all times, in contrast to the fibrocartilagenous portion which is closed at rest, but opens during swallowing. See Figure 3. The cartilaginous tube courses anteromedially and inferiorly to insert into the nasopharynx at the superior border of the superior constrictor where it forms the torus tubarious. The mucosal lining is respiratory epithelium (pseudocolumnar ciliated) that is continuous with the middle ear and nasopharynx.

Peritubal musculature: Four muscles are generally

cited as being associated with the Eustachian tube.

The tensor veli palatini is composed of two distinct bundles of muscle fibers. The tensor veli palatini proper is an inverted triangle with its bony insertions (fixed) in the scaphoid fossa and entire lateral osseous ridge of the sulcus tubae for the course of the eustachian tube. The medial bundle (dilator tubae muscle) inserts into the posterior third of the lateral membranous wall of the Eustachian tube. It is responsible for active dilation of the tube by inferolateral displacement of the membranous wall. Both bundles descend to converge in a tendon that passes under the hamulus of the pterygoid bone to its origin in the posterior border of the horizontal process of the palatine bone (hard palate) and the palatine aponeurosis of the anterior portion of the velum. See Figure 3, 4, 5.

The tensor tympani (not veli) is a separate muscle slip originating from the tubal cartilages and sphenoid bone and inserts into the manubrium of the malleus. It does not appear to be involved in Eustachian tube function.

The salpingopharyngeal muscle arises from the medial and inferior borders of the tubal cartilage. It is composed of thin slips of muscular and tendinous fibers. Generally thought to lack the ability to perform physiologically.

The levator veli palatini originates from the inferior petrous apex and the lower border of the medial lamina of the tubal cartilage. It runs along the floor of the eustachian tube to insert in the dorsal surface of the palate. The muscle is not an active dilator of the tube, rather adds support via its relationship to the tube by loose connective tissue.

II. Physiology of the Eustachian Tube

The Eustachian tube has three primary functions with respect to the middle ear: (1) ventilation of the middle ear space with respect to atmospheric pressure, (2) protection from nasopharyngeal sound, pressure and secretions, and (3) drainage and clearance of middle ear secretions into the nasopharynx. See Figure 6.

1. The Ventilatory Function is the most important function of the Eustachian tube without which the other functions are impaired as well. Ideal tubal function is thought to be intermittent active opening of the eustachian tube via contraction of the tensor veli palatini during swallowing in order to maintain nearly ambient pressures in the middle ear.. When active tubal function is ineffective, functional collapse of the tube persists which results in negative pressure in the middle ear.

2. Protective, drainage and clearance functions: The compliance of the cartilaginous midportion of the eustachian tube seems to be the most critical factor with regard to these functions. For example: Sudden drops in middle ear pressure with an overly compliant tube can lock the Eustachian tube closed. In this case, a perforation or myringotomy would release the lock and promote return of function. However, if the compliance and tensor veli palatini contraction was able to counteract the negative pressure the problem may not have developed in the first place. Inpatients with recurrent or chronic middle ear effusions despite treatment with myringotomy and tubes the problem may result from either a hypercompliant ET with or without (cleft palate) an effective tensor veli palatini to overcome the negative middle ear pressure. Other factors such as mitcociliary function, the length of the midportion, active pump via tubal opening and closing, and surface tension factors are critical considerations as well. If the tube is

hypercompliant and prone to collapse with negative middle ear pressure then all of these factors would be impaired. Inflammation and mechanical impingement would cease mucociliary flow. The pump would be impaired by the inability to overcome the negative pressure lock, and surface tension factors would become more significant based on the higher ratio of surface area to volume in a narrowed tube. This is consistent with observations by Honjo in which he demonstrated the Eustachian tube to pump liquid out of the middle ear in humans however when negative pressure was applied to the middle ear the function was impaired.

Eustachian tube dysfunction appears to be the most important factor in the pathogenesis of middle ear disease. Other contributing factors include infection of the respiratory mucosa, allergy, ciliary dysfunction.

Acute Otitis Media (AOM): In studies by Teele and Co-workers, by age 12 months, 60% of all children had at least one episode of AOM. By age 3 years, nearly 50% had at three or more episodes of acute otitis media. Otitis prone children seem to have their first episode within the first year of life. Uncomplicated cases treated with oral antibiotics. Up to 50% of children will have a persistent middle ear effusion (MEE). Treatment options for the acute MEE including additional antibiotics, decongestants, steroids, and Eustachian tube inflation have not been shown to be significantly more effective than observation in randomized studies. Figure 2 shows the duration of effusion after a single episode of acute otitis media. The mean duration was 40 days in one study. 10% persist to have MEE as long as 3 months (chronic condition) after resolution of the acute process.

Recurrent Acute Otitis Media(RAOM): In the absence of persistent middle ear. effusion recurrent bouts of

acute otitis media should be considered a sign of other. disease processes. Treatment options include chemoprophylaxis, myringotomy and tube insertion. adenoidectomy was recently shown in a randomized trial to not significantly impact the incidence of recurrent acute otitis media.

Otitis Media with Effusion (OME): Investigations of healthy children have revealed a high incidence of asymptomatic middle ear effusion with a peak incidence in the 2nd year of life. In a study of children aged 2-5 years, 53% of children during the first year of the study and 61 % during the second year developed OME. Teele found that the mean time with OME was on average I month for each year of the first two years of 1ife. Some children had middle ear fluid more than half the length of their infancy, however most resolve without medical or surgical intervention. 10% of all bouts of AOM are followed by MEE lasting greater than three months. Treatment options for the acute MEE including additional antibiotics, decongestants, steroids, and Eustachian tube inflation have not been shown to be significantly more effective than observation in randomized studies. Surgical options are usually reserved for. patients with symptoms that do not resolve with observation or medical therapy. Myringotomy and Tubes with and without adenoidectomy has been shown to improve conductive hearing loss secondary to OME and to decrease the amount of time spent with a MEE.

Tympanic Membrane Atelectasis: Focal retraction pockets can result in entrapment of desquamation byproducts resulting in cholesteatoma formation and ossicular erosion. Diffuse tympanic membrane flaccidity is often referred to as an atelectatic tympanic membrane and occurs in 2% of patients with persistent otitis media. The underlying pathophysiology results from

Eustachian tube dysfunction causing on of the tympanic membrane results in remodeling of the tympanic membrane resulting in a persistent state of flaccidity despite treatment of the negative middle ear pressures. A second procedure to treat the persistent atelectatic tympanic membrane will be discussed later in proposed procedures.

Chronic Otitis Media: Tympanic membrane perforation after tube placement (3% incidence after ear tubes) and recurrent or persistent perforations after tympanoplasty (5% failure rate) appear to be related to chronic Eustachian tube dysfunction. Acquired cholesteatomas, recurrent retraction pockets, poor mastoid aeration and atelectatic tympanic membranes have also been reported to.,occur in relation to Eustachian tube dysfunction.

Cleft Palate: Incidence in 1 in 750 births. Stool and Randal reported a 94% incidence of middle ear effusion at the time of myringotomy in cleft plate infants. Children with any form of unrepaired palatal cleft (including bifid uvula, submucous cleft) have a higher incidence of otitis at all ages. The incidence of middle ear disease decreases somewhat after surgical repair of a cleft palate and seems to be related to anatomic correction of the tensor veli palatini.

Craniofacial Anomalies: Down's syndrome 1 in 1000 births. Any abnormality of the midface, palate or skull base can cause Eustachian tube dysfunction including Treacher Collins syndrome, Apert's syndrome, and the mucopolysaccharidosis.

Complications of Otitis Media: Intratemporal complications include hearing loss (conductive and sensorineural), acute and chronic tympanic membrane perforations, chronic suppurative Otitis Media with and without cholesteatoma, retraction pockets and atelectasis, adhesive otitis media, tympanosclerosis, ossicular fixation and discontinuity, Mastoiditis,

petrositis, labrynthitis, and facial paralysis. Intracranial complications including Meningitis, subdural empyema, brain abscess, extradural abscess, lateral sinus thrombosis and otic hydrocephalus are unusual, but have serious potential neurologic sequelae including death.

Complications of Myringotomy and tubes: Otorrhea is the most common requiring treatment with topical and systemic antibiotics. Avoidance of water exposure is necessary. The average tube lasts approximately 9-15 months. Replacement or repeat tube placement comprises 30% of yearly ear tube procedures. Approximately 10% fail to extrude and must be removed. Other complications include tympanic membrane perforations (3%) and cholesteatomas (1%).

Complications of Adenoidectomy: Also rare, however include severe complications including bleeding (1%), nasopharyngeal stenosis and Eustachian tube injury.

The prevalence of eustachian tube dysfunction is not known. There are not reliable objective measures that can be routinely used to screen normal patients for. the presence of ETD. Otologic manifestations of the disorder as outlined seem. to be the best measure of its prevalence relative to clinical significance and will be expanded upon the discussion that follows. However, there is population of adults that present with chronic and recurrent complaints of aural fullness, hearing loss, imbalance, or tinnitis in an otherwise normal appearing ear. The symptoms frequently resolve with autoinsufflation (ETD). This clinical entity frequently fails to respond to medical therapy including nasal steroids, decongestants, antibiotics, allergy evaluation and immunotherapy. There are no broadly accepted surgical therapies for this disorder. The demographics of this patient population are poorly characterized in the literature. Elner et al. studied otologically

normal adults ability to, equilibrate static positive and negative middle ear pressures of 100 mm H20. They showed that 95% of normal adults could equilibrate an applied positive pressure, and that 93% could equilibrate applied negative pressure to some degree. However, 28% of adult subjects could not completely equilibrate either applied positive or negative pressure or both. Therefore, anywhere from 5-28% of the otologically normal (by physical exam) adult population may exhibit symptoms of eustachian tube dysfunction. A UK national study estimated that the prevalence of eustachian tube dysfunction in adults (18-80 years of age) is 0.9%.

Prevalence of Otitis media with effusion: Otitis media with effusion is the most common disease treated by physicians who care for children and the second most common indication for surgery in children (after circumcision).

The annual reports of Vital and Health statistics published for 1993 by the National Center for Health Statistics of the Centers for Disease Control and Prevention estimated 27.845 million cases of acute ear infection in the United States. 14.751 million occurred in children younger that 5 years of age, and 7.501 occurred in children between the ages of 5-17 years of age. The remaining 5.593 million occurred in adults 18 years of age and older. This includes both primary and recurrent cases in 1993. As reported by Teele, 10% of cases of AOME persist beyond 3 months giving us an estimate of 1.4 million cases for children less than 5 years of age in 1993. With regards to chronic otitis media with effusion, the true prevalence is not known.

Health Care expenditures:

A conservative estimate of cost was derived by Gates. His estimate used 2.5 physician visits at 35$ and 1.5 courses of antibiotics (Amoxacillin) for a direct

cost of $ 100 and indirect costs based on a loss of one-half day of work (43.00) plus travel expenses of 10. 00 per visit. Projecting these costs on 14 million results in annual expenditures of 3.15 billion dollars for the care of AOME in children under the age of 5 years. Estimates with regard to children greater than the age of 5 years are more difficult to derive, however treatment of recurrent episodes engenders substantial health care costs for the small group of patients with multiple recurrences. (Gates)

Using similar assumptions as found in the AHCPR commission report for 1993 Gates extrapolated these modified assumptions on the basis of a COME rate of 10% for the 14 million cases of AOME in children with AOME younger than 5 years of age. Direct costs were estimated at $1.484 billion and indirect costs of 0.370 billion for a total cost of 1.854 billion. His total estimate with respect to a total cost of 5 billion dollars spent on indirect and direct costs of treating OME only included children under 5 years of age. (Table 1)

In the Unites States > 25 % of the estimated 120 million prescriptions written for oral antibiotics each year are for the treatment of otitis media. A more recent survey of antimicrobial drug prescribing among office based physicians revealed that not only is the incidence of prescribing for otitis media increasing, there has also been an increase in the use of broader spectrum and more expensive antibiotics which may be contributing to a bacterial resistance problem.

In 1988, using federal data, approximately 800,00 children received 1.3 million tympanostomy tubes. Of these 30% were replacements. In 1994, 45,000 sets of ear tubes were placed in conjunction with adenoidectomy, and 140,000 US children less than 15 years of age underwent adenoidectomy with most having a primary or secondary

diagnosis of otitis; media.

In 1991, the AHCPR Commission estimated that 821,700 cases of Otitis media with effusion occurred in 2 y/o children in 1991, and that 1.09 billion dollars was spent for direct and indirect costs of care in these cases. They found that 52 percent of 2 y/o children were managed without surgery with an average of 4.6 office visits and 25% incurring hearing tests for an average cost of $406.00 per. patient. 42% of children in the sample studied underwent myringotomy and tubes insertion with an average of 5.5 office visits and 40% incurring hearing tests for an average cost of $21 74. 00 per patient. 6% of these children underwent adenoidectomy with an average of seven office visits for pre and postoperative visits, 45 percent underwent hearing tests and $3433. 00 was spent per patient.

Ultimately, the proposed procedure would target patients that suffer from eustachian tube dysfunction unresponsive to medical therapy. This would include adult and pediatric patient populations. Because we do not yet know the effects of radiofrequency treatment on eustachian tube and peritubal muscular development, the pediatric patient should be considered as being composed of two primary groups based on a cutoff age at which an adult-like eustachian tube is developed. Lets say 5 years of age for ease of interpreting above data, although 6 or 7 years of age is probably more accurate. In all three patient populations (two pediatric groups and adults), chronic otitis media with effusion and recurrent otitis media would be relative indications for the proposed procedure. Cleft and Craniofacial pediatric patients known to be at very high risk of chronic eustachian tube dysfunction should be considered separately. The anticipated pediatric (<6 years of age) patient population would include the otitis prone

child, children with recurrent otitis media and chronic otitis media with effusion refractory to medical therapy. In the case of otitis media with effusion, patients may be considered for intervention either primarily or after recurrence with more than one set of myringotomy tubes. In children younger than 5 years of age in 1993, 14 millions incidences of acute otitis media with effusion occurred. Ten percent or 1.4 million cases persisted beyond three months at which time surgical intervention should be considered based upon symptoms of hearing loss and bilaterality of disease. If the proposed procedure was utilized only after treatment failure with at least one set of ear tubes, based upon 30% of 1.3 million myringotomy and tubes procedures were for replacement tubes then we derive a target population of 390,000 each year for this age group. (Table 1)

In 1993, 7.501 million cases of otitis media occurred in children between the ages of 6-17 years of age. The incidence of chronic otitis media with effusion and recurrent otitis media that occurs in this population is poorly characterized. Most cases of acute otitis media resolve and acute otitis media with effusion resolve spontaneously in this patient population. However, within this patient population, there is a clear subset of patients that persist to suffer chronic ear disease requiring multiple sets of myringotomy tubes and chronic ear surgery. If one assumes a 3% rate of persistent tympanic membrane perforations and a I% incidence of cholesteatomas after myringotomy and tube placement (Golz), then 1.3 million myringotomy and tubes performed each year is associated with 39,000 persistent perforations and 13,000 cholesteatomas each year. In addition, the most common cause of failed tympanoplasty (5%) and recurrent cholesteatoma is eustachian tube dysfunction. If one extrapolates from the prevalence of

active chronic otitis media (1.5%) and the incidence of eustachian tube dysfunction(0.9%) demonstrated in the UK study, then based on the 1996 US census estimates for this age group 858,435 and 515,061 patients suffer from active chronic otitis media and eustachian tube dysfunction respectively. Table 2.

The remaining 5.593 million incidences of otitis media in 1993 occurred in adults 18 years of age and older. Again, the incidence of chronic otitis media with effusion and recurrent otitis media that occurs in this population is poorly characterized. If one extrapolates from the prevalence of active chronic otitis media (1.5%) and the incidence of eustachian tube dysfunction (0.9%) demonstrated in the UK study, then based on the 1996 US census estimates for this age group 2.9 million and 1.7 million patients suffer. from active chronic otitis media and eustachian tube dysfunction respectively. (Table 3)

Children with cleft palate or other craniofacial abnormalities that effect eustachian tube dysfunction occur in an estimated 1:750 births utilizing estimates based solely on the incidence of cleft palate (most common) to avoid overlap. Based on the 4.1 million births in the United Stated in 1990 we can derive an approximate target population of 5400 newborns each year with craniofacial defects strongly associated with eustachian tube dysfunction each year. Furthermore, it is estimated based on the 1996 US census population estimates that there is a cleft patient pool of 353,000. (Table 4)

Patients with persistent Eustachian tube dysfunction utilize significant resources with regard to pharmacotherapy, numerous sets of ear tubes, adenoidectomy, in addition complications related to chronic otitis media as well as the indirect costs of a

chronic illness. A treatment that was aimed at the underlying cause of the problem, Eustachian tube dysfunction could make significant strides toward prevention of future recurrences and significant cost savings.

Patient Requirements: Minimally invasive, minimal risk, long-term results, quick recovery, and outpatient/ ambulatory procedures. The proposed procedure is equal to the current surgical standard (myringotomy and tubes) in every way and should provide added benefits of improved longevity, fewer/less severe complications, and fewer repeat and adjunctive procedures.

Targeted Users: General Otolaryngologists including specialty trained pediatric otolaryngologists, otologists and neurotologists.

Proposed Procedure:

Type I Collagen is the primary component of tendinous and ligamentous structures. The application of heat to collagen results in 25-20% contraction and remodeling of collagen. The reaction is temperature dependent occurring maximally between 60-70 degrees Celsius. The reaction can be achieved at a slower rate and in a more precise fashion by treating at a lower temperature for a sustained, precise treatment time. The proposed procedure uses very low levels of radiofrequency energy to shrink the collagen or shorten the tendon of the tensor veli palatini (palate) from its origin in the palate toward the hamulus. These lesions will be resorbed and remodeled resulting in a shortened tendon and improved muscle tone and force of contraction. By effectively, shortening the Tensor veli palatini, we are indirectly decreasing the compliance of the midportion of the cartilaginous Eustachian tube and improving the opening force of contraction. Treatment at the palatal origin is the most accessible, however a

trans nasal approach under endoscopic visualization would be possible as well.

The Envisioned device will have three primary components:

1. Bipolar versus monopolar RF applicator
2. Targeting system: Muscle stimulator
3. Feedback system: Concurrent transtympanic Eustachian Tube testing

Other possible treatments might include treating the salpingopharngeous; or the fascia and constrictors of the nasopharynx, i.e. creating functional medial scar contracture. Treating the levator veli palatini to effectively strengthen support or ablation to decrease tissue bulk in the confines of the Eustachian tube vault. Treating the eustachian tube or the immediate surrounding structures to decrease compliance. However treatment in these cases in the region of the ET vault could prove hazardous due to the adjacent carotid artery.

In adults, all of these procedures could be performed on an outpatient basis or in a minor procedure room under local anesthesia. It is unlikely that sedation would be required. In children, general anesthesia by mask ventilation or endotracheal tube would likely be required.

A programmable radiofrequency generator with temperature and impedance monitoring and a suite of proprietary disposable electrode devices that deliver radiofrequency energy to selected areas. An insulating sleeve at the base of the needle electrode protects surrounding tissue from thermal damage. Thermocouples in the insulation and at the tip of the needle electrode assist in accurate monitoring of tissue temperature, ensuring optimal ablation without excessive heat damage.

Clinical Advantages:

The primary advantage over current therapies is

that the proposed procedure treats the physiologic origin, eustachian tube dysfunction, thereby providing significantly improved long term results. Other. advantages include a significant cost savings and reduced morbidity and complication rate. It benefits from a decreased rate of repeat procedures and complications related to otorrhea, tympanic membrane perforations, cholesteatoma, and complications or otitis media. In addition it is a comparable with regard to invasiveness, procedure time, recovery time and postoperative discomfort.

Other Proposed Otologic Applications:

In light of the large target population, in addition to growth in general otolaryngology, the proposed device would serve as a catalyst for future growth into Otology and Pediatric Otolaryngolgy. Additional devices could then be developed based on this market advantage to complement the otology and pediatric otolaryngology suites.

The atelectatic Tympanic membrane is caused by connective tissue remodeling occurring as a result exposure to a persistent negative middle ear pressure. Once the middle ear pressure has been treated by addressing the underlying Eustachian tube or by myringotomy and tube, a proportion of tympanic membranes will remain flaccid. Radiofrequency induced thermal contraction of the tympanic membrane should restore the normal architecture and compliance of the tympanic membrane. Thermal induced myringotomies, currently lasers, provide intermediate term myringotomies that may prove to be efficacious for some clinical indications.

Various features of the invention are set forth in the following claims.

We Claim:

1. An apparatus for treating Eustachian tube dysfunction including

a means for targeting nerves and muscles;

a bipolar or monopolar radiofrequency electrode; and

a thermocouple.

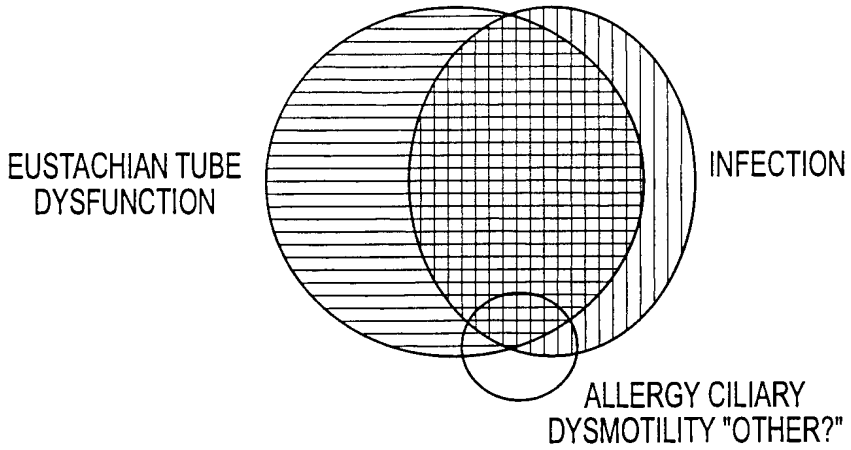

EUSTACHIAN TUBE
DYSFUNCTION
INFECTION
ALLERGY CILIARY
DYSMOTILITY "OTHER?"

FIG. 1

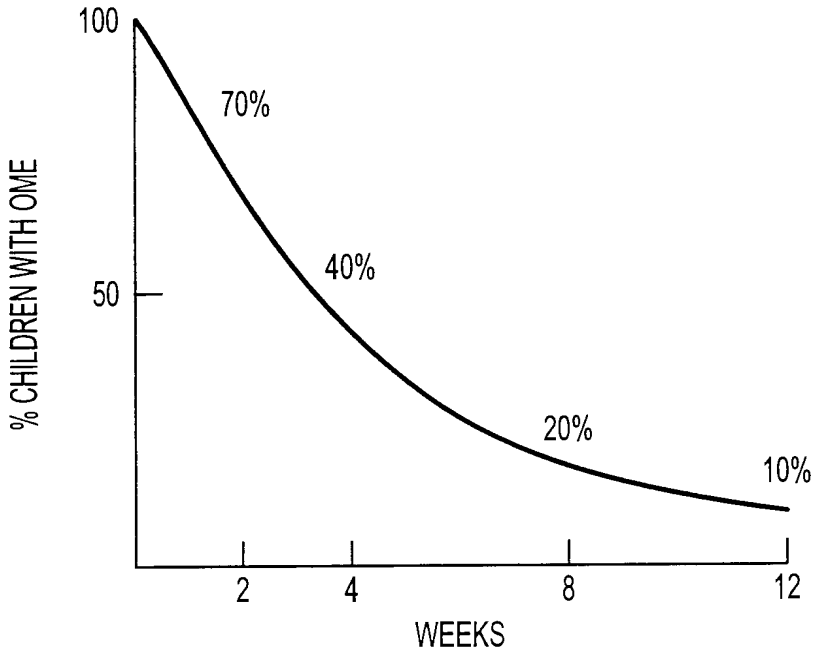


FIG. 2

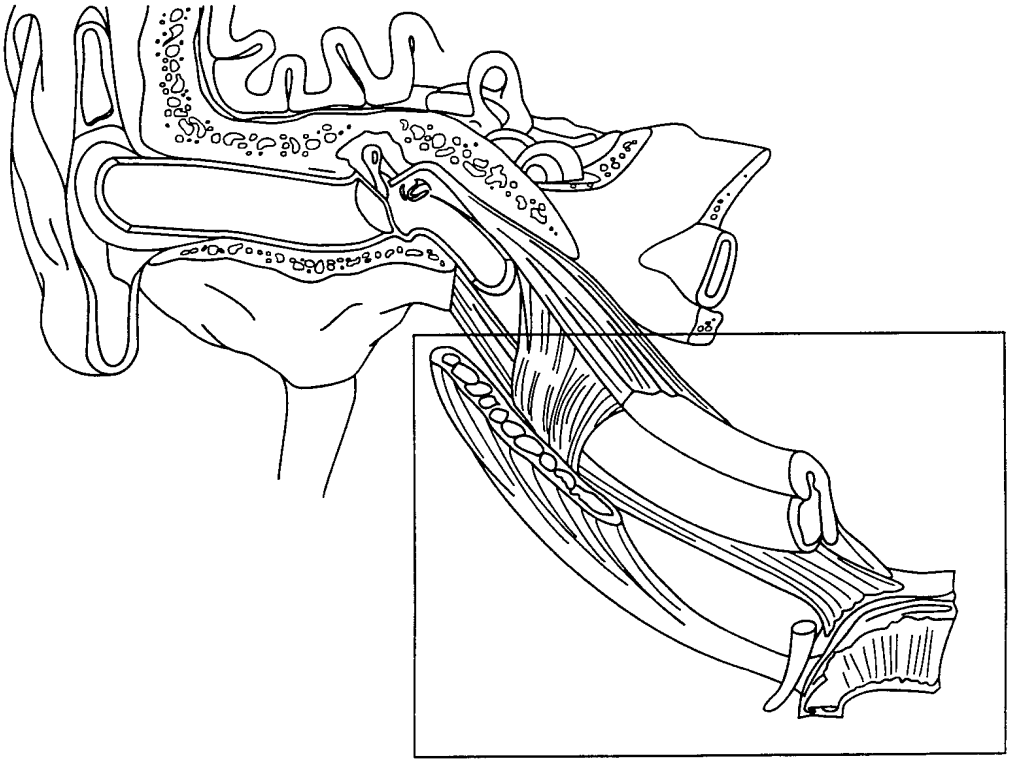


FIG. 3

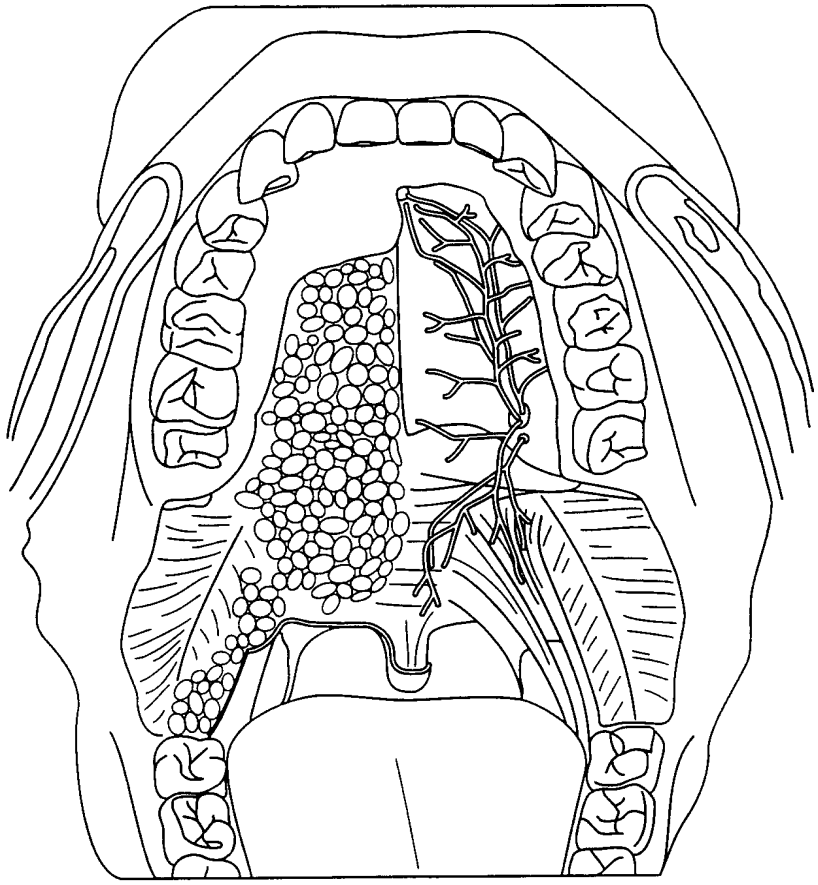


FIG. 4

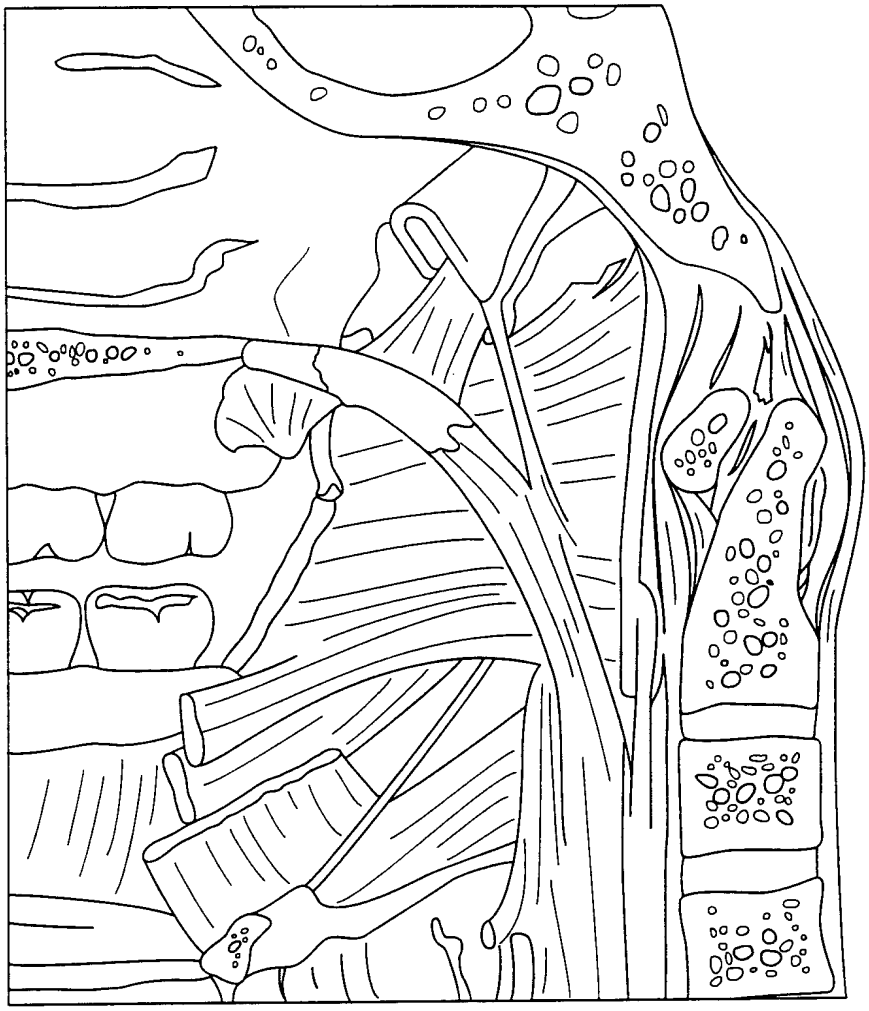


FIG. 5

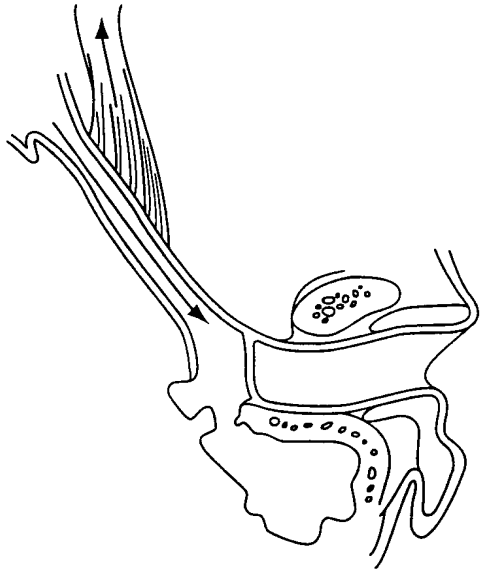


FIG. 6A

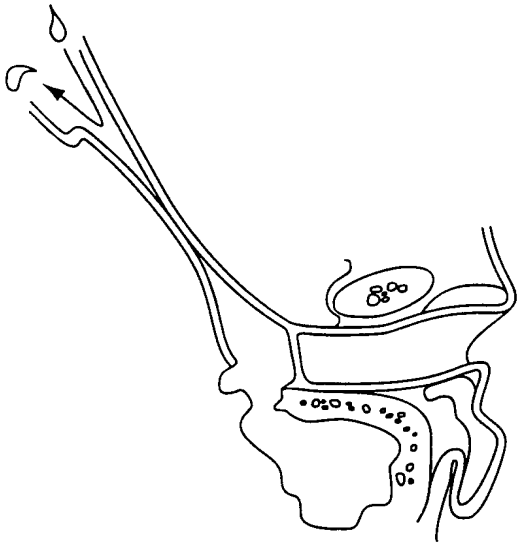


FIG. 6B

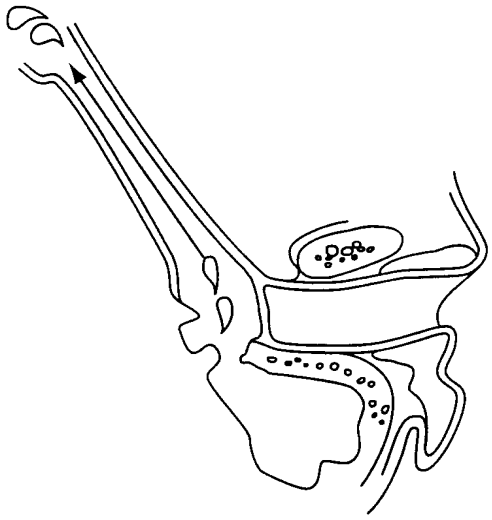


FIG. 6C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/34092

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61B 18/04, 18/18
US CL : 606/27-42
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)
U.S. : 606/27-34, 41, 42

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST - search terms: eustachian, radio frequency, bipolar, electrode, thermocouple

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,823,955A (Kuck et al.) 20 Oct. 1998 (20.10.1998), column 3, lines 28-65, Figures 3A-3G	1
X	US 5,916,214A (Cosio et al.) 29 June 1999 (29.06.1999), column 5, lines 30-53, Figures 3-8	1
X	US 5,893,885A (Webster, Jr.) 13 April 1999 (12.04.1999), column 3, line 56 - column 4, line 48; Figures 1-6	1
X	US 5,853,409A (Swanson et al.) 29 Dec. 1998 (29.12.1998), column 4, lines 28-57, Figures 1-6	1
X	US 5,935,123A (Edwards et al.) 10 Aug. 1999 (10.08.1999), column 3, line 48 - column 4, line 10	1
E, X	US 6,099,524A (Lipson et al.) 08 Aug. 2000 (08.08.2000), column 10, line 66 - Column 11, line 21	1
E, X	US 6,171,305B1 (Sherman) 09 Jan 2001 (09.01.2001), column 7, line 5 - column 8, line 10	1
E, X	US 6,176,857B1 (Ashley) 23 Jan. 2001 (23.01.2001), abstract, Figs 1-2, col. 4, lines 16-35	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 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
21 Feb 2001	17 APR 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Linda Dvorak Telephone No. 703-308-0858

Form PCT/ISA/210 (second sheet) (July 1998)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 October 2015 (08.10.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/153696 A1

(51) International Patent Classification:
A61F 5/08 (2006.01)

(21) International Application Number:
PCT/US2015/023742

(22) International Filing Date:
31 March 2015 (31.03.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/974,534	3 April 2014 (03.04.2014)	US
14/319,087	30 June 2014 (30.06.2014)	US
14/675,689	31 March 2015 (31.03.2015)	US

(71) Applicant: **AERIN MEDICAL INC.** [US/US]; 650 Page Mill Road, Palo Alto, CA 94304 (US).

(72) Inventors: **WOLF, Scott J.**; 319 Trenton Way, Menlo Park, CA 94025 (US). **FRAZIER, Andrew**; 517 Fern Ridge Count, Sunnyvale, CA 94087 (US).

(74) Agent: **SMITH, Scott M.**; Dorsey & Whitney LLP, Columbia Center, 701 Fifth Avenue, Suite 6100, Seattle, Washington 98104-7043 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

[Continued on next page]

(54) Title: POST NASAL DRIP TREATMENT

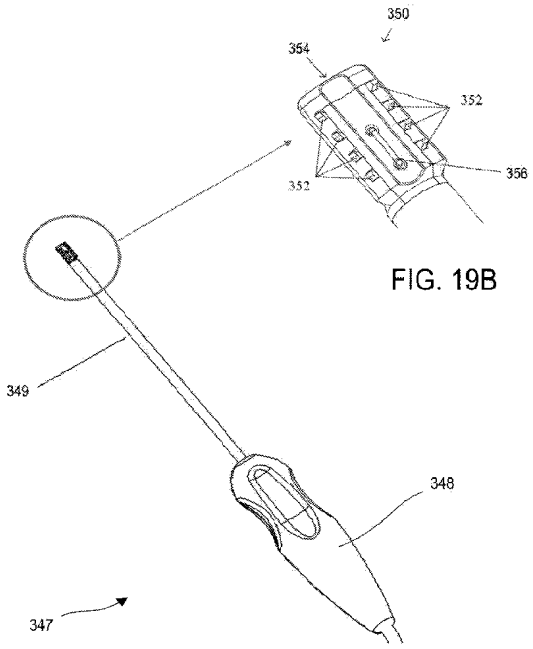


FIG. 19B

FIG. 19A

(57) 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.

WO 2015/153696 A1

SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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))*

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

Published:

— *with international search report (Art. 21(3))*

POST NASAL DRIP TREATMENT

Inventors: Scott J. WOLF
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.

[0117] Examples of Various Electrode Arrangements

[0118] 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.

[0119] 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.

[0120] 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.

[0121] 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).

[0122] 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.

[0123] 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.

[0124] 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.

[0125] 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).

[0126] 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.

[0127] 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.

[0128] 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.

[0129] 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.

[0130] 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.

[0131] 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.

[0132] 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.

[0133] Multi-channel configuration

[0134] 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.

[0135] 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.

[0136] 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.

[0137] 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.

[0138] 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.

[0139] 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.

[0140] 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.

[0141] 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.

[0142] 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.

[0143] 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.

[0144] 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.

[0145] 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.

[0146] 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.

[0147] Examples of Treatment Devices Including Electrodes

[0148] 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.

[0149] 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.

[0150] 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.

[0151] 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.

[0152] 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.

[0153] 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.

[0154] 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.

[0155] 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.

[0156] 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.

[0157] 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.

[0158] 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.

[0159] 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.

[0160] 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.

[0161] 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.

[0162] 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).

[0163] 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.

[0164] 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.

[0165] 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.

[0166] 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.

[0167] 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.

[0168] 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.

[0169] 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.

[0170] 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.

[0171] 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.

[0172] 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.

[0173] 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.

[0174] 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.

[0175] 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.

[0176] 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.

[0177] Profile of treatment element

[0178] 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.

[0179] 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.

[0180] 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.

[0181] 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.

[0182] 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.

[0183] 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).

[0184] 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.

[0185] 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.

[0186] 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.

[0187] 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.

[0188] 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.

[0189] 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.

[0190] 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.

[0191] 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.

[0192] 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.

[0193] 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.

[0194] 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.

[0195] 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 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.

2. 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.

3. 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.

4. The device of claim 3, wherein the electrodes protrude from the treatment surface.

5. The device of claim 4, wherein the electrodes are blunt-tipped electrodes.

6. The device of claim 1, further comprising a thermocouple disposed within the concave trough.

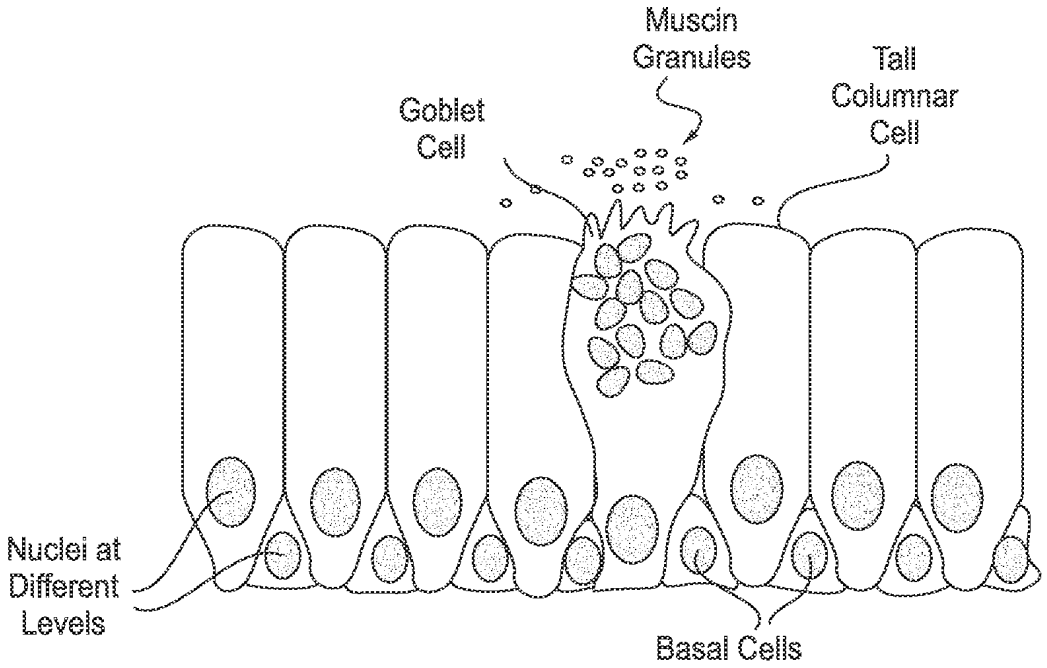

Muscin
Granules
Tall
Columnar
Cell
Goblet
Cell
Nuclei at
Different
Levels
Basal Cells

FIG. 1

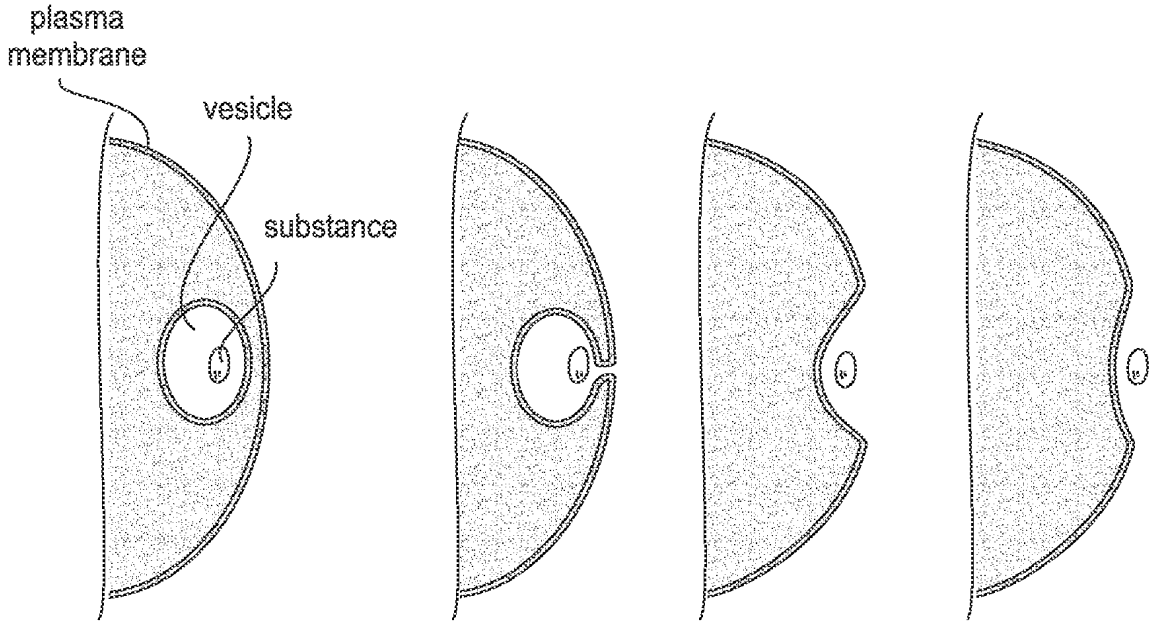

plasma
membrane
vesicle
substance

FIG. 2

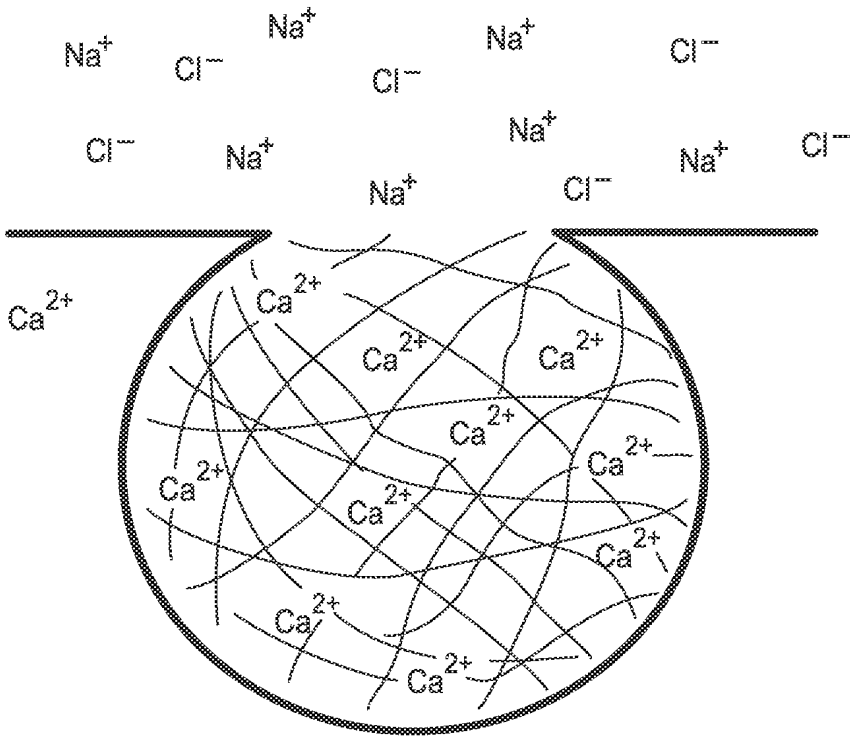


FIG. 3

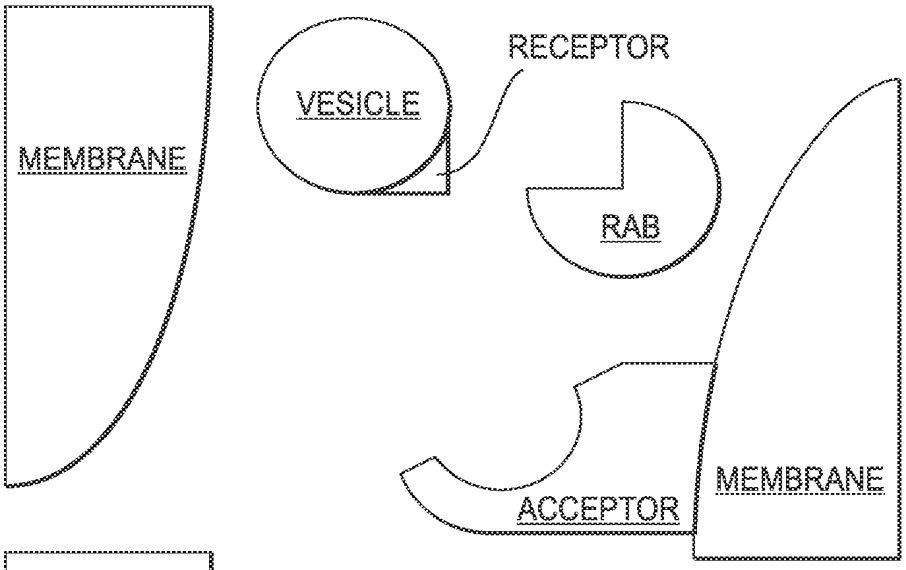


FIG. 4A

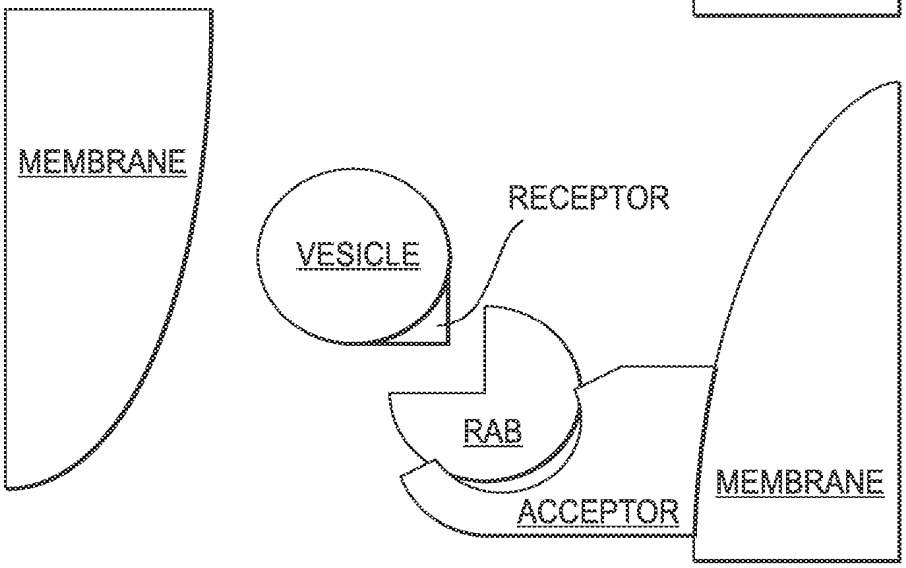


FIG. 4B

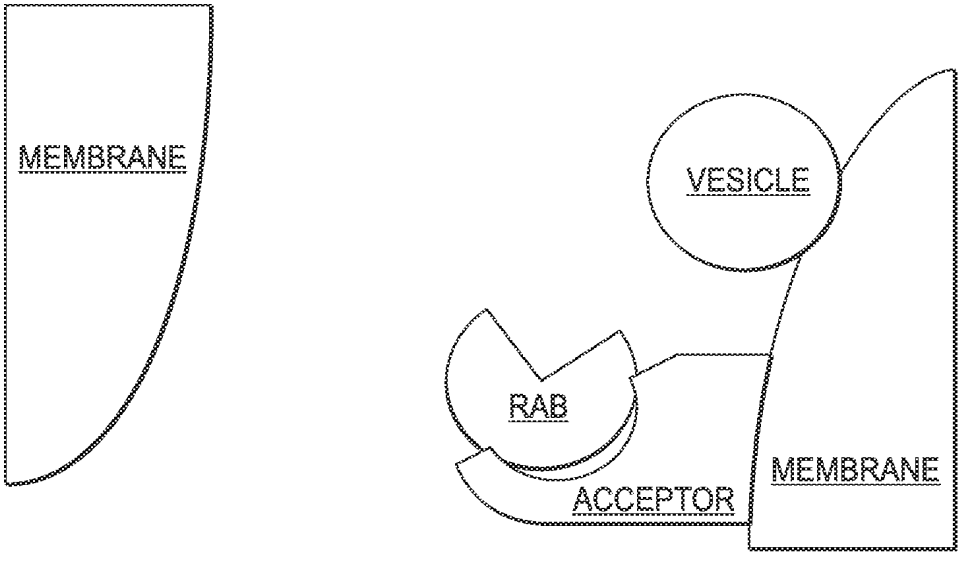


FIG. 4c

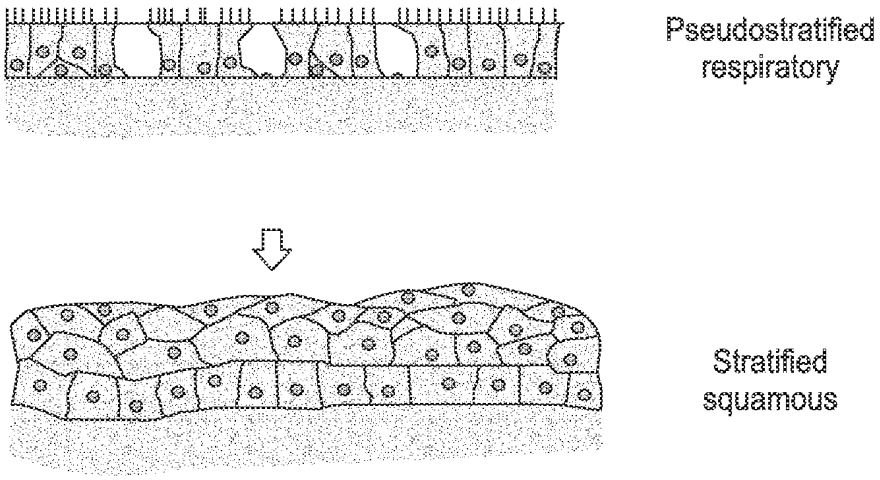

Pseudostratified
respiratory
Stratified
squamous

FIG. 5

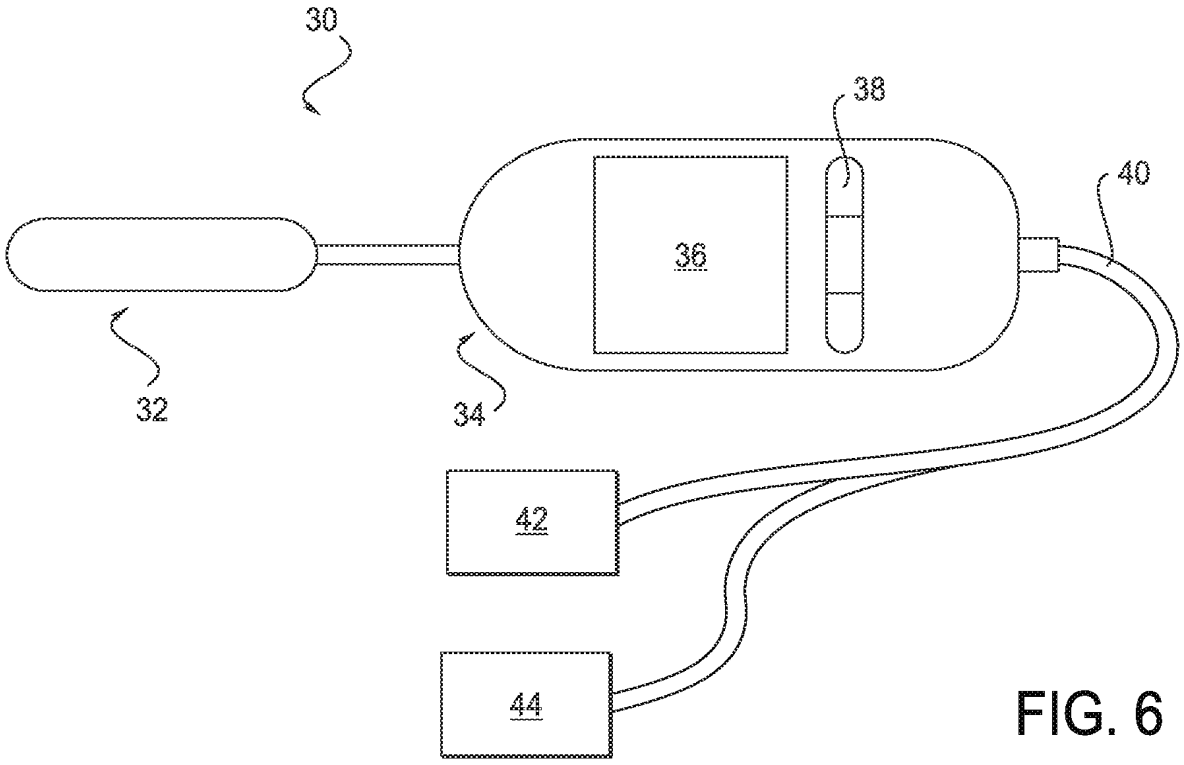

30
38
40
36
32
34
42
44

FIG. 6

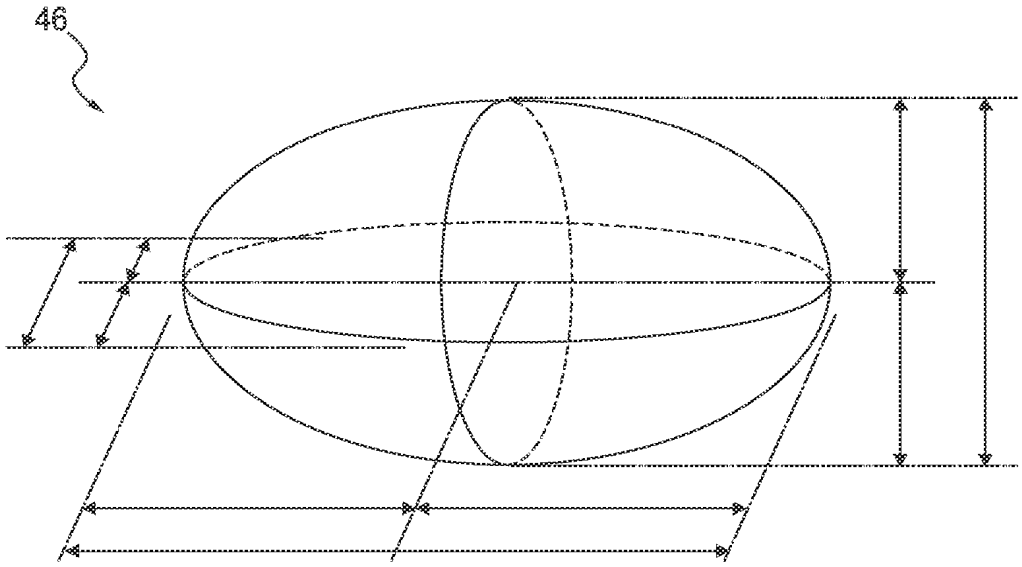


FIG. 7

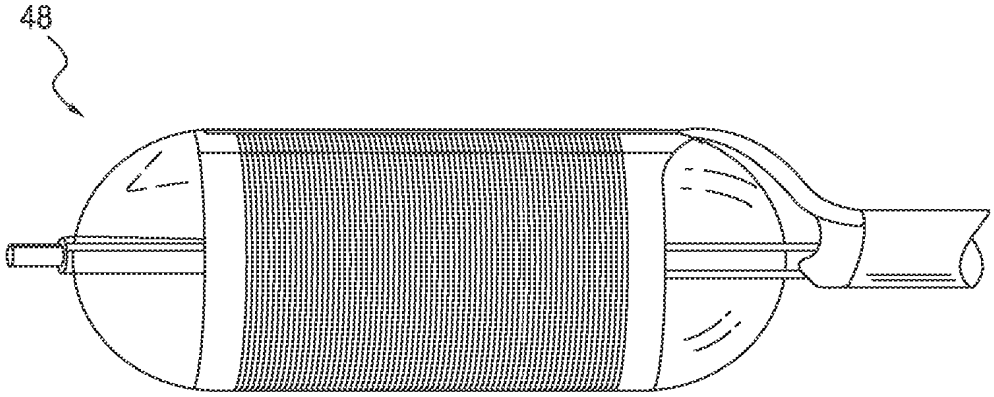


FIG. 8

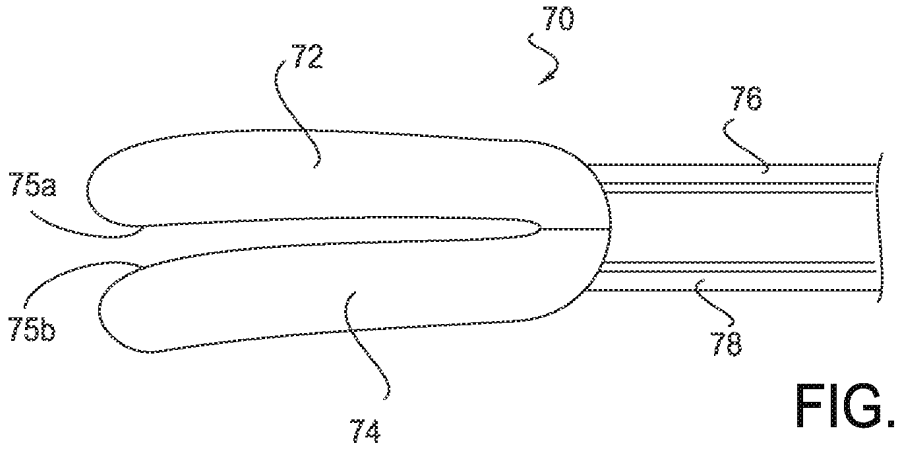


FIG. 9

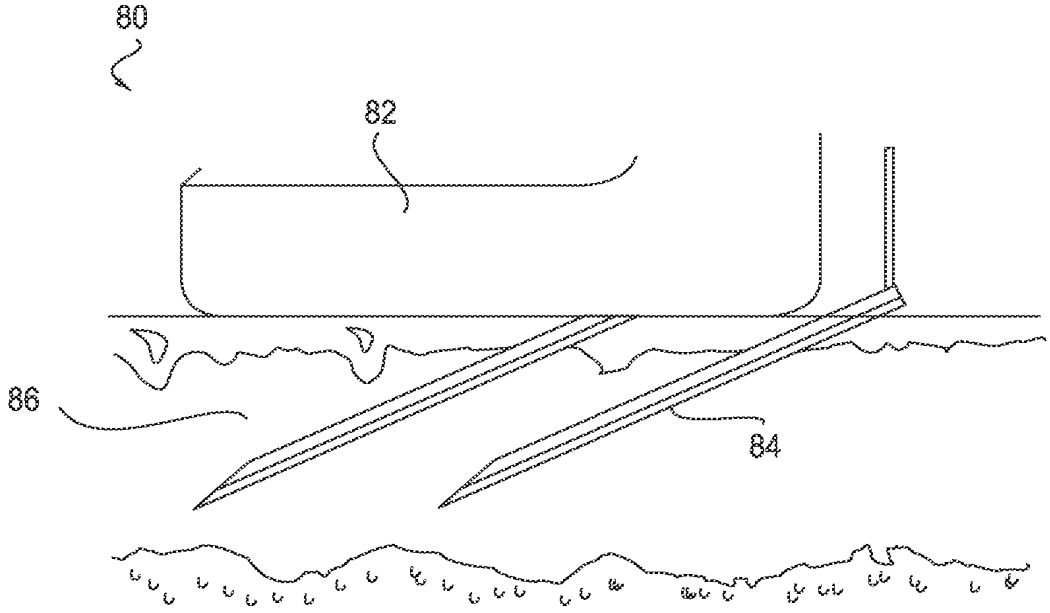


FIG. 10

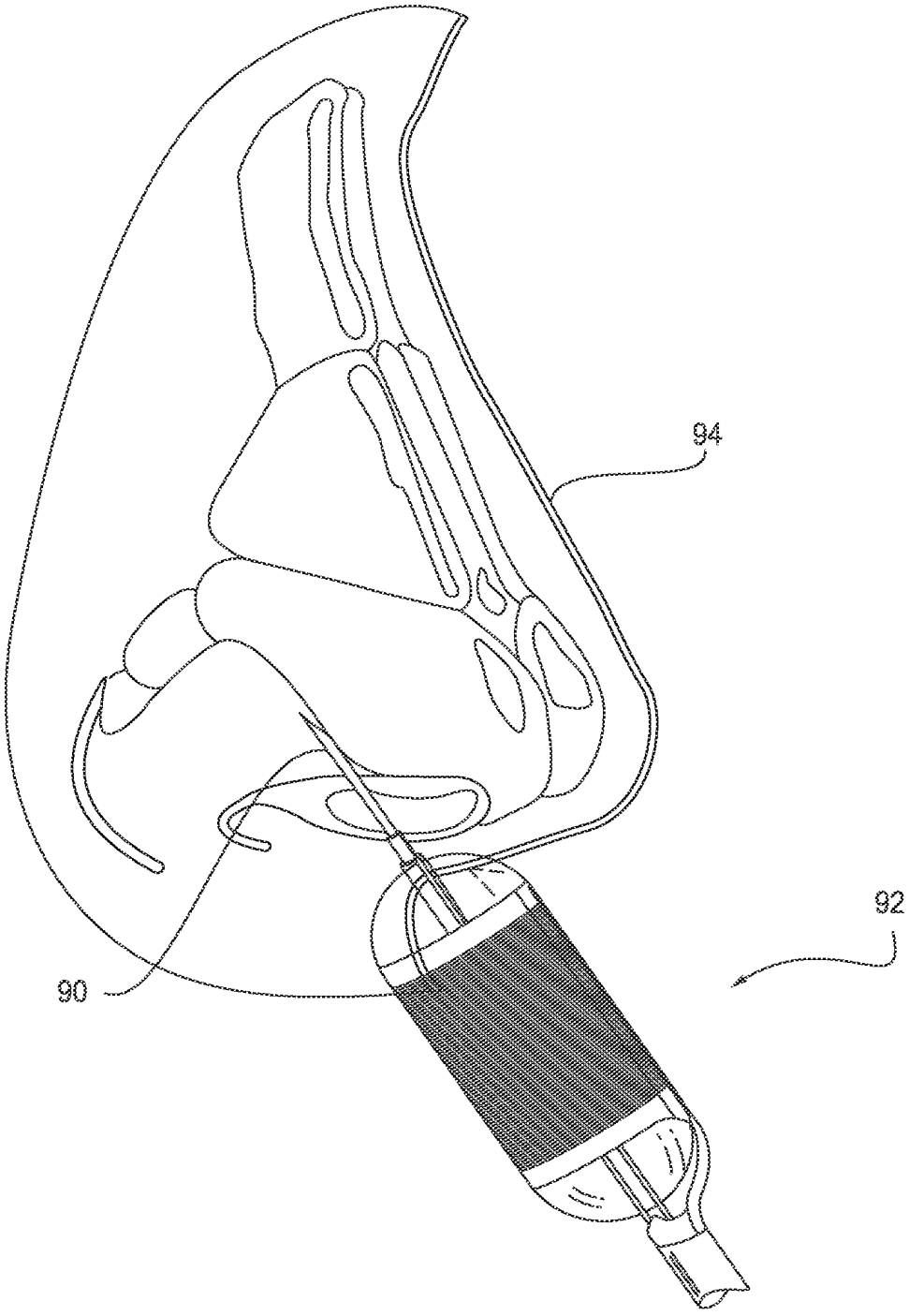


FIG. 11

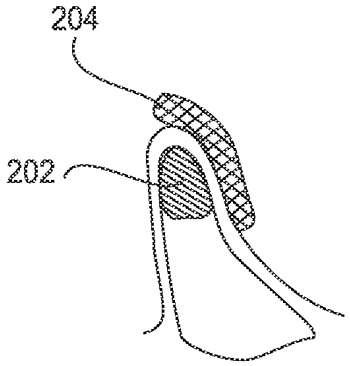


FIG. 12A

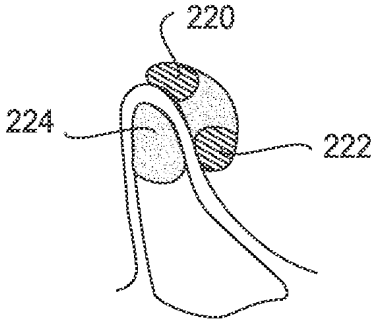


FIG. 12C

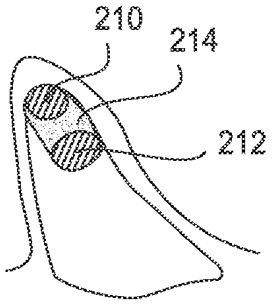


FIG. 12B

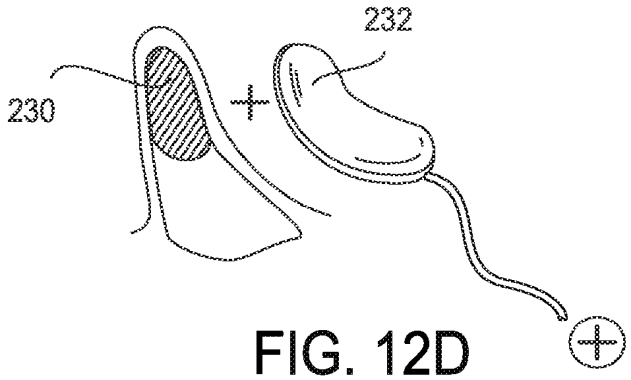


FIG. 12D

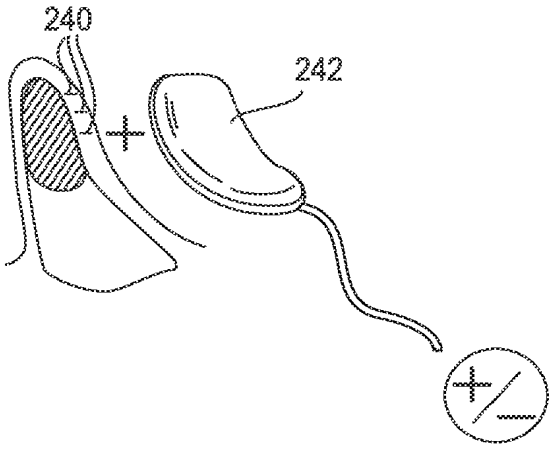


FIG. 12E

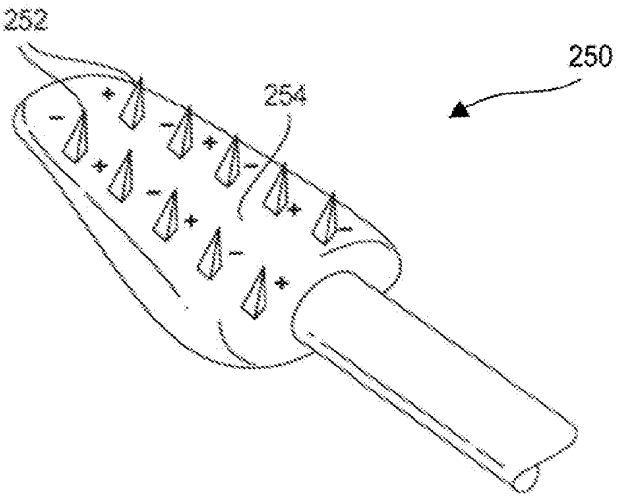


FIG. 13

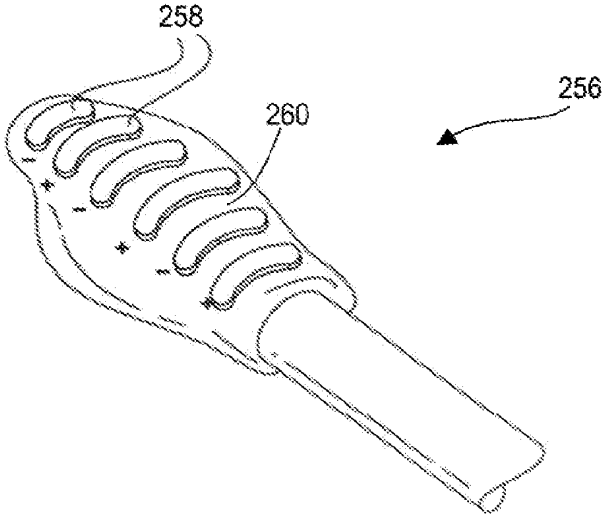


FIG. 14

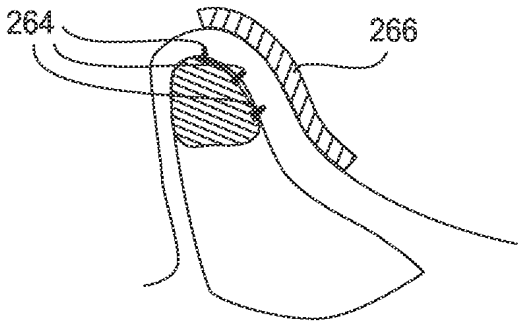


FIG. 15A

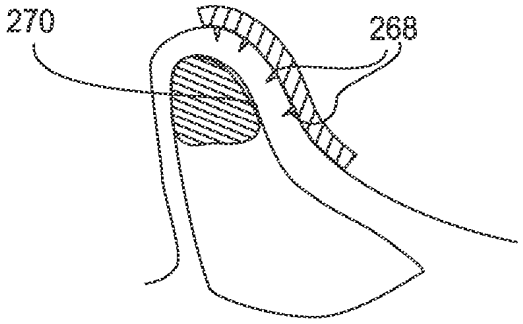


FIG. 15B

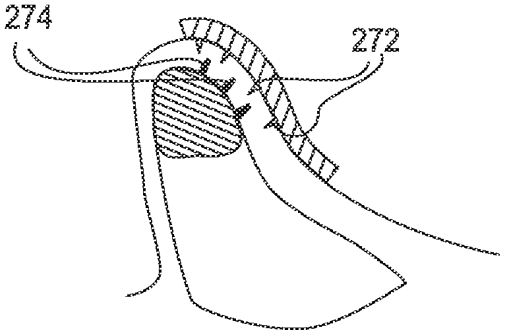


FIG. 15C

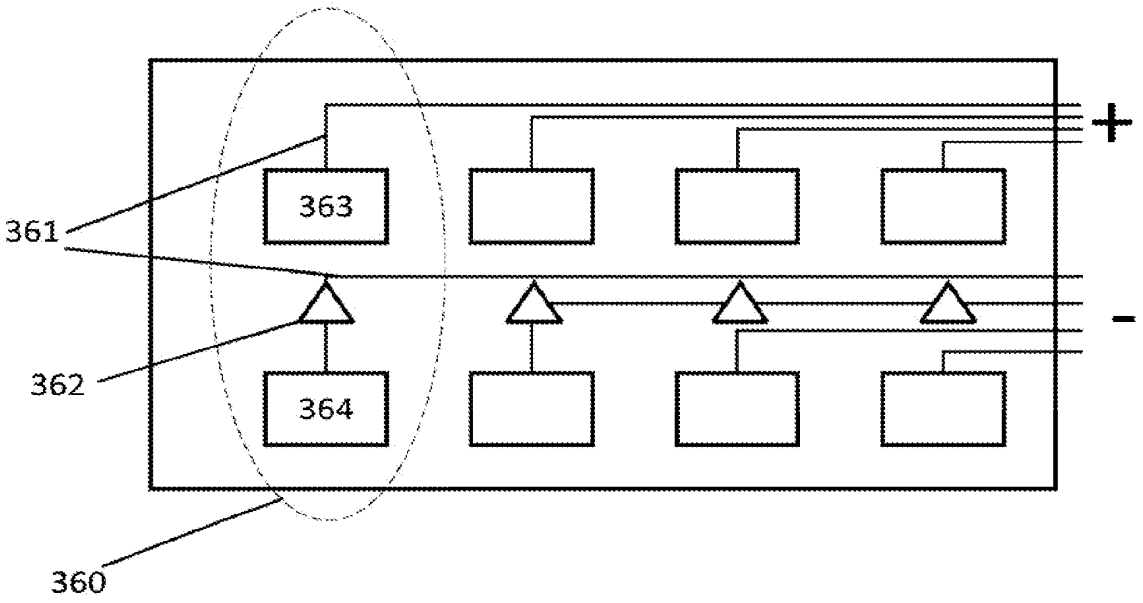


FIG. 16A

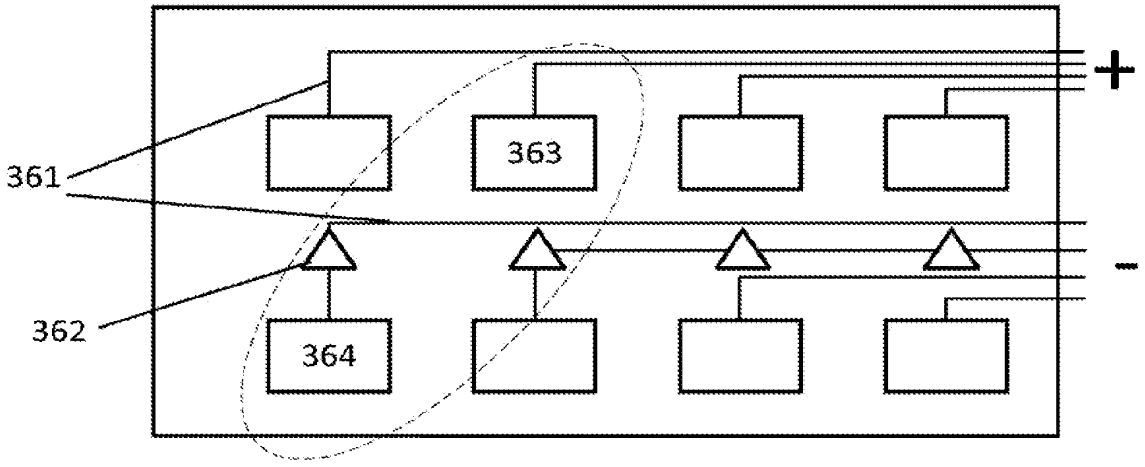


FIG. 16B

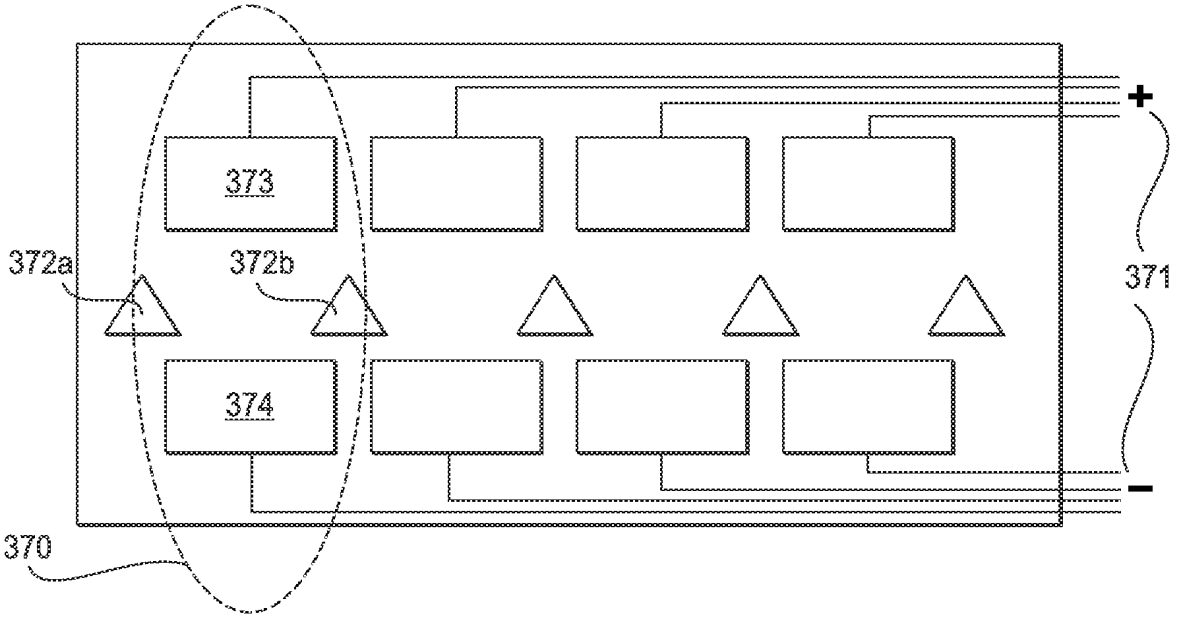


FIG. 16C

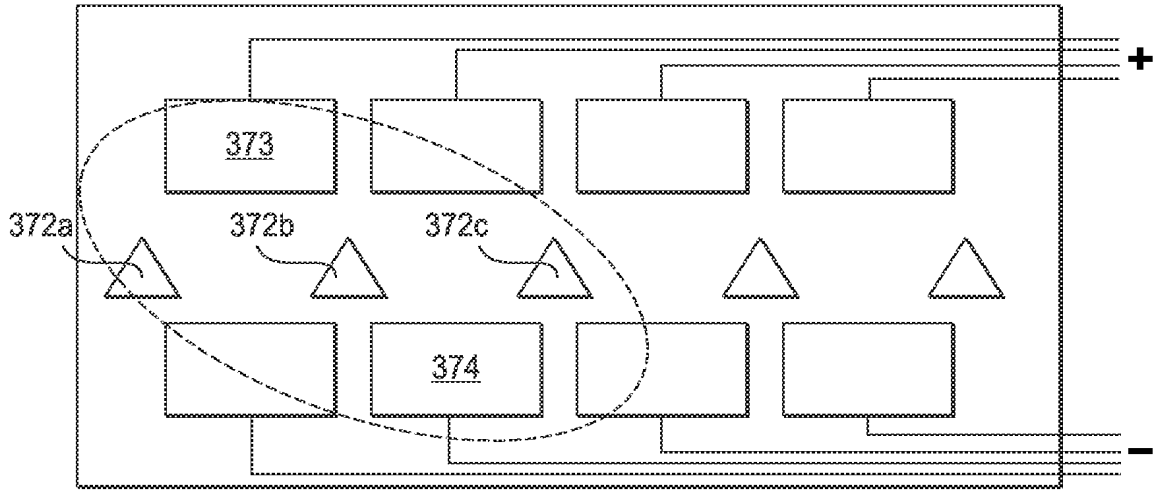


FIG. 16D

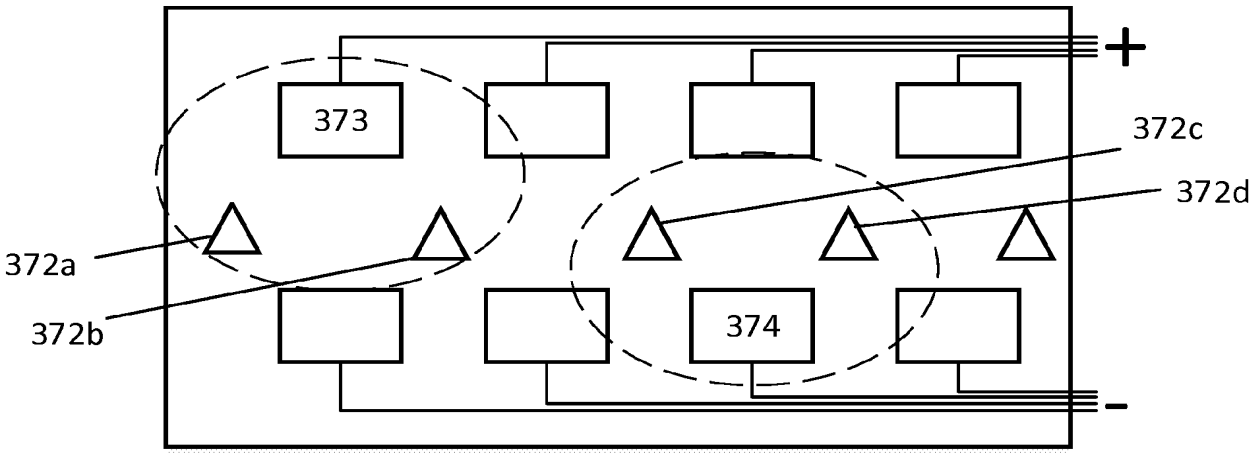


FIG. 16E

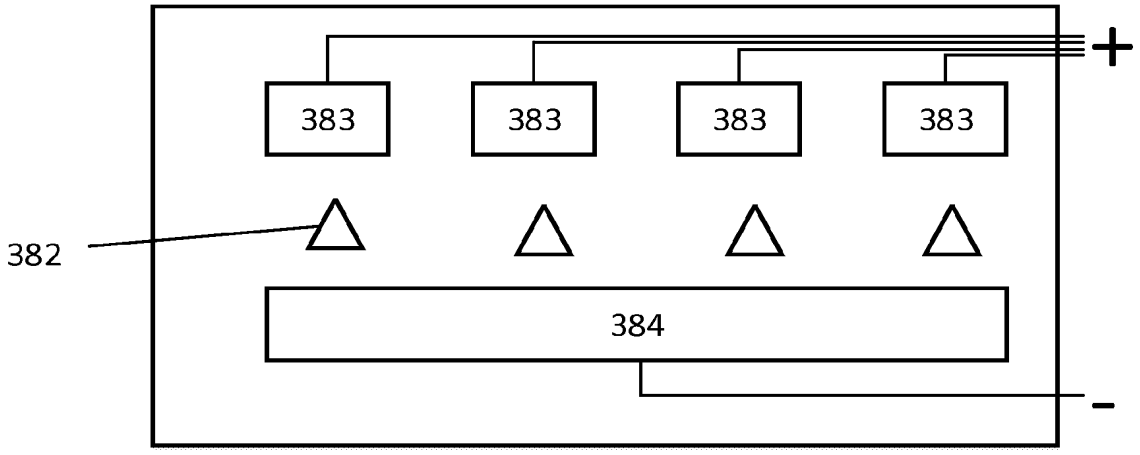


FIG. 16F

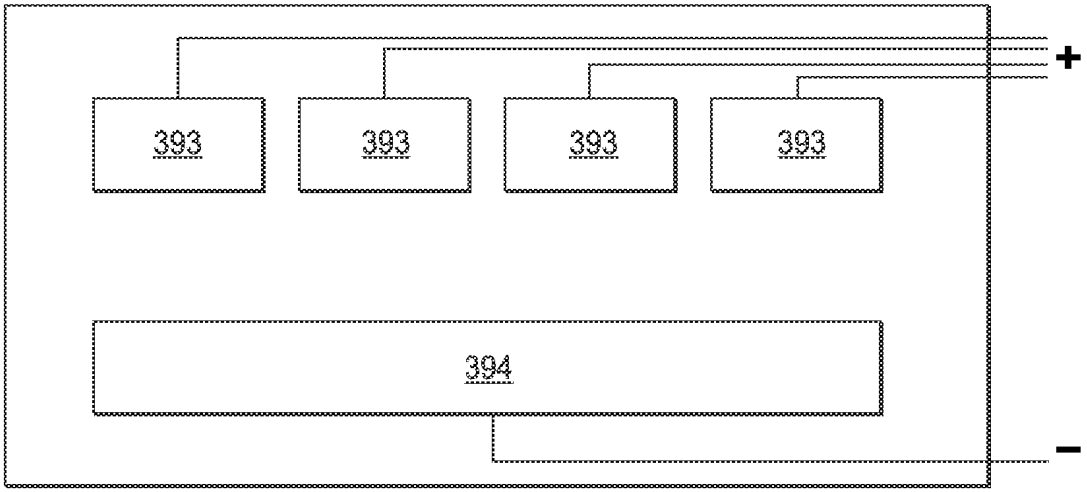


FIG. 16G

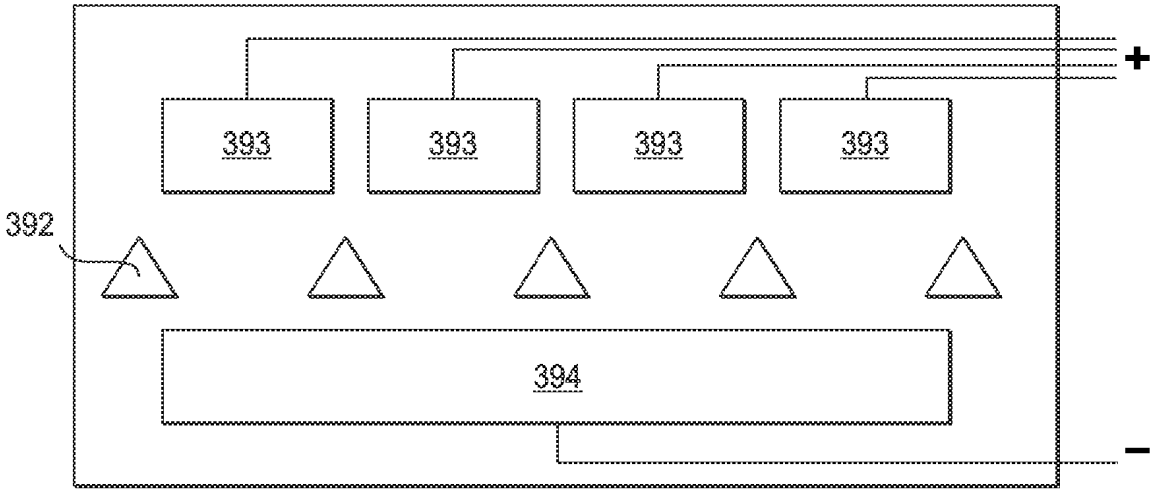


FIG. 16H

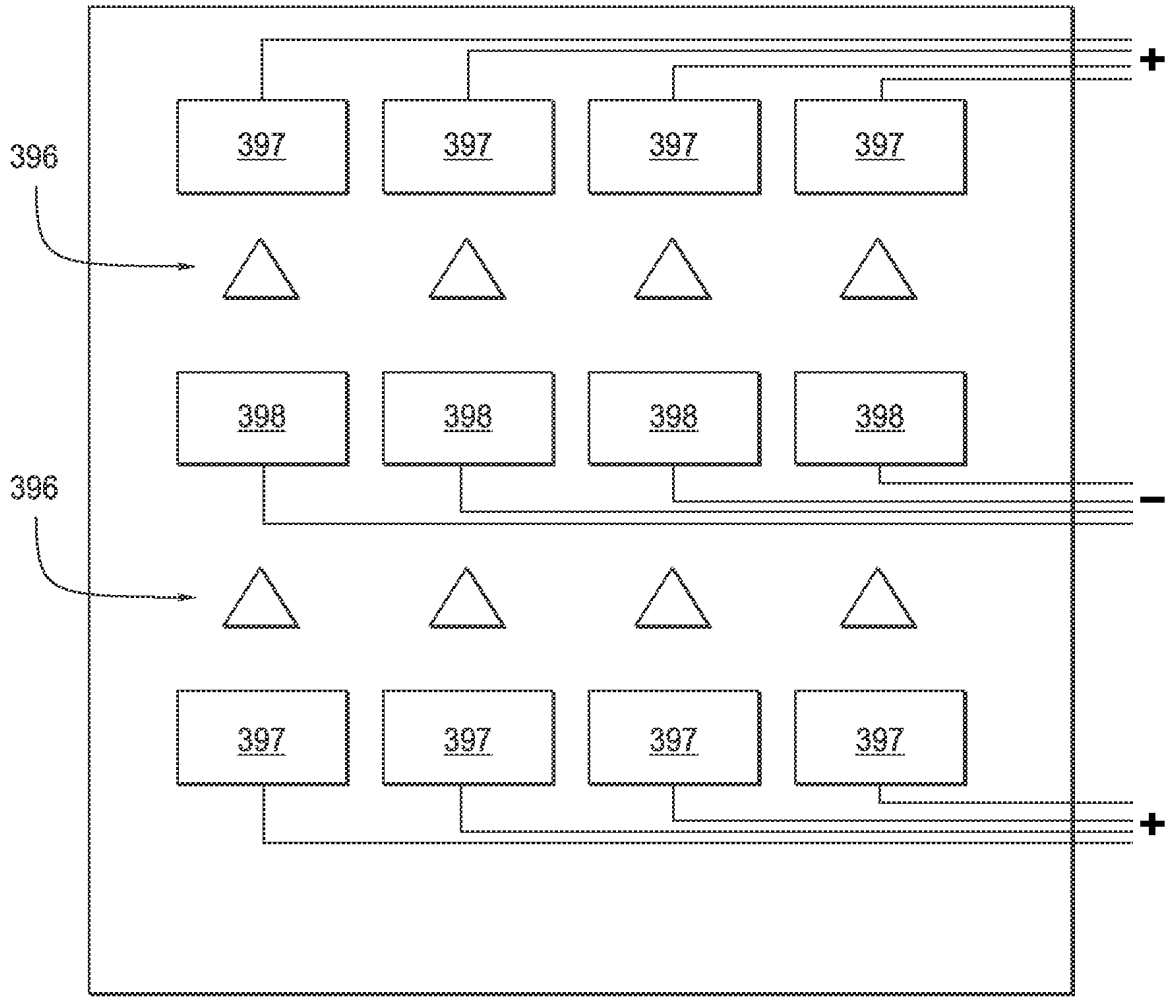


FIG. 16I

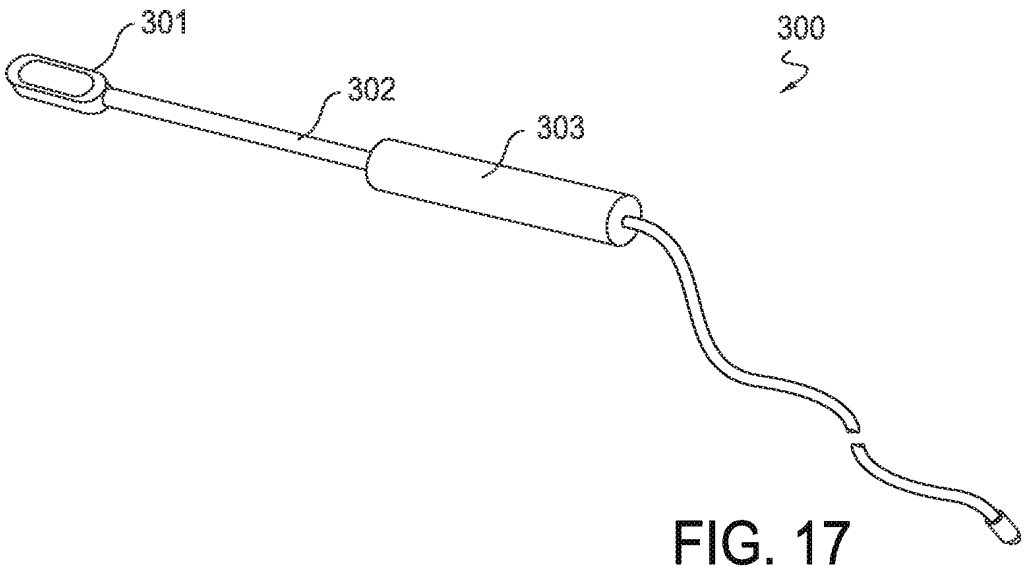


FIG. 17

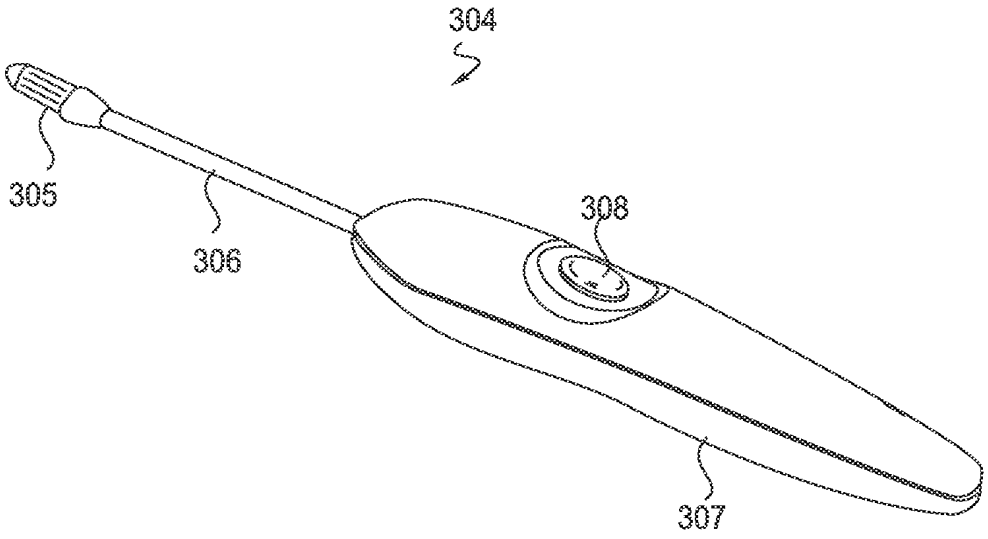


FIG. 18

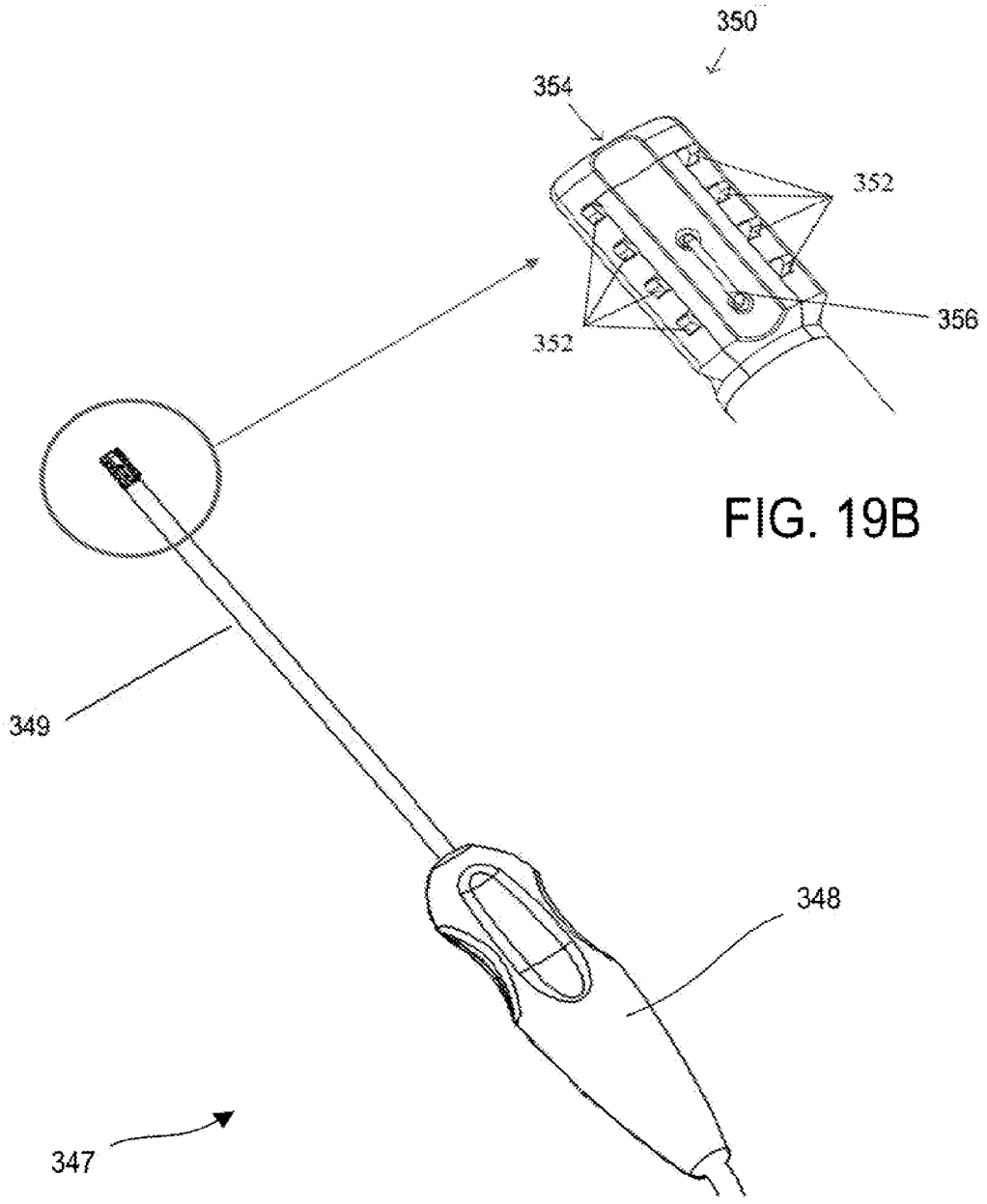


FIG. 19B

FIG. 19A

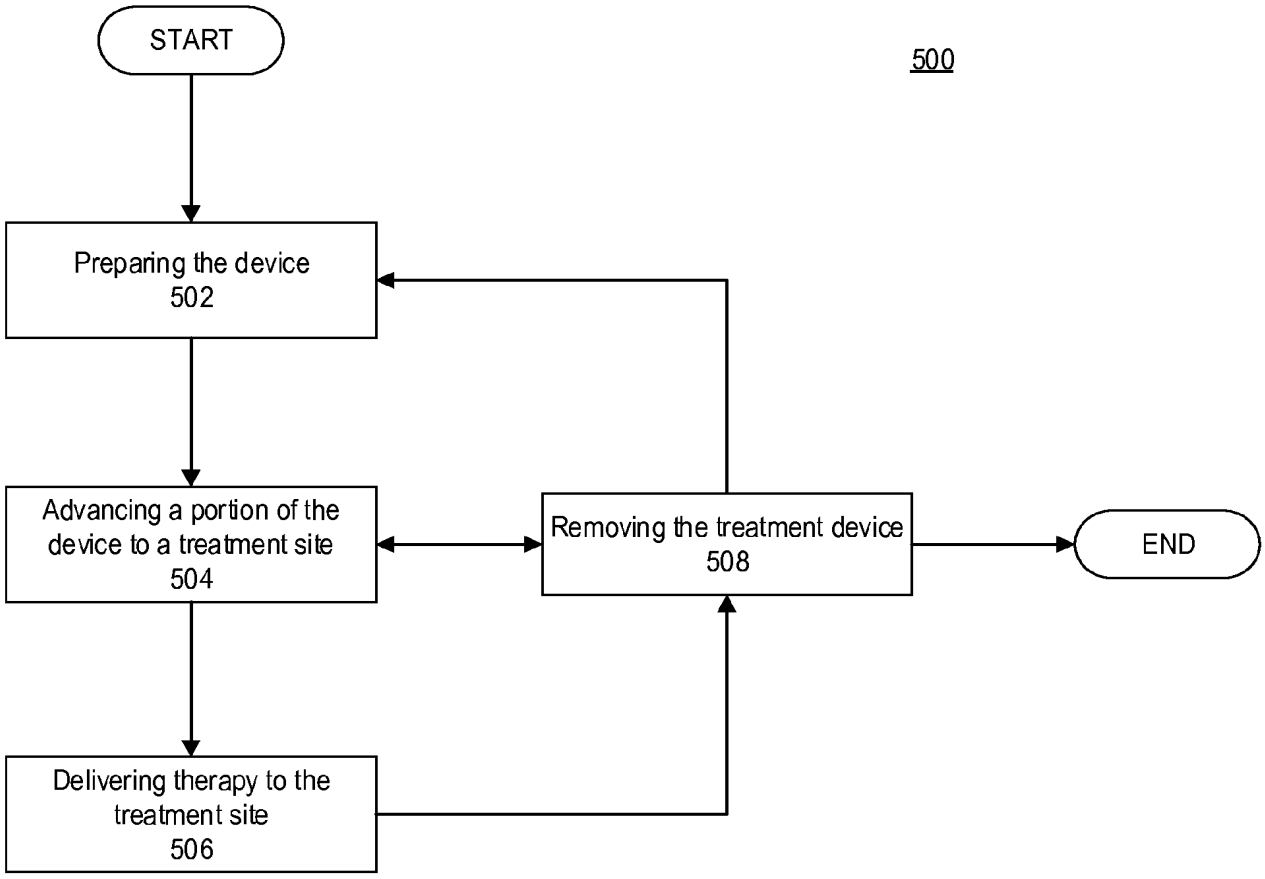

START
500
Preparing the device
502
Advancing a portion of the device to a treatment site
504
Removing the treatment device
508
END
Delivering therapy to the treatment site
506

FIG. 20

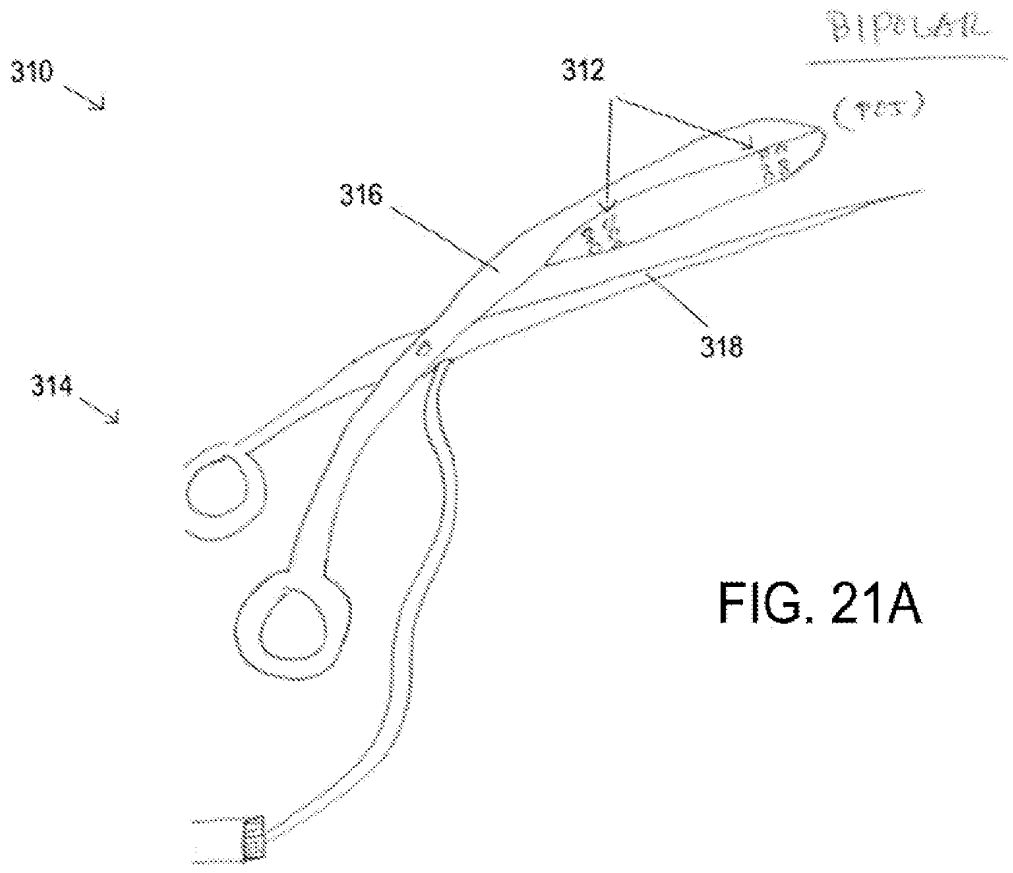


FIG. 21A

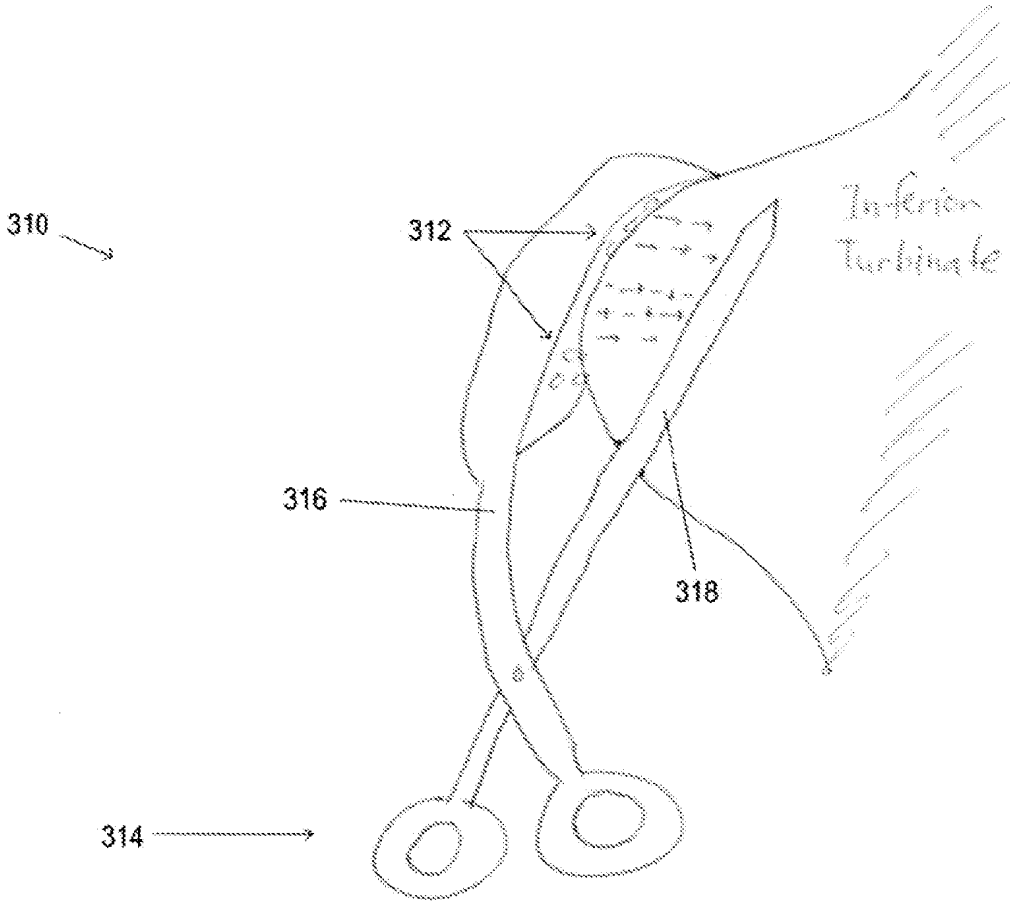


FIG. 21B

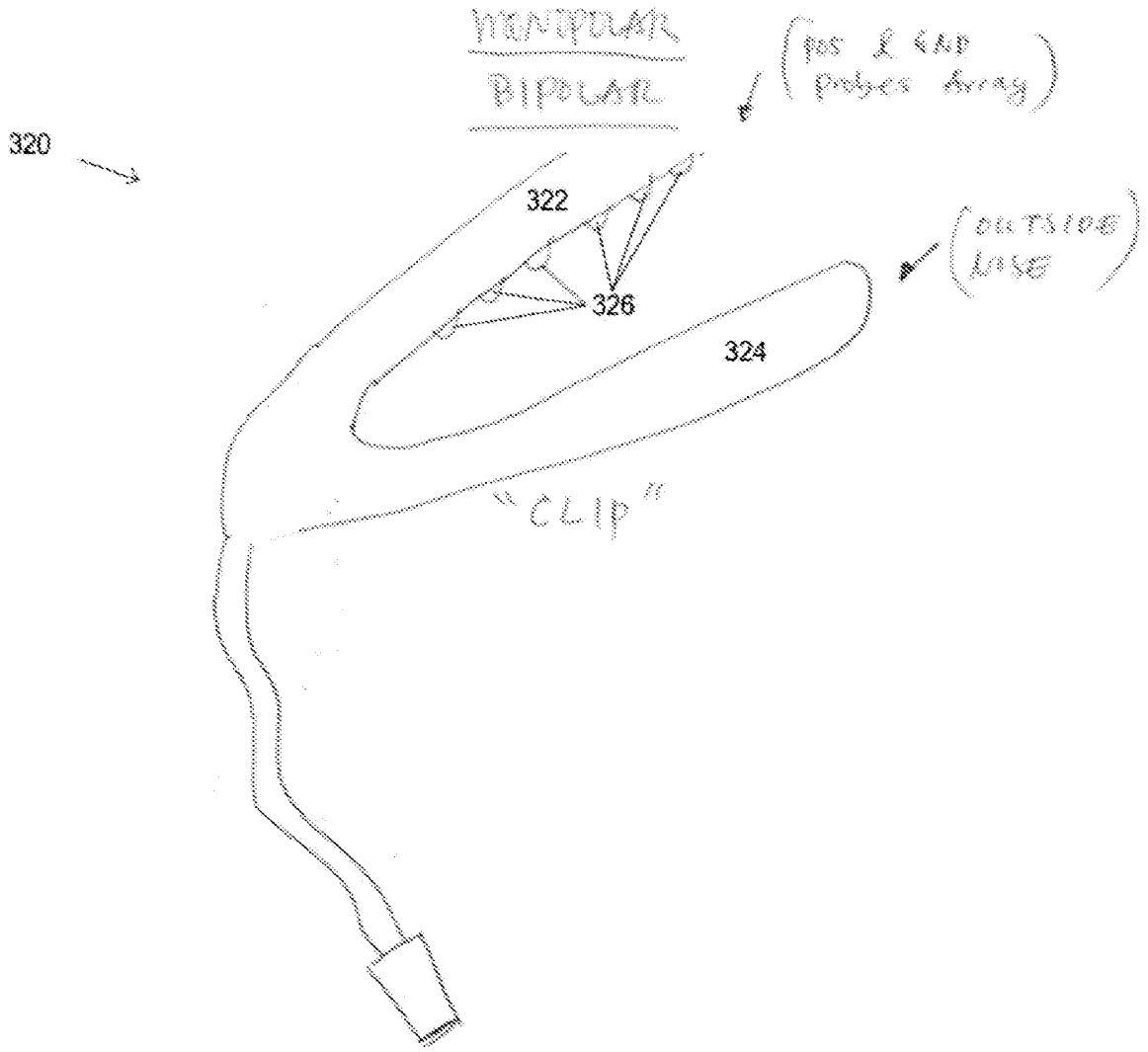


FIG. 22A

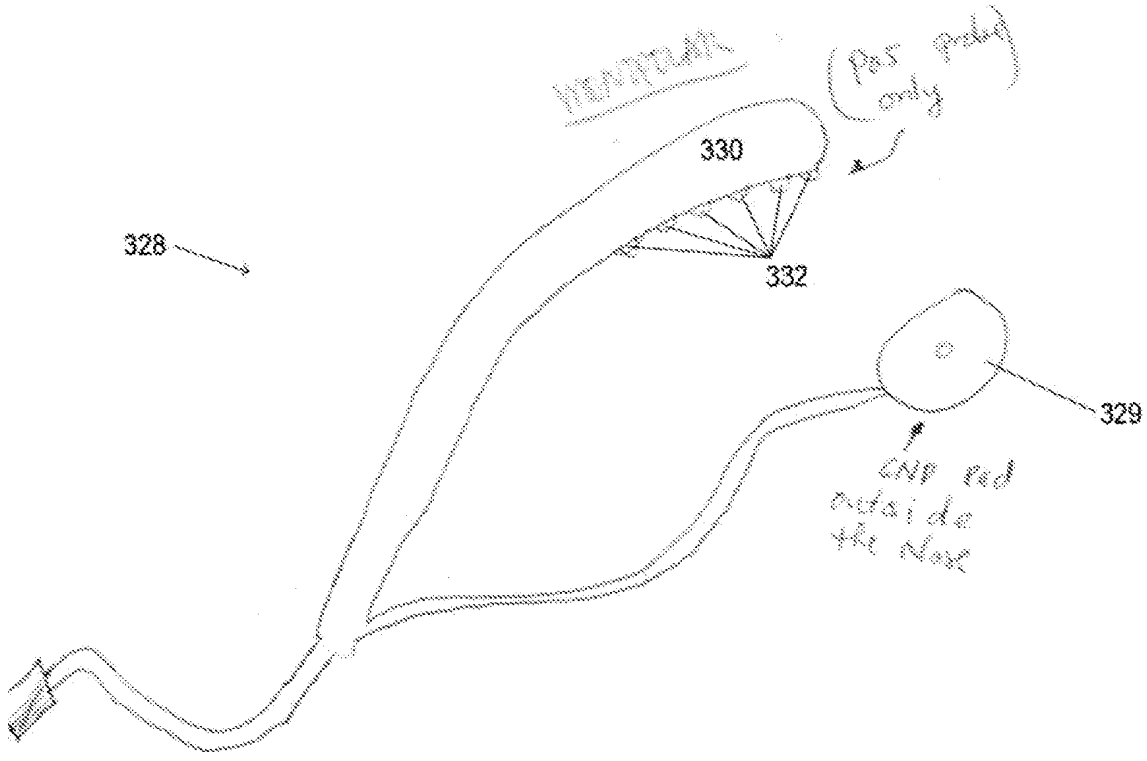


FIG. 22B

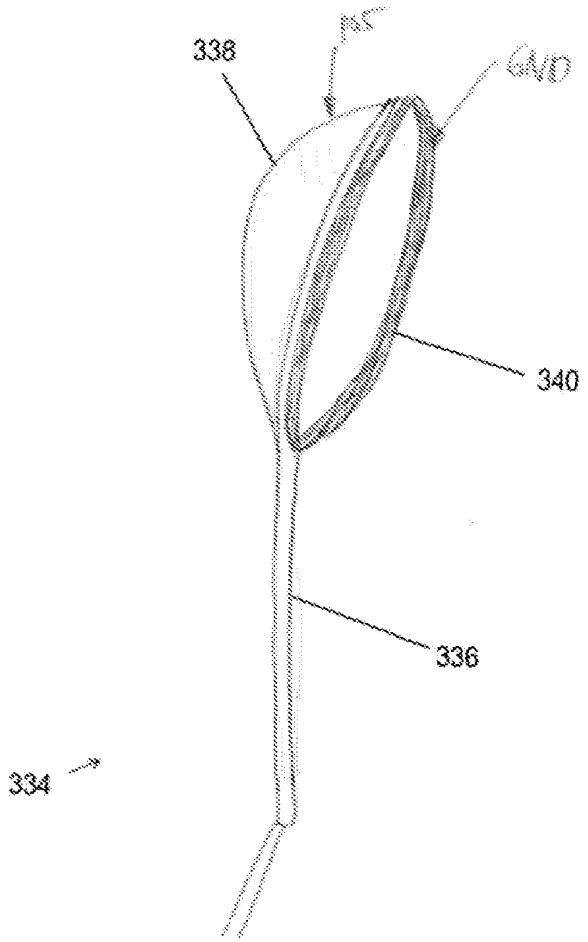


FIG. 23

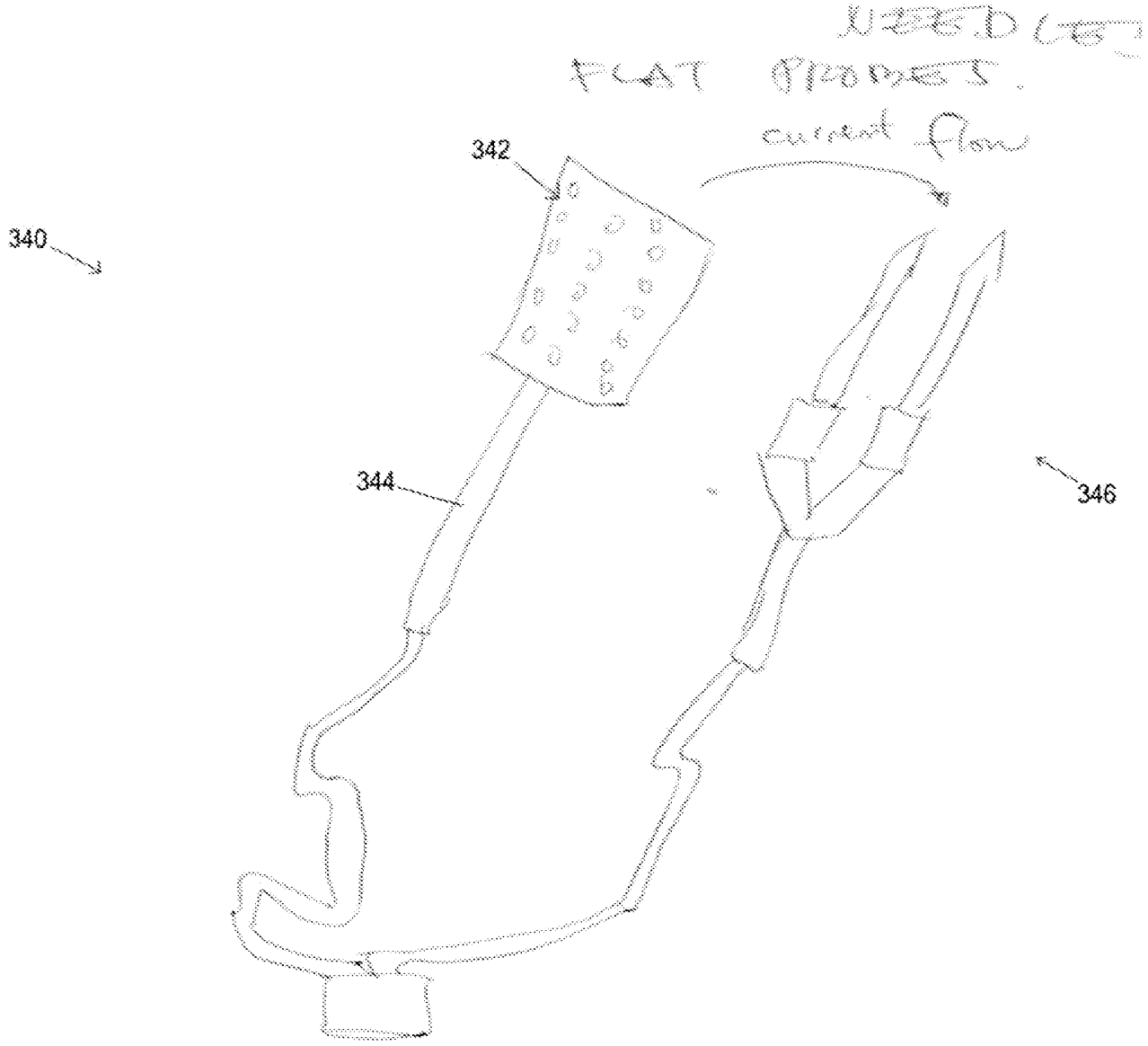


FIG. 24

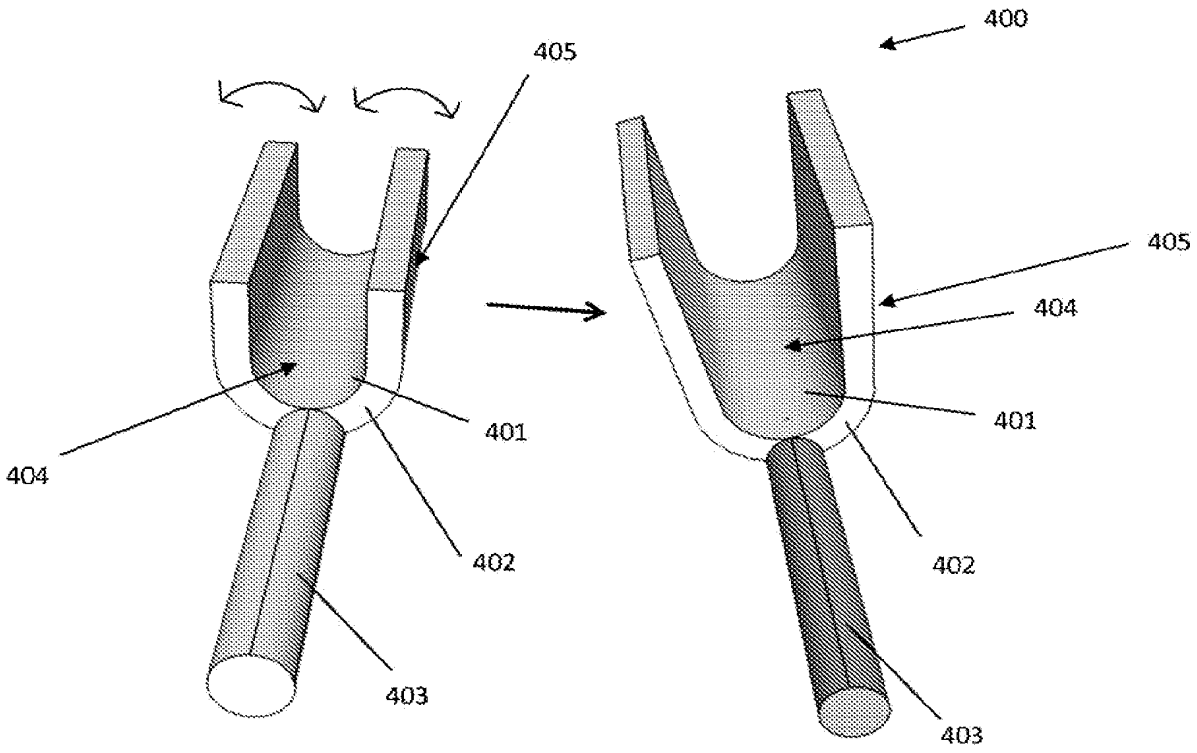


FIG. 25

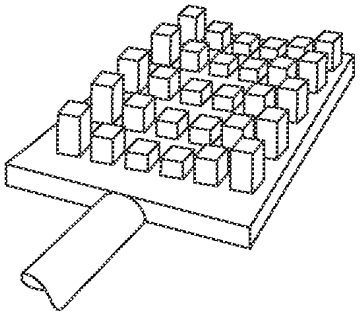


FIG. 26A

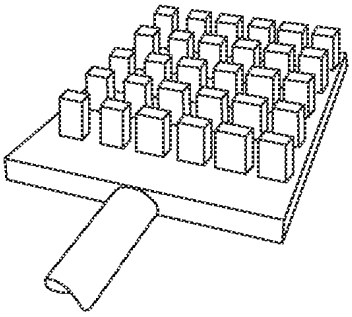


FIG. 26B

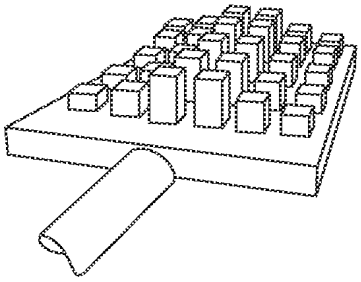


FIG. 26C

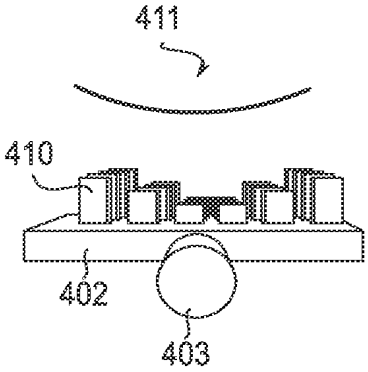


FIG. 26D

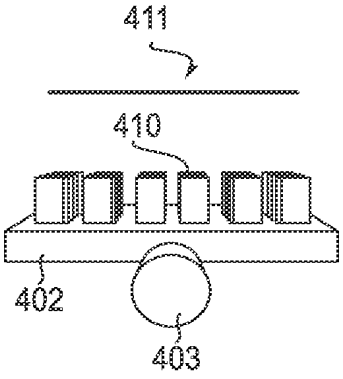


FIG. 26E

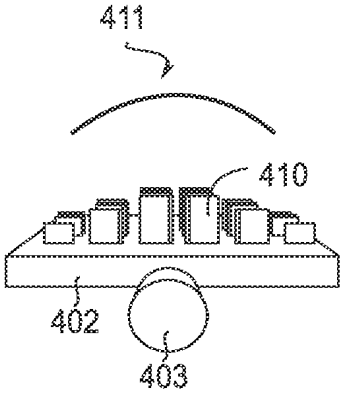


FIG. 26F

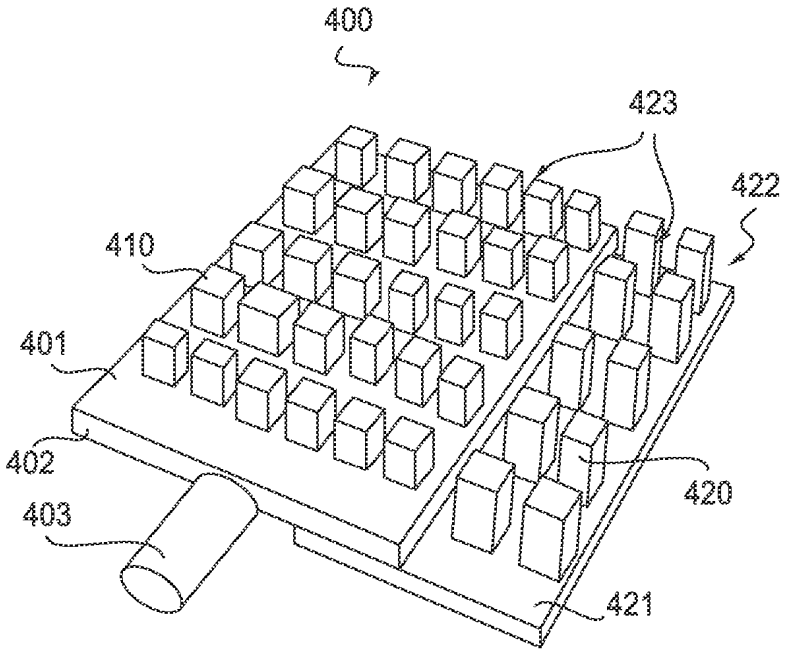


FIG. 27

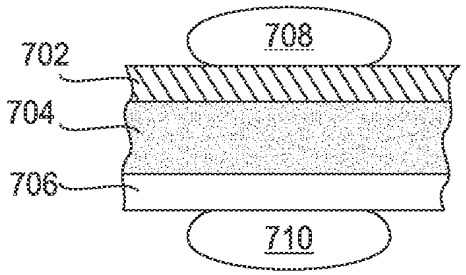


FIG. 28A

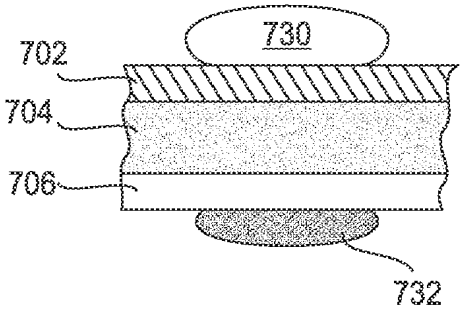


FIG. 28B

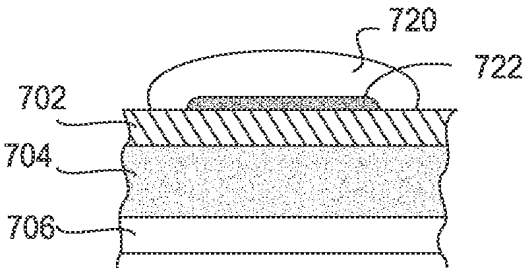


FIG. 28C

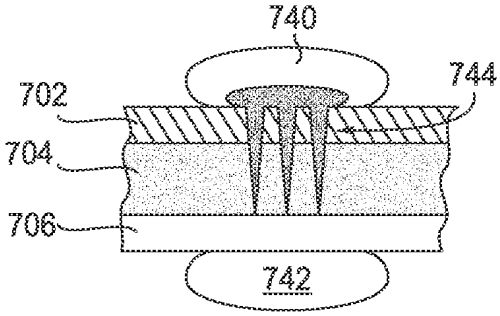


FIG. 28D

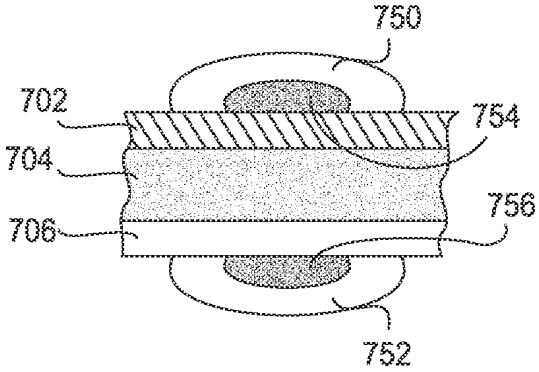


FIG. 28E

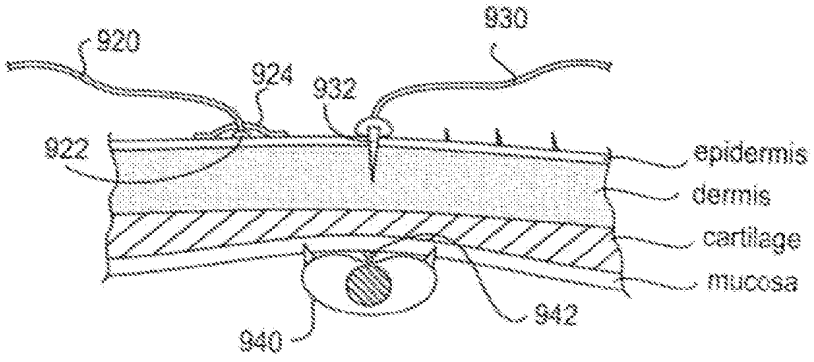


FIG. 29A

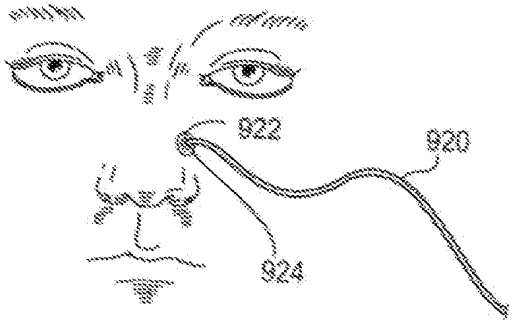


FIG. 29B

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)

Electronic Acknowledgement Receipt

EFS ID:	30342269
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US11
Receipt Date:	12-SEP-2017
Filing Date:	
Time Stamp:	17:32:33
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)	2017-09-12_IDS_17713-0001US11.PDF	631358 2778fbdaab365253b3459e0c6095a24ecbd334bb	no	5

Warnings:

Information:					
2	Foreign Reference	WO2001043653.pdf	1031731 e5071c494e05a10cc8408734f7663a4e3df454b1	no	28
Warnings:					
Information:					
3	Foreign Reference	WO2015153696.pdf	3324044 9b0107b4380e9d359892063b460e9efd17eccef6	no	77
Warnings:					
Information:					
			Total Files Size (in bytes):	4987133	

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	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/686,265	08/25/2017		930	17713.0001US11	12	2

CONFIRMATION NO. 7653

23552
MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

FILING RECEIPT

OC000000094373954

Date Mailed: 09/28/2017

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., SUNNYVALE, CA

Power of Attorney: The patent practitioners associated with Customer Number 23552

Domestic Priority data as claimed by applicant

This application is a CON of 15/272,007 09/21/2016 PAT 9788886
which is a CON of 14/754,087 06/29/2015 PAT 9452010
which is a CON 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 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 Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 09/27/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/686,265**

Projected Publication Date: 01/04/2018

Non-Publication Request: No

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

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Preliminary Class

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

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

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: 15/686,265

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))	12 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 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).			200			
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	930		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/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	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. WOLF
Art Unit	3762
Examiner Name	MANUEL, GEORGE C.
Attorney Docket Number	17713.0001US11

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	9788886		2017-10-17	Wolf et al.	
	2	9801752		2017-10-31	Wolf et al.	
	3	9763723		2017-09-19	Saadat	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20050234439		2005-10-20	Underwood	
	2	20100174283		2010-07-08	McNall	
	3	20120298105		2012-11-29	Osorio	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C.
	Attorney Docket Number	17713.0001US11

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]
	1	199907299	WO		1999-02-18			
	2	2010077980	WO		2010-07-08			
	3	2012174161	WO		2012-12-20			

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]
	1	Supplementary European Search Report for Application No. 15772528, mailed September 26, 2017, 7 pages.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C.
	Attorney Docket Number	17713.0001US11

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)	2017-12-18
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.

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.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : **A61B 17/39** — **A1**

(11) International Publication Number: **WO 99/07299**

(43) International Publication Date: 18 February 1999 (18.02.99)

(21) International Application Number: PCT/US98/11337

(22) International Filing Date: 3 June 1998 (03.06.98)

(30) Priority Data:
08/905,991 5 August 1997 (05.08.97) US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application
US 08/905,991 (CIP)
Filed on 5 August 1997 (05.08.97)

(71) Applicant *(for all designated States except US)*: SOMNUS MEDICAL TECHNOLOGIES, INC. [US/US]; 285 N. Wolfe Road, Sunnyvale, CA 94086 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: EDWARDS, Stuart, D. [US/US]; 658 Westridge Drive, Portola Valley, CA 94028 (US). LAX, Ronald, G. [US/US]; 2740 S.W. Martindown Boulevard #300, Palm City, FL 34990 (US).

(74) Agent: DAVIS, Paul; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).

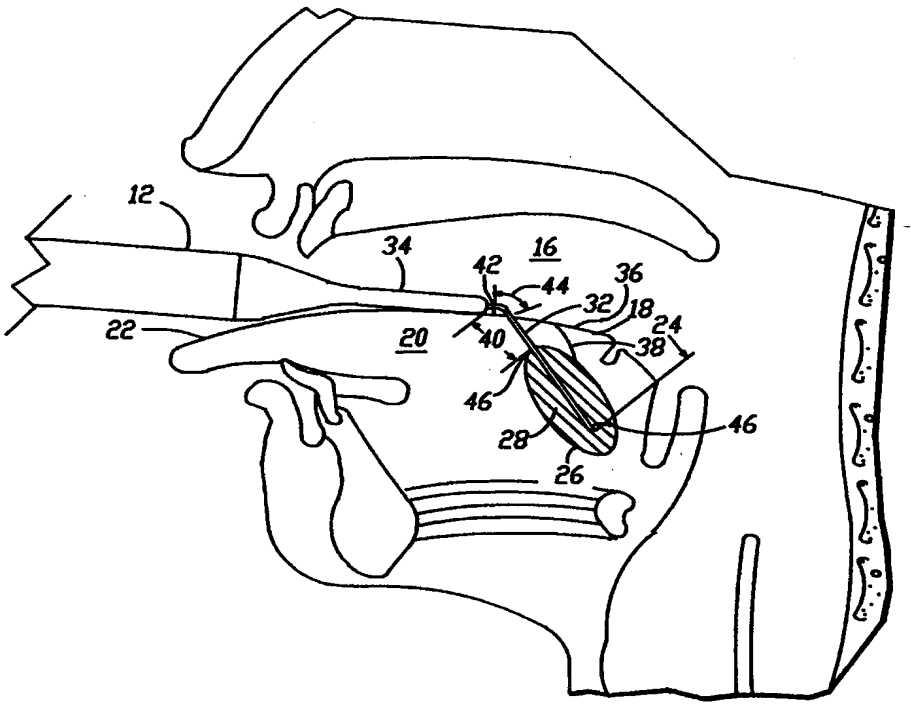
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: CELL NECROSIS APPARATUS USING EM ENERGY

(57) Abstract

An apparatus that reduces a volume of a selected site in an interior of the tongue includes a handpiece means and an electrode means at least partially positioned in the interior of the handpiece means. The electrode means includes an electrode means electromagnetic energy delivery surface and is advanceable from the interior of the handpiece means into the interior of the tongue. An electrode means advancement member is coupled to the electrode means and configured to advance the electrode means an advancement distance in the interior of the tongue. The advancement distance is sufficient for the electrode means electromagnetic energy delivery surface to deliver electromagnetic energy to the selected tissue site and reduce a volume of the selected site without damaging a hypoglossal nerve. A cable means is coupled to the electrode means.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

CELL NECROSIS APPARATUS USING EM ENERGY

BACKGROUND OF THE INVENTION

Cross-Reference to Related Applications

This application is a continuation-in-part of U.S. Patent Application No. 08/642,327, filed May 3, 1996, entitled "Method for Treatment of Airway Obstructions", which application is a continuation-in-part application of U.S. Patent Application No. 08/606,195, filed February 23, 1996, entitled "Method for Treatment of Airway Obstructions", which cross-references U.S. Patent Application No. 08/516,781 filed August 18, 1995, entitled "Ablation Apparatus and System for Removal of Soft Palate Tissue", having named inventors Stuart D. Edwards, Edward J. Gough and David L. Douglass, which is a continuation-in-part of U.S. Application No. 08/239,658, filed May 9, 1994 entitled "Method for Reducing Snoring by RF Ablation of the Uvula" This application is also related to an Application Serial No. 08/642,053, filed 5/3/96, entitled "Method and Apparatus for Treatment of Air Way Obstructions", all incorporated by reference herein.

Field of the Invention

This invention relates to an apparatus for the treatment of air way obstructions, and more particularly to an apparatus for creating selective cell necrosis in interior sections of selected head and neck structures without damaging vital structures.

Description of Related Art

Sleep-apnea syndrome is a medical condition characterized by daytime hypersomnomulence, morning arm aches, intellectual deterioration, cardiac arrhythmias, snoring and thrashing during sleep. It is caused by frequent episodes of apnea during the patient's sleep. The syndrome is classically

subdivided into two types. One type, termed "central sleep apnea syndrome", is characterized by repeated loss of respiratory effort. The second type, termed obstructive sleep apnea syndrome, is characterized by repeated apneic episodes during sleep resulting from obstruction of the patient's upper airway or that portion of the patient's respiratory tract which is cephalad to, and does not include, the larynx.

Treatment thus far includes various medical, surgical and physical measures. Medical measures include the use of medications such as protriptyline, medroxyprogesterone, acetazolamide, theophylline, nicotine and other medications in addition to avoidance of central nervous system depressants such as sedatives or alcohol. The medical measures above are sometimes helpful but are rarely completely effective. Further, the medications frequently have undesirable side effects.

Surgical interventions have included uvulopalatopharyngoplasty, tonsillectomy, surgery to correct severe retrognathia and tracheostomy. In one type of surgical intervention a standard LeFort I osteotomy is combined with a sagittal split ramus osteotomy to advance the maxilla, mandible and chin. Such a procedure may be effective but the risk of surgery in these patients can be prohibitive and the procedures are often unacceptable to the patients.

Physical measures have included weight loss, nasopharyngeal airways, nasal CPAP and various tongue retaining devices used nocturnally. These measures may be partially effective but are cumbersome, uncomfortable and patients often will not continue to use these for prolonged periods of time. Weight loss may be effective but is rarely achieved by these patients.

In patients with central sleep apnea syndrome, phrenic nerve or diaphragmatic pacing has been used. Phrenic nerve or diaphragmatic pacing includes the use of electrical stimulation to regulate and control the patient's diaphragm which is innervated bilaterally by the phrenic nerves to assist or support ventilation. This pacing is disclosed in *Direct Diaphragm Stimulation* by J. Mugica et al. PACE vol. 10 Jan-Feb. 1987, Part II, *Preliminary Test of a Muscular Diaphragm Pacing System on Human Patients* by J. Mugica et al.

from Neurostimulation: An Overview 1985 pp. 263-279 and *Electrical Activation of Respiration* by Nochomovitez IEEE Eng. in Medicine and Biology; June, 1993.

However, it was found that many of these patients also have some degree of obstructive sleep apnea which worsens when the inspiratory force is augmented by the pacer. The ventilation induced by the activation of the diaphragm also collapses the upper airway upon inspiration and draws the patient's tongue inferiorly down the throat choking the patient. These patients then require tracheostomies for adequate treatment.

A physiological laryngeal pacemaker as described in *Physiological Laryngeal Pacemaker* by F. Kaneko et al. from Trans Am Soc Artif Intern Organs 1985 senses volume displaced by the lungs and stimulates the appropriate nerve to open the patient's glottis to treat dyspnea. This apparatus is not effective for treatment of sleep apnea. The apparatus produces a signal proportional in the displaced air volume of the lungs and thereby the signal produced is too late to be used as an indicator for the treatment of sleep apnea. There is often no displaced air volume in sleep apnea due to obstruction.

One measure that is effective in obstructive sleep apnea is tracheostomy. However, this surgical intervention carries considerable morbidity and is aesthetically unacceptable to many patients. Other surgical procedures include a standard Le Fort I osteotomy in combination with a sagittal split ramus osteotomy. This is a major surgical intervention that requires the advancement of the maxilla, mandible and chin.

Generally, there are two types of snoring. They are distinguished, depending on the localization of their origin. The first type of snoring, velar, is produced by the vibration of all of the structures of the soft palate including the velum, the interior and posterior arches of the tonsils and the uvula. Velar snoring results from a vibration of the soft palate created by the inspiratory flow of air, both nasal and oral, which makes the soft palate wave like a flag. The sound intensity of these vibrations is accentuated by the opening of the buccal cavity which acts as a sound box.

The second type, pharyngeal snoring, is a kind of rattle, including even horn whistling. It is caused by the partial obstruction of the oropharyngeal isthmus by the base of the tongue with, now and again, its total exclusion by the tongue base becoming jammed against the posterior wall of the pharynx. This results in a sensation of breathing, apnea, which constitutes the sleep apnea syndrome. These two types of snoring may easily be combined in the same individual.

For some years there have been surgical techniques for correcting apnea. However, maxillary surgery to cure pharyngeal snoring requires major surgery, with the operation lasting several hours, and the uvula-palatopharnygoplasty procedure to correct velar snoring is not without draw backs. This explains the popularity of prosthesis and other preventive devices.

More recently, portions of the soft palate have been removed by laser ablation. If too much tissue is removed, severe consequences result. The degree of laser ablation is difficult to control and multiple treatments are usually required. Further, patients have a high degree of soreness in their throats for many weeks.

U.S. Patent No. 4,423,812 discloses a loop electrode design characterized by a bare active wire portion suspended between wire supports on an electrode shaft. Tissue striping is effected with a bare wire, and the adjacent portions of the wire supports an electrode shaft that is made insulating to prevent accidental burns to the patient, allowing the physician to use these insulated parts to help position and guide the active wire portion during the surgical procedure. However, this requires that the physician shave off, during multiple visits, successive thin superficial layers of the obstructing tissues to avoid gross resection and its adverse affects.

U.S. Patent No. 5,046,512 discloses a method for the treatment of snoring and apnea. The method regulates air flow to the user to an extent comparable to the volume of air which flows through the users nasal passages. An associated apparatus provides a device having a body portion sufficiently

wide to separate the users teeth. It includes an air passage comparable in area to the area of the user's nasal passages.

The use of oral cavity appliances has been proposed frequently for the treatment of sleep disorders. It has been recognized that movement of the mandible forward relative to the maxilla can eliminate or reduce sleep apnea and snoring symptoms by causing the pharyngeal air passage to remain open. Several intra-oral dental appliances have been developed which the user wears at night to fix the mandible in an anterior protruded position. Such dental appliances essentially consist of acrylic or elastomeric bit blocks, similar to orthodontic retainers or athletic mouth guards, which are custom fitted to a user's upper and lower teeth. The device may be adjusted to vary the degree of anterior protrusion.

U.S. Patent 4,901,737 discloses an intra-oral appliance while reducing snoring which repositions the mandible in an inferior, open, and anterior, protrusive, position as compared to the normally closed position of the jaw. Once the dentist or physician determines the operative snoring reduction position for a particular patient, an appropriate mold is taken for the maxillary dentition and of the mandibular dentition to form an appliance template. This device includes a pair of V-shaped spacer members formed from dental acrylic which extend between the maxillary and mandibular dentition to form a unitary mouthpiece.

While such dental appliances have proven effective in maintaining the mandible in a protruded position to improve airway patency, they often result in undesirable side effects. One of the most common side effects is aggravation of the tempromandibular joint and related jaw muscles and ligaments, especially in individuals who have a tendency to grind their teeth during sleep. Aggravation of the tempromandibular joint has be associated with a wide variety of physical ailments, including migraine headaches. Accordingly, many individuals suffering from sleep apnea and snoring disorders are not able to tolerate existing anti-snoring dental appliances for long periods of time.

Opening of obstructed nasal airways by reducing the size of the turbinates has been performed using surgical and pharmaceutical treatments. Examples of surgical procedures include anterior and posterior ethmoidectomy, such as those described in "Endoscopic Paranasal Sinus Surgery" by D. Rice and S. Schaefer, Raven Press, 1988); the writings of M. E. Wigand, Messerklinger and Stamberger; and U.S. Patent No. 5,094,233. For example, as described in U.S. Patent No. 5,094,233, the Wigand procedure involves the transection of the middle turbinate, beginning with the posterior aspect, visualization of the sphenoid ostium and opening of the posterior ethmoid cells for subsequent surgery. In the sphenoidectomy step, the ostium of the sphenoid is identified and the anterior wall of the sinus removed. Following this step, the posterior ethmoid cells may be entered at their junction with the sphenoid and the fovea ethmoidalis can be identified as an anatomical landmark for further dissection. In anterior ethmoidectomy, the exenteration of the ethmoids is carried anteriorly to the frontal recess. Complications, such as hemorrhage, infection, perforation of the fovea ethmoidalis or lamina papyracea, and scarring or adhesion of the middle turbinate, are reported in connection with these procedures.

One of the problems encountered as a result of these procedures is postoperative adhesion occurring between the turbinates and adjacent nasal areas, such as medial adhesion to the septum and lateral adhesion to the lateral nasal wall in the area of the ethmoid sinuses. Otherwise successful surgical procedures may have poor results in these cases. Some surgeons have proposed amputation of a portion of the turbinate at the conclusion of surgery to avoid this complication, resulting in protracted morbidity (crust formation and nasal hygiene problems). The turbinate adhesion problem detracts from these endoscopic surgical procedures. Efforts have been made to reduce the complications associated with the surgical treatment of turbinate tissue, for example by the use of a turbinate sheath device. U.S. Patent No. 5,094,233.

U.S. Patent No. 3,901,241 teaches a cryosurgical instrument which is said to be useful for shrinking nasal turbinates. U.S. Patent No. 3,901,241.

Pharmaceuticals have also been developed for reducing the size of the turbinates. However, pharmaceuticals are not always completely efficacious and generally do not provide a permanent reduction in turbinate size. In addition, pharmaceuticals can have adverse side effects.

A need exists for a method and device for clearing obstructed nasal passageways. It is preferred that the method and device be performable with minimal surgical intervention or post operative complications. It is also preferred that the method and device reduce the size of the turbinate structure without involving surgical cutting or the physical removal of tissue. It is also preferred that the method and device provide a reduction in turbinate structure size to increase air flow in the nasal passageway sufficiently impairing blood flow to the optic nerve and/or retina and create a permanent impairment of vision by the ablation.

It would be desirable to provide an ablation apparatus which eliminates the need for dental appliances for the treatment of snoring and sleep apnea disorders. It would also be desirable to provide a treatment device which is not an intra-oral dental appliance, and which can effectively and safely remove selected portions of the soft palate without providing the patient with undesirable side effects. Further, it would be desirable to provide a tissue ablation device which retains the targeted ablation tissue during the ablation process.

It would be desirable to provide an apparatus for the treatment of snoring which reduces the size of the soft palate and/or uvula with a minimal amount of cutting. It would also be desirable to provide an apparatus for the treatment snoring which is configured to position at least a portion of an energy delivery device into an interior of the soft palate and/or uvula to deliver ablation energy to the interior in order to reduce the size of the soft palate and/or uvula.

SUMMARY OF THE INVENTION

Accordingly, an object of the invention is to provide an apparatus for selective cell necrosis at selected site of different head and neck structures.

Another object of the invention is to provide an apparatus to treat airway obstructions.

Yet another object of the invention is to provide an apparatus that provides controlled cell necrosis of the tongue.

A further object of the invention is to provide an apparatus that provides controlled cell necrosis of the uvula and other soft palate structures.

Still another object of the invention is to provide an apparatus that provides controlled cell necrosis of turbinate structures.

These and other objects of the invention are achieved in a cell necrosis apparatus to reduce a volume of a selected site in an interior of a tongue in an oral cavity. The apparatus includes a handpiece means. An electrode means is coupled to a distal portion of the handpiece means and includes a tissue piercing distal end. The electrode means is configured to be maneuverable in the oral cavity to pierce a tongue surface and advance into an interior of the tongue a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site and create cell necrosis without damaging a main branch of the hypoglossal nerve. A cable means is coupled to the electrode means.

In another embodiment of the invention, a cell necrosis apparatus reduces a volume of a selected site in an interior of a uvula. The apparatus includes a handpiece means. An electrode means is coupled to a distal portion of the handpiece means and includes a tissue piercing distal end. The electrode means is configured to be maneuverable in the oral cavity to pierce a uvula surface, advance into an interior of the uvula a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site , create controlled cell necrosis and reposition the uvula in an oral cavity with reduced necrosis of an exterior mucosal surface of the uvula. A cable means is coupled to the electrode means.

In another embodiment of the invention, a cell necrosis apparatus to reduce a volume of a selected site in an interior of a turbinate structure. The apparatus includes a handpiece means. An electrode means is coupled to a distal portion of the handpiece means including a tissue piercing distal end. The electrode means is configured to be maneuverable in a nostril to pierce a

turbinate structure surface, advance into an interior of the turbinate structure a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site, create controlled cell necrosis of the turbinate structure to increase a size of a nasal passageway. The cell necrosis apparatus delivers insufficient electromagnetic energy to impair blood flow to the optic nerve and/or retina and create a permanent impairment of vision. A cable means is coupled to the electrode means.

In another embodiment of the invention, a cell necrosis apparatus reduces a volume of a selected site in an interior of a soft palate structure. The apparatus includes a handpiece means. An electrode means is coupled to a distal portion of the handpiece means including a tissue piercing distal end. The electrode means is configured to be maneuverable in an oral cavity to pierce a soft palate structure surface, advance into an interior of the soft palate structure a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site, create controlled cell necrosis and reposition the soft palate structure in an oral cavity with reduced necrosis of an exterior mucosal surface of the soft palate structure. A cable means is coupled to the electrode means.

BRIEF DESCRIPTION OF THE FIGURES

Figures 1A-B illustrate lateral view of the oral cavity and the positioning of the cell necrosis apparatus of the present invention in the oral cavity.

Figure 1C depicts a lateral view of the oral cavity illustrating the repositioning of the tongue following treatment.

Figure 2-4 illustrate the creation of various cell necrosis zones.

Figure 5 illustrates the introduction of boluses solution to tissue.

Figure 6A illustrates a perspective view of the cell necrosis apparatus of the present invention coupled to an energy source.

Figure 6B illustrates a close up cross-sectional view of a hollow electrode of the invention utilized to create a cell necrosis zone below a tissue surface.

Figure 7 illustrates a cross-sectional view of the distal end of the electrode of Figure 6B.

Figure 8 illustrates a cross-sectional view of the hollow electrode with a sealing plug to control fluid flow.

Figure 9 illustrates the creation of cell necrosis zones in the uvula and the repositioning of the uvula in the oral cavity.

Figure 10 illustrates the creation of cell necrosis zones in the turbinates and the repositioning of the turbinates in the nasal cavity.

Figure 11 illustrates a cross-sectional view of the arteries of the nasal cavity.

Figure 12 depicts a cross-sectional view of the head illustrating the arteries of the nasal cavity.

Figure 13 depicts a cross-sectional view of the head taken laterally through the nasal cavity illustrating a shrinkage of the turbinates following treatment with the cell necrosis apparatus of the present invention.

Figure 14 depicts a close up cross-sectional view of Figure 13.

Figure 15 depicts a cross-sectional view of the head illustrating the creation of cell necrosis zones in the soft palate structure.

Figure 16 depicts a cross-sectional view of the soft palate structure of Figure 15 illustrating the repositioning of the soft palate structure following creation of the cell necrosis zones.

Figure 17 depicts a block diagram of the feed back control system that can be used with the cell necrosis apparatus as shown in Figures 1A-C.

Figure 18 depicts a block diagram of an analog amplifier, analog multiplexer and microprocessor used with the feedback control system of Figure 17.

Figure 19 depicts a block diagram of a current sensor and voltage sensor connected to the analog amplifier of Figure 18.

DETAILED DESCRIPTION

Referring now to Figures 1A-C, a cell necrosis apparatus 10 is used to reduce a volume of a selected site in an interior of a head and neck structure, and more particularly to a structure that is associated with an airway passage. Suitable anatomical structures include but are not limited to the tongue, uvula, soft palate tissue, tonsils, adenoids, turbinate structures and the like. In Figures 1A-C, cell necrosis apparatus 10 is shown as including a handpiece 12 coupled to an electrode 14. Handpiece 12 can be a proximal portion of electrode 14 that is suitable configured to enable placement and removal of cell necrosis apparatus to and from a selected anatomical structure and may include, in one embodiment, a proximal portion of electrode 12 that is insulated. Handpiece 12 and electrode 14 are sized and of a suitable geometry to be maneuverable in an oral cavity 16, pierce a tongue surface 18 and advance into an interior 20 of a tongue 22 a sufficient distance 24 to a tissue site 26. Electromagnetic energy is delivered to tissue site 26 to create cell necrosis at zone 28 without damaging a main branch of the hypoglossal nerve. A cable 30 is coupled to the electrode 14. For purposes of this disclosure, the main branches of the hypoglossal nerve are those branches which if damaged create an impairment, either partial or full, of speech or swallowing capabilities. As shown in Figure 1C, the treated structure of tongue 22 is repositioned in oral cavity 16. With this cell necrosis, the back of the tongue 22 moves in a forward direction (as indicated by the arrow) away from the air passageway. The result is an increase in the cross-sectional diameter of the air passageway.

Handle 14 is preferably made of an electrical and thermal insulating material. Electrode 14 can be made of a conductive material such as stainless steel. Additionally, electrode 14 can be made of a shaped memory metal, such as nickel titanium, commercially available from Raychem Corporation, Menlo Park, California. In one embodiment, only a distal end of electrode 14 is made of the shaped memory metal in order to effect a desired deflection.

Cell necrosis apparatus 10 can include visualization capability including but not limited to a viewing scope, an expanded eyepiece, fiber optics, video imaging, and the like.

Electrode 14 can include an insulator 32 which can be adjustable in length and in a surrounding relationship to an exterior surface of electrode 14. Insulator 32 serves as a barrier to thermal or RF energy flow. Insulator 32 can be in the form of an sleeve that may be adjustably positioned at the exterior of electrode 14. In one embodiment insulator can be made of a polyamide material and be a .002 inch shrink wrap. The polyamide insulating layer is semi-rigid.

Handpiece 12 can have a reduced diameter at a distal portion 34 to facilitate positioning, maneuverability, provide easier access to smaller openings and improve the visibility in the area where electrode 14 is to penetrate.

To use cell necrosis apparatus 10 in oral cavity 16, a topical and then a local anesthetic is applied to tongue 22. After a suitable period for the anesthesia to take effect, the physician may grasp the body of tongue 22 near the apex, using a gauze pad for a better grip. Tongue 22 is then drawn forward, bringing the body and the root of tongue 22 further forward for improved accessibility. Grasping handpiece 12, the physician positions a distal portion of electrode 14 at tongue surface 18. The position of electrode 14 in Figures 1A-C illustrates cell necrosis zone 28 below a mucosal surface 36 providing a protected zone 38. An insulated portion 40 of electrode 14 prevents delivery of energy to a main branch of a hypoglossal nerve and/or to mucosal surface 36.

Electrode 14 can have an angle 42 at a bend zone 44 which is lateral to a longitudinal axis of handpiece 12. Electrode 14 can be malleable to create different bend zones, depending on the anatomical structure and the insertion position of the anatomical structure. With the use of a bending fixture, not shown, the arc of angle 42 can be adjusted by the physician as needed at the time of treatment.

It will be appreciated that although the term" electrode" in the specification generally means an energy delivery device including but not limited to resistive heating, RF, microwave, ultrasound and liquid thermal jet. The preferred energy source is an RF source and electrode 14 is an RF electrode operated in either bipolar or monopolar mode with a ground pad electrode. In a monopolar mode of delivering RF energy, a single electrode 14 is used in

combination with an indifferent electrode patch that is applied to the body to form the other contact and complete an electrical circuit. Bipolar operation is possible when two or more electrodes 14 are used. Multiple electrode 14 may be used.

When the energy source is RF, an RF energy source may have multiple channels, delivering separately modulated power to each electrode 14. This reduces preferential heating that occurs when more energy is delivered to a zone of greater conductivity and less heating occurs around electrodes 14 which are placed into less conductive tissue. If the tissue hydration or blood infusion in the tissue is uniform, a single channel RF energy source may be used to provide power for the treatment and cell necrosis zones are relatively uniform in size.

One or more sensors 46 can be included and positioned at a distal end of electrode 14, at a distal end of insulator 32, as well as at other positions of cell necrosis apparatus 10. Sensor 46 is of conventional design, including but not limited to thermistors, thermocouples, resistive wires, and the like. A suitable sensor 46 is a T type thermocouple with copper constantene, J type, E type, K type, fiber optics, resistive wires, thermocouple IR detectors, and the like.

Electrode 14 can experience a steep temperature gradient as current moves outward the electrode 14. This causes the tissue that is immediately adjacent to electrode 14 to reach temperatures of 100 degrees C or more while tissue only 5 to 10 mm away may be at or near body temperature. Because of this temperature gradient it is often necessary to place electrode 14 several times or use a plurality of electrodes 14 to create a cell necrosis zone 28 of the desired volume. Because of the aggressive heating immediately proximal of electrode 14 desiccation of tissue adjacent to electrode 14 may result. When the fluid within the tissue is desiccated, no electrical current flows through the tissue and the heating is then terminated. This problem can be solved by using a lower rate of heating which requires extended treatment periods.

Referring now to Figures 2 through 4, an embodiment of the invention is disclosed where electrode 14 includes a hollow lumen 48 and a plurality of apertures through which a fluid medium can flow. Suitable fluid mediums

include but are not limited to cooling and heating fluids, electrolytic solutions, chemical ablation medium, a disinfectant medium and the like.

A suitable electrolytic solution is saline, solutions of calcium salts, potassium salts, and the like. Electrolytic solutions enhance the electrical conductivity of the tissue. When a highly conductive fluid is infused into tissue, the ohmic resistance is reduced and the electrical conductivity of the infused tissue is increased. With this condition there will be little tendency for tissue surrounding electrode 14 to desiccate and the result is a large increase in the capacity of the tissue to carry RF energy. A zone of tissue which has been heavily infused with a concentrated electrolytic solution can then become so conductive as to actually act as an electrode. The effect of the larger (fluid) electrode is that greater amounts of current can be conducted, making it possible to heat a much greater volume of tissue in a given time period.

In addition to the larger electrode area that results from infusion of an electrolytic solution it is then possible to inject one or more boluses 50 of electrolytic solution as shown in Figure 5. RF current 52 can then flow through the infused tissue surrounding electrode 14 and follow the course of least electrical resistance into the infused tissue of the neighboring bolus.

By placing the injections of electrolytic solution according to the need for thermal tissue damage, a single electrode 14 may deliver heating to a large volume of tissue and the shape of cell necrosis zone 28 created may be placed to create cell necrosis in exactly the area desired. This simplifies the control of cell necrosis zone 28 generation and allows the physician to produce larger lesions in a brief session.

Additionally, the conductivity of the injected electrolytic solution can be decreased. While the advantages of avoiding desiccation adjacent to electrode 14 are maintained, higher ohmic resistance is encountered in the infused tissue. This results in greater heating in the tissue closer to electrode 14. Varying the electrical conductivity of the infused tissue can be used to adjust the size of cell necrosis zone 28 and control the extent of thermal damage.

Disinfectant mediums can also be introduced through electrode 14. Suitable disinfectant mediums include but are not limited to Peridex, an oral rinse containing 0.12% chlorhexidine glucinate (1, 1'-hexanethylenebis[5-(p-chlorophenyl) biganide} di-D-gluconate in a base containing water, 11.6% alcohol, glycerin, PEG 40 sorbitan arisoterate, flavor, dosium saccharin, and FD&C Blue No. 1. The disinfectant medium can be introduced prior to, during and after cell necrosis.

Referring now to Figures 6 through 8, electrode 14 may include hollow lumen 48 that is in fluid communication with a control unit 54 which controls the delivery of the fluid via a conduit 56 configured to receive a cooling or heating solution. All of only a portion of a distal portion 14' of electrode 14 is cooled or heating.

The introduction of a cooling fluid reduces cell necrosis of surface layers without the use of insulator 32. This preserves surface mucosal and/or epidermal layers as well as protects a tissue site in the vicinity or in cell necrosis zone 28 from receiving sufficient energy to cause cell necrosis. For instance, it may be desirable to insert electrode 14 into an organ in a position which is adjacent to or even within some feature that must be preserved while treating other areas including but not limited to blood vessels, nerve bundles, glands and the like. The use of cooling permits the delivery of thermal energy in a predetermined pattern while avoiding heating critical structures.

A sealing plug 58 may be positioned in hollow electrode 14 and used to determine the length of electrode 14 that receives the cooling fluid. Sealing plug 58 can include one or more sealing wipers 60 positioned on an outer diameter of sealing plug 50. A fluid tube 62 is coupled to a proximal portion of sealing plug 58 and positioned adjacent to the proximal surface of sealing plug 58. A plurality of fluid distribution ports 64 are formed in fluid tube 62. Cooling fluid, which may be a saline solution or other biologically compatible fluid, is fed from control unit 54 through a small diameter dual lumen tube positioned in conduit 56. Cooling fluid flows through fluid tube 62 to the most distal end where it exits through fluid distribution ports 64 arranged about the

outer diameter of fluid tube 62. Cooling fluid then flows within hollow lumen 48 and is in direct contact with the wall structure of electrode 14, which is typically metallic and provides a highly efficient heat transfer. Cooling fluid flows to the proximal end of electrode protected a 14 and through the second lumen of the fluid tube 62, then to control unit 54 which includes both a supply reservoir and a return reservoir to catch and retained the used cooling fluid.

Electrode 14 may have one or more sensors 46 for sensing the temperature of the tissue. This data is fed back to control unit 54 and through an algorithm is stored within a microprocessor memory of control unit 54. Instructions are sent to an electronically controlled micropump (not shown) to deliver fluid through the fluid lines at the appropriate flow rate and duration to provide control of tissue temperature.

The reservoir of control unit 54 may have the ability to control the temperature of the cooling fluid by either cooling the fluid or heating the fluid. Alternatively, a fluid reservoir of sufficient size may be used in which the cooling fluid is introduced at a temperature at or near that of the normal body temperature. Using a thermally insulated reservoir, adequate control of the tissue temperature may be accomplished without need of refrigeration or heating of the cooling fluid.

Cooling zone 66 is adjustable in size and location by moving sealing plug 58 using a stylet 68 which is controlled by a slider 70 position at handpiece 12. In this manner, the position of cooling zone 66 can be moved along the length of electrode 14 and the area which is cooled is then proximal of sealing plug 58. In the event it is desirable to have cooling zone 66 within a length of electrode 14 then a second sealing plug 58 can be positioned at a distance proximal of the first or distal sealing plug 58 and the cooling fluid then re-enters the second lumen of fluid tube 62 at proximal sealing plug 58. The distance between the two sealing plugs 58 determines the length of cooling zone 66. In this example, the distal and proximal sealing plugs 58 move together when activated by stylet 68, re-positioning cooling zone 66.

In another embodiment, the distal and proximal sealing plugs 58 are adjusted individually. This provides the ability to both change the position and length of cooling zone 66.

In typical use, cooling zone 66 is positioned so that a predetermined thickness of mucosal or epidermal tissue 72 on the surface of the tissue to be treated 74 is protected as indicated at 75 while the desired cell necrosis zone 28 is formed.

An alternative feature is the ability to indicate to the physician the amount of electrode 14 length that is inserted into the tissue and the depth of protected area 32. To accomplish this, a portion of cell necrosis apparatus 10 comes in contact with mucosal or epidermal surface 72. This can be achieved with a contact collar 76 or with a larger surface that is contoured to fit against the organ or anatomical feature to be treated. The dimensional relationship between contact collar 76 and handpiece 12 is maintained by a sleeve 78 through which electrode 14, fluid tube 62 and stylet 68 all pass. With this dimensional relationship maintained, it is then possible to indicate with indexing pointers on handpiece 12 the distance of electrode 14 distal of contact collar 76 or the surface of cell necrosis apparatus 10. The distance of cooling zone 66 is then positioned distal of contact collar 76 or the surface cell necrosis apparatus 10. Because all cooling is within electrode 14 and external insulator 32 is not used, electrode 14 penetrates easily through the tissue without drag or resistance that is present when insulator 32 is present.

In another embodiment, sealing plugs 58 and direct flow of cooling fluid are replaced with a slidable inner cooling plug which may be constructed of a material with efficient heat transfer characteristics. Suitable cooling plug materials include but are not limited to copper, beryllium copper, silver and aluminum alloys. Cooling plug is sized to fit intimately against the inner surface of needle 14. This allows transfer of heat from electrode 14 to cooling the plug. In this embodiment, cooling plug has interior passageways through which cooling fluid passes. This draws heat from the cooling plug.

Although this embodiment does not provide the highly efficient cooling available by having the cooling fluid in direct contact with the inner surface of electrode 14, a more thorough isolation of the cooling fluid from the body is provided. This results from reducing the possibility of experiencing some leakage past sealing plug 58 of the other embodiment.

In yet another embodiment of cooling, heat pipe technology is used. A sealed compartment contains a mixture of gases which have the ability to rapidly vaporize and condense at temperatures which facilitate the transfer of heat with high efficiency. In this embodiment, a cooling module within handpiece 12 cools the proximal end of the tubular heat pipe and heat is conducted from cooling zone 66 to the cooling module.

Cell necrosis apparatus 10 can be used to create cell necrosis in other structures that affect airway passages including but not limited to the uvula, turbinate structures, soft palate structures and tonsils.

As shown in Figures 9 and 10, cell necrosis apparatus 10 is used to create one or more cell necrosis zones 28 in uvula 80. Electrode 12 is configured to be maneuverable in oral cavity 16 , pierce an uvula exterior surface, advance into an interior of the uvula a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site and create controlled cell necrosis. The creation of cell necrosis zones 28 repositions the treated uvula 80 in oral cavity 16 (as indicated by the arrows) while substantially preserving an uvula mucosal layer 82 at an exterior of uvula 80. Cell necrosis zones 28 are created in uvula 80 without creating an ulceration line at a tip 86 of uvula 80. Controlled cell necrosis tightens and reshapes uvula 80.

In creating uvula 80, electrode 12 can have a variety of geometric configurations and may include a curved distal end. The different cell necrosis zones 28 can be stacked in one or more treatment sessions. This permits the physician to control the amount of tissue treated and to assess the results of each session before proceeding with additional procedures. Because exterior mucosal tissue is spared, the patient experiences little pain or discomfort.

Referring now to Figure 10, cell necrosis apparatus 10 is used to create cell necrosis zones 28 in a turbinate structure 88, which can include the interior nasal concha, the middle nasal concha, the superior nasal concha, and combinations thereof. Electrode 14 is configured to be maneuverable in a nostril, pierce a turbinate structure surface 90 advance into an interior of turbinate structure 88 a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site and create controlled cell necrosis of turbinate structure 88 to increase a size of a nasal passageway 90.

Sufficient electromagnetic energy is delivered to the tissue site to create controlled cell necrosis of the turbinate structure without sufficiently limiting blood flow to the optic nerve and/or the retina (Figure 11). As shown in Figure 12 disruption of the blood flow to the optic nerve and/or retina can sufficiently damage the optic nerve and/or retina and create a permanent impairment of vision.

Referring again to Figure 10, electrode 14 creates cell necrosis zones 28 to reduce the size turbinate structure 88 by removing only so much of turbinate structure 88 to increase the size of the nasal passageway but insufficient to create a permanent, (i) dysosmic state, (ii) dry nose condition, (iii) atrophic rhinitis state, (iv) a loss of ciliary function or (v) damage to the nerves of nasal cavity creating a permanent loss of nasal and facial structure activity . The creation of the ablation zones in turbinate structure 88 repositions turbinate structure 88. In one embodiment, no more than 33% of the mucosal layer of the lower turbinate is removed. Further removal may create the dysosmic state, a permanent dry nose condition and/or a loss of ciliary function.

As illustrated in Figures 13 and 14, cell necrosis apparatus 10 provides controlled ablation of turbinate structures 88 and the resulting turbinate structure is repositioned in the nasal cavity, and can "open up" the nasal cavity for allergy sufferers and the like.

In another embodiment (Figures 15 and 16), cell necrosis apparatus 10 reduces a volume of a selected site in an interior of a soft palate structure 94. Electrode 14 is configured to be maneuverable in oral cavity 16, pierce a soft

palate structure surface 96, advance a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site, create controlled cell necrosis zones 28 and reposition soft palate structure 94 in oral cavity 16 with reduced necrosis of an exterior mucosal surface 98 of soft palate structure 94. The creation of cell necrosis zones 28 repositions soft palate structure 94 and tightens the interior tissue of soft palate structure as illustrated by the arrows.

Again, various imaging devices and methods, well known in the art, may be used to position electrode 14 and/or determine the amount of cell necrosis.

In one embodiment, cell necrosis apparatus 10 is coupled to an open or closed loop feedback system. Referring now to Figure 17 an open or closed loop feedback system couples sensor 46 to energy source 92. In this embodiment, electrode 14 is one or more RF electrodes 14. It will be appreciated that other energy delivery devices 14 can also be used with the feedback system.

The temperature of the tissue, or of RF electrode 14 is monitored, and the output power of energy source 92 adjusted accordingly. Additionally, the level of disinfection in the oral cavity can be monitored. The physician can, if desired, override the closed or open loop system. A microprocessor can be included and incorporated in the closed or open loop system to switch power on and off, as well as modulate the power. The closed loop system utilizes a microprocessor 94 to serve as a controller, monitor the temperature, adjust the RF power, analyze at the result, refeed the result, and then modulate the power.

With the use of sensor 46 and the feedback control system a tissue adjacent to RF electrode 14 can be maintained at a desired temperature for a selected period of time without impeding out. Each RF electrode 14 is connected to resources which generate an independent output. The output maintains a selected energy at RF electrode 14 for a selected length of time.

Current delivered through RF electrode 14 is measured by current sensor 96. Voltage is measured by voltage sensor 98. Impedance and power are then calculated at power and impedance calculation device 100. These values can

then be displayed at user interface and display 102. Signals representative of power and impedance values are received by a controller 104.

A control signal is generated by controller 104 that is proportional to the difference between an actual measured value, and a desired value. The control signal is used by power circuits 106 to adjust the power output in an appropriate amount in order to maintain the desired power delivered at respective RF electrodes 14.

In a similar manner, temperatures detected at sensor 46 provide feedback for maintaining a selected power. Temperature at sensor 46 are used as safety devices to interrupt the delivery of energy when maximum pre-set temperatures are exceeded. The actual temperatures are measured at temperature measurement device 102, and the temperatures are displayed at user interface and display 102. A control signal is generated by controller 104 that is proportional to the difference between an actual measured temperature and a desired temperature. The control signal is used by power circuits 106 to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at the sensor 46. A multiplexer can be included to measure current, voltage and temperature, at the sensor 46, and energy can be delivered to RF electrode 14 in monopolar or bipolar fashion.

Controller 104 can be a digital or analog controller, or a computer with software. When controller 104 is a computer it can include a CPU coupled through a system bus. On this system can be a keyboard, a disk drive, or other non-volatile memory systems, a display, and other peripherals, as are known in the art. Also coupled to the bus is a program memory and a data memory.

User interface and display 102 includes operator controls and a display. Controller 104 can be coupled to imaging systems, including but not limited to ultrasound, CT scanners, X-ray, MRI, mammographic X-ray and the like. Further, direct visualization and tactile imaging can be utilized.

The output of current sensor 96 and voltage sensor 98 is used by controller 104 to maintain a selected power level at RF electrode 14. The amount of RF energy delivered controls the amount of power. A profile of

power delivered can be incorporated in controller 104 and a preset amount of energy to be delivered may also be profiled.

Circuitry, software and feedback to controller 104 result in process control, and the maintenance of the selected power setting that is independent of changes in voltage or current, and used to change, (i) the selected power setting, (ii) the duty cycle (on-off time), (iii) bipolar or monopolar energy delivery and (iv) fluid delivery, including flow rate and pressure. These process variables are controlled and varied, while maintaining the desired delivery of power independent of changes in voltage or current, based on temperatures monitored at sensor 46.

Referring to Figure 18, current sensor 96 and voltage sensor 98 are connected to the input of an analog amplifier 110. Analog amplifier 110 can be a conventional differential amplifier circuit for use with sensor 46. The output of analog amplifier 110 is sequentially connected by an analog multiplexer 106 to the input of A/D converter 108. The output of analog amplifier 110 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter 108 to microprocessor 94. Microprocessor 94 may be a type 68HCII available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

Microprocessor 94 sequentially receives and stores digital representations of impedance and temperature. Each digital value received by microprocessor 94 corresponds to different temperatures and impedances.

Calculated power and impedance values can be indicated on user interface and display 102. Alternatively, or in addition to the numerical indication of power or impedance, calculated impedance and power values can be compared by microprocessor 94 with power and impedance limits. When the values exceed predetermined power or impedance values, a warning can be given on user interface and display 102, and additionally, the delivery of RF

energy can be reduced, modified or interrupted. A control signal from microprocessor 94 can modify the power level supplied by energy source 92.

Figure 19 illustrates a block diagram of a temperature/impedance feedback system that can be used to control temperature control fluid flow rate through introducer 14. Energy is delivered to RF electrode 14 by energy source 92, and applied to tissue. A monitor 116 ascertains tissue impedance, based on the energy delivered to tissue, and compares the measured impedance value to a set value. If the measured impedance exceeds the set value a disabling signal 112 is transmitted to energy source 92, ceasing further delivery of energy to electrode 14. If measured impedance is within acceptable limits, energy continues to be applied to the tissue. During the application of energy sensor 46 measures the temperature of tissue and/or electrode 14. A comparator 120 receives a signal representative of the measured temperature and compares this value to a pre-set signal representative of the desired temperature. Comparator 120 sends a signal to a flow regulator 122 representing a need for a higher temperature control fluid flow rate, if the tissue temperature is too high, or to maintain the flow rate if the temperature has not exceeded the desired temperature.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

CLAIMS

1. A cell necrosis apparatus to reduce a volume of a selected site in an interior of a tongue in an oral cavity, comprising:

a handpiece means;

an electrode means coupled to a distal portion of the handpiece means including a tissue piercing distal end, the electrode means being configured to be maneuverable in the oral cavity to pierce a tongue surface and advance into an interior of the tongue a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site and create controlled cell necrosis without damaging a main branch of the hypoglossal nerve; and

a cable means coupled to the electrode means.

2. The apparatus of claim 1, wherein the electrode means is an RF electrode means.

3. The apparatus of claim 2, further comprising:

an RF energy source coupled to the RF electrode means.

4. The apparatus of claim 1, further comprising:

a cooling device means coupled to the electrode means.

5. The apparatus of claim 4, further comprising:

a flow rate control device means coupled to the cooling device means and configured to control a cooling medium flow rate through the cooling device means.

6. The apparatus of claim 1, further comprising:

an insulator means at least partially positioned around an exterior of the electrode means.

7. The apparatus of claim 6, further comprising:

a sensor means coupled to the electrode means.

8. The apparatus of claim 1, further comprising:

a sensor means positioned at a distal end of the electrode means.

9. The apparatus of claim 1, further comprising:

a feedback control device means coupled to the electrode means, a sensor means and an RF energy source means.

10. The apparatus of claim 1, further comprising:

an infusion medium source means coupled to the electrode means.

11. The apparatus of claim 1, wherein the electrode means has an electrode means advancement length extending from an exterior of the handpiece means to the interior of the tongue, wherein the advancement length is sufficient to position the energy delivery surface at the selected site and deliver sufficient electromagnetic energy to create cell necrosis without damaging a main branch of a hypoglossal nerve.

12. A cell necrosis apparatus to reduce a volume of a selected site in an interior of a uvula, comprising:

a handpiece means;

an electrode means coupled to a distal portion of the handpiece means including a tissue piercing distal end, the electrode means being configured to be maneuverable in the oral cavity to pierce a uvula surface and advance into an interior of the uvula a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site and create controlled cell necrosis and a repositioning of the uvula in the oral cavity while substantially preserving an uvula mucosal layer at an exterior of the uvula; and

a cable means coupled to the electrode means.

13. The apparatus of claim 12, wherein the electrode means is configured to create controlled cell necrosis and the repositioning of the uvula without creating an ulceration line at a tip of the uvula.

14. The apparatus of claim 12, wherein the electrode means is configured to create controlled cell necrosis and a tightening of a uvula tissue to reposition the uvula.

15. The apparatus of claim 12, wherein the electrode means is configured to create controlled cell necrosis and a reshaping of a uvula tissue to reposition the uvula.

16. The apparatus of claim 12, wherein the electrode means is an RF electrode means.

17. The apparatus of claim 13, further comprising:
an RF energy source means coupled to the RF electrode means.

18. The apparatus of claim 12, further comprising:
a cooling device means coupled to the electrode means.

19. The apparatus of claim 18, further comprising:
a flow rate control device means coupled to the cooling device means and configured to control a cooling medium flow rate through the cooling device means.

20. The apparatus of claim 12, further comprising:
an insulator means at least partially positioned around an exterior of the electrode means.

21. The apparatus of claim 12, further comprising:

a sensor means coupled to the electrode means.

22. The apparatus of claim 12, further comprising:

a sensor means positioned at a distal end of the electrode means.

23. The apparatus of claim 12, further comprising:

a feedback control device means coupled to the electrode means, a sensor means and an RF energy source means.

24. The apparatus of claim 12, further comprising:

an infusion medium source means coupled to the electrode means.

25. The apparatus of claim 12, wherein the electrode means has an electrode means advancement length extending from an exterior of the handpiece means to the interior of the uvula, wherein the advancement length is sufficient to position the energy delivery surface at the selected site and deliver sufficient electromagnetic energy to create cell necrosis with reduced necrosis of an exterior mucosal surface.

26. A cell necrosis apparatus to reduce a volume of a selected site in an interior of a turbinate structure, comprising:

a handpiece means;

an electrode means coupled to a distal portion of the handpiece means including a tissue piercing distal end, the electrode means being configured to be maneuverable in a nostril to pierce a turbinate structure exterior surface, advance a sufficient distance in an interior of the turbinate structure to a tissue site, deliver electromagnetic energy to the tissue site and create controlled cell necrosis of the turbinate structure to increase a size of a nasal passageway without sufficiently limiting blood flow to the optic nerve and create a permanent impairment of vision; and

a cable means coupled to the electrode means.

27. The apparatus of claim 26, wherein the electrode means creates controlled cell necrosis of without creating a permanent dysosmic state.

28. The apparatus of claim 26, wherein the electrode means creates controlled cell necrosis of the mucosal layer without creating a permanent dry nose condition.

29. The apparatus of claim 26, wherein the electrode means creates controlled cell necrosis of the mucosal layer without creating a permanent atrophic rhinitis condition.

30. The apparatus of claim 26, wherein the electrodes means creates controlled cell necrosis of the mucosal layer without creating a permanent loss of ciliary function.

31. The apparatus of claim 26, wherein the electrode means is an RF electrode means.

32. The apparatus of claim 30, further comprising:
an RF energy source means coupled to the RF electrode means.

33. The apparatus of claim 26, further comprising:
a cooling device means coupled to the electrode means.

34. The apparatus of claim 26, further comprising:
a flow rate control device means coupled to the cooling device means and configured to control a cooling medium flow rate through the cooling device means.

35. The apparatus of claim 26, further comprising:

an insulator means at least partially positioned around an exterior of the electrode means.

36. The apparatus of claim 26, further comprising:
a sensor means coupled to the electrode means.

37. The apparatus of claim 26, further comprising:
a sensor means positioned at a distal end of the electrode means.

38. The apparatus of claim 26, further comprising:
a feedback control device means coupled to the electrode means, a sensor means and an RF energy source means.

39. The apparatus of claim 26, further comprising:
an infusion medium source means coupled to the electrode means.

40. The apparatus of claim 26, wherein the electrode means has an electrode means advancement length extending from an exterior of the handpiece means to the interior of the turbinate structure, wherein the advancement length is sufficient to position the energy delivery surface at the selected site and deliver sufficient electromagnetic energy to the selected tissue site and create controlled cell necrosis of a mucosal layer of a turbinate bone while preserving a sufficient amount of turbinate bone and prevent creating a permanent dry nose condition

41. A cell necrosis apparatus to reduce a volume of a selected site in an interior of a soft palate structure, comprising:
a handpiece means;
an electrode means coupled to a distal portion of the handpiece means including a tissue piercing distal end, the electrode means being configured to be maneuverable in an oral cavity to pierce a soft palate structure surface and

advance into an interior of the soft palate structure a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site, create controlled cell necrosis and reposition the soft palate structure in an oral cavity with reduced necrosis of an exterior mucosal surface of the soft palate structure; and

a cable means coupled to the electrode means.

42. The apparatus of claim 41, wherein the electrode means is configured to create controlled cell necrosis and a tightening of a soft palate tissue to reposition the soft palate structure.

43. The apparatus of claim 41, wherein the electrode means is configured to create controlled cell necrosis and a reshaping of a soft palate tissue to reposition the soft palate structure.

44. The apparatus of claim 41, wherein the electrode means is an RF electrode means.

45. The apparatus of claim 44, further comprising:
an RF energy source means coupled to the RF electrode means.

46. The apparatus of claim 41, further comprising:
a cooling device means coupled to the electrode means.

47. The apparatus of claim 46, further comprising:
a flow rate control device means coupled to the cooling device means and configured to control a cooling medium flow rate through the cooling device means.

48. The apparatus of claim 41, further comprising:
an insulator means at least partially positioned around an exterior of the electrode means.

49. The apparatus of claim 41, further comprising:

a sensor means coupled to the electrode means.

50. The apparatus of claim 41, further comprising:

a sensor means positioned at a distal end of the electrode means.

51. The apparatus of claim 41, further comprising:

a feedback control device means coupled to the electrode means, a sensor means and an RF energy source means.

52. The apparatus of claim 41, further comprising:

an infusion medium source means coupled to the electrode means.

53. The apparatus of claim 41, wherein the electrode means has an electrode means advancement length extending from an exterior of the handpiece means to the interior of the soft palate structure, wherein the advancement length is sufficient to position the energy delivery surface at the selected site and deliver sufficient electromagnetic energy to create cell necrosis with reduced necrosis of an exterior mucosal surface of the soft palate structure.

54. A cell necrosis apparatus to reduce a volume of a selected site in an interior of a turbinate structure, comprising:

a handpiece means;

an electrode means coupled to a distal portion of the handpiece means including a tissue piercing distal end, the electrode means being configured to be maneuverable in a nostril to pierce a turbinate structure exterior surface, advance a sufficient distance in an interior of the turbinate structure to a tissue site, deliver electromagnetic energy to the tissue site and create controlled cell necrosis of the turbinate structure to increase a size of a nasal passageway without sufficiently limiting blood flow to the retina and create a permanent impairment of vision; and

a cable means coupled to the electrode means.

55. The apparatus of claim 54, wherein the electrode means creates controlled cell necrosis of without creating a permanent dysosmic state.

56. The apparatus of claim 54, wherein the electrode means creates controlled cell necrosis of the mucosal layer without creating a permanent dry nose condition.

57. The apparatus of claim 54, wherein the electrode means creates controlled cell necrosis of the mucosal layer without creating a permanent atrophic rhinitis condition.

58. The apparatus of claim 54, wherein the electrodes means creates controlled cell necrosis of the mucosal layer without creating a permanent loss of ciliary function.

59. The apparatus of claim 54, wherein the electrode means is an RF electrode means.

60. The apparatus of claim 59, further comprising:
an RF energy source means coupled to the RF electrode means.

61. The apparatus of claim 54, further comprising:
a cooling device means coupled to the electrode means.

62. The apparatus of claim 54, further comprising:
an insulator means at least partially positioned around an exterior of the electrode means.

63. The apparatus of claim 54, further comprising:

a sensor means coupled to the electrode means.

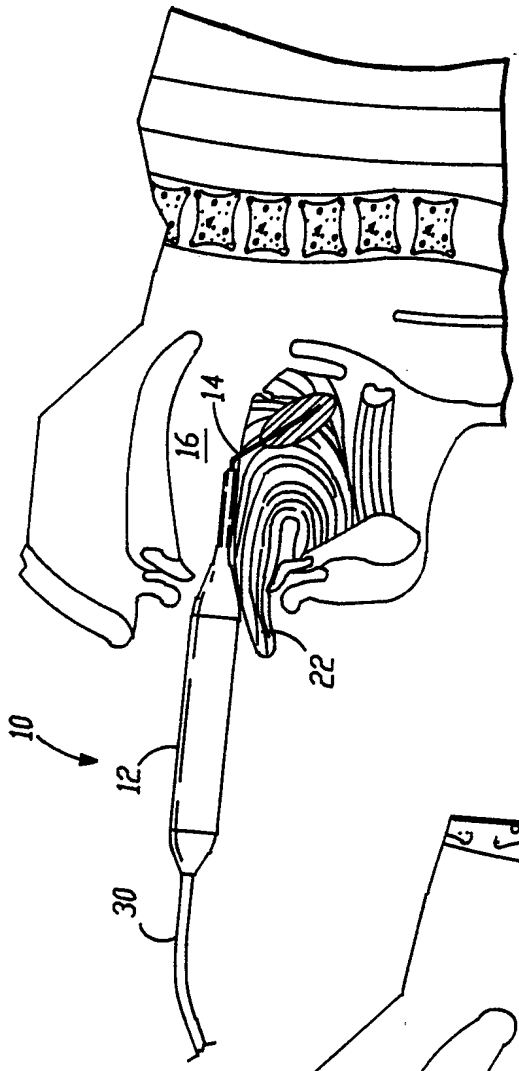


FIG. – 1A

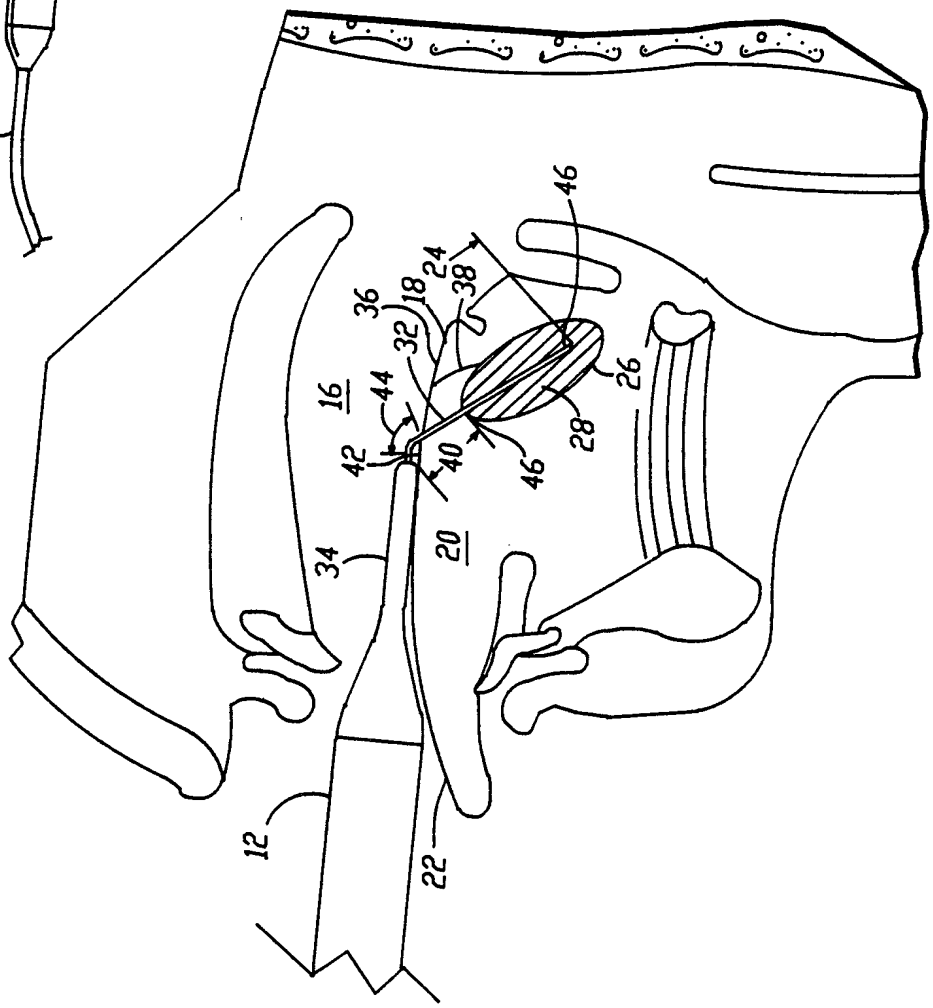


FIG. – 1B

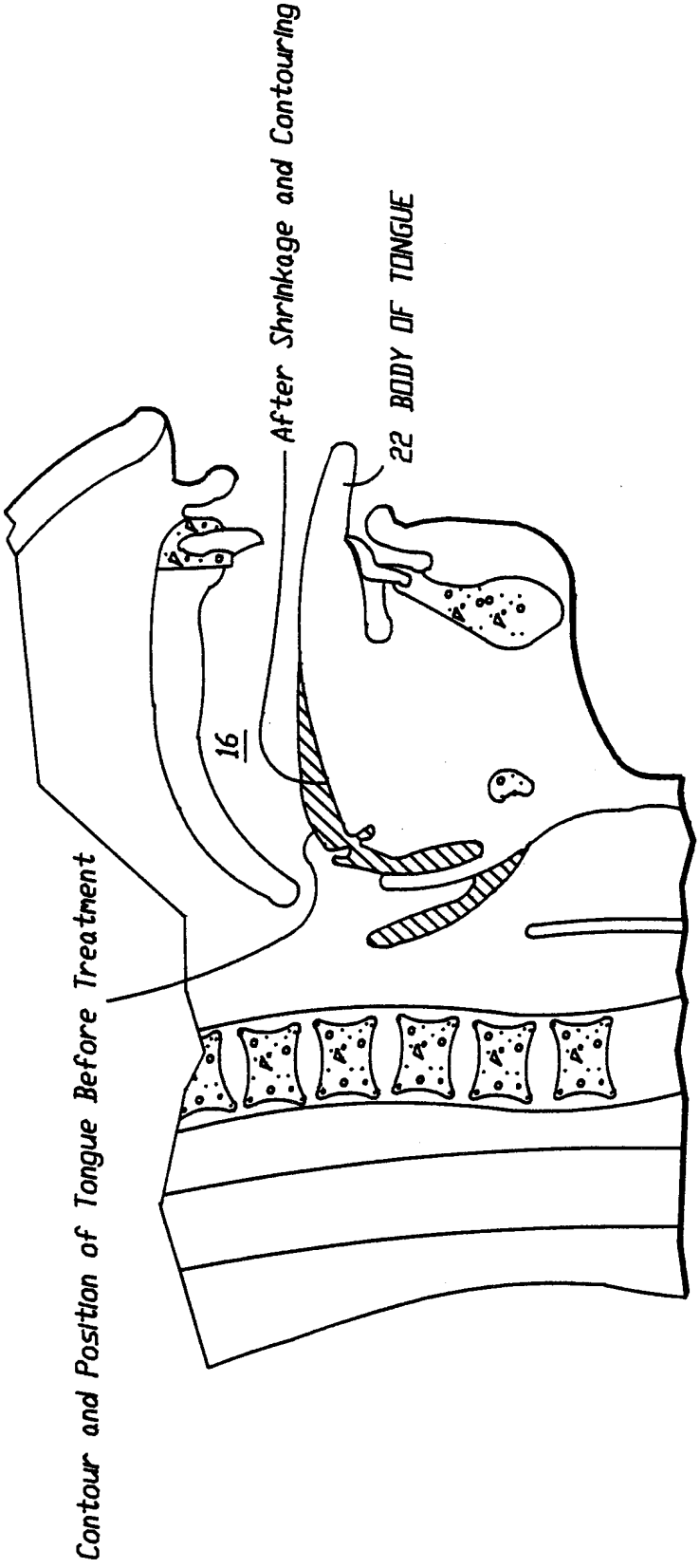

Contour and Position of Tongue Before Treatment
After Shrinkage and Contouring
22 BODY OF TONGUE
16

FIG.—1C

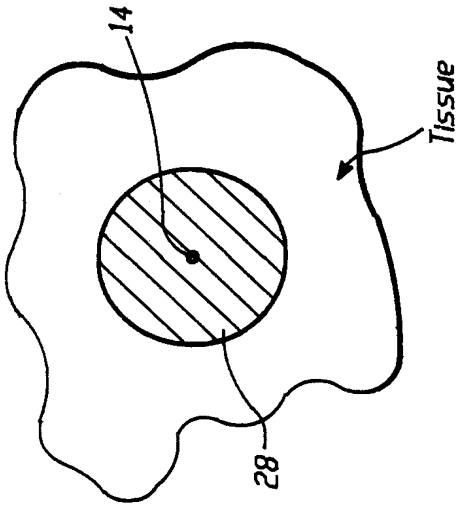


FIG.—3

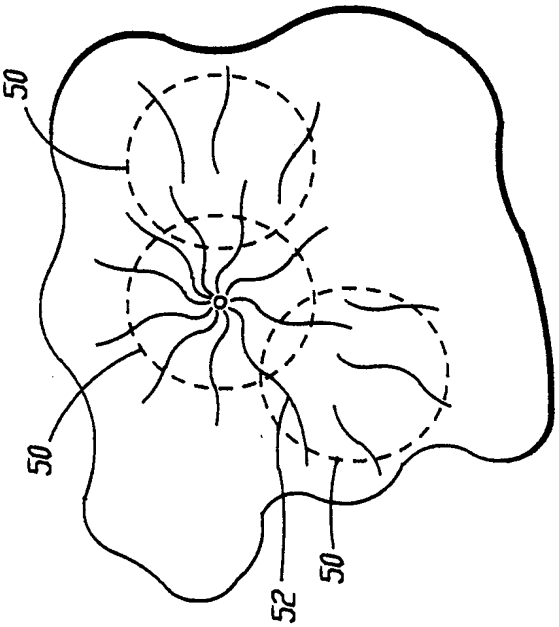


FIG.—5

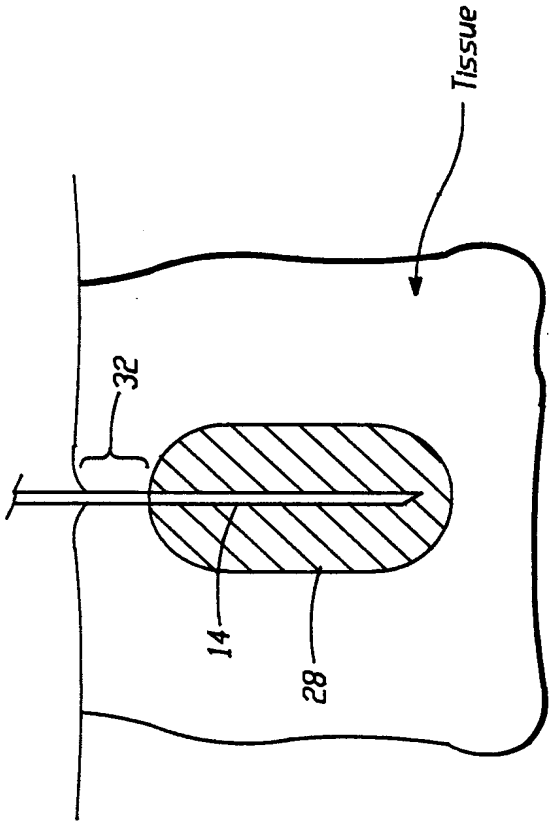


FIG.—2

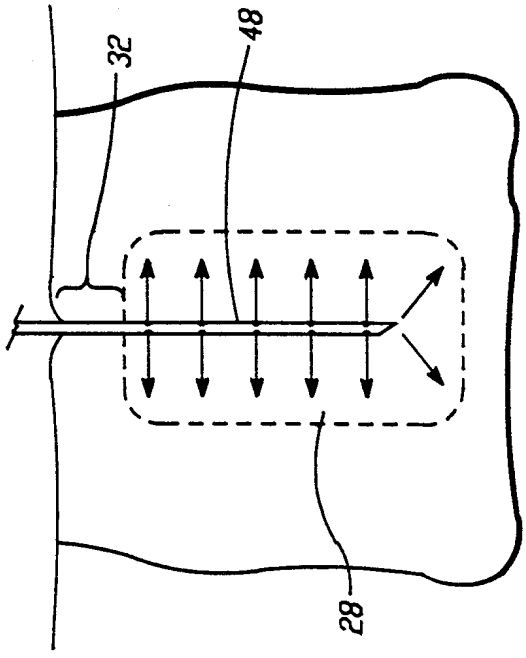


FIG.—4

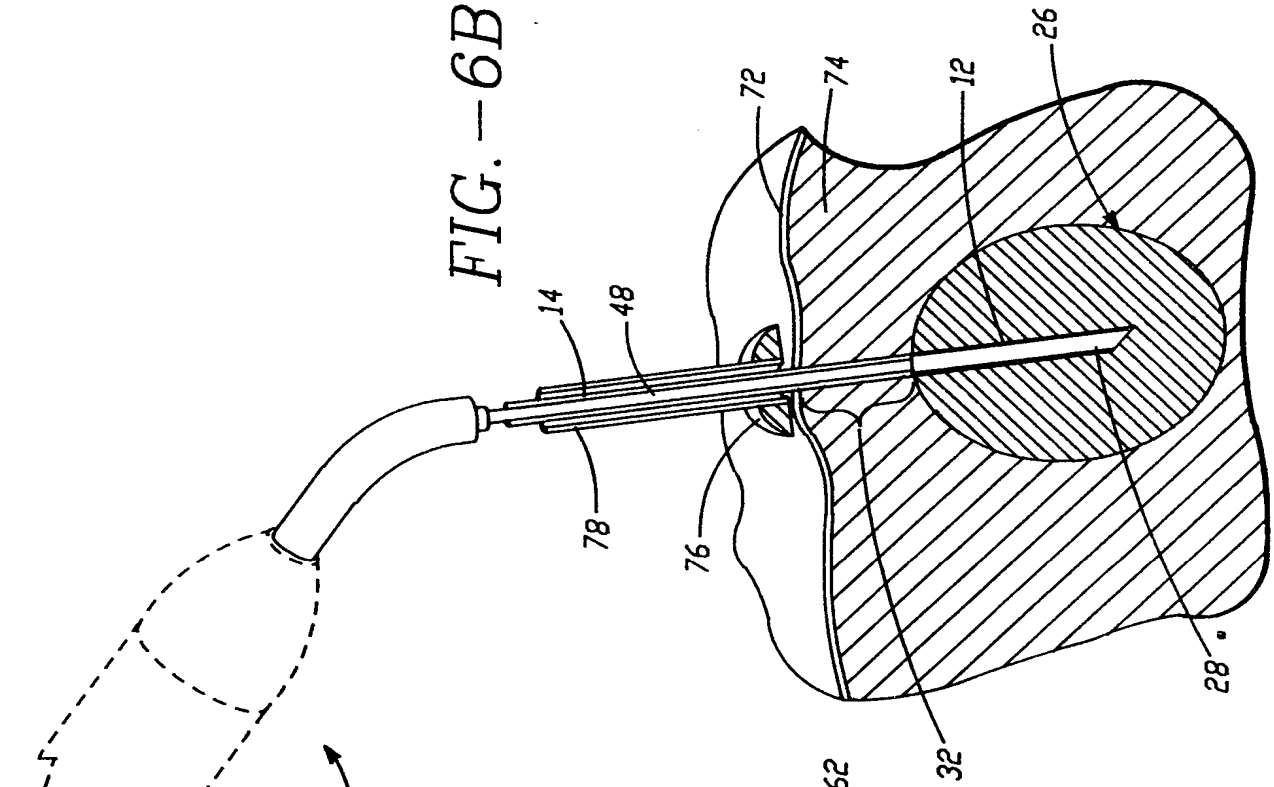


FIG.—6B

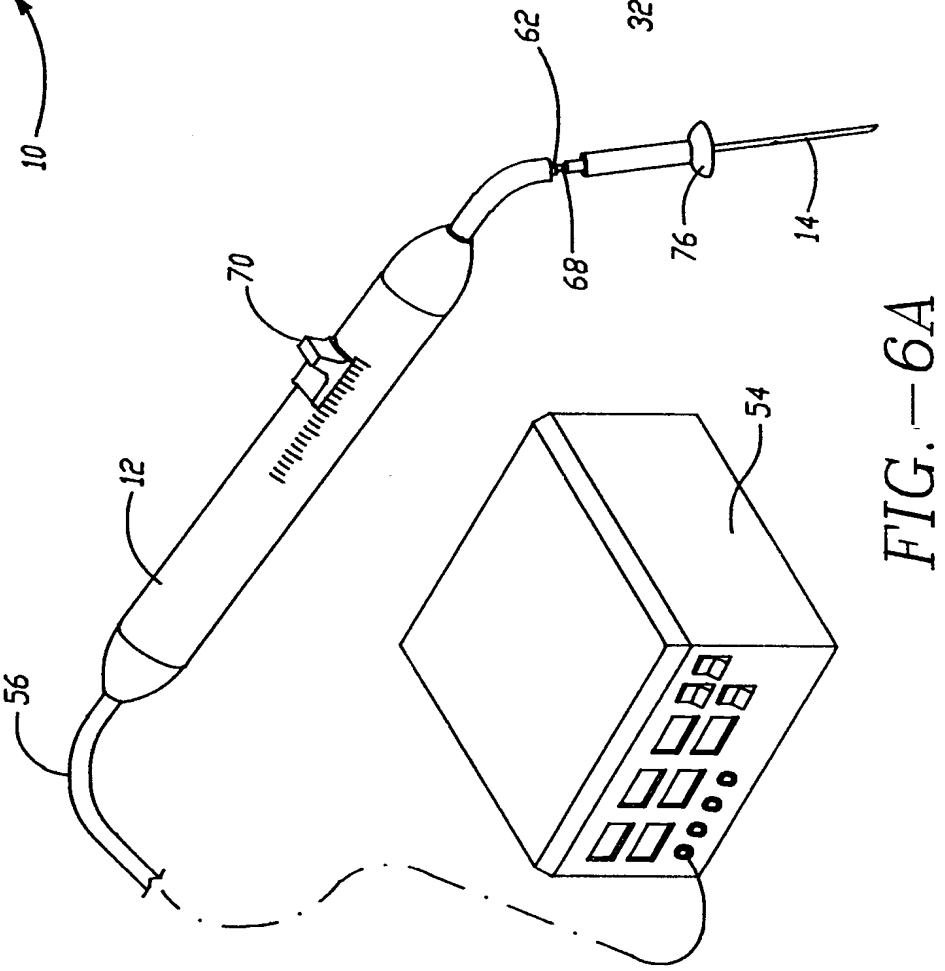


FIG.—6A

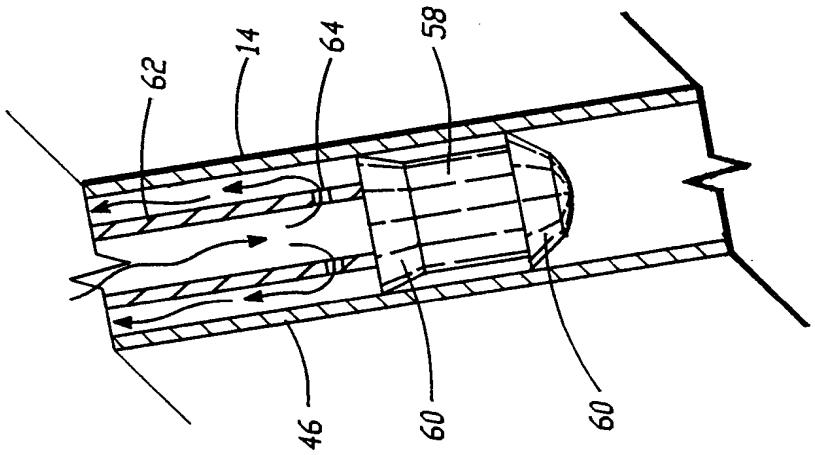


FIG.—8

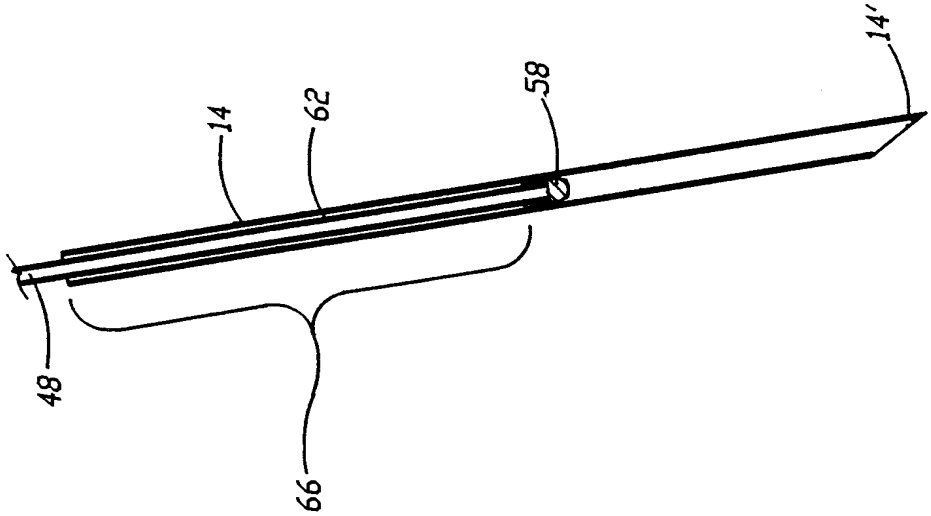


FIG.—7

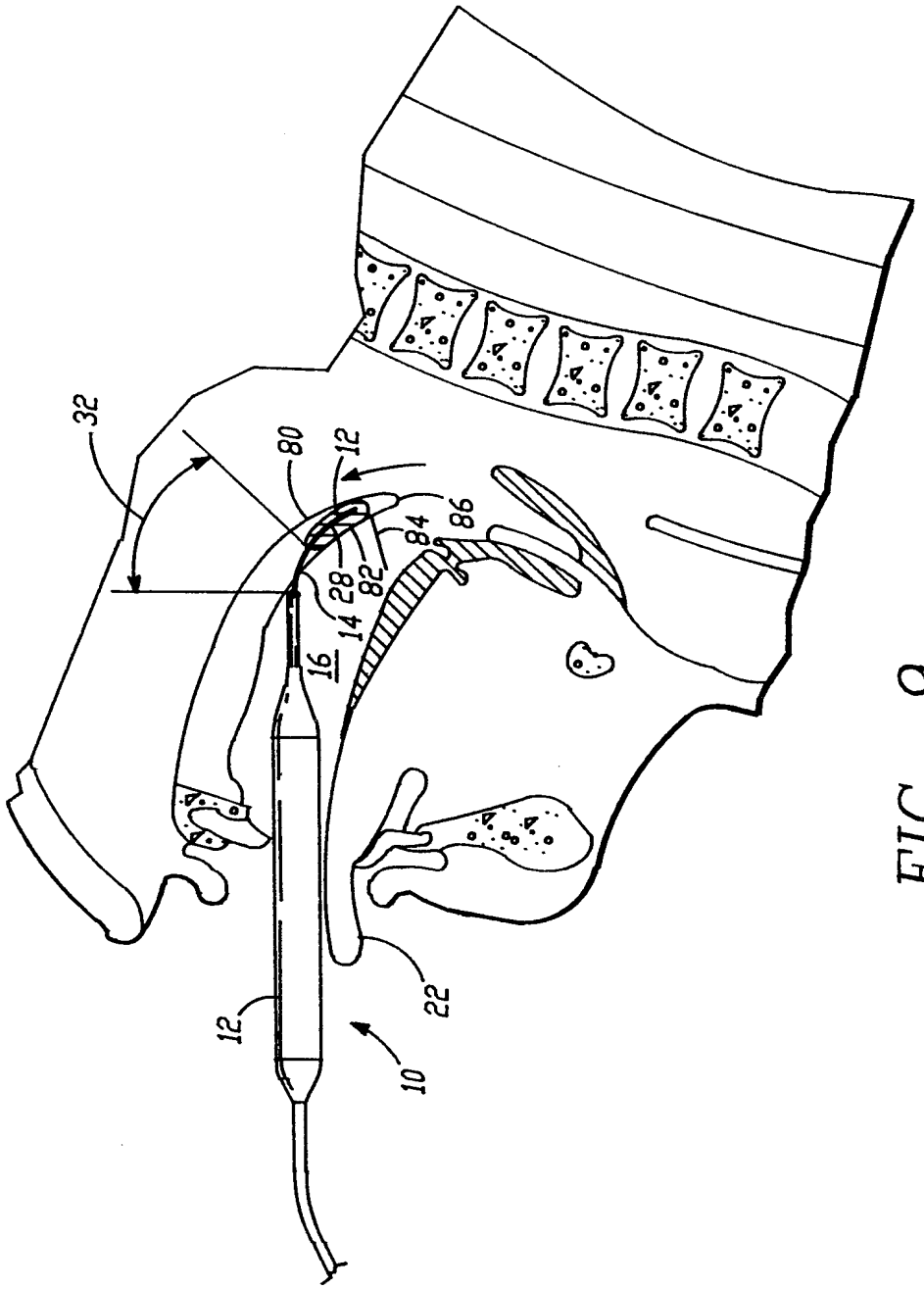


FIG. —9

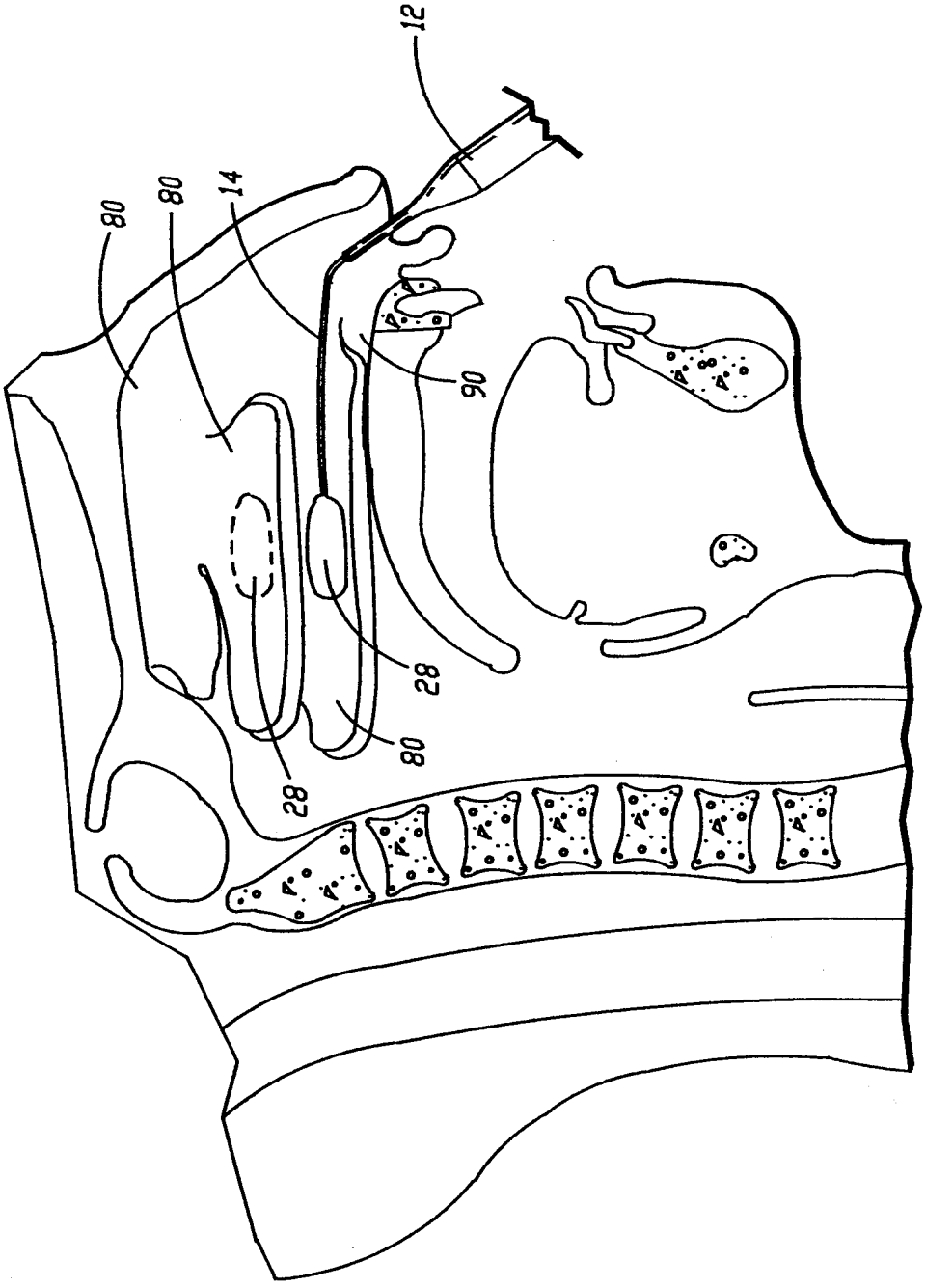


FIG. — 10

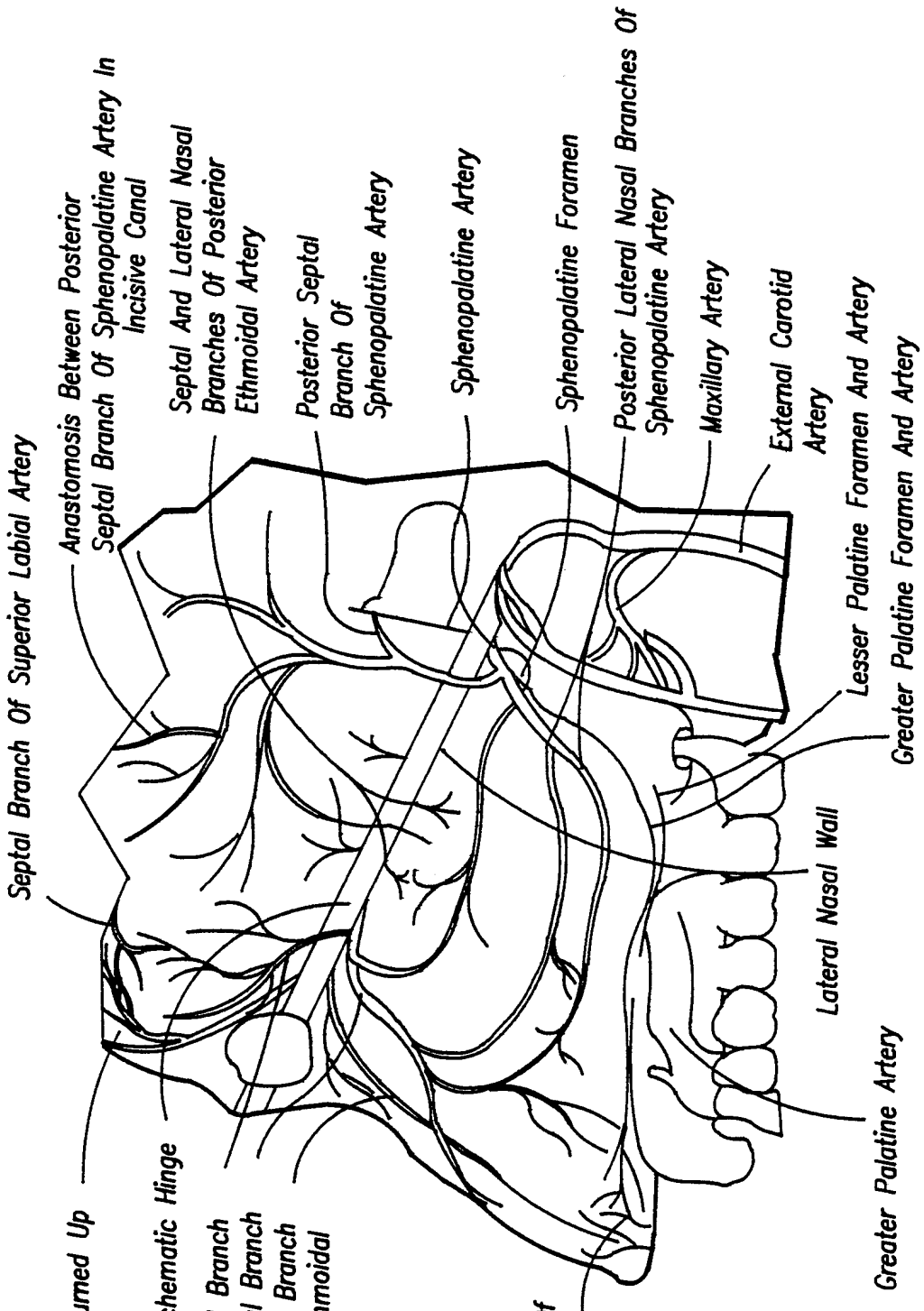

Septal Branch Of Superior Labial Artery
Anastomosis Between Posterior Septal Branch Of Sphenopalatine Artery In Incisive Canal
Septal And Lateral Nasal Branches Of Posterior Ethmoidal Artery
Posterior Septal Branch Of Sphenopalatine Artery
Sphenopalatine Artery
Sphenopalatine Foramen
Posterior Lateral Nasal Branches Of Sphenopalatine Artery
Maxillary Artery
External Carotid Artery
Lesser Palatine Foramen And Artery
Greater Palatine Foramen And Artery
Septum Turned Up
Schematic Hinge
Anterior Septal Branch
Anterior Lateral Branch
External Nasal Branch
Of Anterior Ethmoidal Artery
Alar Branches Of Lateral Nasal Artery (From Facial Artery)
Lateral Nasal Wall
Greater Palatine Artery

FIG. — 11

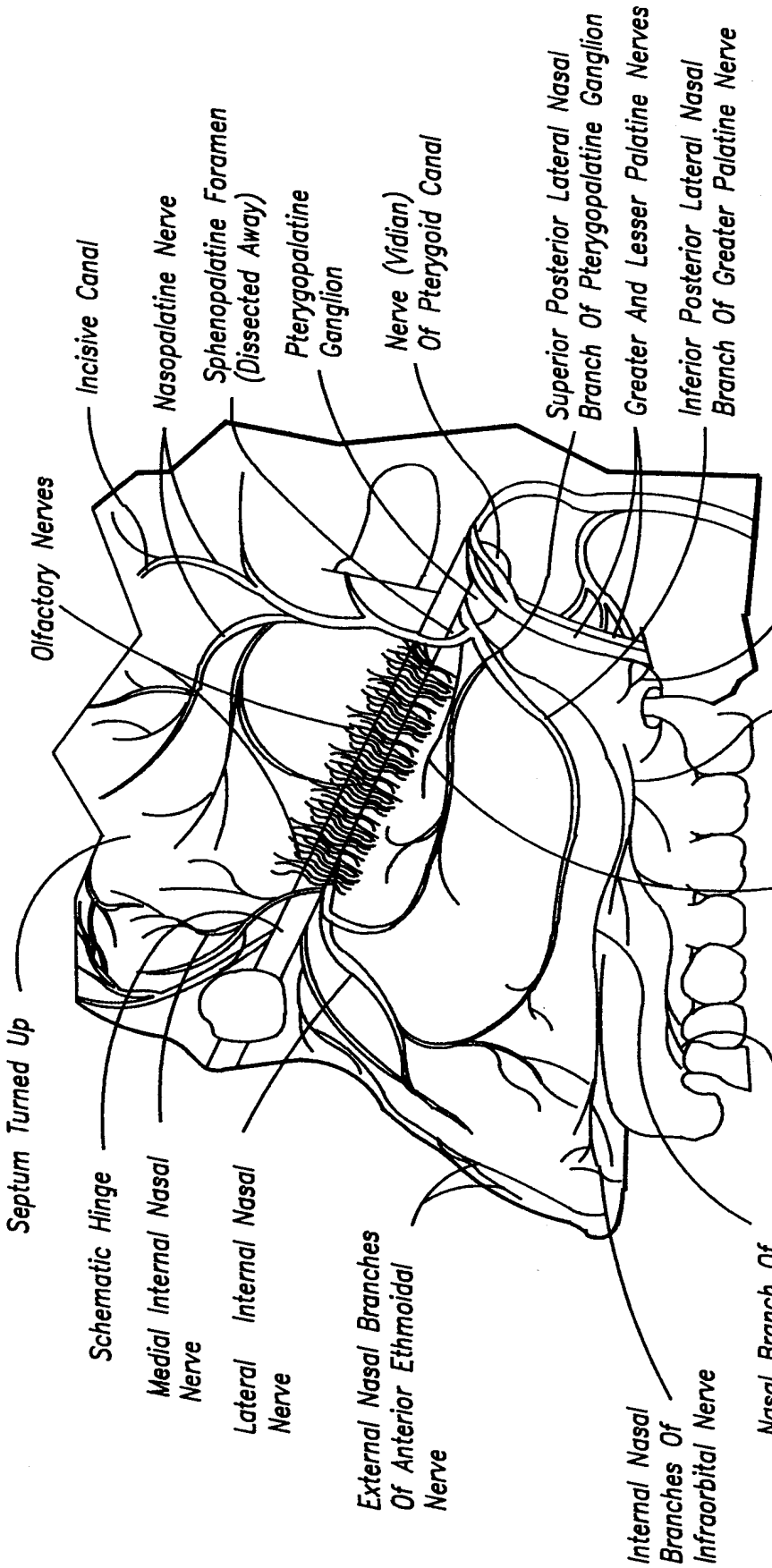

Septum Turned Up
Olfactory Nerves
Incisive Canal
Schematic Hinge
Nasopalatine Nerve
Medial Internal Nasal Nerve
Sphenopalatine Foramen (Dissected Away)
Lateral Internal Nasal Nerve
Pterygopalatine Ganglion
External Nasal Branches Of Anterior Ethmoidal Nerve
Nerve (Vidian) Of Pterygoid Canal
Internal Nasal Branches Of Infraorbital Nerve
Superior Posterior Lateral Nasal Branch Of Pterygopalatine Ganglion
Greater And Lesser Palatine Nerves
Nasal Branch Of Anterior Superior Alveolar Nerve
Inferior Posterior Lateral Nasal Branch Of Greater Palatine Nerve
Lesser Palatine Nerves
Greater Palatine Nerves
Lateral Nasal Wall
Communication Between Greater Palatine And Nasopalatine Nerves At Incisive Canal

FIG. – 12

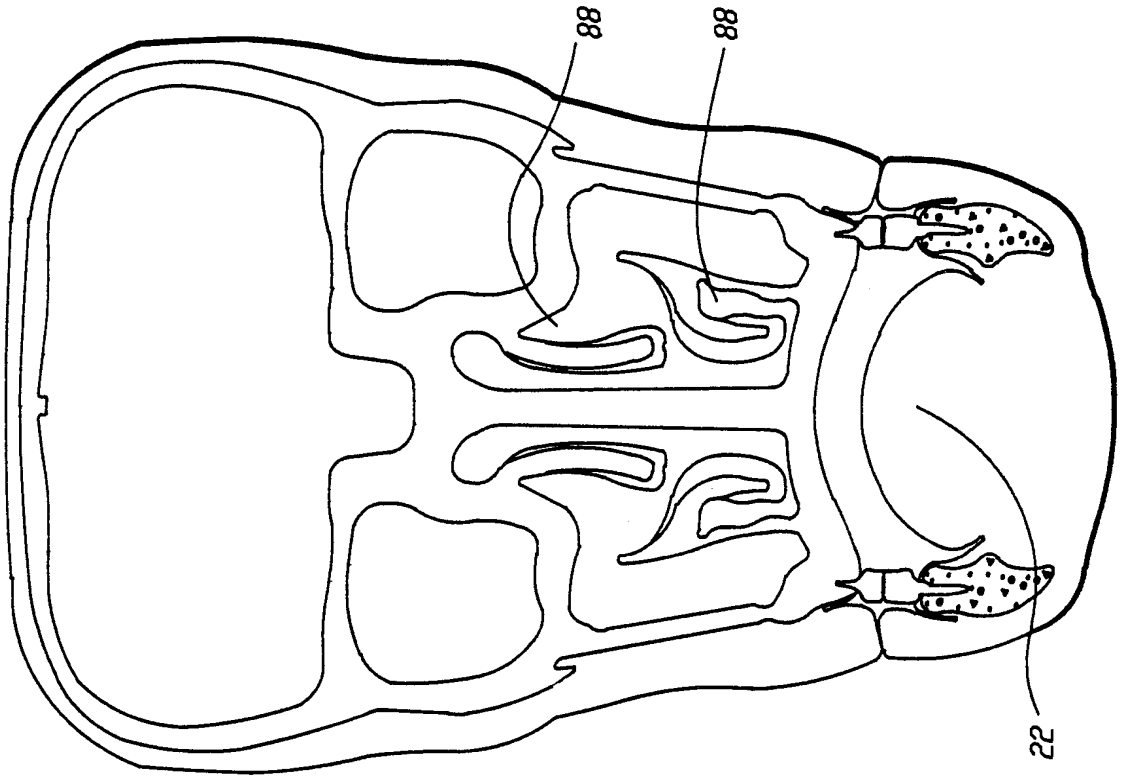


FIG. — 13

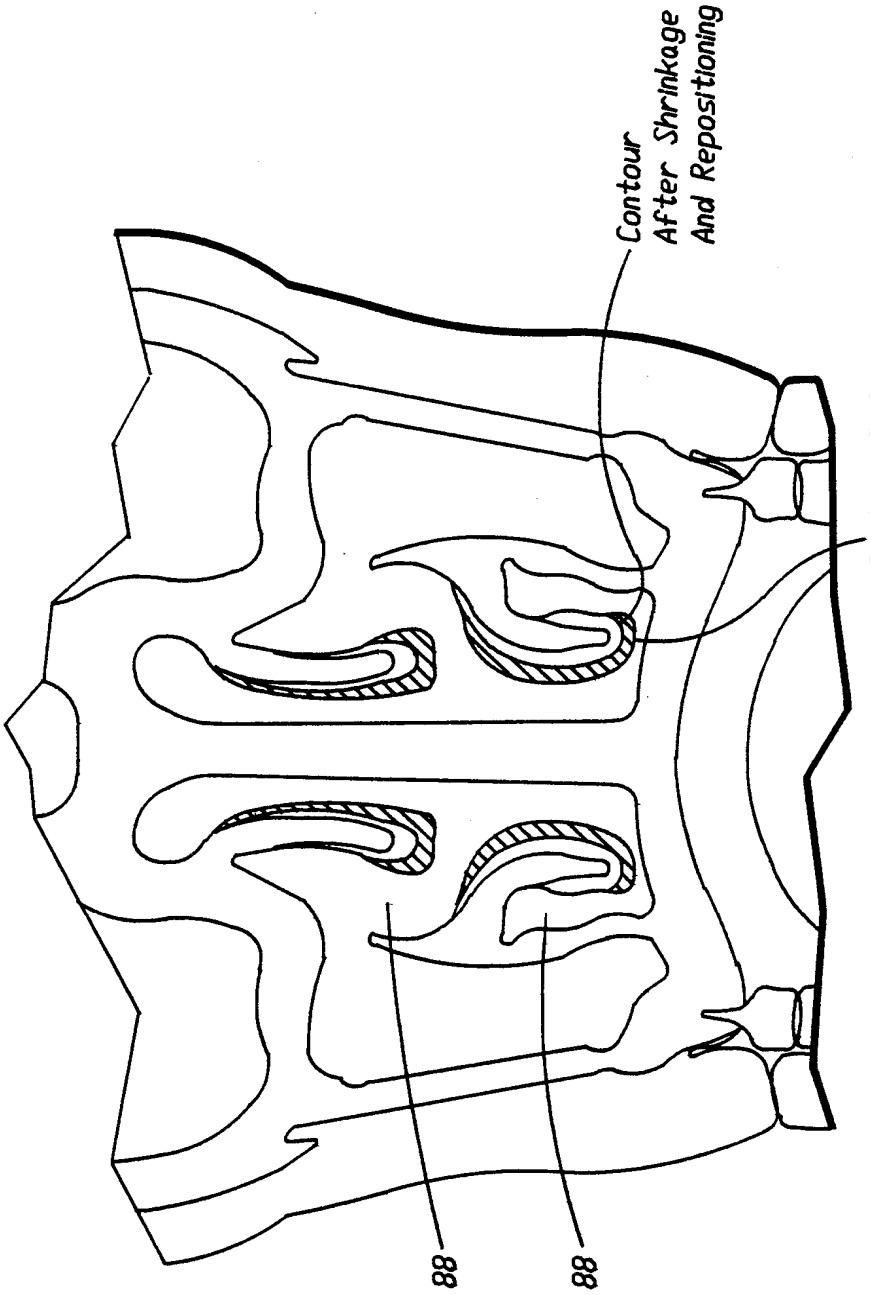

Contour
After Shrinkage
And Repositioning
Contour Before
Treatment
88
88

FIG. – 14

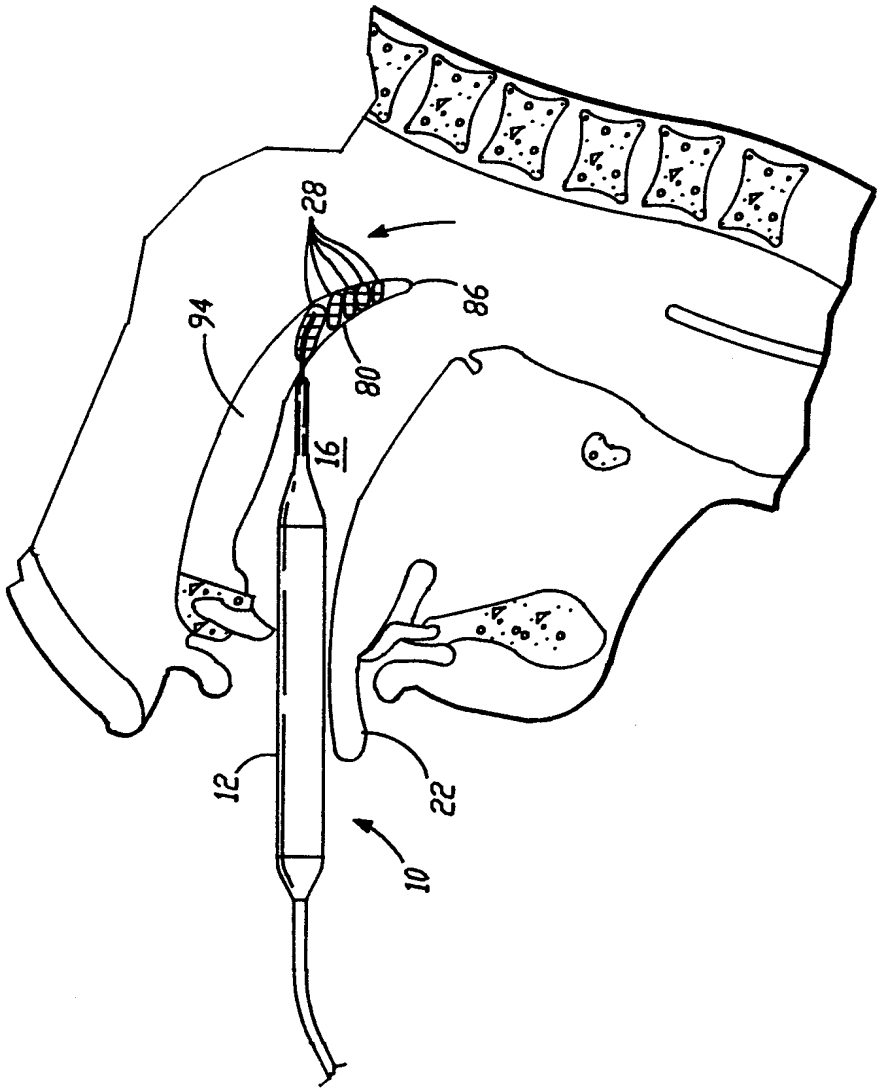


FIG.—15

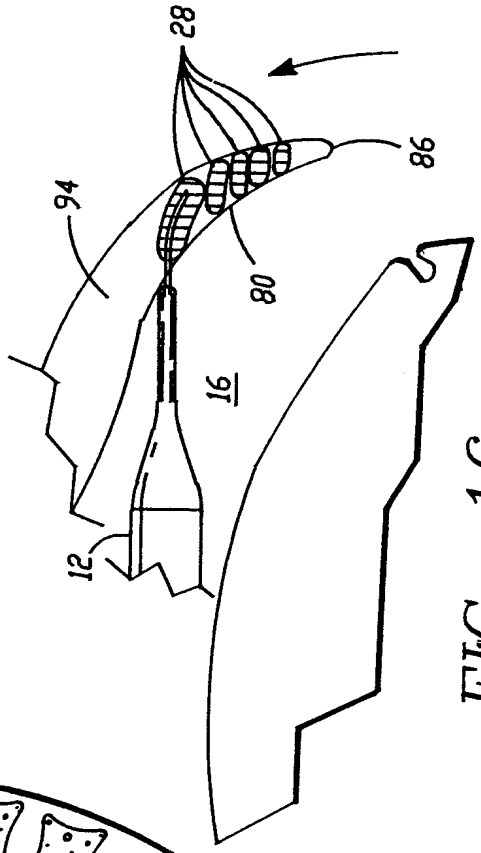


FIG.—16

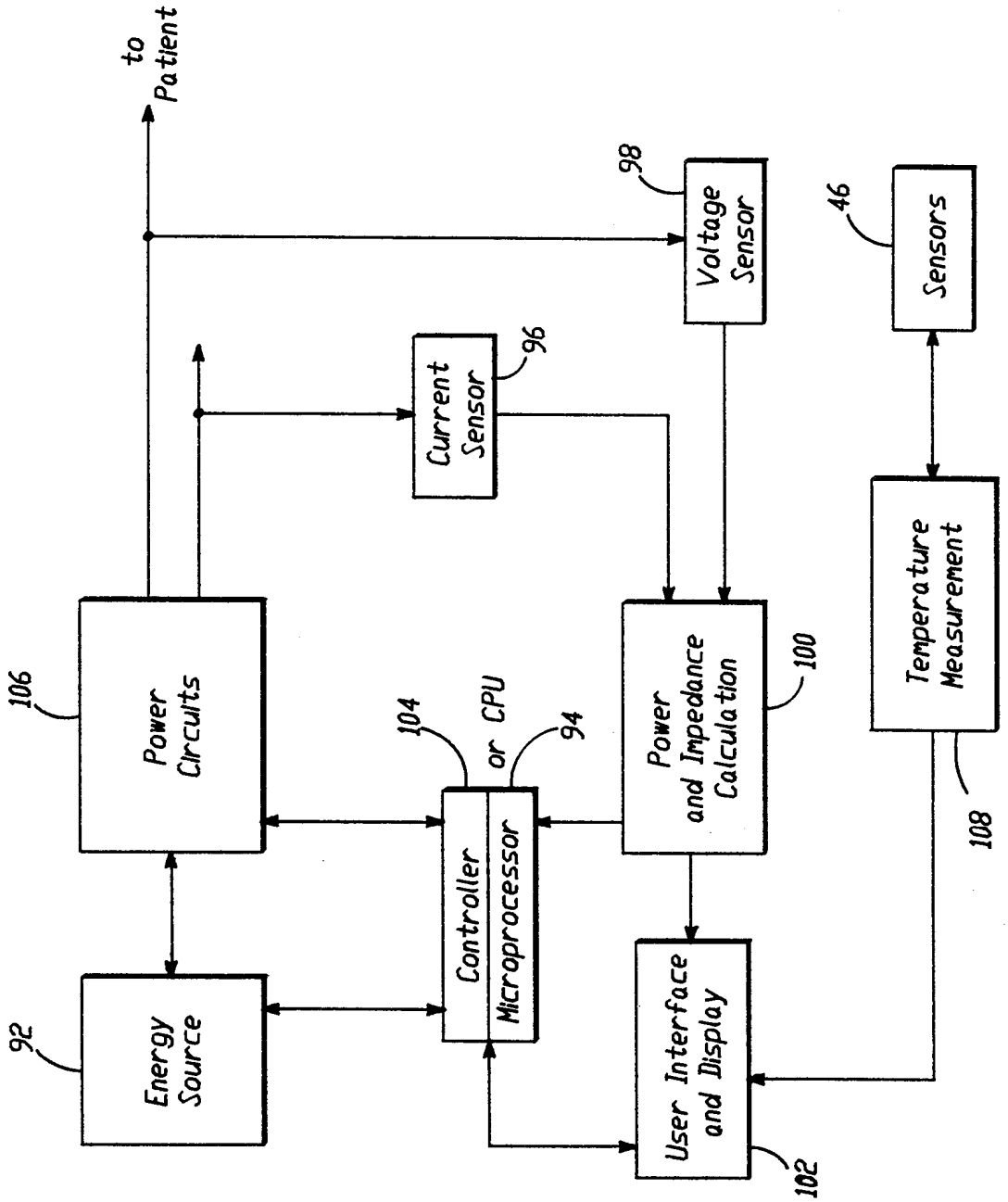

to Patient
98
Voltage Sensor
46
Sensors
Current Sensor
96
Temperature Measurement
106
Power Circuits
104
or CPU
94
Power and Impedance Calculation
100
Controller
Microprocessor
92
Energy Source
User Interface and Display
102
108

FIG. – 17

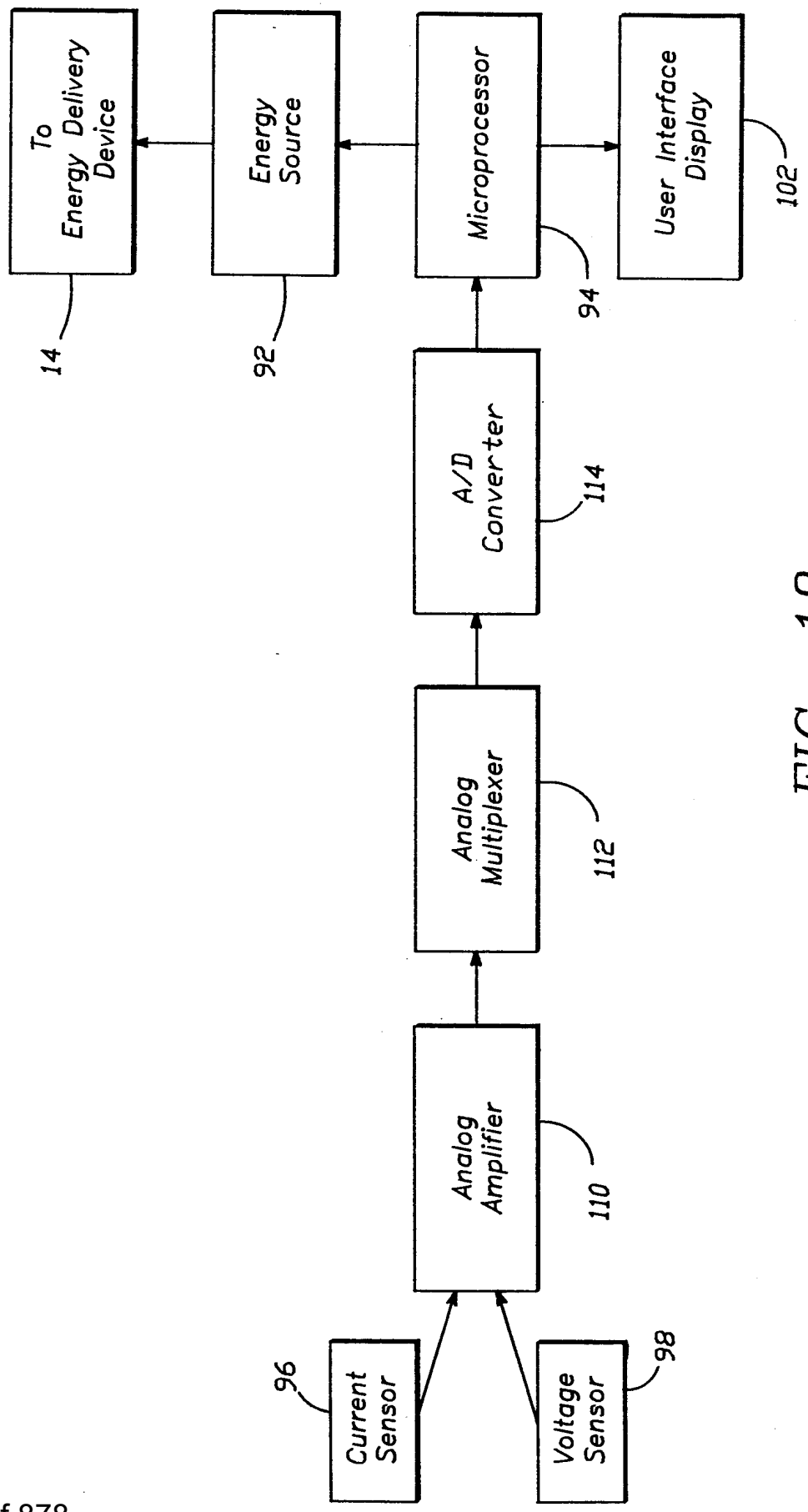

To Energy Delivery Device
Energy Source
Microprocessor
User Interface Display
102
14
92
94
A/D Converter
114
Analog Multiplexer
112
Analog Amplifier
110
Current Sensor
96
Voltage Sensor
98

FIG. – 18

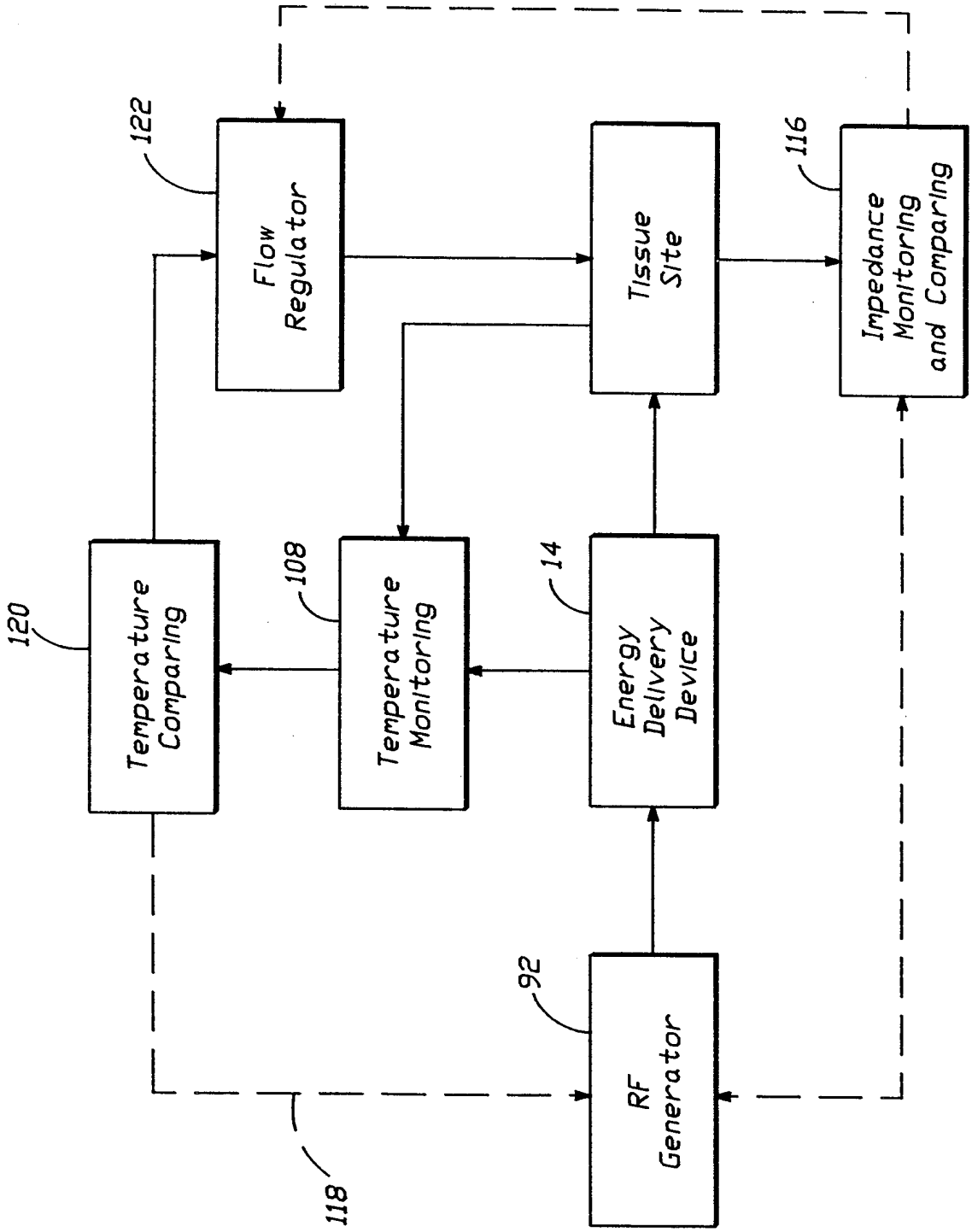

122
Flow Regulator
Tissue Site
116
Impedance Monitoring and Comparing
120
Temperature Comparing
108
Temperature Monitoring
14
Energy Delivery Device
92
RF Generator
118

FIG. – 19

INTERNATIONAL SEARCH REPORT

Inte .ional Application No
PCT/US 98/11337

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

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 6 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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 06741 A (SOMNUS) 27 February 1997 see the whole document	1-63
A	WO 96 18349 A (LORENTZEN) 20 June 1996 see abstract; figure 2A see page 15, line 3-10	3,18,33, 46,61
A	WO 97 06738 A (DOUGLASS ET AL) 27 February 1997	

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

☒ Patent family members are listed in 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 document 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
10 November 1998	17/11/1998

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, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Papone, F

3

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

information on patent family members

Inte onal Application No
PCT/US 98/11337

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9706741 A	27-02-1997	US 5624439 A	29-04-1997
		US 5728094 A	17-03-1998
		AU 6851496 A	12-03-1997
		EP 0850023 A	01-07-1998
		NL 1003813 C	21-05-1997
		NL 1003813 A	20-02-1997
		AU 1968697 A	10-09-1997
		AU 2135597 A	10-09-1997
		AU 2278297 A	10-09-1997
		WO 9730645 A	28-08-1997
		WO 9730646 A	28-08-1997
		WO 9730647 A	28-08-1997
		US 5738114 A	14-04-1998
		US 5800379 A	01-09-1998
		US 5820580 A	13-10-1998
WO 9618349 A	20-06-1996	AU 4252596 A	03-07-1996
		EP 0797408 A	01-10-1997
WO 9706738 A	27-02-1997	US 5674191 A	07-10-1997
		AU 7007896 A	12-03-1997
		NL 1003812 C	02-07-1997
		NL 1003812 A	20-02-1997
		US 5707349 A	13-01-1998
		US 5743870 A	28-04-1998
		US 5817049 A	06-10-1998

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 July 2010 (08.07.2010)

PCT

(10) International Publication Number
WO 2010/077980 A1

(51) International Patent Classification:
A61B 17/32 (2006.01)

(21) International Application Number:
PCT/US2009/068309

(22) International Filing Date:
16 December 2009 (16.12.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/138,077 16 December 2008 (16.12.2008) US
61/138,096 16 December 2008 (16.12.2008) US
61/138,083 16 December 2008 (16.12.2008) US

(71) Applicant *(for all designated States except US)*: **AARDVARK MEDICAL, INC.** [US/US]; P.O. Box 1654, Ross, California 94957 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BAKER, Peter, Christensen** [US/US]; P.O. Box 1654, Ross, California 94957 (US). **TREADWELL, Richard** [US/US]; 48 Hill Point Avenue, San Francisco, California 94117 (US).

(74) Agents: **SPECKMAN, Ann, W.** et al.; Speckman Law Group PLLC, 1201 Third Avenue, Suite 330, Seattle, Washington 98101 (US).

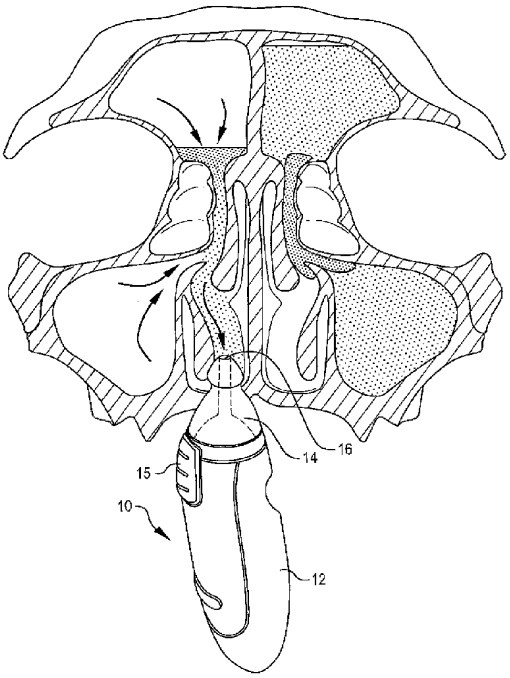
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE,

[Continued on next page]

(54) Title: METHODS AND SYSTEMS FOR DELIVERY OF FLUIDS, AEROSOLS AND ACOUSTIC ENERGY TO TISSUE SURFACES, CAVITIES AND OBSTRUCTED PASSAGES SUCH AS INTRANASAL OSTIA

FIG. 2B



(57) Abstract: Methods and systems for delivering fluids, aerosols, and/or ultrasound energy to target sites on tissue surfaces and within body cavities or lumens, obstructions or undesired materials associated with body cavities and tissue surfaces and, particularly, target sites on tissue surfaces or at obstructions within natural orifices, such as ear, nose and throat passages and, particularly, nasal passages and cavities are provided. In one aspect, methods and systems for delivering fluids and/or aerosols to target sites such as nasal passages at generally high frequency (e.g., ultrasound) pulsation rates and at multiple, alternating pulsation rates are provided. In another aspect, methods and systems for delivering high frequency acoustic energy, including high intensity ultrasound and high intensity focused ultrasound, directly to tissue, or to obstructions in passages or cavities such as nasal passages, sinuses and sinus ostia are provided.

WO 2010/077980 A1

ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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))*

Published:

— *with international search report (Art. 21(3))*

— *with amended claims and statement (Art. 19(1))*

METHODS AND SYSTEMS FOR DELIVERY OF FLUIDS, AEROSOLS AND ACOUSTIC ENERGY TO TISSUE SURFACES, CAVITIES AND OBSTRUCTED PASSAGES SUCH AS INTRANASAL OSTIA

Technical Field

The present invention relates to methods and systems for delivering fluids, aerosols, and/or acoustic energy to tissue surfaces, body cavities or lumens, obstructions or undesired materials associated with body cavities or on tissue surfaces, and particularly to tissue surfaces on or near natural orifices, such as ear, nose and throat passages and, particularly, nasal and sinus passages and cavities. In one aspect, the present invention relates to methods and systems for delivering fluids and/or aerosols to tissue surfaces, body cavities or lumens and obstructions, such as to nasal passages, at generally high frequency (e.g., sonic and/or ultrasound) pulsation rates. In another aspect, the present invention relates to methods and systems for delivering acoustic energy (e.g., sonic and/or ultrasound energy, and including high intensity ultrasound (HIU) and high intensity focused ultrasound (HIFU)) directly to tissue, or to obstructions in passages or cavities such as nasal passages, sinuses and sinus ostia.

Background

Rhinitis is produced by irritation and inflammation of the mucous membranes of the nasal cavities and is generally caused by allergic reactions, environmental irritants, bacteria and/or viruses. Symptoms of rhinitis include runny nose, nasal congestion and post-nasal drip. Rhinitis has been associated not only with discomfort, congestion and nasal conditions, but also sleeping problems, ear conditions and learning challenges. Treatment generally involves administration of antihistamines, leukotriene antagonists, nasal corticosteroids, decongestants, allergen immunotherapies, or saline irrigation of sinus cavities.

Sinusitis is produced by a number of pathologic processes, including inflammation of the sinus cavities, poor mucus transport, obstruction of passages from inflammatory debris and growth of biofilms within the sinuses and their drainage systems (ostea). Additionally, resulting stagnation, edema and poor blood flow in the surrounding tissue further decreases the ability of blood borne assistance in the form of immune modulators and antibiotics to reach the site. Microorganisms encased in biofilms are notoriously difficult to treat, since the biofilm matrix is highly resistant both to the action

of the immune system and to treatment with antibiotics. Sinusitis therapy may involve saline irrigation and administration of aerosols, as well as the administration of drugs such as antibiotics, decongestants, antihistamines and nasal steroids, sinus surgery, balloon sinuplasty and administration of nebulized antibiotics. Response rates for current therapies are generally relatively low, both on a short term and a long term basis. This is likely because of the multifactorial nature of this disease as described above. Each individual therapy used as standard treatment for sinusitis does not address all pathophysiologic causes that accumulate to cause the disease, sinusitis. This is true for other diseases such as chronic ear infections, recurrent skin infections, chronic wounds, vascular plaques, gastroenterologic obstructions and solid tumors.

Nasal irrigators for application of both solutions and aerosols are well known and are used to relieve symptoms of sinusitis and rhinitis, such as nasal congestion. Routine nasal irrigation generally improves symptoms in adults with chronic rhinosinusitis, as well as children with allergic rhinitis. Irrigating fluid, such as saline, may improve nasal ciliary motility and may additionally reduce airway edema and soften the mucus, which allows more effective aspiration. Irrigation and aspiration, or suctioning, is typically performed in hospital or medical office environments using installed, wall suction systems that are quite powerful and can be quite effective. Manual irrigating and/or aspirating devices that are available for home use are generally low flow rate, low aspiration pressure devices. Neti pots and squeeze bottles, for example, are used to irrigate nasal passageways manually and, while they temporarily relieve symptoms, they provide little long term comfort.

U.S. Patent Publication US 2008/0154183 A1 discloses self-contained, motorized devices that provide continuous or intermittent suction, as well as continuous or intermittent, on-demand delivery of irrigating fluid to nasal passages. U.S. Patent Publications US 2009/0281454 A1, 2009/0281482 A1, 2009/0281483 A1 and 2009/0281485 A1 disclose additional features of irrigation and aspiration devices. The disclosures of these patent publications are incorporated herein by reference in their entireties.

Commercial devices provide pulsed mist and/or a pulsating rinse to nasal passages using misting wands. Recent product improvements include a flex tip allowing 360° rotation with a tip locking and release feature, variable, stepless pressure control and a calibrated pulse rate. Different wands may be provided for the pulsed mist and pulsating rinse modes.

Delivery of liquid rinses and mists to nasal passages is described in the patent literature. U.S. Patent Publication US 2007/0299396 A1 discloses a pulsatile irrigation

device producing a calibrated pulsatile rinse of 1200—1250 pulses/min, driven by a piston driven pump assembly. Atomization to droplets of about 15-25 microns is accomplished using a bolt encased in the end of the tip. U.S. Patents 4,776,990, 4,805,614 and WO 2007/129297 disclose devices for home and office use that provide water-saturated, pressurized, heated air to nasal passages.

Many different types of nebulizers and aerosol generators have been developed. Some devices employ ultrasound transducers to nebulize solutions or generate aerosol droplets. U.S. Patent 3,774,602, for example, discloses a disposable, cartridge-type single shot ultrasonic nebulizer for inhalation therapy. U.S. Patent 4,109,863 discloses another apparatus for ultrasonic nebulization of liquid samples or suspensions. U.S. Patent 4,319,144 discloses a nebulization control system for a piezoelectric ultrasonic nebulizer. U.S. Patent 6,357,671 discloses another ultrasonic nebulizer that is controllable to vary the amplitude of the ultrasonic output.

Liquid aerosols may also be produced using micropumps, including electronic micropumps. In one system, a dome-shaped aperture plate or diaphragm having many tapered holes is vibrated at a high rate (e.g., 100,000 times per second). The rapid vibration causes each aperture to act as a micropump, drawing liquid through the holes and ejecting consistently sized droplets.

Liquid projection apparatus having addressable nozzles are also known. U.S. Patent 6,394,363 discloses a device having multiple transducers associated with multiple nozzles for projecting liquid as jets or droplets from selected nozzles. Related liquid projection apparatus are described in PCT International Publications WO 2008/044069 A1, WO 2008/044070 A1, WO 2008/0044071 A1, WO 2008/0044072 A1 and WO 2008/0044073 A1.

Application of ultrasound directly or indirectly to the nasal passages, or to tissue in the nasal passages, has also been proposed. Experimental studies administering low intensity (1 W/cm^2), pulsed (1:9) and continuous therapeutic ultrasound at a frequency of 1 MHz to sinuses by application of an ultrasound soundhead to the skin of the cheeks and forehead were conducted to ascertain the effect on chronic sinusitis and chronic rhinosinusitis. Ansari et al., Therapeutic ultrasound as a treatment for chronic sinusitis, *Physiotherapy Research International*, 9(3) 144-146 (2004); Ansari et al., Physiotherapty for chronic rhinosinusitis: The use of continuous ultrasound, *International Journal of Therapy and Rehabilitation*, July 2007, Vol 14, No 7; Ansari et al., A preliminary study into the effect of low-intensity pulsed ultrasound on chronic maxillary and frontal sinusitis, *Physiotherapy Theory and Practice*, 23(4):211-218, 2007.

The use of high intensity focused ultrasound (e.g., HIFU) is well known for ablation or remodeling of various types of tissue. Ultrasound catheter systems for delivering ultrasound energy for ablating obstructions within blood vessels using an ultrasound transmission wire or ultrasound transmission member are described, for example, in U.S. Patents 7,297,131 and 5,989,208.

A handheld, focused ultrasonic therapeutic device for treating skin lesions involved with gynecological disorders is described in U.S. Patent Publication US 2005/0080359. A supersound treatment apparatus suitable for treatment of rhinitis is described in PCT International Patent Publication WO 2008/009186. Devices targeting ultrasound beams on subepithelial layers of nasal mucosa in the nasal turbinates have been reported to reduce the volume of inferior turbinates, while increasing the volume of nasal ventilation.

U.S. Patent Publication US 2008/0027423 discloses a system for treatment of nasal tissue by application of ultrasound energy directly to tissue regions beneath the surface of the turbinate tissue. Fluid may be infused or injected directly into the turbinate tissue being treated, e.g. to enlarge the size of the turbinates and ensure delivery of ultrasound energy directly to the tissue. U.S. Patent Publications 2007/0144529 and 2008/0027423 relate to injecting fluid into the nasal turbinate using retractable needles at the end of a wand and then delivering ultrasound energy into the turbinate tissue. The treatment is accomplished using frequencies of from 0.5 to 12 MHz, generally from 5 to 12 MHz. Cooling fluid and/or radio frequency (RF) energy may also be delivered from the ultrasound and infusion probe.

Other modalities, including surgical techniques, are also used for treating tissue in intranasal passages. Somnoplasty uses controlled, low-power radiofrequency energy to create one or several submucosal volumetric lesions, which are resorbed over a period of several weeks to reduce unwanted tissue volume and stiffen remaining tissue in desired areas. Electrosurgical techniques are used for ablating, shrinking, coagulating or otherwise modifying tissue, including enlarged or hypertrophied nasal turbinates. In some systems, an active electrode of an electrosurgical probe is positioned in proximity to target tissue in the presence of an electrically conductive fluid. When a high frequency voltage is applied, tissue in proximity to the electrode is ablated, severed, or modified. Endoscopic techniques such as balloon sinuplasty, in which a sinus balloon catheter is positioned across a blocked ostium and inflated to restructure the blocked ostium, are also used for opening blocked passageways. Placement of stents and other implantable devices in sinus passageways is also performed to maintain patency.

Rhinitis and sinusitis remain widespread throughout many populations despite the many devices and systems described in the prior art. Effective and long-lasting reduction of mucus and accumulated inflammatory debris and reduction in the growth of biofilms within the nasal passages, sinuses and their drainage systems, remain challenging despite the proliferation of treatment options. The disclosure presented herein is directed, in part, to providing improved methods and systems for delivery of fluids, aerosols and ultrasound energy to tissue surfaces, cavities and obstructed sites in passages, lumens or cavities such as nasal passages, sinuses and sinus ostia.

Summary

Methods and systems of the present invention employ the application of acoustic energy, such as generally high frequency (e.g., sonic and/or ultrasound) acoustic energy, directly and/or through the delivery of pulsed irrigation fluids and/or aerosol flows, to address a range of pathophysiological processes that accumulate, and interact, to cause various illnesses and conditions, and to produce undesired symptoms. Methods and systems of the present invention may be applied for the treatment of tissue sites such as skin surfaces, organs and internal tissue surfaces, and to obstructions on tissue surfaces or within body cavities, lumens or the like, for disruption and/or removal of the obstruction(s). Some embodiments involve the delivery of acoustic energy directly to tissue or to obstructions, or delivery of pulsed irrigation fluids and/or aerosol flows, and employ multiple modes of administration, such as delivery of acoustic energy and/or irrigation fluid(s) or aerosol(s) at multiple frequencies (e.g. ultrasound and/or sub-ultrasound frequencies), intensities, pulse durations, pulse repetition rates, duty cycles, and the like. Yet other embodiments involve the administration of acoustic energy, or delivery of pulsed irrigation fluids and/or aerosol flows, according to single or multiple modes of operation, in combination with another treatment modality such as administration of an antimicrobial or therapeutic agent, application of electromagnetic radiation, an electrical field, radio frequency energy, laser energy, microwave energy, or the like.

In one aspect, methods and systems of the present invention produce a liquid stream and/or aerosol particles and/or aerosol droplets and deliver the liquid and/or aerosol to a tissue surface, or to a cavity or lumen or an obstruction, at generally high frequency pulsations (generally >1500 Hz) in "sonic" (sub-ultrasound) and/or ultrasonic frequency range(s) and at a generally low pressure. The tissue surface may be an external tissue surface, such as a skin surface or a wound, or it may be a tissue surface in a body cavity or lumen, such as in the vascular system, the respiratory system, the

gastrointestinal system, the reproductive system, or a natural orifice such as the mouth and/or throat, the ear, the nose, including the nasal cavity and nasal passageways. The obstruction may be an obstruction in a body cavity, such as a nasal cavity or passageway or in another natural orifice, or at another internal or external body location and may comprise pathological tissue, cellular debris, or the like. The aerosol may comprise a suspension of fine solid particles, or liquid droplets, or a mixture of solid particles and liquid droplets, and it may be generated using a variety of systems known in the art for generating aerosols.

In some embodiments, delivery of an irrigating liquid and/or aerosol may be accomplished using multiple and/or alternating pulsations having different frequencies, intensities, pulse durations, pulse repetition rates and/or duty cycles. Pulsed delivery using generally high frequency pulsations, or alternating pulsations of different frequencies, may preferentially provide cavity entry (e.g., by Helmholtz principle), biofilm dissolution or reduction, degradation of pathological tissue, acoustic enhancement of delivery of medications or other treatment modalities, improvement of circulation, local immune modulation, and other desired effects. Different operating modalities providing delivery of acoustic energy at multiple frequencies may be provided, and may be selectable by the user, to preferentially promote various functionalities.

Liquid streams and aerosol droplets delivered to tissue surfaces such as skin, natural orifice cavities such as intranasal passages, and to obstructions at a variety of tissue sites by means of generally high frequency pulsations are preferably aqueous and may consist of saline, or may consist essentially of saline (with small amounts of active or inactive compositions dissolved in or carried by the saline). Liquid streams and aerosol droplets delivered using high frequency pulsations may alternatively, or additionally, comprise saline or another carrier solution comprising antibiotics, antimicrobial agents, drugs, or the like, dissolved or suspended in the liquid solution and/or delivered as aerosol particles or droplets. Suitable medications for delivery in a liquid stream or as aerosol particles or droplets may comprise (and are not limited to), in addition to saline, hypertonic saline, lactated ringer's solution, dead sea salt solution, antibiotics, midazolam, fentanyl, insulin, growth hormone, one or more growth factors, gentamycin, clindamycin, ciprofloxacin, cefuroxime, levofloxocin, tobramycin, ampicillin+sulbactam, amphotericin, tobramycin/amphotericin combinations, cefotaxime, ceftriaxone, fluticasone, budesonide, mometasone furoate monohydrate, xylitol, eucalyptus, tea tree oil, capsaicin, grapefruit seed extract, oil of wintergreen, and the like.

Devices of the present invention for delivery of an irrigating liquid and/or aerosol to a desired site on the skin or within the respiratory system or a natural orifice are

generally handheld devices comprising a handle and at least one solution and/or aerosol discharge port. Source liquid for discharging onto tissue surfaces, or for generation of aerosol droplets, may be stored in a reservoir or device assembly separate from the handheld device and provided to the handheld device using appropriate tubing, conduits, and the like. Alternatively, devices of the present invention may incorporate a refillable liquid reservoir for storing source liquid, or mate with a disposable cartridge or liquid reservoir that may be provided in a pre-filled or fillable format and is attachable to and detachable from the device, generally at the handle portion. Device features and configurations, including irrigation and aspiration features, nozzle features, dual function switch features, articulating head features, pump and fluid control features and aspiration features may be similar to those described in U.S. Patent Publications 2008/0154183 A1, US 2009/0281454 A1, 2009/0281482 A1, 2009/0281483 A1 and 2009/0281485 A1, the disclosures of which are incorporated herein by reference in their entireties.

In another aspect, methods and systems of the present invention deliver generally high frequency (e.g., ultrasound) acoustic energy for application directly to tissue surfaces or to obstructions within body cavities or lumens, including blocked sites or obstructions in orifices or lumens such as in nasal passages. In one embodiment, devices of the present invention comprise an insertion wand sized and configured for insertion into at least a portion of a body cavity or lumen, or for contacting a target site on a tissue surface or at an obstruction within a body cavity or lumen, and an acoustic energy delivery member associated with the insertion wand for conveying generally high frequency acoustic energy (e.g., ultrasound energy, including high intensity ultrasound (HIU) and high intensity focused ultrasound (HIFU)) directly to tissues or obstructed sites, such as within nasal passages. Delivery of high frequency acoustic energy provides mechanical and cavitational effects that promote opening of blocked passages and lumens, such as nasal passages, sinuses and sinus ostia. High frequency, generally high intensity acoustic energy may be provided directly to an obstructed site, such as an intranasal passage or another body lumen or cavity, to preferentially disrupt and/or ablate pathological tissue, obstructions, cellular debris and the like, including inflammatory buildup, bony hypertrophy, various types of plaque, and biofilms.

In some embodiments, delivery of acoustic energy at particular frequencies, intensities, pulse durations, pulse repetition rates, and/or duty cycles, may be selected to promote effects such as immune modulation, improved vascularization, bioacoustic effects and improved efficacy of administered agents such as antibiotic, antimicrobial and other agents. Systems and methods of the present invention may also provide delivery of one or more sequences of acoustic energy, with each sequence providing delivery of

acoustic energy at a different frequency, intensity, pulse duration, pulse repetition rate, and/or duty cycle. Multiple sequences may be programmed in the device as multiple programmed protocols may be selectable by a user. In some embodiments, each acoustic energy delivery sequence, or each programmed protocol may target a specific effect, tissue type, administered agent, or the like.

In yet another aspect, methods and systems of the present invention provide delivery of an irrigating liquid and/or generally high frequency acoustic energy (e.g., ultrasound energy) to a desired internal site of a subject using a catheter assembly. In these embodiments, irrigating fluid and/or acoustic energy is provided to a tissue site, or an obstruction, at an internal target site, such as a site in the vascular system, the respiratory system, the gastrointestinal system, the reproductive system, or the like, using an acoustic energy delivery system for delivery of acoustic energy and tubular structures for delivery of an irrigating liquid. Various systems and methods for delivery acoustic energy to internal body sites for purposes of treatment, disruption, ablation and/or removal of undesired tissue or obstructions, and the like, are known in the art and may be used in systems and methods of the present invention. Various types of catheters employing ultrasound transducers are disclosed, for example, in U.S. Patents 5,362,309, 5,318,014, 5,315,998, 5,269,291, 5,197,946, 5,735,811, 5,197,946, 5,989,208, 6,001,069, 6,024,718, 6,623,444, 6,855,123 and 7,297,131, the disclosures of which are incorporated herein by reference in their entireties.

In some embodiments, delivery of an irrigating liquid and/or acoustic energy at particular frequencies, intensities, pulse durations, pulse repetition rates, and/or duty cycles using a catheter-based system, may be selected to promote effects such as immune modulation, improved vascularization, bioacoustic effects and efficacy of administered agents such as antibiotic, anti-restonosis and other agents. Delivery of one or more sequences of acoustic energy, with each sequence providing delivery of acoustic energy at a different frequency, intensity, pulse duration, pulse repetition rate, and/or duty cycle may be provided and multiple sequences may be programmed in a catheter-based system as multiple programmed protocols selectable by a user.

Fluid and/or aerosol particles and/or droplets may be supplied in addition to delivery of high frequency acoustic energy through acoustic energy delivery systems of the present invention, in a continuous or pulsed delivery protocol, to tissue surfaces or to obstructions to promote penetration of blocked sites such as nasal passages, disruption and opening of undesired blockages, and/or to provide cooling of the target site during or following delivery of high frequency (e.g., ultrasound) acoustic energy. Pulsed delivery using high frequency pulsations promotes entry (e.g. by Helmholtz principle), biofilm

dissolution and acoustic enhancement of medications delivered in the liquid stream and/or aerosol droplets.

Devices of the present invention may incorporate one or more aspiration ports for removal of materials from a working site prior to, during or following delivery of fluid and/or aerosol particles/droplets and/or generally high frequency acoustic energy. Multiple delivery ports may be provided for delivery of multiple (different) fluids, or for delivery of multiple types of aerosol particles/droplets, sequentially or simultaneously. Visualization and/or illumination of intranasal target sites may be provided using optical, acoustic, or other types of visualization and illumination systems incorporated in devices of the present invention. An endoscopic port may be provided for delivery of diagnostic and/or therapeutic tools, agents, and the like. Systems for delivering additional diagnostic and/or treatment modalities such as electromagnetic radiation, radio frequency radiation, laser radiation, microwave radiation, and the like, may also be provided in connection with methods and systems of the present invention.

Devices of the present invention may also incorporate one or more systems, such as one or more discrete receptacle(s), for collection of material removed by aspiration. The collected tissue, obstruction and/or debris samples may be subjected to various types of diagnostic testing, characterization, and the like. Multiple collection receptacles may be provided for collection of samples at different stages of a protocol.

Brief Description of the Drawings

Fig. 1 shows a schematic illustration showing a handheld device of the present invention for delivering fluid and/or aerosol particles or droplets to a tissue surface or an obstruction, the device being shown inserted into a user's nostril and the illustration showing, in cross-section, the internal anatomy of the nasal passageways.

Figs. 2A and 2B show schematic diagrams illustrating the use of a device shown in Fig. 1, with Fig. 2A showing insertion of the device into a nostril and operation of the device to distribute an irrigating fluid and/or aerosol pulsed at high frequency in the area of clogged nasal passageways, and Fig. 2B showing aspiration of the loosened material from the passageways following delivery of the irrigating fluid and/or aerosol.

Fig. 3 shows a schematic drawing illustrating another embodiment of a device of the present invention for delivering fluid and/or aerosol particles or droplets and/or high frequency acoustic energy (e.g., ultrasound energy) to a tissue surface.

Fig. 4 shows a schematic drawing illustrating the device of Fig. 3 inserted into a user's nasal passageway to deliver fluid and/or aerosol particles or droplets and/or high frequency acoustic energy (e.g., ultrasound energy) to a tissue surface in the nasal

passageway and shows, schematically in cross-section, the internal anatomy of the nasal passageways.

Fig. 5 shows a schematic drawing illustrating a device similar to that shown in Fig. 3 for placement and expansion of an expandable member (e.g., balloon) in a body cavity and shows, schematically in cross-section, the internal anatomy of the nasal passageways.

Fig. 6 shows a schematic drawing of another device of the present invention inserted into a user's nasal passageway to deliver high frequency acoustic energy (e.g., ultrasound energy) to a tissue surface in the nasal passageway, with or without delivery of fluid and/or aerosol particles or droplets and shows, schematically in cross-section, the internal anatomy of the nasal passageways.

Fig. 7 shows a schematic drawing of another device of the present invention for delivering high frequency acoustic energy (e.g., ultrasound energy) to a tissue surface, with or without delivery of fluid and/or aerosol particles or droplets.

Figs. 8A -8E show schematic diagrams illustrating the use of a device similar to that shown in Figs. 6 and 7, with Fig. 8A showing insertion of the device into a nostril; Fig. 8B showing extension of an active therapeutic component for delivering generally high frequency acoustic energy (e.g., ultrasound energy) to a blockage in a nasal passageway; Fig. 8C schematically showing delivery of acoustic energy through the active therapeutic component to disrupt the blockage; Fig. 8D showing aspiration of debris from the site; and Fig. 8E showing cleared nasal passageways following treatment.

Like numbers have been used to designate like parts throughout the several drawings to provide a clear understanding of the relationship of the various components and features, even though different views are shown. It will be understood that the appended drawings are not necessarily to scale, and that they present a simplified, schematic view of many aspects of systems and components of the present invention. Specific design features, including dimensions, orientations, locations and configurations of various illustrated components may be modified, for example, for use in various intended applications and environments.

Detailed Description

Specific methods and systems of the present invention for pulsed delivery of liquids and/or aerosols, and/or for delivery of generally high frequency, generally high intensity acoustic energy (e.g., ultrasound) to intranasal areas such as nasal passages, sinuses and sinus ostia, are described with reference to the accompanying drawings. It will be appreciated that these specific embodiments are illustrative, and that systems and

methods of the present invention may be used in a variety of applications, as described elsewhere in this specification.

Fig. 1 shows a schematic illustration of one embodiment of device for pulsed delivery of liquids and/or aerosols to a subject's nasal passages. As shown in Fig. 1, device 10 comprises a handle 12, a nostril interface member 14 and a discharge port 16. Handle 12 has a size and configuration that facilitates holding in one or both hands and may include ridges, indentations, curved contours, and the like, to enhance the ergonomic feel and secure handling of the device. Handle 12 may include at least one activation mechanism, such as control 15, for activating one or more device functions. In one embodiment, for example, control 15 may be operated by a user to activate, or inactivate, a pulsatile flow of liquid and/or aerosol from discharge port 16 in nostril interface member 14.

Handle 12 may also house power supply and control elements for operating the device. Power may be supplied to device 10 by physical connection to an electrical power source such as a separate control unit or an electrical outlet by means of a conventional power cord, as is well known in the art. Power may alternatively be supplied by a battery source mounted in the handle. Battery power sources may be provided as replaceable or rechargeable components. Battery charging may be accomplished by direct coupling of battery terminals, or conductive elements provided on the housing, with a power source, or by indirect coupling using, for example, an inductive charging system. Handle 12 may also house control mechanisms, such as mechanical or electronic switches, microprocessors, power supplies, and the like, and may house an aerosol generation device and/or the system for generating pulsatile discharge of liquid and or aerosol droplets.

Handle 12 and nostril interface member 14 may be provided in an integrated, single piece construction, or they may be provided as separate components that are detachable from one another. Nostril interface member 14 comprises at least one discharge port 16 at a distal end of the member, and generally has a size and configuration that permits insertion of a distal end of the interface member and discharge port 16 into the nostril of a user. The distal end of the nostril interface member may have a generally curved or tapered configuration, with a smaller diameter area at the discharge outlet, such that the discharge outlet and distal end of the interface member may be inserted into the nostril, while more proximal surfaces of the nostril interface member contact the nostril opening and effectively "seal" the opening during use of the device. In some embodiments, the nostril interface member may be flexible and may comprise a telescoping structure that permits extension and retraction of the member, or adjustment

of the member to different sizes or configurations. In some embodiments, the nostril interface member may be articulatable with respect to the handle.

In one embodiment, devices of the present invention are capable of delivering a liquid stream in a generally high frequency pulsatile flow. In another embodiment, devices of the present invention are capable of generating aerosol particles and/or droplets, and delivering the aerosol particles and/or droplets in a generally high frequency pulsatile flow. In yet another embodiment, devices of the present invention are capable of selectively delivering a liquid stream, aerosol particles and/or aerosol droplets, simultaneously or sequentially, in a generally high frequency pulsatile flow. Liquid, aerosol particles and/or aerosol droplets may be delivered from a common discharge port sequentially and intermittently, or from multiple, dedicated discharge ports, simultaneously or sequentially, and on a continuous or intermittent basis.

An aspiration channel may optionally be provided for aspiration of material from a site, such as nasal passageways. Aspiration may be provided through a common port as fluid and/or aerosol delivery, or through an additional aspiration port provided in the nostril interface member 14, or through an aspiration port provided in an auxiliary device. Although an aspiration system employing a vacuum device may be provided integrally with the device and an aspiration reservoir may be incorporated into the device or used in connection with the device, aspiration may also be accomplished by interfacing an aspiration channel within the device with a vacuum or suction source provided in a medical facility. Interface tubing may be provided for this purpose.

Figs. 2A and 2B show, schematically, operation of a device as illustrated in Fig. 1. Nostril interface member 14 is inserted into and generally contacted to a user's nostril. For some applications, the nostril interface member may be sized and configured to form a substantially liquid-tight seal against a user's nostril when inserted and upon continued application of pressure in the insertion direction. After insertion and placement of the nostril interface member, the user activates a desired delivery protocol for delivery of a liquid stream, aerosol particles and/or aerosol droplets, simultaneously or sequentially, in a generally high frequency pulsatile flow, through discharge port 16. This is shown schematically by the curved dashed lines. The pulsatile delivery of liquids and/or aerosols facilitates penetration of fluids and particles through passageways and blockages and may also deliver a therapeutic effect to tissue surfaces. Liquids and other material, including debris, mucus, infected tissue, and the like may be withdrawn by aspiration using the same device following pulsatile delivery of liquids and/or aerosols, as shown schematically in Fig. 2B.

Controls may be provided on the device handle, illustrated as actuator 15, or on an accessory device or module, allowing a user to select liquid and/or aerosol delivery modes, or allowing a user to select among various modes of operation or various pre-determined operating programs. In one embodiment, for example, a device such as that illustrated in Fig. 1 may be operated in an aerosol delivery mode whereby, upon activation, aerosol particles and/or droplets are pulsated and discharged from outlet port 16 at a generally low pressure and high frequency. In another embodiment, a single mode device may be operated in a liquid delivery mode whereby, upon activation, a high frequency pulsating liquid stream is discharged from outlet port 16, continuously or intermittently. In yet another embodiment, a user may select pulsating liquid and/or aerosol discharge modes which may also operate on a continuous or intermittent basis.

In some embodiments, multiple pulsating irrigation fluid and/or aerosol delivery options may be programmed in the device, with various operating programs being predetermined and, optionally, selectable by the user. In one embodiment, for example, a control may be actuated by a user to initiate a predetermined or selectable cycle involving multiple irrigation fluid and/or aerosol delivery protocols. Multiple different delivery protocols may involve delivery of irrigation fluid and/or aerosol at pulsation rates having a selected frequency, intensity, pulse duration, pulse repetition rate, duty cycle, and the like. Multiple different delivery protocols may additionally involve delivery of different types (e.g., composition, concentration, osmolarity, and the like) of irrigation fluids, and/or different types (e.g., composition, concentration, particle size, and the like) of aerosols.

In one embodiment, for example, a therapeutic cycle may provide delivery of from one to several different pulsation cycles that correlate with the acoustic properties of each contributing pathologic process that contributes to the disease or symptomology (e.g., sinusitis, ear infection, pneumonia, chronic skin wounds, gastroenterologic processes, tumors, and the like.) Pathologic processes that may be targeted by the therapeutic cycle may include (but are not limited to) biofilms, inflammation, mechanical obstruction, hypertrophy, poor circulation, dysfunctional immune response/modulation, and the like. In alternative embodiments, a user may select pulsating liquid rinse and/or aerosol delivery options by means of multiple selectable actuators. In any of these embodiments, multiple and selectable modes may be implemented, whereby programmed or selectable levels of liquid and/or aerosol flow or volume, aerosol particle and/or droplet size, aerosol particle and/or droplet density, pulsation frequency, temperature, and the like, may be selectable by the user.

In one embodiment, for example, different pulsation characteristics may be provided to promote different effects. Optimal pulsation frequencies for promoting for sinus entry (resonance), biofilm dissolution, drug enhancement, immunomodulation and circulatory regulation may be different; user selectable controls may be provided for selecting pulsation frequencies or modes of operation to promote each of these functions. Alternatively, one or more pre-programmed timing sequences of application of multiple frequencies may be provided.

Aerosol generation may be accomplished using aerosol generators, such as pumps, aperture plates or diaphragms, ultrasound transducers (e.g., piezoelectric crystals), and other systems that are well known in the art. In one embodiment, solution provided at a generally low pressure is conveyed through a standard jet nebulizer to produce aerosol or finely divided liquid droplets. Aerosol droplets generated and discharged by devices of the present invention preferably have a droplet size of from about 0.5μ to about 200μ, in some embodiments from about 1μ to about 100μ, in other embodiments from about 3μ to about 60μ, and in yet other embodiments from about 5μ to about 30, entrained in gas (e.g. air).

Pulsation of the liquid and/or aerosol particles and/or droplets is generally accomplished at a frequency in excess of 100 Hz and may be accomplished at an ultrasound frequency of 20 kHz or higher. Devices of the present invention may provide either or both ultrasonic and sub-ultrasonic (sonic) oscillation of a liquid stream or aerosol as it exits the discharge outlet. A liquid flow may be pulsated at one frequency, such as a frequency less than 10 kHz, while aerosol droplets may be pulsated at a different frequency, generally at a higher frequency. Aerosol may be pulsated at frequencies in excess of about 1500 Hz, and in some embodiments in excess of about 5000 Hz, and generally at frequencies less than 10 MHz. In some embodiments, aerosol is pulsated at frequencies in excess of about 10 kHz, from about 10 kHz to about 100 kHz, in some embodiments from about 15 kHz to about 50 kHz, and in yet other embodiments from about 20 kHz to about 40 kHz.

Aerosol particles or droplets may alternatively be pulsated at two or more alternating frequencies. In one embodiment, aerosol may be pulsated at multiple alternating, sub-ultrasonic frequencies. In another embodiment, aerosol is pulsated at two or more alternating frequencies, with one or both of the frequencies being an ultrasonic frequency. According to one embodiment, for example, aerosol delivery is provided by pulsation at multiple frequencies, such as at an ultrasonic frequency of from about 20 kHz to about 40 MHz and at one or more additional ultrasonic or sub-ultrasonic frequencies.

The pulsation frequency of delivery of liquid and/or aerosol streams may be alternated by providing multiple pulsation generators, or by operating a single pulsation generator differently. Various cycles may be implemented and, in some embodiments, a user may selectively control aerosol generation and pulsation, while in other embodiments, predetermined cycles of aerosol generation and pulsation may be provided. In one embodiment, for example, a column of mist is generated in the space between the transducer and an aerosol discharge orifice when the transducer is operated at the aerosol generation frequency, and the column of mist is then pulsated as it exits the discharge orifice when the device is operated at the pulsation frequency. Cycles may be established, and predetermined, to operate the transducer in an aerosol generation mode for a time sufficient to generate a suitable aerosol column, and then to operate the transducer in the pulsation mode for a time sufficient to discharge the aerosol from the column.

According to some embodiments, a single piezoelectric crystal or another ultrasound generating device may be operated in different modes, sequentially, to produce both aerosol and high frequency pulsations of liquid and/or aerosol. In another embodiment, multiple ultrasound transducers (e.g., two piezoelectric crystals) may be operated in aerosol generation and pulsation modes, respectively, simultaneously or intermittently, to generate aerosol and then to pulsate the generated aerosol at a generally high frequency. A dedicated aerosol generation transducer may be operable, for example, in a single operating condition or in multiple operating conditions, and a dedicated pulsation transducer may, similarly, be operable at a single pulsation frequency, or at multiple selectable pulsation frequencies.

In one embodiment, an aerosol generation system (e.g., a piezoelectric crystal or ultrasound transducer) and an aerosol pulsation system (e.g., an ultrasound transducer) are located separately. An aerosol generation transducer may be located at a liquid solution interface, for example, to generate a column of aerosol droplets extending above the liquid solution interface. An aerosol pulsation system, such as an ultrasound transducer, may be located along an aerosol column or in proximity to an aerosol discharge orifice, providing pulsatile discharge of aerosol from a discharge port.

In another embodiment wherein ultrasound transducers are used both for aerosol generation and pulsation, an aerosol generation transducer and an aerosol pulsation transducer may be located in proximity to one another. Multiple transducers may be collocated, for example, with an aerosol generation transducer provided in a central position, and a pulsation transducer provided as an annular transducer positioned around the central aerosol generation transducer to provide pulsation of the aerosol at discharge.

Multiple transducers may be operated simultaneously to both generate and pulsate aerosol simultaneously. Alternately, an aerosol generator may be operated to generate a column of aerosol and the aerosol pulsation transducer may be operated independently to pulsate the generated aerosol. The aerosol generation transducer may be immersed in liquid and in direct contact with the liquid, or it may be in indirect contact with liquid through a flexible membrane or diaphragm.

Devices of the present invention may additionally incorporate a heater, or a thermostat for controlling the temperature of liquid discharged in a liquid stream, of for controlling the temperature aerosol at or prior to discharge. A heating element may be provided, for example, in proximity to a wall defining the mist column to heat the mist as it moves through the column to a temperature of from about 30-50°C, in some embodiments from about 35-45°C. In some embodiments, the aerosol is heated to a temperature above the average human body temperature (37°C) prior to discharge from the device.

Figs. 3-5 show schematic illustrations of devices of the present invention for delivery of generally high frequency acoustic energy (e.g., ultrasound energy, including high intensity ultrasound (HIU) and high intensity focused ultrasound (HIFU) to tissue sites such as nasal passages. As shown in Fig. 3, device 20 comprises a handle 22, an insertion wand 24 and an acoustic energy delivery member 26. In devices intended for delivery of high frequency acoustic energy to internal sites, such as nasal passageways, insertion wand 24 is configured for insertion through a nostril opening and positioning at least partially within nasal passageways. Insertion wand 24 is generally cylindrical and may be constructed as a flexible, catheter-like structure having at least one longitudinally oriented lumen extending therethrough. External surfaces of the insertion wand may be provided with a surface texture, or coating, such as a hydrophilic or hydrophobic coating, to ease passage of the insertion wand though nasal passages and improve deliverability. External surfaces of the insertion wand may also be provided with antibacterial coatings or coatings through which drugs or other agents are provided.

Insertion wand 24 may incorporate multiple lumens, channels or the like that communicate with source liquids, aerosol particles and/or droplets, vacuum sources, liquid and/or vacuum manifolds, or the like, to provide delivery of liquids, aerosol particles and/or droplets, vacuum, or the like, to intranasal passages. Multiple lumens may be co-axial with respect to one another, or they may be aligned on different axes and be non-concentric with respect to one another. In these embodiments, insertion wand 24 is generally provided with one or more discharge ports 25 in proximity to a distal area, providing intranasal delivery of a liquid and/or aerosol particles and/or droplets. Insertion

wand 24 may, alternatively or additionally, be provided with one or more aspiration ports 27 in proximity to a distal area, providing withdrawal of delivered liquids and degraded materials from an intranasal site when an aspiration system (e.g. vacuum) is activated. A distal end of insertion wand 24 may additionally incorporate an endoscopic port and/or components of a visualization system, such as an optical or ultrasound guidance and/or visualization system.

Energy delivery member 26 may be provided at the tip of the insertion wand and configured for positioning in proximity to and/or contacting blockages within nasal passages, mucous membranes and nasal turbinates, or pathological or undesired tissue. In one embodiment, energy delivery member 26 may comprise a tapered structure, such as a generally conical structure, for focusing and concentrating high frequency and/or high intensity acoustic energy. Conical structures for delivering high intensity focused ultrasound are described, for example, in U.S. Patents 6,666,835, 6,500,133 and 6,217,530. An energy delivery member or surface may be extendible and/or retractable with respect to handle 22 and/or insertion wand 24 to provide desired positioning of the energy delivery member in contact with obstructions and/or tissues for delivery of high frequency acoustic energy.

In another embodiment, as illustrated in Fig. 5, an energy delivery member may comprise a flexible, deformable bladder or inflatable chamber 28 adapted for retaining an acoustically transmissive material, such as a liquid or gel, within its interior volume. The flexible, deformable chamber may be stored in a collapsed condition within wand 24, for example, and expanded, or inflated, at the desired target site from a distal tip of the wand by filling with an acoustically transmissive material. Expandable chamber 28 may be enlarged, at a desired target site, until the walls of the chamber contact a tissue site, or the walls of a cavity or passageway or lumen. Generally high frequency acoustic energy, e.g. ultrasound energy, may be applied to the tissue surfaces or obstructions in contact with the chamber wall by transmission through the acoustically transmissive material and the wall of the inflatable chamber.

The bladder or inflatable member(s) is constructed from a material that has generally high acoustic transmissivity properties and, when filled with an acoustically transmissive material, provides a flexible surface that is expandable and deformable to conform to contours of internal cavities or passageways, such as intranasal passages. The inflatable member may be coated with a drug or another agent, particularly an agent whose activity is enhanced in the presence of high frequency acoustic energy, such as ultrasound energy. The inflatable member may, additionally or alternatively, be permeable or porous to deliver a drug or another agent, particularly an agent whose

activity is enhanced in the present of high frequency acoustic energy, such as ultrasound, to the target site. This embodiment provides effective delivery of ultrasound energy to tissue surfaces, cavities and obstructions over a larger surface area than point contact and provides effective access to target sites that may otherwise be difficult to access with an ultrasound applicator.

A distal end of the energy delivery member is preferably navigable to desired treatment sites, such as tissue surfaces and obstructions, such as blocked sites within nasal passages, where it can be activated to provide mechanical and cavitational effects that promote recanalization of obstructed passages. The energy delivery member may have a pre-formed shape or it may be flexible or conformable, as described above. Energy delivery members having different pre-formed shapes may also be used. A proximal end of energy delivery member 26 is connected or connectable to a generally high frequency acoustic energy generator (e.g., an ultrasound transducer) or acoustic energy coupling, providing delivery of high frequency acoustic energy (e.g., ultrasound) to the energy delivery member.

High frequency acoustic energy delivered through energy delivery member 26 generally has a frequency of greater than about 20 kHz and less than about 25 MHz; in some embodiments from about 20 kHz to about 100 kHz; in some embodiments from about 20 kHz to about 50 kHz; in other embodiments greater than about 100 kHz and less than about 1 MHz; in other embodiments from about 500 kHz to about 15 MHz; and in yet other embodiments greater than about 500 kHz and less than about 5 MHz. The acoustic energy applied through the energy delivery member may be at a generally high intensity of from about 1mW/cm^2 to about 5 W/cm^2; in some embodiments from about 50 mW/cm^2 to about 3 W/cm^2; in other embodiments from about 5-100 mW/cm^2; in yet other embodiments from about 0.1-1.5 W/cm^2. In other embodiments, the acoustic energy applied through the energy delivery member may be a generally high intensity ultrasound of greater than about 1 W/cm^2 and less than about 25 kW/ cm^2. In some embodiments, the acoustic energy applied through energy delivery member has an acoustic intensity from about 10 to about 1,000 W/cm^2; in some embodiments from about 1,000 to about 15,000 W/cm^2; and in yet other embodiments from about 3,000 to about 10,000 W/cm^2. The generally high intensity ultrasound may be sufficient to ablate tissue and/or cellular structures or debris, or it may be at a sub-ablation intensity that is sufficient to disrupt tissue and/or cellular structures or debris but not ablate. The pulse duration and repetition rate may be adjusted and matched to the frequency and intensity of acoustic energy pulses to achieve the desired effect.

The high frequency acoustic energy may be selectably activated on a continuous basis, or ultrasound energy may be applied, through the energy delivery member, on an intermittent basis, and the frequency and/or acoustic intensity may be adjustable and selectable by the operator. Operation of the ultrasound transducer at duty cycles of less than about 80% is generally preferred; in some embodiments at duty cycles of less than 50%; and in yet other embodiments at duty cycles of less than about 30%. Enhancement and/or coupling agents promoting and/or targeting acoustic energy deposition may be used and may be provided to a target site through the insertion wand and/or the energy delivery member.

Handle 22 has a size and configuration that facilitates holding in one or both hands and may include ridges, indentations, curved contours, and the like, to enhance the ergonomic feel and secure handling of the device. Handle 22 may house power supply and control elements for operating the device. Power may be supplied to device 20 by physical connection to an electrical power source such as a separate control unit or an electrical outlet by means of a conventional power cord, as is well known in the art. Power may alternatively be supplied by a battery source mounted in the handle. Battery sources may be replaceable or rechargeable. Battery charging may be accomplished by direct coupling of battery terminals, or conductive elements provided on the housing, with a power source, or by indirect coupling using, for example, an inductive charging system. Handle 22 may also house control mechanisms, such as mechanical knobs 21A, 21B and 21C, or electronic switches, microprocessors, power supplies, and the like. Knobs 21A, 21B and 21C may provide user operable control of irrigation fluid, aerosol delivery, delivery of generally high frequency acoustic energy, selection of multiple modes of operation and/or multiple programmed protocol sequences, aspiration, other operating modalities, and the like.

Liquids and/or aerosols may be delivered through the insertion wand 24 and ports positioned along or generally at a distal end of the insertion wand, similarly to the delivery of liquids and/or aerosols described with reference to the device illustrated in Figs. 1, 2A and 2B. Aspiration may also be provided in devices such as those illustrated in Figs. 3-5, that deliver generally high frequency acoustic energy, such as ultrasound energy. Aspiration may be provided through one or more ports positioned along or generally at a distal end of the insertion wand, similarly to the aspiration feature described with reference to the device illustrated in Figs. 1, 2A and 2B.

Handle 22, insertion wand 24 and energy delivery member 26 may be provided in an integrated, single piece construction, or they may be provided as separate components that are detachable from one another. Handle 22 may be provided as a single- or

multiple-use component. Insertion wands and/or energy delivery members may similarly be provided as integrated components or may be provided separately from one another, with appropriate interfaces for operation. Multiple configurations of insertion wands and/or energy delivery members may be provided for operation on common or multiple handles, with appropriate insertion wands and/or energy delivery members being selectable by a user depending on the circumstances of use. Insertion and energy delivery members may be provided as single- or multiple-use components, although they may generally be provided as sterile, disposable components that are mountable on a reusable handle. Device 20 may incorporate all of the components required for operation, or it may interface with a separate console, or control unit (not shown), that provides electrical power, liquid for infusion or aerosol delivery, operating control features, displays, and the like.

In some embodiments, devices of the present invention are capable of selectively delivering high frequency acoustic energy, a liquid stream, aerosol particles and/or aerosol droplets, simultaneously or sequentially, in one or a plurality of delivery modes: continuous flow; intermittent flow; or high frequency pulsatile flow. Liquid, aerosol particles and/or aerosol droplets may be delivered from a common discharge port sequentially and intermittently, or from multiple, dedicated discharge ports, simultaneously or sequentially, and on a continuous or intermittent basis. Aspiration may be provided, additionally or alternatively, through one or more ports in the insertion wand and/or energy delivery member. Insertion wand 24 may be provided with one or more channels, or lumens, for delivery of liquids, aerosol particles, and/or aerosol droplets to a desired intranasal site, and for removal of material from the site by means of aspiration.

Controls may be provided on the device handle, as illustrated, or on an accessory device or module, allowing a user to select acoustic frequency and/or intensity, liquid and/or aerosol delivery modes, aspiration modes, visualization modalities, or the like. Controls may also be provided allowing a user to select from among various modes of operation or various pre-determined or pre-set operating modes. Devices of the present invention may thus be operated, manually or by selectable automated operation, in a single mode or multiple modes.

In one embodiment, for example, a device such as illustrated in Figs. 3-5 may be operated in a high frequency acoustic energy deposition mode in which the insertion wand and energy delivery member are positioned in a nasal cavity, with the energy delivery member contacting mucus and/or debris forming an obstruction, or tissue desired to be treated. Acoustic energy delivery may be activated at a preset or selectable acoustic energy frequency and/or intensity to heat and/or cavitate and/or ablate mucus and/or

debris forming the obstruction. In another embodiment, the energy delivery member may be positioned to contact tissue and activated at preset or selectable acoustic energy frequency and/or intensity levels to heat and/or cavitate and/or ablate selected tissue sites. Delivery of the high frequency and/or high intensity acoustic energy may be accompanied by infusion of liquids and/or aerosol particles or droplets, and/or by aspiration or liquids, wastes, mucus, and the like, from the site of energy deposition.

In some embodiments, multiple pulsating liquid rinse and aerosol delivery options, as well as multiple energy deposition options, may be programmed in the device, with various operating programs being predetermined and selectable by the user. In alternative embodiments, a user may select pulsating liquid rinse, aerosol delivery and/or energy deposition options by means of multiple selectable actuators. In any of these embodiments, multiple and selectable modes may be implemented, whereby programmed or selectable levels of liquid and/or aerosol flow or volume, aerosol particle and/or droplet size, aerosol particle and/or droplet density, pulsation frequency, temperature, acoustic energy frequency, intensity, pulse repetition rate, duty cycle, and the like, may be selectable by the user.

Figs. 6 and 7 show schematic illustrations of two embodiments of a device for delivery of generally high frequency acoustic energy to nasal passages. As shown in Fig. 6, device 40 comprises a handle 42, an insertion member 44 and an acoustic energy delivery member 46. Insertion member 44 is configured for insertion through a nostril opening and positioning at least partially within nasal passageways. Insertion member 44 is generally cylindrical and may be constructed as a flexible, catheter-like structure having at least one longitudinally oriented lumen extending therethrough. External surfaces of the insertion member may be provided with a surface texture, or coating, such as a hydrophilic or hydrophobic coating, to ease passage of the insertion member though nasal passages and improve deliverability. External surfaces of the insertion member may also be provided with antibacterial coatings or coatings through which drugs or other agents are provided.

Insertion member 44 may incorporate multiple lumens, channels or the like that communicate with source liquids, aerosol particles and/or droplets, vacuum sources, liquid and/or vacuum manifolds, or the like to provide delivery of liquids, aerosol particles and/or droplets, vacuum, or the like, to intranasal passages. Multiple lumens may be co-axial with respect to one another, or they may be aligned on different axes and be non-concentric with respect to one another. In these embodiments, insertion member 44 is generally provided with one or more discharge ports 45 in proximity to a distal area, providing intranasal delivery of a liquid and/or aerosol particles and/or droplets. Insertion

member 44 may, alternatively or additionally, be provided with one or more aspiration ports 47 in proximity to a distal area, providing withdrawal of material from an intranasal site when an aspiration system (e.g. vacuum) is activated. A distal end of insertion member 44 may additionally incorporate components of a visualization system, such as an optical or ultrasound guidance and/or visualization system.

Energy delivery member 46 is generally provided as a structure having a smaller diameter cross-section that that of insertion member 44, providing access to smaller passages or allowing penetration of obstructions. Energy delivery member 46 is configured such that a distal end may be positioned in proximity to and/or contacting a tissue surface such as mucous membranes and nasal turbinates or polyps, bony protuberances, undesired tissue growths or accumulations or blockages within cavities such as nasal passages. In one embodiment, illustrated in Fig. 6, energy delivery member 46 comprises a generally rigid or semi-rigid wire-like structure capable of conveying, and delivering, high frequency acoustic energy (e.g., ultrasound energy, including high intensity ultrasound (HIU) and high energy focused ultrasound (HIFU) by contact with tissue or obstructive material along its length and/or at a distal end of the delivery member. In another embodiment, illustrated in Fig. 7, the energy delivery member may comprise a flexible, steerable structure 48. The energy delivery member may be extendible and/or retractable with respect to handle 42 and/or insertion member 44 to provide desired positioning of the energy delivery member in contact with obstructions and/or tissues for delivery of high frequency acoustic energy.

A distal end of the energy delivery member 46, 48 is preferably navigable to target tissue sites or target blocked sites within cavities, such as nasal passages and blocked ostea, where it can be activated to provide mechanical and cavitational effects that promote recanalization of obstructed passages. The energy delivery member 46, 48 may be extendible and retractable with respect to the insertion member 44, as shown in the simplified operational sequence schematically illustrated in Figs. 8A and 8B. Energy delivery member 46 is generally constructed from an acoustically transmissive material and may have different stiffness properties along its length, providing steerability. The energy delivery member may have a pre-formed shape, illustrated as an angled shape as shown in Fig. 6, or may be flexible or conformable, as illustrated schematically in Fig. 7. Energy delivery members having different pre-formed shapes may also be used. The energy delivery member may be constructed from metallic materials, such as Nitinol. Wire-like energy delivery members may be covered with another acoustically transmissive material, such as a resilient rubber-like material, that may function to delivery high frequency acoustic energy uniformly or in a focused fashion.

A proximal end of energy delivery member 46, 48 is connected or connectable to a generally high frequency acoustic energy generator (e.g., an ultrasound transducer) or acoustic energy coupling, providing delivery of high frequency acoustic energy (e.g., ultrasound) along the length of and to a distal end of the energy delivery member 46, 48. In some embodiments, a guidance member, such as a guidewire-type member, may be provided and operated separately from an energy delivery member. In this embodiment, the guidance member may be advanced and positioned at a desired operating site, and the energy delivery member may then be advanced over, along-side or through the guidance member for positioning and activation at the desired operating site.

High frequency acoustic energy delivered through energy delivery members 46, 48 generally has a frequency of greater than about 20 kHz and less than about 25 MHz; in some embodiments from about 20 kHz to about 100 kHz; in some embodiments from about 20 kHz to about 50 kHz; in other embodiments greater than about 100 kHz and less than about 1 MHz; in other embodiments from about 500 kHz to about 15 MHz; and in yet other embodiments greater than about 500 kHz and less than about 5 MHz. The acoustic energy applied through the energy delivery member may be at a generally high intensity of from about 1mW/ cm^2 to about 5 W/ cm^2; in some embodiments from about 50 mW/ cm^2 to about 3 W/ cm^2; in other embodiments from about 5-100 mW/ cm^2; in yet other embodiments from about 0.1-1.5 W/ cm^2. In other embodiments, the acoustic energy applied through the energy delivery member may be a generally high intensity ultrasound of greater than about 1 W/cm^2 and less than about 25 kW/ cm^2. In some embodiments, the acoustic energy applied through energy delivery member has an acoustic intensity from about 10 to about 1,000 W/cm^2; in some embodiments from about 1,000 to about 15,000 W/cm^2; and in yet other embodiments from about 3,000 to about 10,000 W/cm^2. The generally high intensity ultrasound may be sufficient to ablate tissue and/or cellular structures or debris, or it may be at a sub-ablation intensity that is sufficient to disrupt tissue and/or cellular structures or debris but not ablate. The pulse duration and repetition rate may be adjusted and matched to the frequency and intensity of acoustic energy pulses to achieve the desired effect.

The high frequency acoustic energy may be selectably activated on a continuous basis, or ultrasound energy may be applied, through the energy delivery member, on an intermittent basis, and the frequency and/or acoustic intensity may be adjustable and selectable by the operator. Operation of the ultrasound transducer at duty cycles of less than about 80% is generally preferred; in some embodiments at duty cycles of less than 50%; and in yet other embodiments at duty cycles of less than about 30%. Enhancement and/or coupling agents promoting and/or targeting acoustic energy deposition may be

used and may be provided to a target site through the insertion member and/or the energy delivery member.

Handle 42, insertion wand 44 and energy delivery member 46, 48 may be provided in an integrated, single piece construction, or they may be provided as separate components that are detachable from one another. Handle 42 may be provided as a single- or multiple-use component. Insertion wands and/or energy delivery members may similarly be provided as integrated components or may be provided separately from one another, with appropriate interfaces for operation. Multiple configurations of insertion wands and/or energy delivery members may be provided for operation on common or multiple handles, with appropriate insertion wands and/or energy delivery members being selectable by a user depending on the circumstances of use. Insertion and energy delivery members may be provided as single- or multiple-use components, although they may generally be provided as sterile, disposable components that are mountable on a reusable handle. Device 40 may incorporate all of the components required for operation, or it may interface with a separate console, or control unit (not shown), that provides electrical power, liquid for infusion or aerosol delivery, operating control features, displays, and the like.

In some embodiments, devices of the type illustrated in Figs. 6 and 7 are capable of selectively delivering high frequency acoustic energy, a liquid stream, aerosol particles and/or aerosol droplets, simultaneously or sequentially, in one or a plurality of delivery modes: continuous flow; intermittent flow; or high frequency pulsatile flow. Liquid, aerosol particles and/or aerosol droplets may be delivered from a common discharge port sequentially and intermittently, or from multiple, dedicated discharge ports, simultaneously or sequentially, and on a continuous or intermittent basis. Aspiration may be provided, additionally or alternatively, through one or more ports in the insertion wand and/or energy delivery member. Insertion wand 24 may be provided with one or more channels, or lumens, for delivery of liquids, aerosol particles, and/or aerosol droplets to a desired intranasal site, and for removal of material from the site by means of aspiration.

Controls may be provided on the device handle, as illustrated, or on an accessory device or module, allowing a user to select acoustic frequency and/or intensity, liquid and/or aerosol delivery modes, aspiration modes, visualization modalities, or the like. Controls may also be provided allowing a user to select from among various modes of operation or various pre-determined or pre-set operating modes. Devices of the present invention may thus be operated, manually or by selectable automated operation, in a single mode or multiple modes.

In one embodiment, schematically illustrated in Figs. 8A-8E, a device 40 such as illustrated in Figs. 6 and 7 may be operated in a high frequency acoustic energy deposition mode in which the insertion wand 44 and energy delivery member 46 are positioned in a nasal cavity, as shown in Fig. 8A. Energy delivery member 46 may be extended, as shown in Fig. 8B, to contacting mucus and/or debris forming an obstruction within nasal passageways. Acoustic energy delivery may be activated at a preset or selectable acoustic energy frequency and/or intensity to heat and/or cavitate and/or ablate mucus and/or debris forming the obstruction, as shown schematically in Fig. 8C. In another embodiment, the energy delivery member may be positioned to contact tissue and activated at preset or selectable acoustic energy frequency and/or intensity levels to heat and/or cavitate and/or ablate selected tissue sites. Delivery of the high frequency and/or high intensity acoustic energy may be accompanied by infusion of liquids and/or aerosol particles or droplets. Extraneous materials may be aspirated during and/or following delivery of high frequency and/or high intensity acoustic energy and infusion of liquids and/or aerosol particles, as shown schematically in Fig. 8D to remove obstructions and clear passageways, as illustrated schematically in Fig. 8E.

In some embodiments, multiple pulsating liquid rinse and aerosol delivery options, as well as multiple energy deposition options, may be programmed in the device, with various operating programs being predetermined and selectable by the user. In alternative embodiments, a user may select pulsating liquid rinse, aerosol delivery and/or energy deposition options by means of multiple selectable actuators. In any of these embodiments, multiple and selectable modes may be implemented, whereby programmed or selectable levels of liquid and/or aerosol flow or volume, aerosol particle and/or droplet size, aerosol particle and/or droplet density, pulsation frequency, temperature, acoustic energy frequency, intensity, pulse repetition rate, duty cycle, and the like, may be selectable by the user.

Devices of the present invention may be provided as an integral unit that may be used once or several times and then disposed of, or an integral device may be reused on a frequent basis. Alternatively, as described above, the handle and nostril interface member or delivery wand may be detachable from one another. In a multiple component embodiment, the handle may be provided as a reusable component, while the detachable nostril interface member or delivery wand may be provided as a reusable or disposable element. Single or multiple use “covers” may be provided for covering the nostril interface member or the delivery wand, providing replaceable sterile, or antiseptic surfaces for contacting the nose and nasal passages. Such covers may be flexible and resilient and generally match the outer configuration of the nostril interface member

and/or delivery wand, so that they may be mounted on and closely fitted over the interface member or delivery wand for multiple uses/multiple users, and the like.

The methods and devices may be used for treating common colds, nasal congestion and allergic rhinitis, as well as sinusitis and other nasal conditions. They may be used for treatment of acute or chronic conditions, and they may be used on a frequent basis to cleanse intranasal passages, thereby reducing bacterial infection and the incidence of nasal congestion, colds, sinusitis and the like.

It will be appreciated that the methods and systems of the present invention may be embodied in a variety of different forms, and that the specific embodiments shown in the figures and described herein are presented with the understanding that the present disclosure is considered exemplary of the principles of the invention, and is not intended to limit the invention to the illustrations and description provided herein. Accordingly, the descriptions provided above are considered as being illustrative and exemplary of specific structures, aspects and features within the broad scope of the present invention and not as limiting the scope of the invention.

We claim:

1. A method for treating a target site at a tissue, within a body cavity or at an obstruction, comprising delivering at least one of fluids and aerosols to the target site using a pulsatile flow characterized by pulsations having a frequency of greater than 1500 Hz.

2. The method of claim 1, wherein the frequency of pulsations is in the ultrasound frequency range.

3. The method of claims 1 or 2, comprising delivering an aerosol to the target site at the pulsatile flow having a frequency of greater than 1500 Hz and at a pressure of more than about 10mmHg and less than about 160mmHg.

4. The method of any of claims 1-3, wherein the pulsatile flow is characterized by pulsations having at least two different frequencies.

5. The method of claim 4, wherein the at least two different frequencies include a frequency in a sub-ultrasound frequency range and a frequency in the ultrasound frequency range.

6. The method of claim 1, comprising delivering at least one of fluids and aerosols using pulsatile flows characterized by multiple modes of administration, with each mode of administration being characterized by pulsations having a different frequency, intensity, pulse duration, pulse repetition rate and/or duty cycle.

7. The method of any of claims 1-6, additionally comprising delivering at least one additional treatment modality in combination with the delivery of at least one of fluids and aerosols, wherein the additional treatment modality includes administration of an antimicrobial or therapeutic agent, application of electromagnetic radiation, application of an electrical field, application of radio frequency energy, application of laser energy, and/or application of microwave energy.

8. The method of any of claims 1-7, additionally comprising delivering high frequency acoustic energy to the target site in combination with the delivery of at least one of fluids and aerosols.

9. The method of claim 1, wherein the fluid or the aerosol comprises at least one of the following components: saline, an antibiotic agent, a drug, hypertonic saline, lactated ringer's solution, dead sea salt solution, antibiotics, midazolam, fentanyl, insulin, growth hormone, one or more growth factors, gentamycin, clindamycin, ciprofloxacin, cefuroxime, levofloxocin, tobramycin, ampicillin+sulbactam, amphotericin, tobramycin/amphotericin combinations, cefotaxime, ceftriaxone, fluticasone, budesonide, mometasone furoate monohydrate, xylitol, eucalyptus, tea tree oil, capsaicin, grapefruit seed extract and oil of wintergreen.

10. The method of any of claims 1-9, additionally comprising aspirating material from the target site during and/or following delivery of the fluid and/or aerosol.

11. A system for delivery of at least one of fluids and aerosols to a tissue surface, cavity or obstruction, adapted to deliver a pulsatile flow of fluids and/or aerosols at a pulsation frequency of greater than 1500 Hz.

12. The system of claim 11, wherein the system comprises a handheld device having a handle and at least one fluid and/or aerosol discharge port.

13. The system of claim 11 or 12, adapted to deliver a pulsatile flow of fluids and/or aerosols at a pulsation frequency of greater than 1500 Hz and at a pressure of more than about 10mmHg and less than about 160mmHg.

14. The system of any of claims 11-13, adapted to deliver a pulsatile flow of fluids and/or aerosols at alternating pulsation frequencies corresponding to frequencies that promote entry of the fluid and/or aerosol into a tissue surface, cavity or obstruction; reduce biofilms; degrade pathological tissue; improve circulation; and/or modulate local immune responses.

15. The system of any of claims 11-14, additionally comprising at least one aspiration port.

16. The system of claim 15, additionally comprising a system for collection of material removed by aspiration.

17. A system for delivery of high frequency acoustic energy to a target site at a tissue or at an obstruction within a body cavity or lumen, comprising an insertion wand sized and configured for insertion into a body cavity or lumen and an acoustic energy delivery member associated with the insertion wand for conveying high frequency acoustic energy.

18. The system of claim 17, wherein the acoustic energy delivery member is adapted to deliver high intensity ultrasound (HIU) or high intensity focused ultrasound (HIFU) to the target site.

19. The system of claim 17 or 18, wherein the acoustic energy delivery member is conical and is positioned at a distal portion of the delivery wand.

20. The system of claim 17 or 18, wherein the acoustic energy delivery member is a wire-like member and is extendible from the delivery wand.

21. The system of claim 17 or 18, wherein the acoustic energy delivery member is a flexible, expandable member adapted to be expanded at the target site upon by filling with an acoustically transmissive material.

22. The system of claim 21, wherein the flexible, expandable member is fluid permeable.

23. The system of any of claims 17-21, wherein the insertion wand is sized and configured for insertion into at least a portion of a nasal cavity.

24. The system of any of claims 17-21, wherein the insertion wand is sized and configured for insertion into at least a portion of the vascular system, the respiratory system, the gastrointestinal system, the reproductive system, or a natural orifice.

25. The system of any of claims 17-24, wherein the insertion wand additionally comprises a fluid or aerosol delivery port.

26. The system of any of claims 17-25, wherein the insertion wand additionally comprises an aspiration port.

27. The system of claim 26, wherein the device additionally incorporates a system for collection of material removed by aspiration.

28. The system of any of claims 17-27, wherein the system is adapted to provide delivery of one or more sequences of acoustic energy, with each sequence providing delivery of acoustic energy at a different frequency, intensity, pulse duration, pulse repetition rate, or duty cycle.

29. The system of claim 28, wherein multiple sequences are programmed in the device as multiple programmed protocols selectable by a user.

30. The system of any of claims 17-29, additionally comprising a visualization system for visualization of the target site.

31. The system of any of claims 17-30, additionally comprising an illumination system for illumination of a target site.

32. The system of any of claims 17-31, additionally comprising an endoscopic port for delivery of tools or agents to the target site.

33. A method for delivering high frequency acoustic energy to a target site at a tissue or at an obstruction within a body cavity or lumen, comprising positioning an insertion wand in proximity to the target site, positioning an acoustic energy delivery member associated with the insertion wand at the target site, and conveying high frequency acoustic energy to the target site through the acoustic energy delivery member.

34. The method of claim 33, wherein the high frequency acoustic energy is high intensity ultrasound (HIU) or high intensity focused ultrasound (HIFU).

35. The method of claim 33 or 34, wherein the acoustic energy delivery member is a wire-like member that is extendible from the delivery wand and positioning the acoustic energy delivery member at the target site includes extending the wire-like member from the delivery wand.

36. The method of claim 33 or 34, wherein the acoustic energy delivery member is a flexible, expandable member and positioning the acoustic energy delivery member at the target site includes expanding the flexible, expandable member at the target site by filling it with an acoustically transmissive material.

37. The method of claim 33, additionally comprising delivering at least one of a fluid and an aerosol to the target site using a pulsatile flow characterized by pulsations having a frequency of greater than 1500 Hz.

38. The method of any of claims 33-37, additionally comprising aspirating material from the target site.

39. The method of any of claims 33-38, comprising delivering one or more sequences of acoustic energy, with each sequence providing delivery of acoustic energy at a different frequency, intensity, pulse duration, pulse repetition rate, or duty cycle.

AMENDED CLAIMS
received by the International Bureau onreceived by the International Bureau on
14 April 2010 (14.04.2010)

1. A method for treating a target site at a tissue, within a body cavity or at an obstruction, comprising delivering at least one of fluids and aerosols to the target site using a pulsatile flow characterized by pulsations having a frequency of greater than 1500 Hz.

2. The method of claim 1, wherein the frequency of pulsations is in the ultrasound frequency range.

3. The method of claims 1 or 2, comprising delivering an aerosol to the target site at the pulsatile flow having a frequency of greater than 1500 Hz and at a pressure of more than about 10mmHg and less than about 160mmHg.

4. The method of claims 1 or 2, wherein the pulsatile flow is characterized by pulsations having at least two different frequencies.

5. The method of claim 4, wherein the at least two different frequencies include a frequency in a sub-ultrasound frequency range and a frequency in the ultrasound frequency range.

6. The method of claim 1, comprising delivering at least one of fluids and aerosols using pulsatile flows characterized by multiple modes of administration, with each mode of administration being characterized by pulsations having a different frequency, intensity, pulse duration, pulse repetition rate and/or duty cycle.

7. The method of claims 1 or 2 or 5 or 6, additionally comprising delivering at least one additional treatment modality in combination with the delivery of at least one of fluids and aerosols, wherein the additional treatment modality includes administration of an antimicrobial or therapeutic agent, application of electromagnetic radiation, application of an electrical field, application of radio frequency energy, application of laser energy, and/or application of microwave energy.

8. The method of claims 1or 2 or 5 or 6, additionally comprising delivering high frequency acoustic energy to the target site in combination with the delivery of at least one of fluids and aerosols.

9. The method of claim 1, wherein the fluid or the aerosol comprises at least one of the following components: saline, an antibiotic agent, a drug, hypertonic saline, lactated ringer's solution, dead sea salt solution, antibiotics, midazolam, fentanyl, insulin, growth hormone, one or more growth factors, gentamycin, clindamycin, ciprofloxacin, cefuroxime, levofloxocin, tobramycin, ampicillin+sulbactam, amphotericin, tobramycin/amphotericin combinations, cefotaxime, ceftriaxone, fluticasone, budesonide, mometasone furoate monohydrate, xylitol, eucalyptus, tea tree oil, capsaicin, grapefruit seed extract and oil of wintergreen.

10. The method of claims 1or 2 or 5 or 6, additionally comprising aspirating material from the target site during and/or following delivery of the fluid and/or aerosol.

11. A system for delivery of at least one of fluids and aerosols to a tissue surface, cavity or obstruction, adapted to deliver a pulsatile flow of fluids and/or aerosols at a pulsation frequency of greater than 1500 Hz.

12. The system of claim 11, wherein the system comprises a handheld device having a handle and at least one fluid and/or aerosol discharge port.

13. The system of claim 11 or 12, adapted to deliver a pulsatile flow of fluids and/or aerosols at a pulsation frequency of greater than 1500 Hz and at a pressure of more than about 10mmHg and less than about 160mmHg.

14. The system of claims 11 or 12, adapted to deliver a pulsatile flow of fluids and/or aerosols at alternating pulsation frequencies corresponding to frequencies that promote entry of the fluid and/or aerosol into a tissue surface, cavity or obstruction; reduce biofilms; degrade pathological tissue; improve circulation; and/or modulate local immune responses.

15. The system of claims 14, additionally comprising at least one aspiration port.

16. The system of claim 15, additionally comprising a system for collection of material removed by aspiration.

17. A system for delivery of high frequency acoustic energy to a target site at a tissue or at an obstruction within a body cavity or lumen, comprising an insertion wand sized and configured for insertion into a body cavity or lumen and an acoustic energy delivery member associated with the insertion wand for conveying high frequency acoustic energy.

18. The system of claim 17, wherein the acoustic energy delivery member is adapted to deliver high intensity ultrasound (HIU) or high intensity focused ultrasound (HIFU) to the target site.

19. The system of claim 17 or 18, wherein the acoustic energy delivery member is conical and is positioned at a distal portion of the delivery wand.

20. The system of claim 17 or 18, wherein the acoustic energy delivery member is a wire-like member and is extendible from the delivery wand.

21. The system of claim 17 or 18, wherein the acoustic energy delivery member is a flexible, expandable member adapted to be expanded at the target site upon by filling with an acoustically transmissive material.

22. The system of claim 21, wherein the flexible, expandable member is fluid permeable.

23. The system of claim 18, wherein the insertion wand is sized and configured for insertion into at least a portion of a nasal cavity.

24. The system of claim 18, wherein the insertion wand is sized and configured for insertion into at least a portion of the vascular system, the respiratory system, the gastrointestinal system, the reproductive system, or a natural orifice.

25. The system of claim 23 or 24, wherein the insertion wand additionally comprises a fluid or aerosol delivery port.

26. The system of claim 23 or 24, wherein the insertion wand additionally comprises an aspiration port.

27. The system of claim 26, wherein the device additionally incorporates a system for collection of material removed by aspiration.

28. The system of claim 18, wherein the system is adapted to provide delivery of one or more sequences of acoustic energy, with each sequence providing delivery of acoustic energy at a different frequency, intensity, pulse duration, pulse repetition rate, or duty cycle.

29. The system of claim 28, wherein multiple sequences are programmed in the device as multiple programmed protocols selectable by a user.

30. The system of claim 18, additionally comprising a visualization system for visualization of the target site.

31. The system of claim 18, additionally comprising an illumination system for illumination of a target site.

32. The system of any of claim 18, additionally comprising an endoscopic port for delivery of tools or agents to the target site.

33. A method for delivering high frequency acoustic energy to a target site at a tissue or at an obstruction within a body cavity or lumen, comprising positioning an insertion wand in proximity to the target site, positioning an acoustic energy delivery member associated with the insertion wand at the target site, and conveying high frequency acoustic energy to the target site through the acoustic energy delivery member.

34. The method of claim 33, wherein the high frequency acoustic energy is high intensity ultrasound (HIU) or high intensity focused ultrasound (HIFU).

35. The method of claim 33 or 34, wherein the acoustic energy delivery member is a wire-like member that is extendible from the delivery wand and positioning the acoustic energy delivery member at the target site includes extending the wire-like member from the delivery wand.

36. The method of claim 33 or 34, wherein the acoustic energy delivery member is a flexible, expandable member and positioning the acoustic energy delivery member at the target site includes expanding the flexible, expandable member at the target site by filling it with an acoustically transmissive material.

37. The method of claim 33, additionally comprising delivering at least one of a fluid and an aerosol to the target site using a pulsatile flow characterized by pulsations having a frequency of greater than 1500 Hz.

38. The method of claim 33 or 34, additionally comprising aspirating material from the target site.

39. The method of claim 33 or 34, comprising delivering one or more sequences of acoustic energy, with each sequence providing delivery of acoustic energy at a different frequency, intensity, pulse duration, pulse repetition rate, or duty cycle.

STATEMENT ACCOMPANYING ARTICLE 19 CLAIM AMENDMENTS

Accompanying this letter, Applicants' attorneys/agent submits claim amendments under Article 19 as Replacement Sheets 27-31.

Claims 1-3, 5, 6, 9, 11-13, 16-22, 27, 29, and 33-37 are unchanged. Claims 4, 7, 8, 10, 14, 25, 26, 38 and 39 are replaced by amended claims bearing the same numbers. These claims have been amended to comply with Rule 6.4(a). Claims 15, 23, 24, 28 and 30-32 are replaced by amended claims bearing the same numbers. These claims have been amended to delete multiple dependencies.

It is the understanding of the attorney/agent that no fee is required for this request. **Transmitted herewith are 6 pages, including this letter.**

FIG. 1

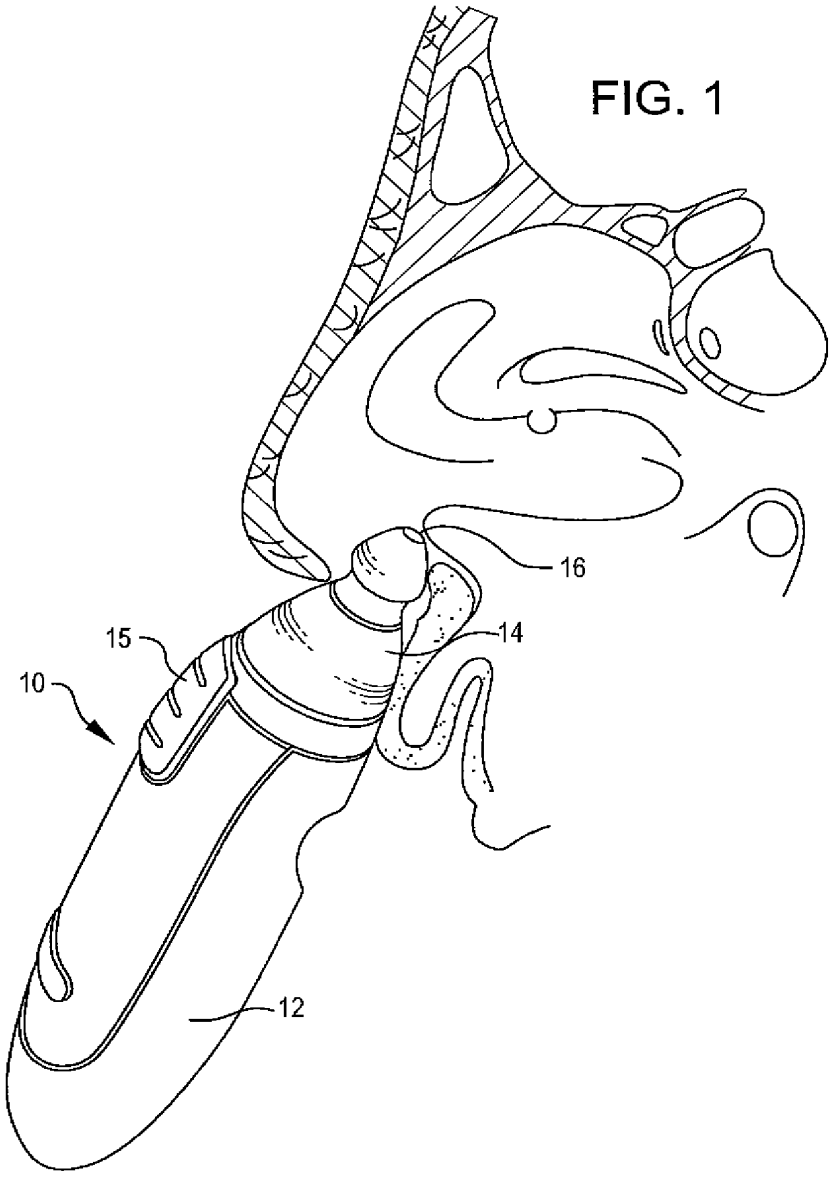


FIG. 2A

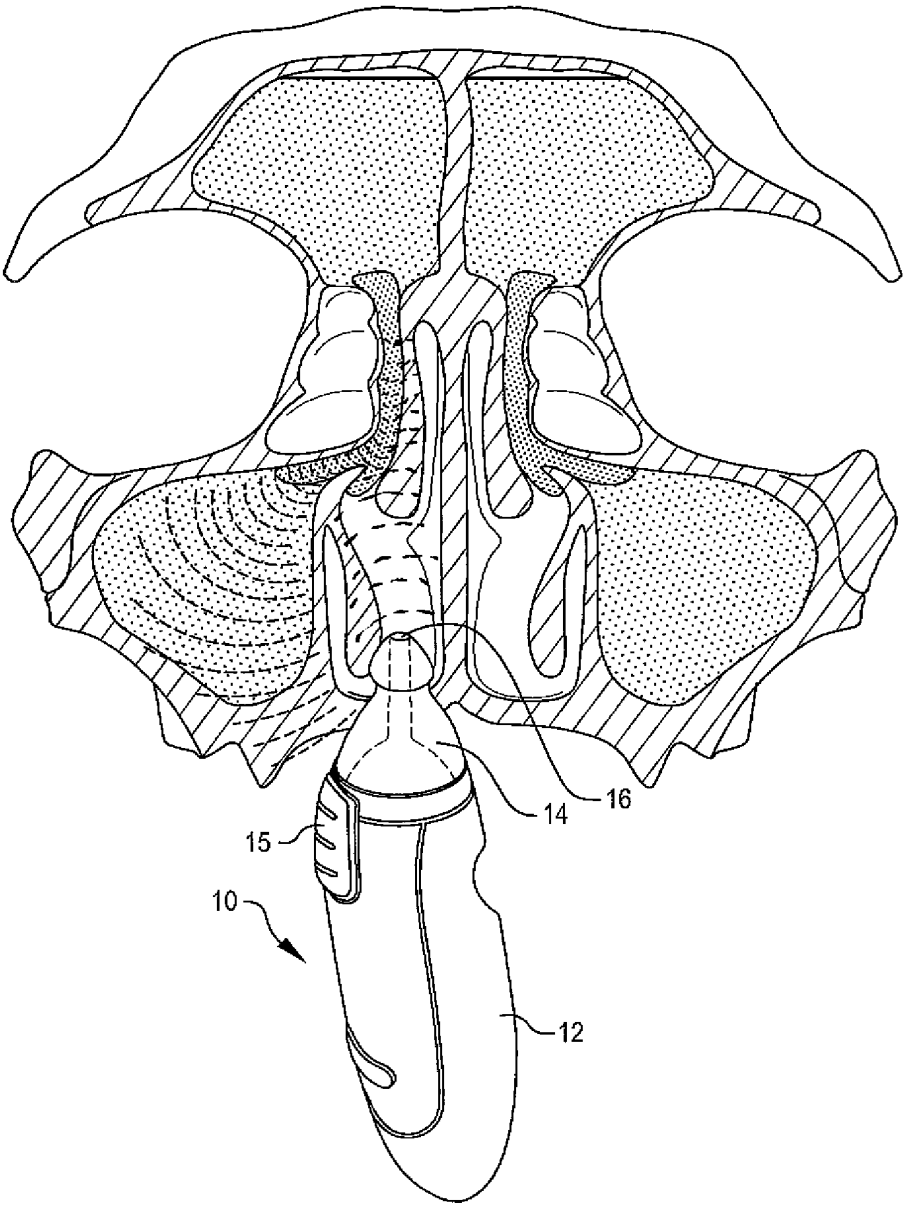


FIG. 2B

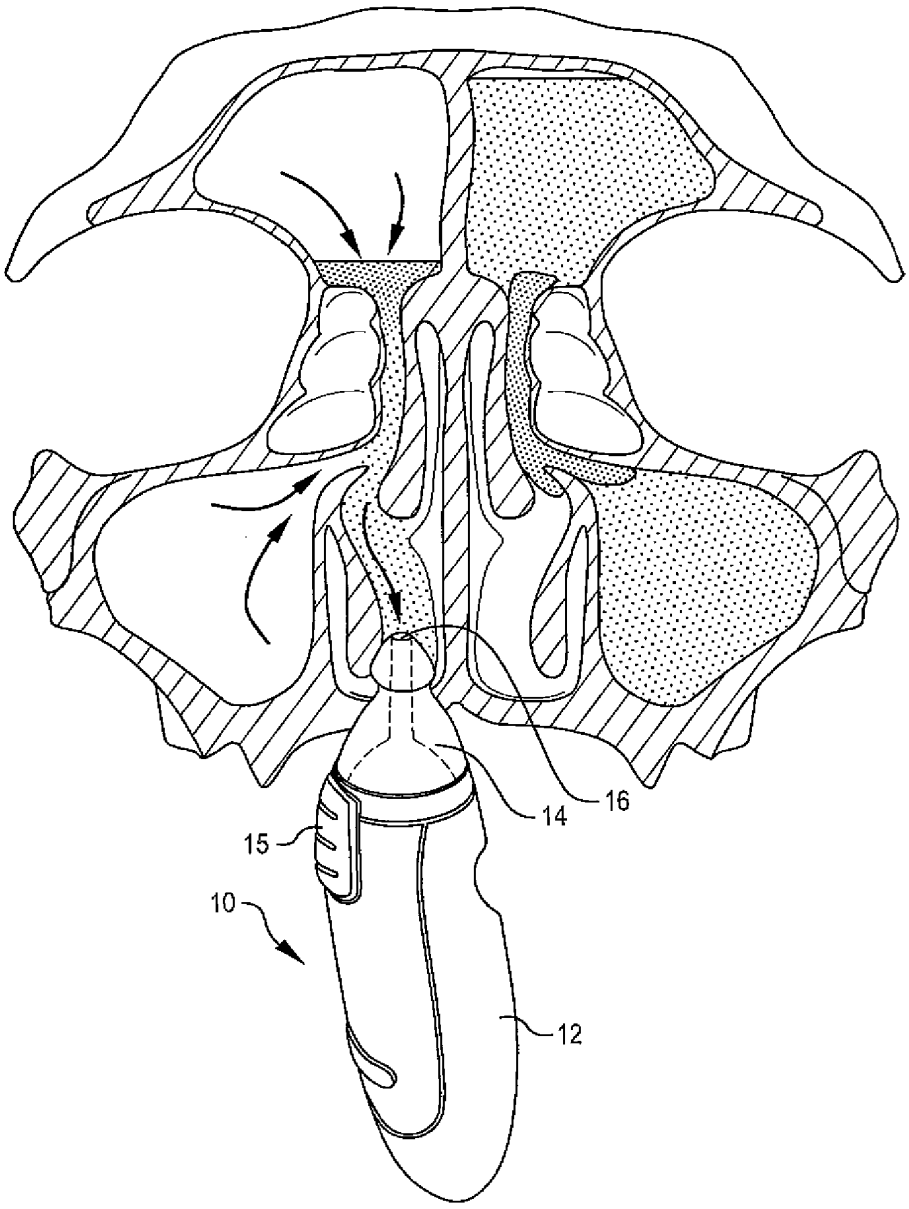


FIG. 3

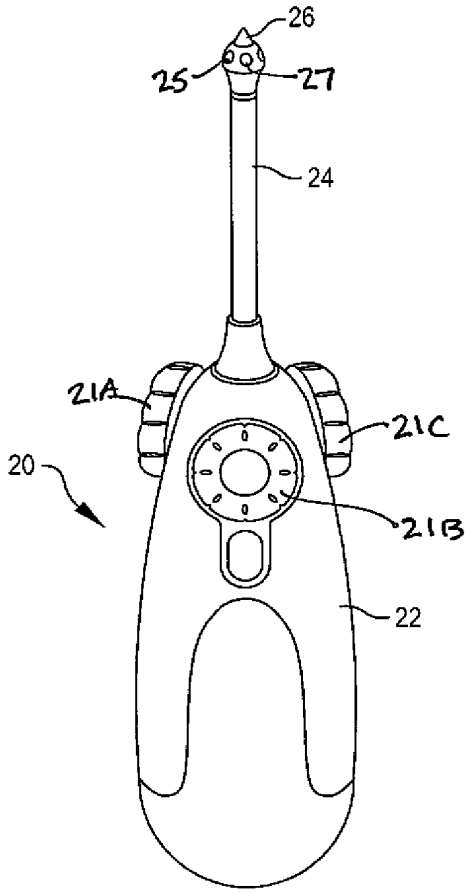


FIG. 4

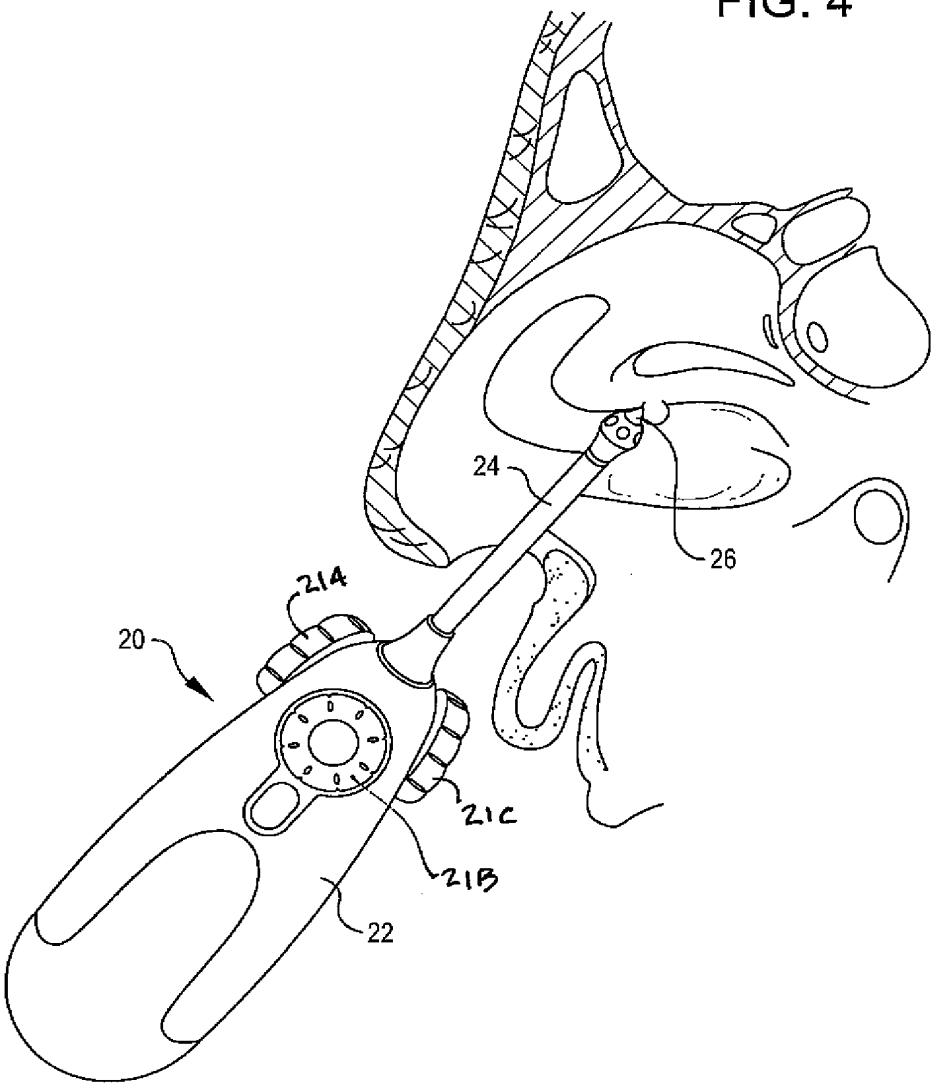


FIG. 5

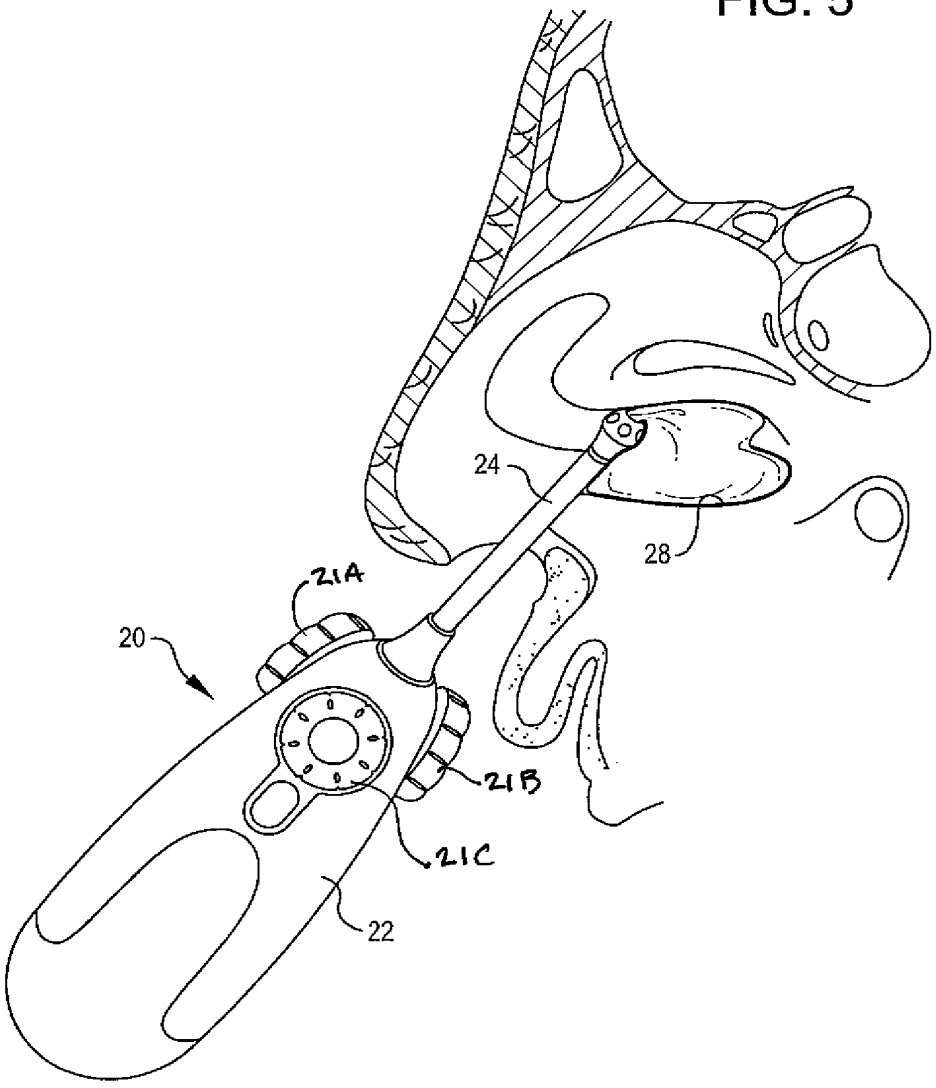
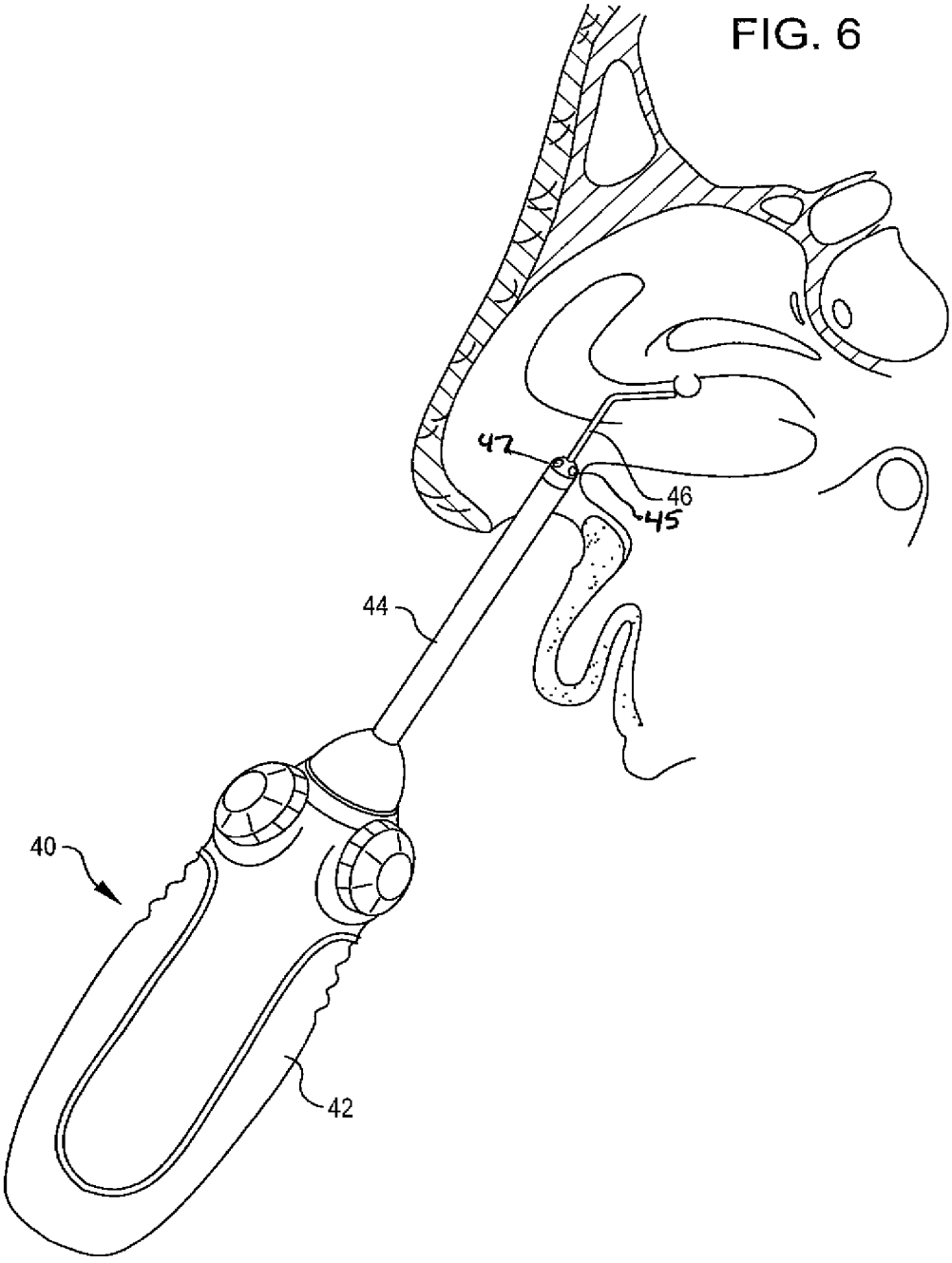


FIG. 6



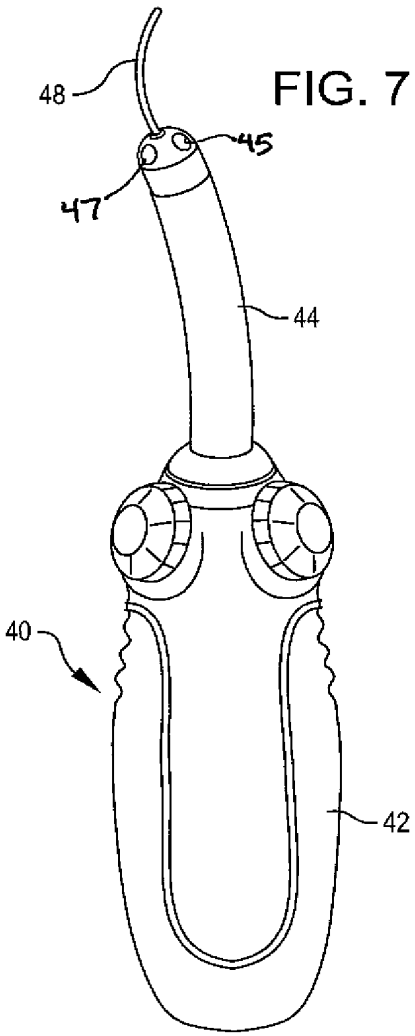


FIG. 7

FIG. 8A

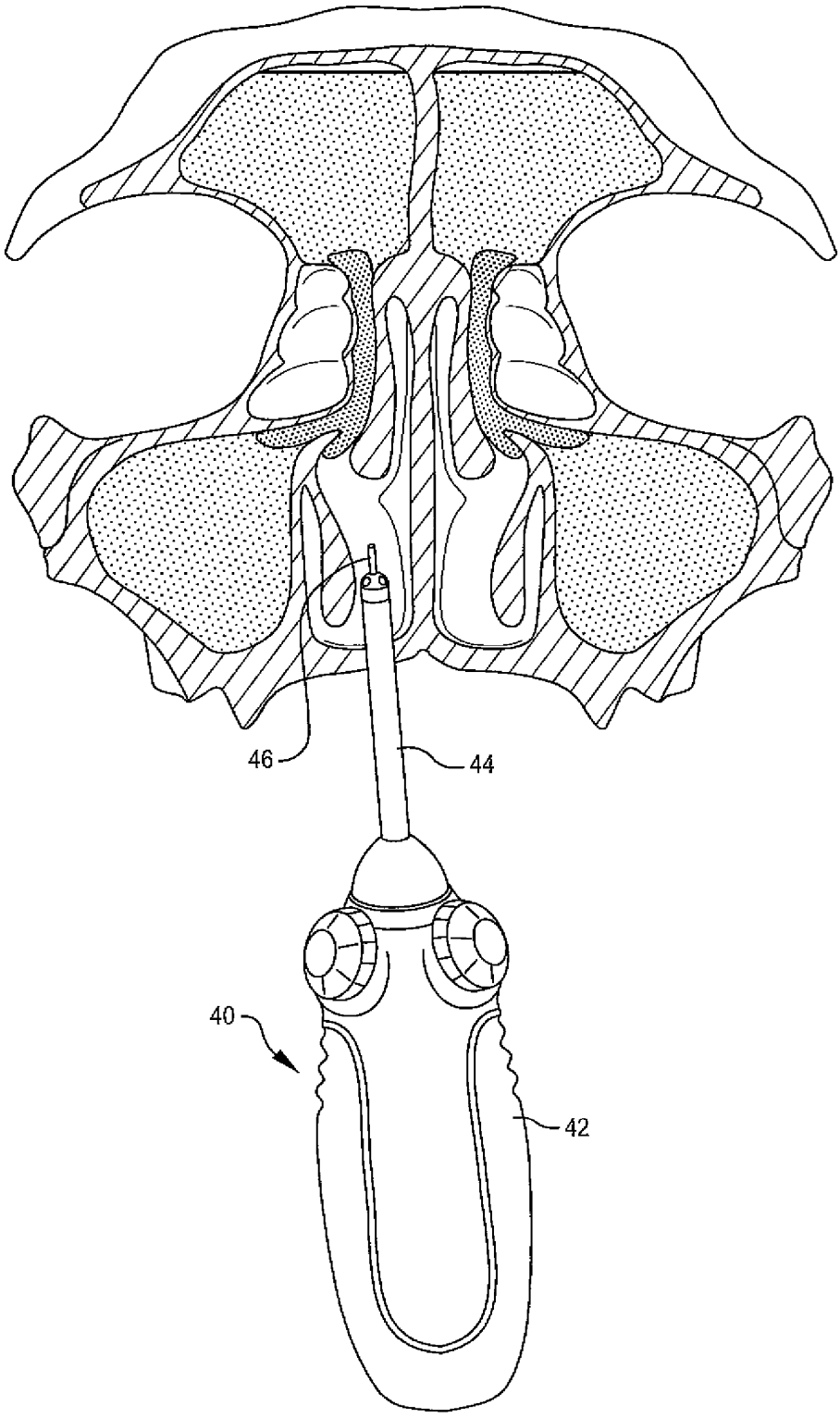


FIG. 8B

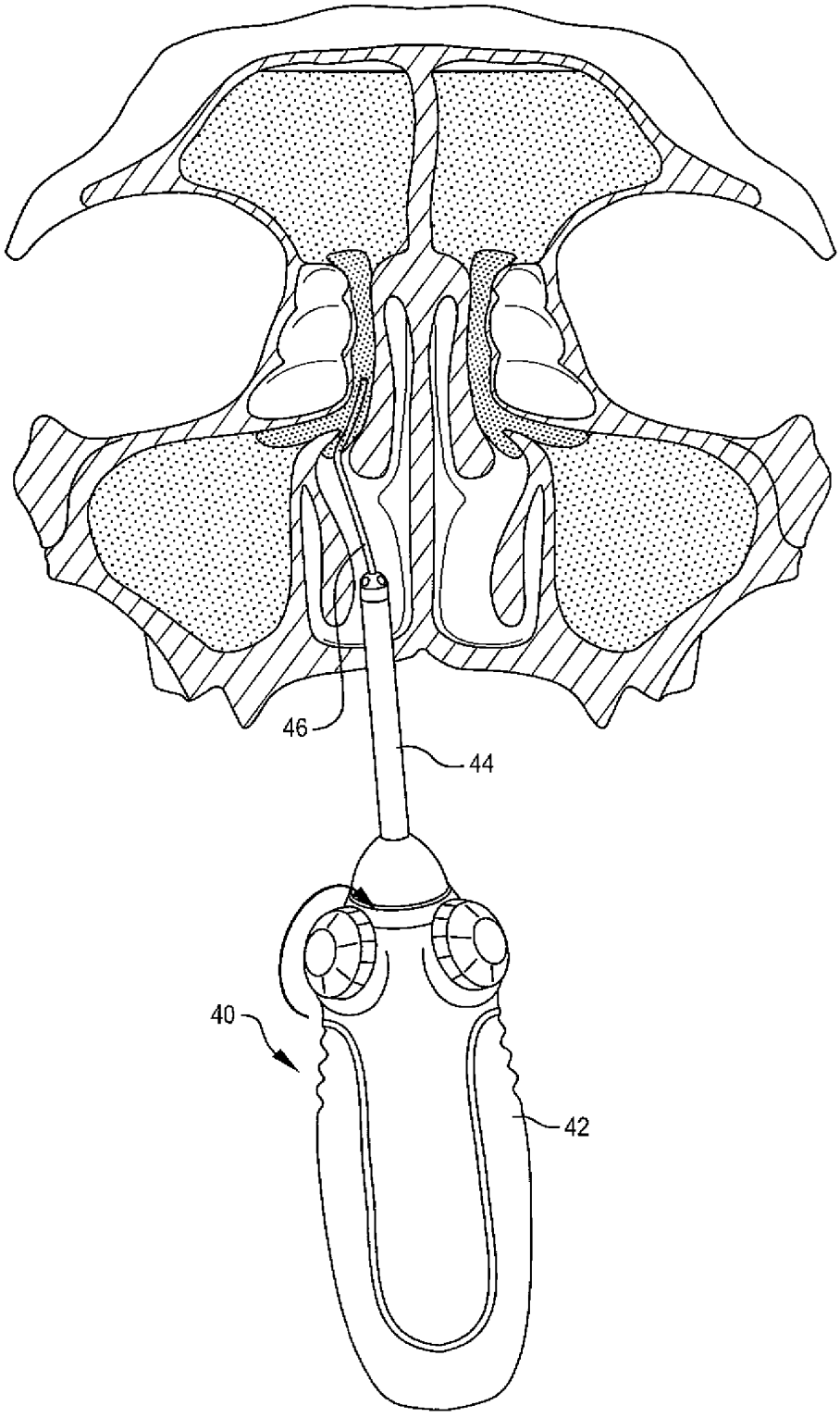


FIG. 8C

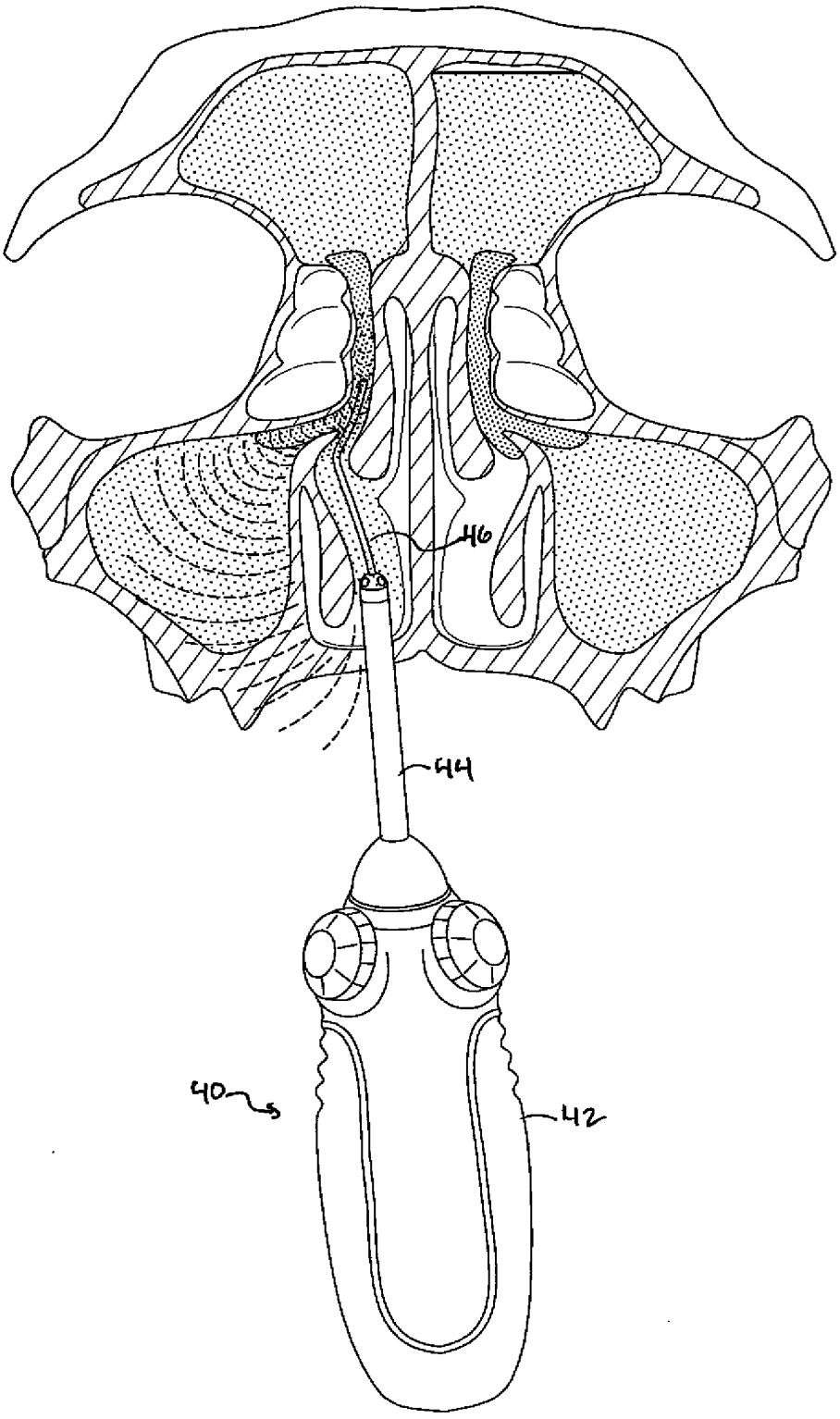


FIG. 8D

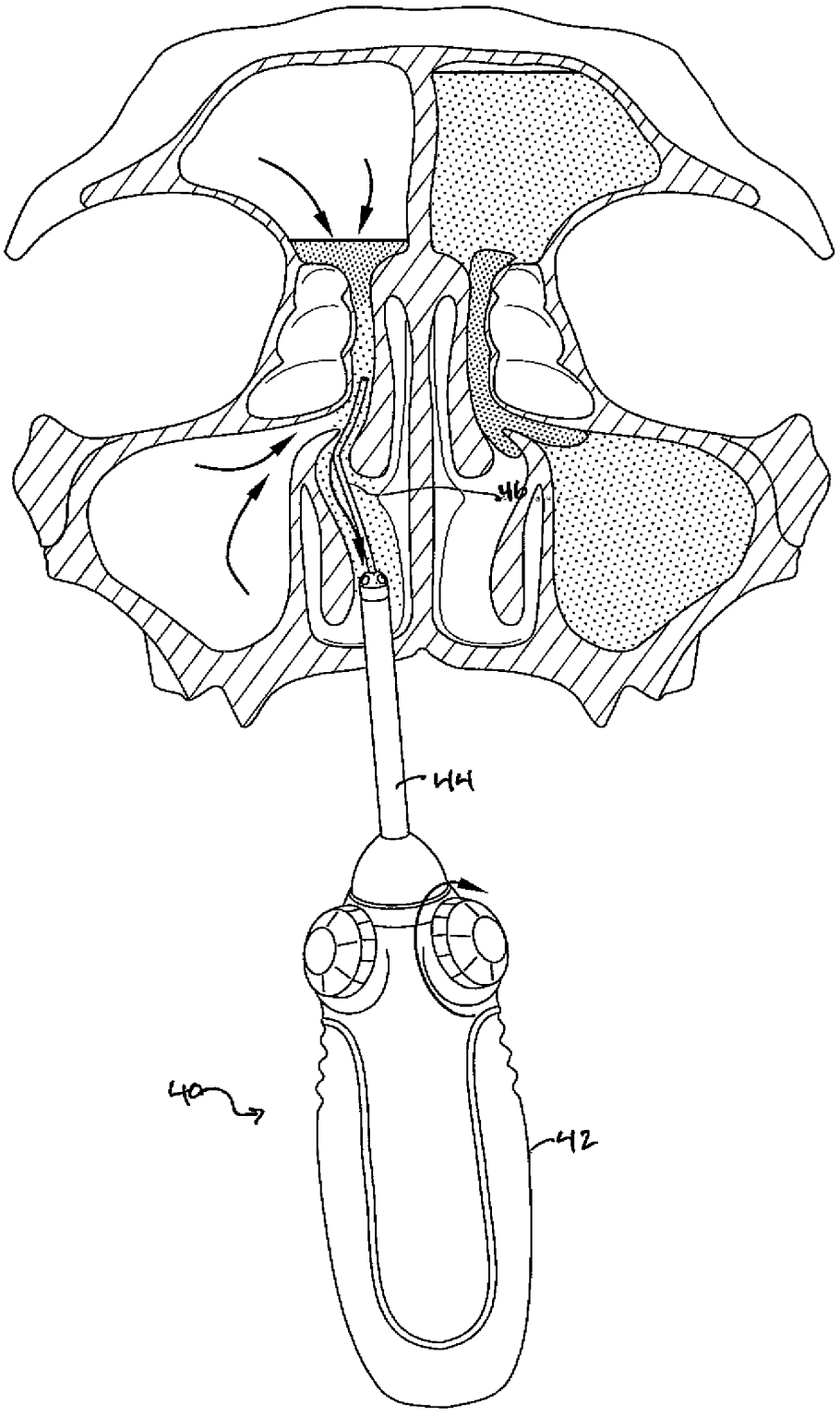
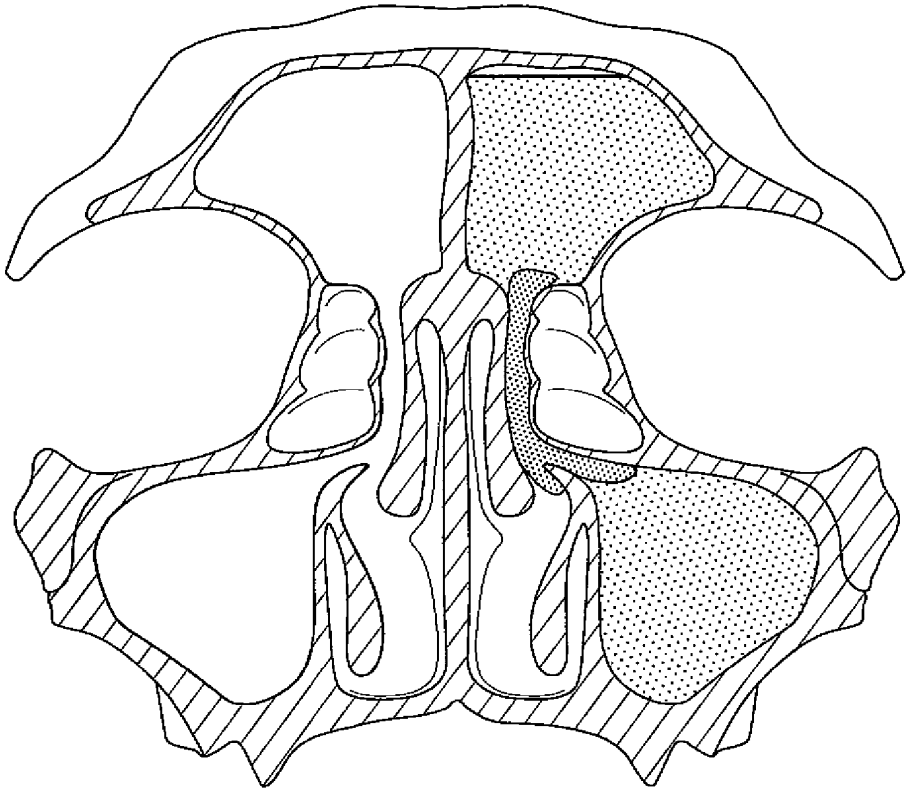


FIG. 8E



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/068309

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/32 (2010.01)
USPC - 604/22
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 17/32 (2010.01)
USPC - 604/22; 606/169

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)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2002/0138036 A1 (BABAEV) 26 September 2002 (26.09.2002) entire document	1, 2, 9, 11, 12, 17, 33, 37 --- 3, 6, 13, 18-22, 34-36
Y	US 2008/0154183 A1 (BAKER et al) 26 June 2008 (26.06.2008) entire document	3, 13
Y	US 2003/0092667 A1 (TACHIBANA et al) 15 May 2003 (15.05.2003) entire document	6, 18, 34
Y	US 2004/0204728 A1 (HAEFNER) 14 October 2004 (14.10.2004) entire document	19
Y	US 2004/0024402 A1 (NITA) 05 February 2004 (05.02.2004) entire document	20, 35
Y	US 2002/0019627 A1 (MAGUIRE et al) 14 February 2002 (14.02.2002) entire document	21, 22, 36

☐ 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
11 February 2010	26 FEB 2010
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)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/068309

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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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.: 4, 5, 7, 8, 10, 14-16, 23-32, 38, 39
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 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.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 December 2012 (20.12.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/174161 A1

(51) International Patent Classification:
A61B 18/12 (2006.01) *A61B 18/00* (2006.01)
A61B 18/14 (2006.01) *A61B 18/16* (2006.01)

(21) International Application Number:
PCT/US2012/042316

(22) International Filing Date:
13 June 2012 (13.06.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/496,930 14 June 2011 (14.06.2011) US
61/603,864 27 February 2012 (27.02.2012) US

(71) Applicant *(for all designated States except US)*: **AERIN MEDICAL, INC.** [US/US]; 319 Trenton Way, Menlo Park, CA 94025 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **WOLF, Scott, J.** [US/US]; 319 Trenton Way, Menlo Park, CA 94025 (US). **FRAZIER, Andrew** [US/US]; 517 Fern Ridge Court, Sunnyvale, CA 94087 (US).

(74) Agent: **ALTMAN, Daniel, E.**; Knobbe Martens Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, CA 92614 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

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

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: DEVICES FOR TREATING NASAL AIRWAYS

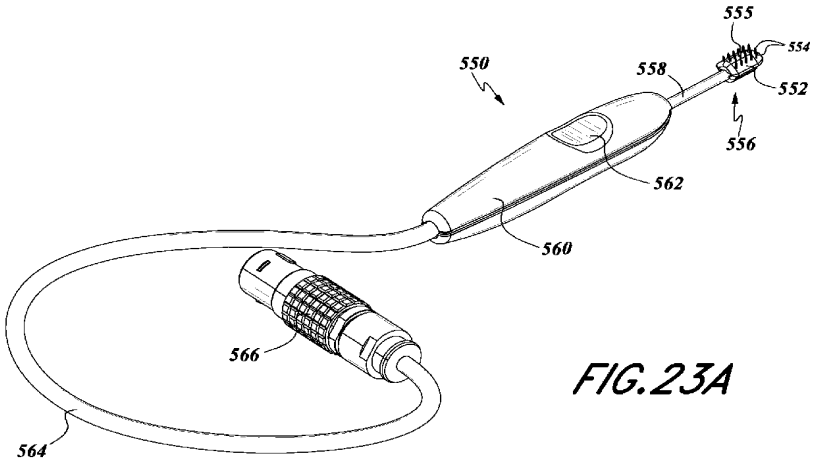


FIG. 23A

(57) **Abstract**: 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.

WO 2012/174161 A1

DEVICES FOR TREATING NASAL AIRWAYS

Cross-Reference to Related Applications

[0001] This application claims the benefit of U.S. Provisional Application No. 61/496,930, filed on June 14, 2011 and U.S. Provisional Application No. 61/603,864, filed on February 27, 2012. The disclosures of each of the priority applications are hereby incorporated by reference in their entireties herein.

Background

Field of the Invention

[0002] This application relates generally to the field of medical devices and treatments, and in particular to systems, devices and methods for treating structures within the nose and upper airway to reduce resistance to airflow and/or change the pressure level in the nose, nasal cavities, and/or and nasal passages and improve airflow and/or the feeling and effects of nasal obstruction during breathing.

Description of the Related Art

[0003] During respiration, the anatomy, shape, tissue composition and properties of the human airway produce airflow resistance. The nose is responsible for almost two thirds of this resistance. Most of this resistance occurs in the anterior part of the nose, known as the internal nasal valve, which acts as a flow-limiter. The external nasal valve structure also causes resistance to nasal airflow. Effective physiological normal respiration occurs at a range of airflow resistance. However, excessive resistance to airflow can result in abnormalities of respiration which can significantly affect a patient's quality of life.

[0004] Inadequate nasal airflow can result from a number of conditions causing an inadequate cross sectional area of the nasal airway in the absence of any collapse or movement of the cartilages and soft tissues of the nasal airway. These include deviation of the nasal septum, turbinate enlargement, mucosal swelling, excessive mucous production, nasal valve insufficiency, narrowing or collapse. No matter what the cause of inadequate nasal airflow, the nasal valve area is still the site of significant nasal

airflow resistance. In more extreme cases, nasal valve dysfunction is a prevalent medical condition. Nasal valve collapse is often due to weakness or malformation of cartilage structures of the nose.

[0005] Cartilage is an avascular tissue composed of a specialized matrix of collagens, proteoglycans, and non-collagen proteins, in which chondrocytes constitute the unique cellular component. Cartilage is specialized connective tissue found in various locations throughout the body. Cartilage basically consists of two components: water and a framework of structural macromolecules (matrix) that give the tissue its form and function. The matrix is highly organized and composed of collagens, proteoglycans and noncollagenous proteins.

[0006] The interaction of water and the macromolecular framework give the tissue its mechanical properties and thus its function. Up to 65% - 80% of the wet weight of cartilage consists of water, the rest is matrix, mainly collagens and proteoglycans. Chondrocytes are specialized cells that produce and maintain the extracellular matrix (ECM) of cartilage. The ECM makes up most of the tissue, where dense, covalently-linked heterotypic collagen fibrils interact with a number of other specialized matrix components.

[0007] The nasal valve was originally described by Mink in 1903. It is divided into external and internal portions. The external nasal valve is the external nasal opening formed by the columella at the base of the septum, the nasal floor, and the nasal rim (the lower region of the nasal wall, also known as the caudal border of the lower lateral cartilage). The nasalis muscle dilates the external nasal valve portion during inspiration.

[0008] The internal nasal valve, which accounts for the larger part of the nasal resistance, is located in the area of transition between the skin and respiratory epithelium. The internal nasal valve area is formed by the nasal septum, the caudal border of the upper lateral cartilage (ULC), the head of the inferior turbinate, and the pyriform aperture and the tissues that surround it.

[0009] The angle formed between the caudal border of the ULC and the nasal septum is normally between about 10°-15° as illustrated in FIG. 1. The internal nasal

valve is usually the narrowest part of the nasal airway and is responsible for more than two thirds of the resistance produced by the nose.

[0010] In 1894, Franke performed nasal-flow experiments in models and cadavers and found that whirl formation occurred near the head of the turbinate during calm breathing. Mink in 1903 developed this concept further in 1920, suggesting that the greatest area of resistance was in the limen nasi or the union of the lobular cartilage and ULCs. In 1940, Uddstromer found that 70% of the resistance of the nose was produced in the internal nasal valve area and the remaining 30% was due to the nasal fossa. Van Dishoeck further investigated the mechanisms of the nasal valve in 1942, and in 1970, Bridger and Proctor wrote about a "flow-limiting segment" that included the limen nasi and the pyriform aperture. In 1972, Bachman and Legler found the pyriform aperture to have the smallest cross-sectional area of the nasal airway. In 1983, Haight and Cole continued the study of Bridger and Proctor and demonstrated that the maximal nasal resistance was localized near the pyriform aperture and depended on engorgement of the head of the inferior turbinate. A description of the nasal valve and its functions are more fully described in Cole, "The Four Components of the Nasal Valve", American Journal of Rhinology , Vol. 17, No. 2, pp. 107-110 (2003). See also, Cole, "Biophysics of Nasal Air Flow: A Review", American Journal of Rhinology , Vol. 14, No. 4, pp. 245-249 (2000).

[0011] Because ventilation involves pressure changes, the nasal airways must be stable both at rest and under the negative pressures created during quiet and forced inspiration. Proper airflow through the nasal airway depends on satisfactory structural stability (and/or resistance to conformational change resulting from pressure changes) of the upper and lower lateral cartilages and soft tissues respectively. Satisfactory skeletal stability is present when the upper and lower lateral cartilages have sufficient structural stability to resist conformational changes resulting from air pressure changes. When either the skeletal or the soft tissue component is congenitally deficient or has been compromised by surgery or trauma, the patient experiences a conformation change of the valves during inspiration, with resultant change in the airflow and/or pressure in the nasal airway. Normally, the upper lateral cartilages move, change shape, partially collapse and/or change nasal airway pressure with all ventilatory flow rates. Thus, even normal nasal valves are affected by respiration. However, a patient with dynamic nasal valve

dysfunction may have a nasal airway walls that inadequately resist the pressure changes and restrict airflow even during normal nasal breathing.

[0012] Inadequate nasal valve structural strength, stiffness or conformation can be a consequence of previous surgery, trauma, aging, or primary weakness of the upper lateral cartilage and is often symptomatic and debilitating. As many as 13% of the patients with chronic nasal obstruction have some degree of nasal valve collapse. Of these patients, 88% have unilateral collapse.

[0013] Poor nasal breathing and/or nasal congestion has profound effects on a person's health and quality of life, which can be measured by validated questionnaires such as the NOSE score, as described in Stewart MG, Witsell DL, Smith TL, Weaver EM, Yueh B, Hannley MT. Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale. Otolaryngol Head Neck Surg 2004;130:157-63.

[0014] Causes of inadequate nasal airflow and the structure of the nasal valve inadequacy can be clinically detected by direct visualization (preferably with minimal disturbance so as not to alter the structure by visualizing) or endoscopic examination. Alternatively, CT, MRI, ultrasound or other non-invasive imaging technologies may be employed. One method of evaluating the potential improvement in nasal airflow from widening the nasal valve area nasal valve obstruction is the cottle test, which involves gently pulling the skin of a patient's cheek laterally away from the nose with two fingers, thereby opening the internal nasal valve.

[0015] Existing methods of correcting nasal valve inadequacy include surgically repositioning the upper lateral cartilage or adding structural grafts to support the lateral wall of the nose. Surgical structural enhancement of the valve can include the use of cartilage grafts and grafts made from a number of materials. The most frequent methods surgically correct internal nasal valve collapse and involve the use of spreader grafts placed between the upper lateral cartilage and septum. Alternately, stents, spreaders or other devices may be implanted to reposition the ULC. Invasive surgical and implant solutions carry substantial risk and discomfort.

[0016] External (non-implanted) nasal dilators which are placed temporarily and removed by the patient are also available. Such external devices are possibly placed

on the outside surface of the nose such as the "Breathe Right" strips as shown for example in U.S. Patents 5,533,499 to Johnson or similar devices taught by US Patent 7,114,495 to Lockwood. Other devices may be temporarily placed in the nasal cavity (but not implanted in the nose), such as those taught in U.S. Pat. No. 7,055,523 to Brown, and U.S. Pat. No. 6,978,781 to Jordan. However, such devices can be uncomfortable, unsightly, and require the patient to remove and replace the device on a periodic basis. These devices can cause skin irritation.

[0017] Poor nasal airflow can also occur in people with a structurally normal nasal and/or nasal valve anatomy, as well as a normal nasal passage cross-sectional area. The strength, structure and resistance to collapse of the nasal passage can also be normal in people with poor nasal airflow. People can have poor nasal airflow from other causes, including deviated septum, allergic rhinitis, non-allergic rhinitis, turbinate hyperplasia, nasal tip ptosis, and nasal polyposis. Whatever the cause, the tissues of the nasal valves are intimately involved in nasal airflow and nasal airflow inadequacy. Thus, there remains an unmet need in the art for non-invasive and minimally invasive methods and devices to improve nasal airflow.

Summary

[0018] Embodiments of the present application are directed to devices, systems and methods for treating nasal airways. Such embodiments may be utilized to improve breathing by decreasing airflow resistance or perceived airflow resistance in the nasal airways. For example, the devices, systems and methods described herein may be utilized to reshape, remodel, strengthen, or change the properties of the tissues of the nose, including, but not limited to the skin, muscle, mucosa, submucosa and cartilage in the area of the nasal valves.

[0019] According to one aspect, a device for treating a patient's nasal airway is provided. In one embodiment, the device comprises an energy delivery element sized to be inserted into a nose or to be delivered external to a nose. The energy delivery element is configured to deliver energy to tissues within the nose and to reshape a region of the nose to a new conformation.

[0020] According to one embodiment, a device for treating a patient's nasal airway comprises an elongate shaft having a proximal end and a distal end. The device

further comprises a handle at the proximal end of the elongate shaft. The device also comprises a treatment element at the distal end of the elongate shaft. The treatment element is sized to be inserted into the nasal airway or to be delivered external to a nose. The treatment element is configured to reshape a region of the nose to a new conformation and comprises an electrode configured to deliver radiofrequency (RF) energy to the nasal tissue.

[0021] Other embodiments of devices for treating a patient's nasal airway include devices that apply other types of treatment. For example, a treatment device may apply energy in the form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser. The treatment device may also be configured to inject a polymerizing liquid or to deliver a cauterizing agent to nasal tissue. Other embodiments are described below.

[0022] The devices described herein may be configured to be positioned internally within the nose, external to the nose, or both. Certain embodiments are configured to be delivered into one nostril, and other embodiments are configured to be delivered into both nostrils. In some embodiments the device may comprise a reshaping element having a shape configured to alter a conformation of a region of the nose to a new conformation. For embodiments utilizing an energy delivery element, the reshaping element may be a separate element from the energy delivery element, or the energy delivery element and the reshaping element may be part of the same element. The energy delivery element and/or reshaping element in one embodiment may have a convex shape to create a concavity in nasal tissue.

[0023] In embodiments utilizing energy delivery, a handle may be provided comprising a button or other input control to active 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, external to the nose or both. For example, when using 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 surfaces are positioned on opposite sides of nasal tissue.

[0024] The device of one energy delivery embodiment may comprise an adaptor configured to be connected to an energy source, such as an RF energy source. The device may also comprise a control system configured to control the characteristics of energy applied to tissue. A thermocouple or other sensor may be provided to measure a temperature near tissue or other tissue or device parameter.

[0025] 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 an energy source, such as an RF energy source. Another component may be a control system for controlling the energy source and/or treatment device. In another embodiment, the device or 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 device that may be used pre-treatment to determine the optimal device and positioning and/or other parameters for using the device to be treat to the nasal airway.

[0026] According to another aspect, a method of treating a patient's nasal airway is provided. In one embodiment, the method comprises alerting a structure, shape or conformation of one or more nasal structures in an area of a nasal valve by applying a treatment sufficient to modify, by reshaping, tissue at or adjacent to the nasal valve.

[0027] According to one embodiment, a method of treating a patient's nasal airway comprises positioning a treatment element within the nasal airway adjacent to nasal tissue to be treated. The treatment element comprises one or more electrodes, such as described above and in further detail below. The method further comprises deforming the nasal tissue into a desired shape by pressing a surface of the treatment element against the nasal tissue to be treated. The method further comprises delivering radiofrequency (RF) energy to the one or more electrodes to locally heat the nasal tissue, wherein delivering RF energy while deforming the nasal tissue causes the nasal tissue to change shape. The method also comprises removing the treatment element from the nasal airway.

[0028] The methods, devices and systems described herein may be used to reshape tissue without a surgical incision or implant. In certain embodiments, the

reshaping of tissue may be accomplished by ablating tissue. In other embodiments, the reshaping of tissue is accomplished without ablation of tissue. In one embodiment, a treatment element is positioned within a nasal passageway. The treatment element may be used to simultaneously mechanically alter the shape of the internal or external nasal valve and apply treatment to tissue of the nose. The treatment applied may comprise modifying a nasal structure in a manner that increases a volumetric airflow rate of air flowing from an exterior of the patient's body into the patient's nasopharynx without changing a shape of an internal nasal valve, said modifying comprising modifying a mechanical property of at least one nasal valve. A positioning element may be used to determine a desired position of a treatment element before the treatment element is delivered to the nasal tissue.

[0029] The treatment may involve delivering energy in the form selected from the group selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser. The nasal tissue to be treated may be cooled prior to, during or after delivering energy. Delivering energy may comprise measuring a temperature near nasal tissue to be treated, and adjusting a level of energy delivered to the tissue. When RF or other types of energy are used, the energy may be delivered to at least one of the nasal valve, tissue near the nasal valve, or the upper lateral cartilage of tissue. For example, RF energy or other energy may be delivered to the one or more electrodes for about 15 seconds to about 1 minute. RF energy or other energy may be delivered to heat an area of tissue to a temperature of about 50°C to about 70°C.

[0030] Other methods not utilizing energy delivery include injecting a polymerizing liquid, delivering a cauterizing agent, or other embodiments described below.

[0031] Energy or treatment may be delivered for a sufficient period of time or in a sufficient quantity to cause a desired effect. For example, the treatment may cause stress relaxation in the nasal tissue without weakening the tissue. The treatment may also be applied to injure a tissue to be re-shaped.

Brief Description of Drawings

[0032] Certain preferred embodiments and modifications thereof will become apparent to those skilled in the art from the detailed description below having reference to the figures that follow.

[0033] FIG. 1 depicts an illustration of bone and cartilage structures of a human nose.

[0034] FIG. 2A illustrates a cross-sectional view illustrating tissues and structures of a human nose.

[0035] FIG. 2B shows a detailed cross-sectional view illustrating a detailed section of the structures of FIG. 2A.

[0036] FIG. 2C illustrates a view of the nostrils illustrating tissues and structures of a human nose.

[0037] FIG. 3 depicts a schematic illustration of a nasal valve re-shaping treatment device.

[0038] FIG. 4A is a perspective illustration of an embodiment of a treatment element shape.

[0039] FIG. 4B depicts a perspective illustration of another embodiment of a treatment element shape.

[0040] FIG. 4C shows a perspective illustration of another embodiment of a treatment element shape.

[0041] FIG. 4D depicts a cross-sectional view of a treatment device comprising a plurality of microneedles puncturing tissue in order to apply treatment at a desired tissue depth.

[0042] FIG. 5A illustrates one embodiment of a clamp-type nasal valve treatment device.

[0043] FIG. 5B illustrates another embodiment of a clamp-type nasal valve treatment device.

[0044] FIG. 6 depicts a partially-transparent perspective view showing a stent implanted in a nose.

[0045] FIG. 7 depicts a perspective view illustrating an energy delivery balloon being inserted into a nose.

[0046] FIGS. 8A-8J depict embodiments of various electrode arrangements for applying energy to the nasal valve area.

[0047] FIGS. 9A and 9B illustrate embodiments of devices for applying energy to the nasal valve area using a monopolar electrode.

[0048] FIGS. 10A and 10B illustrate an embodiment of a device for applying energy to the nasal valve area using a monopolar electrode and an external mold.

[0049] FIGS. 11A and 11B illustrate embodiments of devices for applying energy to the nasal valve area using electrode(s) and a counter-traction element.

[0050] FIGS. 12A and 12B illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously.

[0051] FIGS. 13A-13E illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously, having a mold or counter-traction element for engaging the nose externally.

[0052] FIGS. 14A and 14B illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously, having separate external molds.

[0053] FIGS. 15A-15C illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously, having separate counter-traction elements.

[0054] FIG. 16 shows an embodiment of a system comprising a device for applying energy to the nasal valve area with an external electrode and a separate internal mold.

[0055] FIGS. 17A and 17B illustrate an embodiment of a device for applying energy to the nasal valve area comprising an external electrode and an internal mold.

[0056] FIG. 18 shows an embodiment of a device for applying energy to the nasal valve area comprising an array of non-penetrating electrodes.

[0057] FIGS. 19A and 19B illustrate an embodiment of a device for applying energy to the nasal valve area configured for use in only one nostril.

[0058] FIGS. 20A and 20B illustrate an embodiment of a device for applying energy to the nasal valve area configured for use in either nostril.

[0059] FIGS. 21A and 21B illustrate an embodiment of a device for applying energy to the nasal valve area having a symmetrical shape.

[0060] FIGS. 22A-22G illustrate an embodiment of a device for applying energy to the nasal valve area using a monopolar electrode.

[0061] FIGS. 23A-23G illustrate an embodiment of a device for applying energy to the nasal valve area using an array of needle electrodes.

[0062] FIG. 24A depicts a cross-section of tissue at the nasal valve.

[0063] FIG. 24B depicts heat effects of RF treatment of tissue at the nasal valve.

[0064] FIGS. 25A and 25B illustrate embodiments of devices for applying energy to the nasal valve area incorporating cooling systems.

[0065] FIG. 26 shows an embodiment of a device for applying energy to the nasal valve area incorporating a heat pipe.

[0066] FIG. 27 depicts an embodiment of a device for applying energy to the nasal valve area incorporating heat pipes.

[0067] FIGS. 28A-28E depict embodiments of differential cooling mechanisms.

[0068] FIG. 29 shows an embodiment of a system comprising a device for applying energy to the nasal valve area with electrode needles and a separate cooling mechanism.

[0069] FIG. 30A-30D shows an embodiment of a method for applying energy to the nasal valve area using.

Detailed Description

[0070] The following disclosure provides embodiments of systems and methods for improving breathing by decreasing airflow resistance or perceived airflow resistance at or near a site of an internal or external nasal valve. Such embodiments may include methods and devices for reshaping, remodeling, strengthening, or changing the properties of the tissues of the nose, including, but not limited to the skin, muscle, mucosa, submucosa, and cartilage in the area of the nasal valves.

[0071] While, in some instances, nasal dysfunction can lead to poor airflow, nasal breathing can also be improved in people with normal breathing and/or normal nasal anatomy by decreasing nasal airflow resistance in the nasal valve and associated nasal anatomy. Remodeling or changing the structure of the nasal valve can improve nasal airflow in people with inadequate nasal airflow resulting from causes other than nasal valve dysfunction, such as deviated septum, enlarged turbinates, mucosal swelling, and/or mucous production. The methods and devices described above are generally invasive methods or unsightly devices that a person with normal breathing and/or anatomy may not necessarily be inclined to use or undergo. Thus, there remains an unmet need in the art for non-invasive and minimally invasive methods and devices to decrease nasal airflow resistance or perceived nasal airflow resistance and/or to improve nasal airflow or perceived nasal airflow and the resulting symptoms or sequella of poor nasal airflow including but not limited to snoring, sleep disordered breathing, perceived nasal congestion and poor quality of life through the change of structures within the nose that form the passageways for airflow. Methods and devices described herein may be used to treat nasal airways without the need for more invasive procedures (e.g., ablation, surgery).

[0072] Nasal breathing can be improved in people with normal breathing and/or normal nasal anatomy by decreasing nasal airflow resistance or perceived nasal airflow resistance in the nasal valve and associated nasal anatomy. Restructuring the shape, conformation, angle, strength, and cross sectional area of the nasal valve may

improve nasal airflow. Changing the nasal valve can be performed alone or together with other procedures (e.g., surgical procedures), such as those described above. Such methods and devices can lead to improved nasal airflow, increased volume of nasal airflow in patients with normal or reduced nasal airflow.

[0073] The internal nasal valve area is the narrowest portion of the nasal passage and thus functions as the primary regulator of airflow and resistance. The cross-sectional area of the internal nasal valve area is normally about 55-83 mm^2. As described by the Poiseuille law, airflow through the nose is proportional to the fourth power of the radius of the narrowest portion of the nasal passageway. Thus, changes as small as 1 mm in the size of the nasal valve have an exponential effect on airflow and resistance through the nasal cavity and the entire respiratory system.

[0074] Figs. 1 and 2A-C illustrate anatomical elements of a human nose. The lower lateral cartilage (LLC) includes an external component referred to as the lateral crus and an internal component referred to as the medial crus. The medial crus and septal nasal cartilage create a nasal septum that separates the left and right nostrils. Upper lateral cartilage lies between the lower lateral cartilages and the nasal bone. The left ULC is separated from the right ULC by the septal cartilage extending down the bridge of the nose. The opposing edges of the LLC and ULC may move relative to one another. Disposed between the opposing edges is an accessory nasal cartilage. The septal nasal cartilage and the ULC form an angle (Θ) called the nasal valve angle.

[0075] Fig. 2B illustrates a detailed cross-section of a segment of nose tissue in the area of the intersection of the ULC and the LLC. As shown in the detailed view of FIG. 2A, both inner and outer surfaces of the nasal cartilage are covered with soft tissue including mucosa, sub-mucosa and skin.

[0076] Fig. 2C illustrates a view of the nose as seen from the nostrils. Fig. 2 depicts the nasal valve 1 shown between the septum 2 and the Upper Lateral Cartilage 3. Fig. 2A also depicts the position of the turbinate 4.

[0077] The internal nasal valve area of the nasal airway passage can be visualized prior to and/or during any treatment by any suitable method, including but not limited to direct visualization, endoscopic visualization, visualization by the use of a

speculum, transillumination, ultrasound, MRI, x-ray or any other method. In some embodiments, treatments of the nasal valve area as described herein may be performed in conjunction with or following another procedure (e.g., a surgical procedure such as surgically repairing a deviated septum). In such embodiments, the nasal valve area may be visualized and accessed during surgery. In some embodiments, it may be desirable to visualize the internal nasal valve with minimum disturbance, so as to avoid incorrect assessments due to altering the shape of the nasal valve during visualization. In some embodiments, visualization elements may be incorporated into or combined with treatment devices configured for treating internal and/or external nasal valves.

[0078] Airflow through the nasal passage can be measured prior to and/or during any treatment by any suitable method, including, but not limited to, a nasal cannula connected to a pressure measurement system, rhinomanometry, and rhino-hygrometer. Nasal airflow and resistance can also be evaluated by subjective evaluation before and after a manipulation to increase the cross-sectional area of the nasal passage, such as the Cottle maneuver. In some embodiments, it may be desirable to measure nasal airflow and/or resistance prior to, during and/or after a procedure.

[0079] The internal nasal valve area of the nasal airway passage can be accessed through the nares. In some embodiments, one or more devices may be used to pull the tip of the nose caudally and increase the diameter of the nares in order to further facilitate access to the internal nasal valve for treatment. Such devices may include speculum type devices and retractors. In other embodiments, access to the internal nasal valve may also be achieved endoscopically via the nares, or via the mouth and throat. In some embodiments, visualization devices may be incorporated or combined with treatment devices for treating internal and/or external nasal valves. These and any other access and/or visualization devices may be used with any of the methods and devices below.

[0080] During inhalation, airflow through the nostrils creates an inward pressure at the junction between the upper and lower cartilages. This pressure may be expressed as a function of nasal resistance which may be estimated as 10 centimeters of water per one liter per second in congested patients (see "The Four Components of the

Nasal Valve" by Cole, published in the *American Journal of Rhinology*, pages 107-110, 2003). In response to these low pressures relative to the environment outside the nose, a normal, weakened and/or structurally inadequate nasal valve may move inwardly with the junction between the upper and lower cartilages acting as a hinge point for the inward deflection. Furthermore, a small increase in area through which air flows can greatly decrease the pressure differential in these structures resulting in less inward movement of the internal nasal valve structures. Increasing the cross sectional area of the nasal valve area thus has the beneficial effects of decreasing nasal airflow resistance and decreasing the amount and likelihood of inward movement of the nasal valve structures during inspiration.

[0081] Some embodiments below provide apparatus and methods for increasing the area of the opening at the nasal valve and/or treating nasal valve insufficiency by modifying the structure and/or structural properties of tissues at or adjacent to the internal and/or external nasal valve. Other embodiments below provide apparatus and methods for treating nasal valve insufficiency and/or increasing the area of the opening at nasal valve by re-shaping structures within and/or adjacent to an internal and/or external nasal valve to achieve a more optimum shape and minimize or remove airflow obstructions. Still other embodiments combine the two approaches of re-shaping and modifying tissue and structures of and adjacent to the internal and/or external nasal valves. Still other embodiments provide apparatus and methods for increasing the area of the opening at the nasal valve and treating nasal obstruction resulting from causes other than nasal valve restriction or insufficiency by improving the structure or function of the nasal valve tissue to increase airflow. Still other embodiments below provide apparatus and methods for decreasing airflow resistance in a structurally normal nasal valve and/or increasing the area of the opening at nasal valve by re-shaping structures within and/or adjacent to an internal and/or external nasal valve to achieve a more optimum shape and minimize or remove airflow obstructions. For example, patients having a normal nasal valve anatomy may still benefit from the devices and treatments described herein, as improvement in the nasal valve structure and/or increasing the area of the opening at the nasal valve may improve breathing problems caused by other conditions. Still other

embodiments provide for structural changes in the nasal cavity and airway that improve the relative positions of the structures of the nasal cavity to improve nasal breathing.

[0082] In some embodiments, airflow restrictions to the internal nasal valve may be the result of a smaller-than-optimal internal nasal valve angle, shown as θ in FIG. 2. An internal nasal valve angle (i.e. the angle formed between the caudal border of the ULC and the nasal septum) of less than the normally optimal range of between about 10°-15° can result in airflow restrictions. Thus, in some embodiments, treatments may be designed to re-shape structures at or adjacent to the internal nasal valve in order to increase the internal nasal valve angle sufficiently that after such treatments, the nasal valve angle falls within the optimal range of 10-15 degrees. In some embodiments, the internal valve angle may also be increased to be greater than 15 degrees.

[0083] In some embodiments, airflow restrictions to the internal nasal valve may be the result of a smaller-than-optimal area of the internal nasal valve. An internal nasal valve with a less than optimal area can result in airflow restrictions. Thus, in some embodiments, treatments may be designed to re-shape structures at or adjacent to the internal nasal valve in order to increase the internal nasal valve angle sufficiently that after such treatments, the area of the nasal valve falls within an optimal range. In some embodiments, increasing the area of the opening at the nasal valve without increasing the angle of the nasal valve may improve airflow. In some embodiments, increasing the angle of the nasal valve without increasing the area of the opening at the nasal valve may improve airflow. In some embodiments, both the opening at the area of the nasal valve and the angle of the nasal valve may be increased to improve airflow.

[0084] In some embodiments, nasal airflow can be increased in the presence of normal nasal valve anatomy and/or normal or enlarged nasal valve angle or area.

[0085] With reference to FIG. 2A, in some embodiments, the internal valve angle θ or area may be increased by mechanically pressing laterally outwards against the internal lateral nasal wall. In some embodiments, this outward pressing may be performed by an inflatable balloon (such as those discussed below with reference to FIGs. 4A - 4B) which may be positioned between the upper portion of the nasal septum 20 and the outer lateral wall 22 and then inflated, pressing against the lateral nasal wall

until the nasal valve angle reaches a desired size. Similarly, other mechanical devices such as spreaders or retractors (such as those discussed below with reference to FIGs. 5A & 5B) or molds may be used. In alternative embodiments, short-term removable implants may be used to re-shape the nasal valve. Some examples of short-term implants may include stents, molds or plugs. In further alternative embodiments, external re-shaping elements, such as adhesive strips or face masks may be used to modify the shape of a nasal valve. In some embodiments, energy application or other treatments as described below may be applied to substantially fix the re-shaped tissue in a desired conformational shape before, during or after applying a mechanical re-shaping force (e.g., with the balloon, mechanical devices, molds, short-term implants, or external re-shaping elements described above or any of the mechanical devices described below).

[0086] In another embodiment, a re-shaping device may be used to expand the diameter of the nasal passage at the site of the internal or external nasal valve. The expansion device can be a balloon, user controlled mechanical device, self expanding mechanical device, fixed shape device or any combination thereof. The expansion can increase the diameter over the normal range in order for the diameter to remain expanded after removal of the device and healing of the tissue.

[0087] In some embodiments, a re-shaping device may be used to conformationally change the structure of the internal or external nasal valve anatomy to allow greater airflow without necessarily expanding the diameter of the nasal passage.

[0088] In some embodiments, a re-shaping or remodeling device can be used to conformationally change the structure of areas of the internal nasal valve other than the nasal valve that causes the cross sectional or three dimensional structure of the nasal airway to assume a shape less restrictive to airflow without widening the nasal valve angle.

[0089] In some embodiments, the tissue of the internal and/or external nasal valve and/or surrounding tissues may be strengthened or otherwise modified to resist a conformational change in response to the negative pressure of inspiration. In some embodiments, this strengthening may be performed by applying treatments selected to change mechanical or structural properties of the treated tissue. In some embodiments,

such treatments may include the application of energy to selected regions of nasal valve and/or surrounding tissues.

[0090] 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, or others. In alternative embodiments, the nasal valve and/or surrounding tissues may be strengthened through the application of cryogenic therapy, or through the injection or application of bulking agents, glues, polymers, collagen and/or other allogenic or autogenic tissues, or growth agents.

[0091] Any one or more of the above energy-application mechanisms may also be used to re-shape, remodel, or change mechanical or physiologic properties of structures of a nasal valve or surrounding tissues. For example, in some embodiments, energy may be applied to a targeted region of tissue adjacent a nasal valve such that the tissue modification results in a tightening, shrinking or enlarging of such targeted tissues resulting in a change of shape. In some such embodiments, re-shaping of a nasal valve section may be achieved by applying energy without necessarily applying a mechanical re-shaping force. For example energy can be used to selectively shrink tissue in specific locations of the nasal airway that will lead to a controlled conformational change.

[0092] In alternative embodiments, strengthening and/or conformation change (i.e., re-shaping) of nasal valve tissue to reduce negative pressure during inspiration may include modification of tissue growth and/or the healing and fibrogenic process. For example, in some embodiments energy may be applied to a targeted tissue in the region of the internal nasal valve in such a way that the healing process causes a change to the shape of the nasal valve and/or a change in the structural properties of the tissue. In some embodiments, such targeted energy application and subsequent healing may be further controlled through the use of temporary implants or re-shaping devices (e.g. internal stents or molds, or external adhesive strips).

[0093] 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. 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 (as illustrated for example in FIG. 4D).

[0094] In some embodiments, energy may be delivered into the submucosal tissue to cause a conformational change and/or a change in the physical properties 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.

[0095] FIG. 3 illustrates an embodiment of a nasal valve treatment device 30. The device 30 comprises a treatment element 32 which may be configured to be placed inside the nasal cavity, nasal passage, and/or nasal airway 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.

[0096] 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.

[0097] 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, WiFi (or other 802.11 standard wireless protocol), infrared or any other wired or wireless communication method.

[0098] 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.

[0099] The treatment system may also comprise a power supply 44. In some embodiments, a power supply may be integrally incorporated within the handle section 34. In alternative embodiments, a 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, a power supply 44 may include a battery or other electrical energy storage or energy generation device. In other embodiments, a power supply 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. Alternatively, the power supply 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.

[0100] 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, including the internal and external nasal valves. 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. In some embodiments, the shape of a fixed-shape treatment element may be substantially in a shape to be imparted to the cartilage or other structures of the internal or external nasal valve area.

[0101] In some embodiments, as shown for example in FIG. 3, 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. 4A-4D. In some embodiments, an ellipsoid balloon as shown in FIG. 4A may have an asymmetrical shape. In alternative embodiments, the treatment element 32 may have an asymmetrical "egg-shape" with a large-diameter proximal end and a smaller-diameter distal end. In some embodiments, the element 32 can be shaped so as to impart a shape to the tissue treated that is conducive to optimal nasal airflow. Any suitable solid or expandable medical balloon material and construction available to the skilled artisan may be used.

[0102] FIG. 4B illustrates an embodiment of a treatment element configured to deliver energy to an interior of a nasal valve. In some embodiments, the treatment element of FIG. 4B also includes an expandable balloon.

[0103] FIG. 4C illustrates an embodiment of a bifurcated treatment element 70 having 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 & 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. The shape modification of elements 72, 74 can be accomplished pre-procedure or during the procedure and can be either fixed after modification or capable of continuous modification.

[0104] In some embodiments, a nasal valve treatment system may also comprise a re-shaping device configured to mechanically alter a shape of soft tissue and/or cartilage in a region of a nasal valve in order to impart a desired shape and mechanical properties to the tissue of the walls of the nasal airway. In some embodiments the re-shaping device may be configured to re-shape the internal and/or external nasal valve into a shape that improves the patency of one or both nasal valve sections at rest and during inspiration and/or expiration. In some embodiments, the reshaping device may comprise balloons, stents, mechanical devices, molds, external nasal strips, spreader forceps or any other suitable structure. In some embodiments, a re-shaping device may be integrally formed with the treatment element 32. In alternative embodiments, a re-shaping device may be provided as a separate device which may be used independently of the treatment element 32. As described in more detail below, such re-shaping may be performed before, during or after treatment of the nose tissue with energy, injectable compositions or cryo-therapy.

[0105] With reference to FIGs. 4A - 4C, some embodiments of treatment elements 32 may comprise one or more inflatable or expandable sections configured to expand from a collapsed configuration for insertion into the nasal passageway, to an expanded configuration in which some portion of the treatment element 32 contacts and engages an internal surface of a nasal passageway. 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 32.

[0106] In some embodiments, the treatment element 32 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 there of 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.

[0107] In alternative embodiments, the treatment element 32 can act to change the properties of the internal soft tissue of the nasal airway in conjunction with an external treatment device of fixed or variable shape to provide additional force to change the shape of the internal and/or external nasal valve. In some embodiments, an external mold element can be combined with an internal element.

[0108] FIGs. 5A and 5B illustrate re-shaping treatment devices 80 and 90, respectively. The treatment devices 80 and 90 are structured as clamp devices configured to engage a targeted section of the nasal valve with either a clamping force or a spreading force. In some embodiments, the treatment devices of FIGs. 5A and 5B may include energy delivery elements (of any type described herein) which may be powered by a fluid lumen or cable 86.

[0109] The treatment device of FIG. 5A includes an outer clamp member 82 and an inner clamp member 84 joined at a hinge point 85. In some embodiments, the outer clamp member 82 may include an outwardly-bent section 86 sized and configured to extend around the bulk of a patient's nose when the inner clamp member may be positioned inside the patient's nose. The inner and outer tissue-engaging tips at the distal ends of the inner and outer clamp members may be configured to impart a desired shape to the internal and/or external nasal valve. In some embodiments, the tissue-engaging tips may be removable to allow for sterilization and/or to allow for tips of a wide range of shapes and sizes to be used with a single clamp handle.

[0110] The treatment device of FIG. 5B includes an outer clamp member 92 and an inner clamp member 94 joined at a hinge point 95. The inner and outer tissue-engaging tips at the distal ends of the inner and outer clamp members may be configured to impart a desired shape to the internal and/or external nasal valve. In the illustrated embodiment, the outer clamp member 92 includes a concave inner surface, and the inner clamp member includes a mating convex inner surface. The shape and dimensions of the mating surfaces may be designed to impart a desired shape to the structures of a patient's nose. In some embodiments, the shape of the mating surfaces may be modified by the operator to impart an optimal configuration to the treated tissue. The shape modification of the mating surfaces can be accomplished pre-procedure or during the procedure and can be either fixed after modification or capable of continuous modification.

[0111] In some embodiments, the tissue-engaging tips may be removable to allow for sterilization and/or to allow for tips of a wide range of shapes and sizes to be used with a single clamp handle.

[0112] In alternative embodiments, the devices of FIG. 5A and 5B may be used as spreader devices by placing both clamp tips in one nasal valve and separating the handles, thereby separating the distal tips. In alternative embodiments, the handles may be configured to expand in response to a squeezing force. The shapes of the distal tips may be designed to impart a desired shape when used as a spreading device.

[0113] The re-shaping elements of FIGs. 3-5B are generally configured to be used once and removed from a patient's nose 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. An example of such a stent placed within a patient's nose after treatment is shown in FIG. 6. In some embodiments, the stent may be configured to be removed after a therapeutically effective period of time following the treatment. In some embodiments, such a therapeutically effective period of time may be on the order of days, weeks or more.

[0114] In some embodiments, the treatment element 32 may be configured to deliver heat energy to the nasal valve. In such embodiments, the treatment element 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 nasal tissue. In some embodiments, a high-temperature fluid heating element may comprise flow channels which place high-temperature fluids into conductive contact with nasal tissues (e.g. through a membrane wall) without injecting such fluids into the patients 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.

[0115] US Patent 6,551,310 describes embodiments of endoscopic treatment devices configured to ablate tissue at a controlled depth from within a body lumen by applying radio frequency spectrum energy, non-ionizing ultraviolet radiation, warm fluid or microwave radiation. US Patent 6,451,013 and related applications referenced therein describe devices for ablating tissue at a targeted depth from within a body lumen. Embodiments of laser-treatment elements are described for example in US Patent 4,887,605 among others. US Patent 6,589,235 teaches methods and device for cartilage reshaping by radiofrequency heating. US Patent 7,416,550 also teaches methods and devices for controlling and monitoring shape change in tissues, such as cartilage. The devices described in these and other patents and publications available to the skilled artisan may be adapted for use in treating portions of a nasal valve or adjacent tissue as described herein. US Patent Nos. 7,416,550, 6,589,235, 6,551,310, 6,451,013 and 4,887,605 are hereby incorporated by reference in their entireties.

[0116] 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. Examples of suitable cryogenic therapy delivery elements are shown and described for example in US Patents 6,383,181 and 5,846,235, the entirety of each of which is hereby incorporated by reference.

[0117] 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 32, thereby treating all nasal 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 nasal tissues. In such embodiments, the treatment element 32 may be configured so that energy being delivered to selected regions of the treatment element 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 nasal passageway.

[0118] In some embodiments, the treatment element 32 may be a balloon with energy delivery elements positioned at locations where energy transfer is sufficient or optimal to effect change in breathing. Such a balloon may be configured to deliver energy while the balloon is in an inflated state, thereby providing a dual effect of repositioning tissue and delivering energy to effect a change the nasal valve. In other embodiments, a balloon may also deliver heat by circulating a fluid of elevated temperature though the balloon during treatment. The balloon can also delivery cryotherapy (e.g. by circulating a low-temperature liquid such as liquid nitrogen) while it is enlarged to increase the nasal valve diameter or otherwise alter the shape of a nasal valve. FIG. 7 illustrates an example of an energy-delivery balloon being inserted into a patient's nose for treatment. 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 valve tissue to a desired depth (as shown for example in FIG. 4D and in other embodiments below).

[0119] 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 tightening sections of the epithelium of the inner surface of the nasal valve. In other embodiments, treatments may be targeted at strengthening soft tissues underlying the epithelium. In further embodiments, treatments may be targeted at strengthening cartilage in the area of the upper lateral cartilage. In still further embodiments, treatments may be targeted at stimulating or modifying the tissue of muscles of the nose or face in order to dilate the nasal valve.

[0120] 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 in the nasal valve tissue.

[0121] 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 around a nasal valve 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

nose. 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 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.

[0122] In some embodiments, a treatment element may be configured to treat a patient's nasal valve by applying treatment (energy, cryotherapy, or other treatments) from a position outside the patient's nose. For example, in some embodiments, the devices of FIGs 5A and 5B may be configured to apply energy from an element positioned outside a patient's nose, such as on the skin. In another embodiment, a device may be placed on the external surface of the nose that would pull skin to effect a change in the nasal airway. Treatment may then be applied to the internal or external nasal tissue to achieve a desired nasal valve function.

[0123] In some embodiments, the device is configured to position tissue to be re-shaped. In some embodiments, the device comprises features and mechanisms to pull, push or position the nasal tissue into a mold for re-shaping. For example, suction, counter traction, or compression between two parts of the device may be used.

[0124] In some embodiments, the treatment device comprises one, two, three, four, or more molds configured to re-shape tissue. The mold or re-shaping 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 a nasal valve 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. The mold is configured to impart a shape to the tissues of the nasal valve area to improve airflow or perceived airflow. The mold is configured to act near the apex of the nasal valve angle, the point at which the upper lateral cartilage meets the cartilage of the nasal septum. It may be desirable to treat in an area near, but not at, the nasal valve so as to avoid post procedure scarring and/or adhesions. This may be accomplished by focusing treatment on the lateral part of the nasal valve angle.

[0125] In some embodiments, the mold or re-shaping element comprises a separate or integrated energy delivery or treatment element (e.g., an electrode such as those described below with respect to Figs.8A-8J). The treatment element may be fixed or adjustable in size. For example, the treatment element may be adjusted to better conform to the nasal valve of a patient. In the case of a separate re-shaping element and treatment element, 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.

[0126] In some embodiments, the mold or another part of the device is configured to deliver cooling (discussed in more detail below). In some embodiments, the mold or re-shaping element comprises a balloon configured to reshape and/or deform tissue. A balloon may also be configured to deliver energy such as heat using hot liquid or gas.

Examples of Various Electrode Arrangements

[0127] Described below are embodiments of various treatment devices and, more particularly, electrode arrangements that may be used for applying energy to the nasal valve area. These electrodes may, for example, deliver RF energy to preferentially shape the tissue to provide improved nasal breathing. In some embodiments, one or more electrodes may be used alone or in combination with a tissue shaping device or mold. In other embodiments, one or more electrodes may be integrally formed with a tissue shaping device or mold, so that the electrodes themselves create the shape for the tissue. In some embodiments, the energy delivery devices may utilize alternating current. In some embodiments, the energy delivery devices may utilize direct current. In certain such embodiments, the energy delivery device may comprise a configuration utilizing a grounding pad.

[0128] 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, 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).

[0129] In some embodiments, "mold", "tissue shaper", "re-shaping element" and the like refer to any electrode or non-electrode surface or structure used to shape, configure or deflect tissue during treatment.

[0130] 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 creating a specific shape.

[0131] As shown in Fig. 8A, in some embodiments, bipolar electrodes may be used to deliver energy, with one electrode 202 placed internally in the nasal valve, for example against the upper lateral cartilage, and one electrode 204 placed externally on the outside of the nose. This embodiment may advantageously provide direct current

flow through the tissue with no physical trauma from needles (as shown in some embodiments below). As shown in Fig. 8B, 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. In some embodiments, bipolar electrodes 220, 222 may be both placed externally and may be connected to a passive molding element 224 placed inside the nasal valve adjacent to tissue to be treated, as shown in Fig. 8C. This embodiment may advantageously minimize the potential for mucosal damage. In some embodiments, electrodes placed internally may be shaped to function as a mold or may comprise an additional structure that may function as a mold.

[0132] In some embodiments, a monopolar electrode may be used to deliver energy. As shown in Fig. 8D, 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 molding element placed inside the nasal valve 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 mold or may comprise an additional structure that may function as a mold.

[0133] In some embodiments, monopolar transmucosal needles may be used to deliver energy. The needle electrodes 240 may be placed internally, as shown in Fig. 8E penetrating through the mucosa to the cartilage, and 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 molding 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, and penetrate through to tissue to be treated. Needle configurations may advantageously target the cartilage tissue to be treated specifically.

The monopolar transdermal needles may be used in conjunction with an internal molding device (not shown).

[0134] 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 the mucosa to the cartilage to be treated. In some embodiments, the bipolar transmucosal needles may be used in combination with one or more internal molding elements. The one or more molding 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 cartilage tissue to be treated specifically. The transdermal bipolar needles may be utilized in conjunction with an internal molding element.

[0135] As shown in Fig. 8F, in some embodiments, an array of electrodes comprising one, two, or many pairs of bipolar needles 252 are located on a treatment element configured to be placed into contact with the cartilage. An insulator 254 may be disposed between the bipolar needles 252. An insulator may also be utilized on part of the needle's length to allow energy to be delivered only to certain tissue structures, such as cartilage. The electrodes may be placed either internally or transmucosally or they may be placed externally or transdermally. In the embodiment illustrated in Fig. 8F, the insulator 254 may also function as a mold or molding element. In other embodiments (not shown), the array of electrodes is used in conjunction with a separate tissue re-shaping element.

[0136] Fig. 8G illustrates another embodiment of a treatment element comprises one, two or many pairs of bipolar electrodes 260. As opposed to Fig. 8F, where the pairs of electrodes are arranged side-by-side, the embodiment of Fig. 8G arranges the pairs of electrodes along the length of the treatment element. The electrodes of Fig. 8G are also non-penetrating, in contrast to the needles of Fig. 8F. The electrodes 260 may be placed against either the skin, externally, or the mucosa, internally as a means of delivering energy to target tissue such as cartilage.

[0137] 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, the needles or needle pairs of Figure 8F may be individually controlled to produce an optimal treatment effect. For another example, the separate electrodes of Figs. 8B and 8C 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 nasal tissue/structures does not allow the entire electrode region of the treatment element to engage the tissue. In such embodiments, the nasal tissue that is in contact with the treatment element may receive sufficient energy to treat the tissue.

[0138] Combinations of the described electrode configurations may also be utilized to deliver energy to tissue to be treated (e.g., by being reshaped). For example, transmucosal needles 264 may be placed internally, penetrating through to the tissue to be treated, and an electrode 266 may be placed externally, as shown in Fig. 8H. This embodiment may advantageously target the cartilage tissue specifically and be biased for mucosal preservation. For another example, transdermal needles 268 may be placed externally and an electrode 270 may be placed internally, as shown in Fig. 8I. This embodiment may advantageously target the cartilage tissue specifically and be biased towards skin preservation. For another example bipolar needle electrodes 272, 274 can be placed both transdermally or externally and transmucosally or internally, as shown in Fig. 8J. This embodiment may advantageously target the cartilage tissue 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.

Examples of Treatment Devices Including Electrodes

[0139] Embodiments of treatment devices incorporating treatment elements such as the electrodes described above are illustrated in Figs. 9A-21B. The instrument designs described in these embodiments may be used in a device such as the device 30,

described above, and in the system of Figure 3. In some embodiments, the devices provide tissue re-shaping or molding in addition to energy delivery. Applying energy to the nasal valve may require properly positioning the electrode(s) at the nasal valve, deflecting or deforming the tissue into a more functional shape, 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. Molding and reshaping of the tissues of the nasal valve may allow for non-surgical nasal breathing improvement without the use of implants.

[0140] Fig. 9A depicts a device 300 comprising a single inter-nasal monopolar electrode 301 located at the end of a shaft 302. The shaft is attached to a handle 303. The electrode configuration may be similar to that described with respect to Fig. 8D. Fig. 9B depicts another device 304 comprising 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 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, and in the embodiment illustrated has a convex shape configured to press against and create a concavity in the nasal valve cartilage.

[0141] Fig. 10A depicts a side view of a device 310 comprising a single inter-nasal electrode 312 located at the end of a shaft 314. The shaft is attached to a handle 316. An external mold 318 is attached to the handle 316 and can be moved relative to the electrode shaft 314. The external mold 318 has a curved shape with an inner concave surface that may be moved in order to press against an external surface of a patient's nose to compress tissue between the external mold 318 and the electrode 312. Fig. 10B provides a front view of the device 310.

[0142] Fig. 11A depicts a device 320 comprising a single inter-nasal electrode 322 attached to the end of a shaft 324. The shaft 324 is attached to a handle 326. An internal shaft 328 comprising a tissue-contacting surface is attached to the handle 326.

The internal shaft 328 can be moved relative to the electrode shaft 324 and may provide counter-traction and/or positioning. For example, when the electrode 322 is placed against a patient's upper lateral cartilage, the counter-traction element 328 may be pressed against the patient's nasal septum.

[0143] Fig. 11B depicts a device 450 similar to device 320 of Fig. 11A comprising an inter-nasal electrode 451 located at a distal end of a shaft 452 connected to a handle 454. The device 450 further comprises a counter-traction element 456 connected to a handle 458. Like the device 320 depicted in Fig. 11A, the connection 460 between the two handles 454, 458 is such that squeezing the two handles 454, 458 together causes the electrode 451 and the counter-traction element 456 to move away from each other, spreading the tissue they are contacting.

[0144] Fig. 12A depicts a device 330 comprising a single inter-nasal electrode 332 located at the end of a shaft 334. The shaft 334 is attached to a handle 336. The device 330 comprises another single inter-nasal electrode 338 attached to the end of a shaft 340. The shaft 340 is attached to a handle 342. The device comprises a connection 344 between the two handles 340, 342 that allows simultaneous deformation and treatment of both nostrils.

[0145] Fig. 12B depicts a device 470 similar to device 330 of Fig. 12A comprising a first inter-nasal electrode 472 located at a distal end of a shaft 474 connected to a handle 476. The device 470 comprises a second inter-nasal electrode 478 located at a distal end of a second shaft 480 connected to a second handle 482. The connection 484 between the two handles 476, 482 is such that squeezing the handles 476, 482 together causes the electrodes 472, 478 to move away from one another, spreading any tissue they may be in contact with. The device 470 comprises a ratcheting mechanism 475 between the two handles 476, 482 that allows the relative positions of the electrodes 472, 478 to be locked during treatment.

[0146] Fig. 13A depicts a side view of a device 350 also used for treating two nostrils comprising an inter-nasal electrode 352 attached to the end of a shaft 354. The shaft 354 is attached to a handle 356. As seen in the front view provided in Fig. 13B, the device 350 comprises a second inter-nasal electrode 358. The second inter-nasal

electrode 358 is attached to the end of a shaft which is attached to a handle. A connection between the two handles allows simultaneous deformation and treatment of the nostrils. An external mold 366 is attached to the handles. The mold 366 may be moved relative to the electrode shafts 354, 360 and may provide counter-traction (e.g., against the bridge of the nose) and positioning.

[0147] Figs. 13C-E depicts a device 490 similar to the device 350 shown in Fig. 13A and Fig. 13B. Figs. 13C and 13D depict side and top views of a device 490 comprising a handle 492. The handle 492 bifurcates into a first shaft 494 with a first inter-nasal electrode 496 located at a distal end of the shaft 494 and a second shaft 498 with a second inter-nasal electrode 500 located at a distal end of the shaft 498. The device 490 comprises a mold 502 configured to provide counter-traction or compression of the bridge of the nose. The mold 502 comprises a handle 504. The connection 506 between the handles 492, 504 is such that squeezing the two handles 492, 504 causes the electrodes 496, 600 and the mold 502 to be compressed together. Fig. 13E depicts the device 490 being used on a patient. The arrows indicate the directions in which the handles 492, 504 are configured to be squeezed.

[0148] Fig. 14A depicts a front view of a device 370 comprising an inter-nasal electrode 372 attached to the end of a shaft 374 (shown in top view of Fig. 14B). The shaft 374 is attached to a handle 376. The device 370 comprises a second inter-nasal electrode 378 attached to the end of a second shaft 380. The second shaft 380 is attached to a second handle 382. A connection 384 between the two handles 376, 382 may allow simultaneous deformation and treatment of the nostrils. External molds 386, 388 are attached to the handles and can be moved relative to each electrode shaft 374, 380. The molds 386, 388 may provide counter-traction, compression of tissue, positioning, and external tissue deformation.

[0149] Fig. 15A depicts a front view of device 390 comprising a first inter-nasal electrode 392 and a second inter-nasal electrode 398. As shown in the side view of Fig. 15B, the device 390 comprises a first inter-nasal electrode 392 attached to the end of a shaft 394. The shaft is attached to a handle 396. A second inter-nasal electrode 398 is attached to the end of a second shaft 400, as shown in the top view of Fig. 15C. The

second shaft 400 is attached to a second handle 402. A connection 404 between the two handles 396, 402 may allow simultaneous deformation and treatment of the nostrils. Additional internal shafts 406, 408 comprise tissue-contacting surfaces and are attached to the handles 396,402. The internal shafts 406, 408 may be moved relative to each electrode shaft 394, 400 (shown in Fig. 15B) and may provide counter-traction and positioning.

[0150] Fig. 16 depicts a system 410 comprising a first device having an extra-nasal electrode 412 along a concave surface configured to positioned against an external surface of a patient's nose, the electrode 412 being attached to the end of a shaft 414. The shaft 414 is attached to a handle 416. A separate device 417 comprising an internal tissue mold 418 is attached to a shaft 420. The internal tissue mold is configured to be positioned inside the patient's nasal valve. The shaft 420 is attached to a handle 422. Each handle 422, 416 may be manipulated individually and may apply energy and deformation to create a desired tissue effect.

[0151] Fig. 17A depicts a side view of a device 430 comprising an extra-nasal electrode 431 attached to the end of a shaft 432. The shaft 432 is attached to a handle 434. The device 430 also comprises an internal tissue mold 436 attached to a shaft 438 which is attached to a handle 440. The handles 434, 440 are attached together and may be moved relative to each other to simultaneously deliver energy and deform tissue. Fig. 17B depicts a front view of the device 430.

[0152] Fig. 18 depicts a device 390 comprising pairs of bipolar electrodes 392 located at the distal end of a shaft 394. The electrodes may be similar to the electrodes described with respect to the electrode configuration of Fig. 8G in that they are non-penetrating. The shaft 394 is connected to a handle 398 which comprises a button configured to activate and deactivate the electrodes. As stated above, the device 380 may either comprise a generator or be connected to a remote generator.

[0153] Fig. 19A depicts the treatment element 502 of a treatment device (e.g., device 30). The treatment element 502 of the device comprises a monopolar electrode 504. A cross-section of the treatment element 502 is shown in Fig. 19B. It comprises an asymmetrical shape and has a convex surface where the electrode is positioned

configured to conform to only one of a patient's nostrils (for example, a patient's right nostril). More specifically, the convex surface is configured such that when inserted into the particular nostril, the convex surface would be located adjacent the upper lateral cartilage of the nasal valve of that nostril. The treatment element 502 further comprises a light 506 configured to illuminate the treatment area. For example an LED or a visible laser may be used. The visible laser may experience less diffusion in the tissue. Furthermore, the light 506 can be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The user can then use the light to properly position the device in the desired location. Because the electrode 504 is not centered on the treatment element 502 of the device, a separate device having a mirror-image configuration may be required to treat the other nostril.

[0154] Fig. 20A depicts the treatment element 512 of a treatment device (e.g., device 30). The treatment element 512 of the device comprises two monopolar electrodes 514, 516 provided side-by-side on a convex surface of the treatment element. The cross section of the treatment element 512, shown in Fig. 20B, is configured to conform to the shape either nostril, depending on which side of the device (and accordingly, which of electrode 514 or 516) is placed in contact with the patient's nasal valve. Comprising two monopolar electrodes 514, 516 may allow the same treatment element 512 to be used for treatment in both nostrils, and each electrode may be activated separately depending on which side needs to be utilized. The treatment element 512 also comprises two lights 518, 520 (e.g., LEDs, lasers) configured to illuminate the treatment area for both nostrils. One or both of the lights 518, 520 can also be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The user can then use the light to properly position the device in the desired location.

[0155] Fig. 21A depicts a treatment element 522 of a treatment device (e.g., device 30). The tip 522 of the device comprises a monopolar electrode 524. The tip 522 comprises a symmetrical cross-section as shown in Fig. 21B. The tip 522 comprises a light 526 (e.g., LED) configured to illuminate the treatment area. The light 526 can also be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The symmetrical tip allows the user to treat

either left or right nostril. The user can then use the light to properly position the device in the desired location.

[0156] Figs. 22A-G depict a treatment device 530 similar to the embodiments of Figs. 8D, 9A, and 9B. Figs. 22A and 22F provide perspective views of the device 530. The device 530 comprises a treatment element 532 at its distal tip 534. The treatment element 532 comprises an electrode 535. The body of the treatment element 532, itself, may comprise an insulating material. The treatment element 532 may be provided on an enlarged distal tip 534 of an elongate shaft 536, and as in the embodiment illustrated, may have a convex shape configured to press against and create a concavity in the nasal valve cartilage (e.g., in the upper lateral cartilage near the nasal valve). The distal tip 534 is located at the distal end of shaft 536. The shaft is attached at its proximal end to a handle 538. The handle 538 comprises an input control such as a power button 540 on its front side that may be used to activate and deactivate the electrode. The power button 540 may be positioned in a recess of the handle to allow for finger stability when activating and deactivating the electrode. In other embodiments, the input control is in the form of a switch or dial. Other configurations are also possible as described above.

[0157] The device 530 comprises a flexible wire or cable 542 electrically connected to an adaptor 544. The adaptor 544 can be used to connect the device 530 to a remote generator (not shown). The adaptor 544 may allow transmission of treatment energy between a remote generator and the device 530. The adaptor may also allow transmission of any sensor signals between the device 530 and a generator or control unit. The device 530 may either comprise an integrated generator or be connected to a remote generator. The treatment device 530 may be provided in a system or kit also including the remote generator. The system or kit (with or without the remote generator) may also include a grounding device and/or a cooling device as described above and further below. In some embodiments, the kit incudes a positioning element (e.g., a "cottle" device) configured to help a user locate the optimal treatment area.

[0158] Figs. 22B and 22C depict front and back views of the device. As shown in Figs. 22B and 22C, the handle 538 of the device generally as a rounded elongate shape. Other shapes are also possible. For example the device 530 may have a

square shaped cross section. In some embodiments, a circumference (or width or cross-sectional area) of the handle 538 may increase distally along the length of the handle 538.

[0159] Figs. 22D and 22E depict side views of the device. As shown in Figs. 22D and 22E, the handle 538 of the device 530 may comprise an indentation or recess around the middle of the handle 538. This may allow for enhanced grip and control when a user is holding the device. The indentation or recess may be near the input control or power button 540 to allow a user to easily activate and deactivate the device while holding it in a comfortable position.

[0160] In some embodiments, the shaft has a width or diameter of about 0.125 inches to about 0.25 inches. In some embodiments, the shaft is about 1.5 inches to about 4 inches long. In some embodiments, the shaft comprises a polymer such as polycarbonate or PEEK. In other embodiments, the shaft comprises stainless steel or other metals. The metals may be coated with an external and/or internal insulating coating (e.g., polyester, polyolefin, etc.). The handle may comprise the same material as the shaft, in some embodiments. In some embodiments, the shaft is rigid. This may allow a user of the device increased control over the deformation of nasal tissue. In some embodiments, the shaft comprises some amount of flexibility. This flexibility may allow a user adjust an angle of the distal tip by bending the distal end of the shaft.

[0161] Fig. 22G depicts a larger view of the distal tip 534 of the device 530. As shown best in Fig. 22G, the treatment element 532 comprises a generally elongate shape. The front of the treatment element 532 comprises a shallow, curved surface, providing a convex shape configured to deform the nasal tissue and create a concavity therein. In some embodiments, the front of the treatment element comprises a concave shape. The shape of the front surface of the treatment element may be selected to conform to the nasal tissue. The back of the treatment element 532 also comprises a shallow curved surface. As best seen in Figs. 22D and 22E, the back surface varies in width along the length of the back surface of the treatment element 532. The back surface widens, moving distally along the tip until it is nearly in line with the proximal end of the electrode plate 532. The back surface then narrows towards the distal tip of the treatment element 532. This shape may maximize visualization of the area to be

treated, while, at the same time, providing sufficient rigidity for treatment. Other shapes are also possible. For example, the treatment element may comprise a generally spherical or cylindrical shape. In some embodiments, the treatment element comprises an angular shape (e.g., triangular, conical) which may allow for close conformation to the tissue structures. The treatment element 532 comprises a monopolar electrode plate 532. The monopolar electrode plate 532 can be in the shape of a rectangle having a curved or convex tissue-facing surface. Other shapes are also possible (e.g., square, circular, ovular, etc.). The electrode 532 may protrude slightly from the treatment element 535. This may allow the electrode to itself provide a convex shape configured to create a concavity in tissue to be treated.

[0162] In some embodiments, the treatment element has a width or diameter of about 0.25 inches to about 0.45 inches. In some embodiments, the treatment element is about 0.4 inches to about 0.5 inches long. The treatment element can, in some embodiments, comprise a ceramic material (e.g., zirconium, alumina, silicon glass). Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the treatment element comprises polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the treatment element comprises thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the treatment element comprises thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the treatment element comprises glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0163] In some embodiments, the electrode has a width of about 0.15 inches to about 0.25 inches. In some embodiments, the electrode is about 0.2 inches to about 0.5 inches long. In some embodiments, the treatment element comprises steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive.

In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0164] As shown in the embodiment of Fig. 22G, the treatment element 532 further comprises a pin-shaped structure comprising a thermocouple 533 within an insulating bushing extending through a middle portion of the plate 532. In some embodiments, different heat sensors (e.g., thermistors) may be used. In some embodiments, the thermocouple 533 is configured to measure a temperature of the surface or subsurface of tissue to be treated or tissue near the tissue to be treated. A pin-shape having a sharp point may allow the structure to penetrate the tissue to obtain temperature readings from below the surface. The thermocouple can also be configured to measure a temperature of the treatment element 532 itself. The temperature measurements taken by the thermocouple can be routed as feedback signals to a control unit (e.g., the control unit 42 described with respect to Fig. 3) and the control unit can use the temperature measurements to adjust the intensity of energy being delivered through the electrode. In some embodiments, thermocouples or other sensing devices may be used to measure multiple tissue and device parameters. For example, multiple thermocouples or thermistors may be used to measure a temperature at different locations along the treatment element. In some embodiments, one of the sensors may be configured to penetrate deeper into the tissue to take a measurement of a more interior section of tissue. For example, a device may have multiple sensors configured to measure a temperature at the mucosa, the cartilage, and/or the treatment element itself. As described above, in some embodiments, the sensors described herein are configured to take a measurement of a different parameter. For example, tissue impedance can be measured. These measurements can be used to adjust the intensity and/or duration of

energy being delivered through the treatment element. This type of feedback may be useful from both an efficacy and a safety perspective.

[0165] As shown in Fig. 22G, in some embodiments the thermocouple is within a pin shaped protrusion on the surface of the electrode 532. In other embodiments, the thermocouple can simply be on the surface of the electrode. In other embodiments, the thermocouple can protrude from the surface of the electrode in a rounded fashion. Rounded structures may be pressed into the tissue to obtain subsurface temperature readings. Other configurations and locations for the thermocouple are also possible. The use of thermocouples or temperature sensors may be applied not only to the embodiment of Fig. 22G, but also to any of the other embodiments described herein.

[0166] Figs. 23A-G depict a treatment device 550 similar to the embodiments of Figs. 8F and 18. Figs. 23A and 23F are perspective views of the device 550 and show the device 550 comprising a treatment element 552 at the distal tip 556 of the device 550. The treatment element 552 may be provided on an enlarged distal tip 556 of an elongate shaft 558, and as in the embodiment illustrated, may have a convex shape configured to press against and create a concavity in the nasal valve cartilage (e.g., in upper lateral cartilage of the nasal valve). The distal tip 556 is located at a distal end of shaft 558. The shaft is attached at its proximal end to a handle 560. The handle 560 comprises an input control, such as a power button 562, on its front side that may be used to activate and deactivate the electrode. The power button may be positioned in a recess of the handle to allow for finger stability when activating and deactivating the electrode. In other embodiments, the input control is in the form of a switch or dial. Other configurations are also possible as described above. The device 550 may either comprise a generator or be connected to a remote generator. The device 550 may comprise a flexible wire or cable 564 that connects to an adaptor 566 that is configured to be plugged into a remote generator (not shown). The adaptor 566 may allow transmission of treatment energy between a remote generator and the device 550. The adaptor 566 may also allow transmission of any sensor signals between the device 550 and a generator or control unit. The treatment device 550 may be provided in a system or kit also including the remote generator. The system or kit (with or without the remote generator) may also include a grounding device and/or a cooling device as described above and further below. In some

embodiments, the kit includes a positioning element (e.g., a "cottle" device) configured to help a user locate the optimal treatment area.

[0167] In some embodiments, the shaft has a width or diameter or about 0.235 inches to about 0.25 inches. In some embodiments, the shaft is about 1.5 inches to about 4 inches long. In some embodiments, the shaft and/or handle comprises a polymer such as polycarbonate or PEEK. In other embodiments, the shaft comprises stainless steel or other metals. The metals may be coated with an external and/or internal insulating coating (e.g., polyester, polyolefin, etc.). The handle may comprise the same material as the shaft, in some embodiments. In some embodiments, the shaft is rigid. This may allow a user of the device increased control over the deformation of nasal tissue. In some embodiments, the shaft comprises some amount of flexibility. This flexibility may allow a user adjust an angle of the distal tip by bending the distal end of the shaft.

[0168] Figs. 23B and 23C depict side views of the device. As shown in Figs. 23B and 23C, the handle 560 of the device 550 may comprise an indentation or recess around the middle of the handle 560. This may allow for enhanced grip and control when a user is holding the device. The indentation or recess may be near the input control or power button 562 to allow a user to easily activate and deactivate the device while holding it in a comfortable position.

[0169] Figs. 23D and 23E depict front and back views of the device. As shown in Figs. 23D and 23E, the handle 560 of the device generally comprises a rounded elongate shape. Other shapes are also possible. For example the device 550 may have a square shaped cross section. In some embodiments, a circumference (or width or cross-sectional area) of the handle 560 may increase distally along the length of the handle 560.

[0170] Fig. 23G depicts a larger view of the distal tip 556 of the device 550. As shown best in Fig. 23G, the treatment element 552 comprises a generally elongate shape. The front of the treatment element 552 comprises a shallow curved surface, providing a convex shape configured to deform the nasal tissue and create a concavity therein. In some embodiments, the front of the treatment element comprises a concave shape. The shape of the front surface of the treatment element may be selected to conform to the nasal tissue. The back surface of the treatment element 552 comprises a

shallow curved surface along most of its length. As best seen in Figs. 23B and 23C, the back surface narrows distally along the length of the element 552 from approximately the distal end of the needle electrodes to the distal tip of the treatment element 552. This shape may maximize visualization of the area to be treated, while, at the same time, providing sufficient rigidity for treatment. Other shapes are also possible. For example, the treatment element may comprise a generally spherical or cylindrical shape. In some embodiments, the treatment element comprises an angular shape (e.g., triangular, conical) which may allow for close conformation to the tissue structures. The treatment element 552 comprises a monopolar or bipolar needle array comprising multiple needles 554. In some embodiments, the needles 554 are energized in between select needles to deliver bipolar energy. In other embodiments, the energy is delivered between the needles (554) and a remote grounding pad (not shown). In some embodiments, the electrode needle pairs are arranged horizontally across the treatment element 552. In some embodiments, the electrode needle pairs are arranged vertically across the treatment element 552, or along the direction of the shaft 558 and handle 560. Other configurations are also possible. For example, the needle pairs may be arranged diagonally across the treatment element 552. The treatment element 552 may be placed either internally, with the needle pairs 554 positioned transmucosally or the treatment element 552 may be placed externally with the needle pairs 554 positioned transdermally. The distal tip 556 of the device 550 may also function as a mold or molding element. In a monopolar embodiment, the energy may be selectively delivered between certain sets of needles, all needles, or even individual needles to optimize the treatment effect.

[0171] The treatment element 552 of the device 550 further comprises a pin-shaped structure comprising a thermocouple 555 within an insulating bushing extending through a middle portion of the front surface of the treatment element 552. In some embodiments, different heat sensors (e.g., thermistors) may be used. As described above, in some embodiments, the thermocouple 555 is configured to measure a temperature of the surface or subsurface of tissue to be treated or tissue near the tissue to be treated. A pin-shape having a sharp point may allow the structure to penetrate the tissue to obtain temperature readings from below the surface. The thermocouple can also be configured to measure a temperature of the treatment element 552 itself. The temperature

measurements taken by the thermocouple can be routed as feedback signals to a control unit (e.g., the control unit 42 described with respect to Fig. 3) and the control unit can use the temperature measurements to adjust the intensity of energy being delivered through the electrode. In some embodiments, thermocouples or other sensing devices may be used to measure multiple tissue and device parameters. For example, multiple thermocouples or thermistors may be used to measure a temperature at different locations along the treatment element. In some embodiments, one of the sensors may be configured to penetrate deeper into the tissue to take a measurement of a more interior section of tissue. For example, a device may have multiple sensors configured to measure a temperature at the mucosa, the cartilage, and/or the treatment element itself. As described above, in some embodiments, the sensors described herein are configured to take a measurement of a different parameter. For example, tissue impedance can be measured. These measurements can be used to adjust the intensity and/or duration of energy being delivered through the treatment element. This type of feedback may be useful from both an efficacy and a safety perspective.

[0172] In some embodiments, the treatment element has a width or diameter of about 0.25 inches to about 0.45 inches. In some embodiments, the treatment element is about 0.4 inches to about 0.5 inches long. The treatment element can, in some embodiments, comprise a ceramic material (e.g., zirconium, alumina, silicon glass). Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the treatment element comprises polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the treatment element comprises thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the treatment element comprises thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the treatment element comprises glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0173] In some embodiments, the electrodes have a width or diameter of about 0.15 inches to about 0.25 inches. In some embodiments, the electrode is about 0.2

inches to about 0.5 inches long. In some embodiments, the treatment element comprises steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0174] Energy applied to the tissue to be treated using any combination of the embodiments described in this application may be controlled by a variety of methods. In some embodiments, temperature or a combination of temperature and time may be used to control the amount of energy applied to the tissue. Tissue is particularly sensitive to temperature; so providing just enough energy to reach the target tissue may provide a specific tissue effect while minimizing damage resulting from energy causing excessive temperature readings. For example, a maximum temperature may be used to control the energy. In some embodiments, time at a specified maximum temperature may be used to control the energy. In some embodiments, thermocouples, such as those described above, are provided to monitor the temperature at the electrode and provide feedback to a control unit (e.g., control system 42 described with respect to Fig. 3). In some embodiments, tissue impedance may be used to control the energy. Impedance of tissue changes as it is affected by energy delivery. By determining the impedance reached when a tissue effect has been achieved, a maximum tissue impedance can be used to control energy applied.

[0175] In the embodiments described herein, energy may be produced and controlled via a generator that is either integrated into the electrode handpiece or as part of a separate assembly that delivers energy or control signals to the handpiece via a cable or other connection. In some embodiments, the generator is an RF energy source

configured to communicate RF energy to the treatment element. For example, the generator may comprise a 460 KHz sinusoid wave generator. In some embodiments, the generator is configured to run between about 1 and 100 watts. In some embodiments, the generator is configured to run between about 5 and about 75 watts. In some embodiments, the generator is configured to run between about 10 and 50 watts.

[0176] In some embodiments, the energy delivery element comprises a monopolar electrode (e.g., electrode 535 of Fig. 22G). Monopolar electrodes are used in conjunction with a grounding pad. The grounding pad may be a rectangular, flat, metal pad. Other shapes are also possible. The grounding pad may comprise wires configured to electrically connect the grounding pad to an energy source (e.g., an RF energy source).

[0177] In some embodiments, the energy delivery element such as the electrodes described above can be flat. Other shapes are also possible. For example, the energy delivery element can be curved or comprise a complex shape. For example, a curved shape may be used to place pressure or deform the tissue to be treated. The energy delivery element may comprise needles or microneedles. The needles or microneedles may be partially or fully insulated. Such needles or microneedles may be configured to deliver energy or heat to specific tissues while avoiding tissues that should not receive energy delivery.

[0178] In some embodiments, the electrodes or energy delivery elements described herein comprise steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise

nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0179] In some embodiments, the treatment elements (e.g., non-electrode portion of treatment element) of the devices described herein, including but not limited to Figs. 8A-J, 9A-B, 10A-b, 11A-B, 12A-B, 13A-E, 14A-B, 15A-C, 16, 17A-B, 18, 22A-G, 19A-B, 20A-B, 21A-B, 22A-G, 23A-G, 25A-B, 26, 27, 28A-E, and 29, comprise an insulating material such as a ceramic material (e.g., zirconium, alumina, silicon glass). In some embodiments, the treatment elements comprise an insulating material interposed between multiple electrodes or electrode section. These insulating sections may provide an inert portion of the treatment element that does not delivery energy to the tissue. Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the insulators described herein comprise polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the insulators described herein comprise thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the insulators described herein comprise thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the insulators described herein comprise glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0180] In some embodiments, the handle and/or shaft of the devices comprise the same materials as those described with respect to the insulators. In some embodiments, the handle and/or shaft of the device comprises a metal, such as stainless steel. In other embodiments, the handle and/or shaft of the device comprises a polymer, such as polycarbonate. Other metals and polymers are also contemplated.

[0181] In some embodiments, the device may be used in conjunction with a positioning element that can be used to aid in positioning of the device. The positioning element may be integrated into the device itself or can be separate. The positioning element may be used to determine the optimal placement of the device to achieve maximal increase in efficacy. In some embodiments, a positioning element is configured

to be inserted and manipulated within the nose until the patient reports a desired improvement in breathing. The treatment device may then be used to treat while the positioning element is holding the nose in the desired configuration. In some embodiments, molds described herein may be used for the same purpose.

[0182] In some embodiments, a positioning element comprises a shaft comprising measurement marks indicating depth. For example, a physician may insert this element into the nose to manipulate the tissue to find the depth of treatment at which the patient reports the best breathing experience. The positioning element may comprise marks around the base of the shaft indicating which point of rotation of the device within the nostril provides the best breathing experience. The positioning element may also comprise marks indicating angle of insertion. The physician may then use the measurement marks to guide insertion of the treatment element to the same spot.

[0183] It will be appreciated that any combination of electrode configurations, molds, handles, connection between handles, and the like may be used to treat the nasal valve.

Cooling Systems

[0184] Embodiments of devices configured to heat specific tissue while maintaining lower temperatures in other adjacent tissue are provided. These devices may be incorporated into any of the treatment apparatuses and methods described herein. The nasal valve is an example of a tissue complex that includes adjacent tissues that may benefit from being maintained at different temperatures. Other examples include the skin, which comprises the epidermis, dermis, and subcutaneous fat, the tonsils, which comprise mucosa, glandular tissue, and vessels. Treatment of other tissue complexes is also possible. For example, in some embodiments, the internal structures of the nasal valve may be heated while maintaining a lower temperature in the mucosal lining of the nose and/or skin. In other embodiments, the mucosa may be heated, while maintaining lower temperatures in the skin. 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 cartilage, while excluding another tissue, such as mucosa, without surgical dissection.

[0185] Generally, when using a device 570 with an electrode 572 (e.g., monopolar RF electrode) to heat nasal cartilage, the electrode 572 must be in contact with the mucosa. Fig. 24A shows a cross-section of tissue at the nasal valve. The cross-section shows that the nasal cartilage 704 sits in between a layer of mucosa (internal) 702 and a layer of skin (external) 706. When the electrode 572 is activated, both the mucosa and the cartilage are heated by the current flowing from the electrode to the return (e.g., ground pad), as shown in Fig. 24B. The tissue closest to the electrode 572 receives the highest current density, and thus, the highest heat. A surface cooling mechanism may allow the temperature of the electrode surface to be reduced. Such a cooling mechanism may maintain a lower temperature at the mucosa even though current flow will continue to heat the cartilage.

[0186] Fig. 25A depicts a device 580 configured to treat the nasal valve using an electrode while maintaining a reduced temperature at the mucosa. The device comprises a treatment element 582 comprising an electrode 584 at the distal tip of the device 580. The treatment element 582 is attached to a distal end of a shaft 586, which is attached to the distal end of a handle 588. Input and output coolant lines 590, 592 are attached to a pump and reservoir 594 and extend into the handle 588, through the distal end of the treatment element 582 to the electrode 582 and return back through the shaft 586 and handle 588 to the pump and reservoir 594. The coolant may be remotely cooled in the reservoir and may comprise a fluid or gas. The coolant flowing through the electrode 582 may allow the treatment element 582 to be maintained at a reduced temperature while still allowing current flow to heat the cartilage. Examples of coolant include air, saline, water, refrigerants, and the like. Water may advantageously provide moderate heat capacity and be non reactive. Refrigerants may advantageously be able to transfer significant amounts of heat through phase change. The coolant may flow through internal or external cavities of the electrode or wand tip. For example, Fig. 25B depicts an embodiment of a device 600 comprising a treatment element 602 with an electrode 604 at the distal tip of the device 600. The treatment element 602 is attached to the distal end of a shaft 606 which is attached to the distal end of a handle 608. The handle may be

attached to a cable comprises a lumen or channel 611 through which gas or fluid may flow. The lumen 611 may diverge, near the treatment element 602, into separate external channels flowing over the electrode 604. The lumen 611 and channels 610 or cavities may be attached to a fan or fluid pump 612. In some embodiments, the fan or fluid pump may remotely cool the gas or fluid.

[0187] Fig. 26 depicts another embodiment of a device 620 configured to treat the nasal valve using an electrode 624 while maintaining a reduced temperature at the mucosa and/or skin. The device comprises a treatment element 622 comprising an electrode 624 at its distal end. The treatment element 622 is connected to the distal end of a shaft 626 which is connected to the distal end of a handle 628. The device 620 comprises a heat pipe 630 attached to the electrode 624 or treatment element 622. The heat pipe 630 is configured to transfer heat to a remote heat sink 632. As shown in Fig. 26, the heat sink 632 may be placed in the handle of the device. In some embodiments, the heat sink may be placed remotely. The heat pipe 630 may comprise a sealed tube (e.g., a copper tube) filled with a material that evaporates at a given temperature. When one end of the heat pipe 630 is heated, the fluid may evaporate and flow to the opposite end where it may condense and subsequently transfer heat to the heat sink 632. Using a material such as copper for the heat pipe 630 and/or heat sink 632 may advantageously provide high heat and electrical conductivity.

[0188] Fig. 27 depicts another embodiment of a device 640 configured to treat the nasal valve using a bipolar electrode pair while maintaining a reduced temperature at the skin. The device 640 comprises a first treatment element 642 comprising a first electrode 644 of a bipolar electrode pair at the distal end of a shaft 646. The treatment element 642 comprises a thermocouple pin 650 like that described with respect to Fig. 22G. The shaft 646 is connected to the distal end of a handle 648. The handle 648 is connected to another handle 652 comprising a shaft 654 with a treatment element 656 at its distal tip. The treatment element 656 comprises a second electrode 657 of the bipolar electrode pair. The first and second treatment elements 642, 656 can be placed on either side of nasal tissue. For example, the first treatment element 642 may be in contact with the mucosa and the second treatment element 656 may be in contact with the skin. Similar to the device depicted in Fig. 26, the device of Fig. 27 comprises a heat pipe

within both shafts 654, 646. Thus heat from the tissue is transferred from the treatment elements 642, 656 and is transported down the shafts 654, 646 into an integrated or a remote heat sink (not shown). This heat transfer may keep the skin and the mucosa relatively cool while still delivering sufficient treatment energy to the cartilage. The connection 658 and spring 647 between the two handles 648, 652 is configured to bias the two shafts 646, 654 and treatment elements 642, 656 towards a collapsed state. Squeezing the handles 648, 652 may separate the two shafts 646, 654 and treatment elements 642, 656. Thus, the handles 648, 652 can be squeezed to properly position the device 640 at the nasal tissue to be treated. Releasing the handles 648, 652 can cause the treatment element 642 and the cooling element 656 to contact the tissue. In some embodiments, the device 640 may only comprise one heat pipe. In some embodiments, the device 640 may comprise a treatment element with a monopolar electrode on one shaft and a molding element on the other shaft. Multiple configurations are contemplated. For example, the device may comprise one heat pipe and a bipolar electrode pair. For another example, the device may comprise one heat pipe and a monopolar electrode. For another example, the device may comprise two heat pipes and a monopolar electrode. Other device configurations are also possible.

[0189] The embodiments described with respect to Figs. 25A-27 employ specific differential cooling mechanisms to maintain different and particular temperatures in adjacent tissues. Figs. 28A-28E depicts various examples of more general mechanisms configured to maintain different temperatures in adjacent tissues. Figs. 28A-28E depict examples of differential cooling mechanisms as applied to a cross-section of tissue at the nasal valve, like that shown in Fig. 24A.

[0190] 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 skin 706. In such an embodiment, the first and second elements 708, 710 comprise a cooling apparatus such as those described above (e.g., heatsink, 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. 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. For example, the device 580, described with respect to Fig. 27, may use such a mechanism. 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. Again, the device 580, described with respect to Fig. 27, is an example of a device that may use such a mechanism.

[0191] 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.

[0192] 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.

[0193] 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.

[0194] 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.

[0195] Cooling occurring before, during, or after treatment may effect reduced temperature of the skin and/or mucosa. In some embodiments, attaching passive fins or other structures to the electrode or wand tip may allow for heat dissipation to the surrounding air. In some embodiments, the device may be configured to spray a cool

material such as liquid nitrogen before, during, or after treatment. Using a material such as copper for the passive fins or other structure may advantageously provide high heat and electrical conductivity. In some embodiments, using metals with a high heat capacity in the device (e.g., in the energy delivery element, the re-shaping element, or both) may advantageously provide the ability to resist temperature change during energy delivery. In some embodiments, pre-cooling the electrode (e.g., by refrigeration, submersion, spraying with a cool substance like liquid nitrogen, etc.) may maintain a reduced temperature at the mucosa. Any combination of the cooling methods described herein may be used in conjunction with any of the energy delivery methods described herein (e.g., bipolar RF electrodes, arrays needles, plates, etc.). For example, Fig. 29 depicts an embodiment of a device 800 comprising a treatment element 802 comprising electrode needles 804 at its distal tip. The device 800 may be used in conjunction with a separate cooling device 810 which may comprise channels 812 or cavities to circulate air or fluid. The independent cooling device 810 may, in other embodiments, employ a different cooling mechanism.

[0196] In embodiments using laser energy to heat cartilage, it is possible to use a combination of two or more lasers whose beams converge at a location within the target tissue. This convergence may cause more heat at that junction as compared to locations where only a single beam is acting. The junction may be controlled manually or via computer control. Specific treatment may be provided.

[0197] In some embodiments, insulating material may be used to protect non-target tissue during energy delivery. For example, an electrode needle may be preferentially insulated on a portion of the needle that is in contact with non-target tissue. For another example, flat electrode blades may be insulated on a portion of the blade that is in contact with non-target tissue. Other configurations for heat isolation are also possible.

[0198] Any of the cooling mechanisms or combinations of the cooling mechanisms described herein may be used in conjunction with any of the devices or combinations of devices described herein, or the like.

Examples of Methods of Treatment

[0199] Embodiments of methods for treating nasal airways are now described. Such methods may treat nasal airways by decreasing the airflow resistance or the perceived airflow resistance at the site of an internal or external nasal valve. Such treatments may also address related conditions, such as snoring.

[0200] In one embodiment, a method of decreasing airflow resistance in a nasal valve comprises the steps of inserting an energy-delivery or cryo-therapy device into a nasal passageway, and applying energy or cryo-therapy to a targeted region or tissue of the nasal passageway. For example, in some embodiments, the method may include delivering energy or cryo-therapy to a section of internal nasal valve cartilage in the area of the upper lateral cartilage, or in the area of intersection of the upper and lower lateral cartilage. In alternative embodiments, the method may deliver energy to the epithelium, or underlying soft tissue adjacent to the upper lateral cartilage and/or the intersection of the ULC and the LLC.

[0201] In another embodiment, a method comprises heating a section of nasal valve cartilage to be re-shaped, applying a mechanical re-shaping force, and then removing the heat. In some embodiments, the step of applying a mechanical re-shaping force may occur before, during or after the step of applying heat.

[0202] In some embodiments, the method may further include the step of inserting a re-shaping device into the nasal passageway after applying an energy or cryo-therapy treatment. In such embodiments, a re-shaping device such as an external adhesive nasal strip (such as those described for example in US Patent 5,533,499 to Johnson or US Patent 7,114,495 to Lockwood, the entirety of each of which is hereby incorporated by reference) may be applied to the exterior of the nose after the treatment in order to allow for long-term re-shaping of nasal valve structures as the treated tissues heal over time. In alternative embodiments, a temporary internal re-shaping device (such as those taught in U.S. Pat. No. 7,055,523 to Brown or U.S. Pat. No. 6,978,781 to Jordan, the entirety of each of which is hereby incorporated by reference) may be placed in the nasal passageway after treatment in order to allow for long-term re-shaping of nasal valve

structures as the treated tissues heal over time. In some embodiments, the dilating nasal strips can be worn externally until healing occurs.

[0203] In alternative embodiments, internal and/or external re-shaping devices may be used to re-shape a nasal valve section prior to the step of applying energy or cryo-therapy treatments to targeted sections of the epithelial, soft tissue, mucosa, submucosa and/or cartilage of the nose. In some embodiments, the energy or cryo-therapy treatment may be configured to change the properties of treated tissues such that the tissues will retain the modified shape within a very short time of the treatment. In alternative embodiments, the treatment may be configured to re-shape nasal valve structures over time as the tissue heals.

[0204] In some embodiments, a portion of the nose, the nasal valve and/or the soft tissue and cartilage of the nasal valve may be reshaped using a re-shaping device and then fixed into place. In some embodiments, such fixation may be achieved by injecting a substance such as a glue, adhesive, bulking agent or a curable polymer into a region of the nasal tissue adjacent the target area. Alternatively, such a fixation substance may be applied to an external or internal surface of the nose.

[0205] In some embodiments, an injectable polymer may be injected into a region of the nose, either below the skin on the exterior of the nose, or under the epithelium of the interior of the nose. In some embodiments, an injectable polymer may include a two-part mixture configured to polymerize and solidify through a purely chemical process. One example of a suitable injectable two-part polymer material is described in US Patent Application Publication 2010/0144996, the entirety of which is hereby incorporated by reference. In other embodiments, an injectable polymer may require application of energy in order to cure, polymerize or solidify. A re-shaping device may be used to modify the shape of the nasal valve before or after or during injection of a polymer. In embodiments employing an energy-curable polymer, a re-shaping device may include energy-delivery elements configured to deliver energy suitable for curing the polymer to a desired degree of rigidity.

[0206] In another embodiment, the soft tissue of the upper lip under the nares may be debulked or reshaped to reduce airflow resistance. In some embodiments, such

re-shaping of the upper lip soft tissue may be achieved by applying energy and/or cryotherapy from an external and/or internal treatment element. In some embodiments, the tissue of the upper lip under the nares may be compressed by an internal or external device prior to or during application of the energy or cryo-therapy. For example, devices such as those shown in FIGs. 5A and 5B may be adapted for this purpose by providing tissue-engaging clamp tips shaped for the purpose.

[0207] In another embodiment, the muscles of the nose and/or face are stimulated to dilate the nasal valve area prior to or during application of other treatments such as energy/cryo application or fixation treatments. In such embodiments, the muscles to be treated may include the nasal dilator muscles (nasalis) the levetator labii, or other facial muscles affecting the internal and/or external nasal valves. In some embodiments, the targeted muscles may be stimulated by applying an electric current to contract the muscles, mentally by the patient, or manually by the clinician.

[0208] In some embodiments, the muscles of the nose and/or face may also be selectively deactivated through chemical, ablative, stimulatory, or mechanical means. For example, muscles may be deactivated by temporarily or permanently paralyzing or otherwise preventing the normal contraction of the muscle tissue. Chemical compounds for deactivating muscle tissues may include botulinum toxin (aka "botox"), or others. Ablative mechanisms for deactivating muscle tissue may include RF ablation, laser ablation or others. Mechanical means of deactivating muscle tissues may include one or more surgical incisions to sever targeted muscle tissue.

[0209] In another embodiment, the tissue of the nasal valve may be reshaped by applying energy to the internal and external walls of the nasal valve using a clamp like device as illustrated for example in FIGs. 5A and 5B. One arm of the clamp may provide inward pressure to the external, skin side tissue covering the nasal valve and the other side of the clamp may provide outward pressure to the mucosal tissue on the lateral wall of the nasal airway above the ULC and LLC or both.

[0210] In some embodiments, energy may be applied to the skin of the nose to effect a shrinkage of the skin, epidermis, dermis, subdermal, subcutaneous, tendon, ligament, muscle, cartilage and/or cartilage tissue. The tissue shrinkage is intended to

result in a change of forces acting on the tissues of the nasal valve to improve airflow through the nasal airway.

[0211] In another embodiment, the nasal valve tissue may be damaged or stimulated by energy application, incisions, injections, compression, or other mechanical or chemical actions. Following such damage, a device may be used on the tissue to mold or shape the tissue of the valve during healing. In some embodiments, such a re-shaping device may be temporarily placed or implanted inside or outside the patient's nose to hold a desired shape while the patient's healing process progresses.

[0212] In another embodiment, the aesthetic appearance of the nose may be adjusted by varying the device design and/or treatment procedure. The predicted post-procedure appearance of the nose may be shown to the patient through manipulating the nasal tissue to give a post procedure appearance approximation. The patient may then decide if the predicted post procedure appearance of the face and nose is acceptable or if the physician needs to change parameters of the device or procedure to produce an appearance more acceptable to the patient.

[0213] In another embodiment, reduction of the negative pressure in the nasal airway can be effected to reduce collapse of the structures of the nasal airway on inspiration without changing a shape of the nasal valve. For example, this may be accomplished by creating an air passage that allows flow of air directly into the site of negative pressure. One example of this is creating a hole through the lateral wall of the nose allowing airflow from the exterior of the nose through the nasal wall and into the nasal airway.

[0214] In another embodiment, energy, mechanical or chemical therapy may be applied to the tissue of the nasal airway with the express purpose of changing the properties of the extracellular matrix components to achieve a desired effect without damaging the chondrocytes or other cells of the nasal airway tissue.

[0215] In some embodiments, devices (e.g., devices like those described with respect to Figs. 9A-21B) may be used to provide tissue re-shaping/molding and to impart energy to the nasal valve. The electrode may be placed in contact with the target nasal valve tissue. The electrodes and molds may be moved to shape the tissue as necessary to

achieve improvement in nasal airway. The electrodes may be activated while the tissue is deformed in the new shape to treat the tissue. The electrode may then be deactivated and the device may be removed from the nasal valve area.

[0216] Figs. 30A-30D depict a method for using a device 900 similar to those devices described above, including but not limited to Figs. 8A, 9B, 18, 22A-G, and 23A-G, to provide tissue re-shaping/molding and to impart energy to tissue near the nasal valve.

[0217] The method may include identifying a patient who desires to improve the airflow through their nasal passageways and/or who may benefit from an increase in a cross-sectional area of the opening of the nasal valve. The patient may be positioned either in an upright position (e.g., seated or standing) or be lying down. Local anesthesia may be applied to an area near or surrounding the tissue to be treated. General anesthesia may also be used.

[0218] Optionally, a positioning element, like that described herein, may be used to measure a desired depth or angle of treatment. As described above, the positioning element may be inserted to the desired depth of treatment and rotated to a desired angle of treatment. Marks along the positioning element can indicate the desired depth. Marks along the base of the shaft of the positioning element can indicate the desired angle. The physician or other medical professional administering the treatment can then insert the treatment device to the desired location. The physician may also assess any other characteristics relevant to the treatment of the patient's nose that may influence the manner of treatment. In some embodiments, a re-shaping element may be used to manipulate the nasal tissue into a configuration allowing improved airflow; and treatment may be performed while such a re-shaping element is maintaining the desired configuration of the nasal tissue.

[0219] If the treatment device comprises a monopolar electrode or electrode needles, a ground pad may be attached to the patient. The ground pad may be attached at the patient's torso, for example the shoulder or abdomen. Other locations are also possible, such as the patient's buttocks. Preferably, the point of attachment is a large, fleshy area. After being attached, the ground pad may be plugged into a power source. If

the device is powered by a remote generator (e.g., RF generator), the device may then be plugged into the generator.

[0220] Fig. 30A depicts the nose of a patient prior to insertion of the device. As shown in Fig. 30B, the device is then inserted into a nostril of the patient. The treatment element 802 of the device 800 may be positioned within the nasal airway, adjacent to nasal tissue (e.g., upper lateral cartilage) to be treated. The treatment element 802 may be positioned so that the electrode is in contact with the tissue to be treated. The device 800 (as shown in Fig. 30C) comprises multiple needle electrodes 804. The needle electrodes 804 may be inserted so that they are penetrating or engaging tissue to be treated.

[0221] The treatment element 802 may be used to deform the nasal tissue into a desired shape by pressing a convex surface of the treatment element 802 against the nasal tissue to be treated. Fig. 30C shows an internal view, from the nares, of the treatment element 802 pushing against the upper lateral cartilage 806 of the nose, deforming the upper lateral cartilage 806 and increasing the area of the opening of the nasal valve 808. Fig. 30D depicts an external view of the treatment element 802 deforming the upper lateral cartilage 806. Even from the outside, the nose appears to be bulging near the area to be treated. In some embodiments, the deformation required to treat the nose is not visually detectable. A control input such as button 814 may be used to activate the electrode and deliver energy (e.g., RF energy) to the tissue to be treated.

[0222] In some embodiments, temperature of the area around the electrode during treating is from about 30° C to about 90° C. In some embodiments, temperature of the area around the electrode during treating is from about 40° C to about 80° C. In some embodiments, temperature of the area around the electrode during treating is from about 50° C to about 70° C. In some embodiments, temperature of the area around the electrode during treating is about 60° C. In some embodiments, for example during cryo-therapy, temperature of the area around the electrode may be lower.

[0223] In some embodiments, treating the target tissue comprises treatment for about 1s to about 3 minutes. In some embodiments, treating the target tissue comprises treatment for about 10 s to about 2 minutes. In some embodiments, treating

the target tissue comprises treatment for about 15 s to about 1 minute. In some embodiments, treating the target tissue comprises treatment for about 20 s to about 45 s. In some embodiments, treating the target tissue comprises treatment for about 30 s.

[0224] In some embodiments, treating the target tissue comprises delivering between about 1 and about 100 watts to the tissue. In some embodiments, treating the target tissue comprises delivering between about 5 and about 75 watts to the tissue. In some embodiments, treating the target tissue comprises delivering between about 10 and about 50 watts to the tissue.

[0225] As shown in Figs. 30B and 30D, a thermocouple 812 may be provided on the electrode (e.g., as described with reference to Figs. 22G and 27). In some embodiments, more than one thermocouple may be provided. For example, in embodiments comprising more than one electrode or electrode pair, each electrode or electrode pair may comprise a thermocouple. The thermocouple 812 may monitor temperature of the electrode and provide feedback to a control unit (e.g., control system 42 described with respect to Fig. 3). The control unit may use the data from the thermocouple 812 to regulate temperature and auto-shutoff once treatment has been achieved or in the case of an overly high temperature.

[0226] After treating the tissue, the device 800 may be removed from the nostril. If a grounding pad is used, the grounding pad may be detached from the patient.

[0227] In some embodiments, differential cooling mechanisms may be used to treat the nasal valve using electrodes or other energy delivery elements while maintaining a reduced temperature at the skin and/or mucosa. For example, devices like those described with respect to Figs. 25A-27 or devices employing the differential cooling mechanisms described with respect to Figs. 28A-28E may be used. The cooling system may be activated. The device may then be inserted into the nose and placed in contact with the nasal vale. The device may then be activated. Activation of the device may cause an increase in the cartilage temperature while minimizing the temperature increase in the skin and/or mucosa. The device may then be deactivated and removed from the nose.

[0228] In some embodiments, devices may be used in which insulating material is used to protect non-target tissue during energy delivery. In an embodiment, a device comprises an electrode needle preferentially insulated on a portion of the needle. The needle may be inserted into the cartilage so that the insulated portion is in contact with the mucosa and/or the skin and the non-insulated portion is in contact with the cartilage. The device may be activated, causing an increase in the cartilage temperature while mininuizing temperature increase in the skin and/or mucosa. The device may be deactivated and removed from the nose.

[0229] 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.

What is Claimed is:

1. A device for treating a patient's nasal airway, 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.

2. The device of claim 1, wherein the energy delivery element is configured to be positioned internally within the nose.

3. The device of any of the preceding claims, wherein the energy delivery element comprises a convex shape configured to create a concavity in nasal tissue.

4. The device of any of any of the preceding claims, further comprising:

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

a handle at the proximal end of the elongate shaft,

wherein the energy delivery element is positioned at the distal end of the elongate shaft, the energy delivery element comprising an electrode configured to deliver radiofrequency (RF) energy to nasal tissue.

5. The device of claim 4, wherein the handle comprises a button configured to activate the electrode.

6. The device of any of claims 1-5, wherein the energy delivery element comprises one or more monopolar needles.

7. The device of any of claims 1-5, wherein the energy delivery element comprises a monopolar plate electrode.

8. The device of any of claims 6-7, further comprising a grounding pad.

9. The device of any of claims 1-5, wherein the energy delivery element comprises one or more bipolar electrode pairs.

10. The device of claim 9, wherein a first electrode surface of a bipolar electrode pair is positionable internal to the nose and a second electrode surface of a bipolar electrode pair is positionable external to the nose, so that the two electrode surfaces are positionable on opposite sides of nasal tissue.

11. The device of claim 10, wherein the first electrode surface comprises one or more needles or a plate and the second electrode surface comprises one or more needles or a plate.

12. The device of any of the preceding claims, further comprising an adaptor configured to be connected to an energy source.

13. The device of any of the preceding claims, further comprising a control system configured to control the characteristics of energy applied to tissue.

14. The device of any of the preceding claims, further comprising a thermocouple configured to measure a temperature near tissue to be treated.

15. The device of any of the preceding claims, comprising a re-shaping element having a shape configured to alter a conformation of a region of the nose to a new conformation.

16. The device of claim 15, wherein the energy delivery element and the re-shaping element are separate elements.

17. The device of claim 15, wherein the energy delivery element and the re-shaping element are part of the same element.

18. The device of any of claims 15-17, wherein the energy delivery element and the re-shaping element are both configured to be positioned within a single nostril.

19. The device of claim 16, wherein the energy delivery element and the re-shaping element are configured to be positioned on opposite sides of nasal tissue.

20. A system for treating a patient's nasal airway, the system comprising:
the device of any of claims 1-19; and
an energy source.

21. The system of claim 20, further comprising a cooling mechanism.

22. A method of treating a patient's nasal airway using the device or system of any of claims 1-21.

23. A method of treating a patient's nasal airway by altering a structure, shape or conformation of one or more nasal structures in an area of a nasal valve by applying a treatment sufficient to modify, by reshaping, tissue at or adjacent to the nasal valve.

24. The method of claim 23, wherein the treatment is applied without a surgical incision or surgical implant.

25. The method of any of claims 23-24, further comprising:

positioning a treatment element adjacent to nasal tissue to be treated, wherein the treatment element comprises one or more electrodes;

deforming the nasal tissue into a desired shape by pressing a surface of the treatment element against the nasal tissue to be treated;

delivering radiofrequency (RF) energy to the one or more electrodes to locally heat the nasal tissue, wherein delivering RF energy while deforming the nasal tissue causes the nasal tissue to change shape; and

removing the treatment element from the nasal airway.

26. The method of any of claims 23-24, wherein applying a treatment comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser.

27. The method of any of claims 25-26, wherein delivering energy comprises delivering energy to at least one of the nasal valve, tissue near the nasal valve, or upper lateral cartilage tissue.

28. The method of any of claims 25-26, further comprising cooling nasal tissue to be treated or tissue near the nasal tissue to be treated before, during, or after delivering energy.

29. The method of any of claims 25-28, wherein delivering energy comprises:

measuring a temperature near the nasal tissue to be treated; and

adjusting a level of energy delivered to the tissue.

30. The method of any of claims 25-29, wherein delivering energy comprises delivering energy to one or more electrodes for about 15 seconds to about 1 minute.

31. The method of any of claims 25-30, wherein delivering energy to the one or more electrodes comprises heating an area of tissue surrounding the one or more electrodes to a temperature of about 50° C to about 70° C.

32. The method of any of claims 23-31, further comprising using a positioning element to determine a desired position of a treatment element.

33. The method of any of claims 23-32, wherein applying treatment causes stress relaxation in the nasal tissue without weakening the tissue.

34. The method of any of claims 23-32, wherein applying a treatment comprises injuring a tissue to be re-shaped.

35. The method of any of claims 23-24, wherein applying a treatment comprises injecting a polymerizing liquid.

36. The method of any of claims 23-24, wherein applying a treatment comprises delivering a cauterizing agent to nasal tissue to be treated.

37. The method of any of claims 23-36, wherein the altering a structure, shape or conformation of one or more nasal structures in an area of a nasal valve is performed by positioning a treatment element within a nasal passageway.

38. The method of Claim 37, wherein the treatment element is used to simultaneously mechanically alter the shape of the internal or external nasal valve and apply treatment to tissue of the nose.

39. The method of any of claims 23-38 wherein applying treatment comprises modifying a nasal structure in a manner that increases a volumetric airflow rate of air flowing from an exterior of the patient's body into the patient's nasopharynx without changing a shape of an internal nasal valve, said modifying comprising modifying a mechanical property of at least one nasal valve.

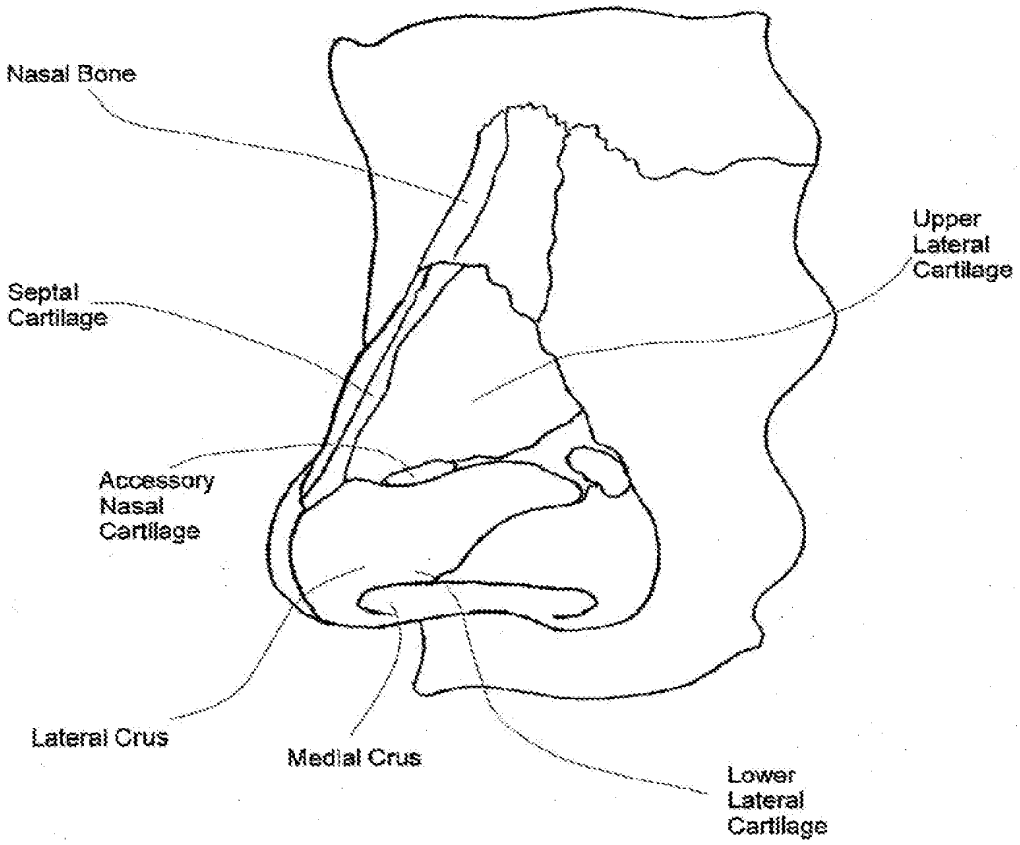

Nasal Bone
Upper Lateral Cartilage
Septal Cartilage
Accessory Nasal Cartilage
Lateral Crus
Medial Crus
Lower Lateral Cartilage

FIG. 1

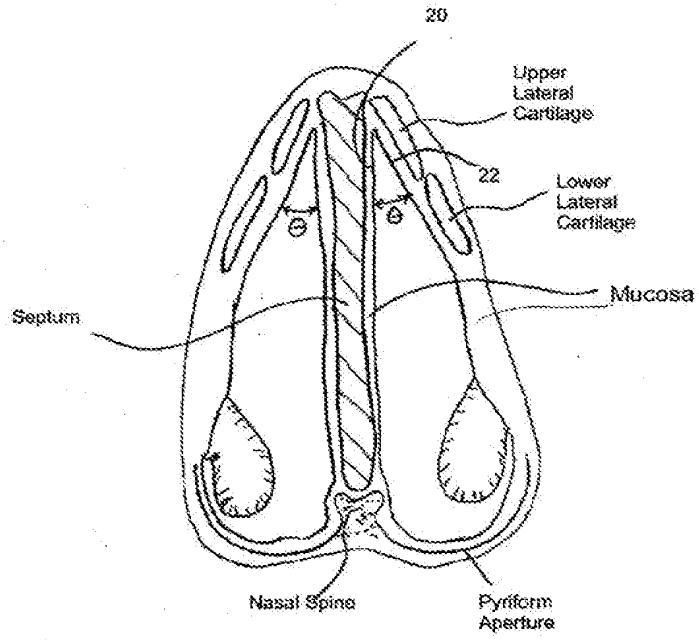

20
Upper Lateral Cartilage
22
Lower Lateral Cartilage
Mucosa
Septum
Nasal Spine
Pyriform Aperture

FIG. 2A

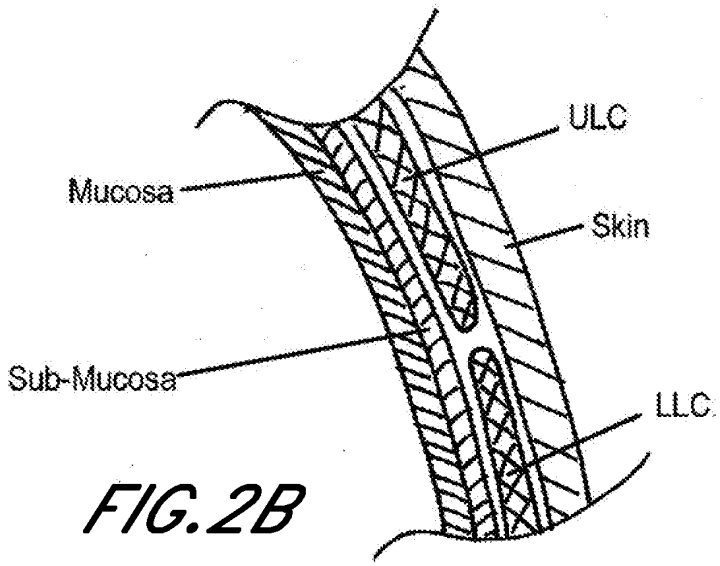

ULC
Mucosa
Skin
Sub-Mucosa
LLC

FIG. 2B

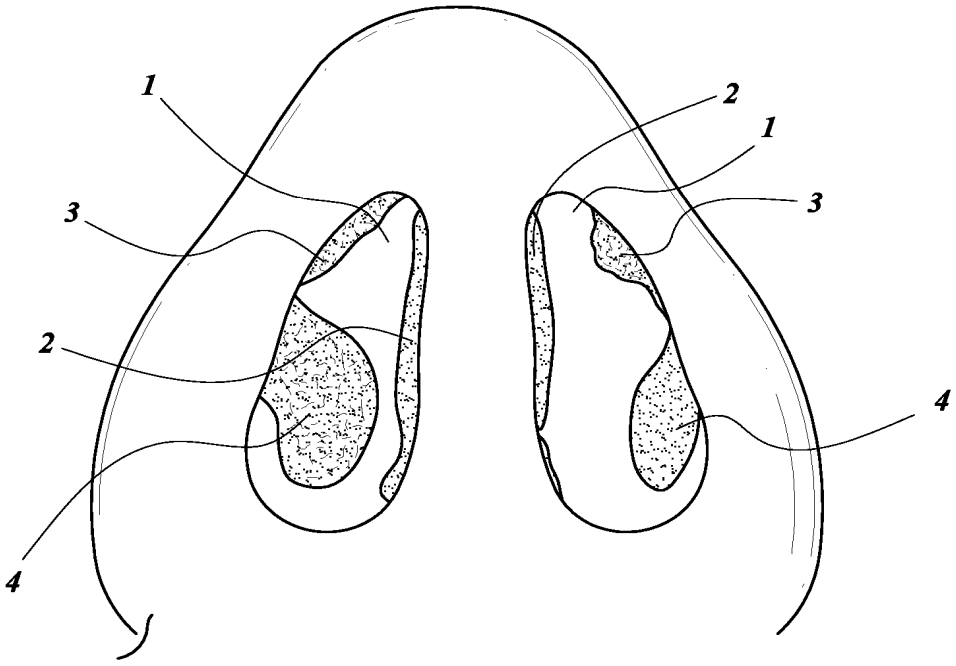


FIG. 2C

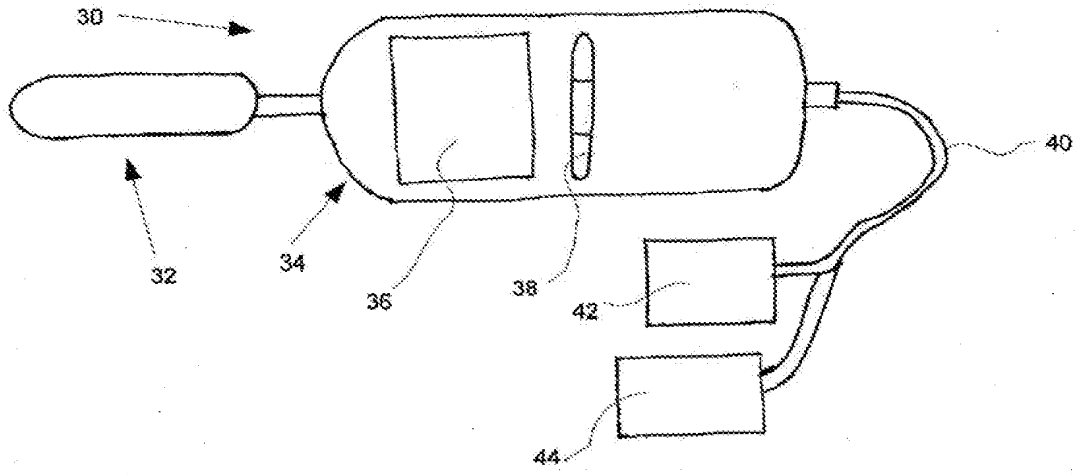


FIG. 3

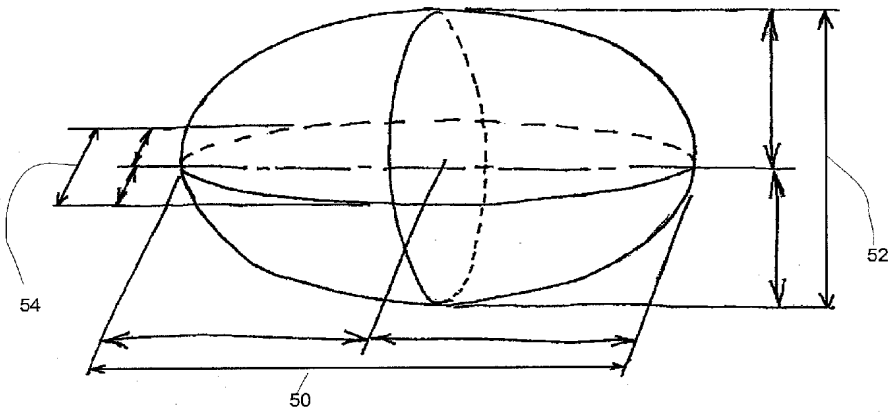


FIG. 4A

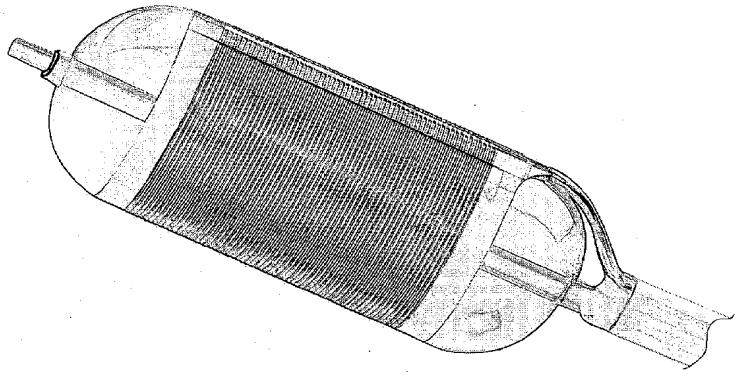


FIG. 4B

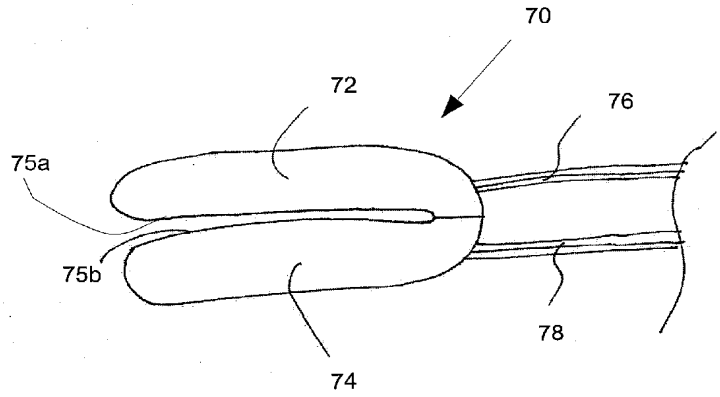


FIG. 4C

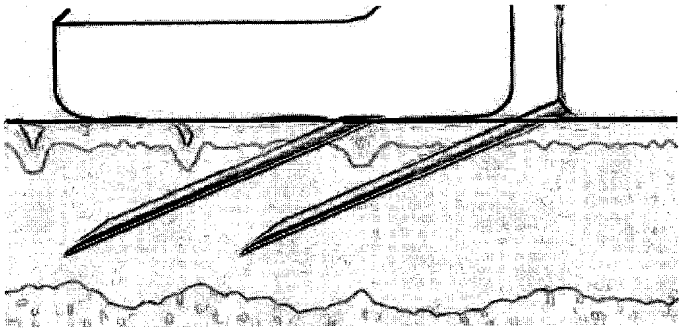


FIG. 4D

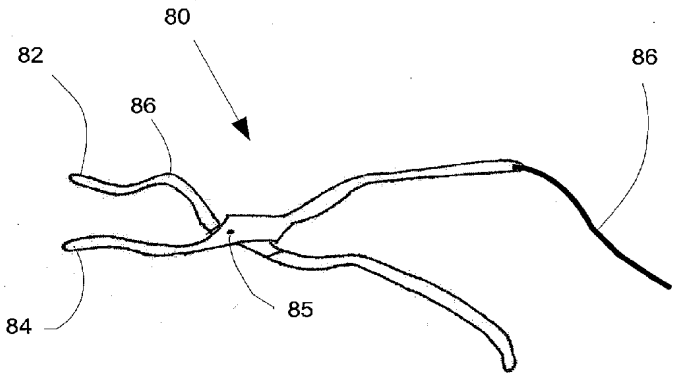


FIG. 5A

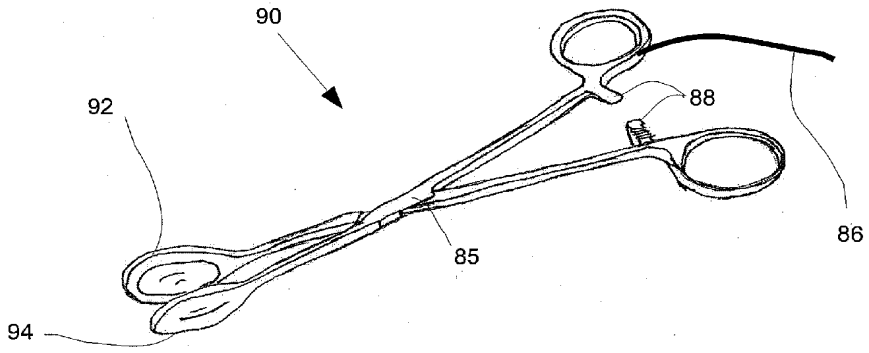


FIG. 5B

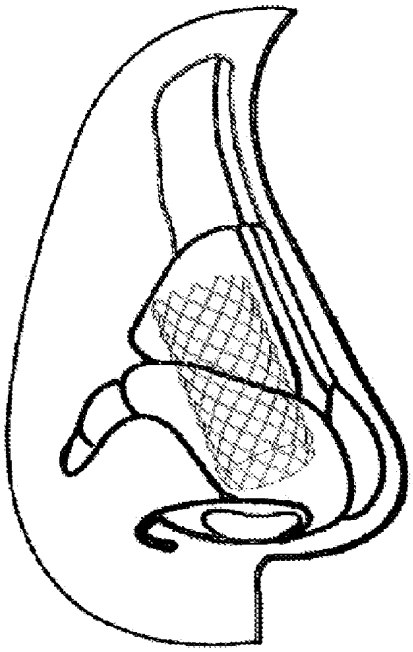


FIG. 6

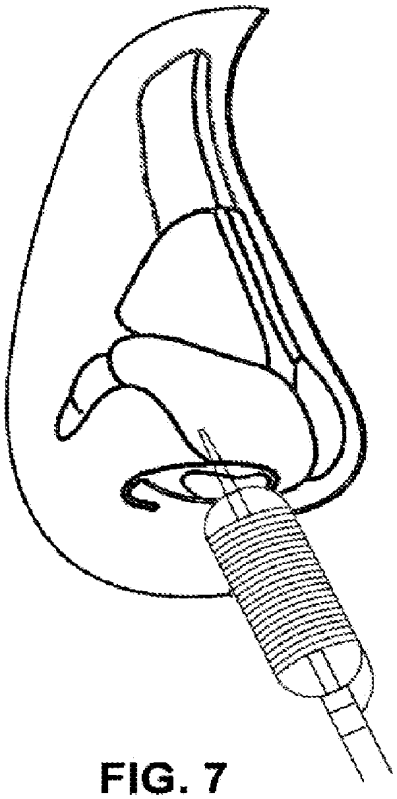


FIG. 7

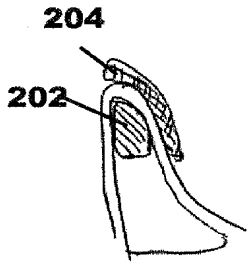


FIG. 8A

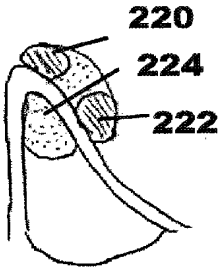


Fig. 8C

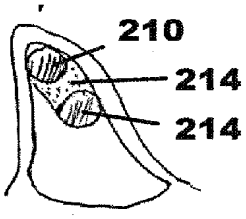


Fig. 8B

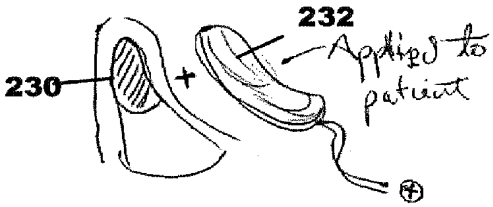


Fig. 8D

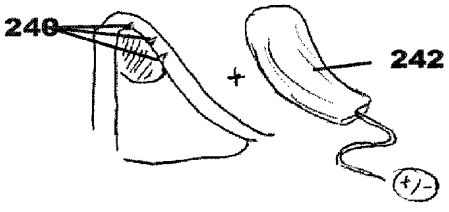


Fig. 8E

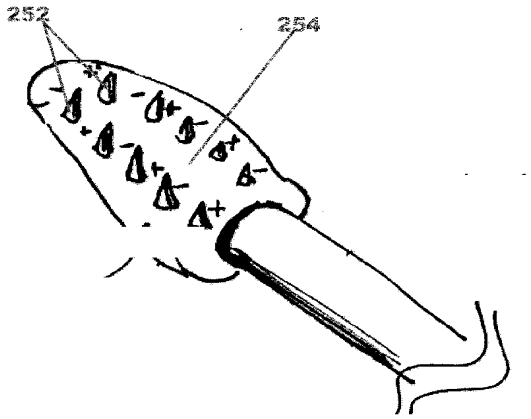


Fig. 8F

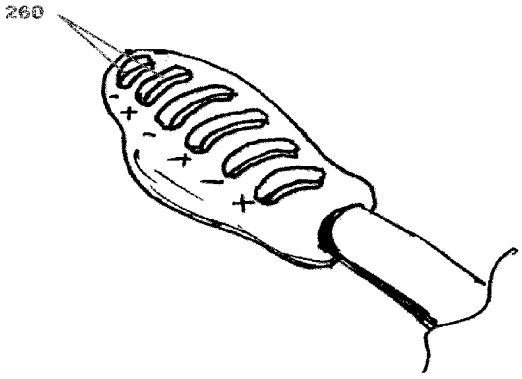


Fig. 8G

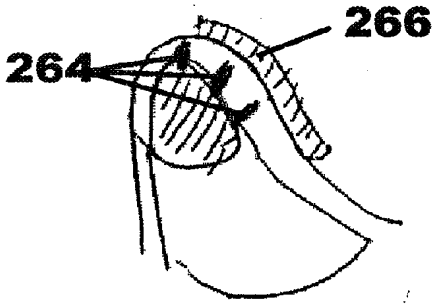


Fig. 8H

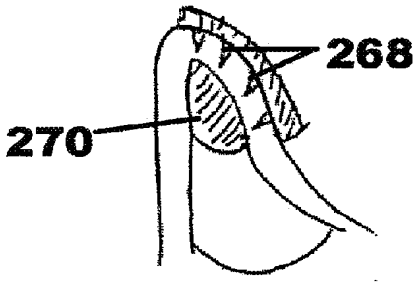


Fig. 8I

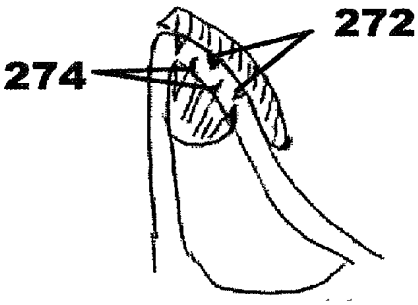


Fig. 8J

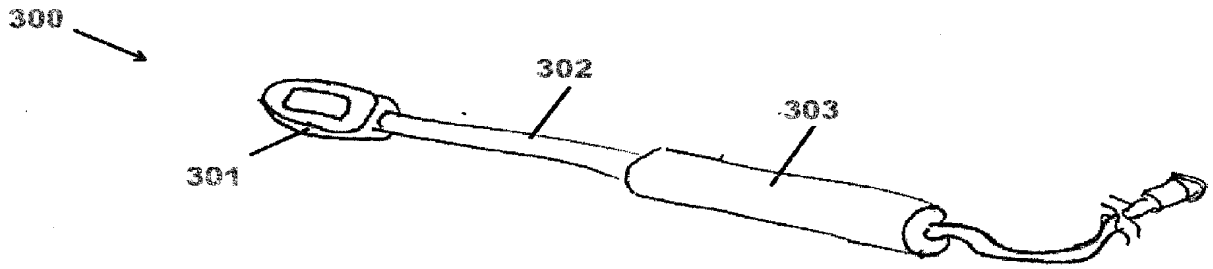


Fig. 9A

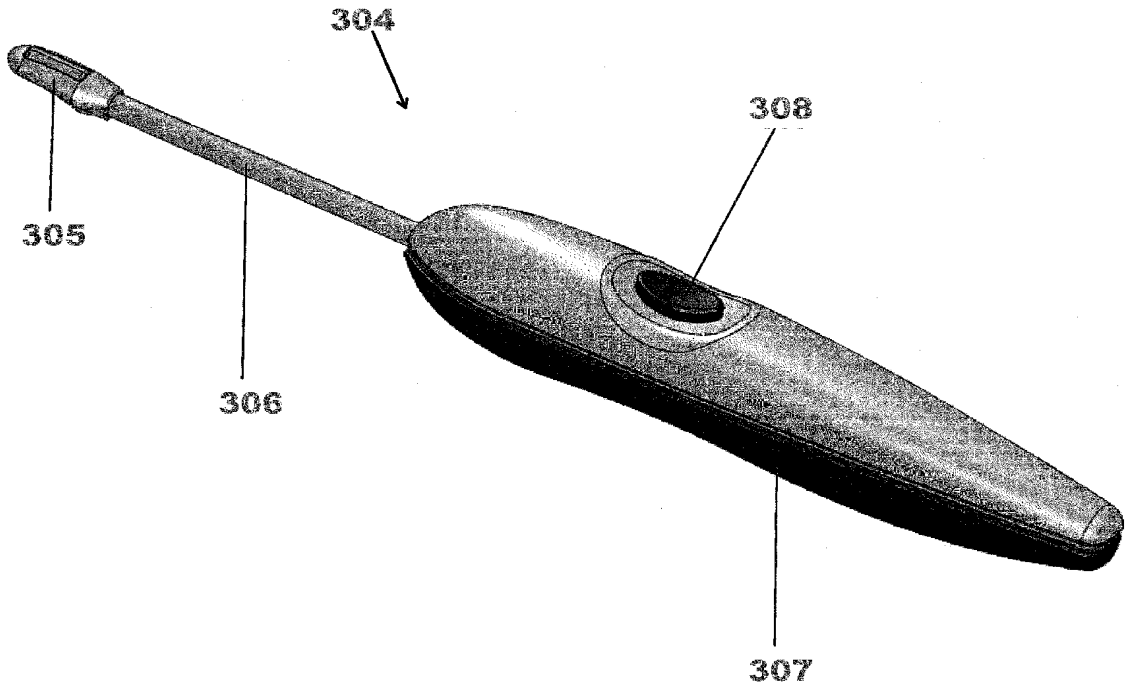


Fig. 9B

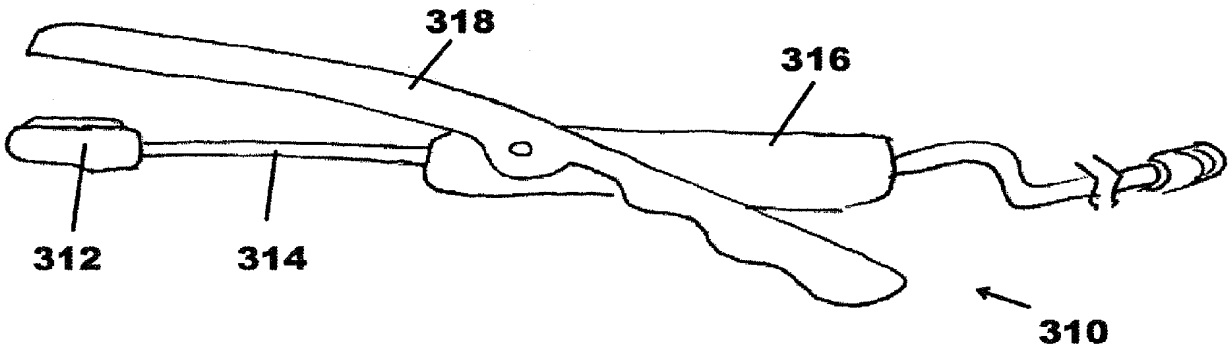


Fig. 10A

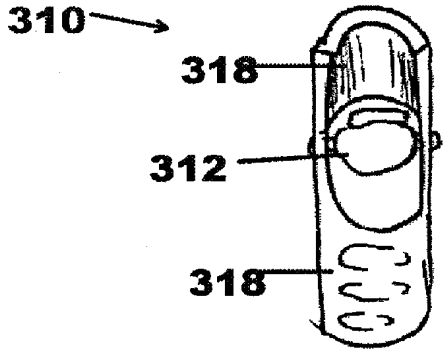


FIG. 10B

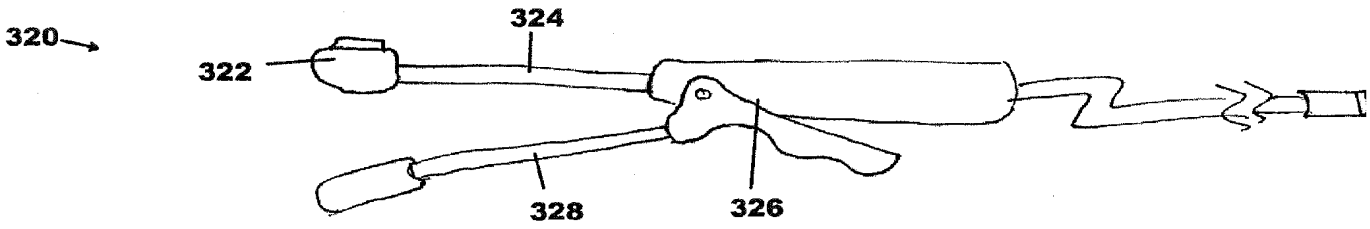


FIG. 11A

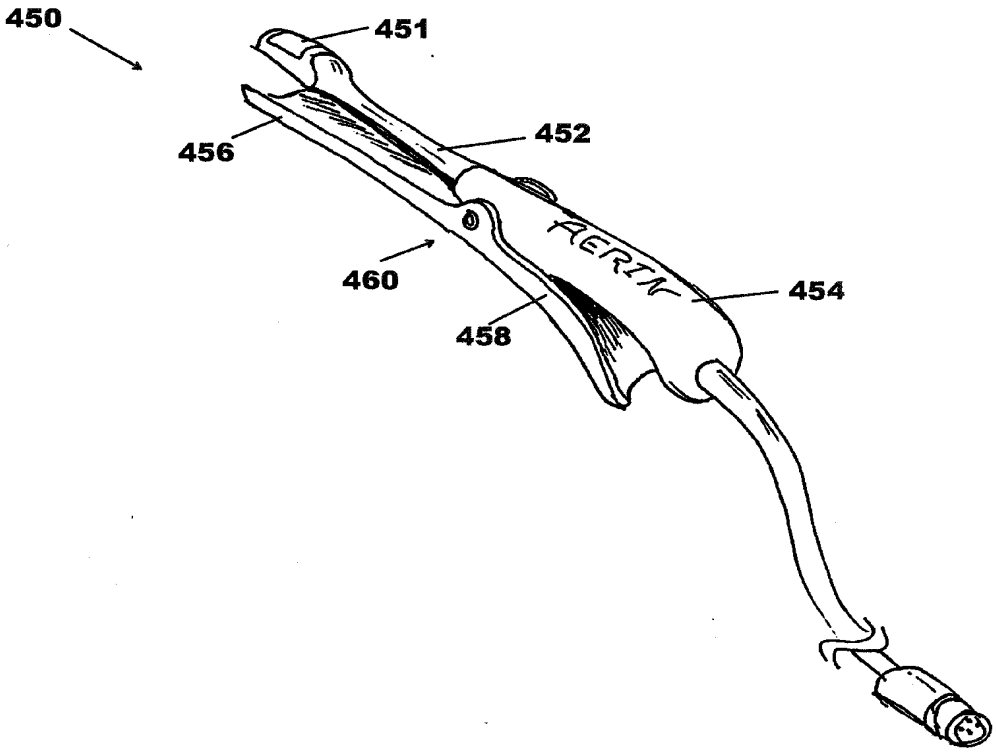


FIG. 11B

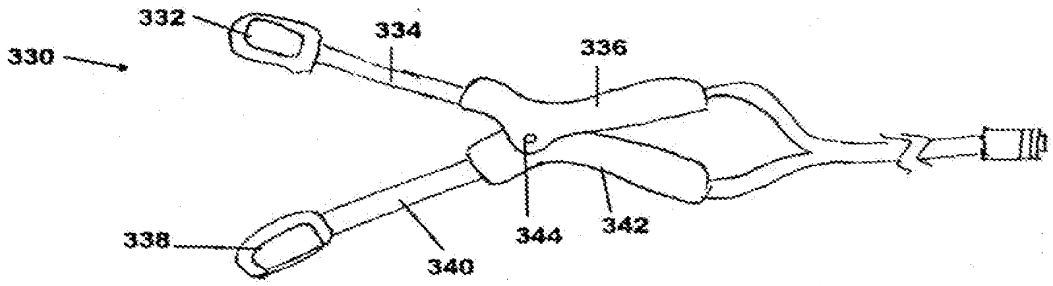


FIG. 12A

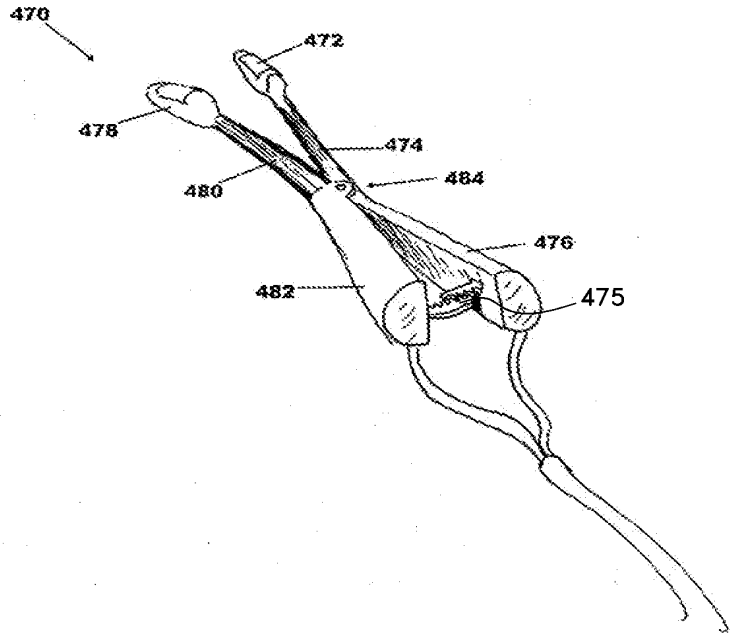


FIG. 12B

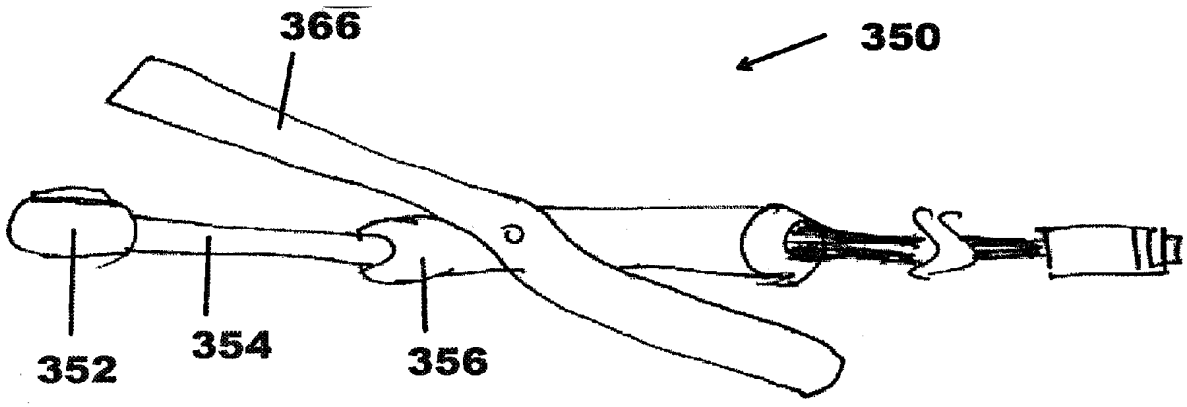


FIG. 13A

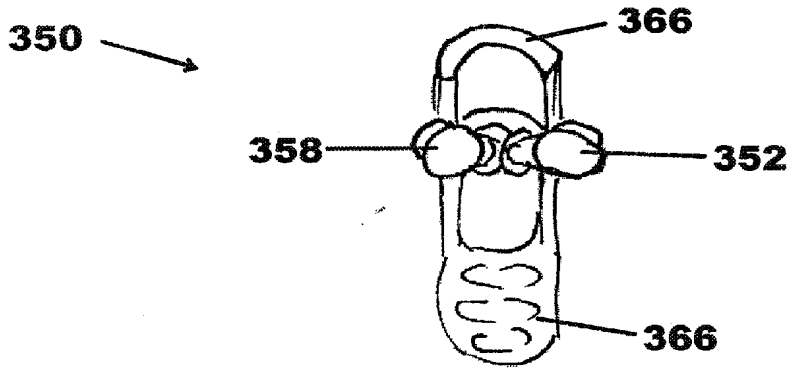


FIG. 13B

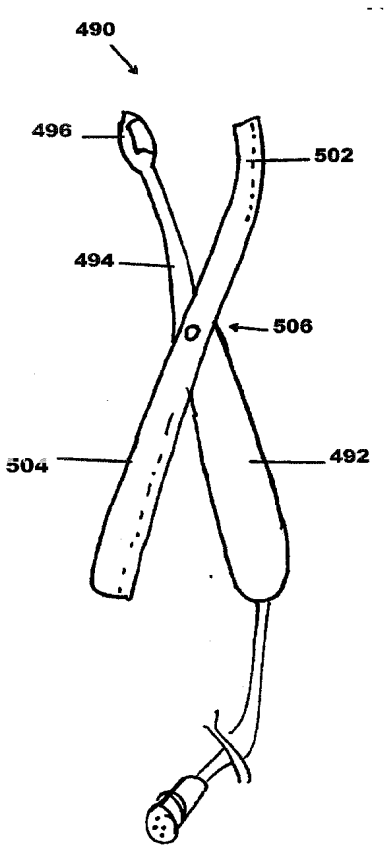


FIG. 13C

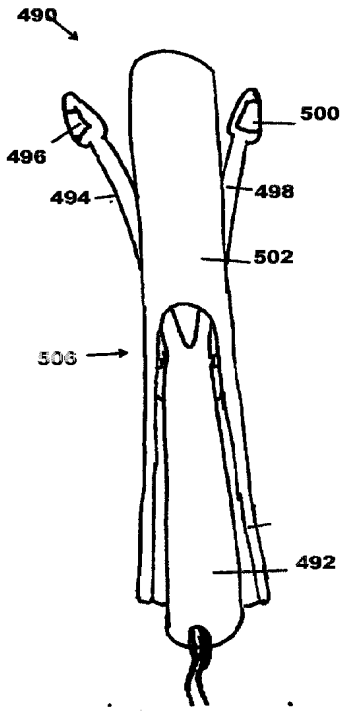


FIG. 13D

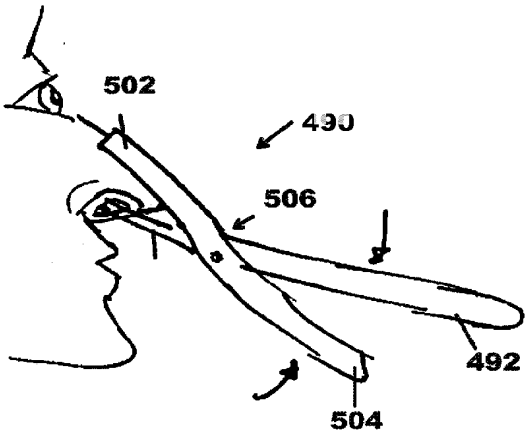


FIG. 13E

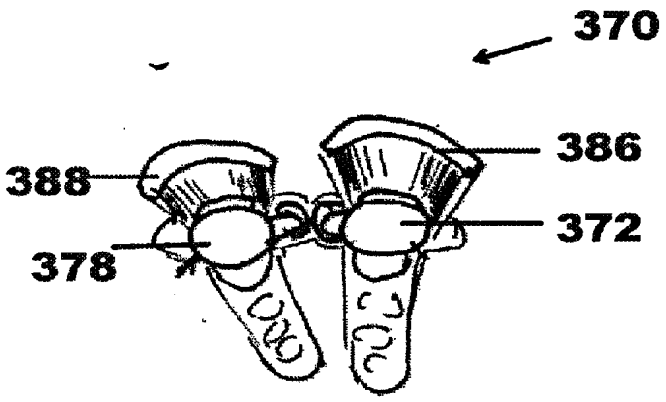


FIG. 14A

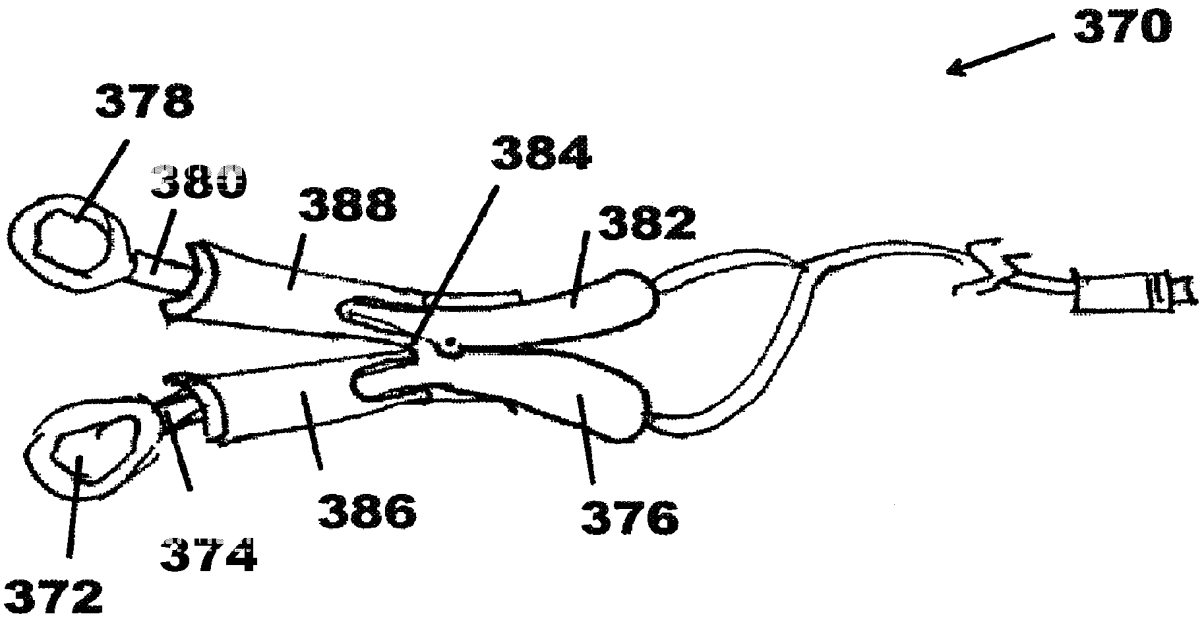


FIG. 14B

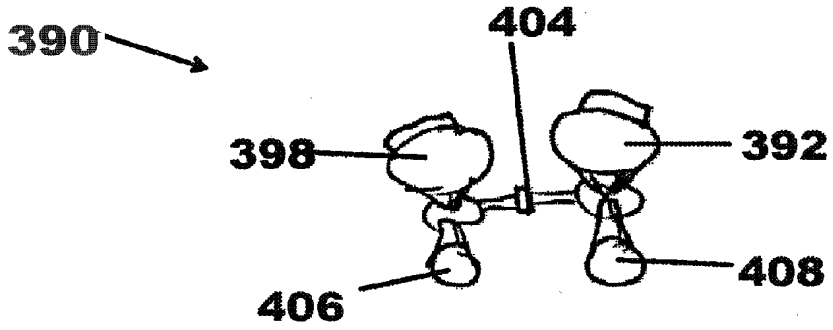


FIG. 15A

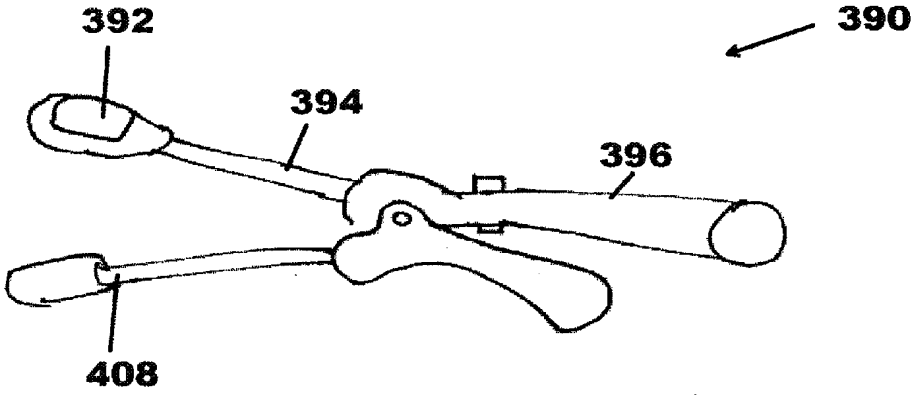


FIG. 15B

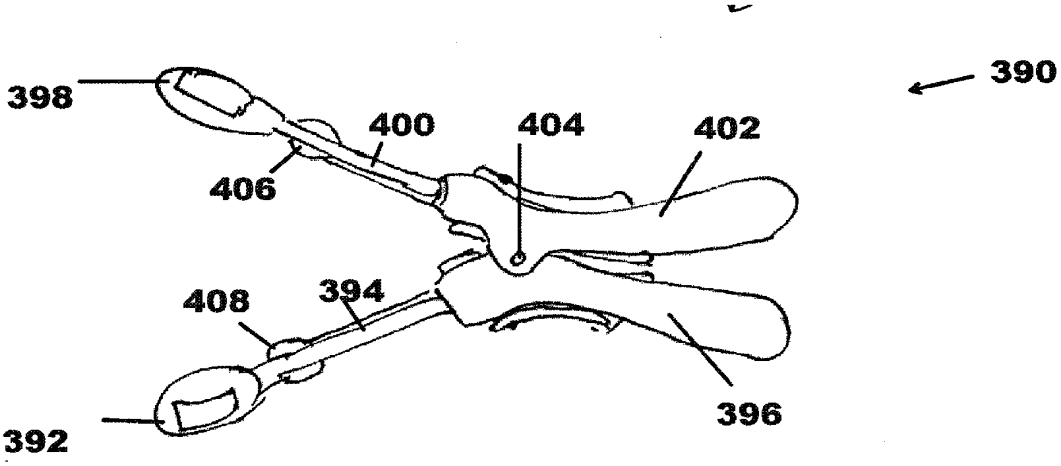


FIG. 15C

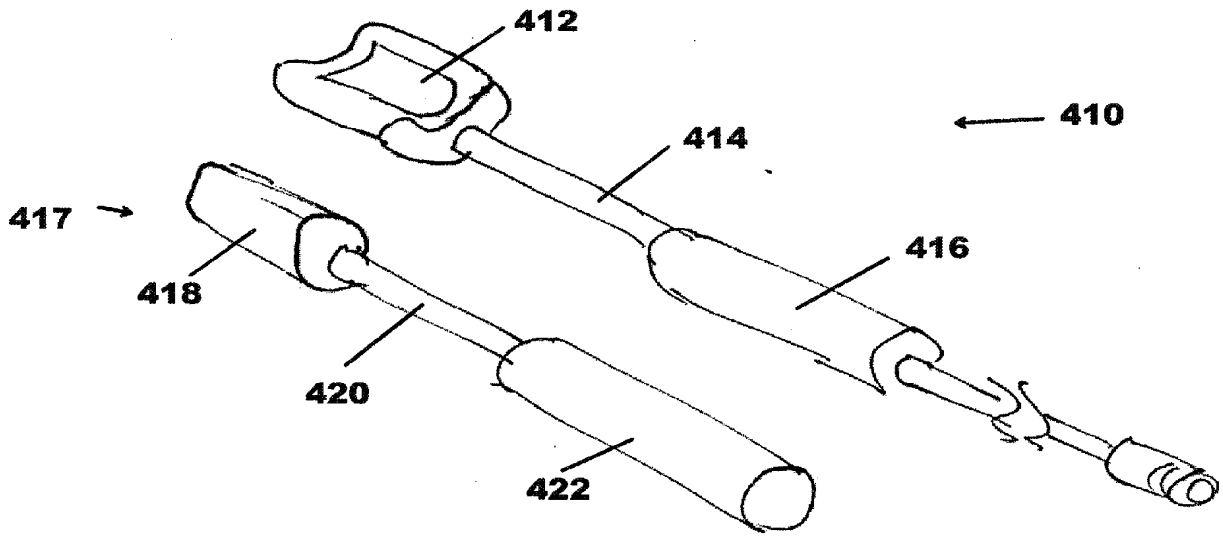


FIG. 16

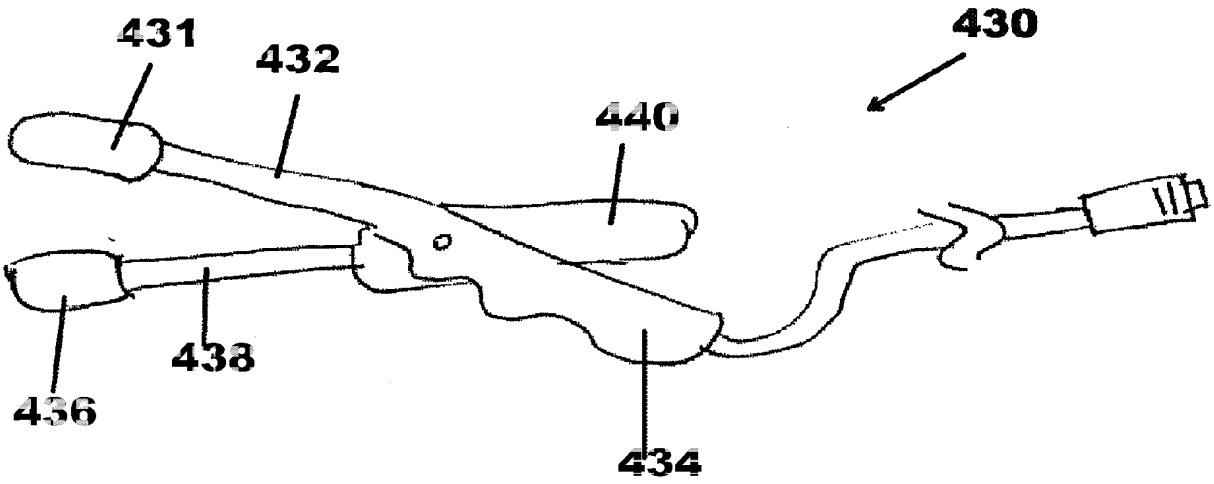


FIG. 17A

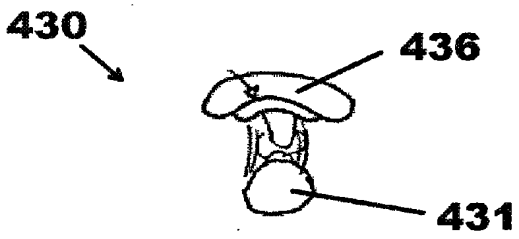


FIG. 17B

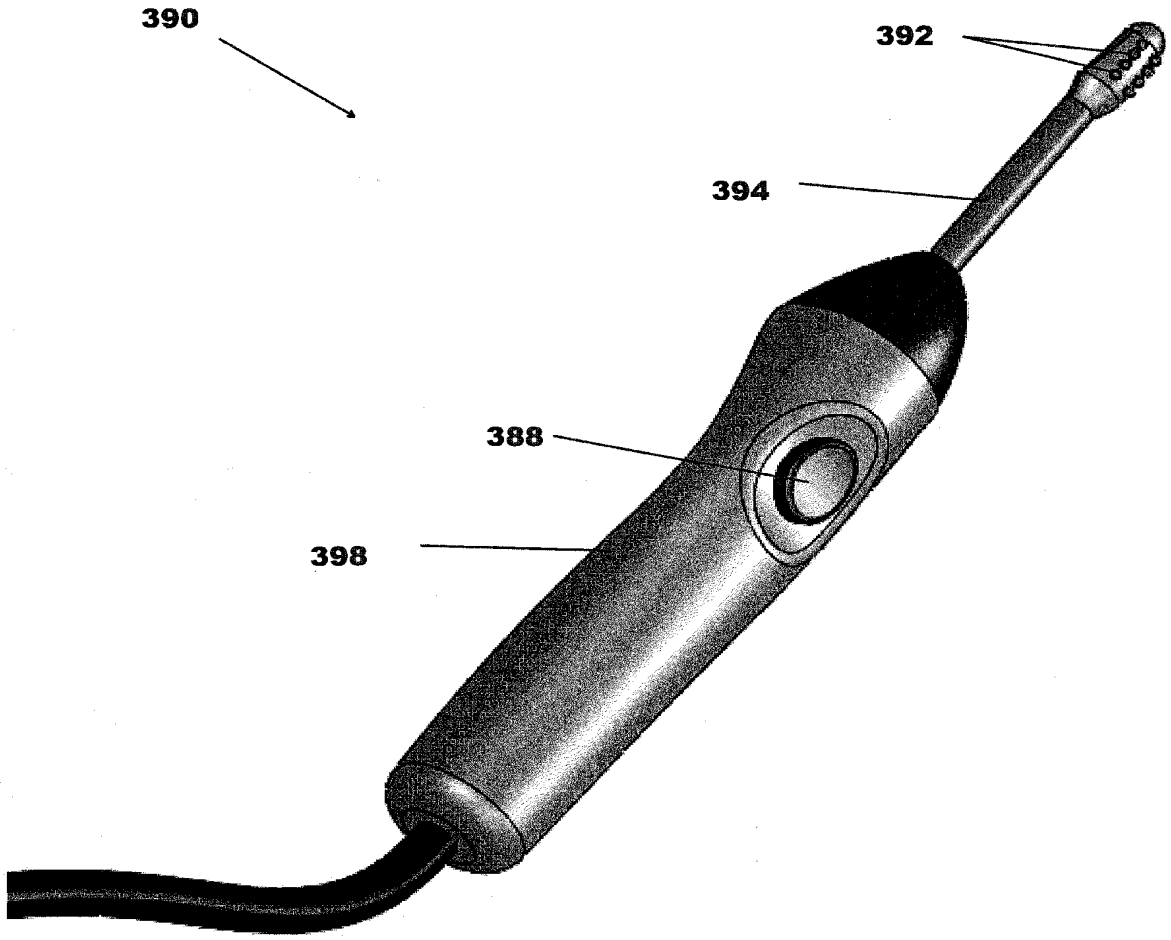


FIG. 18

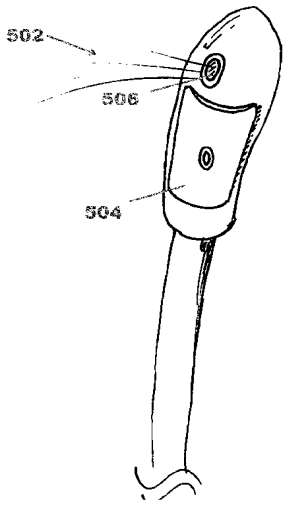


FIG. 19A



FIG. 19B

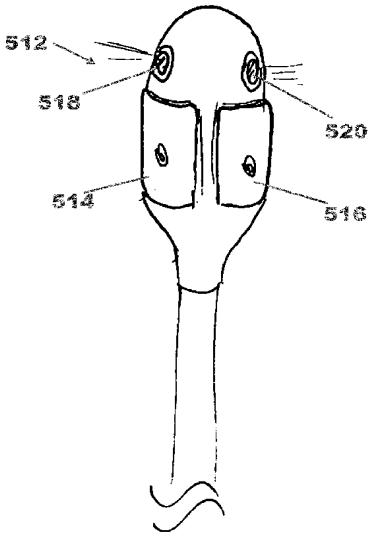


FIG. 20A

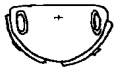


FIG. 20B

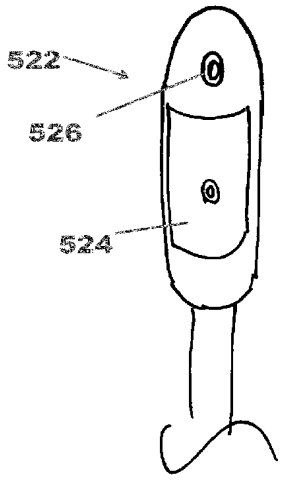


FIG. 21A

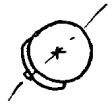


FIG. 21B

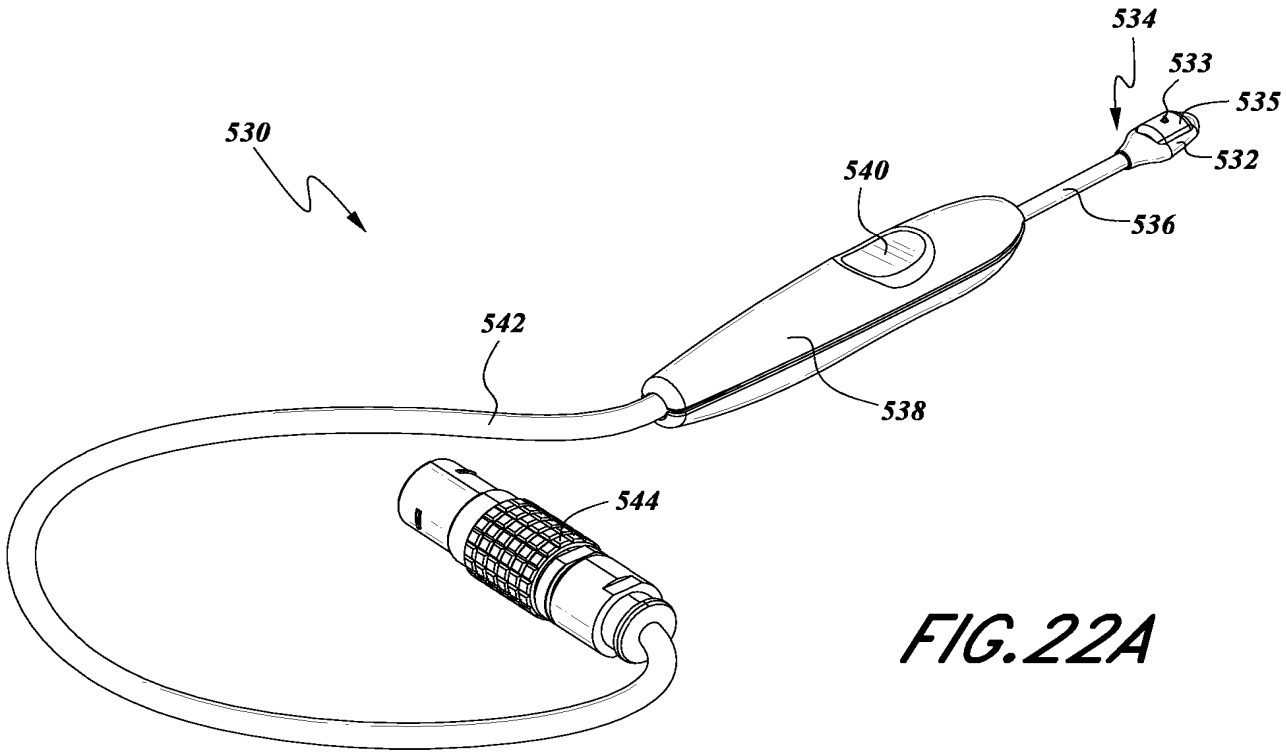


FIG. 22A

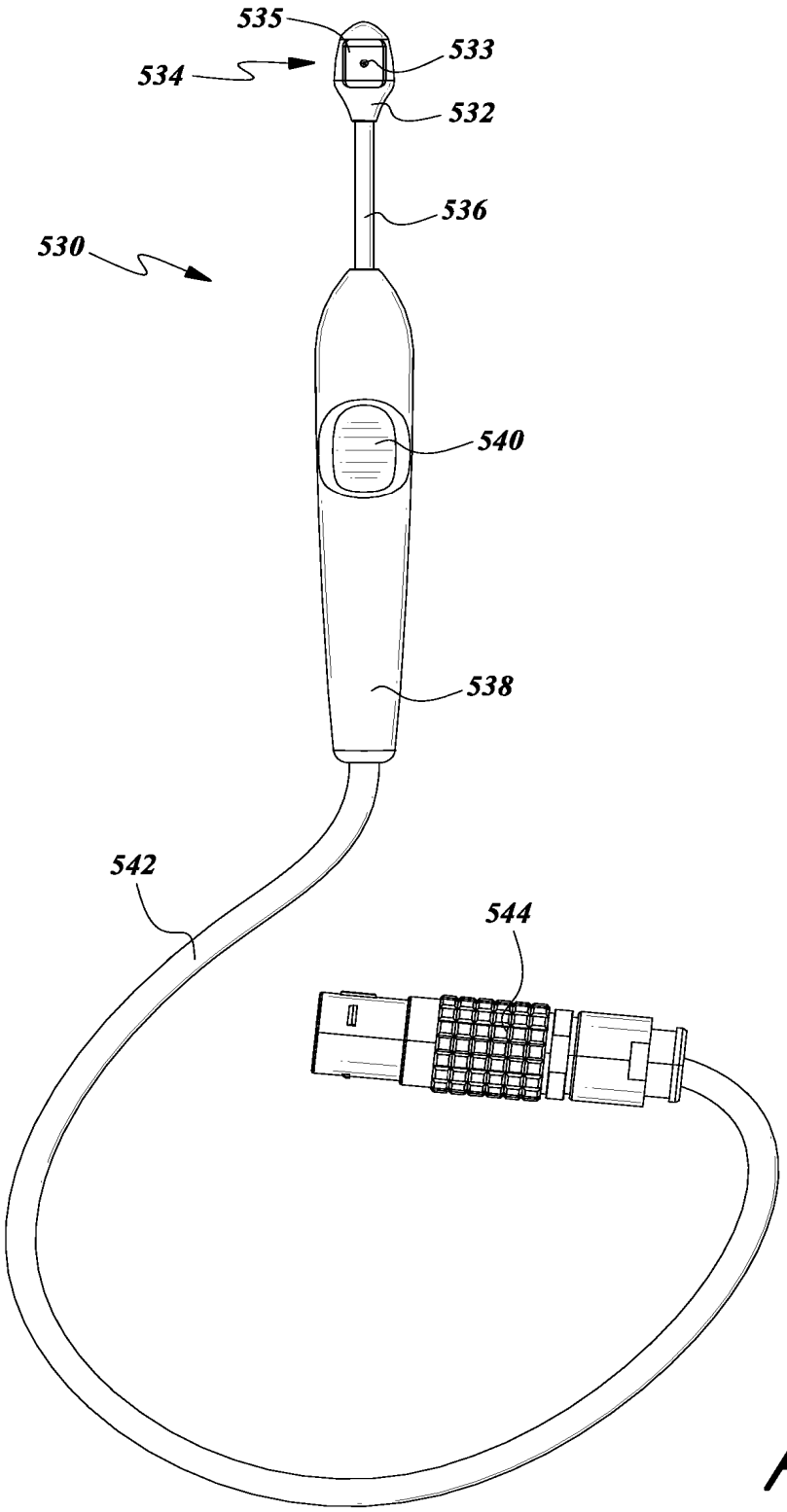


FIG. 22B

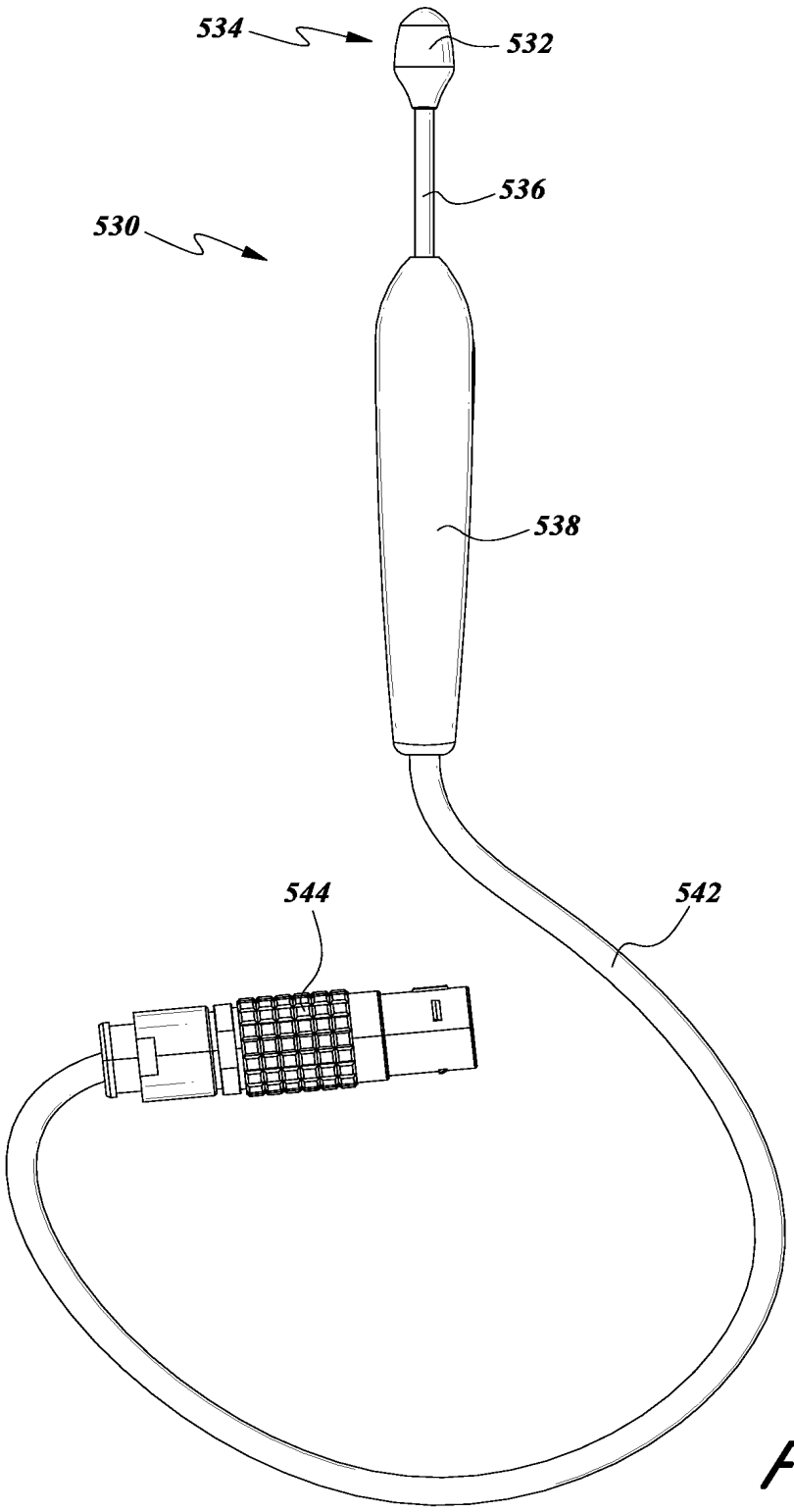


FIG. 22C

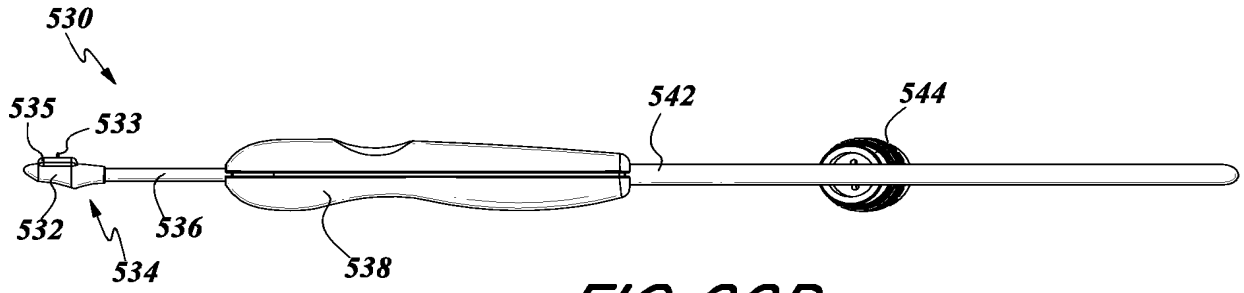


FIG. 22D

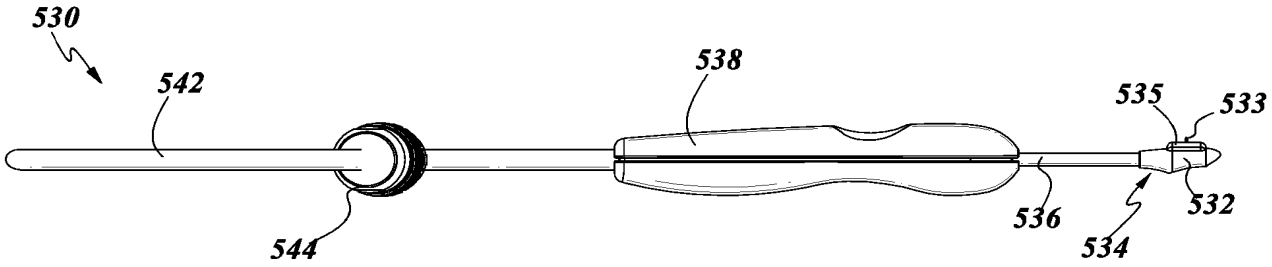


FIG. 22E

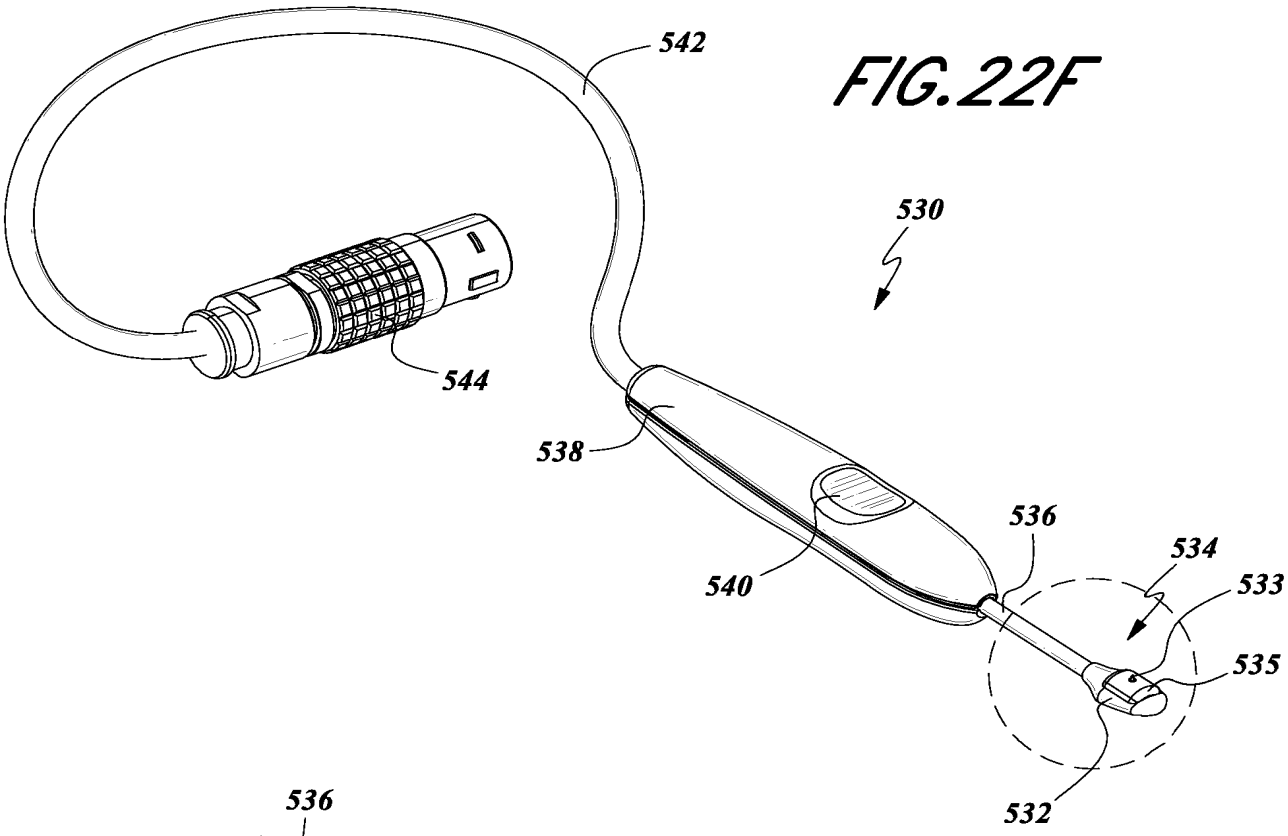


FIG. 22F

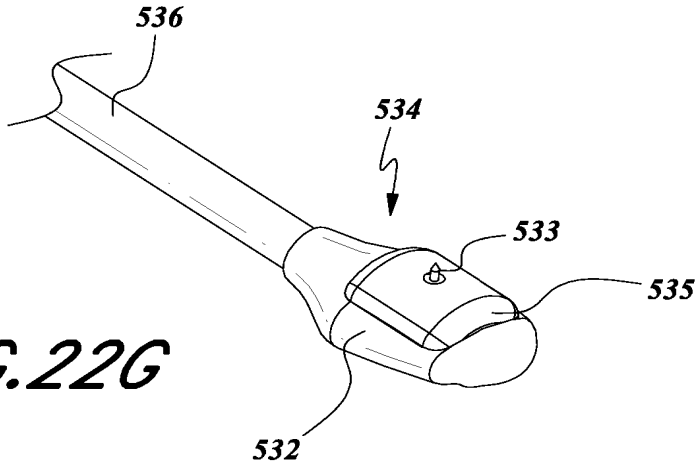


FIG. 22G

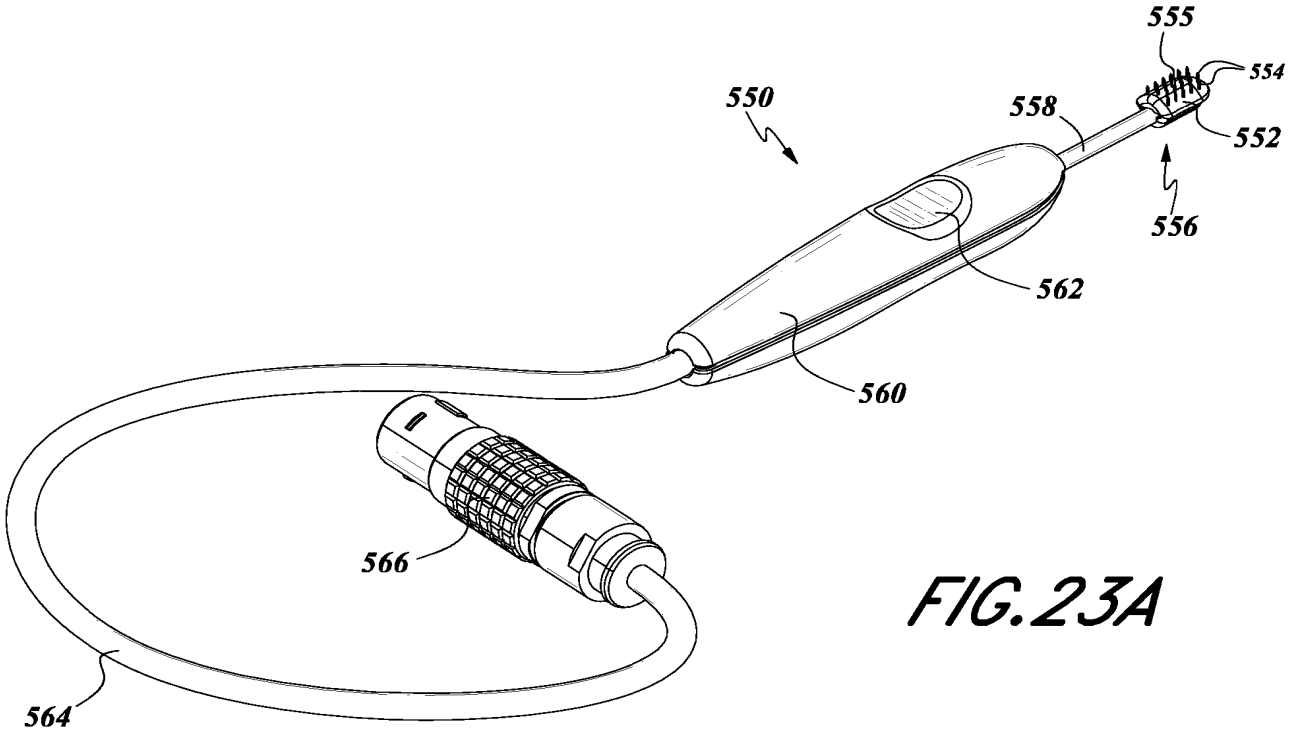


FIG. 23A

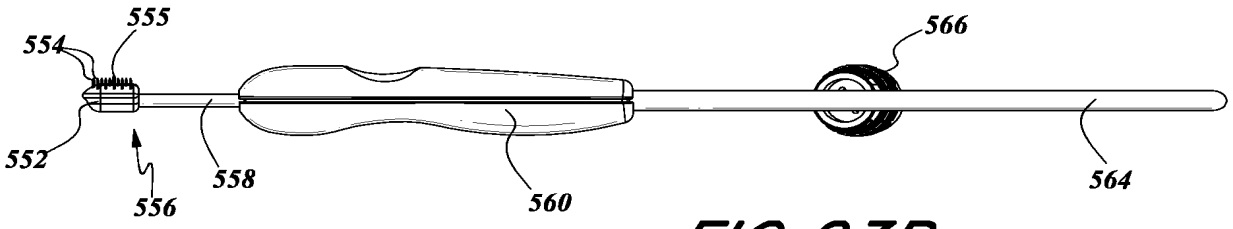


FIG. 23B

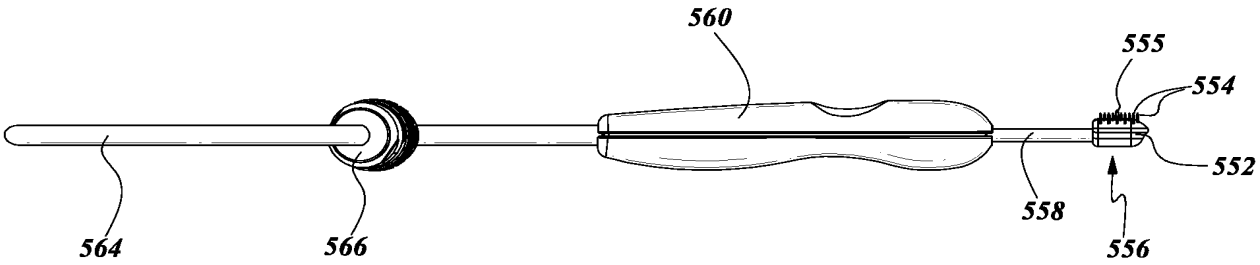


FIG. 23C

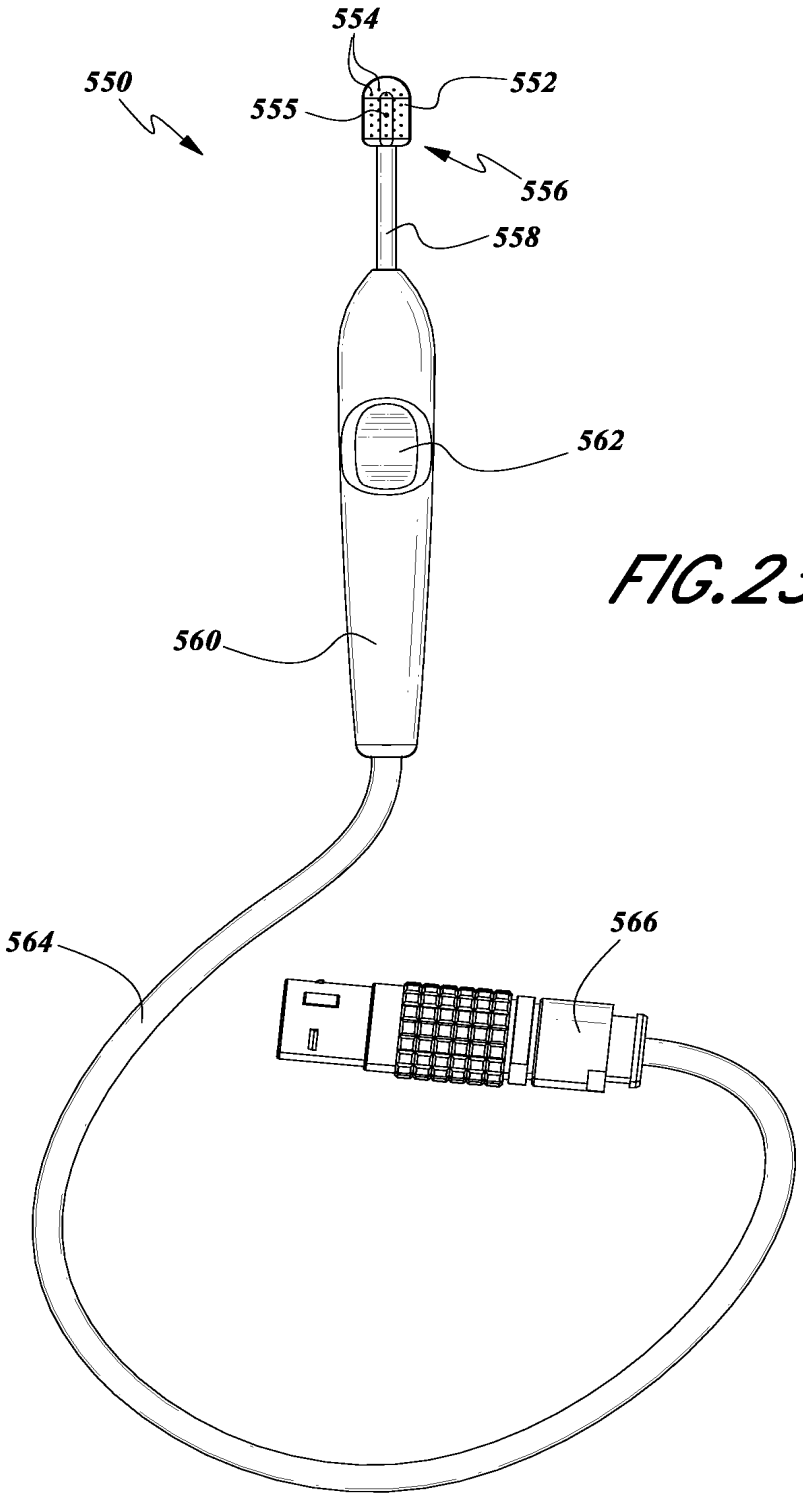


FIG. 23D

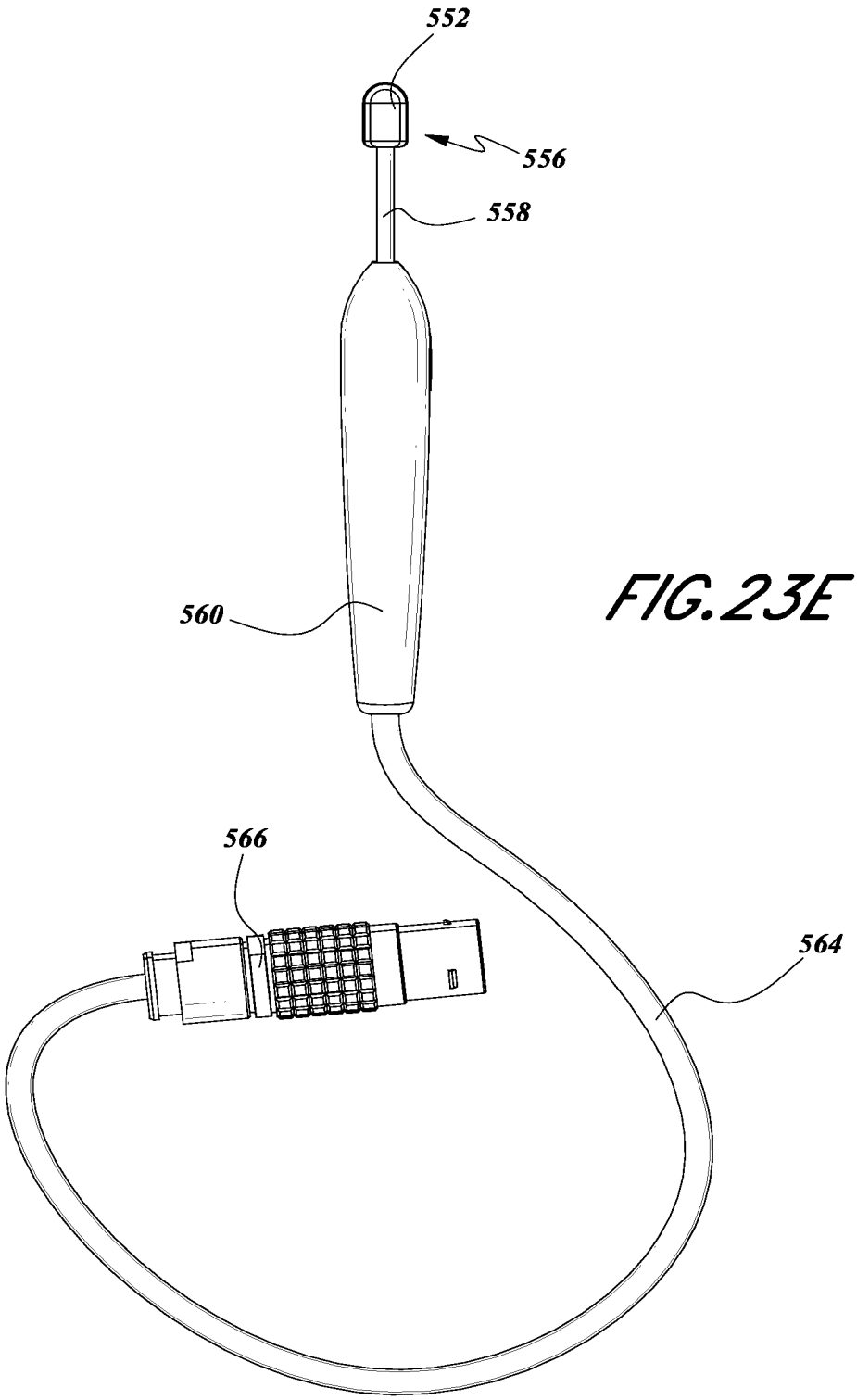


FIG. 23E

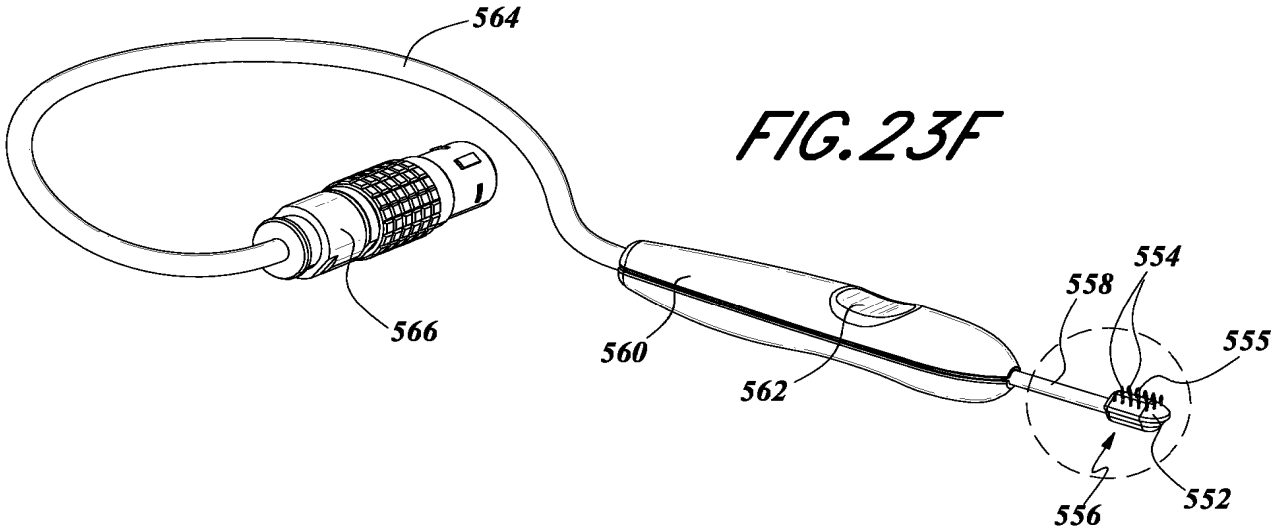


FIG. 23F

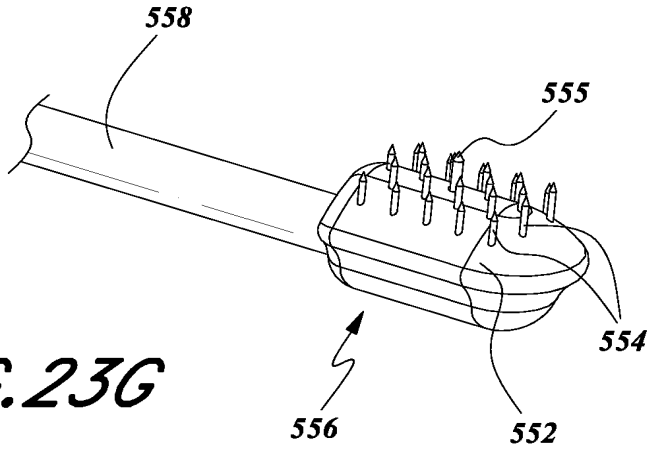


FIG. 23G

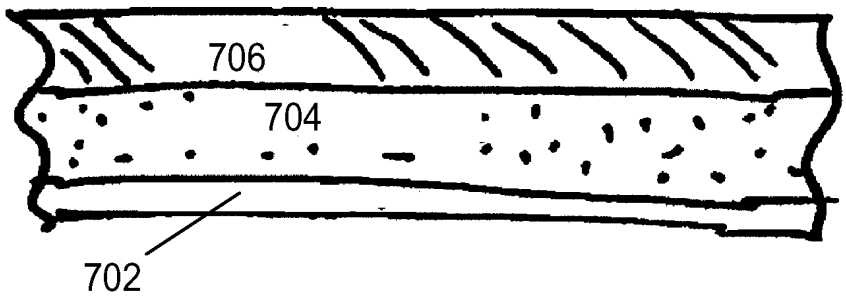


FIG. 24A

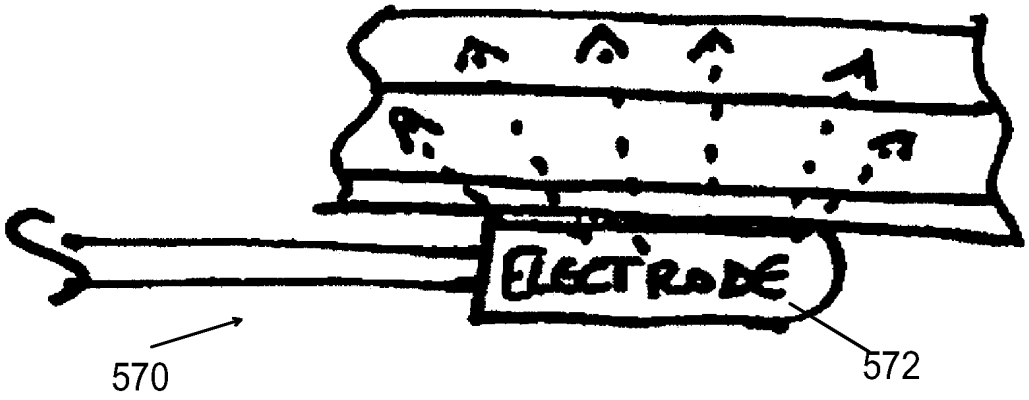


FIG. 24B

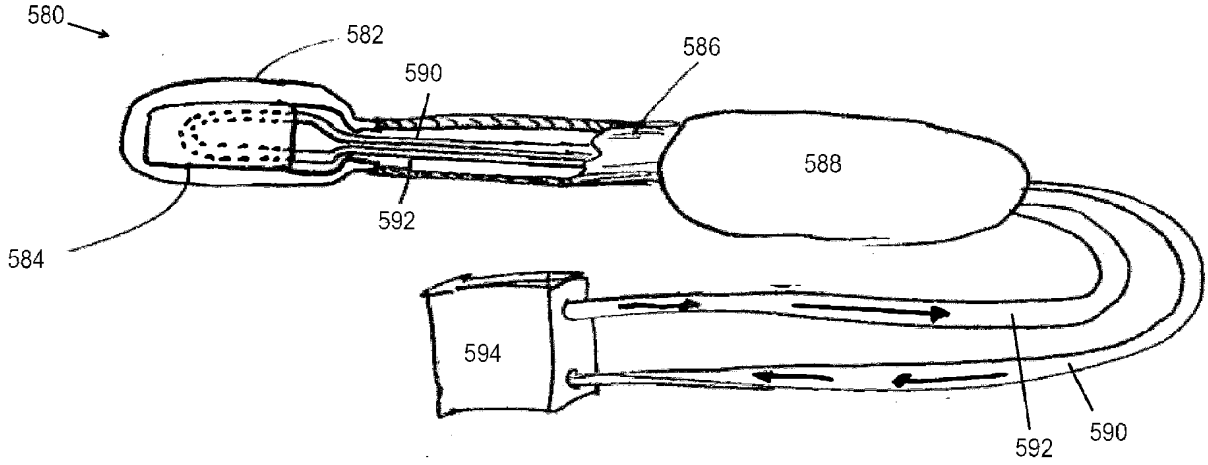


FIG. 25A

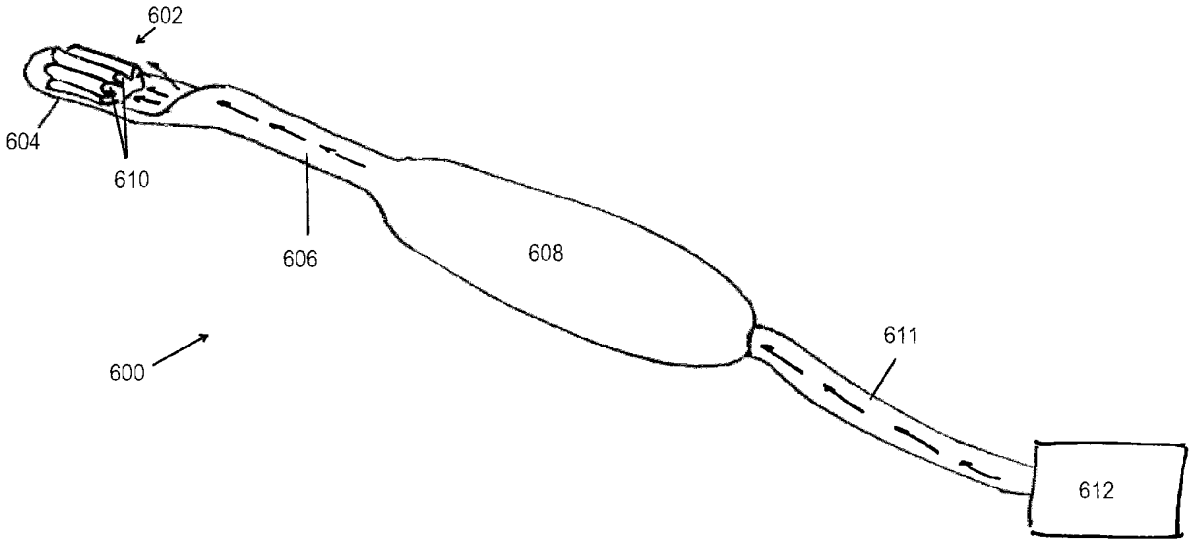


FIG. 25B

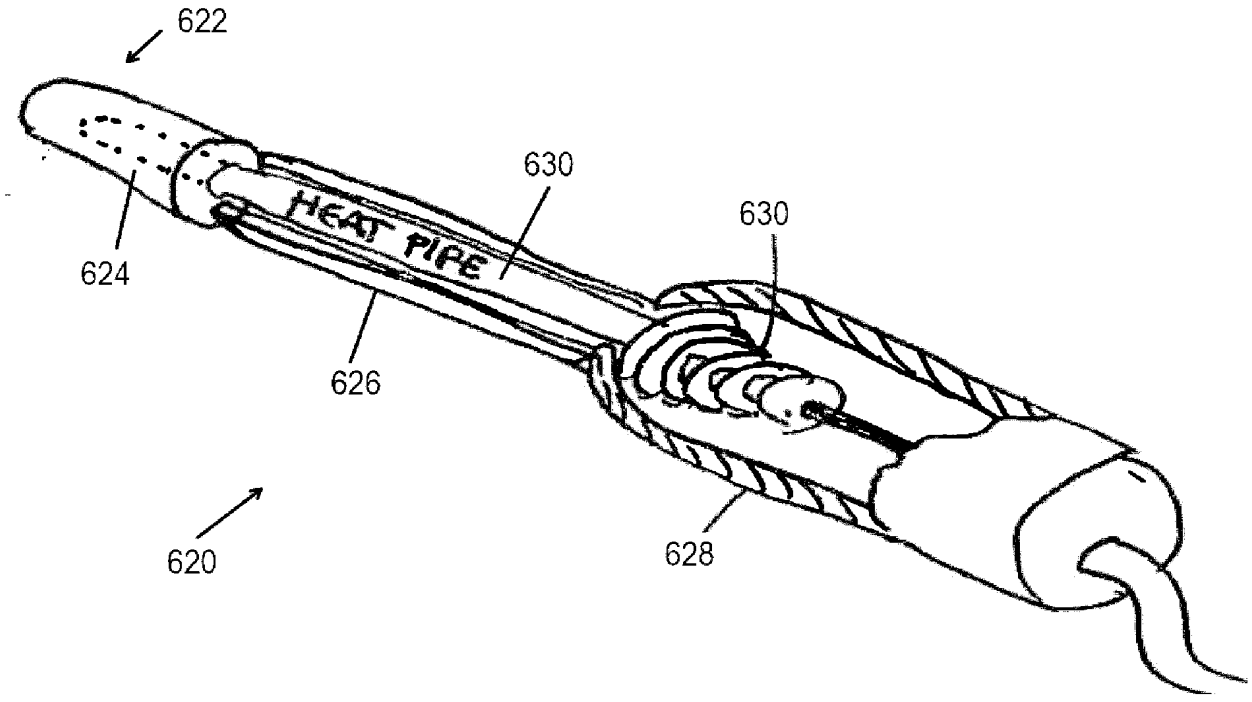


FIG. 26

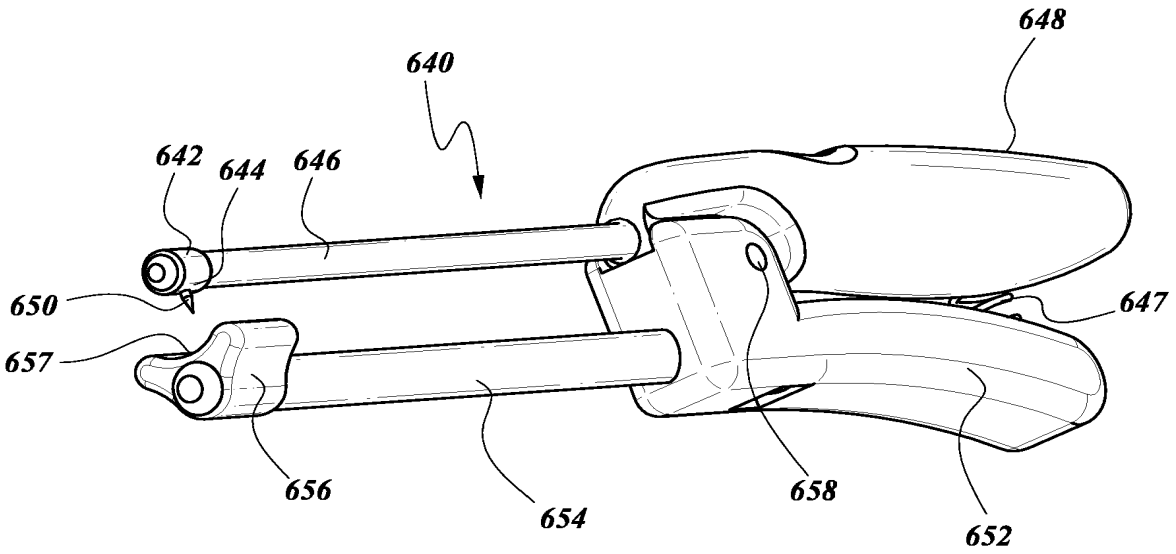


FIG. 27

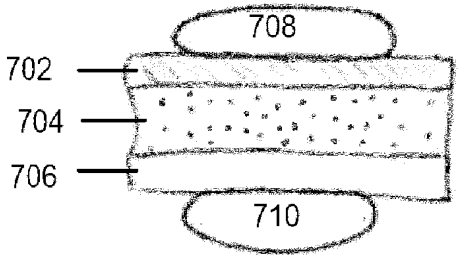


FIG. 28A

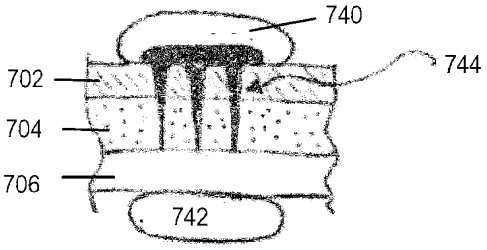


Fig. 28D

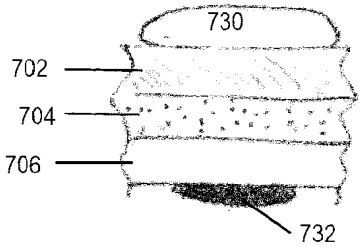


Fig. 28B

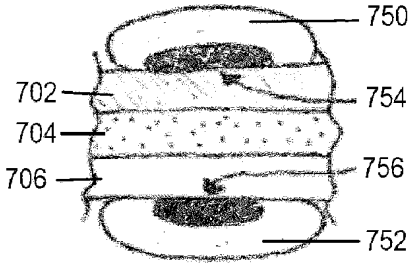


Fig. 28E

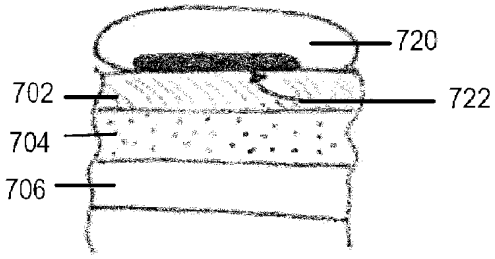


Fig. 28C

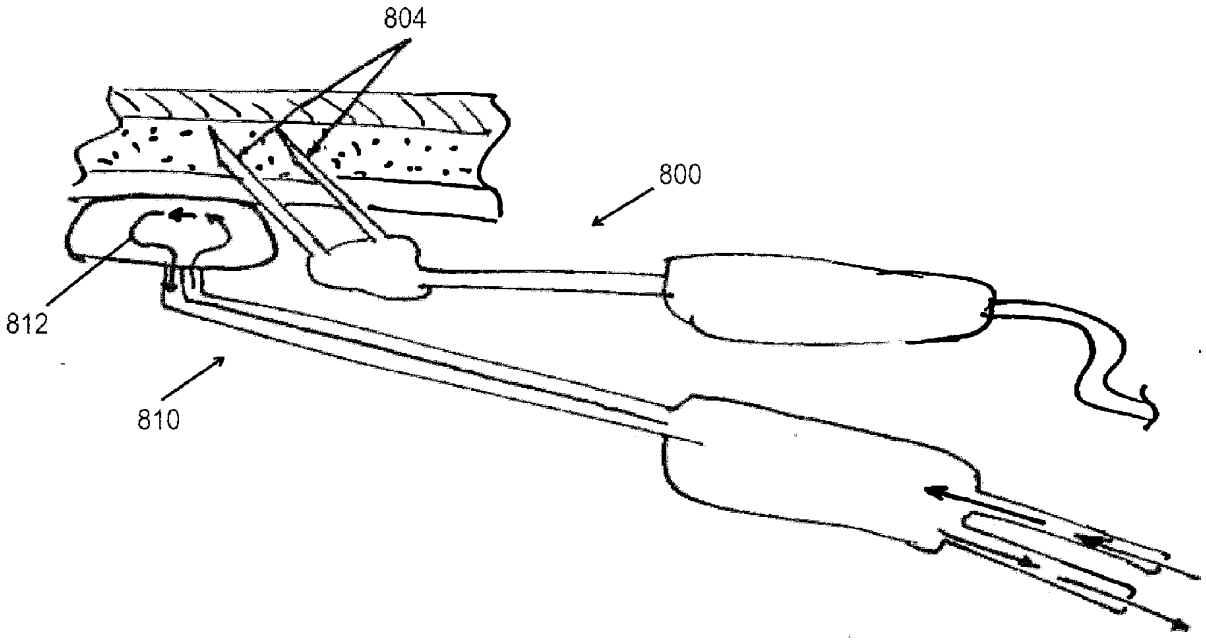


FIG. 29

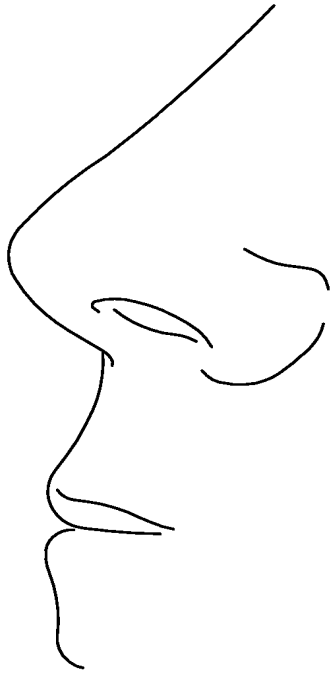


FIG. 30A

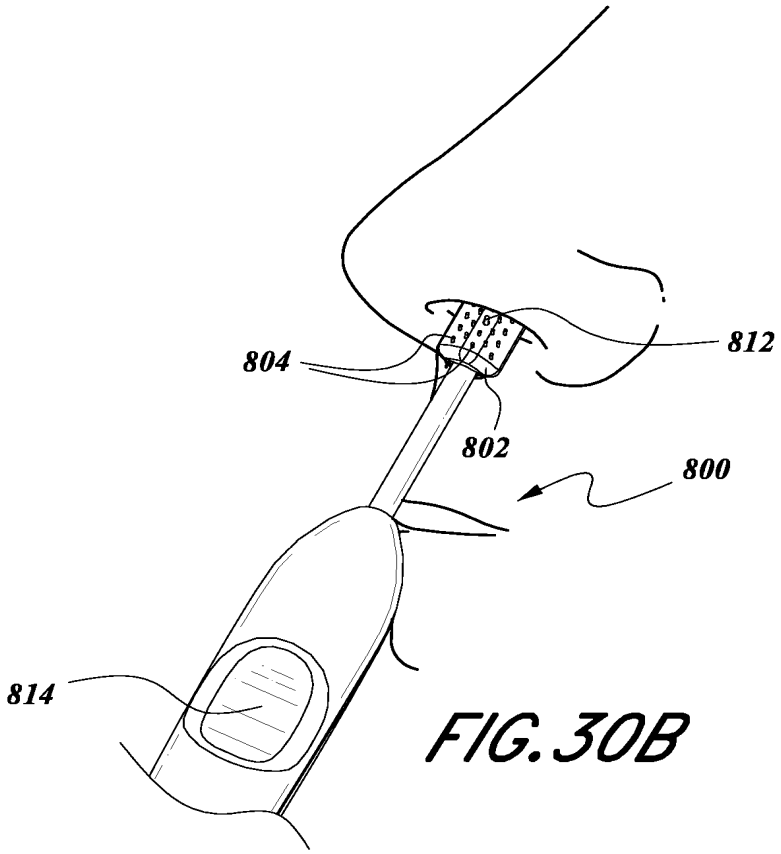


FIG. 30B

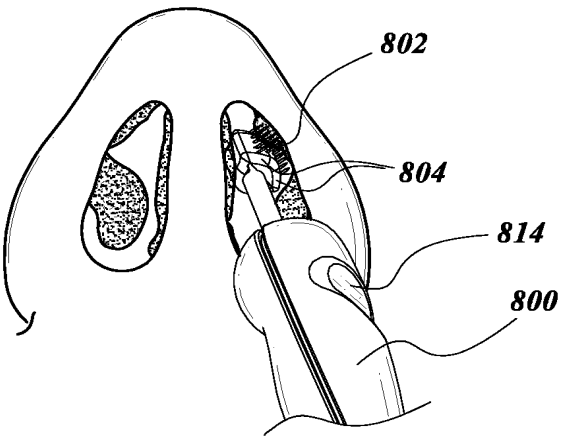


FIG. 30C

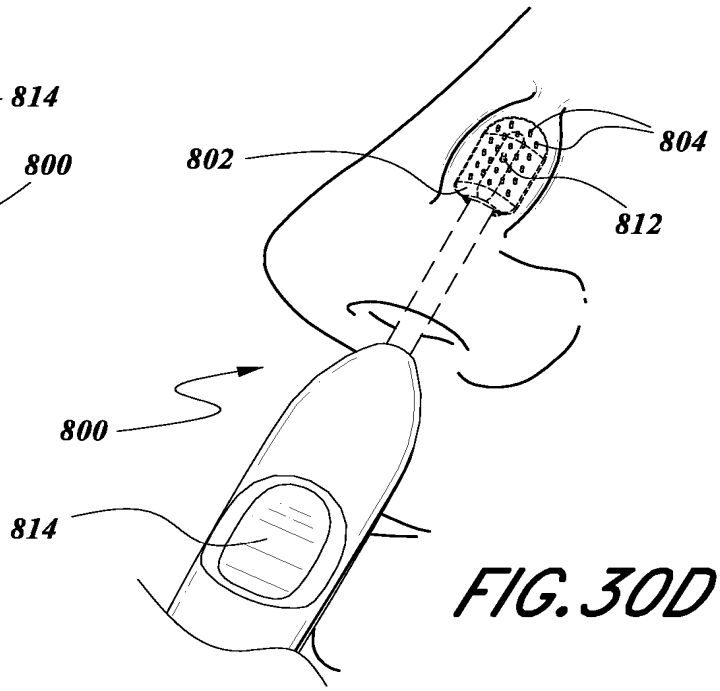


FIG. 30D

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

Form PCT/ISA/210 (second sheet) (April 2005)

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.

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 SEARCH REPORT

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	

Electronic Acknowledgement Receipt

EFS ID:	31262564
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Scott Michael Smith/Juliana Hoffman
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	17713.0001US11
Receipt Date:	18-DEC-2017
Filing Date:	25-AUG-2017
Time Stamp:	17:22:48
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)	2017-12-18_IDS_17713-0001US11.PDF	631260 9994a74cfdc728dbf10eb163da53a4740547405c	no	4

Warnings:

Information:					
2	Foreign Reference	WO1999007299.pdf	1952843 af7d813185b912691b88b1b99d5a973629d63aeb	no	52
Warnings:					
Information:					
3	Foreign Reference	WO2010077980.pdf	2446006 f9c81185428a79fea2618928d8f5568fe131d016	no	54
Warnings:					
Information:					
4	Foreign Reference	WO2012174161.pdf	6233599 6fd3cb386d73c081c08dbd59f7963df8094968eb	no	116
Warnings:					
Information:					
5	Non Patent Literature	2017-09-26_EP15772528.pdf	250785 5fc6bd40bda538e1fae91f8ec40936e7fa175b90	no	7
Warnings:					
Information:					
		Total Files Size (in bytes):	11514493		

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
15/686,265	08/25/2017	Scott J. Wolf	17713.0001US11

CONFIRMATION NO. 7653

23552
MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

PUBLICATION NOTICE

OC000000096461375

Title:METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Publication No.US-2018-0000535-A1
Publication Date:01/04/2018

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 Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, 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 https://portal.uspto.gov/pair/PublicPair. 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

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	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	MANUEL, GEORGE C.
Attorney Docket Number	17713.0001US11

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	9888957		2018-02-13	Wolf et al.	
	2	9913682		2018-03-13	Wolf et al.	
	3	5733280		1998-03-31	Avitall	
	4	7097641		2006-08-29	Arless et al.	
	5	8128617		2012-03-06	Bencini et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20020087155		2002-07-04	Underwood et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C.
	Attorney Docket Number	17713.0001US11

	2	20170360495		2017-12-21	Wolf et al.			
	3	20050240147		2005-10-27	Makower et al.			
	4	20080027423		2008-01-31	CHOI et al.			
	5	20080312644		2008-12-18	Fourkas et al.			
	6	20100241112		2010-09-23	Watson			

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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]
	1	WO 2003024349	WO		2003-03-27			

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]
	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C.
	Attorney Docket Number	17713.0001US11

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C.
	Attorney Docket Number	17713.0001US11

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)	2018-03-12
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.

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.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 March 2003 (27.03.2003)

PCT

(10) International Publication Number
WO 03/024349 A1

(51) International Patent Classification[7]: A61B 18/18

(21) International Application Number: PCT/US02/28488

(22) International Filing Date:
5 September 2002 (05.09.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

09/947,658	5 September 2001 (05.09.2001)	US
60/356,390	12 February 2002 (12.02.2002)	US
60/368,177	27 March 2002 (27.03.2002)	US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier applications:

US	09/947,658 (CIP)
Filed on	5 September 2001 (05.09.2001)
US	60/356,390 (CIP)
Filed on	12 February 2002 (12.02.2002)
US	60/368,177 (CIP)
Filed on	27 March 2002 (27.03.2002)

(71) Applicant *(for all designated States except US)*: **TISSUELINK MEDICAL, INC.** [US/US]; Suite 400, One Washington Center, Dover, NH 03820 (US).

(72) Inventors; and

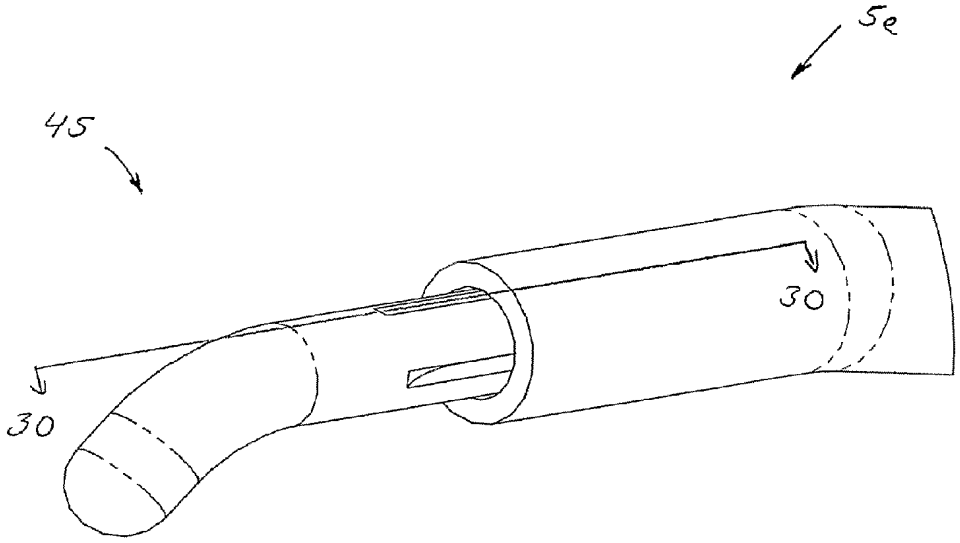
(75) Inventors/Applicants *(for US only)*: **MCCLURKEN, Michael, E.** [US/US]; 26 Deer Meadow Road, Durham, NH 03824 (US). **LIPSON, David** [US/US]; 131 Pheasant Brook Road, North Andover, MA 01845 (US). **LUZZI, Robert** [US/US]; 4 Cragmere Heights Road, Exeter, NH 03833 (US). **OYOLA, Arnold, E.** [US/US]; 49 Nottingham Road, Raymond, NH 03077 (US). **WILSON, Jonathan, E.** [US/US]; 8 Carpenter Street, Amesbury, MA 01913 (US). **MAURER, Christopher, W.** [US/US]; 500 Broadway #2154, Malden, MA 02148 (US). **GREELEY, Roger, D.** [US/US]; 126 Spring Street, Portsmouth, NH 03801 (US).

(74) Agent: **BRUESS, Steven, C.**; Merchant & Gould P.C., P.O. Box 2903, Minneapolis, MN 55402-0903 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT (utility model), AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA,

[Continued on next page]

(54) Title: FLUID-ASSISTED MEDICAL DEVICES, SYSTEMS AND METHODS



(57) Abstract: Surgical devices, systems and methods for treating tissue are provided. Also provided are systems for treating tissue and methods of treating tissue. An exemplary surgical device comprises a handle (20a) having a proximal end and a distal end; a shaft extending distally beyond the distal end of the handle, the shaft having a proximal end and a distal end; an electrode tip (45), at least a portion of the electrode tip extending distally beyond the distal end of the shaft, the electrode tip extending distally beyond the distal end of the shaft comprising a spherical end surface portion (25) and a cylindrical side surface portion, the spherical end surface portion located distal to the cylindrical side surface portion and comprising at least a portion of the distal end surface of the surgical device; and a fluid passage directed to provide a fluid towards the cylindrical side portion of the electrode tip.

WO 03/024349 A1



CH, CN, CO, CR, CU, CZ (utility model), CZ, DE (utility model), DE, DK (utility model), DK, DM, DZ, EC, EE (utility model), EE, ES, FI (utility model), FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK (utility model), SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

FLUID-ASSISTED MEDICAL DEVICES, SYSTEMS AND METHODS

This application is being filed as a PCT International Patent application in the name of TissueLink Medical, Inc. (a U.S. national corporation), for the designation of all countries except the US, and Michael E. McClurken, David Lipson, Robert Luzzi, Arnold E. Oyola, Jonathan E. Wilson, Christopher W. Maurer, and Roger D. Greeley (all US citizens), for the designation of the United States only, on 5 September 2002.

Cross Reference to Related Applications

This patent application is related to United States Patent Application Serial Nos. 60/356,390, filed February 12,2002, and 60/368,177, filed March 27, 2002, both now pending. This patent application is also related to United States Patent Application Serial No. 09/947,658, filed September 5, 2001, now pending, which is a continuation-in-part of United States Patent Application Serial No. 09/797,049, filed March 1, 2001, now pending, which is a continuation of United States Patent Application Serial No. 60/187,114, filed March 6, 2000. This patent application is also related to United States Patent Application Serial No. 09/668,403, filed September 22, 2000, now pending. This patent application incorporates the entire disclosure of each patent application herein by reference to the extent they are consistent.

Field

This invention relates generally to the field of medical devices, systems and methods for use upon a body during surgery. More particularly, the invention relates to electrosurgical devices, systems and methods for use upon tissues of a human body during surgery, particularly open surgery and minimally invasive surgery such as laparoscopic surgery.

Background

Electrosurgical devices configured for use with a dry tip use electrical energy, most commonly radio frequency (RF) energy, to cut tissue or to cauterize blood vessels. During use, a voltage gradient is created at the tip of the device, thereby inducing current flow and related heat generation in the tissue. With sufficiently high levels of electrical energy, the heat generated is sufficient to cut the tissue and, advantageously, to stop the bleeding from severed blood vessels.

Current dry tip electrosurgical devices can cause the temperature of tissue being treated to rise significantly higher than 100 °C, resulting in tissue desiccation,

tissue sticking to the electrodes, tissue perforation, char formation and smoke generation. Peak tissue temperatures as a result of RF treatment of target tissue can be as high as 320 °C, and such high temperatures can be transmitted to adjacent tissue via thermal diffusion. Undesirable results of such transmission to adjacent tissue include unintended thermal damage to the tissue.

Using saline according to the present invention to couple RF electrical energy to tissue inhibits such undesirable effects as sticking, desiccation, smoke production and char formation. One key factor is inhibiting tissue desiccation, which occurs when tissue temperature exceeds 100 °C and all of the intracellular water boils away, leaving the tissue extremely dry and much less electrically conductive. However, an uncontrolled or abundant flow rate of saline can provide too much cooling at the electrode/tissue interface. This cooling reduces the temperature of the target tissue being treated, and the rate at which tissue thermal coagulation occurs is determined by tissue temperature. This, in turn, can result in longer treatment time to achieve the desired tissue temperature for treatment of the tissue. Long treatment times are undesirable for surgeons since it is in the best interest of the patient, physician and hospital, to perform surgical procedures as quickly as possible.

RF energy delivered to tissue can be unpredictable and often not optimal when using general-purpose generators. Most general-purpose RF generators have modes for different waveforms (e.g. cut, coagulation, or a blend of these two) and device types (e.g. monopolar, bipolar), as well as power levels that can be set in watts. However, once these settings are chosen, the actual power delivered to tissue and associated heat generated can vary dramatically over time as tissue impedance changes over the course of RF treatment. This is because the power delivered by most generators is a function of tissue impedance, with the power ramping down as impedance either decreases toward zero or increases significantly to several thousand ohms. Current dry tip electrosurgical devices are not configured to address a change in power provided by the generator as tissue impedance changes or the associated effect on tissue and rely on the surgeon's expertise to overcome this limitation.

Summary of the Invention

In certain embodiments, a system for treating tissue is provided. The system comprises radio frequency power provided from a power source at a power level; an electrically conductive fluid provided from a fluid source at a fluid flow rate; and an electrosurgical device configured to provide the radio frequency power and the electrically conductive fluid to the tissue.

In certain embodiments the conductive fluid is an indicator of tissue temperature. The conductive fluid can relate the tissue temperature to boiling, an amount of boiling, or an onset of boiling of the conductive fluid.

The conductive fluid can cool the tissue or dissipate heat from the tissue. Alternately or additionally, the conductive fluid dissipates heat from at least one of the tissue and the conductive fluid by a boiling of at least a portion of the fluid.

For other embodiments, at least one of the radio frequency power level and the flow rate of the conductive fluid is used to effect a boiling of the electrically conductive fluid. Furthermore, in some embodiments, the effect on boiling may comprise at least one of initiating, increasing, decreasing and eliminating boiling of the electrically conductive fluid.

For other embodiments, the electrically conductive fluid functions to limit the temperature of the tissue at the tissue surface to about a boiling temperature of the electrically conductive fluid.

Generally, the electrically conductive fluid protects the tissue from desiccation. In some embodiments, the conductive fluid protects the tissue from desiccation by boiling at least a portion of the electrically conductive fluid. In other embodiments, the electrically conductive fluid protects the tissue from desiccation by boiling at least a portion of the conductive fluid at a temperature below the temperature of tissue desiccation.

For some embodiments, the electrically conductive fluid is provided to the tissue at the tissue surface and the radio frequency power is also provided to the tissue at the tissue surface. The radio frequency power reaches below the tissue surface into the tissue via (through) the electrically conductive fluid at the tissue surface.

At least one of the radio frequency power level and the conductive fluid flow rate can be adjusted based on a boiling of the conductive fluid. Furthermore, for other embodiments, adjusting at least one of the radio frequency power level and the conductive fluid flow rate based on a boiling of the conductive fluid comprises one of initiating, increasing, decreasing and eliminating boiling of the electrically conductive fluid.

In certain embodiments, a method for treating tissue is provided comprising providing radio frequency power at a power level; providing an electrically conductive fluid at a fluid flow rate; and providing an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue.

Still further, a system for treating tissue is provided, the system comprising radio frequency power provided from a power source at a power level; an

electrically conductive fluid provided from a fluid source at a fluid flow rate; an electrosurgical device configured to provide the radio frequency power and the conductive fluid to the tissue; and a fluid coupling which couples the tissue and the electrosurgical device, the coupling comprising the conductive fluid.

In certain embodiments the fluid coupling is an indicator of tissue temperature. The fluid coupling can function as an indicator of tissue temperature by using boiling; an amount of boiling; or an onset of boiling of the fluid coupling.

For other embodiments, the fluid coupling cools the tissue or dissipates heat from the tissue. The fluid coupling can dissipate heat from at least one of the tissue and the fluid coupling by a boiling of at least a portion of the fluid coupling. For other embodiments, the fluid coupling can limit the temperature of the tissue at the tissue surface to close to a boiling temperature of the fluid coupling.

The fluid coupling can protect the tissue from desiccation. In some embodiments, the fluid coupling protects the tissue from desiccation by boiling at least a portion of the fluid coupling. In other embodiments, the fluid coupling protects the tissue from desiccation by boiling at least a portion of the fluid coupling at a temperature which protects the tissue from desiccation.

For other embodiments, at least one of the radio frequency power level and the conductive fluid flow rate is used to effect a boiling of the fluid coupling. Furthermore, in some embodiments, the effect on boiling may be at least one of initiating, increasing, decreasing and eliminating boiling of the fluid coupling.

The conductive fluid can be provided to the tissue at the tissue surface, and the radio frequency power can also be provided to the tissue at the tissue surface. The radio frequency power can be provided to an area below the tissue surface via (through) the fluid coupling at the tissue surface.

In certain embodiments, a method for treating tissue is provided, the method comprising providing radio frequency power at a power level; providing an electrically conductive fluid at a fluid flow rate; providing an electrosurgical device configured to provide the radio frequency power and the electrically conductive fluid to the tissue; and forming a fluid coupling which couples the tissue and the electrosurgical device. The fluid coupling comprises conductive fluid.

The fluid coupling can be used as an indicator of tissue temperature. This can be done by boiling; an amount of boiling of the fluid coupling; or an onset of boiling of the fluid coupling.

For some embodiments, the fluid coupling is used to cool the tissue or dissipate heat from the tissue by transferring heat to the fluid coupling. The fluid coupling can dissipate heat from at least one of the tissue and the fluid coupling by a boiling of at least a portion of the fluid coupling.

For other embodiments, at least one of the radio frequency power level and the conductive fluid flow rate is adjusted based on a boiling of the fluid coupling. Furthermore, for other embodiments, adjusting at least one of the radio frequency power level and the conductive fluid flow rate based on a boiling of the fluid coupling comprises one of initiating, increasing, decreasing and eliminating boiling of the fluid coupling.

For other embodiments, the temperature of the tissue at the tissue surface is limited to about a boiling temperature of the fluid coupling.

For other embodiments, the tissue is protected from desiccation with the fluid coupling. Furthermore, for other embodiments, the tissue is protected from desiccation with the fluid coupling by a boiling of at least a portion of the fluid coupling. Furthermore, for other embodiments, the tissue is protected from desiccation with the fluid coupling by a boiling of at least a portion of the fluid coupling at a temperature which protects the tissue from desiccation.

The method for treating tissue can further comprise providing the conductive fluid to the tissue at the tissue surface; and providing the radio frequency power to the tissue at the tissue surface and below the tissue surface into the tissue through the fluid coupling.

With regards to specific devices, in certain embodiments a surgical device for treating tissue is provided comprising a handle having a proximal end and a distal end; a shaft extending distally beyond the distal end of the handle, the shaft having a proximal end and a distal end; an electrode tip, at least a portion of the electrode tip extending distally beyond the distal end of the shaft, the electrode tip extending distally beyond the distal end of the shaft comprising a spherical end surface portion and a cylindrical side surface portion, the spherical end surface portion located distal to the cylindrical side surface portion and comprising at least a portion of the distal end surface of the surgical device; and a fluid passage directed to provide a fluid towards the cylindrical side portion of the electrode tip.

In other embodiments, a surgical device for treating tissue is provided comprising a handle having a proximal end and a distal end; a shaft extending distally beyond the distal end of the handle, the shaft having a proximal end and a distal end; an electrode tip, at least a portion of the electrode tip extending distally beyond the distal end of the shaft, the electrode tip extending distally beyond the distal end of the shaft comprising a neck portion and an enlarged head portion, the enlarged head portion located distal to the neck portion and comprising at least a portion of a distal end surface of the surgical device; and a fluid passage directed to provide a fluid towards the enlarged head portion of the electrode tip.

In still other embodiments, a device for treating tissue is provided comprising a handle having a proximal end and a distal end; a shaft extending distally beyond the distal end of the handle, the shaft having a proximal end and a distal end; an electrode tip, the electrode tip comprising a spherical end surface portion and a cylindrical side surface portion, the spherical end surface portion located distal to the cylindrical side surface portion and comprising at least a portion of the distal end surface of the device; a fluid passage connectable to a fluid source; and a plurality of fluid outlet openings in fluid communication with the fluid passage, the fluid outlet openings positioned to provide a fluid from the fluid source around the cylindrical side surface portion of the electrode tip.

In still other embodiments, a device for treating tissue is provided comprising a handle having a proximal end and a distal end; a shaft extending distally beyond the distal end of the handle, the shaft having a proximal end and a distal end; an electrode tip comprising a rounded distal end surface portion configured to blunt dissect tissue and a side surface portion configured to seal tissue from at least one of the flow of bodily fluids and air, the side surface portion having a surface area greater than the surface area of the distal end surface portion; a fluid passage connectable to a fluid source; and at least one fluid outlet opening in fluid communication with the fluid passage, the fluid outlet opening positioned to provide a fluid from the fluid source to the side surface portion of the electrode tip and proximal the distal end surface portion.

In other embodiments, a device for treating tissue is provided comprising a first electrode tip spaced from a second electrode tip, the first and second electrode tips being connectable to different terminals of a radio frequency generator to generate electrical current flow therebetween; at least one fluid passage connectable to a fluid source; at least one fluid outlet opening in fluid communication with the fluid passage, the fluid outlet opening configured to provide a fluid from the fluid source to at least one of a tissue surface and at least one of the first and second electrode tips; and the first and second electrode tips configured to slide over and seal tissue in the presence of a fluid provided from the fluid outlet opening and an electrical current provided from the electrode tips.

Additional methods for treating tissue may also comprise providing tissue having a tissue surface; providing radio frequency power at a power level; providing an electrically conductive fluid at a fluid flow rate; providing an surgical device configured to simultaneously provide the radio frequency power and the electrically conductive fluid to tissue; providing the electrically conductive fluid to the tissue at the tissue surface; forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and the surgical device; providing the radio frequency

power to the tissue at the tissue surface and below the tissue surface into the tissue through the fluid coupling; sealing the tissue against at least one of the flow of bodily fluids and air by at least one of shrinking collagen and coagulating blood in the tissue; and blunt dissecting the tissue.

In other embodiments, methods for treating tissue may also comprise providing tissue having a tissue surface; providing radio frequency power at a power level; providing an electrically conductive fluid at a fluid flow rate; providing an surgical device configured to simultaneously provide the radio frequency power and the electrically conductive fluid to tissue, the surgical device comprising a first electrode tip and a second electrode tip; providing the electrically conductive fluid to the tissue at the tissue surface; forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and the surgical device; providing the radio frequency power to the tissue at the tissue surface and below the tissue surface into the tissue through the fluid coupling; sliding the first electrode tip and the second electrode tip over the tissue surface; and sealing the tissue against at least one of the flow of bodily fluids and air by at least one of shrinking collagen and coagulating blood in the tissue.

Brief Description Of The Drawings

To better understand and appreciate the invention, refer to the following detailed description in connection with the accompanying drawings, hand and computer generated:

FIG. **1** is a block diagram showing one embodiment of a control system of the invention, and an electrosurgical device;

FIG. **2** is a schematic graph that describes the relationship between RF power to tissue (P), flow rate of saline (Q), and tissue temperature (T) when heat conduction to adjacent tissue is considered;

FIG. **3** is schematic graph that describes the relationship between RF power to tissue (P), flow rate of saline (Q), and tissue temperature (T) when heat conduction to adjacent tissue is neglected;

FIG. **4** is a schematic graph that describes the relationship between RF power to tissue (P), flow rate of saline (Q), and tissue temperature (T) when the heat required to warm the tissue to the peak temperature (T) **68** is considered;

FIG. **5** is a graph showing the relationship of percentage saline boiling and saline flow rate (cc/min) for an exemplary RF generator output of 75 watts;

FIG. **6** is a schematic graph that describes the relationship of load impedance (Z, in ohms) and generator output power (P, in watts), for an exemplary generator output of 75 watts in a bipolar mode;

FIG. **7** is a schematic graph that describes the relationship of time (t, in seconds) and tissue impedance (Z, in ohms) after RF activation;

FIG. **8** is a schematic perspective view of a cannula which may be used with an electrosurgical device according to the present invention;

FIG. **9** is a schematic exploded perspective view of an assembly of an electrosurgical device according to the present invention;

FIG. **10** is a schematic longitudinal cross-sectional side view of the tip and shaft of the device of FIG. **9** taken along line 10-10 of FIG. **12**;

FIG. **11** is a schematic close-up longitudinal cross-sectional side view of the tip portion of the device bounded by circle **45** shown in FIG. **10** taken along line 10-10 of FIG. **12**;

FIG. **12** is a schematic distal end view of the tip portion of the device bounded by circle **45** shown in FIG. **10**;

FIG. **13** is a schematic side view of the of the tip and shaft of the device of FIG. **9** with a fluid coupling to a tissue surface of tissue;

FIG. **14** is a schematic close-up cross-sectional side view of an alternative tip portion;

FIG. **15** is a schematic close-up section side view of the tip portion of FIG. **14** taken along line 15-15 of FIG. **14**;

FIG. **16** is a schematic close-up cross-sectional side view of the tip portion of FIG. **14** disposed in a tissue crevice;

FIG. **17** is a schematic graph of impedance **Z** versus time **t** showing changes in impedance represented by impedance spikes;

FIG. **18** is a schematic graph of the impedance **Z** versus boiling of fluid **%**;

FIG. **19** is schematic close-up cross-sectional view of the sleeve taken along line 19-19 of FIG. **15**;

FIG. **20** is a schematic close-up perspective view of an alternative tip portion;

FIG. **21** is a schematic close-up section side view of the tip portion of FIG. **20** taken along line 21-21 of FIG. **20**;

FIG. **22** is a schematic close-up cross-sectional side view of the tip portion of FIG. **20** disposed in a tissue crevice;

FIG. **23** is a schematic close-up front perspective view of the electrode for the tip portion of FIG. **20**;

FIG. **24** is a schematic close-up rear perspective view of the electrode for the tip portion of FIG. **20**;

FIG. **25** is a schematic close up cross-sectional view of a porous electrode with recesses;

FIG. **26** is schematic close up cross-sectional view of an electrode with semi-circular recesses;

FIG. **27** is schematic close up cross-sectional view of an electrode with V-shaped recesses;

FIG. **28** is schematic close up cross-sectional view of an electrode with U-shaped recesses;

FIG. **29** is a schematic close-up perspective view of an alternative tip portion;

FIG. **30** is a schematic close-up section side view of the tip portion of FIG. **29** taken along line 30-30 of FIG. **29**;

FIG. **31** is a schematic close-up front perspective view of the electrode for the tip portion of FIG. **29**;

FIG. **32** is a schematic close-up rear perspective view of the electrode for the tip portion of FIG. **29**;

FIG. **33** is a schematic close-up perspective view of an alternative tip portion;

FIG. **34** is a schematic close-up section side view of the tip portion of FIG. **33** taken along line 34-34 of FIG. **33**;

FIG. **35** is a schematic close-up front perspective view of the electrode for the tip portion of FIG. **33**;

FIG. **36** is a schematic close-up rear perspective view of the electrode for the tip portion of FIG. **33**;

FIG. **37** is a schematic close-up perspective view of an alternative tip portion;

FIG. **38** is a schematic close-up section side view of the tip portion of FIG. **37** taken along line 38-38 of FIG. **37**;

FIG. **39** is a schematic close-up perspective view of an alternative tip portion;

FIG. **40** is a schematic close-up section side view of the tip portion of FIG. **39** taken along line 40-40 of FIG. **39**;

FIG. **41** is a schematic close-up front posterior perspective view of the electrode for the tip portion of FIG. **39**;

FIG. **42** is a schematic close-up front anterior perspective view of the electrode for the tip portion of FIG. **39**;

FIG. **43** is a schematic side view of the tip portion of FIG. **39** with a fluid coupling to a tissue surface of tissue;

FIG. **44** is a schematic front view of the tip portion of FIG. **39** with a fluid coupling to a tissue surface of tissue;

FIG. **45** is a schematic side view of the tip portion of FIG. **39** with a fluid coupling to a tissue surface of tissue;

FIG. **46** is a schematic exploded perspective view of an assembly of an alternative electrosurgical device according to the present invention;

FIG. **47** is a schematic close-up cross-sectional side view of the tip portions of FIG. **46** assembled with a fluid coupling to a tissue surface of tissue;

FIG. **48** is a schematic close-up cross-sectional side view of the tip portions of FIG. **46** assembled with an alternative fluid coupling to a tissue surface of tissue;

FIG. **49** is a schematic exploded perspective view of an assembly of an alternative electrosurgical device according to the present invention;

FIG. **50** is a schematic close-up cross-sectional side view of the tip portions of FIG. **49** assembled with a fluid coupling to a tissue surface of tissue;

FIG. **51** is a schematic exploded perspective view of an assembly of an alternative electrosurgical device according to the present invention;

FIG. **52** is a schematic close-up perspective side view of a distal end portion of the device of FIG. **51**;

FIG. **53** is a schematic close-up cross-sectional side view of a distal end portion of the device of FIG. **51** assembled with a fluid coupling to a tissue surface of tissue;

FIG. **54** is a schematic perspective view of an alternative electrosurgical device according to the present invention;

FIG. **55** is a schematic perspective view of an alternative electrosurgical device according to the present invention;

FIG. **56** is a schematic close-up perspective view of the arms of the device of FIG. **55**;

FIG. **57** is a schematic close-up perspective view of a distal end portion of the device of FIG. **55**;

FIG. **58** is a schematic close-up perspective view of a distal end portion of the device of FIG. **55**;

FIG. **59** is a schematic perspective view of an alternative electrosurgical device according to the present invention;

FIG. **60** is a schematic close-up perspective view of the arms of the device of FIG. **59**;

FIG. **61** is a schematic close-up perspective view of a distal end portion of the device of FIG. **59**;

FIG. **62** is a schematic close-up perspective view of a distal end portion of the device of FIG. **59**;

FIG. **63** is a schematic close-up perspective view of a distal end portion of an alternative electrosurgical device according to the present invention;

FIG. **64** is a schematic close-up perspective view of a distal end portion of the device of FIG. **63** with tissue;

FIG. **65** is a schematic close-up perspective view of the arms of an alternative electrosurgical device according to the present invention;

FIG. **66** is a schematic close-up perspective view of a distal end portion of the arms of the device of FIG. **65** with the collar removed;

FIG. **67** is a schematic close-up perspective view of a distal end portion of the device of FIG. **65**;

FIG. **68** is a schematic close-up perspective view of a distal end portion of the device of FIG. **65** with one arm removed;

FIG. **69** is a schematic close-up perspective view of the collar of the device of FIG. **65**;

FIG. **70** is a schematic close-up perspective view of a distal end portion of an alternative electrosurgical device according to the present invention;

FIG. **71** is a schematic close-up perspective view of a distal end portion of one of the arms of the device of FIG. **70**;

FIG. **72** is a schematic close-up perspective view of a distal end portion of an alternative electrosurgical device according to the present invention;

FIG. **73** is a schematic close-up side view of a distal end portion of the device of FIG. **72**;

FIG. **74** is a schematic perspective view of an alternative electrosurgical device according to the present invention;

FIG. **75** is a schematic perspective view of a handle portion of the device of FIG. **74** assembled with various components;

FIG. **76** is a schematic close-up side view of a portion of the assembly of FIG. **75**;

FIG. **77** is a schematic close-up side view of a portion of the assembly of FIG. **75**;

FIG. **78** is a schematic partial cross-sectional front perspective view of the electrical connections for the device of FIG. **74**;

FIG. **79** is schematic partial cross-sectional rear perspective view of the electrical connections for the device of FIG. **74**;

FIG. **80** is a schematic perspective view of an alternative electrosurgical device according to the present invention;

FIG. **81** is a schematic side view of a handle portion of the device of FIG. **80** assembled with various components;

FIG. **82** is a schematic perspective view of an alternative electrosurgical device according to the present invention;

FIG. **83** is a schematic perspective view of a handle portion of the device of FIG. **82** assembled with various components;

FIG. **84** is a schematic side view of a handle portion of the device of FIG. **82** assembled with various components;

FIG. **85** is a schematic side view of a handle portion of the device of FIG. **82** assembled with various components;

FIG. **86** is a schematic side view of a handle portion of the device of FIG. **82** assembled with various components;

FIG. **87** is a schematic perspective view of an alternative electrosurgical device according to the present invention;

FIG. **88** is a schematic perspective view of a handle portion of the device of FIG. **87**;

FIG. **89** is a schematic side view of a handle portion of the device of FIG. **87**;

FIG. **90** is a schematic perspective view of a handle portion an alternative electrosurgical device according to the present invention; and

FIG. **91** is a schematic side view of the handle portion of FIG. **90**.

FIG. **92** is a schematic perspective view of a handle portion an alternative electrosurgical device according to the present invention; and

FIG. **93** is a schematic side view of the handle portion of FIG. **92**.

Detailed Description

Throughout the present description, like reference numerals and letters indicate corresponding structure throughout the several views, and such corresponding structure need not be separately discussed. Furthermore, any particular feature(s) of a particular exemplary embodiment may be equally applied to any other exemplary embodiment(s) of this specification as suitable. In other words, features between the various exemplary embodiments described herein are interchangeable as suitable, and not exclusive.

The invention provides devices, systems and methods that preferably improve control of tissue temperature at a tissue treatment site during a medical procedure. The invention is particularly useful during surgical procedures upon tissues of the body, where it is desirable to coagulate and shrink tissue, to occlude lumens of blood vessels (e.g. arteries, veins), airways (e.g. bronchi, bronchioles), bile ducts and lymphatic ducts.

The invention includes electrosurgical procedures, which preferably utilize RF power and electrically conductive fluid, to treat tissue. Preferably, a desired tissue temperature range is achieved by adjusting parameters, such as conductive fluid flow rate, that affect the temperature at the tissue/electrode interface. Preferably, the device achieves a desired tissue temperature by utilizing a desired percentage boiling of the conductive solution at the tissue/electrode interface.

In one embodiment, the invention provides a control device, the device comprising a flow rate controller that receives a signal indicating power applied to the system, and adjusts the flow rate of conductive fluid from a fluid source to an electrosurgical device. The invention also contemplates a control system comprising a flow rate controller, a measurement device that measures power applied to the system, and a pump that provides fluid at a selected flow rate.

The invention will be discussed generally with reference to FIG. **1**. FIG. **1** shows a block diagram of one exemplary embodiment of a system of the invention. Preferably, as shown in FIG. **1**, an electrically conductive fluid **24** is provided from a fluid source **1** through a fluid line **2** to a pump **3**, which has an outlet fluid line **4a** that is connected as an input fluid line **4b**, to electrosurgical device **5**. In a preferred embodiment, the outlet fluid line **4a** and the input fluid line **4b** are flexible and are made from a polymeric material, such as polyvinylchloride (PVC) or polyolefin (e.g. polypropylene, polyethylene) and the conductive fluid comprises a saline solution. More preferably, the saline comprises sterile, and even more preferably, normal saline. Although the description herein will specifically describe the use of saline as the fluid **24**, other electrically conductive fluids, as well as non-conductive fluids, can be used in accordance with the invention.

For example, in addition to the conductive fluid comprising physiologic saline (also known as "normal" saline, isotonic saline or 0.9% sodium chloride (NaCl) solution), the conductive fluid may comprise hypertonic saline solution, hypotonic saline solution, Ringers solution (a physiologic solution of distilled water containing specified amounts of sodium chloride, calcium chloride, and potassium chloride), lactated Ringer's solution (a crystalloid electrolyte sterile solution of distilled water containing specified amounts of calcium chloride, potassium chloride, sodium chloride, and sodium lactate), Locke-Ringer's solution (a buffered isotonic solution of distilled water containing specified amounts of sodium chloride, potassium chloride, calcium chloride, sodium bicarbonate, magnesium chloride, and dextrose), or any other electrolyte solution. In other words, a solution that conducts electricity via an electrolyte, a substance (salt, acid or base) that dissociates into electrically charged ions when dissolved in a solvent, such as water, resulting solution comprising an ionic conductor.

While a conductive fluid is preferred, as will become more apparent with further reading of this specification, the fluid **24** may also comprise an electrically non-conductive fluid. The use of a non-conductive fluid is less preferred to that of a conductive fluid as the non-conductive fluid does not conduct electricity. However, the use of a non-conductive fluid still provides certain advantages over the use of a dry electrode including, for example, reduced occurrence of tissue sticking to the electrode of the device **5** and cooling of the electrode and/or tissue. Therefore, it is also within the scope of the invention to include the use of a non-conducting fluid, such as, for example, dionized water.

Returning to FIG. **1**, energy to heat tissue is provided from energy source, such as an electrical generator **6** which preferably provides RF alternating current energy via a cable **7** to energy source output measurement device, such as a power measurement device **8** that measures the RF alternating current electrical power. In one exemplary embodiment, preferably the power measurement device **8** does not turn the power off or on, or alter the power in any way. A power switch **15** connected to the generator **6** is preferably provided by the generator manufacturer and is used to turn the generator **6** on and off. The power switch **15** can comprise any switch to turn the power on and off, and is commonly provided in the form of a footswitch or other easily operated switch, such as a switch **15a** mounted on the electrosurgical device **5**. The power switch **15** or **15a** may also function as a manually activated device for increasing or decreasing the rate of energy provided from the surgical device **5**. Alternatively, internal circuitry and other components of the generator **6** may be used for automatically increasing or decreasing the rate of energy provided from the surgical device **5**. A cable **9** preferably carries RF energy from the power measurement device **8** to the electrosurgical device **5**. Power, or any other energy source output, is preferably measured before it reaches the electrosurgical device **5**.

For the situation where capacitation and induction effects are negligibly small, from Ohm's law, power **P**, or the rate of energy delivery (e.g. joules/sec), may be expressed by the product of current times voltage (i.e. I x V), the current squared times resistance (i.e. I^2 x R), or the voltage squared divided by the resistance (i.e. V^2/R); where the current **I** may be measured in amperes, the voltage **V** may be measured in volts, the electrical resistance **R** may be measured in ohms, and the power **P** may be measured in watts (joules/sec). Given that power **P** is a function of current **I**, voltage **V**, and resistance **R** as indicated above, it should be understood, that a change in power **P** is reflective of a change in at least one of the input variables. Thus, one may alternatively measure changes in such input variables

themselves, rather than power **P** directly, with such changes in the input variables mathematically corresponding to a changes in power **P** as indicated above.

As to the frequency of the RF electrical energy, it is preferably provided within a frequency band (i.e. a continuous range of frequencies extending between two limiting frequencies) in the range between and including about 9 kHz (kilohertz) to 300 GHz (gigahertz). More preferably, the RF energy is provided within a frequency band in the range between and including about 50 kHz (kilohertz) to 50 MHz (megahertz). Even more preferably, the RF energy is provided within a frequency band in the range between and including about 200 kHz (kilohertz) to 2 MHz (megahertz). Most preferably, RF energy is provided within a frequency band in the range between and including about 400 kHz (kilohertz) to 600 kHz (kilohertz). Further, it should also be understood that, for any frequency band identified above, the range of frequencies may be further narrowed in increments of 1 (one) hertz anywhere between the lower and upper limiting frequencies.

While RF electrical energy is preferred, it should be understood that the electrical energy (i.e., energy made available by the flow of electric charge, typically through a conductor or by self-propagating waves) may comprise any frequency of the electromagnetic spectrum (i.e. the entire range of radiation extending in frequency from 10^{23} hertz to 0 hertz) and including, but not limited to, gamma rays, x-rays, ultraviolet radiation, visible light, infrared radiation, microwaves, and any combinations thereof.

With respect to the use of electrical energy, heating of the tissue is preferably performed by means of resistance heating. In other words, increasing the temperature of the tissue as a result of electric current flow through the tissue, with the electrical energy being absorbed from the voltage and transformed into thermal energy (i.e. heat) via accelerated movement of ions as a function of the tissue's electrical resistance.

Heating with electrical energy may also be performed by means of dielectric heating (capacitation). In other words, increasing the temperature of the tissue through the dissipation of electrical energy as a result of internal dielectric loss when the tissue is placed in a varying electric field, such as a high-frequency (e.g. microwave), alternating electromagnetic field. Dielectric loss is the electrical energy lost as heat in the polarization process in the presence of the applied electric field. In the case of an alternating current field, the energy is absorbed from the alternating current voltage and converted to heat during the polarization of the molecules.

However, it should be understood that energy provided to heat the tissue may comprise surgical devices other than electrosurgical devices, energy sources other

than generators, energy forms other than electrical energy and mechanisms other than resistance heating. For example, providing thermal energy to the tissue from energy source with a difference (e.g. higher) in temperature. Such may be provided, for example, to the tissue from a heated device, which heats tissue through direct contact with the energy source (conduction), heats through contact with a flowing fluid (convection), or from a remote heat source (radiation).

Also, for example, providing energy to the tissue may be provided via mechanical energy which is transformed into thermal energy via accelerated movement of the molecules, such as by mechanical vibration provided, for example, by energy source such as a transducer containing a piezoelectric substance (e.g., a quartz-crystal oscillator) that converts high-frequency electric current into vibrating ultrasonic waves which may be used by, for example, an ultrasonic surgical device.

Also, for example, providing energy to the tissue may be provided via radiant energy (i.e. energy which is transmitted by radiation/waves) which is transformed into thermal energy via absorption of the radiant energy by the tissue. Preferably the radiation/waves comprise electromagnetic radiation/waves which include, but is not limited to, radio waves, microwaves, infrared radiation, visible light radiation, ultraviolet radiation, x-rays and gamma rays. More preferably, such radiant energy comprises energy with a frequency of 3×10^{11} hertz to 3×10^{16} hertz (i.e. the infrared, visible, and ultraviolet frequency bands of the electromagnetic spectrum). Also preferably the electromagnetic waves are coherent and the electromagnetic radiation is emitted from energy source such as a laser device.

A flow rate controller **11** preferably includes a selection switch **12** that can be set to achieve desired levels of percentage fluid boiling (for example, 100%, 98%, 80% boiling). Preferably, the flow rate controller **11** receives an input signal **10** from the power measurement device **8** and calculates an appropriate mathematically predetermined fluid flow rate based on percentage boiling indicated by the selection switch **12**. In a preferred embodiment, a fluid switch **13** is provided so that the fluid system can be primed (e.g. air eliminated) before turning the generator **6** on. The output signal **16** of the flow rate controller **11** is preferably sent to the pump **3** motor to regulate the flow rate of conductive fluid, and thereby provide an appropriate fluid flow rate which corresponds to the amount of power being delivered.

In one exemplary embodiment, the invention comprises a flow rate controller **11** that is configured and arranged to be connected to a source of RF power (e.g. generator **6**), and a source of fluid (e.g. fluid source **1**), for example, a source of conductive fluid. The device of the invention receives information about the level of RF power applied to an electrosurgical device **5**, and adjusts the flow rate of the

fluid **24** to the electrosurgical device **5**, thereby controlling temperature at the tissue treatment site.

In another exemplary embodiment, elements of the system are physically included together in one electronic enclosure. One such embodiment is shown by enclosure within the outline box **14** of FIG **1**. In the illustrated embodiment, the pump **3**, flow rate controller **11**, and power measurement device **8** are enclosed within an enclosure, and these elements are connected through electrical connections to allow signal **10** to pass from the power measurement device **8** to the flow rate controller **11**, and signal **16** to pass from the flow rate controller **11** to the pump **3**. Other elements of a system can also be included within one enclosure, depending upon such factors as the desired application of the system, and the requirements of the user.

The pump **3** can be any suitable pump used in surgical procedures to provide saline or other fluid at a desired flow rate. Preferably, the pump **3** comprises a peristaltic pump. With a rotary peristaltic pump, typically a fluid **24** is conveyed within the confines of a flexible tube (e.g. **4a**) by waves of contraction placed externally on the tube which are produced mechanically, typically by rotating rollers which squeeze the flexible tubing against a support intermittently. Alternatively, with a linear peristaltic pump, typically a fluid **24** is conveyed within the confines of a flexible tube by waves of contraction placed externally on the tube which are produced mechanically, typically by a series of compression fingers or pads which squeeze the flexible tubing against a support sequentially. Peristaltic pumps are generally preferred for use as the electro-mechanical force mechanism (e.g. rollers driven by electric motor) does not make contact the fluid **24**, thus reducing the likelihood of inadvertent contamination.

Alternatively, pump **3** can be a "syringe pump", with a built-in fluid supply. With such a pump, typically a filled syringe is located on an electro-mechanical force mechanism (e.g. ram driven by electric motor) which acts on the plunger of the syringe to force delivery of the fluid **24** contained therein. Alternatively, the syringe pump may comprise a double-acting syringe pump with two syringes such that they can draw saline from a reservoir (e.g. of fluid source **1**), either simultaneously or intermittently. With a double acting syringe pump, the pumping mechanism is generally capable of both infusion and withdrawal. Typically, while fluid **24** is being expelled from one syringe, the other syringe is receiving fluid **24** therein from a separate reservoir. In this manner, the delivery of fluid **24** remains continuous and uninterrupted as the syringes function in series. Alternatively, it should be understood that a multiple syringe pump with two syringes, or any number of syringes, may be used in accordance with the invention.

Furthermore, fluid **24**, such as conductive fluid, can also be provided from an intravenous (IV) bag full of saline (e.g. of fluid source **1**) that flows under the influence (i.e. force) of gravity. In such a manner, the fluid **24** may flow directly to the electrosurgical device **5**, or first to the pump **3** located there between. Alternatively, fluid **24** from a fluid source **1** such as an IV bag can be provided through an IV flow controller that may provide a desired flow rate by adjusting the cross sectional area of a flow orifice (e.g. lumen of the connective tubing with the electrosurgical device **5**) while sensing the flow rate with a sensor such as an optical drop counter. Furthermore, fluid **24** from a fluid source **1** such as an IV bag an be provided through a manually or automatically activated device such as a flow controller, such as a roller clamp, which also adjusts the cross sectional area of a flow orifice and may be adjusted manually by, for example, the user of the device in response to their visual observation (e.g. fluid boiling) at the tissue treatment site or a pump.

Similar pumps can be used in connection with the invention, and the illustrated embodiments are exemplary only. The precise configuration of the pump **3** is not critical to the invention. For example, pump **3** may include other types of infusion and withdrawal pumps. Furthermore, pump **3** may comprise pumps which may be categorized as piston pumps, rotary vane pumps (e.g. axial impeller, centrifugal impeller), cartridge pumps and diaphragm pumps. In some embodiments, the pump **3** can be substituted with any type of flow controller, such as a manual roller clamp used in conjunction with an IV bag, or combined with the flow controller to allow the user to control the flow rate of conductive fluid to the device. Alternatively, a valve configuration can be substituted for pump **3**.

Furthermore, similar configurations of the system can be used in connection with the invention, and the illustrated embodiments are exemplary only. For example, the fluid source **1** pump **3**, generator **6**, power measurement device **8** or flow rate controller **11**, or any other components of the system not expressly recited above, may comprise a portion of the electrosurgical device **5**. For example, in one exemplary embodiment the fluid source **1** may comprise a compartment of the electrosurgical device **5** which contains fluid **24**, as indicated at reference character **1a**. In another exemplary embodiment, the compartment may be detachably connected to the electrosurgical device **5**, such as a canister which may be attached via threaded engagement with the device **5**. In yet another exemplary embodiment, the compartment may be configured to hold a pre-filled cartridge of fluid **24**, rather than the fluid directly.

Also for example, with regards to alternative for the generator **6**, an energy source, such as a direct current (DC) battery used in conjunction with inverter

circuitry and a transformer to produce alternating current at a particular frequency, may comprise a portion of the electrosurgical device **5**, as indicated at reference character **6a**. In one embodiment the battery element of the energy source may comprise a rechargeable battery. In yet another exemplary embodiment, the battery element may be detachably connected to the electrosurgical device **5**, such as for recharging. The components of the system will now be described in further detail. From the specification, it should be clear that any use of the terms "distal" and "proximal" are made in reference from the user of the device, and not the patient.

The flow rate controller **11** controls the rate of flow from the fluid source **1**. Preferably, the rate of fluid flow from the fluid source **1** is based upon the amount of RF power provided from the generator **6** to the electrosurgical device **5**. In other words, as shown in FIG. **2**, preferably there is a relationship between the rate of fluid flow **Q** and the RF power **P** indicated by the Y- and X-axes of the schematic graph, respectively. More precisely, as shown in FIG. **2**, the relationship between the rate of fluid flow **Q** and RF power **P** may be expressed as a direct, linear relationship. The flow rate **Q** of conductive fluid **24**, such as saline, interacts with the RF power **P** and various modes of heat transfer away from the target tissue, as described herein.

Throughout this disclosure, when the terms "boiling point of saline", "vaporization point of saline", and variations thereof are used, what is actually referenced for explanation purposes, is the boiling point of the water (i.e. 100°C) in the saline solution given that the difference between the boiling point of normal saline (about 100.16°C) and the boiling point of water is negligible.

FIG. **2** shows a schematic graph that describes the relationship between the flow rate of saline, RF power to tissue, and regimes of boiling as detailed below. Based on a simple one-dimensional lumped parameter model of the heat transfer, the peak tissue temperature can be estimated, and once tissue temperature is estimated, it follows directly whether it is hot enough to boil saline. The total RF electrical power **P** that is converted into heat can be defined as:

$$P = \Delta T/R + \rho c_p Q_l \Delta T + \rho Q_b h_v \qquad (1)$$

where P = the total RF electrical power that is converted into heat.

Conduction. The term [ΔT/R] in equation (1) is heat conducted to adjacent tissue, represented as **70** in FIG. **2**, where:

$\Delta T =$ $(T - T_\infty)$ the difference in temperature between the peak tissue temperature (T) and the normal temperature (T_∞) of the body tissue (°C). Normal temperature of the body tissue is generally 37 °C; and

$R =$ Thermal resistance of surrounding tissue, the ratio of the temperature difference to the heat flow (°C/watt).

This thermal resistance can be estimated from published data gathered in experiments on human tissue (see for example, Phipps, J.H., "Thermometry studies with bipolar diathermy during hysterectomy," *Gynaecological Endoscopy*, 3:5-7 (1994)). As described by Phipps, Kleppinger bipolar forceps were used with an RF power of 50 watts, and the peak tissue temperature reached 320 °C. For example, using the energy balance of equation (1), and assuming all the RF heat put into tissue is conducted away, then R can be estimated:

$$R = \Delta T/P = (320-37)/50 = 5.7 \approx 6 \text{ °C/watt}$$

However, it is undesirable to allow the tissue temperature to reach 320 °C, since tissue will become desiccated. At a temperature of 320 °C, the fluid contained in the tissue is typically boiled away, resulting in the undesirable tissue effects described herein. Rather, it is preferred to keep the peak tissue temperature at no more than about 100 °C to inhibit desiccation of the tissue. Assuming that saline boils at about 100 °C, the first term in equation (1) ($\Delta T/R$) is equal to $(100 - 37)/6 =$ 10.5 watts. Thus, based on this example, the maximum amount of heat conducted to adjacent tissue without any significant risk of tissue desiccation is 10.5 watts.

Referring to FIG. **2**, RF power to tissue is represented on the X-axis as **P** (watts) and flow rate of saline (cc/min) is represented on the Y-axis as **Q**. When the flow rate of saline equals zero ($Q = 0$), there is an "offset" RF power that shifts the origin of the sloped lines **76**, **78**, and **80** to the right. This offset is the heat conducted to adjacent tissue. For example, using the calculation above for bipolar forceps, this offset RF power is about 10.5 watts. If the power is increased above this level with no saline flow, the peak tissue temperature can rise well above 100 °C, resulting in tissue desiccation from the boiling off of water in the cells of the tissue.

Convection. The second term $[\rho c_\rho Q_l \Delta T]$ in equation (1) is heat used to warm up the flow of saline without boiling the saline, represented as **72** in FIG. **2**, where:

ρ = Density of the saline fluid that gets hot but does not boil (approximately 1.0 gm/cm^3);

c_ρ = Specific heat of the saline (approximately 4.1 watt-sec/gm-°C);

Q_l = Flow rate of the saline that is heated (cm^3/sec); and

ΔT = Temperature rise of the saline. Assuming that the saline is heated to body temperature before it gets to the electrode, and that the peak saline temperature is similar to the peak tissue temperature, this is the same ΔT as for the conduction calculation above.

The onset of boiling can be predicted using equation (1) with the last term on the right set to zero (no boiling) ($\rho Q_b h_v = 0$), and solving equation (1) for Q_l leads to:

$$Q_l = [P - \Delta T/R]/\rho c_\rho \Delta T \qquad (2)$$

This equation defines the line shown in FIG. **2** as the line of onset of boiling **76**.

Boiling. The third term [$\rho Q_b h_v$] in equation (1) relates to heat that goes into converting the water in liquid saline to water vapor, and is represented as **74** in FIG. **2**, where:

Q_b = Flow rate of saline that boils (cm^3/sec); and

h_v = Heat of vaporization of saline (approximately 2,000 watt-sec/gm).

A flow rate of only 1 cc/min will absorb a significant amount of heat if it is completely boiled, or about $\rho Q_b h_v = (1)\ (1/60)\ (2{,}000) = 33.3$ watts. The heat needed to warm this flow rate from body temperature to 100 °C is much less, or $\rho c_\rho Q_l \Delta T = (1)\ (4.1)\ (1/60)\ (100 - 37) = 4.3$ watts. In other words, the most significant factor contributing to heat transfer from a wet electrode device can be fractional boiling. The present invention recognizes this fact and exploits it.

Fractional boiling can be described by equation (3) below:

$$Q_l = \frac{\{P - \Delta T/R\}}{\{\rho c_\rho \Delta T + \rho h_v Q_b/Q_l\}} \qquad (3)$$

If the ratio of Q_b/Q_l is 0.50 this is the 50% boiling line **78** shown in FIG. **2**. If the ratio is 1.0 this is the 100% boiling line **80** shown in FIG. **2**.

As indicated previously in the specification, using a fluid to couple energy to tissue inhibits such undesirable effects as sticking, desiccation, smoke production and char formation, and that one key factor is inhibiting tissue desiccation, which

occur if the tissue temperature exceeds 100 °C and all the intracellular water boils away, leaving the tissue extremely dry and much less electrically conductive.

As shown in FIG. **2**, one control strategy or mechanism which can be employed for the electrosurgical device **5** is to adjust the power **P** and flow rate **Q** such that the power **P** used at a corresponding flow rate **Q** is equal to or less than the power **P** required to boil 100% of the fluid and does not exceed the power **P** required to boil 100% of the fluid. In other words, this control strategy targets using the electrosurgical device **5** in the regions of FIG. **2** identified as $T < 100$ °C and $T = 100$ °C, and includes the 100% boiling line **80**. Stated another way, this control strategy targets not using the electrosurgical device **5** only in the region of FIG. **2** identified as $T >> 100$ °C.

Another control strategy that can be used for the electrosurgical device **5** is to operate the device **5** in the region $T < 100$ °C, but at high enough temperature to shrink tissue containing Type I collagen (e.g., walls of blood vessels, bronchi, bile ducts, etc.), which shrinks when exposed to about 85 °C for an exposure time of 0.01 seconds, or when exposed to about 65 °C for an exposure time of 15 minutes. An exemplary target temperature/time for tissue shrinkage is about 75 °C with an exposure time of about 1 second. As discussed herein, a determination of the high end of the scale (i.e., when the fluid reaches 100 °C) can be made by the phase change in the fluid from liquid to vapor. However, a determination at the low end of the scale (e.g., when the fluid reaches, for example, 75 °C for 1 second) requires a different mechanism as the temperature of the fluid is below the boiling temperature and no such phase change is apparent. In order to determine when the fluid reaches a temperature that will facilitate tissue shrinkage, for example 75 °C, a thermochromic material, such as a thermochromic dye (e.g., leuco dye), may be added to the fluid. The dye can be formulated to provide a first predetermined color to the fluid at temperatures below a threshold temperature, such as 75 °C, then, upon heating above 75 °C, the dye provides a second color, such as clear, thus turning the fluid clear (i.e. no color or reduction in color). This color change may be gradual, incremental, or instant. Thus, a change in the color of the fluid, from a first color to a second color (or lack thereof) provides a visual indication to the user of the electrosurgical device **5** as to when a threshold fluid temperature below boiling has been achieved. Thermochromic dyes are available, for example, from Color Change Corporation, 1740 Cortland Court, Unit A, Addison, IL 60101.

It is also noted that the above mechanism (i.e., a change in the color of the fluid due to a dye) may also be used to detect when the fluid reaches a temperature which will facilitate tissue necrosis; this generally varies from about 60 °C for an exposure time of 0.01 seconds and decreasing to about 45 °C for an exposure time of

15 minutes. An exemplary target temperature/time for tissue necrosis is about 55 °C for an exposure time of about 1 second.

In order to reduce coagulation time, use of the electrosurgical device **5** in the region T = 100 °C of FIG. **2** is preferable to use of the electrosurgical device **5** in the region T < 100 °C. Consequently, as shown in FIG. **2**, another control strategy which may be employed for the electrosurgical device **5** is to adjust the power **P** and flow rate **Q** such that the power **P** used at a corresponding flow rate **Q** is equal to or more than the power **P** required to initiate boiling of the fluid, but still less than the power **P** required to boil 100% of the fluid. In other words, this control strategy targets using the electrosurgical device **5** in the region of FIG. **2** identified as T = 100 °C, and includes the lines of the onset of boiling **76** and 100% boiling line **80**. Stated another way, this control strategy targets use using the electrosurgical device **5** on or between the lines of the onset of boiling **76** and 100% boiling line **80**, and not using the electrosurgical device **5** in the regions of FIG. **2** identified as T < 100 °C and T >> 100 °C.

For consistent tissue effect, it is desirable to control the saline flow rate so that it is always on a "line of constant % boiling" as, for example, the line of the onset of boiling **76** or the 100% boiling line **80** or any line of constant % boiling located in between (e.g. 50% boiling line **78**) as shown in FIG. **2**. Consequently, another control strategy that can be used for the electrosurgical device **5** is to adjust power **P** and flow rate **Q** such that the power **P** used at a corresponding flow rate **Q** targets a line of constant % boiling.

It should be noted, from the preceding equations, that the slope of any line of constant % boiling is known. For example, for the line of the onset of boiling **76**, the slope of the line is given by $(\rho c_p \Delta T)$, while the slope of the 100% boiling line **80** is given by $1/(\rho c_p \Delta T + \rho h_v)$. As for the 50% boiling line **78**, for example, the slope is given by $1/(\rho c_p \Delta T + \rho h_v 0.5)$.

If, upon application of the electrosurgical device **5** to the tissue, boiling of the fluid is not detected, such indicates that the temperature is less than 100 °C as indicated in the area of FIG. **2**, and the flow rate **Q** must be decreased to initiate boiling. The flow rate **Q** may then decreased until boiling of the fluid is first detected, at which time the line of the onset of boiling **76** is transgressed and the point of transgression on the line **76** is determined. From the determination of a point on the line of the onset of boiling **76** for a particular power **P** and flow rate **Q**, and the known slope of the line **76** as outlined above (i.e. $1/\rho c_p \Delta T$), it is also possible to determine the heat conducted to adjacent tissue **70**.

Conversely, if upon application of the electrosurgical device **5** to the tissue, boiling of the fluid is detected, such indicates that the temperature is approximately

equal to 100 °C as indicated in the areas of FIG. **2**, and the flow rate **Q** must be increased to reduce boiling until boiling stops, at which time the line of the onset of boiling **76** is transgressed and the point of transgression on the line **76** determined. As with above, from the determination of a point on the line of the onset of boiling **76** for a particular power **P** and flow rate **Q**, and the known slope of the line **76**, it is also possible to determine the heat conducted to adjacent tissue **70**.

With regards to the detection of boiling of the fluid, such may be physically detected by the user (e.g. visually by the naked eye) of the electrosurgical device **5** in the form of either bubbles or steam evolving from the fluid coupling at the electrode/tissue interface. Alternatively, such a phase change (i.e. from liquid to vapor or vice-versa) may be measured by a sensor which preferably senses either an absolute change (e.g. existence or non-existence of boiling with binary response such as yes or no) or a change in a physical quantity or intensity and converts the change into a useful input signal for an information-gathering system. For example, the phase change associated with the onset of boiling may be detected by a pressure sensor, such as a pressure transducer, located on the electrosurgical device **5**. Alternatively, the phase change associated with the onset of boiling may be detected by a temperature sensor, such as a thermistor or thermocouple, located on the electrosurgical device **5**, such as adjacent to the electrode. Also alternatively, the phase change associated with the onset of boiling may be detected by a change in the electric properties of the fluid itself. For example, a change in the electrical resistance of the fluid may be detected by an ohm meter; a change in the amperage may be measured by an amp meter; as change in the voltage may be detected by a volt meter; and a change in the power may be determined by a power meter.

Yet another control strategy which may be employed for the electrosurgical device **5** is to eliminate the heat conduction term of equation (1) (i.e. $\Delta T/R$). Since the amount of heat conducted away to adjacent tissue can be difficult to precisely predict, as it may vary, for example, by tissue type, it may be preferable, from a control point of view, to assume the worst case situation of zero heat conduction, and provide enough saline so that if necessary, all the RF power could be used to heat up and boil the saline, thus providing that the peak tissue temperature will not go over 100 °C a significant amount. This situation is shown in the schematic graph of FIG. **3**.

Stated another way, if the heat conducted to adjacent tissue **70** is overestimated, the power **P** required to intersect the 100% boiling line **80** will, in turn, be overestimated and the 100% boiling line **80** will be transgressed into the $T >> 100$ °C region of FIG. **2**, which is undesirable as established above. Thus, assuming the worse case situation of zero heat conduction provides a "safety factor"

to avoid transgressing the 100% boiling line **80**. Assuming heat conduction to adjacent tissue **70** to be zero also provides the advantage of eliminating the only term from equation (1) which is tissue dependent, i.e., depends on tissue type. Thus, provided ρ, c_p, ΔT, and h_v are known as indicated above, the equation of the line for any line of constant % boiling is known. Thus, for example, the 98% boiling line, 80% boiling line, etc. can be determined in response to a corresponding input from the selection switch **12**. In order to promote flexibility, it should be understood that the input from the selection switch preferably may comprise any percentage of boiling. Preferably the percentage of boiling may be selected in single percent increments (i.e. 100%, 99%, 98%, etc.).

Upon determination of the line of the onset of boiling **76**, the 100% boiling line **80** or any line of constant % boiling there between, it is generally desirable to control the flow rate **Q** so that it is always on a particular line of constant % boiling for consistent tissue effect. In such a situation, the flow rate controller **11** will adjust the flow rate **Q** of the fluid **24** to reflect changes in power **P** provided by the generator **6**, as discussed in greater detail below. For such a use the flow rate controller **11** may be set in a line of constant boiling mode, upon which the % boiling is then correspondingly selected.

As indicated above, it is desirable to control the saline flow rate **Q** so that it is always on a line of constant % boiling for consistent tissue effect. However, the preferred line of constant % boiling may vary based on the type of electrosurgical device **5**. For example, if with use of the device **5**, shunting through saline is not an issue, then it can be preferable to operate close to or directly on, but not over the line of the onset of boiling, such as **76a** in FIG. **3**. This preferably keeps tissue as hot as possible without causing desiccation. Alternatively, if with use of the device **5** shunting of electrical energy (e.g. from one jaw to an opposing jaw of certain copative bipolar devices) through excess saline is an issue, then it can be preferable to operate along a line of constant boiling, such as line **78a** in FIG. **3**, the 50% line. This simple proportional control will have the flow rate determined by equation (4), where **K** is the proportionality constant:

$$Q_1 = K \times P \qquad (4)$$

In essence, when power **P** goes up, the flow rate **Q** will be proportionately increased. Conversely, when power **P** goes down, the flow rate **Q** will be proportionately decreased.

The proportionality constant **K** is primarily dependent on the fraction of saline that boils, as shown in equation (5), which is equation (3) solved for **K** after eliminating **P** using equation (4), and neglecting the conduction term ($\Delta T/R$):

$$K = \frac{1}{\{\rho c_p \Delta T + \rho h_v Q_b/Q_l\}} \quad (5)$$

Thus, the present invention provides a method of controlling boiling of fluid, such as a conductive fluid, at the tissue/electrode interface. In a preferred embodiment, this provides a method of treating tissue without use of tissue sensors, such as temperature or impedance sensors. Preferably, the invention can control boiling of conductive fluid at the tissue/electrode interface and thereby control tissue temperature without the use of feedback loops.

In describing the control strategy of the present invention described thus far, focus has been drawn to a steady state condition. However, the heat required to warm the tissue to the peak temperature (T) may be incorporated into equation (1) as follows:

$$P = \Delta T/R + \rho c_p Q_l \Delta T + \rho Q_b h_v + \rho c_p V \Delta T/\Delta t \quad (6)$$

where $\rho c_p V \Delta T/\Delta t$ represents the heat required to warm the tissue to the peak temperature (T) **68** and where :

- ρ = Density of the saline fluid that gets hot but does not boil (approximately 1.0 gm/cm^3);
- c_p = Specific heat of the saline (approximately 4.1 watt-sec/gm-°C);
- V = Volume of treated tissue
- ΔT = $(T - T_\infty)$ the difference in temperature between the peak tissue temperature (T) and the normal temperature (T_∞) of the body tissue (°C). Normal temperature of the body tissue is generally 37 °C; and
- Δt = $(t - t_\infty)$ the difference in time to achieve peak tissue temperature (T) and the normal temperature (T_∞) of the body tissue (°C).

The inclusion of the heat required to warm the tissue to the peak temperature (T) in the control strategy is graphically represented at **68** in FIG. **4**. With respect to the control strategy, the effects of the heat required to warm the tissue to the peak temperature (T) **68** should be taken into account before flow rate **Q** adjustment being undertaken to detect the location of the line of onset of boiling **76**. In other words, the flow rate **Q** should not be decreased in response to a lack of boiling before at

least a quasi-steady state has been achieved as the location of the line of onset of boiling **76** will continue to move during the transitory period. Otherwise, if the flow rate **Q** is decreased during the transitory period, it may be possible to decrease the flow **Q** to a point past the line of onset of boiling **76** and continue past the 100% boiling line **80** which is undesirable. In other words, as temperature (T) is approached the heat **68** diminishes towards zero such that the lines of constant boiling shift to the left towards the Y-axis.

FIG. **5** is an exemplary graph of flow rate **Q** versus % boiling for a situation where the RF power **P** is 75 watts. The percent boiling **%** is represented on the X-axis, and the saline flow rate **Q** (cc/min) is represented on the Y-axis. According to this example, at 100 % boiling the most desirable predetermined saline flow rate **Q** is 2 cc/min. Also according to this example, flow rate **Q** versus % boiling at the remaining points of the graft illustrates a non-linear relationship as follows:

Table 1 – % Boiling and Flow Rate **Q** (cc/min) at RF Power **P** of 75 watts

0%	17.4
10%	9.8
20%	6.8
30%	5.2
40%	4.3
50%	3.6
60%	3.1
70%	2.7
80%	2.4
90%	2.2
100%	2.0

Typical RF generators used in the field have a power selector switch to 300 watts of power, and on occasion some have been found to be selectable up to 400 watts of power. In conformance with the above methodology, at 0% boiling with a corresponding power of 300 watts, the calculated flow rate **Q** is 69.7 cc/min and with a corresponding power of 400 watts the calculated flow rate **Q** is 92.9 cc/min. Thus, when used with typical RF generators in the field, a fluid flow rate **Q** of about 100 cc/min or less with the present invention is expected to suffice for the vast majority of applications.

As discussed herein, RF energy delivery to tissue can be unpredictable and vary with time, even though the generator has been "set" to a fixed wattage. The schematic graph of FIG. **6** shows the general trends of the output curve of a typical

general-purpose generator, with the output power changing as load (tissue plus cables) impedance **Z** changes. Load impedance **Z** (in ohms) is represented on the X-axis, and generator output power **P** (in watts) is represented on the Y-axis. In the illustrated embodiment, the electrosurgical power (RF) is set to 75 watts in a bipolar mode. As shown in the figure, the power will remain constant as it was set as long as the impedance **Z** stays between two cut-offs, low and high, of impedance, that is, for example, between 50 ohms and 300 ohms in the illustrated embodiment. Below load impedance **Z** of 50 ohms, the power **P** will decrease, as shown by the low impedance ramp **28a**. Above load impedance **Z** of 300 ohms, the power **P** will decrease, as shown by the high impedance ramp **28b**. Of particular interest to saline-enhanced electrosurgery is the low impedance cut-off (low impedance ramp **28a**), where power starts to ramp down as impedance **Z** drops further. This change in output is invisible to the user of the generator and not evident when the generator is in use, such as in an operating room.

FIG. **7** shows the general trend of how tissue impedance generally changes with time for saline-enhanced electrosurgery. As tissue heats up, the temperature coefficient of the tissue and saline in the cells is such that the tissue impedance decreases until a steady-state temperature is reached upon which time the impedance remains constant. Thus, as tissue heats up, the load impedance **Z** decreases, potentially approaching the impedance **Z** cut-off of 50 ohms. If tissue is sufficiently heated, such that the low impedance cut-off is passed, the power **P** decreases along the lines of the low impedance ramp **28a** of FIG. **6**.

Combining the effects shown in FIG. **6** and FIG. **7**, it becomes clear that when using a general-purpose generator set to a "fixed" power, the actual power delivered can change dramatically over time as tissue heats up and impedance drops. Looking at FIG. **6**, if the impedance **Z** drops from 100 to 75 ohms over time, the power output would not change because the curve is "flat" in that region of impedances. If, however, the impedance **Z** drops from 75 to 30 ohms one would transgress the low impedance cut-off and "turn the corner" onto the low impedance ramp **28a** portion of the curve and the power output would decrease dramatically.

According to one exemplary embodiment of the invention, the control device, such as flow rate controller **11**, receives a signal indicating the drop in actual power delivered to the tissue and adjusts the flow rate **Q** of saline to maintain the tissue/electrode interface at a desired temperature. In a preferred embodiment, the drop in actual power **P** delivered is sensed by the power measurement device **8** (shown in FIG. **1**), and the flow rate **Q** of saline is decreased by the flow rate controller **11** (also shown in FIG. **1**). Preferably, this reduction in saline flow rate **Q** allows the tissue temperature to stay as hot as possible without desiccation. If the

control device was not in operation and the flow rate **Q** allowed to remain higher, the tissue would be over-cooled at the lower power input. This would result in decreasing the temperature of the tissue at the treatment site.

The flow rate controller **11** of FIG. **1** can be a simple "hard-wired" analog or digital device that requires no programming by the user or the manufacturer. The flow rate controller **11** can alternatively include a processor, with or without a storage medium, in which the determination procedure is performed by software, hardware, or a combination thereof. In another embodiment, the flow rate controller **11** can include semi-programmable hardware configured, for example, using a hardware descriptive language, such as Verilog. In another embodiment, the flow rate controller **11** of FIG. **1** is a computer, microprocessor-driven controller with software embedded. In yet another embodiment, the flow rate controller **11** can include additional features, such as a delay mechanism, such as a timer, to automatically keep the saline flow on for several seconds after the RF is turned off to provide a post-coagulation cooling of the tissue or "quench," which can increase the strength of the tissue seal. Also, in another embodiment, the flow rate controller **11** can include a delay mechanism, such as a timer, to automatically turn on the saline flow several seconds before the RF is turned on to inhibit the possibility of undesirable effects as sticking, desiccation, smoke production and char formation. Also in another embodiment, the flow rate controller **11** can include a low level flow standby mechanism, such as a valve, which continues the saline flow at a standby flow level (which prevents the flow rate from going to zero when the RF power is turned off) below the surgical flow level ordinarily encountered during use of the electrosurgical device **5**.

An exemplary electrosurgical device of the present invention which may be used in conjunction with the system of the present invention is shown at reference character **5a** in FIG. **9**, and more particularly in FIGS. **9-13**. While various electrosurgical devices of the present invention are described with reference to use with the remainder of the system of the invention, it should be understood that the description of the combination is for purposes of illustrating the remainder of the system of the invention only. Consequently, it should be understood that the electrosurgical devices of the present invention can be used alone, or in conjuction with the remainder of the system of the invention, or that a wide variety of electrosurgical devices can be used in connection with the remainder of the system of the invention. The electrosurgical devices disclosed herein are preferably further configured for both open and laparoscopic surgery. For laparoscopic surgery, the devices are preferably configured to fit through either a 5 mm or 12 mm trocar cannula.

As shown in FIG. **8**, electrosurgical device **5a** may be used in conjunction with a cannula as illustrated at reference character **19,** during laparoscopic surgery such as, for example, a laparoscopic cholecystectomy. Cannula **19** comprises a proximal portion **19a** separated from a distal portion **19b** by an elongated rigid shaft portion **19c**. Proximal portion **19a** of cannula **19** preferably comprises a head portion **19d** connected to rigid shaft portion **19c**, preferably by threaded engagement. Most importantly, cannula **19** has a working channel **19e** which extends through head portion **19d** and shaft portion **19c** from proximal portion **19a** to distal portion **19b** of cannula **19**. In one particular embodiment, during insertion into cannula **19**, electrosurgical device **5a** is configured to enter the proximal end of working channel **19e**, move along the channel **19e** distally, and then be extended from the distal end of the working channel **19e**. In the same embodiment, during retraction from cannula **19**, electrosurgical device **5a** is configured to enter the distal end of working channel **19e**, move along the channel **19e** proximally, and then be removed from the proximal end of working channel **19e**.

Referring back to FIG. **9**, as shown electrosurgical device **5a** comprises a monopolar electrosurgical device. As shown in FIG. **9**, electrosurgical device **5a** preferably includes a rigid, self-supporting, hollow shaft **17**, a proximal handle comprising mating handle portions **20a**, **20b** and a tip portion as shown by circle **45**. Handle **20a**, **20b** is preferably made of a sterilizable, rigid, non-conductive material, such as a polymer (e.g. polycarbonate). As shown in FIGS. **10** and **11**, tip portion **45** includes a contact element preferably comprising an electrode **25** which, as shown, comprises a solid ball having a smooth, uninterrupted surface. Also as shown in FIGS. **10** and **11**, tip portion **45** also comprises a sleeve **82** having a uniform diameter along its longitudinal length, a spring **88** and a distal portion of shaft **17**. As shown in FIG. **10**, the longitudinal axis **31** of the tip portion **45** may be configured at an angle **A** relative to the longitudinal axis **29** of the proximal remainder of shaft **17**. Preferably the longitudinal axis **31** of the tip portion **45** is configured at an angle **A** of about 5 degrees to 90 degrees relative to the longitudinal axis **29** of the proximal remainder of shaft **17**. More preferably, the longitudinal axis **31** of tip portion **45** is configured at an angle **A** of about 8 degrees to 45 degrees relative to the longitudinal axis of **29** of the proximal remainder of shaft **17**.

As shown in FIGS. **10** and **11**, for electrosurgical device **5a**, electrode **25** generally has a spherical shape with a corresponding spherical surface, a portion **42** of which is exposed to tissue **32** (less than 180 degrees and more specifically about 100-120 degrees) at the distal end of device **5a**. When electrode **25** is in the form of a sphere, the sphere may have any suitable diameter. However, the sphere preferably has a diameter in the range between and including about 1 mm to about 7

mm. Although, it has been found that when a sphere is larger than about 4 mm and less than about 2 mm tissue treatment can be adversely effected (particularly tissue treatment time) due to an electrode surface that is respectively either to large or to small. Thus, more preferably the sphere has a diameter in the range between and including about 2.5 mm to about 3.5 mm. Even more preferably, the sphere has a diameter of about 3 mm.

It is understood that shapes other than a sphere can be used for the contact element. Examples of such shapes include oblong or elongated shapes. However, as shown in FIGS. **10** and **11**, preferably a distal end surface of electrosurgical device **5a** always provides a blunt, rounded surface which is non-pointed and non-sharp as shown by electrode **25**.

As shown in FIGS. **10** and **11**, electrode **25,** is preferably located in a cavity **81** of a cylindrical sleeve **82** providing a receptacle for electrode **25**. Among other things, sleeve **82** guides movement of the electrode **25**. Among other things, sleeve **82** also functions as a housing for retaining the electrode **25**.

Also as shown in FIG. **11**, a portion **44** of the electrode **25,** is retained within the cavity **81** while another portion **43** extends distally through the fluid outlet opening provided by circular fluid exit hole **26**. Also as shown, sleeve **82** is connected, preferably via welding with silver solder, to the distal end **53** of shaft **17**. For device **5a**, electrode **25**, sleeve **82** and shaft **17** preferably comprise, and more preferably at least essentially consists of, an electrically conductive metal, which is also preferably non-corrosive, and more particularly stainless steel. Other metals include copper, titanium, gold, silver and platinum. Furthermore, shaft **17** preferably comprises thick walled stainless steel hypo-tubing.

As for cavity **81**, the internal diameter of cavity **81** surrounding the electrode **25**, is preferably slightly larger than the diameter of the sphere, typically by about 0.25 mm. This permits the sphere to freely rotate within the cavity **81**. Consequently, cavity **81** of sleeve **82** also preferably has a diameter in the range of about 1 mm to about 7 mm.

As best shown in FIGS. **11** and **12**, in order to retain the electrode **25,** within the cavity **81** of sleeve **82**, preferably the fluid exit hole **26**, which ultimately provides a fluid outlet opening, of cavity **81** at its distal end **83** comprises a distal pinched region **86** which is reduced to a size smaller than the diameter of the electrode **25,** to inhibit escape of the electrode **25** from the sleeve **82**. More preferably, the fluid exit hole **26** comprises a diameter smaller than the diameter of the electrode **25**.

As best shown in FIG. **12**, the fluid exit hole **26** preferably has a diameter smaller than the diameter of the electrode **25,** which can be accomplished by at least

one crimp **84** located at the distal end **83** of the sleeve **82** which is directed towards the interior of the sleeve **82** and distal to the portion **44** of the electrode **25** confined in cavity **81**. Where one crimp **84** is employed, the crimp **84** may comprise a single continuous circular rim pattern. In this manner, the contact element portion extending distally through the fluid outlet opening (i.e. electrode portion **43**) provided by fluid exit hole **26** has a complementary shape to the fluid outlet opening provided by fluid exit hole **26**, here both circular.

However, as shown in FIG. **12**, the crimp **84** may also comprise a discontinuous circular rim pattern where the crimp **84** is interrupted by at least one rectangular hole slot **85** formed at the distal end **83** of the sleeve **82**. Thus, the fluid outlet opening located at the distal end of the device **5a** may comprise a first portion (e.g. the circular fluid exit hole portion **26**) and a second portion (e.g. the slot fluid exit hole portion **85**). As shown in FIG. **12**, preferably, crimp **84** comprises at least four crimp sections forming a circular rim pattern separated by four discrete slots **85** radially located there between at 90 degrees relative to one another and equally positioned around the fluid outlet opening first portion. Slots **85** are preferably used to provide a fluid outlet opening or exit adjacent the electrode **25**, when the electrode **25** is fully seated (as discussed below) and/or when the electrode **25** is not in use (i.e. not electrically charged) to keep surface portion **42** of the electrode surface of electrode **25** wet. Preferably, slots **85** have a width in the range between and including about 0.1 mm to 1 mm, and more preferably have a width in the range between and including about 0.2 mm to 0.3 mm. As for length, slots **85** preferably have a length in the range between and including about 0.1 mm to 1 mm, and more preferably have a length in the range between and including about 0.4 mm to 0.6 mm.

As shown in FIG. **12**, the contact element portion extending distally through the fluid outlet opening (i.e. electrode portion **43**) extends distally through the fluid outlet opening first portion (e.g. the circular fluid exit hole portion **26**) and does not extend distally through the fluid outlet opening second portion (e.g. the slot fluid exit hole portion **85**). In this manner an edge **91** of the slot **85** remains exposed to tissue **32** to provide a tissue separating edge as discussed below.

It should be understood that the particular geometry of fluid outlet opening provided by the fluid exit hole located at the distal end of the device **5a** to the electrode, is not critical to the invention, and all that is required is the presence of a fluid exit hole which provides fluid **24** as required. For example, the fluid exit hole **26** may comprise an oval shape while electrode **25**, comprises a different shape, such as a round shape.

As shown in FIG. **12**, in addition to slot **85** providing a fluid exit, at least one edge **91** of slot **85** may provide a tissue separating edge adjacent a blunt surface (e.g. surface portion **42** of the electrode **25**) which may be used for blunt dissection when the electrosurgical device **5a** is manipulated, particularly by rotating (e.g. twirling), abrading or impacting. When edge **91** is used in such regard, it is preferred that the edge comprise a sharp edge with a sharp angle which has not been rounded by, for example, a fillet.

Turning to the proximal end of the tip (comprising the electrode **25**, spring **88** and sleeve **82**) of the device **5a** and electrode **25**, as shown in FIG. **11**, preferably the portion of the sleeve **82** proximal to the electrode **25**, also has a proximal pinched region **87** which retains the electrode **25** in the cavity **81** of the sleeve **82** and inhibits escape of the electrode **25** from the cavity **81** of the sleeve **82**, such as a diameter smaller than the diameter of the electrode **25**.

While distal pinched region **86** and proximal pinched region **87** may be used solely to support the electrode **25**, in its position of use, the electrode may be further supported by a compression spring **88** as shown in FIG. **11**. The use of spring **88** is preferred to provide a variable length support within the working length of the spring **88** for overcoming manufacturing tolerances (e.g. length) between the fixed supports (i.e. pinched regions **86** and **87**) of the sleeve **82**. As for maintaining proper location of the spring **88**, sleeve **82** also comprises a lumen **89** as shown in FIG. **11** (i.e. the cavity of an elongated hollow structure, such as a tube or tube like structure; typically cylindrical) which, in addition to providing a direct passage for fluid, provides a guide tube for spring **88**. Furthermore, the surface portion **60** of electrode **25**, which contacts the spring **88** may comprise a flat surface rather than a curvilinear surface to better seat the spring against the electrode **25**.

In addition to the above, spring **88** provides a multitude of functions and advantages. For example, the configuration of the distal pinched region **86**, proximal pinched region **87** and spring **88** offers the ability to move the electrode **25**, distally and proximally within sleeve **82**. As shown in FIG. **11**, spring **88** is located proximal to the electrode **25** between a first load bearing surface comprising the electrode surface **60** and a second load bearing surface comprising the distal end **53** of shaft **17**. In this manner, spring **88** can be configured to provide a decompression force to seat the electrode **25** against the distal pinched region **86**, in this case the perimeter edge **92** of crimp **84**, prior to use of the electrosurgical device **5a**.

Conversely, upon application of the electrode **25**, of the device **5a** against the surface **22** of tissue **32** with sufficient force to overcome the compression force of the spring **88**, spring **88** compresses and the electrode **25** retracts proximally away from distal pinched region **86**, in this case perimeter edge **92** of crimp **84**, changing

the position thereof. In the above manner, the contact element comprising electrode **25** is retractable into the cavity **81** of the housing provided by sleeve **82** upon the application of a proximally directed force against surface **42** of the portion **43** of the electrode **25** extending distally beyond the distal opening **26** located at the distal end **83** of the housing and spring **88** functions as a retraction biasing member.

By making the electrode **25**, positionable in the above manner via spring **88**, in various embodiments the electrosurgical device **5a** can be provided with a damper mechanism which dampens the force of the electrode **25** on tissue **32** being treated.

Furthermore, in various embodiments the electrosurgical device **5a**, an electrode **25** which can be positioned as outlined above can comprise a fluid flow rate adjustment mechanism which incrementally increases the area of the fluid exit hole **26** and the corresponding fluid flow rate in response to the incremental proximal retraction of the electrode **25**. In such an instance the electrode **25** functions as a valve in regulating flow of the fluid **24** through fluid exit hole **26**.

In various embodiments, spring **88** may be used in conjunction with the distal pinched region **86** (e.g. crimp **84** comprising a single continuous circular pattern) to provide a fluid seal between the electrode **25** and the distal pinched region **86** which stops fluid flow from the electrosurgical device **5a**. In this manner, the electrosurgical **5a** device may be used to provide both a wet electrode and dry electrode (i.e. when the fluid flow is on and off, respectively) with the energy and fluid provided sequentially in addition to simultaneously. The incorporation of a dry electrode function into the device of the current invention may be desirable to provide a mechanism for electrosurgical cutting.

Furthermore, in various embodiments of electrosurgical device **5a**, an electrode **25** which can be positioned as outlined above can comprise a declogging mechanism which retracts to provide access for unclogging fluid exit holes, such as fluid exit holes **26** and **85**, which may become flow restricted as a result of loose debris (e.g. tissue, blood) becoming lodged therein. For example, when a biasing force, such as from a handheld cleaning device (e.g. brush) or from pushing the distal tip against a hard surface such as a retractor, is applied to surface **42** of electrode **25** which overcomes the compression force of the spring **88** causing the spring **88** to compress and the electrode **25** to retract, the tip of the handheld cleaning device may by extended into the fluid exit hole **26** for cleaning the fluid exit hole **26**, perimeter edge **92**, slot **85** and edge **91**. Stated another way, an electrode **25**, which can be positioned as outlined, provides a method for declogging a fluid exit hole by increasing the cross-sectional area of the fluid exit hole to provide access thereto.

Also, in various embodiments of the electrosurgical device **5a**, the spring **88** comprises an electrical conductor, particularly when the electrode **25**, is retracted to a non-contact position (i.e. not in contact) with the sleeve **82**.

In other embodiments, proximal pinched region **87** may comprise one or more crimps similar to distal pinched region **86**, such that electrode **25** is retained in sleeve **82** both distally and proximally by crimps. Also, in other embodiments, sleeve **82** may be disposed within shaft **17** rather than being connected to the distal end **53** of shaft **17**. Also, in still other embodiments, sleeve **82** may be formed unitarily (i.e. as a single piece or unit) with shaft **17** as a unitary piece.

As best shown in FIGS. **10** and **11**, the electrode **25** is retained in the sleeve **82** such that a portion **43** of the electrode **25** extends distally beyond distal end **83** of the sleeve **82**. As shown, preferably the surface **42** of this exposed portion **43** of the electrode **25** is blunt and does not comprise any sharp corners. Also, the portion **43** of the electrode **25** which extends distally beyond the distal end **83** of the sleeve **82** is controlled by the shape of the fluid exit hole **26** in sleeve **82** in relation to the shape of the electrode **25**. In other words, the portion **43** of the electrode **25** which extends distally beyond the distal end **83** of the sleeve **82** is controlled by the contact of the electrode surface with the edge **92**.

As shown in FIGS. **10** and **11**, in locations where shaft **17** and sleeve **82** are electrically conductive (for device **5a**, preferably shaft **17** and sleeve **82** are completely electrically conductive and do not comprise non-conductive portions), preferably an electrical insulator **90** (i.e. comprising non-conductive or insulating material) preferably surrounds shaft **17** and sleeve **82** along substantially its entire exposed length (e.g. the portion outside the confines of the handle **20**), terminating a short distance (e.g. at the proximal onset of the crimp **84** or less than about 3 mm) from distal end **83** of the sleeve **82**. Insulator **90** preferably comprises a shrink wrap polymer tubing.

As with the other electrosurgical devices described within, a input fluid line **4b** and a power source, preferably comprising generator **6** preferably providing RF power via cable **9**, are preferably fluidly and electrically coupled, respectively, to the tip portion **45** of the electrosurgical device **5a**.

As indicated above, device **5a** comprises a monopolar device. In other words, a first electrode, often referred to as the active electrode, comprises an electrode of the electrosurgical device **5a** (e.g. electrode **25**) while a second electrode, often referred to as the indifferent or return electrode, comprises a ground pad dispersive electrode located on the patient, typically on the back or other suitable anatomical location. Preferably, both electrodes are electrically coupled to the generator **6** to form an electrical circuit. Preferably the active electrode is

coupled to the generator **6** via a wire conductor from insulated wire cable **9** to the outer surface **18** of the shaft **17** within the confines of the handle **20a, 20b,** typically through a switch **15a**.

In other embodiments, the shaft **17** may be made of an electrical non-conducting material except for a portion at its distal end **53** that comes in contact with sleeve **82**. This portion of shaft **17** that contacts the sleeve **82** should be electrically conducting. In this embodiment, the wire conductor from insulated wire cable **9** extends to this electrically conducting portion of shaft **17**. In still other embodiments, the shaft **17** may completely comprise a non-conducting material as where the wire conductor from insulated wire cable **9** extends directly to the sleeve **82**.

With respect to the fluid coupling, fluid **24** from the fluid source **1** for use with electrosurgical device **5a** preferably is communicated from fluid source **1** through a flexible, polyvinylchloride (PVC) outlet fluid line **4a** to a flexible, polyvinylchloride (PVC) inlet fluid line **4b** connected to the electrosurgical device **5a**. The outlet fluid line **4a** and the inlet fluid line **4b** are preferably connected via a male and female mechanical fastener configuration, preferably comprising a Luer-Lok® connection from Becton, Dickinson and Company. The lumen of the inlet line is then preferably interference fit over the outside diameter of the shaft **17** to provide a press fit seal there between. Additionally an adhesive may be disposed there between to strengthen the seal. Fluid **24** is then communicated down the lumen **23** of the shaft **17** through the lumen **89** and cavity **81** of the sleeve **82** where it is expelled from around and on the exposed surface **42** of the electrode **25**. This provides a wet electrode for performing electrosurgery.

As shown in FIG. **13**, during use of electrosurgical device **5a**, typically a fluid coupling **30** preferably comprising a discrete, localized web and more preferably comprising a triangular shaped web or bead portion providing a film of fluid **24** is provided between the surface **22** of the tissue **32** and electrode **25**. When the user of electrosurgical device **5a** places the electrode **25** at a tissue treatment site and moves the electrode **25** across the surface **22** of the tissue **32**, fluid **24** is expelled around and on the surface **42** of the electrode **25** at the distal end **83** of the sleeve **82** and onto the surface **22** of the tissue **32** via coupling **30**. The fluid **24**, in addition to providing an electrical coupling between the electrosurgical device **5a** and the tissue **32**, lubricates the surface **22** of the tissue **32** and facilitates the movement of electrode **25** across the surface **22** of the tissue **32**. During movement of the electrode **25**, the electrode **25** typically slides across the surface **22** of the tissue **32**, but also may rotate as the electrode **25** moves across the surface **22** of the tissue **32**. Typically the user of the electrosurgical device **5a** slides the electrode

across the surface **22** of the tissue **32** back and forth with a painting motion while using the fluid **24** as, among other things, a lubricating coating. Preferably the thickness of the fluid **24** between the distal end surface of the electrode **25** and the surface **22** of the tissue **32** at the outer edge of the coupling **30** is in the range between and including about 0.05 mm to 1.5 mm. More preferably, the fluid **24** between the distal end surface of the electrode **25** and the surface **22** of the tissue **32** at the outer edge of the coupling **30** is in the range between and including about 0.1 mm to 0.3 mm. Also preferably, in certain embodiments, the distal end tip of the electrode **25** contacts the surface **22** of tissue **32** without any fluid **24** in between.

Another exemplary electrosurgical device of the present invention which may be used in conjunction with the system of the present invention is shown at reference character **5b** in FIGS **14-16**. In this embodiment, electrical insulator **90** preferably terminates proximally to the sleeve **82** where sleeve **82** is connected to the distal end **53** of shaft **17**. In certain embodiments where the sleeve **82** is formed unitary with the shaft **17**, the electrical insulator **90** preferably terminates proximally to proximal pinched region **87**. In this manner, in addition to the spherical surface portion **42** of the electrode **25** and the narrowing surface portion **41**, here conical, of the sleeve **82** being used for treating tissue **32** when exposed thereto, a cylindrical surface **40** of a cylindrical portion **39** of the sleeve **82** and a broadening surface portion **47** of broadening portion **54**, here both conical, of the sleeve **82** also function as electrode surfaces for treating tissue. Thus, the electrode exposed to tissue **32** now comprises a cylindrical surface portion **40** and a broadening surface portion **47** in addition to the spherical surface portion **42** and the narrowing surface portion **41**, with the cylindrical surface portion **40** substantially increasing the surface area of the electrode. As a result, the electrode **25** now also comprises surfaces which are parallel and perpendicular to the longitudinal axis **31** of the tip portion **45**, and more particularly sleeve **82**, of the electrosurgical device **5b**. In the above manner, front end use (e.g. surfaces **41** and **42**), sideways use (e.g. surface **40** and **47**) or oblique use (e.g. surfaces **40**, **41** and **42**) of the electrosurgical device **5b** is facilitated.

In the above manner, the tip portion **45** now comprises a first tissue treating surface (e.g. distal end spherical surface **42**) and a second tissue treating surface (e.g. side surface **40**). As discussed above, preferably the first tissue treating surface is configured for blunt dissection while the second tissue treating surface is configured for coagulation. Additionally, tip portion **45** also comprises a third tissue treating surface (e.g. surface **41**) located between the first tissue treating surface (e.g. surface **42**) and a second tissue treating surface (e.g. surface **40**). Furthermore, tip portion **45** also comprises a fourth tissue treating surface (e.g. surface **47**) located proximal and adjacent to surface **40**.

With device **5a**, when the electrode **25**, is placed directly in contact with surface **22** of tissue **32**, it may be possible for the tissue **32** to occlude fluid flow from the fluid exit holes **26, 85** located at the distal end of the device **5a**. Consequently, for device **5b** fluid exit holes **93, 94** may be located in the cylindrical side portion **39** of the sleeve **82**, either proximal or adjacent to the electrode **25**, and either in addition to or as an alternative to fluid exit holes **26, 85**.

As shown in FIGS. **14** and **15**, at least one fluid exit hole **93** is preferably formed in the cylindrical longitudinal side surface **40** and through the wall of side portion **39** of the sleeve **82** adjacent to electrode **25** when electrode **25** is fully seated. Furthermore, preferably at least one fluid exit hole **94** is formed in the cylindrical side portion **39** of the sleeve **82** proximal to electrode **25** when electrode **25** is fully seated.

Preferably, holes **93, 94** each comprise more than one hole which are equally spaced radially in a circular pattern around the longitudinal axis **31** of the tip portion **45**, and more particularly sleeve **82**. More preferably, holes **93, 94** each comprise four discrete holes equally spaced 90 degrees around the cylindrical side portion **39** of the sleeve **82**. Preferably holes **93, 94** have a diameter in the range between and including about 0.1 mm to 1.0 mm, and more preferably have a length in the range between and including about 0.2 mm to 0.6 mm. Electrode **25** which can be positioned as outlined above can comprise not only a valve for regulating fluid flow from the fluid exit holes, such as fluid exit hole **26**, but also comprise a valve which while opening one fluid flow exit simultaneously closes another fluid flow exit. For example, as electrode **25** retracts proximally, fluid exit hole **26** is opened while fluid exit hole **93** is closed. Stated another way, an electrode **25** which can be positioned as outlined above can provide a mechanism for altering the size and/or location of the fluid exit holes during use of the electrosurgical device **5b** which may be necessary, for example, to direct fluid to a particular tissue location or balance fluid flow among the fluid exit outlets.

Thus, as shown in FIGS. **14** and **15**, surfaces **40, 41** and **47** of the sleeve **82**, and surface **42** of electrode **25** are all active electrode surfaces and can provide electrical energy to tissue **32**. Portions of this combined electrode surface can be wet by fluid flow from holes **26, 94** or **93**, as well as from the hole slots **85** in the crimp **84** adjacent the electrode **25**.

The holes **94, 93** in the cylindrical sleeve **82** of the overall electrode surface are intended to assure that fluid **24** is provided to the smooth, less rough, atraumatic sides of the electrode that are used to produce tissue coagulation and hemostasis (e.g. surfaces **40** and **47**) rather than blunt dissection (e.g. surfaces **41** and **42**). The

most distal portion of the device may have a more rough, but also wetted, electrode surface that can blunt dissect as well as coagulate tissue.

The electrode configuration shown in FIGS. **14** and **15** is particularly useful to a surgeon performing a liver resection. Once the outer capsule of the liver is scored with a dry bovie blade along the planned line of resection the distal tip of tip portion **45** is painted back and forth along the line, resulting in coagulation of the liver parenchyma. As the tissue is coagulated under and around the electrode surfaces **40**, **41** and **42**, the electrode is used to blunt dissect into the coagulated parenchyma, with the edge **91** of the slots **85** around the crimp **84** providing roughness elements that aid in disrupting the tissue **32** and enabling the parting of the tissue **32**.

As shown in FIG. **16**, the device **5b** can be used deeply in a crevice **97** of tissue **32** to blunt dissect the tissue **32** and coagulate it at the same time. Blunt dissection is preferred over sharp dissection, such as with a blade or scissors, since blunt dissection is less likely to tear or damage the larger blood vessels or other vessels. Once identified by blunt dissection, larger vessels can be safely clipped, tied with suture or sealed with some other device. If the larger vessels are not thus first "skeletonized" without being damaged by blunt dissection, they may bleed profusely and require much more time to stop the bleeding. The device can also be used to coagulate first without simultaneous blunt dissection, and then blunt dissect in a separate step.

This technique can also be used on other parenchymal organs such as the pancreas, the kidney, and the lung. In addition, it may also be useful on muscle tissue and subcutaneous fat. Its use can also extend to benign tumors, cysts or other tissue masses found in the urological or gynecological areas. It would also enable the removal of highly vascularized tumors such as hemangiomas.

In FIG. **16** the zone **99** identifies the part of the electrode that has the ability to blunt dissect and coagulate, and the zone **98** identifies the part that is intended primarily for coagulation and hemostasis. The line **100** indicates the depth of the zone of tissue that is coagulated, typically from 3 mm to 5 mm deep.

For the devices disclosed herein, the presence of various fractions of boiling can be visually estimated by the naked eye, or by detecting changes in electrical impedance. FIG. **17** shows a plot of electrical impedance **Z** versus time **t**. The impedance spikes **101** shown in FIG. **17** occur at a frequency of about 1 cycle per second and with an amplitude that is on the same order as the baseline impedance. This frequency is shown in FIG. **17** as the interval **102** between successive impedance spikes. Impedance is directly measurable by dividing the voltage by the current as previously described. The use of electrical impedance to detect the onset

of tissue dessication when impedance rises dramatically as a result of being heated to the point of smoking and charring, but not to detect the presence of boiling, is described above. As shown in FIG **17**, the impedance **Z** may change from a level of about 100 ohms with no boiling, to a level of about 400 ohms or more with a large fraction of the conductive fluid boiling. The percentages of boiling shown are exemplary as are the levels of impedance.

Shown in FIG. **18** is the qualitative nature of the boiling as the % boiling increases, indicated by the small figures for each of five exemplary "regimes" of boiling. In each small figure a portion of the tip of the tip portion **45** of the device **5a** is shown in close proximity to tissue **32**. As boiling begins in regime **104**, there are few small bubbles **37** of vapor in the conductive fluid **24**, here saline, of coupling **30**. As the percentage of boiling increases at regime **106** there are a larger number of small bubbles **37**. As the percentage boiling increases further at regime **107**, the bubbles **37** become much larger. At even higher percentage boiling at regime **108** intermittent threads of saline form and are quickly boiled off. Finally, at the highest level of regime **109**, drops **36** of saline are instantly boiled upon contacting the hot surface **22** of the tissue **32** and arcing occurs from the metal to the tissue **32**.

Returning to FIGS. **14** and **15**, fluid outlet openings are provided by substantially linear through holes **93**, **94** which provide conductive fluid **24** to the treatment site. However, in an alternative embodiment, as shown in FIG. **19**, fluid outlet openings in the sleeve **82** may be provided by holes in the form of tortuous and interconnected pathways **59**, which are formed in a material pervious to the passage of fluid **24**, therethrough, such as a porous material. The discrete, linear through holes **93**, **94** may be either supplemented with or replaced by a plurality of tortuous, interconnected pathways **59** formed in the porous material which, among other things, provides porous surfaces **40**, **41** and **47** to more evenly distribute fluid flow and provide the conductive fluid **24** to tissue **32** at the treatment site. According to the invention, all or a portion of the sleeve **82** may comprise a material pervious to the passage of fluid **24** therethrough as disclosed herein.

In certain embodiments, the contact element, here electrode **25** may also comprise a material pervious to the passage of fluid **24**, therethrough, such as a porous material (e.g. metal, polymer or ceramic) to provide the tortuous pathways **59**. In these embodiments, the porous structure of the electrode **25** allows fluid **24** to not only pass around electrode **25** on the outer porous surface **42** to be expelled, but also allows fluid **24** to pass through the electrode **25**, to be expelled. According to the invention, all or a portion of the electrodes or any particular electrodes for treating tissue **32** may comprise a material pervious to the passage of fluid **24** therethrough as disclosed herein.

Where the contact element and sleeve provide electrodes for treating tissue and compromise a porous material, preferably the porous material further comprises porous metal. Porous sintered metal is available in many materials (such as, for example, 316L stainless steel, titanium, Ni-Chrome) and shapes (such as cylinders, discs, plugs) from companies such as Porvair, located in Henderson, NC.

Porous metal components can be formed by a sintered metal powder process or by injection molding a two-part combination of metal and a material that can be burned off to form pores that connect (open cell) to each other. With sintering, for example, typically solid particles of material are placed in a mold under heat and pressure such that the outer surface of the particles soften and bond to one another with the pores comprising the interstices between the particles. Alternatively, when porosity is formed by burning off material, it is not the interstice between the particles which provides the porosity as with sintering, but rather a partial evisceration of the material generally provided by the removal of a component with a lower melt temperature than the burn off temperature.

While the electrode provided by contact element and/or sleeve preferably comprises an electrically conductive material such as metal, a non-electrically conductive porous contact element and/or sleeve, such as porous polymers and ceramics, can be used to replace an electrically conductive contact element and/or sleeve. While the porous polymers and ceramics are generally non-conductive, they may also be used to conduct the RF energy through the porous polymer and ceramic thickness and porous surface to the tissue to be treated by virtue of conductive fluid **24** contained within the plurality of interconnected tortuous pathways **59**.

Preferably the tortuous passages in the porous materials have a pore size (cross-sectional dimension) in the range between and including about 2.5 micrometers (0.0025 mm) to 500 micrometers (0.5 mm) and more preferably has pore size in the range between and including about 10 micrometers (0.01 mm) to 120 micrometers (0.12 mm). Even more preferably, the porous material has a pore size in the range between and including about 20 micrometers (0.02 mm) to 80 micrometers (0.08 mm).

In addition to possibly providing a more uniform distribution of fluid **24**, the porous materials also may provide other advantages. For example, when the electrode surfaces, such as surfaces **40**, **41**, **42** and **47**, in contact with the surface **22** of tissue **32** are porous and dissipate fluid **24**, the tissue **32** is less apt to stick to the surfaces **40**, **41**, **42** and **47** of the electrode as compared to the situation where the surfaces **40**, **41**, **42** and **47** are not porous. In addition, by providing fluid **24** to surfaces **40**, **41**, **42** and **47** through tortuous pathways **59**, heated and/or electrified fluid **24** can now be provided more uniformly to surfaces **40**, **41**, **42** and **47**, which

may result in a wider tissue treatment region as compared to when the surfaces are not porous.

Preferably the porous material provides for the wicking (i.e. drawing in of fluid by capillary action or capillarity) of the fluid **24** into the pores of the porous material. In order to promote wicking of the fluid **24** into the pores of the porous material, preferably the porous material, and in particular the surface of the tortuous pathways, is hydrophilic. The porous material may be hydrophilic with or without post treating (e.g. plasma surface treatment such as hypercleaning, etching or micro-roughening, plasma surface modification of the molecular structure, surface chemical activation or crosslinking), or made hydrophilic by a coating provided thereto, such as a surfactant.

Though not preferable, it is not necessary that fluid coupling **30** of fluid **24** be present in between the metal electrode surfaces (e.g. **40**, **41**, **42**) and tissue **32** at all locations of tissue treatment and there may be points of direct tissue contact by the electrode surfaces without any fluid coupling **30** therebetween. In such an instance, the convective cooling of the metal electrode by flowing saline is often sufficient to keep the metal electrode and tissue contacting the metal electrode at or below a temperature of 100 °C. In other words, heat may be also first dissipated from the tissue **32** to the electrodes by conduction, then dissipated from the electrodes to the fluid **24** by convection.

Preferably the relationship between the material for electrodes particularly their surfaces (e.g. **40**, **41**, **42**, **47**), and fluid **24** throughout the various embodiments should be such that the fluid **24** wets the surface of the electrodes to form a continuous thin film coating thereon (for example, see FIG. **19A**) and does not form isolated rivulets or circular beads (e.g. with a contact angle, **θ** greater than 90 degrees) which freely run off the surface of the electrode. Contact angle, **θ**, is a quantitative measure of the wetting of a solid by a liquid. It is defined geometrically as the angle formed by a liquid at the three phase boundary where a liquid, gas and solid intersect. In terms of the thermodynamics of the materials involved, contact angle **θ** involves the interfacial free energies between the three phases given by the equation $\gamma_{LV} \cos\theta = \gamma_{SV} - \gamma_{SL}$ where γ_{LV}, γ_{SV} and γ_{SL} refer to the interfacial energies of the liquid/vapor, solid/vapor and solid/liquid interfaces, respectively. If the contact angle **θ** is less than 90 degrees the liquid is said to wet the solid. If the contact angle is greater than 90 degrees the liquid is non-wetting. A zero contact angle **θ** represents complete wetting. Thus, preferably the contact angle is less than 90 degrees.

For clarification, while it is known that the contact angle **θ** may be defined by the preceding equation, in reality contact angle **θ** is determined by a various

models to an approximation. According to publication entitled "Surface Energy Calculations" (dated September 13, 2001) from First Ten Angstroms (465 Dinwiddie Street, Portsmouth, Virginia 23704), there are five models which are widely used to approximate contact angle θ and a number of others which have small followings. The five predominate models and their synonyms are: (1) Zisman critical wetting tension; (2) Girifalco, Good, Fowkes, Young combining rule; (3) Owens, Wendt geometric mean; (4) Wu harmonic mean; and (5) Lewis acid/base theory. Also according to the First Ten Angstroms publication, for well-known, well characterized surfaces, there can be a 25% difference in the answers provided for the contact angle θ by the models. Also for clarification, any one of the five predominate models above which calculates a contact angle θ within a particular range of contact angles θ or the contact angle θ required of a particular embodiment of the invention should be considered as fulfilling the requirements of the embodiment, even if the remaining four models calculate a contact angle θ which does not fulfill the requirements of the embodiment.

The effects of gravity and surface tension tend to wick the fluid **24**, here saline, around the circumference of the cylindrical sleeve **82** to preferably cover the entire active electrode surface. More specifically, the effects of gravity and surface tension on fluid **24** which is located on the electrode surfaces may be modeled by the Bond number $\mathbf{N_{BO}}$. Bond number $\mathbf{N_{BO}}$ measures the relationship of gravitational forces to surface tension forces and may be expressed as:

$\mathbf{N_{BO}}$ = gravitational force/surface tension force

$\mathbf{N_{BO}} = \rho L^2 g/\sigma$

where:

ρ = Density of the saline fluid (approximately 1.0 gm/cm^3);

L = droplet diameter (cm)

g = Gravitational acceleration (980 cm/s^2)

σ = Surface tension (approximately 72.8 dynes/cm @ 20° C)

For a Bond number $\mathbf{N_{BO}} = 1$, the droplet diameter is equal to about .273 cm or about 2.7 mm, which is in the same order of magnitude as the preferred size of the electrode. For the purposes of the present invention, preferably Bond number $\mathbf{N_{BO}}$ for a droplet of fluid **24** on a surface of the electrode **25** is preferably less than 1.

Another tip portion of an exemplary electrosurgical device **5c** of the present invention which may be used in conjunction with the system of the present invention is shown at reference character **45** in FIGS **20-24**. As best shown in FIGS. **20** and **21**, the separate sleeve **82** of embodiments **5a** and **5b** has been eliminated from tip portion **45** of device **5c**. Consequently, the contact element, still preferably

comprising an electrode **25**, is assembled directly with the shaft **17**. Electrode **25** is preferably assembled (e.g. mechanically connected via press fit, mechanical connector, threaded, welded, adhesively bonded) adjacent the distal end **53** of shaft **17**. In certain embodiments, the electrode **25** preferably is detachably assembled to the shaft **17** such that it may be removed from the shaft **17**, preferably manually by human hand, so that the shaft **17** may be used with multiple different contact elements/electrodes, or the shaft **17** may be reuseable and used with disposable contact elements/electrodes.

As shown in FIGS. **20-24**, electrode **25** preferably comprises an enlarged head portion comprising a spherical portion **43** and a corresponding spherical surface portion **42** located at the distal end of the device **5c** which provided a smooth, blunt contour outer surface. More specifically, as shown, the spherical portion **43** and spherical surface portion **42** further provide a domed, hemisphere (i.e. less than a full sphere) and hemispherical surface portion comprising preferably about 180 degrees.

Also as shown in FIGS. **20-24**, the enlarged head portion of electrode **25** preferably also comprises a cylindrical portion **39** and a corresponding cylindrical surface portion **40** located proximal and adjacent to the spherical portion **43** and spherical surface portion **42**, respectively.

Further continuing with FIGS. **20-24**, electrode **25** preferably comprises a connector portion, preferably comprising a shank **46**, which connects the remainder of the electrode **25** to the shaft **17**. Among other things, the connector portion of the electrode **25** is preferably configured to form a connection with a mating connector portion of the shaft **17**. As shown, preferably the shank portion **46** is configured to extend into cavity **50** of shaft **17** which comprises a cylindrical receptacle and provides the mating connector portion for shank **46**. More preferably, surface **48** of the shank portion **46** is configured to mate against and form an interference fit with surface **52** of cavity **50** to provide the connection.

Continuing with FIGS. **20-24**, shank portion **46** is preferably cylindrical and located proximal and adjacent to a neck portion **56**. As shown, here neck portion **56** also comprises a cylindrical portion **57** (having a corresponding cylindrical surface portion **58**) located proximal and adjacent to a broadening portion **54** (having a corresponding broadening surface portion **47**). Here broadening portion **54** and corresponding broadening surface portion **47** are both spherical, and more specifically comprise a domed, hemisphere and hemispherical surface portion comprising preferably about 180 degrees, located proximal and adjacent to the cylindrical portion **39** and cylindrical surface portion **40**.

As shown in FIGS. **20-24**, the cylindrical portion **57** of neck portion **56** preferably has a cross-sectional dimension, here diameter, greater than the cross-sectional dimension, here also diameter, of the shank **46**. In this manner, in certain embodiments, the proximal end of the neck portion **56** may be located adjacent and in contact with the distal end **53** of shaft **17**.

Also as shown in FIGS. **20-24**, electrode **25** comprises at least one recess **64** which provides an elongated fluid flow channel for the distribution of fluid **24**. The use of device **5c**, and in particular recesses **64**, for the distribution of fluid **24** is generally preferred to the fluid exit holes **93**, **94** of device **5b** in particularly deep tissue crevices **97** where tissue **32** can occlude fluid flow from the fluid exit holes located in the cylindrical portion **39** of the electrode **25**.

As shown, electrode **25** preferably comprises a plurality of longitudinally directed recesses **64** and, more specifically, four recesses **64** equally spaced 90 degrees around the shank **46** and/or neck portion **56**, both proximal of cylindrical portion **39**. As best shown in FIG. **24**, in certain embodiments, the recess **64** may comprise a first side wall **64a**, a second opposing side wall **64b**, and a bottom wall **64c**.

In use, when tissue **32** overlies and occludes the fluid outlet opening **55** of recess **64** for a portion of its longitudinal length, thus inhibiting fluid **24** from exiting therefrom, fluid **24** from recess **64** may still be expelled from the electrosurgical device **5c** after flowing longitudinally in the channel **64** to a remote location where the channel **64** is unoccluded and uninhibited to fluid flow exiting therefrom.

However, in certain instances, it may be possible that the recess **64** may be occluded by tissue **32** completely along its longitudinal length, thus completely inhibiting fluid flow from exiting through opening **55**. In order to overcome this problem, at least a portion of the electrode **25** may comprise a material pervious to the passage of fluid **24**, therethrough, such as a porous material described above.

As shown in FIG. **25**, in another embodiment of the electrosurgical device of the present invention, as shown at reference character **5d** in FIG. **25**, the walls **64a**, **64b** of recess **64**, surface **48** of the shank portion **46**, and/or the surfaces of the neck portion **56** of electrode **25** may be porous and connected by a plurality of tortuous pathways **59** in the porous material. Consequently, rather than flowing out of recess **64** from a direct fluid outlet opening **55**, which may be occluded by tissue **32**, the fluid **24** may exit indirectly from recess **64** by first flowing through tortuous pathways **59** of the electrode **25** from side walls **64a**, **64b** of the recess **64** and then exit the electrode **25** from surface **58**, which may be in unoccluded by tissue **32**. Alternatively, if adjacent surface **58** of the electrode **25** is also occluded by tissue **32**, the fluid **24** may continue to flow through tortuous pathways **59** of electrode **25** and

exit electrode **25** from a surface **64a**, **64b** of a recess **64** or surface such as **40**, **42**, **47** or **58** which may be in unoccluded by tissue **32**.

Where the electrode **25** comprises a porous material, recess **64** may be either supplemented with or replaced by the plurality of tortuous, interconnected passages **59** formed in the porous material as shown in FIG. **25**, with porous surfaces such as **40**, **42**, **47** or **58** to more evenly distribute fluid flow and provide conductive fluid **24** to the tissue treatment site. All or a portion of the electrodes can be porous according to the invention.

In other embodiments of the invention, recess **64** may comprise cross-sectional shapes other than rectangular shapes. For example, as shown in FIGS. **26-28** recess **64** comprises a semi-circular shape, a V-shape, or a U-shape respectively, or any combination thereof.

Returning to FIG. **21**, in order to facilitate direct fluid communication of recess **64** with lumen **23** of shaft **17**, preferably recesses **64** of device **5c** are initiated within the confines of shaft **17**. In other words, within the cavity **50** of shaft **17** proximal to distal end **53**. Preferably the configuration of the recesses **64** as provided by geometry (e.g. width, depth) and/or the material and/or surface treatment of the electrode **25** may be arranged such that surface tension will act to retain fluid collected in the recess **64** where the force of gravity is acting to remove the fluid from the recess **64**. However, while it is desirable that a certain predetermined amount of surface tension act to retain fluid collected in the recess **64** in the presence of gravity, the surface tension must be balanced against the inhibition of fluid flow from the recess **64**.

As indicated above, the use of device **5c**, and in particular recesses **64**, for the distribution of fluid **24** is generally preferred to the fluid exit holes **93**, **94** of device **5b** in particularly deep tissue crevices **97** where tissue **32** can occlude fluid flow from the fluid exit holes **93**, **94** located in the cylindrical portion **39** of the electrode **25**. Also, since holes **93**, **94** are not presented with a declogging mechanism, such as provided for such as fluid exit holes **26** and **85**, holes such as **93**, **94** that can be simply occluded by ordinary tissue/electrode contact will sooner or later become irreversibly clogged.

As shown in FIG. **21**, with device **5c** fluid outlet openings **73** are provided by the structure of the electrode **25** (i.e. recesses **64**) at the distal end **53** of the shaft **17** which are protected and sheltered from contact and occlusion from surface **22** of tissue **32**. Fluid outlet openings **73** of device **5c** are protected from occlusion from surface **22** of tissue **32** as the structure of device **5c** defining the openings **73** is at least partially configured for non-contact with surface **22** of tissue **32**. More specifically, here the structure of the device defining the openings **73** is completely

configured for non-contact with surface **22** of tissue **32**. Stated another way, the openings **73** are provided on the device **5c** at a location removed from the tissue surface **22**. Also, as shown, openings **73** are particularly sheltered from occlusion from surface by **22** of tissue **32** by a portion of the shaft **17**. Also as shown, when openings **73** are formed substantially perpendicular to the surface **22** of tissue **32** and thus turned away from direct contact with surface **22** of tissue **32**.

Another tip portion of an exemplary electrosurgical device **5e** of the present invention which may be used in conjunction with the system of the present invention is shown at reference character **45** in FIGS. **29-32**. As best shown in FIGS. **31** and **32**, the broadening portion **54** has been eliminated and the cylindrical portion **39** has an equal cross-sectional dimension, here diameter, with the neck portion **56**. Conversely, for device **5c**, the cylindrical portion **39** has a cross-sectional dimension, there also diameter, greater than the cross-sectional dimension, there also diameter, of the neck portion **56**.

Also as shown in FIGS. **31** and **32**, the cylindrical portion **39** further comprises a rectilinear (straight) cylindrical portion **39a** having a rectilinear cylindrical surface portion **40a** and a curvilinear cylindrical portion **39b** having a curvilinear cylindrical surface portion **40b**. As shown, device **5e** comprises the shape of a hockey stick. The cylindrical portion **39** for device **5c** may be similarly arranged.

Another tip portion of an exemplary electrosurgical device **5f** of the present invention which may be used in conjunction with the system of the present invention is shown at reference character **45** in FIGS **33-36**. As best shown in FIGS. **35** and **36**, the cylindrical portion **39** has a cross-sectional dimension, here diameter, less than the cross-sectional dimension, here also diameter, of the neck portion **56**. As shown the neck portion **56** is located proximal and adjacent to a narrowing portion **49** with a corresponding narrowing surface portion **51**, here both conical.

Also as shown in FIG. **34**, the cylindrical portion **39** further comprises a rectilinear cylindrical portion **39a** having a rectilinear cylindrical surface portion **40a** and a curvilinear cylindrical portion **39b** having a curvilinear cylindrical surface portion **40b**. Furthermore, as shown, the cylindrical portion **39**, and more specifically at least one of the rectilinear cylindrical portion **39a** and the curvilinear cylindrical portion **39b**, comprises a portion of a hook. Preferably, as shown both the rectilinear cylindrical portion **39a** and the curvilinear cylindrical portion **39b** comprise portions of a hook. As shown in FIGS. **35** and **36**, the hook further comprises an L-hook.

Another tip portion of an exemplary electrosurgical device **5g** of the present invention which may be used in conjunction with the system of the present invention

is shown at reference character **45** in FIGS **37-38**. As shown, for device **5g** the cylindrical portion **39**, and more specifically both the rectilinear cylindrical portion **39a** and the curvilinear cylindrical portion **39b** comprise portions of a hook. Also as shown in FIGS. **37** and **38**, the hook further comprises an J-hook.

Another tip portion of an exemplary electrosurgical device **5h** of the present invention which may be used in conjunction with the system of the present invention is shown at reference character **45** in FIGS **39-42**. As shown in FIGS. **39** and **40**, electrode **25** preferably comprises a finger portion **65** (preferably comprising cylindrical portion **39** and cylindrical surface portion **40**) having a distal end (preferably comprising a spherical portion **43** and spherical surface portion **42**) which, among other things, is configured for blunt dissection or electrosurgical dissection of tissue **32**. Electrosurgical dissection occurs when tension or force is applied to tissue while also applying RF energy. The RF energy heats the tissue, thereby weakening it, and the tissue yields or breaks where desired. Surgeons may refer to this type of dissection with a hook-type electrode as "hook and cook". Furthermore, finger portion **65** is also preferably configured to function as a hook, particularly the anterior (i.e. front) surface portion **66** of finger portion **65** which is configured, among other things, to engage and restrain tissue **32**.

As shown, finger portion **65** is rectilinear and forms an L-hook with an angle of about 90 degrees relative to the longitudinal axis **31** of the tip portion **45**, particularly shank **45**. However, finger portion may be formed at angles other than 90 degrees. For example. finger portion **65** may be formed at any angle in the range between and including about 60 degrees relative to the tip portion **45** to about 180 degrees relative to the tip portion **45**, or any other range of angles or particular angle inclusive therein (e.g. 75°, 105°, 120°, 135°, 180°, 90°-135°,90°-180°).

Among other things, electrode **25** preferably comprises a knuckle portion **61** comprising a rounded protuberance having a raised prominence on the posterior (back) surface portion **62** of the electrode **25**. Also as shown, knuckle portion **61** also comprises a rounded protuberance having a raised prominence on the lateral surface portion **75** of the electrode **25**. Among other things, posterior knuckle surface portion **62** and lateral knuckle surface portion **75** formed by knuckle portion **61** are configured for coagulation and stasis (e.g. hemostasis, aerostasis) of tissue **32**.

Key to device **5g** is the cross-sectional dimension of the knuckle **Z** to the cross-section dimension of the finger **F**. When comparing the functions of blunt or electrosurgical dissection and coagulation/hemostasis, the coagulation/hemostasis portion of the electrode **25** preferably comprises a greater surface area than the blunt or electrosurgical dissection portion of the electrode **25**.

As shown in FIG. **36**, preferably the cross-sectional dimension **Z**, of the knuckle portion **61** is greater than cross-section dimension **F** of the finger portion **65**. Here, as shown, the cross-sectional dimensions **Z** and **F** comprise diameters. However, in other embodiments where the cross-sectional dimension **Z** and/or **F** could not properly be considered to comprise a diameter, the cross-sectional dimension **Z** and/or **F** could comprise a width or thickness.

Preferably, the cross-sectional dimension **Z** of the knuckle portion **61** is in the range between and including about 1.6 to 3.3 times greater than the cross-section dimension **F** of the finger portion **65**, with typical dimensions comprising the ratios of 2.5 mm to 1.5 mm (1.6 times) and 2.5 mm to 0.75 mm (3.3 times). Even more preferably, the cross-sectional dimension **Z** of the knuckle portion **61** is in the range between and including about 2 to 2.5 times greater than the cross-section dimension **F** of the finger portion **65**, with typical dimensions comprising the ratios of 2.5 mm to 1.25 mm (2 times) and 2.5 mm to 1 mm (2.5 times).

From the above dimensions, the ratio of the surface area of the knuckle portion **61** to the surface area of the distal end (e.g. surface **42**) of the finger portion **65** may be determined to an approximation using a formula for half the area of a sphere. For the above dimensions, preferably the surface area of the knuckle portion **61** is in the range between and including about 2.8 times to 11 times greater than the surface area the distal end of the finger portion **65**. More preferably, the surface area of the knuckle portion **61** is in the range between and including about 4 times to 6.2 times greater than the surface area the distal end of the finger portion **65**.

Also as shown in FIGS. **39** and **40**, neck portion **56** preferably comprises a cylindrical portion **57** located proximal and adjacent to a spatula portion **67**. As shown, spatula portion **67** comprises a substantially flat anterior surface portion **69** of electrode **25**. In certain embodiments, electrode **25** may comprise one, any combination of, or all of the features of finger portion **65**, knuckle portion **61** and spatula portion **67**.

Turning to use of the devices, similar to device **5b**, device **5c** is particularly useful to a surgeon performing a liver resection. Once the outer capsule of the liver is scored with a dry bovie blade along the planned line of resection the distal tip of tip portion **45** is painted back and forth along the line, with radio frequency power and the flow of fluid **24** on, resulting in coagulation of the liver parenchyma. Once the tissue is coagulated under and around the electrode surface **42** and, as the device 5c enters a crevice **97**, surface **40**, surface **42** of electrode **25** is used to blunt dissect the coagulated parenchyma. Blunt dissection of the coagulated parenchyma is performed by continuous abrading or splitting apart of the parenchyma with the substantially the same back and forth motion as coagulation and with the device **5c**

being held substantially in the same orientation as for coagulation of the liver parenchyma. However, with blunt dissection, the surgeon typically applies more force to the tissue. In various embodiments, once the liver parenchyma is coagulated, blunt dissection may be performed with or without the radio frequency power (i.e. on or off) and/or with or without the presence of fluid **24**.

In addition to liver resections, device **5h** are particularly useful to a surgeon performing a laparoscopic cholecystectomy (abbr. "lap chole") for the case of, for instance, either acute cholecystitis or an intrahepatic gallbladder in that the device provides multi-functional uses. More particularly, device **5h** is useful to the surgeon for coagulation and dissection of an inflamed serosal layer of tissue **32** between the liver and gallbladder, which may include tough, fibrous, highly vascular connecting tissue between the organs.

For coagulation, device **5h** may be positioned in at least three different orientations. For the first orientation, as shown in FIG. **43**, coagulation may be performed with posterior knuckle surface portion **62** formed by knuckle portion **61**. Similar to device **5c**, coagulation with device **5h** is performed with radio frequency power and the flow of fluid **24** on. Preferably power is applied in the coagulation mode of the generator and at a power level in the range between and including about 10 watts to 60 watts. More preferably, the power level is in the range between and including about 20 watts to 50 watts. Even more preferably, the power level is in the range between and including about 30 watts to 40 watts. With respect to motion of surface portion **62** during coagulation, coagulation may be performed with surface portion **62** stationary, or with a painting motion by moving surface portion **62** back and forth substantially along the longitudinal axis **29** or laterally side to side.

For the second orientation, as shown in FIG. **44**, coagulation may be performed with a combination of lateral knuckle surface portion **75** formed by knuckle portion **61** and cylindrical surface portion **40**, and more specifically a lateral cylindrical surface portion of cylindrical surface portion, of finger portion **65**. For the third orientation, as shown in FIG. **45**, coagulation may be performed also with another combination of knuckle portion **61** and finger portion **65**. As shown in FIG. **45**, coagulation may be performed with a posterior cylindrical surface portion of cylindrical surface portion **40** and a posterior surface of knuckle portion **61**. In the various orientations, coagulation may be used to stop active bleeding (e.g. such as a spleen injury comprising a splenic capsule tear) or pre-coagulation of tissue before dissection for bloodless surgery.

Where the surgeon has pre-coagulated the tissue **32**, the surgeon may dissect the tissue **32** with simultaneous mechanical traction (i.e. the process of drawing or

pulling of the tissue **32** with a mechanical device) with anterior (i.e. front) surface portion **66** of finger portion **65** which is configured, among other things, to engage and restrain tissue **32**. More specifically, the surgeon may hook the tissue **32** for dissection against the surface portion **66** of finger portion **65** and apply traction to the tissue **32**, then dissect the tissue **32**.

Since the tissue **32** has been coagulated, dissection may be performed with or without the radio frequency power (i.e. on or off) and/or with or without the presence of fluid **24**. Where the tissue **32** is dissected without fluid **24**, but with the radio frequency power on and with the generator set to the coagulation mode, the process of dissecting may be referred to as "hook and cook" in the art. While dissecting in this manner is fast, it suffers from the problems of significant arcing, the production of smoke and char, and the possibility of inadvertent perforation of the gall bladder wall. Alternatively, dissecting without the radio frequency power on may eliminate the problems of arcing, the production of smoke and char, and the possibility of inadvertent perforation, but may result in bleeding if the tissue 32 is not sufficiently coagulated. In order to overcome the aforementioned issues, dissection of the tissue **32** with traction may be performed similar to coagulation (i.e. in the presence of both radio frequency power and fluid **24**). However, this alternative typically requires more time than "hook and cook".

With regards to the sequence of events for dissect the tissue **32** with traction and using the "hook and cook" technique (i.e. without fluid **24**), the surgeon first engages the tissue **32** on the surface portion **66** of finger portion **65**. The surgeon then applies traction to the engaged tissue **32**. Once complete, the surgeon checks for proper position then applies the radio frequency power. Upon application of the radio frequency power, the tissue **32** yields, separates and breaks. The surgeon then turns the radio frequency power off. This process may then be repeated numerous times as the surgeon incrementally dissects tissue **32** along a length in step-wise fashion.

Certain embodiments of the invention may be particularly configured for bipolar devices. For example, an exemplary bipolar electrosurgical device of the present invention which may be used in conjunction with the system of the present invention is shown at reference character **5i** in FIGS. **46-48**. With a bipolar device, the ground pad electrode located on the patient is eliminated and replaced with a second electrical pole as part of the device. An alternating current electrical circuit is then created between the first and second electrical poles of the device. Consequently, alternating current no longer flows through the patient's body to the ground pad electrode, but rather through a localized portion of tissue preferably between the poles of the bipolar device.

In certain embodiments, an exemplary bipolar surgical device of the present invention may comprise, among other things, multiple, substantially parallel, arms. As shown in FIG. **46**, electrosurgical device **5i** preferably includes two arms comprising rigid, self-supporting, hollow shafts **17a, 17b**, a proximal handle comprising mating handle portions **20a, 20b** and arm tip portions as shown by circles **45a, 45b**. In this embodiment, shafts **17a, 17b** preferably comprise thick walled hypo-tubing. In this manner, the shafts **17a, 17b** have sufficient rigidity to maintain their form during use of the device without kinking or significant bending.

Preferably the arms of device **5i** (comprising shafts **17a, 17b**) are retained in position relative to each other by a mechanical coupling device comprising a collar **95** and inhibited from separating and/or rotating relative to each other. Collar **95** preferably comprises a polymer (e.g. acrylonitrile-butadiene-styrene or polycarbonate) and is preferably located on the distal portion of the arms. More preferably, the collar **95** is located proximal the distal ends **53a, 53b** of the shafts **17a, 17b**. Preferably the collar **95** comprises two apertures **96a, 96b**, preferably comprising opposing C-shapes, configured to receive a portion of the shafts **17a, 17b** which are preferably snap-fit therein. Once the collar **95** is connected to the shafts **17a, 17b**, preferably by a snap-fit connection, the collar **95** may be configured to slide along the length of the shafts **17a, 17b** as to adjust or vary the location of the collar **95** on the shafts **17a, 17b**. Alternatively, the location of the collar **95** may be fixed relative to the shafts **17a, 17b** by welding, for example.

Device **5i** comprises a first arm tip portion **45a** and a second arm tip portion **45b**. As shown, preferably both first arm tip portion **45a** and second arm tip portion **45b** are each individually configured identical to tip portion **45** of device **5a**. As a result, device **5i** has two separate, spatially separated (by empty space) contact elements preferably comprising electrodes **25a, 25b**.

As shown in FIG. **47**, when device **5i** is in use electrodes **25a, 25b** are laterally spaced adjacent tissue surface **22** of tissue **32**. Electrodes **25a, 25b** are connected to a source of alternating electrical current and alternating current electrical field is created between electrodes **25a** and **25b**. In the presence of alternating current, the electrodes alternate polarity between positive and negative charges with current flow from the positive to negative charge.

Similar to device **5a**, for device **5i** fluid **24** is communicated from a fluid source **1** within the lumens **23a, 23b** of the shafts **17a, 17b** through the lumens **89a, 89b** and cavities **81a, 81b** of the sleeves **82a, 82b** where it is expelled from around and on the surface **42a, 42b** of the electrodes **25a, 25b**.

As with use of device **5a**, with use of device **5i** fluid couplings **30a, 30b** preferably comprising discrete, localized webs and more preferably comprising a

triangular shaped web or bead portion providing a film of fluid **24** is provided between the surface **22** of the tissue **32** and the electrodes **25a, 25a**. When the user of electrosurgical device **5i** places the electrodes **25a, 25b** at a tissue treatment site and moves the electrodes **25a, 25b** across the surface **22** of the tissue **32**, fluid **24** is expelled around and on the surfaces **42a, 42b** of the electrodes **25a, 25b** at the distal ends **83a, 83b** of the sleeves **82a, 82b** and onto the surface **22** of the tissue **32** via couplings **30a, 30b**. At the same time, RF electrical energy, shown by electrical field lines **130**, is provided to the tissue **32** at the tissue surface **22** and below the tissue surface **22** into the tissue **32** through the fluid couplings **25a, 25b**.

As with device **5a**, the fluid **24**, in addition to providing an electrical coupling between the electrosurgical device **5i** and the tissue **32**, lubricates the surface **22** of the tissue **32** and facilitates the movement of electrodes **25a, 25b** across the surface **22** of the tissue **32**. During movement of the electrodes **25a, 25b** the electrodes **25a, 25b** typically slide across the surface **22** of the tissue **32**, but also may rotate as the electrodes **25a, 25b** move across the surface **22** of the tissue **32**. Typically the user of the electrosurgical device **5i** slides the electrodes **25a, 25b** across the surface **22** of the tissue **32** back and forth with a painting motion while using the fluid **24** as, among other things, a lubricating coating. Preferably the thickness of the fluid **24** between the distal end surface of the electrodes **25a, 25b** and the surface **22** of the tissue **32** at the outer edge of the couplings **30a, 30b** is in the range between and including about 0.05 mm to 1.5 mm. More preferably, the fluid **24** between the distal end surface of the electrodes **25a, 25b** and the surface **22** of the tissue **32** at the outer edge of the coupling **30a, 30b** is in the range between and including about 0.1 mm to 0.3 mm. Also preferably, in certain embodiments, the distal end tip of the electrode **25** contacts the surface **22** of tissue **32** without any fluid **24** in between.

As shown in FIG. **48**, the fluid coupling for device **5i** may comprise a conductive fluid bridge **27** between electrodes **25a, 25b** which rests on the surface **22** of the tissue **32** and forms a shunt between the electrodes **25a, 25b**. Given this scenario, a certain amount of RF energy may be diverted from going into the tissue **32** and actually pass between the electrodes **25a, 25b** via the conductive fluid bridge **27**. This loss of RF energy may slow down the process of coagulating tissue and producing the desired hemostasis or aerostasis of the tissue.

In order to counteract the loss of energy through bridge **27**, once enough energy has entered the bridge **27** to boil the fluid **24** of bridge **27**, the loss of RF energy correspondingly decreases with the loss of the bridge **27**. Preferably energy is provided into the fluid **24** of the bridge **27** by means of heat dissipating from tissue **32**.

Thus, where a high % boiling of the conductive fluid **24** of the bridge **24** is created, the loss of RF energy through the bridge **27** may either be reduced or eliminated because all the fluid **24** of bridge **27** boils off or a large fraction of boiling creates enough disruption in the continuity of the bridge **27** to disrupt the electrical circuit through the bridge **27**. Thus, one control strategy of the present invention is to reduce the presence of a conductive fluid shunt by increasing the % boiling of the conductive fluid.

Another embodiment of a bipolar device is shown at **5j** in FIGS. **49** and **50**. Similar to device **5i**, electrosurgical device **5j** preferably includes two arms comprising rigid, self-supporting, shafts **17a**, **17b**, a proximal handle comprising mating handle portions **20a**, **20b** and first and second arm tip portions as shown by circles **45a**, **45b**. However, as shown in FIG. **50**, unlike device **5i**, for device **5j** the shafts **17a**, **17b** may comprise solid rods (i.e. do not have lumens) which provide for electrical connection to a power source but do not have lumens for providing conductive fluid through the sleeves **82a**, **82b**. Rather conductive fluid **24** is preferably provided by means of a lumen **122** of a separate fluid line **120**, preferably comprising either a metal (e.g. stainless steel hypo-tubing) or polymer (e.g. PVC tubing) material, extending distally and substantially parallel to the arms along side shafts **17a**, **17b**. In order to minimize the risk of clogging of the lumen **122** at the distal end outlet opening **124** of the fluid line **120**, as shown, preferably the distal end **126** of the fluid line **120** is located proximal and adjacent to the distal end of the device **5j** and more preferably, proximal to spherical surface portions **42a**, **42b** of electrodes **25a**, **25b**, or other tissue treating surfaces of electrodes as the electrode configurations vary.

Also as shown for device **5j**, the outlet opening **124** for the fluid line **120** is preferably spaced uniformly between electrodes **25a**, **25b** such that conductive fluid **24** expelled from the outlet opening **124** may form a fluid coupling comprising the a bridge **27** between the tissue surface **22** and the surface **42a**, **42b** of each of the electrodes **25a**, **25b**. If a collar **95** is used with device **5j** preferably the collar contains a third C-shaped aperture to accommodate fluid line **120** there through.

In certain embodiments, at least a portion of the length of the two arms (comprising the shafts **17a**, **17b** and sleeves **82a**, **82b**) or the two arms and fluid line **120** of device **5j** may be located and housed within the cavity **132**, typically a lumen, of an elongated hollow tubular enclosure **128** as shown in FIG. **49**. The elongated tubular enclosure **128** may or may not be connected to the handle portions **20a**, **20b**. Where the tubular enclosure is not connected to the handle portions **20a**, **20b**, similar to collar **95**, the tubular enclosure **128** may be configured to slide along the length of the shafts **17b**, **17c** as to adjust or vary the location of the enclosure **128** on

the shafts **17a, 17b** or, alternatively, may be fixed relative to the shafts **17a, 17b** by welding, for example.

The elongated tubular enclosure **128** may comprise, for example a wrapping, such as shrink wrap polymer film or shrink wrap polymer tubing, which may be formed and located with the surface of cavity **132** against insulators **90a, 90b** upon the application of heat thereto. In this manner, the elongated members shafts **17a, 17b** or the shafts **17a, 17b** and fluid line **120**, are retained in position relative to each other and inhibited from separating relative to each other.

Another embodiment of a bipolar device is shown at **5k** in FIGS. **51-53**. As shown in FIGS. **51** and **53**, electrosurgical device **5k** preferably includes a housing comprising mating handle portions **20a, 20b** and mating elongated shaft portions **134a, 134b** forming a hollow shaft. As best shown in FIG. **51**, shaft portions **134a, 134b**, preferably comprise two semi-circular elongated portions which are connected to handle portions **20a, 20b**, respectively, preferably as part of a unitary (i.e. single piece) polymer molding.

As best shown in FIG. **53**, electrodes **25a, 25b** are preferably assembled directly with shaft portions **134a, 134b** adjacent the distal end of shaft portions **134a, 134b**. As shown, preferably electrodes **25a, 25b** are mechanically assembled adjacent the distal end of shaft portions **134a, 134b** via a spool configuration. More specifically, preferably electrodes **25a, 25b** comprise locking portions comprising proximal circular flange portions **136a, 136b** and distal circular flange portions **138a, 138b** separated and connected by circular spindles **140a, 140b** there between which form the respective spool configurations.

The circular recesses **142a, 142b** formed between the proximal circular flange portions **136a, 136b** and distal circular flange portions **138a, 138b** provides a receptacle for receiving semi-circular interlocking tab portions **144a, 144b** of distal end portions **146a, 146b** of shaft portions **134a, 134b**.

During assembly, the interlocking tab portions of one of the shaft portions are first located in a portion of the recesses **142a, 142b** of electrodes **25a, 25b**. In other words, for example, electrodes **25a, 25b** may be first assembled with semi-circular interlocking tab portions **144a** of distal end portion **146a** of shaft portion **134a** which then occupy a first semi-circular portion of circular recesses **142a, 142b**. Then, once the electrodes **25a, 25b** have been properly seated with respect to the first shaft portion, here **134a**, the interlocking tab portions of the second shaft portion, here **144b** of shaft **134b**, are located in the remaining semi-circular portion of circular recesses **142a, 142b**. After the electrodes **25a, 25b** have been properly seated with respect to both shaft portions **134a, 134b** and all remaining components are properly located, the shaft portions **134a, 134b** and handle portions **20a, 20b**

may be assembled to one another by use of, for example an adhesive (e.g. cyanoacrylate) or welding.

As best shown in FIG. **53**, electrodes **25a, 25b** of device **5k** preferably comprise spherical portions **43a, 43b** and a corresponding spherical surface portions **42a, 42b** located at the distal end of the device which provided a smooth, blunt contour outer surface. More specifically, as shown, the spherical portions **43a, 43b** and spherical surface portion **42a, 42b** further provide a domed, hemisphere (i.e. less than a full sphere) and hemispherical surface portion comprising preferably about 180 degrees. Also as shown in FIG. **53**, electrodes **25a, 25b** preferably also comprise cylindrical portions 39a, **39b** and a corresponding cylindrical surface portions **40a, 40b** located proximal and adjacent to the spherical portions **43a, 43b** and spherical surface portions **42a, 42b**, respectively.

Electrodes **25a, 25b** of device **5k** are preferably coupled to the generator **6** via wire conductors **38a, 38b** of insulated wires **21a, 21b**. At their distal ends, conductors **38a, 38b** may be coupled to electrodes **25a, 25b** by means of first being inserted into the lumens **148a, 148b** of hollow metal tubes **150a, 150b**, such as hypo-tubes, then crimping the tubes **150a, 150b**. The tubes **150a, 150b** are then preferably inserted and retained in proximal end receptacles **152a, 152b** of electrodes **25a, 25b** by an interference fit. Alternatively, tubes **150a, 150b** may be eliminated and wire conductors **38a, 38b** may be coupled to electrodes **25a, 25b** by welding, soldering, mechanical fasteners or other suitable methods.

For device **5k** conductive fluid **24** is preferably provided by means of a lumen **122** of a separate fluid line **120**, preferably comprising either a metal (e.g. stainless steel hypo-tubing) or polymer (e.g. PVC tubing) material, extending distally and substantially parallel within the lumen of the shaft comprising shaft portions **134a, 134b**.

Similar to device **5j**, in order to minimize the risk of clogging of the lumen **122** at the distal end outlet opening **124** of the fluid line **120**, as shown, preferably the distal end **126** of the fluid line **120** is located proximal to the distal end of the device **5k** and more preferably, proximal to spherical surface portions **42a, 42b** and cylindrical surface portions **40a, 40b** of electrodes **25a, 25b**, or other tissue treating surfaces of electrodes as the electrode configurations vary.

Also similar to device **5j**, for device **5k** the outlet opening **124** for the fluid line **120** is preferably spaced uniformly between electrodes **25a, 25b** such that conductive fluid **24** expelled from the outlet opening **124** may form a fluid coupling comprising the a bridge **27** between the tissue surface **22** and the surface **42a, 42b** of each of the electrodes **25a, 25b**.

The effect of the bipolar devices of the present invention on tissue may be varied by changing the separation distance between the contact elements. Consequently, as shown in FIG. **54**, in contrast to certain other embodiments which the separation distance is unadjustable, bipolar device **5l** provides an adjustment mechanism for changing the separation distance (either increasing or decreasing) between the electrodes **25a, 25b**. As shown in FIG. **54**, the changing of the separation distance between the electrodes **25a, 25b** is provided by a scissors type adjustment mechanism with two arms **117a, 117b** hinged relative to one another in the middle on a pivot **110** preferably comprising a pin. Device **5l** may also comprise a latching mechanism **111** which incrementally fixes the position of the electrodes **25a, 25b** relative to one another during tissue treatment by increasing or decreasing the separation distance.

Furthermore, as shown, the arms **117a, 117b** themselves are preferably hinged on pivots **110a** and **110b**, also preferably comprising pins, which divide the arms **117a, 117b** into proximal arm portions **118a, 118b** and distal arm portions **112a, 112b**. Distal arm portions **112a, 112b** are preferably connected by a linkage **113** which keeps distal arm portions **112a, 112b** and electrodes **25a, 25b** substantially parallel to one another with use of the device **5l**. As shown, linkage **113** comprises a bar **114** fixed to distal arm portion **112b** and having an elongated opening **116** therein. Linkage also comprises a pin **115** fixed to distal arm portion **112a** which moves along and within the opening **116** during use of the device **5l** with the changing of the separation distance between electrodes **25a, 25b**. For device **5l**, tip portions **45a, 45b** may particularly comprise the configuration disclosed with device **5i**.

Another embodiment of a bipolar device is shown at **5m** in FIGS. **55-58**. As best shown in FIGS. **55** and **56** and similar to device **5i**, electrosurgical device **5m** preferably includes two stationary, immobile arms comprising rigid, self-supporting, hollow shafts **17a, 17b**. Shafts **17a, 17b** for device **5m** preferably comprise thick walled hypo-tubing providing sufficient rigidity to maintain their form during use of the device without kinking or significant bending. In certain embodiments, shafts **17a, 17b** may be hand malleable.

As shown throughout FIGS. **55-58** and similar to device **5i**, preferably the arms of device **5m** (comprising shafts **17a, 17b**) are retained in position relative to each other by a mechanical coupling device comprising a collar **95** and inhibited from separating relative to each other. Also as shown throughout FIGS. **55-58**, collar **95** is preferably located on a distal portion of the arms. More preferably, the collar **95** is located adjacent the distal ends **53a, 53b** of the shafts **17a, 17b**. As best shown in FIGS. **57** and **58**, preferably the collar **95** comprises two apertures **96a,**

96b, shown as comprising C-shapes, configured to receive a distal end portion of the shafts arms. Once the collar **95** is mechanically connected to the shafts **17a, 17b**, preferably by a snap-fit or slide-through connection, the location of the collar **95** may be further fixed relative to the shafts **17a, 17b** by, for example, adhesive bonding the collar **95** to shaft insulators **90a, 90b**. Such adhesive bonding may be accomplished, for example, either by use of a separate adhesive or autogenic bonding of the collar **95** to the insulators **90a, 90b** by, for example, welding such as ultrasonic welding.

Collar **95** comprises an electrically insulating (dielectric) material. In some embodiments, the electrically insulating material for collar **95** may comprise a polymer, either thermoplastic or thermoset, reinforced or unreinforced, filled or unfilled. Exemplary polymer materials include, but are not limited to, polyacetal (POM), polyamide (PA), polyamideimide (PAI), polyetheretherketone (PEEK), polyetherimide (PEI), polyethersulfone (PES), polyimide (PI), polyphenylenesulfide (PPS), polyphthalamide (PPA), polysulfone (PSO), polytetrafluoroethylene (PTFE) and syndiotactic polystyrene (SPS). More preferably, the electrically insulating polymer comprises either a liquid crystal polymer and, more particularly, an aromatic liquid crystal polyester which is reinforced with glass fiber, such as Vectra® A130 from Ticona, or Ultem® 10% glass filled polyetherimide from the General Electric Company. Exemplary reinforcement materials for polymers include, but are not limited to, glass fibers and boron fibers. Exemplary filler materials for polymers include mica, calcium carbonate and boron nitride. Reinforcement materials for the polymer material may be preferable for increased strength while filler materials may be preferable for increased heat resistance and/or thermal conductivity. Still other electrically insulating materials for collar **95** may a ceramic such as boron nitride.

As discussed above with reference to device **5i** and FIG. **48**, the fluid coupling to tissue for device **5i** may comprise a conductive fluid bridge **27** between electrodes **25a, 25b** which rests on the surface **22** of the tissue **32** and forms a shunt between the electrodes **25a, 25b**. As discussed above, a certain amount of RF energy may be diverted from going into the tissue **32** and actually pass between the electrodes **25a, 25b** via the conductive fluid bridge **27**. This loss of RF energy may slow down the process of coagulating tissue and producing the desired hemostasis or aerostasis of the tissue. Also as discussed above, the loss of RF energy through the bridge **27** may either be reduced or eliminated because all the fluid **24** of bridge **27** boils off or a large fraction of boiling creates enough disruption in the continuity of the bridge **27** to disrupt the electrical circuit through the bridge **27**. Thus, as indicated above one control strategy of the present invention is to reduce the

presence of a conductive fluid shunt by increasing the % boiling of the conductive fluid.

Rather than increasing the % boiling of the conductive fluid bridge **27** to reduce the presence of a fluid shunt between the electrodes **25a, 25b**, in certain applications it may be advantageous to provide the electrosurgical device with a dam between the electrodes **25a, 25b** which reduces, and preferably prevents, the formation of the conductive fluid bridge **27** between the electrodes **25a, 25b**.

As best shown in FIGS. **57** and **58**, collar **95** of device **5m** preferably further includes a substantially flat, blade-shaped electrical insulator spacer portion **154** located laterally between the electrodes **25a, 25b**. In addition to keeping the electrodes **25a, 25b** separated at a predetermined minimum separation distance (as dictated by the thickness of spacer portion **154**), spacer portion **154** also provides a dam between electrodes **25a, 25b** which reduces, and preferably prevents, the formation of the conductive fluid bridge **27** between the electrodes **25a, 25b**.

Also as best shown in FIGS. **57** and **58**, the distal end surface **156** of spacer portion **154** preferably follows the contour of the adjacent distal end surfaces **158a, 158b** of the electrodes **25a, 25b** such that the distal end surface **156** of spacer portion **154** is substantially flush, and preferably flush, with the adjacent distal end surfaces **158a, 158b** of electrodes **25a, 25b**. In this manner, the spacer portion **156** and the electrodes **25a, 25b** are better configured to slide along the surface of tissue given there are no raised or recessed edges created between the distal end surface **156** of spacer portion **154** and the adjacent distal end surfaces **158a, 158b** of the electrodes **25a, 25b** which could impair sliding movement.

Similar to device **5c**, electrodes **25a, 25b** of device **5m** are preferably assembled adjacent the distal ends **53a, 53b** of shafts **17a, 17b** by connector portions, preferably comprising shank portions **46a, 46b** which connect the remainder of the electrodes **25a, 25b** to shafts **17a, 17b**. Among other things, the connector portion of the electrodes **25a, 25b** are preferably configured to form a connection with a mating connector portion of the shafts **17a, 17b**. Also similar to device **5c**, preferably shank portions **46a, 46b** of device **5m** are configured to extend into cavities **50a, 50b** of shafts **17a, 17b** which comprise cylindrical receptacles and provide the mating connector portions for shank portions **46a, 46b**. Also similar to device **5c**, preferably surfaces **48a, 48b** of shank portions **46a, 46b** of device **5m** are configured to mate against and form an interference fit with surfaces **52a, 52b** of cavities **50a, 50b** to provide the connection.

Similar to device **5c**, shank portions **46a, 46b** of device **5m** are preferably cylindrical and located proximal and adjacent to neck portions **56a, 56b**. As best shown in FIGS. **57** and **58**, neck portions **56a, 56b** comprise cylindrical portions

57a, **57b** preferably having a cross-sectional dimension, here diameter, greater than the cross-sectional dimension, here also diameter, of shank portions **46a**, **46b**. In this manner, similar to device **5c**, in certain embodiments, the proximal end of neck portions **56a**, **56b** of device **5m** may be located adjacent and in contact with distal ends **53a**, **53b** of shafts **17a**, **17b**.

As best shown in FIGS. **57** and **58**, similar to recess **64** of device **5c**, electrodes **25a**, **25b** of device **5m** preferably comprises at least one recess **63a**, **63b** which provides an elongated fluid flow channel and outlet for the distribution of fluid **24**.

Electrodes **25a**, **25b** of device **5m** preferably comprise an enlarged head portion. Each enlarged head portion preferably comprises a side hemispherical portion **160a**, **160b** with a hemispherical surface comprising preferably about 180 degrees. As best shown in FIGS. **57** and **58**, preferably the hemisphere portions **160a**, **160b** are arranged facing away from one another in outwardly facing opposing relation on opposite sides of the device. The hemispherical portions **160a**, **160b** are preferably located laterally of transversely orientated cylindrical medial transition portions **162a**, **162b** which preferably provide the smooth transition between the hemispherical portions **160a**, **160b** and spacer portion **154** of collar **95**. As shown electrodes **25a**, **26b** and spacer portion **154** may comprise abutting flat surfaces **164a**, **164b** which are arranged facing towards and opposing one another. In alternative embodiments, medial transition portions **162a**, **162b** of electrodes **25a**, **25b** may be eliminated resulting in the head portion of electrodes **25a**, **25b** comprising just hemispherical portions **160a**, **160b** with a hemispherical surfaces comprising preferably about 180 degrees.

In certain embodiments spacer portion **154** may comprise a thickness in the range between and including about 0.5 mm to 10 mm, or in any 0.1 mm increment or range therebetween, to provide a separation distance between the electrodes **25a**, **25b** of such. For example, spacer portion **154** comprises a thickness in the range between and including about 1.5 mm to 4 mm.

As an alternative to adjusting the separation distance between the electrodes **25a**, **25b** by changing the thickness of the spacer portion **154**, portions of electrodes **25a**, **25b** may be coated with an thin (e.g. 0.01 to 0.5 mm) electrically insulating coating comprising, for example, a polymer or ceramic material. As shown in FIGS. **59-62**, a portion of the electrodes **25a**, **25b** for device **5n**, here the neck portions **56a**, **56b**, medial transition portions **162a**, **162b** and approximately half of each hemisphere portion **160a**, **160b** of the enlarged head portion are shown with an electrically insulating coating **166** thereon. As a result, the active tissue treating electrode surface is now limited to about quarter-sphere surfaces **168a**, **168b** and the

separation distance between the tissue treating electrode surfaces has been increased by the thickness of the medial transition portions **162a, 162b** of electrodes **25a, 25b**.

Another embodiment of a bipolar device is shown at **5o** in FIGS. **63-64**. Similar to device **5n**, the active tissue treating electrode surface of electrodes **25a, 25b** may be limited to about quarter-sphere surfaces **168a, 168b** (about 90 degrees) with the other surfaces of the electrode extending from the distal end of shaft insulators **90a, 90b** having electrically insulating coating **166** thereon. However, different from device **5n**, the enlarged head portion of the electrodes **25a, 25b** of device **5o** comprise two substantially circular spheres (i.e. except where they join to neck portions **56a, 56b**). The spheres may have any suitable diameter. However, the spheres preferably have a diameter in the range between and including about 0.5 mm to about 7 mm. More preferably the spheres have a diameter in the range between and including about 1.0 mm to about 4 mm. Even more preferably, the spheres have a diameter in the range between and including about 1.5 mm to about 3 mm. Where coating 166 is not located thereon, the active electrical surface of the spheres is about 260 degrees.

Also different from device **5n**, collar **95** of device **5o** does not include spacer portion **154**. With device **5o**, electrodes **25a, 25b** are separated by an air gap therebetween. As a result, as shown in FIG. **64**, when electrodes **25a, 25b** of device **5o** are pressed against the surface **22** of tissue **32** and the tissue **32** against electrodes **25a, 25b** compresses and forms recesses **170a, 170b**, device **5o** is configured to allow tissue **32** located adjacent the gap **172** between the electrodes **25a, 25b** to form a tissue protuberance **174** there into with downward slopes into the recess **170a, 170b**. Since fluid **24** which may exist between the electrodes **25a, 25b** will tend to flow with gravity down the slopes of the tissue protuberance **174** and into the adjoining recesses **170a, 170b**, the possibility of formation of a conductive fluid bridge **27** between electrodes **25a, 25b** is reduced. Furthermore, even if a conductive fluid bridge **27** where to form between the electrodes **25a, 25b** (e.g. where electrodes **25a, 25b** of device **5o** are not pressed against tissue **32** significantly enough to form recesses **170a, 170**, the coating **166** on the inner facing surfaces of the electrodes **25a, 25b** reduces the possibility such a bridge would be electrified by electrodes **25a, 25b** directly.

Another embodiment of a bipolar device is shown at **5p** in FIGS. **65-69**. As best shown in FIG. **66**, the electrodes **25a, 25b** now comprise a hollow metal tubes. More specifically, the distal end portion of the tubes comprise about a 90 degree bend (within about $\pm$ 5 degrees) forming two right angle elbows and which curves the distal end portions towards each other as they extend distally. Furthermore, the

distal ends of the tubes are arranged facing towards and opposing one another. Consequently, the electrodes 25a, 25b are substantially mirror images of each other.

As shown in FIG. **66**, collar **95** has been removed to better show that preferably the electrodes **25a, 25b** comprise circular, stainless steel hypo-tubing. Where the electrodes **25a, 25b** comprise separate pieces from shafts **17a, 17b**, electrodes **25a, 25b** of device **5p** are preferably connected to shafts **17a, 17b** by interference fit of the inner diameter of the shafts **17a, 17b** with the inner diameter of the electrodes **25a, 25b**. However, in order to minimize the number of components and assembly thereof, preferably a single piece of continuous tubing provides both the shaft and the electrode. In other words, as shown, preferably the electrodes **25a, 26b** are provided by the same piece of tubing used for shafts **17a, 17b**.

As best shown in FIGS. **67-69**, preferably device **5p** includes a collar **95** which includes an electrical insulator spacer portion **154** located laterally between the electrodes **25a, 25b**. Furthermore, spacer portion **154** preferably includes at least one recess **176a, 176b** which provides an elongated fluid flow channel and a portion of the fluid passage for the distribution of fluid **24** from openings **178a, 178b**. As shown, both the distal end openings **180a, 180b** of the tubes and openings **178a, 178b** of recesses **176a, 176b** are positioned at a location substantially inaccessible to direct contact with tissue or otherwise configured away from direct contact with tissue as to not become occluded by tissue with use of device **5p**.

Preferably spacer portion **154** includes protrusions **182a, 182b**, and more specifically semi-circular protrusions configured to fit into distal end openings **180a, 180b** and at least partially occlude openings **180a, 180b**. In this manner electrodes **25a, 25b** are retained from movement relative to spacer **154**, as well as the rest of collar **95**.

In certain embodiments, in order that heat may be transferred away from electrodes **25a, 25b** by spacer portion **154**, preferably the material for collar **95** has a thermal conductivity $\mathbf{k_{tc}}$ at 300°K (Kelvin) equal or greater than about 0.01 watt/cm°K. More preferably, the material for collar **95** has a thermal conductivity $\mathbf{k_{tc}}$ at 300°K (Kelvin) equal or greater than about 0.16 watt/cm°K. Even more preferably, the material for collar **95** has a thermal conductivity $\mathbf{k_{tc}}$ at 300°K (Kelvin) equal or greater than about 0.35 watt/cm°K.

The use of openings **178a, 178b** of recesses **176a, 176b** for the distribution of fluid **24** may be preferred to at least one fluid exit opening **184a, 184b** which may be provided on the distal end side of electrodes **25a, 25b** proximal to the distal end (see FIG. **66**), particularly in deep tissue crevices where tissue can occlude fluid flow from openings **184a, 184b**. However, as shown in FIGS. **70-71** for device **5q**,

where fluid exit openings **184a, 184b** are positioned at a location substantially inaccessible to direct contact with tissue or otherwise configured away from direct contact with tissue as to not become occluded by tissue (such as slots shown on the inner side wall of the electrodes **25a, 25b** adjacent the inner radius of the elbow bend and distal end of the electrode), the openings **184a, 184b** may be equally effective as openings **178a, 178b**.

More particularly, as shown, openings **184a, 184b** in FIG. **70-71**, for example, are closer to the inner radius of elbow bend than the other radius of the elbow bend, which aids in reducing occlusion by tissue. However, in other embodiments, the fluid exit openings **184a, 186a** may be closer to the outer radius of elbow bend than the inner radius of the elbow bend, as shown in FIG. **66**. Still, in other embodiments, the fluid exit openings **184a, 186a** may be equidistant the outer radius of elbow bend and the inner radius of the elbow bend, as shown in FIG. **73**.

Another embodiment of a bipolar device is shown at **5r** in FIGS. **72-73**. As shown the distal end of spacer portion **154** includes a recess **186** configured to allow tissue **32** to form a tissue protuberance **174** there into to reduce the possibility of formation of a conductive fluid bridge **27** between electrodes **25a, 25b** as discussed above.

One or more of the devices of the present invention may include assemblies which control power and/or fluid flow to the tissue treating portion of the device. The ability to control the flow of fluid from the device may provide certain advantages over a device not so equipped. These advantages include reducing the amount of fluid at the tissue treatment site and the likelihood of having to apply suction to the treatment site to remove fluid.

For device **5s** in FIGS. **74-79**, a single multi-positional, multi-functional switch and valve assembly **190** comprises a switch button **192**. Button **192** protrudes through an aperture **194** formed in handle portions **20a, 20b**. Button **192** is preferably integrally connected via a single piece polymer molding to a proximally extending switch arm **196** which provides a portion of a fluid flow control mechanism, preferably formed when interacting with handle portion **20a** to turn the flow of fluid **24** to the tissue treating portion of the device on (full flow, i.e. unregulated flow at full flow rate through the tubing) and off (no flow).

More specifically, the fluid flow control mechanism of switch/valve assembly **190** is provided with the changing the separation distance between the proximal end portion **198** of switch arm **196** and wall section **200** of handle portion **20a** as switch arm **196** is moved proximally and distally along track **206** formed and defined by apertures **208** of ribs **210** of handle portion **20a** in response to button **192** being moved proximally and distally in switch button aperture **194**.

As shown in FIG. **76**, fluid line **4b** is located between proximal end portion **198** of switch arm **196** and wall section **200** of handle portion **20a**. As button **192** and switch arm **196** are moved proximally by hand force, thus decreasing separation distance between proximal end portion **198** of switch arm **196** and wall section **200** of handle portion **20a**, fluid line **4b** is externally squeezed and compressed therebetween and its lumen correspondingly occluded to decrease, and preferably completely stop, the fluid flow rate. As exhibited by the above fluid flow control mechanism, preferably the mechanism does not make contact with fluid **24**, thus reducing the likelihood of inadvertent contamination.

Continuing with FIG. **76**, preferably the fluid flow control mechanism of switch/valve assembly **190** comprises a mechanism which holds the arm **196** in a fixed, locked position while compressing and occluding fluid line **4b**. As shown, preferably the locking mechanism comprises a locking tab **202** of handle portion **20a** which holds arm **196** in its locked rearward position by engaging a distal end portion **204** of switch arm **196**.

Locking tab **202** is disengaged from distal end portion **204** of switch arm **196** by depressing button **192**. Upon depressing button **192**, the distal end portion **204** of switch arm also separates from tab **202** and tab **202** disengages from distal end portion **204**. As best shown in FIG. **77**, simultaneously switch arm **196** is forced distally by the decompression of resilient fluid line **4b** such that tab **202** enters detent **212**. Preferably switch arm **196** is also forced distally by decompression of a linear spring **228** which biases proximal movement of arm **196** to the switch's off position against fluid line **4b** with compression thereof, and, with decompression thereof, helps return the switch **192** to its on position upon arm **196** being disengaged from tab **202**. As shown, spring **228** is supported on arm **196** by circular post **234** and is compressed between a flange **238** located at the base of post **234** and one of ribs **210**. Upon distal end portion **204** of arm **196** disengaging from tab **202**, button **192** and switch arm **196** may travel distally until tab **202** engages the proximal end **214** of detent **212**.

Once the flow of fluid **24** has resumed, switch button **192** of switch/valve assembly **190** may now be depressed to activate the flow of electric current to electrodes **25a**, **25b**. As discussed above, electrodes **25a**, **25b** are preferably coupled to the generator **6** via wire conductors **38a**, **38b** of insulated wires **21a**, **21b**. Here, for example, the active and return electrodes comprise electrodes **25a**, **25b**.

As shown in FIGS. **78-79**, electrode **25a** is directly coupled to generator **6** without any additional inclusion of an on/off switch with an associated control circuit therebetween. However, in addition to being directly coupled to generator **6**, the electrical coupling of electrode **25b** to generator **6** now includes the presence of

two separated electrical contacts **216** and **218** which, in the open position, create an open control circuit between electrode **25b** and generator **6**. The wiring of this electrical control circuit with the generator **6** is known in the art and discussed briefly below.

As best shown in FIGS. **77-79**, contacts **216** and **218** are disposed on a platform **222** partially underling switch button **192** and arm **196**. As best shown in FIG. **78**, contact **216** comprises a domed contact which overlies contact **218**. In the open, or undepressed, position, contact **216** remains separated from underlying contact **218** by virtue of the domed configuration of contact **216**, thus resulting in an open control circuit between electrode **25b** and generator **6**. However, when switch button **192** of switch/valve assembly **190** is in its depressed position, post **220** in turn depresses dome contact **216** into contact with contact **218**, thus closing the control circuit between electrode **25b** and generator **6**. The presence of the closed control circuit formed with wire **21c** is then sensed by generator **6** through a low voltage sensor which then provides the set power to electrodes **25a, 25b**.

When a depression force is removed from switch button **192**, contact **216** returns to its pre-depression domed position as a result of its resiliency or elastic memory, thus returning switch button **192** to its undepressed position and reopening the control circuit between electrode **25b** and generator **6**. The presence of the open control circuit is then sensed by the generator which then stops providing power to electrodes **25a, 25b**. Alternatively, where switch button **192** is not used and the physician chooses to activate electrodes **25a, 25b** with a foot pedal switch, the set electrical power to the electrodes **25a, 25b** only flows directly through contact **218** to complete the electrical circuit.

It should be understood that switch/valve assembly **190** is configured such that electrical current cannot be provided to electrodes **25a, 25b** while the flow of fluid **24** is off. As shown in FIG. **77**, when switch button **192** and switch arm **196** are in their proximal position, post **220** does not overlie domed contact **216**. Consequently, if switch button **192** is depressed, post **220** merely makes contact with platform **222** and the electrical circuit between electrodes **25a, 25b** and generator **6** remains opened.

It should also be understood that in the case of a single main fluid passage which may branch into multiple secondary passages, preferably switch/valve assembly **190** acts on the main fluid passage to reduce complexity. As shown in FIGS. **76-77**, preferably switch/valve assembly **190** is located proximal of splitter **240**.

In other embodiments one or more of the devices of the present invention may include a separate power switch and fluid flow valve assembles rather than part

of a single multi-positional switch/valve assembly. As shown in FIGS. **80-81**, device **5t** comprises a switch assembly **224** for turning power on and off to the tissue treating portion of the device and a valve assembly **226** for turning fluid flow on (full flow) and off (no flow) to the tissue treating portion of the device.

As best shown in FIG. **81**, switch button **230** of switch assembly **224** turns fluid flow on and off in substantially the same manner as switch button **192** of switch/valve assembly **190** (i.e. with distal and proximal movement). However, unlike device **5s**, proximal end portion **198** of switch arm **196** of device **5t** includes a roller wheel **236** to aid with compression and decompression of fluid line **4b**.

With regards to power, switch button **232** of valve assembly **226** turns power on and off in substantially the same manner as switch button **192** of switch/valve assembly **190** (i.e. in depressed and unpressed positions). However, unlike switch/valve assembly **190**, with valve assembly **226** power can be turned on and off independently of fluid flow. In other words, switch button **232** of valve assembly **226** can be in the power "on" position while switch button **230** of switch assembly **224** is in the fluid flow "off" position. Thus, the device **5t** can be configured to operate as dry electrosurgical device without fluid **24** being provided simultaneously from the tissue treating portion of the device.

In yet another embodiment, as shown in FIGS. **82-86**, the second valve assembly for turning fluid flow on and off to the tissue treating portion of the device may comprise a roller pinch clamp assembly. As best shown in FIGS. **83-86**, device **5u** includes a roller pinch clamp assembly **242** and, more specifically, an inclined ramp roller pinch clamp assembly (as opposed to a parallel acting clamp).

As best shown in FIGS. **84-85**, the clamp includes a housing provided by handles **20a**, **20b**, a roller wheel **244** having a wheel center axis **246** and a guide pin hub. As shown, the guide pin hub is provided by pair of opposing, integrally formed, cylindrical trunnions **248a**, **248b**, but may also be provided by a separately formed pin. Trunnions **248a**, **248b** are contained within and move along a track **250** preferably provided and defined by opposing trunnion channels **252a**, **252b** formed between wheel upper guide surfaces **254a**, **254b** and wheel lower guide surfaces **256a**, **256b** extending longitudinally and parallel inward from the side wall portions of the handles **20a**, **20b**. As shown, wheel upper guide surfaces **254a**, **254b** are provided by a lip portion of the handles **20a**, **20b** which partially define aperture **258** through which roller wheel partially extends while wheel lower guide surfaces **256a**, **256b** are provided by ribs **260a**, **260b**.

Handles **20a**, **20b** also preferably provide tubing guide surfaces **272a**, **272b** which at least a portion of which provide a clamping surface against which plastic tubing **4b** is clamped by roller **244**. As best shown in FIGS. **84-85**, tubing guide

surfaces **272a, 272b** are provided by ribs **270a, 270b**. In use, fluid line **4b** is externally squeezed and compressed between the outer perimeter surface **262** of roller wheel **244** and at least a portion of tubing guide surfaces **272a, 272b**. In this embodiment, preferably surface **262** is serrated.

Trunnions **248a, 248b** support the movement of roller wheel **244** in two opposing directions, here proximally and distally, along track **250**. As best shown in FIGS. **85-86**, the separation distance between the outer perimeter surface **262** of roller wheel **244** and tubing guide surfaces **272a, 272b** changes throughout the proximal and distal travel of roller wheel **244** along track **250**. More specifically, the separation distance between the outer perimeter surface **262** of roller wheel **244** and tubing guide surfaces **272a, 272b** is greater between the outer perimeter surface **262** of roller wheel **244** and distal end portions **274a, 274b** of tubing guide surfaces **272a, 272b** provided by distal end portions **264a, 264b** of ribs **270a, 270b** than between the outer perimeter surface **262** of roller wheel **244** and proximal end portions **276a, 276b** of tubing guide surfaces **272a, 272b** provided by proximal end portions **266a, 266b** of ribs **270a, 270b**.

As shown in FIGS. **84-85**, when axis **246** of roller wheel **244** is opposing distal end portions **274a, 274b** of tubing guide surfaces **272a, 272b**, preferably the separation distance is configured such that the tubing **4b** may be uncompressed and the lumen of tubing **4b** completely open for full flow therethrough. Conversely, as shown in FIG. **86**, when axis **246** of roller wheel **244** is opposing proximal end portions **276a, 276b** of tubing guide surfaces **272a, 272b** preferably the separation distance is configured such that the tubing **4b** is compressed and the lumen of tubing **4b** is completely blocked so that the flow of fluid through tubing **4b** is prevented.

Distal end portions **274a, 274b** of tubing guide surfaces **272a, 272b** are separated from proximal end portions **276a, 276b** of tubing guide surfaces **272a, 272b** by transition surfaces **278a, 278b** which are provided by transition rib portion **268a, 268b** of ribs **270a, 270b**. Preferably compression of tubing initially begins between transition surfaces **278a, 278b** and the outer perimeter surface **262** of roller wheel **244** and increases as wheel **244** moves proximally along proximal end portions **276a, 276b** of tubing guide surfaces **272a, 272b**. With this configuration, consideration may be given to eliminating at least that portion of distal end portions **274a, 274b** of tubing guide surfaces **272a, 272b** that do not contribute to compression of the tubing **4b**. However, given that of distal end portions **274a, 274b** of tubing guide surfaces **272a, 272b** guide tubing **4b** to splitter **240**, such may not be desirable.

As shown in FIGS. **84-86**, both transition surfaces **278a, 278b** and proximal end portions **276a, 276b** of tubing guide surfaces **272a, 272b** provide sloped

inclining surfaces proximally along their respective lengths which decreases the separation distance between the outer perimeter surface **262** of roller wheel **244** and the tubing guide surfaces **272a, 272b** as the wheel **244** moves proximally. As shown, preferably the transition surfaces **278a, 278b** and proximal end portions **276a, 276b** of tubing guide surfaces **272a, 272b** have different slopes such that the separation distance decreases at a faster rate along transition surfaces **278a, 278b** as compared to proximal end portions **276a, 276b** of tubing guide surfaces **272a, 272b**. In this manner, compression of tubing **4b** is non-linear along the length of travel of wheel **244** with a majority of the compression occurring between roller wheel **244** and transition surfaces **278a, 278b**. More preferably, the lumen of tubing **4b** is completely blocked when roller wheel **244** is compressing the tubing **4b** against the proximal portion of transition surfaces **278a, 278b**, and the added compression of the tubing **4b** along proximal end portions **276a, 276b** of tubing guide surfaces **272a, 272b** provides an additional safety to assure complete blocking of the lumen even where there are variations in the tubing, such as the size of the lumen.

It should be realized that, due to the slope of the transition rib portion **268a, 268b**, as the roller wheel **244** moves proximally relative to transition surfaces **278a, 278b** the lumen of tubing **4b** is blocked incrementally. Thus, in addition to providing an on/off mechanism, the roller pinch clamp assembly **242** can also be used to regulate the fluid flow rate between two non-zero flow values. It should also be realized that the roller pinch clamp assembly **242** of the device may be used in series conjunction with another roller pinch clamp assembly which is typically provided as part of an IV set (i.e. IV bag, IV bag spike, drip chamber, connecting tubing, roller clamp, slide clamp, luer connector). When used in this manner, the roller pinch clamp assembly of the IV set may be used to achieve a primary (major) adjustment for fluid flow rate, while the roller pinch clamp assembly **242** of the device may be used to achieve a secondary (more precise minor) adjustment for the fluid flow rate.

In another embodiment, as shown in FIGS. **87-89** for device **5v**, the roller pinch clamp assembly **242** may include a cover **280** which at least partially closes aperture **258** and/or conceals roller wheel **244**. Among other things, cover **280** reduces the possibility of undesirable foreign fluid (e.g. blood and other bodily fluids) from entering into the confines of handle **20a, 20b** through aperture **258**. Furthermore, cover **280** reduces the exposure of the internal mechanics of the roller pinch clamp assembly **242**. In this manner, cover **280** reduces the possibility of foreign objects (e.g. practitioner's rubber gloves) from entering into the confines of handle **20a, 20b** through aperture **258** and getting snagged, for example, between the trunnions **248a, 248b** and track **250**.

As shown in FIGS. **88-89**, preferably cover **280** overlies and moves distally and proximally with roller wheel **244**, and is configured to provide a switch button portion **282** when wheel **244** is covered within semi-circular receptacle **284** and inaccessible to direct manipulation. Preferably cover **280** is configured to substantially close aperture **258** regardless of the position of the wheel **244**, preferably by means of a distal shield portion **286** and a proximal shield portion **288**. Preferably, distal shield portion **286** and a proximal shield portion **288** each have a length equal to or greater than the length of aperture **258** minus the length of switch button portion **282**.

Also as shown, preferably cover **280** comprises a distal guide portion **290** and a proximal guide portion **292** located beneath distal shield portion **286** and a proximal shield portion **288** on opposing sides of wheel **244**. As shown proximal guide portion **292** and distal shield portion **286** both comprise rectangular guide pins and preferably move along a track **250** similarly to wheel **244**. Wheel **244** partially extends into receptacle **284** which has a slightly larger diameter than wheel **244**.

With movement of switch button portion **282** proximally by a proximal directed force apply by, for example, a finger, the inner surface **294** of distal guide portion **290** makes contact with surface **262** of wheel **244** and pushes wheel proximally. Conversely, with movement of switch button portion **282** distally by a distally directed force apply by, for example, a finger, the inner surface **296** of proximal guide portion **292** makes contact with outer surface **262** of wheel **244** and pushes wheel distally. In this embodiment, the surface **262** of wheel **244** is preferably smooth and wheel **244** preferably comprises a self-lubricating polymer material such as polyacetal.

In another embodiment, as shown in FIGS. **90-91** for device **5w**, the switch button portion **282** of cover **280** may include side portions **298** which cover the opposing sides of wheel **244**. However, unlike embodiment **5v**, a portion of the cover **280** for device **5w** is not contained in or directly guided by track **250** as distal guide portion **290** and proximal guide portion **292** have been eliminated. While the cover **280** for embodiment **5w** still applies directional force to wheel **244** to move wheel **244**, cover **280** now is joined to wheel **244** and conveyed along track **250** by trunnions **248a**, **248b** of wheel **244**. As shown, cover **280** includes two opposing C-shaped apertures **300** which provided wheel hub receptacles for trunnions **248a**, **248b**. As shown, trunnions **248a**, **248b** are located in apertures **300**.

Thus, with movement of switch button portion **282** proximally by a proximal directed force, the inner surface **302** of cover **280** defining apertures **300** makes contact with cylindrical side surface **304** of trunnions **248a**, **248b** and pushes wheel proximally. Conversely, with movement of switch button portion **282** distally by a

distally directed force, the inner surface **302** of cover **280** defining apertures **300** also makes contact with cylindrical side surface **304** of trunnions **248a**, **248b** and pushes wheel distally.

In another embodiment, as shown in FIGS. **92-93** for device **5x,** the switch button portion **282** of cover **280** has been eliminated. Thus, roller wheel **244** is now exposed and may be acted on directly rather than through switch button portion **282.**

While the various embodiments of switch assembles described above have predominately been described with reference to bipolar devices, it should be understood that the various switch assemblies may be equally adaptable to other fluid-assisted medical devices such as the monopolar devices of the present invention.

Bipolar devices **5i-5x** are particularly useful as non-coaptive tissue sealers given they do not grasp tissue. Devices **5i-5x** are particularly useful to surgeons to achieve hemostasis after dissecting through soft tissue as part of hip or knee arthroplasty. The tissue treating portions can be painted over the raw, oozing surface **22** of tissue **32** to seal the tissue **32** against bleeding, or focused on individual larger bleeding vessels to stop vessel bleeding.

Devices **5i-5x** are also useful to stop bleeding from the surface of cut bone tissue as part of any orthopaedic procedure that requires bone to be cut. Bipolar devices **5i-5x** are particularly useful for these applications over a monopolar device **5a** as a much greater surface area **22** of tissue **32** may be treated in an equivalent period of time and with better controlled depth of the treatment.

As is well known, bone, or osseous tissue, is a particular form of dense connective tissue consisting of bone cells (osteocytes) embedded in a matrix of calcified intercellular substance. Bone matrix mainly contains collagen fibers and the minerals calcium carbonate, calcium phosphate and hydroxyapatite. Among the many types of bone within the human body are compact bone and cancellous bone. Compact bone is hard, dense bone that forms the surface layers of bones and also the shafts of long bones. It is primarily made of haversian systems which are covered by the periosteum. Compact bone contains discrete nutrient canals through which blood vessels gain access to the haversian systems and the marrow cavity of long bones. For example, Volkmann's canals which are small canals found in compact bone through which blood vessels pass from the periosteum and connect with the blood vessels of haversian canals or the marrow cavity. Bipolar devices as disclosed herein may be particularly useful to treat compact bone and to provide hemostasis and seal bleeding vessels (e.g. by shrinking to complete close) and other structures associated with Volkmann's canals and Haversian systems.

In contrast to compact bone, cancellous bone is spongy bone and forms the bulk of the short, flat, and irregular bones and the ends of long bones. The network of osseous tissue that makes up the cancellous bone structure comprises many small trabeculae, partially enclosing many intercommunicating spaces filled with bone marrow. Consequently, due to their trabecular structure, cancellous bones are more amorphous than compact bones, and have many more channels with various blood cell precursors mixed with capillaries, venules and arterioles. Bipolar devices as disclosed herein may be particularly useful to treat cancellous bone and to provide hemostasis and seal bleeding structures such as the above micro-vessels (i.e. capillaries, venules and arterioles) in addition to veins and arteries. Such devices may be particularly useful for use during orthopaedic knee, hip, shoulder and spine procedures (e.g. arthroplasty).

During a knee replacement procedure, the condyle at the distal epiphysis of the femur and the tibial plateau at the proximal epiphysis of the tibia are often cut and made more planer with saw devices to ultimately provide a more suitable support structure for the femoral condylar prosthesis and tibial prosthesis attached thereto, respectively. The cutting of these long bones results in bleeding from the cancellous bone at each location. In order to seal and arrest the bleeding from the cancellous bone which has been exposed with the cutting of epiphysis of each long bone, the bipolar devices disclosed herein may be utilized. Thereafter, the respective prostheses may be attached.

Turning to a hip replacement procedure, the head and neck of the femur at the proximal epiphysis of the femur is removed, typically by cutting with a saw device, and the intertrochantic region of the femur is made more planer to provide a more suitable support structure for the femoral stem prosthesis subsequently attached thereto. With respect to the hip, a ball reamer is often used to ream and enlarge the acetabulum of the innominate (hip) bone to accommodate the insertion of an acetabular cup prosthesis therein, which will provide the socket into which the head of the femoral stem prosthesis fits. The cutting of the femur and reaming of the hip bone results in bleeding from the cancellous bone at each location. In order to seal and arrest the bleeding from the cancellous bone which has been cut and exposed, the bipolar devices disclosed herein may be utilized. Thereafter, as with the knee replacement, the respective prostheses may be attached.

The bipolar devices disclosed herein may be utilized for treatment of connective tissues, such as for shrinking intervertebral discs during spine surgery. Intervertebral discs are flexible pads of fibrocartilaginous tissue tightly fixed between the vertebrae of the spine. The discs comprise a flat, circular capsule roughly an inch in diameter and about 0.25 inch thick, made of a tough, fibrous

outer membrane called the annulus fibrosus, surrounding an elastic core called the nucleus pulposus.

Under stress, it is possible for the nucleus pulposus to swell and herniate, pushing through a weak spot in the annulus fibrosus membrane of the disc and into the spinal canel. Consequently, all or part of the nucleus pulposus material may protrude through the weak spot, causing pressure against surrounding nerves which results in pain and immobility.

The bipolar devices disclosed herein may be utilized to shrink protruding and herniated intervertebral discs which, upon shrinking towards normal size, reduces the pressure on the surrounding nerves and relieves the pain and immobility. The devices disclosed herein may be applied via posterior spinal access under surgeon control for either focal shrinking of the annulus fibrosus membrane.

Where a intervertebral disc cannot be repaired and must be removed as part of a discectomy, the devices disclosed herein may be particularly useful to seal and arrest bleeding from the cancellous bone of opposing upper and lower vertebra surfaces (e.g. the cephalad surface of the vertebral body of a superior vertebra and the caudad surface of an inferior vertebra). Where the disc is removed from the front of the patient, for example, as part of an anterior, thoracic spine procedure, the devices disclosed herein may also be particularly useful to seal and arrest bleeding from segmental vessels over the vertebral body.

The bipolar devices disclosed herein may be utilized to seal and arrest bleeding of epidural veins which bleed as a result of the removal of tissue around the dural membrane during, for example a laminectomy or other neurosurgical surgery. The epidural veins may start bleeding when the dura is retracted off of them as part of a decompression. Also during a laminectomy, the devices disclosed herein, may be used to seal and arrest bleeding from the vertebral arch and, in particular the lamina of the vertebral arch.

One or more of the features of the previously described system can be built into a custom RF generator. This embodiment can provide one or more advantages. For example, this type of system can save space and reduce overall complexity for the user. This system can also enable the manufacturer to increase the power delivered into low impedance loads, thereby further reducing the time to achieve the desired tissue effects. This changes the curve of FIG. **5**, by eliminating or reducing the slope of the low impedance ramp **28a** of power versus impedance.

Alternatively, for situations where the high impedance ramp **28b** may be exceeded with use of the devices of the present invention, it may be desirable to provide an impedance transformer **224** in a series circuit configuration between the electrode(s) of the device **5** and the power output of generator **6**. Consequently, the

impedance transformer **224** may be provided with the device **5**, the generator **6** or any of the wire connectors (e.g. wire **21**) connecting device **5** and generator **6**. Impedance transformer **224** is configured to match the load impedance provided to generator **6** such that it is within the working range of the generator **6** and, more preferably in the working range between the low and high cut-offs.

To effectively treat thick tissues, it can be advantageous to have the ability to pulse the RF power on and off. Under some circumstances, the temperature deep in tissue can rise quickly past the 100 °C desiccation point even though the electrode/tissue interface is boiling at 100 °C. This manifests itself as "popping," as steam generated deep in the tissue boils too fast and erupts toward the surface. In one embodiment of the invention, a switch is provided on the control device or custom generator to allow the user to select a "pulse" mode of the RF power. Preferably, the RF power system in this embodiment is further controlled by software.

In some embodiments, it can be desirable to control the temperature of the conductive fluid before it is released from the electrosurgical device. In one embodiment, a heat exchanger is provided for the outgoing saline flow to either heat or chill the saline. The heat exchanger may be provided as part of the electrosurgical device or as part of another part of the system, such as within the enclosure **14**. Pre-heating the saline to a predetermined level below boiling reduces the transient warm-up time of the device as RF is initially turned on, thereby reducing the time to cause coagulation of tissue. Alternatively, pre-chilling the saline is useful when the surgeon desires to protect certain tissues at the electrode/tissue interface and treat only deeper tissue. One exemplary application of this embodiment is the treatment of varicose veins, where it is desirable to avoid thermal damage to the surface of the skin. At the same time, treatment is provided to shrink underlying blood vessels using thermal coagulation. The temperature of the conductive fluid prior to release from the surgical device can therefore be controlled, to provide the desired treatment effect.

In another embodiment, the flow rate controller is modified to provide for a saline flow rate that results in greater than 100% boiling at the tissue treatment site. For example, the selection switch **12** of the flow rate controller **11** (shown in FIG. **1**) can include settings that correspond to 110%, 120% and greater percentages of boiling. These higher settings can be of value to a surgeon in such situations as when encountering thick tissue, wherein the thickness of the tissue can increase conduction away from the electrode jaws. Since the basic control strategy neglects heat conduction, setting for 100% boiling can result in 80% of 90% boiling, depending upon the amount of conduction. Given the teachings herein, the switch of

the flow rate controller can accommodate any desirable flow rate settings, to achieve the desired saline boiling at the tissue treatment site.

Some embodiments of the invention can provide one or more advantages over current electrosurgical techniques and devices. For example, the invention preferably achieves the desired tissue effect (for example, coagulation, cutting, and the like) in a fast manner. In a preferred embodiment, by actively controlling the flow rate of saline, both in quantity (Q vs. P) and location (for example, using gutters to direct fluid distally to tissue, using holes to direct flow of fluid, or other similar methods) the electrosurgical device can create a hot non-desiccating electrode/tissue interface and thus a fast thermally induced tissue coagulation effect.

The use of the disclosed devices can result in significantly lower blood loss during surgical procedures such as liver resections. Typical blood loss for a right hepatectomy can be in the range of 500 – 1,000 cubic centimeters. Use of the devices disclosed herein to perform pre-transection coagulation of the liver can result in blood loss in the range of 50 – 300 cubic centimeters. Such a reduction in blood loss can reduce or eliminate the need for blood transfusions, and thus the cost and negative clinical consequences associated with blood transfusions, such as prolonged hospitalization and a greater likelihood of cancer recurrence. Use of the device can also provide improved sealing of bile ducts, and reduce the incidence of post-operative bile leakage, which is considered a major surgical complication.

The invention can, in some embodiments, deliver fast treatment of tissue without using a temperature sensor built into the device or a custom special-purpose generator. In a preferred embodiment, there is no built-in temperature sensor or other type of tissue sensor, nor is there any custom generator. Preferably, the invention provides a means for controlling the flow rate to the device such that the device and flow rate controller can be used with a wide variety of general-purpose generators. Any general-purpose generator is useable in connection with the fluid delivery system and flow rate controller to provide the desired power; the flow rate controller will accept the power and constantly adjust the saline flow rate according to the control strategy. Preferably, the generator is not actively controlled by the invention, so that standard generators are useable according to the invention. Preferably, there is no active feedback from the device and the control of the saline flow rate is "open loop." Thus, in this embodiment, the control of saline flow rate is not dependent on feedback, but rather the measurement of the RF power going out to the device.

For purposes of the appended claims, the term "tissue" includes, but is not limited to, organs (e.g. liver, lung, spleen, gallbladder), highly vascular tissues (e.g. liver, spleen), soft and hard tissues (e.g. adipose, areolar, bone, bronchus-associated

lymphoid, cancellous, chondroid, chordal, chromaffin, cicatricial, connective, elastic, embryonic, endothelial, epithelial, erectile, fatty, fibrous, gelatiginous, glandular, granulation, homologous, indifferent, interstitial, lymphadenoid, lymphoid, mesenchymal, mucosa-associated lymphoid, mucous, muscular, myeloid, nerve, osseous, reticular, scar, sclerous, skeletal, splenic, subcutaneous) and tissue masses (e.g. tumors).

While preferred embodiments of the present invention have been described, it should be understood that various changes, adaptations and modifications can be made therein without departing from the spirit of the invention and the scope of the appended claims. The scope of the invention should, therefore, be determined not with reference to the above description, but instead should be determined with reference to the appended claims along with their full scope of equivalents. Furthermore, it should be understood that the appended claims do not necessarily comprise the broadest scope of the invention which the Applicant is entitled to claim, or the only manner(s) in which the invention may be claimed, or that all recited features are necessary.

All publications and patent documents cited in this application are incorporated by reference in their entirety for all purposes.

We claim:

1. A surgical device for treating tissue comprising:

a handle having a proximal end and a distal end;

a shaft extending distally beyond the distal end of the handle, the shaft having a proximal end and a distal end;

an electrode tip, at least a portion of the electrode tip extending distally beyond the distal end of the shaft, the electrode tip extending distally beyond the distal end of the shaft comprising a spherical end surface portion and a cylindrical side surface portion, the spherical end surface portion located distal to the cylindrical side surface portion and comprising at least a portion of the distal end surface of the surgical device; and

a fluid passage directed to provide a fluid towards the cylindrical side portion of the electrode tip.

2. The device according to claim 1 wherein:

the fluid passage directed to expel a fluid towards the cylindrical side portion of the electrode tip expels the fluid from an opening at the distal end of the shaft.

3. The device according to claim 2 wherein:

the opening at the distal end of the shaft is located between the electrode tip and the distal end of the shaft.

4. The device according to claim 2 wherein:

the opening at the distal end of the shaft is orientated away from direct contact with tissue.

5. The device according to claim 2 wherein:

the opening at the distal end of the shaft is sheltered from direct contact with tissue.

6. The device according to claim 5 wherein:

the opening at the distal end of the shaft is sheltered from direct contact with tissue by the shaft.

7. The device according to claim 1 wherein:

the fluid passage directed to expel a fluid towards the cylindrical side portion of the electrode tip is also directed to expel the fluid towards the spherical end surface portion of the electrode tip.

8. The device according to claim 1 wherein:
the fluid passage directed to expel a fluid towards the cylindrical side portion of the electrode tip is also directed to expel the fluid distally along the cylindrical side portion of the electrode tip.

9. The device according to claim 1 wherein:
the fluid passage directed to expel a fluid towards the cylindrical side portion of the electrode tip is also directed to expel the fluid away from direct contact with tissue.

10. The device according to claim 1 wherein:
the fluid passage is partially provided by a longitudinally directed elongated recess formed in the electrode tip.

11. The device according to claim 1 wherein:
the electrode tip has a length and is straight along its length.

12. The device according to claim 1 wherein:
at least a portion of the cylindrical side surface portion of the electrode tip comprises a curved cylindrical side surface portion.

13. The device according to claim 11 wherein:
the curved cylindrical side surface portion comprises at least a portion of a hook.

14. The device according to claim 1 wherein:
at least a portion of the cylindrical side surface portion of the electrode tip comprises a straight cylindrical side surface portion.

15. The device according to claim 14 wherein:
the straight cylindrical side surface portion comprises at least a portion of a hook.

16. The device according to claim 1 wherein:
the electrode tip comprises a hook.

17. The device according to claim 16 wherein:
the hook comprises an L-shaped hook.

18. The device according to claim 16 wherein:
the hook comprises an J-shaped hook.

19. The device according to claim 1 wherein:
the electrode tip further comprises a knuckle portion comprising a rounded protuberance.

20. The device according to claim 19 wherein:
the electrode tip knuckle portion has a knuckle portion width;
the electrode tip cylindrical portion has a cylindrical portion width; and
the knuckle portion width is greater than the cylindrical portion width.

21. The device according to claim 1 wherein:
a contact angle (θ) of the fluid on a surface of the electrode tip is less than 90 degrees.

22. The device according to claim 1 wherein:
the fluid on a surface of the electrode tip has a contact angle (θ) of less than 90 degrees.

23. The device according to claim 1 wherein:
the fluid provides a film on a surface of the electrode tip.

24. A surgical device for treating tissue comprising:
a handle having a proximal end and a distal end;
a shaft extending distally beyond the distal end of the handle, the shaft having a proximal end and a distal end;
an electrode tip, at least a portion of the electrode tip extending distally beyond the distal end of the shaft, the electrode tip extending distally beyond the distal end of the shaft comprising a neck portion and an enlarged head portion, the enlarged head portion located distal to the neck portion and comprising at least a portion of a distal end surface of the surgical device; and

a fluid passage directed to provide a fluid towards the enlarged head portion of the electrode tip.

25. A device for treating tissue comprising:
a handle having a proximal end and a distal end;
a shaft extending distally beyond the distal end of the handle, the shaft having a proximal end and a distal end;
an electrode tip, the electrode tip comprising a spherical end surface portion and a cylindrical side surface portion, the spherical end surface portion located distal to the cylindrical side surface portion and comprising at least a portion of the distal end surface of the device;
a fluid passage connectable to a fluid source; and
a plurality of fluid outlet openings in fluid communication with the fluid passage, the fluid outlet openings positioned to provide a fluid from the fluid source around the cylindrical side surface portion of the electrode tip.

26. The device according to claim 25 wherein:
the plurality of fluid outlet openings are positioned proximal to the cylindrical side surface portion of the electrode tip.

27. The device according to claim 26 wherein:
the plurality of fluid outlet openings comprise openings at the distal end of the shaft.

28. The device according to claim 26 wherein:
the plurality of fluid outlet openings comprise four equally spaced openings at the distal end of the shaft.

29. The device according to claim 25 wherein:
the plurality of fluid outlet openings are positioned around the cylindrical side surface portion of the electrode tip.

30. The device according to claim 29 wherein:
the plurality of fluid outlet openings are provided by four equally spaced openings positioned around the cylindrical side surface portion of the electrode tip.

31. A surgical device for treating tissue comprising:
a handle having a proximal end and a distal end;

a shaft extending distally beyond the distal end of the handle, the shaft having a proximal end and a distal end;

an electrode tip comprising a rounded distal end surface portion configured to blunt dissect tissue and a side surface portion configured to seal tissue from at least one of the flow of bodily fluids and air, the side surface portion having a surface area greater than the surface area of the distal end surface portion;

a fluid passage connectable to a fluid source; and

at least one fluid outlet opening in fluid communication with the fluid passage, the fluid outlet opening positioned to provide a fluid from the fluid source to the side surface portion of the electrode tip and proximal the distal end surface portion.

32. A tissue sealing device comprising:

a first electrode tip spaced from a second electrode tip, the first and second electrode tips being connectable to different terminals of a radio frequency generator to generate electrical current flow therebetween;

at least one fluid passage connectable to a fluid source;

at least one fluid outlet opening in fluid communication with the fluid passage, the fluid outlet opening configured to provide a fluid from the fluid source to at least one of a tissue surface and at least one of the first and second electrode tips; and

the first and second electrode tips configured to slide over and seal tissue in the presence of a fluid provided from the fluid outlet opening and an electrical current
provided from the electrode tips.

33. The device according to claim 32 wherein:

the at least one fluid outlet opening is located between the first electrode tip and the second electrode tip.

34. The device according to claim 32 wherein:

the at least one fluid outlet opening is configured to provide the fluid between the first electrode tip and the second electrode tip.

35. The device according to claim 32 wherein:

the at least one fluid outlet opening is configured to provide the fluid to tissue between the first electrode tip and the second electrode tip.

36. The device according to claim 32 wherein:

the first electrode tip provides a first electrode tip distal end surface of the device;

the second electrode tip provides a second electrode tip distal end surface of the device; and

the at least one fluid outlet opening is located proximal to both distal end surfaces.

37. The device according to claim 32 wherein:

the first electrode tip provides a first electrode tip distal end surface of the device;

the second electrode tip provides a second electrode tip distal end surface of the device; and

the at least one fluid outlet opening is located adjacent to both distal end surfaces.

38. The device according to claim 32 wherein:

the at least one fluid outlet opening further comprises at least a first fluid outlet opening and a second fluid outlet opening;

the first fluid outlet opening is configured to provide the fluid to the first electrode tip; and

the second fluid outlet opening is configured to provide the fluid to the second electrode tip.

39. The device according to claim 38 wherein:

the first electrode tip provides a first electrode tip distal end surface of the device;

the second electrode tip provides a second electrode tip distal end surface of the device;

the first fluid outlet opening is located proximal to the first electrode tip distal end surface of the device; and

the second fluid outlet opening is located proximal to the second electrode tip distal end surface of the device.

40. The device according to claim 38 wherein:

the first electrode tip provides a first electrode tip distal end surface of the device;

the second electrode tip provides a second electrode tip distal end surface of the device;

the first fluid outlet opening is located adjacent to the first electrode tip distal end surface of the device; and

the second fluid outlet opening is located adjacent to the second electrode tip distal end surface of the device.

41. The device according to claim 38 wherein:

the first electrode tip provides a first electrode tip distal end surface of the device;

the second electrode tip provides a second electrode tip distal end surface of the device;

the first fluid outlet opening is located on the first electrode tip distal end surface of the device; and

the second fluid outlet opening is located on the second electrode tip distal end surface of the device.

42. The device according to claim 38 wherein:

the first fluid outlet opening is positioned at a location substantially inaccessible to direct contact with the tissue; and

the second fluid outlet opening is positioned located at a location substantially inaccessible to direct contact with the tissue.

43. The device according to claim 32 wherein:

the first electrode tip is separated from the second electrode tip by a separation distance; and

the separation distance between the first electrode tip and second electrode tip is adjustable.

44. The device according to claim 32 wherein:

the first electrode tip is separated from the second electrode tip by a separation distance; and

the separation distance between the first electrode tip and second electrode tip is at least one of incrementally increasable and decreasable by a latching mechanism.

45. The device according to claim 32 wherein:

the first electrode tip is separated from the second electrode tip by a separation distance; and

the separation distance between the first electrode tip and second electrode tip is unadjustable.

46. The device according to claim 32 wherein:

an electrical insulator is located between the first electrode tip and the second electrode tip.

47. The device according to claim 46 wherein:

a portion of the electrical insulator provides a portion of the fluid passage.

48. The device according to claim 46 wherein:

a portion of the electrical insulator provides a dam between the first electrode tip and the second electrode tip.

49. The device according to claim 46 wherein:

the electrical insulator provides an electrical insulator distal end surface of the device;

the first electrode tip provides a first electrode tip distal end surface of the device adjacent a first portion of the electrical insulator distal end surface of the device;

the second electrode tip provides a second electrode tip distal end surface of the device adjacent a second portion of the electrical insulator distal end surface of the device;

the first electrode tip distal end surface of the device adjacent the first portion of the electrical insulator distal end surface of the device is substantially flush with the first portion of the electrical insulator distal end surface of the device;

the second electrode tip distal end surface of the device adjacent the second portion of the electrical insulator distal end surface of the device is substantially flush with the second portion of the electrical insulator distal end surface of the device; and

whereby the transition between the electrical insulator distal end surface of the device and the first and second electrode tip distal end surfaces is substantially smooth and to provide for sliding of the first and second electrode tips along a tissue surface.

50. The device according to claim 32 wherein:
the first electrode tip is separated from the second electrode tip by an electrical insulator.

51. The device according to claim 32 wherein:
the first electrode tip and the second electrode tip are held in position relative to each other by a collar.

52. The device according to claim 32 wherein:
the first electrode tip and the second electrode tip are connected by a linkage.

53. The device according to claim 32 wherein:
the first electrode tip and the second electrode tip are substantially parallel.

54. The device according to claim 32 wherein:
the first electrode tip and the second electrode tip are substantially the same shape.

55. The device according to claim 32 wherein:
the first electrode tip and the second electrode tip are substantially mirror images of each other.

56. The device according to claim 32 wherein:
the first electrode tip comprises a first electrode tip spherical surface; and
the second electrode tip comprises a second electrode tip spherical surface.

57. The device according to claim 56 wherein:
the first electrode tip spherical surface comprises at least a portion of a first electrode tip distal end surface of the device; and
the second electrode tip spherical surface comprises at least a portion of a second electrode tip distal end surface of the device.

58. The device according to claim 56 wherein:
the first electrode tip spherical surface comprises at least a portion of a side surface of the first electrode tip; and
the second electrode tip spherical surface comprises at least a portion of a side surface of the second electrode tip.

59. The device according to claim 58 wherein:
the first electrode tip spherical surface and the second electrode tip spherical surface are on opposite sides of the device.

60. The device according to claim 56 wherein:
the first electrode tip spherical surface comprises a hemi-spherical surface less than 180 degrees; and
the second electrode tip spherical surface comprises a hemi-spherical surface less than 180 degrees; and

61. The device according to claim 56 wherein:
the first electrode tip spherical surface comprises a hemi-spherical surface of about 180 degrees; and
the second electrode tip spherical surface comprises a hemi-spherical surface of about 180 degrees.

62. The device according to claim 56 wherein:
the first electrode tip spherical surface comprises a hemi-spherical surface greater than 180 degrees; and
the second electrode tip spherical surface comprises a hemi-spherical surface greater than 180 degrees; and

63. The device according to claim 56 wherein:
the first electrode tip spherical surface is provided by a first electrically conductive ball; and
the second electrode tip spherical surface is provided by a second electrically conductive ball.

64. The device according to claim 32 wherein:
the first electrode tip comprises a first electrode tip cylindrical surface; and
the second electrode tip comprises a second electrode tip cylindrical surface.

65. The device according to claim 32 wherein:
the first electrode tip comprises a first electrode tip cylindrical surface located proximal to a first electrode tip spherical surface; and
the second electrode tip comprises a second electrode tip cylindrical surface located proximal to a second electrode tip spherical surface.

66. The device according to claim 32 wherein:

the first electrode tip comprises a first electrode tip cylindrical surface located medial to a first electrode tip spherical surface; and

the second electrode tip comprises a second electrode tip cylindrical surface located medial to a second electrode tip spherical surface.

67. The device according to claim 32 wherein:

the first electrode tip comprises a first electrode tip first cylindrical surface located proximal to a first electrode tip second cylindrical surface; and

the second electrode tip comprises a second electrode tip first cylindrical surface located proximal to a second electrode tip second cylinderical surface.

68. The device according to claim 32 wherein:

the first electrode tip comprises a first electrode tip first cylindrical surface transverse to a first electrode tip second cylindrical surface; and

the second electrode tip comprises a second electrode tip first cylindrical surface transverse to a second electrode tip second cylindrical surface.

69. The device according to claim 32 wherein:

the first electrode tip comprises a neck portion and an enlarged head portion relative to the neck portion, the enlarged head portion located distal to the neck portion and comprising at least a portion of a first electrode tip distal end surface of the device; and

the second electrode tip comprises a neck portion and an enlarged head portion relative to the neck portion, the enlarged head portion located distal to the neck portion and comprising at least a portion of a second electrode tip distal end surface of the device.

70. The device according to claim 69 wherein:

the first electrode tip head portion comprises a sphere of greater than 180 degrees; and

the second electrode tip head portion comprises a sphere of greater than 180 degrees.

71. The device according to claim 32 wherein:

the first electrode tip comprises a first electrode tip hollow metal tube;

the second electrode tip comprises a second electrode tip hollow metal tube; and

the first and second electrode tip hollow metal tubes having a bend which curves the tips towards each other as they extend distally.

72. The device according to claim 71 wherein:
the first electrode tip hollow metal tube bend is about 90 degrees; and
the second electrode tip hollow metal tube bend is about 90 degrees.

73. The device according to claim 71 wherein:
the first electrode tip hollow metal tube provides at least one first electrode tip hollow metal tube fluid outlet opening; and
the second electrode tip hollow metal tube provides at least one second electrode tip hollow metal tube fluid outlet opening.

74. The device according to claim 73 wherein:
the first electrode tip hollow metal tube has a first electrode tip hollow metal tube distal end;
the second electrode tip hollow metal tube has a second electrode tip hollow metal tube distal end;
the first electrode tip hollow metal tube fluid outlet opening is located at the distal end of the first electrode tip hollow metal tube; and
the second electrode tip hollow metal tube fluid outlet opening is located at the distal end of the second electrode tip hollow metal tube.

75. The device according to claim 73 wherein:
the first electrode tip hollow metal tube has a first electrode tip hollow metal tube distal end;
the second electrode tip hollow metal tube has a second electrode tip hollow metal tube distal end;
the first electrode tip hollow metal tube fluid outlet opening is located adjacent the distal end of the first electrode tip hollow metal tube; and
the second electrode tip hollow metal tube fluid outlet opening is located adjacent the distal end of the second electrode tip hollow metal tube.

76. The device according to claim 73 wherein:
the first electrode tip hollow metal tube has a first electrode tip hollow metal tube distal end;
the second electrode tip hollow metal tube has a second electrode tip hollow metal tube distal end;

the first electrode tip hollow metal tube fluid outlet opening is located proximal to the distal end of the first electrode tip hollow metal tube; and

the second electrode tip hollow metal tube fluid outlet opening is located proximal to the distal end of the second electrode tip hollow metal tube.

77. The device according to claim 73 wherein:

the first electrode tip hollow metal tube fluid outlet opening is positioned at a location substantially inaccessible to direct contact with the tissue; and

the second electrode tip hollow metal tube fluid outlet opening is positioned at a location substantially inaccessible to direct contact with the tissue.

78. The device according to claim 71 wherein:

the first electrode tip hollow metal tube provides at least one first electrode tip hollow metal tube fluid outlet opening, the bend has an inner bend radius and an outer bend radius and at least a portion of the first electrode tip hollow metal tube fluid outlet opening is closer to the inner bend radius than the outer bend radius;

the second electrode tip hollow metal tube and provides at least one second electrode tip hollow metal tube fluid outlet opening, and bend has an inner bend radius and an outer bend radius and at least a portion of the second electrode tip hollow metal tube fluid outlet opening is closer to the inner bend radius than the outer bend radius.

79. The device according to claim 71 wherein:

the first electrode tip hollow metal tube provides at least one first electrode tip hollow metal tube fluid outlet opening, the bend has an inner bend radius and an outer bend radius and at least a portion of the first electrode tip hollow metal tube fluid outlet opening is closer to the outer bend radius than the inner bend radius;

the second electrode tip hollow metal tube and provides at least one second electrode tip hollow metal tube fluid outlet opening, and bend has an inner bend radius and an outer bend radius and at least a portion of the second electrode tip hollow metal tube fluid outlet opening is closer to the outer bend radius than the inner bend radius.

80. The device according to claim 71 wherein:

the first electrode tip hollow metal tube provides at least one first electrode tip hollow metal tube fluid outlet opening, the bend has an inner bend radius and an outer bend radius and at least a portion of the first electrode tip hollow metal tube

fluid outlet opening is equidistant between the outer bend radius than the inner bend radius;

the second electrode tip hollow metal tube and provides at least one second electrode tip hollow metal tube fluid outlet opening, and bend has an inner bend radius and an outer bend radius and at least a portion of the second electrode tip hollow metal tube fluid outlet opening is equidistant between the outer bend radius than the inner bend radius.

81. The device according to claim 32 further comprising:

a housing having a housing distal end, the first electrode tip and the second electrode tip extending distally beyond the housing distal end.

82. The device according to claim 81 wherein:

the housing having a housing distal end comprises a shaft having a shaft distal end; and

the first electrode tip and the second electrode tip extending distally beyond the shaft distal end.

83. The device according to claim 32 further comprising:

a first housing having a first housing distal end, the first electrode tip extending distally beyond the first housing distal end; and

a second housing having a second housing distal end, the second electrode tip extending distally beyond the second housing distal end.

84. The device according to claim 83 wherein:

the first housing further comprises a first housing cavity, the first electrode tip retractable into the first housing cavity; and

the second housing further comprises a second housing cavity, the second electrode tip retractable into the second housing cavity.

85. The device according to claim 83 wherein:

the first housing further comprises a first housing distal end opening, the first electrode tip extending distally beyond the first housing distal end opening; and

the second housing further comprises a second housing distal end opening, the second electrode tip extending distally beyond the second housing distal end opening.

86. The device according to claim 85 wherein:

the first housing distal end opening further comprises a first housing distal end fluid outlet opening; and

the second housing distal end opening further comprises a second housing distal end fluid outlet opening.

87. The device according to claim 86 wherein:

the first housing distal end fluid outlet opening is configured to provide the fluid to the first electrode tip; and

the second housing distal end fluid outlet opening is configured to provide the fluid the second electrode tip.

88. The device according to claim 32 further comprising:

a first shaft having a first shaft distal end, the first electrode tip extending distally beyond the first shaft distal end; and

a second shaft having a second shaft distal end, the second electrode tip extending distally beyond the second shaft distal end.

89. The device according to claim 88 wherein:

the first shaft further comprises a first shaft distal end opening, the first electrode tip extending distally beyond the first shaft distal end opening; and

the second shaft further comprises a second shaft distal end opening, the second electrode tip extending distally beyond the second shaft distal end opening.

90. The device according to claim 89 wherein:

the first shaft distal end opening further comprises a first shaft distal end fluid outlet opening; and

the second shaft distal end opening further comprises a second shaft distal end fluid outlet opening.

91. The device according to claim 90 wherein:

the first shaft distal end fluid outlet opening is configured to provide the fluid to the first electrode tip; and

the second shaft distal end fluid outlet opening is configured to provide the fluid the second electrode tip.

92. The device according to claim 32 wherein:

the first electrode tip is part of a first arm; and

the second electrode tip is part of a second arm;

93. The device according to claim 92 wherein:
the first arm and the second arm are immobile relative to each another.

94. The device according to claim 92 wherein:
the first arm and the second arm are movable relative to each other.

95. The device according to claim 92 wherein:
the first arm includes a pivot; and
the second arm includes a pivot.

96. The device according to claim 92 further comprising:
a handle having a proximal end and a distal end; and
the first arm and the second arm extend distally beyond the distal end of the handle.

97. The device according to claim 92 wherein:
the first arm comprises a first shaft having a first shaft distal end and the first electrode tip is located distal to the first shaft distal end; and
the second arm comprises a second shaft having a second shaft distal end and the second electrode tip is located distal to the second shaft distal end.

98. The device according to claim 97 wherein:
the first shaft has a first shaft fluid passage, the first shaft fluid passage configured to provide the fluid to the first electrode tip; and
the second shaft has a second fluid passage, the second shaft fluid passage configured to provide the fluid to the second electrode tip;

99. The device according to claim 32 further comprising:
a valve assembly to control a flow of the fluid.

100. The device according to claim 32 further comprising:
a handle; and
the valve assembly is located in the handle.

101. The device according to claim 99 wherein:
the valve assembly is configured to turn the flow of the fluid on and off.

102. The device according to claim 99 wherein:
the valve assembly is configured to adjust the flow of the fluid between two non-zero flow rates.

103. The device according to claim 99 wherein:
the valve assembly is configured to at least one of increase and decrease the flow of the fluid.

104. The device according to claim 99 wherein:
the fluid passage is partially provided within a plastic tubing; and
the valve assembly comprises a roller clamp assembly, the roller clamp assembly having a wheel configured to roll along the plastic tubing to at least partially open and close the fluid passage.

105. The device according to claim 104 wherein:
the wheel rolls proximally and distally.

106. The device according to claim 99 wherein:
the fluid passage is partially provided within a plastic tubing; and
the valve assembly comprises an arm, the arm configured to move in a first direction and a second direction, the first direction to compress the plastic tubing to at least partially close the fluid passage and a second direction to decompress the plastic tubing to at least partially open the fluid passage.

107. The device according to claim 106 wherein:
the arm moves proximally and distally.

108. The device according to claim 99 wherein:
the fluid passage is partially provided within a plastic tubing; and
the valve assembly comprises mechanism configured to compress the plastic tubing to at least partially close the fluid passage.

109. The device according to claim 99 wherein:
the fluid passage is partially provided within a plastic tubing and
the switch assembly comprises mechanism configured to pinch the plastic tubing to at least partially close the fluid passage.

110. The device according to claim 32 further comprising:

a switch assembly to control power, the switch assembly having on and off positions.

a valve assembly to control a flow of the fluid, the valve having on and off positions;

a mechanism which prevents the switch assembly from being in the on position while the valve assembly is in the off position.

111. A method for treating tissue comprising:

providing tissue having a tissue surface;

providing radio frequency power at a power level;

providing an electrically conductive fluid at a fluid flow rate;

providing an surgical device configured to simultaneously provide the radio frequency power and the electrically conductive fluid to tissue;

providing the electrically conductive fluid to the tissue at the tissue surface;

forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and the surgical device;

providing the radio frequency power to the tissue at the tissue surface and below the tissue surface into the tissue through the fluid coupling;

sealing the tissue against at least one of the flow of bodily fluids and air; and

blunt dissecting the tissue.

112. The method of treating tissue according to claim 111 wherein:

the tissue comprises soft tissue.

113. The method of treating tissue according to claim 111 wherein:

the tissue comprises organ tissue.

114. The method of treating tissue according to claim 113 wherein:

the organ tissue comprises liver tissue.

115. The method of treating tissue according to claim 113 wherein:

the organ tissue comprises lung tissue.

116. The method of treating tissue according to claim 113 wherein:

the organ tissue comprises spleen tissue.

117. The method of treating tissue according to claim 113 wherein:
the organ tissue comprises gallbladder tissue.

118. The method of treating tissue according to claim 111 wherein:
the tissue comprises a vessel.

119. The method of treating tissue according to claim 118 wherein:
the vessel comprises a blood vessel.

120. A method for treating tissue comprising:
providing tissue having a tissue surface;
providing radio frequency power at a power level;
providing an electrically conductive fluid at a fluid flow rate;
providing an surgical device configured to simultaneously provide the radio frequency power and the electrically conductive fluid to tissue, the surgical device comprising a first electrode tip and a second electrode tip;
providing the electrically conductive fluid to the tissue at the tissue surface;
forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and the surgical device;
providing the radio frequency power to the tissue at the tissue surface and below the tissue surface into the tissue through the fluid coupling;
sliding the first electrode tip and the second electrode tip over the tissue surface; and
sealing the tissue against at least one of the flow of bodily fluids and air.

121. The method of treating tissue according to claim 120 wherein:
the tissue comprises soft tissue.

122. The method of treating tissue according to claim 120 wherein:
the tissue comprises hard tissue.

123. The method of treating tissue according to claim 120 wherein:
the tissue comprises osseous tissue.

124. The method of treating tissue according to claim 120 wherein:
the tissue comprises bone tissue.

125. The method of treating tissue according to claim 124 wherein: the bone tissue comprises compact bone tissue.

126. The method of treating tissue according to claim 124 wherein: the bone tissue comprises cancellous bone tissue.

127. The method of treating tissue according to claim 124 wherein: the bone tissue comprises long bone tissue.

128. The method of treating tissue according to claim 124 wherein: the bone tissue comprises femur bone tissue.

129. The method of treating tissue according to claim 124 wherein: the bone tissue comprises tibia bone tissue.

130. The method of treating tissue according to claim 124 wherein: the bone tissue comprises innominate bone tissue.

131. The method of treating tissue according to claim 124 wherein: the bone tissue comprises vertebra bone tissue.

132. The method of treating tissue according to claim 120 wherein: the tissue comprises connective tissue.

133. The method of treating tissue according to claim 120 performed as part of an orthopaedic surgical procedure.

134. The method of treating tissue according to claim 120 performed as part of the group consisting of knee, hip, shoulder and spinal surgical procedures.

135. The method of treating tissue according to claim 120 wherein: the tissue comprises a vessel.

136. The method of treating tissue according to claim 135 wherein: the vessel comprises a blood vessel.

137. The method of treating tissue according to claim 120 wherein: the bodily fluid comprises blood.

FIG. 1

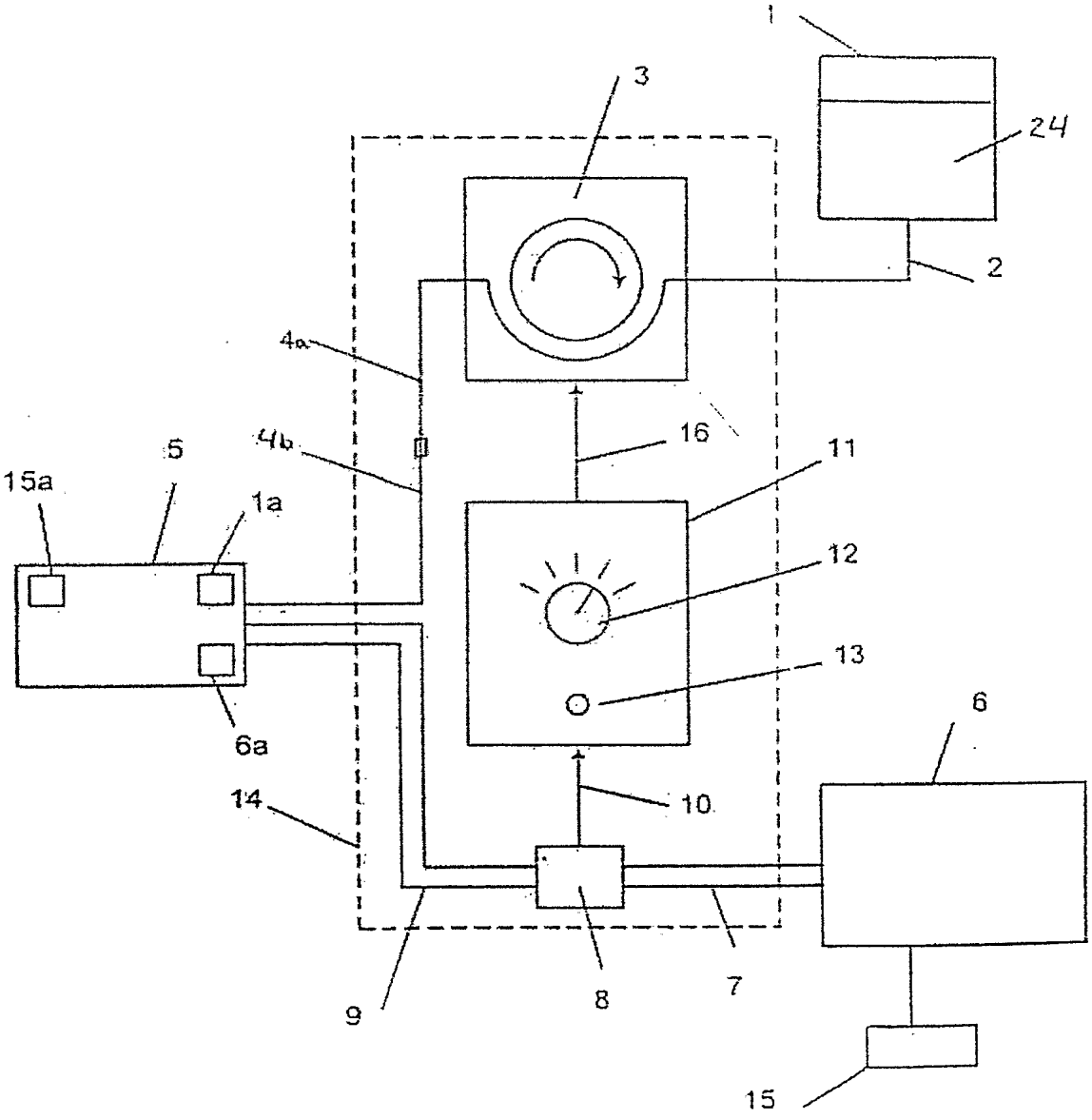


FIG. 2

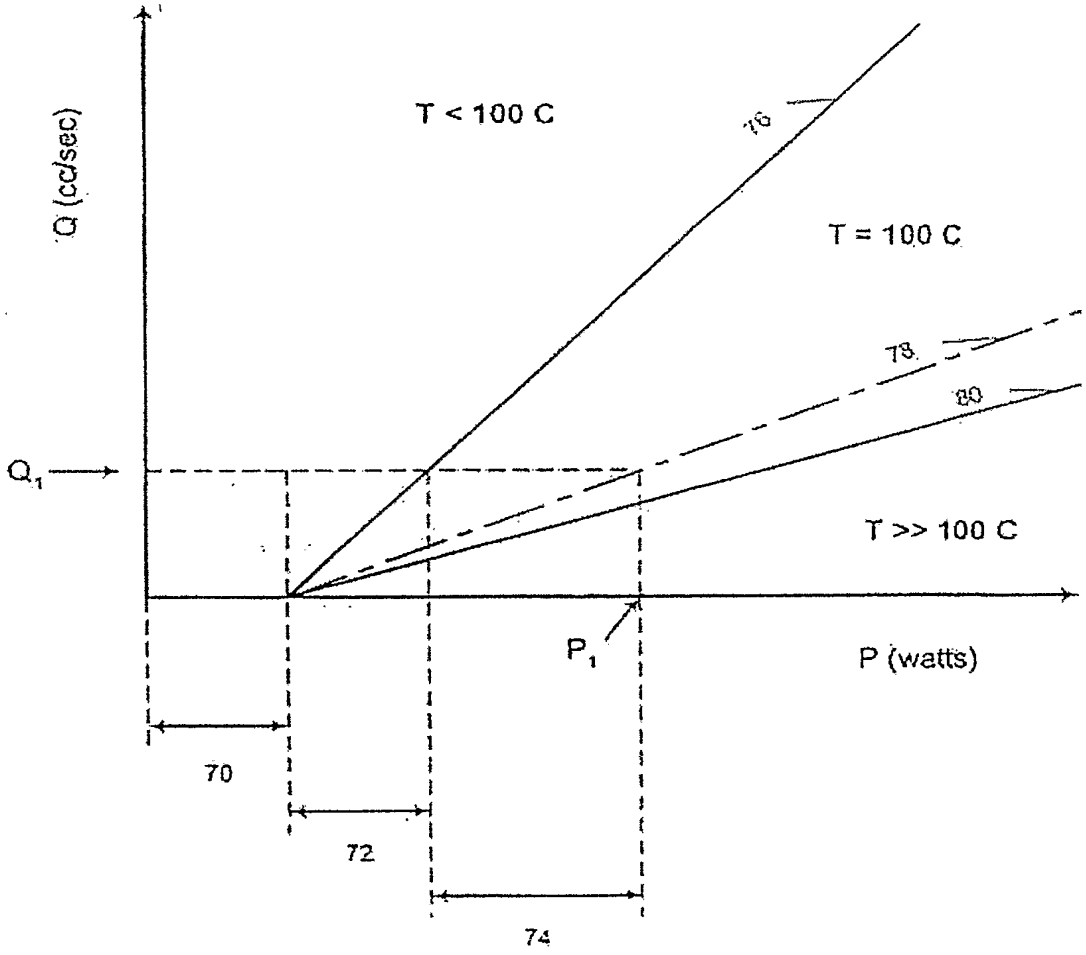


FIG. 3

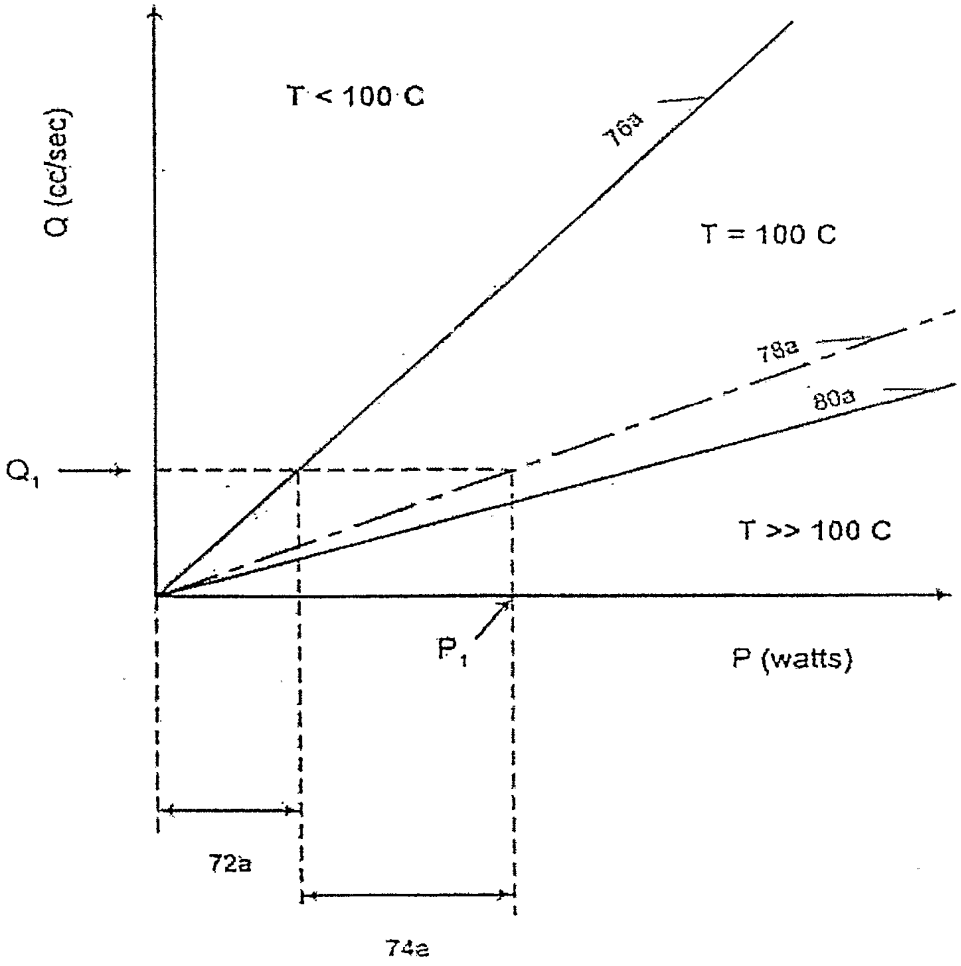


FIG. 4

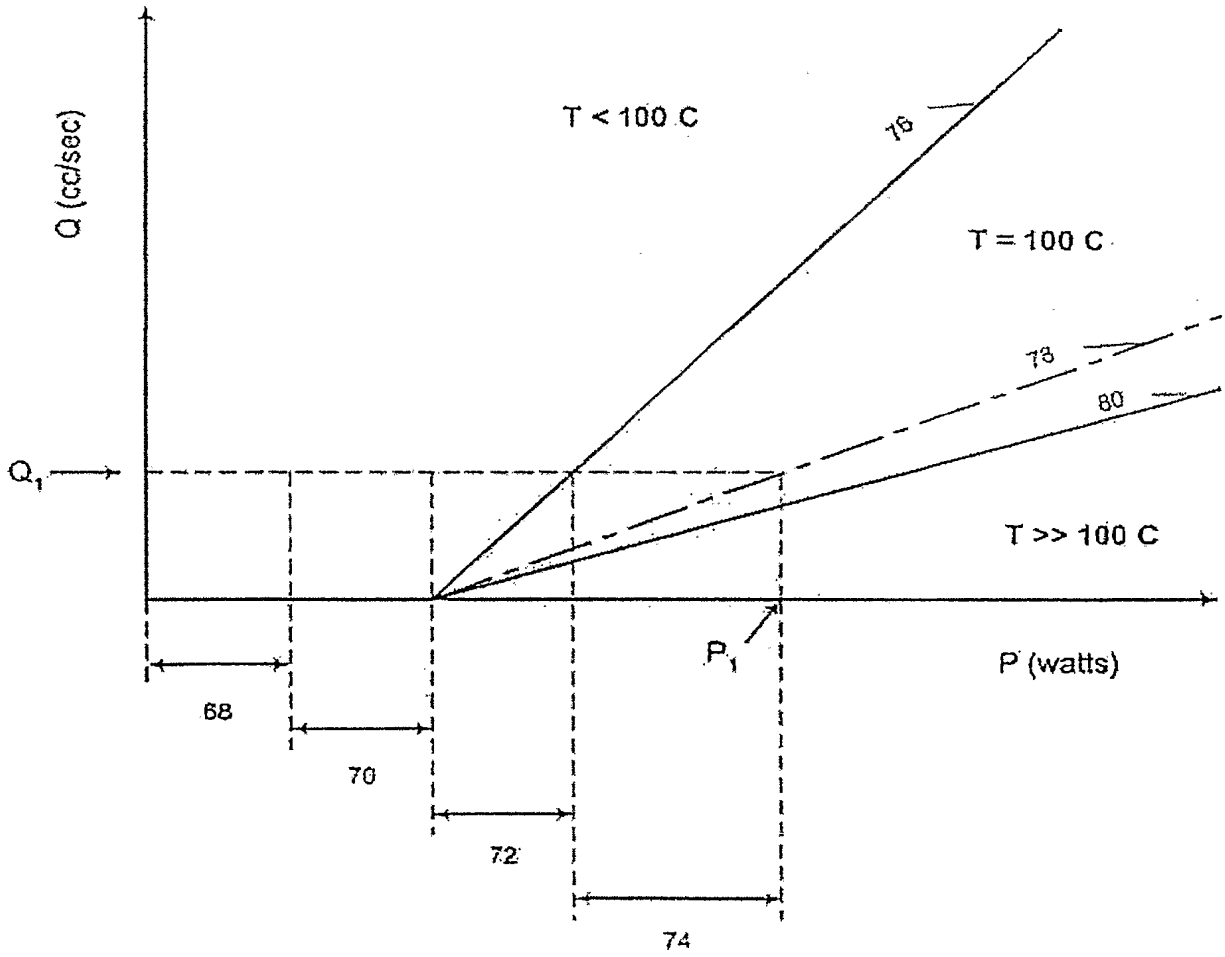


FIG. 5

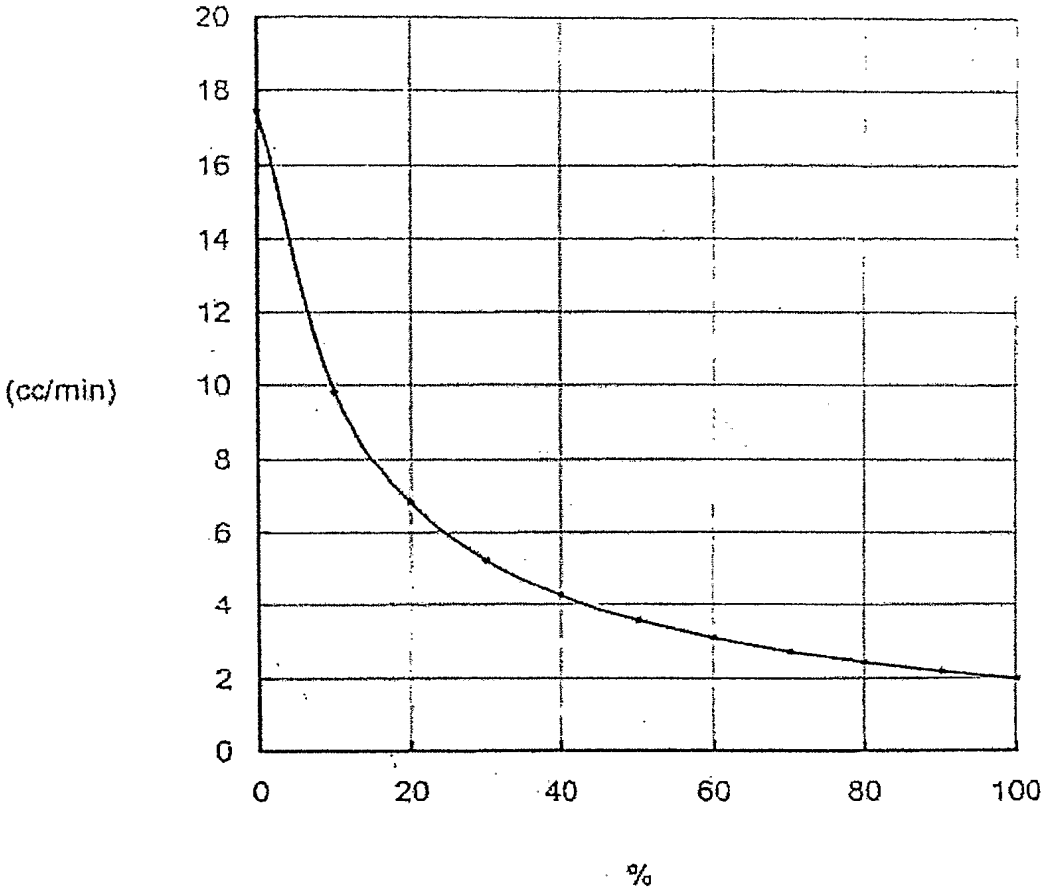


FIG. 6

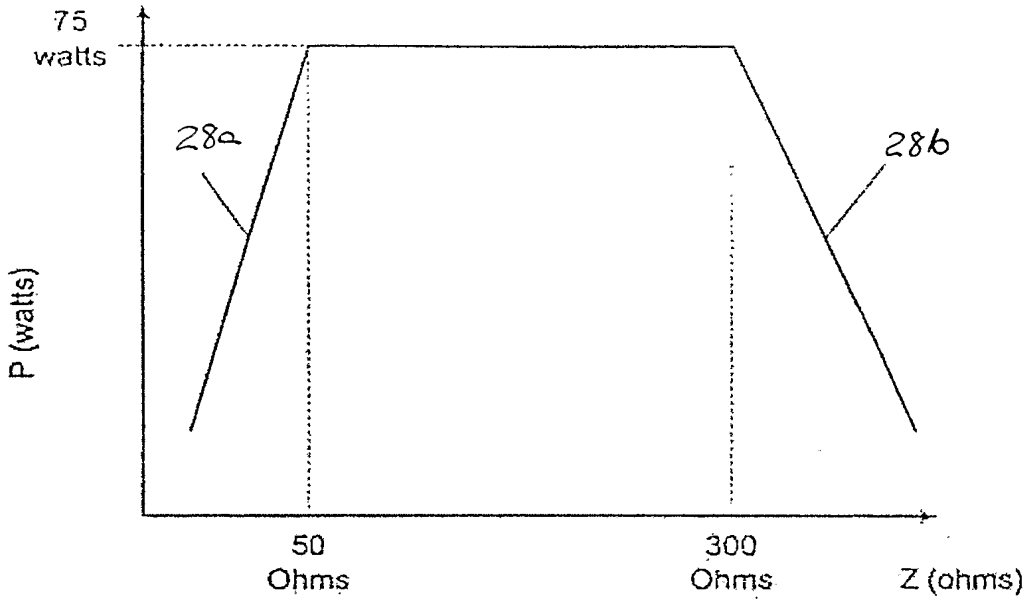
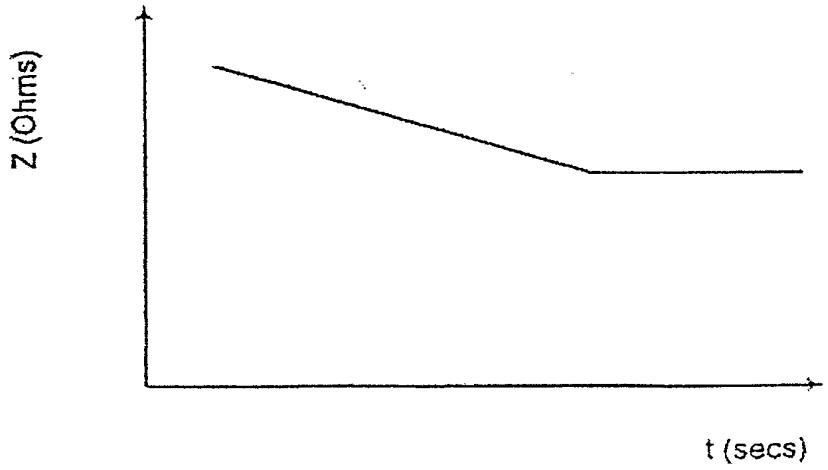


FIG. 7



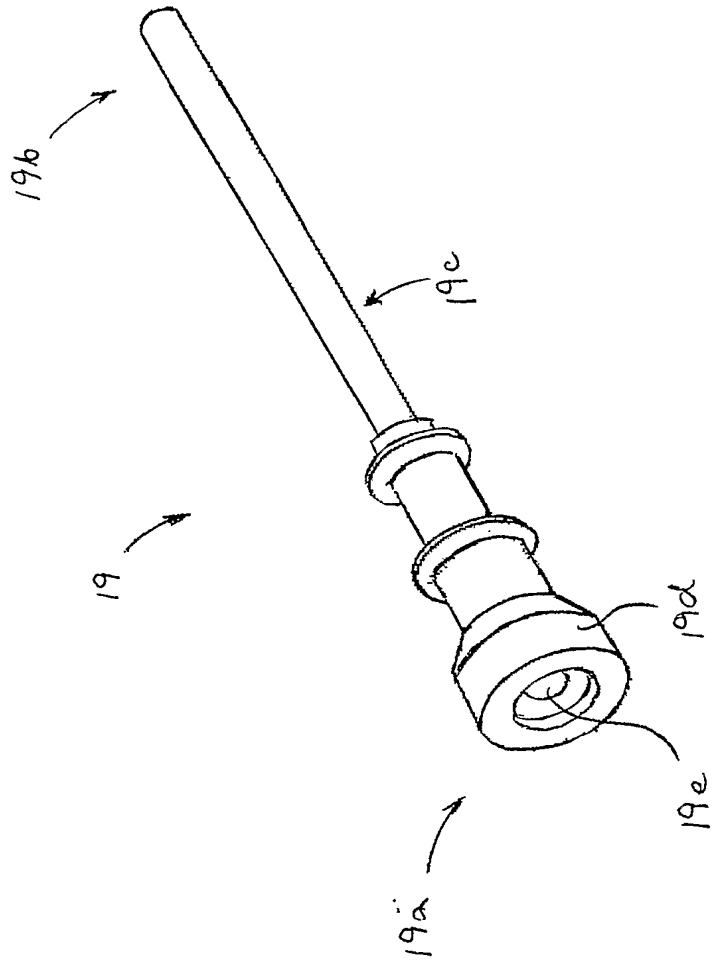


FIG. 8

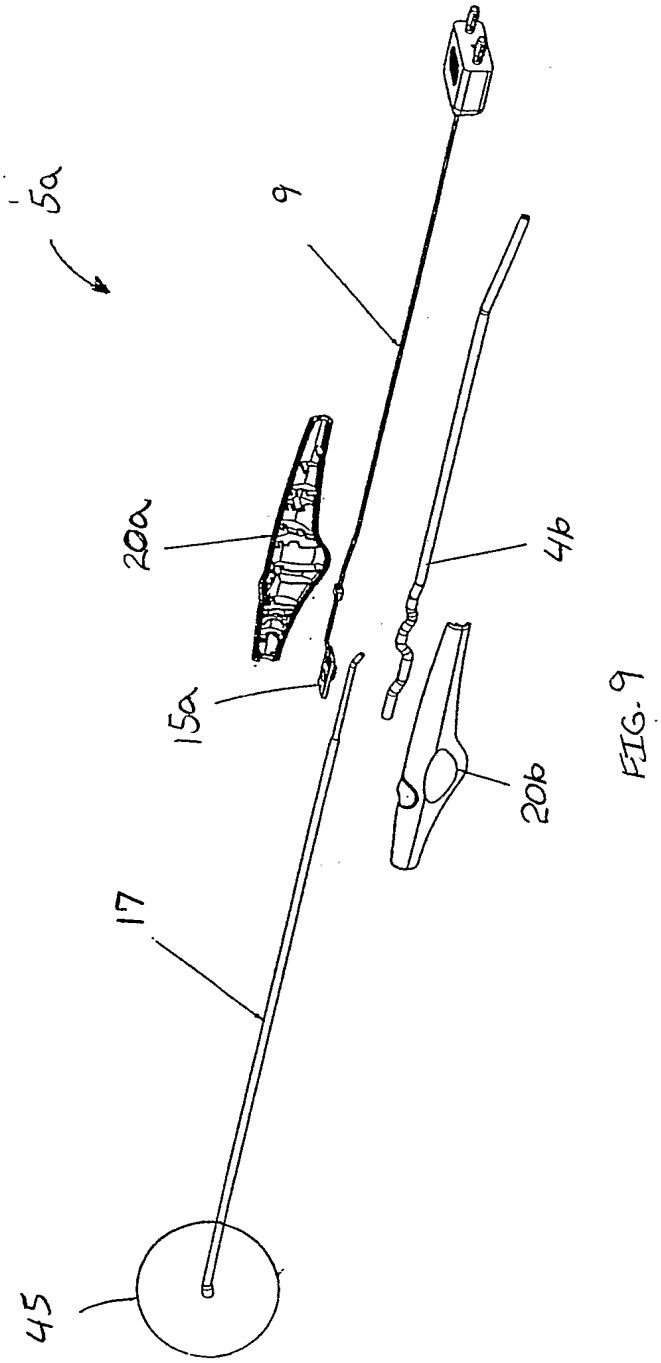


FIG. 9

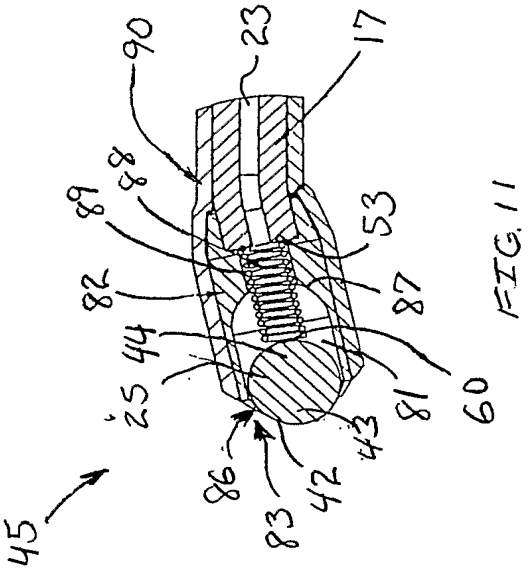


FIG. 11

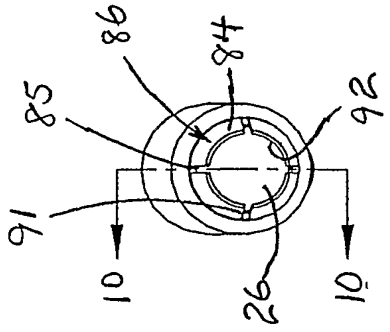


FIG. 12

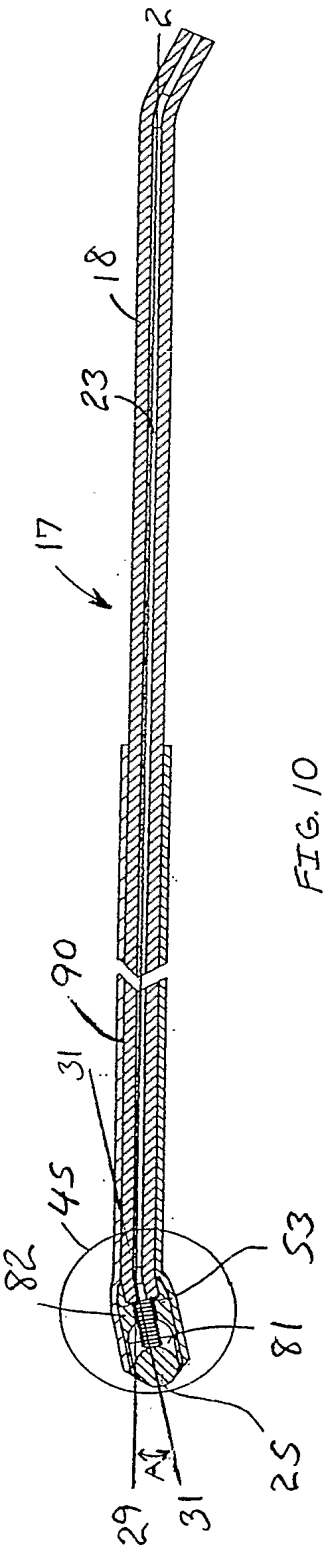


FIG. 10

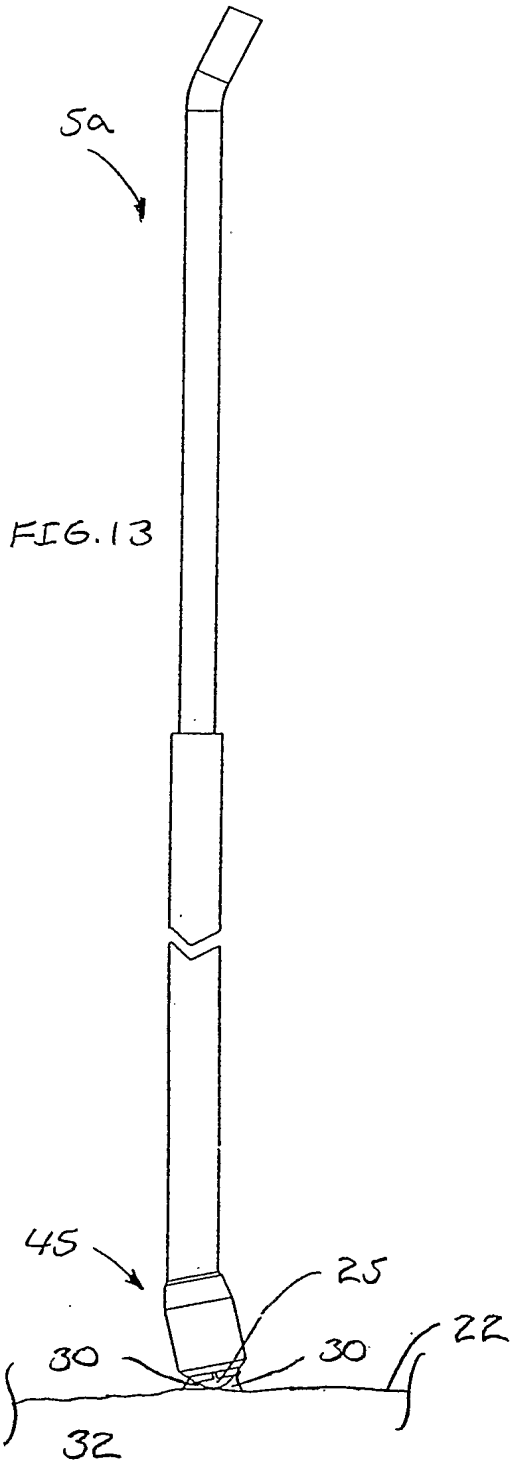


FIG. 13

FIG. 15

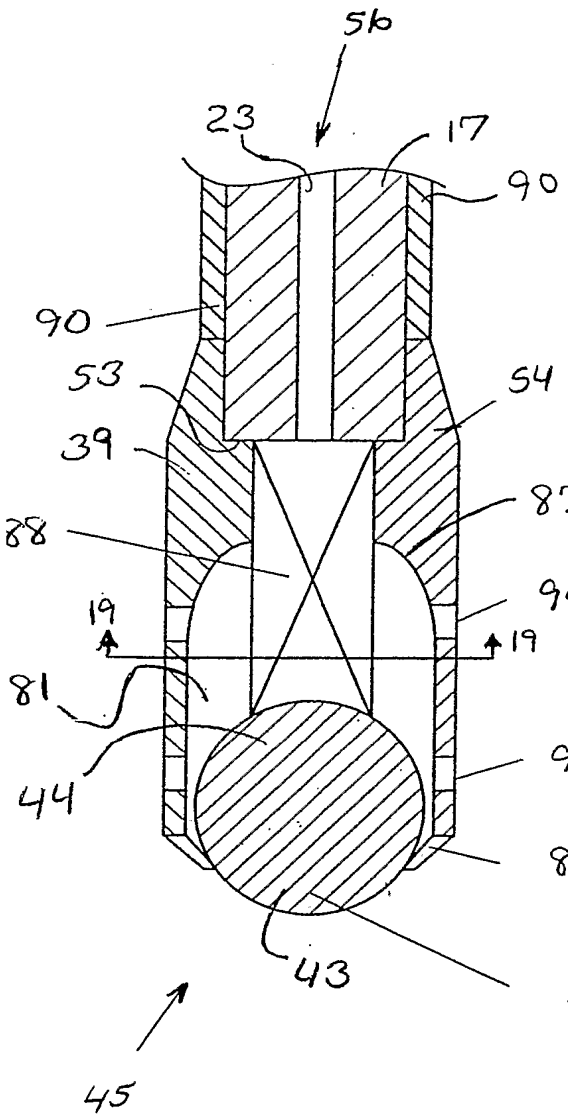

56
23
17
90
90
53
54
39
87
88
19
19
94
81
44
93
84
43
25
45

FIG. 14

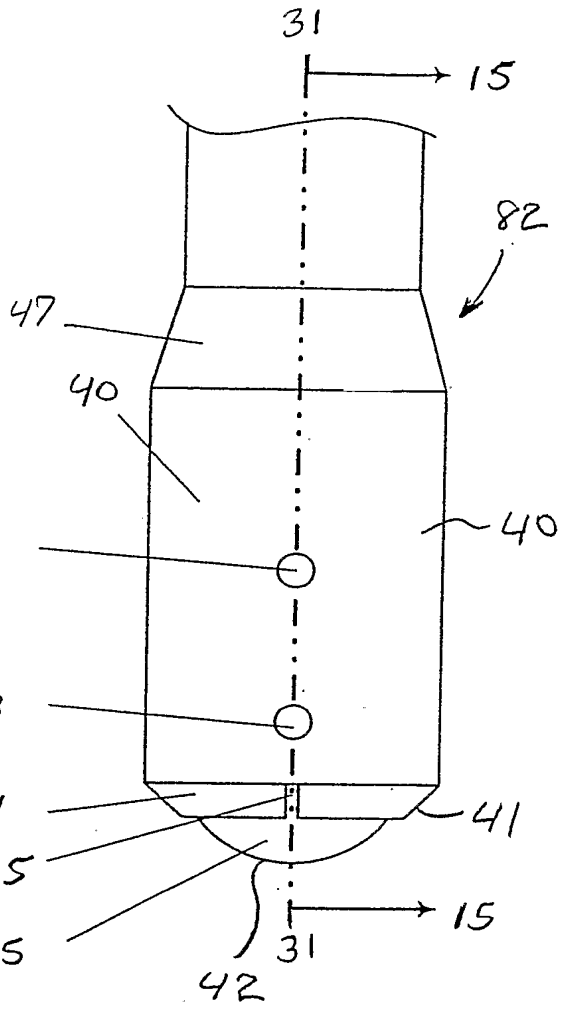

31
15
82
47
40
40
94
93
41
84
85
15
31
42

FIG. 16

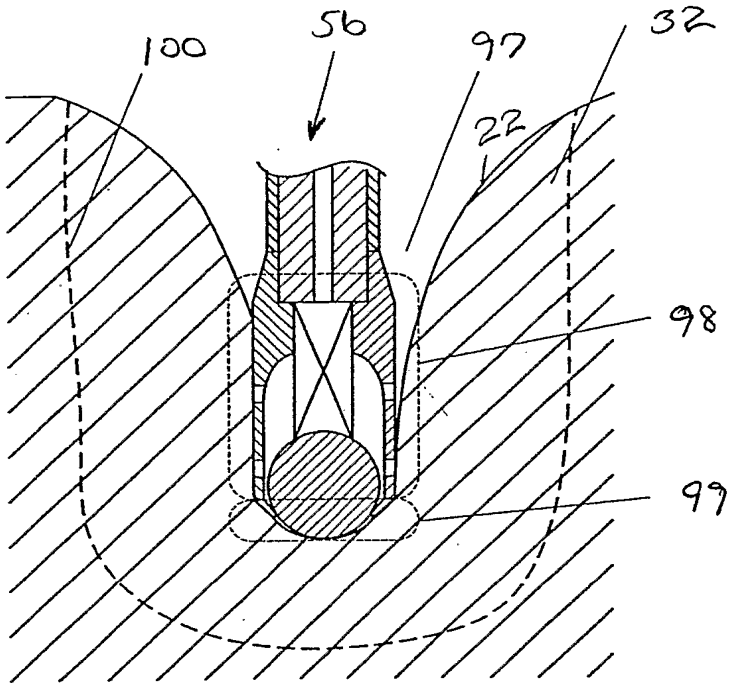


FIG. 17

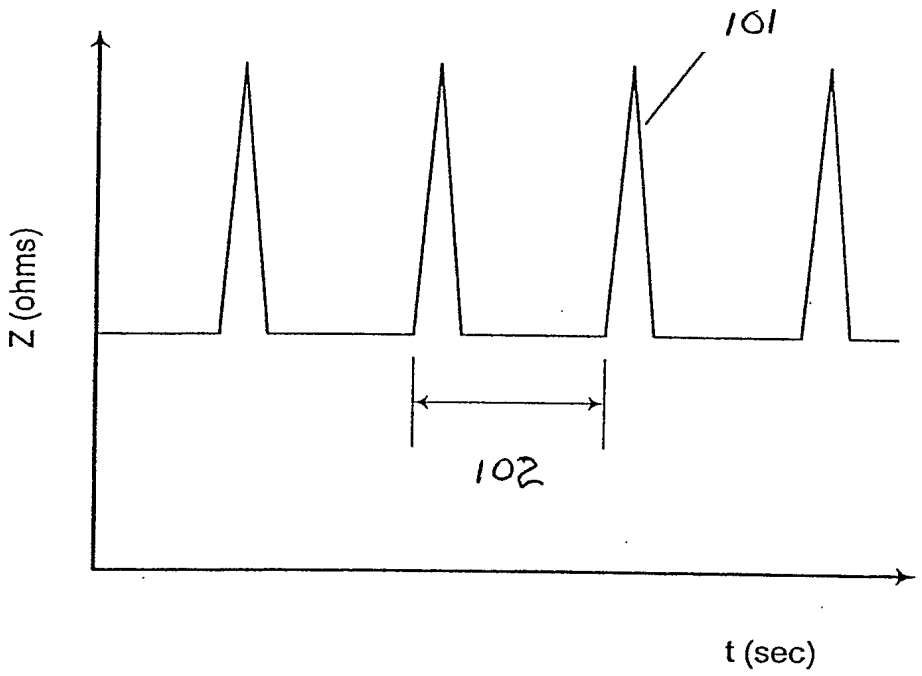
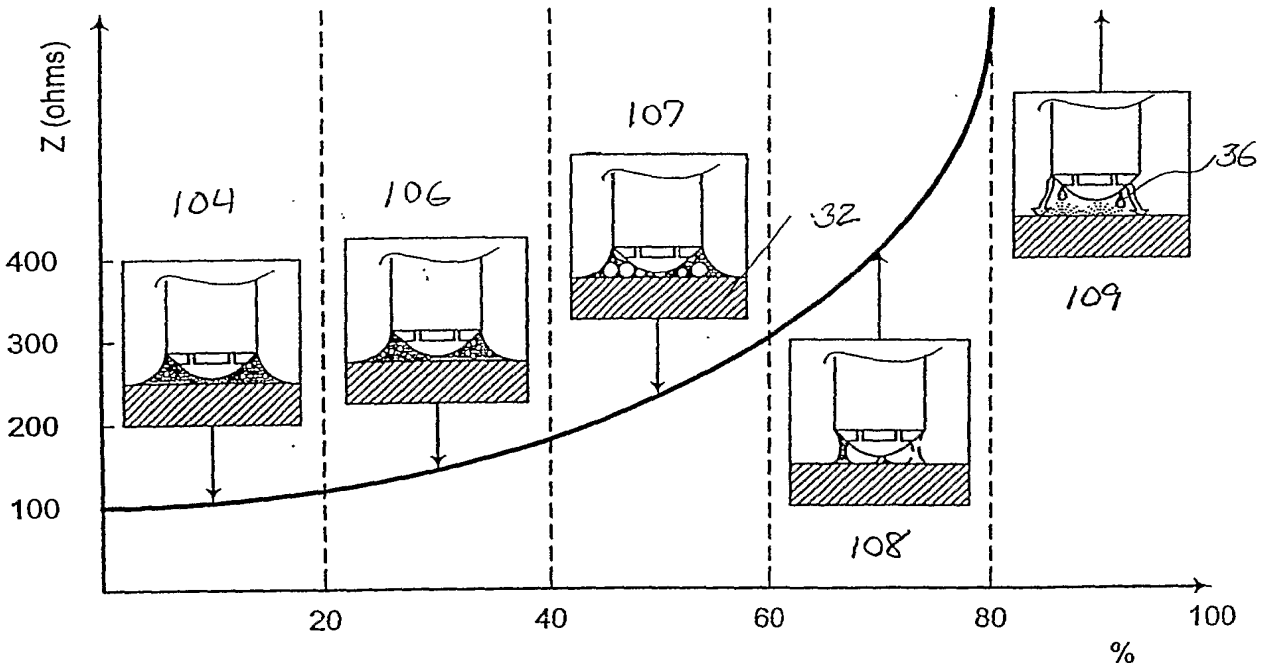


FIG.18



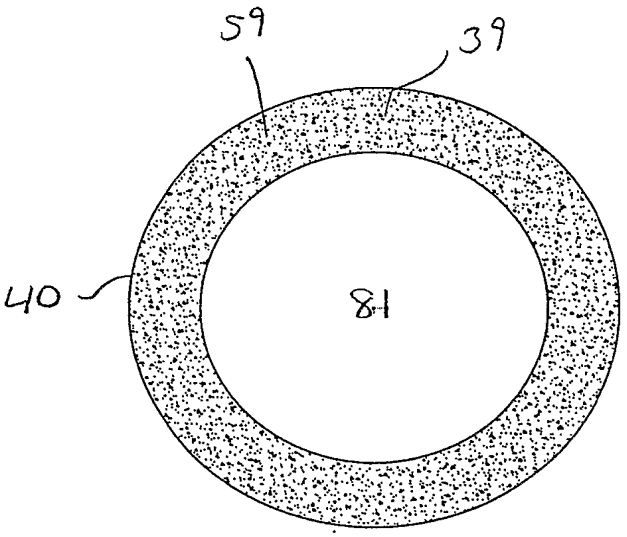


FIG. 19

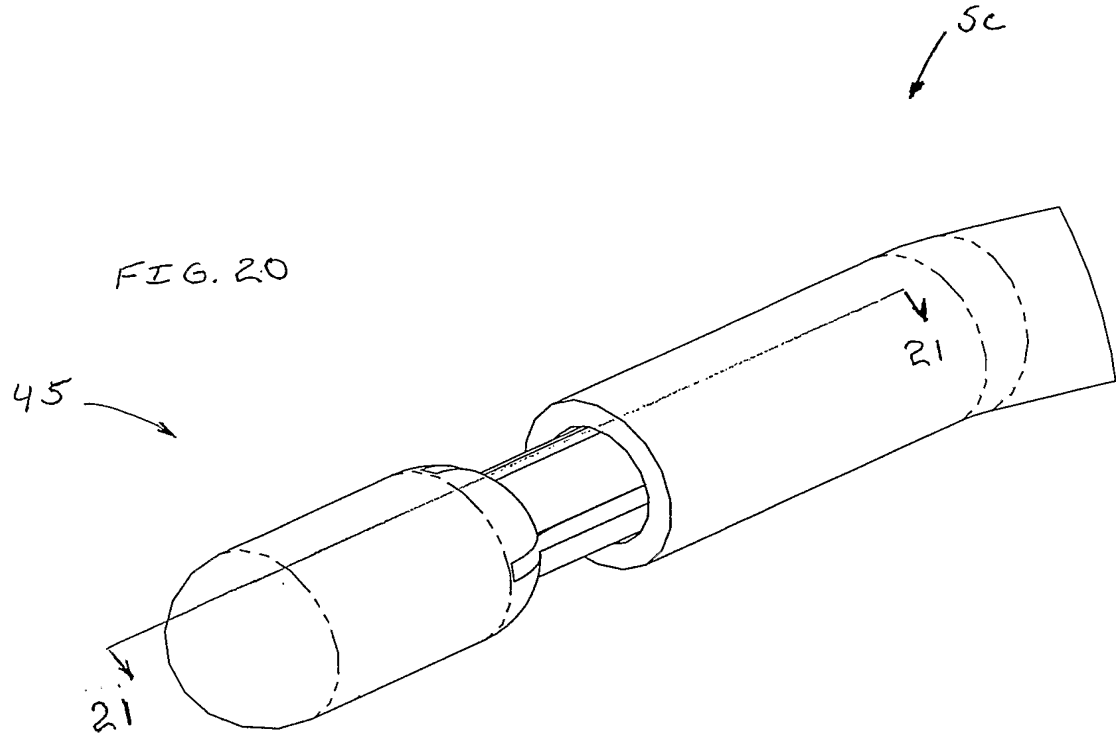

5c
45
21
21

FIG. 20

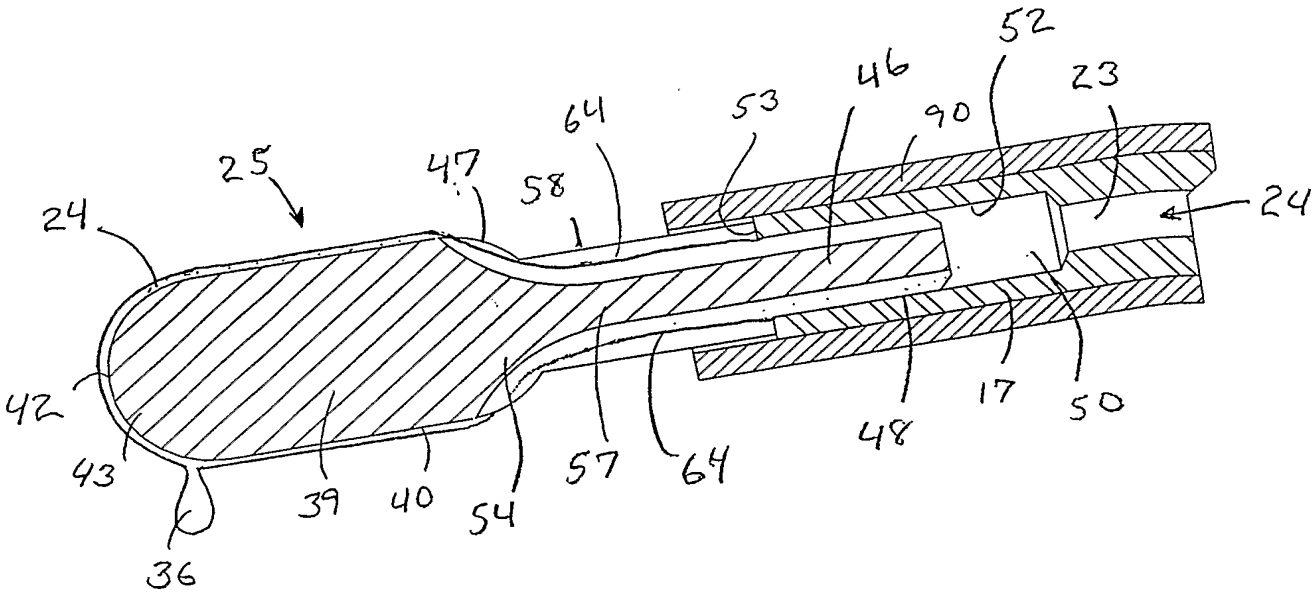

52
46
23
64
53
90
25
47
58
24
24
42
43
39
40
54
57
64
48
17
50
36

FIG. 21

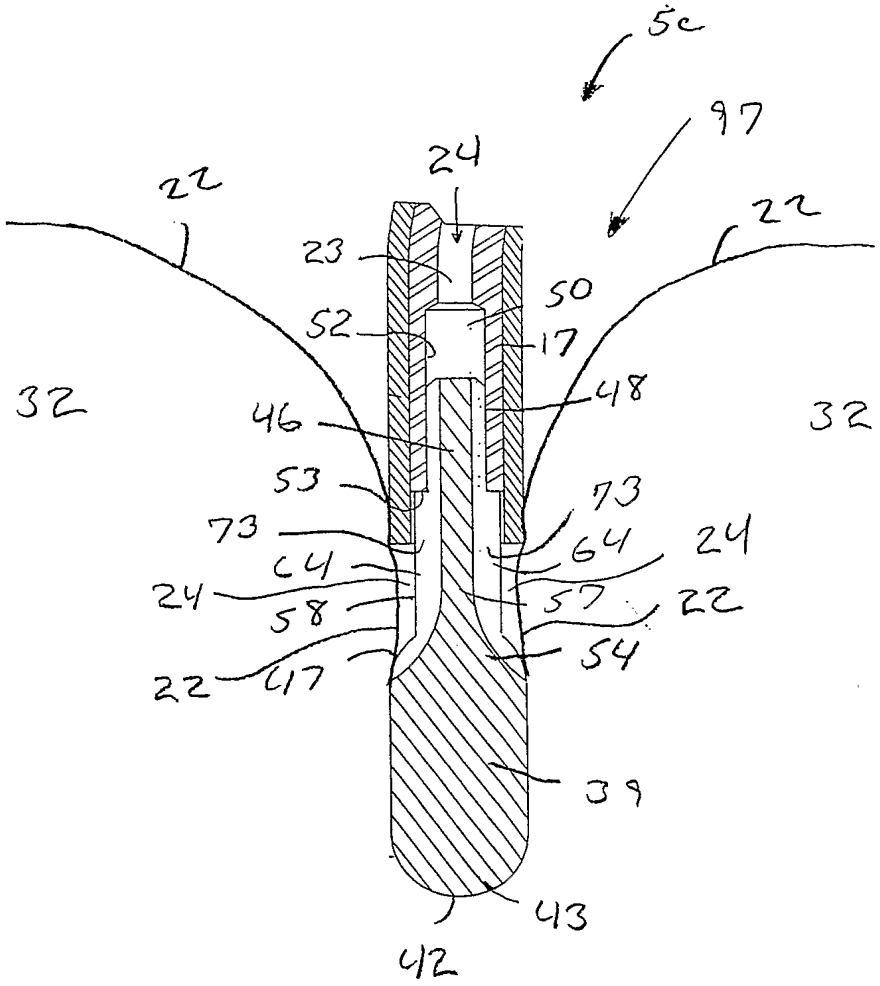
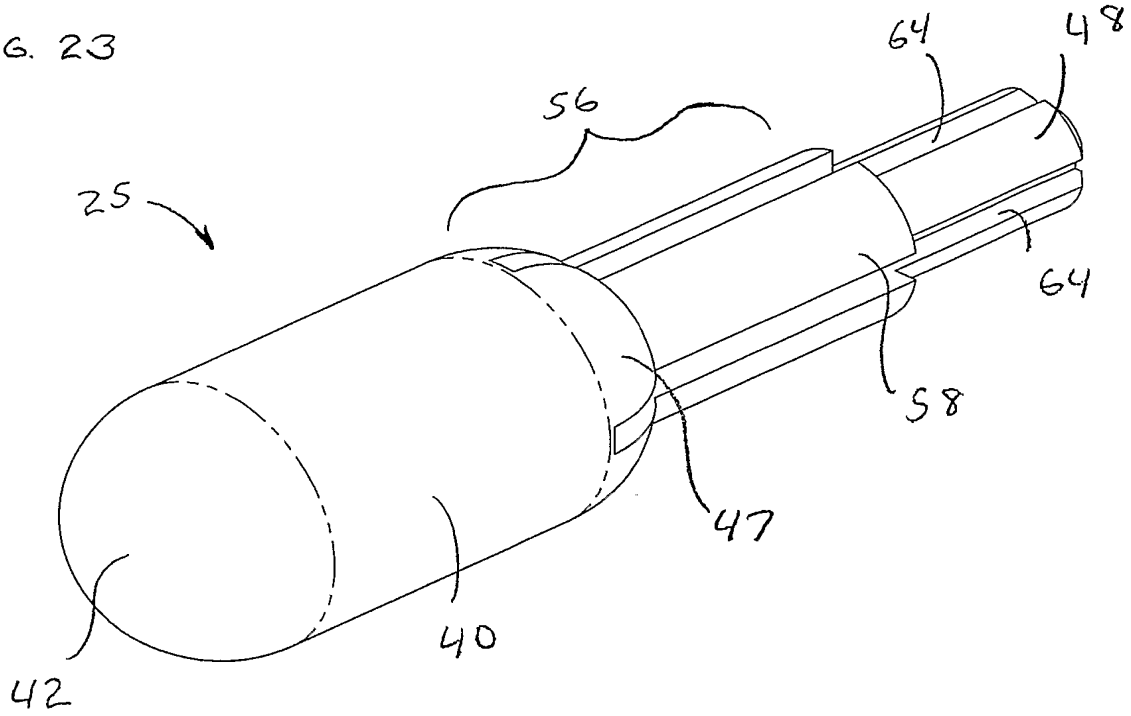

5c
97
24
22
22
23
50
52
17
32
48
32
46
53
73
73
64
24
64
24
57
22
58
54
22
47
39
43
42
32

FIG. 22

FIG. 23



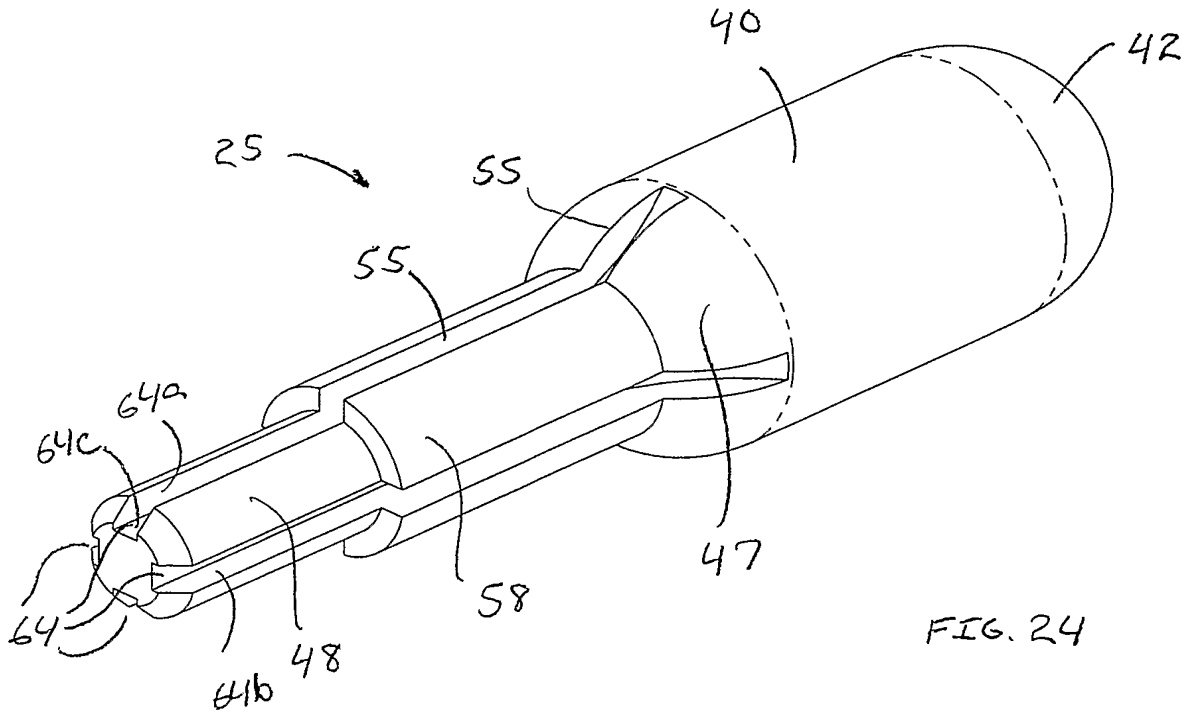


FIG. 24

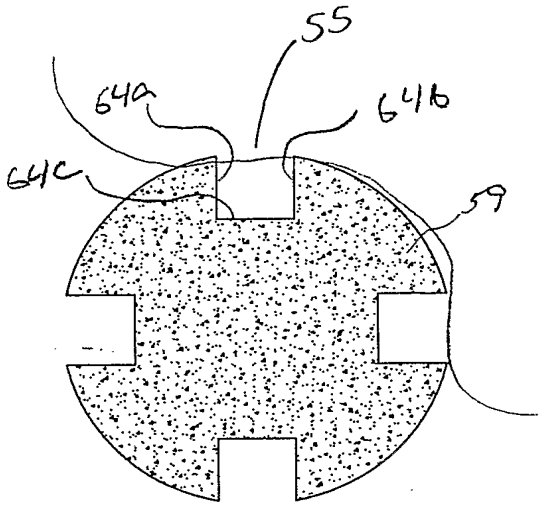


FIG. 25

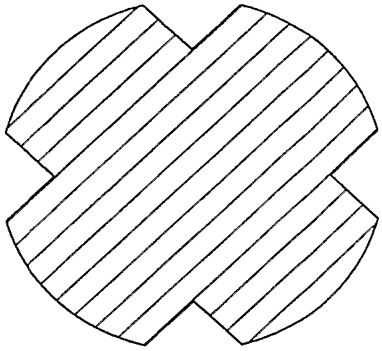


FIG. 27

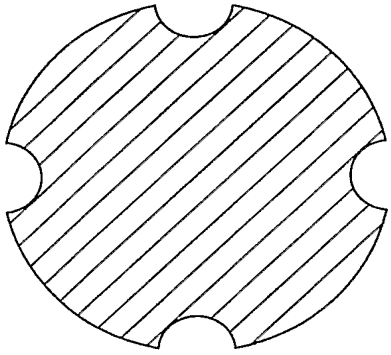


FIG. 26

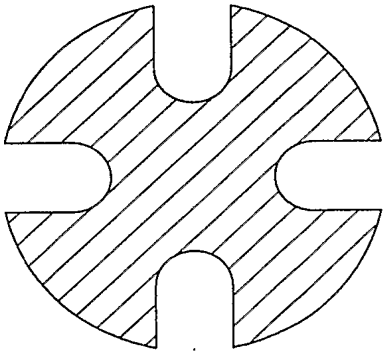
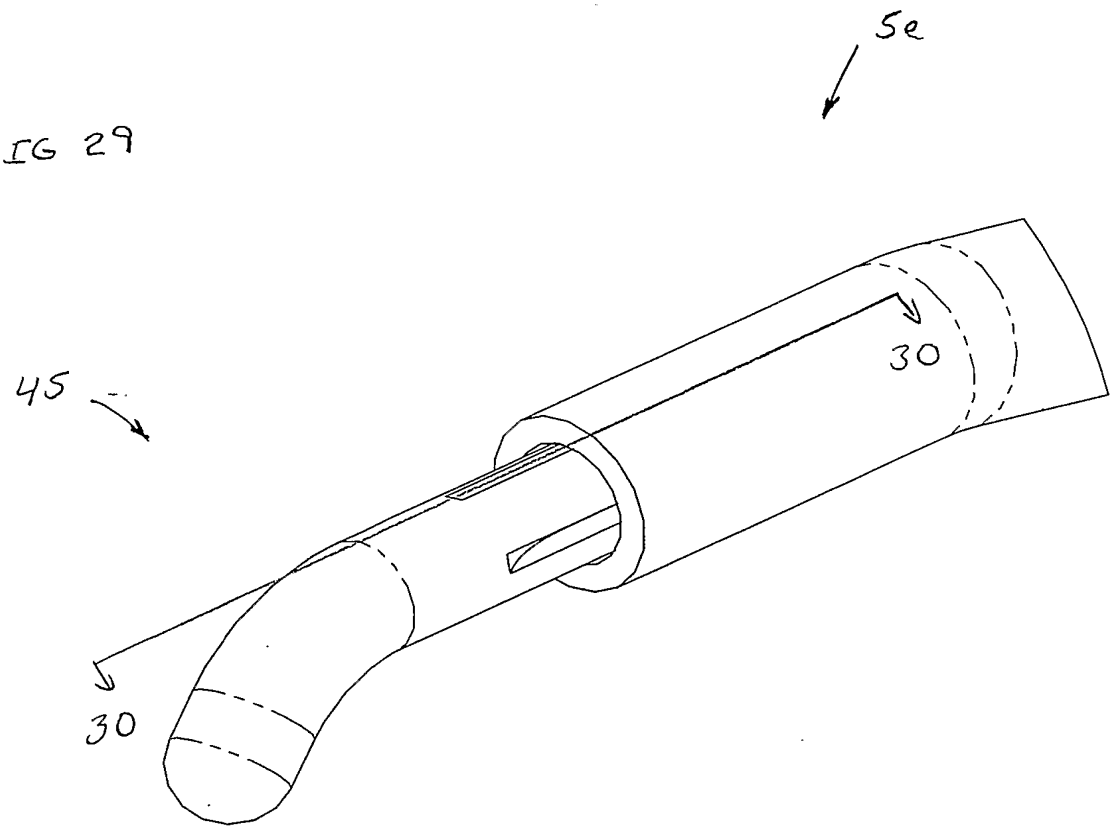


FIG. 28

FIG 29



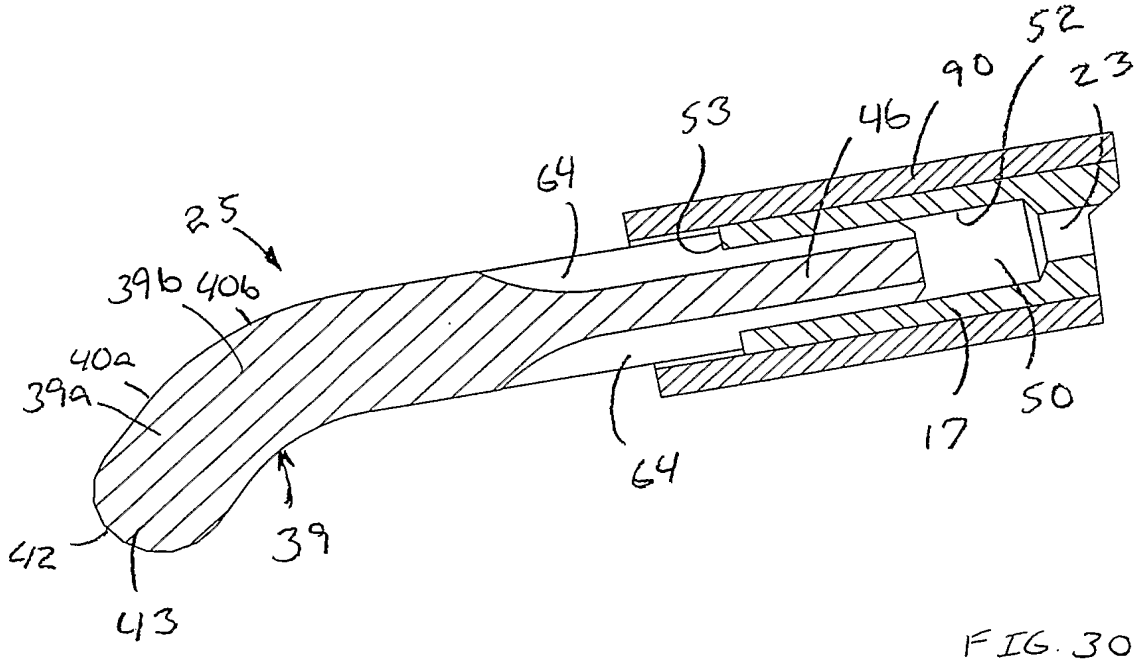
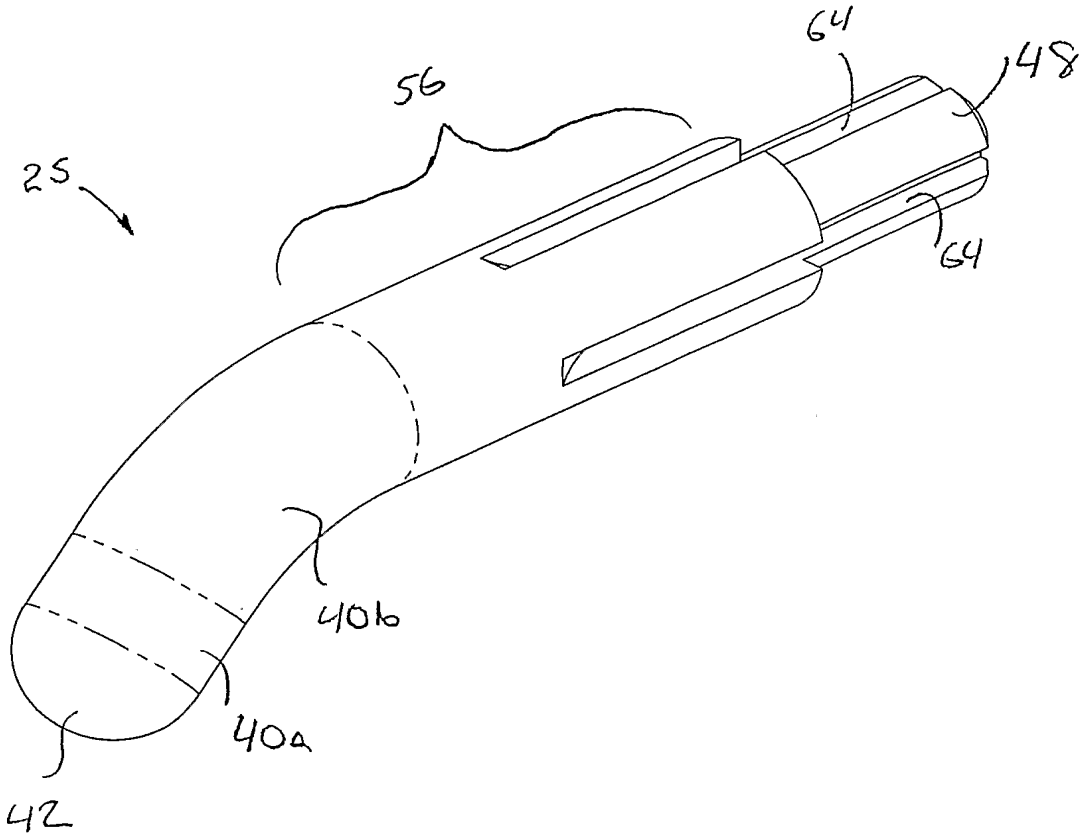


FIG. 30

FIG. 31



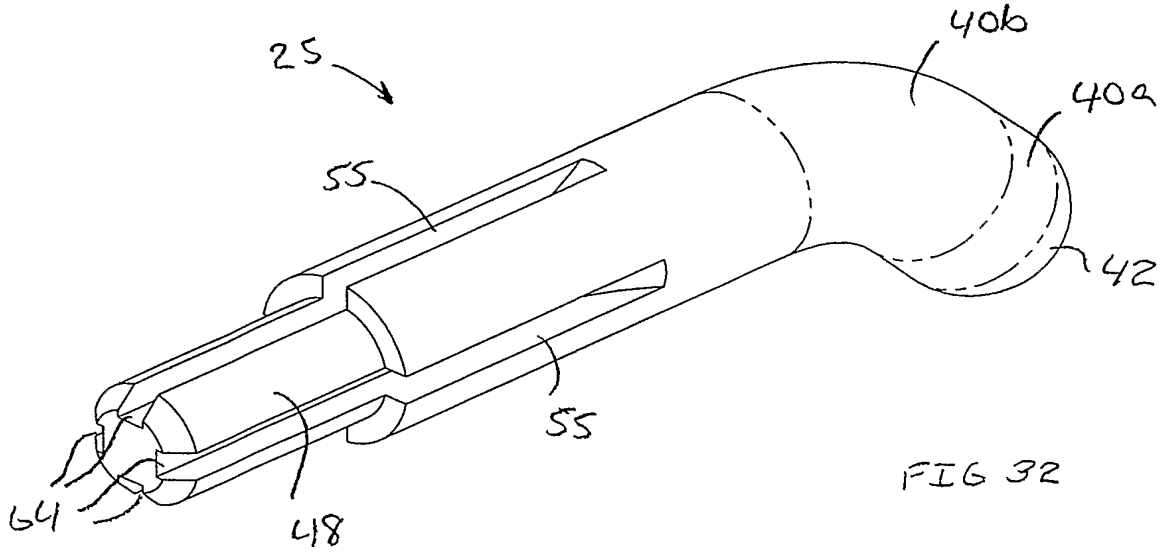


FIG 32

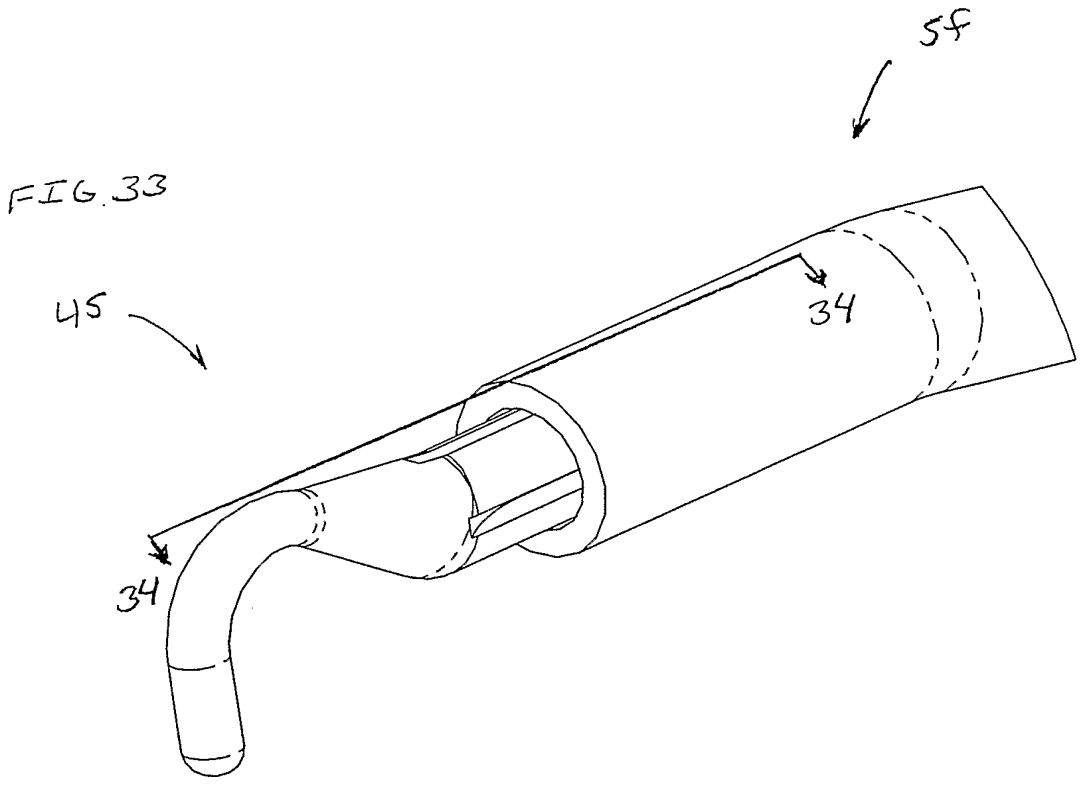

54
45
34
34

FIG. 33

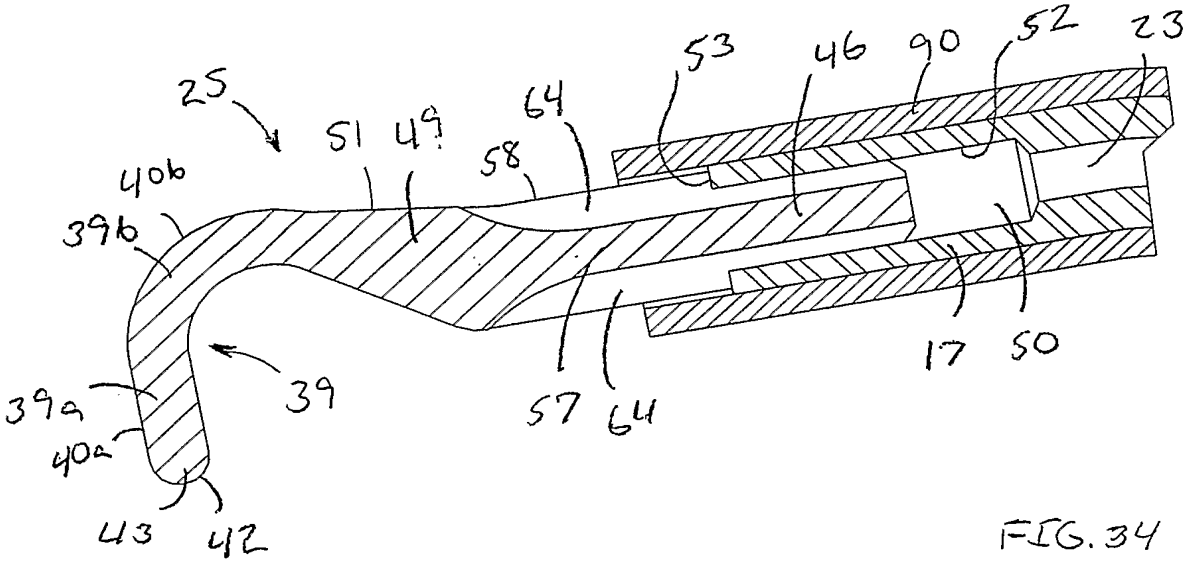
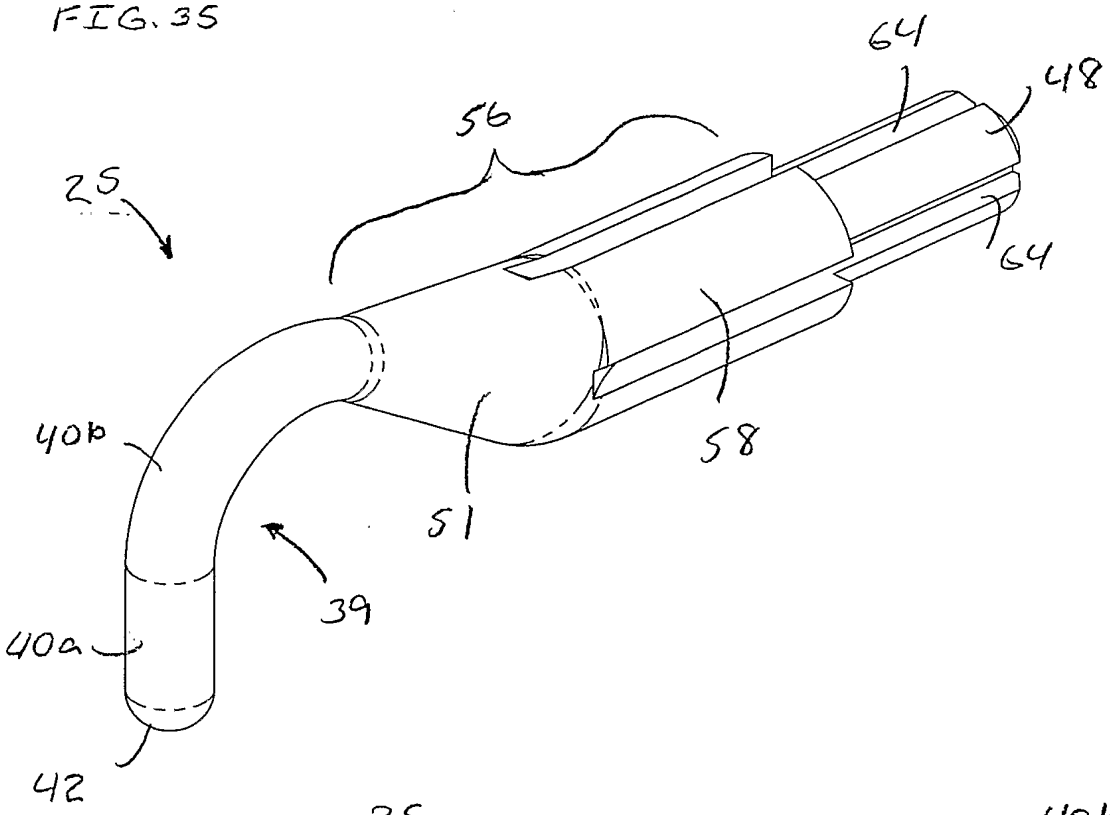

25
51
49
64
58
53
46
90
52
23
40b
39b
39
39a
40a
43
42
57
64
17
50

FIG. 34

FIG. 35



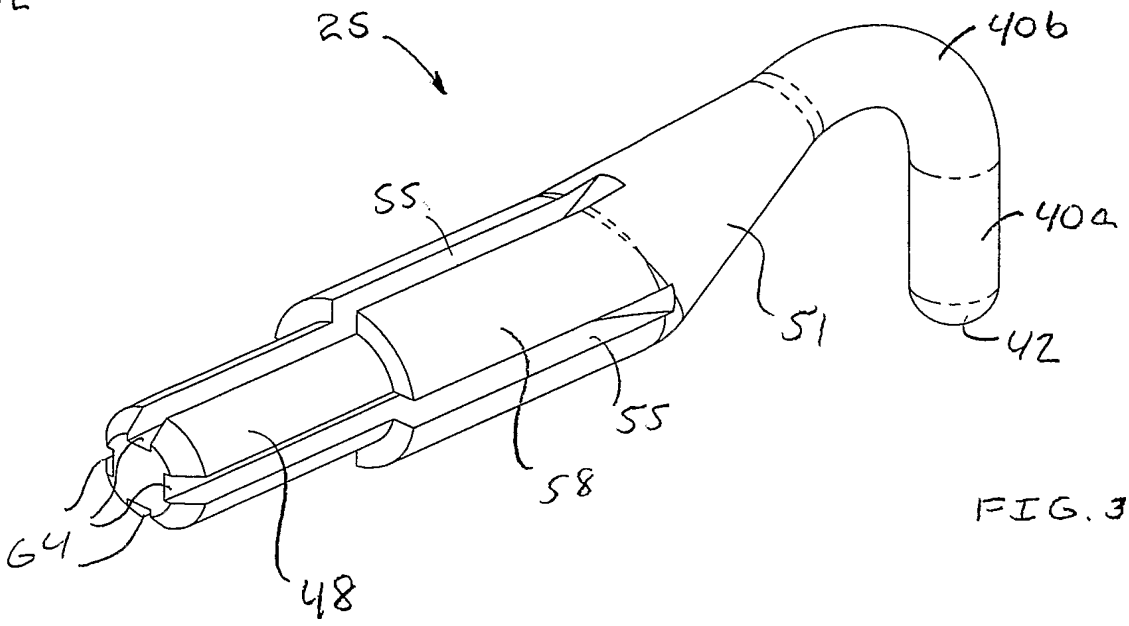


FIG. 36

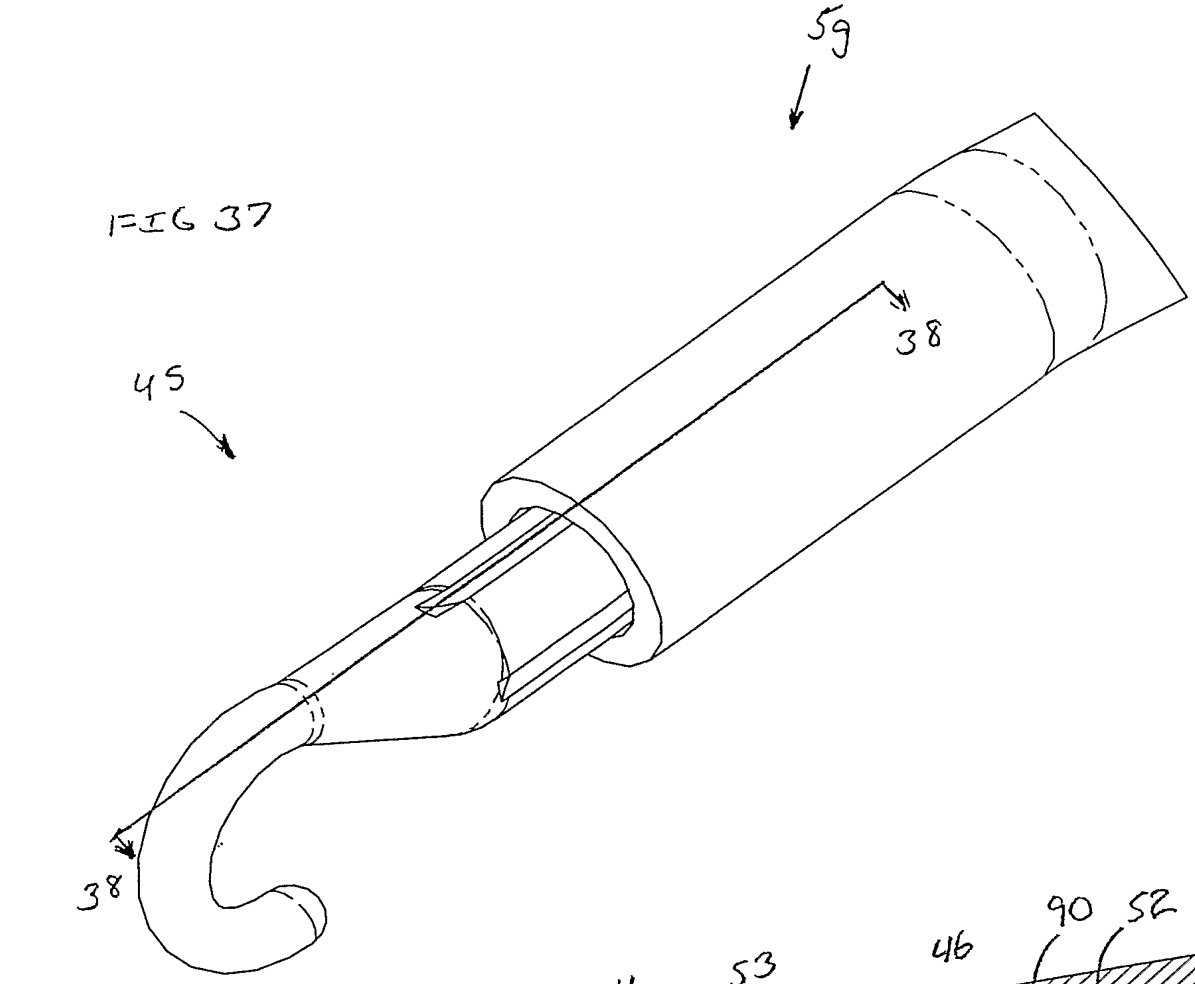


FIG 37

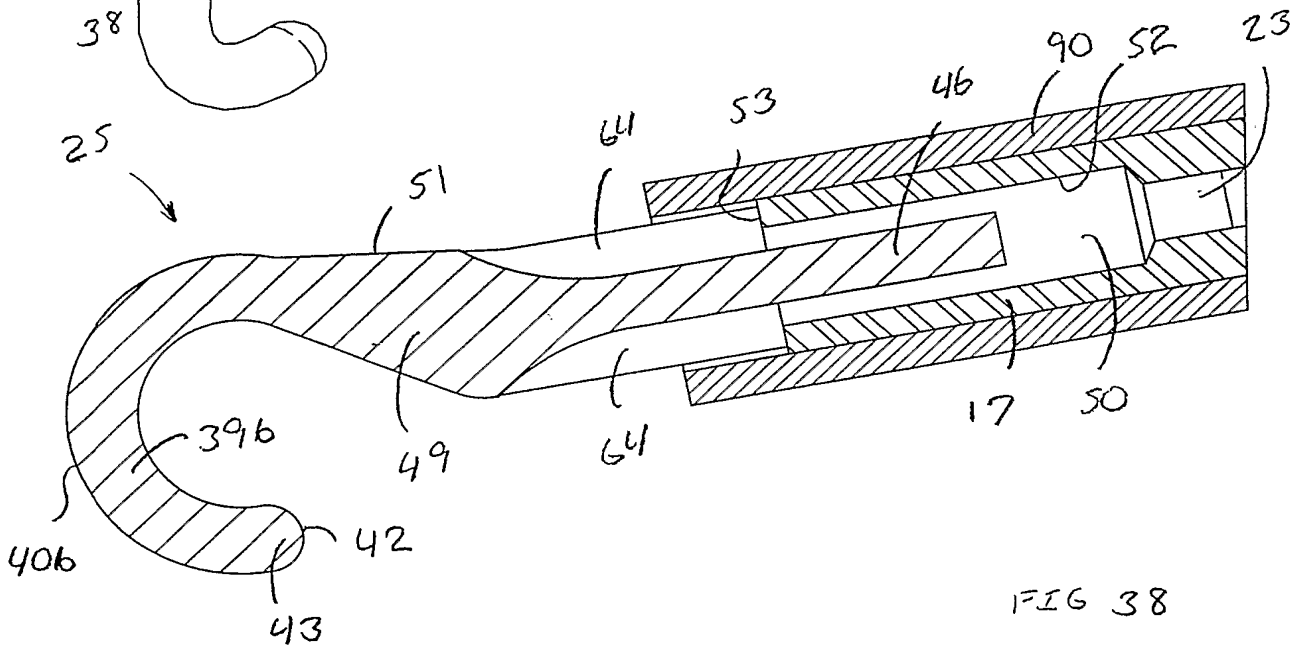
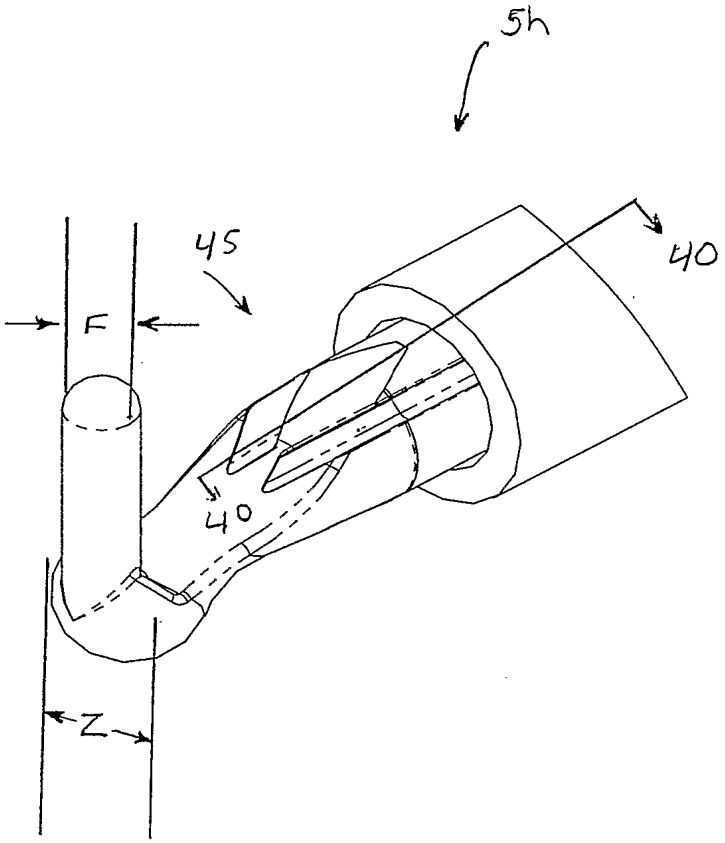


FIG 38

FIG. 39


5h
45
40
F
40
Z

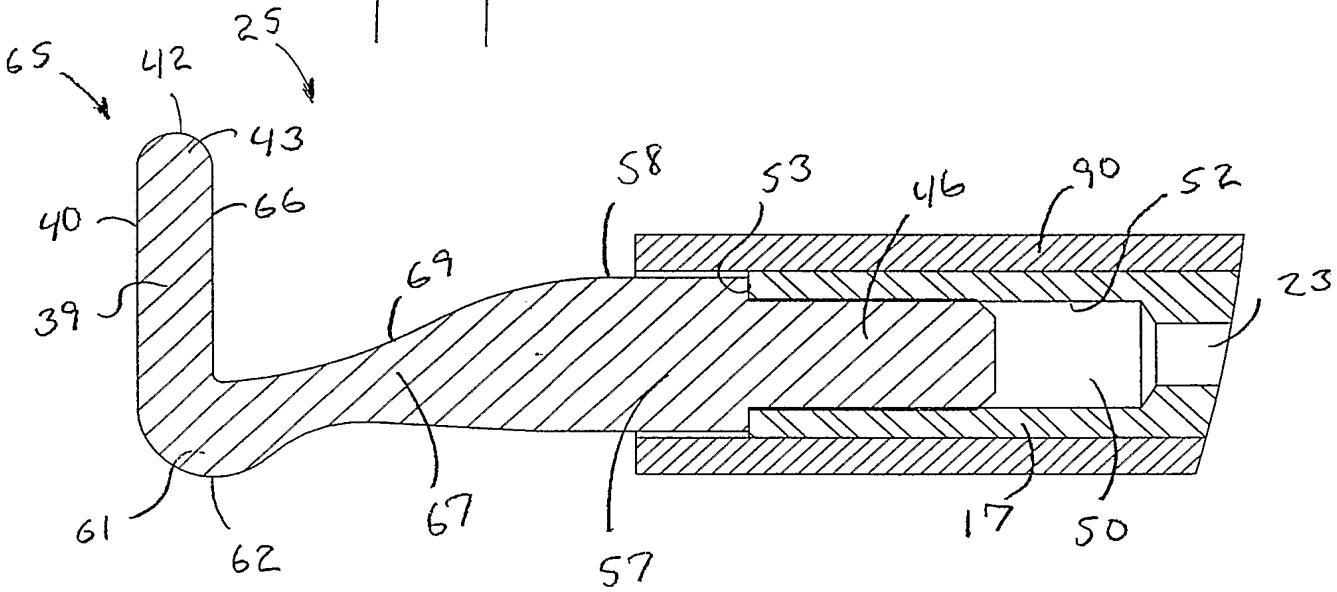
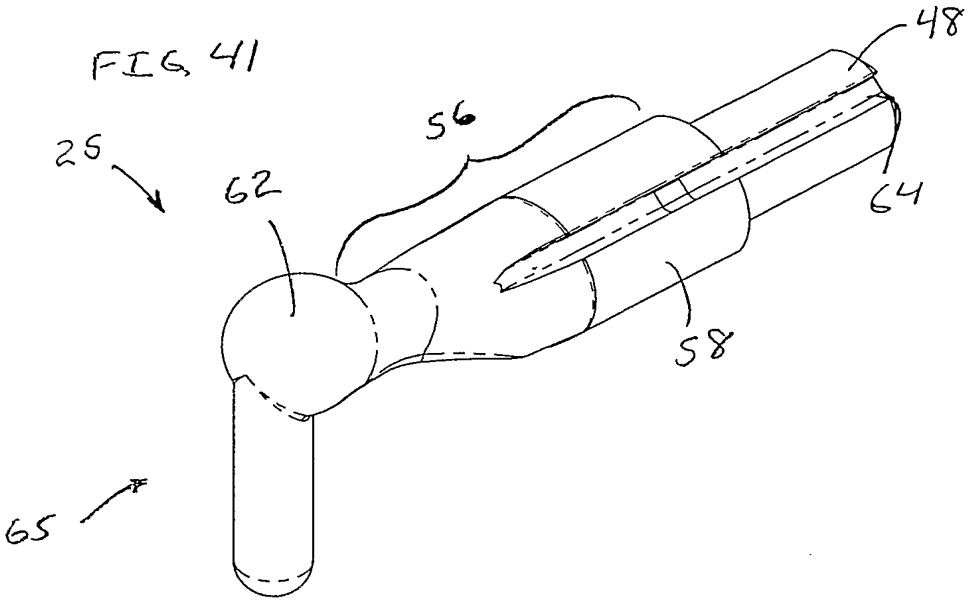

65
42
25
43
40
66
39
69
58
53
46
90
52
23
61
62
67
57
17
50

FIG 40

FIG. 41



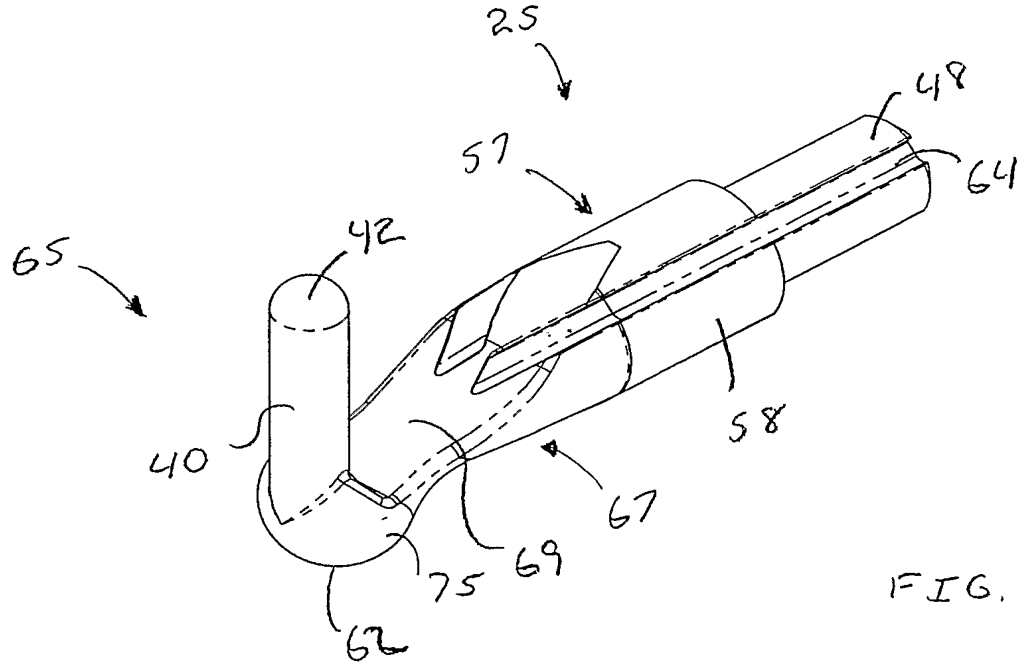


FIG. 42

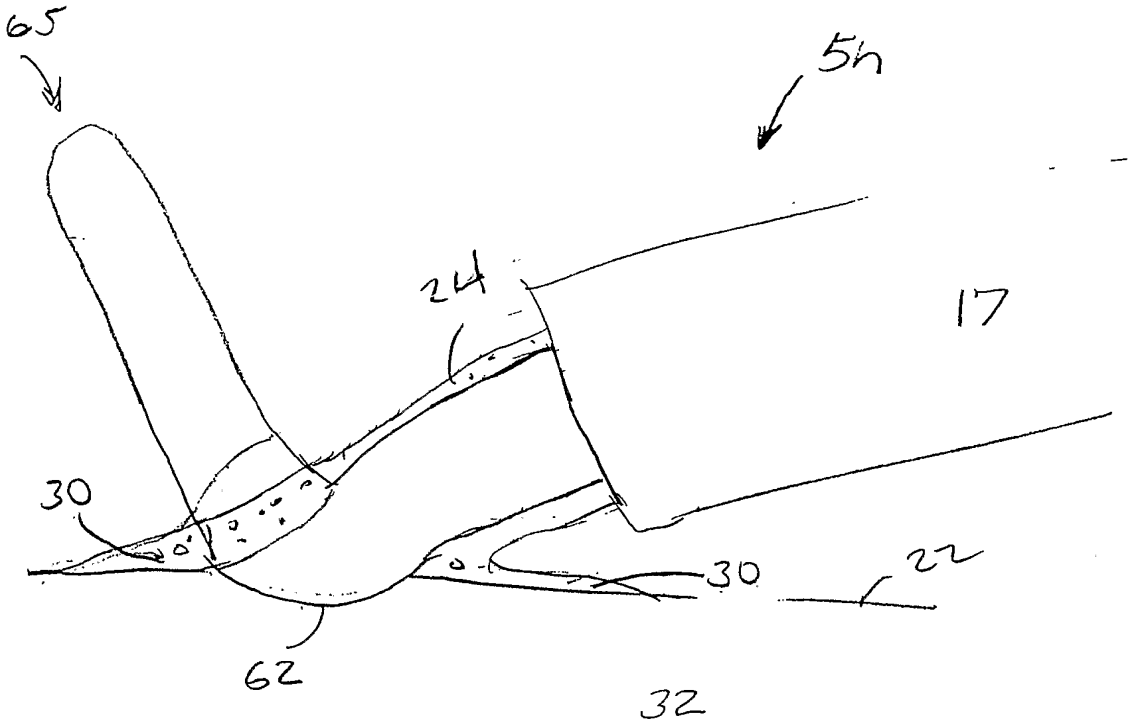


FIG. 43

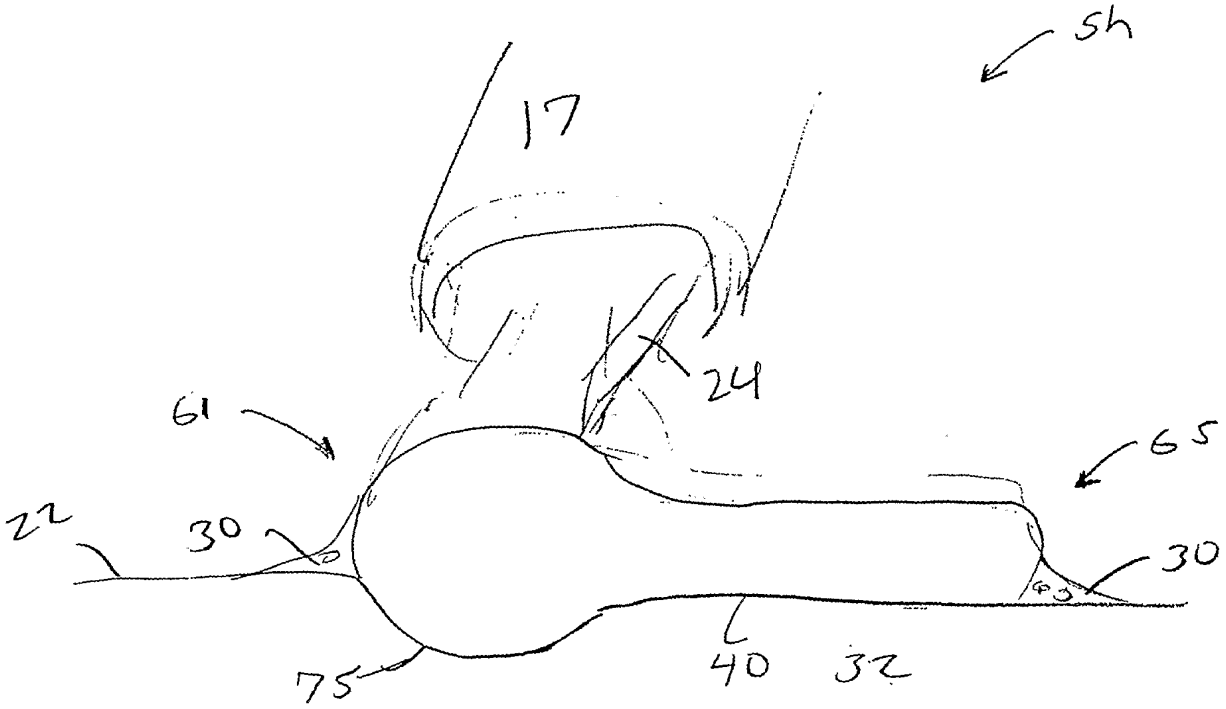


FIG. 44

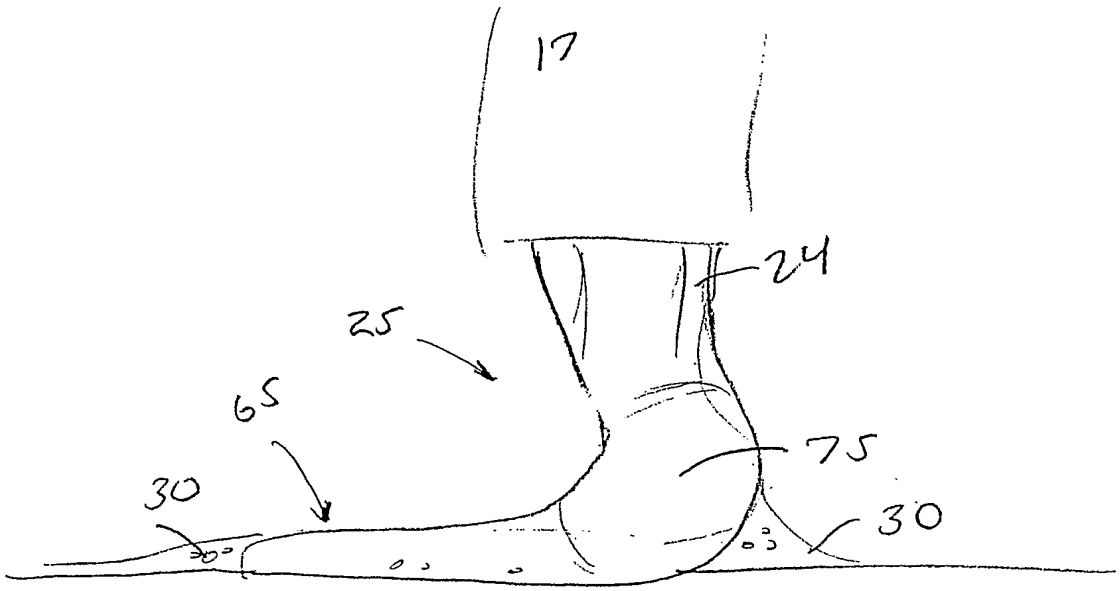


FIG. 45

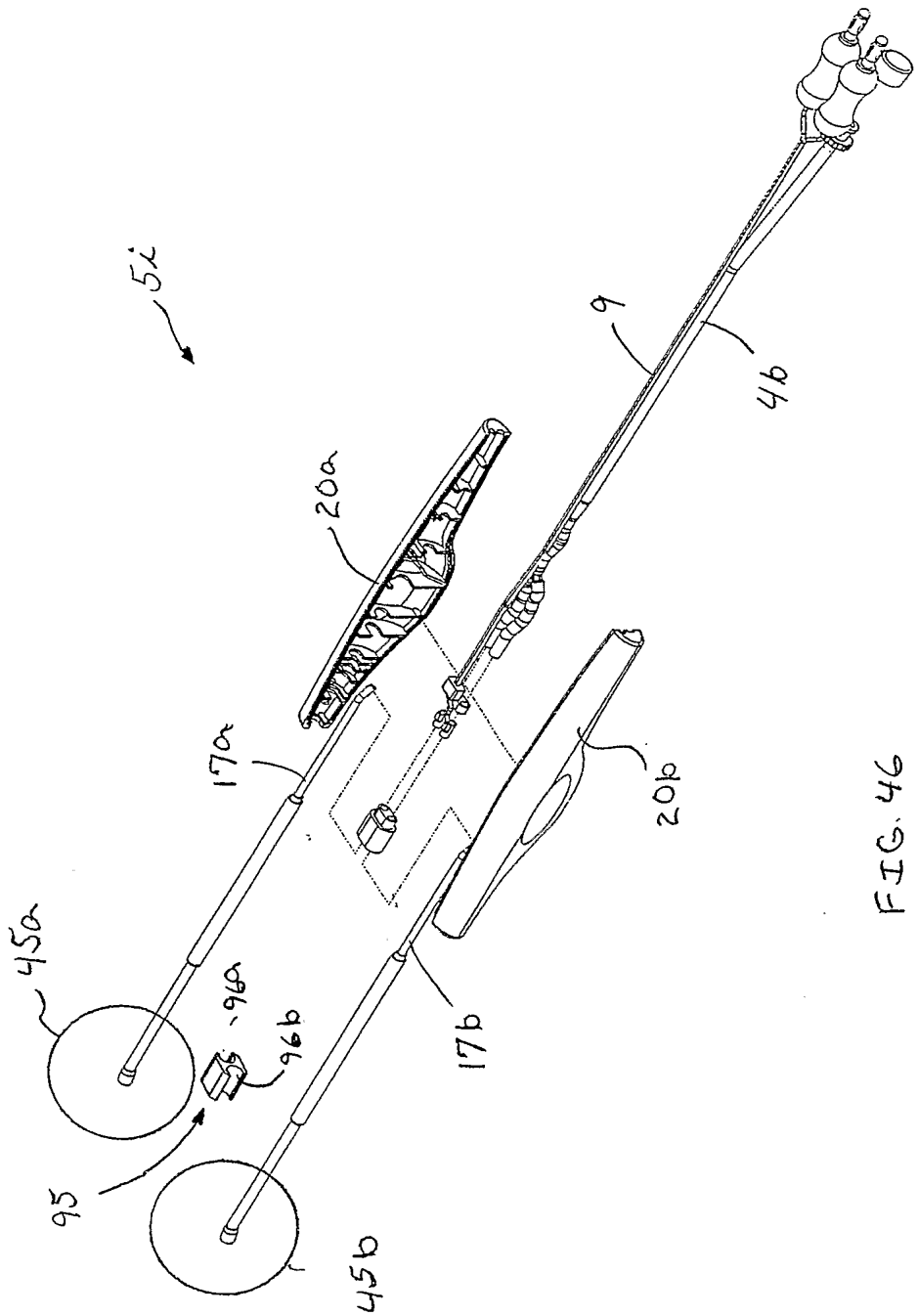


FIG. 46

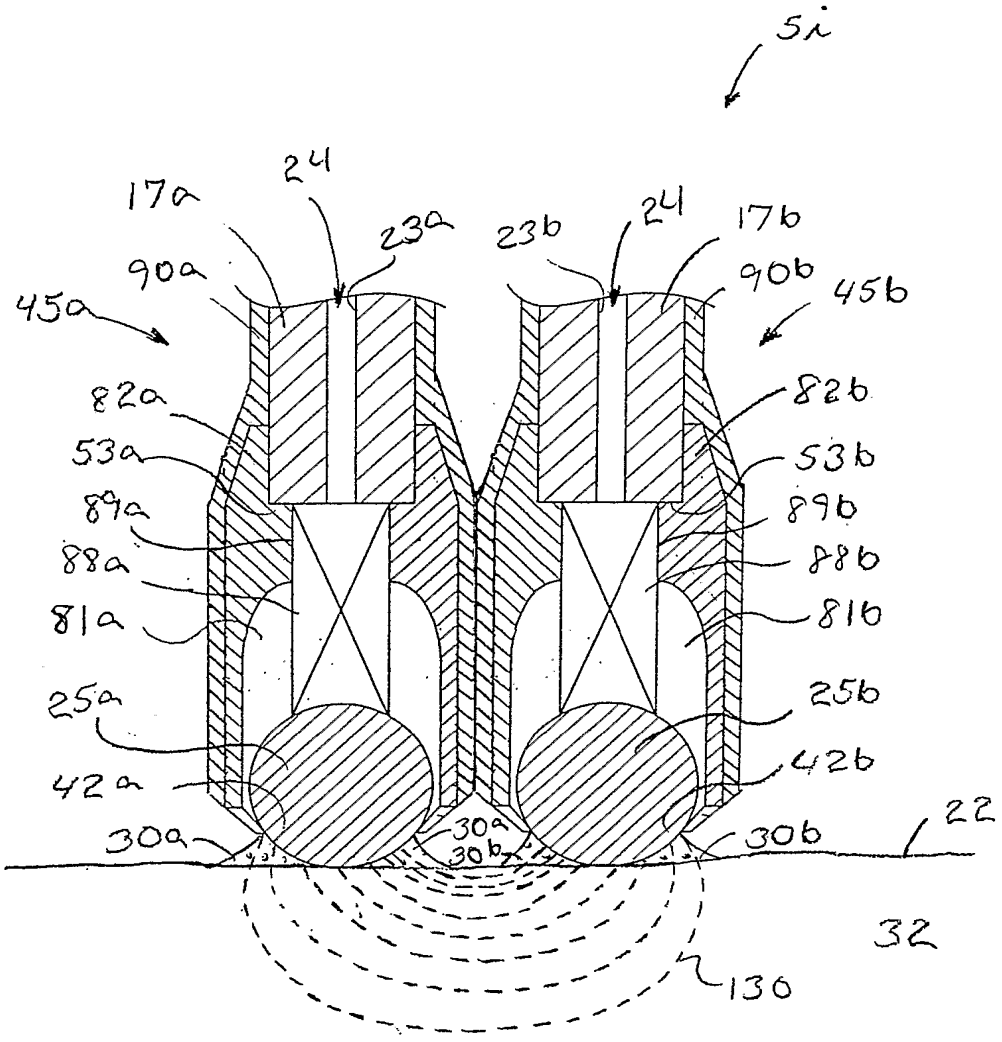

5i
17a
24
23a
23b
24
17b
90a
90b
45a
45b
82a
82b
53a
53b
89a
89b
88a
88b
81a
81b
25a
25b
42a
42b
30a
30a
30b
30b
22
32
130

FIG. 47

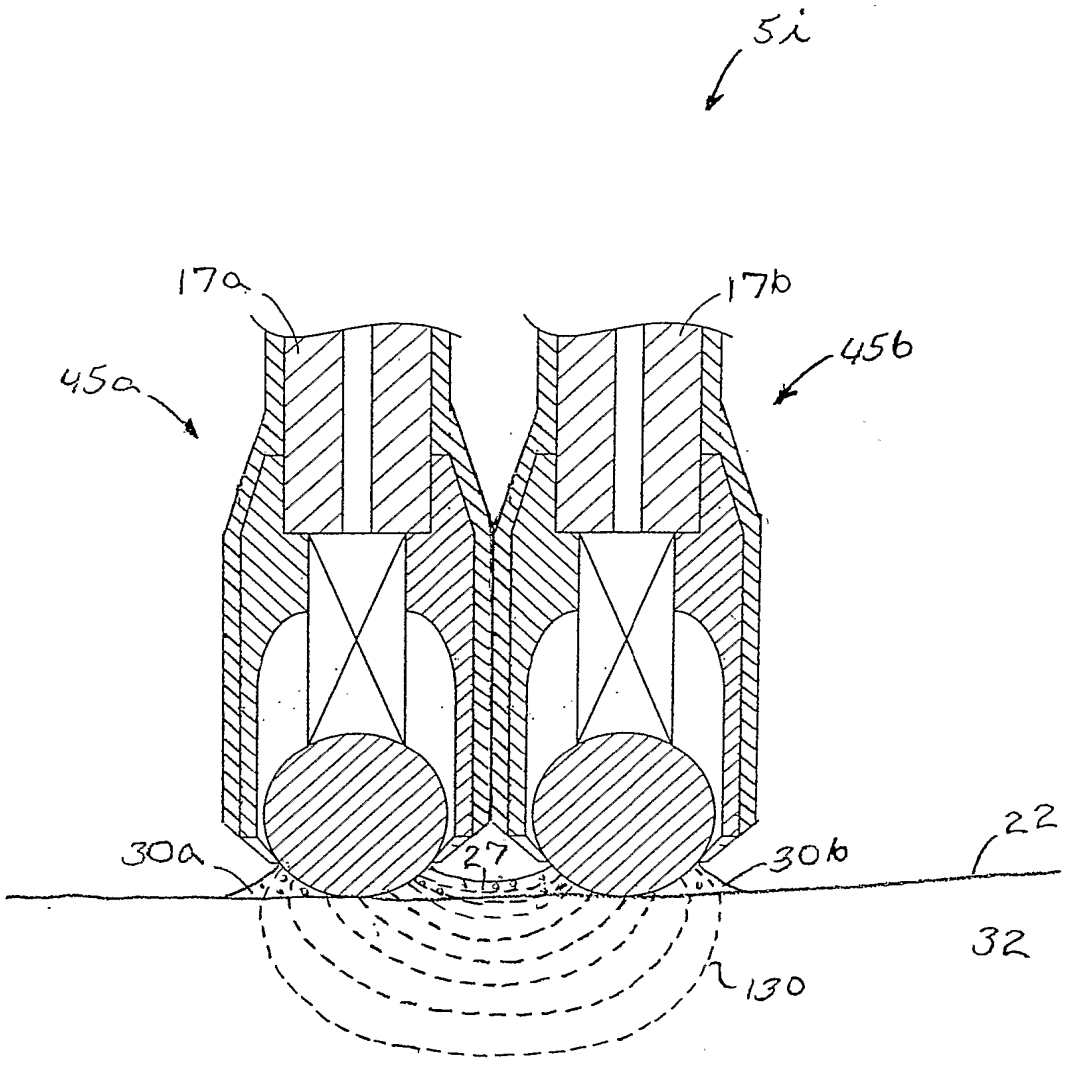


FIG. 48

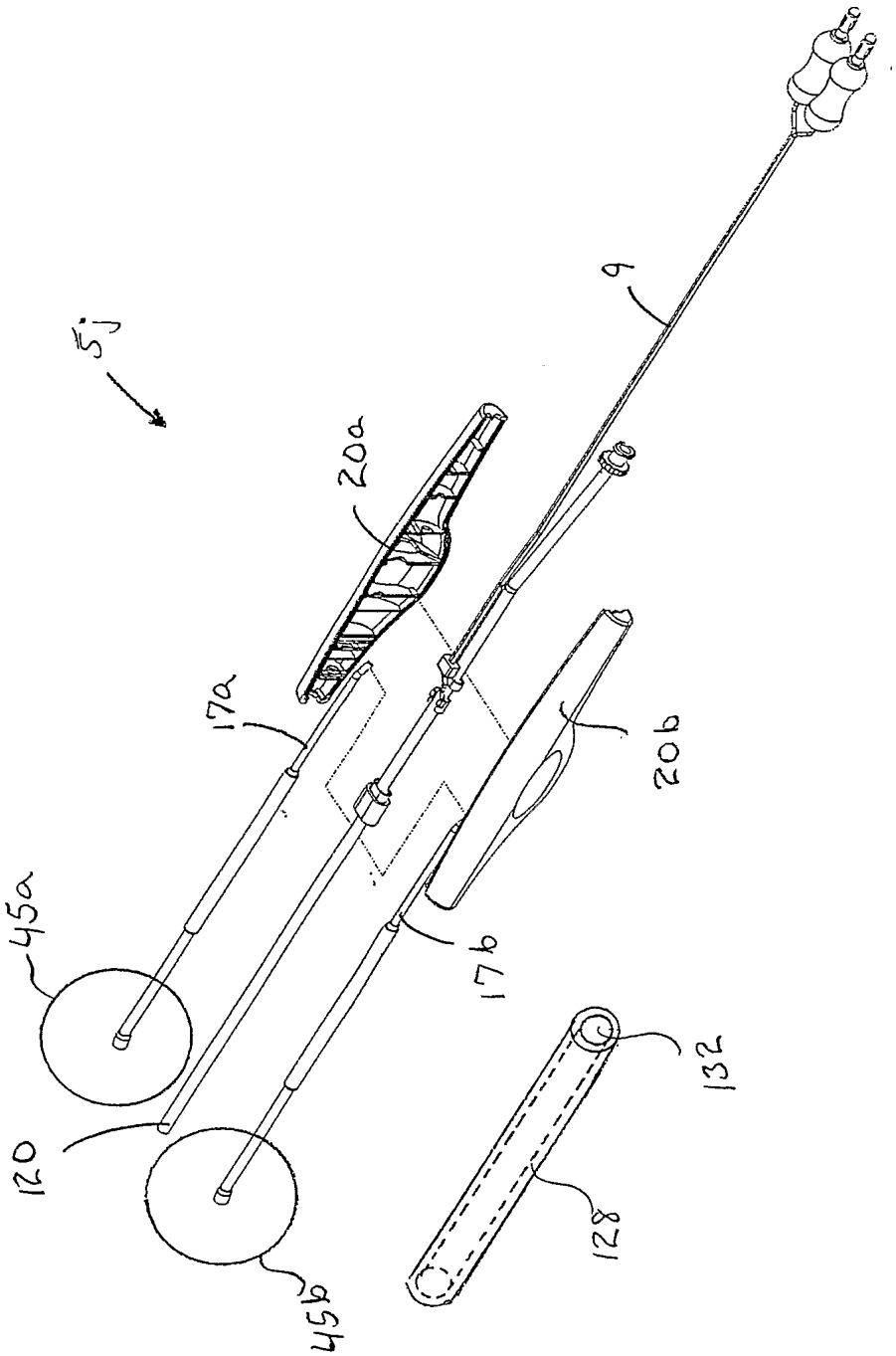


FIG. 49

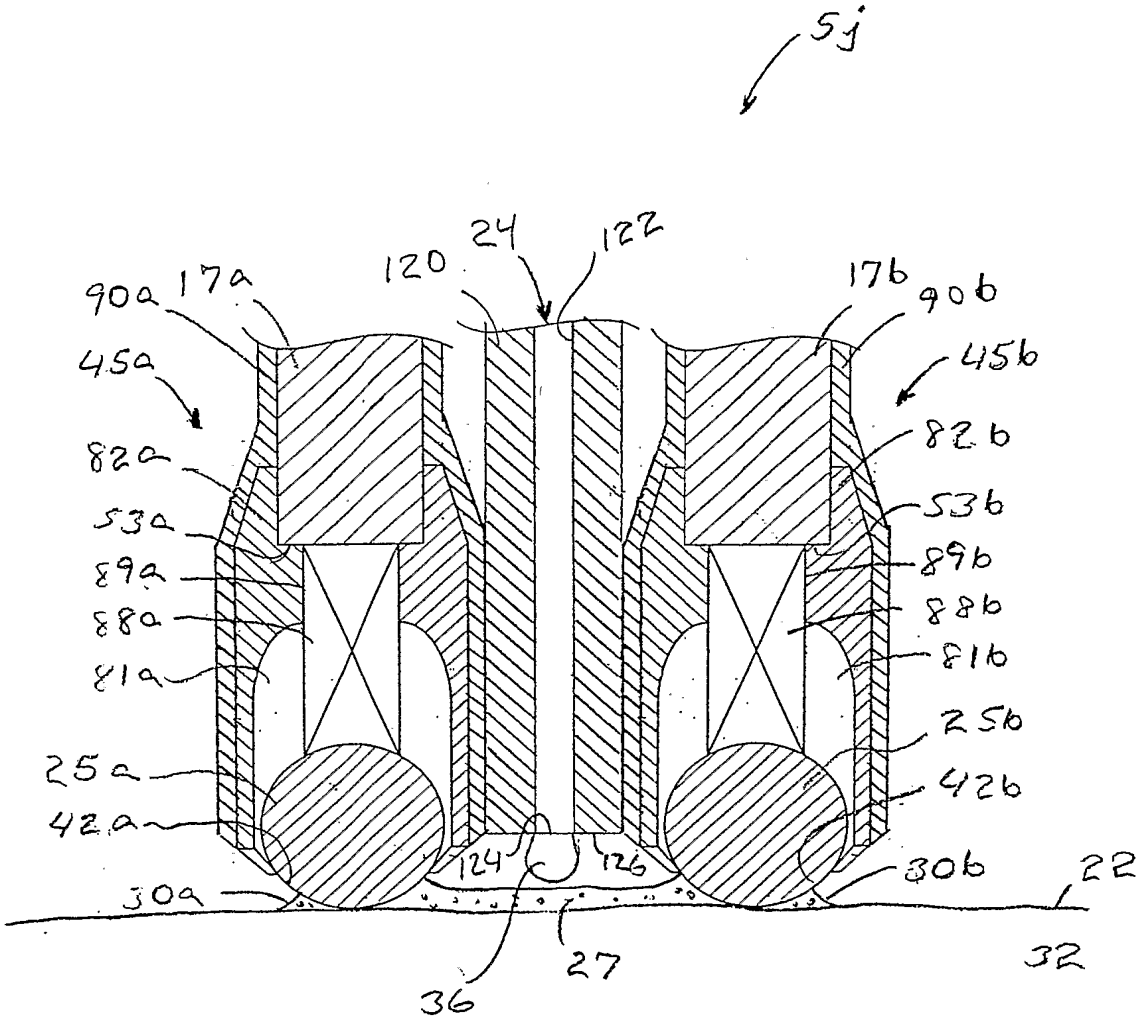

5j
24
122
120
90a
17a
17b
90b
45a
45b
82a
82b
53a
53b
89a
89b
88a
88b
81a
81b
25a
25b
42a
42b
124
126
30a
30b
22
27
36
32

FIG.50

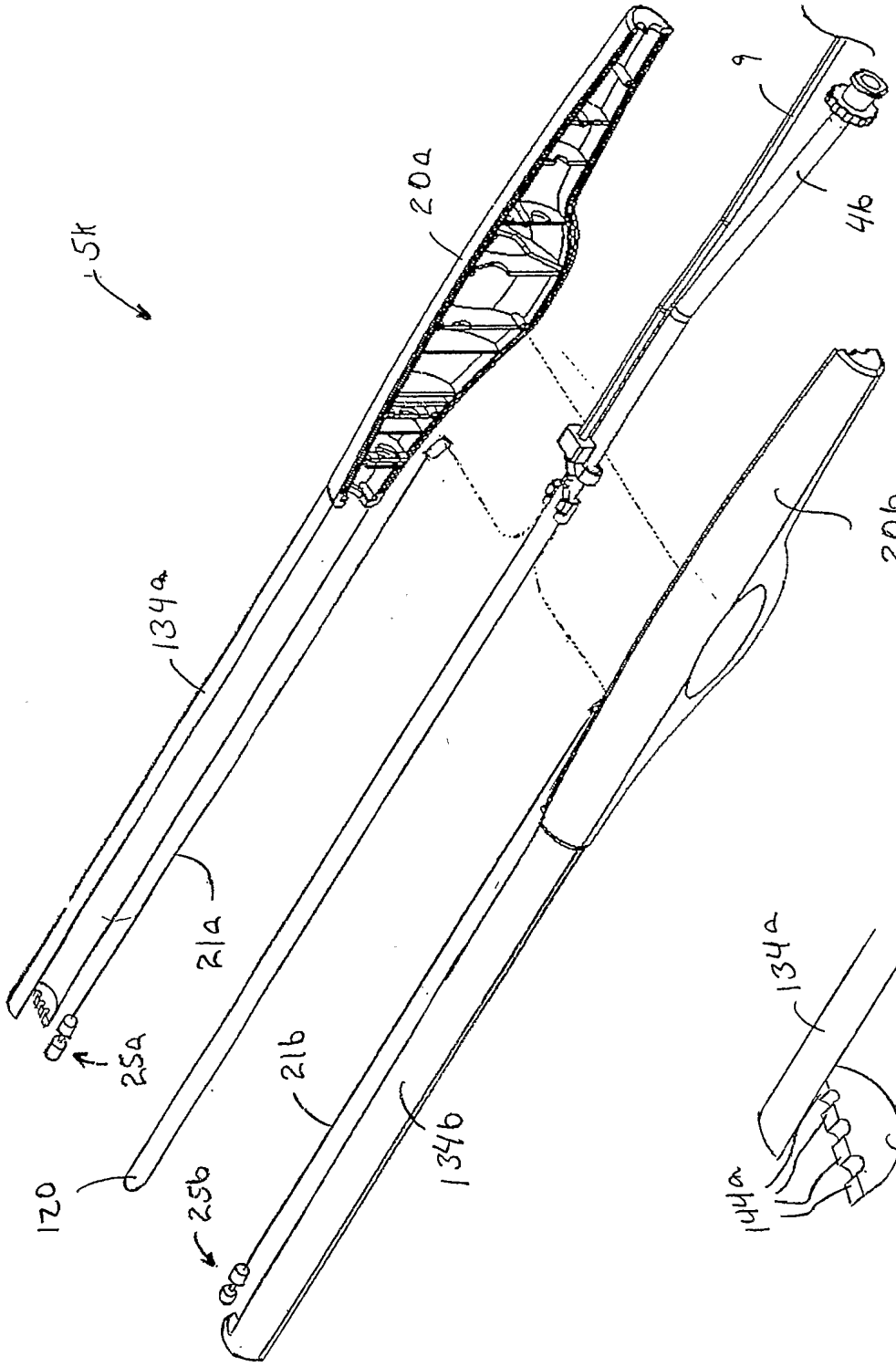


FIG 51

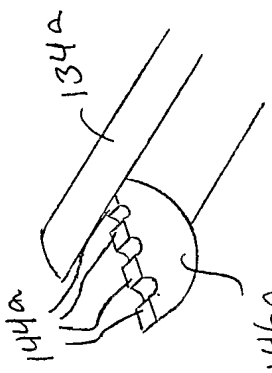


FIG. 52

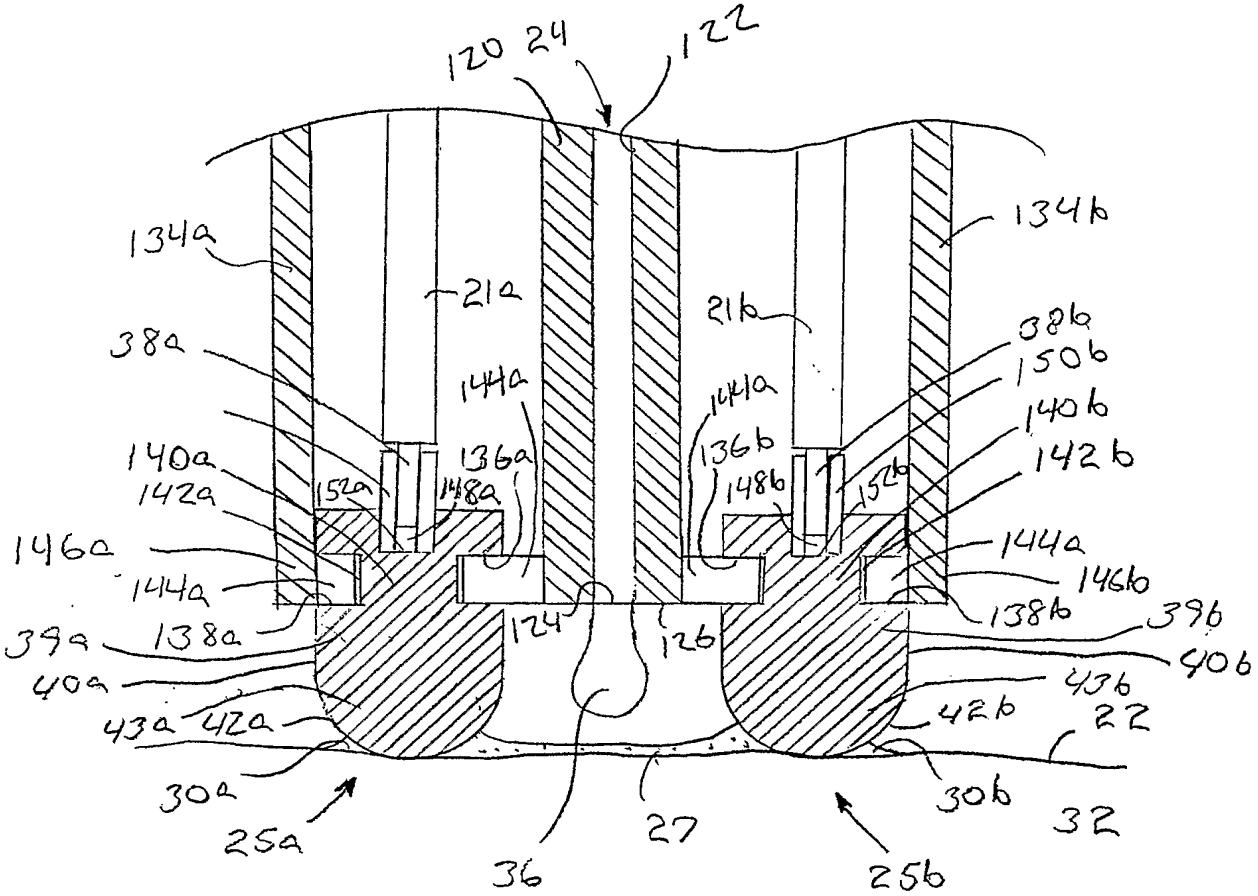

120
24
122
134a
134b
21a
21b
38a
38b
150b
144a
136a
144a
136b
140b
142b
140a
142a
152a
148a
148b
152b
146a
144a
144a
146b
138b
39a
138a
124
126
39b
40b
40a
43b
43a
42a
42b
22
30a
30b
32
25a
27
36
25b

FIG 53

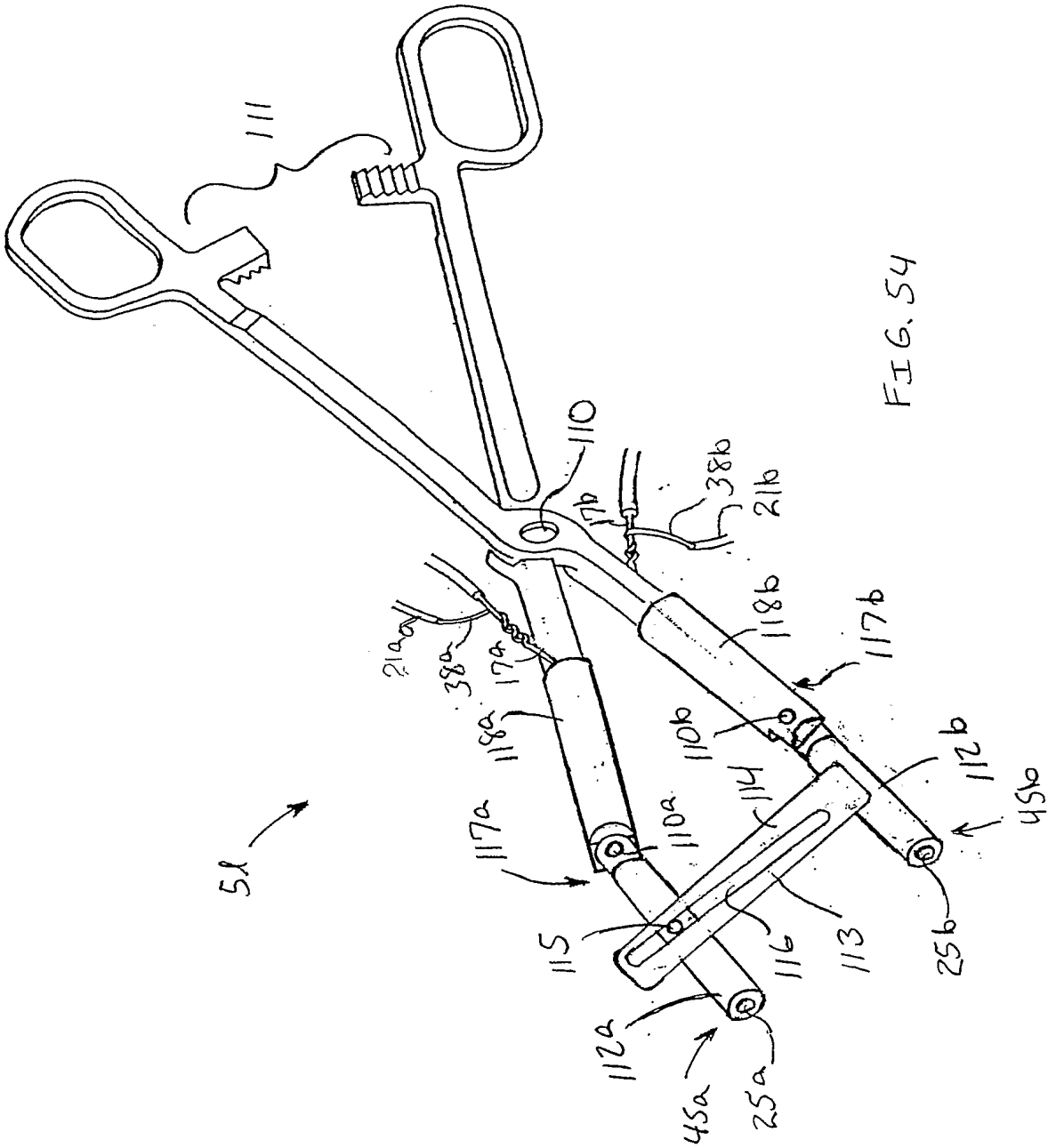

111
110
17b
38b
21b
118b
117b
21a
38a
17a
118a
110b
114
112b
45b
117a
110a
51
115
116
113
25b
112a
45a
25a

FIG. 54

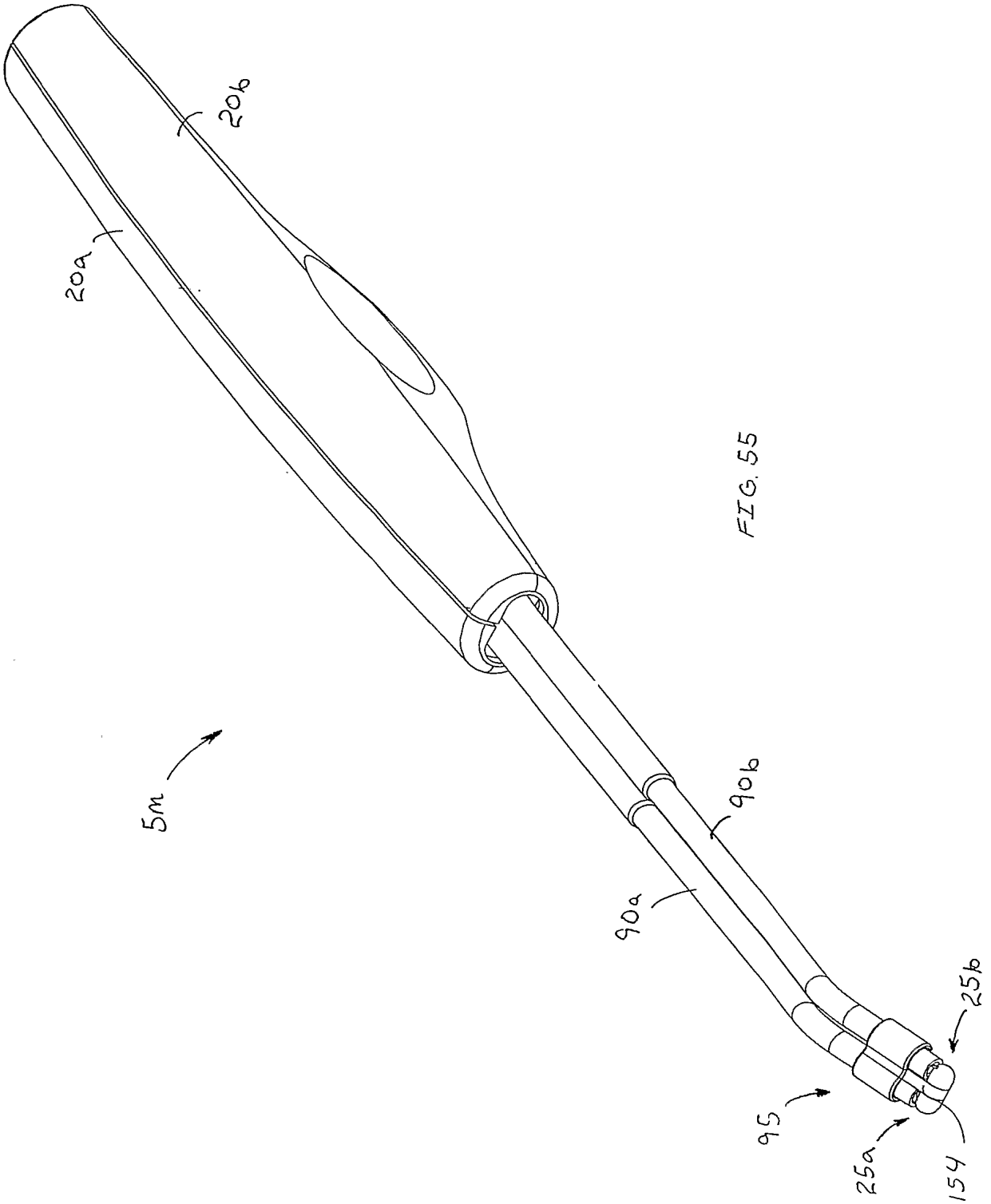


FIG. 55

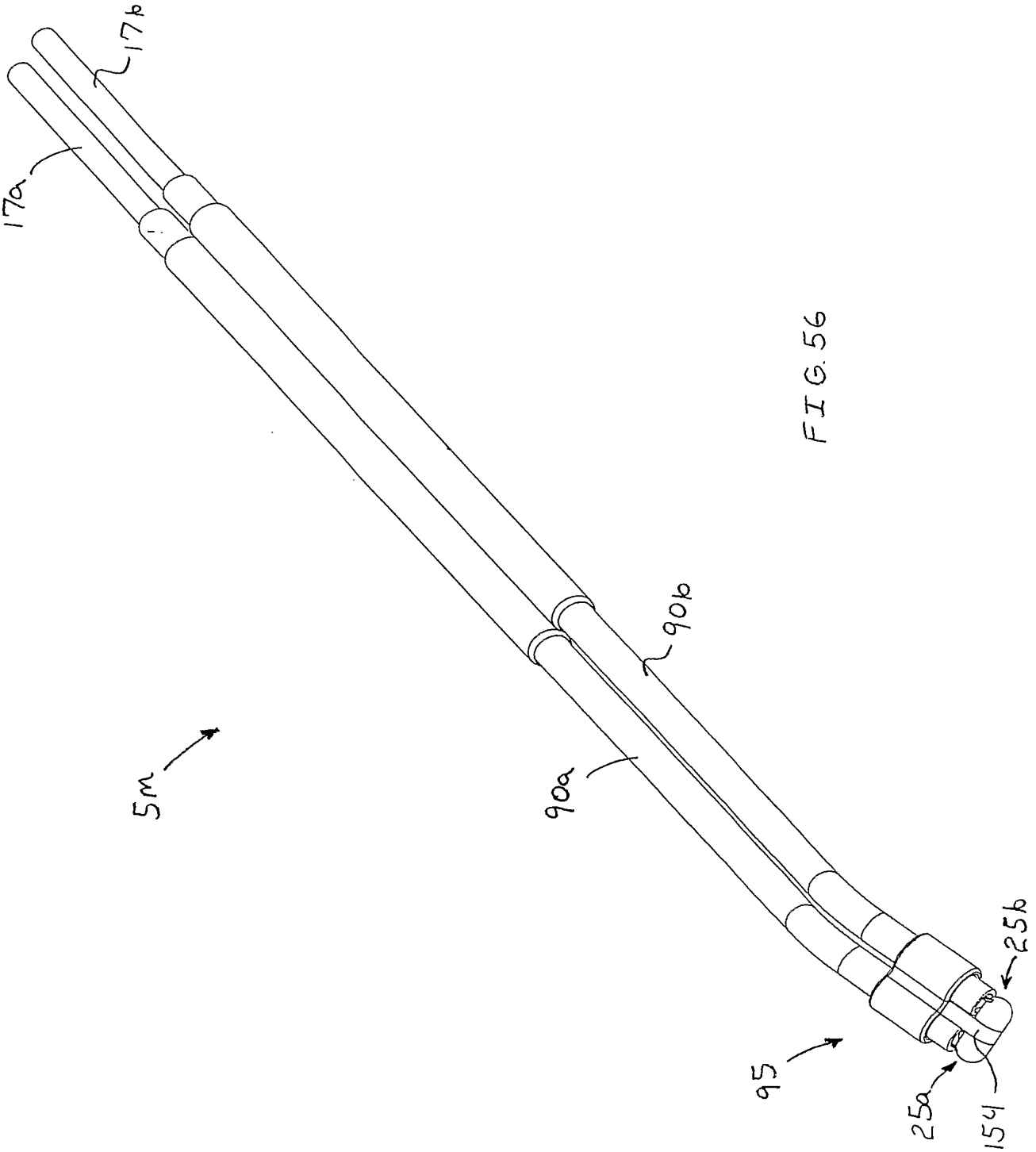


FIG. 56

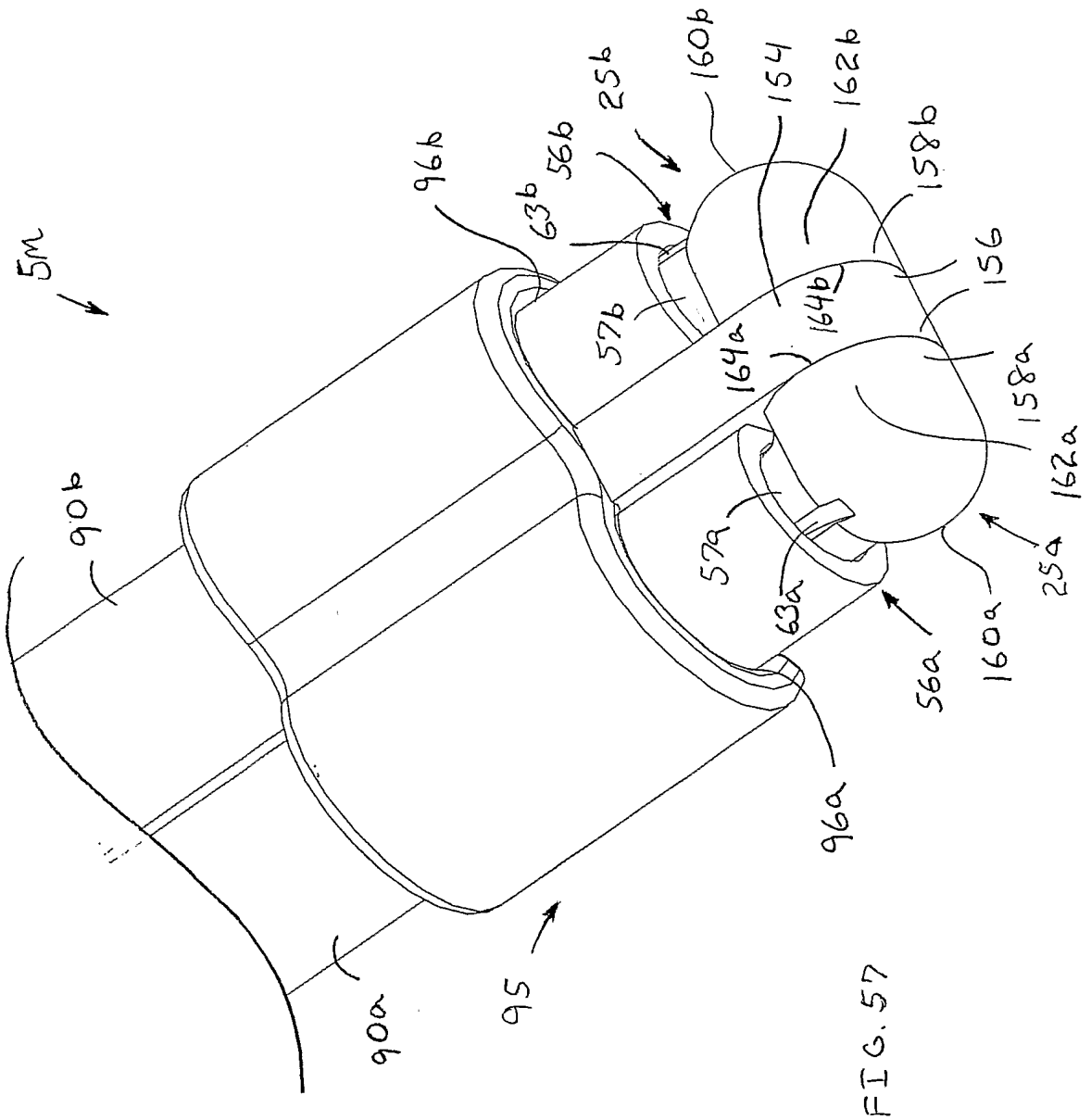

5m
90b
96b
63b
56b
25b
160b
154
162b
158b
156
57b
164b
164a
158a
162a
57a
63a
56a
160a
25a
96a
90a
95

FIG. 57

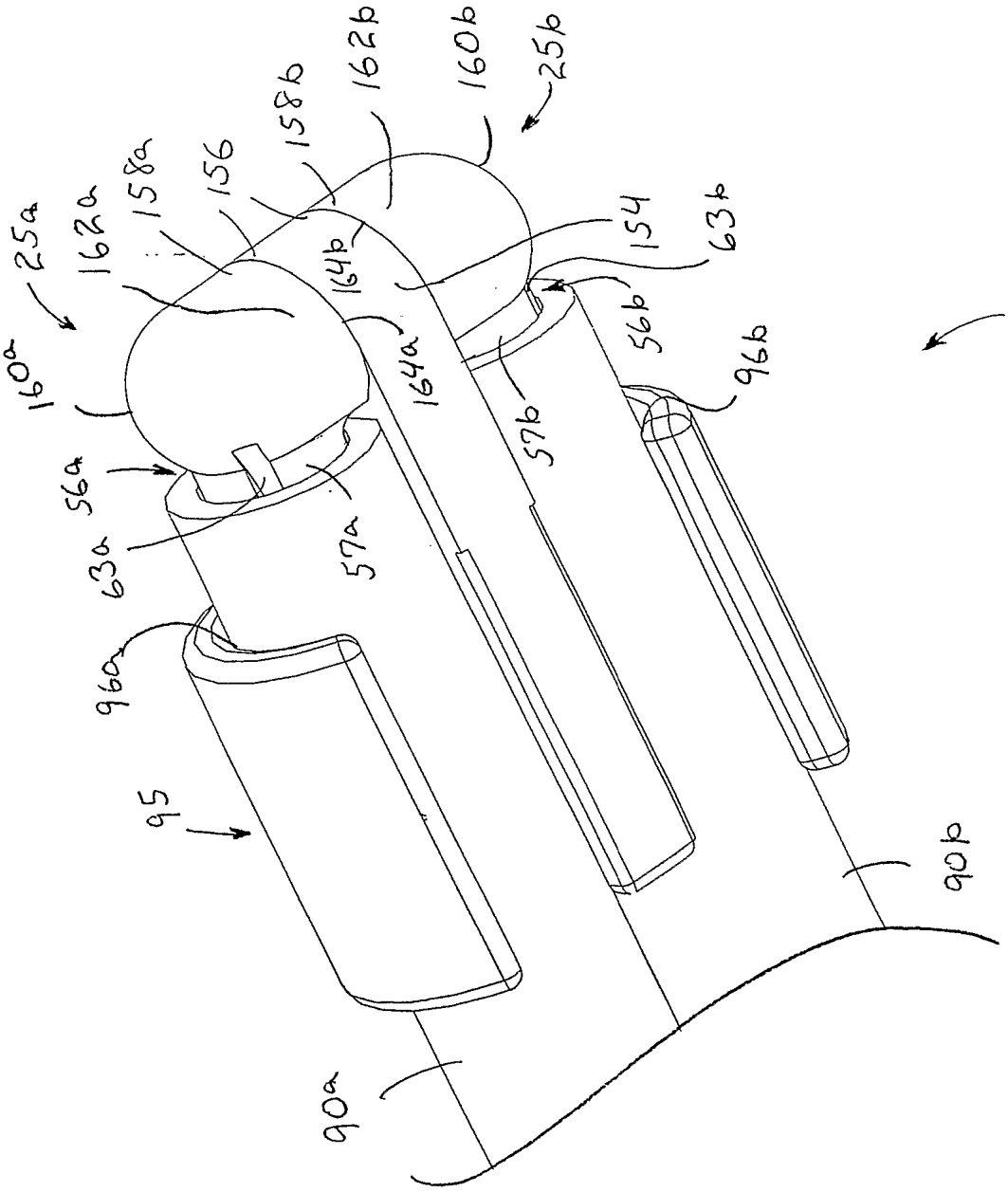

160a
25a
162a
158a
156
158b
162b
160b
25b
154
63b
56b
96b
5M
164b
164a
57b
57a
56a
63a
96a
95
90a
90b

FIG. 58

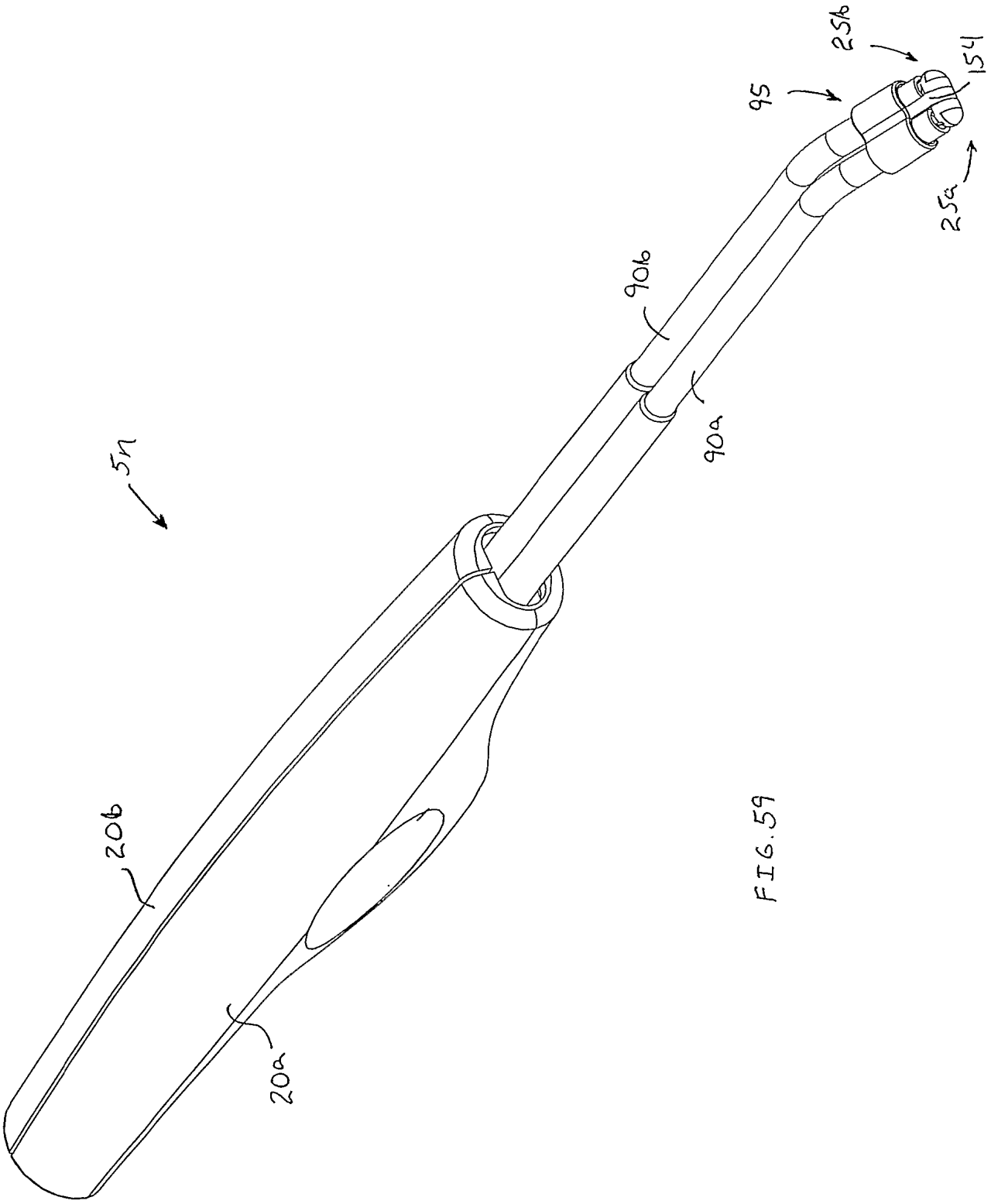


FIG. 59

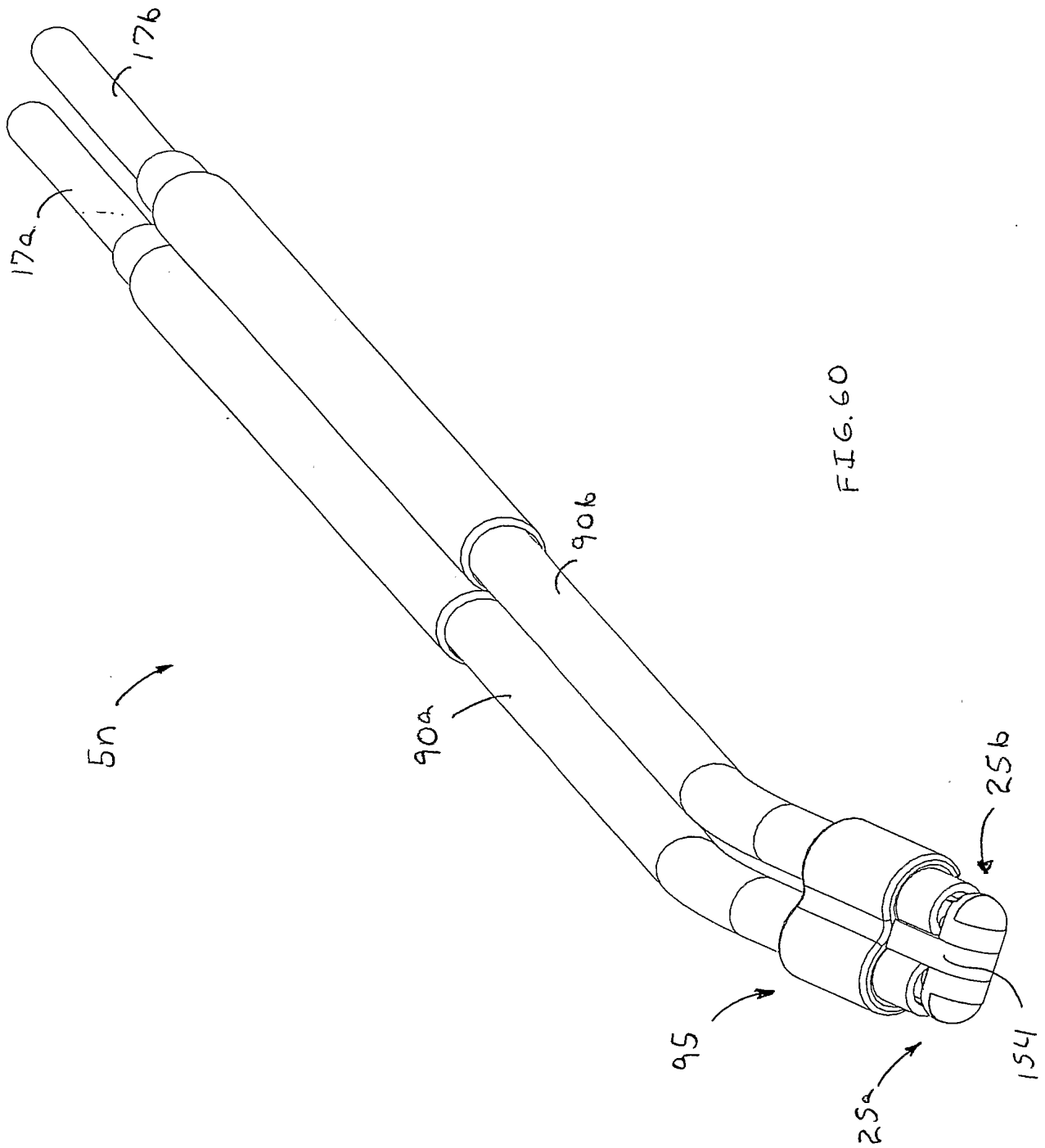


FIG. 60

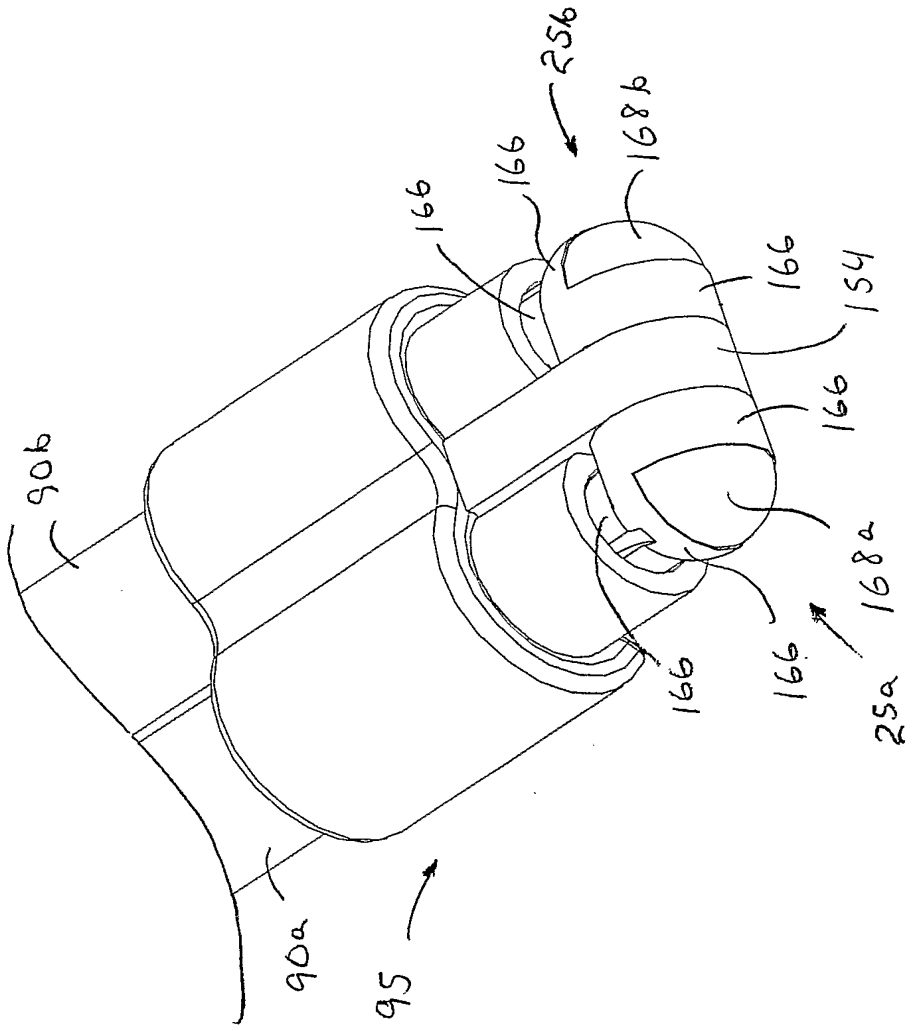


FIG. 61

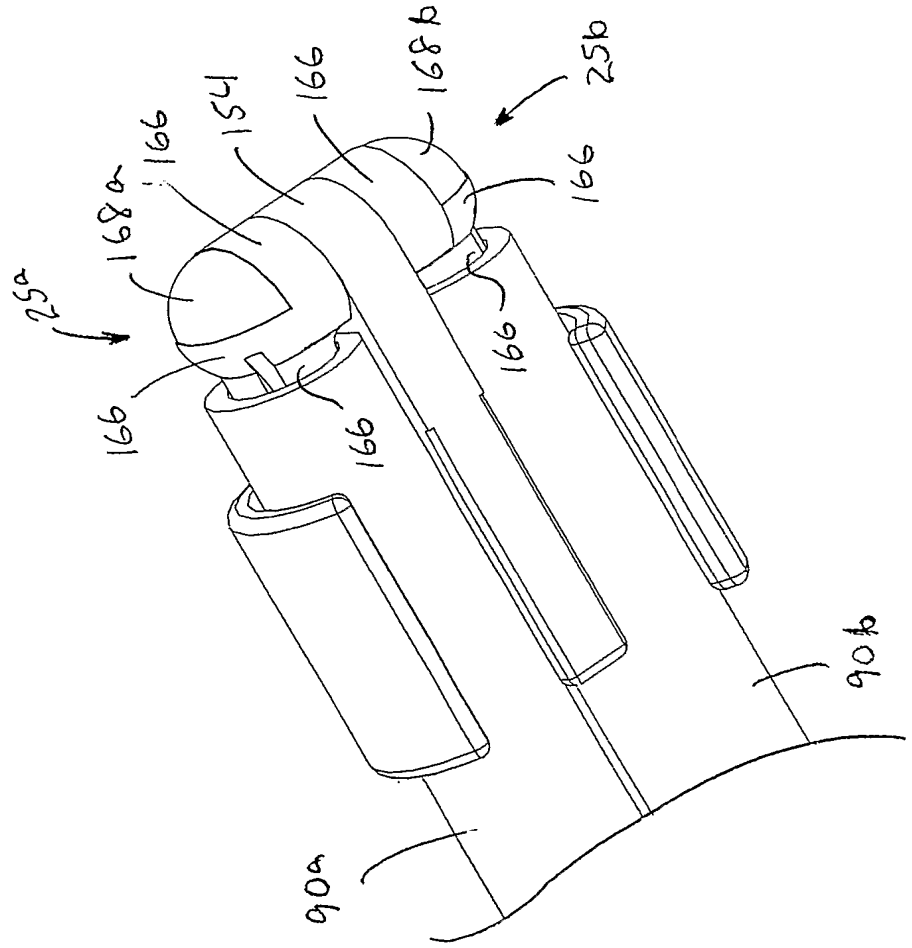


FIG. 62

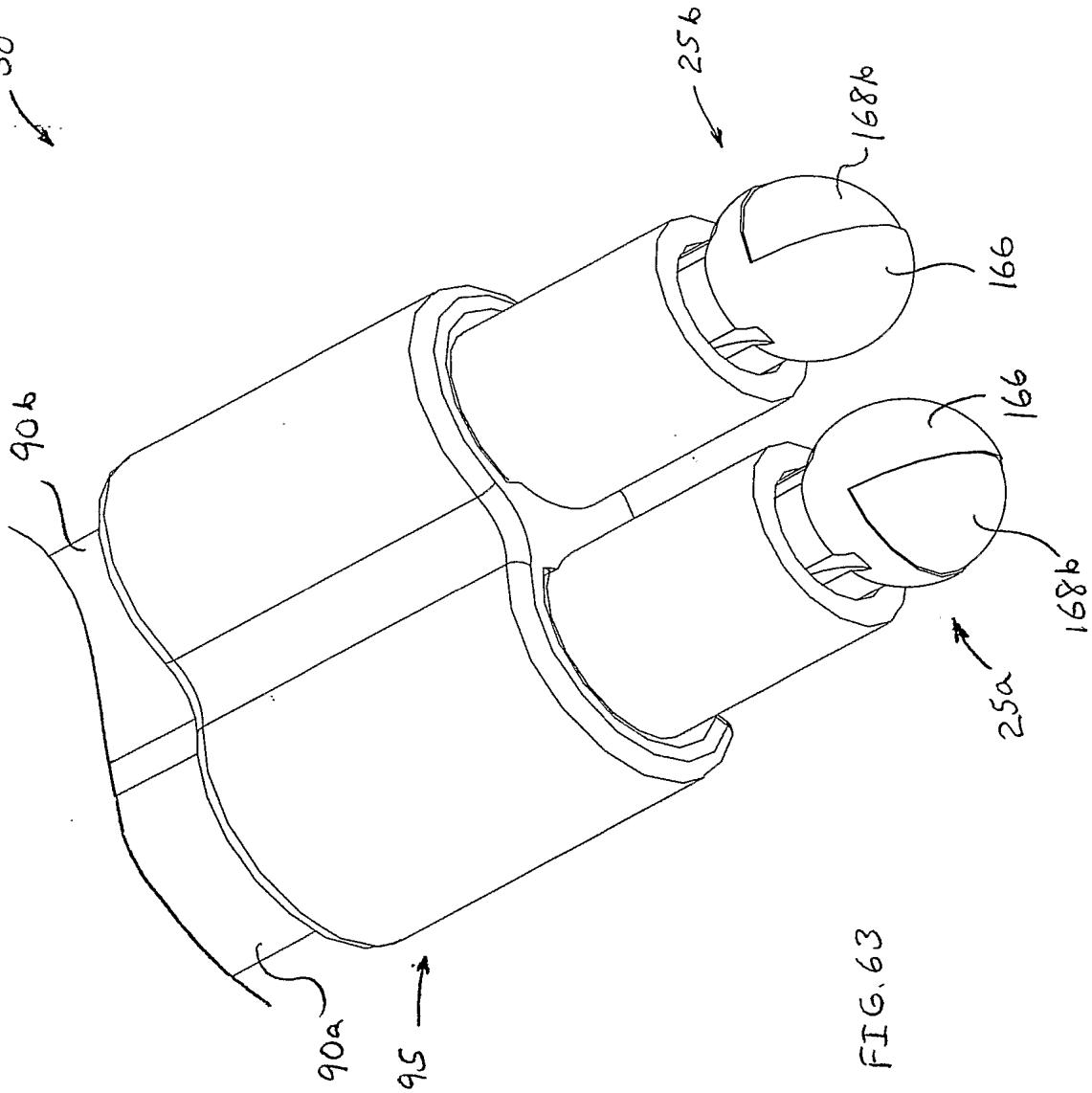


FIG. 63

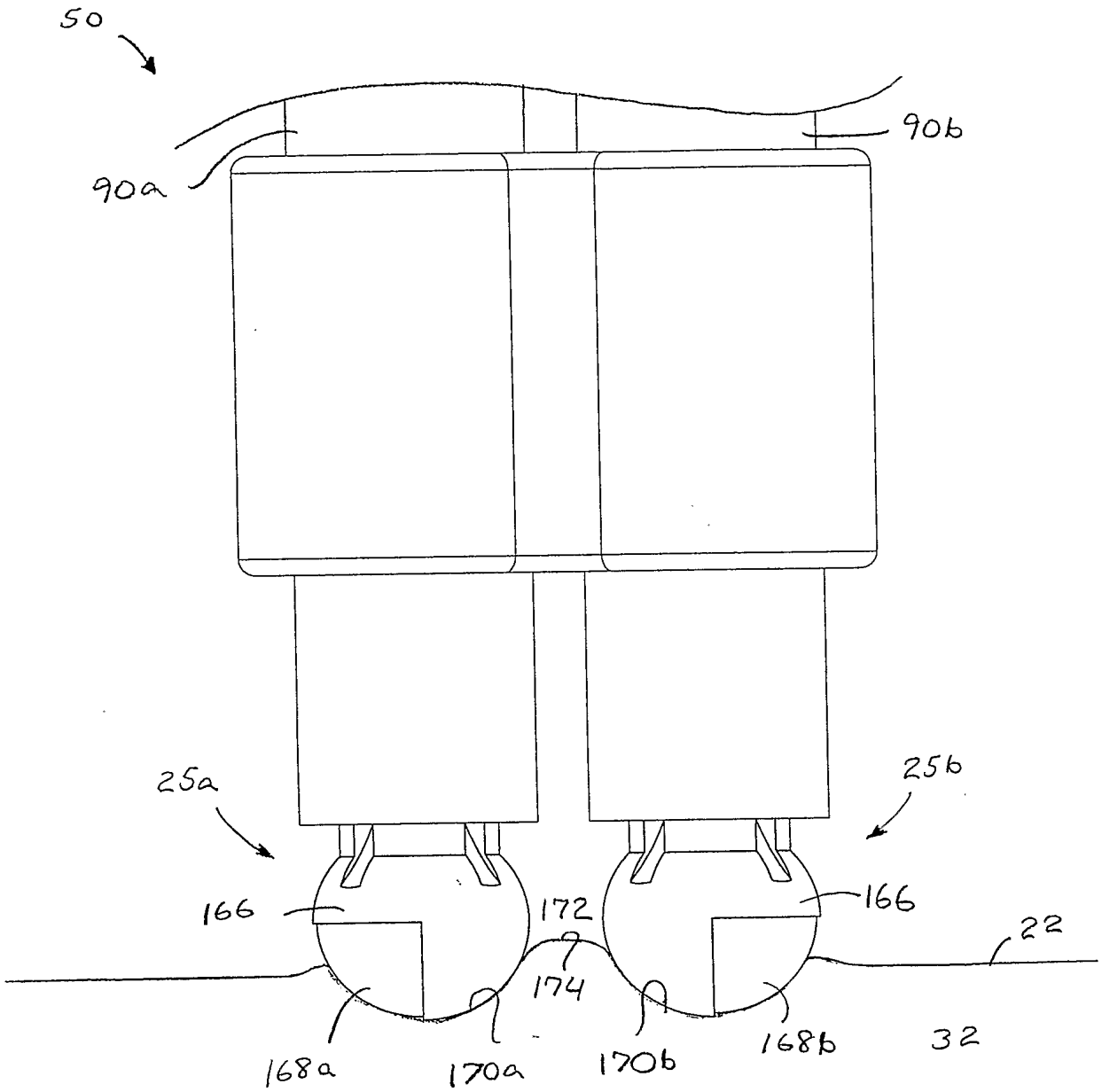


FIG. 64

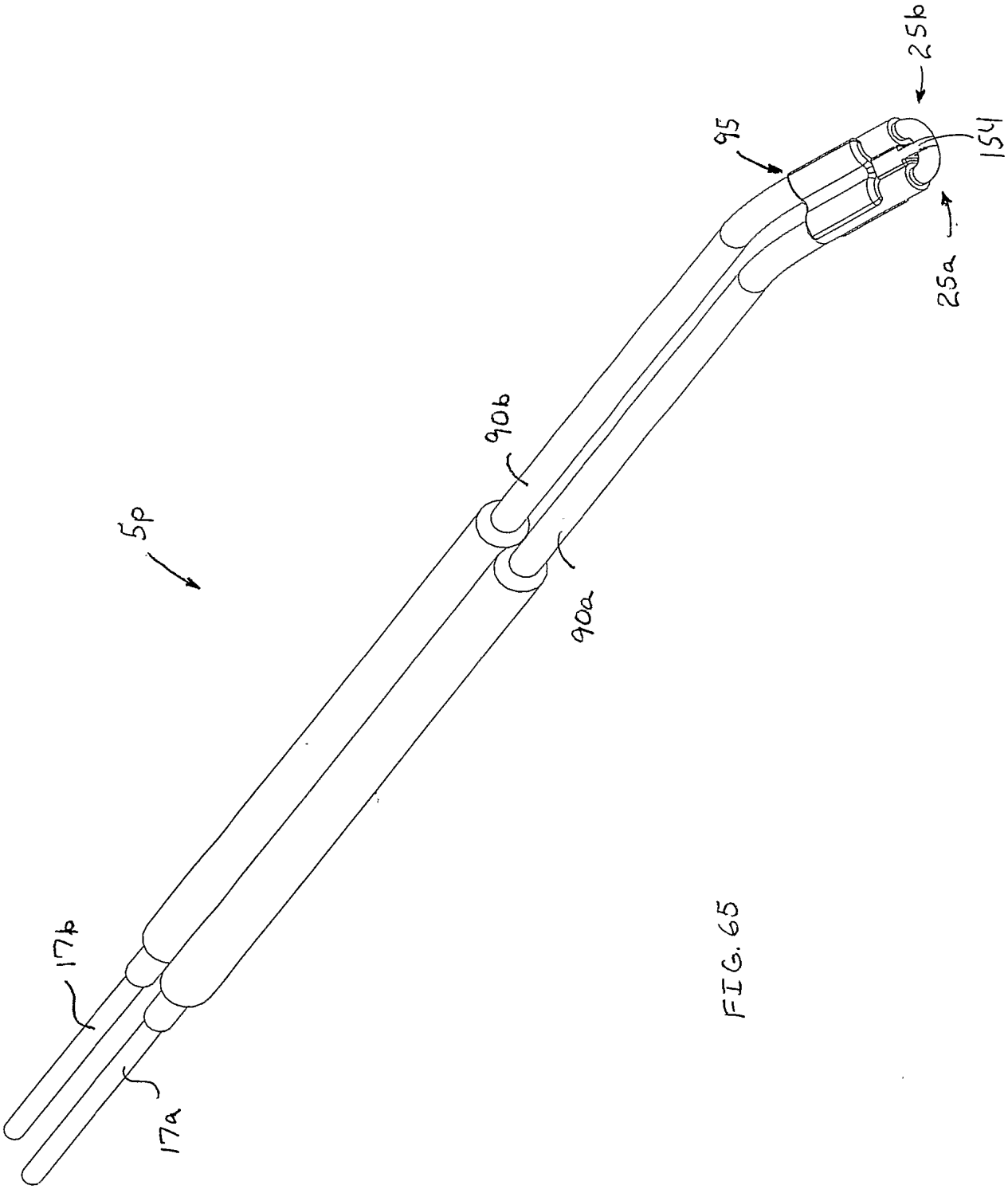


FIG. 65

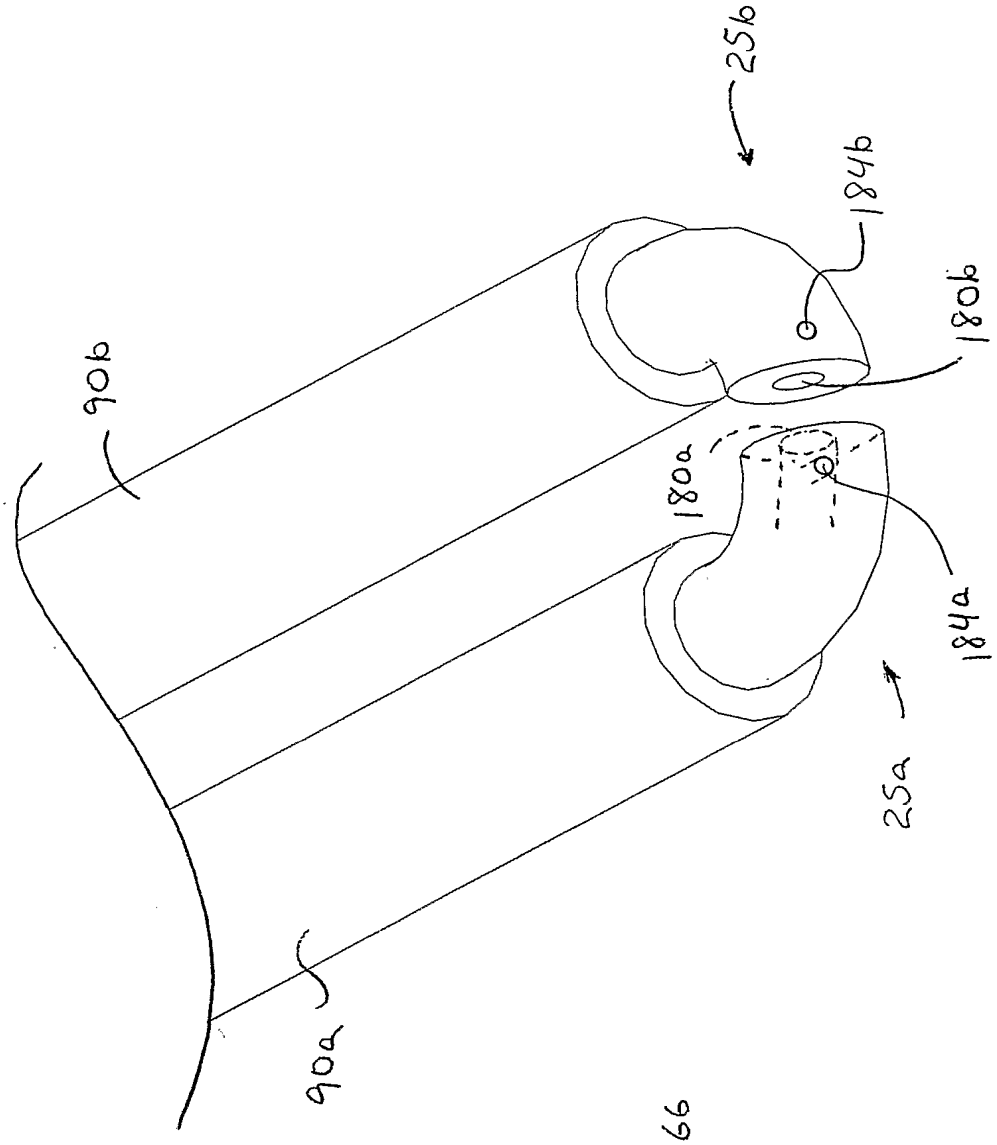


FIG. 66

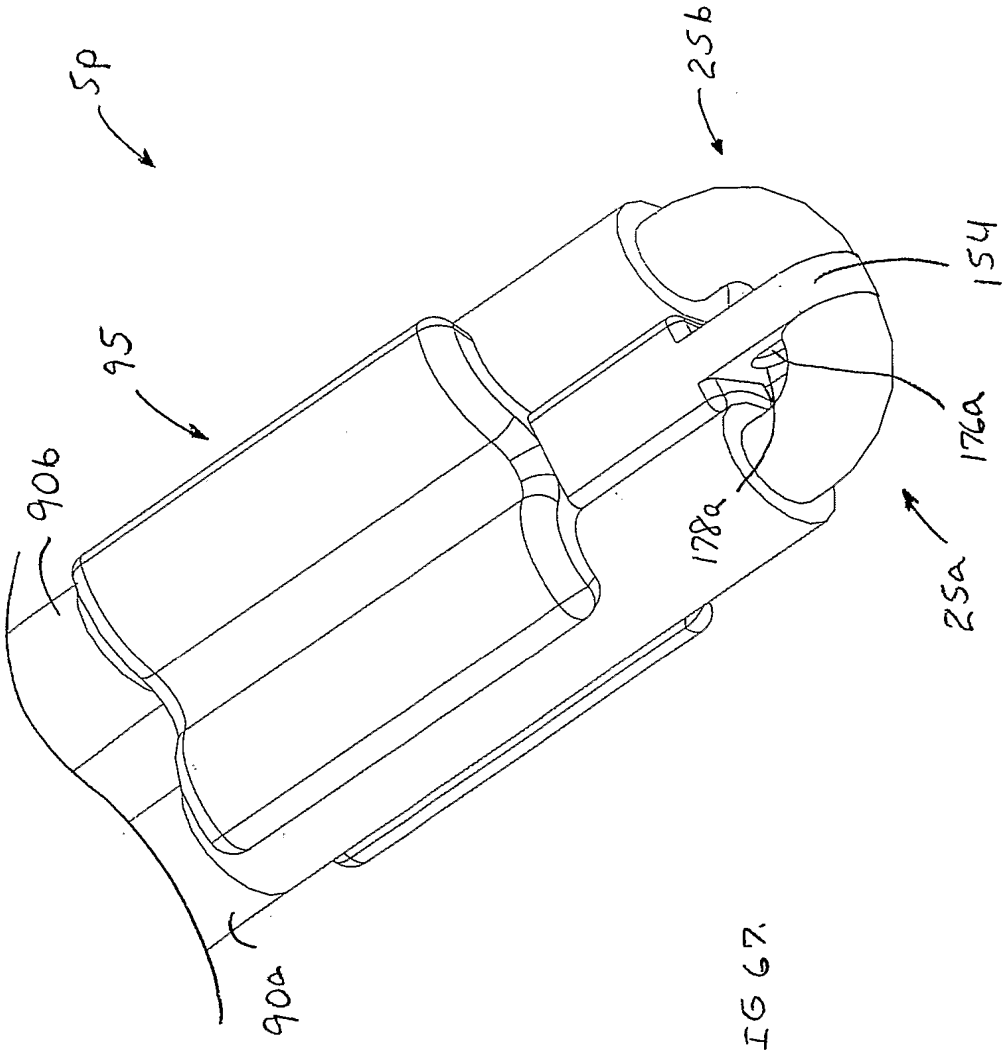


FIG 67.

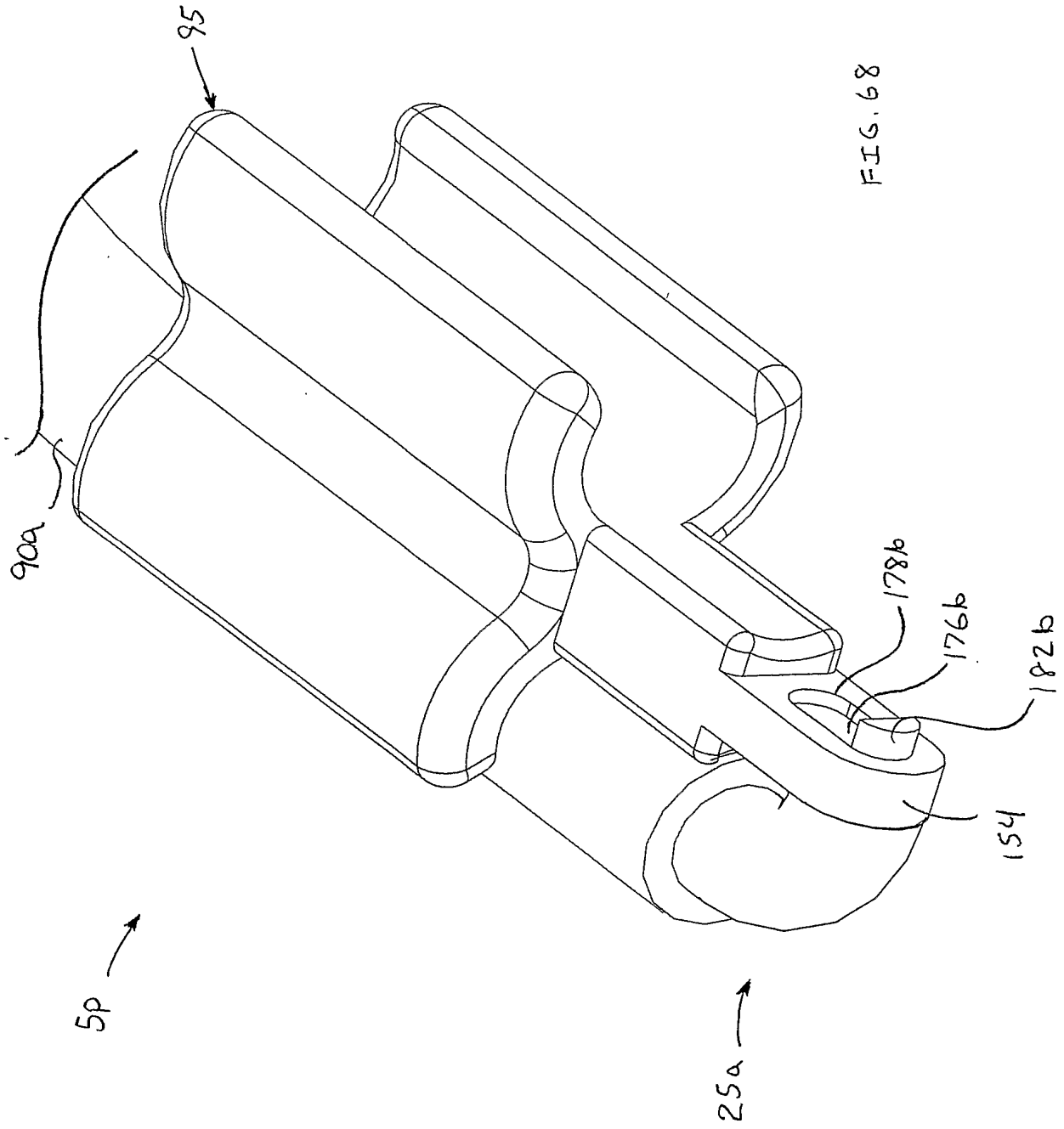


FIG. 68

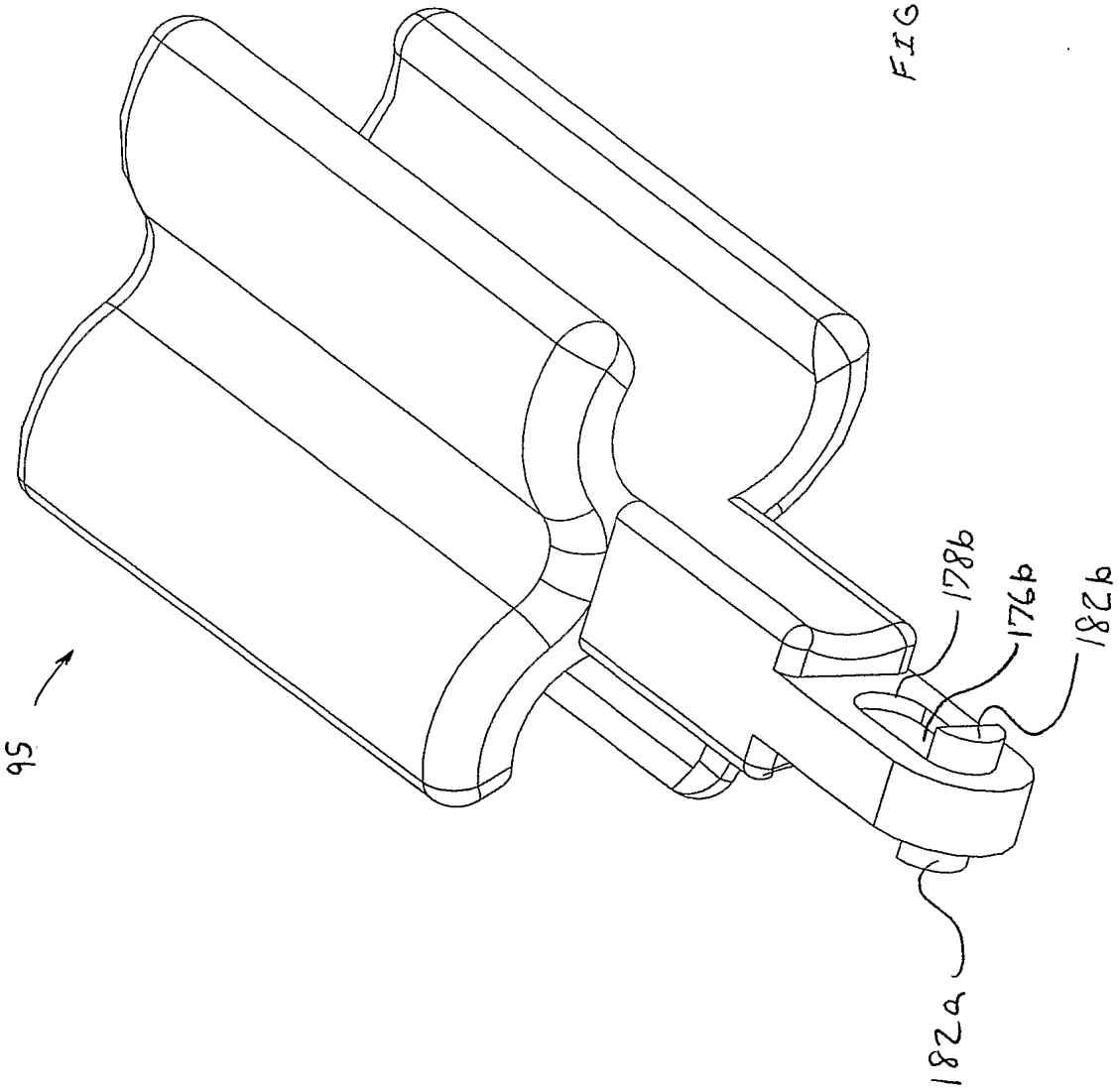


FIG. 69

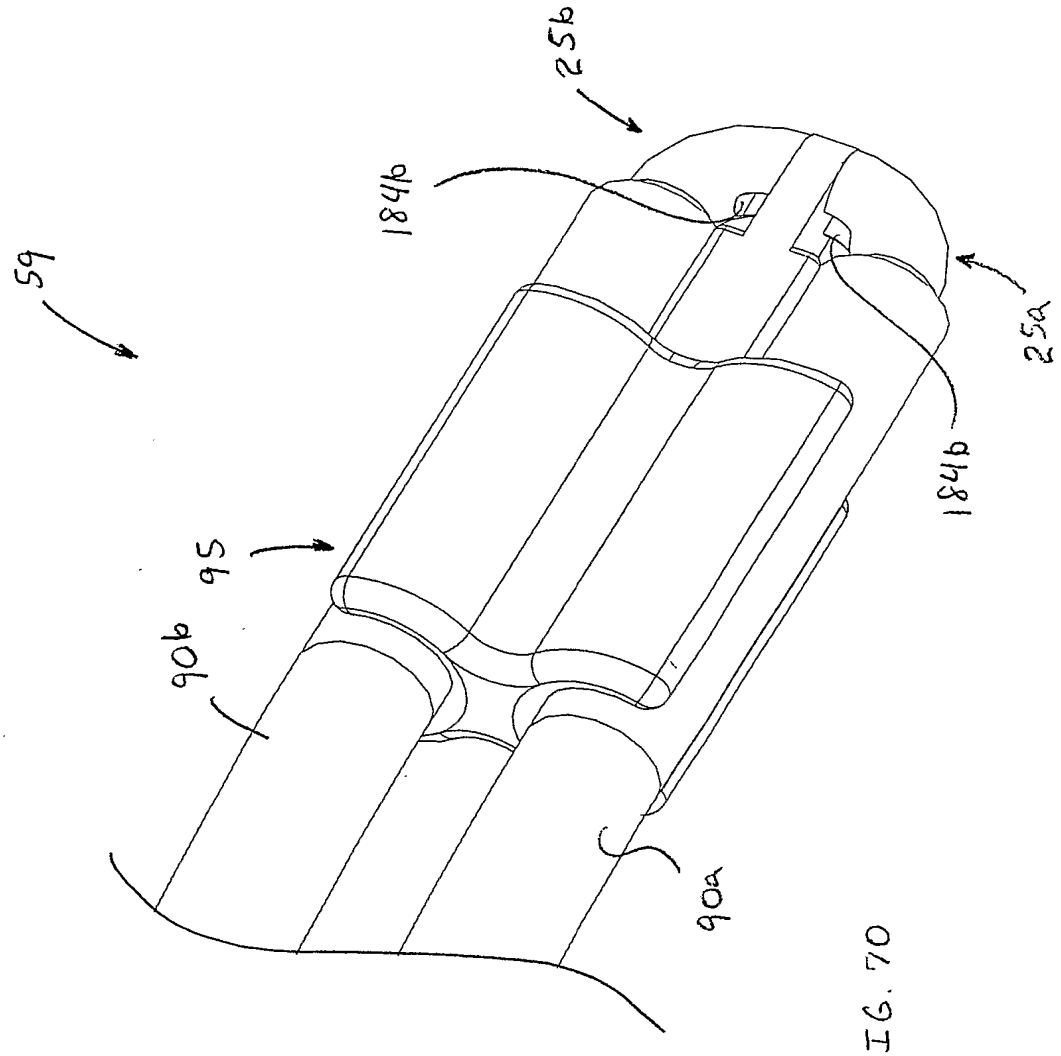


FIG. 70

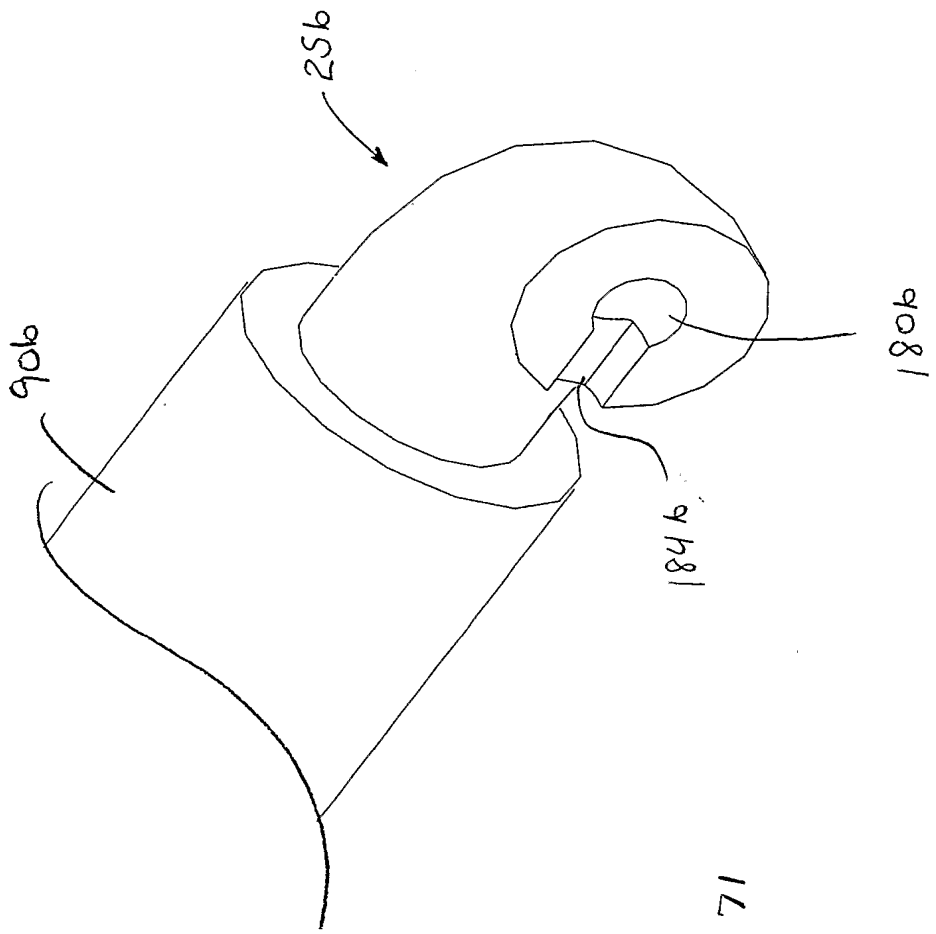


FIG. 71

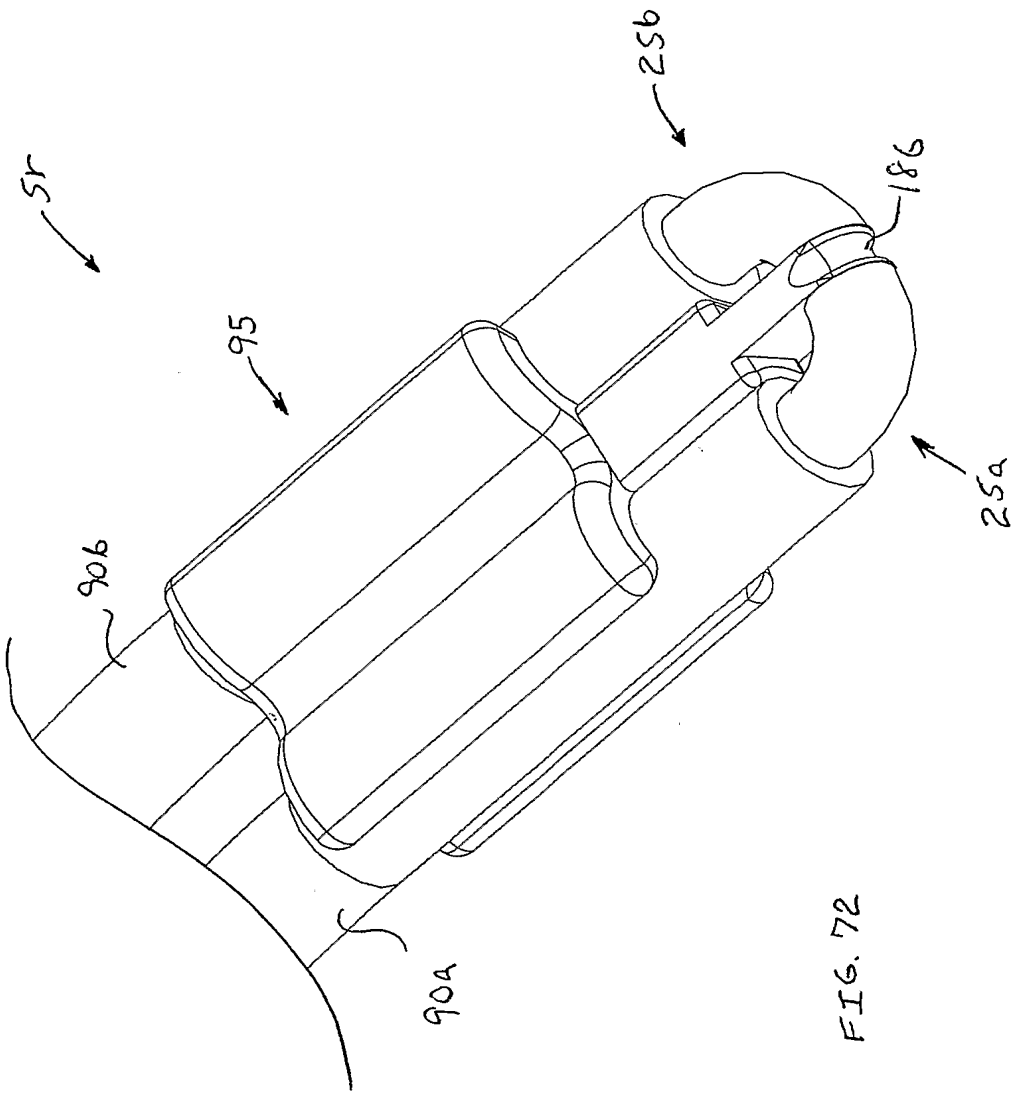


FIG. 72

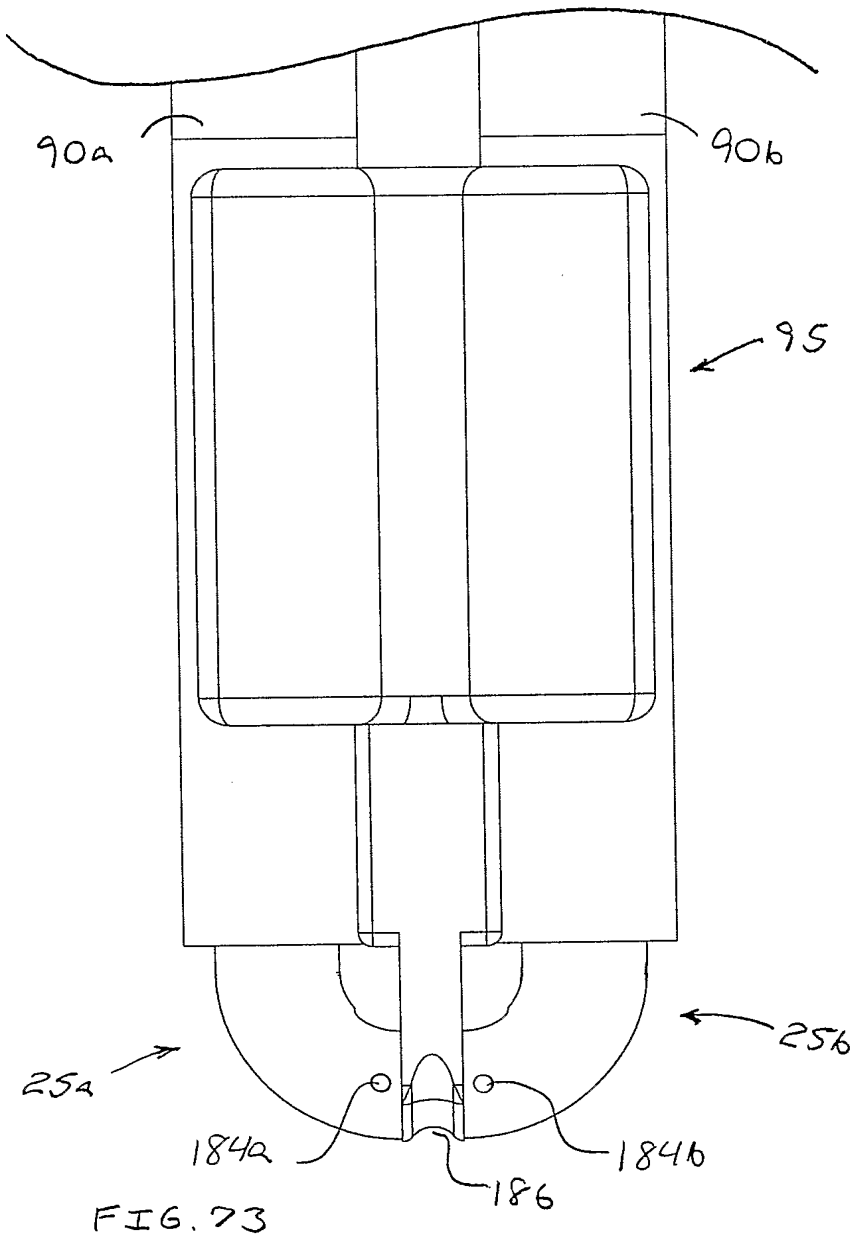


FIG. 73

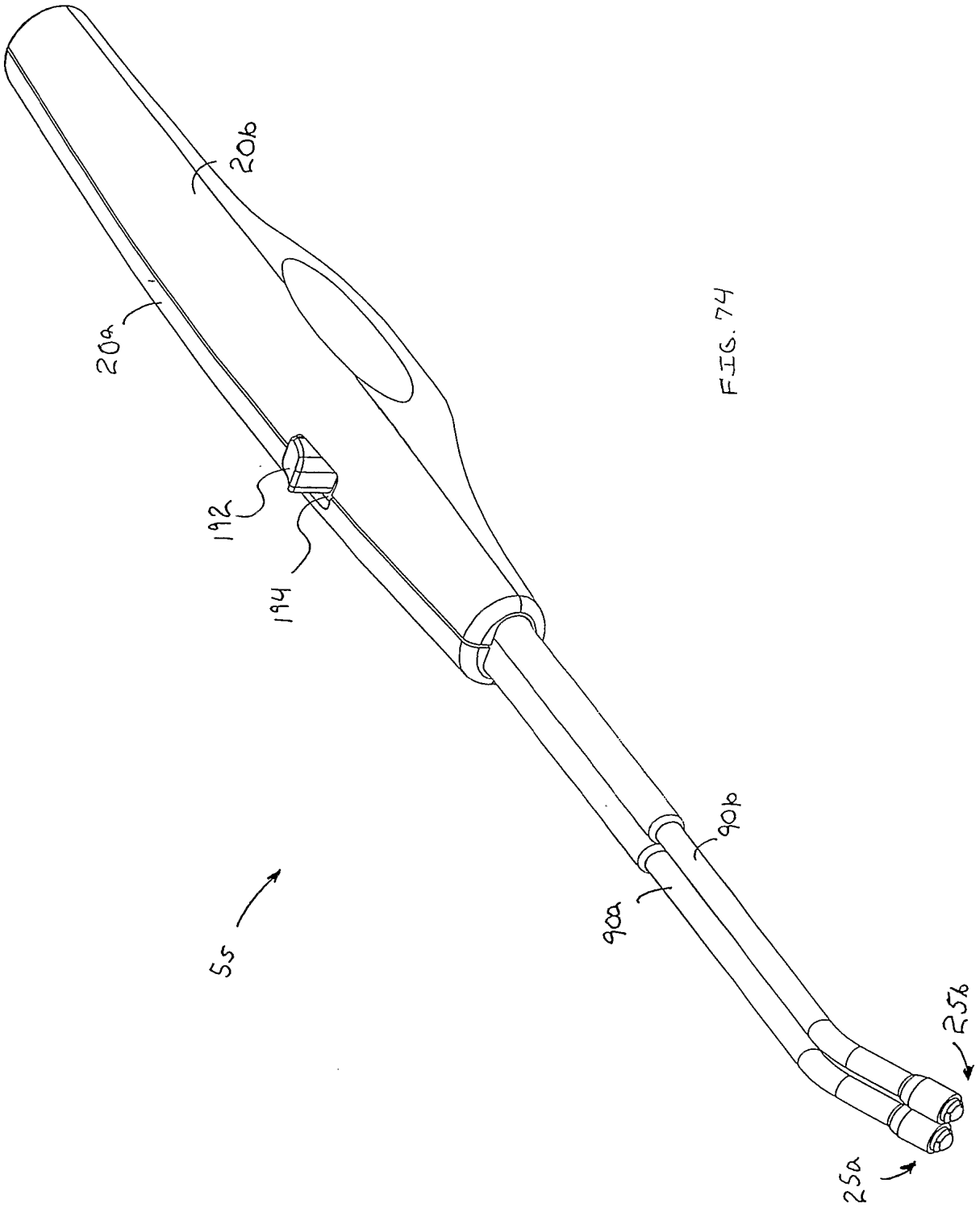


FIG. 74

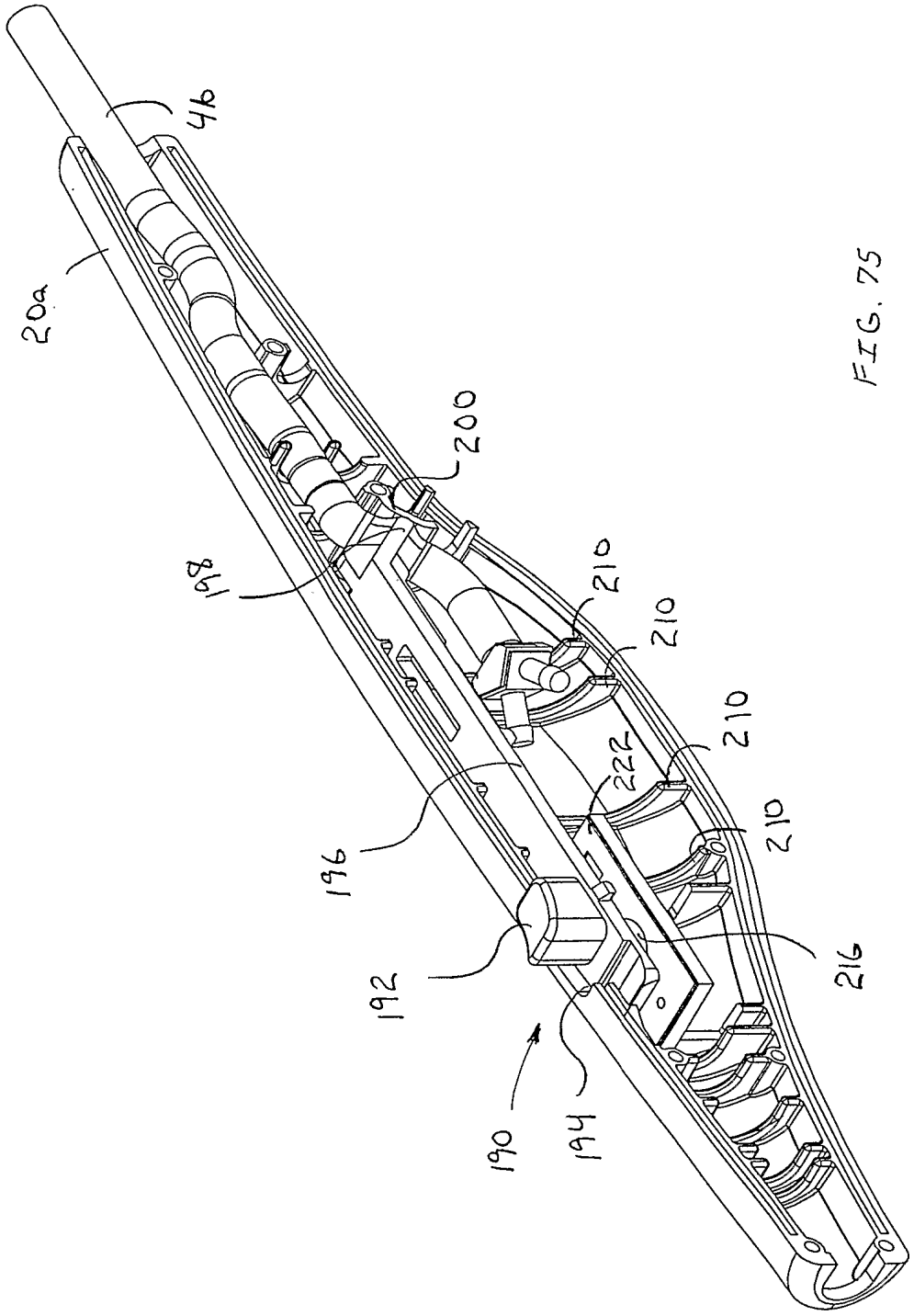


FIG. 75

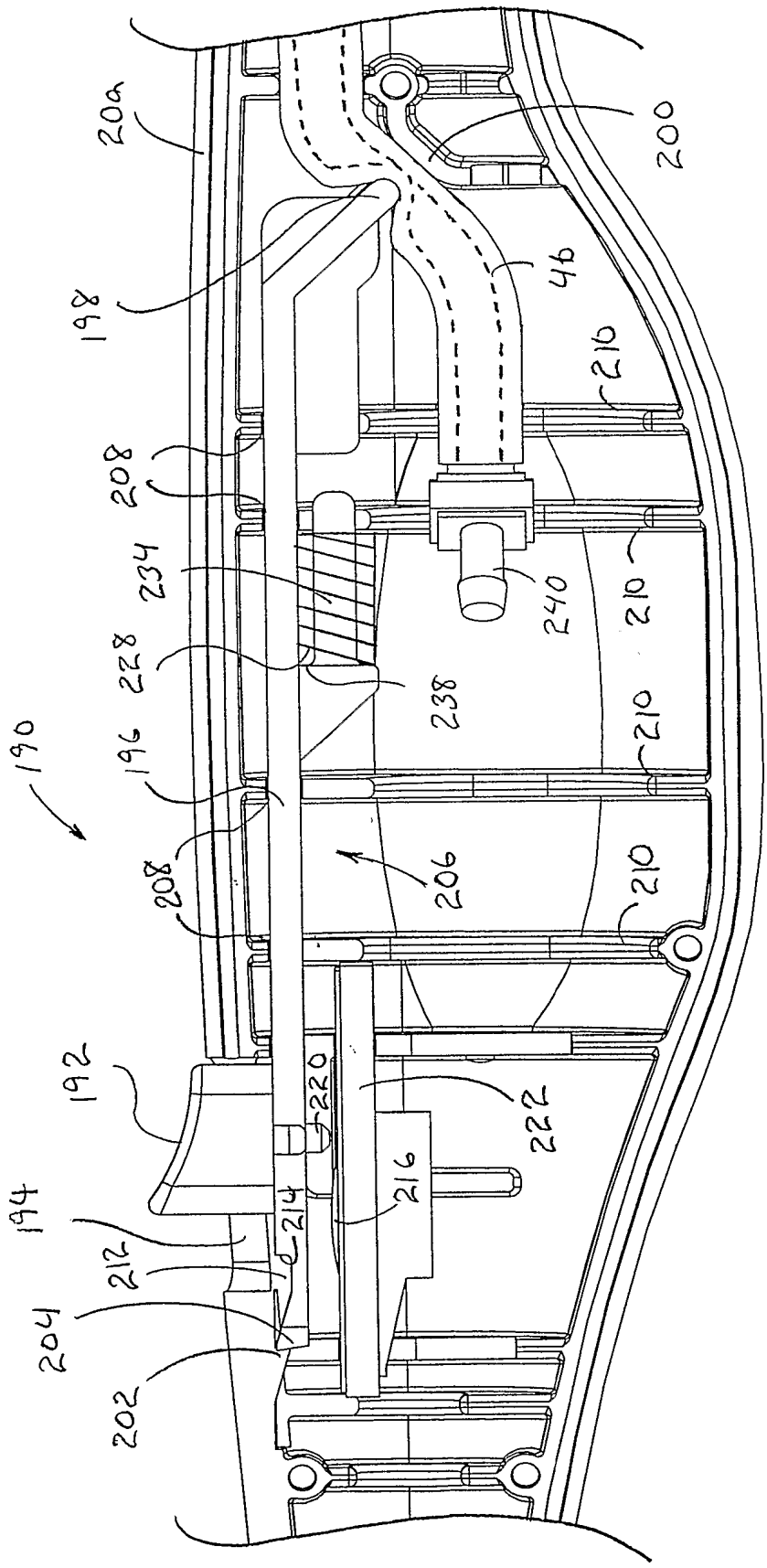

200a
200
198
46
210
208
234
240
210
228
238
210
196
190
208
206
210
192
220
222
216
194
214
212
204
202

FIG 76

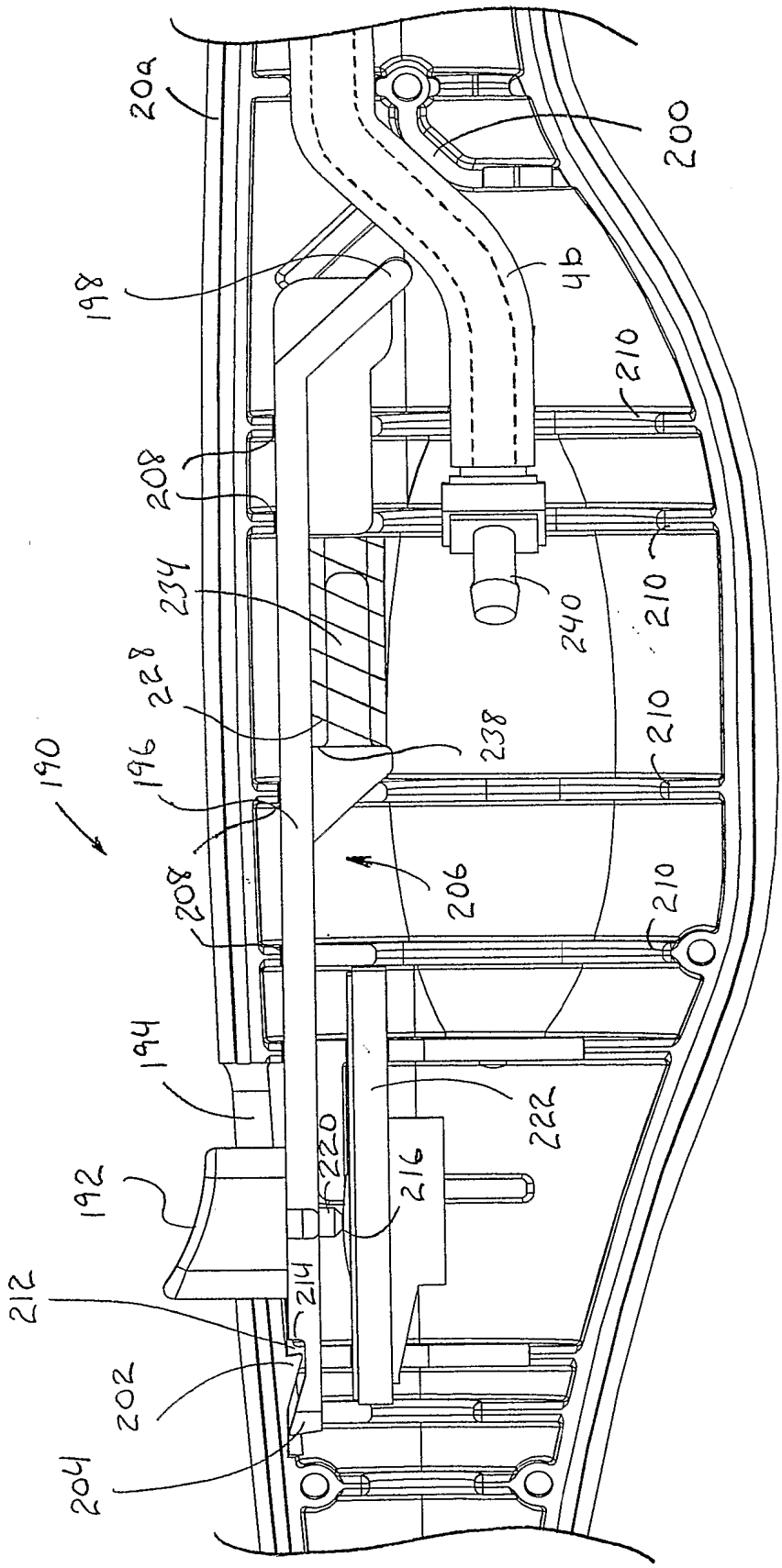

202
200
198
46
210
208
234
240
228
238
196
190
206
194
222
220
216
192
214
212
202
204

FIG. 77

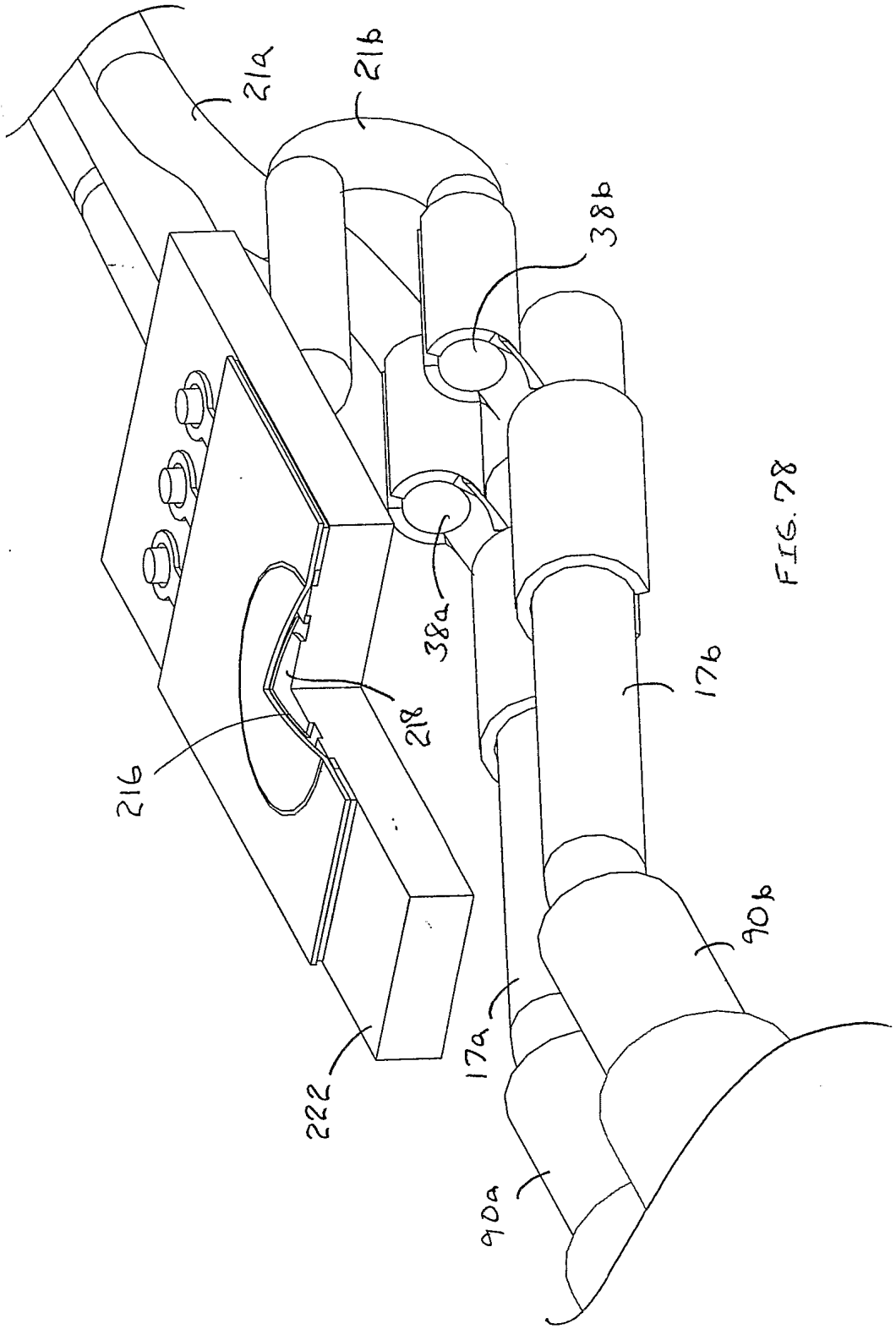


FIG. 78

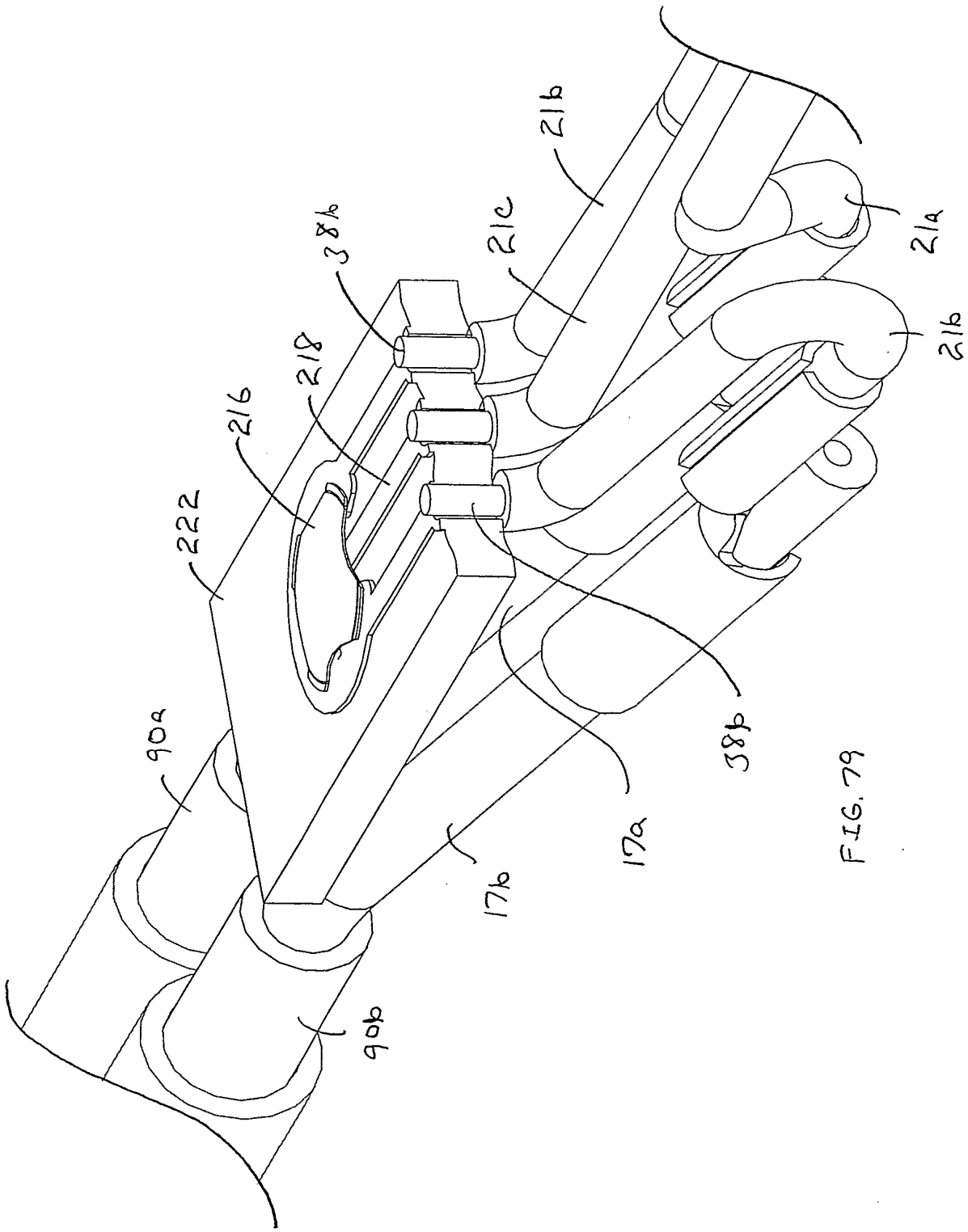


FIG. 79

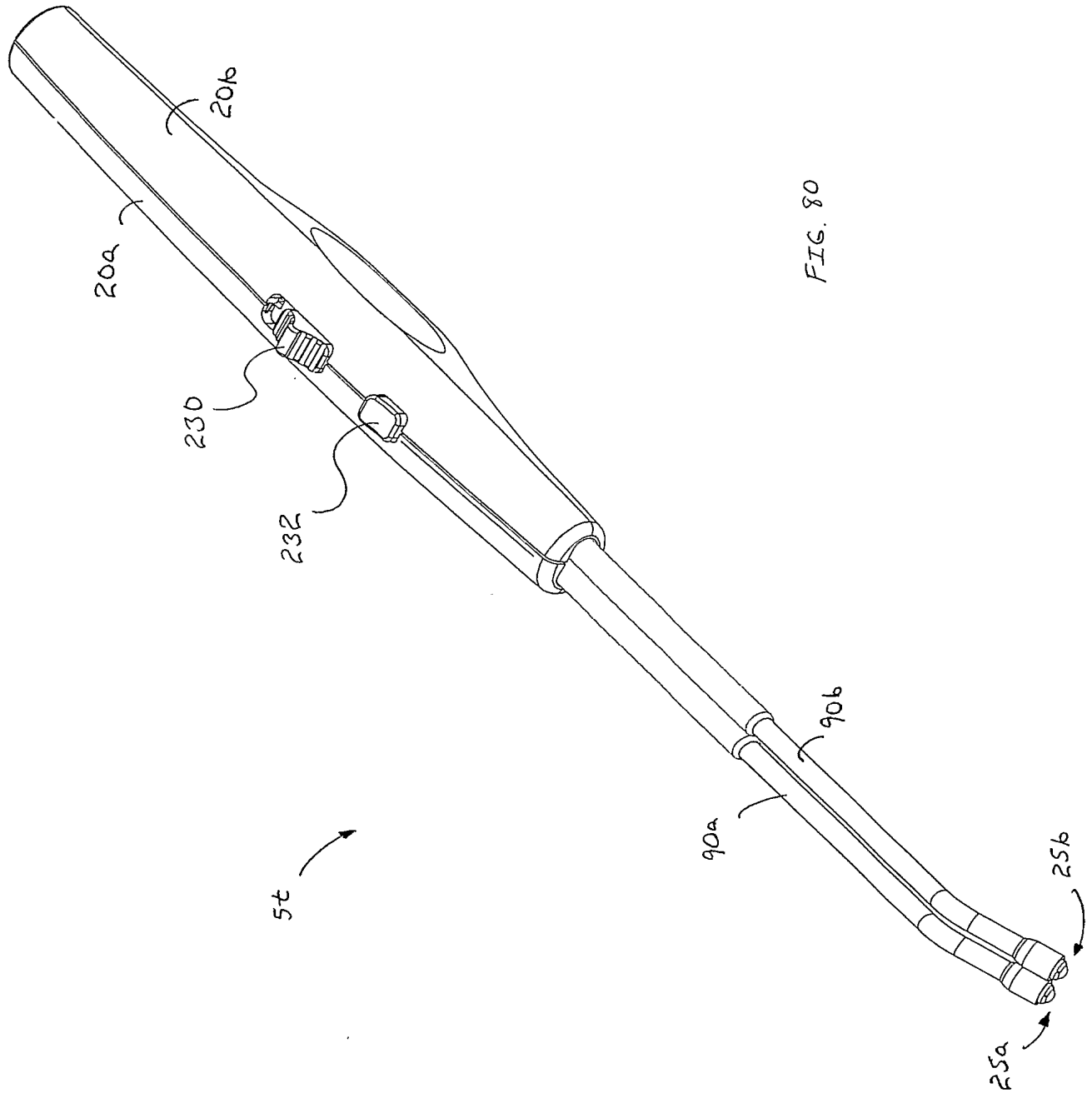


FIG. 80

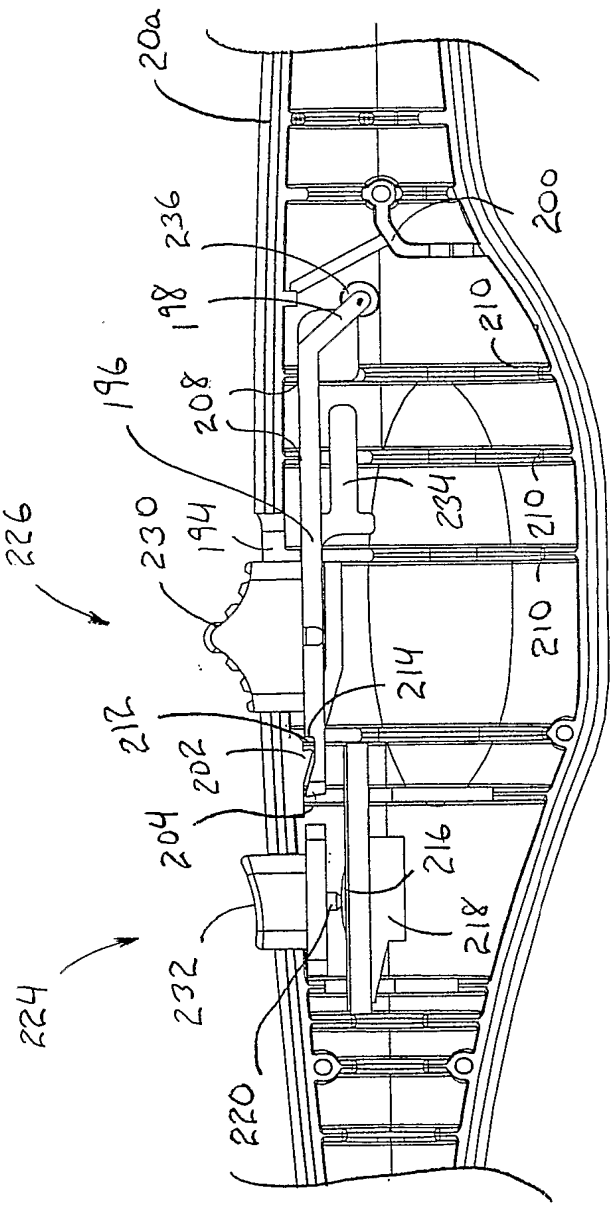

20a
200
236
198
210
196
208
234
210
230
194
226
210
214
212
202
204
216
218
232
224
220

FIG. 81

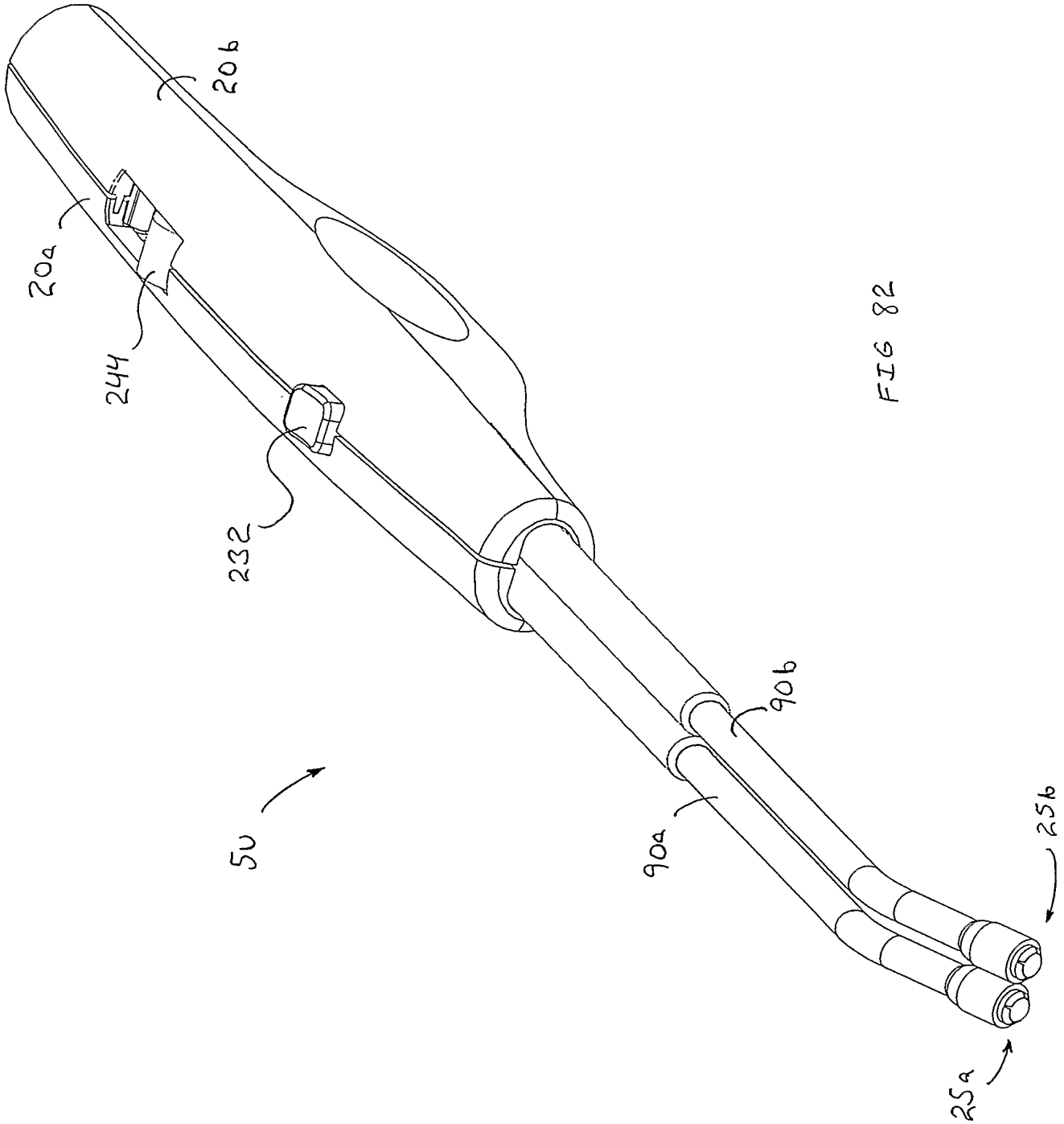


FIG 82

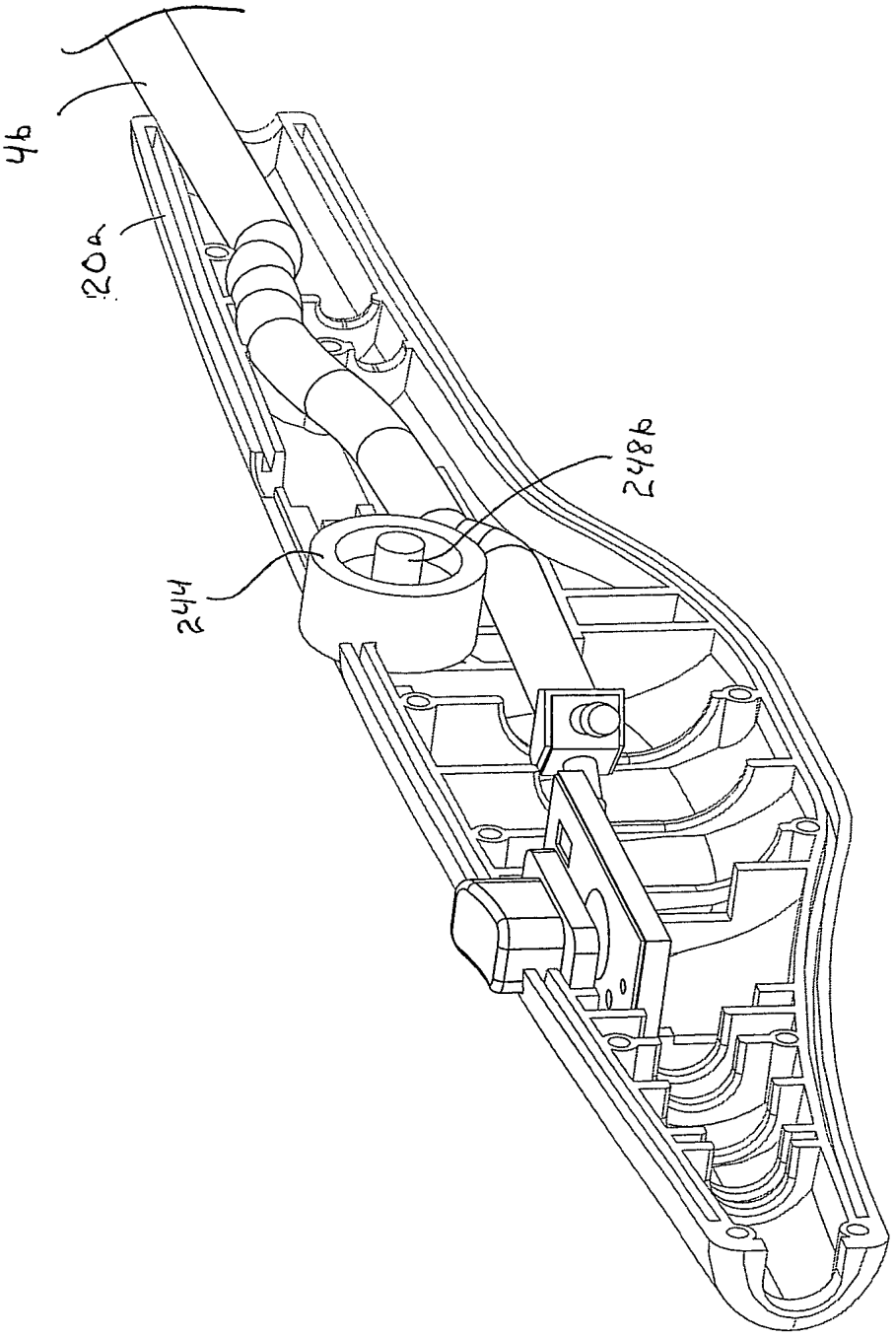


FIG. 83

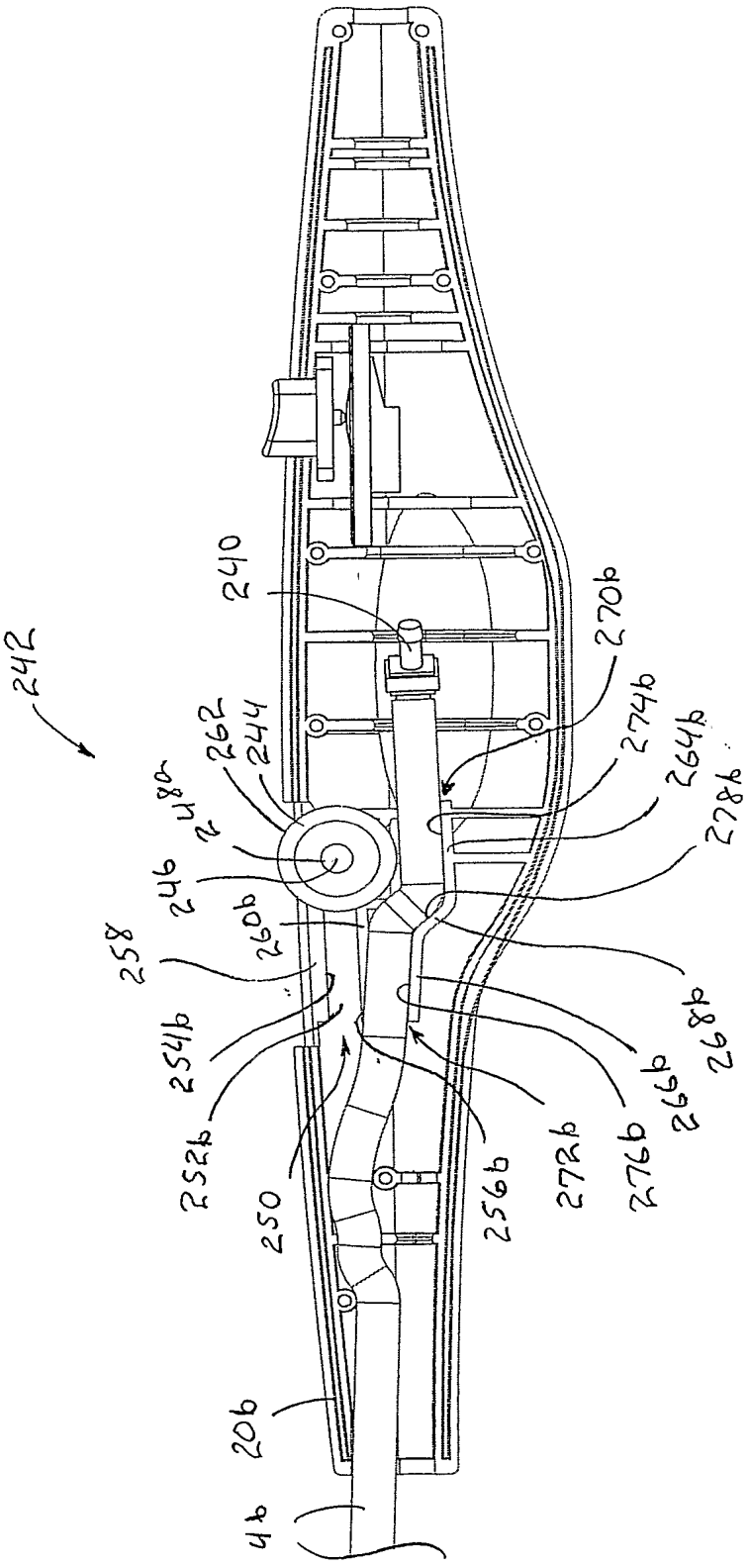

242
240
270b
274b
264b
278b
262
244
248a
246
260b
258
254b
252b
250
256b
272b
276b
266b
268b
206
48

FIG. 84

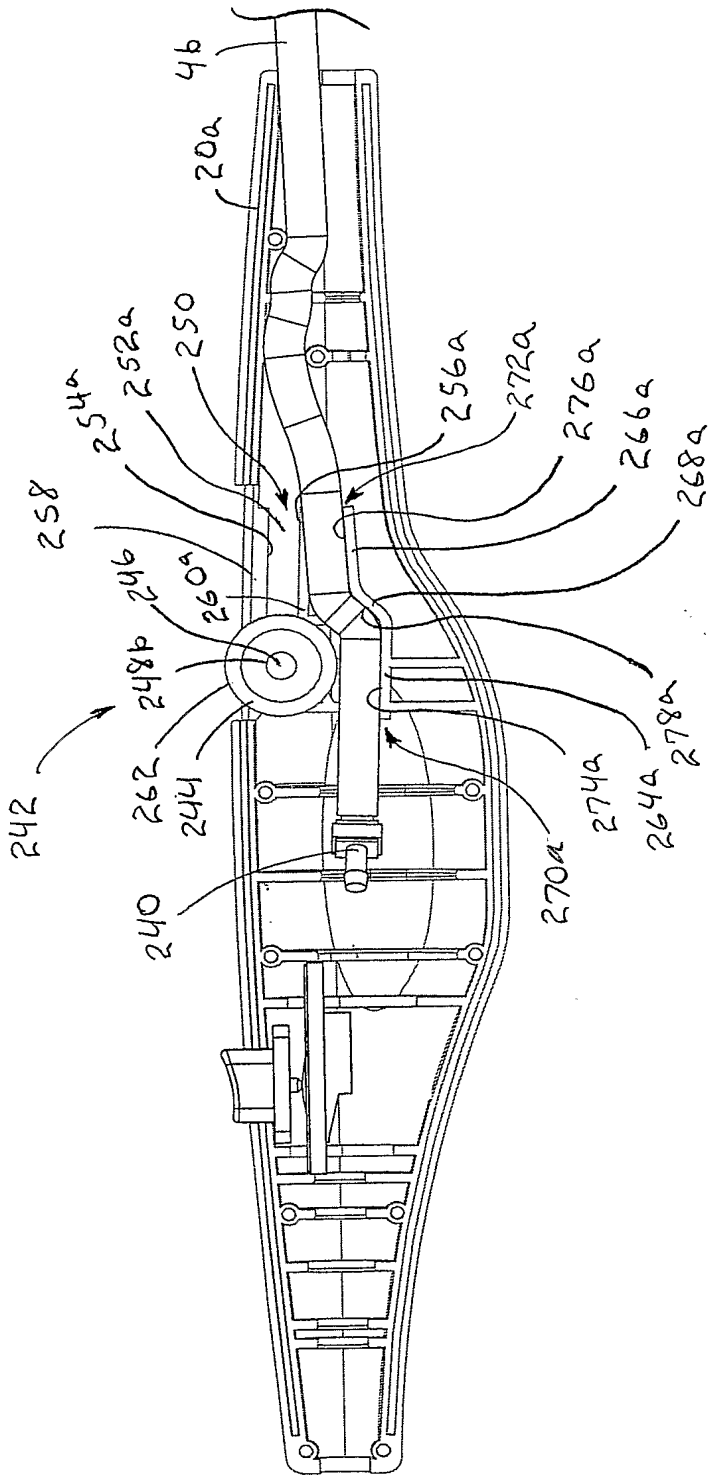

46
20a
250
252a
254a
256a
272a
276a
266a
268a
258
246
260a
248b
262
244
242
240
270a
274a
264a
278a

FIG. 85

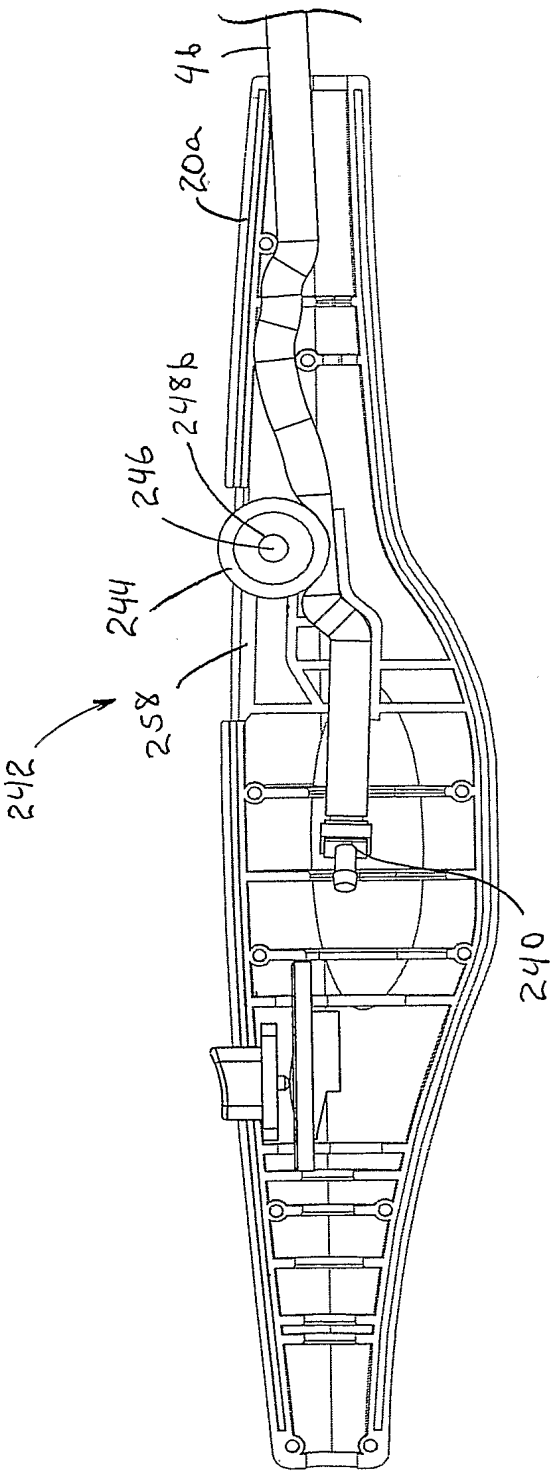


FIG. 86

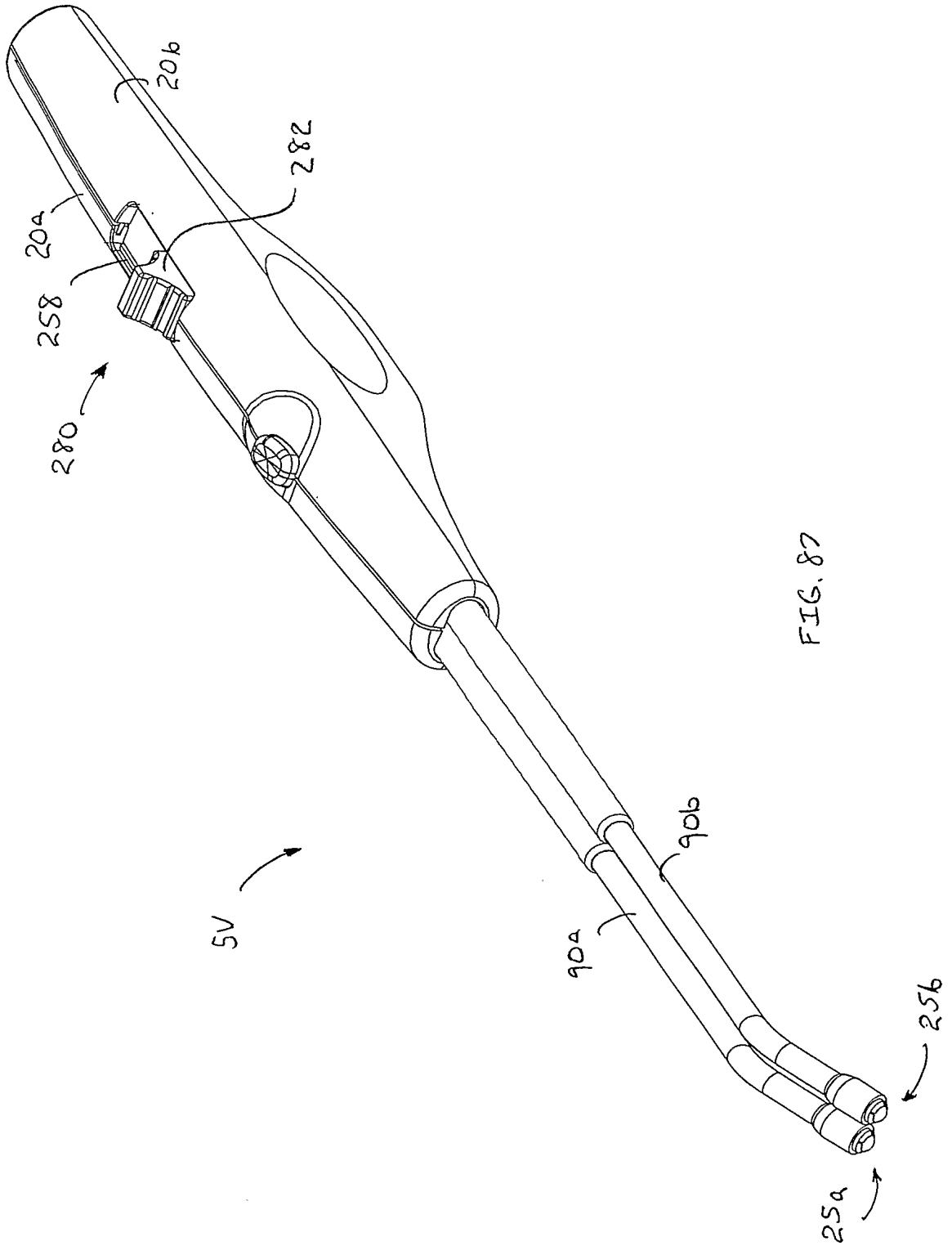


FIG. 87

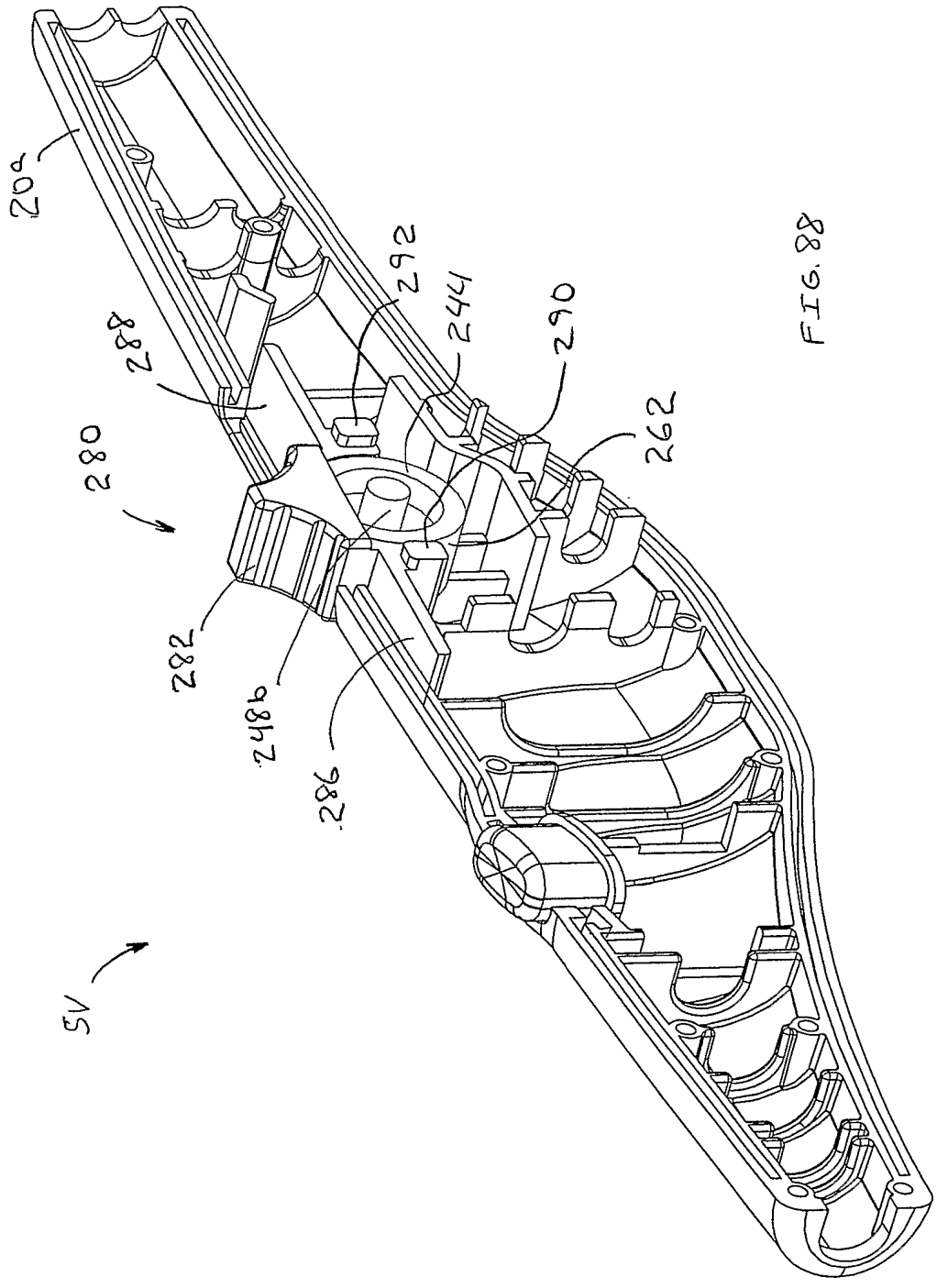


FIG. 88

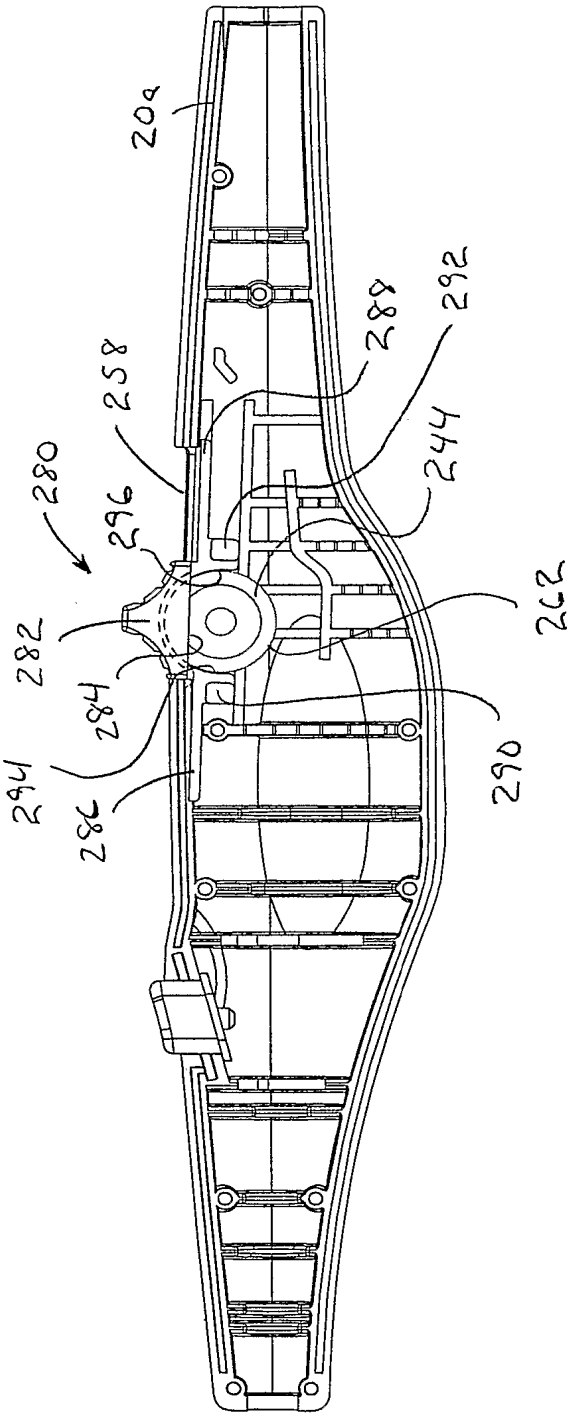


FIG. 89

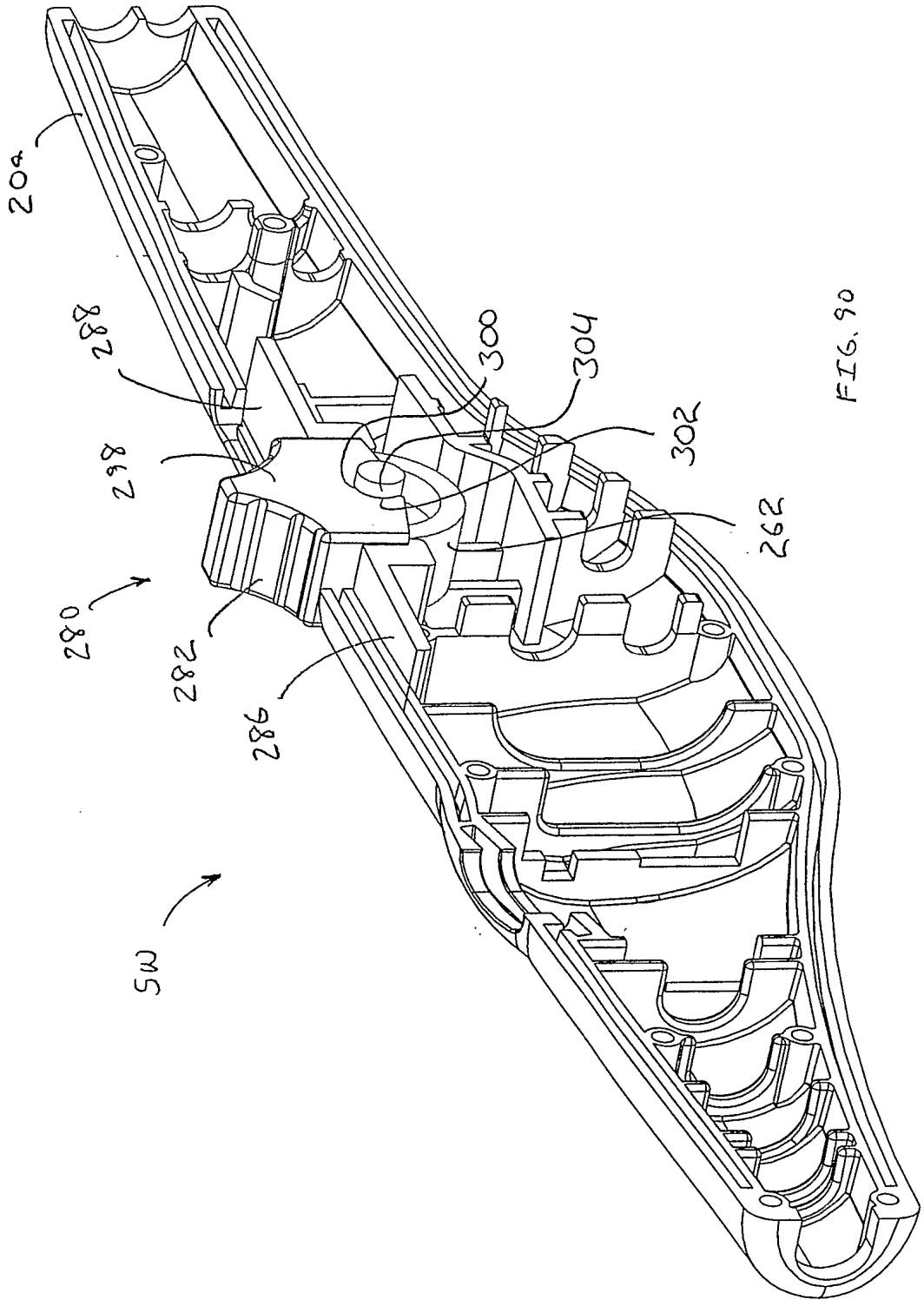


FIG. 90

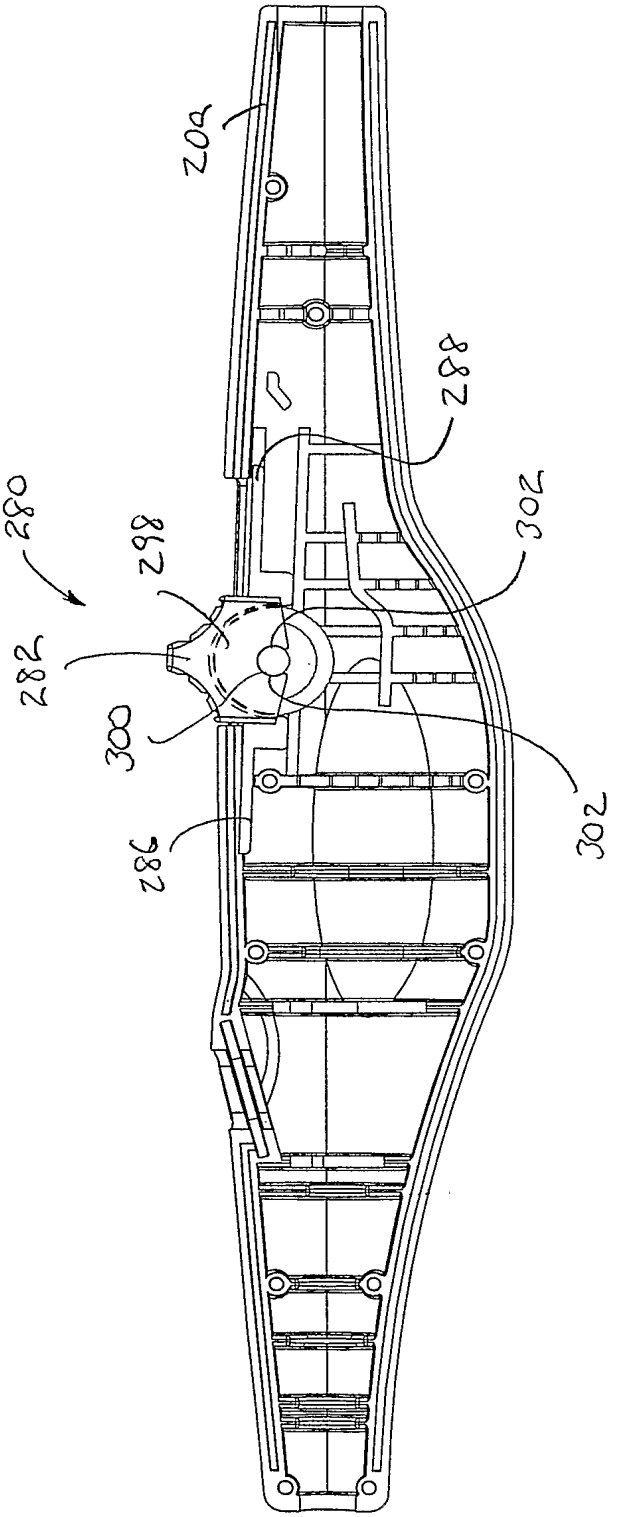


FIG. 91

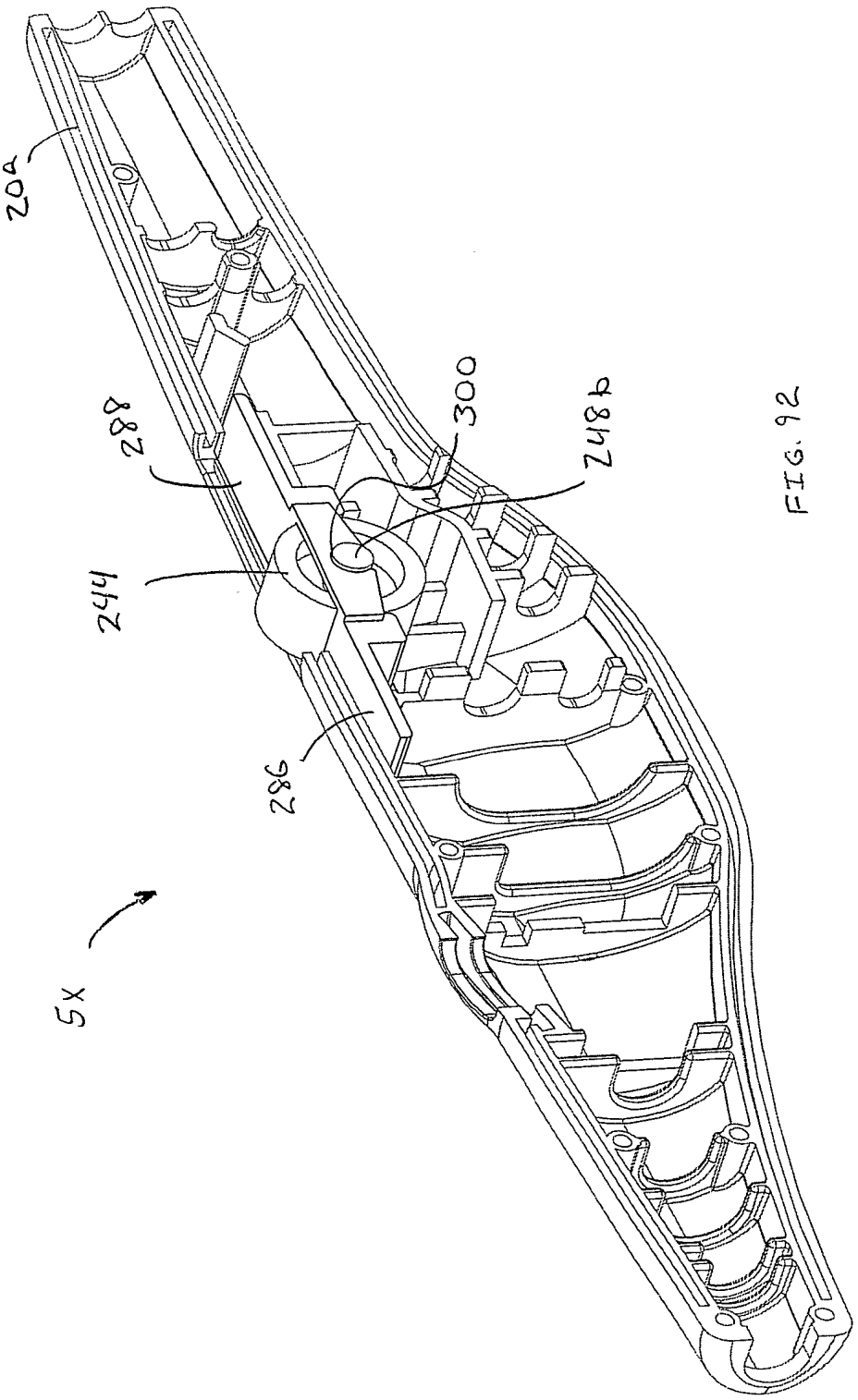


FIG. 92

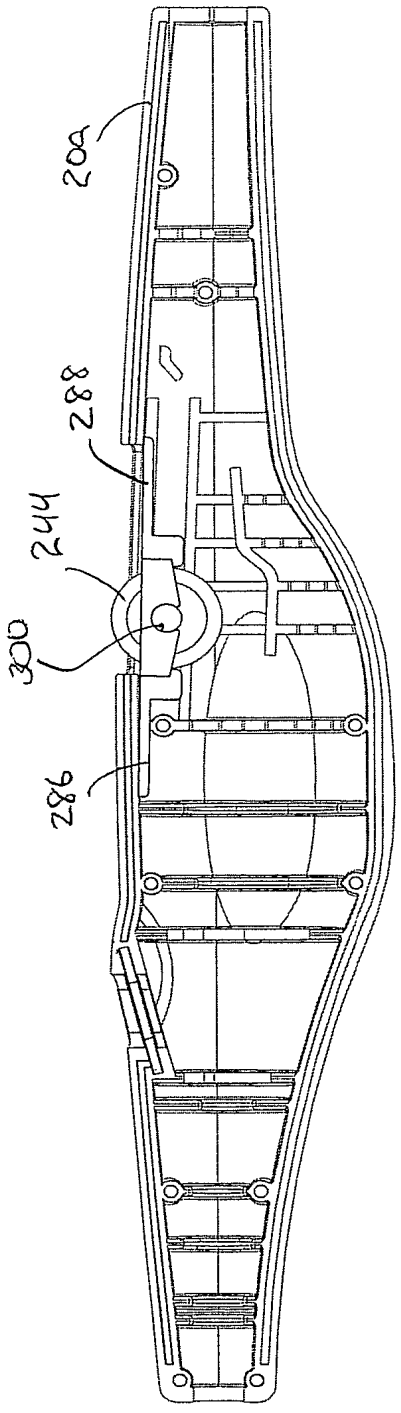


FIG. 93

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/28488

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A 61 B 18/18
US CL : 606/034
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)
U.S. : 606/034, 27-32, 35, 38, 39, 41, 42

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,024,733 A (EGGERS et al.) 15 February 2000, see entire document.	1-137

☐ 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 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
21 October 2002 (21.10.2002)	13 DEC 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Linda C. Dvorak Telephone No. 703/3080858

Form PCT/ISA/210 (second sheet) (July 1998)

Electronic Acknowledgement Receipt

EFS ID:	32028761
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Scott Michael Smith/Juliana Hoffman
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	17713.0001US11
Receipt Date:	12-MAR-2018
Filing Date:	25-AUG-2017
Time Stamp:	18:00:13
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)	2018-03-12_IDS_17713-0001US11.PDF	631336 de6abc779864119c73e46e07d3950b863b2018be	no	5

Warnings:

Information:					
2	Foreign Reference	WO2003024349.pdf	7467624 b07079146544bddb3cdfe47465dff7fed4996f6c	no	174
Warnings:					
Information:					
			Total Files Size (in bytes):	8098960	

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/08a (02-18)
Approved for use through 11/30/2020. 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	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	MANUEL, GEORGE C
Attorney Docket Number	17713.0001US11

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	9943361		2018-04-17	Wolf et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20050288665		2005-12-29	Woloszko et al.	
	2	20090124958		2009-05-14	Li	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]
	1							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C
	Attorney Docket Number	17713.0001US11

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		

If you wish to add additional non-patent literature document citation information please click the Add button Add

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C
	Attorney Docket Number	17713.0001US11

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)	2018-06-11
Name/Print	Scott M. Smith	Registration Number	48,268

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.

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.

Electronic Acknowledgement Receipt

EFS ID:	32865198
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Scott Michael Smith/Juliana Hoffman
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	17713.0001US11
Receipt Date:	11-JUN-2018
Filing Date:	25-AUG-2017
Time Stamp:	17:58:10
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)	2018-06-11_IDS_17713-0001US11.PDF	1034365 c61dc6e417222425fb2cf2e421e39a703e845531	no	4

Warnings:

Information:	
Total Files Size (in bytes):	1034365

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/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	15686265
Filing Date	2017-08-25
First Named Inventor	WOLF
Art Unit	3792
Examiner Name	MANUEL
Attorney Docket Number	17713.0001US11

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	10028780		2018-07-24	Wolf et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20180177542		2018-06-28	Wolf et al.	
	2	20180177546		2018-06-28	Dinger et al.	
	3	20180185085		2018-07-05	Wolf et al.	
	4	20180228533		2018-08-16	Wolf et al.	
	5	20080125626		2008-05-29	Chang et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

	6	20180317997		2018-11-08	Dinger et al.			

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]
	1							

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]
	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

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)	2018-11-26
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.

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.

Electronic Acknowledgement Receipt

EFS ID:	34394375
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Scott Michael Smith/Juliana Hoffman
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	17713.0001US11
Receipt Date:	26-NOV-2018
Filing Date:	25-AUG-2017
Time Stamp:	16:19:12
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)	2018-11-26_IDS_17713-0001US11.PDF	631065 63dcd79a397378fc47c76fa61fbc3240802ce120	no	4

Warnings:

Information:	
Total Files Size (in bytes):	631065

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Scott J. Wolf	Examiner:	George C. Manuel
Serial No.:	15/686,265	Group Art Unit:	3792
Filed:	August 25, 2017	Docket No.:	17713.0001US11
Customer No.:	23552	Confirmation No.:	7653
Title:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Commissioner,

Please consider this Preliminary Amendment before examining the referenced application.

Amendments to the Specification begin on page 2.

Amendments to the Claims begin on page 3.

Remarks begin on page 7.

AMENDMENTS TO THE SPECIFICATION

Please amend the specification beginning at page 1, paragraph 1, as follows:

[0001] This application is a continuation of U.S. [[p]]Patent [[a]]Application Ser. No. 15/272,007, now U.S. Patent No. 9,788,886, filed September 21, 2016, entitled "METHODS AND DEVICES TO TREAT AIRWAYS," which is a continuation of U.S. [[p]]Patent [[a]]Application Ser. No. 14/754,087, now U.S. Patent No. 9,452,010, filed June 29, 2015, which is a continuation of U.S. [[p]]Patent [[a]]Application Ser. No. 14/319,087, now U.S. Patent No. 9,072,597, filed June 30, 2014, which is a continuation-in-part of U.S. [[p]]Patent [[a]]Application Ser. No. 13/495,844, now U.S. Patent No. 8,936,594, filed June 13, 2012, which claims priority to U.S. Provisional Patent Application Ser. Nos. 61/603,864, filed on February 27, 2012, and 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.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A method of treating ~~a patient's~~ an airway in a patient, the method comprising:

advancing a ~~non-expandable, elongate~~ treatment element of a treatment device through a nostril of the patient and into the ~~patient's~~ airway~~, wherein the elongate treatment element includes a tissue-contact surface having a shape~~;

~~contacting~~ expanding the treatment element to contact nasal mucosa lining the airway with at least one [[a]] pair of bipolar[[,]] radiofrequency electrodes on the treatment element ~~protruding from the tissue-contact surface with tissue in the airway~~;

~~applying force against the tissue with the shape of the tissue-contact surface to at least temporarily deform the tissue to a desired shape;~~

delivering radiofrequency energy from the at least one pair of bipolar radiofrequency ~~between the~~ electrodes, to ~~at least one of reshape, remodel, strengthen or~~ change a property of at least one of the nasal mucosa or [[the]] a submucosal tissue underlying the mucosa; and

removing the treatment element from the airway.

2. (Currently Amended) A method as in claim 1, wherein the treatment element comprises a shape memory material, and wherein expanding the treatment element comprises releasing the treatment element from constraint within a delivery device~~ further comprising forming an incision in mucosal tissue of the patient's airway, wherein the tissue to which the radiofrequency energy is delivered comprises submucosal tissue~~.

3. (Currently Amended) A method as in claim [[2]]1, wherein the treatment element comprises an inflatable balloon, and wherein expanding the treatment element comprises passing an inflation fluid into the inflatable balloon through an inflation lumen~~ the incision is formed using a cutting member on the treatment device.~~

4. (Currently Amended) A method as in claim [[2]]1, wherein the radiofrequency energy is delivered to the submucosal tissue, and wherein the submucosal ~~includes~~ tissue is selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

5. (Currently Amended) A method as in claim 1, wherein expanding the treatment element causes expansion of the airway, and wherein the airway remains in at least a partially expanded shape after the treatment element is removed from the airway ~~the shape of the tissue-contact surface comprises a shape selected from the group consisting of a flat shape, a convex shape, and a concave shape~~.

6. (Currently Amended) A method of treating ~~a patient's~~ an airway in a patient, the method comprising:

advancing a treatment element of a treatment device through a nostril of [[a]] the patient and into the ~~patient's~~ airway~~, the treatment device having a radiofrequency electrode needle extending from the treatment element~~;

expanding the treatment element to contact nasal mucosa lining the airway;

~~inserting the radiofrequency electrode needle into tissue of the patient's airway to reach submucosal tissue to be treated;~~

delivering ~~radiofrequency~~ an energy-based treatment ~~using the inserted radiofrequency electrode needle~~ to ~~at least one of reshape, remodel, strengthen or~~ change a property of at least one of the nasal mucosa or a submucosal tissue underlying the nasal mucosa ~~to be treated~~; and

removing the treatment element from the airway.

7. (Currently Amended) The method of claim 6, wherein the energy-based treatment is selected from the group consisting of radiofrequency energy, ultrasound energy, cryotherapy, microwave energy, laser energy, electrical energy and heat energy ~~radiofrequency electrode needle is a first radiofrequency electrode needle of a pair of bipolar radiofrequency needles, and~~

~~wherein delivering radiofrequency energy using the inserted radiofrequency electrode needle comprises delivering radiofrequency energy between the pair of bipolar radiofrequency needles~~.

8. (Currently Amended) The method of claim 6, wherein delivering the energy-based treatment comprises delivering radiofrequency energy from at least one pair of bipolar radiofrequency electrodes on the treatment element ~~the radiofrequency electrode needle is a first radiofrequency electrode needle of multiple radiofrequency electrode needles extending from the treatment element, and wherein delivering radiofrequency energy using the inserted radiofrequency electrode needle comprises selectively delivering energy between one or more sets of the radiofrequency electrode needles or all of the radiofrequency electrode needles~~.

9. (Currently Amended) The method of claim [[6]]8, wherein the treatment element comprises multiple pairs of bipolar radiofrequency electrodes disposed in a pattern, and wherein delivering the energy-based treatment comprises delivering radiofrequency energy between the multiple pairs ~~further comprising applying a grounding pad to the patient, and wherein delivering radiofrequency energy using the inserted radiofrequency electrode needle comprises delivering radiofrequency energy between the radiofrequency electrode needle and the grounding pad~~.

10. (Currently Amended) The method of claim 6, wherein expanding the treatment element comprises allowing a shape memory material of the treatment element to expand to a default shape upon release from a delivery device ~~the radiofrequency electrode needle comprises an insulator on part of the radiofrequency electrode needle, and wherein delivering radiofrequency energy using the inserted radiofrequency electrode needle comprises protecting non-target tissue from the delivered radiofrequency energy using the insulator~~.

11. (Currently Amended) The method of claim 6, wherein expanding the treatment element causes expansion of the airway, and wherein the airway remains in at least a partially expanded shape after the treatment element is removed from the airway ~~further comprising using a mold to shape, configure, or deflect tissue~~.

12. (Currently Amended) The method of claim 6, wherein the energy-based treatment is delivered to the submucosal tissue, and wherein the submucosal ~~includes~~ tissue is selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

REMARKS

Applicant has amended claims 1-12 herein. The amendments add no new matter, and support may be found in Figs. 3, 4A and 4B, as well as paragraphs [0140] and [0141], for example. Favorable consideration is requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

The Commissioner is hereby authorized to charge any additional fees which may be required for entry of these papers or to credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 766-6007

Date: 12/27/18

/Scott M. Smith/

Scott M. Smith
Reg. No.: 48,268

23552
PATENT TRADEMARK OFFICE

Electronic Acknowledgement Receipt

EFS ID:	34704509
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Scott Michael Smith/Juliana Hoffman
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	17713.0001US11
Receipt Date:	27-DEC-2018
Filing Date:	25-AUG-2017
Time Stamp:	14:56:13
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		2018-12-27_PreliminaryAmendment_17713-0001US11.PDF	117071 f336855cff1a08665a7f0e0abb66d802ae379da2	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Specification	2	2
	Claims	3	6
	Applicant Arguments/Remarks Made in an Amendment	7	7
Warnings:			
Information:			
	Total Files Size (in bytes):	117071	

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.
15/686,265	08/25/2017	Scott J. Wolf	17713.0001US11	7653

23552 7590 01/18/2019

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
01/18/2019	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):

USPTO23552@merchantgould.com

Office Action Summary	Application No. 15/686,265	Applicant(s) Wolf et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	AIA 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 _____.

☐ 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) 1-12 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) 1-12 is/are rejected.

8) ☐ Claim(s) _____ 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 8/25/2018 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: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Claim Rejections - 35 USC § 102

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.

> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

Claims 1-12 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Deem et al (US 7,655,243).

Regarding claims 1, 3, 5-9 and 11, Deem et al disclose treating an airway in a patient comprising advancing a treatment element of a treatment device through a nostril of the patient and into the airway. See Fig. 9.

Treatment element 120 is expanded to contact nasal mucosa lining the airway.

Electrode elements 72 and 74 deliver electrical energy and bipolar radiofrequency energy to change a property of at least one of the nasal mucosa or a submucosal tissue underlying the nasal mucosa. See col.7, line 56 to col. 8, line 2 and col. 8, lines 9-12.

The treatment element 100 is removed from the airway following the treatment.

Regarding claims 2 and 10, the treatment element comprises nitinol, a shape memory material. See col. 13, lines 35-44.

Regarding claims 4 and 12, the energy-based treatment is delivered to the submucosal tissue. The tissue includes upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity. See Figs. 10, 11 and 13-32.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GEORGE MANUEL whose telephone number is (571)272-4952.

The examiner can normally be reached on regular business days.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

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 for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/George Manuel/
Primary Examiner
Art Unit: 3792

1/14/2019

Notice of References Cited	Application/Control No. 15/686,265	Applicant(s)/Patent Under Reexamination Wolf et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	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-7655243-B2	02-2010	Deem; Mark E.	A61K38/4886	424/236.1
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

CPC - Searched*		
Symbol	Date	Examiner
A61B17/2816, A61B17/320068, A61B18/02, A61B18/06, A61B18/085, A61B18/1206, A61B18/14, A61B18/1442, A61B18/1445, A61B18/1477, A61B18/1485, A61B18/16, A61B18/1815, A61B18/20, A61B2017/248, A61B2018/00005, A61B2018/00023, A61B2018/0016, A61B2018/00178, A61B2018/0022, A61B2018/00327, A61B2018/00577, A61B2018/00595, A61B2018/00642, A61B2018/00702, A61B2018/00708, A61B2018/00791, A61B2018/00821, A61B2018/00875, A61B2018/00886, A61B2018/0091, A61B2018/00922, A61B2018/00982, A61B2018/00994, A61B2018/0212, A61B2018/0225, A61B2018/0262, A61B2018/1253, A61B2018/126, A61B2018/1425, A61B2018/143, A61B2018/1807, A61B2018/1861, A61B5/01, A61F5/08, A61F5/56, A61F7/10, A61N1/403, A61N5/025, A61N5/0603, A61N5/0625, A61N7/022, F04C2270/041	01/14/2019	GM

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST Search Conducted.	01/14/2019	GM

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/14/2019								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
	10	✓								
	11	✓								
	12	✓								

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	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. Wolf
Art Unit	
Examiner Name	
Attorney Docket Number	17713.0001US11

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	5542916		1996-08-06	Hirsch et al.	
	2	7678069		2010-03-16	Baker et al.	
	3	9125677		2015-09-08	Sobol	
	4	9687288		2017-06-27	Saadat	
	5	9687296		2017-06-27	Wolf et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20170095288		2017-04-06	Wolf et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	2	20170209199		2017-07-27	Wolf et al.	
	3	20170231651		2017-08-17	Dinger et al.	
	4	20020049464		2002-04-25	Donofrio et al.	
	5	20050020901		2005-01-27	Belson	
	6	20120316473		2012-12-13	Bonutti et al.	
	7	20170252089		2017-09-07	Hester	
	8	20170252100		2017-09-07	Wolf et al.	
	9	20170245924		2017-08-31	Wolf et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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]
	1	2001043653	WO		2001-06-21			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	2	2015153696	WO		2015-10-08			

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]
	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/GEORGE MANUEL/	Date Considered	01/14/2019

*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. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

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	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2017-09-12
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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. /G.M./

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.

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. /G.M./

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	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	MANUEL, GEORGE C.
Attorney Docket Number	17713.0001US11

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	9888957		2018-02-13	Wolf et al.	
	2	9913682		2018-03-13	Wolf et al.	
	3	5733280		1998-03-31	Avitall	
	4	7097641		2006-08-29	Arless et al.	
	5	8128617		2012-03-06	Bencini et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20020087155		2002-07-04	Underwood et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C.
	Attorney Docket Number	17713.0001US11

	2	20170360495		2017-12-21	Wolf et al.			
	3	20050240147		2005-10-27	Makower et al.			
	4	20080027423		2008-01-31	CHOI et al.			
	5	20080312644		2008-12-18	Fourkas et al.			
	6	20100241112		2010-09-23	Watson			

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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]
	1	WO 2003024349	WO		2003-03-27			

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]
	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C.
	Attorney Docket Number	17713.0001US11

EXAMINER SIGNATURE			
Examiner Signature	/GEORGE MANUEL/	Date Considered	01/14/2019

*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. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C.
	Attorney Docket Number	17713.0001US11

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)	2018-03-12
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. /G.M./

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.

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. /G.M./

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	15686265
Filing Date	2017-08-25
First Named Inventor	WOLF
Art Unit	3792
Examiner Name	MANUEL
Attorney Docket Number	17713.0001US11

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	10028780		2018-07-24	Wolf et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20180177542		2018-06-28	Wolf et al.	
	2	20180177546		2018-06-28	Dinger et al.	
	3	20180185085		2018-07-05	Wolf et al.	
	4	20180228533		2018-08-16	Wolf et al.	
	5	20080125626		2008-05-29	Chang et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

	6	20180317997		2018-11-08	Dinger et al.			

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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]
	1							

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]
	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/GEORGE MANUEL/	Date Considered	01/14/2019

*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. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

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)	2018-11-26
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. /G.M./

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.

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. /G.M./

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. 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	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. Wolf
Art Unit	3762
Examiner Name	MANUEL, GEORGE C
Attorney Docket Number	17713.0001US11

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	9943361		2018-04-17	Wolf et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20050288665		2005-12-29	Woloszko et al.	
	2	20090124958		2009-05-14	Li	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]
	1							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C
	Attorney Docket Number	17713.0001US11

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		

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/GEORGE MANUEL/	Date Considered	01/14/2019

*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. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C
	Attorney Docket Number	17713.0001US11

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)	2018-06-11
Name/Print	Scott M. Smith	Registration Number	48,268

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. /G.M./

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.

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. /G.M./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"7655243".pn. and shape	USPAT	OR	ON	2019/01/14 20:10
S798	7	(US-10028780-$ | US-15686265-$ | US-20080125626-$ | US-20180177542-$ | US-20180177546-$ | US-20180185085-$ | US-20180228533-$ | US-20180317997-$).DID.	US-PGPUB; USPAT	OR	ON	2019/01/14 13:43
S799	3	(US-15686265-$ | US-20050288665-$ | US-20090124958-$ | US-3943361-$).DID.	US-PGPUB; USPAT	OR	ON	2019/01/14 13:50
S800	10	(US-15686265-$ | US-20020087155-$ | US-20050240147-$ | US-20080027423-$ | US-20080312644-$ | US-20100241112-$ | US-20170360495-$ | US-3128617-$ | US-3888957-$ | US-3913682-$ | US-5733280-$).DID.	US-PGPUB; USPAT	OR	ON	2019/01/14 13:57
S801	6	(US-15686265-$ | US-15772528-$ | US-20050234439-$ | US-20100174283-$ | US-20120298105-$ | US-3763723-$ | US-3788886-$ | US-3801752-$).DID.	US-PGPUB; USPAT	OR	ON	2019/01/14 14:02
S802	13	(US-15686265-$ | US-20020049464-$ | US-20050020901-$ | US-20120316473-$ | US-20170095288-$ | US-20170209199-$ | US-20170231651-$ | US-20170245924-$ | US-20170252089-$ | US-20170252100-$ | US-3125677-$ | US-3687288-$ | US-3687296-$ | US-5542916-$).DID.	US-PGPUB; USPAT	OR	ON	2019/01/14 14:11
S804	114	(US-15686265-$ | US-1887605-$ | US-20020016588-$ | US-20020128641-$ | US-20030144659-$ | US-20030208194-$ | US-20030225403-$ | US-20040220644-$ | US-20050119643-$ | US-20050222565-$ | US-20060235377-$ | US-20060253117-$ | US-20060276817-$ | US-20070066944-$ | US-20070073282-$ | US-20070219600-$ | US-20080027480-$ | US-20080082090-$ | US-20090018485-$ | US-20090143821-$ | US-20090292358-$ | US-20100144996-$ | US-20100152730-$ | US-20110009737-$ | US-20110282268-$ | US-20120039954-$ | US-20120078377-$ | US-20120316557-$ | US-20120323227-$ | US-20120323232-$ | US-20130218158-$ | US-20140088463-$ | US-20140114233-$ | US-20150202003-$ | US-20160287315-$ | US-20160361112-$ | US-20170007316-$ | US-20170014258-$ | US-3072597-$ | US-3137345-$ | US-3179964-$ | US-3179967-$ | US-3237924-$ | US-3317781-$ | US-3317782-$ | US-3415194-$ | US-3433463-$ | US-3452010-$ | US-3452087-$ | US-3486278-$ | US-3526571-$ | US-3936594-$ | US-3986301-$ | US-5045549-$ | US-	US-PGPUB; USPAT	OR	ON	2019/01/14 14:22

		5096033-$ | US-5102907-$ | US-5109268-$ | US-5126657-$ | US-5131579-$ | US-5139546-$ | US-5152143-$ | US-5165173-$ | US-5179803-$ | US-5210355-$ | US-5228079-$ | US-5231569-$ | US-5293941-$ | US-5309386-$ | US-5348008-$ | US-5371926-$ | US-5383181-$ | US-5391028-$ | US-5416491-$ | US-5425151-$ | US-5431174-$ | US-5451013-$ | US-5502574-$ | US-5533499-$ | US-5551310-$ | US-5562036-$ | US-5575969-$ | US-5589235-$ | US-5624439-$ | US-5659106-$ | US-5674191-$ | US-5707349-$ | US-5718702-$ | US-5728094-$ | US-5730719-$ | US-5738114-$ | US-5743870-$ | US-5743904-$ | US-5746224-$ | US-5800429-$ | US-5807306-$ | US-5816095-$ | US-5817049-$ | US-5820580-$ | US-5823197-$ | US-5827277-$ | US-5843021-$ | US-5843077-$ | US-5846235-$ | US-5879349-$ | US-5911027-$ | US-5938659-$ | US-5978781-$ | US-7055523-$ | US-7114495-$ | US-7322993-$ | US-7416550-$ | US-7442191-$ | US-7780730-$ | US-7824394-$ | US-7850683-$).DID.				
S805	1	"15686265"	US-PGPUB; USPAT	OR	ON	2019/01/14 14:28
S806	136	(airway and radiofrequency same electrodes and treat$4 and (mucosa or submucosal)) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	US-PGPUB; USPAT	OR	ON	2019/01/14 14:33
S807	71	(airway and radiofrequency same electrodes and treat$4 and (mucosa or submucosal)) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR	US-PGPUB	OR	ON	2019/01/14 14:34

		A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)				
S808	25	(airway and radiofrequency same electrodes and treat$4 and (mucosa or submucosal) and expand$4 with nasal) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	USPAT	OR	ON	2019/01/14 15:14
S809	1	"7655243".pn. and electrode	USPAT	OR	ON	2019/01/14 17:34
S810	1	"7655243".pn. and expand$4	USPAT	OR	ON	2019/01/14 17:40
S811	1	"7655243".pn. and "22"	USPAT	OR	ON	2019/01/14 17:46
S812	1	"7655243".pn. and "100"	USPAT	OR	ON	2019/01/14 17:47
S813	1	"7655243".pn. and bipolar	USPAT	OR	ON	2019/01/14 18:11
S815	1	"7655243".pn. and bipolar and radiofrequency	USPAT	OR	ON	2019/01/14 18:12

EAST Search History (Interference)

< This search history is empty>

1/ 14/ 2019 8:43:16 PM
C:\ Users\ gmanuel\ Documents\ EAST\ Workspaces\ 11-19-18.wsp

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	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. Wolf
Art Unit	
Examiner Name	
Attorney Docket Number	17713.0001US11

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	4887605		1989-12-19	Angelsen et al.	
	2	5348008		1994-09-20	Bomn et al.	
	3	5533499		1996-07-09	Johnson	
	4	5624439		1997-04-29	Edwards et al.	
	5	5674191		1997-10-07	Edwards et al.	
	6	5707349		1998-01-13	Edwards	
	7	5718702		1998-02-17	Edwards	
	8	5728094		1998-03-17	Edwards	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	9	5730719		1998-03-24	Edwards	
	10	5738114		1998-04-14	Edwards	
	11	5743870		1998-04-28	Edwards	
	12	5743904		1998-04-28	Edwards	
	13	5746224		1998-05-05	Edwards	
	14	5800429		1998-09-01	Edwards	
	15	5807306		1998-09-15	Shapland et al.	
	16	5816095		1998-10-06	Nordell, II et al.	
	17	5817049		1998-10-06	Edwards	
	18	5820580		1998-10-13	Edwards et al.	
	19	5823197		1998-10-20	Edwards	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	20	5827277		1998-10-27	Edwards	
	21	5843021		1998-12-01	Edwards et al.	
	22	5843077		1998-12-01	Edwards	
	23	5846235		1998-12-08	Pasricha et al.	
	24	5879349		1999-03-09	Edwards	
	25	6045549		2000-04-04	Smethers et al.	
	26	6096033		2000-08-01	Tu et al.	
	27	6102907		2000-08-15	Smethers et al.	
	28	6109268		2000-08-29	Thapliyal et al.	
	29	6126657		2000-10-03	Edwards et al.	
	30	6131579		2000-10-17	Thorson et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	31	6139546		2000-10-31	Koenig et al.	
	32	6152143		2000-11-28	Edwards	
	33	6165173		2000-12-26	Kamdar et al.	
	34	6179803		2001-01-30	Edwards et al.	
	35	6210355		2001-04-03	Edwards et al.	
	36	6228079		2001-05-08	Koenig	
	37	6231569		2001-05-15	Bek et al.	
	38	6293941		2001-09-25	Strul et al.	
	39	6309386		2001-10-30	Bek	
	40	6371926		2002-04-16	Thorson et al.	
	41	6383181		2002-05-07	Johnston et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	42	6391028		2002-05-21	Fanton et al.	
	43	6416491		2002-07-09	Edwards et al.	
	44	6425151		2002-07-30	Barnett	
	45	6431174		2002-08-13	Knudson et al.	
	46	6451013		2002-09-17	Bays et al.	
	47	6551310		2003-04-22	Ganz et al.	
	48	6562036		2003-05-13	Ellman et al.	
	49	6575969		2003-06-10	Rittman et al.	
	50	6589235		2003-07-08	Wong et al.	
	51	6659106		2003-12-09	Hovda et al.	
	52	6911027		2005-06-28	Edwards et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	53	6978781		2005-12-27	Jordan	
	54	7055523		2006-06-06	Brown	
	55	7114495		2006-10-03	Lockwood, Jr.	
	56	7322993		2008-01-29	Metzger et al.	
	57	7416550		2008-08-26	Protsenko et al.	
	58	7442191		2008-10-28	Hovda et al.	
	59	7780730		2010-08-24	Saidi	
	60	7824394		2010-11-02	Manstein	
	61	7850683		2010-12-14	Elkins et al.	
	62	8137345		2012-03-20	McNall, III et al.	
	63	8317781		2012-11-27	Owens et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	64	8317782		2012-11-27	Ellman et al.	
	65	8936594		2015-01-20	Wolf et al.	
	66	8986301		2015-03-24	Wolf et al.	
	67	9072597		2015-07-07	Wolf et al.	
	68	9179964		2015-11-10	Wolf et al.	
	69	9179967		2015-11-10	Wolf et al.	
	70	9237924		2016-01-19	Wolf et al.	
	71	9415194		2016-08-16	Wolf et al.	
	72	9433463		2016-09-06	Wolf et al.	
	73	9452010		2016-09-27	Wolf et al.	
	74	9452087		2016-01-27	Holm et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	75	9486278		2016-11-08	Wolf et al.	
	76	9526571		2016-12-27	Wolf et al.	
	77	5938659		1999-08-17	Tu	
	78	6502574		2003-01-07	Stevens	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20020016588		2002-02-07	Wong et al.	
	2	20020128641		2002-09-12	Underwood et al.	
	3	20030144659		2003-07-31	Edwards	
	4	20030208194		2003-11-06	Hovda et al.	
	5	20030225403		2003-12-04	Woloszko et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	6	20040220644		2004-11-04	Shalev et al.	
	7	20050119643		2005-06-02	Sobol et al.	
	8	20050222565		2005-10-06	Manstein	
	9	20060235377		2006-10-19	Earley	
	10	20060253117		2006-11-09	Hovda et al.	
	11	20060276817		2006-12-07	Vassallo et al.	
	12	20070066944		2007-03-22	Nyte	
	13	20070073282		2007-03-29	McGarrigan et al.	
	14	20070219600		2007-09-20	Gertner et al.	
	15	20080027480		2008-01-31	van der Burg et al.	
	16	20080082090		2008-04-03	Manstein	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	17	20090018485		2009-01-15	Krespi et al.	
	18	20090143821		2009-06-04	Stupak	
	19	20090292358		2009-11-26	Saidi	
	20	20100144996		2010-06-10	Kennedy et al.	
	21	20100152730		2010-06-17	Makower et al.	
	22	20110009737		2011-01-13	Manstein	
	23	20110282268		2011-11-17	Baker et al.	
	24	20120039954		2012-02-16	Cupit et al.	
	25	20120078377		2012-03-29	Gonzales et al.	
	26	20120316557		2012-12-13	Sartor et al.	
	27	20120323227		2012-12-20	Wolf et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	28	20120323232		2012-12-20	Wolf et al.	
	29	20130218158		2013-08-22	Danek et al.	
	30	20140088463		2014-03-27	Wolf et al.	
	31	20140114233		2014-04-24	Deem et al.	
	32	20150202003		2015-07-23	Wolf et al.	
	33	20160287315		2016-10-06	Wolf et al.	
	34	20160361112		2016-12-15	Wolf et al.	
	35	20170007316		2017-01-12	Wolf et al.	
	36	20170014258		2017-01-19	Wolf et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	1	101325919	CN		2008-12-17			
	2	2007037895	WO		2007-04-05			
	3	2007134005	WO		2007-11-22			
	4	2015047863	WO		2015-04-02			
	5	2015048806	WO		2015-04-02			

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.	T5
	1	Cole, "Biophysics of nasal airflow: a review," Am J Rhinol., 14(4):245-249, Jul-Aug. 2000.	
	2	Cole, "The four components of the nasal valve," Am J Rhinol., 17(2):107-110, Mar-Apr. 2003.	
	3	International Search Report and Written Opinion for PCT/US15/023742, mailed June 29, 2015, 5 pages.	
	4	International Search Report and Written Opinion for PCT/US2012/042316, mailed Aug. 24, 2012, 15 pages.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

	5	International Search Report and Written Opinion for PCT/US2014/054726, mailed December 23, 2014, 5 pages.
	6	Kjaergaard et al., "Relation of nasal air flow to nasal cavity dimensions," Arch Otolaryngol Head Neck Surg., 135 (6):565-570, Jun 2009.
	7	Singapore Search Report for Application Serial No. 201309238-2, Jun. 9, 2014 for pp. 1-27.
	8	Stupak, "Endonasal repositioning of the upper lateral cartilage and the internal nasal valve," Ann Otol Rhinol Laryngol., 120(2):88-94, Feb. 2011.
	9	Buckley et al., "High-resolution spatial mapping of shear properties in cartilage," J Biomech., 2010 Mar 3;43 (4):796-800, Epub Nov. 5, 2009.
	10	Buckley et al., "Mapping the depth dependence of shear properties in articular cartilage," J Biomech., 41 (11):2430-2437, Epub Jul. 10, 2008.
	11	Griffin et al., "Effects of enzymatic treatments on the depth-dependent viscoelastic shear properties of articular cartilage," J Orthop Res., 32(12):1652-1657, Epub Sep. 5, 2014.
	12	Silverberg et al., "Structure-function relations and rigidity percolation in the shear properties of articular cartilage," Biophys J., 107(7):1721-1730, Oct. 7, 2014.
	13	Stewart et al., "Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale," Otolaryngol Head Neck Surg., 130(2):157-163, Feb. 2004.
	14	Stupak, "A Perspective on the Nasal Valve," Dept. of Otorhinolaryngology, Albert Einstein College of Medicine, Nov. 6, 2009.

If you wish to add additional non-patent literature document citation information please click the Add button Add

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

EXAMINER SIGNATURE			
Examiner Signature	/GEORGE MANUEL/	Date Considered	01/14/2019

*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. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. Wolf
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US11

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	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2017-08-25
Name/Print	Christopher P. Ziolkowski/	Registration Number	73,729

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. /G.M./

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.

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. /G.M./

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	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. WOLF
Art Unit	3762
Examiner Name	MANUEL, GEORGE C.
Attorney Docket Number	17713.0001US11

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	9788886		2017-10-17	Wolf et al.	
	2	9801752		2017-10-31	Wolf et al.	
	3	9763723		2017-09-19	Saadat	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20050234439		2005-10-20	Underwood	
	2	20100174283		2010-07-08	McNall	
	3	20120298105		2012-11-29	Osorio	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15686265
Filing Date	2017-08-25
First Named Inventor	Scott J. WOLF
Art Unit	3762
Examiner Name	MANUEL, GEORGE C.
Attorney Docket Number	17713.0001US11

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	199907299	WO		1999-02-18			
	2	2010077980	WO		2010-07-08			
	3	2012174161	WO		2012-12-20			

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]
	1	Supplementary European Search Report for Application No. 15772528, mailed September 26, 2017, 7 pages.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/GEORGE MANUEL/	Date Considered	01/14/2019

*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. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	Scott J. WOLF
	Art Unit	3762
	Examiner Name	MANUEL, GEORGE C.
	Attorney Docket Number	17713.0001US11

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)	2017-12-18
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. /G.M./

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.

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. /G.M./

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 15/686,265	Filing Date 08/25/2017	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ 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))	minus 20 =	*		x $40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $210 =	
☐ 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	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	02/15/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $230 =	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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ 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.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/RENEE D HAWKINS/
*** 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.	

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.

REMARKS

Claims 1-12 are pending and stand rejected by the Office Action of January 18, 2019. This Amendment amends claims 1-12 and adds new claims 13-16. The amendments add no new matter. For example, support for the amendments may be found in Figs. 3, 4B and 7, as well as paragraphs [0151]-[0154]. Support for new claims 13 and 15 may be found in paragraph [0039], and support for new claims 14 and 16 may be found in paragraph [269]. Applicant respectfully requests examination and consideration of claims 1-16.

Rejection under 35 U.S.C. 102

Claims 1-12 stand rejected under 35 U.S.C. § 102, as allegedly being anticipated by U.S. Patent No. 7,655,243, to Deem et al. (hereinafter "Deem"). Applicant respectfully traverses this rejection.

Although Applicant disagrees with the Office Action's contention that Deem anticipates claims 1-12 as originally filed, in an effort to expedite prosecution, Applicant has amended claims 1-12 to specify that the method involves using a cryotherapy treatment element to remove energy (claim 1) or deliver a cryotherapy treatment (claim 6). Deem never teaches or suggests using cryotherapy. In fact, the sole purpose of applying energy described by Deem is to porate target cells to enhance uptake of a nerve toxin. It is doubtful that cryogenic cooling would work for such a purpose, but in any event, Deem does not teach the use of cryotherapy.

For at least this reason, Applicant respectfully submits that claims 1-12 are patentable over Deem. Applicant thus respectfully requests withdrawal of the rejection of claims 1-12 under 35 U.S.C. § 102.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding, in this application, that previously pending claims are not patentable over the cited references. Rather any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue, at a later date, any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior

prosecution. Accordingly, reviews of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

In view of the foregoing, Applicant respectfully submits that this application now stands in condition for allowance. Should the Examiner believe that a telephone interview would further the prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

The Commissioner is hereby authorized to charge any additional fees which may be required for entry of these papers or to credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903

Date: February 15, 2019

/ Christopher P. Ziolkowski /
Christopher P. Ziolkowski
Reg. No.: 73,729
Direct: (612) 766-6025

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A method of treating an airway in a patient, the method comprising:

advancing a cryotherapy treatment element of a treatment device through a nostril of the patient and into the airway;

expanding the cryotherapy treatment element to contact nasal mucosa lining the airway ~~with at least one a pair of bipolar, radiofrequency electrodes on the treatment element~~;

~~delivering radiofrequency~~ removing energy from submucosal tissue underlying the nasal mucosa by applying cryogenic cooling with the cryotherapy treatment element ~~from the at least one pair of bipolar radiofrequency electrodes~~, to change a property of ~~at least one of the nasal mucosa or a~~ the submucosal tissue ~~underlying the mucosa~~; and

removing the treatment element from the airway.

2. (Currently Amended) A method as in claim 1, wherein the cryotherapy treatment element comprises a shape memory material, and wherein expanding the cryotherapy treatment element comprises releasing the cryotherapy treatment element from constraint within a delivery device.

3. (Currently Amended) A method as in claim 1, wherein the cryotherapy treatment element comprises an inflatable balloon, and wherein expanding the cryotherapy treatment element comprises passing liquid nitrogen ~~an inflation fluid~~ into the inflatable balloon through an inflation lumen.

4. (Currently Amended) A method as in claim 1, wherein ~~the radiofrequency energy is delivered to the submucosal tissue, and wherein~~ the submucosal tissue is selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal

turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

5. (Currently Amended) A method as in claim 1, wherein expanding the cryotherapy treatment element causes expansion of the airway, and wherein the airway remains in at least a partially expanded shape after the cryotherapy treatment element is removed from the airway.

6. (Currently Amended) A method of treating an airway in a patient, the method comprising:

advancing a cryotherapy treatment element of a treatment device through a nostril of the patient and into the airway;

~~expanding~~ contacting the cryotherapy treatment element ~~to contact~~ with nasal mucosa lining the airway;

delivering ~~an energy-based~~ a cryotherapy treatment by circulating a low-temperature liquid through the cryotherapy treatment element to change a property of ~~at least one of the nasal mucosa or~~ a submucosal tissue underlying the nasal mucosa; and

removing the treatment element from the airway.

7. (Currently Amended) The method of claim 6, wherein the cryotherapy treatment element is configured to deliver the cryotherapy treatment uniformly over an entire outer surface of the cryotherapy treatment element ~~energy-based treatment is selected from the group consisting of radiofrequency energy, ultrasound energy, cryotherapy, microwave energy, laser energy, electrical energy and heat energy~~.

8. (Currently Amended) The method of claim 6, wherein delivering the ~~energy-based~~ cryotherapy treatment comprises delivering cryotherapy to a selected tissue depth in order to target the cryotherapy treatment at a specific submucosal tissue ~~radiofrequency energy from at least one pair of bipolar radiofrequency electrodes on the treatment element~~.

9. (Currently Amended) The method of claim [[8]]6, wherein the cryotherapy treatment element comprises a balloon ~~multiple pairs of bipolar radiofrequency electrodes disposed in a~~

~~pattern~~, and wherein circulating the low-temperature liquid comprises inflating the balloon with liquid nitrogen ~~delivering the energy-based treatment comprises delivering radiofrequency energy between the multiple pairs~~.

10. (Currently Amended) The method of claim 6, wherein ~~expanding~~ contacting the cryotherapy treatment element with the nasal mucosa comprises allowing a shape memory material of the cryotherapy treatment element to expand to a default shape upon release from a delivery device.

11. (Currently Amended) The method of claim 6, ~~wherein~~ further comprising expanding the cryotherapy treatment element, wherein expanding the cryotherapy treatment element causes expansion of the airway~~, and wherein the airway remains in at least a partially expanded shape after the treatment element is removed from the airway~~.

12. (Currently Amended) The method of claim 6, wherein ~~the energy-based treatment is delivered to the submucosal tissue, and wherein~~ the submucosal tissue is selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and swell bodies on a floor of the nasal cavity.

13. (New) The method of claim 1, wherein removing the energy comprises changing the property of the submucosal tissue without reshaping the submucosal tissue.

14. (New) The method of claim 1, wherein the submucosal tissue is located in the airway away from the nasal valve.

15. (New) The method of claim 1, wherein delivering the cryotherapy treatment comprises changing the property of the submucosal tissue without reshaping the submucosal tissue.

16. (New) The method of claim 1, wherein the submucosal tissue is located in the airway away from the nasal valve.

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph [0039] of the specification with the following paragraph:

[0039] In various embodiments, the treated mucosal tissue may be located in the nasal valve and/or a part of the nasal airway other than an internal nasal valve of the airway, such as the tissues listed above. The method may further involve applying force to the mucosal tissue with the treatment element before, during and/or after delivering the energy based therapy to deform the mucosal tissue. In some embodiments, delivering the energy based therapy may ~~modifies~~ modify at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue. The treated underlying tissue may include, for example, cartilage, submucosa, muscle, ligament and/or tendon. Optionally, the method may also include cooling the mucosal tissue and/or another tissue in the nasal airway.

Please replace paragraph [0149] of the specification with the following paragraph:

[0149] In some embodiments, the treatment element 32 may be configured to deliver heat energy to the nasal valve. In such embodiments, the treatment element 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 nasal tissue. In some embodiments, a high-temperature fluid heating element may comprise flow channels which place high-temperature fluids into conductive contact with nasal tissues (e.g. through a membrane wall) without injecting such fluids into the ~~patients~~ 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.

Please replace paragraph [0153] of the specification with the following paragraph:

[0153] In some embodiments, the treatment element 32 may be a balloon with energy delivery elements positioned at locations where energy transfer is sufficient or optimal to effect change in breathing. Such a balloon may be configured to deliver energy while the balloon is in an inflated state, thereby providing a dual effect of repositioning tissue and delivering energy to effect a change the nasal valve. In other embodiments, a balloon may also deliver heat by circulating a fluid of elevated temperature though the balloon during treatment. The balloon can also ~~delivery~~ deliver cryotherapy (e.g. by circulating a low-temperature liquid such as liquid nitrogen) while it is enlarged to increase the nasal valve diameter or otherwise alter the shape of a nasal valve. FIG. 7 illustrates an example of an energy-delivery balloon being inserted into a patient's nose for treatment. 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 for a 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 valve tissue to a desired depth (as shown for example in FIG. 4D and in other embodiments below).

Conf. No. 7653

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	WOLF, Scott J.	Examiner:	MANUEL, George C.
Appl. No.:	15/686,265	Art Unit:	3792
Filed:	2017-08-25	Dkt No.:	17713.0001US11
Title:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		

AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Examiner Manuel,

In response to the Non-Final Office Action of January 18, 2019, please consider the following.

Amendments to the specification begin on page 2.

Amendments to the claims begin on page 4.

Remarks begin on page 8.

Electronic Acknowledgement Receipt

EFS ID:	35170976
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US11
Receipt Date:	15-FEB-2019
Filing Date:	25-AUG-2017
Time Stamp:	17:45:00
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		2019-02-15_Amendment_17713-0001US11.pdf	102861 bbe4260387f5e890b88c0957669eeca3ce4976fc	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	8	9
	Claims	4	7
	Specification	2	3
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Warnings:			
Information:			
	Total Files Size (in bytes):	102861	

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/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	15686265
Filing Date	2017-08-25
First Named Inventor	WOLF
Art Unit	3792
Examiner Name	MANUEL
Attorney Docket Number	17713.0001US11

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	9763743		2017-09-19	Lin	
	2	10028781		2018-07-24	Saadat	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20180344378		2018-12-06	Wolf et al.	
	2	20180263678		2018-09-20	Saadat	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]
	1							

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

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]
	1	Chen et al., China Journal of Endoscopy, Vol. 11, No. 3. pp. 239-243, March 2005, [English Translation of Title] "Radiofrequency treatment of nasal posterior-under nerve ethmoidal nerve and infraturbinal for perennial allergic rhinitis under nasal endoscope," [also translated as] "Preliminary exploration of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerve, and inferior nasal concha under nasal endoscopy in the treatment of perennial allergic rhinitis." 9 pages.	
	2	Fang et al., J First Mil Med Univ, Vol. 25 No. 7, pp. 876-877, 2005, [English translation of title] "Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis" [also translated as] "Nasal Endoscopic Surgery Combined with Multisite Radiofrequency Technology for Treating Perennial Allergic Rhinitis," 4 pages.	
	3	Kong et al., Journal of Clinical Otorhinolaryngology, 2005. "Clinical observation on radiofrequency ablation treatment in perennial allergic rhinitis," Retrieved from the Internet: <URL:http://en.cnki.com.cn/Article_en/CJFDTOTAL-LCEH200505015.htm>, 1 page.	
	4	Liu et al., China Journal of Endoscopy, Vol. 14, No. 11, pp. 1127-1130, November 2008, [English Translation of Title] "Impact of treatment of perennial rhinitis by radiofrequency thermo-coagulations to vidian and antirior ethomoidal nerves on mucociliary clearance," [also translated as] "Impact of radiofrequency thermocoagulation of bilateral vidian and anterior ethmoidal nerve cluster regions on nasal mucociliary transport function in perennial allergic rhinitis and vasomotor rhinitis." 12 pages.	
	5	Search Report in European Application No. 18204723.3 dated February 18, 2019, 8 pages.	

If you wish to add additional non-patent literature document citation information please click the Add button [Add]

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

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	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2019-02-28
Name/Print	Christopher P. Ziolkowski	Registration Number	73,729

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.

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.

Electronic Patent Application Fee Transmittal

Application Number:	15686265
Filing Date:	25-Aug-2017
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Attorney Docket Number:	17713.0001US11

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($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	120	120
		Total in USD ($)		**120**

Electronic Acknowledgement Receipt

EFS ID:	35282436
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US11
Receipt Date:	28-FEB-2019
Filing Date:	25-AUG-2017
Time Stamp:	13:12:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$120
RAM confirmation Number	022819INTEFSW13124500
Deposit Account	132725
Authorized User	Juliana Hoffman

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)	2019-02-28_IDS_17713-0001US11.pdf	631931 a422009567968394adf944030d2882ed63948ea1	no	4
Warnings:					
Information:					
2	Non Patent Literature	2019-02-18_EP18204723_ESR.PDF	303576 307519ecfb137770c2b184e1281e3a81e027cc40	no	8
Warnings:					
Information:					
3	Non Patent Literature	Chen2005.PDF	746380 dc0bafe8eaea6296509c8fa8c68fa14b317f429f	no	9
Warnings:					
Information:					
4	Non Patent Literature	Kong2006Abstract.PDF	80984 232ebbbb9a1663ec174e260f43eeae79dc273581	no	1
Warnings:					
Information:					
5	Non Patent Literature	Liu2008.PDF	565281 4ccca5ad59fd99ed86134ea113c45928922e861b	no	12
Warnings:					
Information:					
6	Non Patent Literature	Fang2005.PDF	559127 a9b6e095618724f618297050c96e2108e6b80c99	no	4
Warnings:					
Information:					

7	Fee Worksheet (SB06)	fee-info.pdf	30777 0598cdbe50203aaea613d0cd7698c140f851 2379	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	2918056

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.
15/686,265	08/25/2017	Scott J. Wolf	17713.0001US11	7653

23552 7590 03/19/2019

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
03/19/2019	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):

USPTO23552@merchantgould.com

Office Action Summary	Application No. 15/686,265	Applicant(s) Wolf et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	AIA (FITF) 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 _____.

☐ 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) 1-16 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) 1-16 is/are rejected.

8) ☐ Claim(s) _____ 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: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Claim Rejections - 35 USC § 102

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.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

Claims 1,2, 4-8 and 10-16 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Makower et al (US 2005/0240147) .

Regarding claims 1, 4-8 and 11-16, Makower et al disclose treating an airway in a patient comprising advancing a cryotherapy treatment element comprising an occlude 14 and openings 22 and 24 of a treatment device10 through a nostril a nostril of the patient and into the airway. See Fig. 2A.

Occluder 14 of the cryotherapy treatment element is expanded to contact nasal mucosa lining the airway. Energy is removed from submucosal tissue underlying the nasal mucosa by cryogenic cooling fluid passed through openings 22 and 24 of the cryotherapy treatment element. The cryotherapy

treatment changes a property of the submucosal tissue and the treatment element is removed from the airway.

Regarding claims 2 and 10, Makower et al teach using a shape memory material to guide and position the catheter assembly wherein expanding the cryotherapy treatment element upon release constrains the cryotherapy element in a fixed position. See paragraph [0195].

Claim Rejections - 35 USC § 103

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.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 9 are rejected under 35 U.S.C. 103 as being unpatentable over Makower et al (US 2005/0240147) in view of Askew et al (US 2009/0192505).

Makower et al meet all of the claim limitations except for passing liquid nitrogen into the inflatable balloon through an inflation lumen and inflating the balloon with liquid nitrogen.

Askew et al teach using liquid nitrogen for a cryogen. See paragraph [0058].

One of ordinary skill in the art would have found it obvious to use the teaching of Askew et al for applying liquid nitrogen for the cryogen in the device of Makower et al because Askew et al teach liquid nitrogen is a common cryogen for medical application. It would have been further obvious to use the

liquid nitrogen to inflate the occluder 14 to treat tissue surrounding the occluder because the occluder is positioned proximate tissue for which is desirable to treat.

Response to Arguments

Applicant's arguments with respect to claims 1-12 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GEORGE MANUEL whose telephone number is (571)272-4952.

The examiner can normally be reached on regular business days.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

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 for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/George Manuel/
Primary Examiner
Art Unit: 3792

3/14/2019

Notice of References Cited	Application/Control No. 15/686,265	Applicant(s)/Patent Under Reexamination Wolf et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	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-20050240147-A1	10-2005	Makower, Joshua	A61B17/24	604/96.01
*	B	US-20090192505-A1	07-2009	Askew; Timothy E.	A61B18/0218	606/21
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

CPC - Searched*		
Symbol	Date	Examiner
A61B17/2816, A61B17/320068, A61B18/02, A61B18/06, A61B18/085, A61B18/1206, A61B18/14, A61B18/1442, A61B18/1445, A61B18/1477, A61B18/1485, A61B18/16, A61B18/1815, A61B18/20, A61B2017/248, A61B2018/00005, A61B2018/00023, A61B2018/0016, A61B2018/00178, A61B2018/0022, A61B2018/00327, A61B2018/00577, A61B2018/00595, A61B2018/00642, A61B2018/00702, A61B2018/00708, A61B2018/00791, A61B2018/00821, A61B2018/00875, A61B2018/00886, A61B2018/0091, A61B2018/00922, A61B2018/00982, A61B2018/00994, A61B2018/0212, A61B2018/0225, A61B2018/0262, A61B2018/1253, A61B2018/126, A61B2018/1425, A61B2018/143, A61B2018/1807, A61B2018/1861, A61B5/01, A61F5/08, A61F5/56, A61F7/10, A61N1/403, A61N5/025, A61N5/0603, A61N5/0625, A61N7/022, F04C2270/041	01/14/2019	GM
Search Updated.	03/14/2019	GM

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST Search Conducted.	01/14/2019	GM
EAST Search Updated.	03/14/2019	GM

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/14/2019	03/14/2019							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	✓	✓							
	10	✓	✓							
	11	✓	✓							
	12	✓	✓							
	13		✓							
	14		✓							
	15		✓							
	16		✓							

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"15686265"	US-PGPUB	OR	ON	2019/03/14 12:04
L2	68	(cryotherapy and nasal and submucosal and tissue) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	US-PGPUB	OR	ON	2019/03/14 12:06
L3	1	"20050240147" and balloon	US-PGPUB	OR	ON	2019/03/14 12:38
L4	1	"20050240147" and "300"	US-PGPUB	OR	ON	2019/03/14 13:00
L5	1	"20050240147" and "16"	US-PGPUB	OR	ON	2019/03/14 13:01
L6	1	"20050240147" and cryo$8	US-PGPUB	OR	ON	2019/03/14 13:02
L7	1	"20050240147" and "222"	US-PGPUB	OR	ON	2019/03/14 13:04
L8	1	"20050240147" and "100"	US-PGPUB	OR	ON	2019/03/14 13:23
L9	1	"20050240147" and "14"	US-PGPUB	OR	ON	2019/03/14 13:26
L10	1	"20050240147" and "40"	US-PGPUB	OR	ON	2019/03/14 13:27
L11	1	"20050240147" and "14"	US-PGPUB	OR	ON	2019/03/14 13:30
L12	1	"20050240147" and "22"	US-PGPUB	OR	ON	2019/03/14 13:33
L14	1	"20050240147" and shape	US-	OR	ON	2019/03/14

			PGPUB			14:59
L15	29	(cryotherapy and nasal and submucosal and tissue and nitrogen) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	US-PGPUB	OR	ON	2019/03/14 15:11
S281	2	(US-15811743-$ | US-20030144723-$ | US-20150032184-$ | US-3180287-$ | US-3242115-$ | US-3364680-$ | US-3421331-$ | US-3579244-$ | US-3738143-$ | US-3774945-$ | US-3781577-$ | US-3839576-$ | US-3867977-$ | US-5010455-$ | US-5248066-$ | US-5488623-$ | US-5631294-$ | US-5907294-$ | US-7395112-$ | US-7742829-$).DID.	US-PGPUB	OR	ON	2019/03/13 12:53
S282	19	(US-15811743-$ | US-20030144723-$ | US-20150032184-$ | US-3180287-$ | US-3242115-$ | US-3364680-$ | US-3421331-$ | US-3579244-$ | US-3738143-$ | US-3774945-$ | US-3781577-$ | US-3839576-$ | US-3867977-$ | US-5010455-$ | US-5248066-$ | US-5488623-$ | US-5631294-$ | US-5907294-$ | US-7395112-$ | US-7742829-$).DID.	US-PGPUB; USPAT	OR	ON	2019/03/13 12:54
S283	19	(US-15811743-$ | US-20030144723-$ | US-20150032184-$ | US-3180287-$ | US-3242115-$ | US-3364680-$ | US-3421331-$ | US-3579244-$ | US-3738143-$ | US-3774945-$ | US-3781577-$ | US-3839576-$ | US-3867977-$ | US-6010455-$ | US-6248066-$ | US-6488623-$ | US-6631294-$ | US-6907294-$ | US-7395112-$ | US-7742829-$).DID.	US-PGPUB; USPAT	OR	ON	2019/03/13 12:58
S284	2	"20090210028"	US-PGPUB; USPAT	OR	ON	2019/03/13 18:12
S285	1	"20090210028"	US-PGPUB	OR	ON	2019/03/13 18:12
S286	1	"20090210028" and pulse	US-PGPUB	OR	ON	2019/03/13 18:13
S287	1	"7655243".pn.	USPAT	OR	ON	2019/03/14 08:47
S290	1	"20120174161"	US-PGPUB	OR	ON	2019/03/14 08:52

S292	1	"20140088463"	US-PGPUB	OR	ON	2019/03/14 08:54
S293	1	"20140088463" and cryo$8	US-PGPUB	OR	ON	2019/03/14 08:54

EAST Search History (Interference)

< This search history is empty>

3/ 14/ 2019 3:43:05 PM
C:\ Users\ gmanuel\ Documents\ EAST\ Workspaces\ ~ defaults.wsp

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	15686265
Filing Date	2017-08-25
First Named Inventor	WOLF
Art Unit	3792
Examiner Name	MANUEL
Attorney Docket Number	17713.0001US11

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	9763743		2017-09-19	Lin	
	2	10028781		2018-07-24	Saadat	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20180344378		2018-12-06	Wolf et al.	
	2	20180263678		2018-09-20	Saadat	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]
	1							

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

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]
	1	Chen et al., China Journal of Endoscopy, Vol. 11, No. 3. pp. 239-243, March 2005, [English Translation of Title] "Radiofrequency treatment of nasal posterior-under nerve ethmoidal nerve and infraturbinal for perennial allergic rhinitis under nasal endoscope," [also translated as] "Preliminary exploration of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerve, and inferior nasal concha under nasal endoscopy in the treatment of perennial allergic rhinitis." 9 pages.	
	2	Fang et al., J First Mil Med Univ, Vol. 25 No. 7, pp. 876-877, 2005, [English translation of title] "Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis" [also translated as] "Nasal Endoscopic Surgery Combined with Multisite Radiofrequency Technology for Treating Perennial Allergic Rhinitis," 4 pages.	
	3	Kong et al., Journal of Clinical Otorhinolaryngology, 2005. "Clinical observation on radiofrequency ablation treatment in perennial allergic rhinitis," Retrieved from the Internet: <URL:http://en.cnki.com.cn/Article_en/CJFDTOTAL-LCEH200505015.htm>, 1 page.	
	4	Liu et al., China Journal of Endoscopy, Vol. 14, No. 11, pp. 1127-1130, November 2008, [English Translation of Title] "Impact of treatment of perennial rhinitis by radiofrequency thermo-coagulations to vidian and antirior ethomoidal nerves on mucociliary clearance," [also translated as] "Impact of radiofrequency thermocoagulation of bilateral vidian and anterior ethmoidal nerve cluster regions on nasal mucociliary transport function in perennial allergic rhinitis and vasomotor rhinitis." 12 pages.	
	5	Search Report in European Application No. 18204723.3 dated February 18, 2019, 8 pages.	

If you wish to add additional non-patent literature document citation information please click the Add button [Add]

EXAMINER SIGNATURE

Examiner Signature	/GEORGE MANUEL/	Date Considered	03/14/2019

*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. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

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	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2019-02-28
Name/Print	Christopher P. Ziolkowski	Registration Number	73,729

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. /G.M./

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.

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. /G.M./

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 15/686,265	Filing Date 08/25/2017	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ 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))	minus 20 =	*		x $40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $210 =	
☐ 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	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	04/05/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $230 =	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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ 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.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LASHAWN R MORGAN/
*** 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.	

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.

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. 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.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	15686265	Filing Date	2017-08-25	Docket Number (if applicable)	17713.0001US11	Art Unit	3792
First Named Inventor	WOLF			Examiner Name	MANUEL		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 132725

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. 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.

Signature of Registered U.S. Patent Practitioner			
Signature	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2019-04-05
Name	Christopher P. Ziolkowski	Registration Number	73729

This collection of information is required by 37 CFR 1.114. 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 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.

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

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 records.

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 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.

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. 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	15686265
Filing Date	2017-08-25
First Named Inventor	WOLF
Art Unit	3792
Examiner Name	MANUEL
Attorney Docket Number	17713.0001US11

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20190076185		2019-03-14	Dinger et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]
	1							

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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

	1	

If you wish to add additional non-patent literature document citation information please click the Add button Add

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

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	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2019-04-05
Name/Print	Chistopher P. Ziolkowski	Registration Number	73,729

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.

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.

Electronic Patent Application Fee Transmittal

Application Number:	15686265
Filing Date:	25-Aug-2017
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Attorney Docket Number:	17713.0001US11

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($)
Miscellaneous:				
RCE- 1ST REQUEST	2801	1	650	650
		Total in USD ($)		**650**

Electronic Acknowledgement Receipt

EFS ID:	35643480
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US11
Receipt Date:	05-APR-2019
Filing Date:	25-AUG-2017
Time Stamp:	15:20:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$650
RAM confirmation Number	040819INTEFSW15204800
Deposit Account	132725
Authorized User	Juliana Hoffman

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		2019-04-05_Amendment_17713-0001US11.pdf	90569 8130c83d8d44349bac91668ee7a38a87b308b499	yes	8
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment Submitted/Entered with Filing of CPA/RCE		1	1	
	Claims		2	5	
	Applicant Arguments/Remarks Made in an Amendment		6	8	
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	2019-04-05_RCE_17713-0001US11.PDF	1349936 793934ebbac673501e439b987701fc3f3e608c52	no	3
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	2019-04-05_IDS_17713-0001US11.PDF	1034256 9c0b6e31638bc018a5d71857f319d5e527053557	no	4
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30781 1f8bfbd58e057cb10121b5a02e072b93e0cc98d1	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2505542		

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.

Conf. No. 7653

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	WOLF, Scott J.	Examiner:	MANUEL, George C.
Appl. No.:	15/686,265	Art Unit:	3792
Filed:	2017-08-25	Dkt No.:	17713.0001US11
Title:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		

AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Examiner Manuel,

In response to the Final Office Action of March 19, 2019, please consider the following.

Amendments to the claims begin on page 2.

Remarks begin on page 6.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A method of treating an airway in a patient, the method comprising:

advancing a cryotherapy balloon ~~treatment element~~ of a treatment device through a nostril of the patient and into the airway in an uninflated configuration;

~~expanding~~ inflating the cryotherapy ~~treatment element~~ balloon by circulating a low-temperature liquid into an interior of the cryotherapy balloon, wherein inflating the cryotherapy balloon causes the cryotherapy balloon to contact nasal mucosa lining the airway;

removing energy from submucosal tissue underlying the nasal mucosa by ~~applying cryogenic cooling with~~ maintaining the cryotherapy ~~treatment element~~ balloon in an inflated configuration and continuing to circulate the low-temperature liquid through the interior of the cryotherapy balloon, to change a property of the submucosal tissue;

deflating the cryotherapy balloon by removing the low-temperature liquid from the interior of cryotherapy balloon; and

removing the cryotherapy balloon ~~treatment element~~ from the airway.

2. (Currently Amended) A method as in claim 1, wherein the cryotherapy balloon ~~treatment element~~ comprises a shape memory material, and wherein ~~expanding the cryotherapy treatment element comprises~~ releasing the cryotherapy balloon ~~treatment element~~ from constraint within a delivery device causes the cryotherapy balloon to partially expand.

3. (Currently Amended) A method as in claim 1, wherein the ~~cryotherapy treatment element comprises an inflatable balloon, and wherein expanding the cryotherapy treatment element comprises passing~~ low-temperature liquid comprises liquid nitrogen ~~into the inflatable balloon through an inflation lumen~~.

4. (Currently Amended) A method as in claim 1, wherein the submucosal tissue is selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within [[the]] a nasal valve, nasal septum outside of [[the]] a nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of [[the]]a nasal cavity, a piriform area, and swell bodies on a floor of [[the]]a nasal cavity.

5. (Currently Amended) A method as in claim 1, wherein ~~expanding~~ inflating the cryotherapy balloon ~~treatment element~~ causes expansion of the airway, and wherein the airway remains in at least a partially expanded shape after the cryotherapy balloon ~~treatment element~~ is removed from the airway.

6. (Currently Amended) A method of treating [[an]] a nasal airway in a patient, the method comprising:

advancing a cryotherapy balloon ~~treatment element~~ of a treatment device through a nostril of the patient and into the nasal airway in an uninflated configuration;

inflating the cryotherapy balloon by circulating a low-temperature liquid into an interior of the cryotherapy balloon, wherein inflating the cryotherapy balloon causes the cryotherapy balloon to contact ~~contacting the cryotherapy treatment element with~~ nasal mucosa lining the nasal airway;

delivering a cryotherapy treatment to a selected tissue depth beneath the nasal mucosa by ~~circulating a~~ continuing to circulate the low-temperature liquid through the cryotherapy balloon ~~treatment element~~ to change a property of a submucosal tissue underlying the nasal mucosa;

deflating the cryotherapy balloon by removing the low-temperature liquid from the interior of cryotherapy balloon; and

removing the cryotherapy balloon ~~treatment element~~ from the nasal airway.

7. (Currently Amended) The method of claim 6, wherein the cryotherapy balloon ~~treatment element~~ is configured to deliver the cryotherapy treatment uniformly over an entire outer surface of the cryotherapy balloon ~~treatment element~~.

8. (Currently Amended) The method of claim 6, wherein delivering the cryotherapy treatment comprises delivering cryotherapy to [[a]] the selected tissue depth in order to target the cryotherapy treatment at a specific submucosal tissue.

9. (Currently Amended) The method of claim 6, wherein the ~~cryotherapy treatment element comprises a balloon, and wherein circulating the~~ low-temperature liquid comprises ~~inflating the balloon with~~ liquid nitrogen.

10. (Currently Amended) The method of claim 6, ~~wherein contacting the cryotherapy treatment element with the nasal mucosa comprises~~ further comprising allowing a shape memory material of the cryotherapy balloon ~~treatment element~~ to expand to a default shape upon release from a delivery device.

11. (Currently Amended) The method of claim 6, ~~further comprising expanding~~ wherein inflating the cryotherapy balloon ~~treatment element, wherein expanding the cryotherapy treatment element~~ causes expansion of the nasal airway, and wherein the nasal airway remains in at least a partially expanded shape after the cryotherapy balloon is removed.

12. (Currently Amended) The method of claim 6, wherein the submucosal tissue is selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within [[the]] a nasal valve, nasal septum outside of [[the]] a nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of [[the]]a nasal cavity, a piriform area, and swell bodies on a floor of [[the]]a nasal cavity.

13. (Previously Presented) The method of claim 1, wherein removing the energy comprises changing the property of the submucosal tissue without reshaping the submucosal tissue.

14. (Currently Amended) The method of claim 1, wherein the submucosal tissue is located in the airway away from [[the]] a nasal valve.

15. (Currently Amended) The method of claim [[1]]6, wherein delivering the cryotherapy treatment comprises changing the property of the submucosal tissue without reshaping the submucosal tissue.

16. (Currently Amended) The method of claim [[1]]6, wherein the submucosal tissue is located in the nasal airway away from [[the]]a nasal valve.

REMARKS

Claims 1-16 are pending and stand rejected by the Office Action of March 19, 2019. This Amendment amends claims 1-12 and 14-16. The amendments add no new matter. Applicant respectfully requests examination and consideration of claims 1-16.

Examiner Interview

Applicant wishes to thank the Examiner for the courtesy of participating in a telephonic interview with Examiner's representatives, Scott Smith and Chris Ziolkowski, on April 4, 2019. During the interview, the participants in the call discussed the Office Action, cited references, and proposed claim amendments provided by Applicant. Examiner commented that the proposed amendments overcame the rejections in the Office Action but that he would likely need to conduct a further search. Again, Applicant thanks the Examiner for his willingness to participate in this productive interview. The claim amendments provided herein are identical to the ones discussed during the interview.

Rejection under 35 U.S.C. § 102

Claims 1, 2, 4-8 and 10-16 stand rejected under 35 U.S.C. § 102, as allegedly being anticipated by U.S. Patent Application Pub. No. 2005/0240147, filed by Makower et al. (hereinafter "Makower"). Applicant respectfully traverses this rejection.

As discussed during the examiner interview, independent claims 1 and 6 are amended herein to specify that a cryotherapy balloon is inflated with a low-temperature liquid, and the cryotherapy treatment is provided by the cryotherapy balloon. The claimed method is different than the one described in Makower, which involves using two balloons to close off the nasal cavity and then injecting or spraying fluid into the blocked off nasal cavity. Based on the clear differences between the present independent claims and Makower, as discussed during the examiner interview, Applicant respectfully requests withdrawal of the rejection of claims 1, 2, 4-8 and 10-16 under 35 U.S.C. § 102.

Claim Rejections – 35 U.S.C. § 103

Claims 3 and 9 were rejected under 35 U.S.C. § 103, as allegedly being unpatentable over Makower in view of U.S. Patent Application Pub. No. 2009/0192505, filed by Askew et al. (hereinafter "Askew"). Applicant respectfully traverses this rejection.

As discussed in the interview, Askew is another reference that describes a technique of spraying a cryogenic fluid. By contrast, the present method recites inflating a balloon with low temperature liquid. Thus, Askew does not remedy the deficiencies of Makower, and Applicant respectfully submits that claims 3 and 9 are allowable for at least the same reasons claims 1 and 6 are allowable. Applicant thus requests withdrawal of the rejection of claims 3 and 9 under 35 U.S.C. § 103.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding, in this application, that previously pending claims are not patentable over the cited references. Rather any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue, at a later date, any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviews of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

In view of the foregoing, Applicant respectfully submits that this application now stands in condition for allowance. Should the Examiner believe that a telephone interview would further the prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

The Commissioner is hereby authorized to charge any additional fees which may be required for entry of these papers or to credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903

Date: April 5, 2019

/ Christopher P. Ziolkowski /
Christopher P. Ziolkowski
Reg. No.: 73,729
Direct: (612) 766-6025

Conf. No. 7653

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	WOLF, Scott J.	Examiner:	MANUEL, George C.
Appl. No.:	15/686,265	Art Unit:	3792
Filed:	2017-08-25	Dkt No.:	17713.0001US11
Title:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		

AGENDA FOR EXAMINER INTERVIEW

Not for Official Entry

Applicant thanks Examiner Manuel for scheduling an interview for April 4, 2019, at noon Eastern to discuss the Final Office Action of March 19, 2019, with attorneys of record Scott Smith (Reg. No. 48,268) and Christopher Ziolkowski (Reg. No. 73,729). Scott Smith is Applicant's general counsel and compliance officer. A discussion of the following is proposed:

- *Discussion of rejection under 35 U.S.C. § 102:* Discussion of rejection of claims under Section 102 based on Makower (US 2005/0240147).

- *Discussion of rejection under 35 U.S.C. § 103:* Discussion of rejection of claims under Section 103 based on Makower in view of Askew (US 2009/0192505).

- *Discussion of potential amendments:* Discussion of amendments provided herewith.

POTENTIAL AMENDMENTS

1. (Currently Amended) A method of treating an airway in a patient, the method comprising:

advancing a cryotherapy balloon ~~treatment element~~ of a treatment device through a nostril of the patient and into the airway in an uninflated configuration;

~~expanding~~ inflating the cryotherapy ~~treatment element~~ balloon by circulating a low-temperature liquid into an interior of the cryotherapy balloon, wherein inflating the cryotherapy balloon causes the cryotherapy balloon to contact nasal mucosa lining the airway;

removing energy from submucosal tissue underlying the nasal mucosa by ~~applying cryogenic cooling with~~ maintaining the cryotherapy ~~treatment element~~ balloon in an inflated configuration and continuing to circulate the low-temperature liquid through the interior of the cryotherapy balloon, to change a property of the submucosal tissue;

deflating the cryotherapy balloon by removing the low-temperature liquid from the interior of cryotherapy balloon; and

removing the cryotherapy balloon ~~treatment element~~ from the airway.

2. (Currently Amended) A method as in claim 1, wherein the cryotherapy balloon ~~treatment element~~ comprises a shape memory material, and wherein ~~expanding the cryotherapy treatment element comprises~~ releasing the cryotherapy balloon ~~treatment element~~ from constraint within a delivery device causes the cryotherapy balloon to partially expand.

3. (Currently Amended) A method as in claim 1, wherein the ~~cryotherapy treatment element comprises an inflatable balloon, and wherein expanding the cryotherapy treatment element comprises passing~~ low-temperature liquid comprises liquid nitrogen ~~into the inflatable balloon through an inflation lumen~~.

4. (Currently Amended) A method as in claim 1, wherein the submucosal tissue is selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within [[the]] a nasal valve, nasal septum outside of [[the]] a nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of [[the]]a nasal cavity, a piriform area, and swell bodies on a floor of [[the]]a nasal cavity.

5. (Currently Amended) A method as in claim 1, wherein ~~expanding~~ inflating the cryotherapy balloon ~~treatment element~~ causes expansion of the airway, and wherein the airway remains in at least a partially expanded shape after the cryotherapy balloon ~~treatment element~~ is removed from the airway.

6. (Currently Amended) A method of treating [[an]] a nasal airway in a patient, the method comprising:

advancing a cryotherapy balloon ~~treatment element~~ of a treatment device through a nostril of the patient and into the nasal airway in an uninflated configuration;

inflating the cryotherapy balloon by circulating a low-temperature liquid into an interior of the cryotherapy balloon, wherein inflating the cryotherapy balloon causes the cryotherapy balloon to contact ~~contacting the cryotherapy treatment element with~~ nasal mucosa lining the nasal airway;

delivering a cryotherapy treatment to a selected tissue depth beneath the nasal mucosa by ~~circulating a~~ continuing to circulate the low-temperature liquid through the cryotherapy balloon ~~treatment element~~ to change a property of a submucosal tissue underlying the nasal mucosa;

deflating the cryotherapy balloon by removing the low-temperature liquid from the interior of cryotherapy balloon; and

removing the cryotherapy balloon ~~treatment element~~ from the nasal airway.

7. (Currently Amended) The method of claim 6, wherein the cryotherapy balloon ~~treatment element~~ is configured to deliver the cryotherapy treatment uniformly over an entire outer surface of the cryotherapy balloon ~~treatment element~~.

8. (Currently Amended) The method of claim 6, wherein delivering the cryotherapy treatment comprises delivering cryotherapy to [[a]] the selected tissue depth in order to target the cryotherapy treatment at a specific submucosal tissue.

9. (Currently Amended) The method of claim 6, wherein the ~~cryotherapy treatment element comprises a balloon, and wherein circulating the~~ low-temperature liquid comprises ~~inflating the balloon with~~ liquid nitrogen.

10. (Currently Amended) The method of claim 6, ~~wherein contacting the cryotherapy treatment element with the nasal mucosa comprises~~ further comprising allowing a shape memory material of the cryotherapy balloon ~~treatment element~~ to expand to a default shape upon release from a delivery device.

11. (Currently Amended) The method of claim 6, ~~further comprising expanding~~ wherein inflating the cryotherapy balloon ~~treatment element, wherein expanding the cryotherapy treatment element~~ causes expansion of the nasal airway, and wherein the nasal airway remains in at least a partially expanded shape after the cryotherapy balloon is removed.

12. (Currently Amended) The method of claim 6, wherein the submucosal tissue is selected from the group consisting of upper lateral cartilage, lower lateral cartilage, nasal septum within [[the]] a nasal valve, nasal septum outside of [[the]] a nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of [[the]]a nasal cavity, a piriform area, and swell bodies on a floor of [[the]]a nasal cavity.

13. (Previously Presented) The method of claim 1, wherein removing the energy comprises changing the property of the submucosal tissue without reshaping the submucosal tissue.

14. (Currently Amended) The method of claim 1, wherein the submucosal tissue is located in the airway away from [[the]] a nasal valve.

15. (Currently Amended) The method of claim [[1]]6, wherein delivering the cryotherapy treatment comprises changing the property of the submucosal tissue without reshaping the submucosal tissue.

16. (Currently Amended) The method of claim [[1]]6, wherein the submucosal tissue is located in the nasal airway away from [[the]]a nasal valve.

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.
15/686,265	08/25/2017	Scott J. Wolf	17713.0001US11	7653

23552 7590 04/10/2019

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
04/10/2019	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):

USPTO23552@merchantgould.com

Applicant-Initiated Interview Summary	**Application No.** 15/686,265	**Applicant(s)** Wolf et al.	
	Examiner GEORGE MANUEL	**Art Unit** 3792	**AIA (FITF) Status** Yes

All participants (applicant, applicants representative, PTO personnel):

(1) George Manuel.

(2) Scott Smith.

(3) Christopher Ziolkowski.

(4) _____.

Date of Interview: 04 April 2019.

Type: ☑ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☑102 ☑103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1-16.

Identification of prior art discussed: Makower et al (US 2005/0240147) and Askew et al (US 2009/0192505).

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

It was agreed the proposed amendment would overcome the prior art of record. The proposed claim changes would require an updated and new search and further consideration..

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiners responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicants correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,-
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicants record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiners version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, Interview Record OK on the paper recording the substance of the interview along with the date and the examiners initials.

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

23552 7590 04/24/2019
MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER
MANUEL, GEORGE C

ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 04/24/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/686,265	08/25/2017	Scott J. Wolf	17713.0001US11	7653

TITLE OF INVENTION: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	07/24/2019

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: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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)

23552 7590 04/24/2019

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/686,265	08/25/2017	Scott J. Wolf	17713.0001US11	7653

TITLE OF INVENTION: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	07/24/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
MANUEL, GEORGE C	3792	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 03-09 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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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.
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.
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. _____

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.
15/686,265	08/25/2017	Scott J. Wolf	17713.0001US11	7653

23552 7590 04/24/2019

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
MANUEL, GEORGE C	
ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 04/24/2019

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 30 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. 15/686,265	Applicant(s) Wolf et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	AIA (FITF) 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 the amendment, filed 4/5/2019.
   ☐ 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 1-16 . 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 areply 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 _____.

/GEORGE MANUEL/
Primary Examiner, Art Unit 3792

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

CPC						
Symbol					Type	Version
A61B	/	18	/	02	F	2013-01-01
A61B	/	18	/	1485	I	2013-01-01
A61B	/	18	/	16	I	2013-01-01
A61B	/	18	/	1442	I	2013-01-01
A61B	/	18	/	1815	I	2013-01-01
A61B	/	18	/	20	I	2013-01-01
A61F	/	5	/	08	I	2013-01-01
A61B	/	5	/	01	I	2013-01-01
A61B	/	18	/	06	I	2013-01-01
A61B	/	18	/	1445	I	2013-01-01
A61B	/	18	/	085	I	2013-01-01
A61B	/	18	/	1206	I	2013-01-01
A61B	/	18	/	14	I	2013-01-01
A61B	/	18	/	1477	I	2013-01-01
A61F	/	5	/	56	I	2013-01-01
A61F	/	7	/	10	I	2013-01-01
A61N	/	1	/	403	I	2013-01-01
A61N	/	5	/	025	I	2013-01-01
A61N	/	5	/	0603	I	2013-01-01
A61N	/	5	/	0625	I	2013-01-01
A61N	/	7	/	022	I	2013-01-01
A61B	/	17	/	2816	I	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	/	00005	A	2013-01-01
A61B	/	2018	/	00023	A	2013-01-01
A61B	/	2018	/	143	A	2013-01-01
A61B	/	17	/	320068	A	2013-01-01
A61B	/	2018	/	00577	A	2013-01-01

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	16	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	16 April 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5B

U.S. Patent and Trademark Office

Part of Paper No.: 20190415

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

CPC								
Symbol							Type	Version
A61B	/	2018	/	1807			A	2013-01-01
A61B	/	2018	/	1861			A	2013-01-01
F04C	/	2270	/	041			A	2013-01-01
A61B	/	2018	/	0022			A	2013-01-01
A61B	/	2018	/	00595			A	2013-01-01
A61B	/	2018	/	00642			A	2013-01-01
A61B	/	2018	/	00875			A	2013-01-01
A61B	/	2018	/	00982			A	2013-01-01
A61B	/	2018	/	0212			A	2013-01-01
A61B	/	2018	/	0225			A	2013-01-01
A61B	/	2018	/	00994			A	2013-01-01
A61B	/	2018	/	0262			A	2013-01-01
A61B	/	2018	/	1253			A	2013-01-01
A61B	/	2018	/	126			A	2013-01-01
A61B	/	2018	/	0016			A	2013-01-01
A61B	/	2018	/	00178			A	2013-01-01
A61B	/	2018	/	00791			A	2013-01-01
A61B	/	2018	/	00886			A	2013-01-01
A61B	/	2018	/	1425			A	2013-01-01
A61B	/	2017	/	248			A	2013-01-01
A61B	/	2018	/	00708			A	2013-01-01
A61B	/	2018	/	0091			A	2013-01-01

CPC Combination Sets								
Symbol							Type	Set	Ranking	Version
	/		/							

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	16	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	16 April 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5B

U.S. Patent and Trademark Office — Part of Paper No.: 20190415

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B	/	18	/	02	

NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	16	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	16 April 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5B

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	12	10												
2	2	13	11												
3	3	14	12												
4	4	6	13												
5	5	7	14												
8	6	15	15												
9	7	16	16												
10	8														
11	9														

NONE (Assistant Examiner)	(Date)	Total Claims Allowed: 16	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792 (Primary Examiner)	16 April 2019 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 5B

U.S. Patent and Trademark Office

Part of Paper No.: 20190415

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61B17/2816, A61B17/320068, A61B18/02, A61B18/06, A61B18/085, A61B18/1206, A61B18/14, A61B18/1442, A61B18/1445, A61B18/1477, A61B18/1485, A61B18/16, A61B18/1815, A61B18/20, A61B2017/248, A61B2018/00005, A61B2018/00023, A61B2018/0016, A61B2018/00178, A61B2018/0022, A61B2018/00327, A61B2018/00577, A61B2018/00595, A61B2018/00642, A61B2018/00702, A61B2018/00708, A61B2018/00791, A61B2018/00821, A61B2018/00875, A61B2018/00886, A61B2018/0091, A61B2018/00922, A61B2018/00982, A61B2018/00994, A61B2018/0212, A61B2018/0225, A61B2018/0262, A61B2018/1253, A61B2018/126, A61B2018/1425, A61B2018/143, A61B2018/1807, A61B2018/1861, A61B5/01, A61F5/08, A61F5/56, A61F7/10, A61N1/403, A61N5/025, A61N5/0603, A61N5/0625, A61N7/022, F04C2270/041	01/14/2019	GM
Search Updated.	03/14/2019	GM
Search Updated.	04/16/2019	GM

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
EAST Search Conducted.	01/14/2019	GM
EAST Search Updated.	03/14/2019	GM
EAST Search Updated. Interference Search History Printout.	04/16/2019	GM

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/686,265	Wolf et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
A61B	17/2816, 17/320068, 18/02, 18/06, 18/085, 18/1206, 18/14, 18/1442, 18/1445, 18/1477, 18/1485, 18/16, 18/1815, 18/20, 2017/248, 2018/00005, 2018/00023, 2018/0016, 2018/00178, 2018/0022, 2018/00327, 2018/00577, 2018/00708, 2018/00791, 2018/00821, 2018/00875, 2018/00886, 2018/0091, 2018/00922, 2018/00982, 2018/00994, 2018/0212, 2018/0225, 2018/0262, 2018/1253, 2018/126, 2018/1425, 2018/143, 2018/1807, 2018/1861, 5/01	04/16/2019	GM
A61N	1/403, 5/025, 5/0603, 5/0625, 7/022,	04/16/2019	GM
A61F	5/08, 5/56, 7/10	04/16/2019	GM
F04C	2270/041	04/16/2019	GM

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	1	"15686265"	US-PGPUB	OR	ON	2019/04/16 14:28
L6	94	(liquid with low with temperature and liquid with balloon and (nose or nasal)) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	US-PGPUB; USPAT	OR	ON	2019/04/16 14:40
S750	1	"15686265"	US-PGPUB	OR	ON	2019/04/15 13:53
S751	501	(cryotherapy and balloon) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR	US-PGPUB	OR	ON	2019/04/15 13:55

		A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)				
S752	88	(cryotherapy and balloon and (nose or nasal)) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	US-PGPUB	OR	ON	2019/04/15 13:55

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	82	(cryotherap$4 and balloon and (nose or nasal)) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	USPAT	OR	ON	2019/04/16 13:58
L2	1	"20190076185"	US-PGPUB	OR	ON	2019/04/16 14:00
L4	153	(liquid with balloon and (nose or nasal)) AND ((A61B17/2816 OR A61B17/320068 OR	USPAT	OR	ON	2019/04/16 14:37

		A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)				
L5	38	(liquid with low with temperature and liquid with balloon and (nose or nasal)) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	USPAT	OR	ON	2019/04/16 14:37
S753	82	(cryotherapy and balloon and (nose or nasal)) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR	USPAT	OR	ON	2019/04/15 14:17

		A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)				

4/16/2019 2:46:25 PM
C:\Users\gmanuel\Documents\EAST\Workspaces\3-18-19.wsp

Bibliographic Data

Application No: 15/686,265

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /GEORGE MANUEL/ Examiner's Signature | Initials

Title: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
08/25/2017	606	3792	17713.0001US11
RULE			

APPLICANTS

AERIN MEDICAL, INC., SUNNYVALE, CA, UNITED STATES

INVENTORS

Scott J. Wolf Menlo Park, CA, UNITED STATES

Andrew Frazier Sunnyvale, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 15272007 09/21/2016 PAT 9788886

15272007 is a CON of 14754087 06/29/2015 PAT 9452010

14754087 is a CON of 14319087 06/30/2014 PAT 9072597

14319087 is a CIP of 13495844 06/13/2012 PAT 8936594

13495844 has PRO of 61603864 02/27/2012

13495844 has PRO of 61496930 06/14/2011

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

09/27/2017

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903
UNITED STATES

FILING FEE RECEIVED

$930

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. 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	15686265
Filing Date	2017-08-25
First Named Inventor	WOLF
Art Unit	3792
Examiner Name	MANUEL
Attorney Docket Number	17713.0001US11

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20190076185		2019-03-14	Dinger et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]
	1							

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. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/GEORGE MANUEL/	Date Considered	04/16/2019

*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. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15686265
	Filing Date	2017-08-25
	First Named Inventor	WOLF
	Art Unit	3792
	Examiner Name	MANUEL
	Attorney Docket Number	17713.0001US11

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	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2019-04-05
Name/Print	Chistopher P. Ziolkowski	Registration Number	73,729

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. /G.M./

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.

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. /G.M./

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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)

23552 7590 04/24/2019
MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/686,265	08/25/2017	Scott J. Wolf	17713.0001US11	7653

TITLE OF INVENTION: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	07/24/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
MANUEL, GEORGE C	3792	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 03-09 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 Merchant & Gould P.C.
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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ☒ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 13-2725

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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.
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.
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 /Christopher P. Ziolkowski/ Date 2019-05-13

Typed or printed name Christopher P. Ziolkowski Registration No. 73,729

Electronic Patent Application Fee Transmittal

Application Number:	15686265
Filing Date:	25-Aug-2017
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Attorney Docket Number:	17713.0001US11

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	500	500

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**500**

Electronic Acknowledgement Receipt

EFS ID:	35990589
Application Number:	15686265
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. Wolf
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US11
Receipt Date:	13-MAY-2019
Filing Date:	25-AUG-2017
Time Stamp:	12:59:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$500
RAM confirmation Number	051319INTEFSW13000200
Deposit Account	132725
Authorized User	Juliana Hoffman

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)	2019-05-13_IssueFeeTransmittal_17713-0001US11.PDF	126282 a1a32b07392c12fbe27a6ad7545eb0927a7cc704	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30590 050512204ecdb8446d20e28014b1d95689688952	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	156872		

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.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/686,265	07/02/2019	10335221	17713.0001US11	7653

23552 7590 06/12/2019

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

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 72 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;
Andrew Frazier, Sunnyvale, CA;

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 USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.