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Application Number: 14319087 Document Date: 06/30/2014

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PTO/AIA/15 (03-13)
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UTILITY PATENT APPLICATION TRANSMITTAL

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

Attorney Docket No.	P244992US01 (494912-9)
First Named Inventor	Scott J. WOLF
Title	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
Express Mail Label No.	efs FILING

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [✓] **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. [✓] **Applicant asserts small entity status.** See 37 CFR 1.27
3. [ ] **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. [✓] **Specification** [*Total Pages* 83] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. [✓] **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* 61]
6. **Inventor's Oath or Declaration** [*Total Pages* ____] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. [ ] Newly executed (original or copy)
   b. [ ] A copy from a prior application (37 CFR 1.63(d))
7. [✓] **Application Data Sheet** ** See note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. **CD-ROM or CD-R** in duplicate, large table, or Computer Program (*Appendix*)
   [ ] Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission** (*if applicable, items a. – c. are required*)
   a. [ ] Computer Readable Form (CRF)
   b. [ ] Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] Paper
   c. [ ] Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

ACCOMPANYING APPLICATION PAPERS

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

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

19. CORRESPONDENCE ADDRESS

[✓] The address associated with Customer Number: 75149 **OR** [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	/Scott M. Smith, Reg. No. 48,268/	Date	June 27, 2014
Name (Print/Type)	Scott M. Smith	Registration No. (Attorney/Agent)	48,268

This collection of information is required by 37 CFR 1.53(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.

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

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

I hereby appoint:

■ Practitioners associated with Customer Number: 75149

OR

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

Name	Registration Number	Name	Registration Number

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

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

■ The address associated with Customer Number: 75149

OR

☐

Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

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

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

SIGNATURE of Assignee of Record

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

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

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

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PTO/AIA/14 (03-13)
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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	P244992US01 (494912-9)
	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	Menlo Park	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

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

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		FRAZIER	

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

City	Sunnyvale	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

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

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

Correspondence Information:

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244992US01 (494912-9)
	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	75149		
Email Address	docketingdept-sf@dorsey.com	Add Email	Remove Email

Application Information:

Title of the Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		
Attorney Docket Number	P244992US01 (494912-9)	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	61	**Suggested Figure for Publication (if any)**	

Publication Information:

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

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

Representative Information:

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

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

Domestic Benefit/National Stage Information:

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

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation in part of	13495844	2012-06-13
Prior Application Status	Expired		Remove

PTO/AIA/14 (03-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244992US01 (494912-9)
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

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

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

Foreign Priority Information:

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

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.

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

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

Authorization to Permit Access:

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244992US01 (494912-9)
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

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

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

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

Applicant Information:

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

Applicant 1

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

Clear

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

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

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☒

Organization Name	AERIN MEDICAL, INC.

Mailing Address Information For Applicant:

Address 1	650 Page Mill Road		
Address 2			
City	Menlo Park	**State/Province**	CA
Country	US	Postal Code	94304
Phone Number		Fax Number	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244992US01 (494912-9)
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

Email Address	

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

Assignee Information including Non-Applicant Assignee Information:

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

Assignee 1

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

If the Assignee is an Organization check here. ☐

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

Mailing Address Information For Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

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

Signature:

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

Signature	/Scott M. Smith, Reg. No. 48,268/			Date (YYYY-MM-DD)	2014-06-27
First Name	Scott M.	Last Name	SMITH	Registration Number	48268

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

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244992US01 (494912-9)
	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.**

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 WOLF
Filer:	Scott Michael Smith/Laura Lee Mosier
Attorney Docket Number:	P244992US01 (494912-9)

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

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:				
Claims in excess of 20	2202	27	40	1080
Independent Claims in Excess of 3	2201	2	210	420

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous-Filing:				
Late Filing Fee for Oath or Declaration	2051	1	70	70
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**2500**

Electronic Acknowledgement Receipt

EFS ID:	19443650
Application Number:	14319087
International Application Number:	
Confirmation Number:	7653
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott WOLF
Customer Number:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244992US01 (494912-9)
Receipt Date:	30-JUN-2014
Filing Date:	
Time Stamp:	14:02:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$2500
RAM confirmation Number	312
Deposit Account	502319
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		P244992US01_CIP_Specification.pdf	300305 a85231dc4578af297cac7377d70a47620f87af4b	yes	83

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Specification	1	76
Claims	77	82
Abstract	83	83

Warnings:					
Information:					
2	Drawings-other than black and white line drawings	P244992US01_Drawings_6-25-14.pdf	1435421 7a05c9043a5ce6a9a20b70d71b8fa6056d737a42	no	61
Warnings:					
Information:					
3	Transmittal of New Application	P244992US01_Transmittal_Sheet.pdf	178583 1e766a3c837bd943ea45ef785812f7f3a415fb1e	no	1
Warnings:					
Information:					
4	Power of Attorney	P244992US01_POA.pdf	137089 9e2a81ca4f1838b5e0a7b4d211d0f5c6c68d7871	no	1
Warnings:					
Information:					
5	Application Data Sheet	P244992US01_ADS_Application_Data_Sheet_CIP_Application.pdf	111788 6b0aeaa7c28318a1ee2dfd473142b324bd550706	no	6
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
6	Fee Worksheet (SB06)	fee-info.pdf	41362 bd7a693a26d7b95337e8c8dcfb37ca34f010717a	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2204548		

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.

P244992US01
494912-9

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Inventor: Scott J. WOLF
Andrew FRAZIER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. Patent Application Serial No. 13/495,844, entitled METHODS AND DEVICES TO TREAT NASAL AIRWAYS, 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 co-pending U.S. application entitled METHODS AND DEVICES TO TREAT NASAL AIRWAYS, U.S. application Serial No. 14/026,922, filed September 13, 2013 and co-pending U.S. application entitled METHODS AND DEVICES TO TREAT NASAL AIRWAYS, U.S. application Serial No. 13/495,879, filed June 13, 2012, the entireties of both of which are hereby incorporated by reference in their entireties herein.

FIELD OF THE INVENTION

[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. Patent No. 5,533,499 to Johnson or similar devices taught by U.S. Patent 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. Patent No. 7,055,523 to Brown, and U.S. Patent 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. Patent 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. Patent 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. Patent No. 4,887,605 among others. U.S. Patent No. 6,589,235 teaches methods and device for cartilage reshaping by radiofrequency heating. U.S.

Patent 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. 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.

[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. Patent 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.

[0161] 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

[0162] 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.

[0163] 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).

[0164] 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.

[0165] 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.

[0166] 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.

[0167] 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.

[0168] 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).

[0169] 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.

[0170] 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.

[0171] 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.

[0172] 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.

[0173] 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

[0174] 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.

[0175] 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.

[0176] 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.

[0177] 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.

[0178] 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.

[0179] 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.

[0180] 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.

[0181] 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.

[0182] 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.

[0183] 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.

[0184] 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.

[0185] 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.

[0186] 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.

[0187] 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.

[0188] 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.

[0189] 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.

[0190] 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.

[0191] 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.

[0192] 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.

[0193] 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.

[0194] 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.

[0195] 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.

[0196] 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.

[0197] 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.

[0198] 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.

[0199] 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.

[0200] 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.

[0201] 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.

[0202] 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.

[0203] 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.

[0204] 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.

[0205] 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.

[0206] 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.

[0207] 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.

[0208] 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.

[0209] 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.

[0210] 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.

[0211] 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).

[0212] 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.

[0213] 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.

[0214] 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.

[0215] 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.

[0216] 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.

[0217] 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.

[0218] 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

[0219] 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.

[0220] 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.

[0221] 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.

[0222] 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.

[0223] 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.

[0224] 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.

[0225] 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.

[0226] 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.

[0227] 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.

[0228] 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.

[0229] 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.

[0230] 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.

[0231] 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.

[0232] 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.

[0233] 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

[0234] 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.

[0235] 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.

[0236] 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.

[0237] 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. Patent No. 5,533,499 to Johnson or U.S. Patent 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. Patent No. 7,055,523 to Brown or U.S. Patent 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.

[0238] 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.

[0239] 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.

[0240] 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.

[0241] 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.

[0242] 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.

[0243] 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.

[0244] 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.

[0245] 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.

[0246] 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.

[0247] 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.

[0248] 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.

[0249] 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.

[0250] 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.

[0251] 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.

[0252] 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.

[0253] 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.

[0254] 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.

[0255] 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.

[0256] 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.

[0257] 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.

[0258] 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.

[0259] 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.

[0260] 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.

[0261] 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.

[0262] 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.

[0263] 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.

[0264] 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.

[0265] 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.

[0266] 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).

[0267] 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.

[0268] 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.

[0269] 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.

[0270] 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.

[0271] 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.

[0272] 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.

[0273] 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.

[0274] 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.

[0275] 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.

[0276] 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.

[0277] 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.

[0278] 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.

[0279] 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.

[0280] 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.

[0281] 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.

[0282] 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.

[0283] 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.

[0284] 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.

[0285] 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.

[0286] 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.

[0287] 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.

[0288] 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.

[0289] 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.

[0290] 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.

[0291] 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.

[0292] 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.

[0293] 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.

CLAIMS

What is claimed is:

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

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 at least one of reshape, remodel, strengthen or change a property of the submucosal tissue; and

removing the treatment element from the nasal airway.

2. A method as in claim 1, further comprising forming the incision in the mucosal tissue, using the treatment device.

3. A method as in claim 2, wherein forming the incision comprises cutting the mucosal tissue with a cutting edge of the treatment device.

4. A method as in claim 1, wherein delivering the energy based therapy comprises delivering energy to the submucosal tissue in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.

5. A method as in claim 1, wherein delivering the energy based therapy comprises delivering cryotherapy to the submucosal tissue.

6. A method as in claim 1, 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.

7. A method as in claim 1, further comprising applying force to the submucosal tissue with the treatment element at least one of before, during or after delivering the energy based therapy to deform the submucosal tissue.

8. A method as in claim 7, wherein a tissue contacting surface of the treatment element has a shape selected from the group consisting of convex, concave and flat.

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

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 at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; and

removing the treatment element from the nasal airway.

10. A method as in claim 9, wherein adjusting the shape comprises shaping the treatment element to have a convex treatment surface.

11. A method as in claim 9, wherein adjusting the shape comprises shaping the treatment element to have a concave treatment surface.

12. A method as in claim 9, wherein adjusting the shape comprises adjusting a height of at least one electrode on a treatment surface of the treatment element.

13. A method as in claim 12, wherein adjusting the height comprises adjusting multiple heights of multiple electrodes to form a treatment surface profile.

14. A method as in claim 9, wherein adjusting the shape comprises manipulating a secondary component of the treatment element to increase a surface area of the treatment element.

15. A method as in claim 9, wherein adjusting the shape comprises inflating the treatment element to increase a surface area of the treatment element.

16. A method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device.

17. A method as in claim 9, wherein adjusting the shape comprises rotating the treatment element relative to a shaft of the treatment device.

18. A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.

19. A method as in claim 9, wherein delivering the energy based therapy comprises delivering cryotherapy.

20. A method as in claim 9, wherein the mucosal tissue is located in a part of the nasal airway other than an internal nasal valve of the airway.

21. A method as in claim 20, further comprising:

contacting the treatment element with other mucosal tissue at an additional location in the nasal airway, wherein the additional location is part of the nasal valve; and

delivering the energy based therapy to at least one of the other mucosal tissue or an underlying tissue beneath the other mucosal tissue at the additional location.

22. A method as in claim 20, wherein the wherein mucosal 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.

23. A method as in claim 9, further comprising applying force to the mucosal tissue with the treatment element at least one of before, during or after delivering the energy based therapy to deform the mucosal tissue.

24. A method as in claim 9, wherein delivering the energy based therapy modifies at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue.

25. A method as in claim 9, wherein the underlying tissue is selected from the group consisting of cartilage, submucosa, muscle, ligament and tendon.

26. A method as in claim 9, further comprising cooling at least one of the mucosal tissue or another tissue in the nasal airway.

27. 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, the

method comprising:

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 at least one temperature; and

removing the treatment element from the nasal airway.

28. A method as in claim 27, wherein sensing the at least one temperature comprises sensing multiple temperatures with multiple thermocouples located at or near multiple electrode pairs on the treatment element, wherein each of the multiple thermocouples is located at or near one of the multiple electrode pairs.

29. A method as in claim 28, further comprising 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.

30. A method as in claim 28, wherein adjusting the delivery comprises adjusting delivery to at least one of the electrode pairs separately from at least one other of the electrode pairs.

31. A device for modifying at least one property of at least one tissue in a nasal airway, the device comprising:

a head portion configured for passing through an incision in mucosal tissue to a location between the mucosal tissue and submucosal tissue, the head portion comprising;

an energy based therapy delivery member; and

an incision forming member;

a shaft extending from the head portion; and

a handle attached to the shaft at an opposite end from the head portion, wherein the

handle includes a housing to hold a power source for providing energy to the energy delivery member.

32. A device as in claim 31, wherein the energy delivery member has a contact surface with a convex shape configured to at least temporarily create a concavity in the at least one tissue.

33. A device as in claim 31, wherein the energy delivery member has a contact surface with flat shape.

34. A device as in claim 31, wherein the energy delivery member comprises multiple flexible sections configured to be manipulated.

35. A device as in claim 34, wherein the flexible sections comprise multiple protruding electrodes configured to at least temporarily deform nasal tissue.

36. A device as in claim 35, wherein the protruding electrodes comprise two rows of electrodes, wherein the energy delivery member comprises a bipolar radio frequency delivery member, and wherein radio frequency energy travels from one row of electrodes to the other row of electrodes.

37. A device as in claim 31, wherein the housing is configured to hold at least one battery.

38. A device as in claim 31, further comprising at least one sensor configured to sense at least one of temperature or impedance in nasal tissue.

39. A device as in claim 38, wherein the at least one sensor is attached to the device on or near the energy delivery member.

40. A device as in claim 31, further comprising a tissue cooling member attached to the device at or near the energy delivery member.

41. A device as in claim 31, wherein the energy delivery member comprises at least one electrode pair configured to apply energy to the at least one tissue.

42. A device as in claim 41, further comprising at least one thermocouple configured to sense temperature at each electrode pair.

43. A method as in claim 42, further comprising a processor to determine an average temperature from multiple temperatures sensed by more than one of the at least one thermocouple.

44. A method as in claim 41, wherein each of the at least one electrode pair is adjustable separately from adjustment of any other of the at least one electrode pair.

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

contacting a treatment element of the treatment device with a first mucosal tissue located in a part of the nasal airway other than an internal nasal valve of the airway;

delivering an energy based therapy to at least one of the first mucosal tissue or an underlying tissue beneath the first mucosal tissue, using the treatment element; and

removing the treatment element from the nasal airway.

46. A method as in claim 45, further comprising:

contacting the treatment element with a second mucosal tissue at an additional location that is part of the nasal valve; and

delivering the energy based therapy to at least one of the second mucosal tissue or an underlying tissue beneath the second mucosal tissue at the additional location.

47. A method as in claim 45, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, 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.

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.

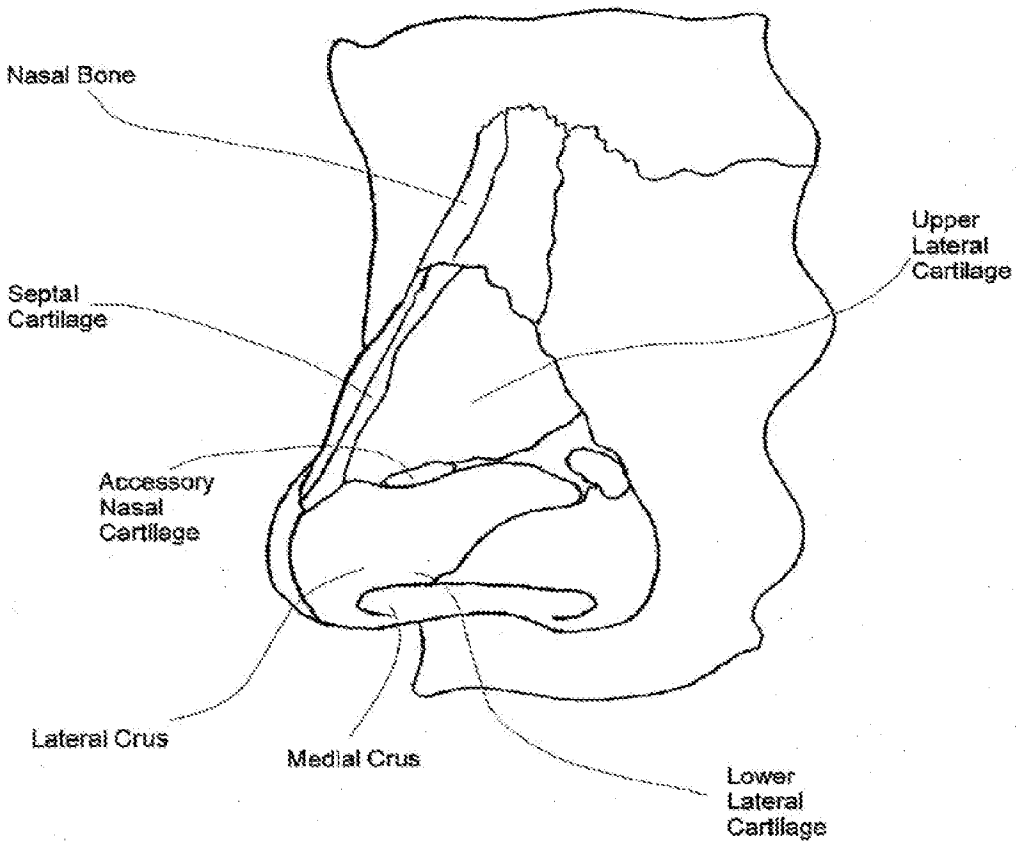

Nasal Bone
Upper Lateral Cartilage
Septal Cartilage
Accessory Nasal Cartilage
Lateral Crus
Medial Crus
Lower Lateral Cartilage

FIG. 1

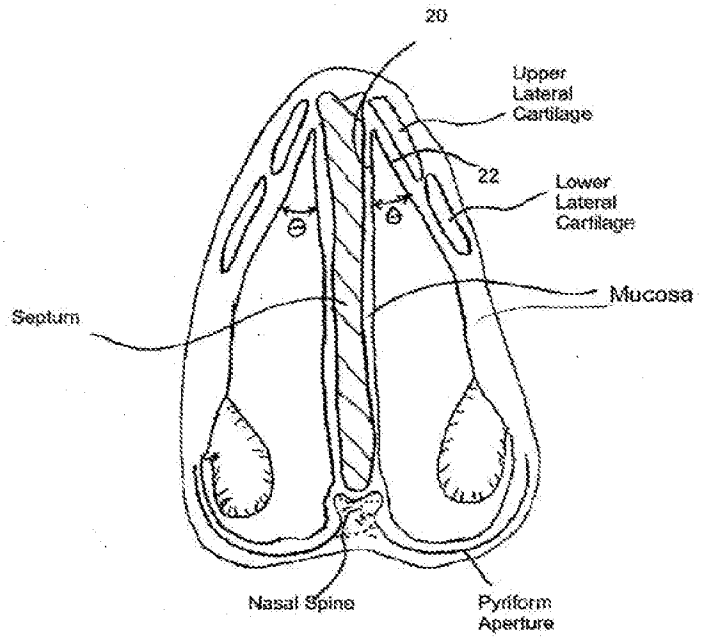

20
Upper
Lateral
Cartilage
22
Lower
Lateral
Cartilage
Mucosa
Septum
Nasal Spine
Pyriform
Aperture

FIG. 2A

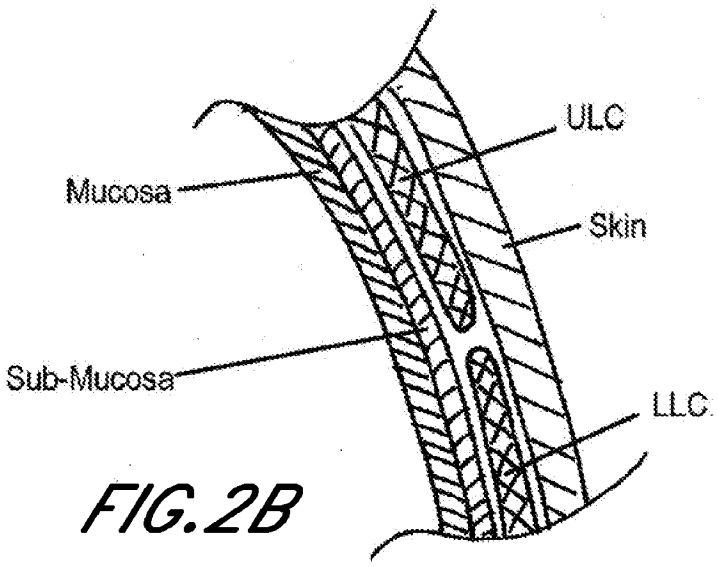

ULC
Mucosa
Skin
Sub-Mucosa
LLC

FIG. 2B

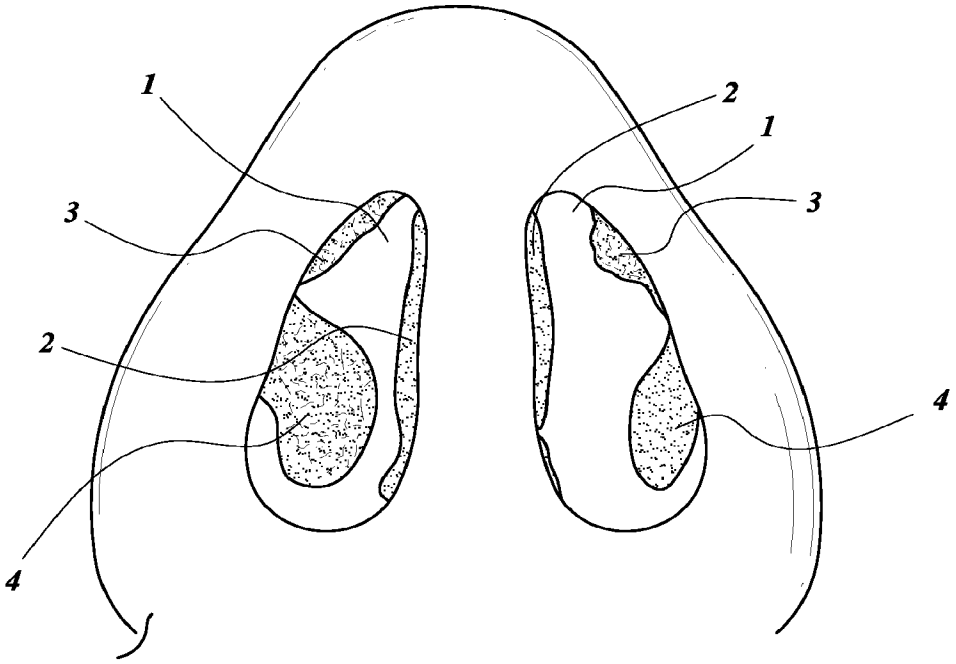


FIG. 2C

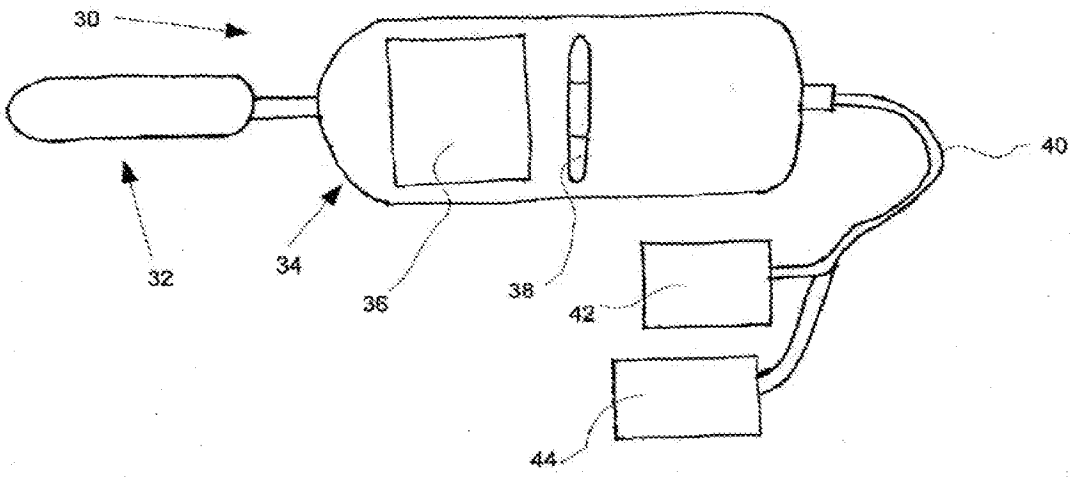


FIG. 3

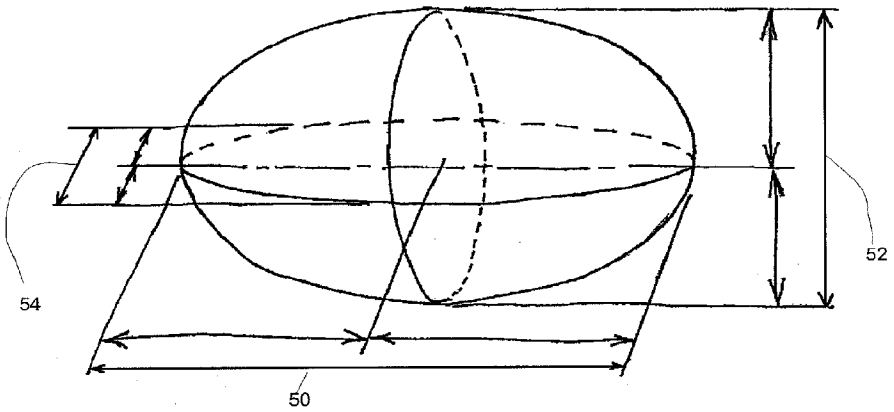


FIG. 4A

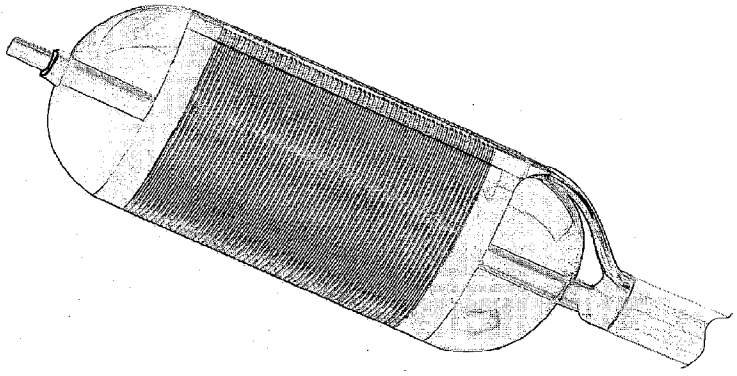


FIG. 4B

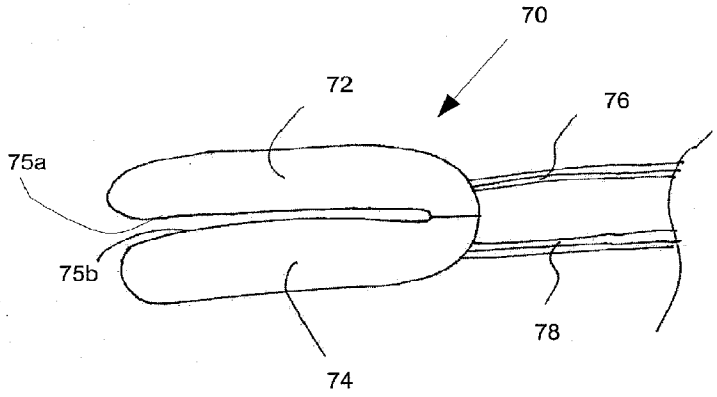


FIG. 4C

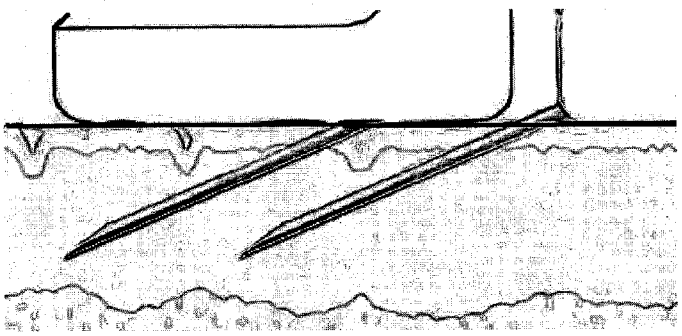


FIG. 4D

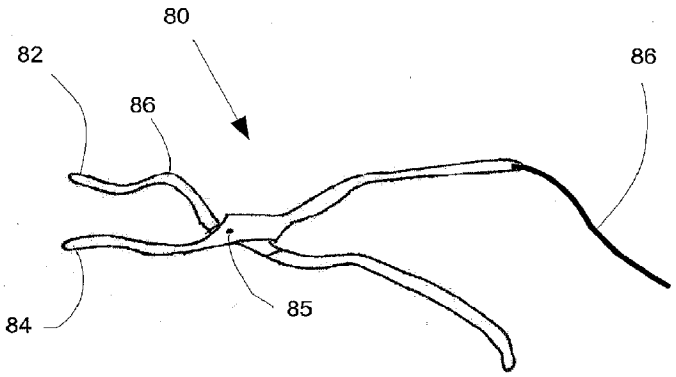


FIG. 5A

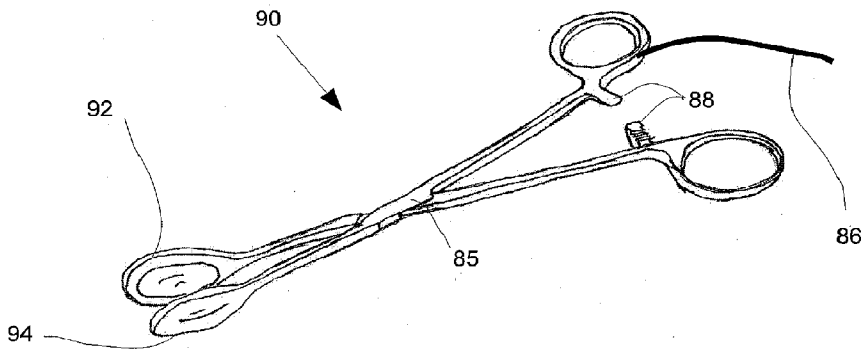


FIG. 5B

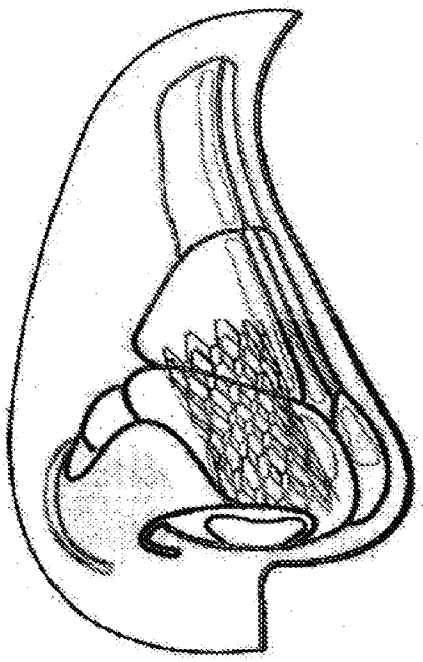


FIG. 6

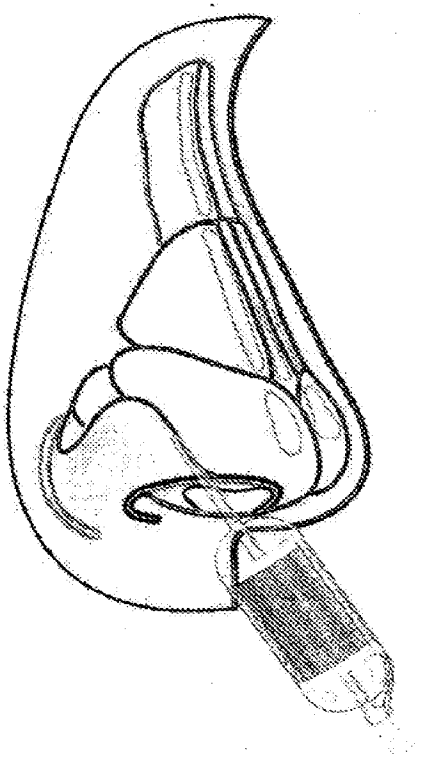


FIG. 7

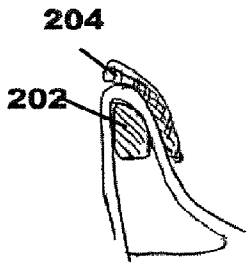


FIG. 8A

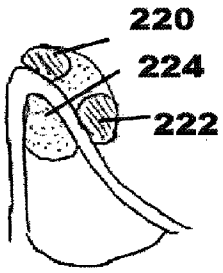


Fig. 8C

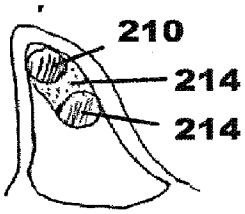


Fig. 8B

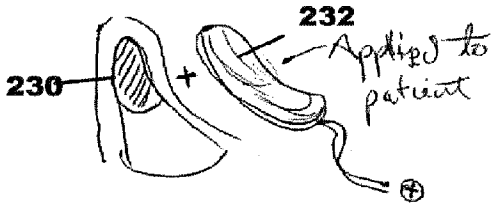


Fig. 8D

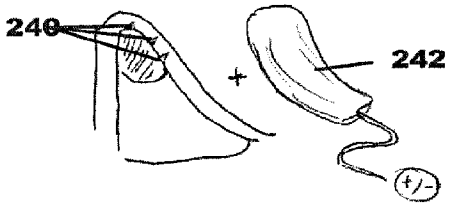


Fig. 8E

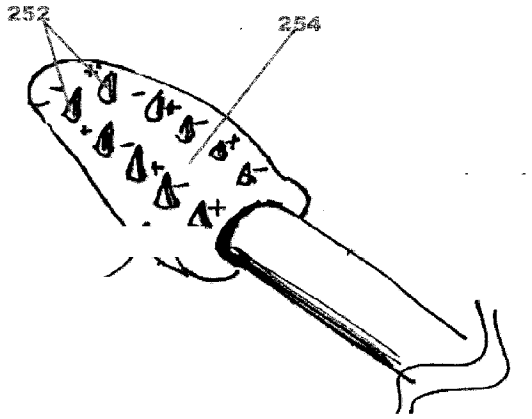


Fig. 8F

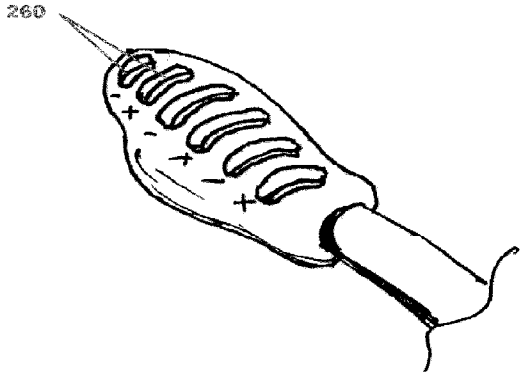


Fig. 8G

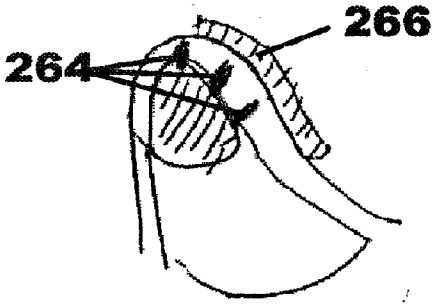


Fig. 8H

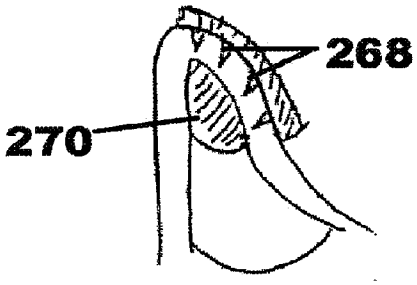


Fig. 8I

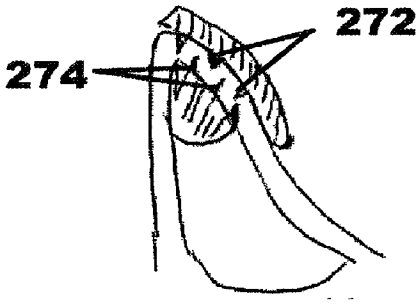


Fig. 8J

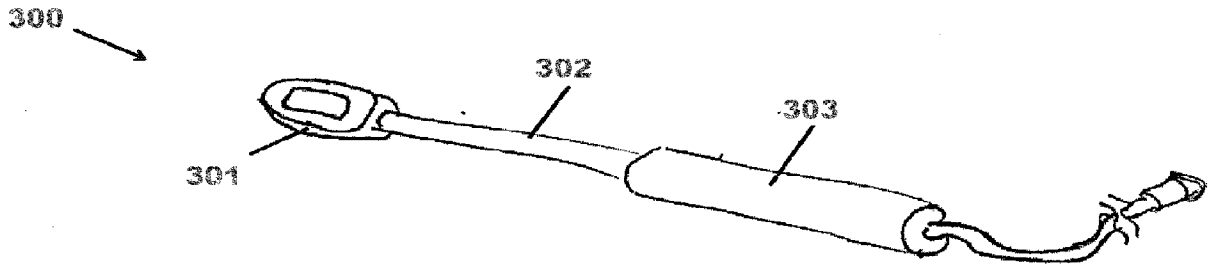


Fig. 9A

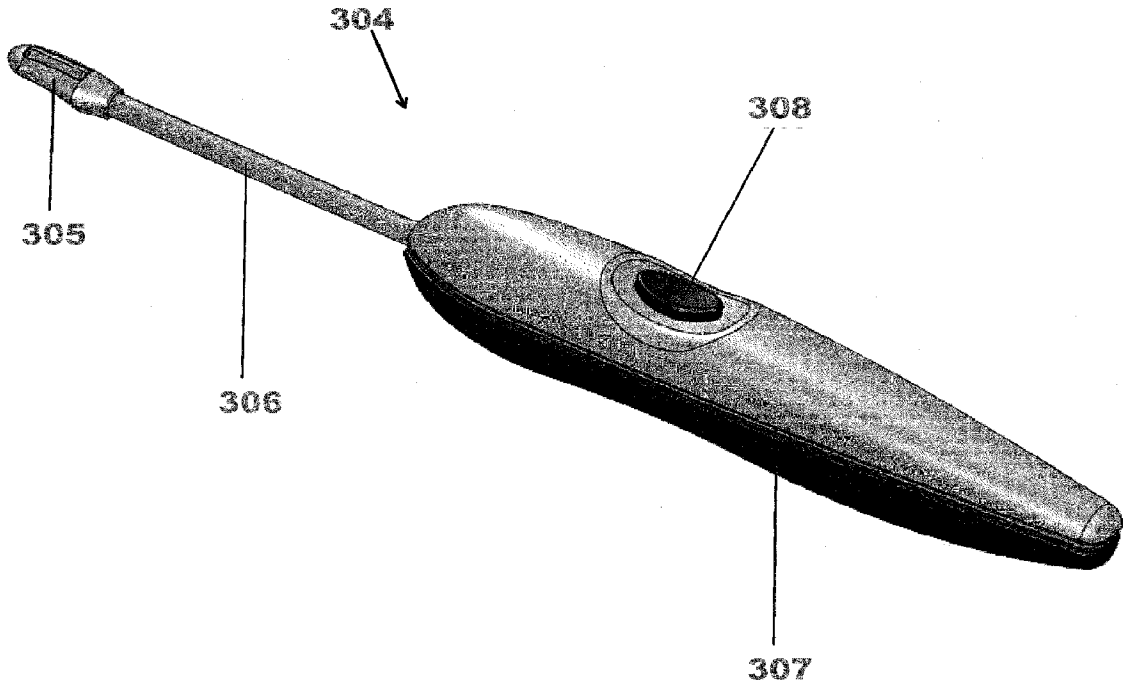


Fig. 9B

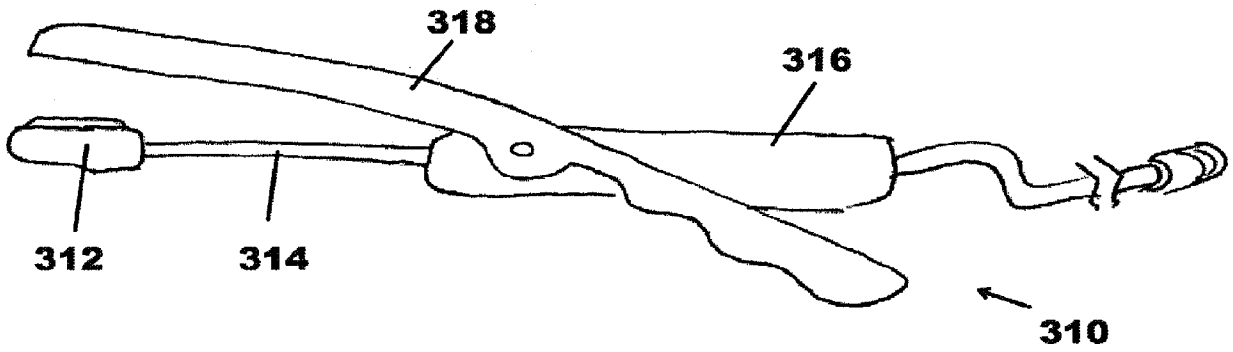


Fig. 10A

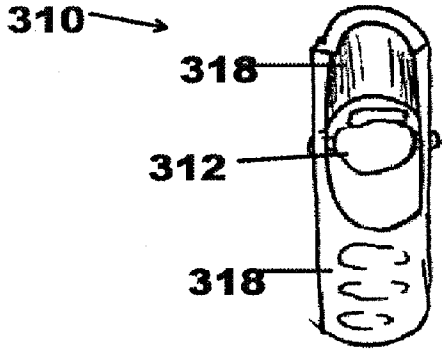


FIG. 10B

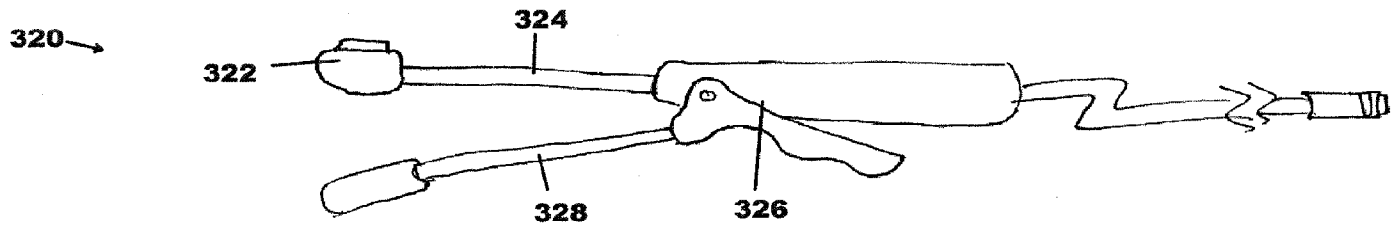


FIG. 11A

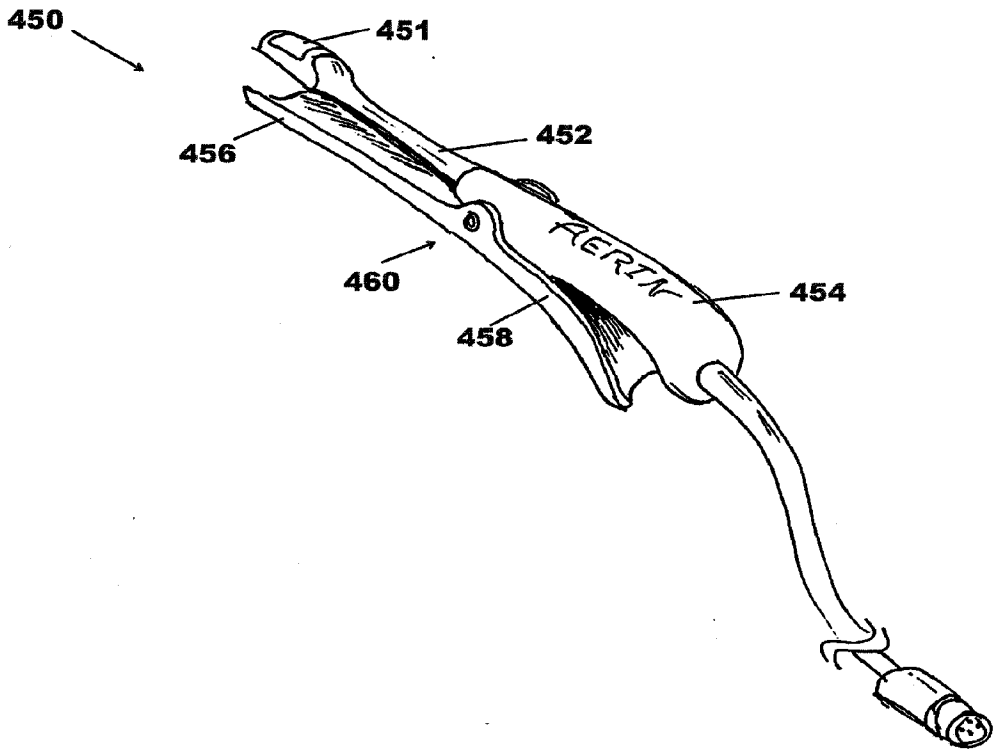


FIG. 11B

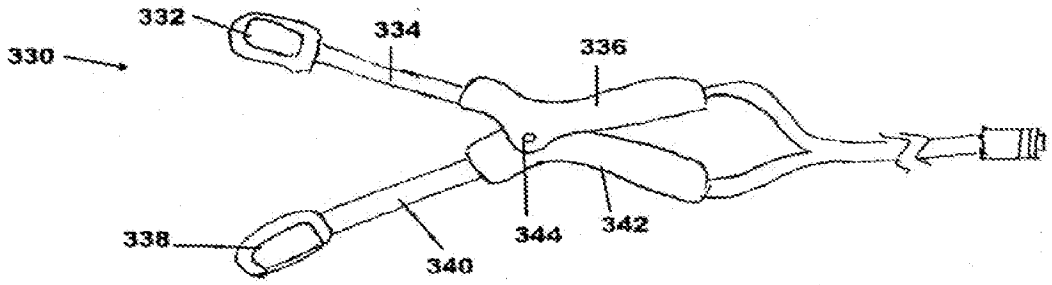


FIG. 12A

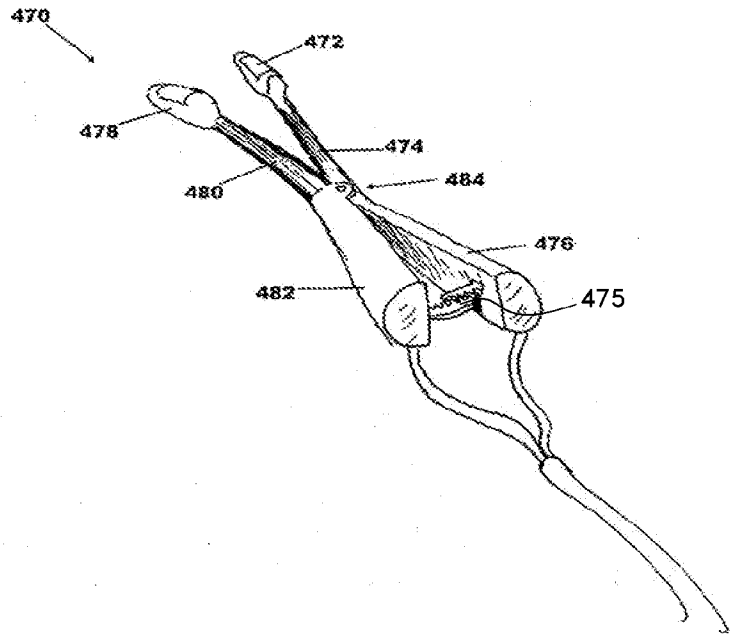


FIG. 12B

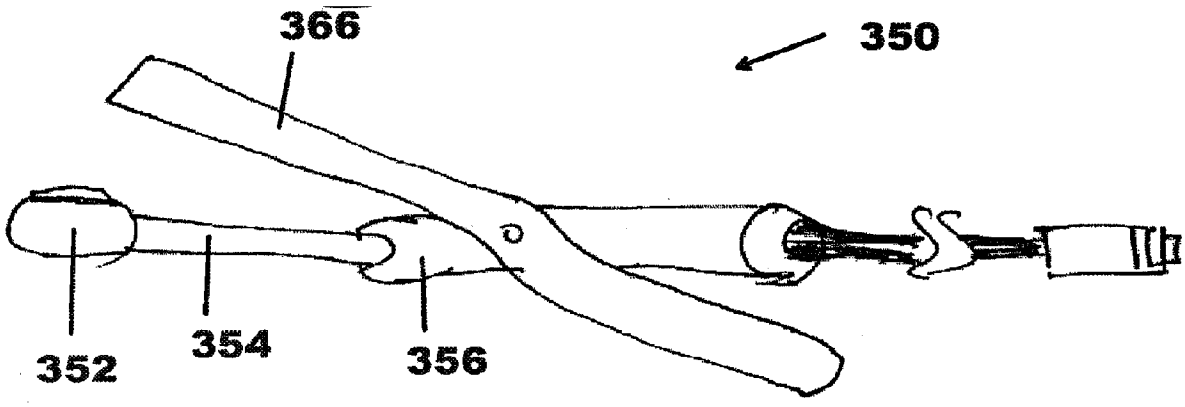


FIG. 13A

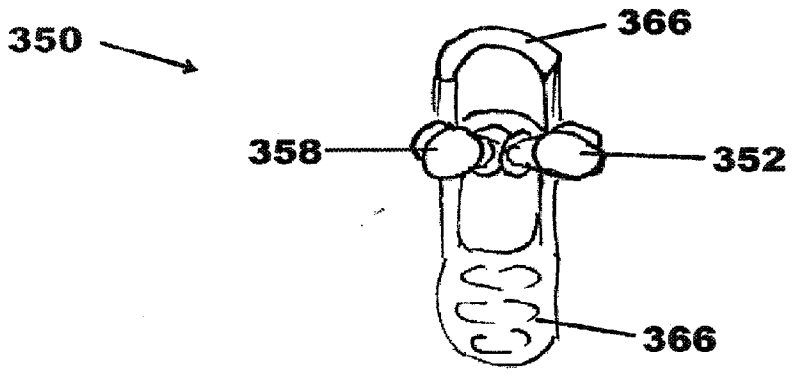


FIG. 13B

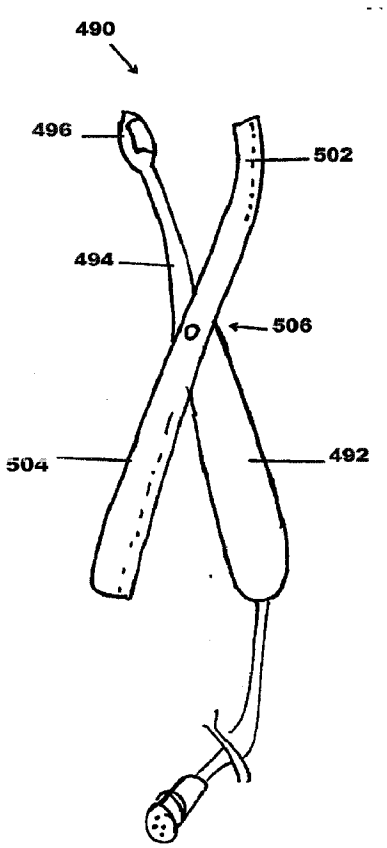


FIG. 13C

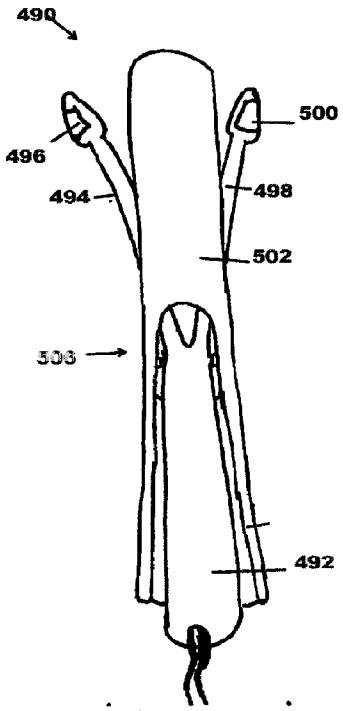


FIG. 13D

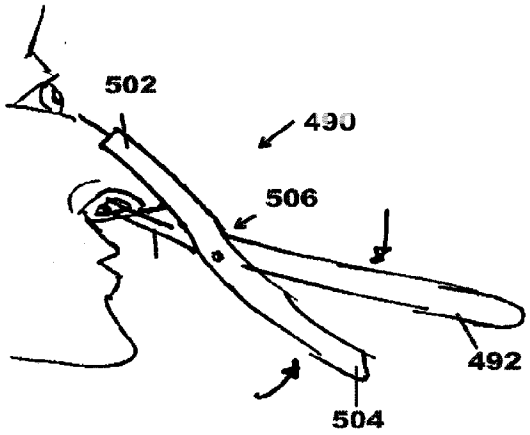


FIG. 13E

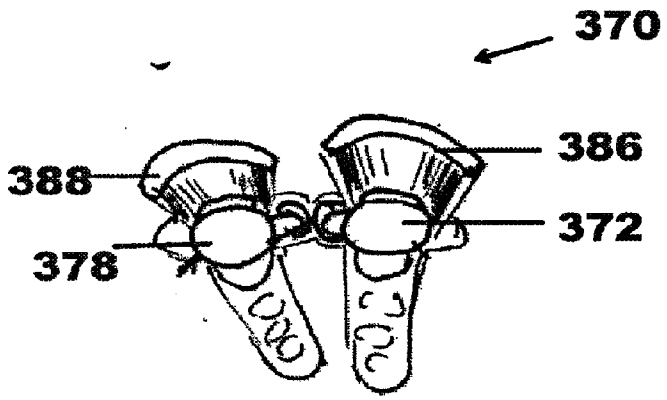


FIG. 14A

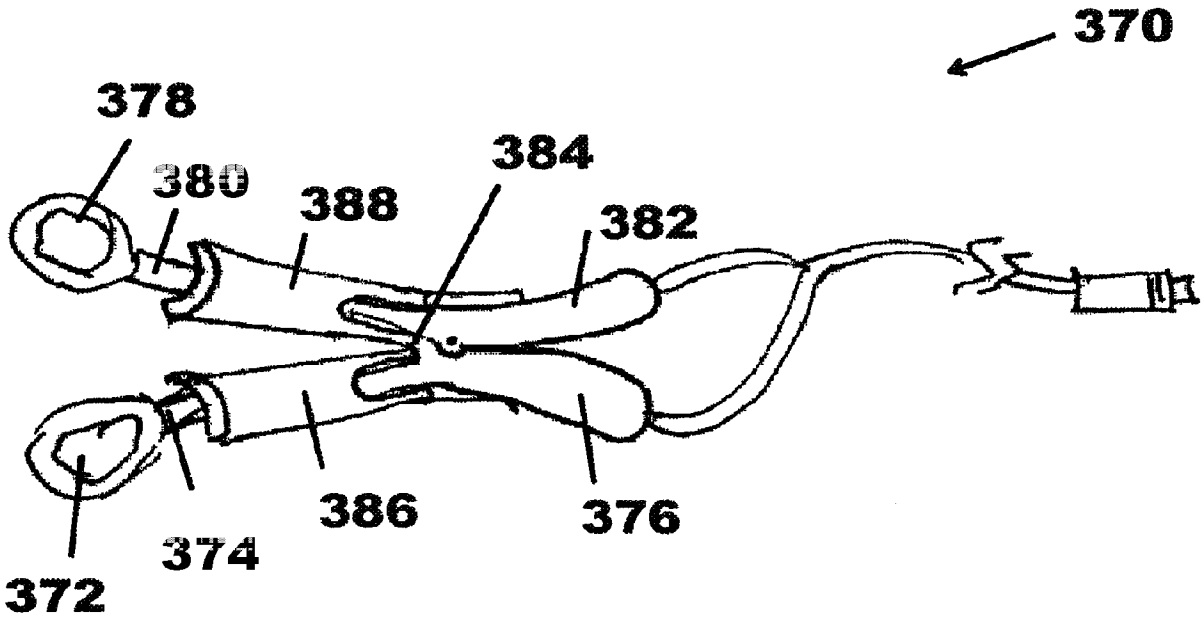


FIG. 14B

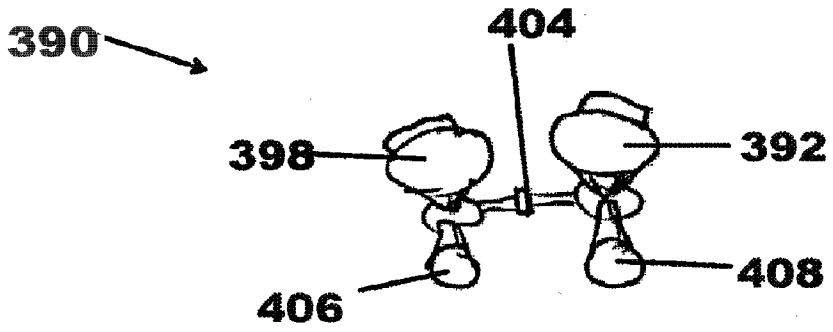


FIG. 15A

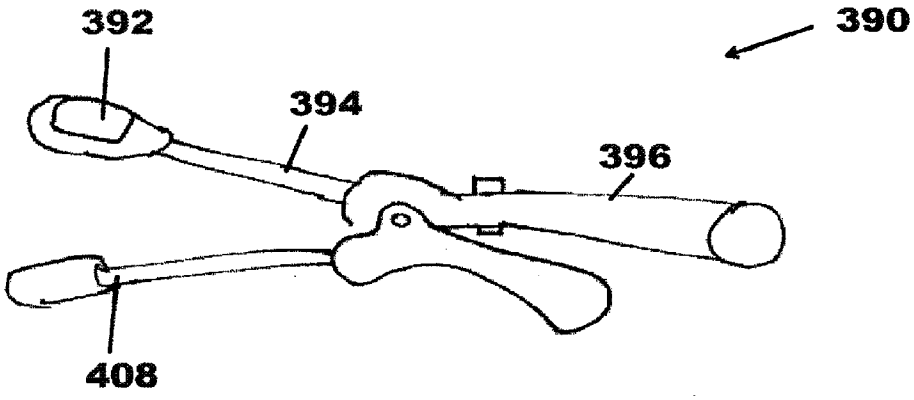


FIG. 15B

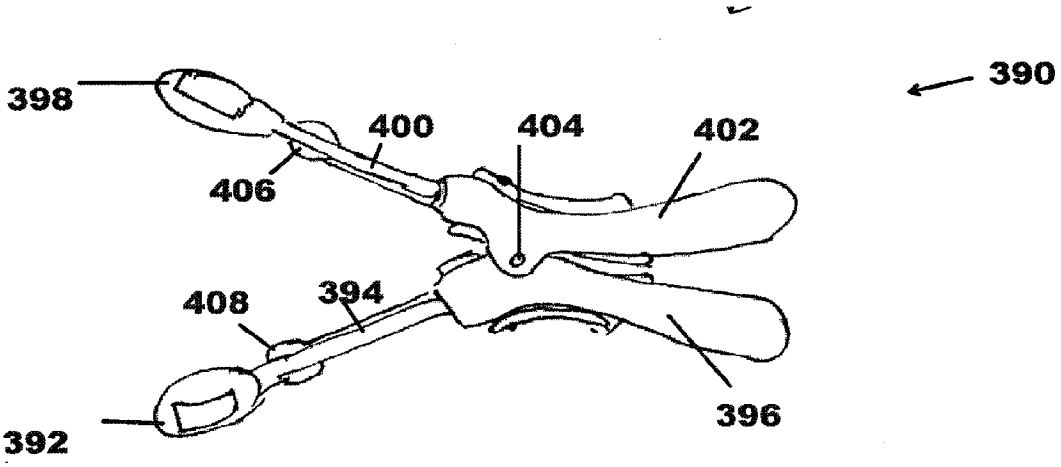


FIG. 15C

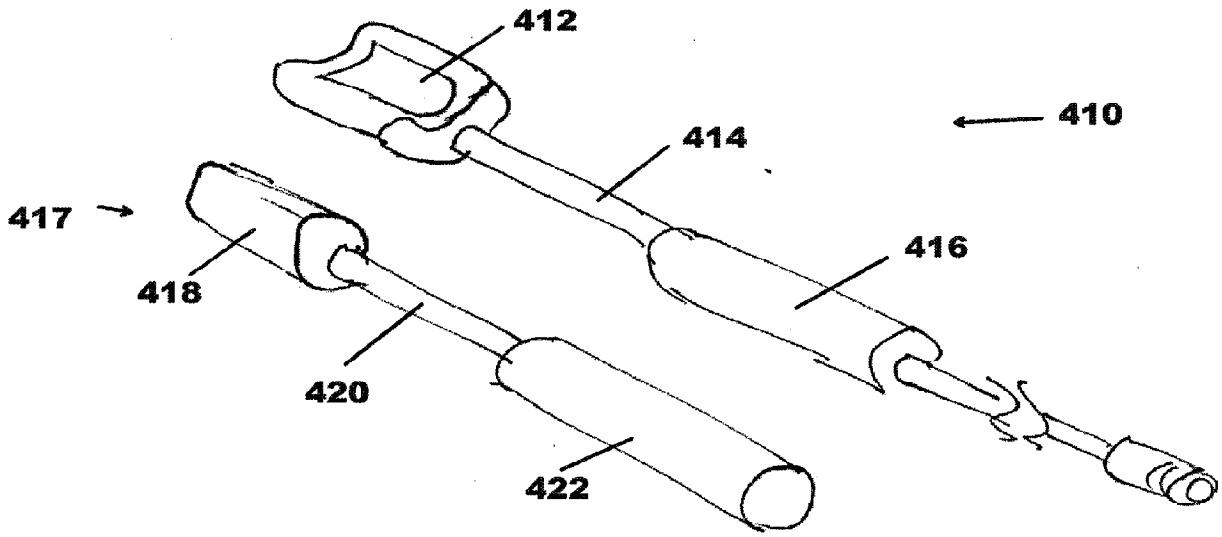


FIG. 16

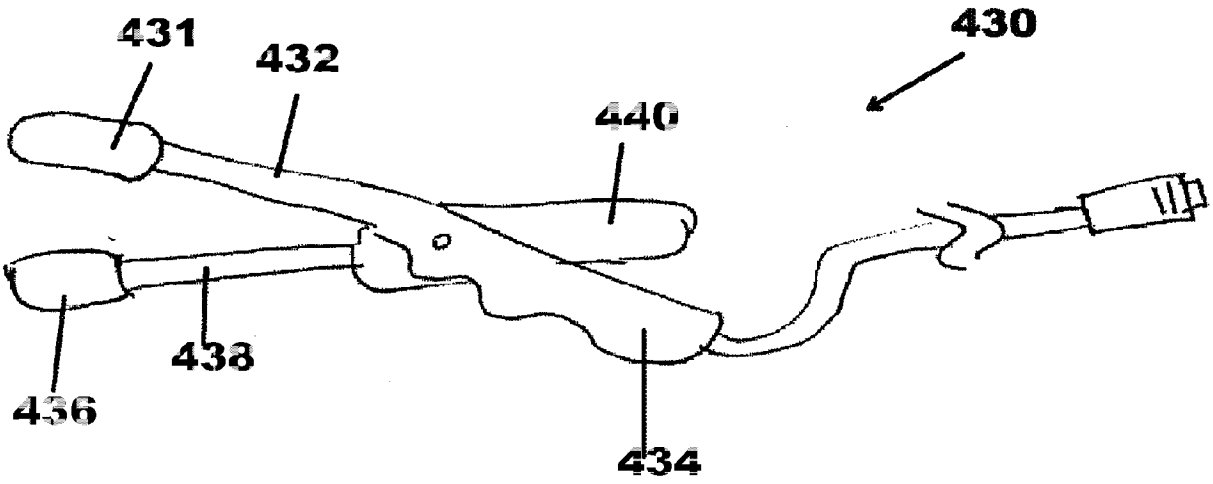


FIG. 17A

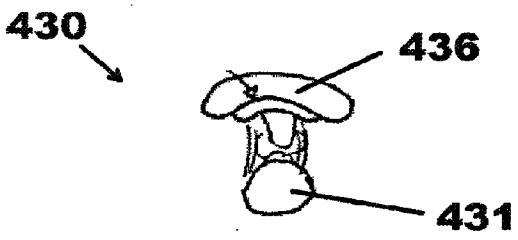


FIG. 17B

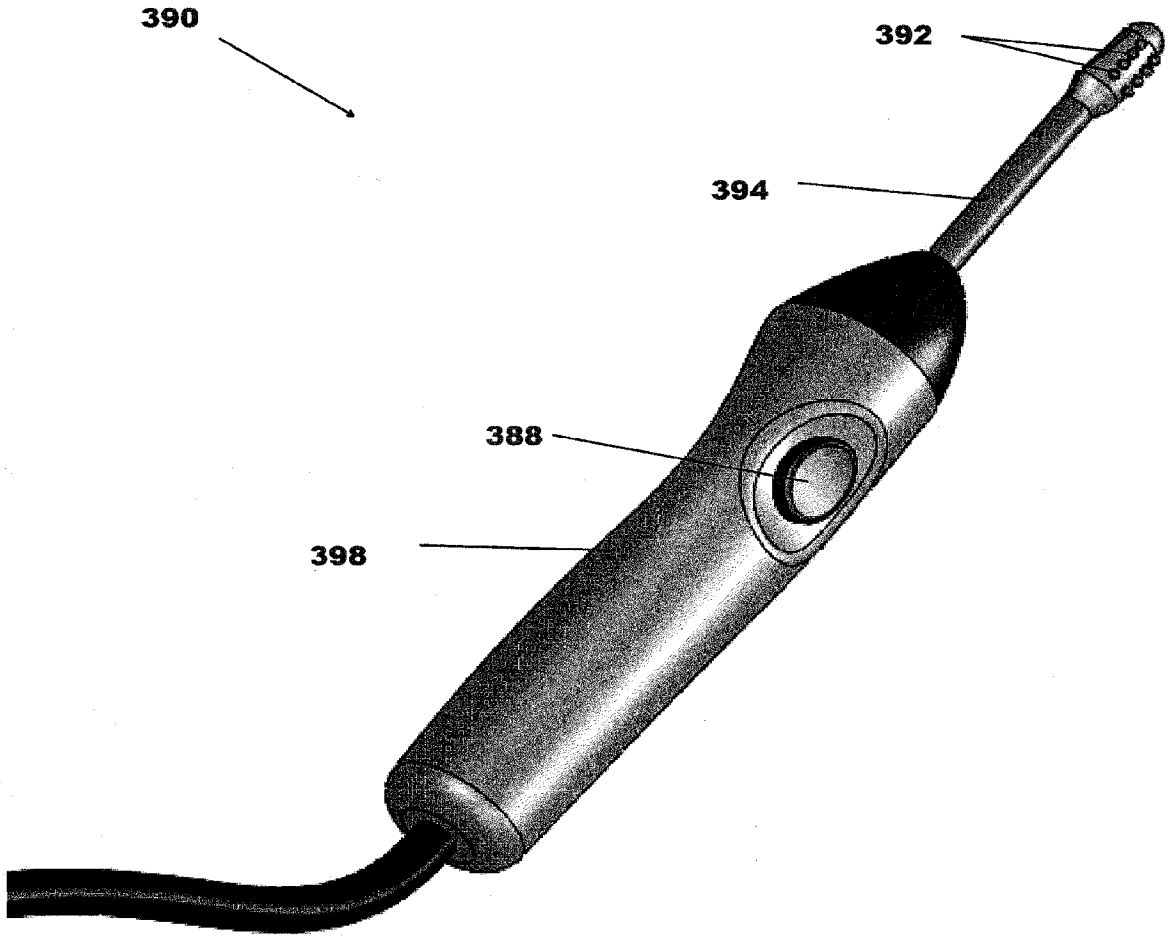


FIG. 18

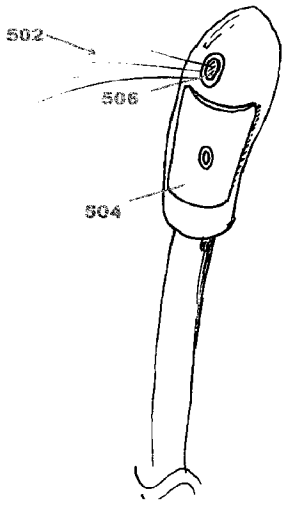


FIG. 19A



FIG. 19B

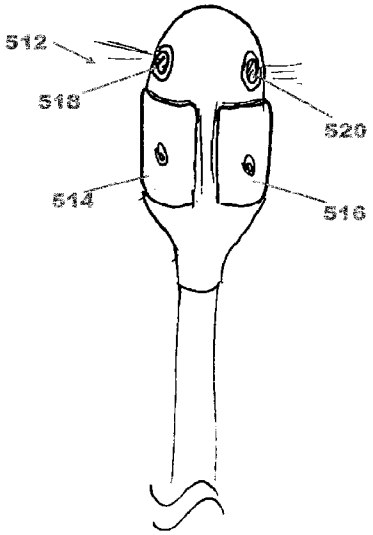


FIG. 20A

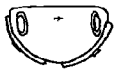


FIG. 20B

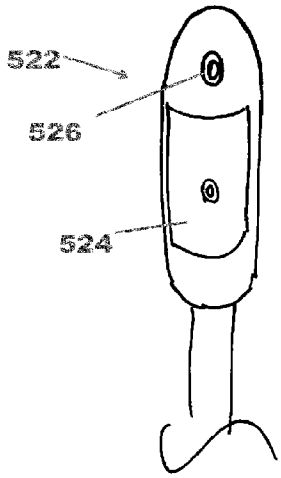


FIG. 21A



FIG. 21B

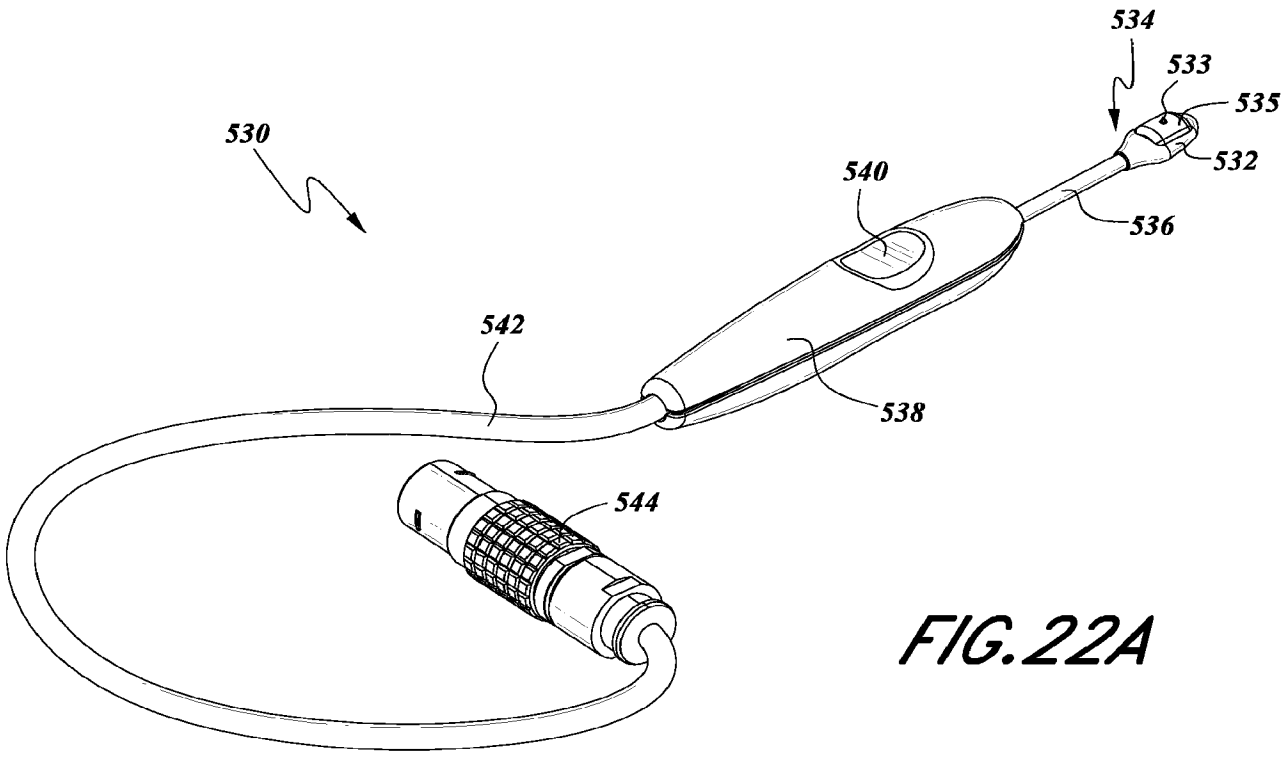


FIG. 22A

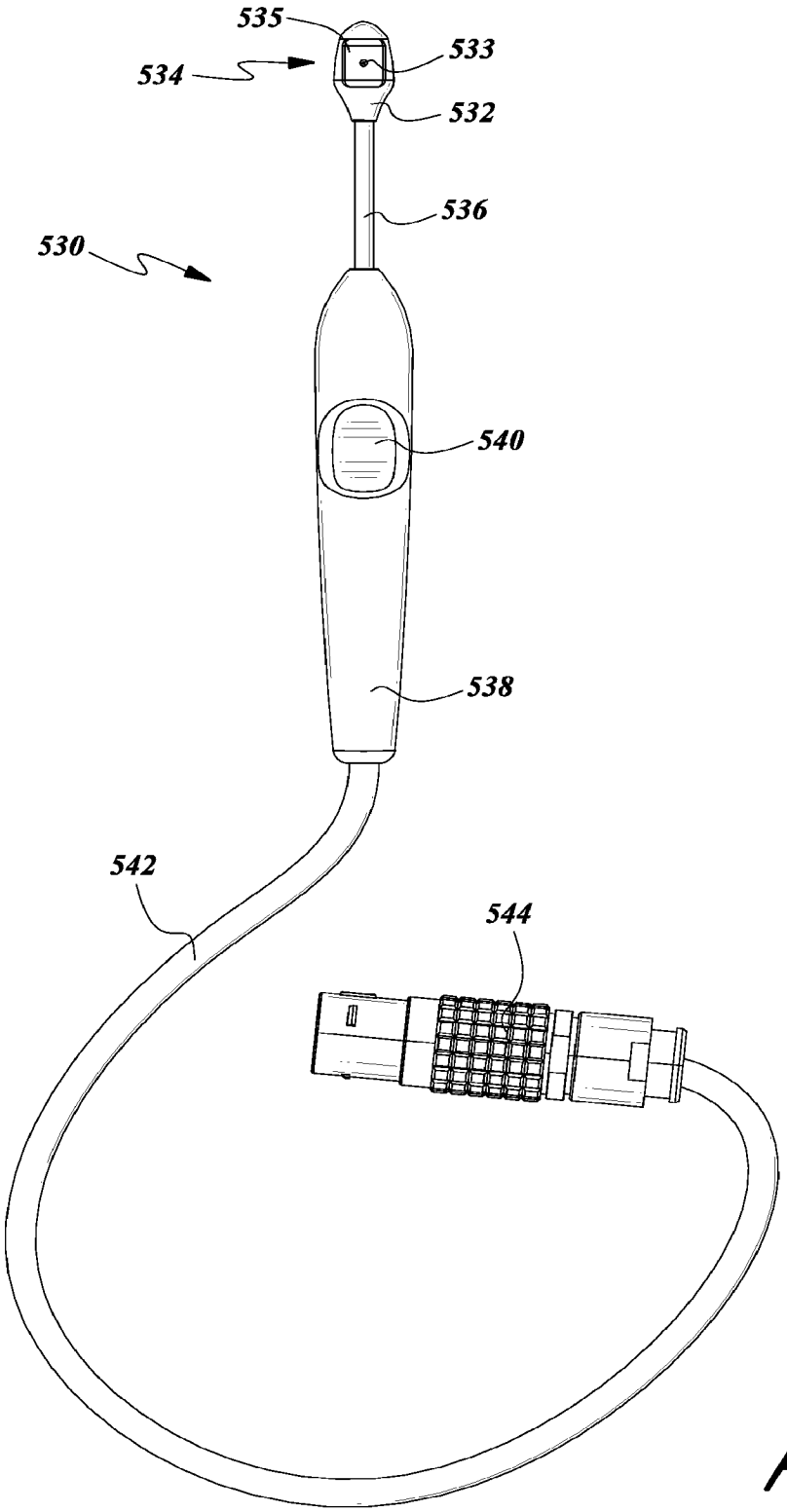


FIG. 22B

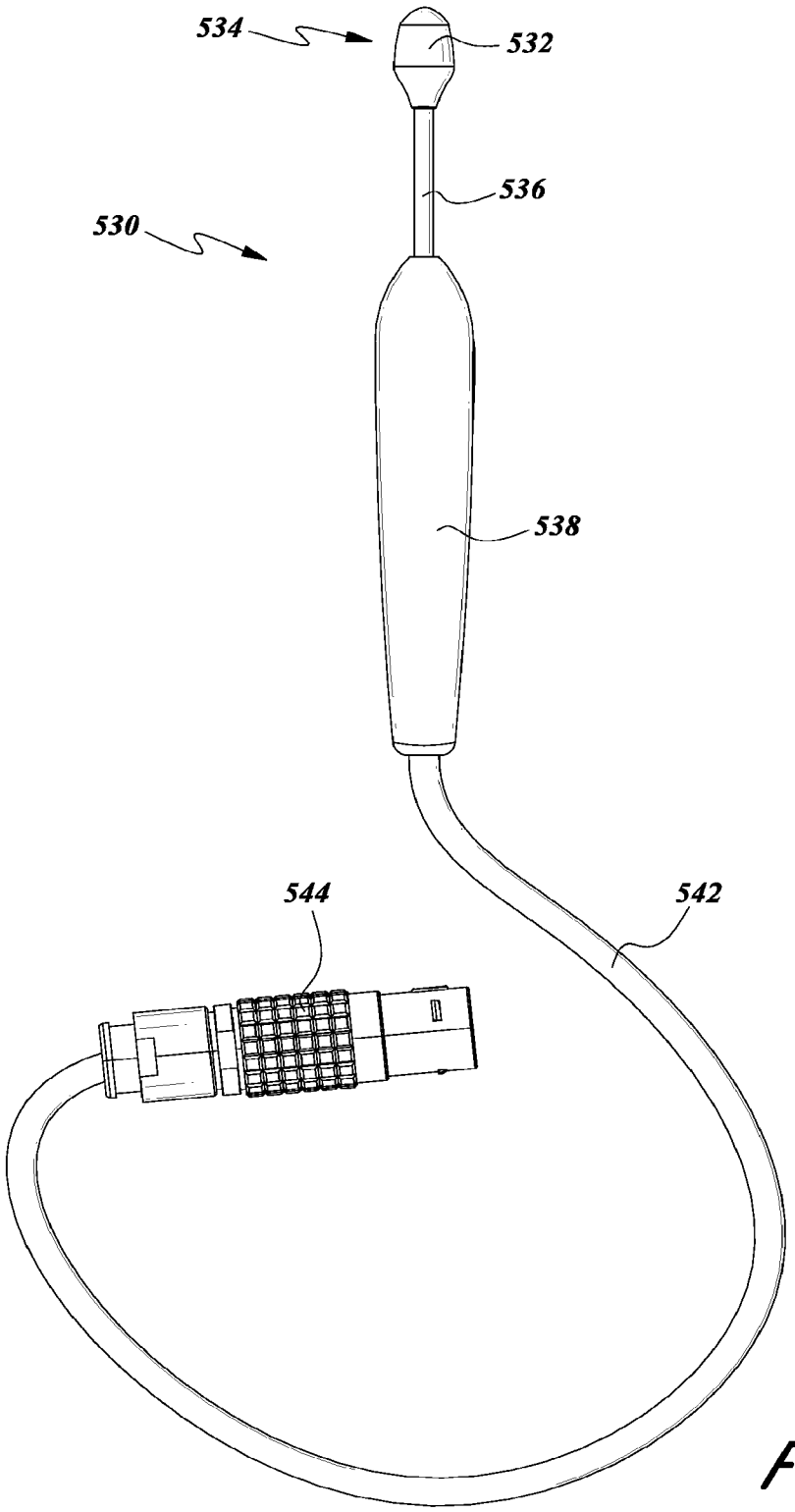


FIG. 22C

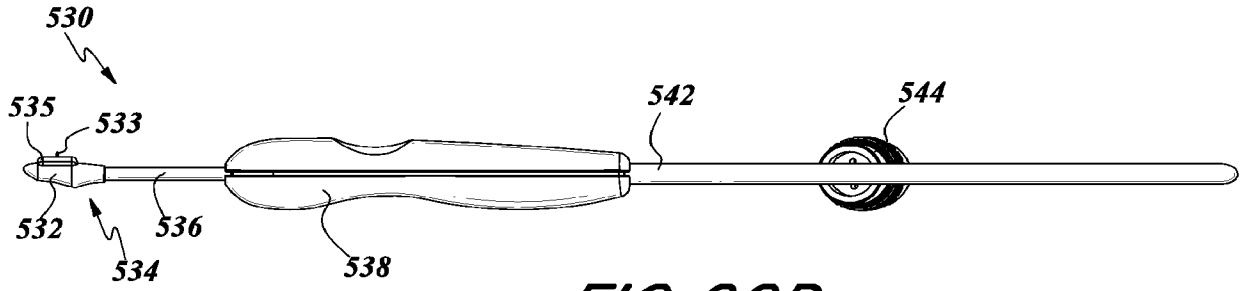


FIG. 22D

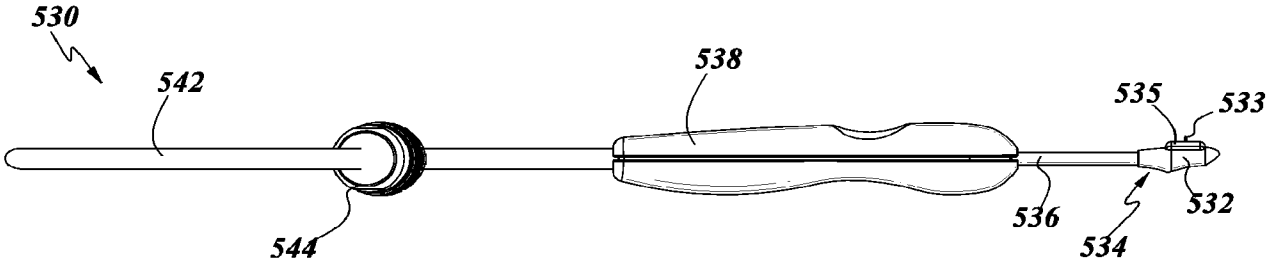


FIG. 22E

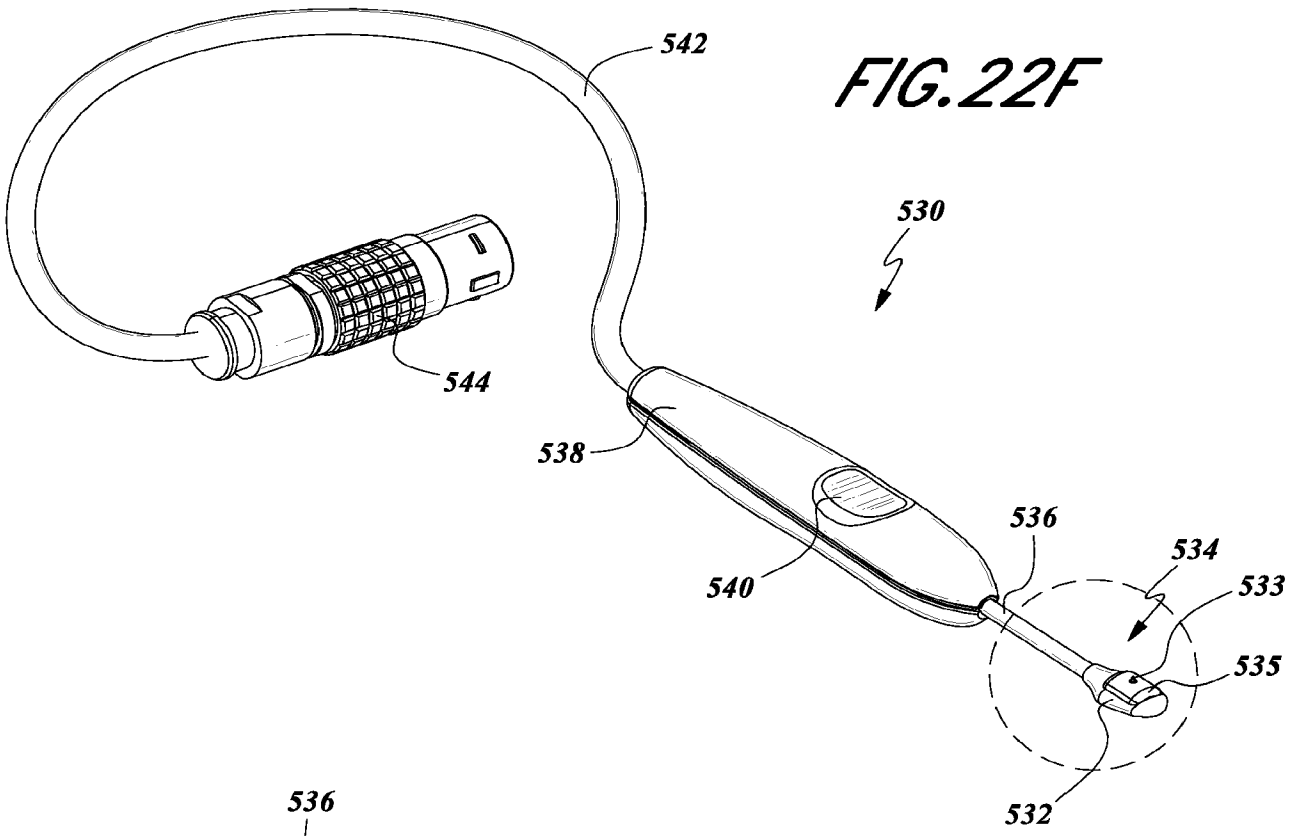


FIG. 22F

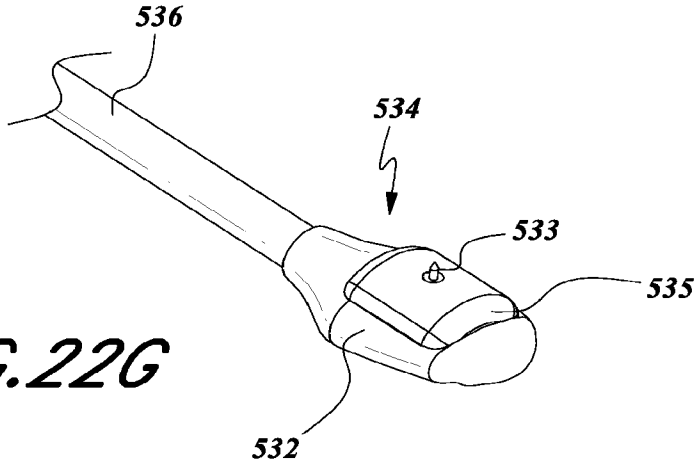


FIG. 22G

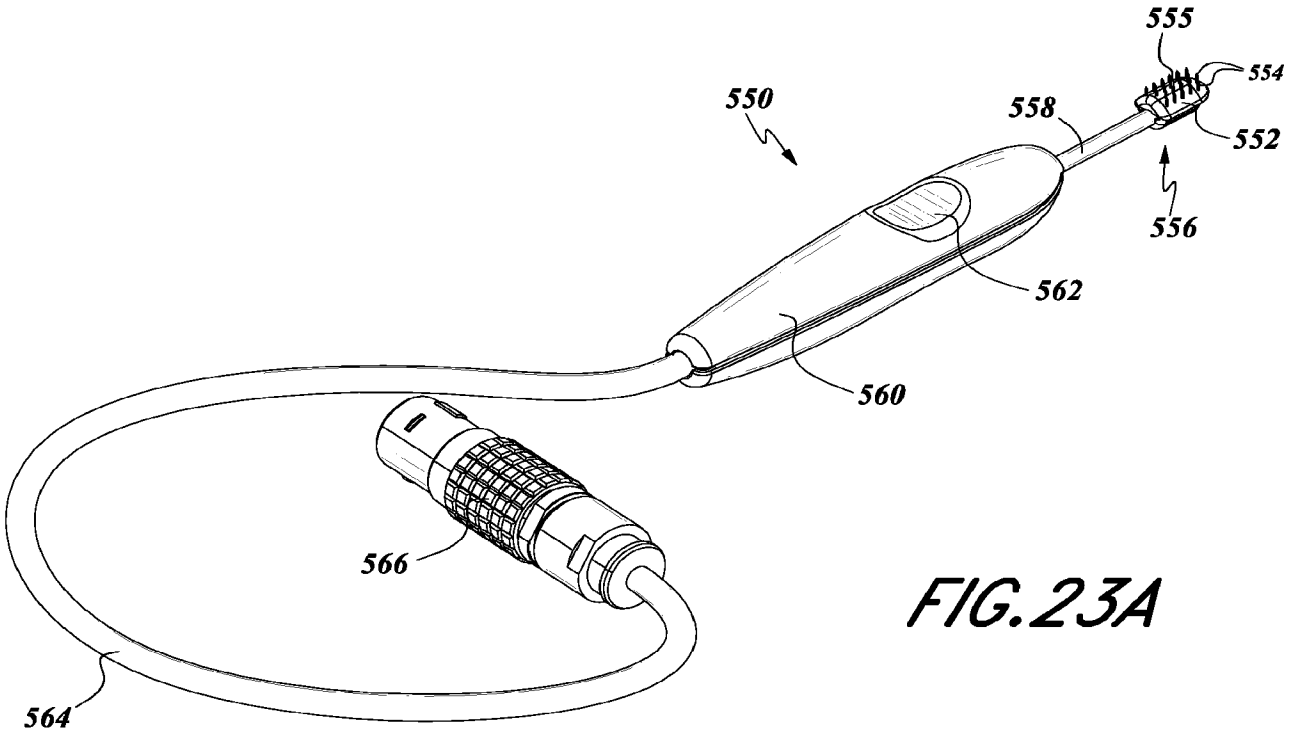


FIG. 23A

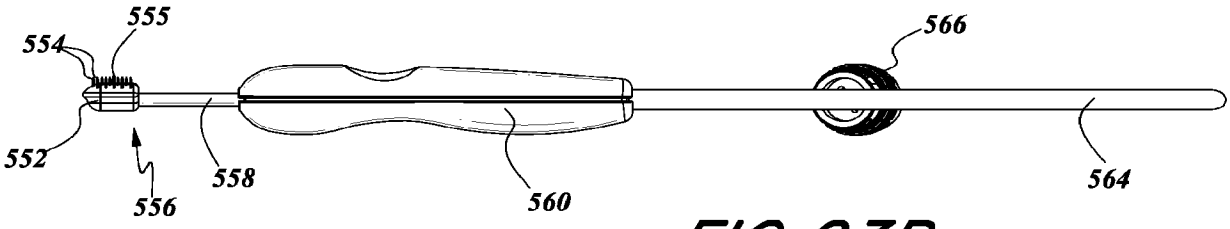


FIG. 23B

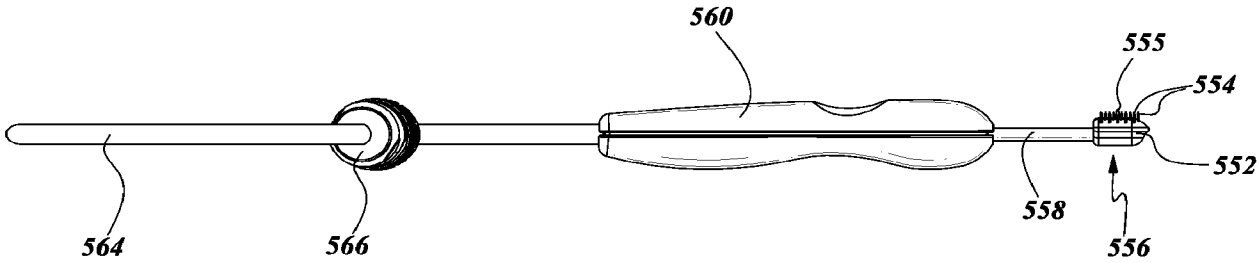


FIG. 23C

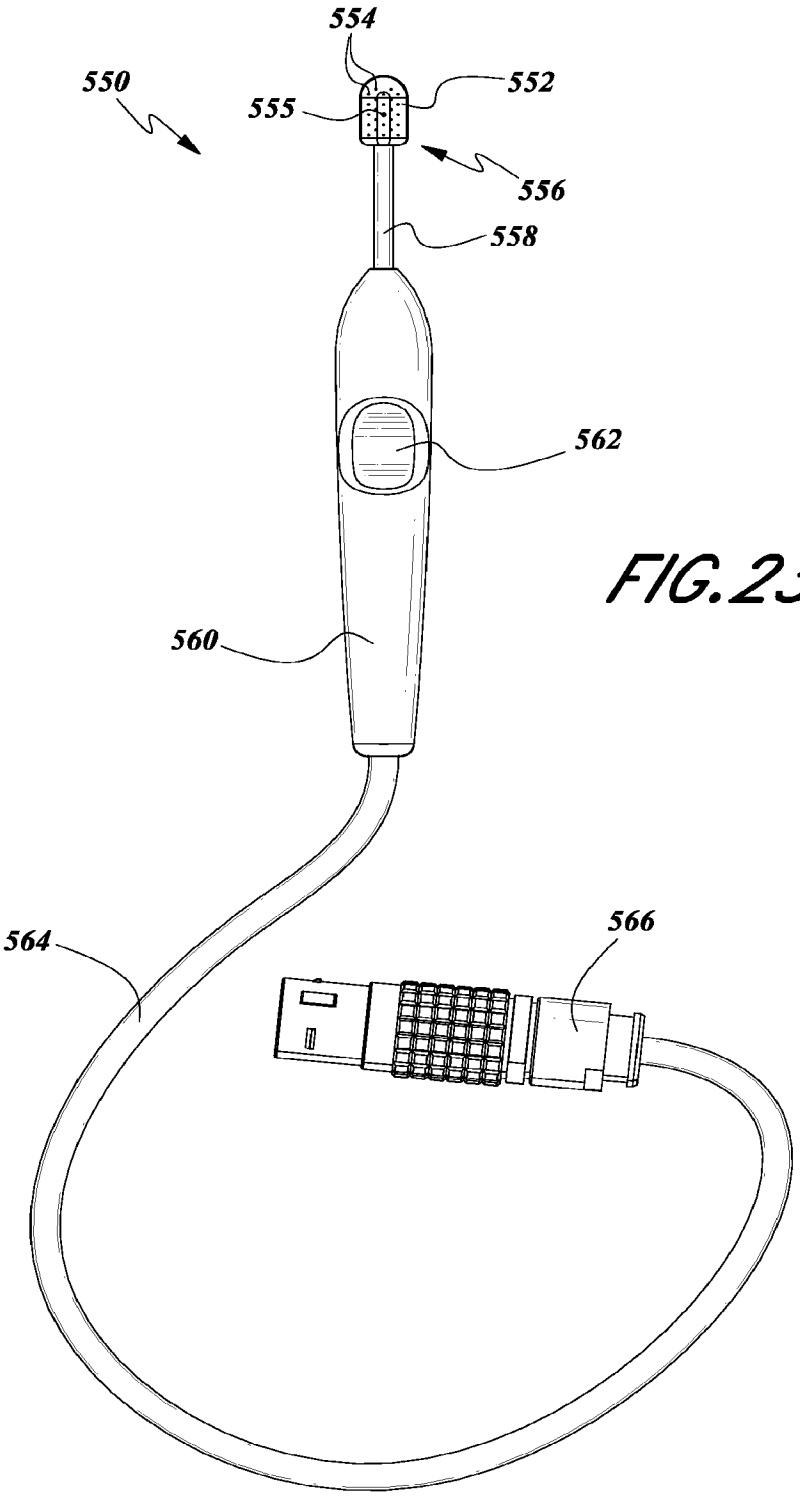


FIG. 23D

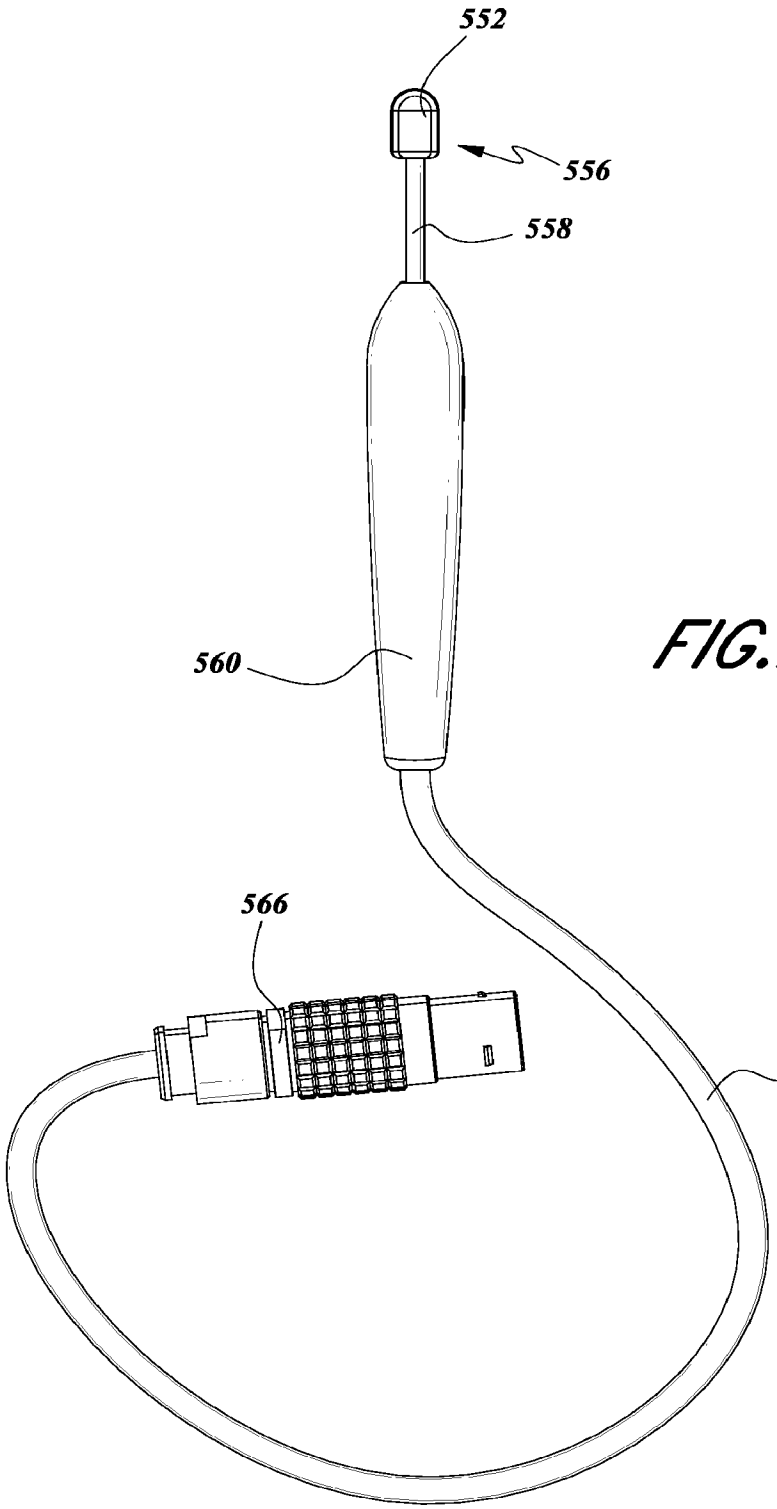


FIG. 23E

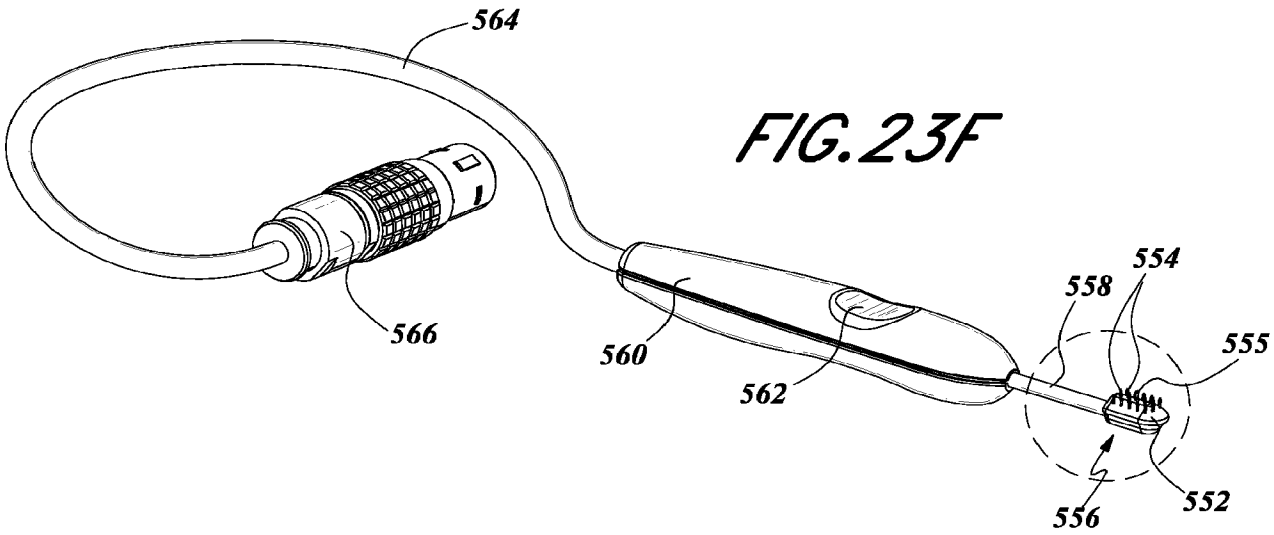


FIG. 23F

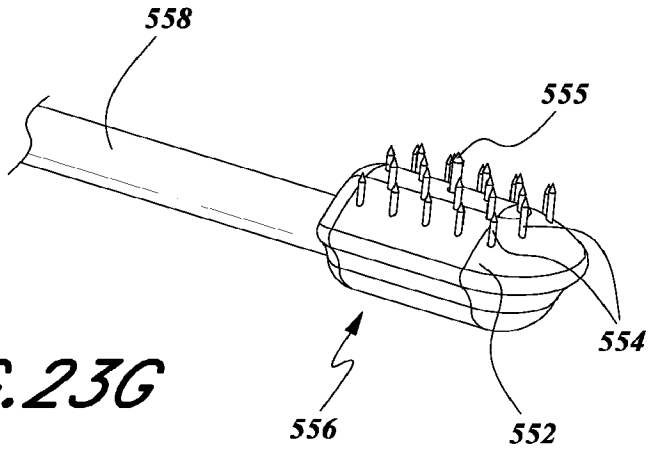


FIG. 23G

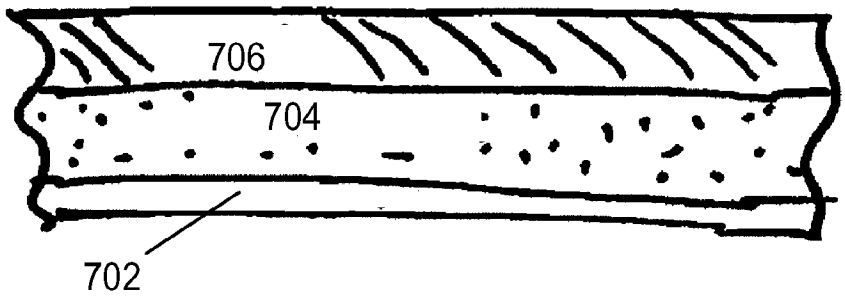


FIG. 24A

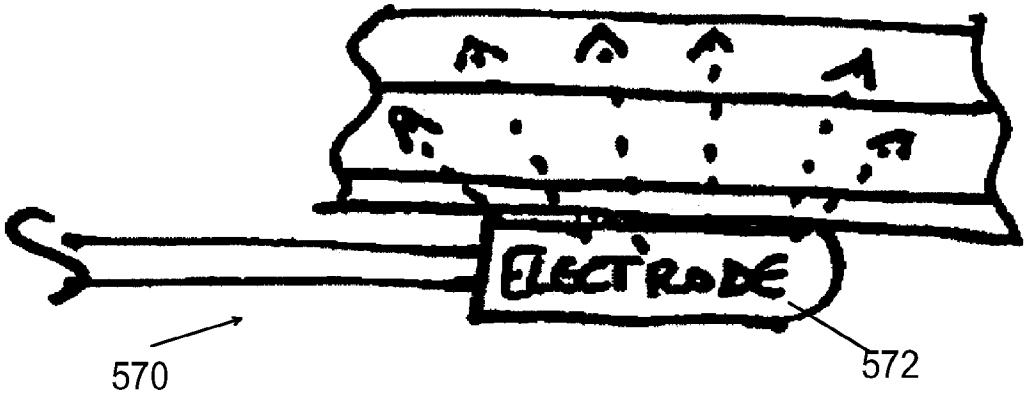


FIG. 24B

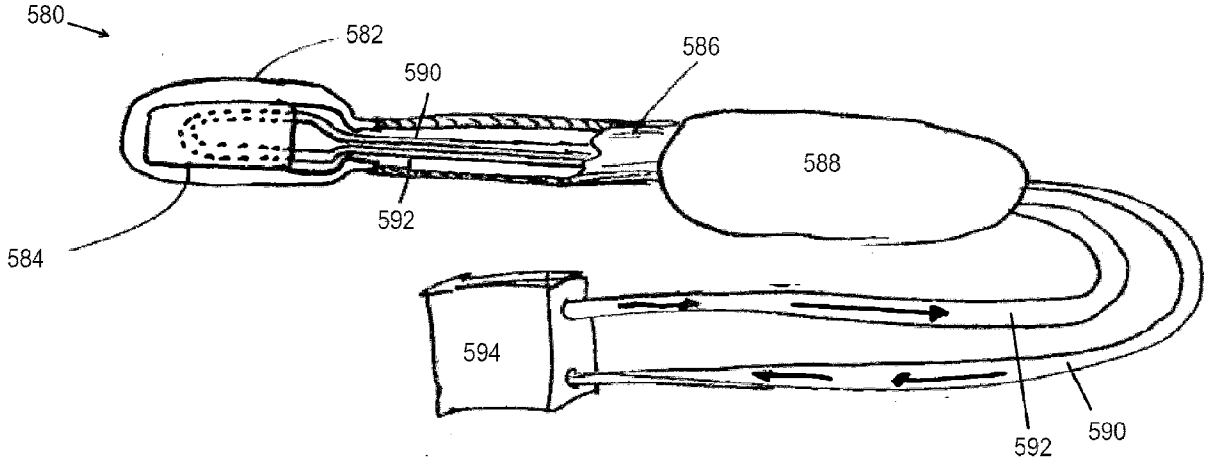


FIG. 25A

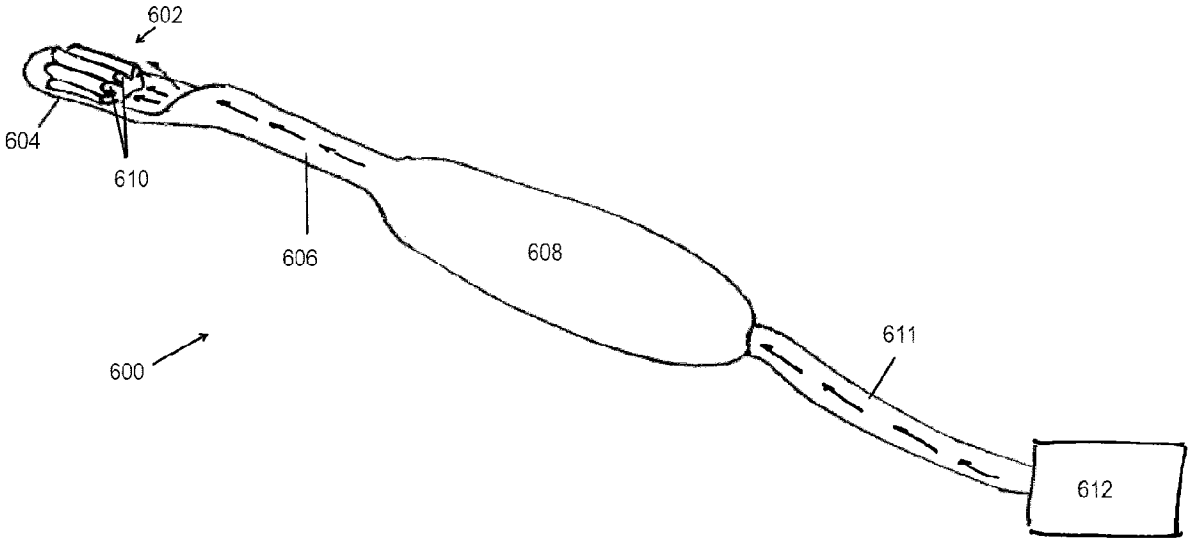


FIG. 25B

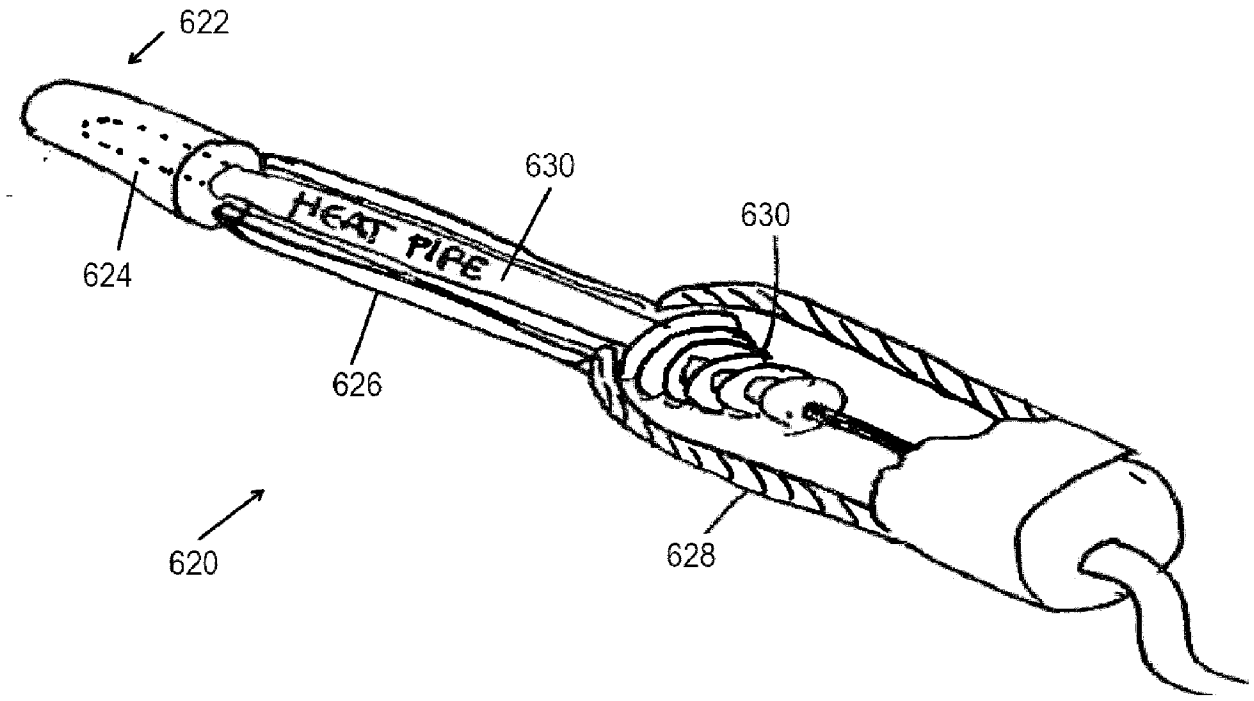


FIG. 26

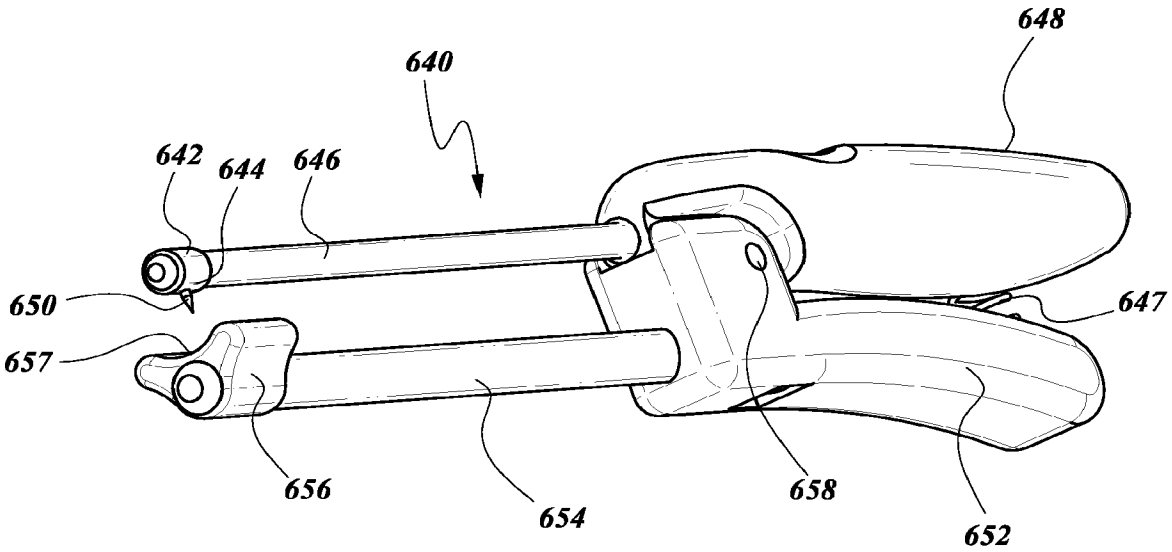


FIG. 27

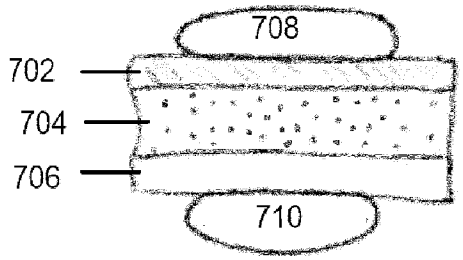


FIG. 28A

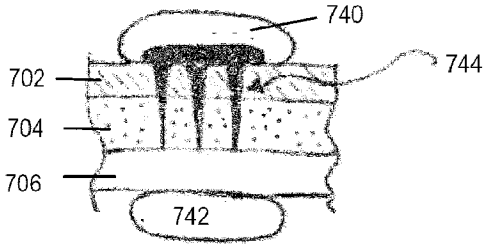


Fig. 28D

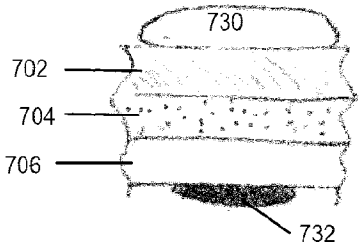


Fig. 28B

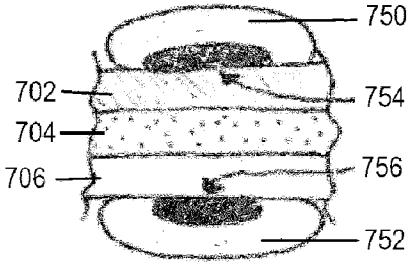


Fig. 28E

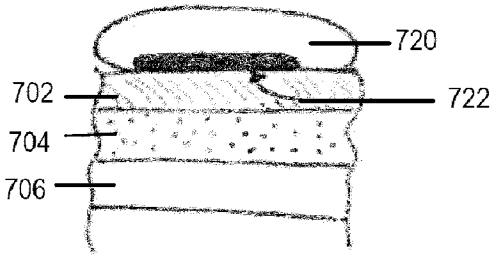


Fig. 28C

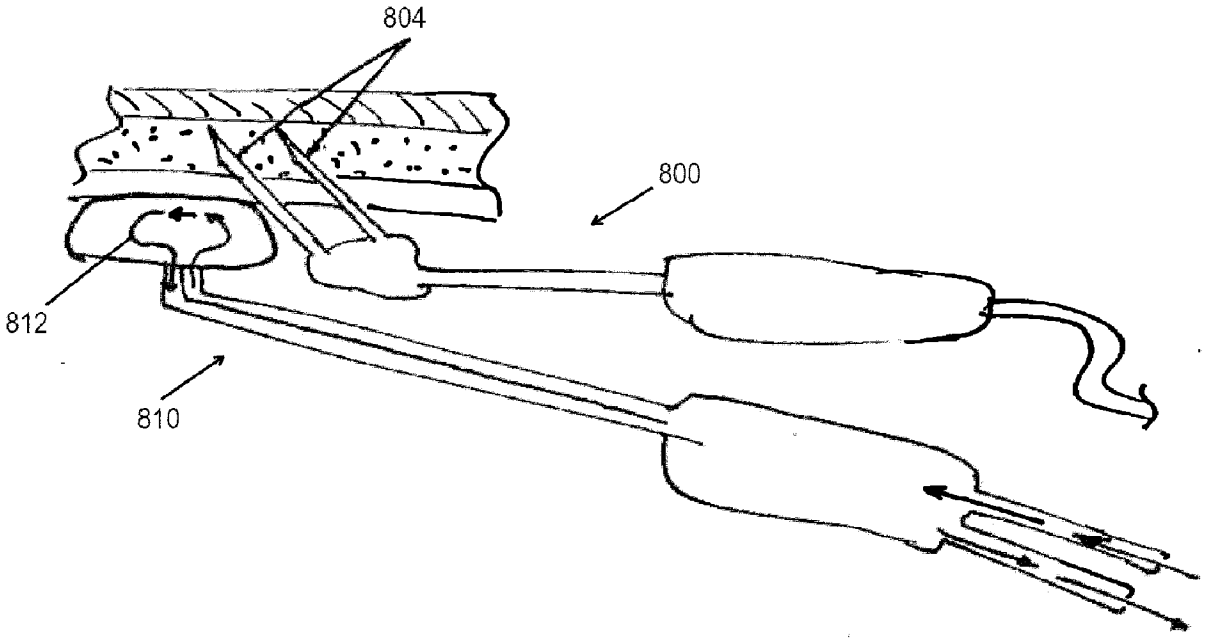


FIG. 29

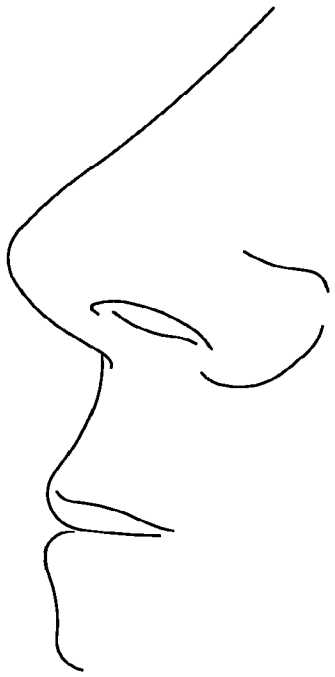


FIG. 30A

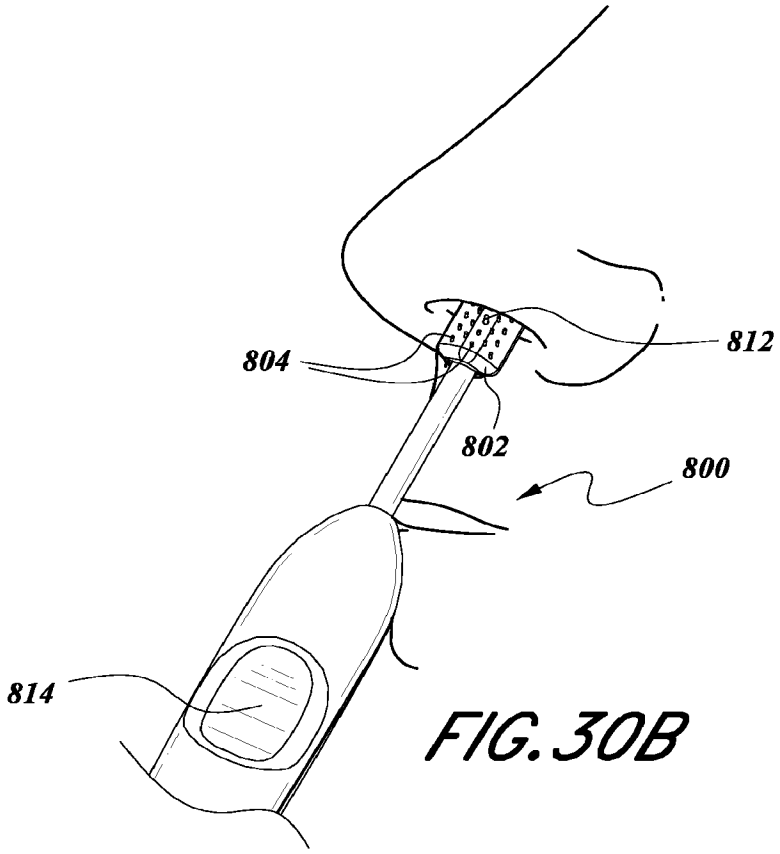


FIG. 30B

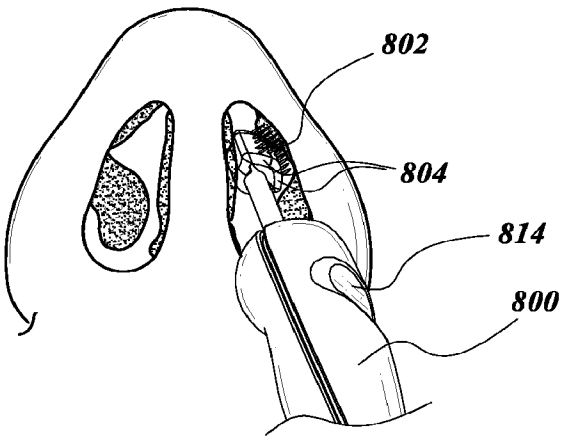


FIG. 30C

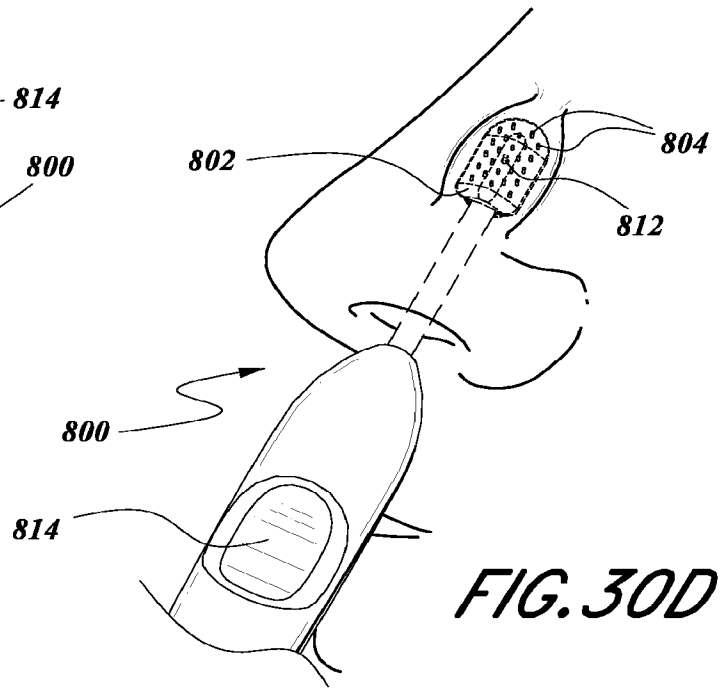


FIG. 30D

FIG. 31

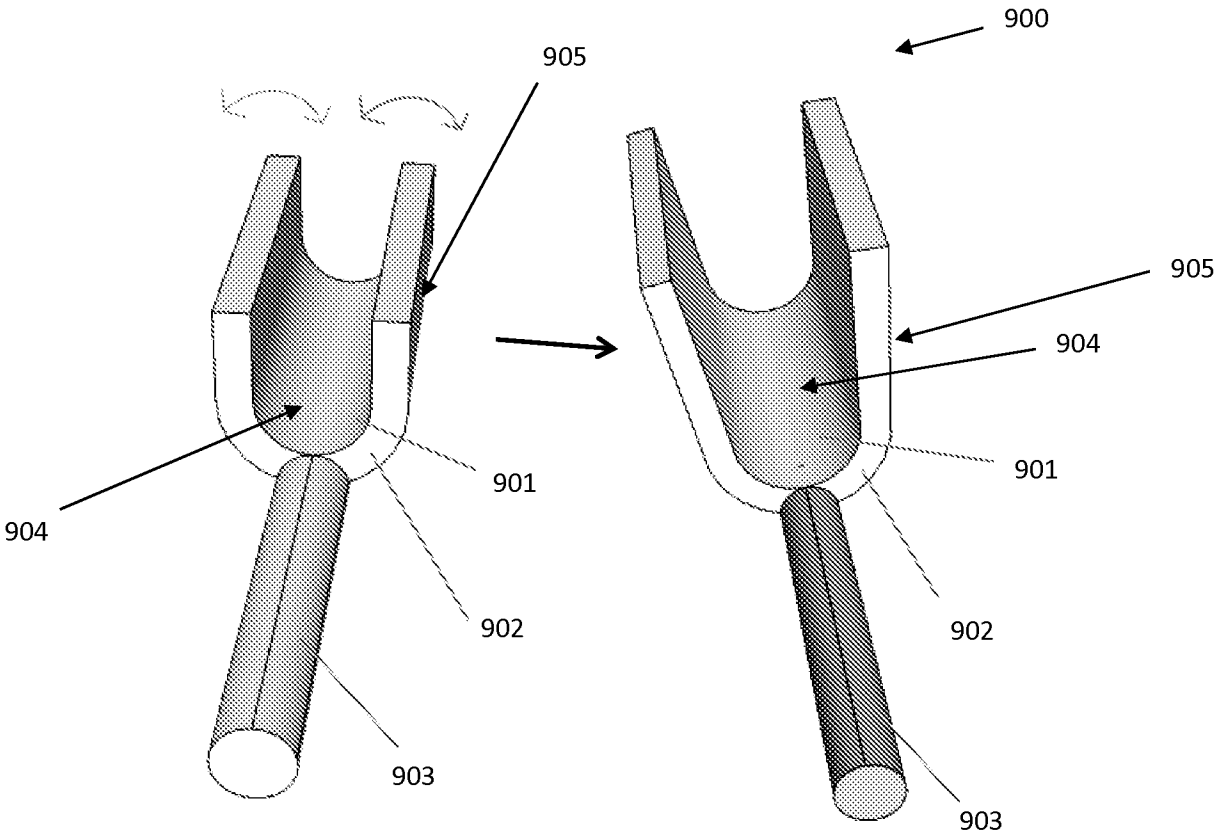


Fig 31

Fig 32A

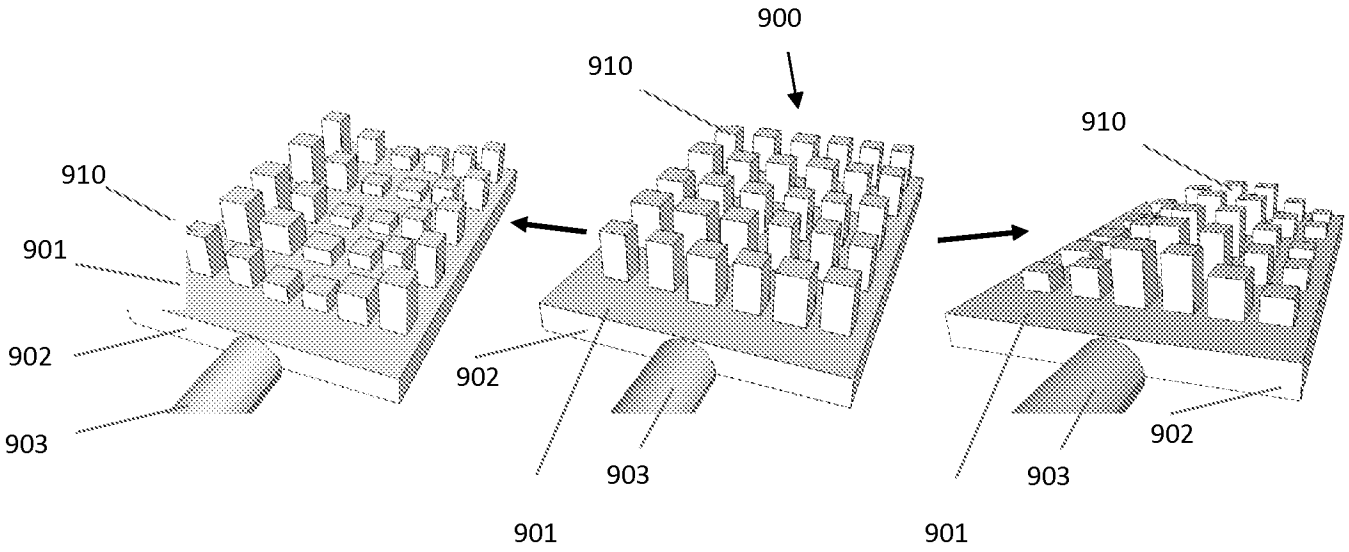


Fig 32B

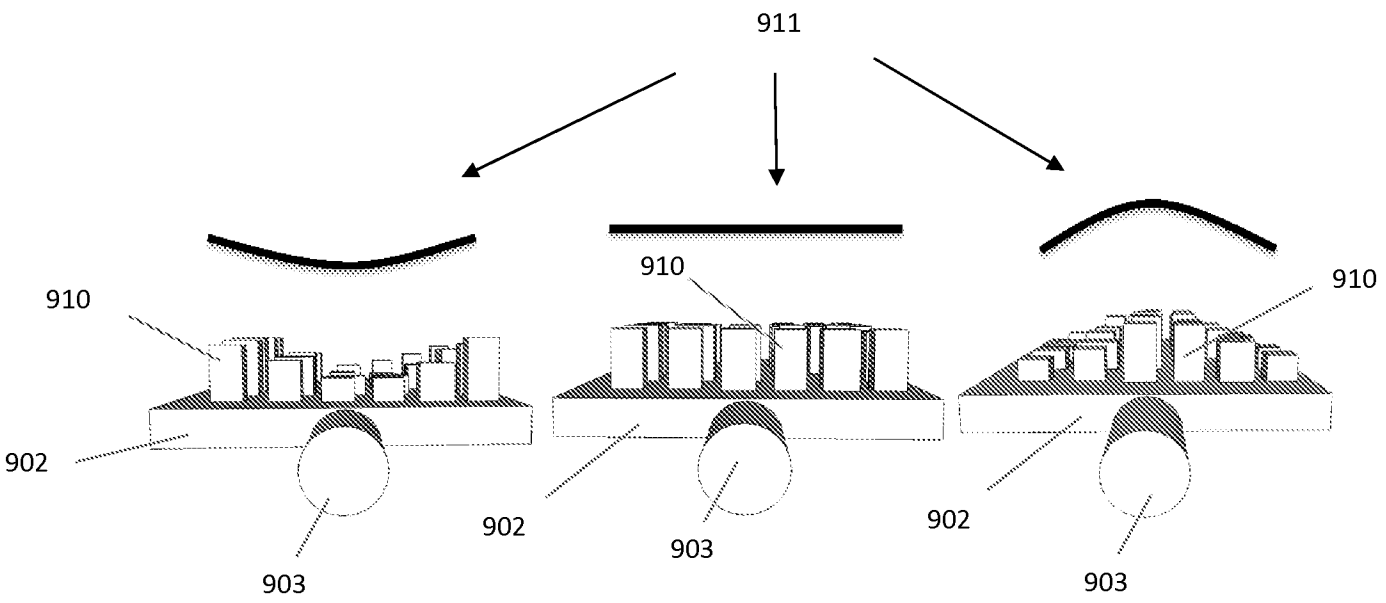


Fig 32B

FIG. 33

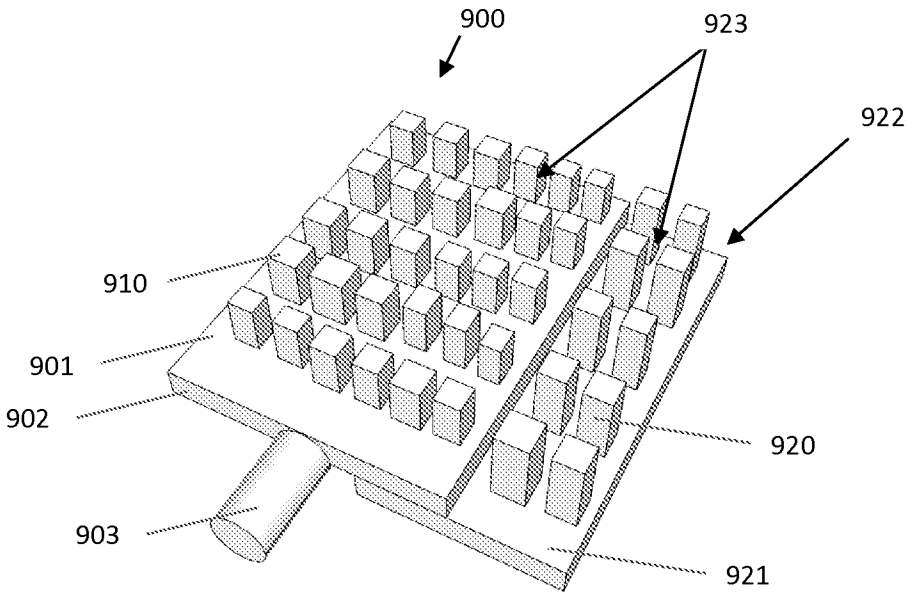


FIG. 34

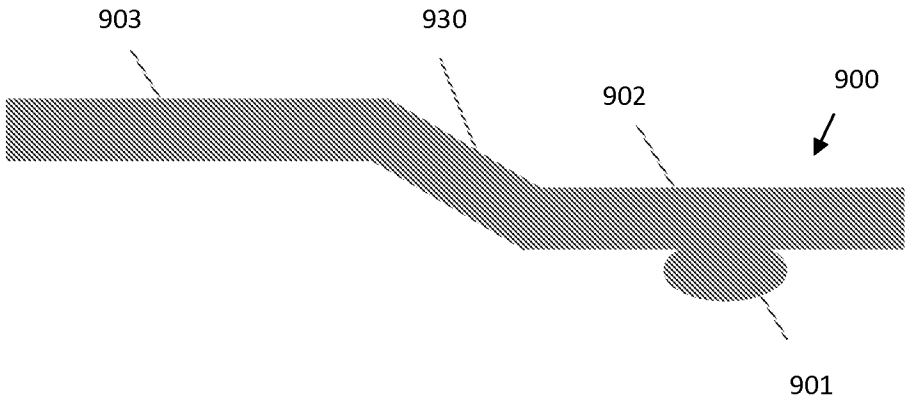


FIG. 35

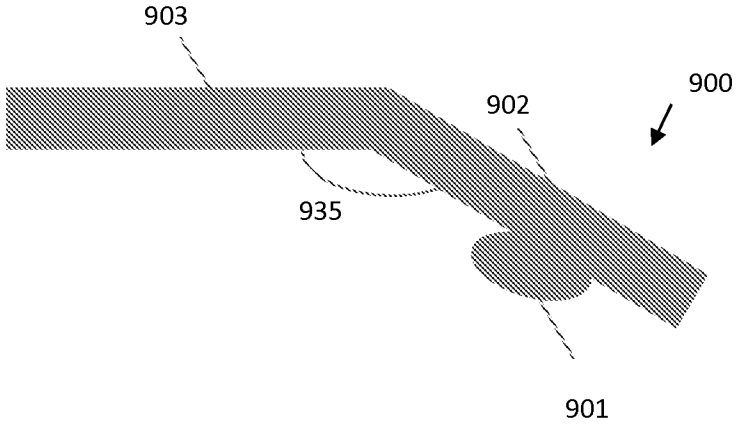


FIG. 36

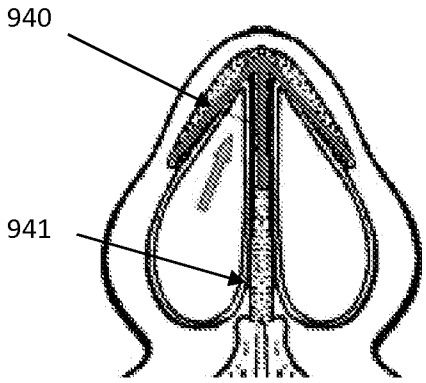


FIG. 37

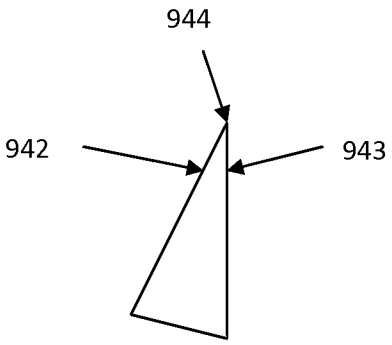


FIG. 38A

FIG. 38B

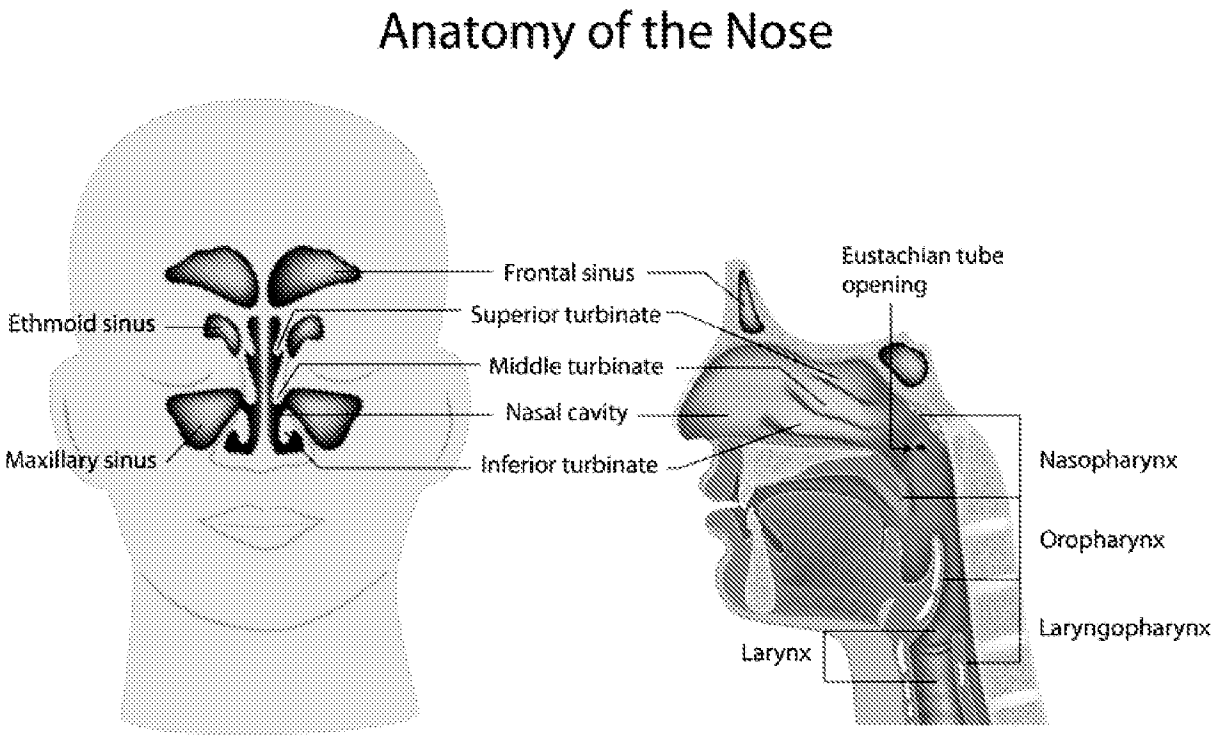


FIG. 39

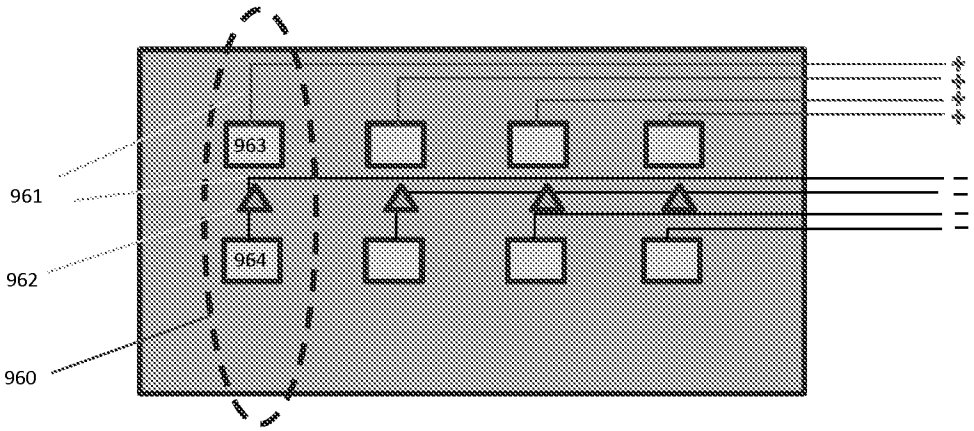


FIG. 40

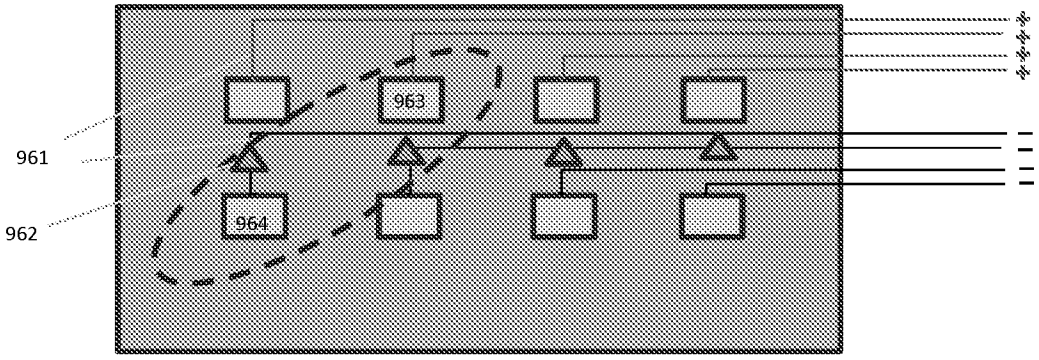


FIG. 41

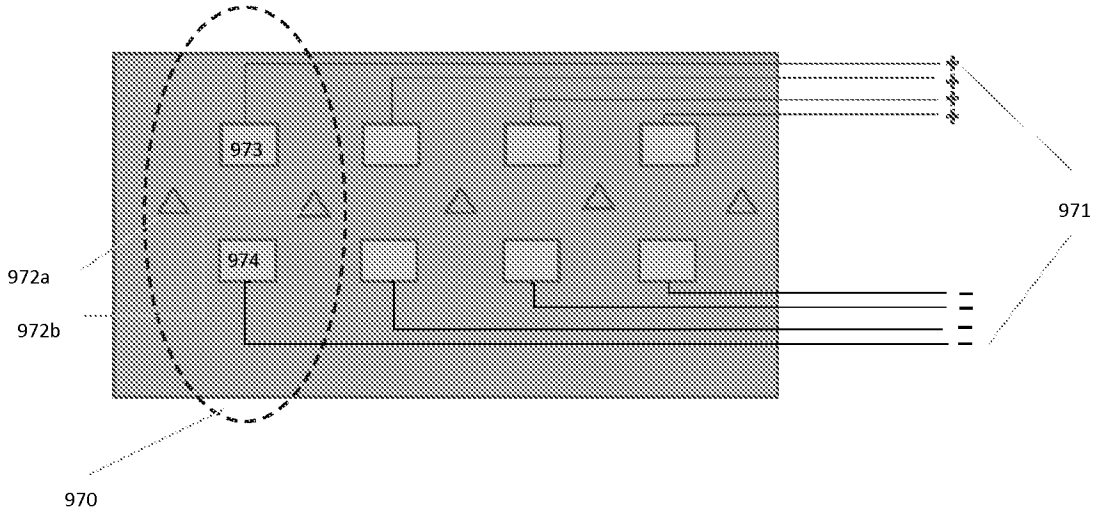


FIG. 42A

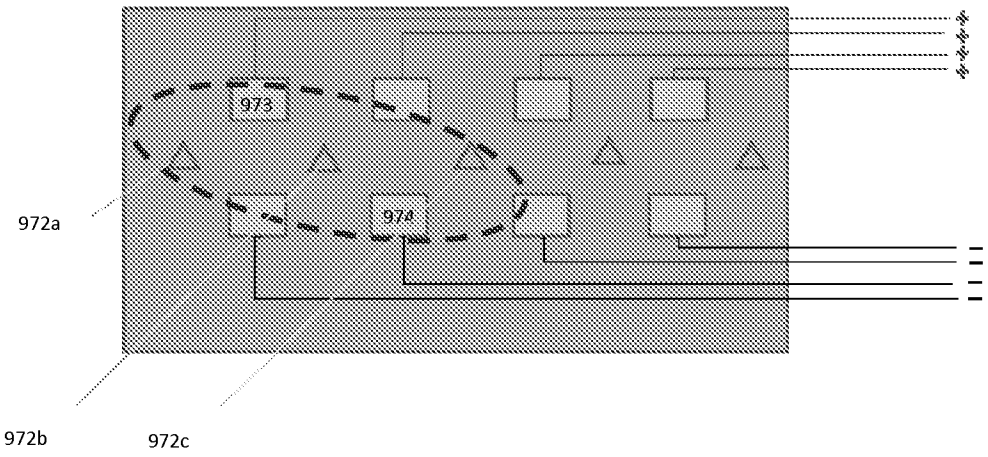


FIG. 42B

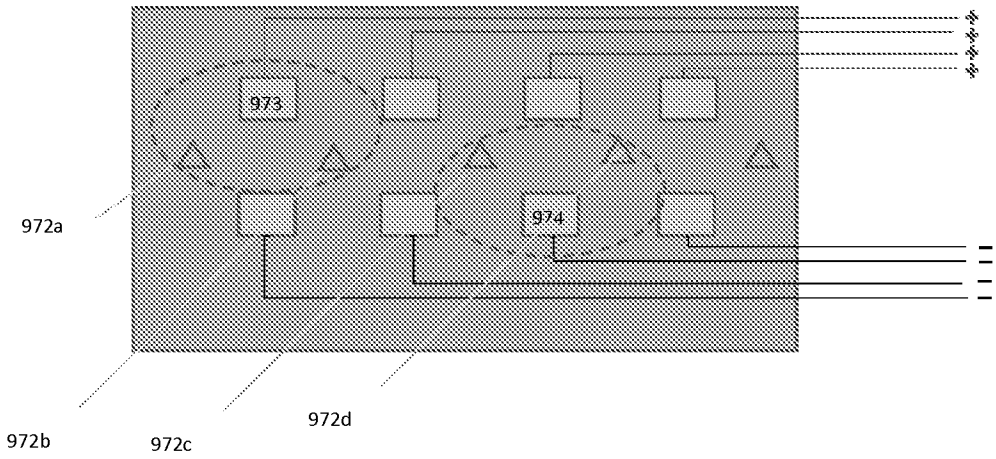


FIG. 43

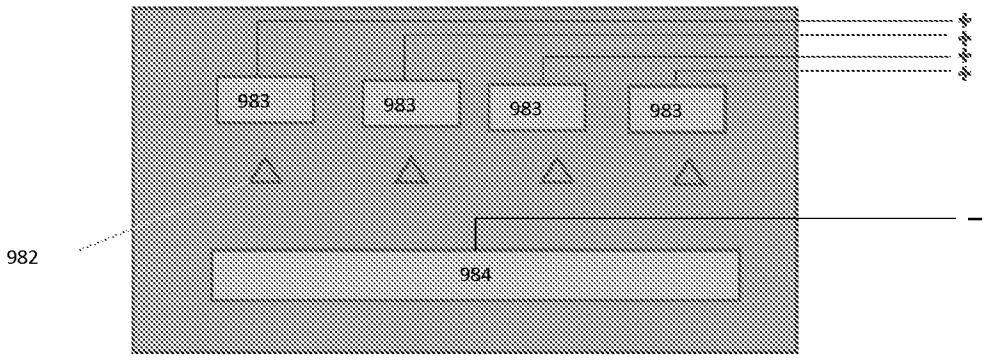


FIG. 44

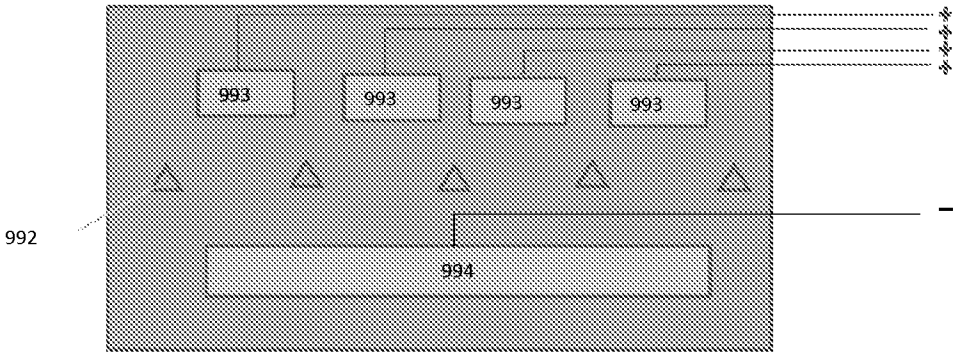


FIG. 45

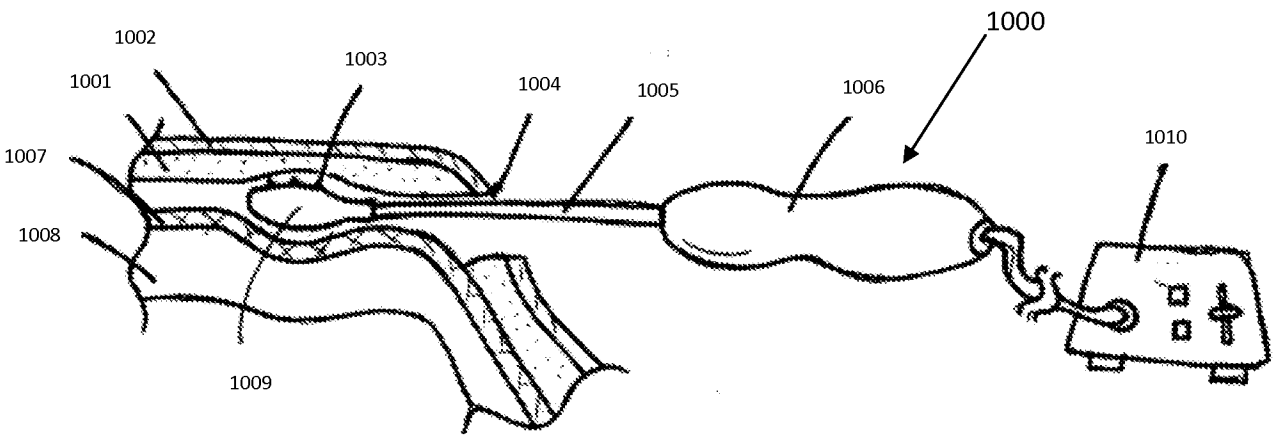


FIG. 46A

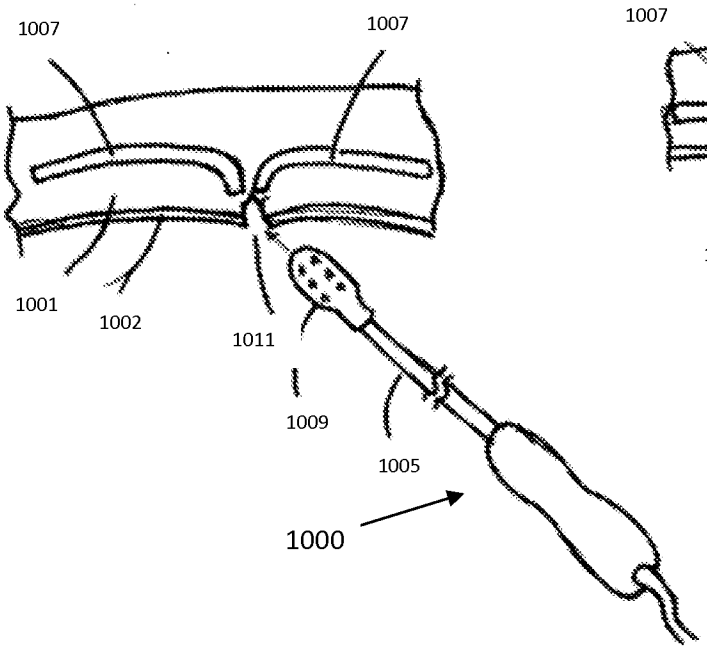


FIG. 46B

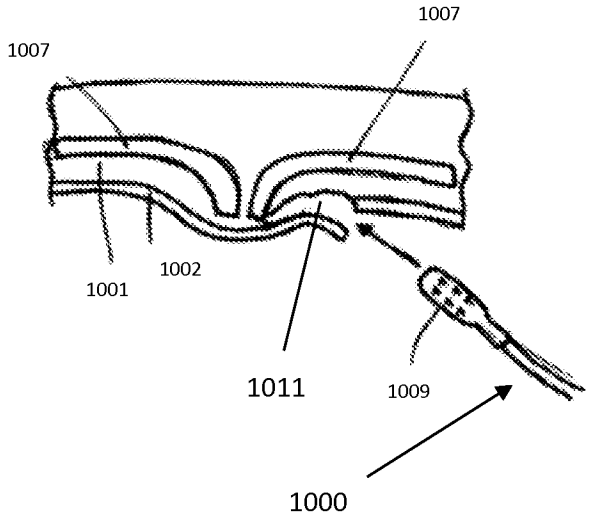
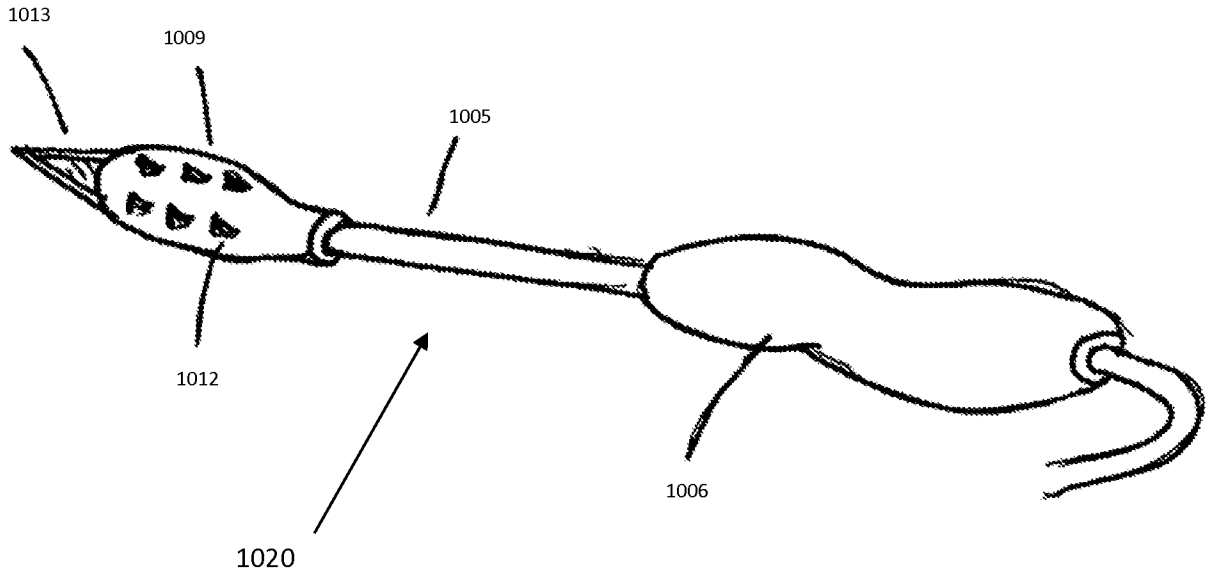


FIG. 47



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/319,087	06/30/2014	Scott J. WOLF	P244992US01 (494912-9)

CONFIRMATION NO. 7653

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

NOTICE



Date Mailed: 07/14/2014

INFORMATIONAL NOTICE TO APPLICANT

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

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

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

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/319,087	06/30/2014	3773	2500	P244992US01 (494912-9)	47	5

CONFIRMATION NO. 7653

75149
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Intellectual Property Department - SF
Columbia Center
701 Fifth Avenue, Suite 6100
Seattle, WA 98104-7043

FILING RECEIPT

OC00000069551015

Date Mailed: 07/14/2014

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., Menlo Park, CA

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

Domestic Priority data as claimed by applicant

This application is a CIP of 13/495,844 06/13/2012
which claims benefit of 61/603,864 02/27/2012
and claims benefit of 61/496,930 06/14/2011

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

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

If Required, Foreign Filing License Granted: 07/11/2014
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/319,087**
Projected Publication Date: 10/23/2014
Non-Publication Request: No

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

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Preliminary Class

606

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.

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LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/319,087

APPLICATION AS FILED - PART I

	(Column 1)	(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE($)	FEE($)		RATE($)	FEE($)
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))	47 minus 20 =	* 27	x 40 =	1080	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	5 minus 3 =	* 2	x 210 =	420			
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	2430		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
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)		(Column 2)	(Column 3)					
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
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.

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

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/319,087
	Filing Date	June 30, 2014
	First Named Inventor	Scott J. WOLF
	Art Unit	7653
	Examiner Name	MANUEL, George C.
	Attorney Docket Number	P244992US01 (494912-9)

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4,887,605		1989-12-19	ANGELSE, *et al.*	
		5,348,008		1994-09-20	BORNN, *et al.*	
		5,674,191		1995-10-07	EDWARDS, *et al.*	
		5,533,499		1996-07-09	JOHNSON	
		5,624,439		1997-04-29	EDWARDS, *et al.*	
		5,823,197		1997-10-20	EDWARDS	
		5,707,349		1998-01-13	EDWARDS	
		5,718,702		1998-02-17	EDWARDS	
		5,728,094		1998-03-17	EDWARDS	
		5,730,719		1998-03-24	EDWARDS	
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		5,843,077		1998-12-01	EDWARDS	
		5,846,235		1998-12-08	PASRICHA, *et al.*	
		5,879,349		1999-03-09	EDWARDS	
		6,045,549		2000-04-04	SMETHERS, *et al.*	
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		6,131,579		2013-10-17	THORSON, *et al.*	
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		6,293,941	B1	2001-09-25	STRUL	
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		6,575,969		2003-06-10	RITTMAN, III, *et al.*	
		6,589,235	B2	2003-07-08	WONG, *et al.*	
		6,659,106	B1	2003-12-09	HOVDA, *et al.*	
		6,911,027	B1	2005-06-28	EDWARDS, *et al.*	
		6,978,781	B1	2005-12-27	JORDAN	
		7,055,523	B1	2006-06-06	BROWN	
		7,114,495	B2	2006-10-03	LOCKWOOD	
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		7,850,683		2010-12-14	ELKINS, *et al.*	
		8,317,782		2012-11-27	OWENS, *et al.*	

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		2002/0016588	A1	2002-02-07	WONG, *et al.*	
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	Attorney Docket Number	P244992US01 (494912-9)

		2006/0276817		2006-12-07	VASSALLO, *et al.*	
		2007/0066944	A1	2007-03-22	NYTE	
		2007/0219600		2007-09-20	GERTNER, *et al.*	
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		2012/0078377		2012-03-29	GONZALES	

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
		2007/037895	WO		2007-04-05	NYTE		
		2007/134005	WO		2007-11-22	FRIEDMAN		

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

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	Examiner Name	MANUEL, George C.
	Attorney Docket Number	P244992US01 (494912-9)

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		COLE, *BIOPHYSICS OF NASAL AIRFLOW: A Review*, American Journal of Rhinology, Vol. 14, No. 4, July-Aug 2000, pp. 245-249	
		COLE, *The Four Components of the Nasal Valve*, *American Journal of Rhinology*, Vol. 17, No. 2, March-April 2003, pp. 107-110	
		KJAERGAARD, *et al.*, *Relation of Nasal Air Flow to Nasal Cavity Dimensions*, Arch Otolaryngol Head Neck Surg., Vol. 135, No. 6, June 2009, pp. 565 – 570	
		SINGAPORE SEARCH REPORT for Application Serial No. 201309238-2, (Docket No. P239600.WO-SG.01), June 9, 2014 for pp. 1-27	
		STUPAK, *A Perspective on the Nasal Valve*, Power Point Presentation, Department of Otorhinolaryngology, Albert Einstein College of Medicine, Nov. 6, 2009, pp. 1-9	
		STUPAK, *Endonasal Repositioning of the Upper Lateral Cartilage and the Internal Nasal Valve*, Annals of Otology, Rhinology & Laryngology, Annals Publishing Company, Vol. 120(2), 2011, pp. 88-94	

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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

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	Attorney Docket Number	P244992US01 (494912-9)

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

CERTIFICATION STATEMENT

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

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

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

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

Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	October 6, 2014
Name/Print	Scott Michael Smith	Registration Number	48268

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

4823-6242-7167

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 April 2007 (05.04.2007)

PCT

(10) International Publication Number
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(51) International Patent Classification:
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PCT/US2006/033739

(22) International Filing Date: 29 August 2006 (29.08.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/232,688 22 September 2005 (22.09.2005) US

(71) Applicant and
(72) Inventor: **NYTE, Christopher, Philip** [US/US]; 24818 SE Mirrormont Place, Issaquah, WA 98027 (US).

(74) Agents: **HAYDEN, Bridget, M.** et al.; DORSEY & WHITNEY LLP, SUITE 1500, 50 South Sixth Street, Minneapolis, MN 55402-1498 (US).

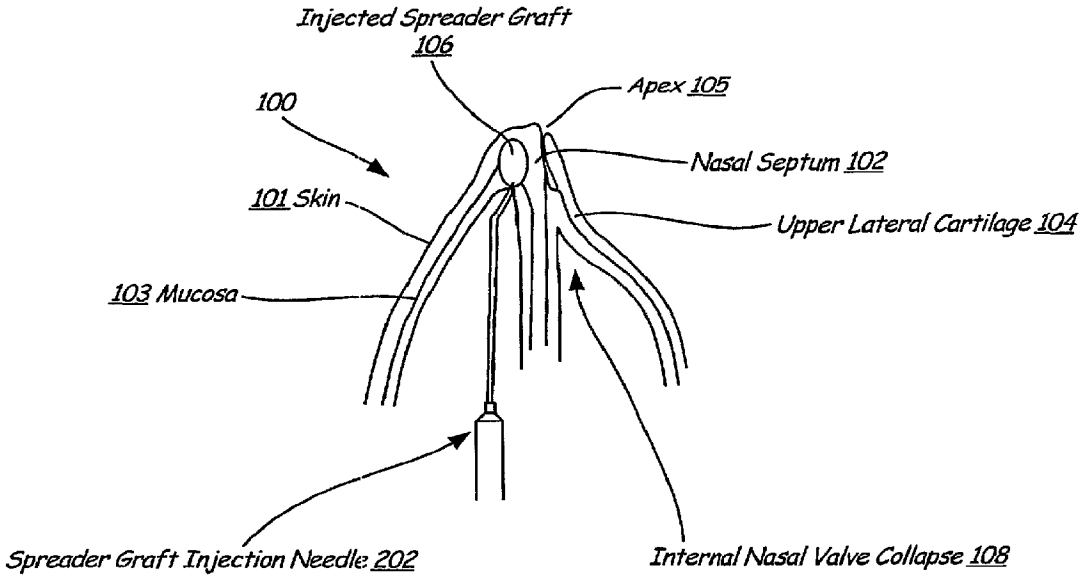
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ,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

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



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

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METHOD AND SYSTEM FOR TREATMENT OF INTERNAL NASAL VALVES

FIELD OF THE INVENTION

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

BACKGROUND OF THE INVENTION

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

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

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

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

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

BRIEF SUMMARY OF THE INVENTION

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

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

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

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

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

[012] In one embodiment, the treatment method may include increasing a patient's internal nasal valve angle so that the treatment results in a 10-15 degree internal nasal valve angle.
[013] The treatment method, according to embodiments of the invention, may be used to treat, nasal snoring, sleep apnea, and/or internal nasal valve collapse.

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

DETAILED DESCRIPTION OF THE INVENTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CLAIMS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

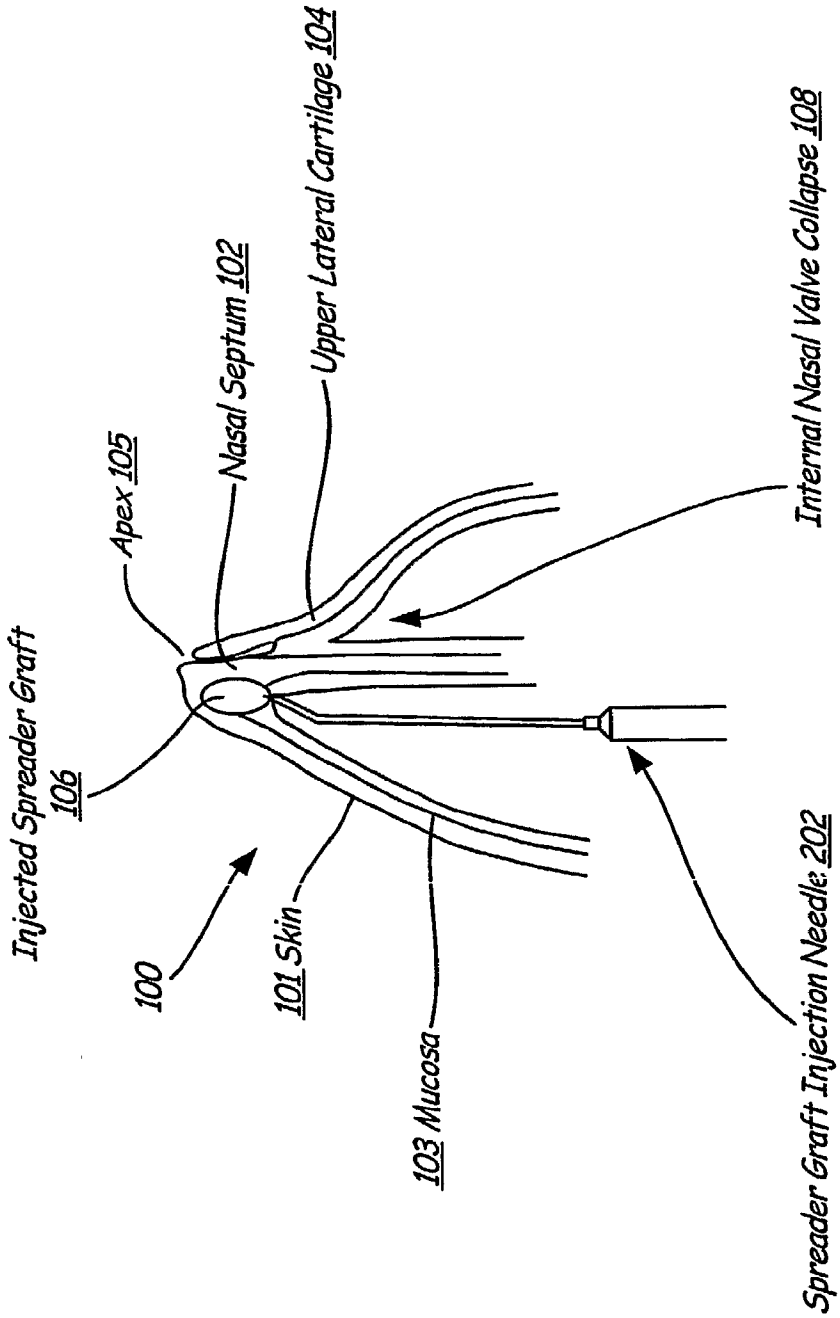

Injected Spreader Graft 106
Apex 105
Nasal Septum 102
Upper Lateral Cartilage 104
Internal Nasal Valve Collapse 108
100
101 Skin
103 Mucosa
Spreader Graft Injection Needle 202

FIG. 1

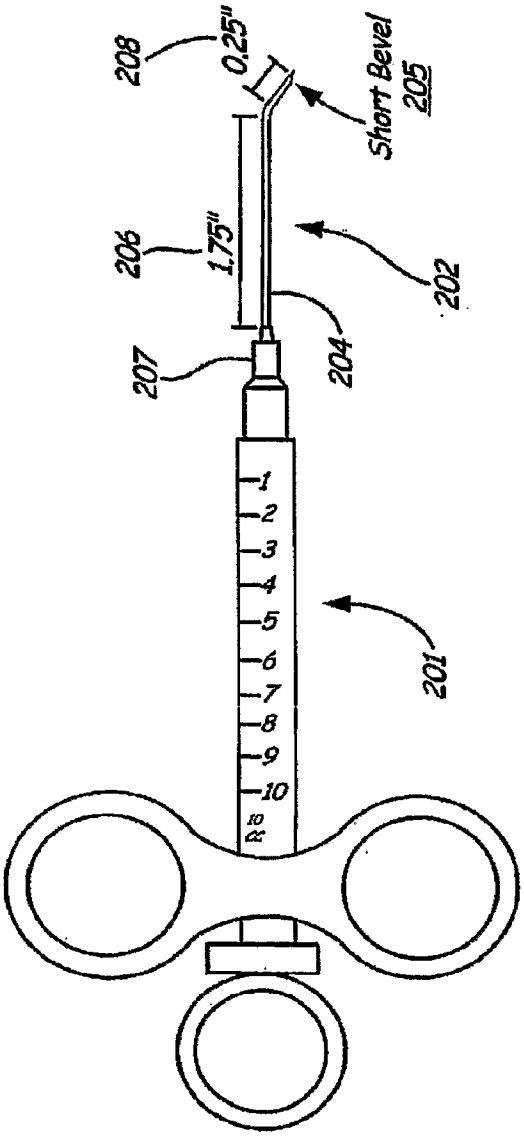


FIG. 2

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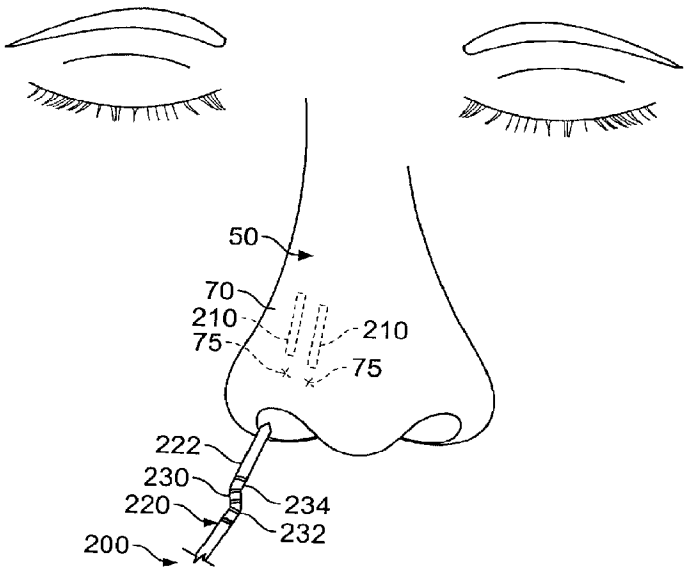
Declarations under Rule 4.17:

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

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

[Continued on next page]

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



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

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Devices and Methods to Treat Nasal Passages

CROSS-REFERENCE TO RELATED APPLICATION

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

TECHNICAL FIELD

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

BACKGROUND

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

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

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

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

SUMMARY

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

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

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

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

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

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

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

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

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

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

DESCRIPTION OF DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

WHAT IS CLAIMED IS:

1. A nasal implant delivery system comprising:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12. A nasal implant delivery system, comprising:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

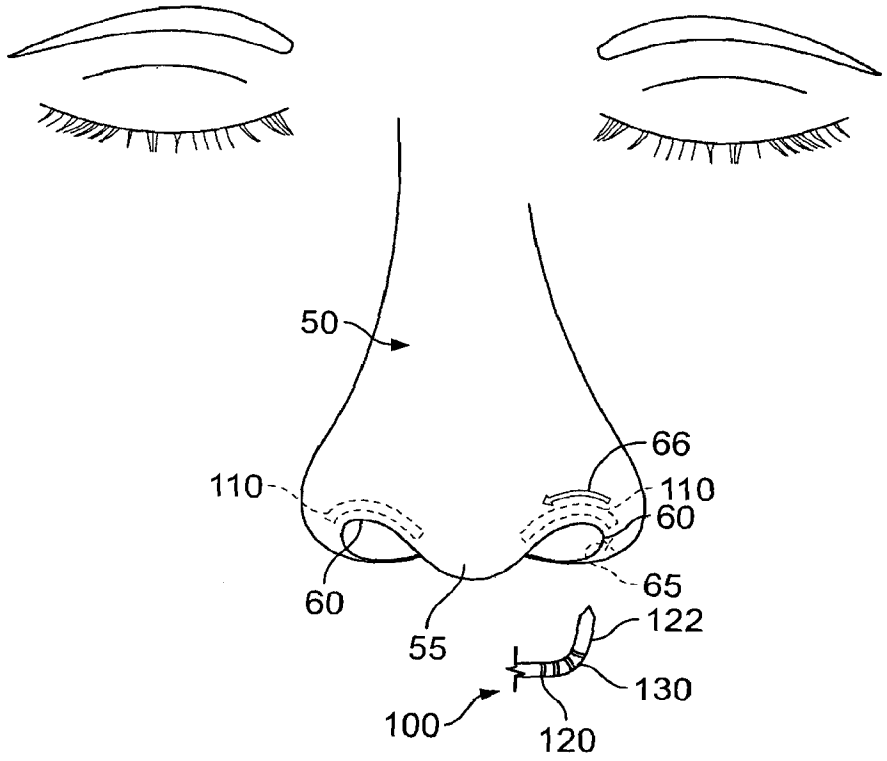


FIG. 1

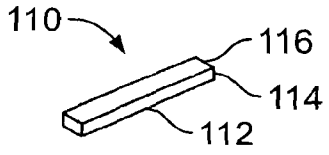


FIG. 2

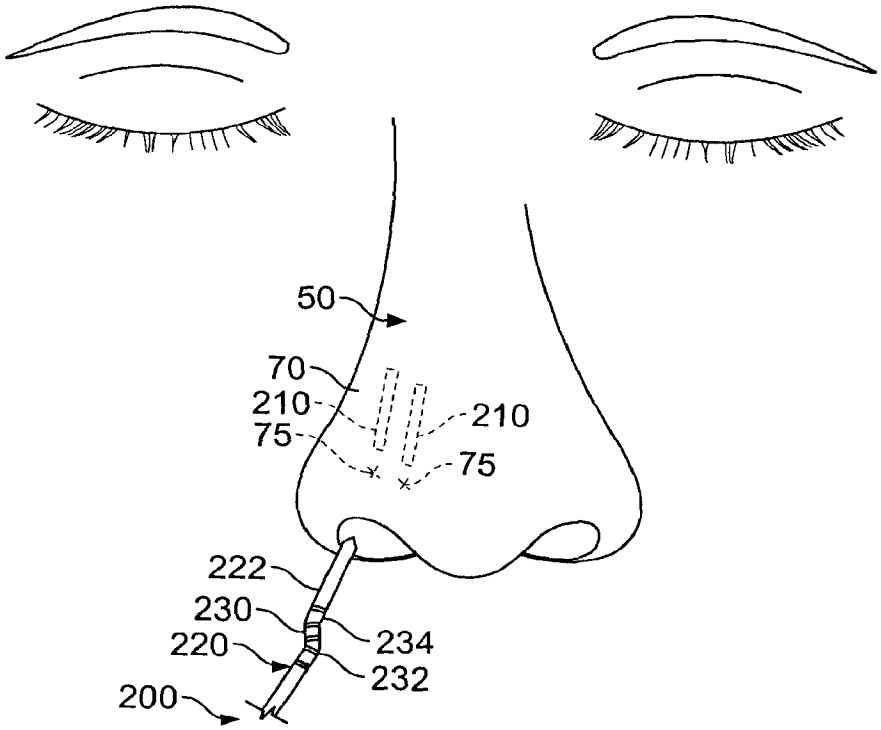


FIG. 3

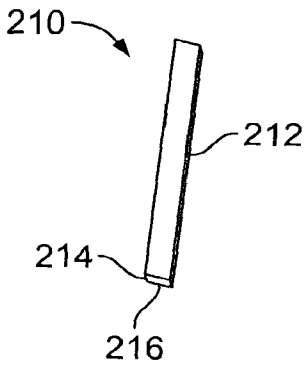


FIG. 4

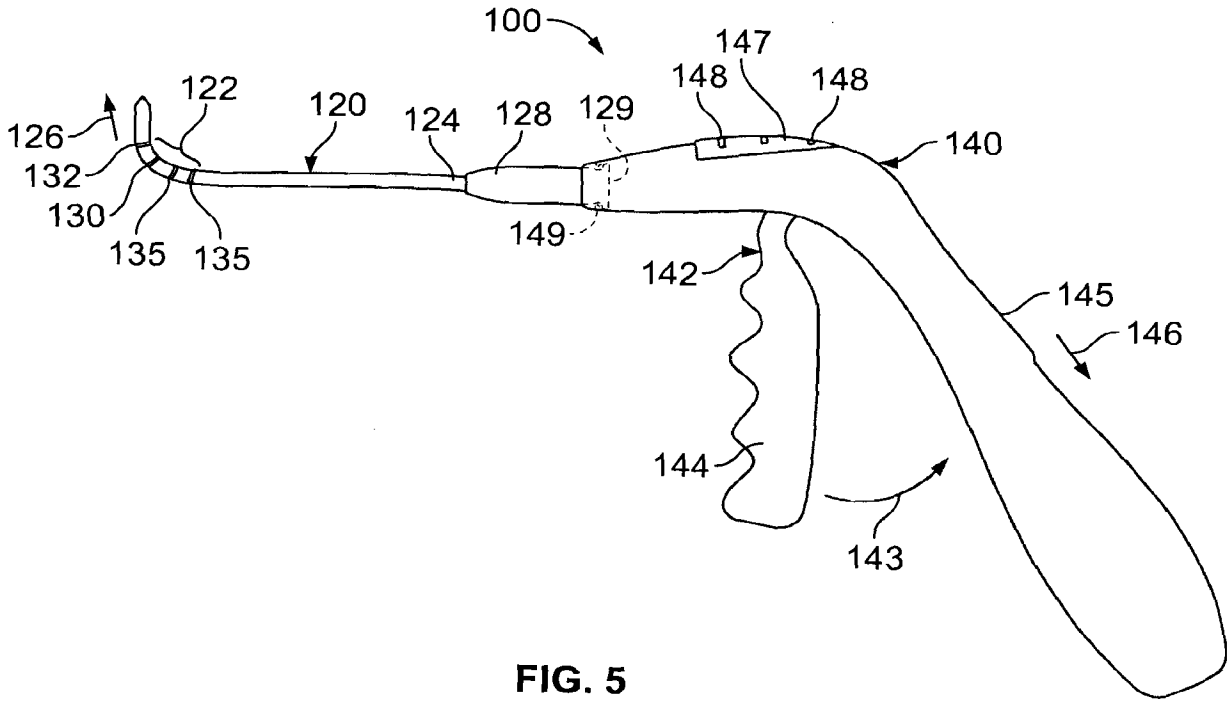


FIG. 5

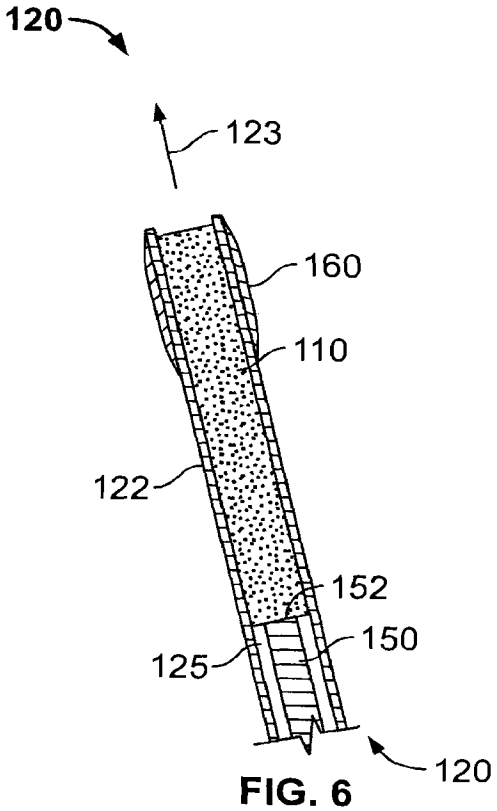


FIG. 6

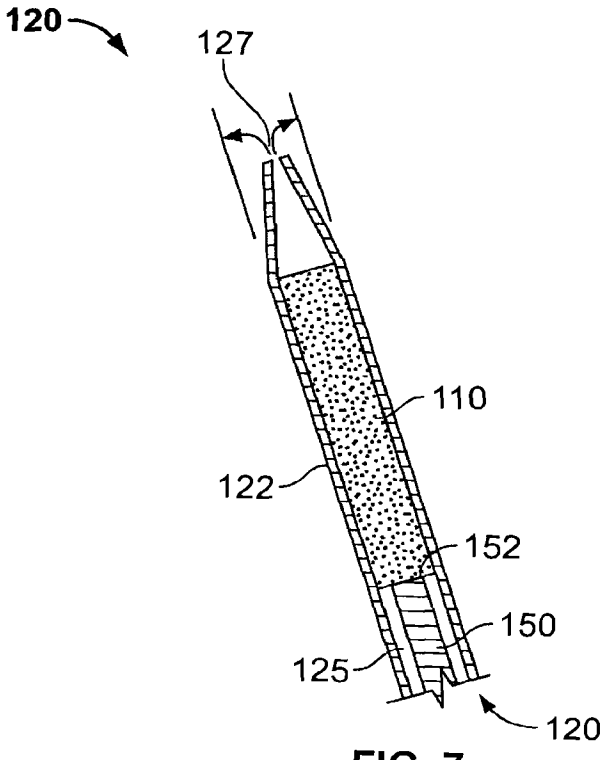


FIG. 7

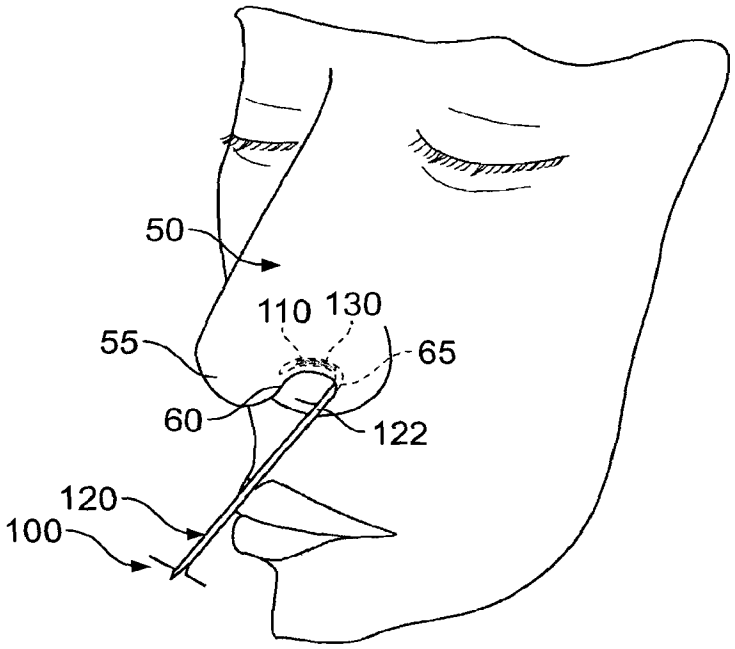


FIG. 8

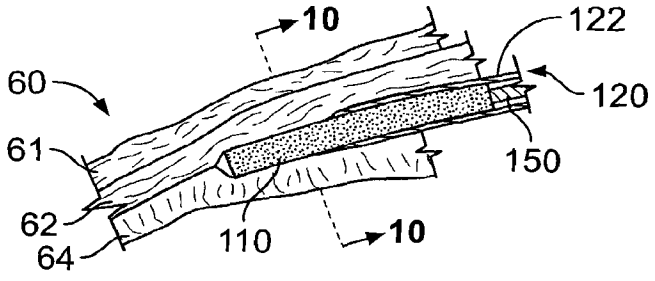


FIG. 9

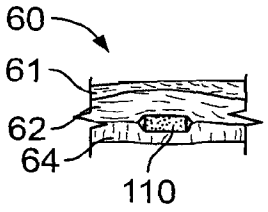


FIG. 10

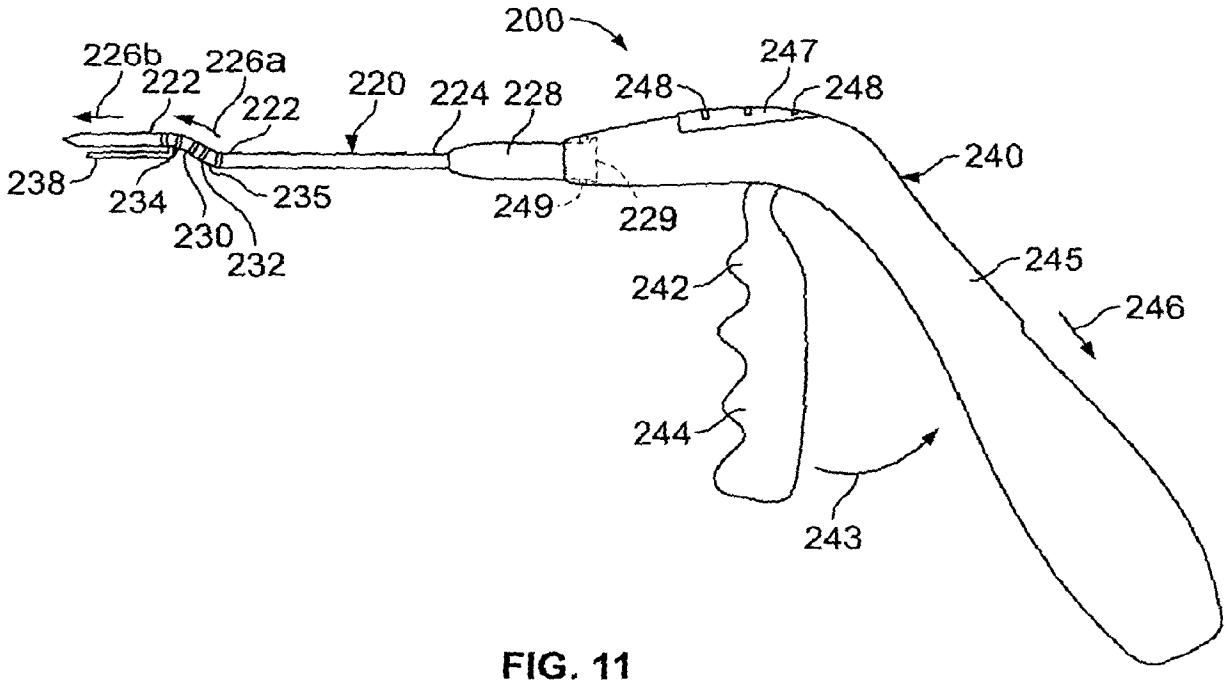


FIG. 11

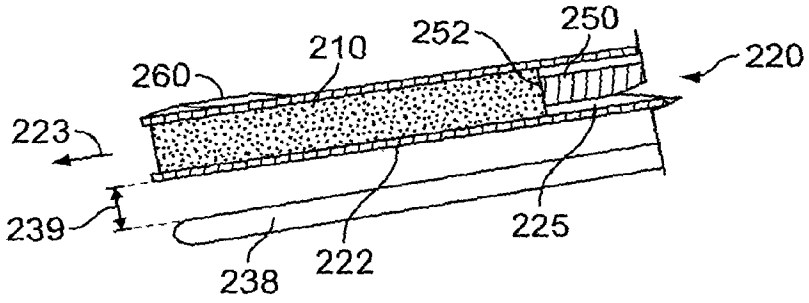


FIG. 12

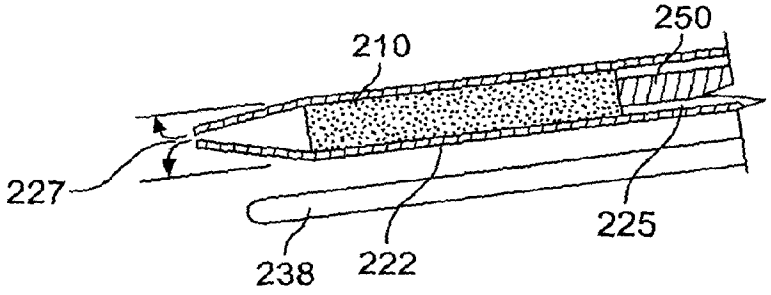


FIG. 13

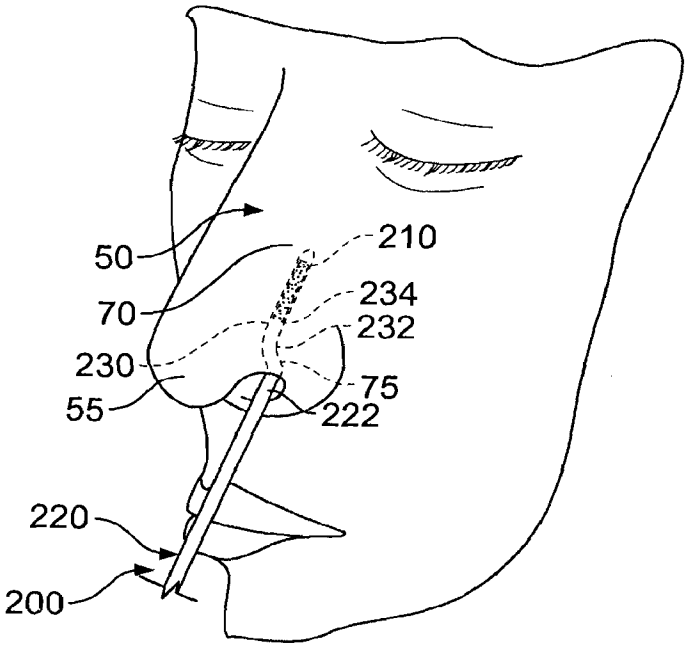


FIG. 14

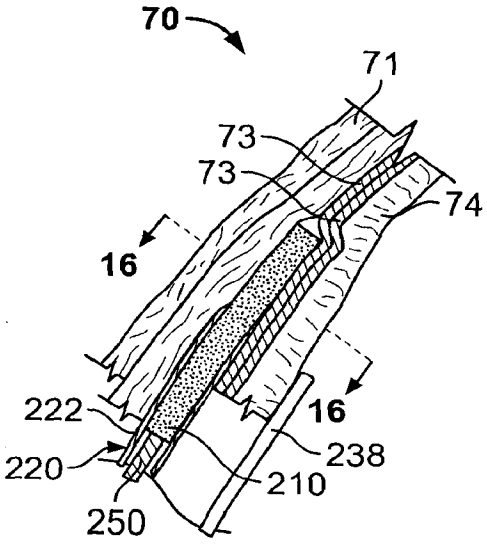


FIG. 15

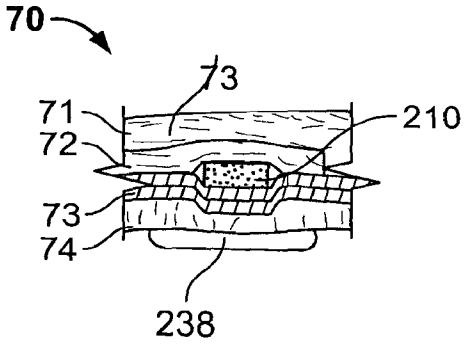


FIG. 16

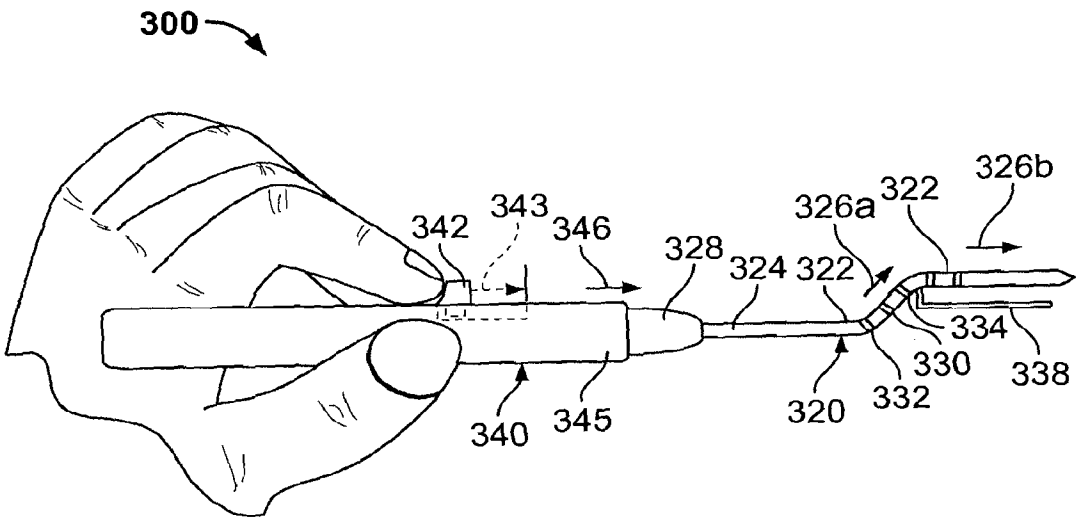

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FIG. 17

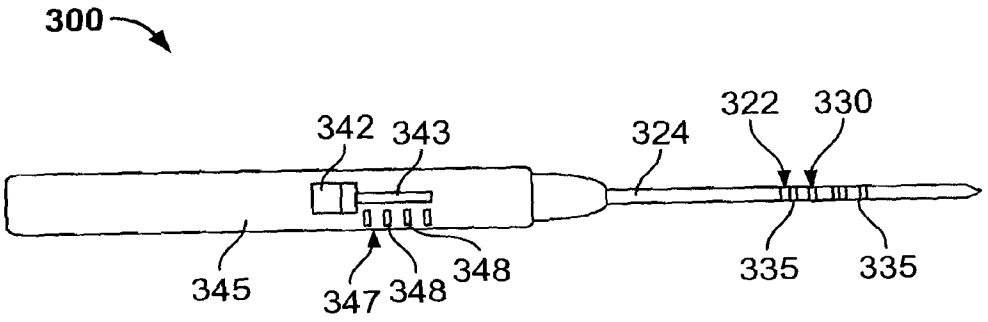

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FIG. 18

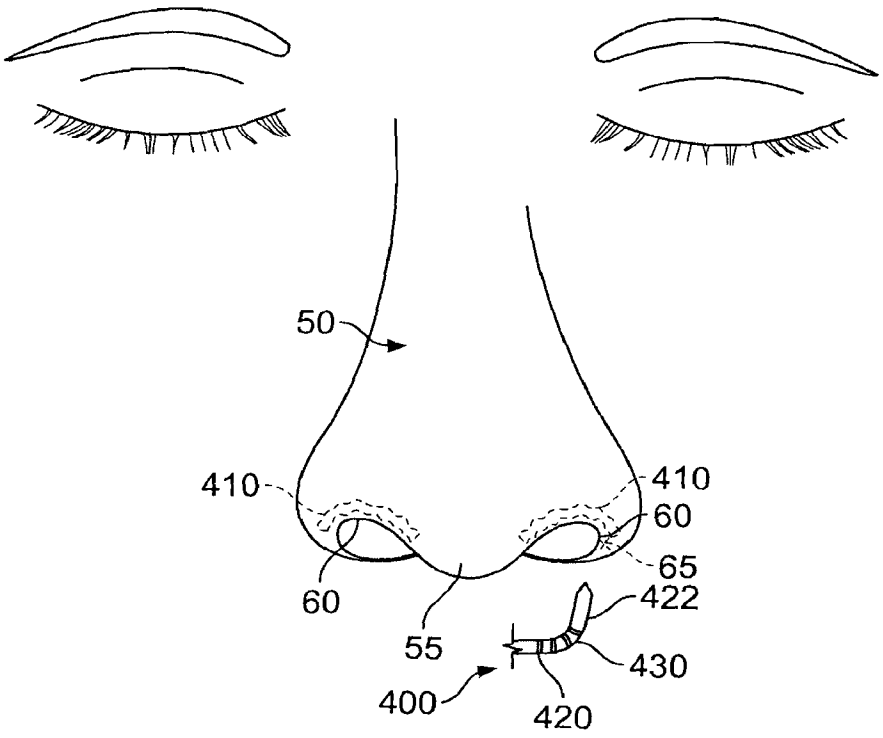

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FIG. 19

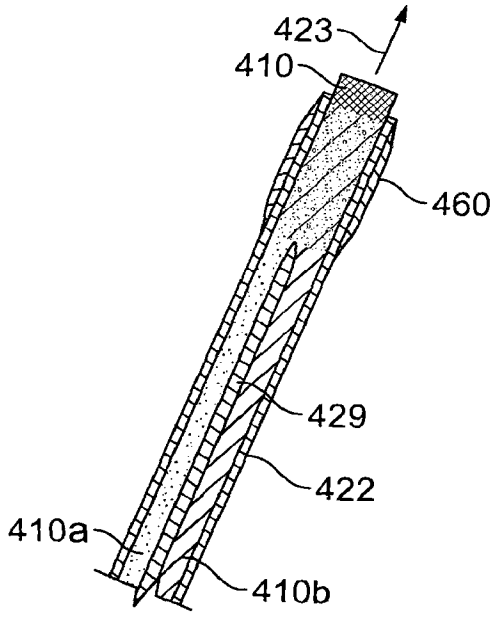

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FIG. 20

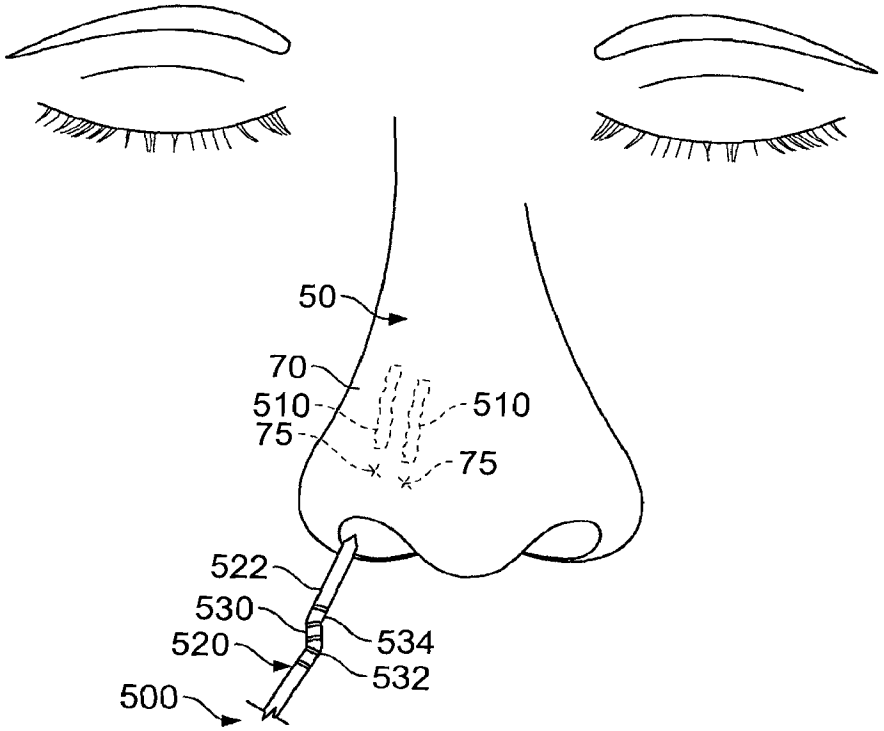


FIG. 21

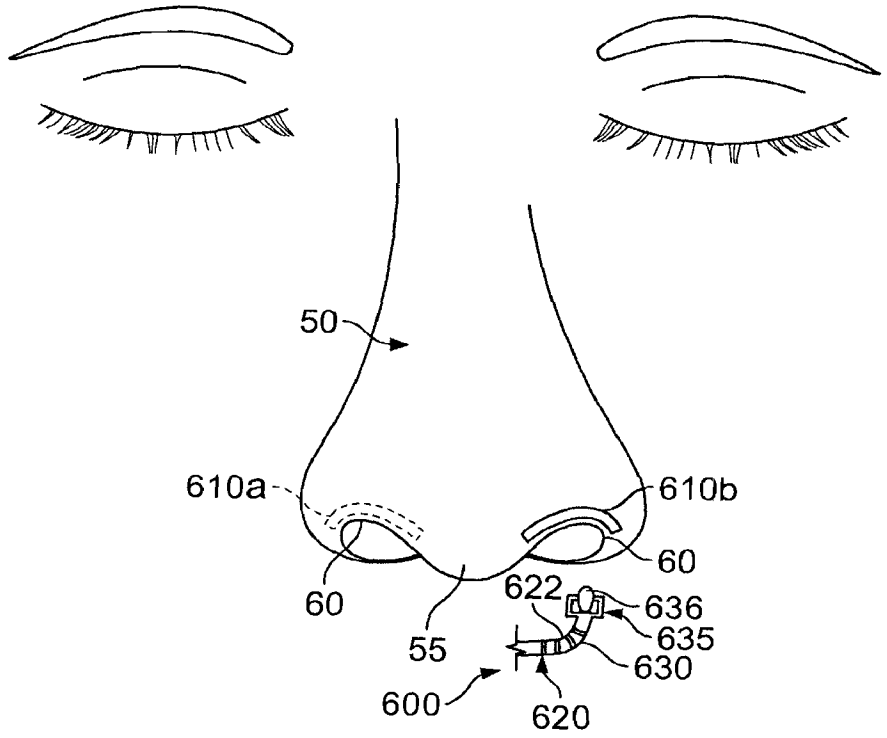


FIG. 22

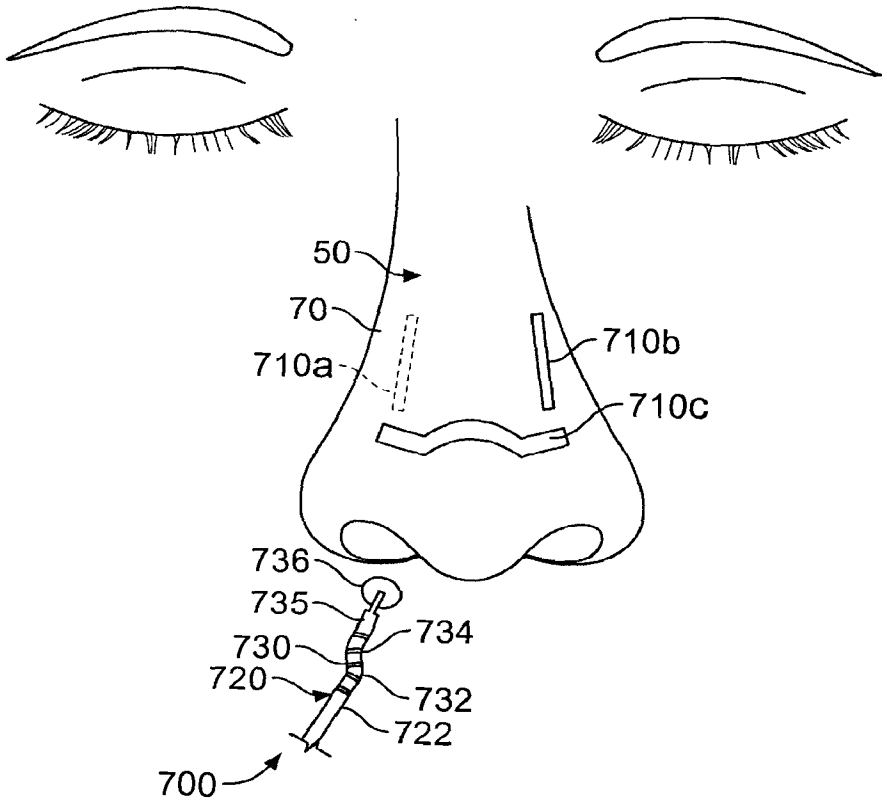


FIG. 23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/068370

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/18(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 8: A61F, A61B, A61K, A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKIPASS(KIPO internal), Delphion, Pubmed (implant, delivery, cannula, lumen, nasal, and similar terms)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"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 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
23 OCTOBER 2007 (23.10.2007)	**23 OCTOBER 2007 (23.10.2007)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea
Facsimile No. 82-42-472-7140

Authorized officer
JEONG, JAE CHEOL
Telephone No. 82-42-481-8385

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2007/068370

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US6936052B2	30.08.2005	US20020156488A1	24.10.2002
		US20040073234A1	15.04.2004
		US20040087970A1	06.05.2004
		US20050131391A1	16.06.2005
		US20050131392A1	16.06.2005
		US20050131393A1	16.06.2005
		US6936052BB	30.08.2005
US6875219B2	05.04.2005	US20040162559A1	19.08.2004
		US6875219BB	05.04.2005
		WO2004073500A2	02.09.2004
		WO2004073500A3	27.01.2005
US6395007B1	28.05.2002	AT288723E	15.02.2005
		AU200035285A1	04.10.2000
		AU775688B2	12.08.2004
		CA2367599A1	21.09.2000
		DE60018048C0	17.03.2005
		EP1161209A1	12.12.2001
		EP1161209B1	09.02.2005
		US20002049449A1	25.04.2002
		US20030036763A1	20.02.2003
		US6395007B1	28.05.2002
		US6770079BB	03.08.2004
		US6887246BB	03.05.2005
		WO0054705A1	21.09.2000
US6512958B1	28.01.2003	US6512958B1	28.01.2003
		WO02087678A1	07.11.2002

Electronic Acknowledgement Receipt

EFS ID:	20342185
Application Number:	14319087
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:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244992US01 (494912-9)
Receipt Date:	06-OCT-2014
Filing Date:	30-JUN-2014
Time Stamp:	18:54:46
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)	P244992US01_IDS_prior_to_1st_OA.pdf	204211 2bf31672f197f44ab37acc00c4c853e16c220dc6	no	6

Warnings:	
Information:	

This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	WO_2007-037895.pdf	589637 73e4fb567467732a0e1411b0db0d48c15f053feb	no	13
Warnings:					
Information:					
3	Foreign Reference	WO_2007-134005.pdf	2163556 bbc0abd75cd37887ffb5eea8b0a0fa2436a93998	no	49
Warnings:					
Information:					
4	Non Patent Literature	Kjaergaard_Nasal_Cavity_Dimensions.pdf	824336 b4690ae8d5be318cd56742176ec061d53b5c2283	no	6
Warnings:					
Information:					
5	Non Patent Literature	Stupak_Endonasal_Repositioning_Upper_Lateral_Cartilage.pdf	1203911 96ec89748e5f3ad4da379a029e9b96ac94b0b0e1	no	7
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Information:					
6	Non Patent Literature	Unknown_Perspective_on_the_Nasal_Valve.pdf	3054629 2c831d0979055ded2f2c318466112ae585d76d68	no	9
Warnings:					
Information:					
7	Non Patent Literature	CABLE_American_Journal_of_Rhinology.pdf	986681 992e7543fc048e496c9fa5d43d1d30f3016b93a6	no	7
Warnings:					
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8	Non Patent Literature	SEGAL_American_Journal_of_Rhinology.pdf	472613 5cbb6928354681b6ef09c34c52e625801bd8923b	no	6
Warnings:					
Information:					
9	Other Reference-Patent/App/Search documents	SGSearchReport.pdf	19489217 e7d952f3b32232fd537c2ddc8df958f552bd5d0f	no	27
Warnings:					
Information:					
			Total Files Size (in bytes):	28988791	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/319,087	06/30/2014	Scott J. WOLF	P244992US01 (494912-9)

CONFIRMATION NO. 7653

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

PUBLICATION NOTICE



Title:METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Publication No.US-2014-0316396-A1
Publication Date:10/23/2014

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/319,087	06/30/2014	Scott J. WOLF	P244992US01 (494912-9)	7653

75149 7590 12/26/2014

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

EXAMINER
MANUEL, GEORGE C

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
12/26/2014	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):

pogson.phoebe@dorsey.com
docketingdept-sf@dorsey.com

Office Action Summary	Application No. 14/319,087	Applicant(s) WOLF ET AL.	
	Examiner GEORGE MANUEL	Art Unit 3762	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

☐ 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) *1-47* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-4,9,18,25,27,31,33 and 38-47* is/are rejected.

8)☒ Claim(s) *5-8,10-17,19-24,26,28-30,32 and 34-37* 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 *6/30/2014* 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 *10/6/2014*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

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

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-4, 9, 18, 25, 27 and 45-47 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, 7-17 of copending Application No. 13/495,844. Although the claims at issue are not identical, they are not patentably distinct from each other because both sets of claims are directed to obvious variations of treating a patient's nasal airway using a treatment device to reshape or alter the shape of nasal tissue, and submucosal tissue is an obvious tissue to treat.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43 and 44 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claims 43 and 44 depend on method steps; however, the claims for which they depend are device claims without method steps, thus rendering claims 43 and 44 as being indefinite.

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 31, 33 and 38-44 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Edwards et al (US 6,416,491).

Edwards et al disclose a device 10 capable of modifying at least one property of at least one tissue in a nasal airway.

A head portion 34 comprises an electrode 14 configured for passing through an incision in mucosal tissue to a location between the mucosal tissue and submucosal tissue. The head portion comprises an energy based therapy delivery member comprising a hollow lumen 48; and an incision forming member, distal portion 14' having a flat shape; a shaft 14 extends from the head portion. A handle 12 is attached to the shaft at an opposite end from the head portion. The

handle includes a housing to hold a power source comprising a fluid via conduit 56 and electrical, RF power via cable 30 and for providing energy to the energy delivery member. Temperatures detected at sensor 46 provide feedback for maintaining a selected power.

Regarding claim 44, bipolar operation is possible when two or more electrodes 14 are used. Multiple electrodes 14 may be used. See col. 8, lines 15-16.

Allowable Subject Matter

Claims 5-8, 10-17, 19-24, 26, 28-30, 32 and 34-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

/George Manuel/
Primary Examiner
Art Unit: 3762

12/22/2014

Notice of References Cited	Application/Control No. 14/319,087	Applicant(s)/Patent Under Reexamination WOLF ET AL.	
	Examiner GEORGE MANUEL	Art Unit 3762	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,416,491	07-2002	Edwards et al.	604/22
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	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.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	34	(nasal and airway and submucosal and tissue) AND ((A61B18/1442 OR A61B18/1485 OR A61B18/16 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/00327 OR A61B2018/00702 OR A61B2018/00821 OR A61B2018/00922 OR A61B2018/143 OR A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2014/12/19 17:05
L2	1	"14319087" and incision	US-PGPUB; USPAT	OR	ON	2014/12/19 17:23
L3	1	"6416491".pn. and sensor and temperature	US-PGPUB; USPAT	OR	ON	2014/12/19 18:50
L4	1	"6416491".pn. and electrodes	US-PGPUB; USPAT	OR	ON	2014/12/19 18:56
L5	30	(nasal and airway and submucosal and tissue) AND 606/41	US-PGPUB; USPAT	OR	ON	2014/12/19 19:06
L6	71	(nasal and airway and mucosal and tissue) AND 606/41	US-PGPUB; USPAT	OR	ON	2014/12/19 19:14
L7	73	(nasal and airway and mucosal and tissue) AND ((A61B18/1442 OR A61B18/1485 OR A61B18/16 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/00327 OR A61B2018/00702 OR A61B2018/00821 OR A61B2018/00922 OR A61B2018/143 OR A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2014/12/19 19:17
S1873	76	("20020016588" | "20030208194" | "20050119643" | "20050222565" | "20060225403" | "20060276817" | "20070066944" | "20070219600" | "20080027480" | "20080082090" | "20090018485" | "20090143821" | "20090292358" | "20100144996" | "20100152730" | "20110009737" | "20120039954" | "20120078377" | "4887605" | "5348008" | "5533499" | "5624439" | "5674191" | "5707349" | "5718702" | "5728094" | "5730719" | "5738114" | "5743870" | "5743904" | "5746224" | "5800429" | "5807306" | "5816095" | "5817049" | "5820580" | "5823197" | "5827277" | "5843021" | "5843077" | "5846235" | "5879349" | "6045549" | "6096033" | "6102907" | "6126657" | "6131579" | "6139546" | "6152143" | "6165173" | "6179803" | "6210355" | "6228079" | "6231569" |	US-PGPUB; USPAT	OR	ON	2014/12/19 09:53

		"6293941" | "6309386" | "6371926" | "6383181" | "6425151" | "6431174" | "6451013" | "6551310" | "6562036" | "6575969" | "6589235" | "6659106" | "6911027" | "6978781" | "7055523" | "7114495" | "7416550" | "7442191" | "7780730" | "7824394" | "7850683" | "8317782").PN.				
S1874	1	"14319087"	US-PGPUB; USPAT	OR	ON	2014/12/19 10:02
S1875	73	(nasal and airway and mucosal and tissue) AND ((A61B18/1442 OR A61B18/1485 OR A61B18/16 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/00327 OR A61B2018/00702 OR A61B2018/00821 OR A61B2018/00922 OR A61B2018/143 OR A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2014/12/19 10:08

EAST Search History (Interference)

< This search history is empty>

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14319087	WOLF ET AL.
	Examiner	Art Unit
	GEORGE MANUEL	3762

CPC- SEARCHED		
Symbol	Date	Examiner
A61B18/1442, A61B18/1485, A61B18/16, A61B2018/00005, A61B2018/00023, A61B2018/00327, A61B2018/00702, A61B2018/00821, A61B2018/00922, A61B2018/143, A61F5/08	12/19/2014	GM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	41	12/19/2014	GM

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search Conducted.	12/19/2014	GM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14319087	WOLF ET AL.
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	GEORGE MANUEL	3762

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/19/2014								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	O								
	6	O								
	7	O								
	8	O								
	9	✓								
	10	O								
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	29	O								
	30	O								
	31	✓								
	32	O								
	33	✓								
	34	O								
	35	O								
	36	O								

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14319087	WOLF ET AL.
	Examiner	**Art Unit**
	GEORGE MANUEL	3762

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/19/2014								
	37	O								
	38	✓								
	39	✓								
	40	✓								
	41	✓								
	42	✓								
	43	✓								
	44	✓								
	45	✓								
	46	✓								
	47	✓								

Receipt date: 10/06/2014 14319087 - GAU: 3762

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

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/319,087
	Filing Date	June 30, 2014
	First Named Inventor	Scott J. WOLF
	Art Unit	7653
	Examiner Name	MANUEL, George C.
	Attorney Docket Number	P244992US01 (494912-9)

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	Attorney Docket Number	P244992US01 (494912-9)

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
		2007/037895	WO		2007-04-05	NYTE		
		2007/134005	WO		2007-11-22	FRIEDMAN		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

Receipt date: 10/06/2014 14319087 - GAU: 3762

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	Art Unit	7653
	Examiner Name	MANUEL, George C.
	Attorney Docket Number	P244992US01 (494912-9)

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		COLE, *BIOPHYSICS OF NASAL AIRFLOW: A Review*, American Journal of Rhinology, Vol. 14, No. 4, July-Aug 2000, pp. 245-249	
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EXAMINER SIGNATURE			
Examiner Signature	/George Manuel/	Date Considered	12/19/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

Receipt date: 10/06/2014 14319087 - GAU: 3762

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Doc description: Information Disclosure Statement (IDS) Filed

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	Art Unit	7653
	Examiner Name	MANUEL, George C.
	Attorney Docket Number	P244992US01 (494912-9)

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

CERTIFICATION STATEMENT

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

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

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

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

Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	October 6, 2014
Name/Print	Scott Michael Smith	Registration Number	48268

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4823-6242-7167

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

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

Courtesy Reminder for
Application Serial No: 14/319,087

Attorney Docket No: P244992US01 (494912-9)
Customer Number: 75149
Date of Electronic Notification: 12/26/2014

This is a courtesy reminder that new correspondence is available for this application. If you have not done so already, please review the correspondence. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:
pogson.phoebe@dorsey.com
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To view your correspondence online or update your email addresses, please visit us anytime at **https://sportal.uspto.gov/secure/myportal/privatepair.** If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov or call 1-866-217-9197.

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

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

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to Final Official Action		
	Application Number	14/319,087
	Filing Date	June 30, 2014
	First Named Inventor	Scott J. WOLF
	Art Unit	7653
	Examiner Name	MANUEL, George C.
	Attorney Docket Number	P244992US01 (494912-9)

U.S. PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2012-0323227		2012-12-20	WOLF, *et al.*	
		2012-0316557		2012-12-13	SARTOR, *et al.*	

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

CERTIFICATION STATEMENT

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

☒ 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).

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)	January 6, 2015
Name/Print	Scott Michael Smith	Registration Number	48268

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4835-5569-5649

Electronic Acknowledgement Receipt

EFS ID:	21200697
Application Number:	14319087
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:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244992US01 (494912-9)
Receipt Date:	13-JAN-2015
Filing Date:	30-JUN-2014
Time Stamp:	18:52:57
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)	P244992US01_Supplemental_IDS_prior_to_FOA.pdf	149513 f0e7443b7723a655d7fbcdd22fdf24f96d034773	no	1

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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.

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P244992US01
(494912-9)

CERTIFICATE OF FILING

I hereby certify that on the date specified below this correspondence is being transmitted electronically via the Office electronic filing system, EFS-Web, on the United States Patent Office Web site, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 18, 2015
/laura lee mosier/
Laura Lee Mosier

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Scott J. WOLF, *et al.*		Examiner:	George C. MANUEL
Application No.	14/319,087	Art Unit:	3762
Filed:	June 30, 2014	Confirmation No.	7653
For:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	Date:	March 18, 2015

AMENDMENT AND RESPONSE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Examiner Manuel

In response to the Office Action mailed on December 26, 2014, Applicants submit the following:

Amendments to the claims are reflected in the listing of claims, which begins on page 2.

Amendments to the drawings begin on page 8.

Remarks begin on page 6.

AMENDMENTS TO THE CLAIMS

This listing of the claims will replace all prior versions and listings of claims in the application:

1. (Original) A method of treating a patient's nasal airway, the method comprising:

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 at least one of reshape, remodel, strengthen or change a property of the submucosal tissue; and

removing the treatment element from the nasal airway.

2. (Original) A method as in claim 1, further comprising forming the incision in the mucosal tissue, using the treatment device.

3. (Original) A method as in claim 2, wherein forming the incision comprises cutting the mucosal tissue with a cutting edge of the treatment device.

4. (Original) A method as in claim 1, wherein delivering the energy based therapy comprises delivering energy to the submucosal tissue in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.

5. (Original) A method as in claim 1, wherein delivering the energy based therapy comprises delivering cryotherapy to the submucosal tissue.

6. (Original) A method as in claim 1, 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.

7. (Original) A method as in claim 1, further comprising applying force to the submucosal tissue with the treatment element at least one of before, during or after delivering the energy based therapy to deform the submucosal tissue.

8. (Original) A method as in claim 7, wherein a tissue contacting surface of the treatment element has a shape selected from the group consisting of convex, concave and flat.

9. (Original) A method of treating a patient's nasal airway, the method comprising:

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 at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; and

removing the treatment element from the nasal airway.

10. (Original) A method as in claim 9, wherein adjusting the shape comprises shaping the treatment element to have a convex treatment surface.

11. (Original) A method as in claim 9, wherein adjusting the shape comprises shaping the treatment element to have a concave treatment surface.

12. (Original) A method as in claim 9, wherein adjusting the shape comprises adjusting a height of at least one electrode on a treatment surface of the treatment element.

13. (Original) A method as in claim 12, wherein adjusting the height comprises adjusting multiple heights of multiple electrodes to form a treatment surface profile.

14. (Original) A method as in claim 9, wherein adjusting the shape comprises manipulating a secondary component of the treatment element to increase a surface area of the treatment element.

15. (Original) A method as in claim 9, wherein adjusting the shape comprises inflating the treatment element to increase a surface area of the treatment element.

16. (Original) A method as in claim 9, wherein adjusting the shape comprises forming at least one bend in a shaft of the treatment device.

17. (Original) A method as in claim 9, wherein adjusting the shape comprises rotating the treatment element relative to a shaft of the treatment device.

18. (Original) A method as in claim 9, wherein delivering the energy based therapy comprises delivering energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light, laser and quantic molecular resonance.

19. (Original) A method as in claim 9, wherein delivering the energy based therapy comprises delivering cryotherapy.

20. (Original) A method as in claim 9, wherein the mucosal tissue is located in a part of the nasal airway other than an internal nasal valve of the airway.

21. (Original) A method as in claim 20, further comprising:

contacting the treatment element with other mucosal tissue at an additional location in the nasal airway, wherein the additional location is part of the nasal valve; and

delivering the energy based therapy to at least one of the other mucosal tissue or an underlying tissue beneath the other mucosal tissue at the additional location.

22. (Original) A method as in claim 20, wherein the wherein mucosal 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.

23. (Original) A method as in claim 9, further comprising applying force to the mucosal tissue with the treatment element at least one of before, during or after delivering the energy based therapy to deform the mucosal tissue.

24. (Original) A method as in claim 9, wherein delivering the energy based therapy modifies at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue.

25. (Original) A method as in claim 9, wherein the underlying tissue is selected from the group consisting of cartilage, submucosa, muscle, ligament and tendon.

26. (Original) A method as in claim 9, further comprising cooling at least one of the mucosal tissue or another tissue in the nasal airway.

27. (Original) 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, the method comprising:

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 at least one temperature; and

removing the treatment element from the nasal airway.

28. (Original) A method as in claim 27, wherein sensing the at least one temperature comprises sensing multiple temperatures with multiple thermocouples located at or near multiple electrode pairs on the treatment element, wherein each of the multiple thermocouples is located at or near one of the multiple electrode pairs.

29. (Original) A method as in claim 28, further comprising 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.

30. (Original) A method as in claim 28, wherein adjusting the delivery comprises adjusting delivery to at least one of the electrode pairs separately from at least one other of the electrode pairs.

31. (Currently Amended) A device for modifying at least one property of at least one tissue in a nasal airway, the device comprising:

a head portion configured for passing through an incision in mucosal tissue to a location between the mucosal tissue and submucosal tissue, the head portion comprising;

an energy based therapy delivery member; and

an incision forming member;

a shaft extending from the head portion; and

a handle attached to the shaft at an opposite end from the head portion, wherein the handle includes a housing to hold a power source for providing energy to the energy delivery member.

wherein the energy delivery member has a contact surface with a convex shape configured to at least temporarily create a concavity in the at least one tissue.

32. Cancelled

33. (Original) A device as in claim 31, wherein the energy delivery member has a contact surface with flat shape.

34. (Original) A device as in claim 31, wherein the energy delivery member comprises multiple flexible sections configured to be manipulated.

35. (Original) A device as in claim 34, wherein the flexible sections comprise multiple protruding electrodes configured to at least temporarily deform nasal tissue.

36. (Original) A device as in claim 35, wherein the protruding electrodes comprise two rows of electrodes, wherein the energy delivery member comprises a bipolar radio frequency delivery member, and wherein radio frequency energy travels from one row of electrodes to the other row of electrodes.

37. (Original) A device as in claim 31, wherein the housing is configured to hold at least one battery.

38. (Original) A device as in claim 31, further comprising at least one sensor configured to sense at least one of temperature or impedance in nasal tissue.

39. (Original) A device as in claim 38, wherein the at least one sensor is attached to the device on or near the energy delivery member.

40. (Original) A device as in claim 31, further comprising a tissue cooling member attached to the device at or near the energy delivery member.

41. (Original) A device as in claim 31, wherein the energy delivery member comprises at least one electrode pair configured to apply energy to the at least one tissue.

42. (Original) A device as in claim 41, further comprising at least one thermocouple configured to sense temperature at each electrode pair.

43. (Currently Amended) A device ~~method~~ as in claim 42, further comprising a processor to determine an average temperature from multiple temperatures sensed by more than one of the at least one thermocouple.

44. (Currently Amended) A device ~~method~~ as in claim 41, wherein each of the at least one electrode pair is adjustable separately from adjustment of any other of the at least one electrode pair.

45. (Currently Amended) A method of treating a patient's nasal airway, the method comprising:

contacting a treatment element of [[the]] a treatment device with a first mucosal tissue located in a part of the nasal airway other than an internal nasal valve of the airway;

delivering an energy based therapy to at least one of the first mucosal tissue or an underlying tissue beneath the first mucosal tissue, using the treatment element; and

removing the treatment element from the nasal airway.

46. (Original) A method as in claim 45, further comprising:

contacting the treatment element with a second mucosal tissue at an additional location that is part of the nasal valve; and

delivering the energy based therapy to at least one of the second mucosal tissue or an underlying tissue beneath the second mucosal tissue at the additional location.

47. (Original) A method as in claim 45, wherein the wherein mucosal tissue includes tissue selected from the group consisting of upper lateral cartilage, lower lateral cartilage, 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

The Office Action of December 26, 2014 rejected claims 1–4, 9, 18, 25, 27, 31, 33, and 38–47, and objected to claims 5–8, 10–17, 19–24, 26, 28–30, 32, and 34–37. This response amends claims 31, 43, 44 and 45 and cancels claim 32. No new matter has been added. Applicants respectfully request reexamination and reconsideration of pending claims 1–31 and 33–47.

Double Patenting Rejection

Claims 1–4, 9, 18, 25, 27, and 45–47 were provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–5 and 7–17 of copending Application No. 13/495,844. A terminal disclaimer, in compliance with 37 C.F.R. § 1.321, is enclosed herewith. Accordingly, the double patenting rejection of Claims 1–4, 9, 18, 25, 27, and 45–47 has been overcome, and such claims are now allowable.

Claim Rejections Under 35 U.S.C. § 112

Claims 43 and 44 were rejected under 35 U.S.C. § 112 as being indefinite for being method claims depending on device claims without method steps. With this response, claims 43 and 44 have been amended to change the typographical error of "method" to "device." Accordingly the indefiniteness rejection of claims 43 and 44 has been overcome.

Claim Rejections Under 35 U.S.C. § 102

The Office Action rejected claims 31, 33 and 38–44 under 35 U.S.C. § 102, as allegedly being unpatentable over U.S. Patent No. 6,416,491 issued to Edwards *et al*. (hereinafter "Edwards"). Applicants respectfully traverse these rejections.

Independent claim 31 has been amended to include the limitation of allowable claim 32. Therefore, Applicants respectfully submit that independent claim 31 is now allowable, as are claims 33–44, which depend therefrom.

Allowable Subject Matter

The Office Action deemed claims 5–8, 10–17, 19–24, 26, 28–30, 32, and 34–37 allowable if rewritten in independent form, but objected to the claims for depending from a rejected base claim. Applicants respectfully traverse these objections.

Independent claims 1, 9, and 27, from which allowable claims 5–8; 10–17, 19–24, and 26; and 28–30 respectively depend, were provisionally rejected on the ground of nonstatutory double patenting. As discussed above, a terminal disclaimer is enclosed herewith, overcoming the double patenting rejection. As such, claims 5–8, 10–17, 19–24, 26, and 28–30 depend from allowable base claims, overcoming the objection.

Independent claim 31, from which allowable claims 34–37 depend, was rejected as anticipated by Edwards. As discussed above, this rejection has been overcome by canceling claim 32 and incorporating its allowable subject matter into independent claim 31. Accordingly, the objection to claim 32 is now moot and the objection to claims 34–37 is overcome because the claims now depend from an allowable base claim.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are 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. Applicants reserve 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, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

With this response, each and every one of pending claims 1–31 and 33–47 is allowable over the prior art. This application now stands in condition for allowance, and notice to that effect is requested. Should the Examiner believe these corrections are not proper and 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.

Respectfully submitted,

DORSEY & WHITNEY LLP

/Scott Smith, Reg. No. 48,268/

Scott M. Smith,
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4810-7792-1058\1

PTO/AIA/25 (04-13)
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TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION	Docket Number (Optional) P244992US01 (494912-9)

In re Application of: Scott J. WOLF

Application No.: 14/319,087

Filed: June 30, 2014

For: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

The applicant, AERIN MEDICAL, INC., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number 13495844, filed, June 13, 2012, as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said **reference** application, "as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application," in the event that: any such patent granted on the pending **reference** application expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

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

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 48268

/Scott M. Smith/	March 16, 2015
Signature	Date
Scott M. Smith	
Typed or printed name	
Attorney for Applicant	(650) 857-1717
Title	Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

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Electronic Patent Application Fee Transmittal

Application Number:	14319087
Filing Date:	30-Jun-2014
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Filer:	Scott Michael Smith/Laura Lee Mosier
Attorney Docket Number:	P244992US01 (494912-9)

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($)
Miscellaneous:				
Statutory or Terminal Disclaimer	1814	1	160	160
		Total in USD ($)		**160**

Electronic Acknowledgement Receipt

EFS ID:	21804353
Application Number:	14319087
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:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244992US01 (494912-9)
Receipt Date:	18-MAR-2015
Filing Date:	30-JUN-2014
Time Stamp:	12:21:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$160
RAM confirmation Number	9257
Deposit Account	502319
Authorized User	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P244992US01_Response_12-26-14_NFOA.pdf	153108 e23384be5c87fb9ee43a0ba4b370763d5332482f	yes	10

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	7
Applicant Arguments/Remarks Made in an Amendment	8	10

Warnings:

Information:

2	Terminal Disclaimer Filed	P244992US01_Terminal_Disclaimer_w-Response_12-26-14_NFOA.pdf	164052 7244628ea586c86e580f1919055367418812 0fc5	no	1

Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	30384 d0ce482df082471bc0fe80758a5eb69c03f57e50	no	2

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/319,087	Filing Date 06/30/2014	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)		
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	**140**
☒ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	**300**
☒ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	**360**
TOTAL CLAIMS (37 CFR 1.16(i))	47 minus 20 =	* 27	x $40 =	**1080**
INDEPENDENT CLAIMS (37 CFR 1.16(h))	5 minus 3 =	* 2	x $210 =	**420**
☐ 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	**2300**

APPLICATION AS AMENDED – PART II

AMENDMENT	03/18/2015	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 46	Minus	** 47	= 0	x $40 =	0
	Independent (37 CFR 1.16(h))	* 5	Minus	***5	= 0	x $210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**0**

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

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

LIE
/AJAY R. DAVID/

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.

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	14/319,087	WOLF ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 3/18/15	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

ANDRE ROBINSON

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

75149 7590 04/02/2015

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

EXAMINER
MANUEL, GEORGE C

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/02/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/319,087	06/30/2014	Scott J. WOLF	P244992US01 (494912-9)	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	$480	$0	$0	$480	07/02/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

75149 7590 04/02/2015
Dorsey & Whitney LLP - PA
Intellectual Property Department
Columbia Center
701 Fifth Avenue, Suite 6100
Seattle, WA 98104-7043

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/319,087	06/30/2014	Scott J. WOLF	P244992US01 (494912-9)	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	$480	$0	$0	$480	07/02/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
MANUEL, GEORGE C	3762	606-041000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/319,087	06/30/2014	Scott J. WOLF	P244992US01 (494912-9)	7653

75149 7590 04/02/2015

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

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/02/2015

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.

Notice Requiring Inventor's Oath or Declaration	Application No. 14/319,087	Applicant(s) Scott J. WOLF	
	Examiner MANUEL, GEORGE C	Art Unit 3762	

This notice is an attachment to the Notice of Allowability (PTOL-37), or the Notice of Allowability For A Design Application (PTOL-37D).

An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 executed by or with respect to each inventor has not yet been submitted.

An oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each inventor (for any inventor for which a compliant oath, declaration, or substitute statement has not yet been submitted) MUST be filed no later than the date on which the issue fee is paid. See 35 U.S.C. 115(f). Failure to timely comply will result in ABANDONMENT of this application.

A properly executed inventor's oath to declaration has not been received for the following inventor(s):

If applicant previously filed one or more oaths, declarations, or substitute statements, applicant may have received an informational notice regarding deficiencies therein.

The following deficiencies are noted:

INFORMAL ACTION PROBLEMS

- A properly executed inventor's oath or declaration has not been received for the following inventor(s): **Scott J. WOLF** and **Andrew Frazier**.
  Applicant may submit the inventor's oath or declaration at any time before the Notice of Allowance and Fee(s) Due, PTOL-85, is mailed.

Questions relating to this Notice should be directed to the Application Assistance Unit at 571-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/319,087	Applicant(s) WOLF ET AL.	
	Examiner GEORGE MANUEL	Art Unit 3762	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment, filed 3/18/15*.
   ☐ 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 *1-31 and 33-47*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 1/13/15
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: 3762

Receipt date: 01/13/2015 14319087 - GAU: 3762

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

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

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

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to Final Official Action		
	Application Number	14/319,087
	Filing Date	June 30, 2014
	First Named Inventor	Scott J. WOLF
	Art Unit	7653
	Examiner Name	MANUEL, George C.
	Attorney Docket Number	P244992US01 (494912-9)

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2012-0323227		2012-12-20	WOLF, *et al.*	
		2012-0316557		2012-12-13	SARTOR, *et al.*	

EXAMINER SIGNATURE

Examiner Signature	/George Manuel/	Date Considered	03/21/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

CERTIFICATION STATEMENT

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

☒ 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).

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)	January 6, 2015
Name/Print	Scott Michael Smith	Registration Number	48268

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

4835-5569-5649

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14319087	WOLF ET AL.
	Examiner	Art Unit
	GEORGE MANUEL	3762

CPC- SEARCHED		
Symbol	Date	Examiner
A61B18/1442, A61B18/1485, A61B18/16, A61B2018/00005, A61B2018/00023, A61B2018/00327, A61B2018/00702, A61B2018/00821, A61B2018/00922, A61B2018/143, A61F5/08	12/19/2014	GM
Search Updated.	3/21/2015	GM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	41	12/19/2014	GM

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search Conducted.	12/19/2014	GM
EAST Search Updated. Interference Search History Printout.	3/21/2015	GM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61B	18/1442, 18/1485, 18/16, 2018/00005, 2018/00023, 2018/00327, 2018/00702, 2018/00821, 2018/00922, 2018/143	3/21/2015	GM
A61F	5/08	3/21/2015	GM

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

BIB DATA SHEET

CONFIRMATION NO. 7653

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/319,087	06/30/2014	606	3762	P244992US01 (494912-9)

APPLICANTS

AERIN MEDICAL, INC., Menlo Park, CA, Assignee (with 37 CFR 1.172 Interest);

INVENTORS

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

**** CONTINUING DATA ***************************

This application is a CIP of 13/495,844 06/13/2012 PAT 8936594
which claims benefit of 61/603,864 02/27/2012
and claims benefit of 61/496,930 06/14/2011

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
07/11/2014

Foreign Priority claimed	☐ Yes ☑ No	☐ Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	☐ Yes ☑ No					
Verified and Acknowledged	/GEORGE MANUEL/ Examiner's Signature	Initials	CA	61	47	5

ADDRESS

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

TITLE

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

FILING FEE RECEIVED		
2500	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Issue Classification	**Application/Control No.**	**Applicant(s)/Patent Under Reexamination**
	14319087	WOLF ET AL.
	Examiner	**Art Unit**
	GEORGE MANUEL	3762

CPC						
Symbol					**Type**	**Version**
A61F		5	/	08	F	2013-01-01
A61B		18	/	1442	I	2013-01-01
A61B		18	/	1485	I	2013-01-01
A61B		2018	/	00005	A	2013-01-01
A61B		2018	/	00023	A	2013-01-01
A61B		2018	/	00327	A	2013-01-01
A61B		2018	/	00702	A	2013-01-01
A61B		2018	/	00821	A	2013-01-01
A61B		2018	/	00922	A	2013-01-01
A61B		2018	/	143	A	2013-01-01
A61B		18	/	16	A	2013-01-01
A61B		18	/	02	A	2013-01-01
A61B		2018	/	0225	A	2013-01-01
			/			
			/			

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	46	
/GEORGE MANUEL/ Primary Examiner.Art Unit 3762	3/21/15	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	12B

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14319087	WOLF ET AL.
	Examiner	**Art Unit**
	GEORGE MANUEL	3762

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
		A	6	1	B	18 / 18 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	46	
/GEORGE MANUEL/ Primary Examiner.Art Unit 3762	3/21/15	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	12B

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14319087	WOLF ET AL.
	Examiner	**Art Unit**
	GEORGE MANUEL	3762

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	17	17	33	34										
2	2	18	18	34	35										
3	3	19	19	35	36										
4	4	20	20	36	37										
5	5	21	21	37	38										
6	6	22	22	38	39										
7	7	23	23	39	40										
8	8	24	24	40	41										
9	9	25	25	41	42										
10	10	26	26	42	43										
11	11	27	27	43	44										
12	12	28	28	44	45										
13	13	29	29	45	46										
14	14	30	30	46	47										
15	15	31	31												
16	16	32	33												

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	46	
/GEORGE MANUEL/ Primary Examiner.Art Unit 3762	3/21/15	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	12B

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	40	(nasal and airway and submucosal and tissue) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 16:37
L3	1	"14319087"	US-PGPUB; USPAT	OR	ON	2015/03/21 16:56
L6	2	("20120316557" | "20120323227").PN.	US-PGPUB; USPAT	OR	ON	2015/03/21 17:02
L7	37	(nasal and airway and submucosal and tissue and energy) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:05
L8	37	(nasal and airway and submucosal and tissue and energy and treat$5) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:05
L9	26	(nasal and airway and submucosal and tissue and energy and treat$5 and incision) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:06
L10	23	(nasal and airway and submucosal and tissue and energy and treat$5 and reshap$4) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:07
L12	80	(nasal and airway and mucosal and tissue and temperature) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:14
L13	76	(nasal and airway and mucosal and tissue and temperature and treatment) AND	US-PGPUB;	OR	ON	2015/03/21 17:15

		((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	USPAT			
L14	22	(nasal with airway and mucosal and tissue and convex same treatment) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:19
L16	22	(nasal with airway and mucosal and tissue and concav$5 same treatment) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:25
L17	15	(nasal with airway and mucosal and tissue and nasal adj valve and element and treatment) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:27
L19	42	(nasal with airway and mucosal and tissue and sens$4 and element and treatment) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:29
L20	38	(nasal with airway and mucosal and tissue and sens$4 and temperature and element and treatment) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:30
L21	15	(nasal with airway and airflow and mucosal and tissue and sens$4 and temperature and element and treatment) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	US-PGPUB; USPAT	OR	ON	2015/03/21 17:31

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	0	"14319087"	USPAT; UPAD	OR	ON	2015/03/21 16:55
L4	20	(nasal and airway and submucosal and tissue) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or	USPAT; UPAD	OR	ON	2015/03/21 17:01

		A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)				
L5	0	("20120316557" | "20120323227").PN.	USPAT; UPAD	OR	ON	2015/03/21 17:02
L11	11	(nasal and airway and submucosal and tissue and energy and treat$5 and reshap$4) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	USPAT; UPAD	OR	ON	2015/03/21 17:12
L15	12	(nasal with airway and mucosal and tissue and convex same treatment) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	USPAT; UPAD	OR	ON	2015/03/21 17:20
L18	4	(nasal with airway and mucosal and tissue and nasal adj valve and element and treatment) AND ((A61B18/1442 or A61B18/1485 or A61B18/16 or A61B2018/00005 or A61B2018/00023 or A61B2018/00327 or A61B2018/00702 or A61B2018/00821 or A61B2018/00922 or A61B2018/143 or A61F5/08).CPC.)	USPAT; UPAD	OR	ON	2015/03/21 17:28

3/21/2015 5:36:10 PM
C:\Users\gmanuel\Documents\EAST\Workspaces\7_26_14.wsp

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

75149 7590 04/02/2015
Dorsey & Whitney LLP - PA
Intellectual Property Department
Columbia Center
701 Fifth Avenue, Suite 6100
Seattle, WA 98104-7043

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Laura Lee Mosier	(Depositor's name)
/Laura Lee Mosier/	(Signature)
April 15, 2015	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/319,087	06/30/2014	Scott J. WOLF	P244992US01 (494912-9)	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	$480	$0	$0	$480	07/02/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
MANUEL, GEORGE C	3762	606-041000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Dorsey & Whitney LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: AERIN MEDICAL INC.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): PALO ALTO, CALIFORNIA

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 502319 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☒ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Scott M. Smith/ Date April 15, 2015
Typed or printed name Scott M. Smith Registration No. 48268

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PTO/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
- ☒ 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:

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LEGAL NAME OF INVENTOR

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

Signature: _____

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	14319087
Filing Date:	30-Jun-2014
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Filer:	Scott Michael Smith/Laura Lee Mosier
Attorney Docket Number:	P244992US01 (494912-9)

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	2501	1	480	480

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**480**

Electronic Acknowledgement Receipt

EFS ID:	22075697
Application Number:	14319087
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:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244992US01 (494912-9)
Receipt Date:	15-APR-2015
Filing Date:	30-JUN-2014
Time Stamp:	19:28:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$480
RAM confirmation Number	5382
Deposit Account	502319
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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)	P244992US01_Issue_Fee_Transmittal_14319087.pdf	1600818 8529e39c034fa448a59de67667d87be14ea2ddb5	no	1
Warnings:					
Information:					
2	Oath or Declaration filed	P244992US01_signed_FRAZIER_Declaration_2015.pdf	1298210 88032c6a873c0a11bf5adf76ed3be541637d921f	no	1
Warnings:					
Information:					
3	Oath or Declaration filed	P244992US01_signed_WOLF_Declaration_2015.pdf	1243107 08654c753596bc39a34d111e4fe5a892b97056cf	no	1
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30548 a0a1c485d11304b162974e6f62e3cafec3303e83	no	2
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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/319,087	06/30/2014	Scott J. WOLF	P244992US01 (494912-9)	7653

75149 7590 04/27/2015

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

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
04/27/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pogson.phoebe@dorsey.com
docketingdept-sf@dorsey.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 14319087
Applicant : Wolf
Filing Date : 06/30/2014
Date Mailed : 04/27/2015

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Daxa Patel/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 14319087 **Drawings filed: 06/30/2014**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 13D-E, 14A, 15C 17B & 19A
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

P244992US01
(494912-9)

CERTIFICATE OF FILING

I hereby certify that on the date specified below this correspondence is being transmitted electronically via the Office electronic filing system, EFS-Web, on the United States Patent Office Web site, addressed to Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 9, 2015
/laura lee mosier/
Laura Lee Mosier

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Scott J. WOLF, *et al.*	
Application No. 14/319,087	
Filed: June 30, 2014	
For: METHODS AND DEVICES TO TREAT NASAL AIRWAYS	
Date of Allowance:	April 2, 2015
Examiner:	George C. MANUEL
Art Unit:	3762
Class-Sub-Class:	606-041000
Confirmation No.	7653
Date:	June 9, 2015

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Notice to File Corrected Application Papers dated April 27, 2015, transmitted herewith are:

[X] Replacement Drawings Sheets, Sheets 1-61. The deficiencies in Figures 13D, 13E, 14A, 15C, 17B and 19A have been corrected as request by the Notice. These figures are clarifications of the originally submitted figures. All refinements, clarifications, and corrections of the drawings are consistent with the original submission, and no new matter is added.

The Commissioner is hereby authorized to charge any deficiency in the payment of the required fee(s) or credit any overpayment to Deposit Account No. 50-2319 (Account No. P244992US01 (494912-9)).

Respectfully submitted,

DORSEY & WHITNEY LLP

/Scott M. Smith, Reg. No. 48,268/
Scott M. Smith,
Reg. No. 48,268

Customer No. 75149
Columbia Center
701 Fifth Avenue, Suite 6100
Seattle, WA 98101-7043
Telephone: (650) 857-1717
Facsimile: (650) 857-1288

Replacement Sheet

1/61

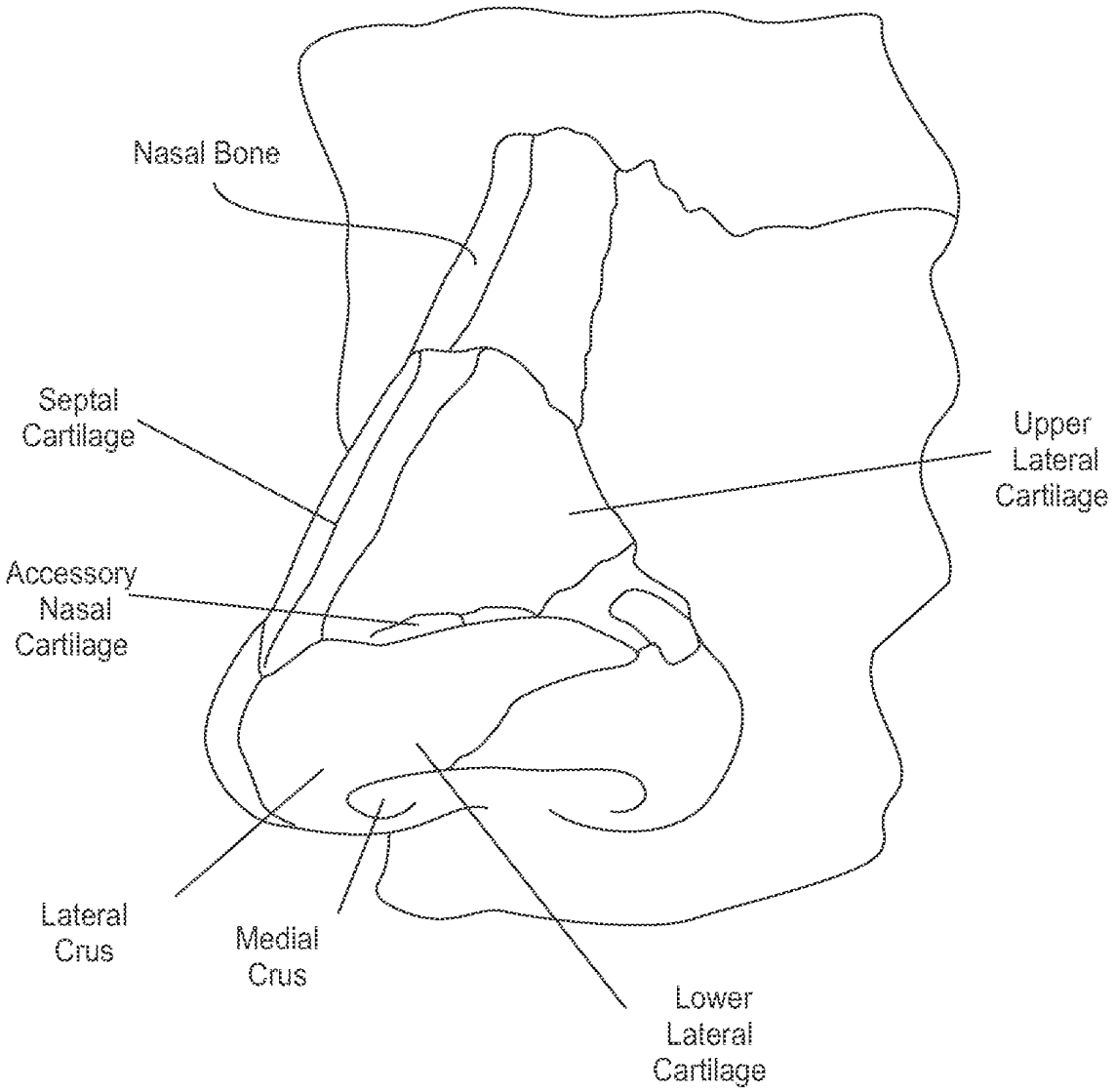


FIG. 1

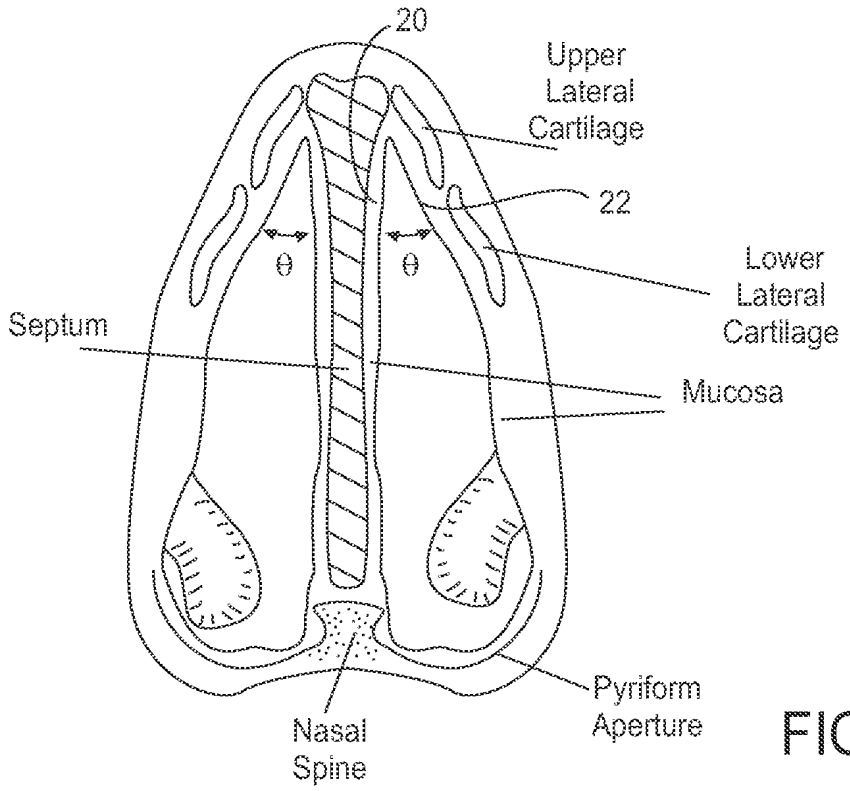

20
Upper
Lateral
Cartilage
22
θ
θ
Lower
Lateral
Cartilage
Septum
Mucosa
Pyriform
Aperture
Nasal
Spine

FIG. 2A

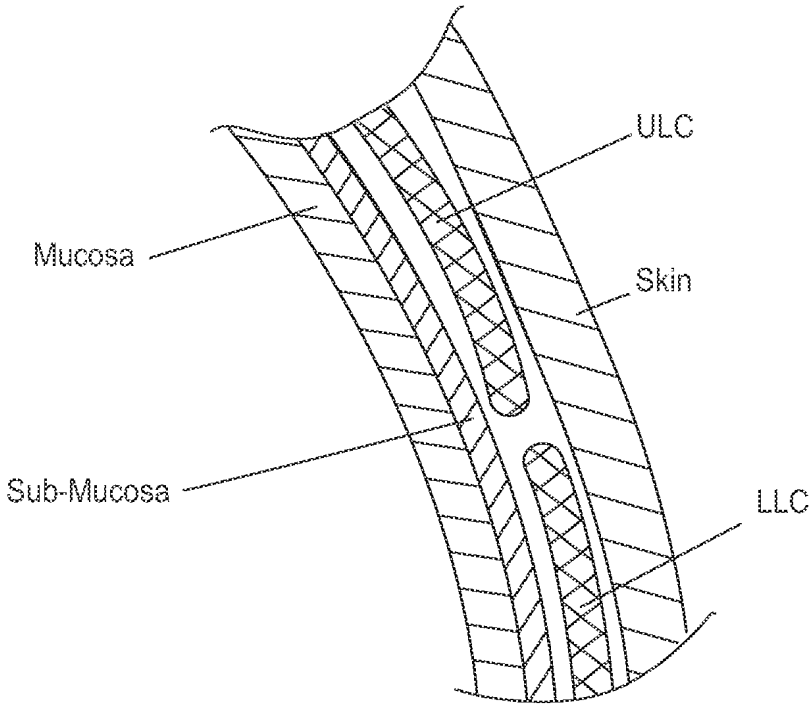

ULC
Mucosa
Skin
Sub-Mucosa
LLC

FIG. 2B

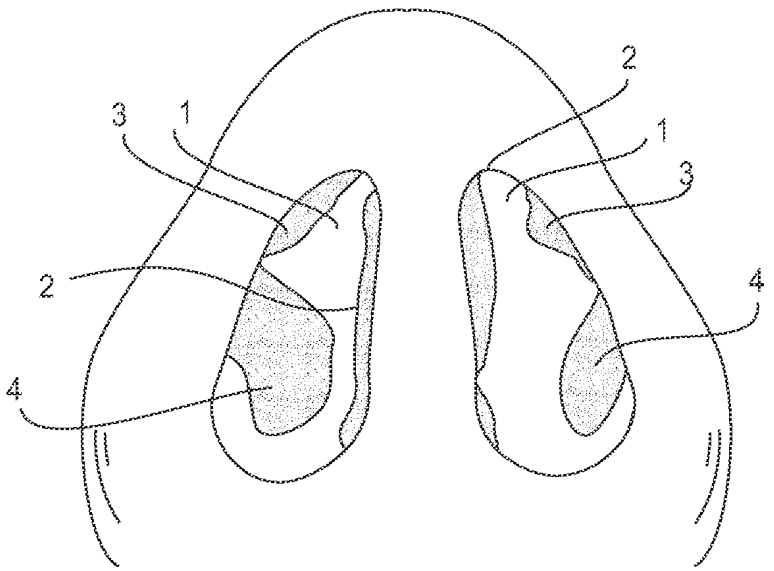


FIG. 2C

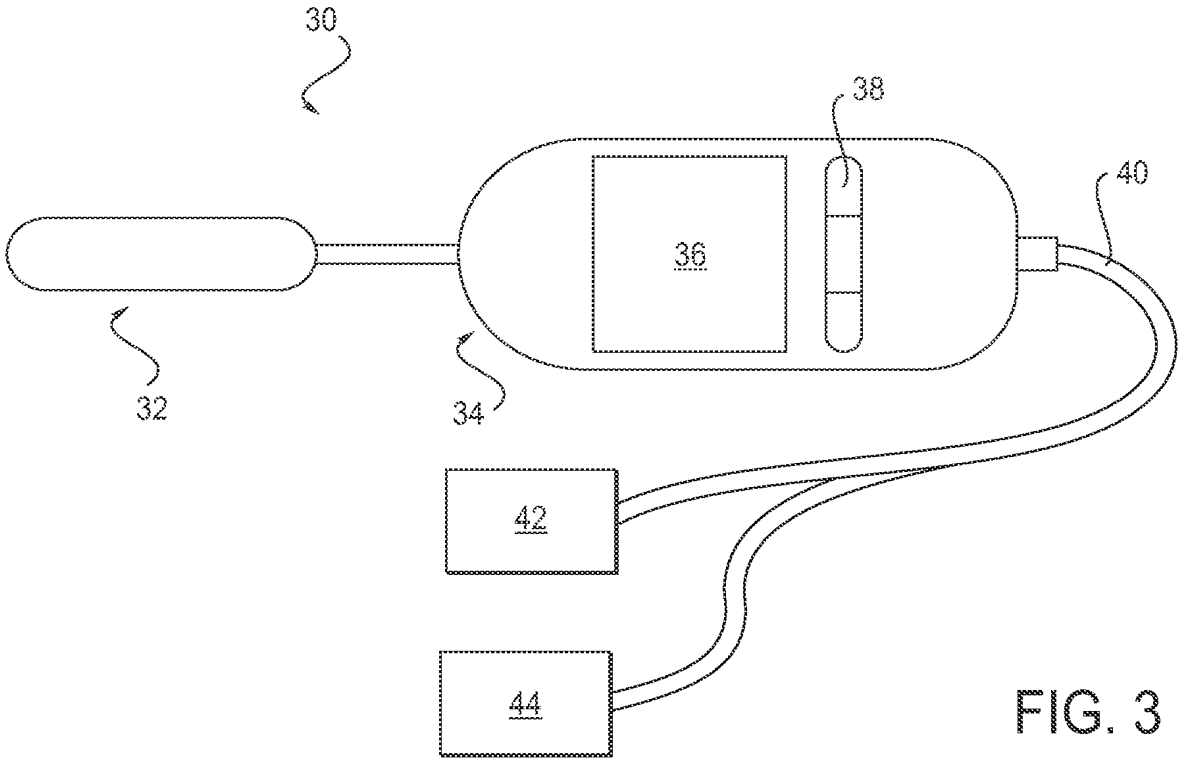


FIG. 3

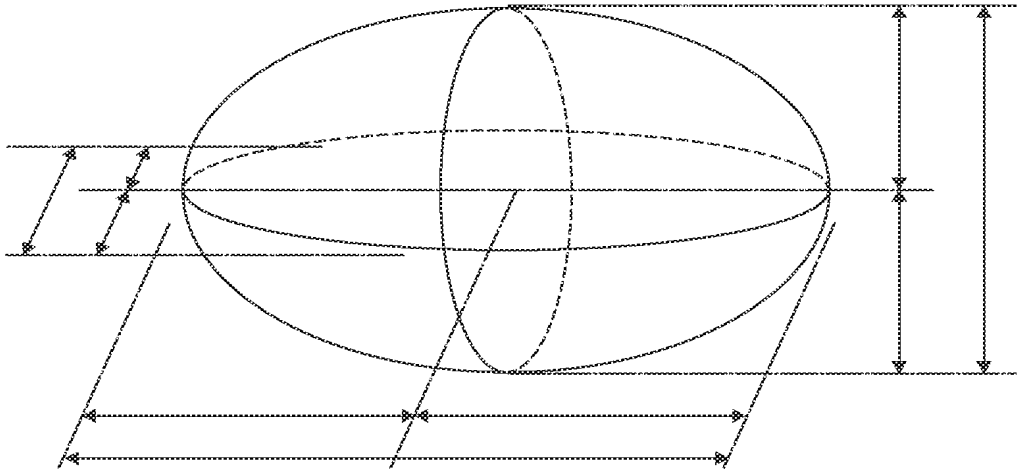


FIG. 4A

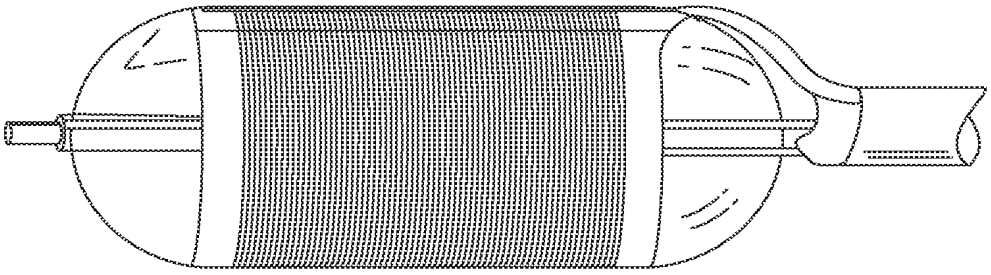


FIG. 4B

Replacement Sheet

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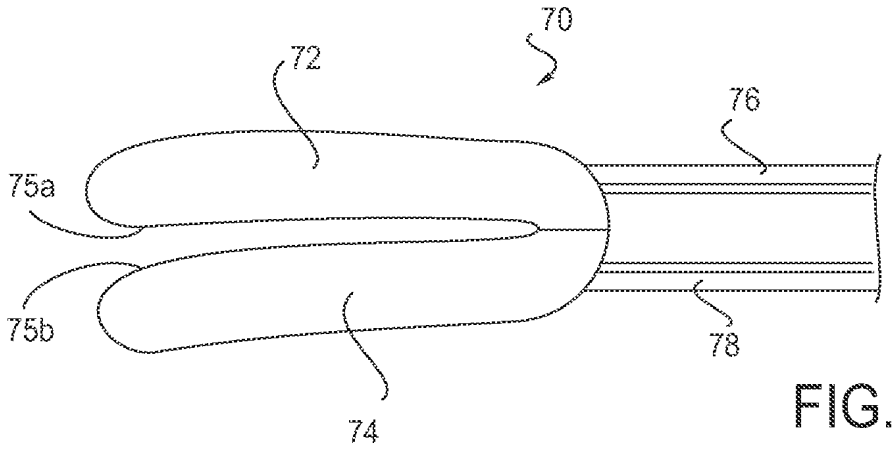


FIG. 4C

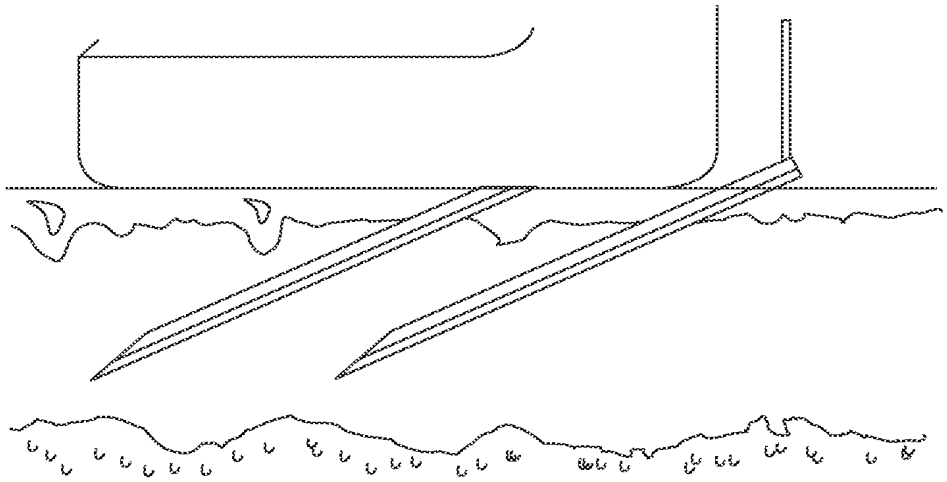


FIG. 4D

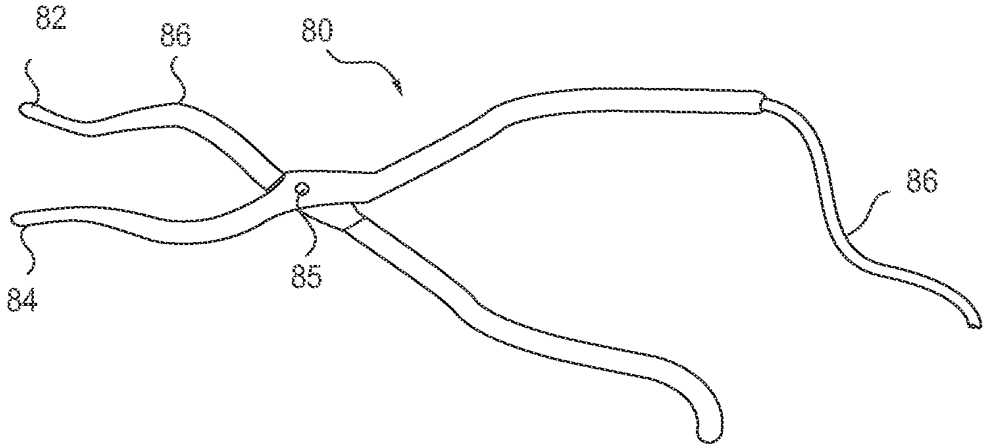


FIG. 5A

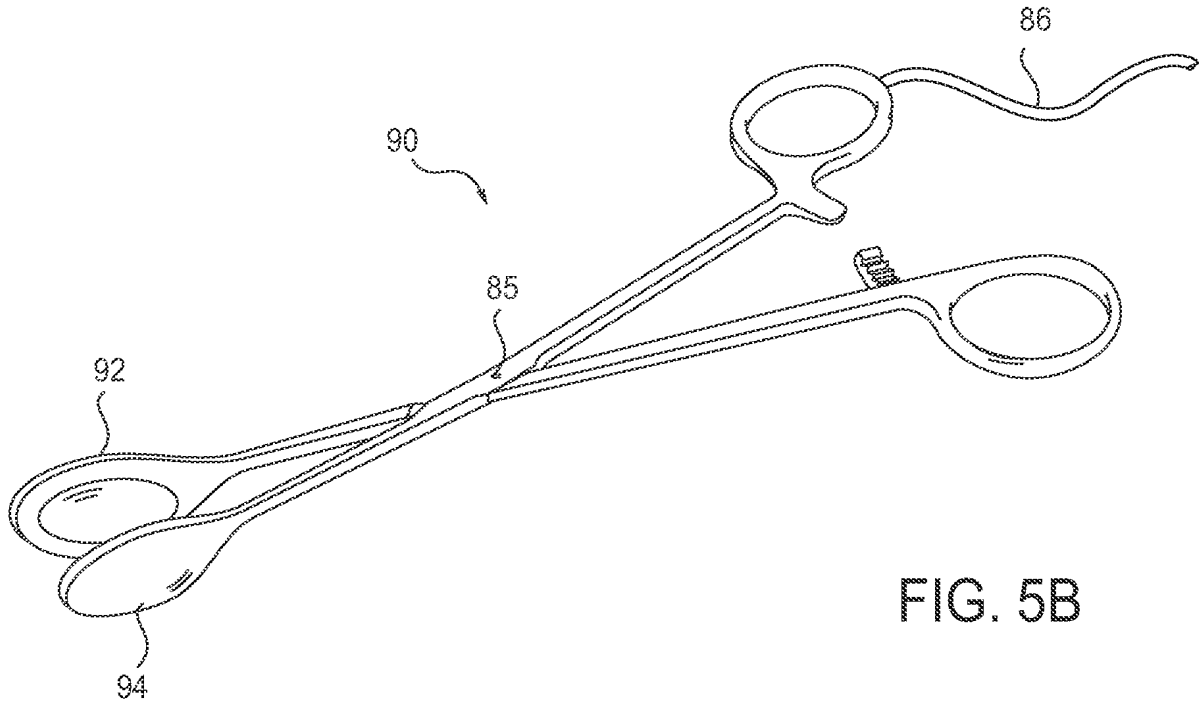


FIG. 5B

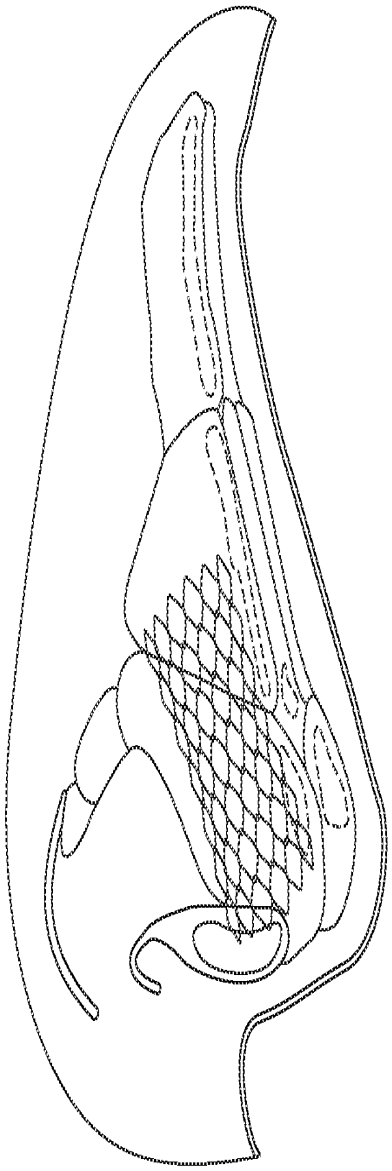


FIG. 6

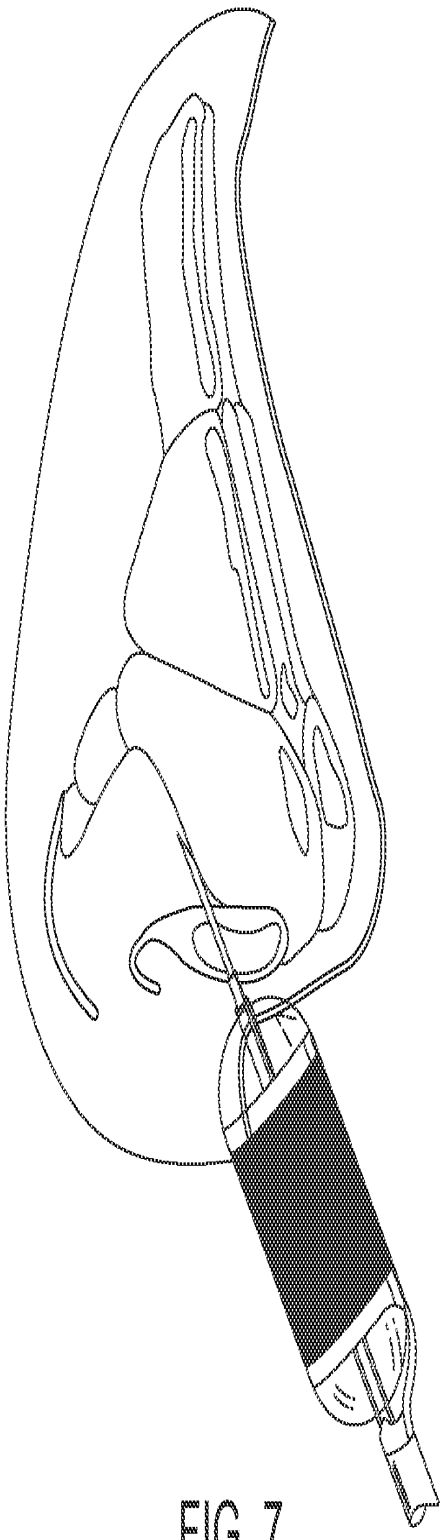


FIG. 7

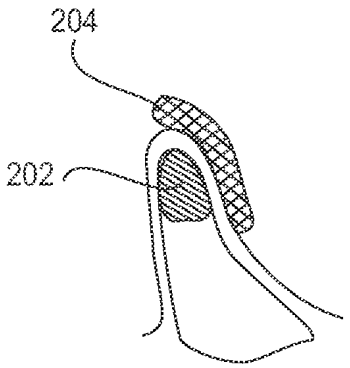


FIG. 8A

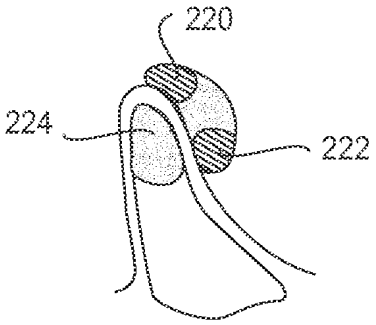


FIG. 8C

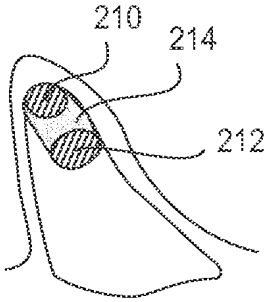


FIG. 8B

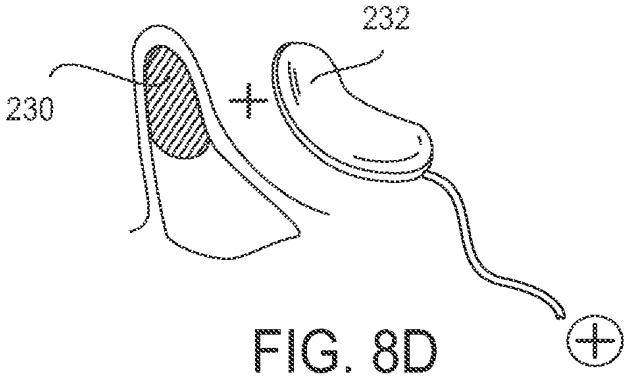


FIG. 8D

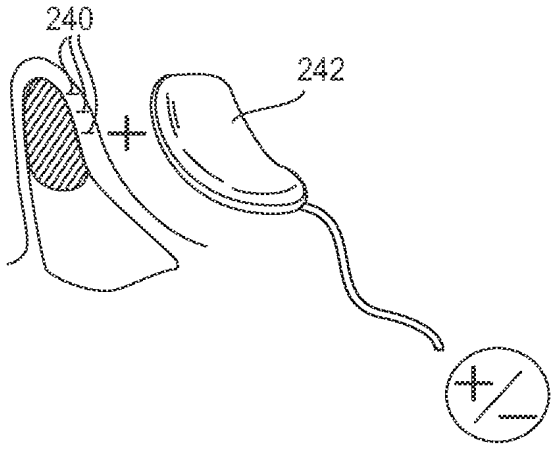


FIG. 8E

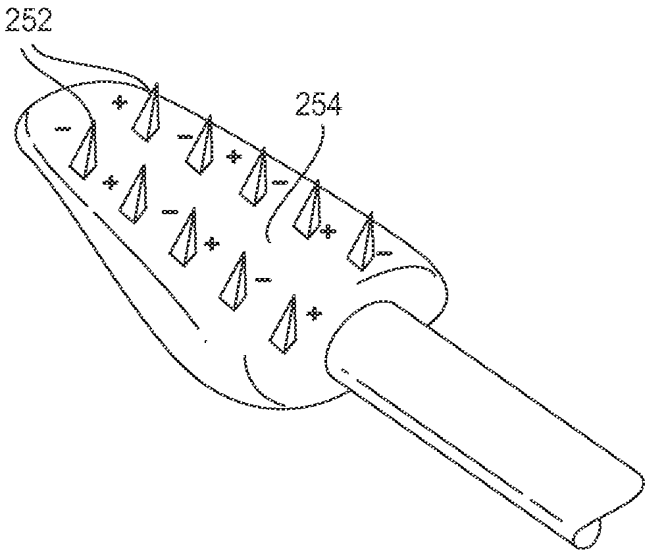


FIG. 8F

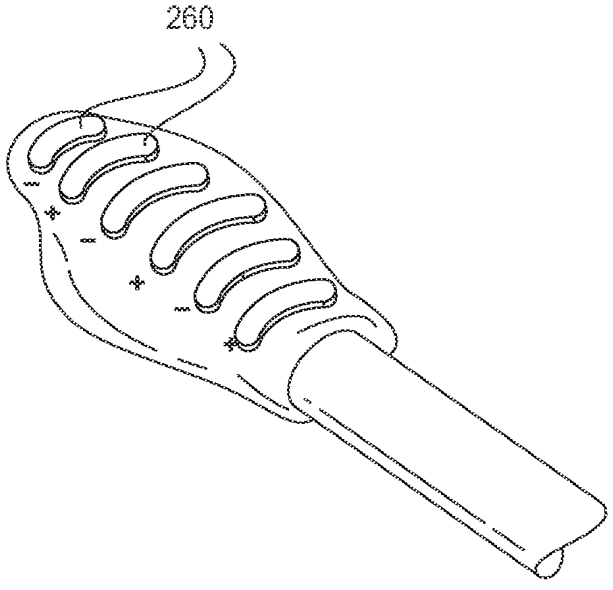


FIG. 8G

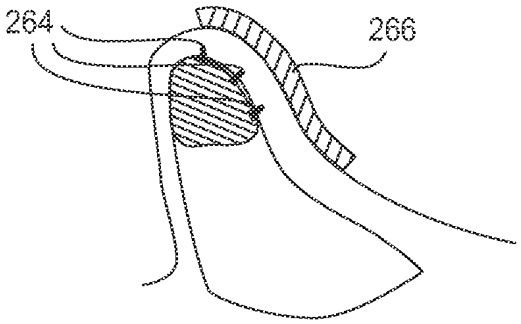


FIG. 8H

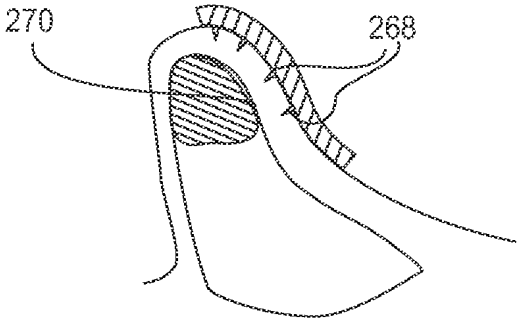


FIG. 8I

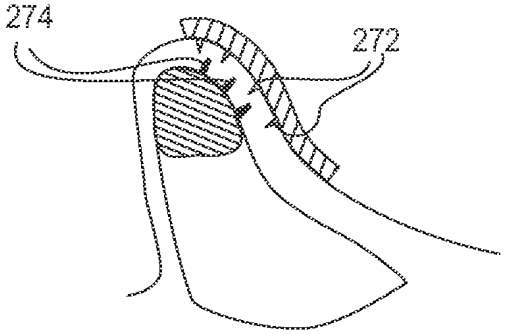


FIG. 8J

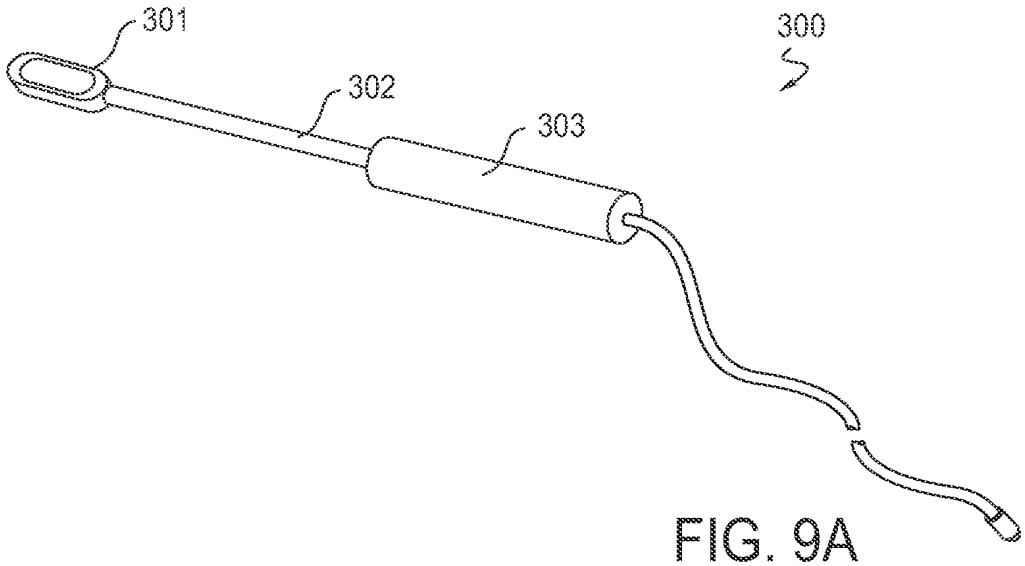


FIG. 9A

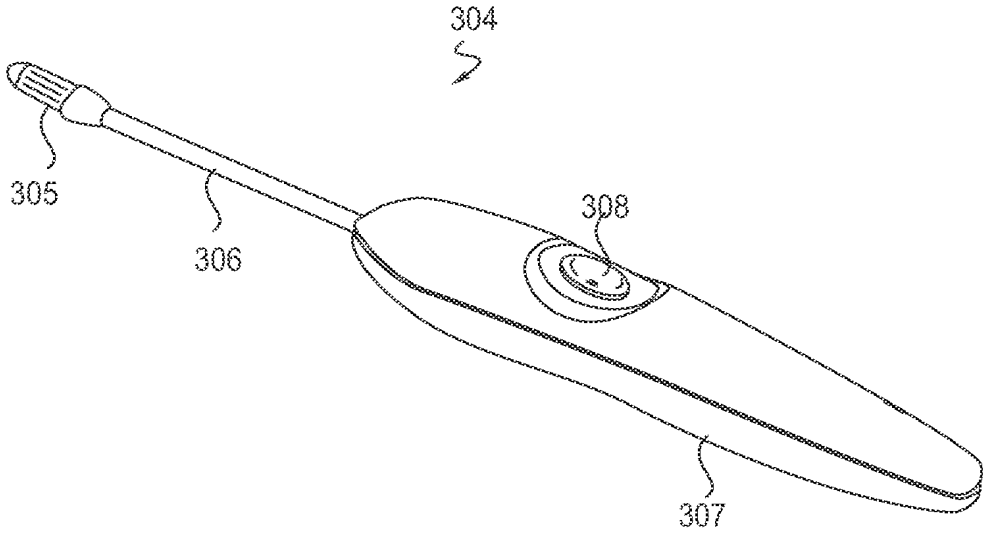


FIG. 9B

Replacement Sheet

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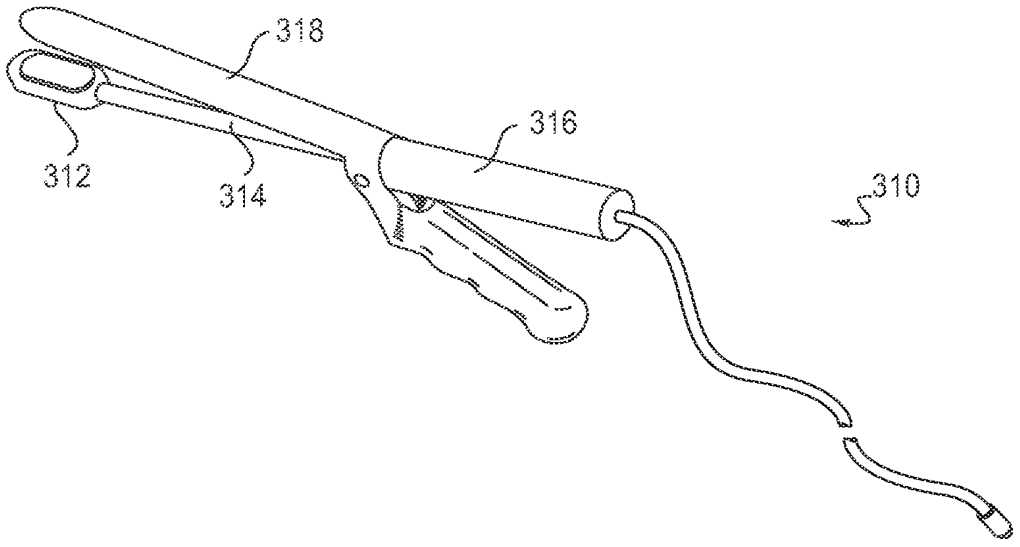


FIG. 10A

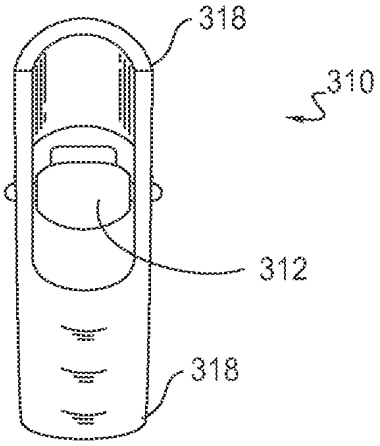


FIG. 10B

Replacement Sheet
14/61

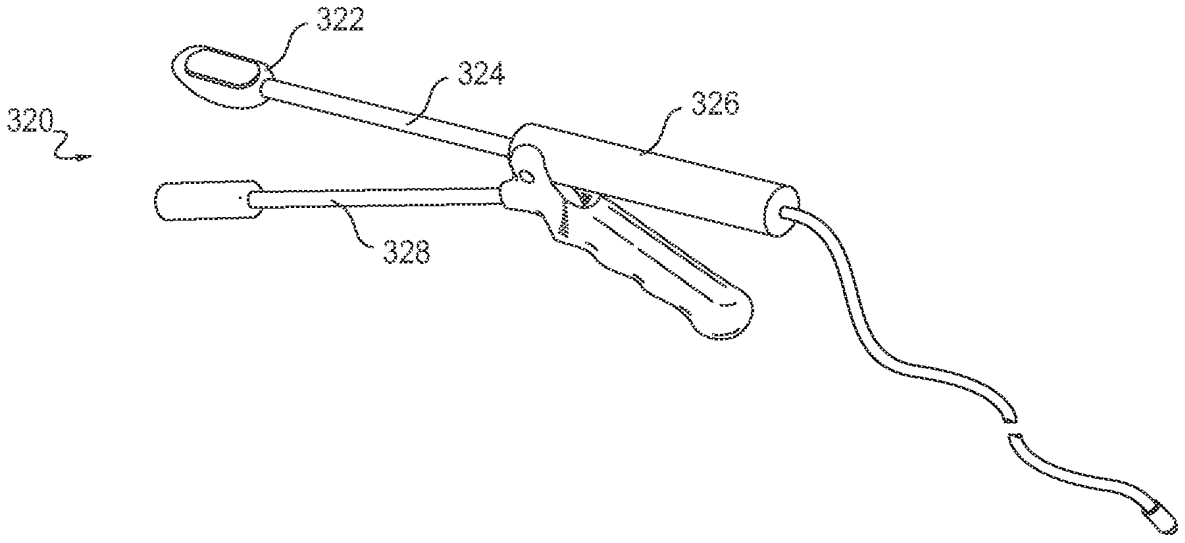


FIG. 11A

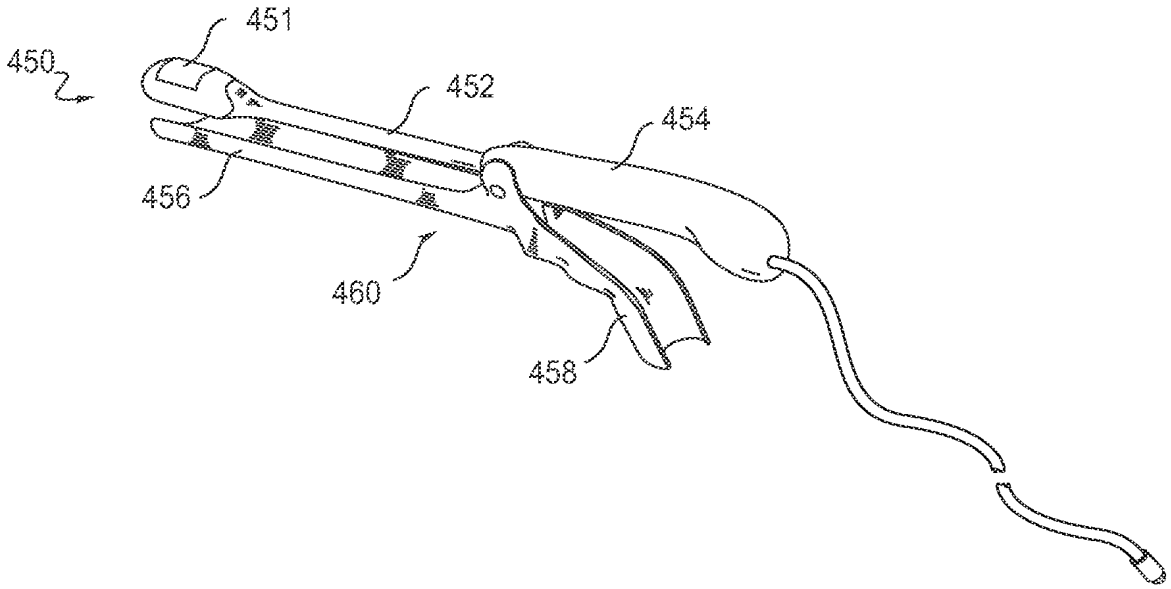


FIG. 11B

Replacement Sheet

15/61

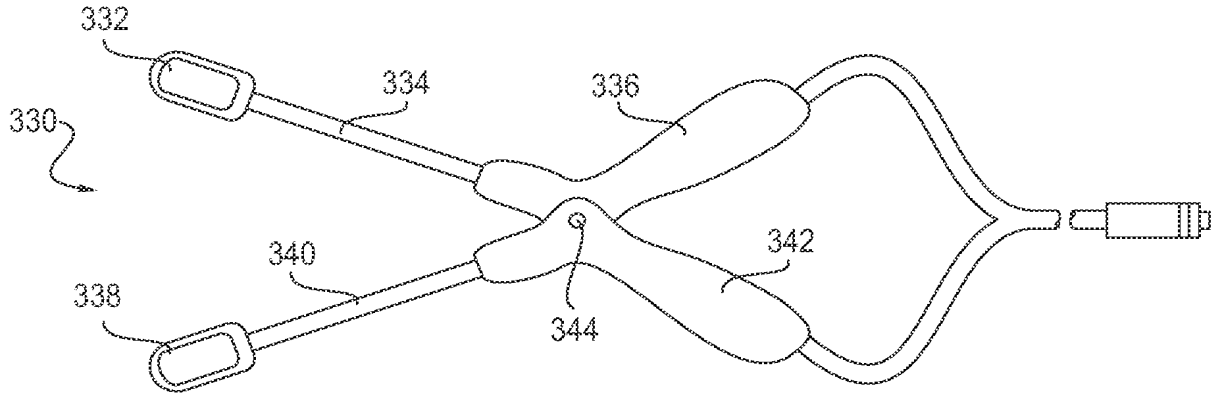


FIG. 12A

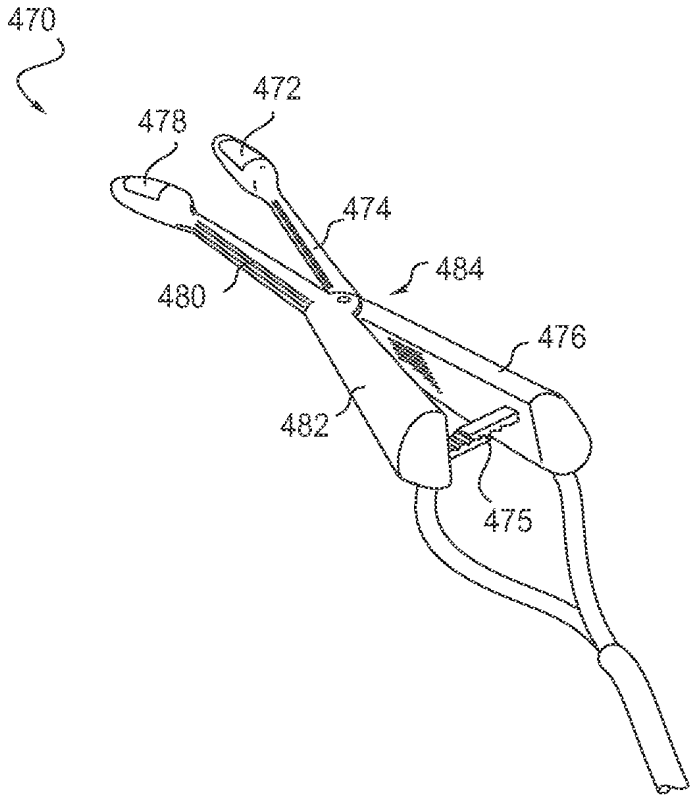


FIG. 12B

Replacement Sheet

16/61

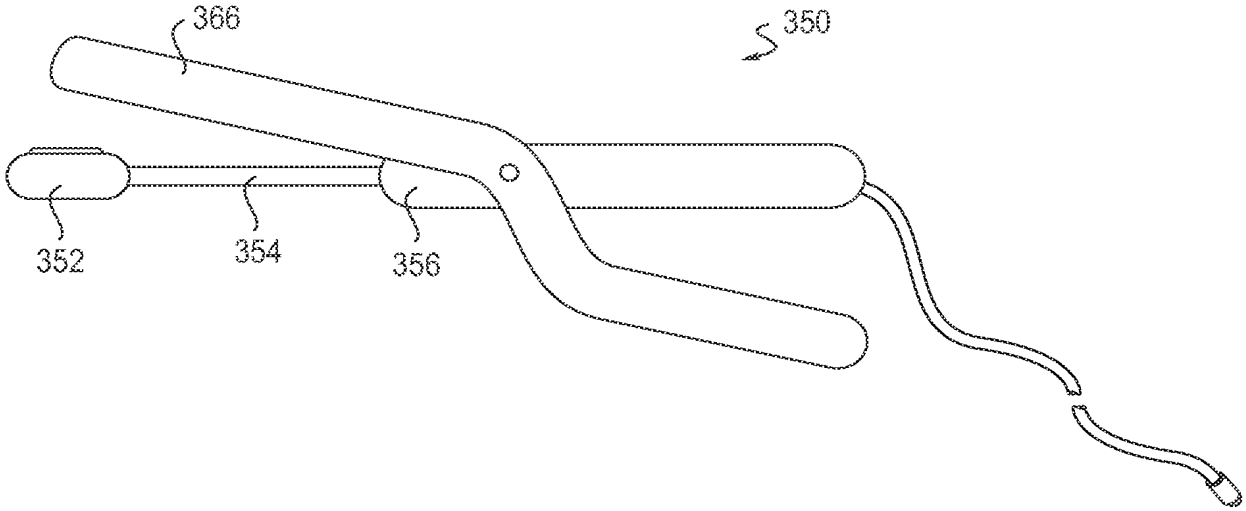


FIG. 13A

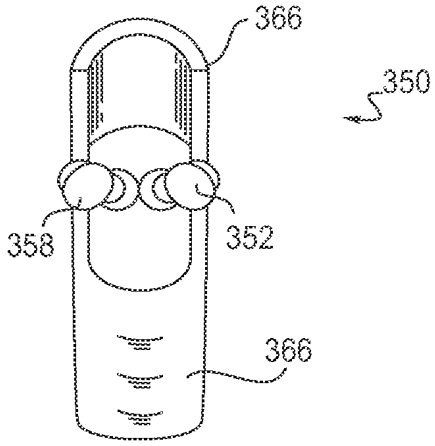


FIG. 13B

Replacement Sheet

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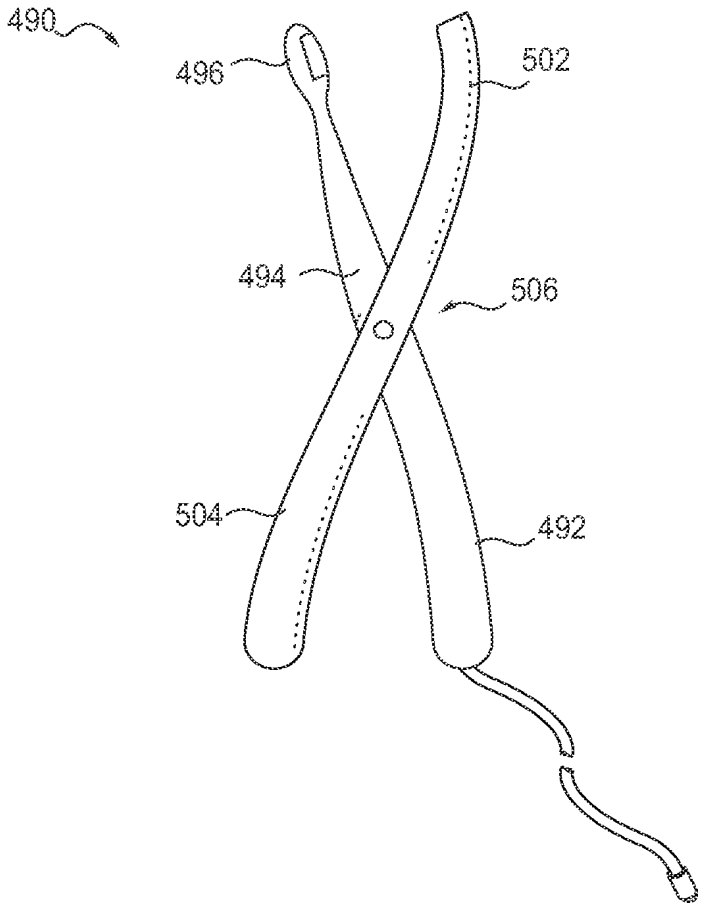


FIG. 13C

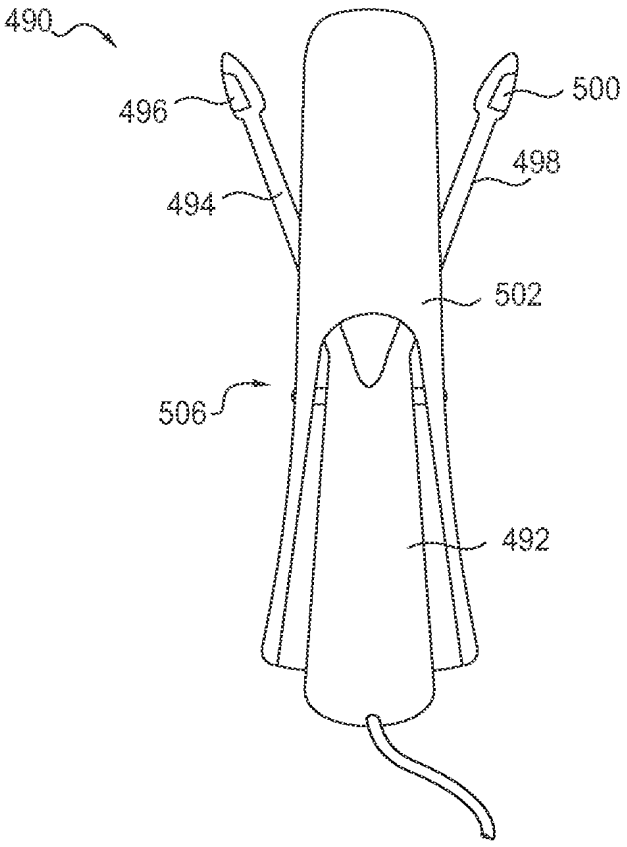


FIG. 13D

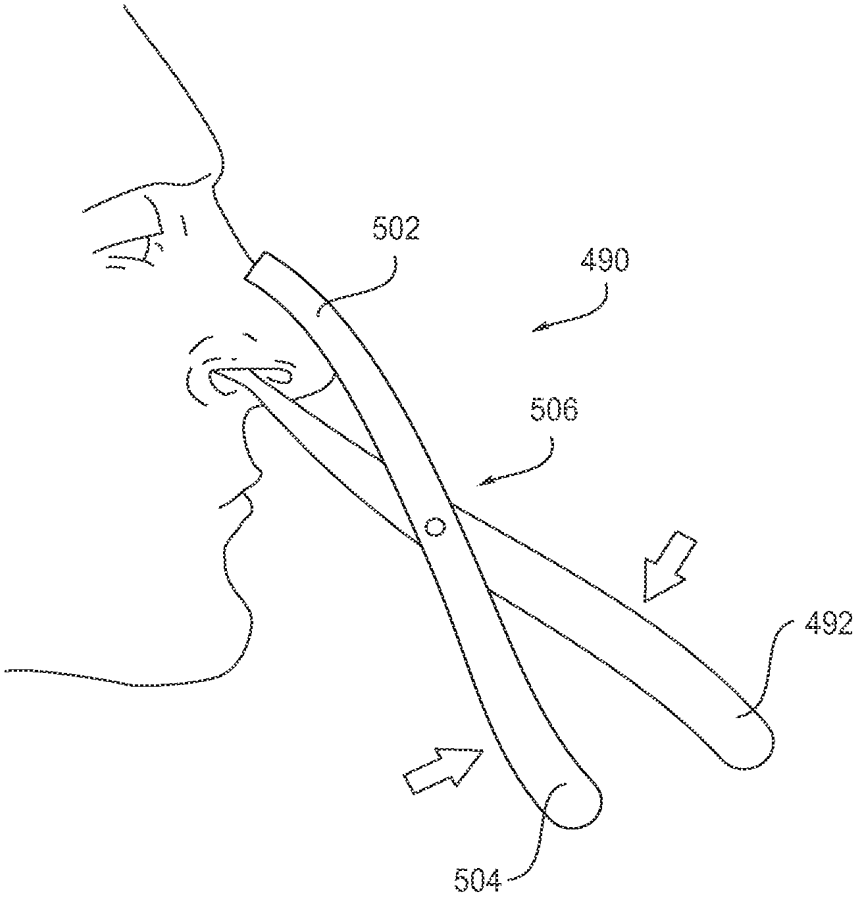


FIG. 13E

Replacement Sheet

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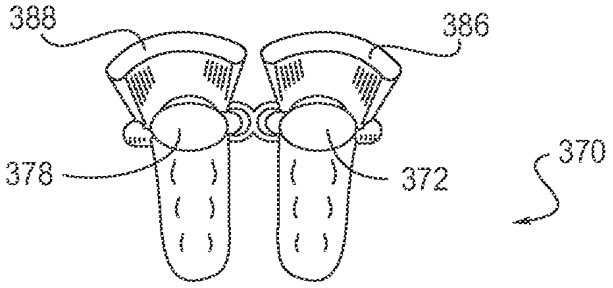


FIG. 14B

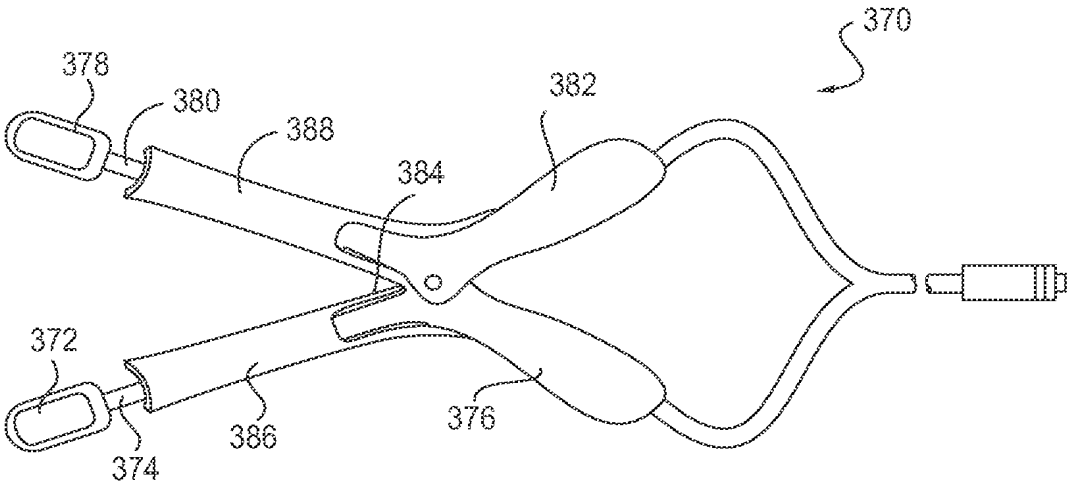


FIG. 14A

Replacement Sheet

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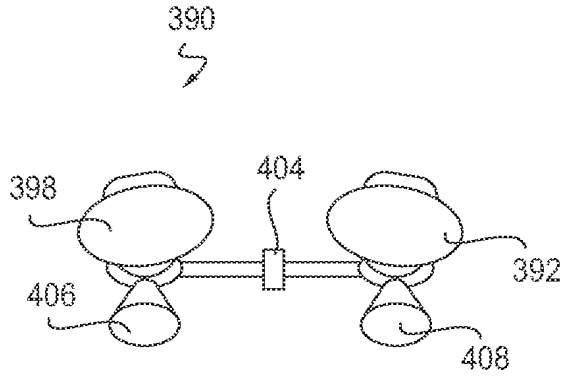


FIG. 15A

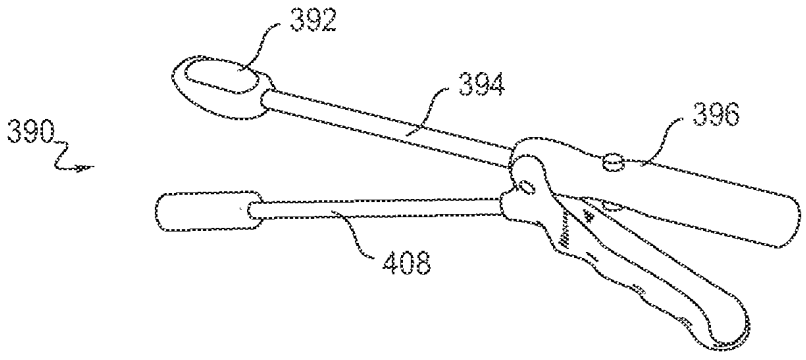


FIG. 15B

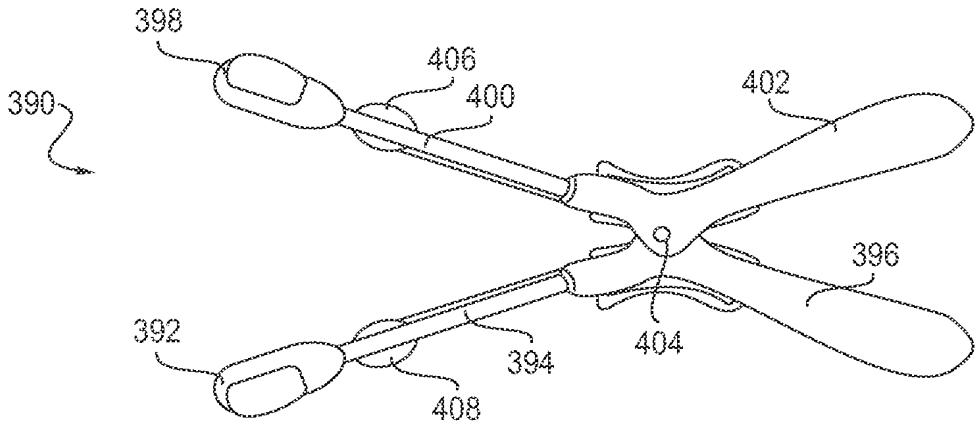


FIG. 15C

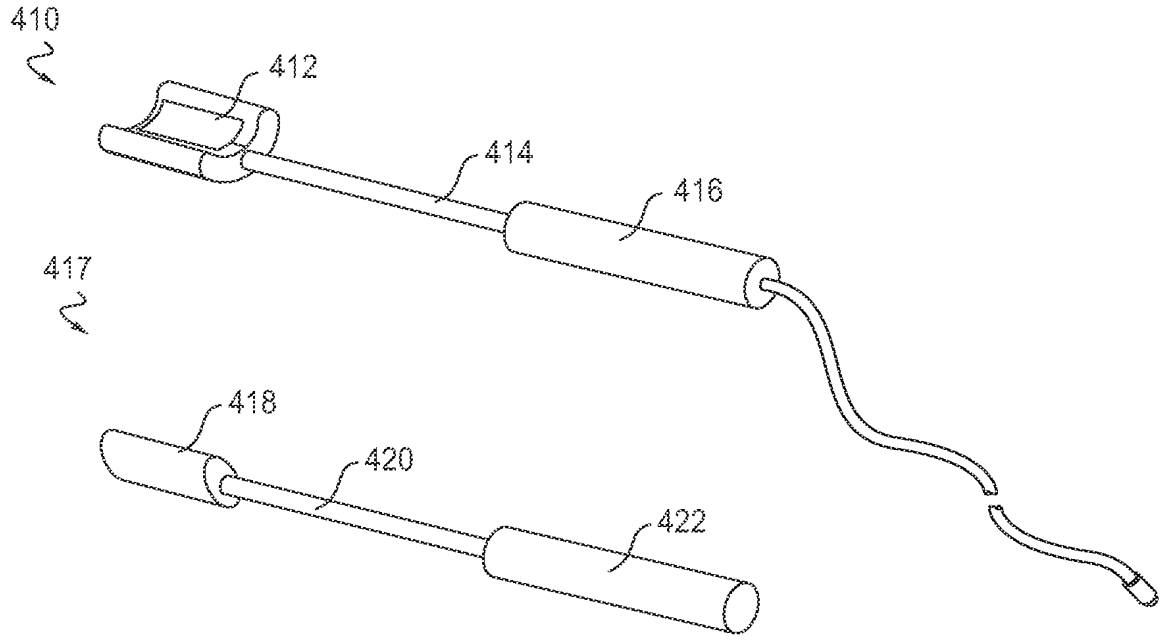


FIG. 16

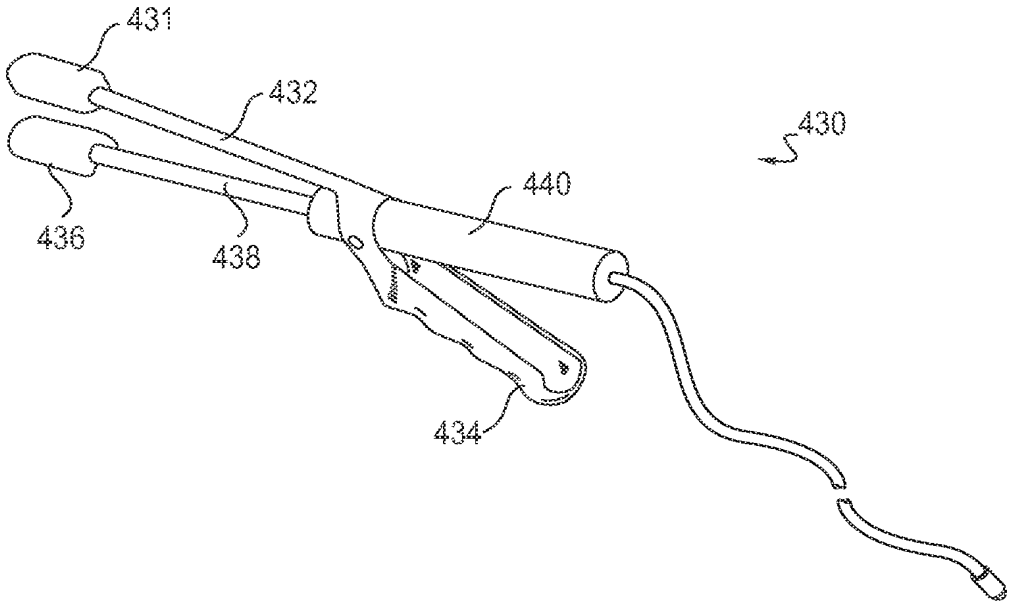


FIG. 17A

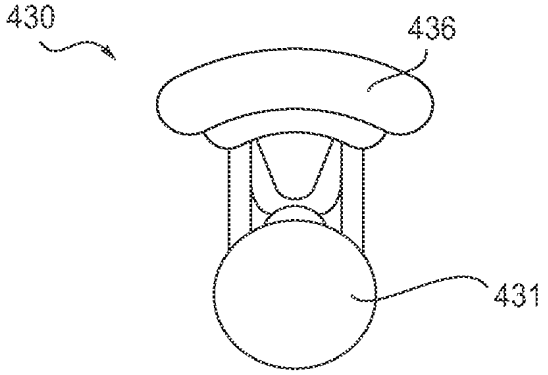


FIG. 17B

Replacement Sheet

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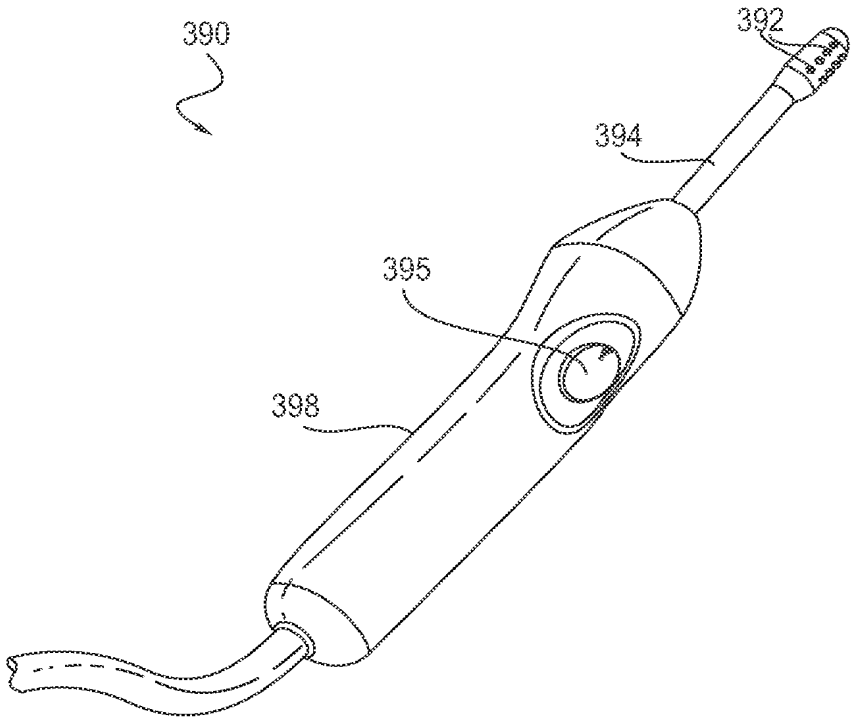


FIG. 18

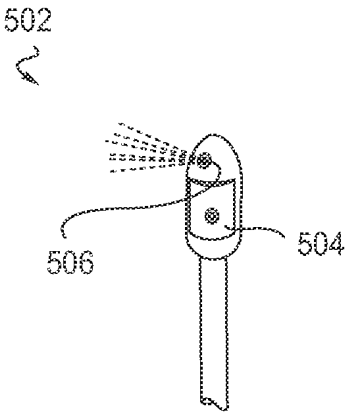


FIG. 19A



FIG. 19B

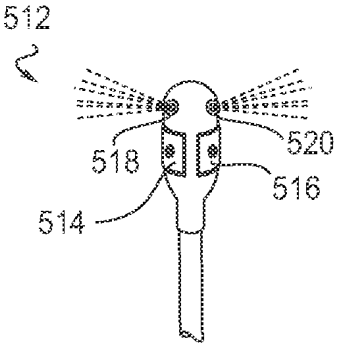


FIG. 20A



FIG. 20B

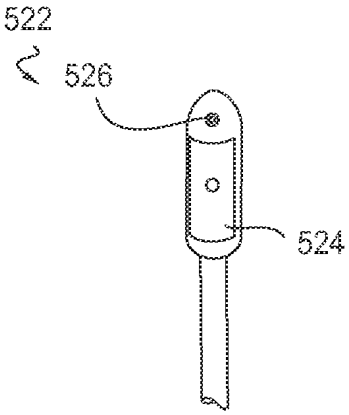


FIG. 21A

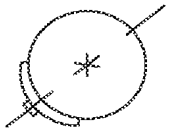


FIG. 21B

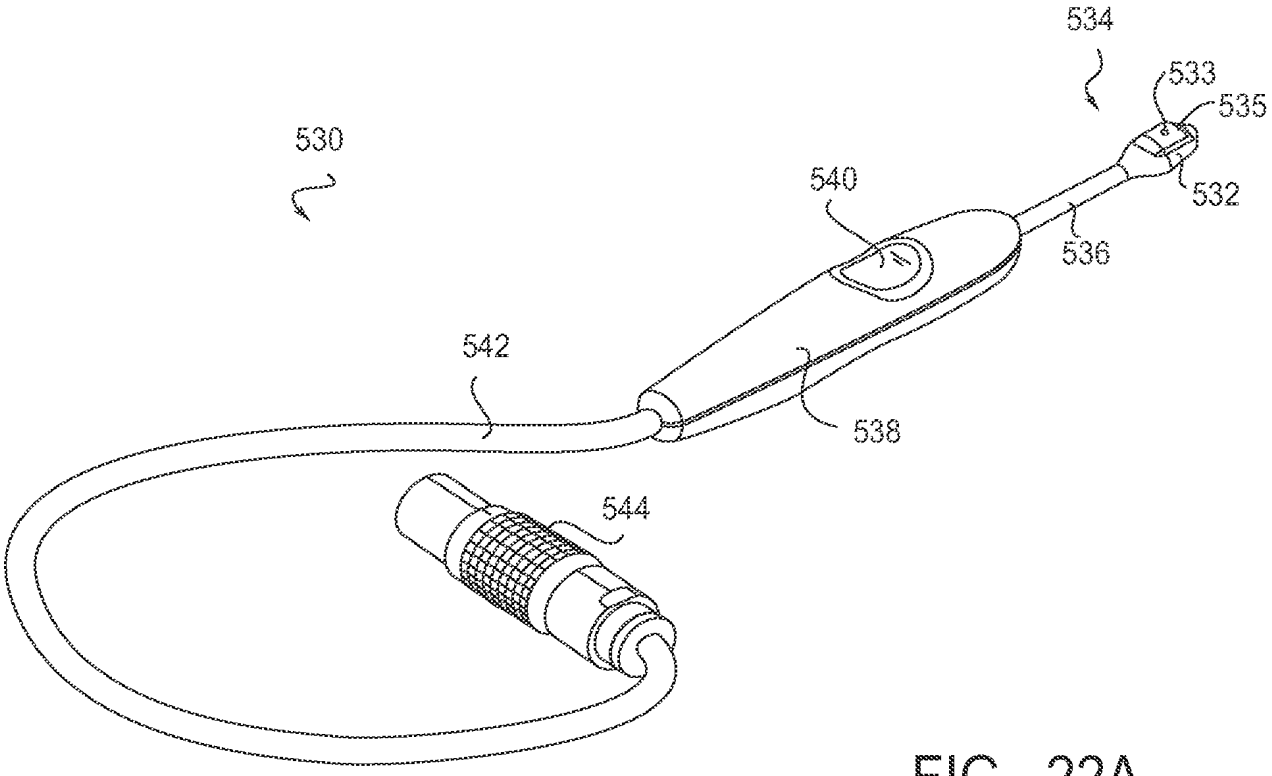


FIG. 22A

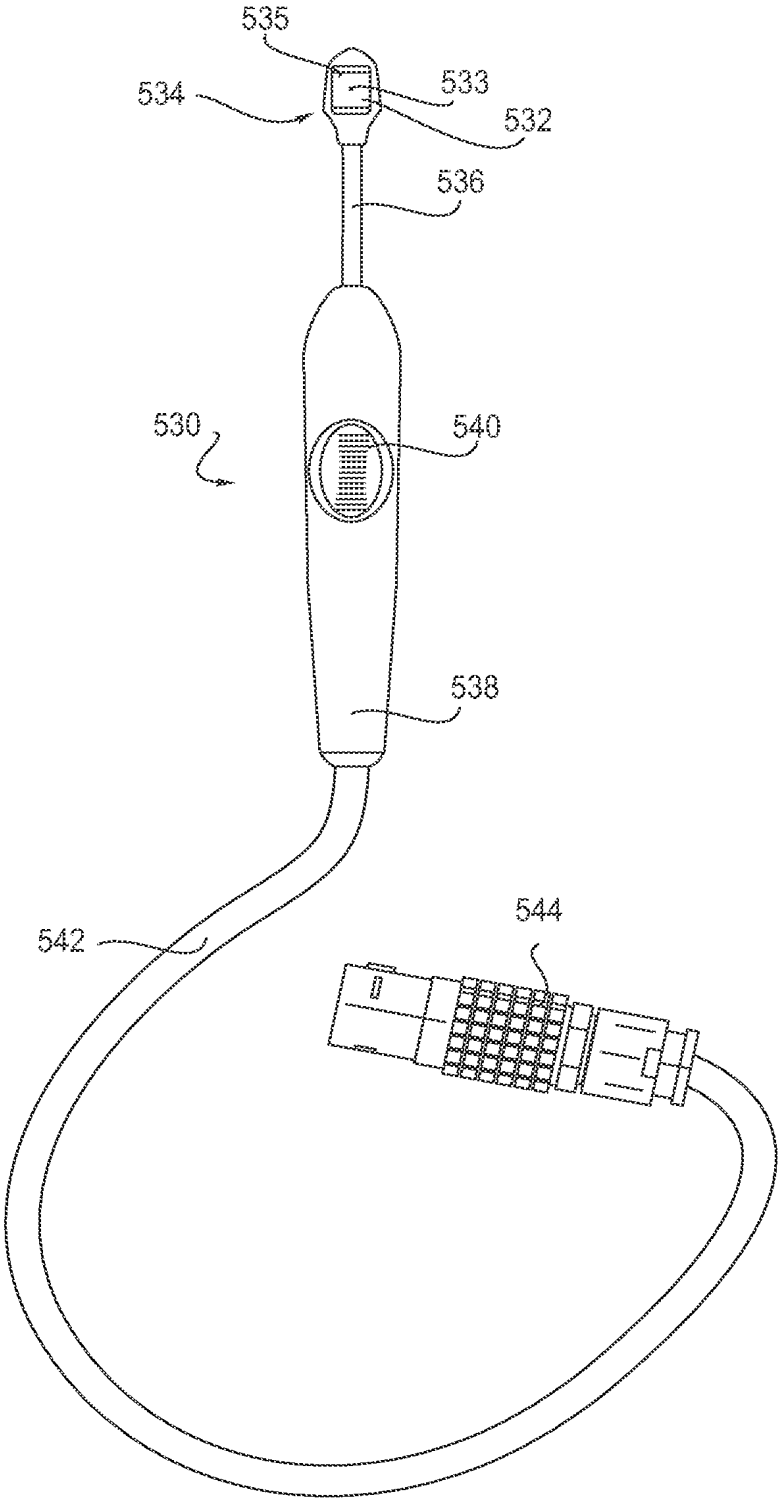


FIG. 22B

Replacement Sheet

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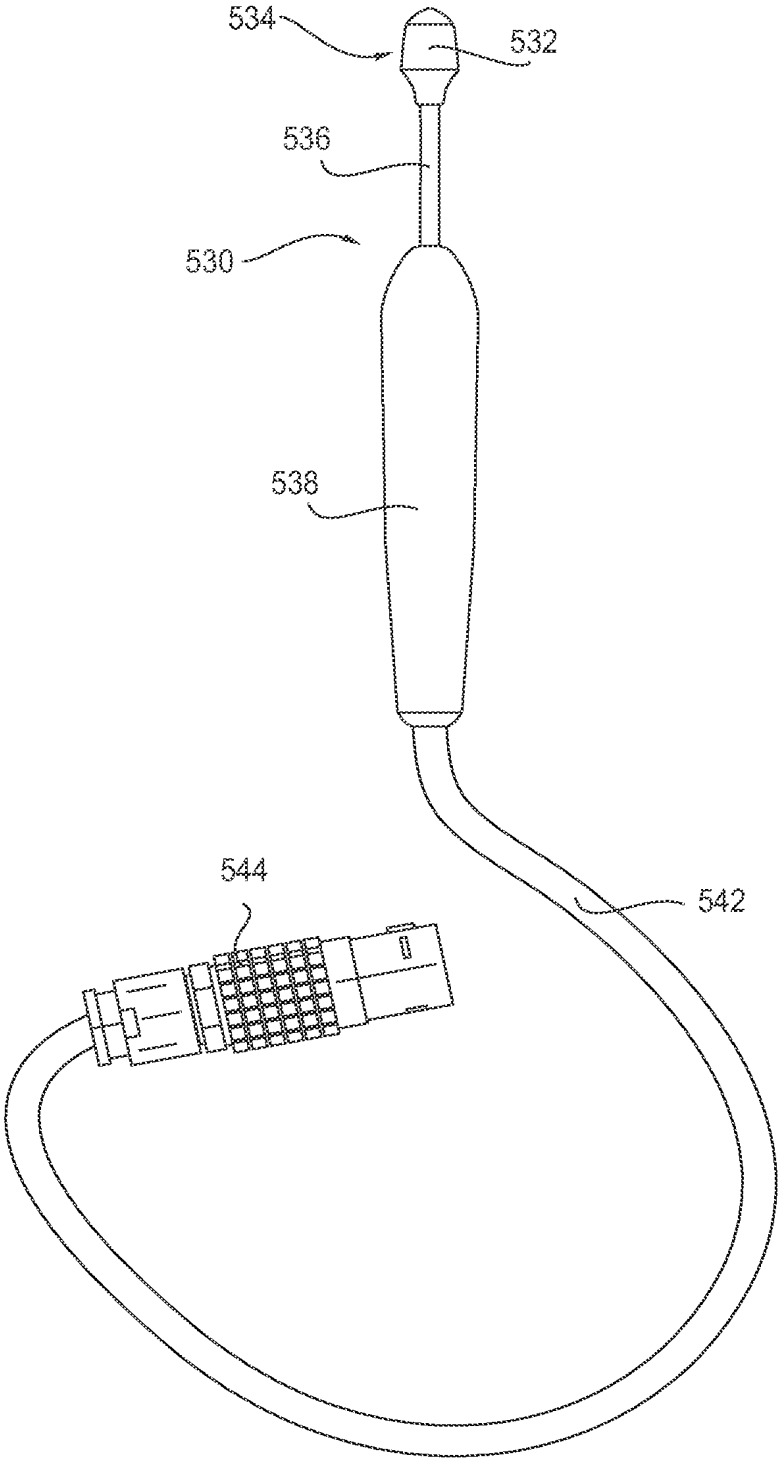


FIG. 22C

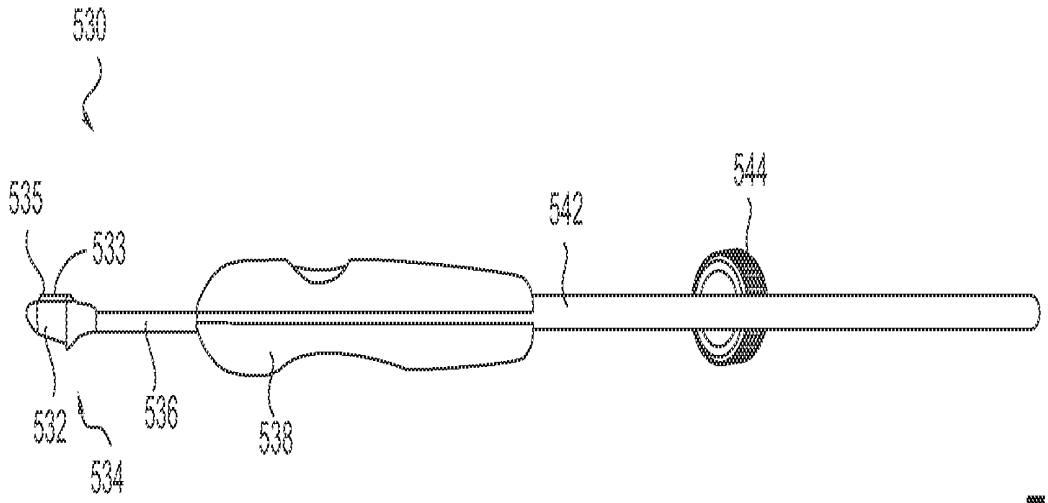


FIG. 22D

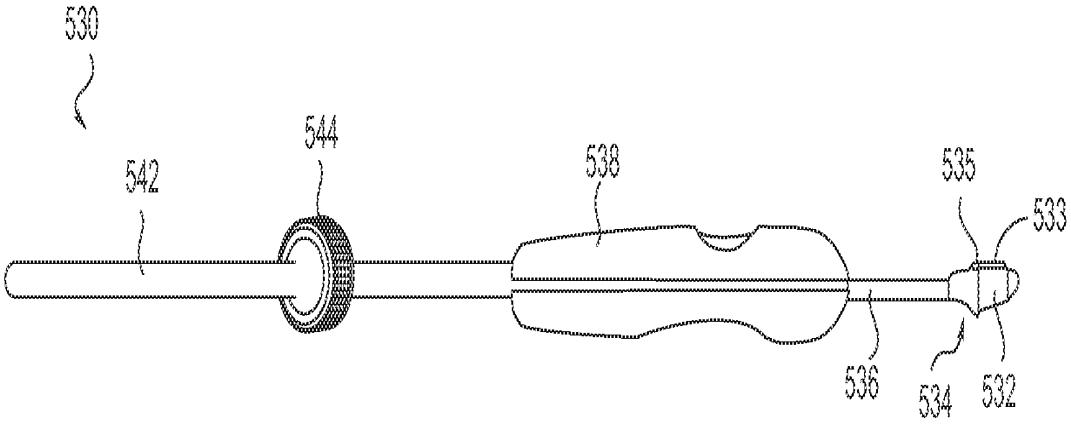


FIG. 22E

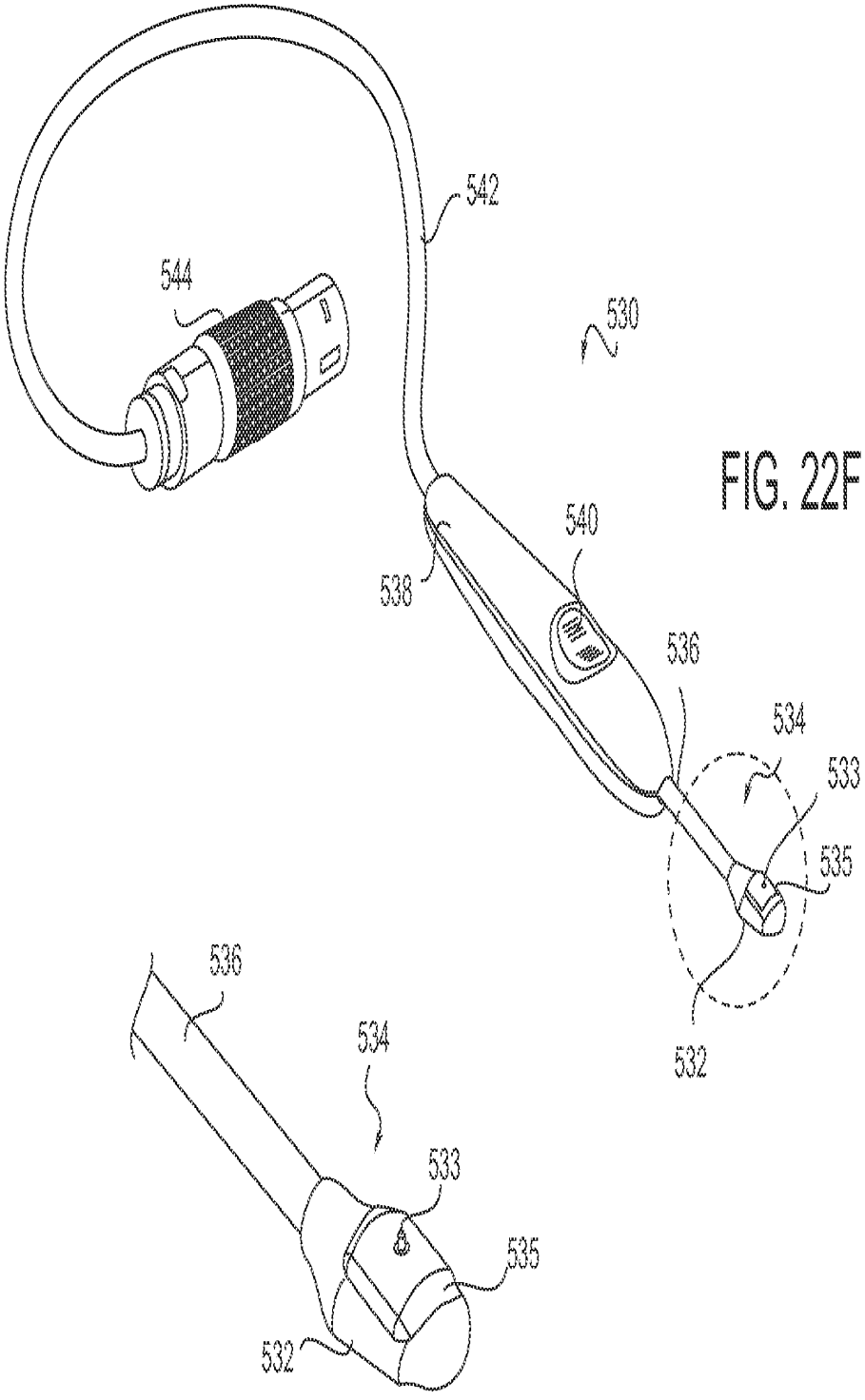


FIG. 22F

FIG. 22G

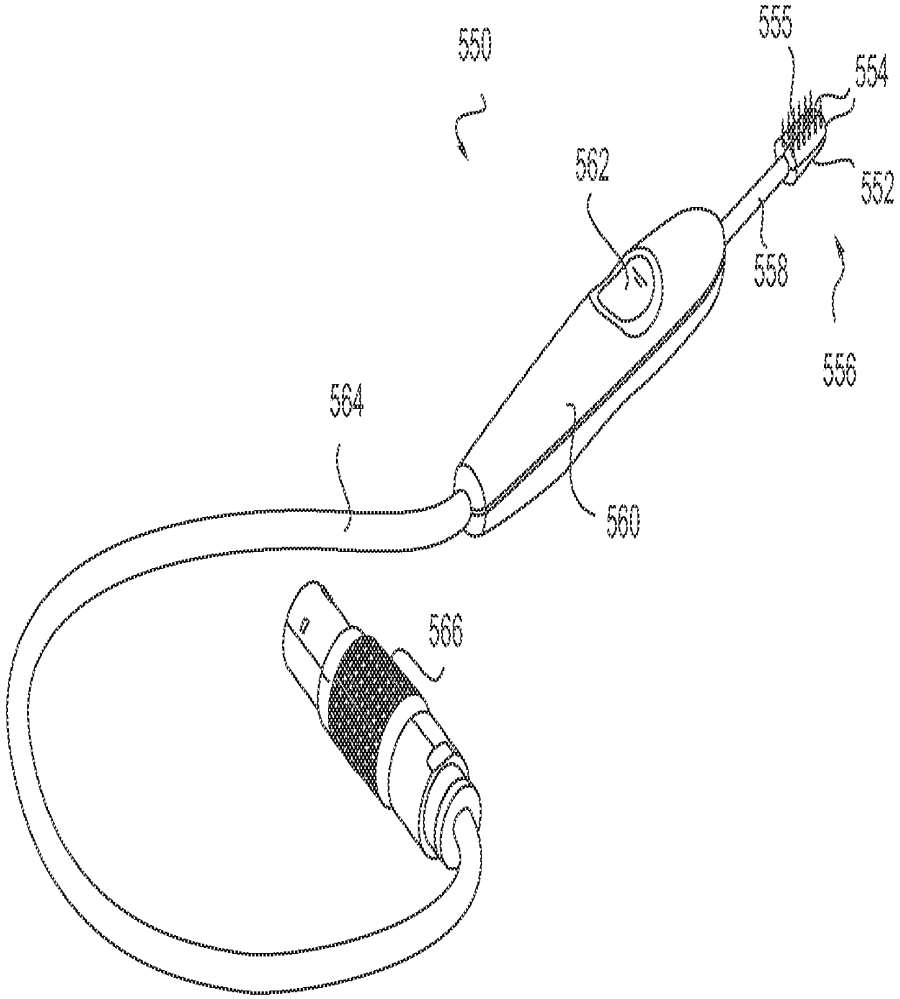


FIG. 23A

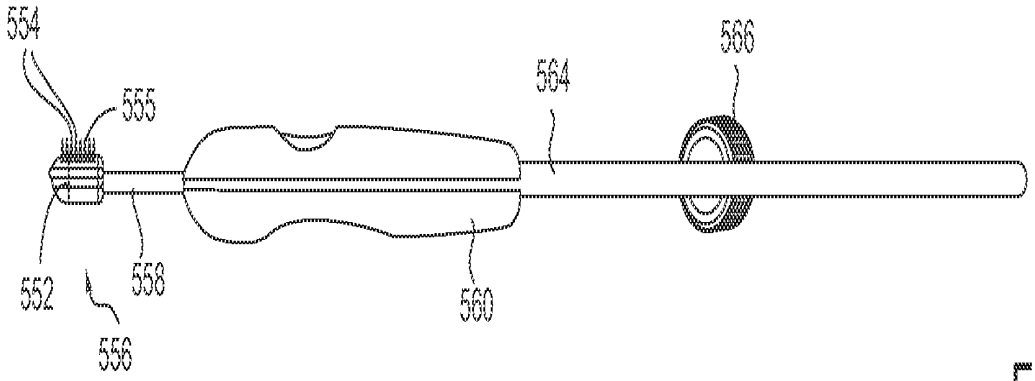


FIG. 23B

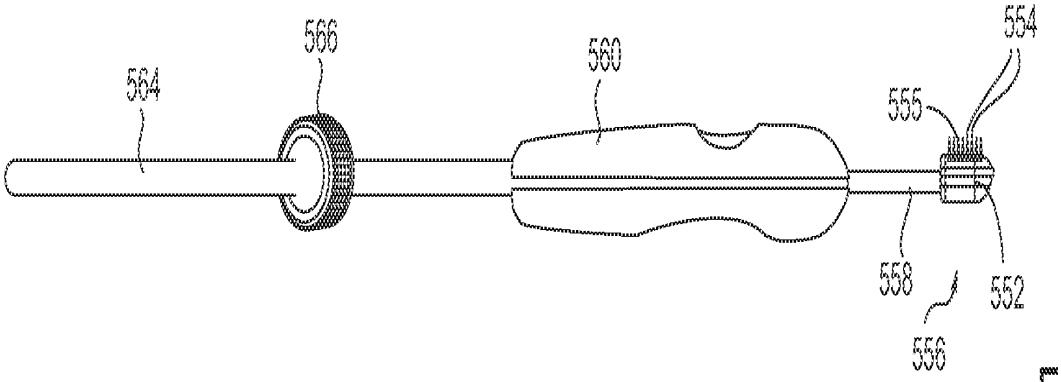


FIG. 23C

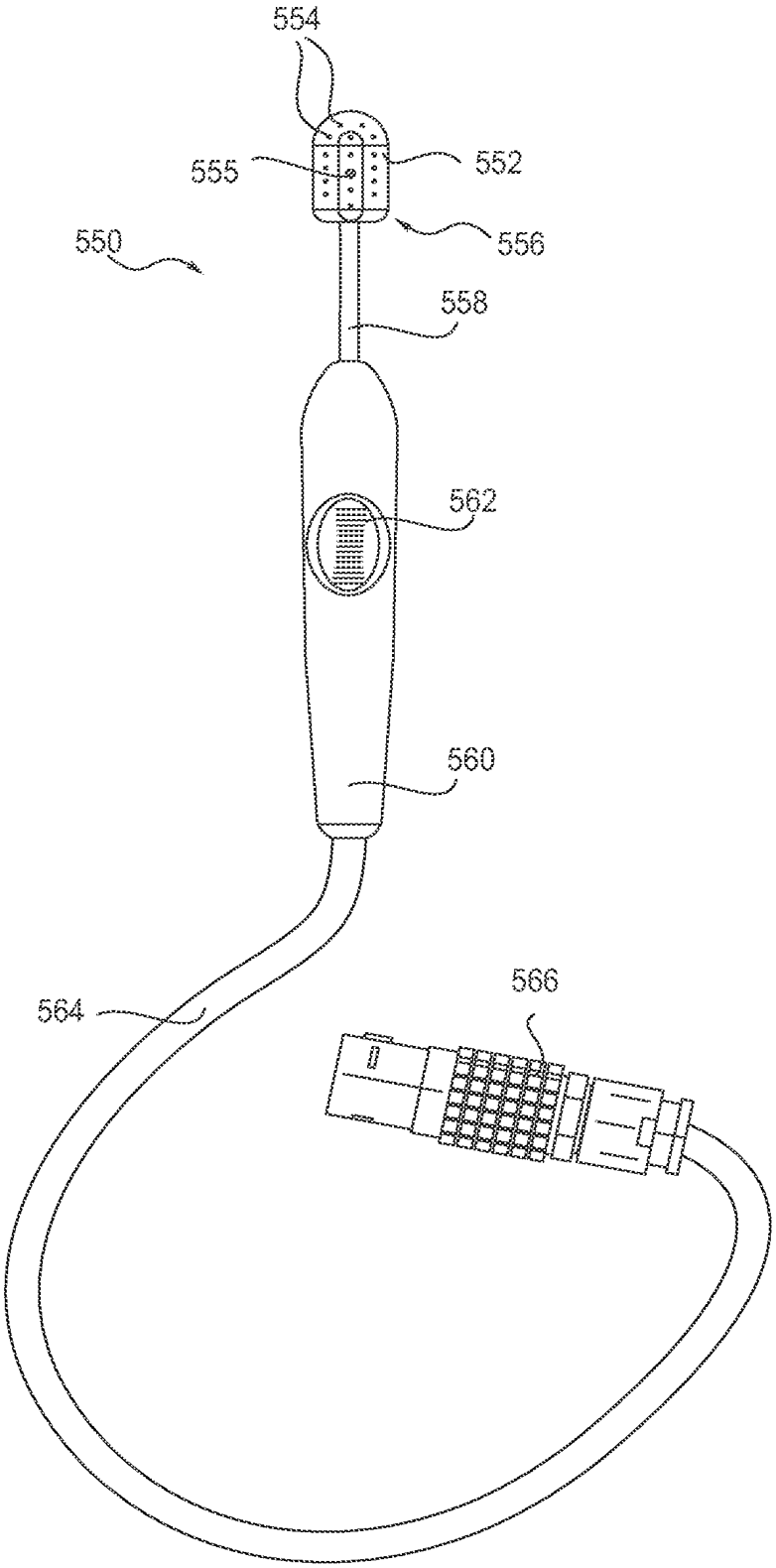


FIG. 23D

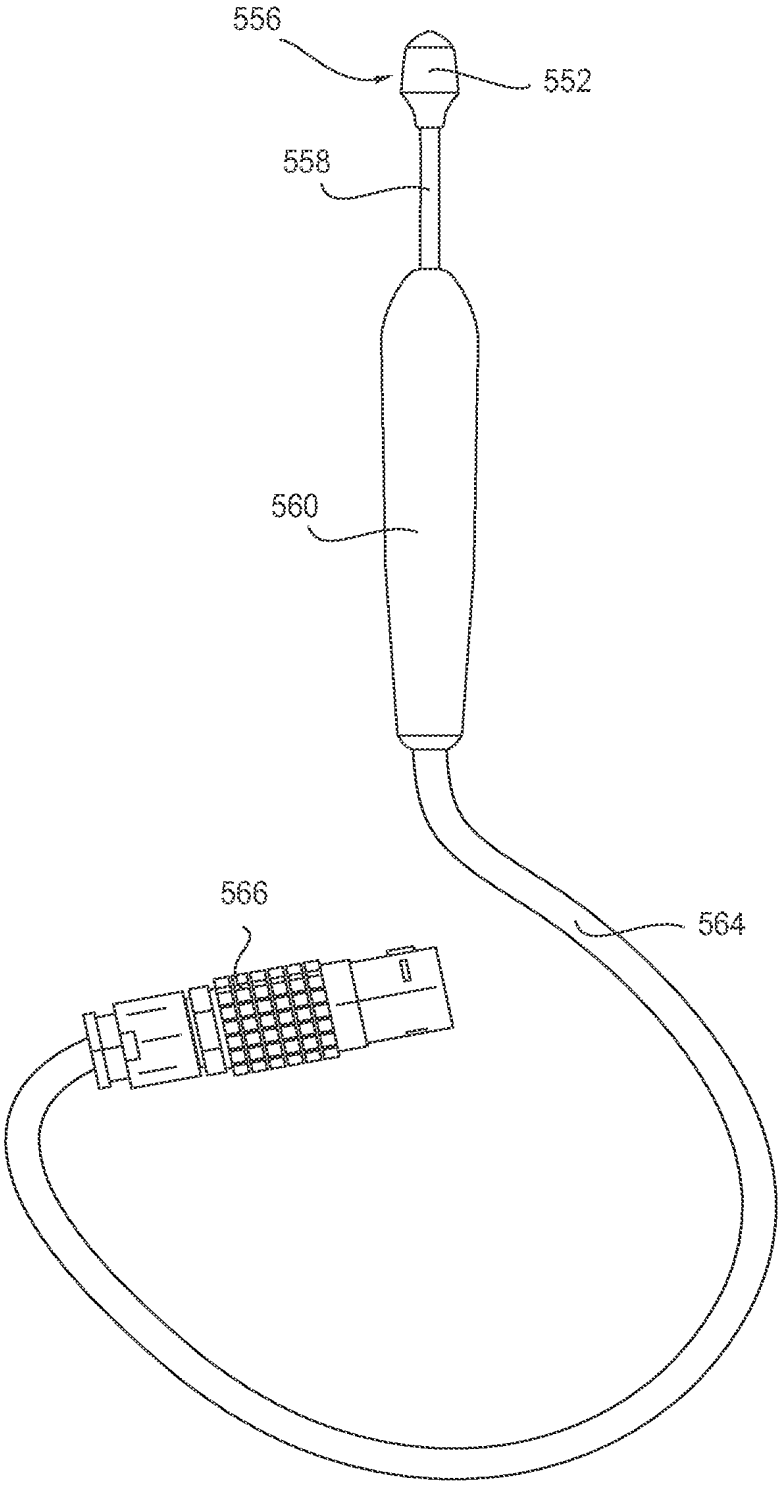


FIG. 23E1

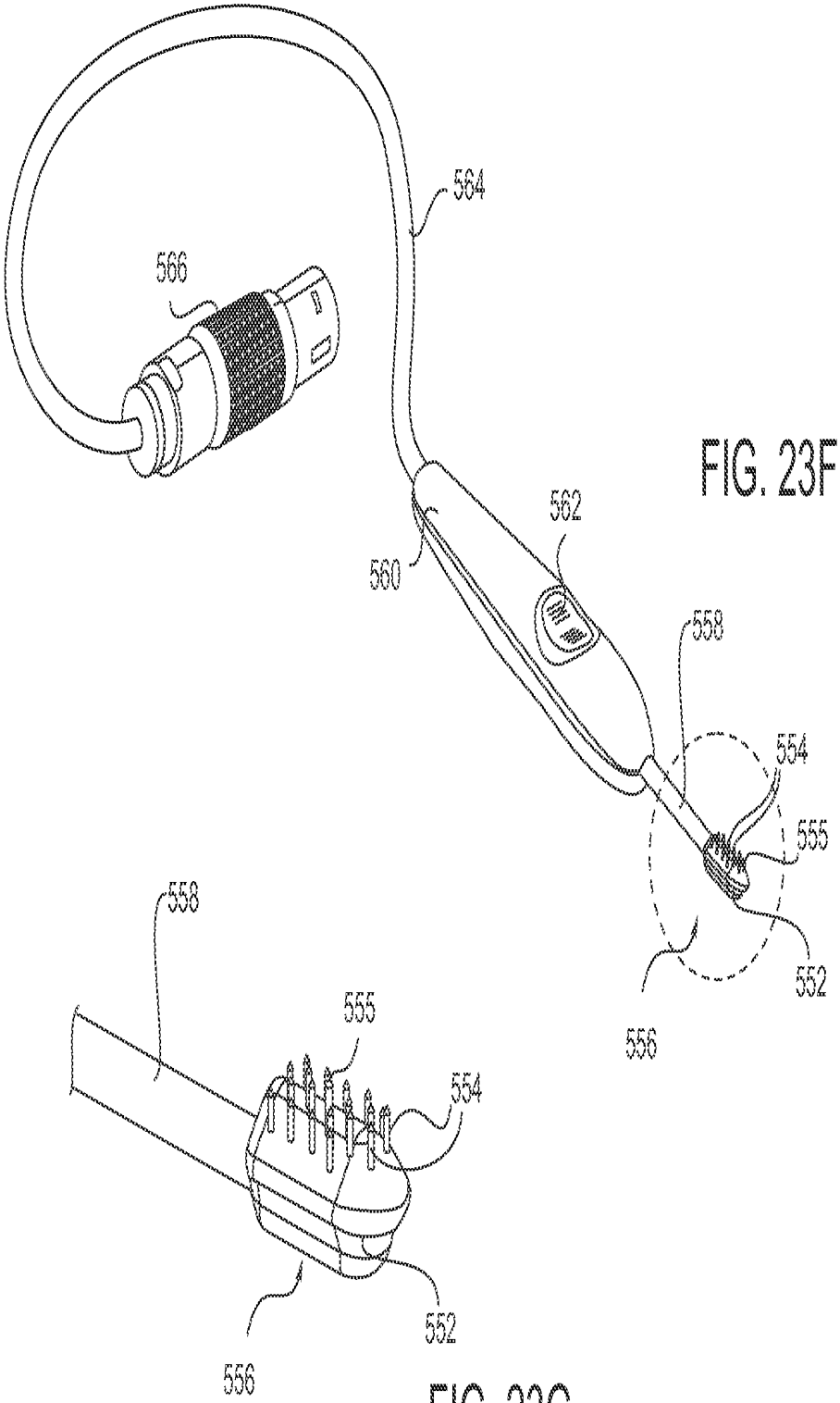


FIG. 23F

FIG. 23G

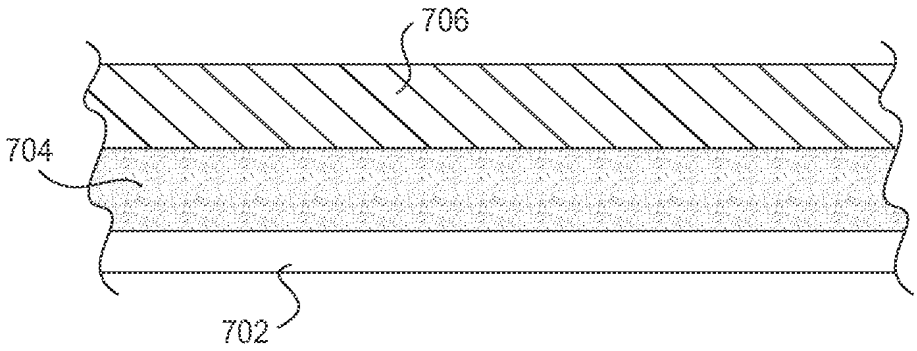


FIG. 24A

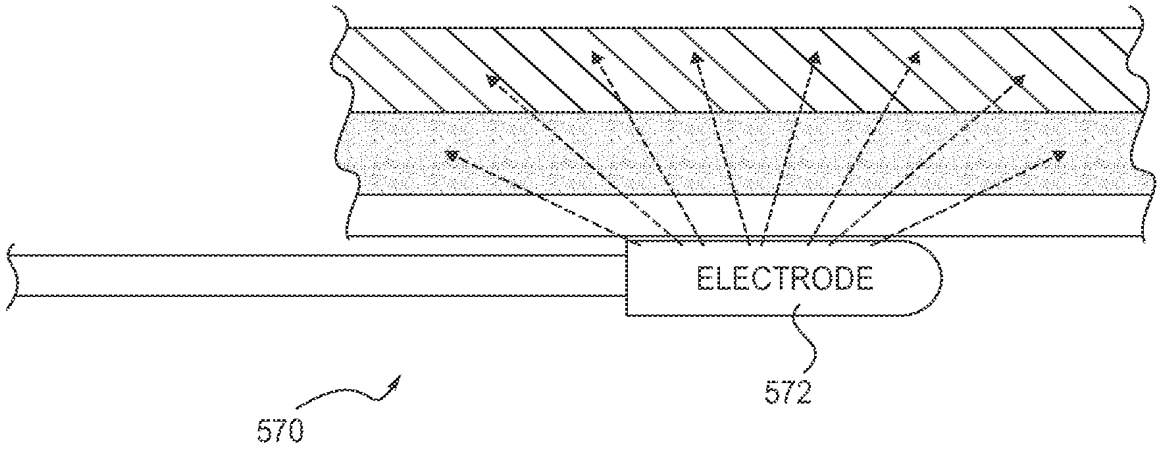


FIG. 24B

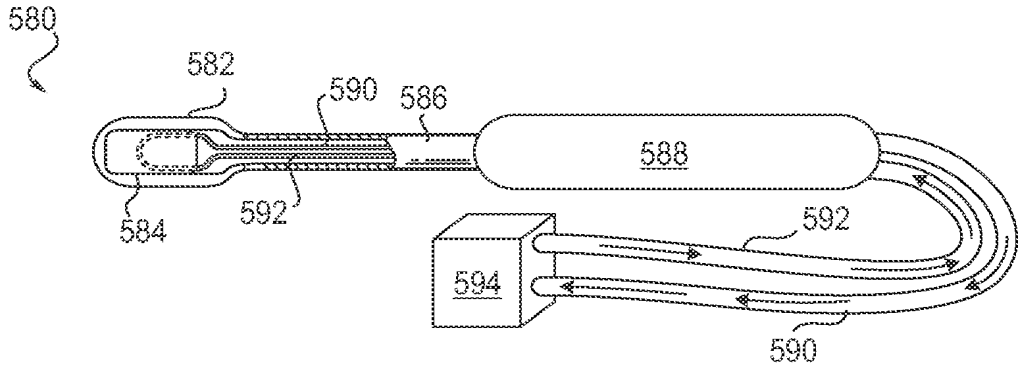


FIG. 25A

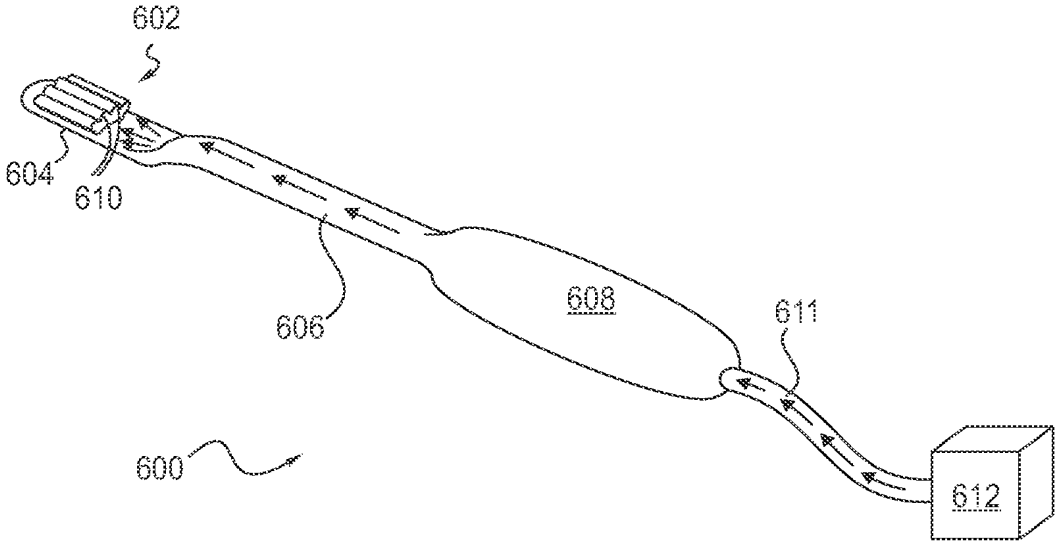


FIG. 25B

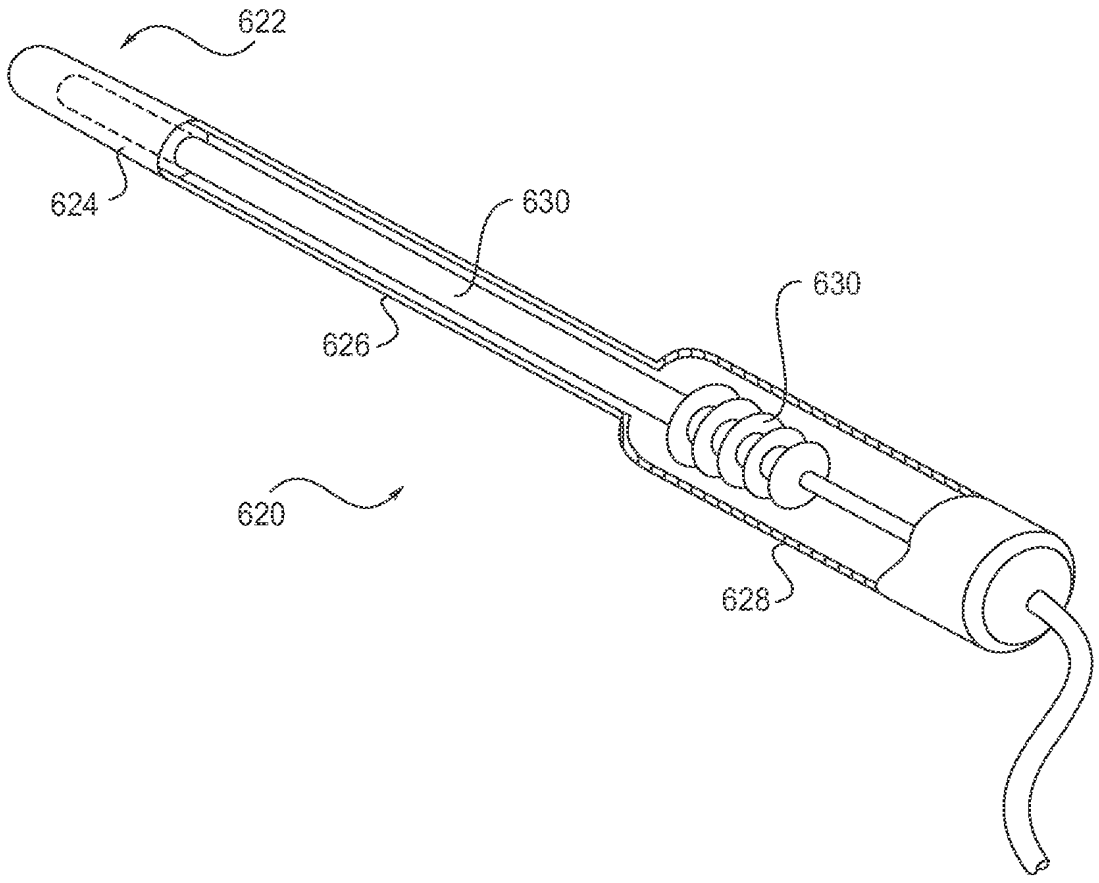


FIG. 26

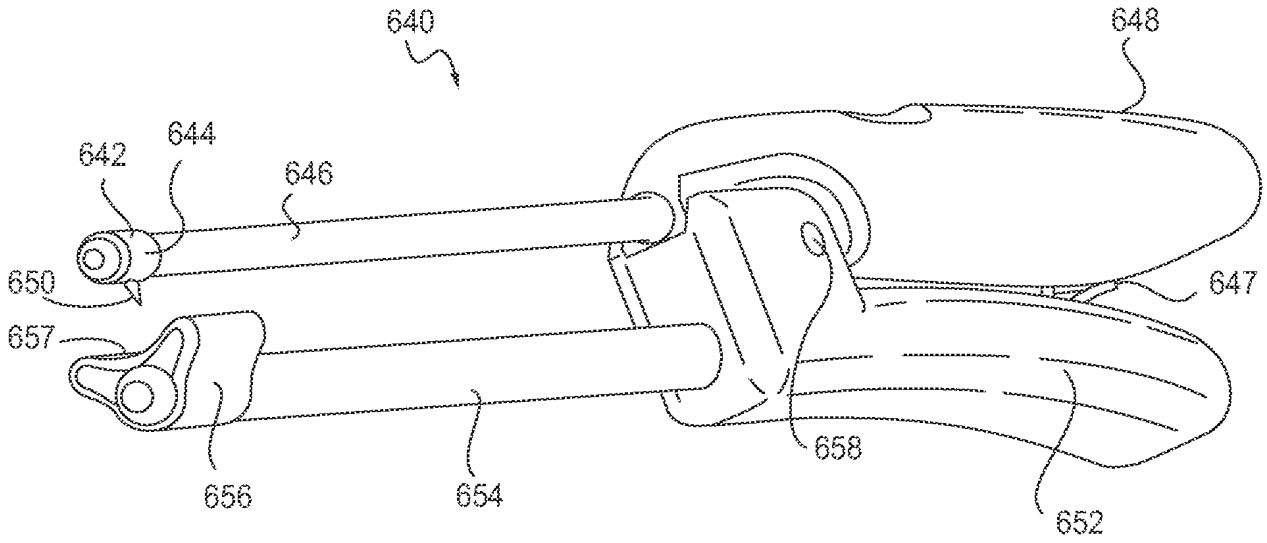


FIG. 27

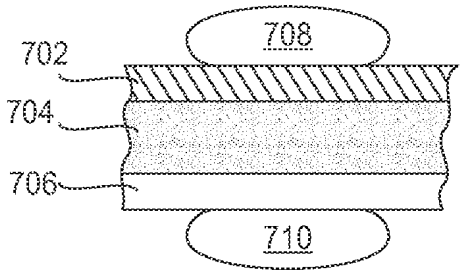


FIG. 28A

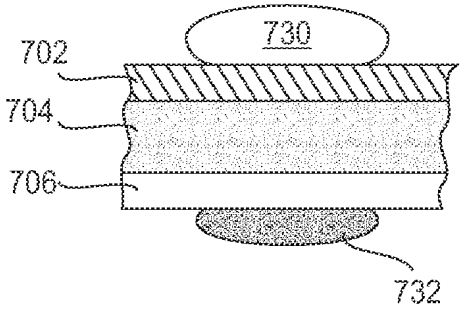


FIG. 28B

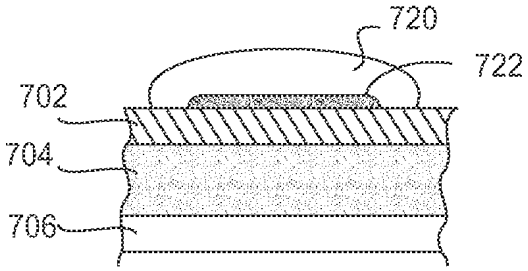


FIG. 28C

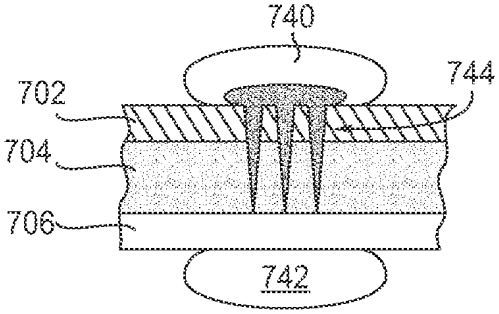


FIG. 28D

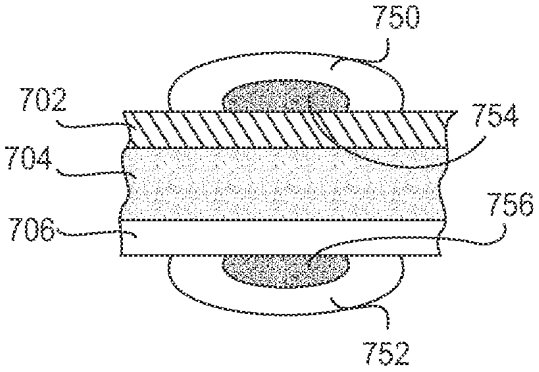


FIG. 28E

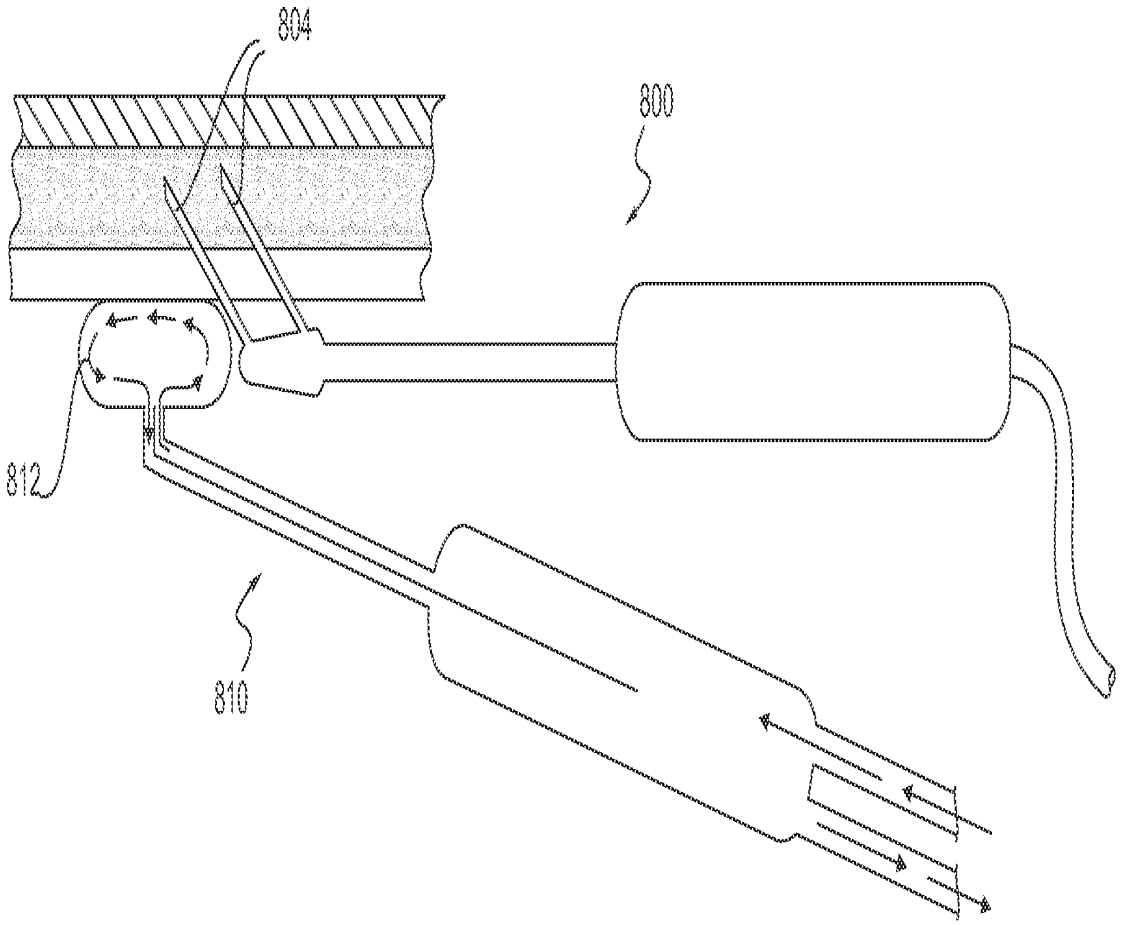


FIG. 29

Replacement Sheet
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FIG. 30A

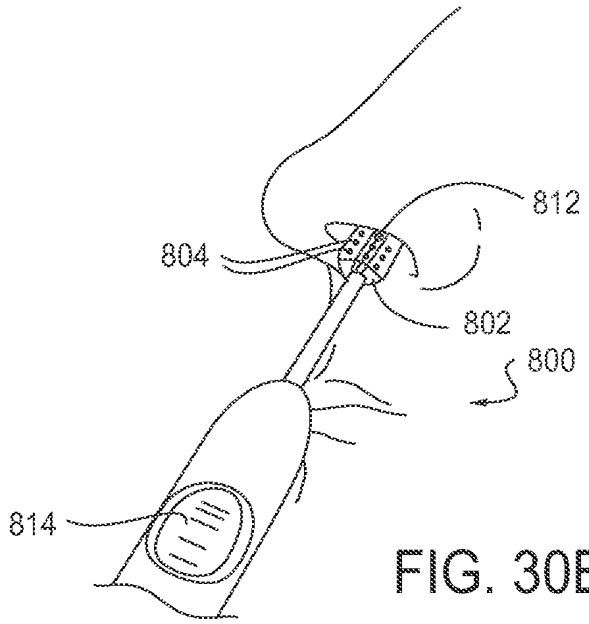


FIG. 30B

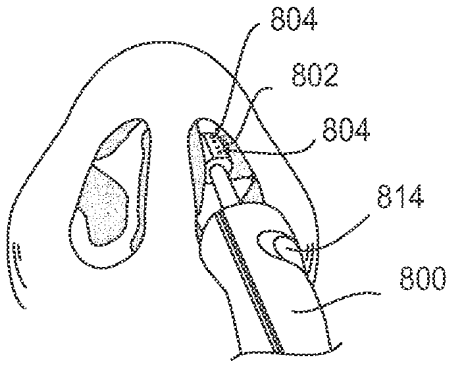


FIG. 30C

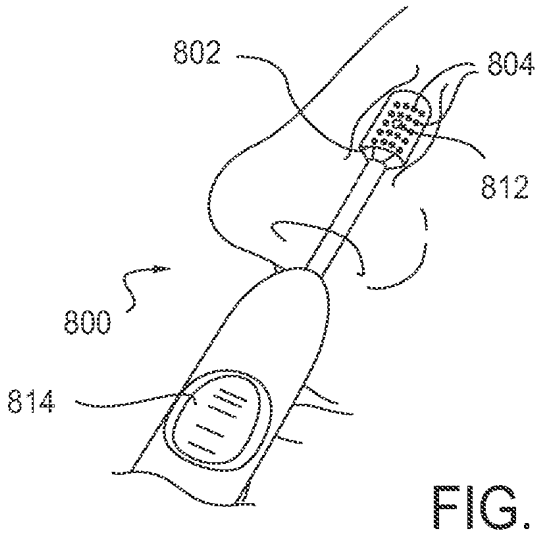


FIG. 30D

Replacement Sheet

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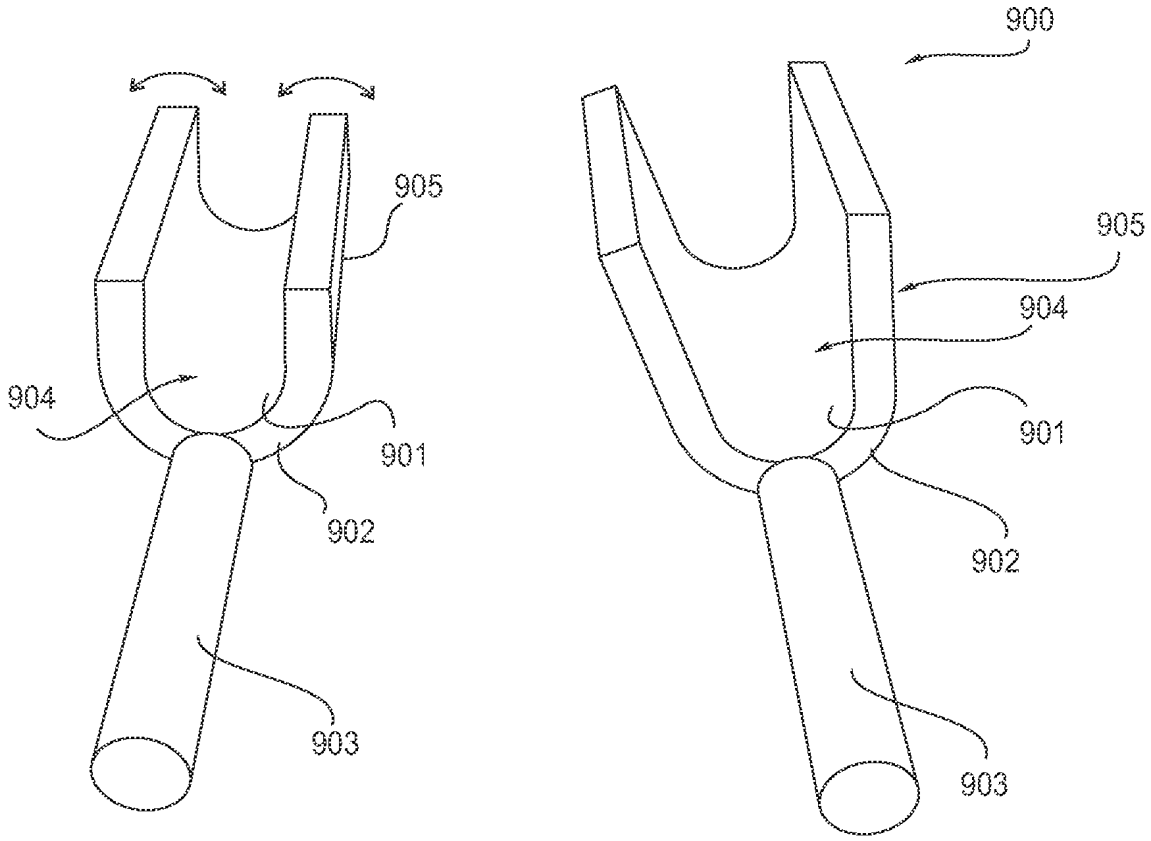


FIG. 31

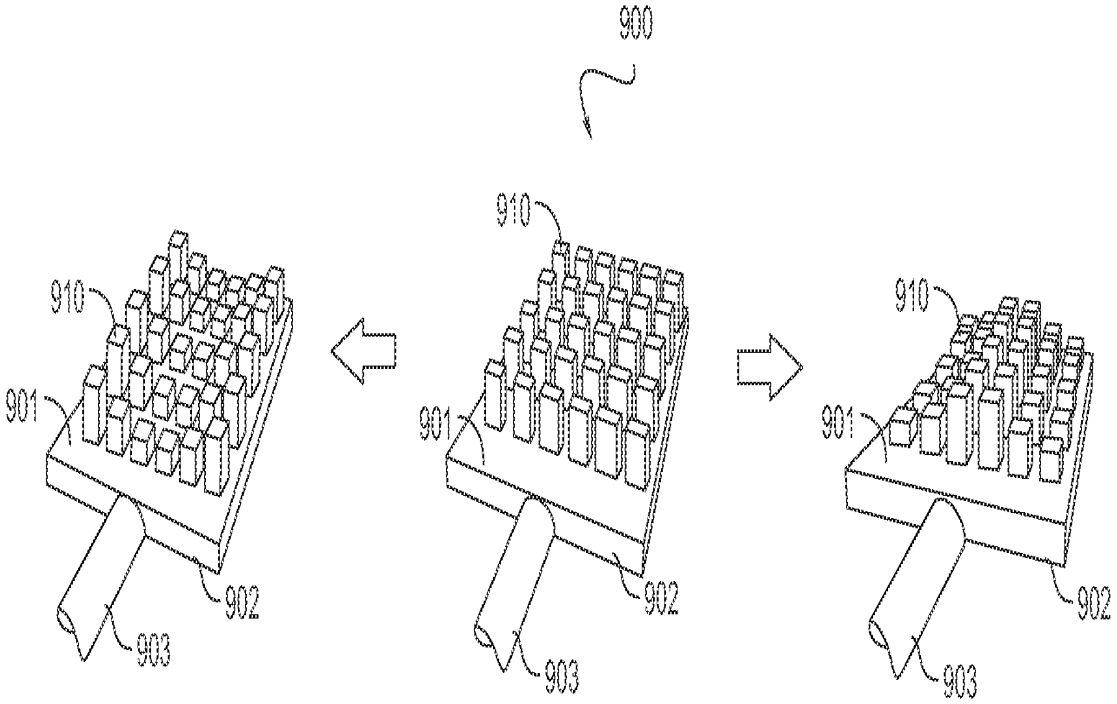


FIG. 32A

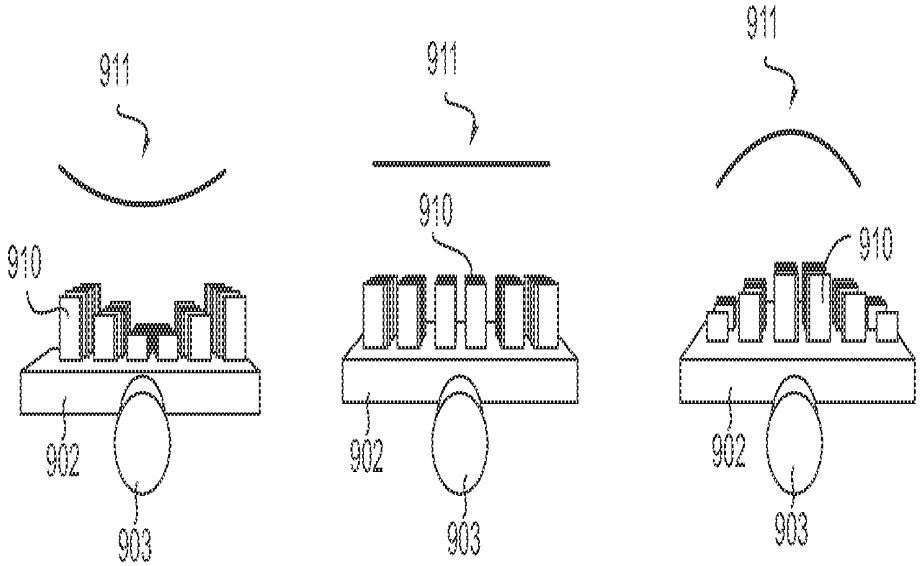


FIG. 32B

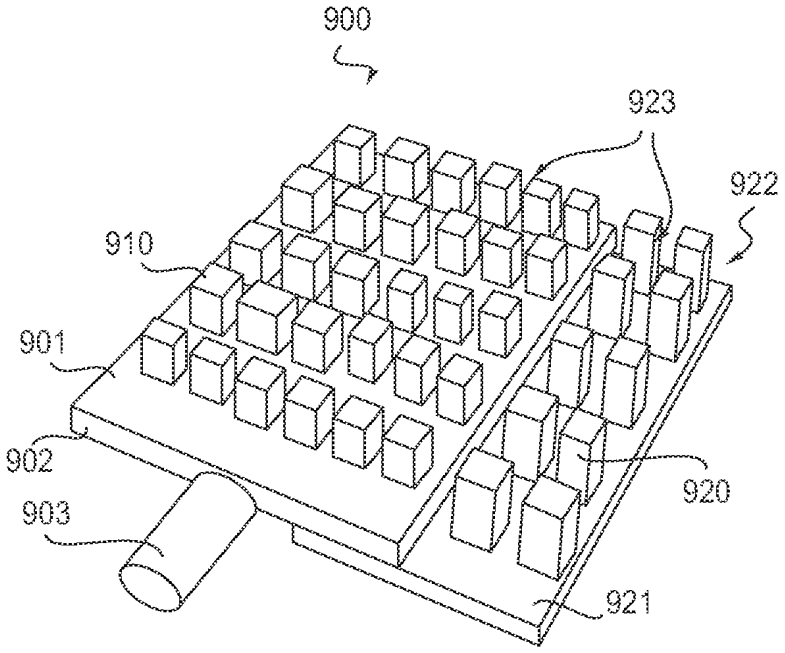


FIG. 33

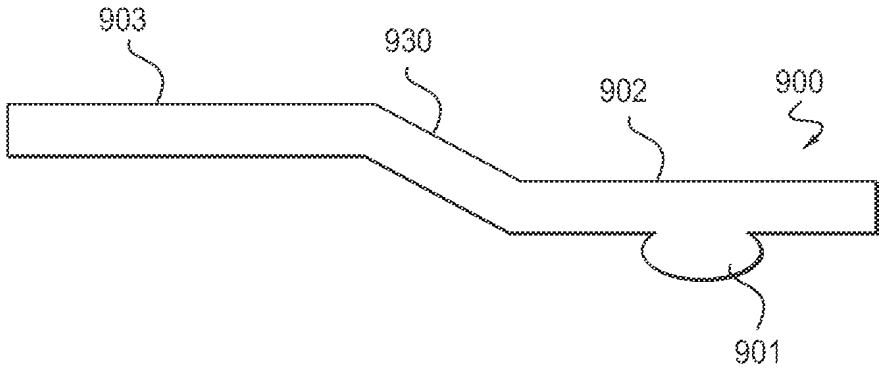


FIG. 34

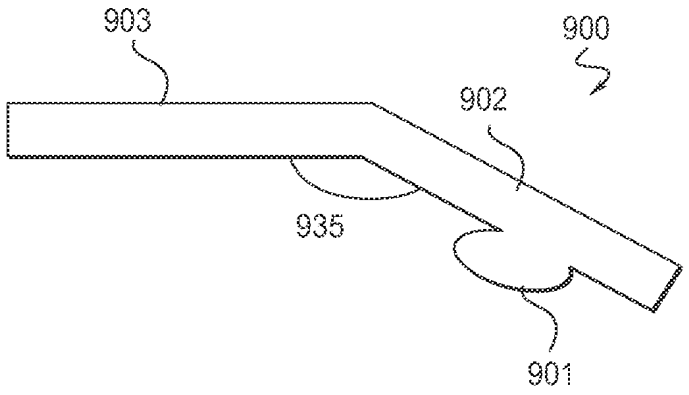


FIG. 35

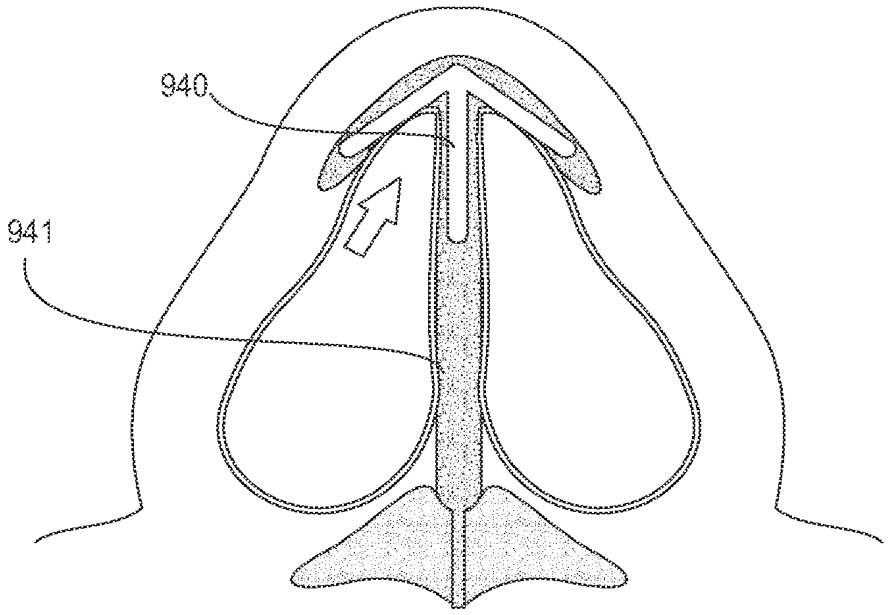


FIG. 36

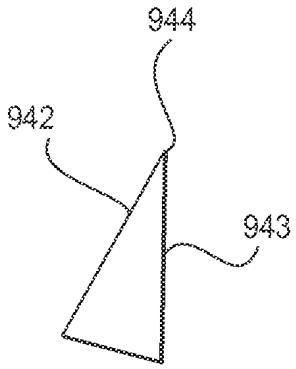


FIG. 37

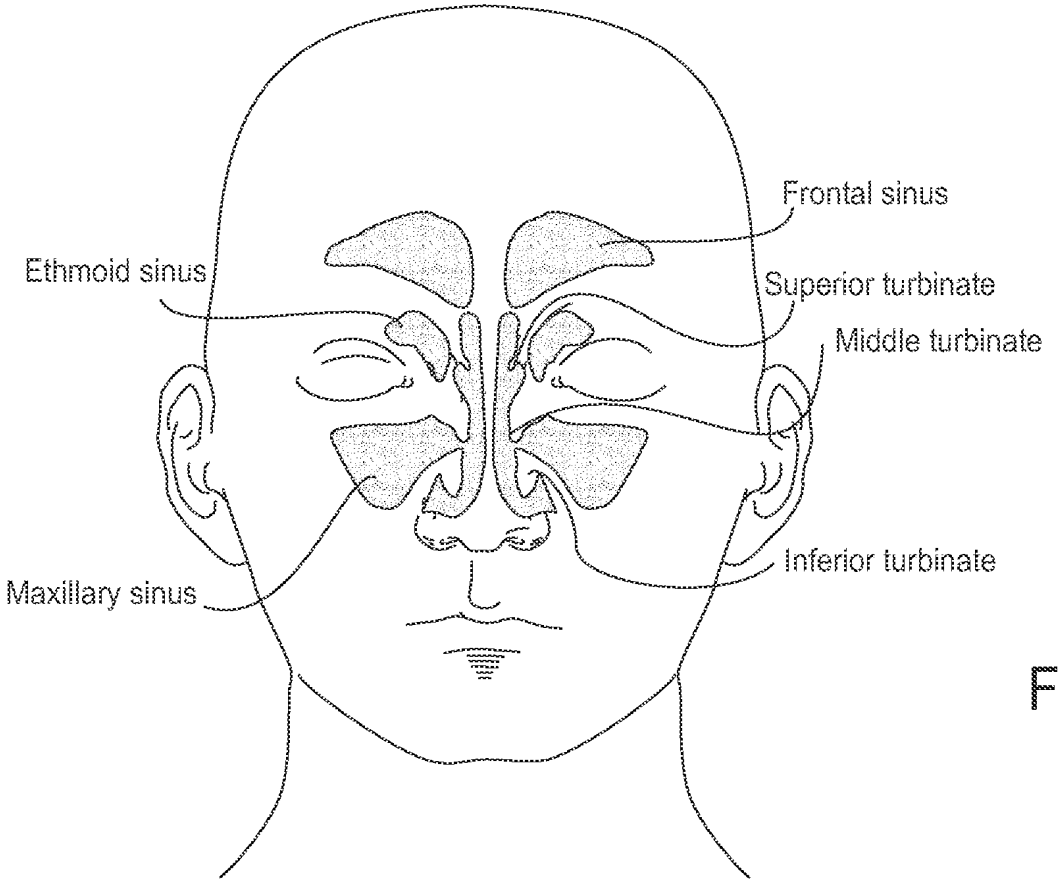


FIG. 38A

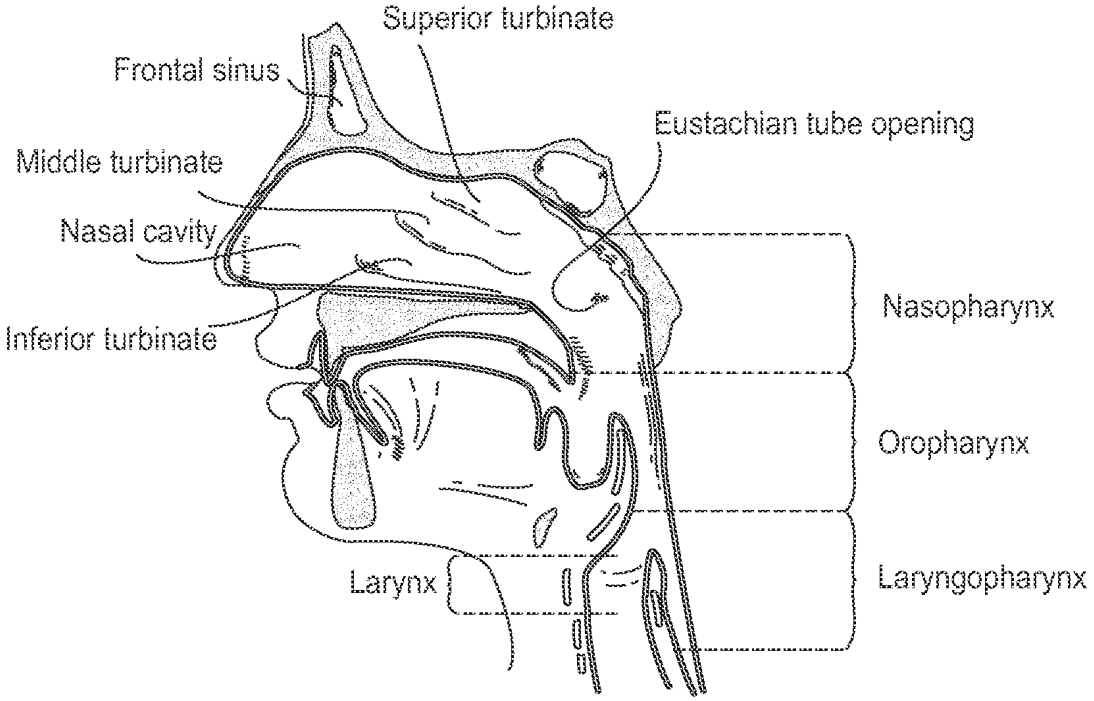


FIG. 38B

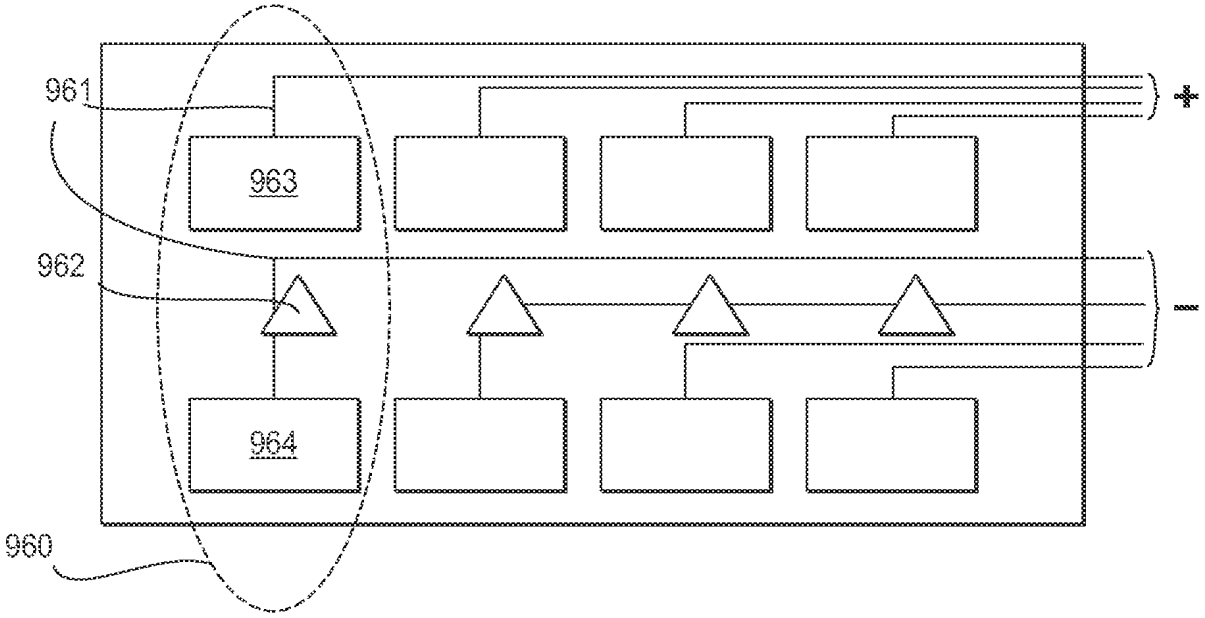


FIG. 39

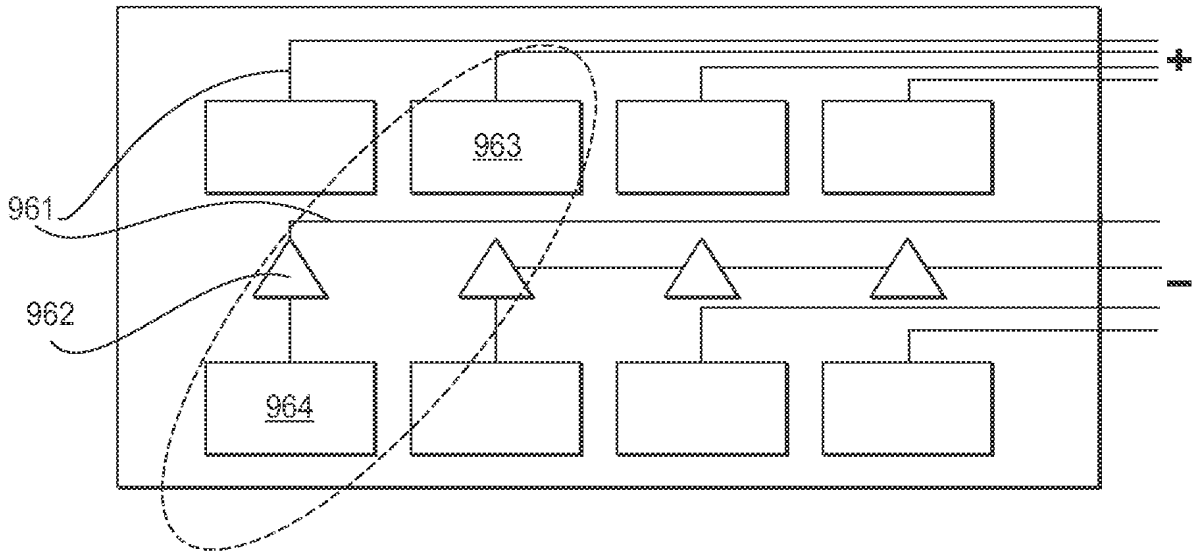


FIG. 40

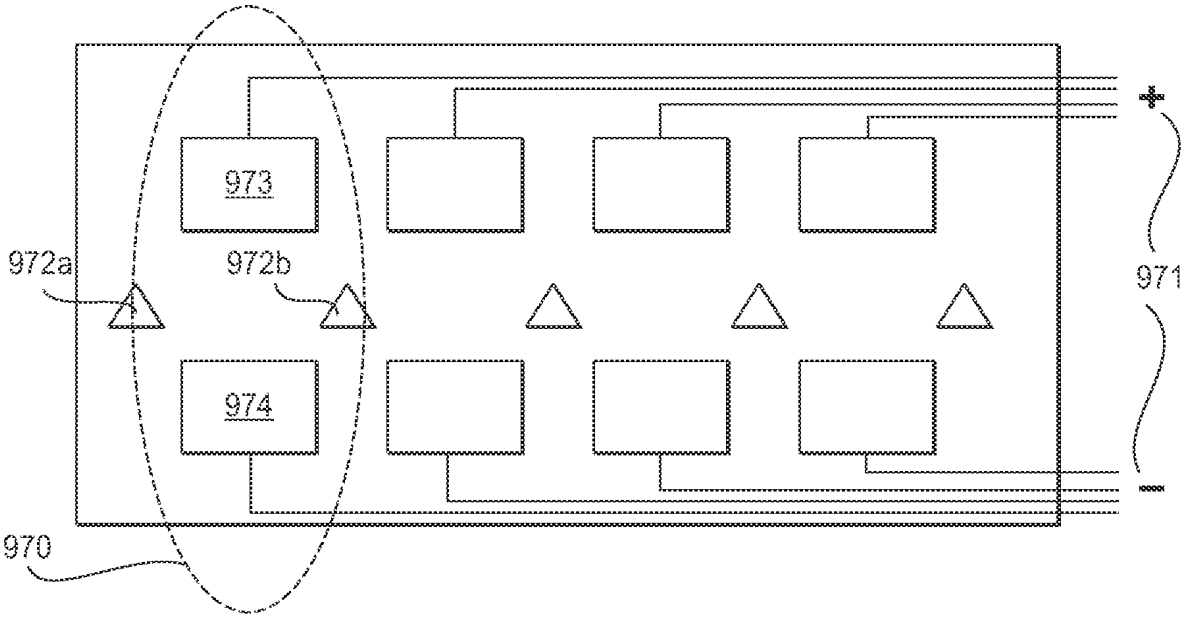


FIG. 41

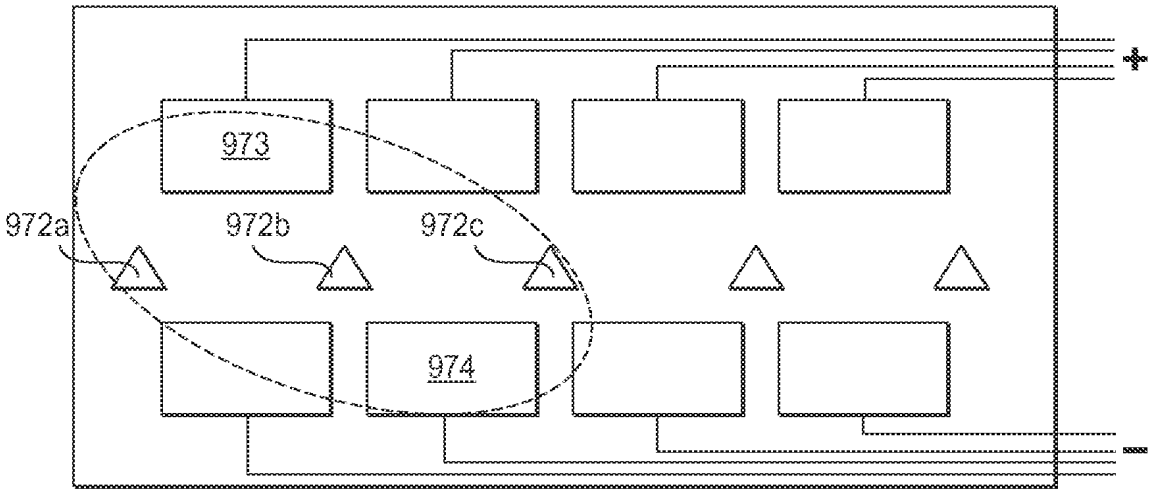


FIG. 42A

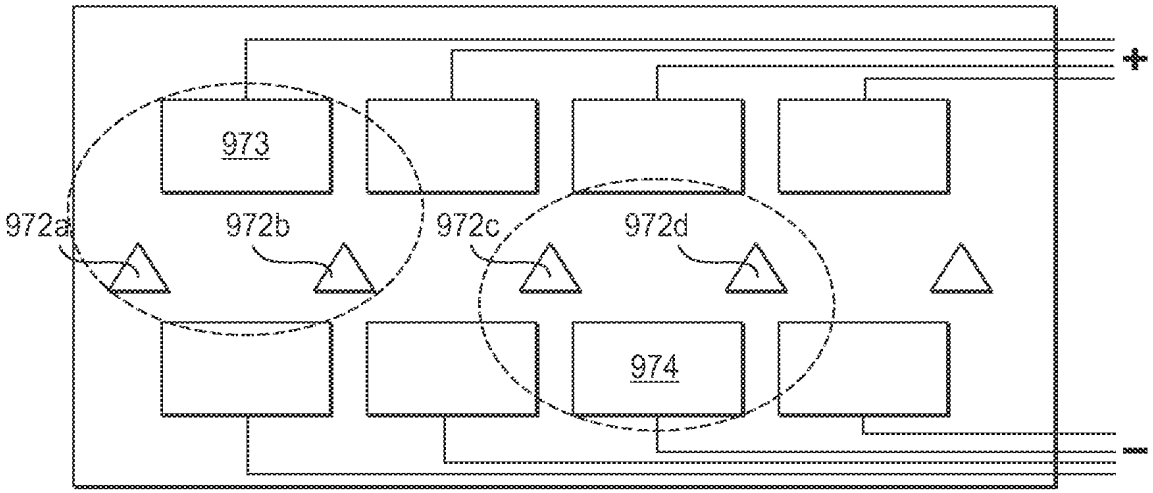


FIG. 42B

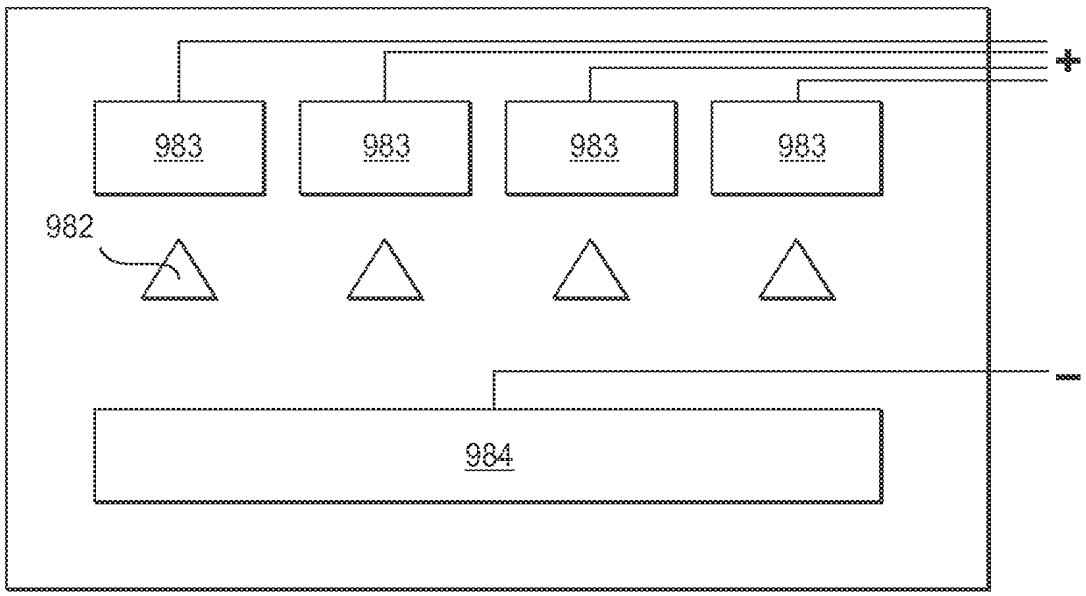


FIG. 43

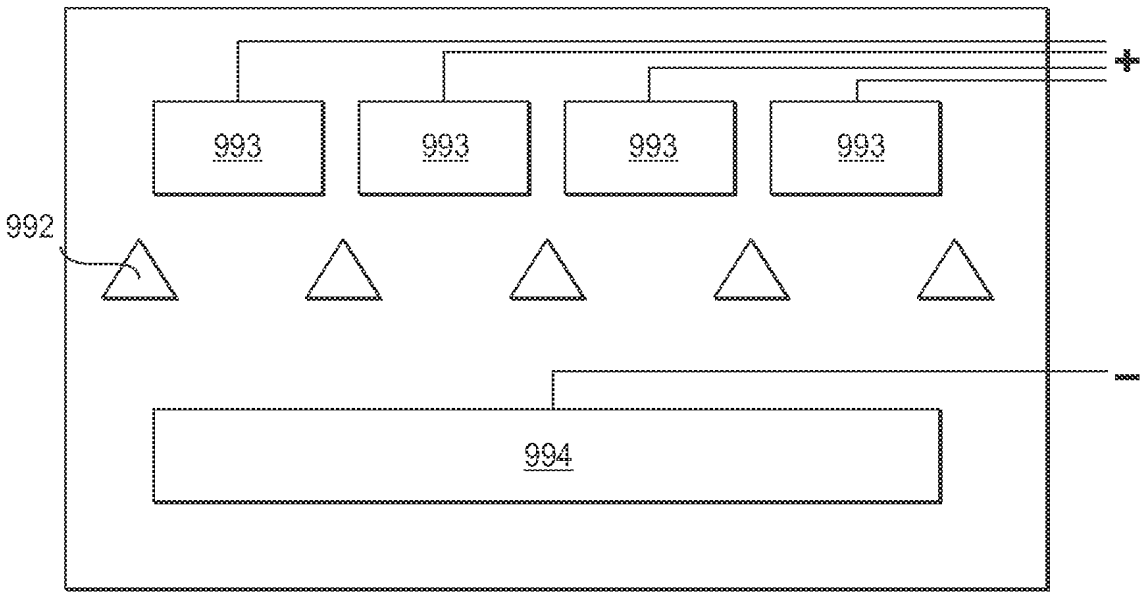


FIG. 44

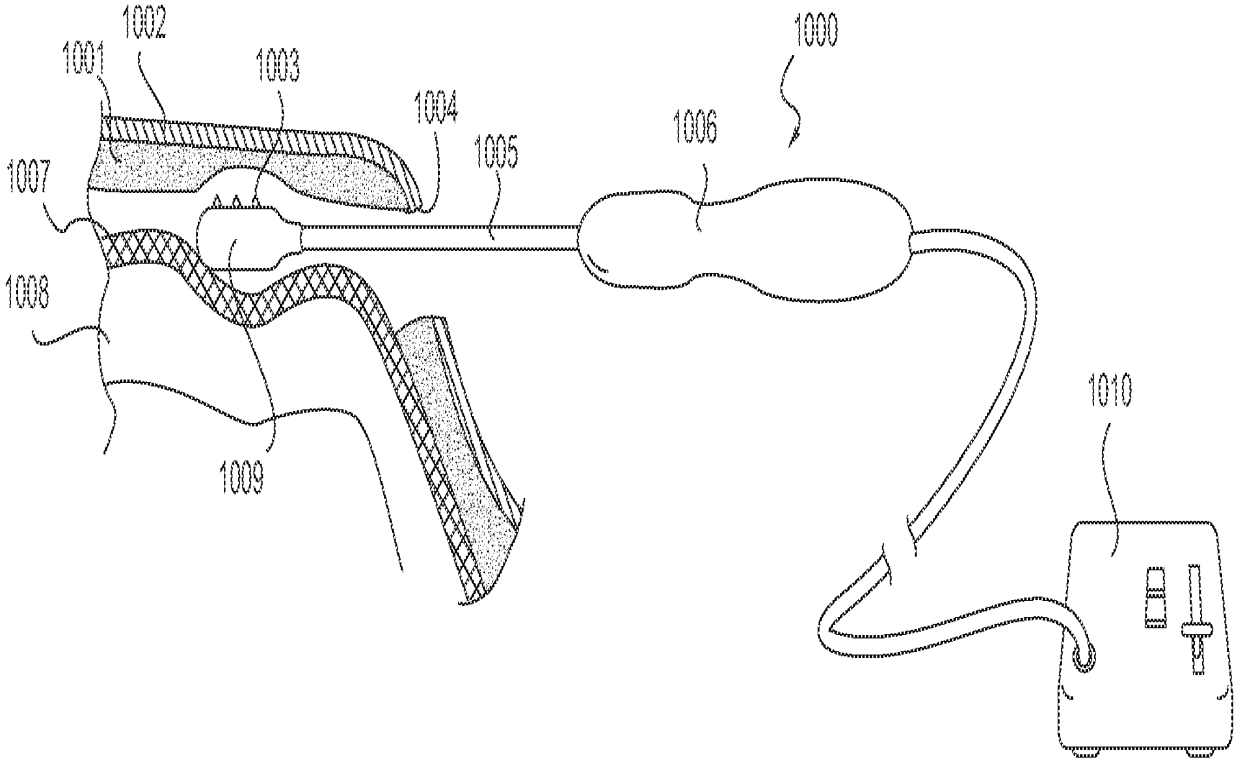


FIG. 45

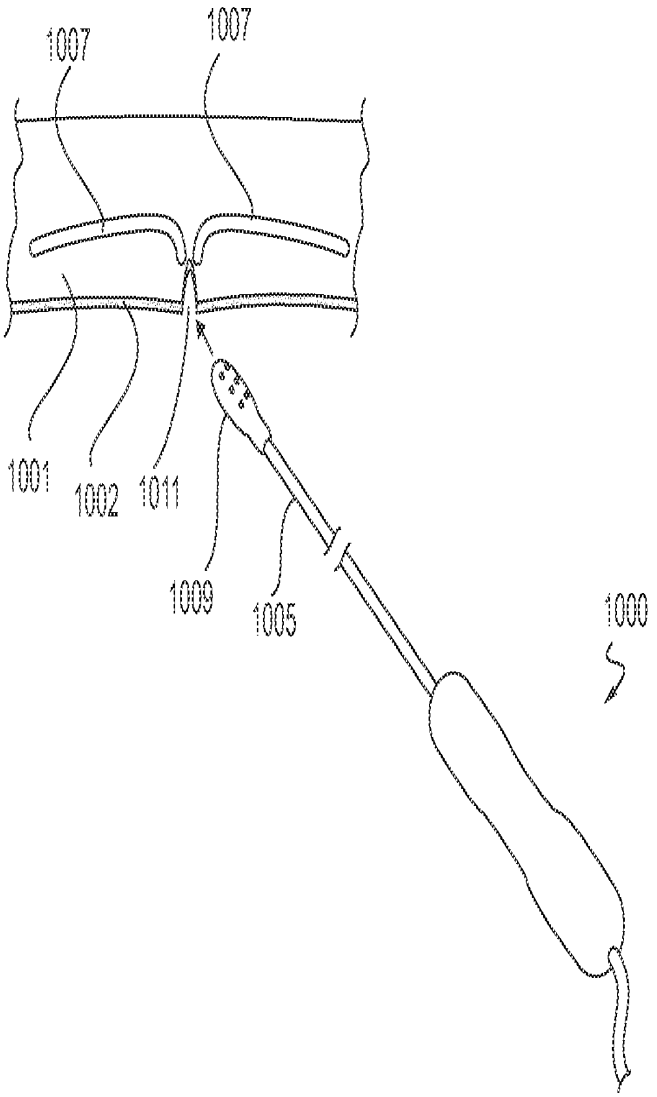


FIG. 46A

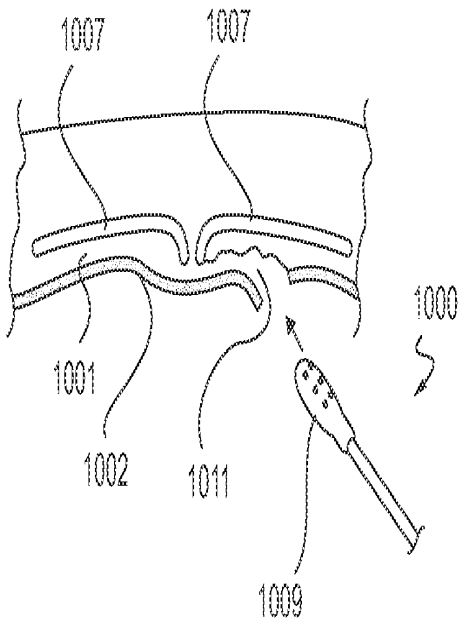


FIG. 46B

Replacement Sheet
60/61

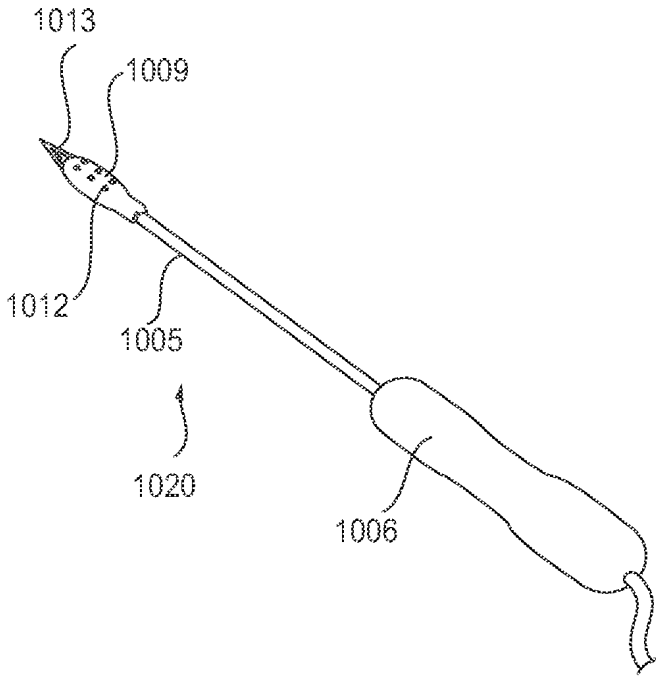


FIG. 47



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/319,087	06/30/2014	Scott J. WOLF	P244992US01 (494912-9)	7653

75149 7590 04/27/2015

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

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
04/27/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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docketingdept-sf@dorsey.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 14319087
Applicant : Wolf
Filing Date : 06/30/2014
Date Mailed : 04/27/2015

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

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(571) 272-4200

Application No. 14319087 **Drawings filed: 06/30/2014**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 13D-E, 14A, 15C 17B & 19A
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

Electronic Acknowledgement Receipt

EFS ID:	22581983
Application Number:	14319087
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:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244992US01 (494912-9)
Receipt Date:	09-JUN-2015
Filing Date:	30-JUN-2014
Time Stamp:	18:25:57
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	Post Allowance Communication - Incoming	P244992US01_Response_4-27-15_Notice.pdf	124272 b8c2dbaaf607f87b434624c75b1f9f9075b7be84	no	1

Warnings:	
Information:	

2	Drawings-only black and white line drawings	P22992US01_Replacement_Drawings_Formalized.pdf	1206378 cc4e0fb7a711ddb60477048e32ee3c0ff8bd65ec	no	61

Warnings:

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Information:

3	Post Allowance Communication - Incoming	P22992US01_Notice_to_Corrected_Application_Papers_Drawings.pdf	117269 ec1418f992913f18000addb4ec22d4c48035a680	no	3

Warnings:

Information:

Total Files Size (in bytes):	1447919

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/319,087	06/30/2014	Scott J. WOLF	P244992US01 (494912-9)	7653

75149 7590 04/27/2015

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

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
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docketingdept-sf@dorsey.com

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Application No. : 14319087
Applicant : Wolf
Filing Date : 06/30/2014
Date Mailed : 04/27/2015

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See attachment(s).

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Application No. 14319087 **Drawings filed: 06/30/2014**

IDENTIFICATION OF DRAWING DEFICIENCIES

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- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
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- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

P244992US01
(494912-9)

CERTIFICATE OF FILING

I hereby certify that on the date specified below this correspondence is being transmitted electronically via the Office electronic filing system, EFS-Web, on the United States Patent Office Web site, addressed to Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 9, 2015
/laura lee mosier/
Laura Lee Mosier

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Scott J. WOLF, *et al.*	
Application No. 14/319,087	
Filed: June 30, 2014	
For: METHODS AND DEVICES TO TREAT NASAL AIRWAYS	
Date of Allowance:	April 2, 2015
Examiner:	George C. MANUEL
Art Unit:	3762
Class-Sub-Class:	606-041000
Confirmation No.	7653
Date:	June 9, 2015

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Notice to File Corrected Application Papers dated April 27, 2015, transmitted herewith are:

[X] Replacement Drawings Sheets, Sheets 1-61. The deficiencies in Figures 13D, 13E, 14A, 15C, 17B and 19A have been corrected as request by the Notice. These figures are clarifications of the originally submitted figures. All refinements, clarifications, and corrections of the drawings are consistent with the original submission, and no new matter is added.

The Commissioner is hereby authorized to charge any deficiency in the payment of the required fee(s) or credit any overpayment to Deposit Account No. 50-2319 (Account No. P244992US01 (494912-9)).

Respectfully submitted,

DORSEY & WHITNEY LLP

/Scott M. Smith, Reg. No. 48,268/
Scott M. Smith,
Reg. No. 48,268

Customer No. 75149
Columbia Center
701 Fifth Avenue, Suite 6100
Seattle, WA 98101-7043
Telephone: (650) 857-1717
Facsimile: (650) 857-1288

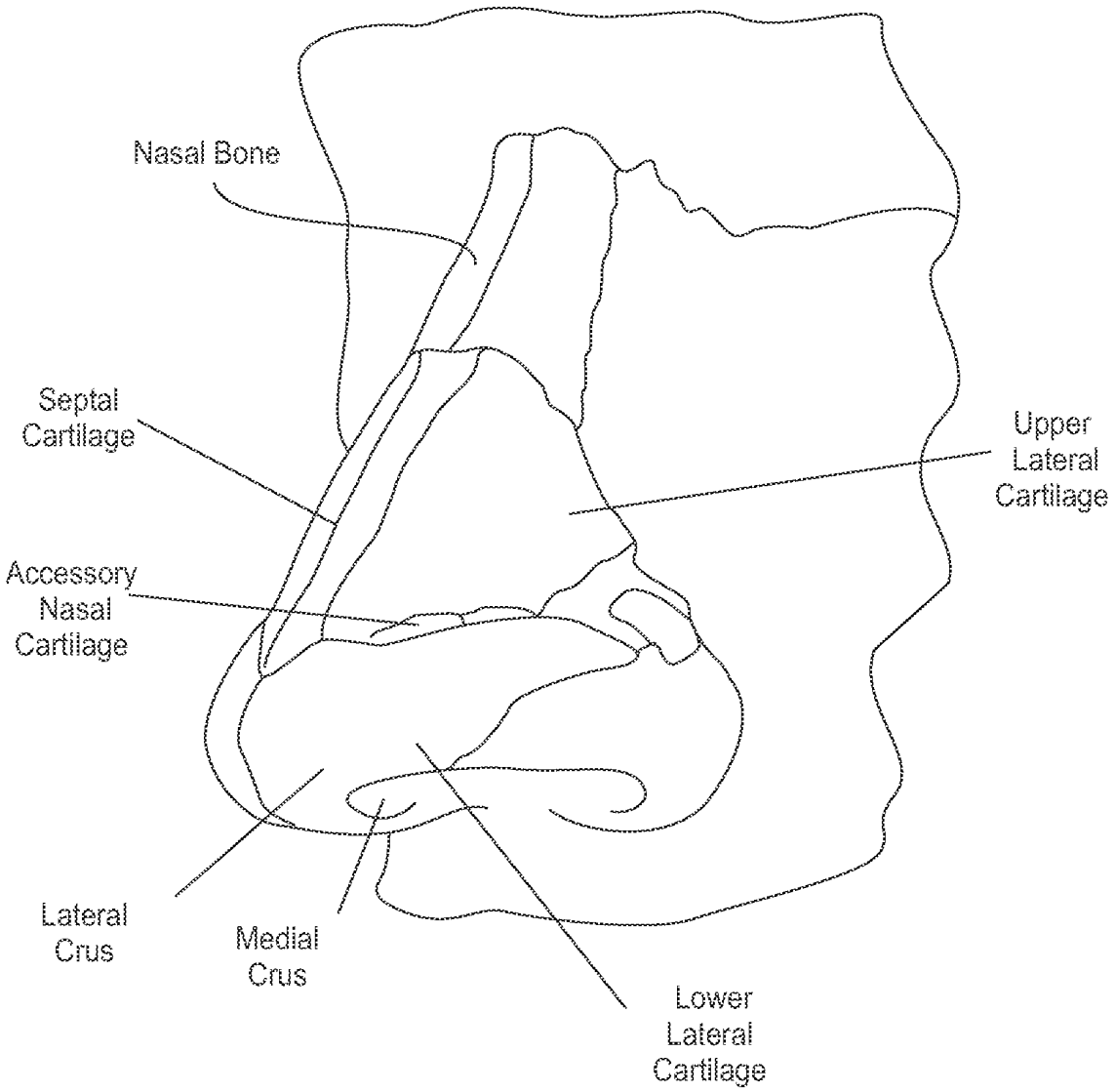

Nasal Bone
Septal Cartilage
Upper Lateral Cartilage
Accessory Nasal Cartilage
Lateral Crus
Medial Crus
Lower Lateral Cartilage

FIG. 1

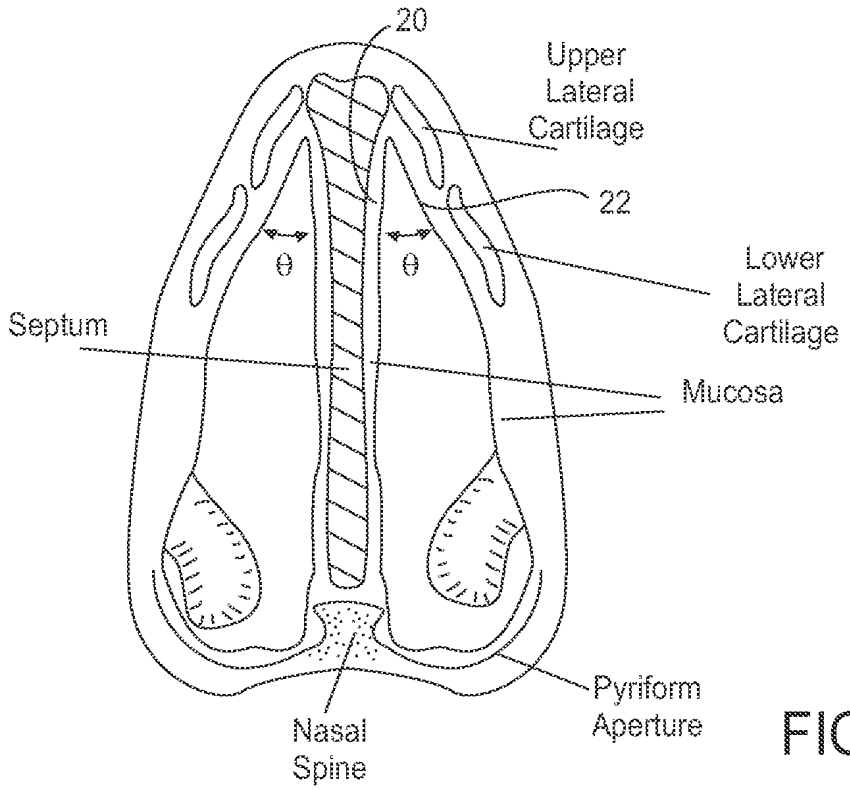

20
Upper
Lateral
Cartilage
22
θ
θ
Lower
Lateral
Cartilage
Septum
Mucosa
Pyriform
Aperture
Nasal
Spine

FIG. 2A

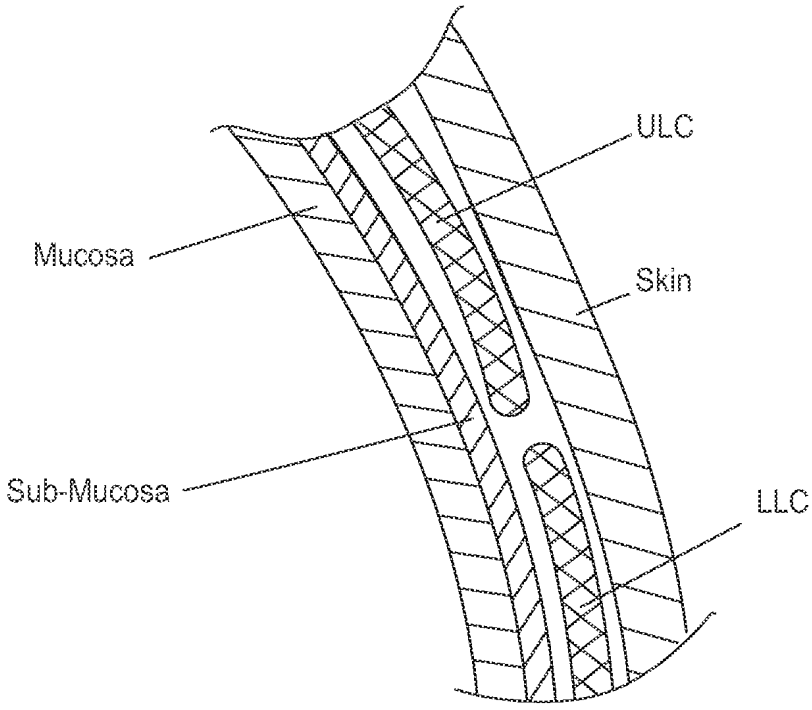

ULC
Mucosa
Skin
Sub-Mucosa
LLC

FIG. 2B

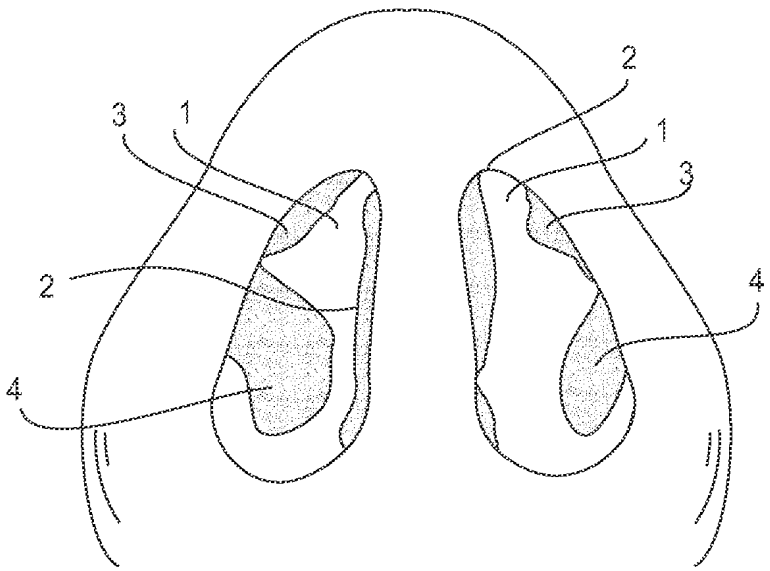


FIG. 2C

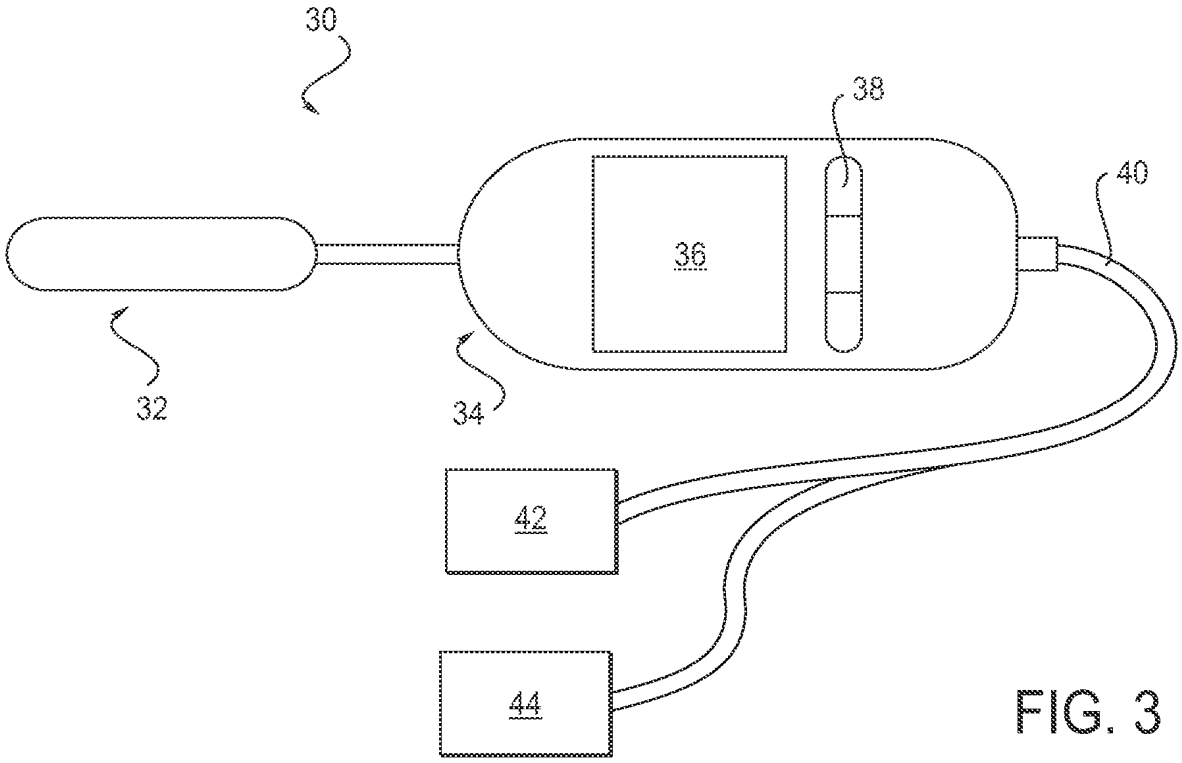


FIG. 3

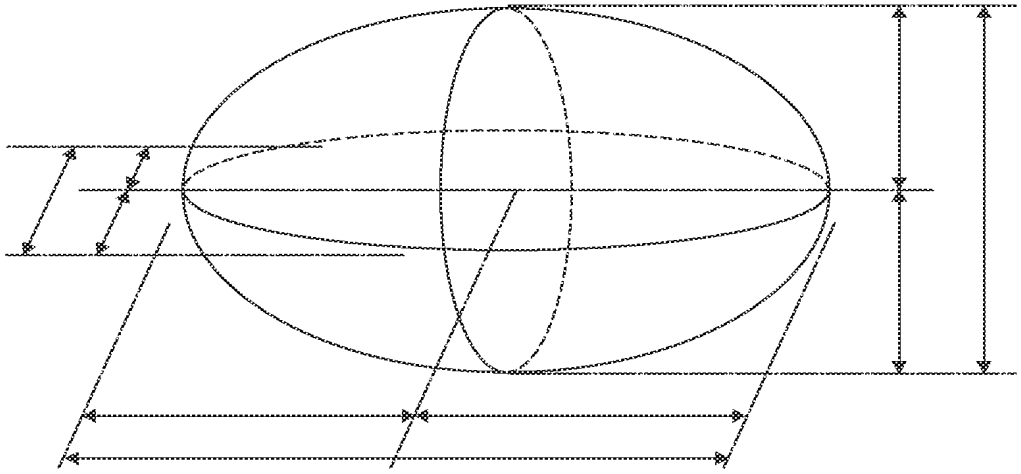


FIG. 4A

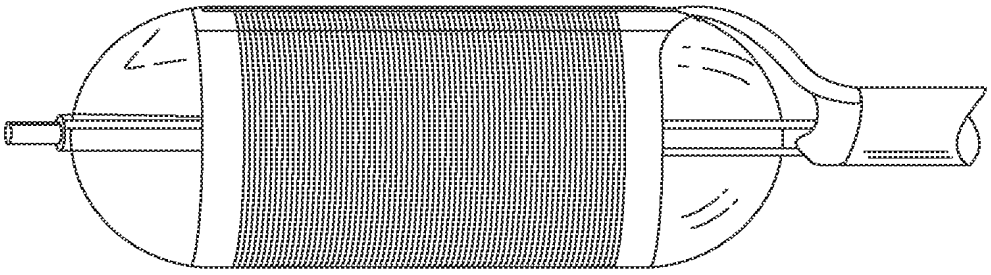


FIG. 4B

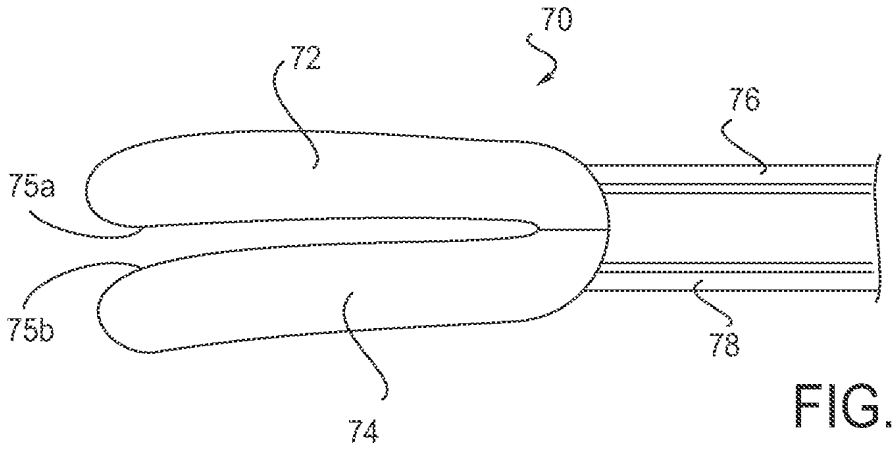


FIG. 4C

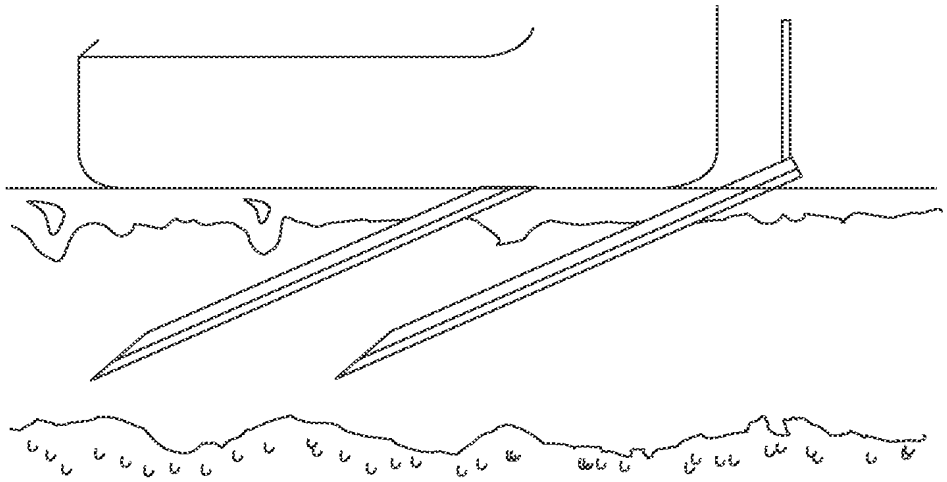


FIG. 4D

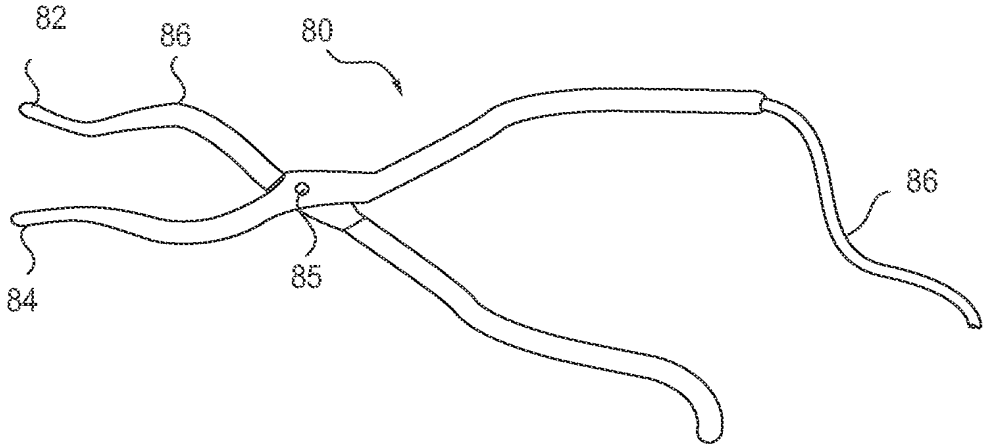


FIG. 5A

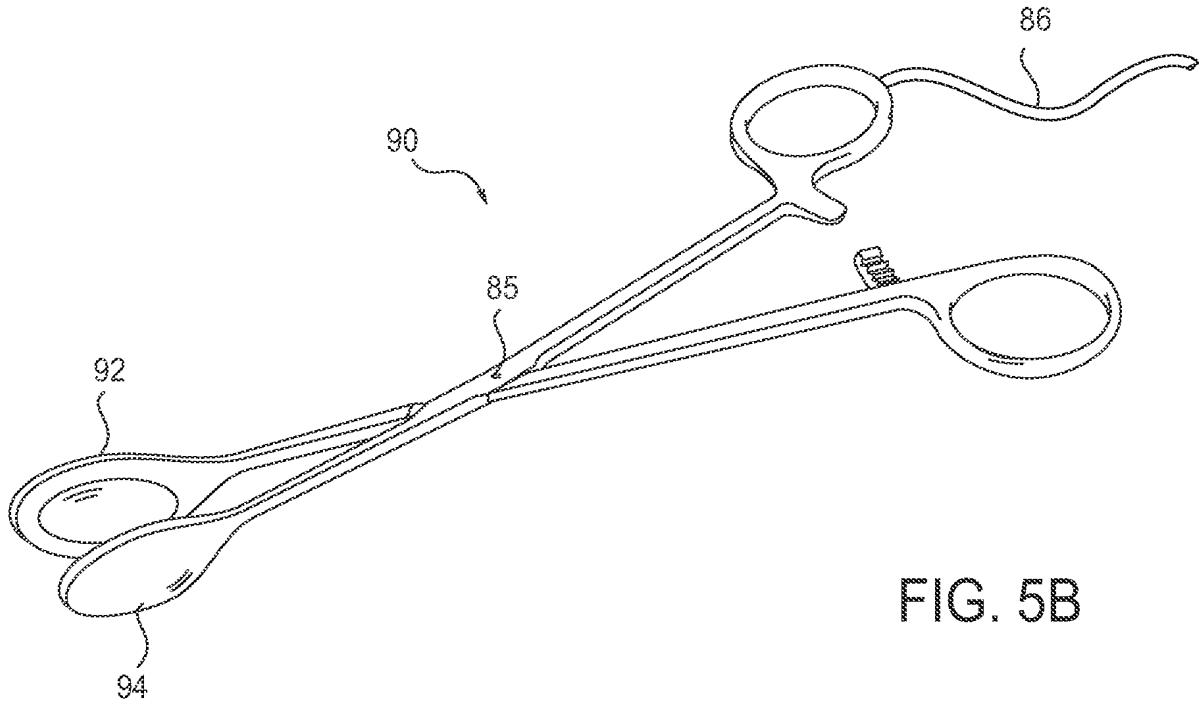


FIG. 5B

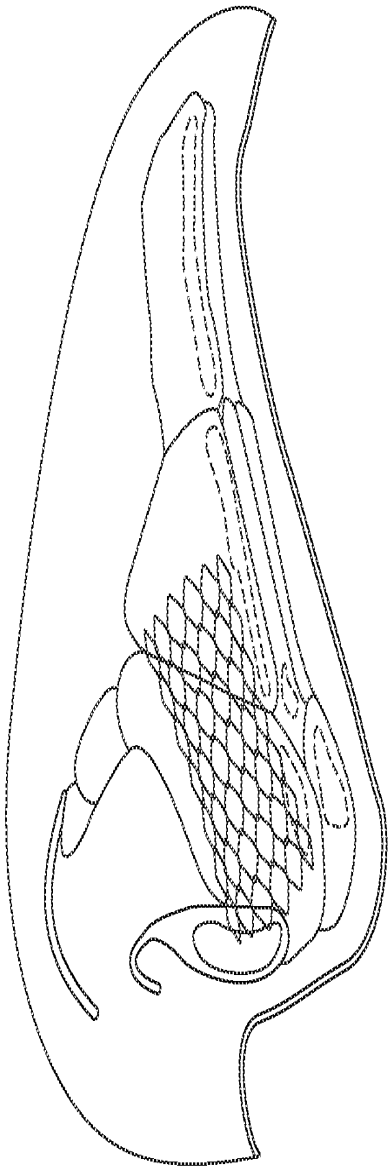


FIG. 6

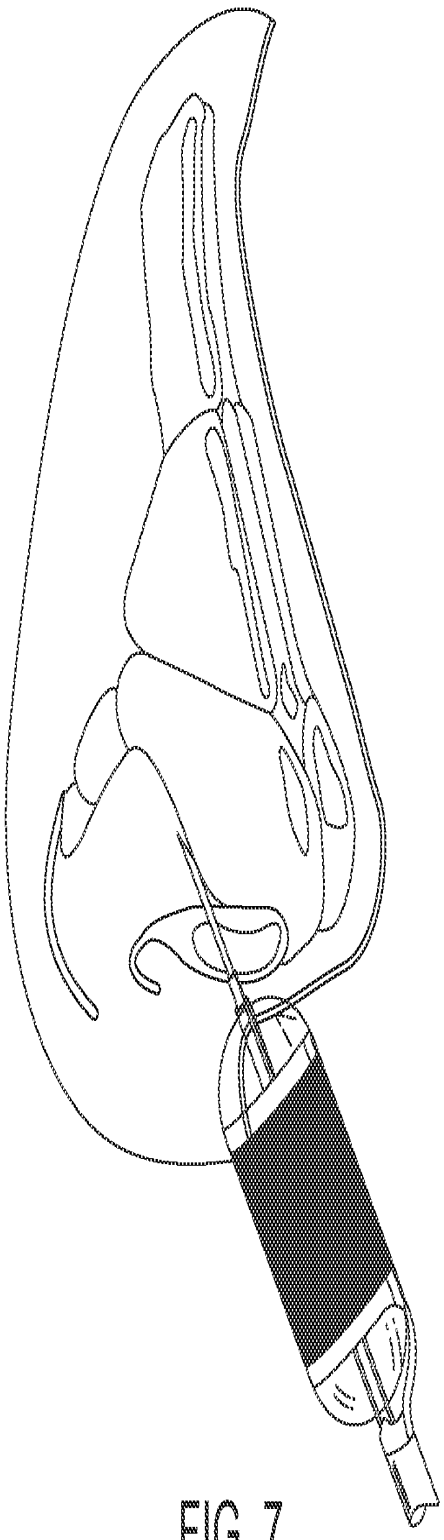


FIG. 7

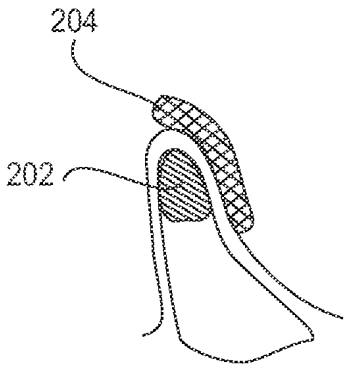


FIG. 8A

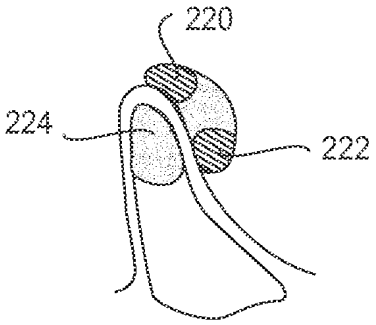


FIG. 8C

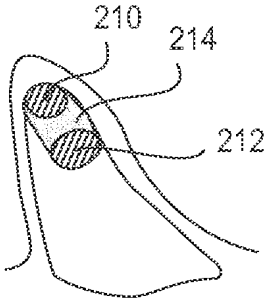


FIG. 8B

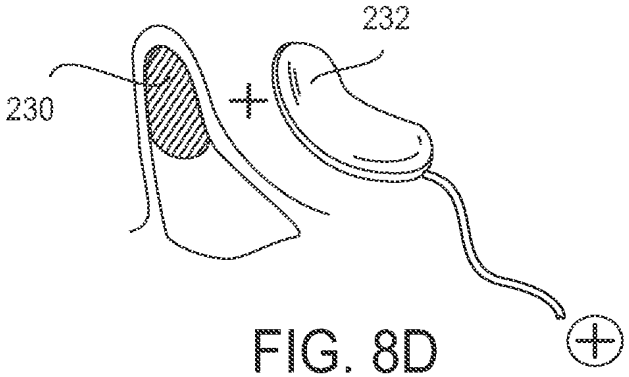


FIG. 8D

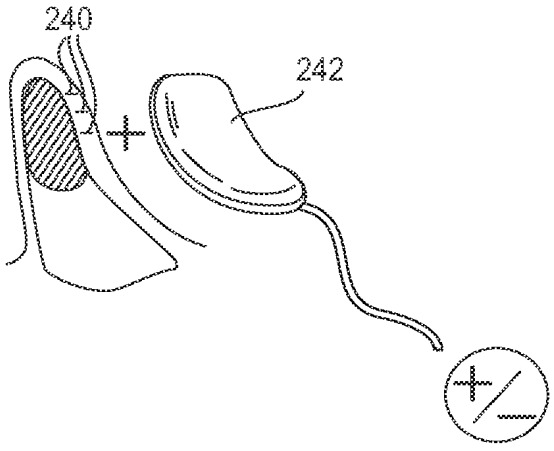


FIG. 8E

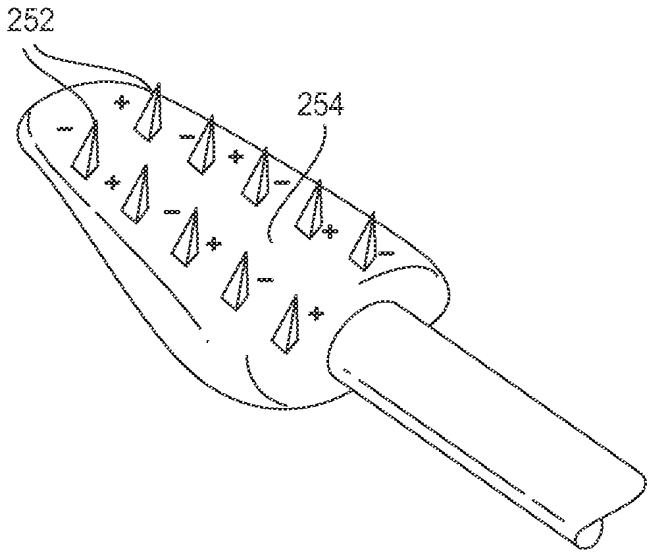


FIG. 8F

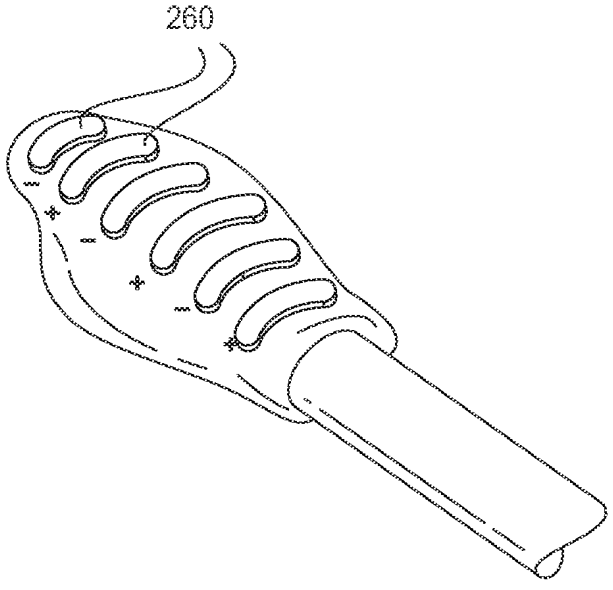


FIG. 8G

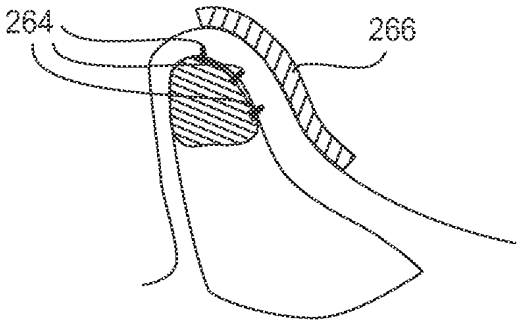


FIG. 8H

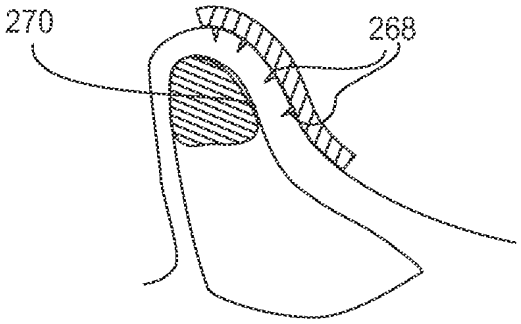


FIG. 8I

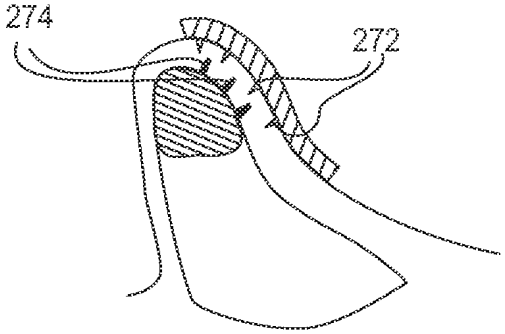


FIG. 8J

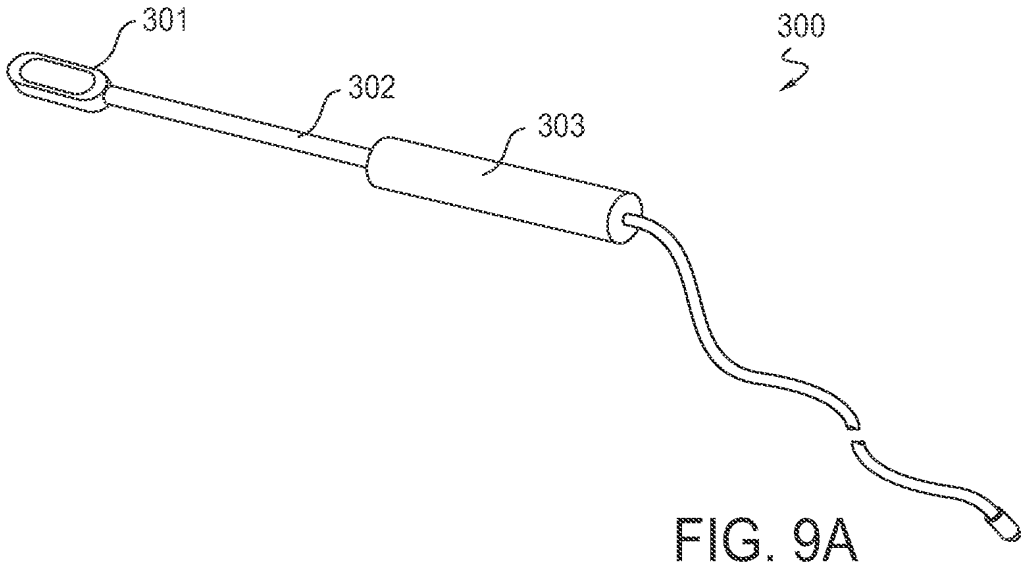


FIG. 9A

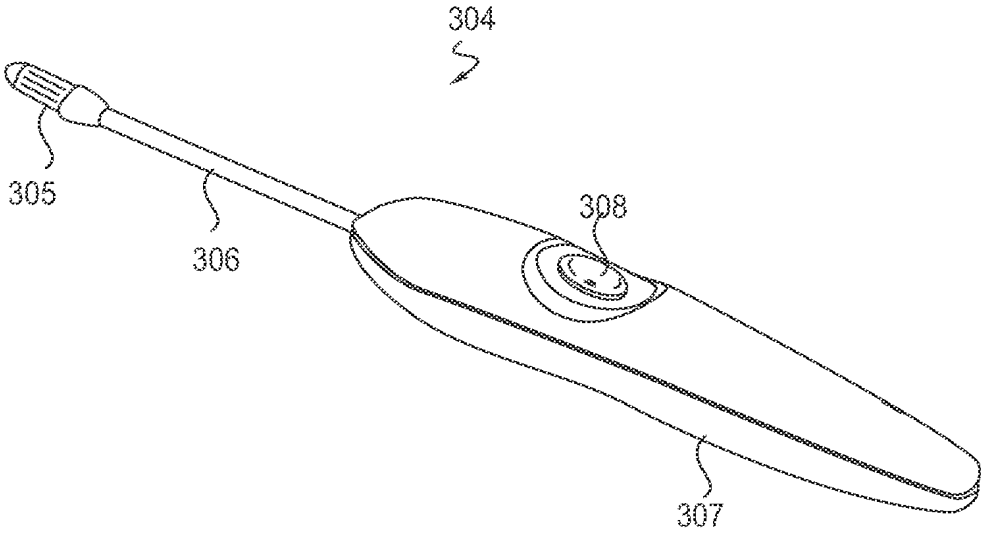


FIG. 9B

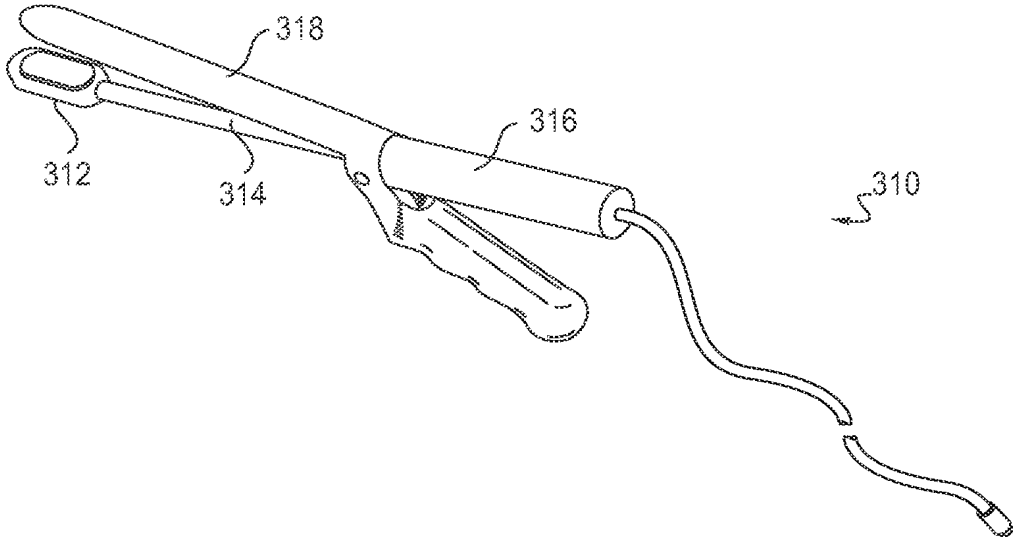


FIG. 10A

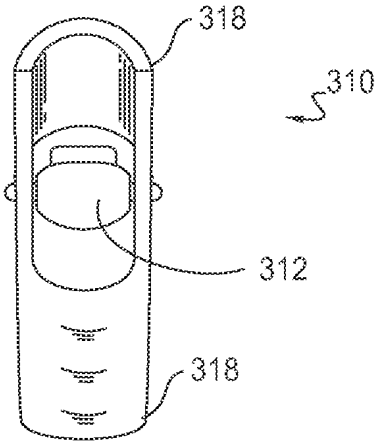


FIG. 10B

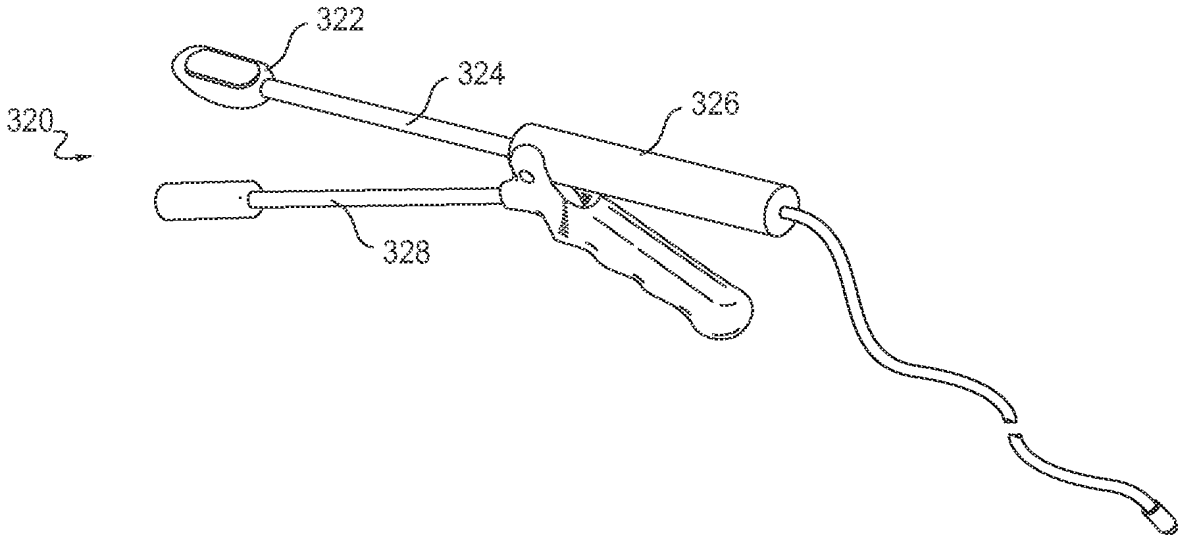


FIG. 11A

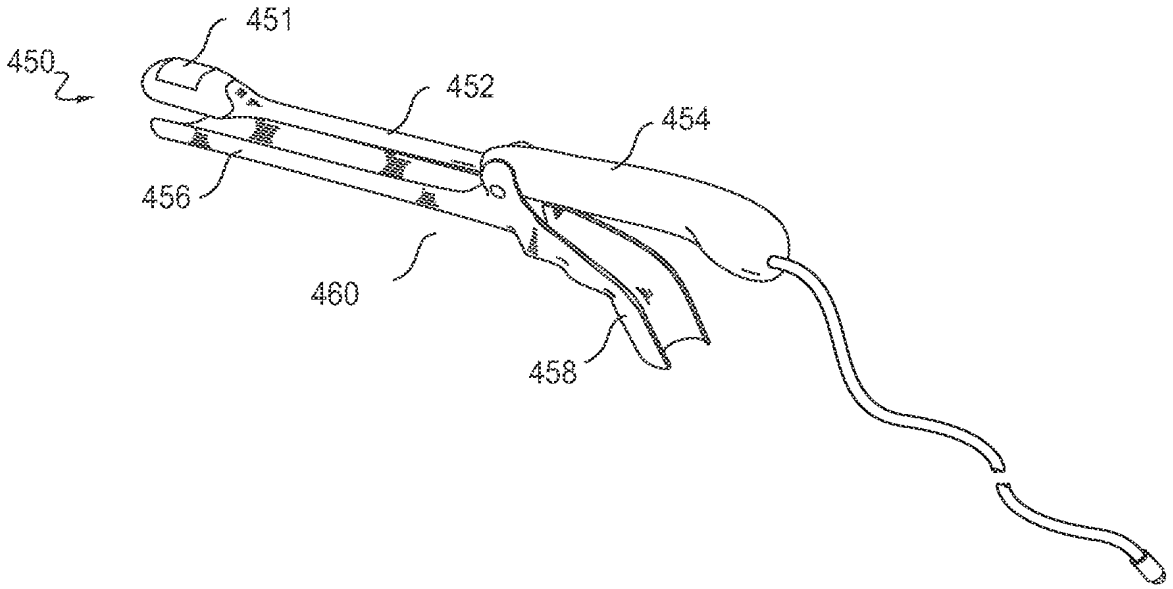


FIG. 11B

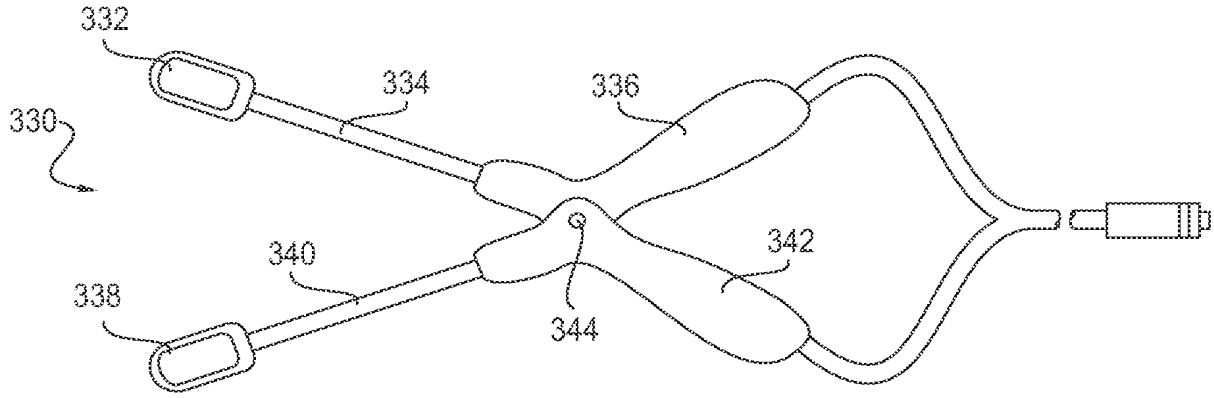


FIG. 12A

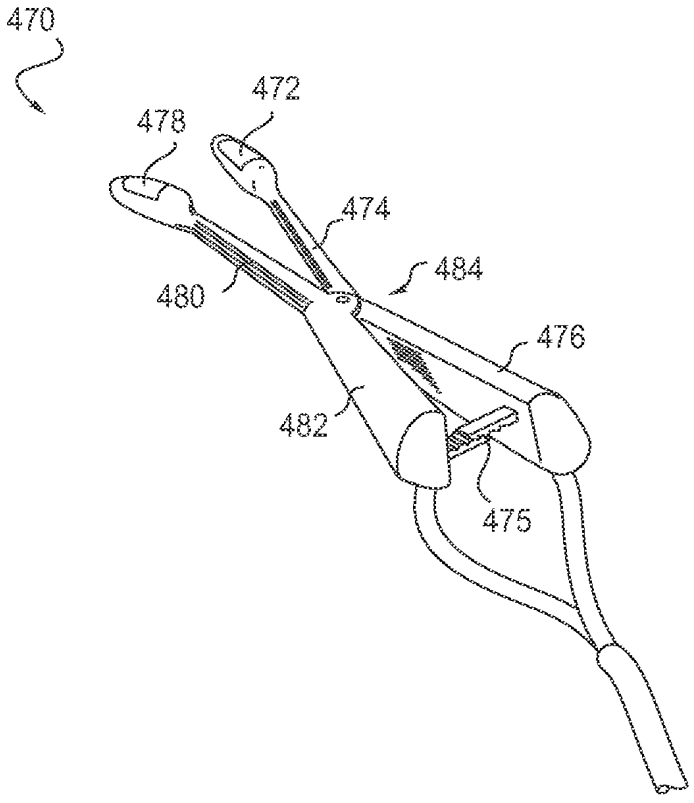


FIG. 12B

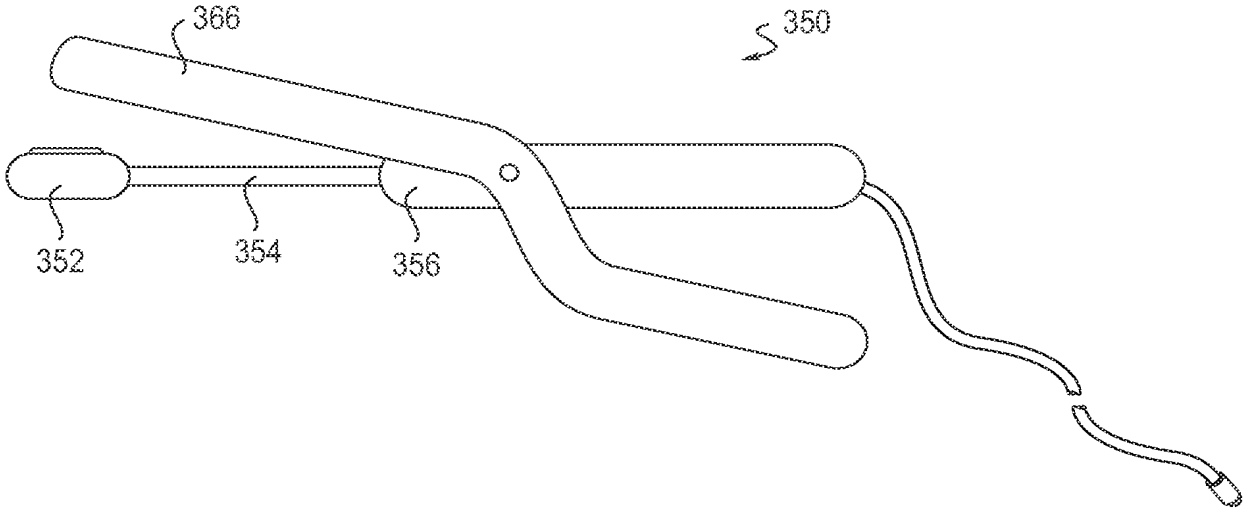


FIG. 13A

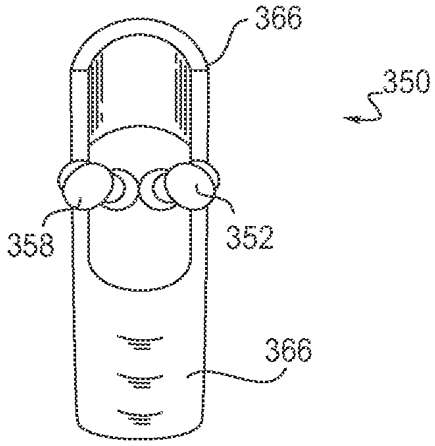


FIG. 13B

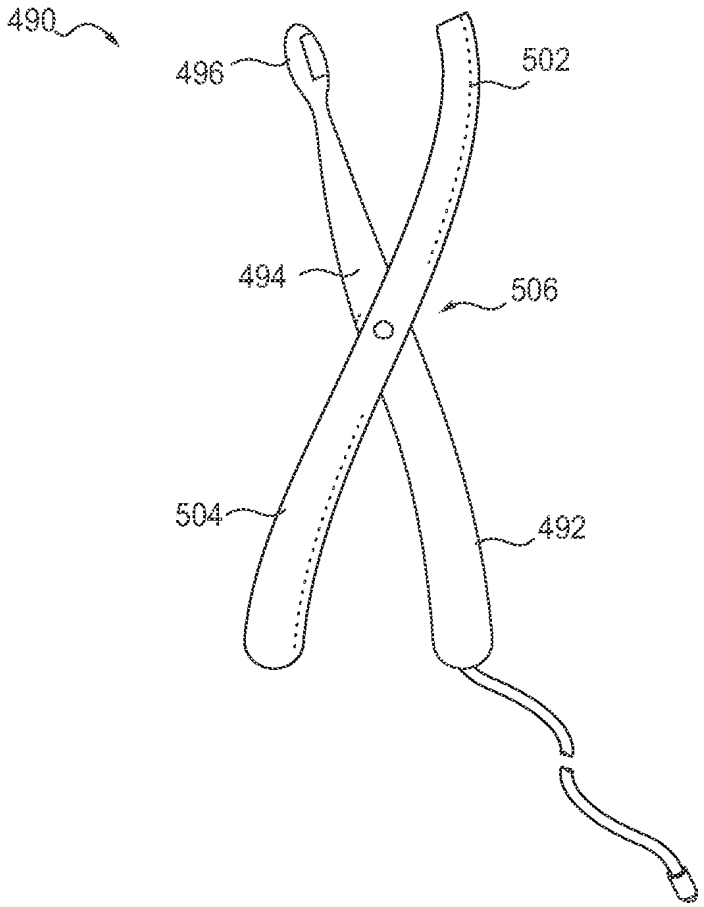


FIG. 13C

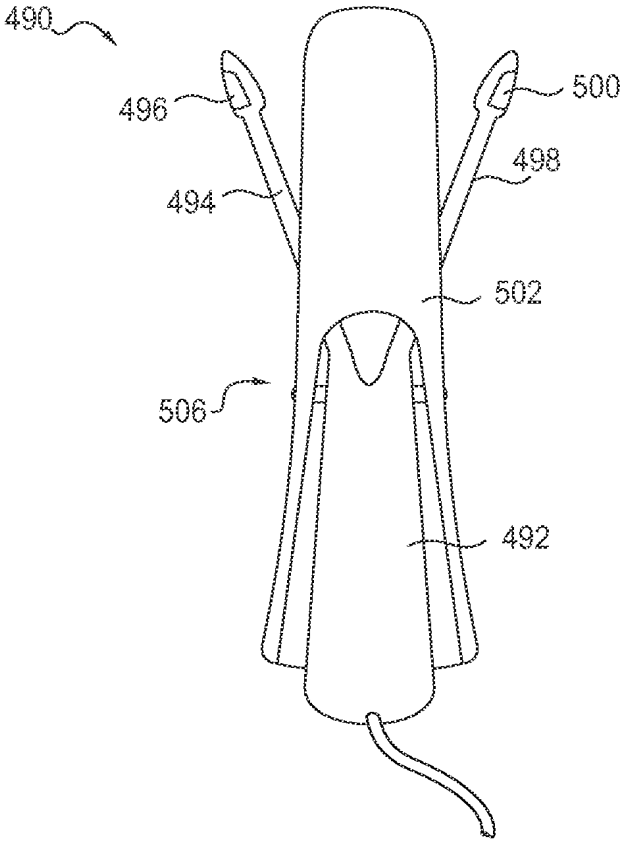


FIG. 13D

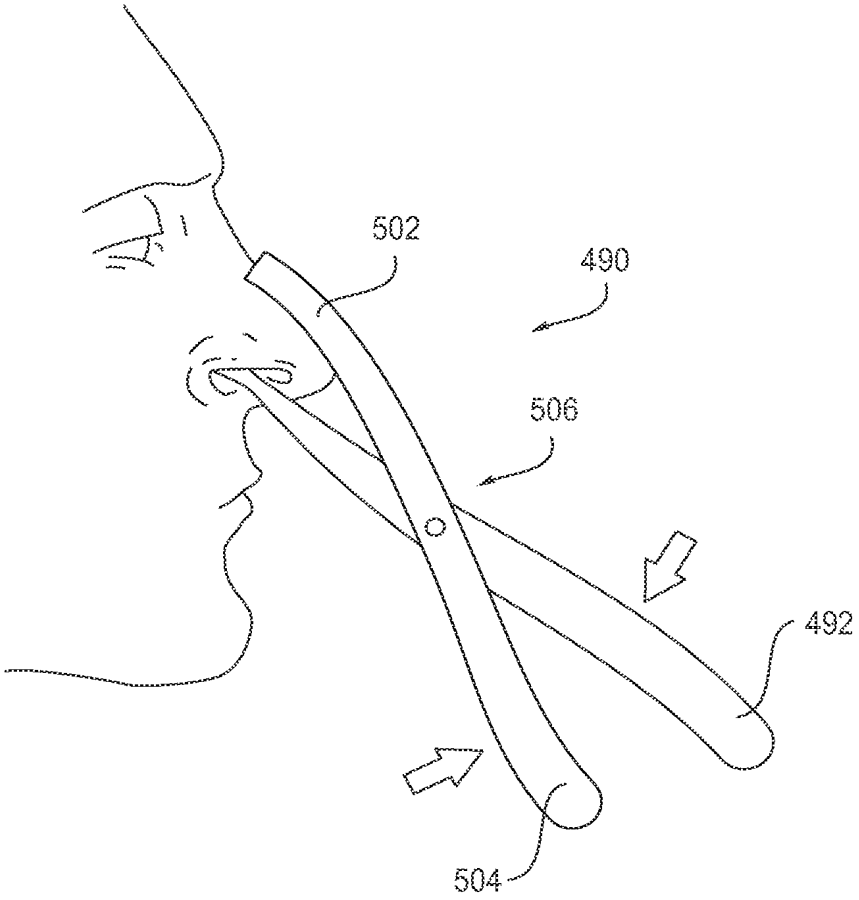


FIG. 13E

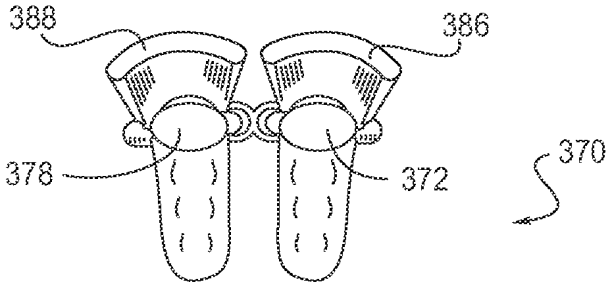


FIG. 14B

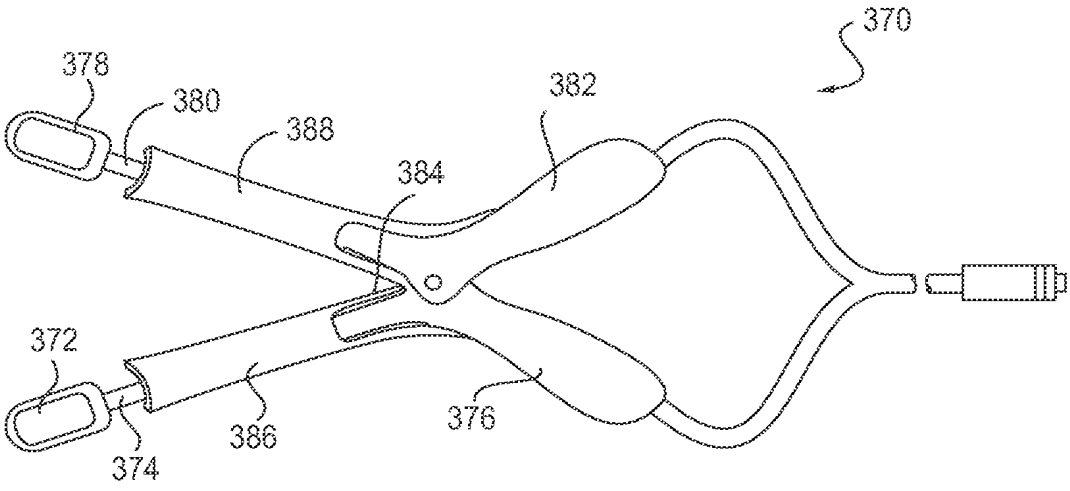


FIG. 14A

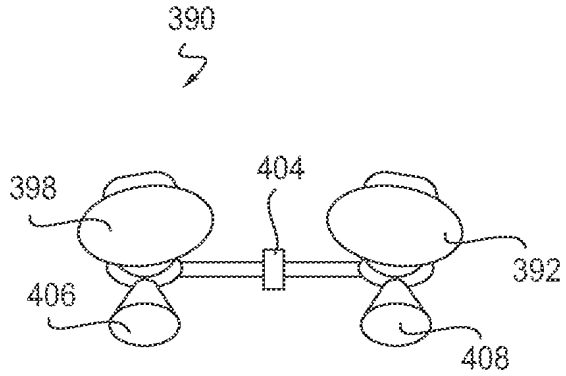


FIG. 15A

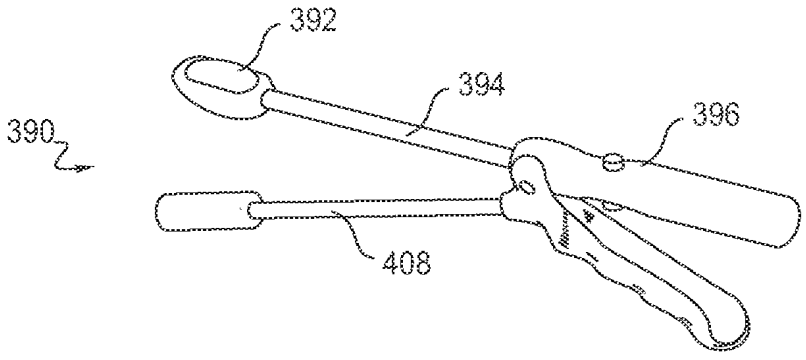


FIG. 15B

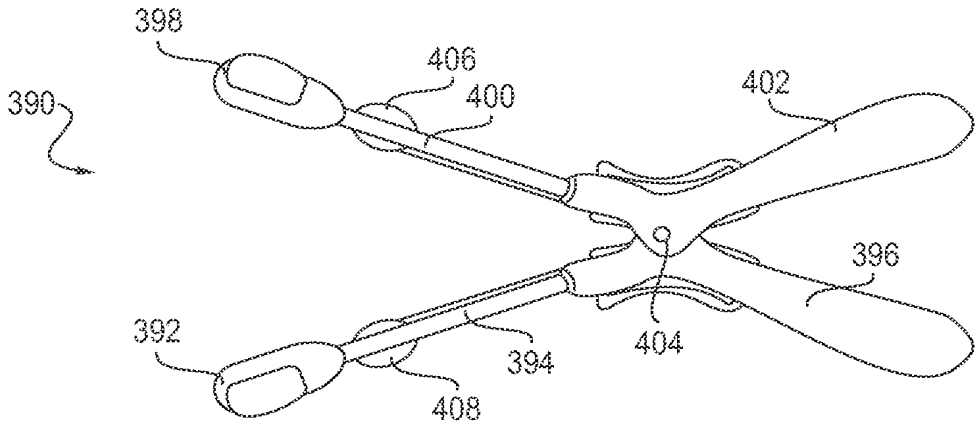


FIG. 15C

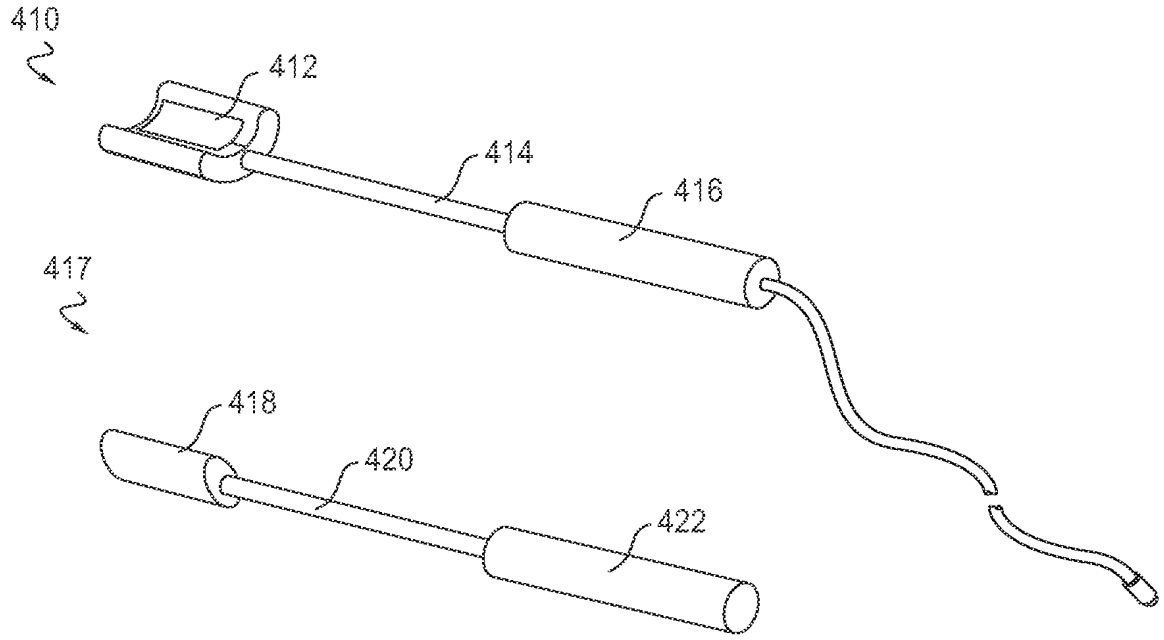


FIG. 16

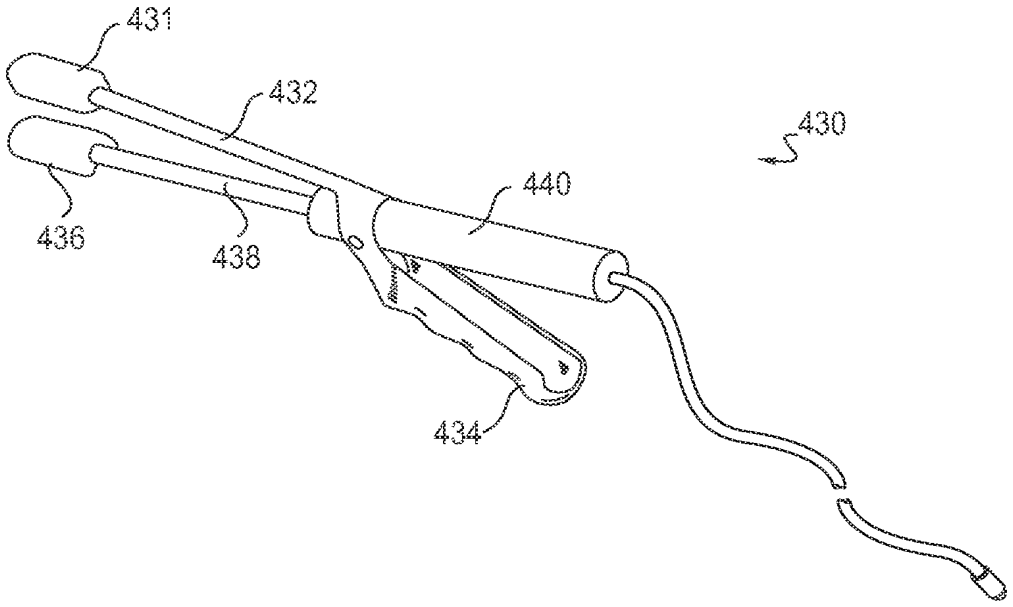


FIG. 17A

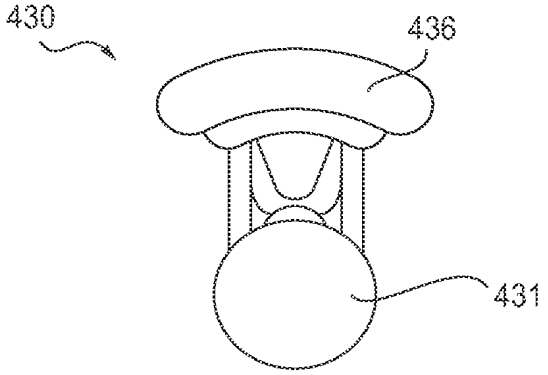


FIG. 17B

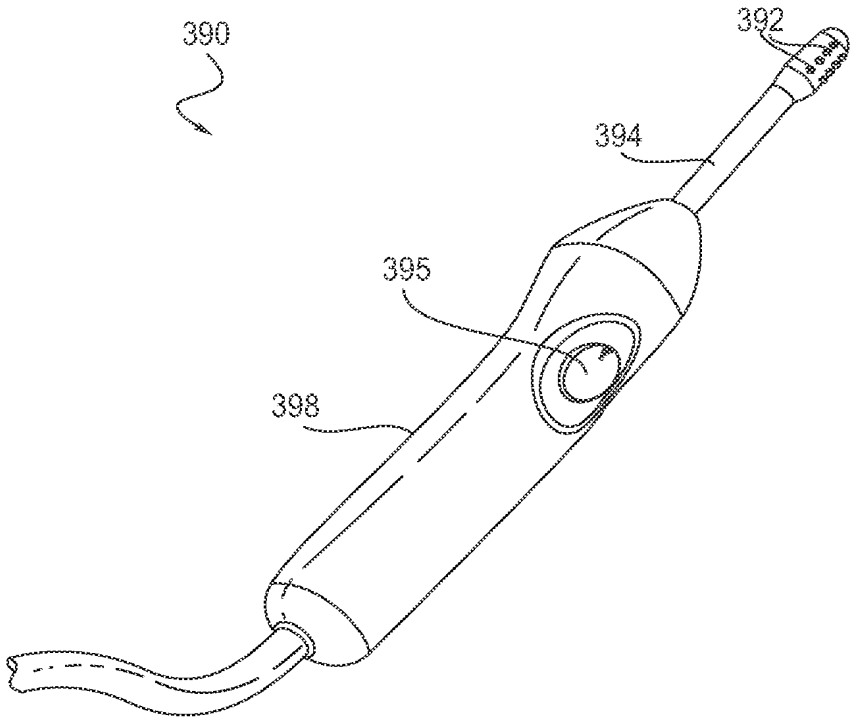


FIG. 18

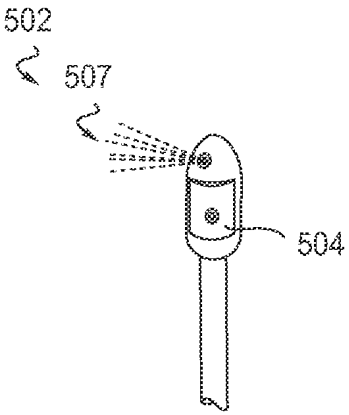


FIG. 19A



FIG. 19B

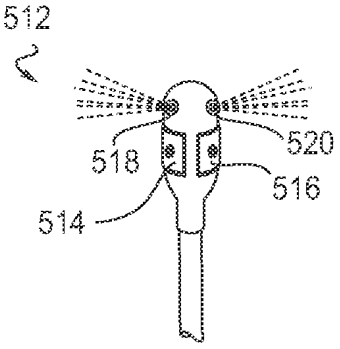


FIG. 20A



FIG. 20B

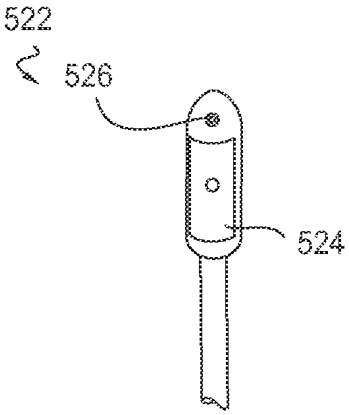


FIG. 21A

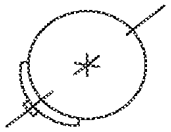


FIG. 21B

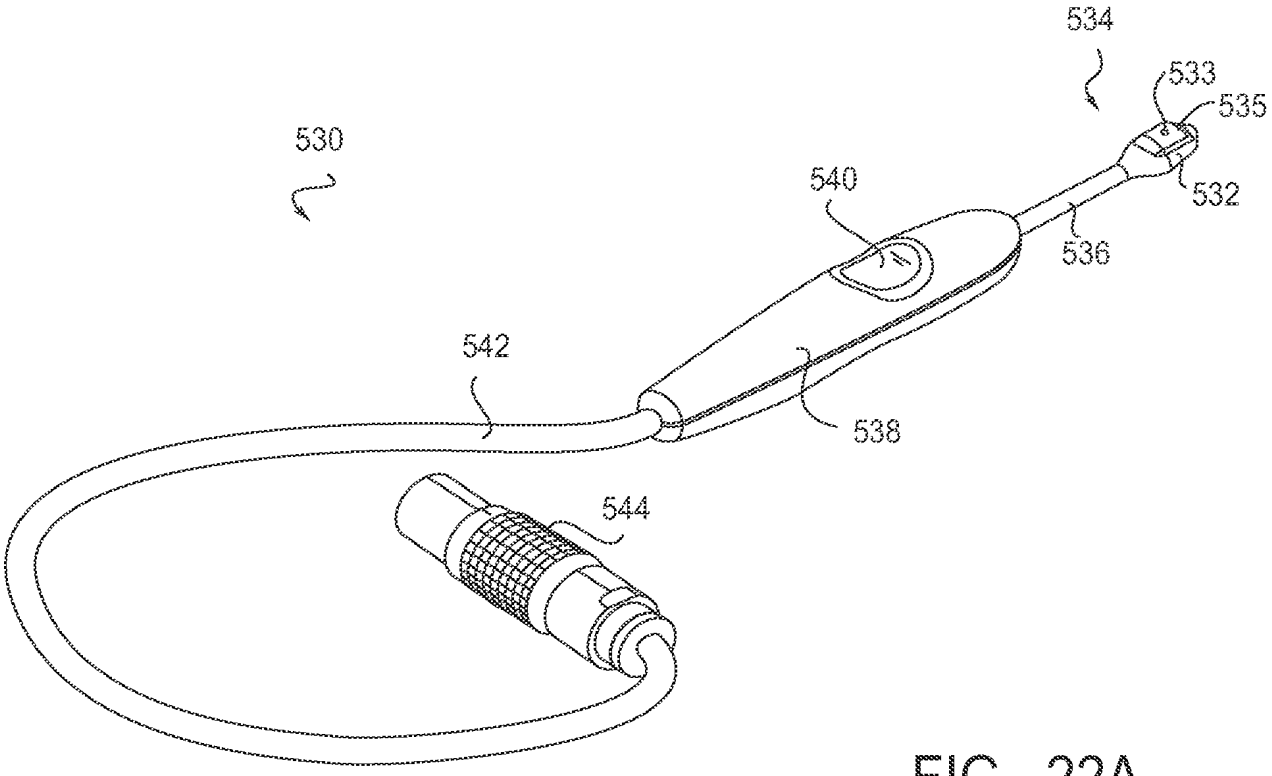


FIG. 22A

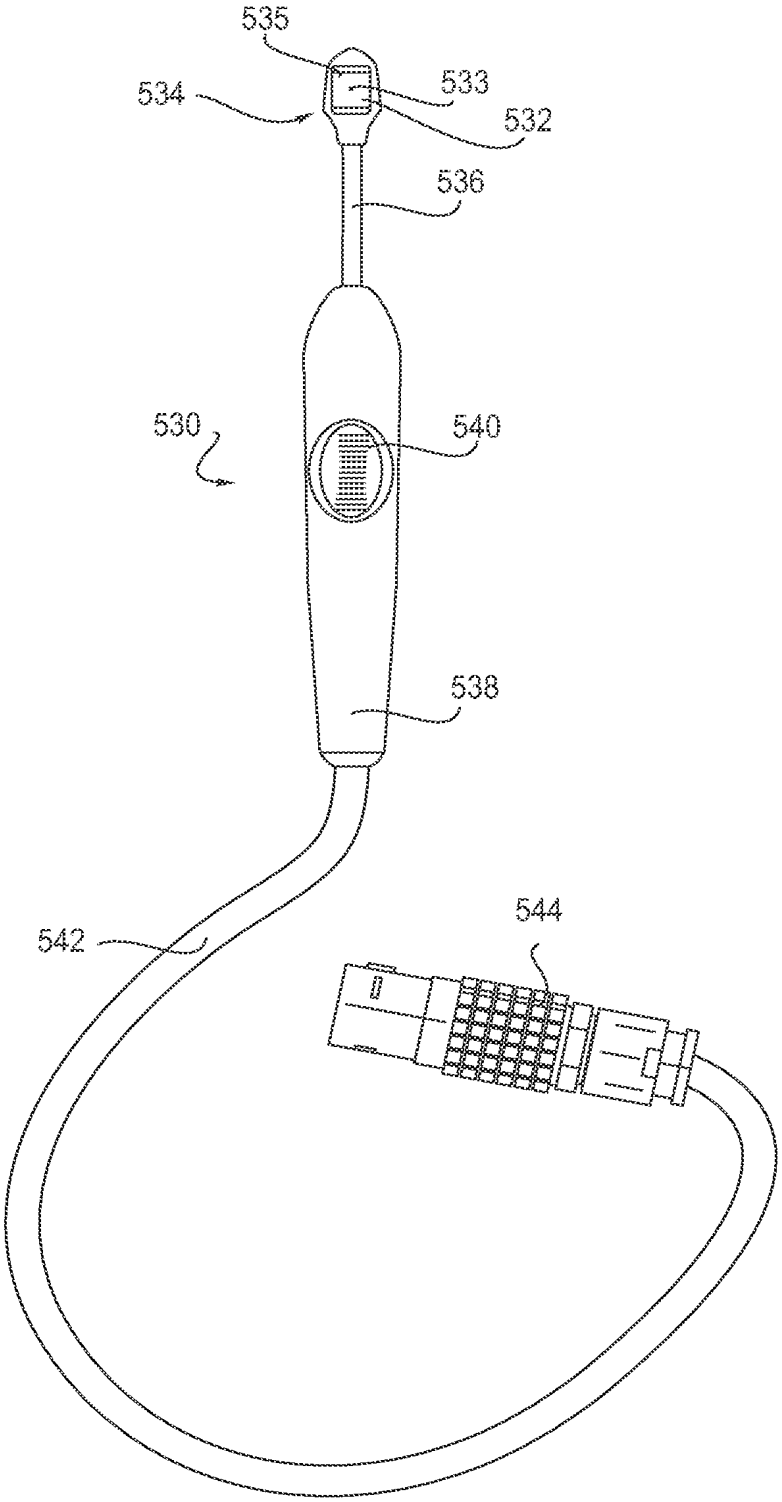


FIG. 22B

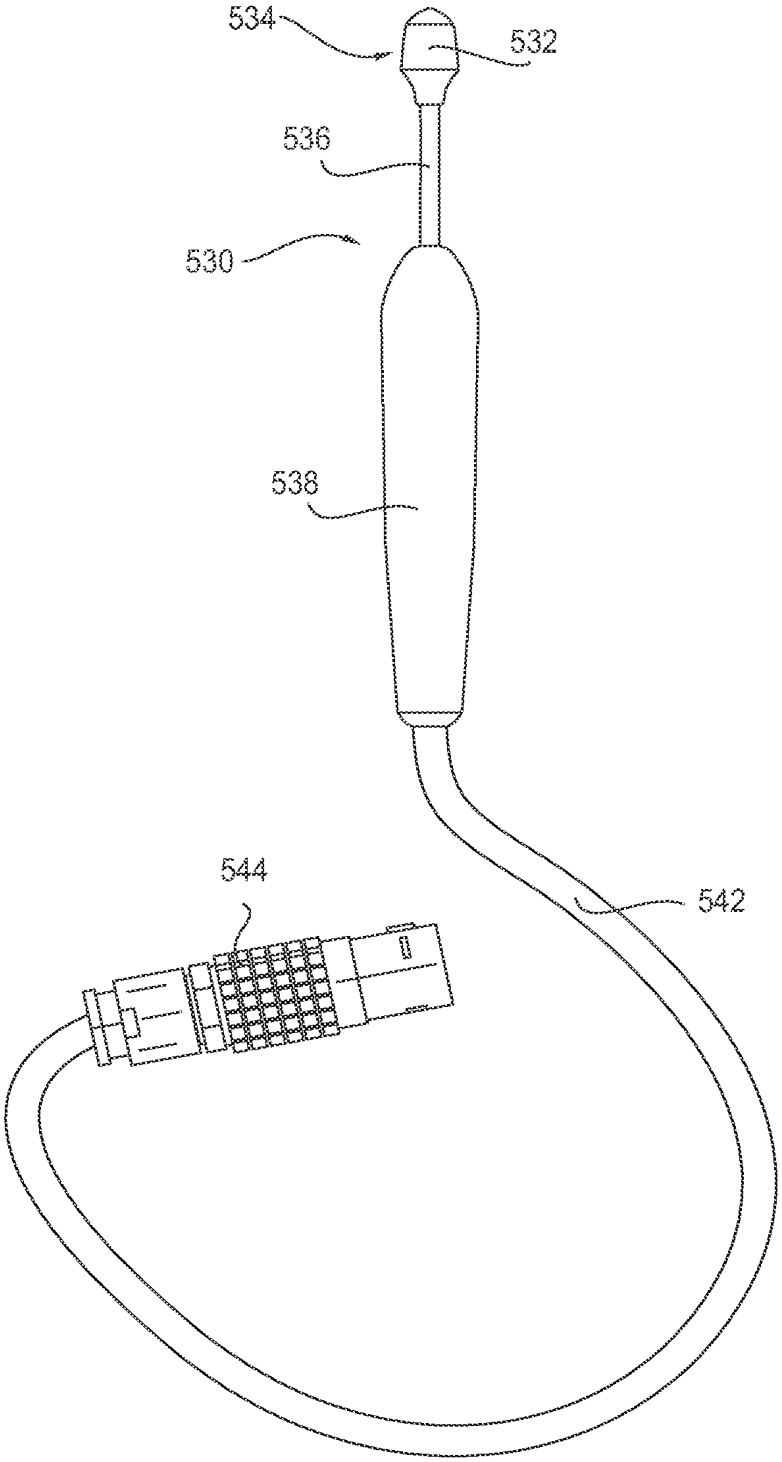


FIG. 22C

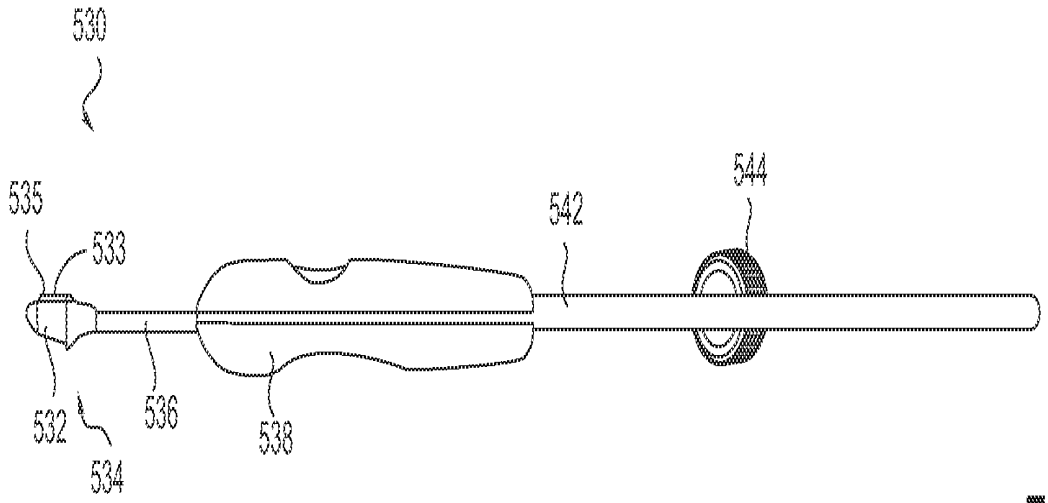


FIG. 22D

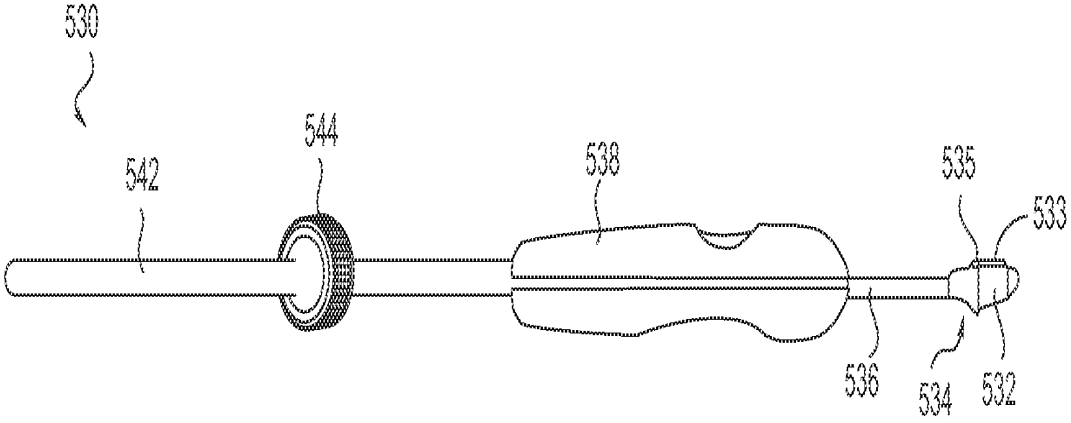


FIG. 22E

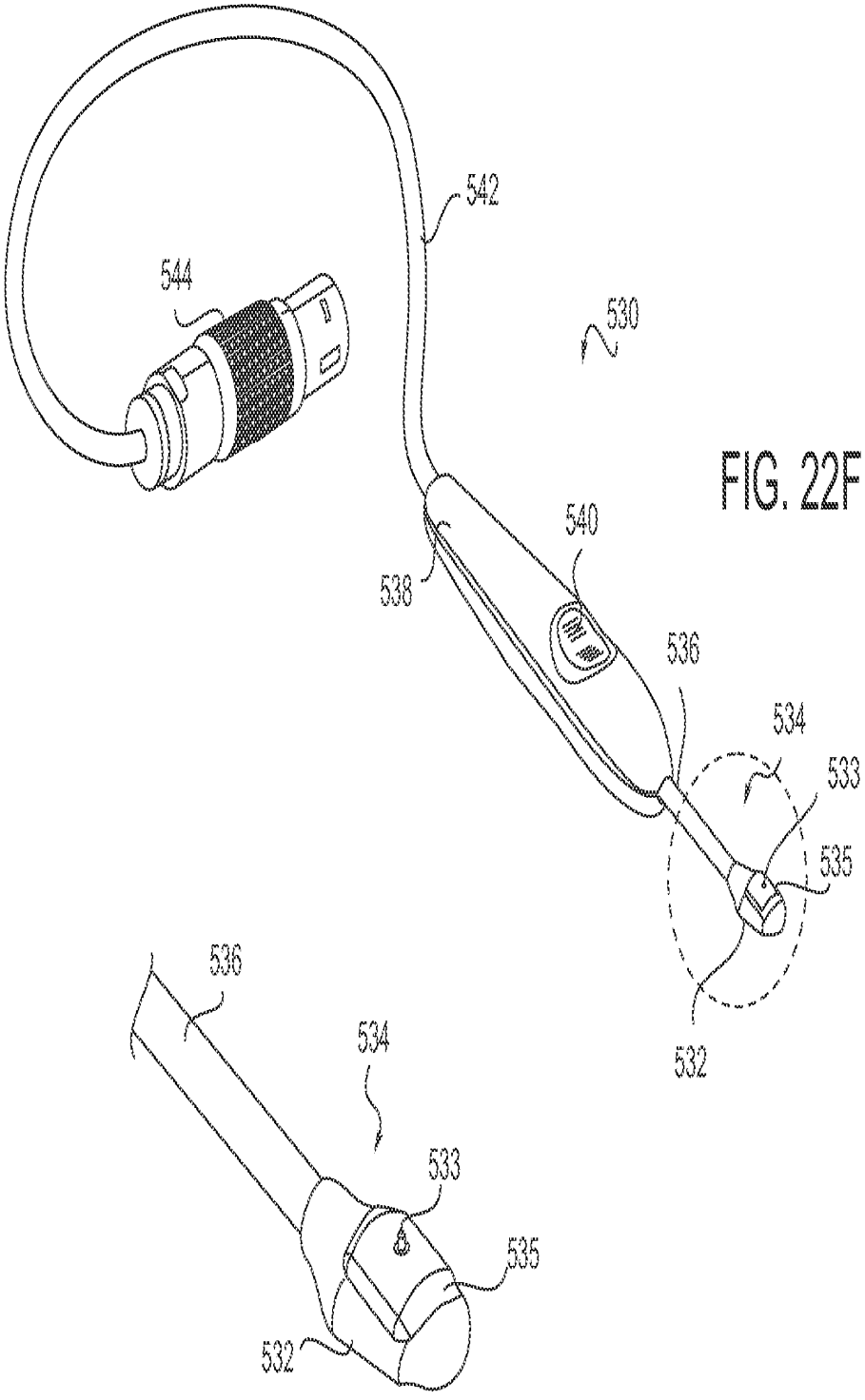


FIG. 22F

FIG. 22G

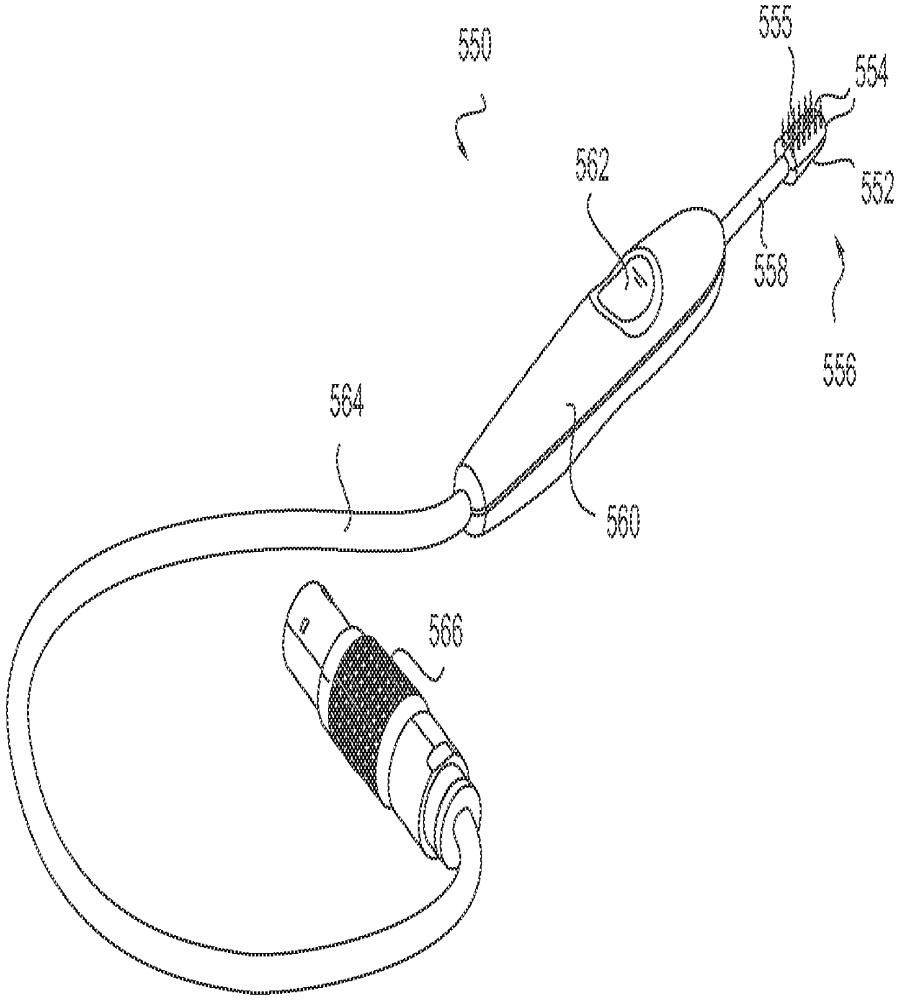


FIG. 23A

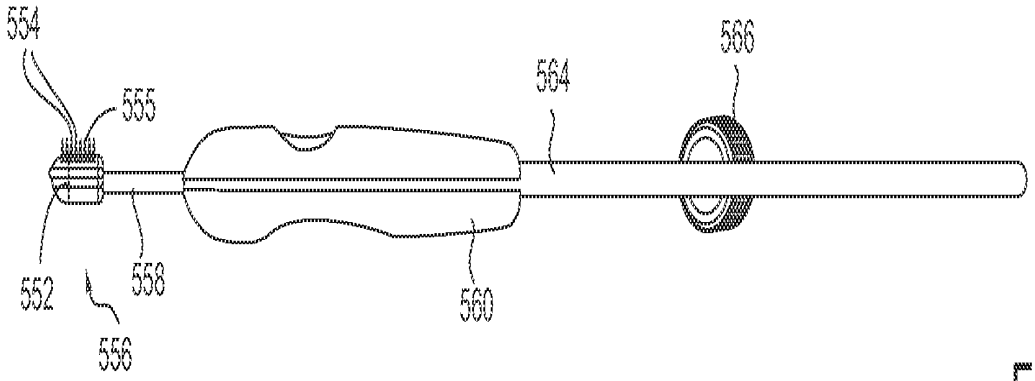


FIG. 23B

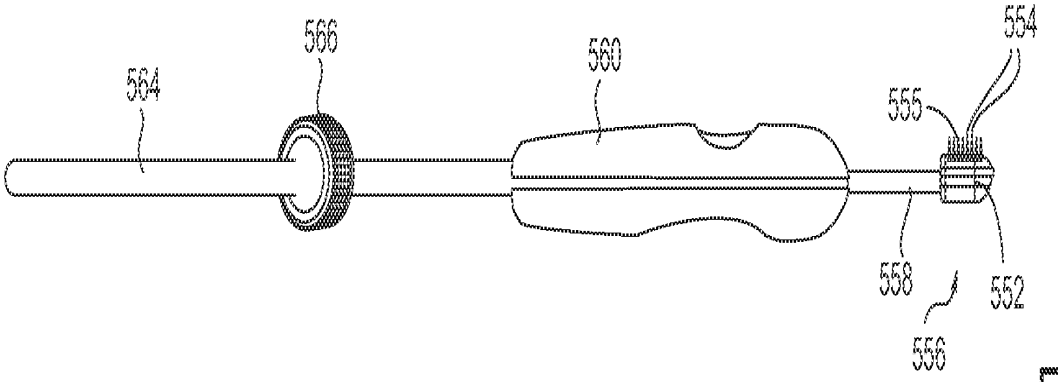


FIG. 23C

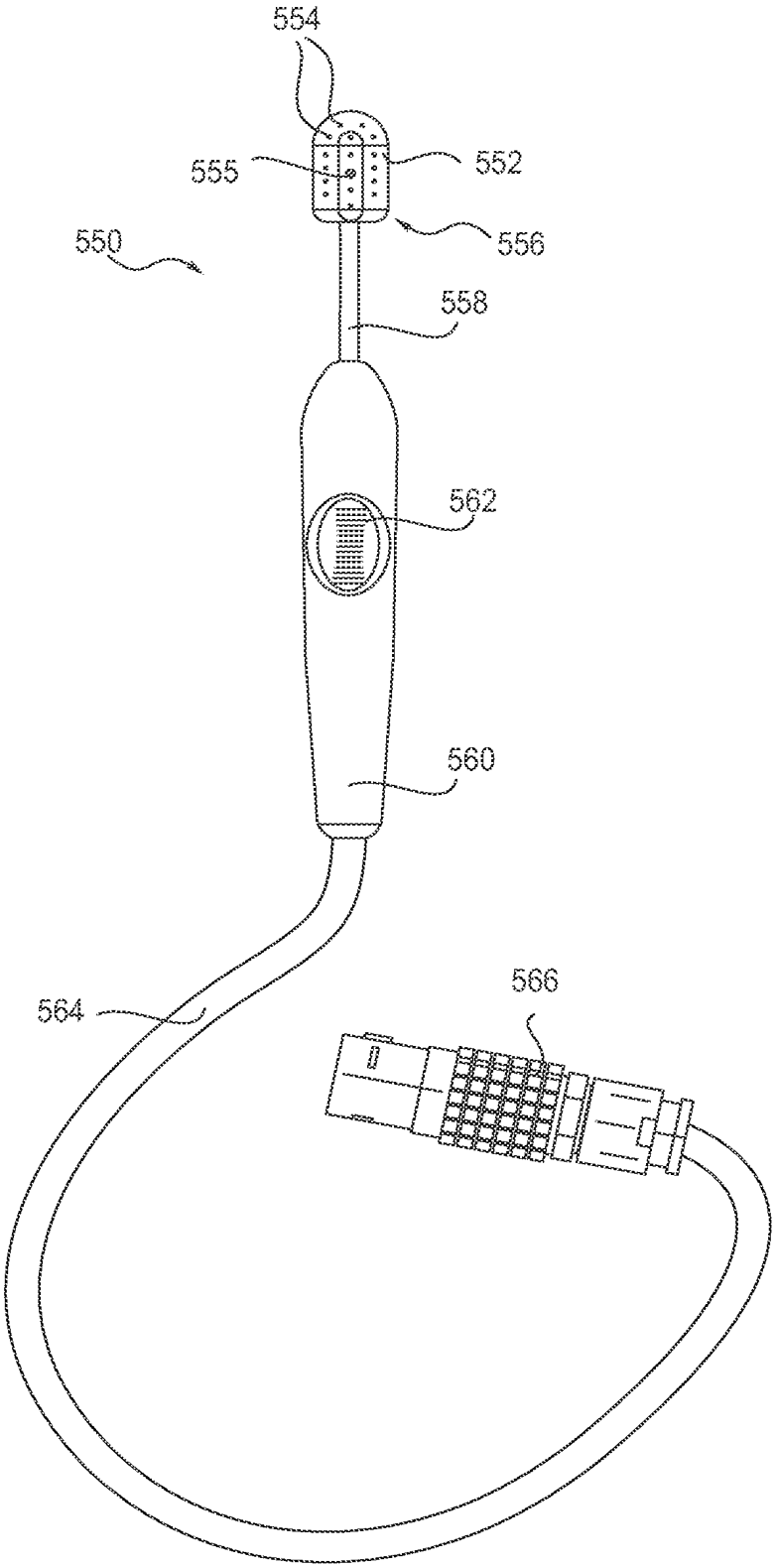


FIG. 23D

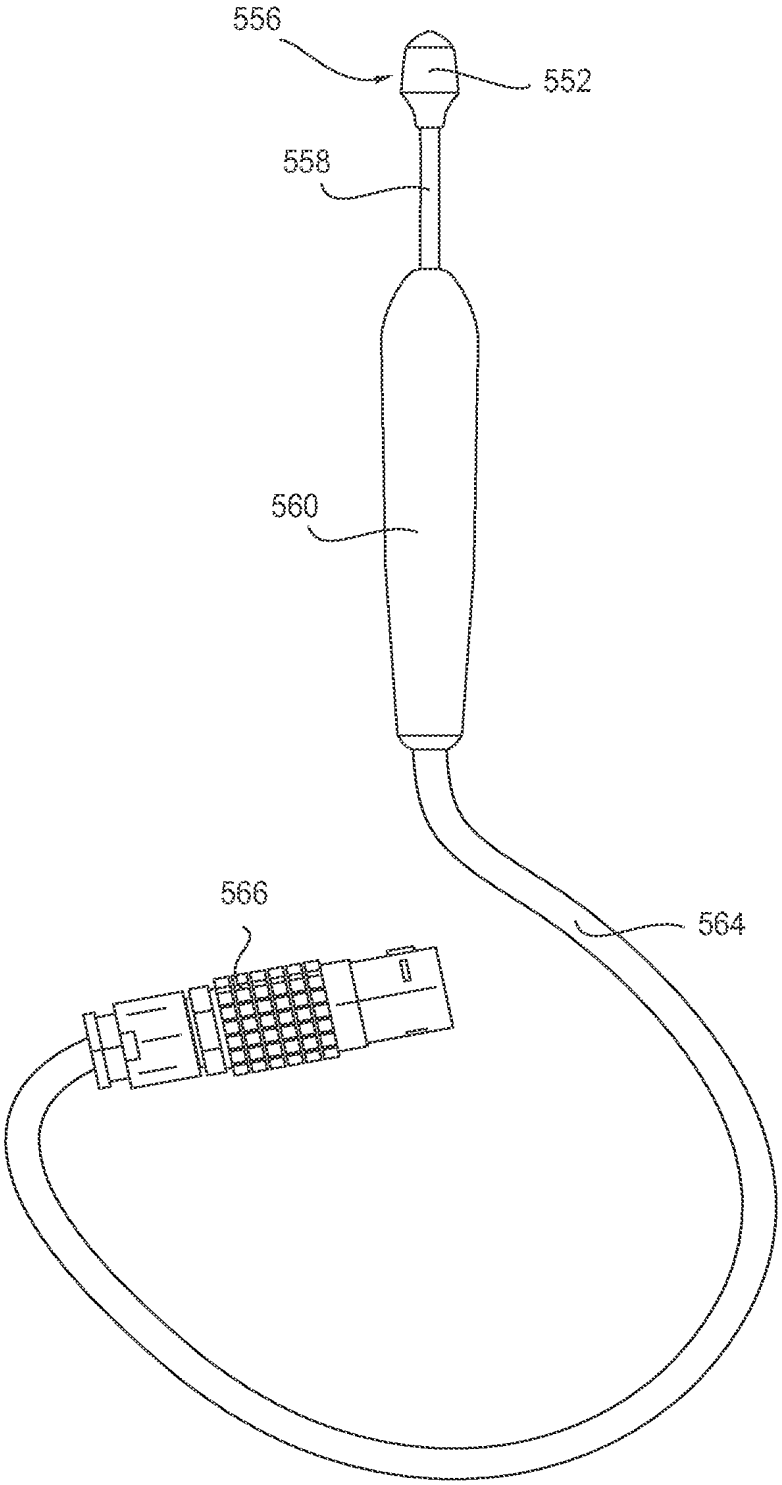


FIG. 23E1

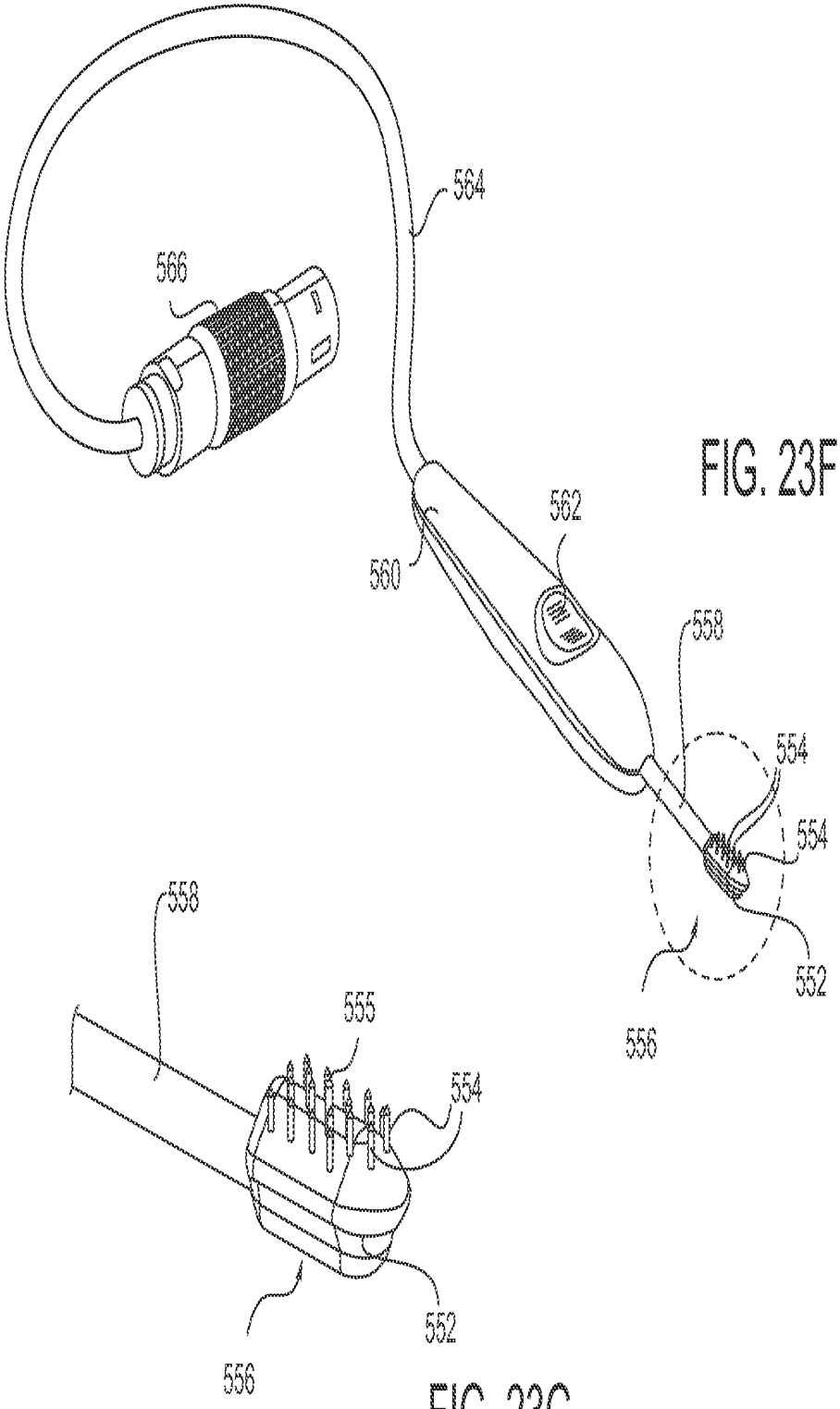


FIG. 23F

FIG. 23G

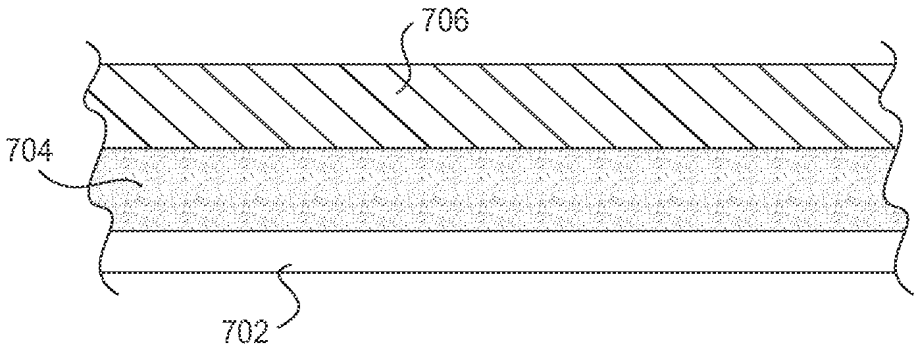


FIG. 24A

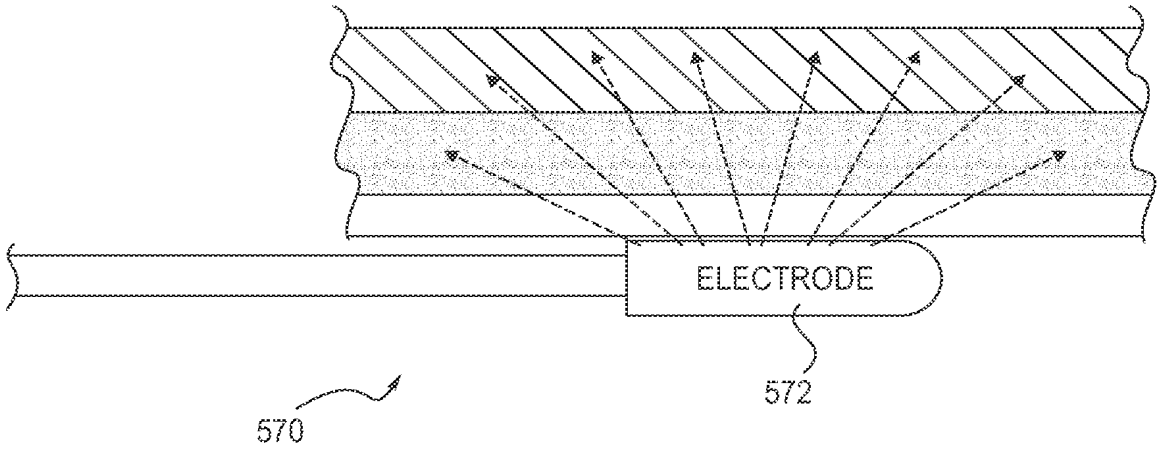


FIG. 24B

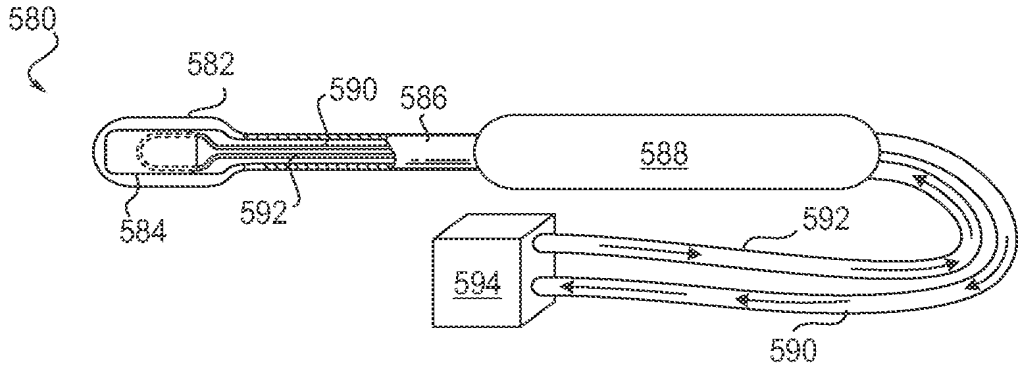


FIG. 25A

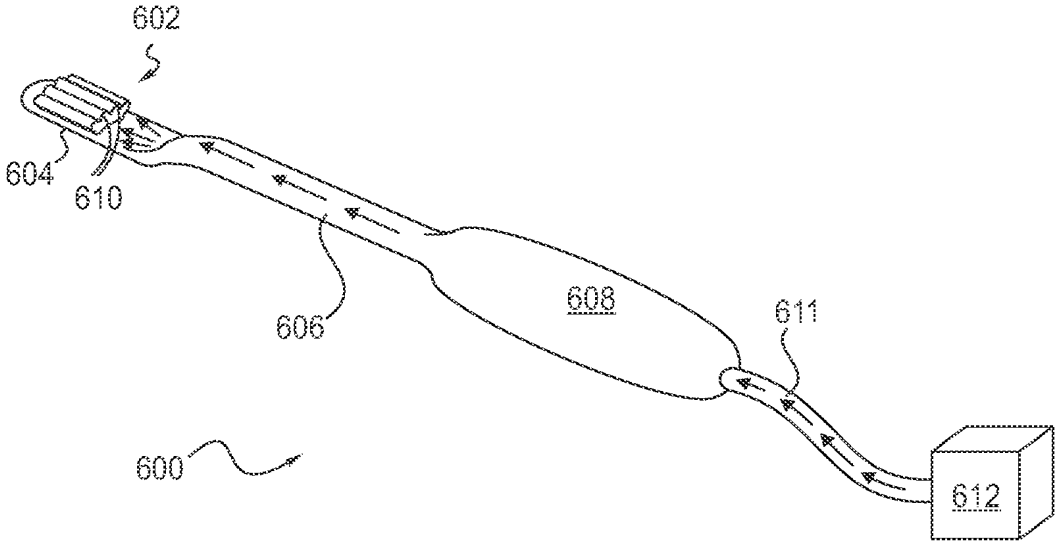


FIG. 25B

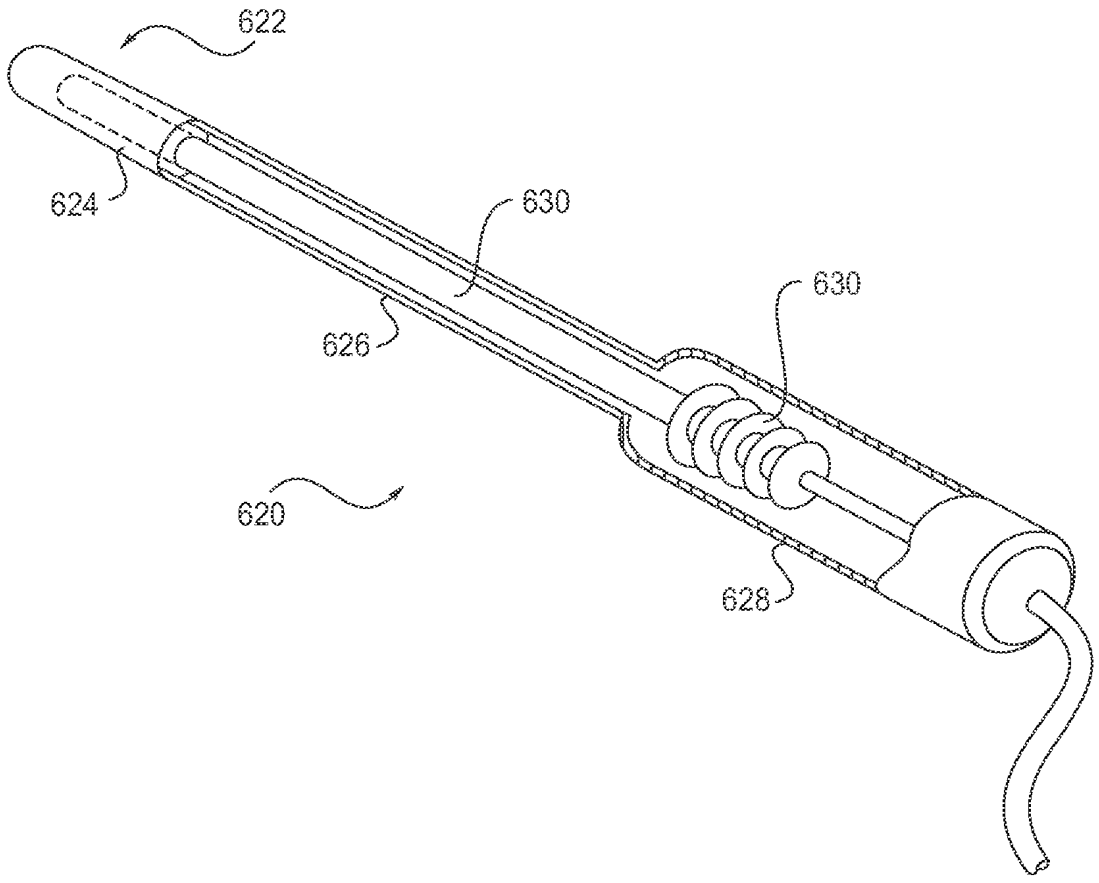


FIG. 26

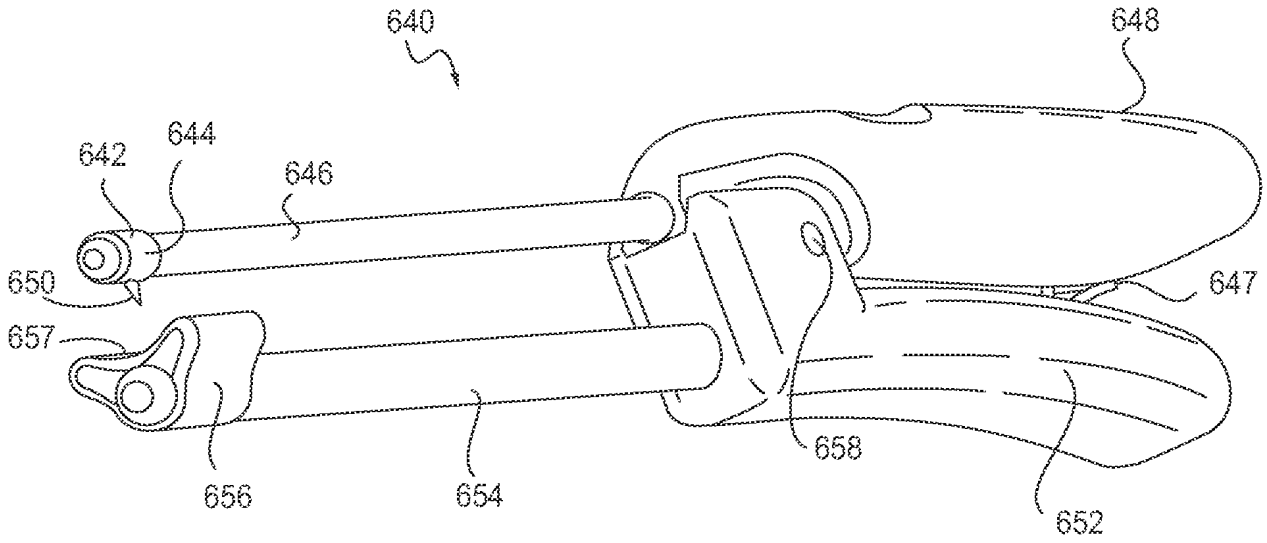


FIG. 27

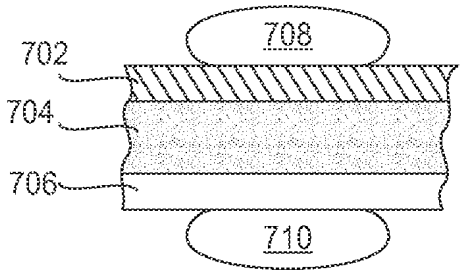


FIG. 28A

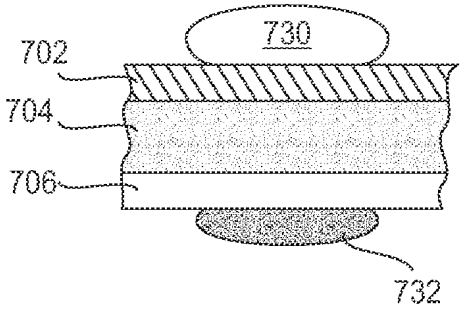


FIG. 28B

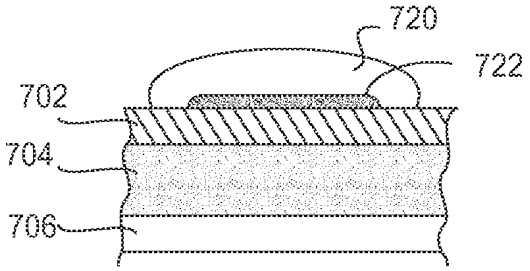


FIG. 28C

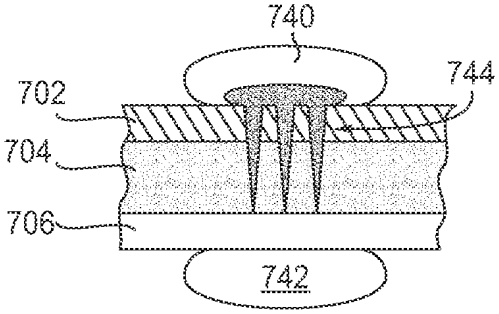


FIG. 28D

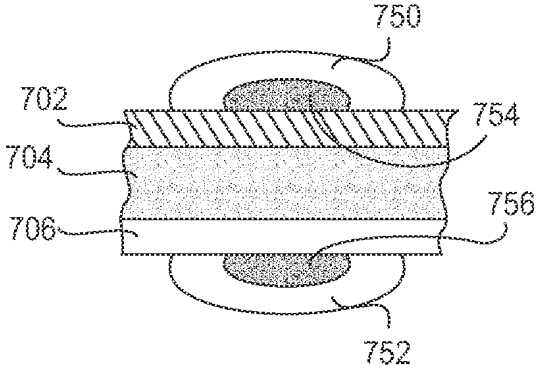


FIG. 28E

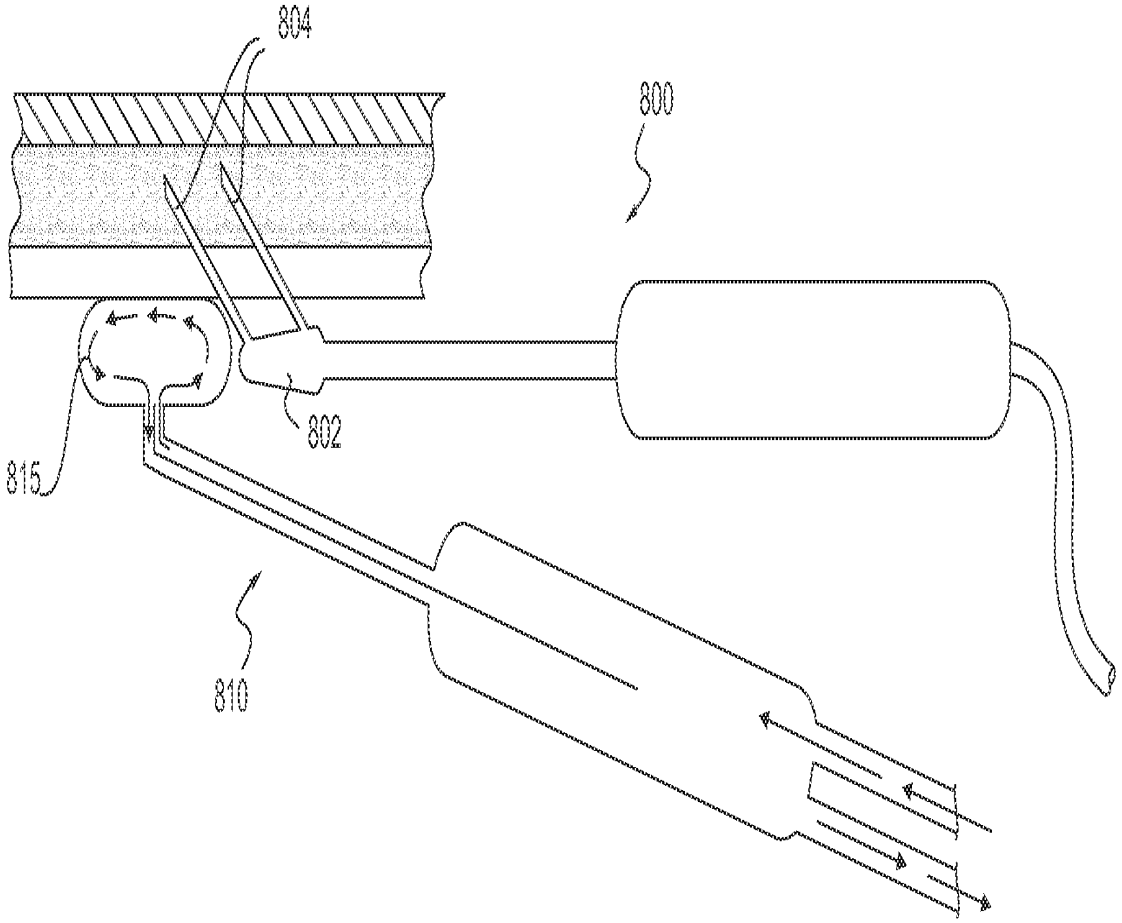


FIG. 29



FIG. 30A

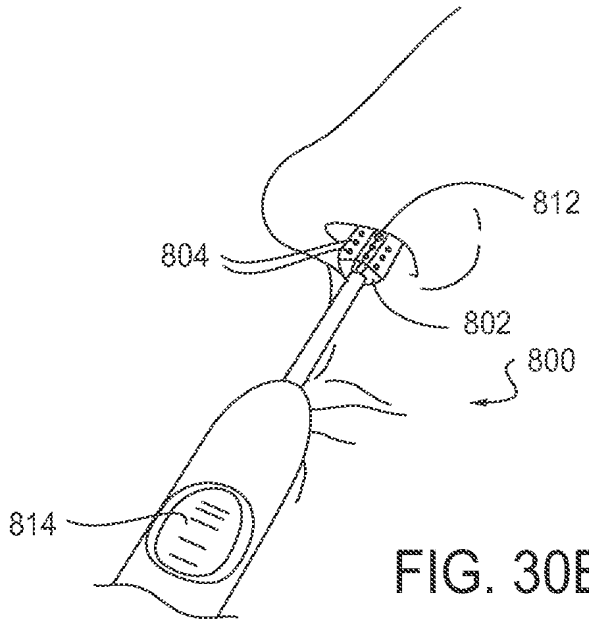


FIG. 30B

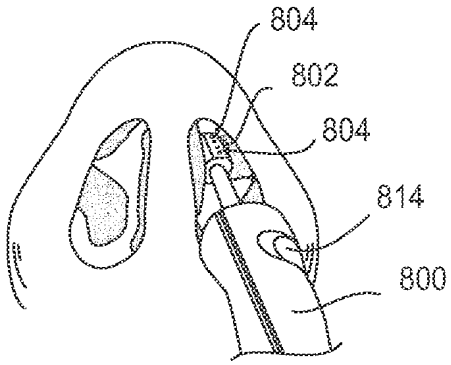


FIG. 30C

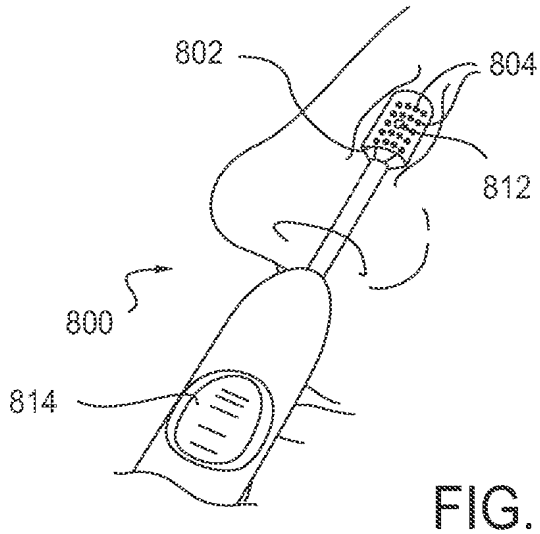


FIG. 30D

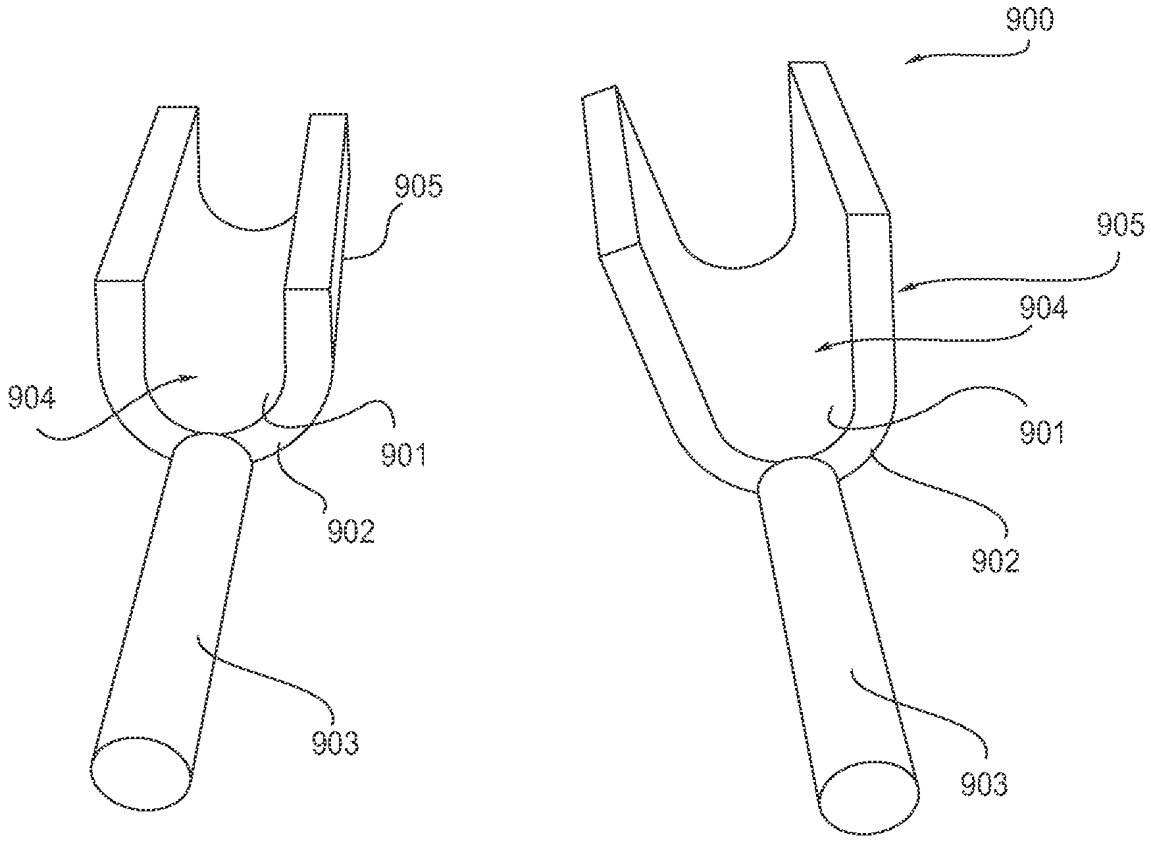


FIG. 31

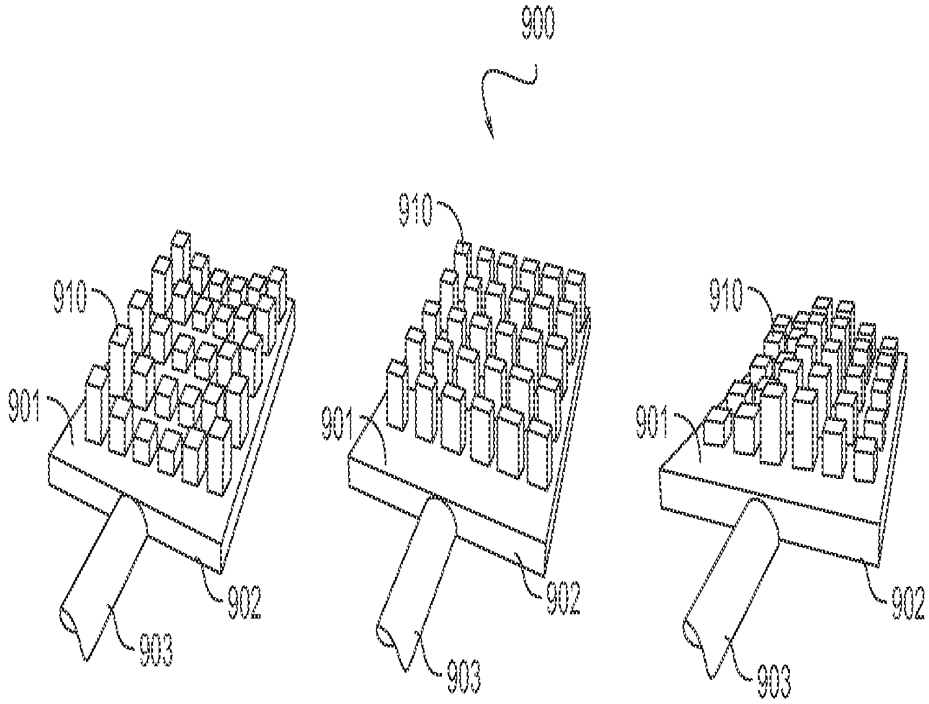


FIG. 32A

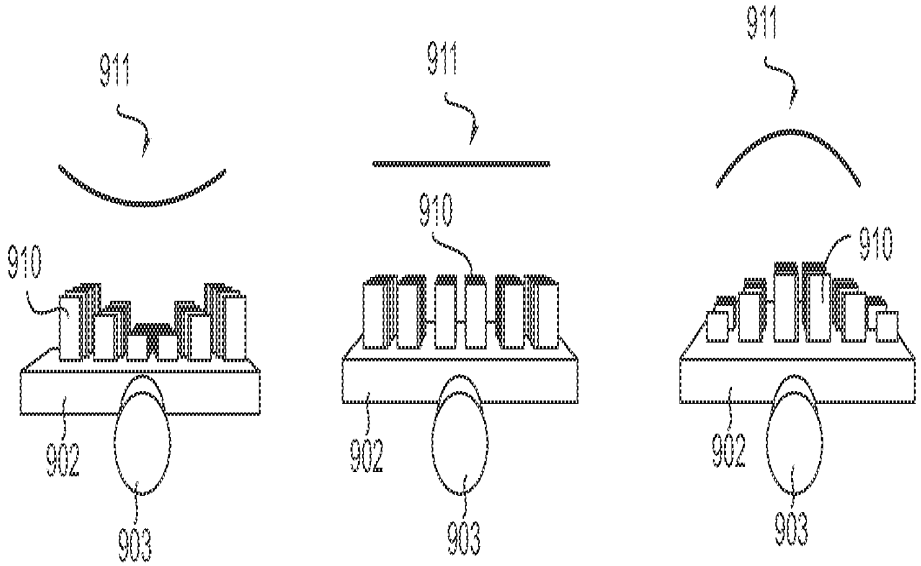


FIG. 32B

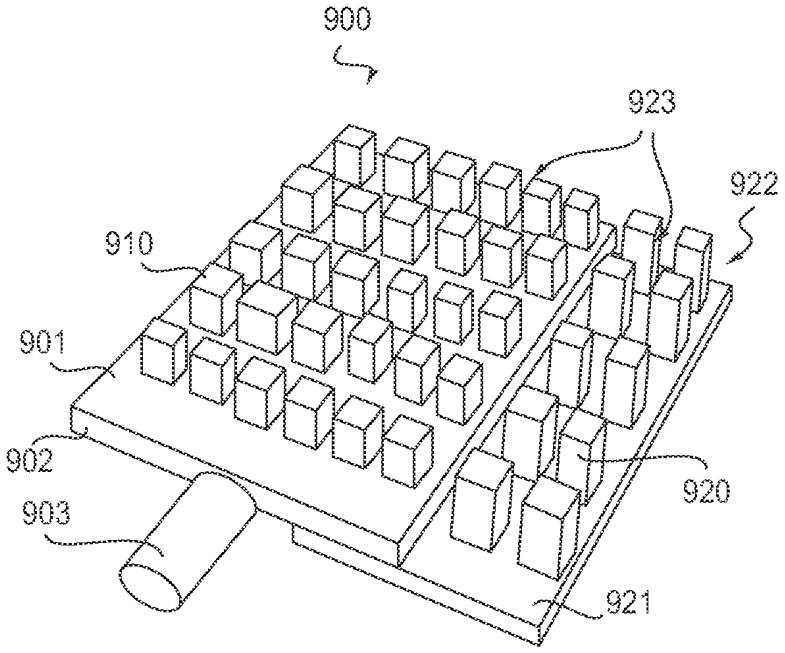


FIG. 33

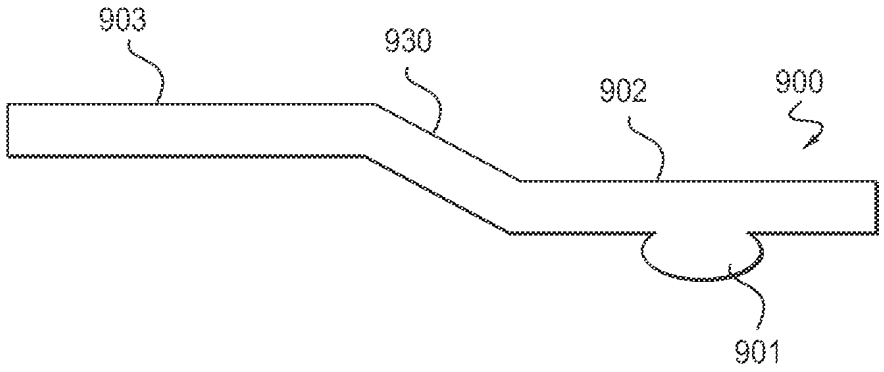


FIG. 34

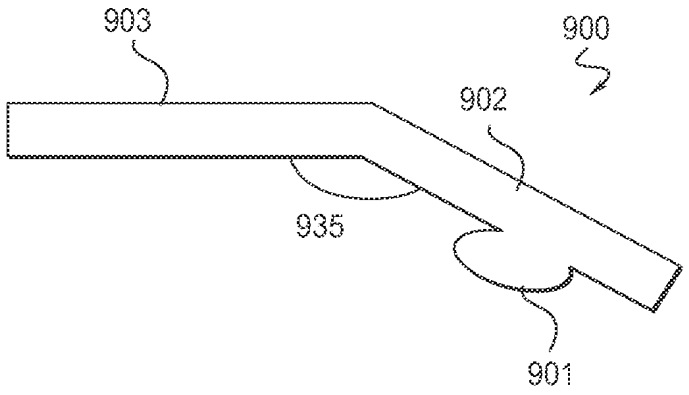


FIG. 35

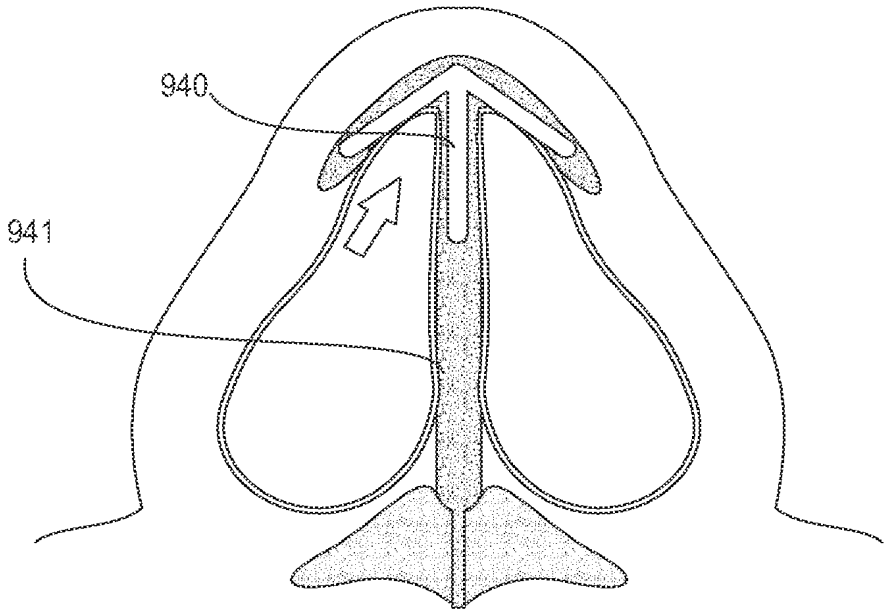


FIG. 36

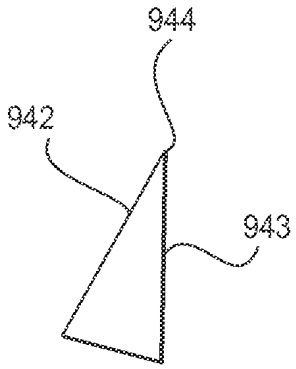


FIG. 37

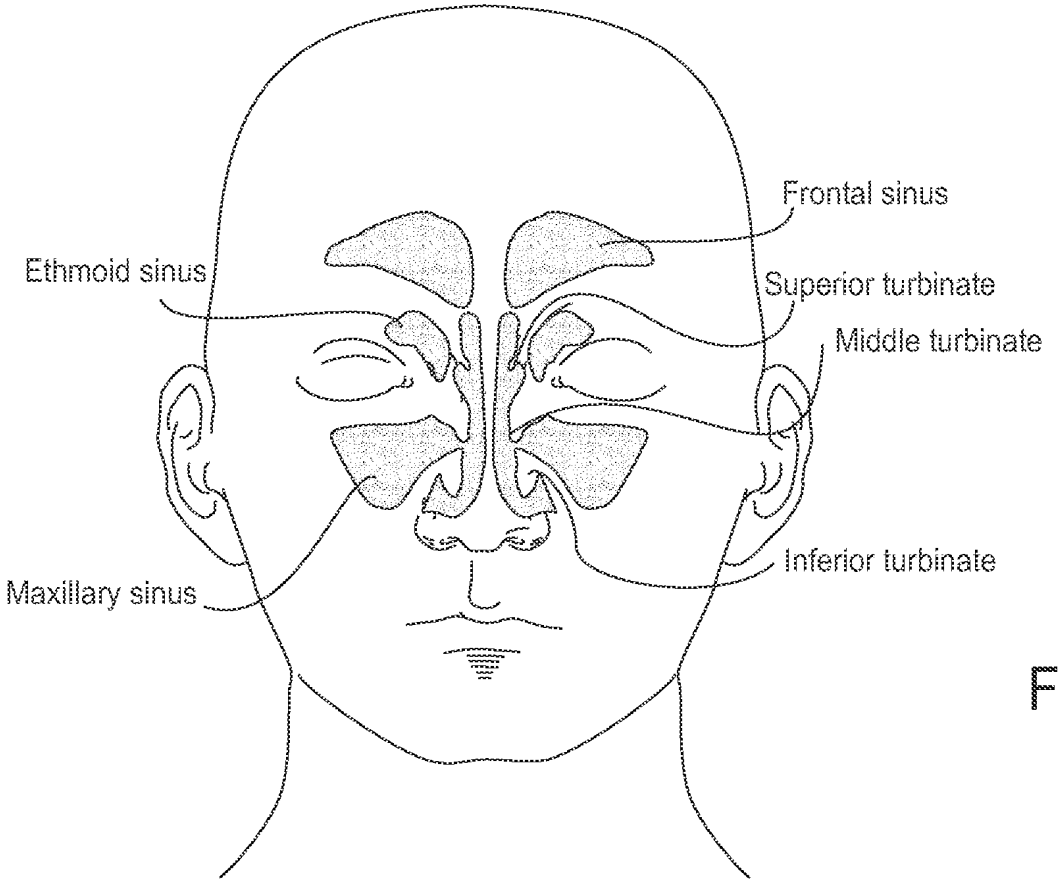


FIG. 38A

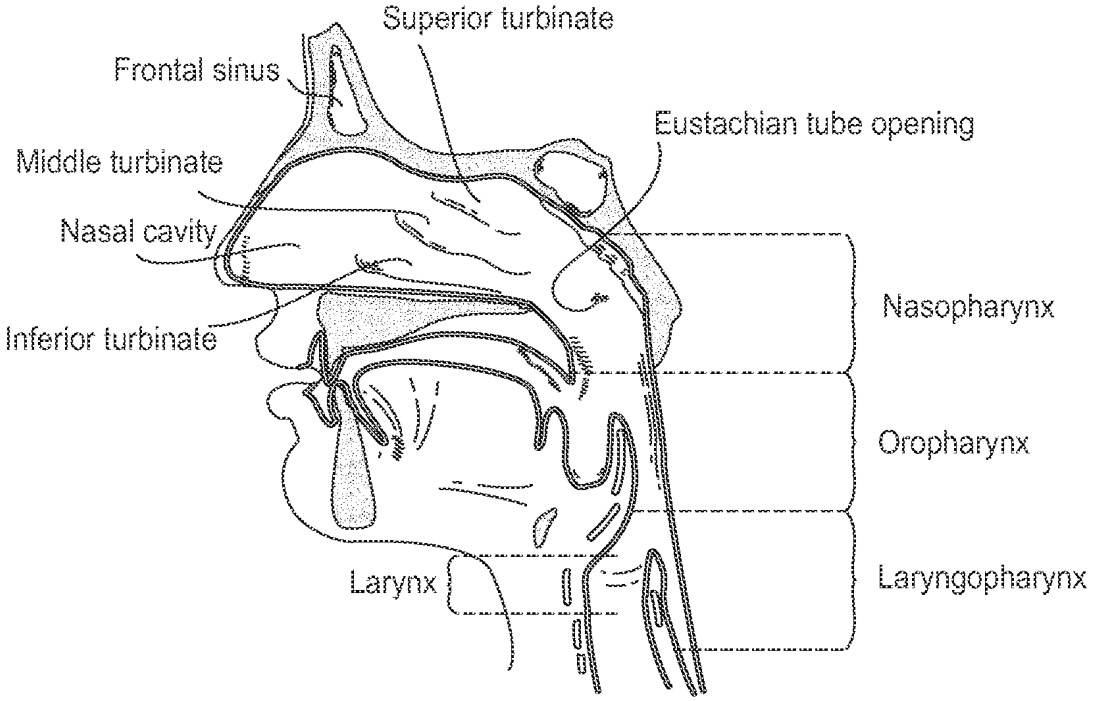


FIG. 38B

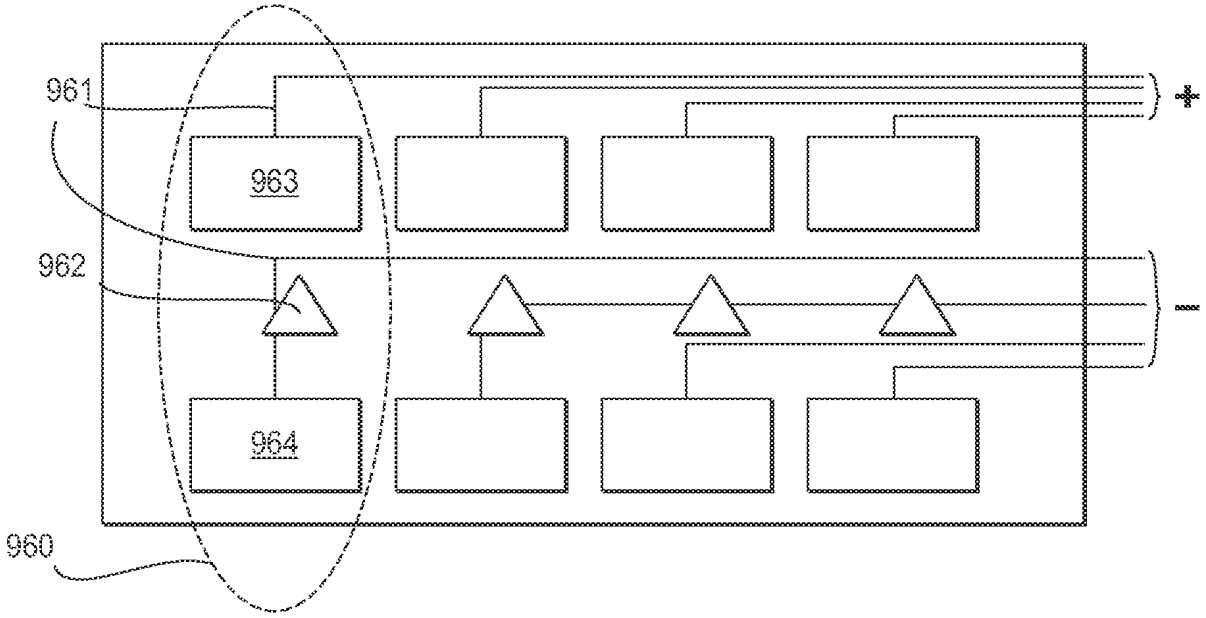


FIG. 39

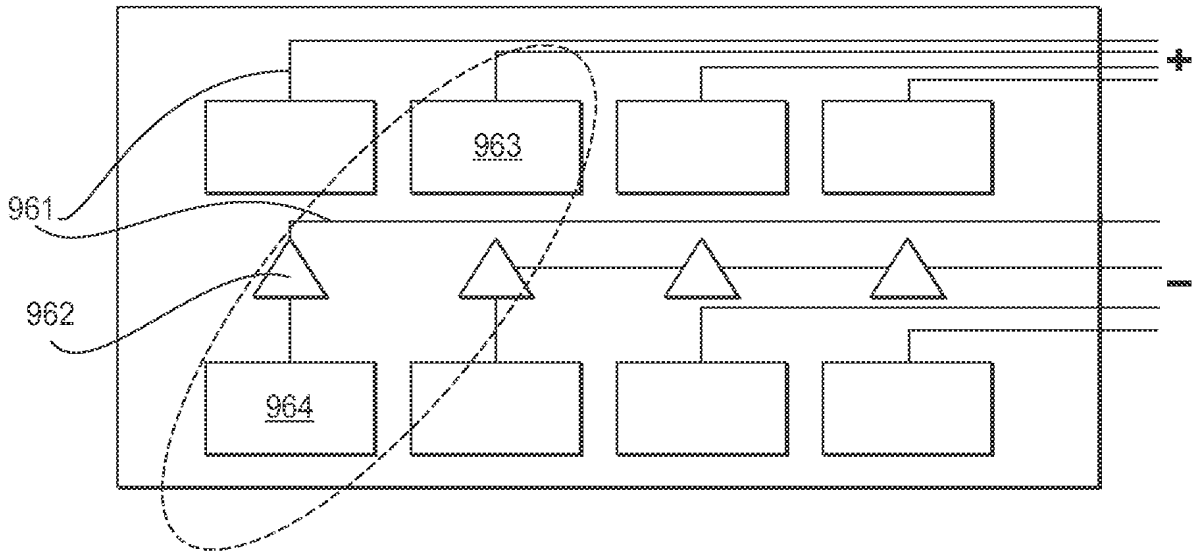


FIG. 40

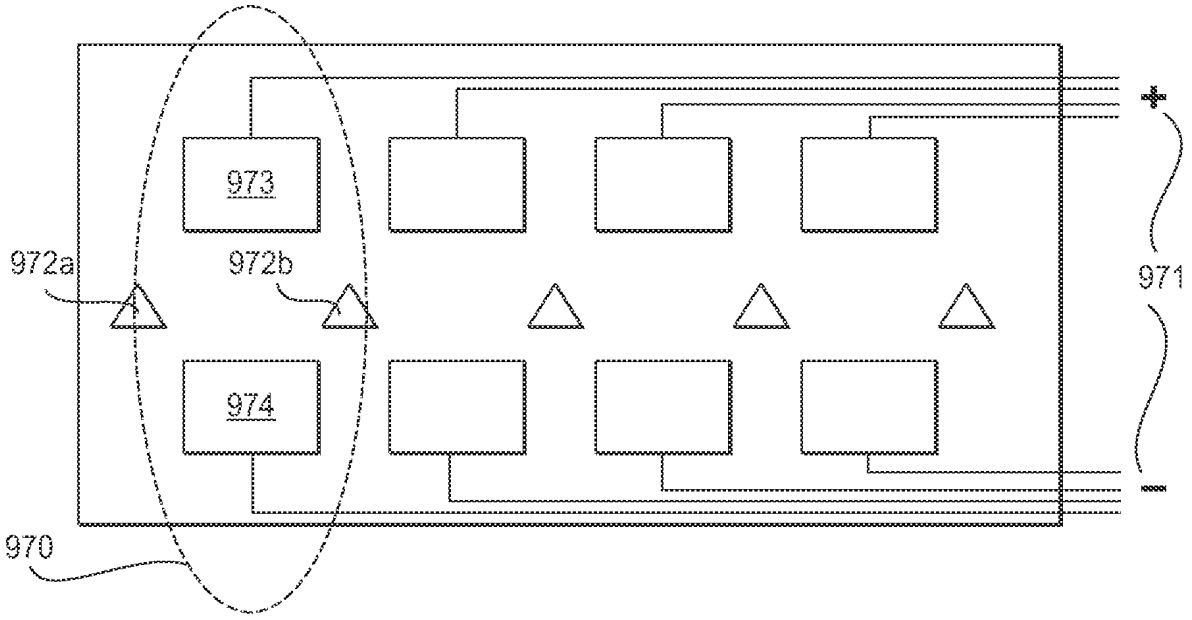


FIG. 41

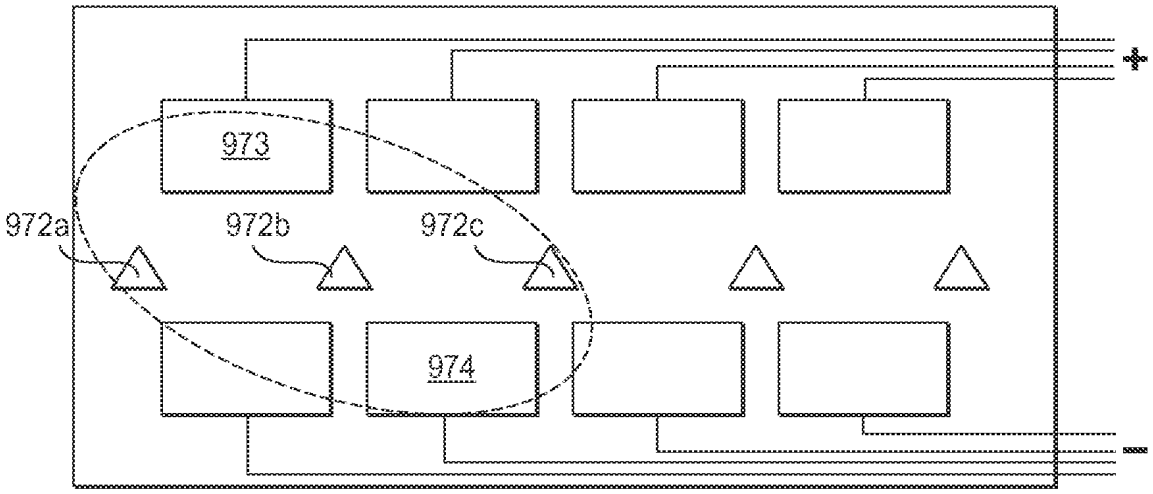


FIG. 42A

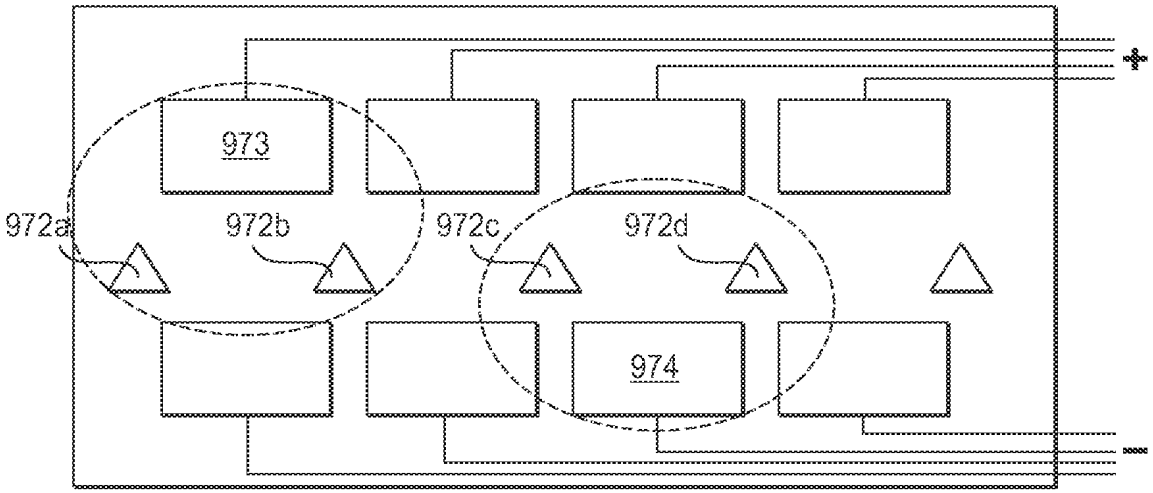


FIG. 42B

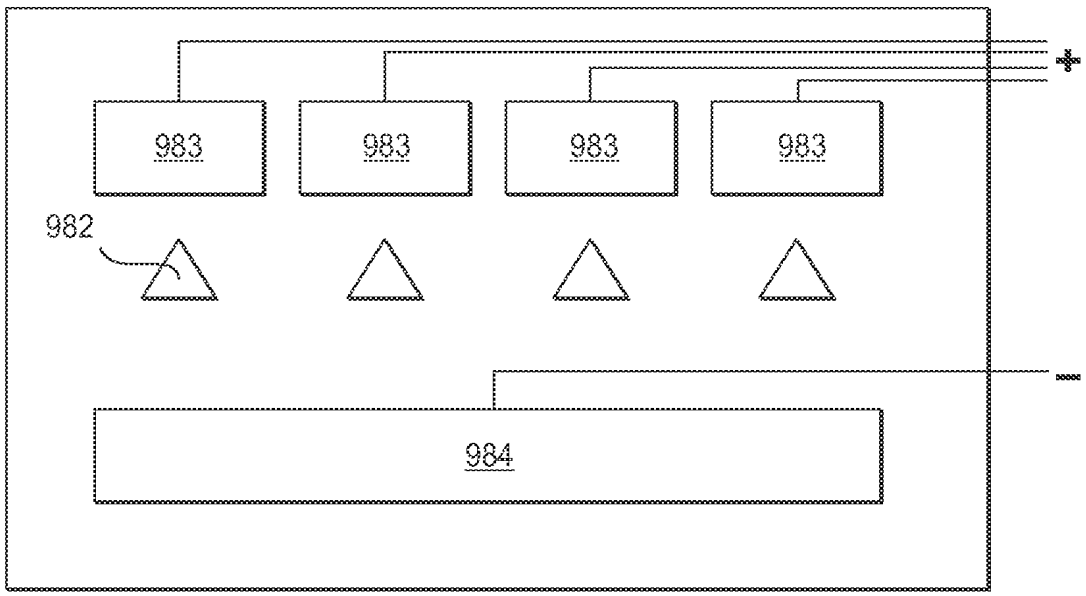


FIG. 43

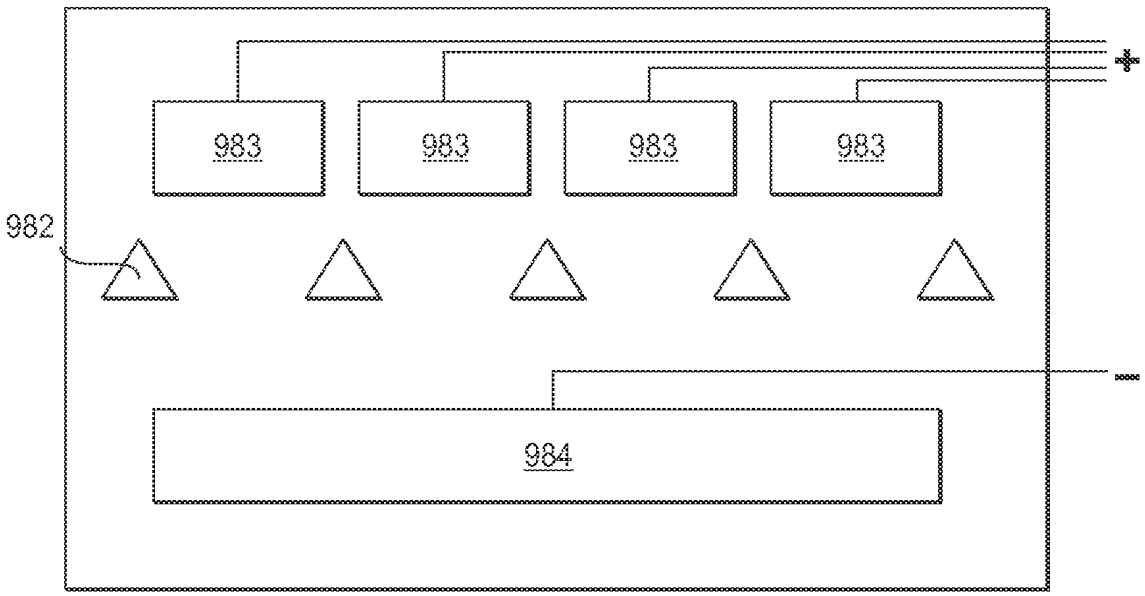


FIG. 44

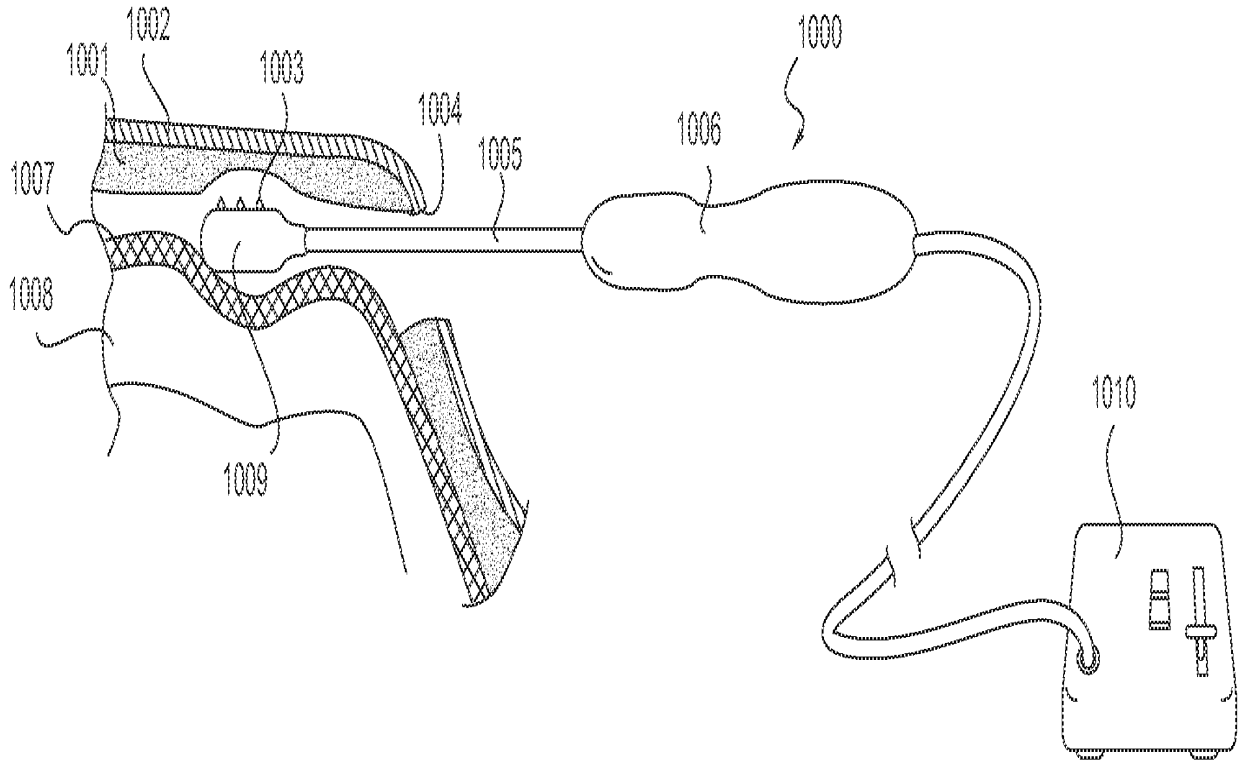


FIG. 45

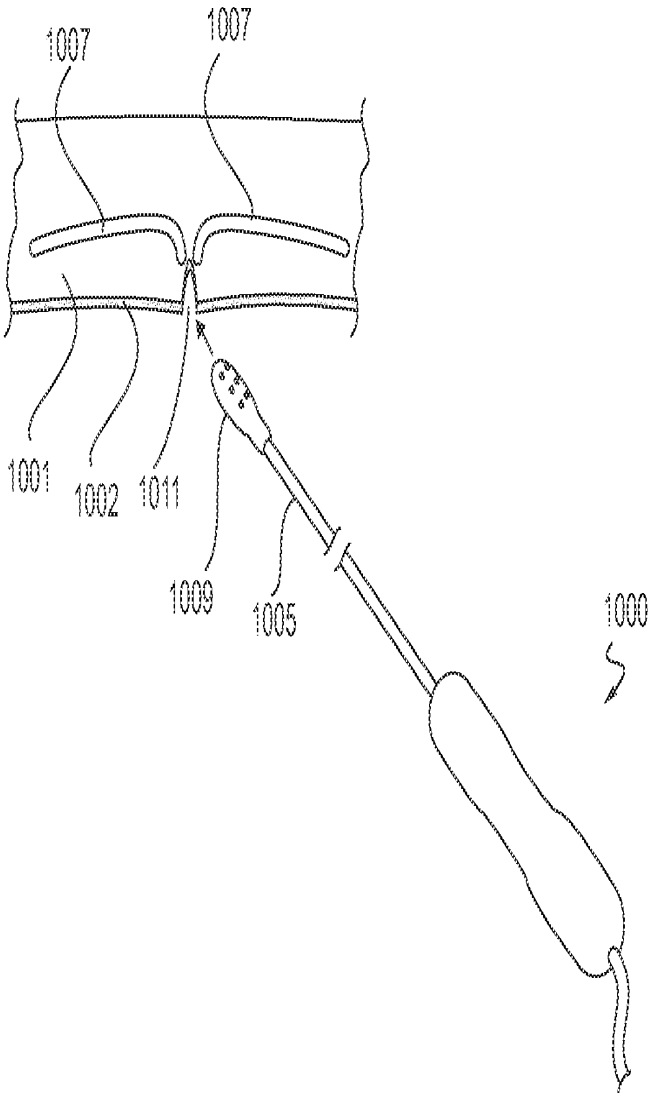


FIG. 46A

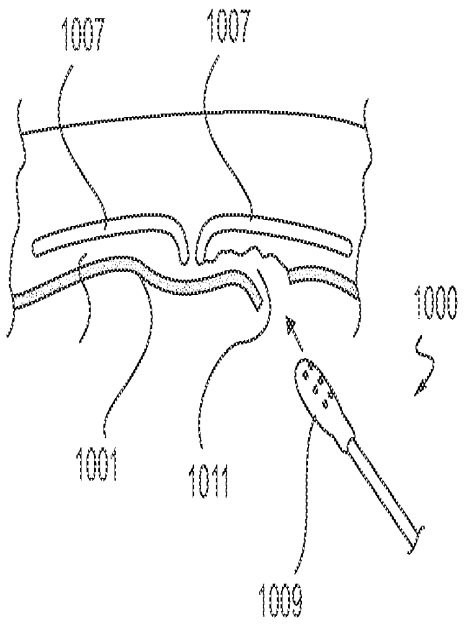


FIG. 46B

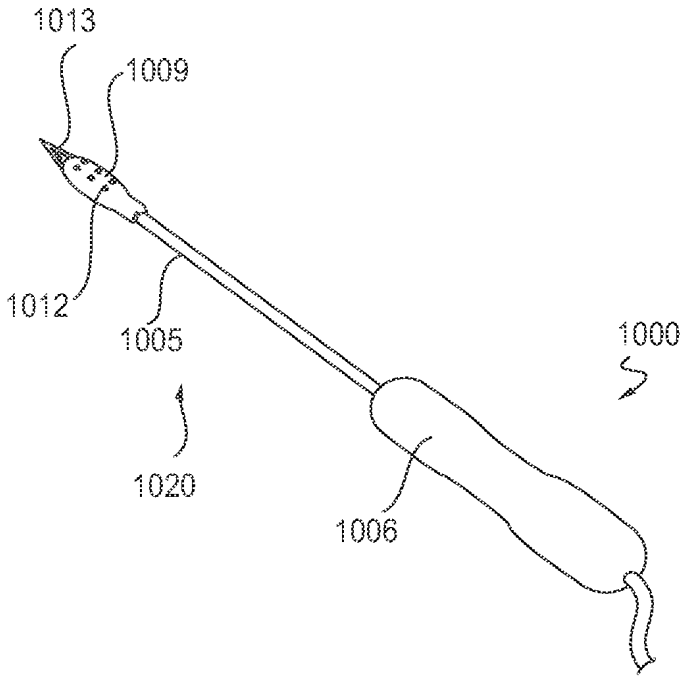


FIG. 47

Electronic Acknowledgement Receipt

EFS ID:	22601160
Application Number:	14319087
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:	75149
Filer:	Scott Michael Smith/Laura Lee Mosier
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244992US01 (494912-9)
Receipt Date:	11-JUN-2015
Filing Date:	30-JUN-2014
Time Stamp:	12:58:19
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	Post Allowance Communication - Incoming	P22992US01_Notice_to_Corrected_Application_Papers_Drawings.pdf	117269 ec1418f992913f18000addb4ec22d4c48035a680	no	3

Warnings:	
Information:	

2	Post Allowance Communication - Incoming	P244992US01_Response_4-27-15_Notice.pdf	124272 b8c2dbaaf607f87b434624c75b1f9f9075b7be84	no	1
Warnings:					
Information:					
3	Drawings-only black and white line drawings	P22992US01_Replacement_Drawings.pdf	1201693 9252896ad57ea52b667b2993f995efff16c4f135	no	61
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
			Total Files Size (in bytes):	1443234	

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<u>New Applications Under 35 U.S.C. 111</u>
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.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
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.

Receipt date: 10/06/2014 14319087 - GAU: 3762

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/319,087
	Filing Date	June 30, 2014
	First Named Inventor	Scott J. WOLF
	Art Unit	7653
	Examiner Name	MANUEL, George C.
	Attorney Docket Number	P244992US01 (494912-9)

		6,575,969		2003-06-10	RITTMAN, III, *et al.*	
		6,589,235	B2	2003-07-08	WONG, *et al.*	
		6,659,106	B1	2003-12-09	HOVDA, *et al.*	
		6,911,027	B1	2005-06-28	EDWARDS, *et al.*	
		6,978,781	B1	2005-12-27	JORDAN	
		7,055,523	B1	2006-06-06	BROWN	
		7,114,495	B2	2006-10-03	LOCKWOOD	
		7,322,993	B2	2008-01-29	METZGER, *et al.*	
		7,416,550	B2	2008-08-26	PROTSENKO, *et al.*	
		7,442,191	B2	2008-10-28	HOVDA, *et al.*	
		7,780,730	B2	2010-08-24	SAIDI	
		7,824,394	B2	2010-11-02	MANSTEIN	
		7,850,683		2010-12-14	ELKINS, *et al.*	
		8,317,782		2012-11-27	~~OWENS, *et al.*~~ Ellman, et al.	

Change(s) applied to document, /D.H.P./ 4/25/2015

	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2002/0016588	A1	2002-02-07	WONG, *et al.*	
		2003/0208194		2003-11-06	HOVDA, *et al.*	
		2003/0225403	A1	2003-12-04	WOLOSZKO, *et al.*	
		2005/0119643		2005-06-02	SOBOL, *et al.*	
		2005/0222565	A1	2005-10-06	MANSTEIN	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

Receipt date: 10/06/2014 14319087 - GAU: 3762

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/319,087
	Filing Date	June 30, 2014
	First Named Inventor	Scott J. WOLF
	Art Unit	7653
	Examiner Name	MANUEL, George C.
	Attorney Docket Number	P244992US01 (494912-9)

		5,843,077		1998-12-01	EDWARDS	
		5,846,235		1998-12-08	PASRICHA, *et al.*	
		5,879,349		1999-03-09	EDWARDS	
		6,045,549		2000-04-04	SMETHERS, *et al.*	
		6,096,033		2000-08-01	TU, *et al.*	
		6,102,907		2000-08-15	SMETHERS, *et al.*	
		6,126,657		2000-10-03	EDWARDS, *et al.*	
Change(s) applied to document, /D.H.P./ 4/25/2015		6,131,579		October 17, 2000 ~~2013-10-17~~	THORSON, *et al.*	
		6,139,546		2000-10-31	KOENIG, *et al.*	
		6,152,143		2000-11-28	EDWARDS	
		6,165,173		2000-12-26	KAMDAR, *et al.*	
		6,179,803		2001-01-30	EDWARDS, *et al.*	
		6,210,355		2001-04-03	EDWARDS, *et al.*	
		6,228,079	B1	2001- 05-08	KOEING	
		6,231,569	B1	2001- 05-15	BEK, *et al.*	
		6,293,941	B1	2001-09-25	STRUL	
		6,309,386	B1	2001-10-30	BEK.	
		6,371,926	B1	2002-04-16	THORSON, *et al.*	
		6,383,181	B1	2002-05-07	JOHNSTON, *et al.*	
		6,425,151	B2	2002-07-30	BARNETT	
		6,431,174		2002-08-13	KUNDSON, *et al.*	
		6,451,013	B1	2002-09-17	BAYS, *et al.*	
		6,551,310	B1	2003-04-22	GANZ, *et al.*	
		6,562,036	B1	2003- 05-13	ELLMAN, *et al.*	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

Receipt date: 10/06/2014 14319087 - GAU: 3762

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

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Prior to First Official Action		
	Application Number	14/319,087
	Filing Date	June 30, 2014
	First Named Inventor	Scott J. WOLF
	Art Unit	7653
	Examiner Name	MANUEL, George C.
	Attorney Docket Number	P244992US01 (494912-9)

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4,887,605		1989-12-19	ANGELSE, *et al.*	
		5,348,008		1994-09-20	BORNN, *et al.*	
		5,674,191		October 7, 1997 ~~1995-10-07~~	EDWARDS, *et al.*	
		5,533,499		1996-07-09	JOHNSON	
		5,624,439		1997-04-29	EDWARDS, *et al.*	
		5,823,197		October 20, 1998 ~~1997-10-20~~	EDWARDS	
		5,707,349		1998-01-13	EDWARDS	
		5,718,702		1998-02-17	EDWARDS	
		5,728,094		1998-03-17	EDWARDS	
		5,730,719		1998-03-24	EDWARDS	
		5,738,114		1998-04-14	EDWARDS	
		5,743,870		1998-04-28	EDWARDS	
		5,743,904		1998-04-28	EDWARDS	
		5,746,224		1998- 05-05	EDWARDS	
		5,800,429		1998-09-01	EDWARDS	
		5,807,306		1998-09-15	SHAPLAND, *et al.*	
		5,816,095		1998-10-06	NORDELL, *et al.*	
		5,817,049		1998-10-06	EDWARDS	
		5,820,580		1998-10-13	EDWARDS, *et al.*	
		5,827,277		1998-10-27	EDWARDS	
		5,843,021		1998-12-01	EDWARDS, *et al.*	

Change(s) applied to document, /D.H.P./ 4/25/2015

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

UNITED STATES PATENT AND TRADEMARK OFFICE

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Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/319,087	07/07/2015	9072597	P244992US01 (494912-9)	7653

75149 7590 06/17/2015

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Scott J. WOLF, Menlo Park, CA;
AERIN MEDICAL, INC., Menlo Park, 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.

Docket No.: P244992.US.01 (494912-9)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Scott J. Wolf	*Patent No.: 9,072,597*	
Appln. No.:	14/319,087	Confirmation No.	7653
Filing Date:	June 30, 2014	Examiner:	George C. Manuel
Title:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	Group Art Unit:	3762

MISCELLANEOUS INCOMING LETTER

Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

FILED VIA EFS-WEB

To the Commissioner:

Applicant respectfully requests that the Patent Office update the name of the Applicant in connection with the above-captioned application as shown below and presented on the revised Application Data Sheet enclosed herewith.

AERIN MEDICAL INC.

It is believed that no payments are due in connection with this filing. The Commissioner is authorized to charge any fees that may be required, including extension fees and other relief under 37 C.F.R. § 1.16 and § 1.17, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

DORSEY WHITNEY LLP
Customer Number 25763

Date: September 20, 2016

By: /Scott M. Smith/
Scott M. Smith, Reg. No. 48,268
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-498
Tel: (612) 492-6714

Electronic Acknowledgement Receipt

EFS ID:	26979207
Application Number:	14319087
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:	75149
Filer:	Scott Michael Smith/Katherine Benton
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	P244992US01 (494912-9)
Receipt Date:	20-SEP-2016
Filing Date:	30-JUN-2014
Time Stamp:	14:56:32
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	Application Data Sheet	P244992US01_REVISED_ADS.pdf	7192824 55bec4132414f2e158fcfdf8bacc3ac12c129ef0	no	6

Warnings:

Information:					
This is not an USPTO supplied ADS fillable form					
2	Miscellaneous Incoming Letter	P244992US01_Request_Update_Applicant_Name.pdf	468535 d194cbe66559eb3882573dd002f1df4fa190e0c2	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	7661359	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/14 (03-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P244992US01 (494912-9)
	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	Menlo Park	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	319 Trenton Way		
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Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		FRAZIER	

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

City	Sunnyvale	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

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Postal Code	94087	Country i	US

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

Correspondence Information:

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

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Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

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

Application Information:

Title of the Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		
Attorney Docket Number	P244992US01 (494912-9)	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	61	**Suggested Figure for Publication (if any)**	

Publication Information:

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

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

Representative Information:

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

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

Domestic Benefit/National Stage Information:

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

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation in part of	13495844	2012-06-13
Prior Application Status	Expired		Remove

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

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

Foreign Priority Information:

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

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.

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

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

Authorization to Permit Access:

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

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

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

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

Applicant Information:

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

Applicant 1

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

Clear

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

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

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☒

Organization Name	~~AERIN MEDICAL, INC.~~ AERIN MEDICAL INC.

Mailing Address Information For Applicant:

Address 1	650 Page Mill Road		
Address 2			
City	Menlo Park	**State/Province**	CA
Country	US	Postal Code	94304
Phone Number		Fax Number	

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	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

Email Address	

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

Assignee Information including Non-Applicant Assignee Information:

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

Assignee 1

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

If the Assignee is an Organization check here. ☐

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

Mailing Address Information For Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country		Postal Code	
Phone Number		Fax Number	
Email Address			

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

Signature:

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

Signature	/Scott M. Smith, Reg. No. 48,268/			Date (YYYY-MM-DD)	2014-06-27
First Name	Scott M.	Last Name	SMITH	Registration Number	48268

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

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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.**