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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/514,316	02/08/2022	11241271	17713.0001US14	2153

23552 7590 01/19/2022

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 305 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.

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

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

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Aerin Medical Inc., Austin, TX;

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.

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PATENT AND TRADEMARK OFFICE

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/514,316	12/23/2021 04:50:36 PM ET	17713.0001US14

Title of Invention

METHODS OF TREATING NASAL AIRWAYS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	2153	FILED BY	Theresa Powless
PATENT CENTER #	60460113	AUTHORIZED BY	Robert Kalinsky
CUSTOMER #	23552	FILING DATE	07/17/2019
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Scott J. WOLF

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 4938	E2021BMG51444476	Theresa Powless

PRE-AUTHORIZED ACCOUNT	PRE-AUTHORIZED CATEGORY
132725	37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees); 37 CFR 1.19 (Document supply fees); 37 CFR 1.20 (Post Issuance fees); 37 CFR 1.21 (Miscellaneous fees and charges)

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2501	UTILITY ISSUE FEE	600.00	1	600.00
			TOTAL AMOUNT:	$600.00

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement

Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/514,316	**12/23/2021 04:50:36 PM ET**	**17713.0001US14**

Title of Invention

METHODS OF TREATING NASAL AIRWAYS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	2153	FILED BY	Theresa Powless
PATENT CENTER #	60460113	FILING DATE	07/17/2019
CUSTOMER #	23552	FIRST NAMED INVENTOR	Scott J. WOLF
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Robert Kalinsky

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2021-12-23--Part B-Fees Xmtl--17713.0001US14.PDF	1	Issue Fee Payment (PTO-85B)	104 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2021-12-23--Part B-Fees Xmtl--17713.0001US14.PDF	653E7C38D0F124882695646A82BBBE484C28FBE13E3A1E2AD CC492E002419B4385177114790B52C6A84D2C217ECCA48AF9 6A2149EE6673E9B066BA7C0BAFA2DA

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PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

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

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

23552 7590 11/03/2021

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

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

Certificate of Mailing or Transmission

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

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/514,316	07/17/2019	Scott J. WOLF	17713.0001US14	2153

TITLE OF INVENTION: METHODS OF TREATING NASAL AIRWAYS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	02/03/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
MANUEL, GEORGE C	3792	606-041000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

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

1 Merchant & Gould P.C.
2
3

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

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Aerin Medical Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Sunnyvale, California

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

4a. Fees submitted: ☒ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 13-2725

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature /Robert A. Kalinsky/ Date December 23, 2021

Typed or printed name Robert A. Kalinsky Registration No. 50,471

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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NOTICE OF ALLOWANCE AND FEE(S) DUE

23552 7590 11/03/2021

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

EXAMINER
MANUEL, GEORGE C

ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 11/03/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/514,316	07/17/2019	Scott J. WOLF	17713.0001US14	2153

TITLE OF INVENTION: METHODS OF TREATING NASAL AIRWAYS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	02/03/2022

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

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

23552 7590 11/03/2021

MERCHANT & GOULD P.C.
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MINNEAPOLIS, MN 55402-0903

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Certificate of Mailing or Transmission

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(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/514,316	07/17/2019	Scott J. WOLF	17713.0001US14	2153

TITLE OF INVENTION: METHODS OF TREATING NASAL AIRWAYS

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nonprovisional	SMALL	$600	$0.00	$0.00	$600	02/03/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
MANUEL, GEORGE C	3792	606-041000

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2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

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

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

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

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

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
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NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/514,316	07/17/2019	Scott J. WOLF	17713.0001US14	2153

23552 7590 11/03/2021

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

EXAMINER	
MANUEL, GEORGE C	
ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 11/03/2021

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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

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

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 16/514,316	Applicant(s) WOLF et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	AIA (FITF) Status Yes

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

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

1. ☑ This communication is responsive to the Terminal Disclaimer, filed 10/11/2021.
   ☐ 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 16-31 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

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

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

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/GEORGE MANUEL/
Primary Examiner, Art Unit 3792

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/514,316	WOLF et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61B17/2816, A61B17/320068, A61B18/02, A61B18/06, A61B18/085, A61B18/12, A61B18/1206, A61B18/14, A61B18/1442, A61B18/1445, A61B18/1477, A61B18/1485, A61B18/16, A61B18/18, A61B18/1815, A61B18/20, A61B2017/248, A61B2017/320069, A61B2017/32007, A61B2018/00005, A61B2018/00023, A61B2018/0016, A61B2018/00178, A61B2018/0022, A61B2018/00327, A61B2018/00577, A61B2018/00595, A61B2018/00642, A61B2018/00702, A61B2018/00708, A61B2018/00791, A61B2018/00821, A61B2018/00875, A61B2018/00886, A61B2018/0091, A61B2018/00922, A61B2018/00982, A61B2018/00994, A61B2018/0212, A61B2018/0225, A61B2018/0262, A61B2018/1253, A61B2018/126, A61B2018/1425, A61B2018/143, A61B2018/1807, A61B2018/1861, A61B5/01, A61F5/08, A61F5/56, A61F7/10, A61N1/403, A61N5/025, A61N5/0603, A61N5/0625, A61N7/022, F04C2270/041	07/14/2021	GM
Search Updated.	10/22/2021	GM

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
EAST Search Conducted. Inventor Name Search Conducted.	07/14/2021	GM

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/514,316	WOLF et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
A61B	17/2816, 17/320068, 18/02, 18/06, 18/085, 18/12, 18/1206, 18/14, 18/1442, 18/1445, 18/1477, 18/1485, 18/16, 18/18, 18/1815, 18/20, 2017/248, 2017/320069, 2017/32007, 2018/00005, 2018/00023, 2018/0016, 2018/00178, 2018/0022, 2018/00327, 2018/00577, 2018/00595, 2018/00642, 2018/00702, 2018/00708, 2018/00791, 2018/00821, 2018/00875, 2018/00886, 2018/0091, 2018/00922, 2018/00982, 2018/00994, 2018/0212, 2018/0225, 2018/0262, 2018/1253, 2018/126, 2018/1425, 2018/143, 2018/1807, 2018/1861, 5/01	10/22/2021	GM
A61N	1/403, 5/025, 5/0603, 5/0625, 7/022	10/22/2021	GM
A61F	5/08, 5/56, 7/10	10/22/2021	GM
F04C	2270/041	10/22/2021	GM

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/514,316	WOLF et al.
	Examiner	**Art Unit**
	GEORGE MANUEL	3792

CPC								
Symbol							**Type**	**Version**
A61B	/	18	/	14			F	2013-01-01
A61B	/	18	/	1485			I	2013-01-01
A61B	/	18	/	02			I	2013-01-01
A61B	/	18	/	1206			I	2013-01-01
A61N	/	1	/	403			I	2013-01-01
A61B	/	2017	/	320069			A	2017-08-01
A61B	/	2017	/	32007			A	2017-08-01
F04C	/	2270	/	041			A	2013-01-01
A61B	/	18	/	16			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	/	00005			A	2013-01-01
A61B	/	2018	/	00023			A	2013-01-01
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A61B	/	2017	/	248			A	2013-01-01
A61B	/	2018	/	00708			A	2013-01-01
A61B	/	18	/	12			A	2013-01-01
A61B	/	18	/	18			A	2013-01-01
A61B	/	18	/	1442			A	2013-01-01
A61B	/	18	/	1815			A	2013-01-01
A61B	/	18	/	20			A	2013-01-01
A61B	/	2018	/	00577			A	2013-01-01
A61B	/	2018	/	1807			A	2013-01-01
A61B	/	2018	/	1861			A	2013-01-01
A61F	/	5	/	08			A	2013-01-01
A61B	/	5	/	01			A	2013-01-01
A61B	/	18	/	06			A	2013-01-01
A61B	/	18	/	1445			A	2013-01-01
A61B	/	2018	/	0022			A	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	16	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	23 October 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	22A

U.S. Patent and Trademark Office — Part of Paper No.: 20211022

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/514,316	WOLF et al.
	Examiner	**Art Unit**
	GEORGE MANUEL	3792

CPC						
Symbol					**Type**	**Version**
A61B	/	2018	/	00595	A	2013-01-01
A61B	/	2018	/	00642	A	2013-01-01
A61B	/	2018	/	00875	A	2013-01-01
A61B	/	2018	/	00982	A	2013-01-01
A61B	/	2018	/	0212	A	2013-01-01
A61B	/	2018	/	0225	A	2013-01-01
A61B	/	18	/	085	A	2013-01-01
A61B	/	2018	/	0262	A	2013-01-01
A61B	/	2018	/	1253	A	2013-01-01
A61B	/	2018	/	126	A	2013-01-01
A61B	/	18	/	1477	A	2013-01-01
A61B	/	2018	/	0016	A	2013-01-01
A61B	/	2018	/	00178	A	2013-01-01
A61B	/	2018	/	00791	A	2013-01-01
A61B	/	2018	/	00886	A	2013-01-01
A61B	/	2018	/	1425	A	2013-01-01
A61F	/	5	/	56	A	2013-01-01
A61N	/	5	/	025	A	2013-01-01
A61N	/	5	/	0603	A	2013-01-01
A61N	/	5	/	0625	A	2013-01-01
A61B	/	17	/	320068	A	2013-01-01
A61B	/	17	/	2816	A	2013-01-01
A61B	/	2018	/	0091	A	2013-01-01
A61B	/	2018	/	00994	A	2013-01-01
A61F	/	7	/	10	A	2013-01-01
A61N	/	7	/	022	A	2013-01-01

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

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	16	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	23 October 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	22A

U.S. Patent and Trademark Office — Part of Paper No.: 20211022

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/514,316	WOLF et al.
	Examiner	**Art Unit**
	GEORGE MANUEL	3792

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B18/14	/	18	/	14	

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	16	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	23 October 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	22A

U.S. Patent and Trademark Office — Part of Paper No.: 20211022

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/514,316	WOLF et al.
	Examiner	**Art Unit**
	GEORGE MANUEL	3792

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	16	10	25												
2	17	11	26												
3	18	12	27												
4	19	13	28												
5	20	14	29												
6	21	15	30												
7	22	16	31												
8	23														
9	24														

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	16	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	23 October 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	22A

U.S. Patent and Trademark Office — Part of Paper No.: 20211022

Bibliographic Data

Application No: 16/514,316

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /GEORGE MANUEL/ Examiner's Signature | Initials

Title: METHODS OF TREATING NASAL AIRWAYS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/17/2019	606	3792	17713.0001US14
RULE			

APPLICANTS

Aerin Medical Inc., Austin, TX,

INVENTORS

Scott J. WOLF, Menlo Park, CA, UNITED STATES

Andrew FRAZIER, Sunnyvale, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 15596455 05/16/2017 PAT 10398489

15596455 is a CON of 15248935 08/26/2016 PAT 9687296

15248935 is a CON of 14864428 09/24/2015 PAT 9433463

14864428 is a CON of 14737196 06/11/2015 PAT 9179967

14737196 is a CON of 14607639 01/28/2015 PAT 9179964

14607639 is a CON of 14026922 09/13/2013 PAT 8986301

14026922 is a CIP of 13495844 06/13/2012 PAT 8936594

13495844 has PRO of 61603864 02/27/2012

13495844 has PRO of 61496930 06/14/2011

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

07/30/2019

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STATE OR COUNTRY

UNITED STATES

ADDRESS

MERCHANT & GOULD P.C.

P.O. BOX 2903

MINNEAPOLIS, MN 55402-0903
UNITED STATES

FILING FEE RECEIVED

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

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	Scott J. WOLF
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	17713.0001US14

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5611798	A	1997-03-18	EGGERS	
	2	9770293	B2	2017-09-26	Dresher	

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020010460	A1	2002-01-24	JOYE et al.	
	2	20040210214	A1	2004-10-21	Knowlton	
	3	20050234443	A1	2005-10-20	Rioux et al.	
	4	20060190022	A1	2006-08-24	Beyar et al.	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	Scott J. WOLF
	Art Unit	3792
	Examiner Name	George C. Manuel
	Attorney Docket Number	17713.0001US14

	5	20080004613	A1	2008-01-03	Barbut et al.	
	6	20090299355	A1	2009-12-03	Bencini et al.	
	7	20110301587	A1	2011-12-08	Deem et al.	
	8	20120029512	A1	2012-02-02	Willard et al.	
	9	20120179154	A1	2012-07-12	Goldberg et al.	
	10	20120310233	A1	2012-12-06	Dimmer et al.	
	11	20130116679	A1	2013-05-09	Van der Weide et al.	
	12	20150164571	A1	2015-06-18	SAADAT	
	13	20180333195	A1	2018-11-22	Greep et al.	

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

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Scott J. WOLF
	Art Unit	3792
	Examiner Name	George C. Manuel
	Attorney Docket Number	17713.0001US14

	1						

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Extended European Search Report for Application No. 21172995.9 mailed July 9, 2021.	

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

EXAMINER SIGNATURE

Examiner Signature	/GEORGE MANUEL/	Date Considered	10/22/2021

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

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	Scott J. WOLF
	Art Unit	3792
	Examiner Name	George C. Manuel
	Attorney Docket Number	17713.0001US14

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Robert A. Kalinsky/	Date (YYYY-MM-DD)	2021-10-11
Name/Print	Robert A. Kalinsky	Registration Number	50471

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

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	18	(nasal and airway and treat$4 and tissue and mucosa same heat$4 and reduc$4 with mucus) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/12 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/18 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2017/320069 OR A61B2017/32007 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	US-PGPUB	OR	ON	2021/10/22 21:35
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EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	14	(nasal and airway and treat$4 and tissue and mucosa same heat$4 and reduc$4 with mucus) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/12 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/18 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2017/320069 OR A61B2017/32007 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	USPAT	OR	ON	2021/10/22 21:37
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Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
* 16/514,316 *	16/514,316	WOLF et al.	
	Examiner	Art Unit	
	MANUEL, GEORGE C	3792	

Document Code - DISQ	Internal Document - DO NOT MAIL

TERMINAL DISCLAIMER	☑ APPROVED	☐ DISAPPROVED
Date Filed: 11 October 2021	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

/CHARRISSA S BROWN/

Technology Center: PLRC

Telephone: (571)272-1558

PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 17713.0001US14

In re Application of: Scott J. WOLF

Application No.: 16/514,316

Filed: July 17, 2019

For: METHODS OF TREATING 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 **prior patent** No. 10,398,489 as the term of said **prior patent** is presently shortened by any terminal disclaimer. 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 the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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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. 50,471

/Robert A. Kalinsky/ — Signature
October 11, 2021 — Date

Robert A. Kalinsky — Typed or printed name

Attorney — Title
(612) 336-4771 — Telephone Number

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	Scott J. WOLF
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	17713.0001US14

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5611798	A	1997-03-18	EGGERS	
	2	9770293	B2	2017-09-26	Dresher	

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	1	20020010460	A1	2002-01-24	JOYE et al.	
	2	20040210214	A1	2004-10-21	Knowlton	
	3	20050234443	A1	2005-10-20	Rioux et al.	
	4	20060190022	A1	2006-08-24	Beyar et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Scott J. WOLF
	Art Unit	3792
	Examiner Name	George C. Manuel
	Attorney Docket Number	17713.0001US14

	5	20080004613	A1	2008-01-03	Barbut et al.	
	6	20090299355	A1	2009-12-03	Bencini et al.	
	7	20110301587	A1	2011-12-08	Deem et al.	
	8	20120029512	A1	2012-02-02	Willard et al.	
	9	20120179154	A1	2012-07-12	Goldberg et al.	
	10	20120310233	A1	2012-12-06	Dimmer et al.	
	11	20130116679	A1	2013-05-09	Van der Weide et al.	
	12	20150164571	A1	2015-06-18	SAADAT	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	Scott J. WOLF
	Art Unit	3792
	Examiner Name	George C. Manuel
	Attorney Docket Number	17713.0001US14

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	1	Extended European Search Report for Application No. 21172995.9 mailed July 9, 2021.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	Scott J. WOLF
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	17713.0001US14

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).

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See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Robert A. Kalinsky/	Date (YYYY-MM-DD)	2021-10-11
Name/Print	Robert A. Kalinsky	Registration Number	50471

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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.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/514,316	10/11/2021 04:19:59 PM ET	17713.0001US14

Title of Invention

METHODS OF TREATING NASAL AIRWAYS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	2153	FILED BY	Theresa Powless
PATENT CENTER #	60349365	AUTHORIZED BY	Robert Kalinsky
CUSTOMER #	23552	FILING DATE	07/17/2019
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Scott J. WOLF

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 4938	E20210AG21153783	Theresa Powless

PRE-AUTHORIZED ACCOUNT	PRE-AUTHORIZED CATEGORY
132725	37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees); 37 CFR 1.19 (Document supply fees); 37 CFR 1.20 (Post Issuance fees); 37 CFR 1.21 (Miscellaneous fees and charges)

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	130.00	1	130.00
2814	STATUTORY DISCLAIMER, INCLUDING TERMINAL DISCLAIMER	170.00	1	170.00
			TOTAL AMOUNT:	$300.00

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/514,316	**10/11/2021 04:19:59 PM ET**	**17713.0001US14**

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CUSTOMER #	23552	FIRST NAMED INVENTOR	Scott J. WOLF
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Robert Kalinsky

Documents

TOTAL DOCUMENTS: 4

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2021-10-11--Amendment--17713.0001US14.PDF	3	Amendment/Req. Reconsideration-After Non-Final Reject	72 KB
2021-10-11--Terminal-Disclaimer_17713.0001US14.PDF	2	Terminal Disclaimer Filed	168 KB
2021-10-11--IDS-7--17713.0001US14.PDF	5	Information Disclosure Statement (IDS) Form (SB08)	1011 KB
Extended-European-Search-Report-for-21172995-9-mailed-07-09-2021.PDF	8	Non Patent Literature	1523 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2021-10-11--Amendment--17713.0001US14.PDF	9F9E93C6578EE279B7DF794D41A3329213AE4F282043DEC2F19B32E771AD4A556C14748B6D5EA69A7B4E1A0C316461FED238C9AE3DF6E466060E16C7213559BF
2021-10-11--Terminal-Disclaimer_17713.0001US14.PDF	F510F261B9E900704FDC478FCC8F808D41635472198EF80A3AB6278F22C823674E1EB49E4669B1A0B9EE1D9CC60EA3BE29E5DBC6DDC1FDB9E2C7CECF09A93D06
2021-10-11--IDS-7--17713.0001US14.PDF	904EDCBF138889CB4A677D69B5229D001F7BBFD9688027484540BC1EF00C903BC16AA5AECDE7175B75DE499EAEE1DC266A9FF4CE1D4A5977A62FBF2DBE2B1B64
Extended-European-Search-Report-for-21172995-9-mailed-07-09-2021.PDF	52AE7CBD3968EC216710D9C4342D8921034DC3876E65A0782EFD27D71FBEB797CEF2513F492C47A249C5B2263954A2789351E80D3577FB727FFD9B6A1B97B899

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

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Scott J. WOLF	Examiner:	MANUEL
Appl. No.	16/514,316	Art Unit:	3792
Filed:	July 17, 2019	Docket No.	17713.0001US14
Customer No.	23552	Confirmation No.:	2153
Title:	METHODS OF TREATING NASAL AIRWAYS		

AMENDMENT

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

Dear Examiner Manuel,

In response to the Non-Final Office Action of July 19, 2021, please consider and enter the following amendments and remarks.

If a petition for an extension of time under 37 C.F.R. § 1.136(a) is necessary to maintain the pendency of this patent application in connection with this response, and is not otherwise requested in this patent application, it is requested that the Commissioner consider this paper to be a petition for an appropriate extension of time and an authorization for the Commissioner to charge the fee as set forth in 37 C.F.R. § 1.17(a) corresponding to the needed extension of time to Deposit Account No. 13-2725.

REMARKS

Claims 16-31 were pending and stand rejected by the Office Action of July 19. 2021. Applicant respectfully requests reexamination and reconsideration for at least the following reasons.

Non-Statutory Double Patenting Rejection

Claims 16-31 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 10,398,489. This rejection is respectfully traversed.

While the correctness the rejection is not conceded, a terminal disclaimer is filed. Reconsideration is therefore requested.

Allowable Subject Matter

Claims 16-31 are rejected, but would be allowable subject to filing an acceptable Terminal Disclaimer.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding, in this application, that previously pending claims are not patentable over the cited references. Rather any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue, at a later date, any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviews of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

In view of the foregoing, Applicant respectfully submits that this application now stands in condition for allowance. Should the Examiner believe that a telephone interview would further the prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: October 11, 2021

/Robert A. Kalinsky/
Name: Robert A. Kalinsky
Reg. No.: 50,471

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/514,316	07/17/2019	Scott J. WOLF	17713.0001US14	2153

23552 7590 07/19/2021

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

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
07/19/2021	ELECTRONIC

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

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

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

USPTO23552@merchantgould.com

Office Action Summary	Application No. 16/514,316	Applicant(s) WOLF et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	AIA (FITF) Status Yes

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

Period for Reply

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

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

Status

1)☑ Responsive to communication(s) filed on 8/25/2020.

☐ 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) 16-31 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) 16-31 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 7/17/2019 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

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

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

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 conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *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 nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to

examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) 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 www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 16-31 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 10,398,489. Although the claims at issue are not identical, they are not patentably distinct from each other because causing a reduction in mucus production in the nasal airway is an obvious result from the claimed radiofrequency energy passing through the nasal mucosa to underlying submucosal tissue as claimed in claim 11 of U.S. Patent No. 10,398,489. Present claims 19, 23 and 24 provide sinusoidal waveform energy and temperature ranges equivalent to the ranges provided in claims 4, 8 and 9 of U.S. Patent No. 10,398,489. Claim 10 of U.S. Patent No. 10,398,489 suggests applying the radiofrequency energy for at least 15 seconds, within the range presently claimed in claim 25 of the present application.

It is reasonable to expect a reduction in mucus using the applied radiofrequency energy as claimed in claims 1-15 of U.S. Patent No. 10,398,489.

A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 416, 82 USPQ2d 1385, 1395 (2007); *Sakraida v. AG Pro, Inc.,* 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.,* 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equip. Corp.,* 340 U.S. 147, 152, 87 USPQ 303, 306 (1950). See MPEP 2143.02.

Regarding claim 30, it is well known and obvious to use conductivity enhancing substances before contacting a treatment element to ensure a solid treatment element/tissue interface is present for the treatment duration.

Regarding claim 31, it would have been obvious to bend a shaft of the treatment device claimed in claims 1-15 of U.S. Patent No. 10,398,489 to position the device for interfacing the treatment device with the nasal mucosa.

Allowable Subject Matter

Claims 16-31 are rejected, but would be allowable subject to filing an acceptable Terminal Disclaimer.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hovda et al (US 2006/0253117) teach a bend in the distal portion of shaft 100 is particularly advantageous in the treatment of sinus tissue as it allows the surgeon to reach the target tissue within the nose as the shaft 100 extends through the nasal passage. In addition, an electrically conducting gel or spray, such as a saline electrolyte or other conductive gel, may be applied the target site. See paragraphs [0090] and [0014].

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

The examiner can normally be reached on regular business days.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George Manuel/
Primary Examiner
Art Unit: 3792

7/14/2021

Notice of References Cited	Application/Control No. 16/514,316	Applicant(s)/Patent Under Reexamination WOLF et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20060253117-A1	11-2006	Hovda; David C.	A61B18/1402	606/48
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/514,316	WOLF et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

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

CLAIMS

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

CLAIM		DATE								
Final	Original	07/14/2021								
	16	✓								
	17	✓								
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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/514,316	WOLF et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

CPC - Searched*		
Symbol	Date	Examiner
A61B17/2816, A61B17/320068, A61B18/02, A61B18/06, A61B18/085, A61B18/12, A61B18/1206, A61B18/14, A61B18/1442, A61B18/1445, A61B18/1477, A61B18/1485, A61B18/16, A61B18/18, A61B18/1815, A61B18/20, A61B2017/248, A61B2017/320069, A61B2017/32007, A61B2018/00005, A61B2018/00023, A61B2018/0016, A61B2018/00178, A61B2018/0022, A61B2018/00327, A61B2018/00577, A61B2018/00595, A61B2018/00642, A61B2018/00702, A61B2018/00708, A61B2018/00791, A61B2018/00821, A61B2018/00875, A61B2018/00886, A61B2018/0091, A61B2018/00922, A61B2018/00982, A61B2018/00994, A61B2018/0212, A61B2018/0225, A61B2018/0262, A61B2018/1253, A61B2018/126, A61B2018/1425, A61B2018/143, A61B2018/1807, A61B2018/1861, A61B5/01, A61F5/08, A61F5/56, A61F7/10, A61N1/403, A61N5/025, A61N5/0603, A61N5/0625, A61N7/022, F04C2270/041	07/14/2021	GM

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST Search Conducted. Inventor Name Search Conducted.	07/14/2021	GM

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/514,316	WOLF et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

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

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	WOLF
Art Unit	4187
Examiner Name	
Attorney Docket Number	17713.0001US14

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7361168		2008-04-22	Makower	
	2	7997278		2011-08-16	Utley	
	3	8114062		2012-02-14	Muni	
	4	10335221		2019-07-02	Wolf et al.	
	5	10376300		2019-08-13	Wolf et al.	
	6	10398489		2019-09-03	Wolf	

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	1	20040193238		2004-09-30	Mosher	
	2	20070049999		2007-03-01	Esch	
	3	20080154237		2008-06-26	Chang	
	4	20080183251		2008-07-31	Azar	
	5	20100204560		2010-08-12	Salahieh	
	6	20100260703		2010-10-14	Yankelson	
	7	20110118726		2011-05-19	De La Rama	
	8	20130158536		2013-06-20	Bloom	
	9	20160045277		2016-02-18	Lin	
	10	20160121112		2016-05-05	Azar	
	11	20190231409		2019-08-01	Wolf et al.	

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Examiner Signature	/GEORGE MANUEL/	Date Considered	07/14/2021

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	WOLF
	Art Unit	4187
	Examiner Name	
	Attorney Docket Number	17713.0001US14

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/ Christopher P. Ziolkowski /	Date (YYYY-MM-DD)	2019-09-11
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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

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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.

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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.

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	6	("10398489".pn. or "9687296".pn. or "9433463".pn. or "9179967".pn. or "9179964".pn. or "8986301".pn. or "8936594".pn.) and heat$4 and mucus and conduct$5	USPAT	OR	ON	2021/07/14 18:00
L2	6	("10398489".pn. or "9687296".pn. or "9433463".pn. or "9179967".pn. or "9179964".pn. or "8986301".pn. or "8936594".pn.) and heat$4 and mucus and bend$5	USPAT	OR	ON	2021/07/14 18:01
L3	6	("10398489".pn. or "9687296".pn. or "9433463".pn. or "9179967".pn. or "9179964".pn. or "8986301".pn. or "8936594".pn.) and heat$4 and mucus and shaft	USPAT	OR	ON	2021/07/14 18:29
L6	13	(nasal and airway and treat$4 and heat$4 and tissue and nasal with shaft with bend$4) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/12 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/18 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2017/320069 OR A61B2017/32007 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	US-PGPUB	OR	ON	2021/07/14 18:48

L7	1	(nasal and airway and treat$4 and heat$4 and tissue and nasal with shaft with bend$4 and conductive adj gel) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/12 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/18 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2017/320069 OR A61B2017/32007 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	US-PGPUB	OR	ON	2021/07/14 18:52
L8	261	(nasal and airway and treat$4 and heat$4 and tissue and mucosa) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/12 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/18 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2017/320069 OR A61B2017/32007 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08	US-PGPUB	OR	ON	2021/07/14 19:21

		OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)				
L9	75	(nasal and airway and treat$4 and tissue and mucosa same heat$4) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/12 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/18 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2017/320069 OR A61B2017/32007 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	US-PGPUB	OR	ON	2021/07/14 19:22
L10	18	(nasal and airway and treat$4 and tissue and mucosa same heat$4 and reduc$4 with mucus) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/12 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/18 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2017/320069 OR A61B2017/32007 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR	US-PGPUB	OR	ON	2021/07/14 19:23

		A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)				
L11	39	(nasal and airway and treat$4 and tissue and mucosa same heat$4 and reduc$4 with mucus)	US-PGPUB	OR	ON	2021/07/14 19:52
L12	16	(nasal and airway and treat$4 and tissue and mucosa same heat$4 and reduc$4 with mucus)	USPAT	OR	ON	2021/07/14 19:57
S1	2	"16514316"	US-PGPUB	OR	ON	2021/07/14 13:20
S3	517	(nasal and airway and treat$4 and heat$4 and tissue) AND ((A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/12 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/18 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2017/320069 OR A61B2017/32007 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00791 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1807 OR A61B2018/1861 OR A61B5/01 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).CPC.)	US-PGPUB	OR	ON	2021/07/14 13:32
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S6	6	("10456185" | "10456186" | "10470814" | "10485603" | "20190282289" | "20190343577").PN.	US-PGPUB; USPAT	OR	OFF	2021/07/14 13:54

S7	17	("10335221" | "10376300" | "10398489" | "20040193238" | "20070049999" | "20080154237" | "20080183251" | "20100204560" | "20100260703" | "20110118726" | "20130158536" | "20160045277" | "20160121112" | "20190231409" | "7361168" | "7997278" | "8114062").PN.	US-PGPUB; USPAT	OR	OFF	2021/07/14 13:55
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S11	119	((("WOLF") near3 ("Scott") near3 ("J"))).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/14 14:19
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EAST Search History (Interference)

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

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	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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	4	2003024349	WO		2003-03-27			
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	7	2010077980	WO		2010-07-08			
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	9	2015047863	WO		2015-04-02			

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

	10	2015048806	WO		2015-04-02			
	11	2015153696	WO		2015-10-08			

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	1	'Buckley et al., "High-resolution spatial mapping of shear properties in cartilage," J Biomech., 2010 Mar 3;43 (4):796-800, Epub Nov. 5, 2009".	
	2	'Buckley et al., "Mapping the depth dependence of shear properties in articular cartilage," J Biomech., 41 (11):2430-2437, Epub Jul. 10, 2008".	
	3	'Chen et al., China Journal of Endoscopy, Vol. 11, No. 3. pp. 239-243, March 2005, [English Translation of Title] 'Radiofrequency treatment of nasal posterior-under nerve ethmoidal nerve and infraturbinal for perennial allergic rhinitis under nasal endoscope," [also translated as] "Preliminary exploration of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerve, and inferior nasal concha under nasal endoscopy in the treatment of perennial allergic rhinitis." 9 pages.".	
	4	'Cole, "Biophysics of nasal airflow: a review," Am J Rhinol., 14(4):245-249, Jul-Aug. 2000".	
	5	'Cole, "The four components of the nasal valve," Am J Rhinol., 17(2):107-110, Mar-Apr. 2003".	
	6	'Fang et al., J First Mil Med Univ, Vol. 25 No. 7, pp. 876-877, 2005, [English translation of title] "Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis" [also translated as] "Nasal Endoscopic Surgery Combined with Multisite Radiofrequency Technology for Treating Perennial Allergic Rhinitis," 4 pages.".	
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	8	"Kjaergaard et al., "Relation of nasal air flow to nasal cavity dimensions," Arch Otolaryngol Head Neck Surg., 135 (6):565-570, Jun 2009".	
	9	"Kong et al., Journal of Clinical Otorhinolaryngology, 2005. "Clinical observation on radiofrequency ablation treatment in perennial allergic rhinitis," Retrieved from the Internet: <URL:http://en.cnki.com.cn/Article_en/CJFDTOTAL-LCEH200505015.htm>, 1 page.".	
	10	"Silverberg et al., "Structure-function relations and rigidity percolation in the shear properties of articular cartilage," Biophys J., 107(7):1721-1730, Oct. 7, 2014".	
	11	"Stewart et al., "Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale," Otolaryngol Head Neck Surg., 130(2):157-163, Feb. 2004".	
	12	"Stupak, "A Perspective on the Nasal Valve," Dept. of Otorhinolaryngology, Albert Einstein College of Medicine, Nov. 6, 2009".	
	13	"Stupak, "Endonasal repositioning of the upper lateral cartilage and the internal nasal valve," Ann Otol Rhinol Laryngol., 120(2):88-94, Feb. 2011".	
	14	"International Search Report and Written Opinion for PCT/US2012/042316, mailed Aug. 24, 2012, 15 pages".	
	15	"International Search Report and Written Opinion for PCT/US2014/054726, mailed December 23, 2014, 5 pages".	
	16	"Liu et al., China Journal of Endoscopy, Vol. 14, No. 11, pp. 1127-1130, November 2008, [English Translation of Title] "Impact of treatment of perennial rhinitis by radiofrequency thermo-coagulations to vidian and antirior ethomoidal nerves on mucociliary clearance," [also translated as] "Impact of radiofrequency thermocoagulation of bilateral vidian and anterior ethmoidal nerve cluster regions on nasal mucociliary transport function in perennial allergic rhinitis and vasomotor rhinitis." 12 pages.".	
	17	"Search Report in European Application No. 18204723.3 dated February 18, 2019, 8 pages.".	
	18	"International Search Report and Written Opinion for PCT/US2015/023742, mailed June 29, 2015, 5 pages".	

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	Attorney Docket Number	17713.0001US14

	19	"Singapore Search Report for Application Serial No. 201309238-2, mailed April 17, 2014, 27 pages".
	20	"Supplementary European Search Report for Application No. 15772528, mailed September 26, 2017, 7 pages".

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Signature	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2019-07-17
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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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.

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(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	WOLF
Art Unit	4187
Examiner Name	
Attorney Docket Number	17713.0001US14

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	1	9247989	B2	2016-02-02	Truckai	
	2	10603059	B2	2020-03-31	Dinger et al.	
	3	10631925	B2	2020-04-28	Wolf et al.	

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	1	20040215235	A1	2004-10-28	Jackson et al.	
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	First Named Inventor	WOLF
	Art Unit	4187
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	Attorney Docket Number	17713.0001US14

	4	20080255642	A1	2008-10-16	Zarins et al.	
	5	20100160906	A1	2010-06-24	Jarrard	
	6	20110288477	A1	2011-11-24	Ressemann et al.	
	7	20200100829	A1	2020-04-02	Wolf et al.	
	8	20200129223	A1	2020-04-30	Angeles et al.	

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Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	2020-05-21
Name/Print	Scott M. Smith	Registration Number	48268

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	1	Extended European Search Report for Application No. 19199126.4, mailed December 9, 2019, 6 pages.	

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Signature	/ Christopher P. Ziolkowski /	Date (YYYY-MM-DD)	2020-02-20
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	WOLF
Art Unit	4187
Examiner Name	
Attorney Docket Number	17713.0001US14

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	D 880694	S	2020-04-07	Ng et al.	
	2	D 881904	S	2020-04-21	Angeles et al.	
	3	9027597	B2	2015-05-12	Kubo	
	4	10722282		2020-07-28	Wolf	

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	1	20060195169	A1	2006-08-31	Gross et al.	
	2	20200170699	A1	2020-06-04	WOLF et al.	

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	3	20200205884	A1	2020-07-02	WOLF et al.	

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Examiner Signature	/GEORGE MANUEL/	Date Considered	07/14/2021

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Signature	/ Christopher P. Ziolkowski /	Date (YYYY-MM-DD)	2020-08-25
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	10485603	B2	2019-11-26	Wolf et al.	
	2	10470814	B2	2019-11-12	Wolf et al.	
	3	10456186	B1	2019-10-29	Wolf et al.	
	4	10456185	B2	2019-10-29	Wolf et al.	

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	1	20190343577	A1	2019-11-14	WOLF et al.	
	2	20190282289	A1	2019-09-19	WOLF et al.	

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	1	2013028998	WO	A2	2013-02-28	HUSZAR et al.		

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Signature	/ Christopher P. Ziolkowski /	Date (YYYY-MM-DD)	2019-12-05
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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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:

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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.

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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)).

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	40374505
Application Number:	16514316
International Application Number:	
Confirmation Number:	2153
Title of Invention:	METHODS OF TREATING NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US14
Receipt Date:	25-AUG-2020
Filing Date:	17-JUL-2019
Time Stamp:	12:57:41
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)	2020-08-25_IDS_17713-0001US14.PDF	1034419 e116b94db9362d75bf21e0f6aea6c9d04e7e20e7	no	4

Warnings:

Information:	
Total Files Size (in bytes):	1034419

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New Applications Under 35 U.S.C. 111

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

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

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

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	WOLF
Art Unit	4187
Examiner Name	
Attorney Docket Number	17713.0001US14

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	9247989	B2	2016-02-02	Truckai	
	2	10603059	B2	2020-03-31	Dinger et al.	
	3	10631925	B2	2020-04-28	Wolf et al.	

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040215235	A1	2004-10-28	Jackson et al.	
	2	20070043350	A1	2007-02-22	Soltesz et al.	
	3	20070244529	A1	2007-10-18	Choi et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	WOLF
	Art Unit	4187
	Examiner Name	
	Attorney Docket Number	17713.0001US14

	4	20080255642	A1	2008-10-16	Zarins et al.	
	5	20100160906	A1	2010-06-24	Jarrard	
	6	20110288477	A1	2011-11-24	Ressemann et al.	
	7	20200100829	A1	2020-04-02	Wolf et al.	
	8	20200129223	A1	2020-04-30	Angeles et al.	

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

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	WOLF
	Art Unit	4187
	Examiner Name	
	Attorney Docket Number	17713.0001US14

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	WOLF
	Art Unit	4187
	Examiner Name	
	Attorney Docket Number	17713.0001US14

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Scott M. Smith/	Date (YYYY-MM-DD)	2020-05-21
Name/Print	Scott M. Smith	Registration Number	48268

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

Privacy Act Statement

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Electronic Acknowledgement Receipt

EFS ID:	39510852
Application Number:	16514316
International Application Number:	
Confirmation Number:	2153
Title of Invention:	METHODS OF TREATING NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Scott Michael Smith/Juliana Hoffman
Filer Authorized By:	Scott Michael Smith
Attorney Docket Number:	17713.0001US14
Receipt Date:	21-MAY-2020
Filing Date:	17-JUL-2019
Time Stamp:	17:26:26
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)	2020-05-21_IDS_17713-0001US14.PDF	1034620 00ce5c4c93857461f3dc898257b1a22c17d09c1a	no	5

Warnings:

Information:	
Total Files Size (in bytes):	1034620

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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

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

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	WOLF
Art Unit	4187
Examiner Name	
Attorney Docket Number	17713.0001US14

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	WO2014022436	WO		2014-02-06			

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	WOLF
	Art Unit	4187
	Examiner Name	
	Attorney Docket Number	17713.0001US14

	1	Extended European Search Report for Application No. 19199126.4, mailed December 9, 2019, 6 pages.

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

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	WOLF
	Art Unit	4187
	Examiner Name	
	Attorney Docket Number	17713.0001US14

CERTIFICATION STATEMENT

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OR

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/ Christopher P. Ziolkowski /	Date (YYYY-MM-DD)	2020-02-20
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	38646912
Application Number:	16514316
International Application Number:	
Confirmation Number:	2153
Title of Invention:	METHODS OF TREATING NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US14
Receipt Date:	20-FEB-2020
Filing Date:	17-JUL-2019
Time Stamp:	16:43:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	2019-12-09_EP19199126.PDF	248613 6c3a523c6690774d3e1c33bdf4bc1f0cf2ea1e4a	no	6

Warnings:

Information:					
2	Foreign Reference	WO2014022436.PDF	2828548 dc4ad168cf5f731361d1de5378a9bbcbf4b4fff0	no	109
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	2020-02-20_IDS_17713-0001US14.PDF	1034315 3aa29a36eb23e365aa33397945223064003370ecc	no	4
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(54) **Title**: ELECTRICAL ENERGY ABLATION SYSTEMS, DEVICES AND METHODS FOR THE TREATMENT OF TISSUE

(57) **Abstract**: A device for ablating target tissue of a patient with electrical energy is provided. An elongate shaft includes a proximal portion and a distal portion, and a radially expandable element is attached to the distal portion. An ablation element for delivering electrical energy to target tissue is mounted to the radially expandable element. The device can be constructed and arranged to ablate the duodenal mucosa of a patient while avoiding damage to the duodenal adventitial tissue. Systems and methods of treating target tissue are also provided.

ELECTRICAL ENERGY ABLATION SYSTEMS, DEVICES AND METHODS FOR THE TREATMENT OF TISSUE

RELATED APPLICATIONS

[001] This application claims the benefit of U.S. Provisional Application Serial Number 61/677,422 (Attorney Docket No. 41714-706.101), filed July 30, 2012, the entire content of which is incorporated herein by reference; this application is also related to PCT Application Serial Number PCT/US2012/021739 (Attorney Docket No. 41714-703-601), filed January 18, 2012; PCT Application Serial Number PCT/US2013/28082 (Attorney Docket No. 41714-704.601), filed February 27, 2013; and PCT Application Serial Number PCT/US2013/37486, filed April 19, 2013; the contents of each are incorporated herein by reference in their entirety.

TECHNICAL FIELD

[002] The embodiments disclosed herein relate generally to systems, devices and methods for treating tissue, particularly gastrointestinal tissue.

BACKGROUND

[003] Diabetes is a metabolic disease in which a person develops high blood sugar because the person's body does not produce enough insulin or the cells of the body are incapable of effectively responding to the produced insulin. Primarily, diabetes is of two types: Type-1 and Type-2. Type-1 diabetes results due to the body's failure to produce enough insulin, and Type-2 diabetes results from the body's autoimmune destruction of pancreatic beta cells and, consequently, the body's failure to produce enough insulin, and Type 2 diabetes is a complex metabolic derangement that causes hyperglycemia through insulin resistance (in which the body's cells fail to properly utilize the produced insulin) and inadequate insulin production to meet the body's needs.

[004] Currently, there are several procedures aimed at treating diabetes based on the above concept. The procedures require major surgery, removal of portions of the gastrointestinal (GI) tract, and/or placement of one or more long-term implants. As with any major surgery, gastric bypass surgery and device implant surgery carry a risk of complications.

[005] Devices have been developed to deliver energy to the body. For example, cardiac ablation devices have been designed to deliver ablative energy to heart tissue. Additionally, urethral resection devices have been designed to burn or cut away portions of a prostate. Each of

these technologies has been modified and adapted toward effective usage in the particular portion of the body to be treated, as well as the particular disease to be treated.

[006] There is a need for systems and methods that can provide a therapeutic treatment of the GI tract by the application of energy to the GI tract. Specifically, there is a need to provide a treatment of diabetes with a procedure in the GI tract that is less invasive than gastric bypass surgery and has other advantages for patients.

SUMMARY

[007] According to one aspect of the present inventive concepts, a device for ablating tissue of a patient with electrical energy includes an elongate shaft with a proximal portion and a distal portion; a radially expandable element attached to the elongate shaft distal portion; and an ablation element mounted to the radially expandable element and configured to deliver electrical energy to target tissue. The device is configured to ablate mucosal tissue (e.g. duodenal mucosal tissue or other small intestine mucosal tissue) while avoiding damaging adventitial tissue or other non-target tissue. The device can be further configured to ablate at least an inner layer of duodenal submucosal tissue and/or an inner layer of other mucosal tissue of the small intestine. The device can be further configured to avoid ablating (e.g. not ablate) at least the outermost portion of submucosal tissue, such as to avoid ablating a layer comprising the outermost 100 microns, or the outermost 200 microns of duodenal submucosal tissue. The device can be further configured to ablate tissue such as: jejunal mucosal tissue; ileal mucosal tissue; and gastric mucosal tissue. The device can be further configured to minimize damage to at least one of the pylorus or the Ampulla of Vater, for example where the device includes an advanceable sheath configured to minimize damage to at least one of the pylorus or the Ampulla of Vater. The device can be further configured to identify the Ampulla of Vater. The device can include a fluid delivery element constructed and arranged to deliver fluid, gel or other material into submucosal tissue, such as to expand the submucosal tissue. The fluid delivery element can comprise multiple fluid delivery elements, such as one or more needles and/or one or more fluid jets. The device can include one or more vacuum ports positioned proximate the multiple fluid delivery elements, such as to stabilize, manipulate or otherwise apply a force to the tissue receiving the expansion material. The submucosal tissue can be expanded to increase a target treatment area. The submucosal tissue can be expanded circumferentially.

[008] The device can be constructed and arranged to perform a target tissue treatment that modifies a tissue property selected from the group consisting of: a secretive property of a portion

of the gastrointestinal tract; an absorptive property of a portion of the gastrointestinal tract; and combinations thereof.

[009] The device can be further configured to minimize distension of duodenal tissue or other small intestine tissue. The device can be further configured to limit forces applied to a duodenal or other tissue wall, such as to limit forces to a level at or below 2.5 psi, or at or below 1 psi. The device can be further configured to apply a force of at least 0.2 psi to a tissue wall, or to apply a force of at least 0.5 psi to a tissue wall. The device can be further configured to avoid damaging tissue selected from the group consisting of: a duodenal muscularis layer; jejunal muscularis layer; ileal muscularis layer; gastric muscularis layer; Ampulla of Vater; bile duct; pancreas; pylorus; muscularis externae; serosa; and combinations of these. The device can be further configured to ablate mucosal tissue in a curved segment of the small intestine, such as a curved segment of the duodenum. The device can be further configured to ablate a tissue layer of at least 500 microns. The device can be further configured to ablate a volume of tissue having a surface area and a depth, where the depth is less than approximately 1.0% its surface area, or less than approximately 0.1% its surface area.

[010] The elongate shaft of the device can be configured to be passed through the working channel of an endoscope. The shaft can have a diameter of less than or equal to 6 mm, or less than or equal to 4.2 mm, or less than or equal to 3.8 mm, or less than or equal to 3.2 mm, or less than or equal to 2.8 mm. The elongate shaft can be configured to pass alongside an endoscope that has been placed in a gastrointestinal tract. The device can be configured for over-the-wire delivery, such as over-the-wire delivery through the gastrointestinal tract.

[011] The device can be configured to treat substantially the entire length of the target tissue simultaneously, such as to treat the entire length of the duodenum simultaneously. The device can be configured to treat a first length of small intestine (e.g. a first length of duodenum) in a first energy application and a second length of small intestine (e.g. a second length of duodenum) in a second energy application. In some embodiments, the first length of duodenum or other length of small intestine overlaps the second length of duodenum or other length of small intestine. In some embodiments, the first length of duodenum or other length of small intestine includes a first central axis and the second length of duodenum or other length of small intestine includes a second central axis non-parallel with the first axis. The device can be configured to treat at least three lengths of small intestine with at least three energy treatments, such as where the at least three lengths of small intestine comprise at least 50% of the length of the duodenum. The device can be configured to deliver the electrical energy based on a measured diameter of the small intestine, for example where the measured diameter is measured by at least one radially

expandable element of the device and/or by one or more radially expandable elements of a separate device.

[012] The device radially expandable element can have a length less than or equal to approximately 20mm. The radially expandable element can be configured to be relatively rigid during the delivery of the electrical energy to the target tissue, for example where the ablation element includes multiple parallel conductors, and where the relatively rigid radially expandable element is configured to maintain spacing between the multiple parallel conductors. The radially expandable element can include at least a portion that is round when expanded. The radially expandable element can include at least a portion that, when expanded, includes a tissue-contacting shape selected from the group consisting of: triangle; rectangle; pentagon; hexagon; trapezoid; and combinations of these. The tissue-contacting shape can be selected to allow an operator to treat one or more target tissue portions without leaving gaps and/or to limit the number of repeated ablations needed to cover a target tissue portion regularly or irregularly shaped area. The radially expandable element can be configured to be folded to a radially compacted state from its radially expanded state. The radially expandable element can be configured to linearize curvilinear gastrointestinal tissue. The radially expandable element can be configured to distend gastrointestinal tissue.

[013] In some embodiments, the radially expandable element includes a balloon, for example a compliant balloon, a non-compliant balloon, and/or a pressure-thresholded balloon. The balloon can include an external surface and the ablation element can be mounted to the balloon external surface. The radially expandable element can further include a scaffold biased in a radially expandable condition. The device can further include at least one inflation lumen in fluid communication with the balloon.

[014] In some embodiments, the radially expandable element includes a radially expandable scaffold. Examples of radially expandable scaffolds include: an expandable cage; a stent-like structure; an array of splines; and combinations of these. The radially expandable scaffold can include multiple filaments configured to expand to a diameter of at least 20mm, or at least 25mm, or at least 30mm, where the device includes a distal portion configured to be slidingly received by a channel with a diameter less than or equal to 6mm. The radially expandable scaffold can include a scaffold resiliently biased in a radially expanded condition. The device can further include a control shaft configured to expand the radially expandable scaffold when retracted. The radially expandable scaffold can include an array of splines, for example where the ablation element includes at least a first electrode mounted to a first spline and a second electrode mounted to the first spline. Alternatively, the ablation element includes at least a first electrode

mounted to a first spline and a second electrode mounted to a second spline. The radially expandable scaffold can include an oval or football shaped scaffold, or a relatively unidiameter scaffold.

[015] In some embodiments, the radially expandable element includes multiple radially deployable arms.

[016] In some embodiments, the radially expandable element includes a radially expandable tube. For example, the radially expandable tube can include a tube resiliently biased in an expanded condition.

[017] In some embodiments, the radially expandable element includes a radially expandable sheet. The radially expandable sheet can include a sheet resiliently biased in an expanded condition, for example where the radially expandable sheet is configured to be furled to transition to a compact condition. The radially expandable sheet can include a sheet resiliently biased in an unexpanded condition, for example where the radially expandable sheet is configured to be unfurled to transition to an expanded condition. The radially expandable sheet can include a foldable sheet, for example a sheet configured to be folded to transition from an expanded state to an unexpanded state and configured to be unfolded to transition from an unexpanded state to an expanded state.

[018] The radially expandable element can have a diameter ranging from 15mm to 30mm. The radially expandable element can have a length ranging from 10mm to 40mm, such as a length ranging from 20mm to 25mm, or a length of less than or equal to 15mm. In some embodiments, the radially expandable element can include at least two radially expandable elements each with a length less than or equal to 25mm, for example less than 20mm.

[019] The radially expandable element can be configured to be moved in a motion selected from the group consisting of: rotation; translation; and combinations thereof. In some embodiments, the radially expandable element can be moved manually, for example by an operator. In some embodiments, the device can include a motion transfer assembly configured to move the radially expandable element. In some embodiments, the ablation element can be configured to deliver a first energy delivery and a second energy delivery, and the radially expandable element can be configured to be moved between the first energy delivery and the second energy delivery. In some embodiments, the ablation element is configured to be moved during the delivery of the electrical energy.

[020] In some embodiments, the radially expandable element includes an expandable helical structure. The radially expandable element can further include a filament comprising the ablation

element and can be configured to be moved along the helical structure, for example where a motion transfer assembly moves the filament during the delivery of electrical energy.

[021] The device can further include a second radially expandable element. In some embodiments, the second radially expandable element can be configured to perform a luminal diameter measurement. In some embodiments, the second radially expandable element includes a second ablation element configured to deliver electrical energy to target tissue. In this embodiment, the first radially expandable element has a first length, and the first radially expandable element and the second radially expandable element are spaced apart by a distance less than or equal to the first length, for example where the second radially expandable element has a second length approximately the same as the first radially expandable element length. In some embodiments, the first radially expandable element has a length of less than or equal to approximately 20mm and the second radially expandable element has a length of less than or equal to approximately 20mm. The device can further include multiple filaments extending between the first radially expandable element and the second radially expandable element. In some embodiments, the multiple filaments include multiple elongate conductors and the multiple elongate conductors include the ablation element. In some embodiments, the ablation element includes multiple electrodes mounted to the multiple filaments. In some embodiments, the ablation element includes a first set of electrodes positioned on the first radially expandable element and a second set of electrodes positioned on the second radially expandable element, for example where the first set of electrodes are configured in a first geometry and the second set of electrodes are configured in a second geometry different than the first, such as where the first geometry and second geometry are configured such that ablation with the first geometry and the second geometry causes substantially full surface ablation of an area of tissue. In some embodiments, the second radially expandable element is positioned within the first radially expandable element, for example where the ablation element includes a first set of electrodes positioned on the first radially expandable element and a second set of electrodes positioned on the second radially expandable element. In some embodiments, the first radially expandable element is positioned within the second radially expandable element, and the second radially expandable element includes insulating material and a set of openings, for example where the insulating material includes an inflatable balloon. In this embodiment, the ablation element can include a top surface area where each opening of the set of openings includes an opening area less than an electrode top surface area.

[022] The device can further include a second radially expandable element distal to the first radially expandable element and a third radially expandable element distal to the second radially

expandable element, where the second radially expandable element includes a second ablation element and the third radially expandable element includes a third ablation element. In some embodiments, the first radially expandable element, the second radially expandable element and the third radially expandable element each includes a length of less than or equal to approximately 20mm. In some embodiments, the first and second ablation elements are separated by a first distance and the second and third ablation elements are separated by a second distance similar to the first distance. In some embodiments, the target tissue includes a set of sequential target tissue portions comprising, in order, a first section, a second section, a third section, a fourth section, and a fifth section, and wherein the first, second and third ablation elements are configured to ablate the first, third and fifth target tissue portions in a first energy delivery and the first and second ablation elements are configured to ablate the second and fourth target tissue portions in a second energy delivery.

[023] The radially expandable element can be configured to be radially compacted to stop the delivery of the electrical energy.

[024] The device can further include a control shaft operably coupled to the radially expandable element, where translation of the control shaft changes the shape of the radially expandable element. For example, retraction of the control shaft causes the radially expandable element to expand and advancement of the control shaft causes the radially expandable element to expand.

[025] The ablation element can be configured to cause non-desiccating ablation of the target tissue. The ablation element can be configured to minimize electrical current driven temperature increase in the outermost 50% of the mucosal layer, for example where the outermost 50% of the mucosal layer is ablated mainly due to thermal conduction. The ablation element can be configured to minimize electrical current driven temperature increase in the outermost 80% of the mucosal layer, for example where the outermost 80% of the mucosal layer is ablated mainly due to thermal conduction.

[026] In some embodiments, at least a portion of the ablation element includes a surface area with a geometric shape comprising: a linear segment; a circle; a rectangle; and combinations of these.

[027] In some embodiments, the ablation element includes at least a single pair of electrodes. The single pair of electrodes can include a first electrode comprising multiple elongate conductors and a second electrode comprising multiple elongate conductors. For example, the first electrode can include a first elongate conductor comprising a major axis that is configured to be relatively parallel to a central axis of a portion of the small intestine (e.g. duodenum) during

delivery of energy where the first elongate conductor major axis that is configured to be relatively parallel to a central axis of a curvilinear portion of the small intestine (e.g. duodenum) during energy delivery. The first elongate conductor major axis can be configured to be relatively parallel to a central axis of a curvilinear portion of the small intestine during energy delivery. The first electrode multiple elongate conductors can include conductors with a length of at least 10mm, for example at least 20mm. The first electrode multiple elongate conductors and the second electrode multiple elongate conductors can be positioned in an interdigitated array, for example where the interdigitated conductors are edge-to-edge spaced at a distance less than or equal to 1.5 mm, for example less than or equal to 1.0 mm or less than or equal to 750 microns. The first electrode multiple elongate conductors and the second elongate multiple elongate conductors can be positioned relatively parallel to each other. The first electrode multiple conductors can include at least 4 elongate conductors.

[028] In some embodiments, the ablation element includes at least one pair of electrodes. The ablation element can be configured to deliver a current, where the current passes substantially through the innermost 50% of the mucosal layer, or through the innermost 20% of the mucosal layer.

[029] In some embodiments, the ablation element includes at least one conductor comprising a height that extends from the radially expandable element at least 100 microns. The at least one conductor can include a tissue contacting surface positioned at least 200 microns from the surface of the radially expandable element, for example where the at least one conductor tissue contacting surface is positioned at least 400 microns from the radially expandable element. The at least one conductor can include an electrically insulating material between the tissue contacting surface and the radially expandable element, for example where the electrically insulating material includes polytetrafluoroethylene.

[030] In some embodiments, the ablation element includes at least 2 electrodes. In some embodiments, the ablation element includes at least 4 electrodes.

[031] In some embodiments, the ablation element includes at least one conductor with a length of approximately between 10mm and 40mm.

[032] In some embodiments, the ablation element includes a first conductor and a second conductor with an edge-to-edge spacing between approximately 200 microns and 2mm.

[033] In some embodiments, the ablation element includes at least one conductor with a width less than or equal to 2.0mm, for example a width less than or equal to 1.5mm or a width less than or equal to 1.0mm, or a width between 400 microns and 700 microns.

[034] In some embodiments, the ablation element includes at least one conductor with a width greater than 230 microns.

[035] In some embodiments, the ablation element includes at least two conductors with a width of approximately 400 microns, for example where the at least two conductors with an edge to edge spacing of approximately 600 microns.

[036] In some embodiments, the ablation element includes at least one conductor with a width of approximately 700 microns, for example where the at least two conductors with an edge to edge spacing of approximately 400 microns.

[037] In some embodiments, the ablation element includes at least one conductor with a width less than or equal to a desired depth of ablation. In some embodiments, the ablation element includes a first conductor and a second conductor separated by a first distance, where the first distance is less than or equal to a desired depth of ablation. In some embodiments, the ablation element includes an array of conductors. For example, the array of conductors can include a circumferential array of conductors such a linear or curvilinear circumferential array of conductors. In some embodiments, the circumferential array of conductors comprises a helical array of conductors. In some embodiments, the circumferential array of conductors includes a 360° array. In some embodiments, the circumferential array of conductors is configured to prevent formation of a full circumferential scar, for example where the array of conductors includes a less than 350° array of conductors such as a 300° to 350° array of conductors. In some embodiments, the circumferential array of conductors includes an array of conductors spanning approximately 45° to 300°, for example where the device is configured to be rotated to treat a 360° segment of target tissue. In some embodiments, the circumferential array of conductors includes multiple pairs of conductors, for example at least five pairs of conductors. In some embodiments, the circumferential array of conductors includes conductors radially edge-to-edge spaced at a distance between approximately 230 microns and 2.0mm, for example at a distance between approximately 400 microns to 600 microns. In some embodiments, the circumferential array of conductors includes conductors radially spaced at a first distance, where the width of the multiple conductors is approximately half of the first distance. In some embodiments, the circumferential array of conductors includes conductors radially spaced with a uniformity of spacing greater than or equal to 95%, for example with a uniformity of spacing greater than or equal to 98%.

[038] In some embodiments, the ablation element includes an elongate copper conductor.

[039] In some embodiments, the ablation element includes a shape selected from the group consisting of: a rectangle; a square; a triangle; a trapezoid; and combinations of these. The

ablation element can be configured to ablate tissue in a shape selected from the group consisting of: a rectangle; a square; a triangle; a trapezoid; and combinations thereof.

[040] In some embodiments, the ablation element includes multiple conductors arranged in an operator adjustable pattern. In some embodiments, the ablation element includes multiple flexible conductors.

[041] In some embodiments, the ablation element is mounted to the radially expandable element by at least one of: a glue joint; a weld; a swage or a molecular bond. In some embodiments, the ablation element is at least partially embedded in the radially expandable element.

[042] The device can further include a flexible substrate, where the ablation element is attached to the flexible substrate. The flexible substrate can include a material selected from the group consisting of: polyamide; a polyester weave; a stretchable polyurethane material; and combinations of these. The flexible substrate can include a heat set configured to enhance folding of the flexible substrate. The ablation element can include multiple conductors deposited on the flexible substrate, for example where the ablation element includes at least one conductor deposited using an ink-jet deposition process, such as where the at least one conductor is deposited by depositing catalytic ink followed by exposure to a copper solution. The ablation element can include at least one conductor deposited using a masked deposition process. The radially expandable element can include at least three splines, where the substrate is attached to the at least three splines. The at least three splines can be arranged in a symmetric circumferential pattern. The at least three splines can form a non-circular cross section when the radially expandable element is expanded. The expandable element can include four splines such that when the expandable element is expanded, the substrate includes a relatively square cross section. The expandable element can include five splines such that when the expandable element is expanded, the substrate includes a relatively pentagonal cross section or a relatively hexagonal cross section.

[043] In some embodiments, the ablation element includes multiple wires.

[044] In some embodiments, the ablation element includes multiple conductors configured to rotate, for example where the multiple conductors are configured to rotate during the delivery of the electrical energy.

[045] In some embodiments, the ablation element includes an anti-stick coating, for example a polytetrafluoroethylene coating.

[046] In some embodiments, the ablation element includes at least one conductor configured to capacitively couple the electrical energy to the target tissue. The device can be configured to

position the at least one conductor such that a gap is present between the ablation element and the target tissue. The device can further include a dielectric covering positioned between the at least one conductor and the target tissue, for example where the dielectric covering comprises polytetrafluoroethylene. The dielectric covering can include a non-uniform thickness covering including dielectric material, for example where the dielectric covering includes a middle portion with a first thickness and an edge portion with a second thickness greater than the first thickness. The non-inform thickness covering can be configured to cause uniform ablation depth of a tissue area.

[047] In some embodiments, the ablation element includes multiple conductors and the device further includes multiple insulators positioned between the multiple conductors. The multiple insulators can include multiple thermal conductors. Examples of insulator materials include: sapphire; fused quartz; fused silica; a polymeric material; glass; and combinations of these.

[048] The device can further include a second ablation element. The second ablation element can include an ablation element selected from the group consisting of: an RF energy delivery element such as one or more electrodes, each comprising one or more elongate conductors; an ultrasonic transducer such as one or more piezo crystals configured to ablate tissue; a laser energy delivery element such as one or more optical fibers and/or laser diodes; a heat delivery element such as a hot fluid filled balloon; a rotating ablation element; a circumferential array of ablation elements; and combinations of these.

[049] The electrical energy delivered by the ablation element can include bipolar radiofrequency energy and/or monopolar radiofrequency energy.

[050] In some embodiments, the elongate shaft distal portion is configured to be at least one of deflected or steered.

[051] The device can further include at least one sensor configured to provide a signal. The device can be configured to deliver the electrical energy based on the at least one sensor signal. Examples of sensors include but are not limited to: temperature sensor; pressure sensor; impedance sensor; visual sensor; and combinations of these. The visual sensor can be configured to provide an image of tissue, for example where the visual sensor includes an imaging device selected from the group consisting of: visible light camera; infrared camera; CT Scanner; MRI; and combinations of these. The device can be configured to deliver the electrical energy based on the visual sensor signal, for example where the device is configured to deliver the electrical energy based on a change in tissue color. The at least one sensor can include multiple temperature sensors, for example multiple temperature sensors positioned with a spacing of at least 1 sensor per 1 cm^2. The ablation element can be configured to deliver the electrical energy

based on one or more signals from the multiple temperature sensors. Examples of temperature sensors include but are not limited to: thermocouple; thermistor; resistance temperature detector; optical temperature sensor; and combinations of these. The at least one sensor can include a sensor configured to assess apposition of a device component with a gastrointestinal wall, for example where the at least one sensor includes a sensor configured to assess apposition of a balloon expanded to contact the gastrointestinal wall. The at least one sensor can include a chemical sensor, for example a carbon dioxide sensor. The at least one sensor can be configured to assess the apposition of the radially expandable element. The device can further include a second radially expandable element, where the at least one sensor is configured to assess the apposition of the second radially expandable element.

[052] The device can further include a conductive gel configured to be applied to the target tissue, for example a gel that is at least thermally or electrically conductive. The thermally conductive gel can be configured to conduct heat into tissue. Alternatively or additionally, the thermally conductive gel can be configured to cool tissue, for example when cool air is delivered to at least one of the gel or the tissue. The electrically conductive gel can be configured to improve transfer of electrical energy to tissue. The conductive gel can be placed on tissue and/or the ablation element prior to expansion of the radially expandable element.

[053] The device can further include an impedance monitoring assembly configured to measure impedance of tissue, for example where the device is configured to deliver the electrical energy to the target tissue based on the measured impedance.

[054] According to another aspect of the present inventive concepts, a system for ablating tissue with electrical energy includes an ablation device, for example an ablation device as has been described hereabove, and an energy delivery unit configured to delivery electrical energy to the ablation element of the ablation device. The system can include a fluid delivery element constructed and arranged to deliver fluid, gel or other material into submucosal tissue, such as to expand the submucosal tissue. The fluid delivery element can comprise multiple fluid delivery elements, such as one or more needles and/or one or more fluid jets. The system can include one or more vacuum ports positioned proximate the multiple fluid delivery elements, such as to stabilize, manipulate or otherwise apply a force to the tissue receiving the expansion material. The submucosal tissue can be expanded to increase a target treatment area. The submucosal tissue can be expanded circumferentially.

[055] The system can be configured to treat mucosal tissue of the small intestine, such as duodenal mucosal tissue.

[056] The system can be constructed and arranged to perform a target tissue treatment that modifies a tissue property selected from the group consisting of: a secretive property of a portion of the gastrointestinal tract; an absorptive property of a portion of the gastrointestinal tract; and combinations thereof. The system can include at least one fluid delivery device constructed and arranged to deliver fluid into submucosal tissue to increase the volume of the target tissue.

[057] The system delivery unit can be configured to perform a non-desiccating ablation of the target tissue.

[058] The system can be configured to deliver energy to the target tissue with an average power density less than or equal to 20 Watts per cm^2, for example an average power density less than or equal to 10 Watts per cm^2 or an average power density less than or equal to 4 Watts per cm^2. The system can be configured to deliver energy to a portion of the target tissue for at least 1 second, or for at least 5 seconds, or for at least 10 seconds, or for at least 20 seconds. The system can be configured to deliver energy to the target tissue at a level that decreases over time.

[059] The system can be configured to modulate the energy delivered to the target tissue. For example, the system can be configured to pulse-width modulate the energy delivered to the target tissue where the pulse-width modulation comprises a cycle time, an on-time and an off-time, where the on-time is no more than 20% of the cycle time. The energy delivery unit can include an electrical energy source less than or equal to a 300 Watt source, for example an electrical energy source less than or equal to a 150 Watt source.

[060] The system can be configured to increase the temperature of the target tissue rapidly during energy delivery to the target tissue, for example at a rate of at least 17.5°C per second. The system can be configured to increase the temperature of the target tissue to a setpoint, where the setpoint temperature ranges between 60°C and 90°C, for example between 65°C and 80°C.

[061] The system can be configured to deliver electrical energy to a setpoint temperature, and maintain the tissue at the setpoint temperature for approximately 2 to 40 seconds. The setpoint temperature can range between 60°C and 90°C, for example between 75°C and 85°C, and the tissue can be maintained at the setpoint temperature for approximately 15 to 25 seconds.

[062] The system can be configured to deliver electrical energy to a setpoint temperature, where one or more energy delivery parameters decay after the setpoint temperature is achieved. For example, the one or more energy delivery parameters decay at a rate configured to match a physiological response of the tissue receiving the electrical energy.

[063] The energy delivery unit can be configured to deliver radiofrequency energy to the ablation element of the ablation device, for example radiofrequency energy at a frequency at or below 1 MHz.

[064] The electrical energy delivered by the ablation element can include monopolar and/or bipolar radiofrequency energy.

[065] The electrical energy delivered by the ablation element can include a power of less than or equal to 300W, such as a power of approximately 260W. In one example, the power decreases from 260W to 0W over approximately 30 seconds.

[066] The energy delivery unit can deliver electrical energy to the ablation element in a current-driven mode.

[067] The system can be configured to deliver electrical energy to tissue and avoid desiccation of the tissue. The system can be configured to deliver electrical energy to tissue and avoid creation of steam. The system can be configured to deliver electrical energy to tissue and avoid detachment of tissue particles. The system can be configured to deliver energy in at least 2 second energy delivery durations, for example where the at least 2 second energy delivery durations are non-continuous.

[068] The system can further include a second ablation device for ablating luminal wall tissue. In some embodiments, the second ablation device is similar to the first ablation device of the system described hereabove. In some embodiments, the second ablation device includes a radially expandable element with a different expanded diameter than the first ablation device radially expandable element. In some embodiments, the first ablation device ablation element includes a first set of multiple conductors, and the second ablation device includes a second ablation element comprising a second set of multiple conductors, where the first set of multiple conductors are arranged in a different pattern than the second set of multiple conductors. The second ablation device can include an ablation device selected from the group consisting of: hot fluid filled balloon device; vapor ablation device; cryoablation device; laser ablation device; ultrasound ablation device; and combinations of these.

[069] The system can further include a cooled fluid delivery device configured to deliver fluid below 37°C to target tissue. The cooled fluid can include a liquid; a gas; and combinations of these. The cooled fluid delivery device can be configured to deliver a cooled gas toward the wall of the small intestine (e.g. duodenal wall). The cooled fluid can be delivery prior to and/or after the delivery of the electrical energy.

[070] The system can further include an endoscope.

[071] The system can further include a tissue expansion device, for example where the tissue expansion device includes a submucosal tissue expansion device configured to expand small intestine submucosal tissue (e.g. duodenal submucosal) tissue prior to the ablation element of the ablation device delivering the electrical energy. The tissue expansion device can comprise one or

more fluid delivery elements, such as one or more needles and/or one or more water jets. The one or more fluid delivery elements can be arranged in a linear or circumferential array. The tissue expansion device can be constructed and arranged to perform a circumferential or near circumferential expansion of tubular tissue, such as a circumferential expansion of submucosal tissue of a segment of the duodenum or other small intestine segment.

[072] The system can further include an insufflation device. In some embodiments, the system further includes an endoscope having a fluid delivery tube where the fluid delivery tube includes and/or is otherwise configured as an insufflation device. The system can be configured to control apposition of the ablation element with target tissue.

[073] The system can further include a tissue cooling device. The tissue cooling device can be configured to apply cooling fluid to tissue, for example prior and/or after the delivery of electrical energy to the tissue. The tissue cooling device can be configured to deliver a tissue cooling gas. Examples of tissue cooling gas include: air; carbon dioxide; nitrogen; nitrous oxide; and combinations of these. The system can further include a drying assembly configured to remove moisture from the cooling gas prior to delivery. The tissue cooling device can provide cooling fluid at a temperature less than or equal to 20°C, or example a cooling fluid at a temperature less than or equal to 0°C.

[074] According to another aspect of the present inventive concepts, a device for ablating tissue of a patient with electrical energy comprises an elongate shaft, a radially expandable element and an ablation element. The elongate shaft has a proximal portion and a distal portion. The radially expandable element is attached to the elongate shaft distal portion. The ablation element is mounted to the radially expandable element. The ablation element is constructed and arranged to deliver electrical energy to target tissue. The device is constructed and arranged to modify a tissue property selected from the group consisting of: a secretive property of a portion of the gastrointestinal tract; an absorptive property of a portion of the gastrointestinal tract; and combinations thereof. The device can further comprise at least one fluid delivery element constructed and arranged to deliver fluid into submucosal tissue to increase the volume of the target tissue. The device can be constructed and arranged as described hereabove.

BRIEF DESCRIPTION OF THE DRAWINGS

[075] The advantages of the technology described above, together with further advantages, may be better understood by referring to the following description taken in conjunction with the accompanying drawings. The drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the technology.

[076] **Fig. 1** is a system for ablating or otherwise treating target tissue, consistent with the present inventive concepts.

[077] **Fig. 2** is a side sectional view of the distal portion of an ablation device inserted into a duodenum, consistent with the present inventive concepts.

[078] **Fig. 2A** is a magnified view of the distal portion of the ablation device of Fig. 2, consistent with the present inventive concepts.

[079] **Fig. 3** is a side sectional view of the distal portion of an ablation device inserted into a curvilinear section of duodenum, consistent with the present inventive concepts.

[080] **Fig. 4A** is perspective and magnified end views of the distal portion of an ablation device comprising a foldable assembly, consistent with the present inventive concepts.

[081] **Fig. 4B** is a perspective view of the ablation device of Fig. 4A, with the foldable assembly 130 in a partially expanded state (e.g. partially unfolded), consistent with the present inventive concepts.

[082] **Fig. 4C** is a perspective view of the ablation device of Fig. 4A, with the foldable assembly in a fully expanded state, consistent with the present inventive concepts.

[083] **Figs. 5A and 5B** are side views of the distal portion of an ablation device comprising a helical coil, consistent with the present inventive concepts.

[084] **Fig. 6** is a side view of the distal portion of an ablation device including multiple expandable assemblies, consistent with the present inventive concepts.

[085] **Fig. 7** is a side sectional view of a distal portion of an ablation device including an expandable assembly comprising a balloon surrounding an expandable scaffold, consistent with the present inventive concepts.

[086] **Fig. 8A** is a side view of a conductor array including two electrodes each comprising multiple elongate conductors, consistent with the present inventive concepts.

[087] **Fig. 8B** is a side view of a conductor array including two electrodes each comprising multiple elongate conductors, consistent with the present inventive concepts.

[088] **Fig. 8C** is a side view of a conductor array including two electrodes each comprising multiple elongate conductors, consistent with the present inventive concepts.

[089] **Fig. 8D** is side and end views of an expandable assembly including a helical array of conductors, consistent with the present inventive concepts.

[090] **Fig. 8E** is an end view of an expandable assembly comprising three splines and a surrounding substrate including multiple electrodes and expanded to a triangular cross section, consistent with the present inventive concepts.

[091] **Fig. 8F** is an end view of an expandable assembly comprising four splines and a surrounding substrate including multiple electrodes and expanded to a square cross section, consistent with the present inventive concepts.

[092] **Fig. 8G** is an end view of an expandable assembly comprising five splines and a surrounding substrate including multiple electrodes and expanded to a pentagonal cross section, consistent with the present inventive concepts.

[093] **Figs. 9A, 9B and 9C** are distal portions of three ablation devices with three different tissue contacting portions, consistent with the present inventive concepts.

[094] **Fig. 10** is a distal portion of an ablation device comprising multiple spline-mounted electrodes, consistent with the present inventive concepts.

[095] **Fig. 10A** is a side sectional view of dielectric covered electrodes mounted on a spline, consistent with the present inventive concepts.

[096] **Fig. 10B** is a side sectional view of an array of electrodes separated by thermal conductors, consistent with the present inventive concepts.

[097] **Fig. 10C** is a top and side sectional view of an electrode with a top surface offset from a spline, consistent with the present inventive concepts.

[098] **Fig. 11** is a distal portion of an ablation device including two expandable elements and intervening conductive filaments, consistent with the present inventive concepts.

[099] **Fig. 12** is a distal portion of an ablation device including rotatable electrodes, consistent with the present inventive concepts.

DETAILED DESCRIPTION OF THE DRAWINGS

[0100] Reference will now be made in detail to the present embodiments of the inventive concepts, examples of which are illustrated in the accompanying drawings. Wherever practical, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0101] The term "and/or" where used herein is to be taken as specific disclosure of each of the two specified features or components with or without the other. For example "A and/or B" is to be taken as specific disclosure of each of (i) A, (ii) B and (iii) A and B, just as if each is set out individually herein.

[0102] It is an object of the present inventive concepts to provide systems, methods and devices for safely and effectively ablating a volume of tissue (the "target tissue"), such as one or more layers of a portion of tubular or solid tissue, such as tissue of an organ or tissue of the gastrointestinal tract of a patient. The systems and device of the present inventive concepts include one or more treatment assemblies configured to treat the target tissue, such as an assembly comprising a radially expandable element configured to be expanded and one or more ablation elements configured to deliver energy such as electrical energy to the target tissue. In some embodiments, the treatment elements are constructed and arranged as described in applicant's co-pending International PCT Application Serial Number PCT/US12/21739, entitled "Devices and Methods for the Treatment of Tissue", filed January 18, 2012, the contents of which is incorporated herein by reference in its entirety.

[0103] A treatment assembly can be configured to treat target tissue in one or more locations of the patient, such as one or more contiguous or discontiguous tissue locations. The target tissue comprises a three dimensional volume of tissue, and can include a first portion, a treatment portion, whose treatment has a therapeutic benefit to a patient; as well as a second portion, a "safety-margin" portion, whose treatment has minimal or no adverse effects to the patient. Non-target tissue can be identified (e.g. prior to and/or during the medical procedure), wherein the non-target tissue comprises tissue whose treatment by the treatment assembly should be reduced or avoided such as to reduce or prevent an undesired effect.

[0104] The target tissue treatment can cause one or more effects to the target tissue such as an effect selected from the group consisting of: modification of cellular function; cell death; apoptosis; instant cell death; cell necrosis; denaturing of cells; removal of cells; and combinations of these. In some embodiments, the target tissue treatment is constructed and arranged to create scar tissue. Target tissue can be selected such that after treatment the treated target tissue and/or tissue that replaces the target tissue functions differently than the pre-treated

target tissue, such as to have a therapeutic benefit. The modified and/or replacement tissue can have different secretions and/or quantities of secretions than the pre-treated target tissue, such as to treat diabetes and/or obesity. The modified and/or replacement tissue can have different absorptive properties than the target tissue, such as to treat diabetes, obesity and/or hypercholesterolemia. The effect of the treatment can occur acutely, such as within twenty four hours, or after longer periods of time such as greater than twenty four hours or greater than one week.

[0105] Target tissue to be treated can comprise two or more tissue portions, such as a first tissue portion treated with a first treatment and/or a first treatment assembly, and a second tissue portion treated with a second treatment and/or a second treatment assembly. The first and second tissue portions can be adjacent and they can contain overlapping portions of tissue. The first and second treatment and/or treatment assemblies can be similar or dissimilar. Dissimilarities can include type and/or amount of energy to be delivered by an energy delivery based treatment assembly. Other dissimilarities can include but are not limited to: target tissue area treated; target tissue volume treated; target tissue length treated; target tissue depth treated; target tissue circumferential portion treated; energy delivery type; energy delivery rate and/or amount; peak energy delivered; average temperature of target tissue treatment; maximum temperature achieved during target tissue treatment; temperature profile of target tissue treatment; duration of target tissue treatment; and combinations of these.

[0106] Target tissue can include tissue of the duodenum, such as tissue including all or a portion of the mucosal layer of the duodenum, such as to treat diabetes and/or obesity while leaving the duodenum anatomically connected after treatment. Replacement tissue can comprise cells that have migrated from one or more of: gastric mucosa; jejunal mucosa; an untreated portion of the duodenum whose mucosal tissue functions differently than the treated mucosal tissue functions prior to treatment; and combinations of these. Replacement tissue can include one or more tissue types selected from the group consisting of: scar tissue; normal intestinal mucosa; gastric mucosa; and combinations of these. In some embodiments, target tissue includes a treatment portion comprising the mucosal layer of the duodenum, and a safety-margin portion comprising a near-full or partial layer of the submucosal layer of the duodenum. In some embodiments, the target tissue comprises nearly the entire length of the mucosal layer of the duodenum, and can include a portion of the pylorus contiguous with the duodenal mucosa and/or a portion of the jejunum contiguous with the duodenal mucosa. Treatment of duodenal or other small intestine tissue can be performed to treat a disease and/or disorder selected from the group consisting of: diabetes; obesity; insulin resistance; a metabolic disorder and/or disease; and

combinations of these. A near full circumferential portion (e.g. approximately 360°) of the mucosal layer of one or more segments of gastrointestinal tissue can be treated. In some embodiments, less than 360° of tubular tissue is treated, such as one or more circumferential portions less than 350°, or between 300° and 350°, such as to prevent a full circumferential scar from being created.

[0107] Target tissue can comprise tissue of the terminal ileum, such as to treat hypercholesterolemia and/or diabetes. In these embodiments, the target tissue can extend into the proximal ileum and/or the colon.

[0108] Target tissue can comprise gastric mucosal tissue, such as tissue regions that produce ghrelin and/or other appetite regulating hormones, such as to treat obesity and/or an appetite disorder.

[0109] Target tissue can comprise bladder wall tissue, such as to treat a disease and/or disorder selected from the group consisting of: interstitial cystitis; bladder cancer; bladder polyps; pre-cancerous lesions of the bladder; and combinations of these.

[0110] Target tissue can comprise tissue selected from the group consisting of: large and/or flat colonic polyps; margin tissue remaining after a polypectomy; and combinations of these. These tissue locations can be treated to treat residual cancer cells.

[0111] Target tissue can comprise airway lining tissue, such as to treat a disease and/or disorder selected from the group consisting of: bronchoalveolar carcinoma; other lung cancers; pre-cancerous lung lesions; and combinations of these.

[0112] Target tissue can comprise at least a portion of the intestinal tract afflicted with inflammatory bowel disease, such that Crohn's disease and/or ulcerative colitis can be treated.

[0113] Target tissue can comprise tissue of the oral cavity, such as to treat one or more of: oral cancers and a pre-cancerous lesion of the oral cavity.

[0114] Target tissue can comprise tissue of the nasopharynx, such as to treat nasal polyps.

[0115] Target tissue can comprise gastrointestinal tissue selected to treat Celiac disease and/or to improve intestinal barrier function.

[0116] The treatment assemblies, systems, devices and methods of the present inventive concepts can be constructed and arranged to avoid treating certain tissue, termed "non-target tissue" herein. Depending on the location of treatment, different non-target tissue can be applicable. In certain embodiments, non-target tissue can comprise tissue selected from the group consisting of: gastrointestinal adventitia; duodenal adventitia; the tunica serosa; the tunica muscularis; the outermost partial layer of the submucosa; Ampulla of Vater such as during

mucosal treatment proximate the Ampulla of Vater; pancreas; bile duct; pylorus; and combinations of these.

[0117] As described herein, room pressure shall mean pressure of the environment surrounding the systems and devices of the present inventive concepts. Positive pressure includes pressure above room pressure or a pressure that is greater than another pressure, such as a positive differential pressure across a fluid pathway component such as a valve. Negative pressure includes pressure below room pressure or a pressure that is less than another pressure, such as a negative differential pressure across a fluid component pathway such as a valve. Negative pressure can include a vacuum but does not imply a pressure below a vacuum.

[0118] The treatment assemblies and expandable elements of the present inventive concepts can be constructed and arranged to automatically and/or manually expand in at least a radial direction. Typical expandable elements include but are not limited to: an inflatable balloon; a radially expandable cage or stent; one or more radially deployable arms; an expandable helix; an unfurlable compacted coiled structure; an unfurlable sheet; an unfoldable compacted structure; and combinations of these. In some embodiments, the expandable elements can comprise a radially expandable tube, such as a sheet of material resiliently biased in a radially expanded condition that can be compacted through a furling operation, or a sheet of material resiliently biased in a radially compact condition that can be expanded through an unfurling operation. The expandable element can comprise a foldable sheet, such as a sheet constructed and arranged to be folded to be radially compacted and/or to be unfolded to radially expand.

[0119] Each of the expandable assemblies and treatment assemblies of the present inventive concepts can include one or more ablation elements, such as electrodes configured to deliver radiofrequency (RF) energy, or other functional elements such as are described in reference to the figures herebelow. The ablation or other functional elements can be mounted on, within (e.g. within the wall) and/or inside of an expandable element such as a balloon or expandable cage. The electrodes of the present inventive concepts comprise an electrically conductive element ("conductor") configured to deliver RF energy to tissue, either through direct contact and/or a capacitive coupling (e.g. electrical energy delivered through a gap and/or dielectric material, such as a dielectric covering positioned between the electrode and tissue to receive electrical energy from the electrode). The electrodes can comprise one or more electrically connected segments of conductive material, such as one or more electrically connected filaments that can be arranged in parallel with one or more electrically connected filaments of a separate (electrically isolated) electrode.

[0120] The balloons of the present inventive concepts can be divided into two general categories: those that are composed of a substantially elastic material, such as silicone, latex, low-durometer polyurethane, and the like; and those that are composed of a substantially inelastic material, such as polyethylene terephthalate (PET), nylon, high-durometer polyurethane and the like. A third category includes balloons which include both elastic and inelastic portions. Within the category of elastic balloons, two subcategories exist: a first sub-category wherein a combination of material properties and/or wall thickness can be combined to produce a balloon that exhibits a measurable pressure-threshold for inflation, i.e. the balloon becomes inflated only after a minimum fluidic pressure is applied to the interior of the balloon; and a second sub-category, wherein the balloon expands elastically until an elastic limit is reached which effectively restricts the balloon diameter to a maximum value. It will be understood that the individual properties of the balloons in each of these categories can be applied to one or more advantages in the specific embodiments disclosed herein, these properties integrated singly or in combination. By way of example only, one or more of the following configurations can be employed: a highly elastic balloon can be used to achieve a wide range of operating diameters during treatment, e.g. during operation a desired balloon diameter can be achieved by adjustment of a combination of fluid temperature and pressure; a substantially inelastic balloon or a balloon that reaches its elastic limit within a diameter approximating a target tissue diameter (e.g. a duodenal mucosal diameter) can be used to achieve a relatively constant operating diameter that will be substantially independent of operating pressure and temperature; a balloon with a pressure-threshold for inflation can be used to maintain an uninflated diameter during relatively low pressure conditions of fluid flow and then achieve a larger operating diameter at higher pressure conditions of flow. Pressure-thresholded balloons can be configured in numerous ways. In one embodiment, a balloon is configured to have a relatively thick wall in its uninflated state, such as to maximize an electrically and/or thermally insulating effect while the balloon is maintained in this uninflated state. The balloon can be further configured such that its wall thickness decreases during radial expansion (e.g. to decrease an electrically and/or thermally insulating effect). In another embodiment, a balloon is configured to have a relatively small diameter in its uninflated state (e.g. a diameter that is small relative to the inner diameter of tubular target tissue such as the diameter of the mucosal layer of duodenal wall tissue), such as to minimize or completely eliminate apposition between the balloon and the surrounding tissue to minimize RF and/or other energy transfer into the surrounding tissue until the balloon is fully inflated. In another embodiment, a balloon and an ablation system or device are configured to circulate a flow of hot fluid through the balloon (e.g. an elastic balloon or an inelastic balloon) at

a sufficiently low enough pressure to prevent apposition of the balloon with target tissue, such as to pre-heat one or more surfaces of the ablation system or ablation device that are in fluid communication with the balloon. In this configuration, when the balloon is fully inflated, the temperature of the fluid of the balloon will be at a desired level or it will rapidly and efficiently reach the desired level for treatment (i.e. minimal heat loss to the fluid path components due to the pre-heating). These configurations provide a method of delivering energy to tissue with a hot fluid filled balloon, as well as a method of "thermal priming" prior to target tissue treatment, such as is described in applicant's co-pending U.S. Provisional Application Serial Number 61/635,810, entitled "Tissue Expansion Devices, Systems and Methods", filed April 19, 2012, the contents of which is incorporated herein by reference in its entirety.

[0121] Treatment Modality 1: APPOSITION BETWEEN A TREATMENT ASSEMBLY AND THE TARGET TISSUE IS ESTABLISHED BY ADJUSTING THE TREATMENT ASSEMBLY DIAMETER. At times during treatment when it is desirable to increase or otherwise modify energy transfer between an ablation element such as an electrode and the target tissue, the treatment assembly diameter (e.g. the diameter of a balloon, deployable cage, expandable tube or other expandable assembly) can be increased *in situ* so as to conform to the native diameter of the target tissue, such as to the native diameter of tubular tissue such as small intestine wall tissue, such as duodenal wall tissue. At times during treatment when it is desirable to stop or otherwise decrease energy delivery between the treatment assembly and the target tissue, the treatment assembly diameter can be reduced *in situ*, such as to prevent or reduce contact of one or more ablation elements (e.g. electrodes or hot fluid filled balloons) with the target tissue. For those cases where the native diameter of the tissue varies substantially within the treatment zone, then a highly elastic or compliant balloon or other expandable element can be employed, such as a balloon or deployable cage which can be adjusted to achieve a wide range of operating diameters.

[0122] Treatment Modality 2: APPOSITION BETWEEN THE TREATMENT ASSEMBLY AND THE TARGET TISSUE IS ESTABLISHED BY CONTROLLING THE DIAMETER OF THE TARGET TISSUE. To initiate and/or increase energy delivery between a treatment assembly and the target tissue, the diameter of the target tissue can be decreased *in situ* so as to approximate and/or conform to the current diameter of the treatment assembly. To stop or otherwise decrease energy delivery between the treatment assembly and the target tissue, the diameter of the target tissue can be increased *in situ*, so as to prevent or reduce contact of tissue (e.g. target tissue and/or non-target tissue) with a treatment assembly. The diameter of the tissue proximate a treatment assembly can be increased or decreased, independent of the treatment

assembly diameter, by means of delivering and/or withdrawing a fluid, to and/or from a lumen surrounded by target tissue, such as by using standard gastrointestinal insufflation techniques. Typical insufflation fluids include but are not limited to: gases such as carbon dioxide or air; liquids such as water or saline solution; and combinations of these. The insufflation fluids can be introduced through the ablation device, through an endoscope such as an endoscope through which the ablation device is inserted, and/or via another device placed proximate the target tissue. Delivery of insufflation fluids can be performed to manipulate tissue, such as to distend and/or elongate tissue. Alternatively or additionally, delivery of insufflation fluids can be performed to move target tissue away from a treatment assembly, such as to stop transfer of energy to target tissue at the end of a thermal dose period as described above. Removal of these insufflation fluids and/or the application of a vacuum or other negative pressure by one or more of the devices described hereabove, can be used to decrease the diameter of the target tissue, such as to bring the target tissue in contact with a treatment assembly. In this tissue diameter controlled approach, a balloon that can be maintained at a substantially constant diameter can be desirable, such as a substantially inelastic balloon such as a balloon with an elastic-limit.

[0123] Referring now to FIG. 1, a system for ablating or otherwise treating target tissue is illustrated, consistent with the present inventive concepts. System 10 is constructed and arranged to treat target tissue TT, which includes one or more tissue portions within a body lumen of a mammalian patient, such as a continuous circumferential segment of a duodenum or other small intestine location. In some embodiments, target tissue TT comprises a treatment portion comprising small intestine mucosal tissue (e.g. duodenal mucosal tissue) and a safety-margin portion comprising at least an innermost layer of the small intestine submucosa (e.g. an innermost layer of the duodenal submucosa). System 10 can be constructed and arranged to treat mucosal tissue while avoiding damage to adventitial tissue. System 10 can include one or more ablation catheters or other ablation devices, such as first ablation device 100 and second ablation device 100'. A supply of electrical energy is provided to at least ablation device 100 by energy delivery unit (EDU) 330, typically a supply of radiofrequency (RF) energy. A device for delivering fluid, fluid delivery unit 340, can be included in system 10, such as to deliver one or more fluids (e.g. one or more cooling and/or warming fluids) to modify the temperature of tissue and/or modify the temperature of one or more system device components. A controlling interface, controller 360 can be operably attached to one or more components of system 10, such as EDU 330, fluid delivery unit 340 and/or another device or assembly of system 10, such as to control and/or monitor one or more parameters of the attached device or assembly.

[0124] In the embodiment of Fig. 1, ablation device 100 includes coaxial shafts 111a and 111b. Shaft 111b has a distal end 112. Shafts 111a and 111b are sized and configured such that shaft 111a slidingly receives shaft 111b, such that they can be advanced and/or retracted in unison or independently. In some embodiments, device 100 comprises a flexible portion (e.g. a portion of shafts 111a and 111b including distal end 112) with a diameter less than 6mm. In some embodiments, the flexible portion comprises a diameter less than 4.2mm, less than 3.8mm, less than 3.2mm or less than 2.8mm, such as to be slidingly received by a working channel of an endoscope that accepts diameters less than 6mm. In some embodiments, device 100 comprises a shaft length of 100cm or longer, or otherwise comprises a length sufficient to be orally and/or nasally inserted to reach the esophagus, stomach, duodenum, jejunum or terminal ileum of a patient. In Fig. 1, shafts 111a and 111b have been inserted through a working channel (e.g. a 6mm working channel), lumen 351, of endoscope 350, typically a gastrointestinal endoscope. Shafts 111a and/or 111b can be inserted over a standard interventional guidewire, such as guidewire 371 shown exiting distal end 112 of shaft 111b. In an alternative embodiment, shafts 111a and 111b are positioned in a side-by-side configuration, such as to be placed in two separate lumens of endoscope 350 or in two other non-coaxial locations. In some embodiments, one or both of shafts 111a or 111b can be inserted alongside endoscope 350 (i.e. not through lumen 351, traveling parallel with but external to endoscope 350). Shaft 111a and 111b can include deflection means constructed and arranged to steer a distal portion of the shaft, such as is described in reference to Figs. 9A - 9C herebelow.

[0125] Ablation device 100 further includes two radially expandable assemblies, expandable assembly 130a, and expandable assembly 130b, mounted to shafts 111a and 111b, respectively. Expandable assemblies 130a and 130b can be constructed and arranged in one or more various forms to treat, modify, measure and/or diagnose target tissue TT and/or other tubular tissue. Expandable assemblies 130a and 130b can comprise an expandable element selected from the group consisting of: an inflatable balloon; a radially expandable stent or cage; an array of splines; one or more radially deployable arms; a spiral or other helical structure; a furlable structure such as a furlable sheet; an unfurlable structure such as an unfurlable sheet; a foldable structure such as a foldable sheet; an unfoldable structure such as an unfoldable sheet; and combinations of these. Expandable assembly 130a can be positioned proximal to expandable assembly 130b as shown in Fig. 1, or alternatively, expandable assembly 130b can be positioned proximal to expandable assembly 130a, such as when expandable assembly 130a is mounted to shaft 111b and expandable assembly 130b is mounted to shaft 111a.

[0126] In some embodiments, expandable assembly 130a and/or 130b comprise a length of at least 10mm, such as a length between 10mm and 40mm, a length between 15mm and 30mm, or a length between 20mm and 25mm. In some embodiments, expandable assembly 130a and/or 130b comprise a length less than or equal to 15mm, such as when configured to treat curvilinear portions of the gastrointestinal tract. Multiple expandable assemblies (e.g. between two and twenty expandable assemblies), such as expandable assemblies 130a and 130b, can be separated along a shaft by a distance less than or equal to 25mm, such as a distance less than or equal to 20mm. In some embodiments, expandable assembly 130a comprises a length, and the separation distance between expandable assembly 130a and 130b is less than or equal to the expandable assembly 130a length. In these embodiments, expandable assembly 130b can comprise a similar length to that of expandable assembly 130a, such as when both expandable assembly 130a and expandable assembly 130b comprise ablation elements.

[0127] Expandable assembly 130a and/or 130b can be constructed and arranged to expand to a diameter of at least 15mm, such as a diameter of at least 20mm, 25mm or at least 30mm. Expandable assembly 130a and/or 130b can be resiliently biased, such as in a radially expanded or radially compacted state. Expandable assembly 130a and/or 130b can be expanded and/or compacted by a control shaft, not shown but described in detail in reference to Fig. 10 herebelow. Expandable assembly 130a and/or 130b can be constructed and arranged to achieve a round or non-round shape (e.g. an oval or football shape) when expanded. Expandable assembly 130a and/or 130b can approximate a tube shape when expanded, such as a unidiameter or varying diameter tube shape. A tissue contacting portion of expandable assembly 130a and/or 130b can comprise a shape selected from the group consisting of: triangle; rectangle; pentagon; hexagon; trapezoid; and combinations of these, examples of which are described in reference to Figs. 9A-9C herebelow. Expandable assembly 130a and/or 130b can be constructed and arranged to unfold to a radially expanded state, or to fold to a radially compacted state, such as is described in reference to Fig. 4A-4C herebelow.

[0128] Expandable assembly 130a can comprise at least one functional element 131a, and expandable assembly 130b can comprise at least one functional element 131b. Functional elements 131a and/or 131b can be elements selected from the group consisting of: an ablation element such as one or more electrodes constructed and arranged to deliver electrical energy such as radiofrequency (RF) energy; a sensor; a transducer; a fluid delivery element such as a needle, a fluid jet, a permeable membrane and/or an exit port; and combinations of these.

[0129] In some embodiments, expandable assembly 130a is constructed and arranged to ablate tissue, and expandable assembly 130b is constructed and arranged to perform at least one non-

ablative function. Expandable assembly 130b can be constructed and arranged to occlude or partially occlude a lumen surrounded by tissue, such as a lumen of the gastrointestinal tract to be occluded during an insufflation procedure. Expandable assembly 130b can be constructed and arranged to manipulate tissue, such as to linearize and/or distend gastrointestinal tissue by frictionally engaging (e.g. when expanded) and applying forces to the tissue (e.g. by advancing and/or retracting shaft 111b). Expandable assembly 130b can be constructed and arranged to test and/or diagnose tissue, such as when expandable assembly 130b is used to measure a diameter of tubular tissue into which it has been inserted. Diameter measurements can be performed in various ways, including but not limited to: injection of a radiopaque fluid into assembly 130b and fluoroscopic measurement of the injected fluid; controlled inflation of assembly 130b to a pressure whose level corresponds to a luminal diameter; and combinations of these. In some embodiments, system 10 includes a separate device, such as a balloon catheter, used to perform a diameter measurement. One or more energy delivery parameters can be adjusted based on the measured diameter of target tissue and/or a target tissue portion.

[0130] In some embodiments, expandable assembly 130b is constructed and arranged to expand or otherwise modify one or more layers of tissue, such as to when functional element 131b comprises one or more needles and/or one or more water jets constructed and arranged to expand submucosal tissue of the gastrointestinal tract. Alternatively or additionally, system 10 can include a separate tissue expansion device, tissue expansion device 390. Expandable assembly 130b and/or tissue expansion device 390 can be constructed and arranged as is described in applicant's co-pending International Application Serial Number PCT/US2013/37485, entitled "Tissue Expansion Devices, Systems and Methods", filed April 19, 2013, the contents of which is incorporated herein by reference in its entirety. Expandable assembly 130b and/or tissue expansion device 390 can include single or multiple fluid delivery elements, such as one or more needles and/or one or more water jets configured to deliver a fluid, gel or other material into tissue. Tissue expansion device 390 includes fluid delivery element 391, which can be attached to a radially expandable assembly, such as expandable assembly 393. Expandable assembly 393 can comprise an expandable balloon. Alternatively or additionally, expandable assembly 130b can include a fluid delivery element, such as fluid delivery element 129 as shown. Fluid delivery elements 391 and/or 129 can be attached to one or more fluid delivery tubes, not shown but attachable to a source of fluid. Fluid delivery elements 391 and/or 129 can be constructed and arranged to cause a circumferential expansion of tissue, such as a circumferential expansion of submucosal tissue of the duodenum or other small intestine location. Fluid delivery elements 391 and/or 129 can comprise an array of fluid delivery

elements, such as a circumferential or linear array of needles and/or water jets. A vacuum can be applied proximate fluid delivery elements 391 and/or 129 to stabilize, manipulate or otherwise apply a force to the tissue receiving the expansion material. A vacuum can be applied via a port proximate the fluid delivery element, such as vacuum port 392 positioned proximate fluid delivery element 391. Tissue expansion can greatly alleviate the need for precision of treatment, such as precision of energy delivery, due to the increased size (e.g. increased depth) of the target tissue including an associated safety-margin of tissue to which treatment causes no significant adverse event (e.g. an expanded submucosal layer prior to a mucosal layer ablation). Treatment of target tissue after submucosal expansion is described in reference to Fig. 2 herebelow.

[0131] Expandable assembly 130a of Fig. 1 includes an ablation element comprising a pair of electrodes, first electrode 136a and second electrode 137a. In some embodiments, three or more electrodes can be included, such as an expandable assembly 130a which includes at least 4 electrodes. Electrodes 136a and/or 137a can be mounted on, within and/or inside of expandable assembly 130a. Electrodes 136a and/or 137a can be positioned to directly contact tissue for RF energy delivery, or they can be separated by a gap and/or dielectric material allowing capacitive coupling transfer of RF energy to tissue.

[0132] Electrodes 136a and/or 137a can comprise multiple elongate conductors, such as multiple elongate copper conductors in the interdigitated, parallel arrangement shown in Fig. 1. Electrodes 136a and/or 137a can comprise flexible conductors, such as flexible copper conductors that flex as expandable assembly 130a transitions between radially compacted and radially expanded conditions. Electrodes 136a and 137a can be attached to expandable assembly 130a with one or more attachment elements such as at least one of: a glue joint; a weld; a swage or a molecular bond. Electrodes 136a and 137a can be at least partially embedded in a portion of expandable assembly 130a, such as within the wall of a balloon when expandable assembly 130a comprises an inflatable balloon. Expandable assembly 130a can comprise a flexible substrate to which electrodes 136a and 137a are attached, such as the flexible substrate described in reference to Fig. 8A herebelow. Electrodes 136a and/or 137a can comprise a wire construction, such as a copper and/or other conductive wire with a diameter less then 500 microns. Electrodes 136a and/or 137a can include one or more anti-stick coatings and/or coverings, such as a coating and/or covering including polytetrafluoroethylene.

[0133] In some embodiments, expandable assemblies 130a and/or 130b comprise a shape that can be adjusted by an operator, such as via a control rod as is described in reference to Fig. and 10 herebelow. In some embodiments, the shape of the arrangement of electrodes 136a and/or

137a (e.g. arrangement between two separate electrodes and/or arrangement of conductors within a single electrode) can be operator modified by adjusting the shape of expandable assembly 130a.

[0134] Electrodes 136a and 137a can comprise capacitively coupled electrodes, such as those described in reference to Fig. 10A herebelow. Electrodes 136a and/or 137a can be constructed and arranged to transfer RF energy to the target tissue via a capacitive coupling including a gap and/or dielectric material between the electrode and the target tissue. A dielectric sheet or other covering can be included, with uniform or non-inform thickness. In some embodiments, a non-uniform thickness comprising thicker edge portions than middle portions can be included, such as to tend to create a uniform ablation depth (e.g. minimizing undesired edge effects along an electrodes perimeter).

[0135] Electrode 136a is electrically attached to wire 138a and electrode 137a is electrically attached to wire 139a. Wires 138a and 139a travel proximally within shaft 111b and are electrically attached to EDU 330, via one or more connections such as one or more operator attachable plugs and/or other electromechanical connections. System 10 can include ground pad 332, such as a standard RF energy delivery ground pad typically placed on the patient's back, such that EDU 330 can supply RF energy to electrodes 136a, 137a and/or any other electrodes of system 10 in monopolar, bipolar and/or combined monopolar-bipolar modes. Electrodes 136a and/or 137a can be configured to ablate various thickness of gastrointestinal tissue, such as at least the innermost 500 microns of small intestine tissue (e.g. at least the innermost 500 microns of duodenal tissue). Electrodes 136a and 137a can be configured to ablate a volume of tissue comprising a surface area and a depth, where the ratio of depth to surface area is less than or equal to 1 to 100 (e.g. less than 1%), or less than or equal to 1 to 1000 (e.g. less than 0.1%). In some embodiments, expandable assemblies 130a and/or 130b are constructed and arranged to be in a relatively rigid state, such as during delivery of electrical energy to target tissue TT. The rigidity can be used to maintain a pre-determined spacing of one or more conductors delivering RF energy, such as the spacing between parallel, neighboring conductors of electrodes 136a and 137a.

[0136] Electrodes 136a, 137a and/or other ablation elements of the present inventive concepts can include copper and/or other conductive materials arranged in various patterns, such that EDU 330 can deliver bipolar energy in associated patterns. Bipolar RF energy can be delivered between a first elongate conductor (e.g. of electrode 136a) and a second elongate conductor (e.g. of electrode 137a), such as two filaments positioned directly next to each other, or two filaments separated by one or more other conductors (e.g. separated by a conductor electrically isolated from the two filaments receiving the bipolar RF energy current delivered by EDU 330). In some

embodiments, electrical energy is delivered between two elongate conductors, such as the pairs of conductors of electrodes 136a and 137a shown, where the spacing between the edges of two neighboring conductors of electrodes 136a and 137a (hereinafter the "edge-to-edge spacing" as illustrated in Fig. 2A) is between 200 micron and 2mm. In some embodiments, the edge-to-edge spacing is less than or equal to 1.5mm, such as less than 1.0mm or less than 750 microns.

[0137] Electrodes 136a, 137a and/or other ablation elements of the present inventive concepts can comprise one or more elongate conductors with a width less than 2.0mm, such as a width less than 1.5mm, less than 1.0mm or between 400 and 700 microns. In some embodiments, at least one electrode comprises one or more elongate conductors with a width of at least 230 microns. In some embodiments, at least one electrode comprises an elongate conductor with a width of at least 400 microns, such as a pair of electrodes comprising a pair of conductors with an edge-to-edge spacing of approximately 600 microns. In some embodiments, at least one electrode comprises an elongate conductor with a width of at least 700 microns, such as a pair of electrodes comprising a pair of conductors with an edge-to-edge spacing of approximately 400 microns. In some embodiments, at least one electrode comprises an elongate conductor with a width whose value is less than or equal to a desired depth of ablation. In some embodiments, a first electrode comprises a first conductor, and a second electrode comprises a second conductor, and the first conductor and the second conductor (hereinafter a "conductor pair" as illustrated in Fig. 2A) have an edge-to-edge spacing that is less than or equal to the desired depth of ablation. In some embodiments, conductor pairs have an edge-to-edge spacing between 230 microns and 2.0 mm, such as a spacing between 400 microns and 600 microns. In some embodiments, at least one conductor of a conductor pair has a width approximately 50% of the edge-to-edge spacing of that conductor pair. In some embodiments, multiple conductor pairs have similar edge-to-edge spacing, such as an edge to edge spacing with a uniformity greater than or equal to 95%, or greater than or equal to 98%.

[0138] Electrodes 136a, 137a and/or other ablation elements of the present inventive concepts can be arranged in an array of electrically connected or electrically isolated conductors, such as a circumferential array of linear and/or curvilinear elongate conductors. The circumferential array can comprise a partial circumferential array of conductors (e.g. as is shown in Fig. 1) such as an array covering approximately 45° to 300° of circumferential area. Partial circumferential arrays of conductors can treat a first target tissue portion and a second target tissue portion in two sequential steps, wherein the array is rotated between energy deliveries. Alternatively, the circumferential array can comprise a full 360° array of conductors (e.g. a full 360° array of interdigitated pairs of conductors comprising a single or multiple pairs of electrodes), such that a

full circumferential volume of target tissue can be treated in a single energy delivery or in multiple energy deliveries that do not require repositioning of ablation device 100. In some embodiments, the circumferential array can be constructed and arranged to avoid creation of a full circumferential scar in tubular tissue, such as an array of between 300° and 350° of one or more electrodes (e.g. a 300° to 350° array of interdigitated pairs of conductors comprising a single or multiple pairs of electrodes). Two or more electrodes can be arranged in a helical array of two or more conductors. Two or more pairs of single or multiple filament conductors can be included, with any combination or arrangement of pairs driven by bipolar RF energy to treat the target tissue. In some embodiments, at least three, four or five pairs of conductors are driven simultaneously or sequentially by bipolar RF energy to treat the target tissue.

[0139] Electrodes 136a, 137a and/or other ablation elements of the present inventive concepts can comprise a sufficient length (singly or in combination) to treat substantially the entire length of the target tissue simultaneously or at least without having to reposition ablation device 100. In some embodiments, the target tissue comprises substantially the entire length of the duodenum. Electrodes 136a, 137a and/or other ablation elements of the present inventive concepts can comprise a sufficient length (singly or in combination) to treat at least 50% of the entire length of the target tissue simultaneously or at least without having to reposition ablation device 100. In some embodiments, the target tissue comprises at least 50% of the length of the duodenum. Electrodes 136a, 137a and/or other ablation elements of the present inventive concepts can be constructed and arranged to treat a first portion of target tissue followed by a second portion of target issue. The first and second treated tissue portions can be overlapping and they can have non-parallel central axes (e.g. tissue portions in a curved portion of the duodenum or other small intestine location). Three or more target tissue portions can be treated, such as to cumulatively ablate at least 50% of the duodenal mucosa.

[0140] In some embodiments, functional element 131b of expandable assembly 130b comprises one or more electrical energy delivery or non-electrical energy delivery ablation elements, such as those described in applicant's co-pending International PCT Application Serial Number PCT/US12/21739, entitled "Devices and Methods for the Treatment of Tissue", filed January 18, 2012, the contents of which is incorporated herein by reference in its entirety. In some embodiments, functional element 131b comprises an ablation element selected from the group consisting of: an RF energy delivery element such as one or more electrodes, each comprising one or more elongate conductors; an ultrasonic transducer such as one or more piezo crystals configured to ablate tissue; a laser energy delivery element such as one or more optical fibers and/or laser diodes; a heat delivery element such as a hot fluid filled balloon; a rotating

ablation element; a circumferential array of ablation elements; and combinations of these. In these embodiments, either or both expandable assembly 130a and 130b can be used to ablate target tissue TT.

[0141] In some embodiments, expandable assemblies 130a and/or 130b comprise inflatable or otherwise expandable balloons, such as one or more of: a compliant balloon; a non-compliant balloon; a balloon with a pressure threshold; a balloon with compliant and non-compliant portions; a balloon with a fluid entry port; a balloon with a fluid exit port; and combinations of these. In some embodiments, expandable assemblies 130a and/or 130b comprise a balloon which is fluidly attached to an inflation tube, such as an inflation tube which travels proximally through shaft 111a and/or 111b and is attached to an inflation port, not shown but typically attached to a handle on the proximal end of ablation device 100.

[0142] In some embodiments, expandable assembly 130b comprises an abrasive element configured for abrading target tissue, such as an abrasive element attached to a balloon or expandable cage.

[0143] Shafts 111a and 111b can include one or more lumens passing therethrough, and can comprise wires and/or optical fibers for transfer of data and/or energy such as RF energy to electrodes 136a and 137a of assembly 130a. Shafts 111a and/or 111b can comprise one or more shafts, such as one or more concentric shafts configured to deliver and/or re-circulate hot and/or cold fluid through expandable assemblies 130a and/or 130b, respectively, such as to deliver a bolus of hot fluid energy and/or other thermal dose as described in applicant's co-pending International Application Serial Number PCT/US2013/28082, entitled "Heat Ablation Systems, Devices and Methods for the Treatment of Tissue", filed February 27, 2013, the contents of which is incorporated herein by reference in its entirety. Device 100 can comprise a single expandable assembly 130a, without inclusion of expandable assembly 130b, as is described in reference to multiple embodiments herebelow.

[0144] Expandable assembly 130a and/or 130b can be constructed and arranged to ablate tissue or otherwise perform a function while positioned in a curved segment of the gastrointestinal tract, such as is described in reference to Fig. 3 herebelow.

[0145] The systems of the prevent inventive concepts are constructed and arranged to ablate or otherwise treat target tissue TT, such as duodenal or other small intestinal mucosal tissue, while avoiding damaging non-target tissue, such as the gastrointestinal adventitia. Target tissue TT can include at least a portion of safety-margin tissue comprising tissue whose ablation causes minimal or no adverse effect to the patient, such as sub-mucosal tissue of the gastrointestinal tract. Target tissue TT can comprise one or more portions of tissue that are treated

simultaneously or sequentially. In some embodiments, the target tissue TT comprises the majority of the length of the duodenal mucosa, such as at least 50% of the duodenal mucosa. In some embodiments, the target tissue TT comprises at least 90% of the duodenal mucosa, or at least 95% of the duodenal mucosa. In some embodiments, the target tissue TT includes the full mucosal thickness of at least a portion of duodenal or other small intestinal tissue, as well as at least the innermost 100 microns of submucosal tissue, or at least the innermost 200 microns of submucosal tissue. In some embodiments, system 10 and/or ablation device 100 is constructed and arranged to avoid ablating at least an outermost layer of small intestine submucosal tissue (e.g. avoid ablating an outermost layer of duodenal submucosal tissue), such as a non-ablated outermost layer that is at least 100 microns thick, or at least 200 microns thick. The target tissue TT can include at least one of ileal mucosal tissue or gastric mucosal tissue.

[0146] Endoscope 350 can be a standard endoscope, such as a standard gastrointestinal endoscope, or a customized endoscope, such as an endoscope including sensor 353 configured to provide information related to the tissue treatment of the present inventive concepts. Endoscope 350 can include camera 352, such as a visible light, ultrasound and/or other visualization device used by the operator of system 10 prior to, during and/or after the treatment of target tissue TT, such as during insertion and/or removal of endoscope 350 and/or shafts 111a and 111b of ablation device 100. Camera 352 can provide direct visualization of internal body spaces and tissue, such as the internal organs of the gastrointestinal tract. Endoscope 350 can be coupled with or otherwise include a guidewire, e.g. guidewire 371, such as to allow insertion of endoscope 350 into the jejunum.

[0147] System 10 can be constructed and arranged to perform insufflation of a body lumen, such as a segment of the gastrointestinal tract. The body lumen can be pressurized, such as by using one or more standard insufflation techniques. Insufflation fluid can be introduced through second lumen 354 of endoscope 350. Second lumen 354 travels proximally and connects to a source of insufflation liquid and/or gas, such as fluid delivery unit 340, and typically a source of air, carbon dioxide, water and/or saline. Alternatively or additionally, insufflation fluid can be delivered by ablation device 100, such as through shaft 111a and/or 111b, and/or through a port in expandable assembly 130a and/or 130b, such as when functional elements 131a and/or 131b, respectively, comprise a fluid delivery port attached to a source of insufflation liquid and/or gas. Alternatively or additionally, a separate device configured to be inserted through endoscope 350 and/or to be positioned alongside endoscope 350, can have one or more lumens configured to deliver the insufflation fluid. System 10 can include one or more occlusive elements and/or devices, such as expandable assemblies 130a, 130b and/or another expandable device configured

to radially expand such as to fully or partially occlude a body lumen, such that insufflation pressure can be achieved and/or maintained over time (e.g. reduce or prevent undesired migration of insufflation fluid). The one or more occlusive elements and/or devices can be positioned proximal to and/or distal to the luminal segment to be insufflated.

[0148] Functional element 131a and/or functional element 131b can comprise a sensor. In some embodiments, functional element 131a, functional element 131b, sensor 353 and/or another sensor of system 10 can comprise a sensor selected from the group consisting of: temperature sensors such as thermocouples, thermistors, resistance temperature detectors and optical temperature sensors; strain gauges; impedance sensors such as tissue impedance sensors; pressure sensors; blood sensors; optical sensors such as light sensors; sound sensors such as ultrasound sensors; electromagnetic sensors such as electromagnetic field sensors; and combinations of these. The sensors can be configured to provide information to one or more components of system 10, such as to controller 360 and/or EDU 330, such as to monitor the treatment of target tissue TT and/or to treat target tissue TT in a closed loop configuration. Energy delivery from EDU 330 can be modified based on one or more sensor readings. In one embodiment, an algorithm of controller 360 and/or EDU 330 processes one or more sensor signals to modify amount of energy delivered, power of energy delivered, voltage of energy delivered, current of energy delivered and/or temperature of energy delivery.

[0149] A sensor such as a chemical detection sensor can be included, such as to confirm proper apposition of expandable assemblies 130a and/or 130b. In this configuration, a chemical sensor such as a carbon dioxide sensor can be placed distal to expandable assemblies 130a and/or 130b, and a fluid such as carbon dioxide gas is introduced proximal to the expandable assemblies 130a and/or 130b. Detection of the introduced fluid can indicate inadequate apposition of expandable assemblies 130a and/or 130b, such as to prevent inadequate transfer of energy to target tissue TT and/or prevent inadequate measurement, modification and/or diagnosis of target tissue TT.

[0150] Functional element 131a, functional element 131b, sensor 353 and/or another sensor of system 10 can comprise a sensor configured to provide information related to the tissue treatment performed by expandable assembly 130a and/or 130b, such as a visual sensor mounted to expandable assembly 130a that is configured to differentiate tissue types that are proximate expandable assembly 130a, such as to differentiate mucosal and submucosal tissue. Applicable visible sensors include but are not limited to: visible light camera; infrared camera; CT Scanner; MRI; and combinations of these. In some embodiments, electrical energy delivered by electrodes 136a, 137a and/or other ablation elements of system 10 is based on one or more signals from the visible sensor, such as a sensor providing a signal correlating to tissue color.

Functional elements 131a and 131b can comprise a sensor configured to provide information related to the tissue treatment performed by expandable assembly 130a and/or 130b, such as a temperature sensor configured to monitor the temperature of treatment provided by expandable assembly 130a and/or tissue proximate expandable assembly 130a. Functional elements 131a and/or 131b can comprise multiple temperature sensors, such as multiple temperature sensors positioned on expandable assembly 130a and/or 130b, respectively, with a spacing of at least one sensor per square centimeter. RF and/or other energy delivered by EDU 330 can be based on signals recorded by the multiple temperature sensors.

[0151] Functional element 131a and/or functional element 131b can comprise a transducer. In these and other embodiments, functional element 131a, functional element 131b, and/or another transducer of system 10 can be a transducer selected from the group consisting of: a heat generating element; a drug delivery element such as an iontophoretic drug delivery element; a magnetic field generator; an ultrasound wave generator such as a piezo crystal; a light producing element such as a visible and/or infrared light emitting diode; and combinations of these.

[0152] EDU 330 is configured to deliver energy to one or more ablation elements of system 10. In some embodiments, EDU 330 is configured to deliver at least RF energy, and system 10 includes ground pad 332 configured to be attached to the patient (e.g. on the back of the patient), such that RF energy can be delivered in monopolar delivery mode to electrode 136a, 137a and/or another electrode of system 10. Alternatively or additionally, EDU 330 can be configured to deliver energy in a bipolar RF mode, such as bipolar energy delivered between electrodes 136a and 137a of expandable assembly 130a. Alternatively or additionally, EDU 330 can be configured to deliver energy in a combined monopolar-bipolar mode.

[0153] EDU 330 can be constructed and arranged to deliver RF and/or other forms of energy to one or more ablation elements of expandable assembly 130a and/or 130b. In some embodiments, EDU 330 delivers energy selected from the group consisting of: RF energy; microwave energy; plasma energy; ultrasound energy; light energy; and combinations of these. Energy can be continuous and/or pulsed, and can be delivered in a closed-loop fashion as described hereabove. Energy delivery parameters such as power, voltage, current and frequency can be held relatively constant or they can be varied by EDU 330. Energy delivery can be varied from a first tissue location (e.g. a first portion of target tissue) to a second location (e.g. a second portion of target tissue), such as a decrease in energy from a first treated location to a second treated location when the second treated location is thinner than the first treated location. Alternatively or additionally, energy delivery can be varied during a single application of energy to a single tissue

location, such as by adjusting one or more energy delivery parameters during a continuous energy delivery.

[0154] System 10 can be further configured to deliver and extract one or more fluids from expandable assembly 130a and/or 130b, such as to pre-heat expandable assembly 130a and/or 130b and/or to deliver heat energy to target tissue TT via the delivered fluids. In one embodiment, fluid delivery unit 340 and/or EDU 330 are configured to deliver one or more supplies of hot fluid, such as hot water or saline when expandable assembly 130a and/or 130b comprises a balloon positioned at the end of one or more fluid delivery tubes, not shown but typically as described in applicant's co-pending International Application Serial Number PCT/US2013/28082, entitled "Heat Ablation Systems, Devices and Methods for the Treatment of Tissue", filed February 27, 2013, the contents of which is incorporated herein by reference in its entirety. In these embodiments, fluid delivery unit 340 and/or EDU 330 typically includes one or more fluid pumps, such as one or more peristaltic, displacement and/or other fluid pumps; as well as one or more heat exchangers and/or other fluid heating elements internal and/or external to device 100. Fluid delivery unit 340 and/or EDU 330 can be constructed and arranged to rapidly deliver and/or withdraw fluid to and/or from expandable assemblies 130a and/or 130b via one or more fluid transport means. Fluid transport means can include a pump configured to deliver fluid at a flow rate of at least 50 ml/min and/or a pump and/or vacuum source configured to remove fluid at a flow rate of at least 50 ml/min. A pump and/or vacuum source can be configured to continuously exchange hot fluid and/or to perform a negative pressure priming event to remove fluid from one or more fluid pathways of device 100. Fluid delivery unit 340, EDU 330 and/or ablation device 100 can include one or more valves in the fluid delivery and/or fluid withdrawal pathways or one or more other valves in the fluid pathway within expandable assemblies 130a and/or 130b. Valves can be configured to control entry of fluid into an area and/or to maintain pressure of fluid within an area. Valves can be used to transition from a heating fluid, such as a fluid of 90°C maintained in a treatment assembly for approximately 12 seconds, to a cooling fluid, such as a fluid between 4°C and 10°C maintained in the assembly element for approximately 30 to 60 seconds. Typical valves include but are not limited to: duck-bill valves; slit valves; electronically activated valves; pressure relief valves; and combinations of these. Fluid delivery unit 340 and/or EDU 330 can be configured to rapidly inflate and/or deflate expandable assemblies 130a and/or 130b. Fluid delivery unit 340 and/or EDU 330 can be configured to purge the fluid pathways of device 100 with a gas such as air, such as to remove cold and/or hot fluid from device 100 and/or to remove gas bubbles from device 100.

[0155] System 10 can include conductive gel 333, constructed and arranged to conduct thermal and/or electrical energy between a component of system 10 and tissue. Conductive gel 333 can be delivered by ablation device 100, such as via a port in expandable assembly 130a and/or 130b, not shown but typically connected to a fluid delivery tube that travels proximally to a handle on device 100, and/or via another device of system 10. Conductive gel 333 can be delivered to at least one of tissue or an external surface of a portion of a device of system 10, such as the external surface of expandable assembly 130a and/or 130b. Conductive gel 333 can be thermally conductive such as to improve heat transfer to tissue. Conductive gel 333 can be thermally conductive such as to improve cooling of tissue, such as when cool air is delivered to gel 333 and/or tissue via a component of system 10. Conductive gel 333 can be electrically conductive to improve transfer of electrical energy to tissue. System 10 can be constructed and arranged to allow an operator to place conductive gel 333 onto tissue prior to expansion of expandable assembly 130a and/or 130b. System 10 can be constructed and arranged to allow an operator to place conductive gel 333 onto electrode 136a and/or 137a prior to electrode 136a and/or 137a, respectively, contacting target tissue and/or delivering RF energy to tissue.

[0156] EDU 330, electrodes 136a and 137a and/or other components of system 10 can be constructed and arranged to treat target tissue TT with a non-desiccating ablation, such as by avoiding tissue temperatures above 100°C, avoiding the creation of steam, or otherwise avoiding deleterious desiccation of tissue. System 10 can be constructed and arranged to minimize heat production in the outermost 50% of a mucosal layer (e.g. to minimize RF current flow in the outermost 50% of a mucosal layer). In these embodiments, the outermost 50% of the mucosal layer can be ablated via thermal conduction (e.g. thermal conduction from the innermost 50% of the mucosal layer). Similarly, system 10 can be constructed and arranged to minimize heat production in the outermost 80% of a mucosal layer, such as to ablate the outermost 80% of the mucosal layer via thermal conduction. System 10 can be constructed and arranged to maximize the flow of current, such as through the innermost 50% of a mucosal layer, or through the innermost 20% of a mucosal layer. In some embodiments, system 10 can be constructed and arranged to avoid detachment of tissue particles.

[0157] EDU 330, electrodes 136a and 137a and/or other components of system 10 can be constructed and arranged to deliver RF energy to target tissue at a power density that averages less than 20 watts per cm^2, such as a power density that averages less than 10 watts per cm^2 or less than 4 watts per cm^2. RF energy can be delivered for a particular portion of target tissue for a time period of at least one second, such as a time period of at least 5 seconds, at least 10 seconds or at least 20 seconds. In some embodiments, RF energy is delivered to target tissue at a

level that decreases (e.g. one or more energy delivery parameter levels decrease) over time. In some embodiments, RF energy delivery comprises a modulated energy delivery, such as a pulse width modulated energy delivery with an "on" portion of the duty cycle below 20%. In some embodiments, EDU 330 comprises an RF source comprising a 300 Watts or less RF source, such as a 150 Watts or less RF source. In some embodiments, EDU 330 is configured to deliver an instantaneous power of less than 300 Watts, or less than 260 Watts, such as an instantaneous power than decreases to zero Watts over approximately 30 seconds. In some embodiments, EDU 330 is configured to deliver RF energy in a current-driven mode. In some embodiments, EDU 330 is configured to deliver RF energy for at least 2 seconds, such as in a continuous and/or pulsed manner. In some embodiments, the frequency of RF energy is maintained below 1.0 Mhz.

[0158] EDU 330, electrodes 136a and 137a and/or other components of system 10 can be constructed and arranged to deliver RF energy to target tissue such that the temperature of at least a portion of the target tissue rises rapidly, such as at a rate of greater than or equal to 17.5°C per second. The RF energy can be delivered to cause the temperature of at least a portion of the target tissue to reach a setpoint temperature between 60°C and 90°C, such as a setpoint temperature between 65°C and 80°C. System 10 can be constructed and arranged to cause the target tissue to elevate to a setpoint temperature and maintain that setpoint temperature, such as by maintaining the setpoint temperature for a time period between 2 and 40 seconds. In these embodiments, the setpoint temperature can be between 60°C and 90°C, such as a setpoint temperature between 75°C and 85°C that is maintained for between 15 and 25 seconds. In some embodiments, after a setpoint temperature is achieved and/or maintained, the RF energy delivered causes a decrease in temperature over time, such as to match a tissue response of the target tissue.

[0159] Controller 360 can include a graphical user interface configured to allow one or more operators of system 10 to perform one or more functions such as entering of one or more system input parameters and visualizing and/or recording of one or more system output parameters. Controller 360 can include one or more user input components (e.g. touch screens, keyboards, joysticks, electronic mice and the like), and one or more user output components (e.g. video displays; liquid crystal displays; alphanumeric displays; audio devices such as speakers; lights such as light emitting diodes; tactile alerts such as assemblies including a vibrating mechanism; and the like). Examples of system input parameters include but are not limited to: type of energy to be delivered such as RF energy, thermal energy and/or mechanical energy; quantity of energy to be delivered such as a cumulative number of joules of energy to be delivered and/or peak amount of energy to be delivered; types and levels of combinations of energies to be delivered;

energy delivery duration; pulse width modulation percentage of energy delivered; temperature of a fluid to be delivered to a expandable element such as a balloon; temperature of a cooling fluid to be delivered; flow rate of a hot fluid to be delivered; volume of a hot fluid to be delivered; number of reciprocating motions for an energy delivery element to transverse; temperature for a treatment assembly such as target temperature and/or maximum temperature; insufflation pressure; insufflation duration; and combinations of these. System input parameters can include information based on patient anatomy and/or conditions such as pre-procedural and/or peri-procedural parameters selected from the group consisting of: mucosal density and/or thickness; mucosal "lift" off of submucosa after a submucosal injection; longitudinal location of target tissue within the GI tract; and combinations of these. Examples of system output parameters include but are not limited to: temperature information such as tissue and/or treatment assembly temperature information; pressure information such as balloon pressure information and/or insufflation pressure information; force information such as level of force applied to tissue information; patient information such as patient physiologic information recorded by one or more sensors; and combinations of these.

[0160] Controller 360 and/or one or more other components of system 10 can include an electronics module, such as an electronics module including a processor, memory, software, and the like. Controller 360 can be configured to allow an operator to initiate, modify and cease treatment of target tissue by the various components of system 10, such as by controlling energy delivery unit 330 and/or fluid delivery unit 340. Controller 360 can be configured to modify one or more RF energy delivery parameters, such as a parameter selected from the group consisting of: voltage; current; frequency; pulse width modulation on-time and/or off-time; a time division multiplexing parameter; and combinations of these. Controller 360 can be configured for manual control, so that the operator first initiates the energy delivery, then allows the associated ablation element to ablate the tissue for some time period, after which the operator terminates the energy delivery.

[0161] Controller 360 and EDU 330 can be configured to deliver energy in constant, varied, continuous and discontinuous energy delivery profiles. Pulse width modulation and/or time division multiplexing (TDM) can be incorporated to achieve precision of energy delivery, such as to ensure ablation of target tissue while leaving non-target tissue intact.

[0162] In some embodiments, where system 10 is constructed and arranged to perform hot fluid ablation, controller 360 can be configured to adjust the temperature, flow rate and/or pressure of fluid delivered to expandable assembly 130a and/or 130b. Controller 360 can be configured to initiate insufflation and/or to adjust insufflation pressure. Controller 360 can be

configured to deliver energy (e.g. from fluid delivery unit 340 and/or EDU 330) and/or other tissue treatment in a closed-loop fashion, such as by modifying one or more tissue treatment parameters based on signals from one or more sensors of system 10 such as those described hereabove. Controller 360 can be programmable such as to allow an operator to store predetermined system settings for future use.

[0163] Controller 360 can comprise an impedance monitoring assembly, such as an impedance monitoring assembly that receives impedance information from one or both of functional element 131a of expandable assembly 130a and/or functional element 131b of expandable assembly 130b. EDU 330 can deliver RF energy to electrodes 136a and/or 137a based on the impedance determined by the impedance monitoring assembly.

[0164] Numerous embodiments of the systems, methods and devices for treating target tissue described hereabove include controlling and/or monitoring the change in target tissue temperature to cause its ablation, such as a temperature increase above 43°C, typically above 60°C, 70°C or 80°C, to ablate at least a portion of the target tissue TT. One or more cooling fluids can be delivered to limit or otherwise control ablation, such as to prevent damage to non-target tissue, such as the adventitial layer of the duodenum or other small intestine segment. Fluid delivery unit 340 can be constructed and arranged to deliver a fluid to tissue and/or a component and/or assembly of system 10, such as to warm and/or cool the tissue, component and/or assembly. Fluid delivery unit 340 can be configured to deliver a cooling fluid to a luminal wall such as a wall of the small intestine (e.g. a duodenal wall), such as prior to a delivery of RF energy, during a delivery of RF energy and/or after a delivery of RF energy. In some embodiments, a chilled fluid, such as a fluid below 20°C, or below 10°C is used to cool tissue prior to, during and/or after delivery of RF energy to tissue. In some embodiments, the chilled fluid is delivered between ablation of a first portion of target tissue and a second portion of target tissue, such as to remove residual heat remaining after the first treatment. The cooling fluid can be delivered through functional element 131a of expandable assembly 130a and/or functional element 131b of expandable assembly 130b, such as when functional element 131a and/or 131b comprises a fluid delivery element such as a nozzle, an exit hole or a permeable membrane. The cooling fluid can be supplied to expandable assembly 130a and/or 130b, such as when expandable assembly 130a and/or 130b comprises a balloon configured to contact tissue. Alternatively or additionally, fluid delivery unit 340 can be fluidly attached to another component of ablation device 100 and/or system 10, the attached component not shown but configured to deliver fluid to tissue and/or a component of system 10 such as to add and/or absorb heat. Fluid delivery unit 340 can comprise a cryogenic source used to deliver fluids at

low temperatures, such as temperatures below 0°C. Examples of fluids delivered include but are not limited to: liquids such as water and/or saline; gases such as carbon dioxide, nitrogen, nitrous oxide and/or air; and combinations of these. Fluid delivery unit 340 can include a desiccant and/or drying assembly configured to dehydrate or otherwise remove moisture from one or more delivered gases prior to their delivery.

[0165] System 10 can include a motion control mechanism, such as motion transfer assembly 335. Motion transfer assembly 335 can be constructed and arranged to rotate, translate and/or otherwise move a component of system 10, such as to move one or more of expandable assemblies 130a and/or 130b of ablation device 100. In some embodiments, motion transfer assembly 335 is configured to rotate and/or axially translate shafts 111a and/or 111b such that expandable assemblies 130a and/or 130b, respectively, are rotated and/or translated. Motion transfer assembly 335 can be configured to rotate expandable assemblies 130a and 130b independently or in unison. Motion transfer assembly 335 can be configured to translate expandable assembly 130a as RF energy is being delivered by at least one of electrodes 136a or 137a. Motion transfer assembly 335 can be configured to translate expandable assembly 130a between a first RF energy delivery and a second RF energy delivery. Motion transfer assembly 335 can include one or more rotational and/or linear drive assemblies, such as those including rotational motors, magnetic and other linear actuators, and the like which are operably connected to shaft 111a and/or 111b. Shafts 111a and/or 111b are constructed with sufficient column strength and/or torque transfer properties to sufficiently rotate and/or translate expandable assemblies 130a and/or 130b, respectively. Motion transfer assembly 335 can be in communication with controller 360, such as to activate, adjust and/or otherwise control motion transfer assembly 335 and thus the motion of expandable assemblies 130a and/or 130b. Motion transfer assembly 335 can be manually driven and/or automatically (e.g. motor) driven. Alternatively or additionally, motion transfer assembly 335 can be used to advance and/or retract expandable assemblies 130a and/or 130b from a first position to treat a first portion of target tissue, to a second position to treat a second portion of target tissue. In this embodiment, repositioning of expandable assemblies 130a and/or 130b can be configured to provide overlapping treatment, such as the overlapping treatment described in reference to Fig. 3 herebelow.

[0166] System 10 can include a second ablation device 100' constructed and arranged to treat target tissue TT. Second ablation device 100' can be of similar or dissimilar construction to ablation device 100. In some embodiments, second ablation device 100' comprises an expandable assembly with a different diameter than expandable assembly 130a of device 100. In

some embodiments, second ablation device 100' comprises an electrode with a different pattern of conductors than electrode 136a and/or 137a of device 100. In some embodiments, second ablation device 100' comprises a device selected from the group consisting of: hot fluid filled balloon device; vapor ablation device; cryoablation device; laser ablation device; ultrasound ablation device; and combinations of these.

[0167] System 10 can further include one or more imaging devices, such as imaging device 370. Imaging device 370 can be configured to be inserted into the patient and can comprise a visual light camera; an ultrasound imager; an optical coherence domain reflectometry (OCDR) imager; and/or an optical coherence tomography (OCT) imager, such as when integral to, attached to, contained within and/or proximate to shaft 111a and/or 111b. Imaging device 370 can be inserted through a separate working channel of endoscope 350, lumen not shown. In one embodiment, imaging device 370 is an ultrasound transducer connected to a shaft, not shown but surrounded by shaft 111a and typically rotated and/or translated to create a multi-dimensional image of the area surrounding imaging device 370. Alternatively or additionally, imaging device 370 can be external to the patient, such as an imaging device selected from the group consisting of: an X-ray; a fluoroscope; an ultrasound image; an MRI; a PET Scanner; and combinations of these. Image and other information provided by imaging device 370 can be provided to an operator of system 10 and/or used by a component of system 10, such as controller 360, to automatically or semi-automatically adjust one or more system parameters such as one or more energy delivery parameters.

[0168] System 10 can further include protective element 380, constructed and arranged to be positioned on, over and/or otherwise proximate non-target tissue to prevent damage to the non-target tissue during energy delivery and/or other tissue treatment event. Protective element 380 can comprise an element selected from the group consisting of: a deployable and/or recoverable cap and/or covering; an advanceable and/or retractable protective sheath; and combinations of these. Protective element 380 can be delivered with endoscope 350 and/or another elongate device such that element 380 can be placed over or otherwise positioned to protect non-target tissue, such as tissue selected from the group consisting of: Ampulla of Vater, bile duct, pancreas, pylorus, muscularis externae, serosa; and combinations of these. In a typical embodiment, protective element 380 is removed within 24 hours of placement, such as by being removed during the procedure after treatment of the target tissue TT.

[0169] System 10 can be constructed and arranged to prevent excessive distension of a segment of the small intestine (e.g. a segment of the duodenum), such as to prevent application of a force that could cause tearing of the serosa. In some embodiments, system 10 is constructed and

arranged such that all tissue contacting components and/or fluids delivered by system 10 maintain forces applied on a gastrointestinal wall below 2.5 psi, such as less than 1 psi. System 10 can be constructed and arranged such that one or more radial expandable assemblies 130 or other radial expandable assemblies or elements apply a force of at least 0.2 psi, such as a force of at least 0.5 psi, such as to improve the quality of apposition of the radially expandable element or assembly. System 10 can be constructed and arranged to avoid or otherwise minimize damage to the muscularis layer of the gastrointestinal tract, such as by controlling energy delivery and/or by minimizing trauma imparted by one or more components of system 10.

[0170] System 10 can further include one or more pharmaceutical and/or other agents 500, such as an agent configured for systemic and/or local delivery to a patient. Agents 500 can be delivered pre-procedurally, peri-procedurally and/or post-procedurally. Agents 500 can be configured to improve healing, such as agents selected from the group consisting of: antibiotics; steroids; mucosal cytoprotective agents such as sucralfate; proton pump inhibitors and/or other acid blocking drugs; and combinations of these. Alternative or in addition to agents 500, pre-procedural and/or post-procedural diets can be employed. Pre-procedural diets can include food intake that is low in carbohydrates and/or low in calories. Post-procedural diets can include food intake that comprise a total liquid diet and/or a diet that is low in calories and/or low in carbohydrates.

[0171] In some embodiments, system 10 does not include a chronically implanted component and/or device, such as where system 10 includes only body inserted devices that are removed at the end of the clinical procedure or shortly thereafter, such as devices removed within 8 hours of insertion, within 24 hours of insertion and/or within one week of insertion. In an alternative embodiment, implant 510 can be included. Implant 510 can comprise at least one of: a stent; a sleeve; and/or a drug delivery device such as a coated stent, a coated sleeve and/or an implanted pump. Implant 510 can be inserted into the patient and remain implanted for a period of at least one month, at least 6 months or at least 1 year.

[0172] Each of the components of system 10 can be removably attached to another component, particularly ablation device 100, controller 360, energy delivery unit 330, motion transfer element 335, fluid delivery unit 340, ground pad 332, endoscope 350 and/or second ablation device 100'. Typical attachment means include but are not limited to mechanical or electromechanical connectors providing an electrical, optical and/or fluidic connection.

[0173] **Referring now to Fig. 2**, a side sectional view of the distal portion of an ablation device inserted into a duodenum is illustrated, consistent with the present inventive concepts. Ablation device 100 comprises shaft 110, a relatively flexible, biocompatible, elongate structure

configured for insertion into a body lumen, such as a lumen of the small intestine, such as the duodenal lumen shown. Shaft 110 is typically connected to a handle on its proximal end, not shown but configured to allow an operator to advance, retract and otherwise manipulate or control ablation device 100. Ablation device 100 can be constructed and arranged for delivery over a guidewire, via a lumen from a proximal portion to a distal portion, or via a rapid exchange sidecar in the distal portion of the device (lumen and sidecar not shown but well known to those of skill in the art). Expandable assembly 130 is mounted to a distal portion of shaft 110, and can comprise an inflatable balloon, cage or other expandable element as described in reference to Fig. 1 hereabove. Shaft 110 is shown inserted through introducer 115 which can comprise an endoscope, sheath, or other body introduction device. Expandable assembly 130 has been positioned in a portion of duodenal tissue that has had a segment of submucosal tissue expanded (e.g. a full circumferential segment of at least 50% of the duodenal submucosa expanded), such as has been described above. Expandable assembly 130 comprises two ablation elements, electrodes 136 and 137, each comprises multiple interdigitated elongate conductors as shown in Fig. 2 and described in detail in reference to Fig. 2A herebelow. Expandable assembly 130 has been radially expanded such as to contact the mucosal surface of the duodenum. Electrodes 136 and 137 are connected to wires 138 and 139, respectively, and constructed and arranged to be attached to an RF energy delivery source, such as EDU 330 of Fig. 1. Electrodes 136 and 137 can cover the full circumference (e.g. approximately 360°) of expandable assembly 130 or they can cover a partial circumference (e.g. an area covering between 45° and 300° of the outer surface of expandable assembly 130).

[0174] Referring additionally to Fig. 2A, a magnified view of electrodes 136 and 137 of Fig. 2 is illustrated, consistent with the present inventive concepts. Electrode 136 comprises multiple elongate conductors 132, each electrically connected to wire 138, and electrode 137 comprises multiple elongate conductors 133 each electrically connected to wire 139. Conductors 132 and 133 are typically in the interdigitated pattern shown such that RF energy can be delivered between the alternative pairs of relatively parallel conductors 132 of electrode 136 and conductors 133 of electrode 137. When expandable assembly 130 is expanded to contact tissue such as mucosal tissue, and RF energy is applied between electrodes 136 and 137, current passes from neighboring edges of conductors 132 and 133, through the contacted tissue, causing heating of the tissue. This heating, combined with conductive heating that occurs in neighboring tissue, ablates the tissue as has been described in reference to Fig. 1 hereabove. The spacing between the edges of the associated pairs of conductors 132 and 133 is termed herein "edge-to-edge" spacing and illustrated in Fig. 2A. Delivery of RF energy between the various pairs of

conductors 132 and 133 is configured to cause at least ablation of the mucosa of the small intestine (e.g. duodenal mucosa). Ablation of at least a portion of the depth of the small intestine submucosa is typically caused by the RF energy delivered and resultant conductive heating. However, ablation of deeper layers, such as the adventitial layers (e.g. muscularis layers and/or serosal layers) is prevented or otherwise reduced to a near atraumatic level. After adequate energy delivery, expandable assembly 130 will be repositioned in a more distal segment of duodenum, with or without radially compacting assembly 130. Subsequently, a second energy delivery can be performed. The steps of repositioning and delivering energy are repeated until an adequate portion of small intestine is treated, typically greater than 50% of the length of the duodenal mucosa, or greater than 90% of the duodenal mucosa length. Alternatively or additionally, other tissue can be treated, such as has been described hereabove.

[0175] Conductors 132 and/or 133 comprise elongate structures whose major axis is positioned relatively parallel to the central axis of a body lumen when expandable assembly 130 is expanded within the body lumen. Conductors 132 and/or 133 and expandable assembly 130 can be constructed and arranged such that conductors 132 and/or 133 remain relatively parallel to the central axis of a body lumen when neighboring and/or within a curvilinear portion of that body lumen. Conductors 132 and/or 133 can be at least 10mm long, such as at least 20mm long. Conductors 132 and 133 can be arranged in the interdigitated pattern shown in Fig. 2A, such that bipolar RF energy passes between neighboring pairs of conductors. Conductors 132 and 133 can have an edge-to-edge spacing as described in reference to Fig. 1 hereabove. One or more pairs of conductors 132 and 133 can be arranged to remain relatively parallel when expandable assembly 130 is radially expanded. Electrodes 136 and/or 137 can include at least four conductors 132 and/or 133, respectively.

[0176] **Referring now to Fig. 3**, a side sectional view of the distal portion of an ablation device inserted into a curvilinear section of duodenum is illustrated, consistent with the present inventive concepts. Ablation device 100 comprises shaft 110, a relatively flexible, biocompatible, elongate structure configured for insertion into a body lumen, such as a lumen of the small intestine, such as the duodenal lumen shown. Shaft 110 is typically connected to a handle on its proximal end, not shown but configured to allow an operator to advance, retract and otherwise manipulate or control ablation device 100. Ablation device 100 can be constructed and arranged for delivery over a guidewire, via a lumen from a proximal portion to a distal portion, or via a rapid exchange sidecar in the distal portion of the device (lumen and sidecar not shown but well known to those of skill in the art). Expandable assembly 130 is mounted to a distal portion of shaft 110, and can comprise an inflatable balloon, cage or other expandable element as

described in reference to Fig. 1 hereabove. Shaft 110 is shown inserted through introducer 115 which can comprise an endoscope, sheath, or other body introduction device. Expandable assembly 130 comprises an array of ablation elements, conductor array 135, such as an array of two or more electrodes which cover a full or partial circumferential portion of expandable assembly 130. In some embodiments, array 135 comprises multiple interdigitated elongate conductors between which bipolar RF energy is delivered, as has been described hereabove. Expandable assembly 130 has been positioned in a distal portion of duodenal tissue, such as a section that has had a segment of submucosal tissue expanded (expansion not shown but described in detail in reference to Fig. 2 hereabove). Relative tissue layer thicknesses and other relative dimensions shown in Fig. 3 are not to scale. Expandable assembly 130 has been radially expanded such as to contact the mucosal surface of the duodenum at a 1st target tissue portion, which is distal to a series of target tissue portions comprising sequential target tissue portions 2 through 6 as shown in Fig. 3. Conductor array 135 is electrically connected to at least two wires, wires 138 and 139, which are constructed and arranged to be attached to an RF energy delivery source, such as EDU 330 of Fig. 1.

[0177] Expandable assembly 130 is sized to allow positioning in the curved segments of the gastrointestinal tract, such as a curved segment of the duodenum, such that expandable assembly 130 can be expanded to fully contact the mucosal wall without exerting undesired force onto tissue. In some embodiments, the length expandable assembly 130 is less than or equal to 30mm, such as less than or equal to 25mm, less than or equal to 20 mm or less than or equal to 15mm. After application of RF energy (e.g. monopolar RF energy, bipolar RF energy and/or combined monopolar and bipolar RF energies), expandable assembly 130 will be repositioned to the 2nd target tissue portion, just proximal to the 1st target tissue portion, with or without contracting assembly 130 prior to the repositioning. Subsequently, second energy delivery can be performed. The steps of repositioning and delivering energy are repeated until target tissue portions 3, 4, 5 and 6 have been treated, typically greater than 50% of the length of the duodenal mucosa, or greater than 90% of the duodenal mucosal length. Alternatively or additionally, other tissue can be treated, such as has been described hereabove.

[0178] Target tissue portions 1 through 6 typically include common or overlapping tissue portions, such as is shown in Fig. 3. While the embodiment of Fig. 3 shows six target tissue portions being treated, more or less segments can be treated. Treatments (e.g. energy deliveries) are typically done in a contiguous manner (e.g. 1st portion followed by 2nd portion, followed by 3rd portion, etc), however any order can be performed.

[0179] **Referring now to Fig. 4A**, perspective and magnified end views of the distal portion of an ablation device comprising a foldable assembly is illustrated, consistent with the present inventive concepts. Ablation device 100 comprises shaft 110, a relatively flexible, biocompatible, elongate structure configured for insertion into a body lumen, such as a lumen of the small intestine, such as a duodenal lumen. Shaft 110 is typically connected to a handle on its proximal end, not shown but configured to allow an operator to advance, retract and otherwise manipulate or control ablation device 100. Ablation device 100 can be constructed and arranged for delivery over a guidewire, via a lumen from a proximal portion to a distal portion, or via a rapid exchange sidecar in the distal portion of the device (lumen and sidecar not shown but well known to those of skill in the art). Expandable assembly 130 is mounted to a distal portion of shaft 110. Shaft 110 is shown inserted through introducer 115 which can comprise an endoscope, sheath, or other body introduction device. Expandable assembly 130 includes substrate 134, a sheet of material which is constructed and arranged to be folded and/or unfolded to radially compacted and expanded conditions, respectively. Substrate 134 can be flexible, and can include one or more heat set folds. Substrate 134 is shown in its radially compacted state in Fig. 4A. In Fig. 4B, a perspective view of the device of Fig. 4A is shown, with expandable assembly 130 in a partially expanded (e.g. partially unfolded). In Fig. 4C, a perspective view of the device of Fig. 4A is shown, with expandable assembly 130 in a fully expanded state. Substrate 134 comprises an array of conductors 135, which have been removed from Figs. 4A and 4B for illustrative clarity. Substrate 134 can be configured to be folded and/or unfolded via one or more control mechanisms, not shown but such as the control rod described in reference to Fig. 10 herebelow. A control rod or other mechanism can be configured to be rotated and/or translated to fold and/or unfold substrate 134. Numerous mechanisms and/or configurations can be used to fold or unfold expandable assembly 130, such as a balloon attached to substrate 134 and positioned to unfold when the balloon is inflated or fold when the balloon is deflated (e.g. a negative pressure is applied to the balloon via one or more inflation tubes or lumens). In some embodiments, introducer 115 can be used to capture (e.g. cause to fold) substrate 134. In some embodiments, substrate 134 can be biased in a folded, partially folded, or fully unfolded states, such as via one or more heat sets used to create folds in a flexible material such as material selected from the group consisting of: polyamide; a polyester weave; a stretchable polyurethane material; and combinations of these.

[0180] Referring now specifically to Fig. 4C, expandable assembly 130 has been radially expanded such as to contact the mucosal surface of the small intestine (tissue not shown). Conductor array 135, now shown, can comprise one or more electrodes, such as one or more

electrodes comprising an array of conductors, such as an array of two or more electrodes which cover a full or partial circumferential portion of expandable assembly 130. In some embodiments, array 135 comprises multiple interdigitated elongate conductors between which bipolar RF energy is delivered, as has been described hereabove in reference to Fig. 2A. Conductor array 135 is electrically connected to at least two wires, wires 138 and 139, which can be constructed and arranged to be attached to an RF energy delivery source, such as EDU 330 of Fig. 1.

[0181] Expandable assembly 130 can be sized to allow positioning in the curved segments of a gastrointestinal segment, such that expandable assembly 130 can be expanded to fully contact the mucosal wall without exerting undesired force onto tissue. In some embodiments, the length expandable assembly 130 is less than or equal to 30mm, such as less than or equal to 25mm, less than or equal to 20 mm or less than or equal to 15mm. After application of RF energy (e.g. monopolar RF energy, bipolar RF energy and/or combined monopolar and bipolar RF energies), expandable assembly 130 can be repositioned for subsequent treatment of one or more additional target tissue portions, as has been described in reference to Figs. 2 and 3 hereabove.

[0182] **Referring now to Figs. 5A and 5B**, side views of the distal portion of an ablation device comprising a helical coil are illustrated, consistent with the present inventive concepts. Ablation device 100 comprises shaft 110, a relatively flexible, biocompatible, elongate structure configured for insertion into a body lumen such as a lumen of the small intestine. Shaft 110 is typically connected to a handle on its proximal end, not shown but configured to allow an operator to advance, retract and otherwise manipulate or control ablation device 100. Ablation device 100 can be constructed and arranged for delivery over a guidewire, via a lumen from a proximal portion to a distal portion, or via a rapid exchange sidecar in the distal portion of the device (lumen and sidecar not shown but well known to those of skill in the art). Continuous with shaft 110 is expandable assembly 130, a flexible tube mounted to the distal end of shaft 110, typically with a diameter approximating the diameter of the distal portion of shaft 110. Shaft 110 is shown inserted through introducer 115 which can comprise an endoscope, sheath, or other body introduction device. Expandable assembly 130 surrounds a curvilinear mandrel 113, typically a stainless steel, nickel titanium alloy or plastic filament which is biased in the helical configuration shown, and travels proximally within shaft 110 to its proximal end. Curvilinear mandrel 113 and expandable assembly 130 are constructed and arranged so that they can be radially compressed, such as to be captured within introducer 115.

[0183] Mounted to the distal end or a distal portion of shaft 110 are electrodes 136 and 137, such as two or more ring shaped electrodes surrounding a segment of expandable assembly 130.

Electrodes 136 and 137 are each electrically attached to one or more wires, as has been described hereabove, traveling on, in or within shaft 110 to be attachable to an energy delivery unit, such as EDU 330 of Fig. 1. In some embodiments, three or more electrodes are included on expandable assembly 130. Expandable assembly 130 and curvilinear mandrel 113 are constructed and arranged such that the deployed helix circumferentially contacts gastrointestinal wall tissue, such as mucosal tissue of the duodenum or other small intestine location. Subsequently, electrodes 136 and 137 contact the tissue, such that RF energy can be delivered by or between electrodes 136 and 137 as has been described hereabove. In some embodiments, electrodes 136 and/or 137 can be covered by a dielectric material, and RF energy delivered to tissue through capacitive coupling, such as is described in reference to Fig. 10A herebelow.

[0184] In some embodiments, after sufficient energy has been delivered to a portion of target tissue, shaft 110 is retracted (e.g. via one or more controls on a proximal handle not shown), causing expandable assembly 130 to equally retract and electrodes 136 and 137 to be positioned proximate a different portion of target tissue. A subsequent energy delivery can be performed, and the repositioning and energy delivery steps repeated until a sufficient portion of gastrointestinal tissue is treated. In some embodiments, energy can be delivered as shaft 110 is retracted (e.g. as electrodes 136 and 137 move along a tissue surface), such as via a manual (e.g. operator driven) and/or automatic (e.g. via a motion transfer assembly such as motion transfer assembly 335 of Fig. 1) retraction. While the foregoing has been described in terms of retraction, advancement of shaft 110 can be performed to reposition electrodes 136 and 137, between and/or during energy deliveries.

[0185] Expandable assembly 130 and curvilinear mandrel 113 can be constructed and arranged to allow sufficient contact in curved segments of a gastrointestinal segment, such that expandable assembly 130 can be expanded to fully contact the mucosal wall without exerting undesired force onto tissue.

[0186] **Referring now to Fig. 6**, a side view of the distal portion of an ablation device including multiple expandable assemblies is illustrated, consistent with the present inventive concepts. Ablation device 100 comprises shaft 110, a relatively flexible, biocompatible, elongate structure configured for insertion into a body lumen such as the lumen of the small intestine. Shaft 110 is typically connected to a handle on its proximal end, not shown but configured to allow an operator to advance, retract and otherwise manipulate or control ablation device 100. Ablation device 100 can be constructed and arranged for delivery over a guidewire, via a lumen from a proximal portion to a distal portion, or via a rapid exchange sidecar in the distal portion of the device (lumen and sidecar not shown but well known to those of skill in the art). Ablation

device 100 comprises a first expandable assembly 130a, a more distal second expandable assembly 130b, and a further distal third expandable assembly 130c, each shown in their radially expanded condition. Expandable assemblies 130a, 130b and/or 130c each can comprise an inflatable balloon, cage or other expandable element as described in reference to Fig. 1 hereabove. Shaft 110 is shown inserted through introducer 115 which can comprise an endoscope, sheath, or other body introduction device. Expandable assemblies 130a, 130b and 130c each comprise an array of conductors, arrays 135a, 135b and 135c, respectively, each connected to one or more wires as shown, and constructed and arranged to receive electrical energy as has been described in detail hereabove. In some embodiments, ablation device 100 includes four or more expandable assemblies, such as four or more expandable assemblies each comprise an array of conductors.

[0187] Expandable assemblies 130a, 130b and/or 130c are sized to allow positioning in the curved segments of a gastrointestinal segment such as a curved segment of the small intestine (e.g. a curved segment of the duodenum), such that each expandable assembly 130a, 130b and 130c can be expanded to fully contact the mucosal wall without exerting undesired force onto tissue. In some embodiments, the length of expandable assemblies 130a, 130b and/or 130c is less than or equal to 30mm, such as less than or equal to 25mm, less than or equal to 20 mm, or less than or equal to 15mm. In some embodiments, two or more of expandable assemblies 130a, 130b and/or 130c comprises a length of less than or equal to 20mm. In some embodiments, expandable assemblies 130a, 130b and/or 130c comprise similar lengths and/or expanded diameters. In some embodiments, expandable assemblies 130a, 130b and/or 130c comprise different lengths and/or expanded diameters. Expandable assemblies 130a, 130b and/or 130c can be separated by similar or different separation distances. In some embodiments, expandable assemblies 130a, 130b and/or 130c are separated by a distance less than the length of the next assembly distal to it, such that untreated target tissue can be treated by retracting shaft 110 and performing a second ablation.

[0188] In some embodiments, conductor arrays 135a, 135b and 135c comprise similar configurations of conductors. In other embodiments, such as the embodiment of Fig. 6, conductor arrays 135a, 135b and 135c comprise different configurations of conductors. For example, conductor arrays 135a and 135b contain pairs of relatively linear conductors that are radially offset from each other. In this offset configuration, energy can be applied to conductor array 135b to treat a partial circumferential segment of gastrointestinal tissue while expandable assembly 130b is at a first axial location. Subsequently, shaft 110 can be advanced such that expandable assembly 130a moves distally to be positioned in the same first axial location.

Delivery of energy to conductor array 135a will cause a different target tissue portion to be treated due to the offset in conductor patterns between array 135b and 135a. Each of the conductor arrays 135a, 135b and 135c, can comprise linear or curvilinear conductors, such as the curvilinear conductor pairs included in expandable assembly 130c.

[0189] After application of RF energy (e.g. monopolar RF energy, bipolar RF energy and/or combined monopolar and bipolar RF energies), shaft 110 can be advanced or retracted to position each of expandable assemblies 130a, 130b and 130c in new locations. Energy delivery can be performed during or after translation of shaft 110, and until a sufficient length of tissue has been treated, as has been described hereabove. In some embodiments, the target tissue comprises a set of sequential target tissue portions comprising, in order, a first section, a second section, a third section, a fourth section, and a fifth section, for example where the expandable assemblies 130a, 130b and 130c are positioned to ablate the first, third and fifth target tissue portions in a first energy delivery and expandable assemblies 130a and 130b are positioned to ablate the second and fourth target tissue portions in a second energy delivery.

[0190] **Referring now to Fig. 7**, a side sectional view of a distal portion of an ablation device including an expandable assembly comprising a balloon surrounding an expandable scaffold is illustrated, consistent with the present inventive concepts. Ablation device 100 comprises shaft 110, a relatively flexible, biocompatible, elongate structure configured for insertion into a body lumen such as a lumen of the small intestine (e.g. into the duodenal lumen). Shaft 110 is typically connected to a handle on its proximal end, not shown but configured to allow an operator to advance, retract and otherwise manipulate or control ablation device 100. Ablation device 100 can be constructed and arranged for delivery over a guidewire, via a lumen from a proximal portion to a distal portion, or via a rapid exchange sidecar in the distal portion of the device (lumen and sidecar not shown but well known to those of skill in the art). Ablation device 100, and the other ablation devices of the present inventive concepts, can include a flexible guidewire tip, such as guidewire tip 116 shown in Fig. 7, configured to support atraumatic advancement of device 100 through a gastrointestinal lumen. Shaft 110 is shown inserted through introducer 115 which can comprise an endoscope, sheath, or other body introduction device.

[0191] Expandable assembly 130 is mounted to a distal portion of shaft 110, and includes an expandable inner cage comprising multiple splines 141 which are attached at their distal ends to hub 144 and at their proximal ends to the distal end of inner shaft 111. Expandable assembly 130 further includes balloon 142 surrounding splines 141. Balloon 142 includes multiple openings 143 as shown. Openings 143 are positioned to coincide with electrodes 136 and 137, each

comprising the multiple elongate conductors shown, mounted to alternating splines 141. In some embodiments, electrodes 136 and/or electrodes 137 comprise a width greater than a diameter of openings 130. In some embodiments, electrodes 136 and/or electrodes 137 comprise a length greater that a diameter of openings 130. Balloon 142 and openings 143 are constructed and arranged such that tissue contacts electrodes 136 and 137 at the predetermined, fixed locations of openings 143, when expandable assembly 130 is positioned in gastrointestinal tissue in its radially expanded state. Openings 143 can comprise one or more different shaped openings, such as openings with a perimeter comprising a geometry selected from the group consisting of; a circle; an oval; and a rectangle.

[0192] Splines 141 can be resiliently biased in a radially expanded condition, such as stainless steel or nickel titanium alloy splines biased in the bowed condition shown. Alternatively, one or more control rods can be included to control expansion, not shown but described in detail in reference to Fig. 10 herebelow. Expandable assembly 130 and splines 141 can be captured such as via retraction of shaft 110 to cause capture within introducer 115, and/or retraction of shaft 111 to cause capture within shaft 110. Electrodes 136 and 137 can comprise a circumferential array of conductors that cover the full circumference (e.g. approximately 360°) of expandable assembly 130 or the array can cover a partial circumference (e.g. an area covering between 45° and 300° of the outer surface of expandable assembly 130). In some embodiments, balloon 142 does not include openings 143, and monopolar and/or bipolar RF energy can be delivered to tissue via capacitive coupling through balloon 142 functioning as a dielectric between electrodes 136 and/or 137 and the target tissue. In some embodiments, one or more electrodes can be positioned on the outer surface of balloon 142, such as one or more electrodes constructed and arranged to deliver monopolar and/or bipolar RF energy to target tissue.

[0193] Electrodes 136 and 137 are connected to one or more wires, not shown but configured to deliver monopolar and/or bipolar RF energy to electrodes 136 and 137, and treat at least a portion of target tissue as described hereabove. After adequate energy delivery, expandable assembly 130 can be repositioned in a different segment of gastrointestinal tissue, with or without radially compacting assembly 130. Subsequently, a second energy delivery can be performed. The steps of repositioning and delivering energy are repeated until the desired complete segment of target tissue is treated. In some embodiments, the target tissue comprises greater than 50% of the length of the duodenal mucosa, or greater than 90% of the duodenal mucosa length. Alternatively or additionally, other tissue can be treated, such as has been described hereabove.

[0194] **Referring now to Fig. 8A**, a side view of a conductor array including two electrodes each comprising multiple elongate conductors is illustrated, consistent with the present inventive concepts. Conductor array 135 comprises substrate 134 onto which electrodes 136 and 137 are attached. Electrodes 136 and 137 comprise multiple elongate conductors in the interdigitated, parallel pattern shown in Fig. 8A. Electrodes 136 and/or 137 can be attached to substrate 134 in various ways, such as with an adhesive bond or mechanical connection such as a weld or swage. In some embodiments, electrodes 136 and/or 137 are deposited onto substrate 134, such as via an ink-jet deposition such as an ink-jet deposition in which catalytic ink is deposited and then exposed to a copper solution. In some embodiments, electrodes 136 and/or 137 are deposited onto substrate 134 using a masked deposition process.

[0195] Electrodes 136 and 137 are attached on their proximal ends to wires 138 and 139, respectively, such as to be attached to wires of an ablation device as has been described hereabove. In some embodiments, substrate 134 comprises material selected from the group consisting of: polyamide; a polyester weave; a stretchable polyurethane material; and combinations of these. Substrate 134 can be biased in the flat configuration shown in Fig. 8A, or it can include a resilient bias, such as a bias into a tube shape. Electrodes 136 and 137 comprise an array of conductors covering substantially the entire surface area of substrate 134, such that when substrate 134 is transitioned to a tubular configuration, electrodes 136 and 137 can deliver RF energy to substantially a full circumferential portion of tubular tissue, such as a segment of small intestine mucosal tissue (e.g. duodenal mucosal tissue).

[0196] Substrate 134 can be to be positioned on the distal end or on a distal portion of a shaft, such as shaft 110 described in reference to numerous figures hereabove, and configured to radially expand to contact luminal wall tissue and/or radially compact to be captured by the shaft of an ablation device. Alternatively, substrate 134 can be mounted to an expandable element, such as a balloon; an expandable cage; a stent-like structure; an array of splines; and combinations of these. In these embodiments, substrate 134 comprises a flexibility sufficient to accommodate the expansion and/or contraction of the expandable element to which it is mounted. In alternative embodiments, three or more electrodes are included on substrate 134.

[0197] **Referring now to Fig. 8B**, a side view of a conductor array including two electrodes each comprising multiple elongate conductors is illustrated, consistent with the present inventive concepts. Conductor array 135 is of similar construction and arrangement as conductor array 135 of Fig. 8A, with the exception that the conductors of electrodes 136 and 137 cover less than substantially the full surface area of substrate 134. In this configuration, a full circumferential ablation is typically performed by a first energy delivery, a rotation of array 135, and at least a

subsequent second energy delivery. Electrodes 136 and 137 are attached on their proximal ends to wires 138 and 139, respectively, as shown. Wires 138 and 139 can be attached to one or more conductors of an ablation catheter, such as to deliver energy to electrodes 136 and 137, respectively, as has been described hereabove.

[0198] **Referring now to Fig. 8C**, a side view of a conductor array including two electrodes each comprising multiple elongate conductors is illustrated, consistent with the present inventive concepts. Conductor array 135 comprises substrate 134 onto which multiple electrodes are mounted. Substrate 134 can be of similar materials, construction and arrangement, and it can be attached to a shaft, deployed in a lumen, and/or deliver energy as described in reference to substrate 134 of Fig. 8A.

[0199] Conductor array 135 of Fig. 8C comprises multiple, varying shape electrodes such as round shaped electrodes 136a and 137a, triangle shaped electrodes 136b and 137b, rectangle shaped electrodes 136c and 137c, and trapezoid shaped electrodes 136d and 137d. Conductor array 135 can comprise various shapes and orientations of electrodes, pairs of electrodes, conductors and/or pairs of conductors, such as those shown in Fig. 8C or otherwise. Conductors of conductor array 135 can comprise a shape selected from the group consisting of: rectangle; square; triangle; trapezoid; and combinations of these. Alternatively or additionally, electrodes 136a-d and/or 137a-d can be constructed and arranged to treat a target tissue portion with a shape selected from the group consisting of: rectangle; square; triangle; trapezoid; and combinations of these. Electrodes 136a-d and electrodes 137a-d are connected to wire bundles 138' and 139', respectively. Wire bundles 138' and 139' can comprise a single conductor, such that each group of electrodes are electrically connected, or it bundles 138' and 139' can comprise multiple, independent conductors, such that that each electrode can be electrically isolated.

[0200] **Referring now to Fig. 8D**, side and end views of an expandable assembly including a helical array of conductors are illustrated, consistent with the present inventive concepts. Expandable assembly 130 comprises substrate 134, configured in the tubular construction shown. Expandable assembly 130 can be attached to the distal end or distal portion of a shaft, such as has been described above. Expandable assembly can comprise an expandable element configured to radially expand and/or contract, not shown but typically a balloon, expandable cage or other expandable element as has been described hereabove.

[0201] Expandable assembly 130 includes electrodes 136 and 137, each comprising the alternating helical geometry shown in Fig. 8D, each helix fixedly mounted to substrate 134 as has been described hereabove. Electrodes 136 and 137 are electrically attached to wires 138 and

139, respectively, such that monopolar and/or bipolar RF energy can be applied to or between electrodes 136 and 137 as has been described hereabove.

[0202] Substrate 134 of Figs 8A-C can be attached to one or more expandable assemblies, such as an array of three or more expandable splines, such that substrate 134 and electrodes 136 and 137 mounted thereon, can be expanded such as to contact target tissue. **Referring now to Fig. 8E**, expandable assembly 130'comprises substrate 134 attached to three splines 141. Splines 141 are constructed and arranged to expand as shown, such that substrate 134 and mounted electrodes 136 and 137 comprise a relatively triangular cross sectional geometry. Target tissue, such as tubular target tissue such as a segment of small intestine tissue, can be distended or otherwise manipulated to electrically contact electrodes 136 and 137 while substrate 134 is expanded to this relatively triangular cross sectional geometry. **Referring now to Fig. 8F**, expandable assembly 130'' comprises substrate 134 attached to four splines 141. Splines 141 are constructed and arranged to expand as shown, such that substrate 134 and mounted electrodes 136 and 137 comprise a relatively square cross sectional geometry. Target tissue, such as tubular target tissue such as a segment of small intestine tissue, can be distended or otherwise manipulated to electrically contact electrodes 136 and 137 while substrate 134 is expanded to this relatively square cross sectional geometry. **Referring now to Fig. 8G**, expandable assembly 130''' comprises substrate 134 attached to five splines 141. Splines 141 are constructed and arranged to expand as shown, such that substrate 134 and mounted electrodes 136 and 137 comprise a relatively pentagonal cross sectional geometry. Target tissue, such as tubular target tissue such as a segment of small intestine tissue, can be distended or otherwise manipulated to electrically contact electrodes 136 and 137 while substrate 134 is expanded to this relatively pentagonal cross sectional geometry. It should be appreciated that six or more splines 141 can be included, such as to expand substrate 134 to a hexagonal or other non-circular geometry. Electrodes 136 and 137 of Figs. 8E-8G can be connected to one or more electrical wires, not shown but traveling proximally for attachment to a source of electrical energy as has been described hereabove.

[0203] **Referring now to Figs. 9A, 9B and 9C**, distal portions of three ablation devices with three different tissue contacting portions are illustrated, consistent with the present inventive concepts. Ablation devices 100a, 100b and 100c of Figs. 9A, 9B and 9C, respectively, are each shown exiting an introducer 115, as has been described hereabove. Ablation devices 100a-c each include shaft 110. Each shaft 110 can include a steering assembly comprising a pull wire 146 attached at its distal end to anchor 147, and at its proximal end to a control on a handle, control and handle not shown but configured to steer the distal portion of shaft 110 by translating pull wire 146. Ablation device 100a of Fig. 9A includes a round array of conductors 135a. Ablation

device 100b of Fig. 9B includes a triangle shaped array of conductors 135b. Ablation device 100c of Fig. 9C includes a rectangle shaped array of conductors 135c. In other embodiments, various other shapes can be employed for an array of conductors, such as one or more shapes used to treat a similarly shaped target tissue portion, or a target tissue portion that can be treated by sequentially delivering electrical energy to tissue through arrays of these one or more shapes. Typical shapes include but are not limited to: triangle; rectangle; pentagon; hexagon; trapezoid; and combinations of these. Conductor arrays 135a-c are connected to one or more wires, not shown but traveling proximally through shaft 110 such as to be attached to an energy delivery unit (e.g. EDU 330 of Fig. 1) such that bipolar and/or monopolar RF energy can be delivered to target tissue.

[0204] **Referring now to Fig. 10**, the distal portion of an ablation device comprising multiple spline-mounted electrodes is illustrated, consistent with the present inventive concepts. Ablation device 100 comprises shaft 110, a relatively flexible, biocompatible, elongate structure configured for insertion into a body lumen such as a lumen of the small intestine. Shaft 110 is typically connected to a handle on its proximal end, not shown but configured to allow an operator to advance, retract and otherwise manipulate or control ablation device 100. Ablation device 100 can be constructed and arranged for delivery over a guidewire, via a lumen from a proximal portion to a distal portion, or via a rapid exchange sidecar in the distal portion of the device (lumen and sidecar not shown but well known to those of skill in the art). Shaft 110 is shown inserted through introducer 115 which can comprise an endoscope, sheath, or other body introduction device.

[0205] Expandable assembly 130 is mounted to a distal portion of shaft 110, and includes an expandable cage comprising multiple splines 141 which are attached at their distal ends to hub 144 and at their proximal ends to the distal end of shaft 110. Splines 141 can be resiliently biased in a radially expanded condition, such as stainless steel or nickel titanium alloy splines biased in the bowed condition shown. Alternatively, one or more control rods, such as control rod 145, can be used to operably expand and/or contract expandable assembly 130, such as when splines 141 are biased in a linear configuration. Control rod 145 is attached at its distal end to hub 144, and at its proximal end to a control of a handle on the proximal end of shaft 110. Advancement of control rod 145 (e.g. via a knob, lever or other control on the handle) causes expandable assembly 130 to radially collapse or compact, and retraction of control rod 145 causes expandable assembly 130 to radially expand.

[0206] Each spline 141 comprises one or more electrodes, such as electrodes 136 and 137 as shown. Each electrode is connected to one or more wires, not shown but configured to deliver

monopolar and/or bipolar RF energy to electrodes 136 and 137, such as to treat at least a portion of target tissue when expandable assembly 130 has been expanded to contact target tissue. After expansion of expandable assembly 130, and performance of a first energy delivery to target tissue, expandable assembly 130 can be repositioned in a different segment of gastrointestinal tissue, with or without radially compacting assembly 130. Subsequently, a second energy delivery can be performed. The steps of repositioning and delivering energy are repeated until the desired segment of target tissue is treated in its entirety. In some embodiments, the target tissue comprises greater than 50% of the length of the duodenal mucosa, or greater than 90% of the duodenal mucosa length. Alternatively or additionally, other tissue can be treated, such as has been described hereabove.

[0207] In some embodiments, electrodes 136 and/or 137 are covered with a dielectric material, covering 148 as shown in the sectional side view of a spline 141 illustrated in Fig. 10A. Covering 148 comprises a dielectric material such as polytetrafluoroethylene, and is configured to cause capacitive coupling of electrodes 136 and/or 137 to target tissue. In some embodiments, electrodes 136 and/or 137 comprise a disk shaped electrode and covering 148 comprises a disk-shaped cover with thicker end portions (versus a thinner middle portion), such that the capacitively coupled RF energy delivered to tissue avoids edge effects (e.g. current concentration along the edge of an electrode 136 and/or 137) and results in uniform depth of tissue ablation.

[0208] In some embodiments, one or more electrodes 136 and/or 137 are separated by a thermally conductive, electrically insulating spacer 149, as shown in the sectional side view of a spline 141 illustrated in Fig. 10B. Spacers 149 are positioned between two or more electrodes 136 and/or 137 and can comprise a thermally conductive, electrically insulating material selected from the group consisting of: sapphire; fused quartz; fused silica; a polymeric material; glass; and combinations of these.

[0209] **Referring now to Fig. 10C**, top and side sectional views of an electrode with a top surface offset from a spline are illustrated, consistent with the present inventive concepts. Electrode 136 comprises a bottom surface mounted to spline 141 (e.g. via a weld or swage attachment) and a top surface positioned at a distance from spline 141, electrode 136 height H as shown. In some embodiments, height H is at least 100 microns, such that the top surface of electrode 136 can extend into tissue with an irregular surface such as into villi of the small intestine (e.g. into villi of the duodenum). In some embodiments, height H is at least 200 microns, or at least 400 microns. Electrode 136 height H can be chosen to maximize or otherwise improve the amount of electrical energy delivered into tissue.

[0210] The sides of electrode 136 (e.g. surfaces relatively orthogonal to or otherwise continuous with the top surface of electrode 136) can be surrounded by an insulating material, such as insulator 148' as shown. Insulator 148' can cover some or all of the bottom surface of electrode 136. Insulator 148' can be constructed and arranged such that only the top surface of electrode 136 is conductive (e.g. to minimize current delivered from electrode 136 side and/or bottom surfaces). Insulator 148' can comprise a low-conductivity material, such as polytetrafluoroethylene, or an electrically insulating coating.

[0211] Spline 141 can comprise multiple electrodes 136 with heights similar to height H such that bipolar RF energy can be delivered between two or more of the electrodes. Alternatively or additionally, an ablation device of the present inventive concepts can comprise multiple splines 141 each with at least one electrode 136, such that bipolar RF energy can be delivered between two or more of the splines.

[0212] **Referring now to Fig. 11**, a distal portion of an ablation device including two expandable elements and intervening conductive filaments is illustrated, consistent with the present inventive concepts. Ablation device 100 comprises shaft 110, a relatively flexible, biocompatible, elongate structure configured for insertion into a body lumen such as a lumen of the small intestine (e.g. the lumen of the duodenum). Shaft 110 is typically connected to a handle on its proximal end, not shown but configured to allow an operator to advance, retract and otherwise manipulate or control ablation device 100. Ablation device 100 can be constructed and arranged for delivery over a guidewire, via a lumen from a proximal portion to a distal portion, or via a rapid exchange sidecar in the distal portion of the device (lumen and sidecar not shown but well known to those of skill in the art). Two expandable assemblies, expandable assemblies 130a and 130b, are mounted to a distal portion of shaft 110 as shown. Expandable assemblies 130a and 130b can comprise an inflatable balloon, cage or other expandable element as described in reference to Fig. 1 hereabove. Shaft 110 is shown inserted through introducer 115 which can comprise an endoscope, sheath, or other body introduction device. Expandable assembly 130b has been positioned in a portion of duodenal tissue that has had a segment of submucosal tissue expanded (e.g. a full circumferential segment of at least 50% of the duodenal submucosa expanded), such as has been described above.

[0213] Positioned between expandable assembly 130a and 130b is a circumferential array of conductors, electrodes 136. Expandable assemblies 130a and 130b and electrodes 136 are positioned and arranged such that when expandable assemblies 130a and 130b are radially expanded to contact gastrointestinal wall tissue (e.g. mucosal tissue), electrodes 136 contact tissue. Electrodes 136 are attached to one or more wires, not shown but configured to allow

delivery of monopolar and/or bipolar by or between and one or more electrodes 136, as has been described hereabove. In some alternative embodiments, one or more electrodes 136 are positioned on one or more filaments extending between expandable assemblies 130a and 130b.

[0214] Ablation device 100, or any of the ablation devices of the present inventive concepts, can be constructed to accommodate over-the-wire delivery, such as by the inclusion of lumen 114 which exits the distal end of shaft 110 and travels proximally, such as to a guidewire introduction port, not shown but typically attached to a proximal handle as has been described hereabove.

[0215] **Referring now to Fig. 12**, a distal portion of an ablation device including rotatable electrodes is illustrated, consistent with the present inventive concepts. Ablation device 100 comprises shaft 110, a relatively flexible, biocompatible, elongate structure configured for insertion into a body lumen such as a lumen of the small intestine (e.g. the lumen of the duodenum). Shaft 110 is typically connected to a handle on its proximal end, not shown but configured to allow an operator to advance, retract and otherwise manipulate or control ablation device 100. Ablation device 100 can be constructed and arranged for delivery over a guidewire, via a lumen from a proximal portion to a distal portion, or via a rapid exchange sidecar in the distal portion of the device (lumen and sidecar not shown but well known to those of skill in the art). Shaft 110 is shown inserted through introducer 115 which can comprise an endoscope, sheath, or other body introduction device.

[0216] Expandable assembly 130 is mounted to a distal portion of shaft 110, and includes an expandable cage comprising multiple splines 141 which are attached at their distal ends to hub 144 and at their proximal ends to the distal end of shaft 110. Splines 141 can be resiliently biased in a radially expanded condition, such as stainless steel or nickel titanium alloy splines biased in the bowed condition shown. Alternatively, one or more control rods, such as control rod 145, can be used to operably expand and/or contract expandable assembly 130, such as when splines 141 are biased in a linear configuration. Control rod 145 is attached at its distal end to hub 144, and at its proximal end to a control of a handle on the proximal end of shaft 110. Advancement of control rod 145 (e.g. via a knob, lever or other control on the handle) causes expandable assembly 130 to radially collapse or compact, and retraction of control rod 145 causes expandable assembly 130 to radially expand. In an alternative embodiment, control rod 145 is attached to the proximal end of splines 141, such that advancement of control rod 145 causes expandable assembly 130 to radially expand, and retraction of control rod 145 causes expandable assembly 130 to radially compact. As stated above, radial compression of expandable assembly 130 can be used to stop or reduce delivery of energy to tissue.

[0217] Attached to splines 141 are multiple electrodes 136a-d. Electrodes 136a-d can be rotatably attached to splines 141 via axels 151 as shown. Electrodes 136a-d are electrically attached to one or more wires, not shown but as described hereabove. Electrodes 136a-d can be attached to the one or more wires via axels 151, such as a frictionally engaging electrical connection that allows electrical energy to be transferred through each axel 151 to the associated electrode 136a-d as the electrode 136a-d is rotating. In some embodiments, electrodes 136a-d are each electrically attached to individual wires such that monopolar and/or bipolar energy can be delivered any of electrodes 136a-d or between any electrodes 136a-d. When expandable assembly 130 is expanded such that electrodes 136a-d contact tissue (e.g. luminal wall tissue), electrodes 136a-d are constructed and arranged such that they rotate along a tissue surface as shaft 110 and/or introducer 115 is advanced or retracted.

[0218] A sufficient quantity of electrodes 136a-d (e.g. one or more on each spline 141), such as to cover a full circumferential (e.g. approximately 360°) axial segment of expandable assembly 130. Alternatively, electrodes 136a-d can cover a partial circumference (e.g. an area covering between 45° and 300°) of the outer surface of an axial segment of expandable assembly 130.

[0219] A first energy delivery can be delivered to electrodes 136a-d, such as to treat target tissue or a portion of target tissue. Subsequently, expandable assembly 130 can be translated axially or distally, and one or more subsequent energy deliveries performed. In some embodiments, RF energy is delivered as the electrodes 136a-d rotate along a tissue surface. The steps of translating and/or repositioning, and delivering energy are repeated until the desired segment of target tissue is treated in its entirety. In some embodiments, the target tissue comprises greater than 50% of the length of the duodenal mucosa, or greater than 90% of the duodenal mucosa length. Alternatively or additionally, other tissue can be treated, such as has been described hereabove.

[0220] The foregoing description and accompanying drawings set forth a number of examples of representative embodiments at the present time. Various modifications, additions and alternative designs will become apparent to those skilled in the art in light of the foregoing teachings without departing from the spirit hereof, or exceeding the scope hereof, which is indicated by the following claims rather than by the foregoing description. All changes and variations that fall within the meaning and range of equivalency of the claims are to be embraced within their scope.

We Claim:

1. A device for ablating tissue of a patient with electrical energy comprising:

an elongate shaft with a proximal portion and a distal portion;

a radially expandable element attached to the elongate shaft distal portion; and

an ablation element mounted to the radially expandable element, wherein the ablation element is constructed and arranged to deliver electrical energy to target tissue;

wherein the device is constructed and arranged to ablate duodenal mucosal tissue while avoiding damaging duodenal adventitial tissue.

2. The device as in any one of the preceding device claims wherein the device is further constructed and arranged to ablate at least an inner layer of duodenal submucosal tissue.

3. The device of claim 2 wherein the device is further constructed and arranged to avoid ablating at least the outermost 100 microns of duodenal submucosal tissue.

4. The device of claim 2 wherein the device is further constructed and arranged to avoid ablating at least the outermost 200 microns of duodenal submucosal tissue.

5. The device as in any one of the preceding device claims wherein the device is further constructed and arranged to ablate tissue selected from the group consisting of: ileal mucosal tissue; jejunal mucosal tissue; gastric mucosal tissue; and combinations thereof.

6. The device as in any one of the preceding device claims wherein the device is further constructed and arranged to ablate gastric mucosal tissue.

7. The device as in any one of the preceding device claims wherein the device is constructed and arranged to minimize damage to at least one of the pylorus or the Ampulla of Vater.

8. The device of claim 7 wherein the device comprises an advanceable sheath constructed and arranged to minimize damage to at least one of the pylorus or the Ampulla of Vater.

9. The device as in any one of the preceding device claims wherein the device is constructed and arranged to identify the Ampulla of Vater.

10. The device as in any one of the preceding device claims wherein the device is constructed and arranged to minimize distension of duodenal tissue.

11. The device of claim 10 wherein the device is constructed and arranged to limit forces applied to the duodenal wall to a level at or below 2.5 psi.

12. The device of claim 11 wherein the device is constructed and arranged to limit forces applied to the duodenal wall to a level at or below 1 psi.

13. The device of claim 10 wherein the radially expandable element is constructed and arranged to apply a force of at least 0.2 psi to the duodenal wall.

14. The device of claim 13 wherein the radially expandable element is constructed and arranged to apply a force of at least 0.5 psi to the duodenal wall.

15. The device as in any one of the preceding device claims wherein the device is further constructed and arranged to avoid damaging a duodenal muscularis layer.

16. The device as in any one of the preceding device claims wherein the device is further constructed and arranged to avoid damaging tissue selected from the group consisting of: duodenal muscularis layer; jejunal muscularis layer; ileal muscularis layer; gastric muscularis layer; Ampulla of Vater, bile duct, pancreas, pylorus, muscularis externae, serosa; and combinations thereof.

17. The device as in any one of the preceding device claims wherein the device is constructed and arranged to ablate duodenal mucosal tissue in a curved segment of duodenum.

18. The device as in any one of the preceding device claims wherein the device is constructed and arranged to ablate a tissue layer of at least 500 microns.

19. The device as in any one of the preceding device claims wherein the device is constructed and arranged to ablate a volume of tissue comprising a surface area and a depth, and wherein the depth is less than approximately 1.0% of the surface area.

20. The device of claim 19 wherein the device is constructed and arranged to ablate a volume of tissue comprising a surface area and a depth, and wherein the depth is less than approximately 0.1% its surface area.

21. The device as in any one of the preceding device claims wherein the elongate shaft is constructed and arranged to be passed through the working channel of an endoscope.

22. The device of claim 21 wherein the elongate shaft comprises a diameter less than or equal to 6 mm.

23. The device of claim 21 wherein the elongate shaft comprises a diameter less than or equal to 4.2 mm.

24. The device of claim 21 wherein the elongate shaft comprises a diameter less than or equal to 3.8 mm.

25. The device of claim 21 wherein the elongate shaft comprises a diameter less than or equal to 3.2 mm.

26. The device of claim 21 wherein the elongate shaft comprises a diameter less than or equal to 2.8 mm.

27. The device as in any one of the preceding device claims wherein the elongate shaft is constructed and arranged to pass alongside an endoscope that has been placed in a gastrointestinal tract.

28. The device as in any one of the preceding device claims wherein the device is constructed and arranged for over-the-wire delivery.

29. The device as in any one of the preceding device claims wherein the device is constructed and arranged to treat substantially the entire length of the duodenum simultaneously.

30. The device as in any one of the preceding device claims wherein the device is constructed and arranged to treat a first length of duodenum in a first energy application and a second length of duodenum in a second energy application.

31. The device of claim 30 wherein the first length of duodenum overlaps the second length of duodenum.

32. The device of claim 30 wherein the first length of duodenum comprises a first central axis and the second length of duodenum comprises a second central axis non-parallel with the first axis.

33. The device of claim 30 wherein the device is constructed and arranged to treat at least three lengths of duodenum with at least three energy treatments and wherein the at least three lengths of duodenum comprise at least 50% of the length of the duodenum.

34. The device as in any one of the preceding device claims wherein the device is constructed and arranged to deliver the electrical energy based on a measured diameter of the duodenum.

35. The device of claim 34 wherein the measured diameter is measured by at least one of the radially expandable element or a separate device.

36. The device as in any one of the preceding device claims wherein the radially expandable element comprises a length less than or equal to approximately 20mm.

37. The device as in any one of the preceding device claims wherein the radially expandable element is constructed and arranged to be relatively rigid during the delivery of the electrical energy to the target tissue.

38. The device of claim 37 wherein the ablation element comprises multiple parallel conductors and wherein the radially expandable element is constructed and arranged to maintain spacing between the multiple parallel conductors.

39. The device as in any one of the preceding device claims wherein the radially expandable element comprises at least a portion that is round when expanded.

40. The device as in any one of the preceding device claims wherein the radially expandable element comprises at least a portion that, when expanded, comprises a tissue-contacting shape selected from the group consisting of: triangle; rectangle; pentagon; hexagon; trapezoid; and combinations thereof.

41. The device as in any one of the preceding device claims wherein the radially expandable element is constructed and arranged to be folded to a radially compacted state from its radially expanded state.

42. The device as in any one of the preceding device claims wherein the radially expandable element is constructed and arranged to linearize curvilinear gastrointestinal tissue.

43. The device as in any one of the preceding device claims wherein the radially expandable element is constructed and arranged to distend gastrointestinal tissue.

44. The device as in any one of the preceding device claims wherein the radially expandable element comprises a balloon.

45. The device of claim 44 further comprising at least one inflation lumen in fluid communication with the balloon.

46. The device of claim 44 wherein the balloon comprises a compliant balloon.

47. The device of claim 44 wherein the balloon comprises a non-compliant balloon.

48. The device of claim 44 wherein the balloon comprises a pressure-thresholded balloon.

49. The device of claim 44 wherein the radially expandable element further comprises a scaffold biased in a radially expandable condition.

50. The device of claim 44 wherein the balloon comprises an external surface and the ablation element is mounted to the balloon external surface.

51. The device as in any one of the preceding device claims wherein the radially expandable element comprises a radially expandable scaffold.

52. The device of claim 51 wherein the radially expandable scaffold comprises a structure selected from the group consisting of: an expandable cage; a stent-like structure; an array of splines; and combinations thereof.

53. The device of claim 51 wherein the radially expandable scaffold comprises multiple filaments constructed and arranged to expand to a diameter of at least 20mm, and wherein the device comprises a distal portion constructed and arranged to be slidingly received by a channel with a diameter less than or equal to 6mm.

54. The device of claim 53 wherein the radially expandable scaffold comprises multiple filaments constructed and arranged to expand to a diameter of at least 25mm, and wherein the device comprises a distal portion constructed and arranged to be slidingly received by a channel with a diameter less than or equal to 6mm.

55. The device of claim 54 wherein the radially expandable scaffold comprises multiple filaments constructed and arranged to expand to a diameter of at least 30mm, and wherein the device comprises a distal portion constructed and arranged to be slidingly received by a channel with a diameter less than or equal to 6mm.

56. The device of claim 51 wherein the radially expandable scaffold comprises a scaffold resiliently biased in a radially expanded condition.

57. The device of claim 51 further comprising a control shaft constructed and arranged to expand the radially expandable scaffold when retracted.

58. The device of claim 51 wherein the radially expandable scaffold comprises an array of splines.

59. The device of claim 58 wherein the ablation element comprises at least a first electrode mounted to a first spline and a second electrode mounted to the first spline.

60. The device of claim 58 wherein the ablation element comprises at least a first electrode mounted to a first spline and a second electrode mounted to a second spline.

61. The device of claim 51 wherein the radially expandable scaffold comprises a football shaped scaffold.

62. The device of claim 51 wherein the radially expandable scaffold comprises a relatively unidiameter scaffold.

63. The device as in any one of the preceding device claims wherein the radially expandable element comprises multiple radially deployable arms.

64. The device as in any one of the preceding device claims wherein the radially expandable element comprises a radially expandable tube.

65. The device of claim 64 wherein the radially expandable tube comprises a tube resiliently biased in an expanded condition.

66. The device as in any one of the preceding device claims wherein the radially expandable element comprises a radially expandable sheet.

67. The device of claim 66 wherein the radially expandable sheet comprises a sheet resiliently biased in an expanded condition.

68. The device of claim 67 wherein the radially expandable sheet is constructed and arranged to be furled to transition to a compact condition.

69. The device of claim 66 wherein the radially expandable sheet comprises a sheet resiliently biased in an unexpanded condition.

70. The device of claim 69 wherein the radially expandable sheet is constructed and arranged to be unfurled to transition to an expanded condition.

71. The device of claim 66 wherein the radially expandable sheet comprises a foldable sheet.

72. The device of claim 71 wherein the foldable sheet is constructed and arranged to be folded to transition from an expanded state to an unexpanded state.

73. The device of claim 71 wherein the foldable sheet is constructed and arranged to be unfolded to transition from an unexpanded state to an expanded state.

74. The device as in any one of the preceding device claims wherein the radially expandable element comprises a diameter ranging from 15mm to 30mm.

75. The device as in any one of the preceding device claims wherein the radially expandable element comprises a length ranging from 10mm to 40mm.

76. The device of claim 75 wherein the radially expandable element comprises a length ranging from 20mm to 25mm.

77. The device of claim 75 wherein the radially expandable element comprises a length of less than or equal to 15mm.

78. The device of claim 75 wherein the radially expandable element comprises at least two radially expandable elements each with a length less than or equal to 25mm.

79. The device of claim 78 wherein the at least two radially expandable elements each comprise a length less than or equal to 20mm.

80. The device as in any one of the preceding device claims wherein the radially expandable element is constructed and arranged to be moved in a motion selected from the group consisting of: rotation; translation; and combinations thereof.

81. The device of claim 80 wherein the radially expandable element is constructed and arranged to be moved manually by an operator.

82. The device of claim 80 further comprising a motion transfer assembly constructed and arranged to move the radially expandable element.

83. The device of claim 80 wherein the ablation element is constructed and arranged to deliver a first energy delivery and a second energy delivery, and the radially expandable element is constructed and arranged to be moved between the first energy delivery and the second energy delivery.

84. The device of claim 80 wherein the radially expandable element is constructed and arranged to be moved during the delivery of the electrical energy.

85. The device as in any one of the preceding device claims wherein the radially expandable element comprises an expandable helical structure.

86. The device of claim 85 wherein the radially expandable element further comprises a filament comprising the ablation element and is constructed and arranged to be moved along the helical structure.

87. The device of claim 86 further comprising a motion transfer assembly constructed and arranged to move the filament.

88. The device of claim 86 wherein the filament is constructed and arranged to be moved during the delivery of the electrical energy.

89. The device as in any one of the preceding device claims further comprising a second radially expandable element.

90. The device of claim 89 wherein the second radially expandable element is constructed and arranged to perform a luminal diameter measurement.

91. The device of claim 89 wherein the second radially expandable element comprises a second ablation element constructed and arranged to deliver electrical energy to target tissue.

92. The device of claim 91 wherein the first radially expandable element comprises a first length, and wherein the first radially expandable element and the second radially expandable element are spaced apart by a distance less than or equal to the first length.

93. The device of claim 92 wherein the second radially expandable element comprises a second length approximately the same as the first radially expandable element length.

94. The device of claim 89 wherein the first radially expandable element comprises a length of less than or equal to approximately 20mm and the second radially expandable element comprises a length of less than or equal to approximately 20mm.

95. The device of claim 89 further comprising multiple filaments extending between the first radially expandable element and the second radially expandable element.

96. The device of claim 95 wherein the multiple filaments comprise multiple elongate conductors and the multiple elongate conductors comprise the ablation element.

97. The device of claim 95 wherein the ablation element comprises multiple electrodes mounted to the multiple filaments.

98. The device of claim 89 wherein the ablation element comprises a first set of electrodes positioned on the first radially expandable element and a second set of electrodes positioned on the second radially expandable element.

99. The device of claim 98 wherein the first set of electrodes are configured in a first geometry and the second set of electrodes are configured in a second geometry different than the first.

100. The device of claim 99 wherein the first geometry and second geometry are constructed and arranged such that ablation with the first geometry and the second geometry causes substantially full surface ablation of an area of tissue.

101. The device of claim 89 wherein the second radially expandable element is positioned within the first radially expandable element.

102. The device of claim 101 wherein the ablation element comprises a first set of electrodes positioned on the first radially expandable element and a second set of electrodes positioned on the second radially expandable element.

103. The device of claim 89 wherein the first radially expandable element is positioned within the second radially expandable element, and wherein the second radially expandable element comprises insulating material and a set of openings.

104. The device of claim 103 wherein the insulating material comprises an inflatable balloon.

105. The device of claim 103 wherein the ablation element comprises a top surface area and wherein each opening of the set of openings comprises an opening area less than an electrode top surface area.

106. The device as in any one of the preceding device claims further comprising a second radially expandable element distal to the first radially expandable element and a third radially expandable element distal to the second radially expandable element, wherein the second radially expandable element comprises a second ablation element and the third radially expandable element comprises a third ablation element.

107. The device of claim 106 wherein the first radially expandable element, the second radially expandable element and the third radially expandable element each comprises a length of less than or equal to approximately 20mm.

108. The device of claim 106 wherein the first and second ablation elements are separated by a first distance and the second and third ablation elements are separated by a second distance similar to the first distance.

109. The device of claim 106 wherein the target tissue comprises a set of sequential target tissue portions comprising, in order, a first section, a second section, a third section, a fourth section, and a fifth section, and wherein the first, second and third ablation elements are constructed and arranged to ablate the first, third and fifth target tissue portions in a first energy delivery and the first and second ablation elements are constructed and arranged to ablate the second and fourth target tissue portions in a second energy delivery.

110. The device as in any one of the preceding device claims wherein the radially expandable element is constructed and arranged to be radially compacted to stop the delivery of the electrical energy.

111. The device as in any one of the preceding device claims further comprising a control shaft operably coupled to the radially expandable element, wherein translation of the control shaft changes the shape of the radially expandable element.

112. The device of claim 111 wherein retraction of the control shaft causes the radially expandable element to expand.

113. The device of claim 111 wherein advancement of the control shaft causes the radially expandable element to expand.

114. The device as in any one of the preceding device claims wherein the ablation element is constructed and arranged to cause non-desiccating ablation of the target tissue.

115. The device as in any one of the preceding device claims wherein the ablation element is constructed and arranged to minimize electrical current driven temperature increase in the outermost 50% of the mucosal layer.

116. The device of claim 115 wherein the outermost 50% of the mucosal layer is ablated mainly due to thermal conduction.

117. The device as in any one of the preceding device claims wherein the ablation element is constructed and arranged to minimize electrical current driven temperature increase in the outermost 80% of the mucosal layer.

118. The device of claim 117 wherein the outermost 80% of the mucosal layer is ablated mainly due to thermal conduction.

119. The device as in any one of the preceding device claims wherein at least a portion of the ablation element comprises a surface area with a geometric shape comprising: a linear segment; a circle; a rectangle; and combinations thereof.

120. The device as in any one of the preceding device claims wherein the ablation element comprises at least a single pair of electrodes.

121. The device of claim 120 wherein the single pair of electrodes comprises a first electrode comprising multiple elongate conductors and a second electrode comprising multiple elongate conductors.

122. The device of claim 121 wherein the first electrode comprises a first elongate conductor comprising a major axis that is constructed and arranged to be relatively parallel to a central axis of a portion of the duodenum during delivery of energy.

123. The device of claim 122 wherein the first elongate conductor major axis is constructed and arranged to be relatively parallel to a central axis of a curvilinear portion of the duodenum during energy delivery.

124. The device of claim 121 wherein the first electrode multiple elongate conductors comprises conductors with a length of at least 10mm.

125. The device of claim 124 wherein the first electrode multiple elongate conductors comprises conductors with a length of at least 20mm.

126. The device of claim 121 wherein the first electrode multiple elongate conductors and the second electrode multiple elongate conductors are positioned in an interdigitated array.

127. The device of claim 126 wherein the interdigitated conductors are edge-to-edge spaced at a distance less than or equal to 1.5 mm.

128. The device of claim 127 wherein the interdigitated conductors are edge-to-edge spaced at a distance less than or equal to 1.0 mm.

129. The device of claim 128 wherein the interdigitated conductors are edge-to-edge spaced at a distance less than or equal to 750 microns.

130. The device of claim 121 wherein the first electrode multiple elongate conductors and the second electrode multiple elongate conductors are positioned relatively parallel to each other.

131. The device of claim 121 wherein the first electrode multiple elongate conductors comprises at least four elongate conductors.

132. The device as in any one of the preceding device claims wherein the ablation element comprises at least one pair of electrodes.

133. The device of claim 132 wherein the ablation element is constructed and arranged to deliver a current, and wherein the current passes substantially through the innermost 50% of the mucosal layer.

134. The device of claim 133 wherein the ablation element is constructed and arranged to deliver a current, and wherein the current passes substantially through the innermost 20% of the mucosal layer.

135. The device as in any one of the preceding device claims wherein the ablation element comprises at least one conductor comprising a height that extends from the radially expandable element at least 100 microns.

136. The device of claim 135 wherein the at least one conductor comprises a tissue contacting surface positioned at least 200 microns from the surface of the radially expandable element.

137. The device of claim 136 wherein the at least one conductor tissue contacting surface is positioned at least 400 microns from the radially expandable element.

138. The device of claim 135 wherein the at least one conductor comprises an electrically insulating material between the tissue contacting surface and the radially expandable element.

139. The device of claim 138 wherein the electrically insulating material comprises polytetrafluoroethylene.

140. The device as in any one of the preceding device claims wherein the ablation element comprises at least two electrodes.

141. The device of claim 140 wherein the ablation element comprise at least four electrodes.

142. The device as in any one of the preceding device claims wherein the ablation element comprises at least one conductor with a length between approximately 10mm and 40mm.

143. The device as in any one of the preceding device claims wherein the ablation element comprises a first conductor and a second conductor with an edge-to-edge spacing between approximately 200 microns and 2mm.

144. The device as in any one of the preceding device claims wherein the ablation element comprises at least one conductor with a width less than or equal to 2.0mm.

145. The device of claim 144 wherein the ablation element comprises at least one conductor with a width less than or equal to 1.5mm.

146. The device of claim 145 wherein the ablation element comprises at least one conductor with a width less than or equal to 1.0mm.

147. The device of claim 146 wherein the ablation element comprises at least one conductor with a width between 400 microns and 700 microns.

148. The device as in any one of the preceding device claims wherein the ablation element comprises at least one conductor with a width greater than 230 microns.

149. The device as in any one of the preceding device claims wherein the ablation element comprises at least two conductors with a width of approximately 400 microns.

150. The device of claim 149 wherein the ablation element comprises at least two conductors with an edge to edge spacing of approximately 600 microns.

151. The device as in any one of the preceding device claims wherein the ablation element comprises at least one conductor with a width of approximately 700 microns.

152. The device of claim 151 wherein the ablation element comprises at least two conductors with an edge to edge spacing of approximately 400 microns.

153. The device as in any one of the preceding device claims wherein the ablation element comprises at least one conductor with a width less than or equal to a desired depth of ablation.

154. The device as in any one of the preceding device claims wherein the ablation element comprises a first conductor and a second conductor separated by a first distance, wherein the first distance is less than or equal to a desired depth of ablation.

155. The device as in any one of the preceding device claims wherein the ablation element comprises an array of conductors.

156. The device of claim 155 wherein the array of conductors comprises a circumferential array of conductors.

157. The device of claim 156 wherein the circumferential array of conductors comprises an array of linear conductors.

158. The device of claim 156 wherein the circumferential array of conductors comprises an array of curvilinear conductors.

159. The device of claim 156 wherein the circumferential array of conductors comprises a helical array of conductors.

160. The device of claim 156 wherein the circumferential array of conductors comprises a 360° array of conductors.

161. The device of claim 156 wherein the circumferential array of conductors is constructed and arranged to prevent formation of a full circumferential scar.

162. The device of claim 161 wherein the circumferential array of conductors comprises a less than 350° array of conductors.

163. The device of claim 162 wherein the circumferential array of conductors comprises a 300° to 350° array of conductors.

164. The device of claim 156 wherein the circumferential array of conductors comprises an array of conductors spanning approximately 45° to 300°.

165. The device of claim 164 wherein the device is constructed and arranged to be rotated to treat a 360° segment of target tissue.

166. The device of claim 156 wherein the circumferential array of conductors comprises multiple pairs of conductors, wherein each pair of conductors is constructed and arranged to deliver bipolar radiofrequency energy.

167. The device of claim 166 wherein the circumferential array of conductors comprises at least five pairs of conductors.

168. The device of claim 156 wherein the circumferential array of conductors comprises conductors radially edge-to-edge spaced at a distance between approximately 230 microns and 2.0mm.

169. The device of claim 168 wherein the circumferential array of conductors comprises conductors radially edge-to-edge spaced at a distance between approximately 400 microns to 600 microns.

170. The device of claim 156 wherein the circumferential array of conductors comprises conductors radially spaced at a first distance, wherein the width of the multiple conductors is approximately half of the first distance.

171. The device of claim 156 wherein the circumferential array of conductors comprise conductors radially spaced with a uniformity of spacing greater than or equal to 95%.

172. The device of claim 171 wherein the circumferential array of conductors comprise conductors radially spaced with a uniformity of spacing greater than or equal to 98%.

173. The device as in any one of the preceding device claims wherein the ablation element comprises an elongate copper conductor.

174. The device as in any one of the preceding device claims wherein the ablation element comprises a shape selected from the group consisting of: a rectangle; a square; a triangle; a trapezoid; and combinations thereof.

175. The device as in any one of the preceding device claims wherein the ablation element is constructed and arranged to ablate tissue in a shape selected from the group consisting of: a rectangle; a square; a triangle; a trapezoid; and combinations thereof.

176. The device as in any one of the preceding device claims wherein the ablation element comprises multiple conductors arranged in an operator adjustable pattern.

177. The device as in any one of the preceding device claims wherein the ablation element comprises multiple flexible conductors.

178. The device as in any one of the preceding device claims wherein the ablation element is mounted to the radially expandable element by at least one of: a glue joint; a weld; a swage or a molecular bond.

179. The device as in any one of the preceding device claims wherein the ablation element is at least partially embedded in the radially expandable element.

180. The device as in any one of the preceding device claims further comprising a flexible substrate, wherein the ablation element is attached to the flexible substrate.

181. The device of claim 180 wherein the flexible substrate comprises a material selected from the group consisting of: polyamide; a polyester weave; a stretchable polyurethane material; and combinations thereof.

182. The device of claim 180 wherein the flexible substrate comprises a heat set constructed and arranged to enhance folding of the flexible substrate.

183. The device of claim 180 wherein the ablation element comprises multiple conductors deposited on the flexible substrate.

184. The device of claim 183 wherein the ablation element comprises at least one conductor deposited using an ink-jet deposition process.

185. The device of claim 184 wherein the at least one conductor is deposited by depositing catalytic ink followed by exposure to a copper solution.

186. The device of claim 183 wherein the ablation element comprises at least one conductor deposited using a masked deposition process.

187. The device of claim 180 wherein the radially expandable element comprises at least three splines and the substrate is attached to the at least three splines.

188. The device of claim 187 wherein the at least three splines are arranged in a symmetric circumferential pattern.

189. The device of claim 187 wherein the at least three splines form a non-circular cross section when the radially expandable element is expanded.

190. The device of claim 187 wherein the expandable element comprises four splines such that when the expandable element is expanded, the substrate comprises a relatively square cross section.

191. The device of claim 187 wherein the expandable element comprises five splines such that when the expandable element is expanded, the substrate comprises a relatively pentagonal cross section.

192. The device of claim 187 wherein the expandable element comprises five splines such that when the expandable element is expanded, the substrate comprises a relatively hexagonal cross section.

193. The device as in any one of the preceding device claims wherein the ablation element comprises multiple wires.

194. The device as in any one of the preceding device claims wherein the ablation element comprises multiple conductors constructed and arranged to rotate.

195. The device of claim 194 wherein the multiple conductors are constructed and arranged to rotate during the delivery of the electrical energy.

196. The device as in any one of the preceding device claims wherein the ablation element comprises an anti-stick coating.

197. The device of claim 196 wherein the anti-stick coating comprises a polytetrafluoroethylene coating.

198. The device as in any one of the preceding device claims wherein the ablation element comprises at least one conductor constructed and arranged to capacitively couple the electrical energy to the target tissue.

199. The device of claim 198 wherein the device is constructed and arranged to position the at least one conductor such that a gap is present between the ablation element and the target tissue.

200. The device of claim 198 further comprising a dielectric covering positioned between the at least one conductor and the target tissue.

201. The device of claim 200 wherein the dielectric covering comprises polytetrafluoroethylene.

202. The device of claim 200 wherein the dielectric covering comprises a non-uniform thickness covering comprising dielectric material.

203. The device of claim 202 wherein the dielectric covering comprises a middle portion with a first thickness and an edge portion with a second thickness greater than the first thickness.

204. The device of claim 202 wherein the non-inform thickness covering is constructed and arranged to cause uniform ablation depth of a tissue area.

205. The device as in any one of the preceding device claims wherein the ablation element comprises multiple conductors and the device further comprises multiple insulators positioned between the multiple conductors.

206. The device of claim 205 wherein the multiple insulators comprise multiple thermal conductors.

207. The device of claim 205 wherein the multiple insulators comprise a material selected from the group consisting of: sapphire; fused quartz; fused silica; a polymeric material; glass; and combinations thereof.

208. The device as in any one of the preceding device claims further comprising a second ablation element.

209. The device of claim 208 wherein the second ablation element comprises an ablation element selected from the group consisting of: an RF energy delivery element such as one or more electrodes, each comprising one or more elongate conductors; an ultrasonic transducer such as one or more piezo crystals configured to ablate tissue; a laser energy delivery element such as one or more optical fibers and/or laser diodes; a heat delivery element such as a hot fluid filled balloon; a rotating ablation element; a circumferential array of ablation elements; and combinations thereof.

210. The device as in any one of the preceding device claims wherein the electrical energy delivered by the ablation element comprises bipolar radiofrequency energy.

211. The device as in any one of the preceding device claims wherein the electrical energy delivered by the ablation element comprises monopolar radiofrequency energy.

212. The device as in any one of the preceding device claims wherein the electrical energy delivered by the ablation element comprises both monopolar and bipolar radiofrequency energy.

213. The device as in any one of the preceding device claims wherein the elongate shaft distal portion is constructed and arranged to be at least one of deflected or steered.

214. The device as in any one of the preceding device claims further comprising at least one sensor constructed and arranged to provide a signal.

215. The device of claim 214 wherein the device is constructed and arranged to deliver the electrical energy based on the at least one sensor signal.

216. The device of claim 214 wherein the at least one sensor comprises one or more sensors selected from the group consisting of: temperature sensor; pressure sensor; impedance sensor; visual sensor; and combinations thereof.

217. The device of claim 214 wherein the at least one sensor comprises a visual sensor constructed and arranged to provide an image of tissue.

218. The device of claim 217 wherein the visual sensor comprises an imaging device selected from the group consisting of: visible light camera; infrared camera; CT Scanner; MRI; and combinations thereof.

219. The device of claim 217 wherein the device is constructed and arranged to deliver the electrical energy based on the visual sensor signal.

220. The device of claim 219 wherein the device is constructed and arranged to deliver the electrical energy based on a change in tissue color.

221. The device of claim 214 wherein the at least one sensor comprises multiple temperature sensors.

222. The device of claim 221 wherein the multiple temperature sensors are positioned with a spacing of at least one sensor per 1 cm^2.

223. The device of claim 221 wherein the ablation element is constructed and arranged to deliver the electrical energy based on one or more signals from the multiple temperature sensors.

224. The device of claim 221 wherein the multiple temperature sensors comprise at least one temperature sensor selected from the group consisting of: thermocouple; thermistor; resistance temperature detector; optical temperature sensor; and combinations thereof.

225. The device of claim 214 wherein the at least one sensor comprises a sensor constructed and arranged to assess apposition of a device component with a gastrointestinal wall.

226. The device of claim 225 wherein the at least one sensor comprises a sensor constructed and arranged to assess apposition of a balloon expanded to contact the gastrointestinal wall.

227. The device of claim 225 wherein the at least one sensor comprises a chemical sensor.

228. The device of claim 227 wherein the at least one sensor comprises a carbon dioxide sensor.

229. The device of claim 225 wherein the at least one sensor is constructed and arranged to assess the apposition of the radially expandable element.

230. The device of claim 225 further comprising a second radially expandable element wherein the at least one sensor is constructed and arranged to assess the apposition of the second radially expandable element.

231. The device as in any one of the preceding device claims further comprising a conductive gel constructed and arranged to be applied to the target tissue.

232. The device of claim 231 wherein the conductive gel comprises a gel that is at least thermally or electrically conductive.

233. The device of claim 231 wherein the conductive gel comprises a thermally conductive gel constructed and arranged to conduct heat into tissue.

234. The device of claim 231 wherein the conductive gel comprises a thermally conductive gel constructed and arranged to cool tissue.

235. The device of claim 234 wherein the thermally conductive gel is constructed and arranged to cool tissue when cool air is delivered to at least one of the gel or the tissue.

236. The device of claim 231 wherein the conductive gel comprises an electrically conductive gel constructed and arranged to improve transfer of electrical energy to tissue.

237. The device of claim 231 wherein the conductive gel is constructed and arranged to be placed on tissue prior to expansion of the radially expandable element.

238. The device of claim 231 wherein the conductive gel is constructed and arranged to be placed on the ablation element prior to expansion of the radially expandable element.

239. The device as in any one of the preceding device claims further comprising an impedance monitoring assembly constructed and arranged to measure impedance of tissue.

240. The device of claim 239 wherein the device is constructed and arranged to deliver the electrical energy to the target tissue based on the measured impedance.

241. A system for ablating tissue with electrical energy comprising:

the ablation device of any of claims 1 through 240; and

an energy delivery unit constructed and arranged to deliver electrical energy to the ablation element of the ablation device.

242. The system as in any one of the preceding system claims wherein the system is constructed and arranged to perform a non-desiccating ablation of the target tissue.

243. The system as in any one of the preceding system claims wherein the system is constructed and arranged to deliver energy to the target tissue with an average power density less than or equal to 20 Watts per cm^2.

244. The system of claim 243 wherein the system is constructed and arranged to deliver energy to the target tissue with an average power density less than or equal to 10 Watts per cm^2.

245. The system of claim 244 wherein the system is constructed and arranged to deliver energy to the target tissue with an average power density less than or equal to 4 Watts per cm^2.

246. The system of claim 243 wherein the system is constructed and arranged to deliver energy to a portion of the target tissue for at least 1 second.

247. The system of claim 246 wherein the system is constructed and arranged to deliver energy to a portion of the target tissue for at least 5 seconds.

248. The system of claim 247 wherein the system is constructed and arranged to deliver energy to a portion of the target tissue for at least 10 seconds.

249. The system of claim 248 wherein the system is constructed and arranged to deliver energy to a portion of the target tissue for at least 20 seconds.

250. The system of claim 243 wherein the system is constructed and arranged to deliver energy to the target tissue at a level that decreases over time.

251. The system as in any one of the preceding system claims wherein the system is constructed and arranged to modulate the energy delivered to the target tissue.

252. The system of claim 251 wherein the system is constructed and arranged to pulse-width modulate the energy delivered to the target tissue.

253. The system of claim 252 wherein the pulse-width modulation comprises a cycle time, an on-time and an off-time, wherein the on-time is no more than 20% of the cycle time.

254. The system of claim 251 wherein the energy delivery unit comprises an electrical energy source less than or equal to a 300 Watt source.

255. The system of claim 254 wherein the energy delivery unit comprises an electrical energy source less than or equal to a 150 Watt source.

256. The system as in any one of the preceding system claims wherein the system is constructed and arranged to increase the temperature of the target tissue rapidly during energy delivery to the target tissue.

257. The system of claim 256 wherein the system is constructed and arranged to increase the temperature of the target tissue at a rate of at least 17.5°C per second.

258. The system of claim 256 wherein the system is constructed and arranged to increase the temperature of the target tissue to a setpoint comprising a temperature between 60°C and 90°C.

259. The system of claim 258 wherein the system is constructed and arranged to increase the temperature of the target tissue to a setpoint comprising a temperature between 65°C and 80°C.

260. The system as in any one of the preceding system claims wherein the system is constructed and arranged to deliver electrical energy to a setpoint temperature, and maintain the tissue at the setpoint temperature for approximately 2 to 40 seconds.

261. The system of claim 260 wherein the setpoint temperature comprises a temperature between 60°C and 90°C.

262. The system of claim 261 wherein the setpoint temperature comprises a temperature between 75°C and 85°C.

263. The system of claim 262 wherein the tissue is maintained at the setpoint temperature for approximately 15 to 25 seconds.

264. The system as in any one of the preceding system claims wherein the system is constructed and arranged to deliver electrical energy to a setpoint temperature, and wherein one or more energy delivery parameters decay after the setpoint temperature is achieved.

265. The system of claim 264 wherein the one or more energy delivery parameters decay at a rate constructed and arranged to match a physiological response of the tissue receiving the electrical energy.

266. The system as in any one of the preceding system claims wherein the energy delivery unit is constructed and arranged to deliver radiofrequency energy to the ablation element of the ablation device.

267. The system of claim 266 wherein the energy delivery unit is constructed and arranged to deliver radiofrequency energy at a frequency at or below 1 MHz.

268. The system as in any one of the preceding system claims wherein the electrical energy delivered by the ablation element comprises bipolar radiofrequency energy.

269. The system as in any one of the preceding system claims wherein the electrical energy delivered by the ablation element comprises monopolar radiofrequency energy.

270. The system as in any one of the preceding system claims wherein the electrical energy delivered by the ablation element comprises both monopolar and bipolar radiofrequency energy.

271. The system as in any one of the preceding system claims wherein the electrical energy delivered by the ablation element comprises a power of less than or equal to 300W.

272. The system as in any one of the preceding system claims wherein the electrical energy delivered by the ablation element comprises a power of approximately 260W.

273. The system of claim 272 wherein the 260W decreases to 0W over approximately 30 seconds.

274. The system as in any one of the preceding system claims wherein the energy delivery unit delivers electrical energy to the ablation element in a current-driven mode.

275. The system as in any one of the preceding system claims wherein the system is constructed and arranged to deliver electrical energy to tissue and avoid desiccation of the tissue.

276. The system as in any one of the preceding system claims wherein the system is constructed and arranged to deliver electrical energy to tissue and avoid creation of steam.

277. The system as in any one of the preceding system claims wherein the system is constructed and arranged to deliver electrical energy to tissue and avoid detachment of tissue particles.

278. The system as in any one of the preceding system claims wherein the system is constructed and arranged to deliver energy in at least 2 second energy delivery durations.

279. The system of claim 278 wherein the 2 second energy delivery durations comprise non-continuous delivery of energy for 2 seconds.

280. The system as in any one of the preceding system claims further comprising a second ablation device for ablating luminal wall tissue.

281. The system of claim 280 wherein the second ablation device comprises an ablation device of any of claims 1 through 240.

282. The system of claim 281 wherein the second ablation device comprises a radially expandable element with a different expanded diameter than the first ablation device radially expandable element.

283. The system of claim 281 wherein the first ablation device ablation element comprises a first set of multiple conductors, and the second ablation device comprises a second ablation element comprising a second set of multiple conductors, and wherein the first set of multiple conductors are arranged in a different pattern than the second set of multiple conductors.

284. The system of claim 280 wherein the second ablation device comprises an ablation device selected from the group consisting of: hot fluid filled balloon device; vapor ablation device; cryoablation device; laser ablation device; ultrasound ablation device; and combinations thereof.

285. The system as in any one of the preceding system claims further comprising a cooled fluid delivery device constructed and arranged to deliver fluid below 37°C to target tissue.

286. The system of claim 285 wherein the cooled fluid delivery device is constructed and arranged to deliver a fluid selected from the group consisting of: a liquid; a gas; and combinations thereof.

287. The system of claim 285 wherein the cooled fluid delivery device is constructed and arranged to deliver a cooled gas toward the duodenal wall.

288. The system of claim 285 wherein the system is constructed and arranged to deliver the cooled fluid prior to the delivery of the electrical energy.

289. The system of claim 285 wherein the system is constructed and arranged to deliver the cooled fluid after to the delivery of the electrical energy.

290. The system as in any one of the preceding system claims further comprising an endoscope.

291. The system as in any one of the preceding system claims further comprising a tissue expansion device.

292. The system of claim 291 wherein the tissue expansion device comprises a submucosal tissue expansion device configured to expand duodenal submucosal tissue prior to the ablation element of the ablation device delivering the electrical energy.

293. The system as in any one of the preceding system claims further comprising an insufflation device.

294. The system of claim 293 further comprising an endoscope comprising a fluid delivery tube wherein the fluid delivery tube comprises the insufflation device.

295. The system of claim 293 wherein the system is constructed and arranged to control apposition of the ablation element with the target tissue.

296. The system as in any one of the preceding system claims further comprising a tissue cooling device.

297. The system of claim 296 wherein the tissue cooling device is constructed and arranged to apply cooling fluid to tissue.

298. The system of claim 297 wherein the tissue cooling device is constructed and arranged to apply cooling fluid to tissue prior to the delivery of electrical energy to the tissue.

299. The system of claim 297 wherein the tissue cooling device is constructed and arranged to apply cooling fluid to tissue after the delivery of electrical energy to the tissue.

300. The system of claim 296 wherein the tissue cooling device is constructed and arranged to deliver a tissue cooling gas.

301. The system of claim 300 wherein the tissue cooling gas comprises a gas selected from the group consisting of: air; carbon dioxide; nitrogen; nitrous oxide; and combinations thereof.

302. The system of claim 300 further comprising a drying assembly constructed and arranged to remove moisture from the cooling gas prior to delivery.

303. The system of claim 296 wherein the tissue cooling device provides cooling fluid at a temperature less than or equal to 20°C.

304. The system of claim 303 wherein the tissue cooling device provides cooling fluid at a temperature less than or equal to 10°C.

305. The system of claim 304 wherein the tissue cooling device provides cooling fluid at a temperature less than or equal to 0°C.

306. The system as in any one of the preceding system claims wherein the system is constructed and arranged to modify a tissue property selected from the group consisting of: a secretive property of a portion of the gastrointestinal tract; an absorptive property of a portion of the gastrointestinal tract; and combinations thereof.

307. The system as in any one of the preceding system claims further comprising at least one fluid delivery device constructed and arranged to deliver fluid into submucosal tissue to increase the volume of the target tissue.

308. A device for ablating tissue of a patient with electrical energy comprising:

an elongate shaft with a proximal portion and a distal portion;

a radially expandable element attached to the elongate shaft distal portion; and

an ablation element mounted to the radially expandable element;

wherein the ablation element is constructed and arranged to deliver electrical energy to a target tissue; and

wherein the device is constructed and arranged to modify a tissue property selected from the group consisting of: a secretive property of a portion of the gastrointestinal tract; an absorptive property of a portion of the gastrointestinal tract; and combinations thereof.

309. The device of claim 306 wherein the device further comprises at least one fluid delivery element constructed and arranged to deliver fluid into submucosal tissue to increase the volume of the target tissue.

310. The device of claim 305 or 306, wherein the device is constructed and arranged as described in any of claims 2 through 240.

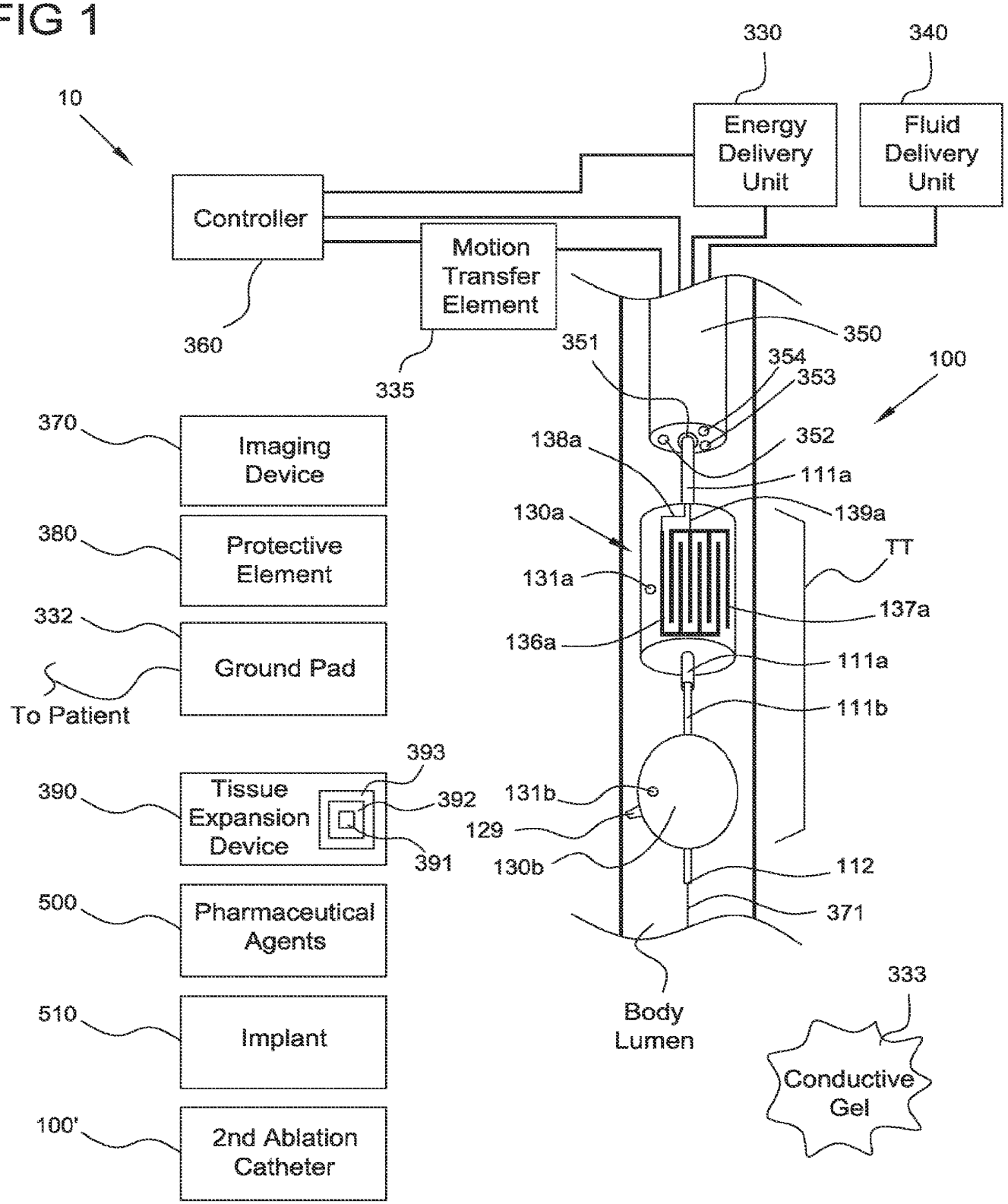
311. A device for ablating tissue as described in reference to the figures.

312. A system for ablating tissue as described in reference to the figures.

313. A method for ablating tissue as described in reference to the figures.

01 / 15

FIG 1


10
Controller
360
Energy Delivery Unit
330
Fluid Delivery Unit
340
Motion Transfer Element
335
350
351
354
353
100
352
138a
111a
139a
130a
TT
131a
137a
136a
111a
111b
131b
129
130b
112
371
Body Lumen
333
Conductive Gel
370
Imaging Device
380
Protective Element
332
Ground Pad
To Patient
393
390
Tissue Expansion Device
392
391
500
Pharmaceutical Agents
510
Implant
100'
2nd Ablation Catheter

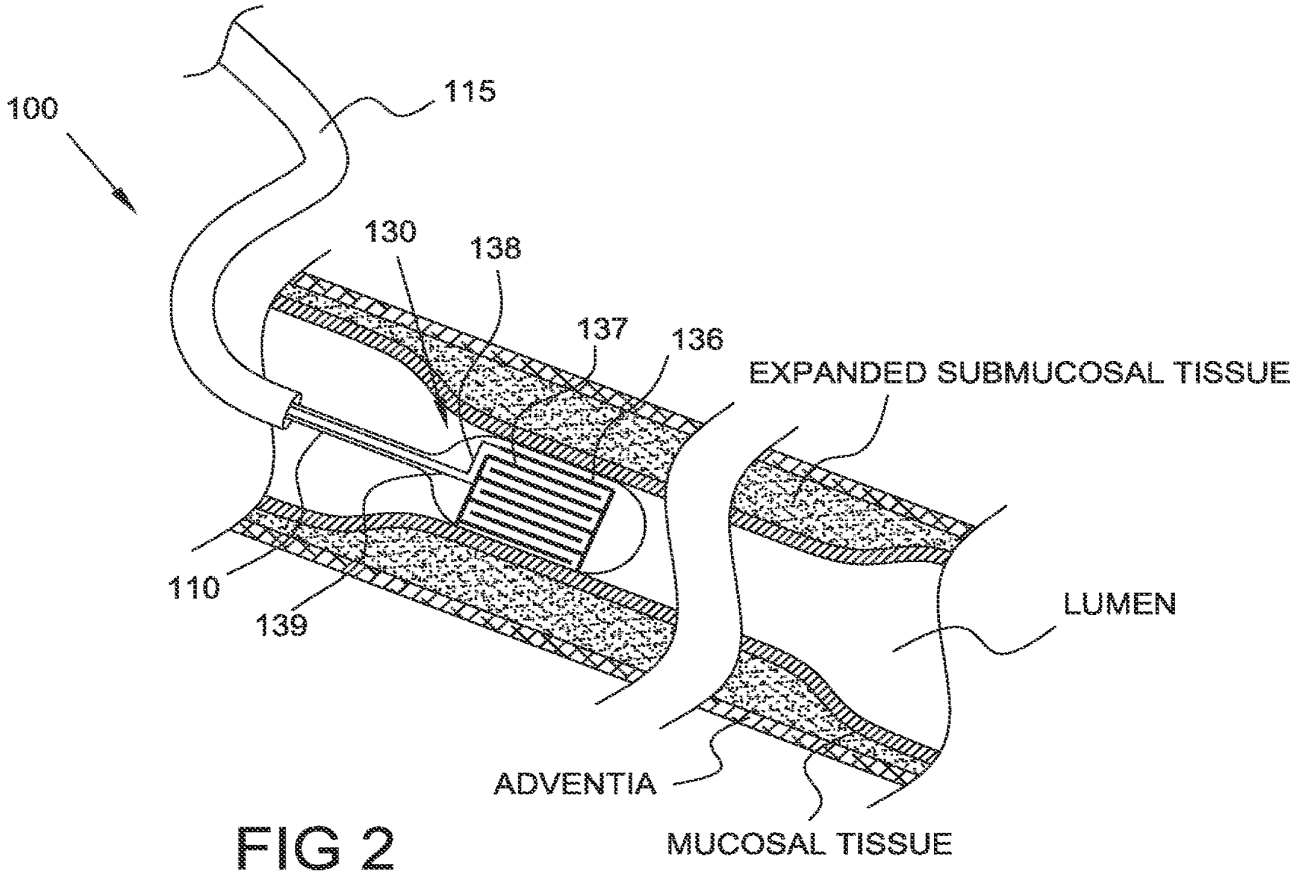

100
115
130
138
137
136
EXPANDED SUBMUCOSAL TISSUE
110
139
LUMEN
ADVENTIA
MUCOSAL TISSUE

FIG 2

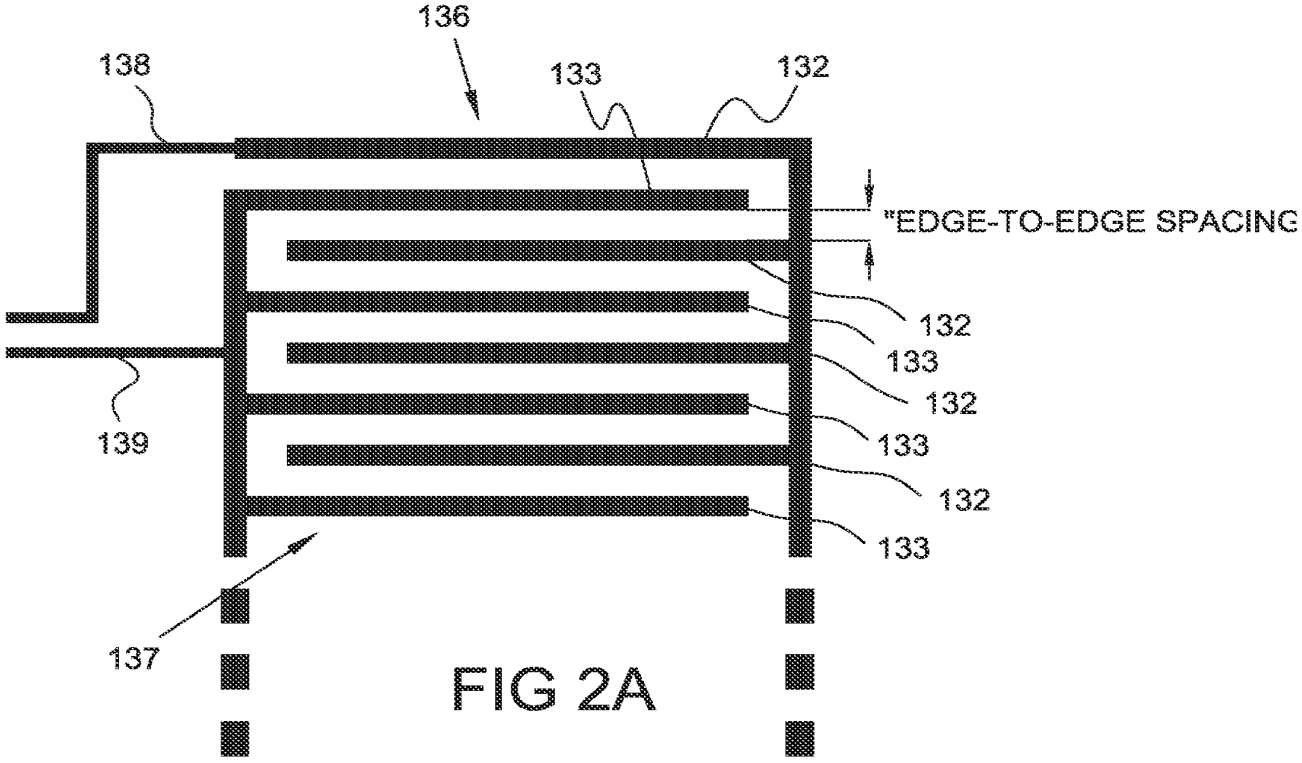

136
138
133
132
"EDGE-TO-EDGE SPACING
132
133
132
133
132
133
139
137

FIG 2A

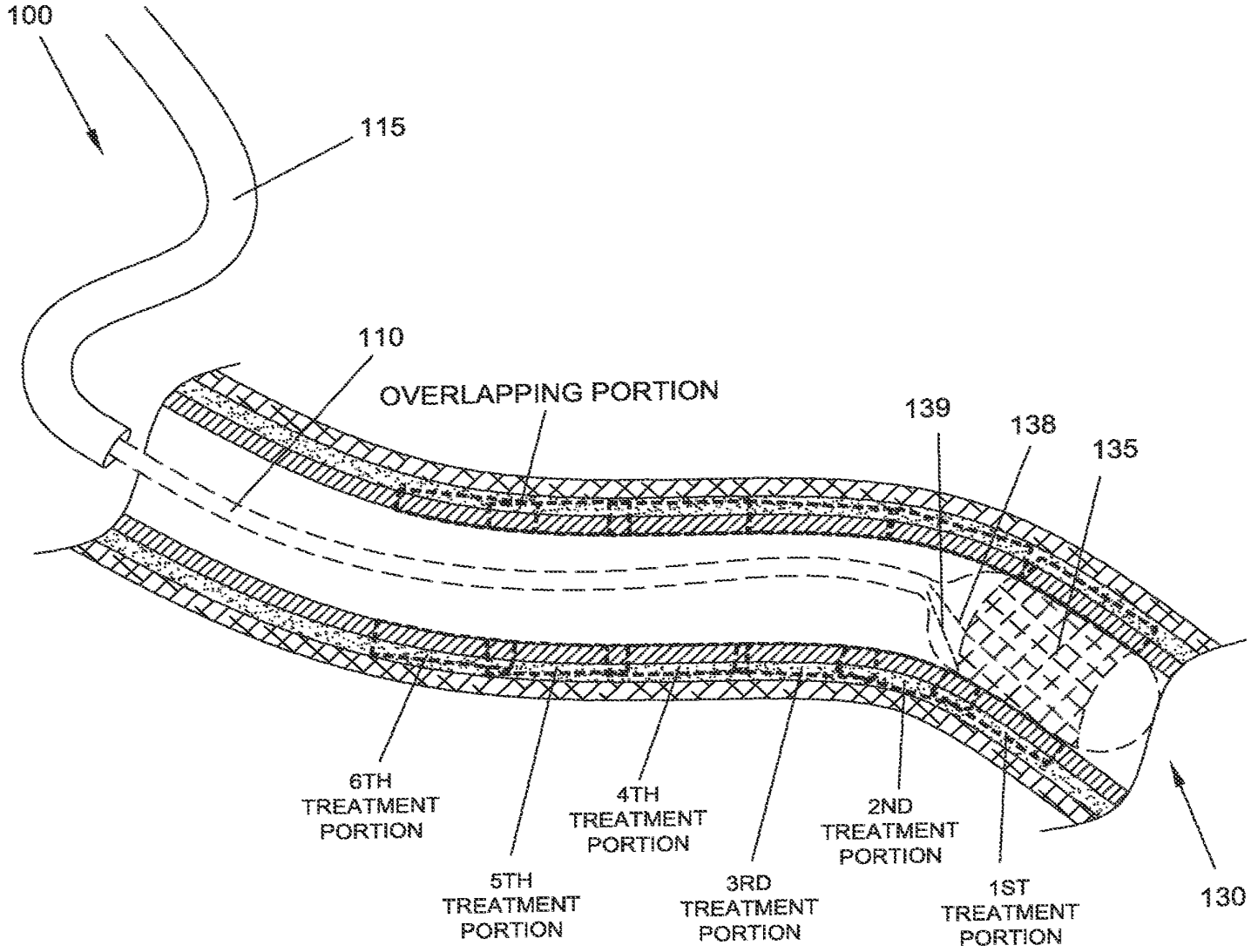

100
115
110
OVERLAPPING PORTION
139
138
135
6TH TREATMENT PORTION
5TH TREATMENT PORTION
4TH TREATMENT PORTION
3RD TREATMENT PORTION
2ND TREATMENT PORTION
1ST TREATMENT PORTION
130

FIG 3

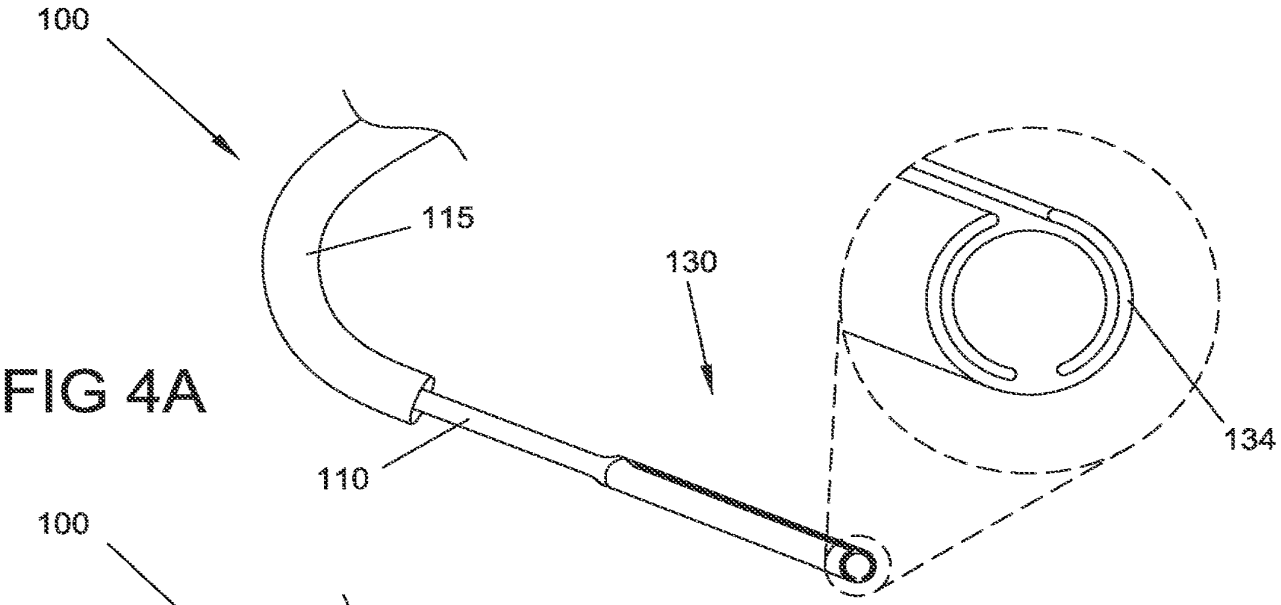


FIG 4A

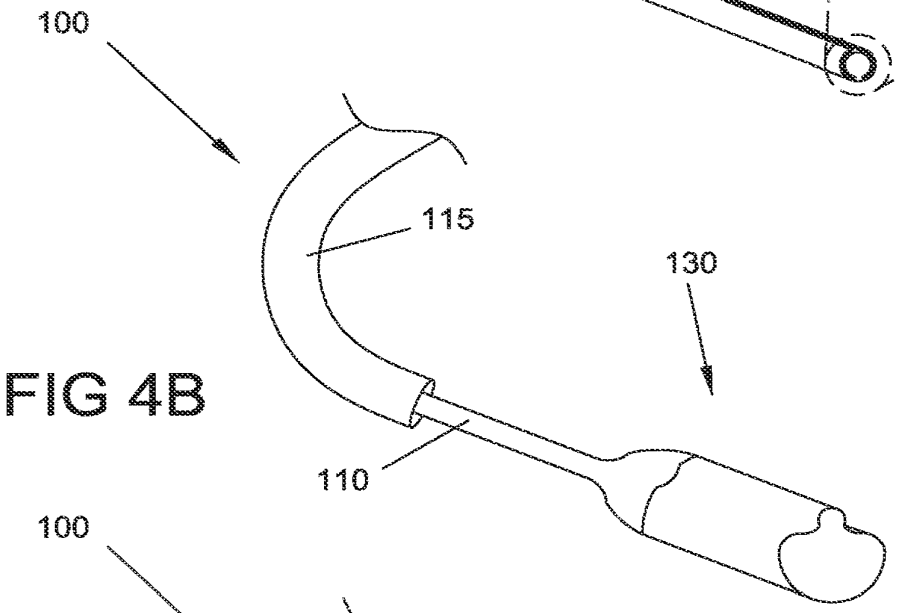


FIG 4B

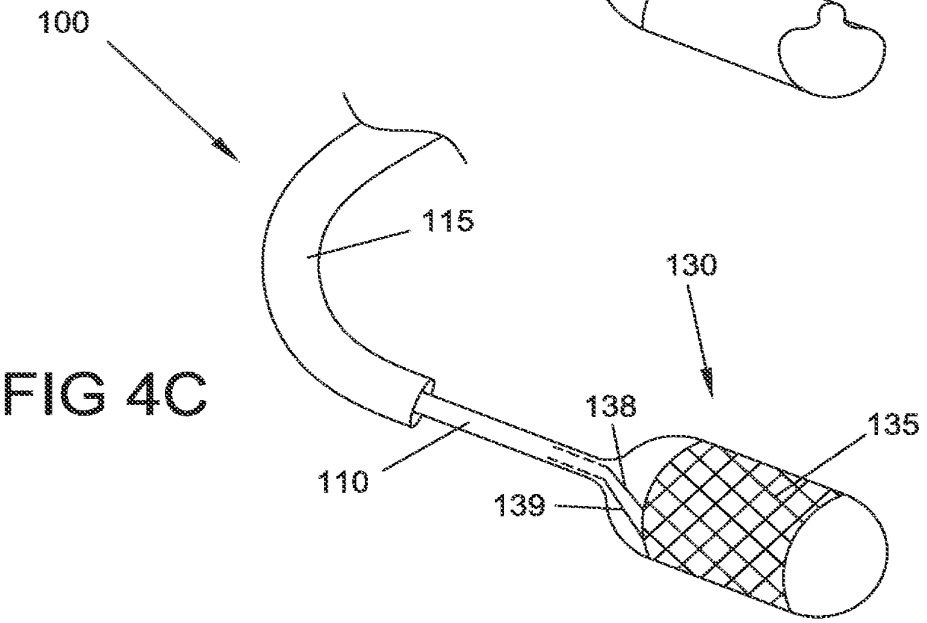


FIG 4C

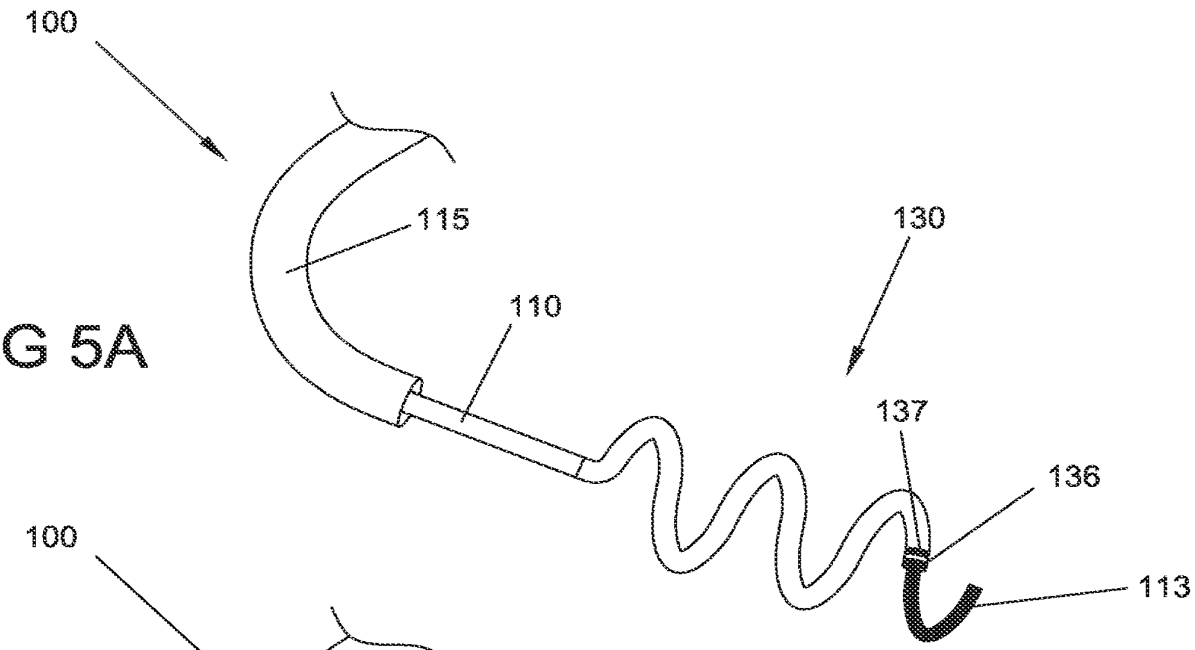


FIG 5A

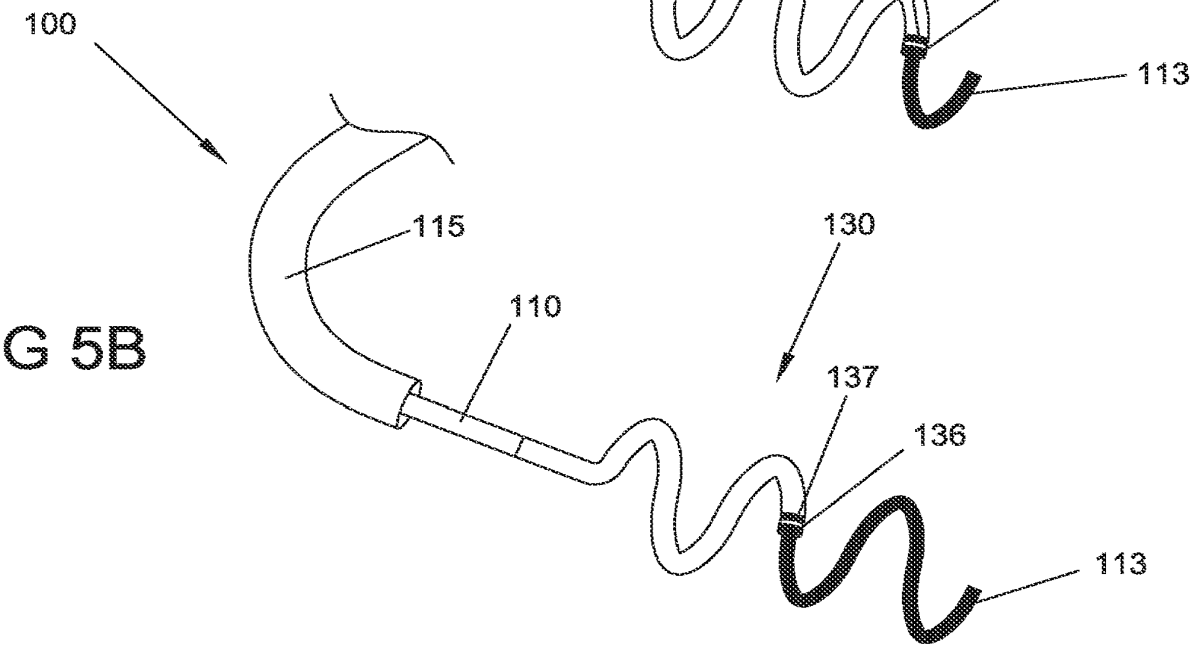


FIG 5B

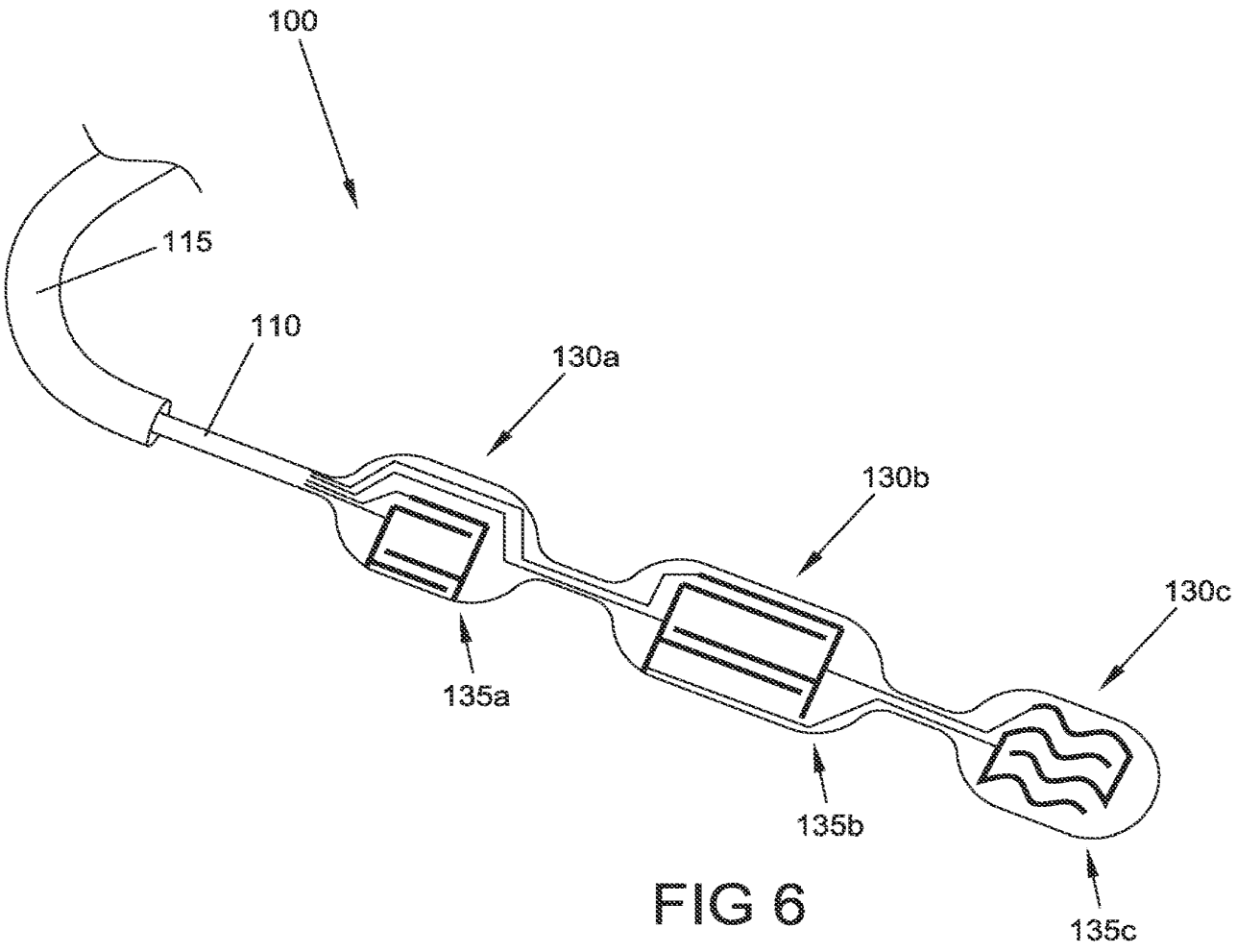


FIG 6

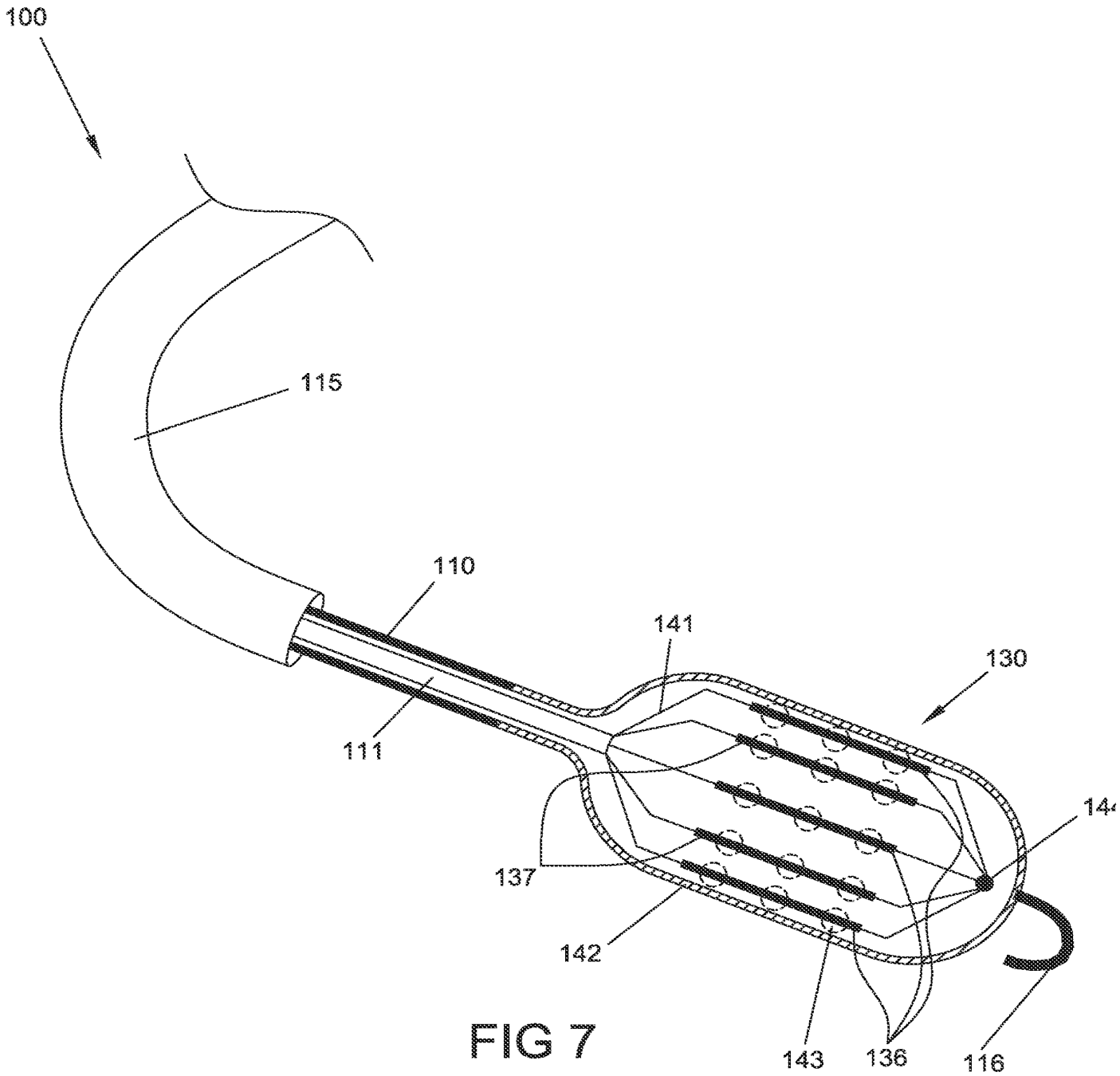


FIG 7

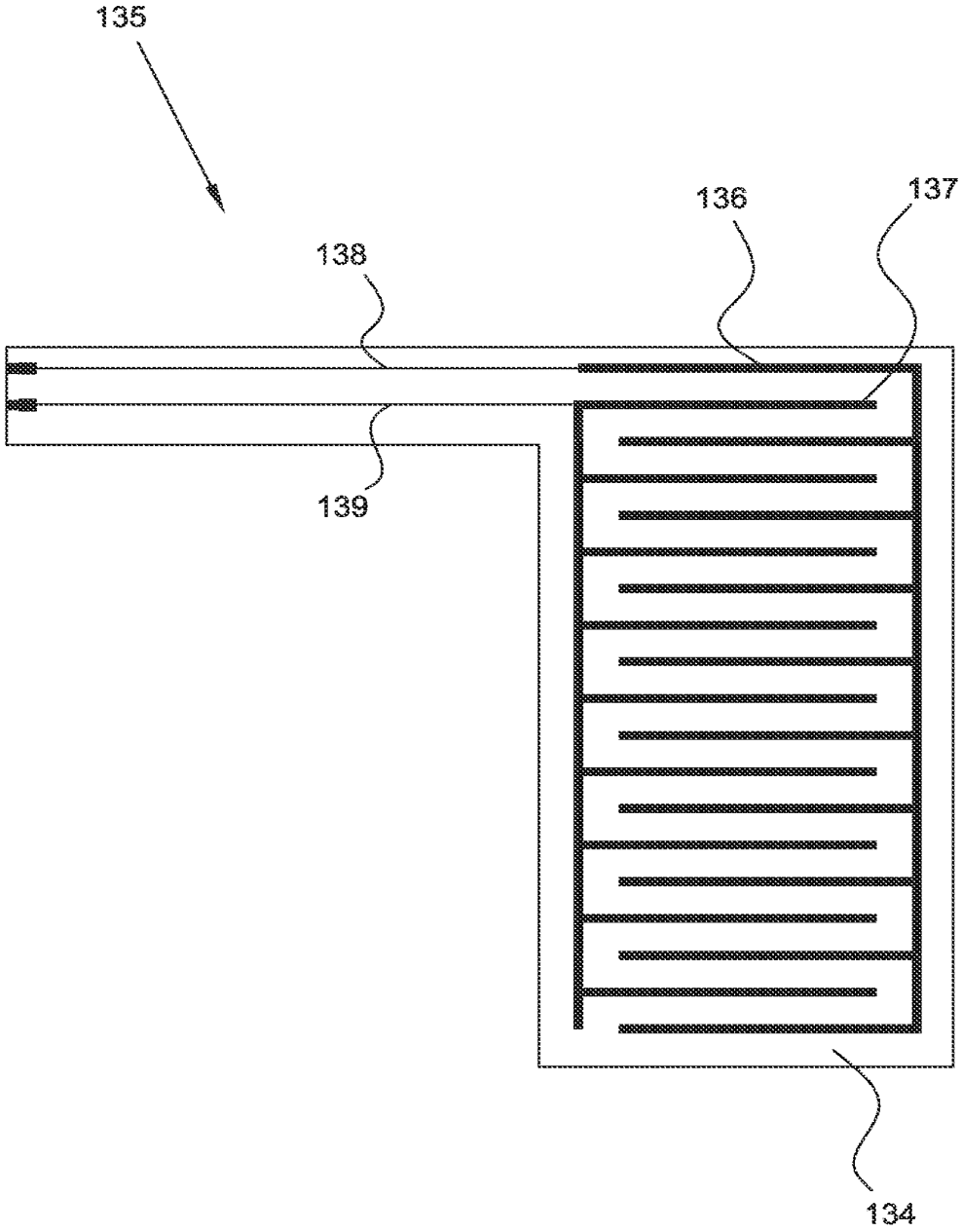


FIG 8A

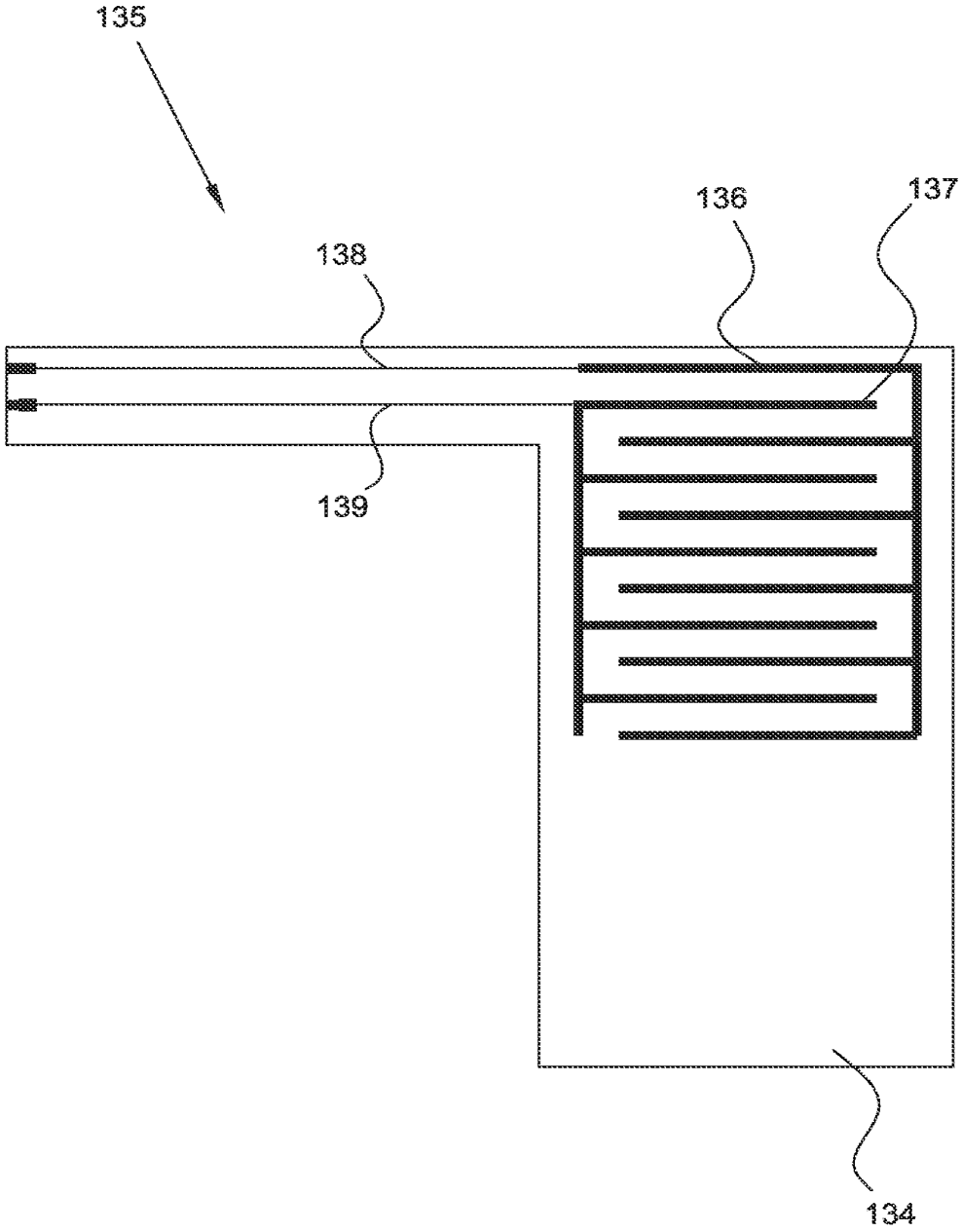


FIG 8B

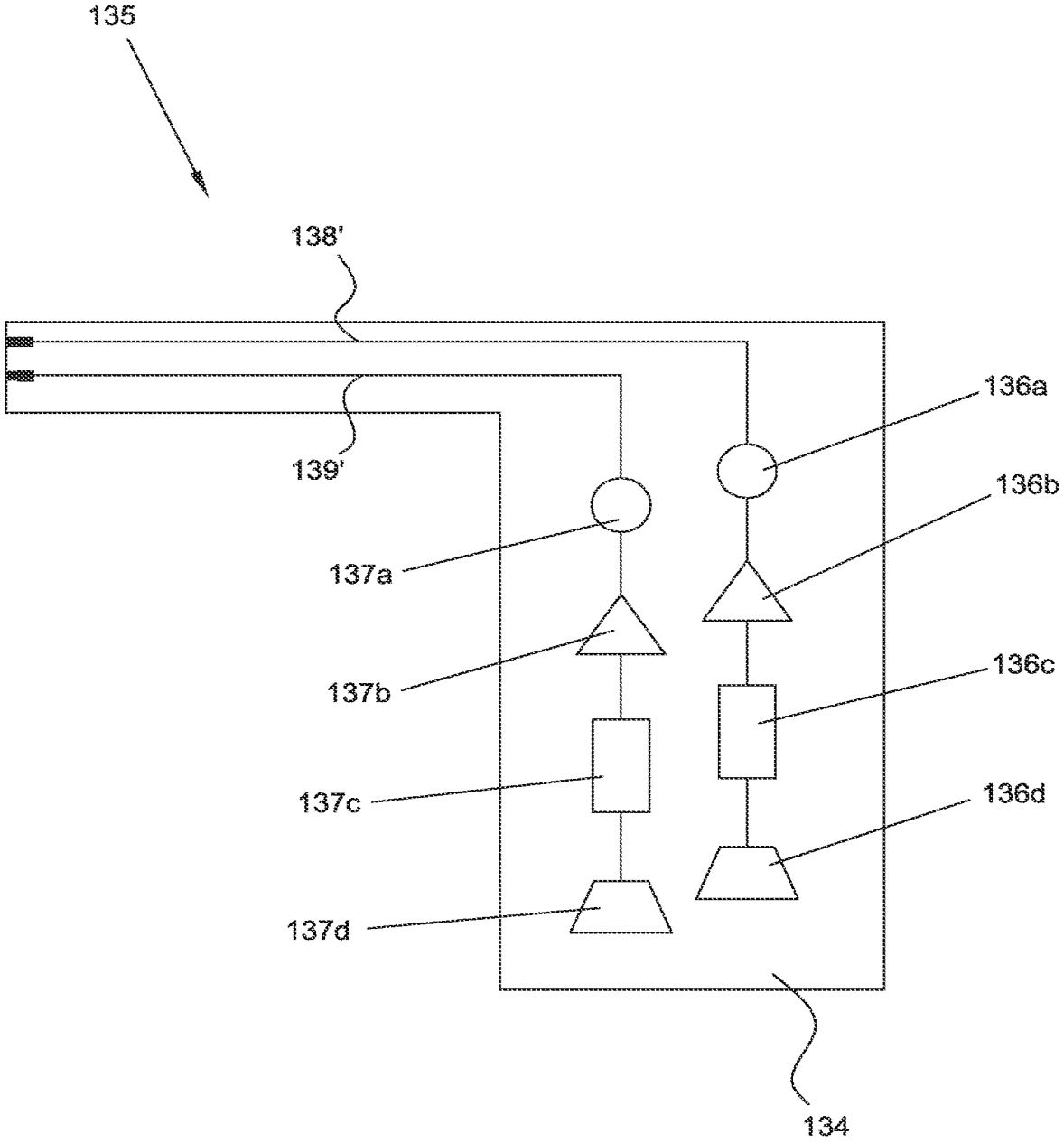


FIG 8C

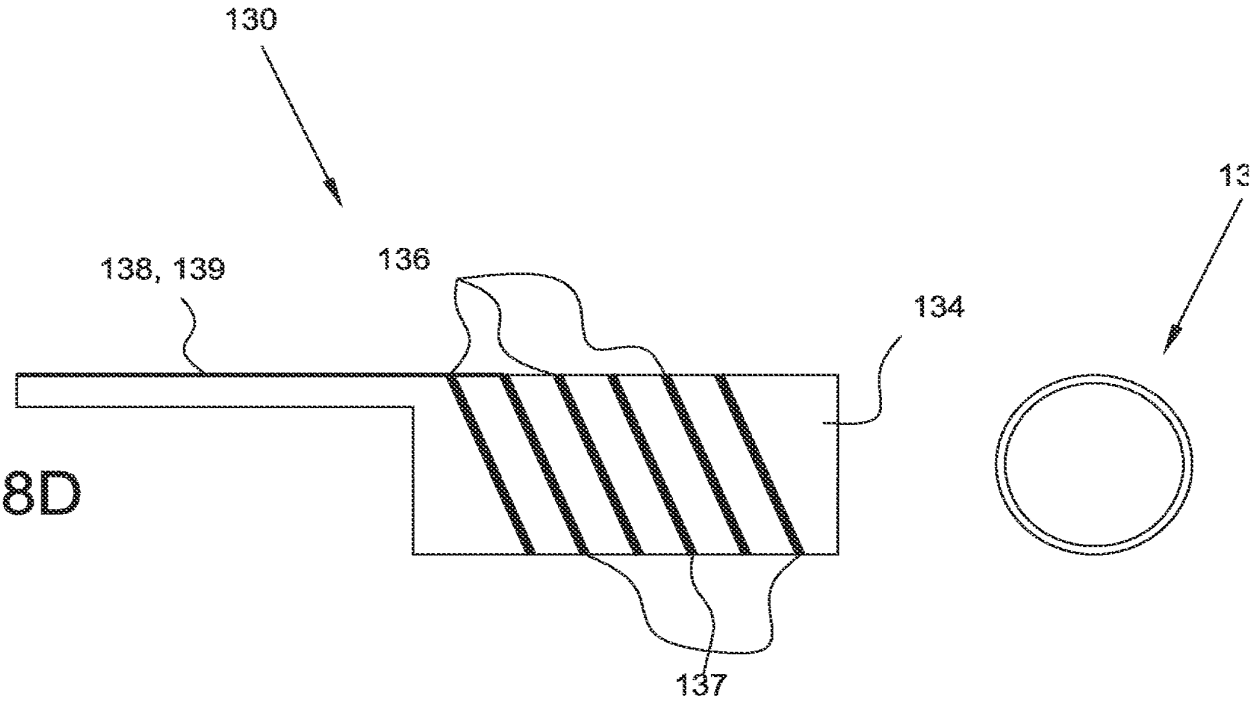


FIG 8D

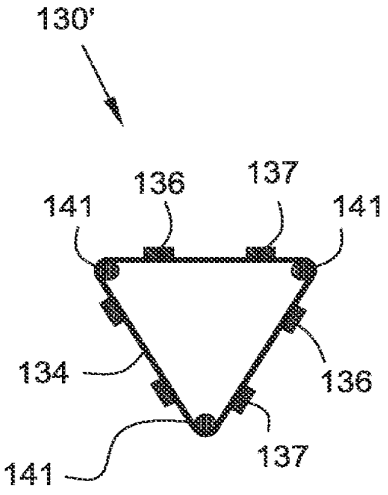


FIG 8E

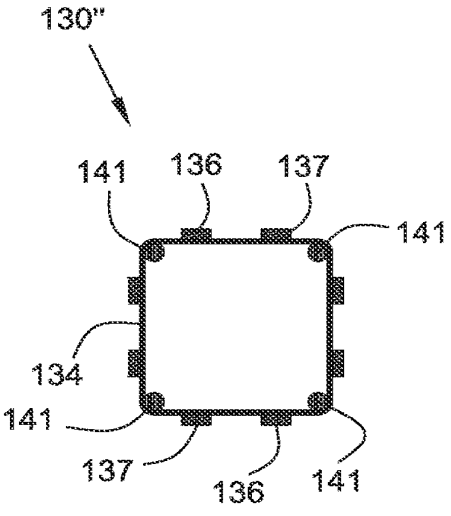


FIG 8F

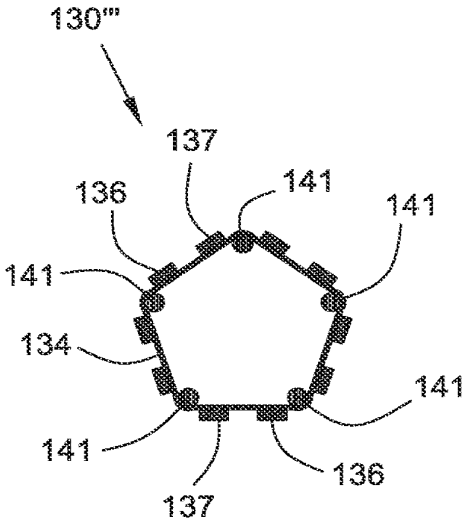


FIG 8G

FIG 9A

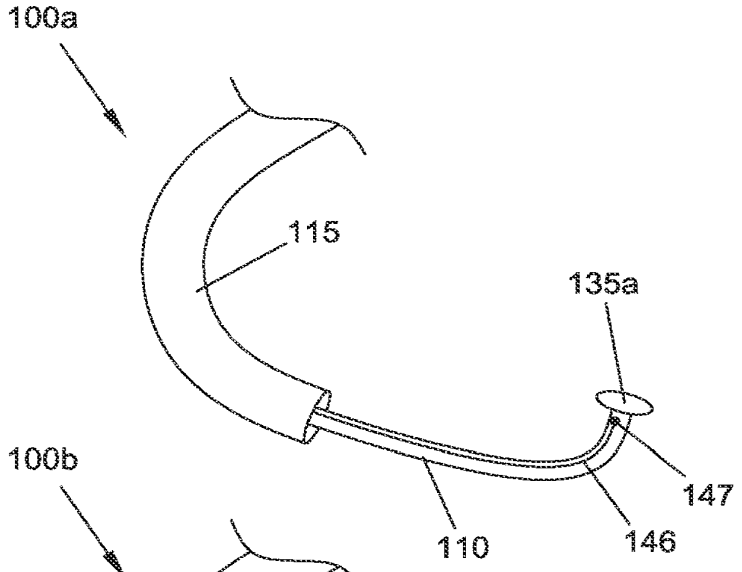


FIG 9B

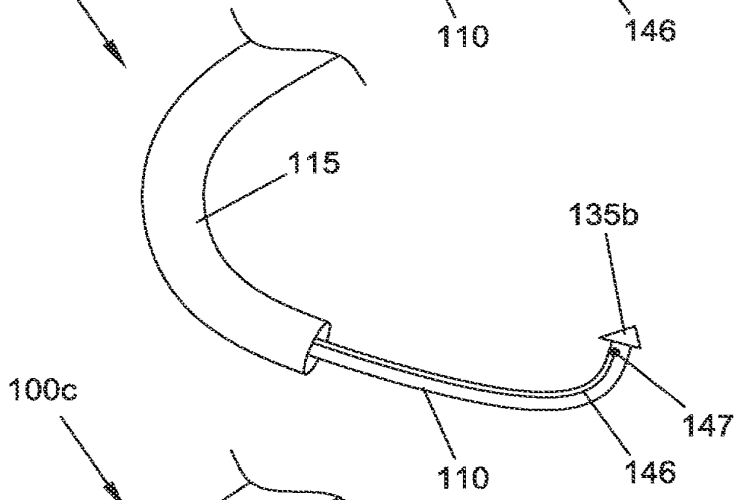


FIG 9C

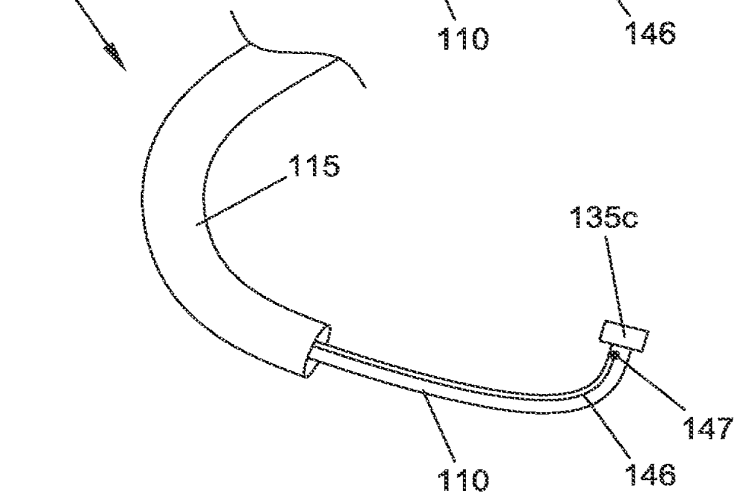
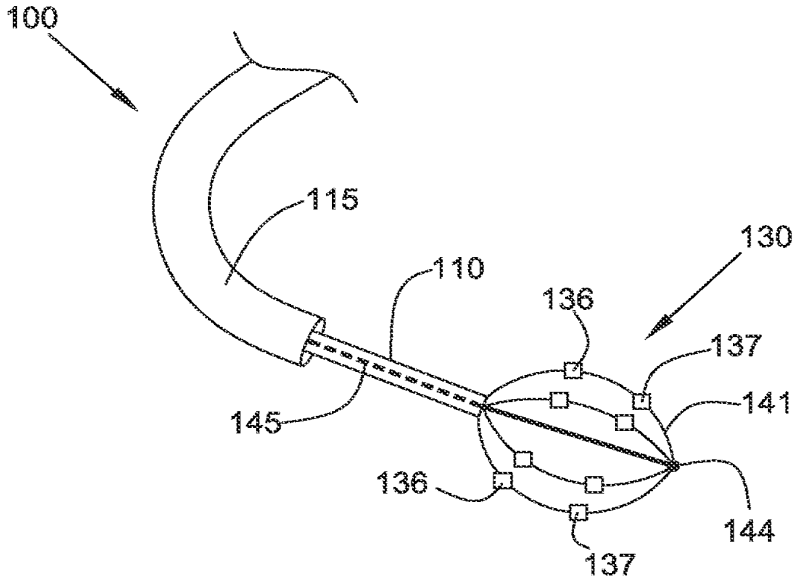


FIG 10



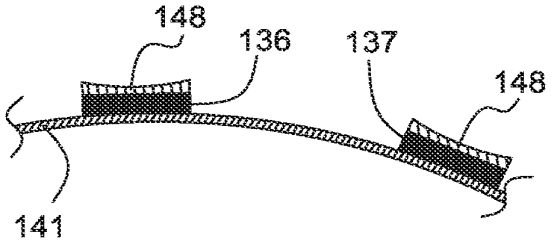


FIG 10A

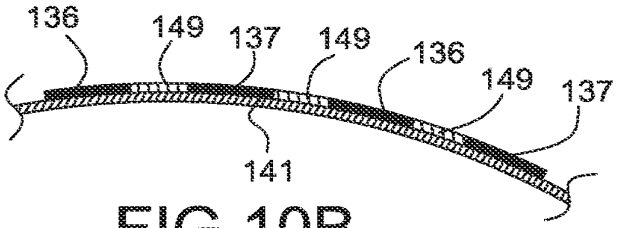
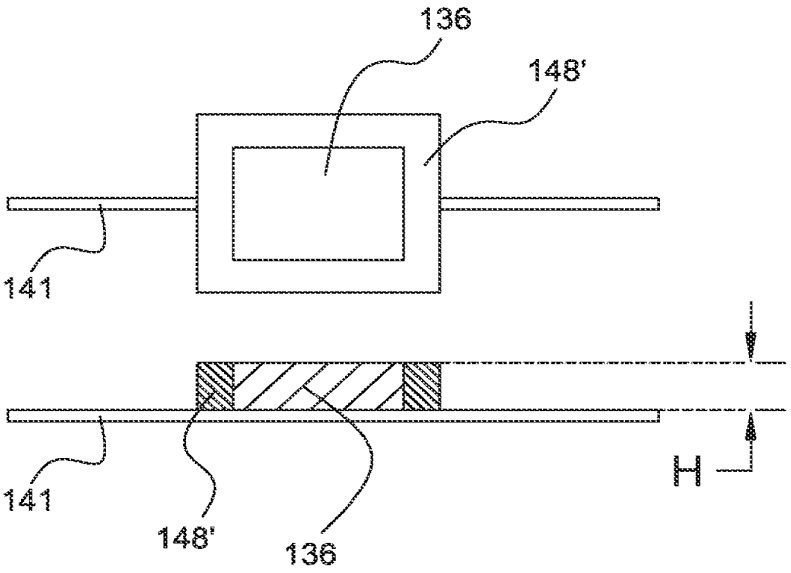


FIG 10B

FIG 10C



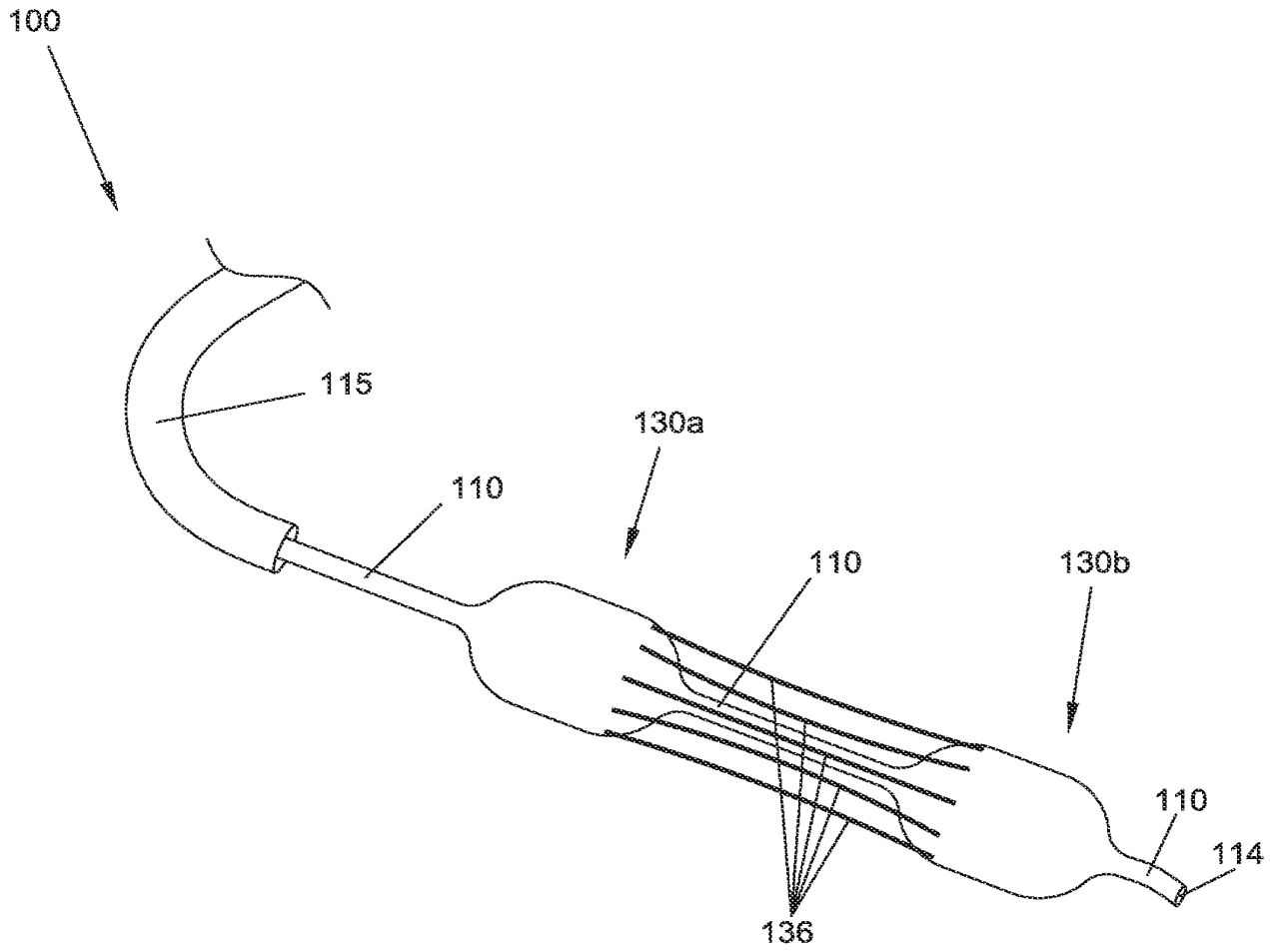


FIG 11

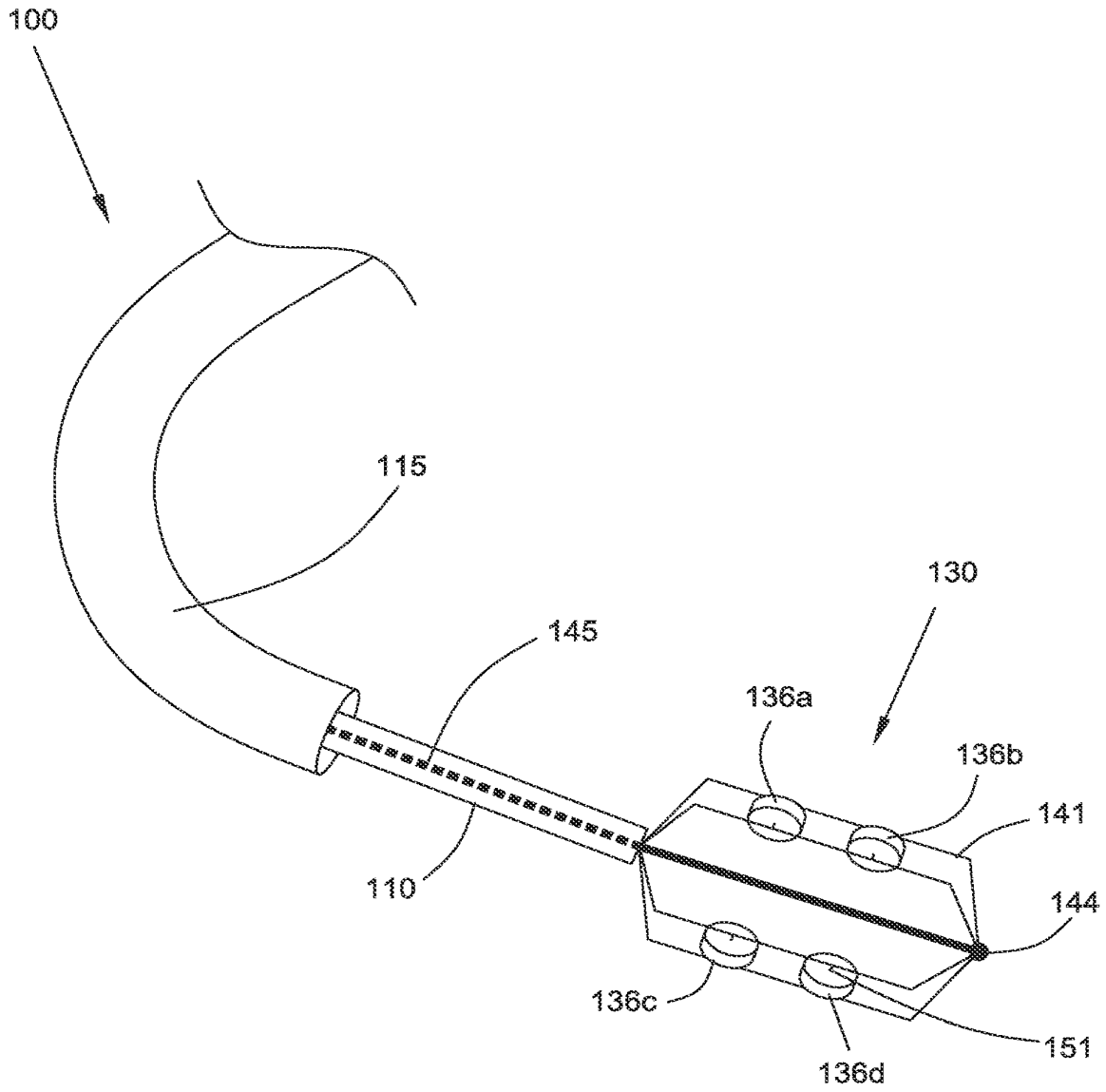


FIG 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/052786

A. CLASSIFICATION OF SUBJECT MATTER

A61B 18/12(2006.01)i, A61B 18/14(2006.01)i, A61M 25/10(2006.01)i, A61M 29/02(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)
A61B 18/12; A61B 18/14; A61F 7/12; A61B 17/32; A61B 18/18; A61F 7/00; A61M 25/10; A61M 29/02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords:ablation, expandable, electrode, mucosa, duodenum

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012-099974 A2 (FRACTYL LABORATORIES, INC.) 26 July 2012 See paragraphs [0116], [0162]-[0167], [0171], [0172], [0204], [0276]; figures 4, 11.	1-5,308
A	US 2008-0275445 A1 (KELLY, D. et al.) 06 November 2008 See paragraphs [0096]-[0099], [0111], [0112], [0118]-[0138]; figures 1-8D.	1-5,308
A	US 2004-0215296 A1 (GANZ, R. A. et al.) 28 October 2004 See paragraphs [0054]-[0058]; figures 3-7.	1-5,308
A	US 2011-0172659 A1 (BRANNAN, J. D.) 14 July 2011 See the entire document.	1-5,308
A	US 2003-0093072 A1 (FRIEDMAN, P.) 15 May 2003 See the entire document.	1-5,308

☐ 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
08 November 2013 (08.11.2013)	**08 November 2013 (08.11.2013)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
Han, Inho
Telephone No. +82-42-481-3362

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/052786

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 313
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 313 pertains to methods for treatment of human body and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

2. ☒ Claims Nos.: (See the extra sheet)
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
(See the extra sheet)

3. ☒ Claims Nos.: (See the extra sheet)
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US2013/052786

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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INTERNATIONAL SEARCH REPORT

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International application No.
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/052786

- **Continued on Box No. II** -

(The Second Reason)

Claims Nos.: 8, 11-14, 20, 22-26, 31-33, 35, 38, 45-50, 52-62, 65, 67-73, 76-79, 81-84, 86-88, 90-105, 107-109, 112, 113, 116, 118, 121-131, 133, 134, 136-139, 141, 145-147, 150, 152, 156-172, 181-192, 195, 197, 199-204, 206, 207, 209, 215-230, 232-238, 240, 244-250, 252-255, 257-259, 261-263, 265, 267, 273, 279, 281-284, 286-289, 292, 294, 295, 297-305, 309, 311, 312 because they relate to parts of the national application that do not comply with the prescribed requirements to such an extent that no meaningful international-type search can be carried out, specifically:

Claims 8, 11-14, 20, 22-26, 31-33, 35, 38, 45-50, 52-62, 65, 67-73, 76-79, 81-84, 86-88, 90-105, 107-109, 112, 113, 116, 118, 121-131, 133, 134, 136-139, 141, 145-147, 150, 152, 156-172, 181-192, 195, 197, 199-204, 206, 207, 209, 215-230, 232-238, 240, 244-250, 252-255, 257-259, 261-263, 265, 267, 273, 279, 281-284, 286-289, 292, 294, 295, 297-305, 309 do not comply with PCT Article 6 because they are referring to unsearchable claims, which do not comply with PCT Rule 6.4(a).

Claims 311-313 are contrary to PCT Rule 6.2(a), because they rely on unnecessary reference to the figures.

(The Third Reason)

Claims Nos.: 6, 7, 9, 10, 15-19, 21, 27-30, 34, 36, 37, 39-44, 51, 63, 64, 66, 74, 75, 80, 85, 89, 106, 110, 111, 114, 115, 117, 119, 120, 132, 135, 140, 142-144, 148, 149, 151, 153-155, 173-180, 193, 194, 196, 198, 205, 208, 210-214, 231, 239, 241-243, 251, 256, 260, 264, 266, 268-272, 274-278, 280, 285, 290, 291, 293, 296, 306, 307, 310 because they dependent claims are not drafted in accordance with second and third sentences of Rule 6.4(a)

Doc code: IDS
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(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	WOLF
Art Unit	4187
Examiner Name	
Attorney Docket Number	17713.0001US14

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	3	10456186	B1	2019-10-29	Wolf et al.	
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Art Unit	4187
Examiner Name	
Attorney Docket Number	17713.0001US14

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	1	2013028998	WO	A2	2013-02-28	HUSZAR et al.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	WOLF
	Art Unit	4187
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/ Christopher P. Ziolkowski /	Date (YYYY-MM-DD)	2019-12-05
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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

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(74) Agents: **WILSON, David B.** et al.; 1800 Broadway, Suite 300, Boulder, Colorado 80302 (US).

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

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(54) Title: SYSTEMS, DEVICES, AND METHODS FOR TREATMENT OF LUMINAL TISSUE

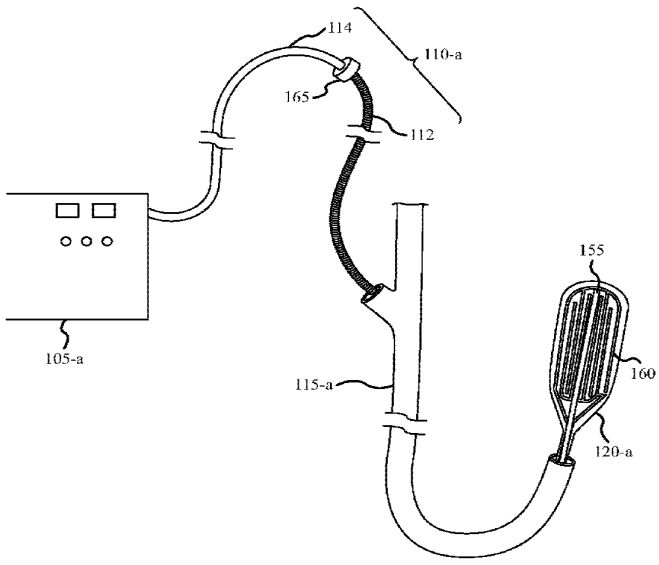

FIG.1B

(57) Abstract: Methods, systems, and devices for providing treatment to a target site are described. The system may include a guide assembly, an expandable support device coupled with the distal end of the guide assembly, and an operative member disposed on the expandable support device. The expandable support device may be configured to transition between a collapsed and expanded configuration. The expandable support device may be supported by one or more flexible supports aligned in parallel with an axis about which the expandable support device collapses and/or multiple splines arranged in a pattern configured to promote transitioning of the expandable support device between an expanded and collapsed configuration. The guide assembly may be configured to provide torque to the expandable support device. The operative member can include multiple electrodes arranged in parallel to the axis about which the expandable support device collapses.

WO 2013/028998 A2

GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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SYSTEMS, DEVICES, AND METHODS FOR TREATMENT OF LUMINAL TISSUE

CROSS REFERENCES

[0001] This application claims priority to U.S. Provisional Patent Application No. 61/527,554, titled "DEVICES AND METHODS FOR TREATMENT OF LUMINAL TISSUE," filed August25, 2011, incorporated by reference in its entirety for all purposes.

BACKGROUND

[0002] Various devices and techniques exist for providing therapy in the body. A common approach to administering treatment or performing diagnostics at a tissue site in the body involves delivering an instrument to the site at a distal end of an elongate catheter or endoscope. A problem exists, however, in that many instruments and devices do not fit within the catheter or endoscope. Currently, some devices may be limited in use because the treatment surface of the device is too large for delivery to the site through a catheter or endoscope.

[0003] The delivery of many existing devices to a treatment site through the use of a catheter or endoscope can also be hindered by the location of the treatment site within the body. In some cases, for example, the device needs to be able to navigate a tortuous path or small diameter body lumens to reach a treatment site. Some known devices lack the ability to bend along tortuous delivery paths

[0004] Another problem may exist with treating a target site significantly larger than the delivery pathway through which the device must pass. In order to treat a large target site, a device with a large treatment surface is often desired. However, if the treatment surface is too large, it may not be possible to deliver the device through narrow lumens. If the treatment surface is reduced to fit within the catheter or endoscope, it may provide too small a surface area for efficient and efficacious delivery of treatment to the relatively large target site.

[0005] There may thus be a need for systems, devices and methods that may overcome the above and/or other disadvantages of known systems and methods.

SUMMARY

[0006] Methods, systems, and devices are described for providing treatment to a target site, such as a site within a body lumen. Systems may include an expandable support device that

may be coupled with a distal end of a guide assembly. An operative member may be disposed on the expandable support device such that moving the expandable support device to the target site using the guide assembly delivers the operative member to the target site. The guide assembly may be utilized to transmit torque and/or to rotate to the expandable support device and/or the operative member.

[0007] The expandable support member may include a solid body of elastomeric material. The elastomeric material may be flexible so that it may transition between a folded, or collapsed configuration and a planar, or expanded, configuration. One or more flexible supports may be coupled with the elastomeric body such that the flexible supports are each aligned parallel to a central axis of the elastomeric body. The flexible supports may be made from at least a highly elastic, such as spring steel, or a superelastic material, such as nitinol, and may be arranged in a single central axis configuration, a wishbone configuration, or a trident configuration.

[0008] The expandable support member may include a solid support member made from at least a highly elastic or superelastic material that is supported by multiple splines located within the perimeter of the solid support member. The multiple splines may be separated by voids so as to create a pattern of splines having a width and spacing that promotes transitioning of the solid support member between a collapsed configuration and an expanded configuration. The splines may be arranged in a pattern wherein a spline arranged to substantially overlap a central axis of the solid support member has splines extending away from the central spline in both directions towards a distal end of the solid support member.

[0009] The operative member may include a flexible circuit capable of bending with the expandable support device upon which it is disposed. The flexible circuit may include multiple electrodes aligned in parallel to one another. The electrodes may also be aligned in parallel to an axis about which the flexible circuit collapses from a planar configuration to a folded configuration so that the electrodes do not substantially impede the transition between an expanded configuration and a collapsed configuration. The flexible circuit may include a first bus at one end of the parallel electrodes and a second bus at the opposite end of the electrodes. The electrodes may be coupled with the first and second bus in an alternating pattern.

[0010] The guide assembly that may be used to move the expandable support device may include a first shaft portion and a second shaft portion separated by a break. Transmission lines may extend through both the first shaft and the second shaft. The break between the first shaft and the second shaft may allow the first shaft to rotate independently of the second shaft. The first shaft may be configured such that rotation of the first shaft transmits torque and/or rotation to the expandable support device.

[0011] In some embodiments, an expandable support device may be configured for delivering an operative member through a working channel to a target treatment area. The expandable support device may include an elastomeric body that is configured to support the operative member and promote expansion of the expandable support device between a collapsed configuration and an expanded configuration. The elastomeric body may include a proximal portion that is configured for coupling the elastomeric body with a guide assembly, a distal portion that is opposite the proximal portion, and a central axis that extends between the distal portion and the proximal portion of the elastomeric body. The expandable support device may also include one or more supports that are coupled with the elastomeric body. The one or more supports may be aligned parallel to the central axis of the elastomeric body. At least one of the supports may include at least a highly elastic or superelastic material.

[0012] The expandable support device may include two supports that are arranged in a wishbone configuration. The expandable support may include three supports that are arranged in a trident configuration. The expandable support device may have a single support that extends along at least a portion of the central axis of the elastomeric body. The expandable support device may have one or more supports that are configured as at least linear supports or longitudinal supports. The expandable support device may include supports that are made from a superelastic material. The superelastic material may include nitinol. The expandable support may include supports that are made from highly elastic material. The highly elastic material may include spring steel. One or more of the supports coupled with the elastomeric body may include polyimide One or more of the supports including polyimide may be disposed at a periphery of the elastomeric body.

[0013] The expandable support device may also include an operative member disposed on the elastomeric body. The operative member disposed on the elastomeric body may be an ablation device. The expandable support device may also include protective padding that

encompasses the distal end of each of the supports. The protective padding may include silicone.

[0014] The proximal portion of the elastomeric body may be tapered in a direction away from the distal end of the elastomeric support. The elastomeric body may also be configured to facilitate movement of the expandable support device into the working channel. The elastomeric body may include silicone. The elastomeric body may be transparent. The elastomeric body may be a molded elastomeric body. The working channel may include at least a portion of an endoscope or a catheter. The supports may be coupled with the elastomeric body using a silicone adhesive. One side of the proximal portion of the elastomeric body may include a marking or a texturing. The marking or texturing may facilitate identifying on which side of the elastomeric body the operative member is positioned.

[0015] Some embodiments include a system for delivering treatment to a target treatment that may include an expandable support device. The expandable support device may be configured for delivering an operative member through a working channel to a target treatment area. The expandable support device may include an elastomeric body, one or more supports coupled with the elastomeric body, and an operative member disposed on the elastomeric body. The elastomeric body may be configured to support an operative member and promote expansion of the expandable support device between a collapsed configuration and an expanded configuration. The elastomeric body may include a proximal portion configured for coupling the elastomeric body with a guide assembly, a distal portion opposite the proximal portion, and a central axis extending between the distal portion and the proximal portion of the elastomeric body. The one or more supports coupled with the elastomeric body may be aligned parallel to the central axis of the elastomeric body. At least one of the supports may include at least a highly elastic or superelastic material.

[0016] The system may also include a guide assembly. The guide assembly may include a guide shaft and a coupling mechanism that is configured to couple the expandable support device to the guide shaft. The system may also include a working channel. The working channel may be configured to receive the expandable support device and the guide assembly. The operative member of the system may include an ablation device. The working channel of the system may include at least a portion of an endoscope or a catheter.

[0017] Some embodiments include a method of delivering an expandable support device to a target treatment area that may a step of providing an expandable support device configured for delivering an operative member through a working channel to a target treatment area. The method may also include a step of inserting the expandable support device into a first end of the working channel and a step of moving the expandable support device through the working channel until the expandable support device passes out of a second end of the working channel. The expandable support device may include an elastomeric body and one or more supports coupled with the elastomeric body. The elastomeric body may be configured to support an operative member and promote expansion of the expandable support device between a collapsed configuration and an expanded configuration. The elastomeric body may include a proximal portion configured for coupling the elastomeric body with a guide assembly, a distal portion opposite the proximal portion, and a central axis extending between the distal portion and the proximal portion of the elastomeric body. The one or more supports may be aligned parallel to the central axis of the elastomeric body. At least one of the supports may include at least a highly elastic or superelastic material. The method may also include positioning the expandable support device into a collapsed position prior to inserting the expandable support device into the working channel.

[0018] Some embodiments include a guide assembly for delivering and positioning an operative member through a working channel to a target treatment area that may include one or more transmission lines, a first shaft enclosing at least a first portion of the one or more transmission lines, and a second shaft enclosing at least a second portion of the transmission lines. The transmission lines may operatively connect the operative member to a power source. The first shaft may be configured for transmitting torque to the operative member. The first shaft and the second shaft may be configured to allow the first shaft to rotate independently of the second shaft.

[0019] The first shaft may include a flexible shaft. The flexible shaft may include stainless steel. The flexible shaft may include two or more layers, with each layer including two or more stainless steel wires wound around a common axis. The flexible shaft may be configured to couple with an expandable support device configured to deliver the operative member through a working channel to a target treatment area.

[0020] The one or more transmission lines may be coupled with the first shaft at a distal end of the first shaft and decoupled from the first shaft at a proximal end of the first shaft.

The guide assembly may also include a protection element. The protection element may be coupled with the first shaft and extend over a portion of the second shaft. The guide assembly may also include a control element. The control element may be coupled with the first shaft and configured to transmit rotational motion to the first shaft. The control element may be coupled with the first shaft for approximately one to one rotational movement between the control element and the first shaft. The control element may be coupled with the first shaft by a crimp tube fixed at one end of the control. A control element and a protection element may be integrated with each other as one element in some cases.

[0021] The first shaft may include a rigid section at the proximal end of the first shaft. The rigid section of the first shaft may be configured to be inserted into the working channel. The rigid section of the first shaft may have a length of at least 2 cm in some embodiments. The first shaft may also include a flexible section that is positioned between the rigid section and the operative member. The second shaft may be coupled with the power source. The second shaft may also be rotationally fixed relative to the power source. The one or more transmission lines may include electrical wires. The first shaft and the second shaft may be configured to axially move the operative member. The first shaft may be configured to axially move the operative member. The first shaft may be located between the operative member and the second shaft. The second shaft may be located between the first shaft and the power source.

[0022] The guide assembly may also include a handle that is coupled with the first shaft. The guide assembly may also include an introducer. The introducer may include a conical section, a cylindrical section, and a channel extending through the conical section and the cylindrical section. The first shaft may extend through the channel. The cylindrical section may be configured to insert into the working channel. The guide assembly may include a docking member. The docking member may include a first end, a second end, and a channel extending through the docking member. The first end of the docking member may be configured to couple with the introducer. The docking member may be configured at least to couple with or be integrated with at least a control element or a protection element.

[0023] Some embodiments include a system for delivering treatment to a target treatment that may include a guide assembly, an expandable support device, and an operative member. The guide assembly may be provided for delivering and positioning the operative member through a working channel to a target treatment area. The guide assembly may include one

or more transmission lines, a first shaft enclosing at least a first portion of the one or more transmission lines, a second shaft enclosing at least a second portion of the transmission lines. The transmission lines may operatively connect the operative member to a power source. The first shaft may be configured for transmitting torque to the operative member. The first shaft and the second shaft may be configured to allow the first shaft to rotate independently of the second shaft. The expandable support device may be configured to deliver the operative member through the working channel to the target treatment area. The expandable support device may be coupled with a distal end of the guide assembly. The operative member may be coupled with the expandable support device.

[0024] The expandable support device of the system may include an elastomeric body configured to support the operative member. The elastomeric body may include a proximal portion configured for coupling the elastomeric body with the guide assembly, a distal portion opposite the proximal portion, and a central axis extending between the distal portion and the proximal portion.

[0025] The system may also include one or more supports coupled with the elastomeric body and aligned parallel to the central axis of the elastomeric body. At least one of the supports may include at least a highly elastic or superelastic material. The operative member of the system may be coupled with the transmission lines.

[0026] Some embodiments include a method of utilizing a guide assembly for delivering an operative member to a target treatment that may include a step of providing a system. The system may include a guide assembly for delivering and positioning the operative member through a working channel to the target treatment area, an expandable support device configured to deliver the operative member through the working channel to the target treatment area and coupled with a distal end of the guide assembly, and an operative member coupled with the expandable support device. The guide assembly may include one or more transmission lines for operatively connecting the operative member to a power source, a first shaft enclosing at least a first portion of the one or more transmission lines, and a second shaft enclosing at least a second portion of the transmission lines. The first shaft may be configured for transmitting torque to the operative member. The first shaft and the second shaft may be configured to allow the first shaft to rotate independently of the second shaft. The method may also include a step of inserting the expandable support device into a first end of the working channel, and a step of moving the expandable support device through the

working channel utilizing the guide assembly until the expandable support device passes out of a second end of the working channel.

[0027] The method may also include a step of positioning the expandable support device into a collapsed position prior to inserting the expandable support device into the working channel. The method may also include a step of rotating the first shaft to provide torque to the operative member.

[0028] Some embodiments include a guide assembly configured for positioning an operative member through a working channel and to a target treatment area that may include one or more transmission lines for operatively connecting the operative member to a power source. The guide assembly may also include a flexible shaft enclosing at least a portion of the one or more power transmission lines. The flexible shaft may be configured for transmitting torque to the operative member. The guide assembly may also include a handle element. The handle element may include a body and a channel extending through the body. The flexible shaft may pass through the channel and the handle element may be configured such that the flexible shaft may move through the channel.

[0029] The guide assembly may also include a rigid shaft coupled with a first end of the handle element. The rigid shaft may be configured such that the flexible shaft may move through the rigid shaft. The rigid shaft may have a length of at least 2 cm in some embodiments. The rigid section may be configured to be inserted into the working channel.

[0030] The guide assembly may also include a power source side shaft. The power source side shaft may be configured to allow the flexible shaft to rotate independently of the power source side shaft. The power source side shaft may be located between the flexible shaft and the power source. The handle element may extend over a portion of the power source side shaft. The flexible shaft may include two or more layers. Each layer may include two or more stainless steel wires wound around a common axis. The flexible shaft may be configured to couple with an expandable support device configured to deliver the operative member through a working channel to a target treatment area. The power source side shaft may be coupled with the power source. The power source side shaft may also be rotationally fixed relative to the power source. The one or more transmission lines may include electrical wires.

[0031] The guide assembly may also include a locking mechanism that is coupled with the handle element. The locking mechanism may be secured to the flexible shaft inside the channel of the handle. The locking mechanism may be configured to move along an axis of the handle element to adjust a length of the flexible shaft extending out of the handle element. The locking mechanism may move along the axis of the handle element when in an unlocked position and may be fixed to the handle element when in a locked position. The handle element may be configured to slide along the flexible shaft and the locking mechanism may be configured to lock the handle element at a position along the flexible shaft.

[0032] The guide assembly may also include a protection element coupled with the flexible shaft. The protection element may extend over a portion of the second shaft. The protection element may be coupled with the flexible shaft at a position between the handle element and the power source side shaft. The flexible shaft and the power source side shaft may be configured to axially move the operative member.

[0033] Some embodiments include a method of delivering an operative member to a target treatment area that may include a step of providing a system. The system may include a guide assembly. The guide assembly may include one or more transmission lines for operatively connecting an operative member to a power source, a flexible shaft enclosing at least a portion of the one or more power transmission lines, and a handle element. The flexible shaft may be configured for transmitting torque to the operative member. The handle element may include a body and a channel extending through the body. The flexible shaft may pass through the channel. The handle element may be configured such that the flexible shaft moves through the channel. The system may also include an operative member coupled with a distal end of the flexible shaft. The method may also include a step of inserting the operative member into a first end of a working channel, a step of moving the operative member through the working channel until the operative member passes out of the second end of the working channel, and a step of rotating the handle element to transmit torque to the operative member. The method may further include a step of positioning the operative member into a collapsed position prior to inserting the operative member into the working channel.

[0034] Some embodiments include a system for delivering treatment to a target area that may include a guide assembly. The guide assembly may include one or more transmission lines for operatively connecting an operative member to a power source, a flexible shaft

enclosing at least a portion of the one or more power transmission lines, and a handle element. The flexible shaft may be configured for transmitting torque to the operative member. The handle element may include a body and a channel extending through the body. The flexible shaft may pass through the channel. The handle element may be configured such that the flexible shaft may move through the channel. The system may also include an expandable support device coupled with a distal end of the flexible shaft and an operative member disposed on the expandable support device. The operative member of the system may include a flexible circuit.

[0035] Some embodiments include an ablation device that may be configured for delivery through a working channel to a target treatment area. The ablation device may include a flexible circuit configured to transition between a collapsed configuration and an expanded configuration. The flexible circuit may include multiple parallel electrodes configured to collapse around an axis parallel to the multiple parallel electrodes.

[0036] The flexible circuit may also include a first bus coupled with a first subset of the multiple parallel electrodes and a second bus coupled with a second subset of the multiple parallel electrodes. The first bus and the second bus may be at least partially covered by one or more insulation layers. The insulation layers may be configured to impede the first and second bus from ablating the target treatment area. The one or more insulation layers may include polyimide.

[0037] The first bus may be located at a first end of the multiple parallel electrodes. The second bus may be located at a second end of the multiple parallel electrodes. The multiple parallel electrodes may be arranged in a row. The first bus and the second bus may be coupled with alternating electrodes in the row. The first bus and the second bus may each be arched. The first bus and the second bus may each include multiple arches. The end of each arch in the multiple arches may be coupled with a single electrode. The first bus may be configured to couple with a positive terminal. The second bus may be configured to couple with a negative terminal or a ground terminal.

[0038] The ablation device may also include an elastomeric body having a first surface and a second surface opposite the first surface. The flexible circuit may be disposed on the first surface of the elastomeric body. In some embodiments, the multiple parallel electrodes may each substantially extend to a distal end of the elastomeric body.

[0039] The elastomeric body having the flexible circuit disposed thereon may be configured to collapse around an axis parallel to the multiple parallel electrodes when disposed within a working channel and expand to a substantially flat orientation when the elastomeric body emerges from the working channel.

[0040] The ablation device may also include a first bus and a second bus disposed on the second surface of the elastomeric body. The first bus may be coupled with a first subset of the multiple electrodes and the second bus may be coupled with a second subset of the multiple electrodes. The elastomeric body may include one or more vias through which the first subset of electrodes couple to the first bus and one or more vias through which the second subset of electrodes couple to the second bus. The first bus and the second bus may be aligned substantially perpendicular to the multiple parallel electrodes. The first bus and the second bus may include copper. The first bus and the second bus may have a hash pattern with multiple void spaces. The first and second bus may be located between a first end of the multiple parallel electrodes and a second end of the multiple parallel electrodes.

[0041] Some embodiments include a system for delivering treatment to a target treatment that may include a guide assembly having a central axis, an elastomeric body coupled with the guide assembly, and a flexible circuit disposed on the elastomeric body. The flexible circuit may include multiple parallel electrodes configured to collapse around an axis parallel to the multiple parallel electrodes and parallel to the central axis of the guide assembly.

[0042] The system may also include one or more supports coupled with the elastomeric body and aligned parallel to the central axis of the guide assembly. At least one of the supports may include a superelastic material. The system may also include a working channel configured to receive the guide assembly, the elastomeric body, and the flexible circuit disposed on the elastomeric body. The elastomeric body and the flexible circuit may be in a collapsed configuration when disposed inside of the working channel. The elastomeric body and the flexible circuit may expand to a substantially flat orientation when the elastomeric body is outside the working channel.

[0043] Some embodiments include a method of delivering an ablation device to a target treatment area that may include a step of providing an ablation device. The ablation device may include a flexible circuit configured to transition between a collapsed configuration and an expanded configuration. The flexible circuit may include multiple parallel electrodes

configured to collapse around an axis parallel to the multiple parallel electrodes. The method may also include a step inserting the ablation device into a first end of a working channel, and a step of moving the ablation device through the working channel until the ablation device passes out of a second end of the working channel. The method may also include a step of positioning the flexible circuit into a collapsed configuration prior to inserting the ablation device into the working channel.

[0044] Some embodiments include an expandable support device configured for delivery through a working channel and to a target treatment area that may include a solid support member having a perimeter and highly elastic or superelastic properties. The expandable support device may also include multiple splines formed in a pattern interior to the perimeter of the solid support member. Multiple voids may be located between adjacent splines. The width and a spacing of the multiple splines may be configured to promote expansion of the support member between a collapsed configuration and an expanded configuration providing a support surface.

[0045] The solid support member may include a proximal end, a distal end, and a central axis extending from the proximal end to the distal end. The pattern of the multiple splines may include a central axis spline substantially overlapping the central axis of the solid support member, a first subset of splines extending from the central axis spline towards a first lateral peripheral edge of the solid support member, and a second subset of splines extending from the central axis spline towards a second lateral peripheral edge of the solid support member opposite the first lateral peripheral edge.

[0046] The first subset of splines may be arranged in parallel to one another. The second subset of splines may be arranged in parallel to one another. The first subset of splines and the second subset of splines may extend from the central axis spline at an angle such that the first and second subsets of splines extend from the central axis spline towards the distal end of the solid support member. The first subset of spines and the second subset of spines may extend from the central axis spline at an angle in the range of from greater than 0 degrees to 90 degrees. The first subset of splines and the second subset of splines may extend from the central axis spline at an angle of about 45 degrees. The first subset of splines and the second subset of splines may have a thickness less than a thickness of the central axis spline.

[0047] The solid support member may include of a metal having shape memory properties. The support surface may define a curved surface in the expanded configuration. The support surface may define a substantially planar surface in the expanded configuration. The predetermined shape may correspond to a tissue surface at a treatment site in a patient. The solid support member may have a thickness of about 0.003 inch in some embodiments.

[0048] The pattern of the multiple splines may include multiple equally spaced vertical splines interconnected by horizontal splines. The expandable support may also include an operative member supported by the multiple splines. The operative member may be coupled with the multiple splines with an elastomeric adhesive. The operative member may include a flexible circuit. The flexible circuit may include multiple electrodes patterned to mirror the pattern of the multiple splines. The operative member may extend across an entire width of the solid support member. The solid support member may include a rounded distal edge. The solid support member may include a tapered proximal edge for promoting retraction of the device into the working channel.

[0049] Some embodiments include a system for delivering treatment to a target area that may include a solid support member having a perimeter and at least a highly elastic or superelastic properties, multiple splines formed in a pattern interior to the perimeter of the solid support member, and multiple voids between adjacent splines. The width and a spacing of the multiple splines may be configured to promote expansion of the support member between a collapsed configuration and an expanded configuration providing a support surface. The system may also include an operative member disposed on the solid support member.

[0050] The solid support member may have a first surface and a second surface opposite the first surface. The multiple splines may be disposed on the first surface and the operative member may be disposed on the second surface. The operative member may include a flexible circuit.

[0051] Some embodiments include a method of delivering an expandable support device to a target treatment area that may include a step of providing an expandable support device. The expandable support device may include a solid support member having a perimeter and at least highly elastic or superelastic properties. The expandable support device may also include multiple splines formed in a pattern interior to the perimeter of the solid support

member and multiple voids between adjacent splines. A width and a spacing of the multiple splines may be configured to promote expansion of the support member between a collapsed configuration and an expanded configuration providing a support surface. The method may also include a step of inserting the expandable support device into a first end of a working channel, and a step of moving the expandable support device through the working channel until the expandable support device passes out of a second end of the working channel. The method may also include positioning the expandable support device into a collapsed configuration prior to inserting the expandable support device into the working channel.

[0052] Some embodiments include an expandable support device configured for delivery through a working channel and to a target treatment area that may include an expandable support member configured for supporting an operative member. The expandable support member may include multiple splines having a width and a spacing selected to promote expansion of the support member between a collapsed configuration and an expanded configuration. A portion of the support member may define a surface in the expanded configuration.

[0053] The multiple splines may include a central axis spline, a first subset of splines extending away from the central axis in a first direction, and a second subset of splines extending away from the central axis spline in a direction opposite the first direction. The first subset of splines may be arranged in parallel to one another. The second subset of splines may be arranged in parallel to one another. The first subset of splines and the second subset of splines may extend away from the central axis spline at an angle such that the first and second subsets of splines extend from the central axis spline towards a distal end of the central axis spline. The first subset of splines and the second subset of splines may extend away from the central axis spline at an angle in the range of from greater than 0 degrees to 90 degrees. The first subset of splines and the second subset of splines may extend away from the central axis spline at an angle of about 45 degrees. The first subset of splines and the second subset of splines may have a thickness less than a thickness of the central axis spline. The multiple splines may include nitinol. The multiple splines may include a central axis spline, multiple secondary splines arranged in parallel to the central axis spline, equally space apart from one another, and on either side of the central axis spline, and multiple interconnecting splines arranged transverse to the secondary splines and interconnecting the secondary splines.

[0054] Some embodiments include a system for providing treatment to a target treatment area that may include an expandable support member configured for supporting an operative member. The expandable support member may include multiple splines having a width and a spacing selected to promote expansion of the expandable support member between a collapsed configuration and an expanded configuration. A portion of the expandable support member may define a surface in the expanded configuration. The system may also include a solid elastomeric body. The expandable support member may be disposed on the solid elastomeric body within a perimeter of the solid elastomeric body. The system may also include an operative member coupled with the solid elastomeric body.

[0055] The multiple splines may include a central axis spline, a first subset of splines extending away from the central axis in a first direction, and a second subset of splines extending away from the central axis spline in a direction opposite the first direction. The first subset of splines may be arranged in parallel to one another. The second subset of splines may be arranged in parallel to one another. The first subset of splines and the second subset of splines may extend away from the central axis spline at an angle such that the first and second subsets of splines extend from the central axis spline towards a distal end of the central axis spline. The first subset of splines and the second subset of splines may extend away from the central axis spline at an angle of about 45 degrees. The operative member may be coupled with the solid elastomeric body with an elastomeric adhesive.

[0056] The operative member may be a flexible circuit. The flexible circuit may include multiple electrodes patterned to mirror the multiple splines. The operative member may extend across an entire width of the solid elastomeric body.

[0057] Some embodiments include a method of delivering an expandable support device to a target treatment area that may include a step of providing an expandable support device configured for delivery through a working channel to a target treatment area. The expandable support device may include an expandable support member configured for supporting an operative member. The expandable support member may include multiple splines having a width and a spacing selected to promote expansion of the support member between a collapsed configuration and an expanded configuration. A portion of the support member may define a surface in the expanded configuration. The method may also include a step of inserting the expandable support device into a first end of the working channel, and a step of moving the expandable support device through the working channel until the expandable

support device passes out of a second end of the working channel. The method may also include a step of positioning the expandable support device into a collapsed position prior to inserting the expandable support device into the working channel.

[0058] The foregoing has outlined rather broadly the features and technical advantages of examples according to the disclosure in order that the detailed description that follows may be better understood. Additional features and advantages will be described hereinafter. The conception and specific examples disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present disclosure. Such equivalent constructions do not depart from the spirit and scope of the appended claims. Features which are believed to be characteristic of the concepts disclosed herein, both as to their organization and method of operation, together with associated advantages will be better understood from the following description when considered in connection with the accompanying figures. Each of the figures is provided for the purpose of illustration and description only, and not as a definition of the limits of the claims.

BRIEF DESCRIPTION OF THE DRAWING

[0059] A further understanding of the nature and advantages of the embodiments may be realized by reference to the following drawings. In the appended figures, similar components or features may have the same reference label. Further, various components of the same type may be distinguished by following the reference label by a dash and a second label that distinguishes among the similar components. If only the first reference label is used in the specification, the description is applicable to any one of the similar components having the same first reference label irrespective of the second reference label.

[0060] FIG. 1A is a schematic diagram of a system for delivering treatment to a target treatment area including components configured according to various embodiments.

[0061] FIG. 1B is schematic diagram of one specific embodiment of the system shown in FIG. 1A.

[0062] FIG. 2 is a cross-sectional view of an expandable support device in a working channel according to various embodiments

[0063] FIGs. 3A-3C are cross-sectional views of a collapsed and expanded expandable support device positioned proximate a target treatment area according to various embodiments.

[0064] FIG. 4 is a simplified line drawing illustrating an expandable support device in an expanded configuration according to various embodiments.

[0065] FIGs. 5A-5F are perspective views of various stages of an expandable support device being passed through a working channel according to various embodiments.

[0066] FIG. 6A is plan view of a flexible support coupled with an expandable support device according to various embodiments.

[0067] FIG. 6B is a plan view of two flexible supports coupled with an expandable support device according to various embodiments.

[0068] FIG. 6C is a plan view of three flexible supports coupled with an expandable support device according to various embodiments.

[0069] FIG. 7 is a side view of a flexible support coupled with an expandable support device according to various embodiments.

[0070] FIG. 8 is a side view of a flexible support coupled with an expandable support device according to various embodiments.

[0071] FIGs. 9A-9C are cross sectional views of varying numbers of flexible supports coupled with an expandable support device according to various embodiments.

[0072] FIGs. 10A-10C are cross-sectional views of varying numbers of flexible supports coupled with an expandable support device according to various embodiments.

[0073] FIG. 11A is a plan view of a patterned solid substrate according to various embodiments.

[0074] FIG. 11B is a plan view of a patterned solid substrate according to various embodiments.

[0075] FIGs. 12A-12B are plan views of a patterned solid substrate according to various embodiments.

[0076] FIGs. 13A-13L are plan views and side views of patterned solid substrates according to various embodiments.

[0077] FIGs. 14A-14B are plan views of an electrode structure for an operative member according to various embodiments.

[0078] FIGs. 15A-15B are plan views of an electrode structure for an operative member according to various embodiments.

[0079] FIG. 16A is a schematic view of an electrode structure for an operative member according to various embodiments.

[0080] FIG. 16B is a cross-sectional view of the electrode structure shown in FIG. 16B according to various embodiments.

[0081] FIGs. 17A-17D are plan views of an operative member according to various embodiments.

[0082] FIGs. 18A-18B are perspective views of a guide assembly according to various embodiments.

[0083] FIGs. 19A-19B are perspective views of a guide assembly according to various embodiments.

[0084] FIG. 20 is a perspective view of a handle element for use with a guide assembly according to various embodiments.

[0085] FIG. 21 is a perspective view of a handle element for use with a guide assembly according to various embodiments.

[0086] FIG. 22 is a perspective view of a distal plug according to various embodiments.

[0087] FIG. 23 is a perspective view of a torque member according to various embodiments.

[0088] FIGs. 24A-24B are perspective and cross-section views, respectively, of a torque member according to various embodiments.

[0089] FIGs. 25A-25B are perspective views of an introducer according to various embodiments.

[0090] FIGs. 26A-26B are perspective views of an introducer according to various embodiments.

[0091] FIGs. 27A-27F are cross-sectional views of a method for making an operative member and coupling it with a flexible support according to various embodiments.

[0092] FIGs. 28A-28E are cross-section views of a method for making a patterned solid support and coupling it to an operative member according to various embodiments.

[0093] FIG. 29 is a flow diagram illustrating a method for using a therapy system according to various embodiments.

[0094] FIG. 30 is a flow diagram illustrating a method for delivering an expandable support device to a target treatment area according to various embodiments.

[0095] FIG. 31 is a flow diagram illustrating a method for utilizing a guide assembly for delivering an operative member to a target treatment according to various embodiments.

[0096] FIG. 32 is a flow diagram illustrating a method for delivering an operative member to a target treatment area according to various embodiments.

[0097] FIG. 33 is a flow diagram illustrating a method for delivering an ablation device to a target treatment area according to various embodiments.

[0098] FIG. 34 is a flow diagram illustrating a method for delivering an expandable support device to a target treatment area according to various embodiments.

[0099] FIG. 35 is a flow diagram illustrating a method for delivering an expandable support device to a target treatment area according to various embodiments.

DETAILED DESCRIPTION

[0100] Methods, systems, and devices are described for providing treatment to a target site, such as a site within a body lumen. Systems may include an expandable support device that may be coupled with a distal end of a guide assembly. An operative member can be disposed on the expandable support device such that moving the expandable support device to the target site using the guide assembly delivers the operative member to the target site. The guide assembly may be utilized to transmit torque and/or to rotate to the expandable support device and/or the operative member.

[0101] The expandable support member can include a solid body of elastomeric material. The elastomeric material can be flexible so that it may transition between a folded, or collapsed configuration and a planar, or expanded, configuration. One or more flexible supports can be coupled with the elastomeric body such that the flexible supports are each

aligned parallel to a central axis of the elastomeric body. The flexible supports can be made from at least a highly elastic, such as spring steel, or a superelastic material, such as nitinol, and can be arranged in a single central axis configuration, a wishbone configuration, a trident configuration, or other configurations, including open and closed configurations.

[0102] The expandable support member can include a solid support member made from a highly elastic or superelastic material that is supported by multiple splines located within the perimeter of the solid support member. The multiple splines can be separated by voids so as to create a pattern of splines having a width and spacing that promotes transitioning of the solid support member between a collapsed configuration and an expanded configuration. The splines can be arranged in a pattern wherein a spline arranged to substantially overlap a central axis of the solid support member has splines extending away from the central spline in both directions towards a distal end of the solid support member.

[0103] The operative member can include a flexible circuit capable of bending with the expandable support device upon which it is disposed. The flexible circuit can include multiple electrodes aligned in parallel to one another. The electrodes can also be aligned in parallel to an axis about which the flexible circuit collapses from a planar configuration to a folded configuration so that the electrodes do not substantially impede the transition between an expanded configuration and a collapsed configuration. The flexible circuit can include a first bus at one end of the parallel electrodes and a second bus at the opposite end of the electrodes. The electrodes can be coupled with the first and second bus in an alternating pattern.

[0104] The guide assembly that can be used to move the expandable support device can include a first shaft portion and a second shaft portion separated by a break. Transmission lines can extend through both the first shaft and the second shaft. The break between the first shaft and the second shaft can allow the first shaft to rotate independently of the second shaft. The first shaft can be configured such that rotation of the first shaft transmits torque and/or rotation to the expandable support device.

[0105] With reference to **FIG. 1A**, a general system 100 for delivering treatment to a target treatment area is shown in accordance with various embodiments. The system 100 may be designed for providing treatment to a target area inside of a body, such as the wall of an organ or lumens in the gastrointestinal tract, for example. The system 100 can include a

power source 105, a guide assembly 110, a working channel 115, and/or an expandable support device 120. The expandable support device 120 may generally be configured to support an operative member that is used to supply therapy to the target treatment area. The system 100 may operate by positioning at least a portion of the working channel 115 inside a body and passing the expandable support device 120 through the working channel 115 using the guide assembly 110 such that the expandable support device 120 may be delivered to a target treatment area inside the body. The power source 105 may then be used to supply power to an operative member disposed on the expandable support device 120 so that therapy can be applied to the target treatment area.

[0106] The expandable support device 120 can be a self-expanding device capable of transitioning between a collapsed configuration and an expanded configuration with little or no use of supplementary expansion mechanisms. The collapsed configuration may be generally used when the expandable support device 120 is inside of the working channel 115. When the expandable support device 120 emerges from the working channel 115, the expandable support device 120 may self-expand, such as by transitioning from a curved orientation (i.e., the collapsed configuration) to a substantially planar orientation (i.e., the expanded configuration).

[0107] The expandable support device 120 can be configured to support an operative member. In some embodiments, the operative member is a therapeutic or diagnostic instrument, such as an ablation element that can provide ablative energy to the target treatment area. Some operative members may be designed so that they make direct contact with a target treatment area, including pressing of the operative member against the target site.

[0108] The expandable support device 120 may be coupled with the guide assembly 110 such that the guide assembly 110 can be used to maneuver the expandable support device 120 through the working channel 115 and at the target treatment area. The guide assembly 110 may include a proximal end 130 and a distal end 135, with the proximal end 130 configured to be coupled with the power source 105 and the distal end 135 configured to be coupled with the expandable support device 120. In some embodiments, the guide assembly 110 includes a break 140 that allows the distal portion of the guide assembly 110 to rotate independently of the proximal portion of the guide assembly 110. The break 140 may typically be located outside of the working channel 115 and proximate the power source 105. Rotating the distal

portion of the guide assembly 110 can provide torque to the expandable support device 120 and allow for better movement and control of the expandable support device 120 at the target treatment area.

[0109] The working channel 115 may include a proximal end 145 and a distal end 150, and can be configured such that the expandable support device 120 can be inserted into the working channel 115 at the proximal end 145 and guided through the length of the working channel 115 using the guide assembly 110 until it emerges from the distal end 150 of the working channel 115. In some embodiments, the expandable support device 120 is positioned in a collapsed configuration prior to being inserted into the working channel 115 so that the expandable support device 120 fits inside of the working channel 115 and remains in a collapsed configuration as the expandable support device 120 moves through the working channel 115. The working channel 115 can be oriented such that the distal end 150 is proximate the target treatment area. In such configurations, the expandable support device 120 may be located near or at the target treatment area when it emerges from the distal end 150 of the working channel 115.

[0110] The power source 105 can generally be provided to provide power to the operative member that may be coupled with the expandable support device 120 and/or the operative member disposed theron. In some embodiments, power is provided from the power source 105 to the expandable support device 120 via one or more transmission lines extending between the power source 105 and the expandable support device 120 and housed within the guide assembly 110.

[0111] **FIG. 1B** illustrates a system 100-a that may be an example of the system 100 shown in FIG. 1A according to various embodiments. The system 100-a may include a generator 105-a, a guide assembly 110-a that may include a first shaft 112 and a second shaft 114, an endoscope 115-a, an expandable support device 120-a, a flexible support 155 extending along the central axis of the expandable support device 120-a, and/or an operative member 160 supported by the expandable support device 120-a.

[0112] The expandable support device 120-a may include a solid elastomeric body on which the operative member 160 is supported. The expandable support device 120-a may thus be a flexible material capable of being curved or folded. The expandable support device

120-a may generally have a paddle shape, including a rounded distal end. The expandable support device 120-a may taper at the proximal end and couple to the guide assembly 110-a.

[0113] Disposed on one surface of the expandable support device 120-a may be an operative member 160 that may be configured to provide treatment to the target treatment area. As shown in FIG. 1B, the operative member 160 may be a series of electrodes aligned in parallel to one another and that extend from the proximal end of the expandable support device 120-a to the distal end of the expandable support device 120-a. The electrodes may be interlaced, with approximately half of the electrodes extending from a first bus located at the proximal end of the expandable support device 120-a and approximately half of the electrodes extending from a second bus located at the distal end of the expandable support device 120-a. The first bus or the second bus may be connected to a positive terminal and the other of the first bus or the second bus may be connected to a negative or ground terminal to thereby provide a bipolar electrode configuration. When connected to the generator 105-a, the electrodes can provide ablative energy to the target treatment area.

[0114] Also included on the expandable support device 120-a may be a flexible support 155, which can be made from nitinol so that the flexible support 155 exhibits superelastic properties. The flexible support 155 may generally extend from the proximal end of the expandable support device 120-a to the distal end of the expandable support device 120-a along a central axis of the flexible support device 120-a. The flexible support 155 can be located on a surface of the expandable support device 120-a opposite the surface on which the operative member 160 may be disposed. The flexible support 155 may give the expandable support device 120-a a desired amount of structure so that the flexible support device 120-a can be transported through the guide assembly 110 without crumpling upon itself. The flexible support 155 can also provide apposition force when the expandable support device 120-a is deflected against a target treatment area, such as tissue.

[0115] The expandable support device 120-a may be coupled with the guide assembly 110, which is split into a first shaft 112 and a second shaft 114. A common set of transmission wires may extend from the generator 105-a to the expandable support device 120-a and through both the first shaft 112 and the second shaft 114. The break 140 shown in FIG. 1A may serve as the dividing point between the first shaft 112 and the second shaft 114, and may allow the first shaft 112 to rotate independently of the second shaft 114. A protection element 165 may be coupled with the first shaft 112 and extend over a portion of the second

shaft 114 to thereby cover the break 140 and protect the transmission lines running through the guide assembly 110. Because the protection element 165 may be coupled with the first shaft 112, the protection element 165 can also serves as a torque handle that can be rotated to rotate the first shaft 112 and provide torque to the expandable support device 120-a. The first shaft 112 may be flexible and can be made from stainless steel, such as coiled stainless steel wires.

[0116] The endoscope 115-a may be provided for accessing a target treatment area within a body. In some embodiments, the endoscope 115-a includes one working channels and the expandable support device 120-a and the guide assembly 110 can be passed through the one working channel in the endoscope 115-a to reach the target treatment area. . The endoscope 115-a can include partitions to create multiple channels, where at least one of the channels may be a working channel, and the expandable support device 120-a and the guide assembly 110 can be passed through one of the channels in the endoscope 115-a to reach the target treatment area. In some embodiments, the endoscope 115-a is passed into the body through the mouth and provides access to the esophagus.

[0117] FIGs. 2-5 provide further detail on the expandable support device 120 illustrated in FIG 1 in accordance with various embodiments. With reference to FIG. 2, the expandable support device 120-b may be coupled with the guide assembly 110-b. Although not shown in FIG. 2, the expandable support device 120-b may carry an operative member for delivering therapy to a target treatment area.

[0118] Expandable support device 120-b is shown in **FIG. 2** in a collapsed configuration within the working channel 115-b in accordance with various embodiments. Two additional channels 205 and 210 may be provided, and the three channels 115-b, 205, 210 may be housed within an outer casing 215. While FIG. 2 shows the outer casing 215 having three channels, the outer casing 215 may have fewer or more channels. The additional channels may be used for a variety of purposes, including for providing suction, aspiration, illumination, magnification, and/or delivery of other instruments to the target treatment area. In some embodiments, the outer casing 215 is an endoscope having one or more channels within the endoscope. A typical endoscope arrangement may have three channels, with one working channel provided for the expandable support device, one channel for a camera and the associated wiring, and one channel for a light source. It may be desirable to provide a working channel capable of receiving two or more devices, such as the expandable support

device 120-b and a suction device. In some embodiments, the expandable support device 120-b is removed when suction is activated.

[0119] One may appreciate that the term working channel may refer to a wide variety of channels used for providing instruments to target areas. For example, in a bronchoscope, a working channel may be referred to as a biopsy port. As will be described further herein, the expandable support device 120 in accordance with various embodiments described herein may be used with a variety of instruments depending on the medical application.

[0120] With reference to **FIG. 3A**, the expandable support device 120-c is shown in a collapsed configuration in accordance with various embodiments. The expandable support device 120-c may be configured for transitioning between the collapsed configuration shown and an expanded configuration shown in **FIG. 3B** or **FIG. 3C**. The expandable support device 120-c may be configured for insertion into a working channel in the collapsed configuration. When the expandable support device 120-c is delivered out of an end of the working channel, it may transition to the expanded configuration. In the expanded configuration, at least one dimension of the expandable support device 120-c may have increased. When an operative member is disposed on the expandable support device 120-c, the operative member may also transition between an expanded configuration and a collapsed configuration. In various embodiments, the expanded configuration is significantly larger than the collapsed configuration and allows the expandable support device 120-c to contact a treatment surface 300. As will be described below, the expandable support device 120-c itself does not necessarily increase in size. Rather, in various respects, "expansion" refers to the radial expansion, increase in three-dimensional space, and/or opening of the device.

[0121] In various embodiments, the expandable support device 120-c is releasably retained in the collapsed configuration by a working channel (not shown in FIG. 3A). One may appreciate from the description herein that the collapsed and expanded configuration may be reversed. In various embodiments, the expandable support device 120-c is configured to self-collapse from an expanded configuration.

[0122] As shown, for example, in FIG. 3A, the expandable support device 120-c may have a rounded or curved shape in the collapsed configuration. The exemplary collapsed shape may generally conform to the inner wall surface of a working channel. The outer surface of the expandable support device 120-c may generally remain in contact with the wall of the

working channel along its entire surface. In some cases, the expandable support device 120-c may be configured such that the collapsed configuration results in different shapes. The expandable support device 120-c may tend to have a rounded shape without creases or sharp radiuses when it collapses. This can be due in part to the operative member disposed on the expandable support device 120-c resisting bending. In some embodiments, the expandable support device 120-c collapses into a U-shape.

[0123] It may be desirable to have a generally uniform radius in the collapsed configuration. It may be desirable for the whole collapsed expandable support device 120-c to expand against the inner wall surface of a working channel. As would be understood by one of skill in the art, this may maximize the chord length and enable the delivery of a larger surface in the working channel.

[0124] One may appreciate that the collapsed configuration size and shape may depend on the particular application and instruments being used. The outer casing 215 may be an endoscope having one or more working channels. A typical endoscope working channel may have a diameter of about 1 mm, about 2 mm, about 3 mm, about 5 mm, about 8 mm, or about 10 mm. In various embodiments, the expandable support device 120-c collapses to permit insertion through a working channel diameter of about 1.2 mm, about 1.7 mm, about 2.0 mm, about 2.6 mm, about 2.8 mm, about 3.7 mm, about 5.0 mm, or about 6.0 mm. Some endoscope working channels may have other diameters.

[0125] Although reference has been made to the outer casing 215 being an endoscope, one may appreciate that the expandable support device 120-c may be used with a variety of delivery instruments including, but not limited to, a catheter. Moreover, the expandable support device 120-c may be delivered through various types of working channels, such as catheter lumens, a cannula lumen, or a lumen in the body of a patient. The expandable support device 120-c may also be configured for use with a variety of other instruments as would be understood by one of skill in the art. For example, the expandable support device 120-c may be delivered using an introducer or other delivery device. The expandable support device 120-c may be held in a collapsed configuration with a sheath, a fastener, or a similar device.

[0126] With reference to FIG. 3B, the expanded configuration of the expandable support device 120-c may have a substantially planar shape relative to the collapsed configuration

shape shown in FIG. 3A. The expandable support device 120-c may have an expanded configuration whereby a surface of the expanded support device 120-c on which the operative member 160-a may be disposed has a generally flat shape with a minimal, laterally-curved bias. The expandable support device 120-c in the expanded configuration may present an outwardly facing treatment surface towards a target treatment area 300. The expandable support device 120-c in the expanded configuration may have a planar treatment surface. In various embodiments, in the expanded configuration most, or all, of the treatment surface is flat. In various embodiments, in the expanded configuration a central portion of the treatment surface is essentially flat and the outer regions are slightly curved.

[0127] With continuing reference to FIG. 3B, the operative member 160-a may be disposed on the expandable support device 120-c. The expandable support device 120-c may be attached to a distal end of a guide assembly 110-c. In an exemplary embodiment, the guide assembly 110-c is positioned within a working channel to guide the expandable support device 120-c through and out of the working channel. The guide assembly 110-c may allow a user to manipulate the expandable support device 120-c from a proximal end of the guide assembly 110-c. The guide assembly 110-c may allow the expandable support device 120-c to be pushed, pulled, and rotated.

[0128] With reference to FIG. 3C, the expanded configuration of the expandable support device 120-c may have a curved shape. In some embodiments, the curved shape of the expanded configuration is less curved than the curved shape of the collapsed configuration shown in FIG. 3A. In other words, the radius of the expandable support device 120-c in the expanded configuration may begreater than the radius of the expandable support device 120-c in the collapsed configuration. Expanded configurations having a curve as shown in FIG. 3C can be beneficial for providing uniform tissue contact against a curved surface, such as can be the case for an esophagus.

[0129] With reference to **FIG. 4,** a simplified schematic view of an expanded support device 120-d in an expanded configuration is shown in accordance with various embodiments. The shape of the expandable support device 120-d in the expanded configuration may be planar. The expandable support device 120-d may define a surface with a slight curvature having a radius "R". The surface of the expandable support device 120-d may have a width "W". As will be described below in additional detail, the width W of the expandable support device 120-d may be wider than a diameter of the working channel

(W_c) from which it is deployed. In various embodiments, however, the radius R is at least an order of magnitude larger than W and W_c. In various embodiments, the ratio R/W is at least 2, at least 5, at least 10, or more than 100. In various embodiments, the expandable support device 120-d in an expanded configuration defines a completely flat surface with no radius.

[0130] It may be desirable to provide an expandable support device 120-d that deploys a relatively large surface area. In other words, it may be desirable to have an expandable support device 120-d in an expanded configuration that has a large width relative to the working channel. The ability of the expanded support device 120-d to expand from the working channel may allow for a W/W_c ratio greater than 1. In various embodiments, the ratio of W/W_c is at least 1. 5, at least 2, at least 5, at least 10, or more than 100. In other embodiments, the ratio of W/W_c may take on other values.

[0131] The general nature of delivery and deployment of the expandable support device in accordance with various embodiments may now be described with reference to FIGs. 5A-5F, which are perspective views of an expandable support device 120-e entering a working channel 115-e at a first end and exiting a working channel 115-e at a second end opposite the first end. As shown in FIGs. 5A-5F, expandable support device 120-e may be configured to expand from the collapsed configuration in working channel 115-e to an expanded configuration out of the working channel 115-e. In **FIG. 5A** and **FIG. 5B**, the expandable support device 120-e may be rolled or folded to accommodate delivery through a small diameter of the working channel 115-e. In **FIG. 5C** and **FIG. 5D**, the expandable support device 120-e may begin to exit the working channel 115-e. In FIG. 5C, only a distal end of the expandable support device 120-e may have emerged from the working channel 115-e, and as a result, the expandable support device 120-e remains mostly in the collapsed configuration. In FIG. 5D, more of the expandable support device 120-e may have emerged from the working channel 115-e, and as a result, the expandable support device 120-e may begin to transition from the collapsed configuration to the expanded configuration. In **FIG. 5E**, the expandable support device 120-e may fully emerge from the working channel 115-e and is therefore in the fully expanded configuration. In the expanded configuration shown in FIG. 5E, the expandable support device 120-e may be unfolded into a generally planar surface shaped to contact a target area. Although referred to as "expansion," the surface of the expandable support device 120-e may change shape during expansion but does not actually change surface area. Rather, the expandable support device 120-e may open up in a

wing-like fashion to present a larger surface area to a treatment area. As shown in FIG. 5E, for example, the expandable support device 120-e in the expanded configuration better conforms to a treatment area.

[0132] In various embodiments, the collapsed configuration has a small contact surface and the expandable support device is configured to expand to provide a broad surface. In the case of treating a gastrointestinal (GI) tract, for example, the contact surface of the expandable support device may be significantly larger in the expanded configuration. This may be due in part because the GI tract has a larger diameter than exemplary working channel. The larger radius of the GI tract wall may present a relatively flatter contact surface. However, a completely flat expandable support device may have poor contact of the expandable support device with the comparatively rounded GI tract wall. In various embodiments, the shape and dimensions of the expanded configuration are selected to conform to the treatment site, such as the inner lumen wall. For example, the expandable support device may have a deployed curviplanar shape that corresponds to the radius of curvature of the treatment area.

[0133] One of skill in the art may appreciate that the inner walls of many body lumens may not be planar or perfectly round. Many body lumens are rough. Some body lumens include trabeculae or folds along the inner surface. In various embodiments, the expandable support device in an expanded configuration has a shape selected based on the wall surface to be treated. For example, the expandable support device in the expanded configuration may include waves or undulations. The expandable support device in the expanded configuration may have a shape that matches the shape of the target surface. The expanded support device in an expanded configuration may have a flat shape to smooth out a rough or folded target surface.

[0134] In various embodiments, expanded support device is configured to improve apposition in the expanded configuration. In various embodiments, the expandable support device has sufficient rigidity in the expanded configuration to provide a contact force at the treatment site and achieve good apposition. In various embodiments, the expandable support device in the expanded configuration has adequate rigidity to apply pressure to the treatment surface, for example, to pressure vasculature in the tissue for hemostasis.

[0135] In general, the expanded force is within a range to allow the expandable support device to be collapsed back into the working channel while providing sufficient expansion

force for delivering treatment. In an exemplary embodiment, operative member disposed on the expandable support device comprises a malleable copper and a thin insulator. As such, the operative member tends to resist changing shape. Thus the expansion force of expandable support device is sufficient to ensure self-expansion in view of the operative member resistance and other environmental factors.

[0136] In various respects, the expansion force is selected to adjust a contact force (also referred to as deflection force) of the expandable support device with the treatment area surface. The expansion force may vary depending on the application. For example, a body lumen in the alimentary tract is typically stronger and able to withstand a greater internal force than a blood vessel. The expansion force may depend on the treatment surface area required. For example, less force may be necessary for an expandable support device configured for deploying in an artery. The expansion force may also vary depending on the treatment. For example, a hemostasis device for the vasculature may require less expansion force than an ablation device for the esophagus. Other factors that can impact the contact force include the flexible support and the working channel deflection.

[0137] In various embodiments, the expandable support device is dimensioned and configured to exert an expansion force (i.e., radial force) of at least 5 GPa when it is in the collapsed configuration. In various embodiments, the expansion force is equal to or greater than the bending strength of the operative member disposed on the expandable support device. In various applications, it may be desirable to reduce the expansion force to reduce the risk of injury to the vessel in which the expandable support device is to be deployed. A large expansion force, for example, may damage a blood vessel. In various embodiments, the expandable support device is configured to deploy gradually, or at selected time intervals, rather than snap open. In various embodiments, the expandable support device is configured to exert a non-uniform expansion force. For example, the outer edges of the expandable support device may exert a lower or higher expansion force. In various embodiments, when the expandable support device is in the expanded configuration the expansion force along its outer edge is at least 0.5 GPa, at least 5 GPa, at least 25 GPa, or at least 40 GPa. Some embodiments may utilize other expansion force values. The expandable support device may include features to reduce the risk of injury such as a curviplanar treatment surface and rounded edges.

[0138] In various embodiments, the expandable support device is configured to apply sufficient force to smooth out the inner wall surface at the treatment site. For example, the expandable support device can be pressed against the inner wall surface to unfold the folds in the wall.

[0139] One may appreciate from the description herein that the expanded configuration of the expandable support device plays a role in the parameters of the expandable support device's contact with the treatment site. If the expandable support device expands to a completely flat shape and is extremely rigid, the expandable support device may not make good contact with a rounded surface. Likewise, if the expandable support device in an expanded configuration has some flexibility, it may be able to conform, to a degree, to the treatment surface. An expandable support device with a rounded surface in an expanded configuration may be less appropriate for contacting a generally flat treatment site. In some applications, it may be desirable to achieve less than full contact of the expandable support member with the treatment site. The expandable support device may have an expanded configuration of a fixed shape and size selected to provide more contact with larger diameter lumens and less contact with smaller diameters lumens, or vice versa. For example, the expanded configuration may have a small radius such that it achieves more contact with a smaller lumen and allows for spot treatment of a larger lumen. This configuration may be appropriate for delivering more energy to differently sized body lumens using the same device.

[0140] In another example, the expanded support device in the expanded configuration may include several different treatment surfaces for different parts of a body. In various embodiments, the treatment surface is on an underside of the expanded support device. In this manner, the expanded support device may be deployed through a narrow aperture (e.g., lower esophageal sphincter) to treat abnormal tissue on the other side (e.g., stomach lining). In one example, the treatment surface is cup-shaped, for example, to treat abnormal cervical tissue.

[0141] In various embodiments, expandable support device include a first treatment surface and at least another treatment surface. The another treatment surface may be substantially planar or another shape. The treatment surface and the another treatment surface may be contiguous.

[0142] In various embodiments, the expanded configuration of expandable support device is adjustable. For example, a supplementary expansion device may be provided to increase expansion—further flatten and unroll the expandable support device—or decrease expansion. In various embodiments, the supplementary expansion device is an expandable member (e.g. a balloon) or an actuator. The expanded configuration may be adjusted manually or automatically. The expanded configuration adjustment may be determined by a user with user controls or predetermined based on preset parameters.

[0143] With reference to **FIG. 5F**, the expandable support device 120-e has a particular expanded shape in accordance with various embodiments. In the expanded configuration, expandable support device 120-e may have body shaped like a paddle. The expandable support device 120-e may have a perimeter with generally parallel sides extending in a longitudinal direction. The expandable support device 120-e may include an atraumatic distal end 1105. The distal end 1105 of the expandable support device 120-e may be rounded to avoid sharp edges and corners that allow the expandable support device 120-e to be moved axially without risking inadvertent perforation or injury of the treatment area. As used herein, the "axial" direction is the direction from the proximal end to the distal end. In various embodiments, the distal end 1105 has a radius of about 0.25 inch. In various embodiments, the distal end 1105 has a radius of about 0.125 inch. The rounded distal end 1105 may meet the side edges at a smooth transition. Thus, at least an outward portion of the periphery of the expandable support device 120-e is rounded to reduce of injury or damage. The rounded distal end 1105 may also promote collapsing and insertion of the expandable support device 120-e into the working channel 115-e.

[0144] A proximal end 1110 of the expandable support device 120-e may be tapered to promote withdrawal of the expandable support device 120-e into the working channel 115-e. In particular, the tapered proximal end 1110 provides an angled contact surface for contacting the edges of the working channel 115-e. As the expandable support device 120-e is withdrawn into the working channel 115-e, the walls of the working channel 115-e may provide a folding force on the expandable support device 120-e to cause the expandable support device 120-e to contract to the collapsed configuration. This folding action is similar to a feather withdrawn into a tube. As will be described below, the expandable support device 120-e may have a structure and configuration carefully selected to promote and

control the collapsing and expanding actions. The proximal end 1110 can also be configured for coupling to the guide shaft 110.

[0145] In some embodiments, one side of the expandable support device 120-e is textured or otherwise marked at the tapered proximal end 1110 to indicate on which side expandable support device 120-e the operative member is disposed. Such texturing or marking can be useful when the expandable support member 120-e is transparent and it becomes difficult for a user to distinguish between the sides of the expandable support device 120-e. The texturing and marking can also be on an operative member disposed on the expandable support device 120-e.

[0146] One may appreciate from the description herein, however, that the shape and configuration of the expandable support device 120-e may vary depending on the application. For example, the expandable support device 120-e may have curved sides or a polygonal-shaped periphery. In various embodiments, the expandable support device 120-e is substantially elliptical. The expandable support device 120-e may also have different cross-sectional shapes when deployed.

[0147] In some embodiments, the expandable support device includes a solid body of elastomeric material. The solid body of elastomeric material can be a molded elastomeric body, including an elastomeric body molded in the shape of a paddle as described above. In some embodiments, the elastomeric material is silicone. The elastomeric body can be transparent, translucent, and/or opaque, for example. A solid elastomeric body can be a suitable material for the expandable support body because of its flexibility and resistance to plastic deformation. The elastomeric material can generally provide the expandable support device with the ability to transition between a collapsed configuration and an expanded configuration, as a generally planar body of elastomeric material can be folded or curved through the application of external force, followed by returning to its planar configuration when the application of external force is removed. The solid elastomeric body used for the expandable support device can have a variety of thicknesses in accordance with various embodiments.

[0148] With reference to **FIG. 6A**, an expandable support device 120-g in the shape of a paddle and which can be made from a solid elastomeric body is provided in accordance with various embodiments, and further includes a flexible support 155-a coupled with the

expandable support device 120-g. The flexible support 155-a can be provided to add additional structural support to the expandable support device 120-g and/or to provide apposition force when the expandable support device 120-g is deflected against a target treatment area. Providing additional support to the expandable support device 120-g can be useful when the expandable support device 120-g is made from a flexible material, such as an elastomeric material. Without a flexible support 155-a coupled with an expandable support device 120-g made from a solid elastomeric body, the expandable support device 120-g may run into problems when being transported through a working channel, such as folding over on itself and creating obstructions within the working channel. When a flexible support 155-a is provided, the expandable support device 120-g may have suitable structure support so as to maintain the expandable support device 120-g in the collapsed configuration while being transported through a working channel.

[0149] As shown in FIG. 6A, the flexible support 155-a may extend from the proximal end 1110-a to the distal end 1105-a of the expandable support device 120-g. In some embodiments, the flexible support 155-a overlaps and is aligned with a central axis extending between the proximal end 1110-a and the distal end 1105-a of the expandable support device 120-g.

[0150] The flexible support 155-a may be made from a flexible material so that it is capable of bending when the expandable support device 120-g is being passed through a non-linear working channel. In some embodiments, the flexible support 155-a is made from at least a highly elastic or superelastic material. The superelastic material can be nitinol, for example. The highly elastic material can be spring steel, for example.

[0151] In FIG. 6A, the expandable support device 120-g may include a single flexible support 155-a, and no further supports may be provided. However, other embodiments may include two or more flexible supports. With reference to **FIG. 6B**, the expandable support device 120-h includes two flexible supports 155-b-1, 155-b-2 arranged in a "wishbone" configuration in accordance with various embodiments. In this wishbone configuration, the flexible supports 155-b-1, 155-b-2 may be arranged in parallel to the central axis of the expandable support device 120-h, but are located at the peripheral edges of the expandable support device 120-h. With reference to **FIG. 6C**, the expandable support device 120-i includes three flexible supports 155-c-1, 155-c-2, 155-c-3 arranged in a "trident" configuration in accordance with various embodiments. In this trident configuration, the

flexible supports 155-c-1, 155-c-3 may be arranged in parallel to the central axis and located at the peripheral edges of the expandable support device 120-i, while support 155-c-2 is aligned with and overlaps the central axis of the expandable support device 120-i. As shown in FIGs. 7 and 8, the peripherally located flexible supports can include taper sections that follow the taper of the expandable support device at the proximal end. While FIGs. 6A-C show using from one to three flexible supports, any number of flexible supports can be used. Additionally, the flexible supports can be linear or longitudinal supports. Other embodiments may utilize other configurations, including open and/or closed configurations.

[0152] In some embodiments where more than one flexible support is provided, the flexible supports can be made from different materials. For example, in the trident configuration shown in FIG. 6C, the flexible support 155-c-2 located along the central axis can be made from nitinol, while the peripherally located flexible supports 155-c-1, 155-c-3 can be made from a different material, such as polyimide. The thickness of each flexible support can also be variable, such as when peripherally located flexible supports 155-c-1, 155-c-3 are thinner than the flexible support 155-c-2 located along the central axis.

[0153] With reference to FIG. 6A, a protective padding 1245 can encompass the distal tip of the flexible support 155-a. When multiple flexible supports are used, a protective padding can encompass some or all of the flexible supports. With reference to FIG. 6B, protective paddings 1245-a-1 and 1245-a-2 encompass the distal tips of flexible supports 155-b-1 and 155-b-2. With reference to FIG. 6C, protective paddings 1245-b-1, 1245-b-2, 1245-b-3 encompass the distal tips of flexible supports 155-c-1, 155-c-2, 155-c-3. The protective padding can be provided to prevent the distal tips of the flexible supports from damaging the target treatment area. In some embodiment, the protective padding comprises silicone layered above and below the distal tips.

[0154] In some embodiments, the flexible supports are configured as straight flexible supports, with no bends, curves, or the like. In other words, the flexible supports may be aligned generally in parallel to the guide assembly. With reference to FIGs. 7 and 8, some embodiments of the flexible support include one or more bends. As shown in **FIG. 7**, the flexible support 155-a-1 may beangled in a downward direction such that the expandable support device 120-g-1 coupled with the flexible support 155-a-1 is also positioned at an angle. As shown in **FIG. 8**, the flexible support 155-a-2 may include two approximately right angle bends so that the flexible support 155-a-2 has two parallel sections on different

planes. The expandable support device 120-g-2 can be coupled with the portion of the flexible support 155-a-2 that is on different plane from the portion of the flexible support 155-a-2 extending out of a working channel. Other configurations are also possible. Generally speaking, the non-linear flexible support can be provided to improve contact between the operative member disposed thereon and the target treatment area.

[0155] Any manner of coupling the flexible supports to the expandable support device can be used. In some embodiments, the flexible supports are coupled the expandable support device using a silicone adhesive. With reference to **FIG. 9A**, **FIG. 9B**, and/or **FIG. 9C**, the flexible supports 155-d, 155-e-1, 155-e-2, 155-f-1, 155-f-2, 155-f-3 can be coupled with their respective expandable support device 120-j, 120-k, 120-l such that the flexible supports are positioned outside of their respective expandable support device 120-j, 120-k, 120-l. With reference to **FIG. 10A**, **FIG. 10B**, and/or **FIG. 10C**, the flexible supports 155-g, 155-h-1, 155-h-2, 155-i-1, 155-i-2, 155-i-3 can be coupled with their respective expandable support device 120-m, 120-n, 120-o such that they are partially embedded within their respective expandable support device 120-m, 120-n, 120-o. The expandable support devices 120-m, 120-n, and 120-o can be overmolded with primer for adhesion to the respective flexible supports 155-g, 155-h-1, 155-h-2, 155-i-1, 155-i-2, 155-i-3.

[0156] In various embodiments, the expandable support device includes a solid substrate in which portions of the solid substrate are selectively removed from the substrate to form a pattern of splines and voids. The pattern formed in the solid substrate can be specifically designed to control the bending or folding of the patterned solid substrate. Removing portions of the solid substrate can generally result in the solid substrate having less strength and folding more easily. In other words, the pattern formed in the solid substrate can influence the bending strength or rigidity of the solid substrate. The pattern may be selected to provide different bending strength in localized regions of the patterned solid substrate. For example, the pattern may be selected to provide greater rigidity along a central region and relatively less bending rigidity along longitudinal outer edges. The resulting patterned solid substrate can be self-expanding. An expansion force such as a balloon inflation force is generally not necessary to expand the solid substrate. In various embodiments, the solid support self-expands to a predetermined shape.

[0157] The selective removal of material and the specific pattern selected can adjust the expansion force of the solid substrate within a specific range to optimize expansion while

allowing collapsing back into a collapsed configuration. In some embodiments, the width and spacing of the splines formed by patterning impacts the ability of the solid substrate to transition between the collapsed and expanded configuration.

[0158] In some embodiments, the solid substrate begins as a plate of solid substrate material, after which the plate is shaped and patterned to provide the final patterned solid substrate suitable for use as a part of the expandable support device. In some embodiments, the plate has a uniform thickness in the range of from 0.002 to 0.004 inch. In various embodiments, the plate has a variable thickness or is patterned to have a variable thickness (i.e., patterned to have splines of varying thickness). The solid substrate may be thin such that the thickness is orders of magnitude smaller than the width and height.

[0159] The solid substrate patterned to include multiple splines and voids can be used alone as the expandable substrate device, or can be used in conjunction with the solid elastomeric body described in greater detail above. When the patterned substrate is used alone for the expandable support device, an operative member can be disposed directly on the patterned substrate. When used in conjunction with the solid elastomeric body described above, the patterned substrate can be disposed on and coupled with a surface of the solid elastomeric body.

[0160] In some embodiments, the patterned solid substrate is disposed on a surface of the solid elastomeric body opposite the surface of the solid elastomeric body on which the operative member is disposed. In some embodiments, the patterned solid substrate is disposed on a surface of the solid elastomeric body, and the operative member is disposed on the patterned solid substrate such that the patterned solid substrate is intermediate the solid elastomeric body and the operative member. When the patterned solid substrate is used in conjunction with the solid elastomeric body, the patterned solid substrate can generally have a perimeter shape similar or identical to the perimeter shape of the solid elastomeric body. For example, when the solid elastomeric body has a paddle shape, the patterned solid substrate can also have a paddle shape. The patterned solid substrate shaped like a paddle can have similar features as the paddle-shaped solid elastomeric body, such as a rounded distal tip and a tapered proximal end. The perimeter of the patterned solid substrate can be interior to the perimeter of the solid elastomeric body, coextensive with the perimeter of the solid elastomeric body, or portions or all of the patterned solid substrate can be exterior to the perimeter of the solid elastomeric body.

[0161] With reference to **FIG. 11A**, a patterned solid substrate 1605 having portions of the patterned solid substrate 1605 removed to form splines 1610 and voids 1615 is shown in accordance with various embodiments. The patterned solid substrate 1605 can include a distal end 1620, a proximal end 1625, and a central axis extending from the proximal end 1625 to the distal end 1620 of the patterned solid substrate 1605.

[0162] The pattern of splines 1610 and voids 1615 can include any pattern that provides support to an operative member and promotes expansion between an expanded configuration and a collapsed configuration. In FIG. 11A, the patterned solid substrate 1605 is shown in an expanded configuration in accordance with various embodiments, which can generally include providing a substantially planar, curviplanar surface, or surface that conforms to the target treatment area surface.

[0163] In various embodiments, including the embodiment shown in FIG. 11A, the patterned solid substrate 1605 includes a central axis spline 1630 that substantially overlaps the central axis of the patterned solid substrate 1605. The central axis spline 1630 can be coupled with the guide assembly 110-e at the proximal end 1625 of the patterned solid substrate 1605. In some embodiments, the guide assembly 110-e and the central axis spline 1630 are a unitary piece. The patterned solid substrate 1605 can also be patterned so as to include an outer perimeter portion 1655 that defines and extends around the outer perimeter of the patterned solid substrate 1605.

[0164] In some embodiments, the patterned solid substrate 1605 is patterned such that a first subset of splines and a second subset of splines are formed. The first subset of splines can be arranged parallel with one another and can extend from the central axis spline towards a first lateral peripheral edge of the patterned solid substrate 1605. The second subset of splines can be arranged parallel to one another and can extend from the central axis spline 1630 towards a second lateral peripheral edge of the patterned solid substrate 1605, the second lateral peripheral edge being opposite the first lateral peripheral edge. In some embodiments, the width and/or thickness of the first subset of splines and the second subset of splines is less than the width and/or thickness of the central axis spline 1630. In some embodiments, the first subset of splines and the second subset of splines extend away from the central axis spline 1630 until they each connect with the outer perimeter portion 1655 of the patterned solid substrate 1605.

[0165] In some embodiments, both the first subset of splines and the second subset of splines extend away from the central axis spline 1630 and towards the distal end 1620 of the patterned solid substrate 1605. In this manner, the first subset of splines and the second subset of splines extend away from the central axis spline 1630 at an angle, which can range from greater than 0 degrees (which would be close to parallel with the central axis spline 1630) to 90 degrees (which would be perpendicular to the central axis spline 1630). In some embodiments, the angle of the first subset of splines is the same as the angle of the second subset of splines, while in other embodiments, the angle of the first subset of splines is different from the angle of the second subset of splines. In some embodiments, the angle of the first subset of splines and the second subset of splines is about 45 degrees. When the first subset of splines and the second subset of splines protrude away from the central axis spline 1630 towards the distal end 1620, this can help promote the transition of the patterned solid substrate 1605 between the expanded configuration and the collapsed configuration when the patterned solid substrate 1605 is being drawn back into a working channel. This spline pattern can behave similar to a feather being drawn back into a tube.

[0166] **FIG. 11B** illustrates a patterned solid substrate 1605-a in accordance with various embodiments that may be an example of the patterned solid substrate 1605 shown in FIG. 11A. The patterned solid substrate 1605-a may include a central axis spline 1630-a, multiple splines 1610-a and multiple voids 1615-a. The multiple splines 1610-a can be divided up into a first subset of splines and a second subset of splines as described above with reference to FIG. 11A. The patterned solid substrate 1605-a can also include a flexible support 155-j as described in greater detail above with respect to FIGs 6-8. The flexible support 155-j, which can be made of nitinol, for example, can be located on either surface of the patterned solid support 1605-a. In some embodiments where the patterned solid support 1605-a is used with a solid elastomeric body, the solid elastomeric body can be located between the patterned solid support 1605-a and the flexible support 155-j.

[0167] The patterned solid support 1605-a can also include vias 1650. The vias 1650 can be provided for coupling an operative member disposed on one side of the patterned solid substrate 1605-a to buses located on the opposite side of the solid patterned substrate 1605-a. Any number of vias 1650 can be provided, and the vias 1650 can be located anywhere throughout the patterned solid substrate 1605-a. As shown in FIG. 11B, the vias 1650 can interrupt the pattern of the patterned solid substrate 1605-a.

[0168] Other patterns in the patterned solid substrate can also be used. In various embodiments, the pattern is a repeating pattern. The pattern may be formed of a repeating shape or shapes. For example, the pattern may be a repeating diamond, triangle, or square. The pattern may be a repeating polygonal shape of three, four, or more sides. In various embodiments, the pattern is formed of two or more different patterns in different regions. For example, outer edges of the patterned solid substrate may have a different pattern than the inner, central region. The patterns may be similarly shaped but formed of splines with different dimensions and spacing. As with the pattern shown in FIGs. 11A and 11B, these other patterns can affect the properties of patterned solid substrate, such as the expansion force of the patterned solid substrate.

[0169] With reference to **FIG. 12A** and/or **FIG. 12B**, an alternate pattern can include a criss-cross pattern with vertical splines 2005 and horizontal splines 2010, where the vertical direction generally includes from the proximal end 1625-a to the distal end 1620-a and substantially parallel to the central axis in accordance with various embodiments. The horizontal splines 2010 can be orthogonal or perpendicular to the vertical splines 2005. The vertical splines 2005 and horizontal splines 2010 can have substantially the same width. The vertical splines 2005 can be elongated from the proximal end 1625-a to the distal end 1620-a of the patterned solid support 1605-b. The horizontal splines 2010 can extend a short distance, typically between adjacent vertical splines 2005. The horizontal 2010 can be offset from each other with non-uniform spacing in an axial direction. Adjacent vertical splines 2005 can be spaced an equidistant amount. The patterned solid substrate 1605-b can also include one or more vias 1650-a at various locations, which may disrupt the pattern. Such a pattern of relatively long vertical splines 2005 with regular spacing can promote the folding or rolling action of the patterned solid substrate 1605-b. In a transverse direction, by contrast, the patterned solid substrate can be relatively rigid. Such rigidity can improve maneuverability and improve apposition force.

[0170] FIGs. 13A to 13L illustrate various alternative patterns suitable for use in the patterned solid substrate in accordance with various embodiments. **FIG. 13A** illustrates a patterned solid substrate 1605-c with a pattern of orthogonal splines that may be similar in various respects to the pattern shown in FIGs. 12A and 12B in accordance with various embodiments. The pattern may include vertically-extending splines 2005-a spaced from each other and horizontally-extending splines 2010-a. The spacing between the splines may vary.

In some embodiments, the spacing between adjacent vertical splines 2005-a along the outer edges is greater than the spacing between adjacent splines in the interior of the pattern. This may be useful to increase the elasticity of the patterned solid substrate 1605-c along the outer edges. The width of each of the splines may vary across the patterned solid substrat 1605-c.

[0171] **FIG. 13B** illustrates a pattern of cross-hatched splines 1610-b in accordance with various embodiments. The pattern depicted in FIG. 13B may be similar in various respects to the pattern shown in FIGs. 12A and 12B, except that the pattern may be skewed in accordance with various embodiments. The pattern need not repeat across the entire body of the patterned solid substrate 1605-d. The pattern can repeat along distal end 1620-b of the patterned solid substrate 1605-d. Along an intermediate section, the pattern can be relatively random. One of the series of splines can be incomplete. The pattern can begin to repeat again along the proximal end 1625-b of the patterned solid substrate 1605-d.

[0172] **FIG. 13C** illustrates a patterned solid substrate 1605-e wherein there can be two different repeating patterns of shapes in accordance with various embodiments. The distal end 1620-c may include a repeating pattern of squares and octagons. The proximal end 1625-c may have a honeycomb-shaped pattern of hexagons.

[0173] **FIG. 13D** illustrates a patterned solid substrate 1605-f having a combination of various patterns in accordance with various embodiments. A distal end 1620-d can include multiple wavy splines 1610-c-1 generally pointed in a common direction, for example, a vertical direction. An intermediate section can have a splines 1610-c-2 in a checkered pattern. A proximal section 1625-d can have a pattern of different splines 1610-c-3. Some of the splines 1610-c-3 can be straight, some can be wavy, and some can have jagged shapes.

[0174] **FIG. 13E** and/or **FIG. 13F** illustrate a patterned solid support 1605-g with a pattern of splines 1610-d in accordance with various embodiments, which may be similar to the pattern shown in FIGs 12A and 12B . The splines 1610-d can be formed into vertical sections and horizontal sections. The horizontal sections can be staggered and have varying lengths. The lengths can be defined by the spacing between vertical spline sections. A spacing between adjacent vertical spline sections can be about 0.016 inch, for example. A width of each of the vertical and horizontal spline sections can be about 0.016 inch. An exception can be the spline sections defining a border of cut-outs. These splines sections can be about 0.008 inch.

[0175] The patterned solid substrate 1605-g can be integrally formed with a central axis flexible support 155-k. The central axis flexible support 155-k can be configured as a backbone that extends along and is aligned with the central axis of the patterned solid substrate 1605-g. The central axis flexible support 155-k can have a width and/or thickness larger than a width and/or thickness of the splines 1610-d. The patterned solid substrate 1605-g can overhang the central axis flexible support 155-k at a distal end 1620-e.

[0176] **FIG. 13G** and/or **FIG. 13H** illustrate a patterned solid substrate 1605-h, which may be similar to the pattern shown in FIGs 12A and 12B, in accordance with various embodiments. The patterned solid substrate 1605-h can have relatively narrower horizontal splines 2005-b, such as, for example, a width of about 0.008 inch. As described herein, the horizontal splines 2010-b can play a role in the expanding and collapsing of the patterned solid substrate 1605-h. In part, the vertical splines 2005-b may roll around each other like a flag whereas the horizontal splines 2010-b generally bend. The narrower spline sections thus can result in a patterned solid substrate 1605-h with a lower expansion/collapsing force. This can make the patterned solid substrate 1605-h easier to retract into the working channel while also lowering the force for expansion.

[0177] FIG. 13I, FIG. 13J, and/or FIG. 13K illustrate patterns with various spline spacings and alternative void dimensions in accordance with various embodiments. The patterns may be otherwise similar to the pattern shown in FIGs. 12A and 12B.

[0178] **FIG. 13I** illustrates a patterned solid substrate 1605-i having a pattern with multiple splines 1610-e arranged vertically and horizontally in accordance with various embodiments. By contrast to some of the spline patterns described above, the horizontal sections adjacent the central axis can be relatively longer thereby providing wider voids. This configuration can result in a lower bending force required adjacent the central axis than along the outer edges of the patterned solid support 1605-i. In operation, the patterned solid substrate 1605-i tends to fold into a U-shape.

[0179] **FIG. 13J** illustrates a patterned solid substrate 1605-j having a pattern with multiple splines 1610-f arranged vertically and horizontally in accordance with various embodiments. By contrast to some of the spline patterns described above, the pattern has can have relatively large voids. The larger voids can result in a weaker patterned solid substrate 1605-j, and by

the same token, a lower expansion force. The relatively uniform distribution and size of the voids can lead to relatively uniform bending.

[0180] **FIG. 13K** and/or **FIG. 13L** illustrate a patterned solid substrate 1605-k having a pattern, which may be similar to the pattern shown in FIGs 12A and 12B, in accordance with various embodiments. FIG. 13L may provide a top end view of the patterned solid substrate 1605-k illustrating a central axis flexible support 155-l positioning relative to the patterned solid substrate 1605-k in the deployed configuration. The patterned solid substrate 1605-k may include multiple splines 1610-g arranged vertically and horizontally. The pattern of splines 1610-g may define voids 1615-b with rectangular shapes. The voids 1615-b may generally have a shorter height than width. By the same token, a space between adjacent horizontal spline sections may generally be smaller than the length of the vertical spline sections. The patterned solid substrate 1605-k can also include a several horizontal spline sections that extend across the entire width of the patterned solid substrate 1605-k. The horizontal sections can be interrupted by a central axis flexible support 155-l.

[0181] The pattern shown can have a lower spline density than some of the previously described patterns. The spline density may refer to a ratio of the area of the splines to an area of the voids in a given section. Put another way, the spline density may refer to the material remaining relative to the amount of material removed to form the voids.

[0182] In any of the patterns used, including those described above, the dimensions of the splines and voids can vary greatly to produce varying effects on the ability to transition the patterned solid substrate between a collapsed configuration and an expanded configuration. The overall dimensions of the patterned solid substrate can also impact the collapsing and expanding of the patterned solid substrate.

[0183] In various embodiments, the width of the patterned solid substrate is about 7 mm. In various embodiments, the width of the patterned solid substrate is about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 8 mm, about 9 mm, or more than 10 mm. In various embodiments, the patterned solid substrate has a width of about 0.2 inch, 0.27 inch, or 0.276 inch. Other embodiments may include other widths of the pattern solid substrate.

[0184] In various embodiments, the splines may be about 0.015 inch in width. The width of the splines may be based on the thickness of the patterned solid substrate. For example,

the width of the splines may be proportional to the thickness of the patterned solid substrate. In various embodiments, a width of the splines is between about 0.008 inch and about 0.02 inch, between about 0.008 inch and about 0.015 inch, between about 0.01 inch and about 0.02 inch, or between about 0.01 inch and about 0.015 inch. Other embodiments may include other widths of the splines.

[0185] In various embodiments where the pattern includes vertical and horizontal splines, the patterned solid substrate includes vertical splines having a width of about 0.008 inch, about 0.01 inch, about 0.012 inch, about 0.015 inch, about 0.016 inch, about 0.02 inch, or about 0.03 inch, and horizontal splines having a width of about 0.008 inch, about 0.01 inch, about 0.012 inch, about 0.015 inch, about 0.016 inch, about 0.02 inch, or about 0.03 inch. In various embodiments, the patterned solid substrate includes vertical splines having a width of about 0.03 inch and horizontal splines having a width of about 0.01 inch, 0.02 inch, or a combination thereof. In various embodiments, the patterned solid substrate includes vertical splines having a width of about 0.016 inch and horizontal splines having a width of about 0.01 inch, about 0.016 inch, about 0.02 inch, or a combination thereof. In various embodiments, the patterned solid substrate includes vertical splines having a width of about 0.016 inch and horizontal splines having a width of about 0.012 inch. In various embodiments, the patterned solid substrate includes vertical splines and horizontal splines having widths of about 0.016 inch. In various embodiments, the patterned solid substrate includes splines having widths ranging from about 0.01 inch to about 0.03 inch. In various embodiments, the patterned solid substrate includes vertical splines and horizontal splines having widths of about 0.008 inch. Other embodiments may include other widths of the splines.

[0186] In various embodiments, a spacing (void width) between adjacent vertical splines is about 0.016 inch, about 0.024 inch, greater than 0.03 inch, or greater than 0.04 inch. In various embodiments, a spacing between adjacent horizontal splines (void length) is about 0.016 inch, about 0.024 inch, greater than 0.05 inch, greater than 0.1 inch, greater than 0.2 inch, or greater than 0.3 inch. As explained herein, the pattern may include splines in an angled orientation whereby the splines are not horizontal or vertical. In various embodiments, a spacing between adjacent splines is about 0.016 inch, about 0.024 inch, greater than 0.05 inch, greater than 0.1 inch, greater than 0.2 inch, or greater than 0.3 inch. Other embodiments may include other widths of the voids.

[0187] The patterned solid substrate can be formed of a material having at least highly elastic or superelastic properties, shape memory properties, or both. In various embodiments, the patterned solid substrate is formed of a superelastic material (SEM). In various embodiments, the patterned solid substrate is formed of a shape memory metal or shape memory alloy (SMA). Suitable materials for the patterned solid substrate may include, but are not limited to, nickel-titanium, copper-aluminum-nickel, copper-zinc-aluminum, iron-manganese-silicon, and alloys of the same. The patterned solid substrate may also be formed of other materials. In some embodiments, the patterned solid substrate is formed of material having highly elastic material, including, but not limited to, spring steel. In some embodiments, highly elastic material includes material having a yield strength in the range of from about 400 MPa to about 1100 MPa.

[0188] In some cases the material of the patterned solid substrate is selected based on the application. For example, if the patterned solid substrate may need to collapse to a larger degree and thus may experience large strains, nitinol may be more suitable than spring steel. One may appreciate from the description herein, however, that a number of factors affect the amount of strain experienced by the component such as the shape, the spline pattern, and the interaction with other components.

[0189] Superelastic materials typically permit large elastic (recoverable) deformations. For example, SEMs may withstand 22.5% deformation with high damping under loads in the kN/mm range for solid wires and about 10 to about 100 N/mm for tubes with an outer diameter of 0.4-2 mm. Recoverable deformations as great as 60% or more have been observed with thin-walled SEM tubes. This phenomenon is sometimes referred to as "giant superelasticity effect" (GSE). In various embodiments, the patterned solid substrate 1605 is formed of a SEM. In various embodiments, the patterned solid substrate 1605 is formed of a material having GSE properties.

[0190] In some embodiments, the patterned solid substrate is formed of nickel-titanium. Nickel-titanium is often referred to as nitinol (i.e., Nickel-Titanium Naval Ordinance Laboratory). Nickel-titanium is known to have both shape memory and superelastic properties. A nickel-titanium alloy is sometimes made from a nearly equal composition of nickel and titanium. The performance of nitinol alloys are generally based on the phase transformation in the crystalline structure, which transitions between an austenitic phase and a martensitic phase. The austenitic phase is generallycalled the high temperature phase, and

the martensitic phase is called the low temperature phase. In the martensitic phase the material has a relatively low tensile strength and is stable at relatively low temperatures. In the austenitic phase, the material generally has a relatively high tensile strength and is stable at temperatures higher than the martensitic phase. The phase transformation is the general mechanism by which superelasticity and the shape memory effect are achieved.

[0191] Shape memory generally implies that the alloy can be inelastically deformed into a particular shape in the martensitic phase, and when heated to the austenitic phase, the alloy transforms back to the particular shape. Thus, at elevated temperatures the material can experience recoverable strains. For typical nitinol, the transformation temperature (Af) may be about 50° Celsius. The Af temperature may vary depending on the application. In various embodiments, the Af temperature of the support member is selected to be about 15° C. In various embodiments, the Af temperature of the support member is selected to below 20° C. Methods for adjusting the transformation temperature of nitinol are generally known as exemplified by U.S. Patent No. 4,283,233 to Goldstein et al, incorporated by reference for all purposes..

[0192] Superelasticity or pseudoelasticity generally refers to the relatively high elasticity of the alloy when placed under stress and without the involvement of heat. For example, it is possible to see reversible strains of 8 percent or more elongation in a superelastic nitinol wire as compared to 0.5 percent reversible strain in a comparable steel wire, for example. The superelastic property may appear in the austenitic phase when stress is applied to the alloy and the alloy changes from the austenitic phase to the martensitic phase. This particular martensitic phase may more precisely be known as stress-induced martensite (SIM). The phase is generally unstable at temperatures above the phase transformation temperature and below the temperature known as Md. At temperatures above Md, stress-induced martensite cannot be achieved and the superelastic properties are lost. Within this temperature range, however, the stress-induced martensite may revert back to the austenitic phase after the force is removed. This phase change may enable the recoverable strains characteristic of nitinol.

[0193] When stress is applied to a specimen of a metal having superelastic characteristics (at or above the transformation temperature), the specimen generally deforms elastically until it reaches a particular stress level where the alloy then undergoes SIM. As the phase transformation progresses, the alloy may undergo significant increases in strain with little or no corresponding increases in stress until the transformation of the austenitic phase to the

martensitic phase is complete. Thus, the metal generally first deforms elastically and then plastically deforms.

[0194] In various embodiments, the patterned solid substrate is formed of a shape memory material. In various embodiments, the patterned solid substrate is entirely formed of a shape memory material. In various embodiments, the patterned solid substrate is formed of a material having superelastic properties. In various embodiments, the patterned solid substrate is entirely formed of a material having superelastic properties. In various embodiments, the patterned solid substrateis formed of nitinol. One may appreciate that other superelastic and/or shape memory materials may be used in accordance with various embodiments of the inventions. The patterned solid substrate may make use of the superelastic properties, shape memory properties, or both properties of the shape memory material.

[0195] In various embodiments, the patterned solid substrate is formed of a shape memory alloy and makes use of the material's unique properties. The shape memory effect may allow the patterned solid substrate to be deformed into the collapsed configuration to facilitate its insertion into a working channel. Thereafter, the patterned solid substrate may be heated within the working channel so that the patterned solid substrate is biased towards a predetermined collapsed shape. The predetermined shape may be a specific shape as described above.

[0196] In various embodiments, the patterned solid substrate is designed to make use of the superelastic properties of the shape memory alloy so it is disposed to expand and collapse within the working channel. The superelastic property may allow the patterned solid substrate to expand against a tissue surface.

[0197] In some embodiments, patterned solid substrate is formed from a nitinol plate having a thickness of 0.003 inch. When the support member is collapsed into a working channel, for example a 2.8 mm working channel, the patterned solid substrate may undergo about 3% to about 4% strain, for example. With conventional materials the patterned solid substrate may plastically deform under these conditions. With nitinol, however, it has been found that the material can undergo about 6% to about 8% strain, for example, without plastic deformation. Thus, the patterned solid substrate can easily fit within the working channel without plastic deformation.

[0198] In various embodiments, patterned solid substrate is formed of a shape memory alloy and configured to maintain the operative member in at least one of the expanded configuration and the collapsed configuration.

[0199] Patterned solid substrate may make use of shape memory properties in other ways. In various embodiments, the patterned solid substrate is formed of a shape memory material with an initial transition temperature (Af) selected to permit the patterned solid substrate to easily roll into the working channel during preparation and expand to a preset shape once exposed to the internal body temperature. For example, the Af temperature may be between room temperature and normal body temperature. In other words, the material may be designed to be in the austenitic phase between room temperature and body temperature. In various embodiments, the Af temperature is between about 23° C and about 37° C, between about 25° C and about 37° C, between about 25° C and about 40° C, between about 25° C and about 45° C, between about 15° C and about 45° C, between about 20° C and about 35° C, between about 15° C and about 20° C, or between about 20° C and about 30° C. Thus, the patterned solid substrate Af temperature may be selected so the patterned solid substrate temperature rises in the body at which point it wants to unroll into an expanded configuration. This process could also be aided by the user flushing the patterned solid substrate with cold water to maintain the temperature below 25° C and flushing the patterned solid substrate with hot water when it is desired to activate expansion.

[0200] An expandable support device, such as any of the expandable support devices described above, can be configured to support an operative member. The operative member can be disposed on an outward facing surface of the expandable support device. The operative member can include any operative member configured for providing therapy to a target treatment area. In some embodiments, the operative member is configured for delivering energy including, but not limited to, radiofrequency (RF) energy, thermal energy, and electromagnetic energy. In various embodiments, the operative member is configured for delivering a heated or cooled fluid or cryogenic fluid. In various embodiments, the operative member is configured for laser treatment, microwave treatment, radio frequency ablation, ultrasonic ablation, photodynamic therapy using photo sensitizing drugs, argon plasma coagulation, cryotherapy, and/or x-ray treatment.

[0201] In some embodiments, the operative member is also configured for transitioning between a collapsed and expanded configuration such that the operative member can collapse

and expand with the expandable support device on which it is disposed. In some embodiments, the operative member is flexible in order to accommodate this transition. In some embodiments, flexible operative member provides negligible resistance to movement of the expandable support device on which it is disposed.

[0202] Other features of the operative member can also be designed to assist the operative member in transitioning between a collapsed and expanded configuration, such as the design of electrodes which can be part of an operative member. In some embodiments, electrodes included as part of the operative member are made from a malleable metal that resists changes to shape but which is capable of bending to a certain extent without plastic deformation. If the malleable metal of the electrodes is too rigid, it will affect, and in some cases prevent, the collapsing and expanding movement. Another approach for making the operative member flexible and conducive to transitioning between a collapsed and expanded configuration can be to design the operative member to decrease the resistance to bending in the desired direction. For example, an operative member including multiple electrodes can include electrodes oriented in a direction parallel to the axis along which the bending of the operative member occurs during transition between collapsing and expanding configurations so that the electrodes generally do not bend as the operative member furls into the collapsed configuration.

[0203] In the case of therapy using radiofrequency energy, for example, the operative member may include an electrode or electrode array connected to an energy source configured as a radiofrequency generator. The RF generator can be connected using a coupling and connection line suited to the transmission of electrical energy to the electrode array. The electrode array may be configured as at least a monopolar or bipolar array of electrodes. In the case of therapy using microwave energy, for example, the operative member can include an appropriate antenna or array connected to an energy source configured as a source of microwave energy. The microwave source can be connected using a coupling and connection line suited to the transmission of microwave energy to the antenna or array. In the case of cryogenic therapy, for example, the operative member can be an appropriate applicator for the cryogenic gas or liquid such as a nozzle, array of nozzles in the case of a spray delivery, or a receptacle for a cryogenic fluid in the case where the therapy is applied via contact with a low temperature receptacle. The cryogenic applicator can be connected to the cryogenic source using a coupling and connection line suited to the

controlled delivery of the cryogenic gas or liquid. In the case of photo-therapy, for example, the operative member can provide the appropriate fixed or moving lens or lens array suited as appropriate for the light source being used. The photonic delivery element can be connected to the light source using a coupling and connection line suited to the controlled delivery of the light or phototherapy energy generated by the phototherapy source.

[0204] With reference to **FIG. 14A**, an operative member 160-b in accordance with various embodiments is shown. The operative member 160-b can be disposed on a surface of an expandable support device 120-p, such as a solid elastomeric support. A flexible support 155-m can be provided on the same surface or on an opposing surface of the expandable support device120-p. The flexible support 155-m can be aligned with the central axis of the expandable support device 120-p. The expandable support device 120-p can be coupled with a guide assembly 110-f, which can be used to move the expandable support device 120-p and the operative member 160-b through a working channel 115-f and around a target treatment area. Both the operative member 160-b and the expandable support device 120-p can be configured to transition between a collapsed and expanded configuration.

[0205] In some embodiments, the operative member 160-b includes a flexible circuit. The flexible circuit can include multiple electrodes 2205. In some embodiments, the flexible circuit further includes a backing layer on which the electrodes are disposed. The backing layer, which can include an insulator, can then be disposed on the expandable support device 120-p. In some embodiments, the electrodes 2205 are disposed directly on the expandable support device 120-p. Various aspects of the flexible circuit are similar to typical integrated circuits and microelectronic devices. The operative member 160-b may include various operative and adjunctive medical devices other than electrodes.

[0206] In some embodiments, the multiple electrodes 2205 are aligned in parallel to one another and can form a row of electrodes 2205 spanning at least a portion of the width of the expandable support device 120-p. The electrodes 2205 can be spaced evenly apart from one another and/or at varying distances. The multiple electrodes 2205 can generally be aligned in parallel with an axis that extends from a distal end 1105-d to a proximal end 1110-d of the expandable support device 120-p on which the operative member 160-b is disposed. In some embodiments, this axis will be a central axis and will generally be located half way between opposing sides of the expandable support device 120-p. In some embodiments, the expandable support device 120-p is configured to collapse around this central axis when

transitioning to a collapsed configuration. By aligning the multiple electrodes 2205 to be parallel with the central axis, the flexible circuit and the electrodes 2205 can also be configured to collapse around the central axis, as the electrodes 2205 will generally not resist the collapsing movement due to their parallel orientation. In such embodiments, the individual electrodes 2205 are not bent or deformed to a significant degree. Rather, the folding or collapsing may occur in the spaces between the electrodes 2205, and more specifically, in the flexible expandable support device 120-p. Consequently the expansion force utilized for expansion can be decreased.

[0207] In some embodiments, the flexible circuit extends to the perimeter of the expandable support device 120-p. Each electrode 2205 can extend from a proximal end 1110-d of the expandable support device 120-p to a distal end 1105-d of the expandable support device 120-p. In some embodiments, such as that shown in FIG. 14A, the multiple electrodes 2205 do not extend into the tapered portion of the proximal end 1110-d of expandable support device 120-p. The row of electrodes 2205 can extend to the lateral peripheral edges of the expandable support device 120-p. In some embodiments, the flexible circuit is generally coextensive with the shape of the expandable support device 120-p. In some embodiments, the flexible circuit is larger than the expandable support device 120-p such that a portion of the flexible circuit extends over a portion of the expandable support device 120-p. In some embodiments, the flexible circuit is smaller than the expandable support device 120-p such that a portion of the expandable support device 120-p extends beyond the perimeter of the flexible circuit. One may appreciate from the description herein that the shapes and positional relationship of the expandable support device 120-p and the operative member 160-b may be varied in other ways.

[0208] In some embodiments, the multiple electrode 2205 provide a bipolar electrode array. In such embodiments, the operative member 160-b can include a first bus 2215 and a second bus 2220. The first bus 2215 can be either a source line or a drain line. When the first bus 2215 is a source line, the second bus 2220 can be a drain line, and when the first bus 2215 is a drain line, the second bus 2220 can be a source line. Depending on whether the first bus 2215 is a source line or a drain line, the first bus 2215 can be coupled with a positive terminal or a negative or ground terminal. Similarly, depending on whether the second bus 2220 is a source line or a drain line, the second bus 2220 can be coupled with a positive terminal or a negative or ground terminal.

[0209] In some embodiments, the first bus 2215 is coupled with a first subset of the multiple electrodes 2205 and the second bus 2220 is coupled with a second subset of the multiple electrodes 2205. The first bus 2215 and the second bus 2220 can couple to alternating electrodes 2205 in the row of electrodes 2205 to thereby define the first subset of electrodes 2205 and the second subset of electrodes 2205.

[0210] In some embodiments, the first bus 2215 is located at a first end of the multiple electrodes 2205 and the second bus 2220 is located at the opposite end of the multiple electrodes 2205. The first bus 2215 and the second bus 2220 can be arched. In some embodiments, the first bus 2215 and the second bus 2220 are each a single arch extending the width of the expandable support device 120-p. The arched first bus 2215 located at the distal end 1105-d of the expandable support device 120-p can be parallel to the curvature of the distal end 1105-d, such as when the expandable support device 120-p has a paddle shape. The arched first bus 2215 at the distal end 1105-d of the expandable support device 120-p can be coupled with the first subset of electrodes 2205, which may extend away from the arched first bus 2215 towards the proximal end 1110-d. In some embodiments, the first subset of electrodes 2205 do not connect with the second bus 2220 at the proximal end 1110-d of the expandable support device 120-p. The arched second bus 2220 located near the proximal end 1110-d of the expandable support device 120-p can have an arch shape in the opposite direction of the first bus 2215 located at the distal end 1105-d. In other words, the arch shape of the second bus 2220 near the proximal end 1110-d of the expandable support device 120-p can curve away from the distal end 1105-d of the expandable support device 120-p. The second subset of electrodes 2205 can be coupled with the arched second bus 2220 at the proximal end 1110-d of the expandable support device 120-p and extend away from the arched second bus 2220 towards the distal end 1105-d of the expandable support device 120-p. In some embodiments, the second subset of electrodes 2205 do not connect with the first bus 2215 at the distal end 1105-d of the expandable support device 120-p.

[0211] With reference to **FIG. 14B**, the first bus 2215 and the second bus 2220 can be at least partially covered with a material 2225 that may prevent or impedes the transmission of energy to the target treatment area in accordance with various embodiments. In some embodiments, the first bus 2215 and the second bus 2220 are covered with an insulation material 2225. Any suitable insulation material 2225 can be used, including, for example, polyimide. Covering the first bus 2215 and the second bus 2220 with insulation material

2225 can be useful to provide an operative member 160-b that delivers a more square treatment pattern, which can provide for more accurate and precise delivery of treatment to a target treatment area. For example, when the operative member 160-b is configured to provide ablative energy, the operative member 160-b having a covered first bus 2215 and second bus 2220 can deliver a square ablative pattern rather than one with rounded and less defined edges so as to provide for more accurate and precise ablation of the target treatment area.

[0212] **FIG. 15A** and **FIG. 15B** illustrate a flexible circuit, which may be similar to the flexible circuit shown in FIGs 14A and 14B, in accordance with various embodiments. The first bus 2215-a and the second bus 2220-a provided can include multiple arches rather than a single arch as shown in FIGs. 15A and 15B. In some embodiments, the end of each arch is coupled with single electrode 2205-a. Thus, the end of each arch included in the first bus 2215-a may be coupled with a single electrode 2205-a in the first subset of electrodes, while the end of each arch included in the second bus 2220-a may be coupled a single electrode 2205-a in the second subset of electrodes. With reference to FIG. 15B, at least a portion of the first bus 2215-a including multiple arches and the second bus 2220-a including multiple arches can be covered with an insulation material 2225-a, such as polyimide.

[0213] While not shown in the FIGs. 14A, 14B, 15A, or 15B, in some embodiments, the first bus and second bus are located on a surface of the expandable support device opposite the surface on which the flexible circuit (including the multiple electrodes) is disposed. FIGs. 17A and/or 17B may show such configurations. In such embodiments, the expandable support device can include one or more vias. The first and second bus can be connected to the first subset of electrodes and the second subset of electrodes, respectively, through the vias that provide a passage way between the front and back surface of the expandable support device. The first bus and the second bus disposed on the second surface of the expandable support device can be aligned substantially perpendicular to the electrodes disposed on the first surface of the expandable support device. The first bus and the second bus can be positioned at opposite ends of the electrodes as shown in FIGs. 14A, 14B, 15A, and 15B, at a location between the first end and second ends of the electrodes, or a combination of the two.

[0214] Any suitable material can be used for the electrodes, first bus, and/or second bus described above. In some embodiments, at least one of the electrodes, first bus, or second bus are made from copper. In some embodiments, the first bus and the second bus are made

from copper. In some embodiments, the first bus and the second bus can include a hash pattern that includes multiple voids within the first bus and the second bus. This hash pattern, and specifically, the multiple voids, can improve the ease with which the first bus and second bus are capable of collapsing when the expandable support device transitions to a collapsed configuration. In embodiments where the first bus and the second bus are aligned perpendicular to the electrodes (and therefore perpendicular to the axis along which the expandable support device will collapse when transitioning to a collapsed configuration), the hash pattern can result in the first bus and the second bus providing less resistance to the collapsing of the expandable support device.

[0215] In some embodiments, the electrodes described above are formed from a patterned layer of electrode material disposed on a backing layer or the expandable support layer. After the layer of electrode material, which can include metal, for example, is disposed on an underlying support, traditional etching techniques can be used to remove portion so the electrode material and provide electrodes in desired pattern, including the patterns described above. In some embodiments, a 1 ounce copper can be used as the electrode material layer, and the electrode material layer can have a thickness of less than 0.01 inch thick. Other amounts of copper and/or thicknesses may be utilized in some embodiments.

[0216] The operative member can be attached to expandable support device with conventional fastening techniques, such as adhesives. In various embodiments, the operative member is attached to the expandable support device along an entire bottom surface. In various embodiments, only a portion of the operative member is attached to the expandable support device. In various embodiments, all or a portion of the periphery of the operative member is attached to the expandable support device. The operative member may be attached to the expandable support device only in selected regions, such as the center of the operative member. In various embodiments, the operative member is attached to the expandable support device in only selected locations to accommodate slippage or shearing between the structures. The operative member and its attachment to the support member can influence movement of the expandable support device between the collapsed to the expanded configurations.

[0217] With reference to **FIG. 16A** and/or **FIG. 16B**, an operative member 160-c in accordance with various embodiments is shown. The operative member 160-c can be an RF ablation circuit for delivering RF ablation to a tissue surface. The operative member 160-c

can include multiple electrodes 2205-b on an insulator material 2405. The electrodes 2205-b can be connected to a power source 105-b. The multiple electrodes 2205-b can be formed in a bipolar array. The electrodes 2205-b can be positioned over a source line first bus 2215-b and a drain line second bus 2220-b. The source line first bus 2215-b can be connected to a positive terminal of power source 105-b by an "in" line 2415, and the drain line second bus 2220-b can be connected to the negative terminal or ground by an "out" line 2420. The source line first bus 2215-b and drain line 2220-b can extend below the electrodes 2205-b. The source line first bus 2215-b and drain line second bus 2220-b may be configured as electrical bus lines. A portion of the multiple electrodes 2205-b can be connected to the source line first bus 2215-b, and the remainder of the electrodes 2205-b connected to the drain line second bus 2220-b. In some embodiments, the electrodes 2205 are alternately connected to the source line first bus 2215-b and drain line second bus 2220-b. When the power source 105-b activates the electrodes 2205-b, energy can travel from the positive electrodes to the ground or negative electrodes.

[0218] Source line first bus 2215-b may be connected to "in" line 2415 through a via 1650-b. Likewise, drain line second bus 2220-b may be connected to "out" line 2420 by a via 1650-b. The vias 1650-b can extend through the expandable support device 120-r. In various embodiments, the electrodes 2205-b include wires that are inserted through the vias 1650-b and connected to an electrical component or circuit below the expandable support device 120-r. In some embodiments, the "in" line 2415 and "out" line 2420 include a bundle of wires (*e.g.*, Litz wires). The wires can extend through the guide shaft 110-g and connect to the power source 105-b at an opposite end. In various embodiments, the vias 1650-b are oversized relative to the electrical connections to accommodate lateral movement or shearing of the connections relative to the expandable support device 120-r during expansion and collapsing.

[0219] The electrodes 2205-b can be elongated and generally face in a common direction. In various embodiments, the electrodes 2205-b are aligned with a central axis of the expandable support device 120-r and/or the guide shaft 110-g. The operative member 160-c may include other configurations such as one or more monopolar electrodes.

[0220] The electrodes may have a length of between about 1 mm and about 10 mm, between about 1 mm and about 7 mm, between about 1 mm and about 6 mm, between about 1 mm and about 5 mm, between about 1 mm and about 3 mm, or between about 1 mm and

about 4 mm. In various embodiments, the electrode length is between about 5 mm and about 50 mm, and in various embodiments about 15 mm. One may appreciate from the description herein that the length of the electrodes may vary depending on the application and expandable support device.

[0221] Each of the electrodes may have a width of about 4 mm, about 3 mm, about 2 mm, about 1 mm, about 0.9 mm, about 0.8 mm, about 0.7 mm, about 0.6 mm, about 0.5 mm, about 0.4 mm, about 0.3 mm, about 0.2 mm, or about 0.1 mm. In various embodiments, each electrode has a width of less than 1 mm. In various embodiments, each electrode has a width of about 0.25 inch. In various embodiments, an average width of the electrodes is about 4 mm, about 3 mm, about 2 mm, about 1 mm, about 0.9 mm, about 0.8 mm, about 0.7 mm, about 0.6 mm, about 0.5 mm, about 0.4 mm, about 0.3 mm, about 0.2 mm, or about 0.1 mm. In various embodiments, an average width of the electrodes is less than 1 mm. One may appreciate from the description herein that the electrodes may have different widths and/or lengths.

[0222] In various embodiments, a spacing between adjacent electrodes is based on the electrode length, width, shape, or a combination of the same. In some embodiments, the spacing between the electrodes is fixed by fastening the electrodes to a backing layer or the expandable support device. The spacing between adjacent electrodes may be between 0 mm and about 1 mm, between about 0 mm and about 0.5 mm, between about 0 mm and about 0.4 mm, between about 0 mm and about 0.3 mm, or between about 0 mm and about 0.2 mm. The spacing between adjacent electrodes may be less than 0.3 mm, less than 0.2 mm, less than 0.1 mm, or less than 0.05 mm. In various embodiments, the spacing between adjacent electrodes is about 0.3 mm. One may appreciate from the description herein that the electrodes may have different spacing.

[0223] One may appreciate that the dimensions and lay out of the electrode may vary depending on the application. For example, if the working channel is larger, it may be desirable to use an expandable support device with a larger treatment surface and/or larger electrodes. A larger target treatment surface can typically require scaling up the constituent elements including the operative members.

[0224] One may appreciate from the description herein that the operative member may be configured differently depending on the application requirements. In various embodiments,

the operative member includes multiple electrode arrays. The arrays can be individually powered. The number and type of electrodes may also vary.

[0225] In various embodiments, the dimensions of the electrodes and spacing between the electrodes are selected to enable controlled depth ablation. Examples of electrode configurations for controlled depth ablation are described in U.S. Patent Nos. 6,551,310 (Ganz et al.), 7,150,745 (Stern et al.); 7,344,535 (Stern et al.); 7,530,979 (Ganz et al.); 7,993,336 (Jackson et al.); 8,012,149 (Jackson et al.); and U.S. Patent Pub. Nos. 2008/0097427 (Stern et al.); 2009/0012513 (Utley et al.), and 2009/0048593 (Ganz et al.); the entire contents of which patents and patent publications are hereby incorporated herein for all purposes. In various embodiments, the power generator and/or a controller are configured to control the application of energy using the operative member to effect ablation of tissue to a controlled depth.

[0226] In some embodiments, the electrodes 2205-b shown in FIGs. 16A and 16B are oriented parallel to an axis about which the collapsing and expanding of the expandable support member 120-r occurs in order to promote the collapsing and expansion functions. Although the electrodes 2205-b can be separated from the expandable support device 120-y by an insulator layer 2405, the electrodes 2205-b may influence each other during bending. For example, if the electrodes 2205-b are fastened to a insulator layer 2405 in a way that makes the resulting circuit more rigid, this may resist bending of the expandable support device 120-r. In various embodiments, the electrodes 2205-b are positioned on the expandable support device 120-r to minimize overlapping with other support structures, such as the support splines. In various embodiments, the electrodes and splines are positioned and configured in an intersecting relationship.

[0227] FIGs. 17A-17D illustrate an operative member 160-d in the form of a flexible circuit in accordance with various embodiments. The operative member 160-d can be attached to a top surface of the expandable support device. **FIG. 17A** shows a top side of operative member 160-d. FIG. 17B shows a back side of the operative member 160-d. FIG. 17C is an enlarged view of a portion of the operative member 160-d as seen from the top side. The operative member 160-d can be configured as an adhesive strip for applying to the expandable support device.

[0228] In some embodiments, the expandable support device on which the operative member 160-d is disposed is about 7 mm to about 8 mm in width. The operative member 160-d can include an electrode array 2505 that extends across all or substantially all of the expandable support device width. In some embodiments, the electrode array 2505 can have a width between about 7 mm and about 8 mm. The width of the expandable support device and/or the electrode array 2505 may depend on the size of the working channel through which they are intended to be deployed.

[0229] In some embodiments, the electrode array 2505 includes twelve electrodes 2205-z in the shape of bars. In some embodiments, the electrodes 2205-c can be formed of 1 ounce copper on each side of an insulator sheet or backing. In some embodiments, each electrode 2205-c can have a width between about 0.2 inch and about 0.3 inch, and preferably 0.25 inch. In some embodiments, the spacing between adjacent electrodes 2205-c can be between about 0.25 inch and about 0.4 inch, and preferably 0.3 inch. The length of the electrodes 2205-c can vary. In some embodiments, the electrodes 2205-c positioned interiorly are longer than the electrodes 2205-c along the sides of the operative member 160-d. In various embodiments, the electrodes 2205-c along the central axis have the greatest length, and the length decreases moving towards the sides of the electrode array 2505. In some embodiments, electrode array 2505 defines a rounded treatment surface. The distal edge 2510 and proximal edge 2515 of the electrode array 2505 can be curved.

[0230] The operative member 160-d can include an array of electrodes 2505 on an insulator material 2405-a with an adhesive backing. The electrodes 2205-c can extend in a longitudinal direction on a top surface of the insulator material 2405-a. As shown in **FIG. 17B**, the back side of the insulator material 2405-a may include a first bus 2215-c and a second bus 2220-c in accordance with various embodiments. As shown in **FIG. 17C**, each of the electrodes 2205-z on the top surface can be connected to one of the first bus 2215-c or the second bus 2220-c by vias 1650-c in accordance with various embodiments. The first bus 2215-c and the second bus 2220-c can be formed of copper over the insulator material 2405-a. The first bus 2215-c and second bus 2220-c can have a hatched pattern.

[0231] The operative member can include solder pads 2520. In some embodiments, the operative member 160-d includes two pads 2520 for the positive and negative terminals. One may appreciate that the operative member 160-d may include one, two, or more pads and

buses depending on the configuration. For example, the operative member 160-d may be configured as a monopolar electrode array with a single bus line.

[0232] With reference to **FIG. 17D**, the operative member 160-d can includes line 2415-a for connecting the first bus 2215-c to a positive terminal and a line 2420-a for connecting the second bus 2220-c to ground in accordance with various embodiments. The lines 2415-a and 2420-a can be connected to the first bus 2215-c and the second bus 2220-c, respectively, by the pads 2520. Pads 2520 can be shaped and positioned for inserting into cut-outs in an expandable support device.

[0233] Although described in terms of an electrode array for RF ablation, one may appreciate that the operative members suitable for use embodiments described herein may be configured for administering other forms of therapy or diagnosis. For example, the techniques described above may be applied to form an antenna for microwave ablation. In another example, the operative member may include sensor elements overlaying the expandable support device. Monopolar RF configurations can also be used in some embodiments. Some embodiments may utilize bipolar RF configurations.

[0234] In various embodiments, the operative members described herein are ablation devices, and in some embodiments, RF ablation devices. In various embodiments, the operative members described herein are configured for thermal ablation. In some embodiments, the operative members described herein are configured to heat surrounding tissue by resistive heating or conduction. Embodiments of operative members described herein can be configured to treat or diagnose the surrounding tissue by other modalities.

[0235] In various embodiments, the operative members described herein are configured for ablation of abnormal tissue in the esophagus. In various embodiments, the operative members described herein are configured for ablation of abnormal tissue in the lower esophageal sphincter. In various embodiments, the operative members described herein are configured for ablation of Barrett's esophagus and/or pre-cancerous tissue in the epithelium without injuring the underlying muscalaris. In various embodiments, the operative members described herein are configured for use in a variety of body lumens and organs including, but not limited to, the gastrointestinal (GI) tract (e.g. the esophagus or duodenum), the alimentary tract, the digestive system (e.g. the bile duct), the cardiovascular system, the endocrine system (e.g. the pancreas), and the respiratory system.

[0236] In various embodiments, the operative members described herein are configured to ablate tissue to a predetermined depth. In various embodiments, the operative members described herein are configured to ablate mucosal tissue without injuring the underlying submucosal tissue. In various embodiments, the operative members described herein are configured to ablate mucosal tissue without injuring the underlying muscalaris. In various embodiments, the operative members described herein are configured to apply the appropriate level of energy to the tissue to achieve an ablation depth that does not extend beyond the submucosa layer of the esophagus. In various embodiments, the operative members described herein are configured to control the depth of ablation to the epithelium. In various embodiments, the operative members described herein are configured for superficial ablation. For example, various embodiments of an operative member may be configured to sear the tissue surface. In various embodiments, the operative members described herein are configured to deliver sufficient energy to initiate regrowth of tissue, for example, in a mucosal layer.

[0237] Controlling the depth of ablation is based on several factors such as power and treatment time. In various embodiments, the power source activates the electrode array with sufficient power and for a sufficient amount of time to ablate tissue to a predetermined depth. In an exemplary embodiment, the power source activates the electrode array with sufficient power and for a length of time necessary to deliver between about 1 J/sq.-cm and about 50 J/sq.-cm, between about 10 J/sq.-cm and about 40 J/sq.-cm, between about 15 J/sq.-cm and about 105 J/sq.- cm, between about 25 J/sq.-cm and about 105 J/sq.-cm, between about 30 J/sq.-cm and about 105 J/sq.-cm, between about 35 J/sq.-cm and about 105 J/sq.-cm, or between about 40 J/sq.-cm and about 105 J/sq.-cm. Other energy per unit area amounts may be utilized in some embodiments.

[0238] In various embodiments, the operative member is configured to deliver between about 10 Watts/sq.-cm and about 50 Watts/sq.-cm, between about 10 Watts/sq.-cm and about 40 Watts/sq.- cm, between about 10 Watts/sq.-cm and about 30 Watts/sq.-cm, between about 15 Watts/sq.-cm and about 30 Watts/sq.-cm, or between about 15 Watts/sq.-cm and about 40 Watts/sq.-cm. Other energy per unit area amounts may be utilized in some embodiments.

[0239] In various embodiments, the power generator is configured to activate the electrodes for between about 10 ms and about 5 minutes, between about 100 ms and about 1 minute, between about 100 ms and about 30 seconds, between about 10 ms and about 1 second,

between about 100 ms and about 1 second, or between about 300 ms and about 800 ms. In various embodiments, the power generator is configured to activate the electrodes for less than 1 second, less than 500 ms, or less than 300 ms. In some embodiments, the operative member is configured to deliver about 40 W/sq.-cm for a duration of about 300 ms to about 800 ms. In some embodiments, the operative member is configured to deliver between about 12 J/sq.-cm to about 15 J/sq.-cm for a duration of about 300 ms to about 800 ms. Other energy per unit area amounts and time amounts may be utilized in some embodiments.

[0240] In some embodiments, a guide assembly is provided for delivering and positioning an expandable support device and an operative member disposed thereon through a working channel and to a target treatment area. The guide assembly can include one or more guide shafts. Each guide shaft can generally include a relatively long and thin cylindrical body. Each guide shaft can include a proximal end and a distal end. In some embodiments, the distal end of one guide shaft is coupled with the expandable support device and the proximal end of one guide shaft is coupled with a power source.

[0241] The material of each guide shaft is generally not limited. Suitable materials for the guide shafts include, but are not limited to, metals and thermoplastics. The material of the guide shafts can be rigid, flexible, or include sections of both rigid and flexible material. In various embodiments, the guide shafts are formed of the same material as the expandable support device. One of the guide shafts may be integrally formed with the expandable support member or formed as a separate piece. When the guide shaft is a separate piece from the expandable support member, the guide shaft can be coupled with the expandable support device using any suitable material or technique, such as, for example, by welding or adhesives.

[0242] In various embodiments, the guide shafts have a uniform thickness. In various embodiments, the guide shafts have a thickness of about 0.01 inch, about 0.012 inch, or about 0.002 inch. In various embodiments, the guide shafts have a thickness of 0.012 inch +/- 0.0005 inch.

[0243] With reference to **FIG. 18A**, a guide assembly 110-h is shown in accordance with various embodiments. The guide assembly 110-h can include two separate shaft sections through which one or more transmission wires 3105 can pass. The first shaft 112-a (which can also be referred to as a distal shaft) and the second shaft 114-a (which can also be

referred to as a proximal shaft or the power source side shaft) are separated by a break 140-a. The first shaft 112-a can extend from the break 140-a up towards the expandable support device coupled with the distal end of the guide assembly 110-h. The second shaft 114-a extends back from the break towards the power source used to supply power to the expandable support device. The first shaft 112-a and the second shaft 114-a can be configured to axially move an expandable support device and an operative member disposed thereon, such as axially through a working channel.

[0244] The one or more transmission lines 3105 can be configured for operatively connecting an operative member to a power source. Accordingly, in some embodiments, the transmission lines 3105 have a proximal end coupled with a power source and a distal end coupled with an operative member on an expandable support device while extending through both the second shaft 114-a and the first shaft 112-a of the guide assembly 110-h. In this manner, the first shaft 112-a and the second shaft 114-a enclose at least a portion of the one or more transmission lines 3105. In some embodiments, the one or more transmission lines 3105 are exposed at the break 140-a due the first shaft 112-a being separated from the second shaft 114-a. In some embodiments, the transmission lines are electrical wires.

[0245] In some embodiments, the first shaft 112-a can be configured such that it is capable of rotating independently of the second shaft 114-a. This can be due at least in part to the break 140-a separating the first shaft 112-a from the second shaft 114-a. In some embodiments, the second shaft 114-a is coupled at a proximal end to the power source. The break 140-a between the first shaft 112-a and the second shaft 114-a can help to ensure that that the coupling between the power source and second shaft 114-a does not impede the transmission of torque from the first shaft 112-a to the expandable support device.

[0246] In some embodiments, the separation of the first shaft 112-a from the second shaft 114-a allows the first shaft 112-a to be configured for transmitting torque to the expandable support member and any operative member disposed thereon. In some embodiments, this is accomplished by coupling at least a portion of the first shaft 112-a to at least a portion of the expandable support device and/or the transmission lines 3105 so that rotation of the first shaft 112-a is transmitted to the expandable support device and/or transmission lines 3105. When the first shaft 112-a is coupled with the transmission line 3105, the transmission lines 3105 can be coupled with the first shaft 112-a at the distal end of the first shaft 112-a while being decoupled with the first shaft 112-a at the proximal end of the first shaft 112-a. This can help

to ensure that the first shaft 112-a is configured to transmit torque to the expandable support device and/or the transmission lines 3105.

[0247] With reference to **FIG. 18B**, in some embodiments, the break 140-a can be covered by a protection element 165-a. The protection element 165-a can be made of any suitable material and can have any shape and/or size that allows it to cover the break 140-a and protect the transmission lines 3105. As shown in FIG. 18B, the protection element 165-a can have a generally cylindrical shape, although other shapes can be used. In some embodiments, the protection element 165-a is coupled with the first shaft 112-a and is sufficiently long to extend over the break 140-a and a portion of the second shaft 114-a. In some embodiments, the protection element 165-a is decoupled from the second shaft 112-a so that the first shaft 112-a can continue to rotate independently of the second shaft 114-a. The coupling of the protection element 165-a to the first shaft can allow the protection element to be configured to transmit rotational motion to the first shaft 112-a. In this manner, the protection element 165-a can also serves as a torque handle that aids a user in rotating the first shaft 112-a to transmit torque to the expandable support device.

[0248] FIG. 18B also shows a working channel 115-g into which the first shaft 112-a can be inserted. In some embodiments, an expandable support device located at the distal end of the first shaft 112-a is inserted into the working channel 115-g in a collapsed configuration, and the guide assembly 110-h is used to move the expandable support device through the working channel 115-g. In some embodiments, the first shaft 112-a will be the predominant portion of the guide assembly 110-h that enters the working channel 115-g. The protection element 165-a can serves as a stopper which prevents further insertion of the guide assembly 110-c into the working channel 115-g.

[0249] The first shaft 112-a can be made from a flexible material, which will allow the first shaft 112-a to move more readily through a working channel 115-g having tortuous path. In some embodiments, the flexible material used for the first shaft 112-a is stainless steel, such as a stainless steel cable material. In some embodiments, first shaft 112-a includes two or more concentric layers, with each layer being made from two or more stainless steel wires wound around a common axis.

[0250] **FIG. 19A** and/or **FIG. 19B** illustrate a guide assembly 110-i in accordance with various embodiments. The guide assembly 110-i is similar in many respects to the guide

aseembly 110-h illustrated in FIGs. 18A and/or 18B. The guide assembly 110-i can include a first shaft 112-b, a second shaft 112-b, and a protection element 165-b located between the first shaft 112-b and the second shaft 114-b. In some embodiments, the first shaft 112-b is configured to extend through a working channel and transmit torque to an expandable support device coupled with the distal end of the first shaft 112-b.

[0251] The protection element 165-b can be positioned between the first shaft 112-b and second shaft 114-b. As shown in FIG. 19A and 19B, the protection element 165-b can include a knurled surface to aid in manipulation by a user. First shaft 112-b can be configured to transmit torque applied to protection element 165-b to an expandable support device to cause rotation. In various embodiments, the first shaft 112-b is configured to transmit up to 5 in.-oz. of torque, and preferably up to 9 in.-oz. of torque.

[0252] The second shaft 114-b can include a tubular body through which an one or more transmission line can be routed to a power source 105-c. The second shaft 114-b may also be configured for receiving other connections. The second shaft 114-b may be formed of plastic such as nylon, a thermoplastic elastomer such as Pebax® (polyether block amide), or polytetrafluoroethylene (PTFE). The second shaft 114-b can be elongated to allow the power source 105-c to be positioned remotely from the patient receiving treatment. In various embodiments, the first shaft 112-b and the second shaft 114-b can be transparent to enable visual inspection by the user. For example, the internal components may include markers or indexes to enable the user to visually verify the axial position of the expandable support device when it is inserted into the patient's body.

[0253] In some embodiments, the transmission line and/or other internal components extend through the entire guide assembly 110-i. In various embodiments, the components are separated into two sections provided with first shaft 112-b and second shaft 114-b alike.

[0254] In some embodiments, the second shaft 114-b is not attached to the internal components such as the transmission wires. This can allow the second shaft 114-b to rotate independently of the internal components. In practice, the second shaft 114-b can be attached to a fixed device like the power source 105-c whereas the internal wires rotate with the expandable support device. Thus, the second shaft 114-b can house the wires without twisting during operation. As may be appreciated by one of skill in the art, the wires are

capable of twisting to a larger degree than the second shaft 114-b. This can allow the second shaft 114-b to be rotated to a significant degree without buckling, crimping, or binding.

[0255] In some embodiments, the second shaft 114-b generally does not play a role in movement of the expandable support device at the distal end of the guide assembly 110-i. Instead, the second shaft 114-b is simply "along for the ride" to house the internal components. The second shaft 114-b can be rigid or flexible.

[0256] First shaft 112-b can be configured to transmit torque to the expandable support device to cause rotation. The first shaft 112-b can be sufficiently flexible to allow it to move through a tortuous working channel, but can also have sufficient rigidity to transmit axial force to the expandable support device. Torque from the protection element 165-b can be transmitted through the first shaft 112-b to the expandable support device thereby causing rotation of the expandable support device. Similarly, an axial force on the protection element 165-b can cause the first shaft 112-b to push on the expandable support device and move it axially.

[0257] The first shaft 112-b can be coupled with expandable support device at a distal end and a protection element 165-b at a proximal end. In some embodiments, the first shaft 112-b also includes a rigid section 3205 at the proximal end. In some embodiments, the rigid section 3205 can serve as a fastener between the protection element 165-b and the first shaft 112-b. The rigid section 3205 can connect the first shaft 112-b to the protection element 112-b rotationally and axially. In some embodiments, rigid section 3205 is a stainless steel hypotube connected to the protection element 165-b. The rigid section 3205 can be crimped to fix the protection element 165-b to the first shaft 112-b. The rigid section 3205 can maintain the alignment of the guide assembly 110-i in the proximal end of a working channel and ensures good torque transfer from the protection element 165-b to the first shaft 112-b. The rigid section 3205 can be configured to be inserted into a working channel. In some embodiments, the rigid section 3205 has a length of about 2 cm. When the rigid section 3205 is included, the first shaft 112-b can be considered to include a rigid section 3205 and a flexible section, with the flexible section being positioned between the expandable support device having an operative member disposed thereon and the rigid section 3205. An introducer may also be used in conjunction with the rigid section 3205 to aid in alignment and movement within the working channel.

[0258] Unlike second shaft 114-b, first shaft 112-b can be rotationally fixed to the transmission wires and the protection element 165-b. In other words, rotation of protection element 165-b can cause the first shaft 112-b to rotate which in turn causes the expandable support device to rotate. At the same time, the wires can rotate based on rotation of the expandable support device. However, second shaft 114-b can remain fixed to the generator while the wires twist internally in some cases. Thus, the first shaft 112-b can be torqueable with the protection element 165-b but the second shaft 114-b is not. Put another way, the first shaft 112-b and the second shaft 114-b can be rotationally decoupled from each other.

[0259] The transmission lines extending through the first shaft 112-b and the second shaft 114-b can be relatively flexible. In some embodiments, the transmission lines are generally not at risk of kinking when the first shaft 112-b is rotated. The transmission lines can simply twist and turn inside the second shaft 114-b. In some embodiments where the transmission lines are only fixed to a distal end of the first shaft 112-b, the transmission lines may be free to also rotate within the first shaft 112-b.

[0260] In various embodiments, guide assembly 110-i is configured to reduce torquing and twisting of the transmission line. The transmission lines may include a proximal end and a distal end that are decoupled from each other. For example, protection element 165-b may include a mechanical device for decoupling rotation of the transmission wires extending distally from the protection element 165-b from the transmission wires at the proximal end. Suitable devices for decoupling rotation of the transmission wires include, but are not limited to, a bearing, a bushing, a stator and core assembly, and the like.

[0261] In various embodiments, protection element 165-b is configured as a quick connector. As may be understood by one of skill from the description herein, the first shaft 112-b and the second shaft 114-b can be configured as independent assemblies, each with their own set of transmission lines. Thus, the protection element 165-b can be configured to easily connect and disconnect to the first shaft 112-b and the second shaft 114-b. This may beneficially improve ease-of-use during surgery. In various embodiments, the first shaft 112-b is disposable and the second shaft 114-b can be re-used.

[0262] Suitable materials for the first shaft 112-b include, but are not limited to, thermoplastics and stainless steel. In various embodiments, the first shaft 112-b is Nylon 12 with a 0.002" x 0.005" stainless steel braid. In various embodiments, the first shaft 112-b is a

0.002" x 0.005" tube formed of Pebax®. In some embodiments, the first shaft 112-b is made of a stainless steel coil shaft. The protection element 165-b may be formed of thermoplastics such as acrylonitrile butadiene styrene (ABS) and other materials. In various embodiments, the second shaft 112-b includes a lubricious liner (e.g. PTFE or FEP) to aid with assembly and rotation of the transmission lines. In various embodiments, transmission lines are a bundle of one or more conductive wires.

[0263] In some embodiments, the guide assembly further includes a handle element. The handle element can be coupled with a first shaft to assist in transmitting torque to the expandable support device and/or to move the expandable support device in an axial direction. In some embodiments, the handle element includes a body and a channel extending through the body. The first shaft can pass through the channel to thereby couple the handle element to the first shaft. In some embodiments, the handle element is configured such that the first shaft can move through the channel. The handle element can also include a rigid section extending off a distal end of the handle element through which the first shaft can also pass. The rigid section on the handle element can be similar in many respect to the rigid section 3205 described above. The rigid section extending from the distal end of the handle element can be at least 2 cm long and can be configured for insertion into a working channel.

[0264] In some embodiments, the handle element is positioned at the proximal end of the first shaft. The handle element can be configured to extend over a portion of the second shaft so that it serves as a protection element for any transmission wires that may be exposed due to a break between the first shaft and the second shaft.

[0265] With reference to **FIG. 20**, a handle element 3305 is shown in accordance with various embodiments. The handle element 3305 can have a generally elongate shape and can be coupled with a first shaft 112-c by virtue of the first shaft 112-c passing through a channel in the body of the handle element 3305. The handle element 3305 can be configured to slide along the first shaft 112-c. In some embodiments, the handle element includes a locking mechanism 3310. The locking mechanism 3310 can be configured to lock the handle element 3305 at a position along the length of the first shaft 112-c. This can be achieved using any suitable locking mechanism 3310. In some embodiments, the locking mechanism 3310 is fixed to the handle element 3305 such that when the locking mechanism 3310 is engaged against the first shaft 112-c (for example, by screwing the locking mechanism 3310 down against first shaft 112-c until the first shaft 112-c is pinched between the locking

mechanism 3310 and the handle element 3305), the handle element 3305 is locked into position by virtue of being fixed to the locking mechanism 3310.

[0266] In some embodiments, the handle element 3305 is provided to control the length of the first shaft 112-c that can be inserted into a working channel. The handle element 3305 can serve as a stopper. When the handle element 3305 is moved towards the distal end of the first shaft 112-c and is locked in place, the handle element 3305 can shorten the amount of first shaft 112-c that can pass into the working channel. When the handle element 3305 is moved towards the proximal end of the first shaft 112-c, the handle element 3305 can increase the amount of first shaft 112-c that can pass into the working channel. In operation, a practitioner can insert the expandable support and the first shaft 112-c into a working channel until the expandable support device emerges from the distal end of the working channel and is brought close to the target treatment area. The handle element 3305 can then slide along the first shaft 112-c towards the distal end until the handle element 3305 rests against entry of the working channel. By locking the handle element 3305 in place at that position, the practitioner can effectively set the length of the first shaft 112-c and ensure that the expandable support device will stay in the desired location near the target area so long as the handle element 3305 is resting against the working channel entry.

[0267] FIG. 20 shows that the handle element 3305 can also include a rigid section 3205-a at the distal end that is configured to be inserted into a working channel and help align the handle element 3305. The rigid section 3205-a may be similar or identical to the rigid section 3205 described above. FIG. 20 also shows that the handle element 3205 can be used in a conjunction with a protection element 165-c. The protection element 165-c can be similar or identical to the protection element 165-b described above. The protection element 165-c can be coupled with the first shaft 112-c and can extend over a portion of the second shaft 114-c to protect exposed transmission lines at the break. The protection element 165-c can also be provided to prevent the handle element 3305 from sliding over the second shaft 114-c.

[0268] With reference to **FIG. 21**, a handle element 3405 in accordance with various embodiments is shown. The handle element 3405 can have a generally elongate shape and can be coupled with a first shaft 112-d by virtue of the first shaft 112-d passing through a channel in the body of the handle element 3405. The handle 3405 can include an axial path 3410 along which a locking mechanism 3415 can slide towards the distal or proximal end of the handle element 3405. The locking mechanism 3415 can be configured to be secured to a

portion of first shaft 112-d located within the channel of the handle element 3405. The locking mechanism can also be locked in place anywhere along the axial path 3410. Accordingly, when in an unlocked position, the locking mechanism 3415 can move along the axial path 3410, but when in the locked position, the locking mechanism 3415 is fixed to the handle element 3405 and cannot slide along the axial path 3410.

[0269] Whether in a locked or unlocked position, the locking mechanism 3405 can remain secured to a portion of the first shaft 112-d. In this manner, the locking mechanism can move the first shaft 112-d in and out of the handle element 3405 when in the unlocked position, and can hold the first shaft 112-d in place when in the locked position. Thus, the handle 3405 is configured to adjust and control the amount of first shaft 112-d extending out of the handle element 3405 and, correspondingly, the length of the first shaft 112-d that can be fed through the working channel. For example, when the handle element 3405 is positioned against the entry of the working channel, the locking mechanism 3415 can be moved towards the proximal end of the handle element 3405 to shorten the length of the first shaft 112-d and pull the expandable support member back towards the working channel. The locking mechanism 3415 can also be moved towards distal end of the handle element 3405 to increase the length of the first shaft 112-d and move the expandable support member closer to the target treatment area. Once a desired position is achieved for the expandable support device, the locking mechanism 3415 can be locked against the handle element 3405 to fix the position of the expandable support device.

[0270] In some embodiments, the guide assembly is coupled with the expandable support device using a torque member. The torque member can be a structure located at the distal end of the first shaft, a structure located at a proximal end of the expandable support device, or a combination of the two. The torque member is generally configured to ensure that torque generated by rotation of first shaft is transmitted to expandable support device. In some embodiments, the guide assembly and/or the torque member are configured such that approximately one to one rotation movement is achieved between the guide assembly and the torque member.

[0271] With reference to **FIG. 22**, a distal plug 3505 in accordance with various embodiments is shown. The distal plug 3505 may include a structure protruding from the proximal end of the expandable support device 120-s. The distal plug 3505 can include a ribbed portion which is inserted into the distal end of the first shaft of the guide assembly.

The distal plug 3505 also may include a cone shaped section 3510 that creates a face edge 3515. This face edge 3515 can rest against the distal edge of the first shaft and is configured to be wider than the diameter of the distal end of the first shaft so that the cone shaped section 3510 cannot be inserted into the first shaft. The distal plug 3505 may be secured within the first shaft by conventional techniques such as glue, adhesives, or interference fit.

[0272] **FIG. 23** shows a torque member 3605 in accordance with various embodiments. The torque member 3605 may be configured for transmitting torque between the guide assembly and a locking member extending from a distal end of an expandable support device. The torque member 3605 can be rigid for enabling application of torque to rotate the expandable support device. The torque member 3605 may include a solid, rigid body and a slot 3610. The slot 3610 may have a thickness corresponding to the thickness of a locking member extending from a distal end of the an expandable support device such that the locking member can be securely received within the slot. In various embodiments, the torque member 3605 can have a width equal to or less than the diameter of the guide assembly at a distal end. The torque member 3605 can have a thickness slightly less than a width of the guide assembly at the distal end. Similarly, the locking member can have a thickness equal to or less than a width/diameter of the working channel. In this manner, the locking member may not need to fold or collapse during withdrawal and can be relatively rigid to enable torque transmission. As used herein, "thickness" refers to a direction into the page and "width" refers to a direction from left to right.

[0273] **FIG. 24A** and/or **FIG. 24B** show another torque member 3705 in accordance with various embodiments, which is configured for transmitting torque between the guide assembly and a locking member extending from a proximal end of an expandable support device. The torque member 3705 can be formed of a rigid material such as a thermoplastic. In some embodiments, the torque member is formed of polycarbonate.

[0274] The torque member 3705 can include a body 3710 having a proximal end 3715 and distal end 3720. The torque member 3705 can be shaped like a peg or a rod with a rounded surface along its length.

[0275] Distal end 3720 may be enlarged and may define a fitting portion 3725 of the torque member 3705. The fitting portion 3725 can extend from the distal end 3720 to a point between the distal end 3720 and proximal end 3715. The fitting portion 3725 can have a

beveled outer surface with a distal edge having a smaller diameter than a proximal edge. The proximal edge of the fitting portion 3725 can include a breaking edge 3730 and a flat surface 3735. The fitting portion 3725 can be configured to be inserted into distal end of a first (i.e., distal) shaft such that breaking edge 3730 abuts a distal end of a first shaft. In various embodiments, the body 3710 has a shape and dimensions corresponding to the inner wall of the first shaft. In some embodiments, the distal and proximal edges of fitting portion 3725 are rounded to reduce the risk of damage, such as perforating, other components. The torque member 3705 may be secured within the first shaft by conventional techniques such as glue, adhesives, or interference fit.

[0276] The torque member 3705 can include a slot 3740 that extends the entire length of the torque member 3705. In various embodiments, the torque member 3705 has a length corresponding to the length of a locking member extending from the distal end of an expandable support device. The slot 3740 can have a width that corresponds to a width of the locking member. The width of the slot 3740 can be less than a width of the torque member 3705. The slot 3740 may be positioned at a distance above a centerline of the torque member 3705.

[0277] In some embodiments, the torque member 3705 has a length of about 0.2 inch. The torque member 3705 can have a width (diameter) of about 0.072 inch, and the fitting portion 3725 can have a maximum width (diameter) of about 0.09 inch. The beveled face of fitting portion 3725 can form an angle of about 15° from a longitudinal axis of the torque member 3705. The fitting portion 3725 can extend from an end of the torque member 3705 and have a length of about 0.039 inch. The slot 3740 can have a width of about 0.056 inch. A bottom of the slot 3740 can be positioned about 0.011 inch above a centerline of the torque member 3705. Other embodiments may include different dimensions.

[0278] The slot 3740 can be configured to allow interlocking of the torque member 3705 with a locking member extending from a distal end of a expandable support device. Referring to FIG. 12A, a locking member 1280 in accordance with various embodiments is illustrated. A throat section 1285 of the locking member 1280 can be held within the slot 3740 and locking section 1290 can be locked against a proximal end 3715 of the torque member 3705.

[0279] With reference to **FIG. 25A** and/or **FIG. 25B**, an introducer 2605 can be used in order to aid with the introduction of an expandable support device into a working channel, such as an endoscope. The introducer 2605 can include a conical section 2610 and a cylindrical section 2615, with a channel extending through both sections. The cylindrical section 2615 can have a uniform outer diameter which can be less than the diameter of an opening of a working channel such that the cylindrical section 2615 can be inserted into the opening of the working channel. In some embodiments, the outer diameter of the cylindrical section 2615 is smaller than the diameter of the working channel opening by only a small degree such that the cylindrical section 2615 fits flushly with the opening of the working channel when inserted in the working channel opening. The conical section 2610 can have a first diameter and a second diameter. The first diameter can be approximately the same as the diameter of the cylindrical section 2615. The second diameter can be larger than the first diameter, and the diameter of the conical section 2610 can increase from the first diameter to the second diameter to thereby form a cone shape. In some embodiments, the cylindrical section 2615 and the conical section 2610 are coaxially aligned.

[0280] When inserted in the working channel opening, the introducer 2605 can provide a wide mouth for inserting an expandable support device into a working channel. More specifically, the second diameter of the conical section 2610 can provide a wider area than the opening of the working channel to thereby make it easier for an operator to guide an expandable support device into a working channel.

[0281] In some embodiments, the introducer 2605 can be used in conjunction with an docking member 2620. In some embodiments, the docking member 2620 is part of a a control element and/or protection element, such as protection element 165 of FIG. 1B. In some embodiments, the docking member 2620 is a separate device from the protection element, but can be coupled with the protection element. The docking member 2620 can have a first end 2625 and a second end 2630, with a channel extending through the docking member 2620 from the first end 2625 to the second end 2630. The first end 2625 can include a coupling mechanism configured for coupling the introducer 2605 with the docking member 2620. In some embodiments, the second diameter of the conical section 2610 includes a coupling mechanism that mates with the coupling mechanism on the first end 2625 of the docking member 2620. Any suitable coupling mechanism can be used to couple the introducer 2605 to the docking member 2620, including, but not limited to, a friction fit, male

and female threading, or clips as shown in FIG. 25A. With reference to FIG. 25B, the introducer 2605 is shown coupled with the docking member 2620.

[0282] With reference to **FIG. 26A** and/or **FIG. 26B**, the docking member 2605 forms a part of the protection element 165-d such that the docking member 2605 and the protection element 165-d are a unitary body. The docking member 2605 can form the distal end of the protection element 165-d and can provide the protection element 165-d with the coupling mechanism used to couple the introducer 2605 to the protection element 165-d. As shown in FIG. 26A, the introducer 2605 can be inserted into an opening of a working channel 115-h and used to aid in the insertion of an expandable support device into the working channel 115-h. As shown in FIG. 26A, an expandable support device has been inserted into the working channel 115-h and a portion of the guide assembly 110-j remains outside of the working channel 115-h.

[0283] With reference to FIG. 26B, the introducer 2605 can be moved away from the working channel 115-h and towards the docking member 2620 of the protection element 165-d. The introducer 2605 generally slides along the guide assembly 110-j by virtue of the guide assembly 110-j passing through the channel of the introducer 2605. When the introducer 2605 reaches the docking member 2620 of the protection element 165-d, the coupling mechanism of each device can be used to couple the introducer 2605 to the protection element 165-d. In this manner, the introducer 2605 can be fixed to a location along the guide assembly 110-j and prevented from sliding back and forth along the guide assembly 110-j due to the protection element 165-d being fixed to the guide assembly 110-j as described in greater detail above. As a result, the introducer 2605 may not disturb the operator or interfere with manipulation of the expandable support device via the guide assembly 110-j and/or the protection element 165-d.

[0284] The manner in which the above described components of the treatment system are manufactured is generally not limited. With reference to FIGs. 27A-F, a method of constructing an operative member on an expandable support device and attaching the expandable support device to a flexible support in accordance with various embodiments is shown. In **FIG. 27A**, an expandable support device 120-t, such as a solid elastomeric body in the shape of a paddle is provided. In **FIG. 27B**, a layer of metallic layer 2705 is disposed on top of the expandable support device using any known technique. As shown in **FIG. 27C**, the metallic layer 2705 is then etched to form an operative member 160-e (for example, a

pattern of electrodes) using any known technique, such as etching using masks. **In FIG. 27D**, a flexible support 155-n is provided, such as a nitinol flexible support. In **FIG. 27E**, an adhesive 2710, such as a silicone adhesive, is provided on a surface of the flexible support 155-n. In **FIG. 27F**, the combination of the expandable support device 120-t and the operative member 160-e is disposed on the adhesive 2710, and time and/or pressure is supplied to secure the combination of the expandable support device 120-t and the operative member 160-e to the flexible support 155-n. Other methods of constructing an operative member may also be utilized in some embodiments.

[0285] FIGs. 28A-28E are sequential views of a method of fabricating a patterned solid support and providing an operative member on top of the patterned solid support in accordance with various embodiments. **FIG. 28A** shows a solid support material 2805 for forming a patterned solid support in accordance with various embodimetns. The solid support material 2805 can be a solid layer of material formed from a shape memory metal alloy such as nitinol. The solid support material 2805 may be formed into a thin, generally planar sheet using known processes such as cutting and rolling.

[0286] Next, solid support material 2805 is patterned using techniques to form patterned solid support 1605-l as shown in **FIG. 28B** in accordance with various embodiments. Examples of suitable patterning techniques include wet and dry etching, lithography, deposition, cutting, and milling. The patterning may define splines in the patterned solid support 1605-l. The patterning may be performed simultaneously with the rolling.

[0287] Next, the operative member is formed as shown in FIGs. 28C and 28D. In some embodiments, the operative member is a flexible circuit with RF electrodes. With reference to **FIG. 28C**, an insulator material 2405-a may be formed using conventional techniques. The exemplary insulator material 2405-a may be formed of a 0.001 inch adhesiveless polyimide sheet.

[0288] As shown in **FIG. 28D**, conductor material may then be added to the insulator material 2405-a and etched to form an operative member 160-f of electrodes. In this step, an adhesive 2815 can also applied to a back side to the insulator material 2405-a. For example, a thin acrylic and/or silicone sheet adhesive 2815 may be applied to the back of the insulator material 2405-a. In an exemplary embodiment, the pattern or electrodes is formed by laser etching.

[0289] **FIG. 28E** shows the assembled operative member 160-f and patterned solid support 1605-l in accordance with various embodiments. As shown in 18E, the electrodes of the operative member 160-f may be positioned over splines of the patterned solid support 1605-l. **FIG. 28E** may be a simplified and exaggerated view of the patterned solid support 1605-l and operative member 160-f. In practice, for example, the relative thicknesses of the layers will vary. Other embodiments may be utilized in fabricating a patterned solid support and providing an operative member on top of the patterned solid support.

[0290] One will appreciate from the description herein that other processes may be used in the fabrication process. For example, the fabrication process may include one or more coating processes. For example, the any portion of the operative member may be coated with a material such as a bioactive agent. In various embodiments, the expandable support device is coated with a biomolecule such as a pharmaceutical agent, nucleic acid, amino acid, sugar, or lipid. In various embodiments, the expandable support device is coated with an antihyperplastic agent such as an antithrombotic agent (e.g. heparin), an antiplatelet agents (e.g. aspirin, arachidonic acid, and prostacyclin), or an antibody to platelet-derived growth factors. Other suitable biological coating materials and additives include endothelial cells, stem cells, and cell growth factors. In various embodiments, the operative member is coated with a biocompatible plastic such as polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polypropylene, or poly(lactide). In various embodiments, the coating is only applied to the expandable support device so as not to interfere with functioning of the operative member. The expandable support device may be coated with a protective layer at any step in the process. For example, the expandable support device may be coated with a barrier layer to prevent oxidation or bioabsorption.

[0291] The fabrication process may also include other steps such as polishing, thermal treatments, and the like. The method of assembling the ablation device may implement other techniques and processes common in the material science, computer, and semiconductor fields. In some embodiments, the operative member is applied directly to the expandable support device via a conductive paint, molding, or laser etching.

[0292] Various embodiments of the systems described herein, including various embodiments of the individual components, can be used in a variety of ways. An embodiment of a particular method is described below.

[0293] In a first step, a clinician may perform a general clinical assessment. This assessment may include assessing the disease target, the type of necessary treatment, and the mode of delivery of the treatment device. Based on the clinical assessment, the clinician may select a proper treatment device. For example, a kit may be provided with multiple operative members configured for different treatments. The kit may include multiple ablation devices, each with differently-sized treatment surfaces, electrode configurations, treatment modalities, etc. The clinician may select a larger ablation device from the kit if the disease target is large. The kit may include an ablation device for treating larger or smaller circumferential sections of the body lumen, for example, a 90 degree section or a 120 degree section.

[0294] Once the operative member has been selected, the clinician may assemble the system. In one example, the kit includes a guide assembly, and multiple expandable support devices having varying operative members disposed thereon. The clinician may slide the selected expandable support device onto a distal end of the guide assembly and secures it in place. In another example, the kit may include multiple pre-assembled systems, each with a guide assembly and an attached expandable support device-operative member combo. In yet another example, the system may include an expandable support-operative member combo configured for treating a variety of disease targets (e.g. one-size-fits-all).

[0295] Once the system is prepared, the clinician may insert the expandable support device-operative member combo through a cap at a proximal end of a working channel, such as an endoscope. At this stage the endoscope may be already inserted and positioned in the patient's body. Typically the distal end of the endoscope is positioned adjacent a target site using conventional techniques.

[0296] The expandable support device-operative member combo may be inserted distal end first. The expandable support device-operative member combo can be pre-biased in the expanded configuration, in which case it may need to be collapsed to fit into the smaller working channel. The clinician may gently squeeze the expandable support device-operative member combo to collapse it for insertion. An introducer may be utilized in some cases. The rounded distal tip of the expandable support device-operative member combo may aid in rolling the device into the working channel. Once the distal end of the expandable support device-operative member combo is inserted, the clinician eases the rest of the expandable support device-operative member combo into the working channel.

[0297] Next, the clinician may push the expandable support device-operative member combo through working channel in the collapsed configuration using guide assembly. The clinician can axially move the expandable support device-operative member combo through the channel like a pipe cleaner using the guide assembly.

[0298] The length of the guide assembly may be matched to the length of the endoscope such that a protection element or handle element is located just proximal the endoscope cap at the entry of the endoscope when the expandable support device-operative member combo is fully inserted. The clinician may use an introducer to assist with insertion. The protection or handle element can be larger than the endoscope working channel and thus acts as an insertion stop. The protection or handle element can also act as a visual clue to the user of the expandable support device-operative member combo position at an opposite end. As the protection or handle element approaches the cap of the endoscope, the user can gauge the position of the expandable support device-operative member combo relative to the distal most end of the endoscope.

[0299] The guide assembly may be oversized to accommodate insertion into a variety of endoscopes and other delivery lumens. In various embodiments, exemplary an elongated rigid portion extending off the distal end of a protection or handle element can be used for axial positioning adjustment with various working channel lengths. As the user pushes and pulls the protection or handle element, the rigid section may remain positioned in the working channel. The rigidity of rigid section can allow for easier axial movement without binding the guide assembly on the inner wall of the working channel.

[0300] The system may be configured for use with a variety of lumens and treatment sites including, but not limited to, the gastrointestinal tract (GI tract), respiratory tract, ear canal, urinary tract, biliary system and bile duct, female reproductive system, organs in the chest (e.g., heart), epidural space, maxillary and face, and hand. The system may be configured for a variety of therapies and procedures using an endoscope including, but not limited to, esophagogastroduodenoscopy (e.g., esophagus, stomach, and duodenum); enteroscopy (e.g., small intestine); colonoscopy or sigmoidoscopy (e.g., large intestine and colon); magnification endoscopy; endoscopic retrograde cholangiopancreatography (ERCP), duodenoscope-assisted cholangiopancreatoscopy, or intraoperative cholangioscopy (e.g., bile duct); rhinoscopy (e.g., nose); bronchoscopy (e.g., lower respiratory tract); cystoscopy (e.g. urinary tract); rectoscopy (e.g. rectum); anoscopy (e.g., anus); proctoscopy; plastic surgery;

orthopedic surgery (e.g., hand surgery like endoscopic carpal tunnel syndrome and epidural space); endodontic surgery; gynoscopy, colposcopy (e.g., cervix), hysteroscopy (e.g., uterus), and falloscopy (e.g. fallopian tubes); laparoscopy; arthroscopy (e.g., interior of a joint); thoracoscopy and mediastinoscopy; amnioscopy; and fetoscopy. The system may be configured for a variety of therapies and procedures using other instruments including, but not limited to, dialysis, catheterization, angioplasty, balloon-based procedures (e.g., balloon septostomy and balloon sinuplasty), electrophysiology, monitoring (e.g., cardiac monitoring), drug delivery, and ear wax removal and treatment of cerumen impaction.

[0301] The endoscope, or other device that includes a working channel such as a catheter,can be inserted into the body using conventional techniques. For example, the endoscope may be inserted through a body orifice or through an incision site (e.g., laparoscopy). As may be appreciated from the description herein, the system may be used in conjunction with other instruments having a lumen such as a catheter, a robotic surgical instrument, and more.

[0302] Typically the working channel may be routed through a body cavity, duct, or vessel to a treatment site. The clinician optionally confirms the working channel distal end is properly positioned at the treatment site before deploying expandable support device-operative member combo. Once the position is confirmed, the clinician may proceed to deploy the expandable support device-operative member combo.

[0303] The system can allow for easy and accurate deployment of the expandable support device-operative member combo. The clinician may axially move the protection or handle element so expandable support device-operative member combo is moved out of a distal end of working channel. As the expandable support device-operative member combo extends outside the working channel, the expandable support device-operative member combo may be released from the working channel wall. The expandable support device-operative member combo self-expands from the collapsed configuration to the expanded configuration without any other significant action on the part of the clinician. The clinician may only need to move the protection or handle element close to the cap to ensure the expandable support device-operative member combo has been deployed at the distal end. The natural "spring" force of the expandable support device against the channel wall may also provide haptic feedback to the user to confirm deployment.

[0304] In various embodiments, the expandable support device-operative member combo is configured to self-expand to the expanded configuration once it unrestrained. In various embodiments, the expandable support device-operative member combo is substantially planar in the expanded configuration. In various embodiments, the plane of the expanded expandable support device-operative member combo is substantially parallel to the target treatment surface. In various embodiments, the plane of the expanded expandable support device-operative member combo is substantially parallel to the longitudinal axis of the guide assembly.

[0305] The torqueable guide assembly may allow the expandable support device-operative member combo to be rotated during or after expansion. The user can easily rotate the expandable support device-operative member combo by rotating, for example, the protection or handle element. Because first shaft is rotationally decoupled from second shaft, the expandable support device-operative member combo can be rotated independently of the second shaft. In an exemplary embodiment, the second shaft is attached to a stationary power source and control unit. Thus, the expandable support device-operative member combo can be rotated without developing kinks and rotational stress.

[0306] In various embodiments, after expansion, the user rotates the expandable support device-operative member combo so the treatment surface faces the tissue surface. The protection or handle element also allows a user to rotate the expandable support device-operative member combo after treatment to treatment other areas of tissue. The user may affect desired contact of expandable support device-operative member combo with the treatment site by deflecting the distal end of endoscope. The user may affect contact by deflecting the expandable support device-operative member combo using guide assembly. For example, the protection or handle element may be manipulated to extend the expandable support device-operative member combo away from an end of the endoscope and toward the treatment site.

[0307] Once the expandable support device-operative member combo is positioned at treatment site, the clinician can administer treatment using the expandable support device-operative member combo. The clinician may activate the power source to deliver energy through the operative member (such as through electrodes). In various embodiments, the power source performs a pre-programmed treatment protocol. In various embodiments, the power source is manually controlled.

[0308] After energy delivery, the clinician may determine whether follow-up treatment is necessary. If so, the treatment site can be prepared for follow-on treatment. For example, the treated tissue can be cleaned away with a cleaning device. The cleaning device may comprise a cleaner attached to the expandable support device-operative member combo. An example of a cleaning device for use with an expandable support device-operative member combo is disclosed in U.S. Patent Pub. No. 2009/0036886 to Utley et al., the entire contents of which is incorporated herein by reference for all purposes.

[0309] After treatment is complete, the clinician may pull on protection or handle element to retract the expandable support device-operative member combo. As the expandable support device-operative member combo is withdrawn, a portion of a tapered edge of expandable support device-operative member combo may contact the working channel. As the expandable support device-operative member combo is withdrawn further, the tapered edge may slide against the working channel wall such that a collapsing or rolling force is applied to the expandable support device. This force may cause the expandable support device, and consequently the operative member disposed thereon, to retract back into the collapsed configuration as it is pulled into the working channel.

[0310] The fully retracted expandable support device-operative member combo can be repositioned safely while in the working channel. The expandable support device-operative member combo device can then be repositioned at a second treatment location using the endoscope. Once the endoscope is repositioned, the expandable support device-operative member combo may be re-expanded out of an end of the endoscope as described above. Alternatively, the expandable support device-operative member combo can be repositioned through the working channel. For example, the clinician can move the expandable support device-operative member combo axially and/or rotate the expandable support device-operative member combo using protection or handle element. When treatment is complete, the expandable support device-operative member combo can be fully retracted and removed from the proximal end of the endoscope.

[0311] With reference to **FIG. 29**, a general method 2900 of using various embodiments of the systems and/or devices described herein is shown in accordance with various embodiments. For example, method 2900 may be implemented utilizing the various embodiments of system 100, expandable support element 120, guide assembly 110, operative member 160, and/or other devices and/or components. At block 2905, a therapy system is

provided. The system can include any embodiments of the therapy system described herein, including any embodiment of the individual components of the system described herein. Generally, the system will include an expandable support device, optionally with an operative member disposed thereon, a guide assembly to which the expandable support device is coupled at a distal end of the guide assembly, and a working channel configured for receiving the expandable support device and the guide assembly.

[0312] At block 2910, the expandable support device is inserted into a first end of the working channel. In some embodiments, the expandable support device is positioned in a collapsed position prior to inserting the expandable support device into the working channel. The distal end of the expandable support device can be rounded for further aid in the insertion of the expandable support device into the working channel.

[0313] At block 2915, the expandable support device is moved through the working channel until the expandable support device emerges out of a second end of the working channel. The guide assembly can be used to aid in the movement of the expandable support device through the working channel and out of the second end of the working channel. In some embodiments, the expandable support device will self transition into an expanded configuration after it passes out of the second end of the working channel.

[0314] After the expandable support device passes out of the working channel, an optional step can be performed wherein a portion of the guide assembly is rotated to provide torque to the expandable support device. In some embodiments, the first shaft portion of the guide assembly is rotated to provide torque to the expandable support device. The first shaft can be rotationally independent of the second shaft.

[0315] Other additional steps that can be performed after the method illustrated in FIG. 29 or any of the methods illustrated in FIGs. 30, 31, 32, 33, 34, and/or 35 can include deflecting the working channel and bringing the expandable support device (which may have an operative member disposed thereon) into contact with a target treatment area and/orproviding an apposition force via the expandable support device (and optionally the flexible support coupled with the expandable support device), and/or delivering energy to the target treatment area. Other steps may also be utilized in accordance with various embodiments.

[0316] With reference to **FIG. 30** a general method 2900 of using various embodiments of the systems and/or devices described herein is shown in accordance with various

embodiments. For example, method 3000 may be implemented utilizing the various embodiments of system 100, expandable support element 120, guide assembly 110, operative member 160, and/or other devices and/or components. Method 3000 may provide for delivering an expandable support device to a target treatment area. Method 3000 may be an example of method 2900 of FIG. 29.

[0317] At block 3005, an expandable support device configured for delivering an operative member through a working channel to a target treatment area may be provided. The expandable support device may include an elastomeric body configured to support an operative member. The elastomeric body may include: a proximal portion configured for coupling the elastomeric body with a guide assembly; a distal portion opposite the proximal portion; and a central axis extending between the distal portion and the proximal portion of the elastomeric body. The expandable support device may include one or more supports coupled with the elastomeric body and aligned parallel to the central axis, where at least one of the supports includes a superelastic material.

[0318] At block 3010, the expandable support device may be inserted into a first end of the working channel. At block 3015, the expandable support device may be moved through the working channel until the expandable support device passes out of a second end of the working channel.

[0319] Some embodiments of method 3000 may include a block 3020 where the expandable support device is torque and/or rotated utilizing the guide assembly. Some embodiments include positioning the expandable support device into a collapsed position prior to inserting the expandable support device into the working channel.

[0320] With reference to **FIG. 31** a general method 3100 of using various embodiments of the systems and/or devices described herein is shown in accordance with various embodiments. For example, method 3100 may be implemented utilizing the various embodiments of system 100, expandable support element 120, guide assembly 110, operative member 160, and/or other devices and/or components. Method 3100 may provide for utilizing a guide assembly for delivering an operative member to a target treatment. Method 3100 may be an example of method 2900 of FIG. 29.

[0321] At block 3105, a system including a guide assembly may be provided. The guide assembly may be configured for delivering and positioning the operative member through a

working channel to the target treatment area. The guide assembly may include: one or more transmission lines for operatively connecting the operative member to a power source; a first shaft enclosing at least a first portion of the one or more transmission lines, the first shaft configured for transmitting torque to the operative member; and a second shaft enclosing at least a second portion of the transmission lines. The first shaft and the second shaft may be configured to allow the first shaft to rotate independently of the second shaft. The system may include an expandable support device configured to deliver the operative member through the working channel to the target treatment area and coupled with a distal end of the guide assembly. The system may include an operative member coupled with the expandable support device.

[0322] At block 3110, the expandable support device may be inserted into a first end of the working channel. At block 3115, the expandable support device may be moved through the working channel utilizing the guide assembly until the expandable support device passes out of a second end of the working channel. In some embodiments, the expandable support device may be positioned into a collapsed position prior to inserting the expandable support device into the working channel. Some embodiments may include a block 3120 that may include rotating the first shaft of the guide assembly to provide torque to the operative member.

[0323] With reference to **FIG. 32,** a general method 3200 of using various embodiments of the systems and/or devices described herein is shown in accordance with various embodiments. For example, method 3200 may be implemented utilizing the various embodiments of system 100, expandable support element 120, guide assembly 110, operative member 160, and/or other devices and/or components. Method 3200 may deliver an operative member to a target treatment area. Method 3200 may be an example of method 2900 of FIG. 29.

[0324] At block 3205, a system may be provided that includes a guide assembly. The guide assembly may include: one or more transmission lines for operatively connecting an operative member to a power source; a flexible shaft enclosing at least a portion of the one or more power transmission lines, the first shaft configured for transmitting torque to the operative member; and a handle element comprising a body and a channel extending through the body and through which the flexible shaft passes, the handle element configured such that

the flexible shaft moves through the channel. The system may also include an operative member coupled with a distal end of the flexible shaft.

[0325] At block 3210, the operative member may be inserted into a first end of a working channel. At block 3215, the operative member may be moved through the working channel until the operative member passes out of the second end of the working channel. At block 3220, the handle element may be rotated to transmit torque to the operative member. Some embodiments may include positioning the operative member into a collapsed position prior to inserting the operative member into the working channel.

[0326] With reference to **FIG. 33,** a general method 3300 of using various embodiments of the systems and/or devices described herein is shown in accordance with various embodiments. For example, method 3300 may be implemented utilizing the various embodiments of system 100, expandable support element 120, guide assembly 110, operative member 160, and/or other devices and/or components. Method 3300 may deliver an ablation device to a target treatment area. Method 3300 may be an example of method 2900 of FIG. 29.

[0327] At block 3305, an ablation device may be provided. The ablation device may include a flexible circuit configured to transition between a collapsed configuration and an expanded configuration. The flexible circuit may include multiple parallel electrodes configured to collapse around an axis parallel to the multiple parallel electrodes.

[0328] At block 3310, the ablation device may be inserted into a first end of a working channel. At block 3315, the ablation device may be moved through the working channel until the ablation device passes out of a second end of the working channel. Some embodiments of method 3300 include positioning the flexible circuit into a collapsed configuration prior to inserting the ablation device into the working channel.

[0329] With reference to **FIG. 34,** a general method 3400 of using various embodiments of the systems and/or devices described herein is shown in accordance with various embodiments. For example, method 3400 may be implemented utilizing the various embodiments of system 100, expandable support element 120, guide assembly 110, operative member 160, and/or other devices and/or components. Method 3400 may deliver an expandable support device to a target treatment area. Method 3400 may be an example of method 2900 of FIG. 29.

[0330] At block 3405, an expandable support device may be provided. The expandable support device may include: a solid support member comprising a perimeter and superelastic properties; and multiple splines formed in a pattern interior to the perimeter of the solid support member and multiple voids between adjacent splines. A width and a spacing of the multiple splines may be configured to promote expansion of the support member between a collapsed configuration and an expanded configuration providing a substantially planar support surface.

[0331] At block 3410, the expandable support device may be inserted into a first end of a working channel. At block 3415, the expandable support device may be moved through the working channel until the expandable support device passes out of a second end of the working channel. In some embodiments, the expandable support device is positioned into a collapsed configuration prior to inserting the expandable support device into the working channel.

[0332] With reference to **FIG. 35,** a general method 3500 of using various embodiments of the systems and/or devices described herein is shown in accordance with various embodiments. For example, method 3500 may be implemented utilizing the various embodiments of system 100, expandable support element 120, guide assembly 110, operative member 160, and/or other devices and/or components. Method 3500 may deliver an expandable support device to a target treatment area. Method 3500 may be an example of method 2900 of FIG. 29.

[0333] At block 3505, an expandable support device configured for delivery through a working channel to a target treatment area may be provided. The device may include: an expandable support member configured for supporting an operative member, the support member comprising multiple splines having a width and a spacing selected to promote expansion of the support member between a collapsed configuration and an expanded configuration. A portion of the support member may define a substantially planar surface in the expanded configuration.

At block 3510, the expandable support device may be inserted into a first end of the working channel. At block 3515, the expandable support device may be moved through the working channel until the expandable support device passes out of a second end of the working

channel. Some embodiments include positioning the expandable support device into a collapsed position prior to inserting the expandable support device into the working channel.

[0334] The foregoing description provides examples, and is not intended to limit the scope, applicability or configuration of the various embodiments. Rather, the description and/or figures provide those skilled in the art with an enabling description for implementing various embodiments. Various changes may be made in the function and arrangement of elements.

[0335] Thus, various embodiments may omit, substitute, or add various procedures or components as appropriate. For instance, it should be appreciated that the methods may be performed in an order different than that described, and that various steps may be added, omitted or combined. Also, aspects and elements described with respect to certain embodiments may be combined in various other embodiments. It should also be appreciated that the following systems, methods, and devices, may individually or collectively be components of a larger system, wherein other procedures may take precedence over or otherwise modify their application.

[0336] The foregoing descriptions of specific embodiments have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise forms disclosed, and obviously many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to explain the principles of the various embodiments and its practical application, to thereby enable others skilled in the art to utilize the various embodiments with various modifications as are suited to the particular use contemplated. It is intended that the scope of the various embodiments be defined by the Claims appended hereto and their equivalents.

CLAIMS

1. An expandable support device configured for delivering an operative member through a working channel to a target treatment area, the device comprising:

an elastomeric body configured to support the operative member and promote expansion of the expandable support device between a collapsed configuration and an expanded configuration, the elastomeric body comprising:

a proximal portion configured for coupling the elastomeric body with a guide assembly;

a distal portion opposite the proximal portion; and

a central axis extending between the distal portion and the proximal portion of the elastomeric body; and

one or more supports coupled with the elastomeric body and aligned parallel to the central axis, wherein at least one of the supports comprises at least a highly elastic or superelastic material.

2. The expandable support device of claim 1, wherein the one or more supports comprises two supports arranged in a wishbone configuration.

3. The expandable support device of claim 1, wherein the one or more supports comprises three supports arranged in a trident configuration.

4. The expandable support device of claim 1, wherein the one or more supports consists of a single support extending along at least a portion of the central axis of the elastomeric body.

5. The expandable support device of claim 1, wherein at least one of the one or more supports is configured as at least a linear support or a longitudinal support.

6. The expandable support device of claim 1, wherein the superelastic material comprises nitinol.

7. The expandable support device of claim 1, wherein the highly elastic material comprises spring steel.

8. The expandable support device of claim 1, wherein at least one of the one or more supports coupled with the elastomeric body comprises polyimide.

9. The expandable support device of claim 8, wherein at least one of the one or more supports comprising polyimide is disposed at a periphery of the elastomeric body.

10. The expandable support device of claim 1, further comprising:
the operative member disposed on the elastomeric body.

11. The expandable support device of claim 10, wherein the operative member is an ablation device.

12. The expandable support device of claim 1, further comprising:
a protective padding encompassing a distal end of each of the one or more supports.

13. The expandable support device of claim 12, wherein the protective padding comprises silicone.

14. The expandable support device of claim 1, wherein the proximal portion of the elastomeric body is tapered in a direction away from the distal portion of the elastomeric body and configured to facilitate movement of the expandable support device into the working channel.

15. The expandable support device of claim 1, wherein the elastomeric body comprises silicone.

16. The expandable support device of claim 1, wherein the elastomeric body is transparent.

17. The expandable support device of claim 1, wherein the elastomeric body is a molded elastomeric body.

18. The expandable support device of claim 1, wherein the working channel comprises at least a portion of an endoscope or a catheter.

19. The expandable support device of claim 1, wherein the one or more supports are coupled with the elastomeric body using a silicone adhesive.

20. The expandable support device of claim 1, wherein one side of the proximal portion of the elastomeric body comprises at least a marking or a texturing to facilitate identifying on which side of the elastomeric body the operative member is positioned.

21. A system for delivering treatment to a target treatment area comprising:

an expandable support device configured for delivering an operative member through a working channel to the target treatment area, the device comprising:

an elastomeric body configured to support the operative member and promote expansion of the expandable support device between a collapsed configuration and an expanded configuration, the elastomeric body comprising:

a proximal portion configured for coupling the elastomeric body with a guide assembly;

a distal portion opposite the proximal portion; and

a central axis extending between the distal portion and the proximal portion of the elastomeric body; and

one or more supports coupled with the elastomeric body and aligned parallel to the central axis, wherein at least one of the supports comprises at least a highly elastic or superelastic material; and

an operative member disposed on the elastomeric body.

22. The system of claim 21, further comprising:

the guide assembly comprising:

a guide shaft; and

a coupling mechanism configured to couple the expandable support device to the guide shaft.

23. The system of claim 22, further comprising:

the working channel configured to receive the expandable support device and the guide assembly.

24. The system of claim 23, wherein the operative member comprises an ablation device and the working channel comprises at least a portion of an endoscope or a catheter.

25. A method of delivering an expandable support device to a target treatment area comprising:

providing the expandable support device configured for delivering an operative member through a working channel to the target treatment area, the device comprising:

an elastomeric body configured to support the operative member and promote expansion of the expandable support device between a collapsed configuration and an expanded configuration, the elastomeric body comprising:

a proximal portion configured for coupling the elastomeric body with a guide assembly;

a distal portion opposite the proximal portion; and

a central axis extending between the distal portion and the proximal portion of the elastomeric body; and

one or more supports coupled with the elastomeric body and aligned parallel to the central axis, wherein at least one of the supports comprises a at least a highly elastic or superelastic material;

inserting the expandable support device into a first end of the working channel; and

moving the expandable support device through the working channel until the expandable support device passes out of a second end of the working channel.

26. The method of claim 25, further comprising:

positioning the expandable support device into a collapsed position prior to inserting the expandable support device into the working channel.

27. A guide assembly for delivering and positioning an operative member through a working channel to a target treatment area, the guide assembly comprising:

one or more transmission lines for operatively connecting the operative member to a power source;

a first shaft enclosing at least a first portion of the one or more transmission lines, the first shaft configured for transmitting torque to the operative member; and

a second shaft enclosing at least a second portion of the transmission lines, wherein the first shaft and the second shaft are configured to allow the first shaft to rotate independently of the second shaft.

28. The guide assembly of claim 27, wherein the first shaft comprises a flexible shaft.

29. The guide assembly of claim 28, wherein the flexible shaft comprises stainless steel.

30. The guide assembly of claim 28, wherein the flexible shaft comprises two or more layers, each layer comprising two or more stainless steel wires wound around a common axis.

31. The guide assembly of claim 28, wherein the flexible shaft is configured to couple with an expandable support device configured to deliver the operative member through the working channel to the target treatment area.

32. The guide assembly of claim 27, wherein the one or more transmission lines are coupled with the first shaft at a distal end of the first shaft and decoupled from the first shaft at a proximal end of the first shaft.

33. The guide assembly of claim 27, further comprising a protection element coupled with the first shaft and extending over a portion of the second shaft.

34. The guide assembly of claim 27, further comprising:
a control element coupled with the first shaft and configured to transmit rotational motion to the first shaft.

35. The guide assembly of claim 34, wherein the control element is coupled with the first shaft for approximately one to one rotational movement between the control element and the first shaft.

36. The guide assembly of claim 34, wherein the control element is coupled with the first shaft by a crimp tube fixed at one end of the control element.

37. The guide assembly of claim 27, wherein the first shaft comprises a rigid section at the proximal end of the first shaft.

38. The guide assembly of claim 37, wherein the rigid section is configured to be inserted into the working channel.

39. The guide assembly of claim 38, wherein the rigid section has a length of at least 2 cm.

40. The guide assembly of claim 37, wherein the first shaft further comprises a flexible section positioned between the rigid section and the operative member.

41. The guide assembly of claim 27, wherein the second shaft is coupled with the power source and is rotationally fixed relative to the power source.

42. The guide assembly of claim 27, wherein the one or more transmission lines comprise electrical wires.

43. The guide assembly of claim 27, wherein the first shaft and the second shaft are configured to axially move the operative member.

44. The guide assembly of claim 27, wherein the first shaft is configured to axially move the operative member.

45. The guide assembly of claim 27, wherein the first shaft is between the operative member and the second shaft and the second shaft is between the first shaft and the power source.

46. The guide assembly of claim 27, further comprising:
a handle coupled with the first shaft.

47. The guide assembly of claim 27, further comprising:
an introducer comprising a conical section, a cylindrical section, and a channel extending through the conical section and the cylindrical section, wherein the first shaft extends through the channel and the cylindrical section is configured to insert into the working channel.

48. The guide assembly of claim 47**Error! Reference source not found.**, further comprising:

a docking member comprising a first end, a second end, and a channel extending through the docking member, wherein the first end of the docking member is configured to couple with the introducer.

49. The guide assembly of claim 48, wherein the docking member is further configured at least to couple with or be integrated with at least a control element or a protection element.

50. A system for delivering treatment to a target treatment area comprising:

a guide assembly for delivering and positioning an operative member through a working channel to the target treatment area, the guide assembly comprising:

one or more transmission lines for operatively connecting the operative member to a power source;

a first shaft enclosing at least a first portion of the one or more transmission lines, the first shaft configured for transmitting torque to the operative member; and

a second shaft enclosing at least a second portion of the transmission lines, wherein the first shaft and the second shaft are configured to allow the first shaft to rotate independently of the second shaft;

an expandable support device configured to deliver the operative member through the working channel to the target treatment area and coupled with a distal end of the guide assembly; and

the operative member coupled with the expandable support device.

51. The system of claim 50, wherein the expandable support device comprises an elastomeric body configured to support the operative member, the elastomeric body comprising:

a proximal portion configured for coupling the elastomeric body with the guide assembly;

a distal portion opposite the proximal portion; and

a central axis extending between the distal portion and the proximal portion.

52. The system of claim 51, further comprising:

one or more supports coupled with the elastomeric body and aligned parallel to the central axis, wherein at least one of the supports comprises at least a highly elastic or superelastic material.

53. The system of claim 50, wherein the operative member is coupled with the transmission lines.

54. A method of utilizing a guide assembly for delivering an operative member to a target treatment area comprising:

providing a system comprising:

the guide assembly for delivering and positioning the operative member through a working channel to the target treatment area, the guide assembly comprising:

one or more transmission lines for operatively connecting the operative member to a power source;

a first shaft enclosing at least a first portion of the one or more transmission lines, the first shaft configured for transmitting torque to the operative member; and

a second shaft enclosing at least a second portion of the transmission lines, wherein the first shaft and the second shaft are configured to allow the first shaft to rotate independently of the second shaft;

an expandable support device configured to deliver the operative member through the working channel to the target treatment area and coupled with a distal end of the guide assembly; and

the operative member coupled with the expandable support device;

inserting the expandable support device into a first end of the working channel; and

moving the expandable support device through the working channel utilizing the guide assembly until the expandable support device passes out of a second end of the working channel.

55. The method of claim 54, further comprising:

positioning the expandable support device into a collapsed position prior to inserting the expandable support device into the working channel.

56. The method of claim 54, further comprising:
rotating the first shaft to provide torque to the operative member.

57. A guide assembly configured for positioning an operative member through a working channel and to a target treatment area, the guide assembly comprising:
one or more transmission lines for operatively connecting the operative member to a power source;
a flexible shaft enclosing at least a portion of the one or more power transmission lines, the flexible shaft configured for transmitting torque to the operative member; and
a handle element comprising a body and a channel extending through the body and through which the flexible shaft passes, the handle element configured such that the flexible shaft may move through the channel.

58. The guide assembly of claim 57, further comprising a rigid shaft coupled with a first end of the handle element and configured such that the flexible shaft may move through the rigid shaft.

59. The guide assembly of claim 58, wherein the rigid shaft has a length of at least 2 cm.

60. The guide assembly of claim 58, wherein the rigid shaft is configured to be inserted into the working channel.

61. The guide assembly of claim 57, further comprising:
a power source side shaft, the power source side shaft configured to allow the flexible shaft to rotate independently of the power source side shaft.

62. The guide assembly of claim 61, wherein the power source side shaft is between the flexible shaft and the power source.

63. The guide assembly of claim 61, wherein the handle element extends over a portion of the power source side shaft.

64. The guide assembly of claim 57, wherein the flexible shaft comprises two or more layers, each layer comprising two or more stainless steel wires wound around a common axis.

65. The guide assembly of claim 57, wherein the flexible shaft is configured to couple with an expandable support device configured to deliver the operative member through the working channel to the target treatment area.

66. The guide assembly of claim 61, wherein the power source side shaft is coupled with the power source and is rotationally fixed relative to the power source.

67. The guide assembly of claim 57, wherein the one or more transmission lines comprise electrical wires.

68. The guide assembly of claim 57, further comprising:
a locking mechanism coupled with the handle element.

69. The guide assembly of claim 68, wherein the locking mechanism is secured to the flexible shaft inside the channel of the handle element and configured to move along an axis of the handle element to adjust a length of the flexible shaft extending out of the handle element.

70. The guide assembly of claim 69, wherein the locking mechanism may move along the axis of the handle element when in an unlocked position and is fixed to the handle element when in a locked position.

71. The guide assembly of claim 68, wherein the handle element is configured to slide along the flexible shaft and the locking mechanism is configured to lock the handle element at a position along the flexible shaft.

72. The guide assembly of claim 61, further comprising:
a protection element coupled with the flexible shaft and extending over a portion of the power source side shaft.

73. The guide assembly of claim 61, wherein the protection element is coupled with the flexible shaft at a position between the handle element and the power source side shaft.

74. The guide assembly of claim 61, wherein the flexible shaft and the power source side shaft are configured to axially move the operative member.

75. A method of delivering an operative member to a target treatment area comprising:

providing a system comprising:

a guide assembly comprising:

one or more transmission lines for operatively connecting the operative member to a power source;

a flexible shaft enclosing at least a portion of the one or more power transmission lines, the flexible shaft configured for transmitting torque to the operative member; and

a handle element comprising a body and a channel extending through the body and through which the flexible shaft passes, the handle element configured such that the flexible shaft moves through the channel; and

the operative member coupled with a distal end of the flexible shaft;

inserting the operative member into a first end of a working channel;

moving the operative member through the working channel until the operative member passes out of the second end of the working channel; and

rotating the handle element to transmit torque to the operative member.

76. The method of claim 75, further comprising:

positioning the operative member into a collapsed position prior to inserting the operative member into the working channel.

77. A system for delivering treatment to a target area comprising:

a guide assembly comprising:

one or more transmission lines for operatively connecting an operative member to a power source;

a flexible shaft enclosing at least a portion of the one or more power transmission lines, the flexible shaft configured for transmitting torque to the operative member; and

a handle element comprising a body and a channel extending through the body and through which the flexible shaft passes, the handle element configured such that the flexible shaft may move through the channel;

an expandable support device coupled with a distal end of the flexible shaft; and

an operative member disposed on the expandable support device.

78. The system of claim 77, wherein the operative member comprises a flexible circuit.

79. An ablation device configured for delivery through a working channel to a target treatment area, the device comprising:

a flexible circuit configured to transition between a collapsed configuration and an expanded configuration, the flexible circuit comprising:

a plurality of parallel electrodes configured to collapse around an axis parallel to the plurality of parallel electrodes.

80. The device of claim 79, wherein the flexible circuit further comprises:

a first bus coupled with a first subset of the plurality of parallel electrodes; and

a second bus coupled with a second subset of the plurality of parallel electrodes.

81. The device of claim 80, wherein the first bus and the second bus are at least partially covered by one or more insulation layers configured to impede the first and second bus from ablating the target treatment area.

82. The device of claim 81, wherein the one or more insulation layers comprise polyimide.

83. The device of claim 80, wherein the first bus is located at a first end of the plurality of parallel electrodes and the second bus is located at a second end of the plurality of parallel electrodes.

84. The device of claim 83, wherein the plurality of parallel electrodes are arranged in a row and the first bus and the second bus couple to alternating electrodes in the row.

85. The device of claim 83, wherein the first bus and the second bus are each arched.

86. The device of claim 83, wherein the first bus and the second bus each comprise a plurality of arches.

87. The device of claim 86, wherein an end of each arch is coupled with a single electrode.

88. The device of claim 80, wherein the first bus is configured to couple with a positive terminal and the second bus is configured to couple with a negative terminal or a ground terminal.

89. The device of claim 79, further comprising:
an elastomeric body having a first surface and a second surface opposite the first surface, wherein the flexible circuit is disposed on the first surface.

90. The device of claim 89, wherein the plurality of parallel electrodes each substantially extend to a distal end of the elastomeric body.

91. The device of claim 89, wherein the elastomeric body having the flexible circuit disposed thereon is configured to collapse around an axis parallel to the plurality of parallel electrodes when disposed within the working channel and expand to a substantially flat orientation when the elastomeric body emerges from the working channel.

92. The device of claim 89, further comprising:
a first bus and a second bus disposed on the second surface of the elastomeric body, wherein the first bus is coupled with a first subset of the plurality of electrodes and the second bus is coupled with a second subset of the plurality of electrodes.

93. The device of claim 92, wherein the elastomeric body comprises one or more vias through which the first subset of electrodes couple to the first bus and one or more vias through which the second subset of electrodes couple to the second bus.

94. The device of claim 92, wherein the first bus and the second bus are aligned substantially perpendicular to the plurality of parallel electrodes.

95. The device of claim 92, wherein the first bus and the second bus comprise copper.

96. The device of claim 95, wherein the first bus and the second bus have a hash pattern with a plurality of void spaces.

97. The device of claim 92, wherein the first and second bus are located between a first end of the plurality of parallel electrodes and a second end of the plurality of parallel electrodes.

98. A system for delivering treatment to a target treatment area comprising:

a guide assembly having a central axis;

an elastomeric body coupled with the guide assembly; and

a flexible circuit disposed on the elastomeric body, the flexible circuit comprising a plurality of parallel electrodes configured to collapse around an axis parallel to the plurality of parallel electrodes and parallel to the central axis of the guide assembly.

99. The system of claim 98, further comprising:

one or more supports coupled with the elastomeric body and aligned parallel to the central axis, wherein at least one of the supports comprises a superelastic material.

100. The system of claim 99, further comprising:

a working channel configured to receive the guide assembly, the elastomeric body, and the flexible circuit disposed on the elastomeric body.

101. The system of claim 100, wherein the elastomeric body and the flexible circuit are in a collapsed configuration when disposed inside of the working channel and wherein the elastomeric body and the flexible circuit expand to a substantially flat orientation when the elastomeric body is outside the working channel.

102. A method of delivering an ablation device to a target treatment area comprising:

providing the ablation device comprising:

a flexible circuit configured to transition between a collapsed configuration and an expanded configuration, the flexible circuit comprising:

a plurality of parallel electrodes configured to collapse around an axis parallel to the plurality of parallel electrodes;

inserting the ablation device into a first end of a working channel; and

moving the ablation device through the working channel until the ablation device passes out of a second end of the working channel.

103. The method of claim 102, further comprising:

positioning the flexible circuit into the collapsed configuration prior to inserting the ablation device into the working channel.

104. An expandable support device configured for delivery through a working channel and to a target treatment area, comprising:

a solid support member comprising a perimeter and highly elastic or superelastic properties; and

a plurality of splines formed in a pattern interior to the perimeter of the solid support member and a plurality of voids between adjacent splines, wherein a width and a spacing of the plurality of splines is configured to promote expansion of the support member between a collapsed configuration and an expanded configuration providing a support surface.

105. The device of claim 104, wherein the solid support member comprises a proximal end, a distal end, and a central axis extending from the proximal end to the distal end, and wherein the pattern of the plurality of splines comprises:

a central axis spline substantially overlapping the central axis of the solid support member

a first subset of splines extending from the central axis spline towards a first lateral peripheral edge of the solid support member;

a second subset of splines extending from the central axis spline towards a second lateral peripheral edge of the solid support member opposite the first lateral peripheral edge.

106. The device of claim 105, wherein the first subset of splines is arranged in parallel to one another and the second subset of splines is arranged in parallel to one another.

107. The device of claim 106, wherein the first subset of splines and the second subset of splines extend from the central spline at an angle such that the first and second subsets of splines extend from the central spline towards the distal end of the solid support member.

108. The device of claim 107, wherein the first subset of spines and the second subset of spines extend from the central axis spline at an angle in the range of from greater than 0 degrees to 90 degrees.

109. The device of claim 107, wherein the first subset of splines and the second subset of splines extend from the central axis spline at an angle of about 45 degrees.

110. The device of claim 105, wherein the first subset of splines and the second subset of splines have a thickness less than a thickness of the central axis spline.

111. The device of claim 104, wherein the solid support member comprises of a metal having shape memory properties.

112. The device of claim 104, wherein the support surface defines a curved surface in the expanded configuration.

113. The device of claim 104, wherein the support surface defines a substantially planar surface in the expanded configuration.

114. The device of claim 104, wherein the support surfaces defines a predetermined shape corresponding to a tissue surface at atreament site in a patient.

115. The device of claim 104, wherein a thickness of the solid support member is about 0.003 inch.

116. The device of claim 104, wherein the pattern of the plurality of splines comprises a plurality of equally spaced vertical splines interconnected by horizontal splines.

117. The device of claim 104, further comprising an operative member supported by the plurality of splines.

118. The device of claim 117, wherein the operative member is coupled with the plurality of splines with an elastomeric adhesive.

119. The device of claim 117, wherein the operative member comprises a flexible circuit.

120. The device of claim 119, wherein the flexible circuit comprises:
a plurality of electrodes patterned to mirror the pattern of the plurality of splines.

121. The device of claim 117, wherein the operative member extends across an entire width of the solid support member.

122. The device of claim 104, wherein the solid support member includes a rounded distal edge.

123. The device of claim 104, wherein the solid support member includes a tapered proximal edge for promoting retraction of the device into the working channel.

124. A system for delivering treatment to a target area comprising:
a solid support member comprising a perimeter and at least a highly elastic or superelastic properties;
a plurality of splines formed in a pattern interior to the perimeter of the solid support member and a plurality of voids between adjacent splines, wherein a width and a spacing of the plurality of splines is configured to promote expansion of the solid support member between a collapsed configuration and an expanded configuration providing a support surface; and
an operative member disposed on the solid support member.

125. The system of claim 124, wherein the solid support member has a first surface and a second surface opposite the first surface, and wherein the plurality of splines are disposed on the first surface and the operative member is disposed on the second surface.

126. The system of claim 124, wherein the operative member comprises a flexible circuit.

127. A method of delivering an expandable support device to a target treatment area comprising:
providing the expandable support device comprising:

a solid support member comprising a perimeter and at least a highly elastic or superelastic properties; and

a plurality of splines formed in a pattern interior to the perimeter of the solid support member and a plurality of voids between adjacent splines, wherein a width and a spacing of the plurality of splines is configured to promote expansion of the solid support member between a collapsed configuration and an expanded configuration providing a support surface;

inserting the expandable support device into a first end of a working channel; and

moving the expandable support device through the working channel until the expandable support device passes out of a second end of the working channel.

128. The method of claim 127, further comprising:

positioning the expandable support device into the collapsed configuration prior to inserting the expandable support device into the working channel.

129. An expandable support device configured for delivery through a working channel and to a target treatment area comprising:

an expandable support member configured for supporting an operative member comprising a plurality of splines having a width and a spacing selected to promote expansion of the exapandable support member between a collapsed configuration and an expanded configuration, wherein a portion of the expandable support member defines a surface in the expanded configuration.

130. The device of claim 129, wherein the plurality of splines comprise:

a central axis spline;

a first subset of splines extending away from the central axis in a first direction; and

a second subset of splines extending away from the central axis spline in a direction opposite the first direction..

131. The device of claim 130, wherein the first subset of splines is arranged in parallel to one another and the second subset of splines is arranged in parallel to one another.

132. The device of claim 131, wherein the first subset of splines and the second subset of splines extend away from the central axis spline at an angle such that the first and second subsets of splines extend from the central axis spline towards a distal end of the central axis spline.

133. The device of claim 132, wherein the first subset of splines and the second subset of splines extend away from the central axis spline at an angle in the range of from greater than 0 degrees to 90 degrees.

134. The device of claim 132, wherein the first subset of splines and the second subset of splines extend away from the central axis spline at an angle of about 45 degrees.

135. The device of claim 130, wherein the first subset of splines and the second subset of splines have a thickness less than a thickness of the central axis spline.

136. The device of claim 129, wherein the plurality of splines comprise nitinol.

137. The device of claim 129, wherein the plurality of splines comprise:
a central axis spline;
a plurality of secondary splines arranged in parallel to the central axis spline, equally spaced apart from one another, and on either side of the central axis spline;
a plurality of interconnecting splines arranged transverse to the secondary splines and interconnecting the secondary splines.

138. A system for providing treatment to a target treatment area comprising:
an expandable support member configured for supporting an operative member comprising a plurality of splines having a width and a spacing selected to promote expansion of the expandable support member between a collapsed configuration and an expanded configuration, wherein a portion of the support member defines a surface in the expanded configuration;
a solid elastomeric body, wherein the expandable support member is disposed on the solid elastomeric body within a perimeter of the solid elastomeric body; and
the operative member coupled with the solid elastomeric body.

139. The system of claim 138, wherein the plurality of splines comprise:
a central axis spline;
a first subset of splines extending away from the central axis in a first direction; and
a second subset of splines extending away from the central axis spline in a direction opposite the first direction.

140. The system of claim 139, wherein the first subset of splines is arranged in parallel to one another and the second subset of splines is arranged in parallel to one another.

141. The system of claim 140, wherein the first subset of splines and the second subset of splines extend away from the central axis spline at an angle such that the first and second subsets of splines extend from the central axis spline towards a distal end of the central axis spline.

142. The system of claim 141, wherein the first subset of splines and the second subset of splines extend away from the central axis spline at an angle of about 45 degrees.

143. The system of claim 138, wherein the operative member is coupled with the solid elastomeric body with an elastomeric adhesive.

144. The system of claim 138, wherein the operative member is a flexible circuit.

145. The system of claim 144, wherein the flexible circuit comprises a plurality of electrodes patterned to mirror the plurality of splines.

146. The system of claim 138, wherein the operative member extends across an entire width of the solid elastomeric body.

147. A method of delivering an expandable support device to a target treatment area comprising:
providing the expandable support device configured for delivery through a working channel to the target treatment area, the device comprising:

an expandable support member configured for supporting an operative member comprising a plurality of splines having a width and a spacing selected to promote expansion of the expandable support member between a collapsed configuration and an expanded configuration, wherein a portion of the expandable support member defines a surface in the expanded configuration;

inserting the expandable support device into a first end of the working channel; and

moving the expandable support device through the working channel until the expandable support device passes out of a second end of the working channel.

148. The method of claim 147, further comprising:

positioning the expandable support device into a collapsed position prior to inserting the expandable support device into the working channel.

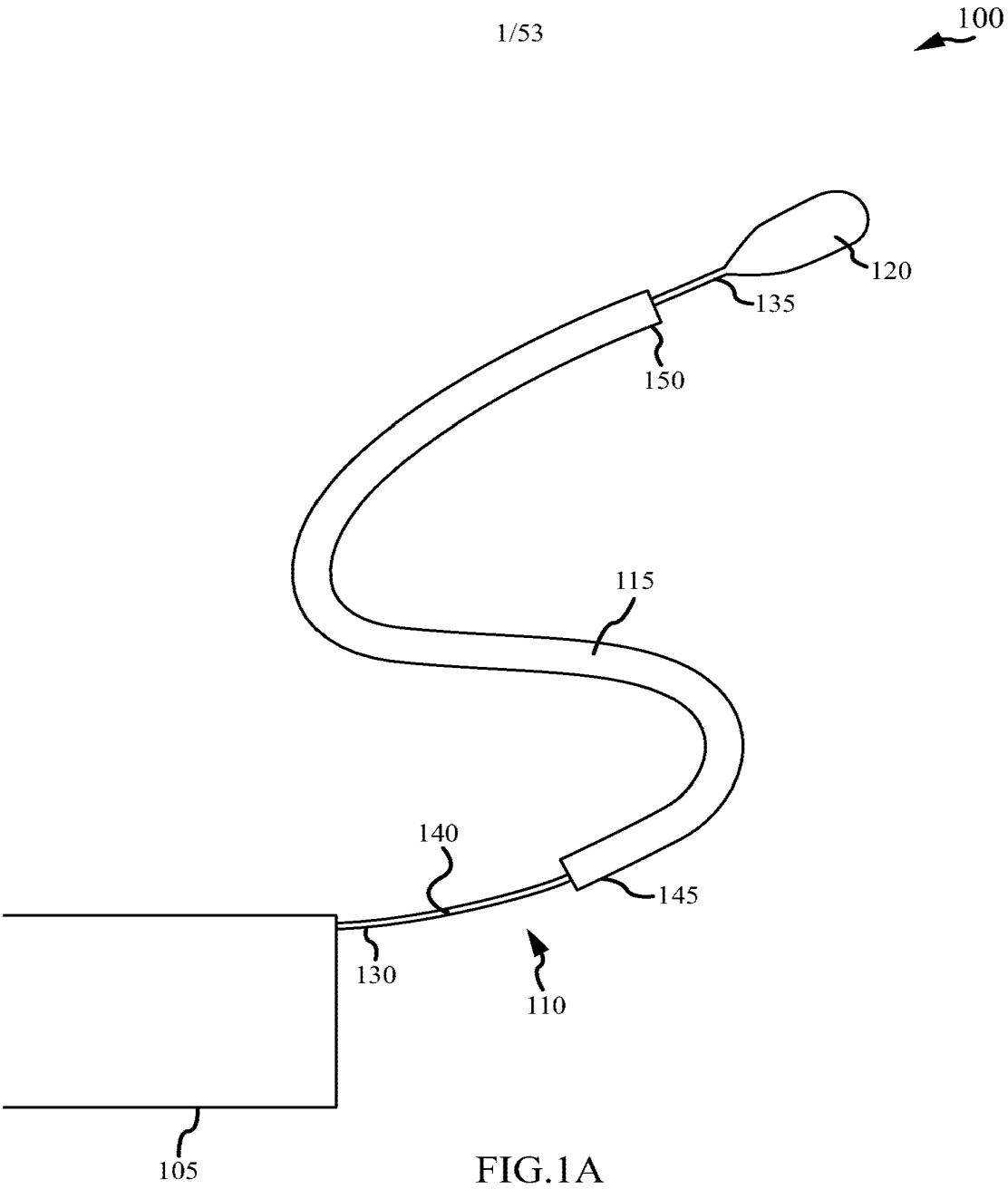

FIG.1A

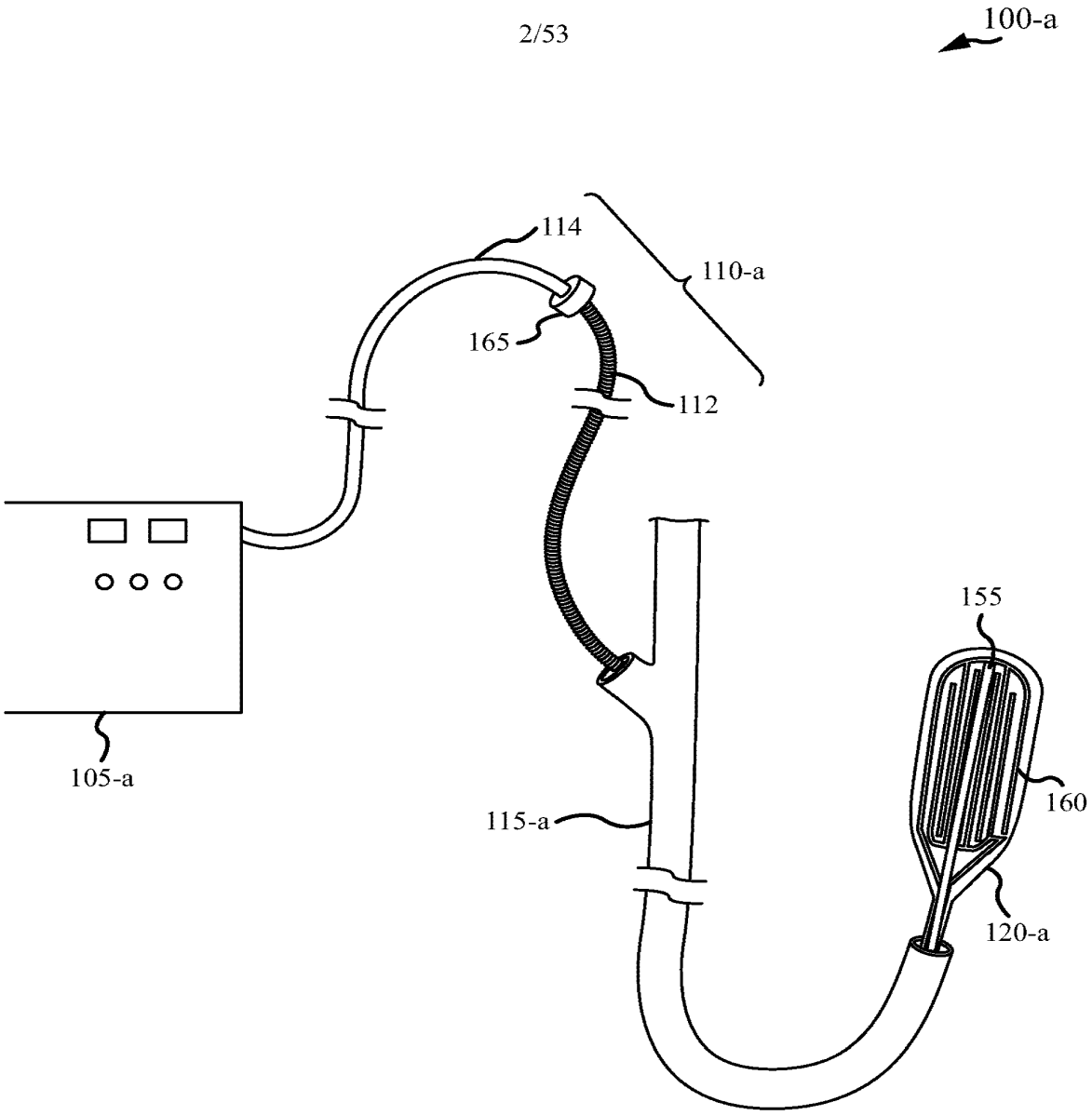

FIG.1B

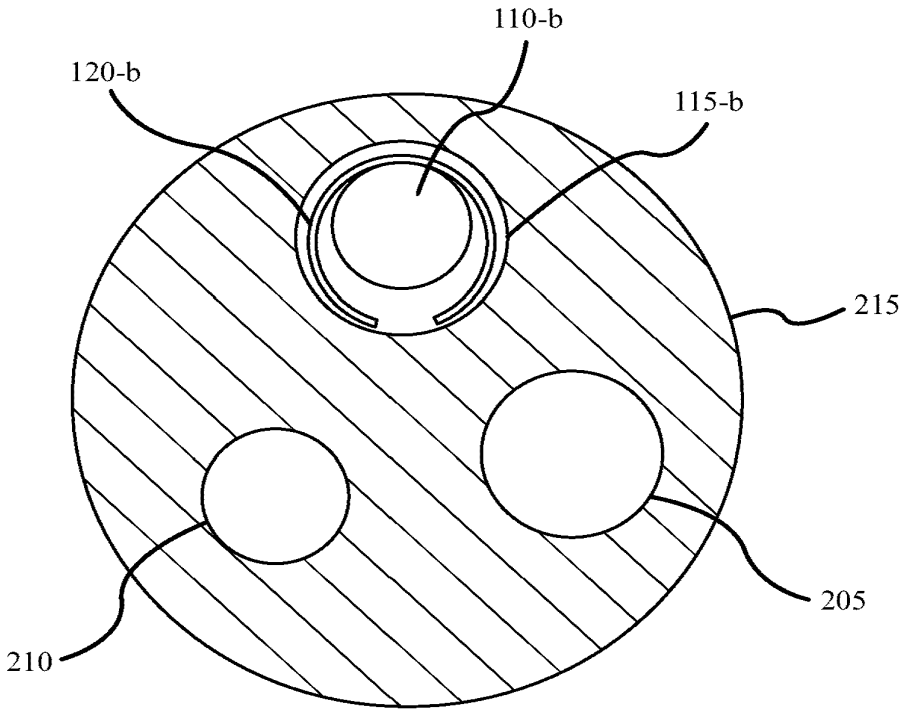

FIG.2

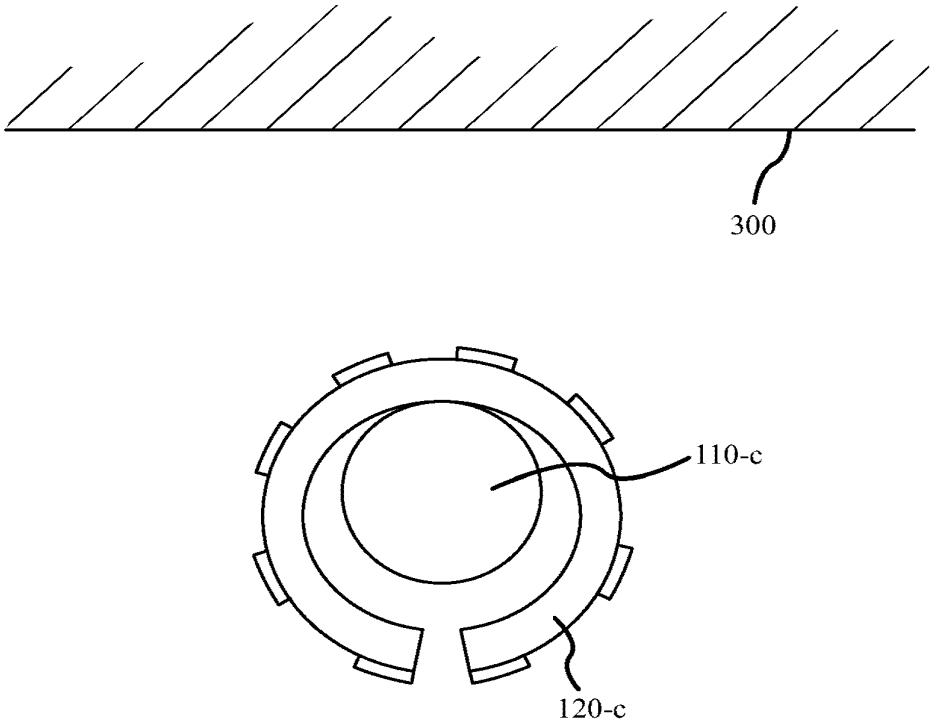

FIG.3A

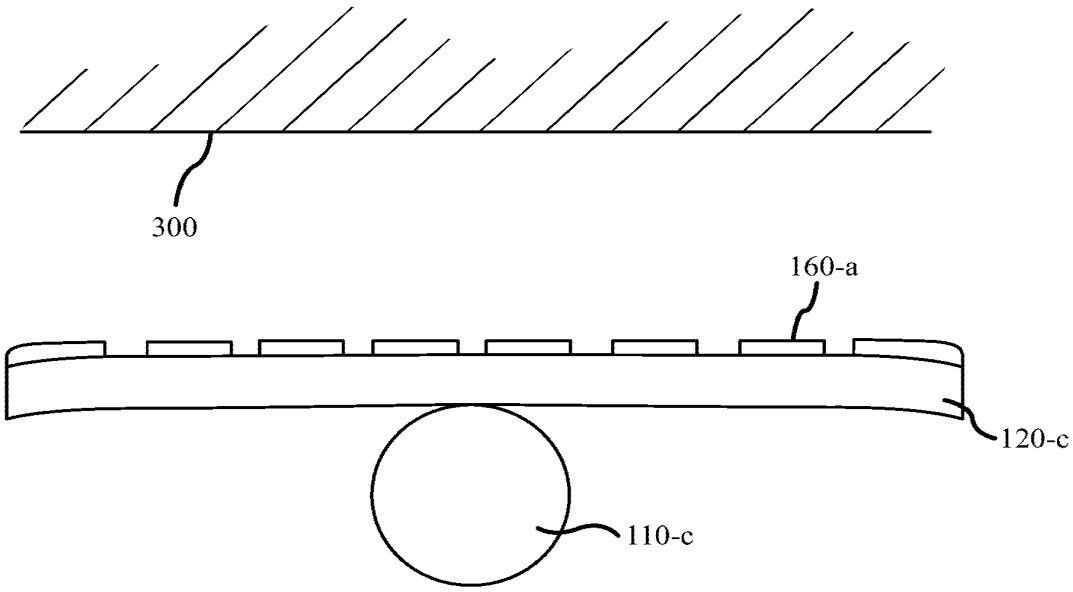

FIG.3B

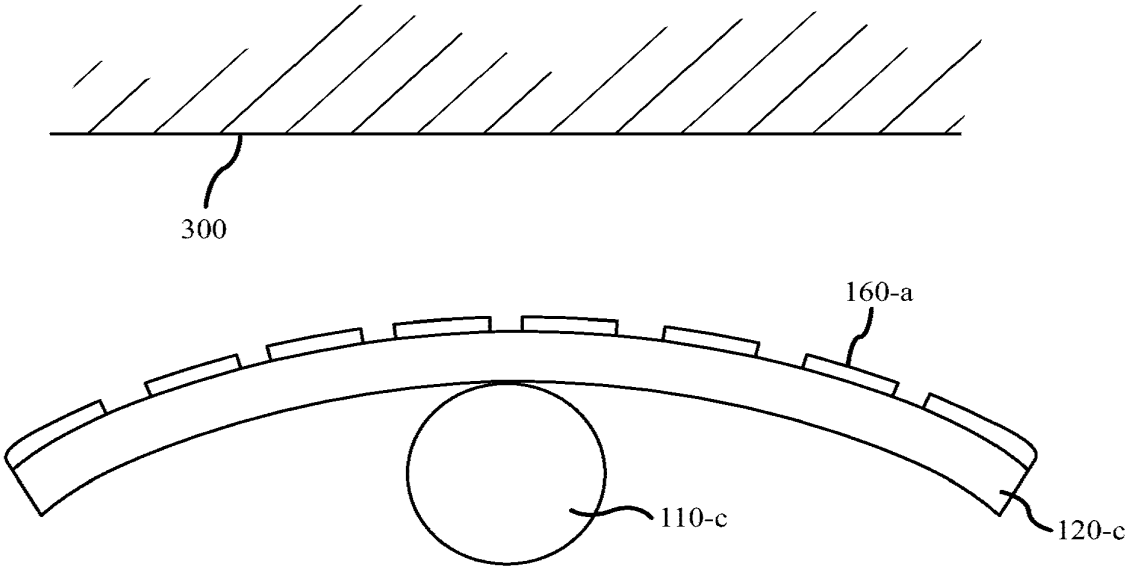

FIG.3C

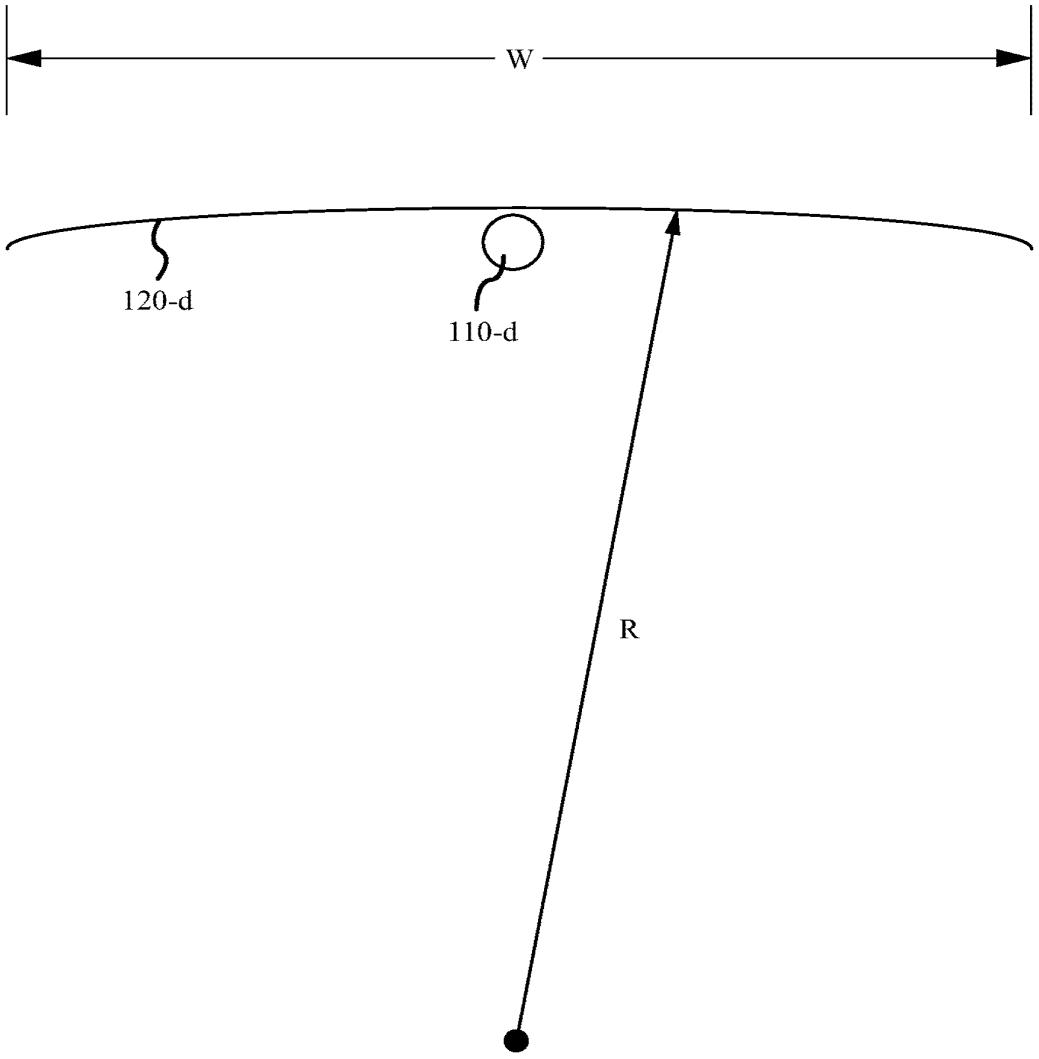

FIG.4

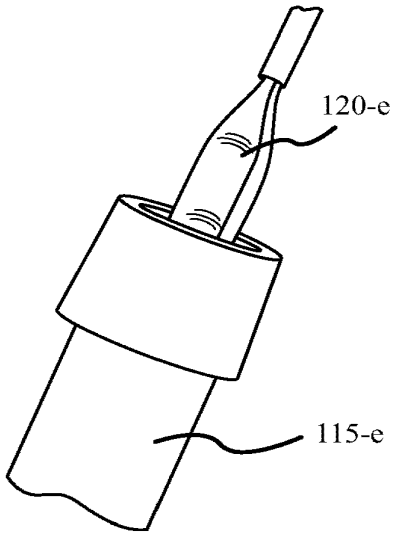

FIG.5A

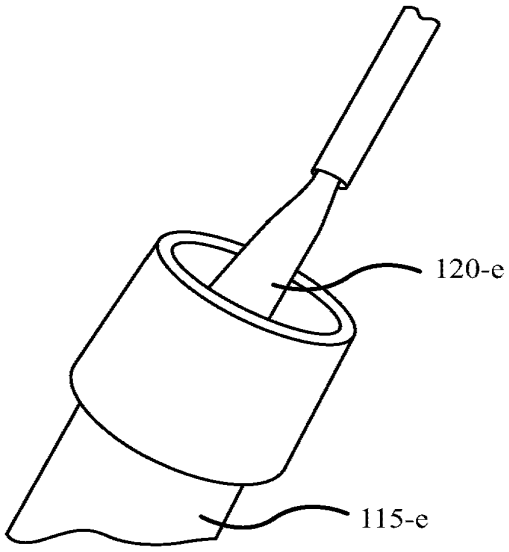

FIG.5B

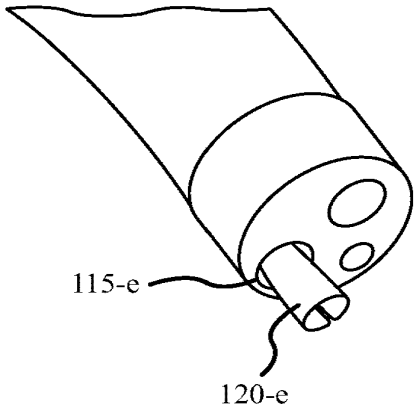

FIG.5C

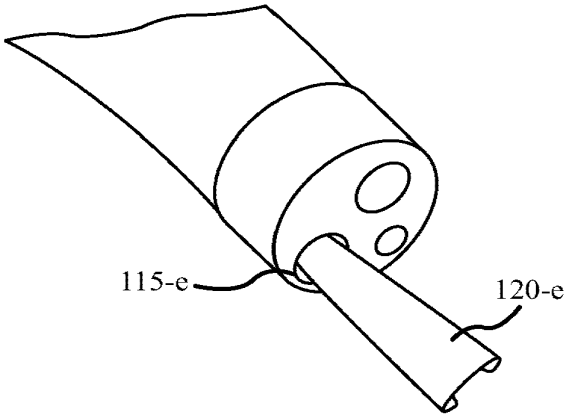

FIG.5D

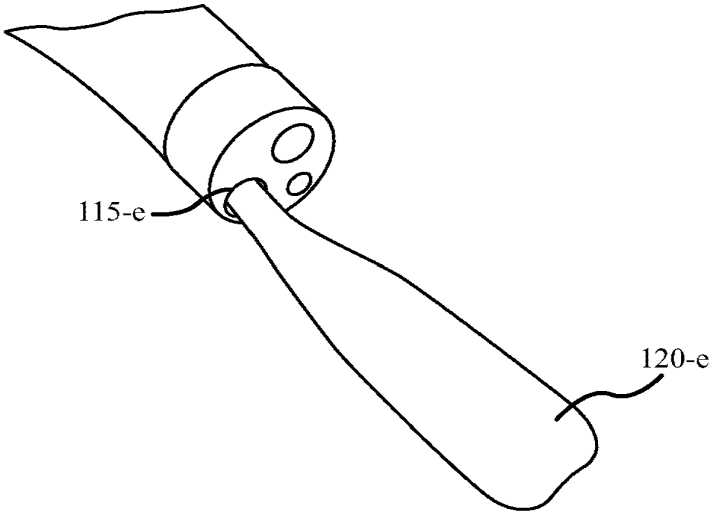

FIG.5E

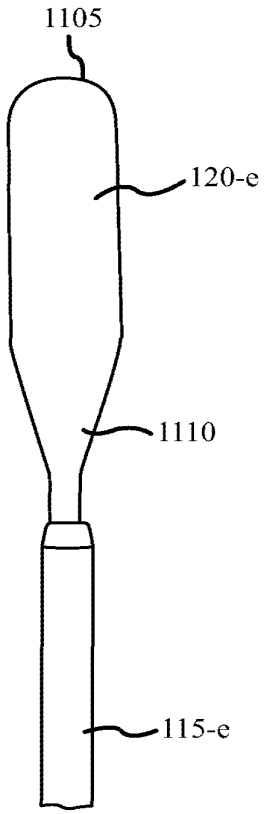

FIG.5F

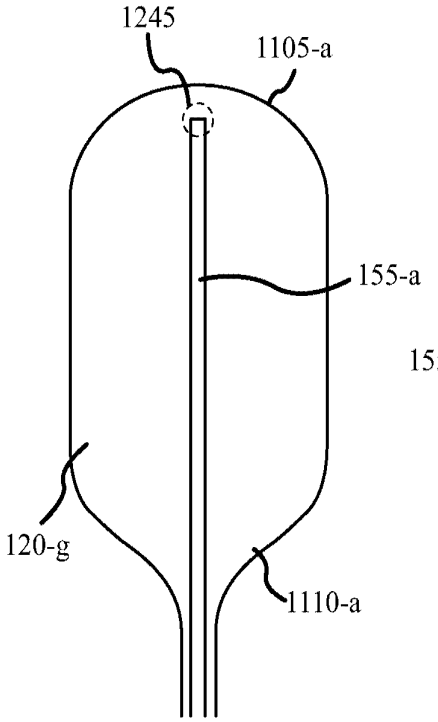

FIG.6A

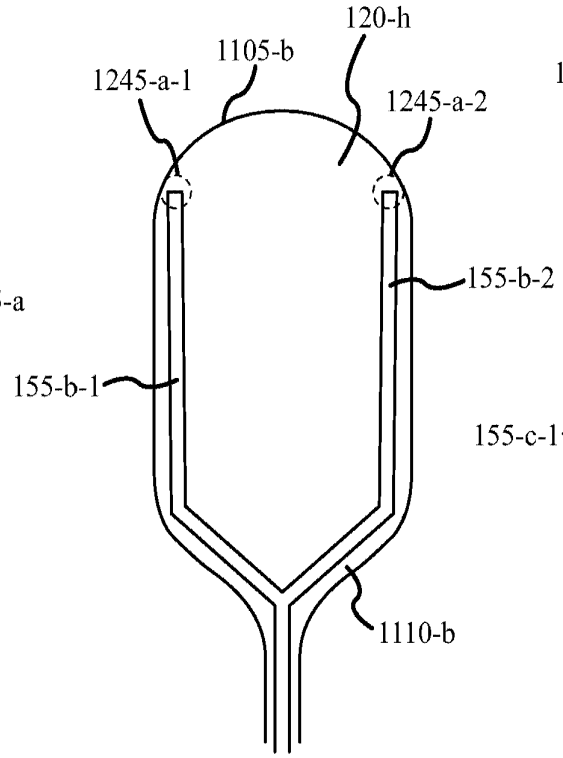

FIG.6B

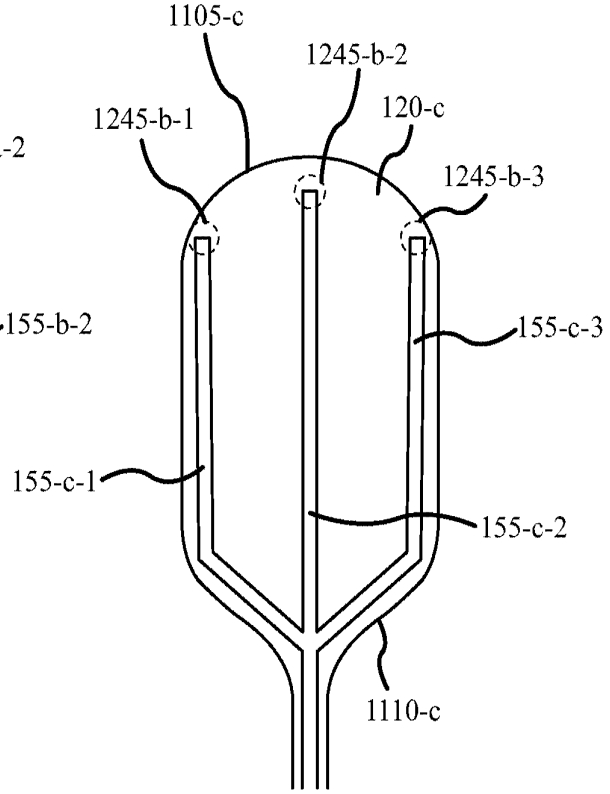

FIG.6C

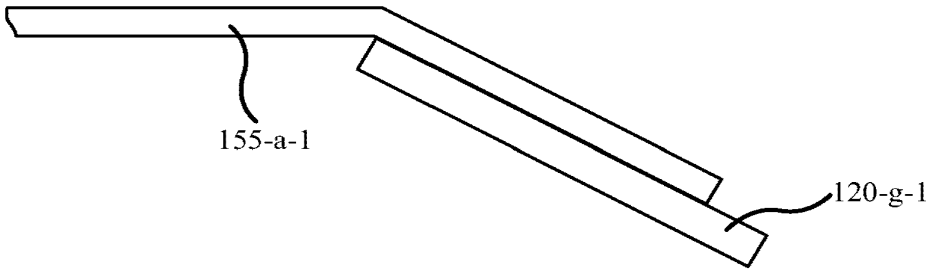

FIG.7

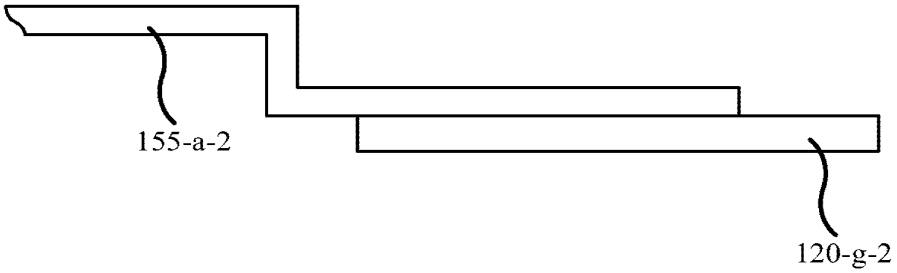

FIG.8

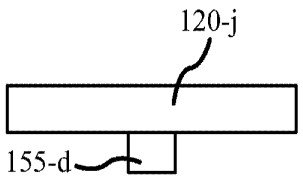

FIG.9A

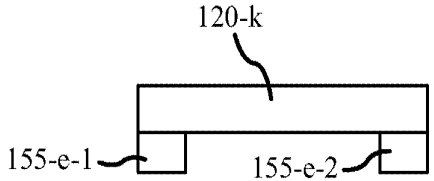

FIG.9B

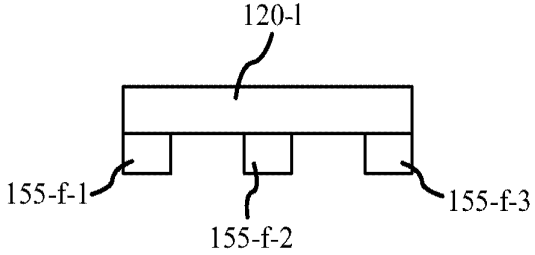

FIG.9C

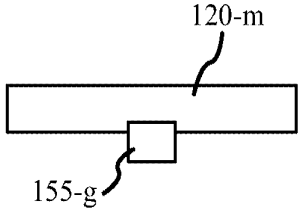

FIG.10A

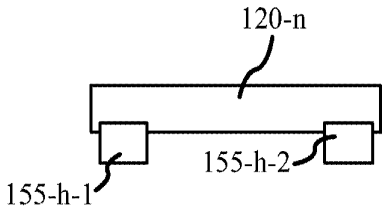

FIG.10B

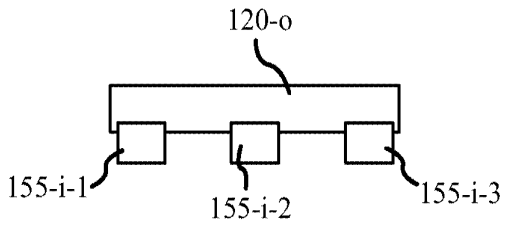

FIG.10C

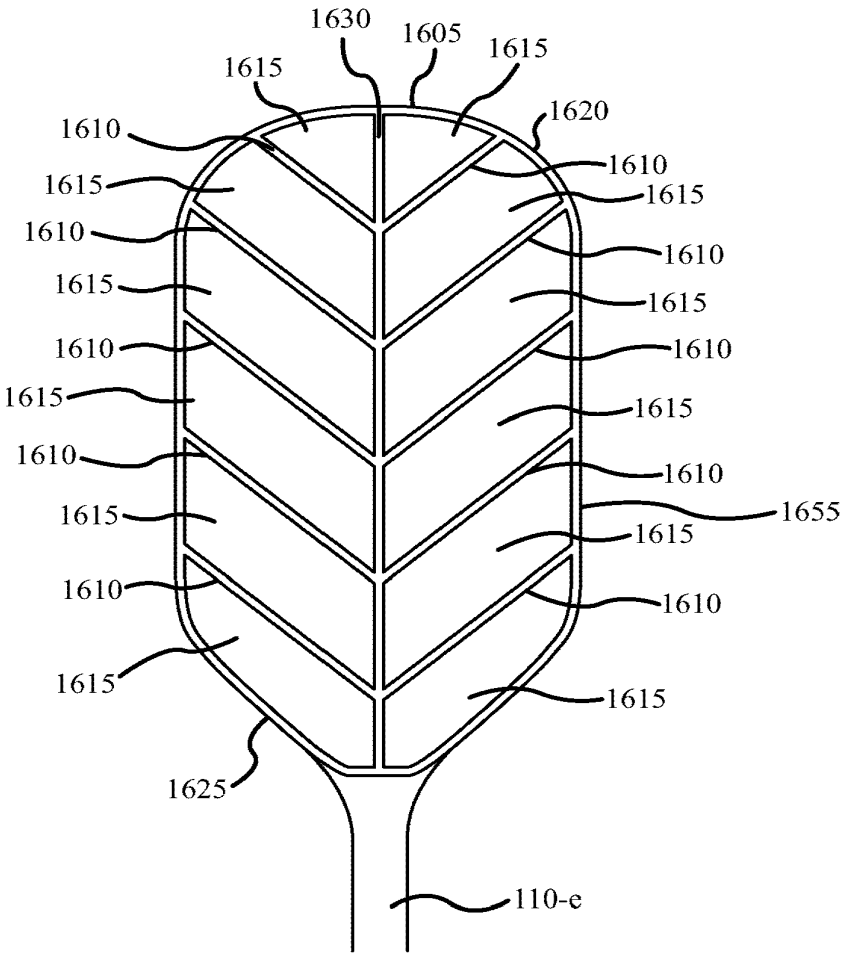
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FIG.11A

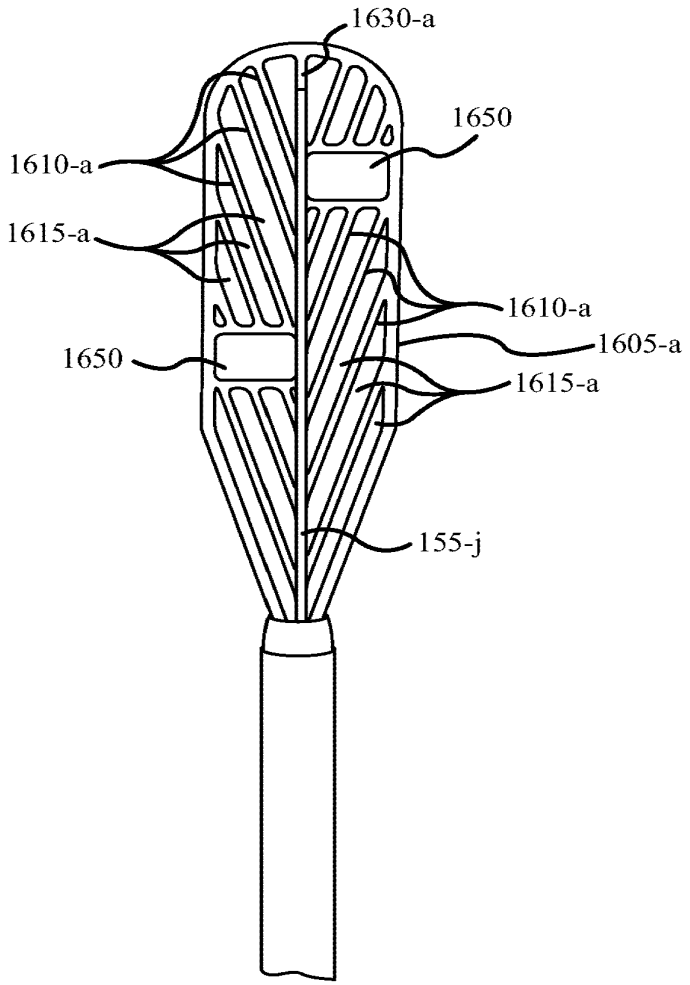

FIG.11B

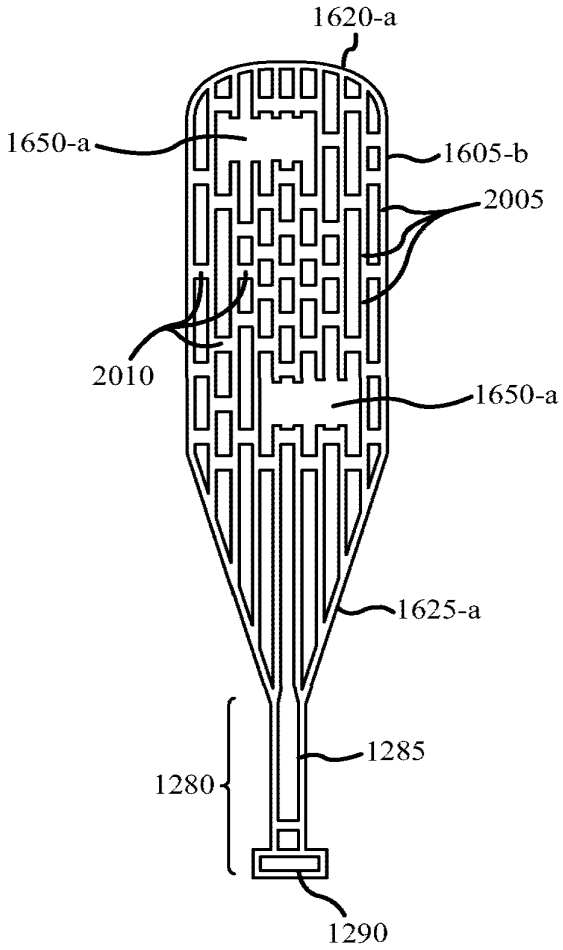

FIG.12A

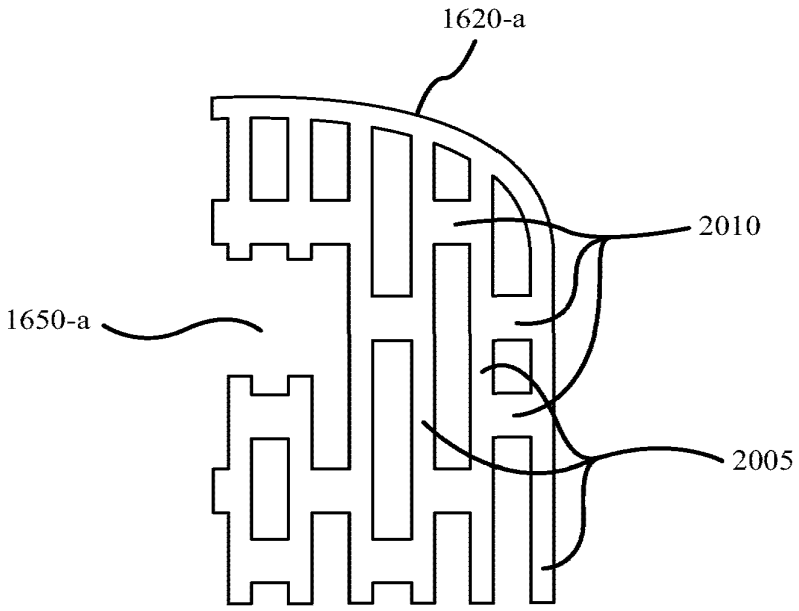

FIG.12B

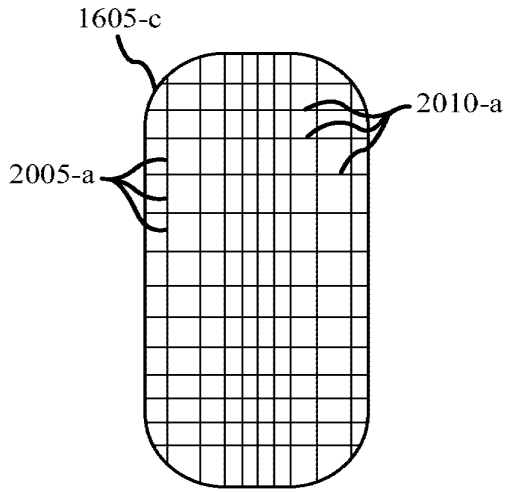

FIG.13A

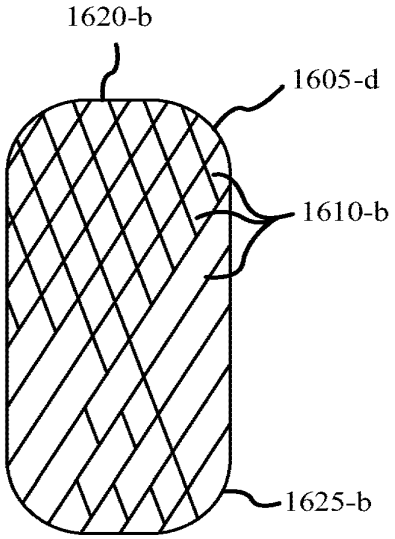

FIG.13B

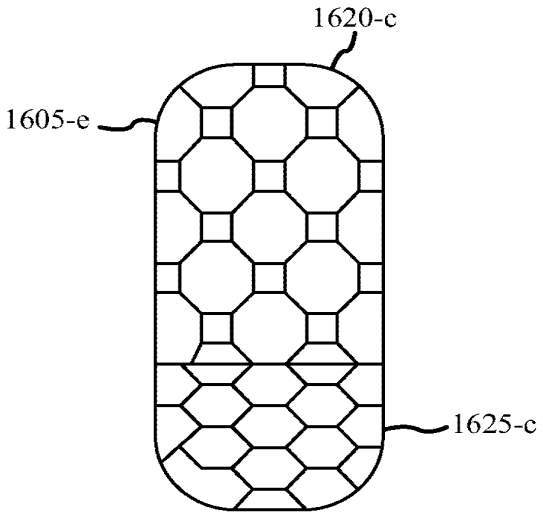

FIG.13C

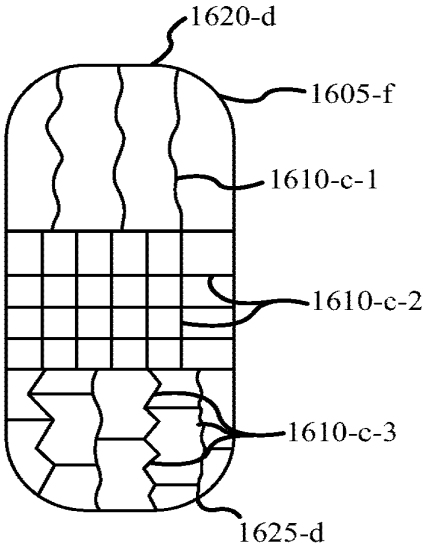

FIG.13D

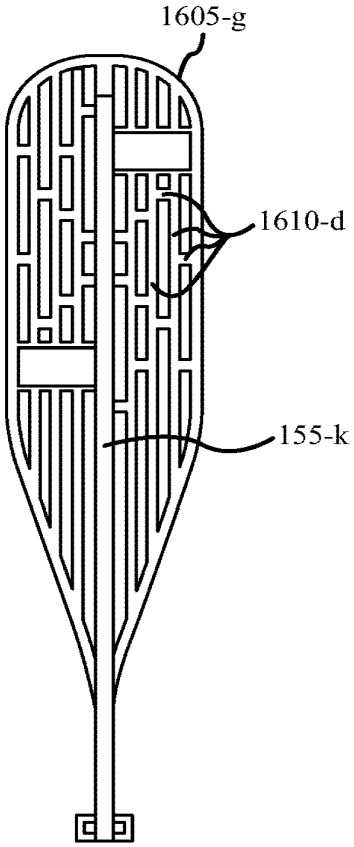

FIG.13E

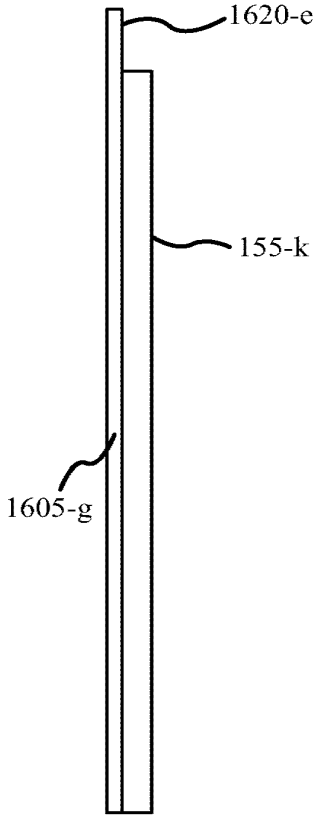

FIG.13F

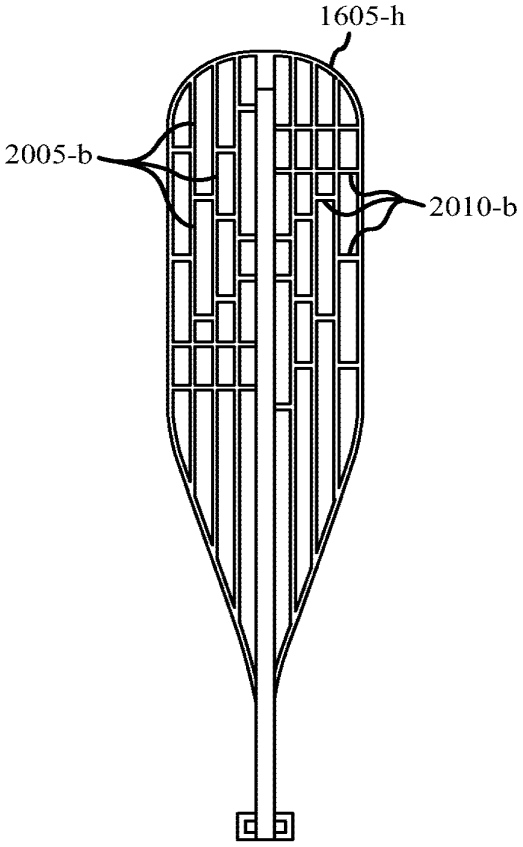

FIG.13G

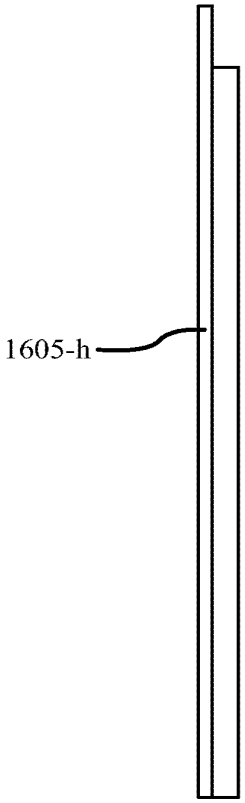

FIG.13H

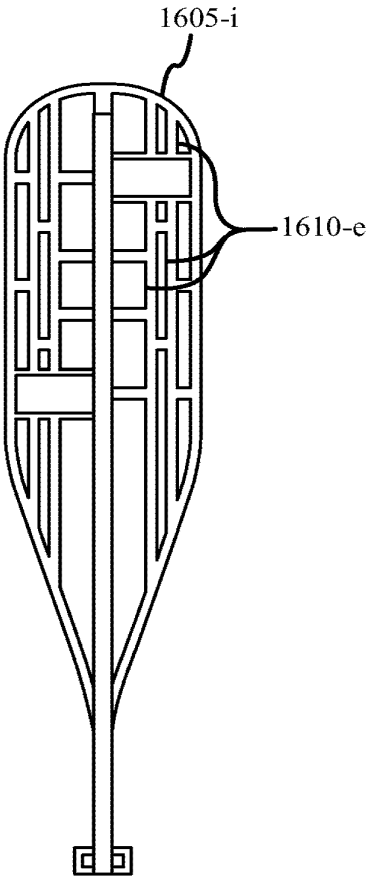

FIG.13I

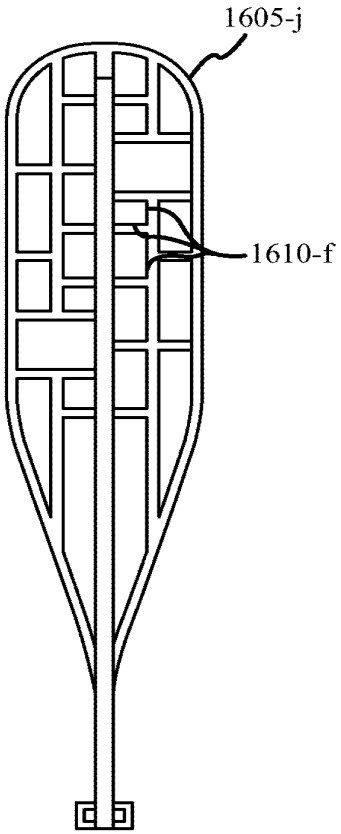

FIG.13J

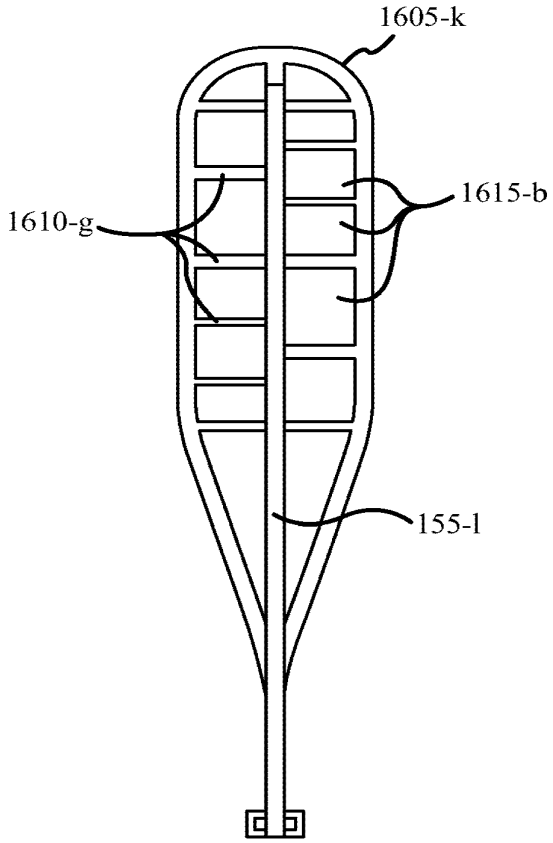

FIG.13K

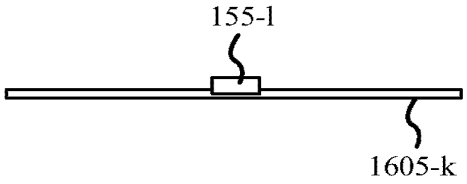

FIG.13L

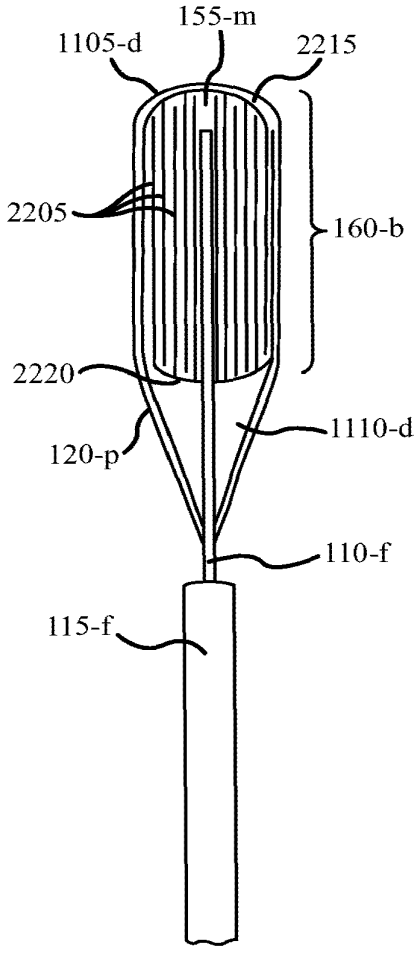

FIG.14A

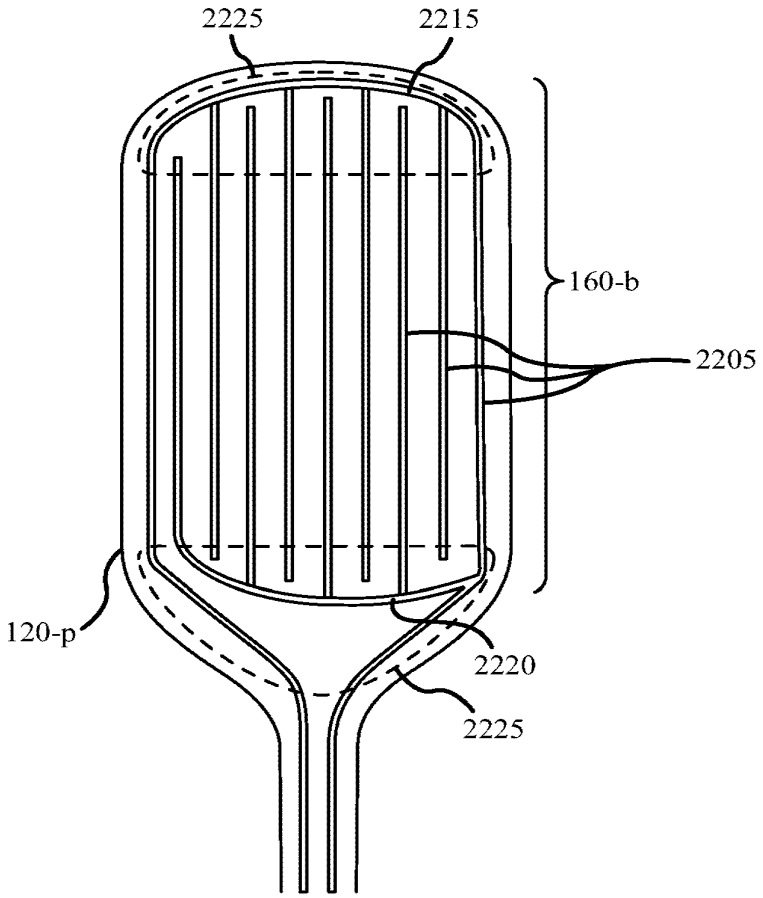

FIG.14B

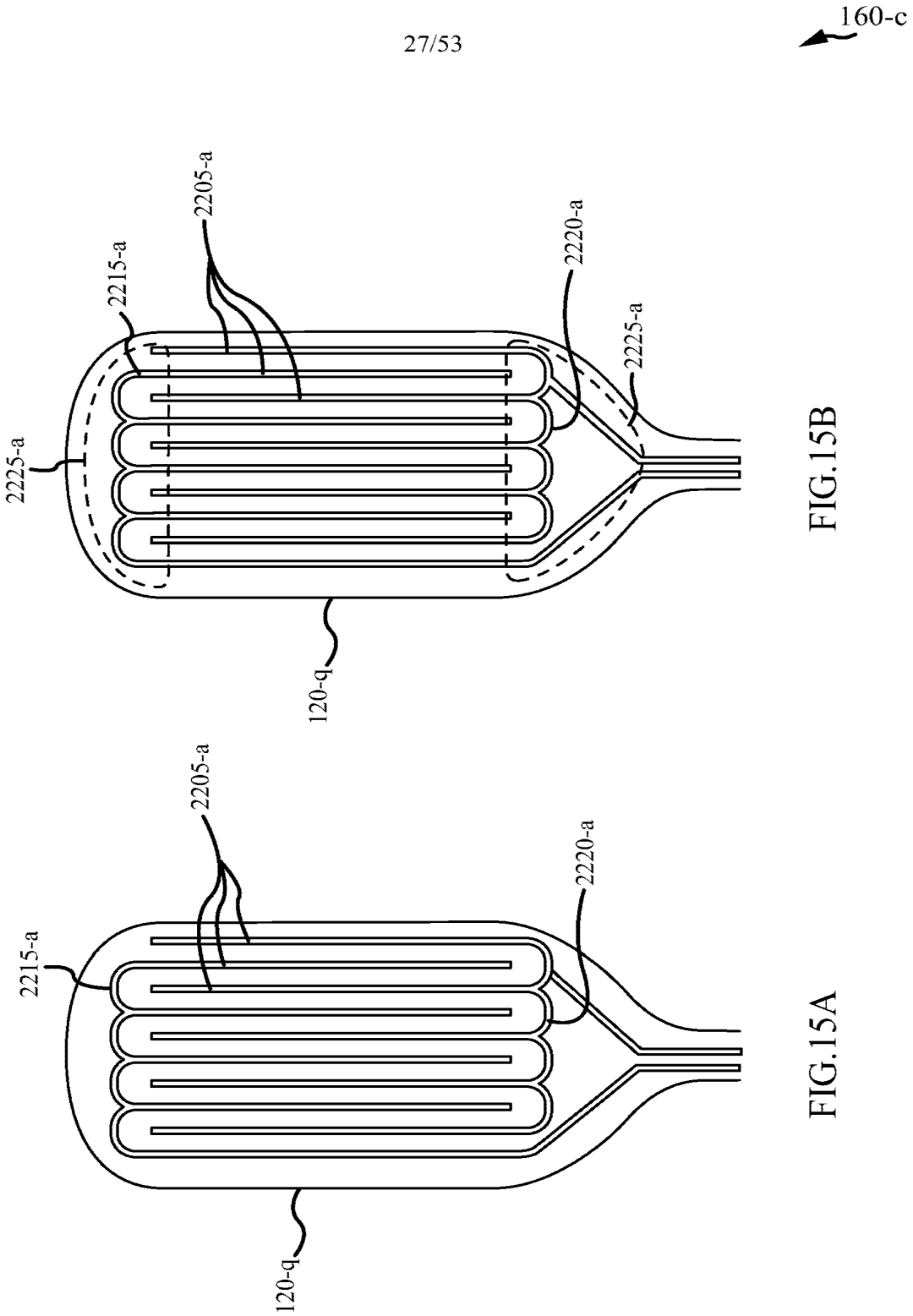

FIG.15B

FIG.15A

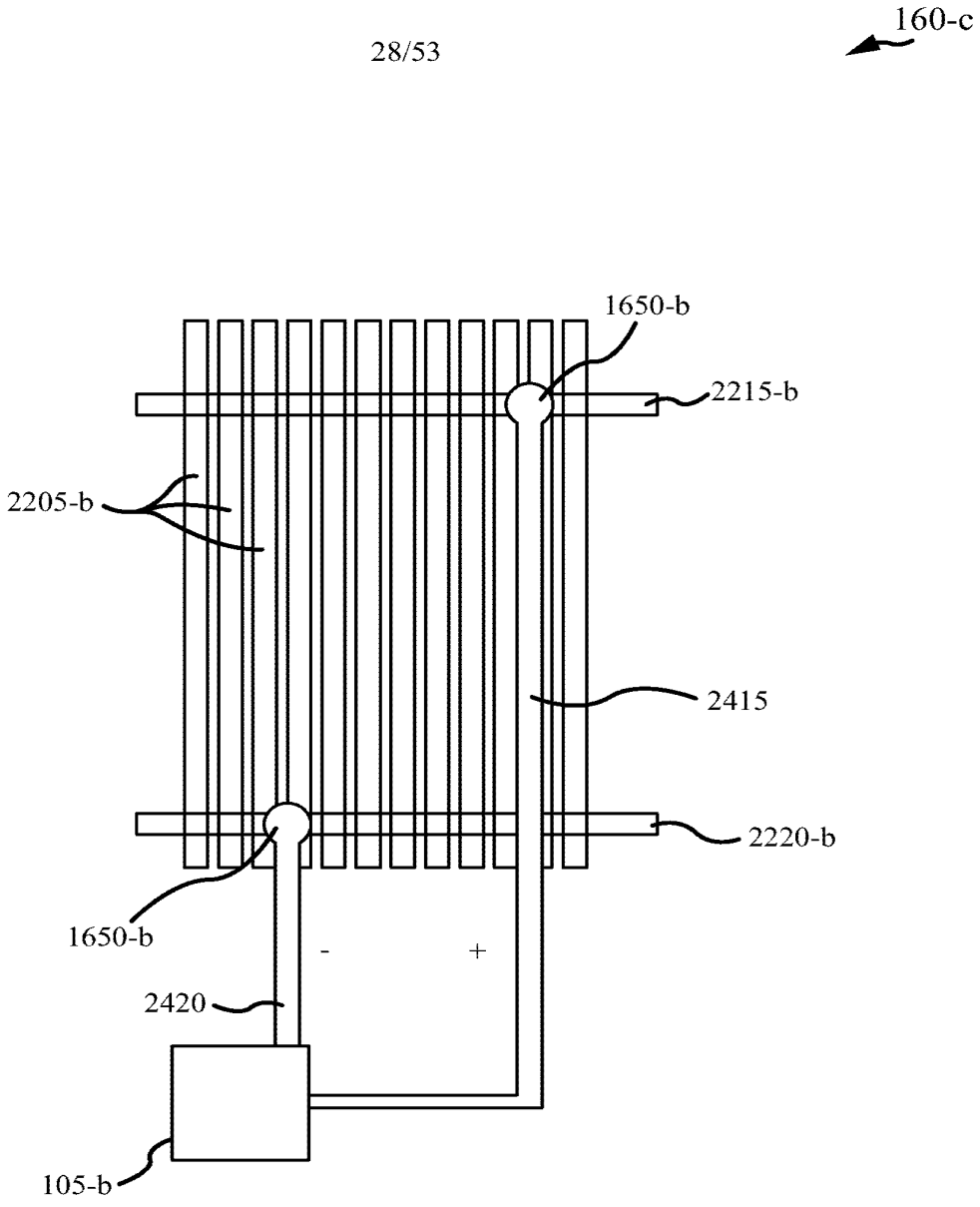

FIG.16A

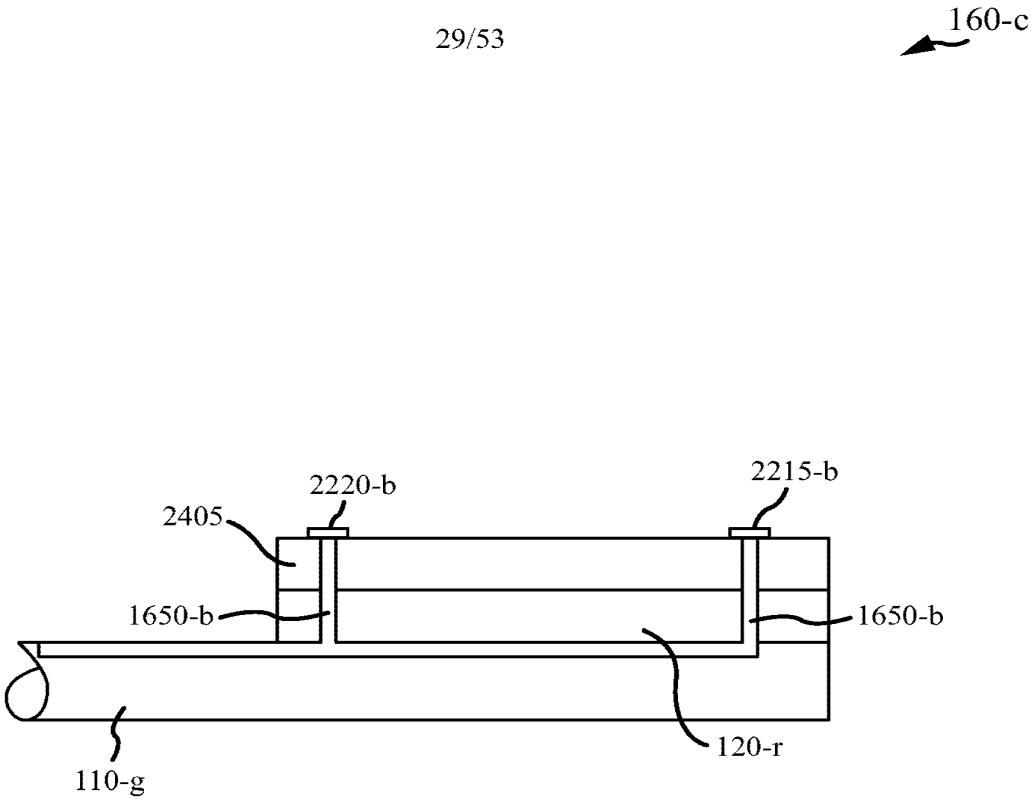

FIG.16B

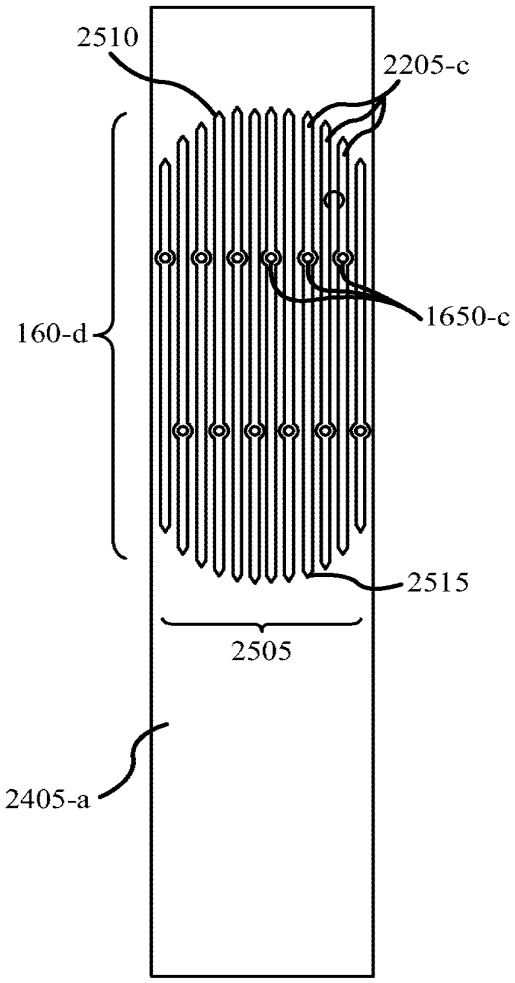

FIG.17A

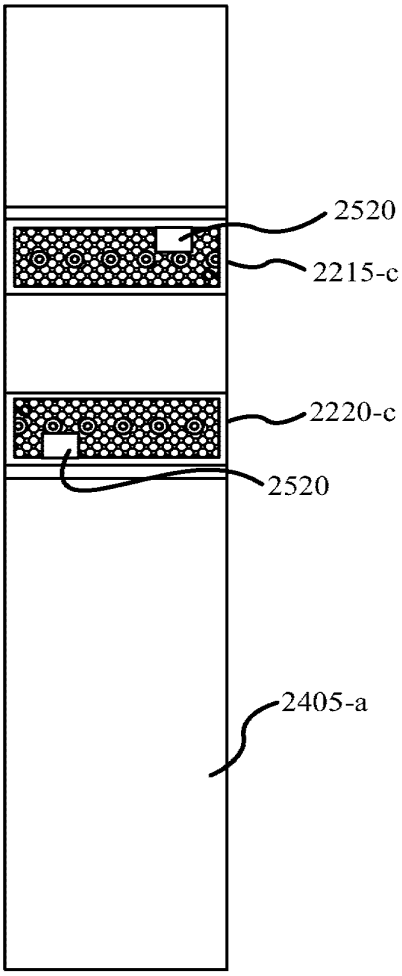

FIG.17B

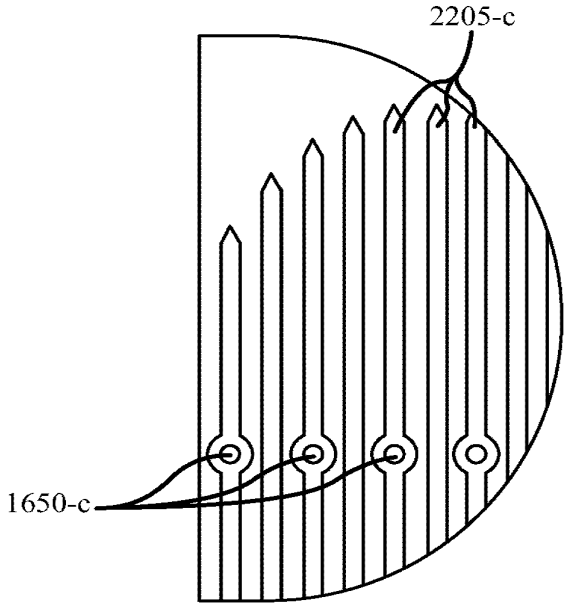

FIG.17C

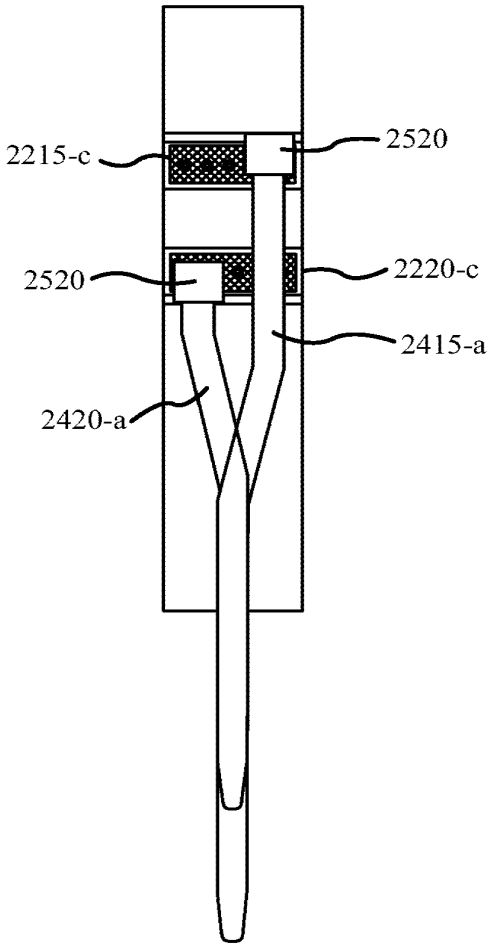

FIG.17D

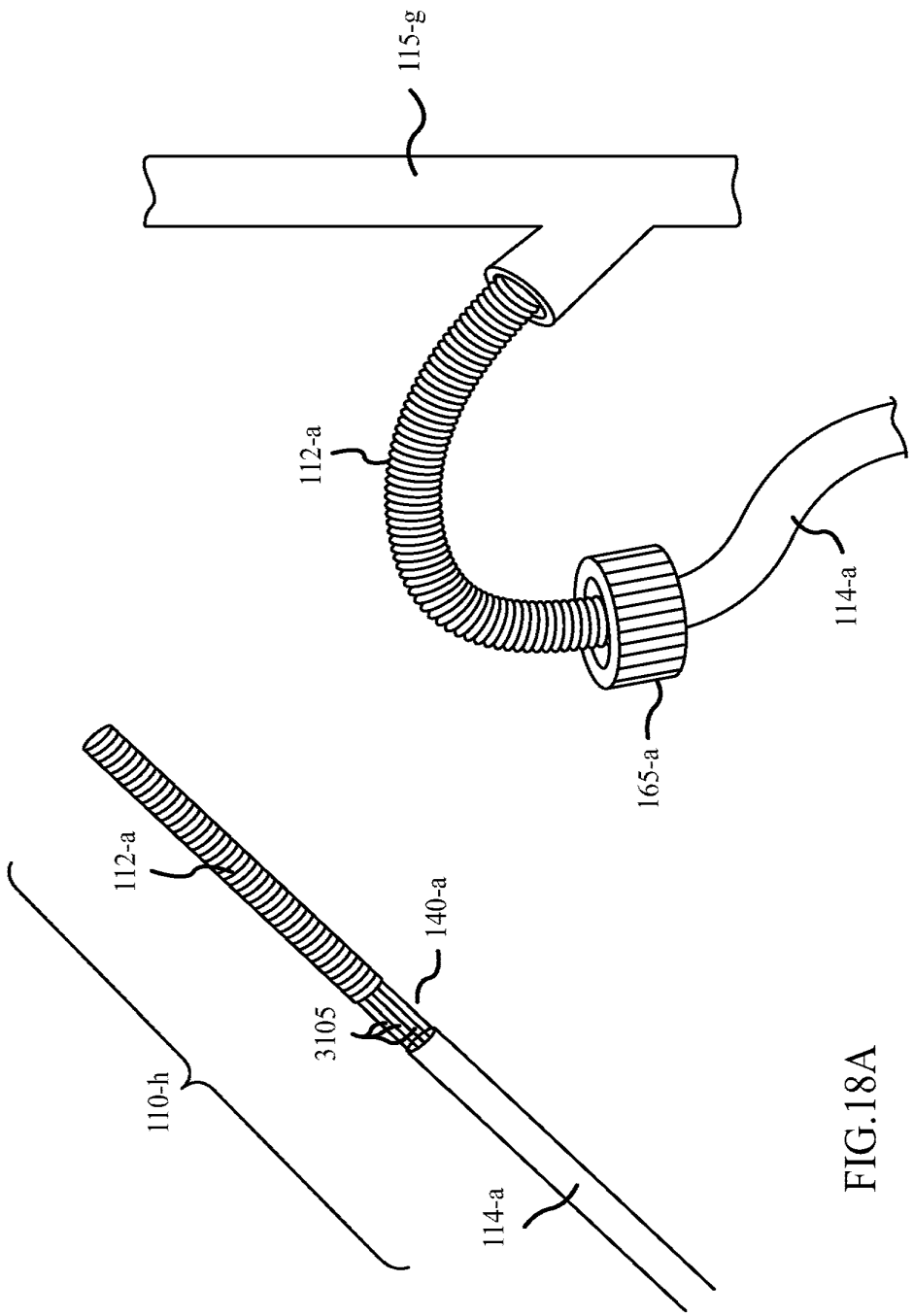

FIG.18B

FIG.18A

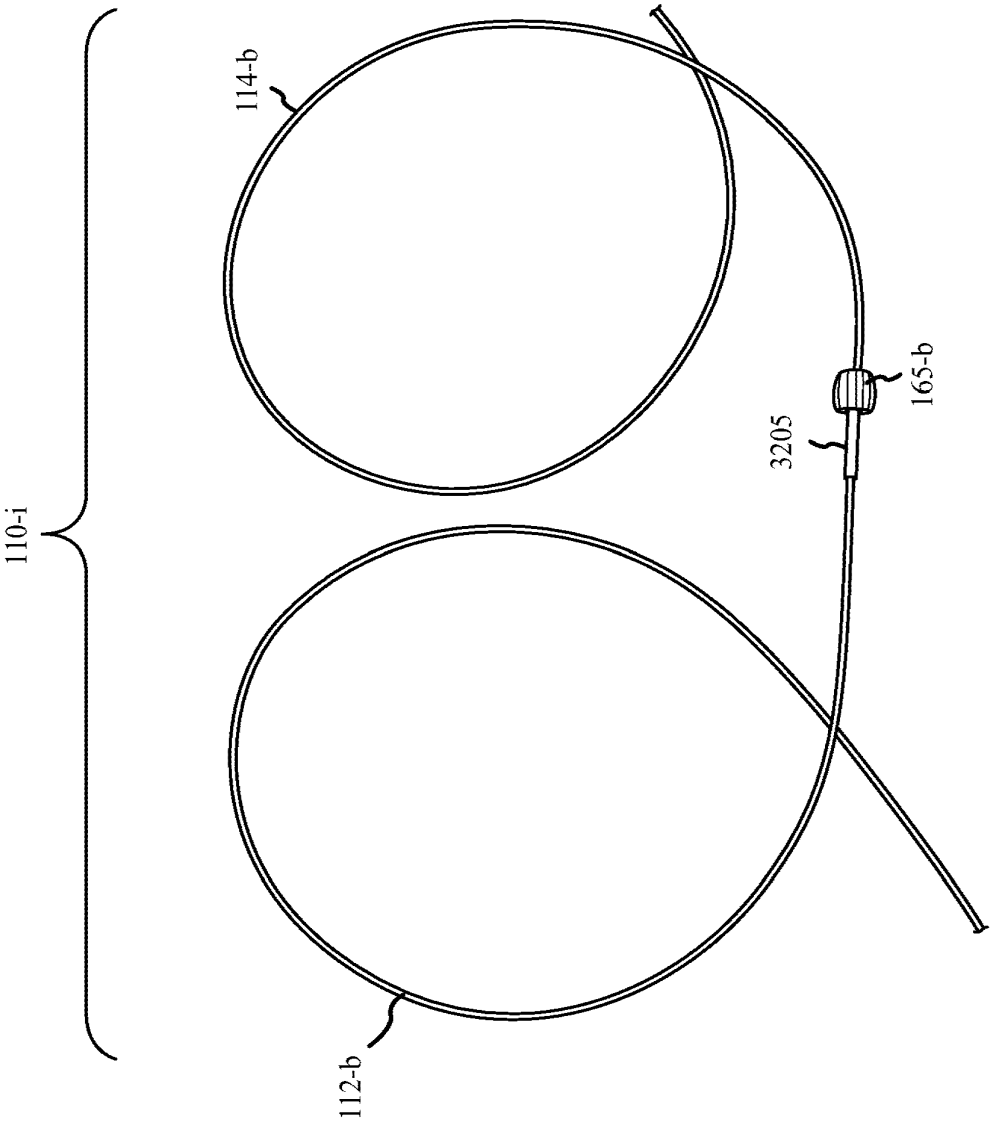

FIG.19A

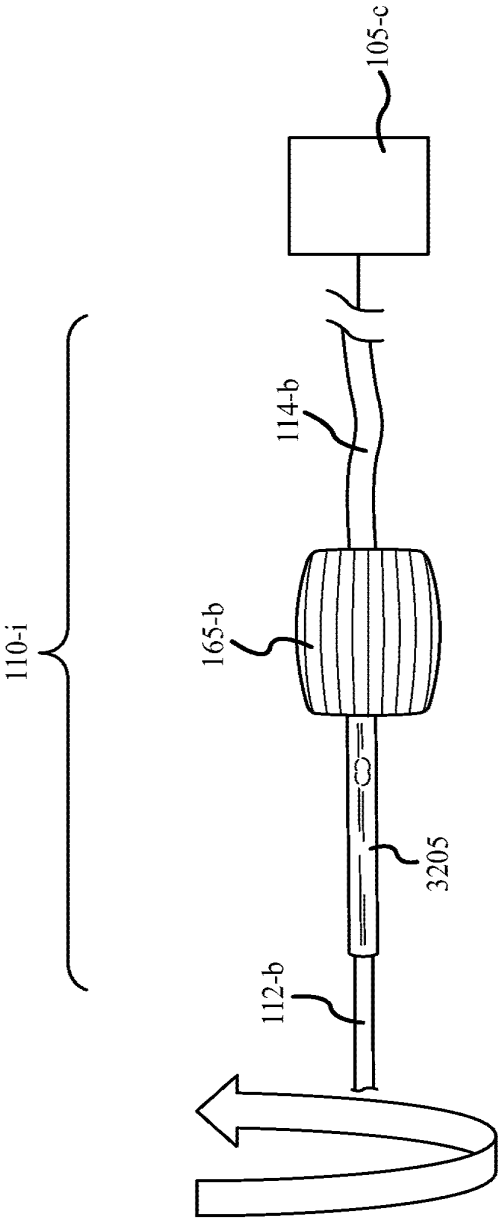

FIG.19B

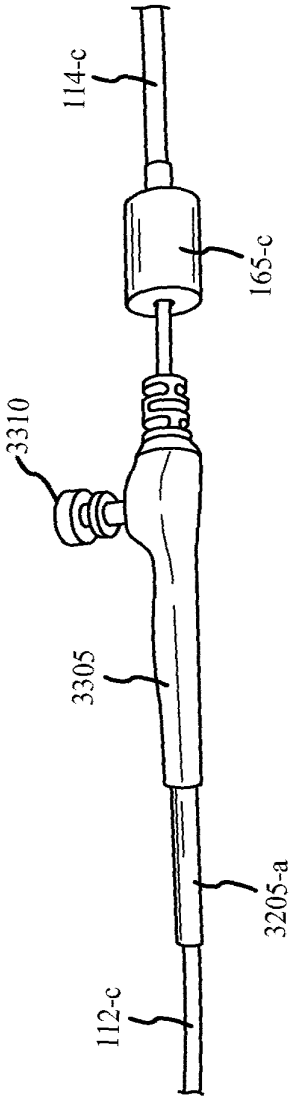

FIG.20

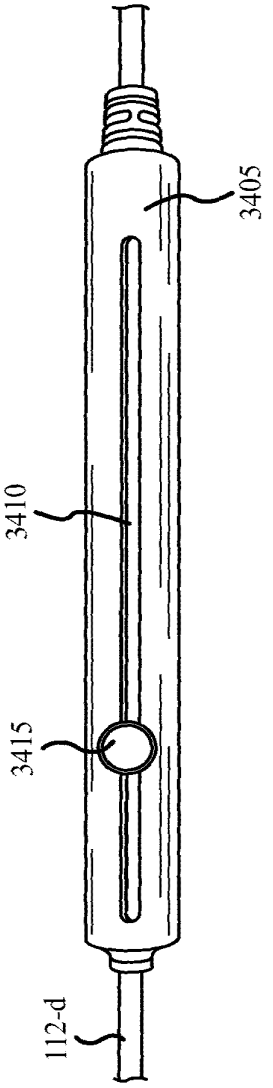

FIG.21

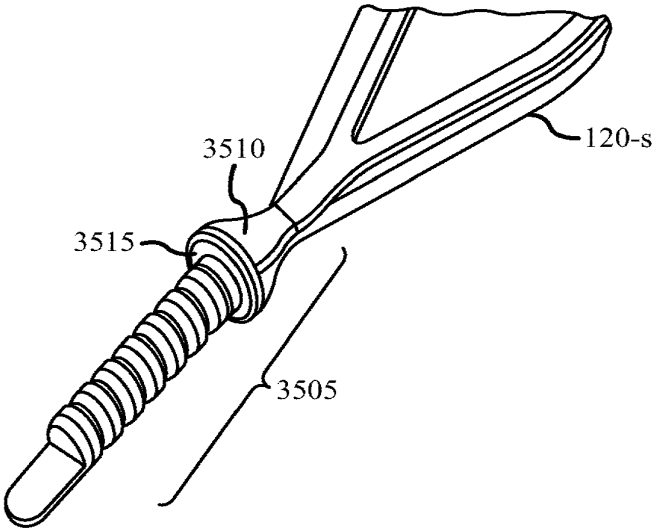

FIG.22

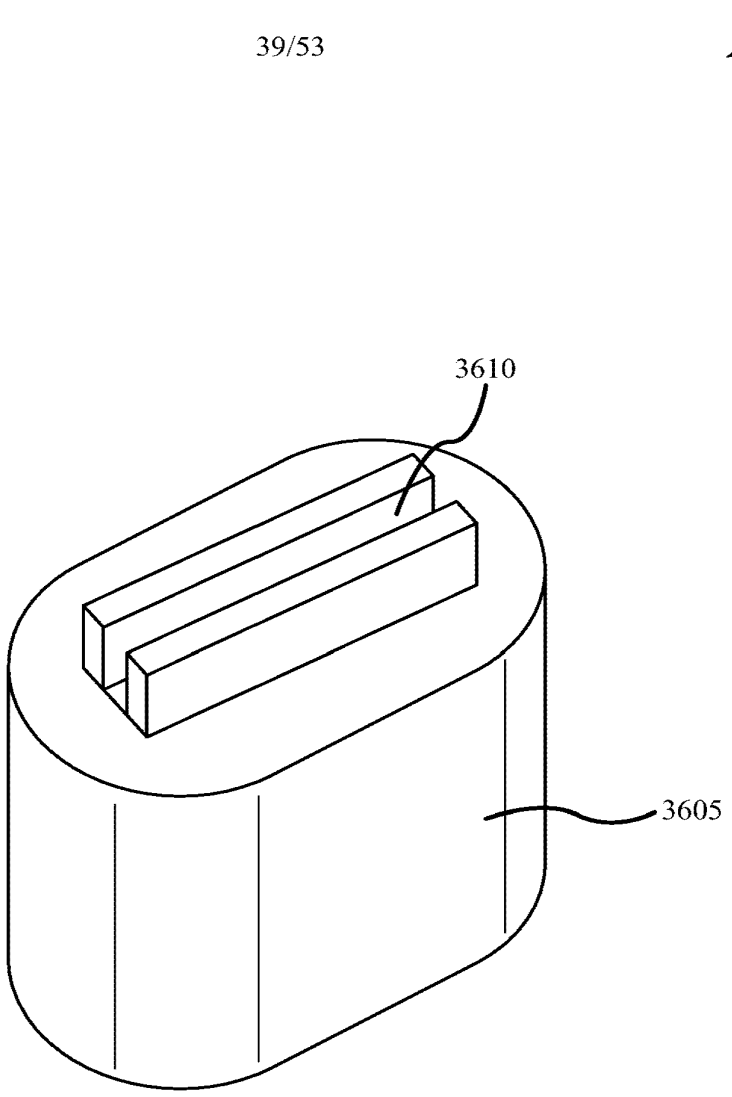

FIG.23

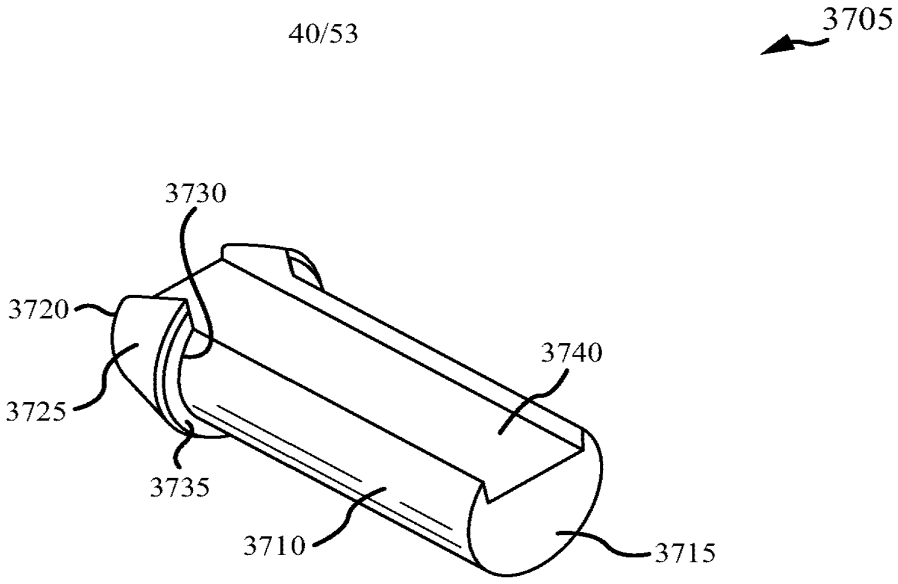

FIG.24A

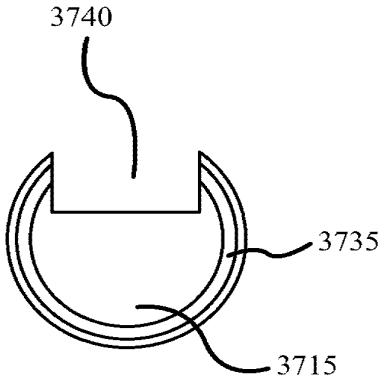

FIG.24B

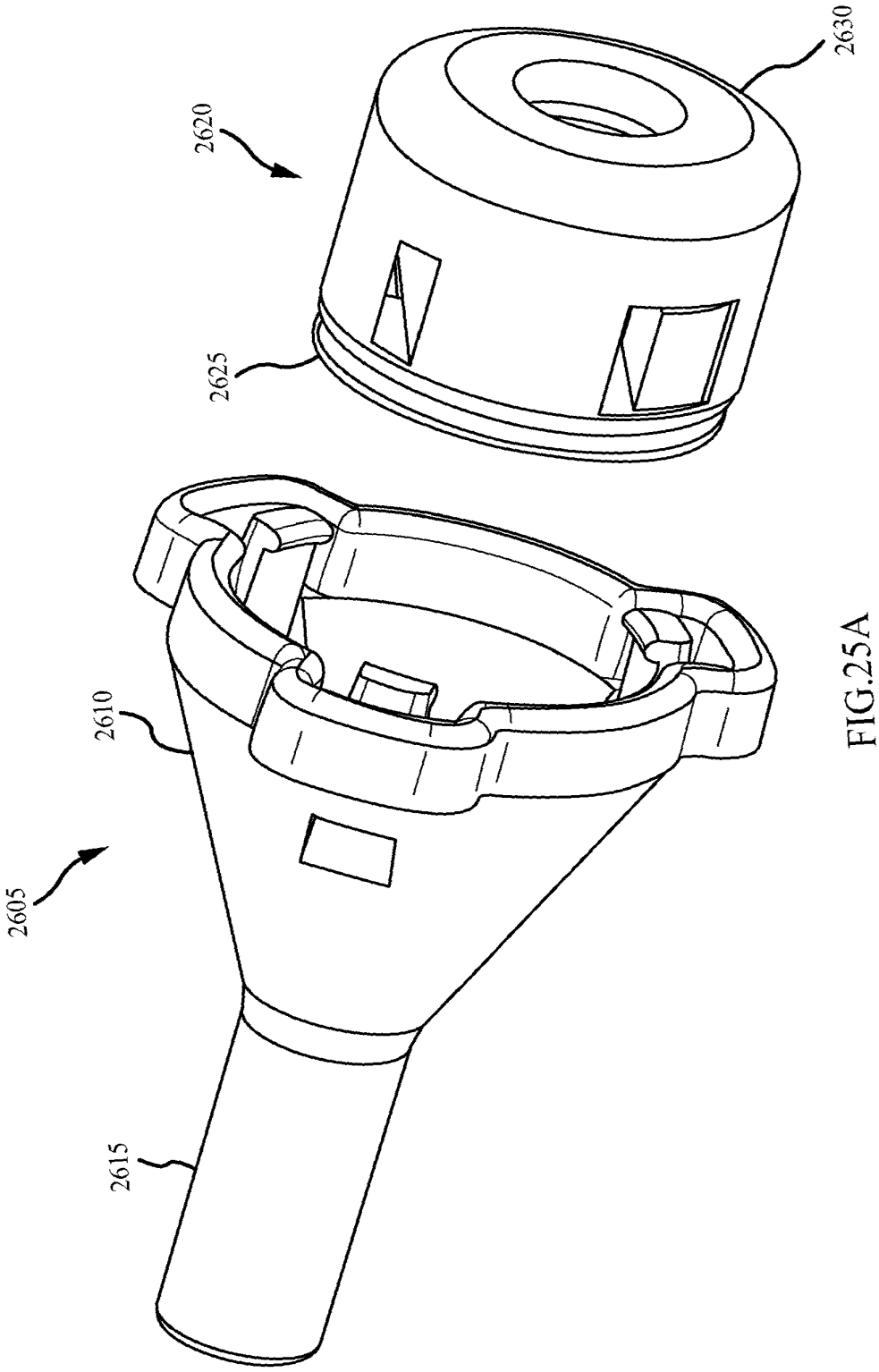

FIG.25A

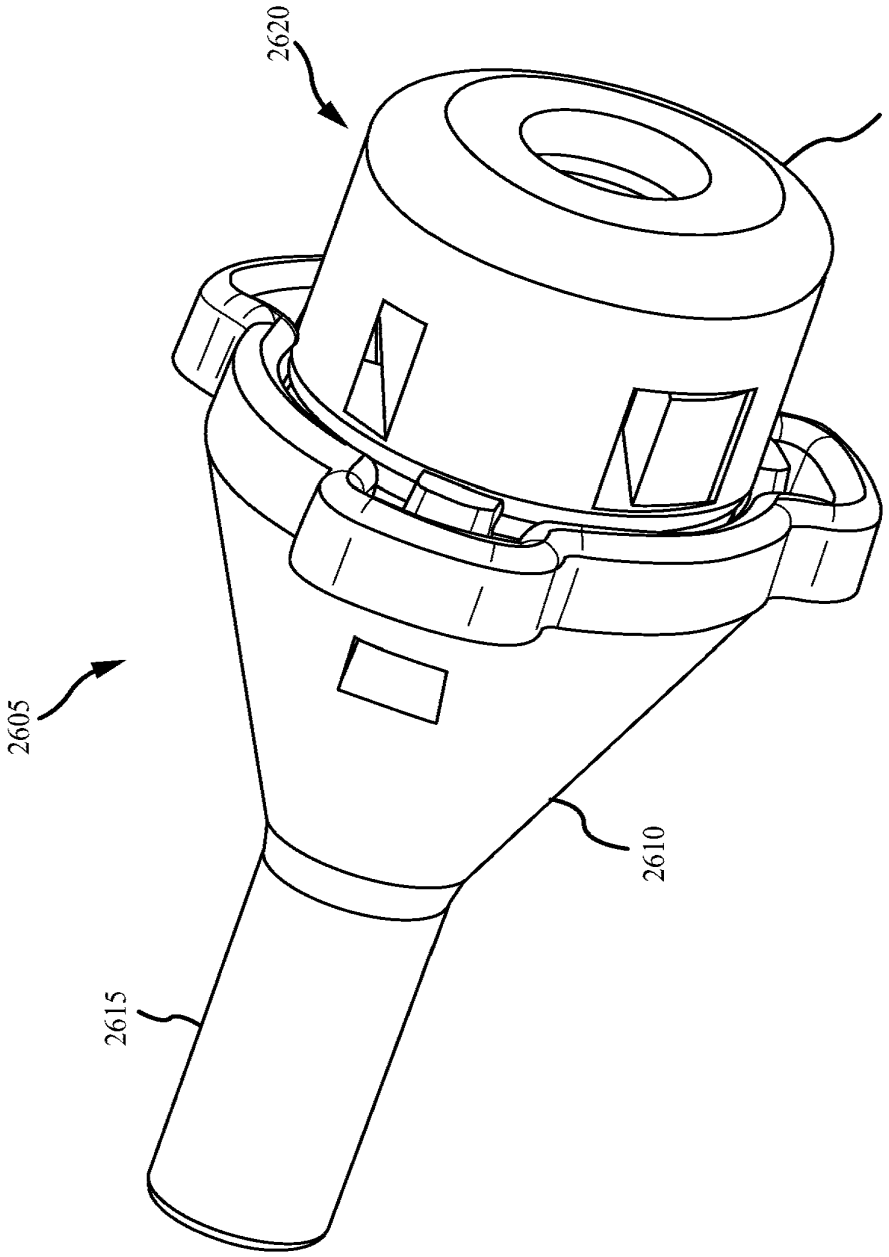

FIG.25B

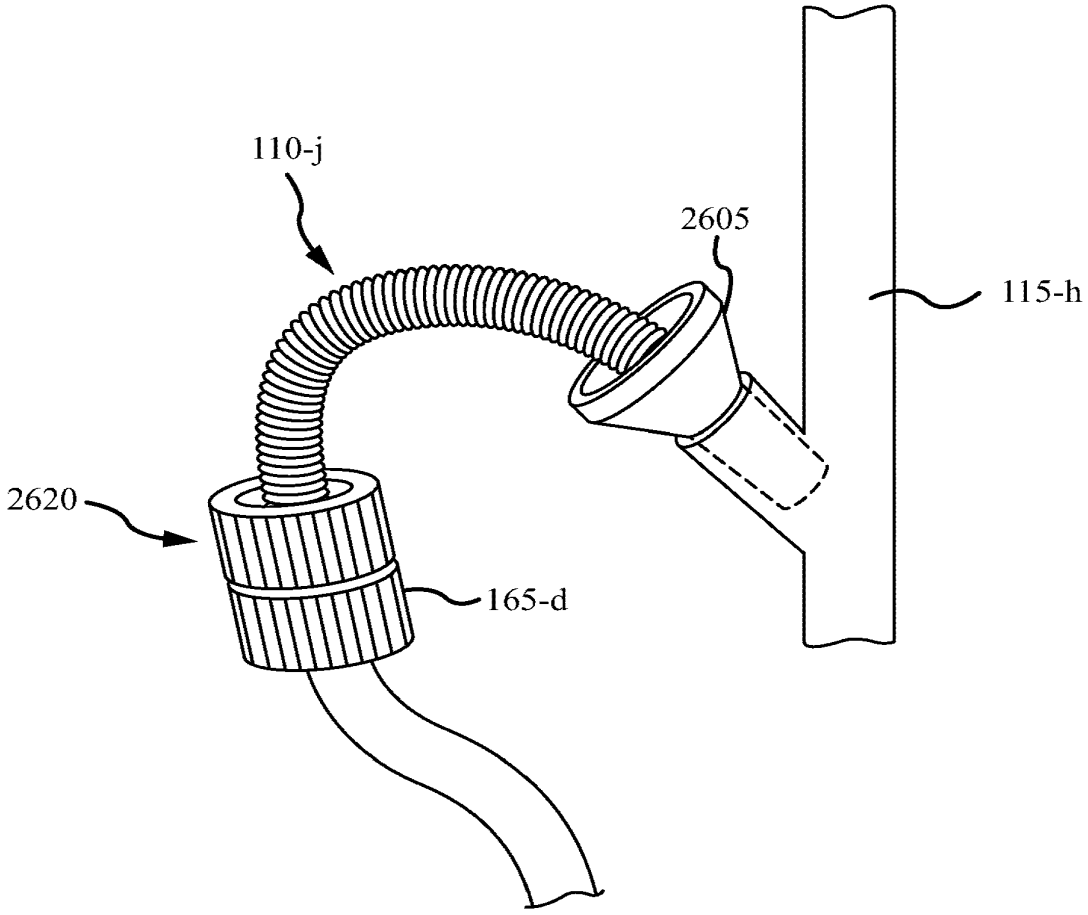

FIG.26A

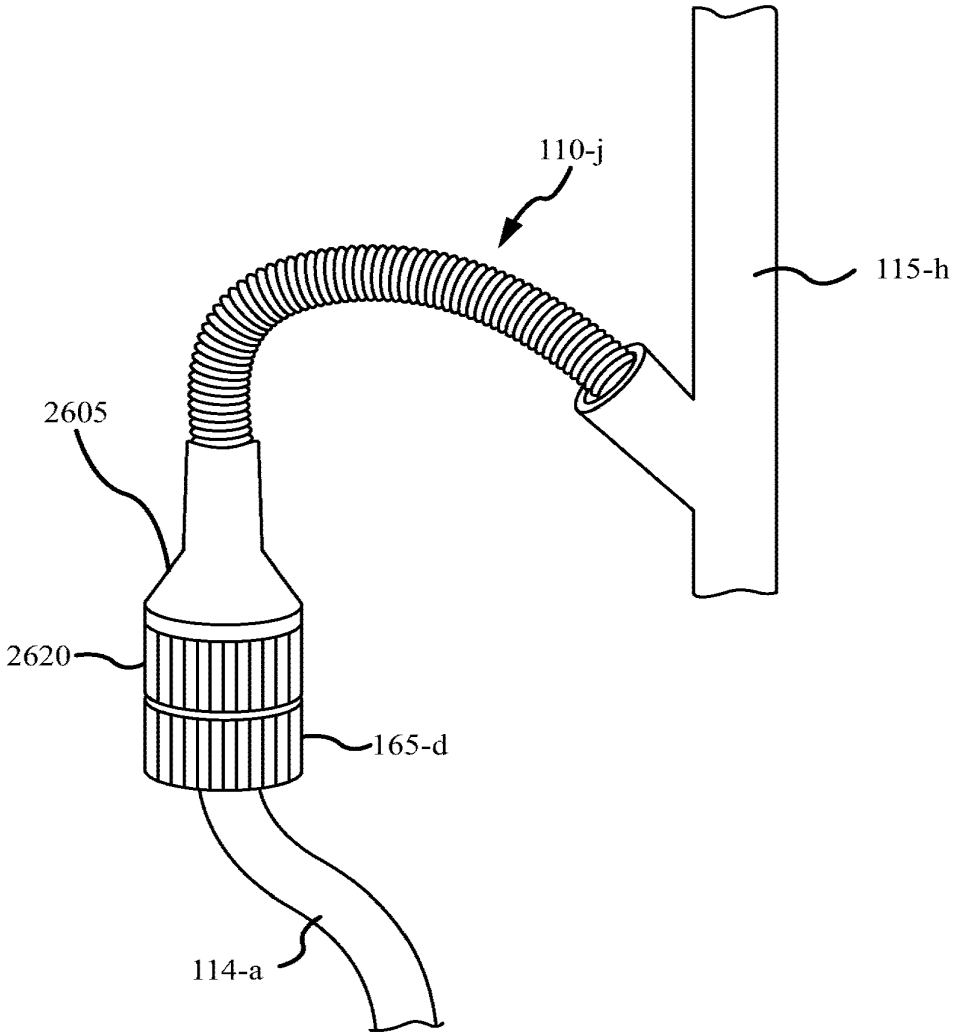

FIG.26B

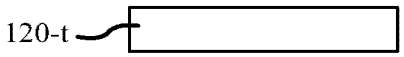

FIG.27A

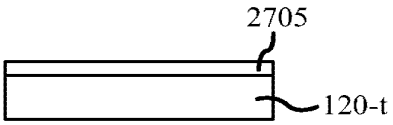

FIG.27B

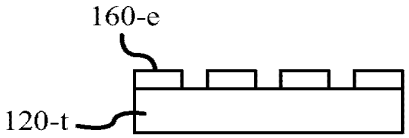

FIG.27C

FIG.27D

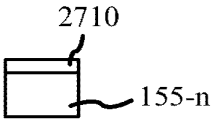

FIG.27E

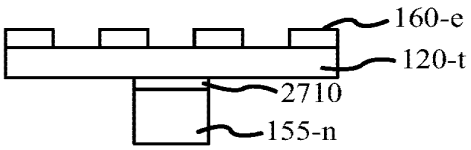

FIG.27F

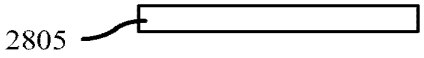

FIG.28A

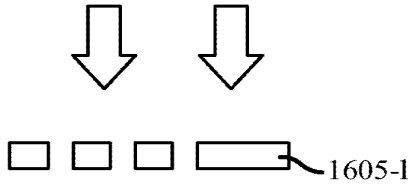

FIG.28B

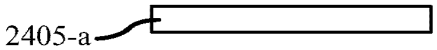

FIG.28C

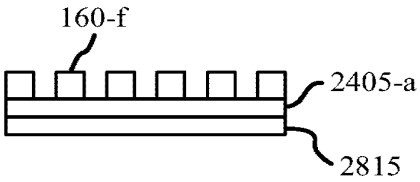

FIG.28D

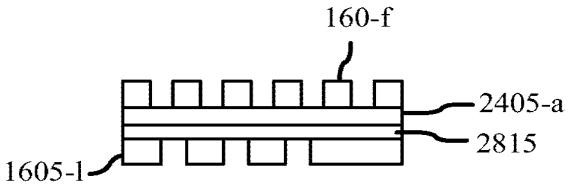

FIG.28E

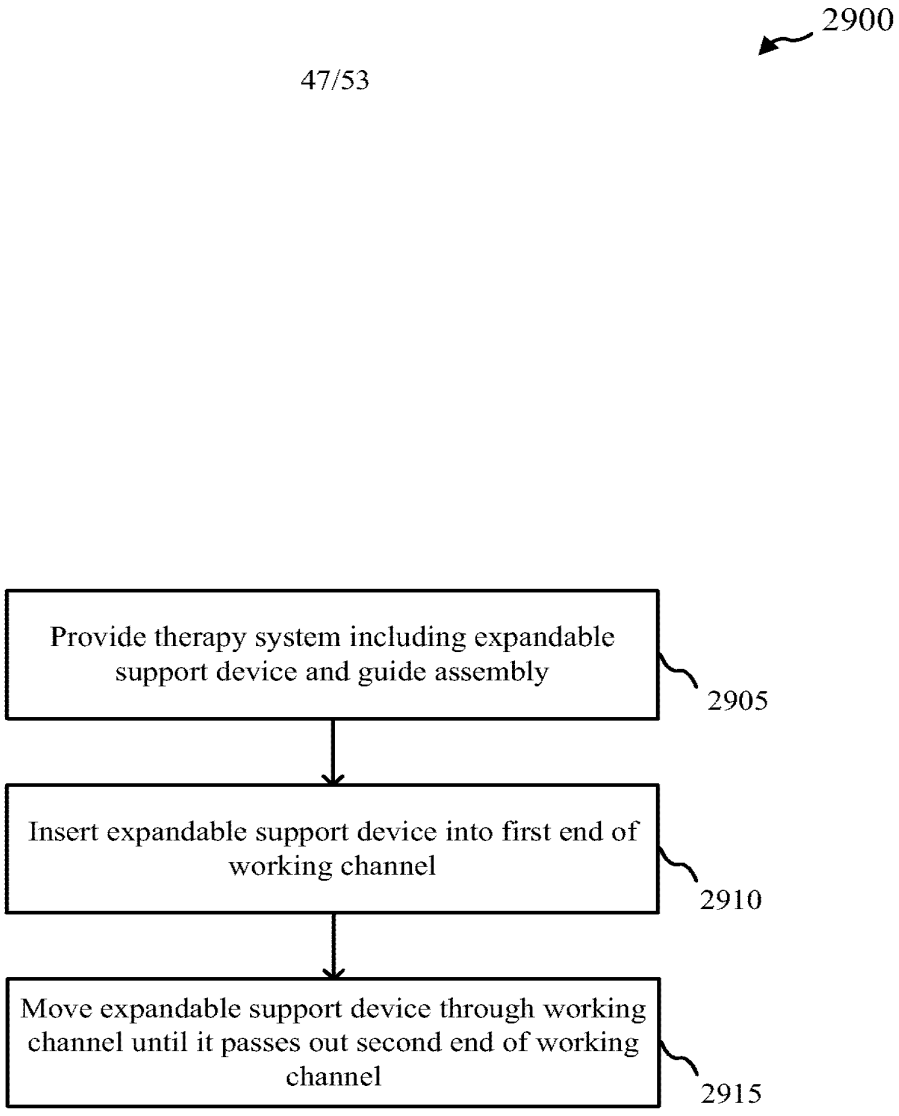
2900
Provide therapy system including expandable support device and guide assembly
2905
Insert expandable support device into first end of working channel
2910
Move expandable support device through working channel until it passes out second end of working channel
2915

FIG. 29

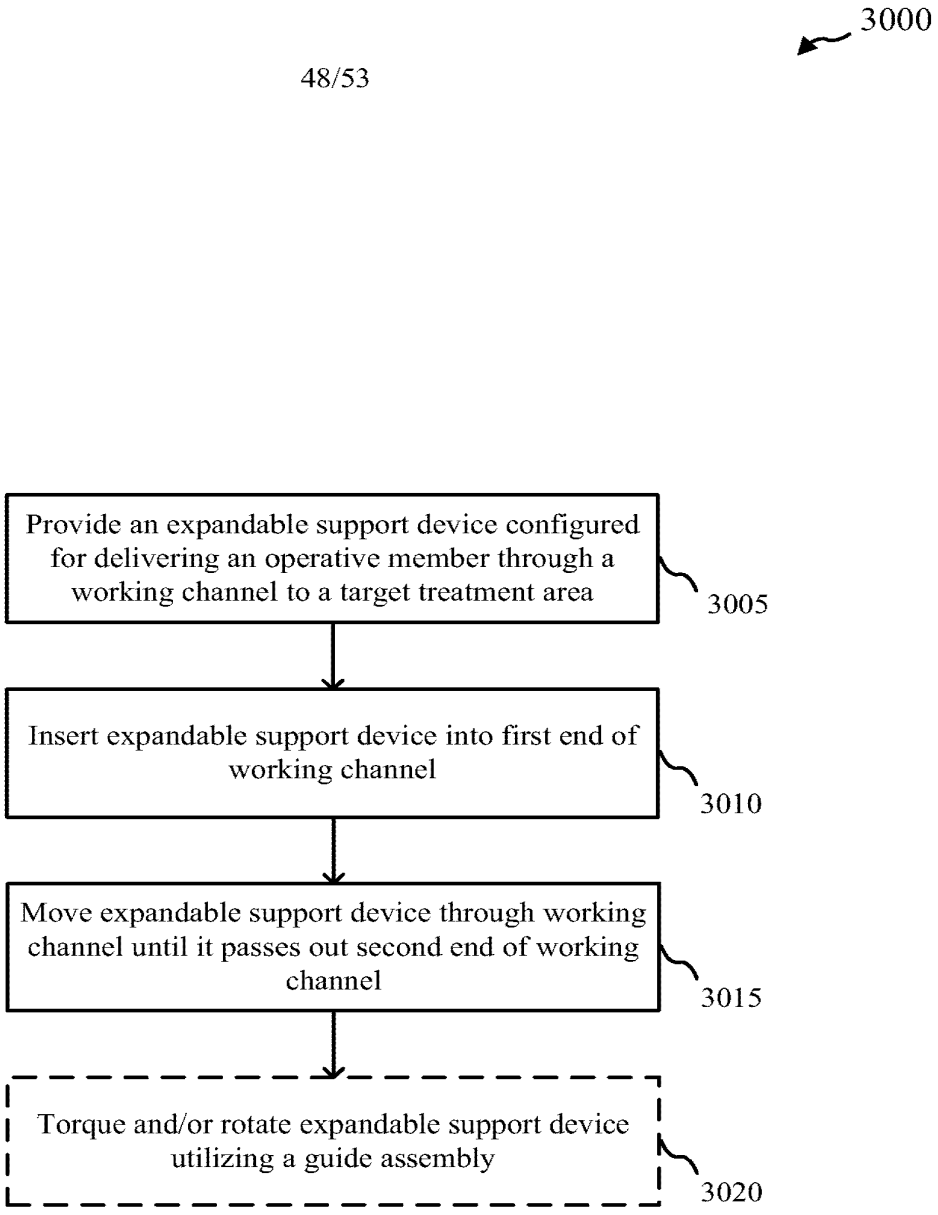
3000
Provide an expandable support device configured for delivering an operative member through a working channel to a target treatment area
3005
Insert expandable support device into first end of working channel
3010
Move expandable support device through working channel until it passes out second end of working channel
3015
Torque and/or rotate expandable support device utilizing a guide assembly
3020

FIG. 30

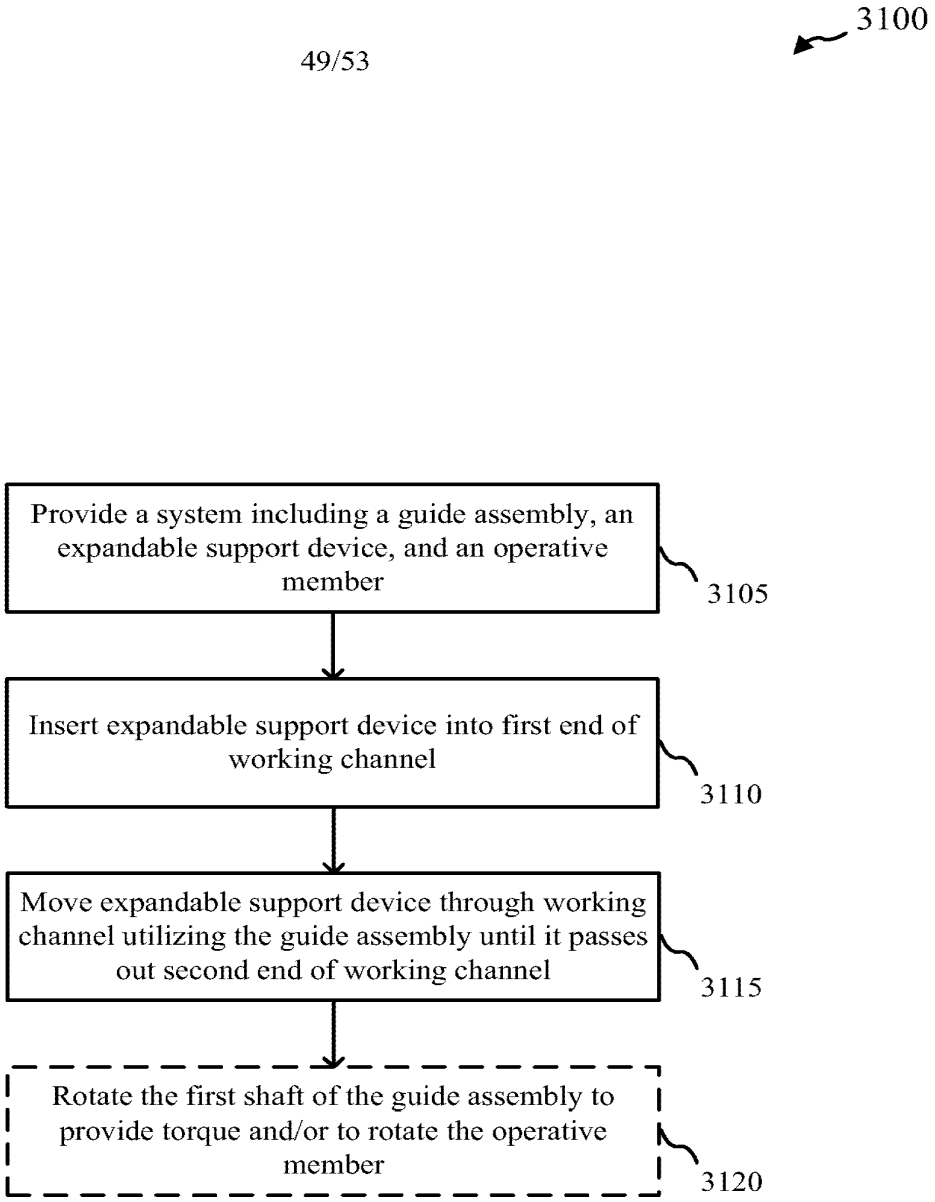
3100
Provide a system including a guide assembly, an expandable support device, and an operative member
3105
Insert expandable support device into first end of working channel
3110
Move expandable support device through working channel utilizing the guide assembly until it passes out second end of working channel
3115
Rotate the first shaft of the guide assembly to provide torque and/or to rotate the operative member
3120

FIG. 31

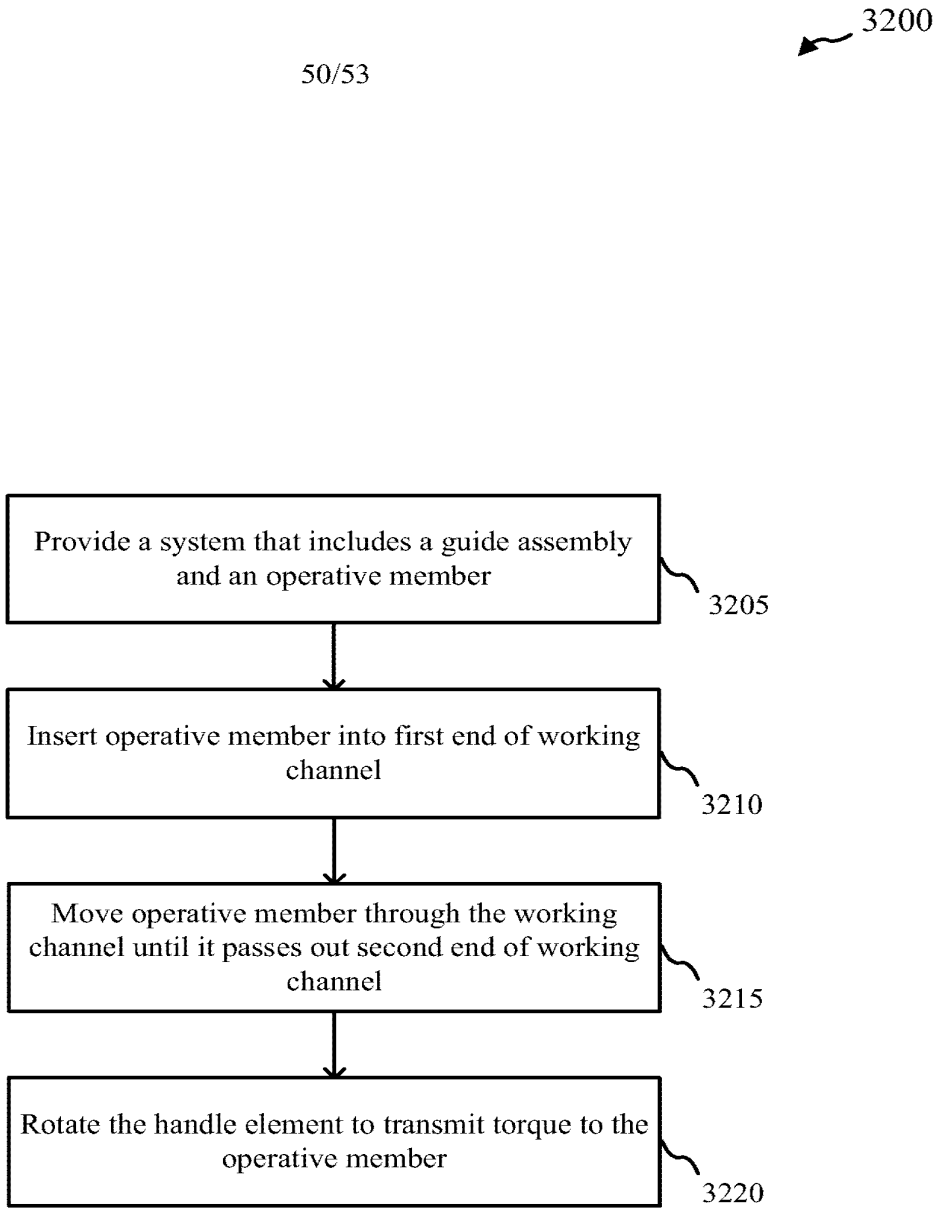
3200
Provide a system that includes a guide assembly and an operative member
3205
Insert operative member into first end of working channel
3210
Move operative member through the working channel until it passes out second end of working channel
3215
Rotate the handle element to transmit torque to the operative member
3220

FIG. 32

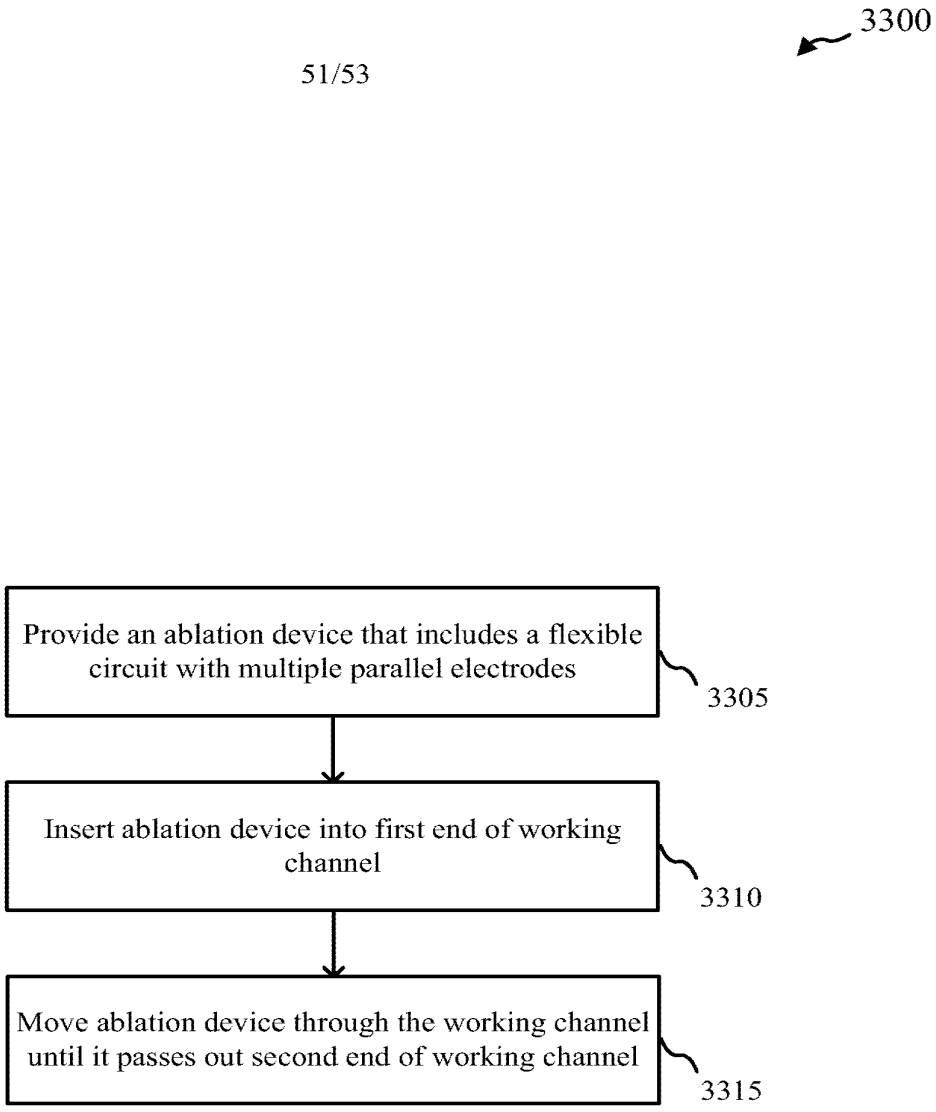
3300
Provide an ablation device that includes a flexible circuit with multiple parallel electrodes
3305
Insert ablation device into first end of working channel
3310
Move ablation device through the working channel until it passes out second end of working channel
3315

FIG. 33

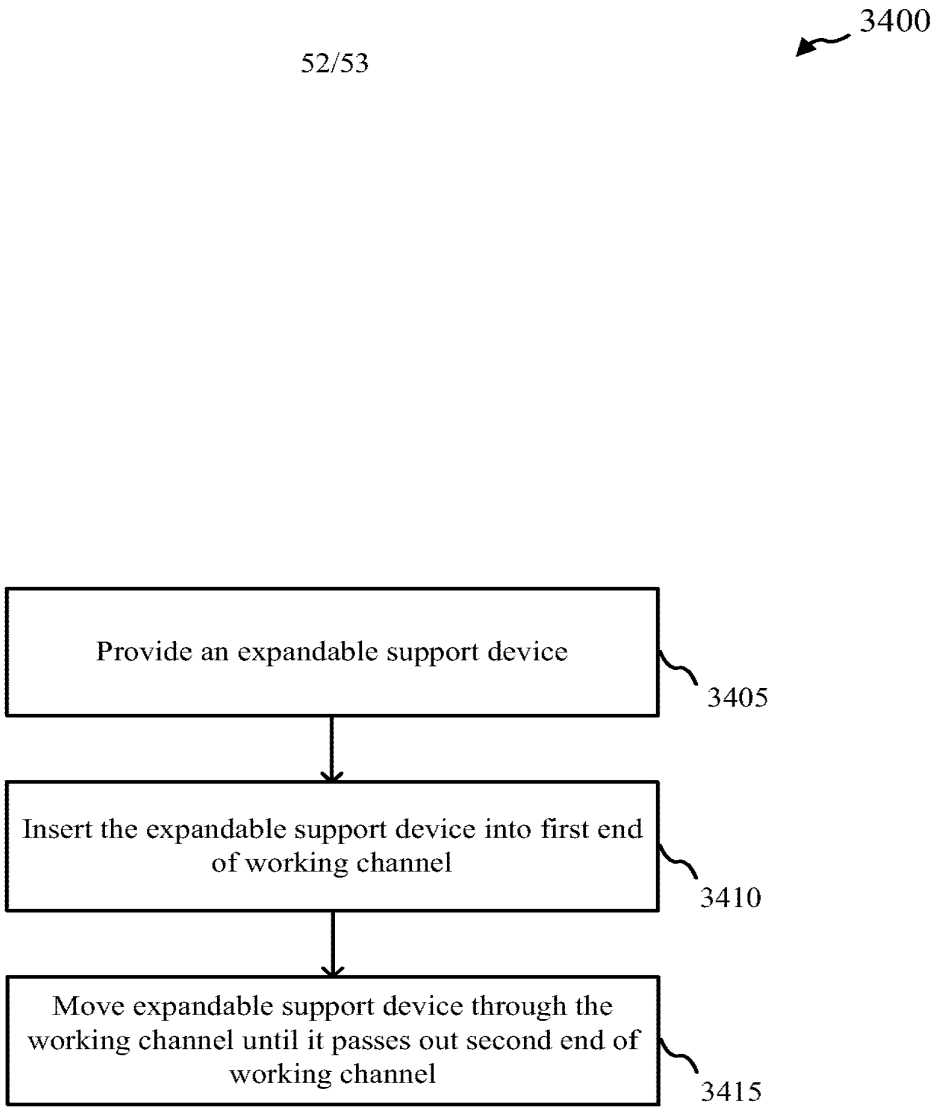
3400
Provide an expandable support device
3405
Insert the expandable support device into first end of working channel
3410
Move expandable support device through the working channel until it passes out second end of working channel
3415

FIG. 34

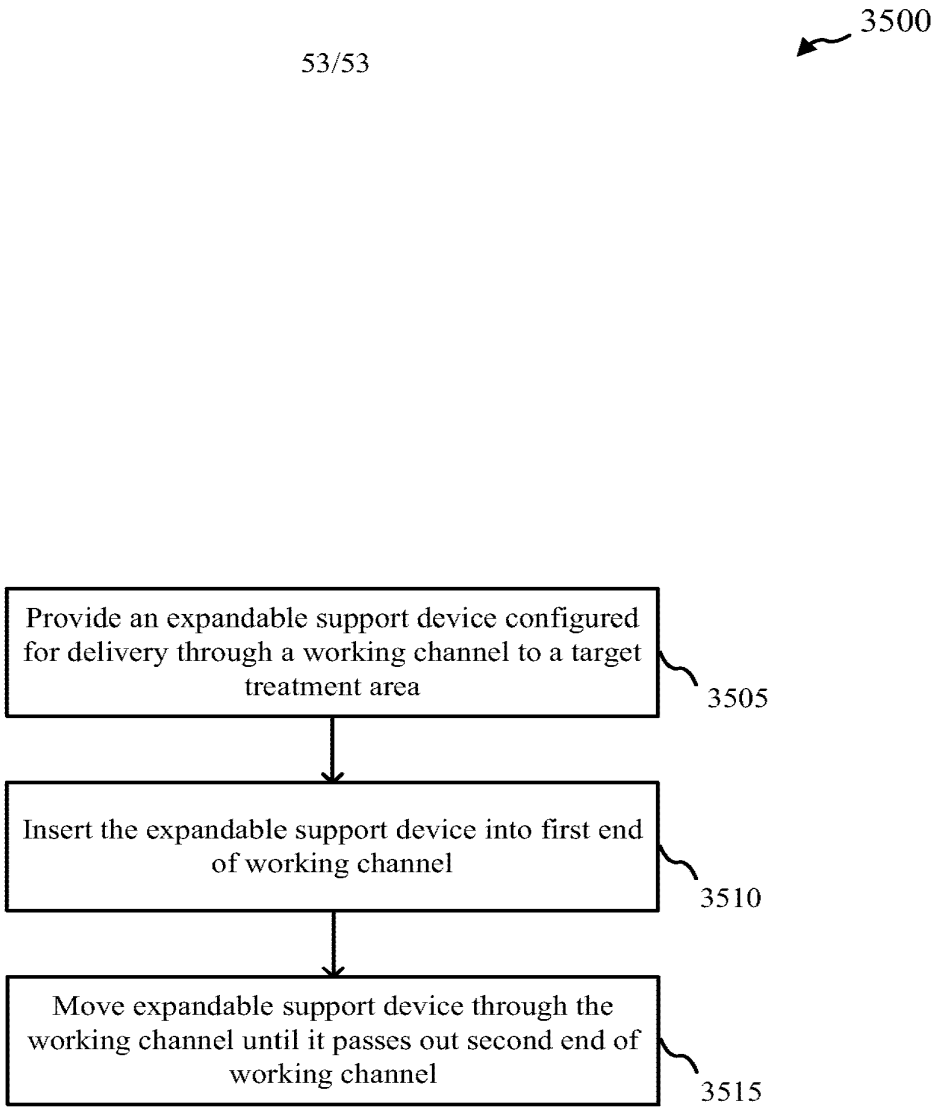
3500
Provide an expandable support device configured for delivery through a working channel to a target treatment area
3505
Insert the expandable support device into first end of working channel
3510
Move expandable support device through the working channel until it passes out second end of working channel
3515

FIG. 35

Electronic Acknowledgement Receipt

EFS ID:	37938252
Application Number:	16514316
International Application Number:	
Confirmation Number:	2153
Title of Invention:	METHODS OF TREATING NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US14
Receipt Date:	05-DEC-2019
Filing Date:	17-JUL-2019
Time Stamp:	12:35:28
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)	2019-12-05_IDS_17713-0001US14.PDF	1034365 440ce3925f6dcef53b7a3de4dd4051979b743f04	no	4

Warnings:

Information:					
2	Foreign Reference	WO2013028998.PDF	6257532 ac8a5b39ad623f939e045f09807c9862b64ba968	no	162
Warnings:					
Information:					
		Total Files Size (in bytes):	7291897		

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/514,316	07/17/2019	Scott J. WOLF	17713.0001US14

CONFIRMATION NO. 2153

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

PUBLICATION NOTICE

OC000000112479565

Title:METHODS OF TREATING NASAL AIRWAYS

Publication No.US-2019-0336196-A1
Publication Date:11/07/2019

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.

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

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

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

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	WOLF
Art Unit	4187
Examiner Name	
Attorney Docket Number	17713.0001US14

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7361168		2008-04-22	Makower	
	2	7997278		2011-08-16	Utley	
	3	8114062		2012-02-14	Muni	
	4	10335221		2019-07-02	Wolf et al.	
	5	10376300		2019-08-13	Wolf et al.	
	6	10398489		2019-09-03	Wolf	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	WOLF
	Art Unit	4187
	Examiner Name	
	Attorney Docket Number	17713.0001US14

	1	20040193238		2004-09-30	Mosher	
	2	20070049999		2007-03-01	Esch	
	3	20080154237		2008-06-26	Chang	
	4	20080183251		2008-07-31	Azar	
	5	20100204560		2010-08-12	Salahieh	
	6	20100260703		2010-10-14	Yankelson	
	7	20110118726		2011-05-19	De La Rama	
	8	20130158536		2013-06-20	Bloom	
	9	20160045277		2016-02-18	Lin	
	10	20160121112		2016-05-05	Azar	
	11	20190231409		2019-08-01	Wolf et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16514316
Filing Date	2019-07-17
First Named Inventor	WOLF
Art Unit	4187
Examiner Name	
Attorney Docket Number	17713.0001US14

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	1							

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16514316
	Filing Date	2019-07-17
	First Named Inventor	WOLF
	Art Unit	4187
	Examiner Name	
	Attorney Docket Number	17713.0001US14

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/ Christopher P. Ziolkowski /	Date (YYYY-MM-DD)	2019-09-11
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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Electronic Acknowledgement Receipt

EFS ID:	37136822
Application Number:	16514316
International Application Number:	
Confirmation Number:	2153
Title of Invention:	METHODS OF TREATING NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US14
Receipt Date:	11-SEP-2019
Filing Date:	17-JUL-2019
Time Stamp:	16:59:58
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)	2019-09-11_IDS_17713-0001US14.PDF	1034856 75464bbb75c47067ec4420250f2cfa7aa58166c3	no	5

Warnings:

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Total Files Size (in bytes):	1034856

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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
16/514,316	07/17/2019		785	17713.0001US14	16	1

CONFIRMATION NO. 2153

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

FILING RECEIPT

OC000000110031792

Date Mailed: 07/31/2019

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

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

Applicant(s)

Aerin Medical Inc., Austin, TX;

Assignment For Published Patent Application

Aerin Medical Inc., Austin, TX

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

Domestic Priority data as claimed by applicant

This application is a CON of 15/596,455 05/16/2017
which is a CON of 15/248,935 08/26/2016 PAT 9687296
which is a CON of 14/864,428 09/24/2015 PAT 9433463
which is a CON of 14/737,196 06/11/2015 PAT 9179967
which is a CON of 14/607,639 01/28/2015 PAT 9179964
which is a CON of 14/026,922 09/13/2013 PAT 8986301
which is a CIP of 13/495,844 06/13/2012 PAT 8936594
which claims benefit of 61/603,864 02/27/2012
and claims benefit of 61/496,930 06/14/2011

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

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Permission to Access Search Results: Yes

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If Required, Foreign Filing License Granted: 07/30/2019

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/514,316**

Projected Publication Date: 11/07/2019

Non-Publication Request: No

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

METHODS OF TREATING NASAL AIRWAYS

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number
16/514,316

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	16 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 230 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	785		TOTAL	

APPLICATION AS AMENDED - PART II

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

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Scott J. WOLF	Examiner:	*unknown*
Appl. No.	16/514,316	Art Unit:	*unknown*
Filed:	July 17, 2019	Docket No.	17713.0001US14
Customer No.	23552	Confirmation No.:	2153
Title:	METHODS OF TREATING NASAL AIRWAYS		

PRELIMINARY AMENDMENT

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

Attention: Commissioner for Patents

Please consider this Preliminary Amendment before examining the referenced application.

Amendments to the Specification begin on page 2.

Amendments to the Claims begin on page 4.

Remarks begin on page 7.

AMENDMENTS TO THE SPECIFICATION

Please amend the specification beginning at page 15, paragraph 92, as follows:

[0092] 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~~ mucus overproduction. 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~~ sequellae 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).

Please amend the specification beginning at page 59, paragraph 231, as follows:

[0231] 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.

Please amend the specification beginning at page 62, paragraph 244, as follows:

[0244] In some embodiments, ~~treating~~ the target tissue ~~comprises treatment~~ is treated for about ~~is to about~~ 3 minutes. In some embodiments, ~~treating~~ the target tissue ~~comprises treatment~~ is treated for about 10 seconds to about 2 minutes. In some embodiments, ~~treating~~ the target tissue

~~comprises treatment~~ is treated for about 15 seconds to about 1 minute. In some embodiments, ~~treating~~ the target tissue ~~comprises treatment~~ is treated for about 20 seconds to about 45 seconds. In some embodiments, ~~treating~~ the target tissue ~~comprises treatment~~ is treated for about 30 seconds.

AMENDMENTS TO THE CLAIMS

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

Listing of Claims:

1.-15. (Canceled)

16. (New) A method for treating a nasal airway to reduce mucus production, the method comprising:

contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;

applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and

removing the treatment element from the nasal airway,

wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue, and

wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.

17. (New) The method of claim 16, wherein the target tissue is selected from the group consisting of mucosa, submucosa, cartilage, muscle, ligament, and tendon.

18. (New) The method of claim 16, further comprising controlling at least one characteristic of the applied radiofrequency energy with a control system coupled with the nasal airway treatment device.

19. (New) The method of claim 16, wherein the radiofrequency energy is applied in the form of a 460 kHz sinusoid wave.

20. (New) The method of claim 16, further comprising:

sensing a temperature of the nasal mucosa using a thermocouple positioned between the two rows of bipolar electrode pairs on the treatment element; and

modifying an amount of the radiofrequency energy applied to the target tissue based on the sensed temperature.

21. (New) The method of claim 16, further comprising displaying one or more parameters of treatment on a console attached to the nasal airway treatment device while the radiofrequency energy is applied, the one or more parameters selected from the group consisting of treatment time, power level, temperature sensed by the treatment element, electric impedance, electric current, and depth of treatment.

22. (New) The method of claim 16, further comprising applying local anesthesia to at least one of the nasal mucosa or the target tissue before applying the radiofrequency energy.

23. (New) The method of claim 16, wherein the radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts.

24. (New) The method of claim 16, wherein applying the radiofrequency energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius.

25. (New) The method of claim 16, wherein the amount of time the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute.

26. (New) The method of claim 16, further comprising, before removing the treatment element from the nasal airway:

repositioning the treatment element to contact a different portion of nasal mucosa; and

applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue for the amount of time to heat the different portion of target tissue.

27. (New) The method of claim 16, wherein the modified at least one property of the target tissue is selected from the group consisting of shrinking, tightening, stiffening, and deactivating the target tissue.

28. (New) The method of claim 16, further comprising repositioning, remodeling, or reshaping the target tissue with the treatment element, wherein the target tissue remains at least partially repositioned, remodeled or reshaped after the target tissue heals.

29. (New) The method of claim 16, wherein applying the radiofrequency energy heats the target tissue to a sub-ablative temperature.

30. (New) The method of claim 16, further comprising applying a conductivity enhancing substance to the nasal mucosa before contacting the treatment element with the nasal mucosa.

31. (New) The method of claim 16, further comprising bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.

REMARKS

This preliminary amendment amends paragraphs [0092], [0231], and [0244] without introducing new matter. Claims 1–15 are canceled without prejudice and claims 16–31 are added without introducing new matter.

Favorable consideration is requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

The Commissioner is hereby authorized to charge any additional fees which may be required for entry of these papers or to credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903

Date: July 25, 2019

/ Christopher P. Ziolkowski /
Christopher P. Ziolkowski
Reg. No.: 73,729
Direct: (612) 766-6025

Electronic Acknowledgement Receipt

EFS ID:	36685978
Application Number:	16514316
International Application Number:	
Confirmation Number:	2153
Title of Invention:	METHODS OF TREATING NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US14
Receipt Date:	25-JUL-2019
Filing Date:	
Time Stamp:	11:18:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2019-07-25_PreliminaryAmendment_17713-0001US14.pdf	109421 3dcd3166e36f3c9da97b795a2be57fd125612a58	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Specification	2	3
	Claims	4	6
	Applicant Arguments/Remarks Made in an Amendment	7	7
Warnings:			
Information:			
	Total Files Size (in bytes):	109421	

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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/82A (07-13)
Approved for use through 01/31/2018. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	
Filing Date	2019-07-17
First Named Inventor	WOLF
Title	METHODS OF TREATING NASAL AIRWAYS
Art Unit	
Examiner Name	
Attorney Docket Number	17713.0001US14

SIGNATURE of Applicant or Patent Practitioner

Signature	/Christopher P. Ziolkowski/	Date (Optional)	
Name	Christopher P. Ziolkowski	Registration Number	73,729
Title (if Applicant is a juristic entity)	Attorney		
Applicant Name (if Applicant is a juristic entity)	AERIN MEDICAL, INC.		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

PTO/AIA/82B (07-13)
Approved for use through 01/31/2018. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 23552

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

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

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

AERIN MEDICAL, INC.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	Fred Dinger		
Title	CEO		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Privacy Act Statement

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	METHODS OF TREATING NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Attorney Docket Number:	17713.0001US14

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	75	75
UTILITY SEARCH FEE	2111	1	330	330
UTILITY EXAMINATION FEE	2311	1	380	380
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**785**

Electronic Acknowledgement Receipt

EFS ID:	36612628
Application Number:	16514316
International Application Number:	
Confirmation Number:	2153
Title of Invention:	METHODS OF TREATING NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Christopher P. Ziolkowski/Juliana Hoffman
Filer Authorized By:	Christopher P. Ziolkowski
Attorney Docket Number:	17713.0001US14
Receipt Date:	17-JUL-2019
Filing Date:	
Time Stamp:	15:16:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$785
RAM confirmation Number	071819INTEFSW15173700
Deposit Account	132725
Authorized User	Juliana Hoffman

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

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	2019-07-17_ADS_17713-0001US14.PDF	1823762 ec47d6db570f3f3df256d5f80509695763 79ccb6	no	9
Warnings:					
Information:					
2		2019-07-17_Specification_17713-0001US14.pdf	321782 18c8ba62abfad17cca085ac2b4b1c7729febd3b4	yes	72

Multipart Description/PDF files in .zip description

Document Description	Start	End
Abstract	72	72
Claims	70	71
Specification	1	69

Warnings:					
Information:					
3	Drawings-only black and white line drawings	2019-07-17_Drawings_17713-0001US14.pdf	4838761 46a13bd081b5e0bf9897b0d7a6b5847a75ff6dbe	no	41
Warnings:					
Information:					
4	Oath or Declaration filed	2019-07-17_Declaration_17713-0001US14.PDF	86848 0633fb201d6bebec940b182c5c2dd3ba359a344b	no	2
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	2019-07-17_IDS_17713-0001US14.PDF	636259 42483eee1c069dc9823cc96d68d6d6cc5bfa76ea	no	21

Warnings:					
Information:					
6	Power of Attorney	2019-07-17_POA_17713-0001US14.PDF	1050454 812f3576b58b2fb7fd2f29018f470cc829213556	no	3
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	35261 a2cfc8d6416d3cc8c5b80822549b842646ca0719	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	8793127		

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

New Applications Under 35 U.S.C. 111

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

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US14
	Application Number	
Title of Invention	METHODS OF TREATING NASAL AIRWAYS	

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

Secrecy Order 37 CFR 5.2:

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

Inventor Information:

Inventor 1 Remove

Legal Name

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

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

City	State/Province	Country of Residence
Menlo Park	CA	US

Mailing Address of Inventor:

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

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		FRAZIER	

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

City	State/Province	Country of Residence
Sunnyvale	CA	US

Mailing Address of Inventor:

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

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

Correspondence Information:

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US14
	Application Number	
Title of Invention	METHODS OF TREATING NASAL AIRWAYS	

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

Customer Number	23552		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	METHODS OF TREATING NASAL AIRWAYS		
Attorney Docket Number	17713.0001US14	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	41	**Suggested Figure for Publication (if any)**	

Filing By Reference:

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

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

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

Publication Information:

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

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

Representative Information:

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

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US14
	Application Number	
Title of Invention	METHODS OF TREATING NASAL AIRWAYS	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
	Continuation of	15/596455	2017-05-16	

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/596455	Continuation of	15248935	2016-08-26	9687296	2017-06-27

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15248935	Continuation of	14864428	2015-09-24	9433463	2016-09-06

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14864428	Continuation of	14737196	2015-06-11	9179967	2015-11-10

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14737196	Continuation of	14607639	2015-01-28	9179964	2015-11-10

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14607639	Continuation of	14026922	2013-09-13	8986301	2015-03-24

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14026922	Continuation in part of	13495844	2012-06-13	8936594	2015-01-20

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US14
	Application Number	
Title of Invention	METHODS OF TREATING NASAL AIRWAYS	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13495844	Claims benefit of provisional	61496930	2011-06-14
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.			Add

Foreign Priority Information:

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US14
	Application Number	
Title of Invention	METHODS OF TREATING NASAL AIRWAYS	

Authorization or Opt-Out of Authorization to Permit Access:

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

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

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

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

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

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

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

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

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US14
	Application Number	
Title of Invention	METHODS OF TREATING NASAL AIRWAYS	

Applicant Information:

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

Applicant 1 Remove

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

Clear

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

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

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Aerin Medical Inc.		
Mailing Address Information For Applicant:			
Address 1	1927 Lohman's Crossing Rd #200		
Address 2			
City	Austin	**State/Province**	TX
Country	US	Postal Code	78734
Phone Number		Fax Number	
Email Address			

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

Assignee Information including Non-Applicant Assignee Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US14
	Application Number	
Title of Invention	METHODS OF TREATING NASAL AIRWAYS	

Assignee 1

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

Remove

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

Organization Name	Aerin Medical Inc.

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	1927 Lohman's Crossing Rd #200		
Address 2			
City	Austin	**State/Province**	TX
Country i	US	Postal Code	78734
Phone Number		Fax Number	
Email Address			

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

Signature:

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

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

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

Signature	/Christopher P. Ziolkowski/			Date (YYYY-MM-DD)	2019-07-17
First Name	Christopher P.	Last Name	Ziolkowski	Registration Number	73729

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US14
	Application Number	
Title of Invention	METHODS OF TREATING NASAL AIRWAYS	

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

Privacy Act Statement

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

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ABSTRACT

A device is described for treating a nasal airway by modifying a property of a nasal tissue of or near a nasal valve of the airway, without using a surgical incision or an implant, to decrease airflow resistance or perceived airflow resistance in the nasal airway. Various embodiments include an elongate shaft, a bipolar radiofrequency delivery member extending from one end of the shaft, and a handle attached to the elongate shaft at an opposite end from the radiofrequency delivery member. The radiofrequency delivery member is sized to be inserted into a nose and configured to at least temporarily deform the nasal tissue and deliver radiofrequency energy. The radiofrequency delivery member includes two rows of protruding electrodes disposed on a tissue contact surface, and the device is configured to deliver radiofrequency energy from one row of electrodes to the other row of electrodes.

CLAIMS

What is claimed is:

1. A method for treating nasal obstruction by modifying submucosal tissue of a nasal airway, the method comprising:

positioning a treatment element of a nasal airway treatment device against target tissue of the nasal airway, wherein the treatment element comprises one or more bipolar electrode pairs;

applying pressure with the treatment element against the target tissue;

applying radiofrequency energy with the one or more bipolar electrode pairs to heat cartilage of the nasal airway; and

reshaping a region of the nasal airway and thereby treating the nasal obstruction, wherein the region remains at least partially reshaped after the treatment element is removed.

2. The method of claim 1, wherein the cartilage is located in an internal nasal valve area of the patient's nasal airway.

3. The method of claim 1, further comprising controlling at least one characteristic of the applied radiofrequency energy with a control system coupled with the nasal airway treatment device.

4. The method of claim 1, further comprising applying a conductivity enhancing substance to the nasal airway.

5. The method of claim 1, wherein applying radiofrequency energy comprises activating the one or more bipolar electrode pairs using an input control.

6. The method of claim 1, further comprising displaying one or more parameters of treatment while the radiofrequency energy is applied, the one or more parameters selected from the group consisting of time, power level, temperature, electric impedance, electric current, and depth of treatment.

7. The method of claim 1, further comprising applying local anesthesia to an area near or surrounding the target tissue.

8. The method of claim 1, wherein the radiofrequency energy is produced by a radiofrequency energy source configured to run between about 1 Watt and about 100 Watts.

9. The method of claim 1, wherein applying the radiofrequency energy comprises heating the cartilage to a temperature of about 50 degrees Celsius to about 70 degrees Celsius.

10. The method of claim 1, wherein the radiofrequency energy is applied to the target tissue for about 15 seconds.

11. A method of decreasing nasal airflow resistance or perceived airflow resistance, the method comprising:

heating submucosal tissue of a nasal airway using a bipolar radiofrequency electrode pair of a treatment element of a nasal airway treatment device, such that the submucosal tissue shrinks, tightens, or stiffens while the submucosal tissue heals, thereby decreasing nasal airflow resistance or perceived airflow resistance within the nasal airway.

12. The method of claim 11, further comprising repositioning the submucosal tissue with the treatment element, wherein the submucosal tissue remains at least partially repositioned after the tissue heals.

13. The method of claim 11, wherein the submucosal tissue comprises cartilage.

14. The method of claim 11, wherein the submucosal tissue is heated to a sub-ablative temperature.

15. The method of claim 11, further comprising:

sensing a temperature using a thermocouple on the nasal airway treatment device; and

modifying the heating of the submucosal tissue based on the sensed temperature.

Attorney Docket No.: 17713.0001US14

METHODS OF TREATING NASAL AIRWAYS

Inventors: Scott J. WOLF
Andrew FRAZIER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 15/596,455 filed May 16, 2017, which is a continuation of U.S. Patent Application No. 15/248,935, entitled "DEVICES TO TREAT NASAL AIRWAYS," filed August 26, 2016, now U.S. Patent No. 9,687,296, which is a continuation of U.S. Patent Application No. 14/864,428, now U.S. Patent No. 9,433,463, entitled "DEVICES TO TREAT NASAL AIRWAYS," filed September 24, 2015, which is a continuation of U.S. Patent Application No. 14/737,196, now U.S. Patent No. 9,179,967, entitled " DEVICES TO TREAT NASAL AIRWAYS," filed June 11, 2015, which is a continuation of U.S. Patent Application No. 14/607,639, now U.S. Patent No. 9,179,964, entitled METHODS AND DEVICES TO TREAT NASAL AIRWAYS, filed January 28, 2015, which is a continuation of U.S. Patent Application No. 14/026,922, now U.S. Patent No. 8,986,301, entitled METHODS AND DEVICES TO TREAT NASAL AIRWAYS, filed September 13, 2013, which is a continuation-in-part of U.S. Patent Application No. 13/495,844, now U.S. Patent No. 8,936,594, entitled METHODS AND DEVICES TO TREAT NASAL AIRWAYS, filed June 13, 2012, which claims priority to U.S. Provisional Patent Application 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.

FIELD OF THE INVENTION

[0002] This application relates generally to the field of medical devices and treatments, and in particular to systems, devices and methods for treating structures within the nose and upper airway to reduce resistance to airflow and/or change the pressure level in the nose, nasal cavities, and/or and nasal passages and thus improve airflow and/or the feeling and effects of nasal obstruction during breathing and/or reduce snoring.

DESCRIPTION OF THE RELATED ART

[0003] During respiration, the anatomy, shape, tissue composition and properties of the human airway produce airflow resistance. The nose is responsible for almost two thirds of this resistance. Most of this resistance occurs in the anterior part of the nose, known as the internal nasal valve, which acts as a flow-limiter. The external nasal valve structure also causes resistance to nasal airflow. Effective physiological normal respiration occurs over a range of airflow resistances. However, excessive resistance to airflow can result in abnormalities of respiration that can significantly affect a patient's quality of life.

[0004] Inadequate nasal airflow can result from a number of conditions causing an inadequate cross sectional area of the nasal airway in the absence of any collapse or movement of the cartilages and soft tissues of the nasal airway. These include deviation of the nasal septum, turbinate enlargement, mucosal swelling, excessive mucus production, and nasal valve insufficiency, narrowing or collapse. No matter what the cause of inadequate nasal airflow, the nasal valve area is still the site of significant nasal airflow resistance. In more extreme cases, nasal valve dysfunction is a prevalent medical condition. Nasal valve collapse is often due to weakness or malformation of cartilage structures of the nose.

[0005] Inadequate nasal airflow can also result from the movement of tissues of the nasal passage during respiration. The nasal passage may have normal anatomy and structure with a nasal passage cross-sectional area in the normal range at rest or during expiration. On inspiration of air through the nose, the nasal tissues can move inward, reducing the cross sectional area of the nasal passage. This movement, sometimes called nasal valve collapse, can be caused by the reduction of pressure in the nose when air flows past the structure of the nose. This pressure reduction pulls the tissues of the nasal passage together, causing a dynamic nasal passage cross sectional area reduction on inspiration.

[0006] The walls of the nasal passage are composed of various tissue types, including the mucosa, submucosa, basal membrane and cartilage. The mucosa, submucosa and basal membrane contain collagen, which gives the tissue structure and elasticity.

[0007] 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.

[0008] The interaction of water and the macromolecular framework gives the tissue its mechanical properties and thus its function. Up to 65%-80% of the wet weight of cartilage consists of water, and 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.

[0009] 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.

[0010] 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.

[0011] The angle formed between the caudal border of the ULC and the nasal septum is normally between about 10 degrees and about 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.

[0012] 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 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. 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).

[0013] 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.

[0014] 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 patients with chronic nasal obstruction have some degree of nasal valve collapse. Of these patients, 88% have unilateral collapse.

[0015] 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, and Hannley M T., "Development and Validation of the Nasal Obstruction Symptom Evaluation (NOSE) Scale," Otolaryngol Head Neck Surg 2004; 130:157-63.

[0016] Causes of inadequate nasal airflow and the structure of 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 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.

[0017] 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.

[0018] External (non-implanted) nasal dilators, which are placed temporarily and removed by the patient, are also available. Such external devices are possibly placed on the outside surface of the nose, such as the "Breathe Right" strips, as shown for example in U.S. Pat. No. 5,533,499 to Johnson, or similar devices taught by U.S. Pat. No. 7,114,495 to Lockwood. Other devices may be temporarily placed in the nasal cavity (but not implanted in the nose), such as those taught in U.S. Pat. No. 7,055,523 to Brown, and U.S. Pat. No. 6,978,781 to Jordan. However, such devices can be uncomfortable, unsightly, and require the patient to remove and replace the device on a periodic basis. These devices can also cause skin irritation.

[0019] 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

[0020] Embodiments of the present application are directed to devices, systems and methods for treating nasal airways. Such embodiments may be utilized to improve breathing by decreasing airflow resistance or perceived airflow resistance in the nasal airways. For example, the devices, systems and methods described herein may be utilized to reshape, remodel, strengthen, or change the properties of the tissues of the nose, including, but not limited to the skin, muscle, mucosa, submucosa and cartilage in the area of the nasal valves.

[0021] 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.

[0022] 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.

[0023] Other embodiments of devices for treating a patient's nasal airway include devices that apply other types of treatment. For example, a treatment device may apply energy in the form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser. The treatment device may also be configured to inject a polymerizing liquid or to deliver a cauterizing agent to nasal tissue. Other embodiments are described below.

[0024] 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.

[0025] 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.

[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 Celsius to about 70 degrees Celsius.

[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 modifying at least one property of at least one tissue of or near 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 a treatment device with the at least one tissue inside the nasal airway, with sufficient force to at least temporarily deform the at least one tissue; applying energy to, or removing energy from, the at least one tissue, using the treatment element; and removing the treatment element from the nostril.

[0035] In some embodiments, the treatment element may have a convex shape, such that contacting the treatment element against the at least one tissue at least temporarily deforms the tissue into a concave shape. In some embodiments, contacting the treatment element with the tissue causes at least one protrusion on the treatment element to deform the tissue.

[0036] Different types of energy that may be applied in alternative embodiments may include, but are not limited to, ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy. In some embodiments, applying the energy involves delivering radiofrequency energy to one or more electrodes of the treatment element to locally heat the at least one tissue, where delivering radiofrequency energy while deforming the at least one tissue causes the tissue to change shape.

[0037] In some embodiments, the at least one tissue may include nasal valve tissue. In some embodiments, the at least one tissue may include nasal mucosa at or near a junction of a pyriform

aperture and a lower lateral cartilage. In some embodiments, the at least one tissue may include upper lateral cartilage.

[0038] In one embodiment, removing energy may involve using cryogenic therapy provided by the treatment element. In some embodiments, the energy is applied to or removed from the at least one tissue while the at least one tissue is deformed. In some embodiments, the energy applied by the treatment element may be generated from a power source within the treatment device.

[0039] Optionally, the method may further involve injecting a substance into the at least one tissue prior to applying the energy, where the applied energy affects the injected substance to help modify the property of the tissue. In other embodiments, the method may involve applying a substance to the at least one tissue or to an outer surface of the nose before applying the energy. Substances may provide any of a number of suitable benefits, such as reducing pain, increasing conductivity of tissue, promoting tightening of tissue, or the like.

[0040] In some embodiments, the property of the tissue is modified without reshaping the at least one tissue. In some embodiments, modifying the property comprises stiffening the tissue, with or without reshaping it. The tissue (or tissues) can be any suitable tissue, such as but not limited to epithelium, cartilage, mucosa, sub-mucosa, muscle, ligament, tendon and skin.

[0041] Some embodiments may further involve cooling the at least one tissue and/or other tissues in or on the nose, before, during, or after applying the energy. In some embodiments, the method may also involve measuring at least one parameter at or near the at least one tissue to be treated and adjusting a level of energy application or removal, based on the measured parameter. For example, in some embodiments, the parameter may be temperature and/or impedance.

[0042] 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 a treatment device with an outer surface of the nose; applying energy to at least one of a subdermal layer or a dermal layer of tissue in the nose, using the treatment element, wherein the tissue is located at least partially above the nasal valve; and cooling at least one of an epidermal layer or a superficial dermal layer of the nose, using the treatment device. In some embodiments, the applied energy comprises

thermal energy, and applying the energy causes at least some of the tissue to tighten. In some embodiments, the method may also involve applying a substance to the outer surface of the nose before applying the energy to enhance at least one of the application of the energy or the cooling epidermal layer or the superficial dermal layer.

[0043] In another aspect, a device for treating a patient's nasal airway by modifying at least one property of at least one tissue of or near a nasal valve of the airway, without using a surgical incision or an implant, to decrease airflow resistance or perceived airflow resistance in a nasal airway, may include: an energy delivery member sized to be inserted into a nose and configured to deliver energy to tissues within the nose to modify the at least one property of the at least one tissue; a shaft extending from the energy delivery member; and a handle attached to the shaft at an opposite end from the energy delivery member, wherein the handle includes a housing to hold a power source for providing energy to the energy delivery member.

[0044] In some embodiments, the energy delivery member may have a contact surface with convex shape configured to at least temporarily create a concavity in nasal 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 protruding electrodes configured to at least temporarily deform nasal tissue. In some embodiments, the 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.

[0045] In some embodiments, the housing of the handle is configured to hold at least one battery. Optionally, some embodiments may also include at least one sensor configured to sense at least one of temperature or impedance in nasal tissue. In some embodiments, the sensor may be attached to the device on or near the energy delivery member. Some embodiments may further include a tissue cooling member attached to the device at or near the energy delivery member.

[0046] These and other aspects and embodiments will be described in further detail below, in reference to the attached drawing figures.

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

[0085] FIGS. 31A and 31B are perspective and side, cross-sectional views, respectively, of a device for applying energy to the nasal valve area, including an internal power source, according to one embodiment.

[0086] FIGS. 32A and 32B are a cross-sectional side view of facial skin and a front view of a face of a patient, respectively, illustrating use of various embodiments of sensors that may be part of a system for applying energy to the nasal valve area, according to one embodiment.

[0087] FIGS. 33A and 33B are a bottom view of a distal end of a treatment device and a cross-sectional view of a nasal passage, respectively, illustrating wings of the treatment device that may be used to help guide the distal end to a desired location in the nasal passage.

[0088] FIGS. 34A-34C are top views of various alternative embodiments of distal ends of treatment devices having different shapes for addressing differently shaped tissues.

[0089] FIG. 35 is a top view of a treatment device and a cross-sectional view of a portion of a nose, in which the treatment device includes an expandable member, according to one embodiment.

[0090] FIG. 36 is a diagrammatic representation of an internal nasal valve, illustrating areas for treatment, according to various embodiments.

DETAILED DESCRIPTION

[0091] 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.

[0092] 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).

[0093] 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.

[0094] 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.

[0095] 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.

[0096] 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 FIG. 2B, 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.

[0097] FIG. 2C illustrates a view of the nose as seen from the nostrils. FIG. 2C depicts the nasal valve 1 shown between the septum 2 and the upper lateral cartilage 3. FIG. 2C also depicts the position of the turbinate 4.

[0098] 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.

[0099] 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.

[0100] 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.

[0101] 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.

[0102] 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.

[0103] 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 and about 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 about 10-15 degrees. In some embodiments, the internal valve angle may also be increased to be greater than 15 degrees.

[0104] 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.

[0105] 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.

[0106] 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).

[0107] 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.

[0108] 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.

[0109] 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.

[0110] 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.

[0111] 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.

[0112] 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.

[0113] 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).

[0114] 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).

[0115] 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.

[0116] 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.

[0117] 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.

[0118] 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.

[0119] 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.

[0120] 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.

[0121] 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.

[0122] 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.

[0123] 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.

[0124] 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.

[0125] 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.

[0126] 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.

[0127] 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.

[0128] 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.

[0129] 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.

[0130] 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.

[0131] 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.

[0132] 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.

[0133] 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.

[0134] 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.

[0135] 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 patient’s nose. In further embodiments, any other suitable heating element may be provided. In further embodiments, the treatment element 32 may comprise elements for delivering energy in other forms such as light, laser, RF, microwave, cryogenic cooling, DC current and/or ultrasound in addition to or in place of heating elements.

[0136] U.S. Pat. No. 6,551,310 describes embodiments of endoscopic treatment devices configured to ablate tissue at a controlled depth from within a body lumen by applying radio

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

[0137] In alternative embodiments, similar effects can be achieved through the use of energy removal devices, such as cryogenic therapies configured to transfer heat energy out of selected tissues, thereby lowering the temperature of targeted tissues until a desired level of tissue modification is achieved. Examples of suitable cryogenic therapy delivery elements are shown and described for example in U.S. Pat. Nos. 6,383,181 and 5,846,235, the entirety of each of which is hereby incorporated by reference.

[0138] 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.

[0139] 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).

[0140] 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.

[0141] 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.

[0142] 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.

[0143] 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.

[0144] 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.

[0145] 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.

[0146] 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.

[0147] 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

[0148] 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.

[0149] 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).

[0150] 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.

[0151] 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.

[0152] 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.

[0153] 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.

[0154] 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).

[0155] 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.

[0156] 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.

[0157] 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.

[0158] 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.

[0159] 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

[0160] 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.

[0161] 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.

[0162] 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.

[0163] 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.

[0164] 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.

[0165] 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 336, 342 that allows simultaneous deformation and treatment of both nostrils.

[0166] 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.

[0167] 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.

[0168] 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.

[0169] 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.

[0170] 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.

[0171] 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.

[0172] 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.

[0173] 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 395 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.

[0174] 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 507 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 507 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.

[0175] 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.

[0176] 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.

[0177] 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.

[0178] The device 530 comprises a flexible wire or cable 542 electrically connected to an adaptor 544. The adaptor 544 can be used to connect the device 530 to a remote generator (not shown). The adaptor 544 may allow transmission of treatment energy between a remote generator and the device 530. The adaptor may also allow transmission of any sensor signals

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

[0179] 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.

[0180] 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.

[0181] 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.

[0182] 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.

[0183] 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.

[0184] 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.

[0185] 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.

[0186] 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.

[0187] 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.

[0188] 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.

[0189] 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.

[0190] 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.

[0191] 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.

[0192] 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.

[0193] 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.

[0194] 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.

[0195] 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.

[0196] 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.

[0197] 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).

[0198] 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.

[0199] 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.

[0200] 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.

[0201] 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.

[0202] 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.

[0203] 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.

[0204] 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

[0205] 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.

[0206] 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.

[0207] 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.

[0208] 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.

[0209] 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.

[0210] 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.

[0211] 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.

[0212] 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.

[0213] 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.

[0214] 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.

[0215] 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.

[0216] 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 815 or cavities to circulate air or fluid. The independent cooling device 810 may, in other embodiments, employ a different cooling mechanism.

[0217] 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.

[0218] 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.

[0219] 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

[0220] 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.

[0221] 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.

[0222] 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.

[0223] In some embodiments, the method may further include the step of inserting a re-shaping device into the nasal passageway after applying an energy or cryo-therapy treatment. In such embodiments, a re-shaping device such as an external adhesive nasal strip (such as those described for example in U.S. Pat. No. 5,533,499 to Johnson or U.S. Pat. No. 7,114,495 to Lockwood, the entirety of each of which is hereby incorporated by reference) may be applied to the exterior of the nose after the treatment in order to allow for long-term re-shaping of nasal valve structures as the treated tissues heal over time. In alternative embodiments, a temporary

internal re-shaping device (such as those taught in U.S. Pat. No. 7,055,523 to Brown or U.S. Pat. No. 6,978,781 to Jordan, the entirety of each of which is hereby incorporated by reference) may be placed in the nasal passageway after treatment in order to allow for long-term re-shaping of nasal valve structures as the treated tissues heal over time. In some embodiments, the dilating nasal strips can be worn externally until healing occurs.

[0224] 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.

[0225] 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.

[0226] 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.

[0227] 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.

[0228] 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.

[0229] 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.

[0230] 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.

[0231] 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.

[0232] 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.

[0233] 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.

[0234] 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.

[0235] 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.

[0236] 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.

[0237] FIGS. 30A-30D depict a method for using a device 800 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.

[0238] 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.

[0239] 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.

[0240] 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.

[0241] 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.

[0242] 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.

[0243] In some embodiments, temperature of the area around the electrode during treating is from about 30 degrees Celsius to about 90 degrees Celsius. In some embodiments, temperature of the area around the electrode during treating is from about 40 degrees Celsius to about 80 degrees Celsius. In some embodiments, temperature of the area around the electrode during treating is from about 50 degrees Celsius to about 70 degrees Celsius. In some embodiments, temperature of the area around the electrode during treating is about 60 degrees Celsius. In some embodiments, for example during cryo-therapy, temperature of the area around the electrode may be lower.

[0244] In some embodiments, treating the target tissue comprises treatment for about is 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.

[0245] 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.

[0246] 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.

[0247] 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.

[0248] 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.

[0249] 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.

Additional Embodiments and Optional Features

[0250] Referring now to FIGS. 31A and 31B, in one embodiment, a device 900 for treating a nasal valve may include an internal power source and thus be cordless. In the embodiment shown, the device 900 includes a handle 902 coupled with a shaft 904, which in turn is coupled with a treatment element 908. The handle 902 may include a power button 910 (or "on/off switch"), a circuit board (912, FIG. 31B) and a space and connections for insertion of batteries 914 as a power source. Treatment element 904 may include multiple needle electrodes 906 for applying RF energy to tissue.

[0251] Any suitable features, elements, materials or the like that have been described above may be applied to the device 900 in a similar way. In various alternative embodiments, the device 900 may include any number, size or type of batteries, depending on the size of the handle 902 and power requirements of the device 900. In some alternative embodiments, the device 900 may include an alternative power source. For example, the batteries 914 may be rechargeable in some embodiments. In other embodiments, it may be possible to plug the device 900 into a power generator for charging, and then unplug the device 900 for use. In yet other alternative embodiments, the device 900 may include a solar power collection member. The advantage of including an internal power source in the device 900 is that this eliminates the need for the device 900 to be connected, via power cord, to a large, table-top generator, as most energy delivery surgical/medical devices require. This allows a physician to perform a nasal valve procedure in any location or patient orientation without having to manage power cables and generators.

[0252] Referring now to FIGS. 32A and 32B, in some embodiments, a system for treating a nasal valve may include one or more sensors. Such sensors may be used to sense any of a number of relevant tissue properties, such as temperature, impedance and the like. The sensors may be located on a treatment device in some embodiments, or alternatively they may be separate from the treatment device and positioned at or near the device during treatment. In some embodiments, the sensor(s) may provide feedback directly to the treatment device. For example if a particular tissue temperature threshold is reached, a sensor (or sensors) may send a signal to a power generator to shut down or decrease power delivered to a treatment device. In alternative embodiment, the sensor(s) may instead provide feedback to a physician or other user, so that the

physician or other user can make treatment adjustments. For example, sensors may provide a warning signal when a particular tissue temperature or impedance is reached, which will help a physician know when to turn off or decrease power delivery to a treatment device. Additionally, sensor(s) may be used to sense one or more tissue properties in any suitable tissue or multiple tissues, such as but not limited to mucosa, cartilage, dermis, epidermis and other types of body soft tissue.

[0253] FIG. 32A illustrates nasal skin in cross section, including mucosa, cartilage, dermis and epidermis. In one embodiment, a sensor device 920 may include an epidermal sensor 922 that is coupled to the epidermis via an adhesive 924. Any suitable sensor 922 (temperature, impedance, etc.) and any suitable adhesive 924 may be used. This embodiment of the sensor device 920 is also illustrated on a patient's face in FIG. 32B.

[0254] In an alternative embodiment, a sensor device 930 may include a transdermal needle sensor 932. In another alternative embodiment, a sensor device 942 may be attached directly to a treatment device 940. As illustrated by these various embodiments, sensors 922, 932 and 942 may be positioned either at or near a treatment location during a treatment. In some embodiments, for example, a sensor 922, 932 may be placed on or in epidermis while a treatment is being performed on mucosa. Alternatively, a sensor 942 may be placed directly on mucosa during a treatment of mucosa. Additionally, in any given embodiment, multiple sensors may be placed at multiple different locations in and/or on tissue. As mentioned above, the sensor devices 920, 930 and 940 may, in various embodiments, provide any of a number of different types of feedback, such as feedback to a user, feedback to a power generator, or both.

[0255] Referring now to FIGS. 33A and 33B, in some embodiments, a treatment device 950 may include a treatment element 952 with wings 954 extending laterally from it. The wings 954 are configured to help direct the treatment element 952 into a particular treatment location/position and/or to prevent the treatment element 952 from contacting tissue that the physician does not want to treat. For example, FIG. 33B illustrates a top, cross-sectional view of a nose N, showing the lateral wall LW, nasal septum S and an intersection I between the lateral wall LW and nasal septum S. In many or most cases, it may be undesirable to treat mucosa at the intersection I with RF energy or other energy delivery or removal devices. The wings 954 will help prevent the treatment element 952 from being advanced far enough toward the intersection I

to actually contact and treat that mucosa. Alternative embodiments may include additional wings or other protrusions or shapes to prevent contact with the intersection I and/or other structures. Some embodiments may include adjustable wings or wings that expand once the electrodes have been placed. Any other size, shape or configuration of one of more wings may be included, according to various embodiments.

[0256] Referring to FIGS. 34A-34C, in various alternative embodiments, treatment elements of nasal valve treatment devices may have different shapes and/or sizes for addressing different types and/or shapes of tissue. For example, as shown in FIG. 34A, in one embodiment, a treatment element 960 of a device may have a square or rectangular profile with a flat distal end, which may be ideal for addressing relatively flat tissue configurations. Two electrodes 962 (or two sets of electrodes) may be used to send an arc of current (e.g., RF current) through tissue in the pattern shown by the multi-headed arrow.

[0257] In another embodiment, as shown in FIG. 34B, a treatment element 970 may have an oval profile with a curved distal end. Two electrodes 972 or sets of electrodes send a current through tissue in an arc. This configuration may be advantageous for addressing tissue having a curved profile. In yet another embodiment, as shown in FIG. 34C, a treatment element 980 may have a flatter curved profile, for example for addressing tissue with a curved shape but not as sharp of an angle as the tissue shown in FIG. 34B. Again, the electrodes 982 send energy through the curved tissue in a curved arc.

[0258] As is evident from FIGS. 34A-34C, a treatment element of a treatment device may have any suitable configuration for advantageously addressing any tissue type and shape. In some embodiments, multiple different treatment devices, each having a differently shaped treatment element, may be provided, and a user may select a treatment device for a particular tissue type and/or shape, based at least in part on the shape of the treatment element of the device.

[0259] Referring to FIG. 35, in another embodiment, a treatment device 1000 for treating a nasal valve and/or tissues near the nasal valve may include an expandable member 1002, such as but not limited to an expandable polymeric balloon. For example, a non-compliant or semi-compliant balloon may be used in some embodiments to expand tissues in and/or around the nasal valve, to achieve one or more of the effects discussed above in relation to the various

embodiments. Although expandable balloon devices (e.g., balloon catheters) have been described previously for use in expanding ostia (openings) of the sinus cavities, they have not been described for use in changing the shape and/or physical characteristics of the nasal valve. In various method embodiments, the expandable member 1002 may be positioned at any of a number of suitable locations at or near a nasal valve and then expanded to deform tissues that make up the nasal valve. In some cases, these tissues may be at least partially deformed permanently or at least for a period of time after the procedure. In other cases, the tissue may only be deformed during the procedure, but one or more properties of the tissue may be affected by the balloon expansion.

[0260] In various alternative embodiments, a treatment device for nasal valve tissue and/or other nasal tissue may use a treatment modality that does not involve delivery of energy to, or removal of energy from, tissue. For example, in some embodiments, the treatment device may create some kind of mechanical injury to one or more tissues to cause a change in shape and/or one or more properties of the tissue. The expandable balloon embodiment described above is one example. Other examples may include, but are not limited to, needles, micro-needles, blades or the like, any of which may be used to cause scar tissue formation and/or tissue contraction. Other embodiments may use sclerotherapy, involving injecting one or more substances (acid, coagulants, etc.) into the target tissue to induce scar tissue formation and/or other changes in the tissue properties. In some cases, one type of tissue (for example, mucosa) may be transformed into a different type of tissue altogether (for example, scar tissue). In other examples, a one or more properties of the tissue may be changed without changing the overall type of tissue. For example, the tissue may be caused to shrink, contract, stiffen and/or the like. One advantage of these non-energy-based embodiments is that they do not require a source of energy. This may make them easier to use and possibly to manufacture and supply.

[0261] In other embodiments, thermal energy may be applied to the nasal valve by applying the energy from an external location on the nose, rather than an internal location within the nasal cavity. For example, in some embodiments, a treatment device may be positioned on the nose and used to deliver thermal energy through the epidermis to the deep subdermal and/or dermal layer above the nasal valve. In some embodiments, the treatment device may also be used to cool the superficial dermis and epidermis, for example. This delivery of energy could, in some

embodiments, act to tighten tissues of the nasal valve, thus preventing collapse during breathing. In an alternative embodiment, instead of using thermal energy to change the tissues, a treatment device may use mechanical means, such as micro-needles, to create a subdermal tissue response, such as scarring, for a similar type of tissue tightening effect.

[0262] In yet other embodiments, some methods for treating a nasal valve may include applying a gel, paste, liquid or similar substance to a surface of the nose during an energy delivery treatment of the nasal valve. Such substances may be applied to target tissue, such as mucosa, non-target tissue, such as epidermis, or a combination of both. The substance (or substances) applied may serve any of a number of different purposes, such as but not limited to modifying conductivity of tissue and providing anesthetic effect. Conductivity enhancing substances may improve the efficiency and/or consistency of energy delivery (such as but not limited to RF energy). Alternatively or additionally, one or more substances may be injected into tissue. For example, saline, Lidocaine, other anesthetic agents, or any other suitable agents, may be injected. Some embodiments may involve applying one substance and injecting another substance.

[0263] In other alternative embodiments, it may be possible to achieve desired changes in tissue properties and/or shapes by injecting substance or applying substance only—in other words, without also applying energy. For example, injecting a sclerotherapy substance into tissue may, in some embodiments, achieve a desired tissue result. In additional alternative embodiments, a method of treating a nasal valve may include injecting a substance into nasal tissue and then curing the substance in order to change the substance's properties and, in turn, at least one of the nasal tissue's properties. A treatment device may be used to cure the substance. In some embodiments, the treatment device may be used to deform the target tissue and cure the substance, while the tissue is deformed, so that the tissue retains approximately the same, deformed shape after the substance is cured and the treatment device is removed. In another alternative embodiment, a surface-based biodegradable agent may be applied and cured to change the shape of the target nasal tissue.

[0264] Referring now to FIG. 36, any of the embodiments discussed above may be used to treat tissue that is considered part of the nasal valve, tissue that is immediately adjacent or near nasal valve tissue, tissue farther away from the nasal valve that affects nasal valve function, or

some combination thereof. FIG. 36 is a diagrammatic illustration of the internal nasal valve. As mentioned previously, the internal nasal valve, which accounts for the larger part of the nasal resistance, is formed by the nasal septum S, the caudal border of the upper lateral cartilage (ULC), the head of the inferior turbinate, and the pyriform aperture P and the tissues that surround it. In FIG. 36, the triangular representation is comprised of the septum S, the pyrifom aperture P, and the lateral wall LW. According to various embodiments, any area within the triangle, immediately outside the triangle, or even more distant from the triangle, may be treated, in order to affect function of the nasal valve. In one embodiment, for example, a treatment area 1010 may be located at a juncture of the pyriform aperture P and the lateral wall LW, and in various embodiments the treatment area 1010 may be located entirely within the triangle or may extend outside of it. This is but one example of an area that may be treated, according to various embodiments.

[0265] One mechanism of action that may be involved in any of the embodiments described above may be to reduce mucus production and/or accumulation in and/or around any treated areas. Although emphasis has been placed on structure and function of the nasal valve in much of the foregoing description, mucus reduction may also be part the beneficial result of any treatment, in some embodiments.

[0266] Although this invention has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

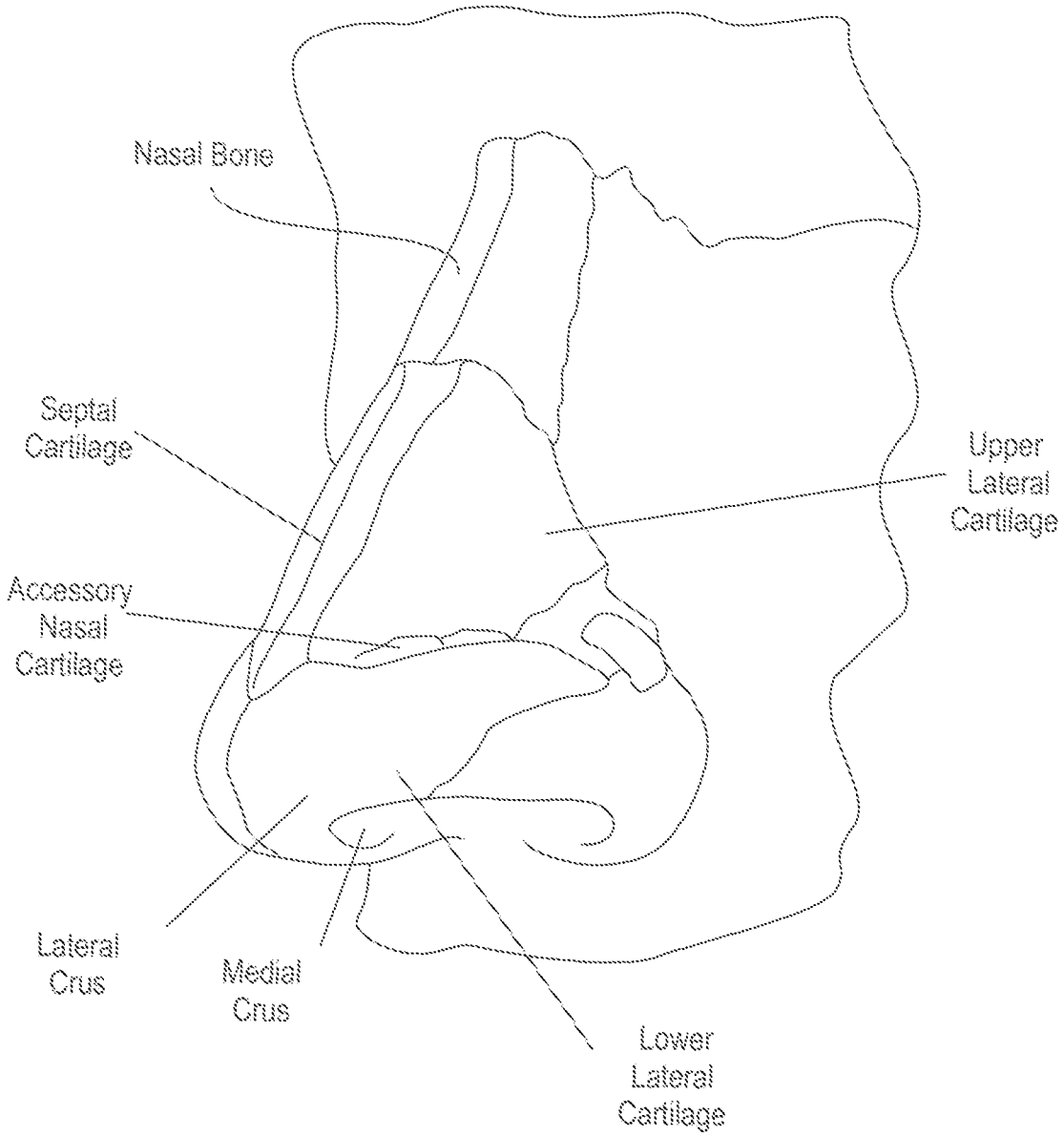

Nasal Bone
Septal Cartilage
Upper Lateral Cartilage
Accessory Nasal Cartilage
Lateral Crus
Medial Crus
Lower Lateral Cartilage

FIG. 1

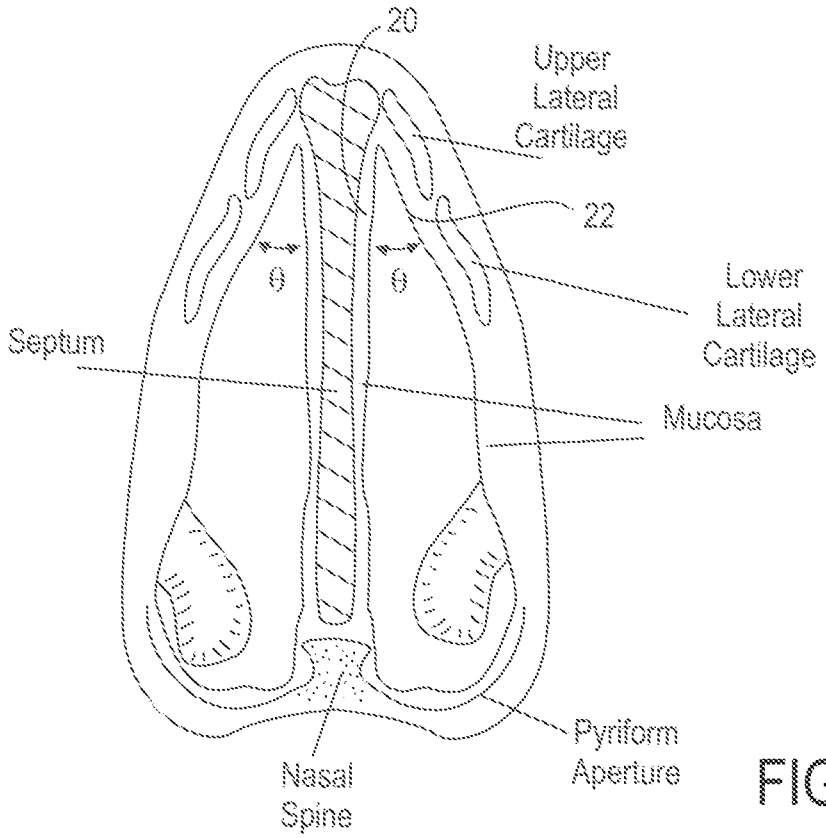

20
Upper
Lateral
Cartilage
22
θ
θ
Lower
Lateral
Cartilage
Septum
Mucosa
Pyriform
Aperture
Nasal
Spine

FIG. 2A

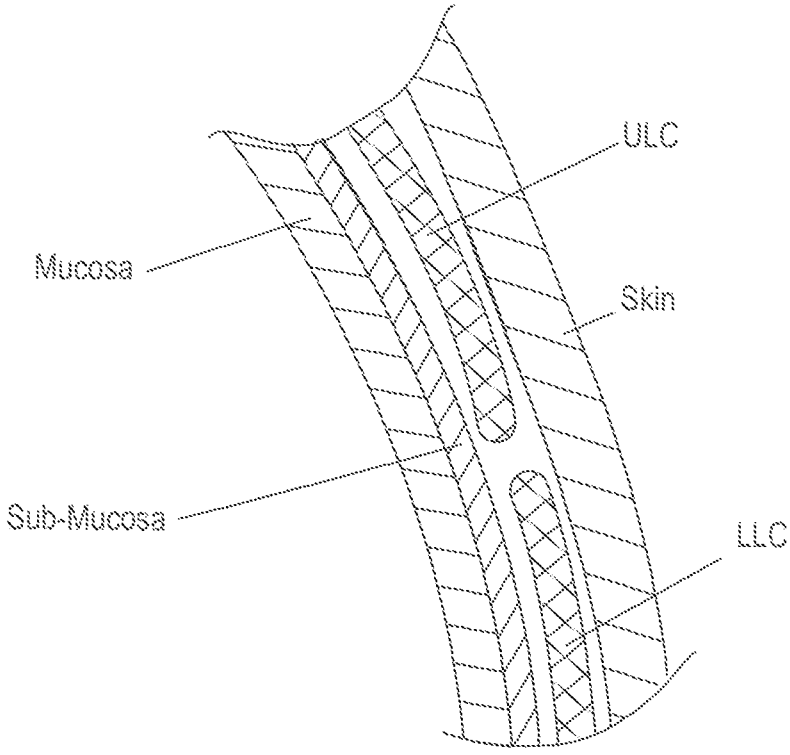

ULC
Mucosa
Skin
Sub-Mucosa
LLC

FIG. 2B

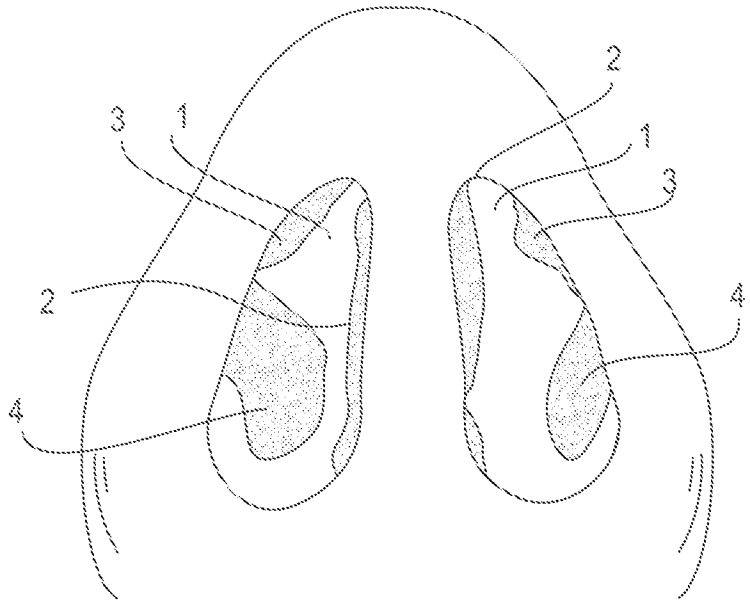


FIG. 2C

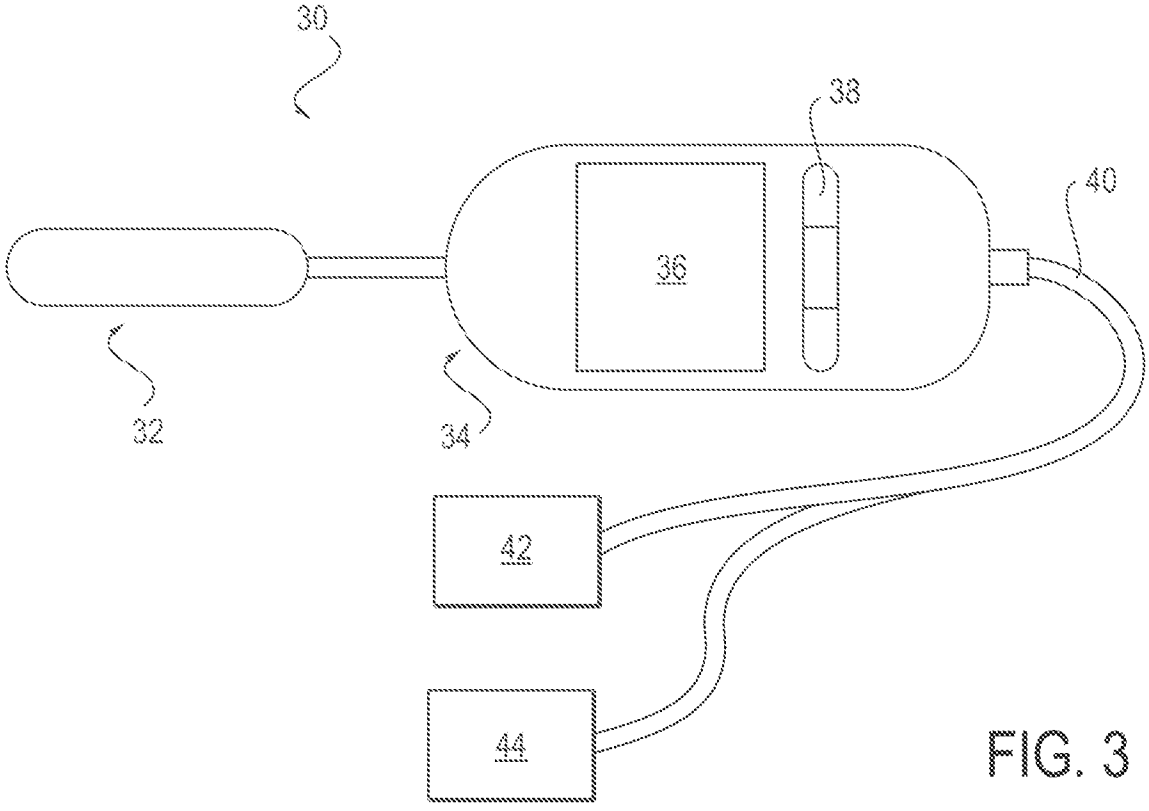


FIG. 3

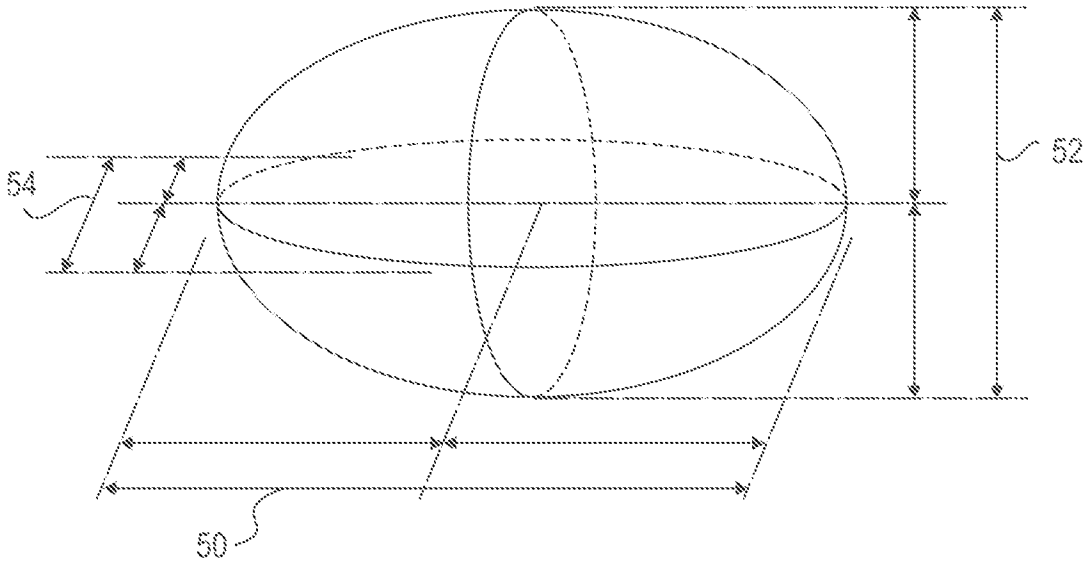


FIG. 4A

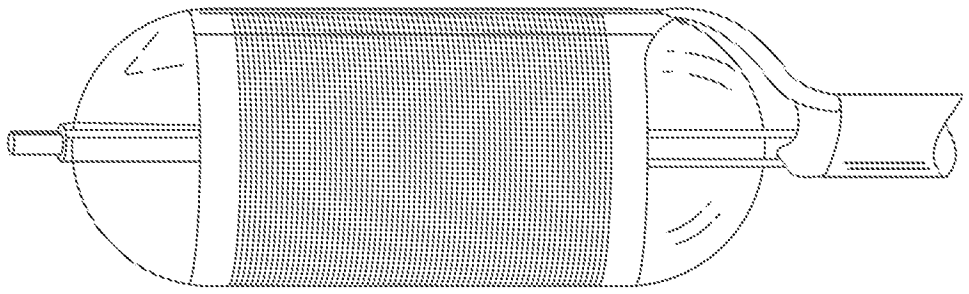


FIG. 4B

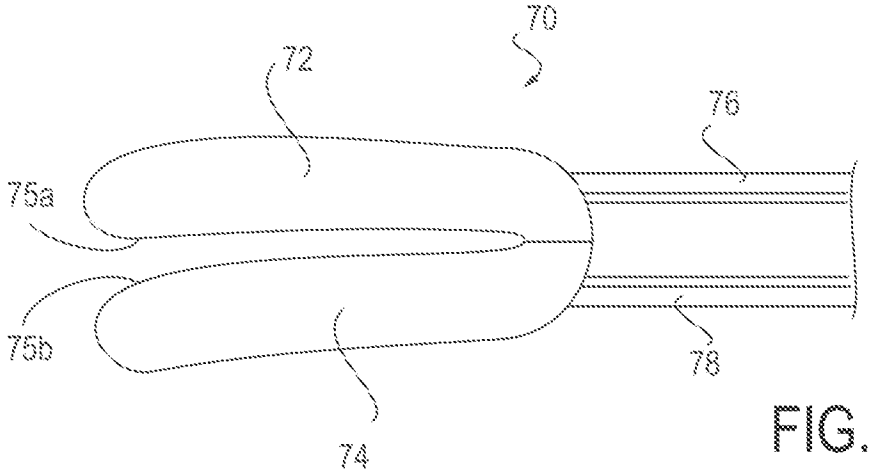


FIG. 4C

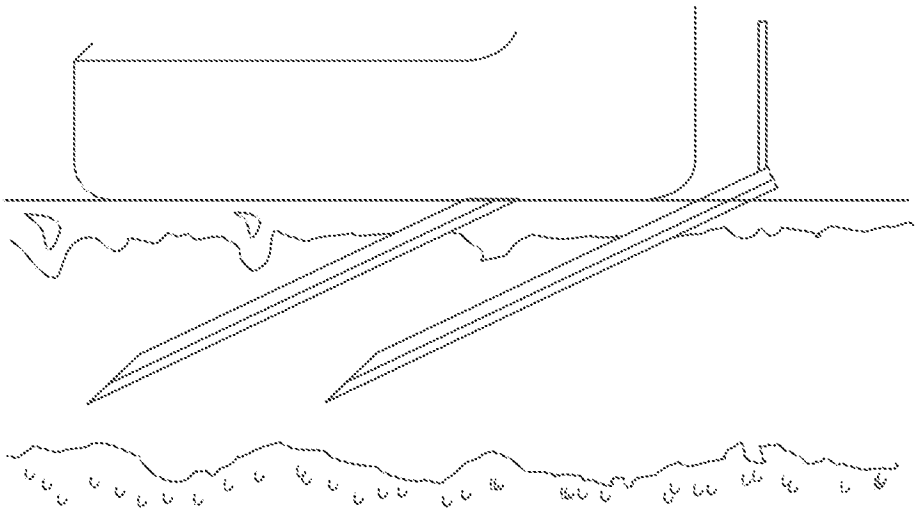


FIG. 4D

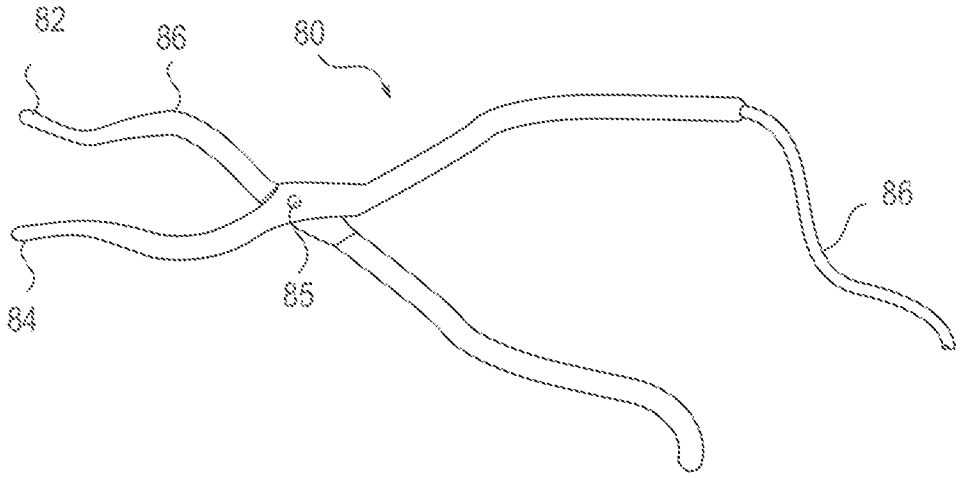


FIG. 5A

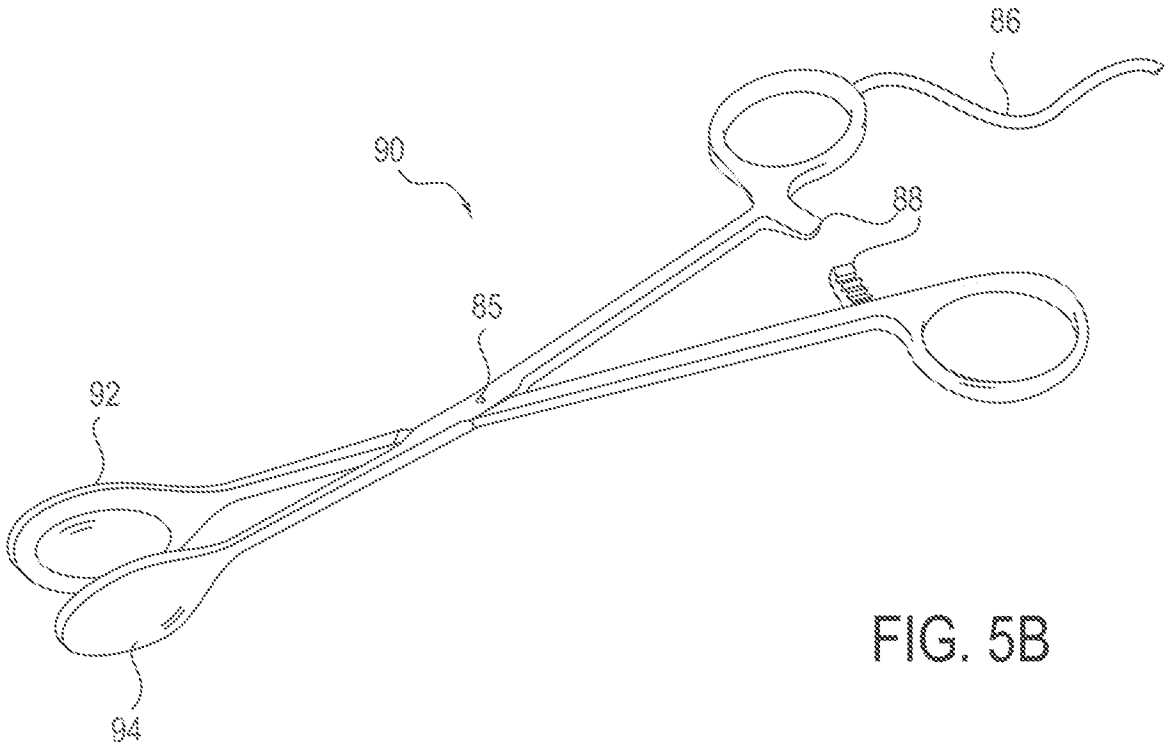


FIG. 5B

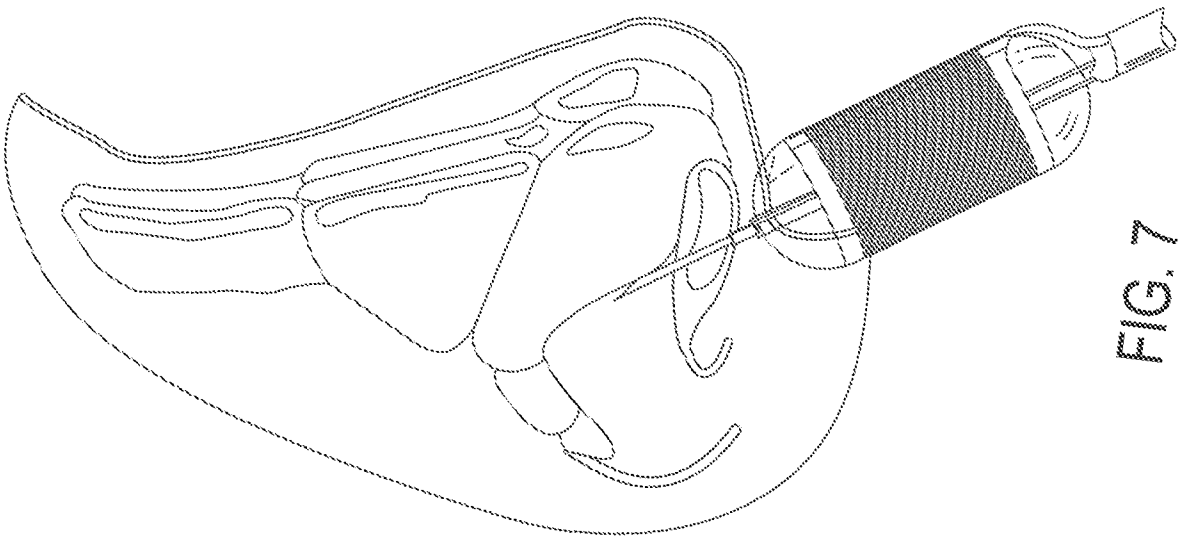


FIG. 7

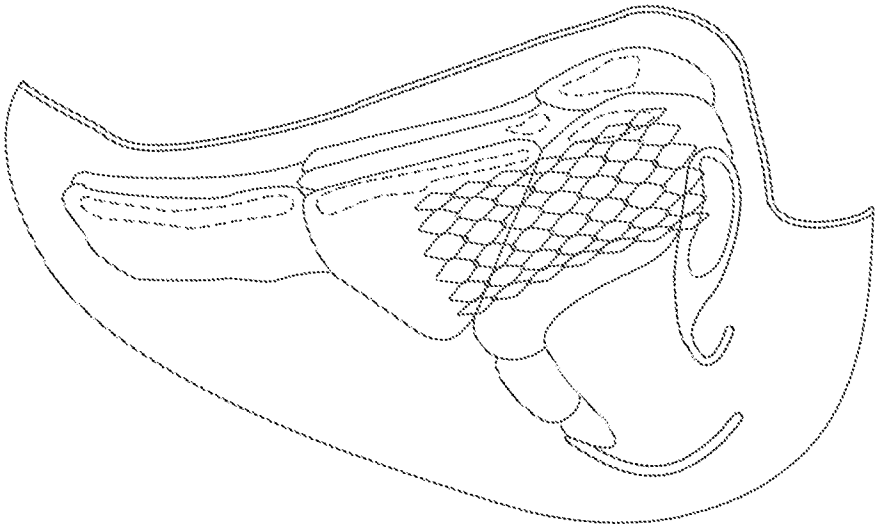


FIG. 6

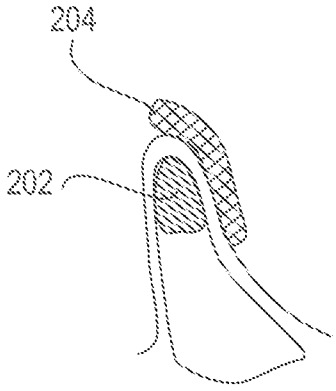


FIG. 8A

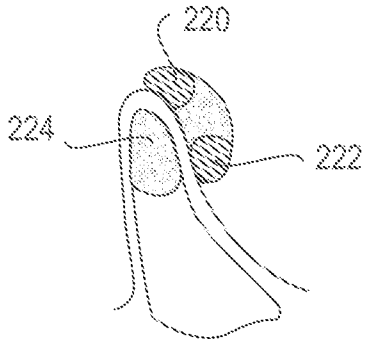


FIG. 8B

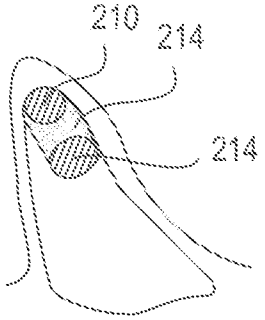


FIG. 8C

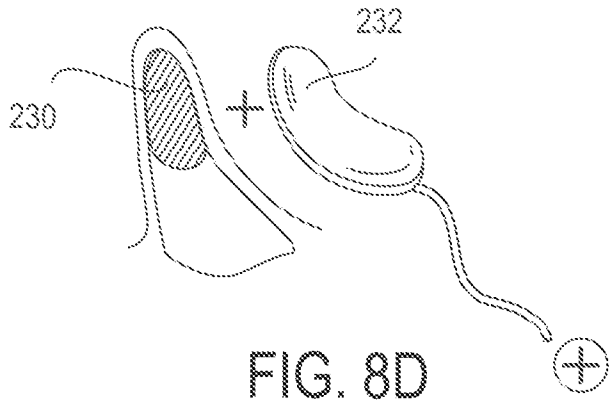


FIG. 8D

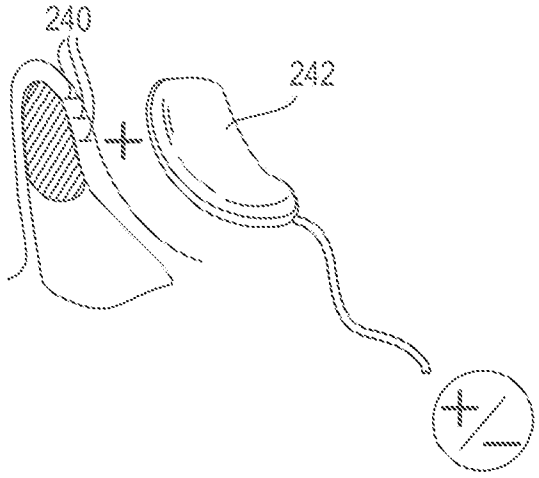


FIG. 8E

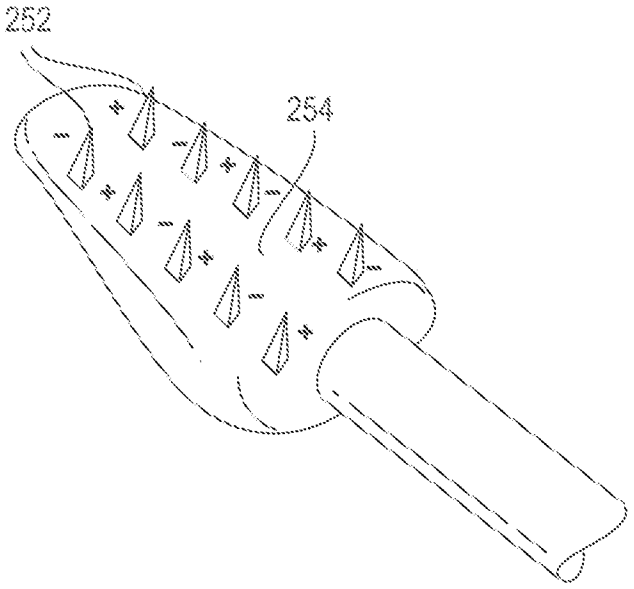


FIG. 8F

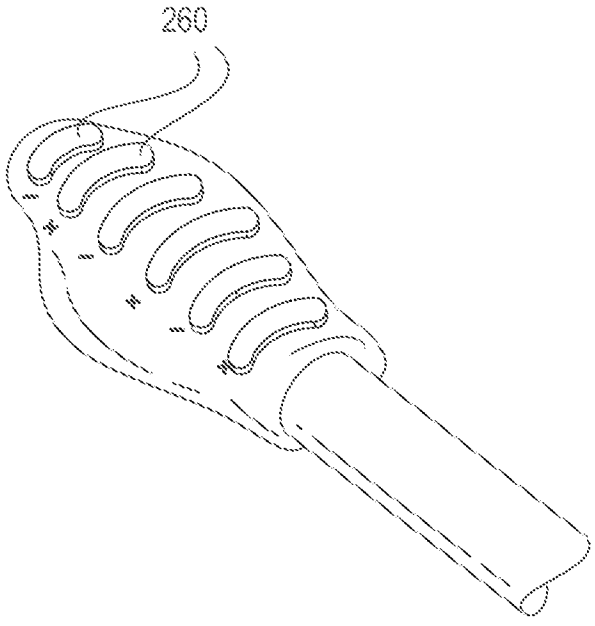


FIG. 8G

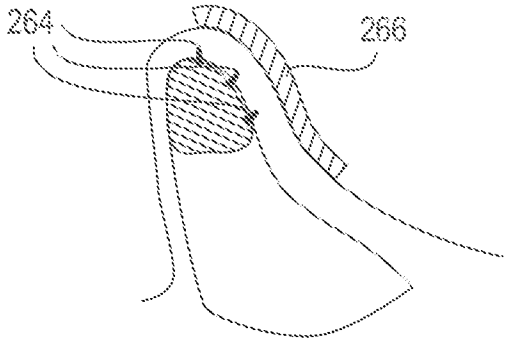


FIG. 8H

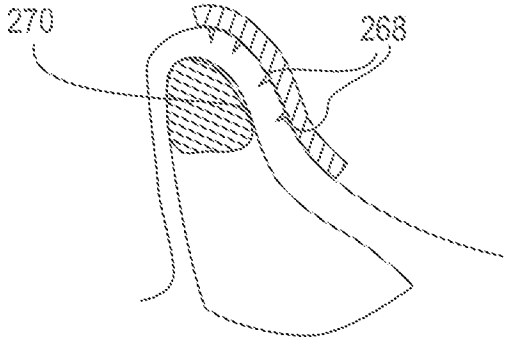


FIG. 8I

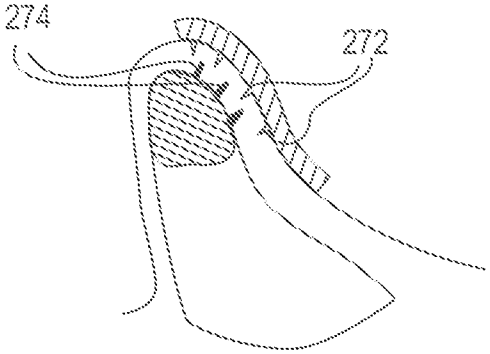


FIG. 8J

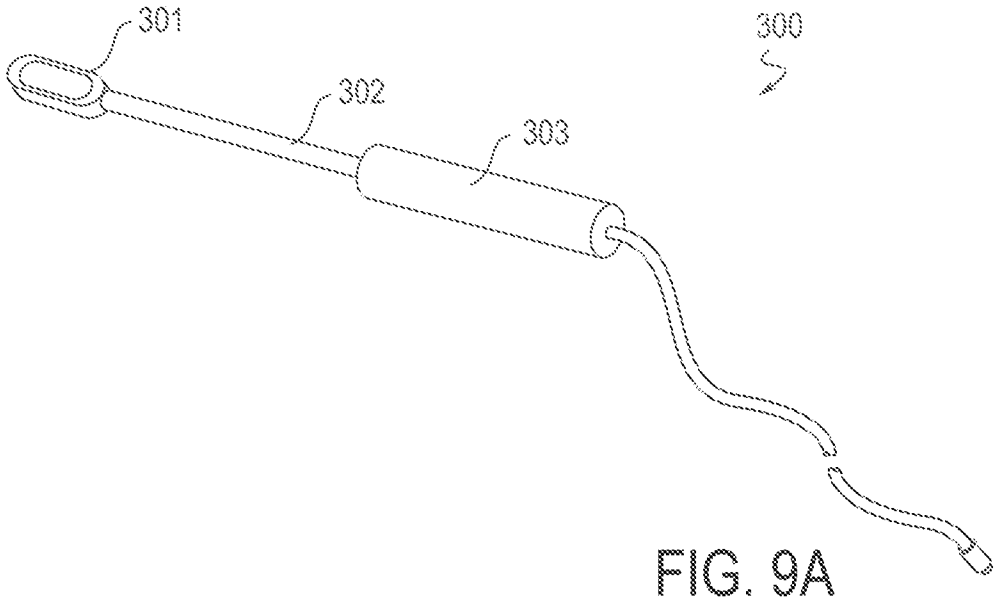


FIG. 9A

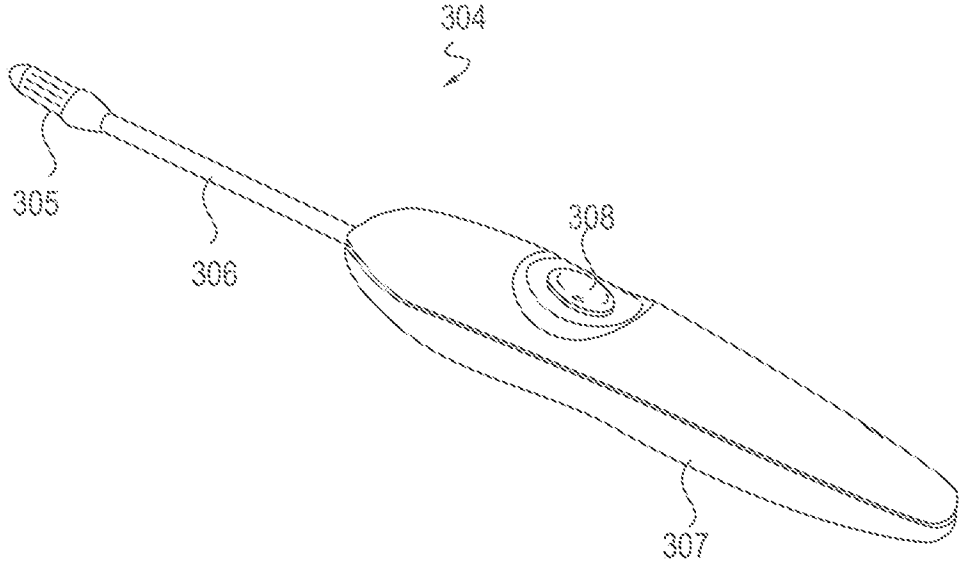


FIG. 9B

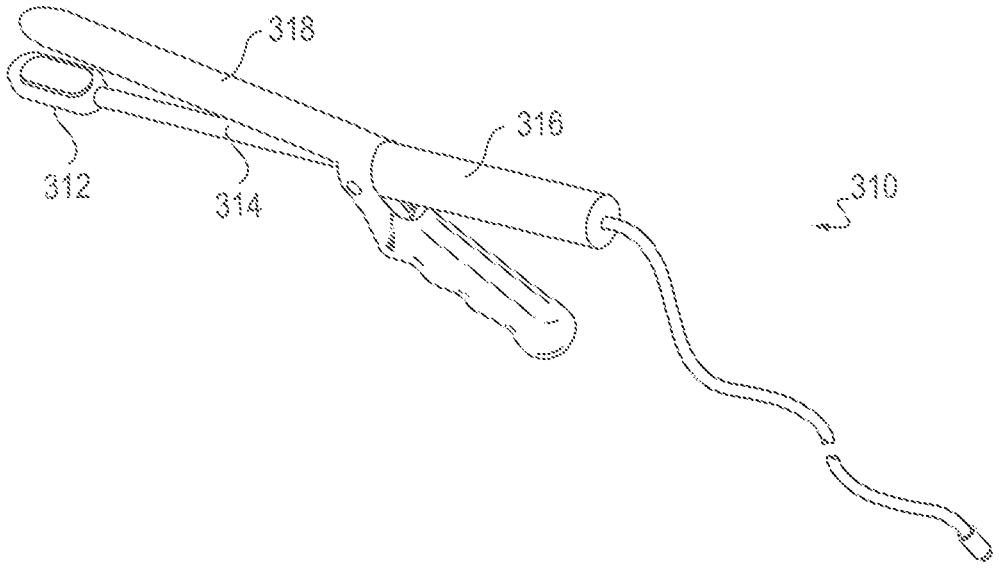


FIG. 10A

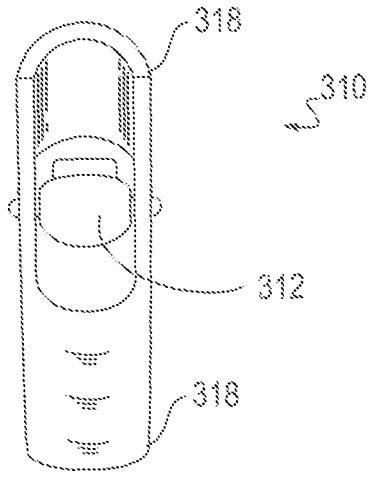


FIG. 10B

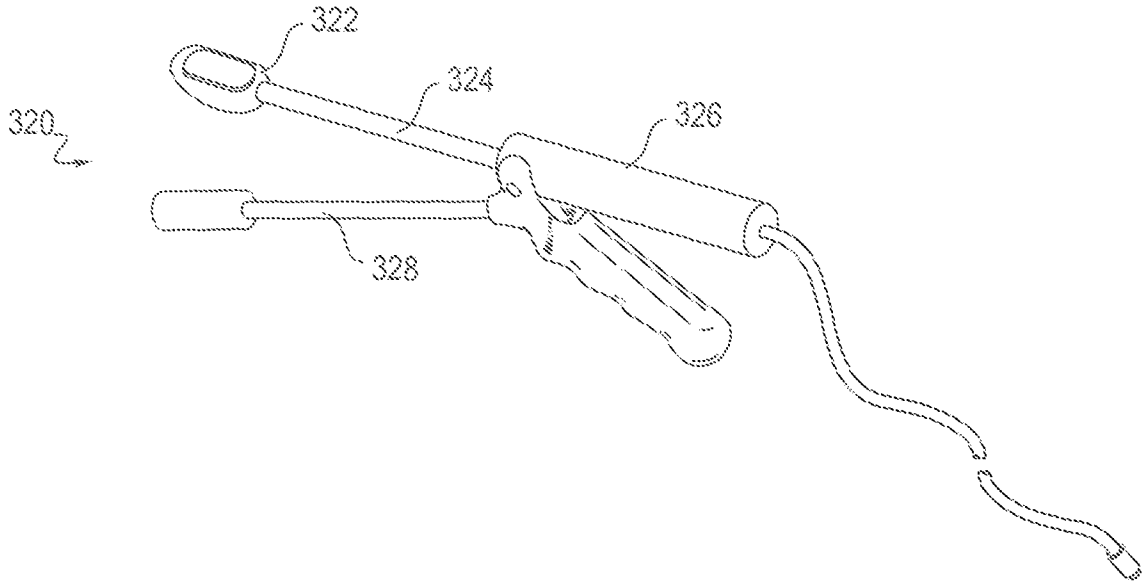


FIG. 11A

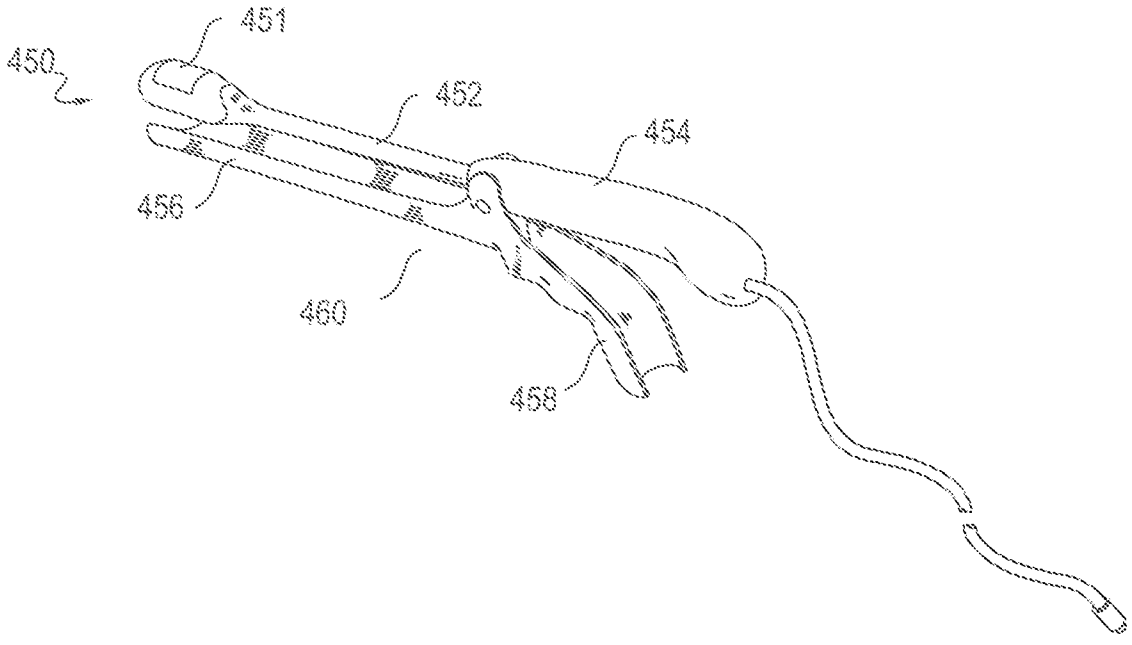


FIG. 11B

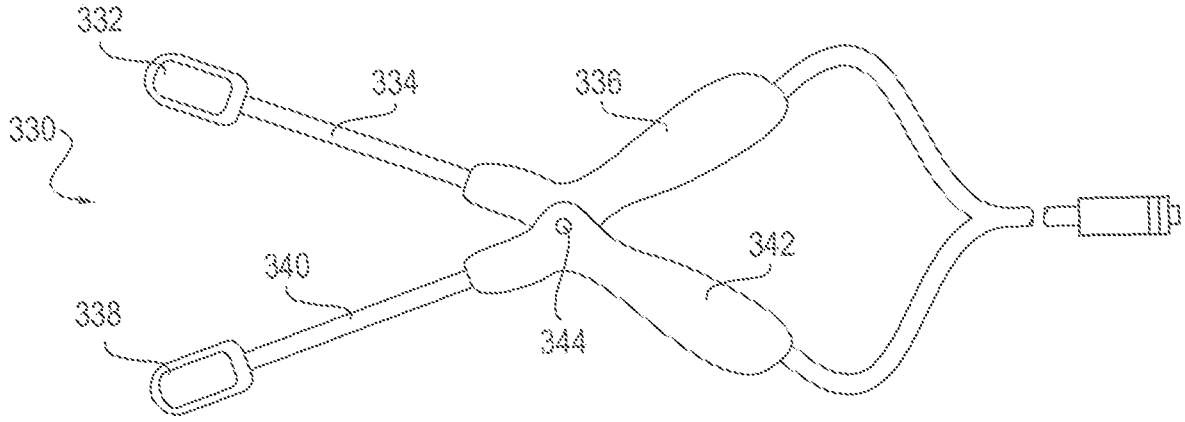


FIG. 12A

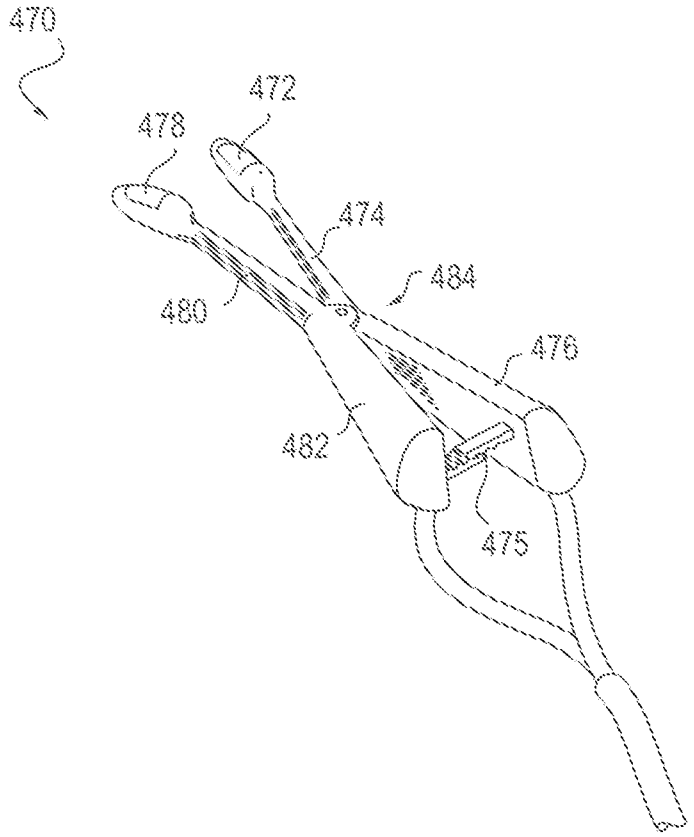


FIG. 12B

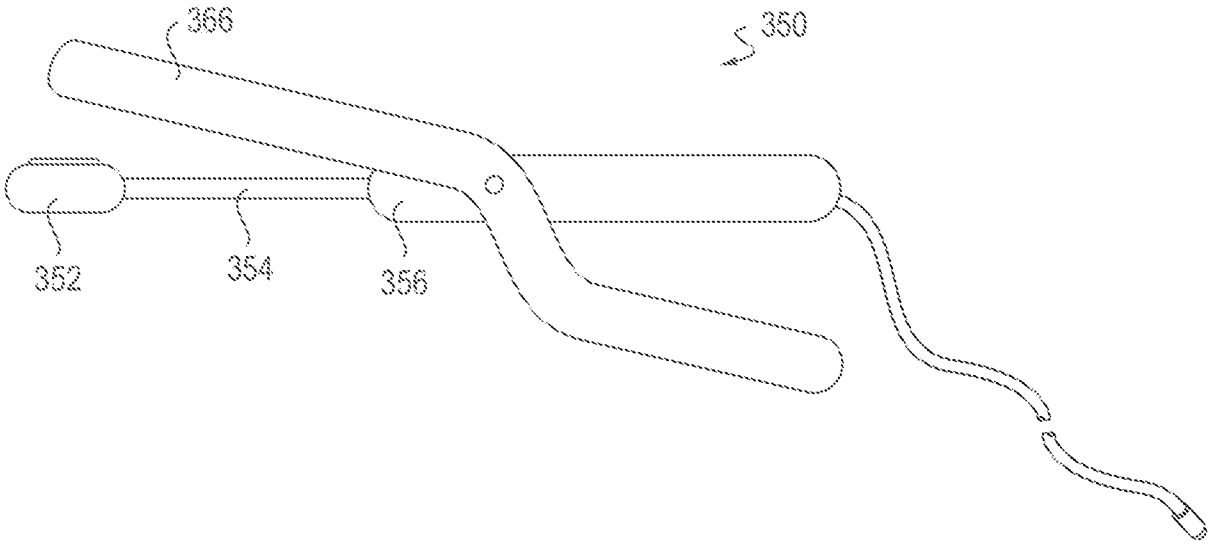


FIG. 13A

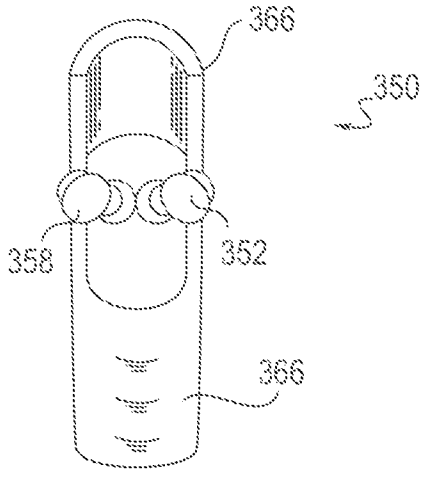


FIG. 13B

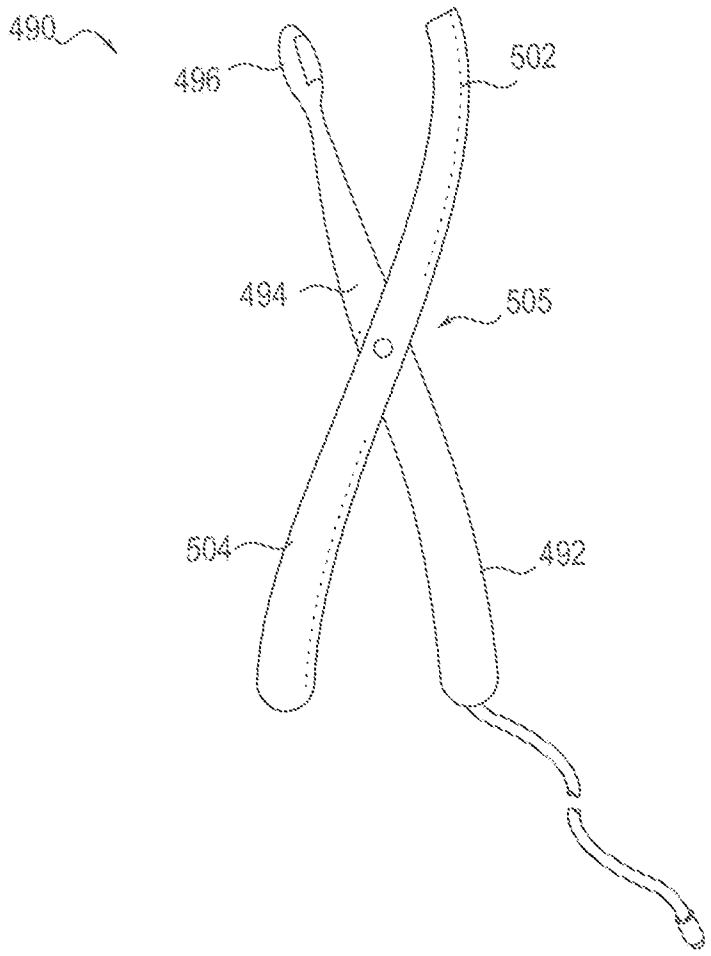


FIG. 13C

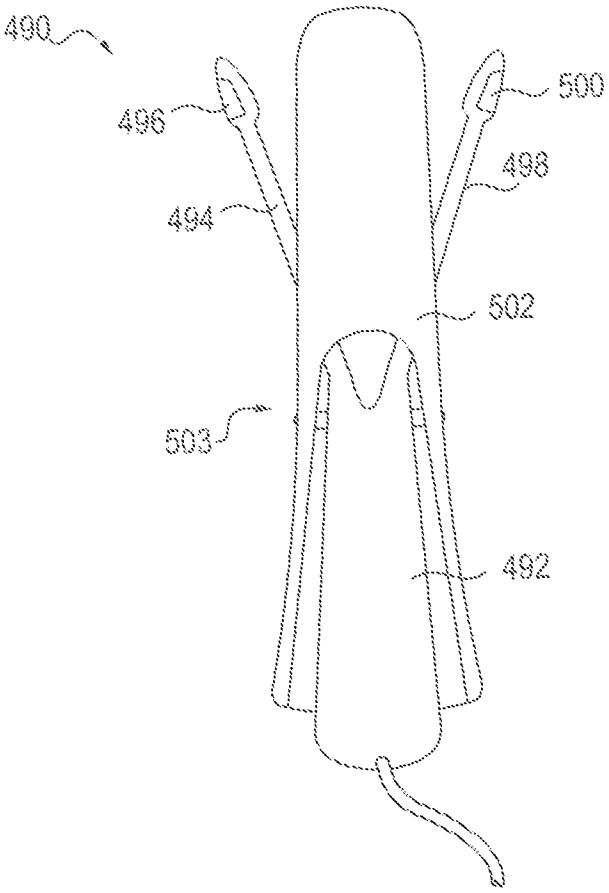


FIG. 13D

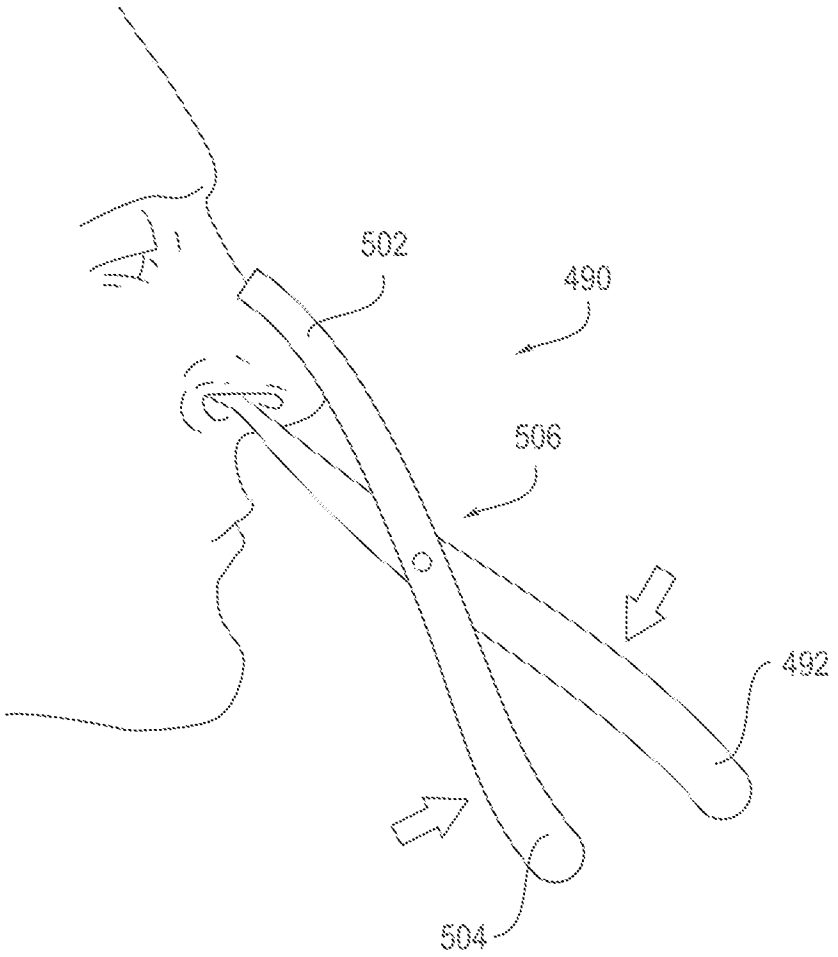


FIG. 13E

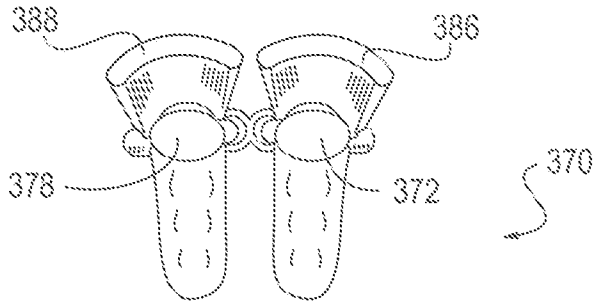


FIG. 14B

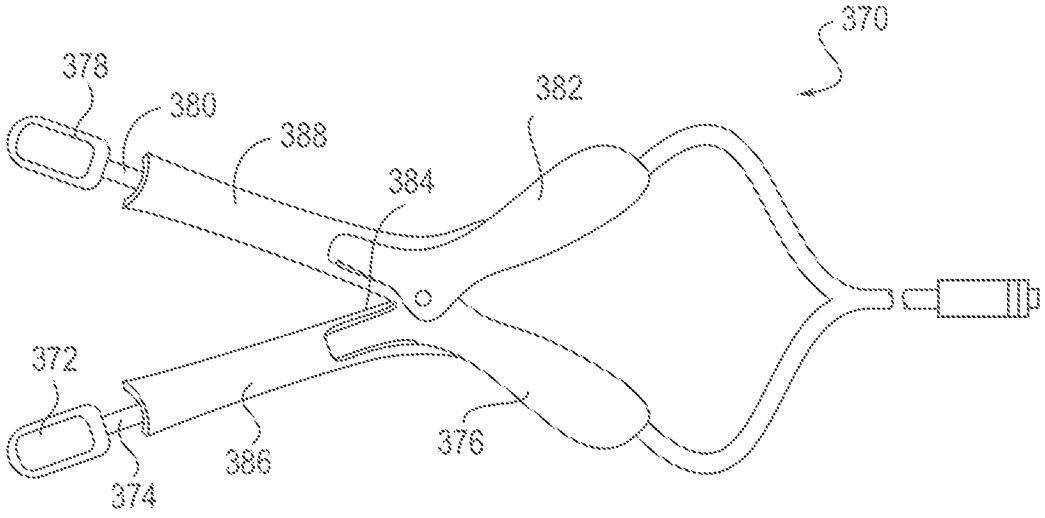


FIG. 14A

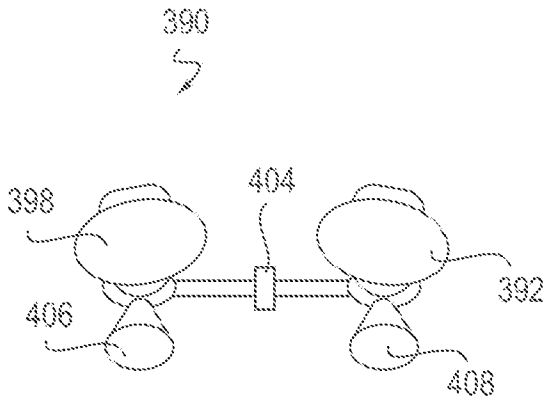


FIG. 15A

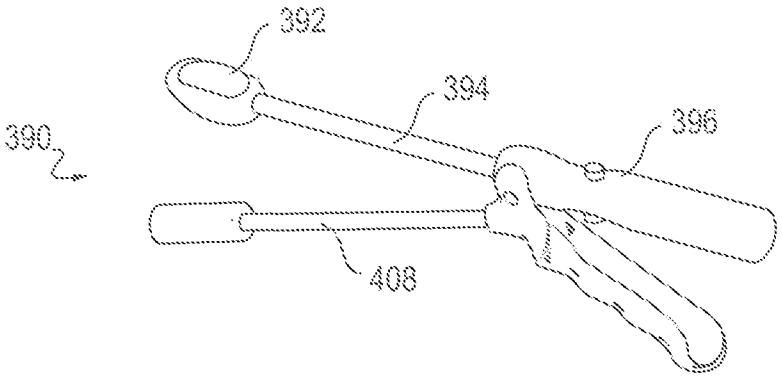


FIG. 15B

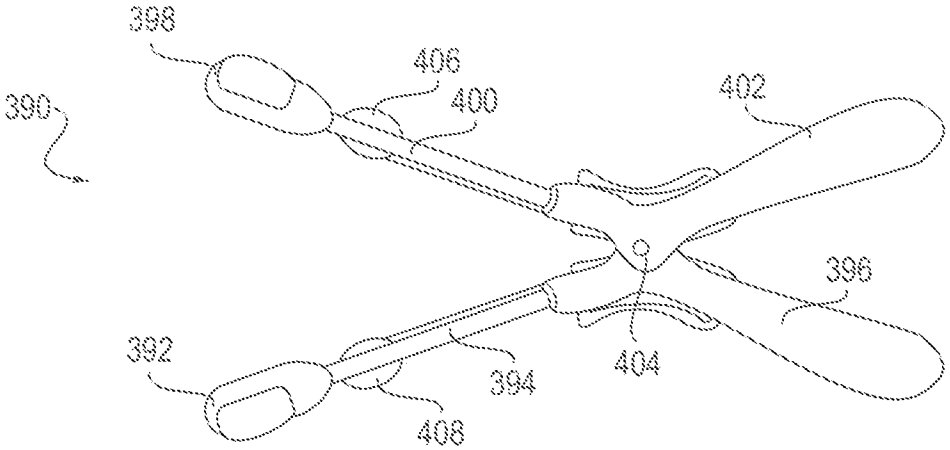


FIG. 15C

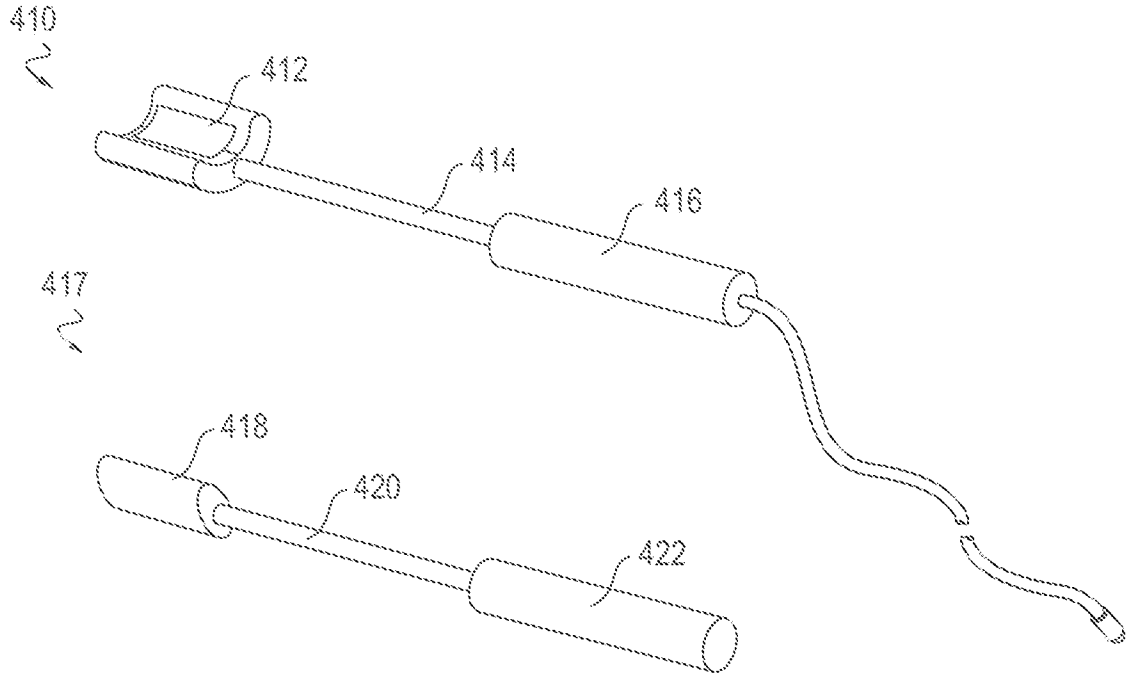


FIG. 16

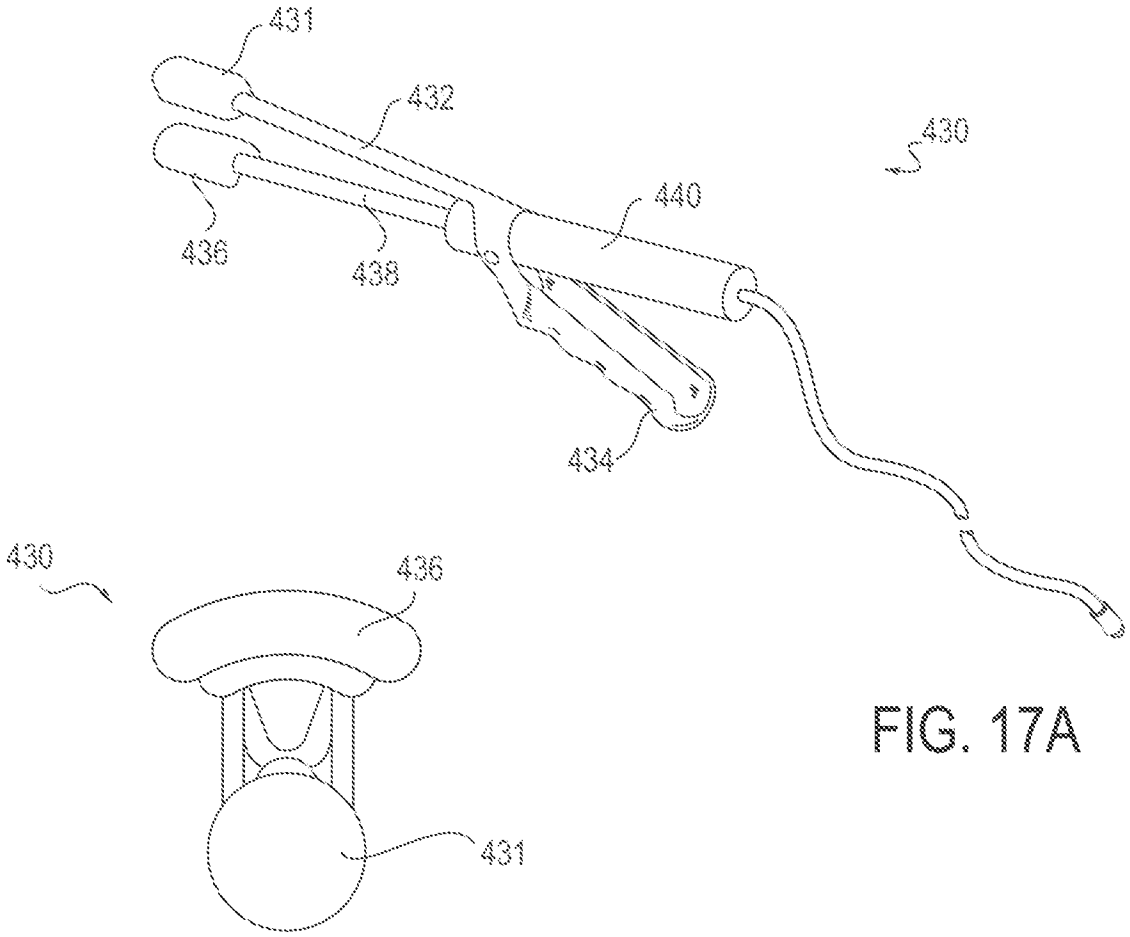


FIG. 17A

FIG. 17B

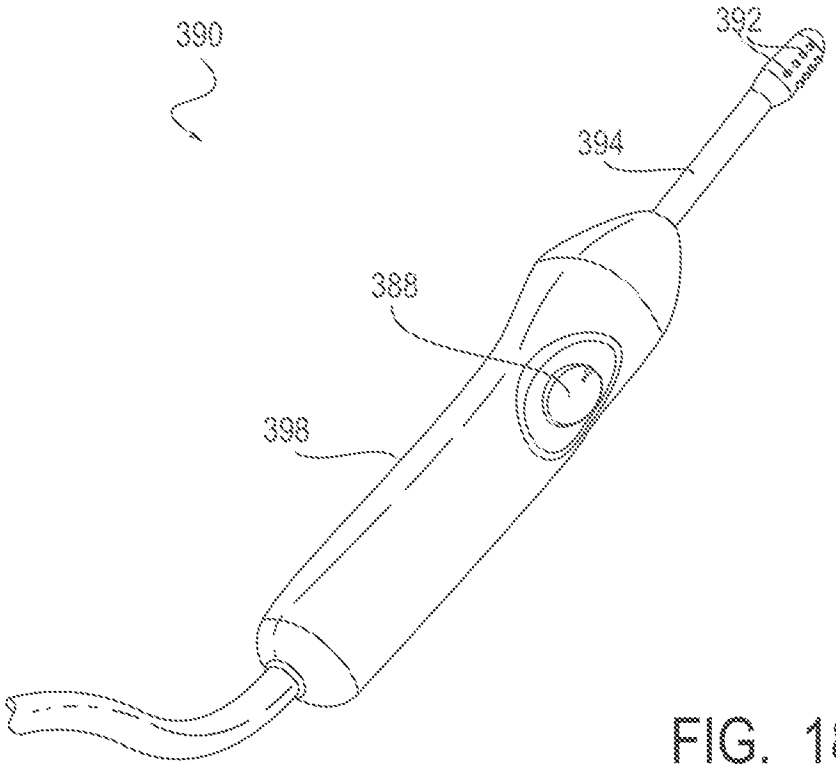


FIG. 18

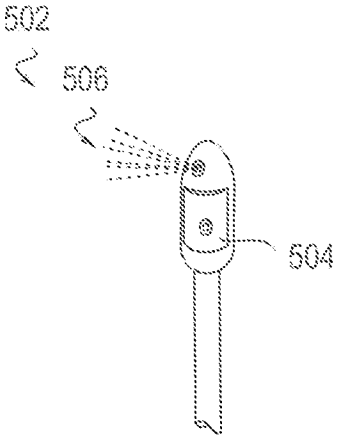


FIG. 19A

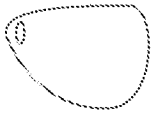


FIG. 19B

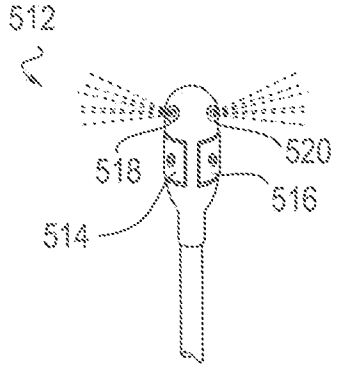


FIG. 20A

FIG. 20B

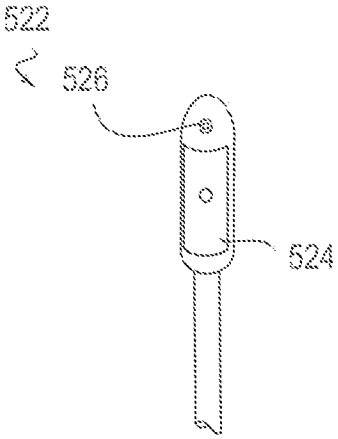


FIG. 21A

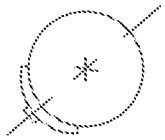


FIG. 21B

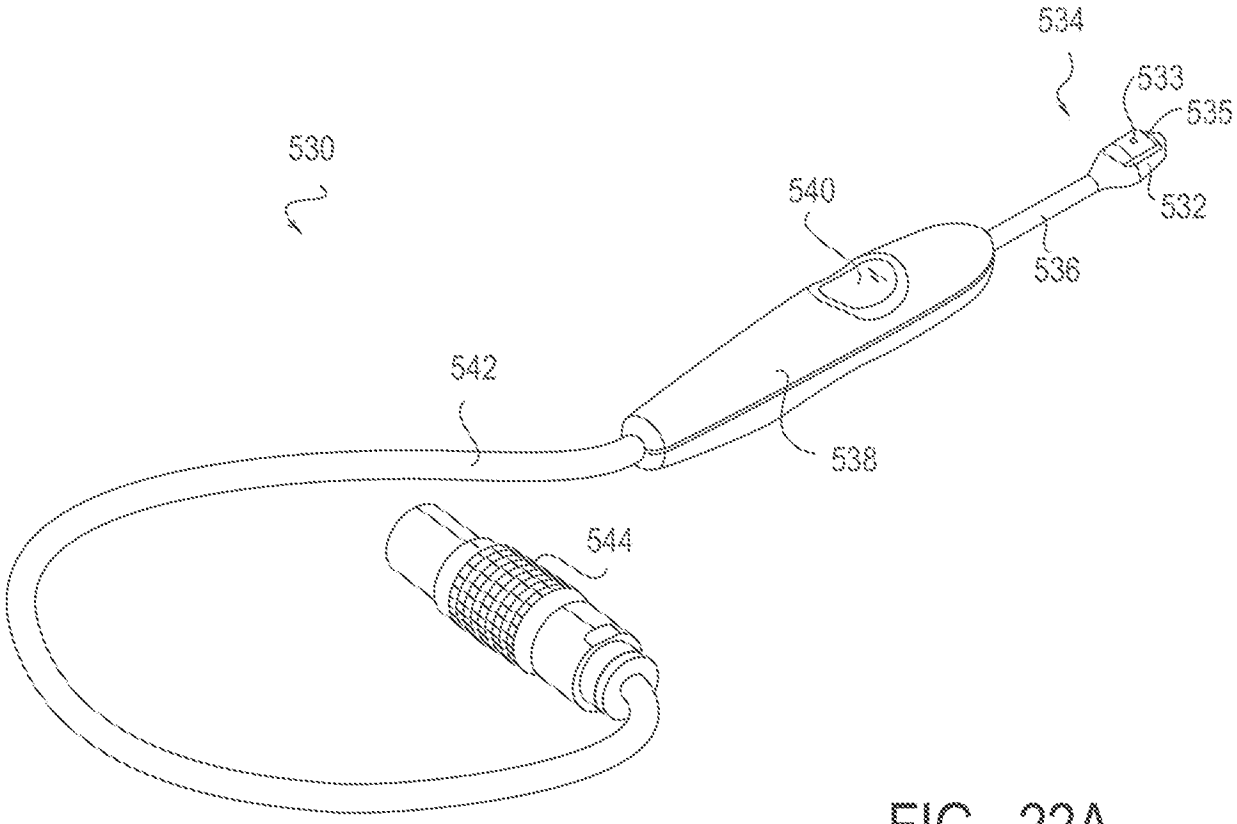


FIG. 22A

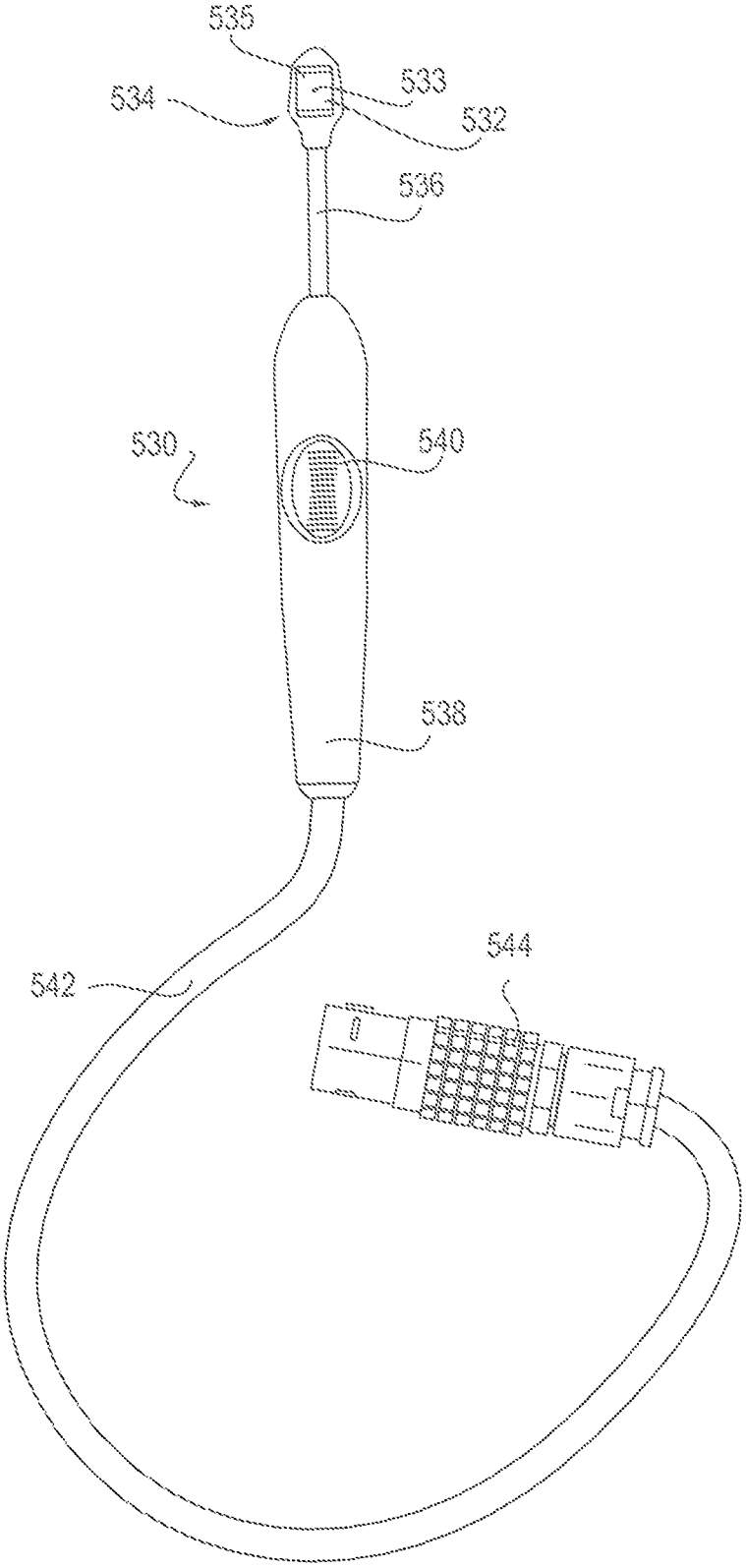


FIG. 22B

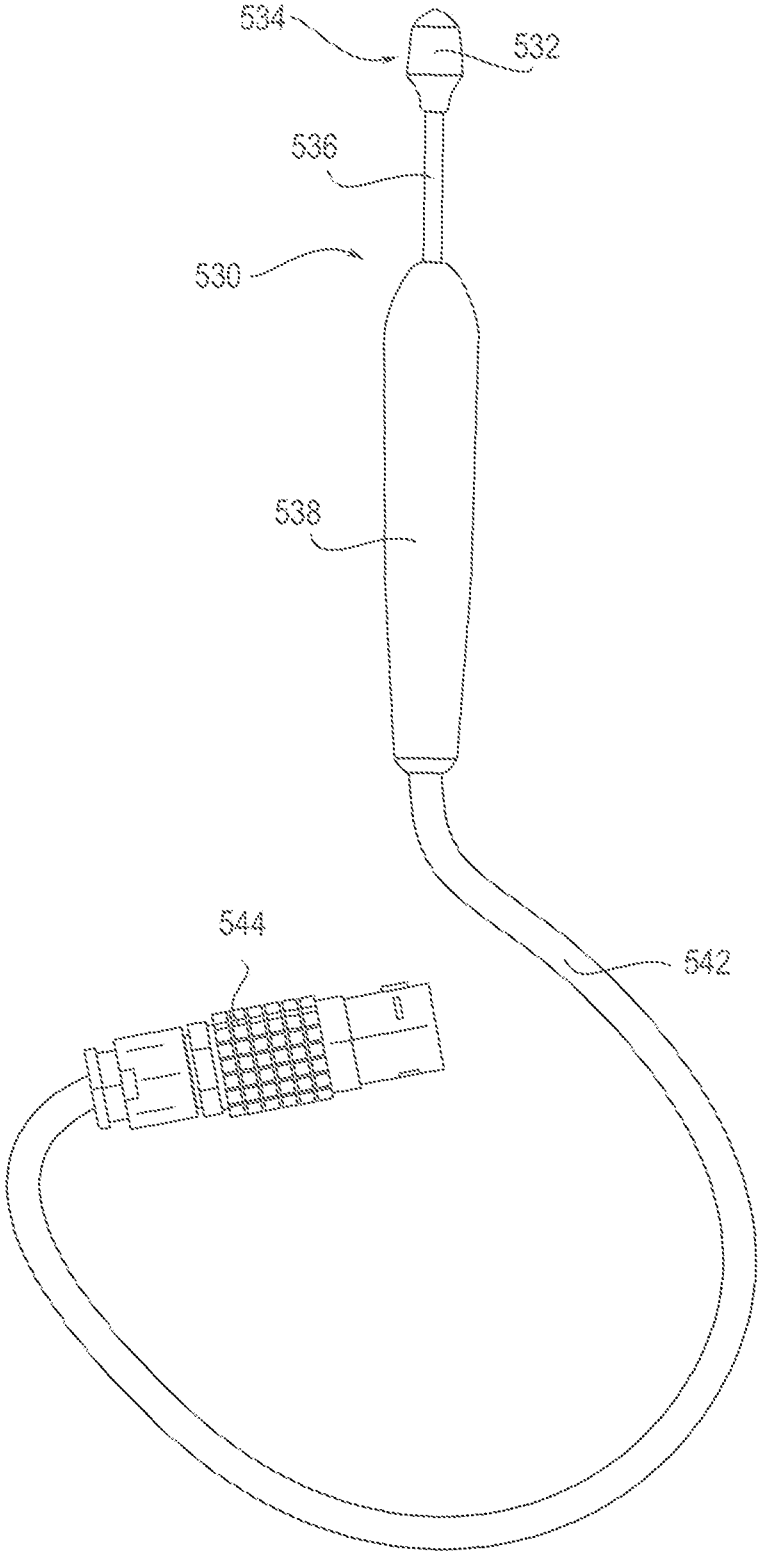


FIG. 22C

FIG. 22D

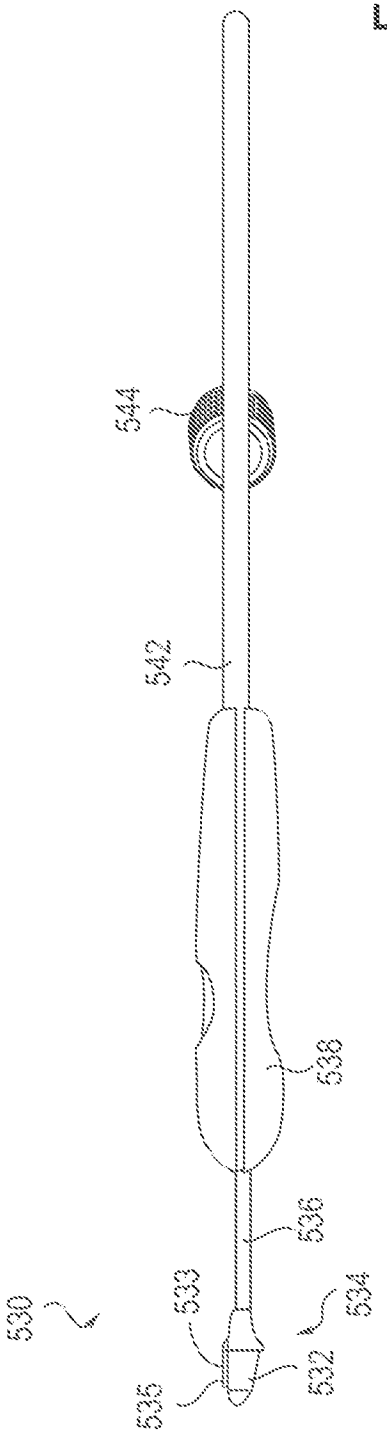
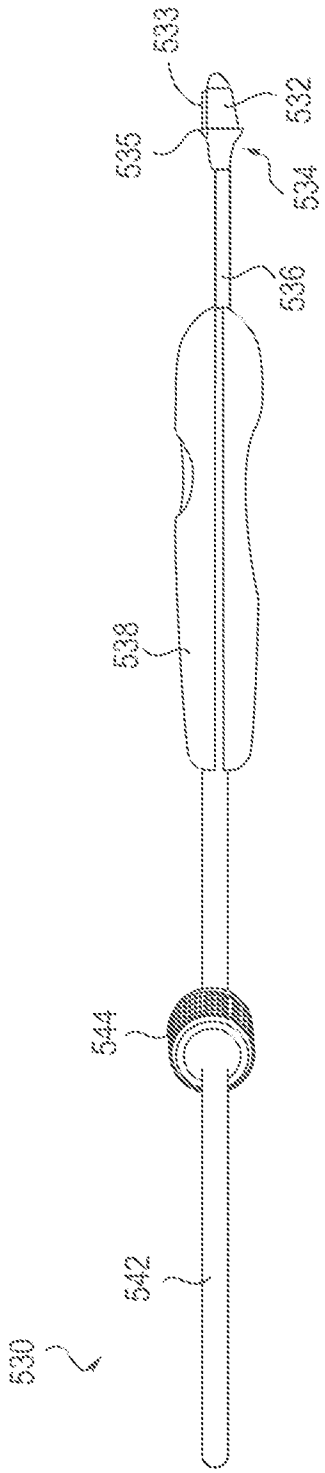


FIG. 22E



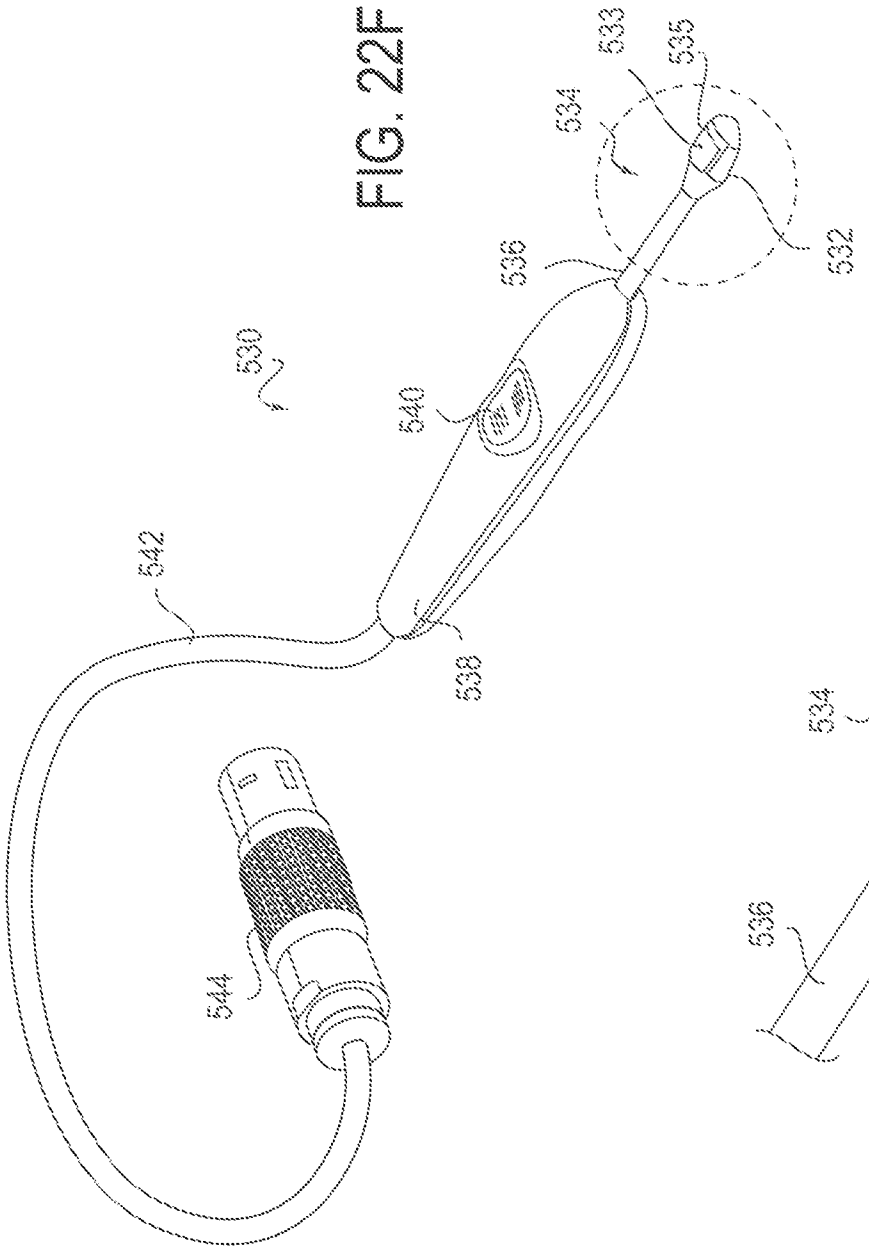


FIG. 22F

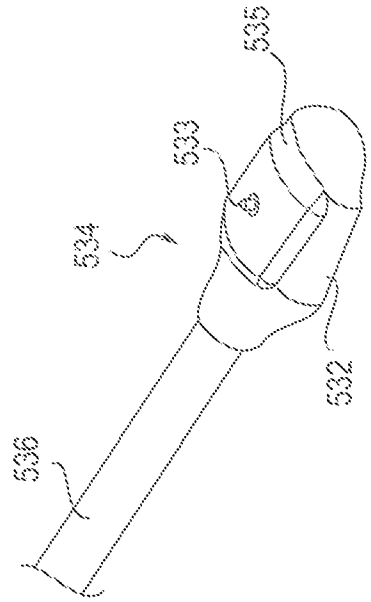


FIG. 22G

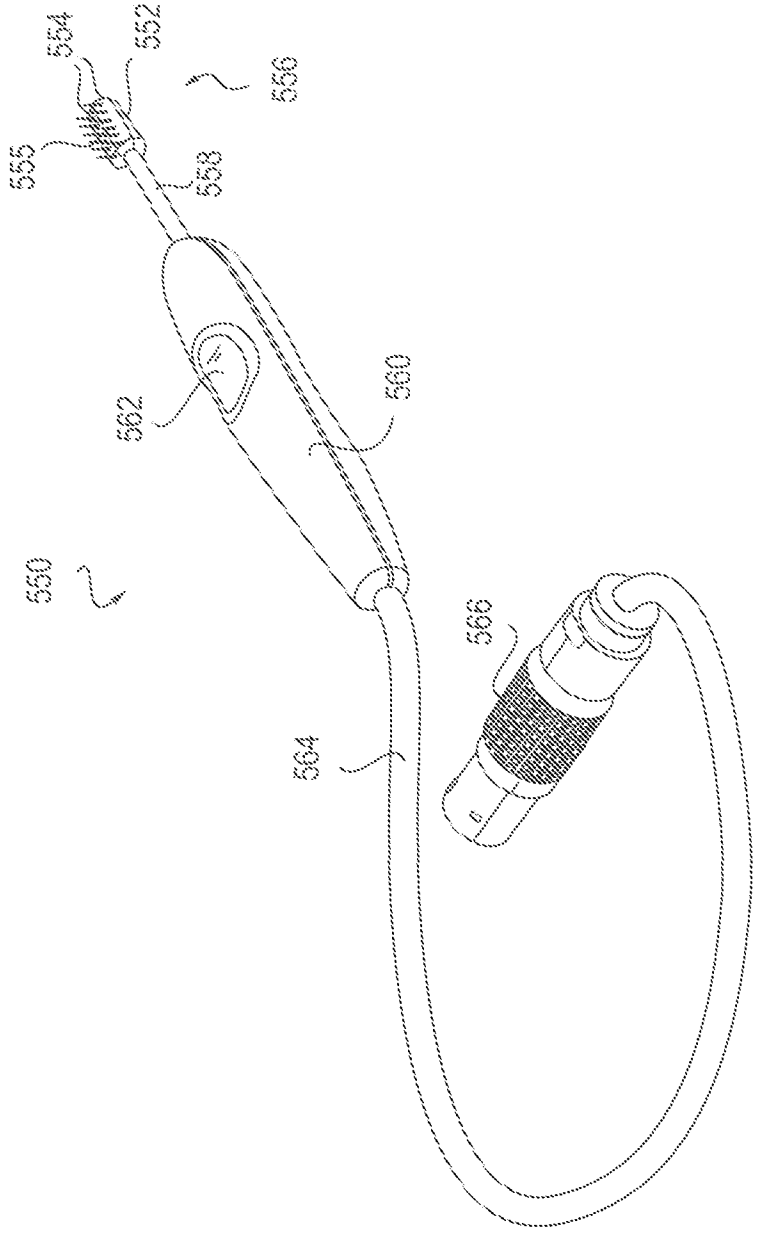


FIG. 23A

FIG. 23B

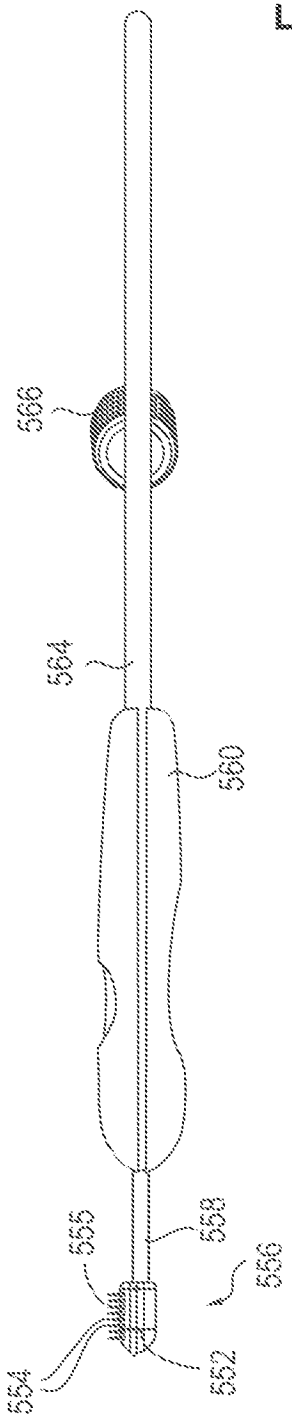
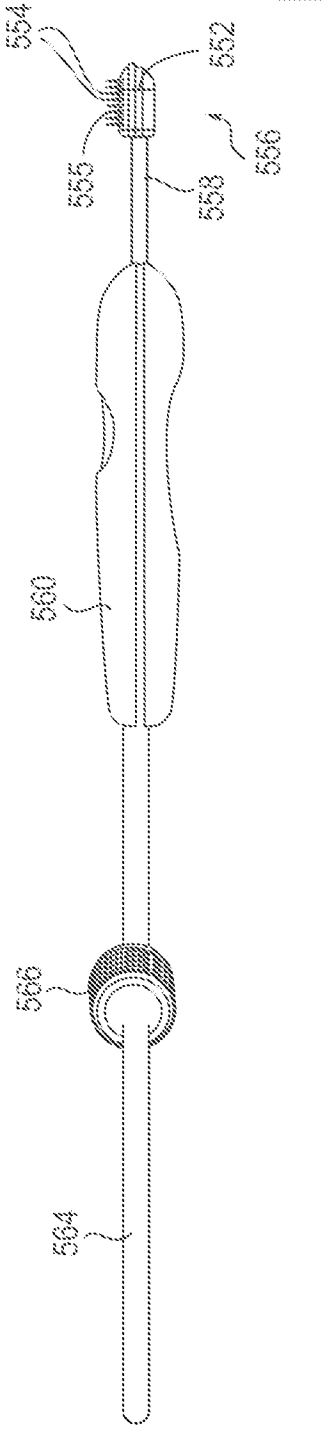


FIG. 23C



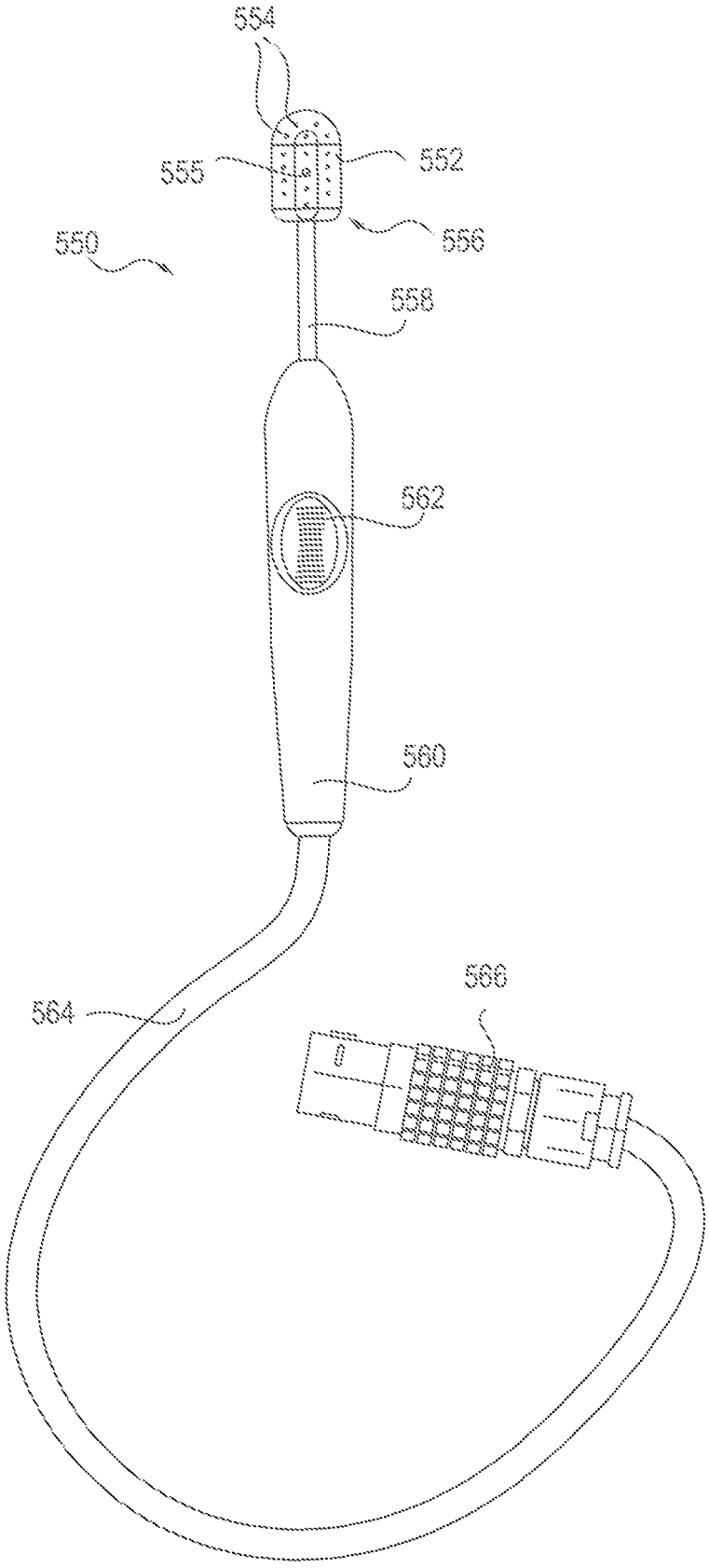


FIG. 23D

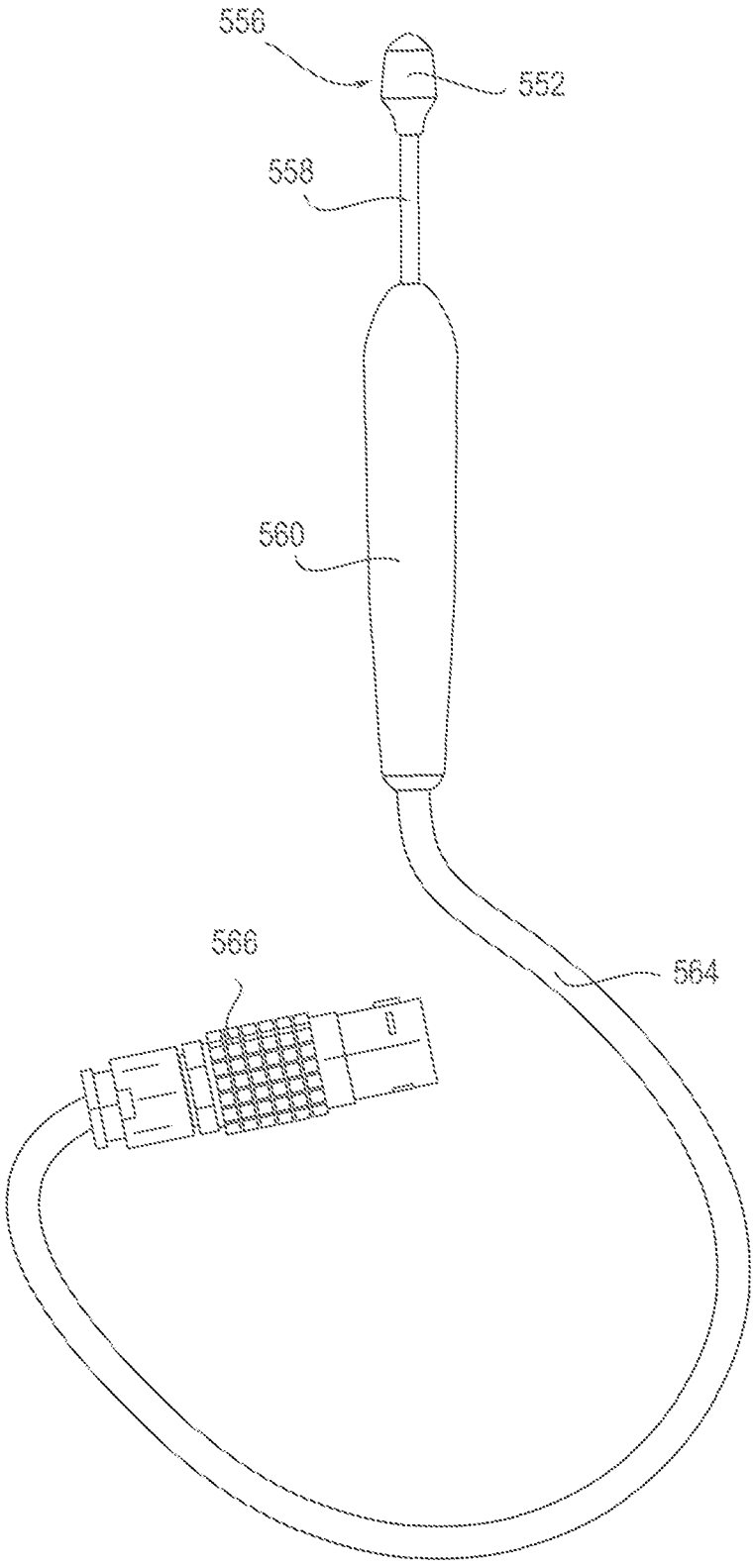


FIG. 23E1

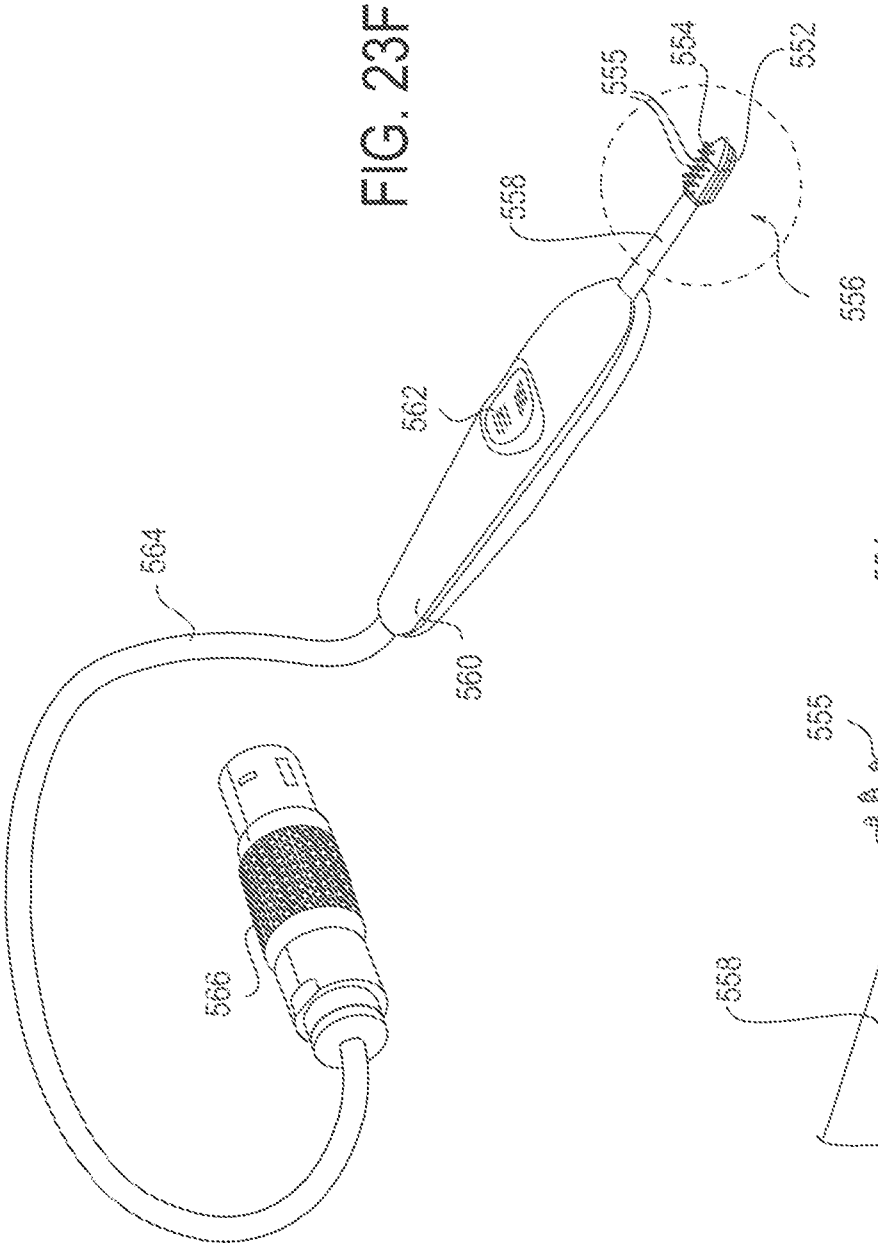


FIG. 23F

FIG. 23G

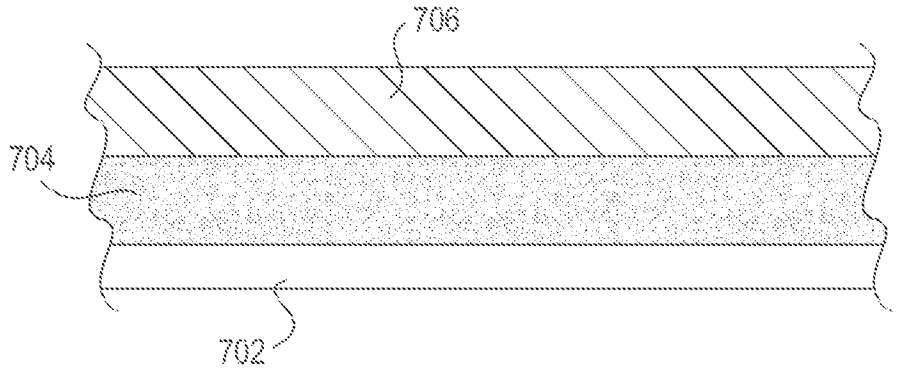


FIG. 24A

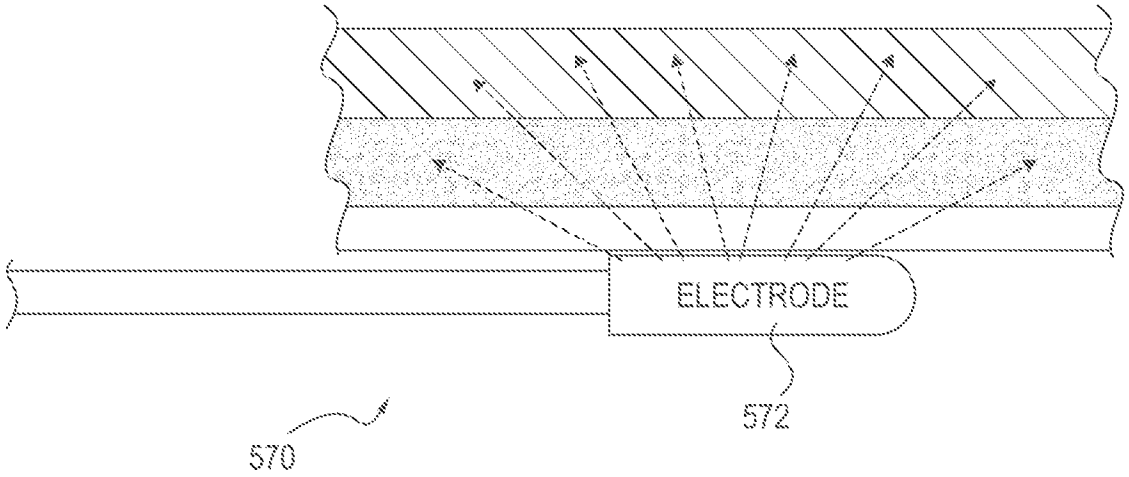


FIG. 24B

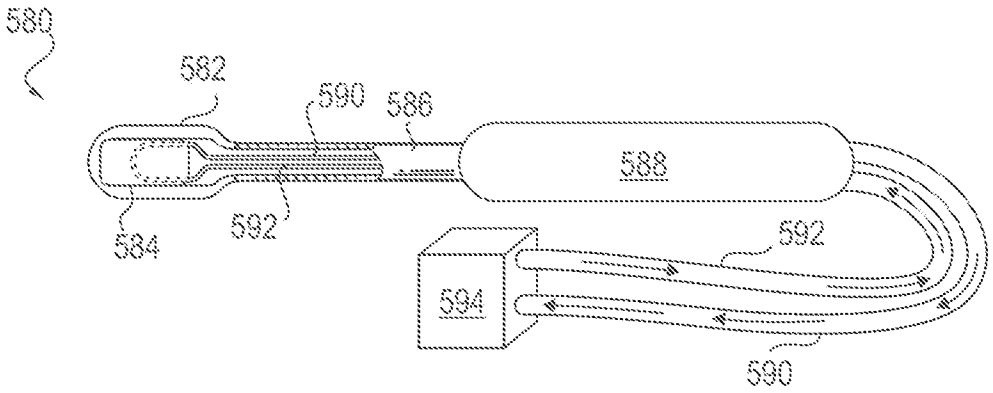


FIG. 25A

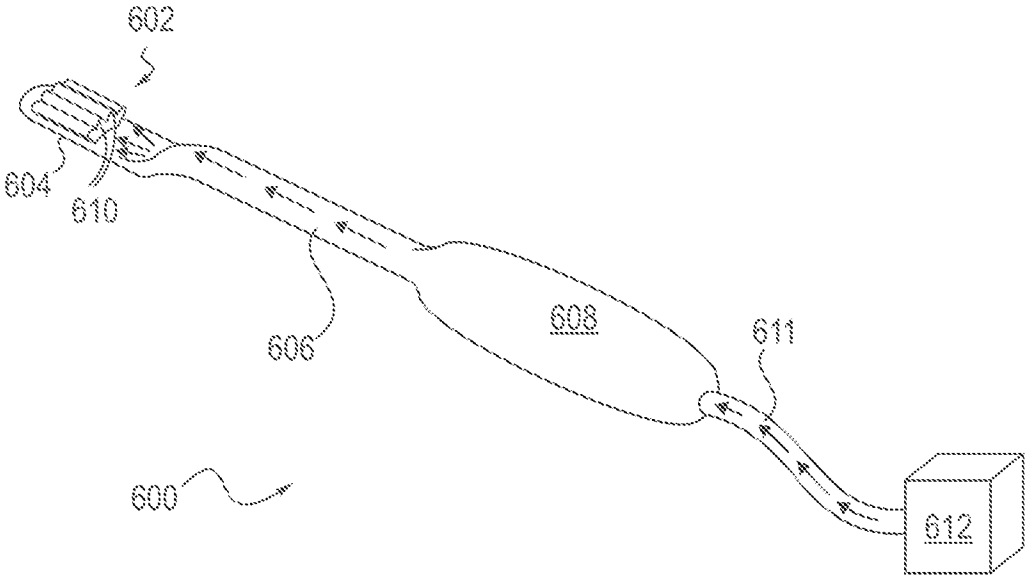


FIG. 25B

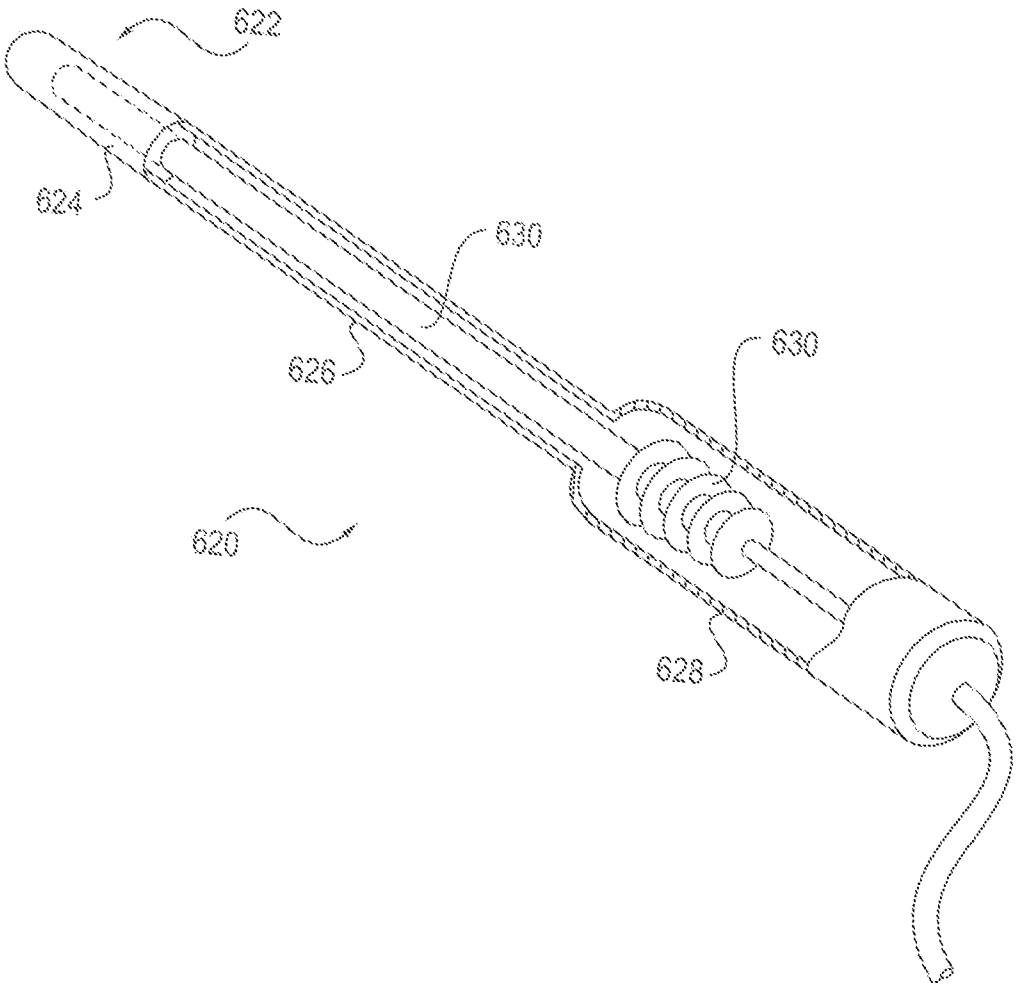

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FIG. 26

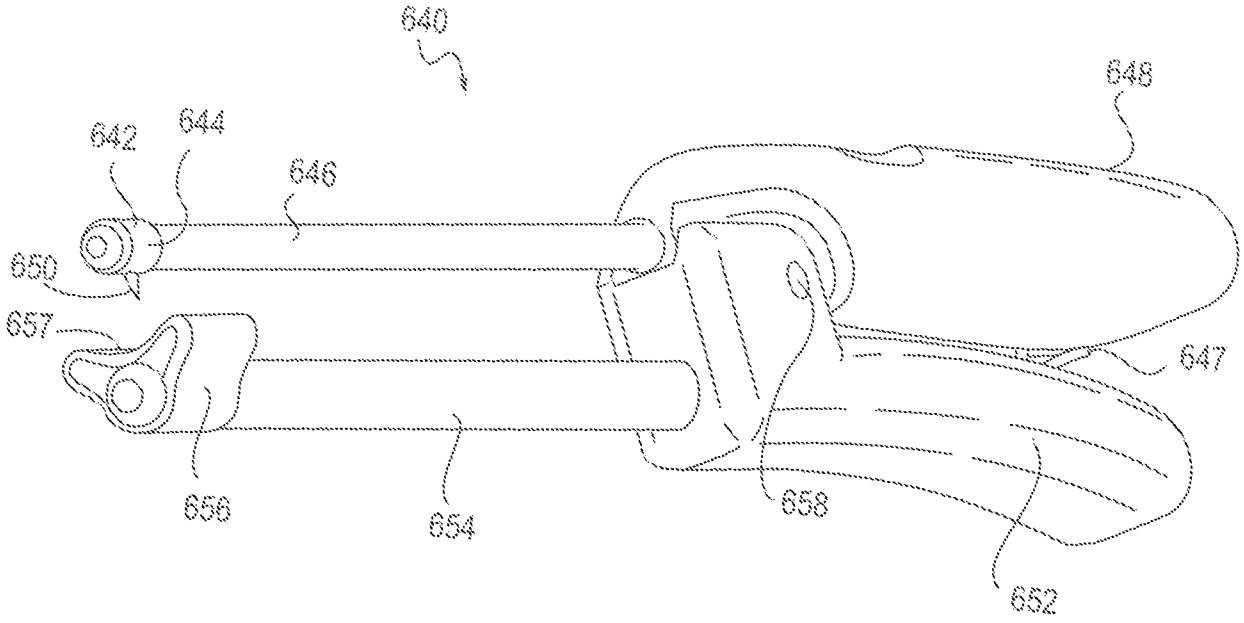
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FIG. 27

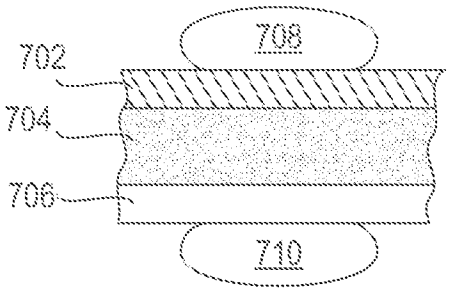

FIG. 28A

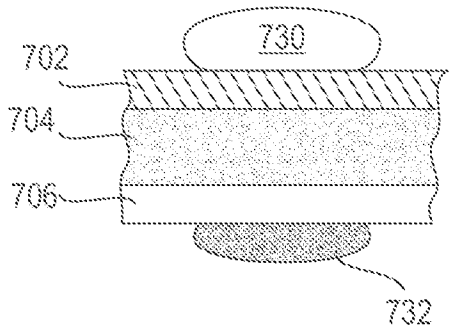

FIG. 28B

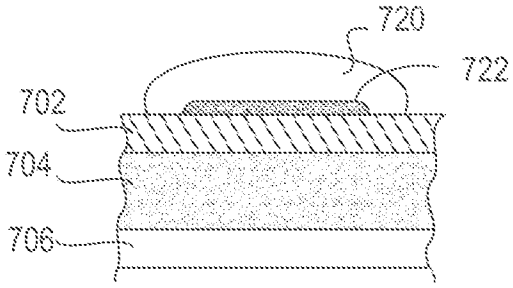

FIG. 28C

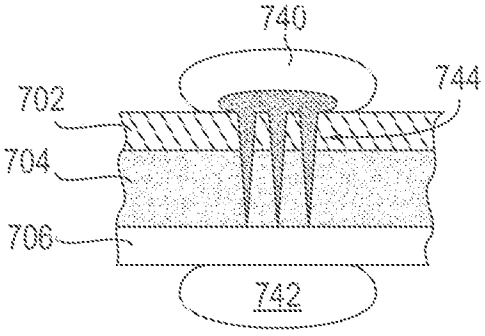

FIG. 28D

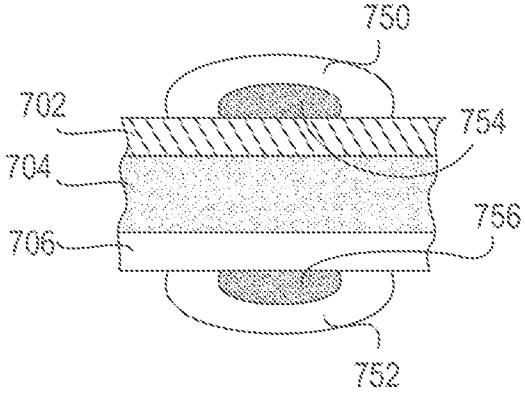

FIG. 28E

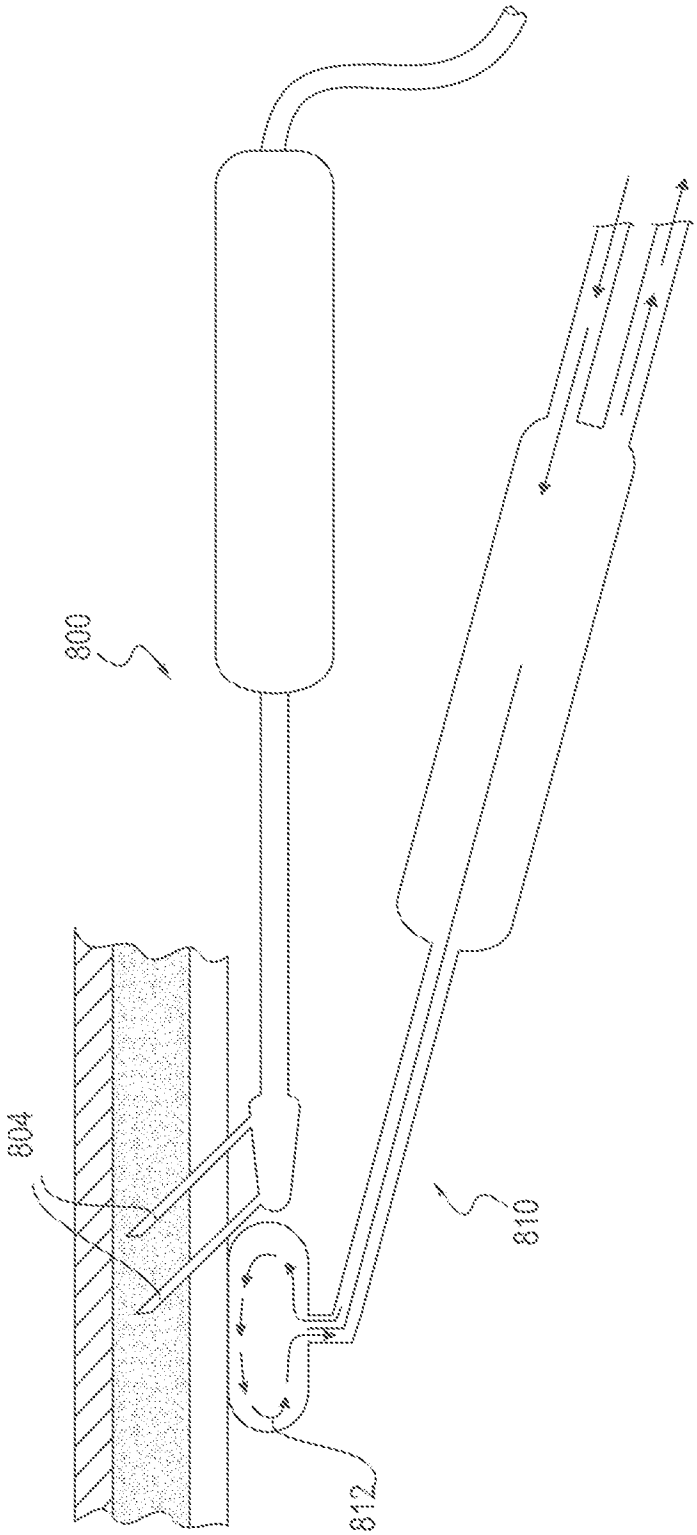

FIG. 29

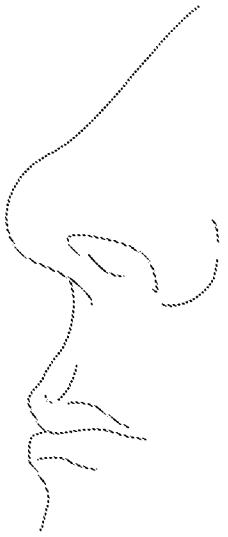

FIG. 30A

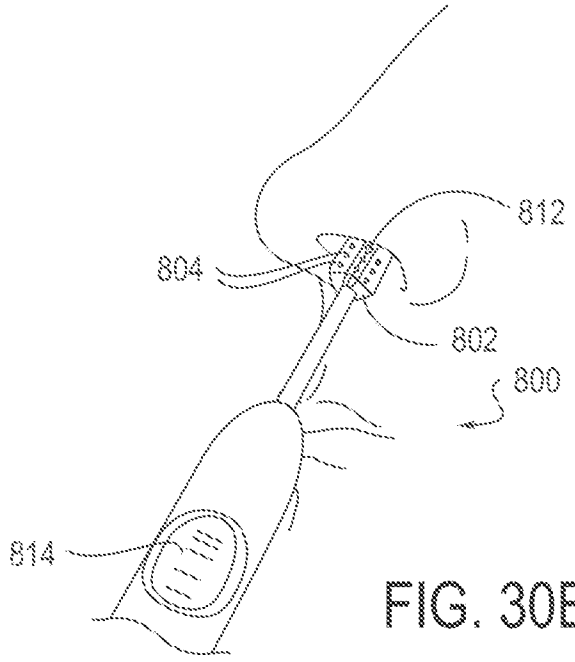

FIG. 30B

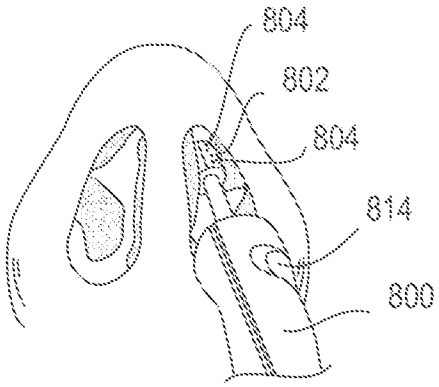

FIG. 30C

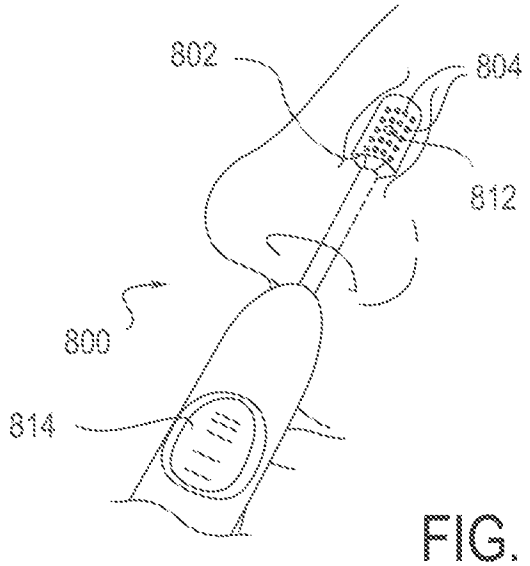

FIG. 30D

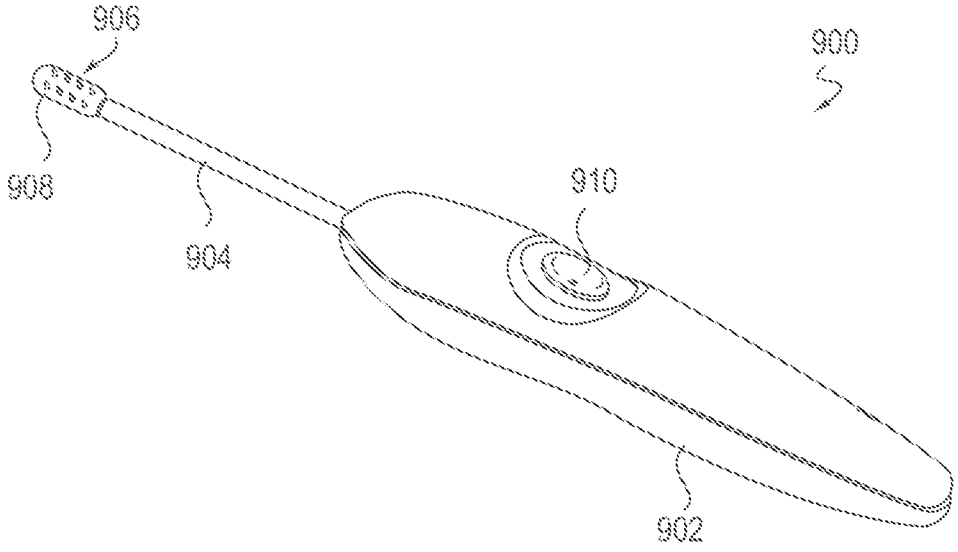

FIG. 31A

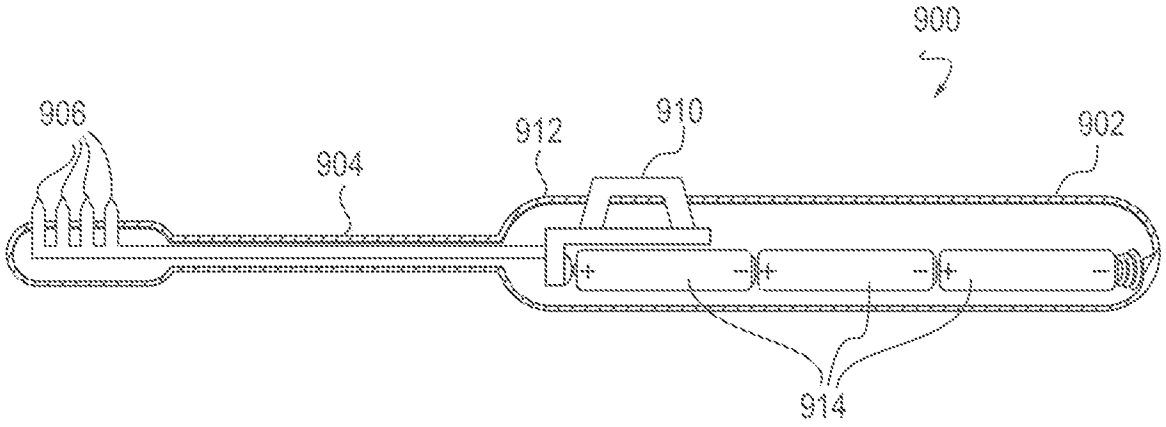

FIG. 31B

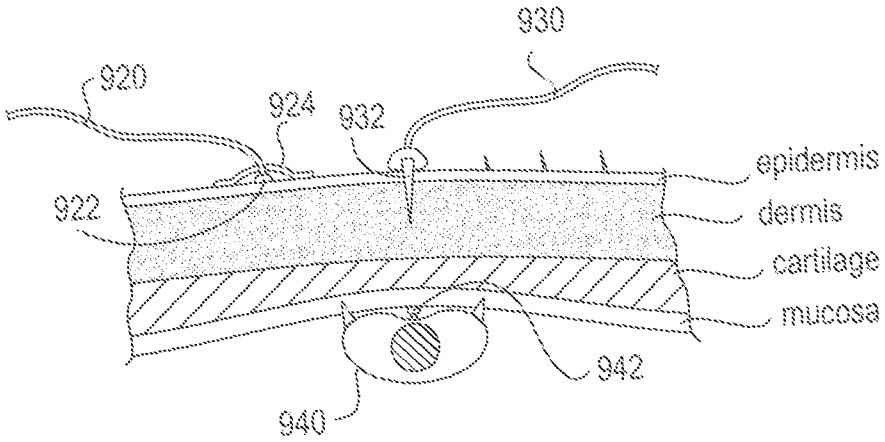

FIG. 32A

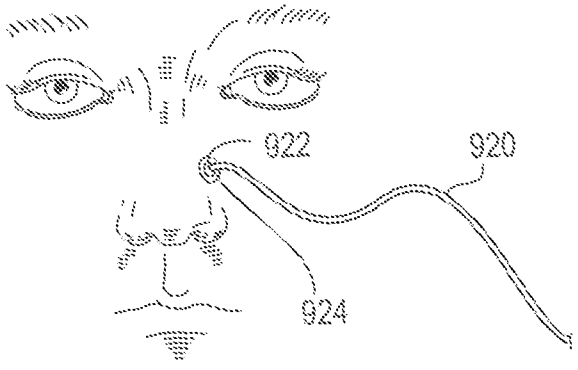

FIG. 32B

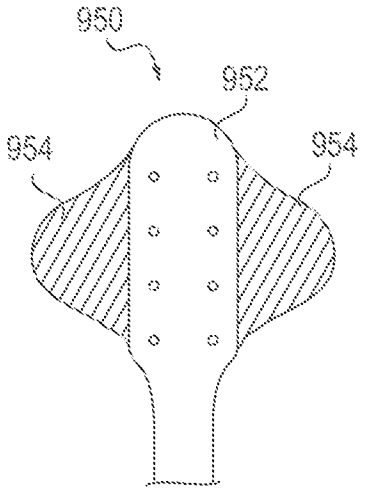

FIG. 33A

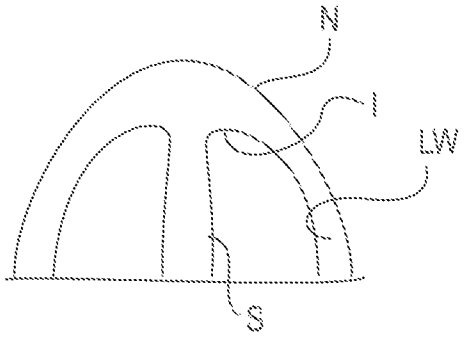

FIG. 33B

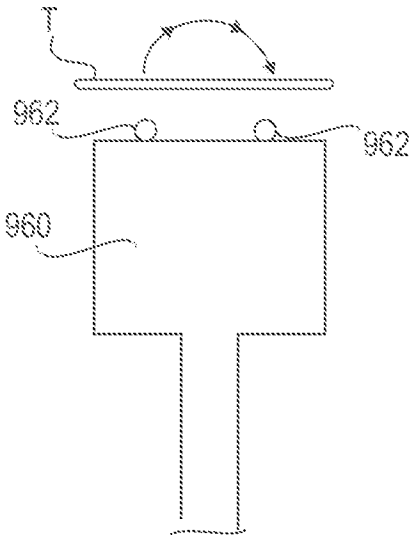

FIG. 34A

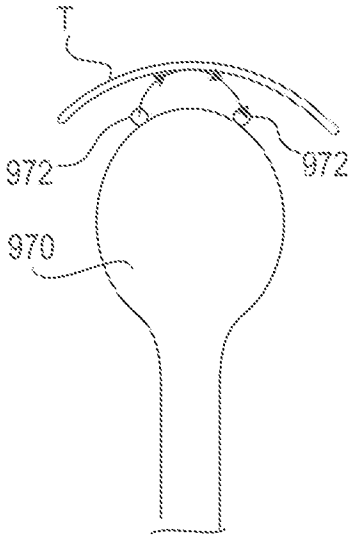

FIG. 34B

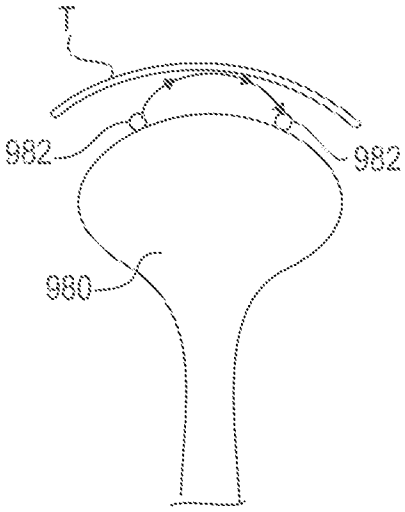

FIG. 34C

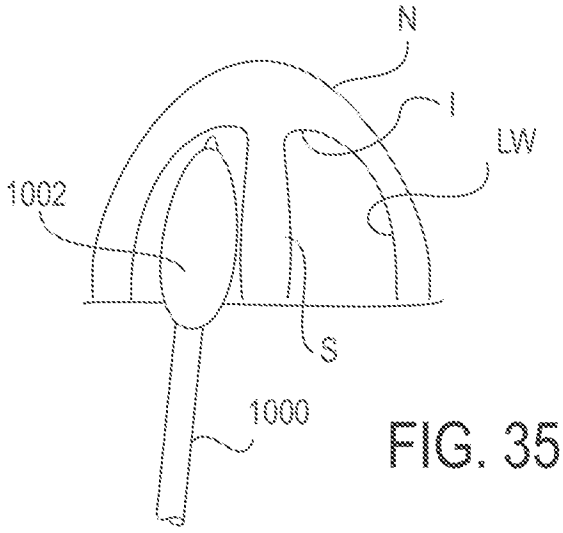

FIG. 35

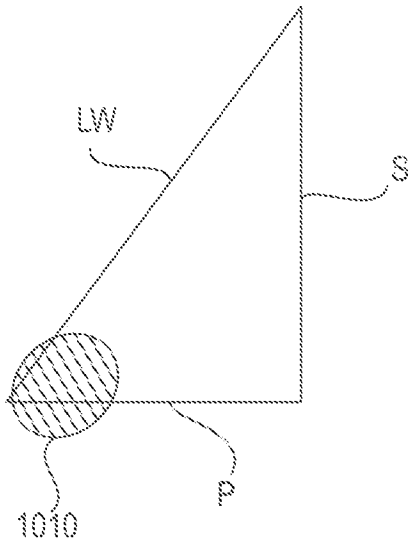

FIG. 36

P240109US01
(494912-5)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Scott J. WOLF, *et al.*		Group Art Unit:	3739
Serial No.:	14/026,922	Examiner:	DVORAK, Linda C.
Filed:	September 13, 2013	Confirmation No.:	5517
For:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	Customer No.:	75149

DECLARATION FOR UTILITY PATENT APPLICATION UNDER 37 CFR 1.63

This Declaration is:
- ■ submitted with initial filing; OR
- ☐ submitted after initial filing (accompanied by surcharge under 37 CFR 1.16(f))

As a below named inventor, I hereby declare that:
This declaration is directed to:
- ☐ the attached application, OR
- ■ United States Application Number or PCT International application number 14/026,922 filed on September 13, 2013.

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

I believe 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.

Direct all correspondence to the address associated with Customer Number 75149.

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State of California

Mailing Address : 319 Trenton Way in Menlo Park, California 94025

Second Inventor:

Signature: _____ Date 25 Feb 2014

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State of California

Mailing Address : 517 Fern Ridge Court in Sunnyvale, California 94087

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
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	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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	Application Number	
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	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
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	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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	Attorney Docket Number	17713.0001US14

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	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US14

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Christopher P. Ziolkowski/	Date (YYYY-MM-DD)	2019-07-17
Name/Print	Christopher P. Ziolkowski	Registration Number	73729

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

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.