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(54) **NASAL AIRWAY TISSUE TREATMENT SYSTEM AND METHOD**

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(73) Assignee: **Aerin Medical Inc.**, Mountain View, CA (US)

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Publication Classification

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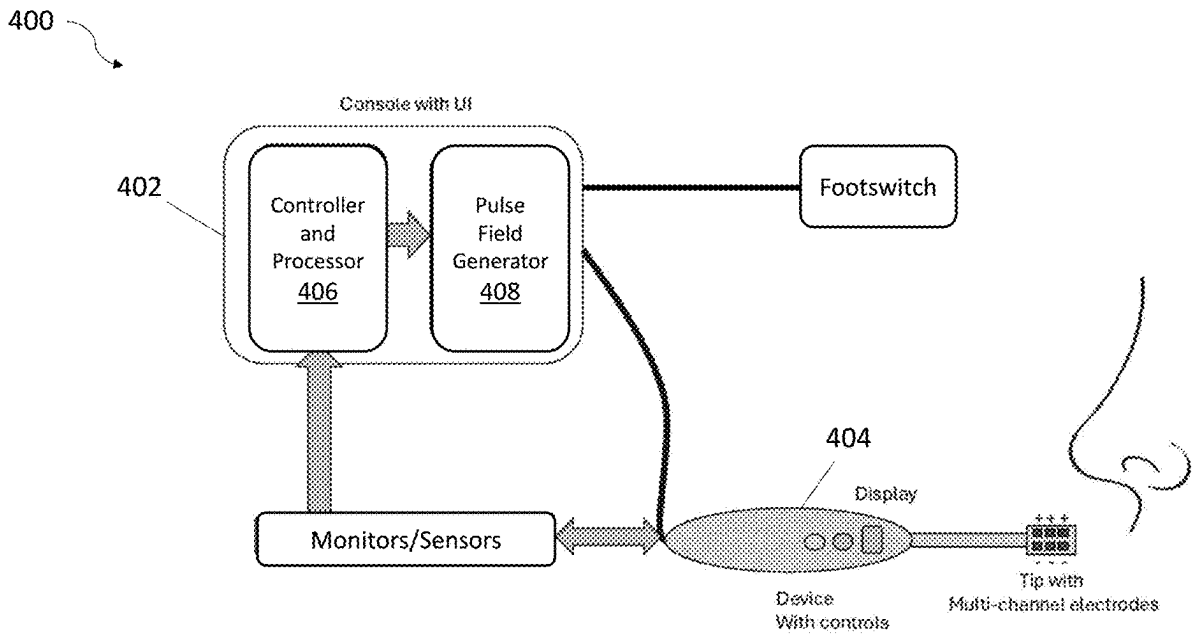
A61B 17/00	(2006.01)
A61B 18/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 18/1485*** (2013.01); *A61B 2017/00893* (2013.01); *A61B 2018/00327* (2013.01); *A61B 2018/00434* (2013.01); *A61B 2018/00577* (2013.01); *A61B 2018/00696* (2013.01); *A61B 2018/00708* (2013.01); *A61B 2018/00821* (2013.01); *A61B 2018/00875* (2013.01); *A61B 2018/1467* (2013.01)

(57) **ABSTRACT**

Systems and methods are provided for treating tissue in a nasal airway. In some embodiments, a console including a pulsed electric field generator is provided to generate pulsed electric field energy in the form of high frequency alternating pulses of energy delivered as a pulse train. The pulsed electric field generator including a plurality of output channels. The system also includes a treatment device including an elongate shaft having a treatment surface on a distal end thereof, the treatment surface including a plurality of electrode pairs configured to deliver the pulsed electric field energy provided by the pulsed electric field generator to a target tissue in the nasal airway. Each of the plurality of output channels is connected with a subset of the plurality of electrode pairs to provide pulsed electric field energy to the plurality of electrode pairs.



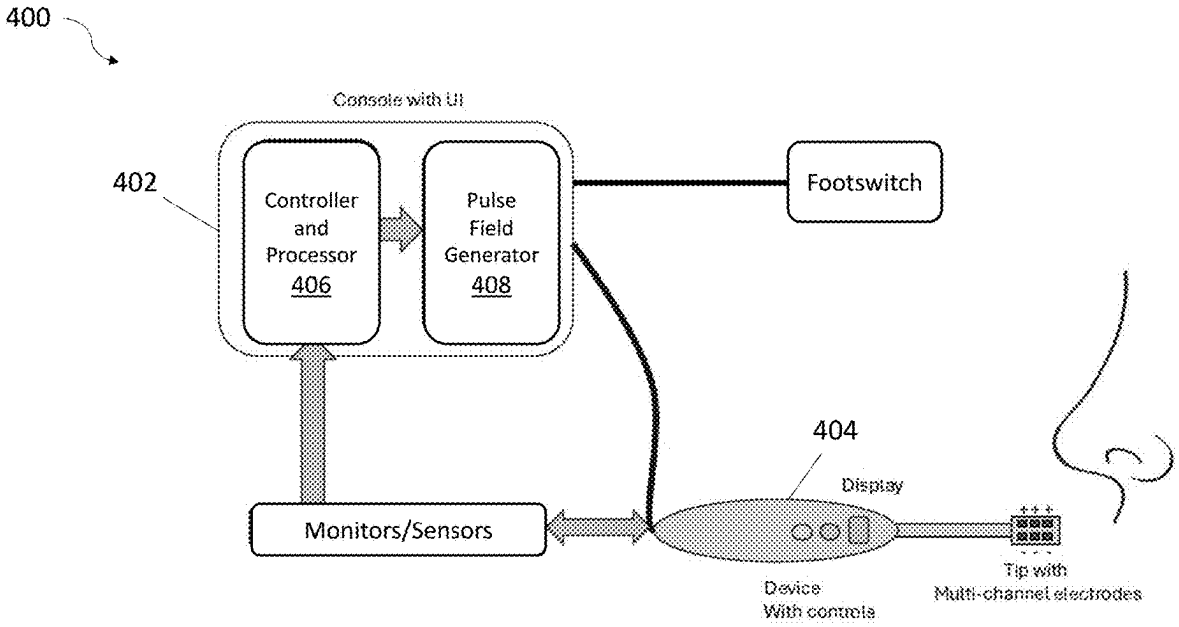

400
Console with UI
402
Controller and Processor 406
Pulse Field Generator 408
Footswitch
404
Display
Monitors/Sensors
Device With controls
Tip with Multi-channel electrodes

FIG. 1

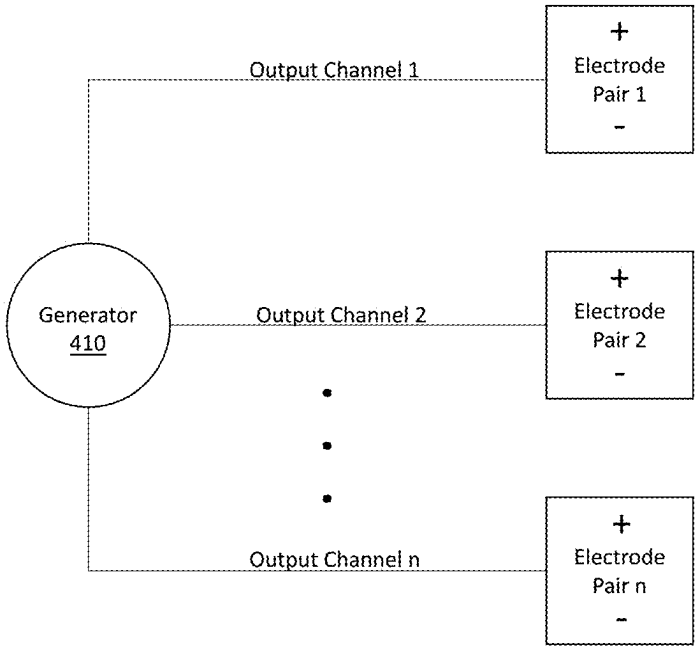

Generator
410
Output Channel 1
Output Channel 2
Output Channel n
+
Electrode
Pair 1
-
+
Electrode
Pair 2
-
+
Electrode
Pair n
-

FIG. 2A

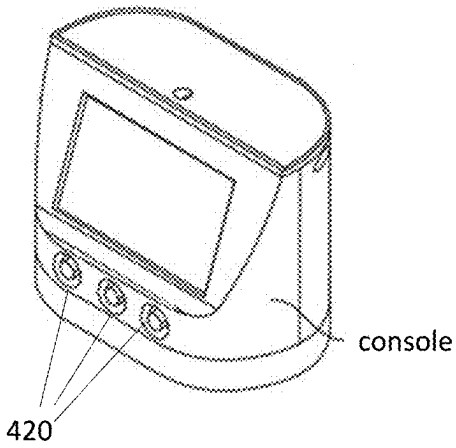


FIG. 2B

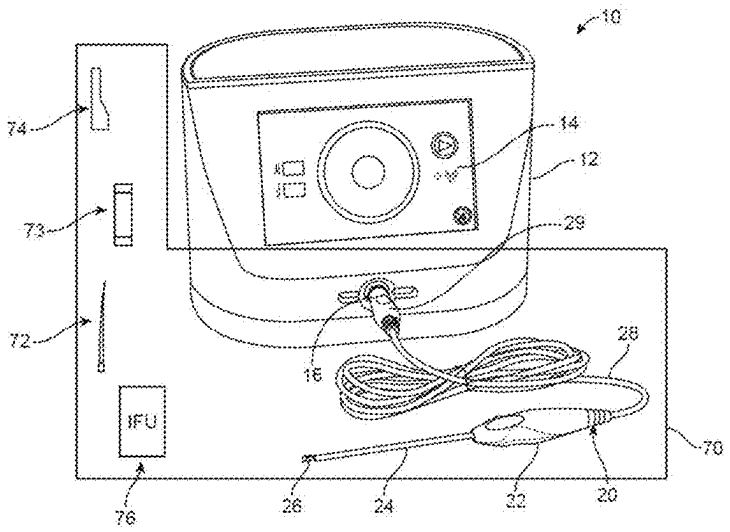


FIG. 3

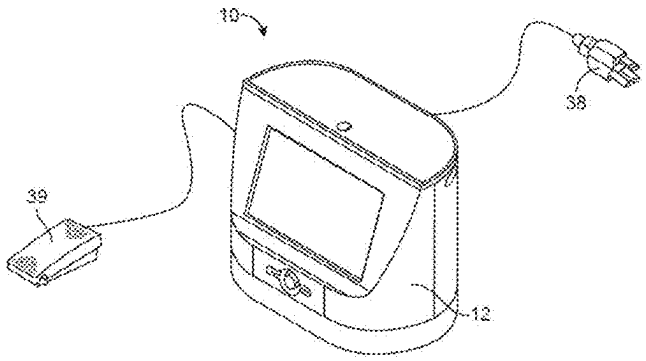


FIG. 4

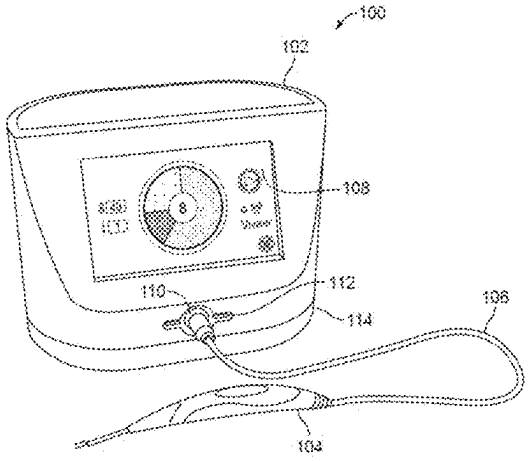


FIG. 5

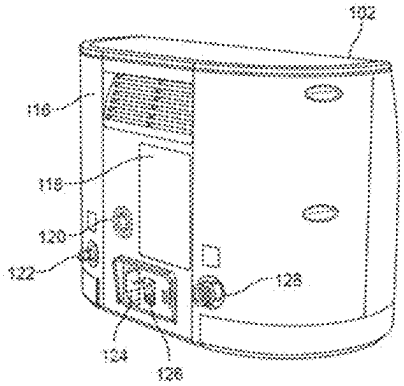


FIG. 6

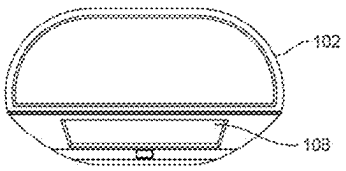


FIG. 7A

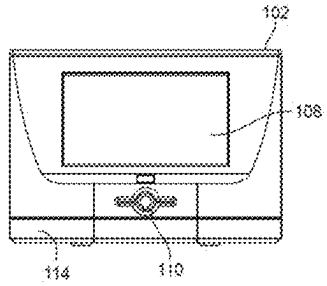


FIG. 7B

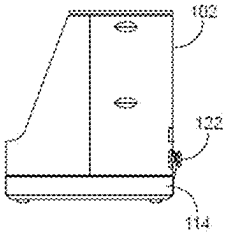


FIG. 7C

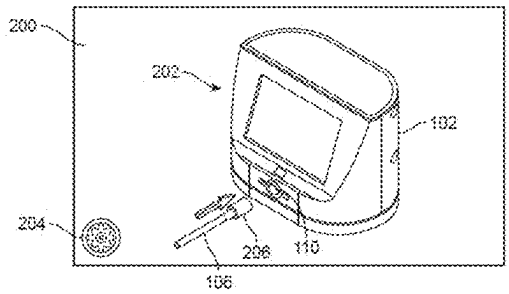


FIG. 8

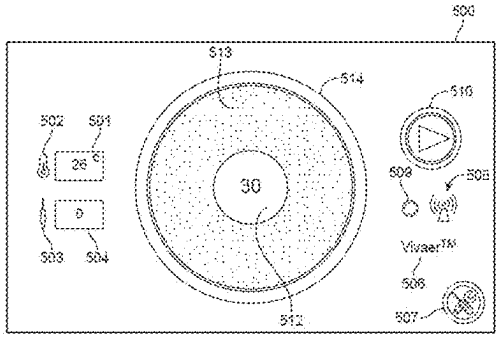
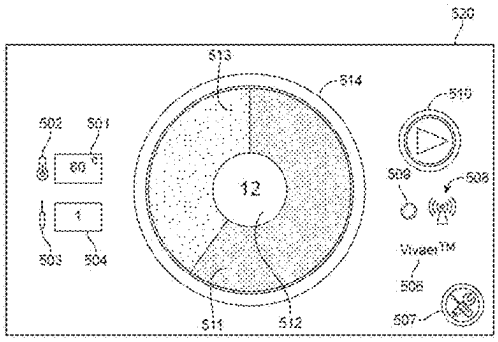

500
513
514
516
502
501
26 °
30
508
509
503
504
Vivaer™
506
507
512

FIG. 9


520
513
514
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502
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80 °
12
508
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503
504
Vivaer™
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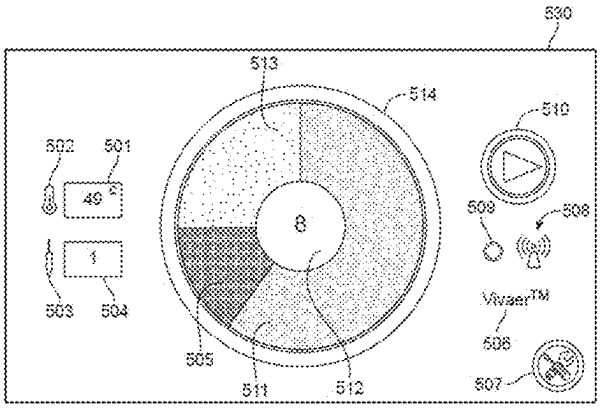
511
512

FIG. 10


530
513
514
510
502
501
49
8
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508
1
503
504
Vivaer™
506
505
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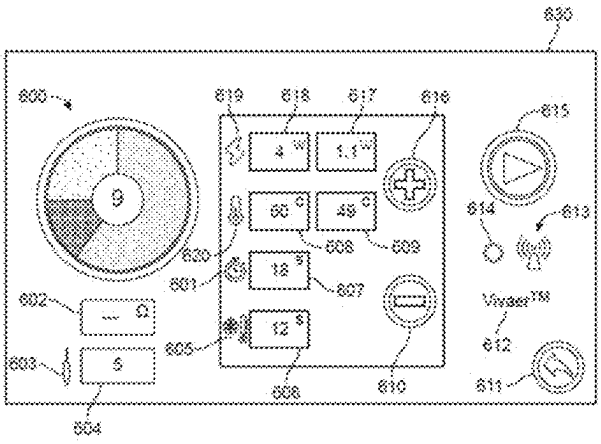
512
507

FIG. 11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600
619
618
617
616
615
614
613
612
611
610
609
608
607
606
605
604
603
602
601
620
4 W
1.1 W
60 °
45 °
12 °
12 °
9
Viewer 150

FIG. 12

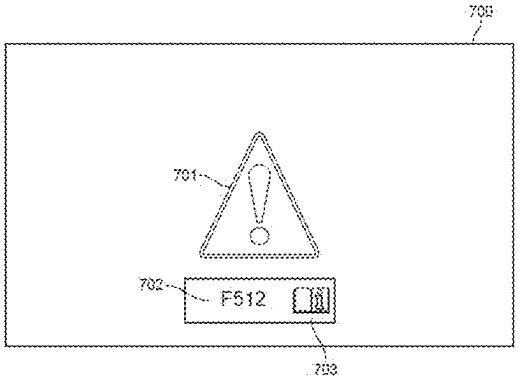


FIG. 13

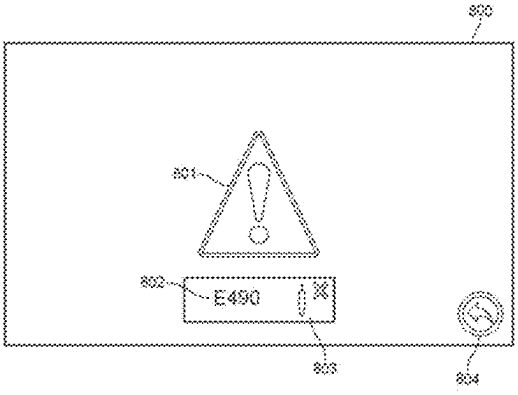


FIG. 14

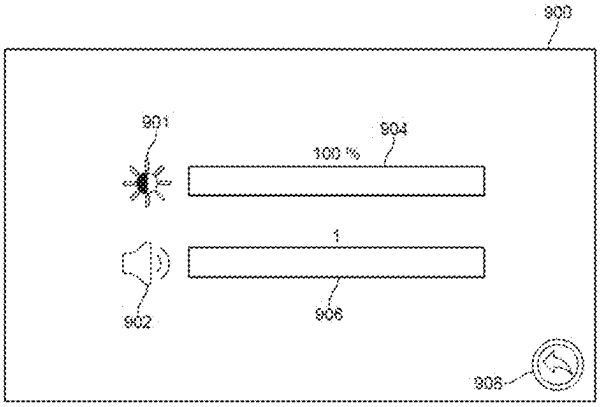


FIG. 15

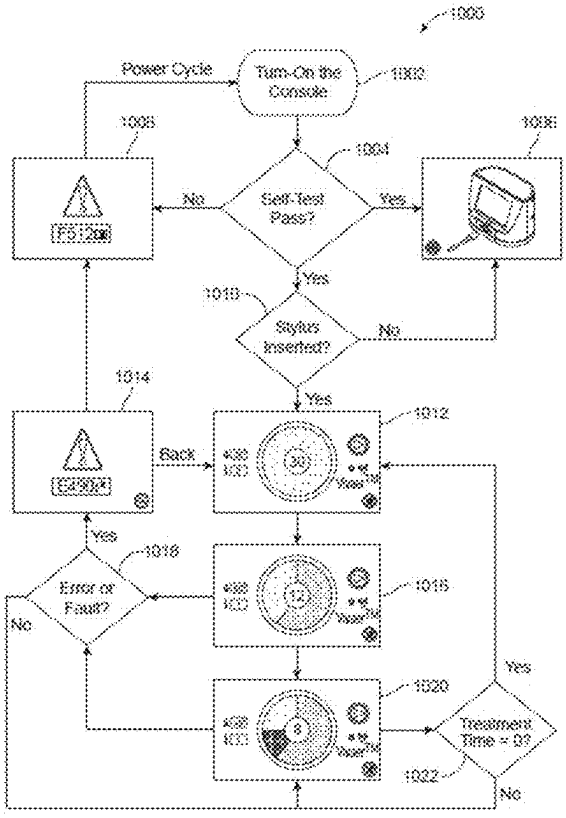

1000
Power Cycle
Turn-On the Console
1002
1008
1004
1006
Self-Test Pass?
No
Yes
Yes
1010
Styles Inserted?
No
Yes
1014
1012
Back
Yes
1018
Error or Fault?
No
1016
1020
Treatment Time = 0?
Yes
1022
No

FIG. 16

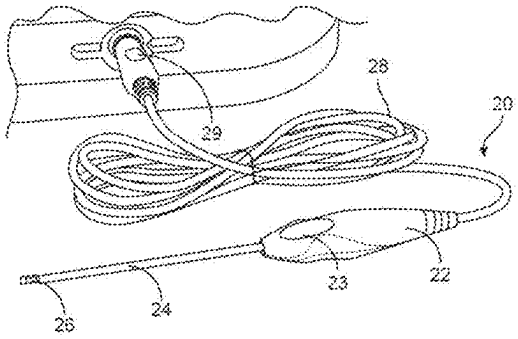


FIG. 17

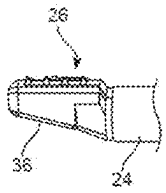


FIG. 18A

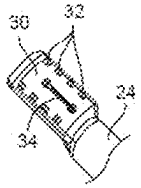


FIG. 18B

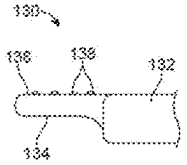


FIG. 19A

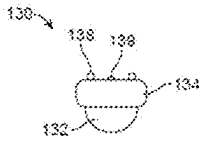


FIG. 19B

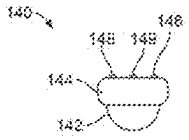


FIG. 20

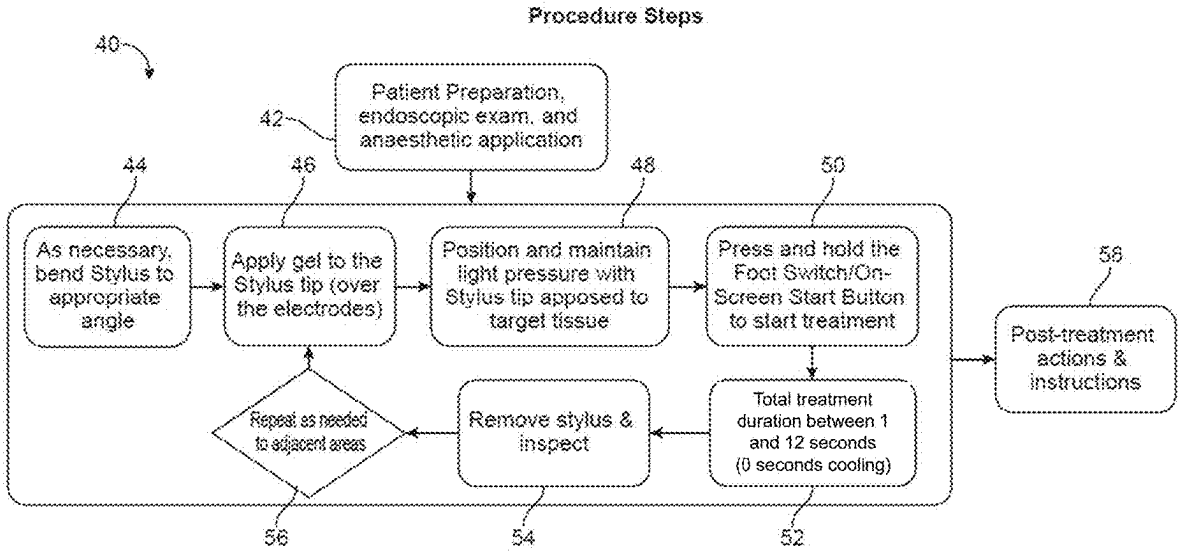

Procedure Steps
40
42
Patient Preparation, endoscopic exam, and anaesthetic application
44
46
48
50
As necessary, bend Stylus to appropriate angle
Apply gel to the Stylus tip (over the electrodes)
Position and maintain light pressure with Stylus tip apposed to target tissue
Press and hold the Foot Switch/On-Screen Start Button to start treatment
56
Post-treatment actions & instructions
Repeat as needed to adjacent areas
Remove stylus & inspect
Total treatment duration between 1 and 12 seconds (0 seconds cooling)
58
54
52

FIG. 21

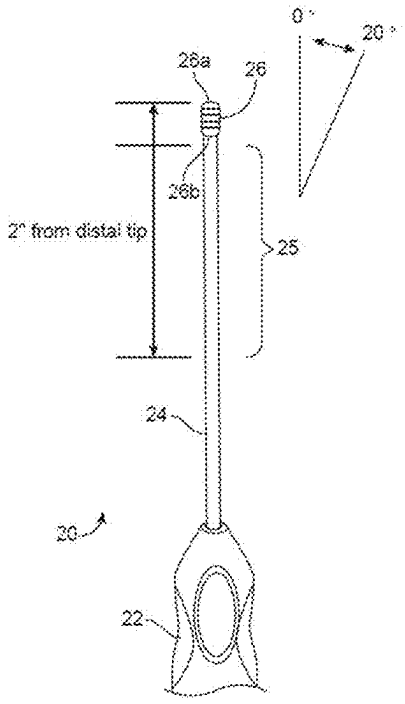


FIG. 22

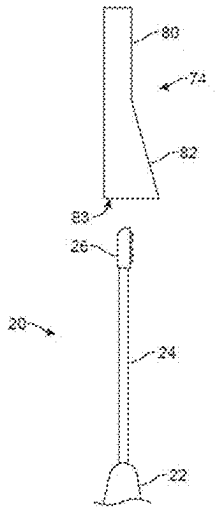


FIG. 23A

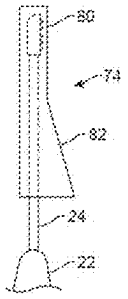


FIG. 23B

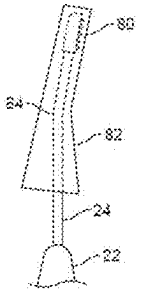


FIG. 23C

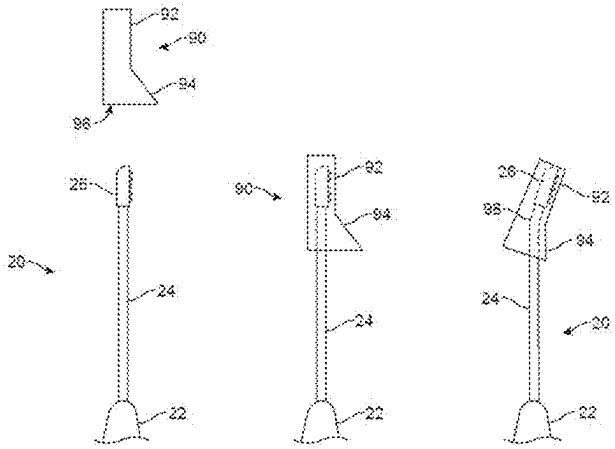


FIG. 24A FIG. 24B FIG. 24C

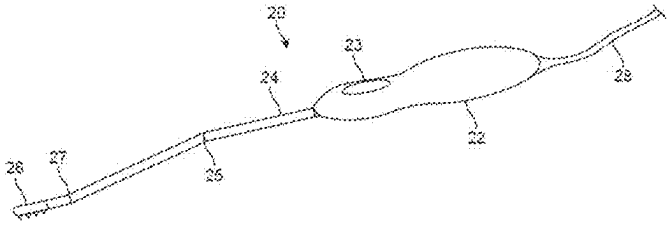


FIG. 25

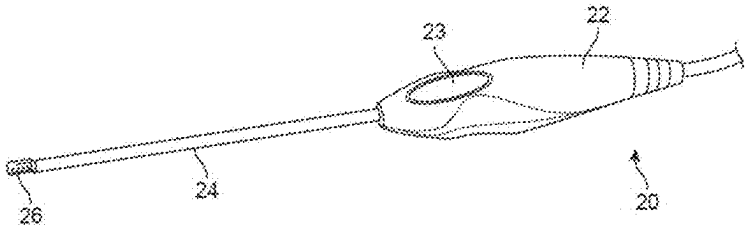


FIG. 26

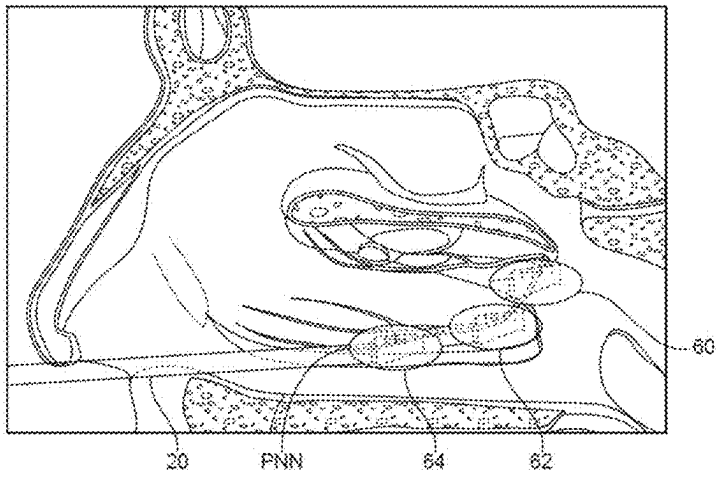


FIG. 27

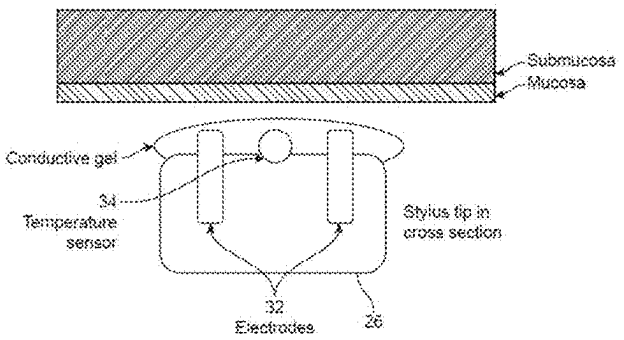

Submucosa
Mucosa
Conductive gel
34
Temperature sensor
Stylus tip in cross section
32
Electrodes
26

FIG. 28A

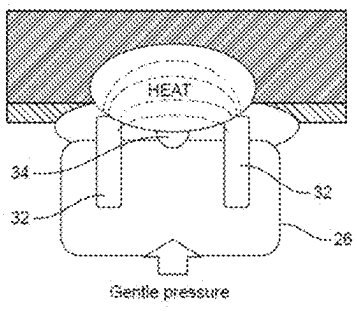


FIG. 28B

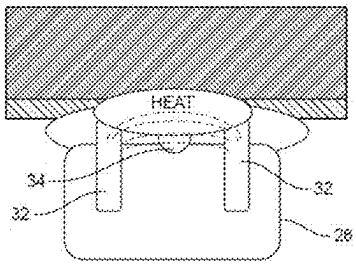


FIG. 29

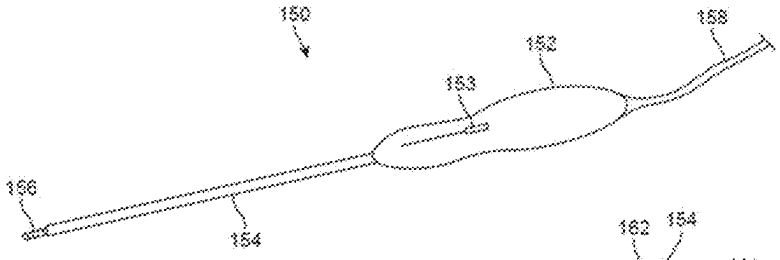


FIG. 30A

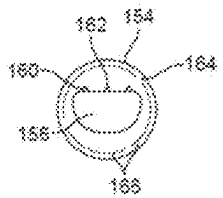


FIG. 30B

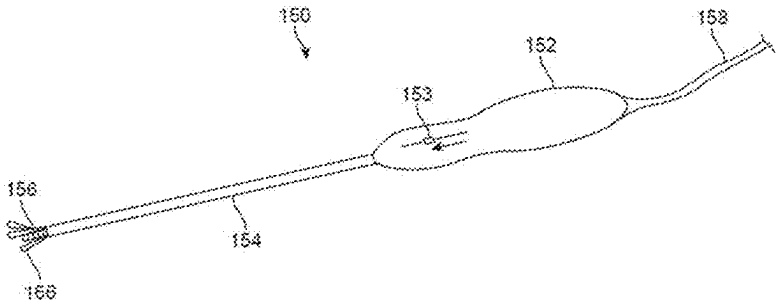


FIG. 30C

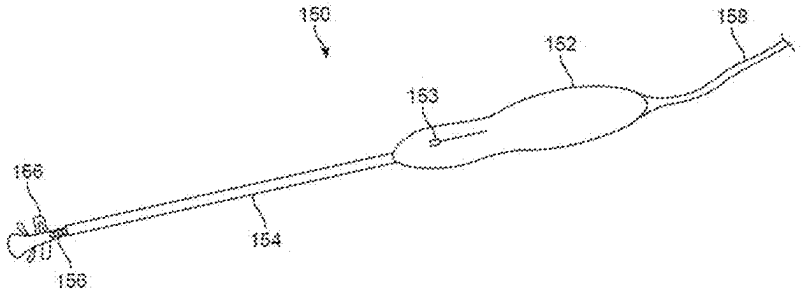


FIG. 30D

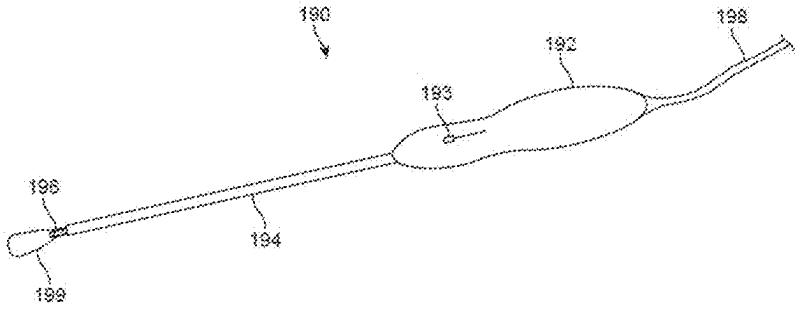


FIG. 31

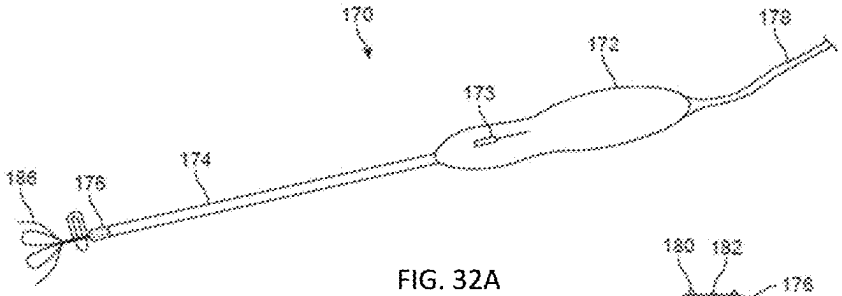


FIG. 32A

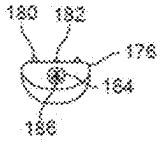


FIG. 32B

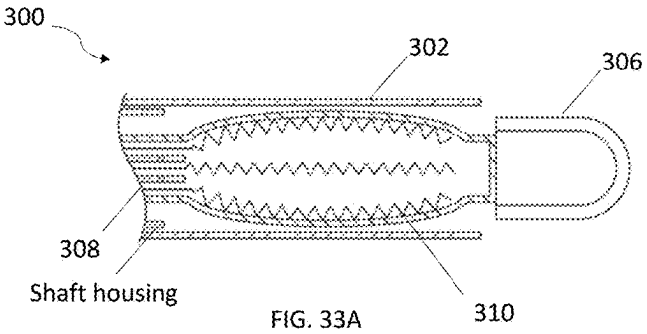


FIG. 33A

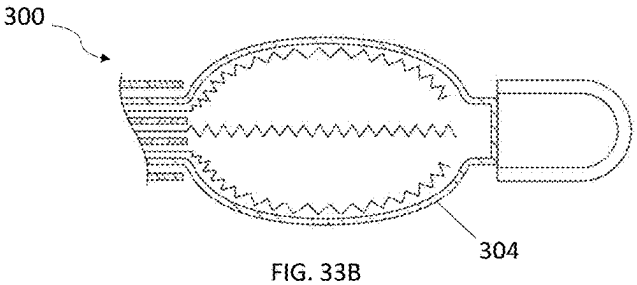


FIG. 33B

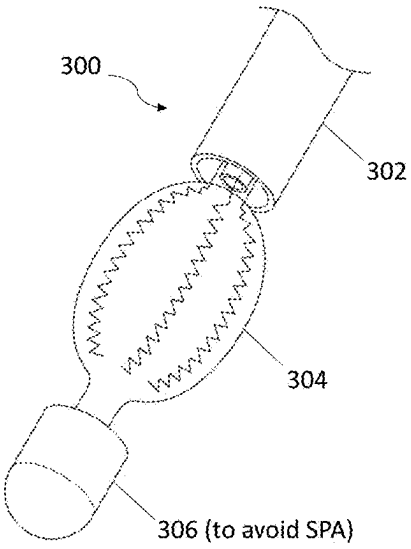


FIG. 33C

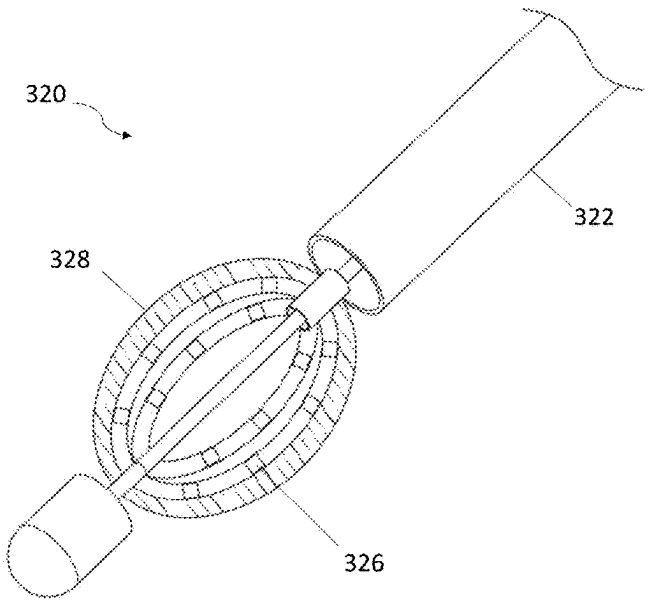


FIG. 34

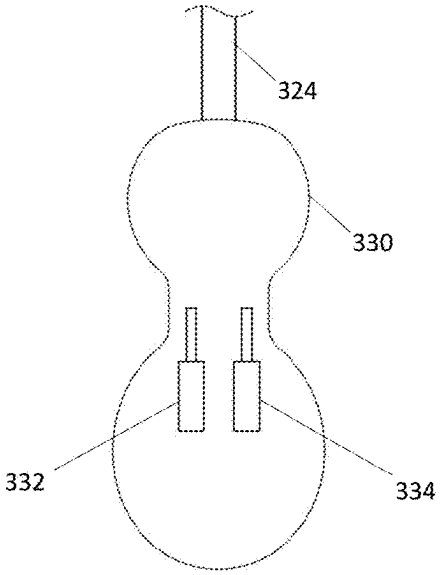
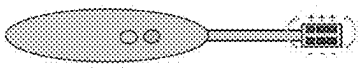
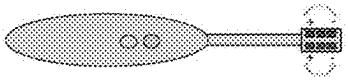


FIG. 35

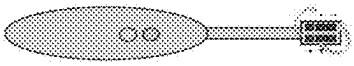
Multi-Channel Electrodes

FIG. 36A 

Electrode Polarity and Electric Field Orientation Ex. 1
Middle pair can be used for impedance sensing

FIG. 36B 

Electrode Polarity and Electric Field Orientation Ex. 2
Middle pair can be used for impedance sensing

FIG. 36C 

Electrode Polarity and Electric Field Orientation Ex. 3

Waveform: Biphasic vs. Monophasic

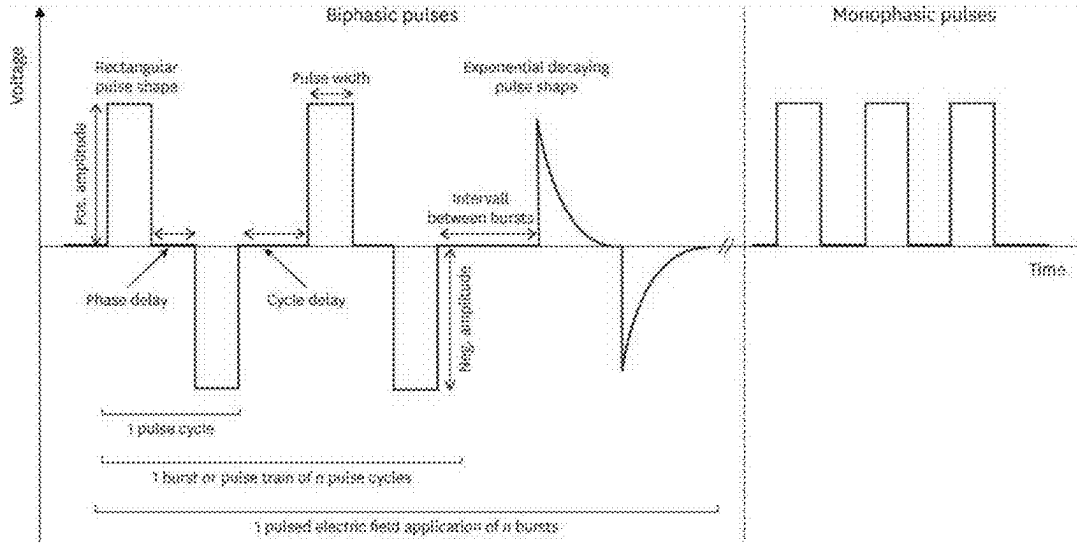


FIG. 37A

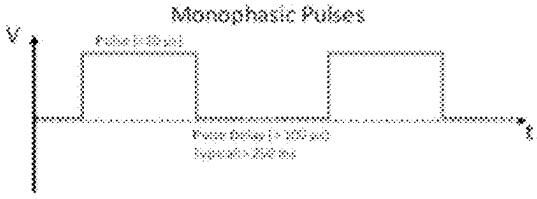


FIG. 37B

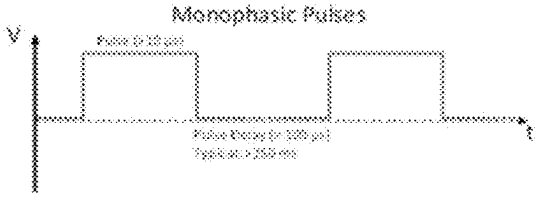


FIG. 37C

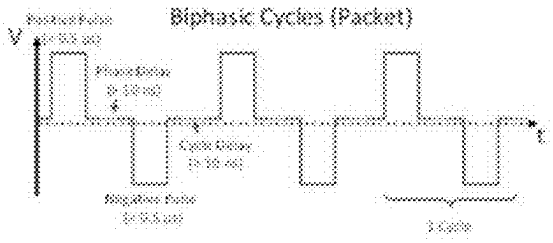


FIG. 37D

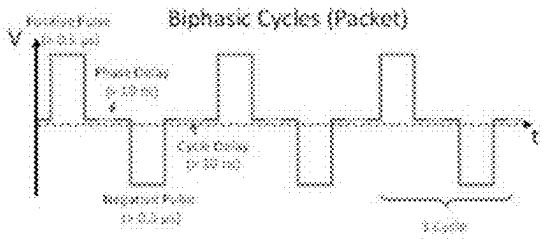


FIG. 37E

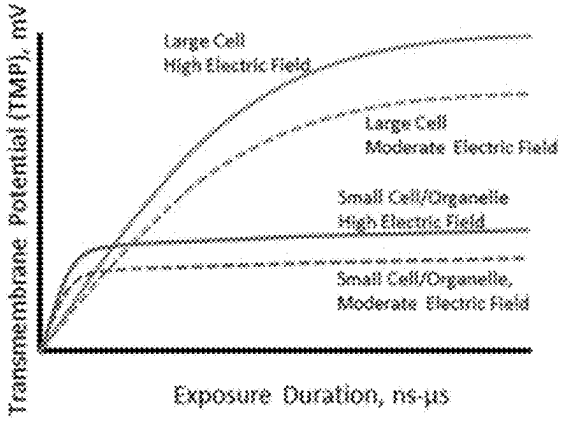


FIG. 37F

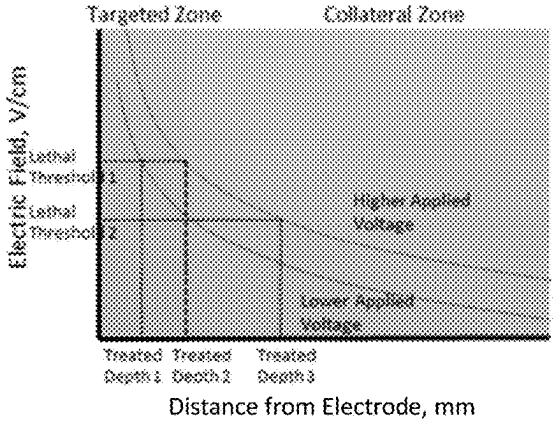


FIG. 37G

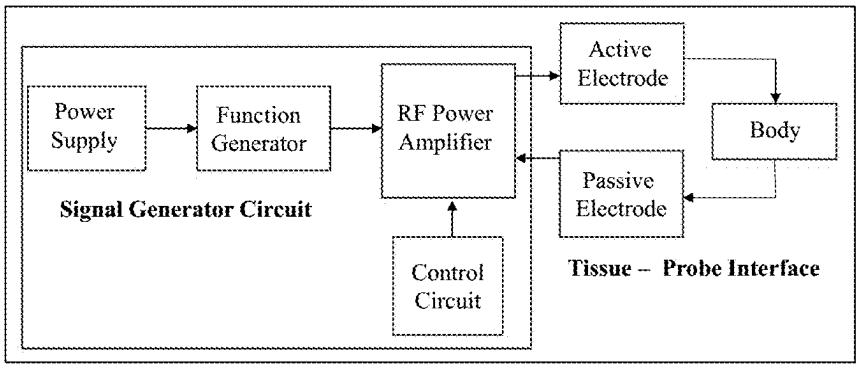
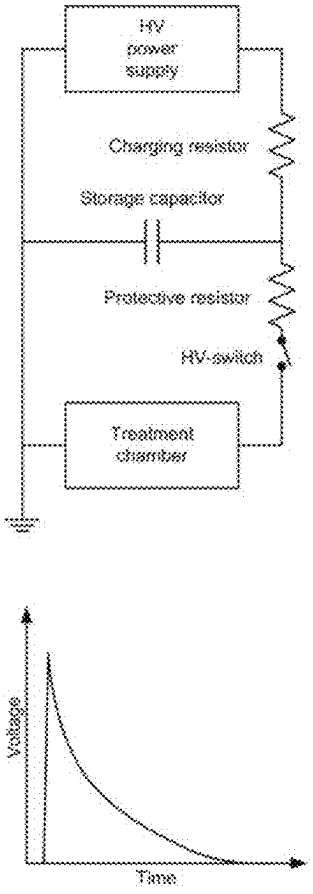

Power Supply
Function Generator
RF Power Amplifier
Active Electrode
Body
Passive Electrode
Signal Generator Circuit
Control Circuit
Tissue – Probe Interface

FIG. 38

FIG. 39A



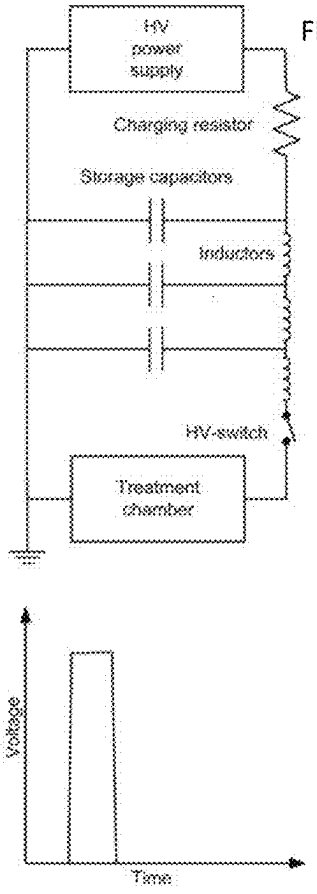


FIG. 39B

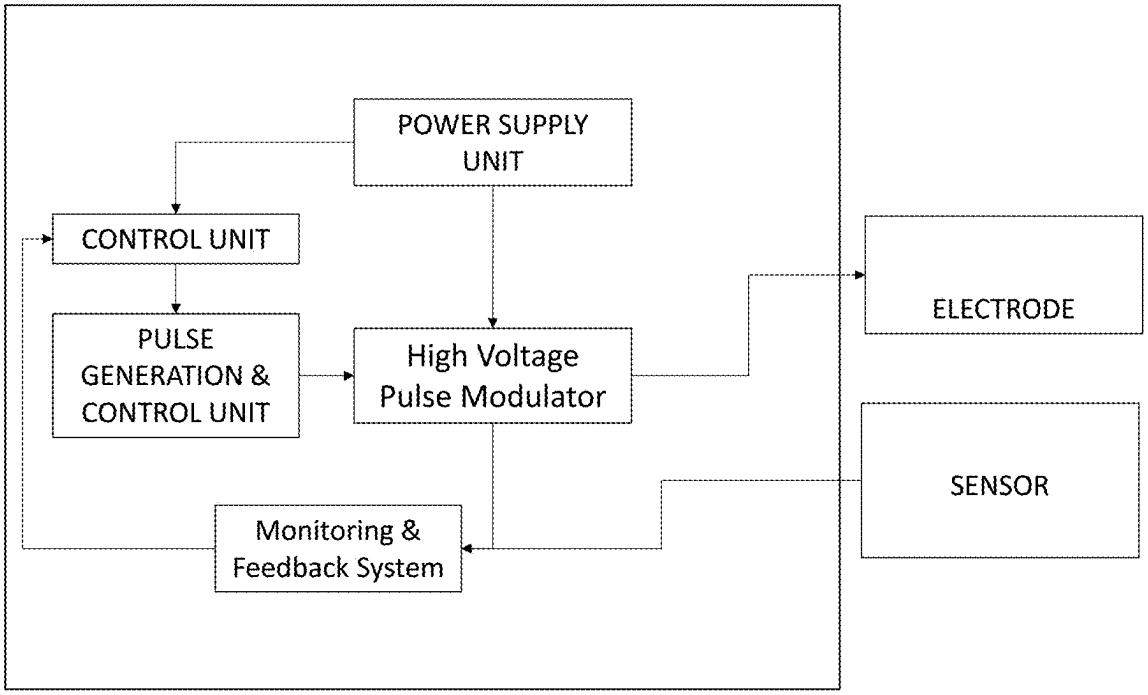

POWER SUPPLY UNIT
CONTROL UNIT
PULSE GENERATION & CONTROL UNIT
High Voltage Pulse Modulator
ELECTRODE
SENSOR
Monitoring & Feedback System

FIG. 40

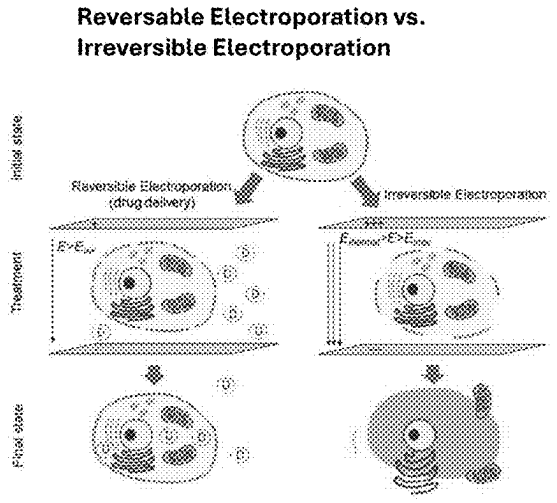


FIG. 41A

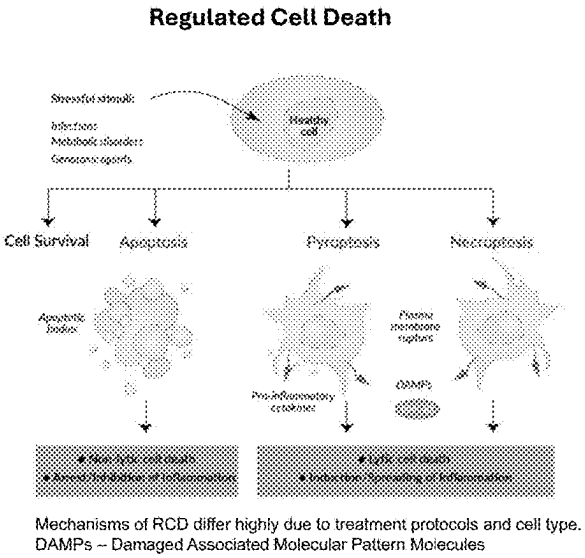


FIG. 41B

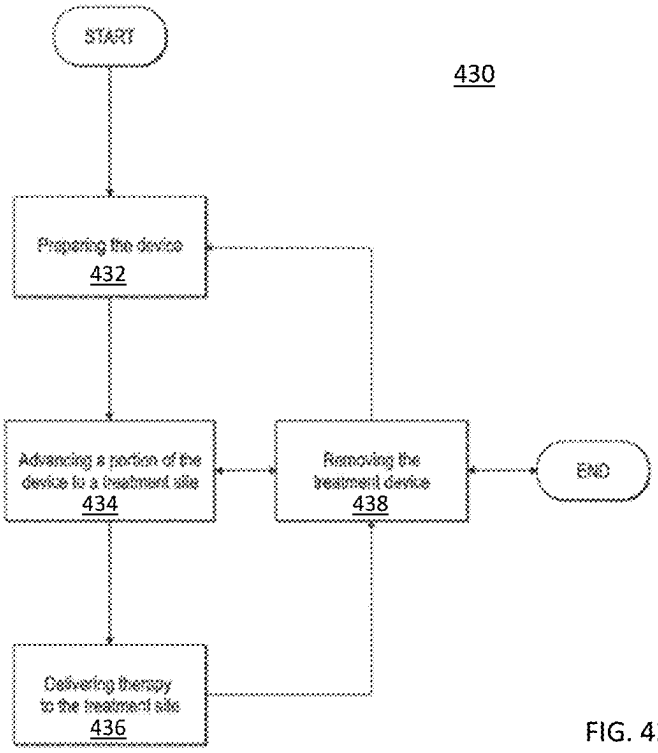

START
430
Preparing the device
432
Advancing a portion of the device to a treatment site
434
Removing the treatment device
438
END
Delivering therapy to the treatment site
436

FIG. 42

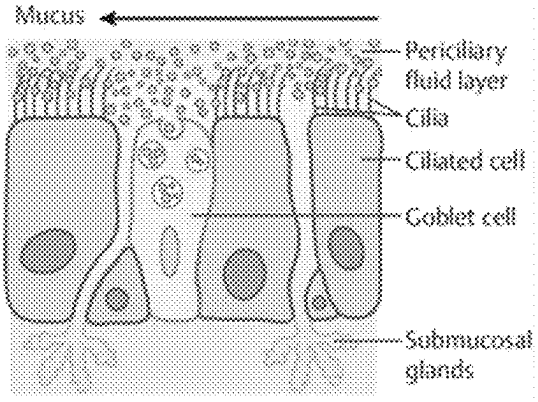


FIG.43A

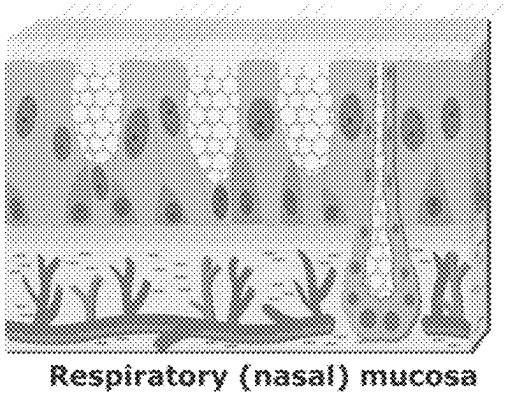


FIG. 43B

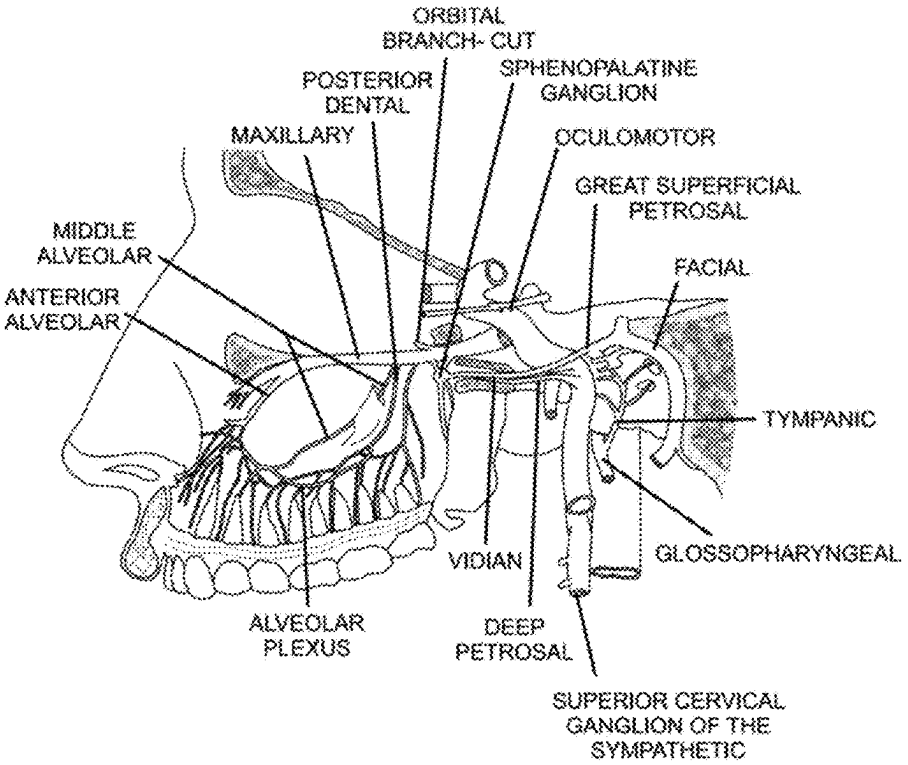

ORBITAL
BRANCH- CUT
SPHENOPALATINE
GANGLION
POSTERIOR
DENTAL
MAXILLARY
OCULOMOTOR
GREAT SUPERFICIAL
PETROSAL
MIDDLE
ALVEOLAR
FACIAL
ANTERIOR
ALVEOLAR
TYMPANIC
VIDIAN
GLOSSOPHARYNGEAL
ALVEOLAR
PLEXUS
DEEP
PETROSAL
SUPERIOR CERVICAL
GANGLION OF THE
SYMPATHETIC

FIG. 44A

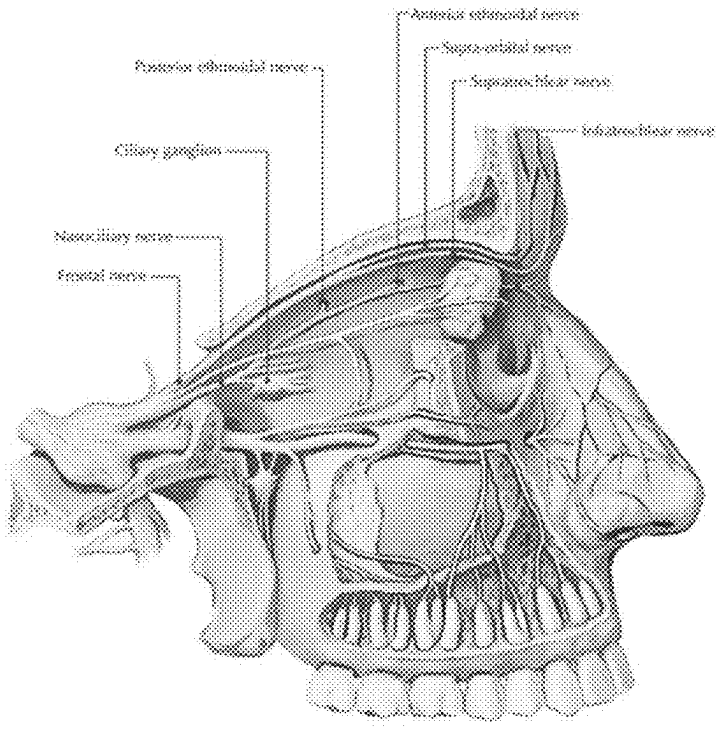

Anterior ethmoidal nerve
Supra-orbital nerve
Supratrochlear nerve
Infratrochlear nerve
Posterior ethmoidal nerve
Ciliary ganglion
Nasociliary nerve
Frontal nerve

FIG. 44B

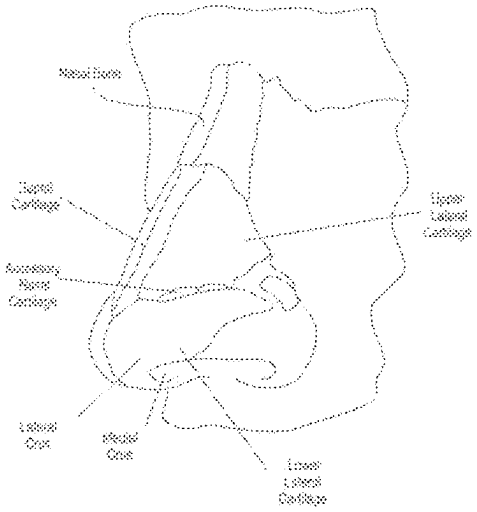


FIG. 45A

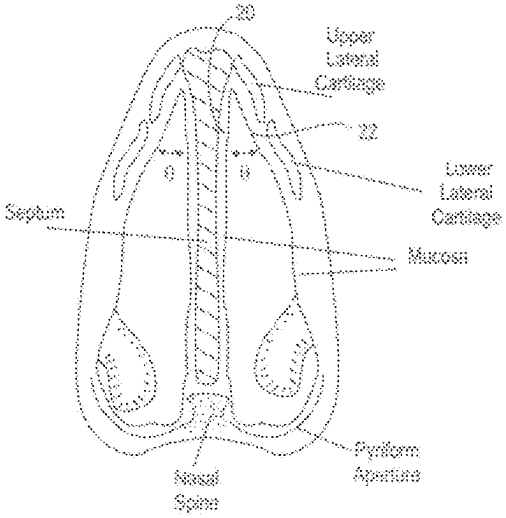


FIG. 45B

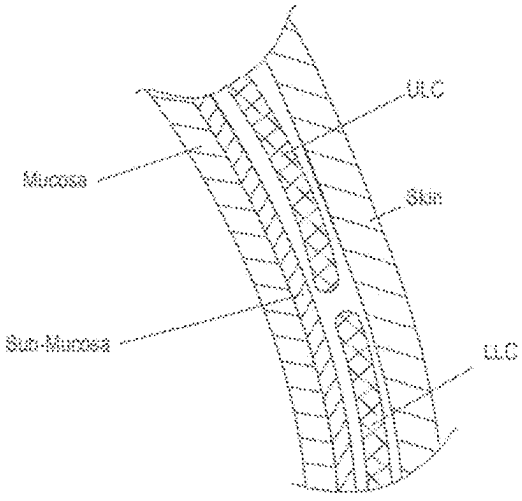


FIG. 45C

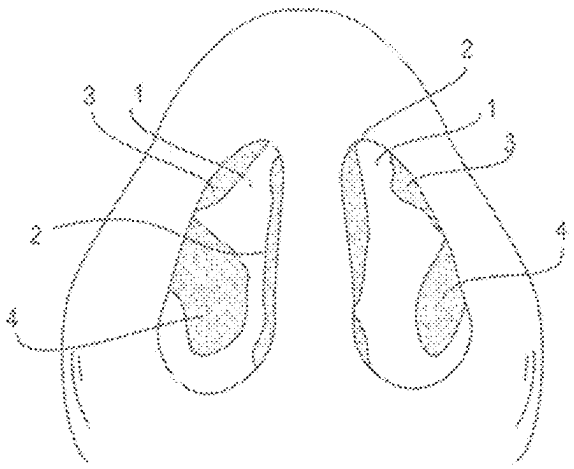


FIG. 45D

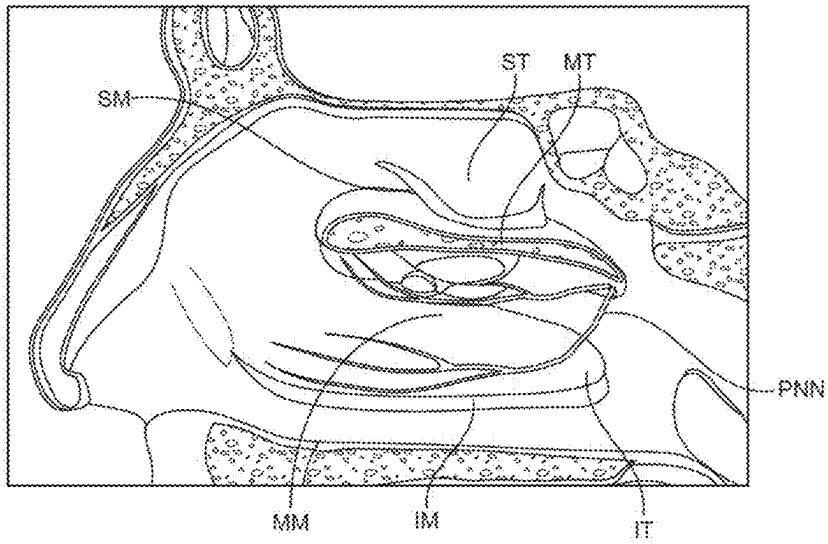


FIG. 45E

NASAL AIRWAY TISSUE TREATMENT SYSTEM AND METHOD

RELATED APPLICATIONS

[0001] This application claims the benefit of and priority to U.S. Provisional Application No. 63/555,150 filed Feb. 19, 2024, the contents of which is hereby incorporated herein by reference in its entirety.

FIELD

[0002] The present application is related to medical devices and methods, and more specifically, relates to a system and method for treating nasal airway tissue using pulsed field energy.

BACKGROUND

[0003] Rhinitis, or inflammation and swelling of the mucous membrane of the nose, causes symptoms such as runny nose, itchy nose, and congestion. Chronic and allergic rhinitis affect tens of millions of patients every year in the United States alone-one of the most common reasons for patients to visit physicians. Typically, rhinitis is treated with medications, such as nasal sprays and allergy shots. Unfortunately, these medications are temporary and are associated with multiple side effects. Surgical options are limited and invasive, typically involving removal of tissue in the nasal cavity.

[0004] The human nasal cavity is an area that extends from inside the two nostrils at the front of the nose to the junction of the nasal cavity with the back of the throat. The nasal septum is a wall of cartilage and bone that separates an anterior portion of the nasal cavity into the two nostrils. The lateral walls and septum of the nasal cavity are formed mainly of cartilage and bone, covered with a mucous membrane (or "nasal mucosa"). Other tissues also reside below the nasal mucosa, such as small blood vessels and nerves. Tissue underlying the nasal mucosa is sometimes referred to generally as submucosal tissue. One of the functions of mucosal tissue is to produce mucus, which helps protect, moisten and clear debris from the nasal cavities. Nerves underlying the nasal mucosa are generally responsible for sensory function—feeling and smelling—and for activating the mucus-producing cells in the nasal mucosa to produce mucus.

[0005] Various treatments for rhinitis have been used but have many drawbacks and side effects. For example, turbinate reduction surgery is one surgical treatment for chronic or allergic rhinitis but is relatively invasive with only temporary effects and can result in complications, such as mucosal sloughing, acute pain and swelling, and bone damage. Transection of the vidian nerve was also used, but can result in side effects including dry eye, because autonomic fibers in the vidian nerve innervate the lacrimal glands.

[0006] Another surgical treatment method for chronic or allergic rhinitis, posterior nasal neurectomy, was initially developed in the late 1990s. Posterior nasal neurectomy involves cutting or cauterizing nerve tissue located in or near the sphenopalatine foramen, an opening in each of the two the lateral walls of the nasal cavity, where the sphenopalatine ganglion is located and out of which multiple nerves branch. This procedure was difficult due to the location posterior location of the nasal cavity and destroying nerves in that area may result in unwanted side effects.

[0007] Therefore, it would be desirable to have improved devices, systems and methods for treating chronic and allergic rhinitis. Ideally, such devices, systems and methods would have longer term effects than medications and be less invasive than currently available surgical techniques.

BRIEF SUMMARY

[0008] In some embodiments, a system is provided for treating tissue in a nasal airway. The system includes a console including a pulsed electric field generator configured to generate pulsed electric field energy in the form of high frequency alternating pulses of energy delivered as a pulse train. The pulsed electric field generator includes a plurality of output channels. The system also includes a treatment device including an elongate shaft having a treatment surface on a distal end thereof, the treatment surface including a plurality of electrode pairs configured to deliver the pulsed electric field energy provided by the pulsed electric field generator to a target tissue in the nasal airway. Each of the plurality of output channels is connected with a subset of the plurality of electrode pairs to provide pulsed electric field energy to the plurality of electrode pairs.

[0009] In some embodiments, the pulsed electric field generator is configured to deliver pulsed field ablation energy to the plurality of electrode pairs. In some embodiments, the pulsed electric field generator is configured to deliver pulsed radiofrequency energy to the plurality of electrode pairs. In some embodiments, the pulse train is configured to be delivered in repeated intervals to create a string of pulse trains with an interval of time between pulse trains to allow for tissue recovery between each pulse train. In some embodiments, the pulsed electric field generator is configured to provide at least one of exponentially decaying, square wave, bipolar, or oscillatory pulses.

[0010] In some embodiments, the plurality of output channels is configured to connect with the plurality of electrode pairs to provide independent pulsed electric energy from each of the plurality of output channels to each of subsets of the plurality of electrode pairs.

[0011] In some embodiments, the system can further include at least one sensor configured to measure a temperature of the target tissue. In some embodiments, the shaft of the treatment device is malleable and has a width of 4 millimeters to 5 millimeters. In some embodiments, the plurality of electrode pairs includes at least two rows of electrodes pairs.

[0012] In some embodiments, a system is provided for treating nasal airway tissue. The system includes a pulsed electric field generator configured to generate pulsed electric field energy in the form of alternating pulses of energy delivered as a pulse train. The pulsed electric field generator includes a plurality of output channels. The system also includes a treatment device including an elongate shaft having a treatment surface on a distal end thereof. The treatment surface includes a first row of electrodes including a first plurality of electrode pairs and a second row of electrodes including a second plurality of electrode pairs configured to deliver pulsed electric field energy provided by the pulsed electric field generator to a target tissue in the nasal airway. Each of the plurality of output channels is

connected with a subset of the first and second plurality of electrode pairs to provide pulsed electric field energy to the plurality of electrode pairs.

[0013] In some embodiments, a method is provided for treating a nasal airway that includes activating a pulsed electric field generator console attached to a treatment device to generate pulsed electric field energy in the form of high frequency alternating pulses of energy delivered as a pulse train, advancing a distal tip of the treatment device into the nasal airway of a patient, contacting a nasal mucosa lining the nasal airway with a treatment surface at a distal end of the treatment device, delivering the pulsed electric field energy from at least a first electrode on the treatment surface to at least a second electrode on the treatment surface to treat a tissue underlying the nasal mucosa lining, and removing the distal tip of the treatment device from the nasal airway.

[0014] In some embodiments, the method further includes moving the distal tip to multiple additional locations within the nasal airway; and delivering the pulsed electric field energy to nasal airway tissue at the multiple additional locations. In some embodiments, the tissue includes at least one nasal nerve selected from the group consisting of a posterior nasal nerve and an anterior ethmoid nerve.

[0015] In some embodiments, the method, further includes sensing a temperature of the nasal mucosa lining with a temperature sensing member on the treatment surface of the distal tip. In some embodiments, the method further includes automatically shutting off delivery of the pulsed electric field energy from the pulsed electric field generator if the temperature is above a predefined acceptable maximum temperature.

[0016] In some embodiments, the method further includes sensing an impedance in the tissue between the first electrode and the second electrode with an impedance sensing member; and automatically shutting off delivery of the pulsed electric field energy from the pulsed electric field generator console to the treatment device if the impedance is outside a predefined acceptable impedance range.

[0017] In some embodiments, the at least the first electrode includes a first row of electrodes, and wherein the at least the second electrode includes a second row of electrodes.

[0018] In some embodiments, the method further includes injecting an anesthetic fluid into the nasal mucosa lining before advancing the distal tip of the treatment device into the nasal airway, to enhance conduction of the pulsed electric field energy through the tissue.

[0019] In some embodiments, delivering the pulsed electric field energy ablates the tissue underlying the nasal mucosa lining. In some embodiments, the tissue includes nerve tissue, and the method further includes delivering the pulsed electric field energy to an additional tissue selected from the group consisting of an inferior turbinate, a middle turbinate, a superior turbinate, a nasal septum, and a septal swell body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] The presently disclosed embodiments will be further explained with reference to the attached drawings, wherein like structures are referred to by like numerals throughout the several views. The drawings shown are not necessarily to scale, with emphasis instead generally being placed upon illustrating the principles of the presently disclosed embodiments.

[0021] FIG. **1** illustrates an exemplary embodiment of a system for treating nasal airway tissue;

[0022] FIGS. **2**A and **2**B illustrate exemplary embodiments of a system for treating tissue having a plurality of output channel for delivering energy to tissue;

[0023] FIG. **3** is a front perspective view of an electrosurgical system for treating nasal airway tissue, according to one embodiment;

[0024] FIG. **4** is a perspective view of the console of FIG. **3**, shown connected to an on/off foot pedal and a power cord, according to one embodiment;

[0025] FIG. **5** is a perspective view of an electrosurgical system, according to an alternative embodiment;

[0026] FIG. **6** is a rear perspective view of the console of the electrosurgical system of FIG. **5**;

[0027] FIGS. **7**A, **7**B, and **7**C are top, front and side views, respectively, of the console shown in FIGS. **5** and **6**;

[0028] FIG. **8** is a screen shot of a standby screen display that may be displayed on an electrosurgical console, according to one embodiment;

[0029] FIG. **9** is a screen shot of a default main screen display on an electrosurgical console, as it appears before the electrosurgery treatment has started, according to one embodiment;

[0030] FIG. **10** is a screen shot of a default main screen display on an electrosurgical console, as it appears during an RF delivery stage of an electrosurgery treatment, according to one embodiment;

[0031] FIG. **11** is a screen shot of a default main screen display on an electrosurgical console, as it appears during a cooling stage of an electrosurgery treatment, according to one embodiment;

[0032] FIG. **12** is a screen shot of a custom treatment settings screen display on an electrosurgical console, as it appears during a cooling stage of an electrosurgery treatment, according to one embodiment;

[0033] FIG. **13** is a screen shot of a fault screen display on an electrosurgical console, according to one embodiment;

[0034] FIG. **14** is a screen shot of an error screen display on an electrosurgical console, according to one embodiment;

[0035] FIG. **15** is a screen shot of a settings screen display on an electrosurgical console, according to one embodiment;

[0036] FIG. **16** is a flow diagram of a method of performing an electrosurgical treatment, using a console as described in the present application, according to one embodiment;

[0037] FIG. **17** is a close-up perspective view of the stylus, cable and connector of the system of FIG. **3**;

[0038] FIGS. **18**A and **18**B are exemplary embodiments of side and top perspective views, respectively, of a distal tip (or "treatment element") of a treatment device or stylus;

[0039] FIGS. **19**A and **19**B are side and front views, respectively, of a distal end of a nasal airway tissue treatment stylus, according to an alternative embodiment;

[0040] FIG. **20** is a front view of a distal end of a nasal airway tissue treatment stylus, according to an alternative embodiment;

[0041] FIG. **21** is a flow chart illustrating an exemplary method for treating nasal airway tissue using the systems described herein;

[0042] FIG. **22** is a top view of the stylus of FIGS. **3** and **17-18**B, illustrating a method for bending the shaft of the stylus, according to one embodiment;

[0043] FIGS. **23**A, **23**B, and **23**C illustrate a method of using a shaft bending tool to bend a stylus, according to one embodiment;

[0044] FIGS. **24**A, **24**B, and **24**C illustrate a method of using a different shaft bending tool to bend a stylus, according to an alternative embodiment;

[0045] FIG. **25** is a perspective view of a nasal airway tissue treatment stylus with two bends in the shaft and bend markers on the shaft, according to one embodiment;

[0046] FIG. **26** is a perspective view of the stylus of FIGS. **3**, **17-18**B, and **22**, illustrating an indicator on the handle showing the direction of treatment, according to one embodiment;

[0047] FIG. **27** is a sagittal view of a human nasal cavity, illustrating a method for treating the posterior nasal nerve with the stylus described herein, according to one embodiment;

[0048] FIGS. **28**A and **28**B illustrate a method for addressing, contacting and treating nasal tissue, according to one embodiment;

[0049] FIG. **29** illustrates an improper treatment contact with nasal mucosa;

[0050] FIGS. **30**A and **30**B are perspective and front views, respectively, of an alternative embodiment of a nasal airway tissue treatment stylus that includes an expandable wire electrode component;

[0051] FIGS. **30**C and **30**D are perspective views of the stylus of FIGS. **30**A and **30**B, illustrating operation of the expandable wire electrode component;

[0052] FIG. **31** is perspective view of another alternative embodiment of a nasal airway tissue treatment stylus that includes an expandable cryotherapy balloon;

[0053] FIGS. **32**A and **32**B are perspective and front views, respectively, of another alternative embodiment of a nasal airway tissue treatment stylus that includes an expandable wire electrode component that advances out of the distal tip of the device;

[0054] FIGS. **33**A, **33**B, and **33**C illustrate exemplary embodiments of a treatment device having an expandable wire electrode component;

[0055] FIGS. **34** and **35** illustrate exemplary embodiments of a treatment device having a multi-electrode treatment element in the form of a basket;

[0056] FIGS. **36**A, **36**B, and **36**C illustrate exemplary embodiments of multi-channel electrodes;

[0057] FIGS. **37**A, **37**B, **37**C, **37**D, **37**E, **37**F, and **37**G illustrate exemplary graphs showing biphasic and monophasic pulses;

[0058] FIGS. **38**, **39**A, **39**B, and **40** illustrate various embodiments of circuits for producing the pulsed energy;

[0059] FIGS. **41**A and **41**B illustrate the mechanism of electroporation and cell death that can be achieved using PFA;

[0060] FIG. **42** illustrates an exemplary flow diagram of an example method of use of the various devices disclosed herein;

[0061] FIGS. **43**A and **43**B show an exemplary cross-sectional view of the mucosa;

[0062] FIGS. **44**A and **44**B show sagittal views of a human nasal cavity;

[0063] FIGS. **45**A, **45**B, **45**C, and **45**D illustrate anatomical elements of a human nose; and

[0064] FIG. **45**E is a sagittal view of a human nasal cavity, illustrating the lateral wall and nasal nerves.

[0065] While the above-identified drawings set forth presently disclosed embodiments, other embodiments are also contemplated, as noted in the discussion. This disclosure presents illustrative embodiments by way of representation and not limitation. Numerous other modifications and embodiments can be devised by those skilled in the art which fall within the scope and spirit of the principles of the presently disclosed embodiments.

DETAILED DESCRIPTION

[0066] The following disclosure provides embodiments of systems and methods for treating nasal conditions, treating migraines, and/or 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. For example, the devices described herein can be used for nerve destruction for posterior nasal nerve treatment for treatment of chronic rhinitis, treatment of migraines through nasal nerve treatments, or other diseases that can be treated with nerve ablation that are in the ears, nose, or throat.

[0067] This application describes various aspects and embodiments of a device, system, and method for treating nasal airway tissue. More particularly, the system includes: (1) a console with an electrosurgical generator and a display; and (2) a treatment device, or stylus, coupled to the console via a cable. In some embodiments, the electrosurgical generator is configured to provide pulsed electric field (PEF) energy for conducing pulsed radiofrequency energy (PRF) or pulsed field ablation (or "PEF ablation") of one or more tissues. In some embodiments, the electrosurgical generator is configured to provide radiofrequency (RF) energy and can be delivered continuously or through short duration pulses to minimize the thermal effect on adjacent tissue. In some embodiments, the electrosurgical generator is configured to provide high-voltage direct current pulses of short duration to induce regulated cell death (e.g. apoptosis) through irreversible electroporation, this treatment modality has minimal thermal effect and can target specific tissues while minimizing collateral damage. In alternative embodiments, the system may be configured to deliver another type of energy, such as but not limited to heat, laser, microwave, cryogenic cooling, DC current or ultrasound.

[0068] The energy delivery system may be designed and used to perform a number of different types of nasal airway tissue treatments. For example, and as further described in the Incorporated References, in some embodiments, the system may be used to reshape, reconfigure and/or change another property of tissue (such as but not limited to cartilage) in or near a nasal valve area within the nose to enhance nasal breathing. In another embodiment, the system may be used to treat soft tissue in an anterior and/or posterior portion of the nasal airway to treat chronic rhinitis, allergic rhinitis, post nasal drip and/or chronic cough. Tissues treated in such a procedure may include nasal nerves (posterior nasal nerve, vidian nerve branches, sphenopalatine ganglion, anterior ethmoid nerve, etc.), submucosal tissue, mucosal

tissue, goblet cells and/or the like. Although the description focuses primarily on treating nerves in the nasal cavity to treat chronic rhinitis, allergic rhinitis, post nasal drip and/or chronic cough, the methods, systems and devices described herein may alternatively be used to perform any suitable procedure in a nasal airway, including but not limited to all procedures described in the Incorporated References.

[0069] The systems disclosed herein can utilize various types of energy, including pulse radiofrequency energy and pulse field ablation energy, to affect the nasal tissue. Pulsed radiofrequency energy technology can be used to deliver electrical energy to modulate or destroy nerves, specifically the posterior nasal nerve. Due to the non-thermal nature of the technology, adjacent tissue damage is minimized (and heals effectively). In some embodiments, the system delivers at least one pulse train at the treatment site to cause irreversible electroporation of the nerve tissue, which induces regulated cell death. The treatments can be delivered using any of the devices described here for precise targeting of the nasal nerves which are located submucosally and run along the middle meatus, middle turbinate, inferior turbinate, and inferior meatus (in addition to nerves located inside the nasal cavity). Pulsed field ablation (PFA) technology can be used to deliver energy to cause cell death, for example, through the use of high voltage pulsing that induce regulated cell death, or apoptosis, through irreversible electroporation of targeted cells.

[0070] FIG. **1** illustrates an exemplary embodiment of a nasal airway treatment system **400** that includes a console **402** for controlling energy delivery to a plurality of pairs of electrodes on a treatment device **404** or stylus and displaying information to the user. The console includes a controller **406** and an energy generator **408**. In some embodiments, the energy generator is a pulsed field generator for producing pulsed energy, such as PFA or PRF.

[0071] In some embodiments, the console includes one or more ports, or output channels, for connecting to the treatment device or stylus, for treating one or more target tissues in the nasal cavity with energy. In some embodiments, each pair of electrodes on the treatment device can be connected to a separate, controlled electrical output channel to allow for different electrode pairs of the treatment element to be activated separately and independently of one another, as shown in FIGS. **2**A and **2**B. For example, FIG. **2**A illustrates a generator **410** that comprises output channel **1** through output channel n for delivering energy to electrodes. For example, FIG. **2**B illustrates a console that includes a plurality of output channels **420** for delivering energy. By controlling the treatment energy flowing through each pair of electrodes using parameters including, but not limited to, temperature, a greater degree of control and accuracy over the treatment energy may be obtained, such that treatments may be repeatable to each electrode pairs or subsets of electrode pairs. In some embodiments, each of the plurality of output channels can be assigned to an individual electrode pair. In some embodiments, each of the plurality of output channels can be assigned to a subset of the plurality of electrode pairs.

[0072] More specifically, 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 output channel to allow for different regions of the treatment element to be activated separately.

[0073] The output channels may also comprise separate or integrated feedback. This may 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.

[0074] Referring to FIG. **3**, in some embodiments, an exemplary embodiment of a nasal airway tissue treatment system **10** includes two primary components: a console **12** and a treatment device or stylus **20**. Similar to the console shown above, the console **12** includes a display **14**, an electrosurgical generator, and electronics (inside the console **12** and thus not visible), and an outlet **16** into which the stylus **20** is plugged. The stylus **20** includes a handle **22**, a shaft **24**, a distal tip **26** (also referred to as a "treatment element"), a cable **28** and a connector **29** for connecting the stylus **20** with the outlet **16**. Many features of the console **12** and the system **10** in general are described further below, in U.S. patent application Ser. No. 16/668,678, and in the other Incorporated References. In some embodiments, the electrosurgical generator is configured to provide pulsed electric field (PEF) energy for conducing pulsed field ablation (or "PEF ablation") of one or more tissues, including but not limited to any suitable nerve tissue.

[0075] The console **12** is a reusable device, which is designed and intended for use with multiple patients. The stylus **20**, on the other hand, is a single-patient, single-use, disposable device. In some embodiments, the stylus **20** may be provided as part of a stylus kit **70**, which may include a curved anesthesia needle **72**, a packet of conductive gel **73**, a shaft bending tool **74** and/or instructions for use **76** (or "IFU"). Anesthesia protocols for anesthetizing the patient's nasal cavity are largely up to the physician, and many different protocols are known to otolaryngologists. In some embodiments, it may be required or strongly recommended to inject anesthetic into the mucosa and/or submucosa in the target area(s), in order to help direct the current delivered by the stylus **20**. This may be helpful in some embodiments, because fluid such as anesthetic is generally conductive for RF. All of these kit components are optional, and any embodiment of the stylus kit **70** may include fewer items or additional items, without departing from the scope of the invention. In some embodiments, the stylus **20** may be provided by itself for use with the console **12**. The stylus **20** may be used for multiple treatments on the same patient at the same time—for example multiple treatment areas in a nostril and/or treatment of both nostrils—and then is disposed of after use on that patient. In an alternative embodiment, the stylus **20** may be sterilizable and reusable.

[0076] In some embodiments, the nasal airway tissue treatment system **10** may be provided with one or more additional components or accessories. For example, and as shown in FIG. **4**, the system **10** typically includes a power cord **38** and a foot switch **39**, both of which attach to the console **12**. FIG. **4** illustrates the console **12** of the nasal airway tissue treatment system **10**, along with a power cord **38** and a foot switch **39**, both of which plug into the back of the console **10**. The foot switch **39** is used by the physician to activate the stylus **20** during a procedure. In alternative

embodiments, the handle **22** of the stylus **20** may include an on/off button or switch, in addition to or as an alternative to the foot switch **39**.

[0077] As another example, the stylus **20** illustrated in FIG. **3** has a relatively long shaft **24**, configured for use in the posterior portion of the nasal cavity to treat nerves to treat rhinitis. In one embodiment, one or more additional styluses may be provided with the system **10**, for performing other procedures. For example, a second stylus with a shorter shaft for addressing tissue in the nasal valve, closer to the front of the nose, may be provided. The curved anesthesia needle **72** for injecting anesthetic into the nasal mucosa is another optional component. The curved needle **72** is designed to be stiffer than a spinal needle and is curved to allow a physician to easily access and inject anesthesia into an area near the back of the nasal cavity. The curved needle **72** can also be reinforced to prevent bending or bowing during injection. The system **10** may also be provided with one or more conductive gel packets **73**, for application to the distal tip **26** of the stylus, to enhance contact of the distal tip **26** with nasal mucosa. The bending tool **74** will be described further below and may be used by the physician to bend the shaft **24** of the stylus **20** in one or more locations. Any other suitable accessories or components may be added to the treatment system **10**, according to alternative embodiments.

[0078] According to various embodiments, the console **12** of the treatment system **10** may include default settings and custom settings. Default settings may include, for example, a power output of 4 Watts, a treatment temperature of 60 degrees Celsius, and a treatment time of 12 seconds. Custom settings may allow a physician to customize settings. For example, such settings could provide for power of 3-5 Watts with an increment interval of 1 Watt, a treatment temperature of 50-70 degrees Celsius with an increment interval of 5 degrees Celsius, and a treatment time of 10-12 seconds with an increment interval of 2 seconds. These are merely examples, however, and should not be interpreted as limiting.

[0079] Referring to FIG. **5**, another example of an electrosurgical system **100** is illustrated. In this embodiment, the stylus **104** has a shorter shaft, such as might be used in treating tissues in the nasal valve area. Thus, the treatment times and protocols, as well as the displays on the display screen **108** of the console **102**, are designed for nasal valve treatment. These features may be adjusted/altered for treatment of nasal nerve(s) to treat rhinitis. Similar to the system above, the electrosurgical system **100** can be modified to provide and deliver any suitable type of energy, including pulsed RF and PFA. In this example, the electrosurgical system **100** includes a console **102**, an energy delivery stylus **104**, and a cable **106** connecting the stylus **104** to the console **102**. The console **102** houses an energy generator, a processor and various electronics, none of which is visible in the figure. The word "console," in this disclosure, is meant to encompass the terms "generator," "box" and any other commonly used terms to describe an electrosurgical system console or generator. The parts of the console **102** that are visible include a touch screen display **108**, a stylus connection port **110**, an "Energy ON" indicator light **112**, and a bottom ring **114**. The touch screen display **108** serves as the main user interface for interacting with the console **102** and will be described further below. The stylus connection port **110** allows a connection end (or "connector") of the stylus **104** to be plugged into it. The stylus connection port **110** is configured to accept only the connection end of the stylus **104** and will not accept or work with counterfeit or other devices. In some embodiments, electronics inside the console **102** may include a stylus identification safety feature that identifies the stylus **104** when it is plugged into the stylus connection port **110**. Such a safety feature may, for example, automatically shut down (or disable powering on) the console **102**, if a user tries to plug in a device other than the stylus **104**.

[0080] The "Energy ON" indicator light **112** indicates when energy is being delivered through the stylus connection port **110** to the stylus **104**. The bottom ring **114**, in this embodiment, lights up when the console **102** is powered on. This lighted ring **114** is an optional feature. Both the "Energy ON" indicator light **112** and the lighted bottom ring **114** may have any color or colors of light. In one embodiment, for example, the "Energy ON" indicator light **112** is blue, and the bottom ring **114** lights up with a white light. This is merely one example, however, and any suitable lighting configuration and combination of colors may be used in alternative embodiments.

[0081] FIG. **6** shows the back of the console **102**. In some embodiments, the console **102** includes an air vent **116**, a product label area **118**, a speaker **120**, an equipotential ground connection port **122**, a main power connection port **124**, a main power switch **126** and foot switch connection port **128**. The equipotential ground connection port **122** is provided at the back of the device.

[0082] FIGS. **7**A, **7**B, and **7**C are top, front and side views, respectively, of the console **102** shown in FIGS. **5** and **6**.

[0083] Referring now to FIG. **8**, an exemplary screen shot of one example of a standby image **200** that may be shown on the display screen **108** of the console **102** is illustrated. The standby image **200** may be displayed after the console **102** is powered on. In some embodiments, the console **102** may perform a power-on self-test before showing the standby image **200**. The standby image includes a console image **202**, a settings button **204** and an animated insert stylus image **206**. The animated insert stylus image **206** shows the connector end of the stylus cable **106** moving toward the console stylus connection port **110**. Thus, the display **200** graphically informs the user that the console **102** is ready for use, awaiting insertion of the connection end of the stylus cable **106** into the connection port **110**.

[0084] Referring now to FIG. **9**, once the physician or other user has attached the stylus **104** to the console **102**, the standby image of FIG. **8** may be replaced by a default main screen image **500**. This main screen image **500** is what the user sees before the procedure has started. Under normal operating conditions, the user can select either default treatment settings or manual treatment settings. The default treatment settings are pre-loaded into the processor of the console **102** and do not require any additional settings inputs from the user. In some embodiments, it may be possible for the user to select from several sets of default settings. Operation under the default settings mode is described in relation to FIGS. **9**, **10**, and **11**, and operation under the custom settings mode is described in relation to FIG. **12**.

[0085] FIG. **10** shows the default image **500** displayed on the display screen **108** of the console **102**, once a valid stylus **104** is connected. In this embodiment, the default image includes a stylus temperature indicator **501**, a temperature icon **502**, a stylus icon **503**, treatment number indicator **504**,

a stylus type connected indicator **506**, a start/stop button **510**, an RF ON indicator light **509**, an energy icon **508**, a custom treatment button **507** and a central, circular, graphical treatment progress display **514**.

[0086] The graphical treatment progress display **514** has several portions, according to the embodiment shown in FIG. **9**. First, there is a total treatment timer **512**, which is displayed as a central circle with a counting down number, representing seconds (or alternatively minutes, or minutes and seconds) remaining in the current procedure. Here, for example, the treatment has not started yet, and the total treatment timer **512** shows a time of 30 seconds, thus indicating that at least the next tissue treatment will last 30 seconds total. Immediately surrounding the central circle total treatment timer **512** is a treatment time indication ring **513**, which acts as an indicator of elapsed and remaining time in the procedure. In the default image **500** of FIG. **9**, the treatment has not started, so the entire outer ring **513** is one initial color. The initial color of the ring **513** indicates time remaining in the treatment, which in this case takes up the entire ring **513**.

[0087] Other indicators on the screen shot image **500** also show that the treatment has not yet started. For example, the "Energy ON" indicator light **509** is not illuminated yet, because the console **102** is not yet delivering energy to the stylus **104**. The treatment number indicator **504** shows that zero treatments have been performed with the stylus **104** that is currently plugged into the console **102**. And the temperature indicator **501** shows a stylus temperature of 26 degrees Celsius. To begin a treatment, the physician user will touch the start/stop button **510** on the touchscreen **108**.

[0088] Referring now to FIG. **10**, a later screen shot **520** of the default settings screen is illustrated. At this stage, energy is being delivered from the console **102** to the stylus **104**, as indicated by the "Energy ON" indicator light **509**. The total treatment timer **512** of the graphical treatment progress display **514** shows that 12 seconds remain in the treatment. The outer ring **513** now includes a darker energy delivery time portion **511**, and the lighter remaining portion of the ring **513** indicates the portion of the total treatment time that is still remaining. As the energy delivery stage of the treatment begins and progresses, the darker energy delivery time portion **511** takes up more and more of the outer ring **513**, moving in a clockwise direction. In other words, the energy deliver indicator **511** starts at zero, at the twelve o'clock position on the ring **513**, and moves around the ring in a clockwise direction.

[0089] Other indicators that the treatment is in progress include the temperature indicator **501** showing a temperature of 60 degrees Celsius and the treatment number indicator **504** showing that this is the first treatment being performed with the stylus **104** currently plugged into the console **102**.

[0090] In some embodiments, the console **102** may be activated, and energy delivered to the stylus **104** in either of two ways—the start/stop button **510** may be touched, or a foot pedal coupled with the console **102** may be depressed. The "Energy ON" indicator **509** lights up when the console **102** is delivering power. The stylus type connected indicator **506** indicates what type of stylus **104** is connected to the console **102**, which in the example shown is a Vivaer™ stylus (Aerin Medical, Inc., www.aerinmedical.com). This indicator **506** may be useful in embodiments where the console **102** is configured for use with multiple different types of styluses. The stylus temperature indicator **501** shows the actual temperature of the distal, treatment end of the stylus **104**. The treatment number indicator **504** displays the number of the treatment currently being completed with the stylus **104** that is attached to the console **102**. Finally, the custom treatment button **507** allows the user to customize one or more treatment parameters. Touching this button **507** will lead the user to a new display screen with different options. In alternative embodiments, the various icons and/or indicators on the default display **520** may be changed or moved. In some embodiments, one or more of the icons and/or indicators may be eliminated.

[0091] Referring now to FIG. **11**, a third screen shot **530** of the default setting screen is illustrated. At a given amount of time into the procedure, the console **102** stops delivering RF energy to the stylus **104**, and a cool down phase begins. The cool down phase is shown on the ring **513** as a differently colored or shaded segment **505**, as compared to the Energy ON segment **511**, and it may be called a cool down timer indicator **505**. The cool down timer indicator **505** moves around the ring in a clockwise direction until the procedure is complete. Any amount of time remaining in the procedure is indicated by the total treatment time remaining portion of the ring **513**.

[0092] In the screen shot of the main screen image **530** shown in FIG. **11**, the current stage of treatment is illustrated as follows: The central circle total treatment timer **512** shows there are eight seconds remaining in the treatment. The Energy ON indicator segment **511** and the cool down timer segment **505** show that the energy delivery portion of the treatment is complete, because the cool down timer segment **505** has started. Since the total treatment time remaining portion of the ring **513** is still visible, this shows the user that the cool down phase is still in process. In a real life scenario, the cool down timer portion **505** would also be moving clockwise, thus easily telling the user what phase the treatment was in. In this case, the total treatment time portion of the ring **513** shows that approximately one fourth of the entire treatment time still remains. The temperature of 49 degrees Celsius in the temperature window also tells the user that the console **102** is in the cooling phase, since the temperature of the stylus **104** has decreased from 60 degrees. Finally, the Energy ON indicator light **509** is not illuminated.

[0093] In various embodiments, any colors, shades, shapes, graphics and/or the like may be used for the various segments **511**, **505** of the outer ring **513**. In one embodiment, for example, the Energy ON timer indicator **511** is navy blue, the cool down timer indicator **505** is gray, and the total treatment time remaining portion **513** is light blue. Any other colors may be used, however, in alternative embodiments. In another alternative embodiment, the entire ring **513** may be one color, and a line that acts as a timer may move clockwise around the ring **513**, similar to a long hand on a clock. In a variation on such an embodiment, the color of the ring **513** behind the moving line may change. Thus, the ring **513** and the segments **511**, **505** may have any suitable size, color scheme or configuration.

[0094] Additionally, the default (or custom) settings of the console **102** may have any suitable ranges and combinations for the various parameters of the console **102**. For example, one timing default setting may have a total treatment time of 30 seconds, an Energy ON time of 18 seconds, and a cooling time of 12 seconds. This is but one example, however, and any number of other time settings may alternatively be used. A default temperature may also be set for energy delivery,

for example 60 degrees Celsius as the maximum temperature. Again, any suitable default settings may be set in various embodiments.

[0095] Referring now to FIG. **12**, as just described, the physician or other user can choose to access a custom treatment screen **630** by touching the custom treatment button **507** on the initial default screen **500** (FIG. **9**). In the embodiment shown, the custom treatment screen **630** includes a graphical treatment progress display **600**, which is smaller but otherwise the same as the graphical treatment progress display **514** of the default screen **500**. The custom treatment screen **630** also includes a timer icon **601**, an impedance display **602**, a stylus icon **603**, a number of treatments indicator **604**, a cooling icon **605**, a set cooling time window **606**, a set Energy ON time window **607**, a set temperature window **608**, an actual temperature indicator **609**, a down button **610**, a back button **611**, a stylus type indicator **612**, an energy icon **613**, an Energy ON indicator **614**, a start/stop button **615**, an up button **616**, an actual power delivery indicator **617**, a set power window **618**, an energy power icon **619** and a temperature icon **620**. As with the previously described default screen **500**, the icons and/or indicators of the custom treatment screen **630** may be moved, changed and/or eliminated, according to various alternative embodiments.

[0096] Through the custom treatment screen **630**, the user can adjust the power (power window **618**), temperature (temperature window **608**), treatment time (energy on time window **607**) and/or cool down time (cooling time window **606**), by touching any one of the set windows and then touching the up button **616** and/or the down button **610** to adjust a given value. To set power, for example, the user may touch the power window **618** and then adjust the temperature by pressing the up button **616** or the down button **610**. The console **102** may be configured to only allow adjustments within ranges. For example, the power on the console **102** may be selected at 3 W, 4 W or 5 W in some embodiments. Maximum stylus temperature may be selected in a range of 50 degrees Celsius to 70 degrees Celsius in some embodiments. Energy delivery time (Energy ON time) may be selected for between 6 seconds and 18 seconds, in 2-second increments, and cooling time may be selected for between 0 seconds and 12, in 3-second increments, in one embodiment. Any other suitable ranges and combinations of ranges may be used, in alternative embodiments, and those provided here are merely examples.

[0097] For the information of the user, the impedance display **602** and stylus usage count **604** are also displayed. The back button **611** can be touched to return to the default screen **500** (FIG. **9**). During treatment, the actual power **617** and temperature reading **609** are also shown. In alternative embodiments of the custom treatment display screen **630**, one or more icons, indicators, buttons and/or windows may be moved, changed or eliminated.

[0098] Referring now to FIG. **13**, in some embodiments, the console **102** may be programmed to display a fault screen **700** when a fatal error of the system **100** occurs. The fault screen **700** may include, for example, a fault error symbol **701** that indicates a serious error has occurred, rendering the console **102** unusable. The fault screen may also include an error code **702**, indicating what kind of error has occurred, and a refer to IFU (instructions for use) symbol **703**. The fault error symbol **701** may be any color or combination of colors, such as a red triangle with a black exclamation point. In some embodiments, after the fault screen **700** appears, the console **102** may only be used after the user turns the console **102** off and turns it back on again.

[0099] Referring now to FIG. **14**, in some embodiments, the console **102** may be programmed to display an error screen **800** when a non-fatal error of the system **100** occurs. The error screen **800** may include, for example, a caution symbol **801** that indicates an error has occurred. The error screen may also include an error code **802**, indicating what kind of error has occurred, an error symbol **803**, and a back button **804**. The caution symbol **801** may be any color or combination of colors, such as a yellow triangle with a black exclamation point. In this embodiment, the user may touch the back button **804** to return to the previous screen being used when the error occurred, and the user may fix the error at that screen.

[0100] FIG. **15** is a screen shot of a settings screen **900**, which may be provided on the display **108** of the console **102**. In this embodiment, the settings screen **900** includes an adjust brightness icon **901**, an adjust volume icon **902**, a sliding bar brightness control **904** and a sliding bar volume control **906**. The brightness control **904** and the volume control **906** may have any color or combination of colors. In some embodiments, a numerical indication of brightness and volume may also be included. The settings screen **900** also includes a back button **904** to allow the user to return to a previous screen.

[0101] Referring now to FIG. **16**, an exemplary method **1000** of using the console **102** of the electrosurgery system **100** is illustrated. First, the user turns on **1002** the console **102**. The console **102** performs a self-test **1004**. If the self-test passes, the console **102** displays the standby screen **1006**. If the console **102** fails the self-test, the fault screen is displayed **1008**. In some embodiments, the fault screen can only be cleared by power cycling the console **102** to repeat the self-test routine. Next, assuming the self-test is passed, the user plugs the stylus **104** into the console **102**. If the correct stylus is inserted **1010**, the console **102** shows the default main screen **1012**. The user presses the start/stop button or a foot switch, and the RF energy delivery portion of the treatment starts **1016**, followed by the cooling portion **1020**. When the treatment is completed **1014**, the screen returns to the default main screen **1012**. If an error occurs during treatment **1018**, the error screen is shown **1014**. The user can press the back button on the error screen to return to the default main screen **1012**. If the error is fatal, the screen changes to the fault screen **1008**. At various points the in method **1000**, the user may also select the custom treatment screen (FIG. **12**) by pressing the custom treatment button **507** on the default screen.

Treatment Device

[0102] FIG. **17** is a more detailed view of the stylus **20**. In this embodiment, the handle **22** includes an oval depression **23**, which faces in the same direction as the treatment surface of the distal tip **26**. The oval depression **23** allows the physician user to know the orientation of the treatment surface at all times and may also be used as a finger or thumb rest. In some embodiments, an on/off button may be positioned where oval depression **23** is illustrated on handle **22**. This on/off button may be used to activate the stylus and thus provide energy to the electrodes at the distal tip **26**. In some embodiments, the physician may use the handle on/off button as an alternative to a foot pedal for this purpose. The

stylus shaft **24** may have any length suitable for reaching the posterior portion of the nasal cavity where the posterior nasal nerves reside. In one embodiment, for example, the shaft **24** is approximately 3.75 inches long, from its connection to the distal tip **26** at one end to its connection with the handle **22** at the opposite end. In some embodiments, the shaft **24** may have different lengths, for example between about 3 inches and about 4 inches in embodiments designed for addressing a posterior portion of the nasal cavity, and between about 1 inch and about 3 inches in embodiments designed for addressing an anterior portion of the nasal cavity, such as the nasal valve. The shaft **24** may also have any suitable width (or "diameter"). For example, in some embodiments, the shaft may have a width of about 4 mm to about 5 mm. The shaft **24** will be described in further detail below.

[0103] Referring now to FIGS. **18**A and **18**B, the distal tip **26** is shown in detail. The distal tip **26** includes a treatment surface **30** (or "tip face"), two rows of four bipolar RF electrodes **32**, and a thermocouple **34** between the electrodes **32**. As illustrated in FIG. **18**A, the bottom surface **36** of the distal tip **26** may be tapered or slanted, to give the distal end of the distal tip **26** a narrower profile to facilitate insertion and advancement of the distal tip **26** into the nostril and to the posterior portion of the nasal cavity. The treatment surface **30** is made of a non-conductive material (e.g., plastic) and may have a slightly convex shape, as illustrated, or may alternatively be flat, concave, or more convex than the shown in FIG. **18**B. The slightly convex shape may help ensure contact of the electrodes **32** and the thermocouple **34** with mucosal tissue during use.

[0104] In some embodiments, the thermocouple **34** may be removed or replaced by a different type (or shape or number) of temperature sensor(s). The system can use one or more temperature sensors to monitor temperature of the treated tissue or adjacent tissues to monitor for changes or to execute a tissue apposition check or monitor other biometric information. The thermocouple **34** (or any temperature sensor) is used to measure temperature of the mucosa and provide the measurements to a processor in the console **12**, which can in turn automatically adjust whether and how much energy is delivered to the stylus **20**. In some embodiments, the distal tip **26** or a portion thereof may be translucent, to facilitate visualization of target tissue and/or nasal mucosa.

[0105] The system can also monitor the impedance of the tissues in contact with the device to monitor for changes or to execute a tissue apposition check or monitor other biometric information. The system may include an optical generator that enables an optical signal, possibly in the near infrared spectrum, to be sent to the tissue and enables monitoring of the treated tissues by confirming tissue has been altered through some property shift, for example, a decrease in oxygenation may indicate that irreversible electroporation has occurred in the targeted tissue.

[0106] FIGS. **19**A and **19**B illustrate, in a side view and a front view, respectively, a distal portion of an alternative embodiment of a nasal airway tissue treatment stylus **130**. In this embodiment, the height or thickness of the distal tip **134** is thinner than in the previously described embodiment and thinner than the shaft **132** of the stylus **130**. The distal tip **134** includes a treatment surface **136**, four pairs of bipolar RF electrodes **138**, and a thermocouple **139**. The thinner distal tip **134** may facilitate passage of the tip **134** through a nostril and around nasal cavity anatomy for positioning at a treatment site in a posterior portion of the nasal cavity. In all other respects, the distal tip **134** may include any of the features of the embodiment described above.

[0107] FIG. **20** is a front view of yet another embodiment of a nasal airway tissue treatment device **140**. This embodiment also includes a shaft **142** and a distal tip **144**, which in turn includes a treatment surface **146**, four pairs of bipolar RF electrodes **148** and a thermocouple **149**. In this embodiment, however, the electrodes and thermocouple are flat, rather that rounded or pointed. They protrude only slightly from the treatment surface **146**. This further helps reduce the overall height or thickness of the distal tip **144** and thus makes it easier to advance the tip **144** through the nostril and nasal cavity. In some embodiments, the electrodes and thermocouple may even be completely flush with the treatment surface.

[0108] FIG. **21** illustrates an exemplary embodiment of a method **40** for using the treatment system **10** to treat nerve tissue (and/or other tissues) in the nasal cavity to treat rhinitis. In this embodiment, the method **40** includes the steps of: preparing the patient **42**, such as with local anesthesia and an endoscopic examination of the nasal cavity; bending the stylus **44**, if desired (explained further below); applying conductive gel to the stylus distal tip **46**, over the electrodes; advancing the distal tip of the stylus into the nostril and contacting it with the treatment area **48**, then maintaining light pressure with the distal tip against the treatment tissue; pressing and holding down the foot switch **50** to start the treatment; continuing to hold down the foot switch for twelve seconds **52** (the treatment time in this embodiment); removing and inspecting the distal tip **54**; and repeating 56 steps **46**, **48**, **50** and **52** as necessary, to treat additional treatment areas. In one embodiment, for example, it is recommended that at least three, twelve-second treatments are performed along the course of the posterior nasal nerve. Any other number of treatments may be performed, however, in alternative embodiments. In some embodiments, each treatment may last a different period of time than 12 seconds, such as between 1 second and 120 seconds, or between 10 seconds and 60 seconds in various embodiments. For example, PFA treatments can be between 1-2 seconds of treatment. For example, PRF treatments can be up to 120 seconds. When a treatment on a patient is complete, a final step may be to provide post-treatment actions and instructions to the patient **58**.

[0109] The method may be repeated for as many treatment areas as desired. In some embodiments, the stylus **20**, the console **12** or both may be configured to allow only a certain number of treatments for any given stylus **20**. This may help prevent reuse of the stylus **20** on multiple patients or overtreatment of any one patient. For example, in one embodiment, the stylus **20** may only be able to deliver sixteen 12-second treatments. In other embodiments, the stylus **20** may be capable of delivering ten to thirty 12-second treatments, for example. In yet other embodiments, the stylus **20** may be capable of delivering any number of treatments, but the console **12** is able to identify each stylus **20** and count or identify how many treatments have been applied with that stylus **20**. The console **12** may be configured to shut down or simply not deliver energy to a stylus **20** that has reached its maximum number of allowed treatments. In other embodiments, a single stylus **20** may be used with the console **12** to deliver as many treatments on one

patient as desired, but once the treatment on that patient is completed, the stylus **20** is rendered inoperable for use with any additional patient(s). Inoperability may be conferred by a computer chip in the handle **22** of the stylus **20**, or alternatively the console **12** may destroy or alter a portion of the stylus **20** when the stylus **20** is unplugged from the console **12** or at some other point at the end of a treatment.

[0110] In some embodiments, the nasal airway tissue treatment stylus **20** may be used for treating several different types of target tissue in one patient. Before treating posterior nasal nerve tissue, after treating that tissue, or both, one or more additional tissues may be treated. Such tissues include mucosa, nerves and/or other tissue of any one of the nasal turbinates, nasal swell bodies, the nasal septum, and mucus producing cells anywhere in the nasal cavity. Therefore, the treatment method illustrated in FIG. **21** may be added to by treating any one or more of these additional tissues. Physicians may often treat the inferior and/or middle turbinate before or after proceeding with the steps in FIG. **21** to treat posterior nasal nerve tissue.

[0111] Referring next to FIG. **22**, a portion of the stylus **20** is shown, illustrating features of the shaft **24**. In this embodiment, the shaft **24** is malleable, so that it can be bent by a physician user and retain the bent shape during use. This may be especially advantageous, for example, in helping the physician advance the distal tip **26** of the device around anatomical structures to a posterior target area in the nasal cavity. As illustrated in FIG. **22**, the distal tip **26** has a distal edge **26***a* and a proximal edge **26***b*. Just proximal to the proximal edge **26***b* of the distal tip **26** is a bend section **25** of the shaft **24**. The bend section **25** is approximately 2 inches in length in this embodiment, and it is the section of the shaft that is recommended for bending. Physician users may be instructed, for example with instructions for use provided with the system **10**, to bend the shaft **24** only within the bend section **25** and not too close to the distal tip **26**. This may help prevent weakness at the areas where the shaft **24** is connected to the distal tip **26** and the handle **22**. In the embodiment shown, the entire shaft **24** is made of a malleable material, but in alternative embodiments only a portion of the shaft **24** might be malleable, such as the bend section **25**.

[0112] The shaft **24** may be manually bent by the physician to the appropriate bend angle. While bending, the physician should support the stylus **20** by the shaft **24**, not by the handle **22** or the distal tip **26**. The bend should be formed in the orientation the electrodes **32** are facing. The shaft **24** may be bent to any suitable angle. In one embodiment, however, it is recommended that the shaft **24** only be bent to a maximum of approximately 20 degrees away from the longitudinal axis of the stylus **20**. Again, this limit on bending may help maintain the structural integrity of the stylus **20**. Bending the shaft **24** at all is entirely optional, and some or even all physicians might decide not to bend the shaft **24** at all. In alternative embodiments, the shaft **24** might be rigid and not malleable. In general, all parts of the stylus **20**, other than the electrodes **32** and the thermocouple **34**, may be made of non-conductive materials, such as any suitable plastic or polymer.

[0113] Referring to FIGS. **23**A, **23**B, and **23**C, in some embodiments a bending tool **74** may be provided for bending the shaft **24** of the stylus **20**. In this embodiment, the bending tool **74** includes a narrow distal portion **80**, a wide proximal portion **82**, and an opening **85** into which the distal tip **26** and a portion of the shaft **24** enter. As illustrated in FIG. **23**B, the bending tool **74** may first be slid down onto the stylus **20**. The bending tool **74** may then be tilted, as shown in FIG. **23**C, to form a bend **84** in the shaft **24**. The bending tool **74** may have any suitable length, to bend the shaft **24** in a desired location. For example, in some embodiments the bending tool **74** is designed to bend the shaft **24** somewhere between one third and one half of the length of the shaft measured from the handle **22**. Alternative embodiments of the bending tool **74** may have any other suitable size, shape and configuration for bending a shaft **24** of a stylus **20**.

[0114] FIGS. **24**A, **24**B, **24**C illustrate the use of another embodiment of a shaft bending tool **90**. In this embodiment, the shaft bending tool **90** includes a narrow distal end **92**, a wide proximal end **94**, and an opening **96**, as with the previous embodiment. In this embodiment, however, the shaft bending tool **90** is significantly shorter than the previously illustrated embodiment. As illustrated in FIG. **24**C, this shorter bending tool **90** creates a bend **98** in the shaft **24** that is much closer to the distal tip **26**. Physicians may want to bend the shaft **24** of the stylus **20** in different locations. Thus, in some embodiments more than one size or shape of bending tool **74**, **90** may be provided. A physician may select one bending tool **74**, **90** to make one bend, or she may use two (or more) different bending tools **74**, **90** to make multiple bends in the shaft **24**.

[0115] Referring to FIG. **25**, as just mentioned, in some cases a physician may bend the shaft **24** of the stylus **20** at two different locations, forming for example a proximal bend and a distal bend. In some embodiments, the shaft **24** may include one or more proximal bend markers **25** and one or more distal bend markers **27**. Bend markers **25**, **27** may be located at any location along the length of the shaft **24** and may be made with paint, etched into the surface, or by any other means. In the illustrated embodiment, two bends are made to give the shaft **24** a bayonet shape, as desired by some physicians to navigate around anatomical structures in the nasal cavity while still positioning the treatment surface of the distal tip **26** in full contact with nasal mucosa on the lateral wall of the nasal cavity. It bears repeating that in various alternative embodiments, the shaft **24** may include any number of bend markers **25**, **27** at any locations and/or the shaft **24** may be bent (with or without markers) at any suitable location or at multiple locations.

[0116] In various embodiments, the shaft **24** may be either more or less malleable, depending on the desired stiffness versus bendability of the shaft **24**. In some embodiments, only certain portions of the shaft, which are designed to be bent, are malleable, while others are stiff. Or certain portions may be more malleable than others. More malleable sections may have a thinner wall than less malleable sections and/or the shaft **24** may be made of different materials in different sections. The latter is likely to complicate manufacturing and increase expense, however, so in at least some embodiments the shaft **24** is made of one piece of material, such as a metal hypotube. In such cases, differences in malleability may be achieved via differences in wall thickness, material selection, material processing, or material heat treatment.

[0117] FIG. **26** is another illustration of the stylus **20**, showing how the oval depression **23** on the top of the handle **22** aligns with the treatment surface **30** of the distal tip **26**. This allows the physician to always know what direction the treatment surface **30** is facing. The oval depression **23** is

configured to provide an ergonomic location for placement of the physician's thumb, but depressions of different shapes may be used in different embodiments. Other alternative embodiments may use any other suitable directional indicator on the handle **22** and/or a proximal portion of the shaft **24**, to show direction of the distal tip **26**.

[0118] FIG. **27** is a sagittal view of the nasal cavity, showing three treatment areas for treating the nasal cavity with the stylus **20**. In this embodiment, the stylus **20** has been used to deliver energy to a first target location **60**, a second target location **62** and a third target location **64**, all of which fall along the path of the posterior nasal nerve PNN. Additional treatments may optionally be provided in the same general area and/or in different areas of the nasal cavity. For example, some physicians may use the stylus **20** to treat a nasal septum, a septal swell body, an inferior turbinate and/or other soft tissue(s) in the nose, all as part of the same treatment on one patient. FIG. **27** is thus provided for illustrative purposes only.

[0119] Referring to FIGS. **28**A and **28**B, two steps of the method for using the nasal tissue treatment system **10** are illustrated diagrammatically. In FIG. **28**A, the distal tip **26** of the stylus **20** is shown in an end-on, cross-sectional view, showing two electrodes **32** and the temperature sensor **34**. The distal tip **26** has conductive gel on its treatment surface **30** and is in position within the nostril, near the mucosa. Next, as illustrated in FIG. **28**B, the physician contacts the mucosa with the distal tip **26**, applies gentle pressure against the mucosa, and presses the foot pedal to activate the stylus **20** and deliver energy from one set of electrodes **32**, through the mucosa, to target tissue(s) in the submucosa, and back to a second set of electrodes **32**. This process generates heat and treats the target submucosal tissues, such as the posterior nasal nerve and/or other nerves. Again, the treatment may be timed by the console **12**, which may automatically stop the delivery of energy after a preset time, such as 12 seconds in one embodiment. The thermocouple **34** measures the temperature of the mucosa it is contacting, and the system **10** uses this measurement to automatically shut off the system **10** if a temperature is too high or otherwise outside of a preset range of acceptable temperatures.

[0120] FIG. **29** illustrates the distal tip **26** in a similar position as shown in FIG. **28**B, but in this case the physician is not applying gentle pressure to the mucosa with the distal tip **26**. As illustrated, it is possible that without application of pressure, the applied energy will not penetrate the submucosa to reach the desired target tissue. In some embodiments, the stylus **20** is designed to determine whether adequate pressure is being applied and to only activate the electrodes **32** when the pressure is applied.

[0121] Referring now to FIGS. **30**A-**30**D, another embodiment of a nasal airway tissue treatment stylus **150** is illustrated. As shown in FIG. **30**A, the stylus **150** includes a handle **152** with a slider **153**, a shaft **154**, a distal tip **156** and a power cord **158**. FIG. **30**B is a front view of the stylus **150**, showing additional features. In this embodiment, the stylus **150** includes a space **164** between the inner wall of the shaft **154** and the outer perimeter of the distal tip **156**. (FIG. **30**B also shows the two rows of electrodes **160** and the thermocouple **162** of the distal tip **156**.) Within the space **164** and around the distal tip **156** resides an expandable wire electrode component **166**, which is moveable out of the distal end of the shaft **154** to allow it to expand and be used for delivering a treatment.

[0122] In use, the stylus **150** may be used first in the configuration shown in FIG. **30**A. The electrodes **160** of distal tip **156** may be used to treat tissue, such as posterior nasal nerve tissue, turbinates, nasal swell bodies and/or the like. In one embodiment, for example, the distal tip **156** may be used to treat one or more nasal turbinates in areas that are anterior to the nasal nerve that will be treated subsequently.

[0123] After treating with the stylus **150** as shown in FIG. **30**A, and referring now to FIG. **30**B, the slider **153** on the handle **152** may be advanced to advance the expandable wire electrode component **166** out of the distal end of the shaft **154**. FIG. **30**D shows the slider **153** further advanced and the expandable wire electrode component **166** fully advanced and expanded. The expandable wire electrode component **166** may include multiple bipolar electrode pairs located at various locations along its length. Optionally, the expandable wire electrode component **166** may also include one or more thermocouples and/or multiple nerve sensors (such as electrodes), which may be used to measure a temperature of nasal mucosa and sense where nerve tissue is located under the mucosa, respectively. In some cases, all electrode pairs may be activated at the same time. Alternatively, only one or more selected electrode pairs may be activated. In some cases, the expandable wire electrode component **166** may be used to determine the location of nerves and then only bipolar electrode pairs located directly over those nerves may be activated.

[0124] In one example, after the stylus **150** has been used in the initial configuration shown in FIG. **30**A to treat one or more turbinates, swell bodies or the like, the stylus **150** may be changed to the expanded configuration shown in FIG. **30**D. In that configuration, the expandable wire electrode component **166** may be used to treat posterior nasal nerves and/or any other nerve tissue the physician wants to treat. In other words, the stylus **150** is used to treat nerve tissue in the FIG. **30**D configuration and used to treat any other tissues in the FIG. **30**A configuration. This is only one example, however, and a physician may use the stylus **150** in any suitable manner. After treatment with the expandable wire electrode component **166** is complete, the expandable wire electrode component **166** may be pulled back into the shaft by sliding the slider **153** proximally. It may also be possible to treat further in the FIG. **30**A configuration after treatment with, and retraction of, the expandable wire electrode component **166**.

[0125] Referring now to FIG. **31**, an alternative embodiment of a nasal airway treatment stylus **190** is similar to the one just described, except that rather than the expandable wire electrode component **166**, this embodiment of the stylus **190** includes an expandable cryotherapy balloon **199**. The stylus **190** also includes a handle **192** with a slider **193**, a shaft **194**, a distal tip **196** and a power cord **198**. In this embodiment, the cryotherapy balloon **199** can be advanced out of the distal end of the shaft **194** using the slider **193**. A source of cryogenic substance, such as nitrous oxide in a small canister, may be attached to the handle **192** and transmitted through a lumen in the shaft **194** to inflate the cryotherapy balloon **199**. The inflated cryotherapy balloon **199** will absorb energy from the nasal airway tissues and thus can be used to ablate posterior nasal nerves and/or any other target nerve tissue or other target tissues. When a treatment is complete, the cryogenic substance may be evacuated from the cryotherapy balloon **199**, causing it to deflate, and the stylus **190** may be removed from the nose.

Optionally, the deflated cryotherapy balloon **199** may be pulled back into the shaft **194** before removal of the stylus **190**, but that may not be necessary. As with the previous embodiment, any suitable nasal airway tissue may be treated with the distal tip **196** of the stylus **190** before inflating the cryotherapy balloon **199** for additional tissue treatment.

[0126] With reference now to FIGS. **32**A and **32**B, another alternative embodiment of a nasal airway tissue treatment device **170** is illustrated in perspective view (FIG. **32**A) and front view (FIG. **32**B). In this embodiment, the stylus **170** includes a handle **172** with a slider **173**, a shaft **174**, a distal tip **176**, an expandable wire electrode component **186**, and a power cord **178**. As best seen in FIG. **32**B, the distal tip **176** includes two rows of bipolar RF electrode pairs **180**, a thermocouple **182** and an opening **184** which leads directly into a lumen in the shaft **174**. The expandable wire electrode component **186** is located inside the opening **184** and the lumen (not visible on these drawings) and may be advanced out of the opening **184** with slider **173** to allow the expandable wire electrode component **186** to expand and be used for treatment. All of the same features and methods of use described above may be applied to this embodiment of the stylus **170**, the primary difference being that the expandable wire electrode component **186** is located within the distal tip **176** and advances out of the opening **184**. The expandable wire electrode component **186** may have any suitable size, shape and configuration of wires, according to various embodiments.

[0127] FIGS. **33**A-**33**C illustrate exemplary embodiments of a treatment device having an expandable wire electrode component with a plurality of electrodes thereon for delivering energy to the target nasal tissue. In some embodiments, the treatment device **300** in is in the form of a sheath balloon. The treatment device **300** includes an elongate sheath **302** with an opening at a distal end such that an expandable member **304**, such as a balloon, can extend therefrom. In some embodiments, the balloon is configured to expand asymmetrically. A standoff **306** is coupled to a distal end of the balloon, which can in the form of a soft-tipped component or in the form of a wire loop. An inflation lumen **308** extends thought the shaft and couples to a proximal end of the balloon is allow the balloon to move from an uninflated configuration (FIG. **33**A) to an inflated configuration (FIGS. **33**B and **33**C) to allow one or more electrodes **310** positioned on the outer surface of the balloon to contact a target tissue for treatment. The one or more electrodes **310** can be positive or negative, and can be symmetrical or asymmetrical. The shape of the electrodes can vary, but the electrodes are configured to expand as the balloon is inflated.

[0128] FIGS. **34** and **35** illustrate exemplary embodiments of a treatment device having a multi-electrode treatment element with multiple channels can be implemented in a symmetrical or asymmetrical basket. The electrode component includes a plurality of sections that are all coupled together at a distal end and a proximal end. In some embodiments, the wire electrode component is configured to deploy into the nasal cavity and expand and conform to the target treatment tissues. In some embodiments, the treatment device **320** in is in the form of a partial and/or asymmetrical basket. The treatment device **320** includes an elongate sheath **322** with an opening at a distal end such that an expandable basket **324** can extend from a distal end of the sheath. The basket can be deployable (either delivered from a sheath or delivered in a collapsed state) and extend from the distal opening of the sheath. Each segment of the basket can include a plurality of electrodes **326** thereon. The basket can also include an optional septal wall shield **328** that can be deployable to protect the basket and the electrodes during use. A handle **330** can be coupled to the proximal end of the shaft and includes features thereon for controlling the basket. In some embodiments, the handle includes an activation device that can function as a slider **332** to control the movement of the sheath relative to the basket. In some embodiments, the handle includes an activation device that can function as a slider **334** to control deployment of the basket/electrodes.

[0129] In some embodiments, the asymmetric basket can be seated against the turbinates and the septal wall. A balloon can be used to deploy the electrodes to deliver energy to a target nasal tissue. In some embodiments, the device allows for conformability with multiple electrode leaflets distributed across the device. Further, the tip length can be "inactive" to ensure that distal portion acts as a standoff from tissues not intended for treatment (for example, the distal tip can be 3 mm to 5 mm).

[0130] FIGS. **36**A, **36**B, and **36**C illustrate exemplary embodiments of multi-channel electrodes. FIG. **36**A illustrates an orientation of electrode polarity and electric field having a middle pair of electrodes used for impedance sensing. In some embodiments, the device can sense impedance which may enable tissue detection and provide treatment alterations to avoid directly delivering energy to a non-target tissue. In some embodiments, the treatment algorithm can monitor the impedance and deliver energy until a certain impedance is reached or a bioelectrical signal is no longer sensed. FIG. **36**B illustrates another orientation of electrode polarity and electric field having a middle pair of electrodes used for impedance sensing. FIG. **36**C illustrates another orientation of electrode polarity and electric field.

Energy Types

[0131] As explained above, various types of energy can be used with the systems and devices described herein to treat nasal tissue to treat rhinitis, nasal obstructions, migraines, other headaches, and other nasal diseases, but in some embodiments, pulsed electric field energy can be used for conducing pulsed field ablation (or "PEF ablation") or using pulsed radiofrequency energy (PRF energy) of one or more tissues, such as but not limited to nerve tissue and various nasal tissue and structures. For example, the energy generator can be in the form of a PEF generator and the various embodiments of electrodes may be operated as PEF ablation electrodes. In any given embodiment, the pulsed electric field generator may be configured to provide exponentially decaying, square wave, bipolar, monophasic, biphasic, and/or oscillatory pulses.

[0132] In some embodiments, the radiofrequency pulses can be delivered using high frequency alternating pulses. In some embodiments, the electrosurgical generator may be configured to output waveforms with high-voltage pulses of alternating direct current with pulses delivered as a pulse train. In some embodiments, the pulses can be monophasic or biphasic. Monophasic pulses are single polarity pulses, where biphasic pulses consist of positive and a negative pulse amplitude. FIGS. **37**A-**37**G illustrate exemplary graphs showing biphasic and monophasic pulses.

[0133] In some embodiments, a pulse train includes one or more monophasic or biphasic pulses delivered as a specified

number of pulses with a prescribed pulse width, pulse amplitude, pulse cycle with a pulse delay and a cycle delay. The pulse delay, or pulse interval, is the duration following each pulse delivery of specified pulse width and pulse amplitude. The pulse cycle is comprised of both a positive and a negative pulse.

[0134] In some embodiments, the pulse train may be delivered in repeated intervals to create a burst, which is a string of pulse trains with some interval between pulse trains to allow for tissue to recover and to minimize thermal effects. The high-voltage pulses may be delivered using rapidly alternating voltages that are positive and negative (biphasic) or positive only (monophasic). The use of biphasic pulses has been shown to reduce the possibility of muscle stimulation when compared to monophasic pulses.

[0135] FIGS. **38**, **39**A, **39**B, and **40** illustrate various embodiments of system diagrams and circuits for producing the pulsed energy delivered to the various treatment devices described herein. FIG. **38** illustrates an exemplary embodiment of a RF generator system that could have some waveform generated by the function generator. FIGS. **39**A and **39**B illustrates exemplary embodiments of circuits used in Pulsed Electric Fields generators to generate a square wave or a decaying wave.

[0136] FIG. **40** illustrates an exemplary embodiment of a charging and switching circuit that could be employed, and that includes a sensor to allow for monitoring temperature to ensure that targeted tissue or some proxy measurement is not exceeded. In some embodiments, the power supply unit is configured to provide power voltages to the high voltage pulse modulator. In some embodiments, the power supply unit generates and provides power voltages which have a voltage level that is controlled by a control signal from the control unit. The control unit can be configured to generate and provide one or more control signals to pulse generation and control unit and to power supply based at least partly information from the monitoring and feedback system regarding temperature. in some embodiments, the control unit, power supply **1560**, pulse generation and control unit, the high voltage pulse modulator, and the monitoring and feedback system can form a feedback loop which causes one or more characteristics of the pulse to be changed based on the feedback information from various sensors.

Pulsed RF

[0137] In some embodiments, the generator may be configured to deliver radiofrequency energy pulses such that there is minimal thermal effect on the targeted tissues and a plurality of pulses are delivered for a specified time while the surface temperature is monitored using a sensor such as a thermocouple to ensure there is minimal thermal effect. As explained above, pulsed radiofrequency energy is typically used for neuromodulation.

[0138] It was found that pulsed radiofrequency impacts many different biological pathways involved in the modulation of chronic neuropathic pain (neuralgia). With regards to nociceptive signaling, PRF treatment modulates ion channels (Na/K ATPase, HCN, P2X3), CGRP, neurotransmitters (aspartate, citrulline, M-ENK, glutamate), postsynaptic receptors (AMPA-R, GABA-B), and synaptic function (KCC2). PRF treatment also modulates immune activity, including microglial markers (CD3, CD56, Iba1), inflammatory cytokines (IL-6, IL-17, IRF8, IFN-γ, TNFα), and intracellular proteins implicated in immune mediated neuropathic pain (BDNF, β-catenin, JNK, p38, ERK1/2). For example, the proposed mechanism of action of PRF pertaining to pain relief relies on a decrease in pro-inflammatory cytokines, an increase in cytosolic calcium concentration, a general effect on the immune system, and a reduction in the formation of free radical molecules.

[0139] For example, the alternating pulses can be in the range of 300-500 kHz and pulsed in the range of 1-50 milliseconds at a pulse frequency of 2-5 Hz with voltage amplitudes ranging from 0-100V. The pulses can be delivered for a duration of 10 to 300 seconds.

[0140] The system can also employ a temperature control setpoint that is measured during energy delivery. The energy delivery ceases until the tissue temperature drops below a specified amount below the temperature control setpoint. Once reached, the pulsing continues to be delivered through the duration of treatment. In some embodiments, the temperature control setpoint or pulse parameters may be adjusted to reach a desired effect on the tissue. In some embodiment, the temperature setpoint can be above 40 degrees Celsius. In some embodiments, to produce a more durable effect with longer lasting effect, the temperature setpoint can be between 50 degrees Celsius to 70 degrees Celsius. In some embodiments, the temperature setpoint can be between 50 degrees Celsius to 55 degrees Celsius. In some embodiments, the temperature setpoint is up to 50 degrees Celsius or up to 55 degrees Celsius. One exemplary setting has the energy being delivered using 20 ms pulsed at 45V at a pulse frequency of 2 Hz for less than 120 seconds with a temperature control setpoint at 42° C.

[0141] For example, pulse trains for PRF are typically around 500 khZ (i.e., 10K cycles/burst at 20 ms). The pulse rate is 2-5 hz (2-5 pulses/second). The pulse width is typically 20 ms. The treatment duration is 120-360 sec. The voltage is between 45-50V. The temperature control point is 42° C. Variation on pulse parameters can be adjusted to potentially alter the therapeutic effect, for example, treating the posterior nasal nerve with a higher voltage and increasing temperature control point may produce sufficiently durable effects. Nerves have been shown to be impacted at temperatures below 60 degrees C. It is possible for a pulse train to be delivered that will produce a durable effect that may last longer than typical PRF chronic pain treatments (e.g. greater than 1 year).

PFA

[0142] In some embodiments, the generator may be configured to deliver PFA energy to the tissue. PFA utilizes high voltage pulsing that induces regulated cell death through irreversible electroporation of the targeted cells. FIGS. **41**A and **41**B illustrate the mechanism of electroporation and cell death that can be achieved using PFA.

[0143] PFA high-voltage pulses can be used to induce irreversible electroporation that creates pore formation in the cellular membrane. This causes biochemical signals to trigger cell death via apoptosis (non-necrotic) or other means of regulated cell death. The large electric fields from PFA energy cause destruction of the nerve function through axonal disintegration and demyelination. There may be some localized effect of electrodes heating the tissue through resistive heating that creates some necrotic lesions, but the primary pathway of the cell death is through apoptosis.

[0144] For example, pulse trains for PFA can have a voltage field of 3800 V/cm (rat sciatic nerve); also pig study

treated with 1500 V/cm. The pulse type can be biphasic or monophasic square waves. The pulse width is 100 microseconds (square). The pulse rate is 10-50 kHz (note: the pulse delay and cycle delay could be varied to allow any thermal energy to dissipate). The pulse count is 10-90+ (10 pulses for rat sciatic, 90 pulses for pig). The applications can be for nerves. Variations on pulse parameters could have an impact on the treatment effect.

[0145] For example, PFA typically uses voltages 1-3 kV, pulse widths from nano to milliseconds. The number of pulses can be dependent on type of tissue being treated.

[0146] For example, the voltage amplitude may range from 1 kV-10 kV such that the electric field strength can range from 0.5 kV/cm to 10 kV/cm with pulse widths ranging from 0.05 microseconds to 200 microseconds with the number of pulses varying from 4 to 200 pulses per pulse train.

[0147] The systems and devices described herein can employ PFA as a non-thermal method to target and ablate nerve tissues. The pulsed field ablation techniques can be used to induce reversible or irreversible electroporation which can lead to Regulated Cell Death of the targeted tissue. The system would promote an immune response that could lead to a reduction in inflammation in the treated areas. The pulse waveforms delivered can be monophasic, biphasic, monopolar, bipolar and asymmetric. The pulse duration can be on the order of nanoseconds to milliseconds delivered with a plurality of voltages for the pulse amplitudes and delivered in a pulse train (bursts of packets of pulses). The electric field generated can range from 20 V/cm up to 100 kV/cm. The pulse train can be formulated to prevent muscle stimulation/contractions while still delivering a sufficient amount of energy to induce irreversible electroporation.

[0148] For PFA, the temperature control setpoint is less important since the energy is delivered so quickly and minimal resistive (joule) heating occurs. In some embodiments, the temperature can be monitored during delivery of PFA energy, which can reduce some of the risk for any undesired thermal buildup attributed to resistive. In some embodiments, thermal buildup ca also be mitigated by increasing the pulse delay as a longer cycle time allows for more tissue recovery time between pulses.

Methods of Treatment

[0149] This application describes various aspects and embodiments of a device, system, and method for treating tissue, including nerve tissue.

[0150] FIG. **42** is a flow diagram of an example method **430** of use of the various devices disclosed herein. In certain implementations, the method **430** may include preparing the device in step **432**, advancing a portion of the device to a treatment site in the nasal cavity in step **434**, delivering therapy to the treatment site in step **436**, and removing the treatment device in step **438**.

[0151] In some embodiments, step **432** of preparing the device may include removing the device from sterile packaging, assembling one or more components of the device, sterilizing the device, attaching the device to an energy source, and/or other preparatory work. In certain implementations, this step may include customizing the device to suit the particular needs of the patient and the clinician. This may include articulating, manipulating, or otherwise changing one or more components of the device.

[0152] The step **434** of advancing a portion of the device to a treatment site in the nasal cavity may follow the preparation of the device in step **432**. For example, the clinician may navigate the patient's nasal anatomy to advance a treatment portion of the treatment device into a nostril of the patient to contact mucosal tissue of the upper airway with a treatment surface of the treatment device. Step **434** may be performed without piercing the mucosal tissue. The goal of the navigation may be to place the treatment element in contact with the treatment site.

[0153] During navigation, the clinician may perform one or more tests to determine whether proper contact with the treatment site has been made. In some embodiments, the clinician may activate one or more pairs of electrodes. Based on measured results, the clinician may determine that proper contact has not been achieved because an energy pathway could not be made between one or more pairs of electrodes and/or that one or more measured electrical parameters (e.g., impedance, voltage, current, temperature, etc.) is outside of a desired range. In some embodiments, the clinician may attempt to apply pressure to the treatment site with the treatment portion and determine by feel whether proper contact has been made. In some embodiments, clinician may take a reading using a thermocouple or an electrode to determine whether proper contact has been made. Based on the one or more tests, the clinician may determine that proper contact has been made between the treatment portion and the treatment site. During navigation, a navigation system may be used to position the device based on previously obtained images.

[0154] Energy can then be delivered to the treatment site in step **436**. As is shown in FIG. **27**, the physician may then move the treatment portion to another treatment site and repeat the steps of confirming contact and delivering energy. For example, as shown in FIG. **27**, the treatment sites include a first target location **60**, a second target location **62** and a third target location **64**, all of which fall along the path of a posterior nasal nerve PNN. Additional treatments may optionally be provided in the same general area and/or in different areas of the nasal cavity. In certain circumstances, the clinician may determine that proper contact has not been made and the physician can then either re-orient the treatment portion or move it to another treatment site.

[0155] Once the treatment is complete, the treatment device may be removed from the nasal cavity in step **438**.

[0156] The steps above and much of the disclosure is described with respect to the nose and nasal cavity, but it will be understood that the systems, devices, and methods described herein can be used in other areas of the body, including but not limited to the mouth, including the soft palate and the base of the tongue, the throat, including nerves in the throat, and the ear canal.

[0157] The systems and methods of the present disclosure can be used to treat various conditions inside or outside of the nasal cavity. Some of the conditions that may be treated by the embodiments described herein include, but are not limited to, rhinitis, asthma, COPD, emphysema, airway inflammation, nasal obstruction and/or congestion, eye inflammation and allergic conjunctivitis, chronic cough, post nasal drip, allergies, nasal polyps, sinusitis, turbinate enlargement, migraine headaches, other headaches (e.g., cluster headaches, nasal contact point headaches, etc.), tinnitus, dizziness, vertigo, dry eye, excessive tearing, empty nose syndrome, pain (e.g., facial nerve pain, trigeminal

neuralgia, complex regional pain syndrome, etc.), sleep apnea, snoring, disordered breathing during sleep, anxiety, mood disorders, middle ear conditions (e.g., otitis media), Eustachian tube dysfunction, herpes zoster, paroxysmal hemicranias, cancer of the head or neck, and reduction of chemical mediators that lead to any of the above-listed conditions. It should be noted that many of these conditions may be co-morbid with one another, and so a treatment of one condition may alleviate one or more other conditions.

[0158] By way of non-limiting example, in some embodiments, the systems and methods of the present disclosure can be used to treat or alleviate rhinitis, which can be generally described as the inflammation of the nasal mucosa due to allergic or non-allergic triggers, which leads to excessive mucus production in the nasal cavity. This increased mucus can cause runny nose (rhinorrhea), post nasal drip syndrome (PNDS), upper airway cough syndrome (UACS), congestion, itching, and sneezing symptoms.

[0159] In some embodiments, the systems and methods of the present disclosure can be used to decrease mucus production in the upper airways. Mucus hypersecretion often occurs when a mucus producing cell displays rapid mucus secretion behavior. In some embodiments, to prevent this, properties of the cell can be modified to inactivate or retard the cell so as to halt or impede the release of mucins into the airway. In some embodiments, modifying the properties of the mucus producing cells may include reducing the rate at which cells produce mucus. In some embodiments, modifying the properties of mucus producing cells may include deactivating some or all mucus producing cells in a region. In some embodiments, the cells can be modified by being locally destroyed and can be replaced with healthier mucosal tissue, which may mean fewer mucous glands, fewer mucus producing cells, less inflammation, or more normal nerve function. While some embodiments may change a property of a tissue, such as an ability of a tissue to produce mucus, other embodiments may change a tissue from one type to another type. One example of this latter change is changing mucosal tissue containing goblet cells to mucosa with fewer goblet cells or scar tissue. These various embodiments may be used to reduce movement of mucus, reduce the amount of mucus produced, reduce frequency of mucus production, change the mucus viscosity/consistency, and/or change the path of mucus flow. In some embodiments, the systems and methods of the present disclosure can be used to apply energy to stimulate or disrupt various nasal nerves (as described below) to decrease mucus production in the upper airways.

[0160] By way of another non-limiting example, in some embodiments, the systems and methods of the present disclosure can be used to treat or alleviate migraine or headaches, such as cluster headaches, nasal contact point headaches, tension headaches, sinus headaches, or similar conditions. In some embodiments, the systems and methods of the present disclosure can be used to apply energy to stimulate or disrupt various nasal nerves (as described below) to alleviate migraines or headaches.

[0161] By way of another non-limiting example, in some embodiments, the systems and methods of the present disclosure can be used to treat or alleviate sleep apnea, disordered breathing during sleep other sleep disorders In some embodiments, tissues of the soft palate in the mouth can be reshaped, strengthened, stiffened or otherwise altered, including but not limited to skin, muscle, mucosa, submucosa and/or cartilage of the soft palate. This change in the soft palate can prevent collapse of the soft palate or vibration of the soft palate during nighttime breathing and thus prevent or at least reduce sleep apnea and/or snoring. One example of this is reducing nasal congestion through treatment of the nasal nerves leading to better breathing during sleep. This also reduces the negative pressure generated in the nasal cavity on inspiration leading to less airway collapse.

[0162] By way of another non-limiting example, in some embodiments, the systems and methods of the present disclosure can be used to treat or alleviate nasal airway obstruction, or to increase airflow, by, for example, modifying or reshaping various structures of the nasal cavity, such as the nasal valve area, turbinates, nasal wall, or similar tissue in the nasal cavity. For example, this can be used for improving breathing by decreasing airflow resistance or perceived airflow resistance at or near a site of an internal or external nasal valve. 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 a deviated septum, enlarged turbinates, mucosal swelling, and/or mucus overproduction.

[0163] By way of another non-limiting example, in some embodiments, the systems and methods of the present disclosure can be used for mucosal resurfacing or remodeling by delivering stimulus to mucosal tissue. A stimulus can be applied to cause local destruction of the mucosal layer and replacement with healthier mucosal tissue, which may mean fewer mucous glands, fewer mucus producing cells, less inflammation, fewer inflammatory cells, or more normal nerve function.

[0164] In some embodiments, the systems and methods of the present disclosure can be used to effect mucosal remodeling through direct stimulus from an agent or a stimulus. The resurfacing of the mucosa replaces the diseased or chronically inflamed mucosal cells with healthy mucosa that has more normal function, such as producing less mucus or other fluids, being less prone to allergy, and having less nerve stimulation and/or less activity of inflammatory cells. In some embodiments, this can be through modification of the cell types that comprise the mucosal layers. In some embodiments, this can include removing nerve ending present in the mucosal layer.

[0165] In some embodiments, the systems and methods of the present disclosure can be used to apply energy to submucosal tissue, such as mucus cells and glands. In some embodiments, the energy is applied to the posterior region of the nasal cavity.

[0166] FIG. **43**A and FIG. **43**B show an exemplary cross-sectional view of the mucosa, according to one or more embodiments herein. In reference to FIGS. **43**A and **43**B, the stimulus can be delivered at a desired depth deeper than the thickness of the mucosa. The mucosal layer of the nasal cavity is between 0.5 mm and 5.0 mm thick, with an average thickness of 3.5 mm. In some embodiments, the energy is applied within submucosal tissue to destroy or vary a function of ciliated cells, goblet cells, or other epithelial cells of the nasal cavity, or mucous or serous glands.

[0167] In some embodiments, the systems and methods of the present disclosure can be used to apply a stimulus to neuromodulate certain nerves within the nasal cavity. In some embodiments, any nerve or combination of nerves in the nasal cavity can be treated to treat various conditions inside or outside of the nasal cavity. Generally, nasal neuromodulation may involve treating one or more nerves to change or disrupt their functions without completely stopping their function. At the same time, however, nasal neuromodulation may involve completely destroying the nerve tissue or stopping the function of one or more nerves while allowing one or more other nerves in the same area to maintain their function. Typically, the systems of the present disclosure will contact the mucosa overlying one or more of these one or more nerves, and energy will be delivered through the mucosa to neuromodulate the nerves. In some embodiments, the treatments of the present disclosure may involve disruption of parasympathetic and/or sensory nerve signals in one or more nerves (e.g., the posterior nasal nerve). In some embodiments, the destruction of submucosal tissue, as discussed above, may also change or disrupt the functions of the nerves in the same region (e.g., the posterior nasal region).

[0168] FIGS. **44**A and **44**B are sagittal views of a human nasal cavity, illustrating the lateral wall and nasal nerves that are related to the treatment of migraines and/or headaches. Referring to FIG. **44**A, a sagittal cross-section of a human nasal cavity is shown. In this cross-sectional view, bone has been removed to illustrate the path of multiple different nerves, such as the vidian nerve and the sphenopalatine ganglion. According to various embodiments and examples described herein, any nerve or combination of nerves may be treated, such as but not limited, to the vidian nerve, vidian nerve branches, the sphenopalatine ganglion and/or any nerve branching from the sphenopalatine ganglion, such as the posterior nasal nerves (PNN), the posterolateral nasal nerves (PLNN), the posterior inferior lateral nasal nerves, and the posterior superior lateral nasal nerves (descending from the sphenopalatine ganglion in FIG. **44**A but not labeled).

[0169] In reference to FIG. **45**A, in some embodiments, nerves in the nasal cavity that can be treated include, but are not limited to, the frontal nerve, nasociliary nerve, ciliary ganglion, posterior nasal nerve, posterior ethmoidal nerve, supra-orbital nerve, infratrochlear nerve, olfactory nerve, trigeminal nerve, nasopalatine nerve, maxillary nerve, sphenopalatine ganglion, anterior nasal nerves, and the anterior ethmoidal nerve and its branches.

[0170] In some embodiments, the present disclosure includes neuromodulation of nerves in the posterior nasal region, such as posterior nasal nerves (PNN), the posterolateral nasal nerves (PLNN), the posterior inferior lateral nasal nerves, and the posterior superior lateral nasal nerves.

[0171] In some embodiments, the systems and methods of the present disclosure can be used to apply energy to reshape one or more tissues in the nasal cavity. FIGS. **45**A, **45**B, **45**C, and **45**D 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.

[0172] FIG. **45**C 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. **45**C and the detailed view of FIG. **45**B, both inner and outer surfaces of the nasal cartilage are covered with soft tissue including mucosa, sub-mucosa and skin. FIG. **45**D illustrates a view of the nose as seen from the nostrils. FIG. **45**D depicts a nasal valve **1** shown between a septum **2** and a upper lateral cartilage **3**. FIG. **45**D also depicts the position of a turbinate **4**.

[0173] In reference to FIG. **45**E, three bony structures covered in mucosal tissue, called the superior, middle and inferior nasal turbinates, extend inwardly from each of the two lateral walls of the nasal cavity. FIG. **45**E shows the right lateral wall of the nasal cavity, including the superior turbinate ST, superior meatus SM, a cut away middle turbinate MT, middle meatus MM, inferior turbinate IT and inferior meatus IM. The downwardly curved edge of each turbinate defines a passageway below each turbinate, known as a meatus. The inferior meatus is located beneath the inferior turbinate, the middle meatus is located beneath the middle turbinate, and the superior meatus is located beneath the superior turbinate.

[0174] In some embodiments, the devices of the present disclosure can be used to conformationally change the structure of one or more of these tissues of the nasal cavity.

[0175] For example, the systems of the present disclosure can be used to reshape the internal or external nasal valve anatomy to allow greater airflow without necessarily expanding the diameter of the nasal passage. In some embodiments, energy may be delivered into the nasal valve, submucosal tissue, lateral walls of the nasal cavity, nasal septum, the inferior anterior, and middle turbinates, or cartilage tissue to cause a conformational change and/or a change in the physical properties of the submucosal tissue or cartilage. For example, in some embodiments, energy may be applied to a targeted region of tissue adjacent to 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. For example, energy delivery may be accomplished by transferring the energy through the tissue covering the submucosa or cartilage such as the epithelium, mucosa, sub-mucosa, muscle, ligaments, tendon and/or skin.

[0176] 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.

[0177] Referring to FIG. **45**E, a sagittal cross-section of a human nasal cavity is shown. In this cross-sectional view, the middle turbinate MT has been removed, to show the path of the posterior nasal nerve PNN. Also shown are the superior turbinate ST, superior meatus SM, middle meatus MM, inferior turbinate IT and inferior meatus IM. Although the systems, devices and methods described herein may be

used to treat other nerves and other tissues in the nasal cavity, the PNN is one of the primary nerve tissue targets for treating chronic rhinitis, allergic rhinitis, post nasal drip, chronic cough, migraines, and/or other headache conditions. Another nerve, the ethmoid nerve (or "ethmoidal nerve") and its branches are not shown in FIG. **45**E, but any treatment device or method described herein may be used for treating the ethmoid nerve and/or its branches instead of, or in addition to, the PNN or any other nasal nerve(s). For the purposes of this application, the term "rhinitis" is used as an inclusive term to describe any one of, or a combination of, chronic rhinitis, allergic rhinitis, post nasal drip and/or chronic cough, as well as any symptoms that stem therefrom. In an actual patient, the PNN and other nasal nerves lie under the nasal mucosa and thus are not visible or on the surface, as they are in FIG. **45**E. This anatomical drawing is provided for illustration purposes only.

[0178] In one aspect of the present disclosure, a system for treating nasal airway tissue includes a console and a stylus. The console includes a housing, a pulsed electric field generator in the housing, a computer processor in the housing, and an outlet on the housing. The stylus includes a handle, a power cord connected to a first end of the handle (the power cord including a connector at an opposite end for connecting to the outlet), a shaft extending from a second end of the handle, and a distal tip extending from a distal end of the shaft. The distal tip includes a treatment surface and multiple electrodes on the treatment surface configured to deliver pulsed electric field energy provided by the pulsed electric field generator.

[0179] In some embodiments, the shaft of the stylus is malleable and has a width of 4 millimeters to 5 millimeters. In some embodiments, the multiple electrodes comprise two rows of protruding, non-piercing electrodes. In some embodiments, the treatment surface is convex. In some embodiments, the shaft of the stylus has a length of at least 3.75 inches.

[0180] Optionally, the system may also include a power cord coupled with the console, and a foot pedal attachable to the console for activating the console to supply the pulsed electric field energy to the stylus. The system may also include an on/off button on the stylus for activating the console to supply the electrical energy to the stylus. In various embodiments, the pulsed electric field generator is configured to provide exponentially decaying, square wave, bipolar, monophasic, biphasic, and/or oscillatory pulses.

[0181] In another aspect of a present disclosure, a method for treating a nasal airway involves activating a pulsed electric field generator console attached to a stylus, advancing a distal tip of the stylus into a nostril of the patient, and contacting nasal mucosa lining the nasal airway with a treatment surface of the distal tip. The method then involves delivering pulsed electric field energy from at least a first electrode on the treatment surface to at least a second electrode on the treatment surface, to treat a tissue underlying the nasal mucosa, and removing the distal tip of the stylus from the nostril.

[0182] In some embodiments, the method may further involve moving the distal tip to multiple additional locations within the nasal airway and delivering the pulsed electric field energy to nasal airway tissue at the multiple additional locations. In some embodiments, the tissue comprises at least one nasal nerve. For example, the nasal nerve may be, but is not limited to, a posterior nasal nerve or an anterior ethmoid nerve.

[0183] In some embodiments, the method may include sensing a temperature of the nasal mucosa with a temperature sensing member on the treatment surface of the distal tip. Such a method may optionally further involve automatically shutting off delivery of the pulsed electric field energy from the console to the stylus if the sensed temperature is above a predefined acceptable maximum temperature. Alternatively or additionally, the method may include sensing an impedance in tissue between the first electrode and the second electrode with an impedance sensing member. Such a method may also include automatically shutting off delivery of the pulsed electric field energy from the console to the stylus if the sensed impedance is outside a predefined acceptable impedance range.

[0184] Optionally, the method may further involve bending the shaft before inserting the distal tip into the nostril. In some embodiments, the first electrode comprises a first row of electrodes, and the second electrode comprises a second row of electrodes. The method may also involve injecting an anesthetic fluid into the nasal mucosa before advancing the distal tip of the stylus into the nostril, to enhance conduction of the delivered electrical energy through the mucosal tissue.

[0185] In some embodiments, delivering the pulsed electric field energy ablates the tissue underlying the nasal mucosa. In some embodiments, the tissue comprises nerve tissue, and the method further involves delivering the pulsed electric field energy to an additional tissue, such as but not limited to an inferior turbinate, a middle turbinate, a superior turbinate, a nasal septum, and a septal swell body.

[0186] Medical devices that use energy to treat tissue in the body are used for a wide variety of procedures, to treat many different conditions and injuries. For example, in some embodiments, an energy delivery device is inserted into a patient's nostril to deliver energy (and sometimes mechanical force) to tissue in the nose. This type of energy delivery treatment may be used to reshape cartilage and/or other structures in the nose and/or to change other properties of tissues, such as nerves underlying the nasal mucosa lining the walls of the nasal cavity. The treatments may address any of a wide variety of conditions, just two examples of which are nasal valve insufficiency (which may cause difficulty breathing through the nose) and chronic or allergic rhinitis. Examples of nasal tissue treatment devices, systems and methods patented by the applicant include U.S. Pat. Nos. 8,936,594; 9,486,278; 8,986,301; 9,027,597; 9,179,964; 9,452,010; 9,415,194; 9,179,967; 9,788,886; 9,801,752; 9,433,463; 10,335,221; 9,943,361; 9,687,296; 10,398,489; 9,237,924; 9,526,571; 9,913,682; 10,028,780; 10,265,115; 10,485,603; 10,376,300; 10,456,186; 10,456,185; 9,888,957; and 10,470,814, and U.S. patent application Ser. No. 16/668,678, all of which are hereby incorporated by reference in this application, and all of which may be referred to collectively herein as the "Incorporated References."

[0187] Although this application is believed to be complete and accurate, any suitable changes may be made to any of the described embodiments and features described above, without departing from the scope of the invention.

We claim:

1. A system for treating tissue in a nasal airway, the system comprising:

a console comprising a pulsed electric field generator configured to generate pulsed electric field energy in the form of high frequency alternating pulses of energy delivered as a pulse train, the pulsed electric field generator comprising a plurality of output channels; and

a treatment device comprising an elongate shaft having a treatment surface on a distal end thereof, the treatment surface comprising a plurality of electrode pairs configured to deliver the pulsed electric field energy provided by the pulsed electric field generator to a target tissue in the nasal airway,

wherein each of the plurality of output channels is connected with a subset of the plurality of electrode pairs to provide pulsed electric field energy to the plurality of electrode pairs.

2. The system of claim **1**, wherein the pulsed electric field generator is configured to deliver pulsed field ablation energy to the plurality of electrode pairs.

3. The system of claim **1**, wherein the pulsed electric field generator is configured to deliver pulsed radiofrequency energy to the plurality of electrode pairs.

4. The system of claim **1**, wherein the pulse train is configured to be delivered in repeated intervals to create a string of pulse trains with an interval of time between pulse trains to allow for tissue recovery between each pulse train.

5. The system of claim **1**, wherein the plurality of output channels is configured to connect with the plurality of electrode pairs to provide independent pulsed electric energy from each of the plurality of output channels to each of subsets of the plurality of electrode pairs.

6. The system of claim **1**, further comprising at least one sensor configured to measure a temperature of the target tissue.

7. The system of claim **1**, wherein the shaft of the treatment device is malleable and has a width of 4 millimeters to 5 millimeters.

8. The system of claim **1**, wherein the plurality of electrode pairs comprises at least two rows of electrodes pairs.

9. The system of claim **1**, wherein the pulsed electric field generator is configured to provide at least one of exponentially decaying, square wave, bipolar, or oscillatory pulses.

10. A system for treating nasal airway tissue, the system comprising:

a pulsed electric field generator configured to generate pulsed electric field energy in the form of alternating pulses of energy delivered as a pulse train, the pulsed electric field generator comprising a plurality of output channels; and

a treatment device comprising an elongate shaft having a treatment surface on a distal end thereof, the treatment surface comprising a first row of electrodes comprising a first plurality of electrode pairs and a second row of electrodes comprising a second plurality of electrode pairs configured to deliver pulsed electric field energy provided by the pulsed electric field generator to a target tissue in the nasal airway;

wherein each of the plurality of output channels is connected with a subset of the first and second plurality of electrode pairs to provide pulsed electric field energy to the plurality of electrode pairs.

11. A method for treating a nasal airway, the method comprising:

activating a pulsed electric field generator console attached to a treatment device to generate pulsed electric field energy in the form of high frequency alternating pulses of energy delivered as a pulse train;

advancing a distal tip of the treatment device into the nasal airway of a patient;

contacting a nasal mucosa lining the nasal airway with a treatment surface at a distal end of the treatment device;

delivering the pulsed electric field energy from at least a first electrode on the treatment surface to at least a second electrode on the treatment surface, to treat a tissue underlying the nasal mucosa lining; and

removing the distal tip of the treatment device from the nasal airway.

12. The method of claim **11**, further comprising moving the distal tip to multiple additional locations within the nasal airway; and delivering the pulsed electric field energy to nasal airway tissue at the multiple additional locations.

13. The method of claim **11**, wherein the tissue comprises at least one nasal nerve selected from the group consisting of a posterior nasal nerve and an anterior ethmoid nerve.

14. The method of claim **11**, further comprising sensing a temperature of the nasal mucosa lining with a temperature sensing member on the treatment surface of the distal tip.

15. The method of claim **14**, further comprising automatically shutting off delivery of the pulsed electric field energy from the pulsed electric field generator if the temperature is above a predefined acceptable maximum temperature.

16. The method of claim **11**, further comprising:

sensing an impedance in the tissue between the first electrode and the second electrode with an impedance sensing member; and

automatically shutting off delivery of the pulsed electric field energy from the pulsed electric field generator console to the treatment device if the impedance is outside a predefined acceptable impedance range.

17. The method of claim **11**, wherein the at least the first electrode comprises a first row of electrodes, and wherein the at least the second electrode comprises a second row of electrodes.

18. The method of claim **11**, further comprising injecting an anesthetic fluid into the nasal mucosa lining before advancing the distal tip of the treatment device into the nasal airway, to enhance conduction of the pulsed electric field energy through the tissue.

19. The method of claim **11**, wherein delivering the pulsed electric field energy ablates the tissue underlying the nasal mucosa lining.

20. The method of claim **19**, wherein the tissue comprises nerve tissue, and wherein the method further comprises delivering the pulsed electric field energy to an additional tissue selected from the group consisting of an inferior turbinate, a middle turbinate, a superior turbinate, a nasal septum, and a septal swell body.

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