UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL, INC.
Patent Owner

Case IPR2024-00277
U.S. Patent No. 11,241,271

PETITIONERS' DEMONSTRATIVES FOR ORAL ARGUMENT

Neurent Medical Inc. et al. v. Aerin Medical Inc.

IPR2024-00277; IPR2024-00278; IPR2024-00282

April 23, 2025

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

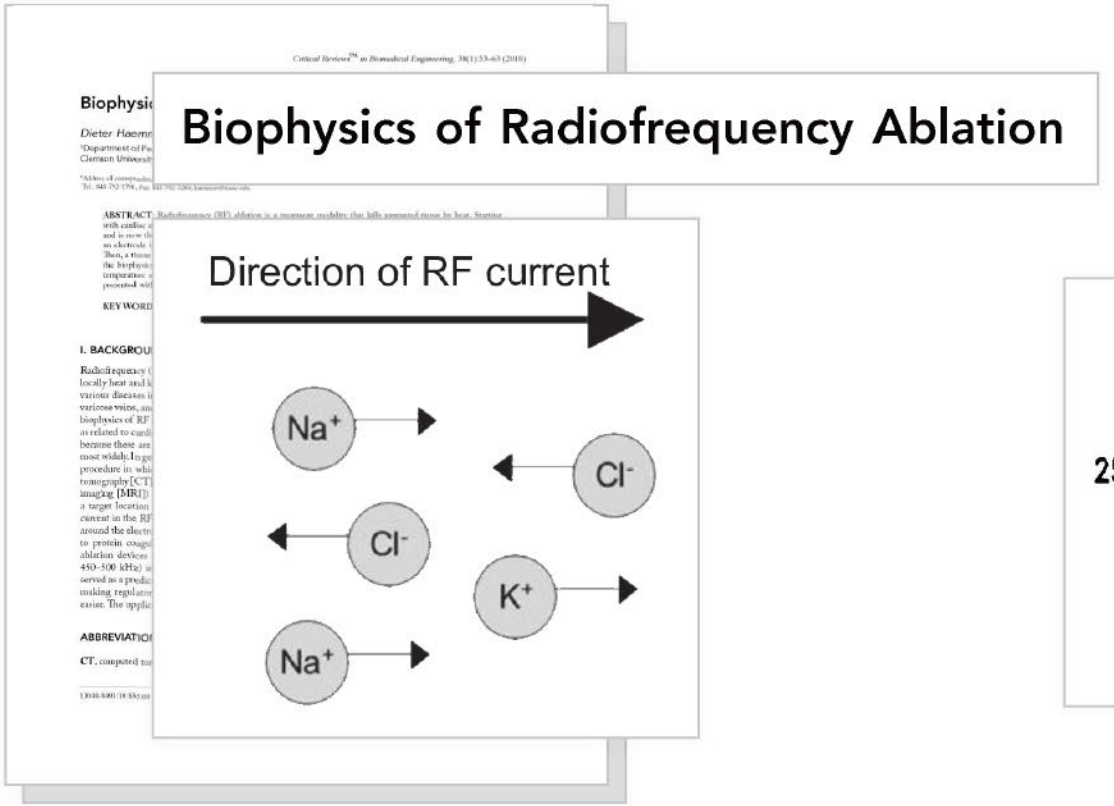
Agenda

1. Technology and Prior Art Overview
2. Stern Discloses the claimed electrode pairs
   - Stern discloses multiple bipolar electrode pairs
   - Stern discloses “two rows” of bipolar electrode pairs
   - A POSITA would have been motivated to arrange bipolar RF electrodes in Edwards-’535 in two rows
3. Stern Discloses “multiple RF output channels”
4. Patent Owner’s Definition of a POSITA Is Incorrect and Irrelevant to Any Disputed Issue

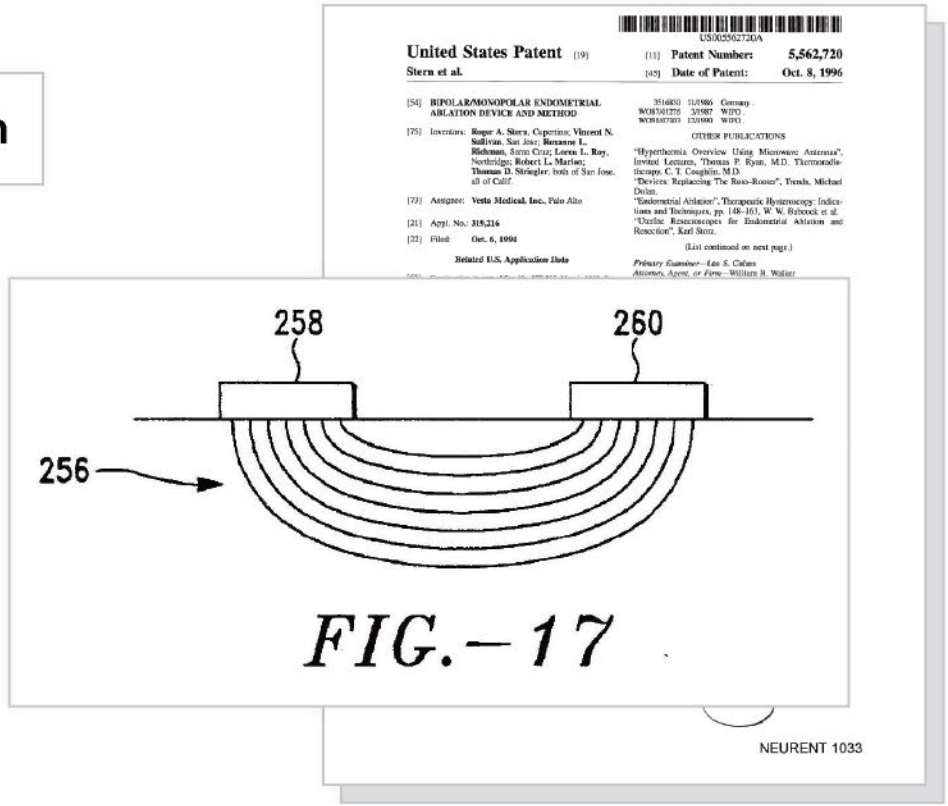
Technology and Prior Art Overview

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Bipolar Radiofrequency (RF) Energy Was Known



Ex.1051, 54; '277 Petition, 8-9; '278 Petition, 11; '282 Petition, 9; '277 Ex.1004, ¶29; '278 Ex.1002, ¶29; '282 Ex.1002, ¶29



Ex.1033, Fig.17; '277 Petition, 12; '278 Petition, 114; '282 Petition, 11; '277 Ex.1004, ¶¶38-40; '278 Ex.1002, ¶38; '282 Ex.1002, ¶41

Bipolar RF Energy Devices Were Used to Treat Nasal Tissue

US006517535B2

(12) **United States Patent**
Edwards

(10) **Patent No.: US 6,517,535 B2**
(45) **Date of Patent: *Feb. 11, 2003**

(54) **APPARATUS FOR ABLATING TURBINATES** (56) **References Cited**

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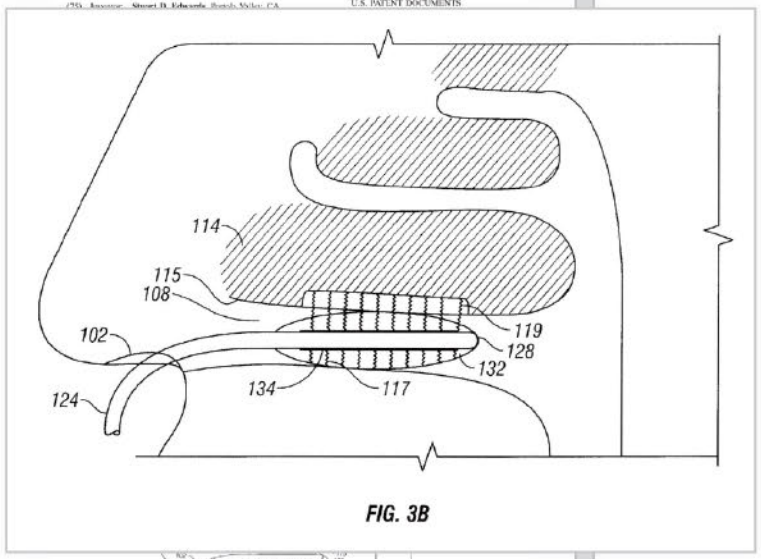


FIG. 3B

NEURENT 1010

Ex.1010, Fig.3B, 10:30-32, 10:52-61; '277 Petition, 35; '278 Petition, 33; '282 Petition, 33-34; '277 Ex.1002, ¶84; '277 Ex.1004, ¶67; '278 Ex.1002, ¶96; '282 Ex.1002, ¶¶105-106

Eur Arch Otorhinolaryngol (2009) 266:1257–1266
DOI 10.1007/s00405-009-0914-y

RHINOLOGY

Radiofrequency thermal ablation for patients with nasal symptoms: a systematic review of effectiveness and complications

Maija L. Hytönen · Leif J. J. Bäck · Antti V. Malmivaara · Risto P. Roine

Received: 1 October 2008 / Accepted: 12 January 2009 / Published online: 3 February 2009

Table 1 Different radiofrequency generators and applicators used in the treatment of ENT-disorders

Name of generator	KHz	Applicators	Polarity	Firm
Celon	465	Single use	Bipolar	Celon AG medical instruments, Germany
Coblator	100	Single use	Bipolar	ArthroCare, TX, USA
Curis RFA	4,000	Multi use	Bipolar	Sutter Medizintechnik GmbH, Germany
ORL-set Marinescu	4,000	Multi use	Bipolar	Sutter Medizintechnik GmbH, Germany
Somnoplasty	465	Single use	Monopolar	Somnus Medical Technologies, CA, USA
Surgitron	4,000	Single use	Bipolar	Ellman International Inc, NY, USA

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Helsinki and Uusimaa Hospital District,
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tion. However, there are many patients in whom nasal blockage remains despite medical treatment.

The inferior turbinate is in the anterior part of the nose and its hypertrophy or mucosal congestion is an important cause for nasal obstruction. If conservative treatment does not produce adequate relief of symptoms, operative treatment of the inferior turbinate is considered. The available methods include, for example, partial or total turbinectomy, electrocautery of the turbinate mucosa, laser vaporization/ reduction/cauterization of the mucosa, mucosal or submucosal microdebrider-assisted turbinoplasty, and cryosurgery.

Springer

NEURENT 1031

Ex.1031, 1258, Table 1; '277 Petition, 17-18; '282 Petition, 13; '277 Ex.1002, ¶45

Bipolar RF Energy Applied to Nasal Tissue + Bipolar RF Control

Edwards-'535 – Bipolar Nasal Ablation

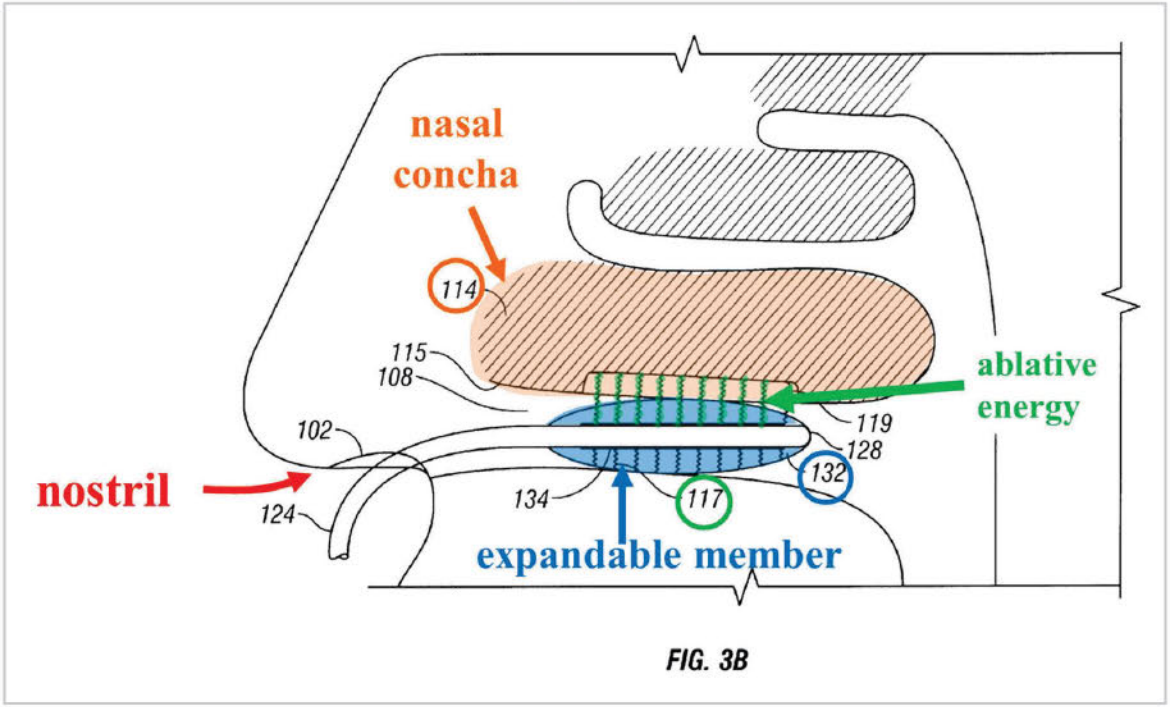
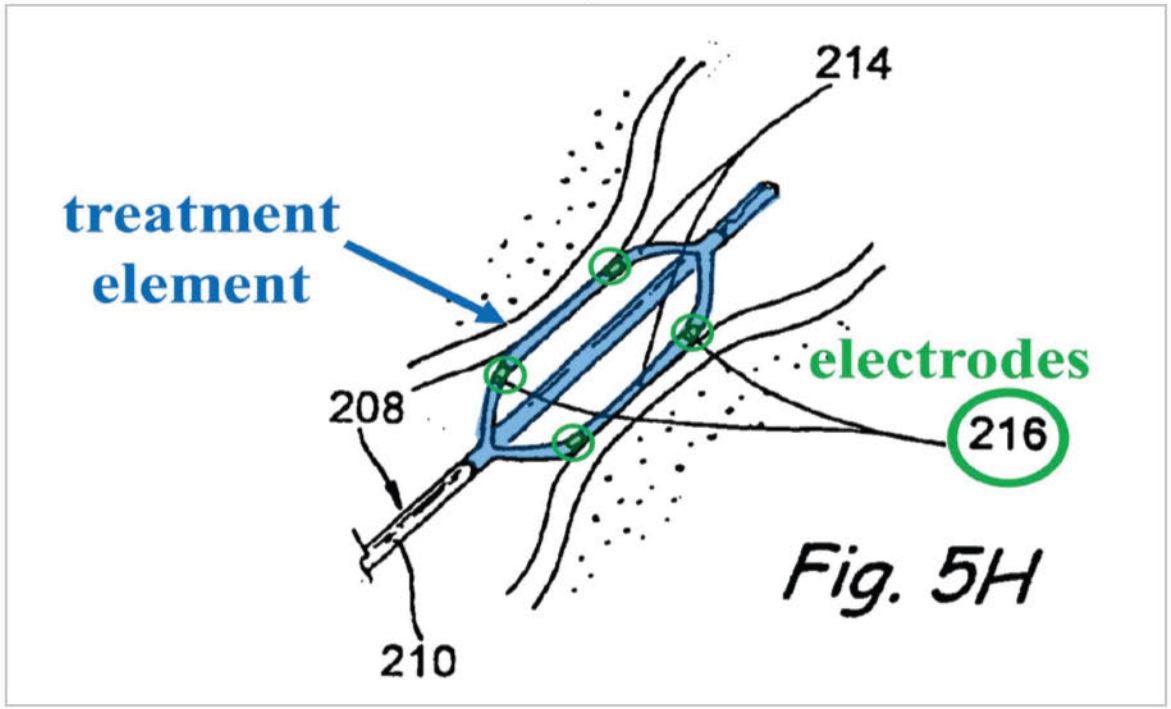


FIG. 3B

'277 Petition, 35-37; '278 Petition, 32-34; '282 Petition, 33-34; '277 Ex.1002, ¶¶84-91; '277 Ex.1004, ¶¶66-67; '278 Ex.1002, ¶¶95-97; '282 Ex.1002, ¶¶105-107

Bipolar RF Energy Applied to Nasal Tissue + Bipolar RF Control

Makower – Nitinol Bipolar Nasal Ablation



'278 Petition, 82; '282 Petition, 67-68;
'278 Ex.1002, ¶¶20-272; '282 Ex.1002, ¶¶238-239

Bipolar RF Energy Applied to Nasal Tissue + Bipolar RF Control

Stern – Bipolar RF Electrode Pairs and Channels

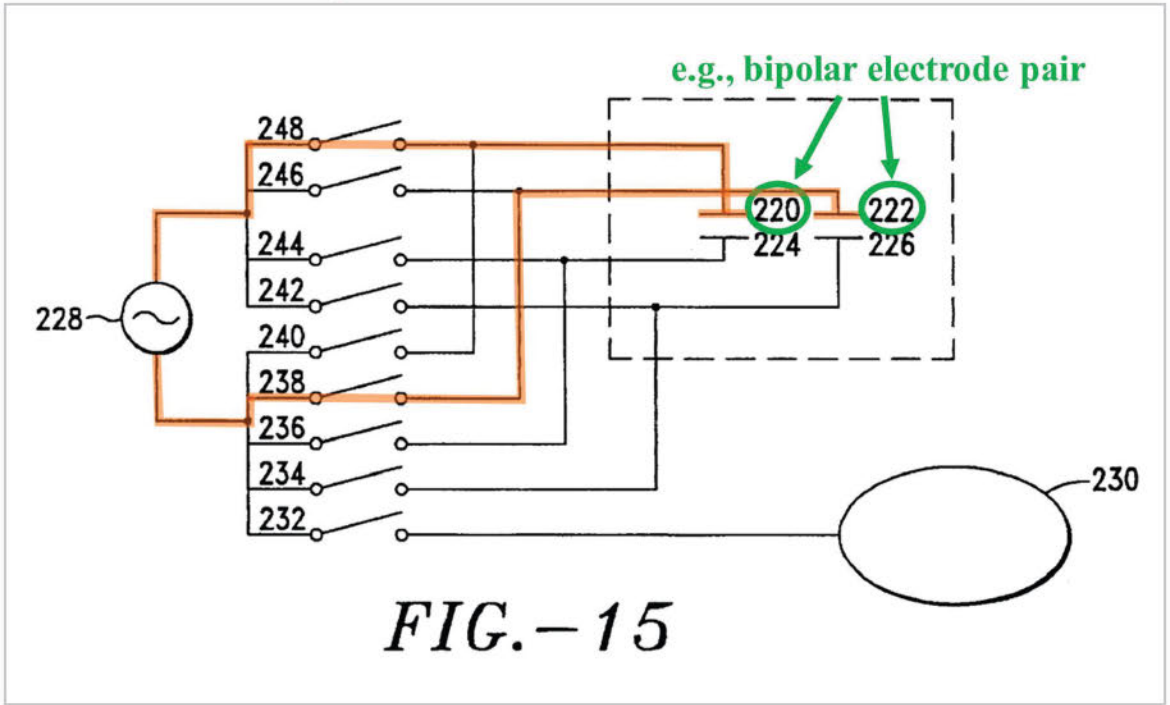


FIG.–15

'277 Petition, 38-41; '278 Petition, 34-36; '282 Petition, 35-36; '277 Ex.1002, ¶92; '277 Ex.1004, ¶¶70-74; '278 Ex.1002, ¶¶98-101; '282 Ex.1002, ¶¶108-111

Bipolar RF Energy Applied to Nasal Tissue + Bipolar RF Control

Edwards-'535 – Bipolar Nasal Ablation

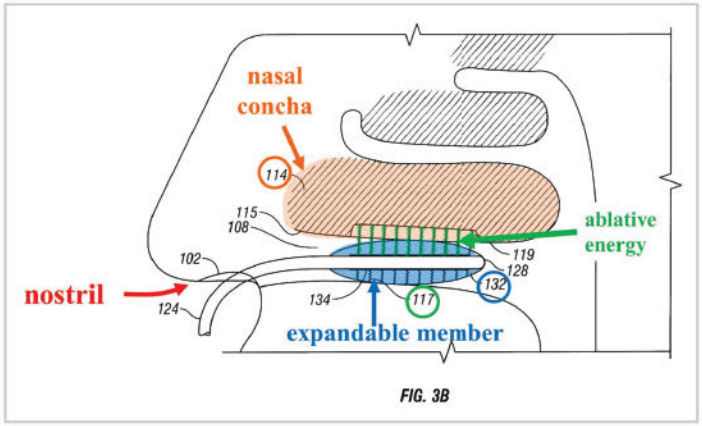


FIG. 3B

Makower – Nitinol Bipolar Nasal Ablation

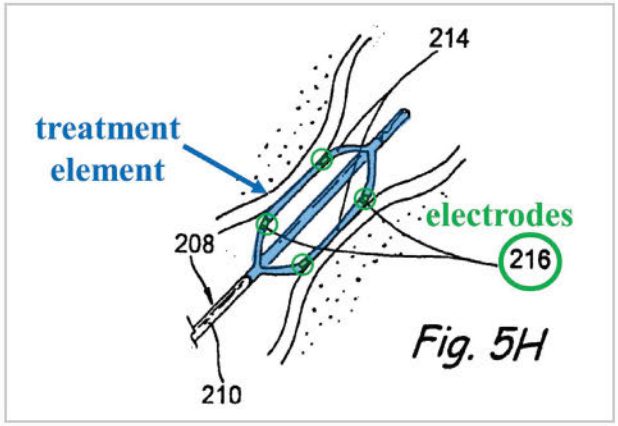


Fig. 5H

Stern – Bipolar RF Electrode Pairs and Channels

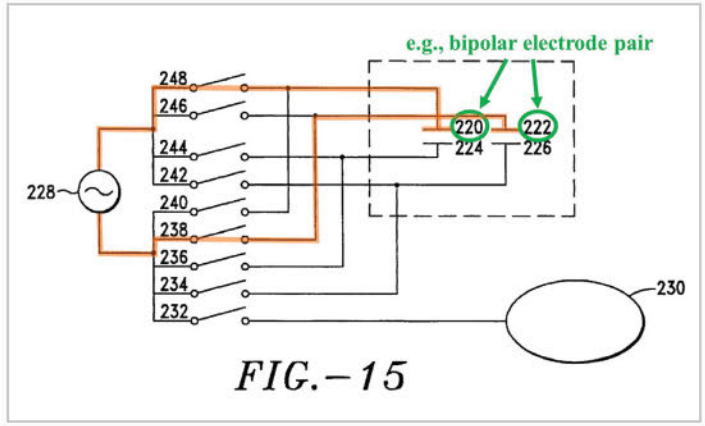
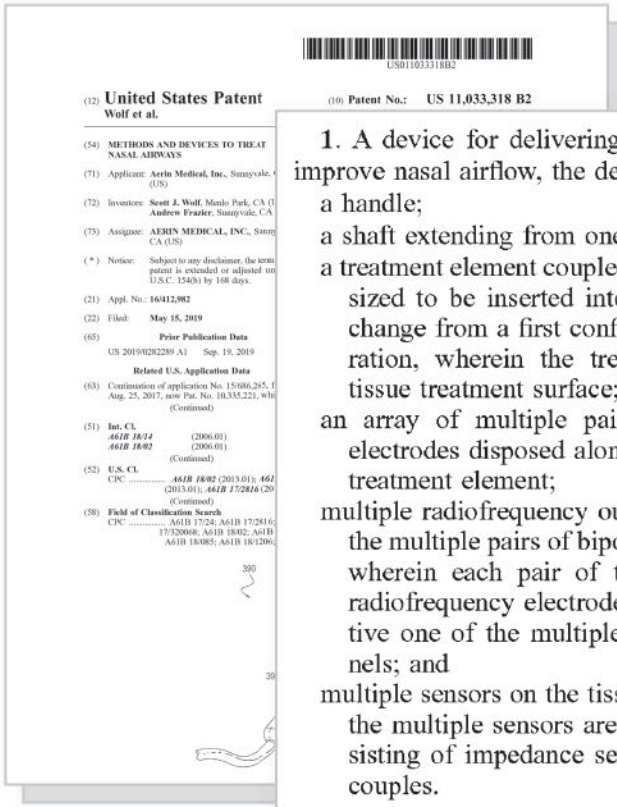


FIG.–15

'277 Petition, 41-49; '278 Petition, 36-41; 282 Petition, 36-40; '277 Ex.1002, ¶¶93-94; '277 Ex.1004, ¶¶75-97; '278 Ex.1002, ¶¶102-122; '282 Ex.1002, ¶¶112-133

Challenged Claims

Representative Independent Claims—'318 and '286 Patent



1. A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:

a handle;

a shaft extending from one end of the handle;

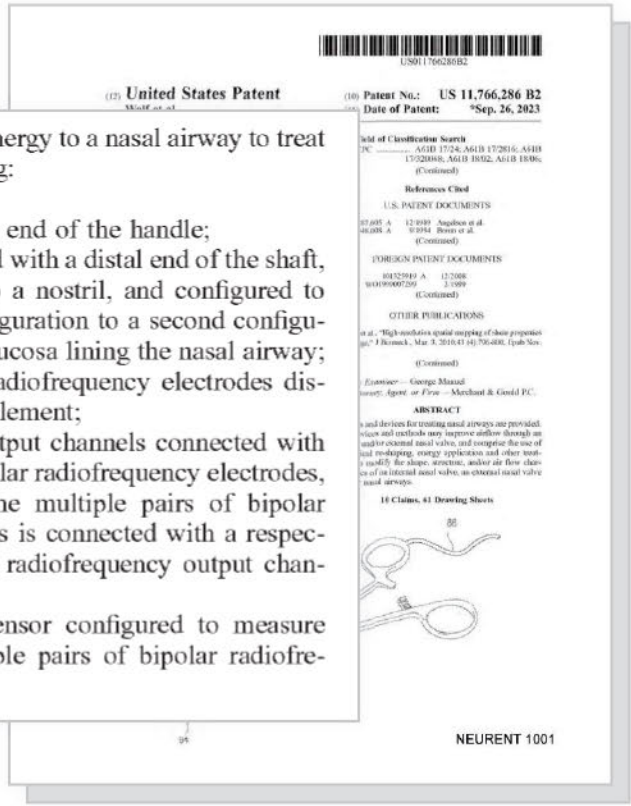
a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration, wherein the treatment element comprises a tissue treatment surface;

an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;

multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels; and

multiple sensors on the tissue treatment surface, wherein the multiple sensors are selected from the group consisting of impedance sensors, electrodes and thermocouples.

'278 Petition, Ex.1001-'318 Patent, Claim 1



1. A device for delivering energy to a nasal airway to treat rhinitis, the device comprising:

a handle;

a shaft extending from one end of the handle;

a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration to contact nasal mucosa lining the nasal airway;

multiple pairs of bipolar radiofrequency electrodes disposed on the treatment element;

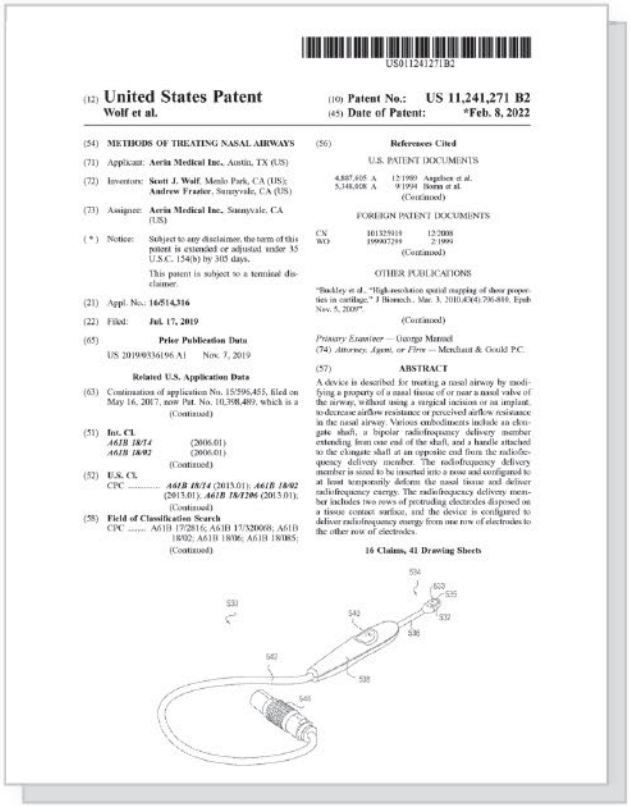
multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels; and

at least one impedance sensor configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes.

'282 Petition, Ex.1001-'286 Patent, Claim 1

Challenged Claims

Representative Independent Claim—'271 Patent



US011241271B2

(12) **United States Patent**
Wolf et al.

(10) **Patent No.: US 11,241,271 B2**
(45) **Date of Patent: *Feb. 8, 2022**

(54) **METHODS OF TREATING NASAL AIRWAYS**

(71) Applicant: **Aeria Medical Inc.**, Austin, TX (US)

(72) Inventors: **Scott J. Wolf**, Menlo Park, CA (US); **Andrew Frazier**, Sunnyvale, CA (US)

(73) Assignee: **Aeria Medical Inc.**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 305 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **16/514,316**

(22) Filed: **Jul. 17, 2019**

(65) **Prior Publication Data**

US 2019/0336196 A1 Nov. 7, 2019

Related U.S. Application Data

(63) Continuation of application No. 15/596,455, filed on May 16, 2017, now Pat. No. 10,398,489, which is a (Continued)

(51) **Int. Cl.**
A61B 18/14 (2006.01)
A61B 18/02 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 18/14*** (2013.01); ***A61B 18/02*** (2013.01); ***A61B 18/1206*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/2816; A61B 17/320068; A61B 18/02; A61B 1806; A61B 18085;
(Continued)

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Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — Merchant & Gould P.C.

(57) **ABSTRACT**

A device is described for treating a nasal airway by modifying a property of a nasal tissue of or near a nasal valve of the airway, without using a surgical incision or an implant, to decrease airflow resistance or perceived airflow resistance in the nasal airway. Various embodiments include an elongate shaft, a bipolar radiofrequency delivery member extending from one end of the shaft, and a handle attached to the elongate shaft at an opposite end from the radiofrequency delivery member. The radiofrequency delivery member is sized to be inserted into a nose and configured to at least temporarily deform the nasal tissue and deliver radiofrequency energy. The radiofrequency delivery member includes two rows of protruding electrodes disposed on a tissue contact surface, and the device is configured to deliver radiofrequency energy from one row of electrodes to the other row of electrodes.

16 Claims, 41 Drawing Sheets

1. A method for treating a nasal airway to reduce mucus production, the method comprising:

contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;

applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and

removing the treatment element from the nasal airway,

wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue, and

wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.

'277 Petition, Ex.1001-'271 Patent, Claim 1

Stern Discloses the Claimed Electrode Pairs

IPR2024-00277; IPR2024-00278; IPR2024-00282

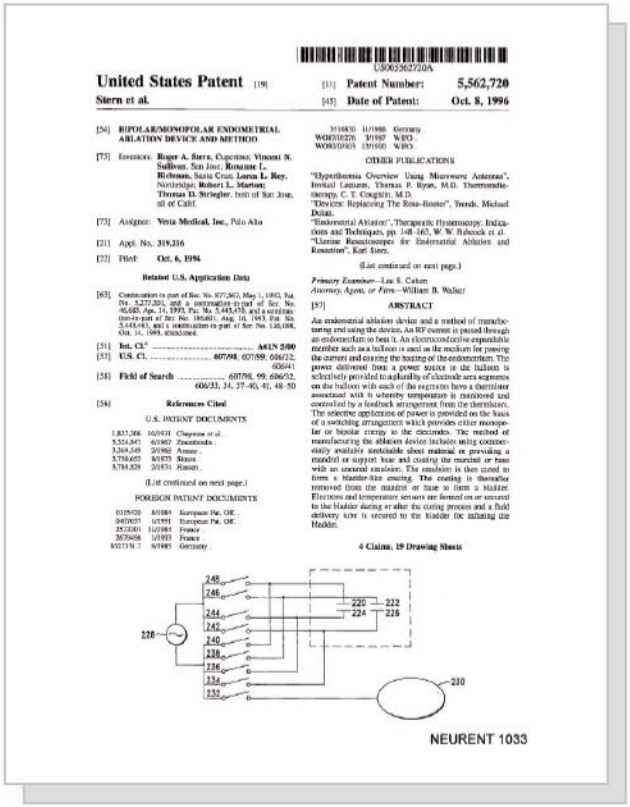
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Stern Discloses Both:

- multiple bipolar electrode pairs
  - "bipolar electrode pairs" – IPR2024-00277
  - "multiple pairs of bipolar radiofrequency electrodes" – IPR2024-00278, IPR2024-00282
- "two rows" of bipolar electrode pairs
  - "two rows of bipolar electrode pairs" – IPR2024-00277
  - "the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes" – IPR2024-00278

E.g., '277 Petition, 38-41; '278 Petition, 34-36; '282 Petition, 35-36; '277 Ex.1002, ¶92; '277 Ex.1004, ¶¶70-74; '278 Ex.1002, ¶¶98-101; '282 Ex.1002, ¶¶108-111

Stern Discloses Multiple Bipolar Electrode Pairs



US005562720A

United States Patent [19]
Stern et al.

[11] **Patent Number: 5,562,720**
[45] **Date of Patent: Oct. 8, 1996**

[54] **BIPOLAR/MONOPOLAR ENDOMETRIAL ABLATION DEVICE AND METHOD**

[75] Inventors: **Roger A. Stern**, Cupertino; **Vincent N. Sullivan**, San Jose; **Roxanne L. Richman**, Santa Cruz; **Loren L. Roy**, Northridge; **Robert L. Morton**; **Thomas D. Striegler**, both of San Jose, all of Calif.

[73] Assignee: **Vesta Medical, Inc.**, Palo Alto

[21] Appl. No.: **319,216**

[22] Filed: **Oct. 6, 1994**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 977,567, May 1, 1992, Pat. No. 5,272,293, and a continuation-in-part of Ser. No. 95,685, Apr. 14, 1993, Pat. No. 5,443,470, and a continuation-in-part of Ser. No. 105,601, Aug. 10, 1993, Pat. No. 5,443,481, and a continuation-in-part of Ser. No. 136,068, Oct. 14, 1993, abandoned.

[51] **Int. Cl.**[6] **A61N 5/00**
[52] **U.S. Cl.** **607/98**; 607/99; 606/32; 606/41
[58] **Field of Search** 607/98, 99; 606/32, 606/33, 34, 37-40, 41, 48-50

[56] **References Cited**

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"Endometrial Ablation", Therapeutic Hysteroscopy: Indications and Techniques, pp. 148-163, W. W. Babcock et al.
"Uterine Resectoscopes for Endometrial Ablation and Resection", Karl Storz.

(List continued on next page.)

Primary Examiner—Lee S. Cohen
Attorney, Agent, or Firm—William B. Walker

[57] **ABSTRACT**

An endometrial ablation device and a method of manufacturing and using the device. An RF current is passed through an endometrium so heat is. An electroconductive expandable member such as a balloon is used as the medium for passing the current and causing the heating of the endometrium. The power delivered from a power source or the balloon is selectively provided to a plurality of electrode area segments on the balloon with each of the segments have a thermistor associated with it whereby temperature is monitored and controlled by a feedback arrangement from the thermistors. The selective application of power is provided on the basis of a switching arrangement which provides either monopolar or bipolar energy to the electrodes. The method of manufacturing the ablation device includes using commercially available stretchable sheet material or providing a mandrel or support base and coating the mandrel or base with an uncured emulsion. The emulsion is then cured to form a bladder-like covering. The coating is thereafter removed from the mandrel or base to form a bladder. Electrodes and temperature sensors are formed on or secured to the bladder during or after the curing process and a fluid delivery tube is secured to the bladder for inflating the bladder.

4 Claims, 19 Drawing Sheets

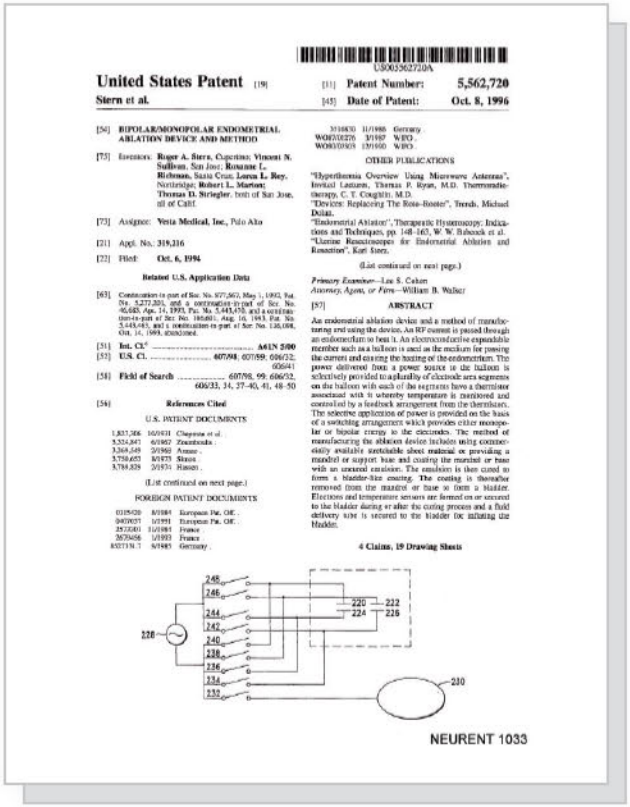
NEURENT 1033

many cases if a bipolar operation is utilized. When a bipolar operation occurs, the flow of the current return is a path between selected pairs of the electrodes. A switching arrangement to be described determines such pairs of electrodes or combinations of electrodes between which the current flows in the return path.

The embodiment of FIG. **15** not only provides a choice between monopolar and bipolar operation but also provides flexibility within the bipolar operation so that any pair or any combination of pairs of electrodes may be utilized together.

Ex.1033, 12:19-24, 13:39-42; '277 Petition, 38-39; '278 Petition, 34-35; '282 Petition, 35-36; '277 Ex.1002, ¶92; '277 Ex.1004, ¶¶70-71; '278 Ex.1002, ¶¶98-101; '282 Ex.1002, ¶¶108-111

Stern Discloses Multiple Bipolar Electrode Pairs



US005562720A

United States Patent [19]
Stern et al.

[11] **Patent Number: 5,562,720**
[45] **Date of Patent: Oct. 8, 1996**

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[75] Inventors: **Roger A. Stern**, Cupertino; **Vincent N. Sullivan**, San Jose; **Roxanne L. Richman**, Santa Cruz; **Loren L. Rey**, Northridge; **Robert L. Morton**; **Thomas D. Striegler**, both of San Jose, all of Calif.

[73] Assignee: **Vesta Medical, Inc.**, Palo Alto

[21] Appl. No.: **319,216**

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[51] **Int. Cl.**[6] **A61N 5/00**
[52] **U.S. Cl.** **607/98**; 607/99; 606/32; 606/41
[58] **Field of Search** 607/98, 99; 606/32, 606/33, 34, 37–40, 41, 48–50

[56] **References Cited**

U.S. PATENT DOCUMENTS

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"Endometrial Ablation", Therapeutic Hysteroscopy: Indications and Techniques, pp. 148–163, W. W. Babcock et al.
"Uterine Resectoscopes for Endometrial Ablation and Resection", Karl Storz.

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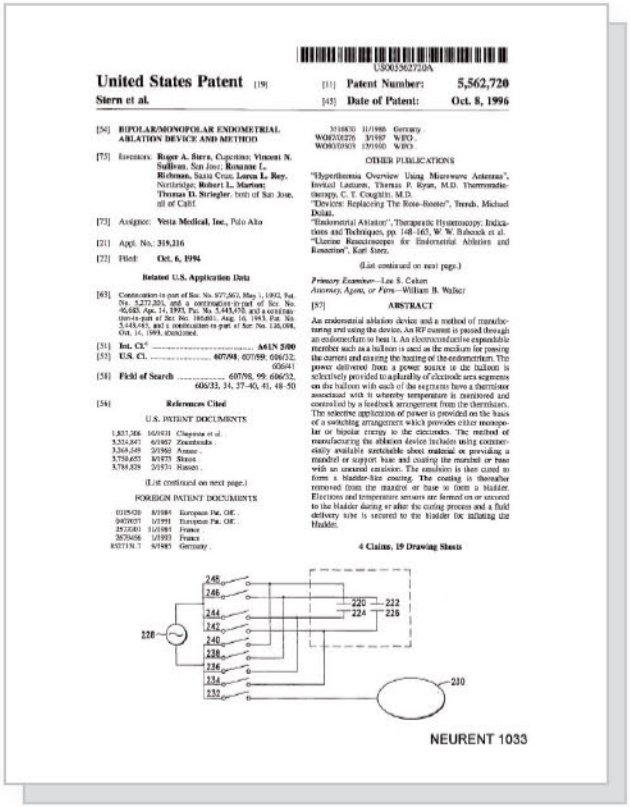
4 Claims, 19 Drawing Sheets

NEURENT 1033

> It is a further object of the present invention to provide a system of selective delivery of either monopolar RF energy to a single electrode or bipolar RF energy to chosen pairs of an array of separate electrodes which are used to bring the endometrial temperature to a desired level.

Ex.1033-'720 Patent, 2:36-40; '277 Petition, 38-39; '278 Petition, 34-35; '282 Petition, 35; '277 Ex.1002, ¶92; '277 Ex.1002, ¶70; '278 Ex.1002, ¶¶98-100; '282 Ex.1002, ¶¶108-110

Stern Discloses Multiple Bipolar Electrode Pairs



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[63] Continuation-in-part of Ser. No. 877,567, May 1, 1992, Pat. No. 5,272,201, and a continuation-in-part of Ser. No. 95,685, Apr. 14, 1993, Pat. No. 5,443,470, and a continuation-in-part of Ser. No. 180,601, Aug. 16, 1993, Pat. No. 5,443,481, and a continuation-in-part of Ser. No. 136,068, Oct. 14, 1993, abandoned.

[51] **Int. Cl.**[6] **A61N 5/00**
[52] **U.S. Cl.** **607/98**; 607/99; 606/32; 606/41
[58] **Field of Search** 607/98, 99; 606/32, 606/33, 34, 37-40, 41, 48-50

[56] **References Cited**

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"Uterine Resectoscopes for Endometrial Ablation and Resection", Karl Storz.

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Primary Examiner—Lee S. Cohen
Attorney, Agent, or Firm—William B. Walker

[57] **ABSTRACT**

An endometrial ablation device and a method of manufacturing and using the device. An RF current is passed through an endometrium so heat is. An electroconductive expandable member such as a balloon is used as the medium for passing the current and causing the heating of the endometrium. The power delivered from a power source or the balloon is selectively provided to a plurality of electrode area segments on the balloon with each of the segments have a thermistor associated with it whereby temperature is monitored and controlled by a feedback arrangement from the thermistors. The selective application of power is provided on the basis of a switching arrangement which provides either monopolar or bipolar energy to the electrodes. The method of manufacturing the ablation device includes using commercially available stretchable sheet material or providing a mandrel or support base and coating the mandrel or base with an uncured emulsion. The emulsion is then cured to form a bladder-like coating. The coating is thereafter removed from the mandrel or base to form a bladder. Electrodes and temperature sensors are formed on or secured to the bladder during or after the curing process and a fluid delivery tube is secured to the bladder for inflating the bladder.

4 Claims, 19 Drawing Sheets

NEURENT 1033

trodes. The step of controlling said radio frequency energy can include selectively providing bipolar energy to selective pairs of said plurality of electrodes.

Ex.1033, 3:38-40; '277 Petition, 38; '278 Petition, 34-35; '282 Petition, 35; '277 Ex.1002, ¶92; '277 Ex.1004, ¶70; '278 Ex.1002, ¶99; '282 Ex.1002, ¶109

PO's Expert Agrees that Stern Discloses Delivering RF Energy Through Different Pairs



Dr. Marom Bikson

PO's Declarant

Q. Sure. You agree Stern has at least two different pairs of bipolar electrodes, correct?

A. **I think we've discussed that Stern allows you to select one pair of electrodes. And then if you return to the situation where the switches were open, you can select then another single, different pair.**

* * *

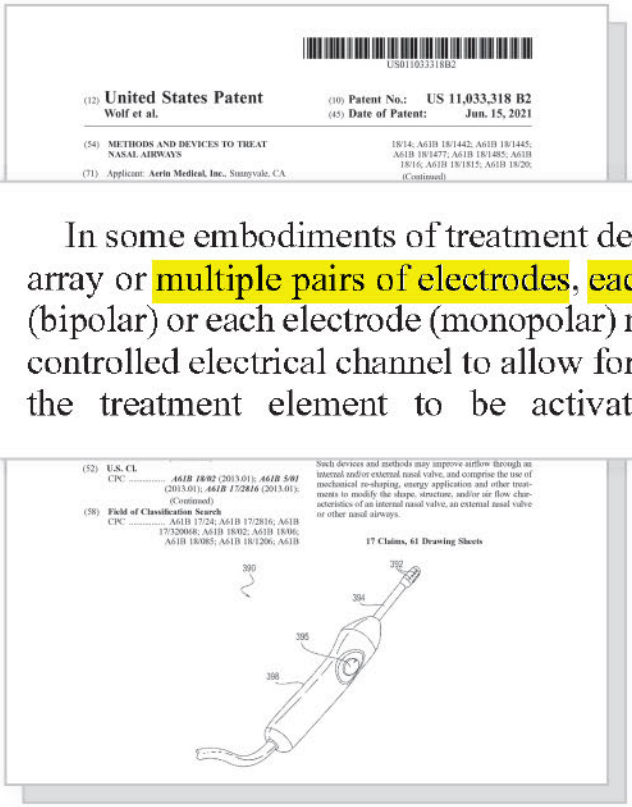
Q. But there are two pairs, correct?

A. **If you were to—we talked about a first case where you had one pair. We talked about a second case where you also had one pair. If you were to then add those up, you would get to the number two.**

'278 Petition, Ex.1084, 113:3-10, 115:6-11; '277 Reply, 3; '278 Reply, 3; '282 Reply, 3

Stern's Disclosure Is Parallel to Disclosure in Challenged Patent

'318 Patent



US011033318B2

(12) **United States Patent**
Wolf et al.

(10) **Patent No.: US 11,033,318 B2**
(45) **Date of Patent: Jun. 15, 2021**

(54) **METHODS AND DEVICES TO TREAT NASAL AIRWAYS**

(71) Applicant: **Aerin Medical, Inc.**, Sunnyvale, CA

18/14; A61B 18/1442; A61B 18/1445; A61B 18/1477; A61B 18/1485; A61B 18/16; A61B 18/1815; A61B 18/20; (Continued)

(52) **U.S. Cl.**
CPC ..... ***A61B 18/02*** (2013.01); ***A61B 5/01*** (2013.01); ***A61B 17/2816*** (2013.01); (Continued)

(58) **Field of Classification Search**
CPC A61B 17/24; A61B 17/2816; A61B 17/320068; A61B 18/02; A61B 18/06; A61B 18/085; A61B 18/1206; A61B

Such devices and methods may improve airflow through an internal and/or external nasal valve, and comprise the use of mechanical re-shaping, energy application and other treatments to modify the shape, structure, and/or air flow characteristics of an internal nasal valve, an external nasal valve or other nasal airways.

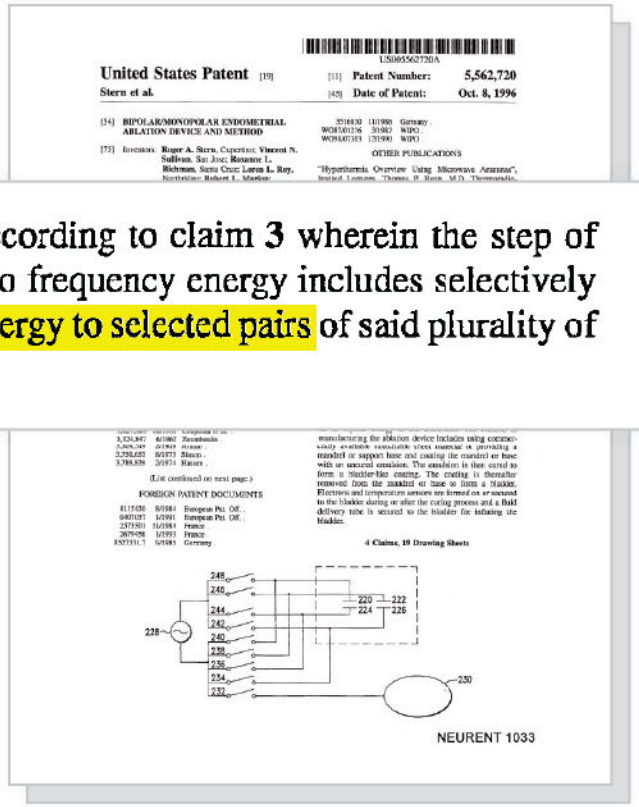
17 Claims, 61 Drawing Sheets

390 392 394 395 398

In some embodiments of treatment devices comprising an array or multiple pairs of electrodes, each pair of electrodes (bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. For

E.g., Ex.1001-318 Patent, 24:45-49; '278 Reply, 4; *see also* '277 Reply, 5; '282 Reply, 4

Stern



US005562720A

United States Patent [19]
Stern et al.

[11] **Patent Number: 5,562,720**
[45] **Date of Patent: Oct. 8, 1996**

[54] **BIPOLAR/MONOPOLAR ENDOMETRIAL ABLATION DEVICE AND METHOD**

[75] Inventors: **Roger A. Stern**, Cupertino; **Vincent N. Sullivan**, San Jose; **Roxanne L. Richman**, Santa Cruz; **Loren L. Roy**, Northridge; **Robert L. Mueller**,

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(List continued on next page.)

FOREIGN PATENT DOCUMENTS

4 Claims, 19 Drawing Sheets

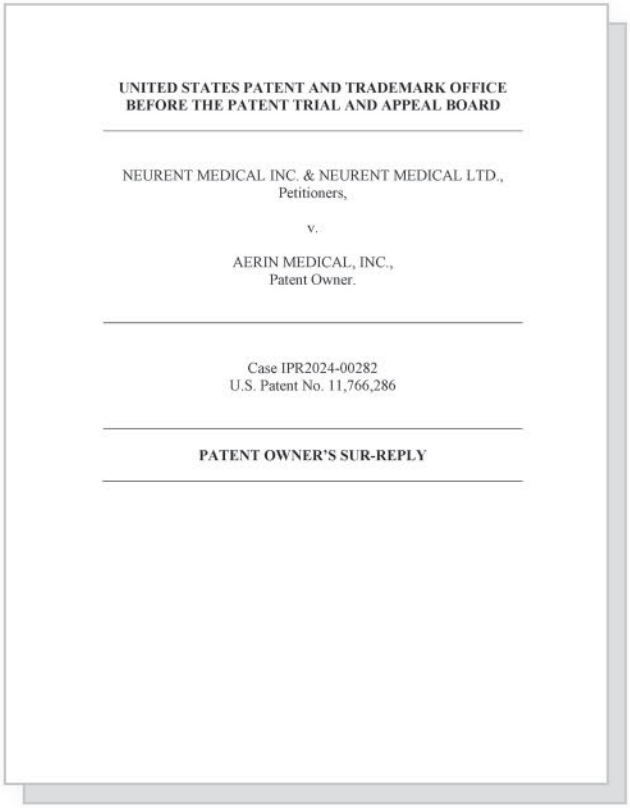
248 246 244 242 240 238 236 234 232 228 220 222 224 226 230

NEURENT 1033

4. The method according to claim 3 wherein the step of controlling said radio frequency energy includes selectively providing bipolar energy to selected pairs of said plurality of electrodes.

'278 Petition, Ex.1033, 20:6-10; '277 Reply, 3; '278 Reply, 3; '282 Reply, 3

Patent Owner Argues Multiple "bipolar pairs" Are Required to Deliver Energy Through Three or More Switches



UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,
Petitioners,

v.

AERIN MEDICAL, INC.,
Patent Owner.

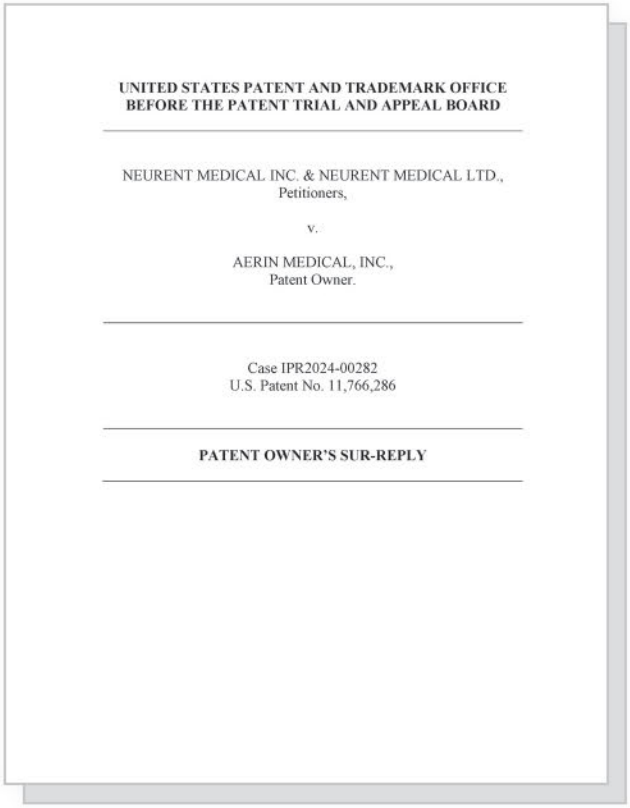
Case IPR2024-00282
U.S. Patent No. 11,766,286

PATENT OWNER'S SUR-REPLY

Bikson, ¶63; Ex-2008 at 202:14-203:4, 204:4-6.) Thus, for Stern's Figure 15 device to comprise "multiple pairs of bipolar radiofrequency electrodes," as claimed, three or more of Stern's switches must be closed. (POR at 18-19; Ex-2001-Bikson, ¶64.) Stern does not teach this. (*Id.*) Rather, Stern teaches a device that, at any given time, comprises at most one pair of electrodes. (*Id.*)

'277 Sur-Reply, 4; '278 Sur-Reply, 2; '282 Sur-Reply, 2

Patent Owner Argues Multiple "bipolar pairs" Are Required to Deliver Energy Through Three or More Switches



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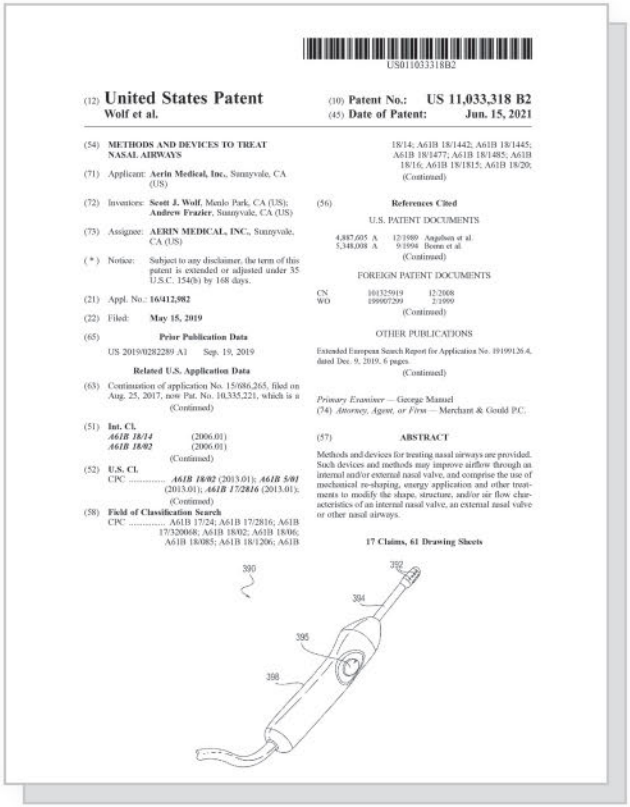
Case IPR2024-00282
U.S. Patent No. 11,766,286

PATENT OWNER'S SUR-REPLY

96:1, 125:9-126:1, 237:10-238:18; Ex-2008 at 17:2-18:13.) Petitioners fail to identify how their proposed combination teaches a device configured to have multiple pairs, as Stern teaches a device that, at any given time, comprises at most one pair of electrodes.

'278 Sur-Reply, 3; '282 Sur-Reply, 3; *see also* '277 Sur-Reply, 4

Stern's Disclosure Compared with the Disclosure of the Challenged Patents



US011033318B2

(12) **United States Patent**
Wolf et al.

(10) **Patent No.: US 11,033,318 B2**
(45) **Date of Patent: Jun. 15, 2021**

(54) **METHODS AND DEVICES TO TREAT NASAL AIRWAYS**

(71) Applicant: **Aerin Medical, Inc.**, Sunnyvale, CA (US)

(72) Inventors: **Scott J. Wolf**, Menlo Park, CA (US); **Andrew Frazier**, Sunnyvale, CA (US)

(73) Assignee: **AERIN MEDICAL, INC.**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 168 days.

(21) Appl. No.: **16/412,982**

(22) Filed: **May 15, 2019**

(65) **Prior Publication Data**

US 2019/0282289 A1 Sep. 19, 2019

Related U.S. Application Data

(63) Continuation of application No. 15/686,265, filed on Aug. 25, 2017, now Pat. No. 10,335,221, which is a (Continued)

(51) **Int. Cl.**
A61B 18/14 (2006.01)
A61B 18/02 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 18/02*** (2013.01); ***A61B 5/01*** (2013.01); ***A61B 17/2816*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/24; A61B 17/2816; A61B 17/320068; A61B 18/02; A61B 18/06; A61B 18/085; A61B 18/1206; A61B 18/14; A61B 18/1442; A61B 18/1445; A61B 18/1477; A61B 18/1485; A61B 18/16; A61B 18/1815; A61B 18/20;
(Continued)

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(Continued)

Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — Merchant & Gould P.C.

(57) **ABSTRACT**

Methods and devices for treating nasal airways are provided. Such devices and methods may improve airflow through an internal and/or external nasal valve, and comprise the use of mechanical re-shaping, energy application and other treatments to modify the shape, structure, and/or air flow characteristics of an internal nasal valve, an external nasal valve or other nasal airways.

17 Claims, 61 Drawing Sheets

an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;

In some embodiments of treatment devices comprising an array or multiple pairs of electrodes, each pair of electrodes (bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. For

In some embodiments, each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately.

Ex.1001-318 Patent, Claim 1

Ex.1001-'318 Patent, 24:45-49, 48:63-65; '278 Reply, 4; *see also* '277 Reply, 5; '282 Reply, 4

Stern's Disclosure Compared with the Disclosure of the Challenged Patents

to provide a feedback temperature for each electrode. The plurality of separate electrodes are independently and sequentially energized and controlled with thermistor temperature feedback control to bring the endometrial temperature to a desired level.

Ex.1033, 2:31-33; '277 Sur-Reply, 6; '278 Sur-Reply, 4; '282 Sur-Reply, 4

In some embodiments of treatment devices comprising an array or multiple pairs of electrodes, each pair of electrodes (bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. For

Ex.1001-'318 Patent, 24:45-49

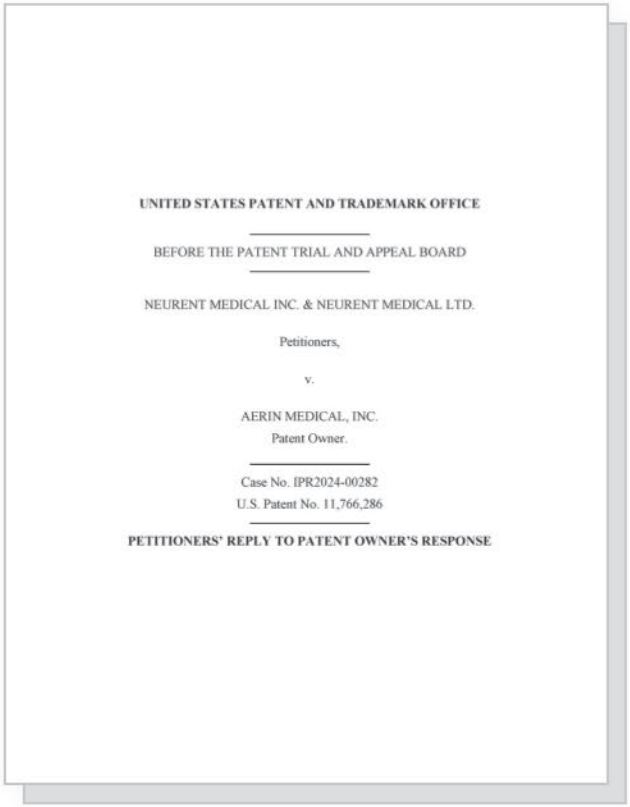
It is a further object of the present invention to provide a system of selective delivery of either monopolar RF energy to a single electrode or bipolar RF energy to chosen pairs of an array of separate electrodes which are used to bring the endometrial temperature to a desired level.

Ex.1033, 2:36-40; '277 Petition, 38-39; '278 Petition, 34-35; '282 Petition, 35; '277 Ex.1002, ¶92; '277 Ex.1004, ¶70; '278 Ex.1002, ¶¶98-100; '282 Ex.1002, ¶¶108-110

In some embodiments, each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately.

Ex.1001-'318 Patent, 48:63-65;
'278 Reply, 4; *see also* '277 Reply, 5; '282 Reply, 4

Patent Owner Did Not Respond to Cited Evidence



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL, INC.
Patent Owner.

Case No. IPR2024-00282
U.S. Patent No. 11,766,286

PETITIONERS' REPLY TO PATENT OWNER'S RESPONSE

have multiple pairs at the same time. (Reply at 5.) Petitioners' argument is based on a single sentence in Stern stating that "any combination of pairs of electrodes may be utilized together." (*Id.* (quoting Ex-1033-Stern at 13:39-43).) Petitioners

'277 Sur-Reply, 5; '278 Sur-Reply, 3; '282 Sur-Reply, 3

Stern discloses "pairs" of bipolar electrodes nine separate times, and there is no dispute that Stern discloses at least two different pairs of bipolar electrodes. Ex.1033-Stern, 2:36-40, 3:38-40, 12:20-22, 12:22-24, 12:29-33, 13:27-31, 13:31-38, 13:39-42, 20:6-9; Ex.1082-Bikson-Tr., 107:16-108:9, 109:4-12, 112:4-12, 113:3-116:20. PO nevertheless argues, incorrectly, that it can avoid Stern's teachings if

'277 Reply, 4; '278 Reply, 3; '282 Reply, 3

Stern Discloses "two rows" of Bipolar Electrode Pairs

- Claim 1, '271 Patent:
  - "two rows of bipolar electrode pairs"
- Claim 15, '318 Patent:
  - "the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes"

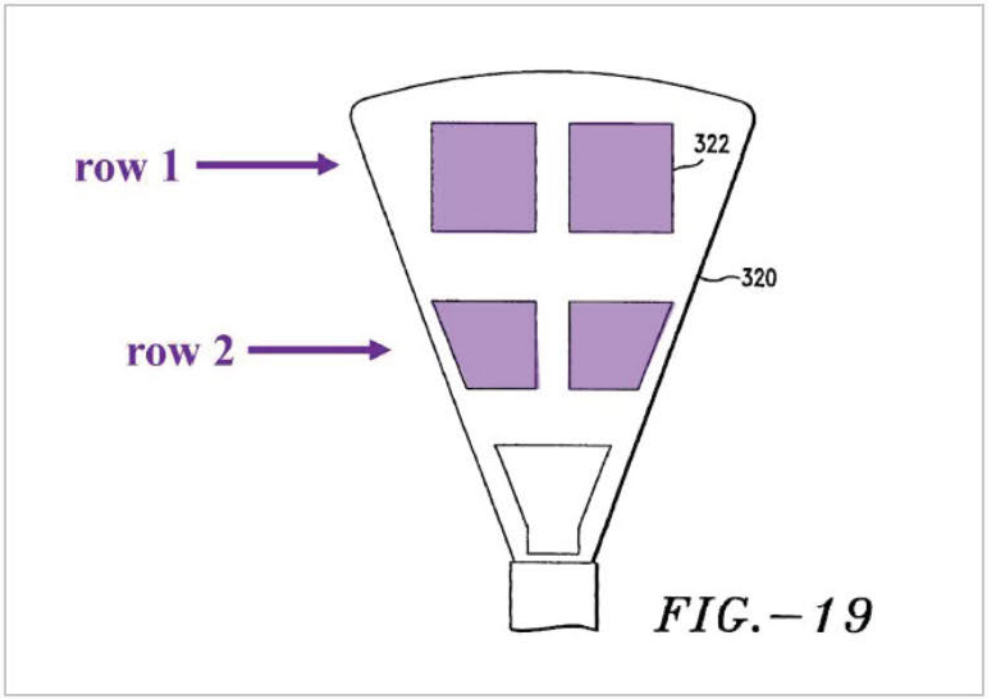


FIG.–19

'277 Petition, 38-41; '278 Petition, 66-67; '277 Ex.1002, ¶92; '277 Ex.1004, ¶¶70-74; '278 Ex.1002, ¶¶212-217

Patents Explain Bipolar Electrode Pairs Are Not in a Single Row

Claim Language

Claim 1, '271 Patent:

wherein the treatment element comprises two rows of bipolar electrode pairs;

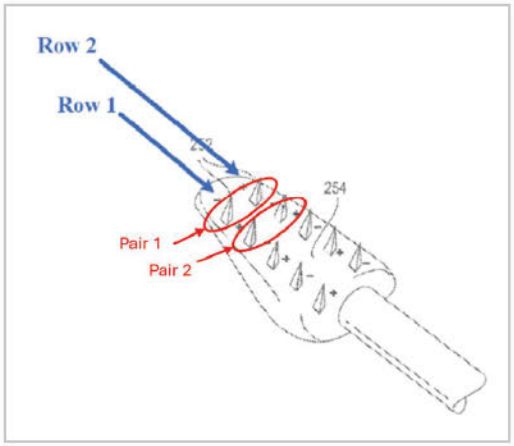
Claim 15, '318 Patent:

15. The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.

Ex.1001-'271 Patent, Claim 1; Ex.1001-318 Patent, Claim 15

Patent Specification

tissue. In some embodiments, the protruding electrodes may include two rows of electrodes, where the energy delivery member comprises a bipolar radio frequency delivery member, and where radio frequency energy travels from one row of electrodes to the other row of electrodes.



Ex.1001-'271 Patent, 8:21-25; '277 Reply, 8; '277 Ex.1083, ¶30; '277 Ex.1097, ¶31

Patents Explain Bipolar Electrode Pairs Are Not in a Single Row

Claim Language

Claim 1, '271 Patent:

wherein the treatment element comprises two rows of bipolar electrode pairs;

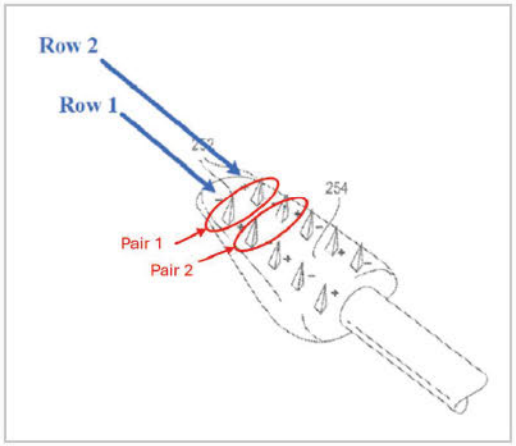
Claim 15, '318 Patent:

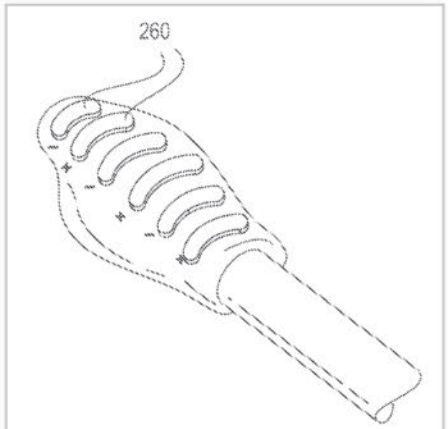
15. The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.

Ex.1001-'271 Patent, Claim 1; Ex.1001-318 Patent, Claim 15

Patent Specification

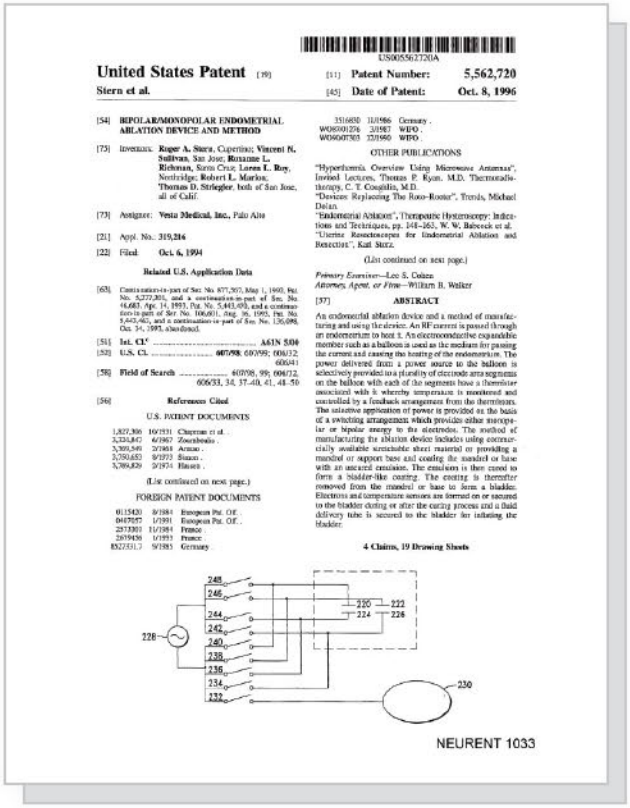
FIG. 8G illustrates another embodiment of a treatment element comprises one, two or many pairs of bipolar electrodes 260. As opposed to FIG. 8F, where the pairs of electrodes are arranged side-by-side, the embodiment of FIG. 8G arranges the pairs of electrodes along the length of the treatment element. The electrodes of FIG. 8G are also





Ex.1001-'271 Patent, 23:56-59; '277 Reply, 8; '277 Ex.1083, ¶30; '277 Ex.1097, ¶31

Prior Art Discloses "two rows" Even Under Patent Owner's Improperly Narrow Interpretation / Construction



US005562720A

United States Patent [19]
Stern et al.

[11] **Patent Number: 5,562,720**
[45] **Date of Patent: Oct. 8, 1996**

[54] **BIPOLAR/MONOPOLAR ENDOMETRIAL ABLATION DEVICE AND METHOD**

[75] Inventors: **Roger A. Stern**, Cupertino; **Vincent N. Sullivan**, San Jose; **Roxanne L. Richman**, Santa Cruz; **Loren L. Roy**, Northridge; **Robert L. Marlow**; **Thomas D. Striegler**, both of San Jose, all of Calif.

[73] Assignee: **Vesta Medical, Inc.**, Palo Alto

[21] Appl. No.: **319,216**

[22] Filed: **Oct. 6, 1994**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 877,707, May 1, 1992, Pat. No. 5,272,301, and a continuation-in-part of Ser. No. 16,683, Apr. 14, 1993, Pat. No. 5,443,693, and a continuation-in-part of Ser. No. 106,801, Aug. 16, 1993, Pat. No. 5,443,463, and a continuation-in-part of Ser. No. 120,090, Oct. 14, 1993, abandoned.

[51] **Int. Cl.**[6] **A61N 5/00**

[52] **U.S. Cl.** **607/98**; 600/99; 606/32; 606/41

[58] **Field of Search** 607/98, 99; 606/32, 606/33, 34, 37–40, 41, 48–50

[56] **References Cited**

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"Endometrial Ablation", Therapeutic Hysteroscopy: Indications and Techniques, pp. 148–163, W. W. Babcock et al.
"Uterine Resectoscopes for Endometrial Ablation and Resection", Karl Storz.

(List continued on next page.)

Primary Examiner—Lee S. Cohen
Attorney, Agent, or Firm—William B. Walker

[57] **ABSTRACT**

An endometrial ablation device and a method of manufacturing and using the device. An RF current is passed through an endometrium to heat it. An electroconductive expandible member such as a balloon is used as the medium for passing the current and causing the heating of the endometrium. The power delivered from a power source to the balloon is selectively provided to a plurality of electrode area segments on the balloon with each of the segments have a thermister associated with it whereby temperature is monitored and controlled by a feedback arrangement from the thermisters. The selective application of power is provided on the basis of a switching arrangement which provides either unipolar or bipolar energy to the electrodes. The method of manufacturing the ablation device includes using commercially available stretchable sheet material or providing a mandrel or support base and coating the mandrel or base with an uncured emulsion. The emulsion is then cured to form a bladder-like coating. The coating is thereafter removed from the mandrel or base to form a bladder. Electrodes and temperature sensors are formed on or secured to the bladder during or after the curing process and a fluid delivery tube is secured to the bladder for inflating the bladder.

4 Claims, 19 Drawing Sheets

NEURENT 1033

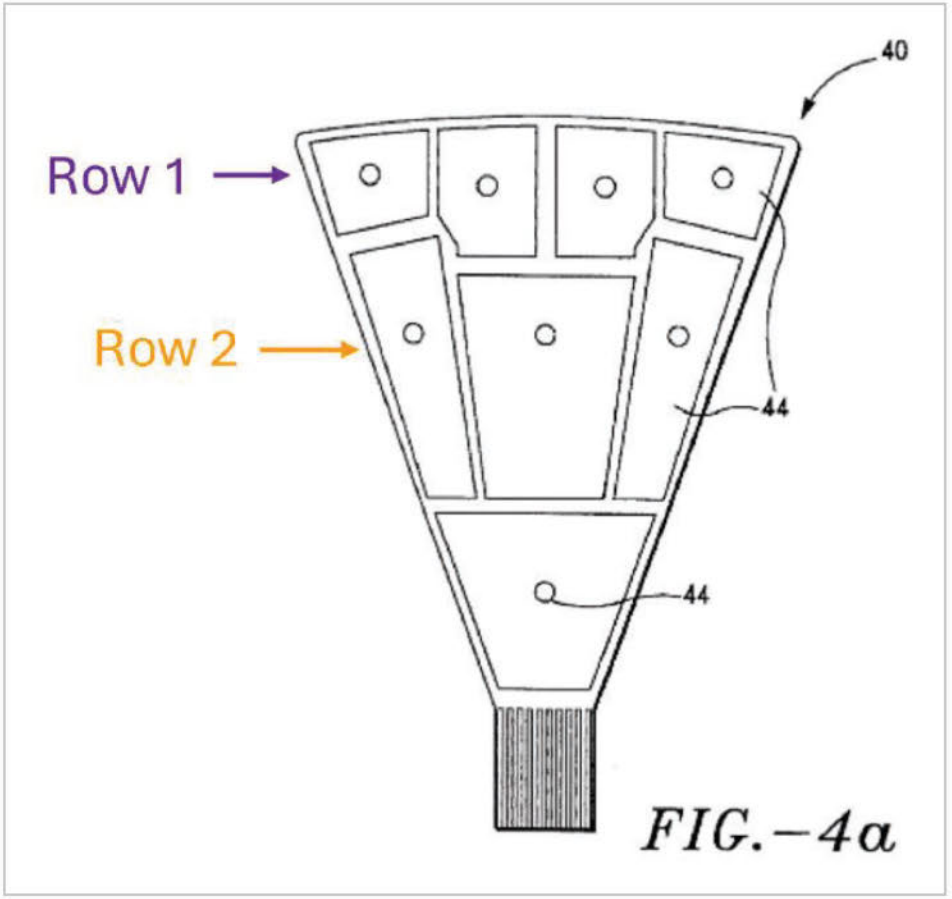


FIG.–4a

Ex.1033, Fig.4a; 277 Reply, 13; '277 Ex.1083, ¶36; Ex.1097, ¶¶38-41

A POSITA Would Have Been Motivated to Modify Edwards-'535 Electrode Arrangement in View of Stern

1. Edwards-'535 itself identifies a reference that has bipolar RF electrodes arranged in multiple rows.

2. Two rows of bipolar electrode pairs facilitates simple spatial resolution of the applied energy.

3. Two rows is an obvious arrangement of parts.

4. Other *KSR* rationales.

'277 Petition, 41-49; '278 Petition, 67; '277 Reply, 16-20; '278 Reply, 28-30

A POSITA Would Have Been Motivated to Modify Edwards-'535 Electrode Arrangement in View of Stern

1. **Edwards-'535 itself identifies a reference that has bipolar RF electrodes arranged in multiple rows.**

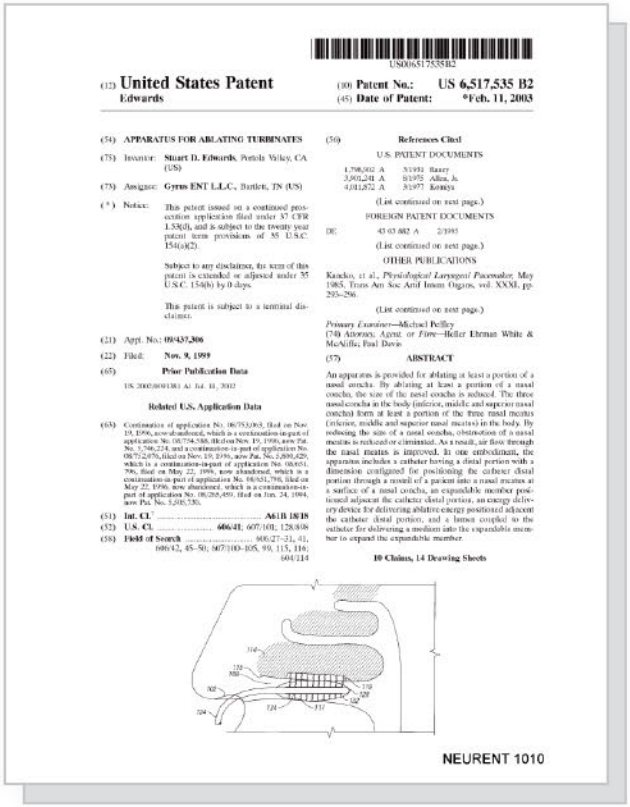
2. Two rows of bipolar electrode pairs facilitates simple spatial resolution of the applied energy.

3. Two rows is an obvious arrangement of parts.

4. Other *KSR* rationales.

'277 Petition, 41-49; '278 Petition, 67; '277 Reply, 16-20; '278 Reply, 28-30

1. Edwards-'535 itself identifies a reference that has bipolar RF electrodes arranged in multiple rows.



US006517535B2

(12) **United States Patent**
Edwards

(10) **Patent No.: US 6,517,535 B2**
(45) **Date of Patent: *Feb. 11, 2003**

(54) **APPARATUS FOR ABLATING TURBINATES**

(75) Inventor: **Stuart D. Edwards**, Portola Valley, CA (US)

(73) Assignee: **Gyrus ENT L.L.C.**, Bartlett, TN (US)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/437,306**

(22) Filed: **Nov. 9, 1999**

(65) **Prior Publication Data**

US 2002/0019583 A1 Jul. 11, 2002

Related U.S. Application Data

(63) Continuation of application No. 08/753,003, filed on Nov. 19, 1996, now abandoned, which is a continuation-in-part of application No. 08/754,588, filed on Nov. 19, 1996, now Pat. No. 5,746,224, and a continuation-in-part of application No. 08/752,670, filed on Nov. 19, 1996, now Pat. No. 5,800,429, which is a continuation-in-part of application No. 08/651,796, filed on May 22, 1996, now abandoned, which is a continuation-in-part of application No. 08/651,798, filed on May 22, 1996, now abandoned, which is a continuation-in-part of application No. 08/265,459, filed on Jun. 24, 1994, now Pat. No. 5,695,530.

(51) **Int. Cl.**[7] **A61B 18/18**

(52) **U.S. Cl.** **606/41**; 607/101; 128/898

(58) **Field of Search** 606/27–31, 41, 606/42, 45–50; 607/100–105, 99, 115, 116; 604/114

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(List continued on next page.)

Primary Examiner—Michael Peffley
(74) *Attorney, Agent, or Firm*—Heller Ehrman White & McAuliffe; Paul Davis

(57) **ABSTRACT**

An apparatus is provided for ablating at least a portion of a nasal concha. By ablating at least a portion of a nasal concha, the size of the nasal concha is reduced. The three nasal conchs in the body (inferior, middle and superior nasal conchs) form at least a portion of the three nasal meatus (inferior, middle and superior nasal meatus) in the body. By reducing the size of a nasal concha, obstruction of a nasal meatus is reduced or eliminated. As a result, air flow through the nasal meatus is improved. In one embodiment, the apparatus includes a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient into a nasal meatus at a surface of a nasal concha, an expandable member positioned adjacent the catheter distal portion, and a lumen coupled to the catheter for delivering a medium into the expandable member to expand the expandable member.

10 Claims, 14 Drawing Sheets

NEURENT 1010

> member. An example of a suitable surface for disposition on the membrane is described in application Ser. No. 08/319,373, "Thin Layer Ablation Apparatus", filed Oct. 6, 1994, which is incorporated by reference. It is noted that a com-

Ex.1010, 8:28-31; '277 Reply, 18-20; '277 Ex.1083, ¶45; '277 Ex.1097, ¶43

Nat'l Steel Car, Ltd. v. Canadian P. Ry., Ltd.

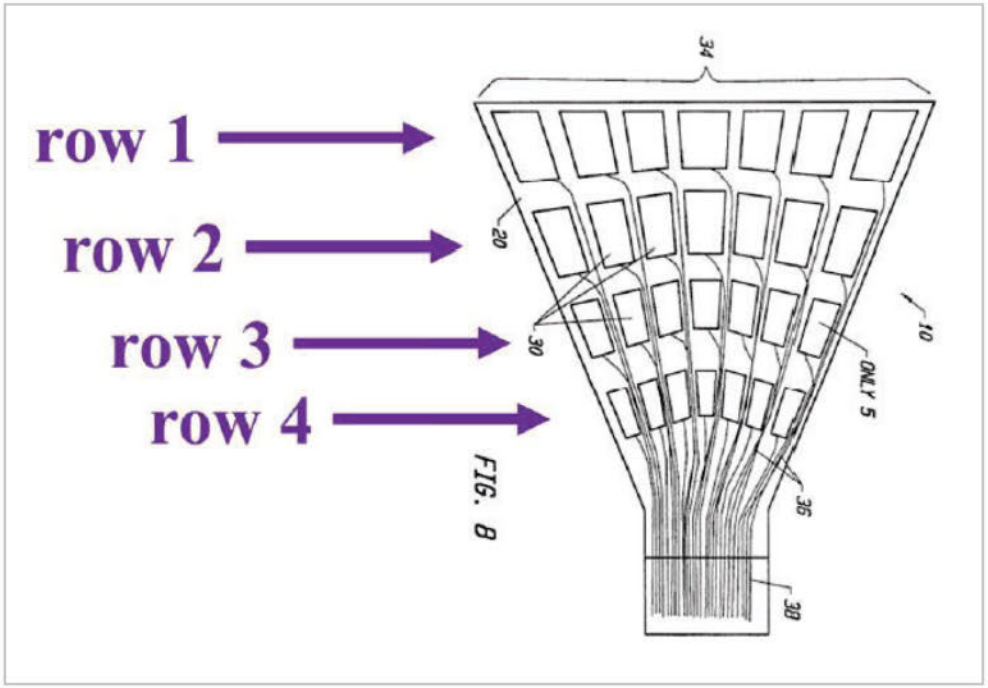
"The motivation to combine can be located either in a prior art reference, or it can be implicit in the knowledge of one of ordinary skill in the art."

Nat'l Steel Car, Ltd. v. Canadian P. Ry., Ltd., 357 F.3d 1319, 1337 (Fed. Cir. 2004)

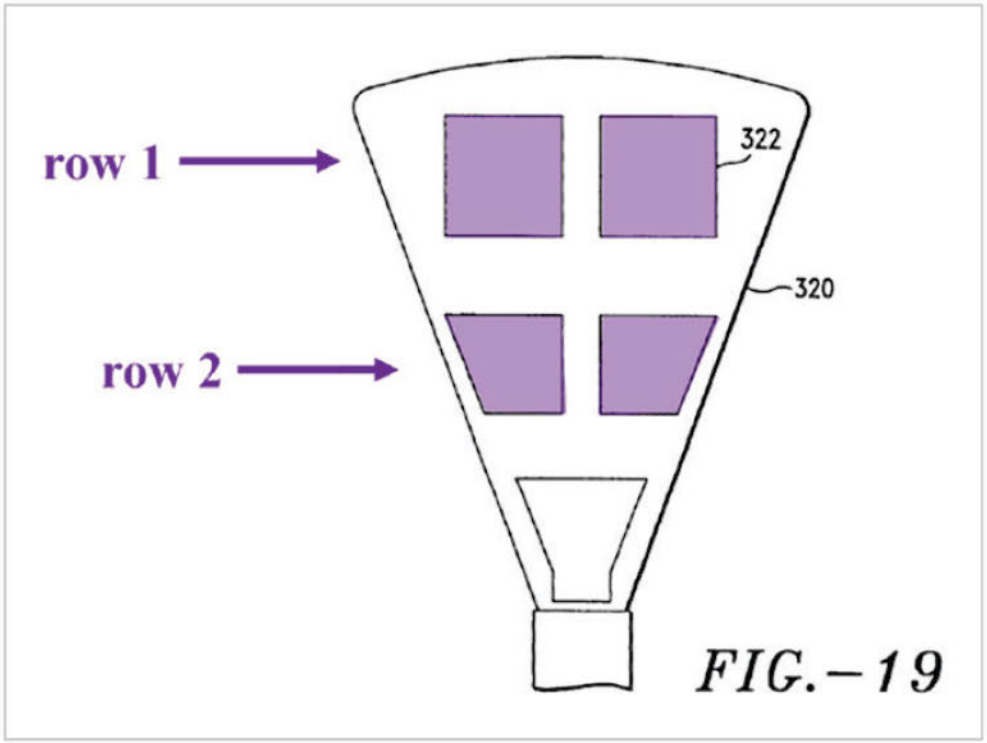
'277 Reply, 18-20

1. Edwards-'535 itself identifies a reference that has bipolar RF electrodes arranged in multiple rows.

Baker

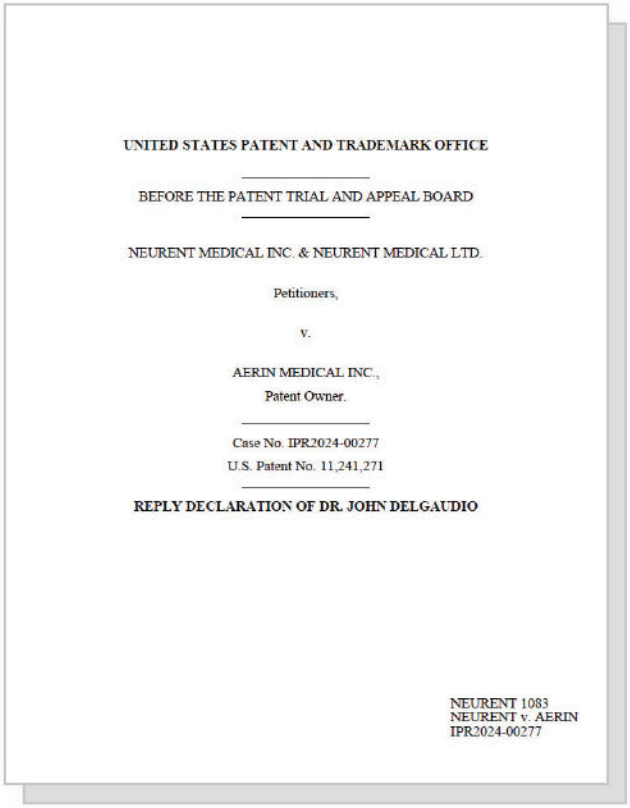


Stern



Ex.1011, Fig. 8; Ex.1033, Fig.19; '277 Petition, 47; '277 Ex.1002, ¶94; '277 Ex.1004, ¶¶94-95

2. Two rows of bipolar electrode pairs facilitates simple spatial resolution of the applied energy.



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL INC.,
Patent Owner.

Case No. IPR2024-00277
U.S. Patent No. 11,241,271

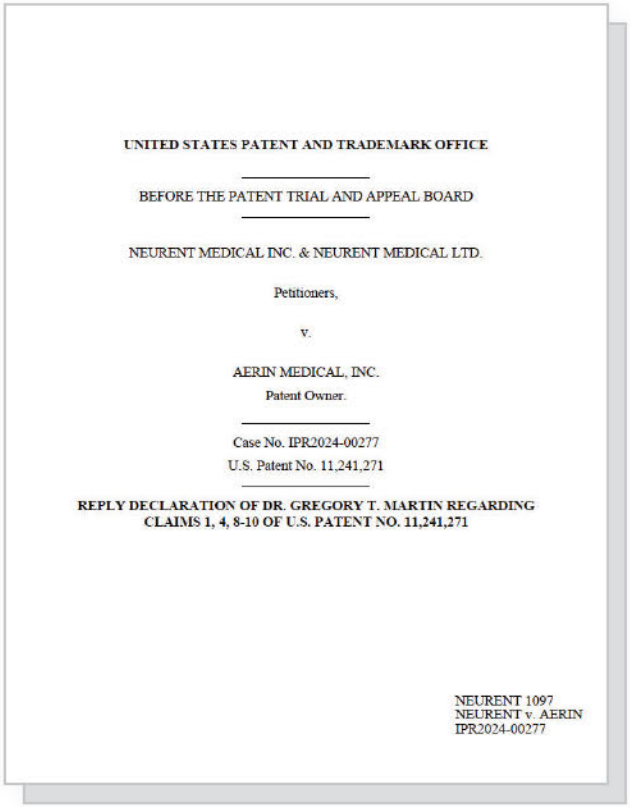
REPLY DECLARATION OF DR. JOHN DELGAUDIO

NEURENT 1083
NEURENT v. AERIN
IPR2024-00277

For example, when treating a smaller portion of a turbinate (or a turbinate of a smaller patient), one row of electrodes may be sufficient to provide the desired even heating and precise control, but when treating a larger portion or a larger patient, two or more rows may be preferred to give control over a larger area of the anatomy.

'277 Reply, 19-20; '277 Ex.1083, ¶ 47

2. Two rows of bipolar electrode pairs facilitates simple spatial resolution of the applied energy.



UNITED STATES PATENT AND TRADEMARK OFFICE

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U.S. Patent No. 11,241,271

REPLY DECLARATION OF DR. GREGORY T. MARTIN REGARDING CLAIMS 1, 4, 8-10 OF U.S. PATENT NO. 11,241,271

NEURENT 1097
NEURENT v. AERIN
IPR2024-00277

Ordered arrangements of electrodes (e.g., those in rows like in Stern) directly support that process by making it easy to determine (1) the location and proximity of electrodes that could be paired and (2) sense the characteristics of energy application local to such pairs. In more random arrangements, it would be

'277 Reply, 19-20; '277 Ex.1097, ¶ 44; '278 Reply, 29-30; '278 Ex.1083, ¶91

3. Two rows is an obvious arrangement of parts.

Edwards-'535 already discloses one row of electrodes, *see, e.g.*, Ex.1010-Edwards-'535, FIG.6, and thus adding another row of electrodes would have involved an obvious duplication of parts. *See, e.g.*, *In re Harza*, 274 F.2d 669 (C.C.P.A. 1960). Ex.1002-Decl., ¶94; Ex.1004-Decl., ¶¶94-95.

'277 Petition, 48

Petition at 47-49, but not Petition at 43-47). Generally, increasing the quantity of a component in a device that functions in the same, predictable way is not patentable. *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 978 (Fed. Cir. 2014).

'277 Reply, 17

4. Other *KSR* rationales.

Additional Motivations to Combine
Straightforward and predictable combination
Combining known prior art elements according to known methods to yield predictable results
Substituting one known element for another to obtain predictable results
Using a known technique to improve similar devices in the same way
Applying a known technique to a known device ready for improvement

'277 Petition, 48-49; '277 Ex.1002, ¶ 94; '277 Ex.1004, ¶97

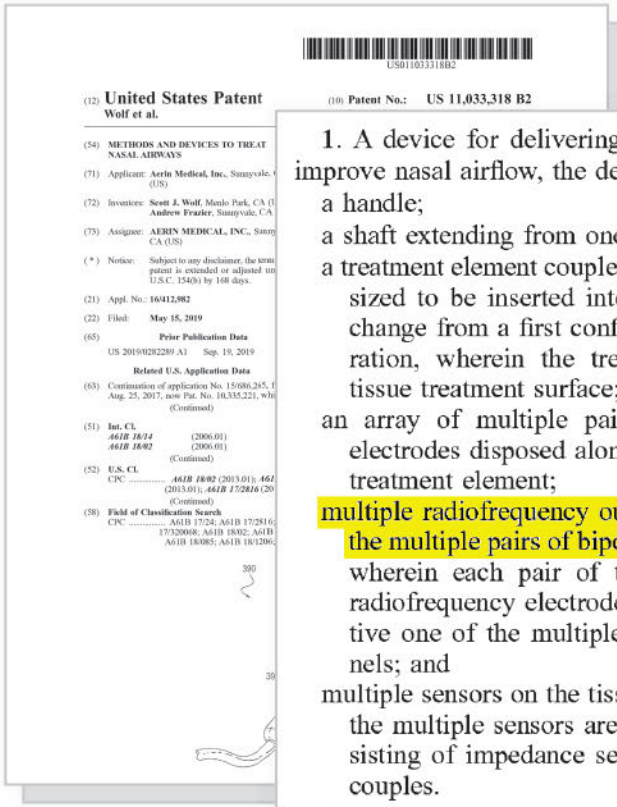
Stern Discloses
“multiple radiofrequency output channels”

IPR2024-00278; IPR2024-00282

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Challenged Claims

Representative Independent Claims—'318 and '286 Patent



1. A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:

a handle;

a shaft extending from one end of the handle;

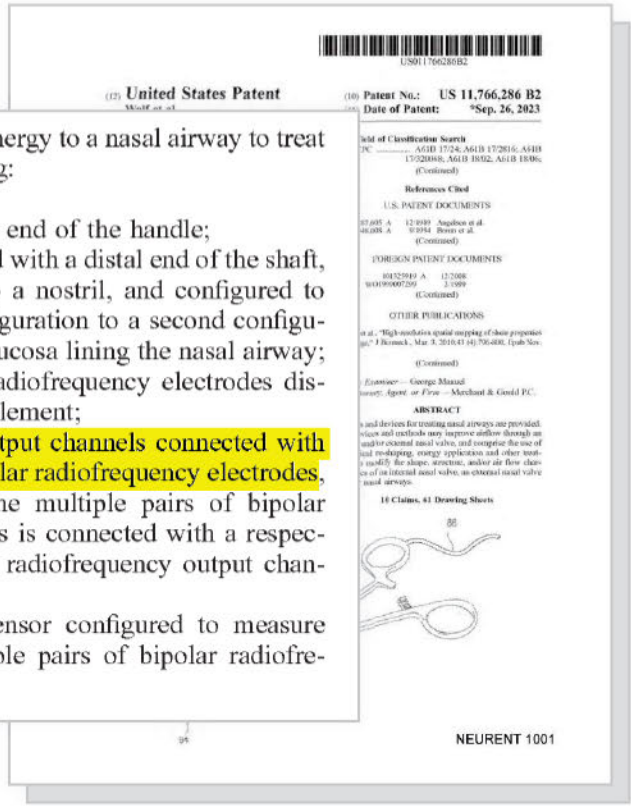
a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration, wherein the treatment element comprises a tissue treatment surface;

an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;

multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels; and

multiple sensors on the tissue treatment surface, wherein the multiple sensors are selected from the group consisting of impedance sensors, electrodes and thermocouples.

'278 Petition, 41-45; Ex.1001-'318 Patent, Claim 1



1. A device for delivering energy to a nasal airway to treat rhinitis, the device comprising:

a handle;

a shaft extending from one end of the handle;

a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration to contact nasal mucosa lining the nasal airway;

multiple pairs of bipolar radiofrequency electrodes disposed on the treatment element;

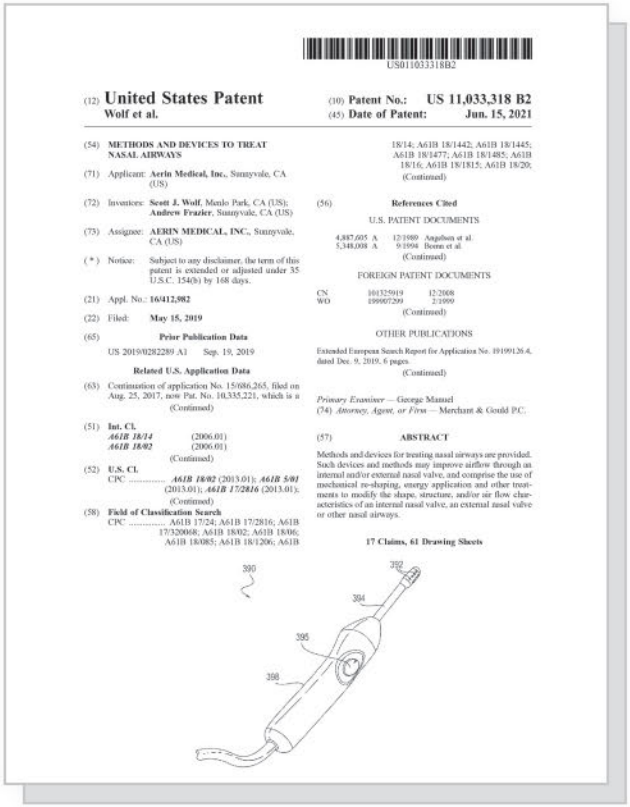
multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels; and

at least one impedance sensor configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes.

NEURENT 1001

'282 Petition, 40-43; Ex.1001-'286 Patent, Claim 1

Patents Describe "output channels" as Individually Controllable Channels Delivering RF Energy to Electrodes



US011033318B2

(12) **United States Patent**
Wolf et al.

(10) **Patent No.: US 11,033,318 B2**
(45) **Date of Patent: Jun. 15, 2021**

(54) **METHODS AND DEVICES TO TREAT NASAL AIRWAYS**

(71) Applicant: **Aerin Medical, Inc.**, Sunnyvale, CA (US)

(72) Inventors: **Scott J. Wolf**, Menlo Park, CA (US); **Andrew Frazier**, Sunnyvale, CA (US)

(73) Assignee: **AERIN MEDICAL, INC.**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 168 days.

(21) Appl. No.: **16/412,982**

(22) Filed: **May 15, 2019**

(65) **Prior Publication Data**

US 2019/0282289 A1 Sep. 19, 2019

Related U.S. Application Data

(63) Continuation of application No. 15/686,265, filed on Aug. 25, 2017, now Pat. No. 10,335,221, which is a (Continued)

(51) **Int. Cl.**
A61B 18/14 (2006.01)
A61B 18/02 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 18/02*** (2013.01); ***A61B 5/01*** (2013.01); ***A61B 17/2816*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/24; A61B 17/2816; A61B 17/320068; A61B 18/02; A61B 18/06; A61B 18/085; A61B 18/1206; A61B 18/14; A61B 18/1442; A61B 18/1445; A61B 18/1477; A61B 18/1485; A61B 18/16; A61B 18/1815; A61B 18/20;
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(Continued)

Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — Merchant & Gould P.C.

(57) **ABSTRACT**

Methods and devices for treating nasal airways are provided. Such devices and methods may improve airflow through an internal and/or external nasal valve, and comprise the use of mechanical re-shaping, energy application and other treatments to modify the shape, structure, and/or air flow characteristics of an internal nasal valve, an external nasal valve or other nasal airways.

17 Claims, 61 Drawing Sheets

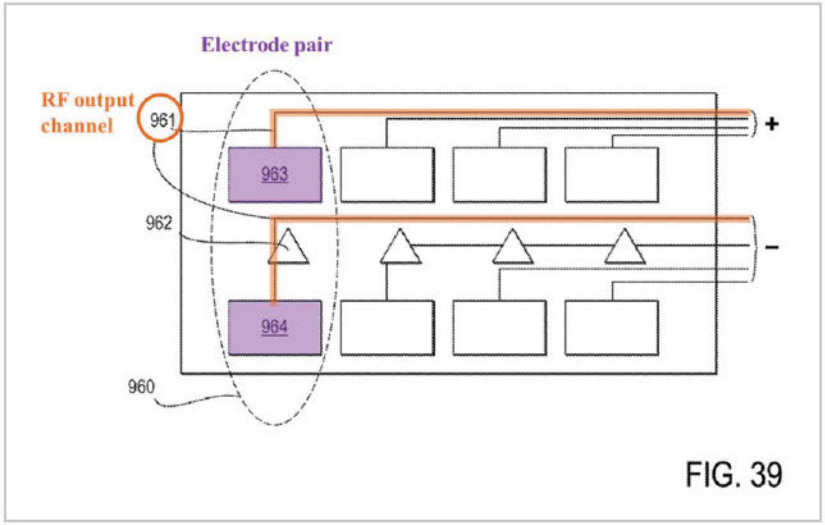
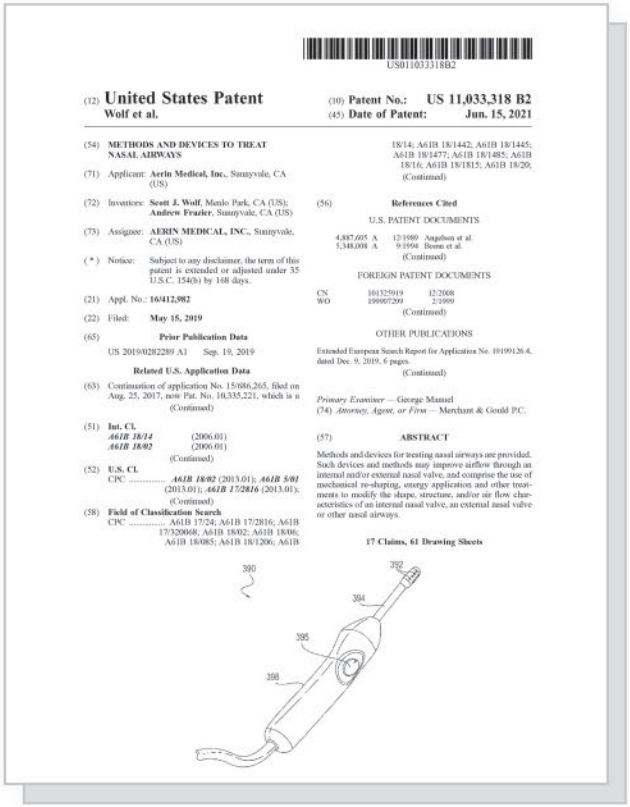


FIG. 39

In some embodiments, each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately.

Ex.1001-'318 Patent, Fig.39, 48:63-65; '278 Reply, 8; '278 Ex.1083, ¶¶32-40; *see also* Ex.1001-'286 Patent, Fig.39, 49:10-12; '282 Reply, 8-9; '282 Ex.1083, ¶¶33-40

Patents Describe "output channels" as Individually Controllable Channels Delivering RF Energy to Electrodes



US011033318B2

(12) **United States Patent**
Wolf et al.

(10) **Patent No.: US 11,033,318 B2**
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A61B 18/02 (2006.01)
(Continued)

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

(58) **Field of Classification Search**
CPC A61B 17/24; A61B 17/2816; A61B 17/320068; A61B 18/02; A61B 18/06; A61B 18/085; A61B 18/1206; A61B 18/14; A61B 18/1442; A61B 18/1445; A61B 18/1477; A61B 18/1485; A61B 18/16; A61B 18/1815; A61B 18/20;
(Continued)

(56) **References Cited**

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(Continued)

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OTHER PUBLICATIONS

Extended European Search Report for Application No. 19199126.4, dated Dec. 9, 2019, 6 pages.
(Continued)

Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — Merchant & Gould P.C.

(57) **ABSTRACT**

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17 Claims, 61 Drawing Sheets

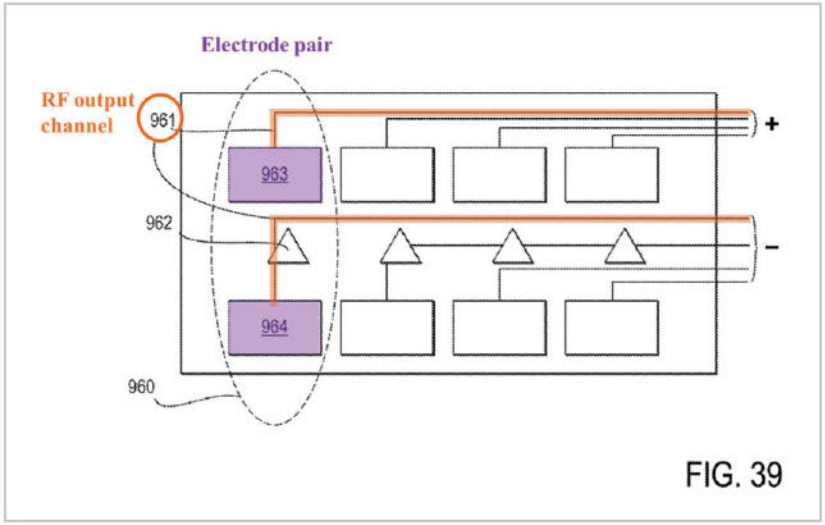
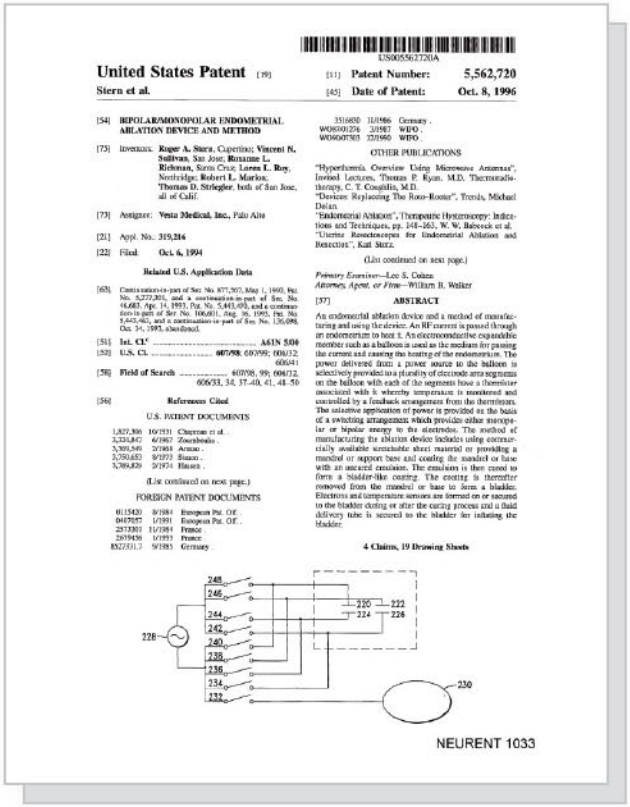


FIG. 39

As shown in FIG. **39**, the nasal treatment device may include one or more thermocouples **962** and an RF output channel **961** assigned to each electrode pair for feedback. An

Ex.1001-'318 Patent, Fig.39, 48:63-65; '278 Reply, 8; '278 Ex.1083, ¶¶32-40; *see also* Ex.1001-'286 Patent, Fig.39, 49:10-12; '282 Reply, 8-9; '282 Ex.1083, ¶¶33-40

Stern Discloses the Same "output channels"



US005562720A

United States Patent [19]
Stern et al.

[11] **Patent Number: 5,562,720**
[45] **Date of Patent: Oct. 8, 1996**

[54] **BIPOLAR/MONOPOLAR ENDOMETRIAL ABLATION DEVICE AND METHOD**

[75] Inventors: **Roger A. Stern**, Cupertino; **Vincent N. Sullivan**, San Jose; **Roxanne L. Richman**, Santa Cruz; **Loren L. Roy**, Northridge; **Robert L. Marlow**, Thornton D. Striegler, both of San Jose, all of Calif.

[73] Assignee: **Vesta Medical, Inc.**, Palo Alto

[21] Appl. No.: **319,216**

[22] Filed: **Oct. 6, 1994**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 877,707, May 1, 1992, Pat. No. 5,272,301, and a continuation-in-part of Ser. No. 16,683, Apr. 14, 1993, Pat. No. 5,443,693, and a continuation-in-part of Ser. No. 106,901, Aug. 16, 1993, Pat. No. 5,542,462, and a continuation-in-part of Ser. No. 120,090, Oct. 14, 1993, abandoned.

[51] **Int. Cl.**[6] **A61N 5/00**

[52] **U.S. Cl.** **607/98**; 607/99; 606/32; 606/41

[58] **Field of Search** 607/98, 99; 606/32, 606/33, 34, 37–40, 41, 48–50

[56] **References Cited**

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"Uterine Resectoscopes for Endometrial Ablation and Resection", Karl Storz.

(List continued on next page.)

Primary Examiner—Lee S. Cohen
Attorney, Agent, or Firm—William B. Walker

[57] **ABSTRACT**

An endometrial ablation device and a method of manufacturing and using the device. An RF current is passed through an endometrium to heat it. An electroconductive expandible member such as a balloon is used as the medium for passing the current and causing the heating of the endometrium. The power delivered from a power source to the balloon is selectively provided to a plurality of electrode area segments on the balloon with each of the segments have a thermister associated with it whereby temperature is monitored and controlled by a feedback arrangement from the thermisters. The selective application of power is provided on the basis of a switching arrangement which provides either monopolar or bipolar energy to the electrodes. The method of manufacturing the ablation device includes using commercially available stretchable sheet material or providing a mandrel or support base and coating the mandrel or base with an uncured emulsion. The emulsion is then cured to form a bladder-like coating. The coating is thereafter removed from the mandrel or base to form a bladder. Electrodes and temperature sensors are formed on or secured to the bladder during or after the curing process and a fluid delivery tube is secured to the bladder for inflating the bladder.

4 Claims, 19 Drawing Sheets

NEURENT 1033

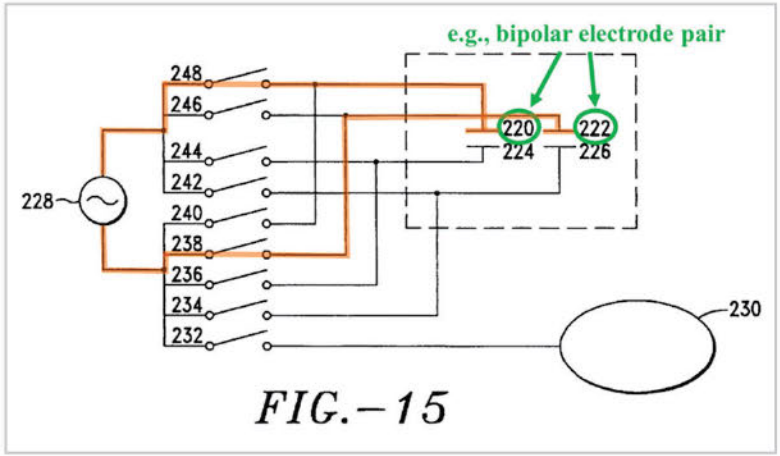
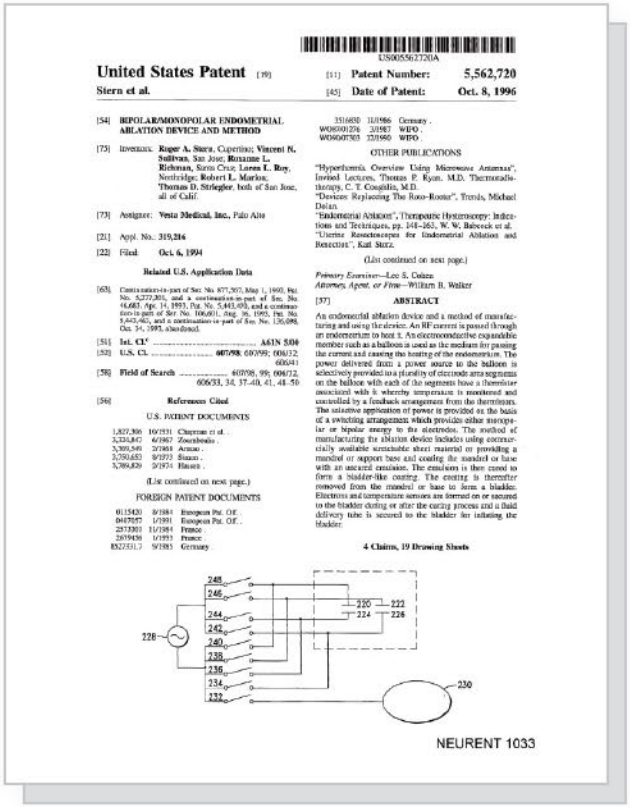


FIG.–15

The device of FIG. **15** provides an apparatus for both bipolar and monopolar application of RF energy with the choice of either bipolar or monopolar being made by control of the switches. Furthermore, not only are the modes selectable by controlling the switches but also within the bipolar mode, for instance, the switches allow for the selective application of RF energy to various combinations of electrodes.

E.g., Ex.1033, FIG.15, 12:38-45; '278 Petition, 42-44; '282 Petition, 41-43; '278 Ex.1002, ¶¶125-128; '282 Ex.1002, ¶¶136-138

Stern Discloses the Same "output channels"



US005562720A

United States Patent [19]
Stern et al.

[11] **Patent Number: 5,562,720**
[45] **Date of Patent: Oct. 8, 1996**

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[75] Inventors: **Roger A. Stern**, Cupertino; **Vincent N. Sullivan**, San Jose; **Roxanne L. Richman**, Santa Cruz; **Loren L. Roy**, Northridge; **Robert L. Marlow**, Thornton D. Striegler, both of San Jose, all of Calif.

[73] Assignee: **Vesta Medical, Inc.**, Palo Alto

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[52] **U.S. Cl.** **607/98**; 607/99; 606/32; 606/41

[58] **Field of Search** 607/98, 99; 606/32, 606/33, 34, 37–40, 41, 48–50

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(List continued on next page.)

Primary Examiner—Lee S. Cohen
Attorney, Agent, or Firm—William B. Walker

[57] **ABSTRACT**

An endometrial ablation device and a method of manufacturing and using the device. An RF current is passed through an endometrium to heat it. An electroconductive expandible member such as a balloon is used as the medium for passing the current and causing the heating of the endometrium. The power delivered from a power source to the balloon is selectively provided to a plurality of electrode area segments on the balloon with each of the segments have a thermister associated with it whereby temperature is monitored and controlled by a feedback arrangement from the thermisters. The selective application of power is provided on the basis of a switching arrangement which provides either unipolar or bipolar energy to the electrodes. The method of manufacturing the ablation device includes using commercially available semistable sheet material or providing a mandrel or support base and coating the mandrel or base with an uncured emulsion. The emulsion is then cured to form a bladder-like coating. The coating is thereafter removed from the mandrel or base to form a bladder. Electrodes and temperature sensors are formed on or secured to the bladder during or after the curing process and a fluid delivery tube is secured to the bladder for inflating the bladder.

4 Claims, 19 Drawing Sheets

NEURENT 1033

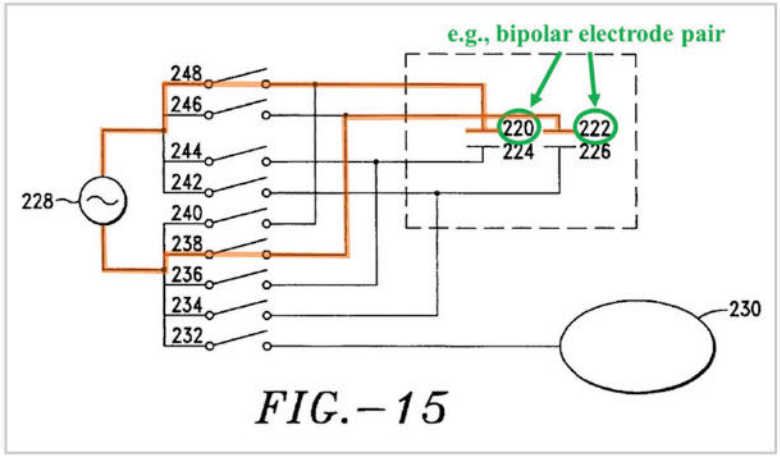


FIG.–15

operation. As an example, if switch **248** is closed as well as switch **236**, then the current will pass from electrode **220** to electrode **224**. In a similar manner, if switch **246** is closed as well as switch **234**, there will be a bipolar operation with current flowing between electrodes **222** and **226**. Clearly bipolar operation is not limited to these **220–224** and **222–226** pair couplings. If switch **248** and switch **238** are closed there will be bipolar operation between the electrodes **220** and **222**.

E.g., Ex.1033, FIG.15, 12:61-13:2; '278 Petition, 42-44; '282 Petition, 41-43; '278 Ex.1002, ¶¶125-128; '282 Ex.1002, ¶¶136-138

Patent Owner's Expert Depicts the Same "output channels"



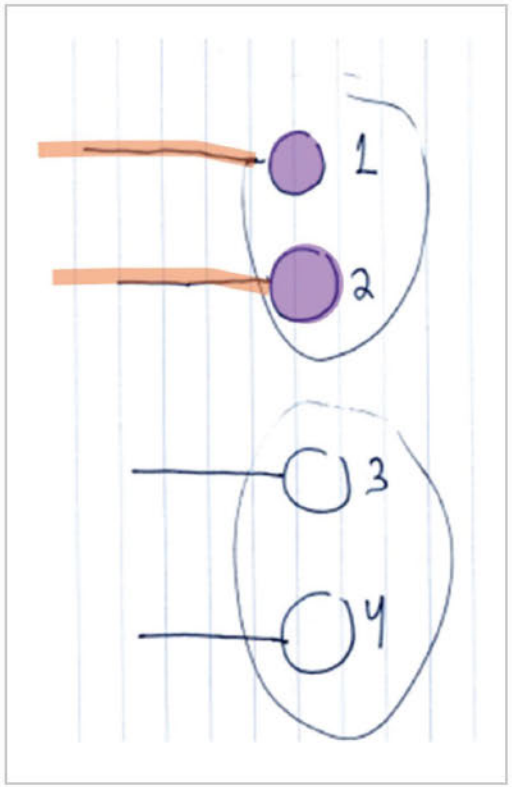
Dr. Marom Bikson

PO's Declarant

Q. Can you draw a device that has multiple radiofrequency output channels as required by [claim 1 of the '318 patent]?

A. **So, again, just hypothetically, I'm drawing four electrodes. I guess I can label them one, two, three, four.**

And I'm drawing wires going to electrodes one and two. And I'm drawing wires going to electrode three and four. And I guess I'll put a circle around one and two and around three and four, so each — this is one bipole and this is another bipole. And the wires coming to them would represent one channel and this would represent another channel.



Ex.1084, 194:13-195:4; '278 Reply, 11-12; '282 Reply, 11-12

Challenged Patent, Patent Owner's Expert, and Stern Disclose the Same "multiple RF output channels"

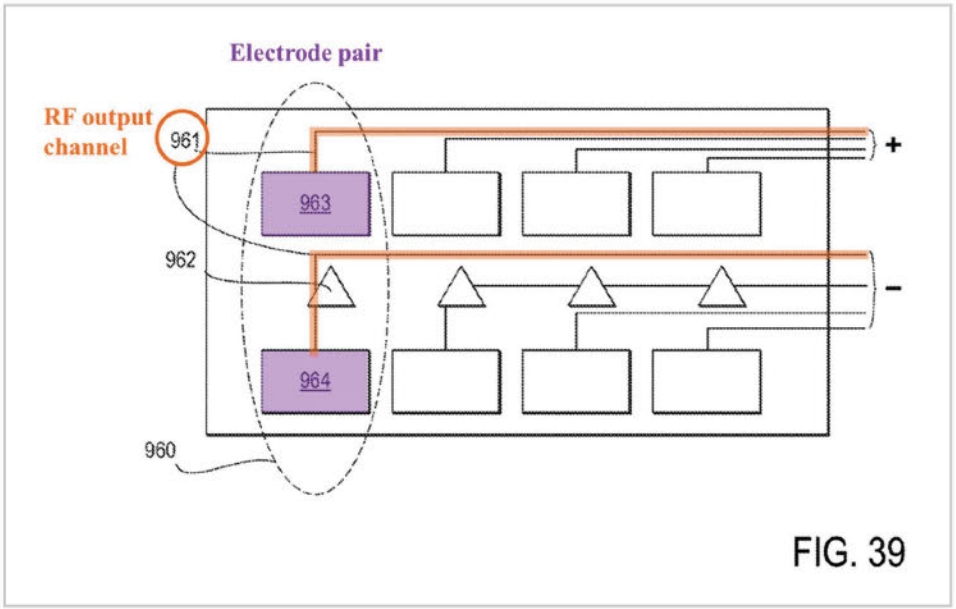
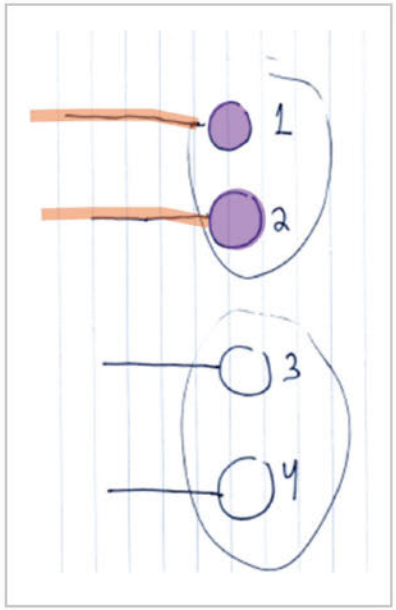
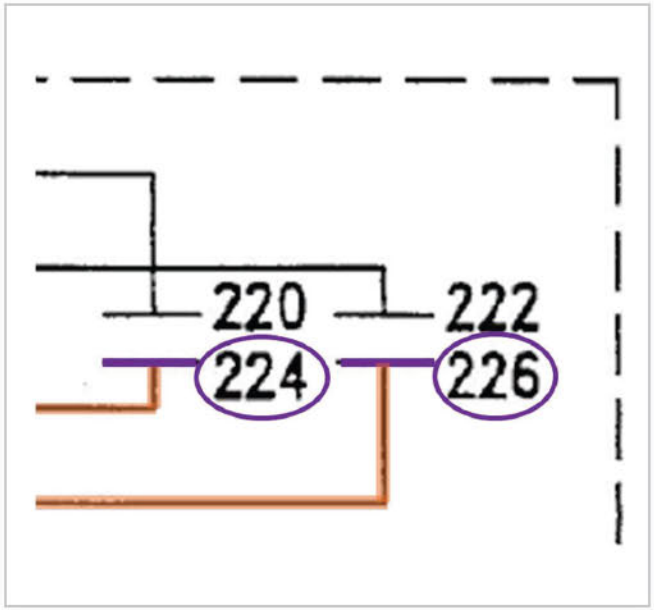


FIG. 39





Ex.1001-318 Patent, Fig. 39; Ex.1087-Bikson-Dep-Ex.E; Ex.1033, Fig. 15; '278 Reply, 14; '282 Reply, 14

Challenged Patent, Patent Owner's Expert, and Stern Disclose the Same "multiple RF output channels"



Dr. Marom Bikson

PO's Declarant

Q. But otherwise in the dashed box in Stern Figure 15, it also shows four electrodes and each electrode is connected to its own wire, correct?

A. The — it's correct that in Figure 15 from Stern you have four electrodes and each electrode is associated with a wire.

Q. Okay. And in your depiction in Bikson Exhibit E, that shows two pairs of bipolar electrodes with multiple radiofrequency output channels, correct?

A. That is what I intended to show, yes.

Ex.1084, 196:6-11; '278 Reply, 12-13; '282 Reply, 12-13

Patent Owner's Narrow Interpretation Is Contradicted by the Challenged Patents

> Accordingly, the correct interpretation of "radiofrequency output channel" is "an output from a radiofrequency generator."

'318 Sur-Reply, 9; '282 Sur-Reply, 9

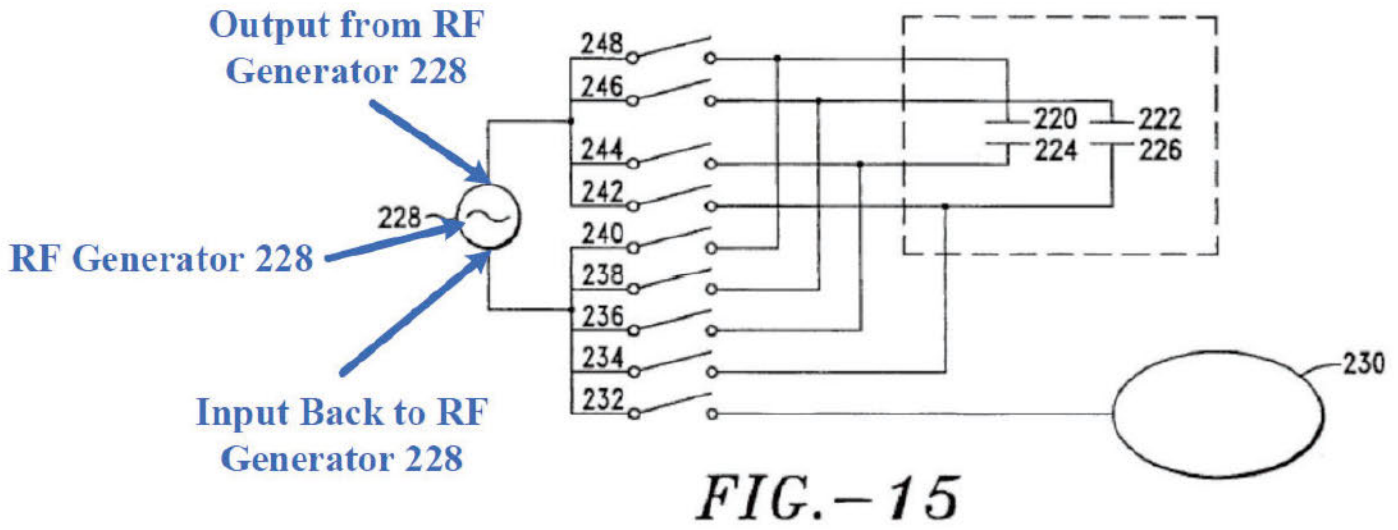
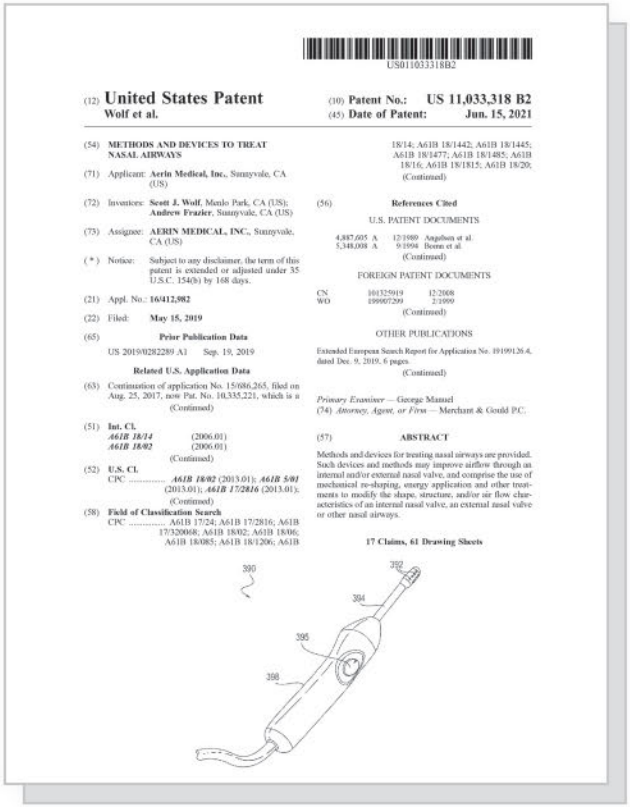


FIG.–15

'318 POR, 24; '282 POR, 23

Patent Owner's Narrow Interpretation Is Contradicted by the Challenged Patents



US011033318B2

(12) **United States Patent**
Wolf et al.

(10) **Patent No.: US 11,033,318 B2**
(45) **Date of Patent: Jun. 15, 2021**

(54) **METHODS AND DEVICES TO TREAT NASAL AIRWAYS**

(71) Applicant: **Aerin Medical, Inc.**, Sunnyvale, CA (US)

(72) Inventors: **Scott J. Wolf**, Menlo Park, CA (US); **Andrew Frazier**, Sunnyvale, CA (US)

(73) Assignee: **AERIN MEDICAL, INC.**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 168 days.

(21) Appl. No.: **16/412,982**

(22) Filed: **May 15, 2019**

(65) **Prior Publication Data**

US 2019/0282289 A1 Sep. 19, 2019

Related U.S. Application Data

(63) Continuation of application No. 15/686,265, filed on Aug. 25, 2017, now Pat. No. 10,335,221, which is a (Continued)

(51) **Int. Cl.**
A61B 18/14 (2006.01)
A61B 18/02 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 18/02*** (2013.01); ***A61B 5/01*** (2013.01); ***A61B 17/2816*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/24; A61B 17/2816; A61B 17/320068; A61B 18/02; A61B 18/06; A61B 18/085; A61B 18/1206; A61B 18/14; A61B 18/1442; A61B 18/1445; A61B 18/1477; A61B 18/1485; A61B 18/16; A61B 18/1815; A61B 18/20;
(Continued)

(56) **References Cited**

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(Continued)

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(Continued)

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Extended European Search Report for Application No. 19199126.4, dated Dec. 9, 2019, 6 pages.
(Continued)

Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — Merchant & Gould P.C.

(57) **ABSTRACT**

Methods and devices for treating nasal airways are provided. Such devices and methods may improve airflow through an internal and/or external nasal valve, and comprise the use of mechanical re-shaping, energy application and other treatments to modify the shape, structure, and/or air flow characteristics of an internal nasal valve, an external nasal valve or other nasal airways.

17 Claims, 61 Drawing Sheets

1. A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:

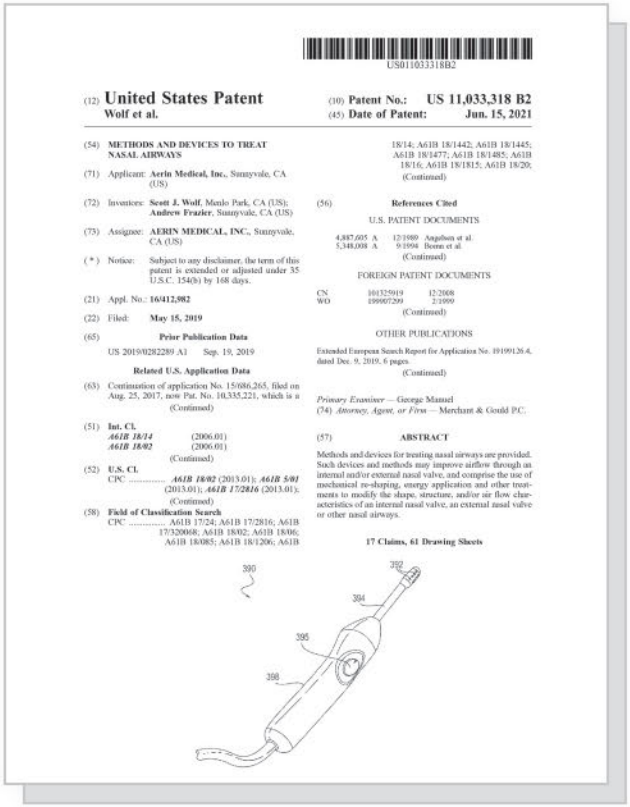
* * *

multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels;

* * *

'278 Petition, Ex.1001-'318 Patent, Claim 1; Ex.1001-286 Patent, Claim 1

Patent Owner's Narrow Interpretation Is Contradicted by the Challenged Patents



US011033318B2

(12) **United States Patent**
Wolf et al.

(10) **Patent No.: US 11,033,318 B2**
(45) **Date of Patent: Jun. 15, 2021**

(54) **METHODS AND DEVICES TO TREAT NASAL AIRWAYS**

(71) Applicant: **Aerin Medical, Inc.**, Sunnyvale, CA (US)

(72) Inventors: **Scott J. Wolf**, Menlo Park, CA (US); **Andrew Frazier**, Sunnyvale, CA (US)

(73) Assignee: **AERIN MEDICAL, INC.**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 168 days.

(21) Appl. No.: **16/412,982**

(22) Filed: **May 15, 2019**

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A61B 18/02 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 18/02*** (2013.01); ***A61B 5/01*** (2013.01); ***A61B 17/2816*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/24; A61B 17/2816; A61B 17/320068; A61B 18/02; A61B 18/06; A61B 18/085; A61B 18/1206; A61B 18/14; A61B 18/1442; A61B 18/1445; A61B 18/1477; A61B 18/1485; A61B 18/16; A61B 18/1815; A61B 18/20;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,887,605 A 12/1989 Angelsen et al.
5,348,008 A 9/1994 Bonn et al.
(Continued)

FOREIGN PATENT DOCUMENTS

CN 101325919 12/2008
WO 1999007299 2/1999
(Continued)

OTHER PUBLICATIONS

Extended European Search Report for Application No. 19199126.4, dated Dec. 9, 2019, 6 pages.
(Continued)

Primary Examiner — George Manuel
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(57) **ABSTRACT**

Methods and devices for treating nasal airways are provided. Such devices and methods may improve airflow through an internal and/or external nasal valve, and comprise the use of mechanical re-shaping, energy application and other treatments to modify the shape, structure, and/or air flow characteristics of an internal nasal valve, an external nasal valve or other nasal airways.

17 Claims, 61 Drawing Sheets

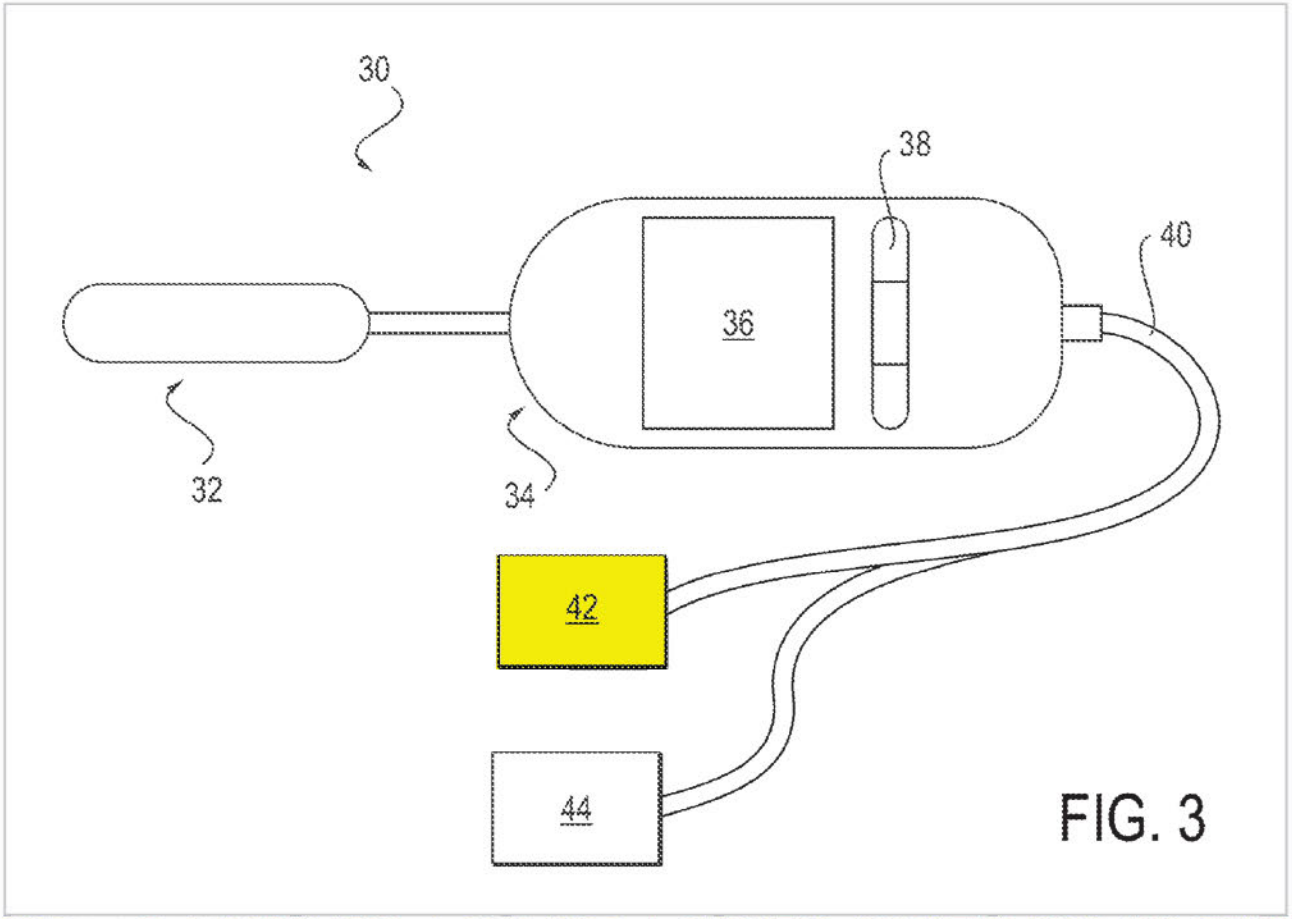


FIG. 3

Ex.1001-318 Patent, Fig. 3, 16:217-31; '278 Reply, 24-25; '282 Reply, 21-22; '278 Ex.1083, ¶¶ 77-79; '282 Ex.1083, ¶¶ 71-72

Patent Owner's Definition of a POSITA Is Incorrect and Irrelevant to Any Disputed Issue

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petitioners' POSITA Definition Is Correct

Petitioners' Definition

A POSITA would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and

(2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including medical devices that deliver energy to tissue.

Less work experience may be compensated by a higher level of education, and vice versa.

Patent Owner's Definition

A POSITA would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of

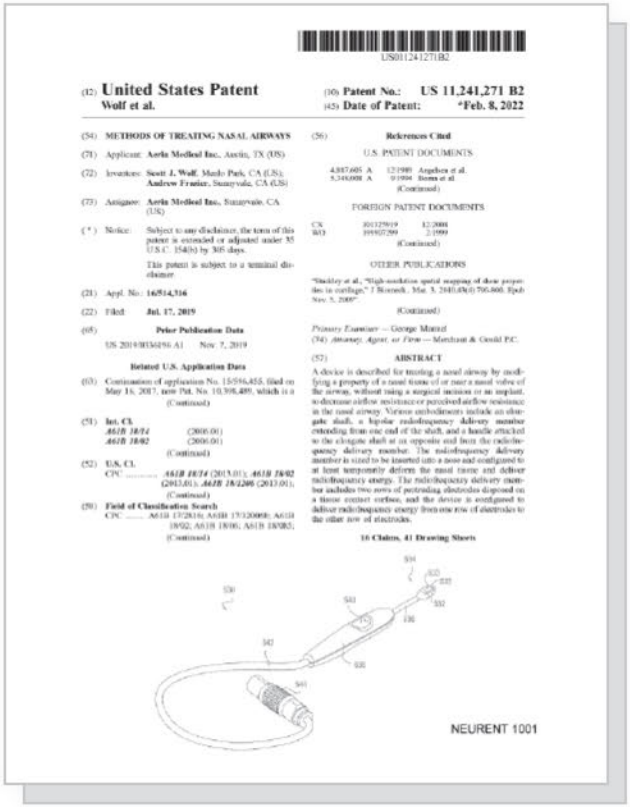
science degree in engineering or a related discipline and

(2) at least three years of experience in the ~~**clinical use,**~~ design **and[[,]]** development, ~~**and/or testing**~~ of medical devices, including medical devices that deliver energy to tissue.

'277 Ex.1083, ¶6; '277 Reply, 28-31

Challenged Claims

Representative Independent Claim—'271 Patent



US011241271B2

(12) **United States Patent**
Wolf et al.

(10) **Patent No.: US 11,241,271 B2**
(45) **Date of Patent: *Feb. 8, 2022**

(54) METHODS OF TREATING NASAL AIRWAYS

(71) Applicant: **Aerin Medical Inc.**, Austin, TX (US)

(72) Inventors: **Scott J. Wolf**, Menlo Park, CA (US); **Andrew Frazier**, Sunnyvale, CA (US)

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

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 305 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **16/514,316**

(22) Filed: **Jul. 17, 2019**

(65) **Prior Publication Data**

US 2019/0336196 A1 Nov. 7, 2019

Related U.S. Application Data

(63) Continuation of application No. 15/596,455, filed on May 16, 2017, now Pat. No. 10,398,489, which is a (Continued)

(51) **Int. Cl.**
A61B 18/14 (2006.01)
A61B 18/02 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 18/14*** (2013.01); ***A61B 18/02*** (2013.01); ***A61B 18/1206*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/2816; A61B 17/320068; A61B 18/02; A61B 18/06; A61B 18/085;
(Continued)

(56) **References Cited**

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(Continued)

Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — Merchant & Gould P.C.

(57) **ABSTRACT**

A device is described for treating a nasal airway by modifying a property of a nasal tissue of or near a nasal valve of the airway, without using a surgical incision or an implant, to decrease airflow resistance or perceived airflow resistance in the nasal airway. Various embodiments include an elongate shaft, a bipolar radiofrequency delivery member extending from one end of the shaft, and a handle attached to the elongate shaft at an opposite end from the radiofrequency delivery member. The radiofrequency delivery member is sized to be inserted into a nose and configured to at least temporarily deform the nasal tissue and deliver radiofrequency energy. The radiofrequency delivery member includes two rows of protruding electrodes disposed on a tissue contact surface, and the device is configured to deliver radiofrequency energy from one row of electrodes to the other row of electrodes.

16 Claims, 41 Drawing Sheets

NEURENT 1001

1. A **method for treating a nasal airway** to reduce mucus production, the method comprising:

contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;

applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and

removing the treatment element from the nasal airway,

wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue, and

wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.

'278 Petition, Ex.1001-'271 Patent, Claim 1

Dr. DelGaudio and Dr. Martin Are POSITAs



Dr. John DelGaudio

Chief of Rhinology, Sinus, and Skull Base Surgery, Emory University School of Medicine

- Practicing otolaryngologist of over 30 years
- Former president of American Rhinologic Society
- Used RF energy devices in the nose for decades
- Routine consultant for medical device designers and manufacturers
- Designed disposable microdebrider device



Dr. Greg Martin

Principal, Tremont Consulting LLC

- Ph.D. in mechanical engineering, MIT
- Designed and developed energy-based medical devices since 1998
- Senior Lecturer at Boston University
- Vice President of R&D for 4 different companies
- Chief Technology Officer for Hemedex, Inc.

'277 Ex.1002, Appendix A; '277 Ex.1004, Appendix A; '277 Reply, 25-28

None of Patent Owner's Arguments Rely on POSITA Definition



Dr. Marom Bikson

PO's Declarant

> 42. I met both parties' definitions of a POSITA as of the time of the invention of the Challenged Claims of the '271 patent. My opinions herein are the same regardless of which definition the Board applies.

'277 Petition, Ex.2001, ¶42; '271 Reply, 25

Date: April 21, 2025

Respectfully Submitted,

By: /David L. Cavanaugh/
David Cavanaugh
Reg. No. 36,476

CERTIFICATE OF SERVICE

I hereby certify that, on April 21, 2025, I caused a true and correct copy of:

- Petitioners' Demonstratives for Oral Argument

to be served on Patent Owner via electronic mail to:

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