Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Robert E. Wright	Nonprovisional Application Number (if known):	
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Daniel C. Higgs/	Date 2020-07-20
Name (Print/Typed) Daniel C. Higgs	Practitioner Registration Number 55265

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☐ *Total of _____ forms are submitted.

Privacy Act Statement

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NBUS.004C1C1
	Application Number	
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Robert	E.	Wright	

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

City	Country of Residence	
Clayton	AU	

Mailing Address of Inventor:

Address 1	Metro Pain Group Pty Ltd
Address 2	Monash House, Ground Floor, 271 Clayton Road
City	Clayton
State/Province	
Postal Code	3168
Country	AU

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Scott	A.	Brandt	

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

City	State/Province	Country of Residence	
Denver	CO	US	

Mailing Address of Inventor:

Address 1	333 S. Monroe St. Unit 113
Address 2	
City	Denver
State/Province	CO
Postal Code	80209
Country	US

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

Correspondence Information:

Petitioner's Exhibit 1006
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NBUS.004C1C1
	Application Number	
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	

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

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

Customer Number	148468		
Email Address	dhiggs@biomerics.com	Add Email	Remove Email
Email Address	dhiggs@medventureholdings.com	Add Email	Remove Email

Application Information:

Title of the Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY		
Attorney Docket Number	NBUS.004C1C1	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	41	**Suggested Figure for Publication (if any)**	2D

Filing By Reference:

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

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

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

Publication Information:

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

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

Representative Information:

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

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

Petitioner's Exhibit 1006
Avanos v. Stratus

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NBUS.004C1C1
	Application Number	
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	

Customer Number	148468

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15092945	2016-04-07
Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15092945	Continuation of	13101009	2011-05-04
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13101009	Claims benefit of provisional	61347351	2010-05-21
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13101009	Claims benefit of provisional	61357886	2010-06-23
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13101009	Claims benefit of provisional	61357894	2010-06-23

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

Foreign Priority Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NBUS.004C1C1
	Application Number	
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	

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

Remove

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

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NBUS.004C1C1
	Application Number	
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	

Authorization or Opt-Out of Authorization to Permit Access:

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

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

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

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

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

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

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

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

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NBUS.004C1C1
	Application Number	
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	

Applicant Information:

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

Applicant 1 — Remove

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

Clear

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

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

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Stratus Medical, LLC		
Mailing Address Information For Applicant:			
Address 1	6030 W. Harold Gatty Dr.		
Address 2			
City	Salt Lake City	**State/Province**	UT
Country	US	Postal Code	84116
Phone Number		Fax Number	
Email Address	dhiggs@medventureholdings.com		

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

Assignee Information including Non-Applicant Assignee Information:

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NBUS.004C1C1
	Application Number	
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Assignee 1

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

Remove

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

Organization Name	Stratus Medical, LLC

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	6030 W. Harold Gatty Dr.		
Address 2			
City	Salt Lake City	**State/Province**	UT
Country i	US	Postal Code	84116
Phone Number		Fax Number	
Email Address	dhiggs@medventureholdings.com		

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

Signature:

Remove

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

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

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

Signature	/Daniel C. Higgs/			Date (YYYY-MM-DD)	2020-07-20
First Name	Daniel	Last Name	Higgs	Registration Number	55265

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NBUS.004C1C1
	Application Number	
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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

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

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

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

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

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

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

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

NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 15/092,945, filed April 7, 2016, titled SYSTEMS AND METHODS FOR TISSUE ABLATION, which is a continuation of U.S. Patent Application No. 13/101,009, filed May 4, 2011, titled SYSTEMS AND METHODS FOR TISSUE ABLATION, which claims priority benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application No. 61/347,351, filed May 21, 2010, titled METHODS AND SYSTEMS FOR SPINAL RADIO FREQUENCY NEUROTOMY, U.S. Provisional Patent Application No. 61/357,886, filed June 23, 2010, titled INTERVERTEBRAL DISC HEATING, and U.S. Provisional Patent Application No. 61/357,894, filed June 23, 2010, titled LARGE FIELD DIRECTIONAL RADIOFREQUENCY NEUROABLATION, each of which is incorporated herein by reference in its entirety.

BACKGROUND

Field

[0002] The present application generally relates to thermal ablation systems and methods, and more particularly to systems and methods for radio frequency (RF) neurotomy, such as spinal RF neurotomy.

Description of the Related Art

[0003] Thermal ablation involves the creation of temperature changes sufficient to produce necrosis in a specific volume of tissue within a patient. The target volume may be, for example, a nerve or a tumor. A significant challenge in ablation therapy is to provide adequate treatment to the targeted tissue while sparing the surrounding structures from injury.

[0004] RF ablation uses electrical energy transmitted into a target volume through an electrode to generate heat in the area of the electrode tip. The radio waves emanate from a non-insulated distal portion of the electrode tip. The introduced radiofrequency energy causes molecular strain, or ionic agitation, in the area surrounding the electrode as the current

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flows from the electrode tip to ground. The resulting strain causes the temperature in the area surrounding the electrode tip to rise. RF neurotomy uses RF energy to cauterize a target nerve to disrupt the ability of the nerve to transmit pain signals to the brain.

SUMMARY

[0005] This application describes example embodiments of devices and methods for tissue ablation, such as spinal radio frequency neurotomy. Systems include needles with deployable filaments capable of producing asymmetrical offset lesions at target volumes, which may include a target nerve. Ablation of at least a portion of the target nerve may inhibit the ability of the nerve to transmit signals, such as pain signals, to the central nervous system. The offset lesion may facilitate procedures by directing energy towards the target nerve and away from collateral structures. Example anatomical structures include lumbar, thoracic, and cervical medial branch nerves and rami and the sacroiliac joint.

[0006] In some embodiments, a needle comprises an elongate member having a distal end, a tip coupled to the distal end of the elongate member, and a plurality of filaments. The tip comprises a bevel to a point. The plurality of filaments is movable between a first position at least partially in the elongate member and a second position at least partially out of the elongate member. The plurality of filaments and the tip are configured to transmit radio frequency energy from a probe to operate as a monopolar electrode.

[0007] In some embodiments, a needle comprises an elongate member having a distal end, a tip coupled to the distal end of the elongate member, and a plurality of filaments. The tip comprises a bevel portion comprising a point on a side of the elongate member. The plurality of filaments is movable between a first position at least partially in the elongate member and a second position at least partially out of and proximate to the side of the elongate member. The plurality of filaments and the tip are configured to transmit radio frequency energy from a probe to operate as a monopolar electrode.

[0008] In some embodiments, a needle comprises an elongate member having a proximal end and a distal end, a tip coupled to the distal end of the elongate member, a plurality of filaments, and a filament deployment mechanism coupled to the proximal end of the elongate member. The tip comprises a bevel portion comprising a point. The plurality of filaments is movable between a first position at least partially in the elongate member and a

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second position at least partially out of the elongate member. The plurality of filaments and the tip are configured to transmit radio frequency energy from a probe to operate as a monopolar electrode. The filament deployment mechanism comprises an advancing hub, a spin collar, and a main hub. The advancing hub includes a stem coupled to the plurality of filaments. The spin collar includes a helical track. The stem of the advancing hub is at least partially inside the spin collar. The main hub comprises a stem comprising a helical thread configured to cooperate with the helical track. The stem of the main hub is at least partially inside the spin collar. The stem of the advancing hub is at least partially inside the main hub. Upon rotation of the spin collar, the filaments are configured to move between the first position and the second position.

[0009] In some embodiments, a needle comprises an elongate member having a distal end, a tip coupled to the distal end of the elongate member, and a plurality of filaments. The tip comprises a point. The plurality of filaments is movable between a first position at least partially in the elongate member and a second position at least partially out of the elongate member. The plurality of filaments and the tip are configured to transmit radio frequency energy from a probe to operate as a monopolar electrode. A single wire comprises the plurality of filaments.

[0010] In some embodiments, a needle comprises an elongate member having a distal end, a tip coupled to the distal end of the elongate member, and a plurality of filaments. The tip comprises a bevel to a point. The plurality of filaments is movable between a first position at least partially in the elongate member and a second position at least partially out of the elongate member. The plurality of filaments and the tip are configured to transmit radio frequency energy from a probe to operate as a monopolar electrode. The tip comprises a stem at least partially in the elongate member. The stem includes a first filament lumen, a second filament lumen, and a third lumen. The bevel portion comprises a fluid port in fluid communication with the third lumen.

[0011] In some embodiments, a needle comprises an elongate member having a proximal end and a distal end, a tip coupled to the distal end of the elongate member, a plurality of filaments, and a rotational deployment mechanism coupled to the proximal end of the elongate member. The tip comprises a bevel to a point. The plurality of filaments is movable between a plurality of positions between at least partially in the elongate member

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and at least partially out of the elongate member. The deployment mechanism comprises indicia of fractional deployment of the plurality of filaments relative to the tip. The plurality of filaments and the tip are configured to transmit radio frequency energy from a probe to operate as a monopolar electrode.

[0012] In some embodiments, a needle comprises an elongate member having a distal end, a tip, and a plurality of filaments. The tip comprises a first body portion and a second body portion. The first body portion includes a tapered portion and a point. The tapered portion includes a plurality of filament ports. The second body portion is coupled to the distal end of the tip. The second body portion is at an angle with respect to the first body portion. The plurality of filaments is movable between a first position at least partially in at least one of the tip and the elongate member and a second position at least partially out of the filament ports. The plurality of filaments and the tip are configured to transmit radio frequency energy from a probe to operate as a monopolar electrode.

[0013] In some embodiments, a method of heating a vertebral disc comprises: positioning a distal end of a needle in a posterior annulus; deploying a filament out of the needle; traversing the posterior annulus from lateral to medial; applying radio frequency energy to the tip and to the filament; and ablating pain fibers in the posterior annulus.

[0014] In some embodiments, a needle for insertion into a patient during an RF ablation procedure comprises a hub, an elongate member fixed to the hub, a tip fixed to the elongate member at a distal end of the needle, a plurality of filaments in at least a portion of the elongate member, an actuator interconnected to the plurality of filaments, and a lumen in the elongate member. The tip is shaped to pierce tissue of the patient. Movement of the actuator relative to the hub moves the plurality of filaments relative to the tip. The lumen and the tip are configured to accept an RF probe such that an electrode of an inserted RF probe, the tip, and the first and second filaments are operable to form a single monopolar RF electrode.

[0015] In some embodiments, a needle for insertion into a patient during an RF ablation procedure comprises a hub, an elongate member fixed to the hub, a tip fixed to the elongate member at a distal end of the needle, a plurality of filaments in at least a portion of the elongate member in a retracted position, and an actuator interconnected to the plurality of filaments. The actuator is operable to move the plurality of filaments relative to the hub, the

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elongate member, and the tip between the retracted position and a fully deployed position. In the fully deployed position, the plurality of filaments extends outwardly and away from the tip. Each filament comprises a distal end that defines a point in the fully deployed position. Each point is distal to the distal end of the needle. The average of all the points is offset from a central longitudinal axis of the elongate member.

[0016] In some embodiments, a needle for insertion into a patient during an RF ablation procedure comprises a hub, an elongate member fixed to the hub, a tip fixed to the elongate member at a distal end of the needle, a plurality of filaments in at least a portion of the elongate member in a retracted position, and an actuator interconnected to the plurality of filaments. The actuator is operable to move the plurality of filaments relative to the hub, the elongate member, and the tip between the retracted position and a deployed position. In the deployed position, the plurality of filaments extends outwardly and away from the tip. Each filament comprises a distal end that defines a point in the deployed position. Each point is distal to the distal end of the needle. Each point is on a common side of a plane that contains a central longitudinal axis of the elongate member.

[0017] In some embodiments, a needle for insertion into a patient during an RF ablation procedure comprises a hub, an elongate member fixed to the hub, a tip fixed to the elongate member at a distal end of the needle, a plurality of filaments in at least a portion of the elongate member in a retracted position, and an actuator interconnected to the plurality of filaments. The plurality of filaments consists of a first filament and a second filament, and the needle contains no filaments other than the first and second filaments. The actuator is operable to move the plurality of filaments relative to the hub, the elongate member, and the tip between the retracted position and a deployed position. In the deployed position, the plurality of filaments extends outwardly and away from the tip. Each filament comprises a distal end that defines a point in the deployed position. Each point is distal to the distal end of the needle. In the deployed position, a midpoint between the distal end of the first filament and the distal end of the second filament is offset from a central longitudinal axis of the needle.

[0018] In some embodiments, a needle for insertion into a patient during an RF ablation procedure comprises a hub, an elongate member fixed to the hub, a tip fixed to the elongate member at a distal end of the needle, a plurality of filaments in at least a portion of

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the elongate member in a retracted position, and an actuator interconnected to the plurality of filaments. The plurality of filaments consists of a first filament and a second filament, and the needle contains no filaments other than the first and second filaments. The actuator is operable to move the plurality of filaments relative to the hub, the elongate member, and the tip between the retracted position and a deployed position. In the deployed position, the plurality of filaments extends outwardly and away from the tip. Each filament comprises a distal end that defines a point in the deployed position. Each point is distal to the distal end of the needle. In their respective deployed positions, each distal end defines a vertex of a polygon. A centroid of the polygon is offset from a central longitudinal axis of the needle.

[0019] In some embodiments, a needle for insertion into a patient during an RF ablation procedure comprises a hub, an elongate member fixed to the hub, a tip fixed to the elongate member at a distal end of the needle, a plurality of filaments in at least a portion of the elongate member in a retracted position, and an actuator interconnected to the plurality of filaments. The plurality of filaments consists of a first filament and a second filament, and the needle contains no filaments other than the first and second filaments. The actuator is operable to move the plurality of filaments relative to the hub, the elongate member, and the tip between the retracted position and a deployed position. In the deployed position, the plurality of filaments extends outwardly and away from the tip. Each filament comprises a distal end that defines a point in the deployed position. Each point is distal to the distal end of the needle. In their respective deployed positions, each of the plurality of filaments points in an at least partially distal direction.

[0020] In some embodiments, a needle for insertion into a patient during an RF ablation procedure comprises a hub, an elongate member fixed to the hub, a tip fixed to the elongate member at a distal end of the needle, a plurality of filaments in at least a portion of the elongate member in a retracted position, and an actuator interconnected to the plurality of filaments. The plurality of filaments consists of a first filament and a second filament, and the needle contains no filaments other than the first and second filaments. The actuator is operable to move the plurality of filaments relative to the hub, the elongate member, and the tip between the retracted position and a deployed position. In the deployed position, the plurality of filaments extends outwardly and away from the tip. Each filament comprises a distal end that defines a point in the deployed position. Each point is distal to the distal end

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of the needle. When the plurality of filaments are in the deployed position, portions of each filament extend outwardly away from the tip. Each portion of each filament extending outwardly away from the tip is straight.

[0021] In some embodiments, a needle for insertion into a patient during an RF ablation procedure comprises a hub, an elongate member fixed to the hub, a tip fixed to the elongate member at a distal end of the needle, a plurality of filaments in at least a portion of the elongate member in a retracted position, and an actuator interconnected to the plurality of filaments. The plurality of filaments consists of a first filament and a second filament, and the needle contains no filaments other than the first and second filaments. The actuator is operable to move the plurality of filaments relative to the hub, the elongate member, and the tip between the retracted position and a deployed position. In the deployed position, the plurality of filaments extends outwardly and away from the tip. Each filament comprises a distal end that defines a point in the deployed position. Each point is distal to the distal end of the needle. When the plurality of filaments is in the deployed position, the tip comprises an angle of at least 200° about the central longitudinal axis of the elongate member that is free of filaments.

[0022] In some embodiments, a method of performing spinal RF neurotomy in a patient comprises moving a tip of a needle to a first position proximate to a target nerve along the spine of the patient, after achieving the first position, advancing a plurality of filaments relative to the tip to a deployed position, and after the advancing step, applying RF energy to the tip and plurality of filaments, wherein said applying generates heat that ablates a portion of the target nerve.

[0023] In some embodiments, a method of performing lumbar RF neurotomy on a medial branch nerve in a patient comprises: moving a tip of a needle to a first position between the transverse and superior articular processes of a lumbar vertebra such that an end point of the tip is proximate to a surface of the vertebra; after achieving the first position, advancing a plurality of filaments relative to the tip to a deployed position; and after advancing the plurality of filaments, applying RF energy to the tip and the plurality of filaments. Said applying generates heat that ablates a portion of the medial branch nerve.

[0024] In some embodiments, a method of performing sacroiliac joint RF neurotomy in a patient comprises: a. moving a tip of a needle to a first position proximate to

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a sacrum of the patient; b. advancing a plurality of filaments relative to the tip to a first deployed position; c. applying RF energy to the tip and plurality of filaments, wherein the applying generates heat that ablates a first volume; d. retracting the plurality of filaments; e. with the tip in the first position, rotating the needle about a central longitudinal axis of the needle to re-orient the plurality of filaments; f. re-advancing the plurality of filaments relative to the tip; and g. re-applying RF energy to the tip and plurality of filaments, wherein the re-applying comprises ablating a second volume proximate to the tip, wherein a center of the first volume is offset from a center of the second volume.

[0025] In some embodiments, a method of performing thoracic RF neurotomy on a medial branch nerve in a patient comprises: moving a tip of a needle to a first position proximate a superior surface of a transverse process of a thoracic vertebra such that an end point of the tip is proximate to the superior surface; after achieving the first position, advancing a plurality of filaments relative to the tip toward a vertebra immediately superior to the thoracic vertebra to a deployed position; and after advancing the plurality of filaments, applying RF energy to the tip and the plurality of filaments, wherein said applying generates heat that ablates a portion of the medial branch nerve between the thoracic vertebra and the vertebra immediately superior to the thoracic vertebra.

[0026] In some embodiments, a method of performing cervical medial branch RF neurotomy on a third occipital nerve of a patient comprises: a. positioning the patient in a prone position; b. targeting a side of the C2/3 Z-joint; c. rotating the head of the patient away from the targeted side; d. locating the lateral aspect of the C2/3 Z-joint; e. moving, after steps a, b, c and d, a tip of a needle over the most lateral aspect of bone of the articular pillar at the juncture of the C2/3 z-joint to a first position contacting bone proximate to the most posterior and lateral aspect of the z-joint complex; f. retracting, after step e, the tip of the needle a predetermined distance from the first position; g. extending, after step f, a plurality of filaments outwardly from the tip and towards the lateral aspect of the C2/3 z-joint such that the plurality of filaments are positioned straddling the lateral joint lucency and posterior to the C2/3 neural foramen; h. verifying, after step g, the position of the tip and filaments by imaging the tip and a surrounding volume; and i. applying, after step h, RF energy to the tip and the plurality of filaments, wherein the applying generates heat that ablates a portion of the third occipital nerve.

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[0027] For purposes of summarizing the invention and the advantages achieved over the prior art, certain objects and advantages of the invention are described herein. Of course, it is to be understood that not necessarily all such objects or advantages need to be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught or suggested herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

[0028] All of these embodiments are intended to be within the scope of the invention herein disclosed. These and other embodiments will become readily apparent to those skilled in the art from the following detailed description having reference to the attached figures, the invention not being limited to any particular disclosed embodiment(s).

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] These and other features, aspects, and advantages of the present disclosure are described with reference to the drawings of certain embodiments, which are intended to illustrate certain embodiments and not to limit the invention.

[0030] Figure 1 is a schematic diagram of an RF neurotomy system being used to perform RF neurotomy on a patient.

[0031] Figure 2A is a perspective view of an example embodiment of a needle that may be used in an RF neurotomy procedure.

[0032] Figure 2B is a cut away perspective view of a portion of the needle of Figure 2A.

[0033] Figure 2C is a partial cut away and partial cross-sectional view of a portion of another example embodiment of a needle that may be used in an RF neurotomy procedure.

[0034] Figure 2D is a perspective view of another example embodiment of a needle that may be used in an RF neurotomy procedure.

[0035] Figure 2E is a perspective view of an example embodiment of filaments formed from a single wire.

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[0036] Figure 3A is a detailed view of an example embodiment of a needle tip with filaments in a fully deployed position.

[0037] Figure 3B is a detailed view of the needle tip of Figure 3A with filaments in a retracted position.

[0038] Figure 3C is a detailed view of another example embodiment of a needle tip with filaments in a deployed position.

[0039] Figure 3D is a detailed view of another example embodiment of a needle tip with filaments in a fully deployed position.

[0040] Figure 3E is a detailed view of the needle tip of Figure 3D with filaments in a retracted position.

[0041] Figure 3F is a cross-sectional view of the needle tip of Figure 3D with filaments in a retracted position.

[0042] Figure 3G is a detailed view of yet another example embodiment of a needle tip with filaments in a deployed position.

[0043] Figs. 3H and 3I are detailed views of still other example embodiments of a needle tip with filaments in a deployed position.

[0044] Figure 4 is a schematic diagram of an example embodiment of an RF probe assembly.

[0045] Figure 5 is a proximal-facing end view of an example embodiment of a needle tip.

[0046] Figure 6 is a side view of an example embodiment of a needle tip.

[0047] Figure 7 is a proximal-facing end view of another example embodiment of a needle tip.

[0048] Figure 8 is a proximal-facing end view of yet another example embodiment of a needle tip.

[0049] Figure 9 is a proximal-facing end view of still another example embodiment of a needle tip.

[0050] Figure 10 is a side view of another example embodiment of a needle tip.

[0051] Figure 11A is an illustration of an example set of isotherms that may be created with the needle of Figure 2A.

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[0052] Figure 11B is an illustration of an example lesion that may be created with the needle of Figure 2A.

[0053] Figure 11C is an illustration of an example lesion that may be created with a single-filament needle.

[0054] Figure 12 is a perspective view of the needle of Figure 2A positioned relative to a lumbar vertebra for performing RF neurotomy.

[0055] Figure 13 is an illustration of a sacrum including target lesion volumes for performing Sacroiliac Joint (SIJ) RF neurotomy.

[0056] Figure 14 is a perspective view of the needle of Figure 2A positioned relative to a thoracic vertebra for performing RF neurotomy.

[0057] Figure 15 is a perspective view of the needle of Figure 2A positioned relative to the C2/3 cervical zygapophyseal joint (z-joint) for performing cervical medial branch RF neurotomy on the third occipital nerve.

[0058] Figure 16A is a perspective view of an example embodiment of a needle tip.

[0059] Figure 16B is a back elevational view of the needle tip of Figure 16A.

[0060] Figure 16C is a front elevational view of the needle tip of Figure 16A.

[0061] Figure 16D is a perspective view of an example embodiment of an elongate member.

[0062] Figure 16E is a perspective view of the needle tip of Figure 16A and the elongate member of Figure 16D.

[0063] Figure 16F is a cross-sectional view of the needle tip and elongate member of Figure 16E along the line 16F-16F of Figure 16E and example embodiments of a filament and an RF probe.

[0064] Figure 16G is a cross-sectional view of another example embodiment of a needle tip and elongate member and example embodiments of a filament and an RF probe.

[0065] Figure 17A is an exploded view of components of the deployment mechanism of Figure 2D.

[0066] Figure 17B is a cross-sectional view of components of the deployment mechanism of Figure 2D.

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[0067] Figure 17C is a perspective view of an example embodiment of an advancing hub and the wire of Figure 2E.

[0068] Figure 17D is a cross-sectional view of an example embodiment of a spin collar.

[0069] Figure 17E is a cross-sectional view of an example embodiment of a main hub, taken along the line 17E-17E of Figure 17B, in exploded view with an example embodiment of an elongate member.

[0070] Figure 18A is an axial view of posterior oblique needle entry.

[0071] Figure 18B is a saggital view of posterior oblique needle entry.

DETAILED DESCRIPTION

[0072] Although certain embodiments and examples are described below, those of skill in the art will appreciate that the invention extends beyond the specifically disclosed embodiments and/or uses and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the invention herein disclosed should not be limited by any particular embodiments described below.

[0073] In the following description, the invention is set forth in the context of apparatuses and methods for performing RF ablation. More particularly, the systems and methods may be used to perform RF neurotomy to ablate portions of target nerves. Even more particularly, the systems and methods may be used to perform spinal RF neurotomy to ablate portions of target nerves along the spine of a patient to relieve pain. For example, embodiments of methods and apparatuses described herein relate to lumbar RF neurotomy to denervate a facet joint between the L4 and L5 lumbar vertebrae. Denervation may be achieved by application of RF energy to a portion of a medial branch nerve to ablate or cauterize a portion of the nerve, thus interrupting the ability of the nerve to transmit signals to the central nervous system. In another example, embodiments described herein relate to sacroiliac joint RF neurotomy.

[0074] Figure 1 illustrates an example embodiment of a system 100 for performing RF neurotomy on a patient 101. The patient 101 may be positioned face down on a table or surface 109 to allow access along the spine of the patient 101. Other patient

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orientations are also possible depending on the procedure. The table 109 may comprise radiolucent materials substantially transparent to x-rays, such as carbon fiber.

[0075] The system 100 may include an RF generator 102 capable of generating an RF energy signal sufficient to ablate target tissue (e.g.: cause lesions in targeted volumes; cauterize targeted portions of target nerves). The RF generator 102 may, for example, be capable of delivering RF energy between about 1 W and about 200 W and between about 460,000 Hz and about 500,000 Hz. A needle 103 capable of conducting (e.g., transmitting or directing) RF energy may be interconnected to the RF generator 102 and may be used to deliver an RF energy signal to a specific site within the patient 101. In some embodiments in which the needle 103 is a monopolar device, a return electrode pad 104 may be attached to the patient 101 to complete a circuit from the RF generator 102, through the needle 103, through a portion of the patient 101, through the return electrode pad 104, and back to the RF generator 102. In some embodiments comprising a bipolar arrangement, the needle 103 may comprise at least one supply electrode and at least one return electrode to define the circuit.

[0076] The RF generator 102 may be operable to control the RF energy emanating from the needle 103 in a closed-loop fashion. For example, the needle 103 and/or an RF probe in the needle 103 may include a temperature measurement device, such as a thermocouple, configured to measure temperature at the target tissue. Data may also be available from the RF generator 102, such as power level and/or impedance, which may also be used for closed-loop control of the needle 103. For example, upon detection of a temperature, a parameter (e.g., frequency, wattage, application duration) of the RF generator 102 may be automatically adjusted.

[0077] Figure 4 illustrates an example RF probe assembly 400 compatible with the needle 103. The RF probe assembly 400 includes an RF probe 401 that may be inserted into a patient (e.g., through the needle 103) and may direct RF energy to the target tissue. In some embodiments, the RF probe 401 may be in electrical communication with the needle 103 to direct RF energy to the target tissue, but is not inserted into the patient. The RF probe 401 may include a thermocouple operable to measure temperature at a distal end 402 of the RF probe 401. The RF probe assembly 400 may include a connector 403 and a cable 404 configured to connect the RF probe 401 to an RF generator (e.g., the RF generator 102).

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[0078] Returning to Figure 1, the system 100 optionally includes an imaging system 105 capable of producing internal images of the patient 101 and the needle 103, for example to facilitate navigation of the needle 103 during a procedure. The system 100 may further include a display device for displaying the generated images to a user performing the procedure. In some embodiments, the imaging system 105 comprises a fluoroscope capable of generating real-time two dimensional images of the needle 103 and internal structures of the patient 101. In certain such embodiments, the imaging system includes an X-ray source 106, an X-ray detector 107, and a controller 108 in electrical communication with the X-ray source 106 and/or the X-ray detector 107. The X-ray source 106 and X-ray detector 107 may be mounted on a movable structure (e.g., a C-arm), to facilitate capturing a variety of images of the patient 101 (e.g., at various angles or projection views). Other imaging systems 105 are also possible (e.g., a computed tomography (CT) scanner).

[0079] Figure 2A illustrates an example embodiment of a needle 103 that may be used in the system 100 for performing RF neurotomy. The needle 103 includes a tip 201 that tapers to a point 301 capable of piercing the skin of a patient. In some embodiments, the tip point tapers to a point substantially at the center of the tip 201 (e.g., a "pencil-point" tip). In some embodiments, the tip point tapers to a point substantially at one side of the tip 201 (e.g., a "cutting" or "beveled" or "lancet" or "Quincke" tip). The needle 103 further includes an elongate member 203 connected to the tip 201 at a distal end 202 of the needle 103 and connected to a hub 204 at a proximal end 205 of the needle 103. The needle 103 includes a longitudinal axis 223 along the center of the elongate member 203.

[0080] Figure 2D illustrates another example embodiment of a needle 103 that may be used in the system 100 for performing RF neurotomy. The needle 103 includes a tip 211 that tapers to a point 301 capable of piercing the skin of a patient. In some embodiments, the tip point tapers to a point substantially at the center of the tip 211 (e.g., a "pencil-point" tip). In some embodiments, the tip point tapers to a point substantially at one side of the tip 211 (e.g., a "cutting" or "beveled" or "lancet" or "Quincke" tip). The needle 103 further includes an elongate member 203 connected to the tip 211 at a distal end 202 of the needle 103 and connected to a hub 204 at a proximal end 205 of the needle 103. The needle 103 includes a longitudinal axis 223 along the center of the elongate member 203.

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[0081] The needle 103 may include a self-contained mechanical mechanism, in the form of deployable filaments 206a, 206b, operable to expand the volume of effective RF energy delivery as compared to known single-electrode RF probes. The filaments 206a, 206b may be at least partially in the elongate member 203 and may be operable to emerge through one or more apertures of the needle 103 proximate to the distal end 202 of the needle 103. In some embodiments, the needle 103 includes a single filament or three or more filaments. The filaments 206a, 206b allow contraction/expansion, offsetting, and/or contouring of the effective RF energy delivery over a selected area of anatomy to adjust lesion geometry produced using the needle 103 to match a desired target volume (e.g., spherical, hemispherical, planar, spheroid, kidney-shaped, catcher's mitt-shaped, oblong, snowman-shaped, etc.). The filaments 206a, 206b may be deployable and/or retractable by moving (e.g., rotating) an actuator 216 relative to the hub 204.

[0082] As will be further described, the needle 103 may further include a tube 207 that includes a lumen 222 therethrough. The lumen 222 may be used to transport fluids to and/or from the target volume. The lumen 222 may also accept the RF probe 401 for delivery of RF energy to the target volume. The lumen 222 may also accept a dummy or temporary probe, for example to occlude the fluid port 210 during insertion. In some embodiments, the RF probe 401 is integrated with the needle 103. In certain such embodiments, the tube 207 need not be present for RF energy delivery, although it may be included to facilitate fluid delivery. In some embodiments, the filaments 206a, 206b include lumens therethrough for the transportation of fluid to and/or from the target volume. In some embodiments, the filaments 206a, 206b do not include lumens therethrough (e.g., being solid). The filaments 206a, 206b may function as thermocouples.

[0083] As RF energy penetrates biological tissue, protein and water molecules oscillate in response to the RF current and the tissue adjacent to the RF electrode is heated. As the tissue heats and coagulates, the biophysical properties of the tissue change. These tissue changes limit penetration of the RF energy beyond a leading edge defined by the shape and size of an active needle tip. Accordingly, the size of a radiofrequency lesion using conventional single needle technology is practically limited after achievement of a certain temperature delivered for a certain time.

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[0084] A needle 103 with deployable filaments 206a, 206b can overcome this obstacle and expand the effective area of RF energy delivery by providing multiple locations (e.g., the tip 201, 211 the filament 206a, and/or the filament 206b) from which the RF energy emanates. The use of multiple filaments 206a, 206b provides additional conduits for RF energy, creating a multiple electrode RF field effect. The size, shape, and location of a lesion created with the needle 103 may be at least partially determined by, for example, the quantity, angle, length, location, and/or orientation of the filaments and RF energy parameters such as wattage, frequency, and/or application duration, one or all of which may be beneficially modified to suit a specific anatomical application by changing various aspects of the filaments as discussed below.

[0085] Where it is desired to create a lesion offset from the central longitudinal axis 223, the lesion may be offset in a desired direction from the central longitudinal axis 223 by rotationally orienting the needle 103. The needle 103 may be used to create a lesion offset from the central longitudinal axis 223 in a first direction. The filaments 206a, 206b may be retracted (e.g., after creating a first lesion), the needle 103 rotated, and the filaments 206a, 206b re-deployed to create a lesion offset from the central longitudinal axis 223 in a second direction (e.g., to create a second lesion).

[0086] Figures 3A and 3B are detailed views of an example embodiment of a distal end 202 of a needle 103 that includes a tip 201. The tip 201 may include a sharpened point 301 (e.g., tapering to a point substantially at the center of the tip 201, a pencil-point tip) for piercing the skin of a patient and facilitating advancement through tissue. The tip 201 may include a tapered portion 302 that transitions the tip 201 from the point 301 to a body portion 303. The body portion 303 is the portion of the tip 201 that is proximal to the tapered portion 302. The body portion 303 may be cylindrical as illustrated, or may be other appropriate shapes. The body portion 303 may have a cross-section that coincides with (e.g., is coaxial with) the cross section of the elongate member 203.

[0087] Figures 3D and 3E are detailed views of another example embodiment of a distal end 202 of a needle 103 that includes a tip 211. The tip 211 may include a sharpened point 301 (e.g., tapering to a point substantially at one side of the tip 201, a cutting or beveled or lancet or Quincke tip) for piercing the skin of a patient and facilitating advancement through tissue. The tip 211 may include a tapered portion 302 that transitions the tip 211

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from the point 301 to a body portion 303. The body portion 303 is the portion of the tip 201 that is proximal to the tapered portion 302. The body portion 303 may be cylindrical as illustrated, or may be other appropriate shapes (e.g., as illustrated in Figure 16A). The body portion 303 may have a cross-section that coincides with (e.g., is coaxial with) the cross section of the elongate member 203. In some embodiments, the tip 211 has a bevel angle between about 10° and about 45°, between about 15° and about 35°, between about 20° and about 30° (e.g., about 25°), combinations thereof, and the like. Other bevel angles are also possible. In some embodiments, the point 301 has an angle between about 40° and about 120°, between about 70° and about 90°, between about 75° and about 85° (e.g., about 79°), combinations thereof, and the like. Other angles are also possible.

[0088] The tip 201, 211, or a non-insulated portion thereof, may act as an RF energy delivery element. The tip 201, 211 may comprise (e.g., be made from) a conductive material such as, for example, stainless steel (e.g., 300 Series Stainless Steel). The tip 201, 211 may be at least partially coated (e.g., with an insulator). The material of the tip 201, 211 and the material of the optional coating may be selected, for example, to act as an insulator, improve radiopacity, improve and/or alter RF energy conduction, improve lubricity, and/or reduce tissue adhesion.

[0089] The tip 201, 211 includes a first filament port or slot 304a (not visible in the views of Figures 3A, 3B, 3D, and 3E) and a second filament port or slot 304b. The geometry of the filament slots 304a, 304b may be selected to allow filaments 206a, 206b to be adequately retracted (e.g., such that the filaments 206a, 206b are in a cross-sectional envelope of the body portion 303 of the tip 201, 211, as shown in Figure 3F) while the needle 103 is inserted into the body, so that the filaments 206a, 206b do not cause any unintended damage to the patient. Such positioning of the filament slots 304a, 304b avoids having filament exit features on the tapered portion 302 and thus avoids potential coring that could be caused by such positioning.

[0090] The internal geometry of the filament slots 304a, 304b may be designed such that the filaments 206a, 206b may be easily retracted and advanced. For example, the internal geometry of the filament slots 304a, 304b may include a transition region 305 that meets the outer surface of the body portion 303 at an angle of about 30°. The transition region 305 may, for example, be curved and/or planar. Advancement of filaments 206a,

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206b without a pre-set bias (e.g., substantially straight) relative to the filament slots 304a, 304b can causes the filaments 206a, 206b to be deflected outwardly as the filaments 206a, 206b move distally along the transition region 305. Depending on the positioning of the transition region 305 relative to where the filaments 206a, 206b are confined (e.g., in the needle 103 of Figure 3A, the filaments 206a, 206b are confined to only longitudinal movement where they enter into the elongate member 203) and on the mechanical properties of the filaments 206a, 206b, various deployment angles of the filaments 206a, 206b relative to the central longitudinal axis 223 may be achieved. Generally, the portions of the filaments 206a, 206b that extend outwardly away from the filament slots 304a, 304b may be unrestrained and thus may take any appropriate form. For example, where there is no pre-set bias, the portions of the filaments that extend outwardly away from the filament slots 304a, 304b (and therefore from the tip) may be substantially straight, such as shown in Figures 2A, 3A, 3C, 3D, 6, 11A-11C, and 14. For another example, when there is a pre-set bias, the portions of the filaments that extend outwardly away from the filament slots may take any appropriate shape, such as, for example, curved as shown in Figure 10.

[0091] The radial orientation of the filament slots 304a, 304b may be selected such that a center point between the filament slots 304a, 304b does not coincide (e.g., is not coaxial with) with the central longitudinal axis 223. For example, as shown in Figures 2A, 3A, 3B, 3D, and 3E, the filament slots 304a, 304b may be positioned such that they are about 120° apart about the circumference of the tip 201, 211. Other filament slot configurations may be configured to achieve the filament placements discussed below. For example, the filament slots 304a, 304b may be between about 45° and about 180° apart about the circumference of the tip 201, 211, between about 90° and about 180° apart about the circumference of the tip 201, 211, between about 90° and about 150° apart about the circumference of the tip 201, 211, combinations thereof, and the like. Other angles are also possible. These configurations may be achieved by varying, for example, the quantity of filament slots, the placement of filament slots about the circumference of the tip 201, 211, and/or the placement of filament slots along the center longitudinal axis 223 to achieve the filament placements discussed below.

[0092] As noted herein, and illustrated in Figures 3A and 3B, the needle 103 may comprise a tube 207 that includes a lumen 222 therethrough. The lumen 222 may be

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employed to accept the RF probe 401 for delivery of RF energy, for the transport of fluids, and/or for occluding a fluid port 210. The tip 201, 211 may include a fluid port 210 that may be in fluid communication with the lumen 222 via a channel through the tip 201, 211. In certain embodiments, the lumen 222 is a dual-purpose lumen that can allow injection of fluids and that can receive the distal end 402 of the RF probe 401 to deliver RF energy to the tip 201, 211, the filament 206a, and/or the filament 206b. In some embodiments, the fluid port 210 is longitudinally spaced from the tip 301 (e.g., by between about 1 mm and about 3 mm). The fluid port 210 may be centrally located (e.g., as illustrated in Figure 3D) or it may be located offset from the center longitudinal axis 223 (e.g., as shown in Figures 2A and 3A). The fluid port 210 may be used to transfer fluid between the region of the tip 201, 211 and the proximal end 205 of the needle 103. For example, during an RF neurotomy procedure, an anesthetic and/or an image enhancing dye may be introduced into the region of tissue around the tip 201, 211 through the fluid port 210. In some embodiments, the fluid port 210 is located along the tapered portion 302 of the tip 201, 211 (e.g., as illustrated in Figures 3A and 3D). In some embodiments, the fluid port 210 is located along the body portion 303 of the tip 201, 211.

[0093] Figure 16A is a perspective view of an example embodiment of the needle tip 211. In some embodiments, the needle 103 does not comprise a tube 207, but the elongate member 203 comprises a lumen 308 therethrough and the tip 211 comprises a lumen 306c therethrough. The lumen 308 and the lumen 306c may be employed to accept the RF probe 401 for delivery of RF energy, for the transport of fluids, and or for occluding the fluid port 210. In certain embodiments, the lumen 308 and the lumen 306c are dual-purpose lumens that can allow injection of fluids and that can receive the distal end 402 of the RF probe 401 to deliver RF energy to the tip 211, the filament 206a, and/or the filament 206b. The filament lumens 306a, 306b may also allow liquid transfer from a proximal end of the needle to the filament ports 304a, 304b.

[0094] In some embodiments, the filament lumens 306a, 306b are sized to inhibit buckling and/or bending of the filaments in the tip 211. In some embodiments, the elongate member 203 may also include filament lumens (e.g., comprising tubes in the elongate member 203). In some embodiments, filament lumens in the elongate member 203 may be formed by an inner member (not shown) extending at least part of the length of the elongate

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member 203. For example, a transverse cross-section of the inner member may have the same cross-section as the portion of the tip 211 illustrated in Figure 3F, including channels in which the filaments may lie and a lumen for passing fluid, an RF probe 401, and/or a dummy probe.

[0095] Figure 16B is a back elevational view of the needle tip 211 of Figure 16A. Figure 16C is a front elevational view of the needle tip 211 of Figure 16A. The needle tip 211 comprises a filament lumen 306a in fluid communication with and terminating at the filament slot 304a, a filament lumen 306b in fluid communication with and terminating at the filament slot 304b, and the lumen 306c. In some embodiments, the lumens 306a, 306b are spaced by about 120° along the circumference of the tip 211. Other angles are also possible. In some embodiments, the lumen 306c is spaced from each of the lumens 306a, 306b by about 120° along the circumference of the tip 211. Other angles are also possible. Referring again to Figure 3F, the filament 206a may be in the filament lumen 306a and the filament 206b may be in the filament lumen 306b. The lumen 306c is in fluid communication with the fluid port 210. In some embodiments, the proximal end of the tip 211 includes a tapered surface, as shown in Figure 16A. When filaments 206a, 206b are in the filament lumens 306a, 306b, the tapered surface may help to guide insertion of an RF probe 401 into the lumen 306c. In some embodiments, the tapered surface has an angle normal to the tip 211 between about 15° and about 75°, between about 30° and about 60°, between about 40° and about 50° (e.g., about 45°), combinations thereof, and the like. Other angles are also possible.

[0096] Figure 16D is a perspective view of an example embodiment of an elongate member 203. The elongate member 203 includes the lumen 308, the filament slot 304a, and the filament slot 304b. In some embodiments, the filament slots 304a, 304b are spaced by about 120° along the circumference of the elongate member 203. Figure 16E is a perspective view of the needle tip 211 of Figure 16A and the elongate member 203 of Figure 16D. As described herein, the elongate member 203 may be coupled to the tip 211 by adhering with conductive epoxy, welding, soldering, combinations thereof, and the like. A proximal portion of the tip 211 can be inserted into the lumen 308 of the elongate member 203. The filament slot 304b of the elongate member 203 is substantially aligned with the lumen 306b of the tip 211, allowing the filament 206b to be deployed out of the lumen 306b.

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Although not illustrated, the filament slot 304a of the elongate member 203 is substantially aligned with the lumen 306a of the tip 211, allowing the filament 206a to be deployed out of the lumen 306a. In some embodiments, each of the filament slots 304a, 304b has a length between about 0.025 inches and about 0.2 inches (approx. between about 0.6 mm and about 3 mm), between about 0.05 inches and about 0.15 inches (approx. between about 1.3 mm and about 3.8 mm), between about 0.075 inches and about 0.125 inches (approx. between about 1.9 mm and about 3.2 mm) (e.g., about 0.105 inches (approx. about 2.7 mm)), combinations thereof, and the like. Other lengths are also possible. In some embodiments, each of the filament slots 304a, 304b has a width between about 0.01 inches and about 0.4 inches (approx. between about 0.25 mm and about 10 mm), between about 0.02 inches and about 0.03 inches (approx. between about 0.5 mm and about 0.76 mm), between about 0.015 inches and about 0.025 inches (approx. between about 0.38 mm and about 0.64 mm) (e.g., about 0.02 inches (approx. about 0.5 mm)), combinations thereof, and the like. Other widths are also possible. In some embodiments, the each of the transition regions 305 has a length between about 0.02 inches and about 0.2 inches (approx. between about 0.5 mm and about 5 mm), between about 0.05 inches and about 0.15 inches (approx. between about 1.3 mm and about 3.8 mm), between about 0.075 inches and about 0.125 inches (approx. between about 1.9 mm and about 3.2 mm) (e.g., about 0.104 inches (approx. about 2.6 mm)), combinations thereof, and the like. Other lengths are also possible. In some embodiments in which the transition regions include curved surfaces, the each of the transition regions 305 has a radius of curvature between about 0.01 inches and about 0.4 inches (approx. between about 0.25 mm and about 10 mm), between about 0.15 inches and about 0.35 inches (approx. between about 3.8 mm and about 8.9 mm), between about 0.2 inches and about 0.3 inches (approx. between about 5 mm and about 7.6 mm) (e.g., about 0.25 inches (approx. about 6.4 mm)), combinations thereof, and the like. Other radii of curvature are also possible. Certain combinations of dimensions of the transition regions 305 and filaments slots 304a, 304b described herein may cause deployment of the filaments 206a, 206b at desired angles (e.g., about 30°).

[0097] The lumen 308 is not visible in Figure 16E because the elongate member 203 covers the lumen 308. Covering the lumen 308 causes fluid inserted into the lumen 308 to exit the fluid port 210, and possibly the filament slots 304a, 304b. In some embodiments,

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for example as illustrated in Figures 3A and 3B, the elongate member 203 may also include a slot proximate to the tube 207. In certain such embodiments, the tube 207 may extend distal to the slot and substantially all fluid inserted into the lumen 222 exits the fluid port 210.

[0098] In the embodiment illustrated in Figure 16E, the body portion 303 of the tip 211 and the elongate member 203, excluding the sleeve 307, have substantially equal diameters, for example to provide a smooth transition between the tip 211 and the elongate member 203. In some embodiments, the elongate member 203 has an inner diameter between about 0.01 inches and about 0.04 inches (approx. between about 0.25 mm and about 1 mm), between about 0.015 inches and about 0.035 inches (approx. between about 0.38 mm and about 0.89 mm), between about 0.02 inches and about 0.03 inches (approx. between about 0.5 mm and about 0.76 mm) (e.g., about 0.025 inches (approx. about 0.64 mm)), combinations thereof, and the like. Other diameters are also possible. In some embodiments, the elongate member 203 has an outer diameter between about 0.01 inches and about 0.05 inches (approx. between about 0.25 mm and about 1.3 mm), between about 0.02 inches and about 0.04 inches (approx. between about 0.5 mm and about 1 mm), between about 0.025 inches and about 0.035 inches (approx. between about 0.64 mm and about 0.89 mm) (e.g., about 0.029 inches (approx. about 0.74 mm)), combinations thereof, and the like. Other diameters are also possible. In some embodiments, the proximal portion of the tip has an outer diameter between about 0.01 inches and about 0.04 inches (approx. between about 0.25 mm and about 1 mm), between about 0.015 inches and about 0.035 inches (approx. between about 0.38 mm and about 0.89 mm), between about 0.02 inches and about 0.03 inches (approx. between about 0.5 mm and about 0.76 mm) (e.g., about 0.025 inches (approx. about 0.64 mm)), combinations thereof, and the like. Other diameters are also possible. In some embodiments, the tip 211 has an outer diameter between about 0.01 inches and about 0.05 inches (approx. between about 0.25 mm and about 1.3 mm), between about 0.02 inches and about 0.04 inches (approx. between about 0.5 mm and about 1 mm), between about 0.025 inches and about 0.035 inches (approx. between about 0.64 mm and about 0.89 mm) (e.g., about 0.029 inches (approx. about 0.74 mm)), combinations thereof, and the like. Other diameters are also possible.

[0099] Figure 16F is a cross-sectional view of the needle tip 211 and the elongate member 203 along the line 16F-16F of Figure 16E. Figure 16F also illustrates an example

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embodiment of a filament 206a in the lumen 308 and the lumen 306a, then exiting via the filament slot 304a, and an RF probe 401 in the lumen 308. In some embodiments, the elongate member 203 and the tip each 211 comprise (e.g., are each made from) a conductive material (e.g., 300 Series Stainless Steel), and can conduct electrical signals from the RF probe 401 to the tip 211 and the filaments 206a, 206b (e.g., due to physical contact of conductive components) to form a monopolar electrode. In some embodiments, the RF probe 401, the filaments 206a, 206b, the tip 211, and/or the elongate member 203 may include features configured to increase physical contact between the components. The cross-sectional view shows the lumen 308 in fluid communication with the lumen 306c and the fluid port 210.

[0100] Figure 16G is another cross-sectional view of an example embodiment of a needle tip 211 and the elongate member 203 along a line similar to the line 16F-16F in Figure 16E. The tip 211 in Figure 16G does not include a fluid port 210, but fluid can permeate out of the filament slots 304a, 304b because the filament slots are in fluid communication with the lumen 308. In some embodiments, the tip 211 includes a lumen 306c, for example to assure placement of or contact with the probe 401 (e.g., as illustrated in Figure 16G). In some embodiments, the tip 211 does not include a lumen 306c, for example to reduce manufacturing costs if the lumen 306c is cut from a solid tip stem.

[0101] As may be appreciated, the channel through the tip 201, 211 may be sized to accommodate a tip of the RF probe 401 that may be inserted into the needle 103. The channel may be sized such that RF energy from the inserted RF probe 401 is satisfactorily communicated from the RF probe 401 to the tip 201, 211, the filament 206a, and/or the filament 206b.

[0102] Figures 3C and 3G are each a detailed view of the distal end 310 of a needle 309 that is an alternate embodiment of the needle 103. The distal end 310 includes a tip 311, 321 that may include a sharpened point 312 for piercing the skin of a patient and facilitating advancement through tissue. The tip 311, 321 may include a tapered portion 313 that transitions the tip 311, 321 from the point 312 to a first body portion 314. The first body portion 314 may be connected to a second body portion 315 at an angle 316. In some embodiments, the angle 316 is about 15°. Other angles 316 are also possible. For example, the angle 316 may be between about 5° and about 90°, between about 10° and about 60°,

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between about 10° and about 45°, between about 10° and about 20°, combinations thereof, and the like. Other angles are also possible. The second body portion 315 may be aligned with an elongate member 317. The elongate member 317 may be similarly configured as the elongate member 203 of Figures 3A, 3B, 3C, and 3D. The angle 316 between the first body portion 314 and the second body portion 315 may aid the user in navigating the needle 309 to a desired position. For example, by rotating the needle 309 such that the first body portion 314 is pointing in a desired direction, subsequent advancement of the needle 309 may result in the needle 309 following a non-straight path biased toward the desired direction.

[0103] The first and second body portions 314, 315 may be cylindrical as illustrated, or they may be of any other appropriate shape. The first and second body portions 314, 315 may have cross-sections that coincide with (e.g., is coaxial with) the cross section of the elongate member 317.

[0104] The tip 311, 321, or a non-insulated portion thereof, may act as an RF energy delivery element. The tip 311, 321 may comprise (e.g., be made from) a conductive material such as, for example, stainless steel (e.g., 300 Series Stainless Steel). The tip 311, 321 may be coated (e.g., with an insulator). The material of the tip 311, 321 and the material of the optional coating may be selected, for example, to act as an insulator, improve radiopacity, improve and/or alter RF energy conduction, improve lubricity, and/or reduce tissue adhesion.

[0105] The filaments 319a, 319b may also act as RF energy delivery elements. The filaments 319a, 319b may be constructed in a manner similar to as described with respect to the filaments 206a, 206b.

[0106] The tip 311 of Figure 3C includes a filament slot 318a and a filament slot 318b. The geometry of the filament slots 318a, 318b may be selected to allow filaments 319a, 319b to be adequately retracted (e.g., such that they are in a cross-sectional envelope of the second body portion 315) while the needle 309 is inserted into the body, so that the filaments 319a, 319b do not cause any unintended damage to the patient (e.g., by being along the second body portion 315). Such positioning of the filament slots 318a, 318b may avoid having filament exit features on the tapered portion 313 and on the first body portion 314, which may avoid potential coring. The internal geometry of the filament slots 318a, 318b may include a transition region that meets the outer surface of the second body portion 315 at

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an angle, and advancement of filaments 319a, 319b without a pre-set bias (e.g., substantially straight) relative to the filament slots 318a, 318b can causes the filaments 319a, 319b to be deflected outwardly as the filaments 319a, 319b move distally along the transition region.

[0107] The configuration and orientation of the filament slots 318a, 318b may be selected such that deployed filaments 319a, 319b may achieve the positioning illustrated in Figure 3C. In Figure 3C, the filaments 319a, 319b are generally positioned in a plane that is perpendicular to a plane that includes the angle 316 between the first and second body portions 314, 315. As illustrated, the filaments 319a, 319b may be positioned such that they extend at an angle (e.g., about 15°, between about 10° and about 90°, between about 10° and about 60°, between about 10° and about 45°, between about 10° and about 20°, combinations thereof, and the like) relative to the plane that includes the angle 316. Other angles are also possible. Other filament slot 318a, 318b configurations may be configured to achieve other desired filament 319a, 319b placements. These configurations may be achieved, for example, by varying the quantity of filament slots and filaments, the placement of filament slots about the circumference of the tip 311, the angle at which the filaments extend away from the first and second body portions 314, 315, and/or the placement of filament slots along the first and second body portions 314, 315.

[0108] Figure 3G illustrates an example embodiment of a tip 321 that includes a filament slot 318a and a filament slot 318b along the first body portion 314. The geometry of the filament slots 318a, 318b may be selected to allow filaments 319a, 319b to be adequately retracted (e.g., such that they are in a cross-sectional envelope of the second body portion 315) while the needle 309 is inserted into the body, so that the filaments 319a, 319b do not cause any unintended damage to the patient. Positioning of the filament slots 318a, 318b along the first body portion 314 may potentially cause coring, so the filaments 319a, 319b may be configured to substantially occlude the filament slots 318a, 318b, which may avoid potential coring. The internal geometry of the filament slots 318a, 319b may lack a transition region and, due to being positioned on the first body portion 314, advancement of the filaments 319a, 319b without a pre-set bias (e.g., substantially straight) can cause the filaments 319a, 319b to continue to advance substantially straight (e.g., along the longitudinal axis of the elongate member 317 and/or the second body portion 315) as the filaments move distally out of the filament slots 318a, 318b. Although not illustrated,

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placement of filament slots along the tapered portion 313 is also possible (e.g., the filaments continuing to advance along the longitudinal axis of the first body portion 314). Although not illustrated, the embodiments depicted in Figures 3A and 3D may be adapted so the filaments 206a, 206b exit along the tapered portion 302.

[0109] The needle 309 may comprise a tube that includes a lumen therethrough, for example as described herein with respect to Figures 3A, 3B, 3D, and 3E. The lumen may be employed to accept an RF probe for delivery of RF energy and/or for the transport of fluids. In this regard, the tip 311 may further include a fluid port 320 that may be in fluid communication via a channel through the tip 311 with the lumen. The fluid port 320 may be used to transfer fluid between the region of the tip 311 and a proximal end of the needle 309.

[0110] In the deployed position as shown in Figure 3C, the distal ends of the filaments 319a, 319b are disposed away from the point 312. In the deployed position as shown in Figure 3G, the distal ends of the filaments 319a, 319b are disposed away from the point 312. In a retracted position (not shown, but similar to as shown in Figures 3B and 3E), the distal ends of the filaments 319a, 319b are entirely within an outer perimeter (e.g., circumference where the second body portion 315 of the tip 311, 321 is round) of the tip 311, 321. In the deployed position, the filaments 319a, 319b act as broadcast antennae for an RF probe inserted into the needle 309. The tip 311 or 321, the filament 319a, and/or the filament 319b may form a monopolar electrode for application of RF energy to the target volume. The filaments 319a, 319b may allow the RF energy from the RF probe to be dispersed over a larger volume than would be possible with the tip 311, 321 alone.

[0111] In general, any or all of the herein variables may be incorporated into a particular embodiment of a needle to yield a needle capable of producing a lesion with a particular size, position and shape relative to the tip of the needle. Such custom sizes, positions and shapes may be designed for specific procedures. For example, a particular lesion size, position and shape may be selected to enable a user to navigate the needle to a particular landmark (e.g., proximate to or touching a bone visible using fluoroscopy) and then orient the needle such that deployed filaments will be operable to produce a lesion at a particular location relative to the landmark. By navigating to a particular internal landmark, as opposed to attempting to visualize a relative position of a needle offset from a landmark, a more accurate and/or consistent positioning of the needle may be achieved. In this regard,

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the skill level required to accurately position the needle for a particular procedure may be reduced.

[0112] The lesion shapes achievable through selection of the herein variables may include, for example, generally spherical, oblong, conical, and pyramidal shapes. The orientation relative to, and the amount of offset from, the tip of such shapes may be selectable. In an embodiment, the tips of the deployed filaments may be positioned distally relative to the point of the tip to provide for a facile positioning of the lesion relative to the tip. Such capability may allow for the needle to be inserted directly toward a target volume. In other embodiments, the tips of the deployed filaments may be positioned at the same axial position along the central longitudinal axis as the point of the tip or the tips of the deployed filaments may be positioned proximally relative to the point of the tip. In other embodiments, some filament endpoints may be located distal to the point of the tip while others are proximal to the point of the tip.

[0113] The elongate member 203 may be in the form of a hollow tube (e.g., sheath, cannula) interconnecting the tip 201, 211 with the hub 204. The elongate member 203 may be configured with adequate strength to allow the needle 103 to pierce a patient's skin and advance to a target area through various tissue types, including, for example, fat and muscle tissue. The elongate member 203 may also be capable of resisting kinking as it is advanced. In some embodiments, the elongate member 203 comprises a rod with a plurality of lumens along its length to accommodate the filaments 206a, 206b, the RF probe 401, and/or a fluid passage.

[0114] The elongate member 203 houses portions of the filaments 206a, 206b and the tube 207, and allows for relative movement of the filaments 206a, 206b. The elongate member 203 may be of any appropriate size and internal configuration to allow insertion into a patient and to house componentry therein. In some embodiments, the elongate member 203 is a 16 gauge round tube or smaller. For example, the elongate member 203 may be 18 gauge or 20 gauge. In some embodiments, the elongate member 203 has a maximum cross-sectional dimension of about 1.7 mm. In some embodiments, the elongate member 203 has a maximum cross-sectional dimension of about 1 mm. The elongate member 203 may have a length selected for performing a specific spinal RF neurotomy procedure on a particular patient. In some embodiments, the elongate member 203 has a length of about 10 cm.

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[0115] In certain embodiments, the elongate member 203 comprises (e.g., is constructed from) an insulative material to reduce (e.g., eliminate) the amount of RF energy emitted along the length of the elongate member 203 when the RF probe 401 is disposed therein. For example, the elongate member 203 may comprise (e.g., be constructed from) polymeric, ceramic, and/or other insulative material. In certain embodiments, the elongate member 203 includes an insulating coating or sleeve 307 (Figures 2D and 16D). In some embodiments, the elongate member is insulated (e.g., constructed from insulative material and/or having an insulating coating 307) except for a distal part having a length between about 5 mm and about 10 mm. Figure 3H illustrates an example embodiment of a needle 309 comprising an insulating coating 330 covering a proximal portion of the tip 321 and coatings 332a, 332b covering a proximal portion of the filaments 319a, 319b. The coating 330 insulates, *inter alia*, the bent area between the first body portion 314 and the second body portion 315 of the tip 321.

[0116] In some embodiments, the elongate member is insulated (e.g., constructed from insulative material and/or having an insulating coating) except for a proximal part. Figure 3I illustrates an example embodiment of a needle 309 comprising an insulating coating 330 covering a distal portion of the tip 321 and coatings 332a, 332b covering a distal portion of the filaments 319a, 319b. In some embodiments in which the distal portion of the tip 321 is, the needle 309 may create a kidney or catcher's mitt shaped lesion, which may be useful, for example, for ablating tissue where the active tip is pressed against the wall of a structure with the device staying in the lumen of a structure. For example, when ablating endocardial lesions in which the device accesses the target through a cardiac chamber, insulating the distal portion of the tip 321, which stays in the chamber, can make the biophysics of the lesion (e.g., impedance, power, heat) more precise because the insulated distal portion of the tip 321 that is surrounded by blood in the chamber will not be part of the field.

[0117] Figures 3H and 3I illustrate example embodiments of insulation of parts of the tip 321 and the filaments 319a, 319b illustrated in Figure 3G. Parts of components of the distal ends of other needle tips described herein may also be insulated (e.g., those illustrated in Figures 3A, 3C, and 3D). In some embodiments, only parts of the tip 321, and not parts of the filaments 319a, 319b, are insulated. In some embodiments, only parts of the filaments

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319a, 319b, and not parts of the tip 321, are insulated. In some embodiments, a distal portion of the tip 321 is insulated (e.g., as illustrated in Figure 3I) and proximal portions of the filaments 319a, 319b are insulated (e.g., as illustrated in Figure 3H). In some embodiments, a distal portion of the filaments 319a, 319b are insulated (e.g., as illustrated in Figure 3I) and a proximal portion of the tip 321 is insulated (e.g., as illustrated in Figure 3H). In some embodiments, the insulative coating or sleeve 330, 332a, 332b may be adjustable. For example, one or all of the sleeves 330, 332a, 332b may be advanced or retracted relative to the tip 321, the filament 319a, and the filament 319b, respectively, to increase or decrease the amount of exposed conductive area.

[0118] The elongate member 203 may include a coating that may improve radiopacity to aid in visualization of the position of the needle 103 using fluoroscopy. The elongate member 203 may include a lubricious coating to improve its ability to be inserted and positioned in the patient and/or to reduce tissue adhesion. The elongate member 203 may include markers 224 along its length to assist in determining the depth to which the needle 103 has entered into the anatomy. The markers 224 may be radiopaque so that they may be viewed under fluoroscopy. A collar (not shown) may be disposed about the elongate member 203 to assist in placement of the tip 201, 211 of the needle 103. For example, the tip 201, 211 may be positioned in a first position, the collar may then be placed against the patient's skin, and then the needle 103 may be advanced and/or withdrawn a certain distance. Such a distance may be indicated, for example, by the distance between the collar and a patient's skin or other anatomy.

[0119] The elongate member 203 may be fixedly interconnected to the tip 201, 211 and the hub 204 in any appropriate manner. For example, the tip 201, 211 may be press fit into the elongate member 203 and the elongate member 203 may be press fit into the hub 204. Other example methods of attachment include adhesive bonding and welding. In some embodiments, the elongate member 203 and the tip 201, 211 are a single unitary structure. The elongate member 203 may be steerable and incorporate controlling mechanisms allowing the elongate member 203 to be deflected or steered after insertion into the anatomy.

[0120] The tube 207 containing the lumen 222 may comprise (e.g., be constructed from) any appropriate material. For example, the tube 207 comprise a conductive material, such as stainless steel (e.g., 300 Series Stainless Steel), such that when the RF probe 401 is

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inserted in the tube 207, the RF energy emitted by the RF probe 401 may be conducted through the tube 207 and into and through the tip 201, 211, the filament 206a, and/or the filament 206b. The tube 207 may be interconnected to the tip 201, 211 such that the lumen 222 is in sealed, fluid communication with the channel through the tip 201, 211. This may be accomplished by a press fit, weld, or any other appropriate method.

[0121] As noted, the lumen 222 may be in fluid communication with the tip 201, 211 at the distal end 202. A proximal end of the lumen 222 may be disposed at the proximal end 205 of the needle 103. In this regard, the lumen 222 may extend from the distal end 202 to the proximal end 205, with the only access being at the distal and proximal ends 202, 205. In some embodiments, the lumen 222 is the only lumen of the needle 103 disposed along the elongate member 203.

[0122] The RF probe 401 inserted into the lumen 222 may be positioned such that an end of the RF probe 401 is proximate to the tip 201, 211. For example, the RF probe 401 may be positioned such that the distal end 402 of the RF probe 401 is in the lumen 222 near the tip 201, 211 or in the channel through the tip 201, 211. RF energy transmitted through the RF probe 401 may then be conducted by the tip 201, 211, the filament 206a, and/or the filament 206b. The size of the lumen 222 may be selected to accommodate a particular size of RF probe 401. For example, the lumen 222 may be configured to accommodate at least a 22 gauge RF probe 401, at least a 21 gauge RF probe 401, or a larger or smaller RF probe 401. For another example, the lumen 222 may have a maximum cross-sectional dimension of less than about 0.85 mm.

[0123] The proximal end of the tube 207 may be operable to receive the RF probe 401. The proximal end of the tube 207 and the actuator 216 may be configured to accept a connector, such as a Luer fitting, such that a fluid source may be connected to the tube 207 (e.g., to deliver fluid through the lumen 222 and out the fluid port 210).

[0124] The needle 103 includes two filaments 206a, 206b in and along elongate member 203. Distal ends of the filaments 206a, 206b are proximate to the tip 201, 211, and proximal ends of the filaments 206a, 206b are fixed to a filament hub 221 discussed below. The filaments 206a, 206b are movable along the central longitudinal axis 223 between a fully deployed position as illustrated in Figures 3A, 3C, 3D, and 3F and a retracted position illustrated in Figures 3B and 3E. Moving the filaments 206a, 206b distally from the retracted

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position moves the filaments 206a, 206b toward the fully deployed position, while moving the filaments 206a, 206b proximally from the deployed position moves the filaments 206a, 206b toward the retracted position. The filaments 206a, 206b may be deployed in intermediate positions between the fully deployed positions and the retracted positions. For example, a mechanism for advancement and/or retraction of the filaments 206a, 206b may include detents indicating partial deployment and/or retraction and a stop indicating full deployment and/or retraction.

[0125] In the fully deployed position, the distal ends of the filaments 206a, 206b, 319a, 319b are disposed away from the tip 201, 211, 311, 321. In the retracted position, the distal ends of the filaments 206a, 206b, 319a, 319b are entirely within an outer perimeter (e.g., circumference where the body portion 303 of the tip 201, 211, 311, 321 is round) of the tip 201, 211, 311, 321. In the deployed position, the filaments 206a, 206b, 319a, 319b can act as broadcast antennae for the RF probe 401 (e.g., RF energy passes from the RF probe 401 to the tip 201, 211, 311, 321 and to the filaments 206a, 206b, 319a, 319b, and into a target volume within a patient). In this regard, together, the RF probe 401 inserted into the lumen 222, the tip 201, 211, 311, 321, and the filaments 206a, 206b, 319a, 319b, may form a monopolar electrode for application of RF energy to the target volume. The filaments 206a, 206b, 319a, 319b allow the RF energy from the RF probe 401 to be dispersed over a larger volume than would be possible with the tip 201, 211, 311, 321 alone.

[0126] The filaments 206a, 206b, 319a, 319b may be constructed from a material operable to conduct RF energy, e.g., a metal such as stainless steel (e.g., 303 Stainless Steel), Nitinol, or shape memory alloy. The filaments 206a, 206b may be coated, for example to enhance and/or inhibit their ability to conduct RF energy. The filaments 206a, 206b may include a lubricious coating to aid in insertion and/or reduce tissue adhesion.

[0127] Figure 2E illustrates an embodiment in which the filaments 206a, 206b are formed from a single wire 206 that is bent at the proximal end. The distal ends of the filaments 206a, 206b are shown as bent, which can be the result of deflection upon exit from a tip 201, 211, shape memory, combinations thereof, and the like. Forming the filaments 206a, 206b from a single wire 206 may provide advantages such as, for example, coherent activation of the filaments 206a, 206b, simultaneous deployment of the filaments 206a, 206b, and/or simultaneous retraction of the filaments 206a, 206b. It will be appreciated that the

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wire 206 may be a single wire or a plurality of wire segments joined together (e.g., via adhering with conductive epoxy, welding, soldering, combinations thereof, and the like). Other filaments described herein may also be coupled or bent at the proximal end. The filaments 206a, 206b illustrated in Figure 2E are substantially parallel, and taper outwards before being bent at the proximal end. In some embodiments, the filaments 206a, 206b are substantially parallel and do not taper out before being bent at the proximal end. In certain such embodiments, the proximal end of the wire 206 is a semi-circle, for example having a radius between about 0.03 inches and about 0.07 inches (approx. between about 0.76 mm and about 1.8 mm), between about 0.04 inches and about 0.06 inches (approx. between about 1 mm and about 1.5 mm), between about 0.05 inches and about 0.055 inches (approx. between about 1.3 mm and about 1.4 mm) (e.g., about 0.052 inches (approx. about 1.32 mm)), combinations thereof, and the like. In some embodiments, the filaments 206a, 206b are parallel and spaced by a distance between about 0.025 inches and about 0.125 inches (approx. between about 0.64 mm and about 3.2 mm), between about 0.05 inches and about 0.1 inches (approx. between about 1.3 mm and about 2.5 mm) (e.g., about 0.075 inches (approx. about 1.9 mm)), combinations thereof, and the like. In some embodiments, the filaments 206a, 206b in the elongate member 203 may be braided, wrapped, or twisted together. Such embodiments may increase column strength, providing resistance to buckling and/or bending in the elongate member 203. In some embodiments, the wire 206 has a diameter between about 0.0025 inches and about 0.04 inches (approx. between about 0.06 mm and about 1 mm), between about 0.005 inches and about 0.025 inches (approx. between about 0.13 mm and about 0.64 mm), between about 0.01 inches and about 0.02 inches (approx. between about 0.25 mm and about 0.5 mm) (e.g., about 0.014 inches (approx. about 0.36 mm)), combinations thereof, and the like. Other diameters are also possible. In some embodiments, the filaments 206a, 206b each have a diameter between about 0.0025 inches and about 0.04 inches (approx. between about 0.06 mm and about 1 mm), between about 0.005 inches and about 0.025 inches (approx. between about 0.13 mm and about 0.64 mm), between about 0.01 inches and about 0.02 inches (approx. between about 0.25 mm and about 0.5 mm) (e.g., about 0.014 inches (approx. about 0.36 mm)), combinations thereof, and the like. Other diameters are also possible. In some embodiments, the filaments 206a, 206 have

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different diameters (e.g., by being formed from different wires, by being formed from portions of wires with different diameters that are coupled to form the wire 206, etc.).

[0128] The distal ends of the filaments may be shaped (e.g., pointed) to improve their ability to move through tissue. For example, the tips of the filaments 206a, 206b in Figure 3A have an outward-facing bevel. In some embodiments, the bevel is at an angle between about 15° and about 45°, between about 20° and about 40°, between about 25° and about 35° (e.g., about 30°), combinations thereof, and the like. In embodiments in which the filaments 206a, 206b each have a diameter of about 0.014 inches (approx. about 0.36 mm) and a bevel of about 30°, the length of the bevel is about 0.024 inches (approx. about 0.61 mm). The tips of the filaments 206a, 206b may have the same shape (e.g., beveled) or different shapes. For another example, the tips of the filaments 206a, 206b in Figure 3D have an inward-facing bevel. In certain embodiments, bevels (e.g., inward-facing bevels) can help to induce splay between the tips of the filaments 206a, 206b (e.g., splay of between about 15° and about 20°) by tracking to one side (e.g., away from the beveled side) upon deployment, which can improve placement of the filaments 206a, 206b. For yet another example, the tips of the filaments 319a, 319b in Figure 3G have a pencil-point. In certain embodiments, a pencil-point tip can help to reduce splay between the tips of the filaments 206a, 206b by substantially straight tracking deployment, which can improve placement of the filaments 206a, 206b. In some embodiments, the filaments 206a, 206b comprise materials with different tensile strength and/or rigidity, and the filaments 206a, 206b, which can affect their ability to flex due to contact with tissue and thus the amount of splay, if any. In certain embodiments in which the filaments 206a, 206b comprise a shape memory material, the deflection to an unconfined state may work with or against the shapes of the tips. In some embodiments, certain filament tips may help to occlude filaments slots, improve interaction with a transition region, etc. Although certain combinations of filament tips are illustrated with respect to certain embodiments herein, the various shapes of the filament tips described herein and otherwise may be selected for any of these embodiments (e.g., the filaments 206a, 206b of Figure 3A may have inwardly-facing bevels or pencil-point tips, the filaments 206a, 206b of Figure 3D may have outwardly-facing bevels or pencil-point tips, the filaments 319a, 319b of Figure 3C may have inwardly-facing bevels or pencil-point

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tips, the filaments 319a, 319b of Figure 3G may have inwardly-facing bevels or outwardly-facing bevels, etc.).

[0129] The positioning of the filaments 206a, 206b of the embodiments illustrated in Figures 3A and 3D will now be described in relation to Figure 5. Figure 5 is an end view of the tip 201 and deployed filaments 206a, 206b of the embodiment illustrated in Figures 2A and 3A. The filaments 206a, 206b are positioned at a filament angle 503 of about 120° apart from each other about the central longitudinal axis 223. This coincides with the positions of the filament slots 304a, 304b discussed herein since the filaments 206a, 206b emerge from the filament slots 304a, 304b. Other filament angles 503 are also possible. For example, the filament angle 503 may be between about 90° and about 180°, between about 90° and about 150°, between about 100° and about 140°, between about 110° and about 130°, combinations thereof, and the like. A filament-free angle 504 of about 240° is defined as the largest angle about the circumference of the tip 201, 211 that is free of filaments. In an embodiment consisting of two filaments 206a, 206b, the filament angle 503 may be less than 180° and the filament-free angle 504 may be correspondingly greater than 180° (e.g., greater than 200° or greater than 240°).

[0130] In Figure 5, the central longitudinal axis 223 is perpendicular to the plane of the illustration. A midpoint 502 is defined between distal ends 501a, 501b of the filaments 206a, 206b, respectively. The midpoint 502 is offset from the central longitudinal axis 223. For example, in some embodiments, the midpoint 502 is offset from the central longitudinal axis 223 by about 2 mm. Other offset values are also possible. For example, the offset may be between about 0.5 mm and about 5 mm, between about 1 mm and about 4 mm, between about 1 mm and about 3 mm, greater than about 0.5 mm, less than about 5 mm, combinations thereof, and the like. When RF energy is transmitted from the tip 201 and both of the filaments 206a, 206b, the RF energy will be transmitted asymmetrically with respect to the central longitudinal axis 223 the cause the RF energy will be emitted from the tip 201 and the filaments 206a, 206b. As oriented in Figure 5, the energy will be biased in an upward direction in the direction from the point 301 toward the midpoint 502. Thus, when RF energy is transmitted during an RF neurotomy procedure, a lesion will be created that is correspondingly offset from the central longitudinal axis 223 in the direction from the point 301 toward the midpoint 502.

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[0131] Referring again to the asymmetric nature of the lesion, the lesion may be substantially a three-dimensional polygon (e.g., with rounded edges) of known dimensions and volume that is offset from the central cannula in a known and predictable way. Different embodiments may have different three-dimensional polygonal structures adapted to the intended ablation target. By contrast, needles without deployable filaments may be used to create asymmetric planar lesions by varying needle insertion during the ablation procedure, and may require substantial ablation volume overlap.

[0132] Figure 6 is a side view of the tip 201 and the filaments 206a, 206b, oriented such that the deployed filament 206b is entirely within the plane of the figure. The filaments 206a, 206b extend from the tip 201 at a common distance, or location, along the central longitudinal axis 223. In some embodiments, the filaments 206a, 206b may extend different distances. The filament 206b is deflected radially outwardly from the central longitudinal axis 223. The filament 206b emerges from the tip 201 at an angle 601 of about 30° from the central longitudinal axis 223, which is parallel to the longitudinal axis of the elongate member 203. The angle 601 may vary, for example, based at least partially on positioning of a transition region 305, mechanical properties of the filament 206b (e.g., shape-memory properties or lack thereof), and the like. In some embodiments, the angle 601 is between about 5° and about 85°, between about 10° and about 60°, between about 20° and about 40°, greater than about 5°, less than about 85°, combinations thereof, and the like. In some embodiments, the angle 601 is related to the angle 503. For example, the angle 601 may be a fraction of the angle 503, such as about ¼. In some embodiments, the angle 601 is unrelated to the angle 503, for example both being independently chosen to produce a certain lesion size or shape. In some embodiments, the distal tips 501a, 501b are positioned distally beyond the point 301 by a distance 602, are disposed at a distance 603 from the central longitudinal axis 223, and/or are disposed at a distance 604 from each other. In some embodiments, the distance 602 is about 3.5 mm, the distance 603 is about 3 mm, and/or the distance 604 is about 4.5 mm. Other distances are also possible. For example, in some embodiments, the distance 602 is between about 0.5 mm and about 6 mm, between about 1 mm and about 5 mm, between about 3 mm and about 4 mm, combinations thereof, and the like. Other distances are also possible. For another example, in some embodiments, the distance 603 is between about 0.5 mm and about 6 mm, between about 1 mm and about 5

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mm, between about 2 mm and about 4 mm, combinations thereof, and the like. Other distances are also possible. For yet another example, in some embodiments, the distance 604 is between about 2 mm and about 7 mm, between about 3 mm and about 6 mm, between about 4 mm and about 5 mm, combinations thereof, and the like. Other distances are also possible.

[0133] The angles described herein (e.g., the angles 503, 601) may be measured with respect to a needle 103 in a deployed state outside of a patient's body, and that the angles may when the needle is inside a patient's body, for example based at least in part on splay of filaments due to beveling.

[0134] The tip 211 and deployed filaments 206a, 206b of the embodiment illustrated in Figure 3D may also have a filament angle 503, a filament-free angle 504, a midpoint 502, an angle 601, distances 602, 603, 604, and other features described herein, for example with respect to Figures 5 and 6. In some embodiments, the portion of the lesion based at least partially on RF energy emitted by the tip 211, and thus the shape of the lesion, may vary based on the position of the point 301 (e.g., in Figure 3d, the point 301 is on the side of the tip 211 that comprises the filaments 206a, 206b).

[0135] The configuration of the filaments 206a, 206b illustrated in Figures 2A, 3A, 3D, 5, and 6 may be operable to produce lesions that are radially offset from the central longitudinal axis 223 and distally offset from the point 301 as compared to a lesion created by the tip 201, 211 without the filaments or a lesion created with the needle 103 with the filaments 206a, 206b in the retracted position.

[0136] Variations in the relative shapes, positions, and sizes of lesions created with the needle may be achieved by repositioning the filaments. For example, as noted herein, the lesion produced by the needle will be in different positions depending on whether the filaments are in the deployed or retracted positions. Lesions having intermediate shapes, positions, and/or sizes may be achieved by positioning the filaments in intermediate positions between the fully deployed (e.g., as illustrated in Figures 3A, 3C, 3D, and 3G) and fully retracted positions (e.g., as illustrated in Figures 3B and 3E). As noted herein, the needle with deployed filaments is operable to produce larger lesion volumes than the needle with retracted filaments. For example, the needle with fully deployed filaments may be operable to produce lesion volumes of about 500 mm^3. Other lesion volumes are also possible. For

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example, the needle with fully deployed filaments may be operable to produce lesion volumes between about 100 mm^3 and about 2,000 mm^3, between about 200 mm^3 and about 1,000 mm^3, between about 250 mm^3 and about 750 mm^3, between about 400 mm^3 and about 600 mm^3, combinations thereof, and the like.

[0137] Further variation in the shape, position, and/or size of lesions created by needles with deployable filaments may be achieved by different configurations of filaments. Variations may include, for example, variations in materials, the number of filaments, the radial positioning of the filaments, the axial positioning of the filaments, the length of the filaments, the angle at which the filaments exit the tip, the shape of the filaments, etc. By varying these parameters, the needle may be configured to produce lesions of various sizes and shapes that are positioned at various locations relative to the tip. Such variations may be specifically tailored to be used in specific procedures, such as RF neurotomy procedures of particular nerves adjacent to particular vertebrae.

[0138] Variations of the materials used for the tip and/or the filaments may be selected to achieve particular lesion sizes, positions, and/or shapes. For example, the tip may comprise (e.g., be made form) a material that does not conduct RF energy, in which case RF energy from the RF probe 401 may be conducted by substantially only the deployed filaments. In certain such embodiments, emitting RF energy from the filaments may provide for a lesion with a larger offset from the central longitudinal axis 223 than would be produced if the tip conducts RF energy and acts as an electrode along with the filaments.

[0139] Another material-related variation that may affect lesion shape, size, and/or position is the addition and placement of insulation over the tip and/or over the filaments. For example, by placing a layer of insulation over a proximal part of the portions of the filaments that extend from the tip when in the deployed position, the shape of the lesion may be altered since RF energy may primarily emanate from the distal, non-insulated part of the filaments. For another example, by placing a layer of insulation over a proximal part of the tip, the shape of the lesion may be altered since RF energy may primarily emanate from the distal, non-insulated part of the tip. Other parts of the filaments and/or tip may also be covered by an insulating material, for example a distal part of the filaments and/or tip, an intermediate part of the filaments and/or tip, combinations thereof, and the like, for example as described with respect to Figures 3H and 3I.

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[0140] Moreover, the materials used in making the filaments and tip may be selected based on RF conductivity. For example, by using a material for the tip that is less conductive of RF energy, the proportion of RF energy emanating from the tip as compared to that emanating from the filaments may be altered resulting in a corresponding change in lesion size, position and/or shape.

[0141] The RF needles and RF probes discussed herein may be constructed from materials that are Magnetic Resonance Imaging (MRI) compatible (e.g., titanium, aluminum, copper, platinum, non-magnetic 300 Series Stainless Steel, etc.). In certain such embodiments, MRI equipment may be used to verify the positioning of the needles and/or portions thereof and/or monitor the progress of an ablation procedure (e.g., RF neurotomy).

[0142] Variations of the number of filaments used for needle may be selected to achieve particular lesion sizes, positions and/or shapes. For example, as illustrated in Figure 7, a third filament 701 may extend from the tip 201' (or other tips described herein such as the tip 211) in a position between filaments 206a, 206b. The tips 501a, 501b of the filaments 206a, 206b and a tip 702 of filament 701 may form a polygon 703 that has a centroid 704. The centroid 704 is offset from the central longitudinal axis 223. Such an arrangement may produce a lesion that is offset from the central longitudinal axis 223 to a different degree than, and shaped differently than, a lesion created by the needle of Figure 5. In general, where a centroid of a polygon formed by the tips of filaments (or, in the case where there are two filaments, the midpoint between them) is offset from the central longitudinal axis 223, a lesion created by such a configuration will be correspondingly offset from the central longitudinal axis 223. The filaments 206a, 206b, 702 are positioned at the same filament angle 503 of about 120° as in the embodiment of Figure 5. Other filament angles 503, in either Figure 5 or Figure 7, are also possible. The embodiment illustrated in Figure 7 has a filament-free angle 504 of about 240°, also the same as in the embodiment of Figure 5. Other filament-free angles 504, in either Figure 5 or Figure 7, are also possible. In general, in embodiments in which the filaments are positioned in a filament angle 503 that is less than about 180°, resultant lesions will be offset from the central longitudinal axis 223 in the direction of the filaments. In embodiments in which the filaments are positioned in a filament angle 503 that is less than about 180°, the filament-free angle is correspondingly greater than about 180° (e.g., greater than about 200° or greater than about 240°).

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[0143] For another example, as illustrated in Figure 8, four filaments 801a-801d are positioned about a tip 201" (or other tips described herein such as the tip 211). The tips of the filaments 801a-801d may form a polygon 802 that has a centroid 803. The centroid 803 is offset from the central longitudinal axis 223. Such an arrangement may produce a lesion that is offset from the central longitudinal axis 223 in the direction of the centroid 803. The filaments 801a-801d are positioned at a filament angle 804 of about 200°. Other filament angles 804 are also possible. The embodiment illustrated in Figure 8 has a filament-free angle 805 of about 160°. Other filament-free angles 805 are also possible. Figure 8 illustrates an embodiment in which the filament-free angle 805 is less than about 180°, but which is capable of producing a lesion offset from the central longitudinal axis 223.

[0144] In the herein-described embodiment of Figures 2A, 3A, 3B, 5, and 6 with two filaments, a midpoint 502 between the filaments was discussed. In embodiments with more than two filaments, a centroid of a polygon formed by the distal ends of the filaments was discussed. Both the midpoints and the centroids may be considered to be "average" points of the filaments for their particular configurations. In such embodiments, the midpoint between filaments in two-filament embodiments and the centroid of the polygon in embodiments with more than two filaments may be offset from the central longitudinal axis of the elongate member. For example, the midpoint or centroid may be offset from the central longitudinal axis by 1 mm or more. In embodiments, the polygon may lie in a plane perpendicular to the central longitudinal axis.

[0145] As illustrated in, for example, Figures 2A, 2D, 3A, 3C, 3D, 3G-3I, 5, 7, 8, 9, and 10, the distal ends of the filaments when fully deployed may be in a common plane. In some embodiments, the common plane is perpendicular or transverse to the central longitudinal axis. In some embodiments, the common plane is distal to the point 301, 312.

[0146] As illustrated in, for example, Figures 2A, 2D, 3A, 3C, 3D, 3G-3I, 5, 7, and 10, the filaments of the needle may all be deployed on a common side of a central plane of the needle (where the central longitudinal axis is entirely within the central plane). In certain such embodiments, the distal ends of the filaments are all on a common side of the central plane. Such a configuration may enable the needle to be used to create a lesion that is offset from the tip of the needle to the same side of the central plane as the deployed filament ends.

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[0147] As illustrated, for example, in Figure 2A, 2D, 3A, 3C, 3D, 3G-3I, and 10, the filaments when fully deployed may point in an at least partially distal direction. In this regard, a vector extending longitudinally from the distal end of a filament and coinciding with a central axis of the portion of the filament out of the tip 211 has at least some distal component. The fully deployed filaments in the embodiments illustrated in Figures 2A, 2D, 3A, 3C, 3D, 3G-3I, and 10 all point in an at least partially distal direction.

[0148] Figure 9 illustrates an embodiment in which the filaments are uniformly distributed about the circumference of the tip 201"". The needle of Figure 9 includes three filaments 901a, 901b, 901c distributed substantially equally about the circumference of the tip 201"", the angles 902a, 902b, 902c between the filaments 901a, 901b, 901c each being about 120°. Such a needle may be operable to produce a lesion that is generally centered along the central longitudinal axis 223. However, the position of the produced lesion longitudinally along the central longitudinal axis 223 may be determined by the configuration (e.g., length, deployment angle, etc.) of the filaments. For example, relatively longer filaments may be operable to produce lesions that are positioned distal to lesions produced by configurations with relatively shorter filaments. For another example, in an embodiment in which the filament 901b is longer than the filaments 901a, 901c, the needle may be operable to create a lesion that is offset from the tip of the needle towards the filament 901b. For yet another example, in an embodiment in which the filaments 901a, 901b are longer than the filament 901c, the needle may be operable to create a lesion that is offset from the tip of the needle towards the filaments 901a, 901b.

[0149] Referring again to Figure 7, if the filament 701 was distal to the filaments 206a, 206b, the resultant lesion may be longer along the central longitudinal axis 223 than lesions resulting from an embodiment in which the filaments 206a, 206b, 701 are each positioned along substantially the same plane perpendicular or transverse to the central longitudinal axis 223. In another variation, as deployed, two or more filaments may be at the same radial position and at different axial positions. Such embodiments may include multiple rows of filaments.

[0150] Referring again to Figures 5 and 6, if the lengths of the deployed portions of the filaments 206a, 206b were increased, the needle may be capable of producing lesions that are more distally positioned than lesions created by the embodiment as shown in Figures

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5 and 6. The effects of lengthening or shortening the deployed length of the filaments may be similar to those discussed herein with respect to partially deploying filaments.

[0151] In some embodiments, the needle includes filaments having deployed portions with different lengths. In certain embodiments in which all of the filaments are deployed and/or retracted by a common actuator and/or are part of the same wire, variations in filament lengths may be achieved by varying the overall length of the filaments. For example, the distal end of a shorter filament may be retracted further into the tip or elongate member than the distal end of a longer filament. The effects of lengthening or shortening the length of the deployed portions of the filaments may be similar to those discussed herein with respect to variations in the axial positioning of filaments emergence from the tip of the needle and/or with respect to partially deploying filaments.

[0152] The angle at which a filament exits a tip (e.g., the angle 601 of Figure 6) may be varied to achieve particular lesion sizes, positions, and/or shapes. For example, if the angle 601 in Figure 6 was about 60°, the needle may be operable to produce a lesion that has a larger maximum cross-sectional dimension in a plane perpendicular to the central longitudinal axis 223 than if the angle 601 was about 30°, for example because the filaments can emanate RF energy at a distance further away from the central longitudinal axis. In some embodiments, the filaments can be deployed at different angles 601 relative to the central longitudinal axis 223.

[0153] Referring again to Figure 10, the deployed portions of the filaments 1001a, 1001b may be curved. As described herein, the term "curved" may mean a continuous curve, a curve in combination with a straight section, a plurality of curves in different directions, combinations thereof, and the like. Such curvatures may be achieved, for example, by filaments 1001a, 1001b comprising shape memory material (e.g., Nitinol) or spring material. When the filaments 1001a, 1001b are retracted, the shape of the tip 201 and/or the elongate member 203 may cause the filaments 1001a, 1001b to be in constrained straightened configurations. As the filaments 1001a, 1001b are advanced toward the fully deployed position, they become unconstrained and return to their curved shapes as shown in Figure 10. The deployed shape of the filaments 1001a, 1001b may be predetermined, or the filaments 1001a, 1001b may comprise (e.g., be made from) a material that may be shaped by a user prior to insertion. The filaments of other embodiments described herein (e.g., Figures

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3A, 3C, 3D, and 3G-3I) may also be curved. In some embodiments, one filament is curved and one filament is straight.

[0154] The curved filaments 1001a, 1001b of Figure 10 are positioned in planes that include the central longitudinal axis 223. In other embodiments, the filaments 1001a, 1001b may be curved in other directions, such as in a corkscrew arrangement. This may be beneficial to assist the filaments in remaining anchored to the tissue during delivery of RF energy. The curved filaments 1001a, 1001b of Figure 10 may be operable to produce a lesion that is flatter in a plane perpendicular to the central longitudinal axis 223 than, for example, the straight filaments 206a, 206b of Figure 6.

[0155] In the embodiment illustrated in Figures 2A and 2B, the filaments 206a, 206b are illustrated as running the entire length of the elongate member 203 from the filament hub 221 to the tip 201. In some embodiments, a single member may run along at least part of the elongate member 203 and the filaments 206a, 206b may be interconnected to the single member at a point proximal to the tip 201.

[0156] The illustrated embodiments show all of the filaments of a given embodiment as commonly deployed or retracted. In some embodiments, one or more filaments may be individually deployed and/or retracted. In some embodiments, a plurality of filaments may exit from the tip at a common location and form a fan-like arrangement as they are deployed.

[0157] Deployment of filaments discussed herein has been described as movement of the filaments relative to a stationary tip. In some embodiments, the filaments may be deployed by pulling the tip back relative to the filaments (e.g., movement of the tip relative to stationary filaments). Movement of the tip rather than the filaments may be advantageous, for example, in embodiments in which the needle is initially advanced until in contact with bone to ensure proper positioning relative to target tissue, and then the tip may be retracted, leaving the filaments (e.g., curved shape memory filaments) in a precise, known position. In some embodiments, the filaments may be deployed by advancing the filaments and retracting the tip.

[0158] Referring again to Figures 2A and 2B, the hub 204 may be fixedly attached to the elongate member 203. The hub 204 may be the primary portion of the needle 103 gripped by the user during insertion and manipulation of the needle 103. The hub 204

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may include an asymmetric feature, such as an indicator 225, that is in a known orientation relative to the asymmetry of the tip 201. In this regard, the indicator 225 may be used to communicate to the user the orientation of the tip 201 within a patient. For example, in the embodiment illustrated in Figure 2A, the indicator 225 is fixed at an orientation circumferentially opposite to the filament slots 304a, 304b. Internally, the hub 204 may include a cavity 213 sized to house a longitudinal protrusion 218 of the actuator 216. The hub 204 may include a hole through which a projection 215 may project into the interior of the cavity 213 to control the motion of the actuator 216 relative to the hub 204 and to secure the actuator 216 to the hub 204. The hub 204 may comprise (e.g., be made from) any appropriate material (e.g., a thermoset plastic, Makrolon® 2548, available from Bayer).

[0159] The actuator 216 may be used to control the motion to deploy and/or retract the filaments 206a, 206b. The actuator 216 is operable to move relative to the hub 204, the elongate member 203, and the tip 201 (e.g., parallel to the central longitudinal axis 223). The actuator 216 includes the longitudinal protrusion 218 extending into the cavity 213 of the hub 204. The outer surface of the longitudinal protrusion 218 includes a helical track 219 sized to accommodate the projection 215. In this regard, as the actuator is rotated relative to the hub 204 (e.g., by a user to deploy the filaments 206a, 206b), the helical track 219 and the projection 215 combine to cause the actuator 216 to move longitudinally (e.g., parallel to the central longitudinal axis 223). The actuator 216 comprises an interface portion 217 that may be gripped by a user when rotating the actuator 216. The interface portion 217 may be knurled or otherwise textured to enhance the user's ability to rotate the actuator 216. The hub 204 may also include a textured or shaped feature (e.g., the indicator 225) configured to enhance the user's ability to rotate the actuator 216 relative to the hub 204. The longitudinal protrusion 218 of the actuator 216 may include an inner cavity 226 sized to accept a filament hub 221 and to allow the filament hub 221 to rotate freely relative to the actuator 216. In this regard, the linear motion of the actuator 216 may be transmitted to the filament hub 221 while the rotational motion of the actuator 216 may not be transmitted to the filament hub 221.

[0160] The actuator 216 may include a Luer fitting 220 or any other appropriate fitting type on a proximal end thereof. The Luer fitting 220 may be in fluid communication with the lumen 222 and provide a connection such that fluid may be delivered into the lumen

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222 and to the fluid port 210 of the tip 201, 211. The Luer fitting 220 may also be configured to allow for the insertion of the RF probe 401 into the lumen 222. The actuator 216 may comprise any appropriate material (e.g., Pro-fax 6523 polypropylene homopolymer, available from LyondellBasell Industries).

[0161] The filaments 206a, 206b may be fixedly interconnected to the filament hub 221. In this regard, the longitudinal movement of the filament hub 221 due to the actuator 216 may be communicated to the filaments 206a, 206b to deploy and retract the filaments 206a, 206b upon rotation of the actuator 216. The filament hub 221 may comprise any appropriate material (e.g., Pro-fax 6523 polypropylene homopolymer, available from LyondellBasell Industries).

[0162] The user can deploy or retract the filaments 206a, 206b by twisting or rotating the actuator 216. For example, as illustrated, a counterclockwise (as seen from the viewpoint of Figure 5) rotation of the actuator 216 relative to the hub 204 will result in the deployment (extension) of the filaments 206a, 206b, while a clockwise rotation of the actuator 216 relative to the hub 204 will result in the retraction of the filaments 206a, 206b.

[0163] The filaments 206a, 206b may be partially deployed or retracted by partially rotating the actuator 216 relative to the hub 204. The actuator 216 and/or the hub 204 may include markings to indicate the position of the filaments 206a, 206b (e.g., the depth or extent of deployment). The actuator 216 and/or the hub 204 may include detents to provide audible and/or tactile feedback of the position of the filaments 206a, 206b.

[0164] In some embodiments, the filaments may be deployed at the user's discretion to a deployed position proximal to, at, or distal to a plane perpendicular or transverse to the central longitudinal axis 223 at the point 301, 312. For example, in some embodiments, full (e.g., 3/3) rotation of the actuator 216 may deploy the filaments in a fully deployed position that is distal to a plane perpendicular or transverse to the central longitudinal axis 223 at the point 301, 312, partial (e.g., 2/3) rotation of the actuator 216 may deploy the filaments in a partially deployed position that is at a plane perpendicular or transverse to the central longitudinal axis 223 at the point 301, 312, and partial (e.g., 1/3) rotation of the actuator 216 may deploy the filaments in a partially deployed position that is proximal to a plane perpendicular or transverse to the central longitudinal axis 223 at the point 301, 312. The actuator 216 and/or the hub 204 may include features such as stops or

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detents to provide audible and/or tactile feedback regarding the extent of deployment (e.g., at 0/3, 1/3, 2/3, and 3/3) and/or the position of the filaments 206a, 206b (e.g., fully retracted, 1/3 deployed, 2/3 deployed, and fully deployed). Other fractions are also possible, including fractions at uneven intervals (e.g., a combination of 1/3, 1/2, and 4/5). In certain embodiments, selectable controlled partial deployment allows for controlled adaptation of the lesion to any particular shape and/or conformance of the filaments to a specific anatomy (e.g., boney anatomy).

[0165] Figures 17A-17E illustrate components of the mechanism at the proximal end 205 of the needle 103 of Figure 2D. The mechanism may also be used, for example, with the needle 103 of Figure 2A and other needles described herein. The components described with respect to Figures 17A-17E may include features described herein with respect to Figures 2B and 2C, and the components described herein, for example with respect to Figures 2B and 2C may include features described herein with respect to Figures 17A-17E. Combinations of components are also possible.

[0166] Figure 17A is an exploded view of components of the deployment mechanism of Figure 2D. The mechanism comprises an advancing hub or slide member 1710, a spin collar or actuator 1720, and a main hub 1730. Figure 17B is a cross-sectional view of the advancing hub 1710, the spin collar 1720, and the main hub 1730 assembled together, as well as half of the wire 206 illustrated in Figure 2E. The advancing hub 1710 includes a stem or longitudinal protrusion 1712. The spin collar 1720 includes a lumen 1721 extending from the proximal end to the distal end. The main hub 1730 includes a lumen 1731 extending from the proximal end to the distal end. When assembled, the stem 1712 of the advancing hub 1710 is in the lumen 1721 of the spin collar 1720 and in the lumen 1731 of the main hub 1730. The advancing hub 1710 may include an annular protrusion 1714 that may interact with an annular protrusion of the spin collar 1720 (e.g., the annular protrusion 1714 having a larger diameter than the annular protrusion 1724) to inhibit the stem 1712 from exiting the proximal end of the lumen 1721. In some embodiments, the annular protrusions 1714, 1724 include tapered surfaces that may interact to allow insertion of the stem 1712 and the annular protrusion 1714 into the lumen 1721 and perpendicular surfaces to inhibit the annular protrusion 1714 and the stem 1712 from exiting the proximal end of the lumen 1721. The main hub 1730 includes a stem or longitudinal protrusion 1734. When

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assembled, the stem 1734 of the main hub 1730 is in the lumen 1721 of the spin collar 1720. Other interactions between the advancing hub 1710, the spin collar 1720, and the main hub 1730 are described herein, for example with respect to Figures 17C-17E.

[0167] Figure 17C is a perspective view of an example embodiment of the advancing hub 1710 and the wire 206 of Figure 2E. The stem 1712 of the advancing hub 1710 comprises a U-shaped recess 1713 configured to interact with the bent proximal portion of the wire 206. Other shapes of the recess 1713 are also possible (e.g., V-shaped). The recess 1713 may complement the shape of the proximal end of the wire 206. In some embodiments, the width of the recess 1713 is slightly smaller (e.g., about 0.001 inches (approx. about 0.025 mm) smaller) than the diameter of the wire 206 such that after being press-fit, the wire 206 is fixedly interconnected to the advancing hub 1710.

[0168] In some embodiments, the stem 1712 is shaped as illustrated in Figure 17C, including a perpendicular or transverse cross-section that includes flat surfaces (e.g., the surface comprising the top of the recess 1713) and arcuate surfaces, for example an ellipse with squared ends. The lumen 1731 of the main hub 1730 may comprise complementary surfaces, for example in a wider proximal portion, such that when the stem 1712 is in the lumen 1731, the advancing hub 1710 is in a fixed rotational position relative to the main hub 1710. Other shapes and rotational fixation configurations are also possible.

[0169] The proximal end of the advancing hub 1710 comprises a fitting 220 (e.g., a Luer fitting or any other appropriate fitting). When assembled, the fitting 220 is proximal to the spin collar 1720. The advancing hub 1710 comprises a lumen 1711 extending from the proximal end to the distal end. A fluid delivery device such as a syringe may be attached to the fitting 220 to deliver fluid through the lumen 1711 and then through the lumen 1731 of the main hub, the lumen 308 of the elongate member 203, the lumen 306c of the tip 211, and out the fluid port 210 of the tip 211. The RF probe 401 may be inserted into the lumen 1711, then into the lumen 1731 of the main hub, then into the lumen 308 of the elongate member 203, then into the lumen 306c of the tip 211. The RF probe 401 may include a fitting configured to interact with the fitting 220. The lumen 1711 may include a wide diameter portion in the area of the fitting 220 and a narrow diameter portion in the area of the stem 1712, and a tapered surface 1715 transitioning from the wide diameter portion to the narrow diameter portion. The tapered surface 1715 may help direct fluid and/or an RF probe 401

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into the narrow diameter portion. In some embodiments, the narrow diameter portion of the lumen 1711 has a diameter between about 0.005 inches and about 0.05 inches (approx. between about 0.13 mm and about 1.3 mm), between about 0.01 inches and about 0.03 inches (approx. between about 0.25 mm and about 0.76 mm), between about 0.015 inches and about 0.025 inches (approx. between about 0.38 mm and about 0.64 mm) (e.g., about 0.02 inches (approx. about 0.5 mm)), combinations thereof, and the like. In some embodiments, the narrow diameter portion of the lumen 1711 has a diameter that is no larger than the diameter of any other lumen of the needle 103 such that fluid pressure will default to the distal end of the needle 103. For example, the narrow diameter portion of the lumen 1711 may have a diameter of about 0.02 inches (approx. about 0.5 mm), the narrow diameter portion of the lumen 1731 may have a diameter of about 0.05 inches (approx. about 1.3 mm), the lumen 308 of the elongate member 203 may have a diameter of about 0.05 inches (approx. about 1.3 mm), and the lumen 306c may have a width of about 0.02 inches (approx. about 0.5 mm). In some embodiments, the lumen 306c may be slightly smaller than the narrow diameter portion of the lumen 1711 and have the same effect, for example due to small losses of fluid through the lumens 306a, 306b and out the filament ports 304a, 304b, which may be acceptable because anesthesia and dye, for example, may permeate through fluid and proximate to the filament ports 304a, 304b even if substantially only dispensed from the fluid port 210. In some embodiments, the advancing hub 1710 comprises a polymer (e.g., Pro-fax 6523 polypropylene homopolymer, available from LyondellBasell Industries).

[0170] Figure 17D is a cross-sectional view of an example embodiment of a spin collar 1720. The cross-section is along the same line as in Figure 17B, but further features are visible because not blocked by the advancing hub 1710 or the main hub 1730. As illustrated in Figure 17B, the lumen 1721 is configured to at least partially contain the stem 1712 and the stem 1734, and not to contact fluid or an RF probe 401. The lumen 1721 comprises a helical track 1722 sized to interact with a corresponding helical thread 1735 (Figure 17A) on the stem 1734 of the main hub 1730. As the spin collar 1720 is rotated relative to the main hub 1730 (e.g., by a user stabilizing the needle and gripping the main hub 1730 with the non-dominant hand and manipulating the spin collar 1720 with the dominant hand), for example, to deploy the filaments 206a, 206b, the helical track 1722 and the helical thread 1735 interact to cause the spin collar 1720 and the advancing hub 1710 to move

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longitudinally parallel to the central longitudinal axis 223. In this regard, a linear motion of the advancing hub 1710 relative to the main hub 1730 may be created while the rotational motion of the spin collar 1720 may not be transmitted to the advancing hub 1710 and the main hub 1730. In some embodiments, between about 1.25 turns and about 1.5 turns of the spin collar 1720 fully deploys the filaments 206a, 206b. In some embodiments, between about 0.75 turns and about 1.25 turns (e.g., one 360° rotation) of the spin collar 1720 fully deploys the filaments 206a, 206b. The configuration of the helical track 1722 and the helical thread 1735 may be adjusted to provide varying levels of filament deployment with varying levels of rotation of the spin collar 1720. An outer surface of the spin collar 1720 may be textured or include features 1723 to assist the user in gripping and twisting or rotating the spin collar 1720 relative to the main hub 1730. In some embodiments, the spin collar comprises the helical thread 1735 and the main hub 1730 comprises the helical track 1722. In some embodiments, the spin collar 1720 comprises a polymer (e.g., Pro-fax 6523 polypropylene homopolymer, available from LyondellBasell Industries).

[0171] Figure 17E is a cross-sectional view of an example embodiment of the main hub 1730, taken along the line 17E-17E of Figure 17B, in exploded view with an example embodiment of an elongate member 203. The proximal end of the elongate member 203, to the right in Figure 17E, includes a partial circumferential portion 1736. The distal end lumen 1731 of the main hub 1730 includes a complementary partial circumferential portion 1737. The partial circumferential portions 1736, 1737 can cause the elongate member 203 to be in a fixed and known rotational orientation with the main hub 1730, for example after assembly because the relative position of the indicator 1733 and the partial circumferential portion 1737 is known. For example, the distal end of the elongate member 203, to the left in Figure 17E, includes the filament ports 304a, 304b on the same side as the partial circumferential portion 1736. Other partial circumferential portions and other complementary shapes are also possible. For example, the partial circumferential portions may comprise interlocking teeth. In some embodiments, the thickness of the partial circumferential portion 1737 is substantially the same as the thickness of the walls of the elongate member 1736 to provide a smooth transition between the lumen 1731 and the lumen 308. In some embodiments, the main hub 1730 comprises clear polycarbonate (e.g., thermoset plastic such as Makrolon® 2548, available from Bayer). In some embodiments, the

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elongate member comprises a hypotube (e.g., comprising 300 Series Stainless Steel) with features such as the filament ports 304a, 304b and the partial circumferential portion 1736 cut out (e.g., by laser, mechanical, chemical, or other cutting methods).

[0172] Other types of mechanisms may be used to control deployment and retraction of the filaments. For example, in some embodiments, the mechanism includes a spring configured to bias the filaments 206a, 206b toward a predetermined position (e.g., fully deployed, fully retracted), analogous to a spring loaded mechanism used in retractable ballpoint pens. For another example, the mechanism may include a roller wheel, for example incorporated into the hub 204, that would advance or retract the filaments 206a, 206b upon rotation, for example with a user's thumb. For yet another example, the hub 204 and the actuator 216 may interact via complimentary threaded features. As the actuator 216 is threaded into the hub 204, the filaments 206a, 206b would advance, and as the actuator 216 is threaded out of the hub 204, the filaments 206a, 206b would retract. For still another example, a Touhy-Borst type mechanism could be incorporated to control the deployment and retraction of the filaments 206a, 206b. Any other appropriate mechanism for controlling linear motion of the filaments 206a, 206b may be incorporated into the needle 103. Any of the mechanisms described herein may be used for controlling deployment and retraction of the filaments of any of the embodiments described herein. For example, the mechanisms illustrated in Figures 2A-2D and 17A-17E may be used to deploy and retract the filaments in Figures 3A, 3C, 3D, 3G-3I, and 5-10.

[0173] Figure 2C is a partial cut away and partial cross-sectional view of a portion of an alternate embodiment of a mechanism 230 comprising a hub 231 and actuator 232 that may be part of a needle 103 used in an RF neurotomy procedure. The hub 231 may be fixedly attached to the elongate member 203. The hub 231 may be the primary portion of the needle 103 gripped by the user during insertion and manipulation of the needle 103. The hub 231 may include an asymmetric feature, such as an indicator 233, that is in an known orientation relative to the asymmetry of the tip 201. In this regard, the indicator 233 may be used to communicate to the user the orientation of the tip 201 within a patient. Internally, the hub 231 may include a cavity 234 sized to house a longitudinal protrusion 235 of a slide member 236. The longitudinal protrusion 235 may include a keyway or key slot 237 that may run along a longitudinal direction of the longitudinal protrusion 235. The internal

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surface of the hub 231 through which the longitudinal protrusion 235 moves may include a mating key (not shown) configured to fit and slide in the key slot 237. Together, the key slot 237 and mating key of the hub 231 may limit the slide member 236 to a linear motion parallel to the central longitudinal axis 223.

[0174] The filaments 206a, 206b may be fixedly connected to the longitudinal protrusion 235 of the slide member 236 for longitudinal movement therewith. In this regard, distal movement (e.g., movement to the right as shown in Figure 2C) of the longitudinal protrusion 235 relative to the hub 231 may cause extension of the filaments 206a, 206b relative to the hub 231, the elongate member 203, and the tip 201. For example, distal movement of the longitudinal protrusion 235 may move the filaments 206a, 206b from a retracted position to a deployed position. For another example, proximal movement (e.g., movement to the left as shown in Figure 2C) of the longitudinal protrusion 235 relative to the hub 231 may result in retraction of the filaments 206a, 206b relative to the hub 231, the elongate member 203, and the tip 201.

[0175] The hub 231 may be made from any appropriate material (e.g., a thermoset plastic, Makrolon® 2548, available from Bayer). The hub 231 may be at least partially transparent such that the position of the longitudinal protrusion 235 and/or other components of the hub 231 may be observable by a user. The hub 231 may further include demarcations (e.g., molded or printed marks) such that the amount of extension of the filaments 206a, 206b may be determined from the position of the longitudinal protrusion 235 and/or other components relative to the demarcations.

[0176] An actuator 232 may be used to control the motion to deploy and/or retract the filaments 206a, 206b fixedly connected to the longitudinal protrusion 235. The actuator 232 may be generally tubular such that it fits around a longitudinal hub projection 238 projecting from the proximal end of the hub 231. At least a portion of the cavity 234 may be in the longitudinal hub projection 238. The actuator 232 may also include an annular feature 239 configured to fit in an annular slot 240 in the slide member 236. The annular feature 239 may be sized relative to the annular slot 240 such that the actuator 232 may rotate relative to the slide member 236 about the central longitudinal axis 223 or an axis parallel thereto while the position of the actuator 232 relative to the slide member 236 along the central longitudinal axis 223 remains fixed. In this regard, the actuator 232 and the slide member

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236 may be configured to move in tandem relation along the central longitudinal axis 223. The annular feature 239 and annular slot 240 may be configured such that, during assembly, the actuator 232 may be pressed onto the slide member 236 and the annular feature 239 may snap into the annular slot 240.

[0177] The inner surface of the actuator 232 may include a helical track 241 sized to accommodate a corresponding mating helical thread 242 on the longitudinal hub projection 238. In this regard, as the actuator 232 is rotated relative to the slide member 236 and the hub 231 (e.g., by a user to deploy the filaments 206a, 206b), the helical track 241 and the helical thread 242 interact to cause the actuator 232 and the slide member 236 to move longitudinally along the central longitudinal axis 223. In this regard, a linear motion of the slide member 236 relative to the hub 231 may be created while the rotational motion of the actuator 232 may not be transmitted to the slide member 236 and the hub 231. An outer surface of the actuator 232 may be textured or include features to assist the user in gripping and twisting or rotating the actuator 232 relative to the hub 231. In some embodiments, the longitudinal hub projection 238 comprises the helical track 241 and the inner surface of the actuator 232 comprises the helical thread 242.

[0178] The proximal end of the slide member 236 may include a Luer fitting 243 or any other appropriate fitting type. The Luer fitting 243 may be in fluid communication with a lumen passing through the slide member 236 and may provide a connection such that fluid may be delivered through the Luer fitting 243 and into the lumen of the slide member 236. In turn, the lumen of the slide member 236 may be in fluid communication with the cavity 234 of the hub 231, which may in turn be in fluid communication with a lumen in the elongate member 223 (e.g., the lumen 222). The lumen in the elongate member 223 may be in fluid communication with the tip 201 (e.g., the fluid port 210). In this regard, fluid may flow into the Luer fitting 243, into and through the lumen in the slide member 236, into and through the cavity 234 of the hub 231, into and through the elongate member 223, and out from fluid portion 210 of the tip 201. The Luer fitting 243, the lumen in the slide member 236, the cavity 234 of the hub 231, and the lumen of the elongate member 223 may all also be configured to allow for the insertion of the RF probe 401 therethrough. The protrusion 235 and the cavity 234 of the longitudinal hub projection 238 may be sized and/or configured to form a fluid seal therebetween, allowing fluid delivered under pressure through the Luer

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fitting 220 to flow through the cavity 238 and into the elongate member 203 substantially without leaking past the interface between the protrusion 235 and the cavity 234 of the longitudinal hub projection 238.

[0179] As described herein, the filaments 206a, 206b may be fixedly interconnected to the slide member 236. Axial movement of the slide member 236 due to the actuator 232 may be thereby communicated to the filaments 206a, 206b to deploy and retract the filaments 206a, 206b upon rotation of the actuator 232. The slide member 236 may be made from any appropriate material (e.g., Pro-fax 6523 polypropylene homopolymer, available from LyondellBasell Industries). The actuator 232 may be made from any appropriate material (e.g., Pro-fax 6523 polypropylene homopolymer, available from LyondellBasell Industries).

[0180] The user can deploy or retract the filaments 206a, 206b by twisting or rotating the actuator 232. By partially rotating the actuator 232 relative to the hub 231, the filaments 206a, 206b may be partially deployed or retracted. The actuator 232 and/or hub 231 may include detents to provide audible and/or tactile feedback of the position of the filaments 206a, 206b. The detents may be configured such that audible and/or tactile feedback associated with engagement of a detent coincides with a predetermined amount of deployment or retraction of the filaments 206a, 206b, as described herein. In this regard, such audible and/or tactile feedback may be used in determining filament position.

[0181] In some embodiments, the needle 103 is a multipolar (e.g., bipolar) device in contrast to the monopolar devices described herein. In certain such embodiments, the filaments are isolated from each other and/or from the tip to enable bipolar operation (e.g., the filaments having one polarity and the tip having a second polarity, one filament having one polarity and one filament and the tip having a second polarity, one filament having one polarity and one filament having a second polarity, etc.). In embodiments in which the needle 103 comprises more than two filaments, elements may be included to allow for selection of the polarity of the certain filaments to aid in lesion shape, size, and/or position control. In some embodiments, the needle 103 may be used in either a monopolar mode or in a bipolar mode as selected by the user. For example, RF probes 401 may include shapes, insulating features, etc. configured to produce monopolarity or bipolarity.

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[0182] The herein-described embodiments of needles may be used in spinal RF neurotomy procedures, which will now be described. In general, for an RF neurotomy procedure, the patient may lie face down on a table so that the spine of the patient is accessible to the user. At any appropriate time before, during, and/or after the procedure, the user may use imaging equipment, such a fluoroscope, to visualize the patient's anatomy and/or to visualize the positioning of equipment (e.g., the needle relative to a target volume).

[0183] The patient may be administered sedatives and/or intravenous fluids as appropriate. The skin of the patient surrounding the procedure location may be prepared and maintained using an appropriate sterile technique. In embodiments in which the needle is monopolar, a return electrode pad 104 may be attached to the patient. A local anesthetic may be injected subcutaneously where the needle will be inserted or along the approximate path of the needle, for example through the needle itself or through a different needle.

[0184] With the filaments in the retracted position, the needle may be introduced into the patient and moved to a target position relative to a target portion of a target nerve or to a target position relative to a target volume in which the target nerve is likely situated (all of which are generally referred to herein as the target nerve or portion of the target nerve). The target nerve may be an afferent nociceptive nerve such as, for example, a medial branch nerve proximate a lumbar facet joint. Introduction of the needle into the patient may include percutaneously using the tip of the needle to pierce the skin of the patient. The moving of the needle may include navigating toward the target position using fluoroscopic guidance. Furthermore, the moving of the needle may include advancing the needle to an intermediate position and then repositioning the needle to the target position. For example, the needle may be advanced until it contacts a bone or other structure to achieve the intermediate position. This may be followed by retracting the needle a predetermined distance to achieve the target position. Such a procedure may be facilitated by the markers 224 or collar discussed herein.

[0185] During the moving of the needle or after the target position has been achieved, the needle may be used to inject an anesthetic and/or a dye proximate to the target nerve. The dye may increase contrast in fluoroscopic images to assist in visualizing the patient's anatomy, which may aid the user in guiding and/or verifying the position of the needle.

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[0186] The needle may be rotated about the central longitudinal axis of the elongate member of the needle to achieve a desired orientation relative to the target nerve. For example, the needle may be rotated such that a lesion created with the needle with the filaments deployed will be offset from the central longitudinal axis toward the target nerve. Such rotation of the needle may be performed prior to insertion of the needle into the patient and/or after insertion into the patient. For example, the user may rotate the needle prior to insertion such that the needle is generally in the desired rotational orientation. Then, after achieving the target position, the user may fine tune the rotational orientation of the needle by rotating the needle to a more precise orientation. As described herein, the hub or another portion of the needle outside the patient's body may indicate the rotational orientation of the needle.

[0187] Once the target position and desired rotational orientation have been achieved, the next step may be to advance one or more filaments of the needle relative to the tip of the needle. The particular needle used for a procedure may have been selected to enable the creation of a particular sized and shaped lesion at a particular position relative to the needle. The particular needle used may be of any appropriate configuration discussed herein (e.g., any appropriate number of filaments, any appropriate filament positioning, monopolar or bipolar, any appropriate deployment and retraction mechanism, etc.).

[0188] In embodiments in which the needle is configured as illustrated in Figures 5 and 6 (e.g., about 120° apart), the advancement of filaments may include advancing the filaments such that when the filaments are in their respective deployed positions, a midpoint between a distal end of the first filament and a distal end of the second filament is offset from the central longitudinal axis of the needle, and the filament endpoints are distal to the tip of the needle. Such deployment may enable the needle to be used to create a lesion that is offset from the tip of the needle toward the midpoint between the deployed filament ends. The lesion created may also be positioned at least partially distal to the tip of the needle.

[0189] Figure 11A is an illustration of an example set of isotherms 1010a-1010c that may be created with the needle 103 of Figure 2A. As illustrated by the set of isotherms 1010a-1010c, RF energy emanating from the tip 201 and from the filaments 206a, 206b, may produce a region of elevated temperature about the tip 201 and the filaments 206a, 206b. The isotherms 1010a-1010c may be offset from the central longitudinal axis 223 such that a

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centroid of the isotherms as viewed in Figure 11A is offset from the central longitudinal axis 223 in the direction of the filaments 206a, 206b. The centroid of the isotherms 1010a-1010c as viewed in Figure 11A may also be distal relative to the tip 201 and between the tip 201 and the distal ends of the deployed filaments 206a, 206b. The isotherms 1010a-1010c may also be shaped such that, as viewed in Figure 11A, the isotherms 1010a-1010c have a maximum cross-sectional dimension along the central longitudinal axis 223 that is greater than a maximum cross dimension in the plane of Figure 11A perpendicular to the central longitudinal axis 223. As visible in the illustrated orientation of Figure 11B, the isotherms 1010a-1010c may have a maximum cross-sectional dimension along the central longitudinal axis 223 that is greater than a maximum cross-sectional dimension perpendicular to the plane of Figure 11A and perpendicular to the central longitudinal axis 223.

[0190] The offset of the centroid of the isotherms 1010a-1010c from the central longitudinal axis 223 may result in greater lesion width in a plane perpendicular to the central longitudinal axis 223, as compared to a similarly-sized straight needle with no filaments. The offset of the centroid of the isotherms 1010a-1010c may also allow for projection of the centroid of a corresponding lesion volume in a direction away from the central longitudinal axis 223. By way of example, such offsets may advantageously enable the execution of the example procedures described herein. Such offsets may advantageously enable the creation of lesion volumes distal (relative to the needle 103) to potentially interfering structures (e.g., an ossified process). Such offsets may advantageously enable the needle 103 to be inserted into a patient at a more desirable angle (e.g., closer to perpendicular to the surface of the patient such as within 30° of perpendicular to the surface of the patient), at a more desirable piercing location, and/or through more desirable tissue than may be attempted using a needle without offset lesion capabilities.

[0191] Figure 11B is an illustration of an example lesion 1011 that may be created with the needle 103 of Figure 2A. In Figure 11B, the needle 103 has been placed perpendicular to a surface 1012. The surface 1012 may, for example, be the surface of a bone, such as a lumbar vertebra. As illustrated, the filaments 206a, 206b are deployed such they are proximate to the surface 1012. In some embodiments, contact with the surface 1012 might undesirably deform the filaments 206a, 206b, but such contact may be avoided, for example by the needle advancement and retraction procedures described herein. The lesion

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1011 has a width along the surface 1012 that is wider than would be created by the needle 103 if the filaments 206a, 206b were not deployed. Such capabilities may, for example, be advantageous where a target structure (e.g., a nerve) is known to be positioned along the surface 1012, but its exact position is unknown. In such a case, the needle 103 may be positioned generally perpendicular to the surface 1012 to achieve the illustrated lesion width along the surface 1012, whereas achieve the same lesion width along the surface 1012 using a the needle 103 without the filaments 206a, 206b deployed would require either multiple repositioning steps or placement of the needle 103 generally parallel to the surface 1012.

[0192] Figure 11C is an illustration of an example lesion 1022 that may be created with a single-filament needle 1020. The single-filament needle 1020 may be similar to the needle 103, although the single-filament needle 1020 includes only a single filament 1021. The filament 1021 may be configured similarly to the filaments 206a, 206b. The single-filament needle 1020 with the filament 1021 deployed may be operable to produce a lesion 1022 that is a flattened version (e.g., thinner in a direction perpendicular to the central longitudinal axis 223, which is the left to right direction as illustrated in Figure 11C) of a lesion that may be produced by the needle 103 with two filaments 206a, 206b deployed. The capability to produce such a lesion shape may be beneficial when it is desirable to have a relatively large lesion in a particular direction (e.g., to compensate for the variability of location of a target nerve) and a relatively small lesion width in another direction (e.g., to avoid a structure such as viscera or a patient's skin). As described herein, certain embodiments of the needle 103 may allow differential or selective deployment and/or activation of the filaments 206a, 206b such that the needle 103 may imitate the single-filament needle 1020.

[0193] In embodiments in which the needle is configured such that all of the filaments of the needle are deployed on a common side of a central plane of the needle (in which the central longitudinal axis is entirely within the central plane), the advancement of filaments may include advancing the filaments such that when the filaments are in their respective deployed positions, the distal ends of all of the filaments are on a common side of the central plane. Such deployment may enable the needle to be used to create a lesion that is offset from the tip of the needle to the same side of the central plane as the deployed filament

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ends. The lesion created may also be positioned at least partially distal to the tip of the needle.

[0194] In embodiments in which the needle is configured as illustrated in Figure 7 or 8, the advancement of filaments may include advancing the filaments such that when the filaments are in their respective deployed positions, each filament distal end defines a vertex of a polygon whose centroid is offset from a central longitudinal axis of the needle. Such deployment may enable the needle to be used to create a lesion that is offset from the tip of the needle toward the centroid. The lesion created may also be positioned at least partially distal to the tip of the needle.

[0195] The advancement of the filaments may be achieved using any of the mechanisms discussed herein. For example, in the embodiment of Figure 2A, rotating the actuator 216 relative to the hub 204 may cause the filaments to advance to the deployed position. The advancement of the filaments may be performed such that each of the plurality of filaments passes through a surface of the needle that is parallel to the central longitudinal axis of the needle. In some embodiments, the filaments of the needle may be advanced to a position that is an intermediate position between the retracted position and the fully deployed position. The degree of deployment may be based on the desired lesion size and/or the accuracy of the placement of needle. For example, the same needle may be used in two different procedures where the variability of the location of a target nerve is greater in the first procedure than it is in the second procedure. In such situation, the greater deployment of the filaments may be used in the first procedure, whereas in the second procedure, a smaller degree of deployment may be used since a smaller lesion may suffice to ensure that the target nerve has been ablated. For another example, after placement of the needle during a procedure, the position of the needle may be determined to be slightly offset from a target position. In such a case, the filaments may be deployed to a greater degree than would have been required if the needle were placed exactly on target. In such a case, the greater degree of deployment may be used to compensate for the needle positioning inaccuracy. In such a case, needle repositioning and possible associated trauma may be avoided.

[0196] During and/or after advancing the filaments to the deployed position, their positions may be confirmed using an imaging system (e.g., using a fluoroscope). Proper filament positioning may also be verified by using the needle to stimulate the target nerve.

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For example, an electrical signal (e.g., up to about 2 volts applied at about 2 Hz) may be applied to the needle and the user may observe any related patient movement (e.g., muscle fasciculation in the territory supplied by the nerve). For another example, an electrical signal (e.g., up to about 1 volt applied at about 50 Hz) may be applied to the needle and the patient may indicate if they feel any associated sensations and their locations to assist in verifying correct needle positioning. Such stimulation (user-observed and/or patient reported) may be used to stimulate a targeted nerve to determine if the deployed position is adequate to achieve denervation of the targeted nerve. In this regard, it is desirable for the stimulation to affect the targeted nerve. Upon determination that the target nerve is stimulated, increased energy may be applied to ablate a volume comprising the target nerve.

[0197] Such stimulation may also be used to attempt to stimulate a nerve that is not targeted for denervation (e.g., a nerve where no denervation is desired) to determine the position of the needle relative to such a non-targeted nerve. In this regard, if the stimulation signal does not stimulate the non-targeted nerve, the user may determine that the position of the needle relative to the non-targeted nerve is such that the application of ablation energy to the needle will not result in significant damage to (e.g., ablation of) the non-targeted nerve. If the stimulation stimulates the non-targeted nerve (e.g., as determined by user observation and/or patient reporting), the needle may be repositioned to avoid damaging the non-targeted nerve. In this regard, it is desirable for the stimulation not to affect the non-targeted nerve.

[0198] After correct needle positioning has been verified (e.g., by imaging and/or stimulation), an anesthetic may be injected through the needle, for example out of at least one of the fluid port 210, 320, the filament ports 304a, 304b, 318a, 318b, the lumen 306c, etc.

[0199] After the filaments have been advanced to the desired position, the next step may be to apply RF energy to the needle using the interconnected RF generator. In embodiments that use a separate RF probe to deliver RF energy, the RF probe may be inserted into a lumen of the needle prior to application of the RF energy. When using such a configuration, the application of RF energy may include applying RF energy to the RF probe and conducting the RF energy away from the probe by the tip and/or filaments.

[0200] The resultant RF energy emanating from the tip and/or the filaments may generate heat that ablates the target nerve. Such ablation may be achieved by creating a lesion volume that includes the target nerve. It is desired that the target nerve be completely

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ablated to prevent incomplete neurotomy which may result in dysesthesia and/or patient discomfort. For example, a lesion with a maximum cross-sectional dimension between about 8 mm and about 10 mm may be created. Larger or smaller lesions may be created by varying filament characteristics (e.g., filament advancement distance) and/or RF energy levels. The created lesion may be offset from the central longitudinal axis of the needle. The center of the lesion may be distal to the tip of the needle. Of note, since the RF energy is emanating from the tip and filaments, a particularly sized lesion may be created with a lower peak temperature (the maximum temperature experienced in the patient) than would be possible if a needle without filaments or without deployed filaments were to be used to create the same-sized lesion. For example, a particular lesion may be achieved with the needle with deployed filaments where the peak temperature is between about 55 °C and about 60 ºC or less than about 70 °C, whereas creation of the same lesion using a needle without filaments or without deployed filaments could require a peak temperature of about 80 ºC. Such lower temperature lesions achievable by a needle with deployed filaments may result in greater patient safety and/or procedure tolerance.

[0201] Before, during, and/or after the application of RF energy, a temperature sensor (e.g., thermocouple) at or near the tip of the needle may be used to monitor the temperature at or near the tip. Such readings may be used as control signals (e.g., a feedback loop) to control the application of RF energy to the needle. For example, control signals and/or temperature data may be used for closed-loop control of the needle 103 by automatic adjustment of a parameter (e.g.., frequency, wattage, and/or application duration of the RF energy, and/or filament deployment length, needle position, etc.) upon detection of a temperature. Feedback loops involving the user are also possible. If it is desired to ablate additional target nerves or to ablate an additional volume to ensure ablation of the original target nerve, the spinal RF neurotomy procedure may continue. In some embodiments, the distal end 402 of the RF probe 401 is a dual-purpose wire that can deliver RF energy to the tip and/or the filaments and that can act as a thermocouple (e.g., having thermosensing properties).

[0202] In embodiments in which the needle is configured to create lesions offset from the central longitudinal axis, and an additional target nerve or target volume is within a volume that may be ablated using the needle in its current position but in a different

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rotational orientation, the procedure may continue as follows. First, after the initial RF energy application, the filaments may be retracted into the needle. Once retracted, the needle may be rotated, and the filaments redeployed. The redeployment may have the same characteristics (e.g., length of the deployed portions of the filaments) as the original deployment or different characteristics. Next, the reoriented needle may be used to at least partially ablate the additional target nerve or target volume. Such retargeting of ablation volumes without repositioning (e.g., without withdrawing the needle from the patient and reinserting), may result in reduced patient trauma as compared to known spinal RF neurotomy procedures, which may require removal and reinsertion of a needle to achieve lesioning of the second target volume. Moreover, such retargeting of ablation volumes without repositioning (e.g., with only rotation of the needle, without additional tissue piercing) may result in the ability to create uniquely shaped lesions from a single insertion position. Such shaped lesions may include, for example, lesions that are in the shape of two or more intersecting spheres or oblong spheroids. The steps of retracting the filaments, rotating the needle, redeploying the filaments, and applying RF energy may be repeated a plurality of times. In some embodiments, an second ablation volume may be defined without rotating the needle, but by different deployment characteristics (e.g., lengths, RF energy parameters, etc.) of the filaments.

[0203] In embodiments in which the additional target nerve or target volume is not within a volume that may be ablated by rotating the needle, the needle may be repositioned. Such repositioning may include partially or fully removing the needle from the patient and then repositioning the needle and repeating the herein-described steps. In some embodiments, the second ablation is performed using a different needle (e.g., a needle with different properties (e.g., longer filaments)) than the original needle.

[0204] When no additional ablation is desired, the filaments of the needle may be retracted, and the needle may be removed from the patient. After removal of the needle, a sterile bandage may be placed over the needle insertion site or sites. The patient may then be held for observation and recovery from the effects of any sedative that may have been administered.

[0205] Examples of specific spinal RF neurotomy procedures will now be described. Generally, steps unique to each procedure will be discussed while steps common

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to any spinal RF neurotomy procedure (e.g., site preparation such as infiltrating the skin and subcutaneous tissues with 1.5% lidocaine to achieve skin anesthesia, nicking the skin to facilitate needle insertion, insertion monitoring with fluoroscopy, stimulation, etc., filament deployment mechanics, needle removal, and the like) will not be further discussed. Each of the procedures is described as being performed with a needle comprising two filaments offset from the central longitudinal axis, for example as described herein. It will be appreciated that the variations in needle configuration discussed herein may be used in these procedures. For example, to increase the offset of the created lesion relative to the central longitudinal axis, curved filaments (e.g., as illustrated in Figure 10) and/or partially insulated filaments (e.g., as illustrated in Figures 3H and 3I) may be used to create a lesion different properties (e.g., greater offset from the central longitudinal axis).

1. Lumbar RF neurotomy of a medial branch nerve proximate a lumbar facet joint.

[0206] This process may include using a needle that enables the creation of lesions that are offset from the central longitudinal axis. The procedure will be described as being performed on the L5 vertebra 1101 of Figure 12 and the needle 103 of Figure 2A. It should be understood that other embodiments of needles described herein and/or other lumbar vertebra may be used in the described procedure or variations thereof.

[0207] The lumbar RF neurotomy process may include positioning the tip 201 of the needle 103 (e.g., using fluoroscopic navigation) such that the tip 201 is in contact with, or proximate to, the groove 1102 between the transverse process 1103 and the superior articular process 1104 of the targeted lumbar vertebra 1101. Such positioning is shown in Figure 12. By contacting the lumbar vertebra 1101, a positive determination of the position of the needle 103 may be made. By way of example, such positioning may be performed such that the needle 103 is within 30° of being perpendicular to the lumber vertebra 1101 at the point of contact with the lumbar vertebra 1101, or at the point of the lumbar vertebra 1101 closest to the tip 201 of the needle 103. Optionally, from such a position, the needle 103 may be retracted a predetermined amount (e.g., between about 3 mm and about 5 mm), for example as measured by markers 224 on the needle 103, as determined using the collar about the elongated member 203 discussed herein, and/or by fluoroscopic navigation.

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[0208] The process may include rotating the needle 103 such that the midpoint 502 is oriented toward the superior articular process 1104 and a medial branch nerve 1105 that is positioned along a lateral face 1106 of the superior articular process 1104. Next, the filaments 206a, 206b may be advanced to the deployed position, as shown in Figure 12. The positions of the needle 103 and the deployed filaments 206a, 206b may be verified using fluoroscopy and/or patient stimulation (e.g., motor and/or sensory). The RF probe 401 may then be inserted into the lumen 222 such that RF energy emanating from the probe 103 will be conducted by the tip 201 and filaments 206a, 206b to the target medial branch nerve 1105 and away from the intermediate branch of the posterior primary ramus.

[0209] Next, RF energy may be applied to the RF probe 401. The RF energy emanating from the needle 103 may be preferentially biased toward the target medial branch nerve 1105. The lesion created by such a procedure may, for example, have a maximum cross-sectional dimension of between about 8 mm and about 10 mm, and may ablate a corresponding portion of the medial branch nerve 1105, thus denervating the facet joint.

[0210] In some embodiments, the needle may be operable to create a generally symmetric lesion relative to its central longitudinal axis (e.g., as illustrated in Figure 9). In certain such embodiments, the sequence of steps may include insert needle, deploy filaments, and apply RF energy.

[0211] In some embodiments, the needle may be inserted to be along the length of a portion of the nerve (as illustrated by needle 103' outlined by broken lines). Such positioning may be similar to known methods of RF neurotomy performed using needles without filaments. After positioning the needle, the filaments may be deployed and a lesion may be created. As noted herein, a needle with deployable filaments that is capable of producing a lesion equivalent to that of a needle without deployable filaments may be smaller in diameter than the needle without deployable filaments. Although positioning of the needle 103' may be similar to known processes, the process utilizing the needle 103' with deployable filaments may cause less trauma and be safer than procedures using a needle without deployable filaments due to the smaller size of the needle with deployable filaments. As discussed herein, the peak temperatures capable of producing the desired lesion volume may be less when using the needle 103' with deployable filaments as compared to a needle without deployable filaments, further contributing to patient safety. The filaments of the

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needle 103' may be partially or fully deployed to achieve a desired lesion location, shape, and/or size.

[0212] It is noted that the illustrated deployment of needle 103 with the filaments 206a, 206b deployed may be used to create a lesion that approximates a lesion that would be created with the needle without filaments that is placed in the position of needle 103' (e.g., parallel to the target nerve 1105). The placement of needle 103 generally perpendicular to the surface of the L5 vertebra 1101 may be less difficult to achieve than the parallel placement of the needle 103'.

2. Sacroiliac Joint (SIJ) RF neurotomy of the posterior rami.

[0213] This process may include using a needle that enables the creation of lesions which are offset from the central longitudinal axis. The procedure will be described as being performed on the posterior rami 1201 of the SIJ of Figure 12 and using the needle 103 of Figure 2A. It should be understood that other embodiments of needles described herein and/or other portions of the SIJ may be used in the described procedure or variations thereof.

[0214] As part of the SIJ RF neurotomy process, it may be desirable to create a series of lesions in a series of lesion target volumes 1203a-1203h lateral to the sacral foramina 1211, 1212, 1213 of a side of the sacrum 1200 to ablate posterior rami 1201 that are responsible for relaying nociceptive signals from the SIJ. Since the exact positions of the rami 1201 may not be known, ablating such a series of target volumes 1203a-1203h may accommodate the variations in rami 1201 positions. The series of target volumes 1203a-1203h may be in the form of one or more interconnected individual target volumes, such as the target volumes 1203a, 1203b. In some embodiments, the process further comprises forming a lesion 1208 between the L5 vertebra 1209 and the sacrum 1200 to ablate the L5 dorsal ramus.

[0215] The SIJ RF neurotomy process may include positioning the tip 201 of the needle 103 (e.g., using fluoroscopic navigation) such that it is in contact with, or proximate to, and in lateral relation to the S1 posterior sacral foraminal aperture (PSFA) 1211 at a first point 1204 that is at the intersection of the two target volumes 1203a, 1203b. Such positioning may be performed such that the needle 103 is oriented within 30° of being

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perpendicular to the sacrum 1200 at the point of contact (or at the point of the sacrum 1200 closest to the tip 201 of the needle 103). By contacting the sacrum 1200, a positive determination of the position of the needle 103 may be made. Optionally, from such a position, the needle 103 may be retracted a predetermined amount (e.g., between about 3 mm and about 5 mm) as measured, for example, by markers 224 on the needle 103, as determined using the collar about the elongated member 203 discussed herein, and/or by fluoroscopic navigation. For example, a contralateral posterior oblique view may be obtained to ascertain that the tip 201 has not entered the spinal canal. For example, a fluoroscopic view may be obtained looking down the length of the needle 103 to verify that the needle 103 is properly offset from the S1 PSFA 1211 and/or a fluoroscopic view may be obtained looking perpendicular to the central longitudinal axis 223 to verify that the needle 103 is not below the surface of the sacrum (e.g., in the S1 PSFA 1211). An electrical signal may be applied to the needle 103 to stimulate nerves proximate to the tip 201 to verify correct needle 103 placement.

[0216] The SIJ RF neurotomy process may include rotating the needle 103 such that the midpoint 502 is oriented toward the first target volume 1203a in the direction of arrow 1205a. Next, the filaments 206a, 206b may be advanced to the deployed position. The position of the needle 103 and the deployed filaments 206a, 206b may be verified using fluoroscopy and/or stimulation (e.g., motor and/or sensory). The RF probe 401 may be inserted into the lumen 222 before, during, and/or after filament deployment such that RF energy emanating from the needle 103 will be conducted by the tip 201 and the filaments 206a, 206b to the first target volume 1203a. Next, RF energy may be applied to the RF probe 401. The RF energy emanating from the needle 103 may be preferentially biased toward the first target volume 1203a. The lesion created by such an application of RF energy may, for example, have a maximum cross-sectional dimension of between about 8 mm and about 10 mm, and may ablate a corresponding portion of the rami 1201.

[0217] Next, the filaments 206a, 206b may be retracted and the needle 103 may be rotated approximately 180° such that the midpoint 502 is oriented toward the second target volume 1203b in the direction of arrow 1205b. Optionally, some lateral repositioning of the needle may performed (e.g., without any needle pull back or with a small amount of needle pull back and reinsertion). Next, the filaments 206a, 206b may be advanced to the

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deployed position. The position of the needle 103 and the deployed filaments 206a, 206b may be verified using fluoroscopy and/or stimulation (e.g., motor and/or sensory). The RF probe 401 may remain in the lumen 222 during the repositioning, or may be removed and then reinserted. Next, RF energy may be applied to the RF probe 401 to create a lesion corresponding to the second target volume 1203b.

[0218] In this regard, with a single insertion of the needle 103, two interconnected lesions (which may also be considered to be a single oblong lesion) may be created. Compared to methods in which an RF probe must be repositioned prior to each application of RF energy, the number of probe repositioning steps may be greatly reduced, reducing patient trauma and procedure duration. In this regard, a continuous region of lesioning may be achieved about the S1 PSFA 1211 such that the lesion occupies a volume surrounding the S1 PSFA 1211 from about the 2:30 clock position to about the 5:30 clock position (as viewed in Figure 13). Such lesioning may help to achieve denervation of the posterior rami proximate to the S1 PSFA 1211.

[0219] The herein procedure may be repeated as appropriate to create lesions corresponding to the entire series of target volumes 1203a-1203h, thus denervating the SIJ. For example, a first insertion may ablate the volumes 1203a, 1203b, a second insertion may ablate the volumes 1203c, 1203d, a third insertion may ablate the volumes 1203e, 1203f, and a fourth insertion may ablate the volumes 1203g, 1203h. In this regard, a similar continuous region of lesioning may be achieved about the S2 PSFA 1212 and a region of lesioning from about the 12:00 clock position to about the 3:00 clock position (as viewed in Figure 13) relative to the S3 PSFA may be achieved about the S3 PSFA 1213. A lesion 1208 may also be created at the base of the superior articular process of the L5 1209 dorsal ramus in the grove between the superior articular process and the body of the sacrum. The needle 103 may be inserted generally perpendicular to the plane of Figure 13 to produce the lesion 1208.

[0220] In some embodiments, three or more lesions may be created with a needle in a single position. For example, a needle positioned at a point 1206 proximate to three target volumes 1203c, 1203d, 1203e, may be operable to create lesions at each of the three target volumes 1203c, 1203d, 1203e, thus further reducing the number of needle repositionings.

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[0221] In some embodiments, each individual lesion corresponding to the series of target volumes 1203 may be created using a needle with deployable filaments in which the needle is repositioned prior to each application of RF energy. In certain such embodiments, the sequence of steps may be insert needle, deploy filaments, apply RF energy, retract filaments, reposition needle, and repeat as appropriate to create each desired lesion. Such a procedure may be conducted, for example, using a needle capable of producing a lesion symmetric to a central longitudinal axis of the needle (e.g., the needle of Figure 9).

3. Thoracic RF neurotomy of a medial branch nerve.

[0222] This process may include using a needle that enables the creation of lesions which are offset from the central longitudinal axis of the needle. Successful treatment of thoracic z-joint pain using radiofrequency ablation of relevant medial branch nerves can be challenging owing to the inconsistent medial branch location in the intertransverse space, especially levels T5-T8. A needle without filaments is generally positioned at multiple locations in the intertransverse space to achieve sufficient tissue ablation for successful medial branch neurotomy. The procedure will be described as being performed on an intertransverse space between adjacent vertebrae 1301, 1302 of the T5 to T8 thoracic vertebrae using Figure 14 and the needle 103 of Figure 2A. It should be understood that other embodiments of needles described herein and/or other vertebrae may be used in the described procedure or variations thereof.

[0223] The process may include obtaining a segmental anteroposterior image at target level defined by counting from T1 and T12. This may be followed by obtaining an image that is ipsalateral oblique about 8° to about 15° off-sagittal plane of the spine to visualize costotransverse joint lucency clearly. This can allow improved visualization of the superior-lateral transverse process, especially in osteopenic patients. The angle can aid in directing the probe to a thoracic anatomic safe zone medial to the lung, reducing risk of pneumothorax.

[0224] The skin entry site for the needle 103 may be over the most inferior aspect of transverse process slightly medial to costotransverse joint. Inserting the needle 103 may include navigating the device over the transverse process over the bone to touch the superior transverse process slightly medial to the costotransverse joint. The process may include

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checking anteroposterior imaging to demonstrate that the tip 201 of the needle 103 is at the superolateral corner of the transverse process. The process may also include checking a contralateral oblique image view (e.g., at ±15°) to demonstrate, for example in "Pinnochio" view, the target transverse process in an elongate fashion. This view can be useful for showing the tip 201 of the needle 103 in relationship to the superolateral margin of the transverse process subadjacent to the targeted medial branch nerve. The process may include retracting the tip 201 slightly (e.g., about 1 mm to about 3 mm). In some embodiments, retracting the tip 201 positions the ports at the superior edge of the process (e.g., visible with a radiopaque marker).

[0225] In some embodiments, medial to lateral placement may be performed entering the skin beneath the segmental spinous process, and navigating the needle 103 over the transverse process to contact a point just proximal to the superolateral corner of the transverse process. The tip 201 may then be advanced to approximate the exit port 304a, 304b of the filaments 206a, 206b with the superior margin of the transverse process, and the filaments 206a, 206b are deployed.

[0226] The process may include rotating the needle 103 such that the midpoint 502 is oriented toward the intertransverse space between the vertebrae 1301, 1302 and the medial branch nerve 1303 that is positioned therein. Next, the filaments 206a, 206b may be advanced ventral into the intertransverse space between the vertebrae 1301, 1302 to the deployed position. The position of the needle 103 and deployed filaments 206a, 206b may be verified using fluoroscopy (e.g., using lateral imaging) and/or stimulation (e.g., motor and/or sensory), for example to rule out proximity to ventral ramus. In some embodiments, the filaments 206a, 206b are deployed in a ventral direction in the intratransverse space, which may be confirmed by obtaining lateral. The RF probe 401 may be inserted into the lumen 222 such that RF energy emanating from the probe 103 will be conducted by the tip 201 and the filaments 206a, 206b to the target medial branch nerve 1303. Next, RF energy may be applied to the RF probe 401. The RF energy emanating from the needle 103 may be preferentially biased toward the volume between the vertebrae 1301, 1302. The lesion created by such a procedure may, for example, have a maximum cross-sectional dimension of between about 8 mm and about 10 mm, and may ablate a corresponding portion of the medial branch nerve 1303. This method can treat the medial branch as it curves out of the

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intratransverse space emerging into the posterior compartment of the back. The directional bias of the lesion may advantageously heat towards the target and away from the skin.

[0227] It is noted that thoracic RF neurotomy performed on other thoracic vertebrae may call for different sizes of lesions. For example, thoracic RF neurotomy performed on the T3-T4 vertebrae may require a smaller lesion volume than the herein-described procedure, and thoracic RF neurotomy performed on the T1-T2 vertebrae may require a still smaller lesion volume. As described herein, the deployment of the filaments of the needle 103 may be varied to achieve such desired target lesion volumes, or different needles may be used (e.g., having shorter filaments in the fully deployed position).

4. Cervical medial branch RF neurotomy.

[0228] Embodiments of needles described herein (e.g., the needle 103 of Figure 2A) are capable of creating a volume of tissue ablation necessary for complete denervation of the cervical zygapophyseal joints, including the C2/3 cervical zygapophyseal joint (z-joint). Tissue ablation for cervical z-joint using embodiments of needles described herein may be accomplished using a single placement and single heating cycle. Such single placement and single heating cycle may avoid unnecessary tissue damage from multiple placements of a filament-free needle, and unintended injury to collateral tissue caused by excessive lesioning. The zone of ablation can be designed to provide sufficient and necessary tissue coagulation for a successful procedure, and thus may be expected to improve the outcomes of patients undergoing spinal radiofrequency neurotomy.

[0229] A cervical medial branch RF neurotomy procedure will be described as being performed on the third occipital nerve at the C2/3 z-joint using the needle 103 as shown in Figure 15. In Figure 15, the needle 103 is positioned between the C2 vertebra 1401 and the C3 vertebra 1402.

[0230] In a first step, the patient may be placed in a prone position on a radiolucent table suited to performing fluoroscopically guided spinal procedures. Sedation may be administered. The patient's head may be rotated away from the targeted side. Sterile skin prep and draping may be performed using standard well-described surgical techniques.

[0231] For Third Occipital Nerve (TON) ablation (C2/3 joint innervation) the lateral aspect of the C2/3 Z-joint is located under either parasagittal or, alternatively,

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ipsilateral oblique rotation of less than or equal to about 30° (e.g., between about 20° and about 30°) of obliquity relative to the true sagittal plane of the cervical spine. The skin entry point may be infiltrated with local anesthetic. Then, the tip 201 of the needle 103 is moved over the most lateral aspect of bone of the articular pillar at the juncture of the C2/3 z-joint to a first position contacting bone proximate to the most posterior and lateral aspect of the z-joint complex, for example using a "gun-barrel" technique to touch the most lateral and posterior aspect of the articular pillar at the point of maximal concavity for level below C2/3 or at the point of maximal convexity at the C2/3 level when targeting the TON.

[0232] Once boney contact is made, the needle 103 may be retracted a predetermined distance (e.g., between about 1 mm and about 3 mm) and the filaments are deployed towards the lateral aspect of the C2/3 z-joint. The filaments will spread to encompass anticipated rostrocaudal variation in the target nerve location. The angle of the filaments with respect to the tip may effectively cover the ventral aspect of the articular pillar up to the border of the superior articular process, thus incorporating benefits of a 30° oblique pass. The needle 103 may be rotated about a central longitudinal axis prior to filament deployment to ensure that deployment will occur in the desired direction.

[0233] Multiplanar fluoroscopic imaging may then be employed to verify that the tip and the filaments are positioned as desired. For example, it may be verified that the filaments are positioned straddling the lateral joint lucency, and posterior to the C2/3 neural foramen. Useful imaging angles include anterior-posterior (AP), lateral, and contralateral oblique (Sluijter) views. To further verify adequate positioning of the needle 103, motor stimulation may be performed by delivering a voltage (e.g., up to about 2 volts) at about 2 Hz to the tip 201 and filaments and/or sensory stimulation may be performed at appropriate voltage (e.g., between about 0.4 volts and about 1 volt) and frequency (e.g., about 50 Hz).

[0234] After position verification, RF energy may be applied to the tip and the plurality of filaments to generate heat that ablates a portion of the third occipital nerve. The cross-sectional dimensions of the lesion (e.g., between about 8 mm and about 10 mm) can incorporate all medial branches as well as the TON, which has a nerve diameter of about 1.5 mm. The directional nature of the lesion, offset towards the filaments, provides a beneficial measure of safety regarding undesired thermal damage to the skin and to collateral structures. Safety concerns may be further satisfied by fluoroscopic observation of the filaments dorsal

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to the intervertebral foramen and/or lack of ventral ramus activation during stimulation (e.g., with 2 Hz and 2 volts). After lesioning, the device may be removed. For levels below the C2/3 z-joint, the procedure may be similar than as described herein with respect to the third occipital nerve, with the exception that the initial boney contact target is at the waist of inflection point of the articular pillar.

[0235] Other spinal RF procedures may also benefit from the asymmetrical application of RF energy from embodiments of the needles described herein. Such asymmetry may, for example, be used to project RF energy in a desired direction and/or limit the projection of RF energy in undesired directions. The configuration of the filaments may be selected for a particular application to produce a desired size, shape, and/or location (relative to the needle tip) of a lesion within the patient. The location of the lesion may be offset distally and/or laterally from the tip of the needle as desired for a particular application.

[0236] It will be appreciated that the delivery of RF energy to tissue in the anatomy can be practiced for a multitude of reasons, and embodiments of the needles described herein may be adapted (e.g., modified or scaled) for use in other medical procedures. For example, embodiments of needles described herein could be used to deliver RF energy as a means to cauterize "feeder vessels," such as in bleeding ulcers and/or in orthopedic applications. For another example, embodiments of the needles described herein could be adapted for use in procedures such as cardiac ablation, in which cardiac tissue is destroyed in an effort to restore a normal electrical rhythm in the heart. Certain such uses could further benefit from the ability of embodiments of needles described herein to deliver fluid through a lumen since, for example, emerging procedures in cardiac therapy may require the ability to deliver stem cells, vascular endothelial growth factor (VEGF), or other growth factors to cardiac tissue. The ability to steer embodiments of the needle described herein may provide significant benefit in the field of cardiovascular drug delivery.

[0237] For example, a needle may be adapted for use in vertebral disc heating. A primary longer needle (e.g., having a length of about 15 cm and a tip with an uninsulated active portion having a length of about 2 mm, although other dimensions are also possible), is placed into the post posterolateral margin of a painful intervertebral disc, for example as

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described elsewhere for provocation discography and/or therapeutic disc access procedures such as Dekompressor® discectomy and disc biacuplasty. Once positioned in the posterior annulus, as confirmed with fluororscopy, tactile feedback, and/or characteristic impedance readings, a single filament is deployed to traverse the posterior annulus in a lateral to medial fashion in the lamella of the annulus fibrosis, for example as illustrated in Figure 18A, which is an axial view of posterior oblique needle entry with the main axial tip in the posterior annulus and deployed a filament moving lateral to medial in the lamella of the posterior annulus, and Figure 18B, which is a saggital view with a filament moving across the posterior annulus from lateral to medial.

[0238] In some embodiments, the filament may act as a thermocouple (e.g., comprising a material having thermosensing properties as described herein) to allow precise measurement of actual temperatures of the annulus. In some embodiments, the filament includes a lumen configured to allow injection of therapeutic substances (e.g., methylene-blue) upon withdrawal for substantially simultaneous chemo-thermo-neurolysis and/or to allow injection of contrast agent for confirmation of intraannular placement that is definite, for example as opposed to potentially dangerous placement in the spinal canal or futile placement in the nucleus pulposus. In some embodiments, the filament has an exit angle greater than about 30°. In some embodiments, the filament includes a beveled Quincke tip oriented to bias away from the spinal canal upon advancement, as needles in tissue track away from bevel angles. In some embodiments, the deployed filament has a length between about 10 mm and about 12 mm. In some embodiments, the needle does not include a lumen for injection of liquid. In certain such embodiments, the area not occupied by a lumen may be used for the filament, which may be more complicated due to use as a thermocouple and/or including a lumen.

[0239] Bipolar or monopolar RF energy is applied to the tip and to the filament, creating a zone of therapeutic heating across the posterior disc annulus and resulting in destruction of the pain fibers in approximately the outer third of the annulus. The procedure may be repeated on the opposite side. In some embodiments, the needle includes a plurality of deployable filaments, and gap between the filaments (e.g., the distance 604 in Figure 6) is between about 2 mm and about 10 mm, between about 4 mm and about 8 mm, between about 5 mm and about 7 mm (e.g., about 6 mm), combinations thereof, and the like.

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Example 1

[0240] Sections of raw muscle tissue were allowed to equilibrate to 37 °C in a distilled water bath. A needle with tines deployed was positioned to contact the tissue surface in 10 trials and was inserted into tissue in 10 trials. A Radionics RFG 3C RF generator energy source was set at 75 °C for 80 seconds. Propagation of tissue coagulation was documented with video and a calibrated Flir T-400 thermal camera. Tissue samples were sectioned and coagulation zones measured. Infrared observation demonstrated symmetric and homogenous lesion progression without hot spots or focal over-impeding. Calculated volume averaged 467 ± 71 mm^3/lesion. Topography was elongate spheroid offset from the central axis toward the filaments. Thus, the needle reliably produced lesions that are potentially useful in spinal applications.

Example 2

[0241] A 47 year-old male with recalcitrant right-sided lumbar zygapophysial joint pain presented for radiofrequency medial branch neurotomy. The diagnosis had been made by greater than 80% relief documented following both intraarticular z-joint injection and confirmatory medial branch blocks.

[0242] The patient was placed in a prone position on the fluoroscopy table and standard monitors were applied. No sedation was administered. The lumbar region was extensively prepped with chlorhexidine-alcohol and draped in routine sterile surgical fashion. The C-arm was adjusted to visualize a true AP of the L4/5 intervertebral disc space with vertebral end plates squared-off, and spinous process positioned between the pedicle shadows. The C-arm was rotated 30°-40° ipsilateral to the target joint until the base of the SAP of the L4 and L5 were clearly visualized. A target point was identified at the midpoint of the base of the SAP, and the overlying skin and subcutaneous tissues were infiltrated with 1.5% lidocaine. A small skin nick was made with an 18-gauge needle to facilitate placement of an embodiment of the needles described herein. Once skin anesthesia was established, the needle, with filaments in the retracted position, was advanced using a gun-barrel approach until boney contact was made with the base of the SAP. The needle was then retracted off the bone slightly, and using the indentation on the hub for orientation, the actuator was

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rotated 360° to fully deploy the filaments. Filaments were felt to touch bone at the base of the SAP. AP, oblique, and lateral images were obtained to document the placement and to confirm that the filaments were directed toward the SAP. In this position, the lesion was biased to cover any variant medial branch situated higher up the SAP. If the filaments were not directed in an ideal fashion, they were retracted, the device was rotated as necessary, and the filaments were redeployed. Motor stimulation at a frequency of 2 Hz up to 2 volts was incrementally administered with brisk activation of the multifidus, but with no activation of any ventral root inenervated musculature. Sensory stimulation at 50 Hz at 0.6 volts elicited a concordant aching in the distribution of the patient's pain. A 22-gauge, 10 cm, 10 mm active tip RFK connected to an independently grounded second RF generator was placed sequentially at the following targets for *in vivo* thermometry: (1) Most inferior and dorsal location in the supra-segmental neural foramen evaluating the potential for thermal injury of spinal nerve; (2) At a point lateral on the transverse process approximating the location of intermediate/lateral branches of the posterior primary rami; (3) At or near the central axis of the needle during stable heating; (4) On the SAP at the base and successively higher on mamilliary process to evaluate heating on the region of potential MB variation (up the SAP). The process was then repeated for denervation of the L5.

[0243] Following the confirmation of safe and optimal placement by fluoroscopy and stimulation, the heating protocol was initiated based on previous branch testing in egg white and chicken meat. The protocol included: 45 °C for 15-30 seconds, await rapid temperature increase signaling primary consolidation of heating and biophysical changes around core axis; 50 °C for 15 seconds; 60 °C for 15 seconds; 70 °C for 10 seconds to record foraminal temperatures only.

[0244] Generator parameters during ablation were appropriate and within the tolerance range for a generically programmed RF generator. The lower starting impedance, relative to a monopolar needle, may be explained by greatly increased conductive surface of the needle. Brief temperature fluctuation was noted as the lesion propagated to encompass the central axis housing the thermocouple. It is anticipated that changes in the generator software may be useful to support various embodiments of the described device. Impedance readings were 75 ohms to 250 ohms. Power ranges were 2 watts to 11 watts, typically 3 watts to 4 watts after 10 seconds into the procedure.

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[0245] The thermal mapping results were as follows: (1) Perineural temperatures (neurogram obtained via TC2) at the supra-adjacent spinal nerve did not increase from a 38 °C baseline; (2) Temperature readings from the TC2 placed near the central axis of the needle reflected delivered temperature from the generator; (3) Temperature readings from the base of the SAP to relatively dorsal position on the SAP exceed the neuroablative threshold of 45 °C.

[0246] The patient experienced minimal discomfort following the procedure. For the sake of full disclosure, it is noted that the patient is an inventor of the present application. No postoperative analgesics were required. The patient reported near complete relieve of his right-sided low back pain within 10 days of the procedure. Bilateral paraspinal EMG at L3, L4, and L5 was performed 20 days after the RF procedure, as documented in Table 1:

Table 1 – Paraspinal EMG

Side	Muscle	Nerve	Root	Ins Act	Fibs	Psw
Left	L3 Parasp	Rami	L3	Nml	Nml	Nml
Left	L4 Parasp	Rami	L4	Nml	Nml	Nml
Left	L5 Parasp	Rami	L5	Nml	Nml	Nml
Right	L3 Parasp	Rami	L3	Nml	Nml	Nml
Right	L4 Parasp	Rami	L4	*Incr	*1+	*1+
Right	L5 Parasp	Rami	L5	*Incr	*1+	*1+

*Needle evaluation of the right L4 paraspinal and the right L5 paraspinal muscles showed increased insertional activity and slightly increased spontaneous activity.

*All remaining muscles showed no evidence of electrical instability.

There was electrodiagnostic evidence of active and acute denervation of the right lumbar paraspinals at the L4 and L5 levels. The contralateral left-sided paraspinals appeared normal. These findings are consistent with the clinical history of recent right lumbar radiofrequency rhizotomy.

[0247] Thus, the needle was safely and effectively used to accomplish lumbar medial branch neurotomy. Thermal mapping demonstrated a safe and effective isotherm consistent with bench predictions, and EMG of the lumbar paraspinals demonstrated objective evidence of medial branch coagulation. The needle appears to extend beneficially on existing techniques and technology. For a first example, facilitated placement for lumbar

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medial branch neurotomy using "down-the-beam" technique akin to diagnostic medial branch block. This approach can be applied to other spinal targets such as cervical z-joint neurotomy, thoracic z-joint neurotomy, sacroiliac joint denervation, central innercation of the lateral C1-2 joint, RF neurotomy thoracic sympathetic chain, RF neurotomy sphlancnic chain at T10, 11, 12, RF neurotomy lumbar sympathetic pain, and RF neurotomy superior hypogastric plexus. For a second example, lab testing and *in vivo* thermal data demonstrates a large volume suited for efficiently dealing with common variations in afferent sensory pathways. The lesion can be directed relative to the central longitudinal axis of the needle toward targets and away from sensitive collateral structures. For a third example, the needle can deliver meaningful motor and/or sensory stimulation for documentation of safe placement. For a fourth example, lesion topography is driven by needle design, and does not require high temperatures (e.g., greater than 80 °C) for extended times. It is believed that 60 °C for 60 seconds is adequate for most targets. Reduced procedural time and/or lower temperatures should translate to fewer complications, expedited recovery, and/or diminished incidence of postoperative pain syndromes/dysesthesias. For a fifth example, relative to other large field lesion technology, the needle is of a uncomplicated and robust design, does not require additional support equipment, and is economical to manufacture.

[0248] Although this invention has been disclosed in the context of certain embodiments and examples, it will be understood by those skilled in the art that the invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In addition, while several variations of the embodiments of the invention have been shown and described in detail, other modifications, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the invention. It should be understood that various features and aspects of the disclosed embodiments can be combined with, or substituted for, one another in order to form varying modes of the embodiments of the disclosed invention. Thus, it is intended that the scope of the invention herein disclosed should not be limited by the particular embodiments described herein.

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WHAT IS CLAIMED IS:

1. A radiofrequency neurotomy needle operable with a radiofrequency probe, the radiofrequency neurotomy needle comprising:

a conductive portion at a distal end of the radiofrequency neurotomy needle;

a tip configured to pierce tissue of a patient;

an elongate member comprising a lumen configured to accept the radiofrequency probe therein such that the radiofrequency probe physically contacts and is electrically connected to the conductive portion, the tip being at a distal end of the elongate member;

a filament electrically connected to the conductive portion and the tip due to physical contact of conductive materials at the distal end of the radiofrequency neurotomy needle such that the filament and the tip operate together as a single electrode, the filament being movable between a retracted position, in which the filament is at least partially in the elongate member, and a deployed position, in which at least a portion of the filament is out of the elongate member; and

an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,

wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion.

2. The radiofrequency neurotomy needle of claim 1, wherein the filament is formed of one of the conductive materials and the tip is formed of another of the conductive materials, and wherein the conductive materials of the filament and the tip are in physical contact when the filament is in the deployed position.

3. The radiofrequency neurotomy needle of claim 2, wherein the tip comprises the conductive portion at the distal end of the radiofrequency neurotomy needle, and wherein the conductive portion is configured to physically contact the distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen.

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4. The radiofrequency neurotomy needle of claim 1, wherein the tip comprises the conductive portion at the distal end of the radiofrequency neurotomy needle.

5. The radiofrequency neurotomy needle of claim 4, wherein the conductive portion is configured to physically contact the distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen.

6. The radiofrequency neurotomy needle of claim 4, wherein the tip comprises a tip lumen that is configured to receive the distal end of the radiofrequency probe.

7. The radiofrequency neurotomy needle of claim 1, wherein the needle further comprises a tube that is separate from the elongate member, and wherein the tube is positioned within the elongate member.

8. The radiofrequency neurotomy needle of claim 7, wherein the lumen is within the tube.

9. The radiofrequency neurotomy needle of claim 7, wherein the tube comprises the conductive portion of the needle.

10. The radiofrequency neurotomy needle of claim 1, wherein the tip and the elongate member are a single unitary structure or are separate components that are fixedly interconnected.

11. The radiofrequency neurotomy needle of claim 1, further comprising an additional filament electrically connected to the conductive portion such that both filaments and the tip operate together as the single electrode, wherein the additional filament is interconnected to the actuator such that both filaments are deployed and retracted by the actuator.

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12. The radiofrequency neurotomy needle of claim 11, wherein when the filaments are deployed, the tip and the filaments are configured to produce a lesion at a target volume of tissue within the patient.

13. The radiofrequency neurotomy needle of claim 12, wherein when the tip and the filaments are configured to produce the lesion so as to be asymmetrical and offset relative to the central longitudinal axis of the radiofrequency neurotomy needle.

14. The radiofrequency neurotomy needle of claim 12, wherein when the filaments are deployed, distal tips of the filaments are distal to the tip of the radiofrequency neurotomy needle such that the filaments and the tip are configured to produce the lesion so as to be distally offset from the tip of the radiofrequency neurotomy needle.

15. The radiofrequency neurotomy needle of claim 12, wherein the tip and the filaments are configured to operate together as the single electrode in a monopolar mode to produce the lesion to have a volume between about 250 mm^3 and about 750 mm^3.

16. The radiofrequency neurotomy needle of claim 12, wherein when the target volume includes a target nerve such that formation of the lesion ablates at least a portion of the target nerve to inhibit the ability of the target nerve to transmit pain signals.

17. The radiofrequency neurotomy needle of claim 1, wherein the lumen is further configured to accept the radiofrequency probe therein such that a distal end of the radiofrequency probe is proximate the tip when the radiofrequency probe physically contacts and is electrically connected to the conductive portion.

18. The radiofrequency neurotomy needle of claim 1, further comprising a fitting configured to provide a connection to a fluid source for injection of fluid through the lumen.

19. The radiofrequency neurotomy needle of claim 18, wherein the radiofrequency neurotomy needle is operable in a first state in which the radiofrequency probe is fully

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separated from the radiofrequency neurotomy needle in a non-inserted state and in which the fitting is connected to the fluid source for injection of fluid through the lumen, and wherein the radiofrequency neurotomy needle is operable in a second state in which the fitting is disconnected from the fluid source and in which the radiofrequency probe is inserted through the fitting into the lumen for delivery of the radiofrequency energy.

20. The radiofrequency neurotomy needle of claim 1, wherein the actuator is configured to rotate about the central longitudinal axis to move the filament between the retracted position and the deployed position.

21. The radiofrequency neurotomy needle of claim 1, wherein a distal tip of the filament is closer to a central longitudinal axis of the radiofrequency neurotomy needle when the filament is in the retracted position as compared with when the filament is in the deployed position.

22. The radiofrequency neurotomy needle of claim 1, wherein the filament and the tip are configured to operate together as the single electrode in a monopolar mode when the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion.

23. A system comprising:
the radiofrequency neurotomy needle of claim 1; and
the radiofrequency probe.

24. The system of claim 23, further comprising a radiofrequency generator and a return electrode pad that is configured to be attached to the patient, wherein the filament and the tip are configured to operate together as the single electrode in a monopolar mode when the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion and when the electrode pad is attached to the patient to complete a circuit from the radiofrequency generator, through the radiofrequency probe, through the needle, through a portion of the patient, through the return electrode pad, and to the radiofrequency generator.

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25. A radiofrequency neurotomy needle operable with a radiofrequency probe, the radiofrequency neurotomy needle comprising:

a tip comprising a conductive material, the tip being configured to pierce tissue of a patient;

a tube comprising a conductive material, the tube being configured to accept the radiofrequency probe therein;

a filament comprising a conductive material, wherein the tip, the tube, and the filament are electrically connected at a distal end of the radiofrequency neurotomy needle due to physical contact, at the distal end of the radiofrequency neurotomy needle, of each of the conductive materials with at least one of the other conductive materials, such that the filament and the tip are operative together as a single electrode, the filament being movable between a retracted position and a deployed position, a distal tip of the filament being closer to a central longitudinal axis of the radiofrequency neurotomy needle when the filament is in the retracted position as compared with when the filament is in the deployed position; and

an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,

wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and in physical contact with at least one of the conductive materials at the distal end of the radiofrequency neurotomy needle.

26. The radiofrequency neurotomy needle of claim 25, wherein the tube is an elongate member, and wherein the tip is at the distal end of the elongate member.

27. The radiofrequency neurotomy needle of claim 25, further comprising an elongate member, the tip being at a distal end of the elongate member, wherein the tube is separate from the elongate member and is positioned within the elongate member.

28. The radiofrequency neurotomy needle of claim 25, wherein the tip comprises a lumen that is configured to receive the distal end of the radiofrequency probe.

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29. A radiofrequency neurotomy needle operable with a radiofrequency probe, the radiofrequency neurotomy needle comprising:

an elongate member comprising a lumen configured to accept the radiofrequency probe therein;

a tip coupled to a distal end of the elongate member and being configured to pierce tissue of a patient, the tip comprising a conductive material configured to physically contact a distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen;

a filament comprising a conductive material, the filament being electrically connected to the tip by way of physical contact with the tip at a distal end of the radiofrequency neurotomy needle such that the filament and the tip are operative together as a single electrode, the filament being movable between a retracted position, in which the filament is in a cross-sectional envelope of the tip, and a deployed position, in which a portion of the filament is outside the cross-sectional envelope of the tip; and

an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,

wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and in physical contact with the conductive material of the tip.

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ABSTRACT

Apparatus for radiofrequency neurotomy are disclosed. Needles with deployable filaments capable of producing lesions at target volumes, which include a target nerve, and systems including such needles are disclosed. Ablation of at least a portion of the target nerve may inhibit the ability of the nerve to transmit signals, such as pain signals, to the central nervous system. The lesion may facilitate procedures by directing energy towards the target nerve and away from collateral structures. Example anatomical structures include lumbar, thoracic, and cervical medial branch nerves and rami and the sacroiliac joint.

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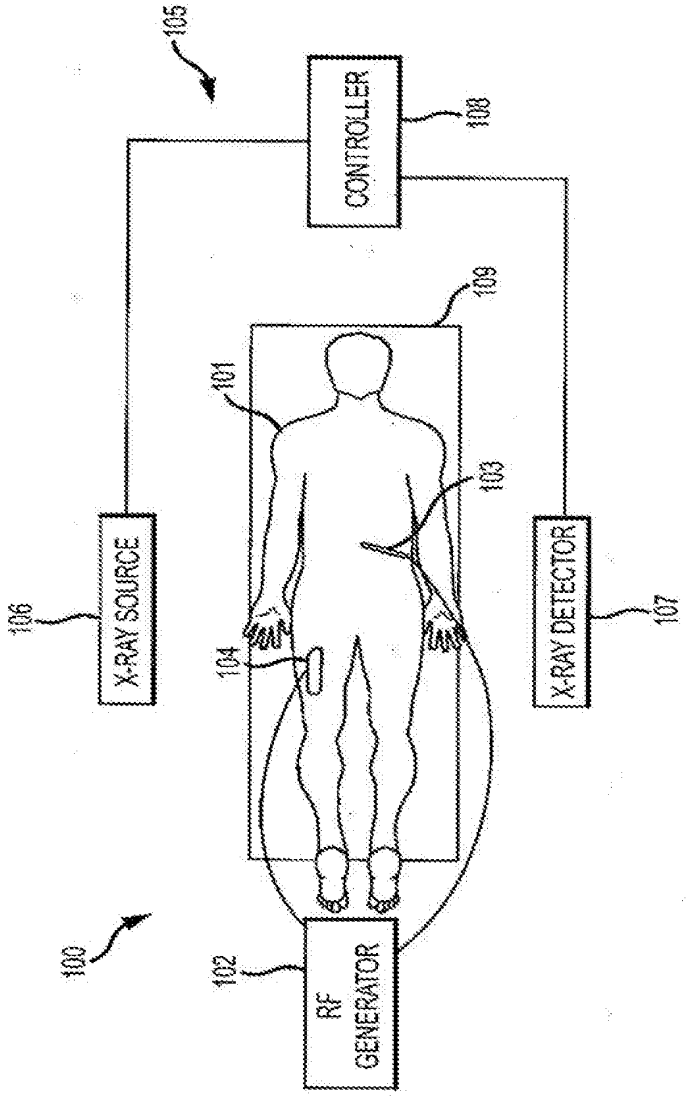

105
CONTROLLER
108
109
101
103
X-RAY SOURCE
106
104
X-RAY DETECTOR
107
100
102
RF GENERATOR

FIG. 1

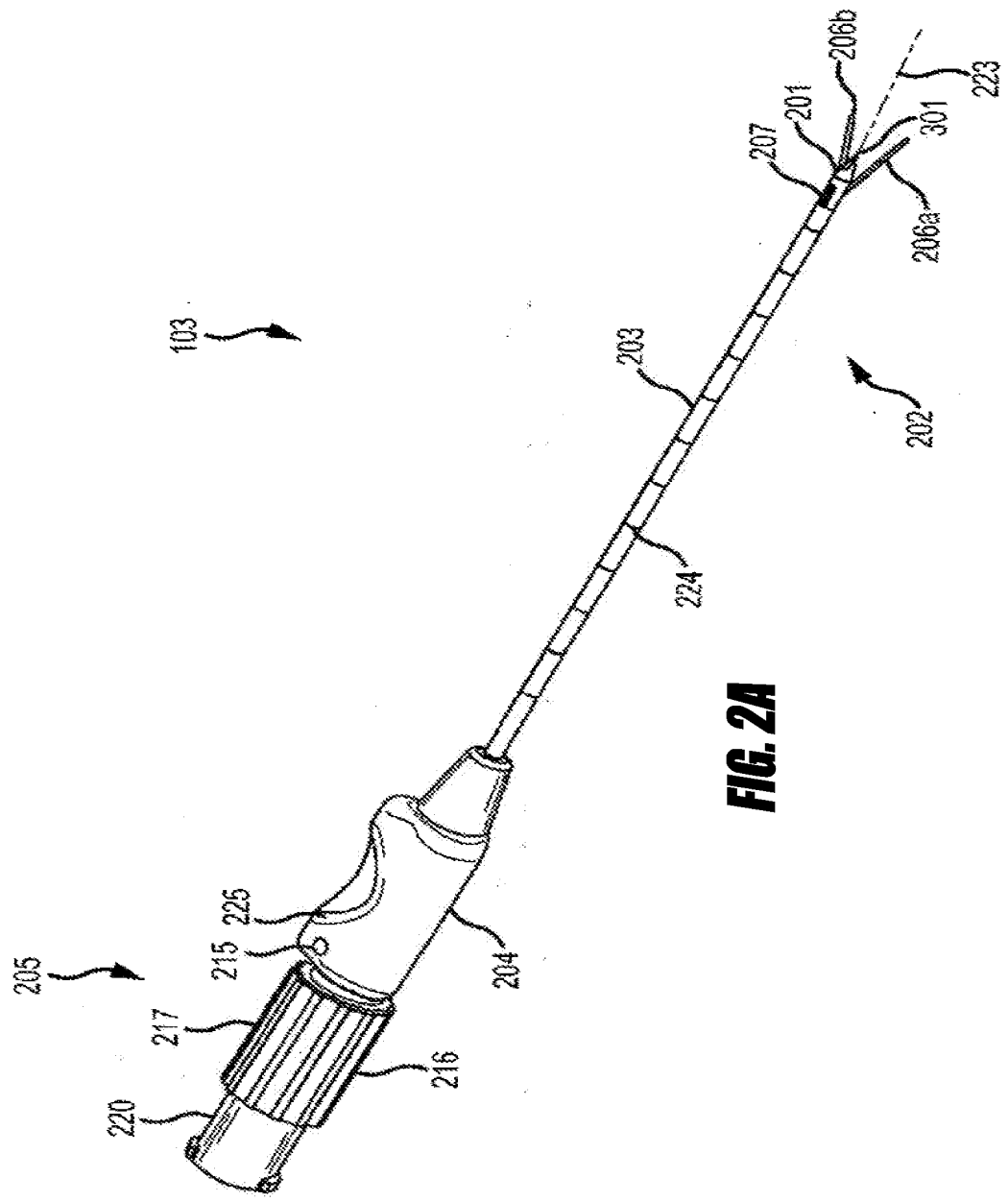

103
205
215
225
217
220
216
204
224
203
202
207
201
206b
223
301
206a

FIG. 2A

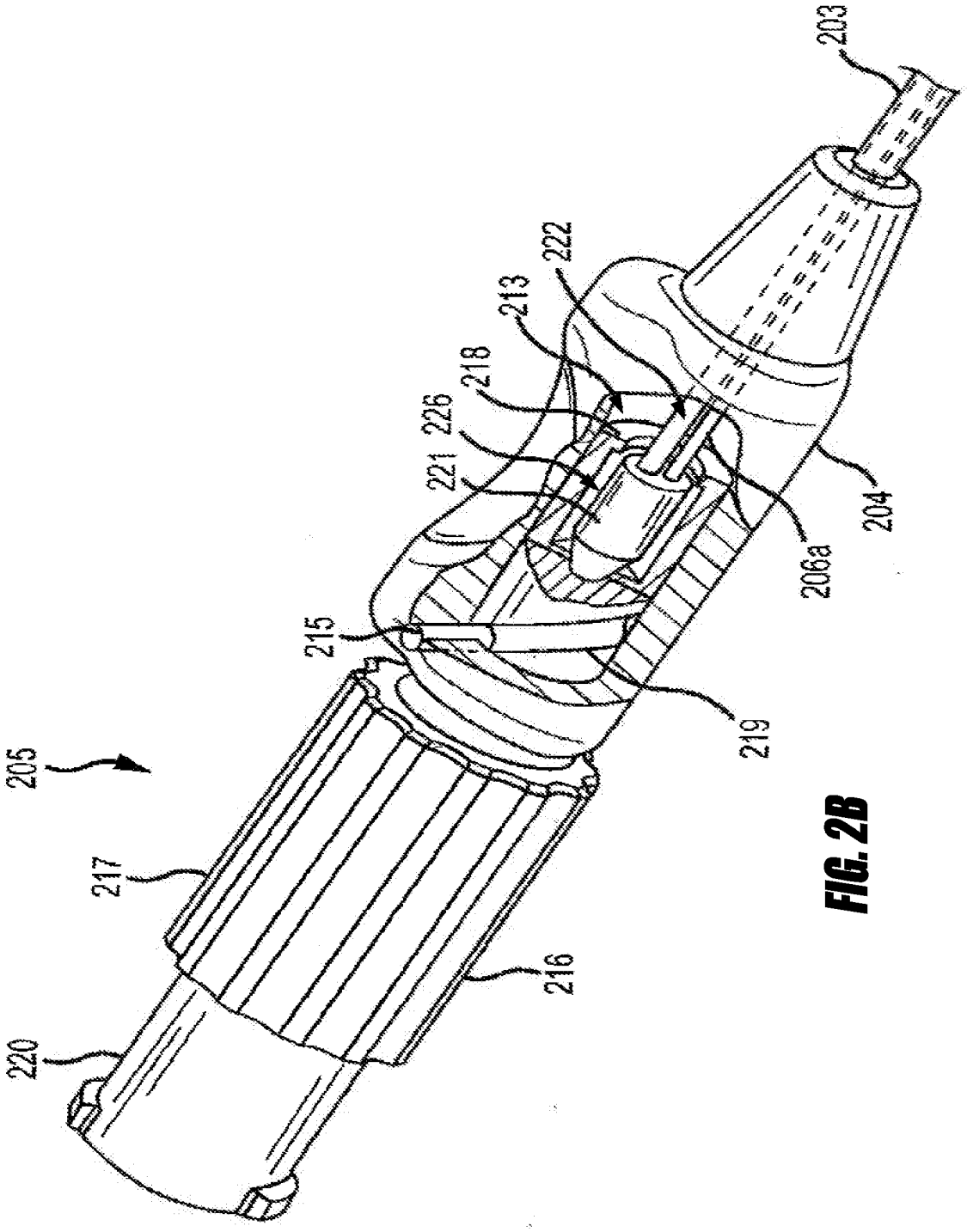


FIG. 2B

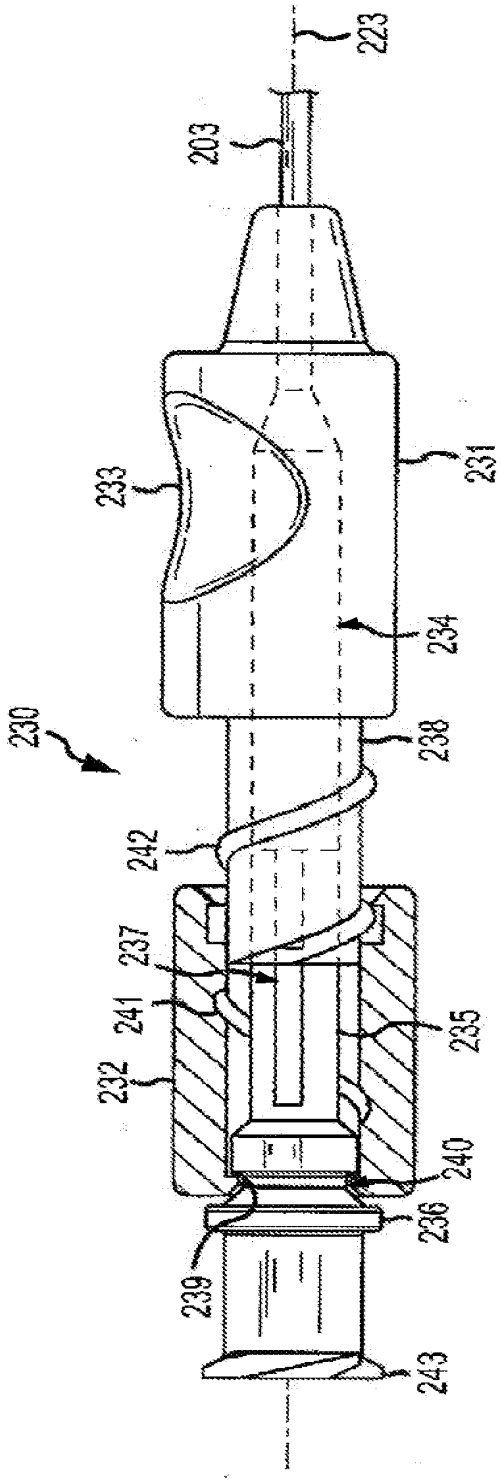


FIG. 2C

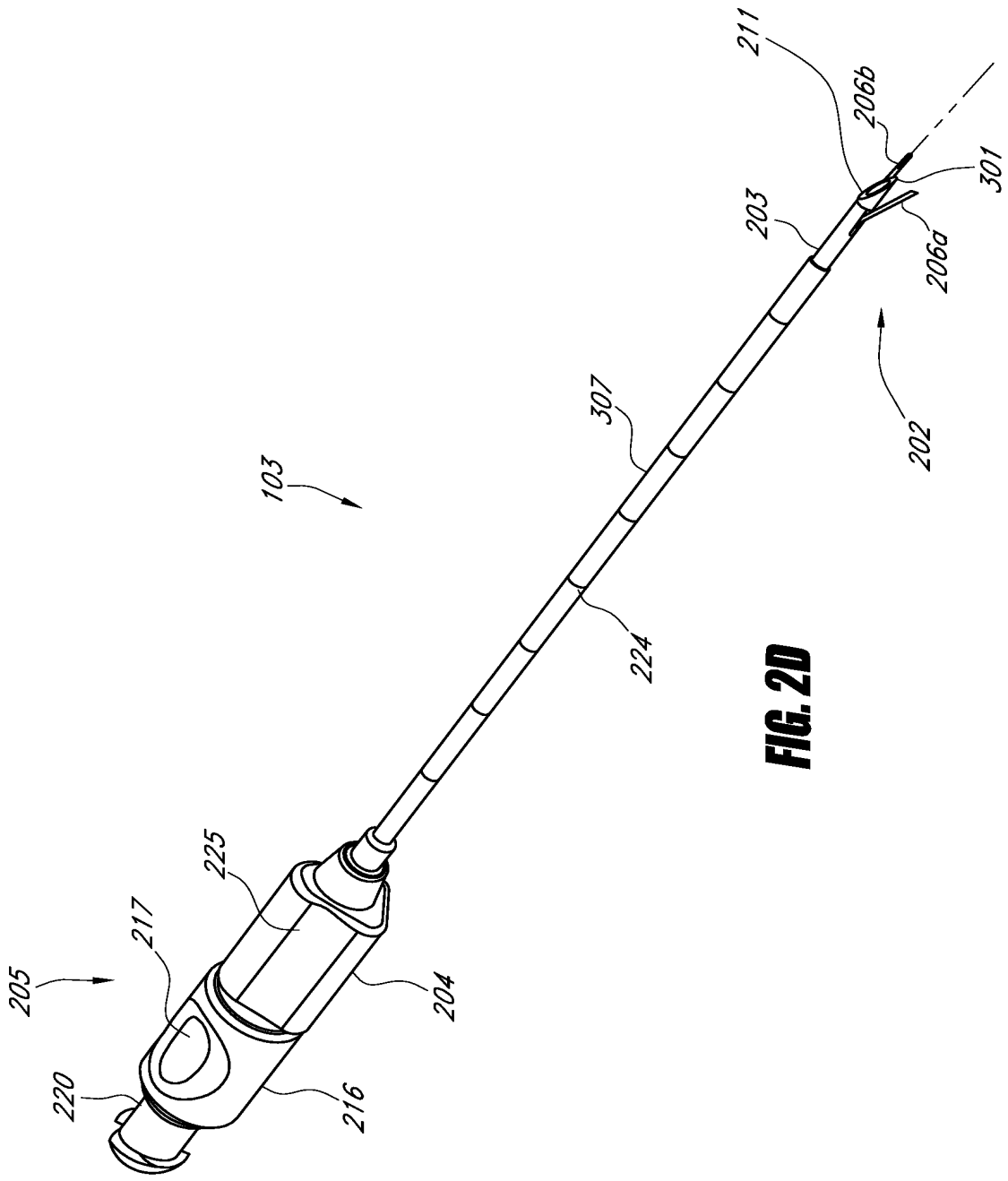


FIG. 2D

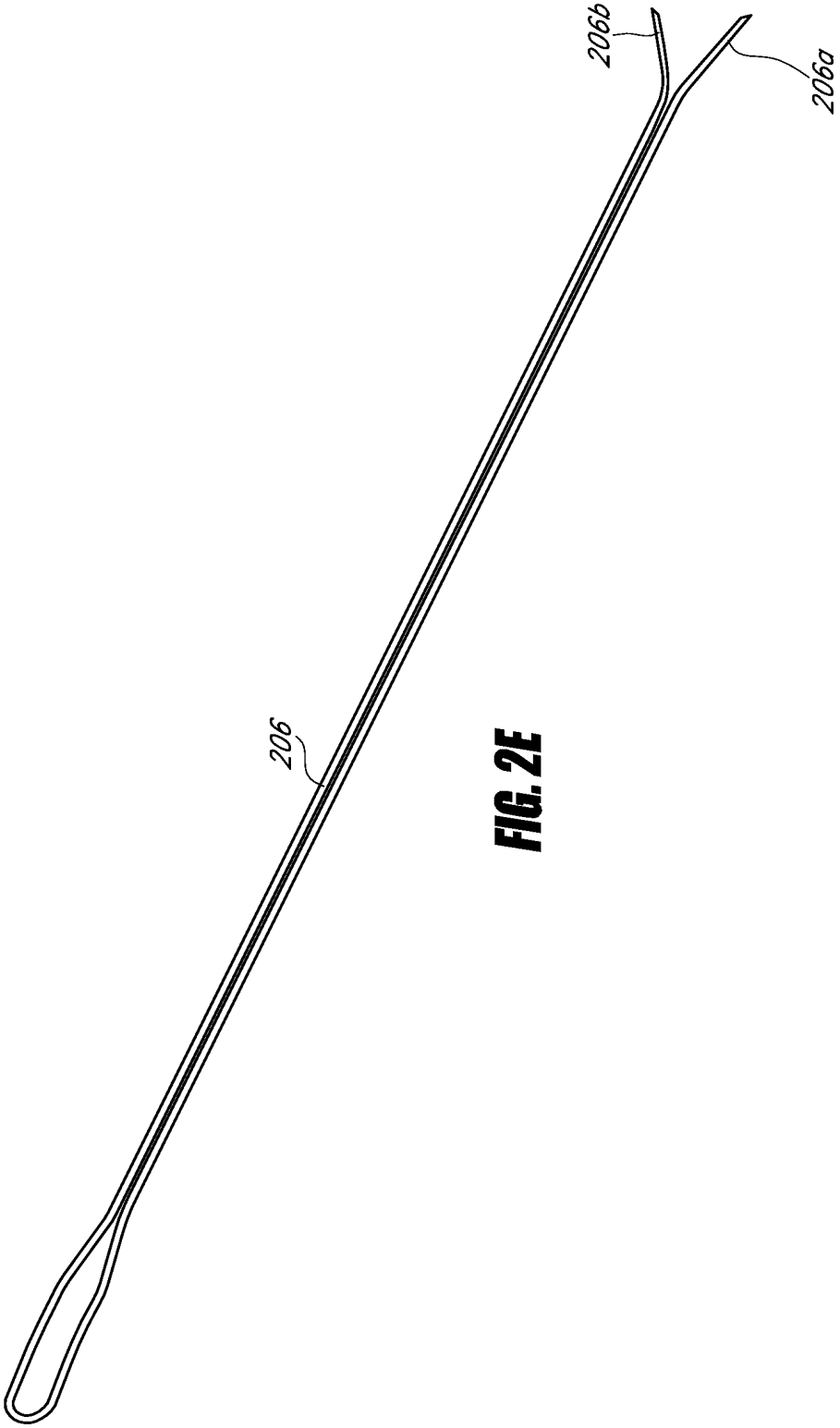


FIG. 2E

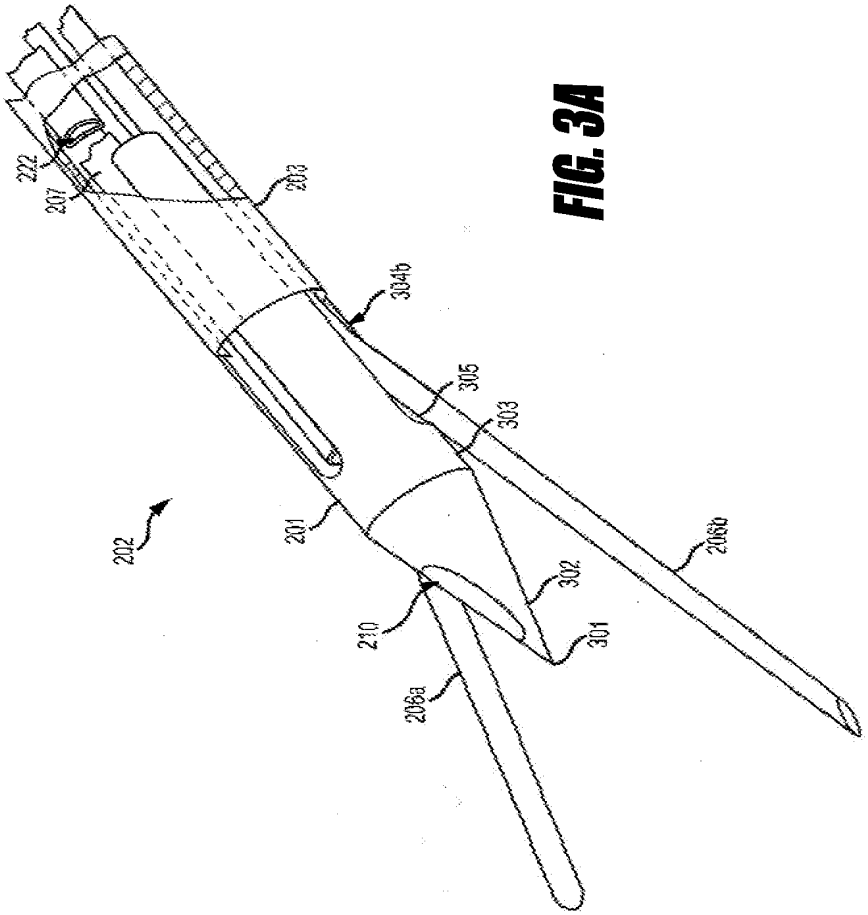


FIG. 3A

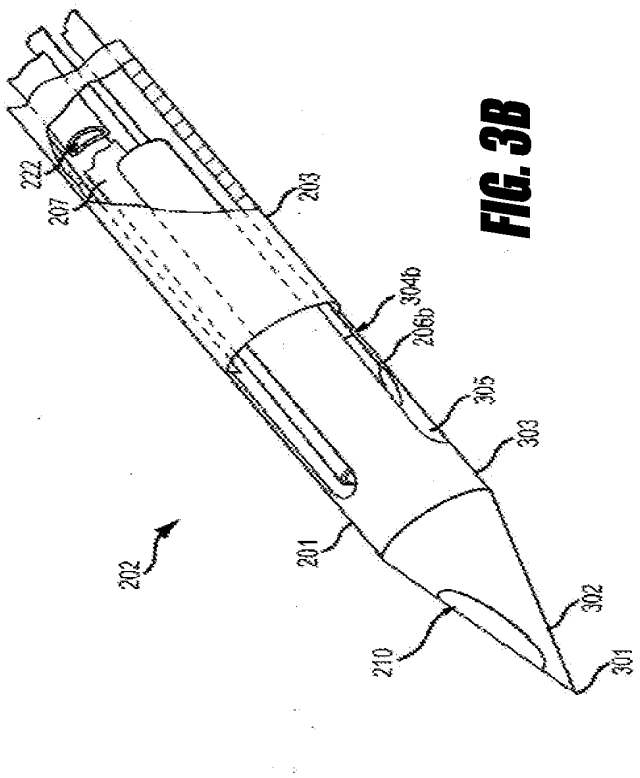


FIG. 3B

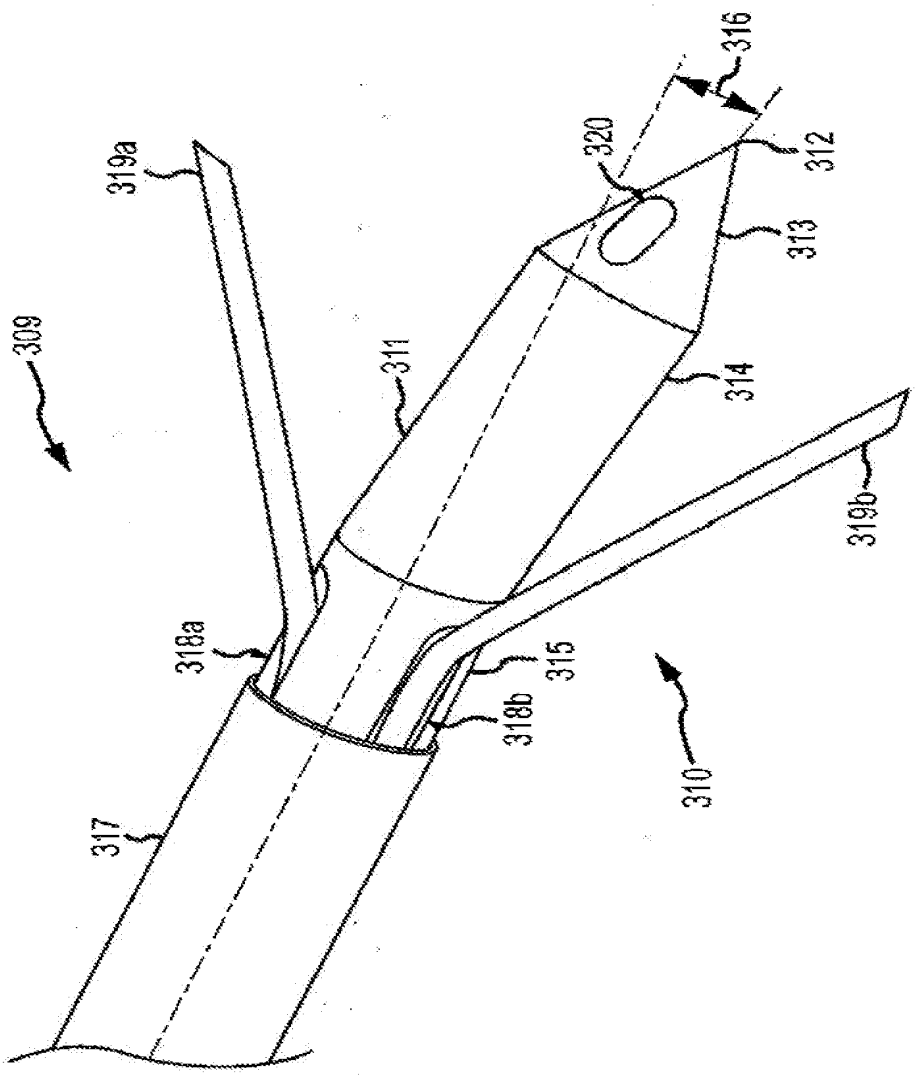


FIG. 3C

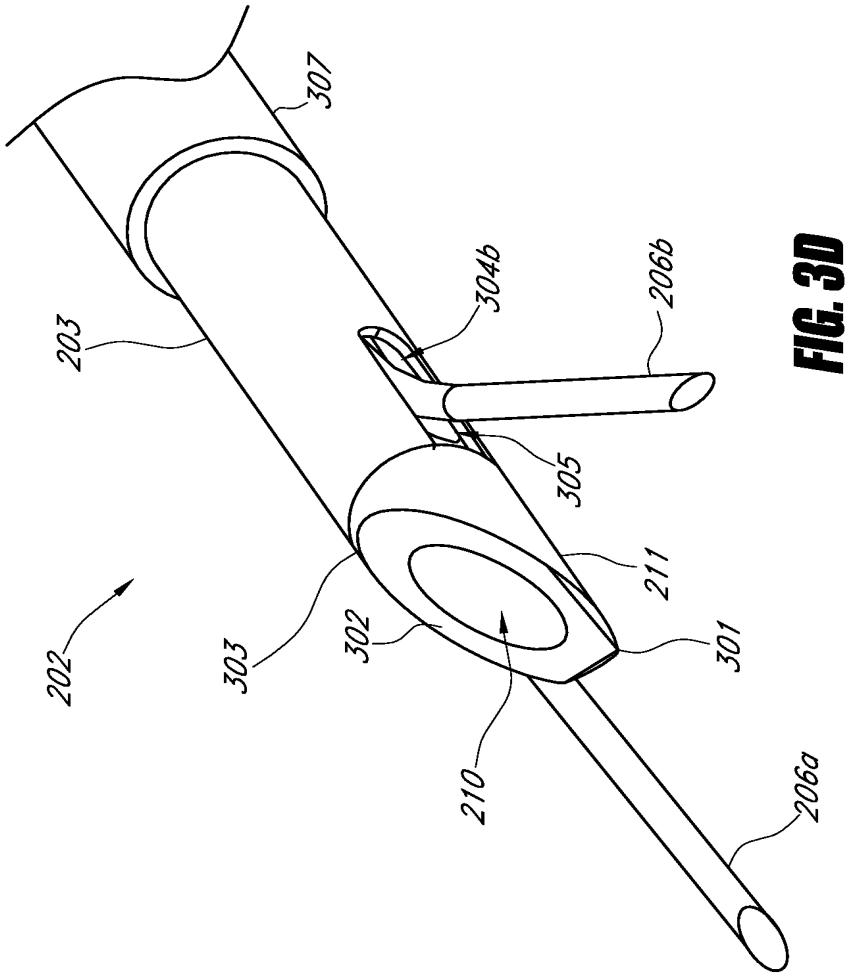


FIG. 3D

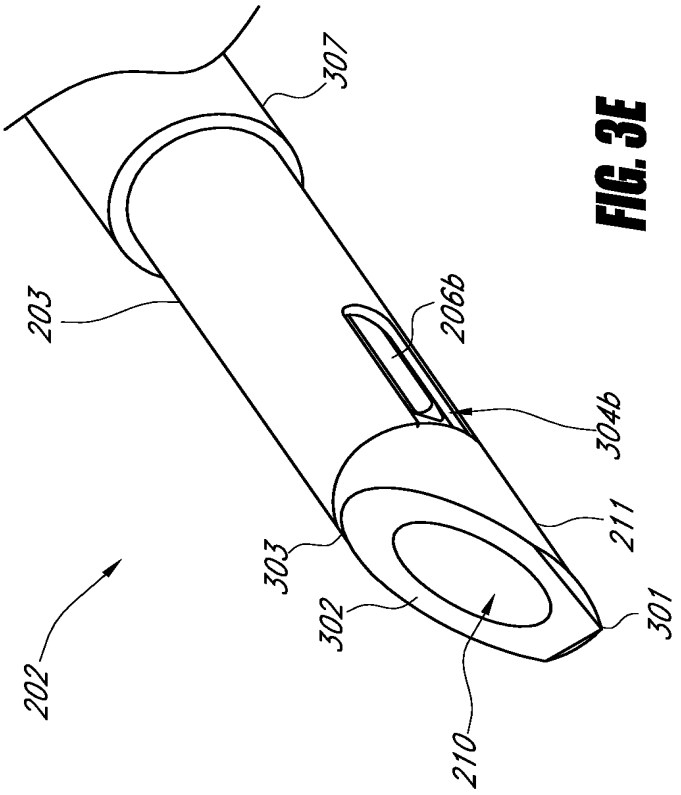


FIG. 3E

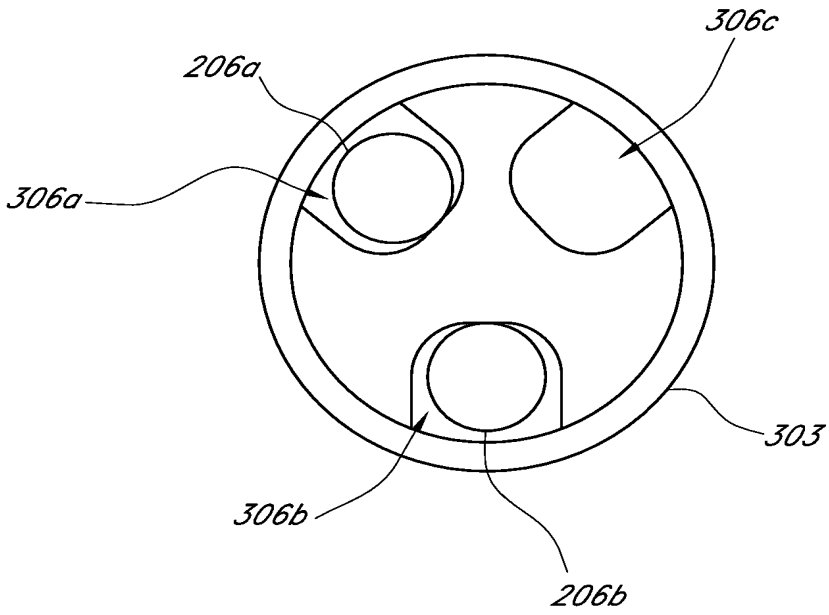


FIG. 3F

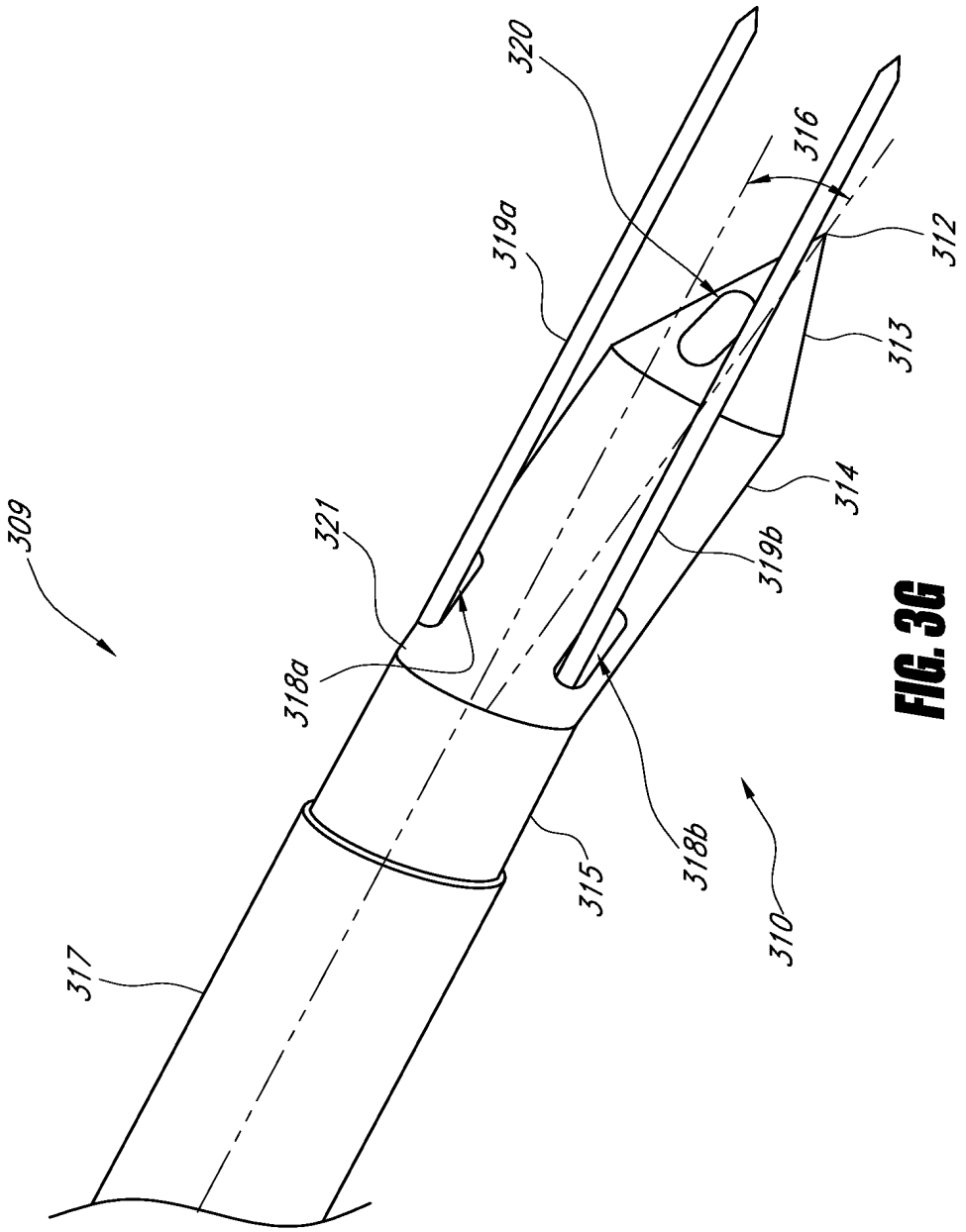


FIG. 3G

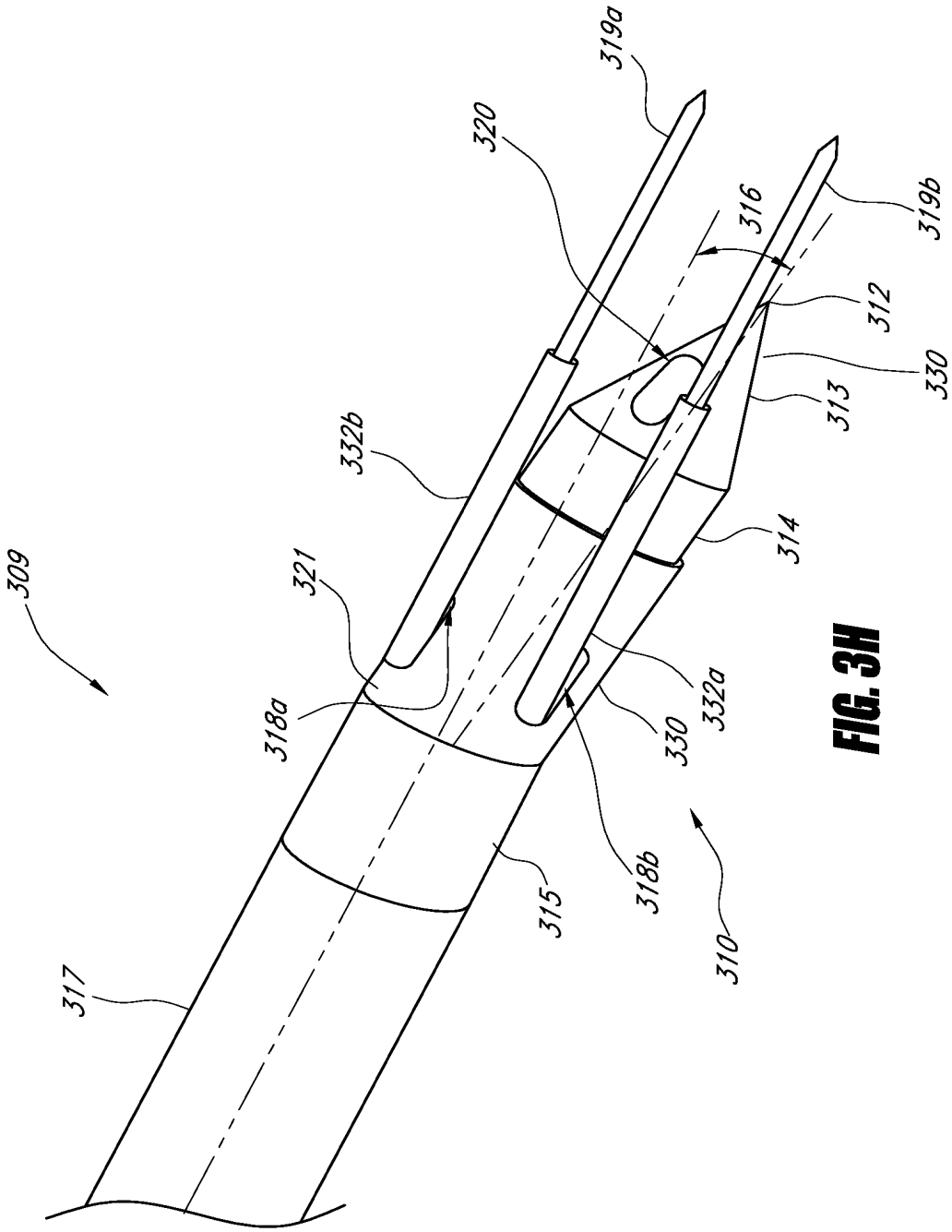

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FIG. 3H

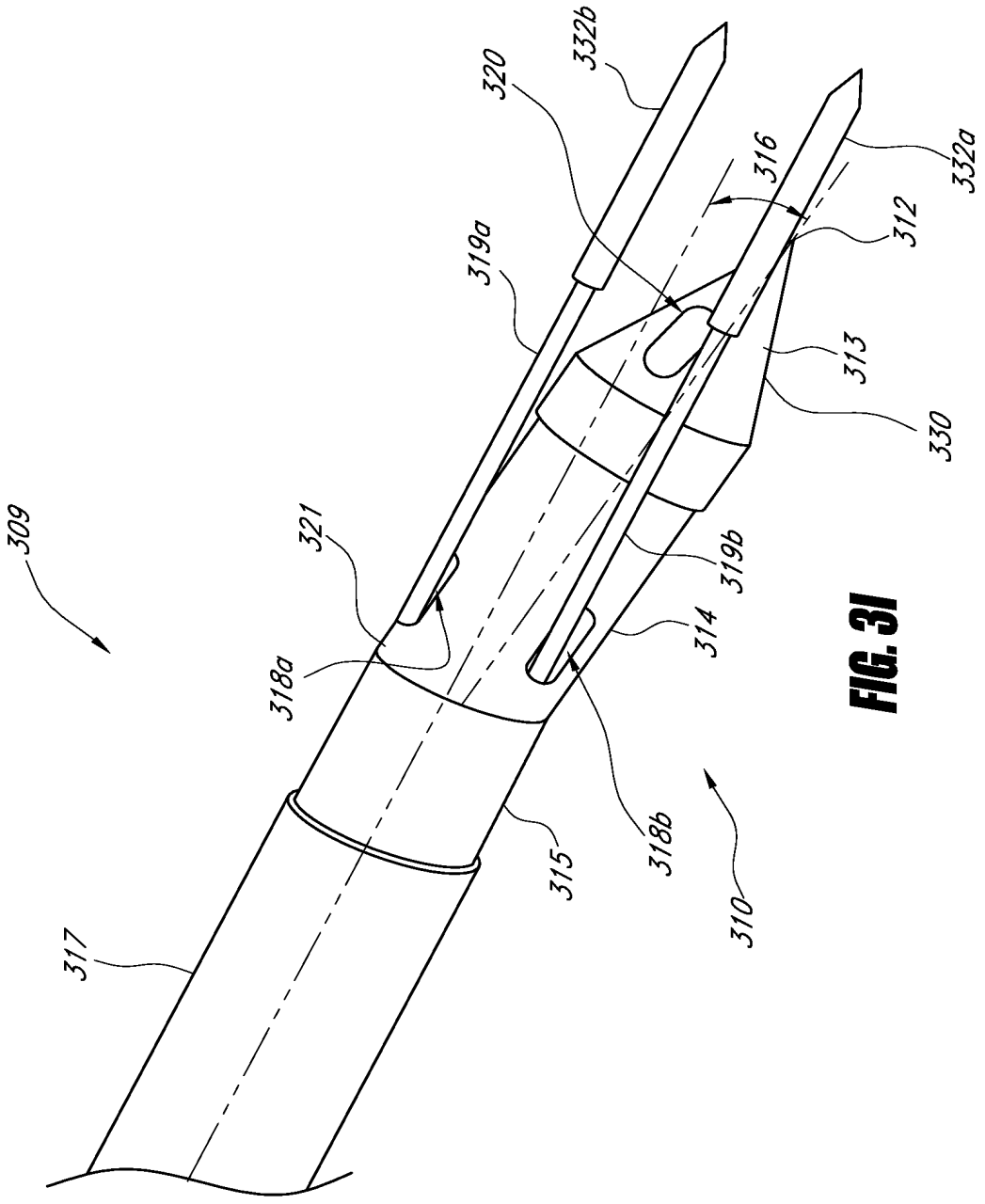

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FIG. 3I

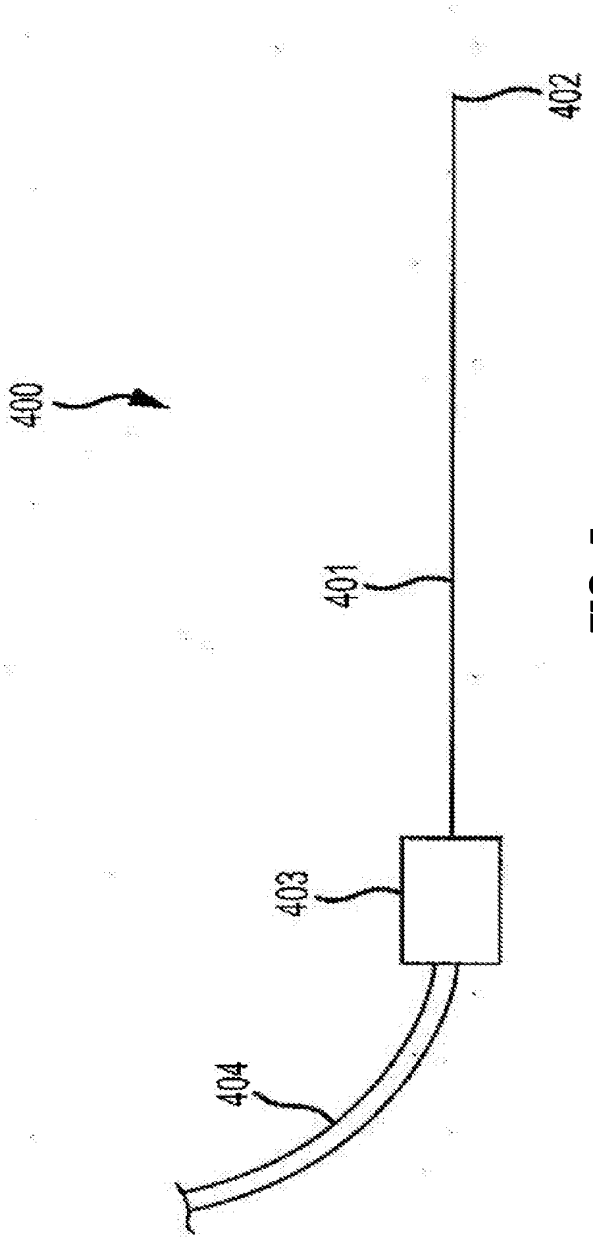


FIG. 4

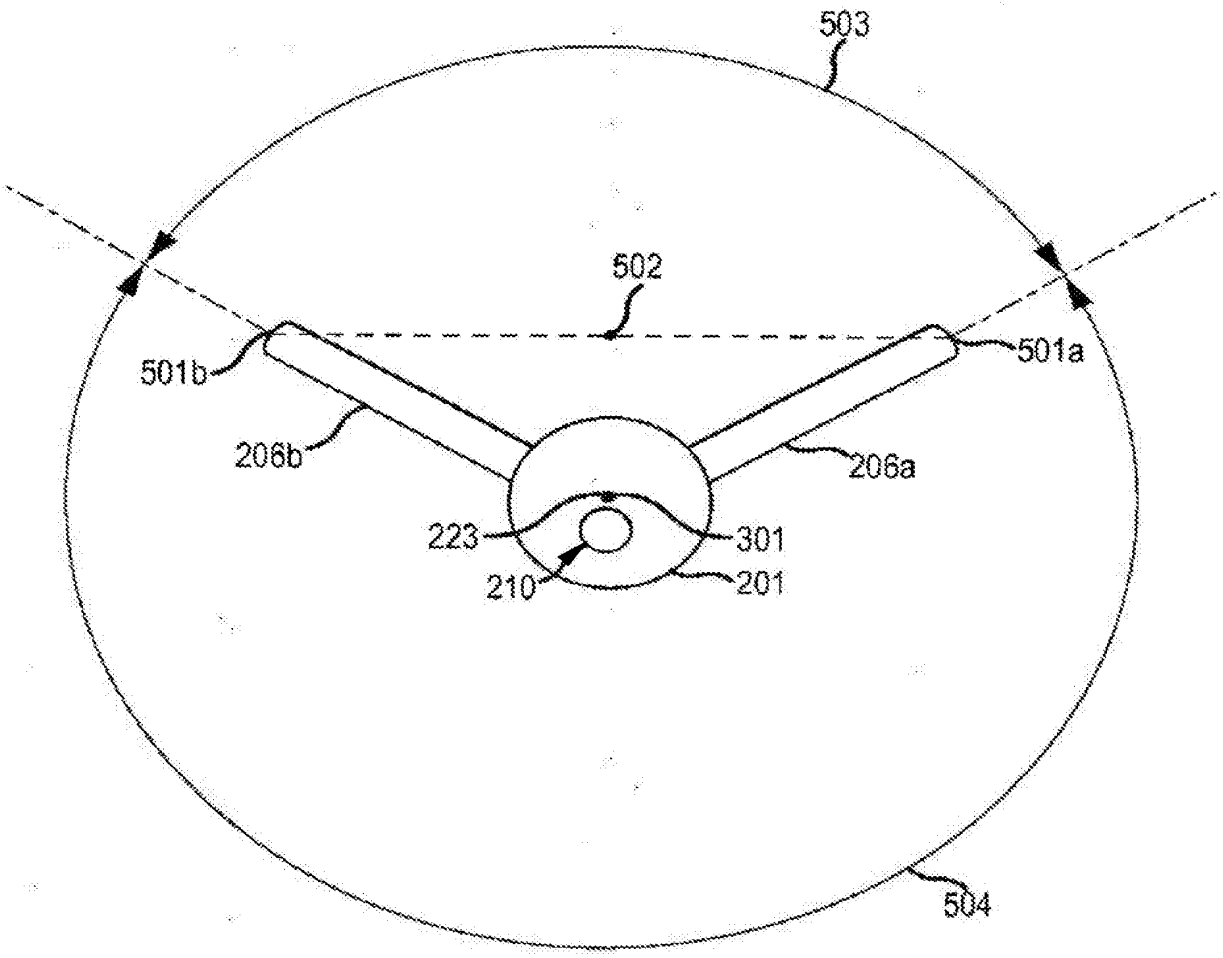


FIG. 5

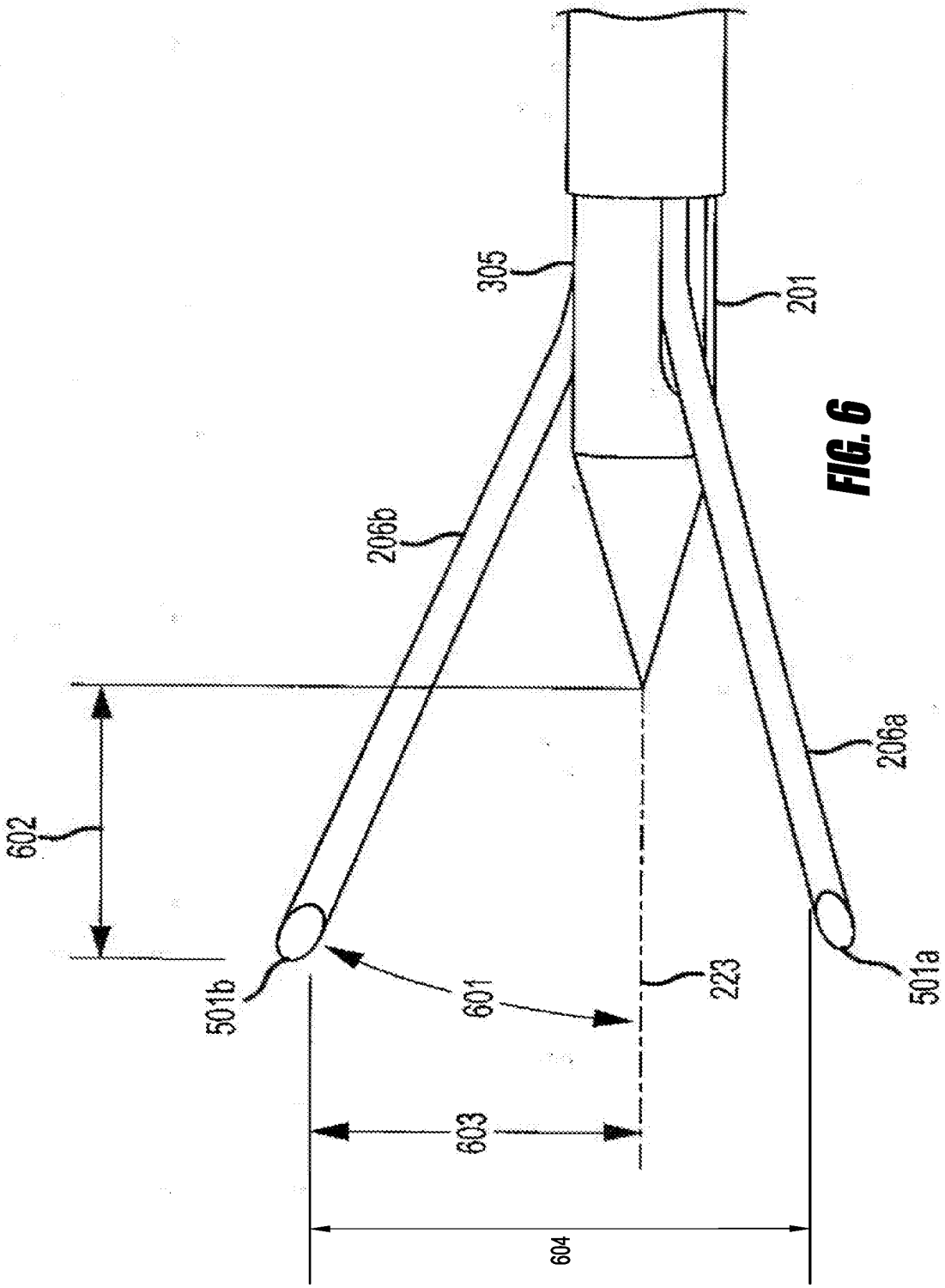


FIG. 6

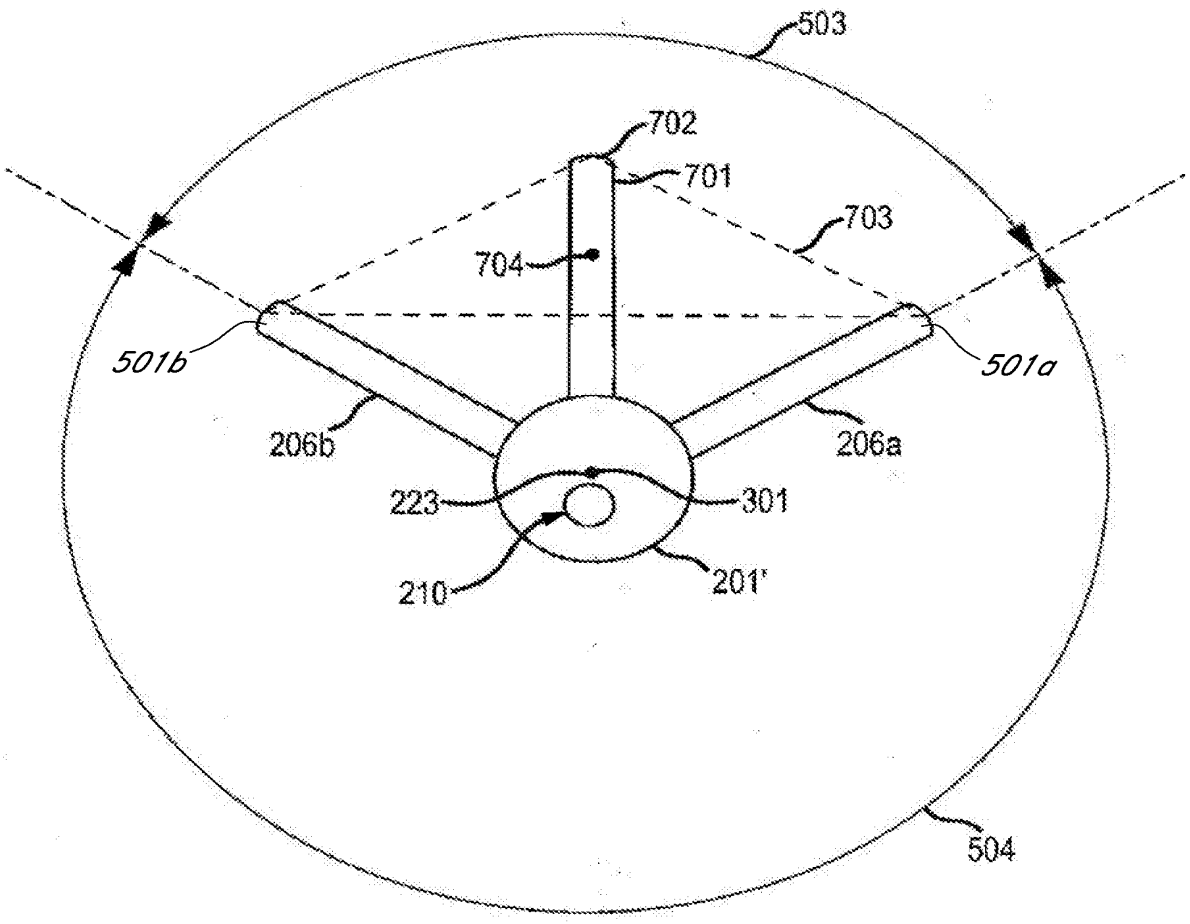


FIG. 7

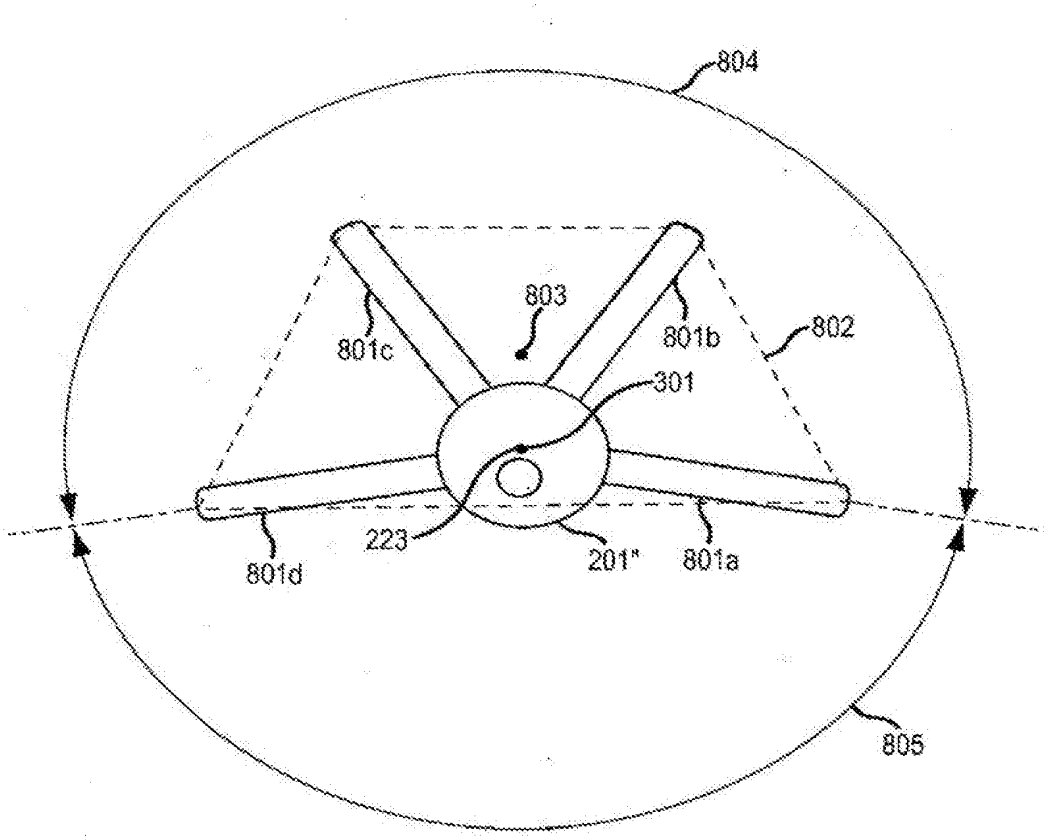


FIG. 8

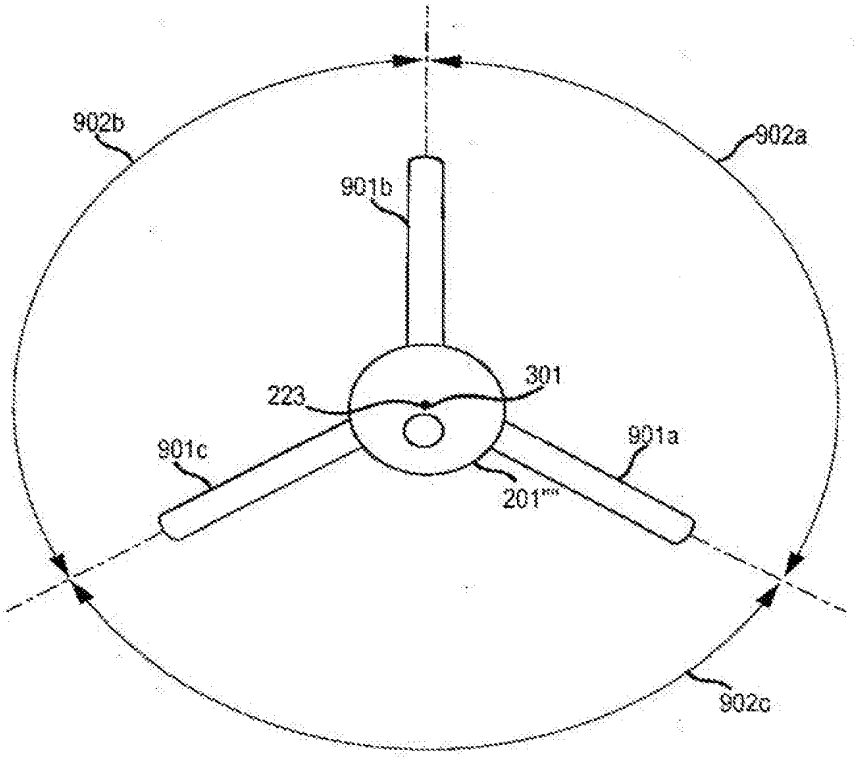


FIG. 9

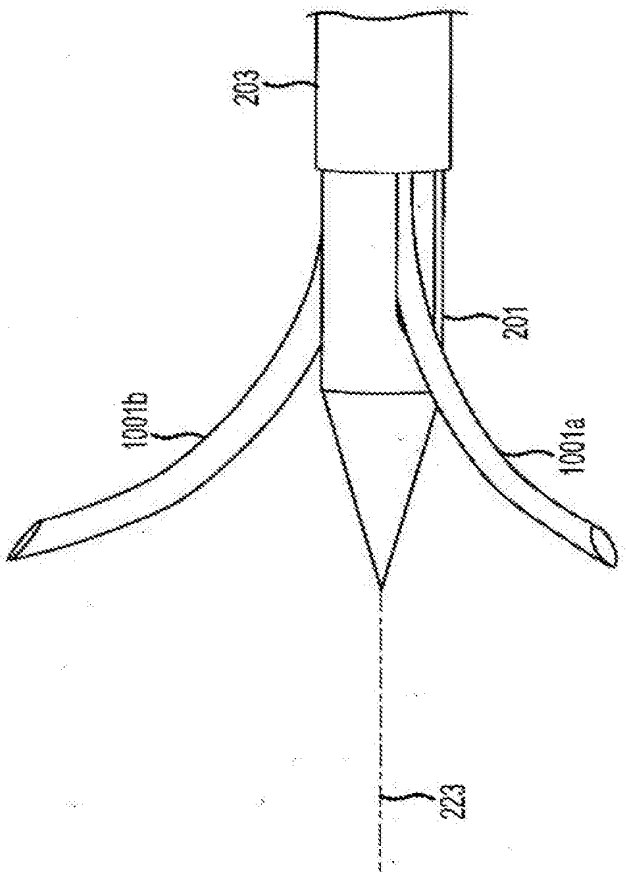


FIG. 10

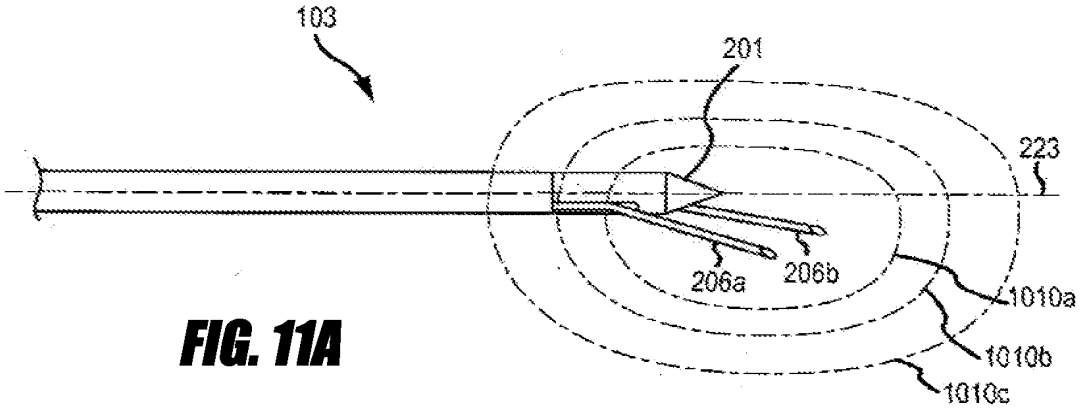


FIG. 11A

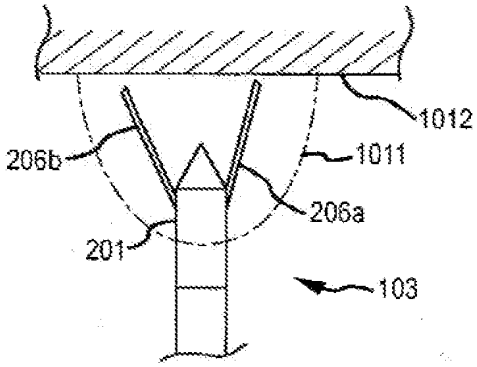


FIG. 11B

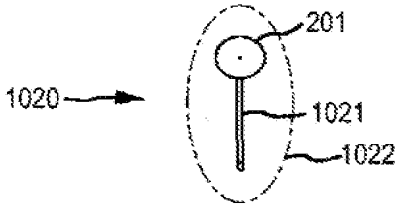


FIG. 11C

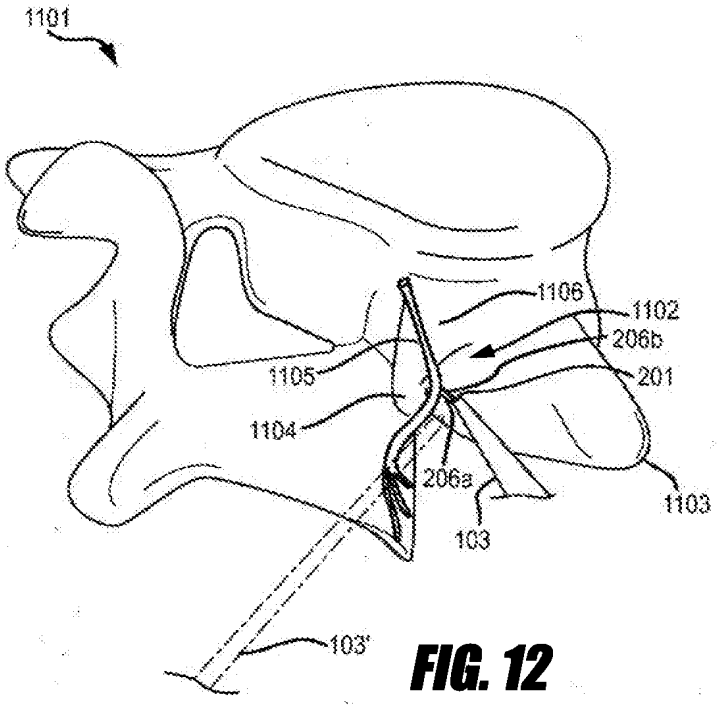


FIG. 12

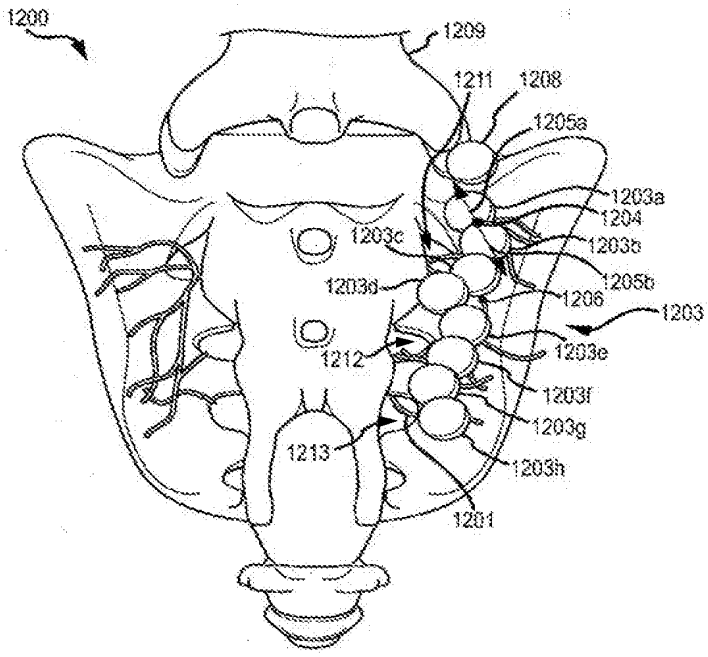

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FIG. 13

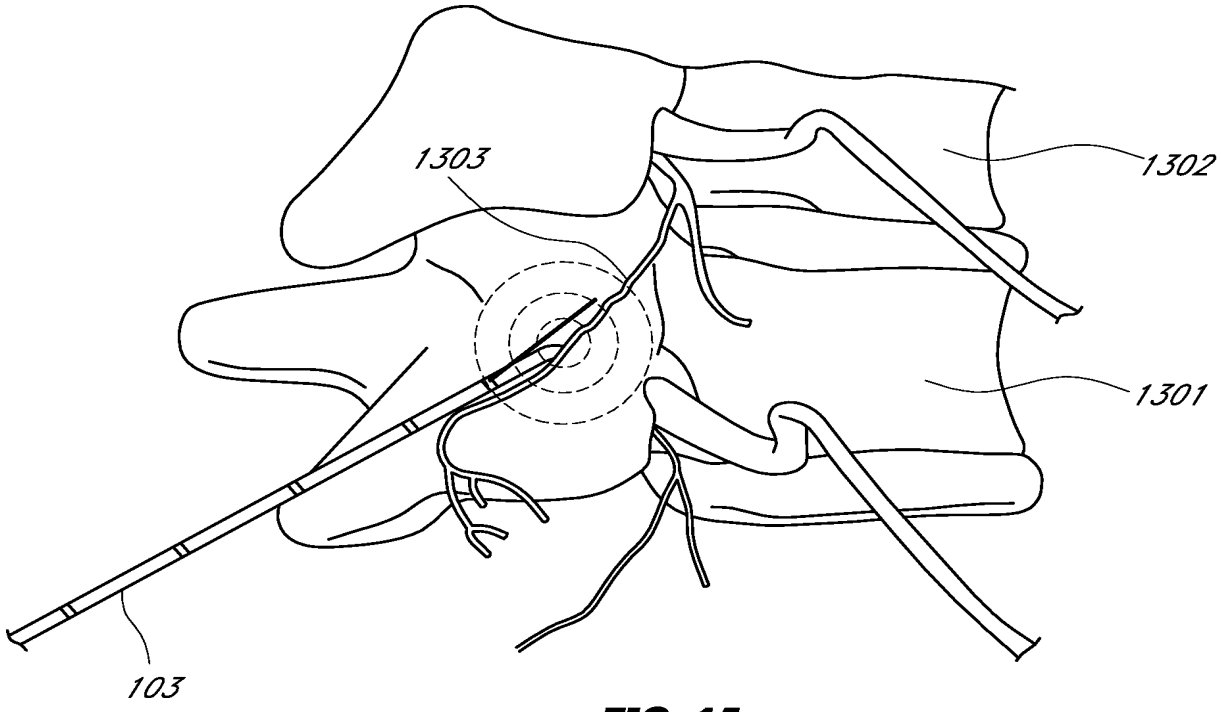


FIG. 14

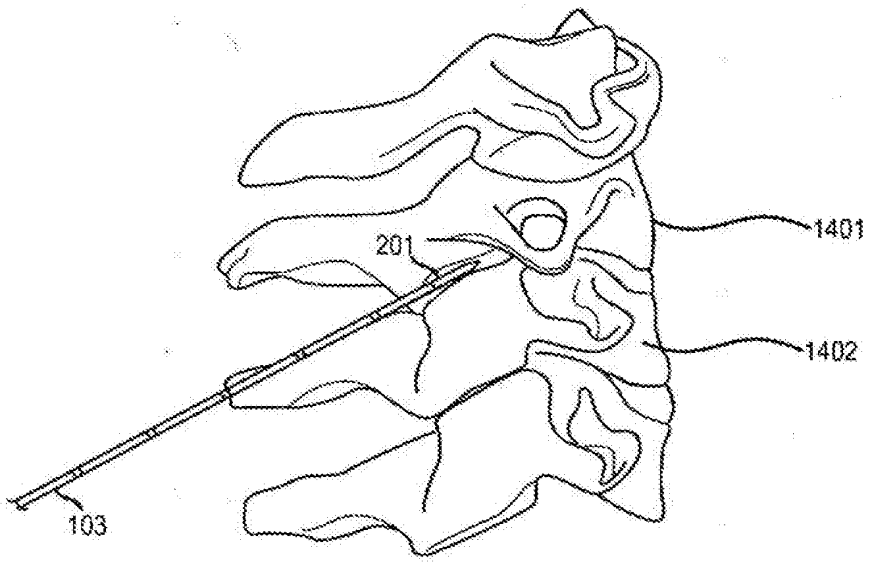


FIG. 15

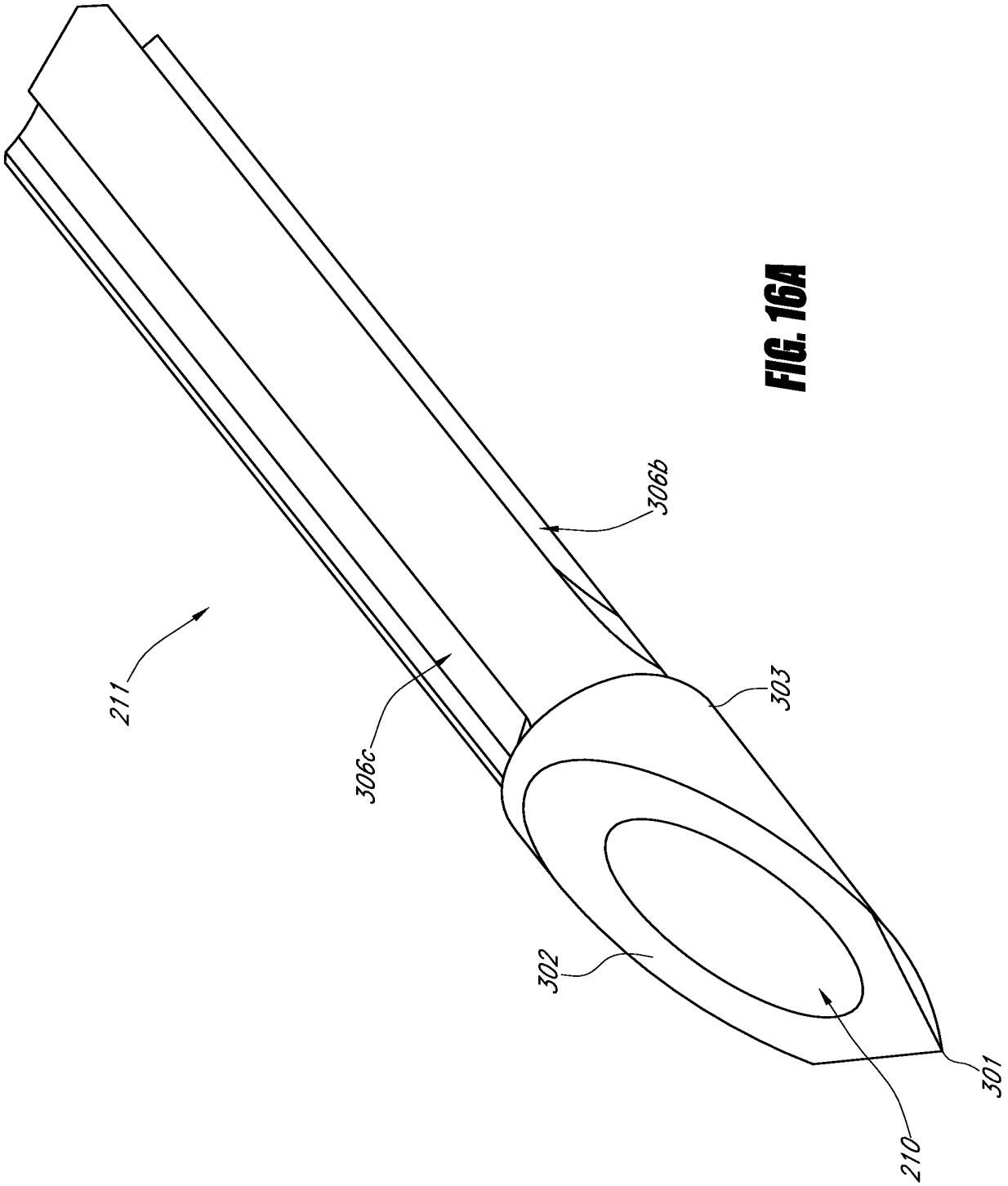


FIG. 16A

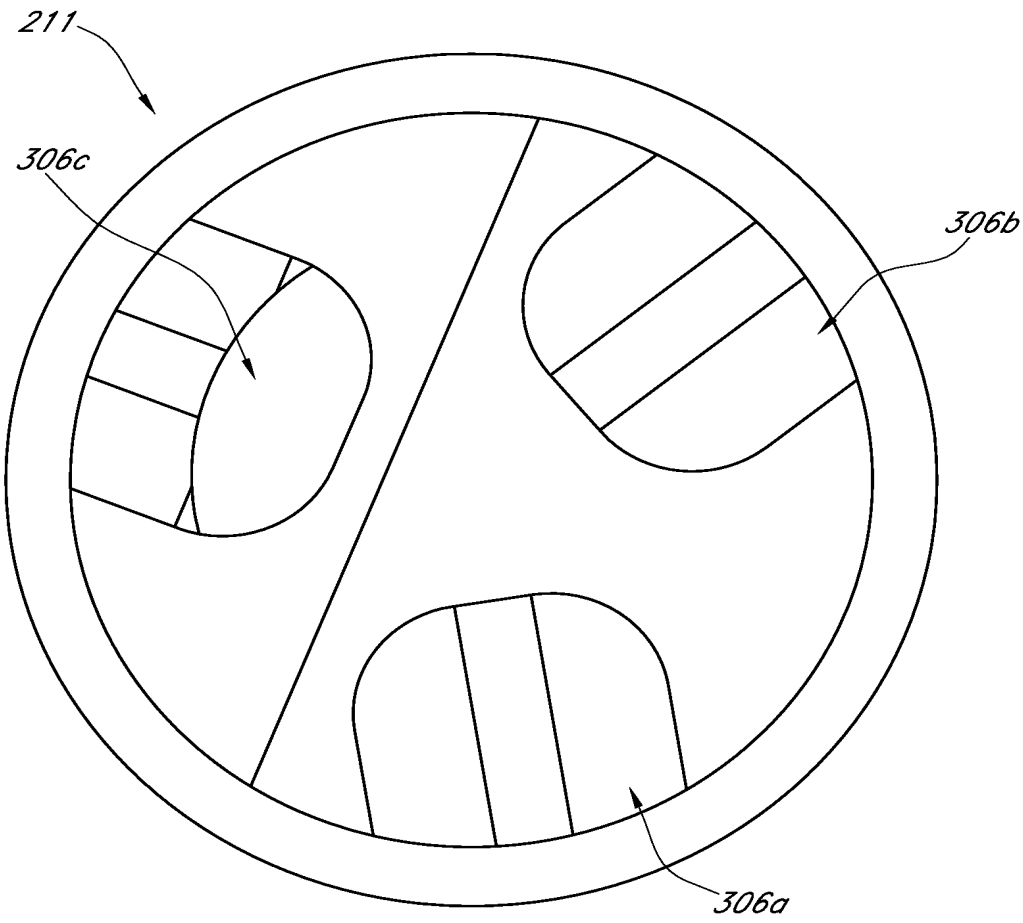


FIG. 16B

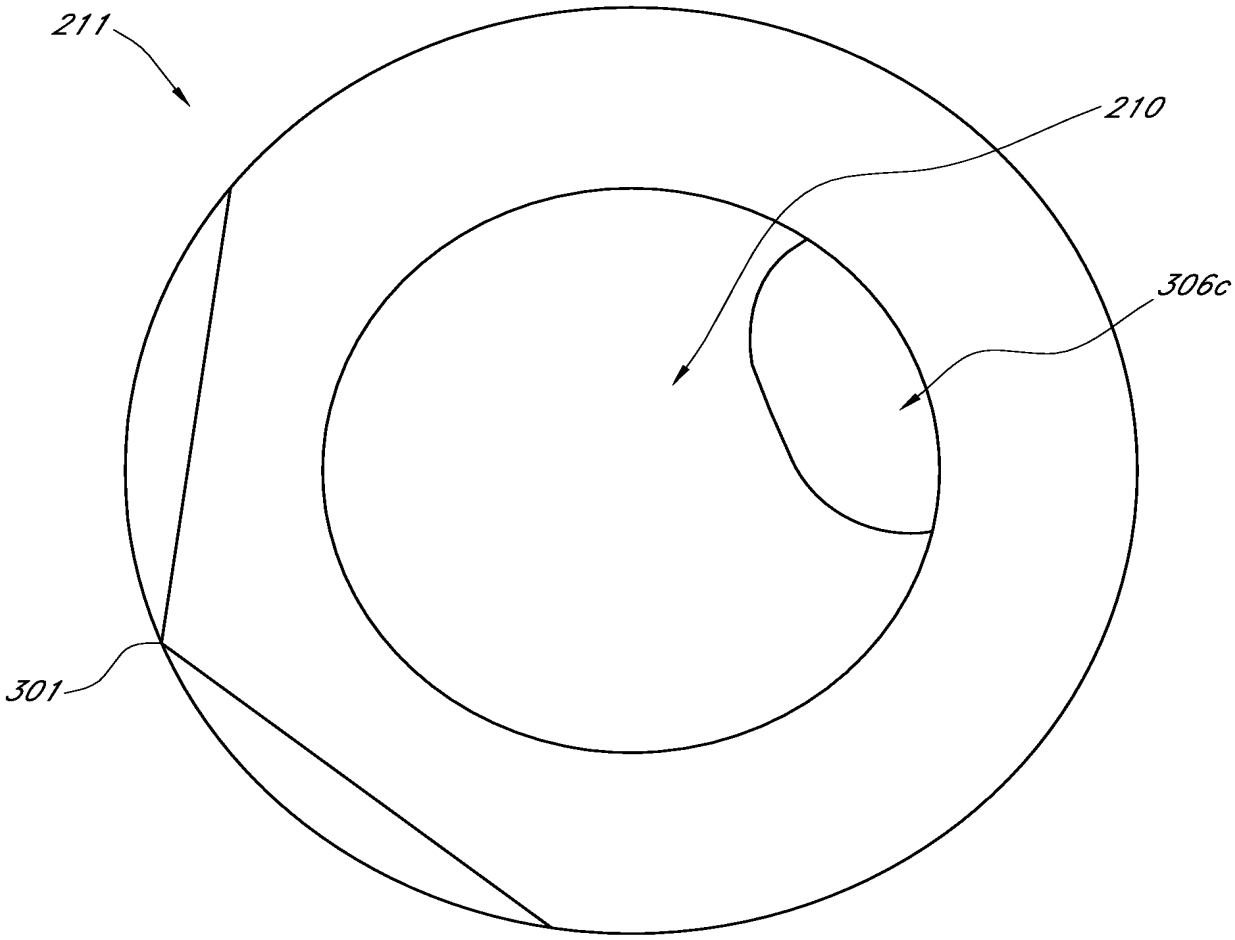


FIG. 16C

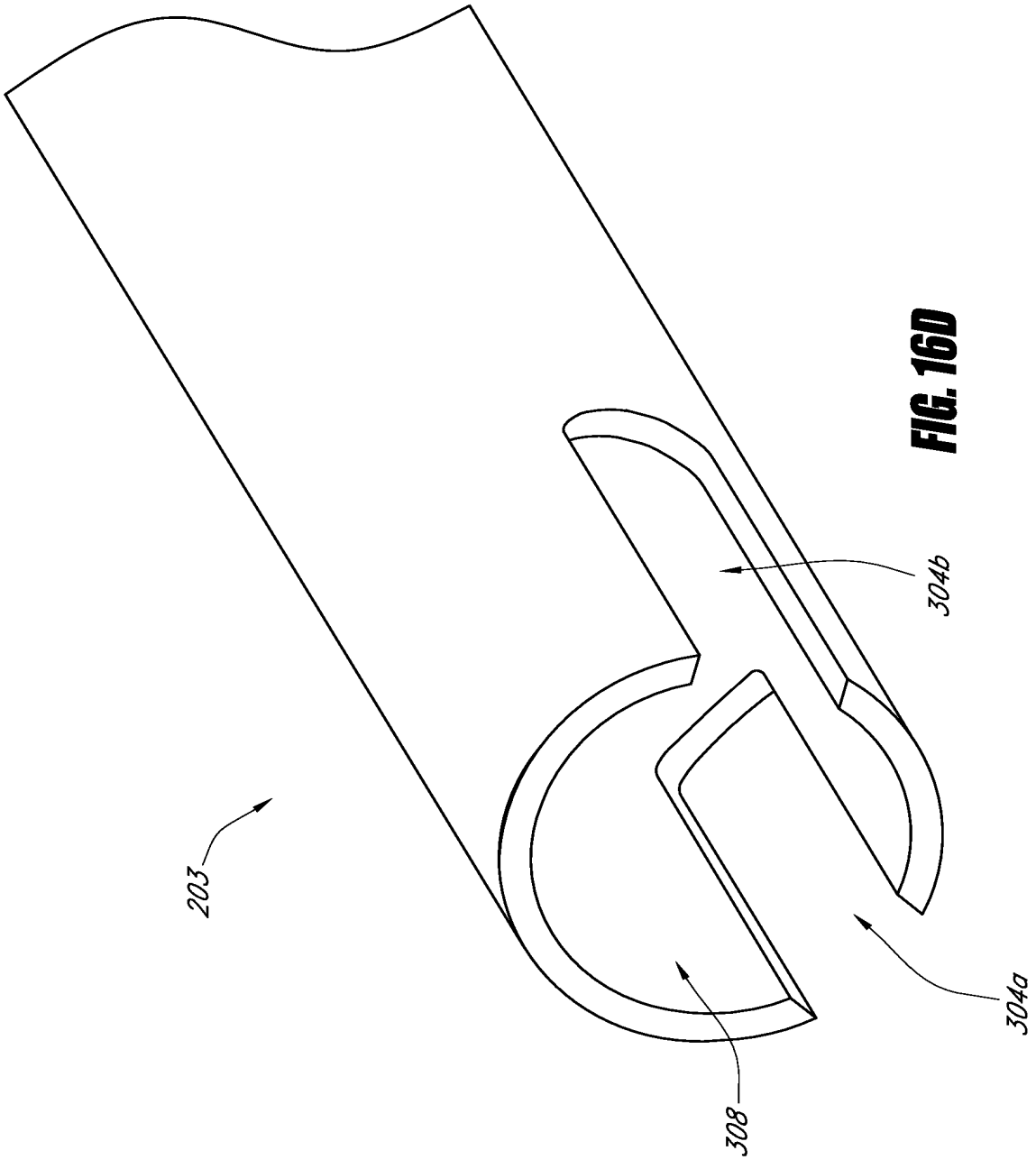


FIG. 16D

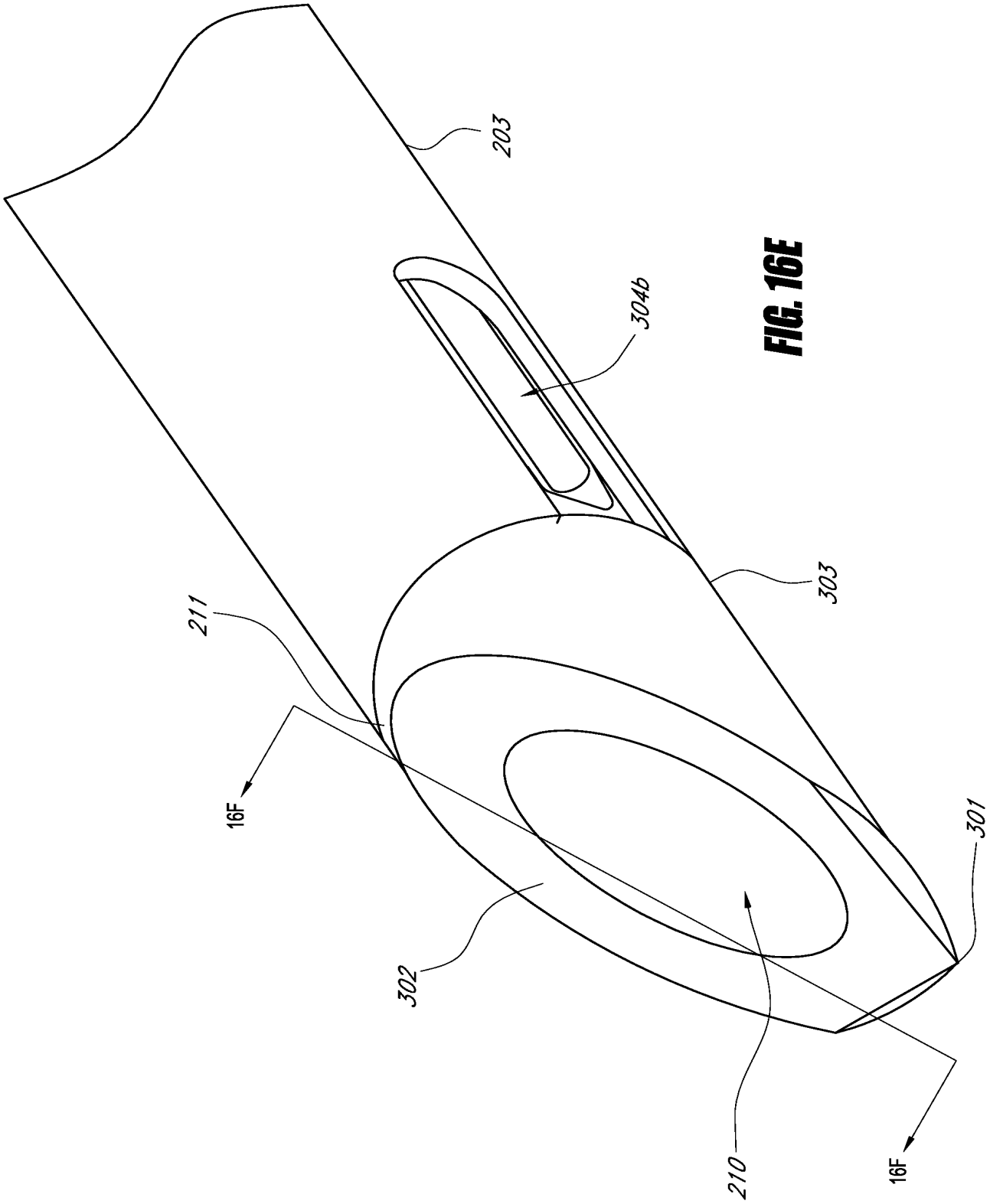


FIG. 16E

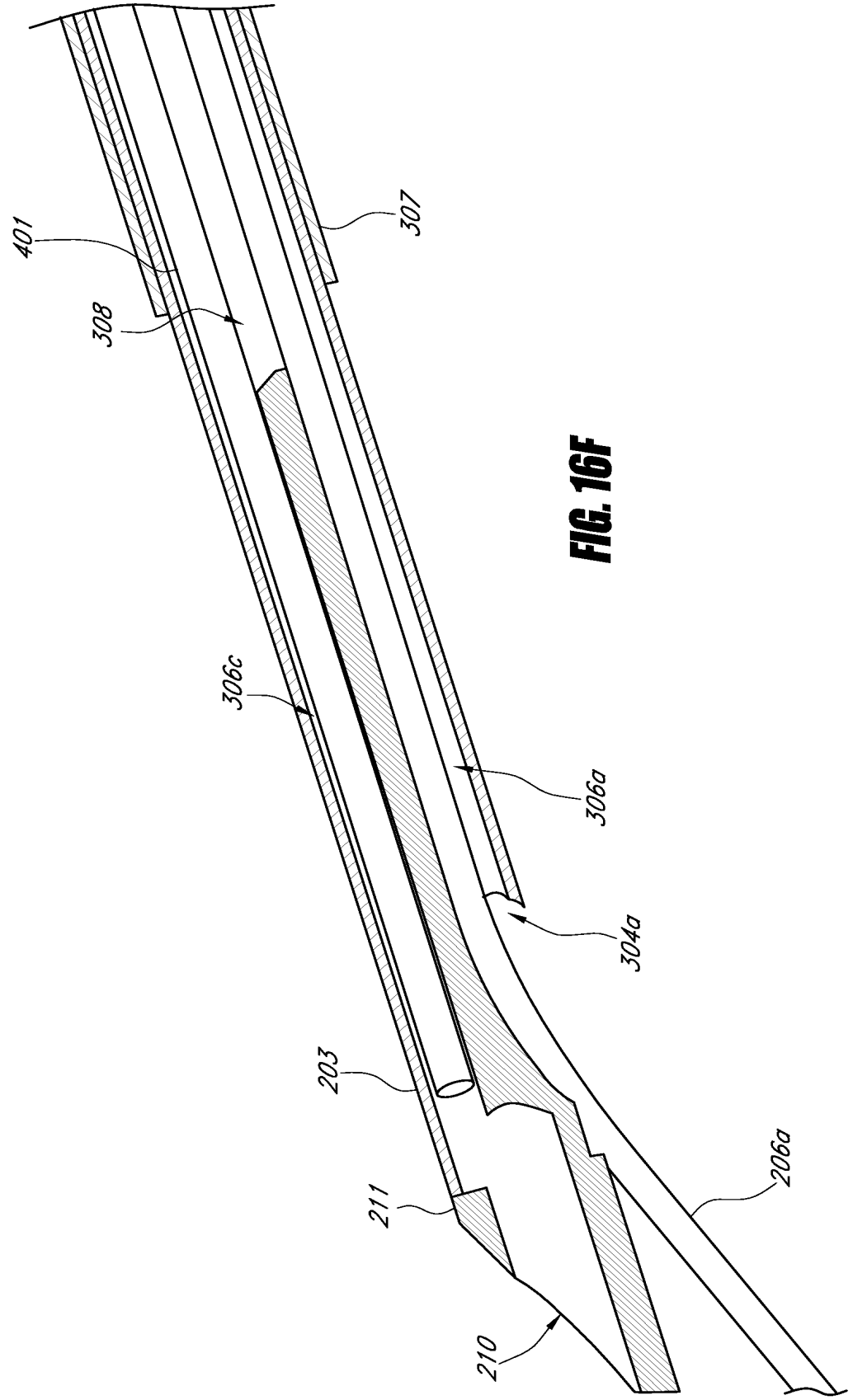


FIG. 16F

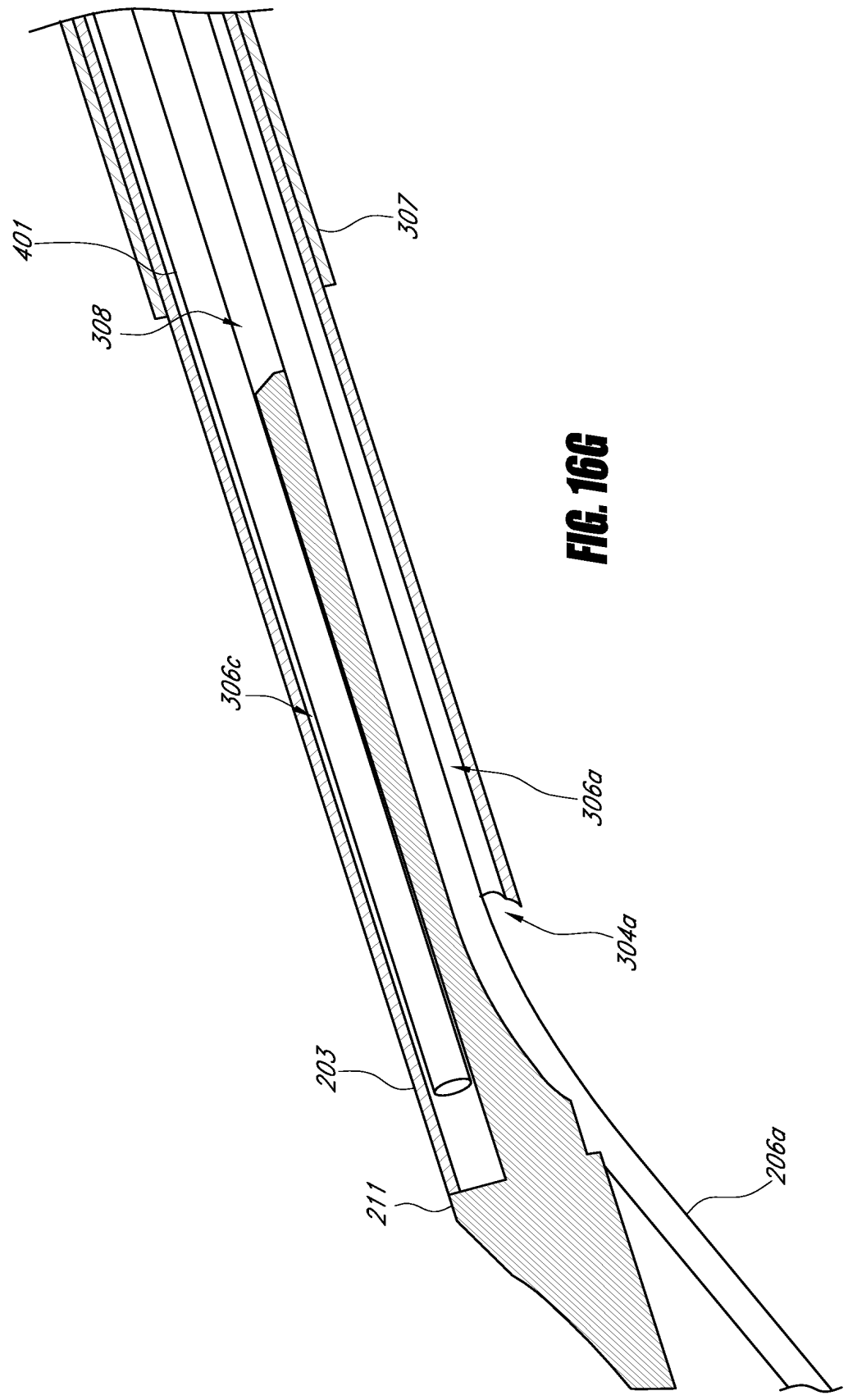


FIG. 16G

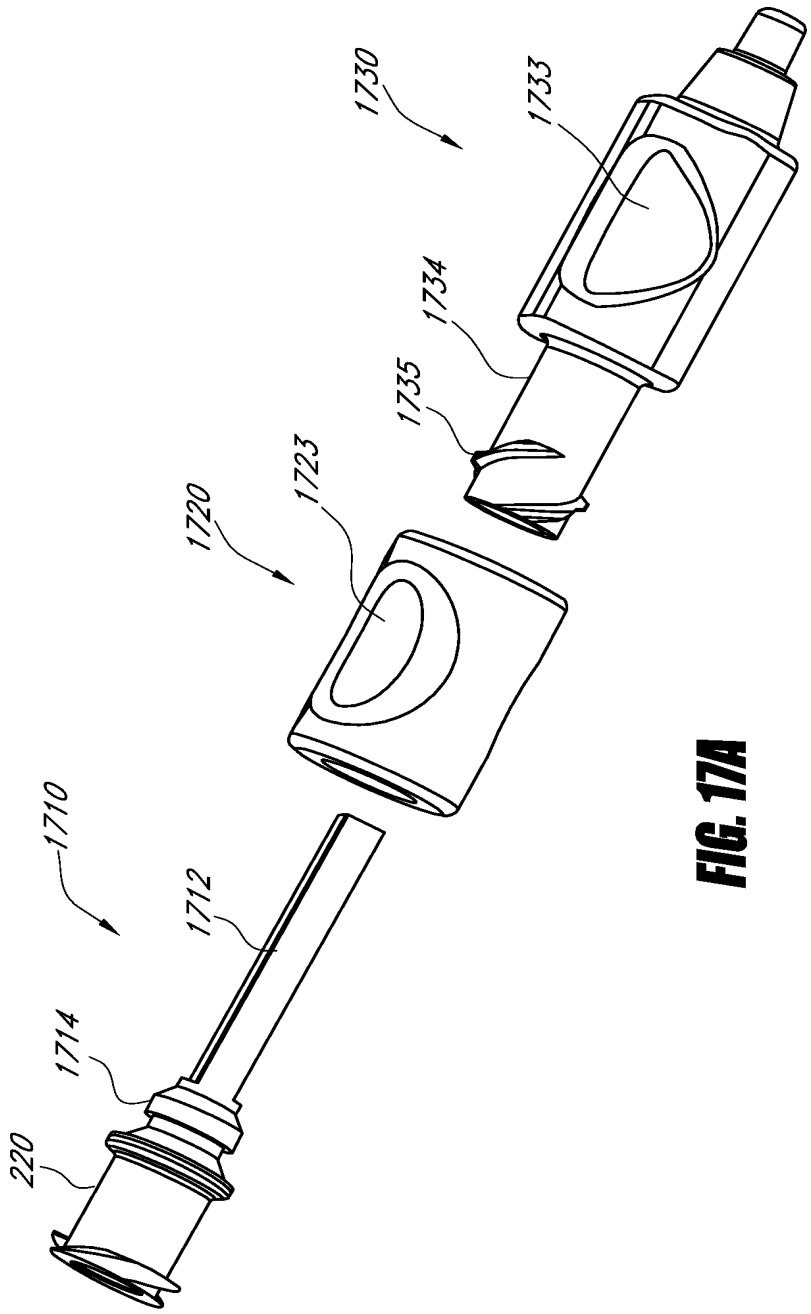


FIG. 17A

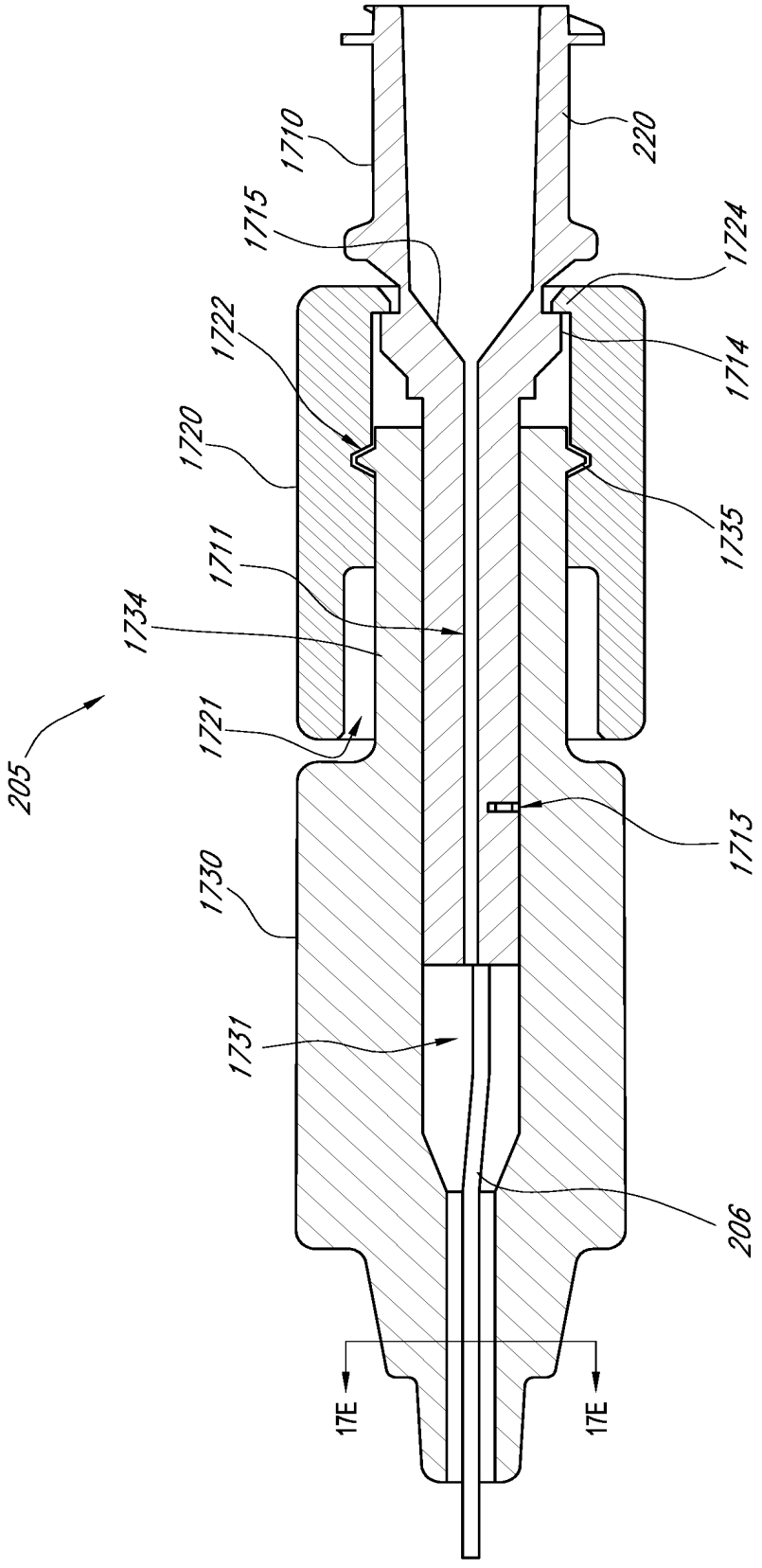

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FIG. 17B

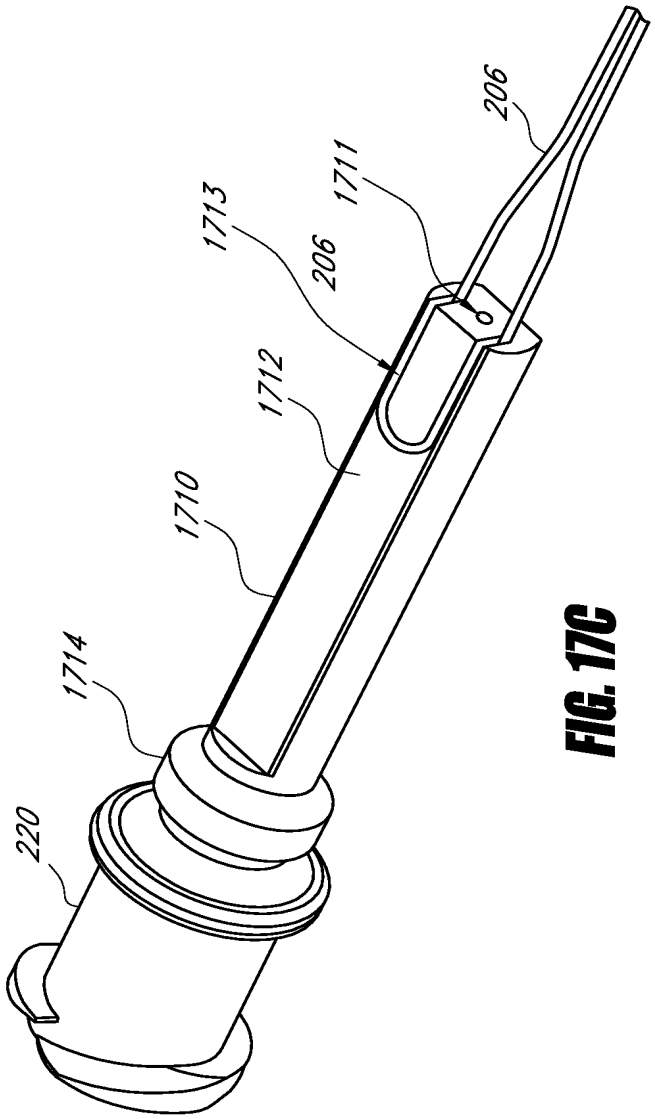


FIG. 17C

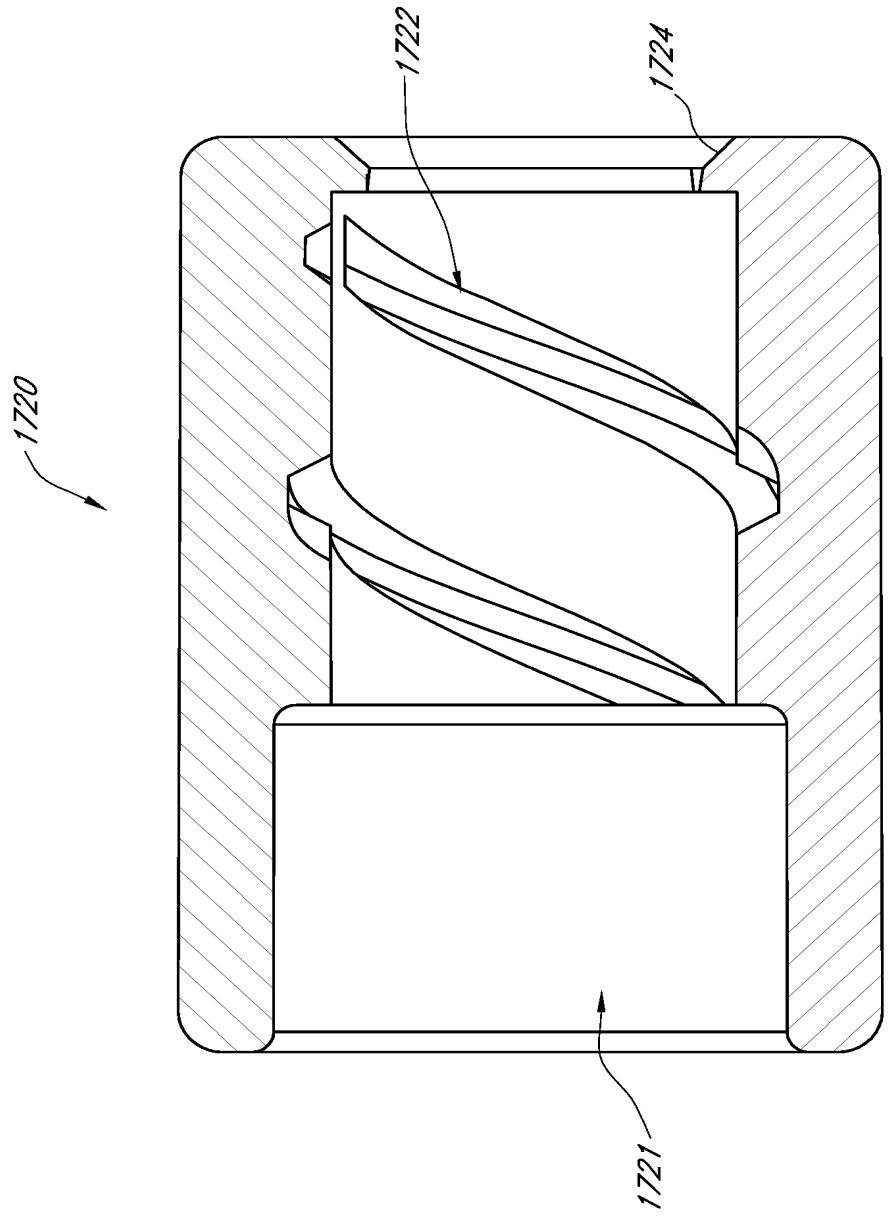


FIG. 17D

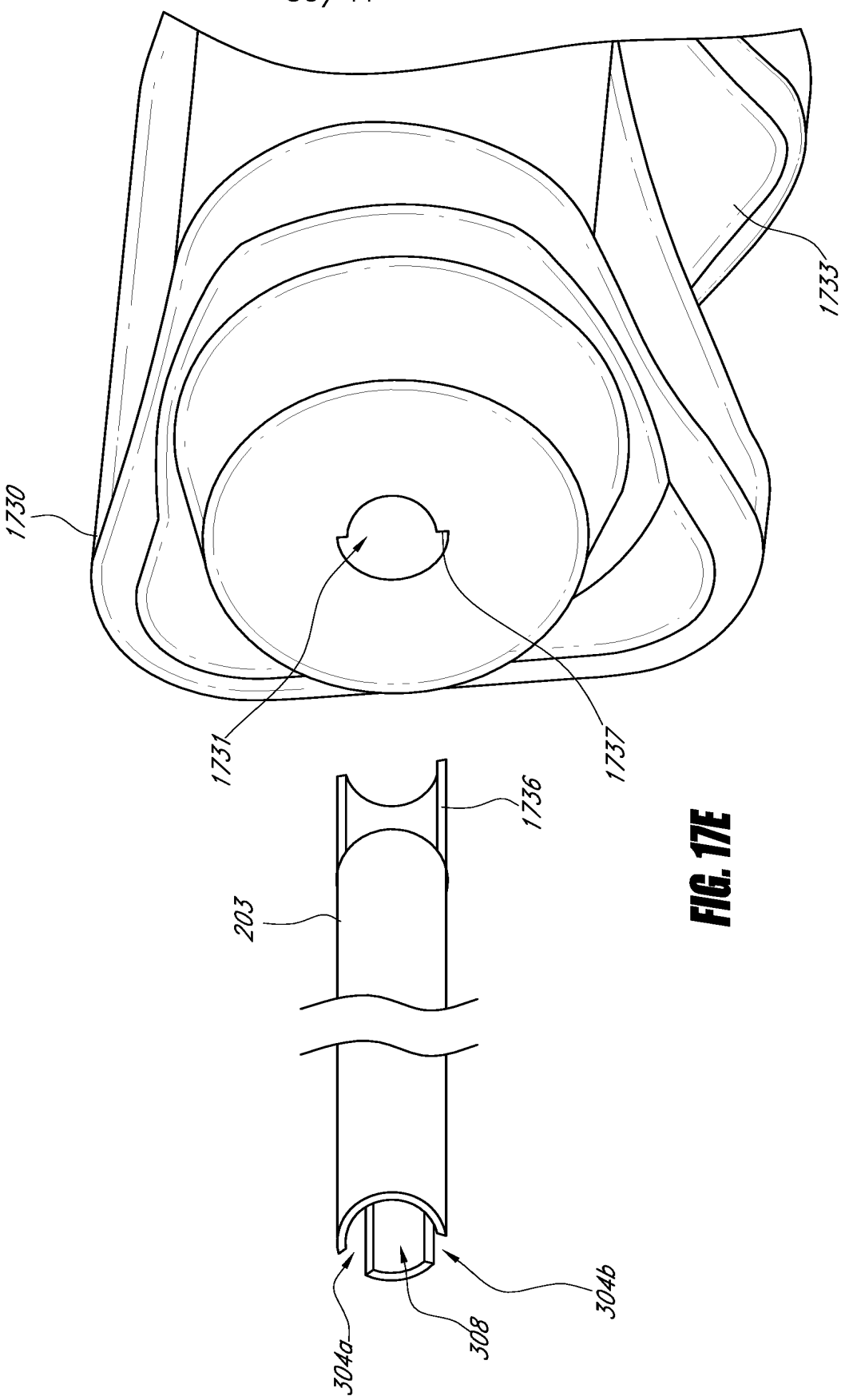


FIG. 17E

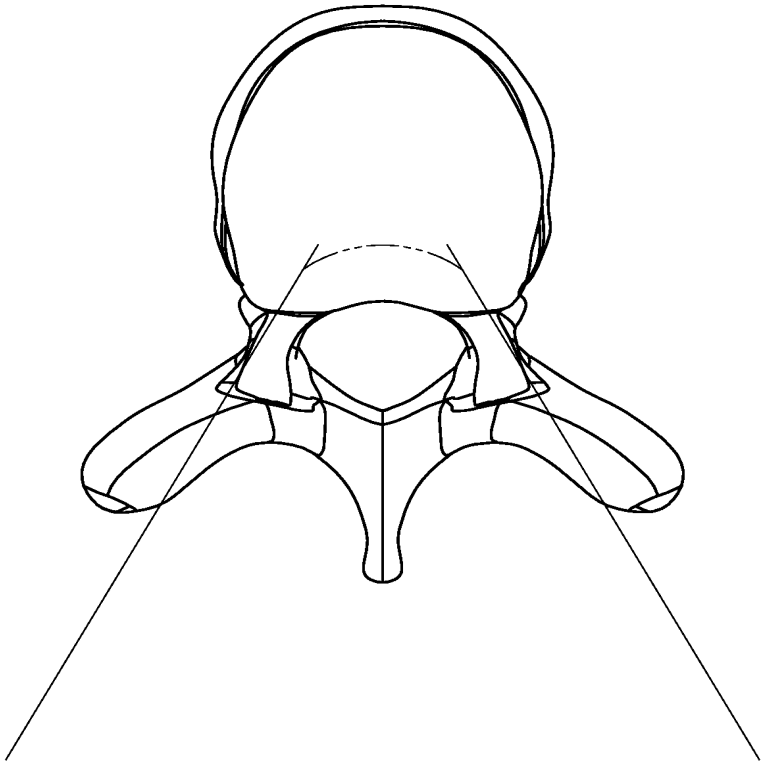


FIG. 18A

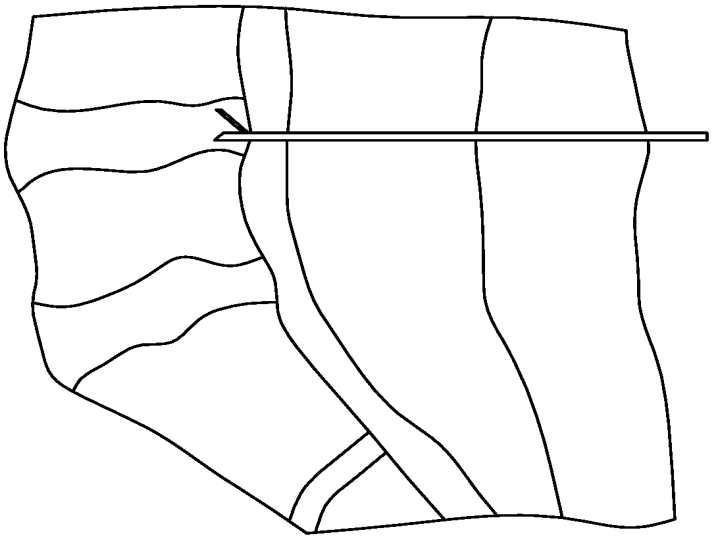


FIG. 18B

PTO/AIA/01 (06-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	SYSTEMS AND METHODS FOR TISSUE ABLATION

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 15/092,945

filed on April 7, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Robert E. Wright Date (Optional): _____

Signature: _____

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

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

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

Privacy Act Statement

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

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

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

PTO/AIA/01 (08-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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filed on April 7, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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LEGAL NAME OF INVENTOR

Inventor: Scott A. Brandt Date (Optional): 2/18/20

Signature: [signature]

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

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

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Filer:	Daniel Christopher Higgs
Attorney Docket Number:	NBUS.004C1C1

Filed as Small Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	75	75
UTILITY SEARCH FEE	2111	1	330	330
UTILITY EXAMINATION FEE	2311	1	380	380
REQUEST FOR PRIORITIZED EXAMINATION	2817	1	2000	2000
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	2202	9	50	450
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70

Petition:		
Patent-Appeals-and-Interference:		
Post-Allowance-and-Post-Issuance:		
Extension-of-Time:		
Miscellaneous:		
	Total in USD ($)	**3305**

Electronic Acknowledgement Receipt

EFS ID:	40053968
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	20-JUL-2020
Filing Date:	
Time Stamp:	19:30:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$3305
RAM confirmation Number	E20207JJ33496879
Deposit Account	602176
Authorized User	Daniel Higgs

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

37 CFR 1.21 (Miscellaneous fees and charges)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.16 (National application filing, search, and examination fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	TrackOne Request	NBUS004C1C1_Track1Req.pdf	128923 e41f229223f37c8f47497ae9d83981ddc6de5b43	no	2
Warnings:					
Information:					
2	Application Data Sheet	NBUS004C1C1_ADS.pdf	1256681 1c1d1e6da8fb1ef27126221fbbe1aa27a57e3e86	no	9
Warnings:					
Information:					
3		NBUS004C1C1_Specification_ASFILED.pdf	425275 4606dd3f2979bca0f6cd7e71ec32538b5ae6d35f	yes	82

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	75
Claims	76	81
Abstract	82	82

Warnings:					
Information:					
4	Drawings-only black and white line drawings	NBUS004C1C1_Drawings_ASFILED.PDF	1325421 c0877928c1dfbb7a5e20b1b3ac4f04a72e7e8cc7	no	41
Warnings:					
Information:					
5	Oath or Declaration filed	15_092945_Declaration_Wright.pdf	484349 cf5bfe73ba2c121fcbef4a243a3607a1967db227	no	2

Warnings:					
Information:					
6	Oath or Declaration filed	15_092945_Declaration_Brandt.pdf	513031 cf775fbc0f48c6e23dbb2eb7555a0c7da358bc6b	no	2
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	41697 3b06d27c1660700680ee8f3527171ef976c522b7	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	4175377		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/933,811

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	29 minus 20 =	* 9	x 50 =	450	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 230 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1235		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

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

AMENDMENT B

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

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

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www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/933,811	07/20/2020		1235	NBUS.004C1C1	29	3

CONFIRMATION NO. 1017

148468
Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

FILING RECEIPT

OC000000118825804

Date Mailed: 07/30/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Robert E. Wright, Clayton, AUSTRALIA;
Scott A. Brandt, Denver, CO;

Applicant(s)

Stratus Medical, LLC, Salt Lake City, UT;

Assignment For Published Patent Application

Stratus Medical, LLC, Salt Lake City, UT

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 15/092,945 04/07/2016 PAT 10716618
which is a CON of 13/101,009 05/04/2011 ABN
which claims benefit of 61/347,351 05/21/2010
and claims benefit of 61/357,886 06/23/2010
and claims benefit of 61/357,894 06/23/2010

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

Permission to Access Application via Priority Document Exchange: Yes

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Permission to Access Search Results: Yes

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

If Required, Foreign Filing License Granted: 07/29/2020
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/933,811**
Projected Publication Date: 11/05/2020
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

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countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

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technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/933,811	07/20/2020	Robert E. Wright	NBUS.004C1C1	1017

148468 7590 08/03/2020

Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

EXAMINER	

ART UNIT	PAPER NUMBER
3794	

NOTIFICATION DATE	DELIVERY MODE
08/03/2020	ELECTRONIC

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

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

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

dhiggs@biomerics.com
dhiggs@medventureholdings.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 16/933,811	**Applicant(s)** Wright et al.	
	Examiner JoAnne L Burke	**Art Unit** OPET	**AIA (FITF) Status** No

1. THE REQUEST FILED 20 July 2020 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to JoAnne Burke at (571)272-4584. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/JOANNE L BURKE/ Lead Paralegal Specialist, OPET	

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/933,811	07/20/2020	Robert E. Wright	NBUS.004C1C1	1017

148468 7590 08/19/2020

Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

EXAMINER	
DEDOULIS, CHRISTINE A	

ART UNIT	PAPER NUMBER
3794	

NOTIFICATION DATE	DELIVERY MODE
08/19/2020	ELECTRONIC

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

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

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

dhiggs@biomerics.com
dhiggs@medventureholdings.com

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Office Action Summary	Application No. 16/933,811	Applicant(s) Wright et al.	
	Examiner CHRISTINE A DEDOULIS	Art Unit 3794	AIA (FITF) Status No

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

Period for Reply

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

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

Status

1)☑ Responsive to communication(s) filed on 20 July 2020.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-29 is/are pending in the application.

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

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-29 is/are rejected.

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

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

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

Application Papers

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

11)☑ The drawing(s) filed on 20 July 2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

2. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Claim Rejections - 35 USC § 112

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

3. Claims 1-29 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

4. Claim 1 recites "[a] radiofrequency neurotomy needle operable with a radiofrequency probe" in line 1 (see preamble). The limitation "a radiofrequency probe" is not positively recited in the preamble, and therefore it is at most unclear to the Examiner if the claim requires a radiofrequency probe or if the needle must be capable of being used with a probe. Similarly, claims 25 and 29 are rejected for the same reasoning.

5. Claims 2-24 are rejected due to their dependency on independent claim 1 and claims 26-28 are rejected due to their dependency on independent claim 25.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-12 and 16-29 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Tullis et al., (hereinafter 'Tullis', U.S. Pat. 7,918,852) in view of Young et al., (hereinafter 'Young', U.S. PGPub. No. 2006/0095029) and Hinchliffe et al. (hereinafter ' Hinchliffe', U.S. PGPub. No. 2002/0143302).

7. **Regarding independent claim 1 and claims 11 and 20**, Tullis discloses a radiofrequency neurotomy needle (cannula 28 in Fig. 2) operable with a radiofrequency probe (electrode assembly 36 in Fig. 2; it is noted that the cannula is capable of use with a radiofrequency probe), the radiofrequency neurotomy needle (cannula 28 in Fig. 2) comprising: a conductive portion at a distal end of the radiofrequency neurotomy needle (col. 6, ll.14-23, cannula 28 has a generally tubular body 29 including electrically conductive outer tube 54 and inner tube 48); a tip (distal end 58) configured to pierce tissue of a patient (col. 5, ll. 41-43; cannula 28 is best suited to pierce and penetrate skin and tissue); an elongate member (body 29) comprising a lumen (lumen of body 29) configured to accept the radiofrequency probe

therein such that the radiofrequency probe physically contacts and is electrically connected to the conductive portion (conductive inner tube 48 and outer tube 54 are configured to receive assembly 36 so that when the assembly 36 is electrically connected to the terminal 86, the inner tube 48 and outer tube 54 are capable of electrically connecting to the RF probe and emitting RF energy; Fig. 12 illustrates that terminal 140 of the electrode assembly 36 contacts the contact pad 93 of the terminal 86 in the cannula 28 causes electrical connection; col. 15, line 60-col. 16, line 8; It is noted that depending upon what kind of probe is inserted into the conductive outer tube 54 (e.g. insulated RF probe or uninsulated RF probe), the probe is capable of electrically connecting to the conductive tube 54 of the cannula 28), the tip (distal end 58) being at a distal end of the elongate member (body 29).

8. Tullis is silent regarding a filament.

9. Young teaches an ablation device (see Fig. 10) similar to that of Tullis and deploying a plurality of filaments (filaments 250 and 256; necessarily meeting claim 11, i.e. an additional filament) from a catheter body (catheter 216). Young further teaches disposing an RF probe (shaft 224, electrodes 225 and 226) within a lumen (293) that is connected to the plurality of filaments so that the RF probe electrically connects both the cannula and the plurality of filaments to an RF source ([0043],[0045] and [0052]).Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the needle of Tullis and incorporate a plurality of filament (filaments 250 and 256) and a shaft (293 and hub 296) in an arrangement as taught by Young, thereby arriving at the claimed invention. Doing so allows for one or more electrodes to extend radially from the distal region of the needle so as to achieve desired energy paths and obtain a desired ablation tissue volume ([0057]-[0058]).

10. However, Tullis in view of Young fail to explicitly disclose an actuator interconnected to the filament to move the filament between the retracted position and the deployed position

11. Hinchliffe teaches a deployment mechanism (Fig. 14) of a plurality of filaments (tines 280) in an elongated member of an ablation device, wherein the deployment mechanism comprises an actuator (actuator 230 in Fig. 14) connected to an inner tube/shaft (270) similar to that of shaft (293) of Tullis/Young combination. Hinchliffe further teaches that rotation of the actuator relative to a hub

(housing 214 and 216) causes deployment or retraction of the plurality of filaments ([0074]-[0075]; meeting the limitations of claim 20). The deployment mechanism comprises an actuator (actuator 230) interconnected to the plurality of filaments, wherein rotation of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein rotation of the actuator in a second direction relative to the hub retracts the plurality of filaments into the lumen to a retracted position ([0075]).

12. Therefore, it would have been obvious to one of ordinary skilled in the art at the time of the invention to modify the engagement between the hub of a needle and the hub of the plurality of filaments in the Tullis/Young combination and provide a deployment mechanism (external threads 235 and 237 along the actuator 230 and threads 227 and 229 on the housing 214 and 216) as taught by Hinchliffe, thereby arriving at the claimed invention. Doing so would allow actuation of the plurality of filaments in three positions: 1) retracted position, 2) a first radially deployable position and 3) a second radially deployable position and the plurality of filaments are retained in any one of the three positions ([0012]) to precisely control deployment of filaments.

13. Tullis discloses that the needle in combination with the RF probe operate in a monopolar mode (col. 21, ll. 58-60: "a monopolar electrode assembly") and Young further teaches that the needle and the plurality of filaments operate in a monopolar mode ([0043], [0045] and [0052], assembly 4 (or 200) and electrodes 26 deliver ablation energy in a monopolar configuration). Taken together, Tullis in view of Young contemplate that RF probe, the plurality of filaments and the needle form 'a single monopolar RF electrode' as claimed, wherein the filament(s) and the tip are configured to transmit radiofrequency energy from the radiofrequency probe when the filament(s) is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion.

14. **Regarding claim 2**, Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 1. Tullis discloses the tip is formed of another of the conductive materials (distal end 58 in Figs. 2 and 6-12; col. 6, ll. 19-27, comprises conductive material). In view of the prior modification, Young discloses wherein the filament is formed of one of the conductive materials ([0036],

[0039], [0040]). Tullis/Young/Hinchliffe combination teaches wherein the conductive materials of the filament and the tip are in physical contact when the filament is in the deployed position (see Fig. 10, Young). See claim 1 above for obviousness rationale statement.

15. **Regarding claim 3,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 2. Tullis discloses wherein the tip (distal end 58 in Figs. 2 and 6-12) comprises the conductive portion at the distal end of the radiofrequency neurotomy needle (cannula 28 in Fig. 2 and 6-12), and wherein the conductive portion is configured to physically contact the distal end of the radiofrequency probe (electrode assembly 36) when the radiofrequency probe is accepted in the lumen (as best illustrated in Figs. 5-12, see electrode assembly 36 within lumen of body 29).

16. **Regarding claim 4,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 1. Tullis further discloses wherein the tip (distal tip 58 in Fig. 2 and 6-12) comprises the conductive portion at the distal end of the radiofrequency neurotomy needle (col. 6, ll.14-23, cannula 28 has a generally tubular body 29 including electrically conductive outer tube 54 and inner tube 48 including distal tip 58).

17. **Regarding claim 5,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 4. Tullis further discloses wherein the conductive portion is configured to physically contact the distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen (as best illustrates in Fig. 5, also see Figs. 6-12, see cannula 28, assembly 36).

18. **Regarding claim 6,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 4. Tullis further discloses wherein the tip (distal tip 58) comprises a tip lumen (lumen or distal tip 58) that is configured to receive the distal end of the radiofrequency probe (as best illustrates in Fig. 5, also see Figs. 6-12, see cannula 28, assembly 36).

19. **Regarding claim 7,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 1. Tullis further discloses wherein the needle further comprises a tube (cannula 28 comprises inner tube 48, outer tube 54 and insulating sleeve 52 in the monopolar electrode assembly,

see col. 21, ll. 58-64) that is separate from the elongate member (insulating sleeve 52 is separate from the inner tube 48 and outer tube 54), and wherein the tube is positioned within the elongate member (Fig. 6).

20. **Regarding claim 8,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 7. Tullis further discloses wherein the lumen is within the tube (cannula 28, lumen of inner tube 48 and outer tube 54 receive assembly 36, see Figs. 5-12 and 15-16).

21. **Regarding claim 9,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 7. Tullis further discloses wherein the tube (inner tube 48, outer tube 54 in Figs. 6-12) comprises the conductive portion of the needle (conductive inner tube 48 and outer tube 54 are configured to receive assembly 36 so that when the assembly 36 is electrically connected to the terminal 86, the inner tube 48 and outer tube 54 are capable of emitting RF energy; also see col.6, ll. 14-35 and col. 15, line 60-col. 16, line 8).

22. **Regarding claim 10,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 1. Tullis further teaches wherein the tip (distal end 58 in Fig. 2) and the elongate member (body 29) are a single unitary structure or are separate components that are fixedly interconnected (see Figs. 2 and 6).

23. **Regarding claim 12,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 11. In view of the prior modification, Young teaches wherein when the filaments (filaments 250 and 256 in Fig. 10) are deployed, the tip and the filaments are configured to produce a lesion at a target volume of tissue within the patient ([0057]-[0058]; see Figs. 7A-7D for lesion formation and see [0043], [0045] and [0052]). See claim 1 above for obviousness rationale statement.

24. **Regarding claim 16,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 12. Tullis/Young/Hinchliffe combination teaches a needle (see claim 1 above) capable of meeting these limitations, wherein when the target volume includes a target nerve such that formation of the lesion ablates at least a portion of the target nerve to inhibit the ability of the target nerve to transmit pain signals. A recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then in meets the claim.

25. **Regarding claim 17,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 1. Tullis further teaches wherein the lumen (lumen of body 29, cannula 28 in Fig. 2) is further configured to accept the radiofrequency probe (electrode assembly 36) therein such that a distal end of the radiofrequency probe is proximate the tip when the radiofrequency probe physically contacts and is electrically connected to the conductive portion (as best illustrated in Fig. 5, electrode assembly 36 is inserted into lumen of body 29 such that a distal end of the assembly 36 is proximate distal tip 58, also see Figs. 11 and 12).

26. **Regarding claim 18,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 1. Tullis further teaches comprising a fitting (at hub 44 in Figs. 2 and 4) configured to provide a connection to a fluid source (syringe 32) for injection of fluid through the lumen (col. 16, ll. 38-48, leading end of the syringe 32 against the bore 72 so that therapeutic fluid/anesthetic is inserted into the through bore 57 of the cannula body 29; it is noted that connection between a syringe and a cannula like that of Tullis necessarily provides for a Leur fitting which is interpreted as connection between round male and female interlocking tubes, slightly tapered to hold together, commonly between hypodermic syringe tips and needles so as to provide a leak-free connection between the two instruments).

27. **Regarding claim 19,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 18. Tullis further teaches wherein the radiofrequency neurotomy needle (cannula 28 in Fig. 2) is operable in a first state in which the radiofrequency probe is fully separated from the radiofrequency neurotomy needle in a non-inserted state (see Fig. 2, for assembly 36 in a non-inserted state) and in which the fitting is connected to the fluid source for injection of fluid through the lumen (see Fig. 4, syringe 32 is connected to cannula 28), and wherein the radiofrequency neurotomy needle is operable in a second state in which the fitting is disconnected from the fluid source and in which the radiofrequency probe is inserted through the fitting into the lumen for delivery of the radiofrequency

energy (see Fig. 5, assembly 36 is inserted through the fitting into the lumen for delivery of the radiofrequency energy).

28. **Regarding claim 21,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 1. In view of the prior modification, Young teaches wherein a distal tip of the filament (filaments 250 and 256 in Fig. 10) is closer to a central longitudinal axis of the radiofrequency neurotomy needle when the filament is in the retracted position as compared with when the filament is in the deployed position (see filaments 250 and 256 in Fig. 10 for deployed position). It is noted that in the retracted position the filaments are necessarily located within the elongate cannula (212), i.e. closer to a central longitudinal axis of the radiofrequency neurotomy needle.

29. **Regarding claim 22,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 1. Tullis/Young/Hinchliffe combination teaches wherein the filament and the tip are configured to operate together as the single electrode in a monopolar mode when the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion. See claim 1 above for obviousness rationale statement.

30. **Regarding claim 23,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 1. Tullis/Young/Hinchliffe combination teaches a system comprising: the radiofrequency neurotomy needle of claim 1 (see claim 1 above); and the radiofrequency probe (assembly 36 in Fig. 2).

31. **Regarding claim 24,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the system according to claim 23. Tullis further comprising a radiofrequency generator (Fig. 1, RF signal generator 156 internal to the control console 22) and a return electrode pad that is configured to be attached to the patient (col. 22, ll. 6-7, "[a] conventional ground pad is used as the return electrode for the monopolar version of this invention").

32. Tullis discloses that the needle in combination with the RF probe operate in a monopolar mode (col. 21, ll. 58-60: "a monopolar electrode assembly") and teaches an electrode pad (col. 22, ll. 6-7). Young further teaches that the needle and the plurality of filaments operate in a monopolar mode ([0043],

[0045] and [0052], assembly 4 (or 200) and electrodes 26 deliver ablation energy in a monopolar configuration). Taken together, Tullis in view of Young contemplate that the RF probe, the plurality of filaments and the needle are capable to operate together as the single electrode in a monopolar mode when the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion and when the electrode pad is attached to the patient to complete a circuit from the radiofrequency generator through the radiofrequency probe, through the needle, through a portion of the patient, through the return electrode pad, and to the radiofrequency generator.

33. **Regarding claim 25**, Tullis discloses a radiofrequency neurotomy needle (cannula 28 in Fig. 2) operable with a radiofrequency probe (electrode assembly 36 in Fig. 2; it is noted that the cannula is capable of use with a radiofrequency probe), the radiofrequency neurotomy needle comprising: a tip (distal end 58) comprising a conductive material (col. 6, ll.14-23, cannula 28 has a generally tubular body 29 including electrically conductive outer tube 54 and inner tube 48), the tip (distal tip 58) being configured to pierce tissue of a patient (col. 5, ll. 41-43; cannula 28 is best suited to pierce and penetrate skin and tissue); a tube (inner tube 48, outer tube 54) comprising a conductive material (col. 6, ll.14-23), the tube being configured to accept the radiofrequency probe therein (Fig. 5). Tullis further discloses wherein the tip, and the tube are electrically connected at a distal end of the radiofrequency neurotomy needle due to physical contact, at the distal end of the radiofrequency neurotomy needle, of each of the conductive materials with at least one of the other conductive materials (conductive inner tube 48 and outer tube 54 are configured to receive assembly 36 so that when the assembly 36 is electrically connected to the terminal 86, the inner tube 48 and outer tube 54 are capable of electrically connecting to the RF probe and emitting RF energy; Fig. 12 illustrates that terminal 140 of the electrode assembly 36 contacts the contact pad 93 of the terminal 86 in the cannula 28 causes electrical connection; col. 15, line 60-col. 16, line 8; It is noted that depending upon what kind of probe is inserted into the tube 54 (e.g. insulated RF probe or uninsulated RF probe), the probe is capable of electrically connecting to the conductive tube 54 of the cannula 28).

34. Tullis is silent regarding a filament.

35. Young teaches an ablation device (see Fig. 10) similar to that of Tullis and deploying a plurality of filaments (filaments 250 and 256) from a catheter body (catheter 216), wherein a distal tip of the filament(s) (filaments 250 and 256) are closer to a central longitudinal axis of the catheter body (catheter 216) when the filament is in the retracted position as compared with when the filament is in the deployed position (see Fig. 10 for deployed position). Young further teaches disposing an RF probe (shaft 224, electrodes 225 and 226) within a lumen (293) that is connected to the plurality of filaments so that the RF probe electrically connects both the cannula and the plurality of filaments to an RF source ([0043],[0045] and [0052]).Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the needle of Tullis and incorporate a plurality of filament (filaments 250 and 256) and a shaft (293 and hub 296) in an arrangement as taught by Young, thereby arriving at the claimed invention. Doing so allows for one or more electrodes to extend radially from the distal region of the needle so as to achieve desired energy paths and obtain a desired ablation tissue volume ([0057]-[0058]).

36. However, Tullis in view of Young fail to explicitly disclose an actuator interconnected to the filament to move the filament between the retracted position and the deployed position

37. Hinchliffe teaches a deployment mechanism (Fig. 14) of a plurality of filaments (tines 280) in an elongated member of an ablation device, wherein the deployment mechanism comprises an actuator (actuator 230 in Fig. 14) connected to an inner tube/shaft (270) similar to that of shaft (293) of Tullis/Young combination. Hinchliffe further teaches that rotation of the actuator relative to a hub (housing 214 and 216) causes deployment or retraction of the plurality of filaments ([0074]-[0075]). The deployment mechanism comprises an actuator (actuator 230) interconnected to the plurality of filaments, wherein rotation of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein rotation of the actuator in a second direction relative to the hub retracts the plurality of filaments into the lumen to a retracted position ([0075]).

38. Therefore, it would have been obvious to one of ordinary skilled in the art at the time of the invention to modify the engagement between the hub of a needle and the hub of the plurality of filaments

in the Tullis/Young combination and provide a deployment mechanism (external threads 235 and 237 along the actuator 230 and threads 227 and 229 on the housing 214 and 216) as taught by Hinchliffe, thereby arriving at the claimed invention. Doing so would allow actuation of the plurality of filaments in three positions: 1) retracted position, 2) a first radially deployable position and 3) a second radially deployable position and the plurality of filaments are retained in any one of the three positions ([0012]) to precisely control deployment of filaments.

39. Tullis discloses that the needle in combination with the RF probe operate in a monopolar mode (col. 21, ll. 58-60: "a monopolar electrode assembly") and Young further teaches that the needle and the plurality of filaments operate in a monopolar mode ([0043], [0045] and [0052], assembly 4 (or 200) and electrodes 26 deliver ablation energy in a monopolar configuration). Taken together, Tullis in view of Young contemplate that RF probe, the plurality of filaments and the needle form 'a single monopolar RF electrode' as claimed, wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe when the filament(s) is in the deployed position and the radiofrequency probe is accepted in the lumen and in physical contact with at least one of the conductive materials at the distal end of the radiofrequency neurotomy needle.

40. **Regarding claim 26,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 25. Tullis further teaches wherein the tube is an elongate member (inner tube 48, outer tube 54 in Figs. 2 and 6-12), and wherein the tip (distal tip 58) is at the distal end of the elongate member (Fig. 6).

41. **Regarding claim 27,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 25. Tullis further teaches elongate member (body 29 of cannula 28 in Fig. 2), the tip (distal tip 58) being at a distal end of the elongate member (Fig. 2), wherein the tube (cannula 28 comprises inner tube 48, outer tube 54 and insulating sleeve 52 in the monopolar electrode assembly, see col. 21, ll. 58-64) is separate from the elongate member (insulating sleeve 52 is separate from the inner tube 48 and outer tube 54) and is positioned within the elongate member (Fig. 6).

42. **Regarding claim 28,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 25. Tullis further teaches wherein the tip (distal tip 58 in Fig. 2) comprises a lumen (lumen or distal tip 58) that is configured to receive the distal end of the radiofrequency probe (as best illustrates in Fig. 5, also see Figs. 6-12, see cannula 28, assembly 36).

43. **Regarding claim 29,** Tullis discloses a radiofrequency neurotomy needle (cannula 28 in Fig. 2) operable with a radiofrequency probe (electrode assembly 36 in Fig. 2; it is noted that the cannula is capable of use with a radio frequency probe), the radiofrequency neurotomy needle comprising: an elongate member (body 29) comprising a lumen (lumen of body 29) configured to accept the radiofrequency probe (electrode assembly 36) therein; a tip (distal tip 58) coupled to a distal end of the elongate member (body 29) and being configured to pierce tissue of a patient (col. 5, ll. 41-43; cannula 28 is best suited to pierce and penetrate skin and tissue), the tip comprising a conductive material configured to physically contact a distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen (conductive inner tube 48 and outer tube 54 are configured to receive assembly 36 so that when the assembly 36 is electrically connected to the terminal 86, the inner tube 48 and outer tube 54 are capable of electrically connecting to the RF probe and emitting RF energy; Fig. 12 illustrates that terminal 140 of the electrode assembly 36 contacts the contact pad 93 of the terminal 86 in the cannula 28 causes electrical connection; col. 15, line 60-col. 16, line 8; It is noted that depending upon what kind of probe is inserted into the tube 54 (e.g. insulated RF probe or uninsulated RF probe), the probe is capable of electrically connecting to the conductive tube 54 of the cannula 28).

44. Tullis is silent regarding a filament.

45. Young teaches an ablation device (see Fig. 10) similar to that of Tullis and deploying a plurality of filaments (filaments 250 and 256) from a catheter body (catheter 216), between a retracted position, in which the filament is in a cross-sectional envelope of the tip (of the catheter 216), and a deployed position, in which a portion of the filament is outside the cross-sectional envelope of the tip (see Fig. 10 for deployed position). Young further teaches disposing an RF probe (shaft 224, electrodes 225 and 226) within a lumen (293) that is connected to the plurality of filaments so that the RF probe electrically

connects both the cannula and the plurality of filaments to an RF source ([0043],[0045] and [0052]).Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the needle of Tullis and incorporate a filament (filaments 250 and 256) and a shaft (293 and hub 296) in an arrangement as taught by Young, thereby arriving at the claimed invention. Doing so allows for one or more electrodes to extend radially from the distal region of the needle so as to achieve desired energy paths and obtain a desired ablation tissue volume ([0057]-[0058]).

46. However, Tullis in view of Young fail to explicitly disclose an actuator interconnected to the filament to move the filament between the retracted position and the deployed position.

47. Hinchliffe teaches a deployment mechanism (Fig. 14) of a plurality of filaments (tines 280) in an elongated member of an ablation device, wherein the deployment mechanism comprises an actuator (actuator 230 in Fig. 14) connected to an inner tube/shaft (270) similar to that of shaft (293) of Tullis/Young combination. Hinchliffe further teaches that rotation of the actuator relative to a hub (housing 214 and 216) causes deployment or retraction of the plurality of filaments ([0074]-[0075]; meeting the limitations of claim 20). The deployment mechanism comprises an actuator (actuator 230) interconnected to the plurality of filaments, wherein rotation of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein rotation of the actuator in a second direction relative to the hub retracts the plurality of filaments into the lumen to a retracted position ([0075]).

48. Therefore, it would have been obvious to one of ordinary skilled in the art at the time of the invention to modify the engagement between the hub of a needle and the hub of the plurality of filaments in the Tullis/Young combination and provide a deployment mechanism (external threads 235 and 237 along the actuator 230 and threads 227 and 229 on the housing 214 and 216) as taught by Hinchliffe, thereby arriving at the claimed invention. Doing so would allow actuation of the plurality of filaments in three positions: 1) retracted position, 2) a first radially deployable position and 3) a second radially deployable position and the plurality of filaments are retained in any one of the three positions ([0012]) to precisely control deployment of filaments.

49. Tullis discloses that the needle in combination with the RF probe operate in a monopolar mode (col. 21, ll. 58-60: "a monopolar electrode assembly") and Young further teaches that the needle and the plurality of filaments operate in a monopolar mode ([0043], [0045] and [0052], assembly 4 (or 200) and electrodes 26 deliver ablation energy in a monopolar configuration). Taken together, Tullis in view of Young contemplate that RF probe, the plurality of filaments and the needle form 'a single monopolar RF electrode' as claimed, wherein the filament(s) and the tip are configured to transmit radiofrequency energy from the radiofrequency probe when the filament(s) is in the deployed position and the radiofrequency probe is accepted in the lumen and in physical contact with the conductive material of the tip.

50. Claim 13 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Tullis in view of Young and Hinchliffe as applied to claims 1-12 and 16-29 above, and further in view of Gough et al., (hereinafter 'Gough', U.S. PGPub No. 2004/0260282).

51. **Regarding claim 13,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 12, but are silent regarding wherein when the tip and the filaments are configured to produce the lesion so as to be asymmetrical and offset relative to the central longitudinal axis of the radiofrequency neurotomy needle.

52. Gough teaches a similar device (device 10 in Fig. 6A, 6C, 7 and 8) as that of Young for delivering energy to tissues comprising a needle (introducer 14) and a plurality of filaments (energy delivery device 16', [0013], [0058]). In Fig. 6C, Gough teaches wherein the central lumen of the needle (lumen 14" of primary antenna 14) comprises lumens (16) that are used to introduce filaments (secondary antenna 16). Gough further teaches wherein the lumens offset relative to the central longitudinal axis of the needle. Given that Young teaches the plurality of filaments consisting essentially of two filaments that can be positioned non-symmetrically ([0062]) and Gough further teaches wherein the lumens are offset relative to the central longitudinal axis of the needle, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Tullis/Young/Hinchliffe combination to incorporate the teaching of Gough to offset relative to the central longitudinal axis of the

radiofrequency neurotomy needle to introduce the filaments in a variety of different geometric configurations ([0063]). Further, in view of the Tullis/Young/Hinchliffe/Gough combination, it is contemplated that the tip and the filaments would be capable of producing a lesion that is asymmetrical and offset relative to the central longitudinal axis of the radiofrequency neurotomy needle.

53. Claim 14 and 15 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Tullis in view of Young and Hinchliffe as applied to claims 1-12 and 16-29 above, and further in view of Young (hereinafter 'Young '965', U.S. PGPub. No. 2006/0084965).

54. **Regarding claim 14,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 12, but are silent regarding wherein when the filaments are deployed, distal tips of the filaments are distal to the tip of the radiofrequency neurotomy needle such that the filaments and the tip are configured to produce the lesion so as to be distally offset from the tip of the radiofrequency neurotomy needle.

55. Young'965 teaches providing a plurality of filaments (filaments 26 in Fig. 7B-7D), wherein when the filaments (26) are deployed, distal tips of the filaments are distal to the tip of the radiofrequency needle (12 in Fig. 7B-7D). Therefore, it would have been obvious to one of ordinary skill in the art before the effective filing date of the invention to have modified the plurality of filaments of Tullis/Young/Hinchliffe combination so that when the filaments are deployed, it extends beyond the distal tip of the needle as taught by Young'965, thereby arriving at the claimed invention. Doing so allows for the plurality of filaments to create increased lesion sizes or to create lesions at different sites within a treatment region ([0040]-[0042]). It is noted that the combination of Tullis/Young/Hinchliffe/Young'965 provides for when the filaments are deployed, distal tips of the filaments are distal to the tip of the radiofrequency neurotomy needle. Furthermore, claim 1 discusses the electrical pathway established between the needle, RF probe and the plurality of filaments and that the combination of Tullis/Young/Hinchliffe/Young'965 is capable of providing the lesion so as to be distally offset from the tip of the radiofrequency neurotomy needle since ablation current travels beyond the distal tips of the plurality of filaments.

56. **Regarding claim 15,** Tullis/Young/Hinchliffe combination teaches all of the limitations of the device according to claim 12. In view of the prior modification, Tullis/Young/Hinchliffe combination teaches wherein the tip and the filaments are configured to operate together as the single electrode in a monopolar mode to produce the lesion (see claim 1 above, claim 1 discusses the electrical pathway established between the needle, RF probe and the plurality of filaments), but are silent regarding to have a volume between about 250 mm^3 and about 750 mm^3.

57. Young '965 teaches a similar configuration (Figs. 1-7) providing a radiofrequency need (12) and a plurality of filaments (filaments 26 in Fig. 7B-7D) configured to operate together as the single electrode in a monopolar mode to produce a lesion ([0033], "the array 30 of electrodes 26 and operative electrode 92 are monopolar electrodes and current will pass form the electrodes 26 and the electrode 92 to the dispersive electrode to thereby deliver ablation energy in a monopolar configuration"). Young '965 further teaches the plurality of filaments may be fully deployed, or may be only partially deployed or deployed incrementally in stages during a procedure in order to create varying and increased lesion sizes or to create lesions at different sites within a treatment region ([0040]-[0042]). Therefore, it would have been obvious to one of ordinary skill in the art before the effective filing date of the invention to have modified the device of Tullis/Young/Hinchliffe combination to produce varying lesion volumes as taught by Young '965, thereby arriving at the claimed invention. It is noted that the combination of Tullis/Young/Hinchliffe/Young'965 provides for the tip and the filaments capable to operate together as the single electrode in a monopolar mode to produce various and increasing lesion volumes, including a volume between about 250 mm^3 and about 750 mm^3. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Double Patenting

58. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple

assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

59. Claims 1-29 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 10,716,618. Although the claims at issue are not identical, they are not patentably distinct from each other because both applications claim a needle, an elongate member comprising a lumen at an interior thereof, the lumen being configured to receive a distal end of a

radiofrequency probe, a filament, and an actuator configured to retract and deploy the filament. Further, both applications are directed towards inserting a radiofrequency probe within the lumen of the needle, wherein the lumen is configured to accept the radiofrequency probe therein to physically contact a conductive portion of the tip and thereby establish an electrically conductive path between the radiofrequency probe, the plurality of filaments, and the tip to transmit radiofrequency energy from the radiofrequency probe to operate as a monopolar electrode, when the radiofrequency probe is inserted into the lumen.

60. Claims 1-29 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 15/098,673 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because both applications are directed towards a needle comprising an elongate member, a tip, a filament and an actuator. The needles in both applications are capable of accepting an RF probe such that an electrode of an inserted RF probe, the tip, and the filament are operable to form a single monopolar RF electrode.

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

Conclusion

61. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE A DEDOULIS whose telephone number is (571)272-2459. The examiner can normally be reached on M-F, 8am to 5pm.

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/C.A.D./
Examiner, Art Unit 3794

/EUN HWA KIM/
Primary Examiner, Art Unit 3794

Notice of References Cited	Application/Control No. 16/933,811	Applicant(s)/Patent Under Reexamination Wright et al.	
	Examiner CHRISTINE A DEDOULIS	Art Unit 3794	Page 1 of 1

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	16/933,811	Wright et al.
	Examiner	Art Unit
	CHRISTINE A DEDOULIS	3794

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Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner
A61B18/1477,1206,	08/10/2020	cd
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US Classification - Searched*			
Class	Subclass	Date	Examiner

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

Search Notes		
Search Notes	Date	Examiner
EAST (class, text, inventor, assignee) search	08/10/2020	cd
discussed application with Primary Eunhwa Kim	08/10/2020	cd

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

/C.A.D./ Examiner, Art Unit 3794	

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	"15092945"	US-PGPUB; USPAT	OR	ON	2020/08/10 13:54
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L11	32	((("Wright") near3 ("Robert") near3 ("E"))).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 14:27
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L32	862	17 and (needle cannula) and filaments	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:42
L33	862	17 and (needle cannula) and filament	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:42
L34	786	17 and (needle cannula) and filament and electrode	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:43
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S6	2	"20020143302"	US-PGPUB; USPAT	OR	ON	2020/08/07 13:40

S7	7	"35695799".FMID.	US-PGPUB; USPAT; FPRS; JPO	OR	ON	2020/08/07 17:26
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EAST Search History (Interference)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	16/933,811
	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 1 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1.	D372,086	07-23-1996	Grasso et al.	
	2.	RE40,279	04-29-2008	Sluijter et al.	
	3.	RE40,388	06-17-2008	Gines	
	4.	4,011,872	03-15-1977	Kamiya	
	5.	4,206,761	06-10-1980	Cosman	
	6.	4,206,762	06-10-1980	Cosman	
	7.	4,281,667	08-04-1981	Cosman	
	8.	4,353,371	10-12-1982	Cosman	
	9.	4,375,220	03-01-1983	Matvias	
	10.	4,378,809	04-05-1983	Cosman	
	11.	4,385,636	05-31-1983	Cosman	
	12.	4,411,266	10-25-1983	Cosman	
	13.	4,565,200	01-21-1986	Cosman	
	14.	4,573,980	03-04-1986	Karrasch et al.	
	15.	4,583,538	04-22-1986	Onik et al.	
	16.	4,593,703	06-10-1986	Cosman	
	17.	4,618,978	10-21-1986	Cosman	
	18.	4,646,752	03-03-1987	Swann et al.	
	19.	4,653,508	03-31-1987	Cosman	
	20.	4,660,568	04-28-1987	Cosman	
	21.	4,676,255	06-30-1987	Cosman	
	22.	4,698,207	10-06-1987	Bringham et al.	
	23.	4,787,886	11-29-1988	Cosman	
	24.	4,796,615	01-10-1989	Bullock et al.	
	25.	4,827,927	05-09-1989	Newton	
	26.	4,838,265	06-13-1989	Cosman et al.	
	27.	4,886,506	12-12-1989	Lovgren et al.	
	28.	4,907,589	03-13-1990	Cosman	

Examiner Signature	Date Considered

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	Art Unit	3794
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U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	29.	4,966,597	10-30-1990	Cosman	
	30.	5,010,897	04-30-1991	Leveen	
	31.	5,160,337	11-03-1992	Cosman	
	32.	5,217,457	06-08-1993	Delahuerga et al.	
	33.	5,230,623	07-27-1993	Guthrie et al.	
	34.	5,233,515	08-03-1993	Cosman	
	35.	5,244,462	09-14-1993	Delahuerga et al.	
	36.	5,257,630	11-02-1993	Braitman et al.	
	37.	5,291,896	03-08-1994	Fonger et al.	
	38.	5,304,114	04-19-1994	Cosman et al.	
	39.	5,304,115	04-19-1994	Pflueger et al.	
	40.	5,312,329	05-17-1994	Beaty et al.	
	41.	5,312,391	05-17-1994	Wilk	
	42.	5,318,013	06-07-1994	Wilk	
	43.	5,324,255	06-28-1994	Passafaro et al.	
	44.	5,334,183	08-02-1994	Wuchinich	
	45.	5,342,292	08-30-1994	Nita et al.	
	46.	5,370,645	12-06-1994	Klicek et al.	
	47.	5,370,675	12-06-1994	Edwards et al.	
	48.	5,372,596	12-13-1994	Klicek et al.	
	49.	5,377,685	01-03-1995	Kazi et al.	
	50.	5,397,301	03-14-1995	Pflueger et al.	
	51.	5,401,272	03-28-1995	Perkins	
	52.	5,421,923	06-06-1995	Clarke et al.	
	53.	5,422,567	06-06-1995	Matsunaga	
	54.	5,423,809	06-13-1995	Klicek	
	55.	5,433,739	07-18-1995	Sluijter et al.	
	56.	5,447,417	09-05-1995	Kuhl et al.	

Examiner Signature	Date Considered

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	57.	5,458,597	10-17-1995	Edwards et al.	
	58.	5,472,441	12-05-1995	Edwards et al.	
	59.	5,472,442	12-05-1995	Klicek	
	60.	5,474,057	12-12-1995	Makower et al.	
	61.	5,484,398	01-16-1996	Stoddard	
	62.	5,496,312	03-05-1996	Klicek	
	63.	5,507,743	04-16-1996	Edwards et al.	
	64.	5,511,564	04-30-1996	Wilk	
	65.	5,514,129	05-07-1996	Smith	
	66.	5,536,267	07-16-1996	Edwards et al.	
	67.	5,541,376	07-30-1996	Ladtkow et al.	
	68.	5,560,358	10-01-1996	Arnold et al.	
	69.	5,562,703	10-08-1996	Desai	
	70.	5,571,147	11-05-1996	Sluijter et al.	
	71.	5,580,665	12-03-1996	Taguchi et al.	
	72.	5,599,345	02-04-1997	Edwards et al.	
	73.	5,599,346	02-04-1997	Edwards et al.	
	74.	5,611,709	03-18-1997	McAnulty	
	75.	5,613,966	03-25-1997	Makower et al.	
	76.	5,628,743	05-13-1997	Cimino	
	77.	5,662,111	09-02-1997	Cosman	
	78.	5,662,620	09-02-1997	Lieber et al.	
	79.	5,662,680	09-02-1997	Desai	
	80.	5,667,488	09-16-1997	Lundquist et al.	
	81.	5,669,904	09-23-1997	Platt, Jr. et al.	
	82.	5,672,173	09-30-1997	Gough et al.	
	83.	5,672,174	09-30-1997	Gough et al.	
	84.	5,683,349	11-04-1997	Makower et al.	

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	Art Unit	3794
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SHEET 4 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

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	85.	5,683,384	11-04-1997	Gough et al.	
	86.	5,701,575	12-23-1997	Taguchi et al.	
	87.	5,720,744	02-24-1998	Eggleston et al.	
	88.	5,728,143	03-17-1998	Gough et al.	
	89.	5,735,847	04-07-1998	Gough et al.	
	90.	5,738,648	04-14-1998	Lands et al.	
	91.	5,748,703	05-05-1998	Cosman	
	92.	5,749,689	05-12-1998	Konig	
	93.	5,755,754	05-26-1998	Rudie et al.	
	94.	5,768,679	06-16-1998	Taguchi et al.	
	95.	5,772,659	06-30-1998	Becker et al.	
	96.	5,778,043	07-07-1998	Cosman	
	97.	5,782,827	07-21-1998	Gough et al.	
	98.	5,792,146	08-11-1998	Cosman	
	99.	5,797,906	08-25-1998	Rhum et al.	
	100.	5,800,484	09-01-1998	Gough et al.	
	101.	5,807,309	09-15-1998	Lundquist et al.	
	102.	5,810,804	09-22-1998	Gough et al.	
	103.	5,827,271	10-27-1998	Buysse et al.	
	104.	5,827,276	10-27-1998	LeVeen et al.	
	105.	5,848,967	12-15-1998	Cosman	
	106.	5,855,576	01-05-1999	LeVeen et al.	
	107.	5,863,290	01-26-1999	Gough et al.	
	108.	5,868,740	02-09-1999	LeVeen et al.	
	109.	5,911,739	06-15-1999	Kordis et al.	
	110.	5,913,855	06-22-1999	Gough et al.	
	111.	5,921,992	07-13-1999	Costales et al.	
	112.	5,925,042	07-20-1999	Gough et al.	

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	113.	5,928,229	07-27-1999	Gough et al.	
	114.	5,935,123	08-10-1999	Edwards et al.	
	115.	5,951,547	09-14-1999	Gough et al.	
	116.	5,968,040	10-19-1999	Swanson et al.	
	117.	5,980,517	11-09-1999	Gough	
	118.	5,983,141	11-09-1999	Sluijter et al.	
	119.	6,006,126	12-21-1999	Cosman	
	120.	6,013,076	01-11-2000	Goble et al.	
	121.	6,014,590	01-11-2000	Whayne et al.	
	122.	6,015,406	01-18-2000	Goble et al.	
	123.	6,016,452	01-18-2000	Kasevich	
	124.	6,039,733	03-21-2000	Buysse et al.	
	125.	6,041,260	03-21-2000	Stern et al.	
	126.	6,044,846	04-04-2000	Edwards	
	127.	6,050,992	04-18-2000	Nichols	
	128.	6,053,937	04-25-2000	Edwards et al.	
	129.	6,059,780	05-09-2000	Gough et al.	
	130.	6,068,627	05-30-2000	Orszulak et al.	
	131.	6,071,280	06-06-2000	Edwards et al.	
	132.	6,080,150	06-27-2000	Gough	
	133.	6,090,105	07-18-2000	Zepeda et al.	
	134.	6,106,521	08-22-2000	Blewett et al.	
	135.	6,117,134	09-12-2000	Cunningham et al.	
	136.	6,122,341	09-19-2000	Butler et al.	
	137.	6,129,726	10-10-2000	Edwards et al.	
	138.	6,132,425	10-17-2000	Gough	
	139.	6,139,519	10-31-2000	Blythe	
	140.	6,139,547	10-31-2000	Lontine et al.	

Examiner Signature	Date Considered

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	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
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	141.	6,143,003	11-07-2000	Cosman	
	142.	6,146,380	11-14-2000	Racz et al.	
	143.	6,161,048	12-12-2000	Sluijter et al.	
	144.	6,165,169	12-26-2000	Panescu et al.	
	145.	6,167,295	12-26-2000	Cosman	
	146.	6,179,834	01-30-2001	Buysse et al.	
	147.	6,210,403	04-03-2001	Klicek	
	148.	6,213,999	04-10-2001	Platt, Jr. et al.	
	149.	6,217,554	04-17-2001	Green	
	150.	6,228,080	05-08-2001	Gines	
	151.	6,228,083	05-08-2001	Lands et al.	
	152.	6,231,570	05-15-2001	Tu et al.	
	153.	6,234,178	05-22-2001	Goble et al.	
	154.	6,235,023	05-22-2001	Lee et al.	
	155.	6,241,725	06-05-2001	Cosman	
	156.	6,241,726	06-05-2001	Chia et al.	
	157.	6,246,912	06-12-2001	Sluijter et al.	
	158.	6,251,106	06-26-2001	Becker et al.	
	159.	6,259,952	07-10-2001	Sluijter et al.	
	160.	6,268,200	07-31-2001	Tucker et al.	
	161.	6,275,725	08-14-2001	Cosman	
	162.	6,277,117	08-21-2001	Tetzlaff et al.	
	163.	6,280,441	08-28-2001	Ryan	
	164.	6,312,426	11-06-2001	Goldberg et al.	
	165.	6,330,478	12-11-2001	Lee et al.	
	166.	6,331,180	12-18-2001	Cosman et al.	
	167.	6,334,861	01-01-2002	Chandler et al.	
	168.	6,352,536	03-05-2002	Buysse et al.	

Examiner Signature	Date Considered

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	16/933,811
	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
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U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	169.	6,402,743	06-11-2002	Orszulak et al.	
	170.	6,402,747	06-11-2002	Lindermann et al.	
	171.	6,405,072	06-11-2002	Cosman	
	172.	6,416,520	07-09-2002	Kynast et al.	
	173.	6,419,653	07-16-2002	Edwards et al.	
	174.	6,419,680	07-16-2002	Cosman et al.	
	175.	6,419,798	07-16-2002	Topolkaraev et al.	
	176.	6,425,887	07-30-2002	McGuckin et al.	
	177.	6,440,127	08-27-2002	McGovern et al.	
	178.	6,447,477	09-10-2002	Burney et al.	
	179.	6,447,505	09-10-2002	McGovern et al.	
	180.	6,451,018	09-17-2002	Lands et al.	
	181.	6,454,765	09-24-2002	Leveen et al.	
	182.	6,458,130	10-01-2002	Frazier et al.	
	183.	6,459,769	10-01-2002	Cosman	
	184.	6,464,704	10-15-2002	Schmaltz et al.	
	185.	6,468,273	10-22-2002	Leveen et al.	
	186.	6,471,698	10-29-2002	Edwards et al.	
	187.	6,478,793	11-12-2002	Cosman et al.	
	188.	6,500,175	12-31-2002	Gough et al.	
	189.	6,506,189	01-14-2003	Rittman, III et al.	
	190.	6,517,534	02-11-2003	McGovern et al.	
	191.	6,530,922	03-11-2003	Cosman et al.	
	192.	6,533,987	03-18-2003	Topolkaraev et al.	
	193.	6,551,311	04-22-2003	Lee et al.	
	194.	6,562,033	05-13-2003	Shah et al.	
	195.	6,565,562	05-20-2003	Shah et al.	
	196.	6,569,159	05-27-2003	Edwards et al.	

Examiner Signature	Date Considered

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	Art Unit	3794
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	197.	6,575,967	06-10-2003	Leveen et al.	
	198.	6,575,969	06-10-2003	Rittman, III et al.	
	199.	6,585,735	07-01-2003	Frazier et al.	
	200.	6,602,249	08-05-2003	Stoddard et al.	
	201.	6,605,085	08-12-2003	Edwards	
	202.	6,610,054	08-26-2003	Edwards et al.	
	203.	6,622,731	09-23-2003	Daniel et al.	
	204.	6,623,481	09-23-2003	Garbagnati et al.	
	205.	6,632,221	10-14-2003	Edwards et al.	
	206.	6,632,222	10-14-2003	Edwards et al.	
	207.	6,638,275	10-28-2003	McGaffigan et al.	
	208.	6,641,580	11-04-2003	Edwards et al.	
	209.	6,645,201	11-11-2003	Utley et al.	
	210.	6,652,515	11-25-2003	Maguire et al.	
	211.	6,652,516	11-25-2003	Gough	
	212.	6,660,002	12-09-2003	Edwards et al.	
	213.	6,660,362	12-09-2003	Lindsay et al.	
	214.	6,663,624	12-16-2003	Edwards et al.	
	215.	6,669,693	12-30-2003	Friedman	
	216.	6,682,526	01-27-2004	Jones et al.	
	217.	6,682,528	01-27-2004	Frazier et al.	
	218.	6,685,701	02-03-2004	Orszulak et al.	
	219.	6,689,127	02-10-2004	Gough et al.	
	220.	6,690,210	02-10-2004	Hadjizada et al.	
	221.	6,692,490	02-17-2004	Edwards	
	222.	6,706,152	03-16-2004	Burazin et al.	
	223.	6,723,092	04-20-2004	Brown et al.	
	224.	6,743,226	06-01-2004	Cosman et al.	

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Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	225.	6,743,229	06-01-2004	Buysse et al.	
	226.	6,746,570	06-08-2004	Burazin et al.	
	227.	6,749,719	06-15-2004	Burazin et al.	
	228.	6,770,070	08-03-2004	Balbierz	
	229.	6,780,180	08-24-2004	Goble et al.	
	230.	6,803,549	10-12-2004	Yu	
	231.	6,814,712	11-09-2004	Edwards et al.	
	232.	6,837,956	01-04-2005	Cowell et al.	
	233.	6,846,448	01-25-2005	Rymer et al.	
	234.	6,847,848	01-25-2005	Sterzer et al.	
	235.	6,852,091	02-08-2005	Edwards et al.	
	236.	6,866,663	03-15-2005	Edwards et al.	
	237.	6,881,214	04-19-2005	Cosman et al.	
	238.	6,889,089	05-03-2005	Behl et al.	
	239.	6,896,675	05-24-2005	Leung et al.	
	240.	6,932,810	08-23-2005	Ryan	
	241.	6,958,062	10-25-2005	Gough et al.	
	242.	6,958,064	10-25-2005	Rioux et al.	
	243.	6,961,602	11-01-2005	Fuimaono et al.	
	244.	6,964,660	11-15-2005	Maguire et al.	
	245.	6,966,908	11-22-2005	Maguire et al.	
	246.	6,974,455	12-13-2005	Garabedian et al.	
	247.	6,997,925	02-14-2006	Maguire et al.	
	248.	7,025,767	04-11-2006	Schaefer et al.	
	249.	7,033,353	04-25-2006	Stoddard et al.	
	250.	7,044,949	05-16-2006	Orszulak et al.	
	251.	7,048,733	05-23-2006	Hartley et al.	
	252.	7,056,320	06-06-2006	Utley et al.	

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	253.	7,074,484	07-11-2006	Topolkaraev et al.	
	254.	7,076,399	07-11-2006	Godara	
	255.	7,087,051	08-08-2006	Bourne et al.	
	256.	7,099,712	08-29-2006	Fuimaono et al.	
	257.	7,108,696	09-19-2006	Daniel et al.	
	258.	7,112,197	09-26-2006	Hartley et al.	
	259.	7,115,124	10-03-2006	Xiao	
	260.	7,138,088	11-21-2006	Wariar et al.	
	261.	7,150,743	12-19-2006	Zvuloni et al.	
	262.	7,150,744	12-19-2006	Edwards et al.	
	263.	7,160,296	01-09-2007	Pearson et al.	
	264.	7,163,536	01-16-2007	Godara	
	265.	7,179,256	02-20-2007	Mest	
	266.	7,179,258	02-20-2007	Buysse et al.	
	267.	7,207,990	04-24-2007	Lands et al.	
	268.	7,258,688	08-21-2007	Shah et al.	
	269.	7,266,414	09-04-2007	Cornelius et al.	
	270.	7,270,660	09-18-2007	Ryan	
	271.	7,270,662	09-18-2007	Visram et al.	
	272.	7,276,064	10-02-2007	Paul et al.	
	273.	7,281,666	10-16-2007	Smith	
	274.	7,294,127	11-13-2007	Leung et al.	
	275.	7,306,596	12-11-2007	Hillier et al.	
	276.	7,311,702	12-25-2007	Tallarida et al.	
	277.	7,340,307	03-04-2008	Maguire et al.	
	278.	7,354,436	04-08-2008	Rioux et al.	
	279.	7,357,798	04-15-2008	Sharps et al.	
	280.	7,371,234	05-13-2008	Young	

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	281.	7,387,626	06-17-2008	Edwards et al.	
	282.	7,387,630	06-17-2008	Mest	
	283.	7,416,549	08-26-2008	Young et al.	
	284.	7,449,020	11-11-2008	Edwards et al.	
	285.	7,468,062	12-23-2008	Oral et al.	
	286.	7,480,533	01-20-2009	Cosman et al.	
	287.	7,517,346	04-14-2009	Sloan et al.	
	288.	7,524,318	04-28-2009	Young et al.	
	289.	7,533,002	05-12-2009	Godara	
	290.	7,549,986	06-23-2009	Rioux et al.	
	291.	7,561,907	07-14-2009	Fuimaono et al.	
	292.	7,593,778	09-22-2009	Chandran et al.	
	293.	7,596,469	09-29-2009	Godara	
	294.	7,615,050	11-10-2009	Cross et al.	
	295.	7,670,336	03-02-2010	Young et al.	
	296.	7,670,337	03-02-2010	Young	
	297.	7,678,106	03-16-2010	Lee	
	298.	7,699,844	04-20-2010	Utley et al.	
	299.	7,704,248	04-27-2010	Dicarlo	
	300.	7,771,420	08-10-2010	Butty et al.	
	301.	7,794,458	09-14-2010	McIntyre et al.	
	302.	7,794,459	09-14-2010	Faure	
	303.	7,797,049	09-14-2010	Christopherson et al.	
	304.	7,799,021	09-21-2010	Leung et al.	
	305.	7,815,571	10-19-2010	Deckman et al.	
	306.	7,819,869	10-26-2010	Godara et al.	
	307.	7,819,871	10-26-2010	Paul et al.	
	308.	7,824,404	11-02-2010	Godara et al.	

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	Art Unit	3794
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	309.	7,828,796	11-09-2010	Wong et al.	
	310.	7,874,986	01-25-2011	Deckman et al.	
	311.	7,875,025	01-25-2011	Cockburn et al.	
	312.	7,892,231	02-22-2011	Elliott	
	313.	7,896,874	03-01-2011	Young et al.	
	314.	2002/0026185	02-28-2002	Gough	
	315.	2002/0029037	03-07-2002	Kim	
	316.	2002/0188275	12-12-2002	McGuckin, Jr.	
	317.	2003/0018332	01-23-2003	Schmaltz et al.	
	318.	2003/0078595	04-24-2003	Cosman	
	319.	2004/0006336	01-08-2004	Swanson	
	320.	2004/0015176	01-22-2004	Cosman	
	321.	2004/0015218	01-22-2004	Finch et al.	
	322.	2004/0100376	05-27-2004	Lye et al.	
	323.	2004/0122482	06-24-2004	Tung et al.	
	324.	2004/0143262	07-22-2004	Visram et al.	
	325.	2004/0176759	09-09-2004	Krishnamurthy et al.	
	326.	2004/0230187	11-18-2004	Lee et al.	
	327.	2004/0260282	12-23-2004	Gough et al.	
	328.	2005/0033279	02-10-2005	Edwards et al.	
	329.	2005/0059964	03-17-2005	Fitz	
	330.	2005/0101944	05-12-2005	Williams	
	331.	2005/0101950	05-12-2005	Gough et al.	
	332.	2005/0165391	07-28-2005	Maguire et al.	
	333.	2005/0171522	08-04-2005	Christopherson	
	334.	2005/0177209	08-11-2005	Leung et al.	
	335.	2005/0177211	08-11-2005	Leung et al.	
	336.	2005/0203503	09-15-2005	Edwards et al.	

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	337.	2005/0234445	10-20-2005	Conquergood et al.	
	338.	2005/0240174	10-27-2005	Pearson et al.	
	339.	2005/0267552	12-01-2005	Conquergood et al.	
	340.	2005/0277918	12-15-2005	Shah et al.	
	341.	2006/0015161	01-19-2006	Longo et al.	
	342.	2006/0089635	04-27-2006	Young et al.	
	343.	2006/0095115	05-04-2006	Bladillah et al.	
	344.	2006/0111702	05-25-2006	Oral et al.	
	345.	2006/0122686	06-08-2006	Gilad et al.	
	346.	2006/0122692	06-08-2006	Gilad et al.	
	347.	2006/0142756	06-29-2006	Davies et al.	
	348.	2006/0173359	08-03-2006	Lin et al.	
	349.	2006/0189972	08-24-2006	Grossman	
	350.	2006/0200121	09-07-2006	Mowery	
	351.	2006/0206127	09-14-2006	Conquergood et al.	
	352.	2006/0206128	09-14-2006	Conquergood et al.	
	353.	2006/0206129	09-14-2006	Conquergood et al.	
	354.	2006/0206130	09-14-2006	Conquergood et al.	
	355.	2006/0206131	09-14-2006	Conquergood et al.	
	356.	2006/0206132	09-14-2006	Conquergood et al.	
	357.	2006/0206133	09-14-2006	Conquergood et al.	
	358.	2006/0206134	09-14-2006	Conquergood et al.	
	359.	2006/0217705	09-28-2006	Godara et al.	
	360.	2006/0247616	11-02-2006	Edwards et al.	
	361.	2006/0259026	11-16-2006	Godara et al.	
	362.	2006/0259027	11-16-2006	Kwan et al.	
	363.	2006/0271036	11-30-2006	Garabedian et al.	
	364.	2007/0006215	01-04-2007	Epstein et al.	

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	365.	2007/0016183	01-18-2007	Lee et al.	
	366.	2007/0027449	02-01-2007	Godara et al.	
	367.	2007/0060921	03-15-2007	Janssen et al.	
	368.	2007/0112342	05-17-2007	Pearson et al.	
	369.	2007/0118191	05-24-2007	Godara	
	370.	2007/0123964	05-31-2007	Davies et al.	
	371.	2007/0156136	07-05-2007	Godara et al.	
	372.	2007/0161905	07-12-2007	Munrow	
	373.	2007/0167943	07-19-2007	Janssen et al.	
	374.	2007/0179380	08-02-2007	Grossman	
	375.	2007/0179491	08-02-2007	Kratoska et al.	
	376.	2007/0185522	08-09-2007	Davies et al.	
	377.	2007/0203402	08-30-2007	Godara et al.	
	378.	2007/0203486	08-30-2007	Young	
	379.	2007/0260234	11-08-2007	Mccullagh et al.	
	380.	2007/0282321	12-06-2007	Shah et al.	
	381.	2008/0015569	01-17-2008	Saadat et al.	
	382.	2008/0033493	02-07-2008	Deckman et al.	
	383.	2008/0045939	02-21-2008	Lee	
	384.	2008/0045940	02-21-2008	Lee	
	385.	2008/0048786	02-28-2008	Feldkamp et al.	
	386.	2008/0065062	03-13-2008	Leung et al.	
	387.	2008/0154259	06-26-2008	Gough et al.	
	388.	2008/0167646	07-10-2008	Godara et al.	
	389.	2008/0167649	07-10-2008	Edwards et al.	
	390.	2008/0208121	08-28-2008	Youssef et al.	
	391.	2008/0228180	09-18-2008	Epstein	
	392.	2008/0228181	09-18-2008	Godara et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	16/933,811
	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 15 OF 20	Attorney Docket No.	NBUS.004C1C1

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16933811
Filing Date	2020-07-20
First Named Inventor	Robert E. Wright
Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2020-07-20
	First Named Inventor	Robert E. Wright
	Art Unit	3794
	Examiner Name	Christine A. Dedoulis
	Attorney Docket Number	NBUS.004C1C1

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See attached certification statement.

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

☒ A certification statement is not submitted herewith.

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

Signature	/Daniel C. Higgs/	Date (YYYY-MM-DD)	2020-10-19
Name/Print	Daniel C. Higgs	Registration Number	55265

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

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	2	DIROS TECHNOLOGY INC, Statement of Cross Claim, BIOMERICS LLC v DIROS TECHNOLOGY INC & M MEDICAL PTY LTD, NSD438/2019, FEDERAL COURT OF AUSTRALIA, May 13, 2019, 5 pages.
	3	DIROS TECHNOLOGY INC., RF Trident Cannulae, Last Accessed August 20, 2019, available at https://dirostech.com/product-details/rf-tridenttrident-hybrid-cannulae/, 7 pages.
	4	DIROS TECHNOLOGY INC., RF Trident Hybrid Cannulae, Last Accessed August 20, 2019, available at https://dirostech.com/product-details/rf-trident-hybrid-cannulae/, 10 pages.
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	6	AHMED ET AL., Principles of and Advances in Percutaneous Ablation, Radiology, February 2011, pp. 351-369, Vol. 258, No. 2.
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	17	CANADIAN INTELLECTUAL PROPERTY OFFICE, Notification of Requisition by the Examiner, Canadian Patent Application No. 2,778,997, June 9, 2017, 7 pages.	☐
	18	CANADIAN INTELLECTUAL PROPERTY OFFICE, Notification of Requisition by the Examiner, Canadian Patent Application No. 2,778,997, May 23, 2019, 5 pages.	☐
	19	INTELLECTUAL PROPERTY INDIA, Examination Report, Indian Patent Application No. 3638/DELNP/2012, March 13, 2019, 5 pages.	☐
	20	JAPAN PATENT OFFICE, Notice of Reasons for Rejection, Japanese Patent Application No. 2012-538056, February 2, 2015, 7 pages.	☒
	21	JAPAN PATENT OFFICE, Notice of Reasons for Rejection, Japanese Patent Application No. 2015-215570, October 24, 2016, 15 pages.	☒
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	27	EUROPEAN PATENT OFFICE, Communication Pursuant to Article 94(3) EPC, European Patent Application No. 11 783 944.9 - 1124, February 28, 2018, 4 pages.	☐
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	41	UNITED STATES PATENT AND TRADEMARK OFFICE, Applicant-Initiated Interview Summary, U.S. Patent Application No. 15/098,673, July 16, 2019, 4 pages.	☐
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Signature	/Daniel C. Higgs/	Date (YYYY-MM-DD)	2020-10-19
Name/Print	Daniel C. Higgs	Registration Number	55265

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Petitioner's Exhibit 1006
Avanos v. Stratus
Page 226 of 462

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(Not for submission under 37 CFR 1.99)

Application Number	16933811
Filing Date	2020-07-20
First Named Inventor	Robert E. Wright
Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

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	2	20070112340		2007-05-17	Thomas et al.	
	3	20080161804		2008-07-03	Rioux et al.	
	4	20080249392		2008-10-09	Mest	
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	1	EUROPEAN PATENT OFFICE, European Search Report and EPO Form 1703 01.91 TRI for European Patent Application No. EP 18215729.7, September 6, 2019, 5 pages.	

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	1	EUROPEAN PATENT OFFICE, Communication Under Rule 71(3) EPC for European Patent Application No. EP 11783944.9, December 18, 2019, 125 pages.	
	2	INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, Search Report for Brazilian Patent Application No. BR112012029263-3, December 6, 2019, 8 pages.	X
	3	UNITED STATES PATENT AND TRADEMARK OFFICE, Applicant-Initiated Interview Summary for U.S. Patent Application No. 15/098,673, February 14, 2020, 3 pages.	☐
	4	UNITED STATES PATENT AND TRADEMARK OFFICE, Form PTO/AIA/25, Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection over a Pending "Reference" Application for U.S. Patent Application No. 15/098,673, February 20, 2020, 2 pages.	☐
	5	UNITED STATES PATENT AND TRADEMARK OFFICE, Office Action in U.S. Patent Application No. 15/098,673, dated March 19, 2020, 37 pages.	☐
	6	CANADIAN INTELLECTUAL PROPERTY OFFICE, Office Action for Canadian Patent Application No. 2,799,505, dated 8 April 2020, 4 pages.	☐
	7	EUROPEAN PATENT OFFICE, Decision to Grant a European Patent Pursuant to Article 97(1) EPC for European Patent Application No. 11783944.9, dated 28 May 2020, 2 pages.	☐
	8	DAVID LAWSON MORRIS, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated 17 April 2020, 29 pages.	☐
	9	SUSANNE MONICA HANTOS, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated 21 April 2020, 765 pages.	☐
	10	PETER DARMOS, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated 21 April 2020, 716 pages.	☐
	11	WILLIAM SAMUAL HUNTER, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated 6 April 2020, 158 pages.	☐

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EFS ID:	40886430
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	19-OCT-2020
Filing Date:	20-JUL-2020
Time Stamp:	23:13:46
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	IDS_Grandparent_Parent_Resubmissions.pdf	112397 ddb5146376854a51ba0db648294bacb8613bc5f7	no	3

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4	Information Disclosure Statement (IDS) Form (SB08)	IDS_NBUS004C1C1_2.pdf	1036880 b810367abfd66ad475b0503c7ec58543ce730592	no	8
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6	Information Disclosure Statement (IDS) Form (SB08)	IDS_NBUS004C1C1_4.pdf	1034682 fcc83daf10c6883411bbfc22f8a908e72f33f0b1	no	4
Warnings:					
Information:					
7	Information Disclosure Statement (IDS) Form (SB08)	IDS_NBUS004C1C1_5_8.pdf	1035438 550a2ddd72b56863876e04c71a4a4c6829246a9d	no	5

Warnings:	
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Total Files Size (in bytes):	5586729

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Robert E. Wright	)	
Application No.:	16/933,811	)	Art Unit: 3794
Filing Date:	July 20, 2020	)	
Title:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	)	
Examiner:	Christine A. Dedoulis	)	
Confirmation No.:	1017	)	
Customer No.:	148468	)	

INFORMATION DISCLOSURE STATEMENT

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

Commissioner:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 488 references and five Forms PTO/SB/08a listing 79, 43, 2, 6, and 15 references, respectively. Each of these references is of record in U.S. Patent Application No. 15/092,945, titled SYSTEMS AND METHODS FOR TISSUE ABLATION, filed April 7, 2016 ("the Parent Application"), of which the present application is a continuation.

37 CFR § 1.97(b)(1)

The present information disclosure statements are being filed within three months of the filing date of the present national application. Accordingly, the Applicant

believes that no fees are required for consideration of the present information disclosure statements, pursuant to 37 C.F.R. § 1.97(b)(1).

References Have Already Been Considered

As the present application is a continuation of the Parent Application, the Applicant believes that the Examiner has already considered the references identified in the PTO/SB/08 Equivalent and the Forms PTO/SB/08a with respect to the present application, pursuant to MPEP § 609.02(II). Accordingly, the Applicant is submitting the present information disclosure statement to ensure these references are ultimately printed on the patent, pursuant to MPEP § 609.2(II).

Copies of All References Omitted

Pursuant to 37 C.F.R. § 1.98(a)(2), copies of U.S. patent application publications and U.S. patents are not required. Further, pursuant to 37 C.F.R. § 1.98(d), copies of the listed foreign patent documents and non-patent literature documents are not required because (1) the Parent Application has been properly identified in this information disclosure statement and is relied on for an earlier effective filing date under 35 U.S.C. § 120, and (2) all information disclosure statements submitted in the Parent Application comply with 37 C.F.R. § 1.98, paragraphs (a) through (c).

Table of U.S. Patent Applications

The Applicant provides the following table to aid the Examiner during prosecution:

Attorney Docket No.	Application No.	Filing Date	Title
NBUS.001A	12/940,974	2010-11-05	METHODS AND SYSTEMS FOR SPINAL RADIO FREQUENCY NEUROTOMY
NBUS.001C1	15/098,673	2016-04-14	METHODS AND SYSTEMS FOR SPINAL RADIO FREQUENCY NEUROTOMY
NBUS.001C1C1	16/933,995	2020-07-20	METHODS FOR RADIO FREQUENCY NEUROTOMY
NBUS.004A	13/101,009	2011-05-04	SYSTEMS AND METHODS FOR TISSUE ABLATION

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Avanos v. Stratus
Page 241 of 462

Attorney Docket No.	Application No.	Filing Date	Title
NBUS.004C1	15/092,945 ***(the Parent Application)***	2016-04-07	SYSTEMS AND METHODS FOR TISSUE ABLATION
NBUS.004C1C1	16/933,811 ***(the Present Application)***	2020-07-20	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

Copies of these patent applications, including any pending claims, office actions, notices of allowance, and/or other communications, are available through PALM and/or PAIR. However, if the Examiner so requests, the Applicant will be happy to provide the Examiner with copies of any applications, pending claims, office actions, notices of allowance, communications, or any other documents, at any time.

DATED this 19th day of October, 2020.

Respectfully submitted,

/Daniel C. Higgs/

Daniel C. Higgs
Attorney for Applicant
Registration No. 55,265

MED VENTURE HOLDINGS, LLC
6030 W. Harold Gatty Drive
Salt Lake City, Utah 84116
(801) 703-1961

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 242 of 462

PTO/SB/08a (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16933811
Filing Date	2020-07-20
First Named Inventor	Robert E. Wright
Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7918852	B2	2011-04-05	Tullis et al.	
	2	10716618	B2	2020-07-21	Wright et al.	
	3	10736688	B2	2020-08-11	Wright et al.	

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060206111	A1	2006-09-14	Young	
	2	20100049192	A1	2010-02-25	Holtz et al.	
	3	20090292259	A1	2009-11-26	Delano et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16933811
	Filing Date	2020-07-20
	First Named Inventor	Robert E. Wright
	Art Unit	3794
	Examiner Name	Christine A. Dedoulis
	Attorney Docket Number	NBUS.004C1C1

	4	20060095029	A1	2006-05-04	Young et al.			

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2571439	EP	B1	2020-06-24	Stratus Medical, LLC		

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

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	LESLIE W. ORGAN, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated July 5, 2020, 19 pages.	
	2	WILLIAM SAMUEL HUNTER, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated July 20, 2020, 32 pages.	
	3	MARC ANDREW RUSSO, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated July 20, 2020, 70 pages.	
	4	PETER DARMOS, Amended Statement of Cross Claim Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated June 5, 2020, 7 pages.	
	5	UNITED STATES PATENT AND TRADEMARK OFFICE, Notice of Allowance in U.S. Patent Application No. 16/933,995, dated October 15, 2020, 12 pages.	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16933811
	Filing Date	2020-07-20
	First Named Inventor	Robert E. Wright
	Art Unit	3794
	Examiner Name	Christine A. Dedoulis
	Attorney Docket Number	NBUS.004C1C1

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16933811
	Filing Date	2020-07-20
	First Named Inventor	Robert E. Wright
	Art Unit	3794
	Examiner Name	Christine A. Dedoulis
	Attorney Docket Number	NBUS.004C1C1

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Daniel C. Higgs/	Date (YYYY-MM-DD)	2020-10-19
Name/Print	Daniel C. Higgs	Registration Number	55265

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

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	40886446
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	19-OCT-2020
Filing Date:	20-JUL-2020
Time Stamp:	23:19:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS_NBUS004C1C1.pdf	1035161 8e422dd4ddbd528c5a64781ac101233675 96f806	no	5

Warnings:

Information:					
2	Foreign Reference	EP2571439B1.pdf	3971474 df61de1a73251fac8c39d53e0e165ad123403856	no	78
Warnings:					
Information:					
3	Non Patent Literature	Organ.pdf	738926 288ad4ac5e4b16b22cfa88e3becf679dd87aa237	no	19
Warnings:					
Information:					
4	Non Patent Literature	Hunter.pdf	481848 88d4724555e2988c3af1c5ef84187198c8e1784c	no	32
Warnings:					
Information:					
5	Non Patent Literature	Russo.pdf	1811383 b23ef14abcc591ae875ec7dd36d3ec87ef9a679c	no	70
Warnings:					
Information:					
6	Non Patent Literature	Darmos.pdf	5948379 6d9335a991d4830c6922596d9ab0b0d05a031c2d	no	7
Warnings:					
Information:					
7	Non Patent Literature	NBUS001C1C1_NOA.pdf	577262 75e69fc3fb0a77798bb15e7519df77a835dcc53d	no	12
Warnings:					
Information:					
			Total Files Size (in bytes):	14564433	

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New Applications Under 35 U.S.C. 111

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New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/933,811	07/20/2020	Robert E. Wright	NBUS.004C1C1

CONFIRMATION NO. 1017

148468
Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

PUBLICATION NOTICE

OC00000121156017

Title:NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

Publication No.US-2020-0345411-A1
Publication Date:11/05/2020

NOTICE OF PUBLICATION OF APPLICATION

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

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

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

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

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

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

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 251 of 462

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/933,811	Filing Date 07/20/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	11/19/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 29	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

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

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

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Robert E. Wright	)	
Application No.:	16/933,811	)	Art Unit: 3794
Filing Date:	July 20, 2020	)	
Title:	NEEDLES AND SYSTENS FOR RADIOFREQUEUNCY NEUROTOMY	)	
Examiner:	Christine A. Dedoulis	)	
Confirmation No.:	1017	)	
Customer No.:	148468	)	

AMENDMENT AND RESPONSE TO OFFICE ACTION

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

Commissioner:

Responsive to the Office Action dated August 19, 2020 ("the Office Action"), the Applicant respectfully requests reconsideration of the pending claims in view of the amendments and remarks herein.

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

Summary of the Interview begins on page 10.

Remarks begin on page 12.

PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) NBUS.004C1C1

In re Application of: Robert E. Wright et al.

Application No.: 16/933,811

Filed: July 20, 2020

For: NEELDES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

The applicant, Stratus Medical, LLC, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 10,736,688 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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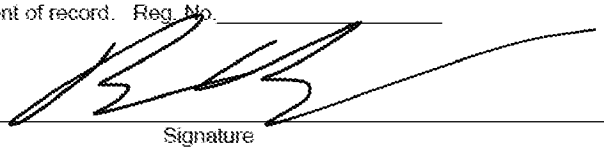
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is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☑ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

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

2. ☐ The undersigned is an attorney or agent of record. Reg. No. _____



Signature — November 19, 2020 (Date)

Bret Boudousquie
Typed or printed name

Chief Executive Officer (Title) — (801) 355-2705 (Telephone Number)

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

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

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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) NBUS.004C1C1

In re Application of: Robert E. Wright et al.

Application No.: 16/933,811

Filed: July 20, 2020

For: NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

The applicant, Stratus Medical, LLC, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 10,716,618 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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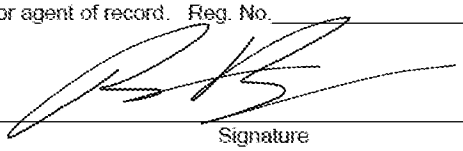
expires for failure to pay a maintenance fee;
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is found invalid by a court of competent jurisdiction;
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2. ☐ The undersigned is an attorney or agent of record. Reg. No. _____



Signature — November 19, 2020 (Date)

Bret Boudousquie
Typed or printed name

Chief Executive Officer (Title) — (801) 355-2705 (Telephone Number)

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

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Electronic Patent Application Fee Transmittal

Application Number:	16933811
Filing Date:	20-Jul-2020
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Filer:	Daniel Christopher Higgs
Attorney Docket Number:	NBUS.004C1C1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	2814	2	170	340
		Total in USD ($)		**340**

Electronic Acknowledgement Receipt

EFS ID:	41177206
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	19-NOV-2020
Filing Date:	20-JUL-2020
Time Stamp:	21:50:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$340
RAM confirmation Number	E2020AIL52025593
Deposit Account	602176
Authorized User	Daniel Higgs

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37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Amendment.pdf	131077 937bd05c415e28ae6812c5c418c2dccfd05c6ff2	yes	17

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Applicant Arguments/Remarks Made in an Amendment	12	17
Applicant summary of interview with examiner	10	11
Claims	2	9
Amendment/Req. Reconsideration-After Non-Final Reject	1	1

Warnings:

Information:

2	Terminal Disclaimer Filed	TD_over_001C1.pdf	514457 8a78582d750c6b2a4b286e89c0cdcf8816980915	no	2

Warnings:

Information:

3	Terminal Disclaimer Filed	TD_over_004C1.pdf	510634 a4ef86f3c6bc2596f2e31bcf045fca0d59ca85cb	no	2

Warnings:

Information:

4	Fee Worksheet (SB06)	fee-info.pdf	30573 43c7622dd65af0b61988f96ef7d74b647242b904	no	2

Warnings:

Information:

Total Files Size (in bytes):	1186741

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New Applications Under 35 U.S.C. 111

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

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

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New International Application Filed with the USPTO as a Receiving Office

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Remarks

This paper is submitted in response to the Office Action mailed August 19, 2020. Claims 1-29 were pending in the Application and stand rejected. By this paper, claims 1-22 and 24-29 are amended and claim 23 is cancelled without prejudice or disclaimer, and new claim 30 is added. The Applicant respectfully submits that all amendments are fully supported by the Application, as originally filed, and that none of the amendments add new matter to the Application.

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

Claims 1-29 stand rejected under 35 U.S.C. § 112(b) as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The Applicant respectfully traverses this rejection. However, in order to expedite prosecution of the present application, the Applicant has amended independent claims 1, 25, and 29, such that "a radiofrequency probe" is now positively recited. The Applicant thus respectfully requests that the rejections under 35 U.S.C. § 112 be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-12 and 16-29 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 7,918,852 to Tullis et al. ("Tullis") in view of U.S. Patent Application Publication No. 2006/0095029 of Young et al. ("Young I") and further in view of U.S. Patent Application Publication No. 2002/0143302 of Hinchliffe et al. ("Hinchliffe"); claim 13 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tullis in view of Young I and Hinchliffe and further in view of U.S. Patent Application Publication No. 2004/0260282 ("Gough"); and claims 14 and 15 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tullis in view of Young I and Hinchliffe and further in view of U.S. Patent Application Publication No. 2006/0084965 to Young ("Young III"). The Applicant respectfully traverses these

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rejections, and does not acquiesce to the characterizations of the teachings of the cited references, as set forth in the Office Action. However, in order to expedite prosecution of the present application, the Applicant has amended independent claims 1, 25, and 29.

As amended, independent claims 1, 25, and 29 recite (emphases added):

1. A system comprising:

a radiofrequency probe; and

a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:

a conductive portion at a distal end of the radiofrequency neurotomy needle;

a tip configured to pierce tissue of a patient;

an elongate member comprising a lumen configured to accept the radiofrequency probe therein such that the radiofrequency probe physically contacts and is electrically connected to the conductive portion, the tip being at a distal end of the elongate member;

a filament electrically connected to the conductive portion and the tip due to physical contact of conductive materials at the distal end of the radiofrequency neurotomy needle such that the filament and the tip operate together as a single electrode, the filament being movable between a retracted position, in which the filament is at least partially in the elongate member, and a deployed position, in which at least a portion of the filament is out of the elongate member; and

an actuator interconnected to the filament to move the

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filament between the retracted position and the deployed position,

wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle.

25. A system comprising:

a radiofrequency probe; and

a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:

a conductive portion at a distal end of the radiofrequency neurotomy needle;

a tip configured to pierce tissue of a patient;

a tube configured to accept the radiofrequency probe therein;

a filament electrically connected to the conductive portion at the distal end of the radiofrequency neurotomy needle due to physical contact, at the distal end of the radiofrequency neurotomy needle, of–conductive materials, wherein the filament and the tip are operative together as a single electrode, the filament being movable between a retracted position and a deployed position, a distal tip of the filament being closer to a central longitudinal axis of the radiofrequency neurotomy needle when the filament is in the retracted position as compared with when the filament is in the

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deployed position; and

an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,

wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle.

31. A system comprising:

a radiofrequency probe; and

a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:

an elongate member comprising a lumen configured to accept the radiofrequency probe therein;

a tip coupled to a distal end of the elongate member and being configured to pierce tissue of a patient, the tip comprising a conductive portion configured to physically contact a distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen;

a filament comprising a conductive material, the filament being electrically connected to the tip by way of physical contact with the tip at a distal end of the radiofrequency neurotomy needle such that the filament and the tip are operative together as a single electrode, the filament being movable between a retracted position, in which

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the filament is in a cross-sectional envelope of the tip, and a deployed position, in which a portion of the filament is outside the cross-sectional envelope of the tip; and

an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,

wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and in physical contact with the conductive portion of the tip.

Agreement was reached in the Examiner Interview conducted on November 16, 2020 ("the Interview," summarized above), that Tullis and Young I fail to teach or render obvious the systems recited in amended claims 1, 25, and 29 in view of at least the emphasized portions of these claims. Hinchliffe fails to remedy the shortcomings of Tullis and Young for at least the reason that Hinchliffe is directed to an apparatus for delivering fluid to treat a lesion, rather than radiofrequency ablation. Accordingly, the Applicant respectfully requests that the rejection under pre-AIA 35 U.S.C. § 103(b) of claims 1, 25, and 29 and all claims that depend from claims 1 and 25—namely, claims 2-24 and claims 26-28, respectively—be withdrawn.

New Claim 30

New claim 30 depends from independent claim 29, and thus is patentable over the cited art for at least the reasons discussed above with respect to claim 29.

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Double Patenting

Claims 1-29 stand rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-72 of U.S. Patent No. 10,716,618 and over claim 1 of U.S. Patent Application No. 15/098,673. The Applicant respectfully notes that U.S. Patent Application No. 15/098,673 has issued as U.S. Patent No. 10,736,688.

The Applicant respectfully traverses these rejections. Nevertheless, the Applicant is submitting herewith a separate Terminal Disclaimer with respect to each of the foregoing patents in order to expedite prosecution of the present application. The Applicant thus respectfully requests that the nonstatutory double patenting rejections be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, the Applicant submits that the Application is in condition for allowance and thus requests the issuance of a Notice of Allowance. Please contact the undersigned attorney in the event that any remaining impediment to the prompt allowance of this application is found that could be clarified by a telephonic interview or may be overcome by an Examiner's Amendment.

DATED this 19th day of November, 2020.

Respectfully submitted,

/Daniel C. Higgs/

Daniel C. Higgs
Attorney for the Applicant
Registration No. 55,265

MED VENTURE HOLDINGS, LLC
6030 W. Harold Gatty Drive
Salt Lake City, Utah 84116
(801) 703-1961

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Summary of the Interview

The Applicant thanks Examiner Christine A. Dedoulis and Examiner Eun Hwa Kim for the courtesy extended to Bret Boudousquie and Daniel C. Higgs in the WebEx/video conference interview ("the Interview") conducted on November 16, 2020. A summary of the Interview follows.

Exhibit/Demonstration

A web-based video demonstration was provided in which a commercial embodiment was shown.

Claims Discussed

Claims 1, 23-25, and 29 were discussed.

Prior Art Discussed

U.S. Patent No. 7,918,852 of Tullis et al. ("Tullis"), U.S. Patent Application Publication No. 2006/0095029 of Young et al. ("Young I"), and U.S. Patent Application Publication No. 2007/0203486 of Young ("Young II") were discussed.

Principal Proposed Amendments

Amendments such as those set forth in amended independent claims 1, 25, and 29 herein were discussed.

Principal Arguments

The Applicant requested clarification regarding the Examiner's combination of Tullis, Young I, and U.S. Patent Application Publication No. 2002/0143302 of Hinchliffe et al. ("Hinchliffe"), as detailed in the Office Action. The Applicant argued that the asserted combination failed to teach every limitation of original claim 1, and further, the references cannot properly be combined as proposed.

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The Examiner proposed incorporating certain limitations from dependent claims 23 and 24 into claim 1. Amendments to independent claims 25 and 29, such as presented herein, were also discussed.

Other Pertinent Matters Discussed

None.

Results

The Applicant thanks Examiner Dedoulis and Examiner Kim for the productive discussion of the Office Action and certain proposed amendments. Agreement was reached that amendments to independent claims 1, 25, and 29, such as those presented herein, overcome the § 112 and § 103 rejections of record.

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Amendments to the Claims

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

1. (Currently amended) A system comprising:

a radiofrequency probe; and

a radiofrequency neurotomy needle operable with [[a]]the radiofrequency probe, the radiofrequency neurotomy needle comprising:

a conductive portion at a distal end of the radiofrequency neurotomy needle;

a tip configured to pierce tissue of a patient;

an elongate member comprising a lumen configured to accept the radiofrequency probe therein such that the radiofrequency probe physically contacts and is electrically connected to the conductive portion, the tip being at a distal end of the elongate member;

a filament electrically connected to the conductive portion and the tip due to physical contact of conductive materials at the distal end of the radiofrequency neurotomy needle such that the filament and the tip operate together as a single electrode, the filament being movable between a retracted position, in which the filament is at least partially in the elongate member, and a deployed position, in which at least a portion of the filament is out of the elongate member; and

an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,

wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle.

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2. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 1, wherein the filament is formed of one of the conductive materials and the tip is formed of another of the conductive materials, and wherein the conductive materials of the filament and the tip are in physical contact when the filament is in the deployed position.

3. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 2, wherein the tip comprises the conductive portion at the distal end of the radiofrequency neurotomy needle, and wherein the conductive portion is configured to physically contact the distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen.

4. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 1, wherein the tip comprises the conductive portion at the distal end of the radiofrequency neurotomy needle.

5. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 4, wherein the conductive portion is configured to physically contact the distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen.

6. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 4, wherein the tip comprises a tip lumen that is configured to receive the distal end of the radiofrequency probe.

7. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 1, wherein the needle further comprises a tube that is separate from the elongate member, and wherein the tube is positioned within the elongate member.

8. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 7, wherein the lumen is within the tube.

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9. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 7, wherein the tube comprises the conductive portion of the needle.

10. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 1, wherein the tip and the elongate member are a single unitary structure or are separate components that are fixedly interconnected.

11. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 1, further comprising an additional filament electrically connected to the conductive portion such that both filaments and the tip operate together as the single electrode, wherein the additional filament is interconnected to the actuator such that both filaments are deployed and retracted by the actuator.

12. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 11, wherein when the filaments are deployed, the tip and the filaments are configured to produce a lesion at a target volume of tissue within the patient.

13. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 12, wherein when the tip and the filaments are configured to produce the lesion so as to be asymmetrical and offset relative to the central longitudinal axis of the radiofrequency neurotomy needle.

14. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 12, wherein when the filaments are deployed, distal tips of the filaments are distal to the tip of the radiofrequency neurotomy needle such that the filaments and the tip are configured to produce the lesion so as to be distally offset from the tip of the radiofrequency neurotomy needle.

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15. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 12, wherein the tip and the filaments are configured to operate together as the single electrode in a monopolar mode to produce the lesion to have a volume between about 250 mm^3 and about 750 mm^3.

16. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 12, wherein when the target volume includes a target nerve such that formation of the lesion ablates at least a portion of the target nerve to inhibit the ability of the target nerve to transmit pain signals.

17. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 1, wherein the lumen is further configured to accept the radiofrequency probe therein such that a distal end of the radiofrequency probe is proximate the tip when the radiofrequency probe physically contacts and is electrically connected to the conductive portion.

18. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 1, further comprising a fitting configured to provide a connection to a fluid source for injection of fluid through the lumen.

19. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 18, wherein the radiofrequency neurotomy needle is operable in a first state in which the radiofrequency probe is fully separated from the radiofrequency neurotomy needle in a non-inserted state and in which the fitting is connected to the fluid source for injection of fluid through the lumen, and wherein the radiofrequency neurotomy needle is operable in a second state in which the fitting is disconnected from the fluid source and in which the radiofrequency probe is inserted through the fitting into the lumen for delivery of the radiofrequency energy.

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20. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 1, wherein the actuator is configured to rotate about the central longitudinal axis to move the filament between the retracted position and the deployed position.

21. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 1, wherein a distal tip of the filament is closer to a central longitudinal axis of the radiofrequency neurotomy needle when the filament is in the retracted position as compared with when the filament is in the deployed position.

22. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 1, wherein the filament and the tip are configured to operate together as the single electrode in a monopolar mode when the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion.

23. (Cancelled)

24. (Currently amended) The system of ~~claim 23~~ claim 1, further comprising a radiofrequency generator and a return electrode pad that is configured to be attached to the patient, wherein the filament and the tip are configured to operate together as the single electrode in [[a]]the monopolar mode when ~~the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion and when~~ the electrode pad is attached to the patient to complete a circuit from the radiofrequency generator, through the radiofrequency probe, through the needle, through a portion of the patient, through the return electrode pad, and to the radiofrequency generator.

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25. (Currently amended) A system comprising:

a radiofrequency probe; and

a radiofrequency neurotomy needle operable with [[a]]the radiofrequency probe, the radiofrequency neurotomy needle comprising:

a conductive portion at a distal end of the radiofrequency neurotomy needle;

a tip ~~comprising a conductive material, the tip being~~ configured to pierce tissue of a patient;

a tube ~~comprising a conductive material, the tube being~~ configured to accept the radiofrequency probe therein;

a filament ~~comprising a conductive material, wherein the tip, the tube, and the filament are~~ electrically connected to the conductive portion at [[a]]the distal end of the radiofrequency neurotomy needle due to physical contact, at the distal end of the radiofrequency neurotomy needle, of ~~each of the conductive materials with at least one of the other conductive materials, such that~~ conductive materials, wherein the filament and the tip are operative together as a single electrode, the filament being movable between a retracted position and a deployed position, a distal tip of the filament being closer to a central longitudinal axis of the radiofrequency neurotomy needle when the filament is in the retracted position as compared with when the filament is in the deployed position; and

an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,

wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and in physical contact with ~~at least one of the conductive materials~~ the conductive portion at the distal end of the radiofrequency neurotomy needle.

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26. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 25, wherein ~~the tube is an elongate member, and wherein the tip is at the distal end of the elongate member~~ the filament is formed of one of the conductive materials and the tip is formed of another of the conductive materials, and wherein the conductive materials of the filament and the tip are in physical contact when the filament is in the deployed position.

27. (Currently amended) The ~~radiofrequency neurotomy needle of claim 25~~ system of claim 26, wherein the tip comprises the conductive portion at the distal end of the radiofrequency neurotomy needle, and wherein the conductive portion is configured to physically contact the distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen ~~further comprising an elongate member, the tip being at a distal end of the elongate member, wherein the tube is separate from the elongate member and is positioned within the elongate member~~.

28. (Currently amended) The ~~radiofrequency neurotomy needle~~ system of claim 25, wherein the tube comprises the conductive portion of the needle ~~tip comprises a lumen that is configured to receive the distal end of the radiofrequency probe~~.

29. (Currently amended) A system comprising:

a radiofrequency probe; and

a radiofrequency neurotomy needle operable with [[a]]the radiofrequency probe, the radiofrequency neurotomy needle comprising:

an elongate member comprising a lumen configured to accept the radiofrequency probe therein;

a tip coupled to a distal end of the elongate member and being configured to pierce tissue of a patient, the tip comprising a conductive ~~material~~ portion

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configured to physically contact a distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen;

a filament comprising a conductive material, the filament being electrically connected to the tip by way of physical contact with the tip at a distal end of the radiofrequency neurotomy needle such that the filament and the tip are operative together as a single electrode, the filament being movable between a retracted position, in which the filament is in a cross-sectional envelope of the tip, and a deployed position, in which a portion of the filament is outside the cross-sectional envelope of the tip; and

an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,

wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and in physical contact with the conductive ~~material~~ portion of the tip.

30. (New) The system of claim 29, wherein the tip comprises a further lumen that is configured to receive the distal end of the radiofrequency probe.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/933,811	07/20/2020	Robert E. Wright	NBUS.004C1C1	1017

148468 7590 11/20/2020

Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

EXAMINER
DEDOULIS, CHRISTINE A

ART UNIT	PAPER NUMBER
3794	

NOTIFICATION DATE	DELIVERY MODE
11/20/2020	ELECTRONIC

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

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

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

dhiggs@biomerics.com
dhiggs@medventureholdings.com

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Applicant-Initiated Interview Summary	**Application No.** 16/933,811	**Applicant(s)** Wright et al.		
	Examiner CHRISTINE A DEDOULIS	**Art Unit** 3794	**AIA (First Inventor to File) Status** No	**Page** 1 of 2

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
CHRISTINE A DEDOULIS	Examiner	WebEx/Video Conference
Eunhwa Kim	Primary Examiner	
Dan Higgs	Attorney of Record	
Bret Boudousquie	Stratus Medical CEO	

Date of Interview: 16 November 2020

Issues Discussed:

35 U.S.C. 103

There was a discussion regarding the 103 rejections of claims 1, 25 and 29. The Applicant gave a helpful overview of the device in view of the rejection and shared an updated video of how the device works. The Examiner explained that as currently recited the RF probe is not positively recited in the claims. The Examiner indicated that if claim 1 was amended to include the subject matter of claims 23 and 24 that the application may be in condition for allowance. As discussed, the claim would need to positively recite the probe, include the structural features of the electrical coupling at the distal end and recite the limitations regarding a single monopolar electrode. The Applicant expressed the intent to amend the independent claims to include these features.

There was also a discussion regarding the limitation "conductive material" in claims 25 and 29. The Applicant expressed the intent to change this language to read a conductive portion or something similar in order to further specify the structural relationship of the tip, tube, and filament at the distal end and how these structures are electrically connected with the probe.

/C.A.D./ Examiner, Art Unit 3794	/EUN HWA KIM/ Primary Examiner, Art Unit 3794

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

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Page 280 of 462

Applicant-Initiated Interview Summary	**Application No.** 16/933,811	**Applicant(s)** Wright et al.		
	Examiner CHRISTINE A DEDOULIS	**Art Unit** 3794	**AIA (First Inventor to File) Status** No	**Page** **2 of 2**

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

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PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16933811
Filing Date	2020-07-20
First Named Inventor	Robert E. Wright
Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16933811
	Filing Date	2020-07-20
	First Named Inventor	Robert E. Wright
	Art Unit	3794
	Examiner Name	Christine A. Dedoulis
	Attorney Docket Number	NBUS.004C1C1

	1	PETER DARMOS, Further Amended Statement of cross claim, as proposed for submission in Federal Court of Australia Case No. NSD 438 of 2019, dated October 2020, 7 pages.
	2	DAVID LAWSON MORRIS, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated October 21, 2020, 37 pages.
	3	UNITED STATES PATENT AND TRADEMARK OFFICE, Office Action in U.S. Patent Application No. 16/933,995, dated October 15, 2020, 49 pages.

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 283 of 462

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16933811
	Filing Date	2020-07-20
	First Named Inventor	Robert E. Wright
	Art Unit	3794
	Examiner Name	Christine A. Dedoulis
	Attorney Docket Number	NBUS.004C1C1

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Daniel C. Higgs/	Date (YYYY-MM-DD)	2020-11-24
Name/Print	Daniel C. Higgs	Registration Number	55265

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

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	16933811
Filing Date:	20-Jul-2020
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Filer:	Daniel Christopher Higgs
Attorney Docket Number:	NBUS.004C1C1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
		Total in USD ($)		**130**

Electronic Acknowledgement Receipt

EFS ID:	41207361
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	24-NOV-2020
Filing Date:	20-JUL-2020
Time Stamp:	01:38:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$130
RAM confirmation Number	E2020AN238520058
Deposit Account	602176
Authorized User	Daniel Higgs

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

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	FORM_PTO_SB_08a_IDS.pdf	1034575 a8a8ede15dcff906fda81597ca7aa72e41c522fc	no	4
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National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
* 16/933,811 *	16/933,811	Wright et al.	
	Examiner	**Art Unit**	
	DEDOULIS, CHRISTINE A	3794	

Document Code - DISQ	**Internal Document - DO NOT MAIL**

TERMINAL DISCLAIMER	☑ APPROVED	☐ DISAPPROVED
Date Filed: **19 November 2020**	**This patent is subject to a Terminal Disclaimer**	

Approved/Disapproved by:

/TRINA STEPTOE/

Technology Center: OPLC

Telephone: (571)272-2577

2 TD`s

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 291 of 462

PTO/AIA/25 (04-13)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION

Docket Number (Optional): NBUS.004C1C1

In re Application of: Robert E. Wright

Application No.: 16/933,811

Filed: July 20, 2020

For: NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

The applicant, Stratus Medical, LLC, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number 16/933,995, filed, July 20, 2020, as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

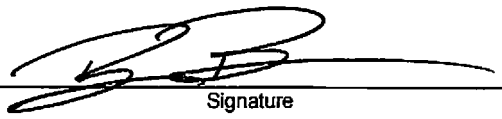
In making the above disclaimer, the applicant does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference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

Check either box 1 or 2 below, if appropriate.

1. ☑ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

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

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Signature — February 1, 2021 (Date)

Bret Boudousquie
Typed or printed name

Chief Executive Officer (Title) — (385) 707-3029 (Telephone Number)

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Privacy Act Statement

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	16933811
Filing Date:	20-Jul-2020
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Filer:	Daniel Christopher Higgs
Attorney Docket Number:	NBUS.004C1C1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
		Total in USD ($)		**170**

Electronic Acknowledgement Receipt

EFS ID:	41803463
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	01-FEB-2021
Filing Date:	20-JUL-2020
Time Stamp:	16:46:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$170
RAM confirmation Number	E202121G47163525
Deposit Account	602176
Authorized User	Daniel Higgs

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

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	Terminal_Disclaimer_001C1C1_final.pdf	183078 60a6f3cc58767be8fff5b5e68f1638db2f3366d5	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30542 4ce97636caa9fa2bae0fbfaf636499fe686b4b03	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	213620		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/AIA/25 (04-13)
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TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION	Docket Number (Optional) NBUS.004C1C1

In re Application of: Robert E. Wright

Application No.: 16/933,811

Filed: July 20, 2020

For: NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

The applicant, Stratus Medical, LLC, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number 16/933,995, filed, July 20, 2020, as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

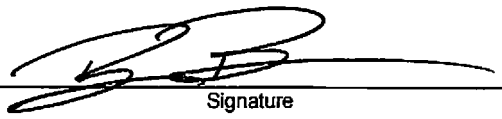
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Signature — February 1, 2021 (Date)

Bret Boudousquie
Typed or printed name

Chief Executive Officer (Title) — (385) 707-3029 (Telephone Number)

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

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Electronic Patent Application Fee Transmittal

Application Number:	16933811
Filing Date:	20-Jul-2020
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Filer:	Daniel Christopher Higgs
Attorney Docket Number:	NBUS.004C1C1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
		Total in USD ($)		**170**

Electronic Acknowledgement Receipt

EFS ID:	41802811
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	01-FEB-2021
Filing Date:	20-JUL-2020
Time Stamp:	16:20:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	Terminal_Disclaimer_001C1C1_final.pdf	183078 60a6f3cc58767be8fff5b5e68f1638db2f3366d5	no	2

Warnings:

Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30542 04a00fc0b561f40cab44b8368142f9425da68606	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	213620		

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New Applications Under 35 U.S.C. 111

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PTO/AIA/25 (04-13)
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In re Application of: Robert E. Wright

Application No.: 16/933,811

Filed: July 20, 2020

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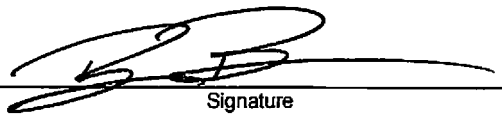
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Signature — February 1, 2021 (Date)

Bret Boudousquie
Typed or printed name

Chief Executive Officer (Title) — (385) 707-3029 (Telephone Number)

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	16933811
Filing Date:	20-Jul-2020
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Filer:	Daniel Christopher Higgs
Attorney Docket Number:	NBUS.004C1C1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
		Total in USD ($)		**170**

Electronic Acknowledgement Receipt

EFS ID:	41802710
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	01-FEB-2021
Filing Date:	20-JUL-2020
Time Stamp:	16:16:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	Terminal_Disclaimer_001C1C1_final.pdf	183078 60a6f3cc58767be8fff5b5e68f1638db2f3366d5	no	2

Warnings:

Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30542 83cfbeb76fea1c4206134a6b2aa819ee1b010b02	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	213620	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
* 16/933,811 *	16/933,811	Wright et al.	
	Examiner	**Art Unit**	
	DEDOULIS, CHRISTINE A	3794	

Document Code - DISQ	**Internal Document - DO NOT MAIL**

TERMINAL DISCLAIMER	☑ APPROVED	☐ DISAPPROVED
Date Filed: **01 February 2021**	**This patent is subject to a Terminal Disclaimer**	

Approved/Disapproved by:

/PAMELA A YOUNG/

Technology Center: OPLC

Telephone: (571)272-3622

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 310 of 462

UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

148468 7590 02/16/2021

Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

EXAMINER
DEDOULIS, CHRISTINE A

ART UNIT	PAPER NUMBER
3794	

DATE MAILED: 02/16/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/933,811	07/20/2020	Robert E. Wright	NBUS.004C1C1	1017

TITLE OF INVENTION: NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	05/17/2021

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

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

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

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

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

148468 7590 02/16/2021
Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/933,811	07/20/2020	Robert E. Wright	NBUS.004C1C1	1017

TITLE OF INVENTION: NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	05/17/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
DEDOULIS, CHRISTINE A	3794	606-041000

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

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

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

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

1 _____
2 _____
3 _____

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

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

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

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

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

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

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

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

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

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

Petitioner's Exhibit 1006
Avanos v. Stryker
Page 312 of 462

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/933,811	07/20/2020	Robert E. Wright	NBUS.004C1C1	1017

148468 7590 02/16/2021

Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

EXAMINER	
DEDOULIS, CHRISTINE A	
ART UNIT	PAPER NUMBER
3794	

DATE MAILED: 02/16/2021

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 16/933,811	Applicant(s) Wright et al.	
	Examiner CHRISTINE A DEDOULIS	Art Unit 3794	AIA (FITF) Status No

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

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

1. ☑ This communication is responsive to the amendment filed 11/19/2020.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-22 and 24-30 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

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

   Certified copies:

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

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

   * Certified copies not received: _____ .

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

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

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

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

Attachment(s)

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

/C.A.D./ Examiner, Art Unit 3794	/EUN HWA KIM/ Primary Examiner, Art Unit 3794

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 315 of 462

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Terminal Disclaimer

2. The terminal disclaimers filed on November 19th, 2020 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of **U.S. Pat. 10,736,688 and U.S. Pat. 10,716,618** have been reviewed and is accepted. The terminal disclaimers have been recorded.

3. The terminal disclaimer filed on February 1st, 2021 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of **co-pending application 16/933,995** has been reviewed and is accepted. The terminal disclaimer has been recorded.

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance: The most pertinent prior art of record is **Tullis et al., (U.S. Pat. 7,918,852)**, which teaches a similar system comprising a radiofrequency neurotomy needle (cannula 28 in Fig. 2) operable with a radiofrequency probe (electrode assembly 36 in Fig. 2). The radiofrequency neurotomy needle (28) comprises an elongate member (29) including a lumen configured to accept the radiofrequency probe (36) and comprises a tip (distal tip 58) coupled to the distal end of the elongate member (29) configured to pierce the tissue of the patient (col. 5, ll. 41-43). In the inserted state, the radiofrequency probe (36) is in physical contact with a conductive portion of the needle (28); tab (150) acts as a connector and facilitates the electrical connection between terminal (140) and associated terminal (86), thereby providing electrical contact with radiofrequency probe (28) and establishing an electrically conductive path.

5. While Tullis teaches a similar system comprising a radiofrequency neurotomy needle (cannula 28 in Fig. 2) operable with a radiofrequency probe (36 in Fig. 2), Tullis is silent regarding the limitations directed towards the filament.

6. **Young et al., (U.S. PGPub. No. 2006/0095029)** is another pertinent piece of prior art. Young teaches an ablation device (see Fig. 10) similar to that of Tullis and deploying a plurality of filaments (filaments 250 and 256) from a catheter body (catheter 216). Young further teaches disposing an RF probe (shaft 224, electrodes 225 and 226) within a lumen (293) that is connected to the plurality of filaments so that the RF probe electrically connects both the cannula and the plurality of filaments to an RF source ([0043],[0045] and [0052]). This configuration would allow for one or more electrodes to extend radially from the distal region of the needle so as to achieve desired energy paths and obtain a desired ablation tissue volume ([0057]-[0058]).

7. **Regarding claim 1**, while these references discuss the relationship between a needle apparatus, radiofrequency probe and a filament, these reference fail to teach "an elongate member comprising a lumen configured to accept the radiofrequency probe therein such that the *radiofrequency probe physically contacts and is electrically connected to the conductive portion*, *the tip being at a distal end of the elongate member; a filament electrically connected to the conductive portion and the tip due to physical contact of conductive materials at the distal end of the radiofrequency neurotomy needle such that the filament and the tip operate together as a single electrode…wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle*" as currently claimed in independent claim 1 in combination with the other limitations of the claim.

8. **Regarding claim 25,** while these references discuss the relationship between a needle apparatus, radiofrequency probe and a filament, these reference fail to teach "the radiofrequency neurotomy needle comprising: *a conductive portion at a distal end of the radiofrequency neurotomy needle…a filament electrically connected to the conductive portion at the distal end of the radiofrequency neurotomy needle due to physical contact, at the distal end of the radiofrequency neurotomy needle, of conductive materials, wherein the filament and the tip are operative together as a single electrode…* wherein the *filament and*

the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle" as currently claimed in independent claim 25 in combination with the other limitations of the claim.

9. **Regarding claim 29,** while these references discuss the relationship between a needle apparatus, radiofrequency probe and a filament, these reference fail to teach "a tip coupled to a distal end of the elongate member and being configured to pierce tissue of a patient, the *tip comprising a conductive portion configured to physically contact a distal end of the radiofrequency probe* when the radiofrequency probe is accepted in the lumen; *a filament comprising a conductive material, the filament being electrically connected to the tip by way of physical contact with the tip at a distal end of the radiofrequency neurotomy needle such that the filament and the tip are operative together as a single electrode…* wherein *the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and in physical contact with the conductive portion of the tip*" as currently claimed in independent claim 29 in combination with the other limitations of the claim.

10. The Examiner has failed to find any other reference which alone or in any fair combination would disclose, fairly suggest or make obvious each and every limitation set forth in independent claims 1, 25 and 29. Therefore, claims 1, 25 and 29 are patentable over the prior art.

11. Accordingly, claims 2-22, 24, 26-28 and 30 are allowed as being dependent on allowed independent claims.

12. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

13. **Claims 1-22 and 24-30 are allowed.**

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE A DEDOULIS whose telephone number is (571)272-2459. The examiner can normally be reached on M-F, 8am to 5pm.

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/C.A.D./
Examiner, Art Unit 3794

/EUN HWA KIM/
Primary Examiner, Art Unit 3794

Examiner-Initiated Interview Summary	**Application No.** 16/933,811	**Applicant(s)** Wright, Robert E.		
	Examiner CHRISTINE A DEDOULIS	**Art Unit** 3794	**AIA (First Inventor to File) Status** No	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
CHRISTINE A DEDOULIS	Examiner	Telephonic
Daniel Higgs	Attorney of Record	

Date of Interview: 30 January 2021

Issues Discussed:

Non-statutory Double Patenting

There was a discussion regarding the non-statutory double patenting over the instant application in view of co-pending application 16/933,995. The Applicant agreed to file a terminal disclaimer.

/Christine A Dedoulis/ Examiner, Art Unit 3794	/EUN HWA KIM/ Primary Examiner, Art Unit 3794

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/933,811	Wright et al.
	Examiner	Art Unit
	CHRISTINE A DEDOULIS	3794

CPC - Searched*		
Symbol	Date	Examiner
A61B2018/1427,00577,0044,1475,143,1253	08/10/2020	cd
A61B18/1477,1206,	08/10/2020	cd

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

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

Search Notes		
Search Notes	Date	Examiner
EAST (class, text, inventor, assignee) search	08/10/2020	cd
discussed application with Primary Eunhwa Kim	08/10/2020	cd
updated search	01/26/2021	cd

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	see attached EAST search history	01/26/2021	cd

/C.A.D./ Examiner, Art Unit 3794	/EUN HWA KIM/ Primary Examiner, Art Unit 3794

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	CHRISTINE A DEDOULIS	3794

CPC								
Symbol							Type	Version
A61B	/	18	/	1477			F	2013-01-01
A61B	/	2018	/	0044			A	2013-01-01
A61B	/	2018	/	1427			A	2013-01-01
A61B	/	2018	/	143			A	2013-01-01
A61B	/	2018	/	1475			A	2013-01-01
A61B	/	18	/	1206			A	2013-01-01
A61B	/	2018	/	00577			A	2013-01-01
A61B	/	2018	/	1253			A	2013-01-01

CPC Combination Sets								
Symbol					Type	Set	Ranking	Version
	/		/					

/Christine A Dedoulis/ Examiner, Art Unit 3794 (Assistant Examiner)	26 January 2021 (Date)	Total Claims Allowed: 29	
/EUN HWA KIM/ Primary Examiner, Art Unit 3794 (Primary Examiner)	29 January 2021 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 2A

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	16/933,811	Wright et al.
	Examiner	**Art Unit**
	CHRISTINE A DEDOULIS	3794

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B18/14	/	18	/	14	

NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

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

/Christine A Dedoulis/ Examiner, Art Unit 3794 (Assistant Examiner)	26 January 2021 (Date)	**Total Claims Allowed:** 29	
/EUN HWA KIM/ Primary Examiner, Art Unit 3794 (Primary Examiner)	29 January 2021 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 2A

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	16/933,811	Wright et al.
	Examiner	**Art Unit**
	CHRISTINE A DEDOULIS	3794

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

/Christine A Dedoulis/ Examiner, Art Unit 3794 (Assistant Examiner)	26 January 2021 (Date)	**Total Claims Allowed:** 29	
/EUN HWA KIM/ Primary Examiner, Art Unit 3794 (Primary Examiner)	29 January 2021 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 2A

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16933811
Filing Date	2020-07-20
First Named Inventor	Robert E. Wright
Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

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	1	BIOMERICS LLC, Statement of Claim, BIOMERICS LLC v DIROS TECHNOLOGY INC & M MEDICAL PTY LTD, NSD438/2019, FEDERAL COURT OF AUSTRALIA, March 22, 2019, 10 pages.	
	2	DIROS TECHNOLOGY INC, Statement of Cross Claim, BIOMERICS LLC v DIROS TECHNOLOGY INC & M MEDICAL PTY LTD, NSD438/2019, FEDERAL COURT OF AUSTRALIA, May 13, 2019, 5 pages.	
	3	DIROS TECHNOLOGY INC., RF Trident Cannulae, Last Accessed August 20, 2019, available at https://dirostech.com/product-details/rf-tridenttrident-hybrid-cannulae/, 7 pages.	
	4	DIROS TECHNOLOGY INC., RF Trident Hybrid Cannulae, Last Accessed August 20, 2019, available at https://dirostech.com/product-details/rf-trident-hybrid-cannulae/, 10 pages.	
	5	FOOD AND DRUG ADMINISTRATION, 510(k) Summary for Diros OWL Sterile Single Use Trident R.F. Insulated Cannulae Models DTR and DTRH, July 30, 2015, 11 pages.	
	6	AHMED ET AL., Principles of and Advances in Percutaneous Ablation, Radiology, February 2011, pp. 351-369, Vol. 258, No. 2.	
	7	CHEN ET AL., Optimizing Electrode Placement Using Finite-Element Models in Radiofrequency Ablation Treatment Planning, IEEE Transactions on Biomedical Engineering, February 2009, pp. 237-245, Vol. 56, No. 2.	
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	10	LAESEKE ET AL., Multiple-Electrode RF Ablation Creates Confluent Areas of Necrosis: Results in in vivo Porcine Liver, Radiology, October 2006, pp. 116-124.	
	11	QUARANTA ET AL., FEM Analysis of RF Breast Ablation: Multiprobe versus Cool-tip Electrode, Anticancer Research, 2007, pp. 775-784.	

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Avanos v. Stratus

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	12	SCHARF ET AL., Ablation of Persistent Atrial Fibrillation Using Multielectrode Catheters and Duty-Cycled Radiofrequency Energy, Journal of the American College of Cardiology, October 6, 2009, pp. 1450-1456, Vol. 54, No. 15.	
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	14	IP AUSTRALIA, Patent Examination Report No. 2, Australian Patent Application No. 2014200132, April 8, 2015, 3 pages.	
	15	IP AUSTRALIA, Examination Report No. 1 for standard patent application, Australian Patent Application No. 2015261694, September 27, 2017, 3 pages.	
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	17	CANADIAN INTELLECTUAL PROPERTY OFFICE, Notification of Requisition by the Examiner, Canadian Patent Application No. 2,778,997, June 9, 2017, 7 pages.	☐
	18	CANADIAN INTELLECTUAL PROPERTY OFFICE, Notification of Requisition by the Examiner, Canadian Patent Application No. 2,778,997, May 23, 2019, 5 pages.	☐
	19	INTELLECTUAL PROPERTY INDIA, Examination Report, Indian Patent Application No. 3638/DELNP/2012, March 13, 2019, 5 pages.	☐
	20	JAPAN PATENT OFFICE, Notice of Reasons for Rejection, Japanese Patent Application No. 2012-538056, February 2, 2015, 7 pages.	☒
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	23	CANADIAN INTELLECTUAL PROPRETY OFFICE, Notification of Requisition by the Examiner, Canadian Patent Application No. 2,799,505, March 17, 2017, 5 pages.	☐
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	25	CNIPA, NATIONAL INTELLECTUAL PROPERTY ADMINISTRATION, PRC, Office Action, Chinese Patent Application No. 201510151627.1, February 22, 2017, 8 pages.	☐
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	27	EUROPEAN PATENT OFFICE, Communication Pursuant to Article 94(3) EPC, European Patent Application No. 11 783 944.9 - 1124, February 28, 2018, 4 pages.	☐
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Petitioner's Exhibit 1006
Avanos v. Stratus

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	34	KOREAN INTELLECTUAL PROPERTY OFFICE, Notice to Submit Response, Korean Patent Application No. 10-2012-7033363, May 4, 2015, 14 pages.	☒
	35	KOREAN INTELLECTUAL PROPERTY OFFICE, Notice to Submit Response, Korean Patent Application No. 10-2015-7004378, September 25, 2017, 13 pages.	☒
	36	MEXICAN INSTITUTE OF INDUSTRIAL PROPERTY, Requirement 1, Mexican Patent Application No. MX/a/2012/013280, February 17, 2015, 4 pages.	☒
	37	MEXICAN INSTITUTE OF INDUSTRIAL PROPERTY, Requirement 2, Mexican Patent Application No. MX/a/2012/013280, May 27, 2015, 8 pages.	☒
	38	UNITED STATES PATENT AND TRADEMARK OFFICE, Office Action, U.S. Patent Application No. 12/940,974, March 16, 2015, 32 pages.	☐
	39	UNITED STATES PATENT AND TRADEMARK OFFICE, Office Action, U.S. Patent Application No. 15/098,673, September 11, 2018, 6 pages.	☐
	40	UNITED STATES PATENT AND TRADEMARK OFFICE, Office Action, U.S. Patent Application No. 15/098,673, June 18, 2019, 15 pages.	☐
	41	UNITED STATES PATENT AND TRADEMARK OFFICE, Applicant-Initiated Interview Summary, U.S. Patent Application No. 15/098,673, July 16, 2019, 4 pages.	☐
	42	UNITED STATES PATENT AND TRADEMARK OFFICE, Office Action, U.S. Patent Application No. 15/098,673, September 3, 2019, 17 pages.	☐
	43	UNITED STATES PATENT AND TRADEMARK OFFICE, Applicant-Initiated Interview Summary, U.S. Patent Application No. 15/098,673, September 18, 2019, 4 pages.	☐

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	Examiner Name	Christine A. Dedoulis
	Attorney Docket Number	NBUS.004C1C1

EXAMINER SIGNATURE			
Examiner Signature	/Christine A Dedoulis/	Date Considered	01/26/2021

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

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Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Daniel C. Higgs/	Date (YYYY-MM-DD)	2020-10-19
Name/Print	Daniel C. Higgs	Registration Number	55265

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

Petitioner's Exhibit 1006
Avanos v. Stratus

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

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

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

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

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

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

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

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

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

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Avanos v. Stratus

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Doc description: Information Disclosure Statement (IDS) Filed

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Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2008-516667	JP		2008-05-22	BOSTON SCIENTIFIC SCIMED, INC.		X

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

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

Petitioner's Exhibit 1006
Avanos v. Stratus

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.D./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16933811
	Filing Date	2020-07-20
	First Named Inventor	Robert E. Wright
	Art Unit	3794
	Examiner Name	Christine A. Dedoulis
	Attorney Docket Number	NBUS.004C1C1

	1	Office Action issued in Japanese Application No. 2012-538056, dated February 2, 2015.	X

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

EXAMINER SIGNATURE

Examiner Signature	/Christine A Dedoulis/	Date Considered	01/26/2021

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

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

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Avanos v. Stratus

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(Not for submission under 37 CFR 1.99)

Application Number	16933811
Filing Date	2020-07-20
First Named Inventor	Robert E. Wright
Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Daniel C. Higgs/	Date (YYYY-MM-DD)	2020-10-19
Name/Print	Daniel C. Higgs	Registration Number	55265

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

Petitioner's Exhibit 1006
Avanos v. Stratus

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Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

Petitioner's Exhibit 1006
Avanos v. Stratus

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PATENT APPLICATION
Docket No.: NBUS.004C1C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Robert E. Wright	
Application No.:	16/933,811	Art Unit: 3794
Filing Date:	July 20, 2020	
Title:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	
Examiner:	Christine A. Dedoulis	
Confirmation No.:	1017	
Customer No.:	148468	

INFORMATION DISCLOSURE STATEMENT

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

Commissioner:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 488 references and five Forms PTO/SB/08a listing 79, 43, 2, 6, and 15 references, respectively. Each of these references is of record in U.S. Patent Application No. 15/092,945, titled SYSTEMS AND METHODS FOR TISSUE ABLATION, filed April 7, 2016 ("the Parent Application"), of which the present application is a continuation.

37 CFR § 1.97(b)(1)

The present information disclosure statements are being filed within three months of the filing date of the present national application. Accordingly, the Applicant

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believes that no fees are required for consideration of the present information disclosure statements, pursuant to 37 C.F.R. § 1.97(b)(1).

References Have Already Been Considered

As the present application is a continuation of the Parent Application, the Applicant believes that the Examiner has already considered the references identified in the PTO/SB/08 Equivalent and the Forms PTO/SB/08a with respect to the present application, pursuant to MPEP § 609.02(II). Accordingly, the Applicant is submitting the present information disclosure statement to ensure these references are ultimately printed on the patent, pursuant to MPEP § 609.2(II).

Copies of All References Omitted

Pursuant to 37 C.F.R. § 1.98(a)(2), copies of U.S. patent application publications and U.S. patents are not required. Further, pursuant to 37 C.F.R. § 1.98(d), copies of the listed foreign patent documents and non-patent literature documents are not required because (1) the Parent Application has been properly identified in this information disclosure statement and is relied on for an earlier effective filing date under 35 U.S.C. § 120, and (2) all information disclosure statements submitted in the Parent Application comply with 37 C.F.R. § 1.98, paragraphs (a) through (c).

Table of U.S. Patent Applications

The Applicant provides the following table to aid the Examiner during prosecution:

Attorney Docket No.	Application No.	Filing Date	Title
NBUS.001A	12/940,974	2010-11-05	METHODS AND SYSTEMS FOR SPINAL RADIO FREQUENCY NEUROTOMY
NBUS.001C1	15/098,673	2016-04-14	METHODS AND SYSTEMS FOR SPINAL RADIO FREQUENCY NEUROTOMY
NBUS.001C1C1	16/933,995	2020-07-20	METHODS FOR RADIO FREQUENCY NEUROTOMY
NBUS.004A	13/101,009	2011-05-04	SYSTEMS AND METHODS FOR TISSUE ABLATION

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.T./

Attorney Docket No.	Application No.	Filing Date	Title
NBUS.004C1	15/092,945 ***(the Parent Application)***	2016-04-07	SYSTEMS AND METHODS FOR TISSUE ABLATION
NBUS.004C1C1	16/933,811 ***(the Present Application)***	2020-07-20	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

Copies of these patent applications, including any pending claims, office actions, notices of allowance, and/or other communications, are available through PALM and/or PAIR. However, if the Examiner so requests, the Applicant will be happy to provide the Examiner with copies of any applications, pending claims, office actions, notices of allowance, communications, or any other documents, at any time.

DATED this 19th day of October, 2020.

Respectfully submitted,

/Daniel C. Higgs/

Daniel C. Higgs
Attorney for Applicant
Registration No. 55,265

MED VENTURE HOLDINGS, LLC
6030 W. Harold Gatty Drive
Salt Lake City, Utah 84116
(801) 703-1961

/Christine A Dedoulis/ 01/26/2021

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	16/933,811
	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 1 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1.	D372,086	07-23-1996	Grasso et al.	
	2.	RE40,279	04-29-2008	Sluijter et al.	
	3.	RE40,388	06-17-2008	Gines	
	4.	4,011,872	03-15-1977	Kamiya	
	5.	4,206,761	06-10-1980	Cosman	
	6.	4,206,762	06-10-1980	Cosman	
	7.	4,281,667	08-04-1981	Cosman	
	8.	4,353,371	10-12-1982	Cosman	
	9.	4,375,220	03-01-1983	Matvias	
	10.	4,378,809	04-05-1983	Cosman	
	11.	4,385,636	05-31-1983	Cosman	
	12.	4,411,266	10-25-1983	Cosman	
	13.	4,565,200	01-21-1986	Cosman	
	14.	4,573,980	03-04-1986	Karrasch et al.	
	15.	4,583,538	04-22-1986	Onik et al.	
	16.	4,593,703	06-10-1986	Cosman	
	17.	4,618,978	10-21-1986	Cosman	
	18.	4,646,752	03-03-1987	Swann et al.	
	19.	4,653,508	03-31-1987	Cosman	
	20.	4,660,568	04-28-1987	Cosman	
	21.	4,676,255	06-30-1987	Cosman	
	22.	4,698,207	10-06-1987	Bringham et al.	
	23.	4,787,886	11-29-1988	Cosman	
	24.	4,796,615	01-10-1989	Bullock et al.	
	25.	4,827,927	05-09-1989	Newton	
	26.	4,838,265	06-13-1989	Cosman et al.	
	27.	4,886,506	12-12-1989	Lovgren et al.	
	28.	4,907,589	03-13-1990	Cosman	

Examiner Signature	Date Considered

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

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PTO/SB/08 Equivalent

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	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 2 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	29.	4,966,597	10-30-1990	Cosman	
	30.	5,010,897	04-30-1991	Leveen	
	31.	5,160,337	11-03-1992	Cosman	
	32.	5,217,457	06-08-1993	Delahuerga et al.	
	33.	5,230,623	07-27-1993	Guthrie et al.	
	34.	5,233,515	08-03-1993	Cosman	
	35.	5,244,462	09-14-1993	Delahuerga et al.	
	36.	5,257,630	11-02-1993	Braitman et al.	
	37.	5,291,896	03-08-1994	Fonger et al.	
	38.	5,304,114	04-19-1994	Cosman et al.	
	39.	5,304,115	04-19-1994	Pflueger et al.	
	40.	5,312,329	05-17-1994	Beaty et al.	
	41.	5,312,391	05-17-1994	Wilk	
	42.	5,318,013	06-07-1994	Wilk	
	43.	5,324,255	06-28-1994	Passafaro et al.	
	44.	5,334,183	08-02-1994	Wuchinich	
	45.	5,342,292	08-30-1994	Nita et al.	
	46.	5,370,645	12-06-1994	Klicek et al.	
	47.	5,370,675	12-06-1994	Edwards et al.	
	48.	5,372,596	12-13-1994	Klicek et al.	
	49.	5,377,685	01-03-1995	Kazi et al.	
	50.	5,397,301	03-14-1995	Pflueger et al.	
	51.	5,401,272	03-28-1995	Perkins	
	52.	5,421,923	06-06-1995	Clarke et al.	
	53.	5,422,567	06-06-1995	Matsunaga	
	54.	5,423,809	06-13-1995	Klicek	
	55.	5,433,739	07-18-1995	Sluijter et al.	
	56.	5,447,417	09-05-1995	Kuhl et al.	

Examiner Signature	Date Considered

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	16/933,811
	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 3 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	57.	5,458,597	10-17-1995	Edwards et al.	
	58.	5,472,441	12-05-1995	Edwards et al.	
	59.	5,472,442	12-05-1995	Klicek	
	60.	5,474,057	12-12-1995	Makower et al.	
	61.	5,484,398	01-16-1996	Stoddard	
	62.	5,496,312	03-05-1996	Klicek	
	63.	5,507,743	04-16-1996	Edwards et al.	
	64.	5,511,564	04-30-1996	Wilk	
	65.	5,514,129	05-07-1996	Smith	
	66.	5,536,267	07-16-1996	Edwards et al.	
	67.	5,541,376	07-30-1996	Ladtkow et al.	
	68.	5,560,358	10-01-1996	Arnold et al.	
	69.	5,562,703	10-08-1996	Desai	
	70.	5,571,147	11-05-1996	Sluijter et al.	
	71.	5,580,665	12-03-1996	Taguchi et al.	
	72.	5,599,345	02-04-1997	Edwards et al.	
	73.	5,599,346	02-04-1997	Edwards et al.	
	74.	5,611,709	03-18-1997	McAnulty	
	75.	5,613,966	03-25-1997	Makower et al.	
	76.	5,628,743	05-13-1997	Cimino	
	77.	5,662,111	09-02-1997	Cosman	
	78.	5,662,620	09-02-1997	Lieber et al.	
	79.	5,662,680	09-02-1997	Desai	
	80.	5,667,488	09-16-1997	Lundquist et al.	
	81.	5,669,904	09-23-1997	Platt, Jr. et al.	
	82.	5,672,173	09-30-1997	Gough et al.	
	83.	5,672,174	09-30-1997	Gough et al.	
	84.	5,683,349	11-04-1997	Makower et al.	

Examiner Signature	Date Considered

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	First Named Inventor	Robert E. Wright
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SHEET 4 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

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	85.	5,683,384	11-04-1997	Gough et al.	
	86.	5,701,575	12-23-1997	Taguchi et al.	
	87.	5,720,744	02-24-1998	Eggleston et al.	
	88.	5,728,143	03-17-1998	Gough et al.	
	89.	5,735,847	04-07-1998	Gough et al.	
	90.	5,738,648	04-14-1998	Lands et al.	
	91.	5,748,703	05-05-1998	Cosman	
	92.	5,749,689	05-12-1998	Konig	
	93.	5,755,754	05-26-1998	Rudie et al.	
	94.	5,768,679	06-16-1998	Taguchi et al.	
	95.	5,772,659	06-30-1998	Becker et al.	
	96.	5,778,043	07-07-1998	Cosman	
	97.	5,782,827	07-21-1998	Gough et al.	
	98.	5,792,146	08-11-1998	Cosman	
	99.	5,797,906	08-25-1998	Rhum et al.	
	100.	5,800,484	09-01-1998	Gough et al.	
	101.	5,807,309	09-15-1998	Lundquist et al.	
	102.	5,810,804	09-22-1998	Gough et al.	
	103.	5,827,271	10-27-1998	Buysse et al.	
	104.	5,827,276	10-27-1998	LeVeen et al.	
	105.	5,848,967	12-15-1998	Cosman	
	106.	5,855,576	01-05-1999	LeVeen et al.	
	107.	5,863,290	01-26-1999	Gough et al.	
	108.	5,868,740	02-09-1999	LeVeen et al.	
	109.	5,911,739	06-15-1999	Kordis et al.	
	110.	5,913,855	06-22-1999	Gough et al.	
	111.	5,921,992	07-13-1999	Costales et al.	
	112.	5,925,042	07-20-1999	Gough et al.	

Examiner Signature	Date Considered

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	113.	5,928,229	07-27-1999	Gough et al.	
	114.	5,935,123	08-10-1999	Edwards et al.	
	115.	5,951,547	09-14-1999	Gough et al.	
	116.	5,968,040	10-19-1999	Swanson et al.	
	117.	5,980,517	11-09-1999	Gough	
	118.	5,983,141	11-09-1999	Sluijter et al.	
	119.	6,006,126	12-21-1999	Cosman	
	120.	6,013,076	01-11-2000	Goble et al.	
	121.	6,014,590	01-11-2000	Whayne et al.	
	122.	6,015,406	01-18-2000	Goble et al.	
	123.	6,016,452	01-18-2000	Kasevich	
	124.	6,039,733	03-21-2000	Buysse et al.	
	125.	6,041,260	03-21-2000	Stern et al.	
	126.	6,044,846	04-04-2000	Edwards	
	127.	6,050,992	04-18-2000	Nichols	
	128.	6,053,937	04-25-2000	Edwards et al.	
	129.	6,059,780	05-09-2000	Gough et al.	
	130.	6,068,627	05-30-2000	Orszulak et al.	
	131.	6,071,280	06-06-2000	Edwards et al.	
	132.	6,080,150	06-27-2000	Gough	
	133.	6,090,105	07-18-2000	Zepeda et al.	
	134.	6,106,521	08-22-2000	Blewett et al.	
	135.	6,117,134	09-12-2000	Cunningham et al.	
	136.	6,122,341	09-19-2000	Butler et al.	
	137.	6,129,726	10-10-2000	Edwards et al.	
	138.	6,132,425	10-17-2000	Gough	
	139.	6,139,519	10-31-2000	Blythe	
	140.	6,139,547	10-31-2000	Lontine et al.	

Examiner Signature	Date Considered

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Petitioner's Exhibit 1006
Avanos v. Stratus

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	16/933,811
	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 6 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	141.	6,143,003	11-07-2000	Cosman	
	142.	6,146,380	11-14-2000	Racz et al.	
	143.	6,161,048	12-12-2000	Sluijter et al.	
	144.	6,165,169	12-26-2000	Panescu et al.	
	145.	6,167,295	12-26-2000	Cosman	
	146.	6,179,834	01-30-2001	Buysse et al.	
	147.	6,210,403	04-03-2001	Klicek	
	148.	6,213,999	04-10-2001	Platt, Jr. et al.	
	149.	6,217,554	04-17-2001	Green	
	150.	6,228,080	05-08-2001	Gines	
	151.	6,228,083	05-08-2001	Lands et al.	
	152.	6,231,570	05-15-2001	Tu et al.	
	153.	6,234,178	05-22-2001	Goble et al.	
	154.	6,235,023	05-22-2001	Lee et al.	
	155.	6,241,725	06-05-2001	Cosman	
	156.	6,241,726	06-05-2001	Chia et al.	
	157.	6,246,912	06-12-2001	Sluijter et al.	
	158.	6,251,106	06-26-2001	Becker et al.	
	159.	6,259,952	07-10-2001	Sluijter et al.	
	160.	6,268,200	07-31-2001	Tucker et al.	
	161.	6,275,725	08-14-2001	Cosman	
	162.	6,277,117	08-21-2001	Tetzlaff et al.	
	163.	6,280,441	08-28-2001	Ryan	
	164.	6,312,426	11-06-2001	Goldberg et al.	
	165.	6,330,478	12-11-2001	Lee et al.	
	166.	6,331,180	12-18-2001	Cosman et al.	
	167.	6,334,861	01-01-2002	Chandler et al.	
	168.	6,352,536	03-05-2002	Buysse et al.	

Examiner Signature	Date Considered

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PTO/SB/08 Equivalent

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	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
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U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	169.	6,402,743	06-11-2002	Orszulak et al.	
	170.	6,402,747	06-11-2002	Lindermann et al.	
	171.	6,405,072	06-11-2002	Cosman	
	172.	6,416,520	07-09-2002	Kynast et al.	
	173.	6,419,653	07-16-2002	Edwards et al.	
	174.	6,419,680	07-16-2002	Cosman et al.	
	175.	6,419,798	07-16-2002	Topolkaraev et al.	
	176.	6,425,887	07-30-2002	McGuckin et al.	
	177.	6,440,127	08-27-2002	McGovern et al.	
	178.	6,447,477	09-10-2002	Burney et al.	
	179.	6,447,505	09-10-2002	McGovern et al.	
	180.	6,451,018	09-17-2002	Lands et al.	
	181.	6,454,765	09-24-2002	Leveen et al.	
	182.	6,458,130	10-01-2002	Frazier et al.	
	183.	6,459,769	10-01-2002	Cosman	
	184.	6,464,704	10-15-2002	Schmaltz et al.	
	185.	6,468,273	10-22-2002	Leveen et al.	
	186.	6,471,698	10-29-2002	Edwards et al.	
	187.	6,478,793	11-12-2002	Cosman et al.	
	188.	6,500,175	12-31-2002	Gough et al.	
	189.	6,506,189	01-14-2003	Rittman, III et al.	
	190.	6,517,534	02-11-2003	McGovern et al.	
	191.	6,530,922	03-11-2003	Cosman et al.	
	192.	6,533,987	03-18-2003	Topolkaraev et al.	
	193.	6,551,311	04-22-2003	Lee et al.	
	194.	6,562,033	05-13-2003	Shah et al.	
	195.	6,565,562	05-20-2003	Shah et al.	
	196.	6,569,159	05-27-2003	Edwards et al.	

Examiner Signature	Date Considered

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PTO/SB/08 Equivalent

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	Application No.	16/933,811
	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
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U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	197.	6,575,967	06-10-2003	Leveen et al.	
	198.	6,575,969	06-10-2003	Rittman, III et al.	
	199.	6,585,735	07-01-2003	Frazier et al.	
	200.	6,602,249	08-05-2003	Stoddard et al.	
	201.	6,605,085	08-12-2003	Edwards	
	202.	6,610,054	08-26-2003	Edwards et al.	
	203.	6,622,731	09-23-2003	Daniel et al.	
	204.	6,623,481	09-23-2003	Garbagnati et al.	
	205.	6,632,221	10-14-2003	Edwards et al.	
	206.	6,632,222	10-14-2003	Edwards et al.	
	207.	6,638,275	10-28-2003	McGaffigan et al.	
	208.	6,641,580	11-04-2003	Edwards et al.	
	209.	6,645,201	11-11-2003	Utley et al.	
	210.	6,652,515	11-25-2003	Maguire et al.	
	211.	6,652,516	11-25-2003	Gough	
	212.	6,660,002	12-09-2003	Edwards et al.	
	213.	6,660,362	12-09-2003	Lindsay et al.	
	214.	6,663,624	12-16-2003	Edwards et al.	
	215.	6,669,693	12-30-2003	Friedman	
	216.	6,682,526	01-27-2004	Jones et al.	
	217.	6,682,528	01-27-2004	Frazier et al.	
	218.	6,685,701	02-03-2004	Orszulak et al.	
	219.	6,689,127	02-10-2004	Gough et al.	
	220.	6,690,210	02-10-2004	Hadjizada et al.	
	221.	6,692,490	02-17-2004	Edwards	
	222.	6,706,152	03-16-2004	Burazin et al.	
	223.	6,723,092	04-20-2004	Brown et al.	
	224.	6,743,226	06-01-2004	Cosman et al.	

Examiner Signature	Date Considered

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Petitioner's Exhibit 1006
Avanos v. Stratus

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	16/933,811
	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 9 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	225.	6,743,229	06-01-2004	Buysse et al.	
	226.	6,746,570	06-08-2004	Burazin et al.	
	227.	6,749,719	06-15-2004	Burazin et al.	
	228.	6,770,070	08-03-2004	Balbierz	
	229.	6,780,180	08-24-2004	Goble et al.	
	230.	6,803,549	10-12-2004	Yu	
	231.	6,814,712	11-09-2004	Edwards et al.	
	232.	6,837,956	01-04-2005	Cowell et al.	
	233.	6,846,448	01-25-2005	Rymer et al.	
	234.	6,847,848	01-25-2005	Sterzer et al.	
	235.	6,852,091	02-08-2005	Edwards et al.	
	236.	6,866,663	03-15-2005	Edwards et al.	
	237.	6,881,214	04-19-2005	Cosman et al.	
	238.	6,889,089	05-03-2005	Behl et al.	
	239.	6,896,675	05-24-2005	Leung et al.	
	240.	6,932,810	08-23-2005	Ryan	
	241.	6,958,062	10-25-2005	Gough et al.	
	242.	6,958,064	10-25-2005	Rioux et al.	
	243.	6,961,602	11-01-2005	Fuimaono et al.	
	244.	6,964,660	11-15-2005	Maguire et al.	
	245.	6,966,908	11-22-2005	Maguire et al.	
	246.	6,974,455	12-13-2005	Garabedian et al.	
	247.	6,997,925	02-14-2006	Maguire et al.	
	248.	7,025,767	04-11-2006	Schaefer et al.	
	249.	7,033,353	04-25-2006	Stoddard et al.	
	250.	7,044,949	05-16-2006	Orszulak et al.	
	251.	7,048,733	05-23-2006	Hartley et al.	
	252.	7,056,320	06-06-2006	Utley et al.	

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	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 10 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

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	253.	7,074,484	07-11-2006	Topolkaraev et al.	
	254.	7,076,399	07-11-2006	Godara	
	255.	7,087,051	08-08-2006	Bourne et al.	
	256.	7,099,712	08-29-2006	Fuimaono et al.	
	257.	7,108,696	09-19-2006	Daniel et al.	
	258.	7,112,197	09-26-2006	Hartley et al.	
	259.	7,115,124	10-03-2006	Xiao	
	260.	7,138,088	11-21-2006	Wariar et al.	
	261.	7,150,743	12-19-2006	Zvuloni et al.	
	262.	7,150,744	12-19-2006	Edwards et al.	
	263.	7,160,296	01-09-2007	Pearson et al.	
	264.	7,163,536	01-16-2007	Godara	
	265.	7,179,256	02-20-2007	Mest	
	266.	7,179,258	02-20-2007	Buysse et al.	
	267.	7,207,990	04-24-2007	Lands et al.	
	268.	7,258,688	08-21-2007	Shah et al.	
	269.	7,266,414	09-04-2007	Cornelius et al.	
	270.	7,270,660	09-18-2007	Ryan	
	271.	7,270,662	09-18-2007	Visram et al.	
	272.	7,276,064	10-02-2007	Paul et al.	
	273.	7,281,666	10-16-2007	Smith	
	274.	7,294,127	11-13-2007	Leung et al.	
	275.	7,306,596	12-11-2007	Hillier et al.	
	276.	7,311,702	12-25-2007	Tallarida et al.	
	277.	7,340,307	03-04-2008	Maguire et al.	
	278.	7,354,436	04-08-2008	Rioux et al.	
	279.	7,357,798	04-15-2008	Sharps et al.	
	280.	7,371,234	05-13-2008	Young	

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	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 11 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

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	281.	7,387,626	06-17-2008	Edwards et al.	
	282.	7,387,630	06-17-2008	Mest	
	283.	7,416,549	08-26-2008	Young et al.	
	284.	7,449,020	11-11-2008	Edwards et al.	
	285.	7,468,062	12-23-2008	Oral et al.	
	286.	7,480,533	01-20-2009	Cosman et al.	
	287.	7,517,346	04-14-2009	Sloan et al.	
	288.	7,524,318	04-28-2009	Young et al.	
	289.	7,533,002	05-12-2009	Godara	
	290.	7,549,986	06-23-2009	Rioux et al.	
	291.	7,561,907	07-14-2009	Fuimaono et al.	
	292.	7,593,778	09-22-2009	Chandran et al.	
	293.	7,596,469	09-29-2009	Godara	
	294.	7,615,050	11-10-2009	Cross et al.	
	295.	7,670,336	03-02-2010	Young et al.	
	296.	7,670,337	03-02-2010	Young	
	297.	7,678,106	03-16-2010	Lee	
	298.	7,699,844	04-20-2010	Utley et al.	
	299.	7,704,248	04-27-2010	Dicarlo	
	300.	7,771,420	08-10-2010	Butty et al.	
	301.	7,794,458	09-14-2010	McIntyre et al.	
	302.	7,794,459	09-14-2010	Faure	
	303.	7,797,049	09-14-2010	Christopherson et al.	
	304.	7,799,021	09-21-2010	Leung et al.	
	305.	7,815,571	10-19-2010	Deckman et al.	
	306.	7,819,869	10-26-2010	Godara et al.	
	307.	7,819,871	10-26-2010	Paul et al.	
	308.	7,824,404	11-02-2010	Godara et al.	

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	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 12 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

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	309.	7,828,796	11-09-2010	Wong et al.	
	310.	7,874,986	01-25-2011	Deckman et al.	
	311.	7,875,025	01-25-2011	Cockburn et al.	
	312.	7,892,231	02-22-2011	Elliott	
	313.	7,896,874	03-01-2011	Young et al.	
	314.	2002/0026185	02-28-2002	Gough	
	315.	2002/0029037	03-07-2002	Kim	
	316.	2002/0188275	12-12-2002	McGuckin, Jr.	
	317.	2003/0018332	01-23-2003	Schmaltz et al.	
	318.	2003/0078595	04-24-2003	Cosman	
	319.	2004/0006336	01-08-2004	Swanson	
	320.	2004/0015176	01-22-2004	Cosman	
	321.	2004/0015218	01-22-2004	Finch et al.	
	322.	2004/0100376	05-27-2004	Lye et al.	
	323.	2004/0122482	06-24-2004	Tung et al.	
	324.	2004/0143262	07-22-2004	Visram et al.	
	325.	2004/0176759	09-09-2004	Krishnamurthy et al.	
	326.	2004/0230187	11-18-2004	Lee et al.	
	327.	2004/0260282	12-23-2004	Gough et al.	
	328.	2005/0033279	02-10-2005	Edwards et al.	
	329.	2005/0059964	03-17-2005	Fitz	
	330.	2005/0101944	05-12-2005	Williams	
	331.	2005/0101950	05-12-2005	Gough et al.	
	332.	2005/0165391	07-28-2005	Maguire et al.	
	333.	2005/0171522	08-04-2005	Christopherson	
	334.	2005/0177209	08-11-2005	Leung et al.	
	335.	2005/0177211	08-11-2005	Leung et al.	
	336.	2005/0203503	09-15-2005	Edwards et al.	

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	First Named Inventor	Robert E. Wright
	Art Unit	3794
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SHEET 13 OF 20	Attorney Docket No.	NBUS.004C1C1

U.S. PATENT DOCUMENTS

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	337.	2005/0234445	10-20-2005	Conquergood et al.	
	338.	2005/0240174	10-27-2005	Pearson et al.	
	339.	2005/0267552	12-01-2005	Conquergood et al.	
	340.	2005/0277918	12-15-2005	Shah et al.	
	341.	2006/0015161	01-19-2006	Longo et al.	
	342.	2006/0089635	04-27-2006	Young et al.	
	343.	2006/0095115	05-04-2006	Bladillah et al.	
	344.	2006/0111702	05-25-2006	Oral et al.	
	345.	2006/0122686	06-08-2006	Gilad et al.	
	346.	2006/0122692	06-08-2006	Gilad et al.	
	347.	2006/0142756	06-29-2006	Davies et al.	
	348.	2006/0173359	08-03-2006	Lin et al.	
	349.	2006/0189972	08-24-2006	Grossman	
	350.	2006/0200121	09-07-2006	Mowery	
	351.	2006/0206127	09-14-2006	Conquergood et al.	
	352.	2006/0206128	09-14-2006	Conquergood et al.	
	353.	2006/0206129	09-14-2006	Conquergood et al.	
	354.	2006/0206130	09-14-2006	Conquergood et al.	
	355.	2006/0206131	09-14-2006	Conquergood et al.	
	356.	2006/0206132	09-14-2006	Conquergood et al.	
	357.	2006/0206133	09-14-2006	Conquergood et al.	
	358.	2006/0206134	09-14-2006	Conquergood et al.	
	359.	2006/0217705	09-28-2006	Godara et al.	
	360.	2006/0247616	11-02-2006	Edwards et al.	
	361.	2006/0259026	11-16-2006	Godara et al.	
	362.	2006/0259027	11-16-2006	Kwan et al.	
	363.	2006/0271036	11-30-2006	Garabedian et al.	
	364.	2007/0006215	01-04-2007	Epstein et al.	

Examiner Signature	Date Considered

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	16/933,811
	Filing Date	July 20, 2020
	First Named Inventor	Robert E. Wright
	Art Unit	3794
(Multiple sheets used when necessary)	Examiner	Christine A. Dedoulis
SHEET 14 OF 20	Attorney Docket No.	NBUS.004C1C1

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Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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U.S. PATENT DOCUMENTS

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Petitioner's Exhibit 1006
Avanos v. Stratus

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

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Examiner Signature /Christine A Dedoulis/	Date Considered 01/26/2021

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Petitioner's Exhibit 1006
Avanos v. Stratus

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16933811
Filing Date	2020-07-20
First Named Inventor	Robert E. Wright
Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	15	20170065335		2017-03-09	Wright et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16933811
Filing Date	2020-07-20
First Named Inventor	Robert E. Wright
Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2017203754	AU		2017-06-22	Diros Technology Inc.		
	2	1211171	CN	A	1999-03-17	RITA MEDICAL SYSTEMS, INC.		X
	3	1338909	CN	A	2002-03-06	Transurgical, Inc.		☒
	4	2418844	CN		2001-02-14	LOW TEMPERATURE TECHNOLOGY TESTING CENTER		☒
	5	1645235	EP	B1	2010-11-08	Covidien AG		☐
	6	1059067	EP	B1	2005-04-06	Sherwood Services AG		☐
	7	2003-527888	JP		2003-09-24	NEOTHERMIA CORPORATION		☒
	8	2009-504201	JP		2009-02-05	HALT MEDICAL, INC.		☒
	9	4290894	JP	B2	2009-04-10	ASUROKEA CORP		☒
	10	2001-527428	JP		2001-12-25	VIDAMED, INC.		☒

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	11	2004-267759	JP		2004-09-30	Depuy Acromed, Inc.		☒
	12	2013-509966	JP		2013-03-21	Wright et al.		☒
	13	96/04860	WO		1996-02-22	ZOMED INTERNATIONAL, INC.		☐
	14	96/16606	WO		1996-06-06	VIDAMED, INC.		☐
	15	97/29702	WO		1997-08-21	RITA MEDICAL SYSTEMS, INC.		☐
	16	97/06740	WO		1997-02-27	GOUGH et al.		☐
	17	97/06855	WO		1997-02-27	GOUGH et al.		☐
	18	97/06857	WO		1997-02-27	GOUGH et al.		☐
	19	99/25260	WO		1999-05-27	RITA MEDICAL SYSTEMS, INC.		☐
	20	00/06046	WO		2000-02-10	RADIOTHERAPEUTICS CORPORATION		☐
	21	01/28446	WO		2001-04-26	NEOTHERMIA CORPORATION		☐

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	22	01/57655	WO		2001-08-09	BAYLOR COLLEGE OF MEDICINE		☐
	23	02/22032	WO		2002-03-21	RADIOTHERAPEUTICS CORPORATION		☐
	24	02/54941	WO		2002-07-18	RITA MEDICAL SYSTEMS, INC.		☐
	25	2006/044105	WO		2006-04-27	BOSTON SCIENTIFIC SCIMED, INC.		☐
	26	2006/104682	WO		2006-10-05	YOUNG		☐
	27	2007/005830	WO		2007-01-11	HALT MEDICAL, INC.		☐
	28	2008/083044	WO		2008-07-10	BOSTON SCIENTIFIC SCIMED, INC.		☐
	29	2011/113943	WO		2011-09-22	VESALIUS MEDICAL TECHNOLOGIES BVBA		☐
	30	2011/146243	WO		2011-11-24	NIMBUS CONCEPTS, LLC		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5

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Examiner Signature	/Christine A Dedoulis/	Date Considered	01/26/2021

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

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

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CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Daniel C. Higgs/	Date (YYYY-MM-DD)	2020-10-19
Name/Print	Daniel C. Higgs	Registration Number	55265

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

Petitioner's Exhibit 1006
Avanos v. Stratus

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

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

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

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

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

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

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

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

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

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

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

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Avanos v. Stratus

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

PTO/SB/08a (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7918852	B2	2011-04-05	Tullis et al.	
	2	10716618	B2	2020-07-21	Wright et al.	
	3	10736688	B2	2020-08-11	Wright et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060206111	A1	2006-09-14	Young	
	2	20100049192	A1	2010-02-25	Holtz et al.	
	3	20090292259	A1	2009-11-26	Delano et al.	

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	4	20060095029	A1	2006-05-04	Young et al.	

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	1	2571439	EP	B1	2020-06-24	Stratus Medical, LLC		

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	LESLIE W. ORGAN, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated July 5, 2020, 19 pages.	
	2	WILLIAM SAMUEL HUNTER, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated July 20, 2020, 32 pages.	
	3	MARC ANDREW RUSSO, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated July 20, 2020, 70 pages.	
	4	PETER DARMOS, Amended Statement of Cross Claim Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated June 5, 2020, 7 pages.	
	5	UNITED STATES PATENT AND TRADEMARK OFFICE, Notice of Allowance in U.S. Patent Application No. 16/933,995, dated October 15, 2020, 12 pages.	

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EXAMINER SIGNATURE			
Examiner Signature	/Christine A Dedoulis/	Date Considered	01/26/2021

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Name/Print	Daniel C. Higgs	Registration Number	55265

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	0	(EP-18215729-$ | VA-223131450-$).DID.	US-PGPUB; USPAT	OR	ON	2021/01/27 09:27
L2	0	(EP-18215729-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/01/27 09:27
L3	14	(US-10716618-$ | US-10736688-$ | US-16933811-$ | US-20060095029-$ | US-20060206111-$ | US-20090292259-$ | US-20100049192-$ | US-2571439-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/01/27 09:28
L4	1	(16/933995).APP.	US-PGPUB; USPAT	OR	ON	2021/01/27 09:28
L5	0	(AI-20060095029-$ | AI-20060206111-$ | AI-20090292259-$ | AI-20100049192-$ | EP-2571439-$ | VA-223131450-$).DID.	US-PGPUB; USPAT	OR	ON	2021/01/27 09:28
L6	53	(US-1059067-$ | US-1211171-$ | US-1290894-$ | US-1338909-$ | US-1645235-$ | US-16933811-$ | US-20020022864-$ | US-20020133148-$ | US-20030199862-$ | US-20040064137-$ | US-20060095029-$ | US-20060206111-$ | US-20070010809-$ | US-20070213703-$ | US-20080249523-$ | US-20090292259-$ | US-20090306604-$ | US-20100049192-$ | US-20110184403-$ | US-20130096549-$ | US-20170065335-$ | US-3262574-$ | US-3402560-$ | US-3512330-$ | US-3518037-$ | US-3675406-$ | US-3753335-$ | US-5045532-$ | US-5105581-$ | US-5210406-$ | US-5216043-$ | US-5221071-$ | US-5287304-$ | US-5383917-$ | US-5461314-$ | US-5471695-$ | US-5486161-$ | US-5699242-$ | US-5740080-$ | US-5749846-$ | US-	US-PGPUB; USPAT	OR	ON	2021/01/27 09:28

		5752804-$ | US-5893847-$ | US-5962587-$ | US-5989004-$ | US-7318822-$ | US-7344533-$ | US-7393351-$ | US-7399299-$ | US-7416549-$ | US-7419487-$ | US-7458971-$ | US-7678107-$ | US-7846157-$ | US-7896871-$).DID.				
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4646752-$ | US-4653508-$ | US-
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4698207-$ | US-4787886-$ | US-
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		0234445-$ | US-0240174-$ | US-0247616-$ | US-0249392-$ | US-0259026-$ | US-0259027-$ | US-0260234-$ | US-0260282-$ | US-0267552-$ | US-0269558-$ | US-0269739-$ | US-0271036-$ | US-0275443-$ | US-0277918-$ | US-0282321-$ | US-0287081-$ | US-0287996-$ | US-0299358-$ | US-1234567-$ | US-20010012956-$ | US-20020026185-$ | US-20020029037-$ | US-20020143302-$ | US-20020188275-$ | US-20030018332-$ | US-20030078595-$ | US-20040006336-$ | US-20040015176-$ | US-20040015218-$ | US-20040059328-$ | US-20040100376-$ | US-20040122482-$ | US-20040143262-$ | US-20040158239-$ | US-20040176759-$ | US-20040199179-$ | US-20040230187-$ | US-20040260282-$ | US-20050033279-$ | US-20050059964-$ | US-20050085804-$ | US-20050101944-$ | US-20050101950-$ | US-20050165391-$ | US-20050171522-$ | US-20050177209-$ | US-20050177211-$ | US-20050203503-$ | US-20050234445-$ | US-20050240174-$ | US-20050267552-$ | US-20050277918-$ | US-20060015161-$ | US-20060084965-$ | US-20060089635-$ | US-20060095115-$ | US-20060111702-$ | US-20060122686-$ | US-20060122692-$ | US-20060142756-$ | US-20060173359-$ | US-20060189972-$ | US-20060200121-$ | US-20060206127-$ | US-20060206128-$ | US-20060206129-$ | US-20060206130-$ | US-20060206131-$ | US-20060206132-$ | US-20060206133-$ | US-20060206134-$ | US-20060217705-$ | US-20060229645-$ | US-20060247616-$ | US-20060259026-$ | US-20060259027-$ | US-20060271036-$ | US-20070006215-$ | US-20070016183-$).DID.				
L9	98	((needle or cannula) and probe and filament).clm.	US-PGPUB; USPAT	OR	ON	2021/01/27 09:34

L16	138	(US-20070112340-$ | US-0004651-$ | US-0006215-$ | US-0006336-$ | US-0012956-$ | US-0015161-$ | US-0015176-$ | US-0015218-$ | US-0015569-$ | US-0016183-$ | US-0018332-$ | US-0024124-$ | US-0026185-$ | US-0027449-$ | US-0029037-$ | US-0033279-$ | US-0033493-$ | US-0042098-$ | US-0045939-$ | US-0045940-$ | US-0048786-$ | US-0054962-$ | US-0056926-$ | US-0059328-$ | US-0059964-$ | US-0060921-$ | US-0065062-$ | US-0071832-$ | US-0076303-$ | US-0078595-$ | US-0084965-$ | US-0089635-$ | US-0095115-$ | US-0099544-$ | US-0099980-$ | US-0100376-$ | US-0101944-$ | US-0101950-$ | US-0111702-$ | US-0112340-$ | US-0112342-$ | US-0114095-$ | US-0118191-$ | US-0122482-$ | US-0122686-$ | US-0122692-$ | US-0123964-$ | US-0130974-$ | US-0131790-$ | US-0138011-$ | US-0142756-$ | US-0143262-$ | US-0143302-$ | US-0154259-$ | US-0156136-$ | US-0158239-$ | US-0161804-$ | US-0161905-$ | US-0165391-$ | US-0167646-$ | US-0167649-$ | US-0167943-$ | US-0171522-$ | US-0173359-$ | US-0176759-$ | US-0177209-$ | US-0177211-$ | US-0179380-$ | US-0179491-$ | US-0185082-$ | US-0185522-$ | US-0187177-$ | US-0187182-$ | US-0187183-$ | US-0188275-$ | US-0189972-$ | US-0198232-$ | US-0200121-$ | US-0203402-$ | US-0203486-$ | US-0203503-$ | US-0206127-$ | US-0206128-$ | US-0206129-$ | US-0206130-$ | US-0206131-$ | US-0206132-$ | US-0206133-$ | US-0206134-$ | US-0208121-$ | US-0213356-$ | US-0217705-$ | US-0221998-$ | US-0222677-$ | US-0228001-$ | US-0228180-$ | US-0228181-$ | US-0230187-$ | US-0234445-$ | US-0240174-$ | US-0247616-$ | US-0248001-$ | US-0249392-$ | US-0259026-$ | US-0259027-$ | US-0260234-$ | US-	US-PGPUB; USPAT	OR	ON	2021/01/27 09:39

		0260282-$ | US-0267552-$ | US-0269558-$ | US-0269739-$ | US-0271036-$ | US-0275443-$ | US-0276539-$ | US-0277918-$ | US-0282321-$ | US-0287081-$ | US-0287996-$ | US-0299358-$ | US-0343542-$ | US-10084965-$ | US-10829203-$ | US-11505900-$ | US-11969039-$ | US-1234567-$ | US-12423024-$ | US-12940974-$ | US-14281667-$ | US-14385636-$ | US-14583538-$ | US-14653508-$ | US-14787886-$ | US-14886506-$ | US-15092945-$ | US-15160337-$ | US-15244462-$ | US-15304115-$ | US-15324255-$ | US-15370675-$ | US-15401272-$ | US-15433739-$ | US-15472442-$ | US-15507743-$ | US-15541376-$ | US-15580665-$ | US-15613966-$ | US-15662680-$ | US-15672174-$ | US-15720744-$ | US-15748703-$ | US-15772659-$ | US-15797906-$ | US-15827271-$ | US-15863290-$ | US-15921992-$ | US-15951547-$ | US-15964773-$ | US-16006126-$ | US-16016452-$ | US-16050992-$ | US-16061963-$ | US-16071280-$ | US-16117134-$ | US-16139519-$ | US-16161048-$ | US-16210403-$ | US-16228083-$ | US-16241725-$ | US-16482178-$ | US-16673093-$ | US-16689103-$ | US-18125712-$ | US-19753966-$ | US-20020010460-$ | US-20020013602-$ | US-20020045434-$ | US-20020049436-$ | US-20020068929-$ | US-20020120260-$ | US-20020120261-$ | US-20020120263-$ | US-20020128638-$ | US-20020143302-$ | US-20020156469-$ | US-20020183731-$ | US-20020188275-$ | US-20020193778-$ | US-20030036752-$ | US-20030109912-$).DID.				
L17	155	(US-20030130575-$ | US-20030181896-$ | US-20030195436-$ | US-20030220635-$ | US-20030220674-$ | US-20040006336-$ | US-20040024391-$ | US-20040082943-$ | US-20040092875-$ | US-20040100376-$ | US-20040122482-$ | US-20040143252-$	US-PGPUB; USPAT	OR	ON	2021/01/27 09:39

| US-20040162551-$ | US-20040167505-$ | US-20040176759-$ | US-20040191229-$ | US-20040204705-$ | US-20040210212-$ | US-20040215178-$ | US-20040215294-$ | US-20040215295-$ | US-20040220497-$ | US-20040220648-$ | US-20040225276-$ | US-20040243116-$ | US-20040267248-$ | US-20040267257-$ | US-20050004563-$ | US-20050033279-$ | US-20050101950-$ | US-20050177147-$ | US-20050177148-$ | US-20050177209-$ | US-20050182394-$ | US-20050203505-$ | US-20050203593-$ | US-20050209565-$ | US-20050209587-$ | US-20050224086-$ | US-20050228288-$ | US-20050234445-$ | US-20050251103-$ | US-20050261753-$ | US-20050276759-$ | US-20050277918-$ | US-20050281530-$ | US-20050283148-$ | US-20060009712-$ | US-20060015092-$ | US-20060069385-$ | US-20060079914-$ | US-20060084962-$ | US-20060089688-$ | US-20060095115-$ | US-20060111732-$ | US-20060122692-$ | US-20060129142-$ | US-20060142785-$ | US-20060173469-$ | US-20060189968-$ | US-20060189972-$ | US-20060190035-$ | US-20060200117-$ | US-20060206128-$ | US-20060206131-$ | US-20060206134-$ | US-20060212028-$ | US-20060212048-$ | US-20060223052-$ | US-20060224149-$ | US-20060229645-$ | US-20060258951-$ | US-20060259029-$ | US-20070203486-$ | US-20070060921-$ | US-20070088217-$ | US-20070123964-$ | US-20070129714-$ | US-20070156125-$ | US-20070161975-$ | US-20070167943-$ | US-20070167959-$ | US-20070179509-$ | US-20070198071-$ | US-20070225781-$ | US-20070255362-$ | US-20070260234-$ | US-20070270925-$ | US-20080027523-$ | US-20080033493-$ | US-20080051775-$ | US-

		20080051776-$ | US-20080077201-$ | US-20080077202-$ | US-20080077211-$ | US-20080154254-$ | US-20080183164-$ | US-20080200910-$ | US-20080269739-$ | US-20080287839-$ | US-20090018623-$ | US-20090018624-$ | US-20090018625-$ | US-20090018626-$ | US-20090018627-$ | US-20090054962-$ | US-20090118722-$ | US-20090138011-$ | US-20090171334-$ | US-20090187183-$ | US-20090228001-$ | US-20090248001-$ | US-20090264876-$ | US-20090299357-$ | US-20091105-$ | US-20100004651-$ | US-20100076303-$ | US-20100114191-$ | US-20100130974-$ | US-20100168725-$ | US-20100198207-$ | US-20100305439-$ | US-20100331883-$ | US-20100623-$ | US-20110144631-$ | US-20110178514-$ | US-20110196267-$ | US-20110288540-$ | US-20120065629-$ | US-20120089211-$ | US-20120259322-$ | US-20120265187-$ | US-20130053851-$ | US-20130253605-$ | US-20130324990-$ | US-20140276539-$ | US-20140248001-$ | US-20140249519-$ | US-20140312-$ | US-20140343542-$ | US-20140343543-$ | US-20140343544-$ | US-2124684-$ | US-2319542-$ | US-2423024-$ | US-2672032-$ | US-3266492-$ | US-3289424-$ | US-3343544-$ | US-3351063-$ | US-3439680-$ | US-3483869-$ | US-3502081-$ | US-3507283-$ | US-3532094-$ | US-3664344-$ | US-3702114-$ | US-3795245-$).DID.				
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5749846-$ | US-5755753-$ | US-

		5755754-$ | US-5768679-$ | US-5778043-$ | US-5782827-$ | US-5792146-$ | US-5800484-$ | US-5807309-$ | US-5810804-$ | US-5814040-$ | US-5827276-$ | US-5848967-$ | US-5855576-$ | US-5860970-$ | US-5868740-$ | US-5879378-$ | US-5891166-$ | US-5891247-$ | US-5897044-$ | US-5899897-$ | US-5911739-$ | US-5913855-$ | US-5916212-$ | US-5925042-$ | US-5928229-$ | US-5935123-$ | US-5954242-$ | US-5954686-$ | US-5968040-$ | US-5976505-$ | US-5980517-$ | US-5983141-$ | US-5991957-$ | US-6003539-$ | US-6013076-$ | US-6014590-$ | US-6015406-$ | US-6031018-$ | US-6032675-$ | US-6035916-$ | US-6036699-$ | US-6039730-$ | US-6039733-$ | US-6041260-$ | US-6041787-$ | US-6044846-$ | US-6051180-$ | US-6053086-$ | US-6053937-$ | US-6059780-$ | US-6068627-$ | US-6080150-$ | US-6080167-$ | US-6090105-$ | US-6106521-$ | US-6122341-$ | US-6126676-$ | US-6129726-$ | US-6132425-$ | US-6139545-$ | US-6139547-$ | US-6141985-$ | US-6142991-$ | US-6143003-$ | US-6146380-$ | US-6165169-$ | US-6167295-$ | US-6179834-$ | US-6182666-$).DID.				
L19	196	(US-6196839-$ | US-6213999-$ | US-6217554-$ | US-6228080-$ | US-6231570-$ | US-6234178-$ | US-6235023-$ | US-6238386-$ | US-6241726-$ | US-6246912-$ | US-6251106-$ | US-6259952-$ | US-6268200-$ | US-6270464-$ | US-6275725-$ | US-6277099-$ | US-6277116-$ | US-6277117-$ | US-6280441-$ | US-6299598-$ | US-6302870-$ | US-6312426-$ | US-6330478-$ | US-6331180-$ | US-6334861-$ | US-6352536-$ | US-6363730-$ | US-6364899-$ | US-6371943-$ | US-6402743-$ | US-6402747-$ | US-6402770-$ | US-6405072-$ | US-6416520-$ | US-6419653-$ | US-6419680-$ | US-	US-PGPUB; USPAT	OR	ON	2021/01/27 09:40

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6454765-$ | US-6458130-$ | US-
6459769-$ | US-6464704-$ | US-
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6478793-$ | US-6494844-$ | US-
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6632221-$ | US-6632222-$ | US-
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6645201-$ | US-6648880-$ | US-
6652515-$ | US-6652516-$ | US-
6660002-$ | US-6660362-$ | US-
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6669693-$ | US-6672095-$ | US-
6682501-$ | US-6682526-$ | US-
6682528-$ | US-6685701-$ | US-
6689127-$ | US-6690210-$ | US-
6692490-$ | US-6699205-$ | US-
6706037-$ | US-6706152-$ | US-
6723092-$ | US-6730042-$ | US-
6739024-$ | US-6743226-$ | US-
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6749624-$ | US-6749719-$ | US-
6761715-$ | US-6764493-$ | US-
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6814712-$ | US-6821283-$ | US-
6837956-$ | US-6840935-$ | US-
6846448-$ | US-6847848-$ | US-
6852091-$ | US-6858025-$ | US-
6866663-$ | US-6881214-$ | US-
6889089-$ | US-6896675-$ | US-
6902554-$ | US-6905492-$ | US-
6932810-$ | US-6958062-$ | US-
6958064-$ | US-6960208-$ | US-
6961602-$ | US-6964660-$ | US-
6966908-$ | US-6968238-$ | US-
6974455-$ | US-6997925-$ | US-

		7001400-$ | US-7025767-$ | US-7033353-$ | US-7033363-$ | US-7044949-$ | US-7048733-$ | US-7050858-$ | US-7056320-$ | US-7074484-$ | US-7076399-$ | US-7081111-$ | US-7081112-$ | US-7083612-$ | US-7087051-$ | US-7094231-$ | US-7099712-$ | US-7108696-$ | US-7112197-$ | US-7115124-$ | US-7138088-$ | US-7150743-$ | US-7150744-$ | US-7160296-$ | US-7163536-$ | US-7179256-$ | US-7179258-$ | US-7195616-$ | US-7207990-$ | US-7217939-$ | US-7250046-$ | US-7258688-$ | US-7266414-$ | US-7270660-$ | US-7270661-$ | US-7270662-$ | US-7276064-$ | US-7281666-$ | US-7294127-$ | US-7306596-$ | US-7311672-$ | US-7311702-$ | US-7340307-$ | US-7354436-$ | US-7357798-$ | US-7367341-$ | US-7371234-$ | US-7387626-$ | US-7387630-$ | US-7402140-$ | US-7416549-$ | US-7422586-$ | US-7449020-$ | US-7468062-$ | US-7480533-$).DID.				
L20	133	(US-7517346-$ | US-7524318-$ | US-7533002-$ | US-7549986-$ | US-7561907-$ | US-7578819-$ | US-7593778-$ | US-7596469-$ | US-7615050-$ | US-7641679-$ | US-7653438-$ | US-7670336-$ | US-7670337-$ | US-7678106-$ | US-7699844-$ | US-7704248-$ | US-7713266-$ | US-7761964-$ | US-7771420-$ | US-7794458-$ | US-7794459-$ | US-7797049-$ | US-7799021-$ | US-7815571-$ | US-7819869-$ | US-7819871-$ | US-7824404-$ | US-7828796-$ | US-7850683-$ | US-7862558-$ | US-7874986-$ | US-7875025-$ | US-7892231-$ | US-7896874-$ | US-7998137-$ | US-8292822-$ | US-8292932-$ | US-8298216-$ | US-8409185-$ | US-8715275-$ | US-8722065-$ | US-8979831-$ | US-9039688-$ | US-9254162-$ | US-9629946-$ | US-9668800-$ | US-D372086-$ | US-20010012956-$ | US-20020026185-$ | US-	US-PGPUB; USPAT	OR	ON	2021/01/27 09:40

		20020029037-$ | US-20020120238-$ | US-20030018332-$ | US-20030078595-$ | US-20040015176-$ | US-20040015218-$ | US-20040059328-$ | US-20040064098-$ | US-20040122312-$ | US-20040143262-$ | US-20040158239-$ | US-20040186435-$ | US-20040230187-$ | US-20040260282-$ | US-20050059964-$ | US-20050101944-$ | US-20050131431-$ | US-20050165391-$ | US-20050171522-$ | US-20050177211-$ | US-20050203503-$ | US-20050240174-$ | US-20050267552-$ | US-20060015161-$ | US-20060058861-$ | US-20060084965-$ | US-20060089635-$ | US-20060111702-$ | US-20060122686-$ | US-20060142756-$ | US-20060173359-$ | US-20060200121-$ | US-20060206127-$ | US-20060206129-$ | US-20060206130-$ | US-20060206132-$ | US-20060206133-$ | US-20060217705-$ | US-20060222667-$ | US-20060241723-$ | US-20060247616-$ | US-20060259027-$ | US-20060271036-$ | US-20070016183-$ | US-20070027449-$ | US-20070112342-$ | US-20070118191-$ | US-20070156136-$ | US-20070161905-$ | US-20070179380-$ | US-20070179491-$ | US-20070203402-$ | US-20070282321-$ | US-20080015569-$ | US-20080045939-$ | US-20080045940-$ | US-20080048786-$ | US-20080065062-$ | US-20080154259-$ | US-20080161804-$ | US-20080167646-$ | US-20080167649-$ | US-20080208121-$ | US-20080228181-$ | US-20080249392-$ | US-20080269740-$ | US-20080269763-$ | US-20090024124-$ | US-20090131790-$ | US-20090187182-$ | US-20090221998-$ | US-20090299358-$ | US-20100056926-$ | US-20100114095-$ | US-20100222677-$ | US-20110009848-$ | US-20110054612-$ | US-20110213356-$ | US-20110288563-$ | US-20120071832-$			

		| US-20120323220-$ | US-20127033363-$ | US-20130281930-$ | US-20140221830-$ | US-20170164942-$).DID.				
L21	817	16 17 18 19 20	US-PGPUB; USPAT	OR	ON	2021/01/27 09:40
L22	379	((needle or cannula) and probe and filament and conduct$4 and ((physical$4 direct) near3 contact$4) and monopolar)	US-PGPUB; USPAT	OR	ON	2021/01/27 09:44
L23	277	((needle or cannula) and probe) and 21	US-PGPUB; USPAT	OR	ON	2021/01/27 09:44
S1	2	"20070203486"	US-PGPUB; USPAT	OR	ON	2020/08/07 08:28
S2	1	"7918852".pn.	US-PGPUB; USPAT	OR	ON	2020/08/07 08:31
S4	2	"20020143302"	US-PGPUB; USPAT	OR	ON	2020/08/07 08:31
S5	2	"20060095029"	US-PGPUB; USPAT	OR	ON	2020/08/07 11:34
S6	2	"20020143302"	US-PGPUB; USPAT	OR	ON	2020/08/07 13:40
S7	7	"35695799".FMID.	US-PGPUB; USPAT; FPRS; JPO	OR	ON	2020/08/07 17:26
S8	2	"20070203486"	US-PGPUB; USPAT; FPRS; JPO	OR	ON	2020/08/07 17:29
S9	10	"35735223".FMID.	US-PGPUB; USPAT; FPRS; JPO	OR	ON	2020/08/07 17:29
S10	2	"20040260282"	US-PGPUB; USPAT	OR	ON	2020/08/10 09:07
S11	2	"20060084965"	US-PGPUB; USPAT	OR	ON	2020/08/10 09:14
S12	2	"15092945"	US-PGPUB; USPAT	OR	ON	2020/08/10 13:54
S13	1	(15/092945).APP.	USPAT; USOCR	OR	ON	2020/08/10 13:56
S14	0	"15098673"	USPAT; USOCR	OR	ON	2020/08/10 14:04
S15	1	"15098673"	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 14:04

S16	0	(15/098673).APP.	USPAT; USOCR	OR	ON	2020/08/10 14:04
S17	14	"43970383".FMID.	US-PGPUB; USPAT; FPRS; JPO	OR	ON	2020/08/10 14:04
S18	0	(15/098673).APP.	USPAT; USOCR	OR	ON	2020/08/10 14:05
S19	0	(15/098673).APP.	USPAT; USOCR	OR	ON	2020/08/10 14:26
S20	7,174	(A61B18/1477 or A61B2018/1427 or A61B2018/00577 or A61B18/1206 or A61B2018/0044 or A61B2018/1475 or A61B2018/143 or A61B2018/1253).cpc.	USPAT; USOCR	OR	ON	2020/08/10 14:27
S21	1	((("STRATUS") near3 ("MEDICAL") near3 ("LLC"))).AS,AANM.	USPAT	OR	ON	2020/08/10 14:27
S22	32	((("Wright") near3 ("Robert") near3 ("E"))).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 14:27
S23	18	((("Brandt") near3 ("Scott") near3 ("A"))).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 14:27
S24	488	(actuator actuate actuating) same (filament electrode) same (hub)	USPAT; USOCR	OR	ON	2020/08/10 14:29
S25	3,869	(actuator actuate actuating) same (filament electrode) same (advanced advancing deploy deployed deploying retract retracted retractibg)	USPAT; USOCR	OR	ON	2020/08/10 14:30
S26	3,985	(actuator actuate actuating) same (filament electrode) same (advanced advancing deploy deployed deploying retract retracted retracting)	USPAT; USOCR	OR	ON	2020/08/10 14:30
S27	432	S20 and S26	USPAT; USOCR	OR	ON	2020/08/10 14:30
S28	17,514	(A61B18/1477 or A61B2018/1427 or A61B2018/00577 or A61B18/1206 or A61B2018/0044 or A61B2018/1475 or A61B2018/143 or A61B2018/1253).cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 14:31
S29	5,980	(actuator actuate actuating) same (filament electrode) same (advanced advancing deploy deployed deploying retract retracted retracting)	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 14:31
S30	956	S28 and S29	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 14:31

S31	107	(US-7099712-$ | US-71081696-$ | US-7108696-$ | US-7112197-$ | US-7115124-$ | US-7138088-$ | US-7150743-$ | US-7150744-$ | US-7160296-$ | US-7163536-$ | US-7179256-$ | US-7179258-$ | US-7198625-$ | US-7207990-$ | US-7258688-$ | US-7266414-$ | US-7270660-$ | US-7270661-$ | US-7270662-$ | US-7276064-$ | US-7281666-$ | US-7294127-$ | US-7306596-$ | US-7311702-$ | US-7340307-$ | US-7354436-$ | US-7357798-$ | US-7387626-$ | US-7387630-$ | US-7416549-$ | US-7449020-$ | US-7468062-$ | US-7480533-$ | US-7517346-$ | US-7524318-$ | US-7533002-$ | US-7561907-$ | US-7593778-$ | US-7596469-$ | US-7615050-$ | US-7670336-$ | US-7670337-$ | US-7678106-$ | US-7699844-$ | US-7704248-$ | US-7761964-$ | US-7771420-$ | US-7794458-$ | US-7794459-$ | US-7797049-$ | US-7799021-$ | US-7815571-$ | US-7819869-$ | US-7819871-$ | US-7824404-$ | US-7828796-$ | US-7874986-$ | US-7875025-$ | US-7892231-$ | US-7896874-$ | US-8206300-$ | US-8292822-$ | US-8414509-$ | US-9629946-$ | US-9903397-$ | US-D372086-$ | US-20010018586-$ | US-20010031941-$ | US-20020026185-$ | US-20020176734-$ | US-20020188275-$ | US-20030078595-$ | US-20040015176-$ | US-20040024300-$ | US-20040100376-$ | US-20040143262-$ | US-20040158239-$ | US-20040199179-$ | US-20040230187-$ | US-20050004563-$ | US-20050033279-$ | US-20050101944-$ | US-20050171522-$ | US-20050177211-$ | US-20050234445-$ | US-20050267552-$ | US-20050283148-$ | US-20050288759-$ | US-20060015161-$ | US-20060095115-$ | US-20060106405-$ | US-20060122686-$ | US-20060142756-$ | US-20060189972-$ | US-20060206127-$ | US-20060206129-$ | US-	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:32

		20060206131-$ | US-20060206133-$ | US-20060217705-$ | US-20060229645-$ | US-20060259026-$ | US-20060271036-$ | US-20070006215-$ | US-20070016183-$ | US-20070077230-$ | US-20070215543-$ | US-20070287996-$ | US-20090105640-$).DID.				
S32	196	(US-5672173-$ | US-5672174-$ | US-5672375-$ | US-5683025-$ | US-5683349-$ | US-5683384-$ | US-5687739-$ | US-5701575-$ | US-5709692-$ | US-5713872-$ | US-5728143-$ | US-5735847-$ | US-5738648-$ | US-5743882-$ | US-5748703-$ | US-5749846-$ | US-5755754-$ | US-5768679-$ | US-5769822-$ | US-5772659-$ | US-5778043-$ | US-5782827-$ | US-5792146-$ | US-5797906-$ | US-5800484-$ | US-5807309-$ | US-5810804-$ | US-5827271-$ | US-5827276-$ | US-5848967-$ | US-5855576-$ | US-5863290-$ | US-5868740-$ | US-5891166-$ | US-5891247-$ | US-5897044-$ | US-5911739-$ | US-5913855-$ | US-5921992-$ | US-5925042-$ | US-5928229-$ | US-5934275-$ | US-5935123-$ | US-5951547-$ | US-5954242-$ | US-5964756-$ | US-5968040-$ | US-5983141-$ | US-5991957-$ | US-5995875-$ | US-6006126-$ | US-6013076-$ | US-6014590-$ | US-6015406-$ | US-6016452-$ | US-6031018-$ | US-6035916-$ | US-6039733-$ | US-6041260-$ | US-6044846-$ | US-6050992-$ | US-6051180-$ | US-6053086-$ | US-6053937-$ | US-6059780-$ | US-6068627-$ | US-6071280-$ | US-6080150-$ | US-6090105-$ | US-6092528-$ | US-6106521-$ | US-6117134-$ | US-6122341-$ | US-6123084-$ | US-6126676-$ | US-6129726-$ | US-6132425-$ | US-6139519-$ | US-6139547-$ | US-6143003-$ | US-6146380-$ | US-6161048-$ | US-6165169-$ | US-6167295-$ | US-6179834-$ | US-6210403-$ | US-6213999-$ | US-6217554-$ | US-	US-PGPUB; USPAT	OR	ON	2020/08/10 16:32

6228080-$ | US-6228083-$ | US-
6231570-$ | US-6234178-$ | US-
6235023-$ | US-6241725-$ | US-
6241726-$ | US-6245070-$ | US-
6246912-$ | US-6251106-$ | US-
6254598-$ | US-6259952-$ | US-
6262008-$ | US-6268200-$ | US-
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6280441-$ | US-6312426-$ | US-
6330478-$ | US-6331180-$ | US-
6352536-$ | US-6379353-$ | US-
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6402770-$ | US-6405072-$ | US-
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6419798-$ | US-6425887-$ | US-
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6517534-$ | US-6530922-$ | US-
6533987-$ | US-6536482-$ | US-
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6645201-$ | US-6652515-$ | US-
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6770070-$ | US-6780180-$ | US-
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6964660-$ | US-6974455-$ | US-
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7033353-$ | US-7048733-$ | US-

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S33	196	(US-4553687-$ | US-4559943-$ | US-4559951-$ | US-4562838-$ | US-4565200-$ | US-4567890-$ | US-4573980-$ | US-4580557-$ | US-4583538-$ | US-4590934-$ | US-4593691-$ | US-4593703-$ | US-4617927-$ | US-4618978-$ | US-4646752-$ | US-4653508-$ | US-4657015-$ | US-4658819-$ | US-4658820-$ | US-4660568-$ | US-4669468-$ | US-4674499-$ | US-4676255-$ | US-4681122-$ | US-4682596-$ | US-4688569-$ | US-4696668-$ | US-4698207-$ | US-4706667-$ | US-4709698-$ | US-4710176-$ | US-4712544-$ | US-4727874-$ | US-4735201-$ | US-4755173-$ | US-4769005-$ | US-4781175-$ | US-4787886-$ | US-4796615-$ | US-4799480-$ | US-4800899-$ | US-4802476-$ | US-4805616-$ | US-4808168-$ | US-4813429-$ | US-4820298-$ | US-4823791-$ | US-4827927-$ | US-4832048-$ | US-4832690-$ | US-4833824-$ | US-4838265-$ | US-4850353-$ | US-4860744-$ | US-4878493-$ | US-4886074-$ | US-4886506-$ | US-4907589-$ | US-4907741-$ | US-4919129-$ | US-4920978-$ | US-4931047-$ | US-4936281-$ | US-4936301-$ | US-4936310-$ | US-4936842-$ | US-4943290-$ | US-4950267-$ | US-4955377-$ | US-4966597-$ | US-4967765-$ | US-4969885-$ | US-4976711-$ | US-4994069-$ | US-4998661-$ | US-4998933-$ | US-5007908-$ | US-5009656-$ | US-5010897-$ | US-5013312-$ | US-5019076-$ | US-5035696-$ | US-5037379-$ | US-5047026-$ | US-5047027-$ | US-5057107-$ | US-5062031-$ | US-5071418-$ | US-5080660-$ | US-5083565-$ | US-5085659-$ | US-5088997-$ | US-5098431-$ | US-5099840-$ | US-5108391-$ | US-5108407-$ | US-5117978-$ | US-5122005-$ | US-5122138-$ | US-5133365-$ | US-	US-PGPUB; USPAT	OR	ON	2020/08/10 16:32

		5133738-$ | US-5154698-$ | US-5158561-$ | US-5160337-$ | US-5167658-$ | US-5167659-$ | US-5171255-$ | US-5171311-$ | US-5178620-$ | US-5190517-$ | US-5195959-$ | US-5196007-$ | US-5197963-$ | US-5201743-$ | US-5207675-$ | US-5217457-$ | US-5217458-$ | US-5217459-$ | US-5221281-$ | US-5226912-$ | US-5230623-$ | US-5232442-$ | US-5233515-$ | US-5239773-$ | US-5244462-$ | US-5249585-$ | US-5250047-$ | US-5250247-$ | US-5257630-$ | US-5258006-$ | US-5259395-$ | US-5261906-$ | US-5265606-$ | US-5267994-$ | US-5267997-$ | US-5269808-$ | US-5277201-$ | US-5277696-$ | US-5281213-$ | US-5304114-$ | US-5304115-$ | US-5304141-$ | US-5312329-$ | US-5312391-$ | US-5324255-$ | US-5334183-$ | US-5342292-$ | US-5370645-$ | US-5372596-$ | US-5374278-$ | US-5377685-$ | US-5379900-$ | US-5397301-$ | US-5401272-$ | US-5422567-$ | US-5423809-$ | US-5425746-$ | US-5433739-$ | US-5437726-$ | US-5447417-$ | US-5472441-$ | US-5472442-$ | US-5474057-$ | US-5484398-$ | US-5487739-$ | US-5503092-$ | US-5507743-$ | US-5507777-$ | US-5507802-$ | US-5511564-$ | US-5514129-$ | US-5532657-$ | US-5536267-$ | US-5540778-$ | US-5541376-$ | US-5542268-$ | US-5560358-$ | US-5562685-$ | US-5562703-$ | US-5569302-$ | US-5571147-$ | US-5580665-$ | US-5599345-$ | US-5599346-$ | US-5607003-$ | US-5611709-$ | US-5613966-$ | US-5628743-$ | US-5639506-$ | US-5643628-$ | US-5648003-$ | US-5649962-$ | US-5662620-$ | US-5662680-$ | US-5667488-$ | US-5669904-$).DID.				
S34	142	(US-20080161804-$ | US-0164184-$ | US-0222019-$ | US-0256625-$ | US-1234567-$ | US-1272004-$ | US-1366756-$ | US-14411266-$ | US-	US-PGPUB; USPAT	OR	ON	2020/08/10 16:32

15098673-$ | US-15112311-$ | US-15217457-$ | US-15232442-$ | US-15291896-$ | US-15318013-$ | US-15370675-$ | US-15421923-$ | US-15458597-$ | US-15496312-$ | US-15569302-$ | US-15639506-$ | US-15662111-$ | US-15672173-$ | US-15720744-$ | US-15735847-$ | US-15749689-$ | US-15782827-$ | US-15800484-$ | US-15810804-$ | US-15863290-$ | US-15897044-$ | US-15925042-$ | US-15928229-$ | US-15951547-$ | US-15980517-$ | US-16053937-$ | US-16129726-$ | US-16277117-$ | US-16334861-$ | US-16416520-$ | US-16440127-$ | US-16458130-$ | US-16478793-$ | US-16536482-$ | US-16803549-$ | US-16932810-$ | US-16966908-$ | US-17044949-$ | US-17270661-$ | US-1735271-$ | US-17371234-$ | US-17549986-$ | US-1814791-$ | US-1889609-$ | US-1932258-$ | US-1943543-$ | US-1952617-$ | US-1983669-$ | US-20020029037-$ | US-20030018332-$ | US-2003425-$ | US-20040006336-$ | US-20040122482-$ | US-20040176759-$ | US-20040260282-$ | US-20050059964-$ | US-20050101950-$ | US-20050165391-$ | US-20050177209-$ | US-20050203503-$ | US-20050222565-$ | US-20050277918-$ | US-20060089635-$ | US-20060111702-$ | US-20060122692-$ | US-20060173359-$ | US-20060206130-$ | US-20060206132-$ | US-20060206134-$ | US-20060259027-$ | US-20060264974-$ | US-20080048786-$ | US-20080154259-$ | US-20090024124-$ | US-20090221998-$ | US-20100256625-$ | US-20110213356-$ | US-20110288540-$ | US-2022065-$ | US-2050904-$ | US-2056377-$ | US-2124684-$ | US-2196171-$ | US-2282008-$ | US-2423024-$ | US-2888928-$ | US-2994324-$ | US-3035580-$ | US-3112003-$ | US-3460539-$ | US-3595239-$ | US-3601126-$ | US-3614414-$ | US-3648001-$ | US-3685518-$ | US-3699967-$ | US-

		3707149-$ | US-3801766-$ | US-3815604-$ | US-3840011-$ | US-3845771-$ | US-3847153-$ | US-3885569-$ | US-3898991-$ | US-3901242-$ | US-3902494-$ | US-3903891-$ | US-3918455-$ | US-3920021-$ | US-3920022-$ | US-3923063-$ | US-3929137-$ | US-3939839-$ | US-3945375-$ | US-3963030-$ | US-3964487-$ | US-3970088-$ | US-3974833-$ | US-4011872-$ | US-4016881-$ | US-4024467-$ | US-4033351-$ | US-4040426-$ | US-4043342-$ | US-4051855-$ | US-4060088-$ | US-4069827-$ | US-4074718-$ | US-4092986-$ | US-4114623-$ | US-4116198-$ | US-4119102-$ | US-4124153-$ | US-4126137-$ | US-4154240-$ | US-4189685-$ | US-4191054-$ | US-4200104-$ | US-4202337-$ | US-4204549-$ | US-4206761-$ | US-4206762-$ | US-4210152-$ | US-4228800-$ | US-4248231-$ | US-4269387-$ | US-4271837-$ | US-4281373-$ | US-4281667-$ | US-4282637-$ | US-4301802-$ | US-4326529-$ | US-4341094-$ | US-4346332-$ | US-4353371-$ | US-4375220-$ | US-4376263-$ | US-4378809-$ | US-4381007-$ | US-4385636-$ | US-4416277-$ | US-4418692-$ | US-4429698-$ | US-4448198-$ | US-4457128-$ | US-4474179-$ | US-4476862-$ | US-4492231-$ | US-4494541-$ | US-4501133-$ | US-4512338-$ | US-4517976-$ | US-4524770-$ | US-4532924-$ | US-4534347-$ | US-4548207-$).DID.				
S35	641	S31 S32 S33 S34	US-PGPUB; USPAT	OR	ON	2020/08/10 16:33
S36	205	S35 and monopolar	US-PGPUB; USPAT	OR	ON	2020/08/10 16:34
S37	231	S35 and (monopolar unipolar)	US-PGPUB; USPAT	OR	ON	2020/08/10 16:34
S38	54	("20040158239" | "20070112340" | "20080161804" | "20080249392" | "20080269558" | "20020022864" | "20020133148" | "20030199862" | "20040064137" | "20060095029" |	US-PGPUB; USPAT	OR	ON	2020/08/10 16:36

		"20060206111" | "20070010809" | "20070213703" | "20080249523" | "20090292259" | "20090306604" | "20100049192" | "20110184403" | "20130096549" | "20170065335" | "5383917" | "5486161" | "5749846" | "5893847" | "6045532" | "6105581" | "6210406" | "6216043" | "6221071" | "6287304" | "6461314" | "6471695" | "6699242" | "6740080" | "6752804" | "6962587" | "6989004" | "7229438" | "7318822" | "7344533" | "7393351" | "7399299" | "7416549" | "7419487" | "7458971" | "7678107" | "7846157" | "7896871" | "8262574" | "8512330" | "8518037" | "8753335" | "9402560" | "9675406").PN.				
S39	49	("20020022864" | "20020133148" | "20030199862" | "20040064137" | "20060095029" | "20060206111" | "20070010809" | "20070213703" | "20080249523" | "20090292259" | "20090306604" | "20100049192" | "20110184403" | "20130096549" | "20170065335" | "5383917" | "5486161" | "5749846" | "5893847" | "6045532" | "6105581" | "6210406" | "6216043" | "6221071" | "6287304" | "6461314" | "6471695" | "6699242" | "6740080" | "6752804" | "6962587" | "6989004" | "7229438" | "7318822" | "7344533" | "7393351" | "7399299" | "7416549" | "7419487" | "7458971" | "7678107" | "7846157" | "7896871" | "8262574" | "8512330" | "8518037" | "8753335" | "9402560" | "9675406").PN.	US-PGPUB; USPAT	OR	ON	2020/08/10 16:37
S40	5	("20040158239" | "20070112340" | "20080161804" | "20080249392" | "20080269558").PN.	US-PGPUB; USPAT	OR	ON	2020/08/10 16:37
S41	8,757	S28 and (needle cannula)	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:42
S42	862	S28 and (needle cannula) and filament	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:42
S43	862	S28 and (needle cannula) and filaments	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:42

S44	862	S28 and (needle cannula) and filament	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:42
S45	786	S28 and (needle cannula) and filament and electrode	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:43
S46	2,186,559	S28 and (needle cannula) and filament (electrode ablat$4 lesion)	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:44
S47	844	S28 and (needle cannula) and filament and (electrode ablat$4 lesion)	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 16:44
S48	57	("10716618" | "10736688" | "20020022864" | "20020133148" | "20030199862" | "20040064137" | "20040158239" | "20060095029" | "20060206111" | "20070010809" | "20070112340" | "20070213703" | "20080161804" | "20080249392" | "20080249523" | "20080269558" | "20090292259" | "20090306604" | "20100049192" | "20110184403" | "20130096549" | "20170065335" | "5383917" | "5486161" | "5749846" | "5893847" | "6045532" | "6105581" | "6210406" | "6216043" | "6221071" | "6287304" | "6461314" | "6471695" | "6699242" | "6740080" | "6752804" | "6962587" | "6989004" | "7229438" | "7318822" | "7344533" | "7393351" | "7399299" | "7416549" | "7419487" | "7458971" | "7678107" | "7846157" | "7896871" | "7918852" | "8262574" | "8512330" | "8518037" | "8753335" | "9402560" | "9675406").PN.	US-PGPUB; USPAT	OR	ON	2021/01/26 08:53
S49	5	(US-16933811-$ | US-18215729-$ | US-20040158239-$ | US-20070112340-$ | US-20080161804-$ | US-20080249392-$ | US-20080269558-$).DID.	US-PGPUB; USPAT	OR	ON	2021/01/26 08:55
S50	7	(US-10716618-$ | US-10736688-$ | US-16933811-$ | US-20060095029-$ | US-20060206111-$ | US-20090292259-$ | US-20100049192-$ | US-2571439-$).DID.	US-PGPUB; USPAT	OR	ON	2021/01/26 08:58
S51	53	(US-1059067-$ | US-1211171-$ | US-1290894-$ | US-1338909-$ | US-1645235-$ | US-16933811-$ | US-20020022864-$ | US-20020133148-$ | US-20030199862-$ | US-	US-PGPUB; USPAT	OR	ON	2021/01/26 09:01

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S52	178	(US-20127033363-$ | US-0004651-$ | US-0006215-$ | US-0006336-$ | US-0012956-$ | US-0015161-$ | US-0015176-$ | US-0015218-$ | US-0015569-$ | US-0016183-$ | US-0018332-$ | US-0024124-$ | US-0026185-$ | US-0027449-$ | US-0029037-$ | US-0033279-$ | US-0033493-$ | US-0042098-$ | US-0045939-$ | US-0045940-$ | US-0048786-$ | US-0054962-$ | US-0056926-$ | US-0059328-$ | US-0059964-$ | US-0060921-$ | US-0065062-$ | US-0076303-$ | US-0078595-$ | US-0084965-$ | US-0085804-$ | US-0089635-$ | US-0095115-$ | US-0099544-$ | US-0099980-$ | US-0100376-$ | US-0101944-$ | US-0101950-$ | US-0111702-$ | US-0112340-$ | US-0112342-$ | US-0114095-$ | US-0118191-$ | US-0122482-$ | US-0122686-$ | US-0122692-$ | US-0123964-$ | US-0130974-$ | US-0131790-$ | US-0138011-$ | US-0142756-$ | US-0143262-$ | US-0143302-$ | US-0154259-$ | US-0156136-$ | US-0158239-$ | US-	US-PGPUB; USPAT	OR	ON	2021/01/26 09:05

0161804-$ | US-0161905-$ | US-0165391-$ | US-0167646-$ | US-0167649-$ | US-0167943-$ | US-0171522-$ | US-0173359-$ | US-0176759-$ | US-0177209-$ | US-0177211-$ | US-0179380-$ | US-0179491-$ | US-0185082-$ | US-0185522-$ | US-0187177-$ | US-0187182-$ | US-0187183-$ | US-0188275-$ | US-0189972-$ | US-0198232-$ | US-0199179-$ | US-0200121-$ | US-0203402-$ | US-0203486-$ | US-0203503-$ | US-0206127-$ | US-0206128-$ | US-0206129-$ | US-0206130-$ | US-0206131-$ | US-0206132-$ | US-0206133-$ | US-0206134-$ | US-0208121-$ | US-0213356-$ | US-0217705-$ | US-0221998-$ | US-0222677-$ | US-0228001-$ | US-0228180-$ | US-0228181-$ | US-0229645-$ | US-0230187-$ | US-0234445-$ | US-0240174-$ | US-0247616-$ | US-0249392-$ | US-0259026-$ | US-0259027-$ | US-0260234-$ | US-0260282-$ | US-0267552-$ | US-0269558-$ | US-0269739-$ | US-0271036-$ | US-0275443-$ | US-0277918-$ | US-0282321-$ | US-0287081-$ | US-0287996-$ | US-0299358-$ | US-1234567-$ | US-20010012956-$ | US-20020026185-$ | US-20020029037-$ | US-20020143302-$ | US-20020188275-$ | US-20030018332-$ | US-20030078595-$ | US-20040006336-$ | US-20040015176-$ | US-20040015218-$ | US-20040059328-$ | US-20040100376-$ | US-20040122482-$ | US-20040143262-$ | US-20040158239-$ | US-20040176759-$ | US-20040199179-$ | US-20040230187-$ | US-20040260282-$ | US-20050033279-$ | US-20050059964-$ | US-20050085804-$ | US-20050101944-$ | US-20050101950-$ | US-20050165391-$ | US-20050171522-$ | US-20050177209-$ | US-20050177211-$ | US-20050203503-$ | US-20050234445-$ | US-20050240174-$ | US-20050267552-$ | US-

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EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L10	98	((needle or cannula) and probe and filament).clm.	US-PGPUB; USPAT	OR	ON	2021/01/27 09:34
L11	36	((needle or cannula) and probe and filament and conduct$4).clm.	US-PGPUB; USPAT	OR	ON	2021/01/27 09:35
L12	26	((needle or cannula) and probe and filament and conduct$4 and contact$4).clm.	US-PGPUB; USPAT	OR	ON	2021/01/27 09:35
L13	4	((needle or cannula) and probe and filament and conduct$4 and ((physical$4 direct) near3 contact$4)).clm.	US-PGPUB; USPAT	OR	ON	2021/01/27 09:36
L14	4	((needle or cannula) and probe and filament and conduct$4 and ((physical$4 direct) near3 contact$4) and monopolar).clm.	US-PGPUB; USPAT	OR	ON	2021/01/27 09:36
L15	0	"Term Removed"	USPAT; *No UPAD	OR	ON	2021/01/27 09:36

1/27/2021 9:56:01 AM
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16933811
Filing Date	2020-07-20
First Named Inventor	Robert E. Wright
Art Unit	3794
Examiner Name	Christine A. Dedoulis
Attorney Docket Number	NBUS.004C1C1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Petitioner's Exhibit 1006
Avanos v. Stratus

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	1	PETER DARMOS, Further Amended Statement of cross claim, as proposed for submission in Federal Court of Australia Case No. NSD 438 of 2019, dated October 2020, 7 pages.
	2	DAVID LAWSON MORRIS, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated October 21, 2020, 37 pages.
	3	UNITED STATES PATENT AND TRADEMARK OFFICE, Office Action in U.S. Patent Application No. 16/933,995, dated October 15, 2020, 49 pages.

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Examiner Signature	/Christine A Dedoulis/	Date Considered	01/26/2021

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OR

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See attached certification statement.

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

A certification statement is not submitted herewith.

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

Signature	/Daniel C. Higgs/	Date (YYYY-MM-DD)	2020-11-24
Name/Print	Daniel C. Higgs	Registration Number	55265

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

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

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

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

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

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

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	1	EUROPEAN PATENT OFFICE, Communication Under Rule 71(3) EPC for European Patent Application No. EP 11783944.9, December 18, 2019, 125 pages.	
	2	INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, Search Report for Brazilian Patent Application No. BR112012029263-3, December 6, 2019, 8 pages.	X
	3	UNITED STATES PATENT AND TRADEMARK OFFICE, Applicant-Initiated Interview Summary for U.S. Patent Application No. 15/098,673, February 14, 2020, 3 pages.	☐
	4	UNITED STATES PATENT AND TRADEMARK OFFICE, Form PTO/AIA/25, Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection over a Pending "Reference" Application for U.S. Patent Application No. 15/098,673, February 20, 2020, 2 pages.	☐
	5	UNITED STATES PATENT AND TRADEMARK OFFICE, Office Action in U.S. Patent Application No. 15/098,673, dated March 19, 2020, 37 pages.	☐
	6	CANADIAN INTELLECTUAL PROPERTY OFFICE, Office Action for Canadian Patent Application No. 2,799,505, dated 8 April 2020, 4 pages.	☐
	7	EUROPEAN PATENT OFFICE, Decision to Grant a European Patent Pursuant to Article 97(1) EPC for European Patent Application No. 11783944.9, dated 28 May 2020, 2 pages.	☐
	8	DAVID LAWSON MORRIS, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated 17 April 2020, 29 pages.	☐
	9	SUSANNE MONICA HANTOS, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated 21 April 2020, 765 pages.	☐
	10	PETER DARMOS, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated 21 April 2020, 716 pages.	☐
	11	WILLIAM SAMUAL HUNTER, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated 6 April 2020, 158 pages.	☐

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Avanos v. Stratus

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	12	DANIEL CHRISTOPHER HIGGS, Affidavit Submitted in Federal Court of Australia Case No. NSD 438 of 2019, dated 6 April 2020, 26 pages.	☐
	13	IP AUSTRALIA, Examination Report No. 1 for Standard Patent Application for Australian Patent Application No. 2019200358, dated 20 April 2020, 3 pages.	☐
	14	CANADIAN INTELLECTUAL PROPERTY OFFICE, Office Action for Canadian Patent Application No. 2,778,997, dated 15 May 2020, 3 pages.	☐
	15	UNITED STATES PATENT AND TRADEMARK OFFICE, Notice of Allowance for U.S. Patent Application No. 15/098,673, dated 9 April 2020, 95 pages.	☐

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Examiner Signature	/Christine A Dedoulis/	Date Considered	01/26/2021

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Signature	/Daniel C. Higgs/	Date (YYYY-MM-DD)	2020-10-19
Name/Print	Daniel C. Higgs	Registration Number	55265

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Bibliographic Data

Application No: 16/933,811

Foreign Priority claimed: ○ Yes ◉ No

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

Verified and Acknowledged: /Christine A Dedoulis/ (Examiner's Signature) | (Initials)

Title: NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/20/2020	606	3794	NBUS.004C1C1
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APPLICANTS

Stratus Medical, LLC, Salt Lake City, UT, UNITED STATES

INVENTORS

Robert E. Wright, Clayton, AUSTRALIA

Scott A. Brandt, Denver, CO, UNITED STATES

CONTINUING DATA

This application is a CON of 15092945 04/07/2016 PAT 10716618

15092945 is a CON of 13101009 05/04/2011ABN

13101009 has PRO of 61357894 06/23/2010

13101009 has PRO of 61357886 06/23/2010

13101009 has PRO of 61347351 05/21/2010

FOREIGN APPLICATIONS

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Doc code: IDS
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	1	20040158239		2004-08-12	Behl et al.	
	2	20070112340		2007-05-17	Thomas et al.	
	3	20080161804		2008-07-03	Rioux et al.	
	4	20080249392		2008-10-09	Mest	
	5	20080269558		2008-10-30	Yahagi et al.	

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	1	EUROPEAN PATENT OFFICE, European Search Report and EPO Form 1703 01.91 TRI for European Patent Application No. EP 18215729.7, September 6, 2019, 5 pages.	

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CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Daniel C. Higgs/	Date (YYYY-MM-DD)	2020-10-19
Name/Print	Daniel C. Higgs	Registration Number	55265

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

Petitioner's Exhibit 1006
Avanos v. Stratus

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.D./

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.P./

Petitioner's Exhibit 1006
Avanos v. Stratus

PTO/AIA/80 (07-17)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

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

I hereby appoint:

[X] Practitioners associated with Customer Number: 148468

OR

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

Name	Registration Number

Name	Registration Number

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

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

[X] The address associated with Customer Number: 148468

OR

[ ]

Firm or individual name		
Address		
City	State	Zip
Country		
Telephone	Email	

Assignee name and address: Stratus Medical, LLC
32303 FM-2978, Magnolia, Texas 77354

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

SIGNATURE of Assignee of Record

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

Signature	Date 2/17/2021
Name Bret Boudousquie	Telephone (385) 707-3029
Title Chief Executive Officer	

This collection of information is required by 37 CFR 1.31, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 18 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Privacy Act Statement

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	41951715
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	18-FEB-2021
Filing Date:	20-JUL-2020
Time Stamp:	00:16:24
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Assignee showing of ownership per 37 CFR 3.73	Statement_3_73_c.pdf	121153 51bd951d214e4bfcd927e82cdb72b1c252ec1f5a	no	3

Warnings:

Information:					
2	Power of Attorney	General_POA.pdf	499536 207ce9b9d22baac939aa03f16b8b97792fae473a	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	620689	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Stratus Medical, LLC

Application No./Patent No.: 16/933,811 Filed/Issue Date: July 20, 2020

Titled: NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

Stratus Medical, LLC, a limited liability company

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

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

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

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

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

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

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

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

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

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

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

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

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

1. From: Robert E. Wright & Scott A. Brandt To: Nimbus Concepts, LLC

   The document was recorded in the United States Patent and Trademark Office at Reel 055271, Frame 0359, or for which a copy thereof is attached.

2. From: Nimbus Concepts, LLC To: Biomerics, LLC

   The document was recorded in the United States Patent and Trademark Office at Reel 055271, Frame 0559, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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Page 426 of 462

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: Biomerics, LLC To: Stratus Medical, LLC

The document was recorded in the United States Patent and Trademark Office at
Reel 055271, Frame 0859, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

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

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

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

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

/Daniel C. Higgs/	February 17, 2021
Signature	Date
Daniel C. Higgs	55,265
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/933,811	07/20/2020	Robert E. Wright	NBUS.004C1C1

CONFIRMATION NO. 1017

148468
Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

POA ACCEPTANCE LETTER

OC000000123512224

Date Mailed: 02/24/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/18/2021.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/atesfai/

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 429 of 462

CORRECTED ADS FORM

Application Number	16933811
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

Inventor Information

****If no data is shown, no data has been corrected****

	Data of Record	Updated Data
Order Number		
Name		
Residence Information		
Residency		
City		
State		
Country of Residence		
Mailing Address of Inventor		
Address 1		
Address 2		
City,State/Province, Postal Code		
Country		

Application Information

	Data of Record	Updated Data
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	
Attorney Docket Number	NBUS.004C1C1	
Entity Type	Small	

Domestic Benefit/National Stage Information

****If no data is shown, no data has been corrected****

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121,365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S. C. 119(e) or 120, and 37 CFR 1.78(a).

		Data of Record	Updated Data
	Prior Application Status		
	Application Number		
	Continuity Type		
	Prior Application Number		
	Filing Date (YYYY-MM-DD)		
	Patent Number		
	Issue Date (YYYY-MM-DD)		

Foreign Priority Information

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 431 of 462

Document Description: Application Data Sheet to update/correct info
Doc Code: ADS.CORR

****If no data is shown, no data has been corrected****

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

		Data of Record	Updated Data
	Application Number		
	Country		
	Filing Date		
	Access Code		

Applicant Information

****If no data is shown, no data has been corrected****
Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

	Data of Record	Updated Data
Applicant Type	ASG	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is		
Name of the Deceased or Legally Incapacitated Inventor		
Applicant is an Organization	Yes	
Name		
Organization Name	Stratus Medical, LLC	
Address 1		32303 FM-2978
Address 2		

City,State/Province,Postal Code	~~Salt Lake City UT~~	Magnolia TX 77354
Country	US	
Phone Number		
Fax Number		
Email Address		

Assignee Information including Non-Applicant Assignee Information

****If no data is shown, no data has been corrected****
Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office

	Data of Record	Updated Data
Order	1	
Applicant is an Organization	Yes	
Name		
Organization Name	Stratus Medical, LLC	

Mailing Address

Address 1	~~6030 W. Harold Gatty Dr.~~	32303 FM-2978
Address 2		
City,State/Province,Postal Code	~~Salt Lake City UT 84116~~	Magnolia TX 77354
Country	US	
Phone Number		
Fax Number		
Email Address		

Signature

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b).

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

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

Signature	/Daniel C. Higgs/	Registration Number	55265
First Name	Daniel	Last Name	Higgs

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 434 of 462

Electronic Acknowledgement Receipt

EFS ID:	42007410
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	24-FEB-2021
Filing Date:	20-JUL-2020
Time Stamp:	12:13:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet to update/ correct info	CorrectedADS.pdf	66213 4d6837f697709b4fe5f278c2c906c0ffdc16a378	no	5

Warnings:

Information:	
Total Files Size (in bytes):	66213

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Robert E. Wright	
Application No.:	16/933,811	Art Unit: 3794
Filing Date:	July 20, 2020	
Title:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	
Examiner:	Christine A. Dedoulis	
Confirmation No.:	1017	
Customer No.:	148468	

Request for Corrected Filing Receipt

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

Commissioner:

The Applicant hereby respectfully requests the issuance of a Corrected Filing Receipt in the above-identified application ("the Application") to accurately reflect the current residence information of Stratus Medical, LLC, which is both the Applicant and the Assignee of the present application.

Submitted herewith is an amended version of the most recently issued Filing Receipt in the Application, mailed on July 30, 2020, which shows the desired change. In particular, the residence of both the Applicant and the Assignee should be changed from "Salt Lake City, UT" to "Magnolia, TX," as shown in the annotations.

Also submitted herewith is a copy of the Notice of Recordation that issued relative to the Application on February 17, 2021 that confirms the residence of the Assignee is Magnolia, TX. For reference, the Notice includes an annotation—specifically, a box around the Assignee residence information.

Also submitted herewith is a copy of the Corrected Application Data Sheet that was filed in the present application on February 24, 2021. For reference, this document includes two annotations—specifically, two boxes around corrections to the address information for Stratus Medical, LLC, which is both the Applicant and the Assignee.

Please contact the undersigned attorney if there are any questions regarding or impediments to the present request.

DATED this 25th day of February, 2021.

Respectfully submitted,

/Daniel C. Higgs/

Daniel C. Higgs
Attorney for Applicant
Registration No. 55,265

MED VENTURE HOLDINGS, LLC
6030 W. Harold Gatty Drive
Salt Lake City, Utah 84116
(801) 703-1961

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 438 of 462

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/933,811	07/20/2020	1235		NBUS.004C1C1	29	3

CONFIRMATION NO. 1017

FILING RECEIPT



OC000000071952604

148468
Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

Date Mailed: 07/30/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

Robert E. Wright, Clayton, AUSTRALIA;
Scott A. Brandt, Denver, CO;

Applicant(s)

Stratus Medical, LLC, ~~Salt Lake City, UT~~; Magnolia, TX

Assignment For Published Patent Application

Stratus Medical, LLC, ~~Salt Lake City, UT~~ Magnolia, TX

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 15/092,945 04/07/2016 PAT 10716618
which is a CON of 13/101,009 05/04/2011 ABN
which claims benefit of 61/347,351 05/21/2010
and claims benefit of 61/357,886 06/23/2010
and claims benefit of 61/357,894 06/23/2010

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

Permission to Access Application via Priority Document Exchange: Yes

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 439 of 462

Permission to Access Search Results: Yes

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

If Required, Foreign Filing License Granted: 07/29/2020
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/933,811**
Projected Publication Date: 11/05/2020
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

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Avanos v. Stratus
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Avanos v. Stratus
Page 442 of 462

UNITED STATES PATENT AND TRADEMARK OFFICE
UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

FEBRUARY 17, 2021

PTAS

DAN HIGGS
6030 W. HAROLD GATTY DR.
SALT LAKE CITY, UT 84116

506506543

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT RECORDATION BRANCH OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE ASSIGNMENT RECORDATION BRANCH AT 571-272-3350. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, MAIL STOP: ASSIGNMENT RECORDATION BRANCH, P.O. BOX 1450, ALEXANDRIA, VA 22313.

RECORDATION DATE: 02/16/2021

REEL/FRAME: 055271/0859
NUMBER OF PAGES: 9

BRIEF: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

DOCKET NUMBER: NBUS.004C1C1

ASSIGNOR:
BIOMERICS, LLC

DOC DATE: 12/23/2019

ASSIGNEE:
STRATUS MEDICAL, LLC
32303 FM-2978
MAGNOLIA, TEXAS 77354

APPLICATION NUMBER: 16933811
PATENT NUMBER:

FILING DATE: 07/20/2020
ISSUE DATE:

TITLE: NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

ASSIGNMENT RECORDATION BRANCH
PUBLIC RECORDS DIVISION

CORRECTED ADS FORM

Application Number	16933811
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

Inventor Information

****If no data is shown, no data has been corrected****

	Data of Record	Updated Data
Order Number		
Name		
Residence Information		
Residency		
City		
State		
Country of Residence		
Mailing Address of Inventor		
Address 1		
Address 2		
City,State/Province, Postal Code		
Country		

Application Information

	Data of Record	Updated Data
Title of Invention	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	
Attorney Docket Number	NBUS.004C1C1	
Entity Type	Small	

Domestic Benefit/National Stage Information

****If no data is shown, no data has been corrected****

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121,365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S. C. 119(e) or 120, and 37 CFR 1.78(a).

		Data of Record	Updated Data
	Prior Application Status		
	Application Number		
	Continuity Type		
	Prior Application Number		
	Filing Date (YYYY-MM-DD)		
	Patent Number		
	Issue Date (YYYY-MM-DD)		

Foreign Priority Information

Document Description: Application Data Sheet to update/correct info
Doc Code: ADS.CORR

If no data is shown, no data has been corrected

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

		Data of Record	Updated Data
	Application Number		
	Country		
	Filing Date		
	Access Code		

Applicant Information

If no data is shown, no data has been corrected
Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

	Data of Record	Updated Data
Applicant Type	ASG	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is		
Name of the Deceased or Legally Incapacitated Inventor		
Applicant is an Organization	Yes	
Name		
Organization Name	Stratus Medical, LLC	
Address 1		32303 FM-2978
Address 2		

City,State/Province,Postal Code	~~Salt Lake City UT~~	Magnolia TX 77354
Country	US	
Phone Number		
Fax Number		
Email Address		

Assignee Information including Non-Applicant Assignee Information

****If no data is shown, no data has been corrected****
Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office

	Data of Record	Updated Data
Order	1	
Applicant is an Organization	Yes	
Name		
Organization Name	Stratus Medical, LLC	
Mailing Address		
Address 1	~~6030 W. Harold Gatty Dr.~~	32303 FM-2978
Address 2		
City,State/Province,Postal Code	~~Salt Lake City UT 84116~~	Magnolia TX 77354
Country	US	
Phone Number		
Fax Number		
Email Address		

Signature

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b).

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

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

Signature	/Daniel C. Higgs/	Registration Number	55265
First Name	Daniel	Last Name	Higgs

Electronic Acknowledgement Receipt

EFS ID:	42023223
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	25-FEB-2021
Filing Date:	20-JUL-2020
Time Stamp:	14:29:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Corrected Filing Receipt	NBUS004C1C1_Request_for_Corrected_FR_with_Attachments.pdf	3933291 095bb28eeaeaf840f8321e2ef907fa7b0e0a12bd	no	12

Warnings:

Information:	
Total Files Size (in bytes):	3933291

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New International Application Filed with the USPTO as a Receiving Office

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UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/933,811	07/20/2020	3794	1235	NBUS.004C1C1	29	3

CONFIRMATION NO. 1017

CORRECTED FILING RECEIPT

148468
Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

OC000000123882087

Date Mailed: 02/26/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

Robert E. Wright, Clayton, AUSTRALIA;
Scott A. Brandt, Denver, CO;

Applicant(s)

Stratus Medical, LLC, Magnolia, TX;

Assignment For Published Patent Application

Stratus Medical, LLC, Magnolia, TX

Power of Attorney: The patent practitioners associated with Customer Number 148468

Domestic Priority data as claimed by applicant

This application is a CON of 15/092,945 04/07/2016 PAT 10716618
which is a CON of 13/101,009 05/04/2011 ABN
which claims benefit of 61/347,351 05/21/2010
and claims benefit of 61/357,886 06/23/2010
and claims benefit of 61/357,894 06/23/2010

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

Permission to Access Application via Priority Document Exchange: Yes

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 451 of 462

Permission to Access Search Results: Yes

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

If Required, Foreign Filing License Granted: 07/29/2020
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/933,811**
Projected Publication Date: Not Applicable
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

Preliminary Class

606

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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NOT GRANTED

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SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 453 of 462

technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 454 of 462

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Robert E. Wright	)	
Application No.:	16/933,811	)	Art Unit: 3794
Filing Date:	July 20, 2020	)	
Title:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY	)	
Examiner:	Christine A. Dedoulis	)	
Confirmation No.:	1017	)	
Customer No.:	148468	)	

Comments on Statement of Reasons for Allowance

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

Commissioner:

In reply to the Notice of Allowability that issued on February 16, 2021 in the above-identified application, the Applicant respectfully submits the following comments on the Statement of Reasons for Allowance ("Statement").

The Applicant thanks the examiner for her diligent review of the application and agrees that the claims are allowable. The Applicant does not, however, acquiesce to any characterizations of the prior art or the present application made in the Statement and takes no position regarding patentability other than positions taken during prosecution. Therefore, the examiner's Statement should not be attributed to the Applicant as an indication of the basis for Applicant's belief that the claims are patentable. To the extent the Statement summarizes or paraphrases the claims, or

otherwise deviates from the language of the claims, the Applicant respectfully submits that the meaning and scope of the claims depend on the actual language of the claims. To the extent the Statement refers to only selected portions of a claim, the Applicant notes that the claims may contain additional limitations other than those mentioned in the Statement, and that patentability is measured against a claim as a whole, not just selected limitations. Other limitations alone or in combination may provide distinguishing aspects over the prior art. To the extent the Statement suggests that the mentioned limitations have any special prominence, the Applicant does not necessarily agree. Further, the dependent claims may include additional limitations that may also provide further reasons for patentability.

DATED this 3rd day of March, 2021.

Respectfully submitted,

/Daniel C. Higgs/

Daniel C. Higgs
Attorney for Applicant
Registration No. 55,265

MED VENTURE HOLDINGS, LLC
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Salt Lake City, Utah 84116
(801) 703-1961

Petitioner's Exhibit 1006
Avanos v. Stratus
Page 456 of 462

PART B - FEE(S) TRANSMITTAL

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

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

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

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

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

148468 7590 02/16/2021
Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

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

Certificate of Mailing or Transmission

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

(Typed or printed name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/933,811	07/20/2020	Robert E. Wright	NBUS.004C1C1	1017

TITLE OF INVENTION: NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	05/17/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
DEDOULIS, CHRISTINE A	3794	606-041000

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

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

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

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

1 Med Venture Management, LLC
2 Daniel C. Higgs
3

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

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

(A) NAME OF ASSIGNEE: Stratus Medical, LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Magnolia, TX

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

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

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

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

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 602176

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

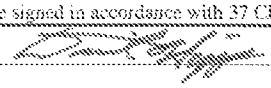
☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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

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

Authorized Signature:  Date: March 3, 2021

Typed or printed name: Daniel C. Higgs Registration No. 55,265

PTOL-85 Part B (08-18) Approved for use through 01/31/2020 OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Petitioner's Exhibit 1006
Avanos v. Stratus
Page 457 of 462

Electronic Patent Application Fee Transmittal

Application Number:	16933811
Filing Date:	20-Jul-2020
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Filer:	Daniel Christopher Higgs
Attorney Docket Number:	NBUS.004C1C1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	600	600

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**600**

Electronic Acknowledgement Receipt

EFS ID:	42076428
Application Number:	16933811
International Application Number:	
Confirmation Number:	1017
Title of Invention:	NEEDLES AND SYSTEMS FOR RADIOFREQUENCY NEUROTOMY
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	148468
Filer:	Daniel Christopher Higgs
Filer Authorized By:	
Attorney Docket Number:	NBUS.004C1C1
Receipt Date:	03-MAR-2021
Filing Date:	20-JUL-2020
Time Stamp:	13:25:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$600
RAM confirmation Number	E202133D26103593
Deposit Account	602176
Authorized User	Daniel Higgs

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

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	NBUS004C1C1_Comments.pdf	86829 7b41a11168fcae3afb5a4a9ae85952e57b292f04	no	2
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	NBUS004C1C1_PTOL_85.pdf	1550774 8ff9c8e1fc02d6cdd34a58cd8a9f07f1a2ab71bc	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30744 aaf6b34b4dfc1a6d8f988fd6d50ec3ec46c592c7	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1668347		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/933,811	04/06/2021	10966782	NBUS.004C1C1	1017

148468 7590 03/17/2021

Med Venture Management, LLC
6030 W. Harold Gatty Dr.
Salt Lake City, UT 84116

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

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

Stratus Medical, LLC, Magnolia, TX;
Robert E. Wright, Clayton, AUSTRALIA;
Scott A. Brandt, Denver, CO;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.