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Title:	SYSTEMS AND METHODS FOR RADIOFREQUEUNCY NEUROTOMY	)	
Examiner:	Christine A. Dedoulis	)	
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P.O. Box 1450
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AMENDMENT AND RESPONSE TO OFFICE ACTION

Commissioner:

Responsive to the Office Action dated December 31, 2025, in the above-identified application, the Applicant respectfully requests reconsideration of the pending claims in view of the amendments and remarks herein.

Amendments to the Claims begin on page 2.

Summary of the Interview begins on page 18.

Remarks begin on page 20.

Amendments to the Claims

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

Listing of Claims:

1. (Currently amended) A system for performing spinal radiofrequency neurotomy on a target medial branch nerve of a human patient, the system comprising:

a radiofrequency probe assembly ~~configured to connect to a radiofrequency generator, the radiofrequency probe assembly~~ comprising:

a radiofrequency probe that emits radiofrequency energy;

a temperature sensor that measures temperature at a distal end of the radiofrequency probe;

a connector at a proximal end of the radiofrequency probe; and

a cable; and

a radiofrequency neurotomy needle comprising:

a first hub;

an elongate member that comprises a hypotube formed of stainless steel that is ~~cannula~~ fixedly attached to the first hub and is 16 gauge or smaller~~, the cannula comprising a lumen that accepts the radiofrequency probe~~;

a layer of insulation around at least a portion of the hypotube;

a tip at a distal end of the elongate member ~~radiofrequency neurotomy needle~~ that is conductive and ~~is shaped~~ comprises a beveled shape to pierce tissue of the human patient;

a ~~plurality~~ set of filaments consisting of three filaments that are conductive and are simultaneously movable between a retracted position and a fully deployed position, the set of filaments being in electrical communication with the tip when in the fully deployed position, each filament having a pre-set bias to curve when deployed;

a tube of which only a portion is housed by the elongate member, the tube being conductive and defining a lumen configured to accept the radiofrequency

probe for transmission of radiofrequency energy to the tube, the lumen further being configured to transport fluid toward a distal end of the radiofrequency neurotomy needle for delivery to a region of tissue near the distal end of the radiofrequency neurotomy needle when the radiofrequency probe is absent from the lumen;

a second hub interconnected to the ~~plurality~~ set of filaments; and

~~an~~ a rotatable actuator interconnected to the second hub, wherein rotation of the actuator relative to the first hub in a first direction causes the second hub to move axially to advance the ~~plurality~~ set of filaments to the fully deployed position and rotation of the actuator relative to the first hub in a second direction that is opposite the first direction causes the second hub to move axially to retract the ~~plurality~~ set of filaments to the retracted position,

wherein, when the set of filaments is in the retracted position, the distal end of the radiofrequency neurotomy needle is straight;

wherein the radiofrequency probe assembly is movable relative to the radiofrequency neurotomy needle such that the radiofrequency probe is insertable into the lumen of the tube;

wherein[[,]] when the radiofrequency probe is ~~accepted~~ inserted in the lumen of the ~~cannula~~ tube and is interconnected to a radiofrequency generator via the cable and when the ~~plurality~~ set of filaments ~~are~~ is in the fully deployed position[[,]]:

each filament is curved radially outwardly away from a central longitudinal axis of the radiofrequency neurotomy needle;

the tube is in electrical communication with the set of filaments and the hypotube;

the tube conducts radiofrequency energy from the radiofrequency probe and directs the radiofrequency energy to the set of filaments;

the ~~tip and the plurality~~ set of filaments ~~together form an electrode that transmits~~ transmits the radiofrequency energy ~~emitted by the radiofrequency probe~~ to a target volume in which the target medial branch nerve is situated; and

the temperature sensor is positioned to monitor temperature of tissue at or near the distal end of the radiofrequency neurotomy needle, ~~and~~

wherein the ~~plurality~~ set of filaments ~~are~~ is advanceable from the retracted position to the fully deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle.

2. (Currently amended) The system of claim 1, wherein[[:]] a proximal portion of the tip has a cross section that coincides with a cross section of the hypotube ~~the radiofrequency probe assembly is separate from the radiofrequency neurotomy needle; and~~

~~the radiofrequency probe is insertable by a user of the system into the lumen of the cannula of the radiofrequency neurotomy needle~~.

3. (Currently amended) The system of claim 1 ~~claim 2~~, wherein the radiofrequency neurotomy needle further comprises a fitting in fluid communication with the lumen of the tube ~~cannula~~,

wherein the fitting is attachable to a fluid delivery device for delivery of fluid through the lumen ~~to a region of tissue around the tip~~, and

wherein the fitting permits the radiofrequency probe to be inserted through the fitting and into the ~~cannula~~ lumen after delivery of fluid through the lumen.

4. (Cancelled)

5. (Currently amended) The system of claim 1 ~~claim 4~~, wherein:

the tip is conductively coupled with the hypotube; and

the tube is in electrical communication with the set of filaments, the tip, and the hypotube due to physical contact of conductive components at the distal end of the radiofrequency neurotomy needle when the set of filaments is in the fully deployed position ~~the temperature measurement device is proximate to the tip of the radiofrequency neurotomy needle when the radiofrequency probe is present in the lumen of the cannula~~.

6. (Currently amended) The system of claim 1, wherein the tip and the hypotube are a single unitary structure ~~wherein:~~

~~the cannula comprises a conductive tube;~~

~~the system further comprises an additional conductive tube in the lumen of the cannula, the additional conductive tube defining an additional lumen into which the radiofrequency probe is received; and~~

~~the radiofrequency energy emitted by the radiofrequency probe is conducted through the additional conductive tube and transmitted by the plurality of filaments and the tip to the target volume~~.

7. (Currently amended) The system of claim 1, wherein the ~~plurality~~ set of filaments and the tip are in physical contact when the ~~plurality~~ set of filaments ~~are~~ is in the fully deployed state.

8. (Previously presented) The system of claim 1, wherein the actuator comprises a helical track, and wherein rotation of the actuator causes the second hub to move linearly relative to the first hub without rotating relative to the first hub.

9. (Currently amended) The system of claim 1, wherein the ~~cannula~~ hypotube is 18 gauge ~~comprises a 16-gauge or smaller sized tube~~.

10. (Currently amended) The system of claim 1, wherein each filament has a maximum cross-sectional dimension between about 0.06 millimeters and about 1 millimeter ~~the cannula comprises:~~

~~a tube that comprises a conductive material; and~~

~~an insulating coating or sleeve~~.

11. (Currently amended) The system of claim 1, wherein[[:]] the set of filaments is the only part of the radiofrequency neurotomy needle that is deployable to extend

radially outwardly relative to the central longitudinal axis ~~the cannula comprises a 16-gauge or smaller sized tube that comprises a conductive material and an insulating coating or sleeve;~~

~~an additional conductive tube is within the cannula, the additional conductive tube defining an additional lumen into which the radiofrequency probe is received;~~

~~a distal end of the radiofrequency probe comprises a temperature measurement device that is proximate to the tip of the radiofrequency neurotomy needle when the radiofrequency probe is received in the additional conductive tube;~~

~~the radiofrequency energy emitted by the radiofrequency probe is conducted through the additional conductive tube and transmitted by the plurality~~ set ~~of filaments and the tip;~~

~~the actuator comprises a helical track; and~~

~~rotation of the actuator causes the second hub to move linearly relative to the first hub without rotating relative to the first hub~~.

12. (Currently amended) The system of claim 1 ~~claim 11~~, wherein:

~~the radiofrequency probe assembly is separate from the radiofrequency neurotomy needle;~~

~~the radiofrequency probe is insertable by a user of the system into the lumen of the cannula of the radiofrequency neurotomy needle;~~

the radiofrequency neurotomy needle further comprises a fitting in fluid communication with the lumen of the tube ~~cannula~~;

the fitting is attachable to a fluid delivery device for delivery of fluid ~~through~~ into the lumen for transport ~~to a region of tissue around the tip;~~, ~~and~~

the fitting permits the radiofrequency probe to be inserted through the fitting and into the ~~cannula~~ lumen after ~~delivery~~ transport of fluid through the lumen;

the tip has a cross section that coincides with a cross section of the hypotube;

the tip is coaxial with the hypotube;

the tip and the hypotube are a single unitary structure;

the layer of insulation leaves a conductive area of the hypotube at a distal end of the elongate member exposed;

each of the filaments is formed of Nitinol;

the set of filaments and the tip are in physical contact when the set of filaments is in the fully deployed state;

the actuator comprises a helical track;

rotation of the actuator causes the second hub to move linearly relative to the first hub without rotating relative to the first hub;

the hypotube is 18 gauge;

each filament has a maximum cross-sectional dimension between about 0.06 millimeters and about 1 millimeter;

the radiofrequency neurotomy needle is operable to produce a lesion at the target volume that is sized between about 100 mm^3 and about 750 mm^3 when the set of filaments is in the fully deployed position within tissue of the human patient;

the tube is in electrical communication with the set of filaments, the tip, and the hypotube due to physical contact of conductive components at the distal end of the radiofrequency neurotomy needle when the set of filaments is in the fully deployed position; and

the set of filaments is the only part of the radiofrequency neurotomy needle that is deployable to extend radially outwardly relative to the central longitudinal axis.

13. (Currently amended) A method of using the system of claim 0 in a spinal radiofrequency neurotomy procedure, the method comprising:

introducing the radiofrequency neurotomy needle into the human patient with the ~~plurality~~ set of filaments in the retracted position;

moving the tip of the radiofrequency neurotomy needle to a target position relative to the target volume, wherein the target medial branch nerve is situated within the target volume;

rotating the actuator relative to the first hub to advance the ~~plurality~~ set of filaments to the fully deployed position; and

with the radiofrequency probe assembly connected to the radiofrequency generator and the radiofrequency probe accepted in the lumen of the tube ~~cannula~~, causing the radiofrequency generator to deliver radiofrequency energy to the radiofrequency probe that is transmitted by the tip and the ~~plurality~~ set of filaments to the target volume, thereby ablating the target medial branch nerve of the human patient to relieve pain of the human patient.

14. (Currently amended) The method of claim 13, ~~wherein~~ further comprising:

prior to said rotating the actuator relative to the first hub:

positioning the tip using fluoroscopic navigation; and

contacting the tip to a bone surface;

prior to ablating the target medial branch nerve of the human patient to relieve pain, retracting the tip from the bone surface; and

one or more of before, during, and after said causing the radiofrequency generator to deliver radiofrequency energy to the radiofrequency probe, causing the sensor to monitor temperature of tissue at or near the tip.

~~the radiofrequency neurotomy procedure is a spinal radiofrequency neurotomy procedure;~~

~~the patient is human; and~~

~~the target nerve is positioned along the spine of the patient~~.

15. (Currently amended) The method of claim 13, wherein[[:]] said moving the tip of the radiofrequency neurotomy needle comprises positioning the radiofrequency neurotomy needle within 30 degrees of being perpendicular to a vertebral surface either at a point of contact with the vertebral surface or at a point of the vertebral surface closest to the tip ~~a distal end of the radiofrequency probe comprises a temperature measurement device; and~~

~~the method further comprises permitting the temperature measurement device to sense a temperature at or near the tip of the radiofrequency neurotomy needle~~.

16. (Currently amended) The method of claim 15, further comprising inserting the radiofrequency probe into the lumen of the tube ~~cannula~~, said inserting taking place after said introducing the radiofrequency neurotomy needle into the human patient and prior to said causing the radiofrequency generator to deliver radiofrequency energy to the radiofrequency probe.

17. (Currently amended) The method of claim 16, wherein the radiofrequency neurotomy needle further comprises a fitting, the method further comprising:

after said introducing the radiofrequency neurotomy needle into the human patient, attaching a fluid delivery device to the fitting; and

causing the fluid delivery device to deliver fluid through the ~~radiofrequency neurotomy needle~~ lumen of the tube and ultimately to [[a]] the region of tissue ~~around the tip~~ near the distal end of the radiofrequency neurotomy needle,

wherein said inserting the radiofrequency probe into the lumen of the tube ~~cannula~~ comprises inserting the radiofrequency probe through the fitting after said causing the fluid delivery device to deliver fluid through the lumen of the tube ~~radiofrequency neurotomy needle~~.

18. (Currently amended) A system for performing radiofrequency neurotomy on a target nerve of a human patient, the system comprising:

a radiofrequency probe assembly ~~configured to connect to a radiofrequency generator, the radiofrequency probe assembly~~ comprising:

a radiofrequency probe that is configured to emit radiofrequency energy;

a temperature sensor operable to measure temperature at a distal end of the radiofrequency probe;

a connector at a proximal end of the radiofrequency probe; and

a cable; and

a radiofrequency neurotomy needle that comprises:

a first hub;

a first tube ~~cannula~~ that is conductive and is fixedly attached to the first hub, the first tube being 16 gauge or smaller;

a tip at a distal end of the first tube that tapers to a point substantially at one side of the tip ~~shaped~~ to pierce tissue of the human patient~~, the tip and the cannula being a single unitary structure~~;

a layer of insulation around at least a portion of the first tube that leaves a conductive area at a distal end of the radiofrequency neurotomy needle exposed;

a second tube of which only a portion is housed by the first tube, the second tube being ~~that is~~ conductive and ~~comprises~~ defining a lumen that accepts the radiofrequency probe for transmission of radiofrequency energy to the second tube, the lumen being configured to transport fluid toward the distal end of the radiofrequency neurotomy needle for delivery to a region of tissue near the distal end of the radiofrequency neurotomy needle~~, wherein a portion of the tube is housed by the cannula~~;

a plurality of filaments that are conductive and are simultaneously movable between a retracted position and a fully deployed position, the plurality of filaments being in electrical communication with the tip when in the fully deployed position, each filament having a pre-set bias to curve outwardly relative to a central longitudinal axis of the radiofrequency neurotomy needle when deployed;

a second hub interconnected to the plurality of filaments; and

~~an~~ a rotatable actuator interconnected to the second hub, wherein rotation of the actuator relative to the first hub in a first direction causes the second hub to move axially to advance the plurality of filaments to the fully deployed position and rotation of the actuator relative to the first hub in a second direction that is opposite the first direction causes the second hub to move axially to retract the plurality of filaments to the retracted position,

wherein, when the radiofrequency probe is accepted in the lumen of the second tube and is interconnected to a radiofrequency generator via the cable and when the plurality of filaments are in the fully deployed position:

the second tube is in electrical communication with the conductive area at the distal end of the radiofrequency neurotomy needle that is left exposed by the layer of insulation, wherein the conductive area comprises a distal portion of the first tube and a portion of each filament that curves radially outwardly relative to the central longitudinal axis;

the second tube is configured to conduct radiofrequency energy that has been emitted from the radiofrequency probe; ~~the radiofrequency probe is configured to emit radiofrequency energy that is conducted through the tube; and~~

the ~~tip and the~~ plurality of filaments ~~together form an electrode that transmits~~ transmit ~~said~~ radiofrequency energy ~~emitted by the radiofrequency probe and~~ that has been conducted through the second tube to a target volume in which the target nerve is situated; and

the temperature sensor is positioned to monitor temperature of tissue at or near the distal end of the radiofrequency neurotomy needle; and

wherein the plurality of filaments are advanceable from the retracted position to the fully deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle.

19. (Currently amended) The system of claim 18, wherein the radiofrequency neurotomy needle is operable to produce a lesion at the target volume that is sized between about 100 mm^3 and about 750 mm^3 when the plurality of filaments are in the fully deployed position within tissue of the human patient ~~plurality of filaments are advanceable from the retracted position to the deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle~~.

20. (Currently amended) The system of claim 18, wherein, when the plurality of filaments are in the retracted position, the distal end of the radiofrequency neurotomy needle is straight;

a proximal portion of the tip has a cross section that coincides with a cross section of the first tube;

the tip and the first tube are a single unitary structure;

the actuator comprises a helical track;

rotation of the actuator causes the second hub to move linearly relative to the first hub without rotating relative to the first hub;

the first tube is 18 gauge;

the radiofrequency neurotomy needle is operable to produce a lesion at the target volume that is sized between about 100 mm^3 and about 750 mm^3 when the plurality of filaments are in the fully deployed position within tissue of the human patient;

when the plurality of filaments are in the fully deployed position, the second tube is in electrical communication with the conductive area at the distal end of the radiofrequency neurotomy needle due to physical contact of conductive components at the distal end of the radiofrequency neurotomy needle;

the plurality of filaments and the tip are in physical contact when the plurality of filaments are in the fully deployed state; and

the plurality of filaments are the only portion of the radiofrequency neurotomy needle that is deployable radially outwardly relative to the central longitudinal axis ~~the plurality of filaments and the tip are in physical contact when the plurality of filaments are in the deployed state~~.

21. (Currently amended) The system of claim 18, wherein:

the radiofrequency probe assembly is separate from the radiofrequency neurotomy needle; and

the radiofrequency probe is insertable ~~by a user of the system~~ into the lumen of the second tube after the plurality of filaments have been moved to the fully deployed position.

22. (Currently amended) The system of claim 21, wherein a proximal portion of the tip has a cross section that coincides with a cross section of the first tube;

the tip and the first tube are a single unitary structure;

the actuator comprises a helical track;

rotation of the actuator causes the second hub to move linearly relative to the first hub without rotating relative to the first hub;

the first tube is 18 gauge;

the radiofrequency neurotomy needle is operable to produce a lesion at the target volume that is sized between about 100 mm^3 and about 750 mm^3 when the plurality of filaments are in the fully deployed position;

when the plurality of filaments are in the fully deployed position, the second tube is in electrical communication with the conductive area at the distal end of the radiofrequency neurotomy needle due to physical contact of conductive components at the distal end of the radiofrequency neurotomy needle;

the plurality of filaments and the tip are in physical contact when the plurality of filaments are in the fully deployed state; and

the plurality of filaments are the only portion of the radiofrequency neurotomy needle that is deployable radially outwardly relative to the central longitudinal axis ~~a distal end of the radiofrequency probe comprises a temperature measurement device, and wherein the temperature measurement device is proximate to the tip of the radiofrequency neurotomy needle when the radiofrequency probe is accepted in the lumen of the tube~~.

23. (Currently amended) The system of claim 22 wherein the radiofrequency neurotomy needle further comprises a fitting in fluid communication with the lumen of the second tube,

wherein the fitting is attachable to a fluid delivery device for delivery of fluid into the lumen when the radiofrequency probe is not present in the lumen ~~through the lumen to a region of tissue around the tip~~, and

wherein the fitting permits the radiofrequency probe to be inserted through the fitting and into the lumen ~~tube~~ after delivery of fluid through the lumen and detachment of the fluid delivery device from the fitting.

24. (Currently amended) A system for performing radiofrequency neurotomy on a target nerve of a human patient, the system comprising:

a radiofrequency probe assembly comprising:

a radiofrequency probe that emits radiofrequency energy;

~~that comprises~~ a temperature ~~measurement device~~ sensor at a distal end of the radiofrequency probe;

a connector at a proximal end of the radiofrequency probe; and

a cable ~~connectable to a radiofrequency generator~~; and

a radiofrequency neurotomy needle comprising:

a first hub;

~~a tip that is conductive and is shaped to pierce tissue of the patient;~~

~~a cannula~~ an elongate member that comprises a first tube that is conductive, is 16 gauge or smaller, and is attached to the first hub~~, the cannula being configured to accept the radiofrequency probe therein such that the distal end of the radiofrequency probe is proximate to the tip~~;

a layer of insulation around at least a portion of the first tube;

a tip at a distal end of the elongate member that is conductive and is tapered to a point so as to pierce tissue of the human patient;

a second tube of which only a portion is housed by the elongate member, the second tube being conductive and defining a lumen that accepts the radiofrequency probe for transmission of radiofrequency energy to the second tube, wherein the lumen is configured to transport fluid toward a distal end of the radiofrequency neurotomy needle for delivery to a region of tissue near the distal end of the radiofrequency neurotomy needle;

a plurality of filaments that are conductive and are simultaneously movable between a retracted position and a fully deployed position, the plurality of filaments being in electrical communication with the tip when in the fully deployed position, each filament having a pre-set bias to curve outwardly relative to a central longitudinal axis of the radiofrequency neurotomy needle when deployed;

a second hub interconnected to the plurality of filaments; and

~~an~~ a rotatable actuator interconnected to the second hub, wherein rotation of the actuator relative to the first hub in a first direction causes the second hub to move axially to advance the plurality of filaments to the fully deployed position and rotation of the actuator relative to the first hub in a second direction that is opposite the first direction causes the second hub to move axially to retract the plurality of filaments to the retracted position,

wherein, when the radiofrequency probe is accepted in the ~~cannula~~ lumen of the ~~radiofrequency neurotomy needle~~ second tube and is interconnected to a radiofrequency generator via the cable so as to emit ~~and emits~~ radiofrequency energy, and when the plurality of filaments are in the fully deployed position:

the second tube is in electrical communication with the plurality of filaments and the first tube;

the second tube is configured to conduct radiofrequency energy that is emitted by the radiofrequency probe and direct the radiofrequency energy to the plurality of filaments;

the ~~tip and the~~ plurality of filaments ~~together form an electrode that transmits~~ transmit the radiofrequency energy emitted by the radiofrequency probe to a target volume ~~to target tissue in which the target nerve is situated to ablate the target tissue~~; and

the temperature measurement device of the radiofrequency probe measures temperature at ~~the target tissue~~ or near the distal end of the radiofrequency neurotomy needle,

wherein the plurality of filaments are advanceable from the retracted position to the fully deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle.

25. (Cancelled)

26. (Cancelled)

27. (Cancelled)

28. (Currently amended) The system of claim 24, wherein the plurality of filaments curves radially outwardly relative to a central longitudinal axis of the radiofrequency neurotomy needle when moved to the fully deployed position, and wherein the plurality of filaments are the only portion of the radiofrequency neurotomy needle that is deployable radially outwardly relative to the central longitudinal axis ~~the plurality of filaments are advanceable from the retracted position to the deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle~~.

29. (Currently amended) The system of claim 28, wherein the radiofrequency probe is insertable into the lumen after the plurality of filaments have been moved to the fully deployed position ~~cannula of the radiofrequency neurotomy needle after deployment of the plurality of filaments~~.

30. (Currently amended) The system of claim 29, wherein the radiofrequency neurotomy needle further comprises~~: a lumen within the cannula; and~~ a fitting in fluid communication with the lumen, the fitting being configured to attach to a fluid delivery device for delivery of fluid through the lumen to [[a]] the region of tissue around the tip, the fitting further being configured to permit the radiofrequency probe to be inserted through the fitting and into the ~~cannula~~ lumen after delivery of fluid through the lumen.

31. (New) The system of claim 1, wherein the radiofrequency neurotomy needle is operable to produce a lesion at the target volume that is sized between about 100 mm^3 and about 750 mm^3 when the set of filaments is in the fully deployed position within tissue of the human patient.

32. (New) The system of claim 24, wherein the tip has a cross section that coincides with a cross section of the first tube;

the tip is coaxial with the first tube;

the tip and the first tube are a single unitary structure;

the actuator comprises a helical track;

rotation of the actuator causes the second hub to move linearly relative to the first hub without rotating relative to the first hub;

the first tube is 18 gauge;

the radiofrequency neurotomy needle is operable to produce a lesion at the target volume that is sized between about 100 mm^3 and about 750 mm^3 when the plurality of filaments are in the fully deployed position within tissue of the human patient;

when the plurality of filaments are in the fully deployed position, the second tube is in electrical communication with the plurality of filaments, the tip, and the first tube due to physical contact of conductive components at the distal end of the radiofrequency neurotomy needle; and

the plurality of filaments are the only portion of the radiofrequency neurotomy needle that is deployable radially outwardly relative to the central longitudinal axis.

33. (New) The system of claim 32, wherein:

the radiofrequency probe is insertable into the lumen after the plurality of filaments have been moved to the fully deployed position;

the radiofrequency neurotomy needle further comprises a fitting in fluid communication with the lumen, the fitting being configured to attach to a fluid delivery device for delivery of fluid through the lumen to the region of tissue around the tip, the fitting further being configured to permit the radiofrequency probe to be inserted through the fitting and into the lumen after delivery of fluid through the lumen.

Summary of the Interview

The Applicant thanks Examiner Dedoulis for the courtesy she extended to the undersigned attorney in the videoconference interview conducted on March 25, 2026. The Applicant generally agrees with the substance of the subsequently issued Applicant-Initiated Interview Summary, dated March 27, 2026, and provides its further summary below.

Exhibit/Demonstration

A brief video demonstrating a method of using a commercial embodiment of a neurotomy needle that includes deployable filaments was shown.

Claims Discussed

Claim 1 and possible amendments thereto were discussed.

Prior Art Discussed

U.S. Patent No. 7,918,852 to Tullis et al. ("Tullis") and U.S. Patent No. 7,195,629 of Behl et al. ("Behl") were discussed.

Principal Proposed Amendments

Possible amendments to claim 1, including some similar to those presented herein, were discussed.

Principal Arguments

The interview focused on the neurotomy devices disclosed in the present application and significant, nonobvious differences between those and the teachings of Tullis and Behl.

Other Pertinent Matters Discussed

The double-patenting rejections in the Office Action and certain forthcoming information disclosure statement submissions were also briefly discussed.

Results

The Applicant thanks Examiner Dedoulis for the productive interview, in which it was agreed that the Applicant would submit claim amendments and arguments for further consideration.

Remarks

This paper is submitted in response to the Office Action mailed December 31, 2025 (the Office Action). Claims 1-30 were pending in the Application. Claims 1-30 stand rejected on the basis of nonstatutory double patenting and obviousness under pre-AIA 35 U.S.C. § 103(a). By this paper, claims 1-3, 5-7, 9-24, and 28-30 are amended and claims 4 and 25-27 are cancelled, each without prejudice or disclaimer, claim 8 remains as previously presented, and new claims 31-33 are added. Accordingly, upon entry of this paper, claims 1-3, 5-26, and 28-33 will be pending in the application. The Applicant respectfully submits that the amendments are fully supported by the Application as originally filed and do not add new matter.

Double Patenting

Claims 1-30 stand rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-29 of U.S. Patent No. 10,966,782 and over claims 1-72 of U.S. Patent No. 10,716,618, as it is asserted that "the claims of U.S. Patent No. 10,966,782 and U.S. Patent No. 10,716,618 anticipate the claims of the application." The Applicant does not acquiesce to any of the foregoing rejections or assertions and reserves the right to argue against each of these.

However, the Applicant's position regarding the double-patenting rejections of the claims, as previously presented, need not be addressed here in view of the present amendments to independent claims 1, 18, and 24. By way of illustrative and nonlimiting examples, none of claims 1-29 of U.S. Patent No. 10,966,782 or claims 1-72 of U.S. Patent No. 10,716,618 anticipates *at least* the limitations of amended independent claims 1, 18, and 24 emphasized below, in combination with the remaining limitations of each respective claim.

Claim 1:

A system for performing spinal radiofrequency neurotomy on a target medial branch nerve of a human patient, the system comprising:

a radiofrequency probe assembly comprising:

a radiofrequency probe that emits radiofrequency energy;

a temperature sensor that measures temperature at a distal end of the radiofrequency probe;

a connector at a proximal end of the radiofrequency probe; and

a cable; and

a radiofrequency neurotomy needle comprising:

a first hub;

an elongate member that comprises a hypotube formed of stainless steel that is fixedly attached to the first hub and is 16 gauge or smaller;

a layer of insulation around at least a portion of the hypotube;

a tip at a distal end of the elongate member that is conductive and comprises a beveled shape to pierce tissue of the human patient;

a set of filaments consisting of three filaments that are conductive and are simultaneously movable between a retracted position and a fully deployed position, the set of filaments being in electrical communication with the tip when in the fully deployed position, **each filament having a pre-set bias to curve when deployed**;

a tube of which only a portion is housed by the elongate member, the tube being conductive and defining a lumen configured to accept the radiofrequency probe for transmission of radiofrequency energy to the tube, the lumen further being configured to transport fluid toward a distal end of the radiofrequency neurotomy needle for delivery to a region of tissue near the distal end of the radiofrequency neurotomy needle when the radiofrequency probe is absent from the lumen;

a second hub interconnected to the set of filaments; and

a rotatable actuator interconnected to the second hub, wherein rotation of the actuator relative to the first hub in a first direction causes the second hub to move axially to advance the set of filaments to the fully deployed position and rotation of the actuator relative to the first hub in a second direction that is opposite the first direction causes the second hub to move axially to retract the set of filaments to the retracted position,

wherein, when the set of filaments is in the retracted position, the distal end of the radiofrequency neurotomy needle is straight;

wherein the radiofrequency probe assembly is movable relative to the radiofrequency neurotomy needle such that the radiofrequency probe is insertable into the lumen of the tube;

wherein when the radiofrequency probe is inserted in the lumen of the tube and is interconnected to a radiofrequency generator via the cable and when the set of filaments is in the fully deployed position:

each filament is curved radially outwardly away from a central longitudinal axis of the radiofrequency neurotomy needle;

the tube is in electrical communication with the set of filaments and the hypotube;

the tube conducts radiofrequency energy from the radiofrequency probe and directs the radiofrequency energy to the set of filaments;

the set of filaments transmits the radiofrequency energy to a target volume in which the target medial branch nerve is situated; and

the temperature sensor is positioned to monitor temperature of tissue at or near the distal end of the radiofrequency neurotomy needle,

wherein the set of filaments is advanceable from the retracted position to the fully deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle.

Claim 18:

A system for performing radiofrequency neurotomy on a target nerve of a human patient, the system comprising:

a radiofrequency probe assembly comprising:

a radiofrequency probe that is configured to emit radiofrequency energy;

a temperature sensor operable to measure temperature at a distal end of the radiofrequency probe;

a connector at a proximal end of the radiofrequency probe; and

a cable; and

a radiofrequency neurotomy needle that comprises:

a first hub;

a first tube that is conductive and is fixedly attached to the first hub, the first tube being 16 gauge or smaller;

a tip at a distal end of the first tube that tapers to a point substantially at one side of the tip to pierce tissue of the human patient;

a layer of insulation around at least a portion of the first tube that leaves a conductive area at a distal end of the radiofrequency neurotomy needle exposed;

a second tube of which only a portion is housed by the first tube, the second tube being conductive and defining a lumen that accepts the radiofrequency probe for transmission of radiofrequency energy to the second tube, the lumen being configured to transport fluid toward the distal end of the radiofrequency neurotomy needle for delivery to a region of tissue near the distal end of the radiofrequency neurotomy needle;

a plurality of filaments that are conductive and are simultaneously movable between a retracted position and a fully deployed position, the plurality of filaments being in electrical communication with the tip when in the fully deployed position, each

filament having a pre-set bias to curve outwardly relative to a central longitudinal axis of the radiofrequency neurotomy needle when deployed;

a second hub interconnected to the plurality of filaments; and

a rotatable actuator interconnected to the second hub, wherein rotation of the actuator relative to the first hub in a first direction causes the second hub to move axially to advance the plurality of filaments to the fully deployed position and rotation of the actuator relative to the first hub in a second direction that is opposite the first direction causes the second hub to move axially to retract the plurality of filaments to the retracted position,

wherein, when the radiofrequency probe is accepted in the lumen of the second tube and is interconnected to a radiofrequency generator via the cable and when the plurality of filaments are in the fully deployed position:

the second tube is in electrical communication with the conductive area at the distal end of the radiofrequency neurotomy needle that is left exposed by the layer of insulation, wherein the conductive area comprises a distal portion of the first tube and a portion of each filament that curves radially outwardly relative to the central longitudinal axis;

the second tube is configured to conduct radiofrequency energy that has been emitted from the radiofrequency probe;

the plurality of filaments transmit radiofrequency energy that has been conducted through the second tube to a target volume in which the target nerve is situated; and

the temperature sensor is positioned to monitor temperature of tissue at or near the distal end of the radiofrequency neurotomy needle; and

wherein the plurality of filaments are advanceable from the retracted position to the fully deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle.

Claim 24:

A system for performing radiofrequency neurotomy on a target nerve of a human patient, the system comprising:

a radiofrequency probe assembly comprising:

a radiofrequency probe that emits radiofrequency energy;

a temperature sensor at a distal end of the radiofrequency probe;

a connector at a proximal end of the radiofrequency probe; and

a cable; and

a radiofrequency neurotomy needle comprising:

a first hub;

an elongate member that comprises a first tube that is conductive, is 16 gauge or smaller, and is attached to the first hub;

a layer of insulation around at least a portion of the first tube;

a tip at a distal end of the elongate member that is conductive and is tapered to a point so as to pierce tissue of the human patient;

a second tube of which only a portion is housed by the elongate member, the second tube being conductive and defining a lumen that accepts the radiofrequency probe for transmission of radiofrequency energy to the second tube, wherein the lumen is configured to transport fluid toward a distal end of the radiofrequency neurotomy needle for delivery to a region of tissue near the distal end of the radiofrequency neurotomy needle;

a plurality of filaments that are conductive and are simultaneously movable between a retracted position and a fully deployed position, the plurality of filaments being in electrical communication with the tip when in the fully deployed position, **each filament having a pre-set bias to curve outwardly relative to a central longitudinal axis of the radiofrequency neurotomy needle when deployed**;

a second hub interconnected to the plurality of filaments; and

a rotatable actuator interconnected to the second hub, wherein rotation of the actuator relative to the first hub in a first direction causes the second hub to move axially to advance the plurality of filaments to the fully deployed position and rotation of the actuator relative to the first hub in a second direction that is opposite the first direction causes the second hub to move axially to retract the plurality of filaments to the retracted position,

wherein, when the radiofrequency probe is accepted in the lumen of the second tube and is interconnected to a radiofrequency generator via the cable so as to emit radiofrequency energy, and when the plurality of filaments are in the fully deployed position:

the second tube is in electrical communication with the plurality of filaments and the first tube;

the second tube is configured to conduct radiofrequency energy that is emitted by the radiofrequency probe and direct the radiofrequency energy to the plurality of filaments;

the plurality of filaments transmit the radiofrequency energy emitted by the radiofrequency probe to a target volume; and

the temperature measurement device of the radiofrequency probe measures temperature at or near the distal end of the radiofrequency neurotomy needle,

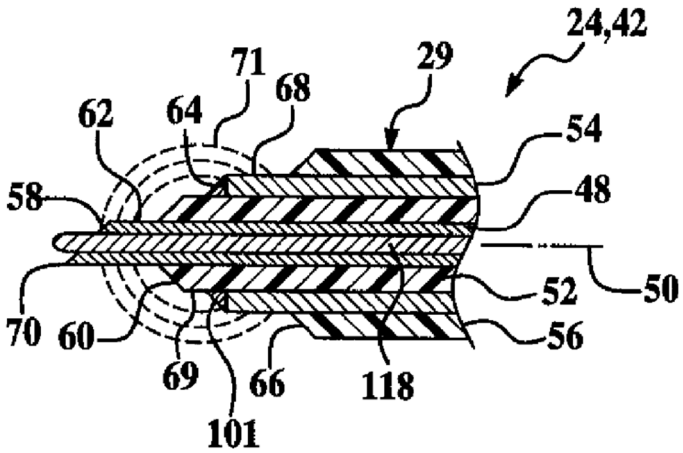
wherein the plurality of filaments are advanceable from the retracted position to the fully deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle.

Claim Rejections – 35 U.S.C. § 103

Claims 1-30 stand rejected under pre-AIA 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 7,918,852 of Tullis et al. ("Tullis") in view of U.S. Patent No. 7,195,629 of Behl et al. ("Behl"). The Applicant does not acquiesce to any aspect of this rejection—including without limitation its characterizations of the claims, interpretations of the teachings of Tullis and Behl, assertions that the those teachings would be obvious to combine, and assertions that all limitations are the claims are met, even if it were to be assumed the teachings could be combined—and reserves the right to argue against any and all aspects of the rejection, whether in the present application or in one or more future applications.

To expedite prosecution of the present application, however, independent claims 1, 18, and 24 have been amended with limitations that plainly are not taught or rendered obvious by Tullis or Behl, whether considered individually or in combination (the latter consideration being solely for the sake of argument, as the Applicant believes the combination of these references proposed in the Office Action is improper). For the sake of brevity, only some of these limitations are discussed hereafter; the Applicant expressly reserves the right to argue the patentability of other or additional limitations of claims 1, 18, and 24 and their dependent claims.

Tullis discloses bipolar and monopolar systems. In the bipolar system, as illustrated in Figure 15 (reproduced on following page), an electrode assembly 24 includes a conductive inner tube 48 and a conductive outer tube 54 that are separated by an insulating inner sleeve 52. (Col. 6, ll. 14-51.) That is, the conductive inner tube 48 and the outer tube 54 are "electrically insulated" from one another to permit bipolar operation of the electrode assembly 24. (*See id.*) A supply electrode 118 is inserted into the inner electrode 48, which establishes a conductive link between an outer wall of a shell 122 of the supply electrode 118 and the inner electrode 48. (Col. 15, ll. 47-59, *see also* Fig. 17.) In contrast, the outer tube 54 is associated with a terminal 86 at the proximal end of the electrode assembly 24. (Col. 15, ll. 55-59, *see also* Fig. 6.)



Tullis, Figure 15

In Tullis's monopolar system, the conductive inner tube 48 and the insulating sleeve 52 are preserved, but the conductive outer tube 54 is omitted. (*See* col. 21, l. 58 to col. 22, l. 23.) Moreover, the shell 122 of the "supply electrode" is "not conductive. Instead, shell 122 serves as an insulating housing" and "is a non-conductive post." (Col. 21, l. 67 to col. 22, l. 23.) Thus, item 118 in the monopolar version does not emit radiofrequency energy to the inner tube 48. Rather, electrical connection between conductive inner tube 48 and a generator is established by way of a "head unit" at a proximal end of the device. (*See* col. 22, ll. 8-23.)

In view of the foregoing, Tullis fails to teach or render obvious <u>at least</u> the portions of amended independent claims 1, 18, and 24 emphasized below. For example, modifying Tullis to arrive at the inventions recited in these amended claims would require fundamental redesign of Tullis's devices in manners contrary to the principles of operation described in Tullis, and would render Tullis's devices unfit for their intended purposes.

<u>Claim 1</u>:

A system for performing spinal radiofrequency neurotomy on a target medial branch nerve of a human patient, the system comprising:

a radiofrequency probe assembly comprising:

a radiofrequency probe that emits radiofrequency energy;

a temperature sensor that measures temperature at a distal end of the radiofrequency probe;

a connector at a proximal end of the radiofrequency probe; and

a cable; and

a radiofrequency neurotomy needle comprising:

a first hub;

an elongate member that comprises a hypotube formed of stainless steel that is fixedly attached to the first hub and is 16 gauge or smaller;

a layer of insulation around at least a portion of the hypotube;

a tip at a distal end of the elongate member that is conductive and comprises a beveled shape to pierce tissue of the human patient;

a set of filaments consisting of three filaments that are conductive and are simultaneously movable between a retracted position and a fully deployed position, the set of filaments being in electrical communication with the tip when in the fully deployed position, each filament having a pre-set bias to curve when deployed;

a tube of which only a portion is housed by the elongate member, the tube being conductive and defining a lumen configured to accept the radiofrequency probe for transmission of radiofrequency energy to the tube, the lumen further being configured to transport fluid toward a distal end of the radiofrequency neurotomy needle for delivery to a region of tissue near the distal end of the radiofrequency neurotomy needle when the radiofrequency probe is absent from the lumen;

a second hub interconnected to the set of filaments; and

a rotatable actuator interconnected to the second hub, wherein rotation of the actuator relative to the first hub in a first direction causes the second hub to move axially to advance the set of filaments to the fully deployed position and rotation of the actuator relative to the first hub in a

second direction that is opposite the first direction causes the second hub to move axially to retract the set of filaments to the retracted position,

wherein, when the set of filaments is in the retracted position, the distal end of the radiofrequency neurotomy needle is straight;

wherein the radiofrequency probe assembly is movable relative to the radiofrequency neurotomy needle such that the radiofrequency probe is insertable into the lumen of the tube;

wherein when the radiofrequency probe is inserted in the lumen of the tube and is interconnected to a radiofrequency generator via the cable and when the set of filaments is in the fully deployed position:

each filament is curved radially outwardly away from a central longitudinal axis of the radiofrequency neurotomy needle;

the tube is in electrical communication with the set of filaments and the hypotube;

the tube conducts radiofrequency energy from the radiofrequency probe and directs the radiofrequency energy to the set of filaments;

the set of filaments transmits the radiofrequency energy to a target volume in which the target medial branch nerve is situated; and

the temperature sensor is positioned to monitor temperature of tissue at or near the distal end of the radiofrequency neurotomy needle,

wherein the set of filaments is advanceable from the retracted position to the fully deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle.

Claim 18:

A system for performing radiofrequency neurotomy on a target nerve of a human patient, the system comprising:

a radiofrequency probe assembly comprising:

a radiofrequency probe that is configured to emit radiofrequency energy;

a temperature sensor operable to measure temperature at a distal end of the radiofrequency probe;

a connector at a proximal end of the radiofrequency probe; and

a cable; and

a radiofrequency neurotomy needle that comprises:

a first hub;

a first tube that is conductive and is fixedly attached to the first hub, the first tube being 16 gauge or smaller;

a tip at a distal end of the first tube that tapers to a point substantially at one side of the tip to pierce tissue of the human patient;

a layer of insulation around at least a portion of the first tube that leaves a conductive area at a distal end of the radiofrequency neurotomy needle exposed;

a second tube of which only a portion is housed by the first tube, the second tube being conductive and defining a lumen that accepts the radiofrequency probe for transmission of radiofrequency energy to the second tube, the lumen being configured to transport fluid toward the distal end of the radiofrequency neurotomy needle for delivery to a region of tissue near the distal end of the radiofrequency neurotomy needle;

a plurality of filaments that are conductive and are simultaneously movable between a retracted position and a fully deployed position, the plurality of filaments being in electrical communication with the tip when in the fully deployed position, each filament having a pre-set bias to curve

outwardly relative to a central longitudinal axis of the radiofrequency neurotomy needle when deployed;

a second hub interconnected to the plurality of filaments; and

a rotatable actuator interconnected to the second hub, wherein rotation of the actuator relative to the first hub in a first direction causes the second hub to move axially to advance the plurality of filaments to the fully deployed position and rotation of the actuator relative to the first hub in a second direction that is opposite the first direction causes the second hub to move axially to retract the plurality of filaments to the retracted position,

wherein, when the radiofrequency probe is accepted in the lumen of the second tube and is interconnected to a radiofrequency generator via the cable and when the plurality of filaments are in the fully deployed position:

the second tube is in electrical communication with the conductive area at the distal end of the radiofrequency neurotomy needle that is left exposed by the layer of insulation, wherein the conductive area comprises a distal portion of the first tube and a portion of each filament that curves radially outwardly relative to the central longitudinal axis;

the second tube is configured to conduct radiofrequency energy that has been emitted from the radiofrequency probe;

the plurality of filaments transmit radiofrequency energy that has been conducted through the second tube to a target volume in which the target nerve is situated; and

the temperature sensor is positioned to monitor temperature of tissue at or near the distal end of the radiofrequency neurotomy needle; and

wherein the plurality of filaments are advanceable from the retracted position to the fully deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle.

Claim 24:

A system for performing radiofrequency neurotomy on a target nerve of a human patient, the system comprising:

a radiofrequency probe assembly comprising:

a radiofrequency probe that emits radiofrequency energy;

a temperature sensor at a distal end of the radiofrequency probe;

a connector at a proximal end of the radiofrequency probe; and

a cable; and

a radiofrequency neurotomy needle comprising:

a first hub;

an elongate member that comprises a first tube that is conductive, is 16 gauge or smaller, and is attached to the first hub;

a layer of insulation around at least a portion of the first tube;

a tip at a distal end of the elongate member that is conductive and is tapered to a point so as to pierce tissue of the human patient;

a second tube of which only a portion is housed by the elongate member, the second tube being conductive and defining a lumen that accepts the radiofrequency probe for transmission of radiofrequency energy to the second tube, wherein the lumen is configured to transport fluid toward a distal end of the radiofrequency neurotomy needle for delivery to a region of tissue near the distal end of the radiofrequency neurotomy needle;

a plurality of filaments that are conductive and are simultaneously movable between a retracted position and a fully deployed position, the plurality of filaments being in electrical communication with the tip when in the fully deployed position, each filament having a pre-set bias to curve outwardly relative to a central longitudinal axis of the radiofrequency neurotomy needle when deployed;

a second hub interconnected to the plurality of filaments; and

a rotatable actuator interconnected to the second hub, wherein rotation of the actuator relative to the first hub in a first direction causes the second hub to move axially to advance the plurality of filaments to the fully deployed position and rotation of the actuator relative to the first hub in a second direction that is opposite the first direction causes the second hub to move axially to retract the plurality of filaments to the retracted position,

wherein, when the radiofrequency probe is accepted in the lumen of the second tube and is interconnected to a radiofrequency generator via the cable so as to emit radiofrequency energy, and when the plurality of filaments are in the fully deployed position:

the second tube is in electrical communication with the plurality of filaments and the first tube;

the second tube is configured to conduct radiofrequency energy that is emitted by the radiofrequency probe and direct the radiofrequency energy to the plurality of filaments;

the plurality of filaments transmit the radiofrequency energy emitted by the radiofrequency probe to a target volume; and

the temperature measurement device of the radiofrequency probe measures temperature at or near the distal end of the radiofrequency neurotomy needle,

wherein the plurality of filaments are advanceable from the retracted position to the fully deployed position without concurrent advancement of the radiofrequency probe relative to the radiofrequency neurotomy needle.

The Applicant respectfully submits that Behl fails to remedy the deficiencies of Tullis with respect to at least the portions of amended claims 1, 18, and 24 emphasized above. For *at least* the foregoing reasons—including others which the Applicant reserves the right to present hereafter—the Applicant respectfully asserts that amended claims 1, 18, and 24 are patentable over Tullis and Behl and requests that the rejection of these claims under 35 U.S.C. § 103 be withdrawn. Moreover, as each of pending claims 2, 3,

5-17, and 31 depends from claim 1; each of pending claims 19-23 depends from claim 18; and each of pending claims 28-30, 32, and 33 depends from claim 24, all of which stand rejected under 35 U.S.C. § 103 in view of Tullis and Behl, the Applicant also requests that the rejections of these dependent claims likewise 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 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 31st day of March, 2026.

Respectfully submitted,

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