Filed: July 26, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,

Petitioner,

v.

STRATUS MEDICAL, LLC,

Patent Owner.

Case IPR2024-01209
Patent 10,966,782

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,966,782

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PETITIONER'S EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 10,966,782 to Wright et al. (issued April 6, 2021) ("'782 Patent")
1002	U.S. Patent No. 10,736,688 to Wright et al. (issued August 11, 2020) ("'688 Patent")
1003	U.S. Patent No. 10,925,664 to Wright et al. (issued February 23, 2021) ("'664 Patent")
1004	U.S. Patent No. 11,806,070 to Wright et al. (issued November 7, 2023) ("'070 Patent")
1005	U.S. Patent No. 10,716,618 to Wright et al. (issued July 21, 2020) ("'618 Patent")
1006	The Complete File History of the '782 Patent, U.S. Patent App. No. 16/933,811 (filed July 20, 2020) (the '811 application)
1007	The Complete File History of the '688 Patent, U.S. Patent App. No. 15/098,673 (filed April 14, 2016) (the '673 application)
1008	The Complete File History of the '664 Patent, U.S. Patent App. No. 16/933,995 (filed July 20, 2020) (the '995 application)
1009	U.S. Patent No. 6,146,380 to Racz et al. (issued November 14, 2000) ("Racz")
1010	U.S. Publication No. 2007/0016183 to Lee et al. (published January 18, 2007) ("Lee")
1011	U.S. Publication No. 2005/0059964 to Fitz (published March 15, 2005) ("Fitz")
1012	U.S. Publication No. 2006/0084965 to Young (published April 20, 2006) ("Young '965")
1013	U.S. Publication No. 2007/0260223 to Scheibe et al. (published November 8, 2007) ("Scheibe")
1014	U.S. Patent No. 7,976,542 to Cosman et al. (filed on March 2, 2006 and issued on July 12, 2011) ("Cosman '542)
1015	U.S. Publication No. 2007/0027449 to Godara et al. (published on February 1, 2007) ("Godara")
1016	U.S. Publication No. 2009/0112201 to Young (published April 30, 2009) ("Young '201")

Exhibit No.	Description
1017	U.S. Patent No. 6,652,516 to Gough (filed November 19, 1999 and issued on November 25, 2003) ("Gough '516").
1018	U.S. Patent No. 5,728,143 to Gough (filed February 14, 1996 and issued on March 17, 1998) ("Gough '143")
1019	Cohen et al., Randomized Placebo-controlled Study Evaluating Lateral Branch Radiofrequency Denervation for Sacroiliac Joint Pain, Anesthesiology, Vol. 109, Issue 2, 279-288 (2008) ("Cohen")
1020	U.S. Patent No. 6,551,302 to Rosinko (filed on October 26, 2000 and issued on April 22, 2003) ("Rosinko")
1021	U.S. Patent No. 5,855,576 to LeVeen et al. (filed on December 12, 1996 and issued on January 5, 1999) ("LeVeen")
1022	U.S. Patent No. 7,918,852 to Tullis et al. (filed May 1, 2006 and published January 18, 2007) ("Tullis")
1023	U.S. Patent No. 4,411,266 to Cosman (issued October 25, 1983) ("Cosman '266")
1024	U.S. Patent No. 7,195,629 to Behl et al. (filed August 18, 2003 and issued March 27, 2007) ("Behl")
1025	U.S. Patent No. 5,782,827 to Gough et al. (filed December 19, 1995 and issued July 21, 1998) ("Gough '827")
1026	U.S. Patent No. 5,928,229 to Gough et al. (filed October 30, 1997 and issued July 27, 1999) ("Gough '229")
1027	U.S. Patent No. 9,078,678 to Zerfas et al. (filed March 21, 2013 and issued July 14, 2015) ("Zerfas")
1028	U.S. Patent App. Pub. No. 2007/0203486 to Young (published August 30, 2007) ("Young '486")
1029	U.S. Patent App. Pub. No. 2005/0159797 to Chandran et al. (published July 21, 2005) ("Chandran")
1030	U.S. Patent App. Pub. No. 2008/0269774 to Garcia et al. (published October 30, 2008) ("Garcia")
1031	Declaration of Dr. Robert D. Tucker (July 26, 2024)
1032	Reserved
1033	Reserved

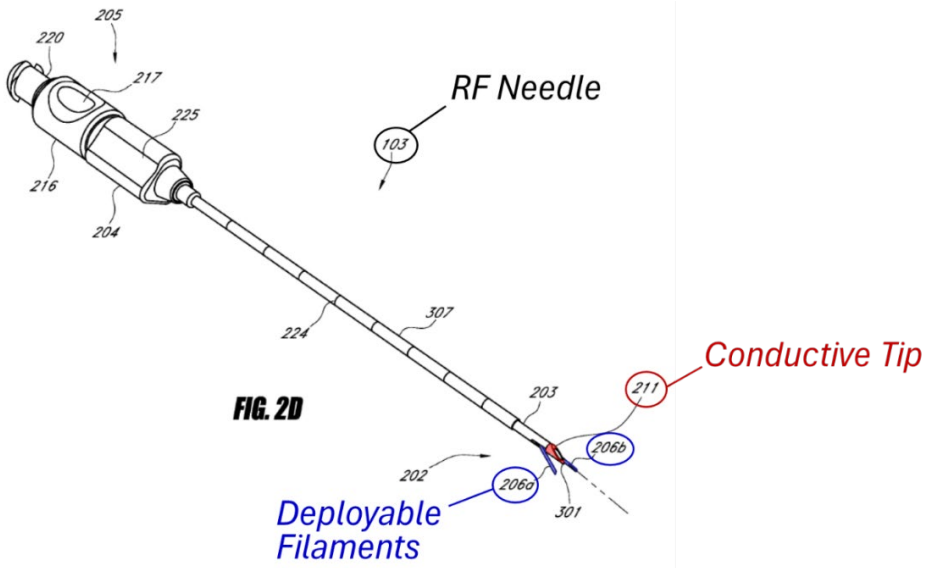
Exhibit No.	Description
1034	Reserved

GLOSSARY

Term	Meaning
"'782 Patent" or "Challenged Patent"	U.S. Patent No. 10,966,782 to Wright et al. (issued April 6, 2021)
"Challenged Claims"	Claims 1-27 of the '782 Patent
"Board"	USPTO Patent Trial and Appeal Board
"POSA"	Person of ordinary skill in the art at the time of the '782 Patent's alleged invention
"RF"	Radiofrequency
"Racz's modified device"	Racz's cannula (10/33) modified by a POSA to include deployable filaments as disclosed in Fitz and Lee.

I. INTRODUCTION

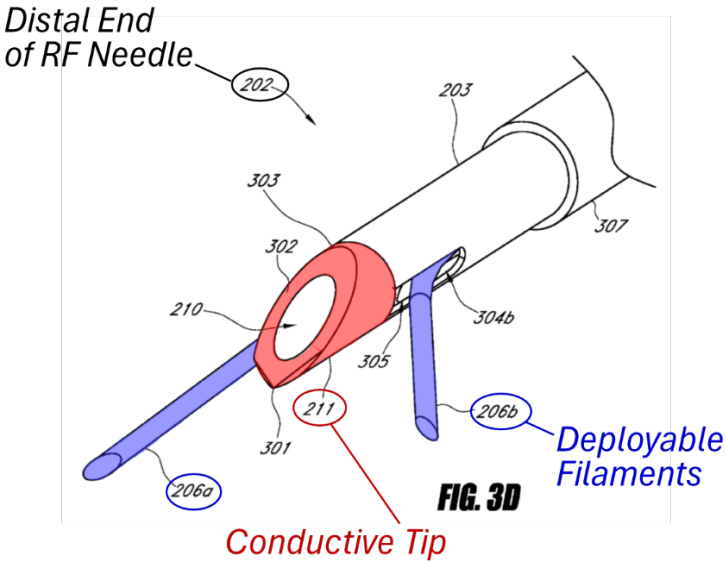
Radiofrequency (RF) ablation is a procedure in which an electrical needle is inserted into targeted patient tissue and activated with RF energy. The RF energy transmitted from the needle's electrode heats the surrounding tissue and generates a lesion, thereby ablating (or destroying) the tissue. Using RF energy to ablate tissue is effective for a variety of treatments. For example, RF ablation may be used to ablate nerve tissue to disrupt the transmission of pain signals (these procedures are also referred to as RF neurotomy). Similarly, RF ablation may be used to destroy liver tumors, uterine fibroids, and other undesirable tissue to treat various conditions.



'782 Patent – Fig. 2D (annotated)

The '782 Patent is directed to an RF neurotomy needle (103) that includes a conductive tip (211) (**shaded red**) and deployable electrode filaments (206a-b)

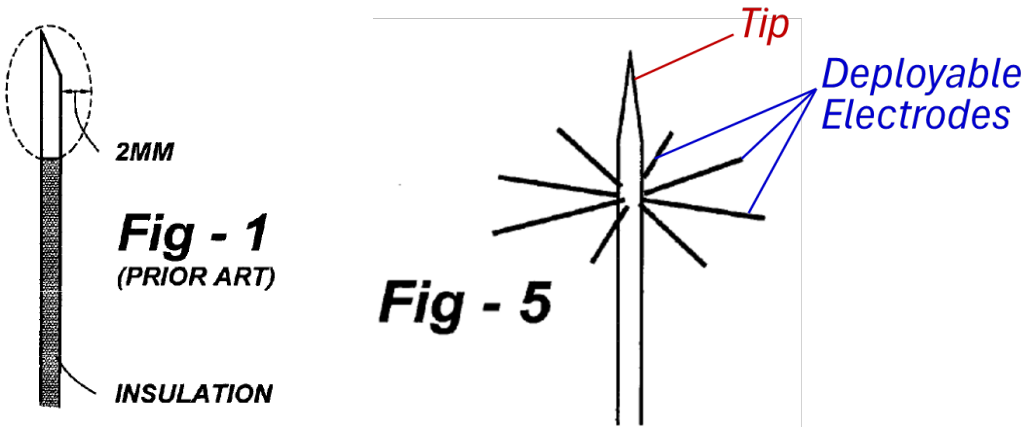
(**shaded blue**) (*see e.g.,* Figs. 2D and 3D). The tip (211) and filaments (206a-b) (when deployed) transmit RF energy and heat tissue in the area near the tip and filaments.



'782 Patent – Fig. 3D (annotated)

According to the '782 Patent, the needle (103) solves a problem associated with single-tip needles (i.e., RF needles having only one electrode tip). Because single-tip needles emanate RF energy from just one location, "the size of a radiofrequency lesion using conventional single needle technology is practically limited." Ex-1001, 10:53-62. Thus, the '782 Patent describes "[a] needle 103 with deployable filaments 206a, 206b [that] 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." Ex-1001, 10:59 to 11:10.

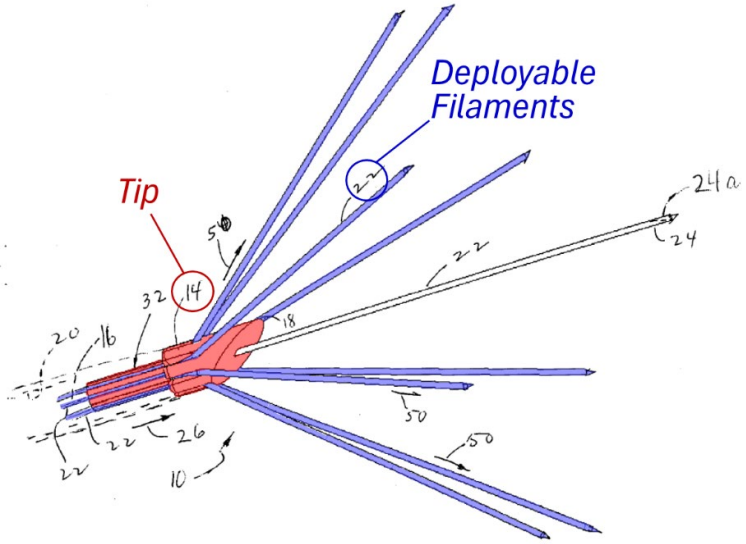
This solution, however, was nothing new. Five years earlier, U.S. Publication No. 2005/0059964 to Fitz disclosed that "[a] problem with current [RF neurotomy needles] is that they do not allow for adequate coverage of the target area" and produce spherical lesions that "extend[] only a few millimeters." Ex-1011, ¶0002, 0004, Fig. 1. To solve this problem, Fitz proposed an "improved-coverage RF neurotomy instrumentation" configured "to deploy a set of electrodes to an area to be treated." Ex-1011, ¶0009, Fig. 5. According to Fitz, the deployable electrodes "enhance the energy coverage area" of RF neurotomy devices compared to single-tip electrodes. *Id*.



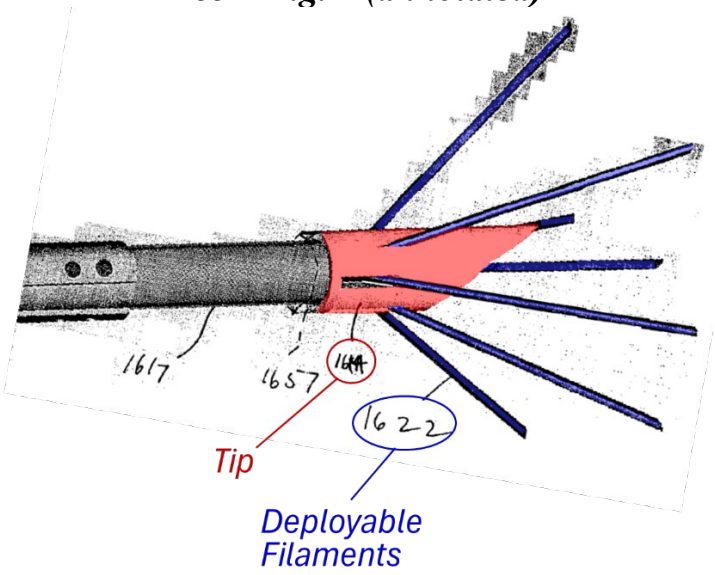
Fitz – Figs. 1 & 5 (annotated)

In fact, by the time of the '782 Patent's alleged invention, deployable filaments were commonly used in RF ablation devices. U.S. Publication No. 2007/0016183 to Lee discloses RF ablation needles that—like the '782 Patent—use channels to guide deployable filaments (**shaded blue**) outwardly around a needle's tip (**shaded red**). Ex-1010, Figs 1, 48. Lee also notes that the number,

pattern, direction, size, and/or length of the filaments can all be varied to generate any desired ablation volume. Ex-1010, ¶0123-0131, 0084, 0012, 0103.



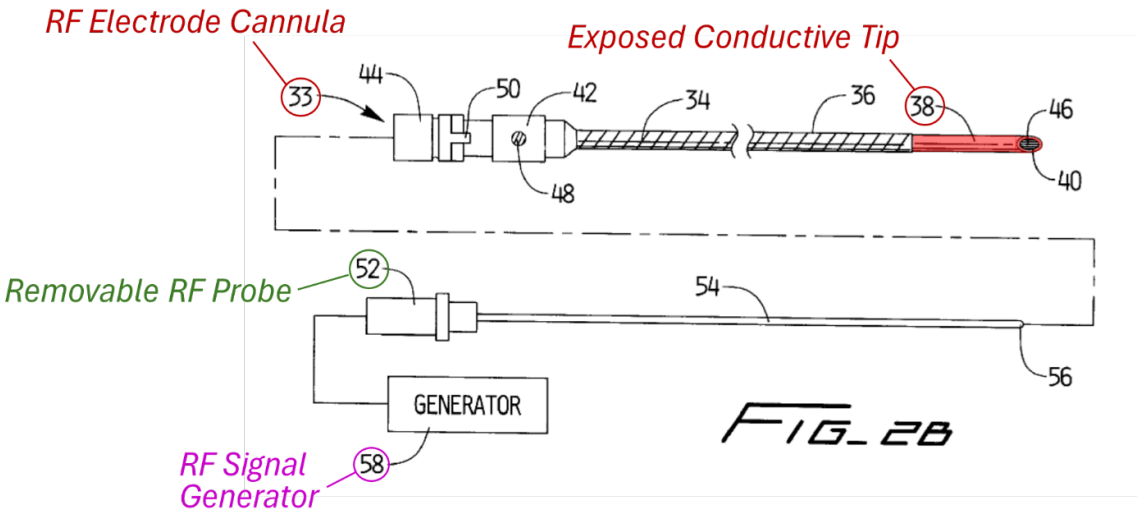
Lee – Fig. 1 (annotated)



Lee – Fig. 48 (annotated)

As the ’782 Patent’s claims recite an amalgamation of well-known RF needle features, multiple references are combined herein to demonstrate obviousness. Most of the claimed RF needle features—including an elongate

cannula, a removable RF probe, a conductive tip, and a monopolar configuration—are conventional features disclosed in U.S. Patent No. 6,146,380 to Racz. As shown below, Racz describes a typical RF neurotomy needle (without deployable filaments).



Racz – Fig. 2B

The claimed features relating to deployable filaments—which were well-known at the time of the invention—are rendered obvious by at least Fitz and Lee (combined with Racz). Fitz discloses that Racz's single-tip device would produce limited ablation volumes and would have motivated a POSA to solve this problem by adding deployable filaments. Lee would have provided further guidance, motivating a POSA to implement deployable filaments on the tip of Racz's device using channels within the cannula. Lee also shows how the filaments can extend outwardly around the needle's tip to advantageously expand and control the ablation volume.

As explained herein, a POSA would have found it obvious to modify Racz's device to include the well-known deployable filaments described in Fitz and Lee. This would have been a matter of routine engineering with entirely predictable results. The combination was obvious—as are the Challenged Claims.

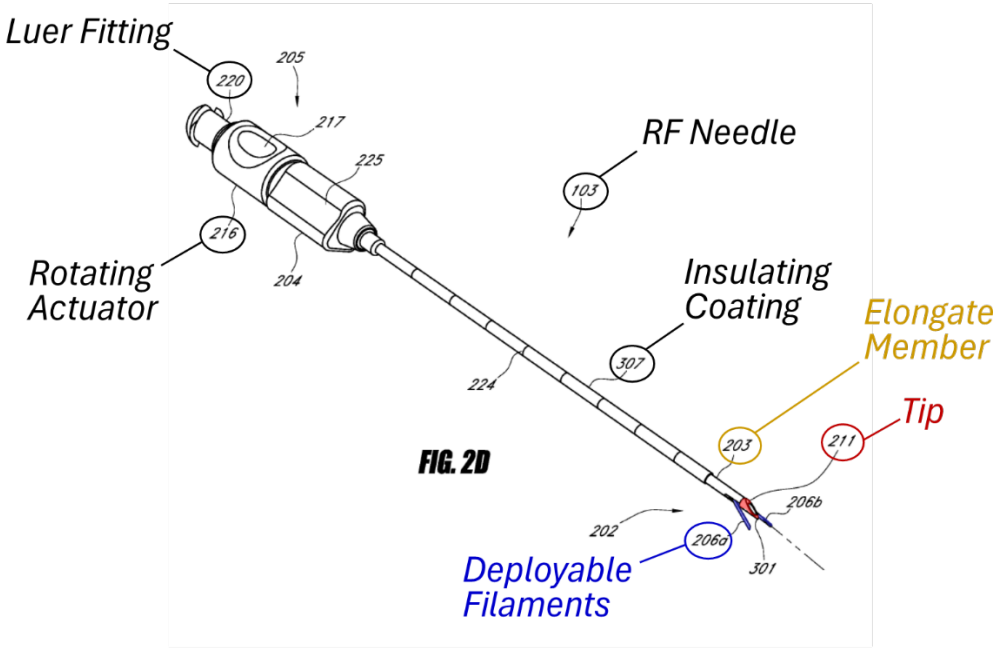
II. THE '782 PATENT

A. Overview

The '782 Patent describes embodiments of an RF needle (103) that can be used for RF neurotomy or "adapted … for use in other medical procedures" using RF energy. Ex-1001, 48:28-47.[1] In Fig. 2D, the needle (103) includes an elongate member (203) having a conductive tip (211) (**shaded red**) and deployable filaments (206a-b) (**shaded blue**). Ex-1001,10:4-17; Ex-1031, ¶89-90. The elongate member (203) is substantially covered with an insulating material (307) while the tip (211) and filaments (206a-b) remain exposed and electrically active. Ex-1001, 10:18-35, 10:63-67, 11:58-67, 19:23-29. A Luer fitting (220) at the proximal end of the needle (103) is configured for receiving (i) a removable RF probe (401) (which is inserted into the elongate member's lumen) and (ii) fluid

[1] The '782 Patent includes 43 figures (labeled 1-18B) showing various needle configurations. One example is described herein for context and brevity.

delivered through the lumen (when the probe (401) is removed). Ex-1001, 21:5-10, 30:12-21.

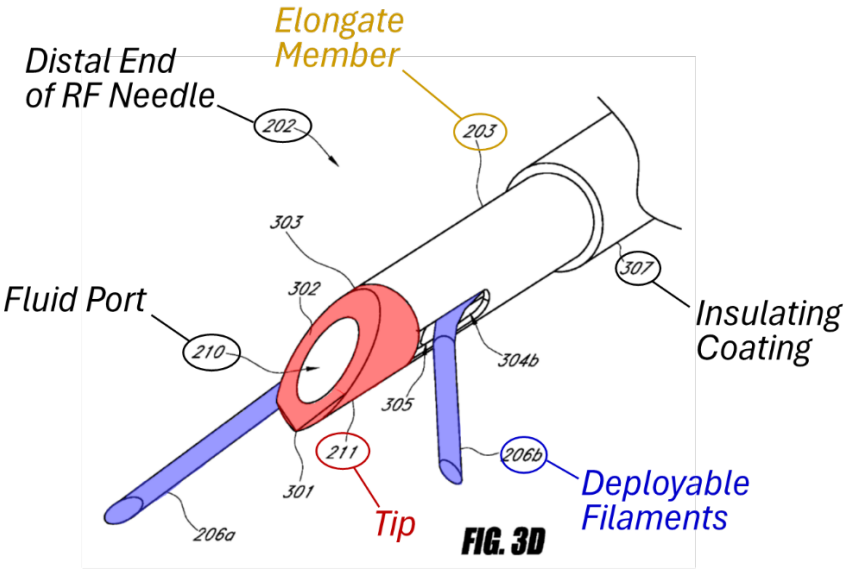


'782 Patent – Fig. 2D

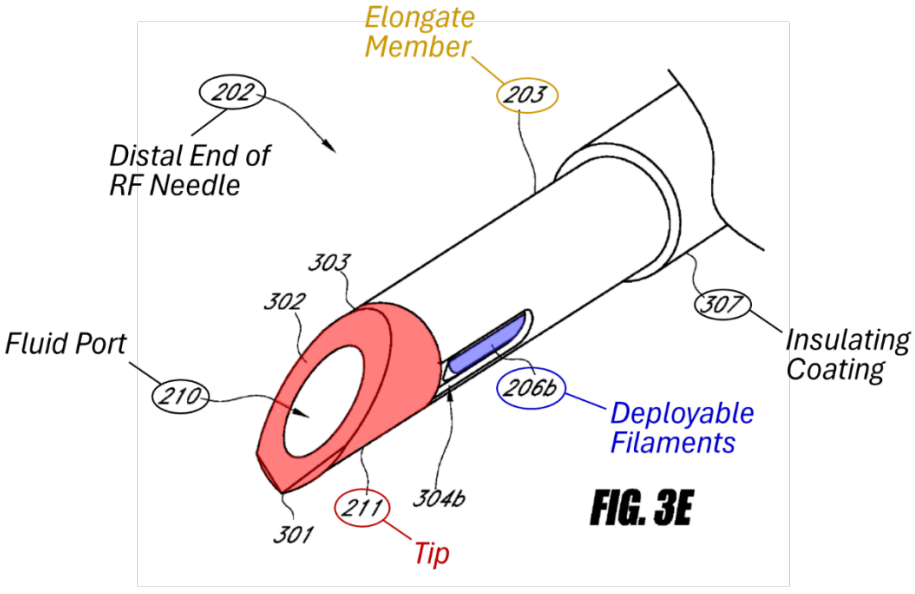
The filaments (206a-b) are deployed/retracted by a rotating actuator (216). Ex-1001, 10:33-35, 29:43-30:45; Ex-1031, ¶91. When deployed, the filaments (206a-b) "expand the volume of effective RF energy delivery as compared to known single-electrode RF probes." Ex-1001, 10:18-27. Additionally, "variation in the shape, position, and/or size of lesions … may be achieved by different configurations of filaments," including varying the number, length, position, and angle of the filaments (206a-b). Ex-1001, 25:34-46, 25:13-33, 26:23-54.

As shown in Figs. 3D-3E, the needle's tip (211) is positioned at the elongate member's distal end. Ex-1001, 10:12-17; Ex-1031, ¶92. The tip (211) includes a

fluid port (210) (e.g., for delivering anesthetic via the Luer fitting (220) when the probe (401) is removed) and a pointed end (301) for "piercing the skin of a patient." Ex-1001, 13:1-35, 9:59-65, 10:6-12.



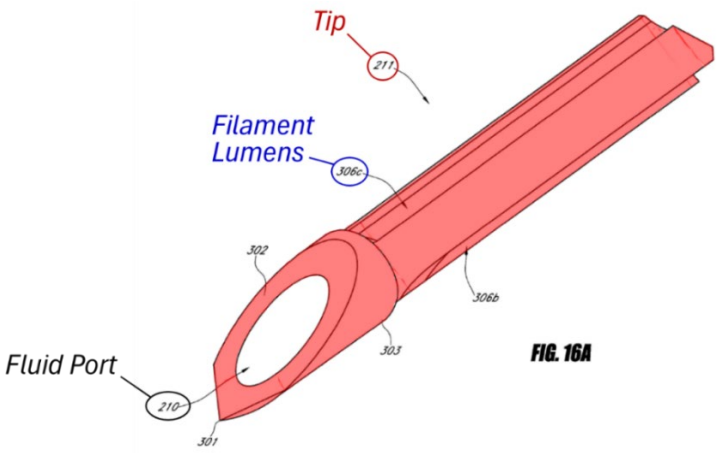
'782 Patent – Fig. 3D



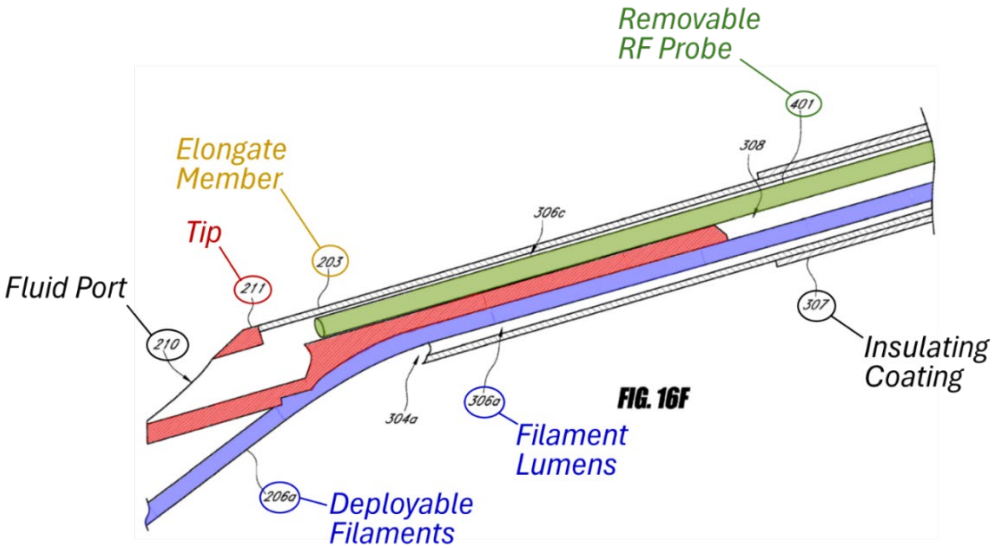
'782 Patent – Fig. 3E

Although the tip (211) and elongate member (203) may be a "unitary structure," Figs. 16A and 16F show a configuration where the tip (211) is a

separate member coupled to the elongate member (203). Ex-1001, 2:1-3, 13:26-27, 14:2-4, 14:18-31, 20:26-33; Ex-1031, ¶93. The tip (211) defines filament lumens (306a-b) (e.g., channels) that guide the filaments (206a-b) in and out of slots (304a-b) when the filaments (206a-b) are deployed/retracted by the actuator (216). Ex-1001, 13:26-14:31.



'782 Patent – Fig. 16A



'782 Patent – Fig. 16F

To transmit RF energy to the tip (211) and filaments (206a-b), the elongate member (203) receives a removable RF probe (401). Ex-1001, 10:36-46, 9:27-38, 15:53-64. The probe (401) conducts RF energy from a generator (102). Ex-1001, 8:63-9:38, Fig. 1. As "the elongate member 203 and the tip … comprise … a conductive material," they 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." Ex-1001, 15:58-64. In this way, the tip (211) and filaments (206a-b) operate together as an electrode. Ex-1031, ¶94.

B. Prosecution History

The '782 Patent issued from U.S. Patent Application No. 16/933,811 (the '811 Application") filed on July 20, 2020. The '811 Application claims priority through a chain of continuation applications (US 15/092,945 and US 13/101,009) to three US provisional applications (61/347,351 filed on May 21, 2010; 61/357,894 filed on June 23, 2010; and 61/357886 filed on June 23, 2010).

The '811 Application was filed with 29 claims, all of which were rejected in a Non-Final Office Action. Ex-1006, 152; Ex-1031, ¶95-97. During an interview, the Examiner requested claim amendments 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." Ex-1006, 280. The

independent claims were amended to include these features and allowed. Ex-1006, 271, 276, 277-78; Ex-1031, ¶98-104.

As explained herein, the features added to secure allowance of the ’782 Patent’s claims were all well-known and obvious. Among the references in the Petition’s Grounds, only Young ’965 was discussed at all during prosecution (and only with respect to two dependent claims). Ex-1006, 167-68, 263-64. None of the remaining references in the Petition’s Grounds were discussed during prosecution. Moreover, because the Examiner was burdened with *more than 500 references* cited during prosecution, it is unsurprising that the relevance of the cited references was not appreciated.

III. LEVEL OF ORDINARY SKILL IN THE ART

The ’782 Patent identifies its technical field as relating to “thermal ablation systems and methods,” which includes RF neurotomy systems. Ex-1001, 1:28-31. A POSA in this field would have had at least (i) a bachelor’s degree in biomedical engineering, or a related field, such as mechanical engineering, biomechanical engineering, or bioengineering, who also has at least 3 years of experience with thermal ablation system and methods; or (ii) an advanced degree in the same areas of academic study with at least 1 years of experience with thermal ablation systems and methods. Ex-1031, ¶105.

IV. CLAIM CONSTRUCTION

Petitioner does not believe that any terms in the Challenged Claims require express construction for purposes of this IPR and does not believe it is necessary to construe any term according to § 112(f). *See* Trial Practice Guide at 44-49; Ex-1031, ¶106. The '782 Patent claims have not been previously construed in any proceeding. Petitioner reserves the right to respond to any claim construction positions offered by Patent Owner.

V. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

A. Standing

Petitioner certifies that the '782 Patent is available for IPR and that Petitioner is not barred or estopped from challenging the claims in this Petition.

B. Identification of Challenge

Claims 1-27 are invalid under the following Grounds:

	Claims	Statute	Prior Art
A	1-27	§ 103(a)	**Racz, Fitz, and Lee**
B	1-27	§ 103(a)	Racz, Fitz, Lee, and **Young '965**
C	1-27	§ 103(a)	Racz, Fitz, Lee, and **Scheibe**
D	1-27	§ 103(a)	Racz, Fitz, Lee, Young '965, and Scheibe
E	7-9	§ 103(a)	Racz, Fitz, Lee, and **Cosman '542**
F	7-9	§ 103(a)	Racz, Fitz, Lee, Cosman '542, and Young '965
G	7-9	§ 103(a)	Racz, Fitz, Lee, Cosman '542, and Scheibe
H	7-9	§ 103(a)	Racz, Fitz, Lee, Cosman '542, Young '965, and Scheibe
I	13	§ 103(a)	Racz, Fitz, Lee, and **Young '201**
J	13	§ 103(a)	Racz, Fitz, Lee, Young '201, and Young '965
K	13	§ 103(a)	Racz, Fitz, Lee, Young '201, and Scheibe
L	13	§ 103(a)	Racz, Fitz, Lee, Young '201, Young '965, and Scheibe
M	15	§ 103(a)	Racz, Fitz, Lee, and **Godara**

	Claims	Statute	Prior Art
N	15	§ 103(a)	Racz, Fitz, Lee, Godara, and Young '965
O	15	§ 103(a)	Racz, Fitz, Lee, Godara, and Scheibe
P	15	§ 103(a)	Racz, Fitz, Lee, Godara, Young '965, and Scheibe

The following references were issued/published more than one year before the '782 Patent's earliest claimed priority date (May 21, 2010) and are therefore prior art under pre-AIA 35 U.S.C. § 102(b): Racz, Fitz, Lee, Young '965, Scheibe, Young '201, and Godara. Cosman '542 was filed on March 2, 2006 (and issued on July 12, 2011) and is therefore prior art under at least pre-AIA 35 U.S.C. § 102(e).

VI. GROUND A: CLAIMS 1-27 ARE OBVIOUS IN VIEW OF RACZ, FITZ, AND LEE.

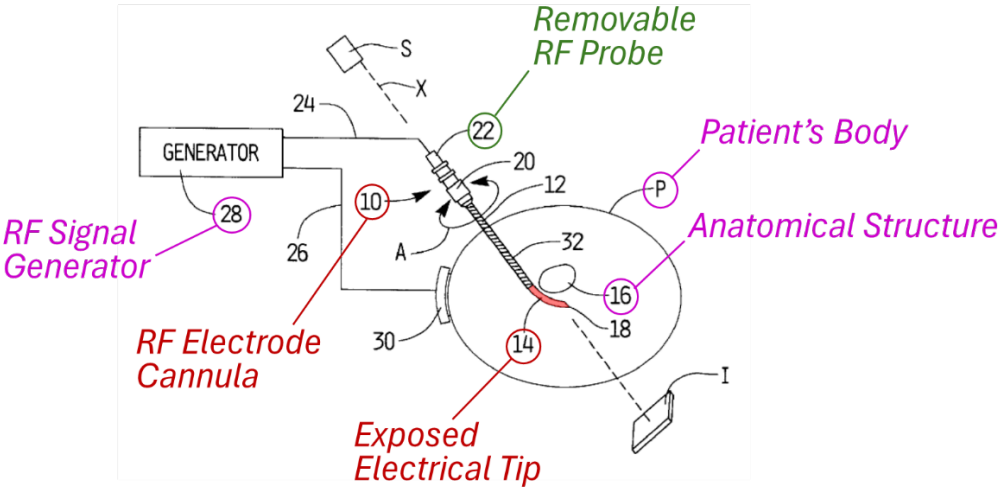
A. Prior Art Overview

1. Overview of Racz

Racz discloses an "apparatus for pain relief that delivers electrical stimulation pulses or high-frequency signals to the vicinity of a neural structure via an electrical needle or cannula." Ex-1009, 1:4-9. Thus, Racz is directed to the same field as the '782 Patent ("thermal ablation systems and methods"). Ex-1001, 1:28-31; Ex-1031, ¶110-12.

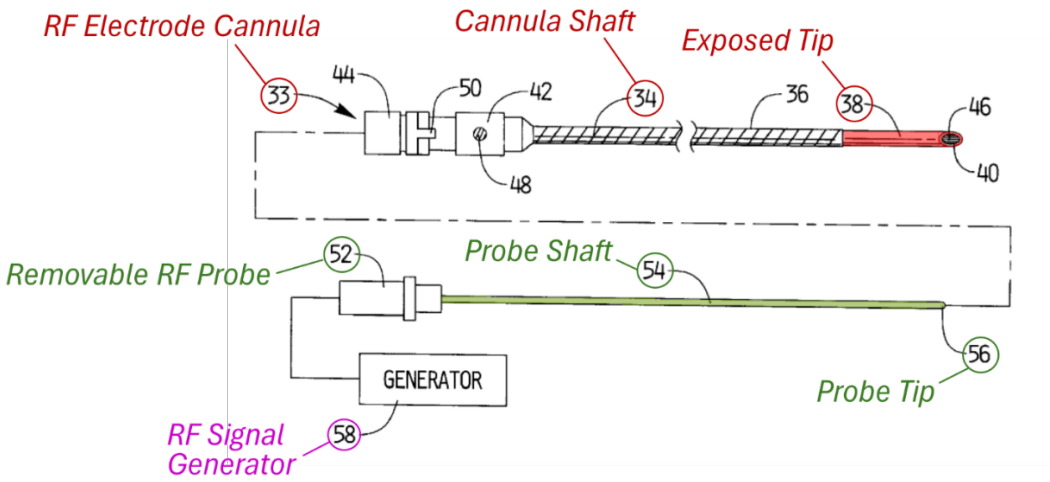
As shown in Figure 1, Racz's system includes a "radio-frequency electrode cannula 10" (aka "electrical needle") that is "inserted directly through the skin of [a] body portion P to locate the [cannula's] tip 14 in a target position within the body." Ex-1009, 3:42-45. Racz shows a "specific embodiment" of the Figure 1

system in Figures 2A/B, which illustrate an electrode cannula (33). Ex-1009, 4:59-62, 5:7-51, Fig. 2A/2B. The cannula (33) corresponds to the cannula (10) and so Petitioner refers to common features in Figures 1 and 2A/2B using the convention "cannula (10/33)." Ex-1009, 4:59 to 5:6; Ex-1031, ¶113, 117. [2]



Racz – Fig. 1 (annotated)

[2] Racz's Figs. 3A/B show another specific embodiment that corresponds to the Figure 1 system. For simplicity, Racz's Figs. 3A/B are only referred to herein when necessary.



Racz – Fig. 2B (annotated)

The cannula (10/33) includes a shaft (12/34) defining an internal lumen. Ex-1009, 5:41-45. The shaft is covered with insulation (36) but includes an uncovered, exposed distal tip (14/38) (**shaded red**). Ex-1009, 4:62-65. The tip (14/38) includes a pointed end (40), which allows the cannula (10/33) to "penetrat[e] tough tissue." Ex-1009, 5:3-5; Ex-1031, ¶114.

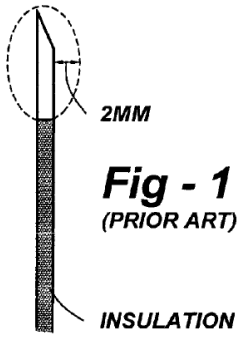
RF energy is conveyed to the cannula's exposed tip (14/38) via a removable electrical probe (22/52), which is connected to a signal generator (28/58). Ex-1009, 3:60-63, 4:18-23, 4:18-20. The electrical probe (22/52) includes a probe shaft (54) (**shaded green**) having a probe tip (56), which may include a temperature sensor. Ex-1009, 5:26-30, Fig. 2B. When the probe (22/52) is fully inserted into the cannula (10/33), "physical contact" between the probe (22/52) and the cannula's tip (14/38) conducts the RF energy to the tip (14/38). Ex-1009, 3:60-65, 4:18-23, 5:41-48, Fig. 2B; Ex-1031, ¶115.

In this way, Racz's cannula (10/33) provides "electrical stimulation or high-frequency heating of tissue near the exposed electrical tip 14." Ex-1009, 3:60 to 4:23, 5:41-51, Fig. 1. Additionally, a reference electrode (30) is placed on the patient's body (P), allowing the tip (14/38) to function as a monopolar electrode. Ex-1009, 4:3-23; Ex-1031, ¶116-117.

2. Overview of Fitz

Fitz is directed to an "improved-coverage" RF neurotomy device. Ex-1011, ¶0001-0002, 0009, Abstract, Claim 1. Thus, Fitz is also directed to the '782 Patent's field. *See* Ex-1001, 1:28-31; Ex-1031, ¶118.

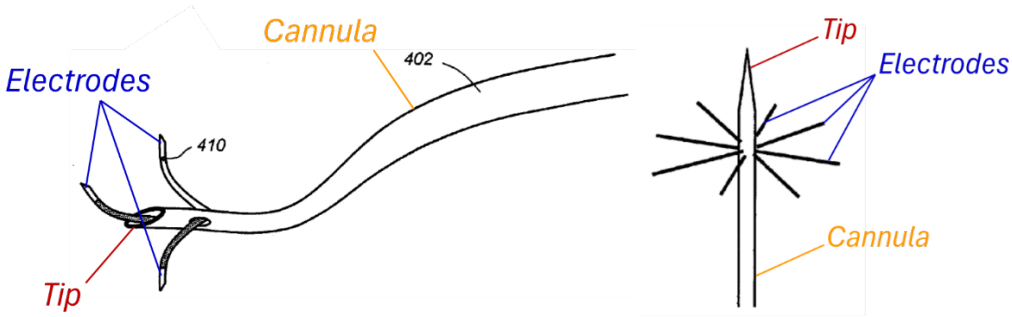
Fitz discloses that a known problem with single-tip RF neurotomy devices was "that they do not allow for adequate coverage of the target area." Ex-1011, ¶0004. As Fitz illustrates in Figure 1, single-tip RF neurotomy needles (like Racz's device) produce lesions that "extend[] only a few millimeters" from the exposed needle tip. Ex-1011, ¶0004-0005. As a result, multiple lesions may be needed to achieve adequate energy coverage. Ex-1011, ¶0004-0005; Ex-1031, ¶119.



Fitz – Fig. 1

To solve the problem of inadequate coverage in single-tip neurotomy devices, Fitz suggests providing a deployable "set of electrodes" that extend outwardly from the "exposed distal tip" of an RF neurotomy cannula. Ex-1011, ¶0009, Abstract, Claim 1; Ex-1031, ¶120. The deployable electrodes may be made from a "shape-memory alloy" and configured to "deliver [RF] energy to a localized region." Ex-1011, ¶0009-0010. By deploying outwardly "to an area to be treated," the deployable electrodes "enhance the energy coverage area" of the neurotomy cannula. Ex-1011, ¶0009, Abstract, Claim 1.

Fitz describes several versions of its deployable electrode neurotomy device. In one example (Fig. 4), an introducer (402) (aka "cannula") includes "a plurality of electrodes … deployed through the tip and/or multiple side ports." Ex-1011, ¶0020, Fig. 4. In another example (Fig. 5), Fitz describes "an introducer having a tip and sufficient side ports to form an array of electrodes once deployed." Ex-1011, ¶0021, Fig. 5. In each example, the electrodes are deployed outwardly from the cannula's distal tip to enhance the device's energy coverage area. Ex-1031, ¶121-123.



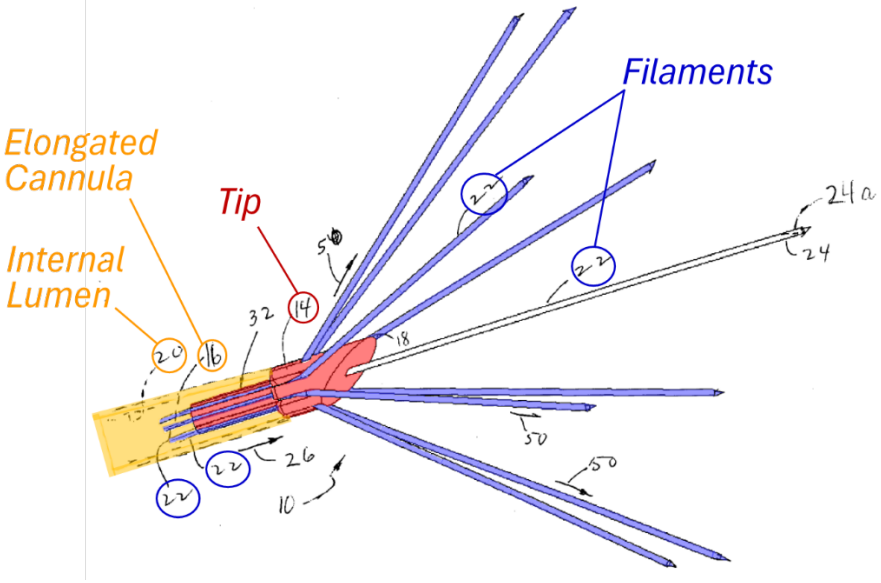
Fitz – Fig. 4 (annotated at left) & Fig. 5 (annotated at right)

3. Overview of Lee

Lee discloses various techniques for deploying electrodes from the tip of an RF ablation device. *See e.g.,* Ex-1010, ¶0012, 0107. Thus, Lee is also directed to the '782 Patent's field. *See* Ex-1001, 1:28-31; Ex-1031, ¶124, 30-33.

Like Fitz, Lee discloses that a deployable-electrode technique can be used to deliver RF energy to a targeted area of tissue. Ex-1010, ¶0084, 0032, Title. In Figure 1, Lee shows a "multiple antenna ablation device" (also referred to as an "ablation trocar" (10)). Ex-1010, ¶0032. The ablation trocar (10) includes a "trocar point" (14) (a tip) (**shaded red**) that is mounted on a cannula (16) **(shaded orange)** and includes a piercing surface (18). Ex-1010, ¶0032, 0091-0092, Fig. 1. A "plurality of stylets 22" (**shaded blue**) are housed within the cannula's internal lumen (20) (when retracted). Ex-1010, ¶0092. The stylets (22) are conductive electrodes and deployed outwardly from the tip (14) to apply RF energy for ablation of a targeted area. Ex-1010, ¶0092, 0107. Lee notes that the stylets (22) may be "springy wire-like members" constructed from a nickel-titanium alloy. Ex-

1010, ¶0092, 0087. In other words, the stylets (22) are filaments. Ex-1031, ¶125-126.

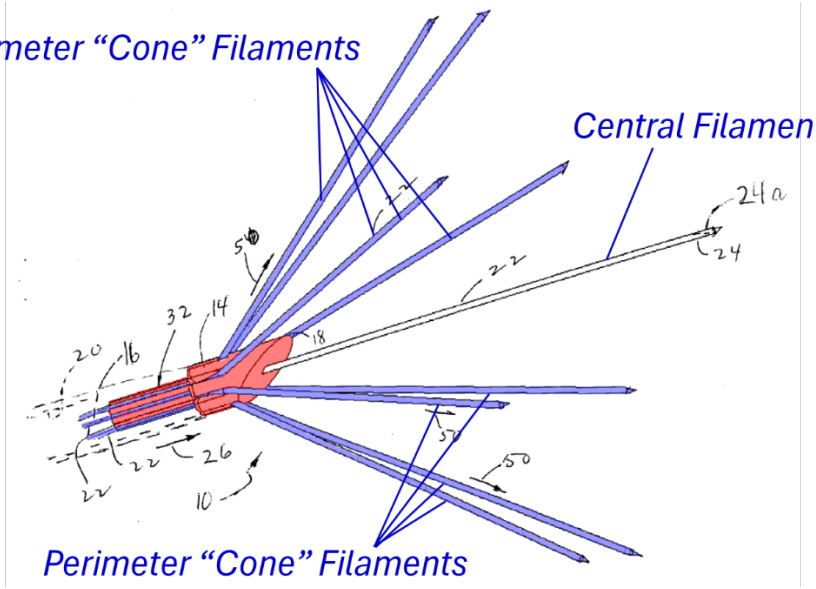


Lee – Fig. 1 (annotated)

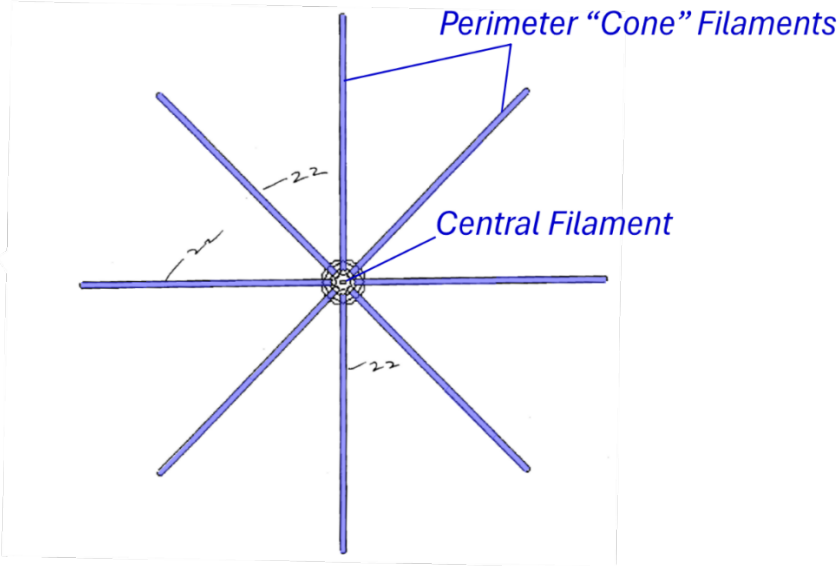
Figure 1 shows Lee's filaments (22) in a deployed position. Ex-1010, ¶0092, 0093, 0099, 0102. The tip (14) includes delivery mandrel surfaces (12) (or "deflection surfaces") comprising channels and ramps positioned in the cannula (16). Ex-1010, ¶0016, 0018, Claims 8, 10. The filaments (22) are positioned around the tip (14) and, when deployed, are guided outwardly by the deflection surface channels/ramps (12). Ex-1010, ¶0091, 0102, Abstract; Ex-1031, ¶127.

Lee's filaments (22) are positioned around the perimeter of the tip (14) and extend outwardly in a "cone" orientation. Ex-1010, ¶0103. An exception is a central filament (22) (unshaded), which is surrounded by the perimeter filaments

(22) and deployed through the center of the trocar point (14). Ex-1010, ¶0092, ¶0102, Figs. 1-3; Ex-1031, ¶128.



Lee – Fig. 1 (annotated)

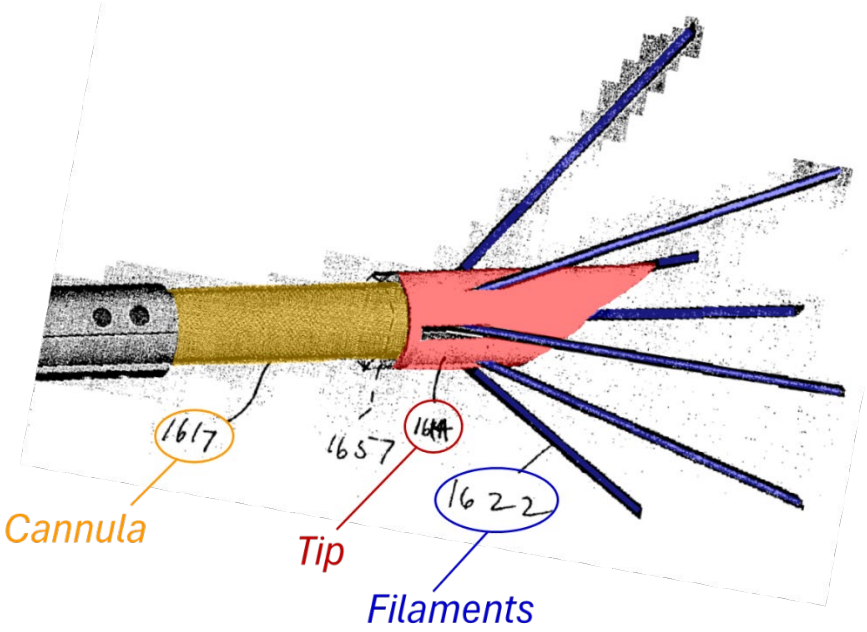


Lee – Fig. 5 (annotated)

Lee discloses that the filaments "define an ablation volume in the target tissue." Ex-1010, ¶0012. Thus, "the destruction of target tissue [occurs] at the site where the electrodes are located." Ex-1010, ¶0084. The ablation volume may be

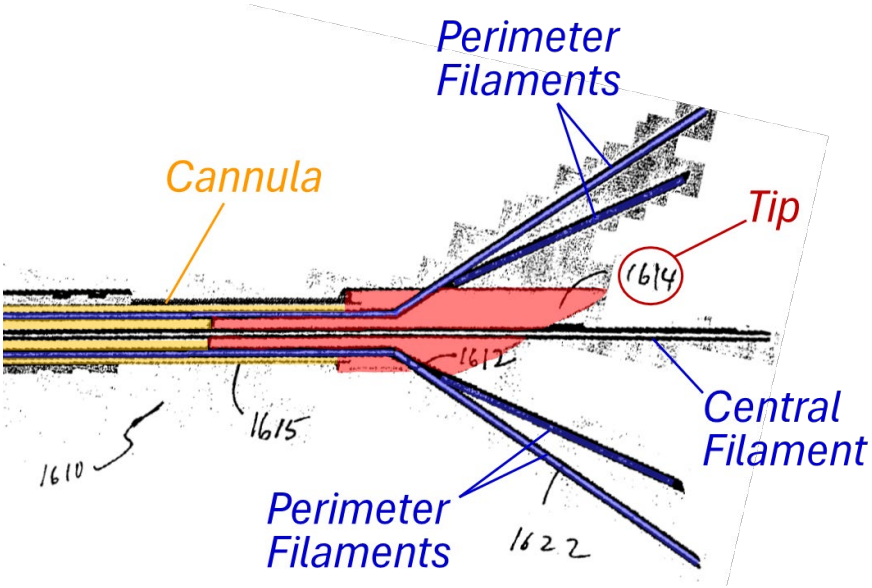
varied by adjusting the filaments' length, direction, arrangement, and/or pattern. *See* Ex-1010, ¶0123-0131, 0084; Ex-1031, ¶129.

Lee provides additional detail regarding filament deployment with reference to a trocar (1610) (Figs. 48-49). The device's cannula (1615) (**shaded orange**) may be a metal tube coated with an insulative material (1617). Ex-1010, ¶0142. The cannula (1615) (aka "hypotube") houses a plurality of metal stylets (1622) (**shaded blue**) (i.e., filaments). Ex-1010, ¶0143; Ex-1031, ¶130. A tip or "trocar point" (1614) (**shaded red**) is secured to the end of the cannula (1615) and includes deflection surfaces (1612) to deflect the filaments (1622) when they are extended outwardly from the tip (1614). Ex-1010, ¶0142-0146. The filaments (1622) transmit RF energy to define an ablation volume. Ex-1010, ¶0146.



Lee – Fig. 48 (cropped and annotated)

Figure 49 shows a cross-sectional view of the device (1610), which illustrates how the filaments (1622) extend through the cannula (1615) and are guided outwardly by the tip's deflection surfaces (1612). Ex-1010, ¶0142, 0146. As illustrated, the deployed filaments (1622) extend outwardly around the tip (14). Ex-1010, ¶0142, 0146; Ex-1031, ¶131. The perimeter filaments (1622) again define a cone shape, while a central filament extends through a passage in the center of the tip (1614) such that the perimeter filaments are positioned around the central filament. Ex-1010, ¶0103, 0146, Figs. 1-3, 48-49.



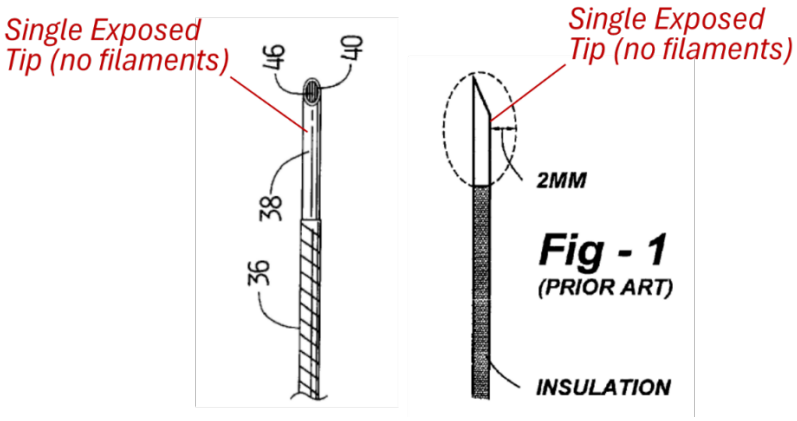
Lee – Fig. 49 (cropped and annotated)

B. Motivation to Combine Racz, Fitz, and Lee.

Considering Racz, Fitz, and Lee together, a POSA would have been motivated to implement deployable filaments on the distal tip (14/38) of Racz's electrode cannula (10/33). "[I]f there's a known technique to address a known

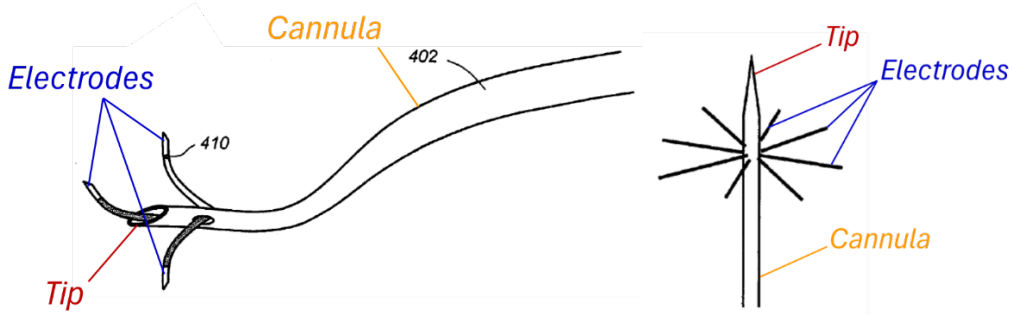
problem using 'prior art elements according to the established functions,' then there is a motivation to combine." *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023) (internal citations omitted). Fitz and Lee disclose a known technique for solving a known problem in RF ablation devices—providing deployable filaments at a distal tip to expand and control the ablation volume compared to single-tip devices with inadequate energy coverage. Ex-1011, ¶0009-0010, Abstract; Ex-1010, ¶0012, 0084, 0123-0131; Ex-1031, ¶132, 60-65, 69-72. Thus, a POSA would have recognized that the Fitz/Lee technique would improve the energy coverage area of Racz's single-tip device. *Id.*

Several factors would have motivated a POSA to combine the references. Four years after Racz's publication, Fitz disclosed that a known problem with single-tip RF neurotomy devices was "that they do not allow for adequate coverage of the target area" and produce lesions extending "only a few millimeters" from the exposed tip. Ex-1011, ¶0004-0005. Fitz also would have confirmed to a POSA that this limited coverage problem would be present in Racz's device due to its single-tip configuration (see comparison below). Ex-1011, ¶0004, 0012, 0017; Ex-1031, ¶133-135.



Racz – Fig. 2B ***Fitz – Fig. 1***

To solve the limited energy coverage problem in Racz's device, Fitz would have motivated a POSA to provide deployable electrodes on Racz's exposed tip (14/38). Ex-1011, ¶0009, Abstract; Ex-1031, ¶136. Fitz instructs that the electrodes may be made from a "shape-memory alloy" and be deployed outwardly from the distal tip "to an area to be treated." Ex-1011, ¶0009-0010, 0018-0021, Abstract, Figs. 4-5. Fitz discloses that this deployable-electrode technique "deliver[s] [RF] energy to a localized region" and solves the inadequate coverage problem of single-tip RF neurotomy needles by "enhanc[ing] the energy coverage area" of the device. Ex-1011, ¶0009-0010.



Fitz – Fig. 4 (annotated at left) & Fig. 5 (annotated at right)

A POSA would have understood from Fitz that implementing deployable electrodes at Racz's distal tip (14/38) has numerous benefits: **(i)** reducing instances where a target nerve "is not lesioned at all" (Ex-1011, ¶0004); **(ii)** reducing the need to create multiple lesions, which is "time-consuming and usually more painful to the patient" (Ex-1011, ¶0005); **(iii)** providing greater flexibility in lesion size/placement as "anatomy differs from patient to patient" (Ex-1011, ¶0004); and **(iv)** expanding the energy coverage area without compromising the device's ability to be "readily deployable through muscle tissue" (Ex-1011, ¶0006-0008). Thus, Fitz would have motivated a POSA to add deployable electrodes to the distal tip (14/38) of Racz's cannula (10/33). Ex-1031, ¶137. As Fitz's device is also an RF neurotomy needle, a POSA would have understood that Fitz's deployable electrodes could be easily implemented onto Racz's tip (14/38). Ex-1031, ¶137.

Nearly two years after Fitz's publication, Lee disclosed a further refinement of the deployable-electrode technique that would have provided additional motivation and guidance to a POSA. Lee discloses that its filaments (22/1622) "define an ablation volume in the target tissue" as "the destruction of target tissue [occurs] at the site where the electrodes are located." Ex-1010, ¶0012, 0084. As a result, "variations in ablation volume" may be achieved by controlling the number of filaments (22/1622) used as well as their length, direction, and arrangement. Ex-1010, ¶0123-0131, 0084. Indeed, the "arrangement of [filaments] may … form any

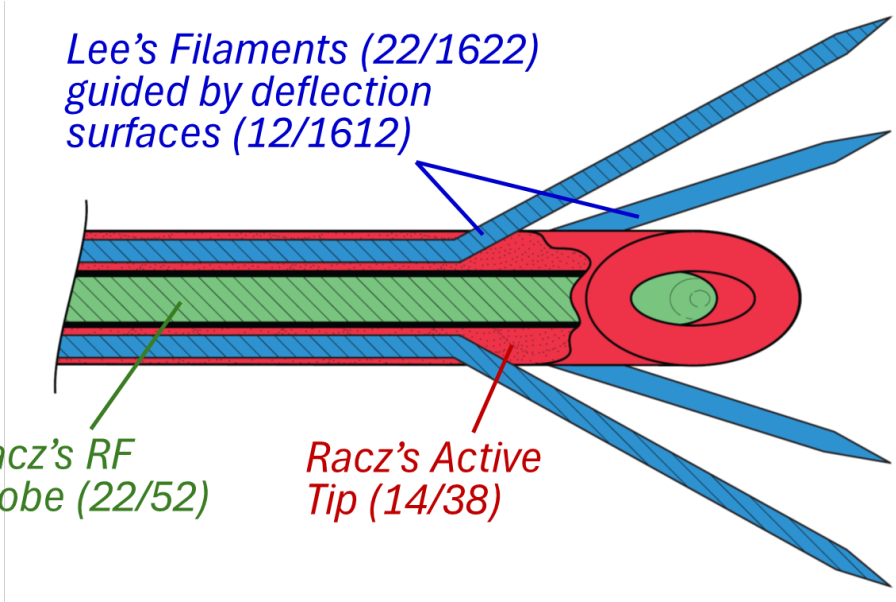
desired pattern" (Ex-1010, ¶0103), and the precision and control offered by the filaments (22/1622) allow "the operator [to] deliver the [radiofrequency] treatment safely and effectively" (Ex-1010, ¶0084). Thus, a POSA would have been further motivated by Lee to add deployable filaments to the distal tip (14/38) of Racz's cannula (10/33) to not just expand—*but also control*—the ablation volume generated by Racz's device. Ex-1031, ¶138-139.

Lee also would have confirmed to a POSA that its deployable filaments (22/1622) would be easily implemented on the distal tip (14/38) of Racz's cannula (10/33). As explained for Claim 1 below (*infra* § VI.C.2), Lee's deployable filaments (22/1622) can be arranged around the inner perimeter of a cannula such that they surround and provide space for a central element. Ex-1010, ¶0094, 0099, 0125, Figs. 1, 23, 49. This would have confirmed to a POSA that Lee's deployable filaments (22/1622) would be easily arranged to accommodate Racz's centrally located removable probe (22/52). Ex-1031, ¶140.

Furthermore, Lee discloses that deflection surfaces (12/1612) (internal channels and ramps) located in the cannula's tip can engage and guide those perimeter filaments (22/1622). Ex-1010, ¶0016, 0018, 0091, 0102, Abstract, Claims 8, 10. Thus, a POSA would understand that providing deflection surfaces in Racz's tip (14/38) would result in Lee's perimeter filaments (12/1622) both physically contacting Racz's active tip (14/38) and being deployed outwardly

around Racz's active tip (14/38). Ex-1031, ¶141-142. In this way, Lee's perimeter filaments (22/1622) would join Racz's existing monopolar tip (14/38) to function together as a single monopolar electrode. *Id.*

Petitioner's expert—Dr. Tucker—illustrates in his declaration one example of how a POSA (motivated by both Fitz and Lee) would have incorporated Lee's deployable filaments (22/1622) as monopolar electrodes at Racz's distal tip (14/38). Dr. Tucker opines that a POSA would have been motivated to implement Lee's deployable filaments (22/1622) while preserving the functionality of Racz's cannula (10/33), active tip (14/38), and removable probe (22/52). Ex-1031, ¶143. According to Dr. Tucker, this implementation would involve nothing more than using prior art elements according to their established functions and combining them in a way that would achieve an expected improvement. *Id.*



Dr. Tucker Declaration at ¶143 (showing one example of how a POSA would modify Racz to include Lee's filaments)

"If a technique has been used to improve one device, and a [POSA] would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023) (internal citations omitted). As explained below with respect to Claim 1's limitations, a POSA would have found implementing Lee's deployable filaments (22/1622) on Racz's tip (14/38) to be a matter of routine engineering, well within the level of ordinary skill in the art, and executable with a reasonable expectation of success. Ex-1031, ¶144-148. The resulting device (Racz's cannula modified to include Lee's filaments) would include every limitation of Claims 1-27.

C. Ground A: Independent Claim 1

1. Racz discloses the preamble [1pre] and limitations [1a]-[1e]

a. [1pre]

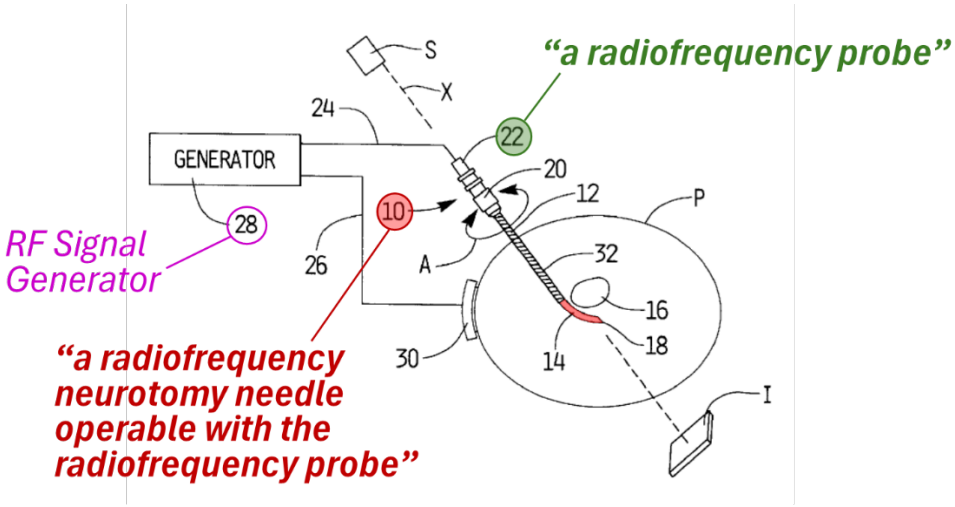
Claim 1's preamble recites "a system" (**[1pre]**). Although the preamble is not limiting, Racz is directed to a "a system for pain relief." Ex-1009, 1:4-9, 2:46-65; Ex-1031, ¶149. Thus, Racz discloses **[1pre]**.

b. [1a] and [1b]

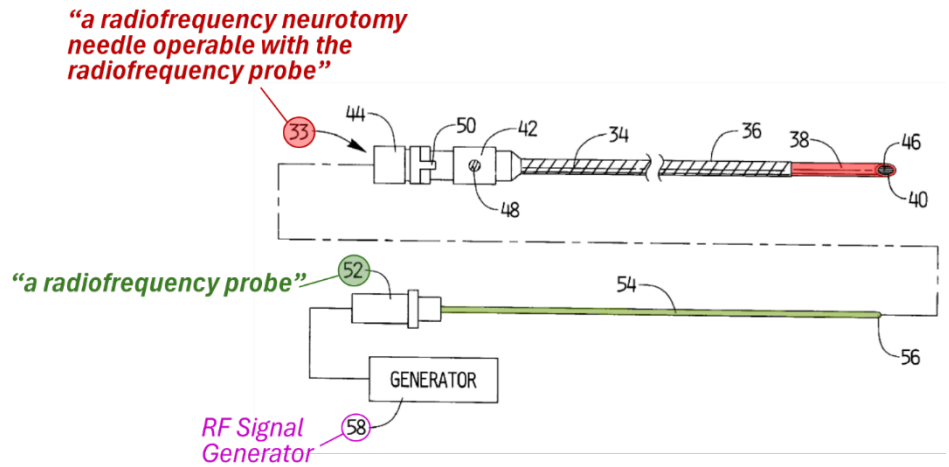
Claim 1 recites that its system includes "a radiofrequency probe" (**[1a]**) and "a radiofrequency neurotomy needle operable with the radiofrequency probe" (**[1b]**). As shown in Figure 1, Racz discloses that its system includes an RF electrode cannula (10/33) configured to receive a removable electrical probe (22/52) (**shaded green**). Ex-1009, 3:38-45, 3:60-65, 4:59-62, 5:7-51, Figs. 1, 2A/B. The electrical probe (22/52) is connected to a signal generator (28), which provides "pulsed radio-frequency output … or other electrical waveforms" (i.e., RF energy). Ex-1009, 2:53-56, 3:66 to 4:20, 5:38-45, 6:4-7, 7:43-50; Ex-1031, ¶150. The probe (22/52) conveys this RF energy to the cannula's tip (14/38). Ex-1009, 4:18-23, 4:1-3. Thus, Racz's electrical probe (22/52) is a "radiofrequency probe" (**[1a]**) operable with the cannula (10/33). Ex-1031, ¶150.

Racz's electrode cannula (10/33) is an "electrical needle" (or "spinal needle") configured to deliver "electrical stimulation pulses or high-frequency signals to the vicinity of a neural structure." Ex-1009, 1:4-10, 2:46-65, 3:24-26,

4:59-62, 5:35-45, 6:38-45, 6:59 to 7:10. With the probe (22/52) inserted, the cannula (10/33) can be used to generate "radio-frequency heat lesions" via the exposed tip (14/38) (**shaded red**) and thereby "modify or coagulate" nerves along a patient's spine. Ex-1009, 4:49-58, 7:43-50. Thus, Racz's electrode cannula (10/33) is a "radiofrequency neurotomy needle operable with the radiofrequency probe" **([1b])**. Ex-1031, ¶151.



Racz – Fig. 1 (annotated to show [1a] and [1b])



Racz – Fig. 2B (annotated to show [1a] and [1b])

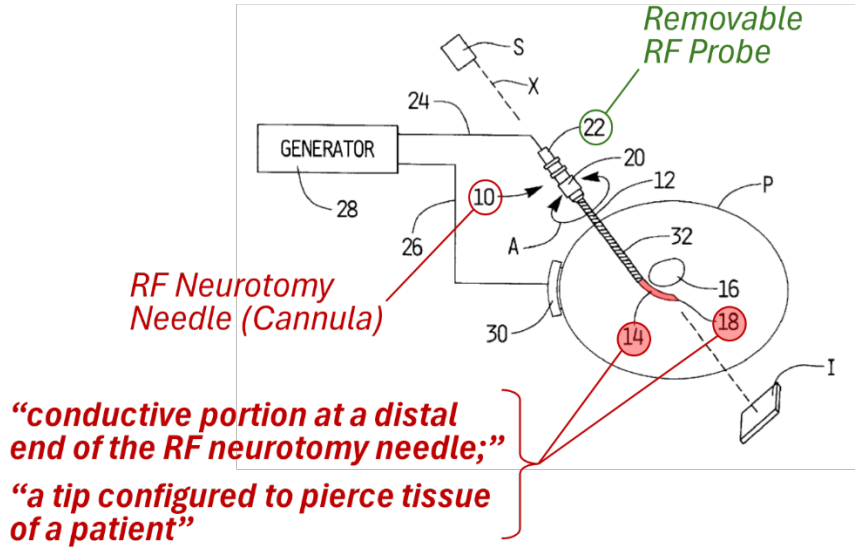
c. [1c] and [1d]

The tip (14/38) of Racz's cannula (10/33) is both a "conductive portion at a distal end of the radiofrequency neurotomy needle" (**[1c]**) and "a tip configured to pierce tissue of a patient" (**[1d]**).[3] Racz discloses that its cannula (10/33) includes an "exposed electrical tip" (14/38) configured to conduct electrical signals for "high-frequency heating" (e.g., generating radio-frequency heat lesions). Ex-1009, 4:18-23, 4:52-58, 3:41-59, 5:38-45, 7:43-50. The tip (14/38) is made of a conductive material (e.g., where the cannula's "shaft (34) comprises a hollow metal tube," the exposed tip (14/38) may be "an extension of the metal tube"). Ex-1009, 4:60 to 5:1, 5:45-48. As such, the physical contact with the probe (22/52) transmits RF energy to the tip (14/38). Ex-1009, 3:60-65, 4:18-23, 5:41-48, Fig. 2B; Ex-1031, ¶152. Thus, Racz's tip (14/38) is "a conductive portion at a distal end of the radiofrequency neurotomy needle" (**[1c]**). *Id.*

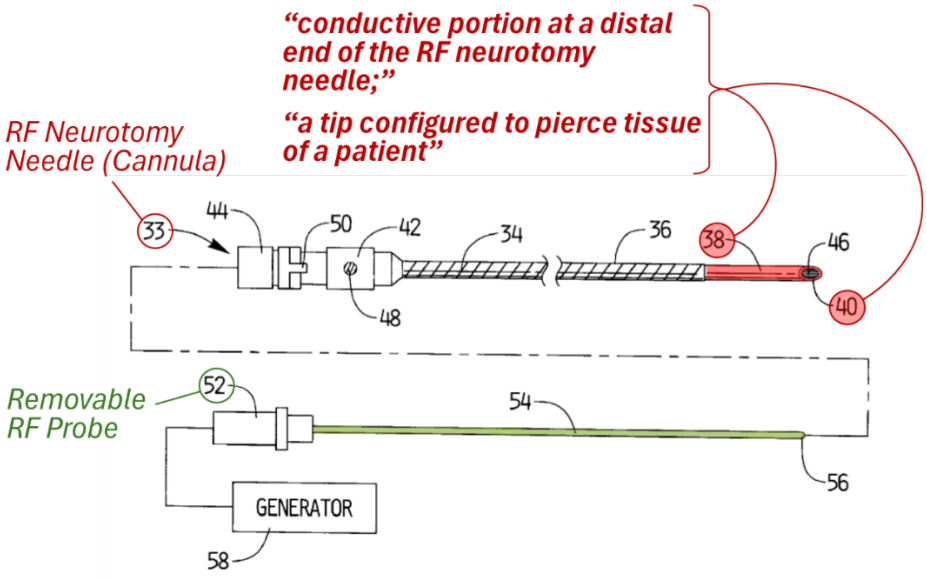
Racz also discloses that the exposed tip (14/38) defines a "self-penetrating point" (18/40). Ex-1009, 3:47-51, 1:28-30, 3:4-7, 5:3-5, 5:31-34. This allows the

[3] Claim 4 confirms that the "conductive portion" [1c] and the "tip" [1d] can be the same portion of the claimed "radiofrequency neurotomy needle." Ex-1001, 52:65-67 ("wherein the tip comprises the conductive portion at the distal end of the radiofrequency neurotomy needle").

cannula (10/33) to be "inserted directly through the skin of the body portion P" and to penetrate "tough tissue near hard, bony structures." Ex-1009, 3:42-45, 3:4-18, 5:3-5, 6:54-58, 5:31-34, Fig. 1 and 2A/2B. Thus, Racz's tip (14/38) is also "a tip configured to pierce tissue of a patient" **[1d]**. Ex-1031, ¶152-153.



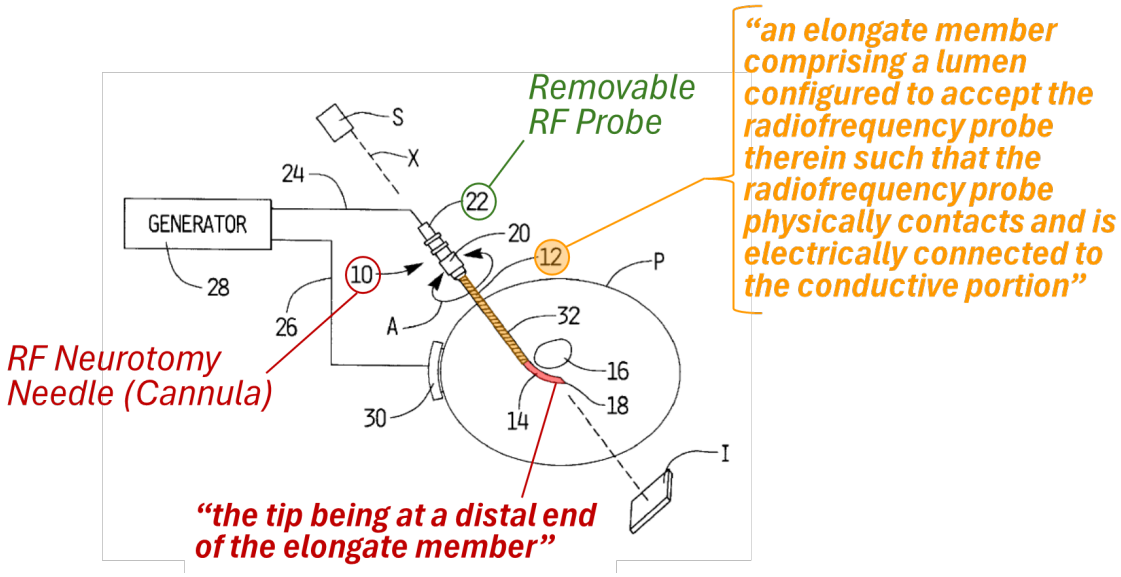
Racz – Fig. 1 (annotated to show [1c] and [1d])



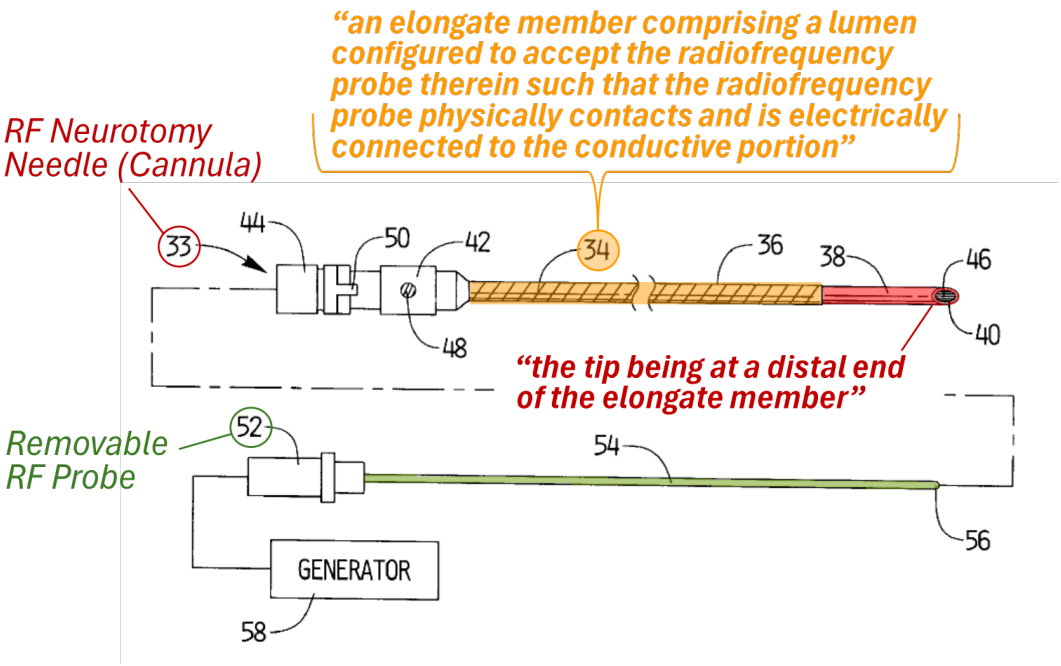
Racz – Fig. 2B (annotated to show [1c] and [1d])

d. [1e]

Racz discloses that its electrode cannula (10/33) comprises "an elongated shaft" (12/34) defining "an internal lumen." Ex-1009, 1:33-36, 2:48-51, 5:41-48, Claim 1, Claim 11. In one example, the shaft (12/34) is a "metal tubular shaft" (i.e., a tube defining an internal lumen). Ex-1009, 2:48-51, Claim 8. Racz discloses that the shaft's lumen accepts the radiofrequency probe (22/52) to transmit RF energy to the tip (14/38). Ex-1009, 3:38-42, 3:60-65, 5:26-28, 5:37-51. Thus, Racz's shaft (12/34) is "an elongate member comprising a lumen configured to accept the radiofrequency probe therein" **[1e]**. Ex-1031, ¶154-155.



Racz – Fig. 1 (annotated to show [1e])



Racz – Fig. 2B (annotated to show [1e])

When Racz's probe (22/52) is "inserted into and received by the shaft 12 of the cannula 10," the "physical relationship between the probe 22 and the shaft 12 facilitates electrical contact between the two elements." Ex-1009, 3:60-65. Thus, "electrical signals from the signal generator 58 are communicated to the exposed distal tip 38 by way of contact between the probe shaft 54 and [the] internal lumen defined by the electrode shaft 34." Ex-1009, 5:41-48, 4:18-23. In other words, the probe (22/52) is electrically connected to the tip (14/38) by "*physical contact* between the probe shaft 54 and the electrode shaft 34." Ex-1009, 5:41-48 (emphasis added); Ex-1031, ¶156.

When inserted into the electrode's lumen, the probe's shaft (54) is configured to extend the full length of the electrode's shaft (12/34) such that the

probe's tip (56) is positioned at the cannula's tip (14/38). *See* Ex-1009, FIG. 2B, Ex-1031, ¶157. Indeed, Racz discloses that the probe's tip (56) may include a temperature sensor (Ex-1009, 5:28-30) and a POSA would have understood that the temperature sensor is for measuring the tissue temperature at the tip (14/38) during ablation. Ex-1009, 8:58-62; Ex-1031, ¶157, 50.[4] The probe's temperature sensor could not accurately measure the tissue temperature during ablation if the probe's tip (56) were not positioned at the cannula's tip (14/38) when the probe (22/52) is inserted. Ex-1031, ¶157.

As Racz's probe shaft (54) extends the full length of the cannula's internal lumen, a POSA would recognize that the "physical contact between the probe shaft 54 and the electrode shaft 34" would occur at least at the conductive portion (14/38) of the cannula (10/33). Ex-1009, 5:45-48; Ex-1031, ¶158. Indeed, as the electrical probe's shaft (54) has a uniform profile and extends the full length of the cannula shaft (12/34), the probe (22/52) would necessarily contact the shaft (12/34) along its full length (including the tip (14/38)). Ex-1031, ¶158. Thus, when Racz's

[4] *See also* Ex-1011, ¶0003 (noting that RF neurotomy devices include "a thermocouple temperature sensor [at the] distal uninsulated tip" and provide "very close proximity of the thermocouple sensor to the tissue the temperature of which must be measured, and very accurate and rapid temperature response").

electrical probe (22/52) (radiofrequency probe) is inserted into the shaft (12/34), "the radiofrequency probe physically contacts and is electrically connected to the conductive portion" **([1e])**.

Racz also discloses that the self-penetrating point (18/40) of the tip (14/38) is positioned at a distal end of the elongate shaft (12/34). Ex-1009, 3:41-42, 3:46-50, 5:3-5, Figs. 1, 2A/B; Ex-1031, ¶159-160. Thus, Racz's exposed distal tip (14/38) having a pointed end (18/40) is a "tip being at a distal end of the elongate member" (**[1e]**).

2. Racz as modified in view of Fitz and Lee discloses limitations [1f], [1g], [1h], and [1i]

As explained above, a POSA would have been motivated to implement Lee's perimeter deployable filaments (22/1622) on the distal tip (14/38) of Racz's cannula (10/33) for the purpose of expanding and controlling the energy coverage area of Racz's device. *Supra* § VI.B ("Motivation to Combine"). Furthermore, a POSA would have found implementing Lee's deployable filaments (22/1622) on Racz's cannula (10/33) to be a matter of routine engineering, well within the level of ordinary skill in the art, and executable with a reasonable expectation of success. *Infra* § VI.C.2.a; Ex-1031, ¶161. Implementing Lee's perimeter deployable filaments (22/1622) on the distal tip (14/38) of Racz's cannula (10/33) would have resulted in a device having the features recited in **[1f]**, **[1g]**, **[1h]**, and **[1i]** (and, as described above, the features of **[1a]-[1e]**).

a. [1f] and [1i]

Although Lee uses the terms "stylet" and "electrode," Lee discloses that these stylets/electrodes (22/1622) are each "a long and straight springy wire-like member" and may be "made of a springy conductive material such as a springy nickel titanium alloy" (i.e., Nitinol). Ex-1010, ¶0092, 0087. Thus, each of Lee's stylets/electrodes (22/1622) is "a filament" (**[1f]**, **[1i])** and are therefore referred to herein as "filaments (22/1622)." Ex-1031, ¶162-163; *see also* Ex-1001, 21:49-52, 21:66 to 22:3, 22:9-11 ("filaments" may be wires and "constructed from a material operable to conduct RF energy, e.g., a metal such as … Nitinol, or shape memory alloy").

Motivated by Fitz/Lee to implement Lee's deployable filaments (22/1622) on the distal tip (14/38) of Racz's cannula (10/33), a POSA would have considered at least the following teachings from both Racz and Lee:

(i) Racz's distal tip (14/38) is electrically active via "physical contact" between the removable probe (22/52) and tip portion (14/38) of the cannula (10/33) (Ex-1009, 5:41-51; *Supra* § VI.A.1);

(ii) Racz discloses that physical contact is an effective method of transmitting RF energy because the probe (22/52) and tip (14/38) are constructed from conductive materials (Ex-1009, 4:62 to 5:5, 5:45-58);

(iii) Lee's filaments (22/1622) are "springy wire-like member[s]" made from a conductive material (e.g., Nitinol) (Ex-1010, ¶0087, 0092, 0017);

(iv) Lee's filaments (22/1622) "may be housed wholly within lumen 20 of cannula 16" (Ex-1010, ¶0092);

(v) Lee's filaments (22/1622) physically contact and are guided by "deflection surfaces" (channels and ramps) at the tip of Lee's RF cannula (Ex-1010, ¶0016, 0018, 0087, 0092, 0102, Claims 8, 10);

(vi) Lee's device includes perimeter filaments (22/1622) arranged around the inner perimeter of the cannula such that they surround and provide space for a central element (a central filament (22/1622) that extends in a straight-forward direction out of the center of the cannula's tip) (Ex-1010, ¶0092, 0102, 0146, Figs. 1-3, 48-49; *supra* § VI.A.3);

(vii) when deployed, Lee's perimeter filaments (22/1622) extend outwardly and around the cannula's tip in a "cone" shape (Ex-1010, ¶0103, Figs. 1, 5, 48-49);

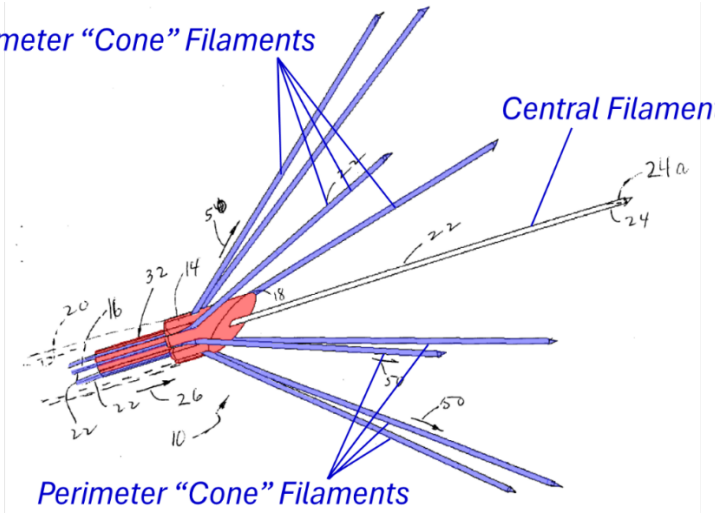
(viii) Lee's filaments (22/1622) are electrically active and—like Racz's tip (14/38)—transmit RF energy to "define an ablation volume in the target tissue" (Ex-1010, ¶0012, *see also* ¶0084); and

(ix) "variations in ablation volume may be achieved by varying the extent to which [filaments] are extended from the distal end of the trocar and the direction in

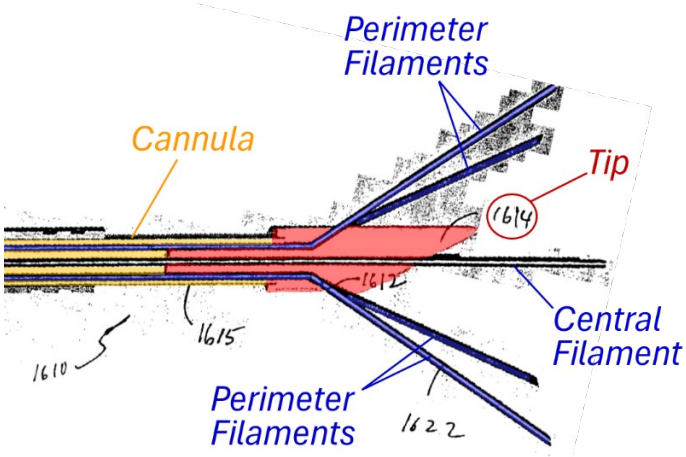
which [filaments] extend" and "the arrangement of [filaments] may … form any desired pattern" (Ex-1010, ¶0123-0131, 0084, 0103); Ex-1031, ¶164.

In view of these teachings in Racz and Lee, a POSA would have found implementing Lee's perimeter filaments (22/1622) on Racz's distal tip (14/38) to be a routine engineering task. Ex-1031, ¶165. A POSA would have recognized that it would be appropriate to implement Lee's perimeter filaments (22/1622) without including Lee's central filament. *See supra* § VI.A.3 (discussing Lee's perimeter/central filaments). Lee discloses that any number and arrangement of filaments may be implemented to provide a desired ablation volume (i.e., the centrally located filament is not always needed). Ex-1010, ¶0103 ("the arrangement of stylets may … form any desired pattern"), ¶0105 (filaments may be used "singly, in combination or in any desired pattern"), ¶0106 ("the patterns of … electrode deployment may be varied to achieve any desired effect"). Additionally, as Racz's exposed distal tip (14/38) is already active, a POSA would have recognized that Lee's central filament would not be necessary (shown below unshaded in Lee's Fig. 1 and 49). Ex-1009, 3:60-63, 4:18-23; Ex-1031, ¶165. Thus, a POSA would have been motivated to implement a plurality of Lee's perimeter filaments (22/1622) around Racz's tip (14/38) to provide a desired ablation volume (e.g., in a full or partial "cone" shape) and omit Lee's central filament. Ex-1031,

¶165. As Lee (and Fitz) confirm, this would improve Racz's device by providing an expanded and controlled energy coverage area.



Lee – Fig. 1 (annotated to show perimeter filaments)



Lee – Fig. 49 (annotated to show perimeter filaments)

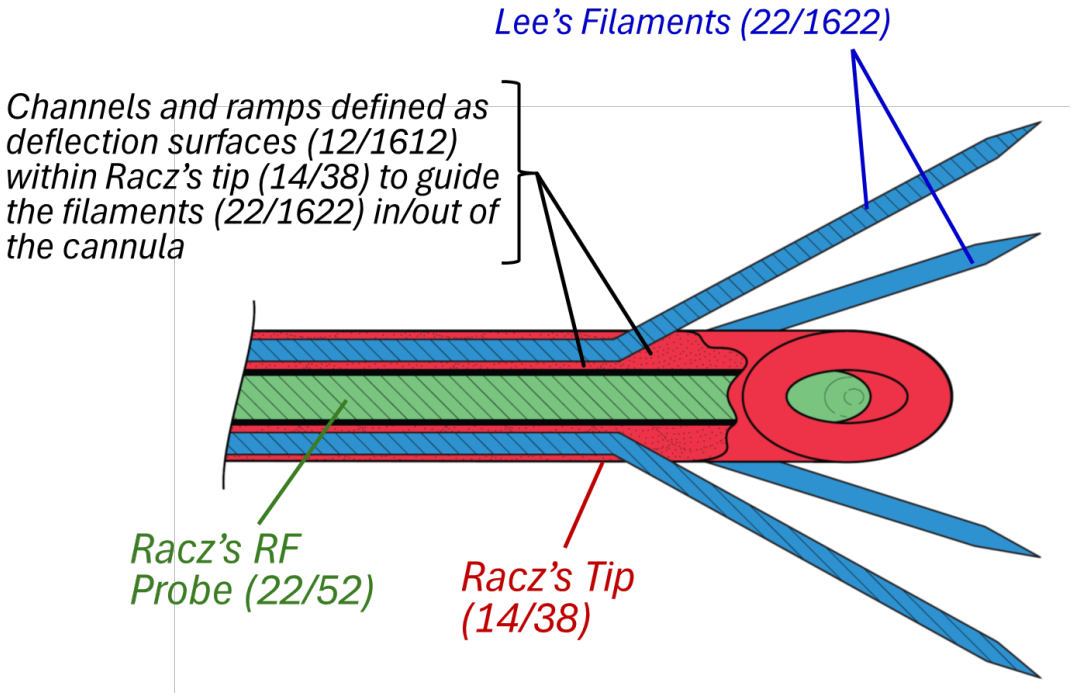
To implement Lee's perimeter filaments (22/1622) on Racz's distal tip (14/38), a POSA would have found it obvious to modify Racz's tip (14/38) to include internal deflection surfaces (12/1612) (e.g., channels and ramps as disclosed in Lee) to guide the perimeter filaments (22/1622) outwardly around Racz's tip (14/38). Ex-1010, ¶0016, 0018, 0092, 0102, Claim 8, Claim 10; Ex-

1031, ¶166. It would have been further obvious to provide openings in Racz's distal tip (14/38) (e.g., in communication with the internal deflection surfaces as disclosed in Lee) such that Lee's perimeter filaments (22/1622) can—when deployed—exit Racz's distal tip (14/38). Ex-1010, ¶0092, 0102; Ex-1031, ¶166.

To preserve the functionality of Racz's removable electrical probe (22/52) and active tip (14/38)—and consistent with Lee's teachings—a POSA would have arranged the perimeter filaments, channels, and ramps around the internal perimeter of Racz's cannula (10/33). Ex-1010, ¶0091, 0092, 0098, 0102; Ex-1031, ¶167. As discussed above, Racz's electrical probe (22/52) is configured to extend the full length of the cannula's shaft (12/34) to supply RF energy to the tip (14/38) and measure tissue temperature. *Supra* § VI.A.1. By omitting Lee's central filament (which would not be needed) and arranging the perimeter filaments, channels, and ramps around the inner perimeter of Racz's cannula (10/33), a POSA would have easily implemented Lee's perimeter filaments (22/1622) without obstructing Racz's cannula (10/33). This would preserve the functionality of Racz's electrical probe (22/52), which is needed to transmit RF energy. Ex-1031, ¶167.

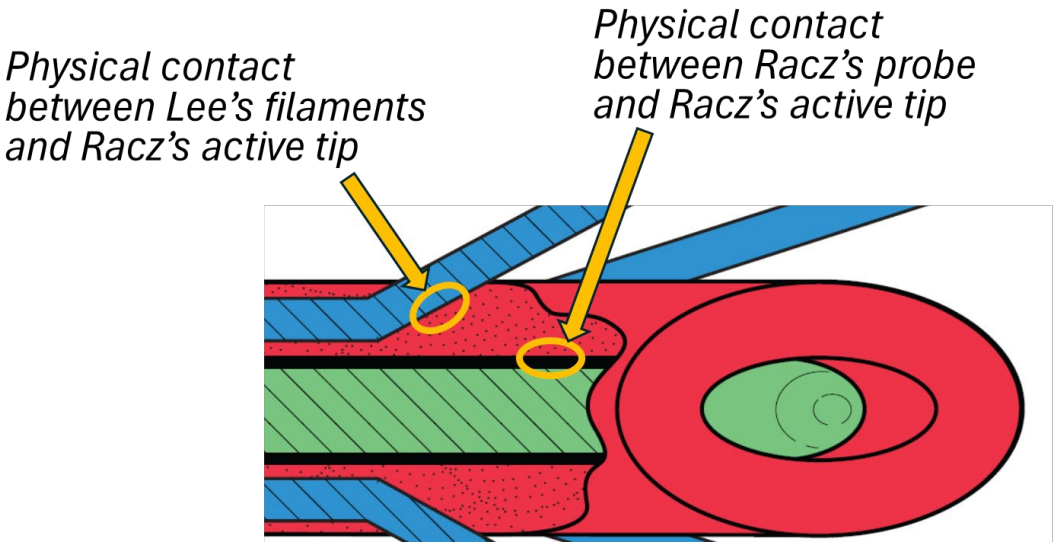
Although the filaments (22/1622) could be implemented in a variety of ways, Petitioner's expert (Dr. Tucker) shows in his declaration one example of how a POSA would have implemented Lee's perimeter filaments (22/1622) and

deflection surfaces (12/1612) around the inner perimeter of Racz's distal tip (14/38) (such that Racz's probe (22/52) could still be received into the cannula's central lumen). Ex-1031, ¶168-169. According to Dr. Tucker, Lee's deflection surfaces (channels and ramps) could be easily formed as an integral portion of Racz's distal tip (14/38) (e.g., by defining internal channels and ramps as a unitary part of the cannula's shaft (12/34)). *Id*. Dr. Tucker notes that, alternatively, the deflection surfaces could be defined on a separate, electrically conductive mandrel secured to the end of Racz's shaft (12/34) and provided with a lumen to receive a distal portion of the electrical probe (22/52) (the mandrel thereby defining both the tip (14/38) and deflection surfaces). *Id.*



Dr. Tucker Declaration at ¶169

With respect to conveying RF energy, Racz discloses that "physical contact" between the electrical probe (52) and the cannula's distal tip (14/38) is an effective method of transmitting RF energy to the distal tip (14/38). Ex-1009, 5:35-45. As discussed above, Lee discloses that its perimeter filaments (22/1622) are electrically active and, when deployed, are guided out of the cannula's distal tip (14/1614) by physical contact with the deflection surfaces (themselves defined at the cannula's active tip (14/38)). Ex-1010, ¶0016, 0018, 0087, 0091, 0102, Claims 8, 10. As shown in the example illustration provided by Dr. Tucker above, when Racz's exposed distal tip (14/38) is modified to include deflection surfaces (channels and ramps), the tip's deflection surfaces will physically contact the filaments (22/1622) to guide them as they are deployed and retracted from Racz's cannula. Ex-1031, ¶170.



Dr. Tucker Declaration at ¶170

As Racz's electrical probe (52), Racz's distal tip (14/38), and Lee's filaments (22/1622) are all constructed from conductive materials, the RF energy from Racz's electrical probe (52) would necessarily be transmitted to the modified device's distal tip (14/38) and perimeter filaments (22/1622). Ex-1009, 4:60 to 5:1, 5:38-48, 7:43-50; Ex-1010, ¶0087, 0092, 0017; Ex-1031, ¶171, 42. Specifically, RF energy from the electrical probe (52) would be transmitted by physical contact to the distal tip (14/38), and the distal tip (14/38)—which defines the deflection surfaces—would transmit RF energy by physical contact to the perimeter filaments (22/1622). Ex-1031, ¶171.

Thus, Racz's electrode cannula (10/33)—as modified by a POSA to include Lee's perimeter filaments (22/1622)—would include "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" **[1f]** and "when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen" the radiofrequency probe will be "in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle" **[1i]**. Ex-1031, ¶172.

The additional limitations in **[1f], [1i]** relating to the tip (14/38) and filaments (22/1622) operating together as a single monopolar electrode also would have been obvious. In Racz's modified device, a POSA would have configured the

active tip (14/38) and perimeter filaments (22/1622) to operate together as a single electrode in a monopolar mode. Ex-1031, ¶173. Racz discloses that its tip (14/38) is configured to operate in a conventional monopolar mode by providing a "reference electrode 30" that is electrically connected to a signal generator (28) and "in contact with the patient's body portion P." Ex-1009, 4:3-23, Fig. 1. In other words, Racz's distal tip (14/38) would already have been configured as a monopolar electrode. Ex-1031, ¶173. Lee discloses that its filaments (22/1622) "may be used in a monopolar fashion with … a return electrode being applied usually in the form a conductive pad in contact with a remote surface on the patient." Ex-1010, ¶0024.

A POSA would have understood that implementing Lee's perimeter filaments (22/1622) at Racz's tip (14/38)—and electrically connecting the monopolar tip (14/38) and perimeter filaments (22/1622) by physical contact using internal deflection surfaces discussed above—would naturally result in the active tip (14/38) and perimeter filaments (22/1622) functioning together as a single monopolar electrode. Ex-1031, ¶174, 76. In other words, when the filaments (22/1622) are deployed and the probe (22/52) is inserted into the cannula (10/33), the filaments (22/1622) and tip (14/38) will transmit RF energy together and operate as a single monopolar electrode. Ex-1031, *Id.*

A POSA also would have had a reasonable expectation of success in implementing this configuration as both Racz and Lee disclose that a monopolar configuration is suitable for RF ablation procedures. Ex-1009, 4:3-23, Fig. 1; Ex-1010, ¶0024; Ex-1031, ¶175, 84-88. In implementing Lee's filaments (22/1622) to expand and control the ablation volume of Racz's device, a POSA would have had no reason to deviate from Racz's monopolar configuration and would have been motivated to electrically connect Lee's filaments (22/1622) to function as a single monopolar electrode with Racz's tip (14/38). Ex-1031, ¶175

Thus, Racz's device—as modified by a POSA in view of Fitz and Lee—would be configured "such that the filament and the tip operate together as a single electrode" **[1f]** and such that "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" **[1i]**. Ex-1031, ¶176.

b. [1g] and [1h]

Lee discloses that its perimeter filaments (22/1622) are configured to be adjusted between a deployed position (where the filaments extend outwardly from the cannula to define the ablation volume) and a withdrawn position (where the filaments are "housed wholly within lumen 20 of cannula 16" during insertion and withdrawal of the device). Ex-1010, ¶0092, 0098-0099, 0106, 0107, Figs. 1-3. Thus, a POSA modifying Racz's electrode cannula (10/33) to include Lee's

perimeter filaments (22/1622) would have configured the filaments to be "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" **[1g]**. Ex-1031, ¶177.

Lee's perimeter filaments (22/1622) "may be connected to suitable advancement and retraction mechanisms" for adjusting the filaments between the deployed and withdrawn positions. Ex-1010, ¶0106. Lee also notes that "[s]uch mechanisms may be of a conventional design." Ex-1010, ¶0106. As confirmed by Dr. Tucker, a POSA would have been motivated (and found it obvious) to connect Lee's perimeter filaments (22/1622) to an actuator that would not obstruct Racz's central lumen for the purpose of preserving the functionality of Racz's electrical probe (22/52) (e.g., a rotating actuator configured to rotate around Racz's central lumen). Ex-1031, ¶178-179. Accordingly, in view of Lee's teaching, a POSA would have found it obvious to provide "an actuator" (i.e., a suitable advancement and retraction mechanism) that is "interconnected to the filament to move the filament between the retracted position and the deployed position" **[1h]**.

For at least these reasons, Claim 1 is obvious in view of Racz, Fitz, and Lee. Ex-1031, ¶180.

D. Ground A: Claims 2-3

Claim 2. Lee's perimeter filaments (22/1622) are constructed from a conductive material (e.g., Nitinol). Ex-1010, ¶0017, 0087, 0092. Likewise, Racz's distal tip (14/38) is made of a conductive material (e.g., metal). Ex-1009, 4:60 to 5:1 (shaft/tip made from a metal tube), 5:38-48, 7:43-50. Thus, in Racz's device modified to include Lee's perimeter filaments, "the filament is formed of one of the conductive materials and the tip is formed of another of the conductive materials" **[2a]**.[5] Ex-1031, ¶181.

As explained for **[1f]**, Racz's tip (14/38) is electrically active and so providing Lee's filaments (22/1622) in channels defined in Racz's tip (14/38) would put the filaments (22/1622) in electrical (and physical) contact with Racz's tip (14/38). *Supra* § VI.C.2.a. When the filaments (22/1622) are deployed, they engage the deflection surfaces in Racz's tip (14/38) and remain in physical contact with Racz's tip (14/38). Thus, in Racz's device modified to include Lee's filaments, "the conductive materials of the filament and the tip are in physical contact when the filament is in the deployed position" **[2b]**. Ex-1031, ¶182. Claim 2 is therefore obvious in view of Racz, Fitz, and Lee.

[5] As explained for **[1f]**, it was obvious to electrically connect the added filaments (22/1622) to Racz's tip (14/38) by physical contact.

Claim 3. As explained for **[1c]** and **[1d]**, Racz's tip (14/38) is both a distal conductive portion and a tip configured to pierce tissue. *Supra* § VI.C.1.c. Thus, Racz's "tip [14/38] comprises the conductive portion at the distal end of the radiofrequency neurotomy needle" **[3a]**. Ex-1031, ¶183.

As explained for **[1e]**, Racz's RF probe (22/52) physically contacts and is electrically connected to the conductive tip (14/38) when the probe (22/52) is inserted into Racz's cannula (10/33). *Supra* § VI.C.1.d. Thus, Racz's "conductive portion [14/38] is configured to physically contact the distal end of the radiofrequency probe when the radiofrequency probe is accepted in the lumen [of the elongate member (10/33)]" **[3b]**. Ex-1031, ¶184. Claim 3 is therefore obvious in view of Racz, Fitz, and Lee.

E. Ground A: Claims 4-6

Claim 4. As explained for **[1c]**, **[1d]**, and **[3a]**, Racz's tip (14/38) is both a distal conductive portion and a tip configured to pierce tissue. *Supra* § VI.C.1.c, VI.D. Thus, Racz's "tip [14/38] comprises the conductive portion at the distal end of the radiofrequency neurotomy needle" **[4]**. Ex-1031, ¶185. Claim 4 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 5. As explained for **[1e]** and **[3b]**, Racz's RF probe (22/52) physically contacts and is electrically connected to Racz's conductive tip (14/38) when the probe (22/52) is inserted into Racz's cannula (10/33). *Supra* § VI.C.1.d, VI.D.

Thus, Racz's "conductive portion [14/38] is configured to physically contact the distal end of the radiofrequency probe [22/52] when the radiofrequency probe is accepted in the lumen" **[5].** Ex-1031, ¶186. Claim 5 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 6. As explained for **[1e]** and **[3b]**, the shaft (54) of Racz's probe (22/52) fully extends through Racz's cannula (10/33) such that the temperature sensor at its tip (56) is positioned at the pointed end (18/40) of the cannula's tip (14/38). *Supra* § VI.C.1.d, VI.D. Thus, the cannula's "internal lumen" necessarily extends through the cannula's distal tip (14/38), thereby defining a tip lumen for receiving the distal end of probe (22/52). Ex-1009, 4:65 to 5:1, 5:41-48. Thus, Racz's "tip [14/38] comprises a tip lumen that is configured to receive the distal end [56] of the radiofrequency probe [22/52]" **[6]**. Ex-1031, ¶187. Claim 6 is therefore obvious in view of Racz, Fitz, and Lee.

F. Ground A: Claims 7-9

Racz's cannula (10/33) includes a "metal tubular shaft [12/34] having insulation [36] over a portion of the shaft," leaving the shaft's tip (14/38) exposed and electrically active. Ex-1009, 2:48-51, 4:62 to 5:5, 5:45-48, 7:43-50. A POSA would have recognized that the insulation (36) surrounding Racz's conductive tube (12/34) could be a separate elongate member (e.g., an insulating sheath or tube positioned around the metal tube (12/34)). Ex-1031, ¶188, 43-45. Insulating Racz's

conductive tube (12/34) using a separate insulating tube positioned around the conductive tube (12/34) was a common technique and would have been an obvious design choice to a POSA. Ex-1031, ¶188; Ex-1014, 5:44-59, 7:13-8:18, 8:30-63; Ex-1017, 5:12-27; Ex-1024, 12:67-13:2; Ex-1015, ¶0042. Likewise, it would have been an obvious design choice for Racz's cannula (10/33) itself to be an insulating tube with a separate, conductive tube provided therein (e.g., where the cannula (10/33) is an insulating tube and a metal tube (like Racz's shaft (12/34)) is positioned therein). Ex-1031, ¶189; Ex-1010, ¶0091, 0125, 0133; Ex-1015, ¶0043. Applying a POSA's knowledge and routine engineering skills, either configuration would merely be a rearrangement of Racz's existing elements—a conductive metal tube (12/34), insulation (36) surrounding the conductive metal tube, and an exposed conductive tip (14/38). Ex-1031, ¶189.

By implementing a separate insulation tube as the insulating portion (36), the separate insulating tube would then comprise an "elongate member" and the metal shaft (12/34) would comprise "a tube that is separate from the elongate member" and "positioned within the elongate member" (**Claim 7**). Ex-1031, ¶190. The tip (14/38) would remain exposed at a distal end of the insulative sleeve and the filaments (22/1622) would remain deployable in/out of the cannula. Additionally, the "tube" (metal shaft 34) would remain configured for receiving Racz's probe (22/52) and would still define the exposed tip (14/38). Ex-1009, 5:37-

48, 4:65-66. In this configuration, "the lumen is within the tube [12/34]" (**Claim 8**) and "the tube [12/34] comprises the conductive portion [14/38] of the needle" (**Claim 9**). Ex-1031, ¶190. Thus, Claims 7, 8, and 9 are obvious in view of Racz, Fitz, and Lee.

As another alternative, a POSA would have recognized that separate tubes could be provided within the metal shaft (12/34)—one for the RF probe (22/52) and one for the liquid (e.g., with Lee's filaments positioned around the two tubes). Ex-1009, 1:30-33; Ex-1031, ¶191. A POSA would be motivated to provide this alternative configuration in scenarios where it is desirable to leave the RF probe (22/52) inserted before/after/during delivery of therapeutic liquid. *See e.g.,* Ex-1009, 1:30-33 ("Open tips can be used to deliver a liquid or other diagnostic or therapeutic agent … to the target *while simultaneously performing electrical treatment*); Ex-1031, ¶191. In this alternative configuration, the cannula's metal shaft (12/34) would comprise an "elongate member" and the separate metal tube for receiving the probe (22/52) would comprise "a tube that is separate from the elongate member" and "positioned within the elongate member"(**Claim 7**). Additionally, "the lumen is within the tube [for receiving the RF probe]" (**Claim 8**) and the tube for receiving the RF probe would form part of "the conductive portion of the needle" (**Claim 9**). Ex-1031, ¶191. For these additional reasons, Claims 7, 8, and 9 are obvious in view of Racz, Fitz, and Lee.

G. Ground A: Claim 10

Claim 10. As explained above, Racz discloses that its cannula (10/33) can be a metal tube defining both the metal shaft (12/34) and the exposed tip (14/38). Ex-1009, 4:60 to 5:1, 5:45-48. Thus, in Racz's device modified to include Lee's deployable filaments, "the tip [14/38] and the elongate member [10/33] are a single unitary structure" **[10]**. Alternatively, as explained for **[1f]/[1i]**, it would have also been obvious to define filament deflection surfaces on a separate tip mandrel secured to the end of Racz's shaft (12/34) such that "the tip and the elongate member are … separate components that are fixedly interconnected." *Supra* § VI.C.2.a; Ex-1031, ¶192-193, 39-40.

Claim 10 is therefore obvious in view of Racz, Fitz, and Lee.

H. Ground A: Claims 11-16

Claim 11. As explained for Claim 1, a POSA would have found it obvious to implement Lee's filaments (22/1622) at Racz's tip (14/38) and would have selected the number/arrangement of filaments (22/1622) based on a desired ablation volume. *Supra* § VI.C.2.a; Ex-1031, ¶194. Lee discloses using multiple filaments (22/1622) to define an ablation volume, which includes at least a second ("additional") filament. Ex-1010, ¶0092, 0103, 0105, 0142, 0146, Figs. 1, 5, 48-49.

As further explained for Claim 1, a POSA also would have implemented Lee's filaments (22/1622) on Racz's tip (14/38) such that the filaments would

physically contact (and be electrically connected to) Racz's tip (14/38), resulting in the filaments (22/1622) and tip (14/38) operating together as a single monopolar electrode. *Supra* § VI.C.2.a; Ex-1031, ¶195. Additionally, a POSA would have interconnected the filaments (22/1622) to an actuator (e.g., a "suitable advancement and retraction mechanism[]") for deployment/retraction. *Supra* § VI.C.2.b; Ex-1031, ¶195; Ex-1010, ¶0106.

Thus, Racz's device modified to include Lee's filaments would include "an additional filament [22/1622] electrically connected to the conductive portion [14/38] such that both filaments [22/1622] and the tip [14/38] operate together as the single electrode" **[11a]** and "the additional filament [22/1622] is interconnected to the actuator such that both filaments are deployed and retracted by the actuator" **[11b]**. Ex-1031, ¶196. Claim 11 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 12. When activated with RF energy, Racz's tip (14/38) produces a "radio-frequency heat lesion" on tissue near the tip. Ex-1009, 7:43-50, 4:18-23. Likewise, when Lee's filaments (22/1622) "exit … into the tissue they define an ablation volume in the target tissue," which a POSA would understand to be a lesion. Ex-1010, ¶0012, 0084, 0123-0131; Ex-1031, ¶197. And in Racz's modified device, Racz's tip (14/38) and Lee's filaments (22/1622) would operate together as a single monopolar electrode. *Supra* § VI.C.2.a; Ex-1031, ¶197. Thus, Racz's

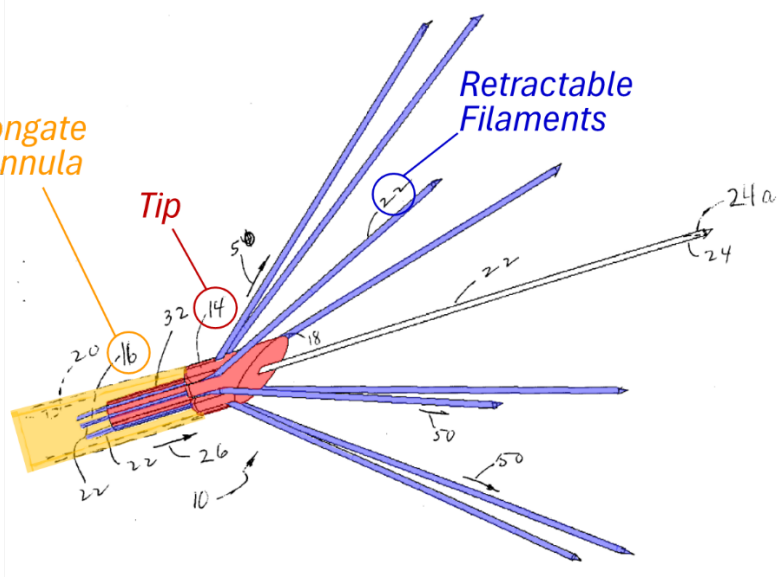
modified device would be configured such that "when the filaments are deployed, the tip and the filaments are configured to produce a lesion at a target volume of tissue within the patient." Claim 12 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 13. The location of Lee's deployed filaments (22/1622) "define[s] an ablation volume in the target tissue." Ex-1010, ¶0012, 0084, 0123-0131; Ex-1031, ¶198. Moreover, "variations in ablation volume may be achieved by varying the extent to which [filaments] are extended from the distal end of the trocar and the direction in which stylets extend." Ex-1010, ¶0129. Thus, a POSA would understand from Lee that the filaments (22/1622) may be adjusted (e.g., in length and/or direction) to define an ablation volume in any desired area relative to the device's tip. Ex-1031, ¶198, 73-75, 79-83.

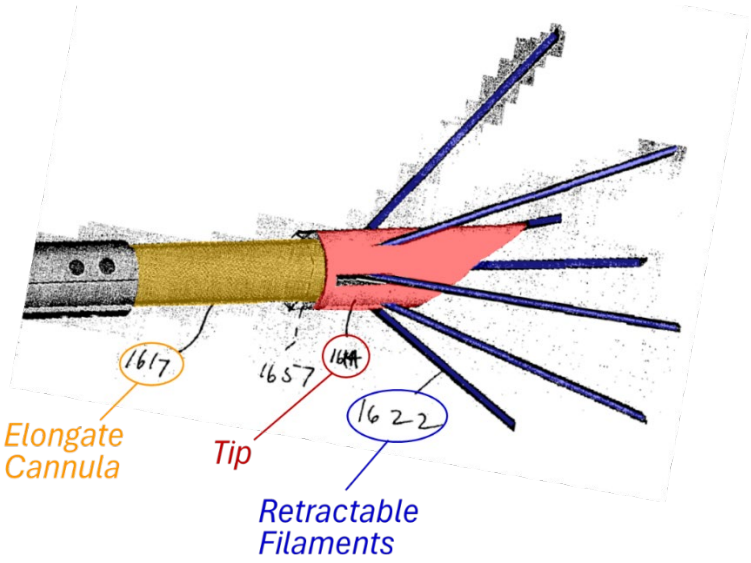
In many scenarios, a POSA would be motivated to define an ablation volume in an area asymmetrical and offset relative to the central longitudinal axis of Racz's device. For example, Racz notes that its tip (14/38) may be configured to apply RF energy "only on one side of the cannula to facilitate directional stimulation or ablation" (e.g., asymmetric relative to the cannula's longitudinal axis). Ex-1009, 8:16-22. Thus, a POSA would be motivated to configure Racz's device modified with Lee's filaments (22/1622) such that "the tip [14/38] and the filaments [22/1622] are configured to produce the lesion so as to be asymmetrical and offset

relative to the central longitudinal axis of the radiofrequency neurotomy needle." Ex-1031, ¶199. Claim 13 is therefore obvious in view of Racz, Fitz, and Lee.

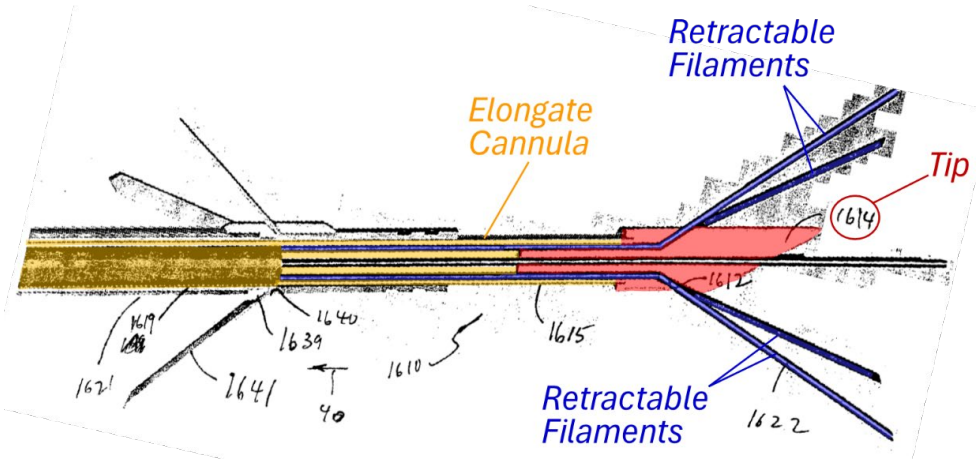
Claim 14. As explained for Claim 1, a POSA would have found it obvious to implement Lee's filaments (22/1622) at Racz's tip (14/38) such that the filament tips are positioned outwardly from and beyond the tip (14/38). *Supra* § 46VI.C.2.b. Lee discloses that "variations in ablation volume may be achieved by varying *the extent to which stylets are extended from the distal end* of the trocar and the direction in which stylets extend." Ex-1010, ¶0129 (emphasis added). As shown below, Lee illustrates how its filaments (22/1622) extend beyond the tip of its device. Ex-1010, Figs. 1, 48, 49; Ex-1031, ¶200.



Lee – Fig. 1 (annotated)

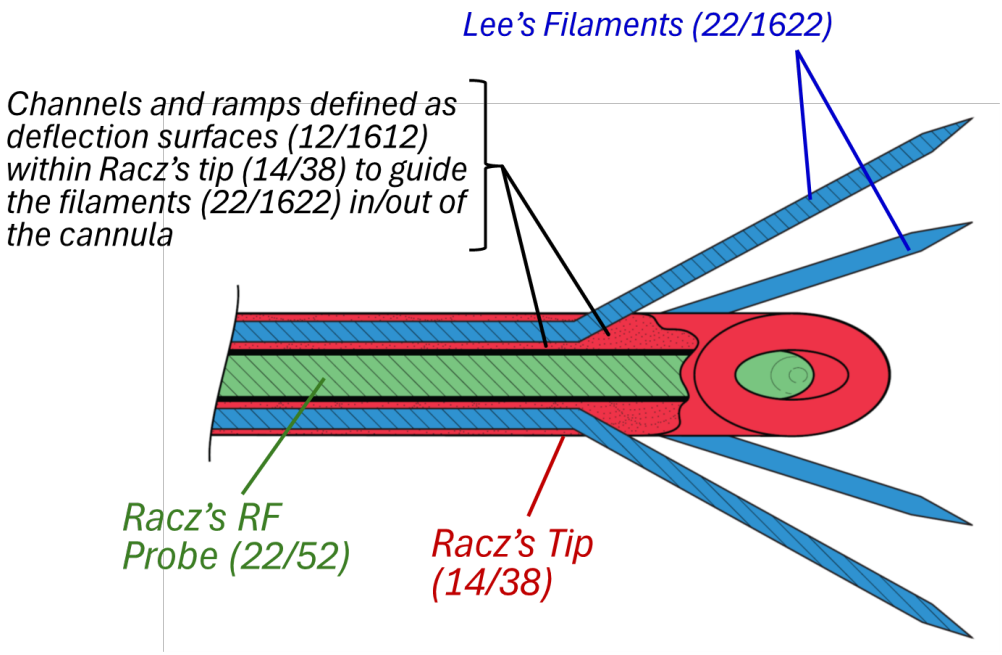


Lee – Fig. 48 (annotated)



Lee – Fig. 49 (annotated)

Configuring the filaments (22/1622) to extend beyond Racz's tip (14/38) would expand the ablation volume, which is the problem Fitz identifies as being present in Racz's unmodified device. *Supra* § VI.B. Petitioner's expert (Dr. Tucker) explains how a POSA—motivated by Fitz/Lee to position the filaments (22/1622) beyond the tip (14/38)—would configure Lee's filaments (22/1622) on Racz's tip (14/38). Ex-1031, ¶201.



Tucker Declaration at ¶201

As "the destruction of target tissue [occurs] at the site where the electrodes are located," the position of Lee's filaments (22/1622) "define[s] [the] ablation volume in the target tissue." Ex-1010, ¶0012, 0084, 0124, 0129. Accordingly, with Lee's filaments (22/1622) implemented such that their tips extend beyond Racz's tip (14/38), the lesion produced would be distally offset from Racz's tip (14/38). Ex-1031, ¶202-203.

Thus, a POSA would have found it obvious to configure Racz's modified device such that "when the filaments [22/1622] are deployed, distal tips of the filaments [22/1622] are distal to the tip [14/38] 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 [14/38] of the radiofrequency neurotomy needle." Claim 14 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 15. As the position of Lee's filaments (22/1622) defines the ablation volume, Lee's filaments (22/1622) can be used to define a desired ablation volume of varying sizes, shapes, and positions. Ex-1010, ¶0012, 0123-0131. According to Lee, this can be accomplished by varying the number, pattern, direction, size, and/or length of the filaments (22/1622) implemented. *Id*. By dictating these characteristics of the filaments (22/1622)—and the size and/or shape of Racz's tip (14/38)—a POSA would be capable of configuring Racz's modified device to produce lesions of any desired volume. Ex-1031, ¶204, 79-83. As explained above, this would occur with Racz's tip (14/38) and Lee's filaments (22/1622) functioning as a single monopolar electrode. *Supra* § VI.C.2.a.

Racz discloses that its device is configured for ablation of tissue proximate to neural structures. Ex-1009, 1:4-10, 2:57-65, 7:43-50. A POSA would have known that, for ablation of tissue proximate to neural structures, a lesion size between 250 mm^3 and about 750 mm^3 would be typical and Racz's device modified with Lee's filaments would be easily configured to provide a volume within this range. Ex-1031, ¶205. Thus, a POSA would have found it obvious to configure "the tip [14/38] and the filaments [22/1622] … 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." Claim 15 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 16. Racz's device is configured "for pain relief [and] delivers electrical stimulation pulses or high-frequency signals to the vicinity of a neural structure" (Ex-1009, 1:4-10, 2:57-65, 7:43-50) and is "advantageous in those clinical situations in which a radio-frequency heat lesion is to be made on the neural structures" (Ex-1009, 7:43-50). Thus, a POSA would have appreciated that Racz's device—modified with Lee's filaments (22/1622)—would be effective for ablation of any desired volume at or near a targeted nerve. Ex-1010, ¶0007, 0012, 0024, 0123, 0129, Claim 16, 33. Ex-1031, ¶206-207.

Accordingly, Racz's modified device would be configured to produce a lesion at a "target volume [that] 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." Claim 16 is therefore obvious in view of Racz, Fitz, and Lee.

I. Ground A: Claims 17-19

Claim 17. As discussed above, the lumen of Racz's shaft (12/34) is configured to receive the probe (22/52) such that the probe physically contacts (and is electrically connected to) the tip (14/38). *Supra* § VI.A.1. Thus, in Racz's modified device, "the lumen is further configured to accept the radiofrequency probe [22/52] therein such that a distal end of the radiofrequency probe is proximate the tip [14/38] when the radiofrequency probe physically contacts and is

electrically connected to the conductive portion [14/38]." Ex-1031, ¶208. Claim 17 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 18. The proximal hub of Racz's cannula may be "a standard hypodermic needle or luer type hub, capable of connection to stylets, electrical probes, syringes, or injection tubes." Ex-1009, 5:66 to 6:7. The hub allows "diagnostic or therapeutic liquids" to be dispensed through the cannula's shaft (12/34) and out of the pointed end (40). Ex-1009, 5:14-18, 6:9-12, 1:29-33. Thus, Racz's modified device includes "a fitting configured to provide a connection to a fluid source for injection of fluid through the lumen." Ex-1031, ¶209, 48-49. Claim 18 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 19. The proximal hub of Racz's cannula is configured for receiving the probe (22/52) (for transmitting RF energy during ablation) and for receiving fluid from a fluid source (e.g., from a syringe or injection tube when the probe (22/52) is removed). Ex-1009, 3:59-65, 5:14-18, 6:9-12, 1:29-33, 5:66 to 6:7, 9:30-39, 10:8-10. As a result, Racz's device 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." Ex-1031, ¶210. Racz's device is further "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." Ex-1031, ¶210. Claim 19 is therefore obvious in view of Racz, Fitz, and Lee.

J. Ground A: Claims 20-23

Claim 20. Lee's filaments (22/1622) may be deployed and retracted by actuators "of a conventional design." *Supra* § VI.C.2.b; Ex-1010, ¶0106. As confirmed by Dr. Tucker, rotational actuators were commonly used in medical devices at the time of the invention. Ex-1031, ¶211-213, 77-78. A POSA would have found it obvious in view of Lee to configure the actuator "to rotate about the central longitudinal axis to move the filament between the retracted position and the deployed position," at least for the purpose of preserving the functionality of Racz's cannula (10/33) (e.g., such that it could receive the probe (22/52). Ex-1031, ¶214. Claim 20 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 21. When retracted, Lee's filaments (22/1622) are "housed wholly within the lumen 20 of [the] cannula." Ex-1010, ¶0092, 0098, Fig. 3. When deployed, Lee's filaments (22/1622) extend outwardly from the cannula (around and beyond the cannula's tip). Ex-1010, ¶0099, 0102, 0129, Figs. 1, 5, 48-49. Thus, the tips of the filaments (22/1622) are positioned within the cannula's shaft (12/34) when retracted (i.e., near the needle's central longitudinal axis) and positioned outward and away from the cannula's shaft (12/34) when deployed (i.e., further from the needle's central longitudinal axis).

Thus, in Racz's modified device, "a distal tip of the filament [22/1622] is closer to a central longitudinal axis of the radiofrequency neurotomy needle [10/33] when the filament is in the retracted position as compared with when the filament is in the deployed position." Ex-1031, ¶215-216. Claim 21 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 22. As discussed for Claim 1, in Racz's modified device, the probe (22/52) is received by the lumen of the shaft (12/34) and is in physical contact with the tip (14/38). *Supra* § VI.C.2.a. The tip (14/38) and filaments (22/1622) function together as a single monopolar electrode. *Id.* Thus, in Racz's modified device, "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." Ex-1031, ¶217. Claim 22 is therefore obvious in view of Racz, Fitz, and Lee.

Claim 23. Racz's system includes a "signal generator 28" for providing "radio-frequency output." Ex-1009, 4:1-9. Racz's signal generator (28) is electrically connected to **(i)** the cannula (10/33) and **(ii)** "a reference electrode 30 in contact with the patient's body portion P." *Id*. Thus, Racz's system includes "a radiofrequency generator [28] and a return electrode pad [30] that is configured to be attached to the patient" **[23a]**. Ex-1031, ¶218.

In Racz's modified device, the tip (14/38) and filaments (22/1622) operate together a single monopolar electrode. *Supra* § VI.C.2.a. Racz also discloses that "electrical connections 24 and 26 [to the signal generator 28], in cooperation with the cannula 10 and the reference electrode 30, form a complete electrical circuit permitting current flow." Ex-1009, 4:9-11. Thus, in Racz's system, "the filament and the tip are configured to operate together as the single electrode in the monopolar mode 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" **[23b]**. Ex-1031, ¶219. Claim 23 is therefore obvious in view of Racz, Fitz, and Lee.

K. Ground A: Independent Claim 24

Independent Claim 24 and its dependent Claims 25-27 are comprised of limitations substantially the same as those discussed above with respect to Claims 1-23. The following claim chart shows where the obviousness of each feature in Claims 24-27 is explained above. Claims 24-27 are therefore obvious in view of Racz, Fitz, and Lee. Ex-1031, ¶220

	Claim Language	Analysis
[24pre]	24. A system comprising:	*Supra* § VI.C.1.a (**[1pre]**)
[24a]	a radiofrequency probe; and	*Supra* § VI.C.1.b (**[1a]**)

	Claim Language	Analysis
[24b]	a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:	*Supra* § VI.C.1.b (**[1b]**)
[24c]	a conductive portion at a distal end of the radiofrequency neurotomy needle;	*Supra* § VI.C.1.c (**[1c]**)
[24d]	a tip configured to pierce tissue of a patient;	*Supra* § VI.C.1.c (**[1d]**)
[24e]	a tube configured to accept the radiofrequency probe therein;	*Supra* § VI.C.1.d (**[1e]**). Racz's shaft (12/34) is a metal tube.
[24f]	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,	*Supra* § VI.C.2.a, VI.D, VI.E (**[1f]** and [**3]-[5]**).
[24g]	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	*Supra* § VI.C.2.b,VI.J (**[1h]** and **[21]**).
[24h]	an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,	*Supra* § VI.C.2.b (**[1h]**)

	Claim Language	Analysis
[24i]	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.	*Supra* § VI.C.2.a (**[1i]**)
[25a]	The system of claim 24, wherein the filament is formed of one of the conductive materials and the tip is formed of another of the conductive materials, and	*Supra* § VI.D (**[2a]**)
[25b]	wherein the conductive materials of the filament and the tip are in physical contact when the filament is in the deployed position.	*Supra* § VI.D (**[2b]**)
[26a]	The system of claim 25, wherein the tip comprises the conductive portion at the distal end of the radiofrequency neurotomy needle, and	*Supra* § VI.D (**[3a]**)
[26b]	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.	*Supra* § VI.D (**[3b]**)

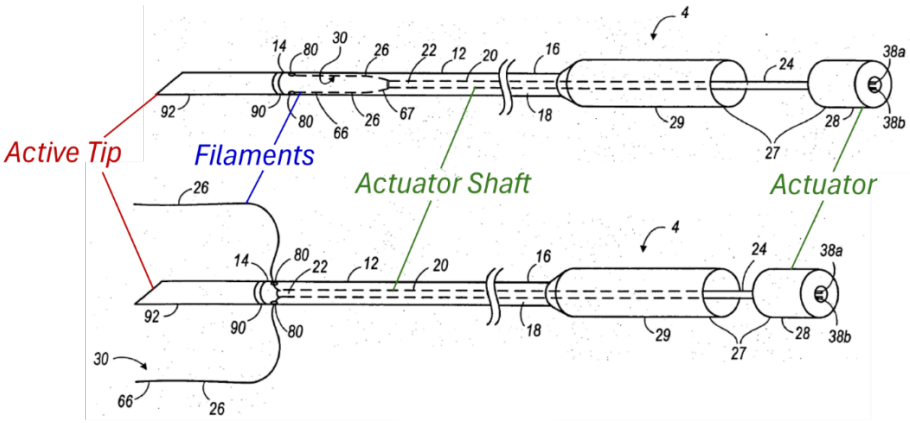
	Claim Language	Analysis
[27]	The system of claim 24, wherein the tube comprises the conductive portion of the needle.	*Supra* § VI.C.1.c, VI.E (**[1c], [1d], [4]**). Racz's shaft (12/34) is a tube and includes the conductive tip (14/38).

VII. GROUND B: CLAIMS 1-27 ARE OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND YOUNG '965

A. Overview of Young '965

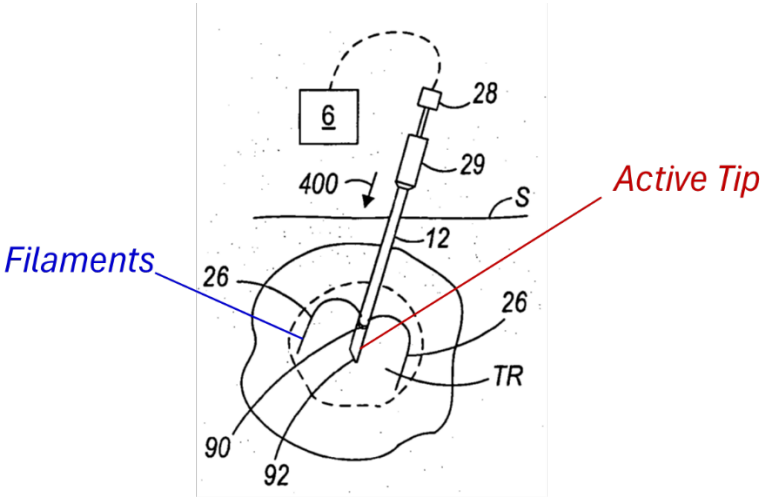
Young '965 discloses a "tissue ablation system" having "a probe assembly 4 configured for introduction into the body of a patient for ablative treatment of target tissue, and a radio frequency (RF) generator 6 configured for supplying RF energy to the probe assembly 4." Ex-1012, ¶0022. Thus, Young '965 is directed to the same field as the '782 Patent. Ex-1001, 1:28-31; Ex-1031, ¶221.

Young '965's device (4) includes a cannula (12) housing an "array 30" of deployable "electrodes 26." Ex-1012, ¶0023, Figs. 2-3. Like Lee's filaments, Young '965's electrodes (26) are small-diameter "electrode tines" or "wires" (i.e., filaments) made from a shape memory alloy (e.g., Nitinol). Ex-1012, ¶0024-25, 0029. The filaments (26) are coupled to an actuator (a shaft (20)) moved within the cannula (12) by a handle assembly (27). Ex-1012, ¶0034-0035. The deployed filaments (26) extend outwardly from and around the device's electrode tip (92). Ex-1012, ¶0031, Figs. 2-3; Ex-1031, ¶222.



Young '965 – Figs. 2 and 3 (annotated)

When activated with RF energy, "[t]he electrode 92 is in conjunction with the array 30 to deliver energy to tissue." Ex-1012, ¶0031, 0022, 0033. As shown below, the filaments (26) and electrode tip (92) create a lesion spanning a treatment region (TR). Ex-1012, ¶0039-0042; Ex-1031, ¶223.



Young '965 – Fig. 7C (annotated)

Young '965's teachings would have further motivated a POSA to implement Lee's filaments (22/1622) on Racz's tip (14/38) in the manner recited in Claims 1, 11, and 20. Ex-1031, ¶224.

B. Ground B: Claim 1

Young '965's electrode tip (92) is configured "for delivering ablation energy in a monopolar configuration," where a dispersive electrode is attached to the patient. Ex-1012, ¶0033. "[T]he array 30 of electrodes 26 and the operative electrode 92 are monopolar electrodes, and current will pass from the electrodes 26 and the electrode 92 to the dispersive electrode to thereby deliver ablation energy in a monopolar configuration." *Id*.

Thus, Young '965 would have confirmed to a POSA that configuring an RF ablation device to have an active tip and deployable filaments operating together as a single monopolar electrode is effective for tissue ablation. Ex-1031, ¶225-226. Considered in combination with Racz, Fitz, and Lee, a POSA would have been further motivated by Young '965 to modify Racz's device such that "the filament [22/1622] and the tip [14/38] are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode" **[1i]**. Ex-1031, ¶226.

Young '965's filaments (26) are interconnected to an actuator shaft (20) and handle assembly (27) to retract and deploy the filaments (26). Ex-1012, ¶0023-0024, 0034-0035, 0037-0038. A POSA would have recognized that Young '965's shaft (20) could be adapted to deploy and retract Lee's filaments (22/1622) from Racz's device (e.g., the shaft (20) could be hollowed and dimensioned to

accommodate Racz's RF probe (22/52)). Ex-1031, ¶227. Thus, a POSA would have been further motivated by Young '965 to modify Racz's device to include "an actuator interconnected to the filament to move the filament between the retracted position and the deployed position" **[1h]**. Ex-1031, ¶227.

Young '965's filaments (26) are as small as 0.2mm (wide) and 0.05mm (thick). Ex-1012, ¶0030. By comparison, Racz discloses that its neurotomy cannula may be as large as 10 gauge (i.e., up to 3.404mm outer diameter and 2.692 mm inner diameter). Ex-1009, 8;9-15; Ex-1031, ¶228. Thus, Young '965 would have confirmed to a POSA that Lee's filaments (22/1622) could be provided in sizes as small as 0.2mm wide and easily implemented into Racz's cannula. Ex-1031, ¶228-229.

Accordingly, Claim 1 (and dependent Claims 2-23) are further obvious in view of Racz, Fitz, Lee, and Young '965.

C. Ground B: Claims 11 and 22-23

As explained for Claim 1, Young '965 renders the limitations in certain dependent claims further obvious in combination with Racz, Fitz, and Lee: **[11a]** ("additional filament" where "both filaments and the tip operate together as the single electrode"); **Claim 22** (filament and tip "operate together as the single electrode in a monopolar mode"); and **Claim 23** (in monopolar mode "the

electrode pad is attached to the patient to complete a circuit"). *Supra* § VII.B; Ex-1031, ¶230.

D. Ground B: Claim 20

Young '965's "handle assembly 27 can be configured such that the electrodes 26 can be deployed by rotating the handle portion 28 relative to the handle body 27." Ex-1012, ¶0038. "[T]he shaft 20 can have a screw-like configuration, which allows the shaft 20 to be distally advanced or proximally retracted by rotation of the shaft 20" and "the array 30 of electrodes 26 is rotatably coupled to the distal end 22 of the shaft 20 such that rotation of the shaft 20 does not rotate the electrodes 26, but move them in an approximate longitudinal direction." *Id*.

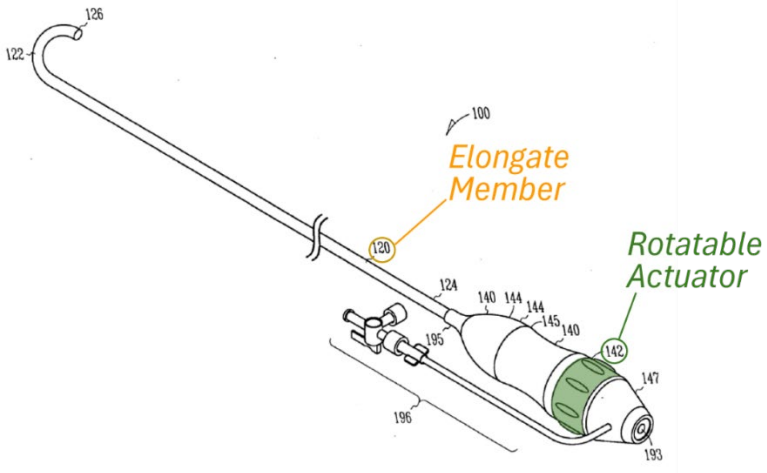
Thus, Young '965 would have further motivated a POSA to configure Racz's device to include an "actuator … configured to rotate about the central longitudinal axis to move the filament between the retracted position and the deployed position." Ex-1031, ¶231-232. Claim 20 is further obvious in view of Racz, Fitz, Lee, and Young '965.

VIII. GROUNDS C AND D: CLAIMS 1-27 ARE OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND SCHEIBE (AND, OPTIONALLY, YOUNG '965)

A. Overview of Scheibe

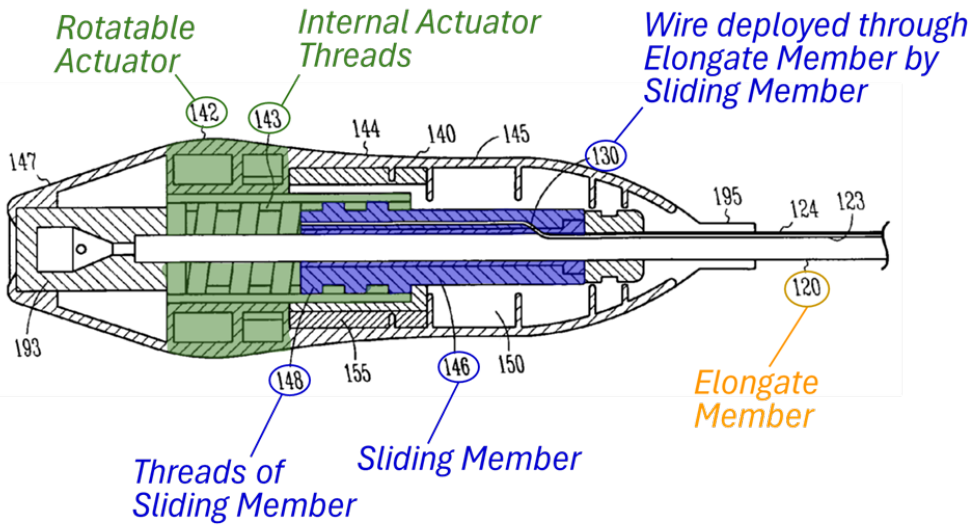
Scheibe discloses a rotational actuator (142) for linearly translating a sliding member (146) within a medical device. Ex-1013, ¶0019, 0021, 0024-0029, 0032-0035. As Scheibe's actuator (142) is adapted for linear translation of a pullwire (130) through the lumen of an elongate body (120), it is reasonably analogous to the '782 patent. *Id*.; ¶Ex-1031, ¶233.

Scheibe's actuator (142) is shown in a deflectable catheter (or sheath), which includes an elongate, deflectable body (120), a housing assembly (140), and a pullwire (130). Ex-1013, ¶0016, Fig. 1. The device's pullwire (130) is secured to a distal end of the deflectable body (120), extends "through a lumen" of the body (120), and "translates longitudinally through the lumen" to deflect a distal end of the body (120). Ex-1013, ¶0017-0018; Ex-1031, ¶234.



Scheibe – Fig. 1 (annotated)

The rotatable actuator (142) (**shaded green**) rotates about the longitudinal axis of Schiebe's device but is otherwise fixed in place. Ex-1013, ¶0025. The rotatable actuator (142) includes internal threads (143) that engage outer threads (148) of a sliding member (146) (**shaded blue**). Ex-1013, ¶0021-0022. When the actuator (142) is rotated, the sliding member (146) moves linearly (without rotating) within the device's housing (140) and around the elongate body (120). Ex-1013, ¶0024-0025, 0029. As the pullwire (130) is secured to the sliding member (146), rotating the actuator (142) causes the pullwire (130) to move linearly within the elongate body (120). Ex-1013, ¶0018-0019, 0035; Ex-1031, ¶235.



Scheibe – Fig. 2 (annotated)

B. Ground C: Claims 1, 11, and 20

A POSA would have been motivated to provide Scheibe's rotatable actuator (142) and sliding member (146) in Racz's device for the purpose of actuating Lee's

filaments (22/1622) without compromising the functionality of Racz's probe (22/52). A POSA would have appreciated that proximal ends of Lee's filaments (22/1622) could be secured to the sliding member (146), thereby allowing the rotatable actuator (142) to retract/deploy the filaments (22/1622) through Racz's shaft (12/34). Ex-1031, ¶236. As the sliding member (146) does not rotate, the filaments (22/1622) would not be twisted. *Id.*

A POSA would also have appreciated that Scheibe's rotatable actuator (142) would be well suited for Racz's device as the rotatable actuator (142) and sliding member (146) are adapted to avoid interference with the lumen of the elongate body (120). This allows the actuator (142/146) to be easily implemented in Racz's device without obstructing Racz's central lumen (which receives the probe (22/52)). Ex-1013, ¶0034-0035, Figs. 2, 5, 7, 9, 10; Ex-1031, ¶237. Scheibe notes that a Luer fitting may be provided at a distal end of its device, confirming that its actuator (142/146) would not obstruct the elongate body (120). Ex-1013, ¶0031. Finally, Scheibe notes that its teachings are not limited to catheters and are relevant to "other types of body stimulating systems." Ex-1013, ¶0037.

Thus, a POSA would have recognized that Scheibe's rotating actuator (142) and sliding member (146) would be a suitable actuator to implement into Racz's device for deployment and retraction of Lee's filaments (22/1622). Ex-1010, ¶0106 (filaments "may be connected to suitable advancement and retraction

mechanisms"); Ex-1031, ¶238. In combination with Racz, Fitz, and Lee, Scheibe would have further motivated to implement "an actuator interconnected to the filament to move the filament between the retracted position and the deployed position" (**Claim 1**), with an "additional filament … interconnected to the actuator such that both filaments are deployed and retracted by the actuator" (**Claim 11**), and such that "the actuator is configured to rotate about the central longitudinal axis to move the filament between the retracted position and the deployed position" (**Claim 20**). Claims 1-27 are therefore further obvious in view of Racz, Fitz, Lee, and Scheibe (Ground C).

C. Ground D: Claims 1, 11, and 20

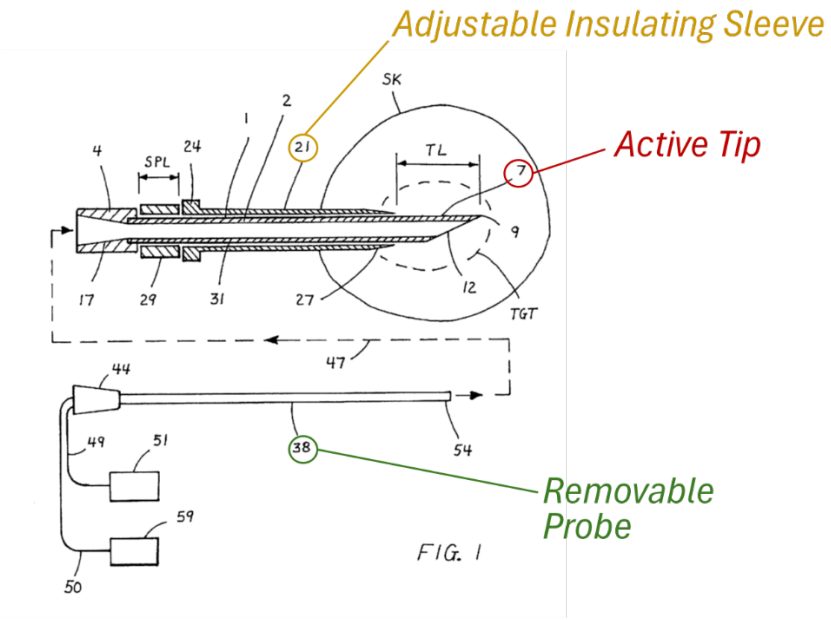
Scheibe may also be considered (optionally) in combination with Young '965, which discloses that rotational actuators can be used to retract and deploy filaments. Ex-1012, ¶0038; Ex-1031, ¶239. Given this teaching, a POSA would be further motivated to select a suitable rotational actuator (such as Scheibe's) for use in deploying Lee's filaments (22/1622) from Racz's device. Ex-1031, ¶239. Claims 1-27 are therefore further obvious in view of Racz, Fitz, Lee, Young '965, and Scheibe (Ground D).

IX. GROUNDS E-H: CLAIMS 7-9 ARE OBVIOUS IN VIEW OF COSMAN '542 (COMBINED WITH THE GROUNDS A-D REFERENCES)

A. Overview of Cosman '542

Cosman '542 is directed to a "high frequency electrode system" for ablating targeted tissue. Ex-1014, 2:44-65, 7:26-29, 8:25-30. Thus, Cosman '542 is directed to the same field as the '782 Patent. Ex-1001, 1:28-31; Ex-1031, ¶240.

Cosman '542 discloses a cannula electrode (1) that includes metal tubing (2) configured to receive a high-frequency probe (38). Ex-1014, 2:43-54, 5:28-44, 6:8-43. Cosman '542's tubing (2) is insulated by an "insulating sleeve" (21) constructed, for example, from "semi-rigid plastic material such as hard Teflon or polyethylene." Ex-1014, 2:54-60. The insulating sleeve (21) is shorter than the tubing (2), thereby defining an uninsulated electrode tip (7). Ex-1014, 5:47-66; Ex-1031, ¶241.



Cosman '542 – Fig. 1 (annotated)

Cosman '542 discloses that "the length TL of the uninsulated electrode tip 7 can be adjusted by the clinician by moving the position of the insulating sleeve 21 on the metal tubing shaft 2" to provide "an appropriate length TL of the uninsulated electrode tip 7." Ex-1014, 5:55-61. Cosman '542 notes that providing a separate, adjustable insulating sleeve (21) allows a clinician to implement a desired electrode tip length without complex or expensive components. Ex-1014, 5:62 to 6:7; Ex-1031, ¶242.

B. Grounds E-H: Claims 7-9

In view of Cosman '542, a POSA would have recognized that Racz's insulation (36) could be a separate insulative sleeve (21/107/177) (as in Cosman '542). Ex-1014, 5:44-59, 7:13-15, 7:37-8:18, 8:30-63; Ex-1009, 2:48-51, 4:62 to 5:5, 5:45-48, 7:37-8:63; Ex-1031, ¶243. Racz notes that "the extent of insulation

vs. exposed electrode can be variable" (Ex-1009, 8:16-18, 8:62 to 9:1) and a POSA would recognize that implementing Cosman '542's adjustable insulative sleeve (21/107/177) would be one way to achieve this. Ex-1031, ¶244. For example, Cosman '542's insulative sleeve can be adjustably secured to the cannula's hub using a threaded engagement. Ex-1014, 7:13-15, 7:37-8:18, Fig. 2. A POSA would have found it a routine engineering exercise to implement Cosman '542's insulative sleeve onto Racz's cannula (10/33) in this way (or the other methods noted in Cosman '542). Ex-1031, ¶243.

By implementing Cosman '542's separate insulative sleeve as the insulating portion (36) around Racz's metal shaft (12/34), the insulative sleeve would comprise an "elongate member" and the metal shaft (12/34) comprises "a tube that is separate from the elongate member" and "positioned within the elongate member" (**Claim 7)**. Ex-1014, 5:44-45, 5:55-59; Ex-1031, ¶244. The tip (14/38) would remain exposed at a distal end of the insulative sleeve and the filaments (22/1622) would remain deployable in/out of the cannula. The "tube" (Racz's metal shaft 34) would remain configured for receiving Racz's probe (22/52) and would still define a tip (14/28). Ex-1009, 5:37-48, 4:65-66. Thus, "the lumen is within the tube [12/34]" (**Claim 8**) and "the tube [34] comprises the conductive portion [14/38] of the needle" (**Claim 9**). Ex-1031, ¶244.

For at least these reasons, Claims 7, 8, and 9 are further obvious in view of Racz, Fitz, Lee, and Cosman '542 (Ground E). For the same reasons, Claims 7-9 are obvious in view of Racz, Fitz, Lee, Cosman '542, and: Young '965 (Ground F; *supra* § VII) or Scheibe (Ground G; *supra* § VIII) or Young '965 and Scheibe (Ground H; *supra* § VIII); Ex-1031, ¶245.

X. GROUNDS I-L: CLAIM 13 IS OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND YOUNG '201 (AND YOUNG '965 OR YOUNG '965 AND SCHEIBE)

Young '201 is directed to "radio frequency (RF) electrosurgical probes or ablation devices for the treatment of tissue." Ex-1016, ¶0002. Thus, Young '201 is in the same field as the '782 Patent. Ex-1001, 1:28-31; Ex-1031, ¶246.

Young '201 discloses that its deployable array (40) electrode tines may have "a non-symmetrical orientation" (i.e., asymmetric). Ex-1016, ¶0031. Young '201's teaching that asymmetric electrode tines are effective for ablation would have further motivated a POSA to configure Racz's device modified to include Lee's filaments (22/1622) such that "the tip [14/38] and the filaments [22/1622] are configured to produce the lesion so as to be asymmetrical and offset relative to the central longitudinal axis of the radiofrequency neurotomy needle." Claim 13 is therefore obvious in view of Racz, Fitz, Lee, and Young '201 (Ground I). For the same reasons, Claim 13 is obvious in view of Racz, Fitz, Lee, Young '201, and:

Young ’965 (Ground J; *supra* § VII) or Scheibe (Ground K; *supra* § VIII) or Young ’965 and Scheibe (Ground L; *supra* § VIII); Ex-1031, ¶247.

XI. GROUNDS M-P: CLAIM 15 IS OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND GODARA (AND YOUNG ’965 OR YOUNG ‘965 AND SCHEIBE)

Godara is directed to an electrosurgical device having “an elongate member” with “electrically exposed conductive portions for delivering energy substantially distal to the elongate member.” Ex-1015, Abstract. Thus, Godara is directed to the same field as the ’782 Patent. Ex-1001, 1:28-31; Ex-1031, ¶248.

Godara’s device is configured for generating lesions at a target tissue site, “for example a nerve” (or “neural tissue”). Ex-1015, ¶0098-0100, 0096, 0003. Godara discloses that lesions “between about 150 mm^3 and about 500 mm^3 in volume … may be particularly useful for lesioning of [spinal] nerves.” Ex-1015, ¶00133. Thus, Godara would have further motivated a POSA to configure Racz’s modified device such that “the tip [14/38] and the filaments [22/1622] 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” (e.g., 400 mm^3). Ex-1031, ¶249. Claim 15 is therefore obvious in view of Racz, Fitz, Lee, and Godara (Ground M). For the same reasons, Claim 15 is obvious in view of Racz, Fitz, Lee, Godara, and: Young ’965 (Ground N; *supra* § VII) or

Scheibe (Ground O; *supra* § VIII) or Young ’965 and Scheibe (Ground P; *supra* § VIII).

XII. CONCLUSION

For the foregoing reasons, Petitioner requests that the Board institute an *Inter Partes* Review and cancel Claims 1-27 of the ’782 Patent.

Respectfully submitted,

/Christopher B. Kelly/
Christopher B. Kelly (Reg. No. 62,573)

XIII. MANDATORY NOTICES

Petitioner Avanos Medical, Inc. submits the following mandatory notices pursuant to 37 C.F.R. § 42.8(a)(2).

A. Real parties-in-interest

Petitioner contends the sole real "party-in-interest" in this Petition is Avanos Medical, Inc. However, in the interest of transparency, Avanos further states that Diros Technology, Inc. of Markham, Ontario, Canada is a wholly owned subsidiary of Avanos Medical, Inc.

B. Related matters

Petitioner is not aware of any other judicial or administrative matters that would affect, or be affected by, a decision in this IPR proceeding.

C. Counsel and service information

Under 37 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioner identifies Christopher B. Kelly (Reg. No. 62,573) as lead counsel and the following back-up counsel: Gregory Carlin (Reg. No. 45,607), Warren Thomas (Reg. No. 70,581), and Lee Hamilton (Reg. No. 80,413). All counsel can be reached by mail at Meunier Carlin & Curfman LLC, 999 Peachtree St, NE, Suite 1300, Atlanta, GA 30309; and by phone at 404-645-7700. Petitioner consents to electronic service by email to the counsel above.

XIV. CLAIMS LISTING

Claim Element	Challenged Claims
[1pre]	A system comprising:
[1a]	a radiofrequency probe; and
[1b]	a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:
[1c]	a conductive portion at a distal end of the radiofrequency neurotomy needle;
[1d]	a tip configured to pierce tissue of a patient;
[1e]	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;
[1f]	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,
[1g]	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
[1h]	an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,
[1i]	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.

Claim Element	Challenged Claims
[2a]	2. The 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
[2b]	wherein the conductive materials of the filament and the tip are in physical contact when the filament is in the deployed position.
[3a]	3. The system of claim 2, wherein the tip comprises the conductive portion at the distal end of the radiofrequency neurotomy needle, and
[3b]	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]	4. The system of claim 1, wherein the tip comprises the conductive portion at the distal end of the radiofrequency neurotomy needle.
[5]	5. The 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]	6. The system of claim 4, wherein the tip comprises a tip lumen that is configured to receive the distal end of the radiofrequency probe.
[7]	The 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]	The system of claim 7, wherein the lumen is within the tube.
[9]	9. The system of claim 7, wherein the tube comprises the conductive portion of the needle.

Claim Element	Challenged Claims
[10]	10. The system of claim 1, wherein the tip and the elongate member are a single unitary structure or are separate components that are fixedly interconnected.
[11a]	11. The 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,
[11b]	wherein the additional filament is interconnected to the actuator such that both filaments are deployed and retracted by the actuator.
[12]	12. The 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]	13. The 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]	14. The 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.
[15]	15. The 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 mm3 and about 750 mm3.
[16]	16. The 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.

Claim Element	Challenged Claims
[17]	17. The 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]	18. The 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]	19. The 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.
[20]	20. The 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]	21. The 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]	22. The 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

Claim Element	Challenged Claims
	accepted in the lumen and is in physical contact with the conductive portion.
[23a]	23. The system of claim 1, further comprising a radiofrequency generator and a return electrode pad that is configured to be attached to the patient,
[23b]	wherein the filament and the tip are configured to operate together as the single electrode in the monopolar mode 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.
[24pre]	24. A system comprising:
[24a]	a radiofrequency probe; and
[24b]	a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:
[24c]	a conductive portion at a distal end of the radiofrequency neurotomy needle;
[24d]	a tip configured to pierce tissue of a patient;
[24e]	a tube configured to accept the radiofrequency probe therein;
[24f]	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,
[24g]	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

Claim Element	Challenged Claims
[24h]	an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,
[24i]	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.
[25]	25. The system of claim 24, 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.
[26]	26. The system of claim 25, 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.
[27]	27. The system of claim 24, wherein the tube comprises the conductive portion of the needle.

CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

Pursuant to 37 C.F.R. § 42.24(d), Petitioner certifies that the foregoing Petition for *Inter Partes* Review contains 13,960 words, excluding the portions as permitted by § 42.24(a).

/Christoher B. Kelly/
Christopher B. Kelly (Reg. No. 62,573)

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), the undersigned certifies that on July 26, 2024, a copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 10,966,782, the associated Power of Attorney, and Exhibits 1001-1031 were served by FedEx Priority Overnight on the correspondence address of record indicated in the Patent Office's public Patent Center system for U.S. Patent No. 10,966,782:

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