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 IPR2024-01211
Patent 10,736,688

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,736,688
(Challenging Claims 18-47 and 53-74)

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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	Reserved
1032	Reserved
1033	Declaration of Dr. Robert D. Tucker (July 26, 2024)

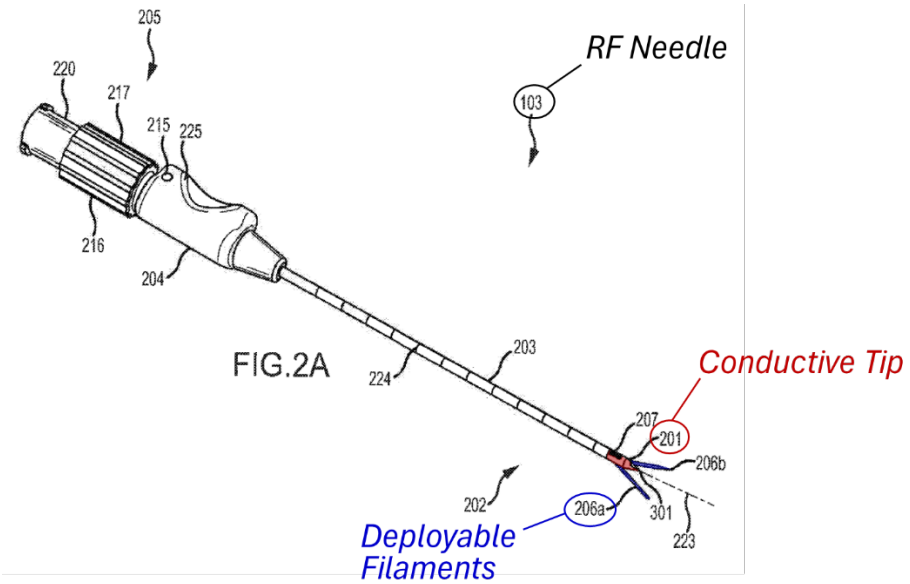
Exhibit No.	Description
1034	Reserved

GLOSSARY

Term	Meaning
"'688 Patent" or "Challenged Patent"	U.S. Patent No. 10,736,688 to Wright et al. (issued August 11, 2020)
"Challenged Claims"	Claims 18-47 and 53-74 of the '688 Patent
"Board"	USPTO Patent Trial and Appeal Board
"POSA"	Person of ordinary skill in the art at the time of the '688 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

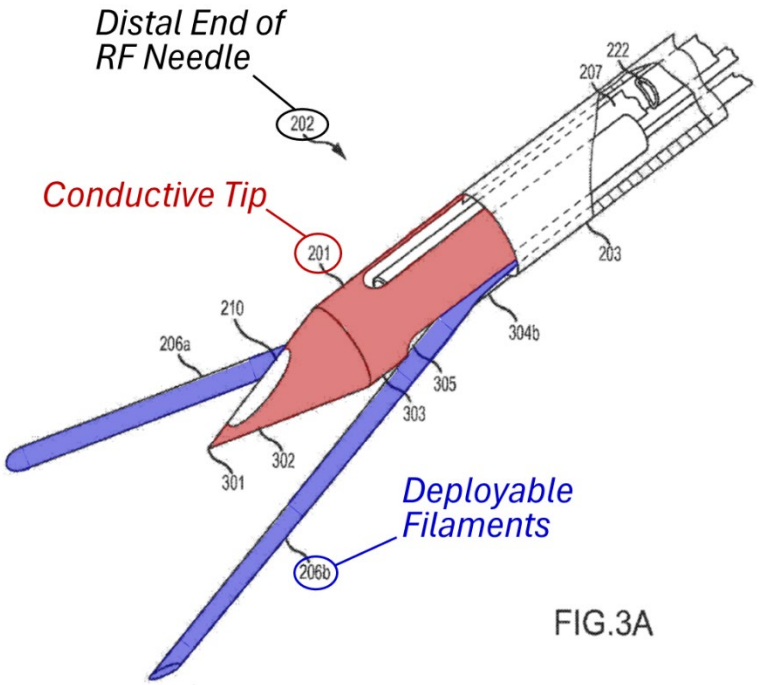
Radiofrequency (RF) ablation is a procedure in which an electrical needle is inserted into targeted patient tissue and activated with RF energy. The RF energy transmitted from the needle's electrode heats the surrounding tissue and generates a lesion, thereby ablating (or destroying) the tissue. Using 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.



'688 Patent – Figure 2A (annotated)

The '688 Patent is directed to an RF neurotomy needle (103) that includes a conductive tip (201) (**shaded red**) and deployable electrode filaments (206a-b)

(**shaded blue**) (*see e.g.,* Figs. 2D and 3D). The tip (201) and filaments (206a-b) (when deployed) transmit RF energy and heat tissue in the area near the tip and filaments.

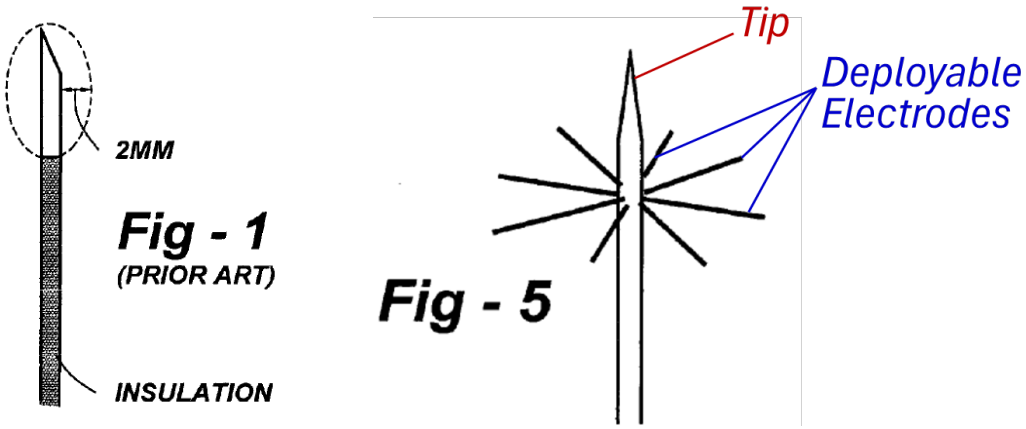


'688 Patent – Figure 3A (annotated)

According to the '688 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 thus practically limited." Ex-1002, 5:66-6:2. Thus, the '688 Patent describes "[a] needle 103 with deployable filaments 206a, 206b [that] overcomes this obstacle and expands the effective area of RF energy delivery by providing multiple locations

(e.g., tip 201 and filaments 206a, 206b) from which the RF energy emanates." Ex-1002, 6:3-9.

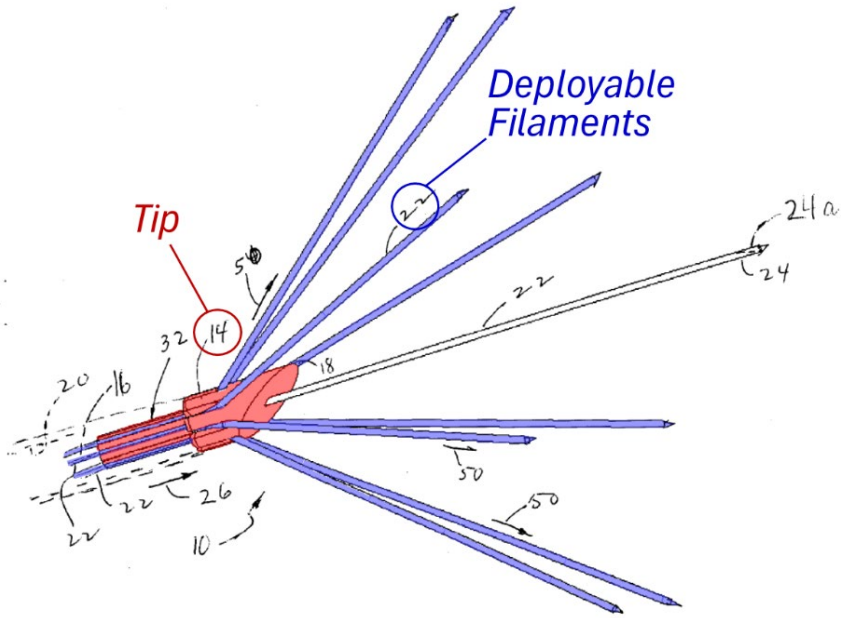
This solution, however, was nothing new. Five years earlier, U.S. Publication No. 2005/0059964 to Fitz disclosed that "[a] problem with current [RF neurotomy needles] is that they do not allow for adequate coverage of the target area" and produce spherical lesions that "extend[] only a few millimeters." 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*.



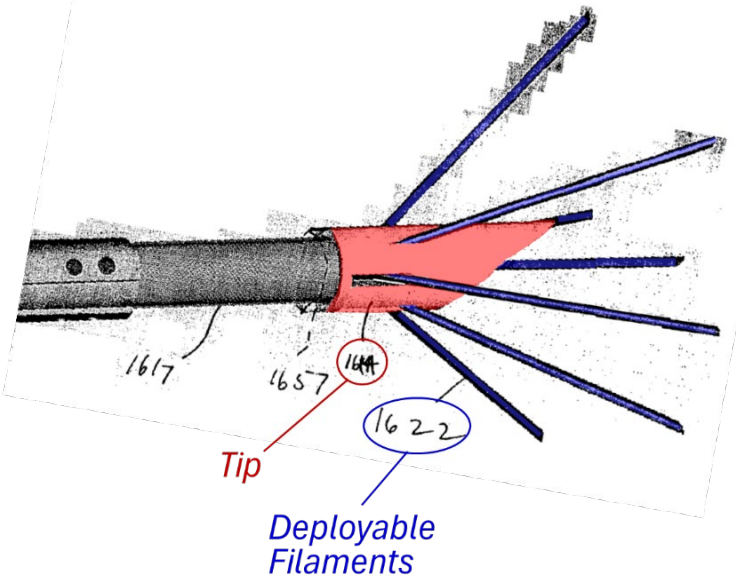
Fitz – Figures 1 & 5 (annotated)

In fact, by the time of the '688 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 '688 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.

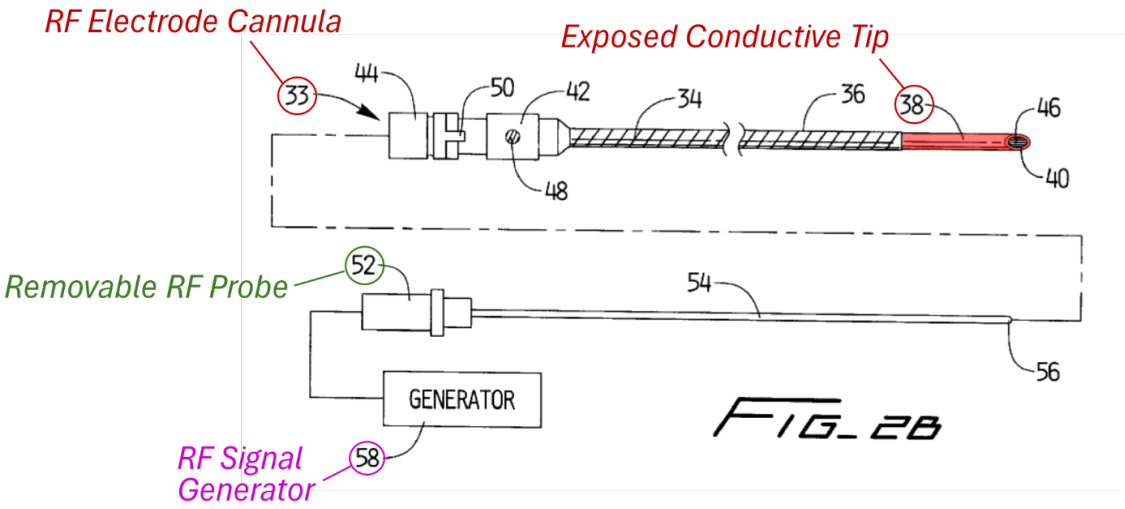


Lee – Figure 1 (annotated)



Lee – Figure 48 (annotated)

As the '688 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 – Figure 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 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.

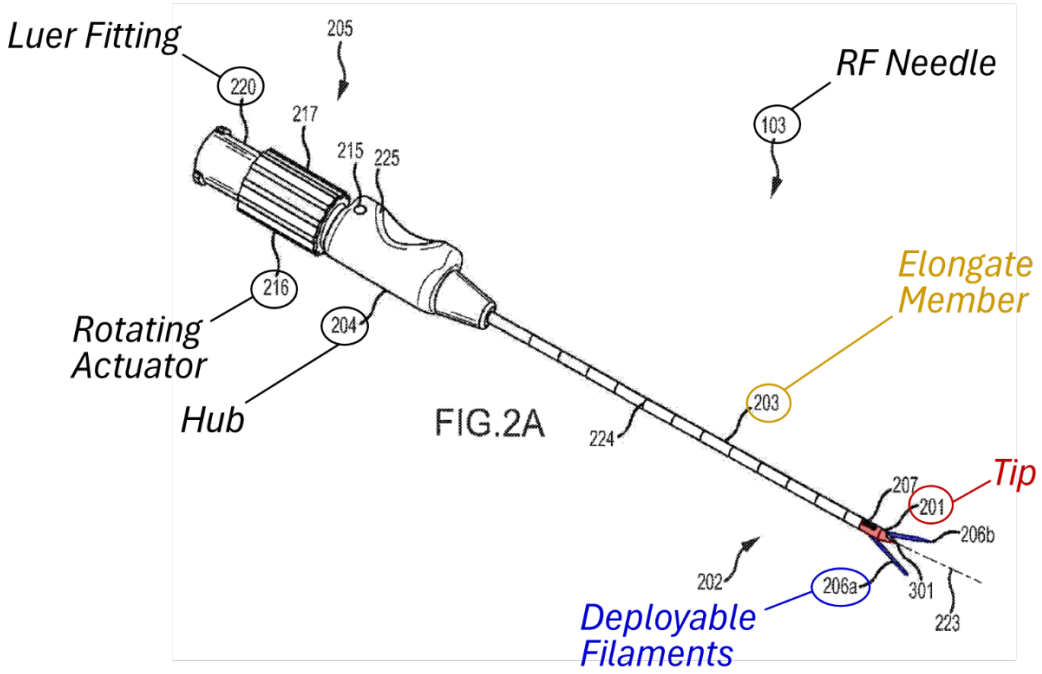
II. THE '688 PATENT

A. Overview

The '688 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-1002, 4:34-56, 30:63-31:14.[1] In Fig. 2A, the needle (103) includes an elongate member (203) having a conductive tip (201) (**shaded red**) and deployable filaments (206a-b) (**shaded blue**). Ex-1002, 5:25-47, 6:37-43; Ex-1033, ¶89-90. The elongate member (203) "may be constructed from an insulative material" while the tip (201) and filaments (206a-b) are conductive and electrically active. Ex-1002, 5:25-47, 8:15-25. A Luer fitting (220) at the proximal end of the needle (103) is configured for receiving (i) a removable RF probe (401) (which is

[1] The '688 Patent includes 21 figures (labeled 1-15) showing various needle configurations. One example is described herein for context and brevity.

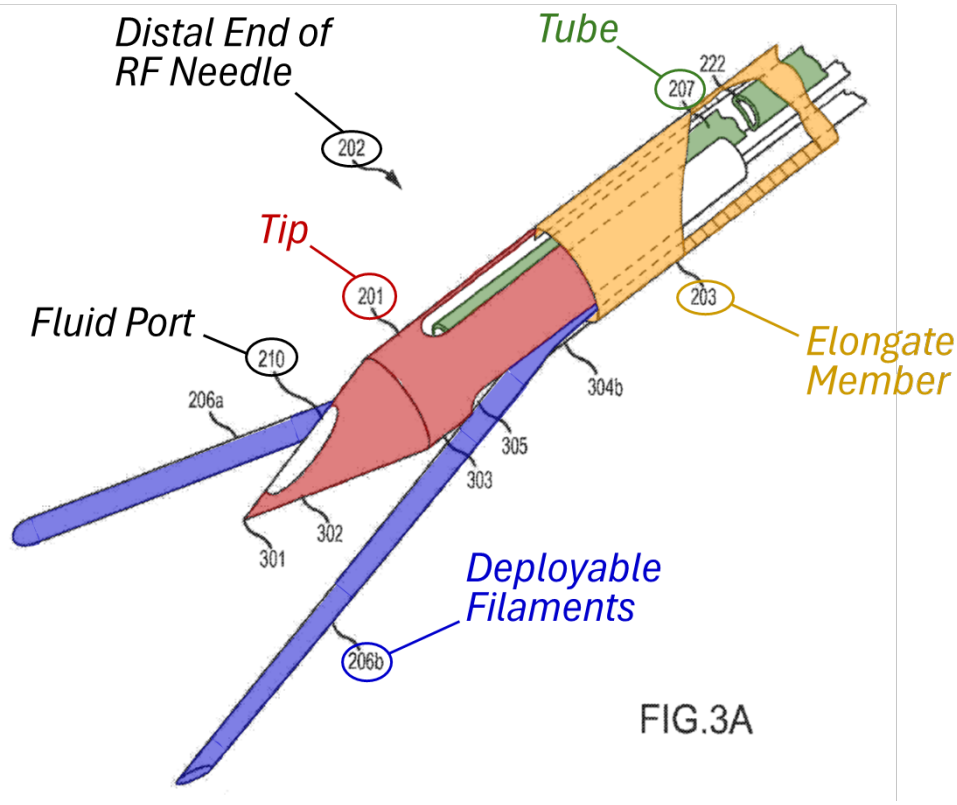
inserted into a tube (207) in the elongate member) and (ii) fluid delivered through the lumen (when the probe (401) is removed). Ex-1002, 4:66-5:7, 5:48-59, 17:47-54.



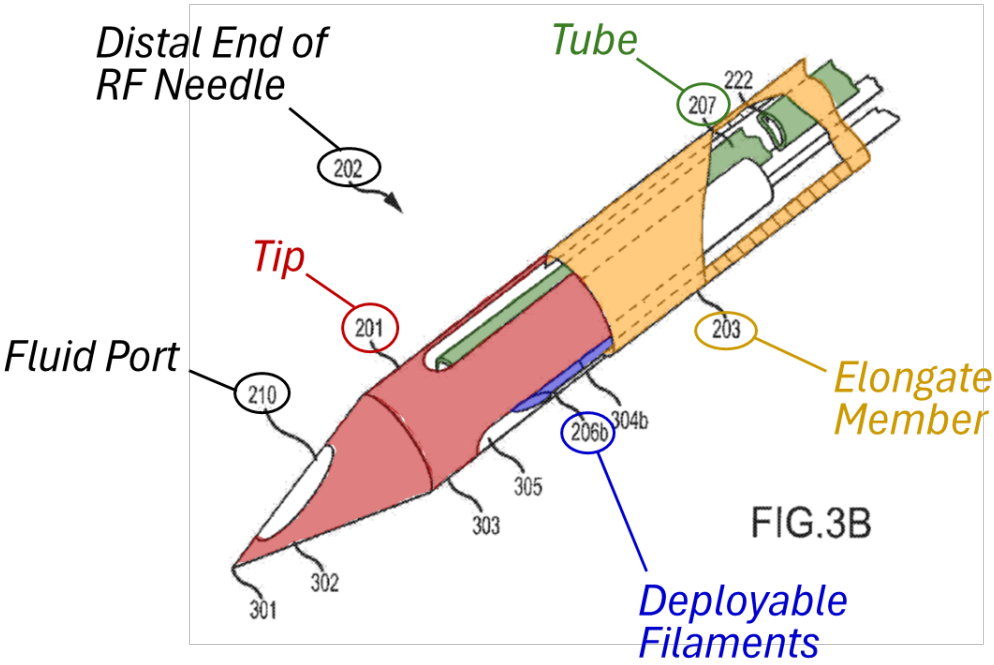
'688 Patent – Fig. 2A

The filaments (206a-b) are deployed/retracted by a rotating actuator (216). Ex-1002, 5:45-47, 17:9-18:32. When deployed, the filaments (206a-b) "expand the volume of effective RF energy delivery as compared to known single-electrode RF probes." Ex-1002, 5:34-41; Ex-1033, ¶91. 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-1002, 11:11-23, 11:57-12:35, 13:37-14:5.

As shown in Figs. 3A-3B, the needle's tip (201) is positioned at the elongate member's distal end. Ex-1002, 5:25-31; 6:25-36; Ex-1033, 92. The tip (201) 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-1002, 5:25-28, 7:34-50, 17:47-53.



'688 Patent – Fig. 3A



'688 Patent – Fig. 3B

Although the tip (201) and elongate member (203) may be a "unitary structure," Figs. 3A and 3B show a configuration where the tip (201) is a separate member "fixedly interconnected" to the elongate member (203). Ex-1002, 8:40-50; Ex-1033, ¶93. The tip (201) defines "filament slots" (304a-b) (e.g., channels) that guide the filaments (206a-b) in and out of the tip (201) when the filaments (206a-b) are deployed/retracted by the actuator (216). Ex-1002, 6:44-7:33.

To transmit RF energy to the tip (201) and filaments (206a-b), "the RF probe 401 is inserted within the tube 207, [and] the RF energy emitted by the RF probe 401 may be conducted through the tube 207 and into and through the tip 201 and filaments 206A, 206b." Ex-1002, 8:52-57, 5:48-58. When the filaments are deployed, "RF energy passes from the RF probe 401 to tip 201 and filaments 206a,

206b, and into a target volume within the patient 101." Ex-1002, 9:43-47. In this way, the tip (201) and filaments (206a-b) operate together as an electrode. Ex-1002, 9:47-53; Ex-1033, ¶94.

B. Prosecution History

The '688 Patent issued from U.S. Patent Application No. 15/098,673 (the '673 Application") filed on April 14, 2016. The '673 Application was a continuation of US 12/940,974 (filed November 5, 2010) and claims priority to two US provisional applications (61/347,351 filed on May 21, 2010 and 61/280,557 filed on November 5, 2009).

During prosecution, the '673 Application grew from 20 to 74 claims, cycled through four Office Actions, and was accompanied by *more than 500 references* submitted to the Examiner. Eventually, the claims were allowed when the Examiner was unable to find disclosure of a removable RF probe having the configuration claimed in the '688 Patent. Ex-1007, 495-96; Ex-1033, ¶95-117.

For the reasons explained herein, the features added to secure allowance of the '688 Patent's claims were well-known and obvious. Among the references in the Petition's Grounds, only Young '965 was discussed during prosecution. Ex-1007, 125, 150-51, 160-69, 188-97; Ex-1033, ¶118. None of the remaining references in the Petition's Grounds were discussed during prosecution.

III. LEVEL OF ORDINARY SKILL IN THE ART

The ’688 Patent identifies its technical field as relating to “thermal ablation systems and methods,” which includes RF neurotomy systems. Ex-1002, 1:16-20. 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-1033, ¶119.

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, 44-49; Expert, ¶120. The ’688 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 ’688 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 18-47 and 53-74[2] are invalid under the following Grounds:

	Claims	Statute	Prior Art
A	18-47, 53-74	§ 103(a)	**Racz, Fitz, and Lee**
B	18-47, 53-74	§ 103(a)	Racz, Fitz, Lee, and **Young '965**
C	18-47, 53-74	§ 103(a)	Racz, Fitz, Lee, and **Scheibe**
D	18-47, 53-74	§ 103(a)	Racz, Fitz, Lee, Young '965, and Scheibe
E	35-46, 54-55, 66-73	§ 103(a)	Racz, Fitz, Lee, and **Cosman '542**
F	35-46, 54-55, 66-73	§ 103(a)	Racz, Fitz, Lee, Cosman '542, and Young '965
G	35-46, 54-55, 66-73	§ 103(a)	Racz, Fitz, Lee, Cosman '542, and Scheibe
H	35-46, 54-55, 66-73	§ 103(a)	Racz, Fitz, Lee, Cosman '542, Young '965, and Scheibe

The following references were issued/published more than one year before the '688 Patent's earliest claimed priority date and are therefore prior art under pre-AIA 35 U.S.C. § 102(b): Racz, Fitz, Lee, Young '965, and Scheibe. 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).

[2] Claims 1-17 and 48-52 have been challenged in a separate IPR petition filed concurrently with this Petition (IPR2024-01210).

VI. GROUND A: CLAIMS 18-47 AND 53-74 ARE OBVIOUS IN VIEW OF RACZ, FITZ, AND LEE.

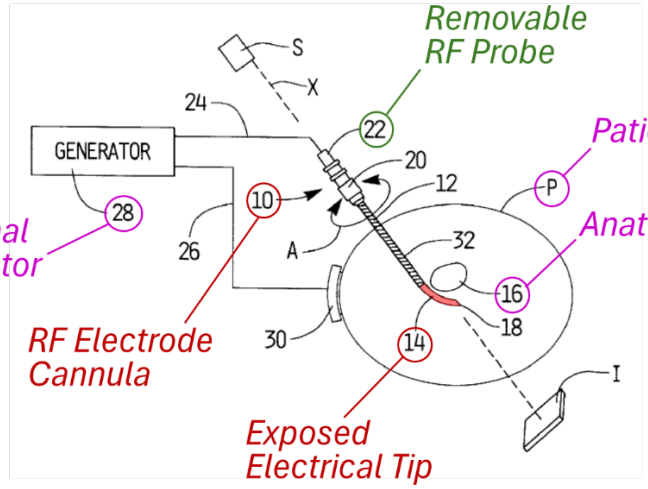
A. Prior Art Overview

1. Overview of Racz

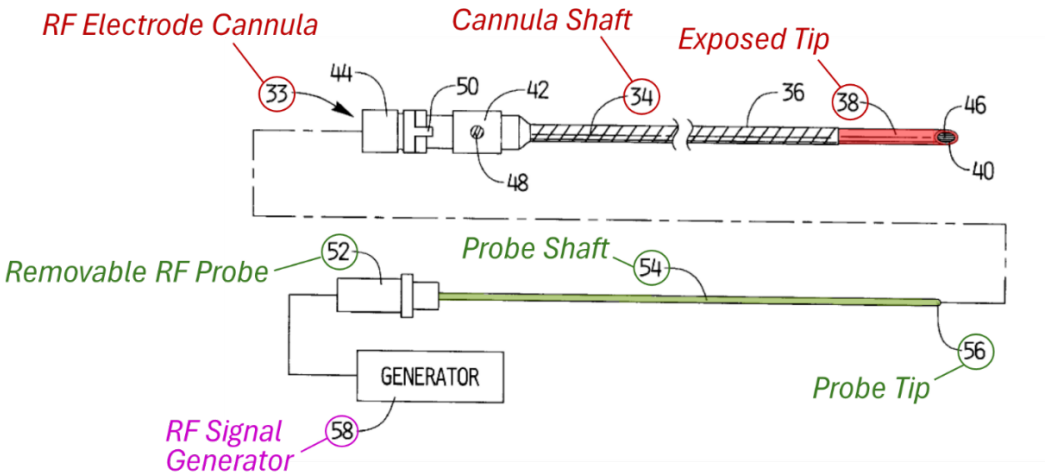
Racz discloses an "apparatus for pain relief that delivers electrical stimulation pulses or high-frequency signals to the vicinity of a neural structure via an electrical needle or cannula." Ex-1009, 1:4-9. Thus, Racz is directed to the same field as the '688 Patent ("thermal ablation systems and methods"). *See* Ex-1002, 1:16-20; Ex-1033, ¶124.

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; ¶125-127, 131.[3]

[3] 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. 1 (annotated)



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-1033, ¶128.

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-1033, ¶129.

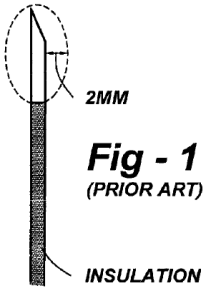
In this way, Racz's cannula (10/33) provides "electrical stimulation or high-frequency heating of tissue near the exposed electrical tip 14." Ex-1009, 3:60 to 4:23, 5:41-51, Fig. 1. Additionally, a reference electrode (30) is placed on the patient's body (P), allowing the tip (14/38) to function as a monopolar electrode. Ex-1009, 4:3-23; Ex-1033, ¶130-131.

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 '688 Patent's field. *See* Ex-1002, 1:16-20; Ex-1033, ¶132.

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 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-1033, ¶133.

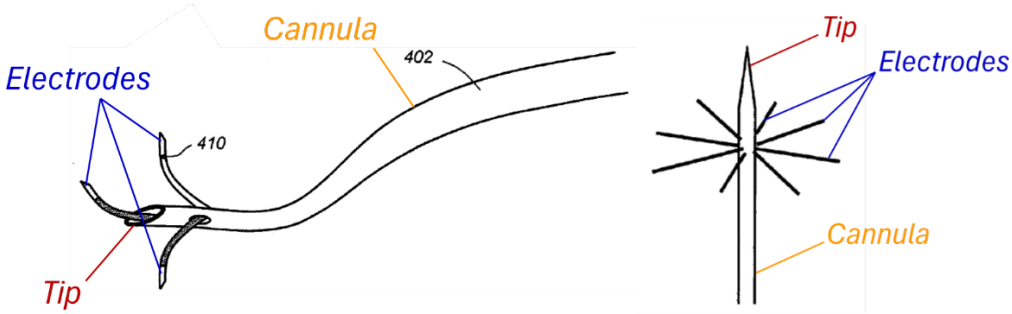


Fitz – Fig. 1

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-1033, ¶134. 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 extending 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-1033, ¶135-137.



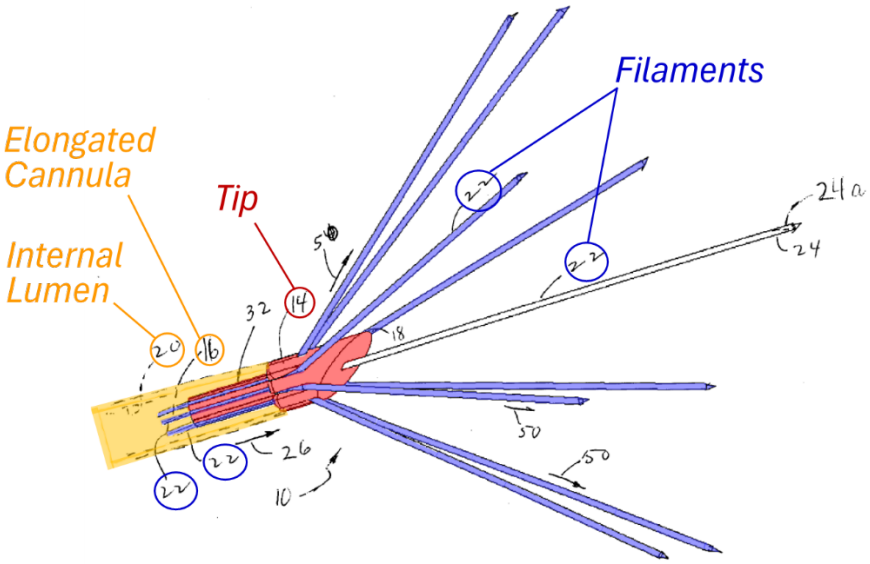
Fitz – Fig. 4 (annotated at left) & Fig. 5 (annotated at right)

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 '688 Patent's field. *See* Ex-1002, 1:16-20; Ex-1033, ¶138, 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. Figure 1 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-1033, ¶139-140.

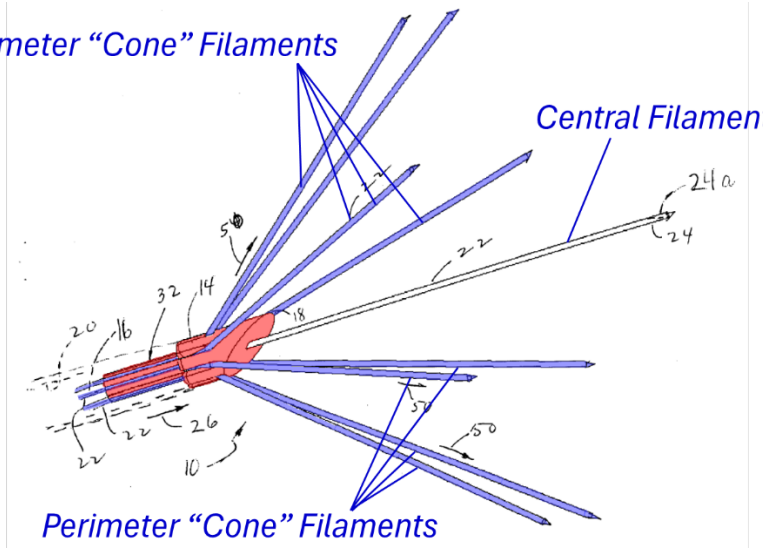


Lee – Fig. 1 (annotated)

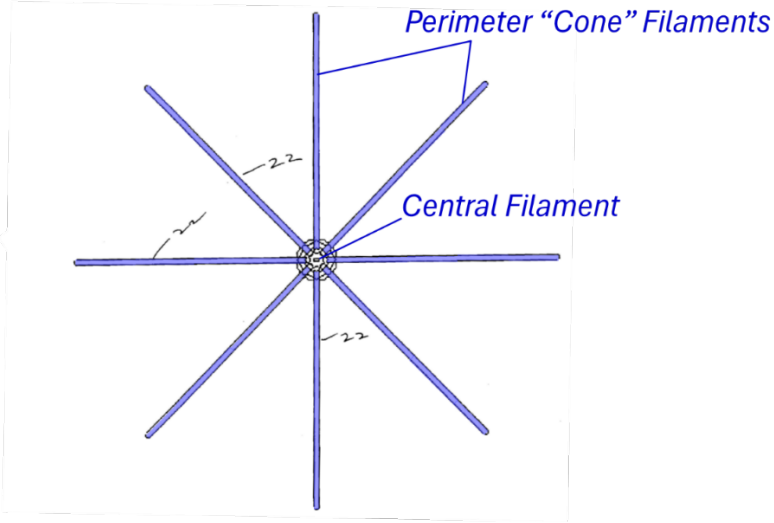
Figure 1 shows Lee's filaments (22) in a deployed position. Ex-1010, ¶0092, 0093, 0099, 0102. The tip (14) includes delivery mandrel surfaces (12) (or "deflection surfaces") comprising channels and ramps positioned in the cannula (16). Ex-1010, ¶0016, 0018, Claims 8, 10. The filaments (22) are positioned around the tip (14) and, when deployed, are guided outwardly by the deflection surface channels/ramps (12). Ex-1010, ¶0091, 0102, Abstract; Ex-1033, ¶141.

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-1033, ¶142.



Lee – Fig. 1 (annotated)

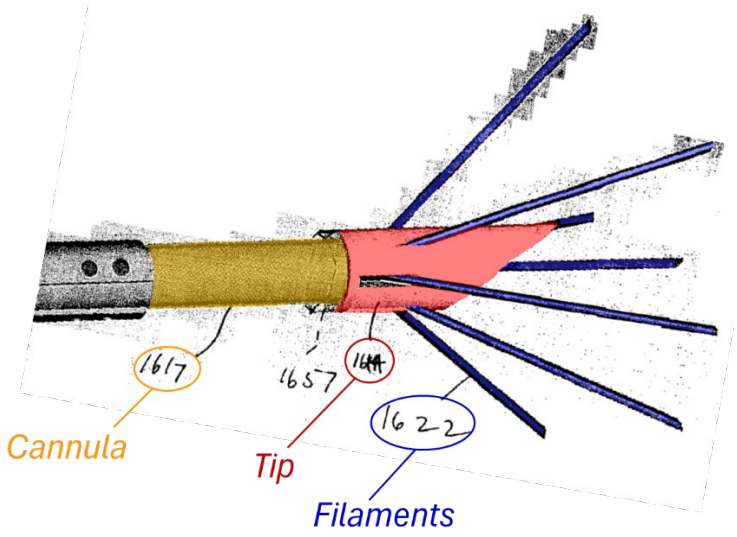


Lee – Fig. 5 (annotated)

Lee discloses that the filaments (22) "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-1033, ¶143.

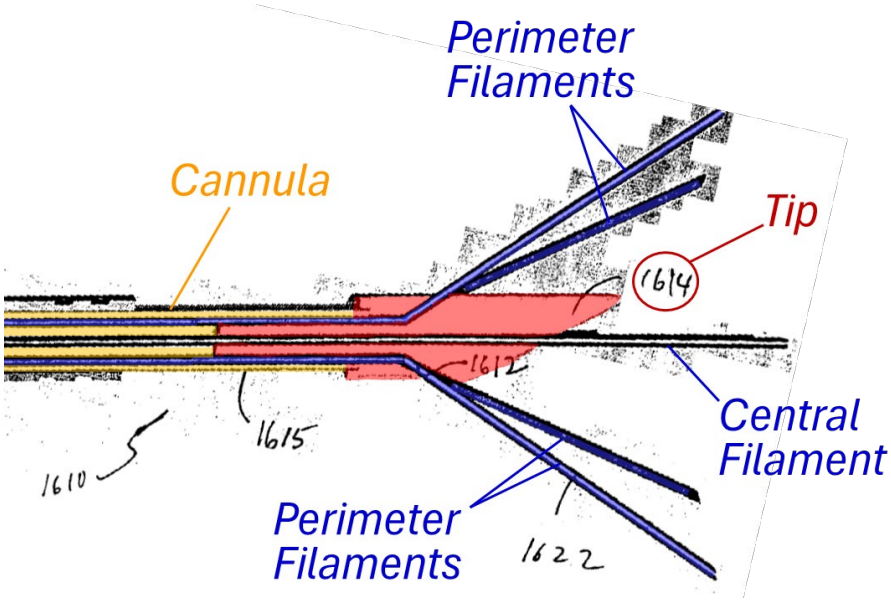
Lee provides additional detail regarding filament deployment with reference to a trocar (1610) (Figs. 48-49). The device's cannula (1615) (**shaded orange**) may be a metal tube coated with an insulative material (1617). Ex-1010, ¶0142. The cannula (1615) (aka "hypotube") houses a plurality of stylets (1622) (**shaded blue**) (i.e., filaments). Ex-1010, ¶0143; Ex-1033, ¶144. 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. The deployed filaments (1622) extend outwardly around the tip (1614). Ex-1010, ¶0142, 0146; Ex-1033, ¶145. 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.



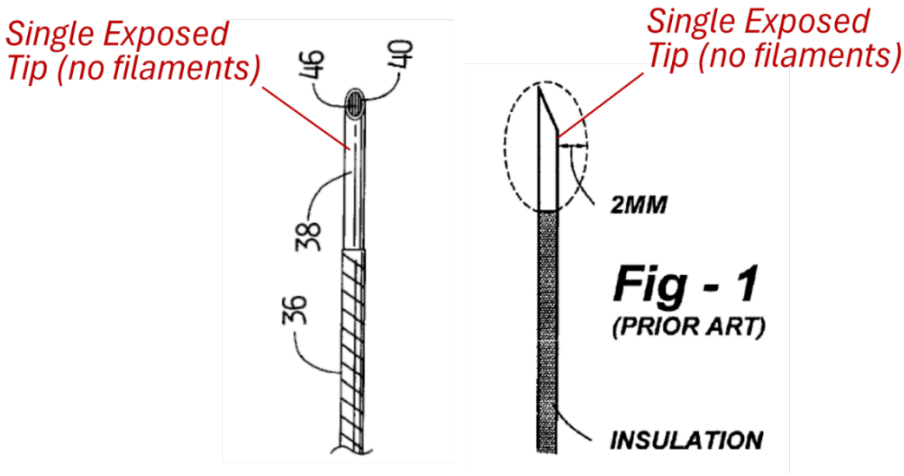
Lee – Fig. 49 (cropped and annotated)

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

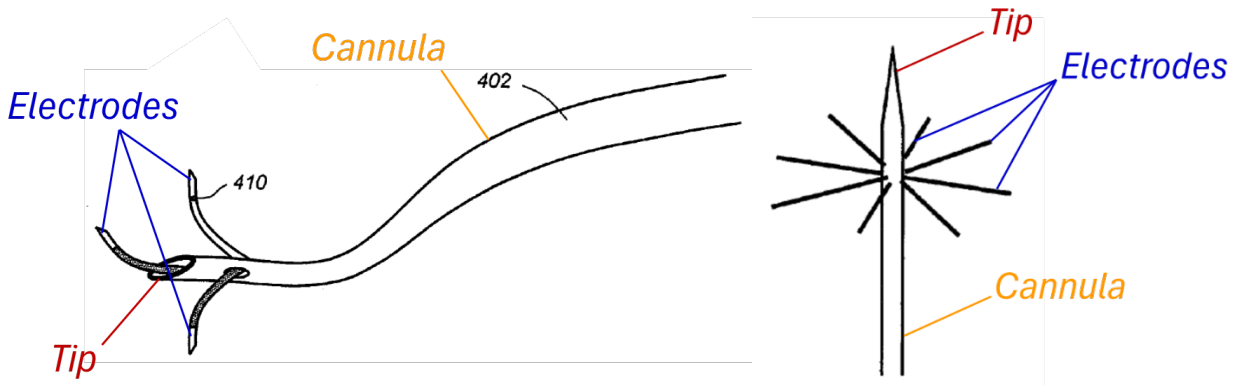
1373, 1380 (Fed. Cir. 2023) (internal citations omitted). Fitz and Lee disclose a known technique for solving a known problem in RF ablation devices—providing deployable filaments at a distal tip to expand and control the ablation volume compared to single-tip devices with inadequate energy coverage. Ex-1011, ¶0009-0010, Abstract; Ex-1010, ¶0012, 0084, 0123-0131; Ex-1033, ¶146, 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-1033, ¶147-149.



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-1033, ¶150. 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-1033, ¶151. 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). *Id*.

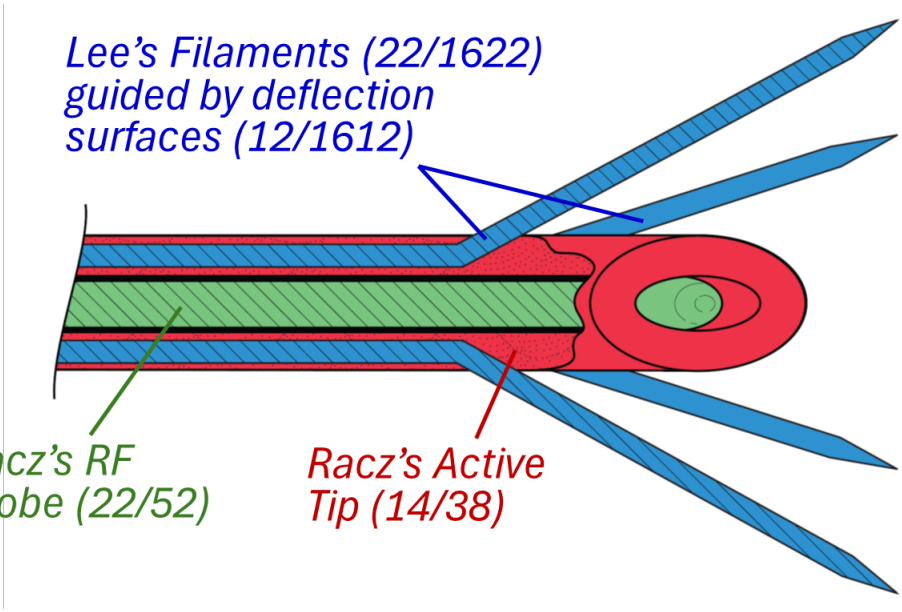
Nearly two years after Fitz's publication, Lee disclosed a further refinement of the deployable-electrode technique that would have provided additional

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) allows "the operator [to] deliver the [radiofrequency] treatment safely and effectively" (Ex-1010, ¶0084). For at least these reasons, 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-1033, ¶152.

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.a), 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. *See* 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-1033, ¶153-154.

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 (22/1622) both physically contacting Racz's active tip (14/38) and being deployed outwardly around Racz's active tip (14/38). Ex-1033, ¶155. 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). Ex-1033, ¶157. 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-1033, ¶158-161. 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 ¶157 (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-1033, ¶162. The resulting device (Racz's cannula modified to include Lee's filaments) would include every limitation of Claims 1, 18-47, and 53-74.

C. Ground A: Independent Claim 1

Claim 1 has been challenged in a separate IPR petition filed concurrently with this Petition (IPR2024-01210). The arguments for Claim 1 have been repeated herein as Challenged Claims 18-47 depend from Claim 1, and the arguments for Claim 1 apply to Claims 53-74 for the reasons provided herein.

1. Racz discloses the preamble [1pre] and limitations [1a]-[1e], [1h], [1i], and [1k]

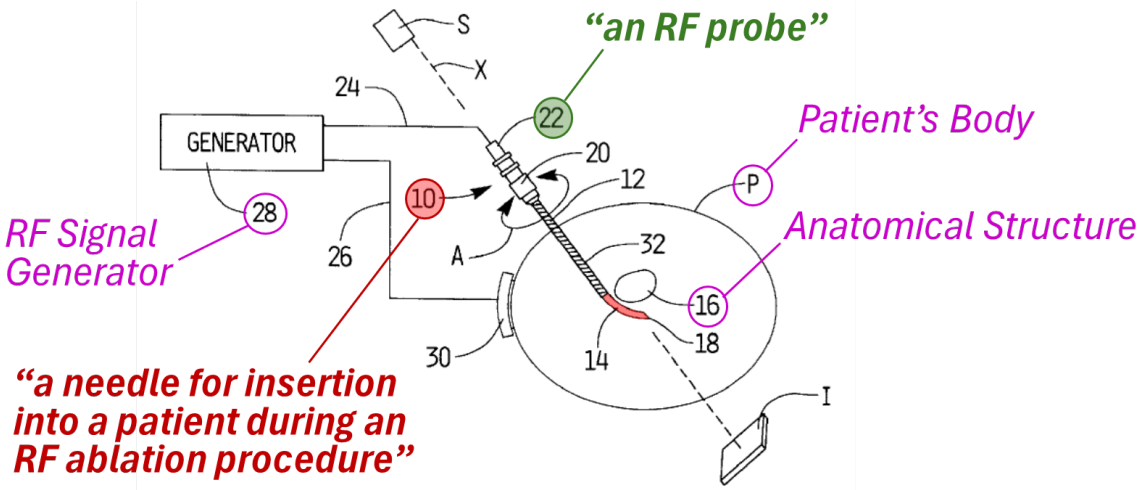
a. [1pre]

Claim 1's preamble recites "a system" (**[1pre]**). Although the preamble is not limiting, Racz is directed to a "a system for pain relief" and discloses **[1pre]**. Ex-1009, 1:4-9, 2:46-65; Ex-1033, ¶163.

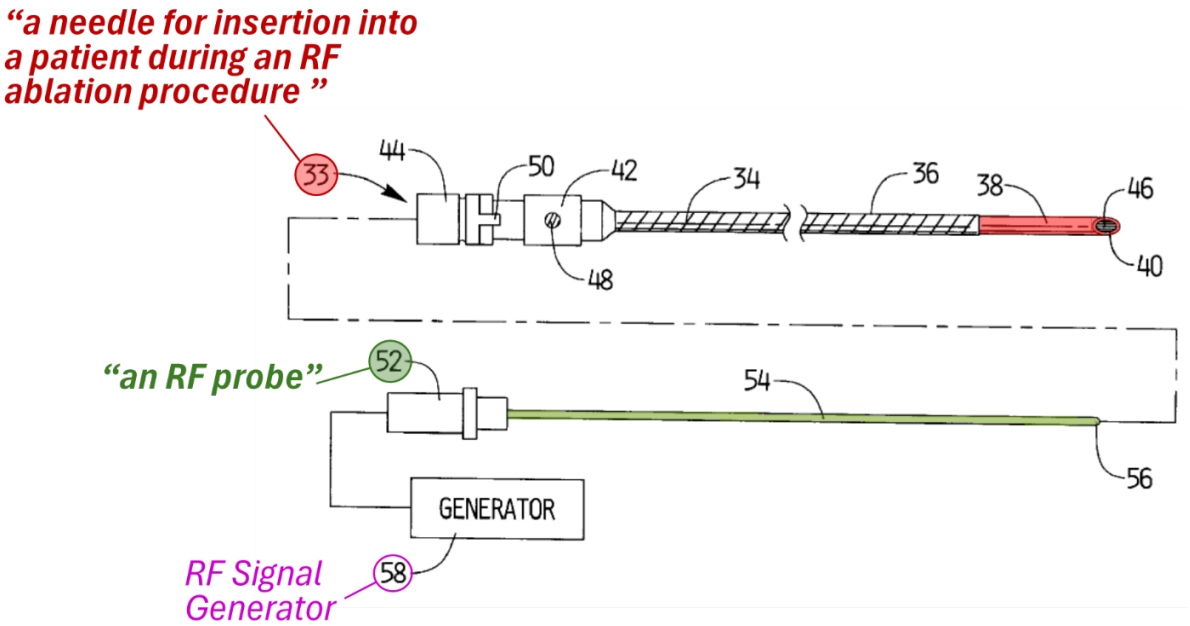
b. [1a] and [1b]

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 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-1033, ¶164. 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 probe (22/52) is a "an RF probe" (**[1a]**). Ex-1033, ¶164.

Racz's 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 (ablation). Ex-1009, 2:53-56; 4:18-23 and 49-58, 7:43-50, Abstract. Thus, Racz's electrode cannula (10/33) is a "a needle for insertion into a patient during an RF ablation procedure" (**[1b]**). Ex-1033, ¶165.



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



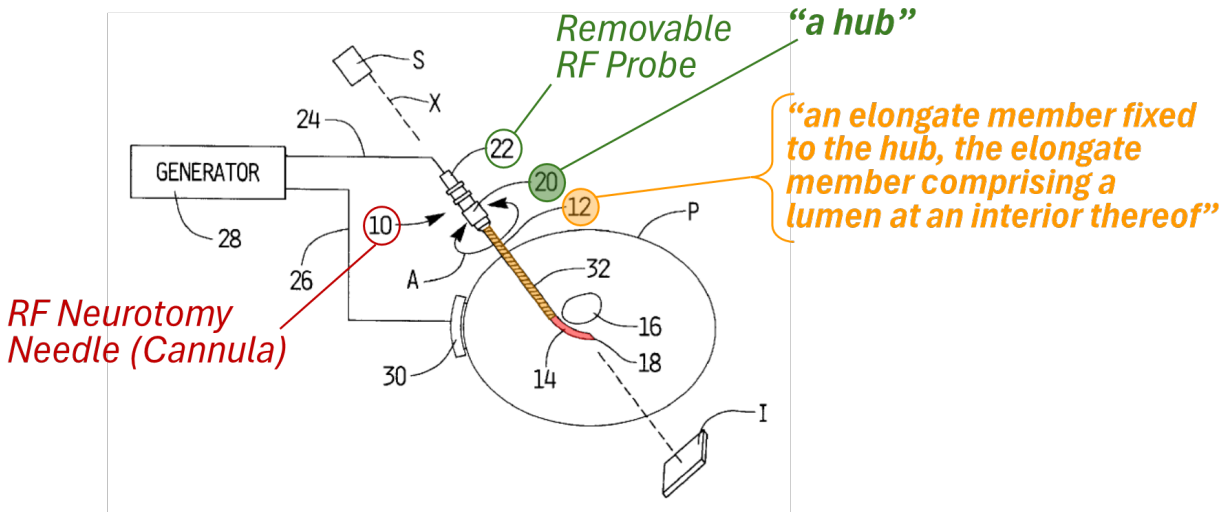
Racz – Fig. 2B (annotated to show [1a] and [1b])

c. [1c] and [1d]

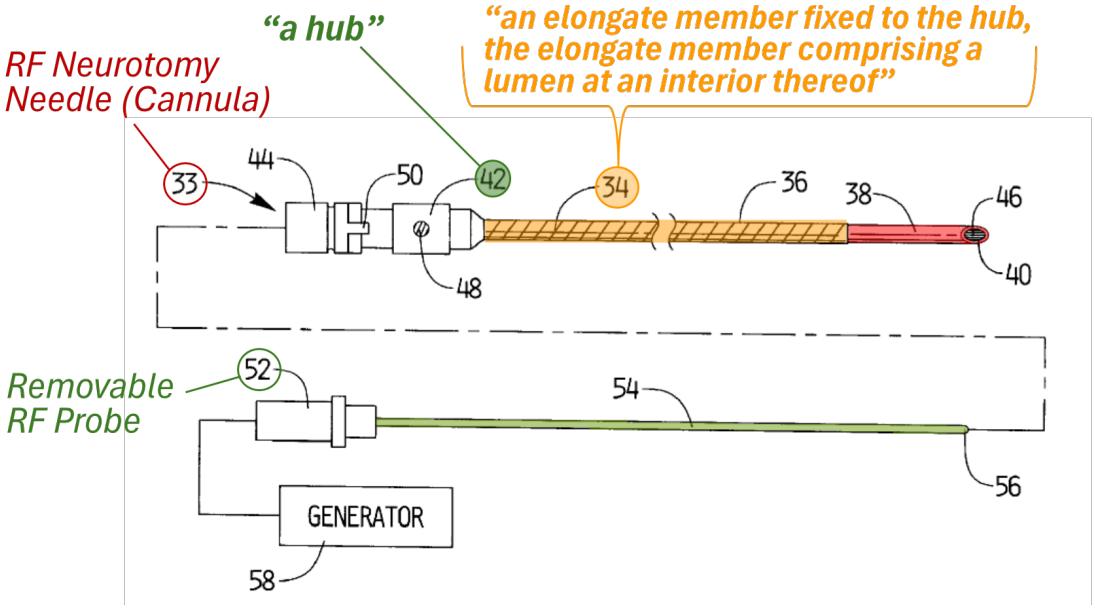
The proximal end of Racz's cannula (10/33) includes a "hub" (20/42/70) that is fixed to cannula's shaft (12/34). Ex-1009, 3:59-4:3, 5:5-20, 5:66-6:17, 9:44-48. In particular, the hub (20/42/70) is "capable of accommodating an electrical probe 22, which includes a segment that is inserted into and received by the shaft 12 of the cannula 10." Ex-1009, 3:59-65. Thus, Racz's cannula (10/33) includes "a hub" **[1c]**. Ex-1033, ¶166.

Racz's 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) via the hub (20/42/70), which is

"mounted at a proximal end of the shaft." Ex-1009, 9:44-48, 3:38-42, 3:60-65, 5:26-28, 5:37-51. Thus, Racz's shaft (12/34) is "an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof" as recited in **[1e]**. Ex-1033, ¶167.



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



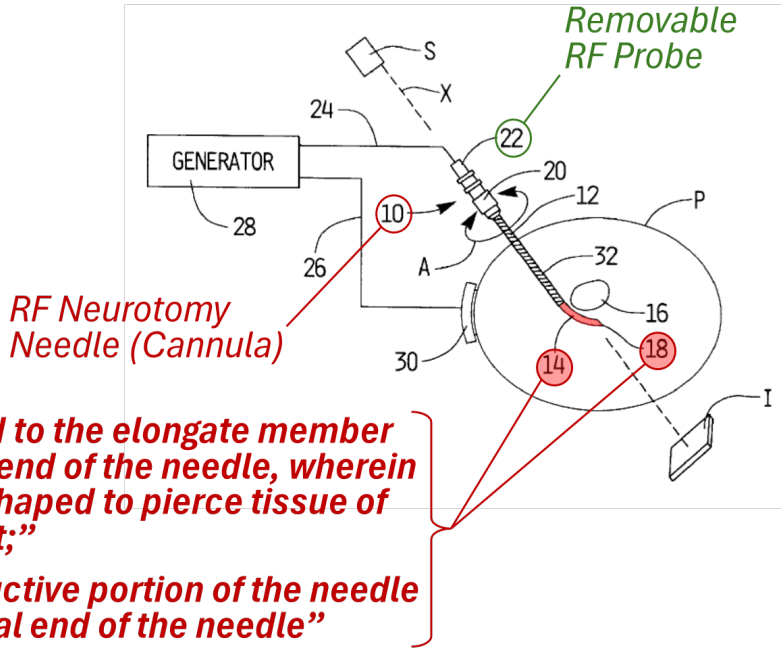
Racz – Fig. 2B (annotated to show [1c] and [1d])

d. [1e] and [1k]

Racz's exposed tip (14/38) is positioned at a distal end of the shaft (12/34) and 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 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 "fixed to the elongate member at a distal end of the needle" and "shaped to pierce tissue of the patient" **[1e]**. Ex-1033, ¶168.

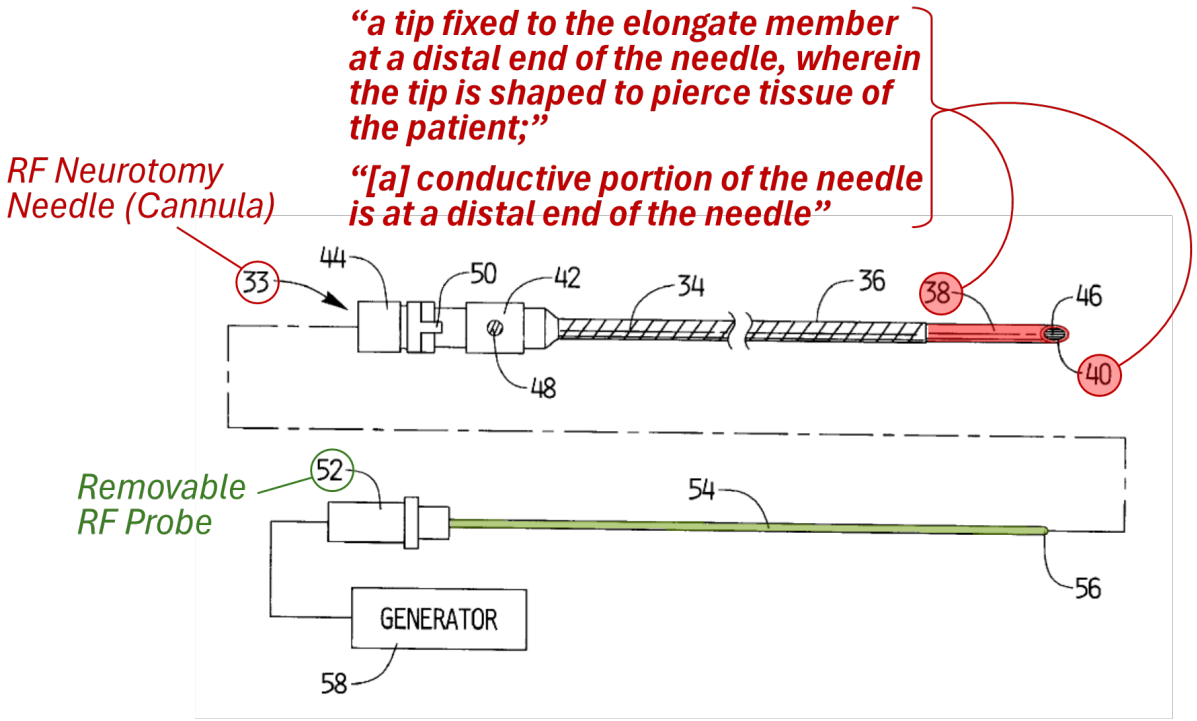
Racz also discloses that the tip (14/38) conducts electrical signals for "high-frequency heating" (e.g., generating radio-frequency heat lesions). Ex-1009, 4:18-23, 4:52-58, 3:41-59, 5:38-45, 7:43-50. The tip (14/38) is made of a conductive material (e.g., where the cannula's "shaft (34) comprises a 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, physical contact with the probe (22/52) transmits RF energy to the tip (14/38) and into patient tissue. Ex-1009, 3:60-65, 4:18-23, 5:41-48, Fig.

2B; Ex-1033, ¶169. Thus, Racz's tip (14/38) is "[a] conductive portion of the needle is at a distal end of the needle" **[1k]**.[4] *Id*.



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

[4] Claim 12 of the '688 Patent confirms that the elongate member and the tip may "comprise a single unitary structure." Claims 48-49 confirm that the needle's "conductive portion" may comprise "the conductive material of the tip."



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

e. [1h]

The proximal hub (20/42/70) of Racz's cannula is a fitting, such as "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/fitting (20/42/70) 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 device includes "a fitting in fluid communication with the lumen, the fitting being configured to provide a connection for injection of fluid through the fitting and through the lumen" **[1h]**. Ex-1033, ¶170.

In addition to receiving fluid from a fluid source, Racz's hub/fitting (20/42/70) is also configured for receiving the probe (22/52) (for transmitting RF

energy). 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. Thus, Racz's fitting is further "configured to allow for insertion of the RF probe into the lumen through the fitting" **[1h]**. Ex-1033, ¶171.

f. [1i]

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-1033, ¶172.

When inserted into the lumen at the interior of the cannula's shaft (12/34), the probe's shaft (54) is configured to extend the full length of the cannula 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-1033, ¶173. 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-1033, ¶173, 50.[5] The probe's temperature sensor could not accurately measure the tissue temperature if the probe's tip (56) were not positioned at the cannula's tip (14/38) when the probe (22/52) is inserted. *Id*.

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 tip (14/38) of the cannula (10/33). Ex-1009, 5:45-48; Ex-1033, ¶174. 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)). *Id*. Thus, when Racz's RF probe (22/52) is inserted into the shaft (12/34) ("the lumen at the interior of the elongate member"), the RF probe will "physically contact a conductive portion of the needle" **[1i]**.

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

For the reasons explained above, a POSA would have been motivated to implement Lee's perimeter deployable filaments (22/1622) on the distal tip (14/38)

[5] *See also* Ex-1011, ¶0003 (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").

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-1033, ¶175. 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]**, **[1j]**, and **[1l]** (and, as described above, the features of **[1a]-[1e], [1h], [1i], and [1k]**).

a. [1f] and [1j]

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, Lee's stylets/electrodes (22/1622) are "a plurality of filaments" **[1f]** and are therefore referred to herein as "filaments (22/1622)." Ex-1033, ¶176-177; *see also* Ex-1002, 9:54-56 ("filaments" may be "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 Racz and Lee (Ex-1033, ¶178):

(i) Racz's distal tip (14/38) is electrically active via "physical contact" between the probe (22/52) and tip (14/38) (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);

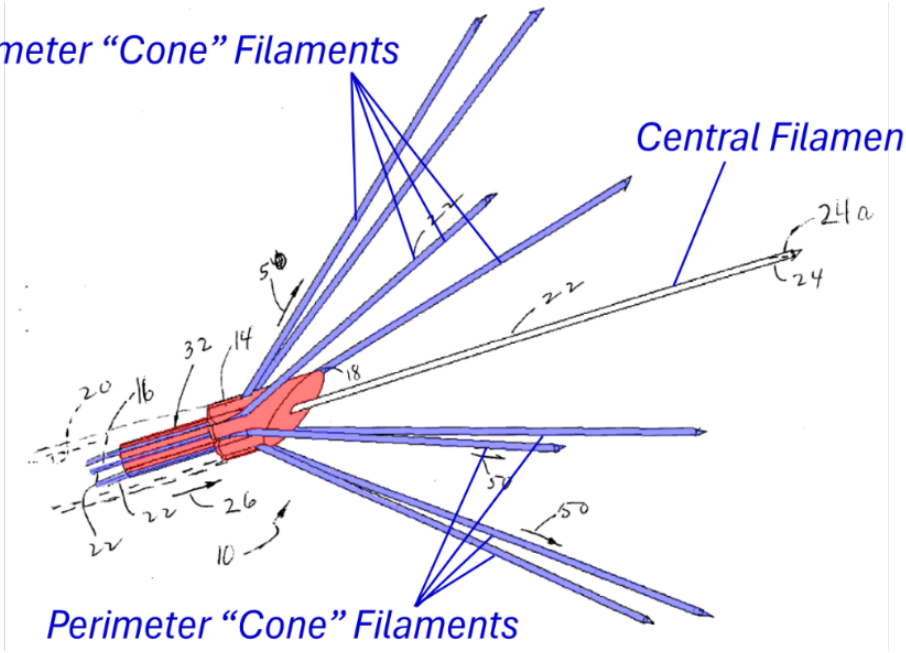
(vii) when deployed, Lee's perimeter filaments (22/1622) extend outwardly and around the cannula's tip in a "cone" shape (Ex-1010, ¶0103, Figs. 1, 5, 48-49);

(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

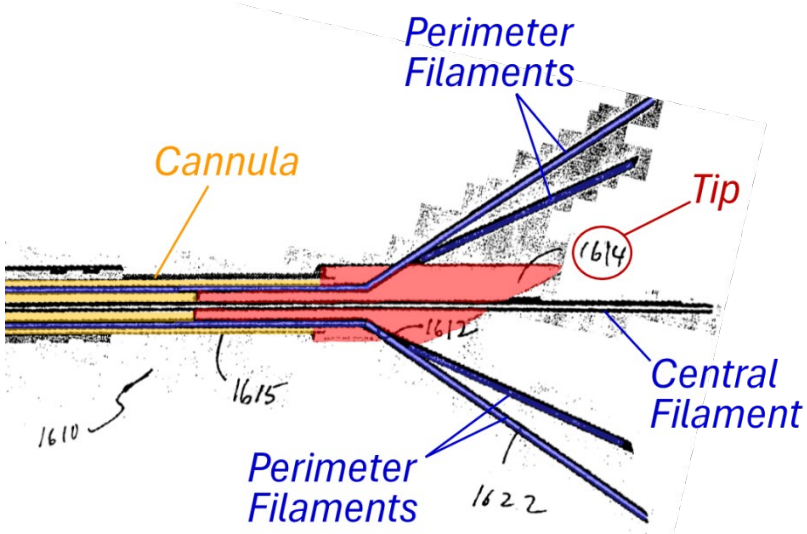
(ix) "variations in ablation volume may be achieved by varying the extent to which [filaments] are extended from the distal end of the trocar and the direction in which [filaments] extend" and that "the arrangement of [filaments] may … form any desired pattern" (Ex-1010, ¶0123-0131, 0084, 0103).

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-1033, ¶179. 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 tip (14/38) is already active, a POSA would have recognized that Lee's central filament would not be necessary. Ex-1009, 3:60-63, 4:18-23; Ex-1033, ¶179. Thus, a POSA would have been motivated to implement 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-1033, ¶179, 73-75, 79-83. As Lee (and Fitz) confirm, this would improve Racz's device by providing an expanded and controlled energy coverage area. Ex-1011, ¶0009-0010, Abstract; Ex-1010, ¶0012, 0084, 0123-0131; Ex-1033, ¶179.



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



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

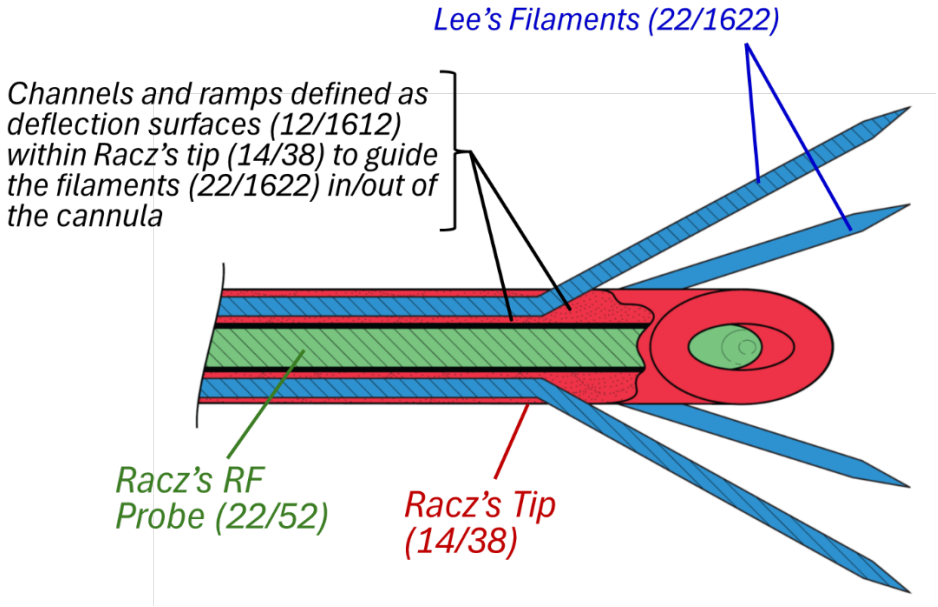
To implement Lee's perimeter filaments (22/1622) on Racz's distal tip (14/38), a POSA would have found it obvious to modify Racz's tip (14/38) to include internal deflection surfaces (12/1612) (e.g., channels and ramps as disclosed in Lee) to guide the perimeter filaments (22/1622) outwardly around Racz's tip (14/38). Ex-1010, ¶0016, 0018, 0092, 0102, Claim 8, Claim 10; Ex-1033, ¶180. It would have been further obvious to provide openings in Racz's distal tip (14/38) (e.g., in communication 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-1033, ¶180.

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-1033,

¶181. As discussed above, Racz's 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 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-1033, ¶181-182.

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) would still be received into the cannula's central lumen). Ex-1033, ¶183. According to Dr. Tucker, Lee's deflection surfaces (channels and ramps) would 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)). Ex-1033, ¶183. Dr. Tucker notes that, alternatively, the deflection surfaces would 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

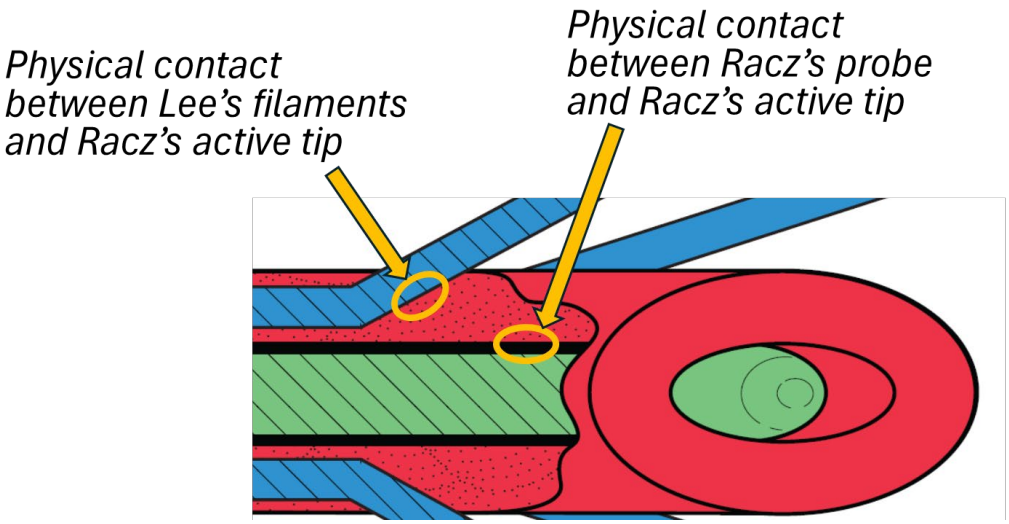
distal portion of the electrical probe (22/52) (the mandrel thereby defining both the tip (14/38) and deflection surfaces). Ex-1033, ¶183, 39-40.



Dr. Tucker Declaration at ¶183

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 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, 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-1033, ¶184.



Dr. Tucker Declaration at ¶184

As Racz's probe (22/52), Racz's tip (14/38), and Lee's filaments (22/1622) are all constructed from conductive materials, the RF energy from Racz's probe (52) would be transmitted to the modified device's 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-1033, ¶185, 42. Specifically, RF energy from the probe (52) would be transmitted by physical contact to the tip (14/38), and the tip (14/38)—which defines the deflection surfaces—would transmit RF energy by physical contact to the perimeter filaments (22/1622). Ex-1033, ¶185.

For at least these reasons, Racz's cannula (10/33)—as modified by a POSA to include Lee's perimeter filaments (22/1622)—would include "a plurality of filaments" **[1f]** and be configured such that the RF probe (22/52) physically

contacts a conductive portion of the needle to "thereby electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments" **[1j]**. Ex-1033, ¶186.

The additional limitations in **[1j]** 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 tip (14/38) and perimeter filaments (22/1622) to operate together as a single monopolar electrode. Ex-1033, ¶187. Racz's tip (14/38) is configured to operate in a 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 tip (14/38) would already have been configured as a monopolar electrode. Ex-1033, ¶187. 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.

Accordingly, a POSA would have understood that implementing Lee's perimeter filaments (22/1622) at Racz's monopolar tip (14/38)—and electrically connecting the tip (14/38) and perimeter filaments (22/1622) by physical contact using internal deflection surfaces discussed above—would naturally result in the tip (14/38) and perimeter filaments (22/1622) functioning together as a single

monopolar electrode. Ex-1033, ¶188, 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. *Id*.

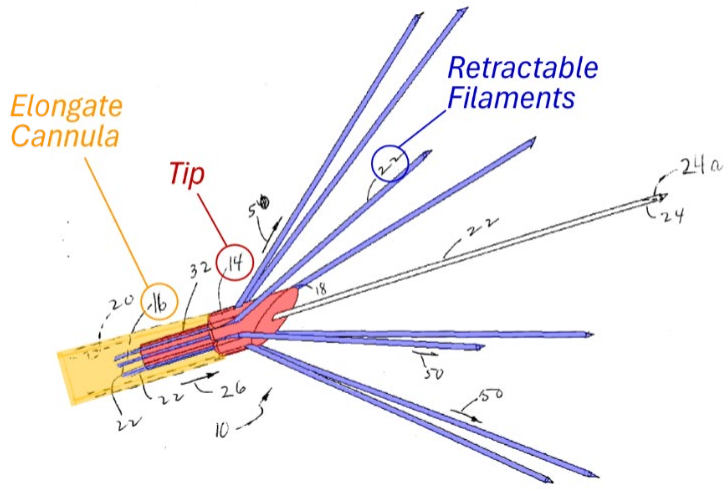
A POSA also would have had a reasonable expectation of success in implementing this configuration as both Racz and Lee disclose that a monopolar configuration is suitable for RF ablation procedures. Ex-1009, 4:3-23, Fig. 1; Ex-1010, ¶0024; Ex-1033, ¶189, 84-88. In implementing Lee's filaments (22/1622) 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-1033, ¶189.

Thus, Racz's device—as modified by a POSA in view of Fitz and Lee—would be configured "such that the RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode" as further recited in **[1j]**.

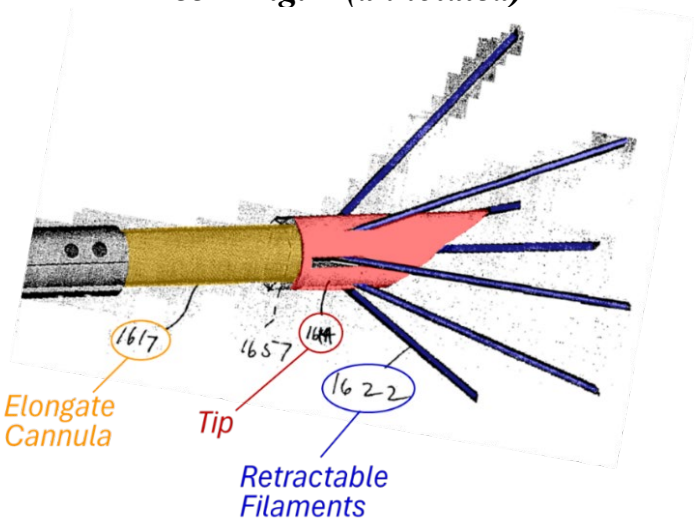
b. [1g] and [1l]

Lee discloses that its perimeter filaments (22/1622) are configured to be adjusted between deployed and withdrawn positions. In the withdrawn position, 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.

In the deployed position, the filaments (22/1622) extend outwardly from the cannula (and distally beyond the cannula's tip) to define the ablation volume. *Id*. Indeed, 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. *See e.g.*, Ex-1010, Figs. 1, 48, 49; Ex-1033, ¶190-191.



Lee – Fig. 1 (annotated)



Lee – Figure 48 (annotated)

Thus, a POSA implementing Lee's filaments (22/1622) on the tip (14/38) of Racz's device would have been motivated to configure the filaments (22/1622) to be positioned distally beyond the tip (14/38) in a deployed configuration (e.g., to expand the ablation volume of Racz's device) and to be positioned within the shaft (12/34) in a withdrawn configuration (e.g., to enable effective withdrawal and insertion of Racz's modified device). Ex-1033, ¶192.

To adjust the filaments (22/1622) between the deployed and withdrawn positions, Lee's perimeter filaments (22/1622) "may be connected to suitable advancement and retraction mechanisms" (i.e., an actuator). 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-1033, ¶193, 77-78. Moreover, as Racz's hub (20/42/70) is fixed to the cannula's shaft (12/34) and the filaments (22/1622) must move relative to the shaft (12/34) to be withdrawn/retracted, movement of the actuator to adjust the filaments (22/1622) would necessarily be in first/second direction relative to the hub (20/42/70). *Id*.

Accordingly, in view of Lee's teachings, a POSA modifying Racz's cannula (10/33) to include Lee's perimeter filaments (22/1622) would have been motivated (and would have found it obvious) to implement "an actuator" that is "interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member" **[1g]**. Ex-1033, ¶194.

As explained with respect to **[1f]** and **[1j]**, a POSA would have implemented Lee's filaments (22/1622) in Racz's device by arranging the perimeter filaments, channels, and ramps around the inner perimeter of Racz's cannula (10/33) for the purpose of not obstructing the interior lumen of Racz's shaft (12/34). *Supra* § VI.C.2.a. This would preserve the functionality of Racz's electrical probe (22/52), which is needed to transmit RF energy to Racz's tip (14/38). *Id.* In this configuration, Racz's probe (22/52) would be insertable (and withdrawable) from the cannula (10/33) without interfering with filaments (22/1622) or their associated actuator. Ex-1033, ¶195. Thus, regardless of whether the probe (22/52) is in an inserted or non-inserted state, the filaments (22/1622) would be adjustable between their deployed position and retracted position. *Id*.

Accordingly, a POSA modifying Racz's cannula (10/33) to include Lee's perimeter filaments (22/1622) would have configured the filaments (22/1622) and probe (22/52) such that "when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position" **[1l]**. Ex-1033, ¶196.

For at least these reasons, Claim 1 is obvious in view of Racz, Fitz, and Lee. Ex-1033, ¶197.

D. Ground A: Claims 18-25, 27, and 29-33

As discussed above with respect to **[1h]**, Racz's proximal hub (20/42/70) is "a fitting." *Supra* § VI.C.1.e. When Racz's RF probe (22/52) is not inserted into the shaft's internal lumen, Racz's hub/fitting (20/42/70) provides a connection for coupling the shaft (12/34) to a fluid source (e.g., "syringes" or "injection tubes"). Ex-1009, 5:66-6:12; 8:67. Fluid injected from the fluid source through the hub/fitting (20/42/70) is directed through the shaft's internal lumen and out of the opening (46) of the tip (14/38). Ex-1009, 5:14-18, 5:66-6:8, 6:9-12, 8:54-57, 1:29-33, Abstract. Thus, Racz's modified device is configured such that:

- "the fitting is configured to be coupled to a fluid source and the lumen is configured to conduct fluid from the fluid source when the RF probe is not positioned within the needle" **[18];**

- "the fitting is configured to provide a connection to a fluid source for said injection of fluid through the fitting and through the lumen" **[19]**;
- "the fitting is configured to be connected with the fluid source and to permit fluid to pass through the fitting and through the lumen when the RF probe is not present within the lumen" **[21]**;
- "the lumen is configured to deliver fluid through the tip at the distal end of the needle" **[25];** and
- "the lumen is configured to deliver fluid through the tip at the distal end of the needle" **[27].** Ex-1033, ¶198.

Racz discloses that its hub/fitting (20/42/70) can be a "Luer fitting," which a POSA would understand is configured to accept a fluid source's mating Luer fitting (a connector) to connect the fluid source to the needle (10/33). Ex-1009, 5:66-6:8; Ex-1033, ¶199.

- "the fitting comprises a Luer fitting configured to be connected with the fluid source when the RF probe is fully separated from the needle, such that none of the RF probe is within the needle" **[20a]**;
- "the Luer fitting further being configured to separately permit the RF probe to be inserted into the lumen through the Luer fitting when the Luer fitting is not connected with the fluid source" **[20b]**;
- "the fitting is configured to accept a connector of the fluid source" **[23]**;
- "the fitting comprises a Luer fitting and the connector of the fluid source comprises a Luer fitting" **[24]**; and
- "the fitting comprises a Luer fitting" **[31].** Ex-1033, ¶199.

Lee's filaments (22/1622) would be positioned around the internal lumen to avoid obstructing the lumen and preserve the functionality of Racz's RF probe (22/52). S*upra* § VI.C.2.a. Fluid injected through the shaft (12/34) (when the RF

probe is removed) would therefore pass through the fitting (20/42/70), the shaft's internal lumen, and the tip (14/38)—both when the filaments are in the retracted and deployed positions. Ex-1033, ¶200; *supra* § VI.C.2.b. Thus, Racz's modified device is configured such that:

- "when the plurality of filaments are in the retracted position, the fitting is configured to connect to a fluid source and to permit fluid from the fluid source to pass through the fitting, through the lumen, and through the tip at the distal end of the needle" **[33].**

Racz's hub/fitting (20/42/70) separately permits the RF probe (22/52) to be inserted through the fitting and into the shaft (12/34). 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. In other words, Racz's hub/fitting (20/42/70) serves a dual purpose—receiving the RF probe (22/52) to transmit RF energy and, when the probe is removed, connecting to a fluid source for injecting fluid through the needle. Ex-1033, ¶201.

- "the fitting is further configured to permit the RF probe to be inserted into the lumen through the fitting when the fitting is not connected with the fluid source" **[22];**
- "the fitting is configured to provide the connection for the injection of fluid through the fitting separately from allowing for insertion of the RF probe into the lumen through the fitting" **[29];**

As shown in Figures 1-3, the hub/fitting (20/42/70) is positioned at a proximal-most position at a proximal end of the needle (10/33). Ex-1009, Figs. 1-3, 6:14-17. A POSA would appreciate that this position of the hub/fitting (20/72/40) enables the hub/fitting to perform its dual function of receiving the RF

probe (22/52) and connecting the needle (10/33) to a fluid source. Ex-1033, ¶202. Thus, a POSA would understand that the hub/fitting (20/42/70) will necessarily be in a more proximal position than other components of Racz's modified device (e.g., the actuator). Ex-1033, ¶202. Thus, Racz's modified device includes:

- "the fitting is at a proximal end of the needle such that the actuator is positioned distally relative to a proximal end of the fitting" **[30];**
- "the Luer fitting is at a proximal-most position at a proximal end of the needle" **[32];** and

Accordingly, Claims 18-25, 27, and 29-33 are each obvious in view of Racz, Fitz, and Lee. Ex-1033, ¶203.

E. Ground A: Claims 26, 28, and 34

Lee discloses that its filaments (22/1622) are each "springy wire-like member" and "made of … a springy nickel titanium alloy" (i.e., Nitinol). Ex-1010, ¶0092, 0087. The filaments (22/1622) are illustrated as solid members and function exclusively as "electrically conductive stylets for applying RF energy." Ex-1010, ¶0092, Figs. 1, 5, 23-25, 48, 49. Lee makes no mention of the filaments (22/1622) either having a lumen or transporting fluid therethrough. Thus, "each filament of the plurality of filaments [22/1622] is devoid of any lumen therethrough for the transportation of fluid" **[26a]**. Ex-1033, ¶204.

As discussed above with respect to **[1h]** and **[18-25]**, fluid injected via Racz's hub (20/42/70) passes through the internal lumen of the needle's shaft

(12/34) and out of the tip's opening (46). *Supra* § VI.C.1.e, VI.D. As Lee's filaments (22/1622) define no lumens themselves—and because the filaments (22/1622) would have been positioned in channels defined around the internal lumen (to avoid obstructing the lumen when Racz's RF probe (22/52) is inserted) (*supra* § VI.C.2.a)—fluid injected through the shaft (12/34) would not pass through the filaments (22/1622). Ex-1033, ¶205. Thus, in Racz's modified device, "fluid injected through the needle passes through the lumen at the interior of the elongate member [12/34] and through the tip [14/38] of the needle without passing through an interior of any of the plurality of filaments [22/1622]" **[26b]**. Ex-1033, ¶205.

Racz's modified device would also include the limitations of Claims 28 and 34, which are substantially identical to Claim 26. Accordingly, Claims 26, 28, and 34 are obvious in view of Racz, Fitz, and Lee. Ex-1033, ¶206.

F. Ground A: Claims 35-38

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 metal 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-1033, ¶207. Insulating

Racz's metal 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 in selecting an insulating material (36). Ex-1033, ¶207; 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 metal 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, with the metal tube either defining the tip (14/38) or being in conductive contact with a separate tip secured to the insulating tube). Ex-1033, ¶207; Ex-1010, ¶0091, 0125, 0133; Ex-1015, ¶0043. Applying a POSA's knowledge of the art and routine engineering skills, either configuration would merely be a rearrangement of the existing elements disclosed in Racz—a conductive metal tube (12/34), insulation (36) surrounding the conductive metal tube, and an exposed conductive tip (14/38). Ex-1033, ¶207.

By implementing a separate insulation tube as the insulating portion (36), the separate insulating tube would then comprise an "elongate member" and the metal conductive tube would comprise a "tube that is a separate member relative to the elongate member" with "the tube defining the lumen at the interior of the elongate member" **[35]**. Ex-1033, ¶208. The separate insulating tube (elongate

member) would be fixed to Racz's hub (20/42/70) as the metal tube (12/34) is also secured to the hub (20/42/70) and the insulating material (36) covers the entirety of the metal tube (except for the exposed tip (14/38)). Ex-1009, 3:60-65; Ex-1033, ¶208. The tip (14/38) would also remain "fixed" to the separate insulating tube (elongate member) (e.g., via connection with the metal shaft (12/34), hub (20/42/70), and/or the insulating tube itself). Ex-1033, ¶208.

Additionally, as the "tube" (the shaft 12/34) is metal and defines the cannula's exposed tip (14/38), "the tube [12/34] comprises a conductive material, and wherein the conductive portion of the needle [the tip 14/38] comprises the conductive material of the tube" **[36]**. Ex-1009, 4:60 to 5:1, 5:45-48; Ex-1033, ¶209. As explained for Claims 1, 18-25, 27, and 29-33, the tube (i.e., the metal shaft (12/34)) is: "configured to transport fluid therethrough" (when the RF probe is removed) and "configured to separately conduct therethrough RF energy emitted by the RF probe" (when the RF probe is inserted) **[37]** and also "configured to conduct the RF energy into and through the tip and the plurality of filaments" **[38]**. *Supra* §VI.C.1.e, VI.C.1.f. Thus, Claims 35-38 are each obvious in view of Racz, Fitz, and Lee.

G. Ground A: Claims 39-47 and 53-74

Claims 39-47 and 53-74 are comprised of limitations substantially the same as those discussed above with respect to Claims 1 and 18-38. The following claim

chart shows where the obviousness of each feature in Claims 39-47 and 53-74 is explained above and provides additional detail for certain claims in the interest of clarity. For the reasons identified in the following chart (and discussed above), Claims 39-47 and 53-74 are each obvious in view of Racz, Fitz, and Lee. Ex-1033, ¶210.

	Claim Language	**Analysis**
[39]	39. The system of claim 1, [*same as 35*].	*Supra* § VI.F (**[35]**)
[40]	40. The system of claim 39, [*same as 26*].	*Supra* § VI.E (**[26]**)
[41]	41. The system of claim 39, [*same as 36*].	*Supra* § VI.F (**[36]**)
[42]	42. The system of claim 41, [*substantially the same as 37*].	*Supra* § VI.F (**[37]**)
[43]	43. The system of claim 42, [*same as 38*].	*Supra* § VI.F (**[38]**)
[44]	44. The system of claim 39, wherein the tube is positioned at an interior of the elongate member when the plurality of filaments are in the retracted position.	*Supra* § VI.F (**[35-38]**). The "tube" (shaft (12/34)) is positioned at an interior of the elongate member (separate insulation sheath) when the filaments are retracted and deployed. Ex-1033, ¶210.
[45]	45. The system of claim 39, wherein the tube is in fluid communication with the tip at the distal end of the elongate member	*Supra* § VI.F (**[35-38]**). The "tube" (shaft (12/34)) defines the tip (14/38) and shares a common lumen with the tip. Ex-1009, 4:60 to 5:1, 5:14-

	Claim Language	Analysis
	when the plurality of filaments are in the retracted position.	18, 5:45-48, 5:66-6:8, 6:9-12, 8:54-57, 1:29-33, Abstract. Thus, the "tube" is in fluid communication with the tip (both when the filaments are retracted and deployed). Ex-1033, ¶210.
[46]	46. The system of claim 39, wherein the fluid passes from a fluid source, through the fitting, and through the tube when the fluid source is coupled to the fitting, and wherein the RF probe is separately received within the tube when fluid is not being transported through the tube.	*Supra* § VI.F (**[35-38]**). Fluid is injected through the fitting (20/42/70) and through the lumen of the "tube" (shaft (12/34)) when the RF probe is removed and a fluid source is coupled to the fitting. Ex-1009, 4:60 to 5:1, 5:14-18, 5:45-48, 5:66-6:8, 6:9-12, 8:54-57, 1:29-33, Abstract. This fluid is delivered to a target volume in the patient. *Id*. When the fluid source is not coupled, the RF probe is insertable into the "tube" (shaft (12/34)) to transmit RF energy to the tube's tip (14/38) and thereby to the target volume of the patient. Ex-1033, ¶210.
[47]	47. The system of claim 1, wherein a fluid source is coupled with the fitting and fluid is transported through the lumen to a target volume within the patient when the system is in a first operational state in which the RF probe is fully separated from the needle, such that none of the of the RF probe is within the needle, and wherein the lumen accepts the RF probe for delivery of RF energy to the target volume when the system is in a second operational state in which fluid is not transported through the lumen of the needle.	
[53pre]	53. A system comprising:	*Supra* § VI.C.1.a (**[1pre]**)

	Claim Language	Analysis
[53a]	an RF probe that comprises an electrode; and	*Supra* § VI.C.1.b (**[1a]**). The shaft (54) of Racz's RF probe (22/52) is an "electrode." Ex-1009, 5:26-28 and 41-48; Ex-1033, ¶210.
[53b]	[*same as 1b*]	*Supra* § VI.C.1.b (**[1b]**).
[53c]	[*same as 1c*]	*Supra* § VI.C.1.c (**[1c]**).
[53d]	[*same as 1d*]	*Supra* § VI.C.1.c (**[1d]**).
[53e]	[*same as 1e*]	*Supra* § VI.C.1.d (**[1e]**).
[53f]	[*same as 1f*]	*Supra* § VI.C.2.a (**[1f]**).
[53g]	[*same as 1g*]; and	*Supra* § VI.C.2.b (**[1g]**).
[53h]	[*same as 1h*]	*Supra* § VI.C.1.e (**[1h]**).
[53i]	[*substantially the same as 1i*]	*Supra* § VI.C.1.f (**[1i]**). The probe's shaft (54) physically contacts the tip (14/38), which is the conductive portion of Racz's needle (10/33).
[53j]	[*substantially the same as 1j*]	*Supra* § VI.C.2.a (**[1j]**).
[53k]	[*substantially the same as 1l*]	*Supra* § VI.C.2.b (**[1l]**).
[54]	54. The system of claim 53, wherein the needle further comprises a conductive tube that is a separate member relative to the elongate member, the conductive tube defining the lumen at the interior of the elongate member and further defining the conductive portion of the needle that the electrode of the RF probe physically contacts, wherein, when the RF probe is inserted into the lumen defined by the conductive tube, the conductive tube is configured to conduct RF energy emitted by the RF probe through the conductive	*Supra* § VI.F, VI.G (**[35-38], [44-47]**).

	Claim Language	Analysis
	tube and into and through the tip and the plurality of filaments.	
[55]	55. The system of claim 54, wherein the fitting is configured to provide a connection to a fluid source for said injection of fluid through the fitting and through the lumen when the RF probe is fully separated from the needle in the non-inserted state, such that none of the RF probe is within the needle.	*Supra* § VI.D, VI.D, VI.F, VI.G (**[19], [20a]**, **[35-38], [44-47]**).
[56pre]	56. A system comprising:	*Supra* § VI.C.1.a (**[1pre]**)
[56a]	[*same as 1a*]; and	*Supra* § VI.C.1.b (**[1a]**).
[56b]	[*same as 1b*]	*Supra* § VI.C.1.b (**[1b]**).
[56c]	[*same as 1c*]	*Supra* § VI.C.1.c (**[1c]**).
[56d]	[*same as 1d*]	*Supra* § VI.C.1.c (**[1d]**).
[56e]	[*same as 1e*]	*Supra* § VI.C.1.d (**[1e]**).
[56f]	[*same as 1f*]	*Supra* § VI.C.2.a (**[1f]**).
[56g]	[*same as 1g*], and	*Supra* § VI.C.2.b (**[1g]**).
[56h]	[*same as 1h, but recites "Luer" fitting*]	*Supra* § VI.C.1.e (**[1h]**). Racz's hub/fitting (20/42/70) can be a Luer fitting. Ex-1009, 5:66-6:8.
[56i]	[*same as 1i*]	*Supra* § VI.C.1.f (**[1i]**).
[56j]	[*substantially the same as 1j*]	*Supra* § VI.C.2.a (**[1j], [53a]**).
[56k]	[*same as 1k*].	*Supra* § VI.C.1.d (**[1k]**).
[57]	57. The system of claim 56, [*substantially the same as 20*].	*Supra* § VI.D (**[20a-b]**).
[58]	58. The system of claim 56, [*same as 23 and 24*].	*Supra* § VI.D (**[23-24]**).

	Claim Language	Analysis
[59]	59. The system of claim 56, [*same as 25*].	*Supra* § VI.D (**[25]**).
[60]	60. The system of claim 59, [*substantially the same as 26*].	*Supra* § VI.E (**[26]**).
[61]	61. The system of claim 56, [*substantially the same as 26*].	*Supra* § VI.E (**[26]**).
[62]	62. The system of claim 56, [*same as 30 and 31*].	*Supra* § VI.D (**[30-31]**).
[63]	63. The system of claim 62, [*same as 32*].	*Supra* § VI.D (**[32]**).
[64]	64. The system of claim 56, wherein, when the plurality of filaments are in the retracted position and the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the Luer fitting is configured to connect to the fluid source and to permit fluid from the fluid source to pass through the Luer fitting, through the lumen, and through the tip at the distal end of the needle.	*Supra* § VI.D (**[20, 33]**).
[65]	65. The system of claim 64, [*substantially the same as 26*].	*Supra* § VI.E (**[26]**).
[66]	66. The system of claim 56, [*same as 35 and 39*].	*Supra* § VI.F (**[35]**)

	Claim Language	Analysis
[67]	67. The system of claim 66, [*substantially the same as 26 and 40*].	*Supra* § VI.E (**[26]**)
[68]	68. The system of claim 66, [*same as 36 and 41*].	*Supra* § VI.F (**[36]**)
[69]	69. The system of claim 68, [*substantially the same as 37 and 42*].	*Supra* § VI.F (**[37]**)
[70]	70. The system of claim 69, [*same as 38 and 43*].	*Supra* § VI.F (**[38]**)
[71]	71. The system of claim 66, [*same as 44*].	*Supra* § VI.F, VI.G (**[35-38], [44]**)
[72]	72. The system of claim 66, [*same as 45*].	*Supra* § VI.F, VI.G(**[35-38], [45]**)
[73]	73. The system of claim 66, [*same as 46*].	*Supra* § VI.F, VI.G (**[35-38], [46]**)
[74]	74. The system of claim 56, [*same as 47*].	*Supra* § VI.F, VI.G (**[35-38], [47]**)

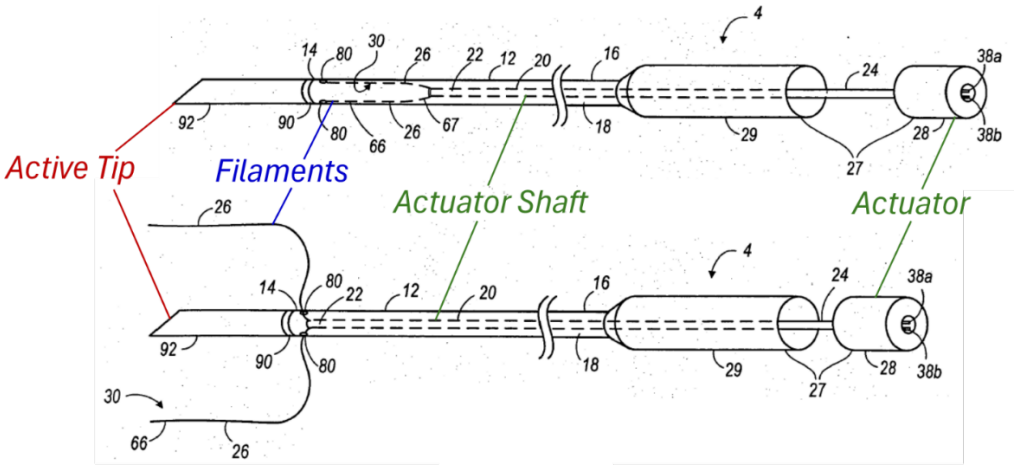
VII. GROUND B: CLAIMS 18-47 AND 53-74 ARE OBVIOUS IN VIEW OF RACZ, FITZ, LEE, AND YOUNG '965

A. Overview of Young '965

Young '965 discloses a "tissue ablation system" having "a probe assembly 4 configured for … ablative treatment of target tissue, and a radio frequency (RF) generator 6 configured for supplying RF energy to the probe assembly 4." Ex-

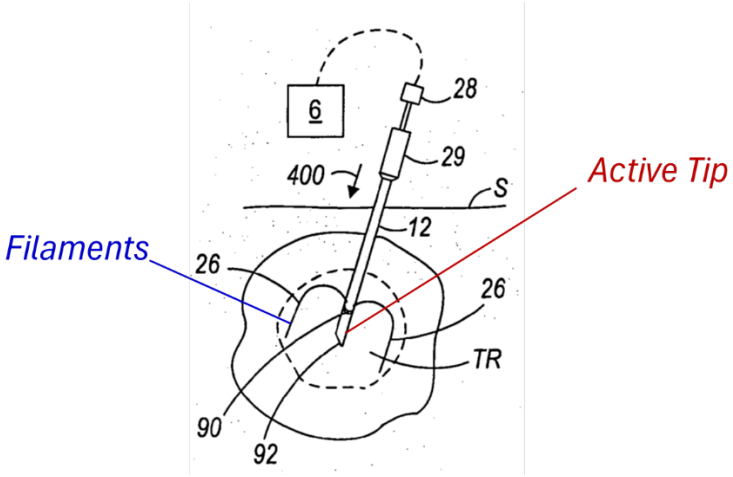
1012, ¶0022. Thus, Young '965 is directed to the same field as the '688 Patent. *See* Ex-1002, 1:16-20; Ex-1033, ¶211.

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-1033, ¶212.



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-1033, ¶213-214.



Young '965 – Fig. 7C (annotated)

B. Ground B: Claims 1, 53, and 56

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-1033, ¶215-216. 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 RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode" **[1j]**. Ex-1033, ¶216.

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) would be easily adapted to deploy and retract Lee’s filaments (22/1622) from Racz’s device (e.g., the shaft (20) hollowed and dimensioned to accommodate Racz’s RF probe (22/52)). Ex-1033, ¶217. Thus, a POSA would have been further motivated by Young ’965 to modify Racz’s device to include “an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member” **[1g]** and “wherein, when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position” **[1l]**. Ex-1033, ¶217.

Young ’965’s filaments (26) are as small as 0.2mm (wide) and 0.05mm (thick). Ex-1012, ¶0030. By comparison, Racz’s 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-1033, ¶218. Thus, Young '965 would have confirmed to a POSA that Lee's filaments (22/1622) would be implemented in sizes as small as 0.2mm wide and easily implemented into Racz's cannula (10/33). Ex-1033, ¶218.

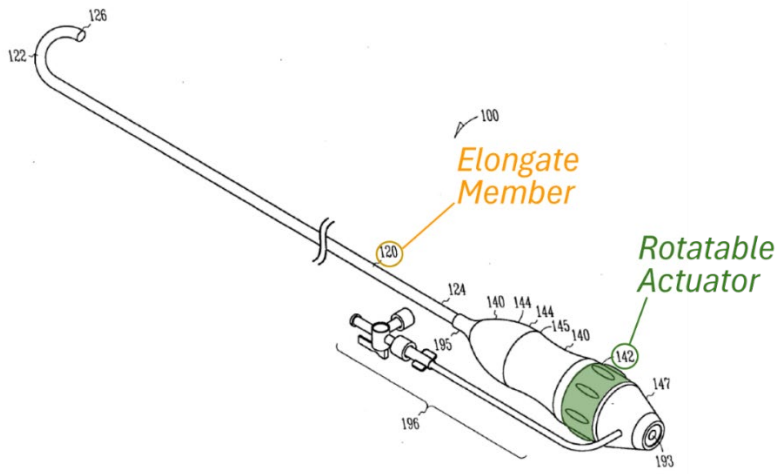
Thus, Claims 18-47 (which depend from Claim 1) are therefore further obvious in view of Racz, Fitz, Lee, and Young '965 (Ground B). Ex-1033, ¶219. Additionally, as noted above, Claims 53 and 56 are comprised of limitations substantially the same as Claim 1. *Supra* § VI.G. Thus, for the reasons explained above, Claim 53 (and dependent Claims 54-55) and Claim 56 (and dependent Claims 57-74) are also obvious in view of Racz, Fitz, Lee, and Young '965 (Ground B).

VIII. GROUNDS C AND D: CLAIMS 18-47 AND 53-74 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 analogous to the '688 patent. *Id*.; Ex-1033, ¶220.

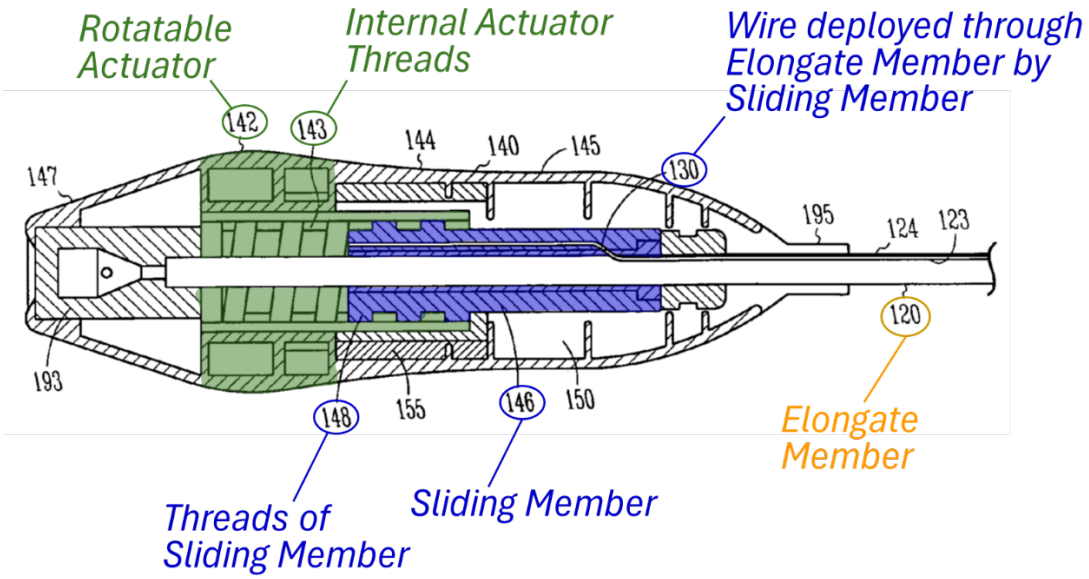
Scheibe's actuator (142) is shown in a deflectable catheter (or sheath), which includes an elongate, deflectable body (120), a handle assembly (140), and a pullwire (130). Ex-1013, ¶0016, Fig. 1. The device's pullwire (130) extends "through a lumen" of the body (120) and "translates longitudinally through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



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; Ex-1033, ¶221-222. The rotatable actuator (142) includes internal threads (143) that engage outer threads (148) of a sliding member (146) (**shaded blue**). Ex-1013, ¶0021-0022 Ex-1033, ¶221-222. When the actuator (142) is rotated, the sliding member (146) moves linearly (without rotating) within the device's housing (144) 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.



Scheibe – Fig. 2 (annotated)

B. Ground C: Claims 1, 53, and 56

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). Ex-1033, Ex-1033, ¶223. As Scheibe's pullwire (130) is secured to its sliding member (146), a POSA would have appreciated that proximal ends of Lee's filaments (22/1622) are securable to the sliding member (146) in the same manner. Ex-1013, ¶0018-0019, 0035; Ex-1033, ¶223. Because Scheibe's pullwire (130) is moved through its elongate body (120), a POSA also would have appreciated that the rotatable actuator (142) would retract and deploy Lee's filaments (22/1622)

through Racz's shaft (12/34). Ex-1033, ¶223. Moreover, Scheibe's actuator (142)—by rotating—would move in first/second directions relative to Racz's hub (20/42/70) to deploy and withdraw the filaments (22/1622). Ex-1033, ¶223. As the sliding member (146) does not rotate, rotation of the actuator (142) would also not twist the filaments (22/1622). Ex-1033, ¶223.

A POSA would also have appreciated that Scheibe's rotatable actuator (142) and sliding member (146) are adapted to avoid interference with the lumen of the elongate body (120), thereby enabling them 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-1033, ¶224. Indeed, Scheibe's disclosure of a Luer fitting provided at the distal end of its device confirms that the actuator (142) and sliding member (146) would not obstruct the elongate body (120). Ex-1013, ¶0031. Moreover, Scheibe teachings are not limited to catheters and apply to "other types of body stimulating systems," such as RF needles. Ex-1013, ¶0037; Ex-1033, ¶224. By avoiding interference with the internal lumen of the shaft (12/34), Scheibe's actuator would enable deployment and withdrawal of Lee's filaments (22/1622) regardless of whether the probe (22/52) is inserted. Ex-1033, ¶224-225.

A POSA would have easily implemented Scheibe's actuator (142) and sliding member (146) into Racz's modified device. Ex-1033, ¶226. As one

example, a POSA would have recognized that Racz's hub (20/42/70) can be replaced with Scheibe's handle assembly (140). Ex-1033, ¶226. Scheibe's handle assembly (140) provides a hub for Racz's shaft (12/34). Ex-1013, ¶0019-0020, Fig. 1. Additionally, like Racz's hub (20/42/70), Scheibe's handle assembly (140) includes a "luer fitting [that] allows a variety of external components with a mating luer fitting to be attached to the proximal end of the [assembly]" and "allows other devices to be passed into and through the passage of the [device]." Ex-1013, ¶0031; Ex-1009, 5:66 to 6:7. Thus, Scheibe's handle assembly (140) could be implemented into Racz's device without impacting the functionality of Racz's probe (22/52) or fluid delivery. Ex-1033, ¶226.

Accordingly, a POSA would have recognized that Scheibe's rotating actuator (142) and sliding member (146) would be a suitable filament actuator to implement into Racz's device. Ex-1010, ¶0106; Ex-1033, ¶227. Thus, in combination with Racz, Fitz, and Lee, Scheibe would have further motivated a POSA to implement "an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member" **[1g]** and "wherein,

when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position" **[1l]**. Ex-1033, 227-228.

Accordingly, Claims 18-47 (which depend from Claim 1) are further obvious in view of Racz, Fitz, Lee, and Scheibe (Ground C). Additionally, as noted above, Claims 53 and 56 are comprised of limitations substantially the same as Claim 1. *Supra* § VI.G. Thus, for the reasons explained above for Claim 1, Claim 53 (and dependent Claims 54-55) and Claim 56 (and dependent Claims 57-74) are also obvious in view of Racz, Fitz, Lee, and Scheibe (Ground C).

C. Ground C: Claims 30 and 62

Implementing Scheibe's actuator (142) as explained for Claim 1 would have resulted in the actuator (142) being "positioned distally relative to a proximal end of the fitting [20/42/70]" as Racz's hub/fitting (20/42/70) would remain "at a proximal end of the needle" **[30]**. Ex-1033, ¶229. Indeed, Scheibe's own Luer fitting is positioned at a proximal end relative to the actuator (142) (which is at a more distal position). Ex-1013, 0031, Fig. 1. Thus, Claim 30 and Claim 62 (which includes substantially the same limitation as Claim 30) are further obvious in view of Racz, Fitz, Lee, and Scheibe (Ground C).

D. Ground D

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-1033, ¶230. 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-1033, ¶230. Furthermore, as discussed above in Ground B, Young '965 provides supporting disclosure for additional features in Claims 1, 53, and 56. *Supra* § VII.B. Thus, Claims 18-47 and 53-74 are further obvious in view of Racz, Fitz, Lee, Young '965, and Scheibe (Ground D).

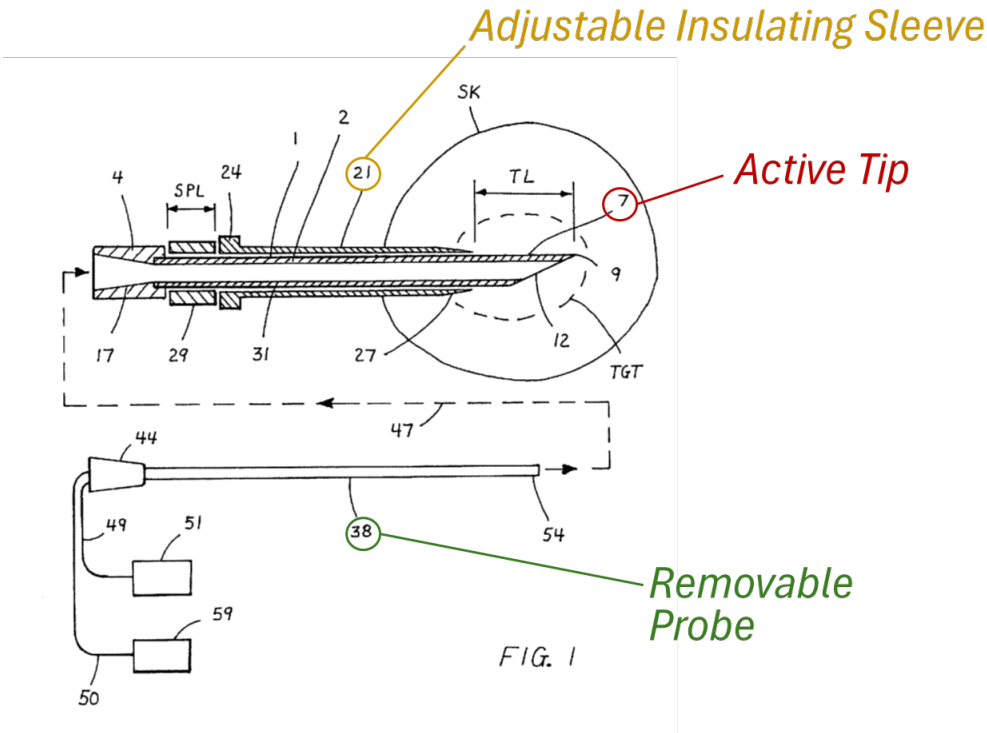
IX. GROUNDS E-H: CLAIMS 35-46, 54-55, AND 66-73 ARE OBVIOUS IN VIEW OF COSMAN '542 (COMBINED WITH THE GROUNDS A-D REFERENCES)

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 '688 Patent. *See* Ex-1002, 1:16-20. Ex-1033, ¶231.

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'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-1033, ¶232.



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-1033, ¶233.

B. Grounds E-H: Claims 35-46, 54-55, and 66-73

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 disclosed 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-1033, ¶234. 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) as the insulation (36) would be one way to achieve this. Ex-1033, VI.F. For example, Cosman '542 discloses that its 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. Ex-1033, ¶234.

By implementing Cosman 542's insulative sleeve as the insulating portion (36), the insulative sleeve would then comprise an "elongate member" and Racz's metal conductive tube would comprise a "tube that is a separate member relative to the elongate member" with "the tube defining the lumen at the interior of the elongate member" **[35]**. Ex-1033, ¶235. Cosman 542's insulative sleeve (elongate member) would be fixed to Racz's hub (20/42/70) (e.g., via threaded engagement). Ex-1009, 3:60-65; Ex-1014, 7:37-8:18, Fig. 2; Ex-1033, ¶235. The tip (14/38)

would also remain "fixed" to Cosman '542's insulative sleeve (elongate member) as it is integral with the shaft (12/34) and the insulative sleeve both surrounds the shaft (12/34) and is also secured to Racz's hub (20/42/70). Ex-1033, ¶235.

Additionally, as the "tube" (the shaft 12/34) is metal and defines the cannula's exposed tip (14/38), "the tube [12/34] comprises a conductive material, and wherein the conductive portion of the needle [the tip 14/38] comprises the conductive material of the tube" **[36]**. Ex-1009, 4:60 to 5:1, 5:45-48; Ex-1033, ¶236. As explained for Claims 1, 18-25, 27, and 29-33, the tube (i.e., the metal shaft (12/34)) is: "configured to transport fluid therethrough" (when the RF probe is removed) and "configured to separately conduct therethrough RF energy emitted by the RF probe" (when the RF probe is inserted) **[37]** and also "configured to conduct the RF energy into and through the tip and the plurality of filaments" **[38]**. *Supra* §VI.C, VI.D.

Claims 39-46, 54-55, and 66-73 are comprised of limitations disclosed by the combination of Racz, Fitz, Lee, and Cosman '542 (Ground E) for the reasons discussed above with respect to Claims 35-38 and those discussed above in Ground A. *Supra* § VI; Ex-1033, ¶237. For at least these reasons, Claims 35-46, 54-55, and 66-73 are each further obvious in view of Racz, Fitz, Lee, and Cosman '542 (Ground E). For the same reasons, Claims 35-46, 54-55, and 66-73 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).

X. CONCLUSION

For at least the foregoing reasons, Petitioner requests that the Board institute an *Inter Partes* Review and cancel Claims 18-47 and 53-74 of the ’688 Patent.

Respectfully submitted,

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

XI. 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.

XII. CLAIMS LISTING

Claim Element	Challenged Claims
[1pre]	A system comprising:
[1a]	an RF probe; and
[1b]	a needle for insertion into a patient during an RF ablation procedure, the needle comprising:
[1c]	a hub;
[1d]	an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof;
[1e]	a tip fixed to the elongate member at a distal end of the needle, wherein the tip is shaped to pierce tissue of the patient;
[1f]	a plurality of filaments;
[1g]	an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member; and
[1h]	a fitting in fluid communication with the lumen, the fitting being configured to provide a connection for injection of fluid through the fitting and through the lumen, the fitting further being configured to allow for insertion of the RF probe into the lumen through the fitting,
[1i]	wherein the lumen at the interior of the elongate member is configured to accept the RF probe therein to physically contact a conductive portion of the needle and
[1j]	thereby electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments, and such that the RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode,
[1k]	wherein the conductive portion of the needle is at a distal end of the needle, and
[1l]	wherein, when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the

Claim Element	Challenged Claims
	needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position.
[18]	18. The system of claim 1, wherein the fitting is configured to be coupled to a fluid source and the lumen is configured to conduct fluid from the fluid source when the RF probe is not positioned within the needle.
[19]	19. The system of claim 1, wherein the fitting is configured to provide a connection to a fluid source for said injection of fluid through the fitting and through the lumen.
[20a]	20. The system of claim 19, wherein the fitting comprises a Luer fitting configured to be connected with the fluid source when the RF probe is fully separated from the needle, such that none of the RF probe is within the needle,
[20b]	the Luer fitting further being configured to separately permit the RF probe to be inserted into the lumen through the Luer fitting when the Luer fitting is not connected with the fluid source
[21]	21. The system of claim 19, wherein the fitting is configured to be connected with the fluid source and to permit fluid to pass through the fitting and through the lumen when the RF probe is not present within the lumen.
[22]	22. The system of claim 21, and wherein the fitting is further configured to permit the RF probe to be inserted into the lumen through the fitting when the fitting is not connected with the fluid source.
[23]	23. The system of claim 19, wherein the fitting is configured to accept a connector of the fluid source.
[24]	24. The system of claim 23, wherein the fitting comprises a Luer fitting and the connector of the fluid source comprises a Luer fitting.

Claim Element	Challenged Claims
[25]	25. The system of claim 19, wherein the lumen is configured to deliver fluid through the tip at the distal end of the needle.
[26a]	26. The system of claim 25, wherein each filament of the plurality of filaments is devoid of any lumen therethrough for the transportation of fluid, and
[26b]	wherein fluid injected through the needle passes through the lumen at the interior of the elongate member and through the tip of the needle without passing through an interior of any of the plurality of filaments.
[27]	27. The system of claim 1, wherein the lumen is configured to deliver fluid through the tip at the distal end of the needle.
[28a]	28. The system of claim 1, wherein each filament of the plurality of filaments is devoid of any lumen therethrough for the transportation of fluid, and
[28b]	wherein fluid injected through the needle passes through the lumen at the interior of the elongate member and through the tip at the distal end of the needle without passing through an interior of any of the plurality of filaments.
[29]	29. The system of claim 1, wherein the fitting is configured to provide the connection for the injection of fluid through the fitting separately from allowing for insertion of the RF probe into the lumen through the fitting.
[30]	30. The system of claim 1, wherein the fitting is at a proximal end of the needle such that the actuator is positioned distally relative to a proximal end of the fitting.
[31]	31. The system of claim 1, wherein the fitting comprises a Luer fitting.
[32]	32. The system of claim 31, wherein the Luer fitting is at a proximal-most position at a proximal end of the needle.

Claim Element	Challenged Claims
[33]	33. The system of claim 1, wherein, when the plurality of filaments are in the retracted position, the fitting is configured to connect to a fluid source and to permit fluid from the fluid source to pass through the fitting, through the lumen, and through the tip at the distal end of the needle.
[34a]	34. The system of claim 33, wherein each filament of the plurality of filaments is devoid of any lumen therethrough for the transportation of fluid, and
[34b]	wherein fluid injected through the needle passes through the lumen at the interior of the elongate member and through the tip at the distal end of the needle without passing through an interior of any of the plurality of filaments.
[35]	35. The system of claim 33, further comprising tube that is a separate member relative to the elongate member, the tube defining the lumen at the interior of the elongate member.
[36]	36. The system of claim 35, wherein the tube comprises a conductive material, and wherein the conductive portion of the needle comprises the conductive material of the tube.
[37]	37. The system of claim 36, wherein the tube is configured to transport fluid therethrough, and wherein the tube is further configured to separately conduct therethrough RF energy emitted by the RF probe.
[38]	38. The system of claim 37, wherein the tube is further configured to conduct the RF energy into and through the tip and the plurality of filaments.
[39]	39. The system of claim 1, further comprising a tube that is a separate member relative to the elongate member, the tube defining the lumen at the interior of the elongate member.

Claim Element	Challenged Claims
[40]	40. The system of claim 39, wherein each filament of the plurality of filaments is devoid of any lumen therethrough for the transportation of fluid, and wherein fluid injected through the needle passes through the lumen defined by the tube and through the tip at the distal end of the needle without passing through an interior of any of the plurality of filaments.
[41]	41. The system of claim 39, wherein the tube comprises a conductive material, and wherein the conductive portion of the needle comprises the conductive material of the tube.
[42]	42. The system of claim 41, wherein the tube is configured to transport fluid therethrough when the RF probe is absent from the lumen, and wherein the tube is further configured to separately conduct therethrough RF energy emitted by the RF probe when the RF probe is present within the lumen.
[43]	43. The system of claim 42, wherein the tube is further configured to conduct the RF energy into and through the tip and the plurality of filaments.
[44]	44. The system of claim 39, wherein the tube is positioned at an interior of the elongate member when the plurality of filaments are in the retracted position.
[45]	45. The system of claim 39, wherein the tube is in fluid communication with the tip at the distal end of the elongate member when the plurality of filaments are in the retracted position.
[46]	46. The system of claim 39, wherein the fluid passes from a fluid source, through the fitting, and through the tube when the fluid source is coupled to the fitting, and wherein the RF probe is separately received within the tube when fluid is not being transported through the tube.
[47]	47. The system of claim 1, wherein a fluid source is coupled with the fitting and fluid is transported through the lumen to a target

Claim Element	Challenged Claims
	volume within the patient when the system is in a first operational state in which the RF probe is fully separated from the needle, such that none of the of the RF probe is within the needle, and wherein the lumen accepts the RF probe for delivery of RF energy to the target volume when the system is in a second operational state in which fluid is not transported through the lumen of the needle.
[53pre]	53. A system comprising:
[53a]	an RF probe that comprises an electrode; and
[53b]	a needle for insertion into a patient during an RF ablation procedure, the needle comprising:
[53c]	a hub;
[53d]	an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof;
[53e]	a tip fixed to the elongate member at a distal end of the needle, wherein the tip is shaped to pierce tissue of the patient;
[53f]	a plurality of filaments;
[53g]	an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position that extends distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member; and
[53h]	a fitting in fluid communication with the lumen, the fitting being configured to provide a connection for injection of fluid through the fitting and through the lumen, the fitting further being configured to allow for insertion of the RF probe into the lumen through the fitting,
[53i]	wherein the lumen is configured to accept the RF probe therein such that the electrode of the RF probe physically contacts a conductive portion of the needle and
[53j]	thereby electrically connects the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments, and such that

Claim Element	Challenged Claims
	the electrode of the inserted RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode, and
[53k]	wherein when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments of the needle are positionable in the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member.
[54]	54. The system of claim 53, wherein the needle further comprises a conductive tube that is a separate member relative to the elongate member, the conductive tube defining the lumen at the interior of the elongate member and further defining the conductive portion of the needle that the electrode of the RF probe physically contacts, wherein, when the RF probe is inserted into the lumen defined by the conductive tube, the conductive tube is configured to conduct RF energy emitted by the RF probe through the conductive tube and into and through the tip and the plurality of filaments.
[55]	55. The system of claim 54, wherein the fitting is configured to provide a connection to a fluid source for said injection of fluid through the fitting and through the lumen when the RF probe is fully separated from the needle in the non-inserted state, such that none of the RF probe is within the needle.
[56pre]	56. A system comprising:
[56a]	an RF probe; and
[56b]	a needle for insertion into a patient, the needle comprising:
[56c]	a hub;
[56d]	an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof;
[56e]	a tip fixed to the elongate member at a distal end of the needle, wherein the tip is shaped to pierce tissue of the patient;
[56f]	a plurality of filaments;
[56g]	an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the

Claim Element	Challenged Claims
	actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member; and
[56h]	a Luer fitting in fluid communication with the lumen, the Luer fitting being configured to provide a connection to a fluid source for injection of fluid through the Luer fitting and through the lumen, the Luer fitting further being configured to allow for insertion of an RF probe into the lumen through the Luer fitting,
[56i]	wherein the lumen at the interior of the elongate member is configured to accept the RF probe therein to physically contact a conductive portion of the needle and
[56j]	thereby electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments, and such that an electrode of the inserted RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode;
[56k]	wherein the conductive portion of the needle is at a distal end of the needle.
[57]	57. The system of claim 56, wherein the Luer fitting is configured to be connected with the fluid source when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, and wherein the Luer fitting is further configured to separately permit the RF probe to be inserted into the lumen through the Luer fitting when the Luer fitting is not connected with the fluid source.
[58]	58. The system of claim 56, wherein the Luer fitting is configured to accept a Luer connector of the fluid source.
[59]	59. The system of claim 56, wherein the lumen is configured to deliver fluid through the tip at the distal end of the needle.
[60]	60. The system of claim 59, wherein each filament of the plurality of filaments is devoid of any lumen therethrough for the transportation of fluid, and wherein fluid injected through the needle

Claim Element	Challenged Claims
	passes through the lumen at the interior of the elongate member and through the tip without passing through an interior of any of the plurality of filaments.
[61]	61. The system of claim 56, wherein each filament of the plurality of filaments is devoid of any lumen therethrough for the transportation of fluid, and wherein fluid injected through the needle passes through the lumen at the interior of the elongate member and through the tip at the distal end of the needle without passing through an interior of any of the plurality of filaments.
[62]	62. The system of claim 56, wherein the Luer fitting is at a proximal end of the needle such that the actuator is positioned distally relative to a proximal end of the Luer fitting.
[63]	63. The system of claim 62, wherein the Luer fitting is at a proximal-most position at the proximal end of the needle.
[64]	64. The system of claim 56, wherein, when the plurality of filaments are in the retracted position and the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the Luer fitting is configured to connect to the fluid source and to permit fluid from the fluid source to pass through the Luer fitting, through the lumen, and through the tip at the distal end of the needle.
[65]	65. The system of claim 64, wherein each filament of the plurality of filaments is devoid of any lumen therethrough for the transportation of fluid, and wherein fluid injected through the needle passes through the lumen at the interior of the elongate member and through the tip at the distal end of the needle without passing through an interior of any of the plurality of filaments.
[66]	66. The system of claim 56, further comprising a tube that is a separate member relative to the elongate member, the tube defining the lumen at the interior of the elongate member.

Claim Element	Challenged Claims
[67]	67. The system of claim 66, wherein each filament of the plurality of filaments is devoid of any lumen therethrough for the transportation of fluid, and wherein fluid injected through the needle passes through the lumen defined by the tube and through the tip at the distal end of the needle without passing through an interior of any of the plurality of filaments.
[68]	68. The system of claim 66, wherein the tube comprises a conductive material, and wherein the conductive portion of the needle comprises the conductive material of the tube.
[69]	69. The system of claim 68, wherein the tube is configured to transport fluid therethrough, and wherein the tube is further configured to conduct therethrough RF energy emitted by the RF probe.
[70]	70. The system of claim 69, wherein the tube is further configured to conduct the RF energy into and through the tip and the plurality of filaments.
[71]	71. The system of claim 66, wherein the tube is positioned at an interior of the elongate member when the plurality of filaments are in the retracted position.
[72]	72. The system of claim 66, wherein the tube is in fluid communication with the tip at the distal end of the elongate member when the plurality of filaments are in the retracted position.
[73]	73. The system of claim 66, wherein the fluid passes from the fluid source, through the Luer fitting, and through the tube when the fluid source is coupled to the Luer fitting, and wherein the RF probe is separately received within the tube when fluid is not being transported through the tube.
[74]	74. The system of claim 56, wherein the fluid source is coupled with the Luer fitting and fluid is transported through the lumen to a target volume within the patient when the system is in a first operational

Claim Element	Challenged Claims
	state in which the RF probe is fully separated from the needle, such that none of the of the RF probe is within the needle, and wherein the lumen accepts the RF probe for delivery of RF energy to the target volume when the system is in a second operational state in which fluid is not transported through the lumen 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 13,466 words, excluding the portions as permitted by § 42.24(a).

/Christopher 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. 10,736,688, the associated Power of Attorney, and Exhibits 1001-1030 and 1033 and 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. 10,736,688:

Daniel Higgs
MED VENTURE MANAGEMENT, LLC
299 S. MAIN STREET
SUITE 2300
SALT LAKE CITY, UT 84111

/Felice M. Ernst/
Felice M. Ernst, Paralegal
Meunier Carlin & Curfman LLC
999 Peachtree St, NE
Suite 1300
Atlanta, GA 30309