

Avanos Med., Inc. v. Stratus Med., LLC

IPR2024-01209 – U.S. Pat. 10,966,782

IPR2024-01210 – U.S. Pat. 10,736,688

IPR2024-01211 – U.S. Pat. 10,736,688

IPR2024-01212 – U.S. Pat. 10,925,664

Stratus's Demonstrative Exhibits

Oral Argument

USPTO, Alexandria, VA

November 6, 2025

Agenda

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- **Background** [slides 4-8]
- **Challenges** [slides 9-32]
- **Field of the Invention** [slide 33]
- **Definition of a Person of Ordinary Skill in the Art (POSITA)** [slides 34-36]
- **Non-Analogous Art** [slide 37]
- **Inadequate Motivation to Combine** [slide 38]
- **Teachings Away** [slides 39-45]
 - Racz's teaching away from flimsy filaments
 - Racz's teaching away from a straight tip
 - Lee's teaching of anchors
- **No Reasonable Expectation of Success** [slides 46-56, 61]

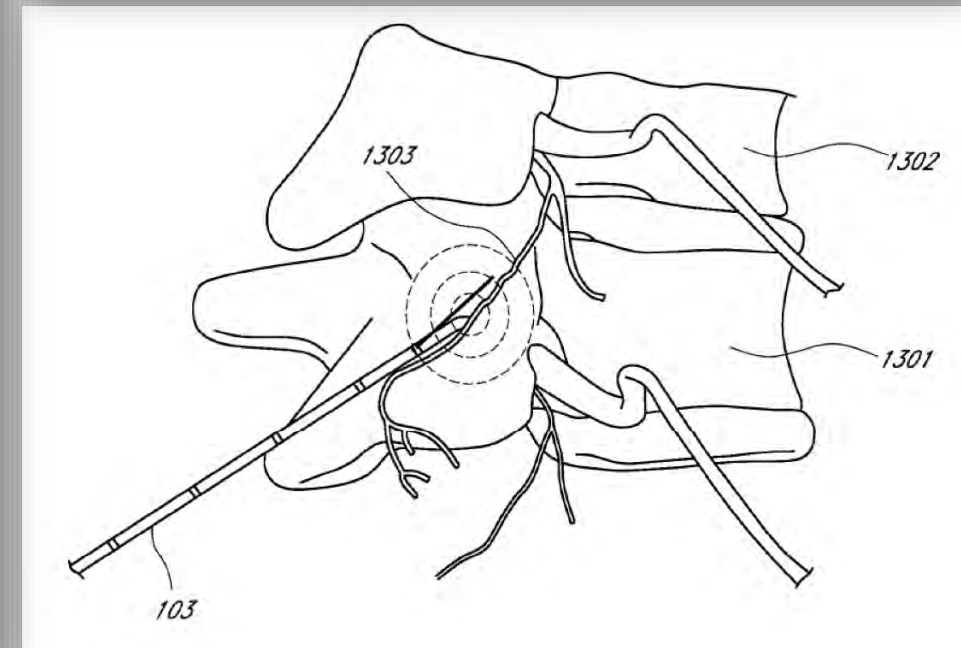
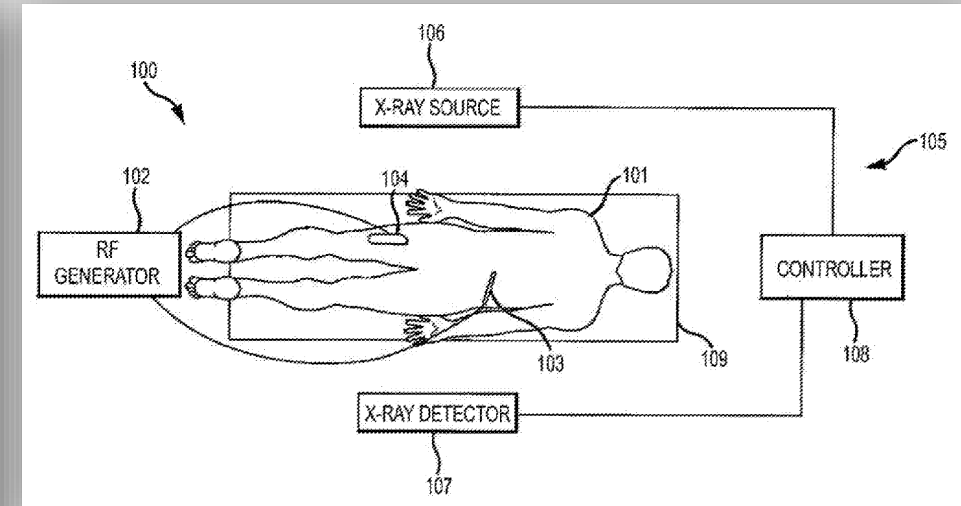
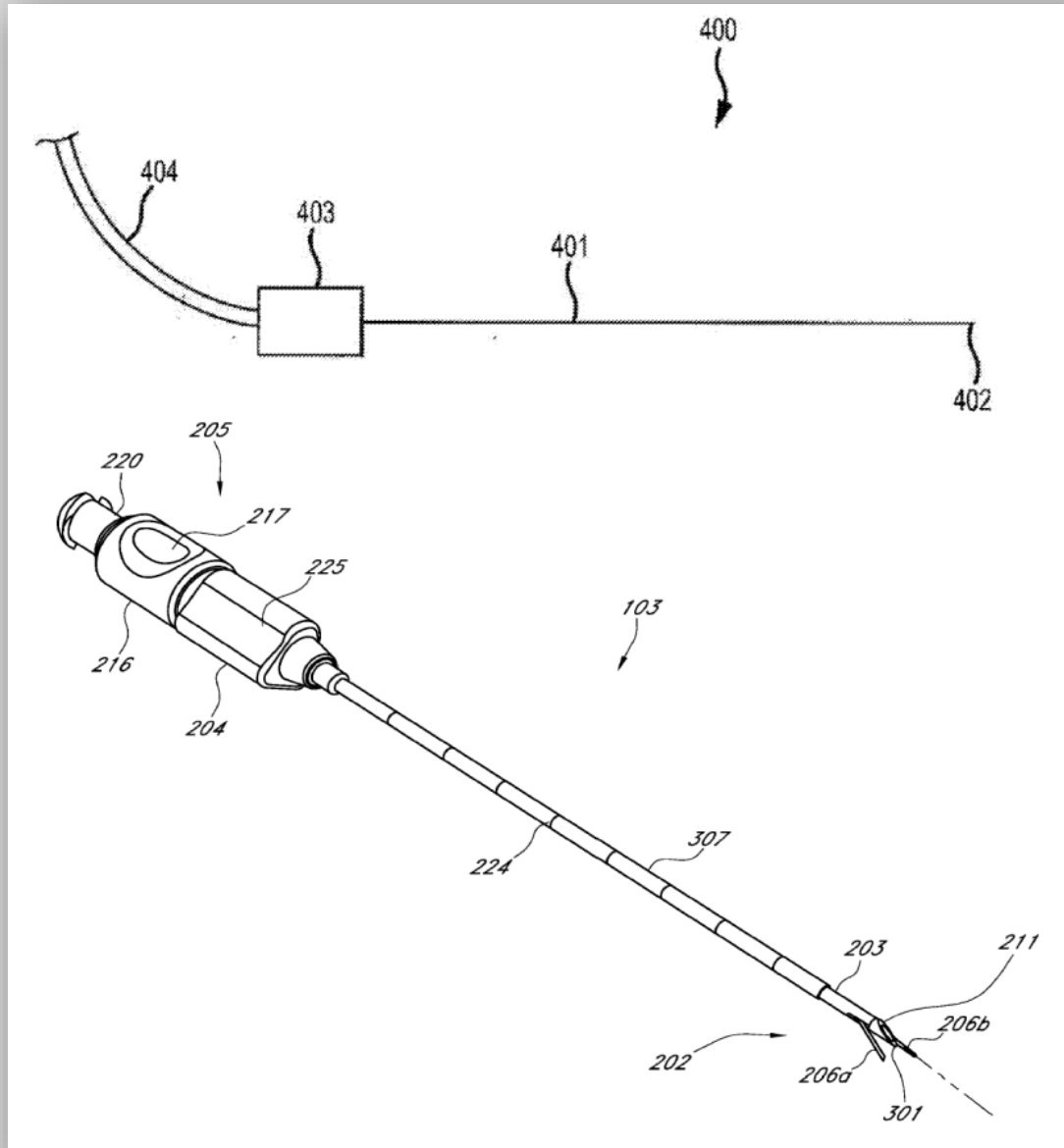
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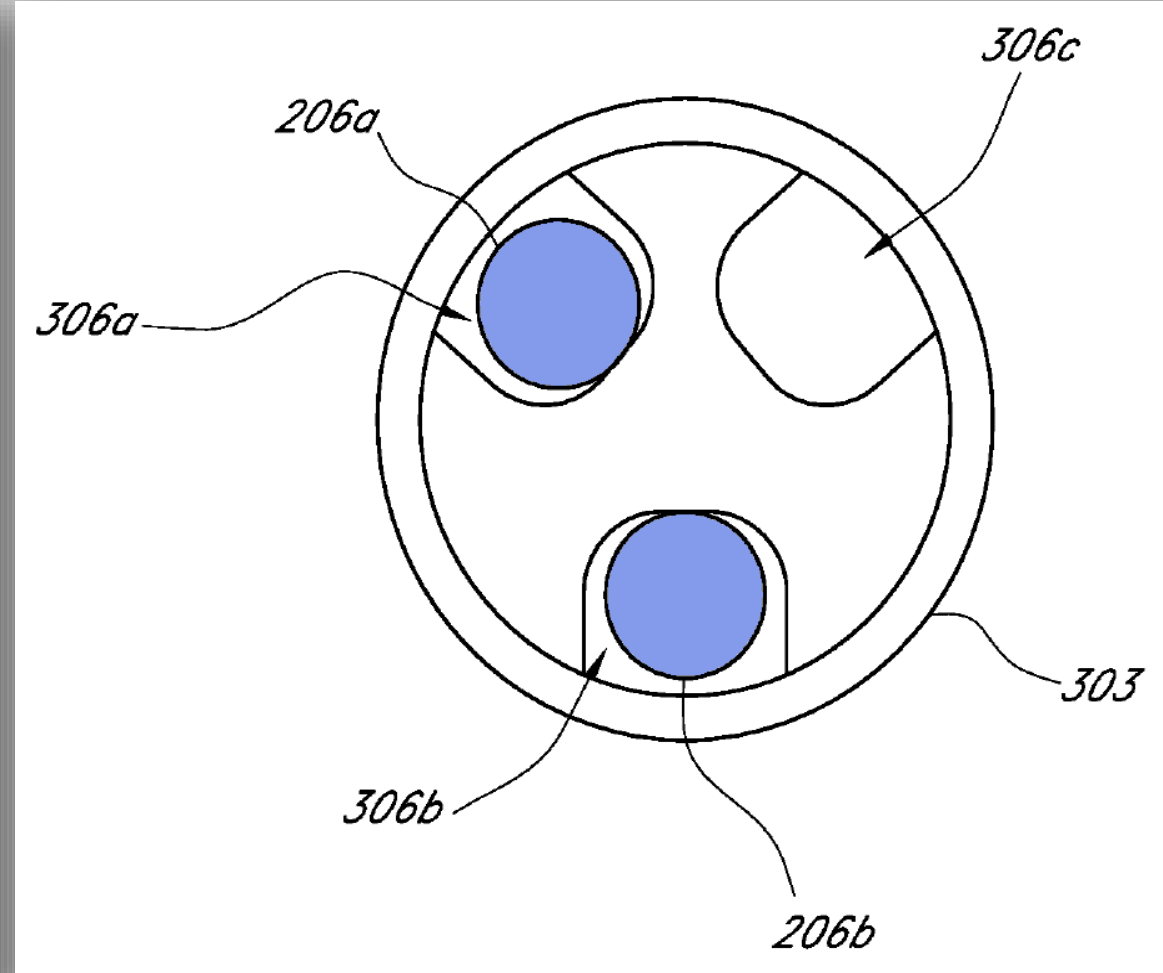
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- **New Surreply Evidence (Exs. 2044 and 2045)** [slides 57-59]
- **Stratus's Motion to Exclude Ex. 1063** [slide 60]
- **The Prior Art is Not Enabling** [slide 62]
- **Problems with Young '965** [slide 63]
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- **Objective Indicia of Nonobviousness** [slide 65-73]
 - Long-Felt Need
 - Copying
 - Praise
 - Commercial Success
- **Petitioner's Motion to Exclude** [slide 74]
- **Document Key** [slide 75]

Background – Stratus Patents

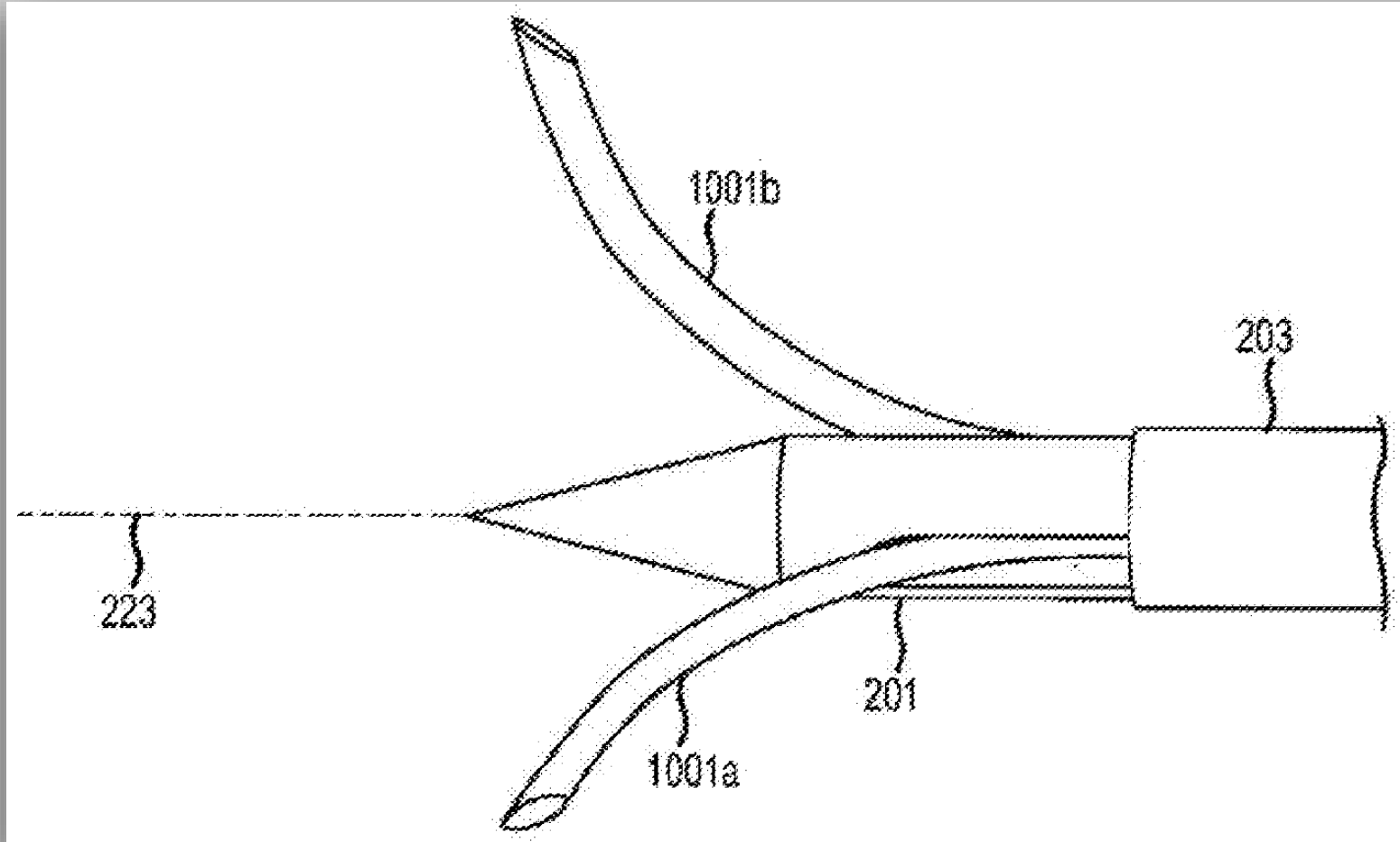
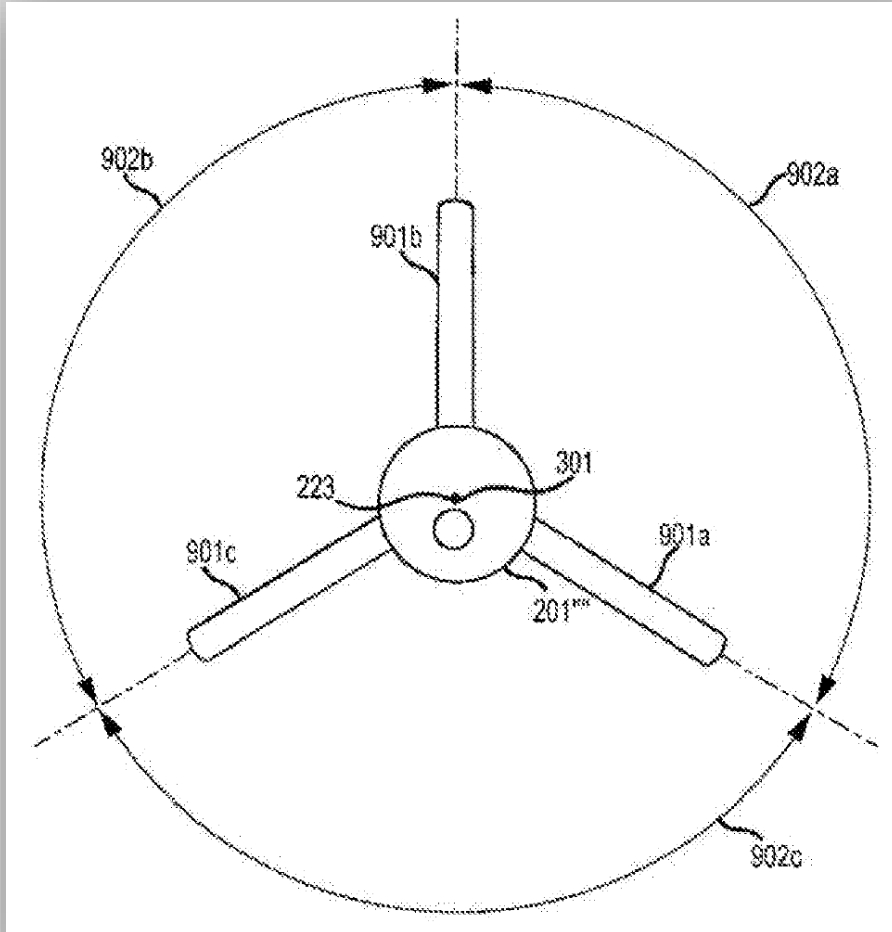
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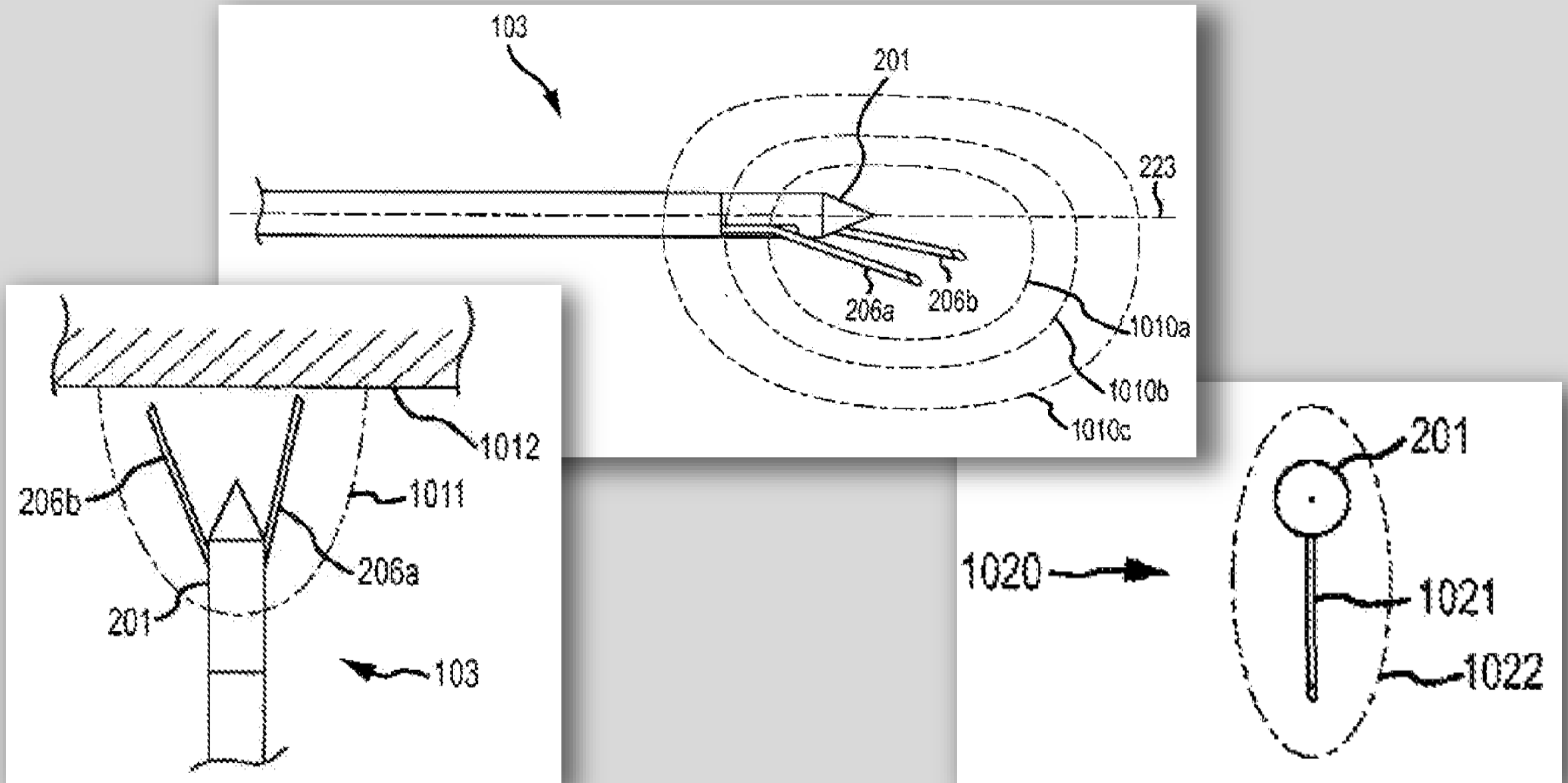
Background – Stratus Patents

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Background – Stratus Patents

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Background – Representative Claim

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1. A system comprising:
 - a radiofrequency probe; and
 - a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:
 - a conductive portion at a distal end of the radiofrequency neurotomy needle;
 - a tip configured to pierce tissue of a patient;
 - an elongate member comprising a lumen configured to accept the radiofrequency probe therein such that the radiofrequency probe physically contacts and is electrically connected to the conductive portion, the tip being at a distal end of the elongate member;
 - a filament electrically connected to the conductive portion and the tip due to physical contact of conductive materials at the distal end of the radiofrequency neurotomy needle such that the filament and the tip operate together as a single electrode, the filament being movable between a retracted position, in which the filament is at least partially in the elongate member, and a deployed position, in which at least a portion of the filament is out of the elongate member; and
 - an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,
- wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle.

Single Base Combination of References for ALL Challenged Claims

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-01209

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

-01212

	Claims	Statute	Prior Art
A	1-10, 18-26, 28-29	§ 103(a)	Racz, Fitz, and Lee
B	1-10, 18-26, 28-29	§ 103(a)	Racz, Fitz, Lee, and Young '965
C	1-10, 18-26, 28-29	§ 103(a)	Racz, Fitz, Lee, and Scheibe
D	1-10, 18-26, 28-29	§ 103(a)	Racz, Fitz, Lee, Scheibe, and Young '965
E	11-17, 19, 27, and 29	§ 103(a)	Racz, Fitz, Lee, and Godara
F	11-17, 19, 27, and 29	§ 103(a)	Racz, Fitz, Lee, Godara, and Young '965
G	11-17, 19, 27, and 29	§ 103(a)	Racz, Fitz, Lee, Godara, and Scheibe
H	11-17, 19, 27, and 29	§ 103(a)	Racz, Fitz, Lee, Godara, Young '965, and Scheibe
I	18 and 28	§ 103(a)	Racz, Fitz, Lee and Cohen
J	18 and 28	§ 103(a)	Racz, Fitz, Lee, Cohen, and Young '965
K	18 and 28	§ 103(a)	Racz, Fitz, Lee, Cohen, and Scheibe
L	18 and 28	§ 103(a)	Racz, Fitz, Lee, Cohen, Young '965, and Scheibe

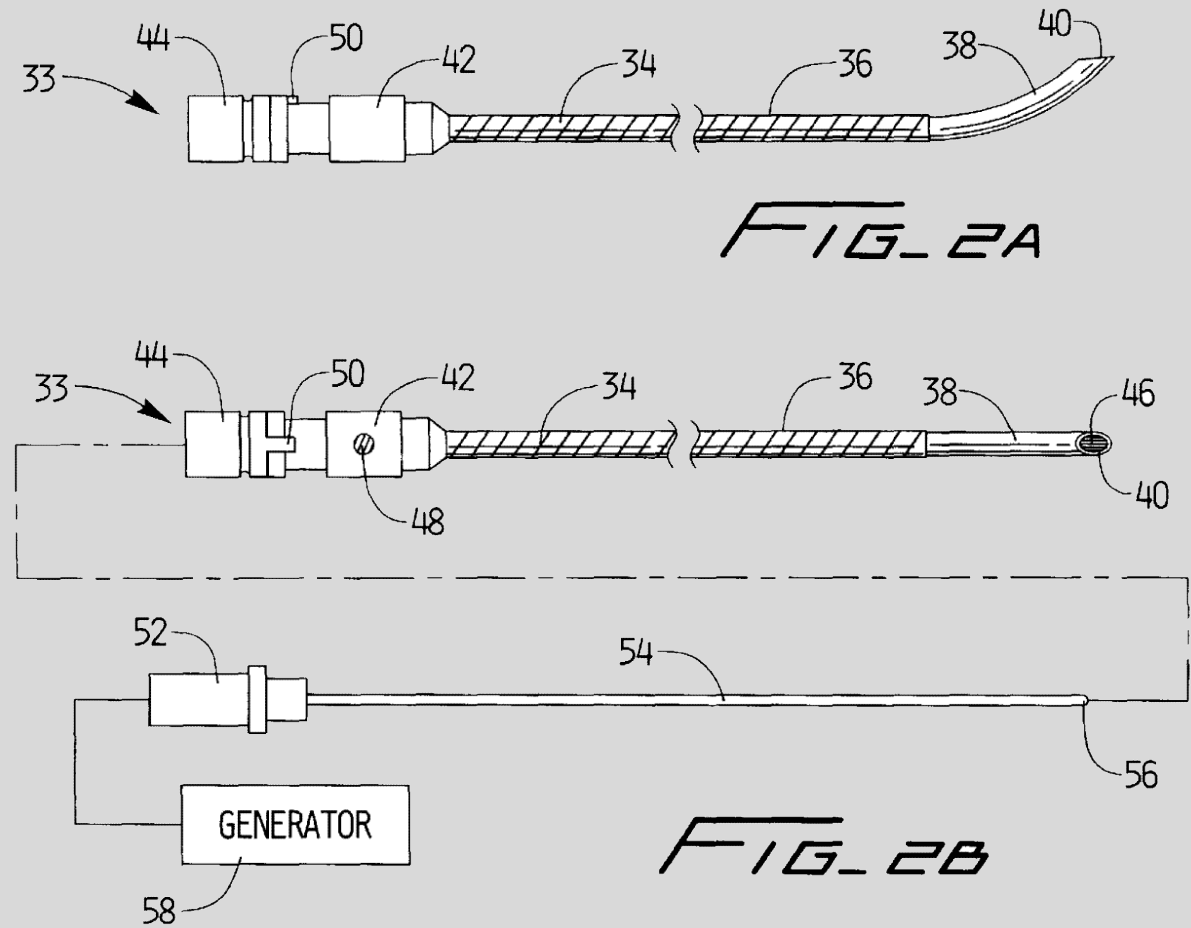
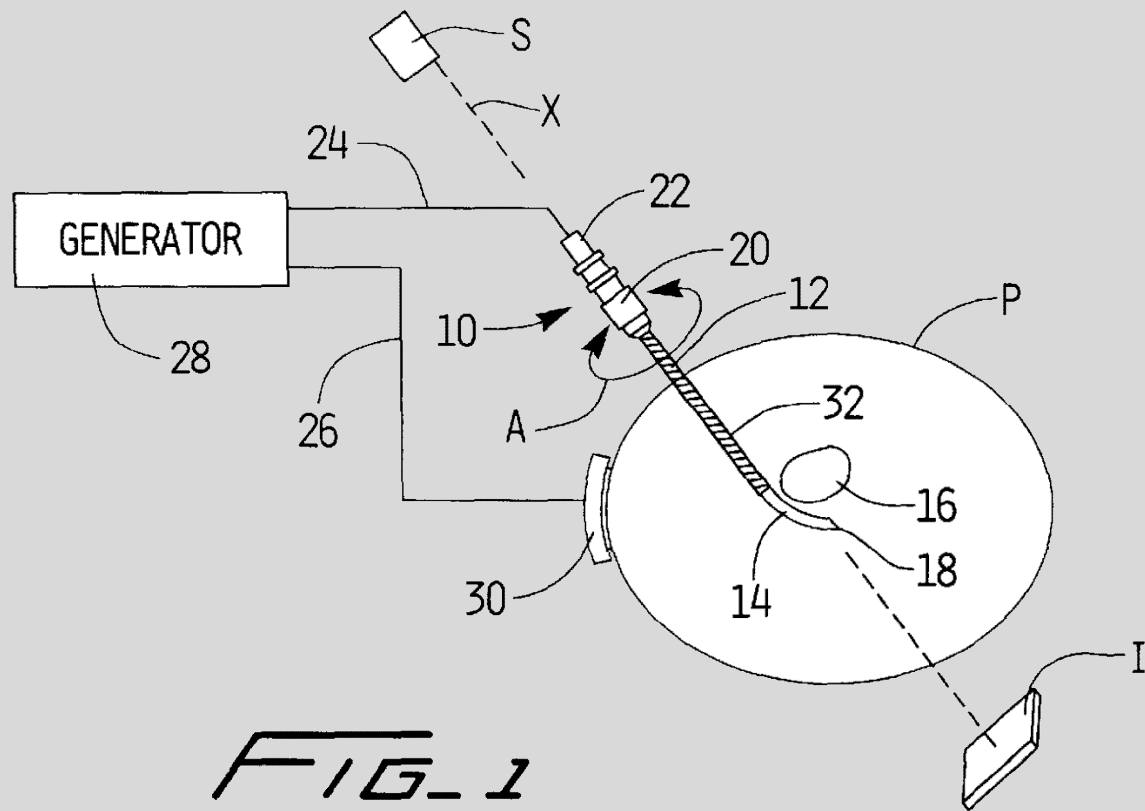
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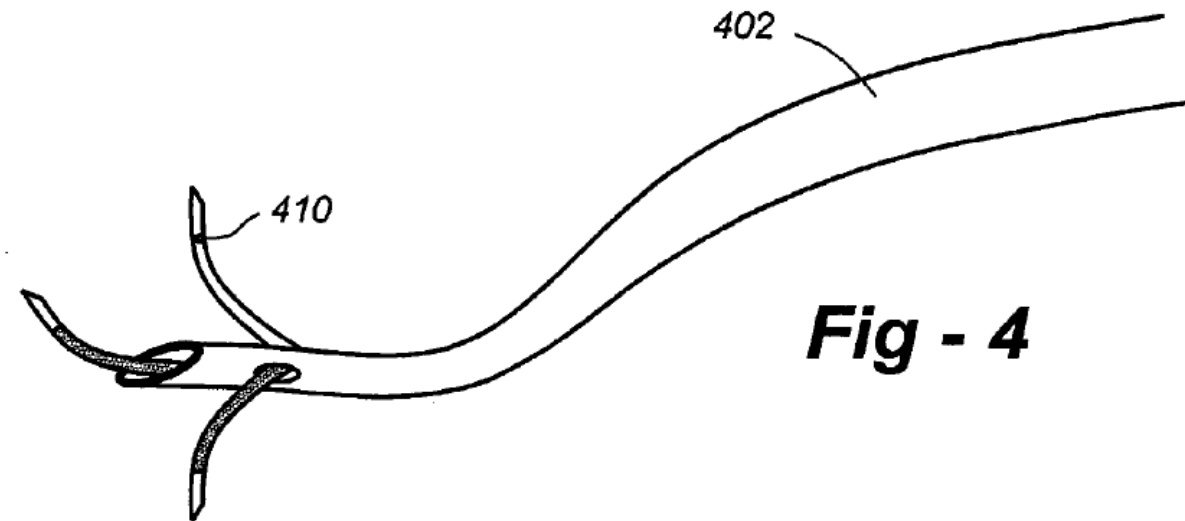
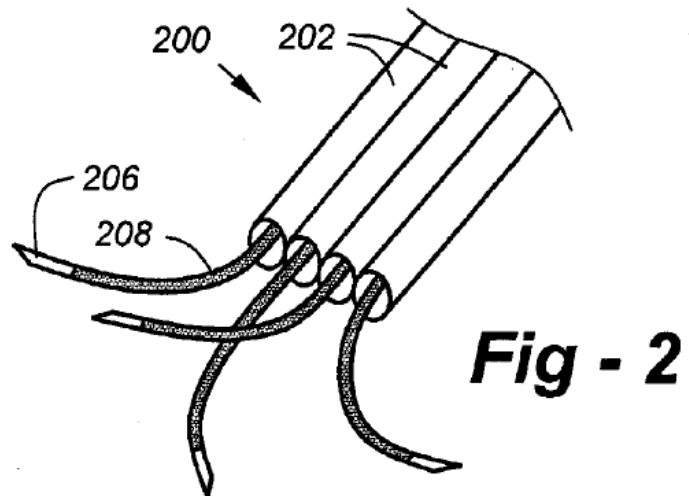
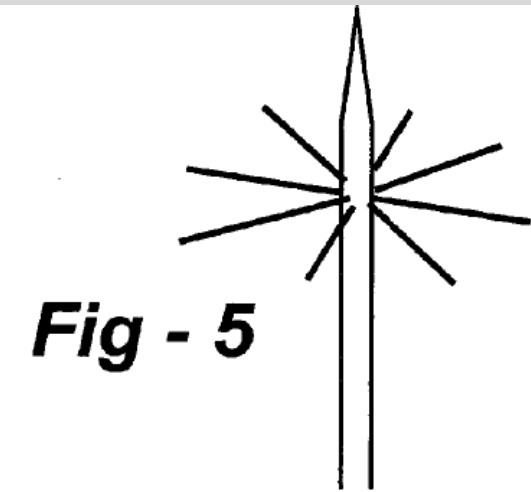
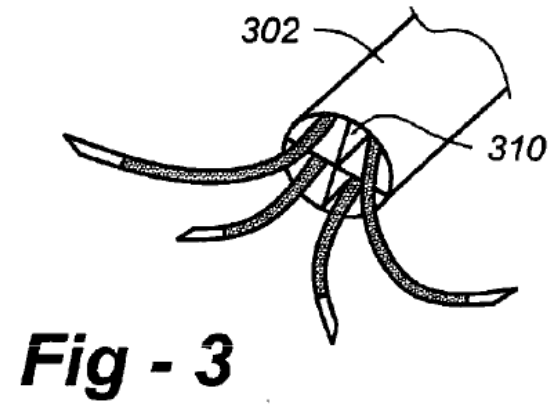
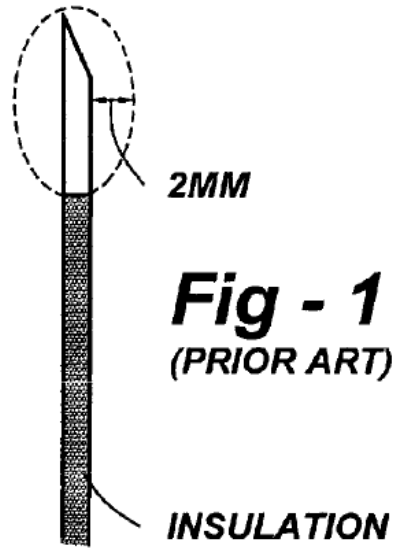
	Claims	Statute	Prior Art
A	1, 6-9, 12-14, 17, 48-52	§ 103(a)	Racz, Fitz, and Lee
B	1, 6-9, 12-14, 17, 48-52	§ 103(a)	Racz, Fitz, Lee, and Young '965
C	1-9, 12-14, 17, 48-52	§ 103(a)	Racz, Fitz, Lee, and Scheibe
D	1-9, 12-14, 17, 48-52	§ 103(a)	Racz, Fitz, Lee, Young '965, and Scheibe
E	9	§ 103(a)	Racz, Fitz, Lee, and Young '201
F	9	§ 103(a)	Racz, Fitz, Lee, Young '201, and Young '965
G	9	§ 103(a)	Racz, Fitz, Lee, Young '201, and Scheibe
H	9	§ 103(a)	Racz, Fitz, Lee, Young '201, Young '965, and Scheibe
I	10, 11, 15	§ 103(a)	Racz, Fitz, Lee, and Gough '516
J	10, 11, 15	§ 103(a)	Racz, Fitz, Lee, Gough '516, and Young '965
K	10, 11, 15	§ 103(a)	Racz, Fitz, Lee, Gough '516, and Scheibe
L	10, 11, 15	§ 103(a)	Racz, Fitz, Lee, Gough '516, Young '965, and Scheibe
M	16	§ 103(a)	Racz, Fitz, Lee, and Rosinko
N	16	§ 103(a)	Racz, Fitz, Lee, Rosinko, and Young '965
O	16	§ 103(a)	Racz, Fitz, Lee, Rosinko, and Scheibe
P	16	§ 103(a)	Racz, Fitz, Lee, Rosinko, Young '965, and Scheibe

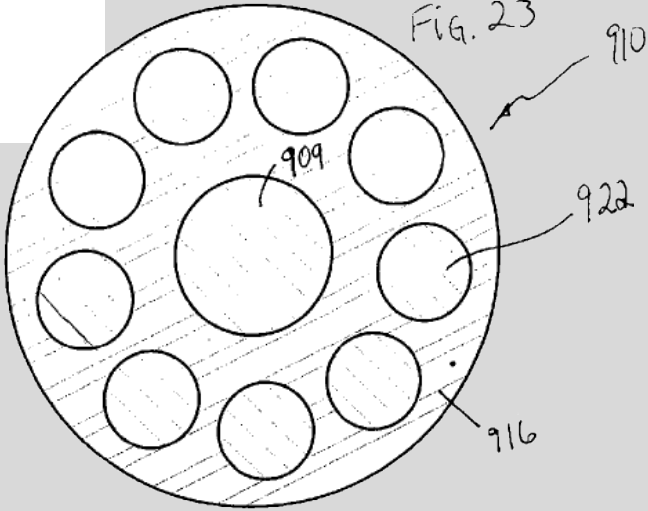
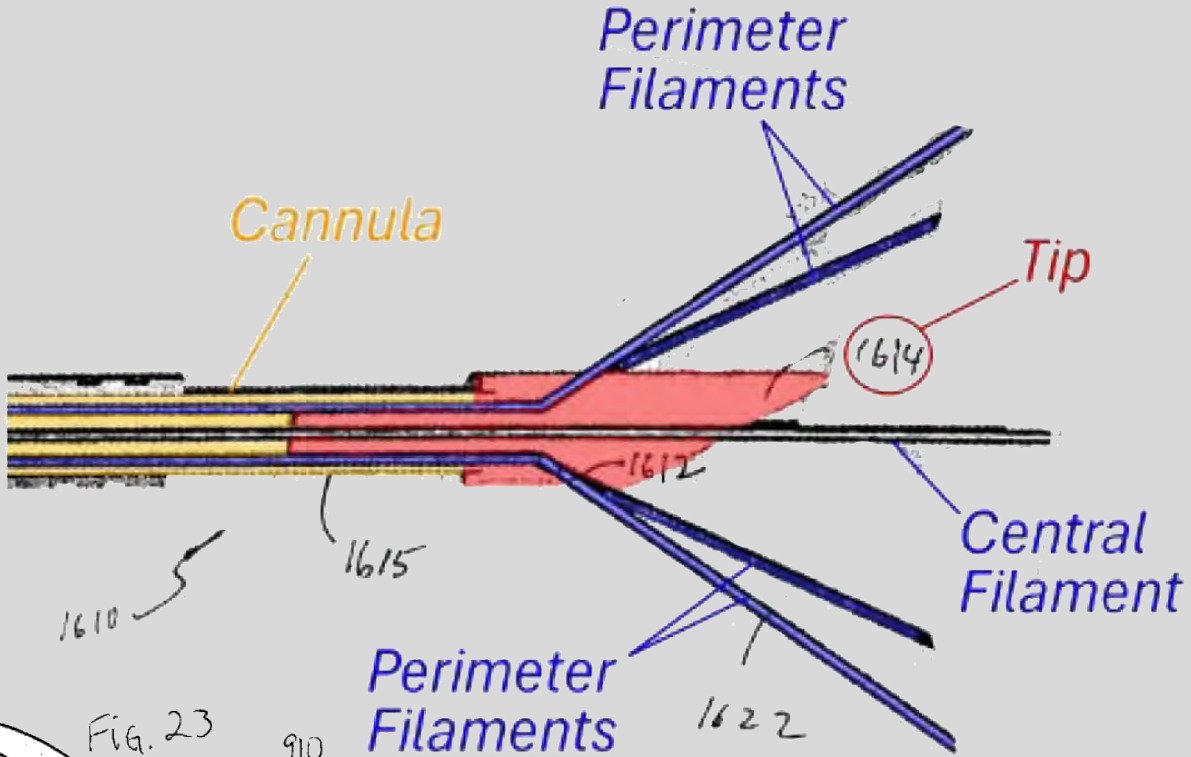
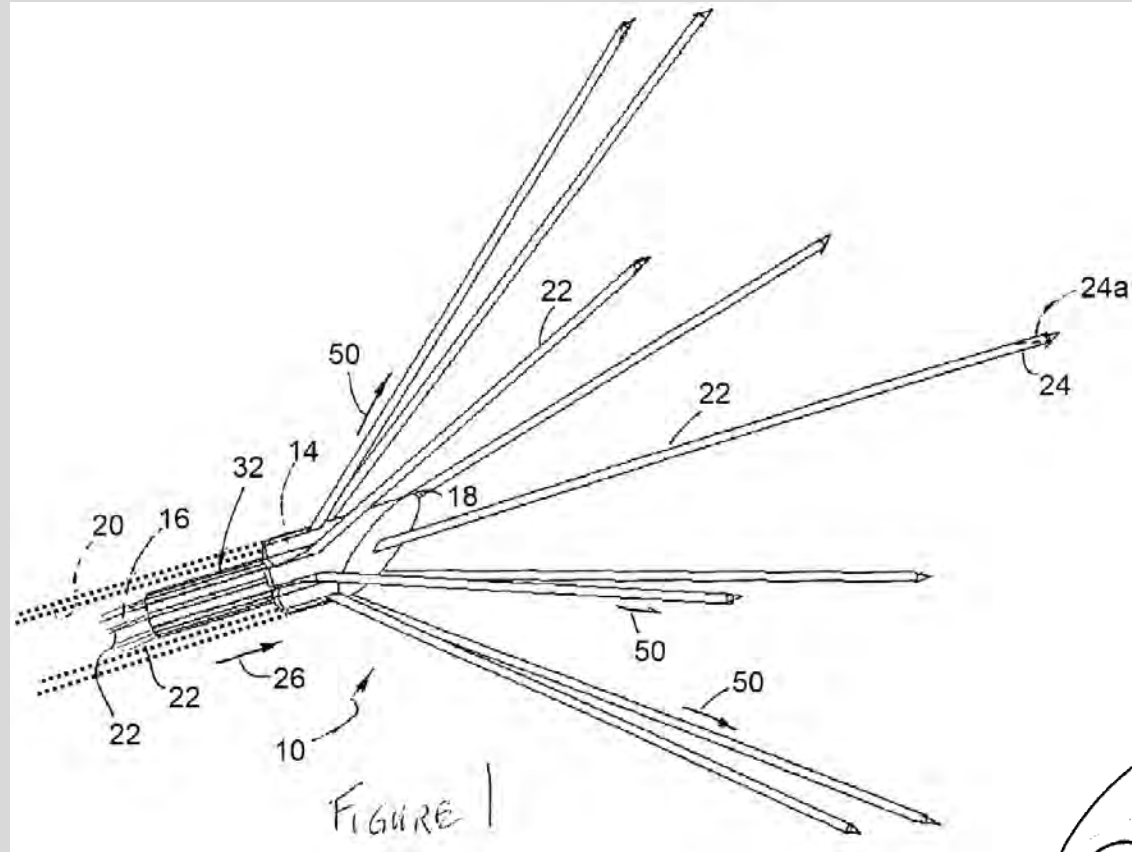
-01211

	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

Racz

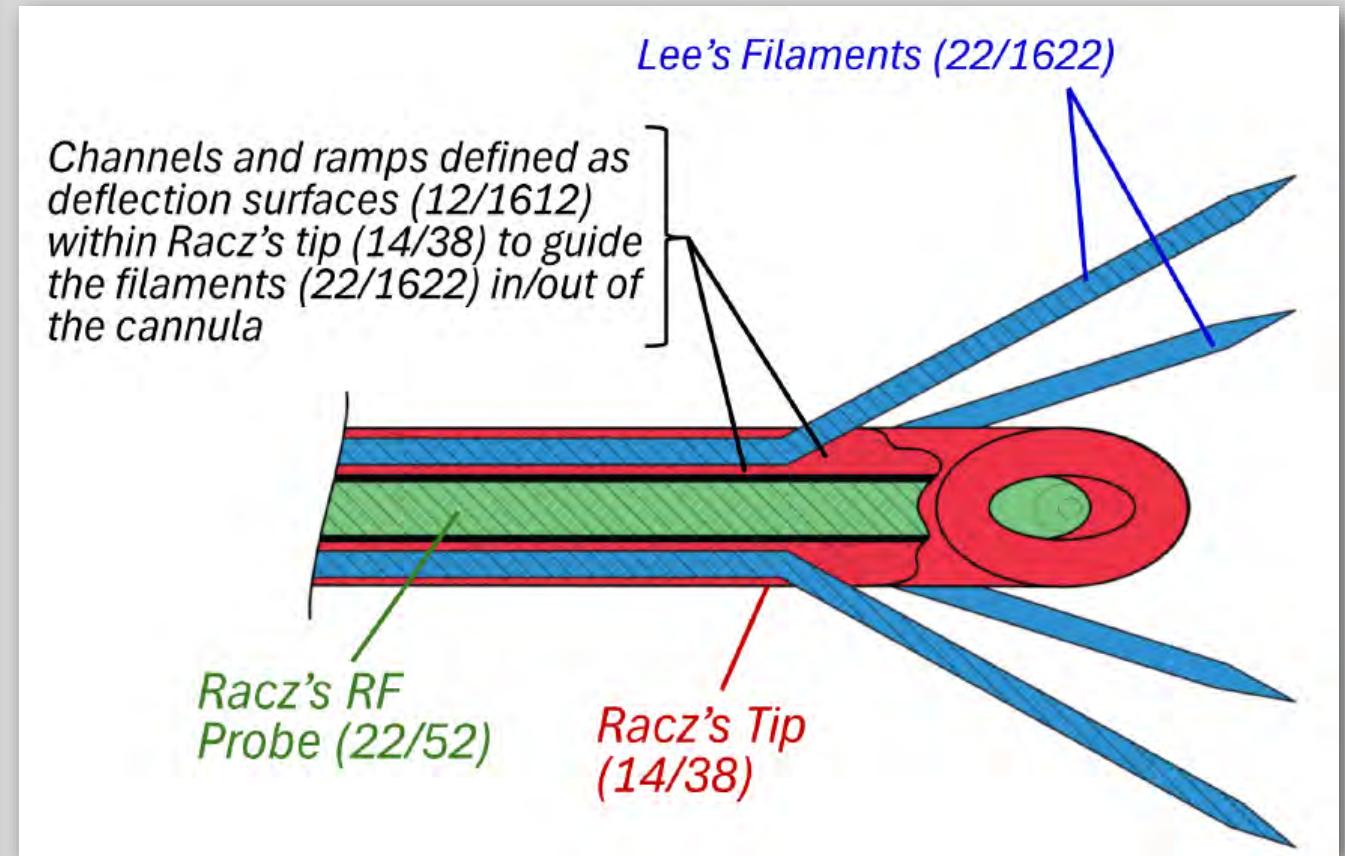
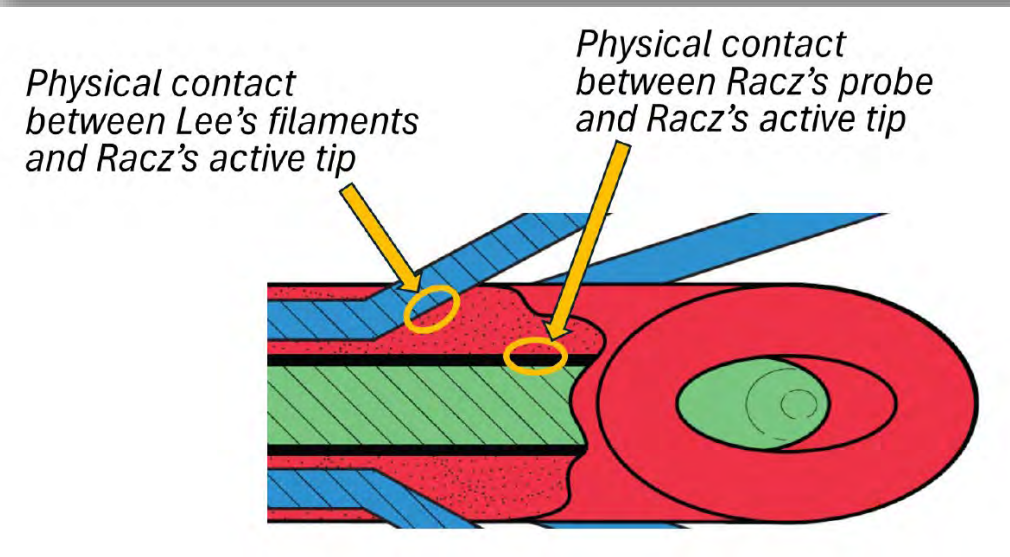
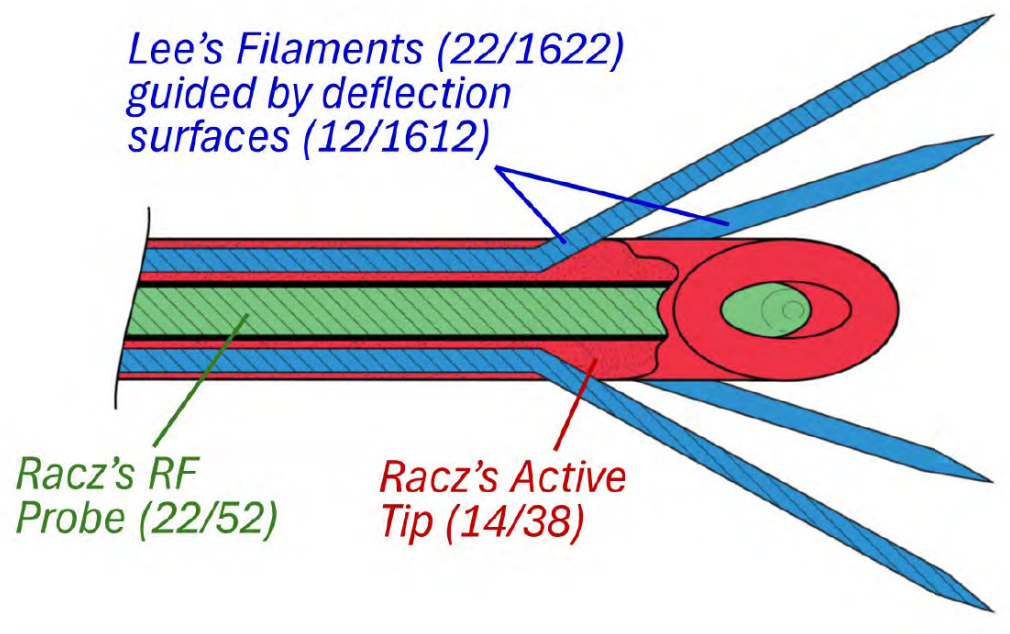






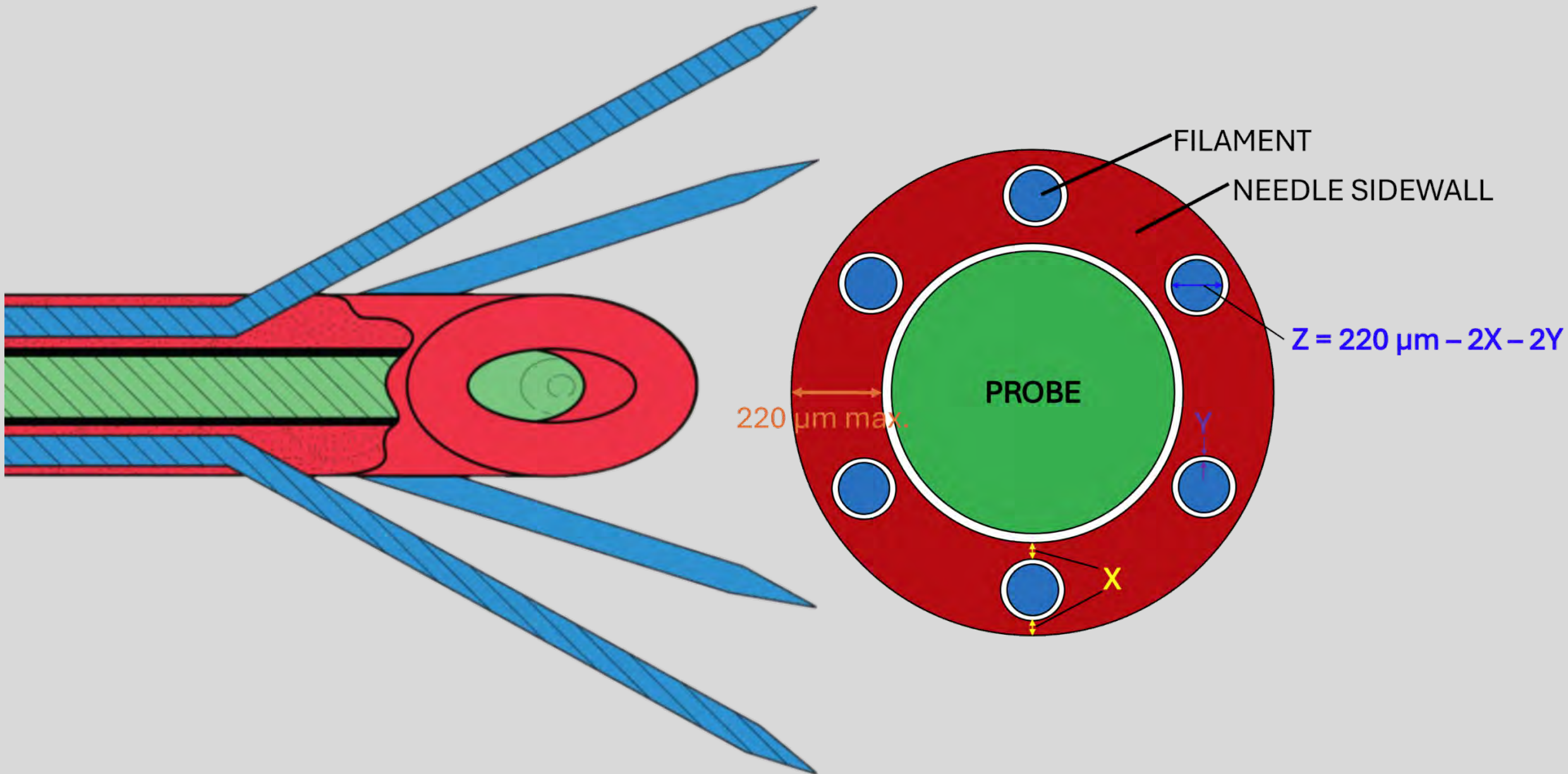
Racz's Modified Device

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Racz's Modified Device

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Racz's Modified Device – Petition

GLOSSARY

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

Racz's Modified Device – Petition

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Nearly two years after Fitz's publication, Lee disclosed a further refinement of the deployable-electrode technique that would have provided additional motivation and guidance to a POSA. Lee discloses that its filaments (22/1622) "define an ablation volume in the target tissue" as "the destruction of target tissue [occurs] at the site where the electrodes are located." Ex-1010, ¶0012, 0084. As a result, "variations in ablation volume" may be achieved by controlling the number of filaments (22/1622) used as well as their length, direction, and arrangement. Ex-1010, ¶0123-0131, 0084. Indeed, the "arrangement of [filaments] may ... form any desired pattern" (Ex-1010, ¶0103), and the precision and control offered by the filaments (22/1622) allow "the operator [to] deliver the [radiofrequency] treatment safely and effectively" (Ex-1010, ¶0084). Thus, a POSA would have been further motivated by Lee to add deployable filaments to the distal tip (14/38) of Racz's cannula (10/33) to not just expand—but also control—the ablation volume generated by Racz's device. Ex-1031, ¶138-139.

Moreover, Lee discloses that deflection surfaces (12/1612) (internal SA that its deployable filaments engage and guide those filaments) (18, 0091, 0102, Abstract, ¶0001, 0002, 0003, 0004, 0005, 0006, 0007, 0008, 0009, 0010, 0011, 0012, 0013, 0014, 0015, 0016, 0017, 0018, 0019, 0020, 0021, 0022, 0023, 0024, 0025, 0026, 0027, 0028, 0029, 0030, 0031, 0032, 0033, 0034, 0035, 0036, 0037, 0038, 0039, 0040, 0041, 0042, 0043, 0044, 0045, 0046, 0047, 0048, 0049, 0050, 0051, 0052, 0053, 0054, 0055, 0056, 0057, 0058, 0059, 0060, 0061, 0062, 0063, 0064, 0065, 0066, 0067, 0068, 0069, 0070, 0071, 0072, 0073, 0074, 0075, 0076, 0077, 0078, 0079, 0080, 0081, 0082, 0083, 0084, 0085, 0086, 0087, 0088, 0089, 0090, 0091, 0092, 0093, 0094, 0095, 0096, 0097, 0098, 0099, 0100, 0101, 0102, 0103, 0104, 0105, 0106, 0107, 0108, 0109, 0110, 0111, 0112, 0113, 0114, 0115, 0116, 0117, 0118, 0119, 0120, 0121, 0122, 0123, 0124, 0125, 0126, 0127, 0128, 0129, 0130, 0131, 0132, 0133, 0134, 0135, 0136, 0137, 0138, 0139, 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1966, 1967, 1968, 1969, 1970, 1971, 1972, 1973, 1974, 1975, 1976, 1977, 1978, 19

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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)

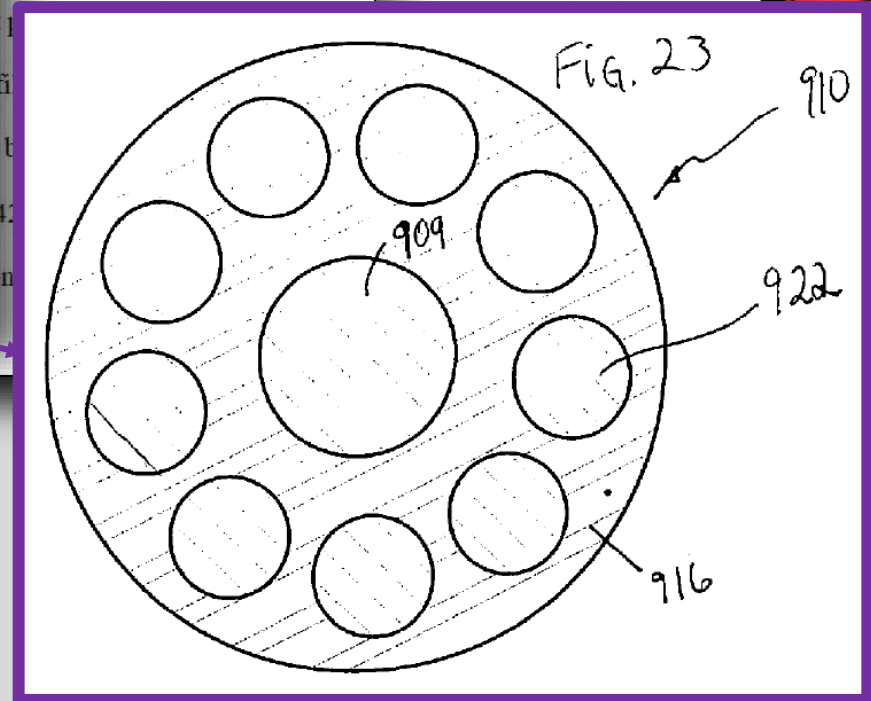
“define an ablation volume in the target tissue” (22/1622, ¶0123-0131, 0084. Indeed, the “desired pattern” (Ex-1010, ¶0103), and filaments (22/1622) allow “the operator safely and effectively” (Ex-1010, ¶0084) motivated by Lee to add deployable filaments to the distal tip (14/38) of Racz's cannula (10/33) to not just expand—but also control—the ablation volume generated by Racz's device. Ex-1031, ¶138-139.

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

Furthermore, Lee discloses that deflection surfaces (12/1612) (internal) engage and guide those filaments (22/1622) to the target tissue. Ex-1010, ¶0091, 0102, Abstract.

Lee's Filaments (22/1622)

in his declaration one example would have incorporated Lee's electrodes at Racz's distal tip



one example of Lee's filaments)

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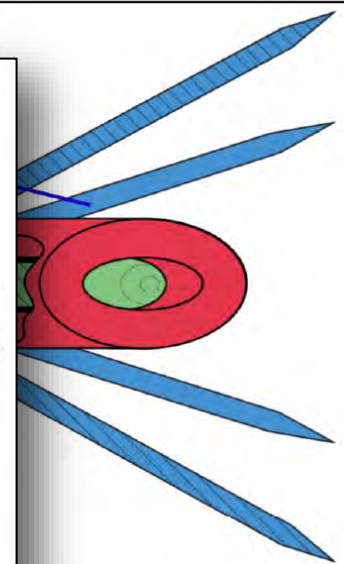
Nearly two years after Fitz's publication, Lee disclosed a further refinement of the deployable-electrode technique that would have provided additional motivation and guidance to a POSA. Lee discloses that its filaments (22/1622) "define an ablation volume in the target tissue" (22/1622, ¶0010) [occurs] at the site where the electrode is deployed. As a result, "variations in ablation volume" (22/1622, ¶0010) of filaments (22/1622) used as well as filaments (22/1622) can be arranged in a desired pattern" (Ex-1010, ¶0103), and filaments (22/1622) allow "the operator to safely and effectively" (Ex-1010, ¶0084) motivated by Lee to add deployable filaments to the distal tip (14/38) of the cannula (10/33) to not just expand—but also control—the ablation volume generated by Racz's device. Ex-1031, ¶138-139.

Lee also would have contemplated that filaments (22/1622) would be easily implemented in a POSA (10/33). As explained for Claim 1, filaments (22/1622) can be arranged in a desired pattern that they surround and provide support to the active tip (14/38) of a located removable probe (22/52).

Furthermore, Lee discloses that deflection surfaces (12/1612) (internal channels and ramps) located in the cannula's tip can engage and guide those perimeter filaments (22/1622). Ex-1010, ¶0016, 0018, 0091, 0102, Abstract, Claims 8, 10. Thus, a POSA would understand that providing deflection surfaces in Racz's tip (14/38) would result in Lee's perimeter filaments (12/1622) both physically contacting Racz's active tip (14/38) and being deployed outwardly around Racz's active tip (14/38). Ex-1031, ¶141-142. In this way, Lee's perimeter filaments (22/1622) would join Racz's existing monopolar tip (14/38) to function together as a single monopolar electrode. *Id.*

Lee's Filaments (22/1622)

As in his declaration one example of how a POSA would have incorporated Lee's filaments at Racz's distal tip, Lee has been motivated to implement filaments (22/1622) serving the functionality of Racz's active tip (14/38) of the probe (22/52). Ex-1031, ¶143. This would involve nothing more than combining the functions and combining the functions of Lee's filaments (22/1622) with Racz's active tip (14/38) to provide improvement. *Id.*



Showing one example of how a POSA would modify Racz to include Lee's filaments)

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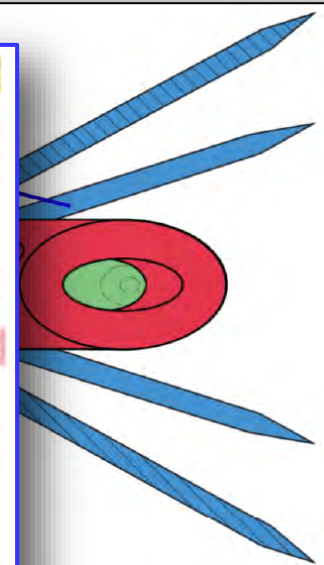
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Nearly two years after Fitz's publication, Lee disclosed a further refinement of the deployable-electrode technique that would have provided additional motivation and guidance to a POSA. Lee discloses that its filaments (22/1622) "define an ablation volume in the target tissue" (Ex-1010, ¶0103), and that "variations in ablation volume" result, "due to the geometry of the filaments (22/1622) used as well as the arrangement of the filaments (22/1622) at the site where the electrode is deployed." (Ex-1010, ¶0103). Indeed, the "desired pattern" (Ex-1010, ¶0103), and the "arrangement of the filaments (22/1622) allow 'the operator to safely and effectively' (Ex-1010, ¶008) define an ablation volume." (Ex-1010, ¶0103). Lee also would have contemplated that the filaments (22/1622) would be easily implemented in a POSA (10/33). As explained for Claim 1, the filaments (22/1622) can be arranged in a pattern that they surround and provide support for the active tip (14/38) of the removable probe (22/52). (Ex-1010, ¶0125, Figs. 1, 23, 49. This would allow the filaments (22/1622) to be easily integrated with the located removable probe (22/52) of the POSA (10/33). Lee's disclosure is motivated by Lee to add deployable filaments to the distal tip (14/38) of the cannula (10/33) to not just expand—but also control—the ablation volume generated by Racz's device. Ex-1031, ¶138-139.

Furthermore, Lee discloses that the filaments (22/1622) (channels and ramps) located in the perimeter filaments (22/1622). Claims 8, 10. Thus, a POSA would result in Racz's tip (14/38) would result in physically contacting Racz's active tip (14/38) around Racz's active tip (14/38). The filaments (22/1622) would join together as a single monopolar electrode.

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

Lee's Filaments (22/1622)



...ing one example of how a POSA would modify Racz to include Lee's filaments)

Racz's Modified Device – Petition

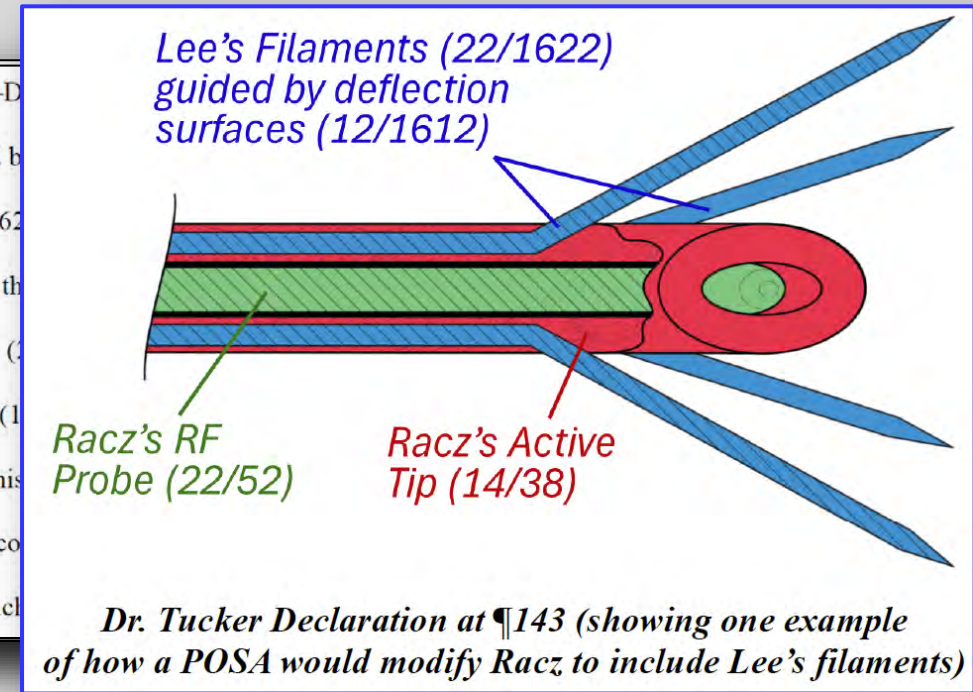
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Nearly two years after Fitz's publication, Lee disclosed a further refinement of the deployable-electrode technique that would have provided additional motivation and guidance to a POSA. Lee discloses that its filaments (22/1622) "define an ablation volume in the target tissue" (22/1622) would be easily implemented (10/33). As explained for Claim 1, filaments (22/1622) can be arranged that they surround and provide a desired pattern" (Ex-1010, ¶0103), and filaments (22/1622) allow "the operator safely and effectively" (Ex-1010, ¶008) motivated by Lee to add deployable filaments to the distal tip (14/38) of a cannula (10/33) to not just expand—but also control—the ablation volume generated by Racz's device. Ex-1031, ¶138-139.

Lee also would have contemplated (22/1622) would be easily implemented (10/33). As explained for Claim 1, filaments (22/1622) can be arranged that they surround and provide a desired pattern" (Ex-1010, ¶0103), and filaments (22/1622) allow "the operator safely and effectively" (Ex-1010, ¶008) motivated by Lee to add deployable filaments to the distal tip (14/38) of a cannula (10/33) to not just expand—but also control—the ablation volume generated by Racz's device. Ex-1031, ¶138-139.

Furthermore, Lee discloses channels and ramps) located in the perimeter filaments (22/1622). Ex-1010, Claims 8, 10. Thus, a POSA would result in Racz's tip (14/38) would result in physically contacting Racz's active tip (14/38). According to Dr. Tucker, this filaments (22/1622) would join R together as a single monopolar el

Petitioner's expert—Dr. Tucker opines that of how a POSA (motivated by deployable filaments (22/1622) (14/38). Dr. Tucker opines that Lee's deployable filaments (22/1622) would join R together as a single monopolar el



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

perimeter filaments (22/1622) on Rac2's distal tip have found it obvious to modify Rac2's tip (14/38) to surfaces (12/1612) (e.g., channels and ramps as the perimeter filaments (22/1622) outwardly around 10, ¶0016, 0018, 0092, 0102, Claim 8, Claim 10; Ex- been further obvious to provide openings in Rac2's communication with the internal deflection surfaces as Lee's perimeter filaments (22/1622) can—when distal tip (14/38). Ex-1010, ¶0092, 0102; Ex-1031, ¶166.

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

the functionality of Racz's removable electrical probe (22/52) (14/38)—and consistent with Lee's teachings—a POSA would have implemented perimeter filaments, channels, and ramps around the internal cannula (10/33). Ex-1010, ¶0091, 0092, 0098, 0102; Ex-1031, ¶166. Above, Racz's electrical probe (22/52) is configured to extend along the cannula's shaft (12/34) to supply RF energy to the tip (14/38) to raise the temperature. *Supra* § VI.A.1. By omitting Lee's central filament (22/1622) and not being needed, a POSA would not be needed) and arranging the perimeter filaments, channels, and ramps around the inner perimeter of Racz's cannula (10/33), a POSA would have implemented Lee's perimeter filaments (22/1622) without including Lee's central filament (22/1622) around the cannula (10/33). This would preserve the functionality of Racz's removable electrical probe (22/52), which is needed to transmit RF energy. Ex-1031,

implementing Lee's perimeter filaments (22/1622) on Racz's distal tip (14/38) to provide a desired ablation volume. Ex-1010, ¶0091, 0092, 0098, 0102; Ex-1031, ¶166. Above, Racz's electrical probe (22/52) is configured to extend along the cannula's shaft (12/34) to supply RF energy to the tip (14/38) to raise the temperature. *Supra* § VI.A.1. By omitting Lee's central filament (22/1622) and not being needed, a POSA would not be needed) and arranging the perimeter filaments, channels, and ramps around the inner perimeter of Racz's cannula (10/33), a POSA would have implemented Lee's perimeter filaments (22/1622) without including Lee's central filament (22/1622) around the cannula (10/33). This would preserve the functionality of Racz's removable electrical probe (22/52), which is needed to transmit RF energy. Ex-1031, ¶166. As Lee (and Fitz) confirm, this would improve Racz's device by providing an expanded and controlled energy coverage area.

Racz's Modified Device – Petition

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it would be appropriate to implement Lee's perimeter filaments (including Lee's central filament. *See supra* § VI.A.3 (discussing perimeter/central filaments). Lee discloses that any number and arrangement of filaments may be implemented to provide a desired ablation volume (a centrally located filament is not always needed). Ex-1010, ¶0103 (arrangement of stylets may ... form any desired pattern"), ¶0105 (used "singly, in combination or in any desired pattern"), ¶0106 ("electrode deployment may be varied to achieve any desired effect as Racz's exposed distal tip (14/38) is already active, a POSA would have recognized that Lee's central filament would not be necessary (shown unshaded in Lee's Fig. 1 and 49). Ex-1009, 3:60-63, 4:18-23; Ex-1031, ¶166. A POSA would have been motivated to implement a plurality of Lee's perimeter filaments (22/1622) around Racz's tip (14/38) to provide a desired

(e.g., in a full or partial "cone" shape) and omit Lee's central filament. Ex-1031, ¶165. As Lee (and Fitz) confirm, this would improve Racz's device by providing an expanded and controlled energy coverage area.

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

perimeter filaments (22/1622) on Racz's distal tip (14/38). Ex-1010, ¶0092, 0102; Ex-1031, ¶166. 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 shown in Lee's Fig. 1 and 49) around the perimeter filaments (22/1622) outwardly around the tip (14/38). Ex-1010, ¶0016, 0018, 0092, 0102, Claim 8, Claim 10; Ex-1031, ¶166. It would have been further obvious to provide openings in Racz's cannula (10/33) for communication with the internal deflection surfaces as shown in Lee's Fig. 1 and 49. Lee's perimeter filaments (22/1622) can—when implemented around Racz's distal tip (14/38). Ex-1010, ¶0092, 0102; Ex-1031, ¶166.

Racz's Modified Device – Petition

In view of these teachings in Racz and Lee, a POSA would have found implementing Lee's perimeter filaments (22/1622) on Racz's distal tip (14/38) to be a routine engineering task. Ex-1031, ¶165. A POSA would have recognized that

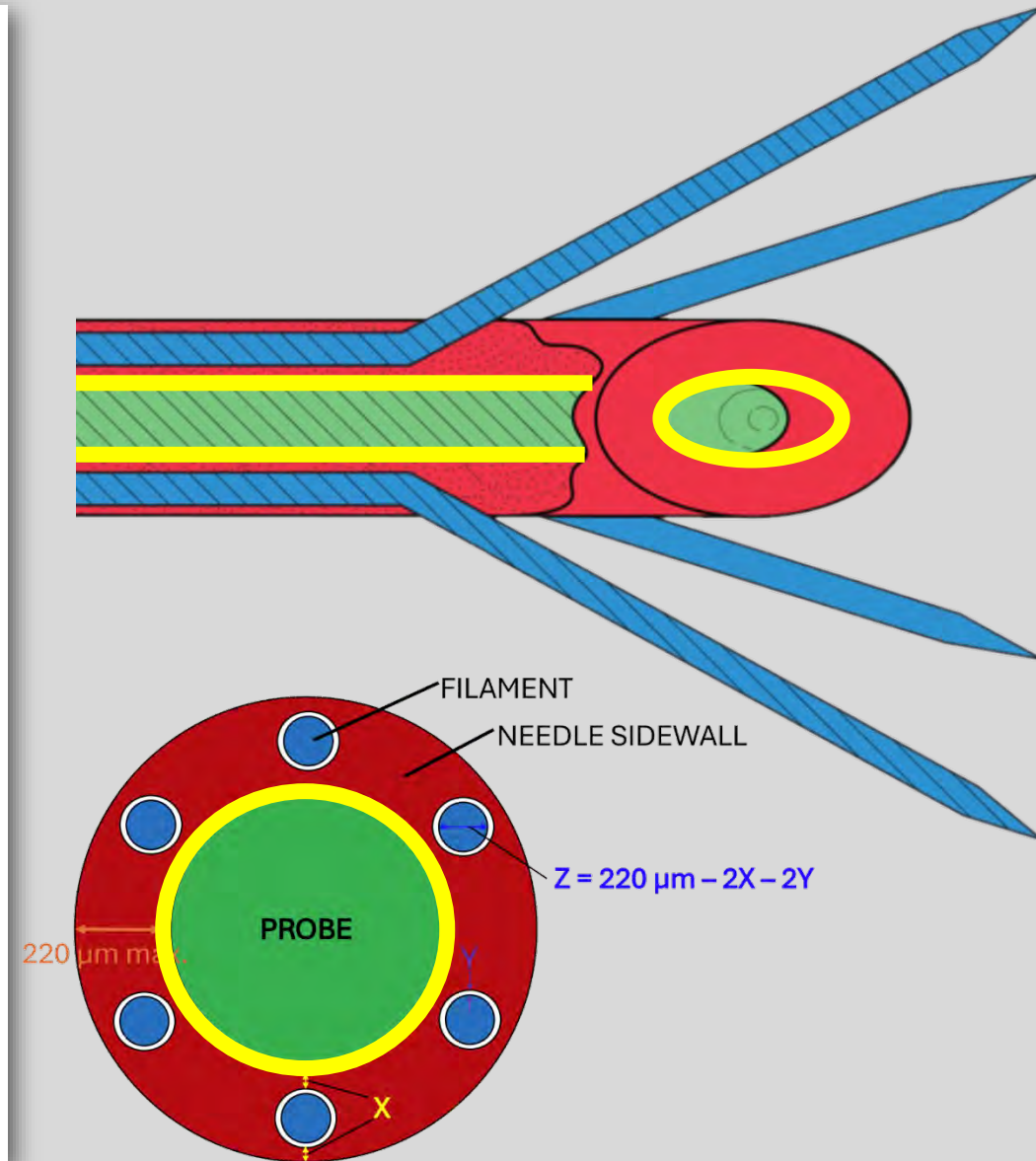
it would be appropriate to implement Lee's perimeter filaments (22/1622) including Lee's central filament. *See supra* § VI.A.3 (discussing perimeter/central filaments). Lee discloses that any number and arrangement of filaments may be implemented to provide a desired ablation volume (a centrally located filament is not always needed). Ex-1010, ¶0103 (arrangement of stylets may ... form any desired pattern"), ¶0105 (used "singly, in combination or in any desired pattern"), ¶0106 (electrode deployment may be varied to achieve any desired effect). As Racz's exposed distal tip (14/38) is already active, a POSA would have recognized that Lee's central filament would not be necessary (shaded in Lee's Fig. 1 and 49). Ex-1009, 3:60-63, 4:18-23; Ex-1031, ¶166. A POSA would have been motivated to implement a plurality of Lee's perimeter filaments (22/1622) around Racz's tip (14/38) to provide a desired ablation volume (e.g., in a full or partial "cone" shape) and omit Lee's central filament. Ex-1031, ¶165. As Lee (and Fitz) confirm, this would improve Racz's device by providing an expanded and controlled energy coverage area.

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

To implement Lee's perimeter filaments (22/1622) on Racz's distal tip (14/38), a POSA would have found it obvious to modify Racz's tip (14/38) to include internal deflection surfaces (12/1612) (e.g., channels and ramps as disclosed in Lee) to guide the perimeter filaments (22/1622) outwardly around Racz's tip (14/38). Ex-1010, ¶0016, 0018, 0092, 0102, Claim 8, Claim 10; Ex-1031, ¶166. It would have been further obvious to provide openings in Racz's distal tip (14/38) (e.g., in communication with the internal deflection surfaces as disclosed in Lee) such that Lee's perimeter filaments (22/1622) can—when deployed—exit Racz's distal tip (14/38). Ex-1010, ¶0092, 0102; Ex-1031, ¶166.

Racz's Modified Device – Petition

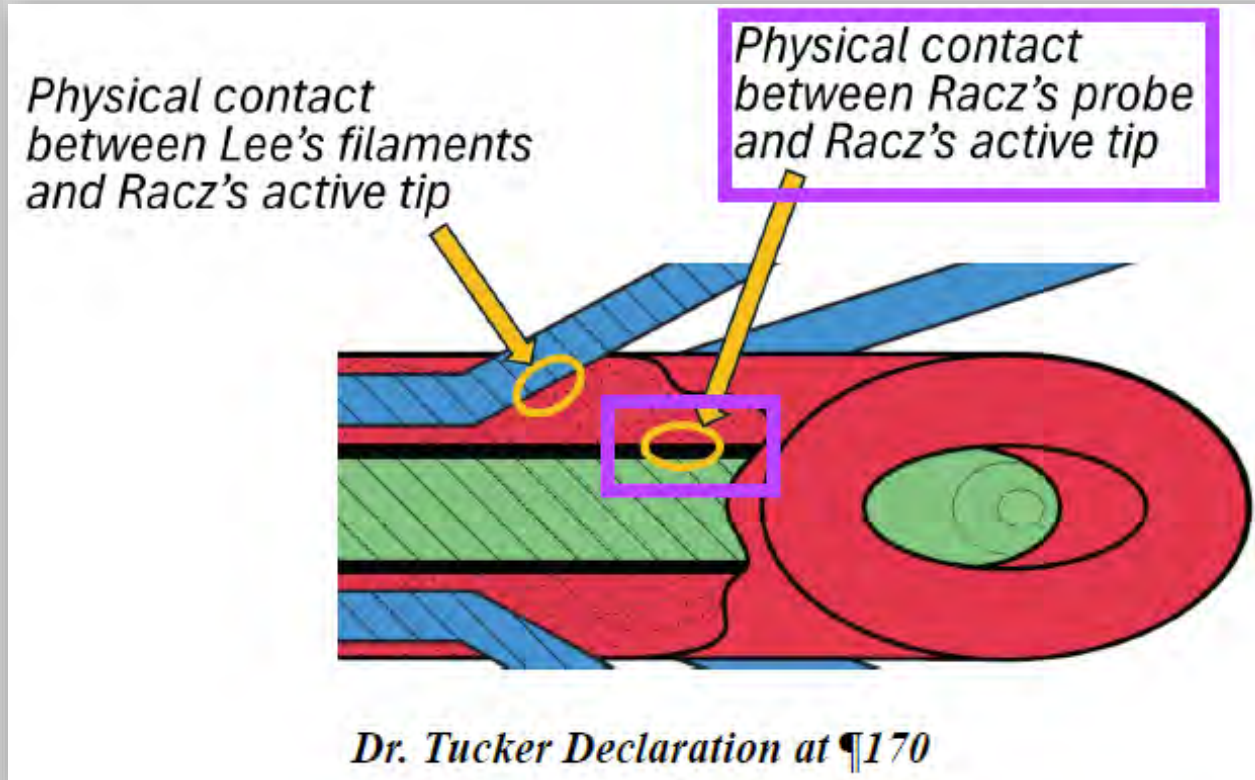
To preserve the functionality of Racz's removable electrical probe (22/52) and active tip (14/38)—and consistent with Lee's teachings—a POSA would have arranged the perimeter filaments, channels, and ramps around the internal perimeter of Racz's cannula (10/33). Ex-1010, ¶0091, 0092, 0098, 0102; Ex-1031,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



Racz's Modified Device – Petition

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



Racz's Modified Device – Petition

Although the filaments (22/1622) could be implemented in a variety of ways, Petitioner's expert (Dr. Tucker) shows in his declaration **one example** of how a POSA would have implemented Lee's perimeter filaments (22/1622) and deflection surfaces (12/1612) around the inner perimeter of Racz's distal tip (14/38) (such that Racz's probe (22/52) could still be received into the cannula's central lumen). Ex-1031, ¶168-169. According to Dr. Tucker, Lee's deflection surfaces (channels and ramps) could be easily formed as an integral portion of Racz's distal tip (14/38) (e.g., by defining internal channels and ramps as a unitary part of the cannula's shaft (12/34)). *Id.* Dr. Tucker notes that, **alternatively**, the deflection surfaces could be defined on a separate, electrically conductive mandrel secured to the end of Racz's shaft (12/34) and provided with a lumen to receive a distal portion of the electrical probe (22/52) (the mandrel thereby defining both the tip (14/38) and deflection surfaces). *Id.*

Racz's Modified Device – Dr. Tucker's Declaration

145. As a **first example**, it is my opinion that a POSA would be able to define **channels (as disclosed in Lee) as an integral part of Racz's cannula** and dimension the channels to accommodate Lee's filaments. A POSA would understand from Lee's disclosure of channels and ramps within a tip (14), that such channels could be formed within the tip of Racz's cannula. Doing so would merely require recognizing that the channels and ramps defined on Lee's tip could be formed as an integral part of Racz's tip, and therefore that the channels would be part of Racz's cannula. Forming channels in Racz's cannula with an integral tip would only be an application of the ordinary skill of a POSA. Moreover, I note that Lee shows how its perimeter filaments can be arranged around a central element (Lee's central filament). *Supra* § VII.A.3. A POSA would have been motivated to preserve the functionality of Racz's probe (22/52) would therefore have provided the channels for guiding the deployable filaments (22/1622) around the lumen that receives the RF probe (22/52) (e.g., a similar way to how the perimeter channels and filaments are arranged to accommodate Lee's central filament).

147. As a **second example**, it is also my opinion that a POSA would also have been able to implement the combination of Racz and Lee using **a separate tip defining channels** (as disclosed in Lee). Ex-1010, ¶¶0012, 0016, 0018, 0022, 0087, 0092, 0142. The decision to **form the channels for filaments in a separate tip attached to the cannula** would also have been a matter of routine engineering in the same way that making the tip integrated to the cannula would be. For example, Lee discloses that its tip mandrel can be made from metal, define channels and deflection surfaces, and be attached to a cannula. Ex-1010, ¶¶0025, 0051, 0118, 0119. Because Racz discloses that its tip (14/38) is active, a POSA would have secured Lee's tip to the end of the cannula in a way that would electrically connect the tip to the cannula's shaft (and the removable probe and the deployable filaments). *See* Ex-1010, ¶0119 (a POSA would simply not include the insulating plastic annular member 813). Forming an electrical connection between conductive materials by touching them together is a matter of routine engineering that would be within the skill of a POSA. In view of Lee's teachings, a POSA would have had a reasonable expectation of success in defining channels to guide deployable filaments on a separate tip secured to the cannula (as disclosed in Lee) and configuring the tip to be conductive and engage the removable RF probe (as disclosed in Racz).

Racz's Modified Device – Petition

30

35 U.S.C. § 312

(a) Requirements of Petition. — A petition filed under section 311 may be considered only if—

(3) the petition identifies, in writing and with ***particularity***, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim . . .

37 C.F.R. § 42.104

In addition to the requirements of §§ 42.6, 42.8, 42.22, and 42.24, the petition must set forth:

(b) Identification of challenge. Provide a statement of the ***precise*** relief requested for each claim challenged. The statement must identify the following:

(2) The ***specific*** statutory grounds under 35 U.S.C. 102 or 103 on which the challenge to the claim is based and the patents or printed publications relied upon for each ground;

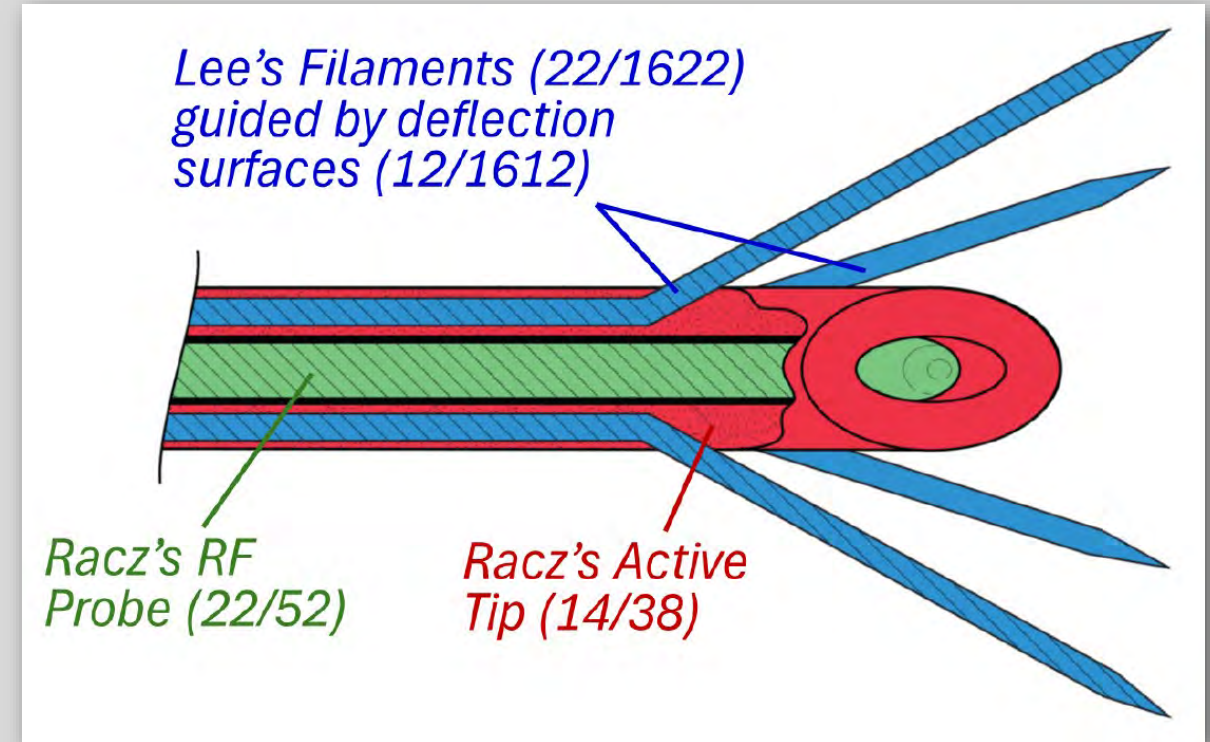
It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify “with particularity” the “evidence that supports the grounds for the challenge to each claim.” 35 U.S.C. § 312(a)(3). . . . Unlike district court litigation — where parties have greater freedom to revise and develop their arguments over time and in response to newly discovered material — the expedited nature of IPRs bring[s] with it **an obligation for petitioners to make their case in their petition to institute.**

Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1369 (Fed. Cir. 2016) (emphasis added).

Petition's Vagueness and Incompleteness

32

- Only one partial view.
- Only one perspective.
- Is tip bent or straight?
- No dimensions, no scale.
- No description of this device left of this drawing.
- Does RMD include anchors like Lee?
- Are filaments electrically connected to generator at proximal end?
- Are any features of Fitz included?
- Lack of clarity regarding differences between Tucker's first and second examples.
- Not resolved by Tucker's declarations or deposition.



Field of the Invention

33

Field

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

76.

. . .

For example, RF

ablations for treatment of tumors are generally performed by a doctor specialised in the treatment of the organ affected by the tumour. Thus, RF ablations of uterine fibroids (which are technically a type of tumour) involve the uterus, and thus are performed by gynecologists. Similarly, RF ablations of bone tumours are performed by orthopaedic surgeons, of liver tumours are performed either by upper gastrointestinal or hepatic surgeons, and of thyroid tumours are performed by endocrine surgeons. Separately, RF ablations of the heart to treat arrhythmias are performed by cardiologists. As a result, there has historically been little to no cross-talk between or cross-pollination of the various fields in which RF ablations are performed.

77.

In like manner, there was no (and still today there are no) medical RF devices that are usable in all forms of RF ablation procedures. Nor are there RF generators (the “electrical boxes” that supply RF energy to medical RF devices) that are capable of use with all forms of RF ablation procedures. Rather, the various RF devices and the RF generators that supply energy thereto are and have always been highly specialized and narrowly tailored for the procedures in which they are used. This is in large part due to the peculiarities of human tissue. For example, ablating heart tissue is a very different from ablating a cancerous tumour for at least the reasons that the respective tissues involved have different impedances and other electrical properties and require different pathways through the human anatomy for proper device placement.

Person of Ordinary Skill in the Art

34

The Petitioner's Proposal

A POSA in this field would have had at least (i) a bachelor's degree in biomedical engineering, or a related field, such as mechanical engineering, biomechanical engineering, or bioengineering, who also has at least 3 years of experience with thermal ablation system and methods; or (ii) an advanced degree in the same areas of academic study with at least 1 years of experience with thermal ablation systems and methods. Ex-1031, ¶105.

Stratus's Proposal

[A] combination of (1) an interventional pain-specialist physician with significant experience performing RF neurotomy procedures and (2) an engineer with a degree in biomedical engineering or a related field and experience in the design and development of devices and methods for applying electromagnetic energy to nerves. The POSITA should have either a bachelor-level degree with three years of the design/development experience noted above or an advanced degree with one year of the design/development experience noted above. Such a POSITA could be a team of two or more people working together.

Person of Ordinary Skill in the Art

35

Tucker's Deficiencies Under (1)

16 Q So have you ever performed an RF
17 neurotomy procedure on a live human patient?
18 A Oh, heavens no. You know, I'm not --
19 that's -- I'm not an anesthesiologist or a
20 surgeon.

15 Q Is it your opinion that this size range
16 is appropriate for a neurotomy needle?
17 A I think it's a good point to start, and
18 I would go out and canvass physicians that do this
19 and ask them how big can you tolerate and how
20 small can you tolerate, and I think that's how you
21 decide. Those are starting points. 10 to 30.

Tucker's Deficiencies Under (2)

7 Q Dr. Tucker, did you do any engineering
8 calculations to calculate the forces under which
9 Lee's stylets would deform?
10 A No, not for this case. ...

5 Q But for this case, did you do any
6 engineering calculations to determine the forces
7 under which Lee's stylets would break?
8 A No, not at all. I didn't.

8 Q Okay. Did you do any engineering
9 calculations regarding the feasibility of Racz's
10 modified device?
11 A No. ...

13 Q ... do the filaments eventually get to a
14 point where they go into channels in the main
15 cannula sidewall as like shown here on page 85?
16 A Again, I'm not -- I'm not an industrial
17 engineer, but that to me would make more sense.

Person of Ordinary Skill in the Art

Stratus's Experts

158. Quite simply, RF neurotomy needles are 22 gauge through 16 gauge in size. RF neurotomy needles are most typically available in 22, 20, 18, and 16 gauges, although some RF neurotomy needles fall between these sizes.

159. Cannulae larger than 16 gauge (e.g., 10 gauge) or smaller than 22 gauge (e.g., 30 gauge) are not suitable for RF neurotomy because they:

- (a) are not suitably navigable to target nerves; and
- (b) pose too great a risk of harming patients.

228. If Racz's modified device is intended for use in neurotomy, as Dr. Tucker says, then it would have to be as much smaller scale than Lee's device for ablating uterine fibroids. I understand that an RF neurotomy needle must be between 16 and 22 gauge in size. The smaller the gauge number, the bigger the needle. A 16-gauge needle has an outer diameter of approximately 1.651 mm with a wall thickness of 0.229 mm. A 22-gauge needle has an outer diameter of approximately 0.718 mm with a wall thickness of 0.152 mm.

235. I have considered whether a POSITA might have been able to drill the channels in the sidewalls of the tip/needle in Racz's modified device, as proposed by Dr. Tucker. In my opinion that would be impossible. As an example, consider a 16 gauge needle 5 cm long. The outer diameter is approximately 1.65 mm, the inner diameter (through which the RF probe is inserted) is approximately 1.19 mm, leaving a wall thickness of approximately 0.22 mm. Assuming a stylet diameter of 0.1 mm, a POSITA would have to solve the problem of drilling a 0.1 mm diameter hole at least 5 cm long down a 0.22 mm thick sidewall while keeping the hole centered in the sidewall over the whole length.

Experts Say Lee is Not Analogous Art

172. Lee is not concerned with RF neurotomy, whereas Fitz and Racz are. This is a significant difference. RF neurotomy is a particular special case of RF ablation with several notable differences.

173. First, RF neurotomy devices and the nerves they target are considerably smaller than most other RF ablation devices and the tissues they target. This has significant ramifications on the design of RF neurotomy devices as compared to other RF ablation devices. The space constraints of RF neurotomy devices sometimes precludes designs that may be possible only in larger devices.

174. While it can be desirable to increase the ablation volume for both RF neurotomy and non-neurotomy applications, that desire is animated by different considerations. In tumour ablation, for example, a larger ablation volume is desirable because complete ablation of the entire tumour is the clinical objective, even if that means some collateral damage to nearby tissue. Indeed, in cancerous tumour removal or treatment, including RF ablation, the clinicians and surgeons often refer to “margins” to excise or treat a tumour. That refers to extra tissue surrounding the tumour. In RF neurotomy, on the other hand, the reason for desiring increased ablation volume is to increase the likelihood that the relatively tiny nerve tissue targets are not missed during the ablation. Indeed, in RF neurotomy, it is almost uniformly undesirable to ablate beyond the target nerve in order to avoid damaging other nerve structures that can be located nearby (see, e.g., the discussion above).

• • •

181. It is my opinion that Lee has limited or no relevance to Racz and Fitz.

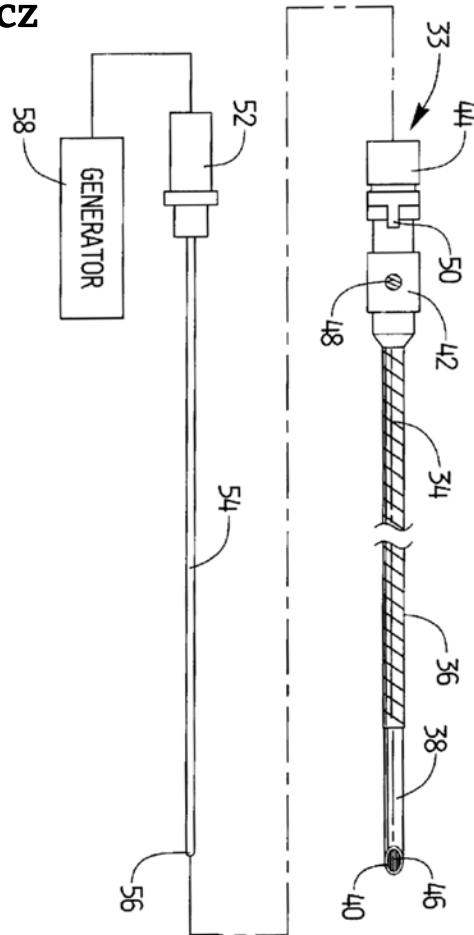
157. Given the differences between RF neurotomy and other fields of RF ablation, a POSITA would not have been reasonably likely to find Lee at all in a literature search. If a POSITA did become aware of Lee, the POSITA would likely dismiss Lee as irrelevant to the field of RF neurotomy. If a POSITA were to consider Lee at all, the POSITA would give little weight to Lee’s teachings because of the limited relevance of other types of RF ablation to RF neurotomy

158. It is also my opinion that a POSITA would not consider Lee reasonably pertinent to the specific problem of increasing ablation volume for RF neurotomy. Lee’s solution to a similar problem for RF ablation of uterine fibroids is not readily applicable to RF neurotomy because of the differences in, for example, needle size, target tissue size, surrounding tissue type. For example, I understand that the needles used for RF neurotomy are 16 gauge maximum and often smaller. Also, a POSITA would consider Lee’s stylets inappropriate for use in RF neurotomy because, for example, they would be too fragile and/or deformable if they contact bone, such as spinal bones near the most common (by far) neurotomy sites. If a POSITA in search of a way to increase ablation volume for RF neurotomy were to come across Lee (which is unlikely for reason I explain above), the POSITA would, at most, take from Lee the general idea of deployable stylets but not Lee’s implementation of deployable stylets. In that sense, Lee is cumulative to Fitz, which also discloses the general idea deployable electrodes to increase ablation volume. But a POSITA would still be left wondering how to incorporate that general idea into an RF neurotomy needle in a workable way. Neither Fitz nor Lee teaches that.

Inadequate Motivation to Combine

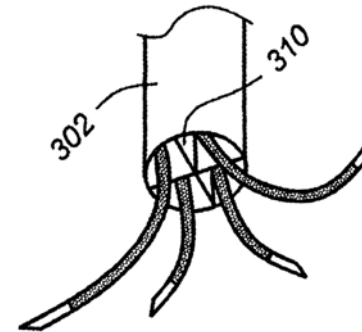
Filament-less devices with
removable RF probes for distal
energization

Racz

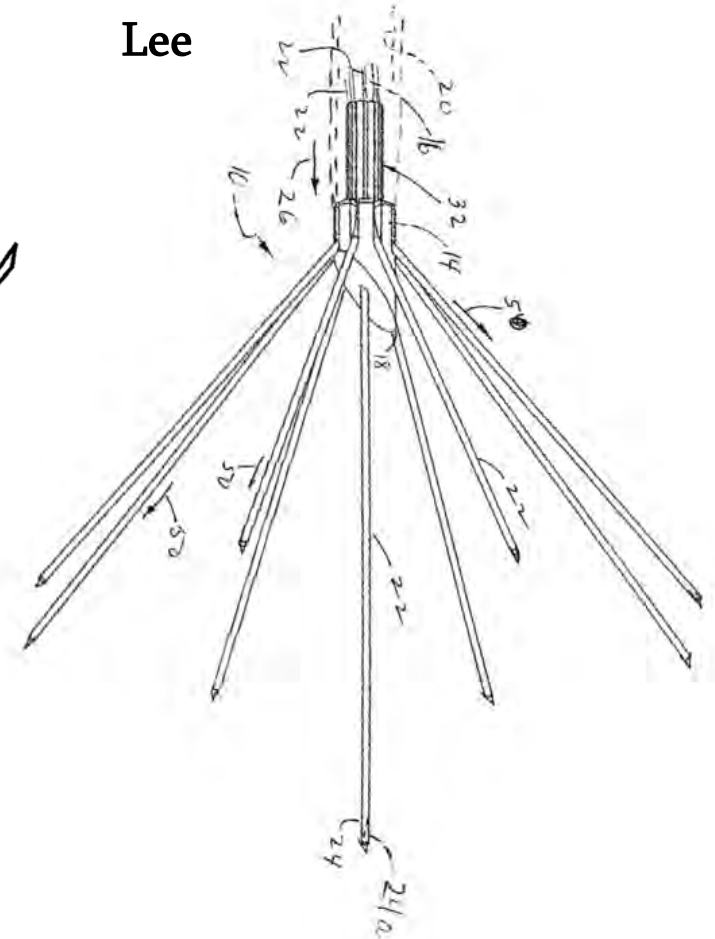


Probe-less filamented devices in which deployable
filaments are energized at the proximal end

Fitz



Lee



1. Racz: Deployment of a flexible electrode from an RF neurotomy cannula
2. Racz: Straightening of RF disclosed tip
3. Lee: Omission of anchors, where tines deployed simultaneously

Racz Teaches Away from Deployable Electrodes Like RMD's

Stimulation and high frequency electrodes having expandable and flexible curved tips are known. Examples of such electrodes are the TEW Electrode Kit and the ZHK Electrode Kit, both manufactured by Radionics. Those electrodes both have flexible, curved tips, which extend from the straight shaft of an enclosing cannula to extend off-axis in an arc. This is useful in certain neural regions such as the trigeminal ganglion or the pituitary gland, or any area where the target region is very soft or fluid filled. Such flexible off-axis electrodes have a limitation that their tips cannot penetrate tough tissue or encounter hard bone without being damaged or diverted.

Parts of System Criticized by Racz	Corresponding Feature of Racz's Modified Device
"enclosing cannula"	Racz's needle body
"straight shaft"	the proximal portion of Racz's needle body
"flexible electrodes" . . .	Lee's electrodes that extend through the sidewall of Racz's needle body
. . . that "extend off-axis" "from the straight shaft of [the] enclosing cannula"	Lee's electrodes extending out of the shaft, as depicted in the renditions, extend off axis relative to the Racz needle

Racz Teaches Away from Deployable Electrodes Like RMD's ⁴¹

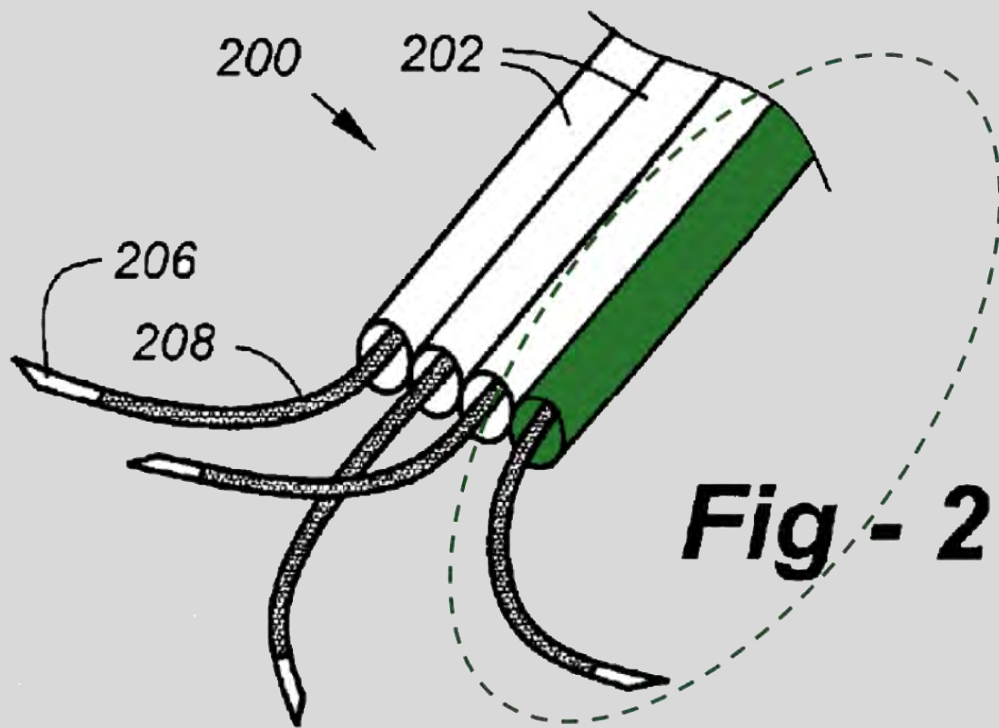
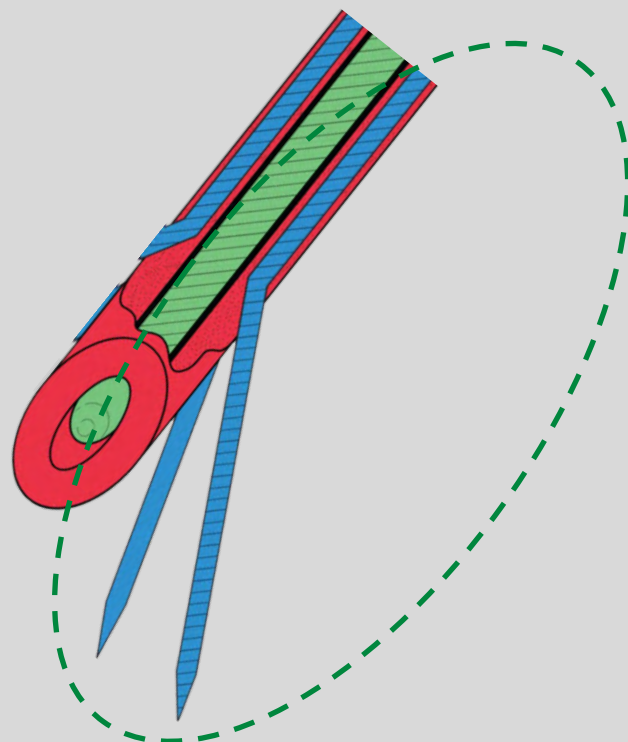


Fig - 2

Fitz (Annotated)



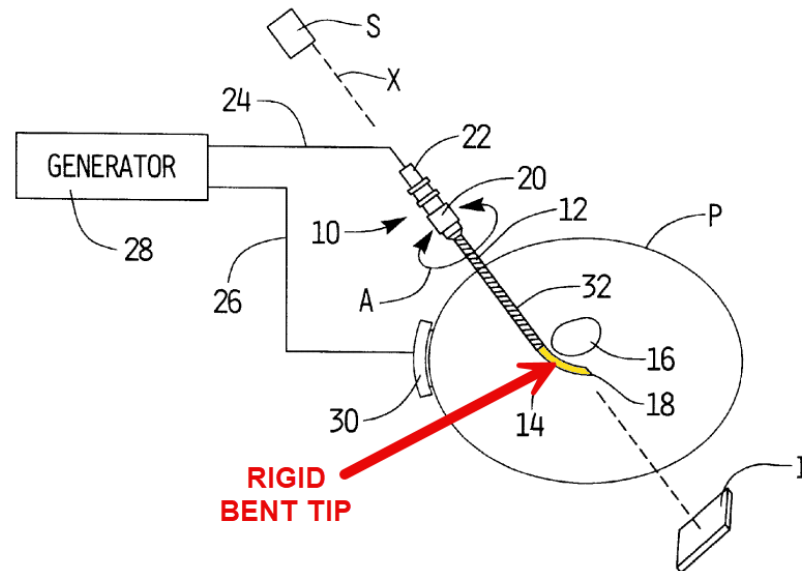
Radionics TEW Kit



RMD

Racz Teaches Away from a Straight Tip

United States Patent [19]		[11] Patent Number:	6,146,380
Racz et al.		[45] Date of Patent:	Nov. 14, 2000
[54] BENT TIP ELECTRICAL SURGICAL PROBE		5,433,739 7/1995 Sluijter et al.	607/99
[75] Inventors: Gabor B. Racz , Lubbock, Tex.; Phillip Finch , Parkerville, Australia		5,605,539 2/1995 Buelna et al.	606/49
[73] Assignee: Radionics, Inc. , Burlington, Mass.		5,807,395 9/1998 Mulier et al.	606/41
		FOREIGN PATENT DOCUMENTS	
[21] Appl. No.: 09/004,992		1391626 4/1988 U.S.S.R.	606/41
[22] Filed: Jan. 9, 1998		Primary Examiner—Lee Cohen	
[51] Int. Cl. ⁷		[57] ABSTRACT	
[52] U.S. Cl.		A medical needle or cannula for stimulation or ablation includes a rigid bent tip for simplified placement at target sites within a patient's anatomy. The curved tip or shaft is used to steer the device within the patient's body and to avoid critical anatomical structures. The device is partially insulated and has a tip that is at least partially electrically exposed; a connection to an external signal generator provides electrical stimulation or high-frequency heating of the patient's tissue proximal to the exposed tip. The device includes a longitudinal passage to facilitate the injection of fluids or the insertion of instruments through the cannula or needle.	
[58] Field of Search		12 Claims, 2 Drawing Sheets	
[56] References Cited			
U.S. PATENT DOCUMENTS			
3,828,780 8/1974 Morrison, Jr.			
3,943,932 3/1976 Woo			
4,301,802 11/1981 Poler			
4,411,266 10/1983 Cosman			



6,146,380		9		10	
ration may be devised. Moreover, the curvature of the tip may be permanently established upon manufacture of the device, or in an alternative embodiment, may be modified by bending a semi-malleable structure at the time of surgery by the clinician. A family of needles or cannulae with different geometries may be created according to the invention.		It should be noted that the terms needle, probe, cannula, etc. as used herein all denote medical and surgical tools that can accommodate the bent tip structure disclosed and claimed. There is no intention to restrict any particular embodiment of the invention to fewer than all of the foregoing implements. Furthermore, certain exemplary clinical applications have been discussed herein as those in which the invention can be successfully employed to the clinician's advantage. However, the invention is not limited to use in such applications, and other medical and surgical procedures would be apparent to a practitioner of ordinary skill.		4. The cannula of claim 1, wherein the distal tip portion defines a blunt end.	
Thus, while certain exemplary structures and operations have been described, the invention is not so limited, and its scope is to be determined according to the claims set forth below.		What is claimed is:		5. The cannula of claim 4, wherein the blunt end is closed to fluid flow.	
1. A hollow cannula for insertion into a patient's body and adapted to receive an electrical signal from a signal generator to be transmitted to a target region in the patient's body, comprising:		an electrically insulated elongated shaft defining a longitudinal passage;		6. The cannula of claim 5, wherein the longitudinal passage is adapted to pass a fluid flow, and wherein the distal tip portion defines a radial window adapted to allow fluid passage for delivery to the patient's body.	
a distal tip portion coupled to the elongated shaft, the distal tip portion defining an aperture in communication with the longitudinal passage, the aperture adapted to allow introduction of fluid into the patient's body; and		an electrical connection for receiving the electrical signal, the electrical connection coupled to the distal tip portion;		7. The cannula of claim 1, wherein the electrical connection comprises a probe adapted to be received by the shaft.	
wherein the distal tip portion includes an uninsulated, rigidly bent portion to facilitate placement of the distal tip portion at the target region, and wherein at least a portion of the distal tip portion comprises an electrically conductive surface that defines a treatment area.		2. The cannula of claim 1, further comprising a hub mounted at a proximal end of the shaft remote from the distal tip portion, wherein the hub includes a marker to indicate the orientation of the bent portion when the cannula is inserted into the patient's body.		8. The cannula of claim 1, wherein the elongated shaft comprises a metal tube.	
3. The cannula of claim 1, wherein the distal tip portion defines a sharp end to facilitate insertion into the patient's body.		10. The cannula of claim 1 where the rigidly bent portion is curvilinear.		9. The cannula of claim 1 where the rigidly bent portion is defined by a radial arc.	
12. An instrument for transmitting an electrical signal to a target region in a patient's body, comprising:		an electrically insulated elongated shaft;		11. A hollow cannula for insertion into a patient's body and adapted to receive an electrical signal from a signal generator to be transmitted to a target region in the patient's body, comprising:	
a distal tip portion coupled to the elongated shaft, the distal tip portion defining an aperture in communication with the longitudinal passage, the aperture adapted to allow introduction of fluid into the patient's body, wherein the distal tip portion includes an uninsulated, rigidly bent portion to facilitate placement of the distal tip portion at the target region, and wherein at least a portion of the distal tip portion comprises an electrically conductive surface that defines a treatment area; and		an electrical connection for receiving the electrical signal, the electrical connection coupled to the distal tip portion.			

Petitioner's Characterization of Racz's Bent-Tip Teachings

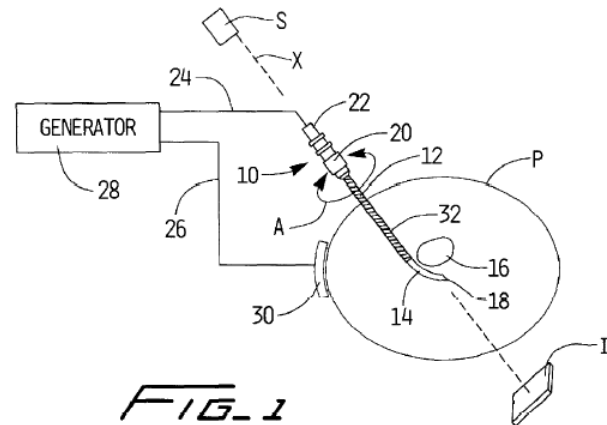
43

Regardless, Racz's bent tip is useful in "difficult-to-reach" areas of the spine—not in all neurotomy applications. Ex-1009, 2:3-25, 2:39-41. Straight-tip neurotomy needles were well-known and effective. Ex-1046, 44:16-45:13; Ex-1009, 1:43-2:2. At most, Racz suggests a preference for a bent tip in limited scenarios but never requires it. Ex-1045, 129:15-131:2, 133:17-134:10. Likewise, Lee is unequivocal that its anchors are optional. Ex-1010, ¶¶0090; 0104. This is not 2017) (expressing a "preference" without criticizing, discrediting, or discouraging investigation "into the claimed invention" is not teaching away).

Experts Say Racz Teaches Away from a Straight Tip

A. Racz

97. The title of Racz is “Bent Tip Electrical Surgical Probe.” Racz explains that the purpose of the invention is to deliver “anesthesia, pain relief, or other treatment involving a firmly curved tip needle electrode” (Racz 2:45-47). The basic invention is a single metal tube with a bent tip, and a single lumen through which fluids or a probe may be introduced. This is illustrated in Racz Fig. 1, reproduced below:



98. The tip is non-insulated, and the remainder of the needle is insulated. The bend at the tip is the *raison d’etre* of the invention. As Racz explains, “A further advantage of using a small-gauge spinal needle with a curved or bent distal end is that it can be accurately steered into narrow and relatively difficult-to-access portions of a patient’s spine” (Racz 6:59-63). The invention involves “a firmly curved tip needle electrode.” (Racz 2:46-48) Each of the three independent claims recite “wherein the distal tip portion includes an uninsulated, rigidly bent portion to facilitate placement of the distal tip portion at the target region.”

1. Racz’s Curved Tip

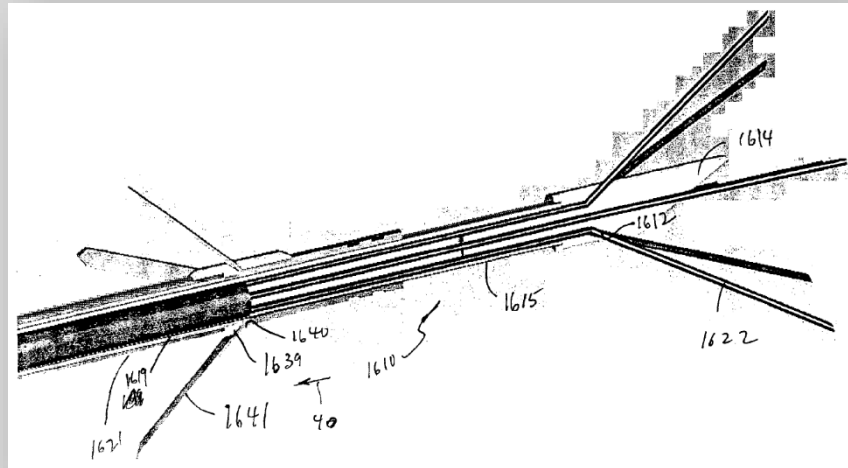
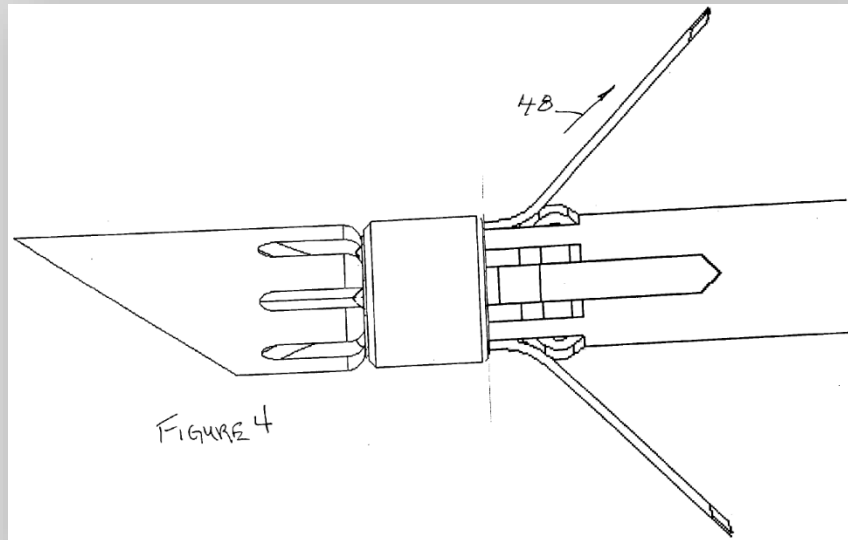
151. The focus of Racz’s disclosure is that straight RF neurotomy electrodes, such as the SMK Needle, are deficient and thus a permanently bent tip at the distal end of the cannula is a necessary improvement. *See id.* at 1:25-67; 2:1-43. In view of Racz’s disparagement of such straight electrodes and Racz’s insistence of the need for a “firmly curved tip needle electrode,” it is my opinion that a POSITA would understand that (a) Racz’s devices, and any variations thereof, require a permanently bent tip and (b) this permanently bent tip must have some degree of curvature—it cannot be a straight. *See id.* at 2:45-67; 3:1-15.

152. Thus, when Racz states that “[t]hose individuals skilled in the art will recognize that many variations of the electrode geometries depicted in FIGS. 1-3 are possible without departing from the invention. . . . [t]he shape and degree of tip curvature may vary widely,” this means that variations of Racz’s electrode geometries must have *at least some* curvature at the tip. *Id.* at 8:10-16.

153. A POSITA would understand that elimination of a curve from the tip of Racz’s needle would effectively remove Racz’s invention from Racz’s needle. As reflected even in the very title of Racz, the invention of Racz is a “BENT TIP.” *Id.* at [title].

154. Stated otherwise, a POSITA would not see elimination of *all* curvature from Racz’s tip as an option when varying Racz’s “electrode geometries” because this variation would constitute a wholesale departure from Racz’s invention. *See id.* at 8:10-16.

Lee Teaches Away from Anchor Removal



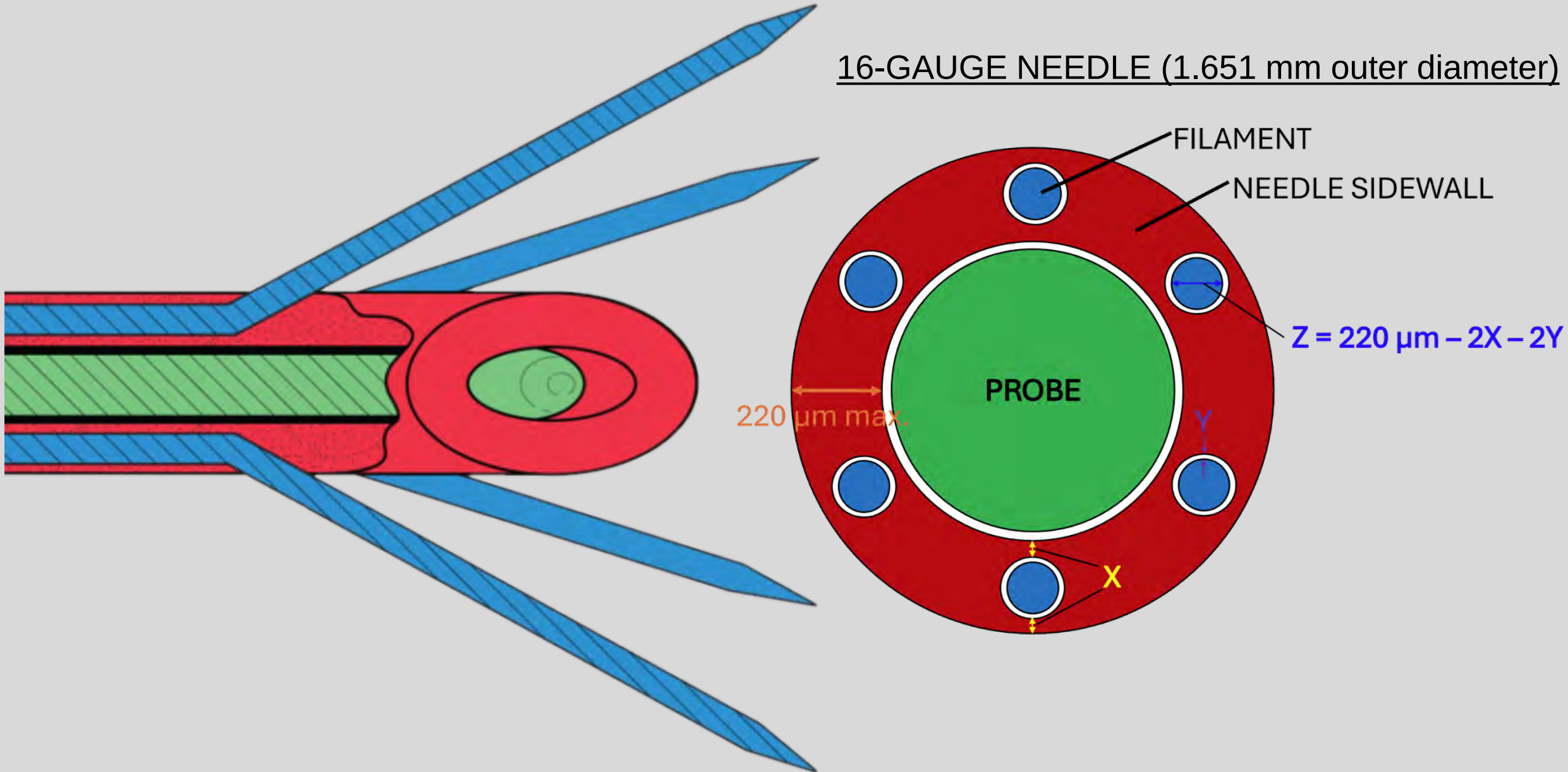
[0102] As the anchors are advanced with their tips moving in the direction indicated by arrow 48, they pierce the surrounding tissue and thus anchor the trocar point 14 against retrograde motion when stylets 22 are advanced. The stylets are advanced by causing them to move from the position illustrated in FIG. 3 in the directions of arrow 26. This causes them to bear against delivery mandrel surfaces 12, deflecting them laterally and outwardly in the directions indicated by arrows 50 (FIG. 1). This results in the distal end of the trocar 10 taking the configuration illustrated in FIG. 1.

[0103] While the arrangement of stylets may be may to form any desired pattern, in the illustrated embodiment, a cone is achieved as can be seen with reference to FIGS. 1 and 5.

[0104] If desired, anchors may first be deployed one at a time to minimize unwanted displacement of the distal end of trocar 10. Likewise, if desired, anchors may not be deployed. An implementation of a use of the inventive trocar 10 without the anchors would be promoted by advancing the ends of stylets 22 one at a time, thus minimizing their tendency to displace the trocar.

Racz's Modified Device

46



No Reasonable Expectation of Success to Make RMD

47

citations omitted). As explained below with respect to Claim 1's limitations, a POSA would have found implementing Lee's deployable filaments (22/1622) on Racz's tip (14/38) to be a matter of routine engineering, well within the level of ordinary skill in the art, and executable with a reasonable expectation of success. Ex-1031, ¶144-148. The resulting device (Racz's cannula modified to include Lee's filaments) would include every limitation of Claims 1-27.

148. As I explained below with respect to Claim 1's limitations, in my opinion, 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. The resulting device (Racz's cannula modified to include Lee's filaments) would include every limitation of Claims 1-27.

Dr. Tucker on Reasonable Expectation of Success to Make RMD

- He disavowed responsibility for making RMD.
 - “I’m not a manufacturing engineer I think a person of ordinary skill in the art that’s a manufacturing guy would know how to do that.” Tucker Dep. Tr. (Ex. 2020) 87:15-88:1.
 - “I don’t know, Matt, I’m not an engineer. That is a manufacturing engineer.” *Id.* 131:10-11.
 - “I’m not an industrial engineer.” *Id.* 133:16-17.
- He never consulted with a manufacturing engineer. *Id.* 88:2-5.
- A POSITA, according to his definition, need not have any manufacturing experience. *Id.* 88:20–89:9.
- He did not attempt to build an example of RMD. *Id.* 89:20-90:2.
- According to him, this is not a case about manufacturing patents:
 - “[T]his is not a manufacturing patent.” *Id.* 88:4-5.
 - “[T]hese aren’t manufacturing patents.” *Id.* 159:10
 - “Man, Matt, come on. This is not a manufacturing patent.” *Id.* 130:6-7
 - “[N]o comment on making it. If they had a manufacturing patent, we could talk about manufacturing. But it’s not.” *Id.* 178:5-7.
 - “I have no comments on manufacturing.” *Id.* 180:3.
- But, he admitted that not every design on paper can be physically realized. *Id.* 179:8-14.

Crosby on Reasonable Expectation of Success to Make RMD ⁵⁰

- Peter Crosby **explained** how no known techniques would reasonably be expected to make the filament channels in Racz's modified device:
 - Machine drilling (Crosby Decl. ¶¶ 235-245)
 - Laser drilling (*Id.* ¶ 238)
 - Drawing (*Id.* ¶ 246)
 - Casting (*Id.* ¶ 248)
 - Sintering (*Id.*)
 - Injection molding (*Id.* ¶ 249)
 - Extrusion (*Id.* ¶ 250)
 - 3D printing (*Id.* ¶ 251)
- Not possible at length of neurotomy needle (at least 5 cm) (*Id.* ¶ 243)
- Even more impossible with a bent tip (*Id.* ¶¶ 244, 247)
- Needle sidewall would be structurally too weak (*Id.* ¶ 239)
- The petitioner offered no contrary expert testimony

Reasonable Expectation of Success – Racz on Needle Size

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10 Those individuals skilled in the art will recognize that
many variations of the electrode geometries depicted in
FIGS. 1–3 are possible without departing from the inven-
tion. Various sized electrodes can be made, from extremely
15 small gauges (e.g., 30 gauge) to much larger sizes (e.g., 10
gauge). Also, the shape and degree of tip curvature may vary
widely. The shape of the tip and the extent of insulation vs.
exposed electrode can be variable, depending on the appli-
cation. For example, in FIGS. 1 and 2, the exposure of the
20 tip 14 or 38 may be only on one side of the cannula to
facilitate directional stimulation or ablation; the exposed
portion of the tip need not extend all the way around the tip
azimuthally.

It should be noted that the terms needle, probe, cannula,
etc. as used herein all denote medical and surgical tools that
can accommodate the bent tip structure disclosed and
claimed. There is no intention to restrict any particular
10 embodiment of the invention to fewer than all of the
foregoing implements. Furthermore, certain exemplary
clinical applications have been discussed herein as those in
which the invention can be successfully employed to the
clinician's advantage. However, the invention is not limited
15 to use in such applications, and other medical and surgical
procedures would be apparent to a practitioner of ordinary
skill.

Reasonable Expectation of Success – Dr. Russo on Needle Size⁵²

158. Quite simply, RF neurotomy needles are 22 gauge through 16 gauge in size. RF neurotomy needles are most typically available in 22, 20, 18, and 16 gauges, although some RF neurotomy needles fall between these sizes.

159. Cannulae larger than 16 gauge (e.g., 10 gauge) or smaller than 22 gauge (e.g., 30 gauge) are not suitable for RF neurotomy because they:

- (a) are not suitably navigable to target nerves; and
- (b) pose too great a risk of harming patients.

160. In the case of cannulae that are larger than 16 gauge (e.g., 10 gauge), the cannulae are:

- (a) too stiff to navigate within the constraints of the relevant anatomy; and
- (b) so large that they damage delicate anatomic structures through which they pass when being advanced to a target nerve.

For reference, a 10-gauge needle has a diameter larger than one tenth of an inch.

161. In the case of cannulae that are smaller than 22 gauge (e.g., 30 gauge), the cannulae are:

- (a) insufficiently stiff to navigate predictably and consistently to target nerves, which are notoriously difficult to target even when using needles having an appropriate stiffness; and
- (b) so delicate that they risk bending or breaking in manners that can damage tissue or, in the case of breaking, deleteriously leave a shard within the patient, which on top of any immediate negative effects, could additionally prevent the patient from undergoing future MRIs in ongoing care.

For reference, a 30-gauge needle has a diameter of about one hundredth of an inch.

Reasonable Expectation of Success – Needle Size

Tullis

Length (mm) of Contact 62, Ins. Ring 69, Contact 68	Equivalent Active Tip Length (mm)	Bipolar Cannula Diameter	
2.3, 1.3, 9	2.5	20G	20
3.5, 15, 10	2.5	20G	
2, 2, 2	5.0	20G	
3.5, 2.5, 6	5.0	20G	
2.8, 2.8, 2.8	7.5	20G	
5, 4, 5	10	20G	25
6, 5, 6	15	20G	

It should be appreciated that the above 20 G (20 Gauge) diameter is the outer diameter of the insulating outer sleeve 56. This diameter is exemplary, not limiting. Other cannulae of this invention, both monopolar and bipolar, may have outer diameters ranging from 12 G to a smaller diameter 26 G. For electrode assemblies 24 used for denervation procedures, the diameter of the cannula 28, which is the diameter of the supply electrode assembly 36, is preferably 16 G or more and more preferably 18 G or more.

Cosman

1. In one example, the tubing 1 can be a rigid metal tubing. The diameter of the tubing can suit the clinical application. For example, for treatment of nerves near the spinal cord, dorsal root ganglia, or medial branches of the neck, the tubing can be in the range of 0.5 millimeters or less up to 1.5 millimeters or more, depending on the size of the neural target structure. In another example for nerves in the lumbar region, the diameter of the tubing can be in the range of 1 to 2 millimeters, according to the target site. In one example, for spinal high frequency treatment of pain, the tubing can range in gauge size from 23 gauge for the smaller range to 22, 20, 19, 18, 17, or 16 gauge for larger target sites. In the example of high frequency heat ablation of cancerous tumors throughout the body, the diameter of metal tubing 2 can range from 0.5 millimeters to 3 millimeters or larger. The length of the cannula shaft 1 can vary depending on the depth of target tissue in the body. Electrodes of 1 to 5 centimeters in shaft length can be appropriate for shallow targets such as in the neck. In another example, shafts of 5 to 15 or 20 centimeters are appropriate for deeper spinal targets. In another example for tissue ablation, shafts of 100 to 400 or more millimeters are appropriate.

Reasonable Expectation of Success – Needle Size

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Godara

[0040] The size and shape of probe 100 may vary depending on the application, and the invention is not limited in this regard. For example, in some embodiments, the transverse cross sectional shape of probe 100 may be substantially circular. In other embodiments, the cross-sectional shape may be substantially polygonal, elliptical, or any other desired shape. In some embodiments, the length from distal end 106 to proximal end 110 of probe 100 may be between about 5 cm and about 40 cm and the outer diameter of shaft 122 may be between about 0.65 mm and about 2.00 mm (between about 20 AWG and about 12 AWG). In one specific example, the length of the probe may be about 7.5 cm, the outer diameter may be about 1.5 mm, and the transverse cross-sectional shape may be substantially circular. The shape of distal end 106 may vary depending on the application. Possible shapes include, but are not limited to, blunt, rounded, sharp, and beveled.

Godara

[0138] In addition to the treatment of pain-causing conditions, methods and devices of the present invention may be used for other applications, such as cardiac ablation, for example in cases of atrial tachycardia, is removal or treatment of scar tissue, treatment of varicose veins, treatment of hyperparathyroidism, and ablation of malignancies or tumours, for example in the lung, liver, or bone. In general, these conditions may be treated by lesioning at least one target site associated with a symptom or cause of a patient's condition. For example, in the case of atrial tachycardia, devices and methods of the present invention may be used to form a lesion at the His Bundle region of the heart. In the case of hyperparathyroidism, devices and methods of the present invention may be used to form a lesion at one or more parathyroid glands.

Reasonable Expectation of Success – Needle Size

Shealy

The technique for radiofrequency facet denervation: Prior to the procedure, lateral and AP roentgenograms of the lumbar spine are taken to locate the facets. Obliques are also helpful in demonstrating the degree of osteoarthritic change. The patient is placed prone on a fluoroscopy table, the back is prepared and draped as for a myelogram. The patient is alert and should be able to discuss with the surgeon sensations during the procedure and thus is given only mild pre-operative sedation. The patient's legs are usually wrapped with elastic bandages to prevent vasovagal hypotension during the procedure. The facets that are to be tested for possible denervation are located under X-ray guidance and 1 per cent lidocaine is placed intradermally in the site above each

facet in question. A #12 gauge special thin-walled needle with a solid stylet is introduced directly through the skin and muscle to touch the facet. In most patients this would be carried out at L3–4, L4–5, and L5–S1 bilaterally. The radiofrequency probe is then advanced through the needle, the needle is drawn back up the shaft of the electrode and out of the skin. The radiofrequency electrode is electrically insulated along its shaft except for a 7 mm exposed tip (Fig. 1). The RF electrode is now manipulated over the edge of the facet, down to the depth of the intertransverse ligament and approximately lateral to the center of the facet (Fig. 2). The elastic resilience of the intertransverse ligament is very distinctly felt, but a lateral roentgenogram or a C-arm fluoroscope will confirm the depth of the electrode.

Reasonable Expectation of Success – Needle Size

56

'782 Patent

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

Reasonable Expectation of Success – Kalpakjian

57

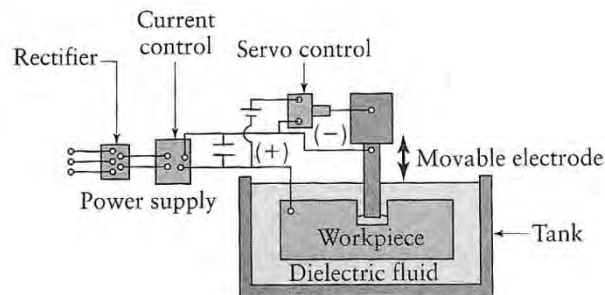
Stratus's remaining hodgepodge of arguments are equally flawed. Crosby offers *unsupported* assertions about the ineffectiveness of nitinol filaments (Ex-2006, ¶¶276-282) and the inability to manufacture the Petition's combination (Ex-2006, ¶¶221-260). This testimony is entitled to no weight. 37 C.F.R. § 42.65(a). Moreover, Mr. Crosby's calculations on filament strength are completely wrong. Ex-2006, ¶¶276-279 (using bending moment formula); Ex-1045, 258:1-263:12 (Crosby thought he was calculating Euler moment); Ex-1062, 342-343 (bending moment formula Crosby used), 748 (different Euler formula). And an engineering textbook refutes Crosby's testimony that the proposed combination would be "impossible" to manufacture. Ex-2006, ¶¶234-253; Ex-1063, 541, 546 (EDM and LBM allow for 0.1mm and 0.005mm precision, respectively).

9.13 Electrical-Discharge Machining

The principle of *electrical-discharge machining* (EDM), also called *electrodischarge* or *sparkerosion machining*, is based on erosion of metals by spark discharges (Table 9.4). We know that when two current-conducting wires are allowed to touch each other, an arc is produced. If we look closely at the point of contact between the two wires, we note that a small portion of the metal has been eroded away, leaving a small crater. Although this phenomenon has been known since the discovery of electricity, it was not until the 1940s that a machining process based on this principle was developed. The EDM process has become one of the most important and widely accepted production technologies in manufacturing industries.

The EDM system (Fig. 9.32) consists of a shaped tool (**electrode**) and the workpiece, which are connected to a dc power supply and placed in a **dielectric** (electrically

FIGURE 9.32 Schematic illustration of the electrical-discharge-machining process.

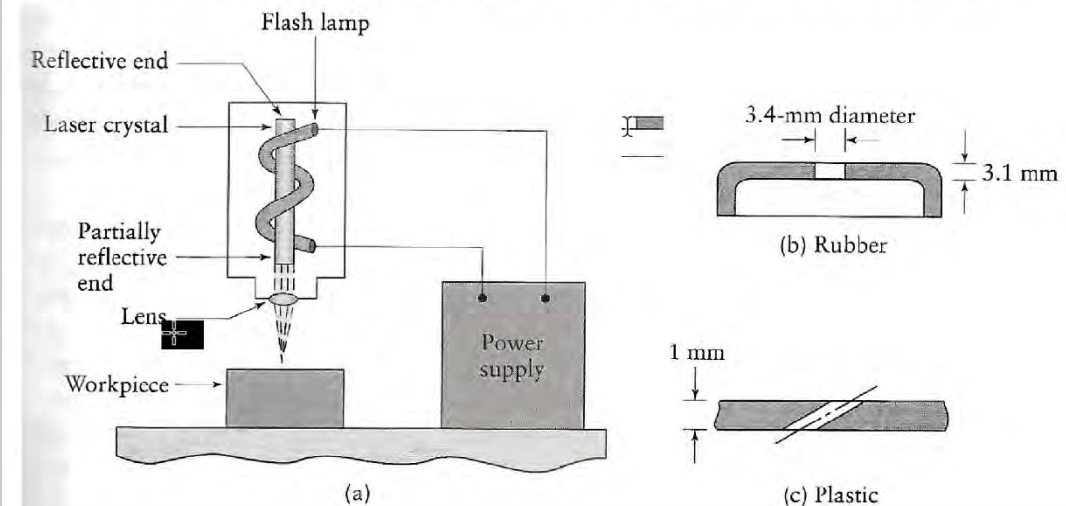


Electrodes for EDM are usually made of graphite, although brass, copper, or copper-tungsten alloy may be used. The tools are shaped by forming, casting, powder metallurgy, or machining. Electrodes as small as 0.1 mm (0.005 in.) in diameter have been used. Tool wear is an important factor, since it affects dimensional accuracy and the shape produced. Tool wear can be minimized by reversing the polarity and using copper tools, a process called **no-wear EDM**.

9.14 High-Energy-Beam Machining

9.14.1 Laser-beam machining

In *laser-beam machining* (LBM), the source of energy is a laser (an acronym for *Light Amplification by Stimulated Emission of Radiation*), which focuses optical energy on the surface of the workpiece (Fig. 9.36a). The highly focused, high-density energy melts and evaporates portions of the workpiece in a controlled manner. This process, which does not require a vacuum, is used to machine a variety of metallic and nonmetallic materials. There are several types of lasers used in manufacturing operations.



Laser-beam machining is used widely in cutting and drilling metals, nonmetals, and composite materials (Figs. 9.36b and c). The abrasive nature of composite materials and the cleanliness of the operation have made laser-beam machining an attractive alternative to traditional machining methods. Holes as small as 0.005 mm (0.0002 in.), with hole depth-to-diameter ratios of 50 to 1, have been produced in various materials, although a more practical minimum is 0.025 mm (0.001 in.). Extreme caution should be exercised with lasers, as even low-power lasers can cause damage to the retina of the eye if proper precautions are not observed.

9.16 | Design Considerations

The important design considerations for the processes and operations described in this chapter are outlined as follows:

In electrical-discharge machining, the bulk of the workpiece should preferably be preshaped by other processes to reduce machining time; deep slots and narrow openings should be avoided; and, for economic production, the surface finish specified should not be too fine.

3. **High-energy-beam processes.** Any adverse effects of the processes on surface finish and integrity should be considered. In laser-beam machining, dull and unpolished workpiece surfaces are preferable, and designs should avoid deep cuts or very sharp profiles. In electron-beam machining, part size and shape are limited by the size of the vacuum chamber, and if a part requires machining on only a small portion, consideration should be given to making the part in a number of small components.

9.16.6 Laser- and electron-beam machining

1. Designs with sharp corners should be avoided since they can be difficult to produce.
2. Deep cuts will produce tapered walls.
3. The reflectivity of the workpiece surface is an important consideration in laser-beam machining; dull and unpolished surfaces are preferable.
4. Any adverse effects on the properties of the machined parts caused by high local temperatures and heat-affected zone should be investigated.

Fed. Rule Evid. 106

Remainder of or Related Writings or Recorded Statements.

If a party introduces all or part of a statement, an adverse party may require the introduction, at that time, of any other part — or any other statement — that in fairness ought to be considered at the same time. The adverse party may do so over a hearsay objection.

No Reasonable Expectation of Success to Use RMD

61

278. As an example, the ultimate yield strength of Nitinol (the material suggested by Dr. Tucker) can be as high as 895 MPa. In comparison, for this exercise, I assume a yield strength of 1000 MPa to simplify the calculations. If the filaments are 0.2 mm in diameter as suggested by Dr. Tucker (Ex. 1031 Tucker Decl. ¶228), then the radius is 0.1 mm = 10^{-4} m, then the section modulus S is calculated to be $((\pi \times (1 \times 10^{-4})^3) / 4) = 7.85 \times 10^{-13} \text{ m}^3$. Assuming a filament length of 10 mm and a potential bend point halfway along (5 mm), then the maximum bending force would be $10^9 \text{ Pa} \times 7.85 \times 10^{-13} / 0.005 = 0.1570 \text{ N}$. This is equivalent to 0.016 kg, or a force of 16g or about **half an ounce**. This simply would not work – it is not enough force to penetrate tissue, and a physician could not regulate the applied force with that accuracy.

279. Even if I consider MP35N in place of Nitinol, it would not work. MP35N is a biocompatible metal alloy with a higher yield strength. MP35N can have a yield strength as high as 1793 MPa. If I round up to 2000 MPa to simplify the calculations, the resulting maximum bending force is **just one ounce**. Again, this is much too weak for a physician to achieve reliable deployment of the filaments through the target tissue in a predictable manner. A POSITA with the relevant perspective and understanding of a relevant physician (*i.e.*, an interventional pain-medicine specialist who performs RF neurotomy procedures), would likely consider this to present too great a risk of filament deformation or render it unusable.

215. Moreover, I and other pain doctors would have serious concerns regarding the performance characteristics of tines that are sufficiently small to pass through channels within the sidewall of a 16- to 22-gauge needle. **Tines having such a small cross section present significant risks of being damaged or deflected.** A POSITA would also understand that they would be **incapable of generating a desirable ablation volume.** I address each of these clear drawbacks in turn below.

217. A POSITA would understand “Lee’s Filaments” in “Racz’s modified device” would be so small as to face **significant risks of breakage.** Dr Tucker even suggests that these filaments could be as small as “0.2mm (wide) and 0.05mm (thick).” Ex. 1031 at 88, 143. This is extremely small (just 50 microns thick!) and not practical in real-world applications. **I do not view filaments that are this thin as translating to clinical human safety.**

219. “Lee’s Filaments” in “Racz’s modified device” also would have a **high risk of bending** while passing through tissue or potentially encountering bone, likely **in unpredictable manners.** Such uncontrolled bending is unacceptable for neurotomy, where precisely targeting miniscule targets is necessary, as I have

The references used in an obviousness challenge must collectively teach a POSITA how to make the claimed invention. *See Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989); *Bristol-Myers Squibb v. Ben Venue Labs, Inc.*, 246 F.3d 1368, 1374 (Fed. Cir. 2001). An enabling disclosure requires that one skilled in the art can make and use the invention from the disclosure without undue experimentation. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Problems with Young '965

296. Moreover, the IPR Petitions and Dr. Tucker's declarations state that a "POSA would have recognized that Young '965's shaft (20) could be adapted to deploy and retract Lee's filaments (22/1622) from Racz's device." (IPR2024-01209, Paper 1 at 69; *see also* Ex. 1031 at ¶ 227) This proposal would require a substantial redesign of Racz's modified device, Young '965's shaft (20), or both, yet neither the petitions nor the declarations provide details of how such a redesign could be implemented.

297. In Young '965, the *proximal ends* of the deployable electrodes (26) are connected to the *distal end* of the shaft (20), as shown in both the retracted and deployed positions illustrated in Figures 5 and 6, respectively (reproduced below). Yet in Dr. Tucker's two examples of Racz's modified device, as I understand them, Lee's electrodes extend longitudinally through the sidewall of Racz's needle body, all the way past the proximal end of that needle body. It is not evident how these proximal ends could then be attached to the distal end of the shaft (20), for if the shaft (20) is to function in the same way that it does in Young '965, then its distal end must reside in the general vicinity of the side ports of Racz's modified device in both the retracted and deployed positions (see Figures 5 and 6 below). It is even less evident how distal movement of the shaft (20) would then effectuate distal movement Lee's filaments in this arrangement.

188. If Young '965 were to be redesigned in the manner proposed by Dr. Tucker, such that "the shaft (20) . . . [were to] accommodate Racz's RF probe (22/52)," Racz's temperature sensor would be positioned at the distal tip of Young '965's shaft (20), as shown below in the annotated version of Young '965's Figure 6. Ex. 1031 at ¶ 227.

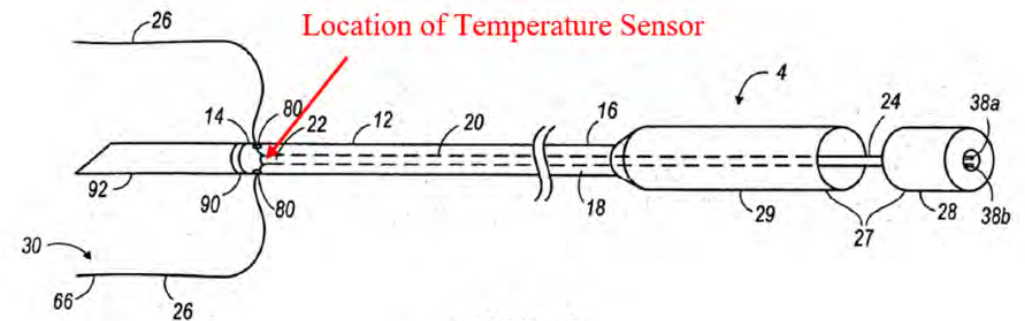
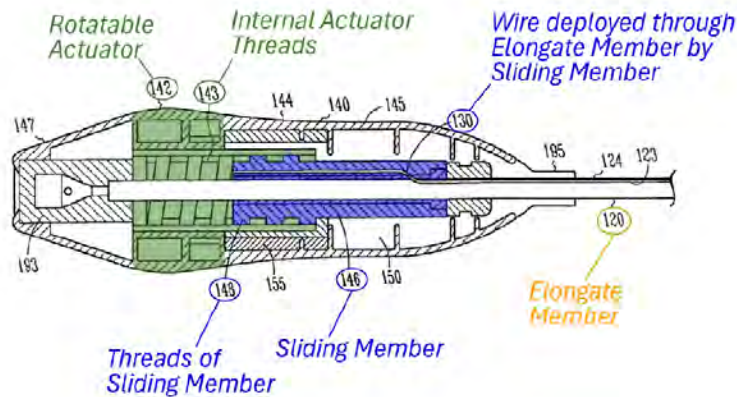
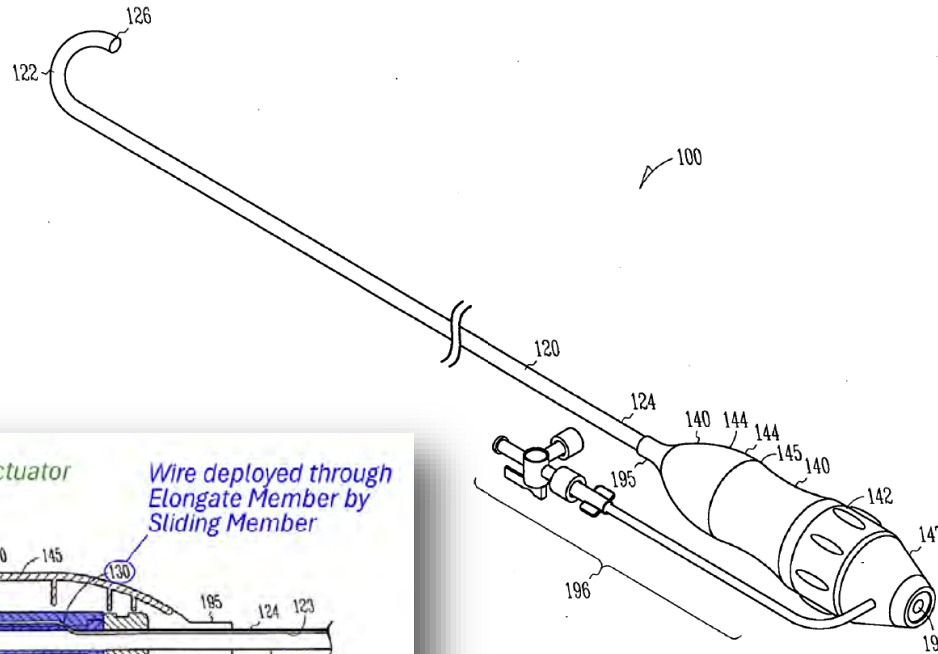


FIG. 6

189. The location of the temperature sensor in Young '965's modified device would not be suitable for RF neurotomy procedures. The temperature sensor would be far from the ablation zone. Moreover, it does not appear that there would be good thermal conductivity from (a) the distal end portion of the cannula (16) that would be positioned within the ablation zone to (b) the temperature sensor.

Problems with Scheibe

Finally, Scheibe notes that its teachings are not limited to catheters and are relevant to “other types of body stimulating systems.” Ex-1013, ¶0037.



Scheibe is even less relevant to Racz and Fitz than are Lee and Young '965.

See Russo Decl. ¶ 190; Crosby Decl. ¶ 298. A deflectable catheter assembly is not in the same field as RF neurotomy needles. See Russo Decl. ¶¶ 191-193. No amount of reliance by the petitioner and Dr. Tucker on a clearly erroneous statement in Scheibe that mischaracterizes “deflectable catheter assemblies” as implantable leads for cardiac stimulation systems can render Scheibe analogous to RF neurotomy devices. See *id.*

Scheibe is indeed non-analogous because it additionally lacks reasonable pertinence to the petition’s stated objectives. A POSITA would not

find a rotational actuator mechanism that is intended to create tension on a “pullwire” that remains fixed within a distal end of a flexible catheter sheath to deflect the sheath, as taught by Scheibe, as being reasonably pertinent to the objective of pushing tines out of a distal end of a stiff cannula.

Objective Indicia of Nonobviousness

65

Objective indicia “can be *the most probative* evidence of non-obviousness” and “avert the trap of hindsight.” *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010) (emphasis added) (citation omitted).

1. Long-Felt-But-Unmet Need
2. Copying
3. Praise
4. Commercial Success

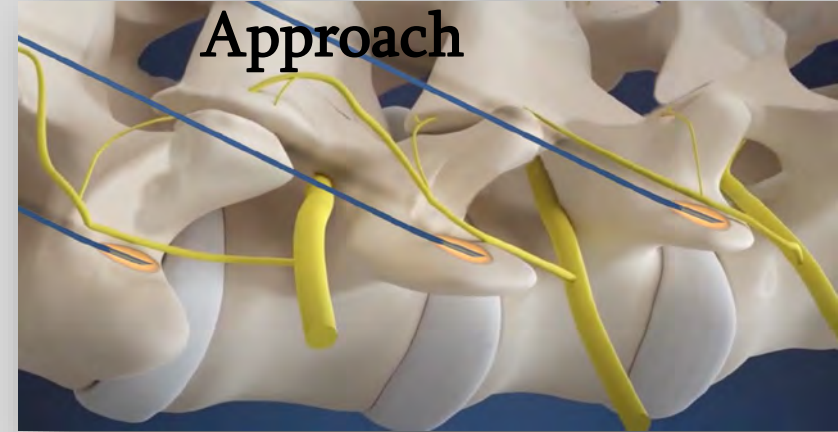
Long-Felt-But-Unmet Need

Stratus's invention satisfies a long-felt need that interventional pain-specialist physicians experienced when performing RF neurotomy. Those physicians needed a simpler, safer, and more reliable way to approach and ablate a target nerve.

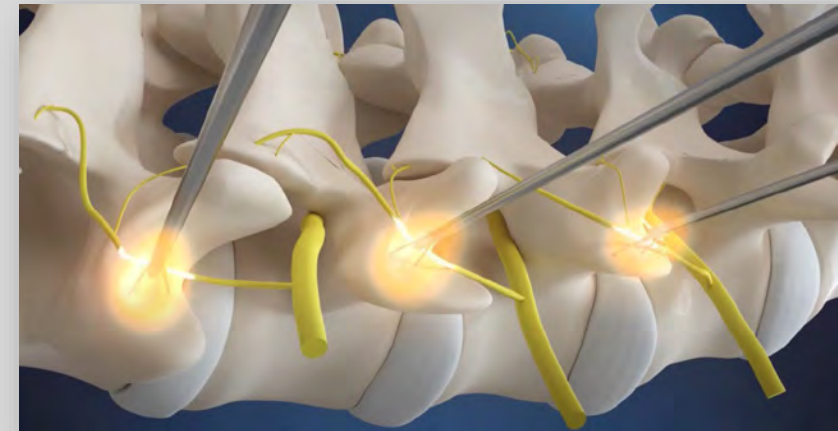
Dr. Russo provides a history of RF neurotomy, *see id.* ¶¶ 89-107, and concludes “the RF neurotomy field experienced somewhat of an ‘ice age’ in terms of product development throughout the 1990s and 2000s.” *Id.* ¶ 115 (emphasis added). He describes introduction of the Nimbus device as “a ‘game changer’ in the RF neurotomy field” because of the deployable/retractable tines that yield a lesion with a unique shape (illustrated below alongside a traditional needle lesion shape). *Id.* ¶ 117 (emphasis added).



Parallel Approach



Perpendicular Approach



Multifidus-Sparing RF Neurotomy Technique

Long-Felt-But-Unmet Need – Perpendicular Approach

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5 Q In your opinion, Dr. Russo, is the NIMBUS
6 device superior to the use of cooled RF with the
7 perpendicular approach?

8 MR. KELLY: Objection, form.

9 THE WITNESS: With the perpendicular
10 approach, the NIMBUS -- yes, it is, because there are
11 times when you wish to do a perpendicular approach, but
12 the anatomy dictates that you need to switch your plan
13 in that individual and go to a parallel approach. And
14 in that scenario, you would not be able to proceed with
15 the operation solely with a cooled RF device at hand.

17 Q As between the NIMBUS device and a cooled RF
18 device, do you have a preference which one you would
19 prefer to use?

20 MR. KELLY: Objection, form.

21 THE WITNESS: Very much so. That's based
22 on variety of factors. The first is cost. Most of the

20 ... The "one more" is related to the fact
21 that I have a subtle ability to determine the exact
22 position and -- and not -- not shape, but the position
23 of the lesion with a NIMBUS, of which I have no control
24 with the cooled RF. So the cooled RF will make a
25 globular spherical lesion. If pushed up against bone,
1 of course it's not a true sphere, because it can't
2 dissolve the bone. So it -- it is -- it is a sphere
3 with a truncated cutoff base, but nevertheless
4 it's -- it's spherical, and I cannot prevent it from
5 being spherical. However, because of the times related
6 to the NIMBUS, I can choose to be exactly perpendicular,
7 and I know the pyramidal globular shape I'll create.

8 But the anatomy may mean that I actually
9 want to be a little bit off perpendicular so that I will
10 then have the globular shape at a slight angle. So I
11 can adapt the globular shape of my lesion to the anatomy
12 I see in front of me. Whereas if I move the cooled RF
13 off exactly perpendicular, it's still a sphere. It's a
14 sphere, it doesn't matter where I do it, it will remain
15 a sphere, because the sphere is what it produces.

16 So I -- I lose the specificity of choice,

1 Exhibit 1015. And my question is -- well, first of all,
2 you say in your declaration that you believe the NIMBUS
3 device was a game changer that brought the RF neurotomy
4 field out of the Ice Age.

5 A Yes.

6 Q Do you remember that?

7 A Yes, yes.

8 Q Okay. So is that still your opinion, even if
9 you assume that those clinicians like yourself, pain
10 specialist physicians, were well aware of the teachings
11 in Godara about the use of -- alleged use of an RF, a
12 cooled RF device, that can be used in a perpendicular
13 approach?

14 MR. KELLY: Objection, form.

15 THE WITNESS: Yes, it is. ...

Long-Felt-But-Unmet Need - MSRFN

can readily be identified to verify placement via X-ray. *See id.* ¶ 126. Alternatively, Dr. Russo has developed a “multifidus-sparing” RF neurotomy technique that does not damage the multifidus muscle during the ablation procedure, and the Nimbus device is especially well-suited for that technique. *See Russo Decl.* ¶¶ 128-136; Ex. 2005.

Moreover, Dr. Russo has developed an improved “multifidus-sparing RF neurotomy technique (MSRFN technique)” using the Nimbus device that cuts by half the number of ablations and X-ray images needed and does not damage the multifidus muscle that runs along the spine. *Id.* ¶¶ 128-133. “The MSRFN technique is not possible with traditional RF needle cannulae that do not have expandable tines” but is well-suited for the invention. *Id.* ¶ 134.

Evidence regarding the MSRFN Technique is *unchallenged*.
See Reply at 21-22; Surreply at 23.

134. The MSRFN technique is not possible with traditional RF needle cannulae that do not have expandable tines due to the narrow prolate spheroid shape and small size of the lesions created thereby, which I have discussed previously. The MSRFN technique also is not possible with cooled RF systems, such as Avanos’s COOLIEF* system, because the lesions created thereby are not the right shape and are oversized.

Long-Felt-But-Unmet Need - MSRFN

128. In addition to enabling the parallel approach for medial branch denervation, the unique properties of the Nimbus Device have empowered further innovations in RF neurotomy and improved RF neurotomy techniques that are beneficial to practitioners and patients.

129. As one example, I have pioneered a new technique for denervation of the facet joint capsule to treat facet-joint pain using the Nimbus Device. This technique is an advantageous alternative to the parallel and perpendicular medial branch denervation techniques previously discussed. I describe this technique, called the multifidus-sparing RF neurotomy technique (MSRFN technique), in my article “Russo et al., *Development and Description of a New Multifidus-Sparing Radiofrequency Neurotomy Technique for Facet Joint Pain*, Pain Practice, 21(7): 747-758 (Apr. 13, 2021).” A copy of this peer-reviewed article is included as Exhibit No. 2005.

130. By targeting the facet joint capsule, the MSRFN technique advantageously avoids denervation of the multifidus muscle, which is thought to be important in recovering from low back pain. The medial branches targeted in the parallel and perpendicular approaches supply not only the facet joint, but also the multifidus muscle, and there is good evidence that conducting RF neurotomy using these approaches denervates this muscle. In most patients—generally, those under 70 years of age—it is desirable to preserve the multifidus muscle, as this may assist with rehabilitation after a procedure.

131. Moreover, because the parallel and perpendicular approaches target the medial branches of the dorsal root that supplies the facet joint, two separate ablations above and below a facet joint are required. By instead targeting the facet joint capsule in the MSRFN technique, only a single ablation is required to achieve the same denervation objectives. The MSRFN technique is thus quicker and easier to perform, reduces radiation exposure to both the practitioner and patient, and can reduce the patient’s discomfort.

132. The MSRFN technique is also simpler because only a single fluoroscopic view (30 degrees ipsilateral oblique) is needed, whereas other techniques require two different views to confirm correct probe placement relative to bony landmarks. This use of only one fluoroscopic view further reduces radiation exposure.

133. The MSRFN technique also has safety hallmarks similar to those of the perpendicular approach. The RF needle can be inserted until contacting the capsule, which thus acts as an anatomical backstop. The practitioner thus can avoid risks of inserting the needle too deep or ablating too far associated with the parallel approach.

the commercial success is attributable to the advantages that follow from the claimed invention. See Russo Decl. ¶ 120-121. The improved size and shape of the ablation volume of the Nimbus device is a result of the claimed tip and deployable filaments. See *id.* That is what has enabled the advantageous “perpendicular approach” and multifidus-sparing RF neurotomy technique and otherwise satisfied the long-felt-but-unsolved needs, bringing RF neurotomy out of its “ice age.” *Id.* ¶ 115, 122, 128, 129, 134.

The Reply, referencing a new declaration from Dr. Tucker, highlights minor differences between the Nimbus and Trident devices in an attempt to demonstrate that Diros did not copy Nimbus when developing Trident. Reply, 24. But those minor differences are irrelevant, as **identity** is not the proper standard: copying is present where there is “access to, and **substantial similarity** to, the patented product.” *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) (emphasis added).

510(k) SUMMARY

Technological elements those are different between the subject and the predicate devices;

The DTR and DTRH included in this submission have an expandable tip, equivalent to NIMBUS that is currently marketed by Biomerics. LLC and cleared under K121773.



Stratus Medical Ranked Number 483 Fastest-Growing Company in North America on the 2024 Deloitte Technology Fast 500™



MAGNOLIA, Texas, Nov. 21, 2024 /PRNewswire/ — Stratus® Medical announced it ranked 483 on the Deloitte Technology Fast 500™, a ranking of the 500 fastest-growing technology, media, telecommunications, life sciences, fintech, and energy tech companies in North America, now in its 30th year. Stratus Medical grew 212% during the three-year period evaluated.

Stratus® Medical was recognized in Malibu, CA this week by the Pepperdine Most Fundable Companies List

Stratus Medical was recognized in Malibu, CA this week by the Pepperdine Most Fundable Companies List. Stratus competed against more than 2,300 early-stage US companies in a rigorous process to be named one of 17 Most Fundable Companies for 2024.

Commercial Success

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“[S]ales figures alone” can be “evidence of commercial success.” *Tec Air*, 192 F.3d at 1360–1361. In this case, Stratus’s sales figures provide compelling evidence of commercial success.

“[S]ales figures coupled with market data provide stronger evidence of commercial success.” *Tec Air*, 192 F.3d at 1360-1361. Stratus’s market data is at least as compelling as its sales figures.

Cody Jorgensen’s testimony of the commercial success of Nimbus is based on personal knowledge gained from six years in marketing roles with Stratus. *See* Jorgensen Decl. ¶¶ 2, 4. While certain of the specific figures he analyzed were obtained from third parties, he testified this data is consistent with his own knowledge of this market. *See* Jorgensen Dep. Tr. (Ex. 1047-48), 19:4-18, 74:2-13, 87:13-89:22.

The Reply attempts to overcome the presumed nexus by arguing that Stratus has not presented adequate evidence of sales of the “complete, ‘claimed invention.’” Reply, 25. However, there is no legal or logical requirement that all components of the claimed invention be sold together in one transaction. Like a razor handle and a razor blade, the probe and needle (called an “electrode” by Stratus) components of the Nimbus system must be used together, even if sold separately. *See* Jorgensen Dep. Tr., 28:12-18, 36:2-20. Thus, sales of Stratus’s electrodes are evidence of use of the full Nimbus system.

Commercial Success

Avanos Medical, Inc. Announces Agreement To Acquire Diros Technology Inc.

June 30, 2023

Unique timed-probe technology further differentiates Avanos portfolio

ALPHARETTA, Ga., June 19, 2023 /PRNewswire/ – Avanos Medical, Inc. (NYSE: AVNS) today announced it has entered into a definitive agreement to acquire Diros Technology Inc., a leading manufacturer of innovative radiofrequency (RF) products used to treat chronic pain conditions.

Based in Toronto, Canada, Diros Technology has been at the forefront of radiofrequency ablation (RFA) technology since its founding. In the global market, over one million RFA procedures are performed annually in the treatment of chronic musculoskeletal pain. For chronic pain management, Diros Technology's products deliver RF energy through precisely placed, minimally invasive probes that heat nervous tissue near the probe's tip, deactivating the nerve's ability to transmit pain signals.

The addition of Diros' unique RF Trident™ technology is expected to further enhance Avanos' pain management treatment options and complement its premium COOLIEF* Cooled Radiofrequency product offering.

"The acquisition of Diros Technology strengthens Avanos' leadership position in RF technology by providing a full range of high-quality, differentiated pain management products," said Avanos Chief Executive Officer, Joe Woody. "We expect our enhanced portfolio will offer significant opportunities to deliver non-opioid-based, minimally invasive treatments to patients throughout the world. With this comprehensive suite of RF offerings, we believe Avanos is poised for future growth across all major sites of patient care: hospitals, ambulatory surgery centers and physician's offices."

The transaction is expected to close in the third quarter of 2023, subject to customary closing conditions. Avanos will finance the acquisition through a combination of funds from its existing credit facility and available cash. The company estimates that the new business will be immediately accretive to revenue growth, gross margins, operating margins and EPS.

The Company plans to share additional details about the transaction during its Investor Day event on June 20, 2023.

The petitioner maligns Stratus's exclusion of the petitioner's COOLIEF* product from its comparative market data as a "sleight-of-hand," but the petitioner's focus on COOLIEF* is the true misdirection. Reply, 27. Stratus excluded COOLIEF* for the same reason Avanos acquired Diros's copycat Trident product line: COOLIEF* and Trident (and by extension, Nimbus) are in *different* markets. The petitioner admitted as much in its press release regarding the acquisition of Diros: "The addition of Diros' unique RF Trident™ technology is expected to ... *complement* [Avanos's] premium COOLIEF* Cooled Radiofrequency product offering." Ex. 1029, 1 (emphasis added); *see also id.* (petitioner CEO stating, "With this comprehensive *suite* of RF offerings, we believe Avanos is poised for future growth across all major sites of patient care." (emphasis added)). Avanos presumably would not acquire and promote a product line that would cannibalize sales of its premium-priced COOLIEF* in the same market.

Petitioner's Motion to Exclude

The petitioner had every opportunity to contest the accuracy of Mr. Jorgensen's underlying data. Indeed, the petitioner went to great lengths questioning whether Mr. Jorgensen could have possibly known the confidential information of other companies in the U.S. RFA cannula market. One of those companies is Avanos, the petitioner. The petitioner had access to its own sales and sales force data, it could have easily undermined Mr. Jorgensen's market data by showing inconsistencies between that data and the petitioner's actual data. But the petitioner provided no such conflicting data. The petitioner opted instead to provide data regarding its COOLIEF* device, a device that was excluded from the U.S. RFA cannula market, which has no bearing on the accuracy of Mr. Jorgensen's data regarding the petitioner's products that were included in the U.S. RFA cannula market.

Case Document Key

Document / Exhibit	-01209	-01210	-01211	-01212
Petition	1	1	1	1
Inst. Dec'n	8	9	9	8
Response	13 (OCO)	15 (OCO)	15 (OCO)	13 (OCO)
	14	16	16	14
Reply	30 (OCO)	32 (OCO)	32 (OCO)	30 (OCO)
	31	33	33	31
Surreply	40 (OCO)	42 (OCO)	42 (OCO)	40 (OCO)
	41	43	43	41
Racz	1009			
Lee	1010			
Fitz	1011			
Tucker Decl.	1031	1032	1033	1034
Tucker Dep. Tr.	2020			
Russo Decl.	2001			
Russo Dep. Tr.	1046			
Crosby Decl.	2006			
Crosby Dep. Tr.	1045			