IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

STRATUS MEDICAL, LLC, Plaintiff, v. AVANOS MEDICAL, INC., and DIROS TECHNOLOGY, INC., Defendants.	C.A. No. **Jury Trial Demanded**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Stratus Medical, LLC ("Stratus") hereby files this Complaint for patent infringement against Defendants Avanos Medical, Inc. ("Avanos") and Diros Technology, Inc. ("Diros") (collectively, "Defendants"), and in support alleges as follows:

PARTIES

1. Plaintiff Stratus is a Texas limited liability company registered under the laws of the State of Utah, and with a its principal place of business at 32303 FM-2978, Magnolia, Texas 77354.

2. Defendant Avanos is a Delaware corporation with its principal place of business at 5405 Windward Parkway, Suite 100 South, Alpharetta, Georgia 30004.

3. Defendant Diros is a Canadian corporation with its principal place of business at 120 Gibson Drive, Markham, Ontario L3R 2Z3, Canada.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising out of Defendants' unauthorized importing, distributing, offering for sale, and selling of radiofrequency ("RF") needles in

violation of Plaintiff's patent rights. Because this action for infringement arises under the patent laws of the United States, 35 U.S.C. § 271, *et seq.*, this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Avanos in that at all times pertinent hereto, upon information and belief, Avanos has had systemic activities in this District and has committed and/or is committing infringing acts in Delaware and this District. More specifically, upon information and belief, Avanos offers for sale and sells RF needles, including the infringing products, in this District for use in this District as well as across the United States. Additionally, upon information and belief, Avanos is a corporation incorporated in Delaware and thus this Court has general jurisdiction over Avanos.

6. This Court has personal jurisdiction over Diros in that at all times pertinent hereto, upon information and belief, Diros regularly conducts business in this District and the State of Delaware, has purposefully availed itself of the privilege of conducting business in this District and the State of Delaware, thereby invoking the benefits and protections of Delaware law, has established sufficient minimum contacts with the State of Delaware such that Diros should reasonably and fairly anticipate being brought into court in Delaware, and has purposefully reached out to and directed their activities to Avanos, a resident of Delaware. This action arises out of or results from the foregoing activities.

7. This Court also has personal jurisdiction over Defendants pursuant to 10 Del. C. § 3104 and Fed. R. Civ. P. 4(k)(2). Diros places infringing products into the stream of commerce knowing they will be sold and used in the State of Delaware and elsewhere in the United States, and economically benefits from the retail sale of infringing products in the State of Delaware. Diros alone or through other parents and/or subsidiaries as agents, makes the Accused Products

and supplies and/or makes available the Accused Products to Avanos, which markets and sells the Accused Products. Together, the division of labor between making, manufacturing, marketing and sales amongst the Defendants amounts to an organized association, establishing a distribution channel for the Accused Products in the United States. Defendants know or can reasonably foresee that a termination point of the distribution channel targeted to the United States includes this District.

8. As to Avanos, venue is proper in the District of Delaware pursuant to 28 U.S.C. §§ 1391(b) and (c)(2) and 1400(b) because Avanos at least resides in, is subject to personal jurisdiction in, and has committed and continues to commit acts of infringement in this District.

9. As to Diros, venue is proper in the District of Delaware pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Diros is a foreign corporation and, as noted above, has committed and continues to commit acts of infringement in this District.

PATENTS-IN SUIT

10. Stratus is the assignee and owner of United States Patent No. 10,925,664 ("the '664 Patent"). The '664 Patent, which is entitled "Methods for Radio Frequency Neurotomy," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on February 23, 2021. A true and correct copy of the '664 Patent is attached hereto as **Exhibit A**.

11. Stratus is the assignee and owner of United States Patent No. 10,966,782 ("the '782 Patent"). The '782 Patent, which is entitled "Needles and Systems for Radiofrequency Neurotomy," was duly and legally issued by the USPTO on April 6, 2021. A true and correct copy of the '782 Patent is attached hereto as **Exhibit B**.

12. Stratus is the assignee and owner of United States Patent No. 10,736,688 ("the '688 Patent"). The '688 Patent, which is entitled "Methods and Systems for Spinal Radio

Frequency Neurotomy," was duly and legally issued by the USPTO on August 11, 2020. A true and correct copy of the '688 Patent is attached hereto as **Exhibit C**.

13. The '664, '782, and '688 Patents are collectively referred to herein as the "Patents-in-Suit."

BACKGROUND

Stratus' Innovative Technology

14. Stratus was founded in 2019 and is a pioneer in the business of improving clinical outcomes for patients suffering from chronic pain and other ailments.

15. Stratus has been able to succeed in the marketplace due to its innovative technologies, including its development and sale of innovative RF devices for the treatment of pain, which allow for faster procedure times, lower cost, and better patient outcomes that include reproducible and durable pain relief.

16. Given Stratus' innovation in the RF device industry, including RF needles, Stratus has obtained patents to protect its innovations, as detailed above.

Defendants' Infringement

17. Defendants have infringed and continue to infringe one or more claims of each of the Patents-in-Suit by, at minimum, importing, distributing, offering for sale, and selling infringing products and services in the United States and in this District, thereby directly and/or indirectly infringing each of the Patents-in-Suit.

18. The RF needles accused of infringing the Patents-in-Suit include, without limitation, Diros' Trident™ RF Cannulae model DTR ("DTR") and Diros' Trident™ RF Hybrid Cannulae model DTRH ("DTRH") (collectively the "Accused Products"), which are RF needles used for RF procedures.

19. According to Diros, the DTR and the DTRH differ in that the DTR "requires a separate component, an RF Probe/Temperature Sensor, to be inserted into its lumen," while the DTRH "has an RF Probe/Temperature Sensor permanently installed inside it."

20. One benefit of the Patents-in-Suit is that they incorporate an expandable electrode that creates a large volume and optimally shaped lesion. Similar to the innovations disclosed and claimed in Patents-in-Suit, Diros advertises that a benefit of the Accused Products is their incorporation of an expandable electrode through the use of deployable tines that create a "shaped lesion whose large base encompasses the nerve" via "an assembly designed for ease of use to innovatively produce a unique lesion at the cannula's bare tip."

21. Diros heavily advertises the Accused Products on its website (dirostech.com), but also offers for sale the Accused Products through Avanos, its parent company. For example, Avanos offers the Accused Products for sale and, on information and belief, will ship the infringing Accused Products or Accused Products to be used for infringing purposes to customers in this District.

22. Diros touts the Accused Products as being "innovative." But any innovative aspects of the Accused Products are the innovations of Stratus, not Diros.

COUNT I

INDIRECT INFRINGEMENT OF UNITED STATES PATENT NO. 10,925,664

23. Stratus repeats and realleges each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

24. The '664 Patent is valid and enforceable.

25. Since at least July 26, 2024, Defendants have had actual and/or constructive notice of the '664 Patent and Defendants knew or should have known about their infringement

based on their filing of an *inter partes* review proceeding (IPR2024-01212) against the ’664 Patent on this date.

26. Despite such actual and/or constructive knowledge, Defendants continue to import, distribute, offer for sale, and sell the DTR, thereby infringing the ’664 Patent. Defendants have also continued to sell the DTR and distribute product literature and website materials, thereby encouraging and inducing end users to use the DTR in the customary and intended manner, which Defendants knew would infringe the ’664 Patent.

27. Doctors and/or other end users of Defendants’ DTR product have directly infringed and will continue to directly infringe the ’664 Patent, both literally and/or under the doctrine of equivalents. Doctors and/or other end users directly infringe the ’664 Patent under 35 U.S.C. § 271(a) by using in the United States and in this District products covered by one or more claims of the ’664 Patent, including the DTR. As one example, use of the DTR infringes at least claim 1 of the ’664 Patent.

28. Defendants have actively, knowingly, and intentionally continued to induce infringement of the ’664 Patent, literally and/or under the doctrine of equivalents, by importing, offering for sale, and selling the DTR to their customers and by aiding, abetting, and encouraging its customers’ use of the DTR with knowledge that such use directly infringes one or more claims of the ’664 Patent and with the intent to cause such infringement. That Defendants knew their actions were inducing infringement of the ’664 Patent, or that Defendants were willfully blind to such infringement, is further evidenced by the fact that Defendant Diros was sued in Australia on various Australian counterparts to the Patents-in-Suit in Federal Court of Australia Proceeding No. NSD 438 of 2019, said Australian counterpart patents (Australian Standard Patent No. 2015261694 and Australian Standard Patent No. 2011235709) having similar claim

scope as the ’664 Patent. Thereafter, Diros stopped selling the Accused Products in Australia and continues to not sell the Accused Products in Australia. Upon information and belief, Avanos became aware of these facts as part of its acquisition of Diros in July 2023.[1] Avanos thereafter filed an *inter partes* review proceeding (IPR2024-01212) against the ’664 Patent, listing Diros as an Avanos subsidiary under the “Real parties-in-interest” section.

29. Defendants have also actively, knowingly, and intentionally continued to contributorily infringe the ’664 Patent, literally and/or under the doctrine of equivalents, by importing, offering for sale, and selling the DTR to their customers, which is especially made, designed, and adapted for use in a manner that infringes one or more claims of the ’664 Patent. As evidenced by the Instructions For Use of the DTR, attached hereto as **Exhibit I**, the DTR has no substantial non-infringing uses. The DTR is specifically designed to be used with an RF probe and, when combined, intended to be used in a monopolar mode of operation, such that Defendants knew use of the DTR would infringe one or more claims of the ’664 Patent.

30. The chart provided in **Exhibit D** attached hereto depicts and describes how use of the DTR practices the invention claimed by the ’664 Patent and meets each and every element of at least claim 1 of the ’664 Patent. Stratus reserves the right to modify its infringement theories as discovery progresses in this case; it shall not be estopped for infringement contention or claim construction purposes by the information contained in **Exhibit D**. The chart provided in **Exhibit D** is intended to satisfy the notice requirements of Rule 8(a)(2) of the Federal Rules of

[1] *Avanos Medical, Inc. Announces Agreement to Acquire Diros Technology Inc.* (June 30, 2023), https://avanos.com/news/avanos-medical-inc-announces-agreement-to-acquire-diros-technology-inc/; Avanos Medical, Inc. Announces Third Quarter 2023 Results (Nov. 1, 2023), https://avanos.investorroom.com/2023-11-01-Avanos-Medical,-Inc-Announces-Third-Quarter-2023-Results (“On July 24, we closed the acquisition of Diros Technology, Inc.”).

Civil Procedure; it does not represent Stratus' preliminary or final infringement contentions or preliminary or final claim construction positions.

31. Stratus is entitled to recover damages adequate to compensate Stratus for Defendants' infringement.

32. Defendants' conduct has caused and will continue to cause Stratus substantial damages, including irreparable harm, for which Stratus has no adequate remedy at law unless and until Defendants are enjoined from infringing the '664 Patent.

COUNT II

INDIRECT INFRINGEMENT OF UNITED STATES PATENT NO. 10,966,782

33. Stratus repeats and realleges each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

34. The '782 Patent is valid and enforceable.

35. Since at least July 26, 2024, Defendants have had actual and/or constructive notice of the '782 Patent and Defendants knew or should have known about their infringement based on their filing of an *inter partes* review proceeding (IPR2024-01209) against the '782 Patent on this date.

36. Despite such actual and/or constructive knowledge, Defendants continue to import, distribute, offer for sale, and sell the DTR, which, in combination with an RF probe that is also sold by Defendants, infringes the '782 Patent. Defendants have also continued to sell the DTR and distribute product literature and website materials thereby encouraging and inducing end users to combine the DTR with an RF probe in the customary and intended manner, which Defendants knew would infringe the '782 Patent.

37. Doctors and/or other end users of Defendants' DTR product have directly infringed and will continue to directly infringe the '782 Patent, both literally and/or under the doctrine of equivalents. Doctors and/or other end users directly infringe the '782 Patent under 35 U.S.C. § 271(a) by combining the DTR with an RF probe in the United States and in this District a completed apparatus covered by one or more claims of the '782 Patent. As one example, the combination of the DTR and an RF probe infringes at least claim 1 of the '782 Patent.

38. Defendants have actively, knowingly, and intentionally continued to induce infringement of the '782 Patent, literally and/or under the doctrine of equivalents, by importing, offering for sale, and selling the DTR to their customers to be combined with an RF probe in a manner that infringes one or more claims of the '782 Patent and by aiding, abetting, and encouraging its customers' to make and/or use of the combination with knowledge that making and/or using such combination directly infringes one or more claims of the '782 Patent and with the intent to cause such infringement. That Defendants knew their actions were inducing infringement of the '782 Patent, or that Defendants were willfully blind to such infringement, is further evidenced by the fact that Defendant Diros was sued in Australia on various Australian counterparts to the Patents-in-Suit in Federal Court of Australia Proceeding No. NSD 438 of 2019, said Australian counterpart patents (Australian Standard Patent No. 2015261694 and Australian Standard Patent No. 2011235709) having similar claim scope as the '782 Patent. Thereafter, Diros stopped selling the Accused Products in Australia and continues to not sell the Accused Products in Australia. Upon information and belief, Avanos became aware of these facts as part of its acquisition of Diros in July 2023. Avanos thereafter filed an *inter partes* review proceeding (IPR2024-01209) against the '782 Patent, listing Diros as an Avanos subsidiary under the "Real parties-in-interest" section.

39. Defendants have also actively, knowingly, and intentionally continued to contributorily infringe of the ’782 Patent, literally and/or under the doctrine of equivalents, by importing, offering for sale, and selling the DTR to their customers, which is especially made, designed, and adapted to be combined with an RF probe in a manner that directly infringes one or more claims of the ’782 Patent. As evidenced by the Instructions For Use of the DTR, attached hereto as **Exhibit I**, the DTR has no substantial non-infringing uses. The DTR is specifically designed to be used with an RF probe and, when combined, intended to be used in a monopolar mode of operation, such that Defendants knew the combination would infringe one or more claims of the ’782 Patent.

40. The chart provided in **Exhibit E** attached hereto depicts and describes how combining the DTR with an RF probe practices the invention claimed by the ’782 Patent and meets each and every element of at least claim 1 of the ’782 Patent. Stratus reserves the right to modify its infringement theories as discovery progresses in this case; it shall not be estopped for infringement contention or claim construction purposes by the information contained in **Exhibit E**. The chart provided in **Exhibit E** is intended to satisfy the notice requirements of Rule 8(a)(2) of the Federal Rules of Civil Procedure; it does not represent Stratus’ preliminary or final infringement contentions or preliminary or final claim construction positions.

41. Stratus is entitled to recover damages adequate to compensate Stratus for Defendants’ infringement.

42. Defendants’ conduct has caused and will continue to cause Stratus substantial damages, including irreparable harm, for which Stratus has no adequate remedy at law unless and until Defendants are enjoined from infringing the ’782 Patent.

COUNT III

DIRECT INFRINGEMENT OF UNITED STATES PATENT NO. 10,966,782

43. Stratus repeats and realleges each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

44. Without permission or authorization from Stratus and in violation of 35 U.S.C. § 271(a), Defendants have imported, distributed, offered for sale, and sold and continues to import, distribute, offer for sale, and sell—in this District and elsewhere in the United States—the DTRH which directly infringes, literally and/or under the doctrine of equivalents, at least claim 1 of the ’782 Patent.

45. The chart provided in **Exhibit F** attached hereto depicts and describes how the DTRH practices the invention claimed by the ’782 Patent and meets each and every element of at least claim 1 of the ’782 Patent. Stratus reserves the right to modify its infringement theories as discovery progresses in this case; it shall not be estopped for infringement contention or claim construction purposes by the information contained in **Exhibit F**. The chart provided in **Exhibit F** is intended to satisfy the notice requirements of Rule 8(a)(2) of the Federal Rules of Civil Procedure; it does not represent Stratus’ preliminary or final infringement contentions or preliminary or final claim construction positions.

46. Stratus is entitled to recover damages adequate to compensate Stratus for Defendants’ infringement.

47. Defendants’ conduct has caused and will continue to cause Stratus substantial damages, including irreparable harm, for which Stratus has no adequate remedy at law unless and until Defendants are enjoined from infringing the ’782 Patent.

COUNT IV

INDIRECT INFRINGEMENT OF UNITED STATES PATENT NO. 10,736,688

48. Stratus repeats and realleges each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

49. The ’688 Patent is valid and enforceable.

50. Since at least July 26, 2024, Defendants have had actual and/or constructive notice of the ’688 Patent and Defendants knew or should have known about their infringement based on their filing of *inter partes* review proceedings (IPR2024-01210 and IPR2024-01211) against the ’688 Patent on this date.

51. Despite such actual and/or knowledge, Defendants continue to import, distribute, offer for sale, and sell the DTR, which, in combination with an RF probe that is also sold by Defendants, infringes the ’688 Patent. Defendants have also continued to sell the DTR and distribute product literature and website materials, thereby encouraging and inducing end users to combine the DTR with an RF probe in the customary and intended manner, which Defendants knew would infringe the ’688 Patent.

52. Doctors and/or other end users of Defendants’ DTR product have directly infringed and will continue to directly infringe the ’688 Patent, both literally and/or under the doctrine of equivalents. Doctors and/or other end users directly infringe the ’688 Patent under 35 U.S.C. § 271(a) by combining the DTR with an RF probe in the United States and in this District a completed apparatus covered by one or more claims of the ’688 Patent. As one example, the combination of the DTR and an RF probe infringes at least claim 1 of the ’688 Patent.

53. Defendants have actively, knowingly, and intentionally continued to induce infringement of the ’688 Patent, literally and/or under the doctrine of equivalents, by importing,

offering for sale, and selling the DTR to their customers to be combined with an RF probe in a manner that infringes one or more claims of the ’688 Patent and by aiding, abetting, and encouraging its customers’ to make and/or use of the combination with knowledge that making and/or using such combination infringes one or more claims of the ’688 Patent and with the intent to cause such infringement. That Defendants knew their actions were inducing infringement of the ’688 Patent, or that Defendants were willfully blind to such infringement, is further evidenced by the fact that Defendant Diros was sued in Australia on various Australian counterparts to the Patents-in-Suit in Federal Court of Australia Proceeding No. NSD 438 of 2019, said Australian counterpart patents (Australian Standard Patent No. 2015261694 and Australian Standard Patent No. 2011235709) having similar claim scope as the ’688 Patent. Thereafter, Diros stopped selling the Accused Products in Australia and continues to not sell the Accused Products in Australia. Upon information and belief, Avanos became aware of these facts as part of its acquisition of Diros in July 2023. Avanos thereafter filed *inter partes* review proceedings (IPR2024-01210 and IPR2024-01211) against the ’688 Patent, listing Diros as an Avanos subsidiary under the “Real parties-in-interest” sections.

54. Defendants have also actively, knowingly, and intentionally continued to contributorily infringe of the ’688 Patent, literally and/or under the doctrine of equivalents, by importing, offering for sale, and selling the DTR to their customers, which is especially made, designed, and adapted to be combined with an RF probe in a manner that directly infringes one or more claims of the ’688 Patent and with the intent to cause such infringement. As evidenced by the Instructions For Use of the DTR, attached hereto as **Exhibit I**, the DTR has no substantial non-infringing uses. The DTR is specifically designed to be used with an RF probe and, when

combined, intended to be used in a monopolar mode of operation, such that Defendants knew the combination would infringe one or more claims of the ’688 Patent.

55. The chart provided in **Exhibit G** attached hereto depicts and describes how combining the DTR with an RF probe practices the invention claimed by the ’688 Patent and meets each and every element of at least claim 1 of the ’688 Patent. Stratus reserves the right to modify its infringement theories as discovery progresses in this case; it shall not be estopped for infringement contention or claim construction purposes by the information contained in **Exhibit G**. The chart provided in **Exhibit G** is intended to satisfy the notice requirements of Rule 8(a)(2) of the Federal Rules of Civil Procedure; it does not represent Stratus’ preliminary or final infringement contentions or preliminary or final claim construction positions.

56. Stratus is entitled to recover damages adequate to compensate Stratus for Defendants’ infringement.

57. Defendants’ conduct has caused and will continue to cause Stratus substantial damages, including irreparable harm, for which Stratus has no adequate remedy at law unless and until Defendants are enjoined from infringing the ’688 Patent.

COUNT V

DIRECT INFRINGEMENT OF UNITED STATES PATENT NO. 10,736,688

58. Stratus repeats and realleges each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

59. Without permission or authorization from Stratus and in violation of 35 U.S.C. § 271(a), Defendants have imported, distributed, offered for sale, and sold and continues to import, distribute, offer for sale, and sell—in this District and elsewhere in the United States—the DTRH which directly infringes at least claim 1 of the ’688 Patent.

60. The chart provided in **Exhibit H** attached hereto depicts and describes how the DTRH practices the invention claimed by the ’688 Patent and meets each and every element of at least claim 1 of the ’688 Patent. Stratus reserves the right to modify its infringement theories as discovery progresses in this case; it shall not be estopped for infringement contention or claim construction purposes by the information contained in **Exhibit H**. The chart provided in **Exhibit H** is intended to satisfy the notice requirements of Rule 8(a)(2) of the Federal Rules of Civil Procedure; it does not represent Stratus’ preliminary or final infringement contentions or preliminary or final claim construction positions.

61. Stratus is entitled to recover damages adequate to compensate Stratus for Defendants’ infringement.

62. Defendants’ conduct has caused and will continue to cause Stratus substantial damages, including irreparable harm, for which Stratus has no adequate remedy at law unless and until Defendants are enjoined from infringing the ’688 Patent.

PRAYER FOR RELIEF

WHEREFORE, Stratus respectfully prays for judgment as follows:

A. For a judgment that Defendants have infringed the ’664 Patent;

B. For a judgment that Defendants have infringed the ’782 Patent;

C. For a judgment that Defendants have infringed the ’688 Patent;

D. For an order that Defendants and their respective agents, servants, officers, directors, employees and all persons in privity or active concert or participation with Defendants, directly or indirectly, are permanently enjoined from infringing, inducing others to infringe, or contributing to the infringement of the Patents-in-Suit;

E. For a judgment and award requiring Defendants to pay Stratus' damages in an amount adequate to compensate Stratus for Defendants' infringement, including lost profits but in no event less than a reasonably royalty pursuant to 35 U.S.C. § 284;

F. For a judgment and award of any supplemental damages sustained by Stratus for any continuing post-verdict infringement up until entry of judgment and beyond, with accounting as needed;

G. For an order finding that this case is exceptional under 35 U.S.C. § 285 and awarding Stratus its costs, expenses, and disbursements incurred in this action, including reasonable attorneys' fees as available by law to be paid by Defendants;

H. For an award of pre-judgment interest, post-judgment interest, and costs in this action to the full extent allowed under the law; and

I. For an award of such other relief as the Court may deem just and proper.

JURY DEMAND

Stratus demands a trial by jury on all issues so triable.

/s/ Frederick L. Cottrell, III
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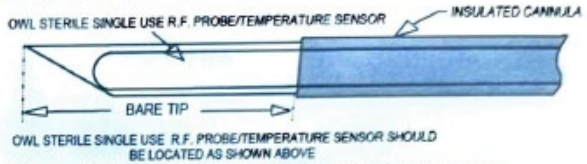
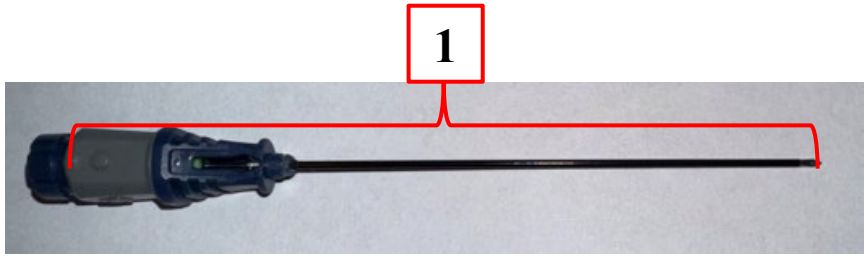
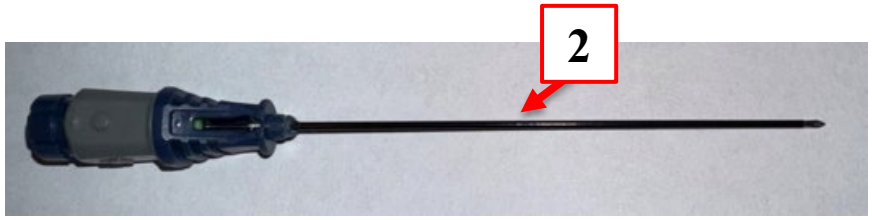
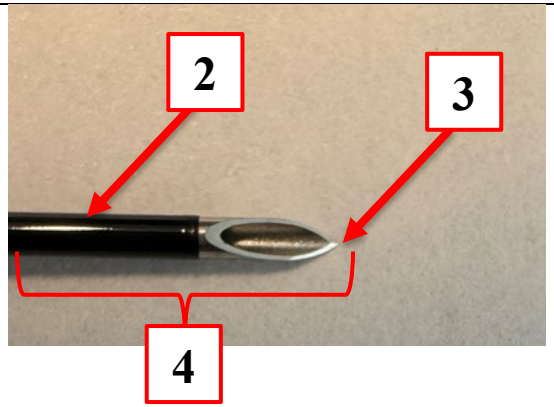
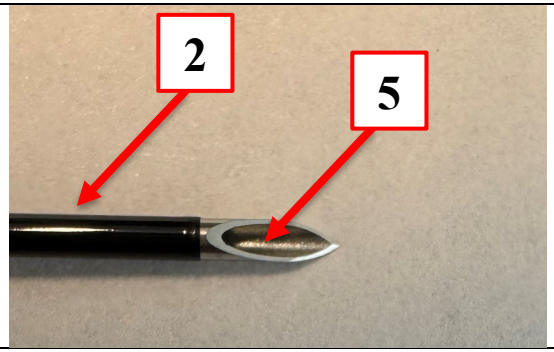
Dated: May 2, 2025

EXHIBIT D

U.S. Patent No. 10,925,664	Trident RF Insulated Cannula (Model DTR)	
A method comprising:	To the extent the preamble is limiting, the Procedure Section of the Diros Instructions For Use ("IFU") of the DTR is pictured and describes a method of using the DTR. (**Exhibit I** (*Instructions For Use OWL Sterile Single Use Trident™ RF Insulated Cannula, Model DTR*, Diros Document 174 at p. 5 (2020)).	***6.3 Procedure*** 1. Assemble all required equipment for the intended procedure and position the patient as necessary. 2. Attach the Return Path Electrode (GD-Pad). Read and follow the manufacturer's instructions for use of the GD-Pad electrode to determine proper placement. Always use return path electrodes that meet or exceed ANSI/AAMI HF-18 requirements. 3. Inspect the part number of the RF Probe/Temperature Sensor to ensure that it is the correct length to match the length of the Trident™ RF Insulated Cannula. 4. Test the match by removing the stylet from the cannula and slowly inserting the RF Probe/Temperature Sensor into the cannula. Do not use excessive force to avoid damage to the RF Probe. The tip of the RF probe must lie within the bare tip of the RF cannula, see Figure 2. Otherwise the measured temperature will be incorrect. To further verify this, note the position of the handle of the RF Probe, Figure 1 (**9**) relative to the threaded top section of the Actuator, Figure 1 (**4c**). Then remove the RF Probe from the RF Cannula, place it parallel to and alongside the cannula and confirm that the tip of the RF Probe is no more than a mm short of the end of the RF Cannula bevel, but does not extend beyond it. Reinsert the Stylet into the RF Cannula. 5. Connect the plug of the intermediate cable to an input of the Multi-Lesion Adaptor or to the Probe receptacle on the RF Generator. Maintain access to the probe connection end of the intermediate cable in order to facilitate easy attachment to the RF Probe/Temperature Sensor to it.  Figure 2. Correct position of RF Probe/Temperature Sensor within the Trident™ RF Insulated Cannula. Tines are not shown.

U.S. Patent No. 10,925,664	Trident RF Insulated Cannula (Model DTR)	
		6. Re-insert the stylet into the Trident™ RF Insulated Cannula and ensure that the tines are fully withdrawn into it. A distinct click will be heard to indicate full withdrawal. Following superficial anesthesia hold the cannula *only* by its hub (not by the actuator) and insert it into the patient at a predetermined skin site and, using fluoroscopic guidance, position the active tip at the desired lesion location. 7. Once the cannula is properly positioned carefully remove the stylet from the cannula and insert the full length of the RF Probe/Temperature Sensor down the shaft of the Sterile Single Use Trident™ RF Insulated Cannula. 8. Plug the probe connector to the probe connection of the intermediate cable. Check if device is reading room temperature before placing it into a patient. 9. If proper connection is made, then the RF Generator should read within correct ranges of impedance and body temperature. Otherwise check all connections listed above. 10. Apply sensory and/or motor electrical stimulation as indicated by your protocol to verify correct electrode placement. If the results of stimulation are not acceptable and repositioning of the cannula is required, first fully withdraw the tines into the cannula and then reposition. Repeat electrical stimulation as indicated. 11. Lesion as necessary. Refer to the RF Generator User's Manual for more information. Upon completion, remove the RF Probe/Temperature Sensor and instill anesthetic and steroid if in accordance with your protocol. When connecting/disconnecting the RF Cannula to the syringe, ensure once again to grasp the cannula only by its hub. Upon completion of the procedure, remove the Trident™ RF Insulated Cannula (with RF Probe/Temperature Sensor still in it if no anesthetic applied). 12. Dispose of single use products properly.

U.S. Patent No. 10,925,664	Trident RF Insulated Cannula (Model DTR)	
inserting a needle into a patient, the needle comprising;	The DTR device has a needle [1] that is configured and intended to be inserted into a patient. For example, in Step 6 of the Procedure, the IFU instructs a user to insert the device into the patient "at a predetermined skin site." (**Exhibit I** at p. 5).	 6. Re-insert the stylet into the Trident™ RF Insulated Cannula and ensure that the tines are fully withdrawn into it. A distinct click will be heard to indicate full withdrawal. Following superficial anesthesia hold the cannula *only* by its hub (not by the actuator) and insert it into the patient at a predetermined skin site and, using fluoroscopic guidance, position the active tip at the desired lesion location.
an elongate member;	As shown, the DTR device's needle has an elongate member [2].	

U.S. Patent No. 10,925,664	Trident RF Insulated Cannula (Model DTR)	
a piercing tip at a distal end of the elongate member;	As shown, the DTR device's needle has a tip [3], which is fixed to the elongate member [2] at the distal end [4]. The tip [3] is sharp and beveled and thus would be understood to be shaped for the purpose of piercing the tissue of a patient. Moreover, as previously discussed, in Step 6 of the Procedure, the IFU instructs a user to insert the needle into the patient "at a predetermined skin site." (**Exhibit I** at p. 5).	
a lumen within the elongate member; and	As shown, the DTR's needle has a lumen [5] within the elongate member [2].	

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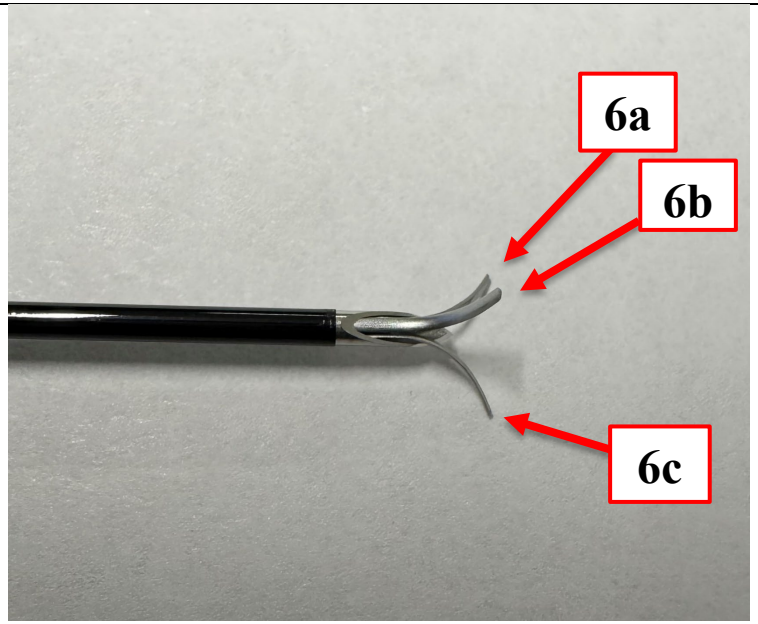
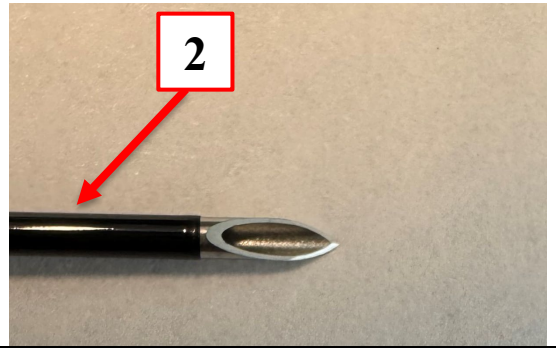
a filament in a retracted position in which the filament is at least partially disposed within the elongate member;	The DTR's needle comprises filaments [6a-c] which are visible when in the deployed position, as shown in the first image to the right. As shown in the second image to the right, the filaments [6a-c] are not visible because they are at least partially disposed within the elongate member [2].	 

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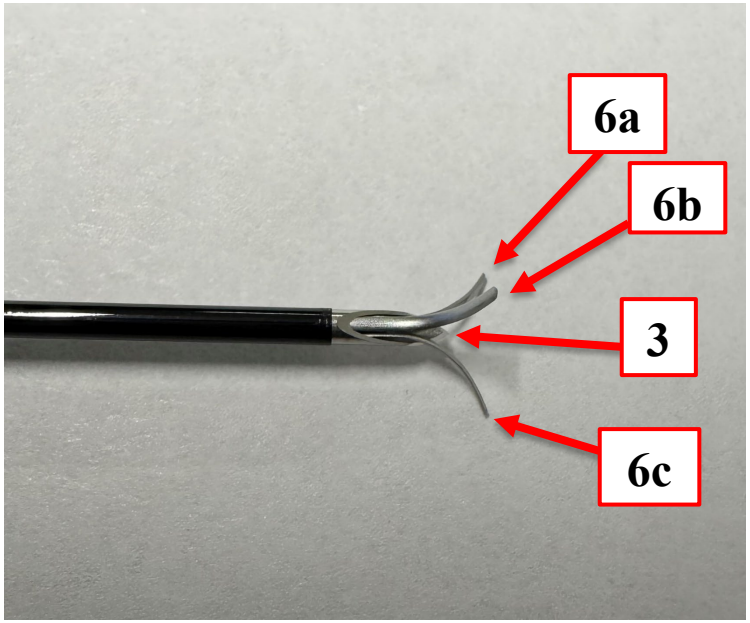
moving the filament to a deployed position within the patient in which at least a distal end of the filament is out of the elongate member and disposed away from the tip;	As described in the DTR IFU, the "[c]annula hub/handle is equipped with a mechanism that allows deployment and retraction of 3 tines [i.e., filaments]." (**Exhibit I** at p. 1; *see also id.* at p. 4 (further describing deployment and retraction of filaments)). As shown in the second image at right, the distal ends of the filaments [6a-c] extend beyond and are disposed away from the tip [3] in the deployed position. As described in Step 6 of the Procedure, the DTR's needle is inserted into the patient "at a predetermined skin site." (**Exhibit I** at p. 5). As previously discussed, the needle is inserted using the the tip at the distal end of the needle, the tip being sharp and beveled and therefore configured and intended to be inserted into a patient. As later described in Step 10 of the Procedure, "sensory and/or motor electrical stimulation" is then applied to the patient. (**Exhibit I** at	*The Cannula hub/handle is equipped with a mechanism that allows deployment and retraction of 3 tines*  10. Apply sensory and/or motor electrical stimulation as indicated by your protocol to verify correct electrode placement. If the results of stimulation are not acceptable and repositioning of the cannula is required, first fully withdraw the tines into the cannula and then reposition. Repeat electrical stimulation as indicated. . . .

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	p. 5). In the Important notes following the Procedure, the tines (i.e, filaments) "must be fully deployed before stimulation, otherwise results will be erroneous." (*Id.*) Further, Step 10 states, "If the results of stimulation are not acceptable and repositioning of the cannula is required, first fully withdraw the tines [i.e., filaments]." (*Id.*) Because Step 10 occurs after the tip [3] of the needle is inserted into the patient in Step 6, the method would be understood to require the filaments [6a-c] to be in the deployed position within the patient at some point during or prior to Step 10, when it becomes possible to determine that the results of stimulation are not acceptable such that repositioning is required.	12. Dispose of single use products properly. ⚠ ***Important notes:*** • *Tines must be fully deployed before stimulation, otherwise results will be erroneous.*
inserting a radiofrequency probe into the lumen of the needle such that the radiofrequency probe contacts a conductive portion of the needle at a distal end of the needle to thereby establish an	As described in Step 7 of the Procedure, "insert the full length of the RF Probe/Temperature Sensor down the [lumen] of the [DTR device]." (**Exhibit I** at p. 5).	7. Once the cannula is properly positioned carefully remove the stylet from the cannula and insert the full length of the RF Probe/Temperature Sensor down the shaft of the Sterile Single Use Trident™ RF Insulated Cannula.

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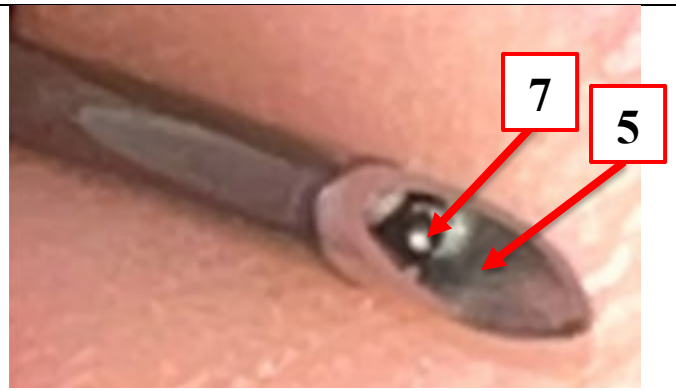
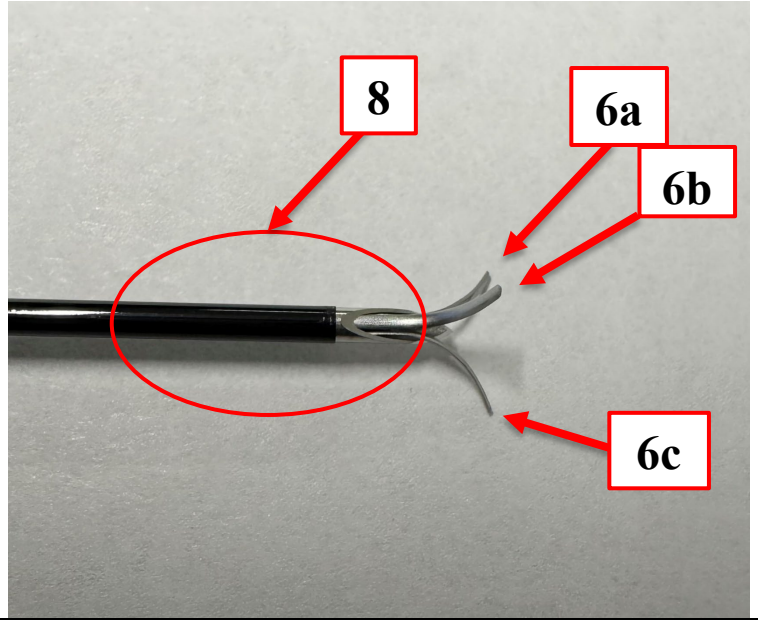
electrically conductive path from the radiofrequency probe to the filament; and	As shown, the lumen [5] of the DTR device's needle is configured to and does accept the radiofrequency "RF" probe [7] therein. As described in the DTR IFU, "Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode." (**Exhibit I** at p. 3). Thus, it would be understood that physical contact occurs between the uninsulated exterior surface of the RF probe [7] and the uninsulated interior surface of the lumen [5] within the circle [8] of the last photo to the right, and that this physical contact thereby establishes an electrically conductive path from the RF probe [7] to the filaments [6a-c].	 

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		** The second image above showing the RF probe [7] fully inserted into the lumen [5] of the needle depicts the related DTRH device. Upon information and belief, the needle of the DTRH device is substantively the same as the needle of DTR when it is combined with the required RF probe and thus the same features are present in the needle of the DTR.*
operating the radiofrequency probe, the tip, and the filament as a monopolar electrode, with radiofrequency energy from the radiofrequency probe being conducted to the filament through the electrically conductive path and transmitted by the filament.	As described in Step 10 of the Procedure in the DTR IFU, "sensory and/or motor electrical stimulation" is applied to the patient. (**Exhibit I** at p. 5). As described in the Warnings and Precautions Section of the DTR IFU, the RF generator must be set in the "monopolar mode of operation." (**Exhibit I** at p. 6). This instructs that the DTR device is intended to only be used as a monopolar electrode. As described in the DTR IFU, "Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode." (**Exhibit I** at p. 3). The current applied is radiofrequency energy, which is conducted from the RF probe [7] to the filaments [6a-c] such that the filaments [6a-	10. Apply sensory and/or motor electrical stimulation as indicated by your protocol to verify correct electrode placement. If the results of stimulation are not acceptable and repositioning of the cannula is required, first fully withdraw the tines into the cannula and then reposition. Repeat electrical stimulation as indicated. **⚠ WARNINGS AND PRECAUTIONS** Inspect all components for damage prior to each use. If components are damaged in any manner they must not be used. Damaged components must be discarded or returned for evaluation/repair. Damaged components may result in patient or operator injury. • Check if device is reading room temperature before placing it into a patient • Do not start treatment without verification of correct placement • Do not start treatment if device doesn't read body temperature and impedance . . .

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	c] transmit the current to the patient.	• Application of RF energy may cause undesirable neuromuscular stimulation. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Set RF generator in monopolar mode of operation. **4. *Return Path Electrodes*** RECOMMENDATIONS FOR RETURN PATH (GROUND, REFERENCE) ELECTRODES The return path (also termed ground, reference, indifferent, neutral or dispersive electrode) electrode serves to complete the current path through the patient. Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode. It must find a return path back to the RF

EXHIBIT E

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1. A system comprising:	To the extent the preamble is limiting, the Trident RF Insulated Cannula, Model DTR ("DTR") is pictured and is part of a system.	
a radiofrequency probe; and	As described in the Diros Instructions For Use ("IFU") of the DTR, which users are expected to follow when using the DTR, an "RF Probe/Temperature Sensor" is required equipment for use of the DTR. (**Exhibit I** (*Instructions For Use OWL Sterile Single Use Trident™ RF Insulated Cannula, Model DTR*, Diros Document 174 at p. 5 (2020)). Further, an "RF Probe/Temperature Sensor" is specifically listed in steps 3-5, 7, and 11 of the Procedure. (*Id.*). The radiofrequency "RF" probe [1] is shown inside the lumen.	**6. Directions for Use** **6.1 Equipment Required** Radiofrequency lesion procedures should be performed in a specialized clinical setting with fluoroscopic equipment. The RF equipment required for the procedure is as follows: It is important to use the correct size lesion/temperature probe Q-ty: 1 — Equipment: OWL Sterile Single Use Trident™ RF Insulated Cannula, model DTR Q-ty: 1 — OWL RF Probe/Temperature Sensor. Use probe of matching length. (i.e. 5cm DTR cannula with 5cm probe) D466-005, D467-005-TC, D467-005-TCH — 5cm probe D466-010, D467-010-TC, D467-010-TCH — 10cm probe D466-015, D466-015-TC, D466-015-TCH — 15cm probe D466-020, D466-020-TC, D466-020-TCH — 20cm probe Q-ty: 1 — Corresponding connecting cable For probe models: D466-005, D466-010, D466-015, D466-020 — Cable models: 463-103-TM-S, 463-103-S, 463-103-S (IEC), For probe models: D467-005-TC, D467-010-TC, D466-015-TC, D466-020-TC — Cable models: H4-S2F-S, 463-103-HCT-S For probe models: D467-005-TCH, D467-010-TCH, D466-015-TCH, D466-020-TCH — Cable models: H4-H4-S, 463-103-TCH-S, 463-103-BPTCH-S Q-ty: 1 — OWL Radiofrequency generator, URF-3AP Q-ty: 1 — OWL Disposable Indifferent dispersive electrode (GD-Pad) meeting ANSI/AAMI standard HF-18 requirements for electrosurgical electrodes, models D7506, D7506NC	

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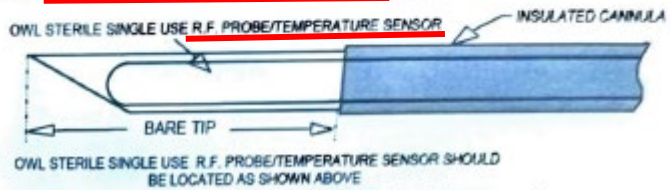
		6.3 Procedure 1. Assemble all required equipment for the intended procedure and position the patient as necessary. . . . 3. Inspect the part number of the RF Probe/Temperature Sensor to ensure that it is the correct length to match the length of the Trident™ RF Insulated Cannula. 4. Test the match by removing the stylet from the cannula and slowly inserting the RF Probe/Temperature Sensor into the cannula. Do not use excessive force to avoid damage to the RF Probe. The tip of the RF probe must lie within the bare tip of the RF cannula, see Figure 2. Otherwise the measured temperature will be incorrect. To further verify this, note the position of the handle of the RF Probe, Figure 1 (**9**) relative to the threaded top section of the Actuator, Figure 1 (**4c**). Then remove the RF Probe from the RF Cannula, place it parallel to and alongside the cannula and confirm that the tip of the RF Probe is no more than a mm short of the end of the RF Cannula bevel, but does not extend beyond it. Reinsert the Stylet into the RF Cannula. 5. Connect the plug of the intermediate cable to an input of the Multi-Lesion Adaptor or to the Probe receptacle on the RF Generator. Maintain access to the probe connection end of the intermediate cable in order to facilitate easy attachment to the RF Probe/Temperature Sensor to it.  Figure 2. Correct position of RF Probe/Temperature Sensor within the Trident™ RF Insulated Cannula. Tines are not shown. . . .

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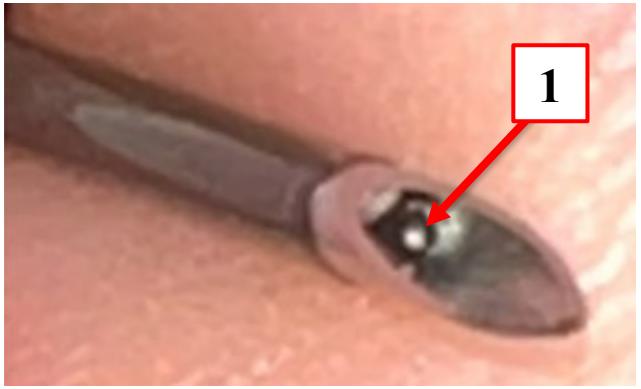
		7. Once the cannula is properly positioned carefully remove the stylet from the cannula and insert the full length of the RF Probe/Temperature Sensor down the shaft of the Sterile Single Use Trident™ RF Insulated Cannula. . . . 11. Lesion as necessary. Refer to the RF Generator User's Manual for more information. Upon completion, remove the RF Probe/Temperature Sensor and instill anesthetic and steroid if in accordance with your protocol. When connecting/disconnecting the RF Cannula to the syringe, ensure once again to grasp the cannula only by its hub. Upon completion of the procedure, remove the Trident™ RF Insulated Cannula (with RF Probe/Temperature Sensor still in it if no anesthetic applied).  ** The last image above showing the RF probe [1] combined with the needle depicts the related DTRH device. Upon information and belief, the needle of the DTRH device is substantively the same as the needle of DTR when it is combined with the required RF probe and thus the same features are present in the needle of the DTR.*

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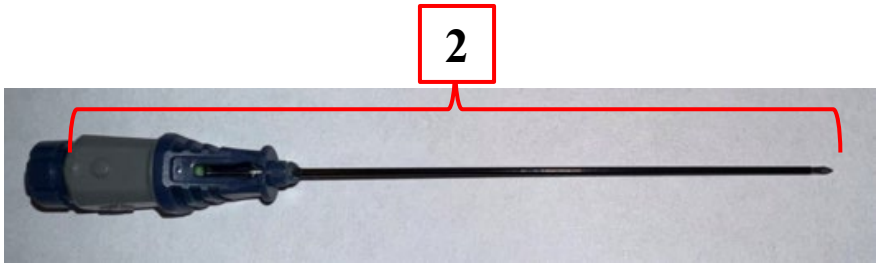
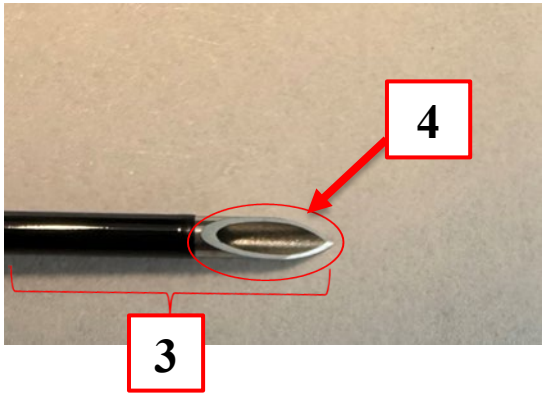
a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:	The DTR device has a needle [2] with the tip at the distal end configured for insertion into a patient. As described in the DTR IFU, the DTR "may be used . . . for radiofrequency lesioning," which is a radiofrequency neurotomy procedure, thus making the needle a radiofrequency neurotomy needle. (**Exhibit I** at p. 2).	
a conductive portion at a distal end of the radiofrequency neurotomy needle;	As shown, the distal end [3] of the needle of the DTR device has an uninsulated portion. The distal end [3] extends past the insulation to include internal elements. The conductive portion includes the uninsulated portion [4] of the DTR device's needle as well as the internal elements at the distal end [3].	

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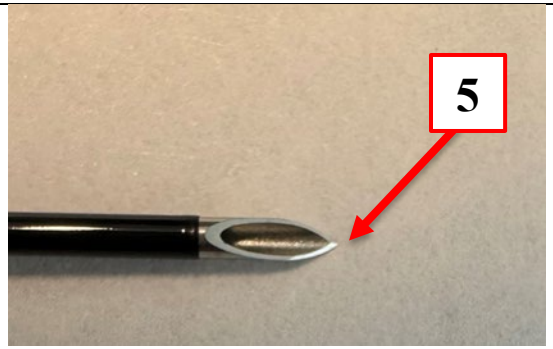
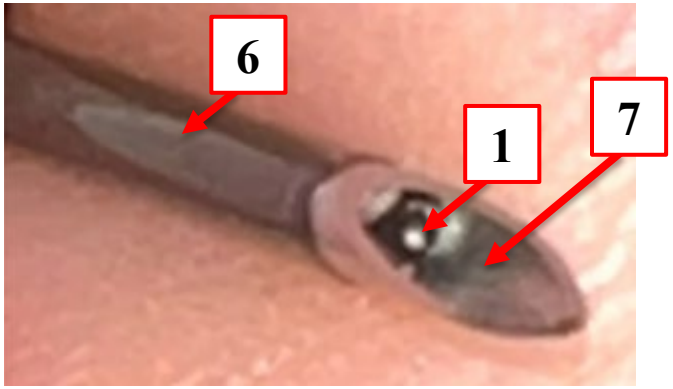
a tip configured to pierce tissue of a patient;	As shown, the DTRH device's needle has a tip [5]. The tip [5] is sharp and beveled and thus would be understood to be shaped for the purpose of piercing the tissue of a patient.	
an elongate member comprising a lumen configured to accept the radiofrequency 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;	As shown, the DTR device's needle has an elongate member [6], comprising an interior lumen [7]. As shown, the lumen [7] at the interior of the DTR device's elongate member [6] is configured to and does accept the RF probe [1] therein. As described in the DTR IFU, "Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode." (**Exhibit I** at p. 3). Thus, it would be understood that physical contact occurs between the uninsulated exterior surface of the RF probe [1] and the	 

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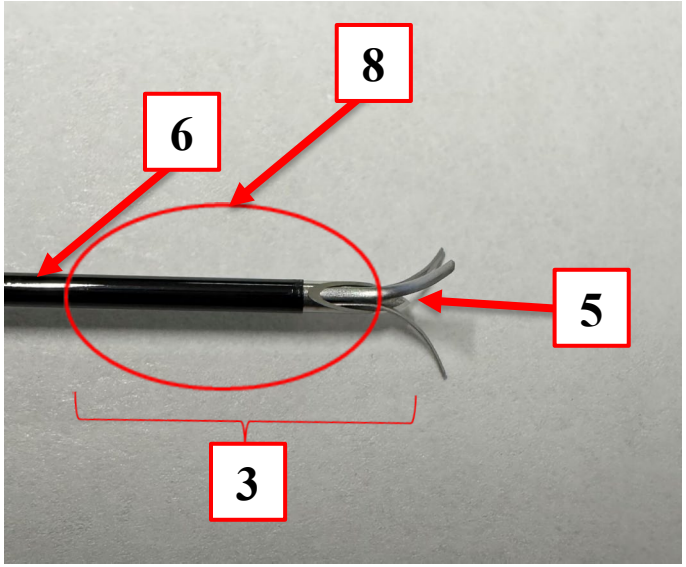
	uninsulated interior surface of the lumen [7] within the circle [8] of the third photo to the right, and that this physical contact thereby electrically connects the RF probe [1] to the conductive portion that includes the tip [5] at the distal end [3] of the elongate member [6].	 ** The second image above showing the RF probe [1] being accepted into the lumen [7] of the needle depicts the related DTRH device. Upon information and belief, the needle of the DTRH device is substantively the same as the needle of DTR when it is combined with the required RF probe and thus the same features are present in the needle of the DTR.*

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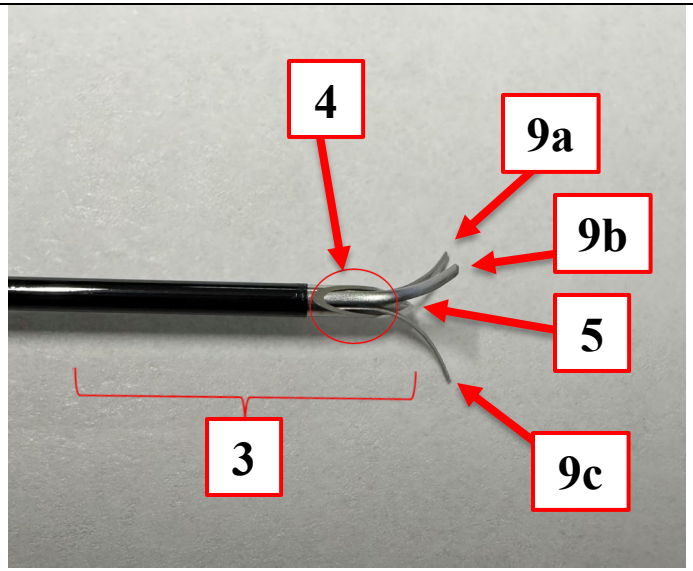
a filament electrically connected to the conductive portion and the tip due to physical contact of conductive materials at the distal end of the radiofrequency neurotomy needle such that the filament and the tip operate together as a single electrode,	As shown, the DTR device's needle comprises a filament, in fact it comprises three filaments [9a-c]. As shown, physical contact is made between the uninsulated exterior surface of the filaments [9a-c] and the uninsulated portion of the DTR device's needle within circle [4]. This physical contact thereby electrically connects the filaments [9a-c] to the conductive portion that includes the tip [4] at the distal end [3] of the DTR device's needle. Further, given that the filaments [9a-c] and the tip [5] are electrically connected via physical contact, they must operate together as a single electrode in a circuit.	

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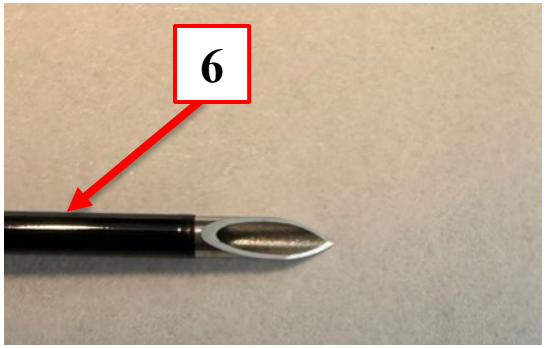
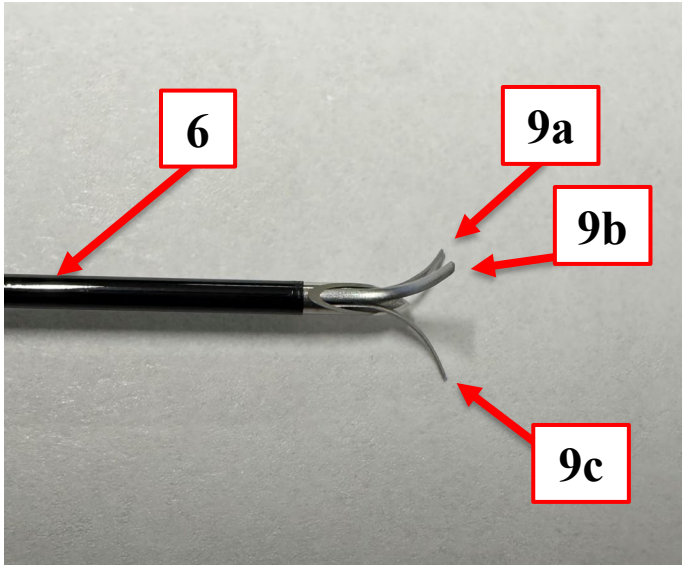
the filament being movable between a retracted position, in which the filament is at least partially in the elongate member, and a deployed position, in which at least a portion of the filament is out of the elongate member; and	As shown in the first image at right in which the DTR device is in the retracted position, i.e., with the filaments disposed within at least a portion of the elongate member [6]. As shown in the second image at right in which the DTR device is in the deployed position, i.e., with the filaments [9a-c] out of the elongate member [6]. As described in the DTR IFU, the "[c]annula hub/handle is equipped with a mechanism that allows deployment and retraction of 3 tines [i.e., filaments]." (**Exhibit I** at p. 1; *see also id.* at p. 4 (further describing deployment and retraction of filaments)).	 

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an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,	The DTR device's needle has an actuator portion [10] as shown in the image at right in which the DTR device is in the retracted position. The actuator portion [10] is interconnected to the filaments such that rotating the actuator portion [10] imparts movement of the filaments between the retracted position and the deployed position. As described in the DTR IFU, the "[c]annula hub/handle is equipped with a mechanism that allows deployment and retraction of 3 tines [i.e., filaments]." (**Exhibit I** at p. 1; *see also id.* at p. 4 (further describing deployment and retraction of filaments)).	

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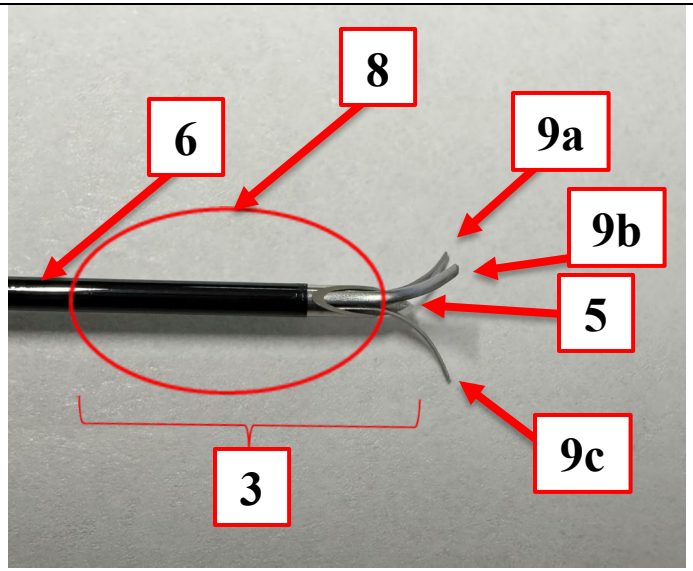
wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle.	As described in the DTR IFU, "Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode." (**Exhibit I** at p. 3). Thus, it would be understood that physical contact occurs between the uninsulated exterior surface of the RF probe [1] and the uninsulated interior surface of the lumen [7] within the circle [8] of the first photo to the right, and that this physical contact thereby electrically connects the RF probe [1] to the tip [5] and the filaments [9a-c]. The circle [8], representing the area where physical contact is made between the RF probe [1] and the conductive portion, is at the distal end [3]. Further, the RF probe, the tip, and the filaments are all electrically connected so they must operate together as a single electrode in a circuit. As described in the DTR IFU, the RF generator must be set in the "monopolar mode of operation." (**Exhibit I** at p. 6).	 **⚠ WARNINGS AND PRECAUTIONS** *Inspect all components for damage prior to each use. If components are damaged in any manner they must not be used. Damaged components must be discarded or returned for evaluation/repair. Damaged components may result in patient or operator injury.* • Check if device is reading room temperature before placing it into a patient • Do not start treatment without verification of correct placement • Do not start treatment if device doesn't read body temperature and impedance . . .

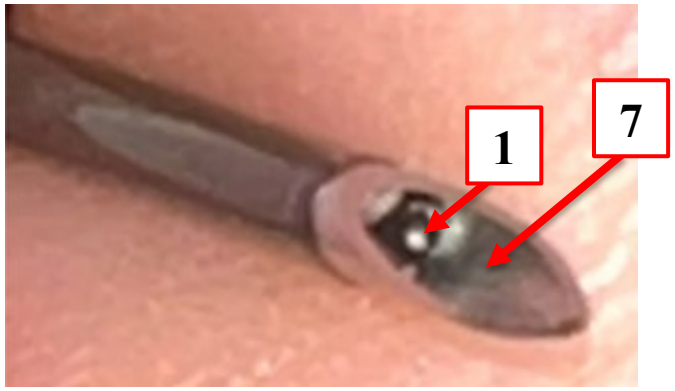
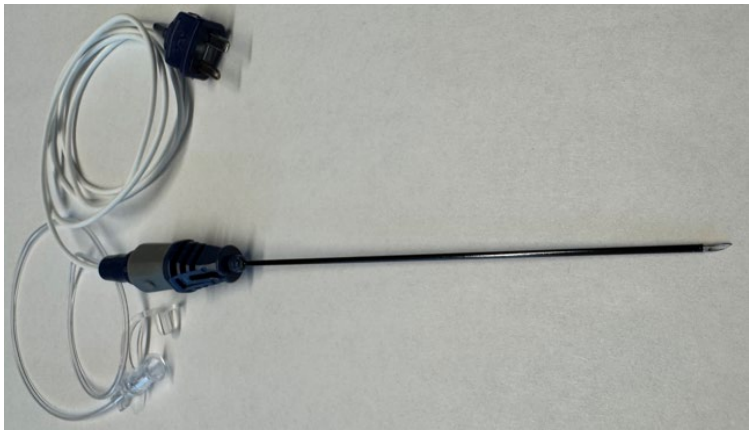
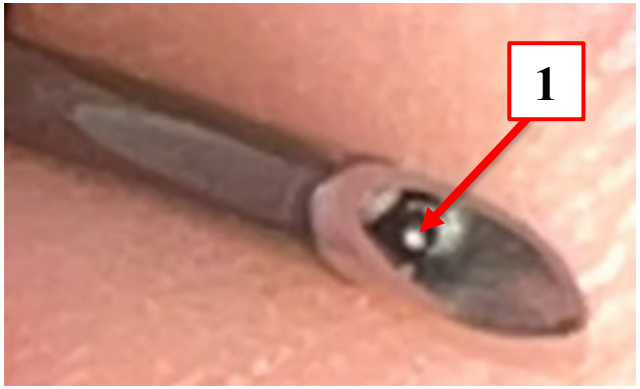
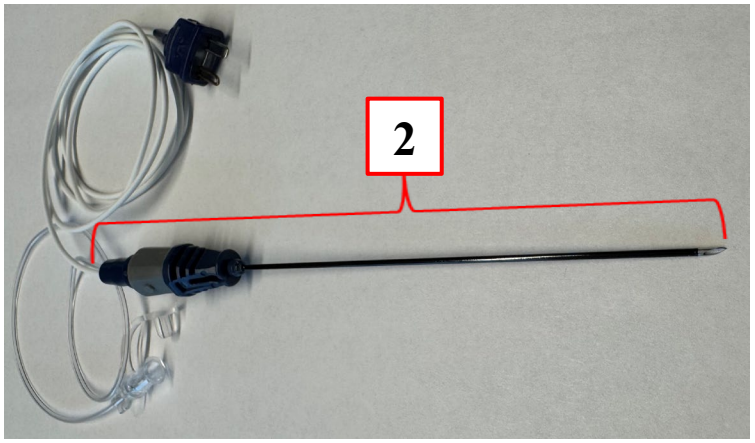
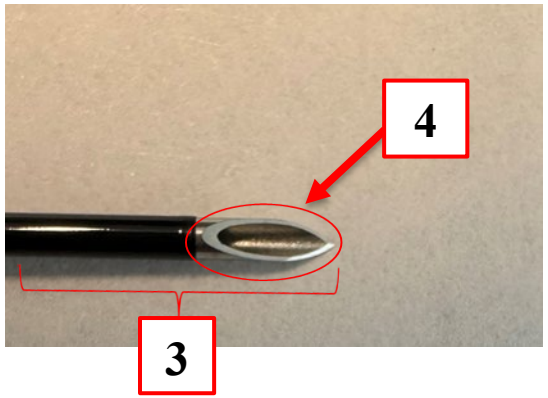
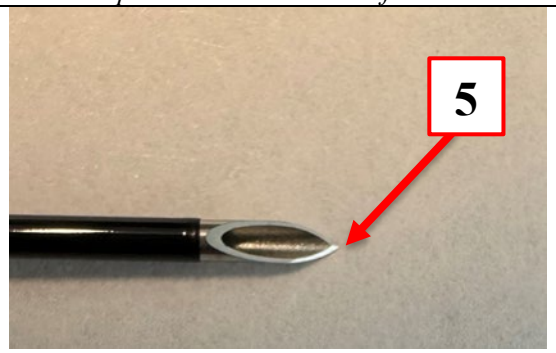
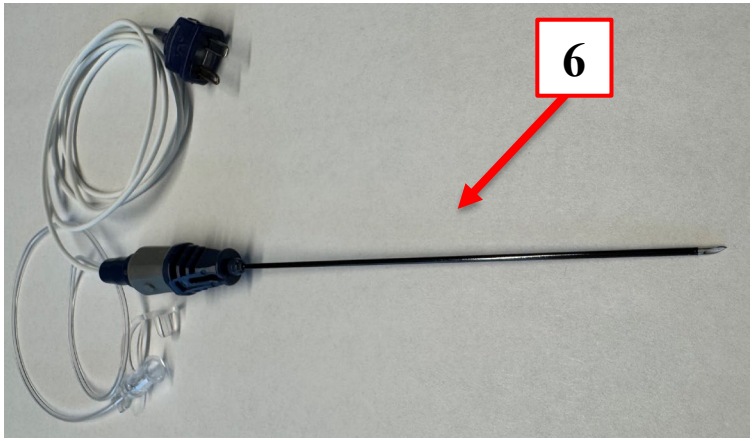
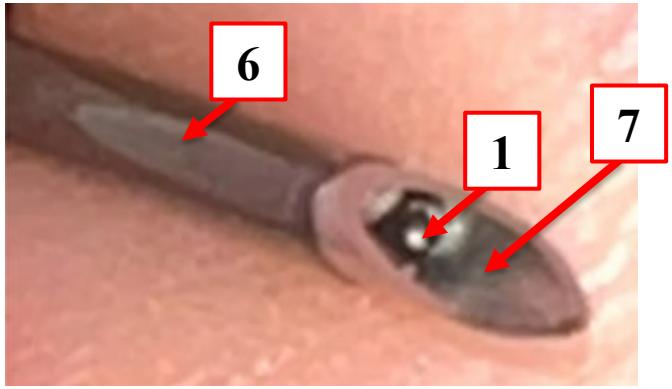
U.S. Patent No. 10,966,782	Trident RF Insulated Cannula (Model DTR)	
	As shown in the last image to the right, the RF probe [1] is accepted into the lumen [7].	• Application of RF energy may cause undesirable neuromuscular stimulation. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Set RF generator in monopolar mode of operation.  ** The last image above showing the RF probe [1] being accepted into the lumen [7] of the needle depicts the related DTRH device. Upon information and belief, the needle of the DTRH device is substantively the same as the needle of DTR when it is combined with the required RF probe and thus the same features are present in the needle of the DTR.*

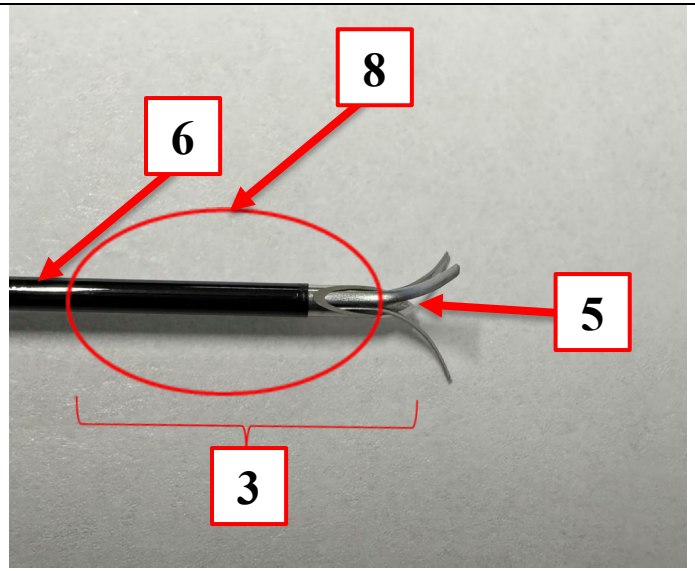
EXHIBIT F

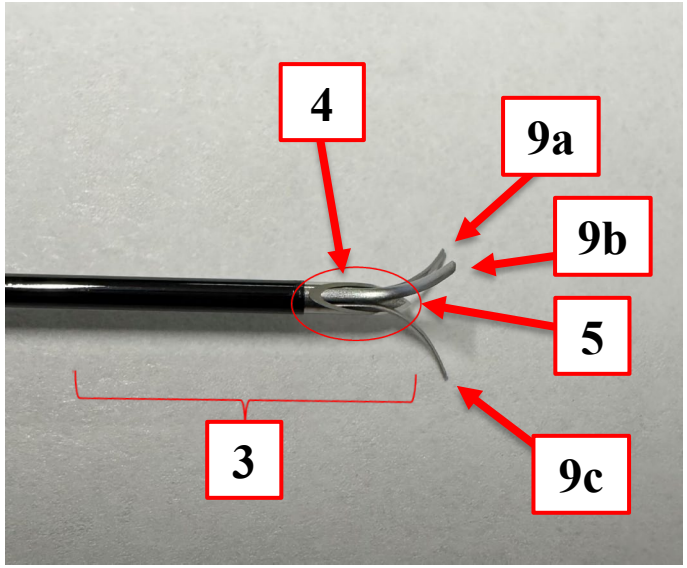
U.S. Patent No. 10,966,782	**Trident RF Insulated Cannula (Model DTRH)**	
1. A system comprising:	To the extent the preamble is limiting, the Trident Hybrid RF Insulated Cannula, Model DTRH ("DTRH") is pictured and is part of a system.	
a radiofrequency probe; and	As described in the Diros Instructions For Use ("IFU") of the DTRH, which users are expected to follow when using the DTRH, the DTRH "has an RF Probe/Temperature Sensor permanently installed inside it." (**Exhibit J** (*Instructions For Use OWL Sterile Single Use Trident™ Hybrid RF Insulated Cannula, Model DTRH*, Diros Document 175 at p. 4 (2023)). The radiofrequency "RF" probe [1] is shown inside the lumen.	

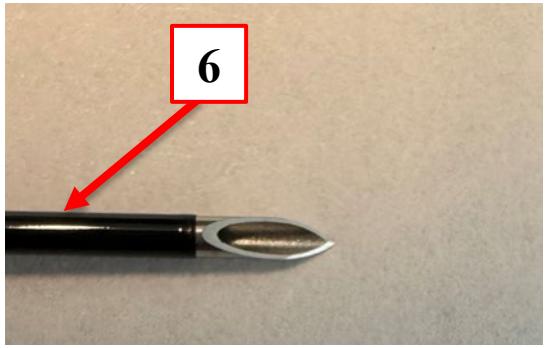
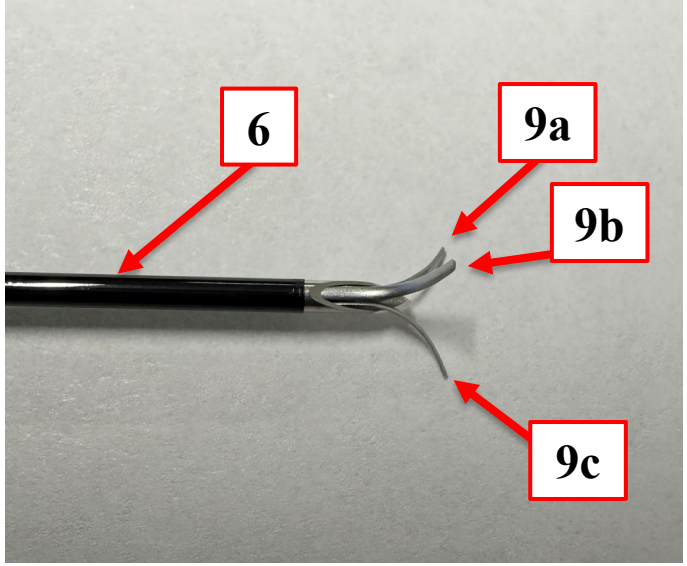
U.S. Patent No. 10,966,782	Trident RF Insulated Cannula (Model DTRH)	
a radiofrequency neurotomy needle operable with the radiofrequency probe, the radiofrequency neurotomy needle comprising:	The DTRH device has a needle [2] that is operable with the radiofrequency probe [1]. As described in the DTRH IFU, the DTRH "may be used . . . for radiofrequency lesioning," which is a radiofrequency neurotomy procedure, thus making the needle a radiofrequency neurotomy needle. (**Exhibit J** at p. 2).	
a conductive portion at a distal end of the radiofrequency neurotomy needle;	As shown, the distal end [3] of the needle of the DTRH device has an uninsulated portion [4]. The distal end [3] extends past the insulation to include internal elements. The conductive portion includes the uninsulated portion [4] of the DTRH device's needle as well as the internal elements at the distal end [3].	 ** The image above depicts the related DTR device. Upon information and belief, the needle of the DTR device is*

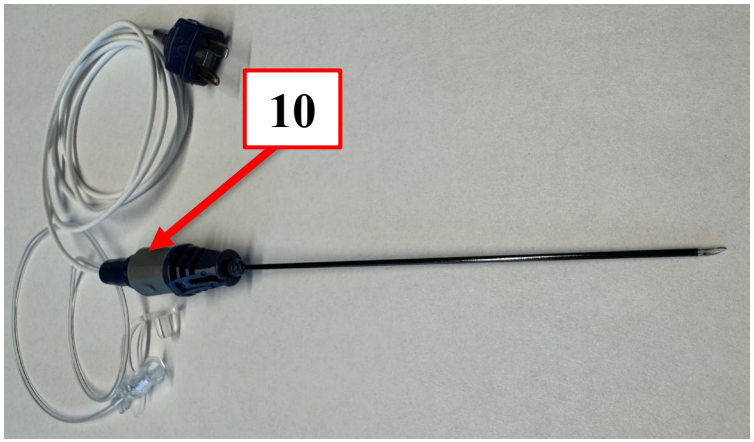
U.S. Patent No. 10,966,782	Trident RF Insulated Cannula (Model DTRH)	
		substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.
a tip configured to pierce tissue of a patient;	As shown, the DTRH device's needle has a tip [5]. The tip [5] is sharp and beveled and thus would be understood to be shaped for the purpose of piercing the tissue of a patient.	 ** The image above depicts the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*

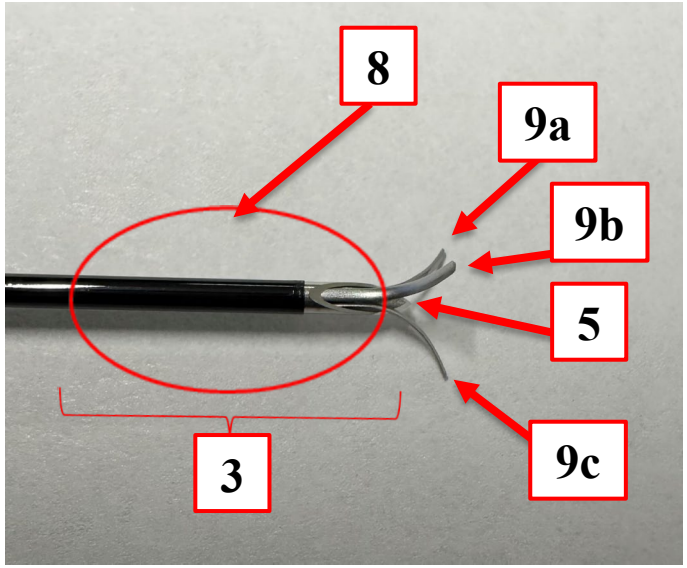
U.S. Patent No. 10,966,782	Trident RF Insulated Cannula (Model DTRH)	
an elongate member comprising a lumen configured to accept the radiofrequency probe therein such that the radiofrequency probe physically contacts and is electrically connected to the conductive portion, the tip being at a distal end of the elongate member;	As shown, the DTRH device's needle has an elongate member [6], comprising an interior lumen [7]. As shown, the lumen [7] at the interior of the DTRH device's elongate member [6] is configured to and does accept the RF probe [1] therein. As described in the DTRH IFU, "Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode." (**Exhibit J** at p. 3). Thus, it would be understood that physical contact occurs between the uninsulated exterior surface of the RF probe [1] and the uninsulated interior surface of the lumen [7] within the circle [8] of the third photo to the right, and that this physical contact thereby electrically connects the RF probe [1] to the conductive portion that includes the tip [5] at the distal end [3] of the elongate member [6].	 

U.S. Patent No. 10,966,782	Trident RF Insulated Cannula (Model DTRH)	
		 ** The third image above showing the distal end [3], tip [5], and elongate member [6] of the needle depicts the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*

U.S. Patent No. 10,966,782	Trident RF Insulated Cannula (Model DTRH)	
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,	As shown, the DTRH device's needle comprises a filament, in fact it comprises three filaments [9a-c]. As shown, physical contact is made between the uninsulated exterior surface of the filaments [9a-c] and the uninsulated portion of the DTRH device's needle within circle [4]. This physical contact thereby electrically connects the filaments [9a-c] to the conductive portion that includes the tip [5] at the distal end [3] of the DTRH device's needle. Further, given that the filaments [9a-c] and the tip [5] are electrically connected via physical contact, they must operate together as a single electrode in a circuit.	 ** The image above depicts the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*

U.S. Patent No. 10,966,782	Trident RF Insulated Cannula (Model DTRH)	
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	As shown in the first image at right in which the DTRH device is in the retracted position, i.e., with the filaments disposed within at least a portion of the elongate member [6]. As shown in the second image at right in which the DTRH device is in the deployed position, i.e., with the filaments [9a-c] out of the elongate member [6]. As described in the DTRH IFU, the "[c]annula handle is equipped with a mechanism that allows deployment and retraction of 3 tines [i.e., filaments]." (**Exhibit J** at p. 1; see also *id.* at p. 5 (further describing deployment and retraction of filaments)).	 

U.S. Patent No. 10,966,782	Trident RF Insulated Cannula (Model DTRH)	
		** The images above depict the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*
an actuator interconnected to the filament to move the filament between the retracted position and the deployed position,	The DTRH device's needle has an actuator portion [10] as shown in the image at right in which the DTRH device is in the retracted position. The actuator portion [10] is interconnected to the filaments such that rotating the actuator portion [10] imparts movement of the filaments between the retracted position and the deployed position. As described in the DTRH IFU, the "[c]annula handle is equipped with a mechanism that allows deployment and retraction of 3 tines [i.e., filaments]." (**Exhibit J** at p. 1; see also *id.* at p. 5 (further describing deployment and retraction of filaments)).	

U.S. Patent No. 10,966,782	Trident RF Insulated Cannula (Model DTRH)	
wherein the filament and the tip are configured to transmit radiofrequency energy from the radiofrequency probe and operate together as the single electrode in a monopolar mode when the filament is in the deployed position and the radiofrequency probe is accepted in the lumen and is in physical contact with the conductive portion at the distal end of the radiofrequency neurotomy needle.	As described in the DTRH IFU, "Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode." (**Exhibit J** at p. 3). Thus, it would be understood that physical contact occurs between the uninsulated exterior surface of the RF probe [1] and the uninsulated interior surface of the lumen [7] within the circle [8] of the first photo to the right, and that this physical contact thereby electrically connects the RF probe [1] to the tip [5] and the filaments [9a-c]. The circle [8], representing the area where physical contact is made between the RF probe [1] and the conductive portion, is at the distal end [3]. Further, the RF probe, the tip, and the filaments are all electrically connected so they must operate together as a single electrode in a circuit. As described in the DTRH IFU, the RF generator must be set in the "monopolar mode of operation." (**Exhibit J** at p. 6).	 ⚠ **WARNINGS AND PRECAUTIONS** Inspect all components for damage prior to each use. If components are damaged in any manner they must not be used. Damaged components must be discarded or returned for evaluation/repair. Damaged components may result in patient or operator injury. • Check if device is reading room temperature before placing it into a patient • Do not start treatment without verification of correct placement • Do not start treatment if device doesn't read body temperature and impedance • Do not move device during treatment . . .

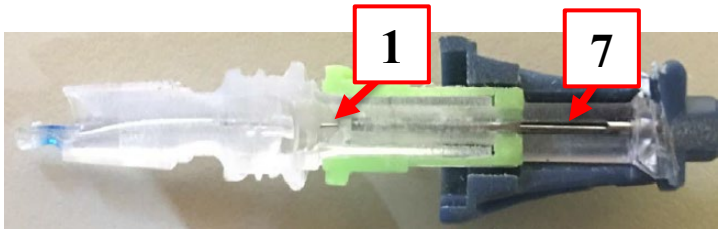
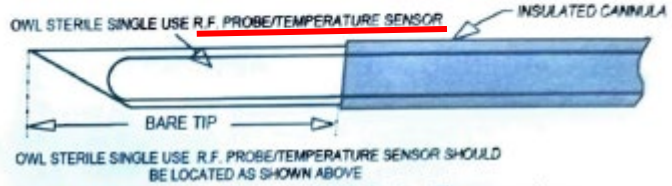
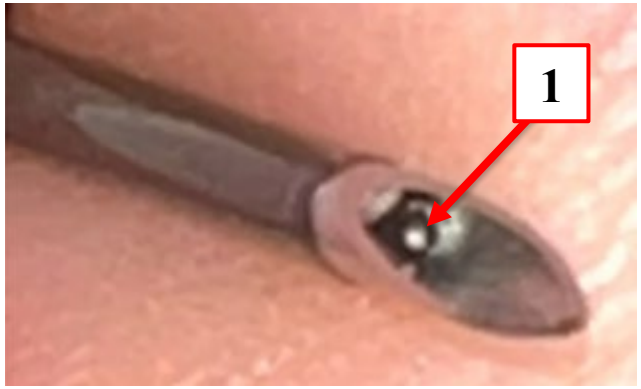
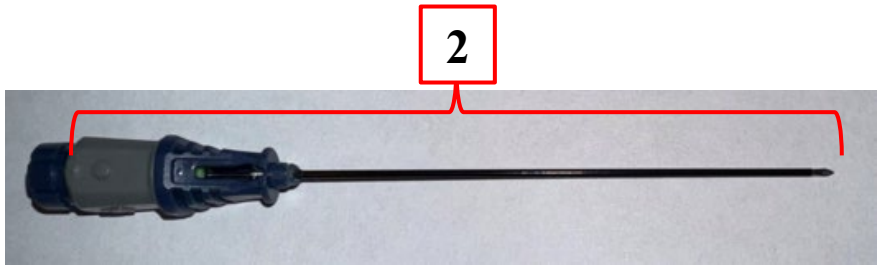
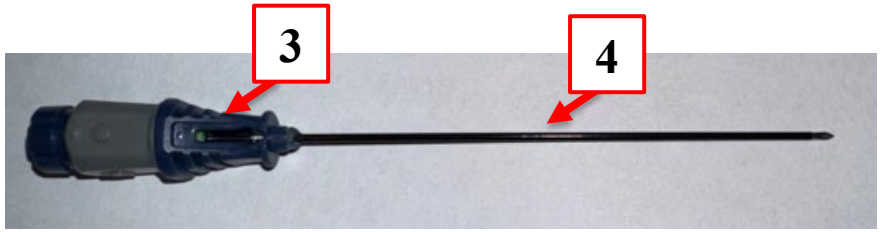
U.S. Patent No. 10,966,782	Trident RF Insulated Cannula (Model DTRH)	
	As shown in the last image to the right, the RF probe [1] is accepted into the lumen [7].	• Application of RF energy may cause undesirable neuromuscular stimulation. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Set RF generator in monopolar mode of operation. • Use the correct size return path electrodes to avoid burns at this site. (Refer to information in section Return Path Electrodes) • The interference produced by the operation of RF Generator may adversely influence the operation of other electronic  ** The first image above showing the tip [5] and filaments [9a-c] of the needle depicts the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*

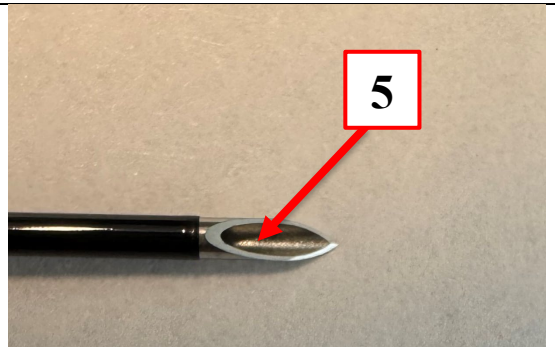
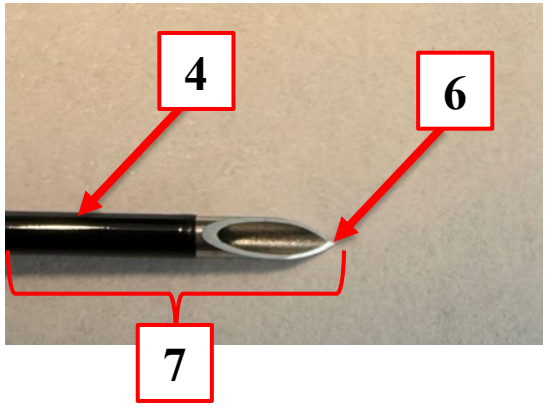
EXHIBIT G

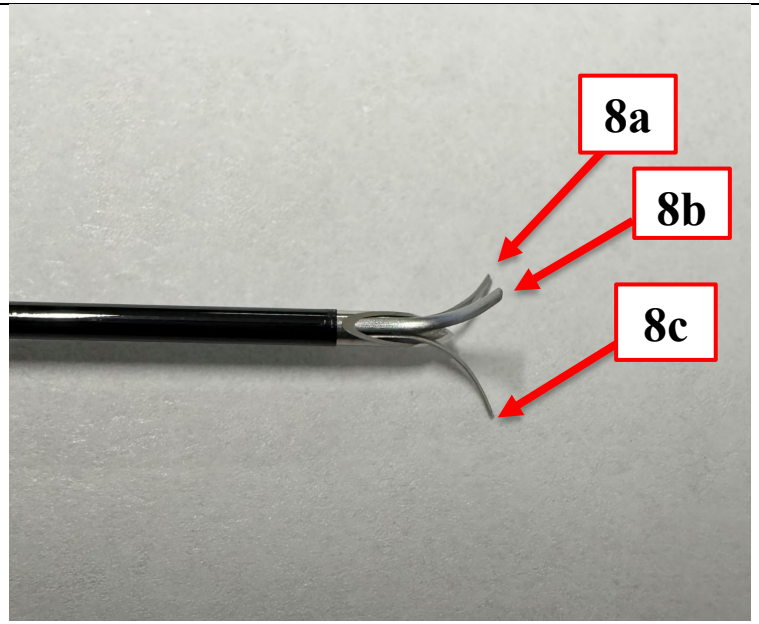
U.S. Patent No. 10,736,688	Trident RF Insulated Cannula, Model DTR	
1. A system comprising:	To the extent the preamble is limiting, the Trident RF Insulated Cannula, Model DTR ("DTR") is pictured and is part of a system.	
an RF probe; and	As described in the Diros Instructions For Use ("IFU") of the DTR, which users are expected to follow when using the DTR, an "RF Probe/Temperature Sensor" is required equipment for use of the DTR. (**Exhibit I** (*Instructions For Use OWL Sterile Single Use Trident™ RF Insulated Cannula, Model DTR*, Diros Document 174 at p. 5 (2020)). Further, an "RF Probe/Temperature Sensor" is specifically listed in steps 3-5, 7, and 11 of the Procedure. (*Id.*). The RF probe [1] is shown inside the lumen.	**6. Directions for Use** **6.1 Equipment Required** Radiofrequency lesion procedures should be performed in a specialized clinical setting with fluoroscopic equipment. The RF equipment required for the procedure is as follows: It is important to use the correct size lesion/temperature probe Q-ty: Equipment 1: OWL Sterile Single Use Trident™ RF Insulated Cannula, model DTR 1: OWL RF Probe/Temperature Sensor. Use probe of matching length. (i.e. 5cm DTR cannula with 5cm probe) D466-005, D466-010, D466-015, D466-020 / D467-005-TC, D467-010-TC, D466-015-TC, D466-020-TC / D467-005-TCH, D467-010-TCH, D466-015-TCH, D466-020-TCH / 5cm probe, 10cm probe, 15cm probe, 20cm probe 1: Corresponding connecting cable For probe models: D466-005, D466-010, D466-015, D466-020 — Cable models: 463-103-TM-S, 463-103-S, 463-103-S (IEC), For probe models: D467-005-TC, D467-010-TC, D466-015-TC, D466-020-TC — Cable models: H4-S2F-S, 463-103-HCT-S For probe models: D467-005-TCH, D467-010-TCH, D466-015-TCH, D466-020-TCH — Cable models: H4-H4-S, 463-103-TCH-S, 463-103-BPTCH-S 1: OWL Radiofrequency generator, URF-3AP 1: OWL Disposable Indifferent dispersive electrode (GD-Pad) meeting ANSI/AAMI standard HF-18 requirements for electrosurgical electrodes, models D7506, D7506NC

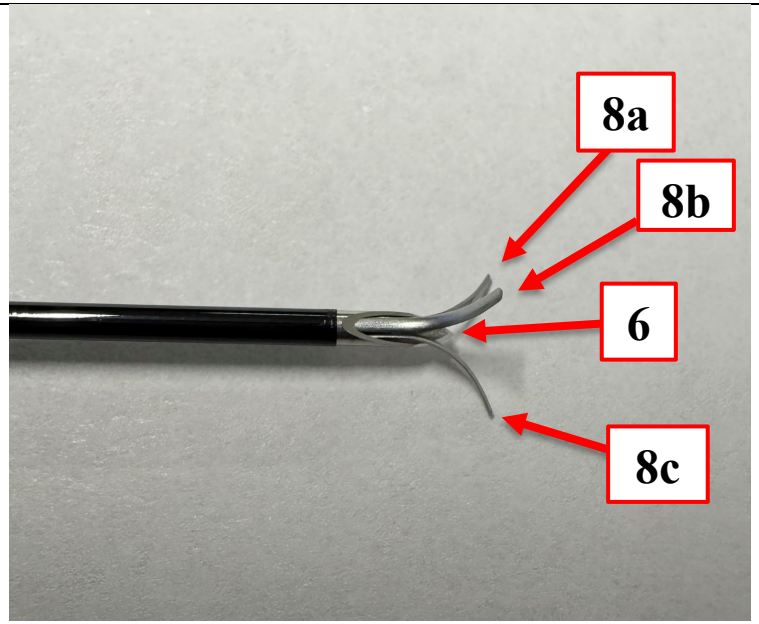
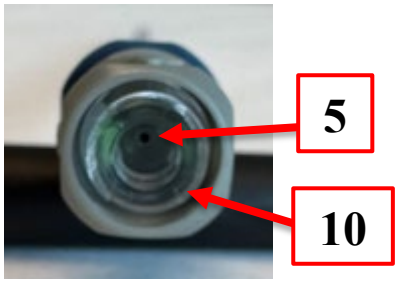
U.S. Patent No. 10,736,688	Trident RF Insulated Cannula, Model DTR	
		6.3 Procedure 1. Assemble all required equipment for the intended procedure and position the patient as necessary. . . . 3. Inspect the part number of the RF Probe/Temperature Sensor to ensure that it is the correct length to match the length of the Trident™ RF Insulated Cannula. 4. Test the match by removing the stylet from the cannula and slowly inserting the RF Probe/Temperature Sensor into the cannula. Do not use excessive force to avoid damage to the RF Probe. The tip of the RF probe must lie within the bare tip of the RF cannula, see Figure 2. Otherwise the measured temperature will be incorrect. To further verify this, note the position of the handle of the RF Probe, Figure 1 (**9**) relative to the threaded top section of the Actuator, Figure 1 (**4c**). Then remove the RF Probe from the RF Cannula, place it parallel to and alongside the cannula and confirm that the tip of the RF Probe is no more than a mm short of the end of the RF Cannula bevel, but does not extend beyond it. Reinsert the Stylet into the RF Cannula. 5. Connect the plug of the intermediate cable to an input of the Multi-Lesion Adaptor or to the Probe receptacle on the RF Generator. Maintain access to the probe connection end of the intermediate cable in order to facilitate easy attachment to the RF Probe/Temperature Sensor to it.  Figure 2. Correct position of RF Probe/Temperature Sensor within the Trident™ RF Insulated Cannula. Tines are not shown. . . .

U.S. Patent No. 10,736,688	Trident RF Insulated Cannula, Model DTR	
		7. Once the cannula is properly positioned carefully remove the stylet from the cannula and insert the full length of the RF Probe/Temperature Sensor down the shaft of the Sterile Single Use Trident™ RF Insulated Cannula. . . . 11. Lesion as necessary. Refer to the RF Generator User's Manual for more information. Upon completion, remove the RF Probe/Temperature Sensor and instill anesthetic and steroid if in accordance with your protocol. When connecting/disconnecting the RF Cannula to the syringe, ensure once again to grasp the cannula only by its hub. Upon completion of the procedure, remove the Trident™ RF Insulated Cannula (with RF Probe/Temperature Sensor still in it if no anesthetic applied).  ** The last image above showing the RF probe [1] of the needle depicts the related DTRH device. Upon information and belief, the needle of the DTRH device is substantively the same as the needle of DTR when it is combined with the required RF probe and thus the same features are present in the needle of the DTR.*

U.S. Patent No. 10,736,688	Trident RF Insulated Cannula, Model DTR	
a needle for insertion into a patient during an RF ablation procedure, the needle comprising:	The DTR device has a needle [2] with the tip at the distal end configured for insertion into a patient. As described in the DTR IFU, the DTR "may be used . . . for radiofrequency lesioning," which is an RF ablation procedure. (**Exhibit I** at p. 2).	
a hub;	The DTR device's needle has a hub portion [3], which constitutes a hub.	
an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof;	As shown, the DTR device's needle has an elongate member [4], which is fixed to the hub [3] and has an interior lumen [5].	

U.S. Patent No. 10,736,688	Trident RF Insulated Cannula, Model DTR	
		
a tip fixed to the elongate member at a distal end of the needle, wherein the tip is shaped to pierce tissue of the patient;	As shown, the DTR device's needle has a tip [6], which is fixed to the elongate member [4] at the distal end [7] of the DTR device's needle. The tip [6] is sharp and beveled and thus would be understood to be shaped for the purpose of piercing the tissue of a patient.	

U.S. Patent No. 10,736,688	Trident RF Insulated Cannula, Model DTR	
a plurality of filaments;	As shown, the DTR device's needle comprises a plurality of filaments [8a-c].	
an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to	The DTR device's needle has an actuator portion [9] as shown in the first image at right in which the DTR device is in the retracted position, i.e., with the filaments disposed within at least a portion of the elongate member [4]. The actuator portion [9] is interconnected to the plurality of filaments [8a-c] such that rotating the actuator portion [9] in a first direction or a second direction	

U.S. Patent No. 10,736,688	Trident RF Insulated Cannula, Model DTR	
the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member; and	relative to the hub imparts movement of the plurality of filaments [8a-c] between the deployed position and the retracted position, respectively. As shown in the second image at right, the plurality of filaments [8a-c] extend distally beyond the tip [6] in the deployed position.	
a fitting in fluid communication with the lumen, the fitting being configured to provide a connection for injection of fluid through the fitting and through the lumen, the fitting further being configured to allow for insertion of the RF probe	The DTR device's needle has a fitting [10], which is in fluid communication with the lumen [5] and is configured to allow for injection of fluid through the lumen [5]. As described in the DTR IFU, a user is instructed to remove the RF probe [1] from the DTR to inject fluid through the lumen without removing	

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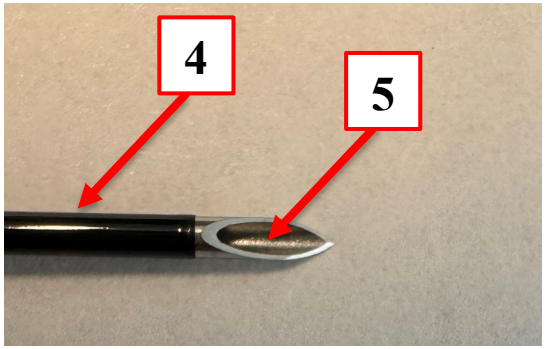
into the lumen through the fitting,	the fitting. (*See* **Exhibit I** at p. 5, step 11). Thus, it would be understood that the same fitting that is configured to provide a connection for injection of fluid is also configured to allow for insertion of the RF probe [1].	11. Lesion as necessary. Refer to the RF Generator User's Manual for more information. Upon completion, remove the RF Probe/Temperature Sensor and instill anesthetic and steroid if in accordance with your protocol. When connecting/disconnecting the RF Cannula to the syringe, ensure once again to grasp the cannula only by its hub. Upon completion of the procedure, remove the Trident™ RF Insulated Cannula (with RF Probe/Temperature Sensor still in it if no anesthetic applied).
wherein the lumen at the interior of the elongate member is configured to accept the RF probe therein to physically contact a conductive portion of the needle and thereby electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments, and	As shown, the lumen [5] at the interior of the DTR device's elongate member [4] is configured to and does accept the RF probe [1] therein. As described in the DTR IFU, "Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode." (**Exhibit I** at p. 3). Thus, it would be understood that physical contact occurs between the uninsulated exterior surface of the RF probe [1] and the uninsulated interior surface of the lumen [5] within the circle [11] of the photo to the right, and that this physical contact thereby electrically connects the RF probe [1] to the tip [6] and the plurality of filaments [8a-c].	

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		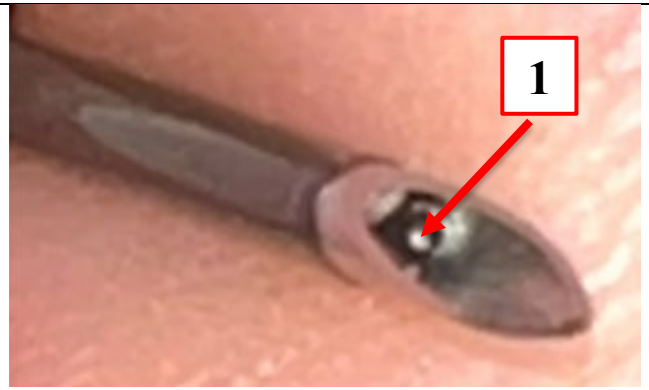 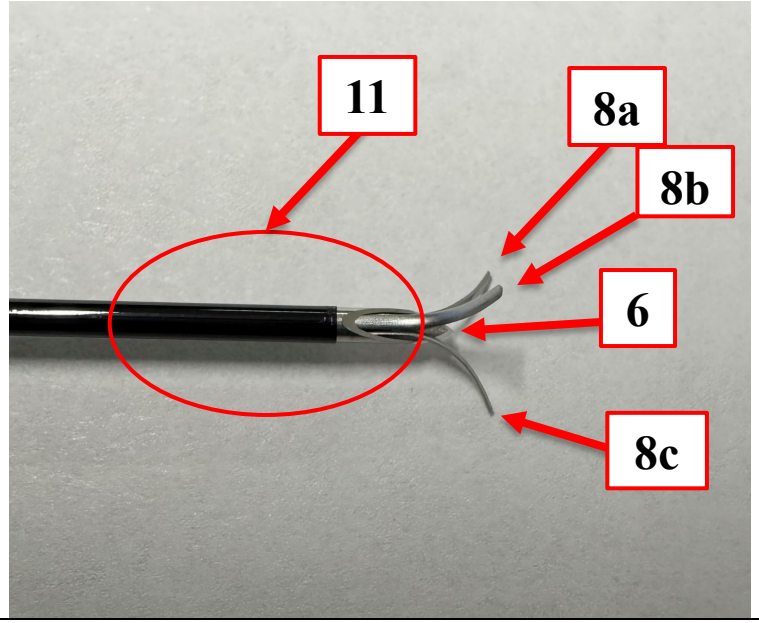

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		** The second image above showing the RF probe [1] of the needle depicts the related DTRH device. Upon information and belief, the needle of the DTRH device is substantively the same as the needle of DTR when it is combined with the required RF probe and thus the same features are present in the needle of the DTR.*
such that the RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode,	As described in the DTR IFU, the RF generator must be set in the "monopolar mode of operation." (**Exhibit I** at p. 6). Further, the RF probe, the tip, and the plurality of filaments are all electrically connected so they must operate together as a single electrode in a circuit.	⚠ **WARNINGS AND PRECAUTIONS** Inspect all components for damage prior to each use. If components are damaged in any manner they must not be used. Damaged components must be discarded or returned for evaluation/repair. Damaged components may result in patient or operator injury. • Check if device is reading room temperature before placing it into a patient • Do not start treatment without verification of correct placement • Do not start treatment if device doesn't read body temperature and impedance . . . • Application of RF energy may cause undesirable neuromuscular stimulation. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Set RF generator in monopolar mode of operation.

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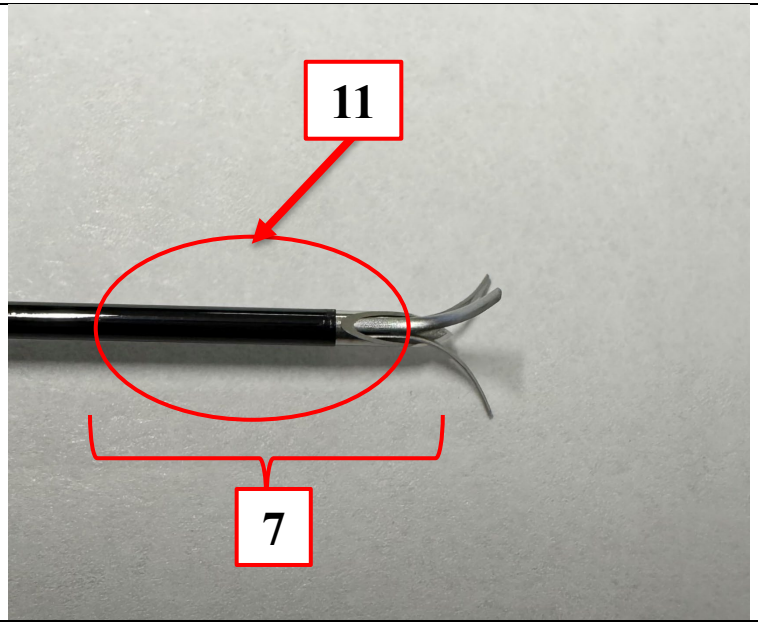
wherein the conductive portion of the needle is at a distal end of the needle, and	The RF probe, the tip, and the plurality of filaments are all conductive and physical contact between them occurs within the circle [11] of the photo to the right at the distal end [7] of the needle.	

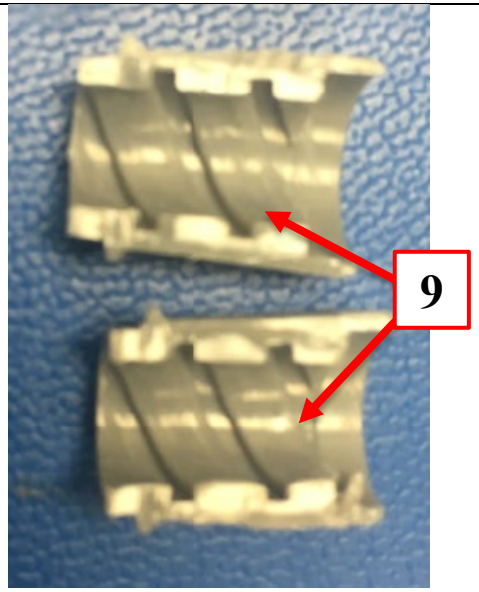
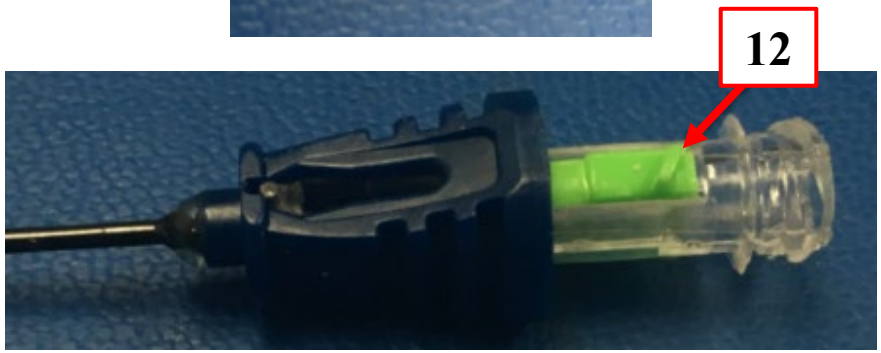
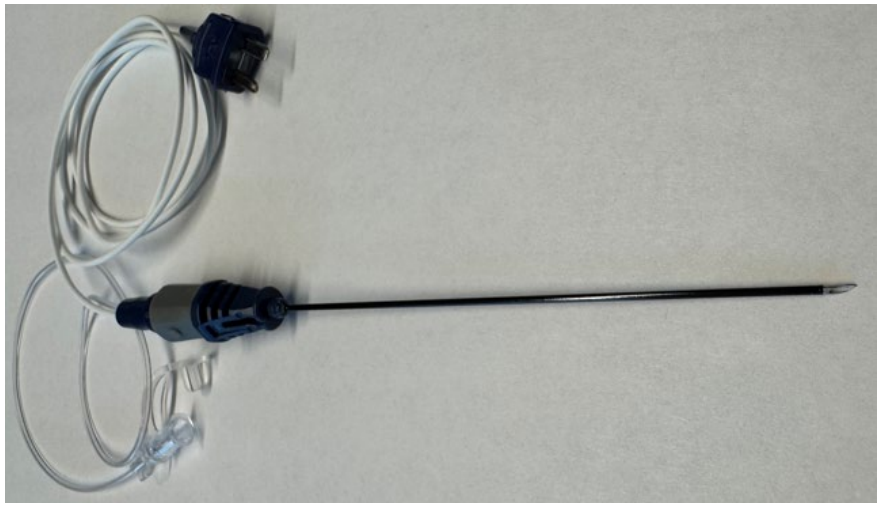
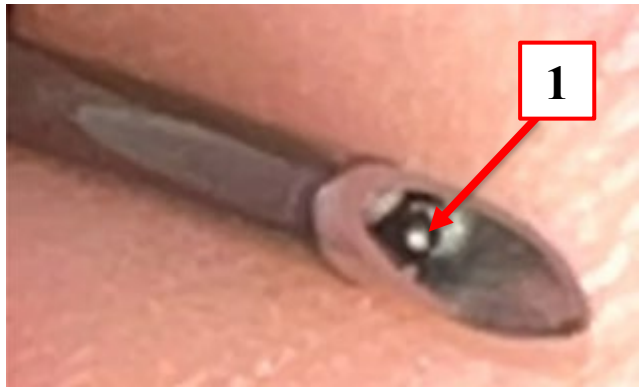
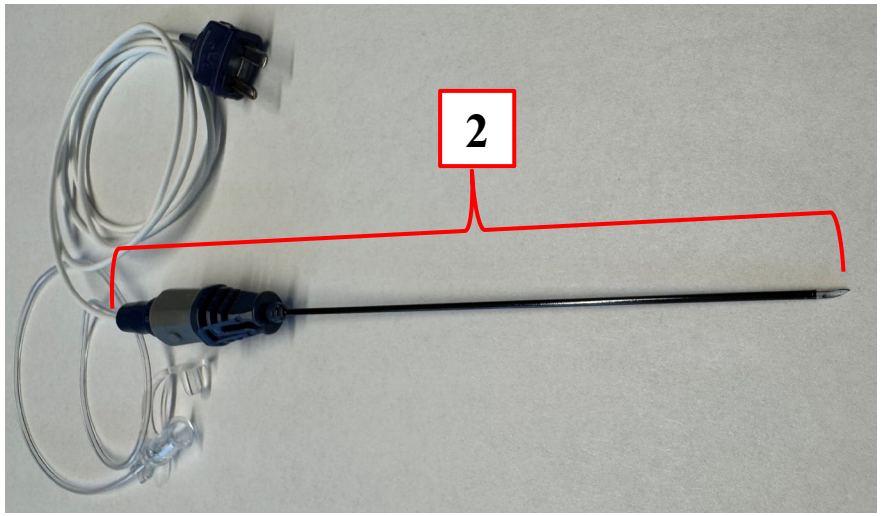
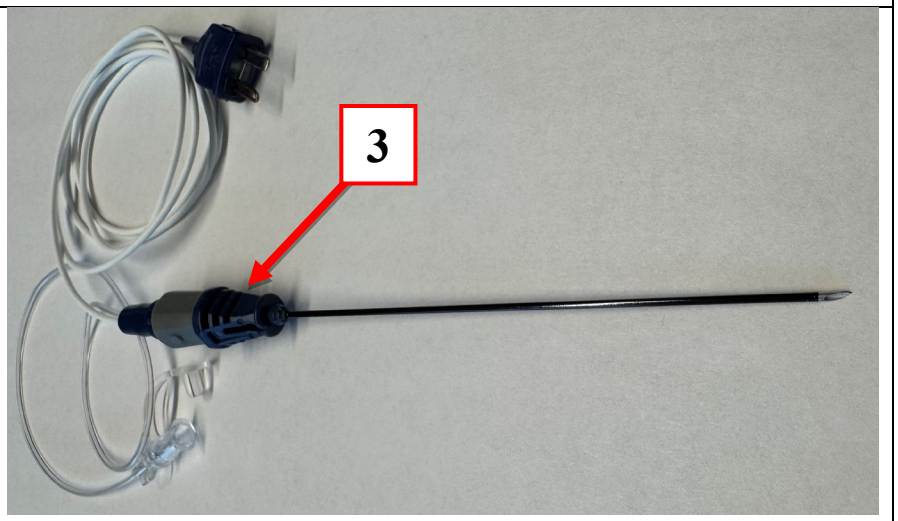
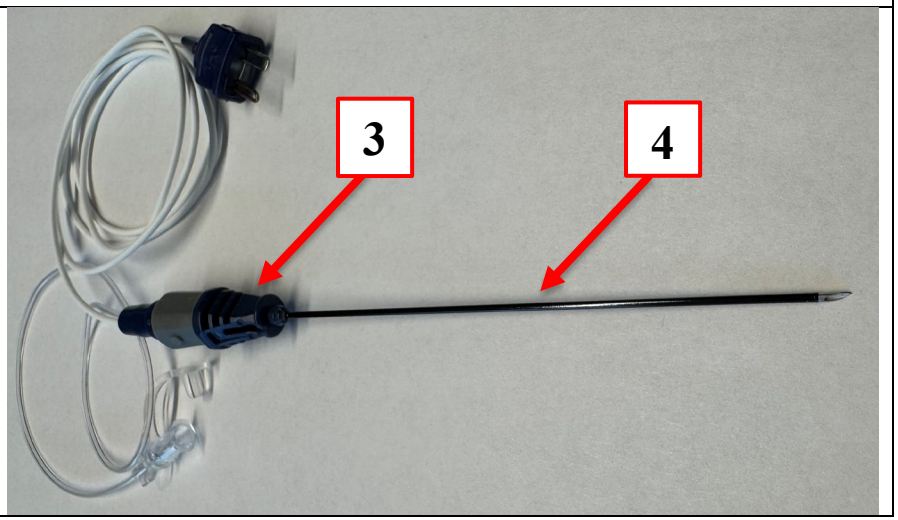
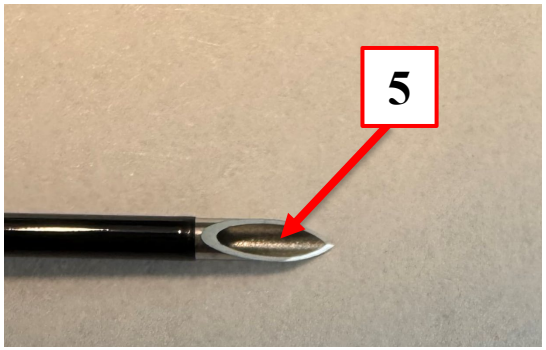
U.S. Patent No. 10,736,688	Trident RF Insulated Cannula, Model DTR	
wherein, when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position.	As shown, the actuator portion [9] has been split revealing internal threading such that the groove [12] imparts movement on the plurality of filaments. Rotating the actuator portion [9] imparts movement of the plurality of filaments between the retracted position and the deployed position. Further, the actuator portion [9] has this capability regardless of whether the RF probe is in a non-inserted state, as shown, or whether the RF probe is in an inserted state. As described in the DTR IFU, the "[c]annula hub/handle is equipped with a mechanism that allows deployment and retraction of 3 tines [i.e., filaments]." (**Exhibit I** at p. 1; *see also id.* at p. 4 (further describing deployment and retraction of filaments)).	 

EXHIBIT H

U.S. Patent No. 10,736,688	Trident Hybrid RF Insulated Cannula, Model DTRH	
1. A system comprising:	To the extent the preamble is limiting, the Trident Hybrid RF Insulated Cannula, Model DTRH ("DTRH") is pictured and is part of a system.	
an RF probe; and	As described in the Diros Instructions For Use ("IFU") of the DTRH, which users are expected to follow when using the DTRH, the DTRH "has an RF Probe/Temperature Sensor permanently installed inside it." (**Exhibit J** (*Instructions For Use OWL Sterile Single Use Trident™ Hybrid RF Insulated Cannula, Model DTRH*, Diros Document 175 at p. 4 (2023)). The RF probe [1] is shown inside the lumen.	

U.S. Patent No. 10,736,688	Trident Hybrid RF Insulated Cannula, Model DTRH	
a needle for insertion into a patient during an RF ablation procedure, the needle comprising:	The DTRH device has a needle [2] with the tip at the distal end configured for insertion into a patient. As described in the DTRH IFU, the DTRH "may be used . . . for radiofrequency lesioning," which is an RF ablation procedure. (**Exhibit J** at p. 2).	

U.S. Patent No. 10,736,688	Trident Hybrid RF Insulated Cannula, Model DTRH	
a hub;	The DTRH device's needle has a hub portion [3], which constitutes a hub.	
an elongate member fixed to the hub, the elongate member comprising a lumen at an interior thereof;	As shown, the DTRH device's needle has an elongate member [4], which is fixed to the hub [3] and has an interior lumen [5].	

U.S. Patent No. 10,736,688	Trident Hybrid RF Insulated Cannula, Model DTRH	
		 ** The second image above showing the interior lumen [5] of the needle depicts the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*

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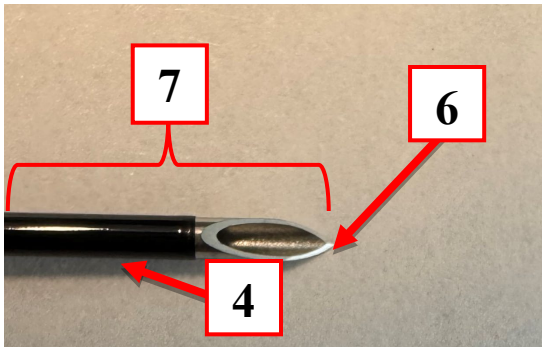
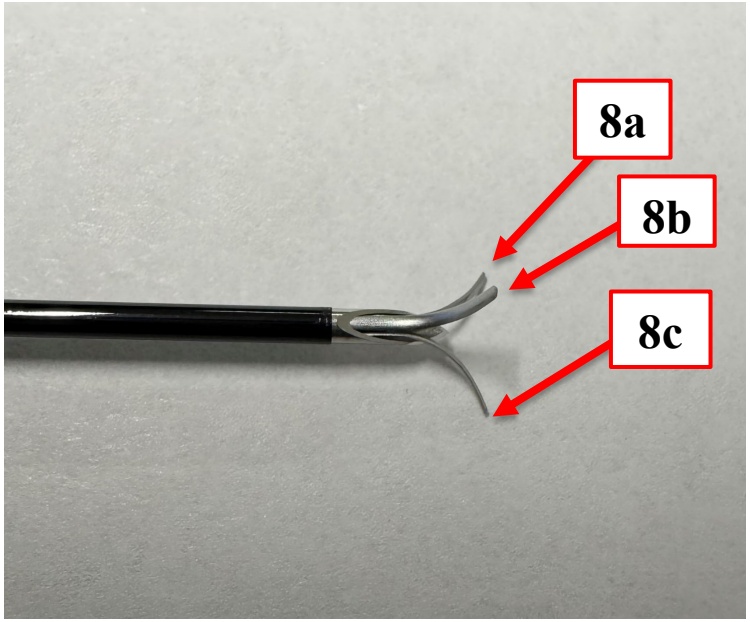
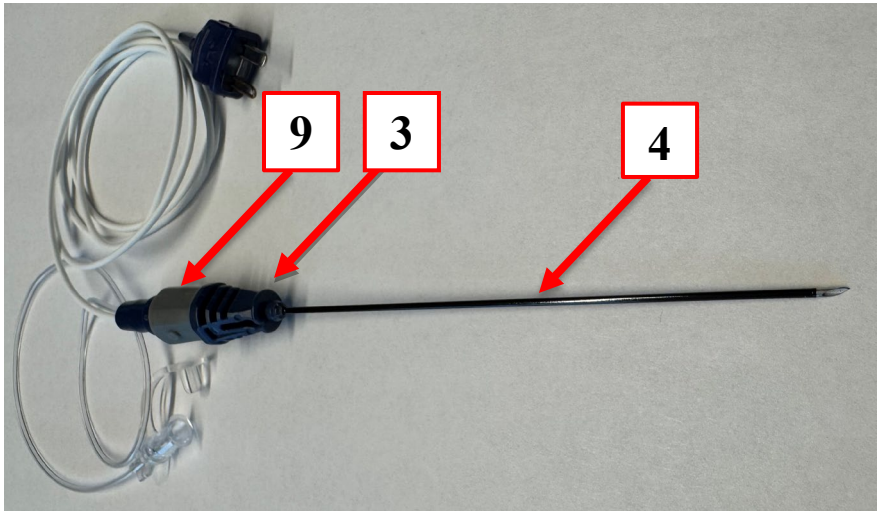
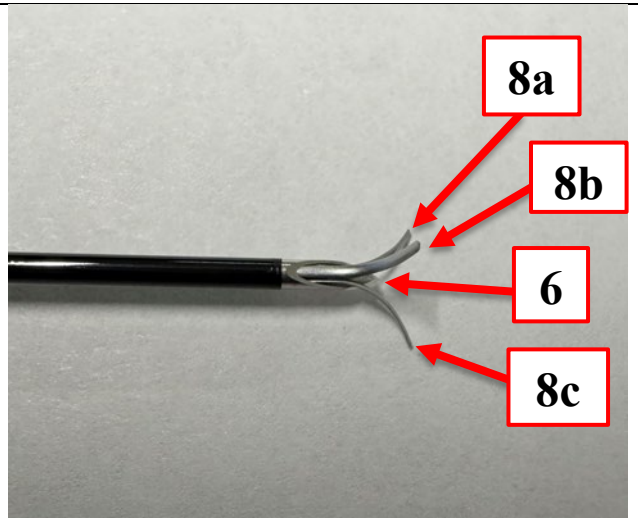
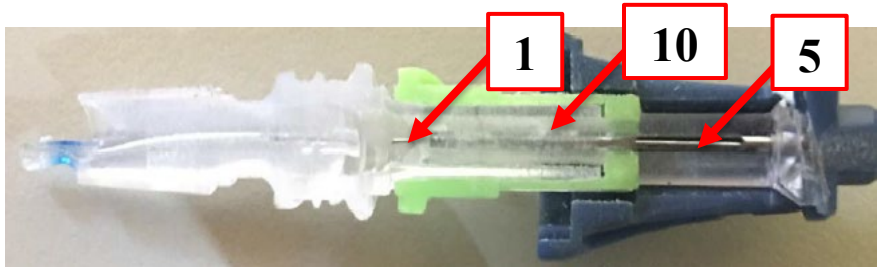
a tip fixed to the elongate member at a distal end of the needle, wherein the tip is shaped to pierce tissue of the patient;	As shown, the DTRH device's needle has a tip [6], which is fixed to the elongate member [4] at the distal end [7] of the DTRH device's needle. The tip [6] is sharp and beveled and thus would be understood to be shaped for the purpose of piercing the tissue of a patient.	 ** The image above depicts the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*

U.S. Patent No. 10,736,688	Trident Hybrid RF Insulated Cannula, Model DTRH	
a plurality of filaments;	As shown, the DTRH device's needle comprises a plurality of filaments [8a-c].	 ** The image above depicts the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*

U.S. Patent No. 10,736,688	Trident Hybrid RF Insulated Cannula, Model DTRH	
an actuator interconnected to the plurality of filaments, wherein movement of the actuator in a first direction relative to the hub moves the plurality of filaments relative to the tip to a deployed position distally beyond the tip, and wherein movement of the actuator in a second direction relative to the hub retracts the plurality of filaments to a retracted position in which the plurality of filaments are disposed within at least a portion of the elongate member; and	The DTRH device's needle has an actuator portion [9] as shown in the first image at right in which the DTRH device is in the retracted position, i.e., with the filaments. disposed within at least a portion of the elongate member [4]. The actuator portion [9] is interconnected to the plurality of filaments [8a-c] such that rotating the actuator portion [9] in a first direction or a second direction relative to the hub portion [3] imparts movement of the plurality of filaments [8a-c] between the deployed position and the retracted position, respectively. As shown in the second image at right, the plurality of filaments [8a-c] extend distally beyond the tip [6] in the deployed position. As described in the DTRH IFU, the "[c]annula handle is equipped with a mechanism that allows deployment and retraction of 3 tines [i.e., filaments]." (**Exhibit J** at p. 1; see also *id.* at p. 5 (further describing deployment and retraction of filaments)).	

U.S. Patent No. 10,736,688	Trident Hybrid RF Insulated Cannula, Model DTRH	
		 ** The second image above showing the tip [6] and filaments [8a-c] of the needle depicts the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*
a fitting in fluid communication with the lumen, the fitting being configured to provide a connection for injection of fluid through the fitting and through the lumen, the fitting further being configured to allow for insertion of the RF probe	The DTRH device's needle has a fitting [10], which is in fluid communication with the lumen [5] and is configured to allow for injection of fluid through the lumen [5]. As shown, the RF probe [1] is inserted through the lumen [5], thus demonstrating that the fitting is configured to allow for insertion of the RF probe [1] into the lumen [5]	

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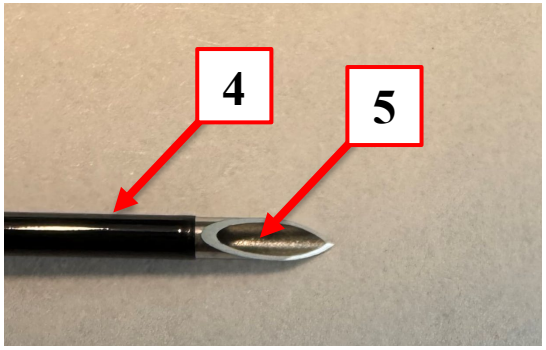
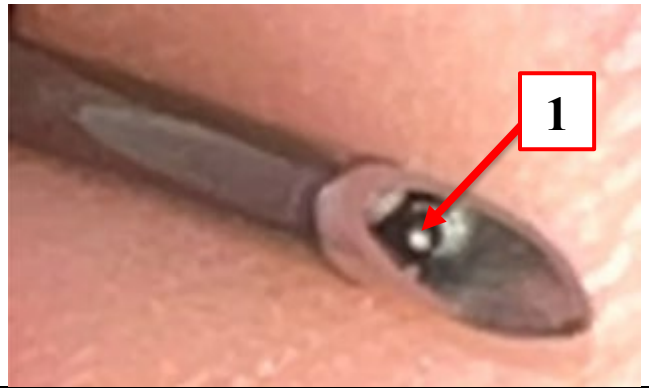
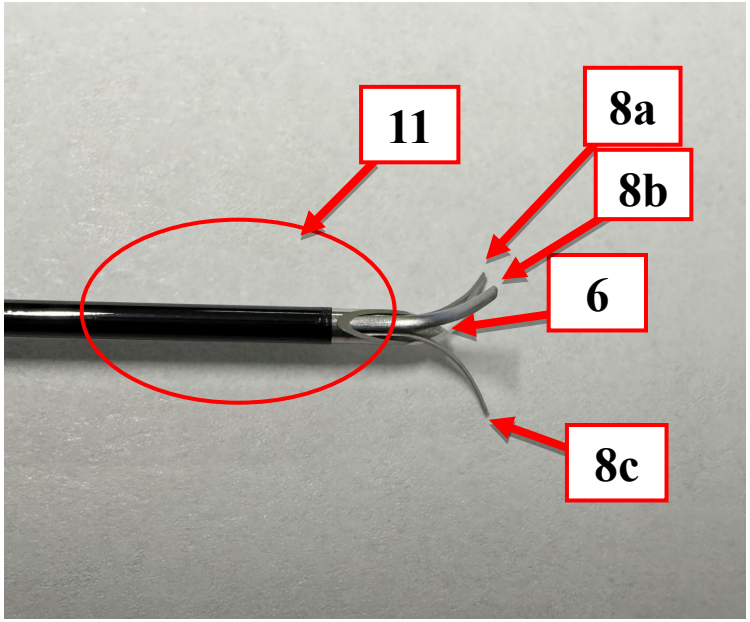
into the lumen through the fitting,	through the fitting [10].	
wherein the lumen at the interior of the elongate member is configured to accept the RF probe therein to physically contact a conductive portion of the needle and thereby electrically connect the RF probe to the tip and the plurality of filaments, such that energy emitted by the RF probe passes through the tip and the plurality of filaments, and	As shown, the lumen [5] at the interior of the DTRH device's elongate member [4] is configured to and does accept the RF probe [1] therein. As described in the DTRH IFU, "Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode." (**Exhibit J** at p. 3). Thus, it would be understood that physical contact occurs between the uninsulated exterior surface of the RF probe [1] and the uninsulated interior surface of the lumen [5] within the circle [11] of the photo to the right, and that this physical contact thereby electrically connects the RF probe [1] to the tip [6] and the plurality of filaments [8a-c].	 

U.S. Patent No. 10,736,688	Trident Hybrid RF Insulated Cannula, Model DTRH	
		 ** The first and third images above depict the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*

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such that the RF probe, the tip, and the plurality of filaments operate together as a single monopolar RF electrode,	As described in the DTRH IFU, the RF generator must be set in the "monopolar mode of operation." (**Exhibit J** at p. 6). Further, the RF probe, the tip, and the plurality of filaments are all electrically connected so they must operate together as a single electrode in a circuit.	⚠ **WARNINGS AND PRECAUTIONS** Inspect all components for damage prior to each use. If components are damaged in any manner they must not be used. Damaged components must be discarded or returned for evaluation/repair. Damaged components may result in patient or operator injury. • Check if device is reading room temperature before placing it into a patient • Do not start treatment without verification of correct placement • Do not start treatment if device doesn't read body temperature and impedance • Do not move device during treatment . . . • Application of RF energy may cause undesirable neuromuscular stimulation. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Set RF generator in monopolar mode of operation. • Use the correct size return path electrodes to avoid burns at this site. (Refer to information in section Return Path Electrodes) • The interference produced by the operation of RF Generator may adversely influence the operation of other electronic

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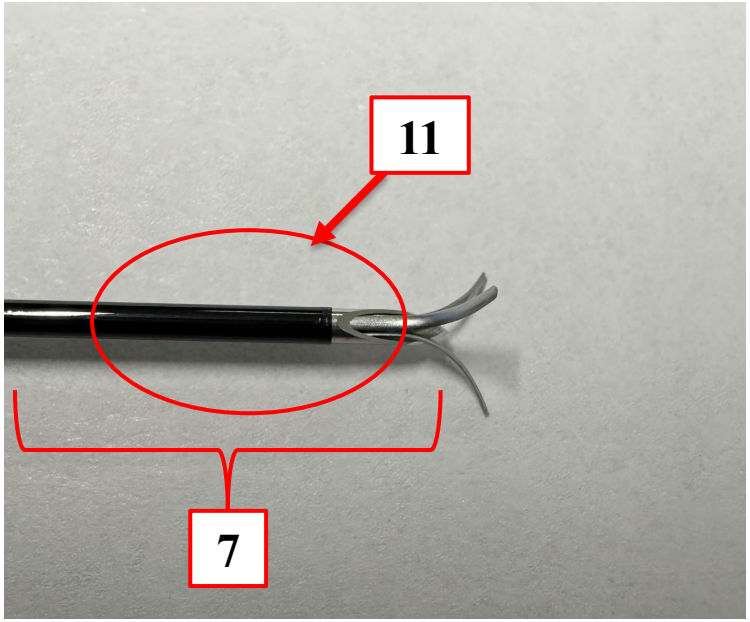
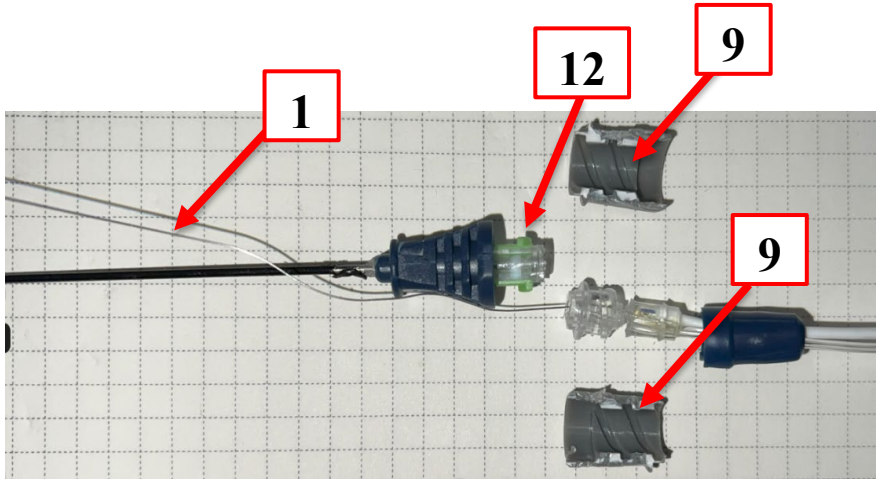
wherein the conductive portion of the needle is at a distal end of the needle, and	The RF probe, the tip, and the plurality of filaments are all conductive and physical contact between them occurs within the circle [11] of the photo to the right at the distal end [7] of the needle.	 ** The image above depicts the related DTR device. Upon information and belief, the needle of the DTR device is substantively the same as the needle of DTRH and thus the same features are present in the needle of the DTRH.*

U.S. Patent No. 10,736,688	Trident Hybrid RF Insulated Cannula, Model DTRH	
wherein, when the RF probe is fully separated from the needle in a non-inserted state, such that none of the RF probe is within the needle, the plurality of filaments are movable via the actuator from the retracted position, in which the plurality of filaments are disposed within said at least a portion of the elongate member, to the deployed position.	As shown, the actuator portion [9] has been split revealing internal threading such that the groove [12] imparts movement on the plurality of filaments. Rotating the actuator portion [9] imparts movement of the plurality of filaments between the retracted position and the deployed position. Further, the actuator portion [9] has this capability regardless of whether the RF probe [1] is in a non-inserted state, as shown, or whether the RF probe [1] is in an inserted state. As described in the DTRH IFU, the "[c]annula handle is equipped with a mechanism that allows deployment and retraction of 3 tines [i.e., filaments]." (**Exhibit J** at p. 1; *see also id.* at p. 5 (further describing deployment and retraction of filaments)).