

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,
Petitioner,

v.

STRATUS MEDICAL, LLC,
Patent Owner.

IPR2024-01209
U.S. Patent No. 10,966,782

IPR2024-01210
U.S. Patent No. 10,736,688

IPR2024-01211
U.S. Patent No. 10,736,688

IPR2024-01212
U.S. Patent No. 10,925,664

DECLARATION OF A/PROFESSOR MARC ANDREW RUSSO

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I, Marc Andrew Russo, declare as follows:

I. INTRODUCTION

1. I have been retained by Laurence & Phillips IP Law (L&P), which represents Stratus Medical, LLC (Stratus), to provide my independent expert analysis and opinions in connection with the following *inter partes* reviews (IPRs) at the United States Patent Trial and Appeal Board of the United States Patent and Trademark Office (USPTO):

IPR No.	U.S. Pat. No.
IPR2024-01209	10,966,782 (the '782 Patent)
IPR2024-01210	10,736,688 (the '688 Patent)
IPR2024-01211	10,736,688
IPR2024-01212	10,925,664 (the '664 Patent)

2. I will refer to the '782 Patent, the '688 Patent, and the '664 Patent collectively as the "Stratus Patents."

3. I am being compensated at a rate of AUD \$3,000 per hour for my work on these cases, including providing this declaration. I have no financial interest in Stratus or the Stratus Patents, and my compensation is not dependent on the outcome of these cases or any related proceeding. My compensation does not in any way affect the substance of my testimony in this declaration.

4. I previously served as an expert witness for Stratus in Federal Court of Australia Proceeding No. NSD 438 of 2019, in which Stratus asserted two of its

Australian patents—counterparts to the Stratus Patents—against Diros Technology, Inc. (Diros). I understand that the parties settled that Australian lawsuit in October 2021 and that the Petitioner, Avanos Medical, Inc. (Avanos), later acquired Diros. I understand that Avanos has identified Diros as its wholly owned subsidiary.

5. I wrote a preface to a practice guide titled “Robert E. Wright, *Radiofrequency Ablation in Interventional Pain Management Using RF Multitined Expandable Electrode* (1st ed. n.d.),” which preface is provided herewith as Exhibit No. 2003. I understand that Stratus provided financial support for the publication of this practice guide, but I received no compensation from Stratus or any other party for my contribution.

6. I have, and I have had, no relationship with Stratus other than those listed above. With respect to Stratus’s Nimbus Device, I have pioneered a new technique using this device, which is well-suited for treating facet joint point. I performed this research without support from or compensation by Stratus. Additionally, I describe this technique in my article “Russo et al., *Development and Description of a New Multifidus-Sparing Radiofrequency Neurotomy Technique for Facet Joint Pain*, Pain Practice, 21(7): 747-758 (Apr. 13, 2021),” a copy of which is included herewith as Exhibit No. 2005. I likewise authored this article without support or compensation from Stratus.

7. I coauthored the article “Marc Russo et al., *A History of the Development of Radiofrequency Neurotomy*, J. of Pain Research 2021:14, 1389-3907 (Dec. 24, 2021)” with Dr Robert Wright, who is one of the inventors of the Stratus Patents. A copy of this article is included herewith as Exhibit No. 2004. I received no support or compensation from Stratus for my contribution to this article.

II. QUALIFICATIONS AND EXPERTISE

8. I am a Specialist Pain Medicine Physician and have treated over 50,000 patients since establishing Hunter Pain Clinic (now Hunter Pain Specialists), Australia's first multidisciplinary private pain clinic, in 1999. I am the Director of Hunter Pain Specialists, Director of Hamilton Day Surgery, and the Co-Director of Innervate Pain Management Services. I am the Director and Principal Investigator of Genesis Research Services. I was a Co-Founder of the Newcastle Anaesthetic Peri-operative Service group. I am the Immediate Past-President of the International Neuromodulation Society (INS) and I am the founding president of the Neuromodulation Society of Australia and New Zealand (NSANZ). A copy of my *curriculum vitae* outlining my professional experience and memberships is included as Exhibit No. 2002.

9. In 1989, I was awarded a Bachelor of Medicine and Bachelor of Surgery (MBBS) from the University of Sydney, Australia.

10. From 1990 to 1992, I was a Resident at Gosford Hospital and Muswellbrook Practice in New South Wales, Australia.

11. In 1993, I was awarded a Diploma of Anaesthesia from Royal College of Anaesthetists, London, United Kingdom.

12. From 1993 to 1999, I was an Anaesthetic Registrar at John Hunter Hospital in Newcastle in New South Wales. In 1999, I became a Fellow of the Australian and New Zealand College of Anaesthetists (FANZCA).

13. When I began practising as an anaesthetist, I developed an interest in acute and chronic pain, and I decided to pursue a career in both anaesthesia and pain medicine. In 1999, I was appointed a Fellow at the West Australian Pain

Management Centre, Sir Charles Gardiner Hospital in Perth, Western Australia, where I specialised in pain medicine. In 1999, I was also appointed a Fellow of the Royal Flying Obstetrics & Gynaecological Service in Roma, Queensland, Australia.

14. Since 1999, I have been appointed a Fellow of the Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists (FFPMANZCA).

15. In 1999, I founded and became a Director of Hunter Pain Clinic (now Hunter Pain Specialists). Around 2 ½ years later, I stopped practising as an anaesthesiologist and became a fulltime pain medicine specialist.

16. In 2001, I founded and became a Director of Hamilton Day Surgery, and Co-Director of Innervate Pain Management Services.

17. In 2005, I founded and became a Director of the Australian Pain Research Centre, Hunter Clinical Research, which now operates as Genesis Research Services, to further the study of pain management.

18. In 2016, I founded and became a Director of Sydney Pain Specialists, and served in the Director role until 2019.

19. In 2015, I became a Conjoint Lecturer at the University of Newcastle, Australia, in the School of Medicine and Public Health, College of Health, Medicine and Wellbeing.

20. Since 2021, I have been a Conjoint Associate Professor at the University of Newcastle, Australia, in the School of Medicine and Public Health, College of Health, Medicine and Wellbeing.

21. Since 2020, I have been an Honorary Associate Professor at the University of Hong Kong, Department of Anaesthesiology.

22. I was the founding president of the Neuromodulation Society of Australia and New Zealand (NSANZ).

23. I was elected by my peers to serve as President of the International Neuromodulation Society (INS) from 2021-2024. INS is one of the most prominent global organizations for interventional pain medicine and is internationally respected. As noted on its website, INS

is a non-profit group of clinicians, scientists and engineers dedicated to the scientific development and awareness of neuromodulation—the alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body. The San Francisco-based INS was formed in 1989 and educates and promotes the field through meetings, its peer-reviewed journal *Neuromodulation: Technology at the Neural Interface*, mentorship, and chapter websites. The INS also provides information for patients and produces rolling news briefs about this rapidly evolving field.”

International Neuromodulation Society, <https://www.neuromodulation.com> (last visited May 14, 2025).

24. I currently serve on the Examination Committee, Professional Standards Committee, Research and Innovation Committee, and Procedures Working Group for the Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists (ANZCA).

25. My current external appointments (and the approximate date of each appointment) are listed below:

- Deputy Chair, Pain Australia [July 2024].

- Interim Director, Australian Medicinal Cannabis Association Board [September 2022].
- Deputy Chair, HMRI Brain Neuromodulation Research Program [2022].
- Member, Procedures Clinical Care Standard Working Group, Faculty of Pain Medicine, ANZCA [November 2018].
- Member, Procedures Working Group, Faculty of Pain Medicine, ANZCA [March 2018].
- NSW Regional Representative, Professional Standards Committee, Faculty of Pain Medicine, ANZCA [June 2017].
- Member, Research and Innovation Committee, Faculty of Pain Medicine, ANZCA [January 2017].

26. I have published over approximately 100 papers and book chapters in the field of pain medicine. I am a reviewer for the National Health and Medical Research Council (NHMRC), as well as a number of international journals, including:

- *The Lancet*, which is one of the world's most prestigious medical journals;
- *Neuromodulation: Technology at the Neural Interface*, the official journal of the International Neuromodulation Society;
- *Pain Practice*, the official journal of the World Institute of Pain;
- *Pain Medicine*, the official journal of the American Academy of Pain Medicine;
- *Pain and Therapy*, an international, open-access, peer-reviewed, rapid publication journal publishing high-quality research on the use of pain therapies and devices;

- *Case Reports in Medicine*, an open access, peer-reviewed journal; and
- *The Journal of Spinal Cord Medicine*, which is published on behalf of the Academy of Spinal Cord Injury Professionals.

27. Throughout my career, I have regularly consulted a number of journal publications in the pain field. The journals which I have regularly reviewed to keep up to date with the state of knowledge in the RF neurotomy field include those I mentioned above and *Pain*.

28. Over the course of my career I have presented at more than approximately 100 conferences in Australia and internationally on various topics, including interventional pain medicine and interventional pain management treatments. I regularly attend and have attended conferences or meetings relevant to my practice as a pain specialist, including those organised by the IASP (International Association for the Study of Pain), American Academy of Pain Medicine, American Pain Society, International Society for the Study of the Lumbar Spine, and the International Spinal Injection Society.

29. I am currently a member of the following advisory boards:

- Medical Advisory Committee Member, Lingard Private Hospital [February 2014].
- Consultant, Seqirus (a CSL company) [October 2013].
- Medical Advisory Committee Member, Hamilton Day Surgery Centre [2011].

30. I have previously been a consultant or member of advisory boards (medical, scientific, or both) for Medtronic, Boston Scientific, Abbott (St Jude),

Nevro Corp., Mainstay Medical, Cymbalta Pain, Saluda Medical, Mudjala Medical, Nalu Medical, Spine Thera, and Mundipharma.

31. I am a named inventor on U.S. Patent Application No. 15/090,580 relating to systems and methods for spinal cord stimulation and International Application No. PCT/AU2021/050028 relating to systems and methods for stimulating neurons.

32. I maintain numerous professional memberships, including Pain Australia, International Neuromodulation Society, Neuromodulation Society of Australia and New Zealand, Australian Pain Society, International Association for the Study of Pain, Australasian Neuroscience Society, Spine Society of Australia, and Australian Medical Association.

33. I have practised pain medicine continuously since about 1999. In my current practice, I typically perform 10 to 15 RF neurotomy procedures per day.

34. When I state my opinion in this declaration on what I consider the knowledge, understanding or practice of interventional pain specialists generally to be, this is based upon my own knowledge and experience, including my interactions with, and observations of the work of, professional colleagues since about 1999 in working as a pain medicine specialist, and my knowledge and experience of pain syndromes and disorders.

III. BACKGROUND OF THESE CASES

A. Stratus Patents

35. I understand that the patent application that led to the '782 Patent was filed at the USPTO on July 20, 2020 and claims benefit or priority to several earlier-

filed patent applications. The first provisional application to which priority is claimed was filed on May 21, 2010, and the first utility patent application to which priority is claimed, by way of a series of continuations, was filed on May 4, 2011.

36. I understand that the patent application that led to the '688 Patent was filed at the USPTO on April 14, 2016 and claims benefit or priority to several earlier-filed patent applications. The first provisional application to which priority is claimed was filed on November 5, 2009, and the first utility patent to which priority is claimed, by way of continuation, was filed on November 5, 2010.

37. I understand that the patent application that led to the '664 Patent was filed at the USPTO on July 20, 2020 and claims benefit or priority to several earlier-filed patent applications. The first provisional application to which priority is claimed was filed on November 5, 2009, and the first utility patent to which priority is claimed, by way of a series of continuations, was filed on November 5, 2010.

38. I understand that the '688 and '664 Patents have essentially the same disclosure, including drawings and text, except for the claims. I understand that the '782 Patent includes much of the same text and many of the same drawings as the '688 and '664 Patent and further includes additional text and drawings.

39. I understand that Stratus makes and sells an RF neurotomy device called the “Nimbus® Multitined Expandable Electrode” (Nimbus Device), which is covered by the Stratus Patents.

B. IPR Petitions

40. I understand that Avanos filed four IPR petitions to instigate the IPRs listed above on July 26, 2024. I will refer to these IPR petitions collectively as the “IPR Petitions.”

41. I understand that the IPR Petitions rely on the following references, which the IPR Petitions allege to be prior art to the Stratus Patents:

- Racz: US 6,146,380
- Fitz: US 2005/0059964A1
- Lee: US 2007/0016183 A1
- Young '965: US 2006/0084965 A1
- Scheibe: US 2007/0260223 A1

42. I understand that each IPR petition was filed with a declaration from Dr Robert Tucker. I understand that those declarations are Exhibits 1031, 1032, 1033, and 1034 in IPR2024-01209, IPR2024-01210, IPR2024-01211, and IPR2024-01212, respectively. I will refer to those declarations collectively as the “Tucker Declarations.”

C. Related Cases

43. I understand that Stratus has related patents in Australia for the same or similar inventions claimed in the Stratus Patents. I understand that, in the lawsuit identified in paragraph 4, *supra*, Diros attempted to invalidate the related Stratus Australian patents as part of an effort to enter the Australian market with two related RF neurotomy devices called “Trident™” and “Trident™ Hybrid” (the Trident Devices) that are similar to Stratus’s Nimbus Device. I understand that case settled under confidential terms, which I do not know. I understand that Stratus’s Australian patents remain in effect and that Stratus’s Nimbus Device continues to be sold and used in Australia. In contrast, the Trident Devices, which were available in the Australian market prior to the Australian proceeding, to my knowledge have not been available in the Australian market since the Australian proceeding settled.

44. I understand that approximately 20 months after settlement of the Australian proceeding that involved Diros, Avanos acquired Diros. I further understand that either Avanos or Diros continues to make the Trident Devices, and that Avanos presently sells the Trident Devices in the United States.

IV. SUMMARY OF OPINIONS

45. As explained in more detail in section VII below, it is my opinion that a person of ordinary skill in the art would have the knowledge and skills of an interventional pain specialist, such as myself.

46. It is also my opinion, as explained in more detail in section VIII-A below, that Racz teaches that its tip must be curved.

47. It is also my opinion, as explained in more detail in section VIII-A below, that a person of ordinary skill in the art would not interpret Racz as teaching that neurotomy needles can be sized larger than 16 gauge or smaller than 22 gauge.

48. It is also my opinion, as explained in more detail in section VIII-C below, that Lee has limited or no relevance to Racz and Fitz.

49. It is also my opinion, as explained in more detail in section VIII-D below, that Young '965 has limited or no relevance to Racz and Fitz.

50. It is also my opinion, as explained in more detail in section VIII-E below, that Scheibe has limited or no relevance to Racz and Fitz.

51. It is also my opinion, as explained in more detail in section X below, that a POSITA would not have found it obvious to combine the teachings of Racz, Fitz, and Lee to arrive at "Racz's modified device."

V. APPLICABLE LEGAL PRINCIPLES

52. I am not a patent attorney, but I understand aspects of U.S. patent law that are relevant to my analysis and opinions. I summarize my understanding of some relevant patent law principles below.

53. I understand that in an IPR, the burden of proof is on the petitioner to show that each challenged claim is unpatentable and that the petitioner must do so by the preponderance of the evidence.

54. Even though none of the challenges in these IPRs are anticipation challenges, I recount my understanding of key aspects of anticipation for completeness.

55. I understand that, for a patented invention to be anticipated, a single prior-art reference alone must disclose every limitation in a claim, thus “anticipating” the claim.

56. I understand that, for anticipation to exist, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art (POSITA).

57. I understand that anticipation requires that each element of the claim at issue be found, either expressly or under principles of inherency, in the reference.

58. I understand that inherent disclosure requires that the feature necessarily be present in the reference. The mere possibility that the feature is present is not enough to support inherent disclosure.

59. I understand that anticipation requires more than simply locating each element entirely within a single document, but that document must also disclose those elements arranged together as in the claim.

60. I also understand that invalidity by anticipation requires that the prior-art reference's teaching of the claimed invention must teach a POSITA how to make and use the invention without undue experimentation.

61. I understand that, for a patented invention to be obvious, there must be prior-art references that alone or in combination would have rendered the claimed invention obvious to a POSITA at the time of the invention.

62. I understand that for a claim to be found obvious, every limitation of the claim must result from either a combination of the teachings of multiple prior-art references or a modification of a single prior-art reference.

63. I understand that the factors that should be assessed in the obviousness analysis include at least: (1) the scope and content of the prior art; (2) the differences between the prior art and the claim at issue; (3) the level of ordinary skill in the art; and (4) objective evidence as indicia of nonobviousness.

64. I understand that obviousness must take into account the ordinary knowledge, skills, and creativity of a POSITA.

65. I understand that a reason must be shown that would have prompted a POSITA to have combined or modified known elements in the fashion claimed by the patent at issue. Assertions that a combination or modification would have been obvious cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

66. I understand that there must be a reasonable expectation of success in making or practicing the claimed invention based on the combination or modification of the prior-art reference(s) used to render a claimed invention obvious.

67. I also understand that the combination cannot modify a prior-art reference such that it would render the reference unsatisfactory for its intended purpose, change the principle of operation of a reference, or require a substantial redesign or reconstruction of the reference.

68. I understand that obviousness does not require that the teachings of the references be bodily incorporated together; rather, the focus is on the concepts taught by the references.

69. I understand that prior-art references must be considered as a whole, including aspects that teach away from a claimed invention or that may rebut a showing of obviousness.

70. I further understand that the obviousness inquiry must guard against slipping into use of hindsight and resist the temptation to read into the prior art the teachings of the invention in the patent at issue. Isolated elements from the prior art should not be picked and chosen and then combined using the invention as a blueprint if such a combination would not have been obvious at the time of the invention. In other words, it is impermissible to use the patent as a template (or reason) for combining prior-art references because that would be applying hindsight. A POSITA would have needed a reason to combine the references to create the claimed invention independent of the patent.

71. I also understand that obviousness requires that the prior-art references collectively must teach a POSITA how to practice the invention without undue experimentation.

72. I understand that in view of the dates in section III.A, *supra*, the relevant dates for determining what a POSITA would have found obvious are one or more of November 5, 2009; May 21, 2010; November 5, 2010; and May 4, 2011, which I will consider collectively as November 5, 2009 through May 4, 2011 (the Relevant Dates).

73. I have not considered objective evidence of nonobviousness in this reexamination, but I know that there is such evidence, which further supports my opinion that the claims of the Stratus Patents are not obvious.

VI. RADIOFREQUENCY ABLATION

74. In this section, I refer to diagrams to illustrate my opinions. I confirm that these diagrams reflect my own knowledge and understanding of the matters I discuss.

75. “Ablation” refers to the removal or destruction of tissue. “Thermal ablation” refers to the destruction of tissue through the application of heat – that is, it is a physical event. “RF ablation” is a category of thermal ablation and refers to the destruction of tissue using heat generated from RF energy. RF ablation, as a clinical technique, is used in many different clinical applications, across separate medical fields.

76. There was no (and still today there are no) generalist “RF ablation” medical practitioners. Rather, the use of RF ablation as a treatment or therapy for a

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

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

78. Before the Relevant Dates, as an interventional pain specialist practising in the pain medicine field, the particular application of RF ablation relevant to me, and which I practised, was RF ablation of nerves, or

“RF neurotomy.” RF neurotomy is used to treat pain arising from joints, particularly joints in the spine. To use a taxonomy analogy, thermal ablation is a family of clinical techniques, RF ablation is a genus, and RF neurotomy is a species.

79. RF neurotomy was (and still today is) a highly specialised field of practice. As at the Relevant Dates, RF neurotomy was performed almost exclusively by pain specialists and, even then, only a minority of pain specialists performed this procedure, being interventional pain specialists such as myself. As at the Relevant Dates, I spent approximately one third of my time in the operating room, with approximately 40% of my operating workload consisting of neurotomy procedures. And I spent the other two thirds of my time consulting, including consulting in relation to RF neurotomy procedures.

80. As at the Relevant Dates, I was aware that RF ablation techniques were also used by specialists in medical fields other than the pain medicine field, for clinical applications other than the destruction of nerves. For example, I was aware that RF ablation was used to destroy tumours in the cancer field and to treat cardiac arrhythmias in the cardiology field. However, as an interventional pain specialist, I do not, and did not before the Relevant Dates, perform RF ablation procedures to ablate tumours or to treat cardiac arrhythmias. Such procedures were performed by interventional radiologists, surgeons of the relevant specialties, or cancer surgeons, in the case of cancerous tumours, and by cardiologists, in the case of cardiac arrhythmias.

81. Based upon my training, experience, and activities described herein, I have a very good knowledge and understanding of the state of knowledge of those working in the RF neurotomy field in Australia as at the Relevant Dates, and today, and I am aware that the level of knowledge in Australia in the RF neurotomy field

was similar to that in comparable markets, such as the United States and elsewhere in North America, before and during the Relevant Dates and since that time.

82. Before and during the Relevant Dates I regularly kept up to date with developments in the RF neurotomy field (as I do today). Since 2002 I have had an automatic search set up on PubMed to search for publications which mention “radiofrequency and pain” and “pulsed RF and pain.” I received a regular update from PubMed of any publications which met the search criteria. If I had wanted to better understand how a particular product or device that I used functioned, and I could not find that information in other literature, from time to time I would read relevant patent literature, but I did not conduct regular searches for patents.

83. Although I have, and had before the Relevant Dates, a general awareness of the use of RF ablation techniques in the cancer and cardiology fields, as an interventional pain specialist, I did not have detailed knowledge of the techniques or technologies used in those other fields, and I did not keep up to date with developments in the use of RF ablation techniques in those other medical fields. In my view, the literature and technologies used in those other clinical fields are not, and were not before the Relevant Dates, relevant to the practice of RF neurotomy, as the applicable anatomical and clinical considerations are not the same. The goal of any RF neurotomy procedure was (and is) to deliver energy to ablate a miniscule and precise area encompassing a target nerve in spinal joints (in the vast majority of neurotomy procedures), which are difficult to access and vary anatomically between patients. As I explain in more detail below, RF neurotomy was (and is) not a curative procedure. In contrast, before the Relevant Dates, I was aware that the goal of RF tumour ablation was to ablate, with the intention of permanently destroying and killing, tumour masses (for example, cancerous spherical tumour masses in the liver). I was also aware that the goal of RF cardiac ablation was to destroy a very

small area of tissue in the atrial wall of the heart to permanently remove the cause of rapid and irregular heartbeats. Cardiac ablation was performed by threading a long, thin and flexible catheter endolumenally (that is, through the lumen of a blood vessel, not through tissue) to reach the heart.

A. Overview of RF Neurotomy

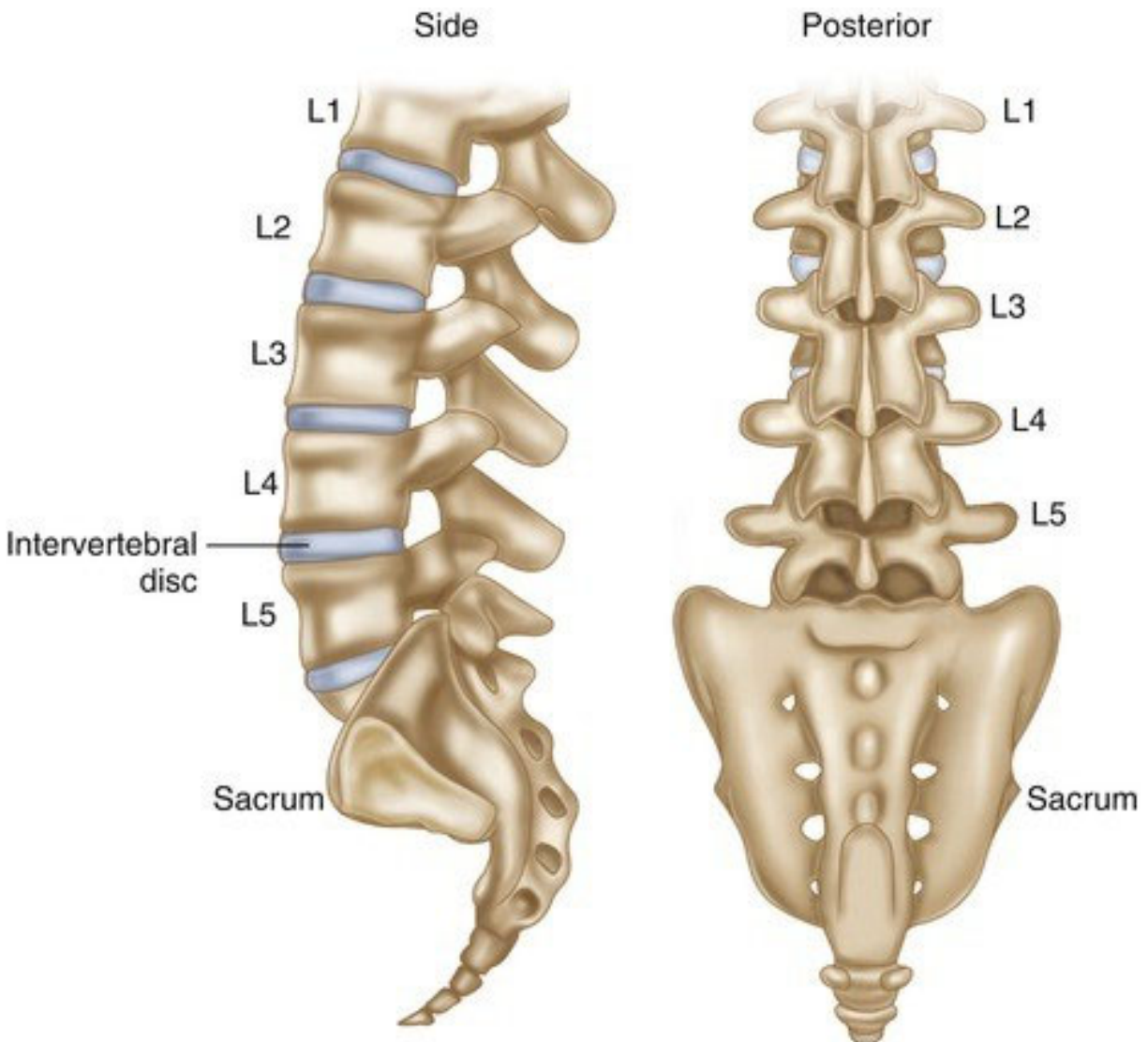
84. RF neurotomy is a minimally invasive procedure used to treat pain arising from joints, particularly in the spine, such as facet joint pain and sacroiliac joint pain. RF neurotomy procedures employ RF energy to selectively produce a lesion of pain-generating nerves (target nerves). Increased tissue temperature, beyond 45°C, leads to irreversible tissue injury and to cell necrosis, and is the therapeutic basis for RF neurotomy. The heat is targeted to create a small lesion within a nerve, which disrupts the pain signal. Radiofrequency is a term used to classify energy at a frequency in the range of 3 kHz to 300 GHz. In clinical applications, the energy is applied, within that range, typically at a frequency between 400 and 500 kHz.

85. RF neurotomy is performed by interventional pain specialists. Before the Relevant Dates, I regularly performed RF neurotomy to denervate facet joints and sacroiliac joints. Interventional pain specialists perform other procedures to manage and treat pain, such as nerve blocks and implantation of neuromodulation devices. A nerve block is an anaesthetic and/or anti-inflammatory injection that targets a certain *nerve* or group of *nerves* to diagnose and treat pain. Neuromodulation refers to the alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body.

86. The facet joints (or zygapophyseal joints or Z-joints) are synovial joints between the vertebrae of the spine. A synovial joint is a joint characterised by the presence of a fluid-filled joint cavity contained within a fibrous capsule. The facet joints help the spine to bend, twist and extend in different directions, but also to limit movement of the spine. The facet joints in the spinal column are located posteriorly to the vertebral body. At each spinal level, there is a pair of facet joints, spanning from the cervical to the lumbar spine. There are ten facet joints (five pairs) in the lumbar spine (the vertebrae of the lumbar spine are shown in Figure 1, below).¹

1 Extracted from Cooper G. (2015) Clinical Anatomy of the Lumbosacral Spine. In: Non-Operative Treatment of the Lumbar Spine. Springer, Cham.

Figure 1



87. As shown in Figure 2, below,² each facet joint is surrounded by a capsule of connective tissue and produces synovial fluid to lubricate the joint. The surfaces of the joint are coated with cartilage that helps each joint to move smoothly. Nerves that branch off from the spinal cord pass through the facet joints. The nerves

2 Extracted from Manchikanti L., Schultz D.M., Falco F.J.E., Singh V. (2018) Lumbar Facet Joint Interventions. In: Manchikanti L., Kaye A., Falco F., Hirsch J. (eds) *Essentials of Interventional Techniques in Managing Chronic Pain*. Springer, Cham.

that serve the facet joints themselves are called the medial branches. Each facet joint is innervated by two medial branch nerves, with one branch specific to its own vertebral level and the other branch from the level above (see Figure 3, below).³ Lumbar facet joints receive their nerve supply from the medial branches of the dorsal rami of the spinal nerves.

3 Extracted from Kusper T.M., Cantu B., Knezevic N.N., Candido K.D. (2019) Low Back Pain. In: Abd-Elsayed A. (eds) Pain. Springer, Cham.

Figure 2

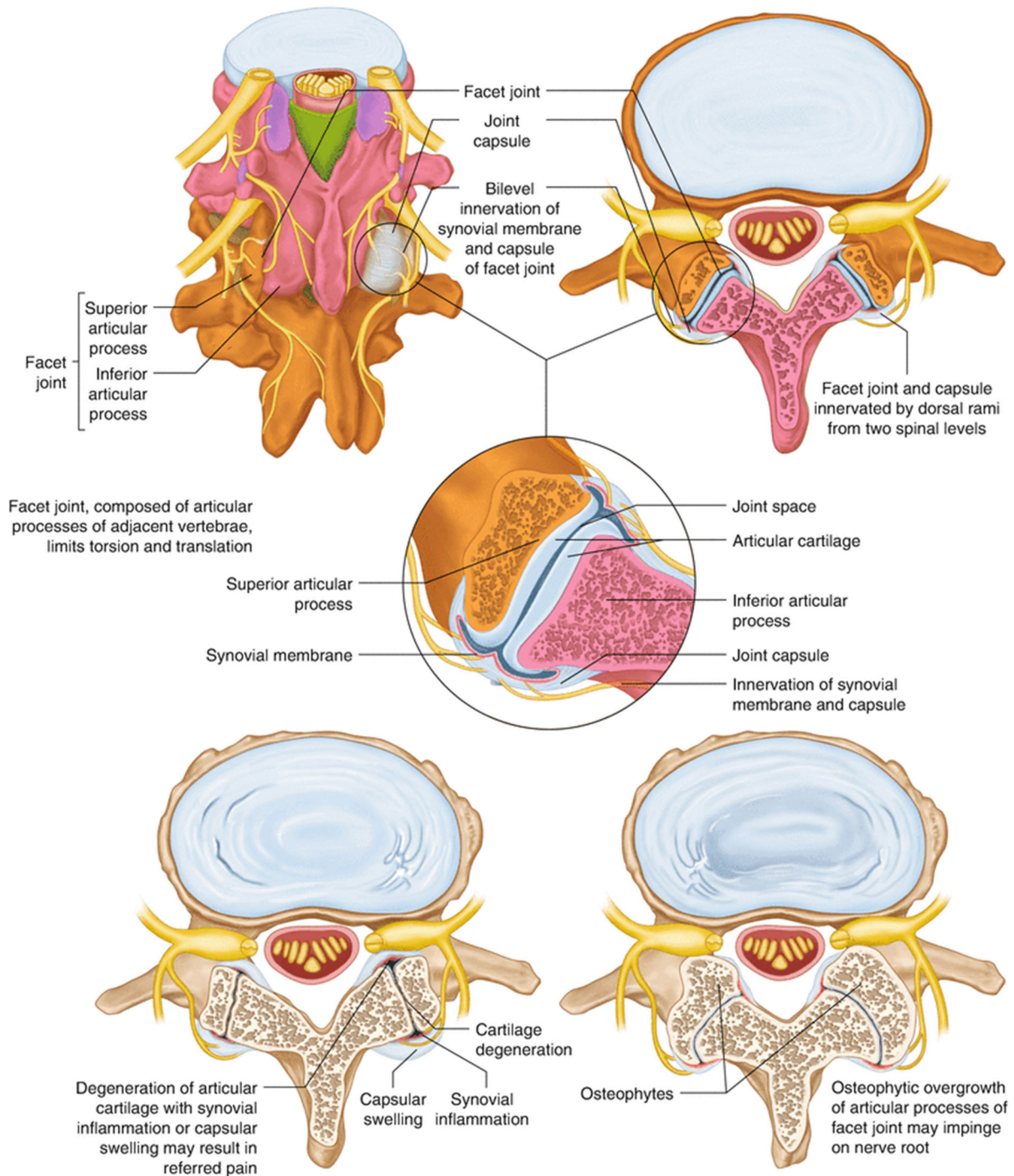
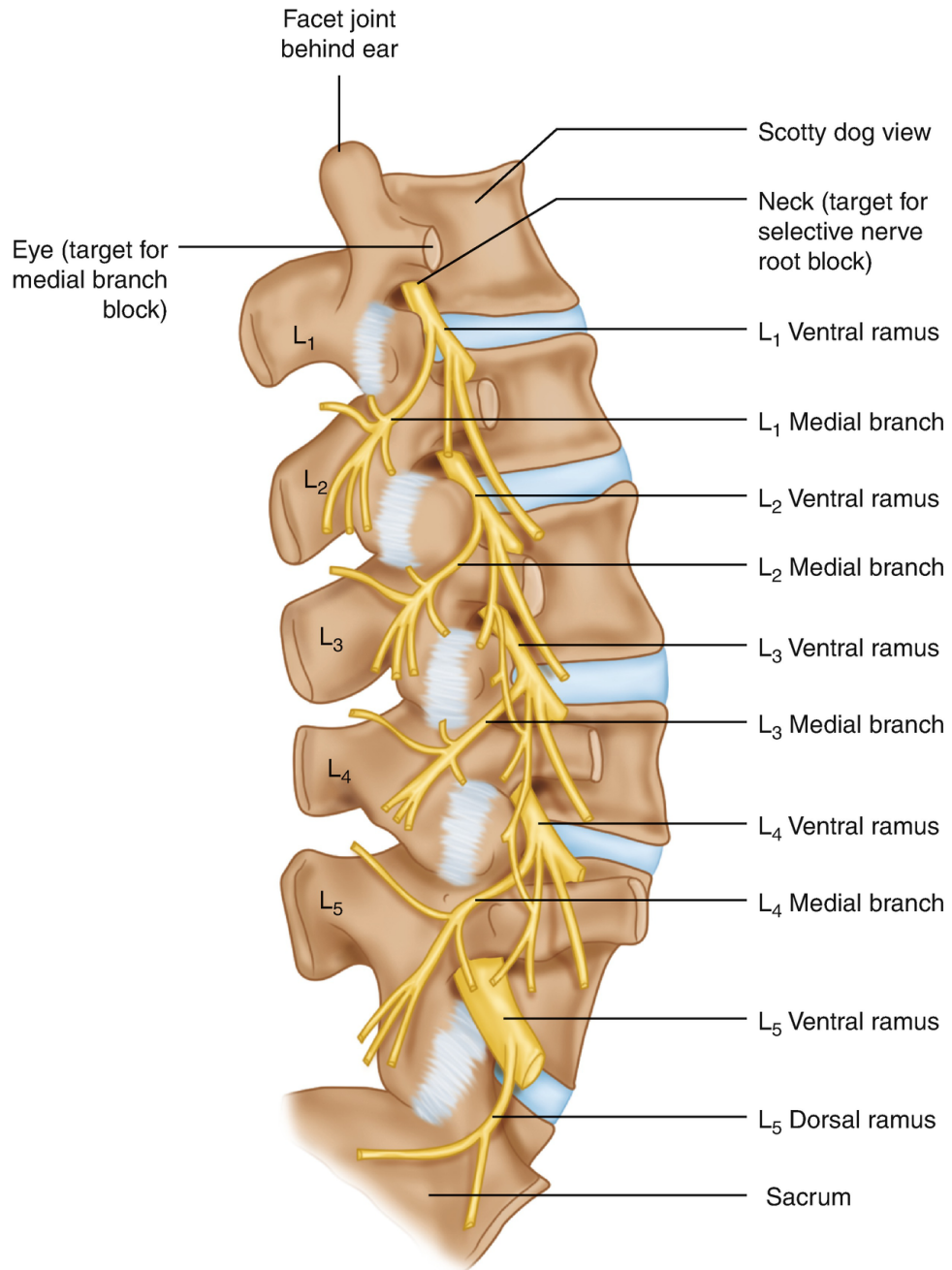
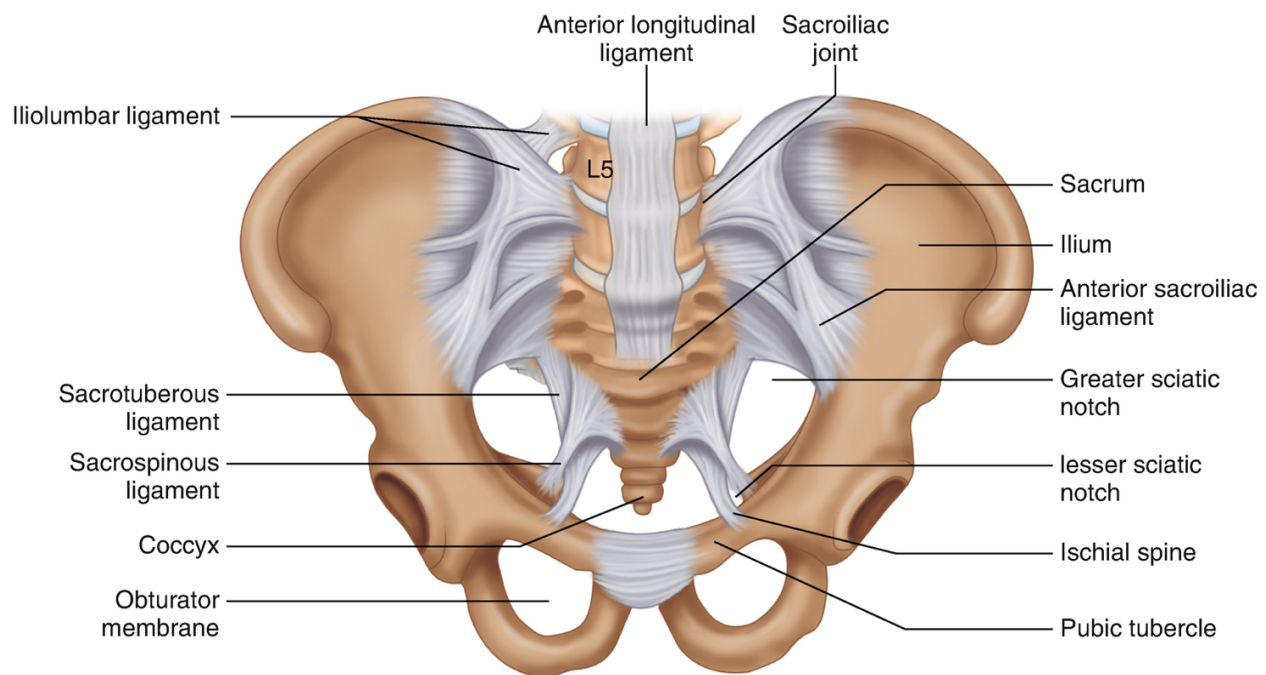


Figure 3



88. The sacroiliac joint is a synovial joint between the ilium and the sacrum bones of the pelvis. As can be seen in Figure 4, below,⁴ there are two sacroiliac joints which sit on each side of the spine. They are connected by strong ligaments. Their main job is to act as shock absorbers, transmitting and absorbing the forces of the upper body to the pelvis and legs.

Figure 4



B. History of RF Neurotomy

89. As previously noted, I am a coauthor of the article “Marc Russo et al., *A History of the Development of Radiofrequency Neurotomy*, J. of Pain Research 2021:14, 1389-3907 (2021).” That article and the following discussion of the history of radiofrequency neurotomy are drawn from my decades of studying and practicing in this field.

4 Extracted from Ehrhardt K.P., Jones M.R., Kaye A.D. (2019) Sacroiliac Joint. In: Abd-Elseyed A. (eds) Pain. Springer, Cham.

90. Historically, low back pain was considered to be an inflammatory condition. Treatments varied but were essentially unsuccessful.

91. During World War I, Vincent Nesfield, an English surgeon, developed the procedure percutaneous neurotomy (sometimes called “Nesfield’s treatment”). In 1914, Nesfield began attempting to treat cases of “trench back,” a condition caused by the collapse of earth or sandbags onto a person in a trench, or developed in the process of digging a trench. While it was generally thought that this condition related to contusion of the muscles and fascia, Nesfield thought the cause was a sensory nerve caught up in muscle or tendon. Nesfield used a fine, long, curved ophthalmic scalpel to make an incision on either side of the spine, and moved it back and forth vertically attempting to cut the relevant nerve. He never published his technique.

92. In 1960, Dr William Skyrme Rees, a Welsh urological surgeon, saw a patient who had been treated by Nesfield. Rees subsequently began practising “Nesfield’s treatment” in the UK.

93. In 1965, Rees emigrated to Australia and began a specialised practice treating patients with chronic lower back pain. Rees further refined the concept of “Nesfield’s treatment” to be one of dividing the sensory nerve to the facet joint (the dorsal ramus nerve).

94. In 1971, Rees published a paper on his technique, “multiple bilateral subcutaneous rhizolysis,” in which he described severing the nerves to the facet joints percutaneously using a scalpel.

95. Anatomist Dr Nikolai Bogduk later dissected cadavers, on which Rees had performed his technique, and revealed that Rees’ technique was based on false

anatomy. Bogduk demonstrated that the facet joint nerve was never divided in the procedure, only the fascia of muscle. Bogduk concluded that Rees was in fact performing a fasciotomy procedure for muscles in spasm, thereby relieving the spasm. Rees' technique all but ceased to be used after 1980.

96. The next major step forward in the treatment of facet joint pain was the shift from the scalpel to the use of RF energy. The use of RF lesioning techniques dates back to the 1950s, but the first clinical application of an RF lesion in spinal facet pain was reported in 1974 by renowned American neurosurgeon Dr C Norman Shealy, inventor of both Transcutaneous Electrical Nerve Stimulation (TENS) and spinal cord stimulation, and surgeon to John F Kennedy.

97. In 1970, Shealy travelled to Australia to learn percutaneous rhizolysis from Rees. Shealy published his experience of using Rees' technique on 24 patients, reporting a 20% incidence of unacceptable haematoma formation.

98. In 1971, Shealy devised the technique of percutaneous RF denervation of the facet joints by medial branch nerve neurotomy, derived from the principles used with gasserian ganglion thermal RF (a technique used to treat trigeminal neuralgia, a chronic pain condition affecting the trigeminal nerve in the face). Shealy first described his technique in a 1974 paper as follows:

Under fluoroscopic guidance 14 gauge thin-walled cannulae are guided adjacent to the centers of tender facet joints. A radiofrequency thermister electrode (19 cm long, 1-2 mm diameter) is passed through one needle, the needle is withdrawn, and the electrode is slipped over the edge of the facet and advanced to the intertransverse ligament. A lateral x-ray film confirms the position of the electrode and its distance from the main nerve root

Shealy, *Facets in back and sciatic pain. A new approach to a major pain syndrome*, Minn Med. 57(3):199-203 (1974).

99. Shealy worked with Eric Cosman Snr (a Professor of Physics) and his father Bernard Cosman (an electrical engineer), US medical device entrepreneurs and founders of Radionics (originally called Cosman and Company), to design the SRK Shealy Rhizolysis Kit. The Cosmans had built the first commercial RF lesion generator in the 1950s. The original SRK Shealy Rhizolysis Kit comprised a set of 14-gauge spinal needles (also referred to as cannulas) that could be inserted percutaneously. Gauge refers to the inner measurement or opening of the needle, and the higher the number, the smaller the needle. A 16-gauge RF electrode, insulated except for an exposed 7 mm distal tip, could then be passed through the 14-gauge spinal needle/cannula, and could be advanced so that the electrode tip contacts the medial branch innervating the selected facet joint. Shealy's technique was performed using the SRK Shealy Rhizolysis Kit by neurosurgeons under general anaesthesia, due to the pain involved in needle placement.

100. In 1974, Eric Cosman Snr and Dr C Ray designed a variant of the SRK Shealy Rhizolysis Kit – the RRE Ray Rhizotomy Electrode Kit – produced by Radionics. The 16-gauge RRE Ray Rhizotomy Electrode Kit comprised a tissue penetrating tip, an insulated shaft, and an integrated temperature sensor, and eliminated the need for the spinal needles/cannulas.

101. In or around 1976, Dutch anaesthesiologist Menno Sluijter and Eric Cosman Snr designed the SMK Kit electrode series, having finer gauge needles/cannulas (22-gauge, 20-gauge and 18-gauge variants) than the SRK Shealy Rhizolysis Kit and RRE Ray Rhizotomy Electrode Kit. These finer gauge electrode kits were transformational, as they allowed the procedure to be performed on

patients under sedation (as opposed to general anaesthesia) and in procedure rooms by anaesthesia-based pain specialists (rather than operating room-based neurosurgeons) and significantly increased the number of patients who could be treated and the number of specialists who could be trained in the technique. The use of the smaller gauge needles/electrodes meant small volume lesions were created, and thus more lesions were required to achieve a successful neurotomy over the same area.

102. Shealy's technique has been modified and refined over time, as knowledge of the anatomical and physiological basis for the technique improved. In 1979, Bogduk modified the technique described by Shealy to improve accuracy, having identified that, in Shealy's technique, the electrode was being placed somewhat remotely from the target nerve. Despite those findings, and Bogduk recommending a revised technique, many continued to use Shealy's original technique.

103. In the early 1980s, Sluijter developed refined techniques for cervical, thoracic, lumbar, and sacral spinal pain syndromes using percutaneous RF techniques.

104. In 1987, Bogduk demonstrated that the lesion made by the RF neurotomy device did not extend distally from the tip of the electrode, but instead spread sideways about the longitudinal axis of the electrode, with the result that an electrode placed perpendicularly to the course of the nerve would not reliably coagulate the nerve. Bogduk's findings meant that, in order to be effective, the needles/cannulas containing the electrode should instead be placed parallel to the target nerve(s).

105. A further version of Sluitjer's electrode system, available before the Relevant Dates, was the produced by Cosman Medical, Inc (the company founded by Eric Cosman Snr following the sale of Radionics). In use, this RF neurotomy device was placed parallel to the target nerve(s), consistent with Bogduk's findings.

106. Other manufacturers of RF generators and RF neurotomy devices before the Relevant Dates included Smith & Nephew and Stryker Instruments. The RF neurotomy devices produced by these other manufacturers were similar to, and worked in a similar way to, the Radionics and Cosman Medical, Inc devices I described above.

107. As noted in my article *A History of the Development of Radiofrequency Neurotomy*, referenced above, cooled radiofrequency ablation is another technology that eventually found application in radiofrequency neurotomy. With cooled radiofrequency ablation, the active tip design was relatively unchanged, but a cooling system allowed for controlled enlarged lesions to be performed without inducing tissue charring. Cooled radiofrequency ablation was first developed in the late 1990s for use in the cardiac field for arrhythmia management, and then found application in tumour ablation as a method to enlarge the tumour destruction volume. The technology was first introduced into the pain management field via custom designed equipment for treatment of sacroiliac joint pain. It was eventually applied to medial branch neurotomy in 2014.

C. RF Neurotomy Procedures

1. Parallel Placement

108. As at the Relevant Dates, a RF neurotomy procedure was typically carried out as follows. With the patient prone on the operative table, the specialist

would carefully insert a needle/cannula through the skin around the spine and, under fluoroscopic guidance, place it parallel and adjacent to the target nerve. The specialist would insert the RF electrode into the needle/cannula. A small amount of electrical stimulation was applied to elicit feedback on electrode placement. The patient received a small amount of sedation but would remain awake enough to respond to the electrical stimulation. The device was carefully held in place while the surrounding tissue temperature was increased gradually through the application of RF energy (for example, increasing by 10°C every 5-10 seconds starting from ambient temperature). The RF energy was transmitted to the surrounding tissue from the RF electrode via the uninsulated tip of the needle/cannula. A final lesion was made at 80-90°C for 60 to 90 seconds.

109. The RF energy worked through a closed circuit, with the RF electrode acting as the circuit's cathode, and grounding pads applied to the patient's body acting as the anode, and RF energy being conducted from the RF generator to the RF electrode and through the tissue to the grounding pads. That is, the system operated as a monopolar RF system (compared with a bipolar RF system, in which current flows between two electrodes without a grounding pad). The application of voltage between electrodes connected by tissue in this closed circuit created an electrical field which caused current to flow. Oscillating voltage moved ions in the tissue electrolytes back and forth, generating friction and heat (between 80-90°C) in the tissue, which in turn heated the electrode tip. The heat from the tip dissipated in the tissue, leading to coagulation necrosis, and was responsible for the resulting lesion. The heat was primarily generated in the tissue around the electrode's active tip and created concentric tissue lesions of lower temperature as the distance from the tip increased.

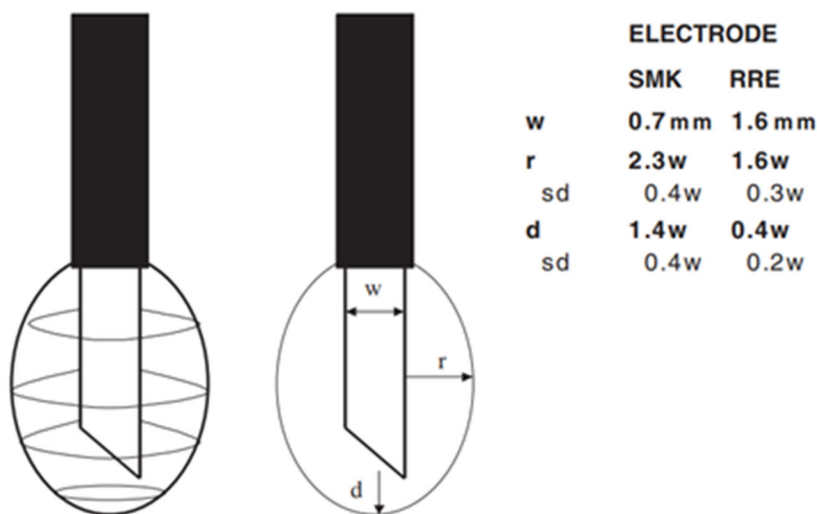
110. As one facet joint is innervated by two medial branch nerves, RF neurotomy was (and is) performed at two levels on one side. The procedure could be performed on both sides or more than one spinal level on the same side. As at the Relevant Dates (and still today), the goal of any RF neurotomy procedure was to achieve complete destruction of the tissue of the target nerve and minimal destruction of the surrounding tissue. Meticulous placement of the needle/cannula (containing the electrode) near the target nerve was critical for the success of RF neurotomy procedures. Therefore, comprehensive knowledge of the topography of the target nerve tissues, as well as surgical precision, was required in order to successfully navigate through tissue, muscle, and around bone, to reach the target area and create a very precise and controlled lesion encompassing the target nerve, while avoiding causing damage to surrounding structures. Consistent optimal placement of the RF electrode, parallel and adjacent to the target nerve, was difficult, even for very experienced interventional pain specialists.

111. The size of the desired ablation area depended on the size of the target nerve. For each target nerve (each medial branch), the RF neurotomy device was introduced into the patient (or “passed”) twice at different angles, and lesions made in several locations along the course of the target nerve, to accommodate possible variations in the exact location of the nerve. The medial branch nerve is tiny—about 10 times thicker than a human hair. And although the device was passed twice and several lesions made, the position of the tip of the device at the target was changed only ever so slightly (for example, by 2 mm).

112. Lesion size was determined by numerous factors, including tip gauge, tip length, temperature and time. The geometry of each lesion was a prolate spheroid or egg shape. As I described above, before the Relevant Dates it was known that there was minimal lesion formation distally beyond the electrode tip, with a

circumferential lesion produced around the electrode tip (as shown in Figure 5, below).⁵ The total volume of the ablated area (after making the necessary number of lesions) was approximately 0.5 cm³.

Figure 5



The geometry of the lesion generated by a thermal radiofrequency current. The volume of tissue coagulated assumes the shape of a prolate spheroid, i.e., elliptical in longitudinal section and circular in transverse section. The radial extent (r) of the lesion beyond the surface of the electrode and its distal extent (d) beyond the tip of the electrode are functions of the width (w) of the electrode. The inset shows the actual dimensions of lesions generated by two types of electrodes [9,10]. SMK, RRE = electrode types manufactured by Radionics Inc., Burlington, MA.

113. RF neurotomy procedures were (and still today are) not without risks. Such risks included infection, damage to surrounding blood vessels and nerves during needle insertion (which may result in excessive bleeding and/or irreversible

5 Extracted from Nikolai Bogduk, MD, PhD, DSc, Pulsed Radiofrequency, *Pain Medicine*, Volume 7, Issue 5, September 2006, Pages 396–40 (original figure numbering omitted).

neurologic damage causing long-term numbness and tingling), and heat damage to structures adjacent to the target nerve.

114. While the aim of RF neurotomy was to alleviate the patient's pain, the procedure was (and still today is) not a permanent cure, but rather a palliative treatment. Most patients experienced some pain relief after RF neurotomy, but the amount varied by cause of pain and location. The procedure could fail if the electrode was not placed optimally near the target nerve or if anatomic variations were not effectively incorporated into the lesion. The procedure could provide pain relief for many months, and possibly a couple of years. Pain would recur because coagulated nerves can regenerate. In such cases, the procedure was usually repeated. The failure rate was a shortcoming of RF neurotomy before the Relevant Dates.

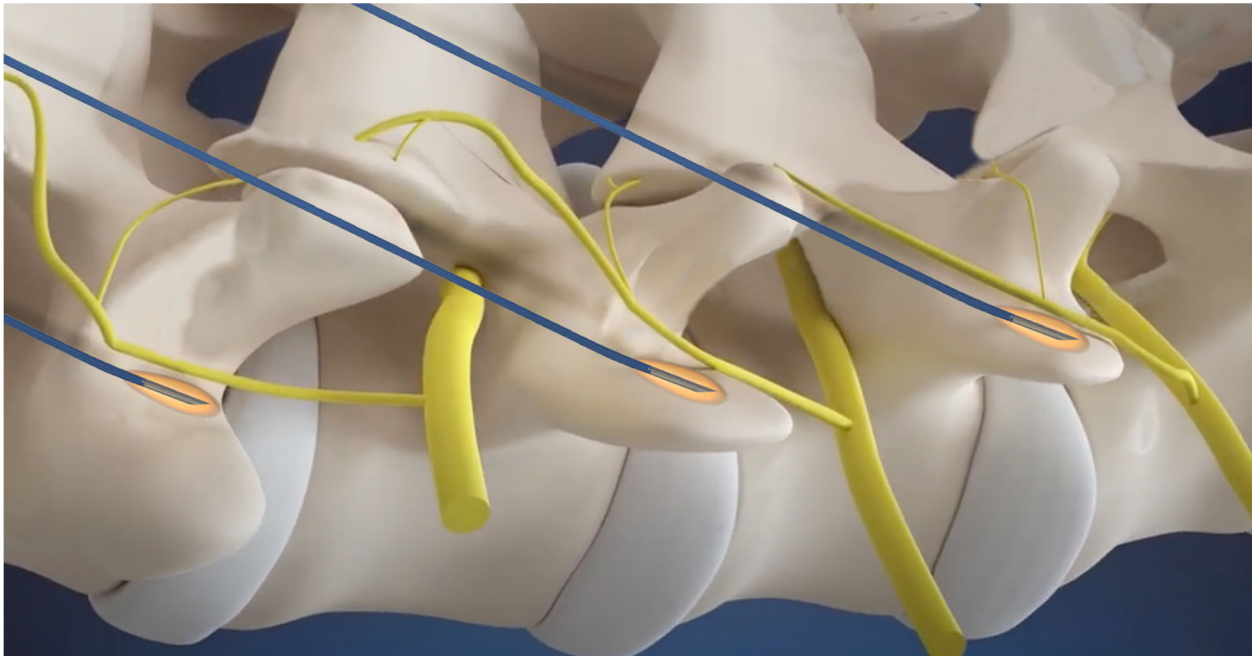
115. Notwithstanding that shortcoming, after all of the developments I described above, the collaboration (of the kind I described elsewhere in this declaration) between medical specialists and engineers/industry stagnated, and the RF neurotomy field experienced somewhat of an "ice age" in terms of product development throughout the 1990s and 2000s. In my view, the reasons for this lack of new product development included that some of the companies that manufactured RF neurotomy devices were relatively small companies, as well as a pervasive "groupthink" among specialists practising RF neurotomy, including myself, that the technology had peaked. The advances in the technology used in the RF neurotomy field were largely in the RF generators, rather than the RF neurotomy devices. For example, in 1998, Sluijter published on the use of pulsed RF neurotomy of the dorsal root ganglion. Pulsed RF neurotomy applies an intermittent burst of electrical current to the target nerve, at a temperature of about 42°C, but does not heat it.

116. As far as development of RF neurotomy devices was concerned, little changed until the release of the Nimbus Device, which occurred after the Relevant Dates. The Nimbus Device was invented by Denver pain specialist Dr Robert Wright. I first met Dr Wright after the Relevant Dates at a conference. I recall that I first became aware of the Nimbus Device in 2013 at a conference. I first began using the Nimbus Device in early 2014.

117. My view, and I believe the view of others working in the RF neurotomy field, is that the Nimbus Device was a “game changer” in the RF neurotomy field. The Nimbus Device enabled interventional pain specialists, including myself, to use a different and, for many reasons, superior anatomical pathway to reach the medial branch through positioning near the facet joint.

118. As discussed above, as at the Relevant Dates, traditional RF neurotomy needles required “parallel” placement of their active tips alongside a medial branch nerve due to the shape of the small ablation volume produced thereby to maximise the likelihood of successfully lesioning the medial branch nerve. That is, by placing an active tip alongside and substantially parallel to the medial branch nerve and the surface of the bone over which that medial branch nerve passes, the ablation volume created by the tip would have the greatest probability of encompassing the targeted portion of the medial branch. Three such parallel placements of traditional RF neurotomy needle tips alongside three medial branches are depicted in Figure 6 below.

Figure 6



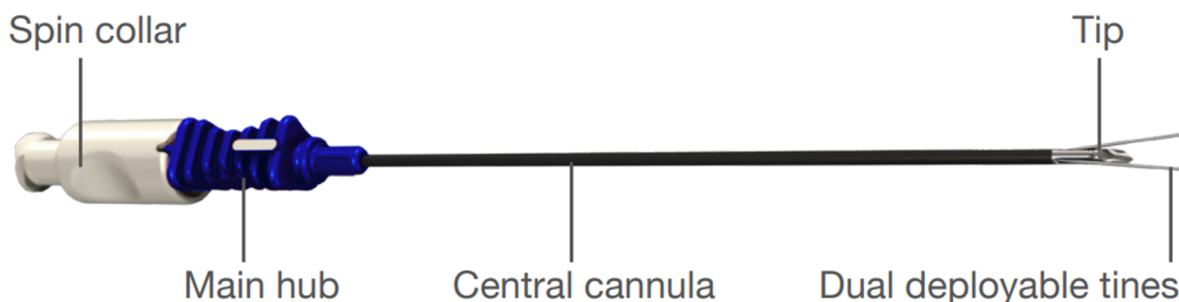
2. Perpendicular Placement

119. Using a “perpendicular” placement of the traditional RF neurotomy needles would not effectively or reliably lesion the medial branch because these needles produce only a small ablation region at and distal to their tips, as previously discussed at paragraphs above and as shown below in Figure 8. With a perpendicular placement, the RF neurotomy needle is situated generally perpendicular to the medial branch nerve and the surface of the bone over which that medial branch nerve passes, such that the distal tip of the RF neurotomy needle generally points at, or in the vicinity of, the medial branch nerve, thus exposing the medial branch nerve to only a small portion of the ablation volume generated by the RF neurotomy needle. For reference, perpendicular placements of Nimbus Device devices are depicted in Figure 9 below.

120. In contrast to traditional RF neurotomy needles, the Nimbus Device employs two small tines, which can be deployed from the tip of the needle/cannula

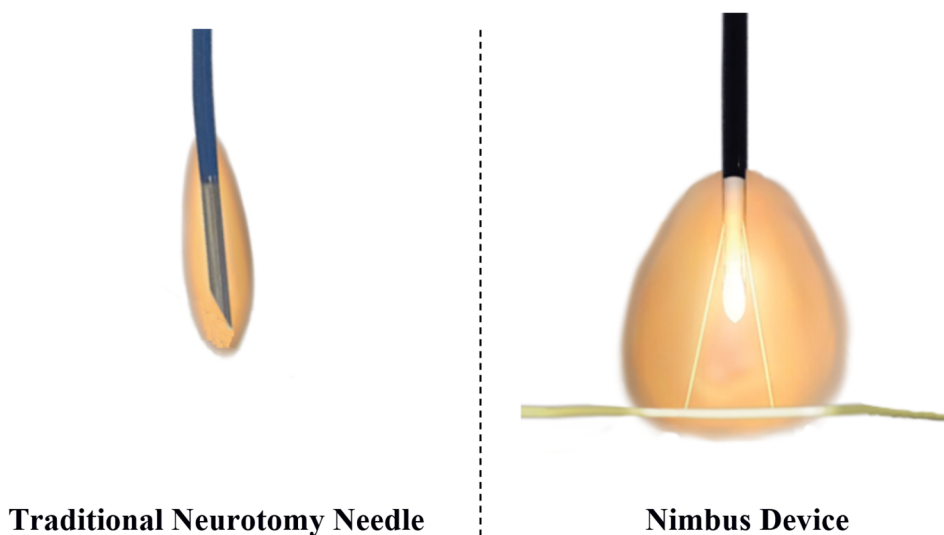
(see Figure 7, below). The deployment of the tines is controlled by a rotatable spin collar. An RF probe (not shown in image below) is inserted into the needle, and RF energy is conducted through the tip of the needle/cannula and the tines, in a monopolar system. The Nimbus Device was the first neurotomy needle with deployable tines.

Figure 7



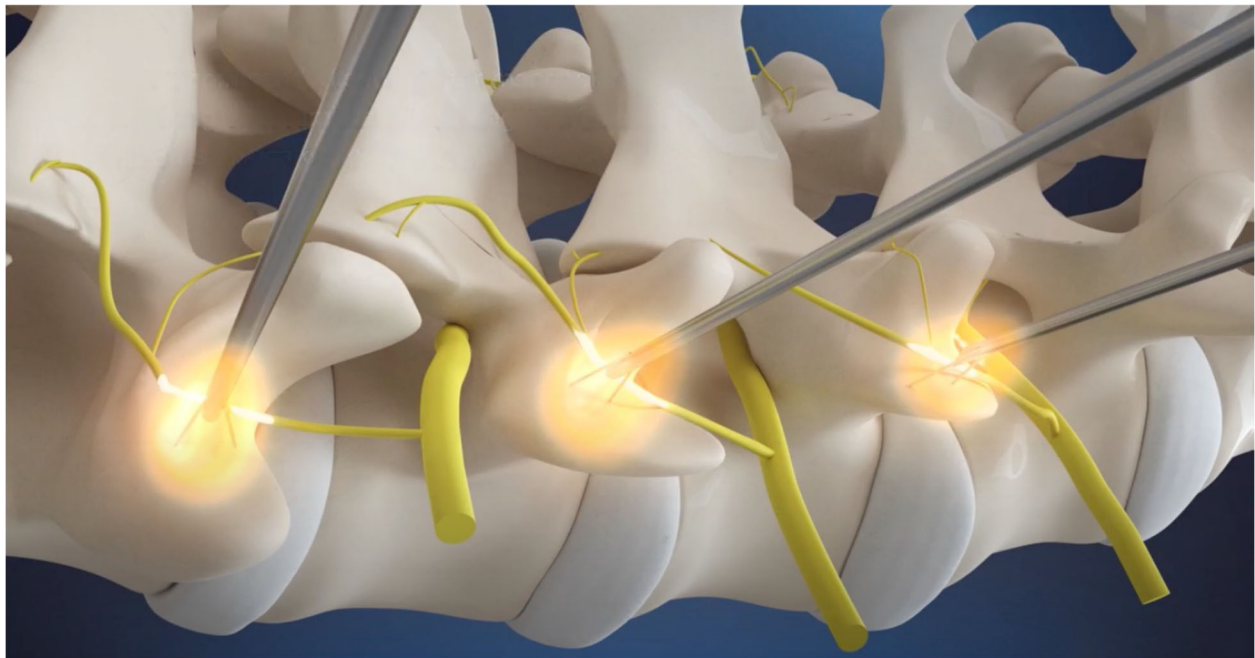
121. The presence of the Nimbus Device tines results in RF energy being applied across a larger area compared with traditional RF neurotomy needles, as shown in the side-by-side comparison in Figure 8 below. Moreover, the ablation volume created by the Nimbus Device is expanded beyond the needle tip, as compared with the traditional RF neurotomy needle.

Figure 8



122. With its expanded lesion profile, the Nimbus Device permits effective use of the perpendicular approach to the medial branch nerve, as illustrated in Figure 9 below. In this image, perpendicular placements of three Nimbus Device devices at three adjacent vertebral levels are depicted, which can be contrasted with the parallel placements of traditional RF neurotomy needles shown in Figure 6 above.

Figure 9



123. The perpendicular approach thus enabled by the Nimbus Device has numerous advantages over the parallel approach, including being safer, faster, and easier to learn.

124. The perpendicular approach is safer due to the presence of inherent anatomical safeguards. As can be appreciated from Figure 9 above, with this approach, the practitioner advances the needle until the tip hits bone. The needle tip is then slightly retracted from the bone surface and the tines are deployed. The bone thus serves as a safety backstop that assists in accurate placement of the device. In

contrast, no such backstop exists with the parallel placement described above with respect to Figure 6. If a practitioner inadvertently advances the needle tip too far using this approach, the larger nerve root (depicted in a relatively vertical orientation in Figures 6 and 9) could be damaged by the needle tip itself or by subsequent ablation, which can result in at least temporary paralysis or other nerve injury.

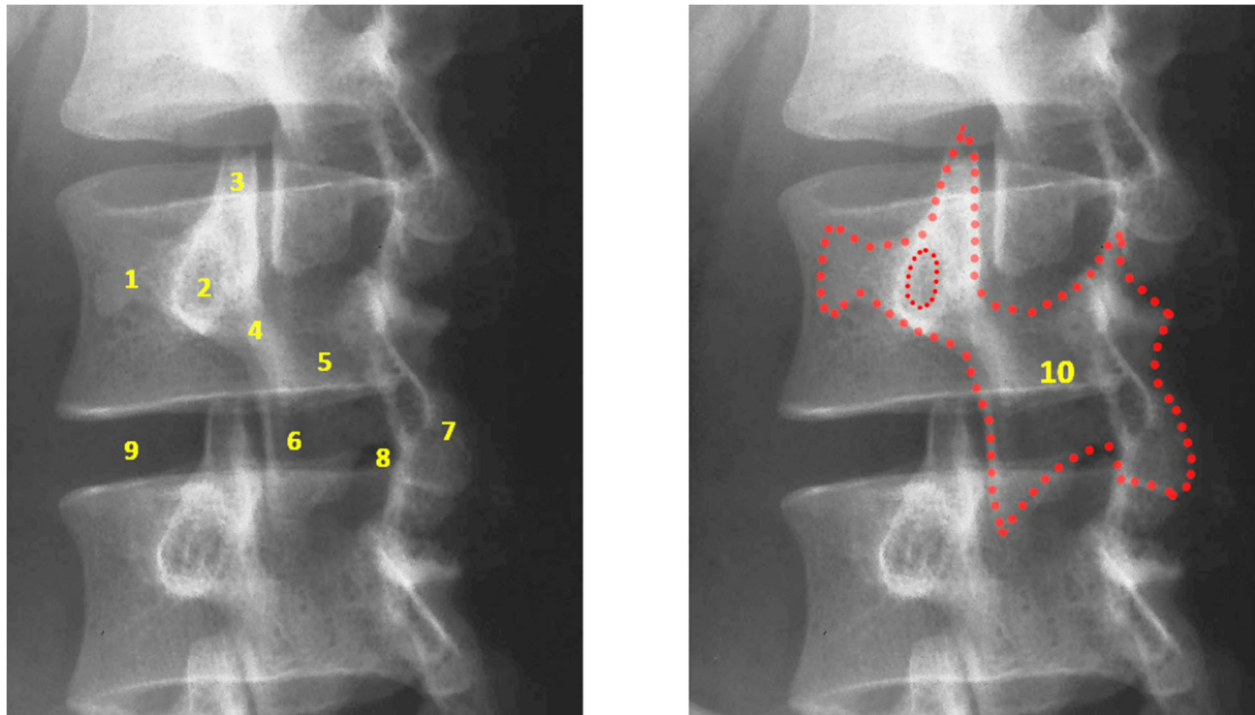
125. The perpendicular approach is also faster, when used with the Nimbus Device, because it allows medial branch nerve ablation procedures to be completed with fewer heat cycles and less damage to surrounding tissue, as compared with the parallel approach. With the perpendicular Nimbus Device approach, only a single lesion (and only a single pass of the device) is required to thoroughly coagulate the target nerve.

126. The perpendicular approach is also more easily learnt by interventional pain specialists than is the parallel approach because the so-called “eye of the Scotty dog” can be used as a target point. The “eye of the Scotty dog” is an artifact readily visible in X-ray images of a healthy spine along the pathway used for perpendicular needle placement. The artifact resembles the eye of a Scottish terrier, as identified in Figure 10 below with the number “2” in the image on the left and with a dotted oval in the image on the right.⁶ The “eye of the Scotty dog” corresponds with the portions of the bone over which the medial branch nerve passes—these same regions are generally “highlighted” in yellow by the depiction of ablation zones in Figure 9 above. As the “eye of the Scotty dog” pathway is the same pathway typically used for medial branch blocks (injections of anaesthetic near the medial branches), use of

⁶ Extracted from Daniel MacManus, Scottie dog sign (spine), Figure 3, available at <https://radiopaedia.org/articles/scottie-dog-sign-spine> (last revised Mar. 9, 2025).

this well-known pathway further contributes to its ease of adoption by these interventional pain specialists.

Figure 10



127. Due to it being safer and easier to use, the perpendicular needle placement made possible by the Nimbus Device facilitated medial branch neurotomy for skilled practitioners, and these features in combination with it being easier to learn enabled a greater number of specialists to perform such RF neurotomy procedures.

3. Multifidus-Sparing Technique

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

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

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

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

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

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

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

135. The MSRFN technique has gained significant popularity Australia. It is also becoming more widely adopted in other regions of the world, including the U.S.

136. In my current practice, I use the Nimbus Device to treat all patients who require facet-joint radiofrequency neurotomy. I treat approximately 70 percent of these patients (generally those under the age of 70) using the MSRFN technique, and I treat the remaining 30 percent using the perpendicular approach.

VII. PERSON OF ORDINARY SKILL IN THE ART

137. As I described above, product development efforts in the RF neurotomy field were directed to the RF generators, rather than the RF neurotomy devices (that is, the needles and electrodes), in the years immediately before the Relevant Dates.

138. I believe that if an improved RF neurotomy device were to be developed as at the Relevant Dates, the process would begin with an interventional pain specialist, such as myself. This is because a detailed knowledge of the anatomy and physiology of pain pathways, and the sources and causes of different types of pain, as well as the existing RF neurotomy techniques, including the devices used to perform those techniques, would all have been essential to design an improved RF neurotomy device before the Relevant Dates.

139. Even with this detailed knowledge, however, I would not have been able to develop an improved RF neurotomy device entirely on my own. I believe this is also true of other interventional pain specialists. I believe assistance from a person or team with engineering expertise would be needed. I expect that the interventional pain specialist would have needed to explain to an engineer what was trying to be achieved with the improved device and would have relied on the engineer to help translate that into aspects of the design and development of the improved device.

140. I also believe it would not have been possible for an engineer to design and develop an improved RF neurotomy device without closely collaborating with an interventional pain specialist for at least the reasons noted above.

141. If I had been looking to develop an improved RF neurotomy device at the Relevant Dates, my starting point, and I expect the starting point of others practising RF neurotomy, would have been existing RF neurotomy devices.

142. In my world, a POSITA would include a junior doctor, fellow, or a consultant pain specialist or neurosurgeon performing RF neurotomy procedures on patient with three months of experience with thermal ablation systems. I believe three months would be sufficient, as one becomes skilled in the art very quickly as a doctor. I would not altogether exclude engineers from the definition of a POSITA, but it is necessary to include physicians who actually use RF neurotomy devices.

143. In my experience, inventions in this space typically start with a doctor. Doctors are the ones who see the patients, who diagnose and treat the conditions, and who know the limitations of existing devices in practice.

144. In my experience, if a device fails to achieve a clinical outcome, a biomedical engineer would not know this without the assistance of a doctor. Biomedical engineers are not the ones who see the patients for follow up visits after procedures—that is the role of doctors. A doctor may, for example, see that a device has caused an issue with one or more patients and then consult with an engineer to gain possible insight into that issue. Based on information gained from the engineer, if any, the doctor might then cogitate on the matter and develop his own solutions to the issue.

145. I understand that Gabor B. Racz, William R. Fitz, and Bruce Lee, the only or first-named inventors of the Racz, Fitz, and Lee references, respectively, are all medical doctors. Specifically, Gabor B. Racz is a board-certified anaesthesiologist who served as the acting director of pain services at Texas Tech University Health Science Center in Lubbock, Texas; and Philip Finch (who is also an inventor of Racz) is an Australian pain physician. *See* Exhibit Nos. 2021, 2022. Willaim R. Fitz is a pain physician in Ohio. *See* Exhibit No. 2023. And Bruce Lee is a board-certified gynaecologist in Southern California. *See* Exhibit No. 2024.

146. The inventorship of Racz and Fitz is consistent with the qualifications that I deem necessary for a POSITA in the RF neurotomy space, as each of these RF neurotomy references was invented by pain medicine specialists.

147. The inventorship of Racz, Fitz, and Lee also demonstrates the lack of cross-pollination of RF neurotomy and other specialties, such as gynaecology, in which RF ablation is also employed. Whereas the RF neurotomy devices of Racz and Fitz were invented solely by pain medicine specialists, Lee’s uterine fibroid ablation device was invented by a gynaecologist.

VIII. ALLEGED PRIOR ART

A. Racz Is Directed to RF Neurotomy

148. Racz discloses a “radio-frequency electrode cannula” into which an “electrical probe” is inserted. Ex. 1009 at 3:39-40, 60-63. Racz indicates its apparatus “for pain relief . . . delivers electrical stimulation pulses or high-frequency signals to the vicinity of a neural structure via an electrical needle or cannula.” *Id.* at 1:7-9.

149. Racz’s device bears similarities to the RF neurotomy devices I discussed in Section VI-B, *supra*. Indeed, in his “Background of the Invention” section, Racz discusses the “SMK Needle electrodes from Radionics,” which I similarly described in my “History of RF Neurotomy” section above. *See id.* at 1:43-65.

150. A POSITA would conclude that the thrust of Racz’s disclosure pertains to RF neurotomy.

1. Racz's Curved Tip

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

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

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

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

2. Racz's Gauges

155. Racz states that “[t]hose individuals skilled in the art will recognize that many variations of the electrode geometries depicted in FIGS. 1-3 are possible without departing from the invention. Various sized electrodes can be made, from extremely small gauges (e.g., 30 gauge) to much larger sizes (e.g., 10 gauge).” *Id.* at 8:10-15. Although I have mentioned it before, I again note that for gauge sizes, increasing gauge numbers correspond with decreasing sizes; decreasing gauge numbers correspond with increasing sizes.

156. To properly evaluate the foregoing passage of Racz, it is necessary to understand what a POSITA would know about RF neurotomy needles independent of Racz’s disclosure, and it is also important to evaluate this passage in the proper context of Racz’s own disclosure.

157. To the extent the IPR Petitions and Dr Tucker, whether in his declarations or deposition, allege that Racz’s foregoing passage teaches that an RF neurotomy needle can be sized from 30 gauge on the small end to 10 gauge on the large end, I disagree.

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

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

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

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

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

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

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

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

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

162. Even in cordotomy procedures, in which a tiny needle is inserted into the spinal cord of a patient to create a miniscule lesion (e.g., 0.5 mm by 0.5 mm) with pinpoint precision, a 22-gauge needle may be used.

163. Thus, a POSITA would know, independent from Racz, that RF neurotomy needles cannot be as large as 10 gauge or as small as 30 gauge, and are instead sized only from 16 gauge to 22 gauge.

164. Even Racz’s own teachings would cause a POSITA to recognize that needle gauges larger than 16 gauge or smaller than 22 gauge would, in Racz’s own phrasing, “depart[] from the invention” of Racz. *Id.* at 8:12-13.

165. Much of Racz’s disclosure is directed to specific neurotomy procedures in which a bent tip can be beneficial. *See, e.g., id.* at 6:59-67; 7:1-25. Racz recognizes that for neurotomy procedures, the “cannulae . . . must be placed with accuracy and care to avoid injury to critical neural structures” and “avoidance of injury to delicate anatomic structures is of primary importance,” in the regions and contexts of lumbar joints, sacroiliac joints, and nerve blocking of spinal roots. *Id.* at 6:26-29; 7:13-21. These are issues that would arise if an RF neurotomy needle were larger than 16 gauge.

166. Racz further recognizes that having too much flexibility is undesirable for neurotomy needles. “Such flexible off-axis electrodes have a limitation that there [sic] tips cannot penetrate tough tissue or encounter hard bone without being damaged or diverted.” *Id.* at 2:34-37. These are issues that would arise if an RF neurotomy needle were smaller than 22 gauge.

167. Thus, a POSITA reading Racz as a whole and with experience-based appreciation of the concerns Racz mentions would understand that needle gauges larger than 16 gauge or smaller than 22 gauge would raise the concerns I note in the two paragraphs immediately above, respectively.

168. In summary, Racz does not teach or fairly suggest to a POSITA that its devices could be constructed with a cannula larger than 16 gauge or smaller than 22 gauge and still be suitable for use as an RF neurotomy needle.

169. For completeness, I refer to my discussion of Dr Tucker's deposition in Section XI-A below, in which Dr Tucker misapplied a gauge size range from a different reference, Tullis, in a similar fashion.

B. Fitz Is Directed to RF Neurotomy

170. Fitz purports to be directed to "[i]mproved-coverage RF neurotomy instrumentation." Ex. 1011 at [abstract].

171. Fitz does not teach or suggest to a POSITA activation of its electrodes via an insertable probe. In this regard, Fitz only discloses that "[e]ach electrode has a proximal end configured for attachment to a source of energy." *Id.*

C. Lee Has Limited or No Relevance to Racz and Fitz

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

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

174. While it can be desirable to increase the ablation volume for both RF neurotomy and non-neurotomy applications, that desire is animated by different considerations. In tumour ablation, for example, a larger ablation volume is desirable because complete ablation of the entire tumour is the clinical objective, even if that means some collateral damage to nearby tissue. Indeed, in cancerous tumour

removal or treatment, including RF ablation, the clinicians and surgeons often refer to “margins” to excise or treat a tumour. That refers to extra tissue surrounding the tumour. In RF neurotomy, on the other hand, the reason for desiring increased ablation volume is to increase the likelihood that the relatively tiny nerve tissue targets are not missed during the ablation. Indeed, in RF neurotomy, it is almost uniformly undesirable to ablate beyond the target nerve in order to avoid damaging other nerve structures that can be located nearby (see, e.g., the discussion above).

175. The properties of tumour tissue and tissues ablated in RF neurotomies also differ in fundamental manners. For example, tumours (including uterine fibroids) are characterized by their vascularity—blood vessels carry blood to and from the tumour. During an ablation procedure, blood passing through the tumour carries heat away from the ablation site, thus requiring input of further energy. In spinal RF neurotomy procedures, however, there are no blood vessels in the target area that would take away energy as it is being applied.

176. As a further example, tissue of cancerous tumours may be less dense and more friable than surrounding tissue, which can yield impedance characteristics (e.g., low impedance) that vary from normal tissue, whereas tissue of uterine fibroids (another type of tumour) can be more dense than surrounding tissue with other varied impedance characteristics. In spinal RF neurotomy procedures, however, the densities and impedances are those of normal tissue.

177. Another significant difference is that the physicians who perform RF neurotomy procedures (pain-treatment specialists) are different specialists from the physicians who perform other RF ablation procedures, as I note above. The physicians in these different specialties live in different professional worlds, read different professional literature, attend different conferences, etc.

178. Additionally, the frequency with which RF neurotomy procedures are performed is many times more often than all other RF ablation procedures. A pain-treatment specialist may perform numerous (perhaps more than a dozen) RF neurotomy procedures each day, whereas RF ablation of tumours, for example, is a relatively rare event. Moreover, most RF neurotomy patients must repeat the procedure periodically as nerve tissue regenerates.

179. This difference in procedure frequency and volume significantly impacts the design and construction of the RF ablation devices used for neurotomy as compared to other applications. For example, it can be quite valuable to have removable, reusable parts—like an RF probe—in an RF neurotomy device, whereas reusability is simply not a factor in the other RF ablation treatments because of their relative rarity.

180. A further difference between the neurotomy devices of Racz and Fitz and the tumour ablation device of Lee is apparent from Lee’s inability to deliver anaesthetic to a target site. Both Racz and Fitz state anaesthetic delivery as an objective of their devices, but Lee does not—every device disclosed in Lee lacks the ability to deliver anaesthetic. RF neurotomy procedures require delivery of anaesthetic to a target nerve through the RF neurotomy needle before a nerve can be ablated. This is a crucial step, as many RF neurotomy procedures are conducted under sedation, rather than under general anaesthesia, and others do not even use sedation. In contrast, Lee’s device would only be used when the patient is under general anaesthesia, so there would be no need to deliver anaesthetic to the patient when using this device.

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

D. Young '965 Has Limited or No Relevance to Racz and Fitz

182. Young '965 is directed to devices for treatment of tissue anomalies and cancers. Ex. 1012 at ¶ 0002. For example, Young '965 discusses difficulties encountered during ablation due to bloodflow through the target tissue. *Id.* at ¶ 0006. Young '965 is devoid of any disclosure regarding the ablation of nerves.

183. Like Lee, Young '965 also lacks the ability to deliver anaesthetic to a treatment site.

184. Young '965 thus is not concerned with RF neurotomy. For reasons such as those described above with respect to Lee, I see Young '965 as having limited or no relevance to Racz and Fitz.

185. Dr Tucker asserts that “a POSA would have recognized that Young '965's shaft (20) could also be adapted to deploy and retract Lee's filaments (22/1622) from Racz's device (e.g., the shaft (20) could be hollowed and dimensioned to accommodate Racz's RF probe (22/52)).” Ex. 1031 at ¶ 227. I disagree.

186. I do not see any reason for a POSITA to hollow out Young '965's shaft so it can accommodate Racz's RF probe. Dr Tucker provides no reasoning as to why a POSITA would be motivated to do so. Moreover, there are significant reasons that a POSITA would be dissuaded from doing this.

187. As just one example, Racz discloses that the distal tip (56) of its RF probe (52) includes a temperature sensor. Ex. 1009 at 5:28-29. The inclusion of a temperature sensor at the distal tip of an RF probe is a standard practice. The purpose of the temperature sensor is to monitor the temperature at the ablation zone during ablation. Accordingly, it is desirable for the temperature sensor to be as close as

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

Ex. 1031 at ¶ 227.



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E. Scheibe Has Limited or No Relevance to Racz and Fitz

190. Scheibe is directed to a deflectable catheter assembly and is not concerned with RF neurotomy. Ex. 1013 at [abstract]. I see this reference as having limited or no relevance to Racz, Fitz, or Lee.

191. I note that the IPR Petitions and the Tucker Declarations repeatedly cite to the following passage from Scheibe, although they only quote the final six words thereof:

Although the use of the implantable device has been described for use as a lead in, for example, a cardiac stimulation system, the implantable device could as well be applied to other types of body stimulating systems.

See, e.g., IPR2024-01209, Paper 1 at p. 74 and Ex. 1031 at ¶¶ 233, 237 (each quoting Ex. 1013 at ¶ 0037). It appears that the IPR Petitions and the Tucker Declarations rely on this passage to demonstrate that a POSITA would naturally see that Scheibe’s teachings are relevant to other “stimulating systems,” such as those of Racz, Fitz, and Lee. *See id.* This is incorrect.

192. A POSITA would immediately recognize that Scheibe’s quoted passage does not correspond with the rest of Scheibe’s teachings. Deflectable catheter assemblies are clearly not “implantable device[s]” that can be used as leads in “cardiac stimulation system[s].” Ex. 1013 at ¶ 0037

193. Regardless, a POSITA would not consider either deflectable catheter assemblies or leads for cardiac stimulation systems as being relevant to Racz, Fitz, or Lee.

194. Moreover, I do not believe that a POSITA would find a rotational actuator mechanism that is intended to create tension on a “pullwire” that remains fixed within a distal end of a flexible catheter sheath to deflect the sheath, as taught by Scheibe, as being reasonably pertinent to the objective of pushing tines out of a distal end of a stiff cannula. See Ex. 1013 at ¶¶ 16, 17, 26. These are nearly antithetical objectives.

IX. STRATUS PATENTS

195. The following statement, or one similar thereto, appears near the beginning of each Stratus Patent:

The present invention is directed toward improved methods, systems, and related apparatuses for performing thermal ablation in general, and in particular, improved methods, systems and related apparatuses for performing RF neurotomy, specifically in the region of the spine of a patient.

Ex. 1002 at 1:58-62; *see also* Ex. 1001 at 1:56-58.

196. The '688 and '664 Patents further state that:

RF neurotomy uses RF energy to cauterize a target nerve to disrupt the ability of the nerve to transmit pain signals to the brain. Known RF neurotomy methods typically use a single RF probe generating a generally oval or oblate spheroid lesion. The RF probe is positioned in an attempt to include the target nerve within the oval or oblate spheroid lesion. In various procedures, access to a target nerve may be limited (e.g., limited to a restricted angular range), thereby raising significant

challenges to medical personnel to create sufficient lesions to provide optimal clinical outcomes. Additionally, anatomical variations of the nerve location relative to anatomical landmarks provide additional challenges.

Ex. 1002 at 1:42-54.

197. The limitations or challenges described in this passage were recognised limitations or challenges in the RF neurotomy field before the Relevant Dates. As I stated above, to successfully capture the target nerve in the lesion required comprehensive knowledge of the topography of the target nerve tissues, as well as surgical precision, and the RF neurotomy procedures could fail if the electrode was not placed optimally near the target nerve or if anatomic variations were not effectively incorporated into the lesion.

198. The Stratus Patents each include the following statement, or one similar thereto:

In the following description, the invention is set forth in the context of apparatus and methods for performing RF ablation. More particularly, the systems and methods may be used to perform RF neurotomy to ablate portions of target nerves. Even more particularly, the systems and methods may be used to perform spinal RF neurotomy to ablate portions of target nerves along the spine of a patient to relieve pain. For example, embodiments of methods and apparatuses described herein relate to lumbar RF neurotomy to denervate a facet joint between the L4 and L5 lumbar vertebrae. Denervation is achieved by application of RF energy to a portion of a medial branch nerve to ablate or cauterize a portion of the nerve, thus interrupting the ability of the nerve to

transmit signals to the central nervous system. In another example, embodiments described herein relate to sacroiliac joint RF neurotomy.

Ex. 1002 at 4:18-34; *see also* Ex. 1001 at 8:40-55.

199. In my opinion, including based upon the above passage, the Stratus Patents are directed to the field of RF neurotomy, and particularly spinal RF neurotomy, and it describes new devices and methods for performing RF neurotomy. I do, and did before the Relevant Dates, regularly perform RF neurotomy to denervate facet joints between the L4 and L5 lumbar vertebrae, as well as sacroiliac joint RF neurotomy.

200. The limitation of the single needle technology described in the above passage was a recognised limitation in the RF neurotomy field before the Relevant Dates. As I state above, it was known before the Relevant Dates that there was minimal lesion formation distally beyond the electrode tip, with a circumferential lesion produced around the electrode tip. The Stratus Patents state that the invention overcomes that obstacle by employing the use of multiple filaments to provide additional conduits for RF energy and to allow adjustment of lesion geometry and size (see, for example, column 3, lines 9-19 of the '688 Patent).

201. The Stratus Patents describe a number of advantages provided by the invention described therein, which I have experienced as a result of using the Nimbus Device, including that it enables the needle to be inserted into a patient at a more desirable angle than would be required when using a needle without offset lesion capabilities (see, for example, column 22, lines 9-27 of the '688 Patent), and that it may be used to ablate a larger target area without the need to reposition the needle (for example, without withdrawing the needle and reinserting it), which may result in reduced patient trauma (see, for example, column 24, line 60 to column 25,

line 8 of the '688 Patent). As I state above, the Nimbus Device allows interventional pain specialists to use a simplified technique to reach the target nerve, and also produces more optimally shaped lesions to capture target nerves in the facet joints and sacroiliac joints, with fewer heat cycles and with less heat damage to surrounding tissues.

202. The devices used in the RF neurotomy field as at the Relevant Dates did not have both a removeable RF probe and deployable and retractable filaments.

X. RESPONSE TO DECLARATION OF DR TUCKER

203. I comment here on only a few of the items discussed in Dr Tucker's declaration with which I disagree. While further points of disagreement should be apparent from other sections of this declaration, I do not necessarily address every point of disagreement.

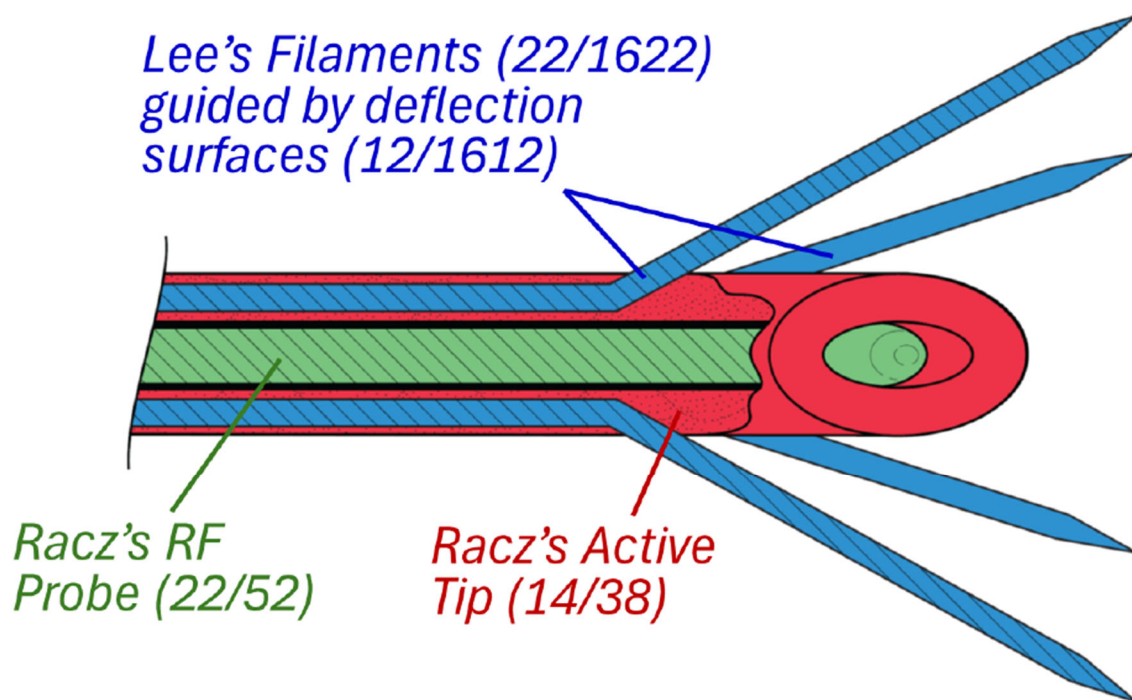
204. Initially, I note that Dr Tucker is a pathologist who has never performed an RF neurotomy procedure on a live human patient. Ex. 2020 at 9:5-6; 10:3-18; 12:16-20.

205. I further note that Dr Tucker has no personal knowledge of the size of RF neurotomy needles. *Id.* at 142:3 to 146:16. Dr Tucker admits that he would need to defer to the understanding of physicians who actually perform RF neurotomy procedures to determine what sizes are appropriate for RF neurotomy needles. *See id.* at 142:15-21.

206. I do not see anything in the Tucker Declarations, Dr Tucker's *curriculum vitae*, or Dr Tucker's Deposition to suggest that Dr Tucker has any meaningful experience with the performance of RF neurotomy procedures using

RF neurotomy needles. As I consider such experience indispensable for determining what a POSITA would have known as at the Relevant Dates with respect to RF neurotomy needles, I disagree with Dr Tucker's conclusory statements of what would have been obvious to a POSITA.

207. For example, I disagree with Dr Tucker's unsupported conclusion that "Racz's modified device" illustrated in his declarations (reproduced below), to the extent it is manufacturable, could function as a "radiofrequency neurotomy needle."



208. I also disagree with Dr Tucker's unsupported statements that "Racz's modified device" would have been obvious to a POSITA as at the Relevant Dates.

209. There are many details of "Racz's modified device" that I do not understand from Dr Tucker's description of this device. For example, I cannot determine whether the tip illustrated above is supposed to be curved or straight. I assume that it must be curved because the red portion is identified in the image above

as “Racz’s Active Tip,” and Racz disclosed that its tip must be curved (as I have discussed previously). But the tip appears to be illustrated in a straight configuration, which is contrary to Racz’s teachings.

210. As a further example, Dr Tucker indicates that Racz’s electrode cannula, as incorporated into “Racz’s modified device,” is a “radiofrequency neurotomy needle.” Ex. 1031 at 91, *see also id.* at 99-111. From this, I must assume that the cannula of Racz’s modified device is sized between 16 gauge and 22 gauge. But I am unclear as to how channels could be formed in the sidewall of such a small cannula to receive the blue components identified in the image above as “Lee’s Filaments guided by deflection surfaces” (which I identify hereafter as “Lee’s Filaments”).

211. And even assuming that “Lee’s Filaments” could be arranged within the sidewall as illustrated, I am unclear as to what mechanism would be used to advance and retract these components through the sidewall of “Racz’s Active Tip.”

212. Despite these and other confusing aspects of Racz’s modified device, it is my understanding that “Lee’s Filaments” are meant to fit within channels in the sidewall of a needle body sized between 16 gauge and 22 gauge, as depicted in Dr Tucker’s illustration.

213. While I do not understand Dr Tucker’s “second example,” I believe it would at least have the same size needle tip as the “first example,” and thus would also be between 16 gauge and 22 gauge with channels running through its sidewall for “Lee’s Filaments.” *See id.* at 86-89.

214. With respect the foregoing assumptions regarding “Racz’s modified device,” at the scales involved in RF neurotomy, my initial impression is that such a

device, if manufacturable, would be extremely and impractically costly. I have never seen a device similar to what is illustrated in which deployable tines are advanced through channels within the thin sidewall of a needle.

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

216. But first, I again note that Racz itself warns against the very arrangement depicted in “Racz’s modified device” for some of the reasons I will discuss hereafter. Specifically, Racz warns against advancing flexible elements from a cannula in the types of environments encountered in RF neurotomy procedures:

Those electrodes both have flexible, curved tips, which extend from the straight shaft of an enclosing cannula to extend off-axis in an arc. This is useful in certain neural regions such as the trigeminal ganglion or the pituitary gland, or any area where the target region is very soft or fluid filled. Such flexible off-axis electrodes have a limitation that there [sic] tips cannot penetrate tough tissue or encounter hard bone without being damaged or diverted.

1009 at 2:30-38. Because “Lee’s Filaments” would have extremely small cross sections in Racz’s modified device, they would possess the very properties that Racz discourages for RF neurotomy needles. That is, they would be “flexible” and incapable of “penetrat[ing] through tissue or encounter[ing] hard bone without being

damaged or diverted” as they “extend from the straight shaft of an enclosing cannula to extend off-axis.” *Id.*

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

218. In my experience, practitioners would not use a device that presented any possible risk of breaking off within a patient, particularly in the vicinity of nerves. The risk of such breakage is heightened near bone, which is where spinal and other forms of RF neurotomy procedures are performed.

219. “Lee’s Filaments” in “Racz’s modified device” also would have a high risk of bending while passing through tissue or potentially encountering bone, likely in unpredictable manners. Such uncontrolled bending is unacceptable for neurotomy, where precisely targeting miniscule targets is necessary, as I have previously discussed. With a device such as “Racz’s modified device” illustrated above, the configuration of the deployed tines would vary in unpredictable and potentially unrepeatable manners, as they would be influenced differently by the tissue through which they pass from one patient to the next. The tines of an RF neurotomy needle such as disclosed in the Stratus Patents must be deployed in predictable, repeatable, and reliable way to ensure proper targeting of a nerve.

220. As a further complication, bending of such small tines could prevent their retraction after use. The narrow entrances of the side ports into which “Lee’s Filaments” must be withdrawn appear to heighten this risk.

221. If “Lee’s Filaments” were unable to retract into the needle tip, this would damage delicate structures of the patient during retraction of the full device from the patient, as the un-retracted tine or tines (depending on whether they are individually or collectively retractable) would still be sticking radially outward by some amount. This scenario could also increase the likelihood of one or more of the tines breaking off within the patient.

222. A further complication that can arise from “Lee’s Filaments” being too flexible due to their tiny profile is a tendency of the tines to spread further apart from one another than intended. To achieve an effective ablation volume that can target nerves in the effective manners discussed in other sections above, it is desirable for the individual ablation patterns from each filament to have some degree of overlap or confluence. Such overlap can be appreciated from the ablation volume of the Nimbus Device depicted in Figure 8 above. If the filaments are too far from one another, their ablation coverages will not overlap, leaving gaps in the ablation volume. The device would thus be unable to provide a predictable and repeatable ablation patterns upon which a practitioner could rely.

223. Even in the absence of undesired bending, however, “Lee’s Filaments” would still be unsuitable for expanding the ablation volume of “Racz’s Active Tip” because they are so thin. Dr Tucker’s proposed design thus causes “Lee’s Electrodes” to be so small that they are unsuitable for their stated purpose.

224. It is difficult to achieve meaningful ablation volumes from electrodes that are 22 gauge or smaller. Even if it were to be assumed that the cannula size of Racz’s modified device is 16 gauge, thus making the device as large as possible while still qualifying as an RF neurotomy needle, “Lee’s Filaments” would necessarily be much smaller than 22 gauge in order to fit within the needle’s

sidewall. “Lee’s Filaments” thus would be incapable of providing ablation volumes that could meaningfully expand the ablation volume of “Racz’s Active Tip.” This situation would worsen if smaller cannula gauges were used for “Racz’s modified device.”

225. Thus, “Lee’s Filaments” ultimately would fail to provide an expanded ablation volume that would improve upon the performance of Racz’s unaltered device. This undercuts the very motivation that Dr Tucker relies upon for combining the teachings of Racz, Fitz, and Lee. *See* Ex. 1031 at 78-81.

226. In sum, the tiny, flexible tines that would be required for “Racz’s modified device” make this device unsuitable for RF neurotomy: the tines could break, could bend in unpredictable manners, and in any event, would be so small that they would fail to achieve their stated purpose of expanding an ablation volume.

227. In view of the foregoing, I strongly disagree with Dr Tucker’s unsupported assertion that “Racz’s modified device” could function as a “radiofrequency neurotomy needle.” Ex. 1031 at 91, *see also id.* at 99-111.

228. In view of the foregoing, I also strongly disagree with Dr Tucker’s assertion that a POSITA would have found it obvious to combine the teachings of Racz, Fitz, and Lee to create “Racz’s modified device”—no POSITA who has real-world experience performing RF neurotomy procedures on actual human patients would have ever arrived at such a device.

XI. RESPONSE TO DEPOSITION OF DR TUCKER

229. I comment here on only a few of the items discussed in Dr Tucker’s deposition with which I disagree. While further points of disagreement should be

apparent from other sections of the present declaration, I do not necessarily address every point of disagreement.

A. Cannula Size for RF Neurotomy Needles

230. In his deposition, Dr Tucker confirmed that he did not personally know what sizes are appropriate for RF neurotomy needles, and thus would need to rely on more knowledgeable physicians or patent literature to determine this information. *See* Ex. 2020 at 142:3 to 146:16.

231. In discussing paragraph 46 of his declaration (Exhibit 1031), Dr Tucker repeatedly indicated that one of the “guys” (patentees) he listed in this paragraph had identified 12 gauge is an appropriate upper limit for the size for RF neurotomy needles. *Id.* at 133:5; 143:4-18; 144:8-10; 145:9-20. This is clearly wrong.

232. In his testimony, Dr Tucker must have been referencing his following quotation in paragraph 46 of his declaration:

Ex-1022, 7:32 (cannulas used can range ‘from 12 G[auge] to a smaller 26 G[auge]’).”

Ex. 1031 at ¶ 46 (quoting Ex. 1022, 7:32).

233. But this quotation omits crucial information. The full quote from Exhibit 22 (U.S. Patent No. 7,918,852 of Tullis et al.) is as follows:

Other cannulae of this invention, both monopolar and bipolar, may have outer diameters ranging from 12 G[auge] to a smaller diameter 26 G[auge]. For electrode assemblies 24 used *for denervation procedures*, *the diameter of the cannula 28*, which is the diameter of

the supply electrode assembly 36, *is preferably 16 G[auge] or more and more preferably 18 G[auge] or more.*

Ex. 1022 at 7:30-36 (emphases added).

234. Thus, even the patent literature that Dr Tucker attempted to used in his declaration and deposition testimony to identify unreasonably large sizes for RF neurotomy needles instead confirms the true range that I have I identified throughout this declaration: 16 gauge is the maximum acceptable size for neurotomy needles.

235. This episode from Dr Tucker’s deposition is just one among many demonstrating that Dr Tucker does not possess the necessary understanding of RF neurotomy procedures to credibly comment on what would or would not have been obvious to an appropriately defined POSITA.

236. I reiterate that a POSITA would independently know that RF neurotomy needles range in size from 16 gauge to 22 gauge for the reasons previously discussed.

B. Scope of the Term “RF Neurotomy”

237. In his deposition, Dr Tucker admitted to being confused as to whether the term “RF neurotomy” applies only to spinal nerves or whether it also applies to “peripheral nerves.” See Ex. 2020 at 196:5-17; 198:6-17. Ultimately, he concluded that RF neurotomy applies to both spinal nerves and peripheral nerves. *Id.*

238. Dr Tucker’s confusion regarding the term “RF neurotomy” may stem from his inexperience with RF neurotomy procedures, as he has never performed an RF neurotomy on a human patient. *Id.* at 12:16-20.

239. Regardless, application of the term “RF neurotomy” solely to spinal nerves would be understandable, as I estimate that more than 99.5 percent of all RF neurotomy procedures are performed on spinal nerves, such as lumbar, thoracic, and cervical medial branch nerves.

240. Whether RF neurotomy applies solely to spinal nerves or additionally to peripheral nerves makes little difference in the present case, however. RF neurotomy needles used for performing neurotomies on peripheral nerves, whether via thermal ablation or via pulsed RF, are similar to other RF neurotomy needles described above with respect to spinal procedures. For example, in both instances, the RF neurotomy needles are sized from 16 gauge to 22 gauge.

C. Dyes Do Not Make Nerves Visible Under Fluoroscopy

241. In his deposition, Dr Tucker suggested that a practitioner could avoid inadvertently deploying a pointed stylet into a non-targeted nerve near the spine during a RF neurotomy procedure because it is possible to use certain dyes that render nerves visible under X-rays, such as used in fluoroscopy. Ex. 2020 at 58:9 to 60:7.

242. This is false. I am unaware of any dye that renders nerves visible under X-rays.

243. While it is possible to inject dye into the spine to identify an anatomical tract within which a nerve will be located, such as a hole in a bone, this does not make the nerve itself visible. The dye only assists in highlighting the tract.

244. There is also a procedure that used to be employed more than it is today called myelogram fluoroscopy. This procedure involves the injection of a large amount of dye (e.g., 50 mL) into the fluid around the spinal cord. This can show the

anatomical outline of the spinal cord. This procedure is not used in RF neurotomy and, in any event, became a relatively rare alternative to MRI scans after the advent of MRI machines.

245. Importantly, practitioners who are experienced in RF neurotomy would not inject dye near a nerve during an RF neurotomy procedure. This would be counterproductive, as the dye would obscure the anatomical markers (e.g., bones) in the very region where the practitioner is trying to accurately position the needle tip based on those very anatomical makers. Practitioners wish to see the bony anatomy in an unobscured fashion when using fluoroscopy so they may reference the contours of that bony anatomy to approximate the positions of the nerves, which are not visible under fluoroscopy.

XII. CONCLUSION

246. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment, or both under Section 1001 of the Title 18 of the United States Code, and that such willful false statements may jeopardize the validity or enforceability of the Stratus Patent.

247. I agree to be reasonably available for cross-examination regarding the content of this declaration in the United States during the time allotted for such cross-examination in these cases.

Executed this 21st day of May 2025.

A handwritten signature in black ink that reads "Marc A Russo". The signature is written in a cursive, flowing style. The first name "Marc" is followed by a middle initial "A" and the last name "Russo".

Marc Andrew Russo