UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AVANOS MEDICAL, INC.
Petitioner,

v.

STRATUS MEDICAL, LLC,
Patent Owner.

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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

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DECLARATION OF CODY JORGENSEN

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I, Cody Jorgensen, declare as follows:

I. INTRODUCTION

1. I am writing to provide information in connection with the above-identified *inter partes* reviews brought by Avanos Medical, Inc. (Avanos) against the following patents owned by Stratus Medical, LLC ("Stratus"): U.S. Patent Nos. 10,736,688; 10,925,664; and 10,966,782 (collectively, "Stratus Patents").

2. I have personal knowledge of the facts stated in this declaration.

3. I reserve the right to amend or supplement this declaration, as appropriate, if additional relevant information becomes available to me.

II. PERSONAL BACKGROUND AND ROLES AT STRATUS

4. I serve as the Director of Marketing for Stratus. I have been employed by Stratus for nearly six years, beginning in July 2019. I started as a Marketing Specialist and then progressed to roles as Marketing Manager and Senior Manager of Marketing. I have served as the Director of Marketing since January 2023.

5. Stratus began marketing its Nimbus® Multitined Expandable Electrode (Nimbus device) in the U.S. in 2020. I assisted with this U.S. marketing launch and have participated in marketing the Nimbus device since then.

6. I also have personally dealt with back pain from an accident. I have been treated with the Nimbus device in three RF neurotomy procedures and can personally attest that this product is highly effective.

III. STRATUS AND ITS NIMBUS DEVICE

7. Stratus is a medical device company focused on reducing pain and suffering and improving the quality of life for chronic pain patients through innovation. Stratus's foundational technology is the Nimbus device, which uses radiofrequency energy to ablate nerves that transmit pain.

8. The Nimbus device has an expandable, multi-tined end that creates a large and optimally shaped lesion for treating targeted nerves to provide reproducible and sustained pain relief.

9. The Nimbus device is used in combination with an RF generator and an RF probe. Stratus does not sell RF generators, but it does sell RF probes—both reusable and disposable versions—that are used with the Nimbus device.

10. The Nimbus device is easy to use, is compatible with a variety of RF neurotomy generators, lowers overall procedure cost for a hospital/treatment center, and has been validated in many independent clinical studies.

11. The packaging for the Nimbus device is marked with patent information, including the identification of a publicly accessible website at which each of the Stratus Patents is listed and associated with the Nimbus device.

12. The Nimbus device was developed and has always been manufactured in the United States, but initially was marketed almost exclusively in Australia by a small sales representative.

IV. COMMERCIAL SUCCESS OF THE NIMBUS PRODUCTS

13. Stratus has enjoyed remarkable commercial success with the Nimbus device.

14. [redacted] of Stratus's revenue is from sales of the Nimbus device and associated RF probes, so Stratus's success in the market is [redacted]. This applies to Stratus's successes in other areas as well, such as those discussed in Section VII below.

15. Stratus began marketing the Nimbus device in the U.S. in 2020. The chart below depicts Stratus's total U.S. revenue by quarter from 2020 through 2024. Despite having [redacted], Stratus has consistently achieved major year-over-year growth.

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Stratus's U.S. Revenue Since U.S. Launch of Nimbus Device

16. In contrast, the U.S. market in which Stratus competes, which I refer to as the "RFA cannula market," has had a compound annual growth rate of [redacted] over the same period (that is, since 2019). It is [redacted] market sized at about [redacted].

17. [redacted], who are among the top ten largest medical device companies in the world (*see* Ex. 2027 at 2), have historically [redacted]. Setting aside [redacted] for the moment, the diagram below depicts market shares of the remaining market participants from 2019 (the year before Stratus began marketing the Nimbus device in the U.S.) through 2024. It demonstrates that in this short period, Stratus—a startup minnow among legacy whales—[redacted]

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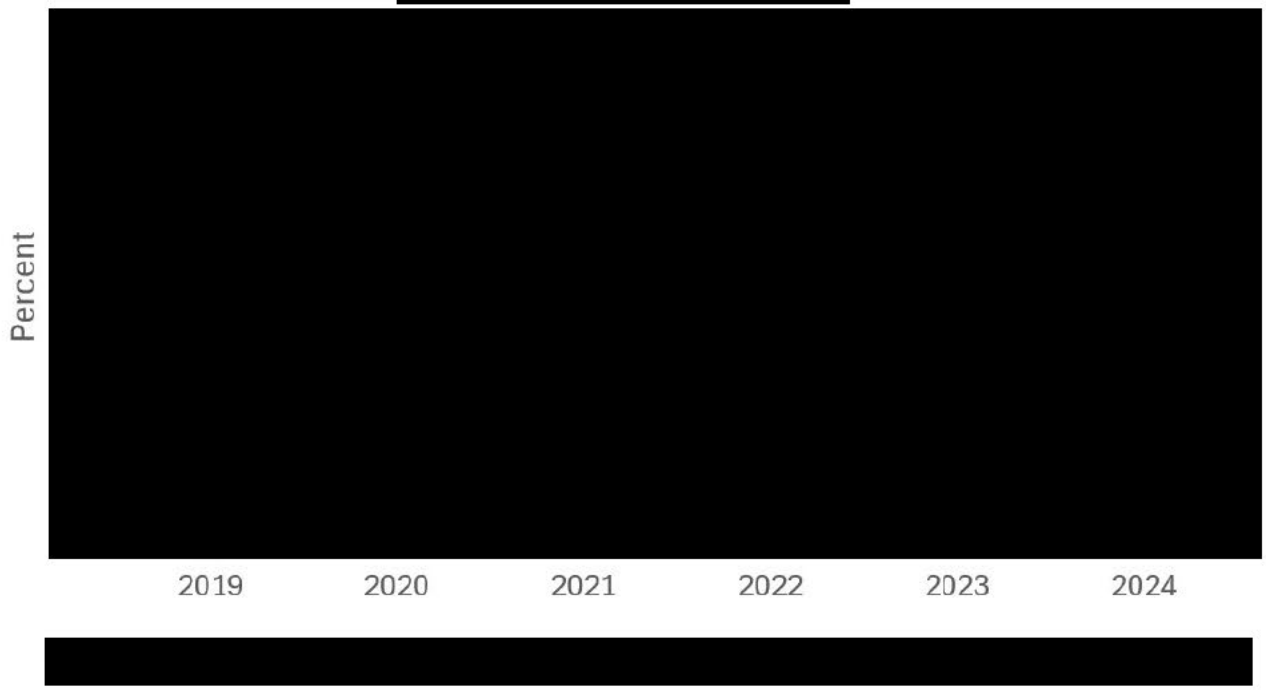
[redacted]. Stratus has [redacted] its share of the RFA cannula market to [redacted].

U.S. RFA Cannula Market

[redacted]



[redacted]

18. Note [redacted] over this same period.

19. The following chart shows side-by-side comparisons of the full U.S. RFA cannula market, including [redacted], as it existed in 2020 and 2024. The size of each company's salesforce is provided at the bottom of the chart.

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U.S. RFA Cannula Market: 2020 vs. 2024

20. The above chart provides a better understanding of the uneven playing field on which Stratus is competing. In the 5-year timespan depicted, Stratus went from [redacted] in its first year to having [redacted], and it did so with [redacted]. In contrast, every other significant market participant has had [redacted]

21. As [redacted] have historically had [redacted] in the U.S. RFA cannula market, the foregoing chart somewhat obscures [redacted]. The following chart provides a better view of company performance. The chart

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shows the compounded annual growth rates (CAGR) of U.S. RFA cannula market participants from 2020 through 2024. Compounded annual growth rates demonstrate growth rates over a set period in a way that helps smooth the effects of year-to-year fluctuations.

CAGR of U.S. RFA Cannula Market Participants
2020 through 2024

[redacted]

22. With a [redacted], Stratus is [redacted]. While Stryker and Abbott still have the dominant share of the relevant market, their growth rates are [redacted]. They

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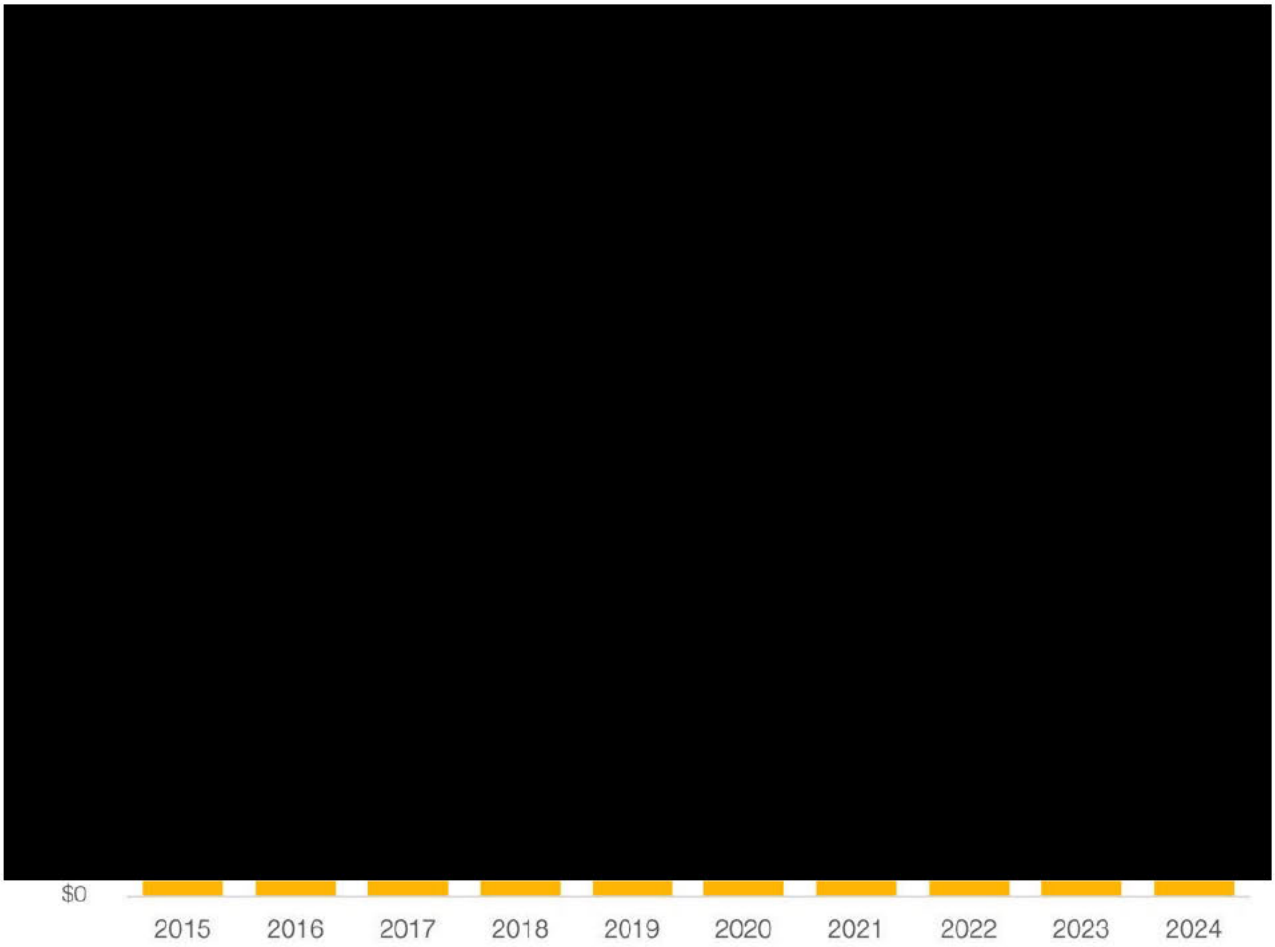
may have had an [redacted], but Stratus is [redacted].

23. Note [redacted] as compared with Stratus's [redacted].

24. The chart below provides another view of Stratus's [redacted]. This chart depicts year-by-year snapshots of the U.S. RFA cannula market, as divided among market participants.

U.S. RFA Cannula Market



25. In the five years preceding Stratus's entrance into this market (from 2015 through 2019), there was [redacted] of the U.S. RFA cannula market. The market disturbance from the advent of Covid-19 is apparent in the 2020 data, while Stratus's entrance into the market that same year [redacted]. Thereafter, [redacted].

26. Note [redacted] in the five years before Stratus entered this market as compared with [redacted].

27. The cannula is considered a consumable item. However, the cannula is used with a power generator, which is a type of capital equipment. [redacted] are often used by some of the medical device companies that involve [redacted]. Such an approach is [redacted] in the RFA cannula market because they [redacted]. Because so many entities are [redacted], this system [redacted] in certain segments of the market. These factors enable [redacted]

[redacted].

V. COPYING

28. As I have noted above, the Nimbus device was developed in the United States.

29. As part of that development process, approval to market the device in the United States was obtained from the U.S. Food and Drug Administration (FDA).

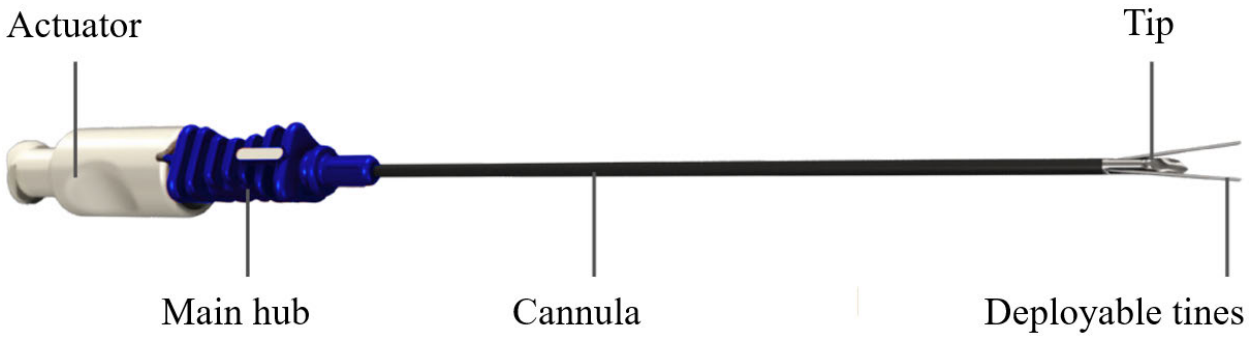
30. Although the Nimbus device was cleared for marketing in the U.S., the Nimbus device was initially marketed almost exclusively in Australia.

31. Just a few years after the Nimbus device entered the RF neurotomy market, a company called Diros Technology Inc. (Diros) attempted to introduce into Australia a line of products that copied the Nimbus device. I address that matter in the following section.

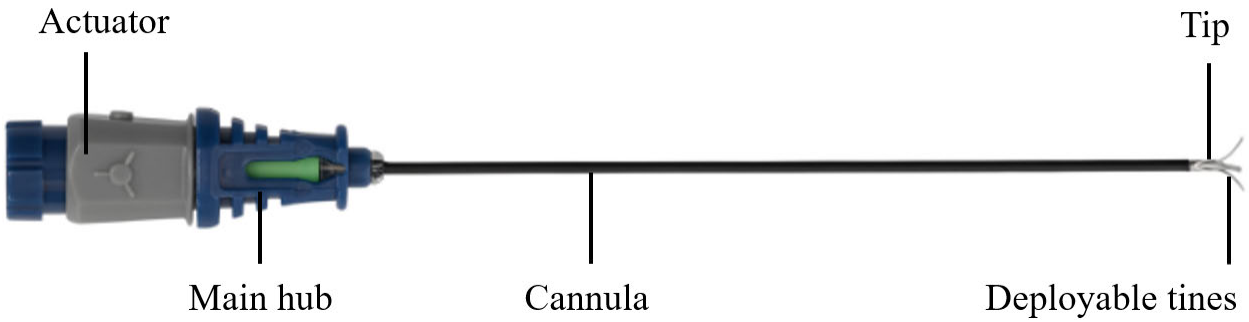
32. The copied products are known as Trident™ (the "Trident device") and Trident™ Hybrid (the "Trident Hybrid device," collectively with the Trident device, the "Trident devices"). It is sufficient for my present discussion to focus primarily on the Trident device.

33. I provide below images of the Nimbus device and the Trident device, from which the similarities are clear.

Nimbus Device



Trident Device



34. Like the Nimbus device, the Trident device has a cannula, a tip for piercing tissue of a patient, deployable tines that extend past a distal end of the tip, a main hub attached to the cannula, and a rotatable actuator that rotates relative to the main hub to deploy and retract the tines.

35. Similarly, both the Nimbus device and the Trident device are operable with a removable RF probe, which is inserted into the cannula and provides RF energy to the tip and tines.

36. Like the Nimbus device, the Trident device is used for RF neurotomy.

37. The Nimbus and Trident devices are marketed and sold to the same consumers and target consumers, which are hospitals, clinics, doctors' offices, and the like in which interventional pain specialists perform RF neurotomy procedures on patients.

38. By way of background, to have the FDA approve a new medical device for commercialization in the U.S., there is a process known as a 510(k) Premarket Notification. In this process, a company compares (a) the medical device that it wishes to market to (b) one or more devices that have already been approved by the FDA. If the company can convince the FDA that the devices are "substantially equivalent," the FDA approves the new device. In this process, a previously approved device is known as a "predicate device."

39. When Diros sought FDA approval of its Trident devices, Diros used the Nimbus device as one of its predicate devices. Ex. 2019 at 4, 8.

40. Diros asserted to the FDA that the Trident devices "have an expandable tip, equivalent to NIMBUS [*i.e.*, the Nimbus device]." *Id.* at 8. Diros further indicated that the "size of the lesion is comparable to that . . . created by NIMBUS device when 17Ga 10mm devices are compared." *Id.* at 9.

41. The only potential difference Diros noted between the Trident devices and Nimbus device was the material of which the tines are formed, and this is because Diros did not know what material is used for the Nimbus device's tines. *See id.* at 8.

42. The FDA agreed that the Trident devices are "substantially equivalent . . . [to the] predicate devices," including the Nimbus device, and ultimately granted clearance to the Trident devices. *Id.* at 1.

VI. AVANOS'S ACQUISITION OF THE TRIDENT DEVICES

43. Stratus pursued a patent infringement lawsuit against Diros in Australia that was based on Diros's marketing of its Trident devices in Australia, and Diros alleged in the same lawsuit that Stratus's Australian patents were invalid for being obvious over a combination of prior art references.

44. In late 2021, that litigation settled on confidential terms that I largely do not know and, in any event, would not divulge.

45. I understand that the Trident devices have not been available in Australia since that litigation settled.

46. I also understand that Stratus's Australian patents remain in force.

47. As regards [redacted] I refer to my previous notes regarding [redacted] the U.S. RFA cannula market since the time Stratus began selling the Nimbus device in the U.S.

48. Avanos sells a product called COOLIEF* that provides large-volume lesions similar in volume to those created by the Nimbus device. COOLIEF* uses Cooled Radiofrequency (Cooled RF) technology, in which fluid circulates through an

electrode to cool the region around an exposed tip during ablation to enable larger lesions, which has some significant disadvantages relative to the Nimbus device. For example, Cooled RF requires expensive capital equipment that includes a specialized pump for circulating fluid through an electrode. COOLIEF* requires longer procedure times and has higher procedure costs, as compared with the Nimbus device.

49. Accordingly, since it first began marketing the Nimbus device in the U.S., Stratus has seen [redacted].

50. On June 30, 2023, Avanos announced that it had entered into a definitive agreement to acquire Diros and touted that the "addition of Diros' unique RF Trident™ technology is expected to further enhance Avanos' pain management treatment options and complement its premium COOLIEF* Cooled Radiofrequency product offering." Ex. 2029 at 1.

51. Avanos completed the acquisition of Diros on July 24, 2023. Ex. 2030 at 1.

52. Avanos filed the present IPRs against Stratus's Patents on July 26, 2024.

VII. PRAISE FOR THE NIMBUS PRODUCTS

53. Stratus and its Nimbus device have received awards and accolades for its innovation and effectiveness.

54. Stratus Medical was recognized as one of the fastest-growing companies in North America on the Deloitte Technology Fast 500™, a ranking of the 500 fastest-growing technology, media, telecommunications, life sciences, fintech, and energy tech companies in North America. *See* Ex. 2025. Stratus Medical grew 212% during the three-year period evaluated. The growth is attributable to physician adoption of the Nimbus device that has been driven by its predictable and durable pain relief, faster procedure times, and lower cost.

55. Stratus Medical was also recognized as one of the 2024 Pepperdine Graziadio Most Fundable Companies. *See* Ex. 2026. More than 2,000 early-stage US startups from across all 50 states vied to be one of the 18 companies honored to be included on the list. The winners were chosen based on several company variables including financial projections, market opportunity, intellectual property, competitive advantage, and management-team expertise.

VIII. CERTIFICATION

56. In signing this declaration, I recognize that this declaration will be filed in support of Stratus in IPR2024-01209, IPR2024-01210, IPR2024-01211, and IPR2024-01212 at the U.S. Patent and Trademark Office.

57. I reserve the right to supplement my opinions in the future to respond to any arguments that Avanos Medical raises and to consider new information as it becomes available to me.

58. I acknowledge that, as part of these IPRs, I may be subject to cross-examination in the United States regarding the content of this declaration. If cross-examination is required of me, I will make myself reasonably available for cross-examination within the United States during the time allotted for cross-examination

59. 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 and, further, that these statements were made with the knowledge that willful false statements and the like are punishable by fine, imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity and/or enforceability of the patents in the reviews.

Dated: May 22, 2025

Respectfully submitted,

Cody Jorgensen