

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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Case IPR2024-01209  
Patent 10,966,782

Case IPR2024-01210  
Patent 10,736,688

Case IPR2024-01211  
Patent 10,736,688

Case IPR2024-01212  
Patent 10,952,664

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**REPLY DECLARATION OF DR. ROBERT TUCKER**

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## **I. INTRODUCTION**

1. I have been asked to review and respond to certain issues raised in the Institution Decision, Patent Owner's Response(s), and the declarations of Stratus's supporting witnesses in case numbers IPR2024-01209, IPR2024-01210, IPR2024-01211, and IPR2024-01212. With respect to the issues addressed herein, I am providing one Reply declaration to address all four IPR matters.

2. I continue to be compensated at the rate of \$700/hour for my work in this proceeding. My compensation does not depend on the outcome of this proceeding.

## **II. MATERIALS CONSIDERED.**

3. In forming my opinions expressed in this declaration, I have reviewed and considered the additional documents identified in the list below, each of which were provided to me by counsel for Avanos at Meunier Carlin & Curfman LLC. In forming my opinions, I have also relied on my education, experience, and the materials I identified in my original declarations.

| <b>Exhibit No.</b> | <b>Description</b>                                               |
|--------------------|------------------------------------------------------------------|
| n/a                | Institution Decision, Case IPR2024-01209, Paper 8 (Feb. 6, 2025) |
| n/a                | Institution Decision, Case IPR2024-01210, Paper 9 (Feb. 6, 2025) |
| n/a                | Institution Decision, Case IPR2024-01211, Paper 9 (Feb. 6, 2025) |
| n/a                | Institution Decision, Case IPR2024-01212, Paper 8 (Feb. 6, 2025) |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                        |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| n/a                | Patent Owner's Response, Case IPR2024-01209, Paper 13 (May 23, 2025)                                                                      |
| n/a                | Patent Owner's Response, Case IPR2024-01210, Paper 15 (May 23, 2025)                                                                      |
| n/a                | Patent Owner's Response, Case IPR2024-01211, Paper 15 (May 23, 2025)                                                                      |
| n/a                | Patent Owner's Response, Case IPR2024-01212, Paper 13 (May 23, 2025)                                                                      |
| 2001               | Declaration of Prof. Marc Andrew Russo                                                                                                    |
| 2006               | Declaration of Peter Crosby                                                                                                               |
| 2015               | Declaration of Cody Jorgensen                                                                                                             |
| 2019               | FDA 510(k) Approval No. K150371, <i>Diros OWL Sterile Single Use Trident™ R.F. Insulated Cannulae Models DTR and DTRH</i> (Jul. 30, 2015) |
| 1064               | FDA 510(k) Approval No. K190259, <i>Vesta RF Cannula</i> (Feb. 7, 2020)                                                                   |

### III. LEVEL OF SKILL IN THE ART

#### A. The Board's comment regarding "at least" in the level of skill definition.

4. In my first declarations (Exs-1031, 1032, 1033, and 1034), I opined that a person having ordinary skill in the art ("POSA") would have "at least (i) a bachelor's degree in biomedical engineering, or a related field, such as mechanical engineering, biomechanical engineering, or bioengineering, who also has at least 3 years of experience with thermal ablation system and methods; or (ii) an advanced

degree in the same areas of academic study with at least 1 years of experience with thermal ablation systems and methods.” *See e.g.*, Ex-1031, ¶105.

5. In my review of the Institution Decisions, I noted that the Patent Trial and Appeal Board indicated that “Petitioner’s open-ended language ‘at least’ expands the ranges of education and experience indefinitely with no upper bound, thereby encompassing those of extraordinary skill. Therefore, we do not adopt this aspect of Petitioner’s formulation.” *See e.g.*, Institution Decision, Case IPR2024-01209, Paper 8 at 12.

6. In response to this comment from the Board, I would like to clarify that in forming the opinions expressed in my first declarations for these IPRs, I considered the perspective of POSA having the *minimum* amounts of experience included in my opinion about the level of skill in the art. In other words, in forming my opinions, I assumed that the POSA had either (i) a bachelor’s degree in biomedical engineering, or a related field, such as mechanical engineering, biomechanical engineering, or bioengineering with *3 years* of experience with thermal ablation system and methods, or (ii) an advanced degree in the same areas of academic study with *1 year* of experience with thermal ablation systems and methods.

7. For this reason, if the Board were to remove the word “at least” from the level of skill that I articulated in my original declarations, none of the opinions

I expressed in those declarations would change, and I hereby reaffirm my opinions under the Board’s revised definition (with “at least” removed).

**B. Stratus’s definition of the level of skill.**

8. I also note that Stratus, and its witnesses Mr. Crosby and Prof. Russo, have proposed a different definition of the level of skill in the art. Although I disagree with this definition, it would not change any of the opinions I have previously expressed in my first declarations (Exs-1031, 1032, 1033, and 1034).

9. Stratus proposes that a POSA should have “a combination of (1) an interventional pain-specialist physician with significant experience performing RF neurotomy procedures and (2) an engineer with a degree in biomedical engineering or a related field and experience in the design and development of devices and methods for applying electromagnetic energy to nerves. The POSITA should have either a bachelor-level degree with three years of the design/development experience noted above or an advanced degree with one year of the design/development experience noted above. Such a POSITA could be a team of two or more people working together.” *See* Patent Owner’s Response, Case IPR2024-01209, Paper 13 at 30 (May 23, 2025) (herein “POR”). Stratus also indicates “that the appropriate clinical experience performing RF neurotomy is three months.”

10. As an initial matter, I disagree that experience as “an interventional pain-specialist physician with significant experience performing RF neurotomy procedures” is necessary with respect to the subject matter of the Stratus patents. In particular, I meet Stratus’s engineer definition (item (2)), and I did not find it challenging to understand the patents, the prior art, or any other evidence at issue in these proceedings.

11. Regardless, I have again considered all of the testimony provided in my first declarations under Stratus’s definition of the level of skill and hereby reaffirm that none of my opinions would change under this definition of the level of the skill.

#### **IV. RESPONSE TO ALLEGATIONS OF COPYING.**

12. In his declaration, Cody Jorgensen asserts that the Diros Trident™ and Trident™ Hybrid products “copied the Nimbus device.” Ex-2015, ¶¶31-32. Stratus repeats this assertion in its Patent Owner Response. POR at 66-67.

13. Counsel for Avanos asked me to consider these allegations of copying and provide my opinions. To form my opinions, I was provided physical samples of Diros Trident™ and Stratus Nimbus® products, and I physically inspected those products. The specific physical products I inspected and considered are: **(A)** the Stratus Nimbus® Cannula (Ref: NIM-150-10BB) and the Stratus Nimbus® Disposable RF Thermocouple Electrode (Ref: NDP-150-27-SS) (together, the

“Stratus Nimbus®”); and **(B)** the Diros Trident™ RF Insulated Cannula (Ref: DTR-018/100/5) and Diros Owl RF Probe/Temperature Sensor (Ref: D467-010-TC) (together, the “Diros Trident™”).

14. I asked counsel for Avanos to take photos of the packaging for each product that was provided to me for inspection. Photos of the packaging for the products I received and inspected are shown below.

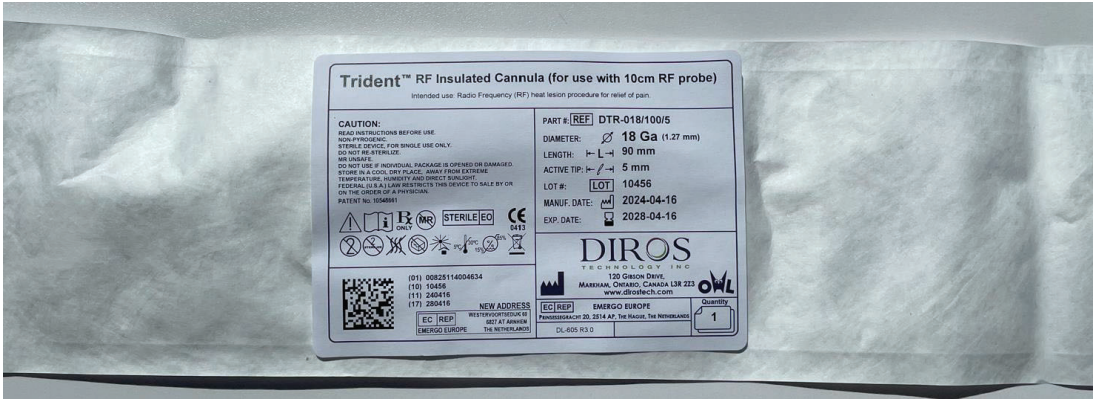


*Stratus Nimbus® Cannula (Ref: NIM-150-10BB)*

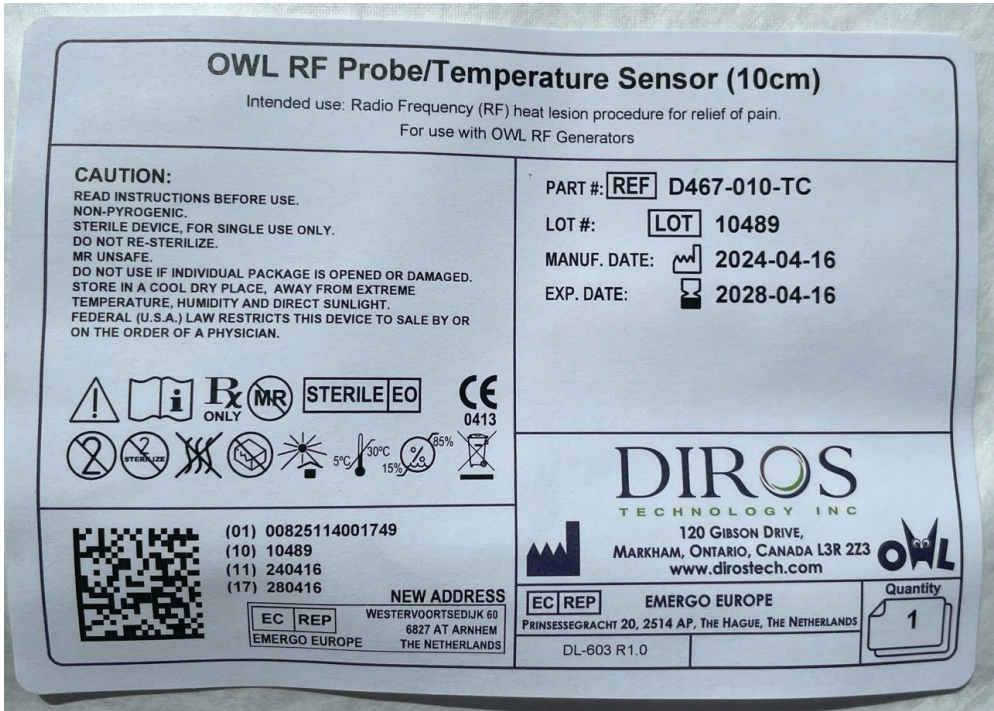


*Stratus Nimbus® Disposable RF Thermocouple Electrode (Ref: NDP-150-27-SS)*

Avanos Exhibit 1042  
Avanos v. Stratus



*Diros Trident™ RF Insulated Cannula (Ref: DTR-018/100/5)*



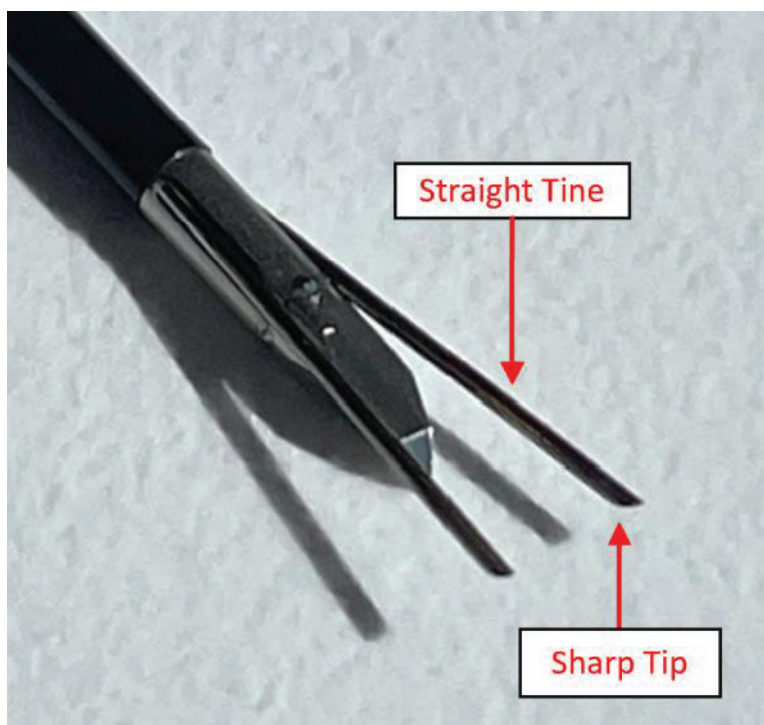
*Diros Owl® RF Probe/Temperature Sensor (Ref: D467-010-TC)*

15. I inspected the physical samples of the Stratus Nimbus® and the Diros Trident™ that were enclosed within the packaging shown above. For the purpose of preparing this report, I also asked counsel to take a series of pictures of the Stratus Nimbus® and Diros Trident™ products that I physically inspected. The

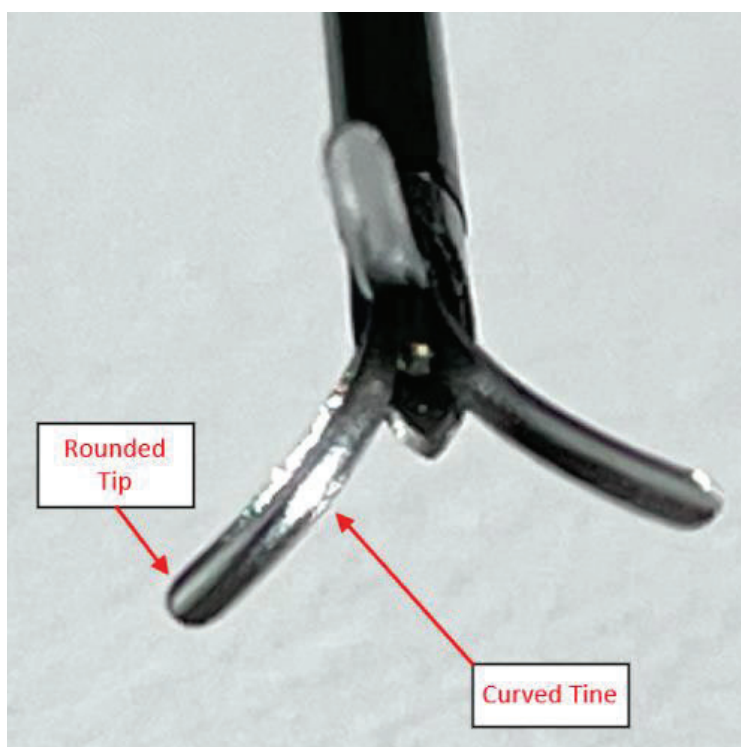
photos of the Diros Trident™ and Stratus Nimbus® in this section are fair and accurate representations of the Stratus Nimbus® and Diros Trident™ products that I personally inspected for preparing this report. The annotations to the drawings are indicated with red text and arrows and were made, at my direction, by counsel.

16. Based on my inspection of the Stratus Nimbus® and Diros Trident™, it is my opinion that the Diros Trident™ does not duplicate or replicate the Stratus Nimbus® and is not a “copy” of the Stratus Nimbus® as Stratus and Mr. Jorgensen suggest. I base this conclusion on numerous differences that I observed in inspecting the physical products. In my opinion, these differences, which are only examples and not intended to be an exhaustive list, show that the Diros Trident™ is not a copy of the Stratus Nimbus®.

17. **Different Tine Shape & Tine Tip Profile:** When deployed from the needle, the Stratus Nimbus® tines are straight. I also noticed that the Stratus Nimbus® tines have pointed tips. By contrast, when the Diros Trident™ tines are deployed, the tines assume a curved shape. The Diros Trident™ tines also appear to have tips that are not pointed and are more rounded than the Stratus Nimbus® tines.



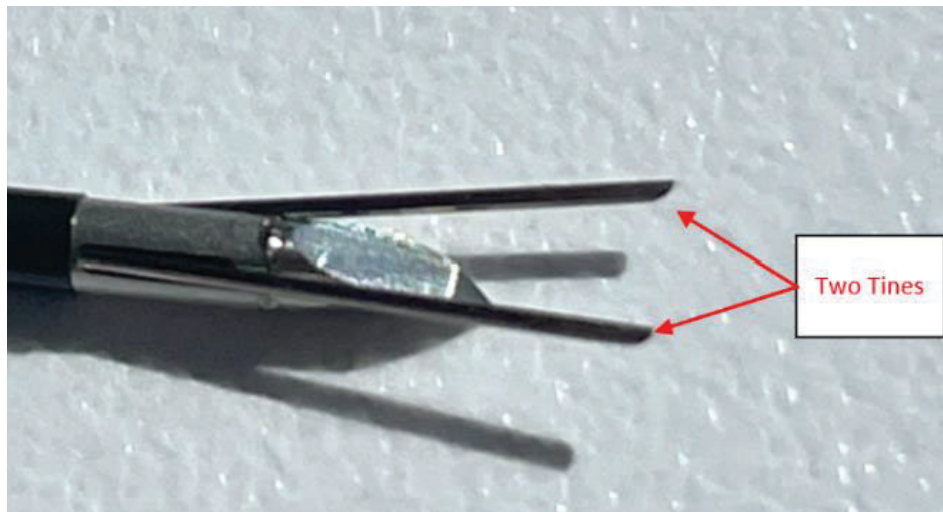
*Stratus Nimbus® Tines (Deployed)*



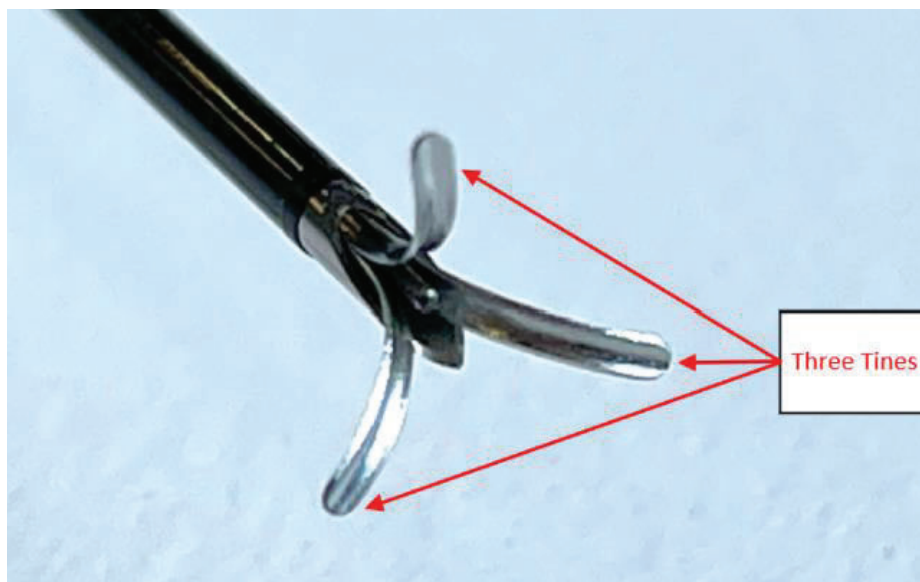
*Diros Trident™ Tines (Deployed)*

18. **Different Material:** According to FDA 510(k) filings by Stratus, my understanding is that the Stratus Nimbus® tines are made of stainless steel. Ex-1064, page 8 (indicating materials for Nimbus® include “Tines: Stainless Steel”). By contrast, the Diros Trident™ tines assume a curved shape, such that I expected that they were formed from a shape memory alloy. The FDA 510(k) approval for the Diros Trident™ indicates that this is correct: the Diros Trident™ uses tines made from Nitinol, which is a well-known shape memory alloy, unlike stainless steel. Ex-2019, page 7.

19. **Different Number of Tines:** The Stratus Nimbus® has two deployable tines. By contrast, the Diros Trident™ has three deployable tines.



***Stratus Nimbus® Tines – Annotated***

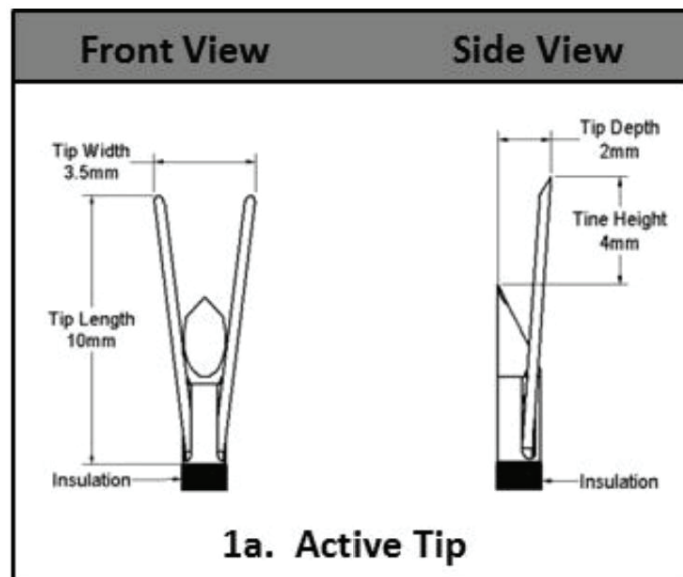


***Diros Trident™ Tines – Annotated***

20. **Different Arrangement of Deployed Tines:** The two tines of the Stratus Nimbus® are bilaterally symmetrical. The Stratus Nimbus® tines are symmetrical along one plane (e.g., the front view, shown below), but not along other planes (e.g., the side view shown below). In other words, the Stratus Nimbus® has no tines on one “side” of the needle. By contrast, the three tines of the Diros Trident™ are *rotationally* symmetrical. That is, each of the three Diros Trident™ tines is offset from the others by about 120 degrees, and each extends approximately the same distance from the longitudinal axis of the cannula. In other words, rotating the Diros Trident™ 120 degrees results in the same pattern of tines.

21. To show the difference in the arrangement of the deployed tines, I have provided below an illustration from the Stratus Nimbus® Instructions For

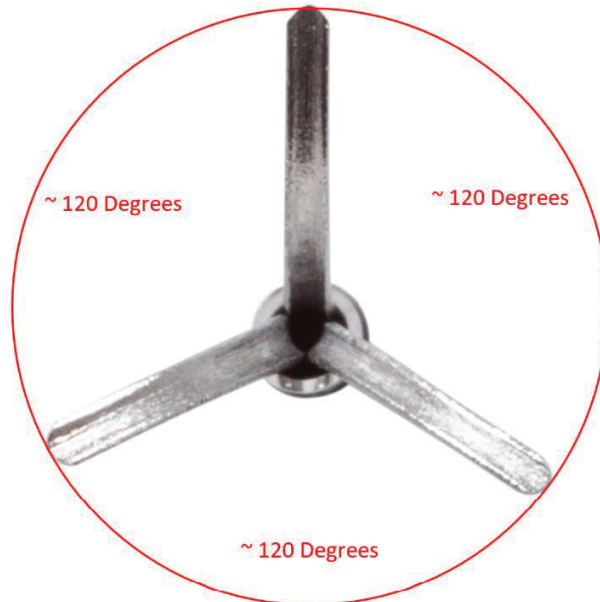
Use (IFU) obtained from Stratus's website.<sup>1</sup> While I rely on my physical inspection of the product, the IFU image below is a fair and accurate representation of the physical layout of the tines on the Stratus Nimbus® that I physically inspected. I also provide a photo from the Diros website showing the Diros Trident™ viewed *down the central axis* of the cannula.<sup>2</sup> Again, while I rely on my physical inspection of the product, this photo from the Diros website is also a fair and accurate representation of the Diros Trident™ device that I personally inspected. The images below illustrate the different arrangement of the tines and different kinds of symmetry they present.



<sup>1</sup> <https://stratusmedical.com/wp-content/uploads/2024/07/Nimbus-14x8-Layout-Rev-J-Digital-1.pdf>

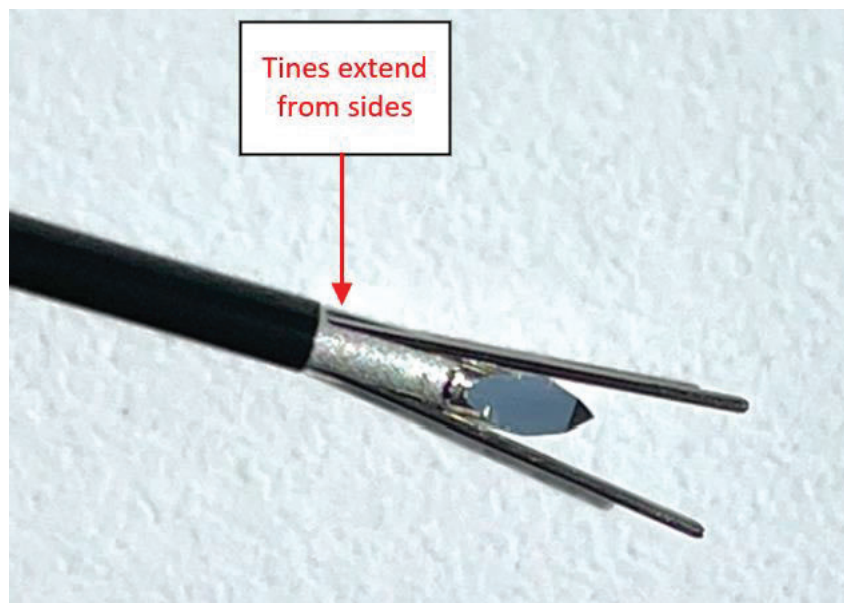
<sup>2</sup> <https://www.dirostech.com/product-details/rf-tridenttrident-hybrid-cannulae/>

### ***Stratus Nimbus® Tine Arrangement***

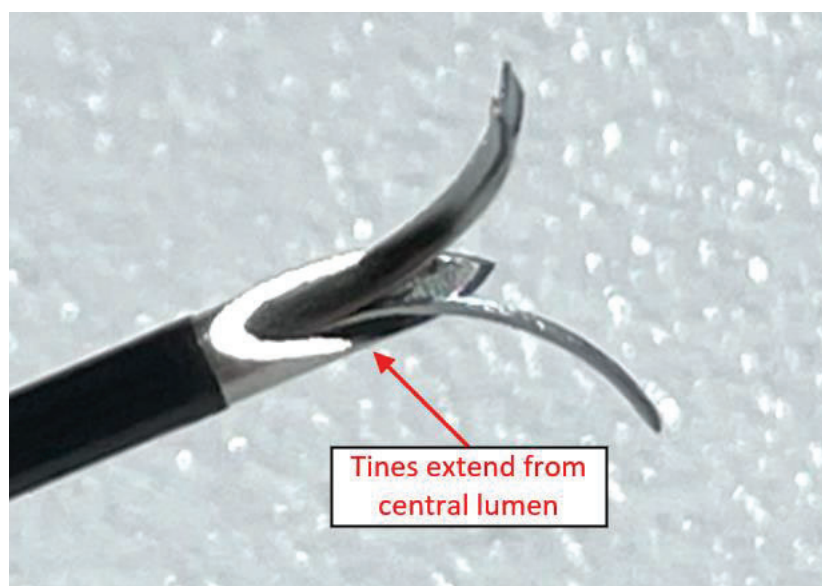


### ***Diros Trident™ Tine Arrangement***

22. ***Different Deployment Location:*** The Stratus Nimbus® and Diros Trident™ also deploy their tines from different parts of their respective devices. As shown below, the Stratus Nimbus® cannula has a closed tip, so the Stratus Nimbus® tines are deployed from channels positioned behind the device's distal tip. By contrast, the Diros Trident™ has an open tip and deploys the tines *directly from* the open tip and out of the device's central lumen.



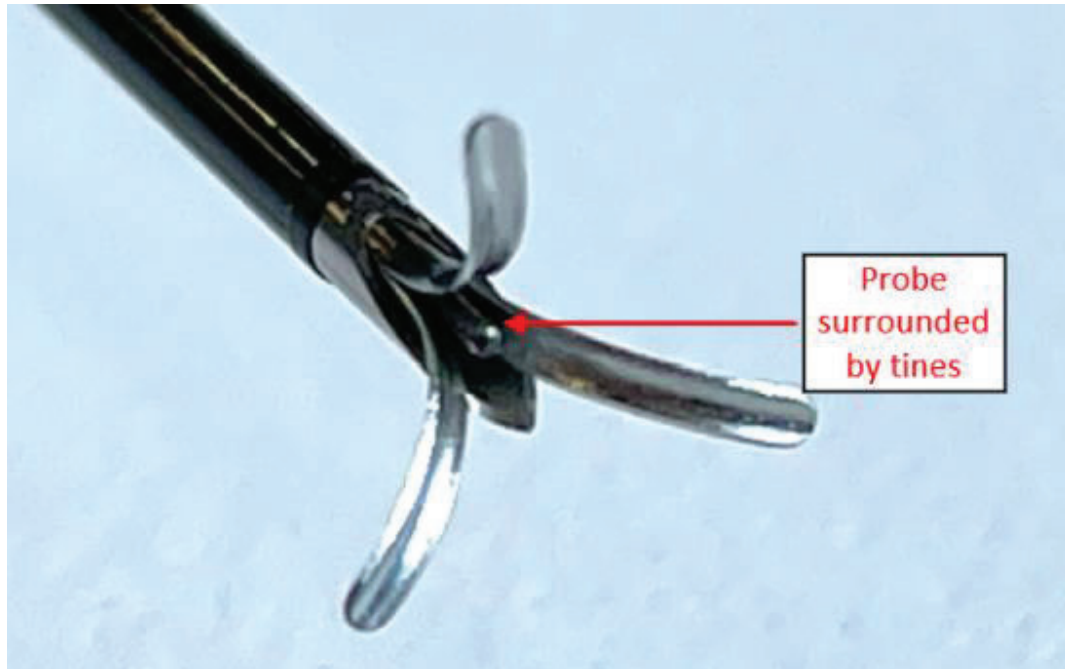
*Stratus Nimbus® Deployment Location*



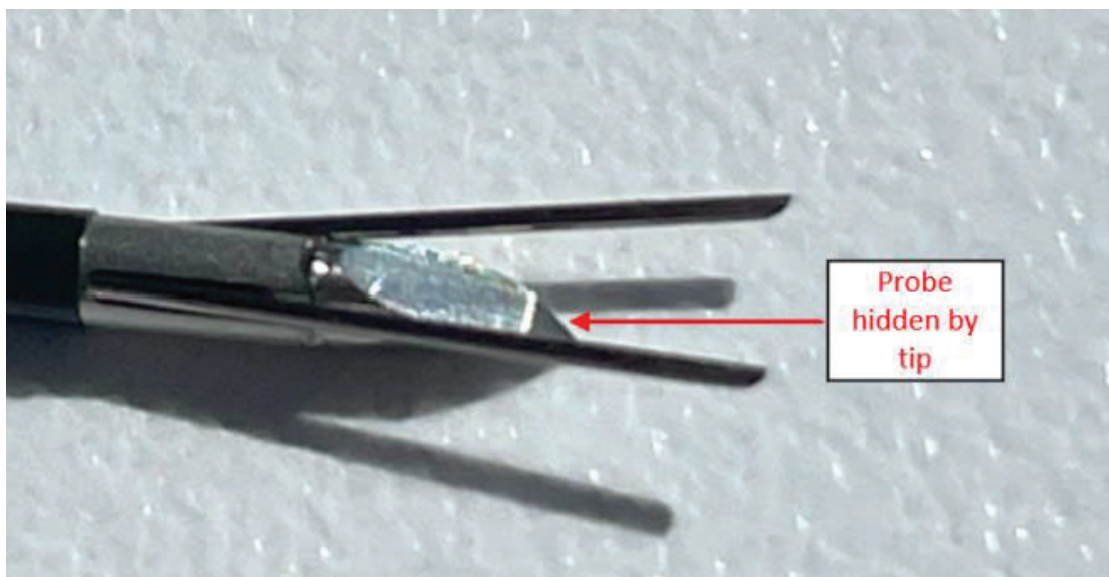
*Diros Trident™ Deployment Location*

23. ***Different Probe Connection:*** The Stratus Nimbus® probe is removable and inserted into the tip of the needle. By contrast, the Diros Trident™ has a removable probe that—when inserted—is surrounded by the tines and does

not touch the needle's tip. And unlike the Stratus Nimbus®, the probe's tip is exposed via the central lumen as can be seen below.



*Diros Trident™ Tip*



*Stratus Nimbus® Tip*

24. I am aware that Diros sells another RF cannula named the “RF Trident™ Hybrid Cannulae” (the “Diros Trident™ Hybrid”). The Diros Trident™ Hybrid has the same deployable tine arrangement as the Diros Trident™, so all my observations with respect to the tines, their material, their arrangement, and their deployment apply equally to the Diros Trident™ Hybrid.<sup>3</sup> Additionally, the Diros Trident™ Hybrid lacks a removable probe, as shown and explained on Diros’s website. *See* POR, page 14 (agreeing that the Diros Trident™ Hybrid’s probe is not removable). The lack of a removable probe further differentiates the Diros Trident™ Hybrid from the Stratus Nimbus®.

25. For all the foregoing reasons, it is my opinion that the Diros Trident™ and the Diros Trident™ Hybrid do not replicate the Stratus Nimbus®. While each product uses the general idea of deployable filaments to expand ablation volume, and they have some features common to *all* RF neurotomy needles (including conventional, non-tined needles), they have substantially different configurations. As I have explained, the Diros Trident™ includes numerous features making it significantly different from the Stratus Nimbus® and certainly not a “copy.”

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<sup>3</sup> *See* <https://www.dirostech.com/product-details/rf-trident-hybrid-cannulae>

## V. CONCLUSION

26. I declare that all statements made herein on 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 so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code

Executed on: September 5, 2025

Signature: 

By: Dr. Robert Tucker