UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

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Case IPR2024-01257
Patent No. 11,744,691

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**EXPERT DECLARATION OF AQUILLA S. TURK, III, D.O.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,744,691**

IMPERATIVE Ex. 1022
IPR Petition - US 11,744,691

## TABLE OF CONTENTS

**Page No.**


I. INTRODUCTION ..... 1

A. Engagement ..... 1

B. Experience and Qualifications ..... 2

II. INARI'S EFFORT TO DISTINGUISH NEUROVASCULAR TREATMENTS FROM DVT AND PE ..... 7

III. THE PROCEDURE FOR ASPIRATING BLOOD CLOTS FROM THE BRAIN IS NOT "SIGNIFICANTLY DIFFERENT" FROM ASPIRATING CLOTS FROM THE LUNGS OR LEGS ..... 9

IV. CATHETER DEVELOPERS ROUTINELY ADAPT CATHETERS FOR USE IN OTHER PARTS OF THE VASCULATURE ..... 12

V. BLOOD CLOTS VARY, AS DO THE CATHETERS USED TO TREAT THEM ..... 17

## TABLE OF EXHIBITS

| Exhibit No. | Description |
|---|---|
| 1001 | U.S. Patent No. 11,744,691 ("the '691 patent") |
| 1002 | '691 Patent Prosecution History |
| 1003 | Expert Declaration of Troy Thornton |
| 1004 | Resume of Troy Thornton |
| 1005 | U.S. Patent No. 8,734,374 B2 to Aklog et al. ("Aklog") |
| 1006 | U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. ("Garrison") |
| 1007 | WIPO Publication No. WO 2006/124307 to Goff et al. ("Goff") |
| 1008 | U.S. Patent Publication No. 2003/0116731 A1 to Hartley ("Hartley") |
| 1009 | U.S. Patent No. 6,776,770 B2 to Treretola ("Treretola") |
| 1010 | U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al. |
| 1011 | U.S. Patent No. 8,535,283 B2 to Heaton et al. ("Heaton") |
| 1012 | U.S. Patent Publication No. 2005/0004534 A1 to Lockwood et al. ("Lockwood") |
| 1013 | U.S Patent Publication No. 2015/0352325 A1 to Quick et al. ("Quick") |
| 1014 | U.S. Patent No. 5,938,645 to Gordon |
| 1015 | U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al. |
| 1016 | U.S. Patent No. 7,998,104 B2 to Chang ("Chang") |
| 1017 | U.S. Patent No. 8,157,760 B2 to Criado et al. ("Criado") |
| 1018 | U.S. Patent No. 6,481,439 B1 to Lewis et al. |

| Exhibit No. | Description |
|---|---|
| 1019 | U.S. Patent No. 8,075,510 B2 to Aklog et al. |
| 1020 | WIPO Publication No. WO 2018/019829 A1 to Brady et al. ("Brady") |
| 1021 | U.S. Patent Application No. 16/117,519 (the "519 application") |
| 1022 | Expert Declaration of Dr. Aquilla S. Turk, III, DO |
| 1023 | Resume of Dr. Aquilla Turk, III, D.O. |
| 1024 | Shani, Jacob M.D., et al., Mechanical Manipulation of Thrombus: Coronary Thrombectomy, Intracoronary Clot Displacement, and Transcatheter Aspiration, 72 Am. J. Cardiol. 116G-118G (1993) |
| 1025 | Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008) |
| 1026 | Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014) |
| 1027 | Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014) |
| 1028 | April 24, 2024 Letter from Inari to Imperative Care |
| 1029 | Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label, blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019) |
| 1030 | Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005). |

I, Dr. Aquilla S. Turk, III, do hereby declare:

# I. INTRODUCTION

## A. Engagement

1. I am a practicing interventional neuroradiologist at the Prisma Health-Upstate Southeastern Neurological and Spine Institute. I am also the Chief Medical Officer of Imperative Care, Inc. (hereinafter referred to as "Imperative Care" or "Petitioner"). I have been asked to provide my expertise regarding the aspiration of blood clots from the vasculature based on my extensive experience treating such conditions. I understand that this declaration will be submitted as part of an *inter partes* review petition filed by Imperative Care before the United States Patent and Trademark Office. I understand that the *inter partes* review petition will challenge the patentability of one or more patents owned by Inari Medical, Inc. ("Inari" or "Patent Owner").

2. I reserve the right to supplement, change, clarify, or modify my opinions should additional information and/or documentation become available to me. I also reserve the right to submit a rebuttal declaration in response to any declaration(s) submitted on behalf of the Inari.

3. I have a pre-existing relationship with Imperative Care to serve as the company's Chief Medical Officer. My compensation in no way depends upon the

substance of my testimony in this declaration or the outcome of this or any other *inter partes* review proceeding.

## B. Experience and Qualifications

4. My experience and qualifications are summarized in my *curriculum vitae*, a copy of which is included as Exhibit 1023.

5. At the Prisma Health-Upstate Southeastern Neurological and Spine Institute, I specialize in neuroendovascular surgery to treat patients suffering from complications and symptoms associated with stroke. One of the procedures I perform is mechanical thrombectomy (i.e., physical removal of clots from blood vessels), and specifically mechanical thrombectomy using aspiration systems that remove blood clots with suction. I am very familiar with, and have personally used, nearly all the commercially available mechanical thrombectomy devices on the market including devices made and sold by Penumbra and Imperative Care.

6. I obtained a Bachelor of Science in microbiology from the University of Florida. I then obtained my medical degree in osteopathic medicine from Nova Southeastern University in southern Florida. After obtaining my medical degree, I completed my first year of residency in radiology at The Cleveland Clinic Foundation, Department of Diagnostic Radiology. I subsequently completed my residency in diagnostic radiology at the University of Wisconsin Hospital and Clinics. I then served as an accredited fellow for an additional year in

neuroradiology and an unaccredited year in neurointerventional surgery at the University of Wisconsin Hospital and Clinics. After completing my fellowship, I became an Instructor at the University of Wisconsin Hospital and Clinics. I was later elevated to an Assistant Professor and an Associate Professor.

7. I next served as the Director of Neurointerventional Surgery at the Medical University of South Carolina, a position I held from 2007-2018. I also served as a professor at the medical school during this time. During my time as Director, the Medical University of South Carolina was one of the busiest neurointerventional surgery centers in the country and we built the department from myself to include four other neurointerventional surgeons.

8. In 2018, I became the Chief Medical Officer of Corindus Vascular Robotics. Corindus developed the CorPath robotic system for endovascular coronary and peripheral vascular interventions. The system helps physicians to precisely control guide catheters, guidewires, balloon or stent implants via integrated imaging. During my time as the Chief Medical Officer, Siemens Healthineers acquired Corindus for approximately $1.1 billion.

9. In 2018, I also became the Chief Medical Officer at Imperative Care, Inc. In my role as Chief Medical Officer, I provided input on product performance from the surgeon's perspective and helped support the development and launch of Imperative Care's products.

10. I have authored several book chapters relating to endovascular procedures, several of which specifically address mechanical thrombectomy, including "Direct Aspiration thrombectomy for acute stroke: Evolution of technique and evidence" in *Management of Ischemic Stroke in 21 Century,* and "Thrombectomy Techniques: A direct aspiration first pass technique (ADAPT) in *Acute Ischemic Stroke – A Case-based Guide to Management.* I have also co-authored well over 100 journal articles, many of which relate to mechanical aspiration thrombectomy. One of those articles, "ADAPT FAST Study: a direct aspiration first pass technique for acute stroke thrombectomy" (Ex. 1027), was selected as one of the best articles published in 2014 in the Journal of Neurointerventional Surgery. *See JNIS,* Vol. 6, No. 10 (Dec. 2014).

11. I also served as the Primary Investigator (PI) and primary author for the COMPASS Trial, the only randomized trial comparing aspiration against stent retrievers for treating acute ischemic stroke in the United States. Between June 2015 and July 2017, we assigned 270 patients to treatment: 134 to aspiration first pass and 136 to stent retriever first line. Our trial showed that a direct aspiration as first pass thrombectomy conferred non-inferior functional outcome at 90 days compared with stent retriever first line thrombectomy. Our research is summarized in Exhibit 1029.

12. I was a member of the editorial board for the American Journal of Neuroradiology, the leading medical journal on neuroimaging. I have also served on numerous industry advisory boards, including the boards of companies actively involved in developing mechanical aspiration thrombectomy devices such as Penumbra, Silk Road, and Imperative Care.

13. In addition to Penumbra and Imperative Care, I have actively consulted from many other medical device companies, including (1) Q'Apel Medical Inc., which makes access device technology for vascular interventions, (2) Lazarus Effect, which developed a mesh cover for stent retrievers of blood clots and was acquired by Medtronic, (3) Nfocus Neuromedical, Inc., which developed an intrasaccular device to treat brain aneurysms and was acquired by Medtronic, (4) Medina Medical, which developed an embolization coil for treating brain aneurysms and was acquired by Medtronic, (5) Pulsar Vascular, Inc., which developed a minimally invasive, self-expanding implant for treating intracranial aneurysms and was acquired by Codman Neuro, (6) Serenity Medical, which develops a stent to treat symptoms of idiopathic intracranial hypertension, (7) Cerebrotech Medical Systems Inc., which focuses on the development of portable neurotechnology solutions to diagnose stroke, (8) EndoStream Medical, which develops devices to treat brain aneurysms, (9) Viz.ai, which uses artificial intelligence to improve clinical workflow and diagnose stroke faster, and (10)

Radical Catheter Technologies, which develops next-generation catheters. I have also consulted for some for some of the largest companies in our industry, including Medtronic, Stryker, Micrvention-Terumo, Cerenovus, and Cordis.

14. I have also developed new methods to extract blood clots from the vasculature. For example, in the early 2010s, I helped pioneer a technique to quickly remove blood clots from the cerebral vasculature using an aspiration catheter. We referred to this new technique as a direct aspiration first pass technique (or ADAPT for short), which was the subject of the 2014 article I mentioned above.

15. A surgeon using ADAPT would insert a large guide catheter into the patient's vasculature, typically through a small incision in the groin, and advance the catheter to the cervical or carotid artery. The surgeon would then advance an aspiration catheter through the guide catheter until the distal end of the aspiration catheter was positioned near the occlusion or clot. The surgeon would initiate aspiration using a 20- or 60-mL syringe or an aspiration pump, such as the commercially available Penumbra aspiration pump, to grab the clot. Once the surgeon confirmed that the clot was attached to the aspiration catheter, the surgeon would slowly withdraw the catheter and clot through the vasculature. My co-authors and I concluded that ADAPT was a fast, simple, efficient, and safe strategy to achieve revascularization in patients with acute ischemic stroke. The

journal articles attached as Exhibits 1026-1027 describe some of my early experiences with the technique.

## II. INARI'S EFFORT TO DISTINGUISH NEUROVASCULAR TREATMENTS FROM DVT AND PE

16. I am aware that Inari sent a letter to Imperative Care alleging that the use and sale of Imperative Care's Symphony™ Thrombectomy System infringes certain Inari patents. I understand that one of the patents Inari identified in the letter was U.S. Patent No. 11,744,691 ("the '691 patent"), which claims "An aspiration system with accelerated response." I am aware that in response to these allegations, Imperative Care provided Inari with a 38-page letter explaining that the "aspiration system described in Claim 1 of the '691 patent was already known and taught by the prior art, including, but not limited to, Garrison I." Garrison I is U.S. Patent Publication No. 2015/0173782, which I understand is Exhibit 1006 in this proceeding.

17. Garrison generally describes aspiration catheters "for the treatment of acute ischemic stroke." Ex. 1006 (Garrison) at [0002]. Garrison specifically discloses creating an accelerated response in the aspiration catheter by (1) closing a valve (e.g., stopcock) between the pump and the aspiration catheter, (2) turning on the pump to generate negative pressure in the system between the pump and valve, and (3) opening the valve after generating the negative pressure to "enable the maximum level of aspiration in a rapid fashion with one user." *Id.* at [0134].

18. I am aware that Inari responded to Imperative Care's invalidity positions based on Garrison I as follows:

> More specifically, Imperative Care relies heavily on [Garrison I], asserting that Garrison I renders invalid the relevant claims of the '382 and '691 patents. We disagree. Garrison I related to neurovascular procedures, whereas both Inari's products and the Symphony product are designed to treat deep vein thrombosis (DVT) and/or pulmonary embolisms (PE). As you know, DVT and PE treatments are **significantly different** from treatments for neurovascular clots. For one thing, neurovascular thrombosis treatments **require much smaller catheters**, and the vasculature and the nature of **the clots are different** for DVT or PE. For at least these reasons, the Patent and Trademark Office has allowed Inari patent claims over Garrison I.

Inari's letter is attached hereto as Exhibit 1028.

19. The letter continued, "Similarly, the '382 and '691 patents have dependent claims that are directed to DVT and/or PE applications that use larger catheter sizes and are distinguishable from Garrison I."

20. I disagree with Inari's over-simplified arguments, particularly those bolded above. A clot might reside in the venous or arterial system, in the brain, lungs, legs, or elsewhere in the body. In all cases, aspiration thrombectomy involves placing a tube (catheter) near the clot and vacuuming the clot into the tube. Physicians and catheter designers understand the desirability of picking the right sized catheter for a particular clot, taking into account such things as target vessel size and access pathway. While there can be some differences between treating neurovascular occlusions and DVT or PE, the procedures have far more

similarities than differences. Notably, the procedures use common components (e.g., aspiration catheters, pumps, valves, etc.), common access and delivery techniques, and common processes for clot removal (e.g., aspiration). The heavy overlap between the procedures is illustrated by the real-world up-sizing of commercial neurovascular aspiration catheters for treating DVT and PE. As explained below, Inari's argument that treating DVT and PE is "significantly different" from treating neurovascular clots is inconsistent with my real-world experiences and observations.

## III. THE PROCEDURE FOR ASPIRATING BLOOD CLOTS FROM THE BRAIN IS NOT "SIGNIFICANTLY DIFFERENT" FROM ASPIRATING CLOTS FROM THE LUNGS OR LEGS

21. The general procedure for aspirating a blood clot from a blood vessel is similar regardless of whether the physician is removing the clot from the brain, lungs, legs, or any other part of the body. Generally, a physician inserts an aspiration catheter into the patient's vasculature through a small incision in the skin. In many cases, the incision is made near the patient's groin to access the femoral vein or artery. For example, when I use aspiration catheters to remove blood clot in the brain, I regularly access the patient's vasculature through the femoral artery. Nearly all peripheral vascular surgeries including DVT and PE aspiration procedures gain access to the patient's blood vessels from the same femoral access, either artery or vein.

22. After gaining access to the affected vasculature, the physician then advances the aspiration catheter toward the blood clot. In most cases, the physician will have pre-placed a guidewire or smaller catheter to help direct the aspiration catheter through the appropriate blood vessels. The physician will use imaging to track the progress of the aspiration catheter and determine when the tip of the aspiration catheter is near the clot. Once the aspiration catheter is near the clot, the physician will initiate aspiration (i.e., suction). In some simpler systems, aspiration occurs by withdrawing the plunger on a syringe attached to the aspiration catheter. In other cases, aspiration is initiated by a pump or generator attached to the aspiration catheter.

23. One of the techniques my fellow surgeons and I have done since the early 2010s is to place a tube clamp on the tubing running from the aspiration catheter to the syringe or pump. We then pull back the syringe or turn on the pump to create negative pressure in the tubing before removing the tube clamp. This technique increases the suction immediately applied to the clot. The suction caused by the syringe or pump draws the clot into the catheter. The physician may also advance and withdraw the aspiration catheter within the patient to capture the clot material, not unlike vacuuming in everyday life. Some aspiration systems also include additional tools to help grab or break up the clot. Once the physician captures the clot, the aspiration catheter is withdrawn from the patient.

These basic aspiration procedures are the same regardless of where the clot is located and have been used for decades.

24. Additionally, the mechanical components required to aspirate a blood clot from the brain (cerebral occlusion) are the same as those required to aspirate a clot from the legs (DVT) or lungs (PE). The aspiration systems that I am aware of include an aspiration catheter that can be advanced through the vasculature to the blood clot. The catheter is attached at one end to a pressure source, such as a pump, generator, or syringe. Many aspiration systems also include some type of container to collect the aspirated material. Further, because the aspiration catheter is typically advanced over a guidewire or through a guide catheter (or sometimes both), the aspiration systems I have worked with include a hemostasis valve. While the sizes of some components may vary depending on the clot locations, these basic aspiration components are common across different clot locations.

25. Further, surgeons sometimes use aspiration catheters designed for one part of the vasculature to treat another part of the vasculature, further demonstrating that the components and procedures are the same regardless of clot location. For example, the Penumbra Indigo® Aspiration System was designed to remove blood clots from arteries and veins in the peripheral vasculature. However, I know surgeons who used the Penumbra Indigo for ***cerebral*** venous thrombectomies because the catheter was larger than many of the neurovascular

aspiration catheters available at the time. While the cerebral arteries are generally small, the cerebral veins are larger, often on the order of 6-10mm, and can accommodate larger catheters. This real-world use of the same aspiration catheter for neuro and peripheral applications supports my opinions that aspiration procedures, regardless of clot type, have far more similarities than differences.

## IV. CATHETER DEVELOPERS ROUTINELY ADAPT CATHETERS FOR USE IN OTHER PARTS OF THE VASCULATURE

26. Physicians have used aspiration catheters to remove blood clots, embolisms, and related occlusions from patient blood vessels for decades. Many of the earliest aspiration procedures were developed for cardiac applications. Attached as Exhibit 1024 is an exemplary article from the American Journal of Cardiology published in 1993 describing the treatment of patients suffering from acute myocardial infarction. In the described procedure, the co-authors used an aspiration catheter to remove blood clots from the left main coronary artery or the right coronary artery of five patients. The journal article explains that the "clots were aspirated … by advancing an 8 F guiding catheter to the vicinity of the thrombus and applying manual suction with a 20 mL syringe." Ex. 1024 at 116G. This basic aspiration procedure is not significantly different from the aspiration procedures used today to extract clots from the brain, legs, and lungs.

27. Once cardiologists demonstrated that aspiration catheters could effectively remove clots from the heart and surrounding vasculature, physicians

naturally expanded the procedure to other parts of the body. In the late 2000s, Penumbra commercially released a mechanical thrombectomy system ("the Penumbra System) to remove blood clots from the cerebral vasculature. The Penumbra system included an aspiration catheter attached to a generator to create suction. Attached as Exhibit 1025 is a 2008 article from the American Journal of Neuroradiology describing early experiences with the Penumbra System. As with the prior cardiac applications, a guide catheter was inserted through the patient's vasculature to a position near the clot. An aspiration catheter (referred to in the article as a "reperfusion catheter") was then inserted through the guide catheter until it was "proximal to the clot." Ex. 1025 at 1410. "The aspiration pump was then turned on to initiate revascularization." *Id.* I was an early adopter of the Penumbra System and used it often in my practice.

28. The development of cerebral aspiration catheters, such as the Penumbra System, was facilitated by advances in catheter technology. As I explained in my 2014 article describing ADAPT, the procedure was enabled by advances in catheter technology that "included very large, easily trackable, aspiration thrombectomy catheters that can now more easily and reliably navigate the cerebrovasculature." Ex. 1027 at 260. These new catheters allowed surgeons to traverse very tortuous blood vessels, such as those found in the brain, and reach more remote locations.

29. Moreover, the advances were not restricted to neurovascular aspiration catheters but extended to aspiration catheters for treating PE and DVT. The use of advanced catheter technology to treat a range of medical problems is not an anomaly. Rather, medical device companies routinely adapt procedures and components initially developed for one medical procedure for another.

30. Once medical device companies successfully developed aspiration catheters to treat blood clots in the brain, they again expanded the use of the catheters to other portions of the body including the lungs and peripheral vasculature to treat conditions like PE and DVT. Several thrombectomy companies started by developing aspiration catheters for the neurological space before adapting their technology to treat the lungs and peripheral vasculature. For example, Penumbra's original aspiration system was designed to treat blood clots in the brain. Once Penumbra developed an effective device for neurovascular applications, Penumbra upsized its device for use in the lungs and peripheral vasculature. While the size of some components changed within some versions of the system, the operation and organization of the components largely remained the same.

31. This same progression occurred at Imperative Care. Imperative Care initially developed mechanical aspiration catheters to treat cerebral occlusions. After successfully developing these products, Imperative Care expanded to

treating blood clots in the peripheral vasculature (e.g., DVT). Naturally, Imperative Care built upon its neurovascular aspiration catheters when developing products for the peripheral vasculature. For example, Imperative Care's neuro pump is also used with its products for the peripheral vasculature.

32. Thus, the real-world development of aspiration catheters demonstrates that aspiration thrombectomy for neurovascular applications is not a separate field or discipline from aspiration thrombectomy for the lungs and peripheral vasculature. While the location of the blood clot is different, the basic procedure of applying suction through a catheter to remove the clot is the same.

33. Further, the adaptation of neurovascular aspiration catheters for the lungs and peripheral vasculature is not surprising given that surgeons solved many difficult issues when developing the neurovascular catheters. Treating blood clots in the brain (cerebral occlusions) is much more difficult than treating blood clots in the lungs (PE) and peripheral arteries (DVT) for several reasons.

34. First, the catheters used to extract cerebral blood clots typically traverse a longer distance than the catheters used to treat the peripheral arteries. The neurovascular catheters often extend from an incision in the groin all the way to the brain.

35. Second, the catheters for treating cerebral occlusions must navigate blood vessels that are often more tortuous than the vessels encountered in the

lungs and peripheral vasculature. The tortuosity of the vessels makes it challenging to advance the catheter to the treatment location.

36. Third, the cerebral arteries are more delicate than the peripheral vasculature because they lack a robust muscularis layer and must rely on the adventitial layer for their durability. Consequently, the arteries are more deformable and, therefore, require softer and more flexible aspiration catheters that will not damage the blood vessels. A perforation or tear out of the cerebral vasculature would be devastating for the patient.

37. Fourth, time is critical in treating a cerebral blood clot. Studies have shown that a typical patient loses 1.9 million neurons each minute in which stroke is untreated. Ex. 1030. The clot is blocking blood flow to the brain and, in many cases, causing long-term damage. Thus, the surgeon must treat the cerebral blood clot quickly and this places additional constraints on the catheters. As a consequence, the stakes are extremely high when treating cerebral blood clots. If issues arise during the procedure, the surgeon may have limited options to resolve the issue and save the patient from long-term brain damage. Such high stakes are less common when treating the lungs and peripheral vasculature. Given all of these challenges, it is not surprising that surgeons could readily transfer the cerebral technology to simpler applications, like the lungs and peripheral vasculature. And indeed, they did. Moreover, while a catheter designed to treat

PE and DVT may not be configured to reach a clot in the cerebral vasculature due to size or stiffness, a catheter designed to treat cerebral occlusions could reach a clot in the peripheral vasculature or lungs because it would have the appropriate size and flexibility.

## V. BLOOD CLOTS VARY, AS DO THE CATHETERS USED TO TREAT THEM

38. Inari's argument bolded above that the "nature of the clots are different" between cerebral clots and DVT/PE misses the point. Cerebral clots vary in their composition based on specific location, age of the clot, and patient-specific factors. Not all cerebral clots are soft, small, or easy to aspirate. In my practice, I have encountered cerebral clots that are fibrous and difficult to extract. I do not think a single descriptor can be applied to cerebral clots, just as a single descriptor cannot be applied to clots in the lungs and peripheral vasculature. In some cases, the consistency of the clots extracted from the brain and lungs or legs will be the same and in some cases they will be different. But regardless of clot type, aspiration thrombectomy involves aspirating the clot into the catheter.

39. I also do not agree that aspiration catheters used for the cerebral vasculature are "much smaller" than aspiration catheters used for the lungs and peripheral vasculature. There can be overlap in catheter sizes used for the cerebral vasculature and, for example, pulmonary embolisms in the lungs. In some situations, the blood vessels requiring treatment will be approximately the same

diameter. Moreover, surgeons have successfully used catheters to remove PEs or DVTs that are smaller than some of the largest catheters currently on the market (e.g., 20 or 24 French). In fact, Penumbra, one of the current market leaders in mechanical aspiration thrombectomy, sells aspiration catheters of 7F and 12F for removing occlusions in the lungs and peripheral vasculature, including PE and DVT. Likewise, Imperative Care sells the Prodigy™ Thrombectomy System, which is an aspiration system used to treat the peripheral vasculature that includes aspiration catheters ranging from 5F to 8F.

40. Moreover, while some clots in some peripheral vessels can be larger than typical clots in the brain, it would be inaccurate to suggest that larger clots are necessarily more difficult to remove. In my experience, for example, cerebral and peripheral clots can be extracted with similar levels of suction. As an example, I have treated cerebral clots with suction generated by a 60 mL syringe. Inari's FlowTriever, which Inari markets for extracting PEs and DVT, is sold with a 60-cc syringe, which is approximately the same volume as a 60 mL syringe and would create the same amount of suction.

41. Further, while some commercially available aspiration catheters for the peripheral vasculature have diameters larger than typical neurovascular catheters, I do not see that as a significant difference between the procedures and devices. Medical catheters have long been sold in a range of sizes, so I do not

believe that merely changing the size of the catheter adds anything to the art. Moreover, surgeons have developed a range of ways to deal with issues caused by larger catheters. One such issue is the aspiration of large volumes of blood. However, well before 2018, physicians had developed ways to reinfuse aspirated blood into the patient. Moreover, it is important to point out that if a physician is using a simple syringe to generate suction, such as with Inari's FlowTriever, then the physician can control the blood loss by monitoring the number of syringes used. Simply put, the aspiration of large blood volumes does not make extracting clots from the lungs or peripheral vasculature "significantly different' from extracting clots from the cerebral vasculature.

42. I reserve the right to supplement my opinions in the future to address or respond to any arguments that Inari may raise, as well as new information that may become available.

43. I declare that the foregoing is true and correct, and further that the foregoing statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on August 6, 2024, in Greenville, SC.

Aquilla S. Turk, III, DO