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On behalf of **Imperative Care, Inc.**

By: Joshua J. Stowell (Reg. No. 64,096)
Joseph R. Re (Reg. No. 31,291)
Brian C. Barnes (Reg. No. 75,805)
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Tel.: (949) 760-0404
Fax: (949) 760-9502
Email: BoxImperative384@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case IPR2025-01562
Patent No. 12,109,384

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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Exhibit No.	Description
1001	U.S. Patent No. 12,109,384 (“the ’384 patent”)
1002	Prosecution History of the ’384 Patent
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1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
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1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
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1014	Google Dictionary Definition of “String”
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1026	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
1027	Imperative Care, Inc.'s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
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1030	Patent Owner Response for <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 3) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Apr. 18, 2025)
1031	Supplemental Declaration of Paul J. Zalesky submitted in IPR2024-01157
1032	Robert C. Allen, <i>The Gore DrySeal Sheath</i> , Supp. Endovascular Today (Feb. 2011) (“Allen”)
1033	Cara M. Michelson, et al., <i>Use of a Modified Cardiopulmonary Bypass Circuit for Suction Embolectomy with the Angiovac Device</i> , 49 J. Extra Corpor. Tech., 299-303 (2017) (“Michelson”)
1034	Jacques Kpodonu, Manual of Thoracic Endoaortic Surgery (2010) (“Kpodonu”)
1035	510(k) Summary – K123990, Sentrant Introducer Sheath with Hydrophilic Coating (Apr. 26, 2013) (“Sentrant”)
1036	Matthew Kruse, <i>Thoracic Endovascular Aortic Repair (TEVAR) Sheaths</i> , CTSNet (Jan. 18, 2011) (“Kruse”)
1037	Cook Medical, Endovascular Aortic Repair – Abdominal: Zenith Endovascular Grafts (2012) (“Zenith Brochure”)
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1039	U.S. Patent Pub. No. 2017/0080200 A1 (“Bickhart”)
1040	U.S. Patent No. 11,730,942 B2 to Fantuzzi (“Fantuzzi”)
1041	U.S. Patent No. 8,777,893 B2 to Malewicz (“Malewicz”)
1042	U.S. Patent No. 5,125,903 to McLaughlin (“McLaughlin”)
1043	U.S. Patent No. 8,808,350 B2 to Schreck (“Schreck”)

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1044	Order Denying Motion for Preliminary Injunction (Dkt. #136) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued September 29, 2025)
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1051	Decision Referring the Petition to the Board (Paper 9) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. July 31, 2025)
1052	Decision Referring the Petitions to the Board (Paper 11) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01021 (P.T.A.B. Oct. 10, 2025)
1053	Decision Referring the Petitions to the Board (Paper 11) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01025

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1056	Final Written Decision Determining All Challenged Claims Unpatentable (Paper 33) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 7, 2026)
1057	Final Written Decision Determining All Challenged Claims Unpatentable (Paper 36) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 9, 2026)
1058	May 8, 2024 Restriction Requirement Issued for U.S. Patent Application No. 18/598,482
1059	July 26, 2024 Notice of Allowance Issued for U.S. Patent Application No. 18/598,482
1060	Supplemental Expert Declaration of Troy Thornton
1061	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated March 24, 2026 from IPR2025-00728
1062	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated August 21, 2026
1063	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated August 27, 2025 from IPR2025-00156
1064	R.C. Hibbeler, Engineering Mechanics: Statics (12th ed. 2009)
1065	Marks' Standard Handbook for Mechanical Engineers (8th ed. 1978)

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2001	Declaration of Paul J. Zalesky
2002	Merriam-Webster's Collegiate Dictionary (11th ed. 2014)
2003	Declaration of Troy L. Thornton in Support of <i>Inter Partes</i> Review of U.S. Patent No. 11,697,011
2004	Final Written Decision Determining All Challenged Claims Unpatentable (Paper 35) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 16, 2026)
2005	Petition for <i>Inter Partes</i> Review (Paper 1) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. Mar. 3, 2025)
2006	Petition for <i>Inter Partes</i> Review (Paper 1) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jul. 8, 2024)
2007	Deposition Transcript of Troy Thornton (November 20, 2025) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156
2008	Supplemental Declaration of Paul J. Zalesky (EX2009) in <i>Inter Partes</i> Review of U.S. Patent No. 11,865,291
2009	Deposition Transcript of Troy L. Thornton dated May 28, 2026
2010	Supplemental Declaration of Paul J. Zalesky (EX2008) in <i>Inter Partes</i> Review of U.S. Patent No. 11,697,012
2011	Deposition Transcript of Troy L. Thornton dated June 25, 2025, in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156
2012	Deposition Transcript of Troy L. Thornton dated August 15, 2025, in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157

I. INTRODUCTION

The Board has instituted six IPRs (including this IPR) challenging PO's patents claiming a valve with a filament. (Paper 10; Exs. 1025-1026, 1029, 1045-1046.) The Board recently issued Final Written Decisions in three of those IPRs ("Related FWDs") where it found every challenged claim invalid in view of Schaffer combined with Hartley and/or Eller – the same prior art combined in Grounds 1-3. (Ex. 1061, 41-68; Ex. 1056, 43-71; Ex. 1057, 43-62.) The Board also rejected PO's argument raised herein that a POSITA would not have been motivated to combine Schaffer with Hartley or Eller.

The POR raises only two unresolved disputes relating to limitations reciting: (1) a "first filament" and "second filament" configured into loops¹ and (2) actuators "movably coupled" to a housing (claim 9)². PO's arguments regarding these limitations fail to distinguish the prior art.

Schaffer, Hartley, and Eller disclose or render obvious the first and second filament limitations in two ways. First, a POSITA would have been motivated to substitute two strings or wires forming first and second loops for Schaffer's U-shaped actuating members. Notably, the Board has already concluded that a

¹ The Board will address a claim reciting first and second filaments in IPR2025-00728.

² The Board will address a claim reciting "movably coupled" in IPR2025-00989.

POSITA would have been motivated to substitute one string/wire forming a loop for Schaffer's actuating members. (Ex. 1056, 51-71.) Here, Eller expressly suggests using at least two wires and further discloses that POSITAs possessed the skill to select the appropriate number of filaments. PO's argument that two filaments distinguishes the prior art where one filament did not is unpersuasive, particularly because the '384 patent never identifies *any* advantages to two filaments.

Second, Hartley's string and Eller's wire indisputably include a plurality of threads, which satisfy the Board's construction of "filament." PO's attempt to distinguish these prior-art strings and wires by importing a requirement for "separate" first and second filaments into the claims is unsupported. "Separate" never appears in the claims, specification, or prosecution history, and PO identifies no lexicography or disclaimer to support importing the term.

PO's arguments regarding "movably coupled" in claim 9 also fail to distinguish the prior art. Schaffer describes a housing with two actuator buttons that "are configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second position." (Ex. 1005, [0076].) The actuator buttons cannot be uncoupled from the housing. Thus, the buttons are "movably coupled" under the plain and ordinary meaning of the term.

Accordingly, the challenged claims 1-4, 6-18, and 20-30 are unpatentable and Petitioner respectfully requests a final written decision cancelling the claims.

**II. CLAIMS 1-4, 6-18, AND 20-30 ARE OBVIOUS OVER SCHAFFER
WITH HARTLEY AND/OR ELLER (GROUNDS 1-3)**

**A. Schaffer With Hartley And/Or Eller Renders Obvious The First And
Second Filament Limitations**

PO argues that Schaffer combined with Hartley and/or Eller does not render obvious a valve having a “first filament extending in a first loop around the tubular member” and a “second filament extending in a second loop around the tubular member.” PO is incorrect.

**1. POSITAs Would Have Been Motivated To Replace Schaffer's U-
shaped Actuating Members With Two Strings/Wires**

Hartley indisputably discloses a first filament extending in a loop around a tubular member. The Board should view PO's argument that adding another identical filament is nonobvious skeptically. The '384 patent consistently describes the alleged invention as including “at least one filament.” (Ex. 1001, 2:2-5:23, 8:5-16, 9:7-53.) The patent never emphasizes the *number* of filaments or describes advantages of two filaments. (See Ex. 1062, 24:5-25:20.) If two filaments were the patent's inventive aspect, one would expect greater discussion.

Here, evidence reflects that a POSITA would have found it obvious to substitute two strings or wires each forming loops for Schaffer's U-shaped actuating members. (Petition, 37-40, 47-50; Ex. 1003, ¶¶78-84, 102-106.) A POSITA would have been motivated to use two strings/wires because: (1) the combination entails a simple substitution of known elements to achieve predictable results; (2) two

strings/wires provide a more robust and reliable seal; (3) Eller suggests using two wires to seal a hemostasis valve and confirms that POSITAs possessed the skill to “select a suitable number of wire members”; and (4) Hartley suggests looping a string twice around the tube. (*Id.*)

PO's expert agrees that looping two filaments around the tube would provide “[t]he ability to apply a greater total amount of force of constriction” compared to one filament. (Ex. 1063, 94:6-17.) He also testified that the redundancy of two looped filaments provides “an added protective feature.” (*Id.*, 98:16-25.) He also agrees with Eller that POSITAs would have possessed the skill to select the appropriate number of wires. (Ex. 1061, 44:16-22.) PO's argument that a POSITA would not have been motivated to use two strings/wires despite these admissions fails for the following reasons.

a. The Combination Is A Simple Substitution

PO repeats its argument from the related IPRs that combining Eller's wires or Hartley's strings with Schaffer's valve would not be a simple substitution because no single reference discloses a valve with two strings/wires attached to two actuators. (POR, 52-58.) In the Related FWDs, the Board found that PO's “argument is tantamount to a complaint that none of Schaffer, Hartley, or Eller is anticipating,” which does not rebut Petitioner's obviousness grounds. (Ex. 2004, 66-67; Ex. 1056, 69-70; Ex. 1057, 61.)

The Petition identifies simple ways to incorporate two strings/wires into Schaffer's valve. (Petition, 34-35, 45-46.) PO responds that Hartley's string or Eller's wire would not "predictably seal" because "either of Schaffer's buttons could be depressed independently to move the string/wire unpredictably." (POR, 52-54, 66-67.) But PO fails to explain why the sealing would be unpredictable, or so ineffective as to offset the many advantages of two strings/wires. PO's conclusory arguments cannot rebut Petitioner's evidence (and the Board's previous conclusion) that the combination would have "require[d] no more than ordinary skill." (Ex. 2004, 67; Ex. 1056, 69; Ex. 1003, ¶¶84, 104.)

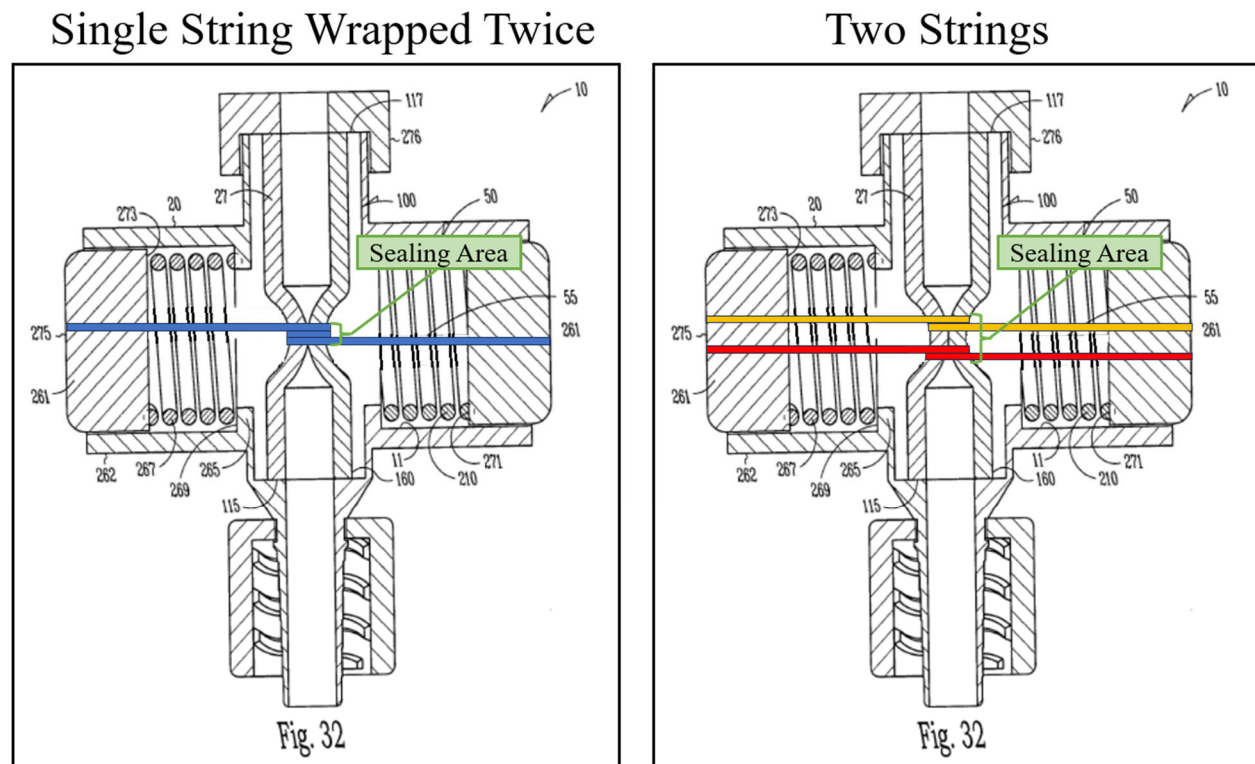
PO's related argument that "more plausible" modifications to Schaffer's valve existed also lacks merit. (POR, 65.) As the Board recognized in the Related FWDs, "obviousness is not limited to the best or simplest solution." (Ex. 2004, 67-68; Ex. 1056, 69-70; Ex. 1057, 61-62.)

b. Two Strings/Wires Create A More Robust And Reliable Seal

A POSITA would have recognized that "two loops of string would apply constricting force along a greater length of the tubular member, thereby creating a larger sealing area and a more robust seal." (Ex. 1003, ¶79; *infra* §II.A.1.d.ii-iii.) PO's expert agreed that two looped filaments would provide "[t]he ability to apply a greater total amount of force of constriction" to the valve. (Ex. 1063, 94:6-17.) PO's arguments to the contrary in the POR fail to rebut this evidence.

i. Two Strings/Wires Enable A Wider Sealing Area

Two strings or wires each looped once around the tube creates a wider sealing area for tools inserted through the valve:

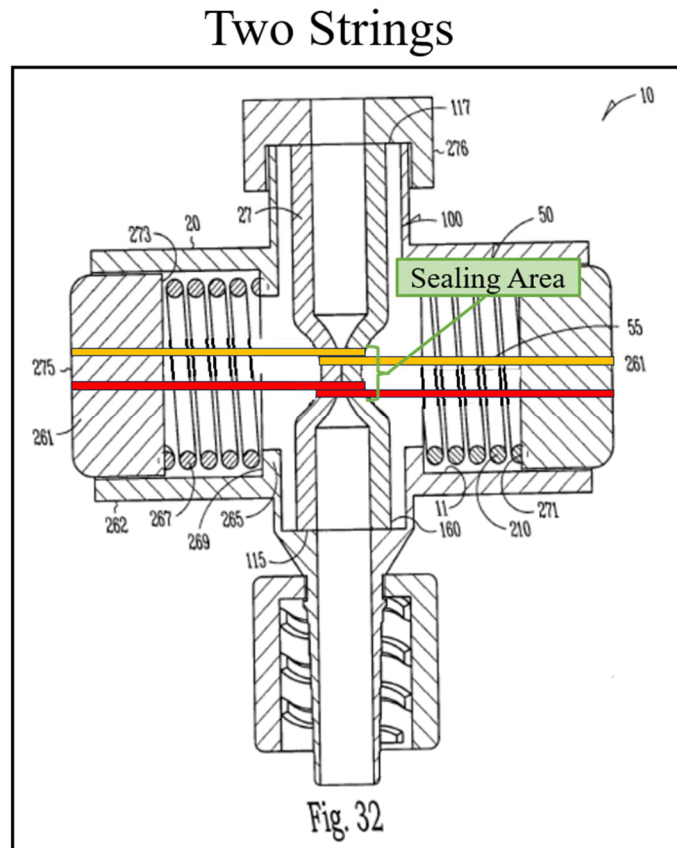


(Ex. 1060, ¶23; Petition, 38; Ex. 1003, ¶81.)

PO counters that the “sealing area” of the strings is limited to the width of the strings and therefore, “whether wound twice or formed into two loops, the windings and loops have the same sealing width.” (POR, 36.) PO is incorrect.

Schaffer's seal module (tube) is a “flexible, elongate tubular structure” formed from “highly elastic, deformable, compliant and yet virtually non-compressible”

materials. (Ex. 1005, [0081].) As the string/wire constricts the tube, the tube portion between strings/wires also constricts to create the sealing area:



(Ex. 1060, ¶25.) PO's expert confirmed that the space between the strings would constrict along with the strings. (Ex. 1062, 84:15-85:11.) Thus, the sealing area is wider than two strings, and PO's argument is incorrect.

PO also argues that a small gap between the strings could “create a stagnant blood pool from back bleed, that could lead to thrombus (clot) formation in the gap.” (POR, 37.) A POSITA would not have expected a “stagnant blood pool” to form between the strings. (Ex. 1060, ¶¶26-28.) The area between the strings is small and

constricts around the instrument with the strings, eliminating any gap for blood to “pool.” (*Id.*, ¶26.) Further, the procedures using these valves typically take minutes, not hours or days, and the valve is repeatedly opened and closed during the procedure. (*Id.*, ¶27.) Therefore, any blood between the strings would not be “stagnant” long enough to form clots, particularly because the patients receive anticoagulants to inhibit clot formation. (*Id.*; *see also* Ex. 1062, 109:10-110:4 (acknowledging coagulation takes time).)

ii. Two Strings/Wires Provide Beneficial Redundancy

Another benefit of two strings/wires is that the “second string would help ensure that the valve seals even if one of the strings were to fail to tighten around the tubular member.” (Ex. 1003, ¶82.) PO’s expert concedes that the second string is like a “spare tire” and “an added protective feature.” (Ex. 1062, 40:10-42:3; Ex. 1063, 98:16-25.)

However, PO argues: (1) two strings “might interfere with one another,” which “may [] offset” the redundancy benefits, and (2) the strings/wires are made from durable materials eliminating the need for redundancy. (POR, 38.) Both arguments fail to rebut Petitioner’s evidence.

PO speculates that the strings/wires would “move laterally along Schaffer’s seal modules when Schaffer’s actuator buttons 261 are depressed” and “*might* interfere with one another” or “*may* move uncontrollably.” (*Id.* (emphasis added).)

PO never explains how this movement would negatively impact valve operation. Nor does PO explain why the movement would deter a POSITA from using two strings/wires, particularly when two strings/wires have many undisputed advantages. PO also fails to account for simple solutions to the movement, such as using a stiffer string or wire. (Ex. 1060, ¶35; Ex. 1062, 96:19-97:18.) PO's speculation coupled with its failure to provide substantive analysis cannot rebut the obviousness grounds.

Further, no references support PO's argument. Eller discloses using at least two wires to seal a hemostasis valve but never suggests the filaments would negatively interfere. (Ex. 1007, 5:1-6, 16:7-19; Ex. 1061, 43:2-44:3, 45:7-46:10.) Further, even if interference occurred, Eller discloses that POSITAs possessed the skill to optimize the filaments. (Ex. 1007, 16:7-15; *see also* Ex. 1001, 12:61-62 (presuming POSITAs could resolve interference); Ex. 1062, 95:11-96:9 (confirming interference is “unlikely”).)

Moreover, even if filament interference were a concern, PO fails to show the concern would outweigh the advantages of a second filament. *See, e.g., Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (“[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.”). The selection of one or two strings/wires “amounts to an engineering tradeoff—a

decision well within the level of ordinarily skilled artisans.” *In re Mouttet*, 686 F.3d 1322, 1330 (Fed. Cir. 2012).

PO's argument that durable strings/wires require no redundancy is also misplaced. PO incorrectly presumes that fragility is the only reason a string/wire might fail to seal. (POR, 38-39; Ex. 1060, ¶36.) But a string/wire may not seal because the tool is irregularly shaped and/or sized. (*Id.*; *see also* Ex. 1062, 44:13-45:22 (admitting a complex geometry may not seal).) A second string can compensate by forming the seal at a different location. Moreover, PO has repeatedly argued that strings/wires are *not* durable. (Ex. 2004, 47; Ex. 1056, 49; Ex. 1057, 41.) If PO is correct, then a second string provides beneficial redundancy. (Ex. 1060, ¶36.)

c. Eller Discloses Using Two Filaments

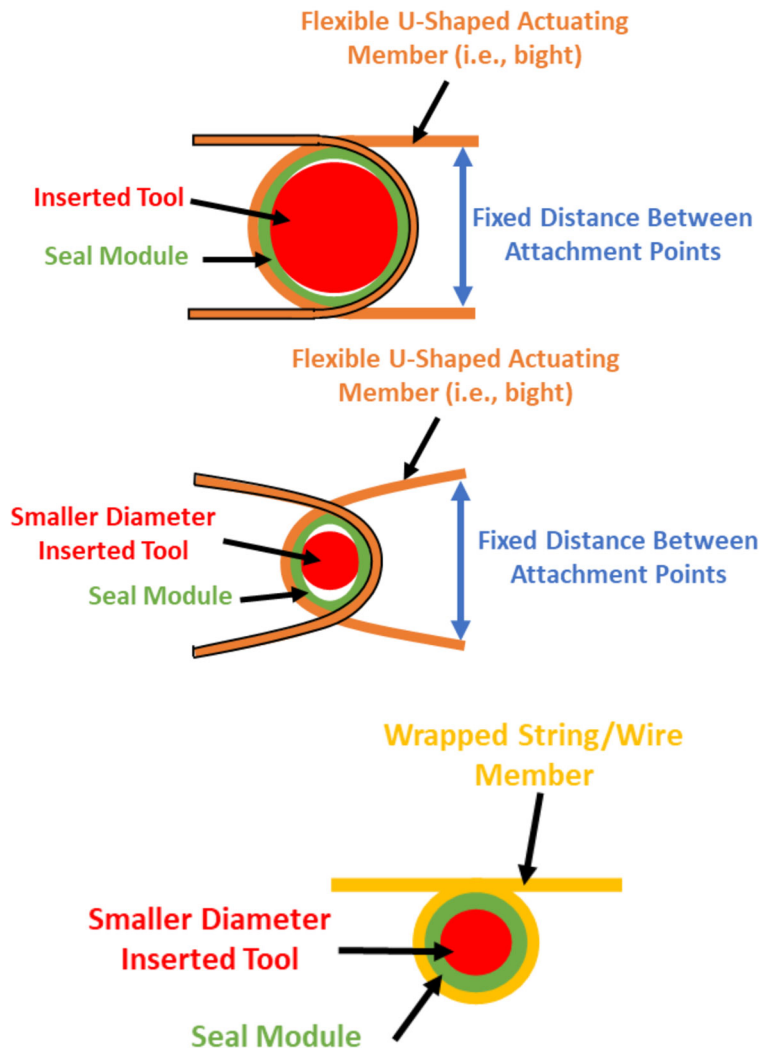
Eller expressly discloses using first and second wires (filaments) to constrict a tube in a hemostasis valve and teaches that POSITAs possessed the skill to select an appropriate number of wires. (Ex. 1007, 16:7-19; POR, 40-54.) But PO argues that Eller would not have motivated a POSITA to use two strings/wires *looped* around Schaffer's tube because Eller does not disclose an embodiment with two wires each forming loops. (POR, 41-52.)

Once again, this “argument is tantamount to a complaint that [neither] Schaffer ... or Eller is anticipating” and “it does not account adequately for the art's

combined teachings.” (Ex. 1057, 43 n. 18, 61.) For obviousness, “it suffices ... that a [POSITA] would have been motivated to combine the prior art in a way such that the combination discloses the claim limitation.” (*Id.*, 61 (quoting *Masimo Corp. v. Apple Inc.*, No. 2022-1894, 2024 WL 111647 at *3 (Fed. Cir. Jan. 10, 2024).)

Further, PO ignores that POSITAs had two options for arranging Eller's two wires within Schaffer: (1) form each wire in a U-shape around the tube like Schaffer's preferred embodiment or (2) form each wire in a loop around the tube like Eller's and Hartley's preferred embodiments. (Ex. 1060, ¶11; Ex. 1003, ¶73; Petition, 34; Ex. 1062, 55:22-56:8.) These finite options would have been simple, predictable, and obvious to a POSITA. (*Id.*); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Similarly, a POSITA would have expected loops to form a better seal in some circumstances than U-shaped members:



(Ex. 1003, ¶111; Ex. 1060, ¶13.) PO never disputes the benefit of loops over U-shaped actuating members.

Accordingly, Eller would have motivated a POSITA to loop two of Eller's wires or Hartley's strings around Schaffer's tube. (Ex. 1003, ¶¶102-106; Ex. 1060, ¶¶7-15.)

d. Hartley Suggests Looping A String Twice Around The Tube

A POSITA would have been motivated to use two strings/wires based on Hartley's suggestion to wind a string "preferably twice around the cylindrical diaphragm." (Ex. 1006, [0031].) A POSITA forming two loops had two options: (1) loop one string around the tube twice, or (2) loop two strings around the tube once. (Ex. 1003, ¶79.)

A POSITA would have recognized advantages to the latter: (1) two strings reduce the friction on the tube; (2) two strings enable a wider sealing area; and (3) two strings provide redundancy. (*Id.*, ¶¶80-82.) PO fails to rebut the second and third advantages for the reasons discussed above. (*Supra* §II.A.1.b.i-ii.) PO also fails to rebut the frictional advantage.

PO incorrectly argues that two strings/wires would create the same friction as a single string looped twice "[b]ecause the *same amount (e.g., length) of string* contacts the diaphragm/seal module in each arrangement." (POR, 33.) PO's expert admitted he performed no calculations to reach this opinion. (Ex. 1062, 106:3-107:6.)

The friction of a string/wire against a cylinder increases exponentially with the wrap angle (θ) of the string/wire:

$$T_1 = T_2 e^{\mu\theta}$$

where:

T_1 = holding force on one end of the string

T_2 = holding force on other end of the string

μ = coefficient of friction

θ = total wrap angle of the string in radians

(Ex. 1060, ¶20; Ex. 1064, 422; Ex. 1065, 3–31–3–32.) Assuming that $T_2 = 1$ and $\mu = 0.5$, the force required to overcome the friction of a single string looped twice is:

$$T_{\text{Twice Wrapped}} = e^{2\pi}$$

(Ex. 1060, ¶21.) Contrastingly, the force required to overcome the friction for two strings/wires each looped once is:

$$T_{\text{String 1}} = e^{\pi}$$

$$T_{\text{String 2}} = e^{\pi}$$

$$T_{\text{Total}} = T_{\text{String 1}} + T_{\text{String 2}} = 2e^{\pi}$$

(*Id.*) Thus, two strings/wires looped once around the tube create significantly less friction, which would advantageously reduce the force needed to use the valve. (*Id.*)

e. **Mr. Thornton Has Consistently Testified POSITAs Would Have Been Motivated To Use Two Strings/Wires**

PO argues Mr. Thornton testified that “a POSA would not ‘have been motivated to use two separate strings ... as opposed to [Hartley’s disclosure of] a single string looped twice around the tubular member.” (POR, 31.) Mr. Thornton gave no such testimony.

Rather, Mr. Thornton testified that looping a single string twice around the tubular member “could have some negatives of adding additional friction and make it more difficult to compress the tubular member.” (Ex. 2009, 42:14-20; *see also id.*, 44:12-24.) Mr. Thornton also testified that looping two strings/wires once would not cause those negative effects and would provide potential benefits. (*Id.*, 42:21-44:7, 46:3-47:23, 51:10-18.) Mr. Thornton never testified that a POSITA would not have been motivated to use two strings/wires.

Mr. Thornton's testimony that a POSITA “would find it most obvious to use a single string wrapped around once” does not create inconsistencies. (*See* POR, 32.) Mr. Thornton testified:

Q. If your option was to wrap around two times or use two strings, **why might a person of ordinary skill in the art use one string to wrap around twice?**

A. I think I said I don't see where a person of skill in the art would -- would wrap around twice.

Q. Perhaps they didn't want to use two strings before cost, manufacturing. **Are there any other reasons they might not want to use two strings?**

A. I just think a person of skill in the art would find it most obvious to use a single string wrapped around once. If there was a benefit to spacing the strings apart, then **I think a person of skill in the art would most likely consider a second string wrapped around once.**

(Ex. 2009, 45:4-21 (emphasis added).) Mr. Thornton's testimony confirms that a POSITA would have been motivated to use one or two strings wrapped once around the tube instead of a single string wrapped twice. (*Id.*; *see also* Ex. 1003, ¶¶78-84.) Moreover, "[o]bviousness is not limited to the best or simplest solution." (Ex. 1057, 61 (citing *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021).) Even if the "most desirable" solution involved a single string/wire, that would not undercut Petitioner's evidence of other obvious solutions. *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004).

2. Hartley's String/Eller's Wire Include First and Second Filaments

The prior art also renders the first and second filament limitations obvious because the strands in Hartley's string and Eller's wire comprise first and second filaments. PO counters that the claims "require *separate* first and second filaments as shown in Figure 7 rather than a *single* filament composed of different threads or strands as Petitioner asserts and similar to Figure 6." (POR, 24 (emphasis added).) PO's argument is unsupported.

The claims do not describe the filaments as "separate" or use any similar term. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). Likewise, PO does not argue that the plain and ordinary meaning of any claim term includes a "separate" limitation.

Likewise, the specification never describes the filaments as “separate.” *Id.* Instead, the specification broadly describes a “filament” to include (1) a single strand or (2) a plurality of strands. (Ex. 1001, 9:16-23.) The patent also states that “***the filament 150*** can comprise multiple filaments,” establishing that a single “filament” can include multiple, smaller filaments. (*Id.*, 12:61-64 (emphasis added).)

PO argues that Figure 7 supports a “separate” limitation. (Ex. 1062, 66:9-21.) But the importation of limitations from the preferred embodiment violates a central tenet of claim construction law. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc). PO never identifies any lexicography to support a narrower meaning of first/second filament. *Id.* at 1316. Similarly, PO never identifies any “intentional disclaimer, or disavowal, of claim scope by the inventor” that would support importing “separate” into the claims. *Id.*; *see also*, *MBO Lab'ys., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007).

PO argues that “the '384 Patent is explicit that a single filament can comprise a single strand (e.g., monofilament) or a ‘plurality of strands,’ but a single filament does not become both a first and second filament simply because of multiple strands twisted together.” (POR, 25 (citing Ex. 1001, 9:16-21).) But PO's argument is inconsistent with the patent. As discussed above, the specification teaches, “***the filament 150*** can comprise multiple filaments.” (Ex. 1001, 12:61-62 (emphasis added); *see also id.*, 9:21-23.)

Further, PO oversimplifies the disclosure. The patent states: “the filament *can comprise a single strand* such as, *for example*, a monofilament” or “the filament *can comprise a plurality of strands* that can be, *for example*, twisted, woven, grouped, and/or fused to form the filament.” (Ex. 1001, 9:16-21 emphasis added.) The patent uses broad, open-ended terms such as “comprise” and “example” to ensure that “the filament” encompasses any configuration of strands. Further, the monofilament “example” would not make sense if a filament could comprise only a monofilament (i.e., a “separate” filament) as PO argues. The more reasonable reading is that “filament” encompasses monofilaments or individual strands within a larger bundle of strands.

The deposition of PO's expert reflects the uncertainty produced by importing “separate” into the claims. PO's expert testified that “separate” filaments are not limited to Figure 7 and do *not* require a gap between the filaments. (Ex. 1062, 68:4-10.) He confirmed that parallel filaments with no gap between them are “separate” filaments because they are “a separate physical entity.” (*Id.*, 68:11-69:19.) He further contends that an “individual thread is a separate entity prior to being wound into a string,” but is “no longer a separate entity in a configuration of a string.” (*Id.*, 69:20-70:11.) Yet, he could not explain when two filaments cease being “separate physical entities.” When asked “how many points would the threads have to interact at for them to no longer be separate physical entities,” PO's expert conceded,

“There’s no straightforward answer to that question, frankly.” (*Id.*, 72:15-73:13; *see also id.*, 77:5-80:13 (changing definition to require “discrete physical exterior”).) The ’384 patent never uses “separate physical entity,” and the expert’s inability to reasonably define the phrase illustrates the problem with importing “separate” into the claims.

PO also argues the restriction during prosecution limits the claims to Figure 7. *See Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1351-52 (Fed. Cir. 2013) (“The election of an invention in response to an ambiguous restriction requirement in turn cannot be said to provide any guidance forming a basis for narrowing a broadly drafted claim.”). Yet, as discussed above, PO’s expert argues the claims are not limited to Figure 7, and he confirmed the restriction did not influence his opinions regarding the ’384 patent. (Ex. 1062, 99:10-102:10; Exs. 1058-1059.)

Further, the original claims *all* required first and second filaments configured in loops around the tube. (Ex. 1002, 340-345.) The restriction found that those claims covered the sub-species in Figures 6-9. (*Id.*, 231-232). Thus, because the original claims covered Figure 6, which discloses a “single filament,” the strands within the single filament must meet the first and second filament limitations. While PO elected the Figure 7 sub-species for examination, PO never amended the claims to require “separate” first/second filaments or otherwise exclude Figure 6. (*Id.*, 212-220.) Moreover, even if the restriction somehow excepted Figure 6, the restriction

was withdrawn before allowance. (*Id.*, 18.) Thus, the restriction supports Petitioner's understanding of the claim scope.

PO also argues that Mr. Thornton provided “contradictory obviousness positions” regarding filament and testified that a POSITA “could pick and choose the meaning of filament.” (POR, 27.) PO is incorrect. Mr. Thornton accurately testified that the '384 patent “has a very broad definition of filament in that column 9,” which includes “a monofilament” and “one or several threads, lines, cords, et cetera.” (Ex. 2009, 39:12-40:1.) Thus, rather than “render[ing] the term filament meaningless,” Mr. Thornton gives full effect to the patent disclosure. (*Id.*, 39:3-11; *see also id.*, 35:5-22; POR, 27.)

B. POSITAs Would Have Been Motivated to Combine Schaffer with Hartley and/or Eller

The Petition demonstrated that challenged claims 1-4, 6-18, and 20-30 would have been obvious in view of Schaffer's valve combined with Hartley's strings and/or Eller's wires. (Petition, §§VI, VII.) In the Related FWDs, the Board found those same invalidity grounds rendered the challenged claims obvious. (Ex. 2004, 49-68; Ex. 1056, 43-71; Ex. 1057, 43-62.) PO again argues that a POSITA would not have been motivated to combine Hartley's strings or Eller's wires with Schaffer's valve. (POR, §III.F.) PO raises identical arguments to the ones the Board rejected in the related IPRs. (Ex. 2004, 49-68; Ex. 1056, 43-71; Ex. 1057, 43-62.) PO has not identified any issue that the Board previously misapprehended or

overlooked. *See* 37 C.F.R. § 42.71(d). Thus, the Related FWDs resolve PO's challenges to the motivation to combine.

1. Hartley's Strings or Eller's Wires Seal More Effectively In Some Situations

A POSITA would have been motivated to combine Schaffer with Hartley or Eller because “Hartley's string [or Eller's wire] may seal more effectively across a wider range of diameters and shapes for the inserted devices (e.g., other catheters or tools) than Schaffer's U-shaped actuating members.” (Petition, 30, 44-45; Ex. 1003, ¶¶71, 92.) In the Related FWDs, the Board found that Hartley's string or Eller's wire “would provide more uniform constriction and compression around the outer diameter of some commonly-used tools and including tools with diverse shapes and sizes.” (Ex. 2004, 54; Ex. 1056, 56; Ex. 1057, 54.) PO provides no reason for the Board to deviate from its prior decisions.

Instead, PO repeats its argument from the related IPRs that Schaffer's valve would not form any gaps because it “forms a complete seal” due to a gelatinous seal member 165. (POR, 62-64.) The Board rejected this argument for several reasons.

First, Schaffer's highly compliant, gelatinous seal module is an optional embodiment. (Ex. 1003, ¶109; Ex. 2004, 58-59; Ex. 1056, 60-61; Ex. 1057, 58.) Second, PO's expert, Dr. Zalesky, “does not disagree that a flexible string or wire would have carried [an] advantage” over Schaffer's actuating members. (Ex. 2004, 54; Ex. 1056, 56; *see also* Ex. 1016, 86:19–87:4.) Third, “even in Schaffer's

preferred embodiments that use a highly-compliant, ‘sticky’ or ‘gelatinous’ material ... Schaffer teaches that such embodiments are capable of forming a *nearly* fluid/gas tight seal.” (Ex. 2004, 57 (emphasis in original); Ex. 1056, 58; Ex. 1005, [0059].) Accordingly, “Schaffer does not ... teach that its valves provide a perfect seal in all embodiments and under all circumstances.” (Ex. 2004, 53-54, 56-57; Ex. 1056, 56-58.)

PO also repeats its argument from the related IPRs that Schaffer combined with Hartley’s string or Eller’s wire would not seal “around multiple/irregularly shaped instruments.” (POR, 66.) The Board rejected this argument because it “presumes that Schaffer’s valve includes the highly compliant seal module,” which Schaffer describes as an optional feature. (Ex. 2004, 60; Ex. 1056, 62; Ex. 1003, ¶112.) The same reasoning applies here.

2. Hartley’s Strings Or Eller’s Wires Would Not Change Schaffer’s “Principles Of Operation”

PO argues that Petitioner’s combinations would “require departing from Schaffer’s principles of operation.” (POR, 65.) PO similarly argues that Petitioner’s combinations would “fundamentally change[] how Schaffer seals.” (*Id.*, 68.) However, the Board found in the Related FWDs that Schaffer’s “principle of operation is materially unchanged if Hartley’s string or Eller’s wire is substituted for Schaffer’s U-shaped actuating members.” (Ex. 2004, 63; Ex. 1056, 65; Ex. 1003, ¶¶113-124.) PO does not identify any error in the Board’s prior findings.

PO also repeats its argument from the related IPRs that using a string/wire in Schaffer would impact manufacturability. (POR, 64.) The Board previously rejected this argument, finding that “the engineering techniques needed to implement [a string or wire into Schaffer] would have been routine and straightforward.” (Ex. 2004, 66; Ex. 1056, 67-68; Ex. 1003, ¶119.) Thus, manufacturability would not have dissuaded a POSITA from combining the references. (Ex. 1003, ¶¶116-121; Ex. 2004, 65-66; Ex. 1056, 66-67.)

3. The Combination Is A Simple Substitution Of Known Elements

PO repeats its argument from the related IPRs that combining Schaffer with Hartley's string or Eller's wire would not be a simple substitution of known elements because no single reference discloses a valve with a string/wire attached to two actuators.³ (POR, 54-58, 64-67.) As discussed above, the Board previously rejected this argument, finding it “is tantamount to a complaint that none of Schaffer, Hartley, or Eller is anticipating” and does not undermine Petitioner's obviousness grounds. (*Supra* §II.A.1.a; Ex. 2004, 66-67; Ex. 1056, 69-70.)

4. A Finite Number Ways Existed To Constrict A Hemostasis Valve

PO also repeats its argument from the related IPRs that “Petitioner has failed to demonstrate that the options and solutions for ‘constricting the lumen of a tubular

³ PO also suggests that a limitation is absent from the combination. (POR, 54-58.) That argument also fails. (Ex. 1057, 43 n.18, 61.)

member in a hemostasis valve' were finite, identified, and known.” (POR, 67.) Yet, the Board found in the Related FWDs that the evidence demonstrates four known options for constricting a hemostasis valve. (Ex. 2004, 55-56; Ex. 1057, 57; Ex. 2011, 118:4-15.) A POSITA would have found it obvious to select any of these finite, predictable options. (Ex. 1003, ¶¶72, 94; Ex. 2004, 55-56; Ex. 1056, 57.)

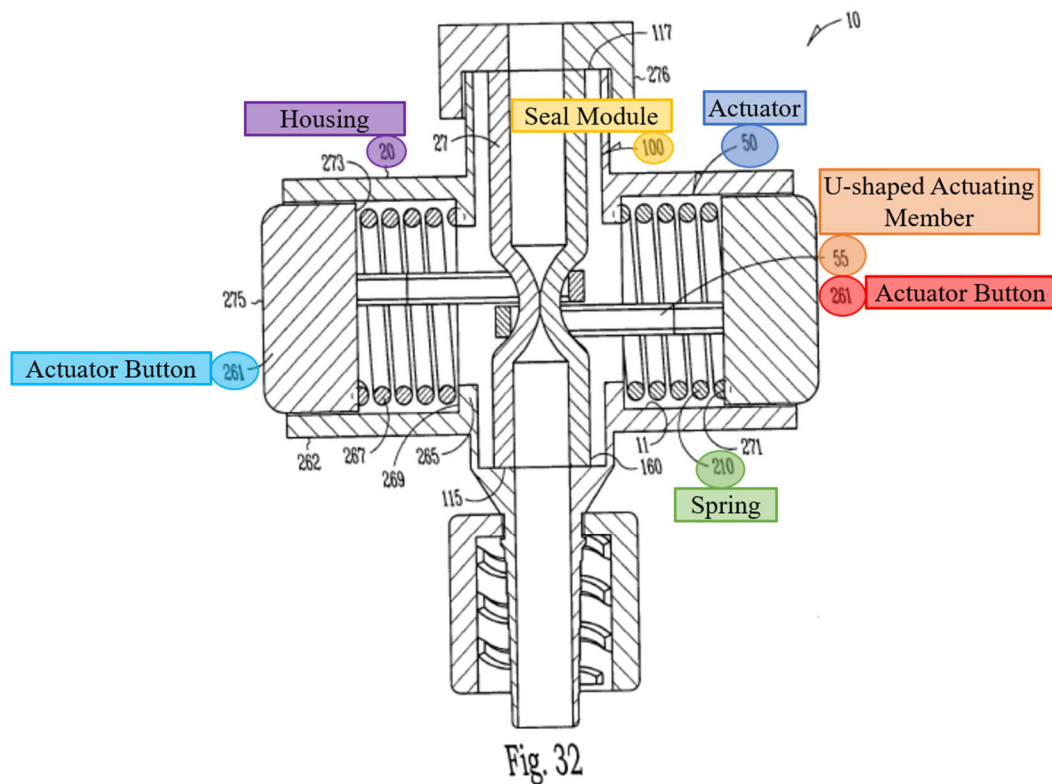
C. Petitioner's Combinations Are Not Based on Hindsight

PO also repeats its argument that Petitioner has proposed “evolving theories of obviousness” based on hindsight. (POR, 58-62.) PO is incorrect.

Petitioner has consistently explained that POSITAs would have recognized several ways to improve Schaffer's valve. (*See, e.g.*, Ex. 2004, 41-45; Ex. 1056, 43-47; Ex. 1057, 34-38.) PO's suggestion that a POSITA can recognize only one obvious solution is incorrect. *See, e.g., Intel Corp.*, 21 F.4th at 800; *In re Fulton*, 391 F.3d at 1200. The Board rejected PO's similar hindsight arguments in the Related FWDs. (Ex. 2004, 52-53; Ex. 1056, 54-55; Ex. 1057, 62 n.21.)

D. Claim 9 - Schaffer's Actuator Buttons Are Movably Coupled To The Housing

Dependent claim 9 requires a “rigid housing” and that the “actuators are movably coupled to the housing.” Schaffer's valve includes a housing 20 and two actuator buttons that are coupled to the housing within the cylindrical outer wall 262:



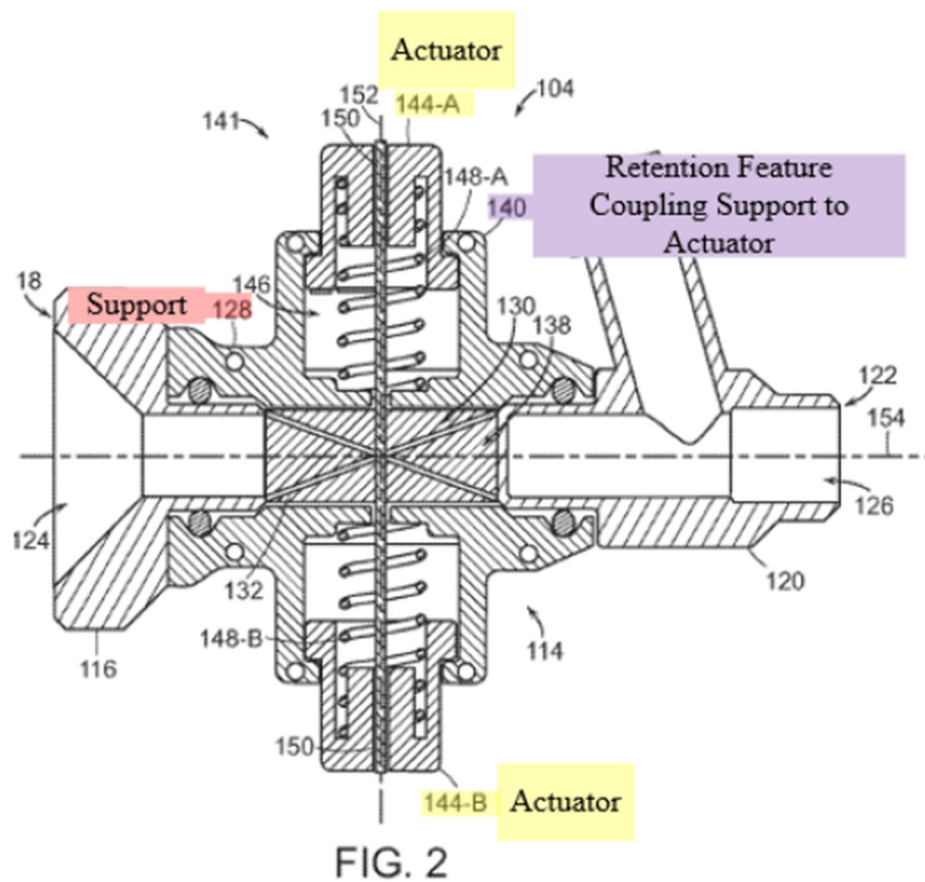
(Petition, 63-64; Ex. 1005, [0076], Fig. 32.) Schaffer's actuator buttons "are configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second position." (Ex. 1005, [0076]; *see also id.*, [0077] ("each actuator 50 slides along the cylindrical interior wall 11 of the housing 20").) Schaffer's housing also includes an inner flange 265 that restrains the resilient members 267 and actuator buttons 261. (*Id.*) Thus, Schaffer's actuator buttons are "movably coupled" to Schaffer's housing at least because the buttons are retained within the housing's cylindrical walls and move along the walls. (*Id.*; Ex. 1003, ¶¶154-155.)

PO argues that “Schaffer’s actuator buttons 261 are not ‘movably coupled to’ the housing 20” because the “actuator buttons 261 and the actuating members 55 are held in place only by the resistive force of the seal module 100 against the U-shaped actuating members 55.” (POR, 71.) But that is not true. As shown above, Schaffer’s actuator buttons fit within the cylindrical walls of Schaffer’s housing and slide along the walls. (Ex. 1003, ¶¶154-155.) The inner flange further restricts the actuator buttons. (*Id.*) Thus, the cylindrical housing and inner movably couple the buttons to the housing. PO presents no evidence to suggest that the friction fit between the actuator buttons and the cylindrical walls do not help hold the buttons in place.

Further, even if Schaffer’s actuator buttons were “held in place only by the resistive force of the seal module 100 against the U-shaped actuating members,” Schaffer’s actuator buttons would still be movably coupled to the housing through the actuating members (or Hartley’s strings/ Eller’s wires) and seal module. (See Ex. 1005, [0076]-[0077], [0083], Figs. 30-34); *see, e.g., Bradford Co. v. Conteyor N. Am., Inc.*, 603 F.3d 1262, 1270-71 (Fed. Cir. 2010) (construing “coupled” to encompass direct or indirect attachment); *Mizuho Orthopedic Sys., Inc. v. Allen Med. Sys., Inc.*, 610 F. Supp. 3d 367, 372-373 (D. Mass. 2022) (similar); *Allen Med. Sys., Inc. v. Schuerch Corp.*, No. CV 15-13024-GAO, 2020 WL 3489611, at *3 (D. Mass. June 26, 2020) (similar).

PO also argues that Schaffer's actuator buttons are not "indirectly coupled via Hartley's string or Eller's wire to the housing 20." (POR, 72.) But the cited evidence does not mention indirect coupling. (*Id.*; Ex. 2008, ¶99.) PO's argument also conflicts with the '384 patent, which discloses that components can be indirectly "coupled" to each other "via one or several other components of the valve." (Ex. 1001, 11:35-37.)

PO also argues that Schaffer's valve is distinguishable from the valve pictured in Figure 2 of the '384 patent because it lacks retention features:



(See POR, 72-73; Ex. 1035, 57:15-22.) But none of the challenged claims recite a “retention feature.” (Ex. 1061, 55:4-8, 57:23-58:1); *see, e.g., Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 792 (Fed. Cir. 2010) (warning against importing limitations from preferred embodiments).

Further, the retention features are *optional*. (Ex. 1001, 8:17-23); *see, e.g., Trovan Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1306 (Fed. Cir. 2002) (warning against importing limitations). PO's expert confessed he erroneously believed the retentions features were required, undermining his opinions. (Ex. 1062, 121:3-19.) If these optional retention features were removed from Figure 2, then Figure 2 would look almost identical to Schaffer.

III. MR. THORNTON'S TESTIMONY IS CREDIBLE

PO repeats its argument from the related IPRs that Mr. Thornton's testimony should be afforded little weight because Petitioner's proposed POSITA definition does not require experience designing hemostasis valves. (POR, 17-18.) In the Related FWDs, the Board found that a POSITA would have “engineering experience related to products in the field of the invention, which involves endovascular devices and the surgical procedures that use such devices,” but does not need firsthand experience designing such devices, including hemostasis valves. (Ex. 1061, 13.) The Board also found that Mr. Thornton qualifies as a POSITA and is “capable of credibly testifying about the issues in dispute” from a POSITA's perspective. (*Id.*,

14.) PO does not identify any reason for the Board to reach a different conclusion here.

IV. CONCLUSION

Petitioner has established by a preponderance of the evidence that the challenged claims are unpatentable and, therefore, requests that the Board cancel the claims.

Respectfully submitted,

KNOBBE MARTENS OLSON & BEAR, LLP

Dated: September 1, 2026 By: /Joshua J. Stowell/
Joshua J. Stowell (Reg. No. 64,096)
Joseph R. Re (Reg. No. 31,291)
Brian C. Barnes (Reg. No. 75,805)

Attorneys for Petitioner
Imperative Care, Inc.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this **PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE** contains 5,587 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24 (c).

Dated: September 1, 2026 By: /Joshua J. Stowell/
Joshua J. Stowell (Reg. No. 64,096)
KNOBBE MARTENS OLSON & BEAR, LLP

CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e), a true and correct copy of **PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE and EXHIBITS 1058-1065** are being served electronically on April 9, 2026, to the e-mail addresses shown below:

Joseph Hamilton
Reg. No. 51,770
hamilton-ptab@perkinscoie.com
Inari-Imperative@perkinscoie.com
PERKINS COIE LLP
1888 Century Park East, Suite 1700
Los Angeles, CA 90067-1721
Tel: (310) 788-3271

ajtessar@hollandhart.com;
dtkeese@hollandhart.com;
tjbervik@hollandhart.com

Paul Parker
Reg. No. 38,264
parker-ptab@perkinscoie.com
Matthew Williams
Reg. No. 77,516
williams-ptab@perkinscoie.com
PERKINS COIE LLP
1201 Third Avenue, Suite 4900
Seattle, WA 98101-3099
Tel: (206) 359-8000

Dated: September 1, 2026

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)
KNOBBE MARTENS OLSON & BEAR, LLP