

Petitioner Imperative Care's Demonstratives For Oral Argument

October 29, 2025

Imperative Care, Inc. v. Inari Medical, Inc.
IPR2024-01157 (Patent 11,697,011)

Imperative Care v. Inari Medical
IPR2024-01157
Imperative Care Ex. 1023

Outline of Petitioner's Oral Argument

- ⌚ Overview of IPR Proceedings
- ⌚ Schaffer + Hartley or Eller Render the Challenged Claims Obvious
- ⌚ Schaffer Anticipates or Renders The Challenged Claims Obvious
- ⌚ The Board Should Deny PO's Motion to Exclude

Overview of IPR Proceedings

IPR Grounds

Ground	References	Basis	Challenged Claims
1	Schaffer	35 U.S.C. § 102	1-9
2	Schaffer	35 U.S.C. § 103	1-9
3	Schaffer + Hartley	35 U.S.C. § 103	1-9
4	Schaffer + Eller	35 U.S.C. § 103	1-9
5	Hartley + Eller	35 U.S.C. § 103	1-3, 5-6, 9

Issues In Dispute

Grounds 3-4: Schaffer + Hartley or Eller

- ⦿ Would a POSITA have been motivated to combine Schaffer + Hartley or Eller?

Grounds 1-2: Schaffer

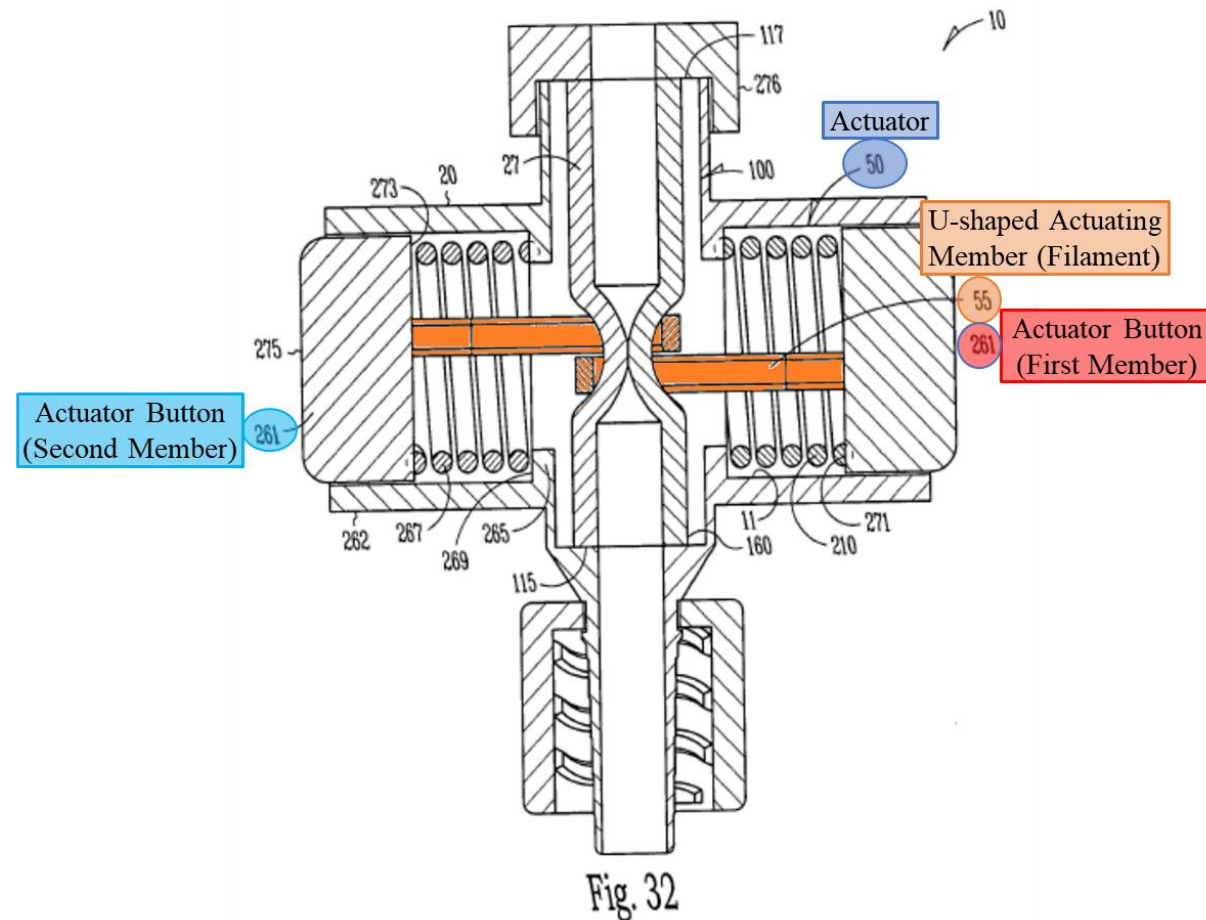
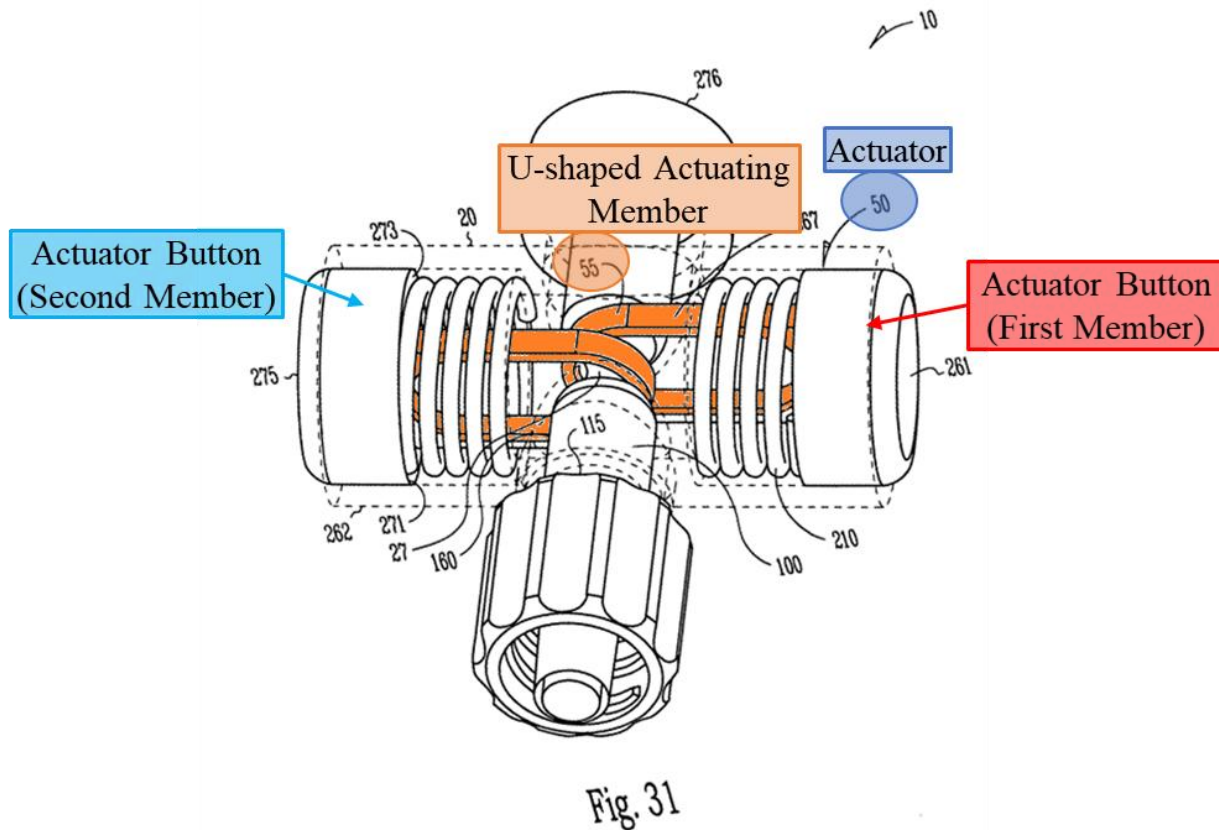
- ⦿ Does the term “filament” require a “thin, flexible length of material”?
- ⦿ Does Schaffer disclose a “filament” regardless of construction?
- ⦿ Do Schaffer’s actuating members “circumferentially constrict”?
- ⦿ Do Schaffer’s actuating members form a “loop”? (Claim 3 only)

Issues Not In Dispute

- ⌚ No dispute that Hartley and Eller disclose a “filament”
- ⌚ PO raises no arguments concerning Schaffer + Hartley or Eller and the dependent claims
- ⌚ PO raises no arguments concerning dependent claims 2 and 4-9
- ⌚ No dispute that Petitioner’s references qualify as prior art
- ⌚ No evidence of secondary considerations of nonobviousness

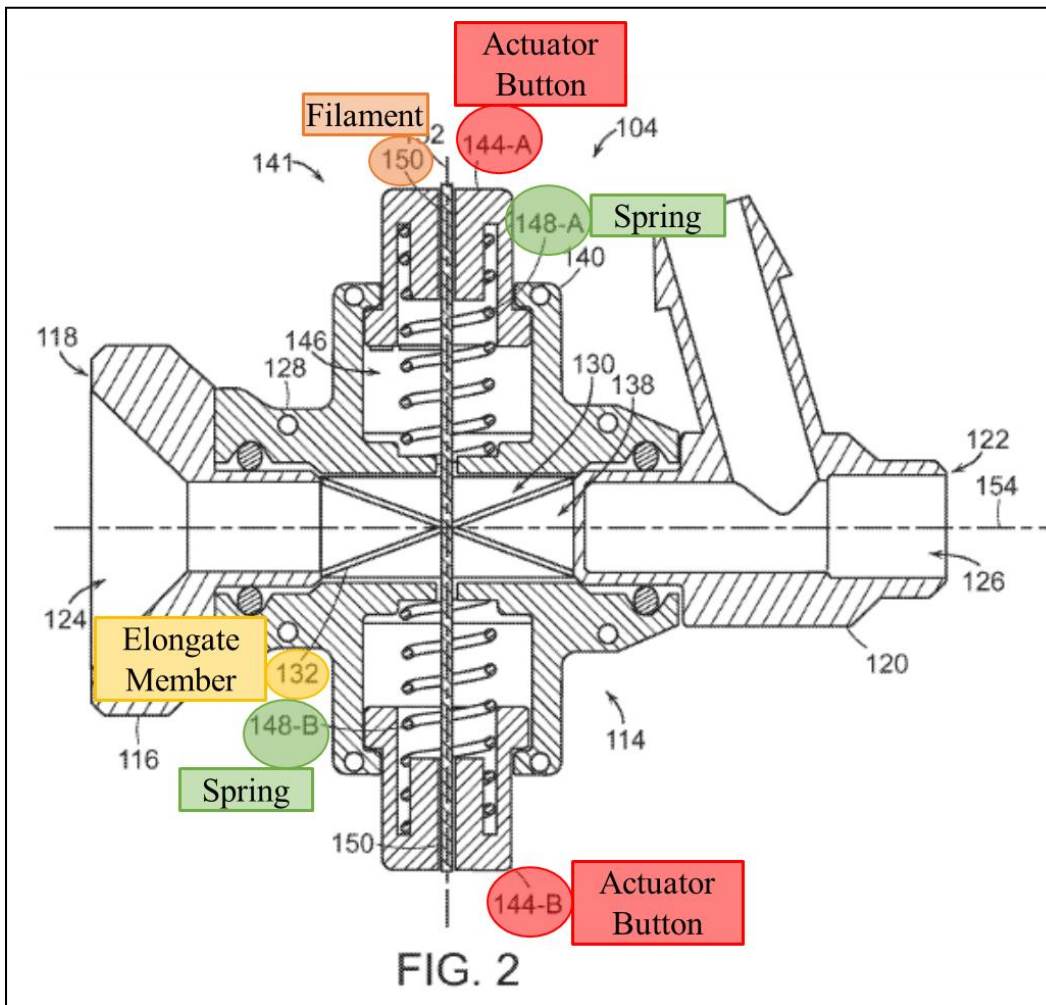
Grounds 3-4: Schaffer + Hartley or Eller Renders the Claims Obvious

Overview of Schaffer

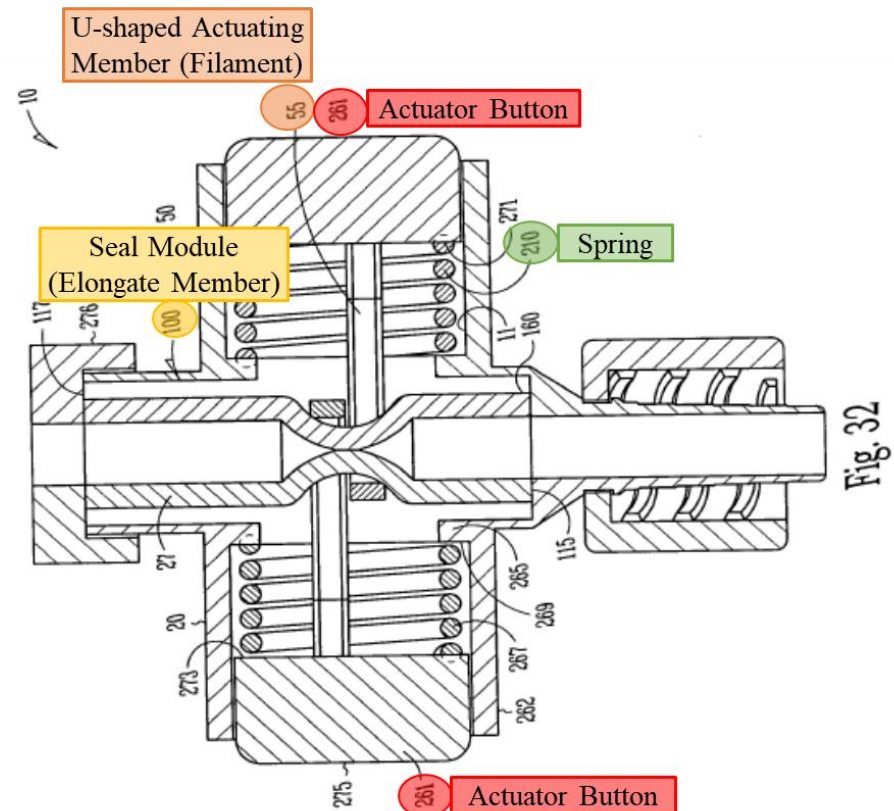


Schaffer Compared To The '011 Patent

'011 Patent



Schaffer



Hartley Discloses a “Filament”

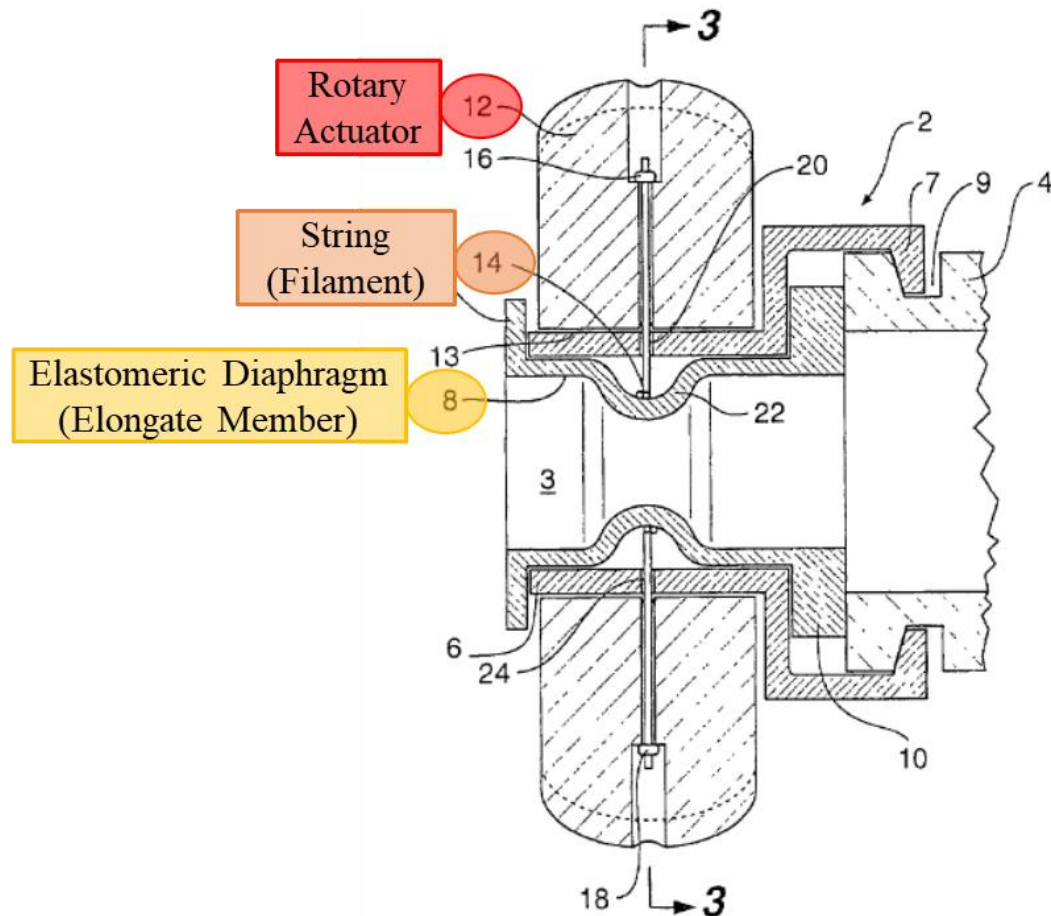


Fig 1

(57)

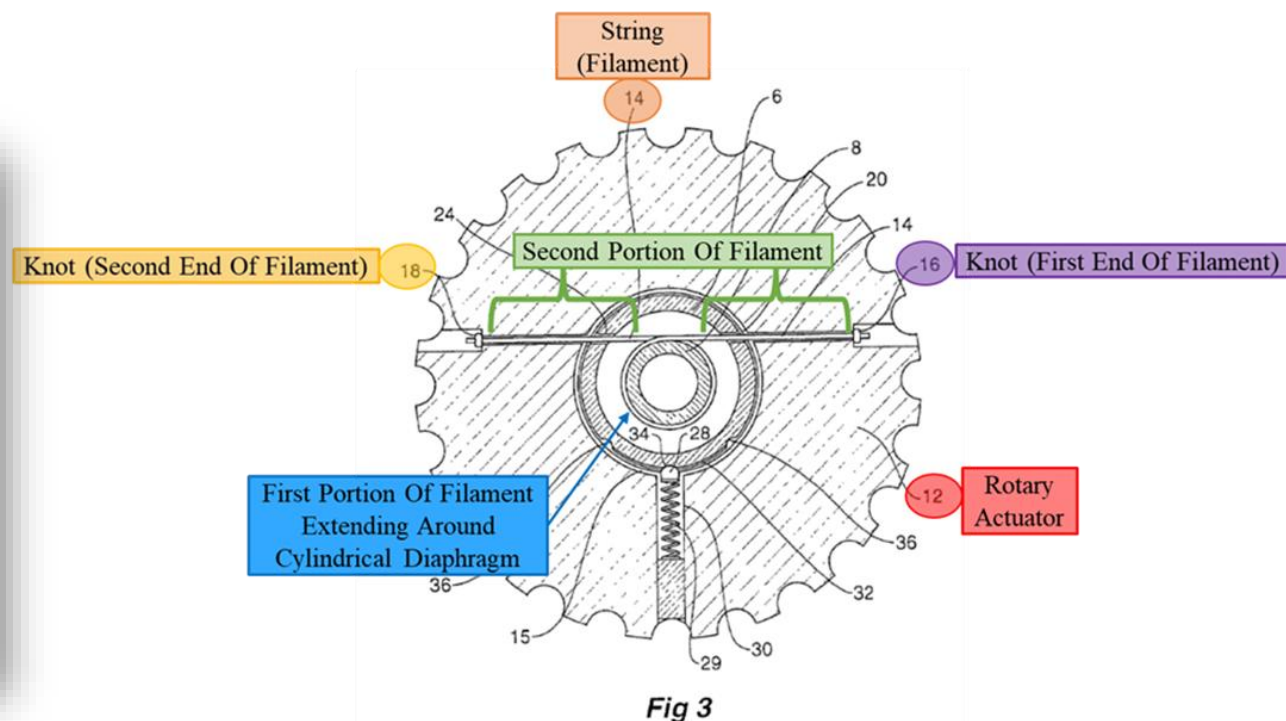
ABSTRACT

An access valve (2) for a laparoscopic device or a intraluminal deployment device has a cylindrical diaphragm (8) with a longitudinal aperture (3), a flexible member (14) is passed circumferentially around the cylindrical diaphragm and an extension arrangement to pull the flexible member radially and/or tangentially to constrict the diaphragm to at least partially close off the longitudinal aperture. A rotary actuator may be used (12).

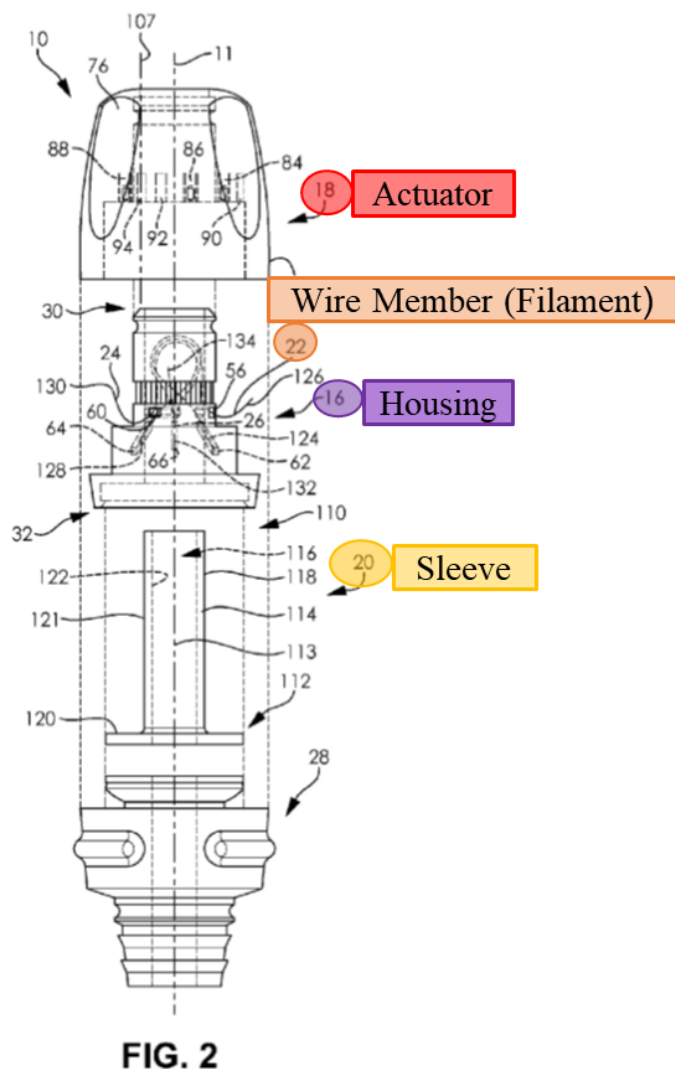
[0017] The flexible member may be a string, suture or band or other suitable material.

Simple Methods to Attach Hartley's Filament to Actuator

diaphragm. A string 14 is mounted into the rotary actuator with a knot 16 at one end and then passes through an aperture 20 in the cylindrical housing 6 and then is wound preferably twice around the cylindrical diaphragm 8 preferably in a recessed region 22 and then passes through a further aperture 24 in the cylindrical housing before being fixed by knot 18 again in the rotary actuator. Rotation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted.



Eller Discloses a “Filament”



FIGS. 1, 2, 3, 4, 5, 6, 7, 8A, 8B, 8C, 9A, 9B, 9C, 10A, 10B, and 10C illustrate an embodiment of a selective fluid barrier valve device 10 that has a lengthwise axis 11, a proximal end 12, a distal end 14, a housing 16, an actuator 18, a sleeve 20, a first wire member 22, a second wire member 24, a third wire member 26, and a connector 28. The

ment. Example materials considered suitable to form a wire member include biocompatible materials, materials that can be made biocompatible, braided materials, wound materials, twisted materials, noncompliant materials, metals such as steel, stainless steel, titanium, nickel-titanium alloys, polymers, polypropylene, polyester, Nylon, polyethylene, polyvinyl chloride, polystyrene, compliant materials, flexible materials (e.g., materials that are relatively more flexible than the material that forms the housing), and any other material considered suitable for a particular embodiment.

Simple Methods to Attach Eller's Filament to Actuator

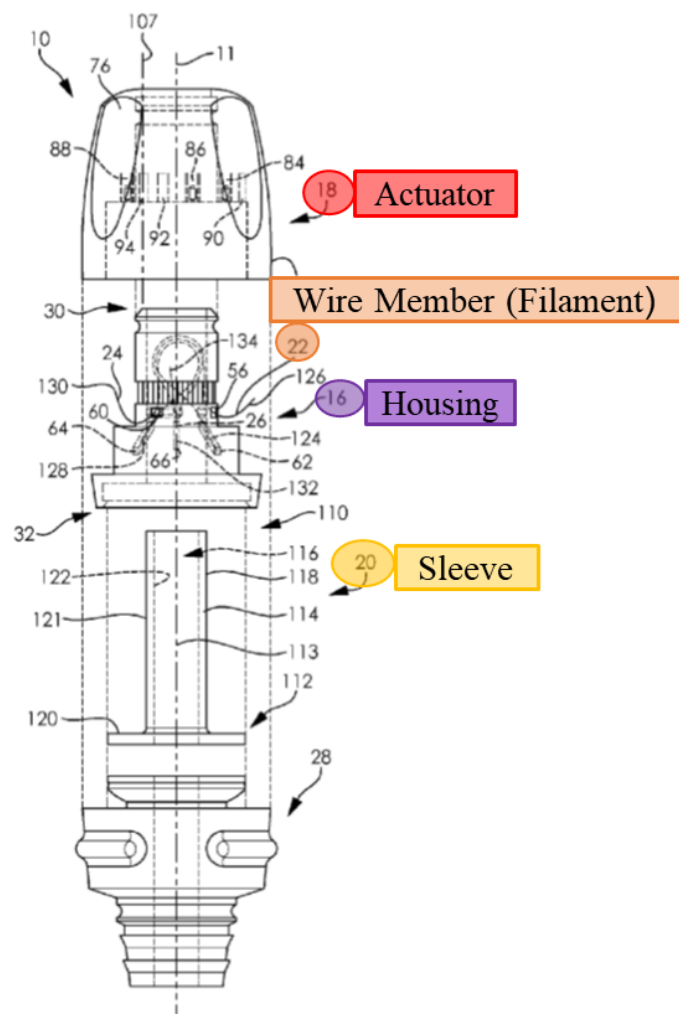


FIG. 2

Attachment between a wire member and a housing and/or an actuator can be accomplished using any suitable method or technique, and skilled artisans will be able to select a suitable method or technique to attach a wire member to a housing and/or an actuator according to a particular embodiment based on various considerations, including the material(s) that forms the wire member. Example methods and techniques considered suitable to attach a wire member to a housing and/or an actuator include using adhesives, welding, fusing, providing a friction fit between the wire member and the housing and/or actuator, and any other method or technique considered suitable for a particular embodiment. For example, a wire member can have an

First Motivation to Combine Schaffer + Hartley

80. A person of ordinary skill in the art would have been motivated to replace Schaffer's U-shaped actuating members with Hartley's string/flexible member for several reasons. First, a person of ordinary skill in the art would have been motivated by Hartley's disclosure that its valve employing the string can "close over a range of diameters of devices passed through the valve or can close completely down to be self sealing." Ex. 1006 at [0037]. A person of ordinary skill in the art would have known that multiple tools of varying sizes could be required for a medical procedure, so Hartley's ability to seal around a range of diameters would have been beneficial. A person of ordinary skill in the art would have also recognized that a stasis valve should seal and prevent leakage of fluid

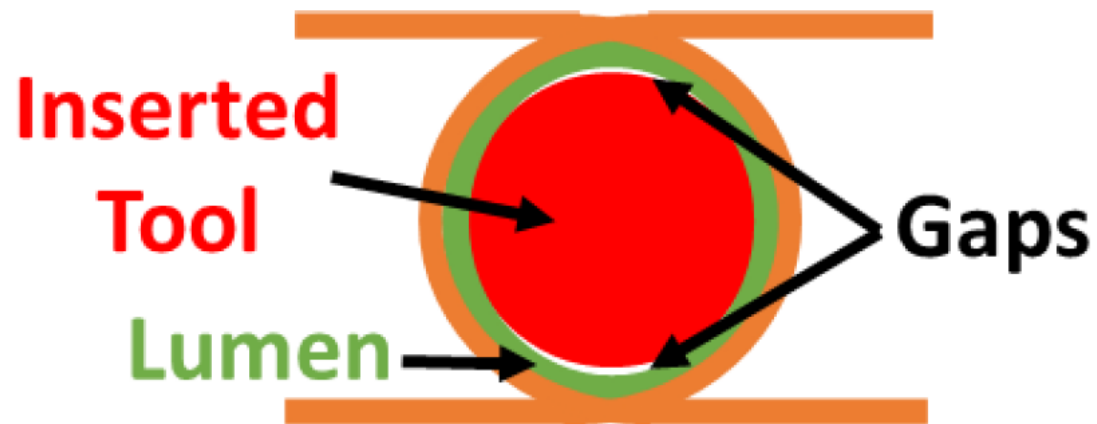
even when no tool is inserted through the valve, such as at the beginning or end of a medical procedure. Thus, Hartley's stated ability of its string to completely close the lumen when no tool is inserted would have also been a valuable benefit to a person of ordinary skill.

First Motivation to Combine Schaffer + Eller

93. A person of ordinary skill in the art would have been motivated to replace Schaffer's U-shaped actuating members with Eller's wire member for several reasons. First, a person of ordinary skill in the art would have been motivated by Eller's description that the wire member can form a seal around one or more medical devices passed through the valve to prevent fluid from leaking around the device. Ex. 1007 (Eller) at 15:21-40, 17:38-43, 18:3-8. A person of ordinary skill in the art would have also recognized that a stasis valve should seal and prevent leakage of fluid when a tool is inserted through the valve during a procedure. Thus, Eller's ability to seal around such devices would have been beneficial to a person of ordinary skill.

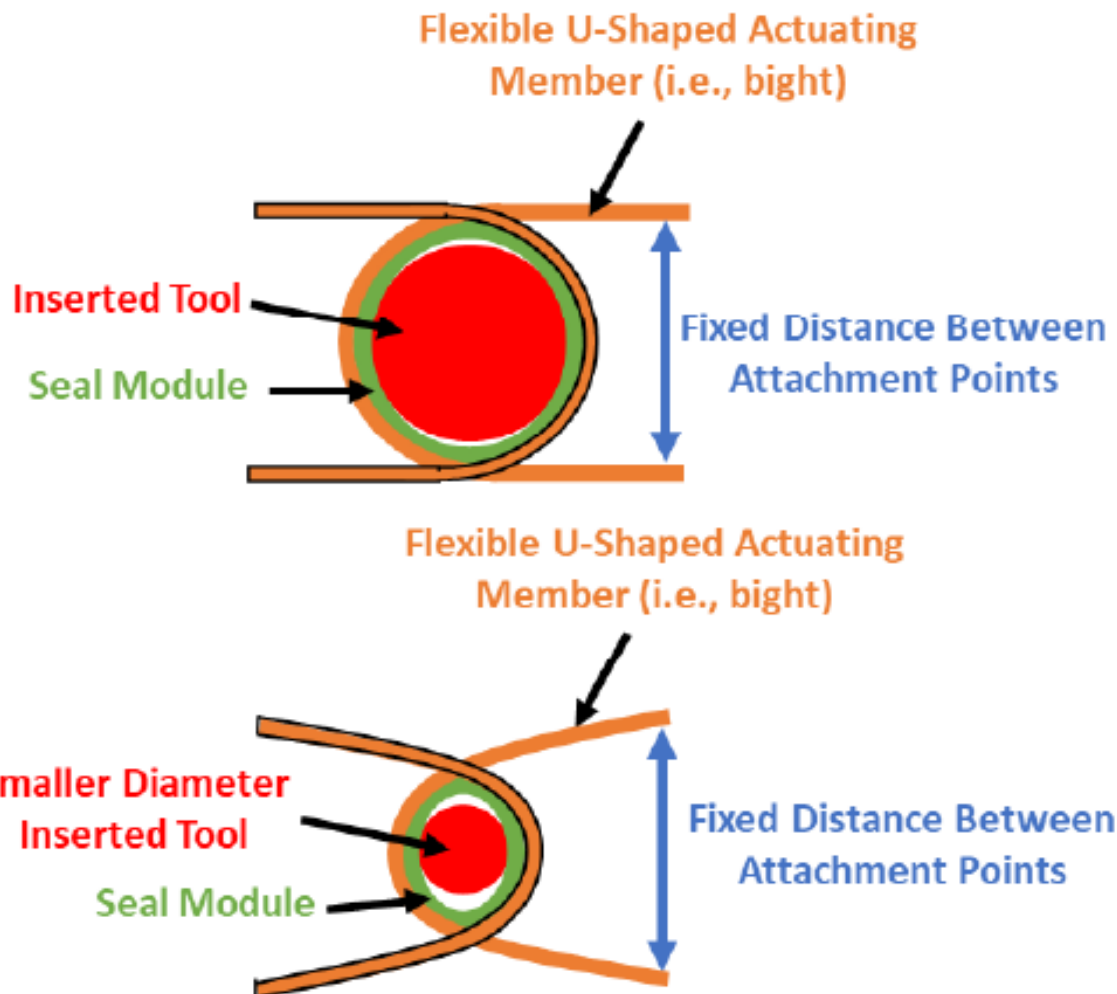
Second Motivation to Combine Schaffer + Hartley or Eller

81. Second, a person of ordinary skill in the art would have recognized that Hartley's flexible string may better seal the valve than Schaffer's metallic/plastic U-shaped actuating members. Hartley's flexible string may better conform to varying diameters than Schaffer's U-shaped members. A person of ordinary skill in the art would have recognized that if a tool did not fit the size of Schaffer's U-shaped members, small gaps could form between the tool and the valve's lumen, as illustrated in the graphic below:



However, Hartley's string encircles and, depending on the materials, may conform to the size and shape of a wider range of tools used with the valve. This ability to accommodate more tools would have been a highly desirable feature to a person of ordinary skill in September 2017.

Gaps Due to Shape and Attachment to Buttons



Thornton Supp. Decl.

Id. at Fig. 31. Because of this arrangement, even when the U-shaped actuating members (or bights) are relatively flexible, the fixed attachment points to the actuator buttons may prevent the U-shaped actuating members from completely conforming to the exterior of a tool with a smaller diameter than the distance between the attachment points, as I've illustrated below:

PO's Argument Schaffer Would Not Form Small Gaps Lacks Support

PO Response

A. Petitioner's Stated Motivation to Modify Schaffer or Combine Schaffer with Hartley or Eller Is Contradicted by Schaffer and the Statements of Petitioner and Its Expert

First, Petitioner's asserted motivation to modify Schaffer alone or substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members is manufactured from whole cloth. Based on its expert's statements, Petitioner

Indeed, Schaffer's valve does form a complete seal with or without instruments inserted therethrough. Specifically, Schaffer discloses that its rigid U-

Schaffer Forms a “Nearly Fluid/Gas Tight Seal”

PO Response

Indeed, Schaffer’s valve does form a complete seal with or without instruments inserted therethrough. Specifically, Schaffer discloses that its rigid U-shaped members 55 do not result in gaps due to the inclusion of sealing member 165. EX1005, ¶[0059]; EX2008, ¶¶129-153. Schaffer discloses that its valve creates a “nearly fluid/gas tight seal under very light compression,” a functionality achieved using materials that, for example, “can be compared to a gelatinous substance.” EX1005, ¶[0059]. Schaffer discloses that this compliant material ensures a complete

Schaffer

[0059] In one embodiment, the third central seal member 165 includes material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible. Materials 166 include modified vinyl, silicone, polyurethane or a combination thereof. The basic materials are, in one option, modified by compounding them with waxes and/or oils or un-cross-linked modifiers. Such materials are commonly available as “C-Flex” or “Kraton” in the range of 5 to 15 (shore A), as examples. The shore hardness of the material 166 is, in another option, in the range of between 15-20 shore on the “00” scale. This provides a material 166 that is extremely soft and compliant and intrinsically “sticky”. An extremely low shore hardness of the third central seal member 165 material 166 allows the third central seal member 165 to be easily compressed upon itself or upon an inserted instrument. For illustrative purposes only, the nature of the material 166 of the third central seal member 165 can be compared to a gelatinous substance. The material 166 exhibits a “selfclosing” nature in that it sticks occlusively to itself forming a nearly fluid/gas tight seal under very light compression.

Figs. 30-34 Do Not Require “Third Seal Member 165”

Schaffer

[0075] FIGS. 30-34 illustrate one embodiment of the stasis valve 10 including a seal module 100 having a lumen sized to allow the passage of fluids or gases. The seal module 100 includes a containment structure 160 with a proximal end 115 and a distal end 117. The seal module 100 is formed of one or more seal members, as discussed above. In another option, the seal module 100 and/or any of its respective seal members can be formed of one or more materials, including their relative properties, as discussed above.

Schaffer

[0076] In one option, two circular actuators 50 are at least partially circumferentially disposed about a portion of the seal module 100 movable from a first position to a second position on opposing sides of the housing 20. The actuators

[0077] In the first position the actuating members 55 of the actuators 50 are, in one option, disposed and at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210). The lumen 193 of the third seal member 165 is at least partially collapsed by the compressive force 67. In the second position, the actuators 50 are disposed away from the portion 108 of the seal module 100 by a compressive force 67 (e.g. by depressing the distal end 275 of the actuator button 261). As each actuator button 261 is depressed, each actuator 50 slides along the cylindrical interior wall 11 of the housing 20. The

Schaffer Discloses Many Other Seal Module Materials

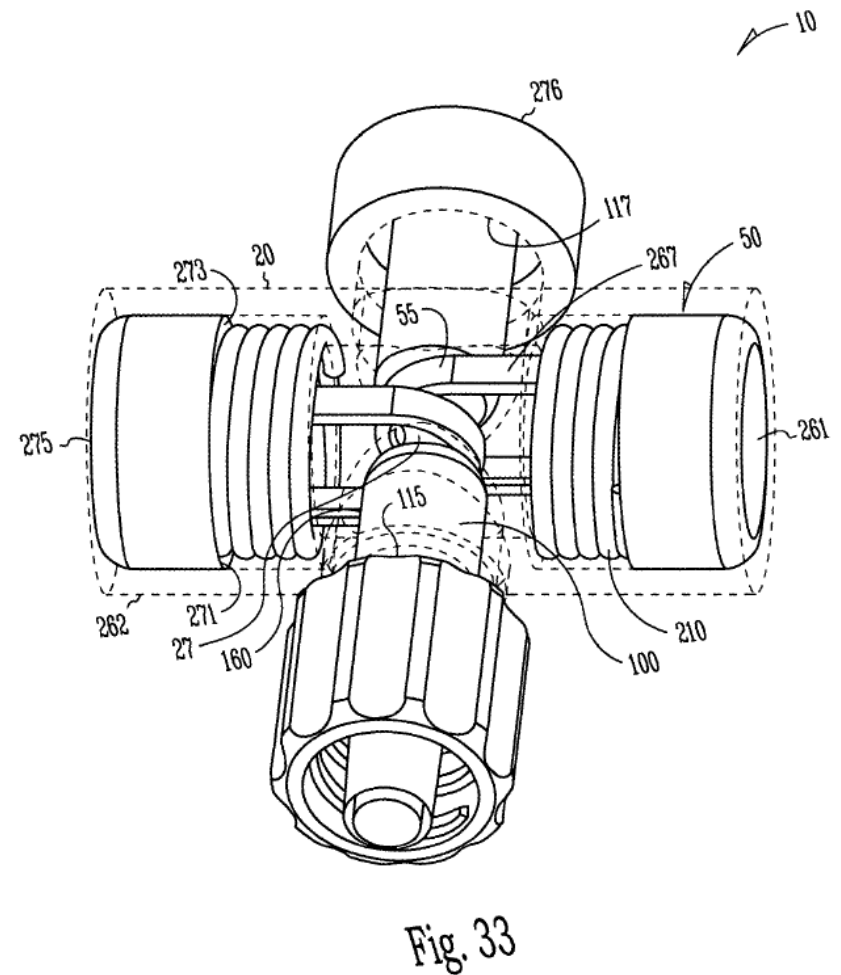
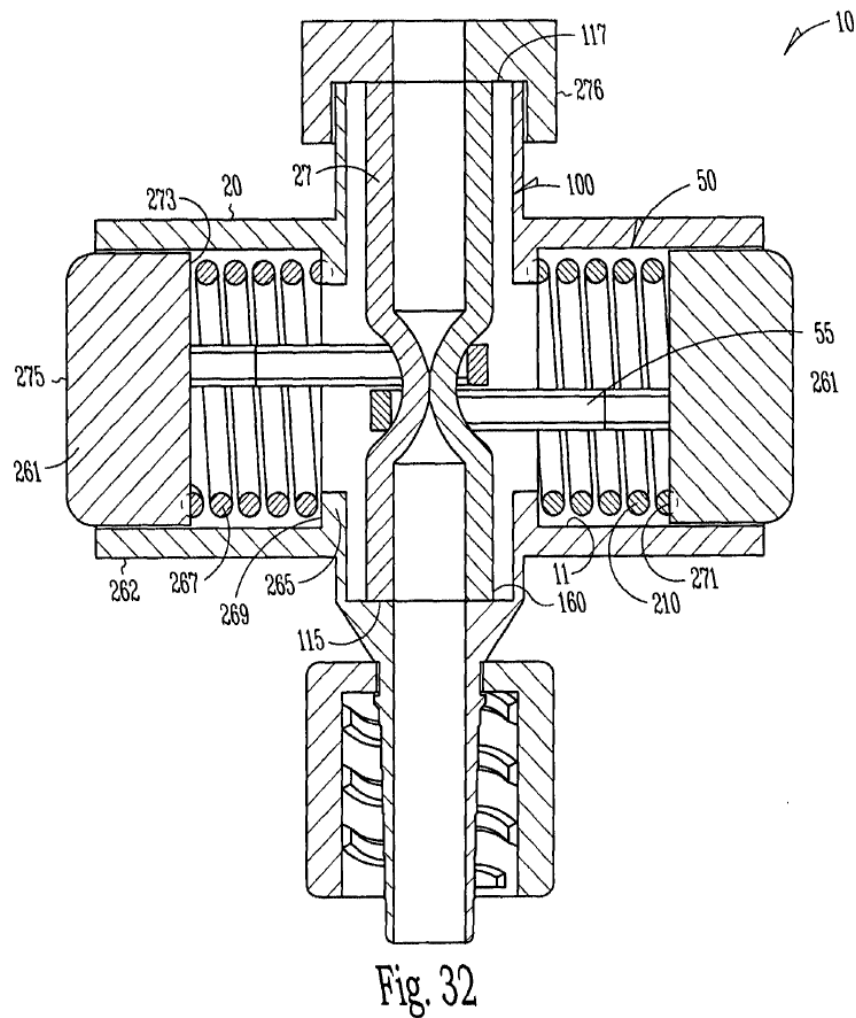
Schaffer

seal. In one option, a relatively **high durometer material** is used as the septum material for the first and second seal members **170** and **180** because it provides a low frictional coefficient against most inserted instruments while providing a competent seal. In another embodiment, one or more of the first, second, and third seal members **170**, **180**, and **165** includes **self-lubricating, lubricious or coated septum materials**. Such materials include **specialty silicones, natural latex, various synthetic rubbers or elastomeric compounds of polyurethane, vinyl or the like**. The low friction nature of the first and second seal members **170**, **180** is in contrast to the highly deformable and compliant nature of the third central seal member **165**.

Thornton Supp. Decl.

[0059]; *see also id.* at [0081]. **Schaffer discloses many other materials that would not be “sticky” or “gelatinous” that could make up that same portion of the valve, such as modified vinyl, silicone, or polyurethane.** *Id.* Nothing in Schaffer suggests that the third valve portion must be made with a “sticky” or “gelatinous” substance in all embodiments.

Figures 30-34 Do Not Identify Item 165



A “Sticky” Seal Would Not Work for Figs. 30-34

Schaffer

[0059] In one embodiment, the third central seal member 165 includes material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible. Materials 166 include modified vinyl, silicone, polyurethane or a combination thereof. The basic materials are, in one option, modified by compounding them with waxes and/or oils or un-cross-linked modifiers. Such materials are commonly available as “C-Flex” or “Kraton” in the range of 5 to 15 (shore A), as examples. The shore hardness of the material 166 is, in another option, in the range of between 15-20 shore on the “00” scale. This provides a material 166 that is extremely soft and compliant and intrinsically “sticky”. An extremely low shore hardness of the third central seal member 165 material 166 allows the third central seal member 165 to be easily compressed upon itself or upon an inserted instrument. For illustrative purposes only, the nature of the material 166 of the third central seal member 165 can be compared to a gelatinous substance. The material 166 exhibits a “selfclosing” nature in that it sticks occlusively to itself forming a nearly fluid/gas tight seal under very light compression.

Thornton Supp. Decl.

33. Third, a person of ordinary skill in the art would have recognized that highly “sticky” or “gelatinous” materials would not work well with the seal modules disclosed in Figures 31-34 because those seal modules must “retract to an uncollapsed configuration” when the tension on the module is released by the actuating members. *See id.* at [0077]. A seal module made of very “sticky” or “gelatinous” materials would not have the requisite resilience to return to its uncollapsed configuration. Thus, even if the seal module had some stickiness, a person of ordinary skill in the art would have understood that the seal module cannot be so sticky as to prevent the seal module from retracting to its unsealed state when the constricting force from the actuating members is removed. *See id.*; *see also id.* at [0054] (“The third central seal member 165 is sized and configured to maintain an open lumen 193 when no compressive force 67 is applied.”).

PO Cites No Evidence Petitioner Contradicted the Motivation to Combine

PO Response

Indeed, Petitioner's expert admitted at deposition that if Schaffer forms a complete seal, there would be no need to modify Schaffer's U-shaped actuating members, as follows:

Q. So if Shafer's U-shaped members formed a complete seal around multiple tools, there would be no reason to include Ellers' wire member or Hartley's string in Shafer; isn't that correct?

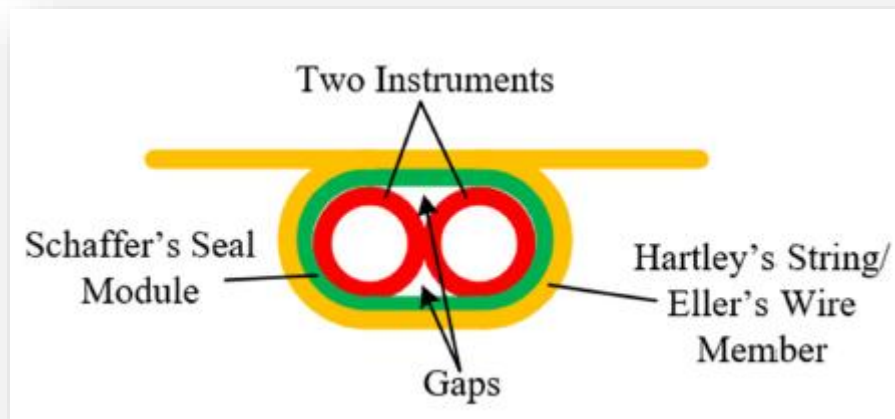
THE WITNESS: If it worked perfectly for all the range of tools, then there probably wouldn't be a need to make adjustments and move to a string-type member.

EX2007, 116:18-117:2.

PO's Argument Regarding Two Instruments Not Probative

PO Response

Petitioner's proposed combination would actually seal less effectively around multiple instruments inserted through Schaffer's valve and/or when an instrument is irregularly shaped—scenarios for which Schaffer's valve is designed to form a seal as explained above. For example, if two circular instruments were inserted side-by-



PO Cites A Different Embodiment in Schaffer

PO's reliance on this section erroneous because:

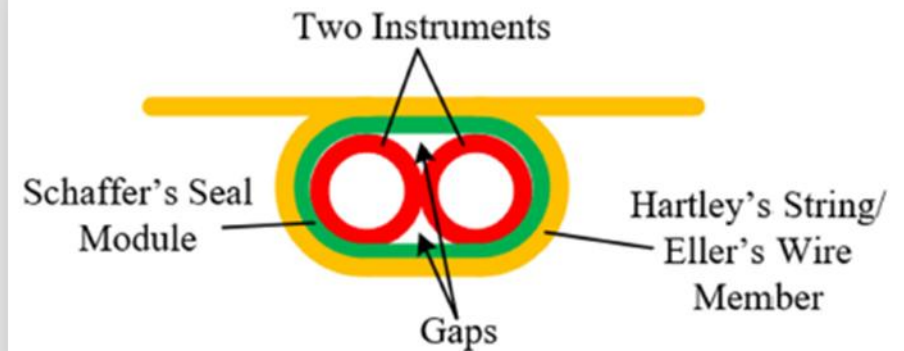
- Disclosure applies to Figs. 12-15
- Disclosure applies to an “embodiment”
- Disclosed embodiment requires three seal members

[0068] In yet another embodiment, two or more instruments 260 are inserted into the valve antegrade, for example, in the distal end 117 of the containment structure 160 while the lumen 193, 190, and 191 of the seal members 165, 170, and 180, are in an open configuration, or in another option, while the lumen 193 of the third central seal member 165 in a closed configuration. The instruments 260 frictionally engage the lumen 190 of the first seal member 170 and forces it distally away from the second seal member 180 and the third central seal member 165. The first seal member 170 forms a seal against the instruments 260. The back pressure from the retrograde flow 270 against the first seal member 170 forces the first seal member 170 toward the distal end 117 of the containment structure 160 compressing the third central seal member 165 and collapsing it circumferentially against the instruments 260 forming a second, complete seal. The material 166 of the third central seal member 165 is so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped.

PO's Drawing Is Inaccurate

Thornton Supp. Decl.

Patent Owner Response at 52. Patent Owner's illustration does not depict the compliant sealing member described in Schaffer's Paragraph [0068]. The sealing member depicted in Patent Owner's illustration is not "so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped." In addition, Patent Owner does not explain how the illustration would be any different if the string/wire member were replaced with two U-shaped actuating members. Because of the non-compliant seal depicted in the illustration,



Third Motivation to Combine Schaffer + Hartley or Eller

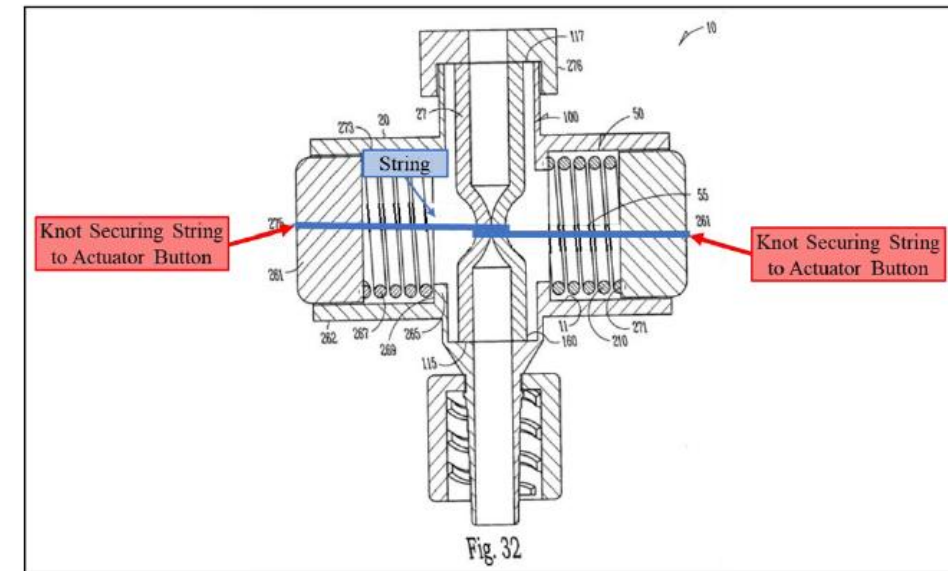
82. Third, the combination of Hartley's string and Schaffer's valve would have merely entailed the substitution of one known element (Hartley's string) for another (Schaffer's U-shaped actuating members) and would have yielded the predictable results of constricting the central lumen of Schaffer's valve to form a seal. I do not see any significant technical challenges that a person of ordinary skill would have confronted in substituting Hartley's string for Schaffer's U-shaped actuating members, and I believe that the substitution would have been well within the level of ordinary skill in September 2017.

Simple Methods May Be Used to Combine Hartley with Schaffer

Thornton Decl.

84. A person of ordinary skill in the art would have had reasonably expected success in substituting Hartley's string for Schaffer's U-shaped actuating members for multiple reasons. First, Hartley teaches a simple method for attaching its string to an actuator – a knot at the terminal ends of the string. Ex. 1006 (Hartley) at [0031]. A person of ordinary skill in the art would have reasonably expected that this same method could be used to attach Hartley's string to each of Schaffer's actuator buttons. For example, small holes could be made in each of Schaffer's actuator buttons, and each end of the string could be threaded through the hole on the opposite buttons and knotted on the other side. This

Demonstrative Illustration
Schaffer + Hartley's String



Simple Methods May Be Used to Combine Eller with Schaffer

97. A person of ordinary skill in the art would have had reasonably expected success in substituting Eller's wire member for Schaffer's U-shaped actuating members for multiple reasons. First, Eller states that the "[a]ttachment between a wire member and a housing and/or actuator can be accomplished using any suitable method or technique, and skilled artisans will be able to select a suitable method or technique to attach a wire member to a housing and/or an actuator according to a particular embodiment based on various considerations, including the material(s) that forms the wire member." Ex. 1007 (Eller) at 14:37-43. Eller then provides several exemplary ways to secure its wire member to an actuator, "including using adhesive, welding, fusing, providing a friction fit between the wire member and the ... actuator, and any other method or technique considered suitable for a particular embodiment." *Id.* at 14:43-49. Eller's

PO Fails to Explain Why the Combination Is Not Simple

PO Response

Such a substitution is also not “simple” because a POSA would understand that controlling a string or wire with two independently movable actuators—rather than one actuator as taught by Schaffer, Hartley, and Eller—would increase the complexity and variability of Schaffer’s valve and make the valve more difficult to manufacture. *Id.* at ¶128. Petitioner’s proposed combinations of Schaffer and

Fourth Motivation to Combine Schaffer + Hartley or Eller

83. Fourth, as Schaffer recognizes, fluid stasis valves generally comprise “a resilient material in compression within a housing or clamping member.” Ex. 1005 (Schaffer) at [0003]. There were a finite number of ways to compress the resilient material in a stasis valve to create a seal in September 2017. Hartley and Schaffer disclose two such methods – Hartley’s single string and Schaffer’s two U-shaped actuating members formed from aluminum or plastic. As I discuss in the following section, Eller discloses a third option: one or more wire members. *Infra* §VI.A.3.b.iii. A person of ordinary skill in the art in September 2017 would have found it obvious to select from these finite, predictable options. And as I explain below, they would have had a reasonable expectation of success in implementing them.

PO's Fails to Identify Other Methods to Constrict a Tube

PO Sur-Reply

third option: one or more wire members.” *Id.*; EX1003, ¶83. But at deposition in the related ’012 IPR, **Petitioner’s expert admitted** that there were more than those three ways to **constrict a tubular member** in a hemostasis valve including those disclosed in Schaffer ’616 (EX2010, 105:24-106:4, 106:12-14), Wong (*Id.* at 106:15-19), Kees (*Id.* at 108:14-20, 110:7-19), Myers (*Id.* at 111:9-23), his previous work on a hemostatic-type clamp prototype (*Id.* at 106:20-24), and more (*Id.* at 112:5-114:24).

Mr. Thornton Explained Schaffer/Hartley/Eller Are Different

Thornton Depo. Transcript

Q So is this another finite predictable option to compress the lumen and seal the hemostasis valve?

MR. STOWELL: Objection. Vague.

THE WITNESS: It's still compressing a flexible tube. The mechanism of moving the compressing members is different than the one shown in Schaffer and Schaffer 616 that we've discussed so far.

BY MR. HAMILTON:

Q Is it similar to Schaffer's U-shape member?

A I would characterize it as a different mechanism.

Q Okay. So this is another finite predictable option that's different from Schaffer's two U-shaped

actuating members, Hartley's string, and Eller's wire member, correct?

MR. STOWELL: Objection. Vague.

THE WITNESS: I believe it uses a different mechanism to cause the pinching. The basic point of compressing a tubular member is similar among, really, all of these, all of these design options.

Options Still Finite if Different “Pinch” Valves Included

Thornton Depo. Transcript

Q Okay. So I just want to be clear. On page 74 when you say, These finite predictable options, you're not listing all the options in this paragraph; is that correct?

A Well, as I said earlier, there are a finite number of -- there were a finite number of ways to compress the resilient material in a hemostasis valve. Hartley and Schaffer disclosed two of them, U-shape members versus strings. I would still say that those are, you know -- the few other types that we've talked about today are still a finite number. There's not an infinite number of ways to compress a piece of tubing.

Schaffer's "Principles of Operation" Remain Unchanged

39. Given the similarities in the sealing mechanisms employed by Schaffer, Hartley, and Eller, a person of ordinary skill would have reasonably expected that Schaffer's valve would function with the same principles of operation when the U-shaped actuating members are replaced with Hartley's string or Eller's wire member. When Schaffer's actuator buttons are undepressed, the compression springs would pull each respective end of the string/wire member in opposite directions, causing the string/wire member to constrict Schaffer's seal module and seal the valve. When the actuator buttons are depressed, the tensioning force from the compression springs would be relaxed, allowing the string/wire member to loosen and disengage (i.e., release the constricting force) the seal module, permitting the seal module return to its open, unsealed state.

The String/Wire Permit Forcible Disengagement

Schaffer

the distal end 275 of the actuator button 261). As each actuator button 261 is depressed, each actuator 50 slides along the cylindrical interior wall 11 of the housing 20. The proximal end 273 of each actuator button 261 compresses the distal end 271 of each resilient member 267 which in turn, the proximal end 269 of each resilient member 267 compresses against the inner flange wall 265 of the housing 20. Such movement allows each engaged actuating member 55 to forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough. As the actuator 50 is disposed away from the portion 108 of the seal module 100, the lumen 193 of the third seal member 165 is able to retract in an unsealed configuration.

String/Wire Does Not Compromise “Ease of Manufacturing”

Schaffer

[0083] In an example where the stasis valve 10 includes two actuators 50, the stasis valve 10 is assembled by inserting the actuator button 261 and resilient member 267 (e.g., spring 210) into one side of the housing 20. The actuator button 261 and resilient member 267 (e.g., spring 210) are inserted into an opposing side of the housing 20. Each actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50. Each actuator button is released and the cap 276 secured to the housing 20, for example, with an adhesive. Further, the connecting member 35 is snapped onto the housing. The materials used and the assembly thereof of the stasis valve 10 as described herein can include any of the earlier disclosed embodiments or a combination thereof.

String/Wire Does Not Compromise “Durability”

Zalesky Depo. Tr. (PO’s Expert)

Q. Are you aware of any durable string materials that can be used to manufacture medical devices?

A. So, yeah, polypropylene, polyurethane, suture catgut are amazingly durable.

Q. Are you aware of any durable wires that can be used to manufacture medical devices?

A. There are certain small-braid constructions that are probably more durable than a rolled or drawn small wire. But again, testing would have to confirm that.

Q. And were polypropylene, polyurethane sutures and catgut available prior to 2017?

A. Yes.

Q. And what about the small-braid constructions for the wires that you referred to? Were those available prior to 2017?

A. Yes.

Grounds 1-2: Schaffer Anticipates the Claims or Renders Them Obvious

Summary of PO's Arguments

- ⦿ “Filament” limited to a “thin, flexible length of material”
- ⦿ Schaffer’s actuating members are “rigid”
- ⦿ Schaffer’s actuating members do not “circumferentially constrict” the seal module
- ⦿ Schaffer’s actuating members do not form a “loop” – Claim 3 only

Petitioner's Construction of "Filament"

Thornton Decl.

47. I have reviewed the claims, specification, and prosecution history of the '011 patent, and in my opinion, a person of ordinary skill in the art in September 2017 would have understood that the term "filament" in the claims of the '011 patent to mean at least: "one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes."

“Filament” Not Limited to Thin, Flexible Materials

'011 Patent

The constricting mechanism **141** can include at least one filament **150** that extends at least partially around the elongate member **132**. In some embodiments, the at least one filament **150** can circumferentially constrict the elongate member **132** to collapse and seal the elongate member **132** when the constricting mechanism **141** is in the first configuration. The filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal. In some embodiments, the filament **150** can be nylon, stainless steel, nitinol, silicone, or the like. In some embodiments, the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament. In some embodiments, the filament **150** can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

PO Has Filed Other Claims Requiring a “Flexible” Filament

PO’s ’384 Patent

1. A valve assembly, comprising:
a tubular member defining a lumen;
a first filament extending in a first loop around the tubular member, wherein the first filament is flexible;
a second filament extending in a second loop around the tubular member, wherein the second filament is flexible;

“Thin” and “Flexible” Inject Ambiguity

Thornton Supp. Decl.

9. I have reviewed the '011 patent and it never describes the filament as “thin” or “flexible.” In addition, the '011 patent does not provide any criteria for flexibility that would help a person of ordinary skill in the art determine whether a specific material was, in fact, “flexible.” While the '011 patent identifies some potential dimensions for the “filament(s),” the patent states that those dimensions are exemplary, not mandatory. *See* Ex. 1001 ('011 patent) at 14:18-46. Likewise, the '011 patent does not provide any information regarding the “filaments” mechanical properties, such as hardness, stiffness, ductility, and malleability from which a person of ordinary skill in the art could glean information about flexibility. Because flexibility exists along a spectrum, I would not be able to tell

PO Does Not Identify Objective Boundaries for “Flexible”

Zalesky Dep. Tr. (PO’s Expert)

Q. How flexible does a material need to be in order to constitute a filament, under your construction?

A. I'm laughing because the word "very" comes to mind. I don't have a quantitative answer to that.

Q. How would you test whether a material has enough of an ability to conform to a structure that it's surrounding to constitute a filament?

A. One way to do it would be simply wrap the filament around a chosen structure, such as a tubular element or a catheter, and observe its compliance and its coaption to the external wall of the device.

Q. How compliant would the material need to be in order to constitute a filament?

A. Again, very. But I think it would be more of a visual observation of its property.

PO's Expert Admits His Definition Depends on Trial and Error

Zalesky Dep. Tr. (PO's Expert)

Q. How would a person of ordinary skill in the art go about determining whether a given material is compliant enough to be a filament or to not be a filament?

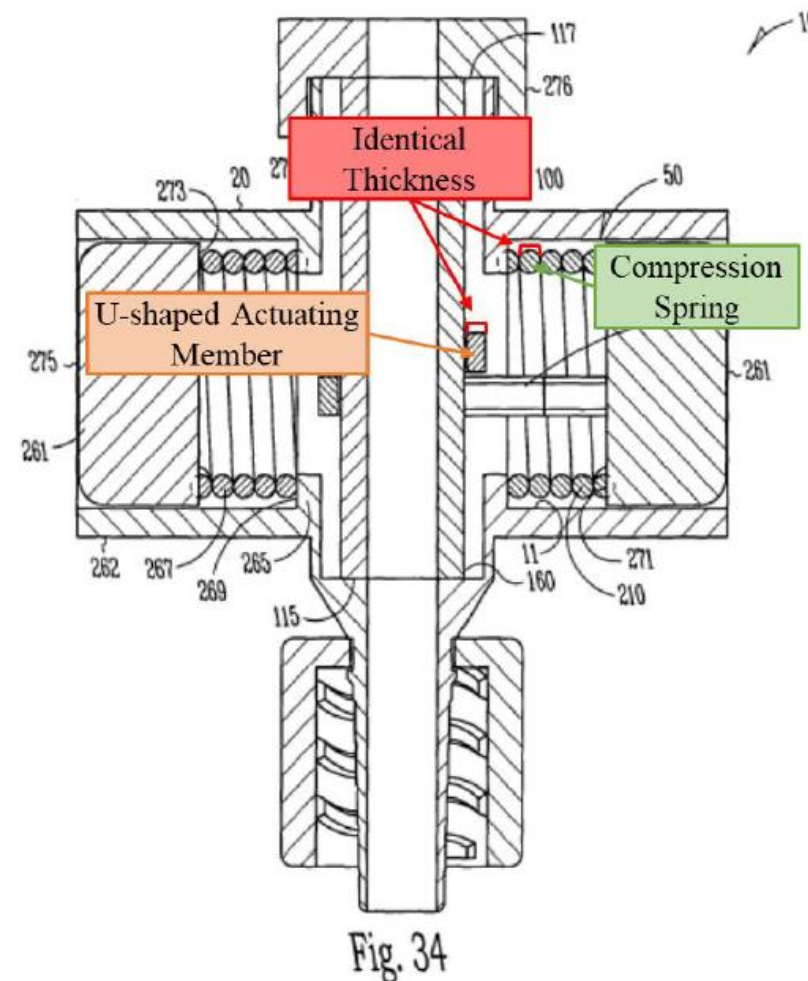
MR. HAMILTON: Objection, incomplete hypothetical.

A. Primarily trial and error.

Schaffer's Actuating Members Are Thin and Flexible

Thornton Supp. Decl.

21. Figures 31-34 of Schaffer also convey to a person of ordinary skill in the art that the U-shaped actuating members are **thin and flexible**. Schaffer's figures illustrate the actuating members as plastic or metal pieces with a thickness that is substantially less than their length. *See* Ex. 1005 (Schaffer) at Figs. 31-34. In addition, although Schaffer does not provide precise dimensions for the U-shaped actuating members, **a person of ordinary skill in the art would have recognized that they would be thin and flexible based on the depiction of the actuating members in relation to the other components of the hemostasis valve.** For example, Schaffer depicts the actuating members having the same thickness as the coils of the compression spring, which must be relatively flexible to function:



Made From Machining Does Not Mean “Rigid”

Thornton Supp. Decl.

23. Patent Owner and Dr. Zalesky also argue that the actuating members in Schaffer are “rigid” based on the following description:

The stasis valve 10, in one option, is made from machining pre-existing amounts of metals and/or plastics. For example, [t]he actuating member 55 and the actuating button 261 is machined from aluminum.

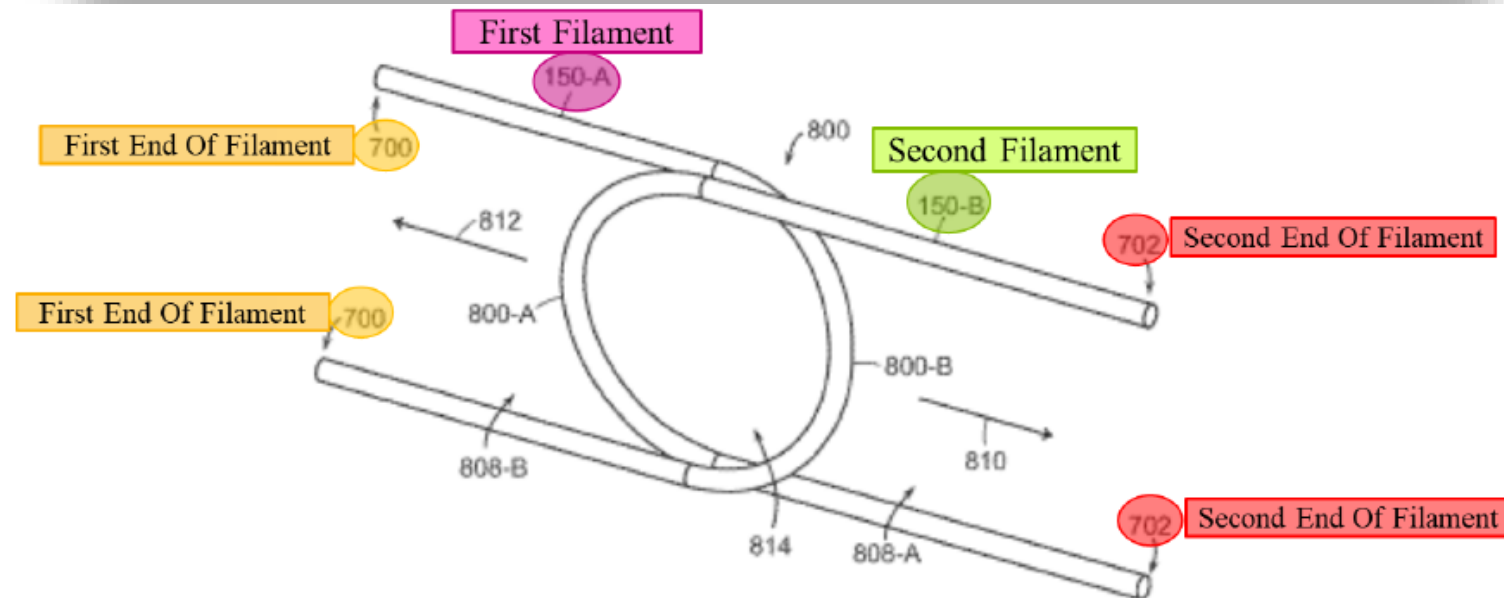
Ex. 1005 (Schaffer) at [0082]. However, the description that a device is “made from machining” is not dispositive of whether the finished product is rigid or flexible. In the case of aluminum, for example, **if enough material is removed during machining, then the final product would not be rigid.** In his deposition, Dr. Zalesky agreed that metallic or polymeric filaments could be manufactured by machining. Ex. 1015 (Zalesky Tr.) at 99:7-17.

Schaffer's Actuating Members Circumferentially Constrict

1. A valve, comprising:
 - a tubular member defining a lumen configured to slidably receive a catheter;
 - a constricting mechanism including at least one filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and
 - a biasing system configured to bias the first member and the second member to the first position.

The “Filament” Can Include Multiple Sub-Filaments

In some embodiments, the filament 150 can comprise multiple filaments, and specifically, as shown in FIGS. 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B. In embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702. The first and second filaments 150-A,



The '011 Patent Says Bights Encircle and Constrict

'011 Patent

herein as a constricting area 814. The elongate member 132 can be received within the **encircled area 814**. In embodiments in which bights 800-A, 800-B overlap to define the encircled area 814, the movement of the constricting mechanism 141 to the first configuration can result in and/or include the first bight 800-A moving in the direction indicated by the arrow 810 and/or the second bight 800-B moving in the direction indicated by the arrow 812, which movement of the bights 800-A, 800-B **decreases the size of the encircled area 814 and constricts, collapses, and/or seals the elongate member 132** extending through the encircled area 814.

PO's Expert Admitted Bights "Circumferentially Constrict"

Zalesky Dep. Tr. (PO's Expert)

Q. What properties of the filament illustrated in Figures 8 and 9 require flexibility?

A. In particular, the ability to circumferentially circumscribe or circumferentially impose a force.

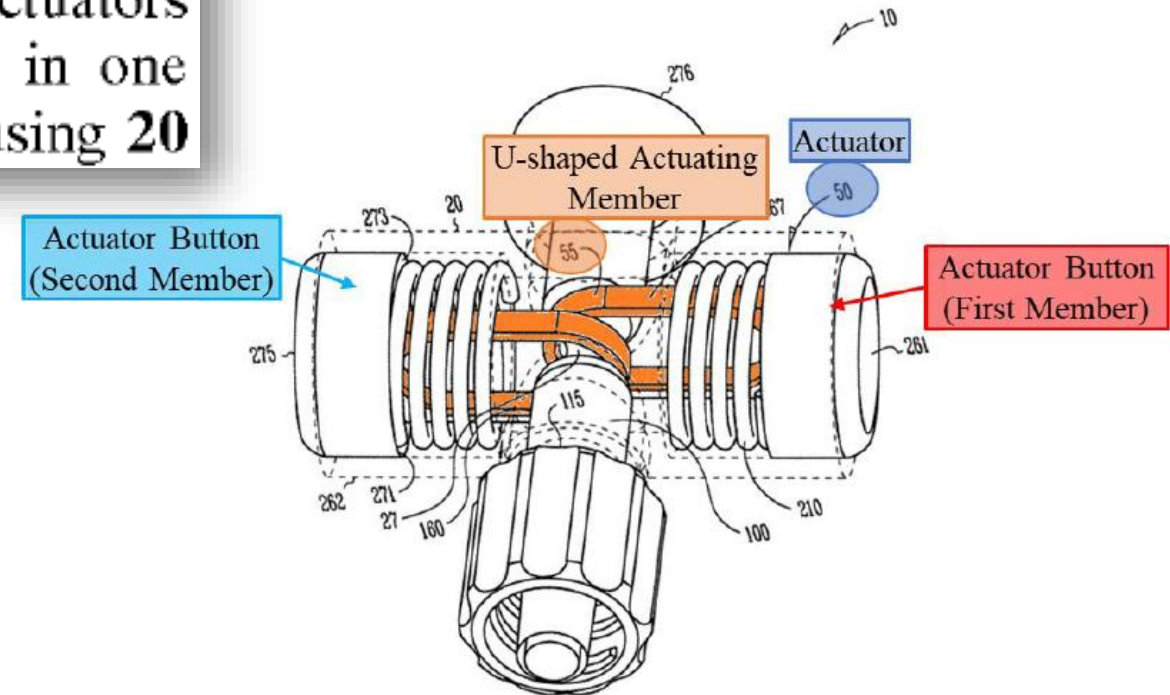
Q. Does the filament that's illustrated in Figures 8 and 9 circumferentially circumscribe the tubular member?

A. It would in the final configuration. This is showing a -- one particular static positioning of the filament.

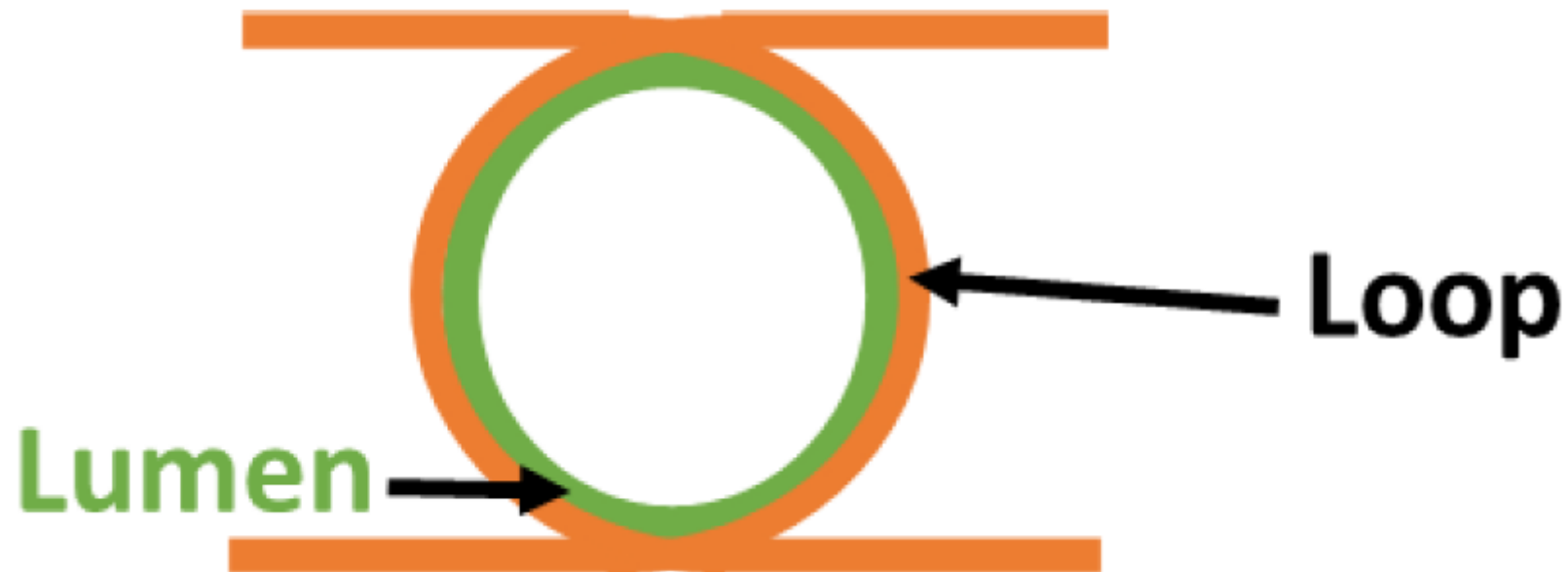
Schaffer's Actuating Members "Circumferentially Constrict"

Schaffer

[0076] In one option, two circular actuators **50** are at least partially circumferentially disposed about a portion of the seal module **100** movable from a first position to a second position on opposing sides of the housing **20**. The actuators **50** each include an **actuating member 55** which, in one option, is U-shaped. The outer wall **262** of the housing **20**



Schaffer Forms a “Loop”



PO's Motion to Exclude Based on POSITA Definition Should Be Denied

- ⦿ PO's definition of a POSITA not supported
- ⦿ Mr. Thornton's POSITA definition goes to the weight of his testimony
- ⦿ PO fails to show the differences in the parties' POSITA definitions are material

Mr. Thornton's POSITA Definition Based on Real-World Experience

35. Based on my review of the specification and claims of the '011 patent, it is my opinion that a person of ordinary skill in the art would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience.

36. I can make this assessment because during my career, I had experience assigning engineers to work on mechanical design projects, including projects to design hemostasis valves or incorporate them into catheter-based projects. For such projects, I would assign an engineer with the experience described above.

PO Does Not Identify Basis For POSITA Definition

Zalesky Supp. Decl. (PO's Expert)

68. A POSITA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2 to 4 years of product design or engineering experience designing medical devices in the field of the '011 Patent. A person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard.

PO's Expert Is Inconsistent

Zalesky Dep. Tr. (PO's Expert)

Q. So a person of ordinary skill in the art does not need to have prior experience designing a hemostasis valve. Is that right?

A. I think that's fair. Yes.

Q. But they wouldn't specifically need experience in designing the devices. Is that correct?

MR. HAMILTON: Objection, asked and answered.

A. Yeah. I think that's correct.

PO's Motion to Exclude Ex. 1008 Should Be Denied

- ⦿ No dispute Ex. 1008 authentic and available before priority date
- ⦿ Ex. 1008 is not “extrinsic evidence”
- ⦿ Permissible to consider prosecution history to interpret prior art reference
- ⦿ Permissible to consider “extrinsic evidence” to interpret prior art reference

