

The Patent Trial and Appeal Board

Imperative Care, Inc.,

Petitioner,

v.

Inari Medical Inc.,

Patent Owner.

Case No. IPR2024-01157

Patent Owner's Demonstratives

INARI-2012

Imperative Care, Inc. v Inari Medical, Inc.

IPR2024-01157

'011 Patent

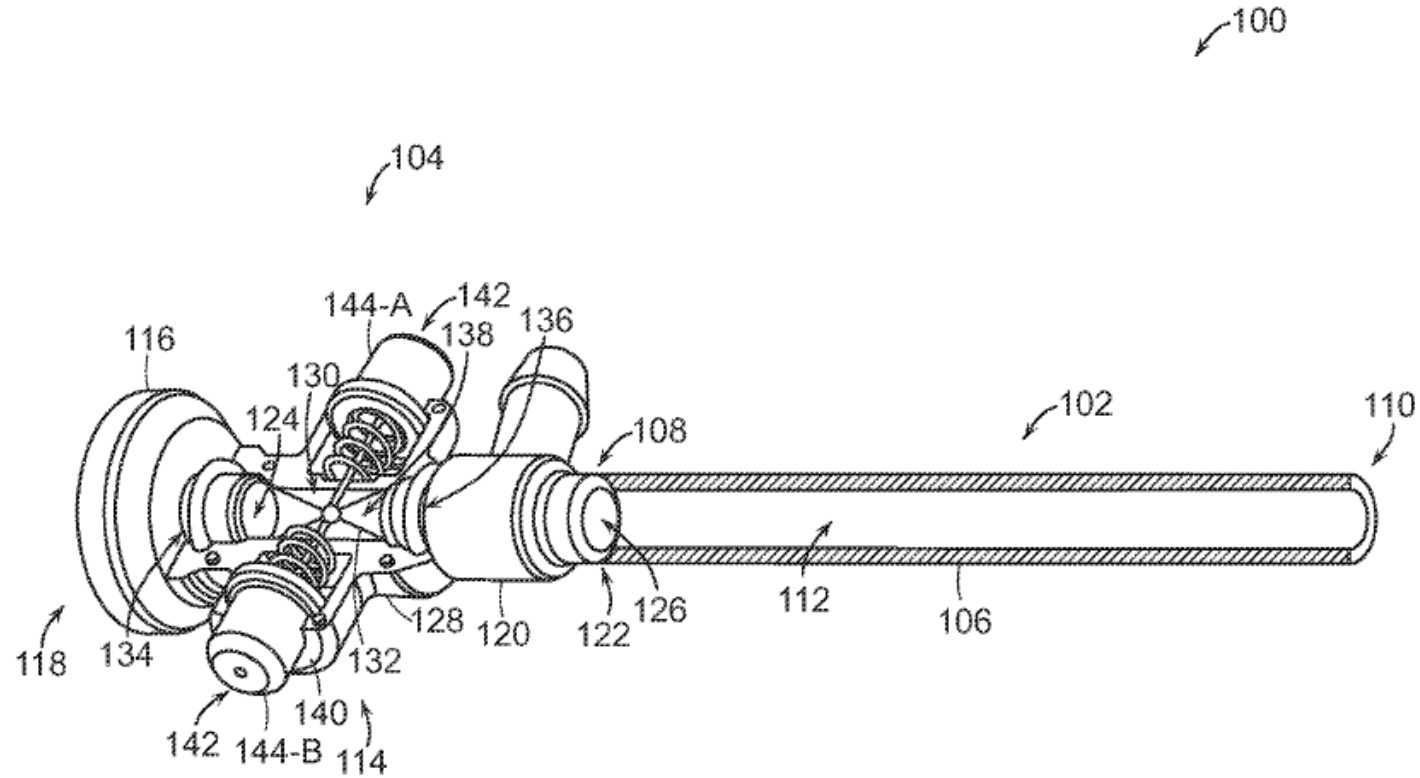
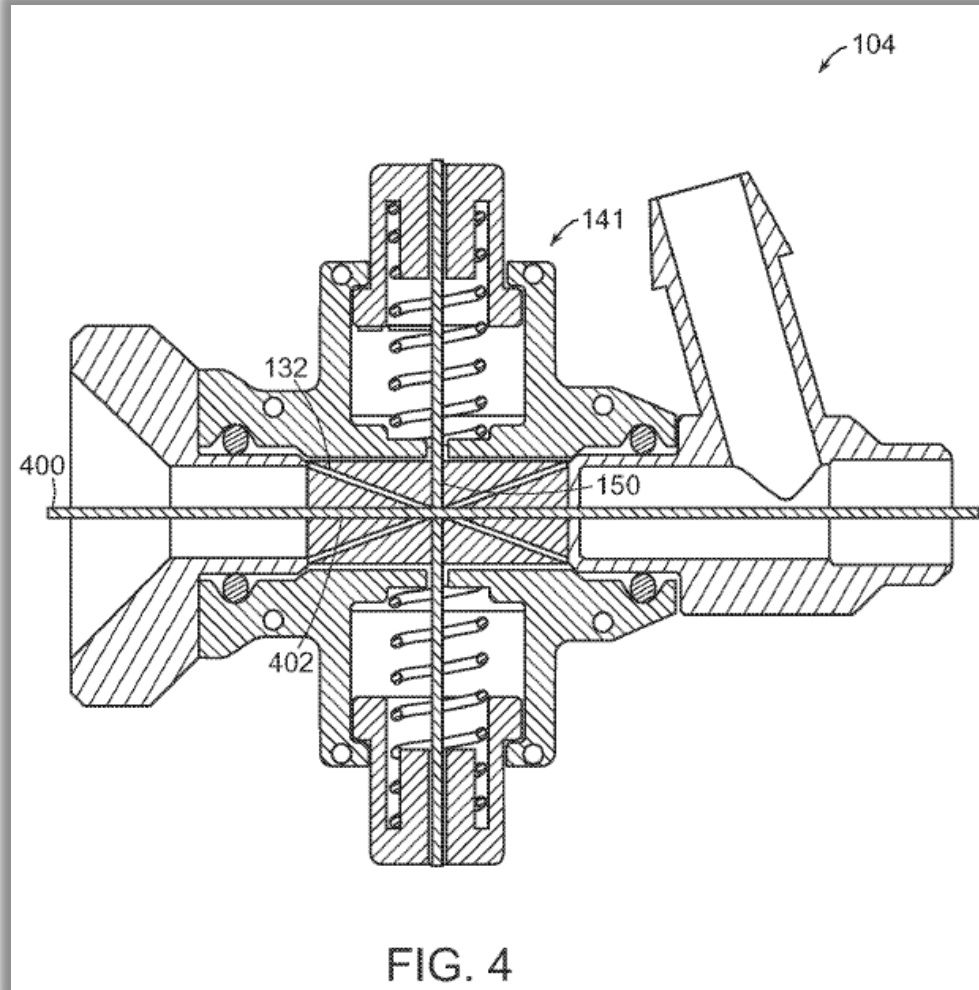


FIG. 1

EX1001 ('011 Patent).

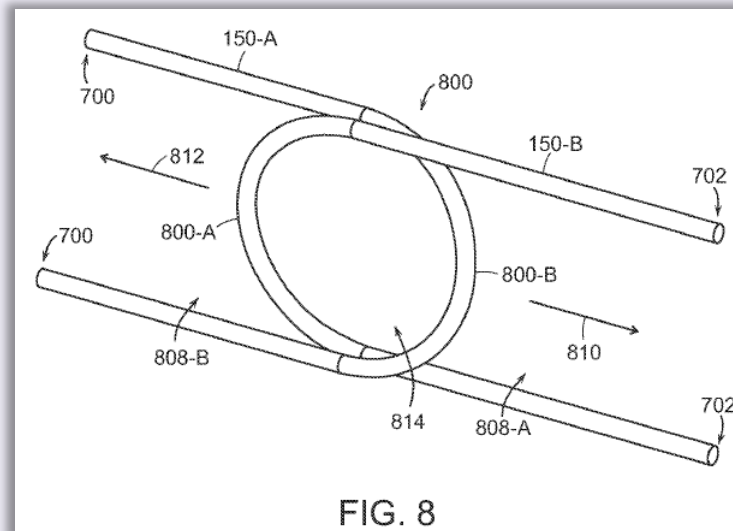
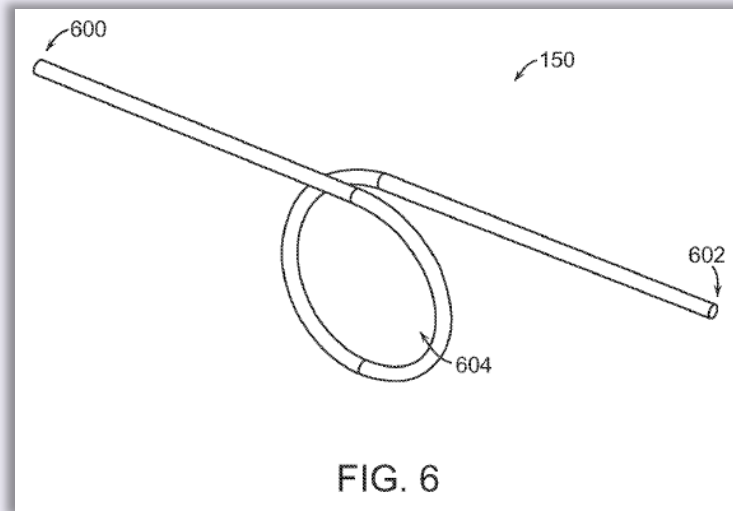
POR p. 6-10.

'011 Patent Claim 1



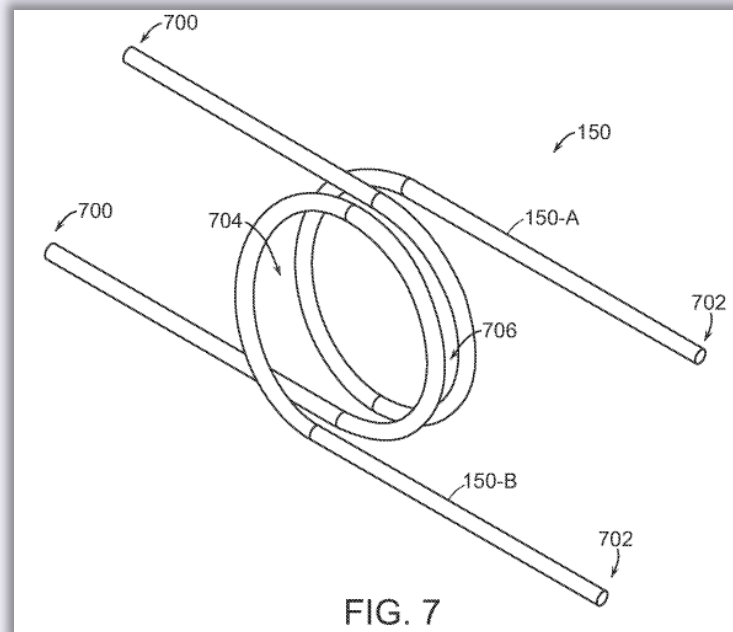
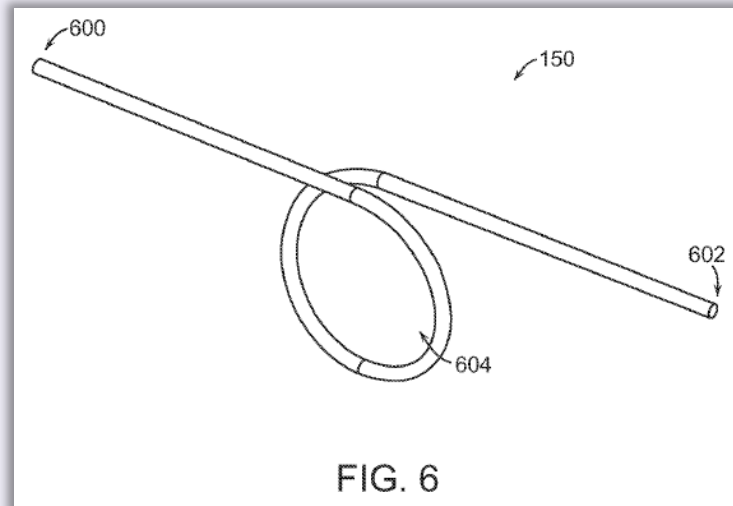
1. A valve, comprising:
 - a tubular member defining a lumen configured to slidably receive a catheter;
 - a constricting mechanism including at least one filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member 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.

'011 Patent Claim 1



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.

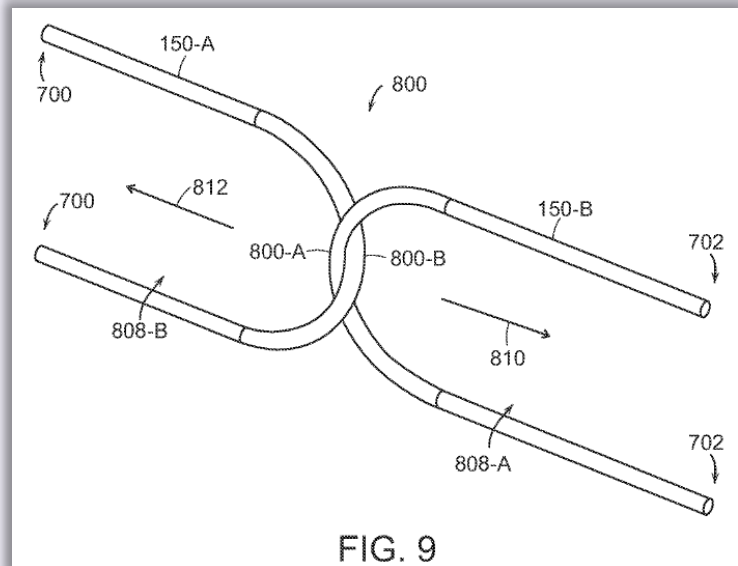
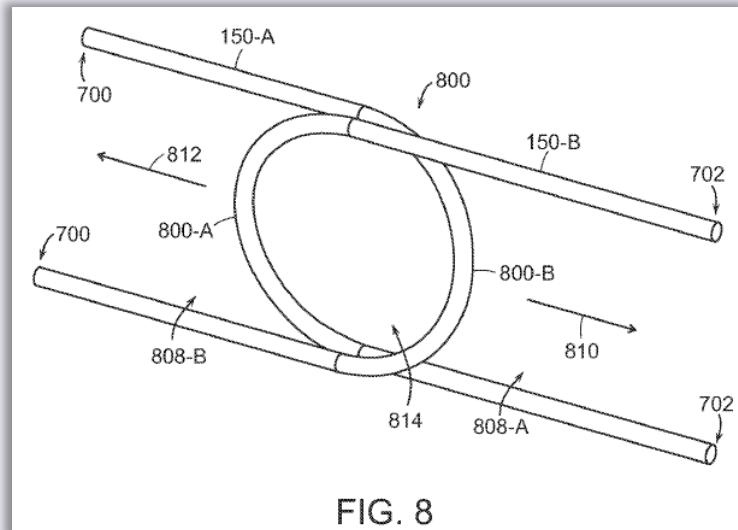
'011 Patent



The filament **150** can be arranged in a variety of configurations. In some embodiments, the filament **150** can be configured to form **a single loop 604** that can extend around the elongate member **132** and/or through which the elongate member **132** can be received as shown in FIG. 6, and in some embodiments, the filament **150** can be configured to form **multiple loops, and specifically a first loop 704 and a second loop 706** as shown in FIG. 7. The first and second loops **704, 706** can each receive the elongate member **132**. In some embodiments, **a diameter or size of the loop 604, or of the loops 704, 706 can decrease when the constricting mechanism 141 is moved from the second configuration to the first configuration.**

EX1001 ('011 Patent) 13:29-41.

'011 Patent



As seen in FIGS. 8 and 9, multiple bights, and specifically the first and the second bights 800-A, 800-B can be positioned and oriented such that the first bight 800-A has a first orientation or first direction as indicated by arrow 810, and

the second bight has a second orientation or second direction as indicated by the arrow 812. In some embodiments, the first orientation is different from the second orientation such that the first and second receiving areas 808-A, 808-B overlap and define an encircled area 814, also referred to 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.

POSA:

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.**

'011 Patent Field

26. The prior art references applied in this Declaration are analogous art that is usable in an obviousness combination. The references are from the same field as the '011 patent, e.g., hemostasis valves for use during intravascular procedures. The references are also pertinent to the problem the inventor was focused on, e.g., sealing a catheter during intravascular procedures to minimize blood leaks.

EX1003 (Thornton Decl.) ¶26.

5 Q. So then is it fair to say, in selecting a
6 hemostasis valve for use with a procedure, to determine
7 the design requirements for the hemostasis valve, you
8 would need to understand the needs of the procedure?

9 MR. STOWELL: Objection. Form.

10 THE WITNESS: I think, as engineers, we
11 always design to the needs of the physician, the
12 procedure, the environment, the sterilization plan,
13 which was another design requirement I just thought
14 of.

15 BY MR. HAMILTON:

16 Q. And all those requirements relate to the needs
17 from the procedure; is that right?

18 MR. STOWELL: Objection. Form.

19 THE WITNESS: Needs from the physician,
20 the needs of the procedure, the needs of the
21 patient.

EX2007 (3-19-2025 Thornton Tr.) 24:5-21.

Claim Construction: Filament

PO's Construction:

“a thin, flexible length of material formed by one or more strands of material.”

Petitioner's Construction:

“one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

“Filament”

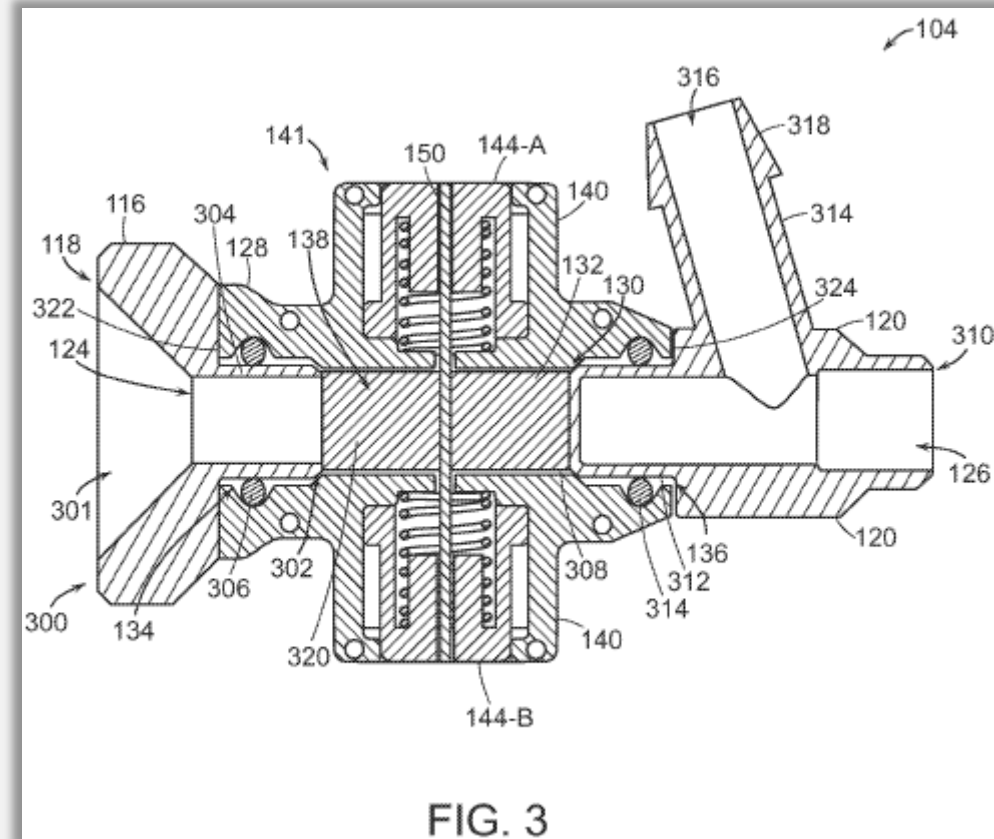
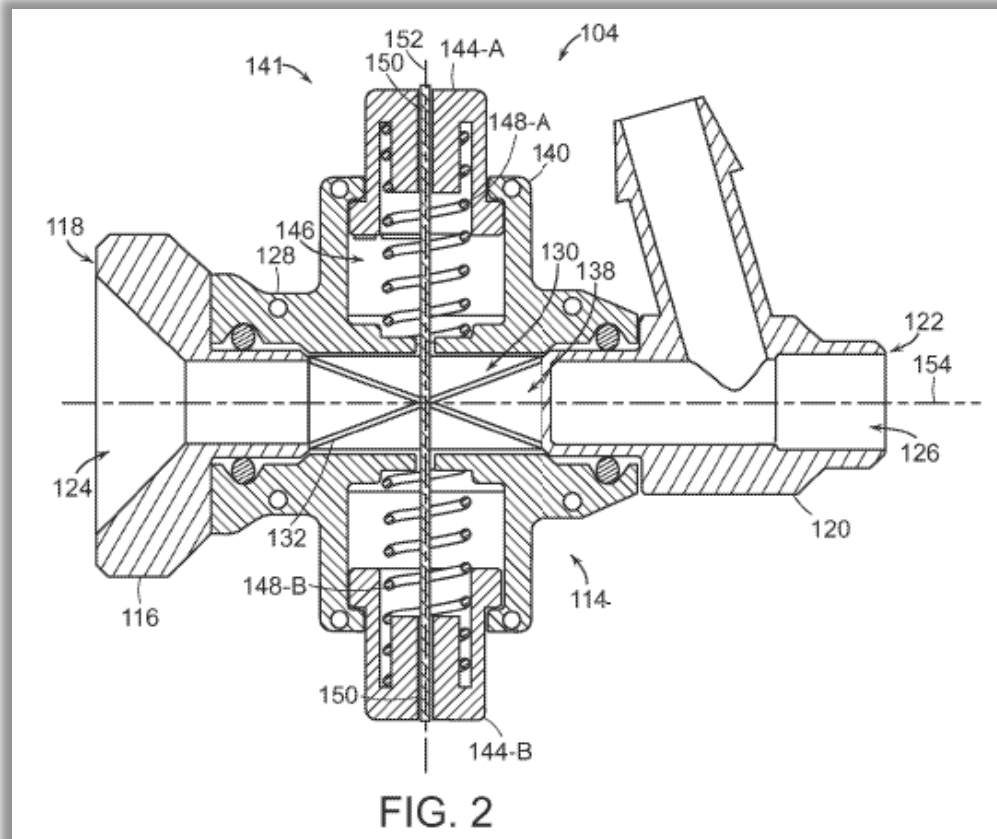
fil·a·ment \ˈfi-lə-mənt\ *n* [MF, fr. ML *filamentum*, fr. LL *filare* to spin — more at FILE] (1594) : **a single thread or a thin flexible threadlike object, process, or appendage**: as **a** : a tenuous conductor (as of carbon or metal) made incandescent by the passage of an electric current; *specif* : a cathode in the form of a metal wire in an electron tube **b** (1) : a thin and fine elongated constituent part of a gill (2) : an elongated thin series of cells attached one to another or a very long thin cylindrical single cell (as of some algae, fungi, or bacteria) **c** : the anther-bearing stalk of a stamen — see FLOWER illustration — **fil·a·men·ta·ry** \.fil-ə-ˈmen-t(ə-)rē\ *adj* — **fil·a·men·tous** \-ˈmen-təs\ *adj*

EX2002 (Meriam-Webster’s Collegiate Dictionary) 4.

'011 Patent Claim 1

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.

'011 Patent Specification



into the retention features 140 of the housing 128. In this second position, the filament 150 is loosened, thereby allowing the expansion of the elongate member 132 and the unsealing of the central lumen 138 of the elongate member 132.

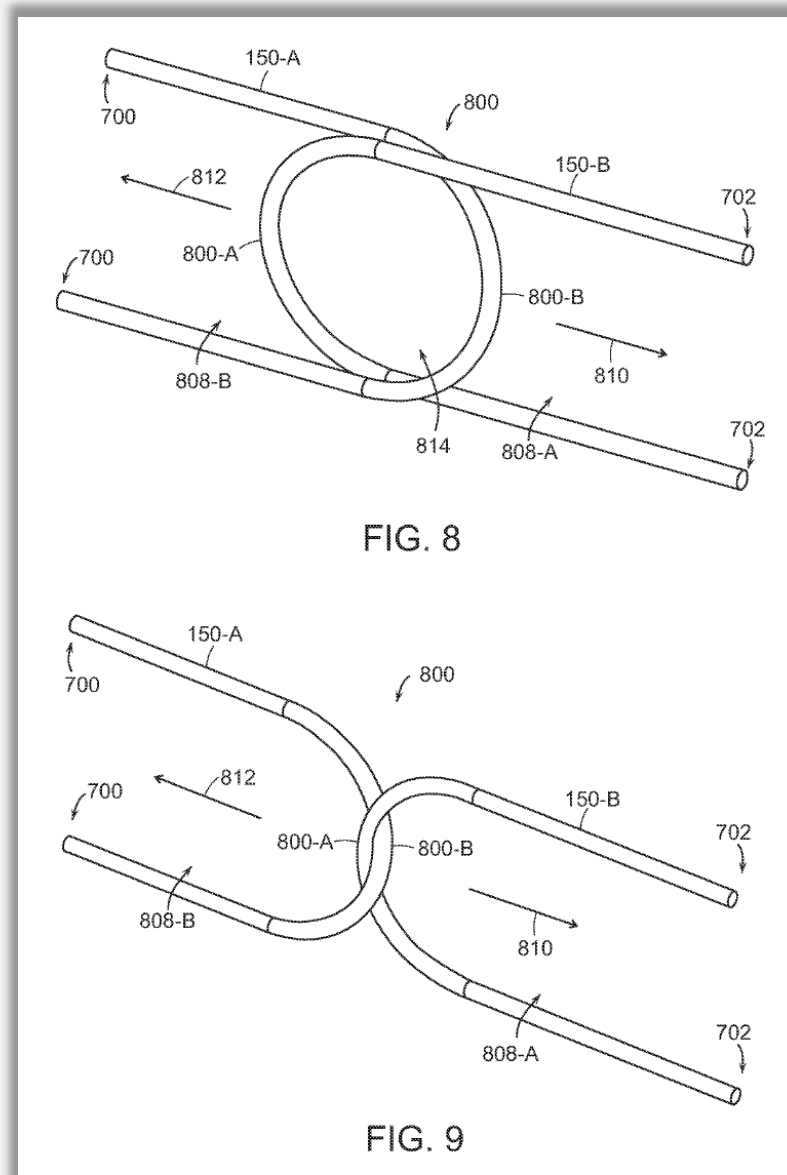
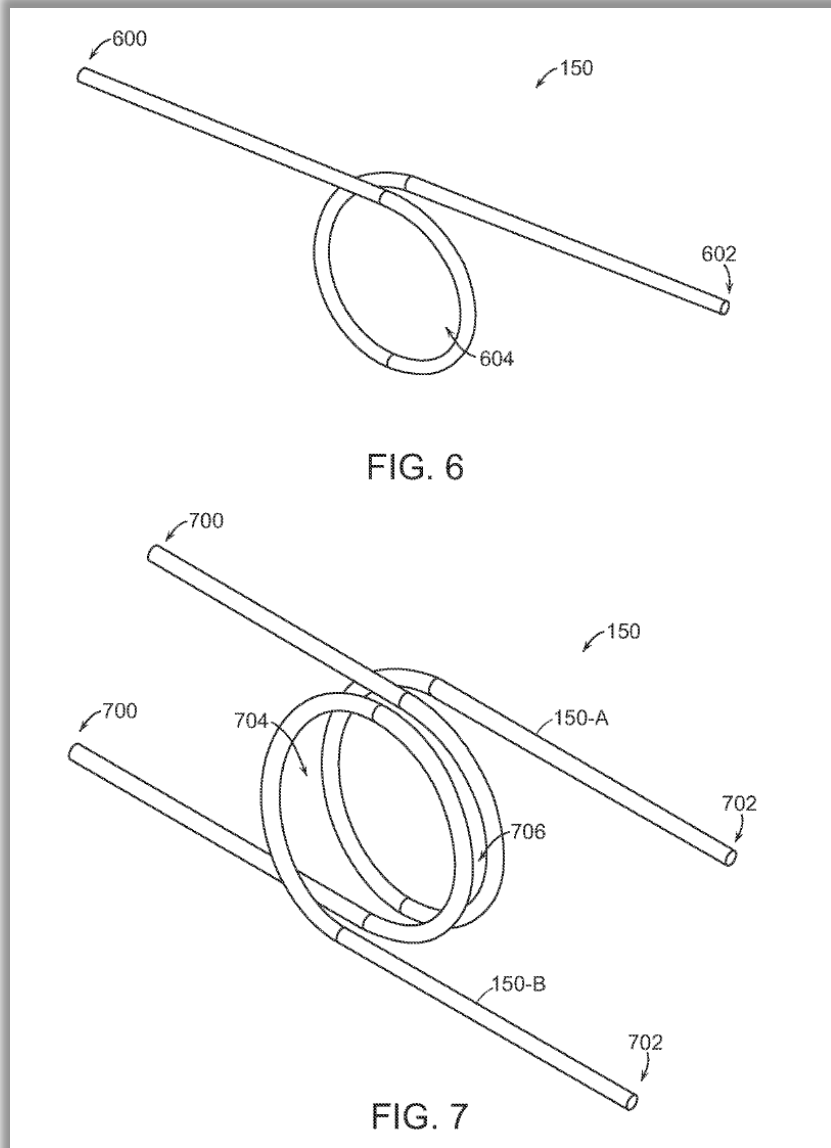
EX1001 ('011 Patent) 9:55-59.

'011 Patent Specification

ration. 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.

EX1001 ('011 Patent) 9:10-20.

'011 Patent Specification



EX1001 ('011 Patent).

Grounds 1 and 2:

Schaffer does not anticipate or render obvious a “filament” or “the filament circumferentially constricts the lumen to create a seal” as recited in claim 1.

Schaffer's balance.

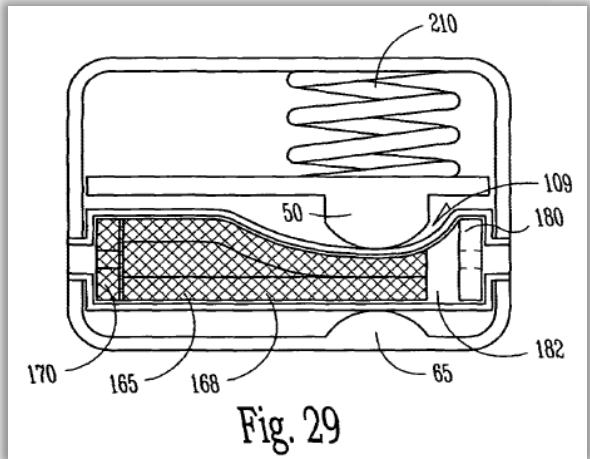
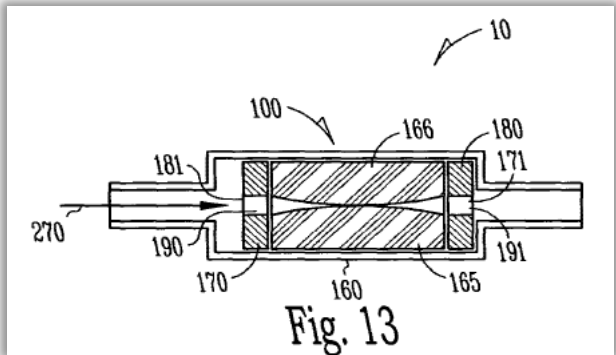
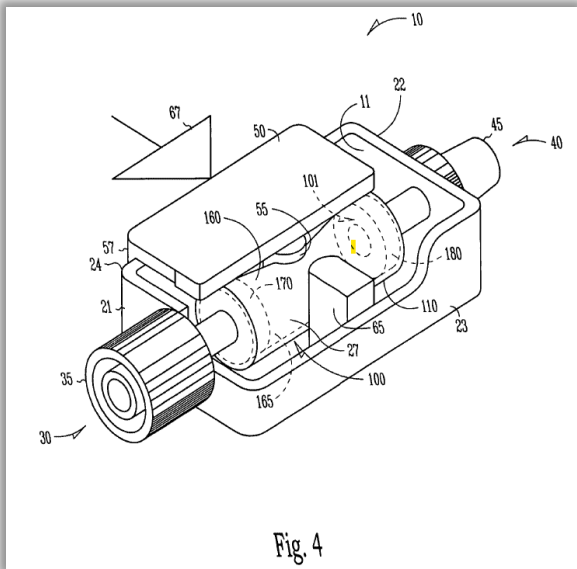
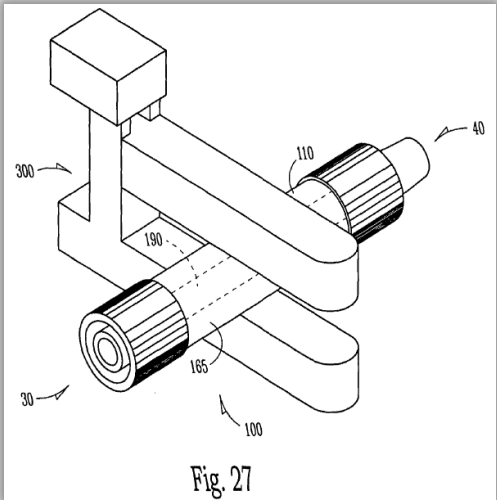
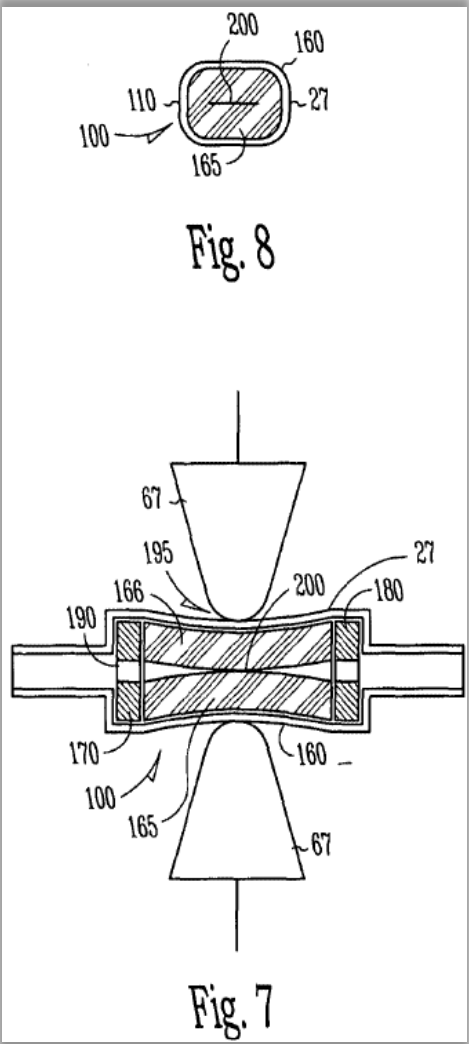
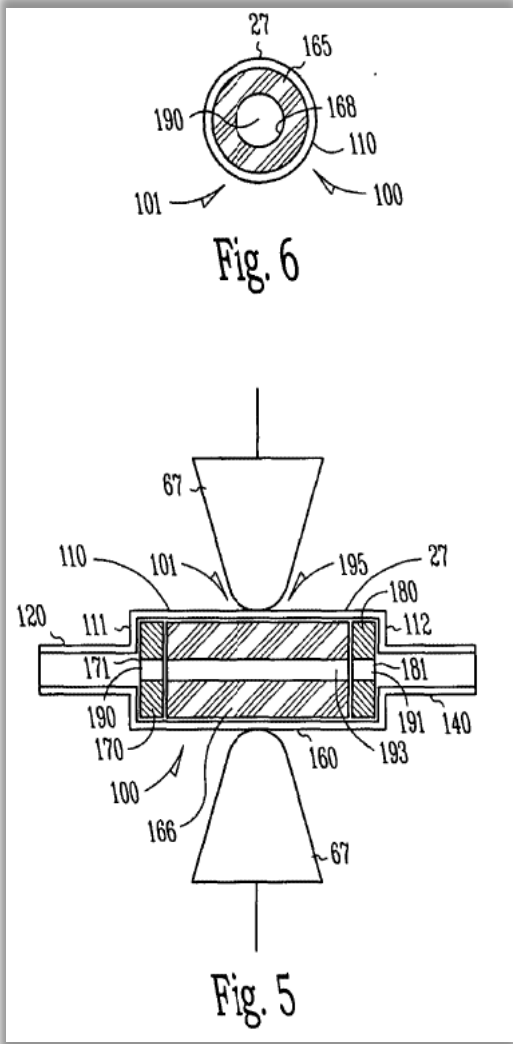
[0006] The existing devices do not perform a complete seal against leakage in the presence of a wide range of instruments or in the presence of multiple instruments. For instance, a single valve element with no instrument in place is generally not optimized for sealing in the presence of an instrument. Often a combination of seals is employed to address these issues, for instance: U.S. Pat. Nos. 6,083,207 and 6,024,729 employ primary seal portions in combination with “duckbill-valves” or “O” closure valves.

[0007] Thus, the problems are complex and involve a balance between closing force, opening force, friction, compression and durability. If a valve is inordinately tight, having a closed lumen, it may not allow the insertion of soft, flexible instrumentation such as a “floppy-tip” guidewire, a delicate laser fiber or a soft-tipped catheter. Some catheters, optical fibers and fluid transmission tubes are very delicate and can be damaged by excessive compression or insertion force.

[0008] Accordingly, what is needed is a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.

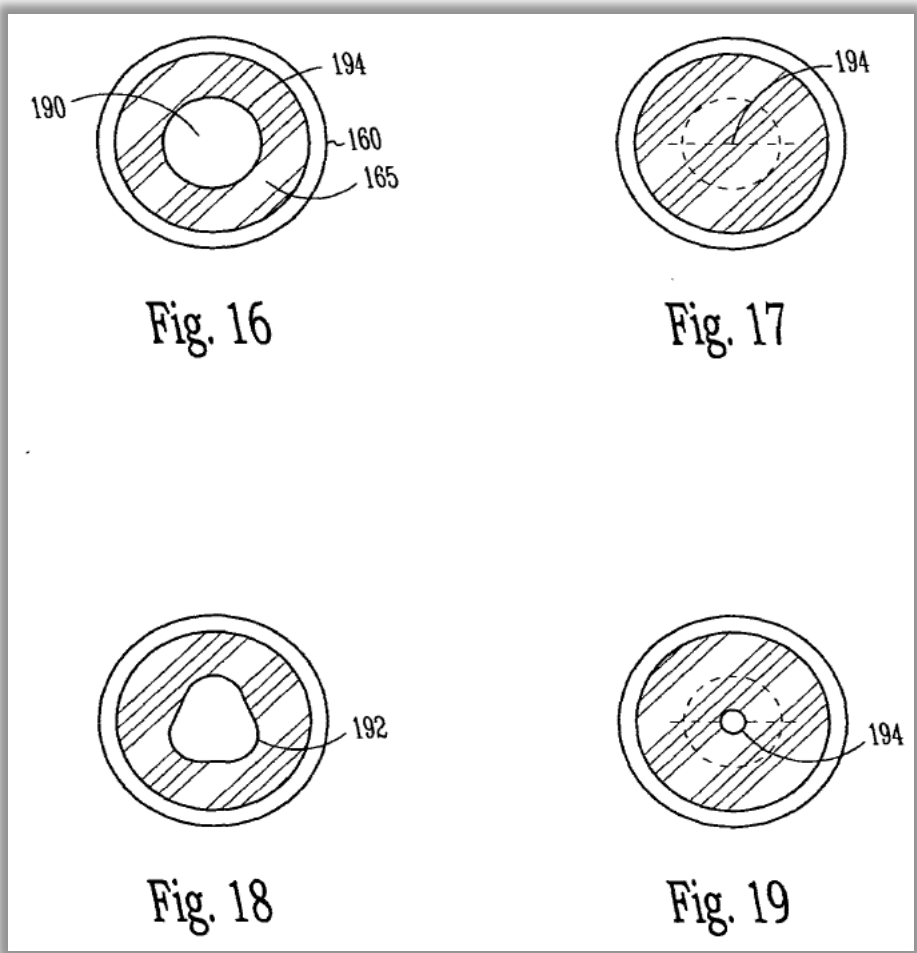
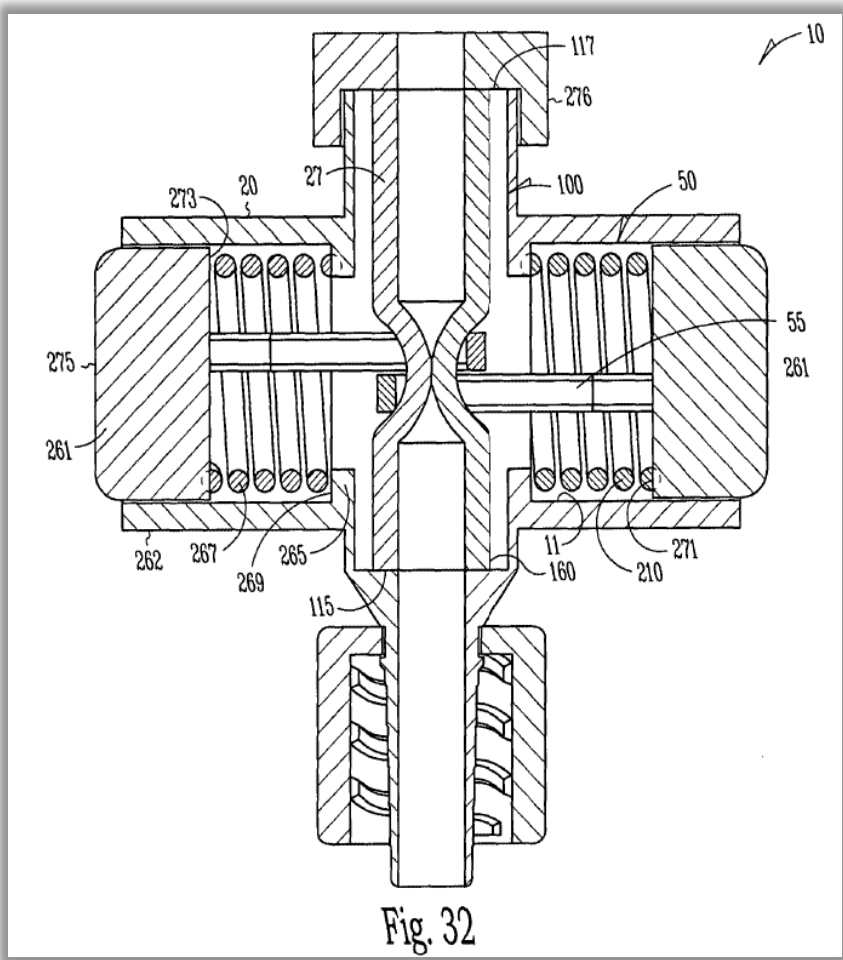
EX1005 (Schaffer) ¶¶6, 7, 8.

Schafer's principle of operation.



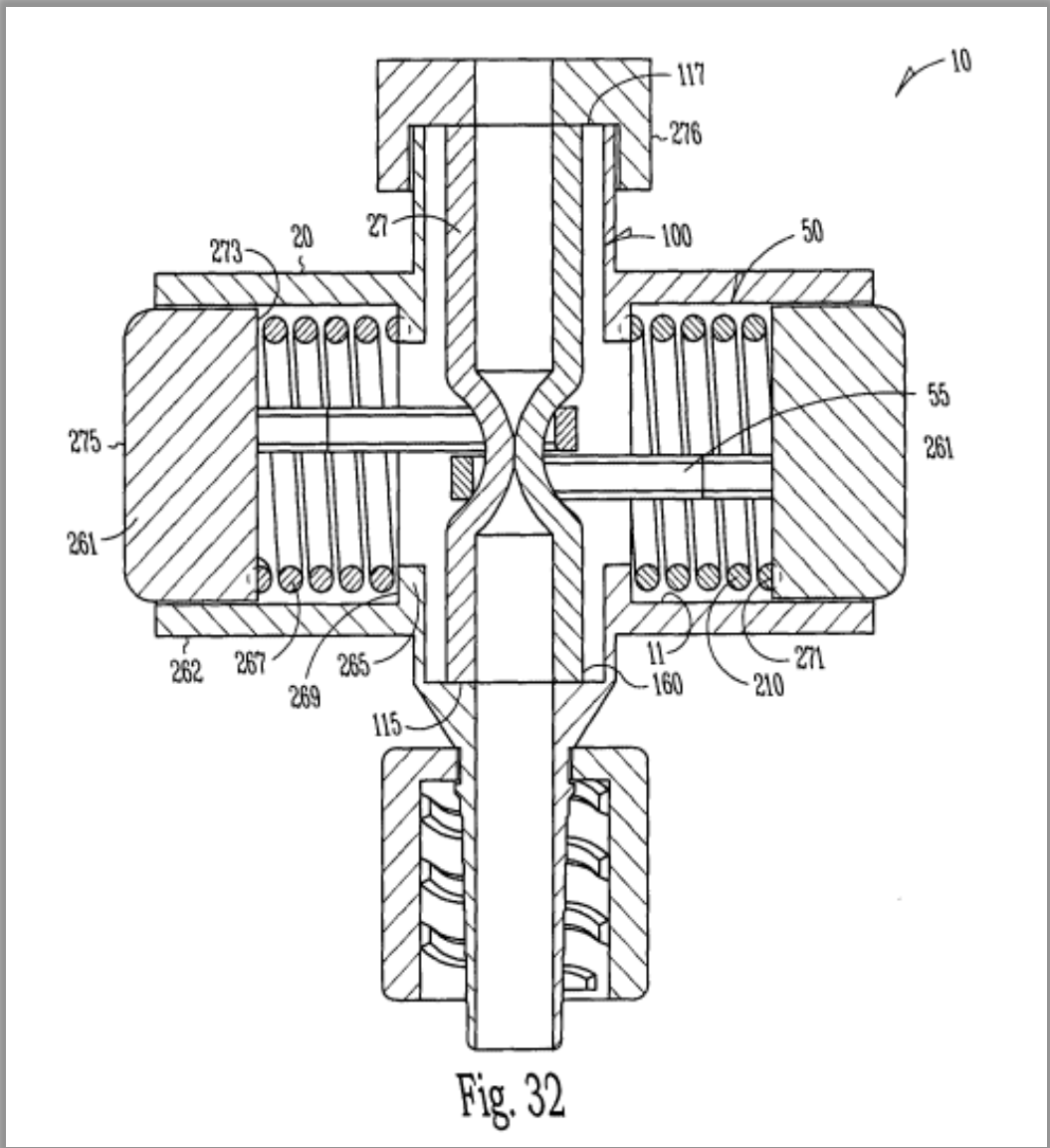
EX1008.

Schafer's principle of operation.



EX1008.

Schafer does not anticipate claim 1.



EX1008.

Schaffer's seal member 165.

[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

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.

EX1005 (Schaffer) ¶77.

Schaffer does not anticipate claim 1.

For example, The **actuating member 55** and the actuating button **261** **is machined from aluminum**. In another example, the **actuating member 55** and the actuating button **261** are **machined from plastic** where the housing **20**, in one option, is machined from ABS plastic. In another example, the

EX1005 (Schaffer) ¶82.

[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.

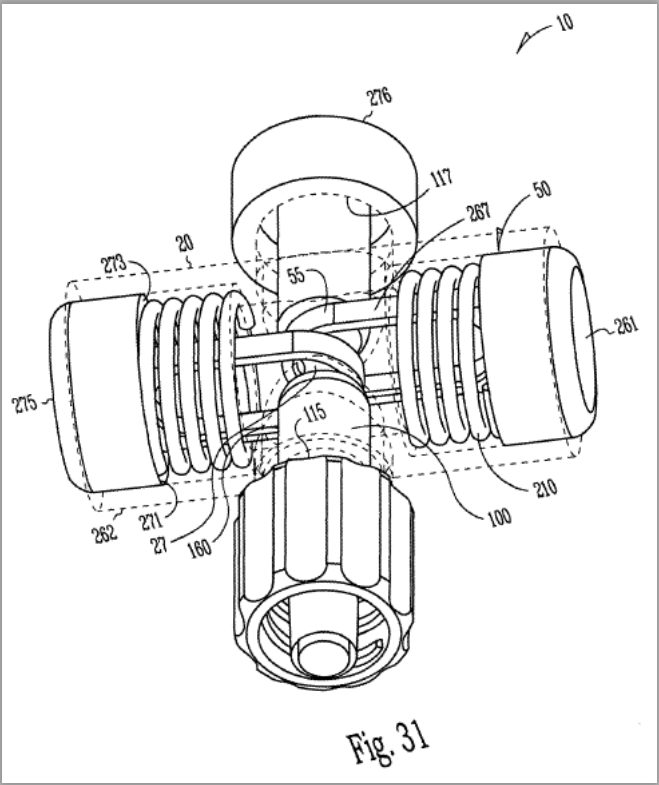
EX1005 (Schaffer) ¶83.

Grounds 3 and 4:

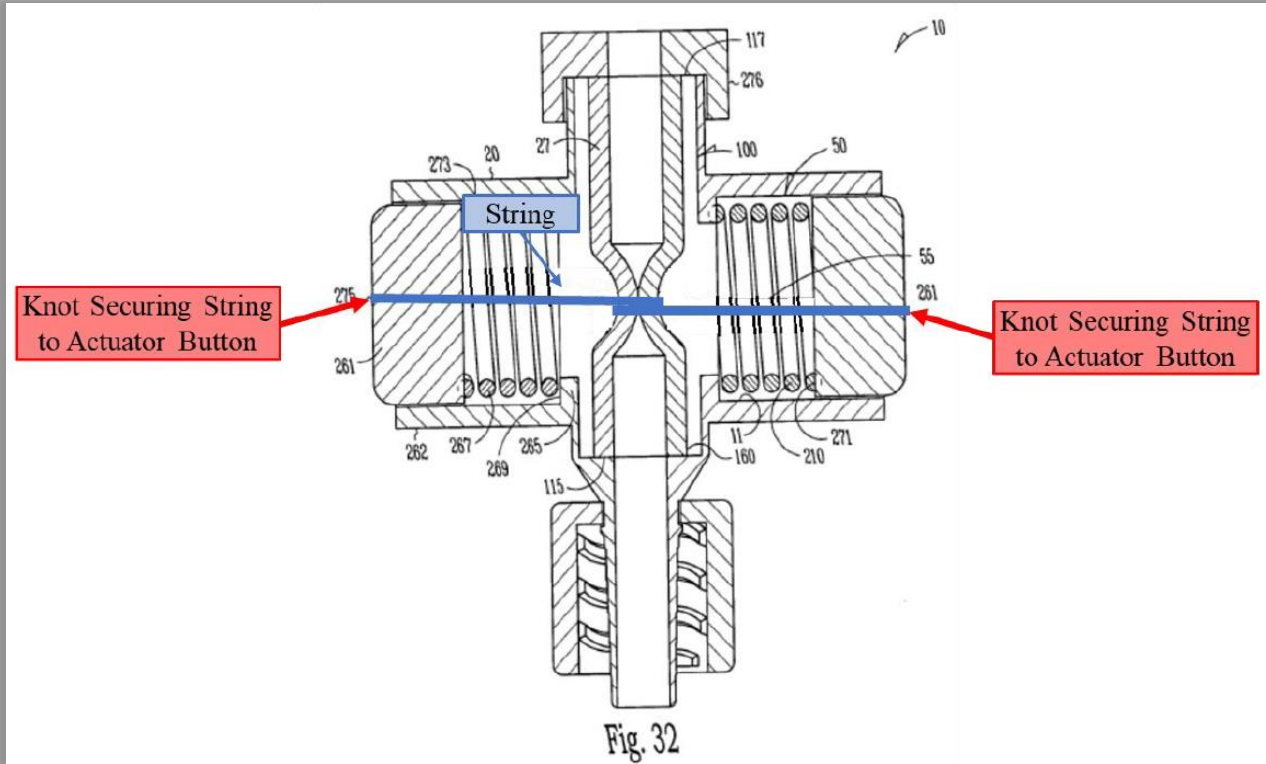
A POSA would not have combined Schaffer with Hartley or Eller to arrive at claim 1:

- does not improve sealing,
- not a simple substitution,
- solutions to purported sealing problem were not finite, identified, and known.

Schaffer, Hartley, and Eller.

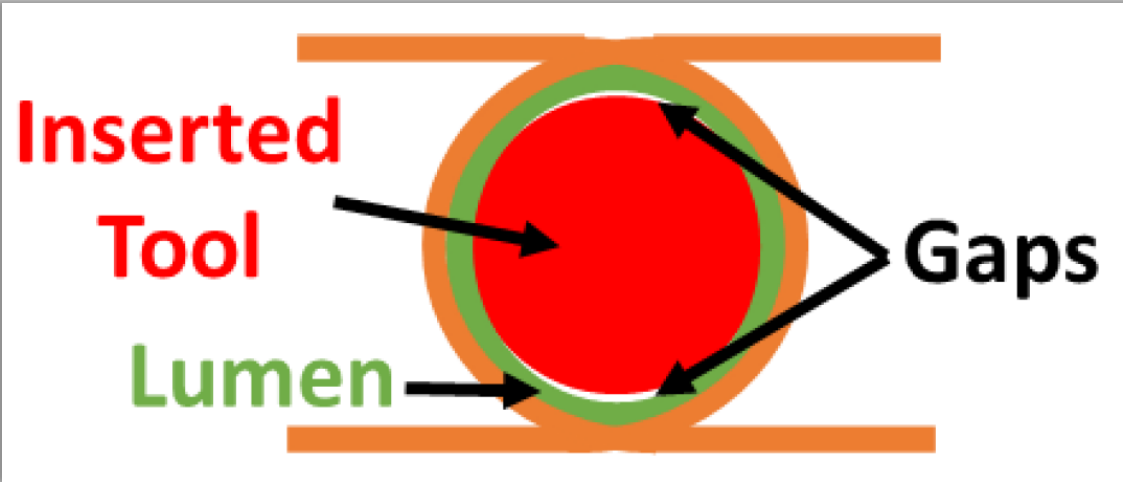


EX1008.

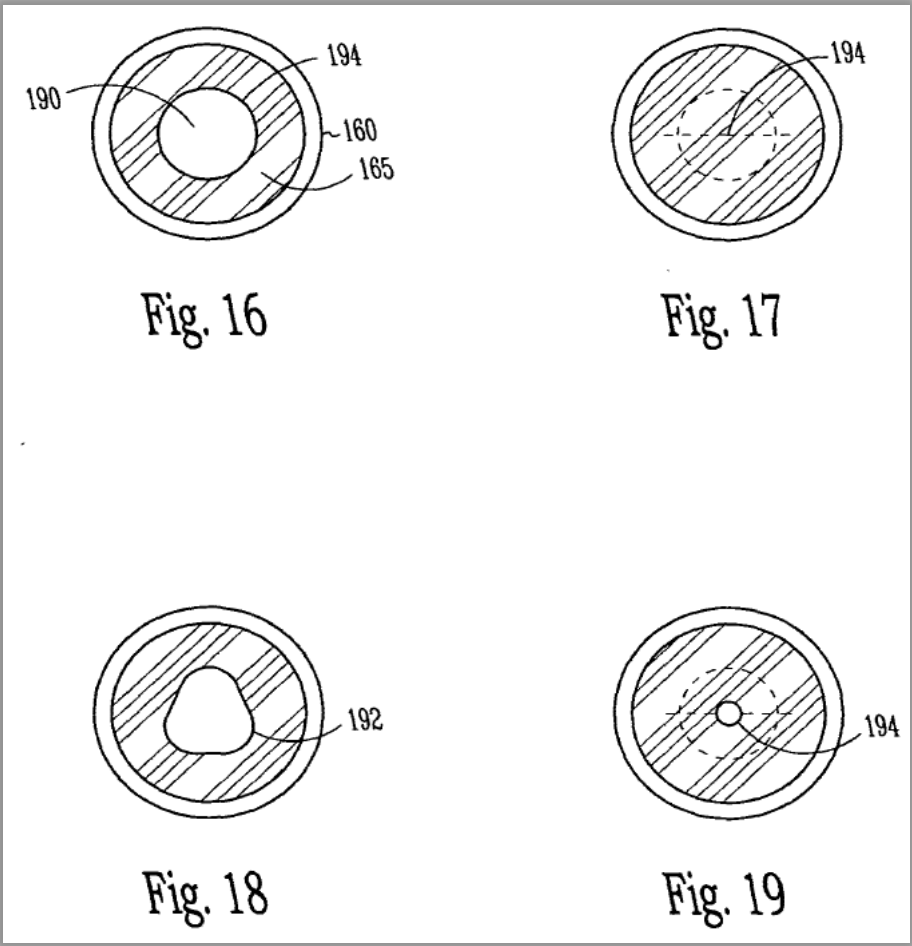


Pet. at 38.

Schaffer does not form gaps.



Pet. at 36.



EX1008.

POR at 46-52.

Schaffer's seal member 165.

[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.

EX1005 (Schaffer) ¶59.

[0060] With particular reference to FIGS. 10A, 10B, 16-19, the highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194 of the lumen 193 when at least one side of compressive force 67 is exerted upon the central region 195 with respect to the central portion 110 of the containment structure 160. The compressive load may be supplied by a movable, sliding or hinged, actuator 50 that maintains a compressive load upon the third central seal member 165 under the influence of a spring 210 or other resilient material. The spring 210 provides a compressive load between the actuating member 55 of the actuator 50 and the stationary member 65 positioned in the interior wall 11 of the housing 20.

EX1005 (Schaffer) ¶60.

Schaffer's seal member 165.

[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.

EX1005 (Schaffer) ¶59.

[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.

EX1005 (Schaffer) ¶75.

of ABS plastic. In one option, 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.

EX1005 (Schaffer) ¶81.

POR at 19.

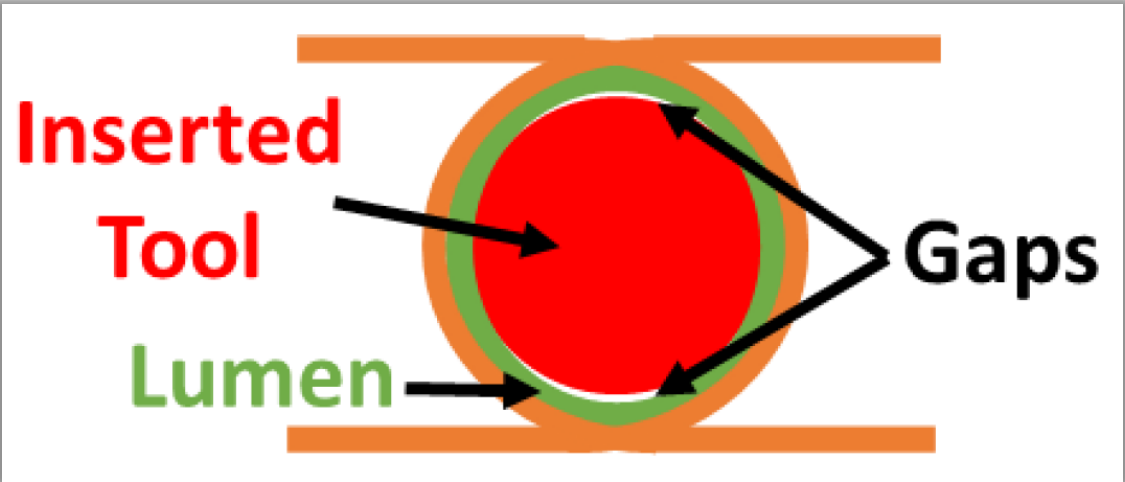
Schaffer's seal member 165.

[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

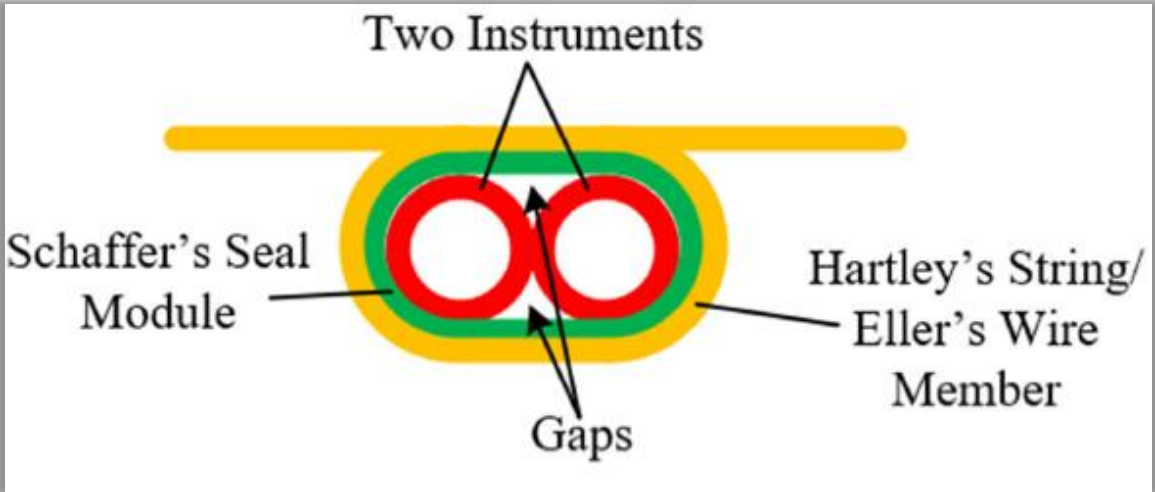
proximal end 273 of each actuator button 261 compresses the distal end 271 of each resilient member 267 which in turn, the proximal end 269 of each resilient member 267 compresses against the inner flange wall 265 of the housing 20. Such movement allows each engaged actuating member 55 to forcibly disengage 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.

EX1005 (Schaffer) ¶77.

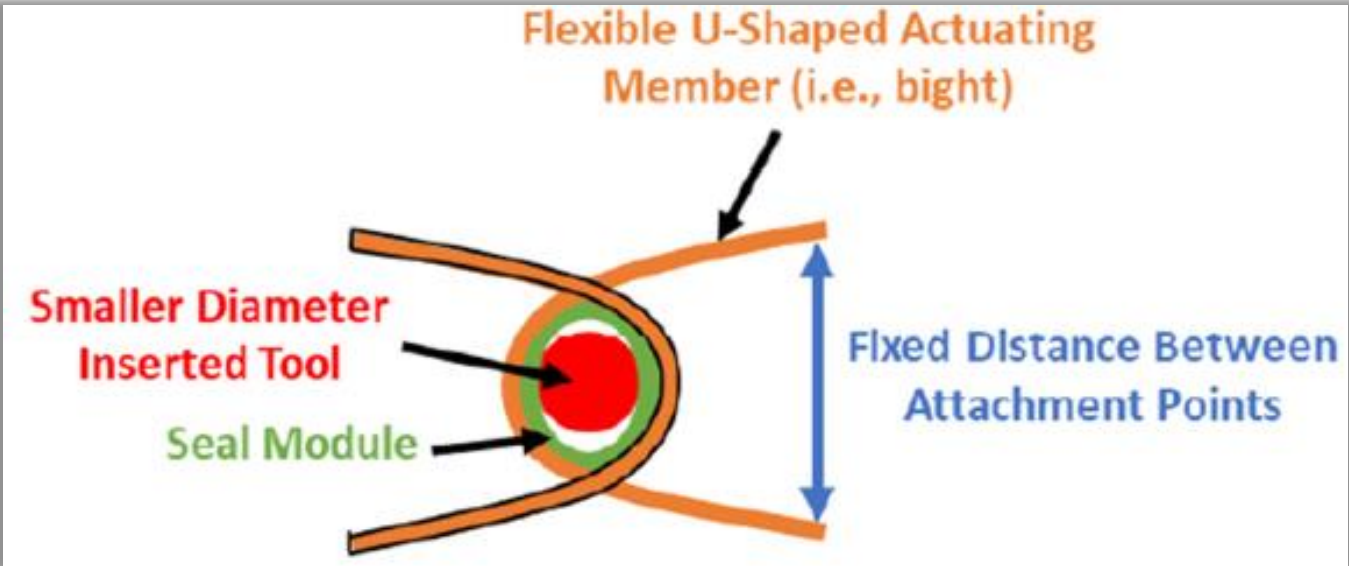
Schaffer's seal member 165.



Pet. at 36.

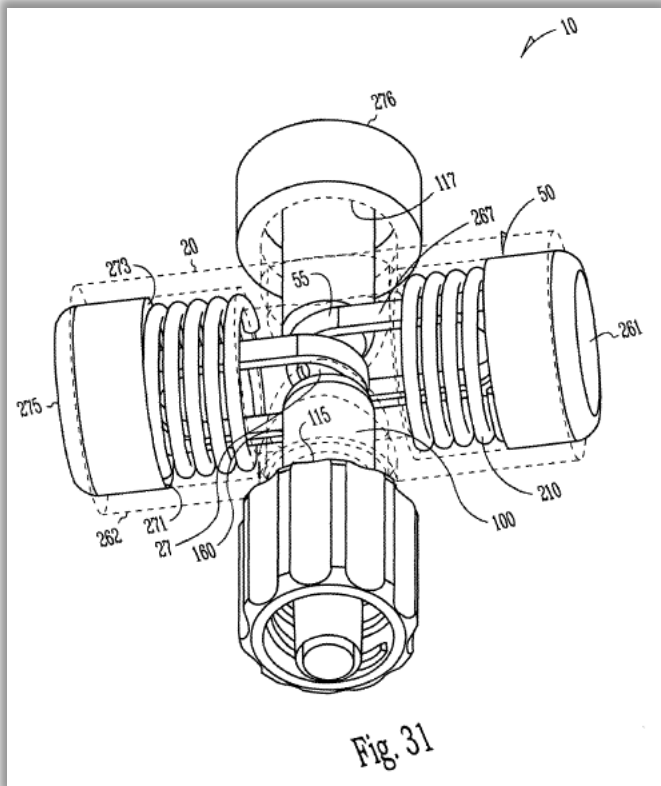


POR at 52.

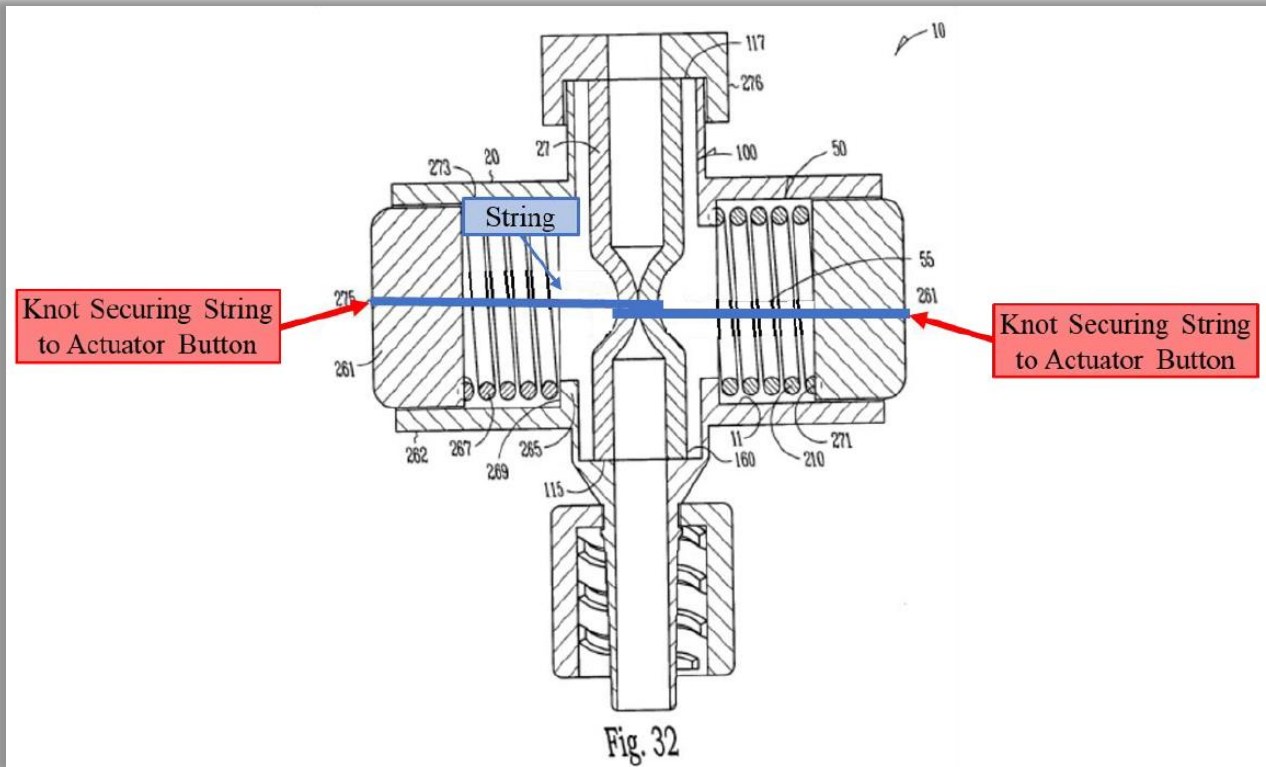


Reply at 24.

Proposed modification is not a simple substitution of one known element for another.

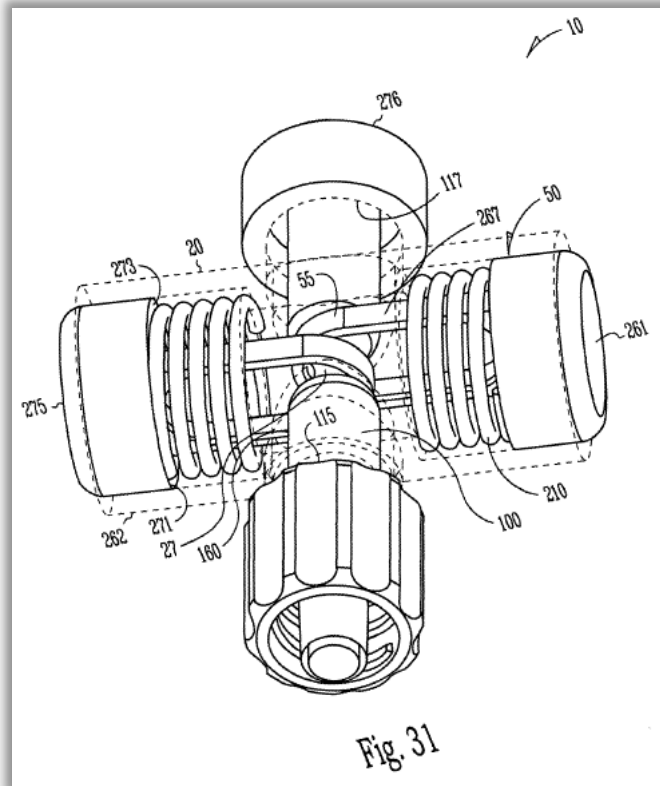


EX1008.



Pet. at 38.

Proposed modification is not a simple substitution of one known element for another.



EX1008.

Q In the embodiment, do either of those U-shaped actuating members -- are either of those U-shaped actuating members attached to two different buttons?

A Each of the U-shaped members are attached to a different button.

Q So then is it fair to say that one button will control the movement of one U-shaped actuating member and a different button will control the movement of another U-shaped actuating member?

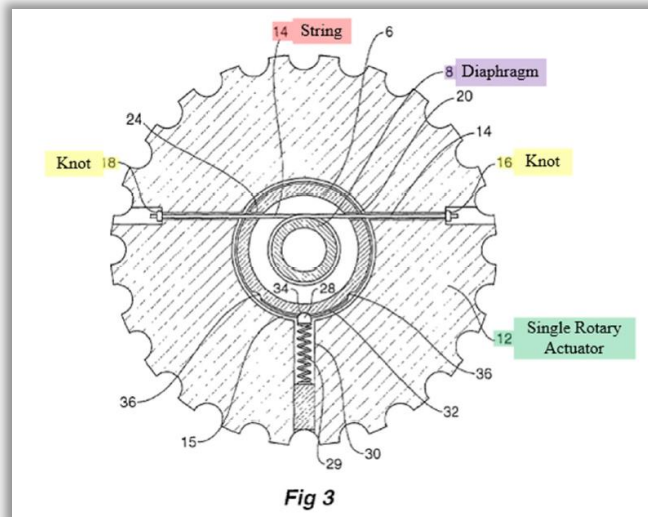
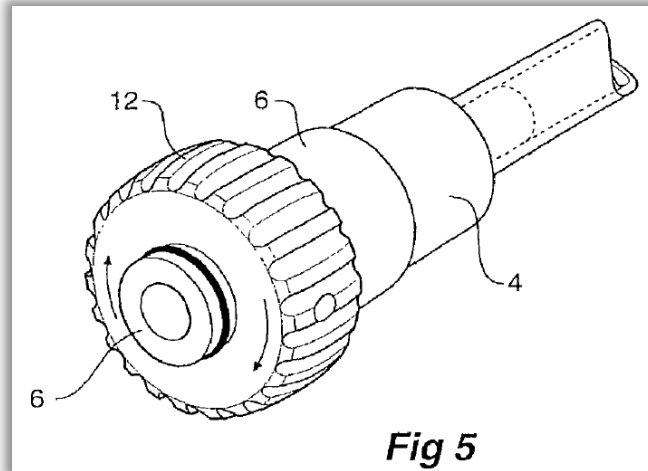
A Yes.

EX2010 (6-25-2025 Thornton Tr.) 57:13-22.

POR at 63-68.

PO Sur-Reply at 20-25.

Proposed modification is not a simple substitution of one known element for another.



Q Let's take a look at Figures 3 and 4. Do Figures 3 and 4 depict a single string connected on each end to a single rotating actuating member?

A Yes, I can describe it that way.

Q And because the two ends of the string are connected to a single rotating rotator, let's say, those two ends cannot move independently of each other, can they?

MR. STOWELL: Objection. Vague.

THE WITNESS: Yeah, they would move together as the actuator is rotated.

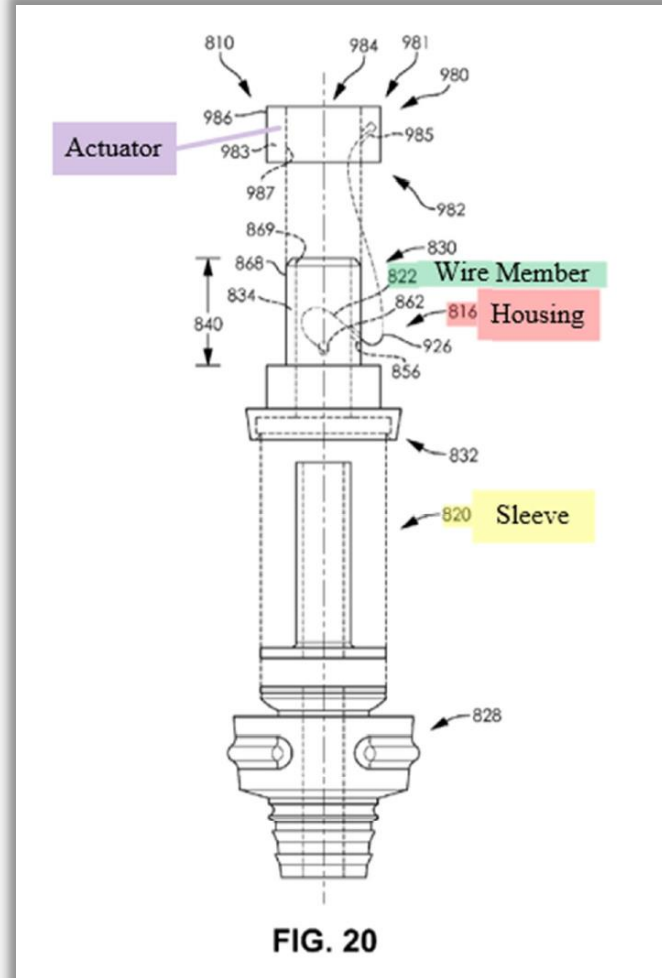
EX2010 (6-25-2025 Thornton Tr.) 77:12-22.

EX1006 (Hartley).

POR at 63-68.

PO Sur-Reply at 20-25.

Proposed modification is not a simple substitution of one known element for another.



EX1007 (Eller).

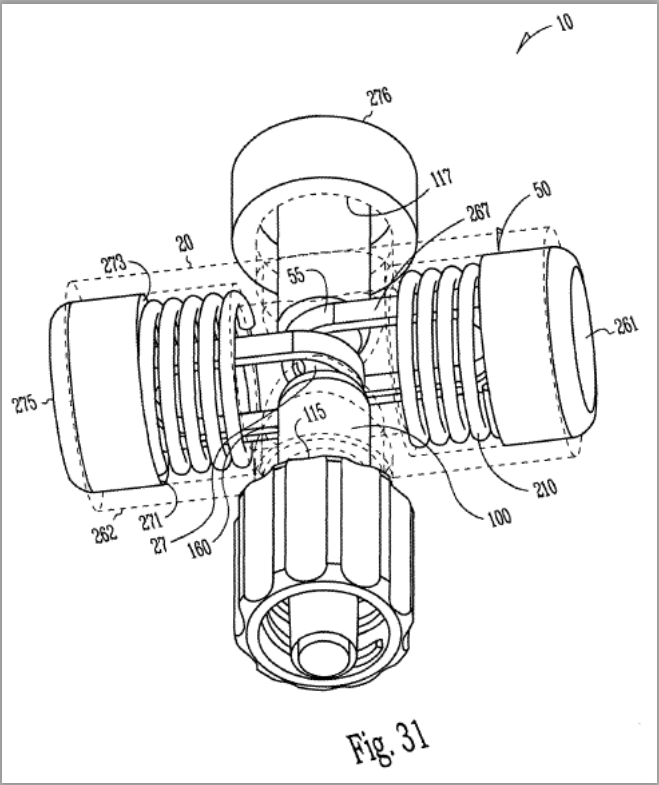
Q So whether one -- I think you had said wire member, or multiple wire members are used, they are all attached to a single [actuator] in Eller, correct?

MR. STOWELL: Objection. Vague. Misstates document.

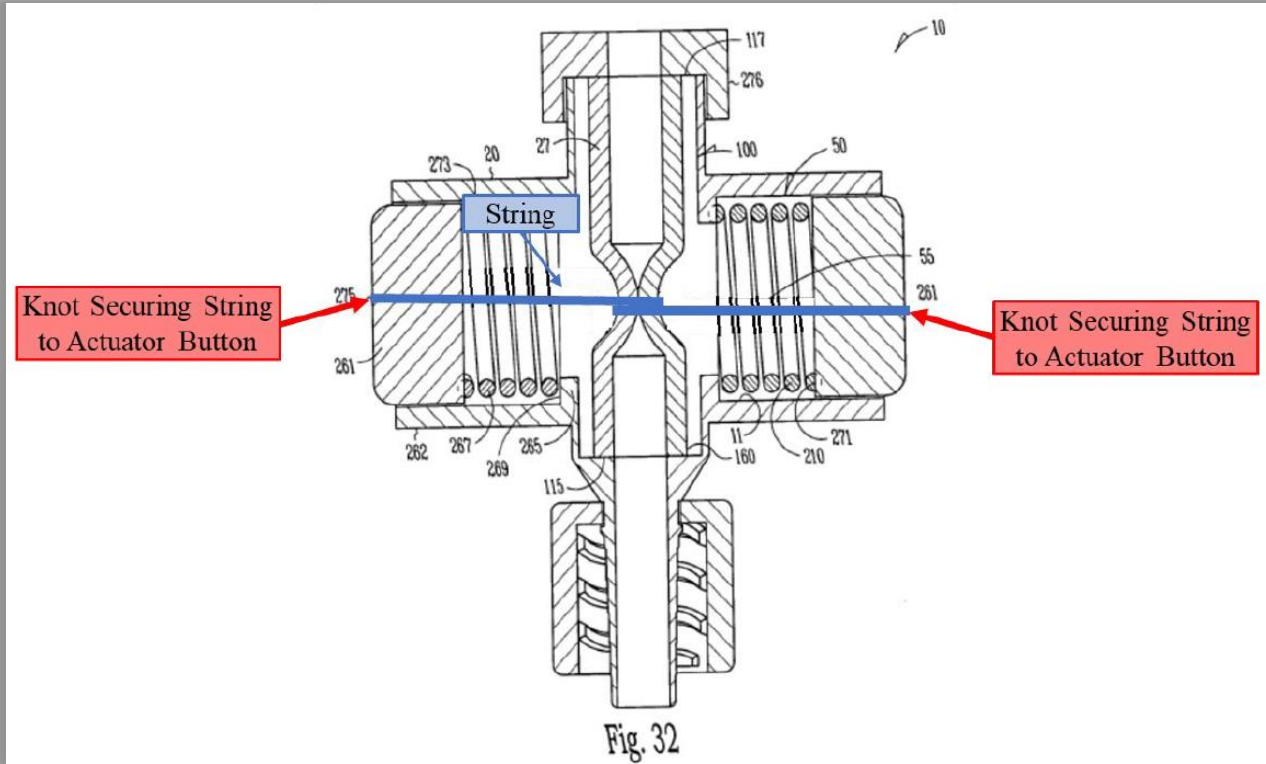
THE WITNESS: I'm not sure if all the embodiments work that way. But that's my understanding for the embodiments shown in Figure 18, 19, for instance. 20 through 22 would operate that way.

EX2010 (6-25-2025 Thornton Tr.) 80:21-81:3.

Proposed modification is not a simple substitution of one known element for another.

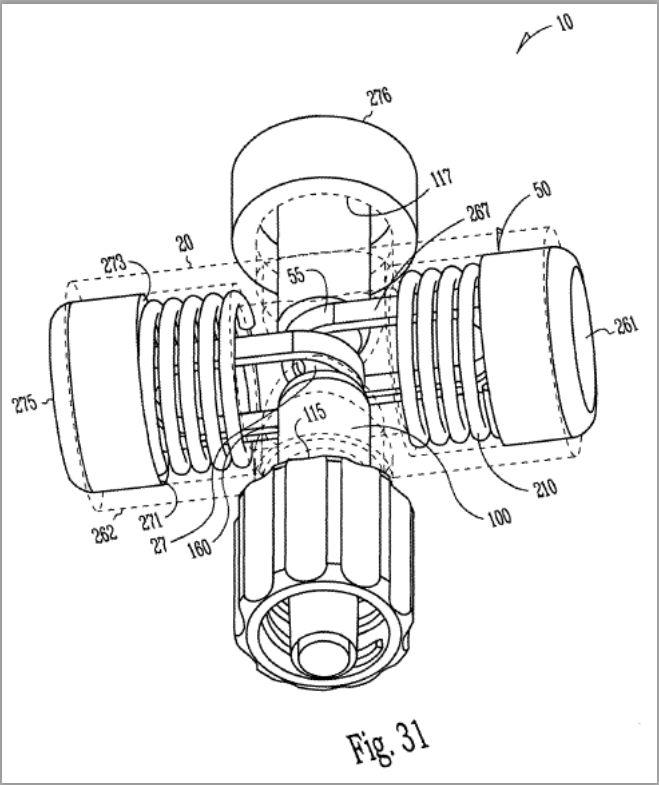


EX1008.

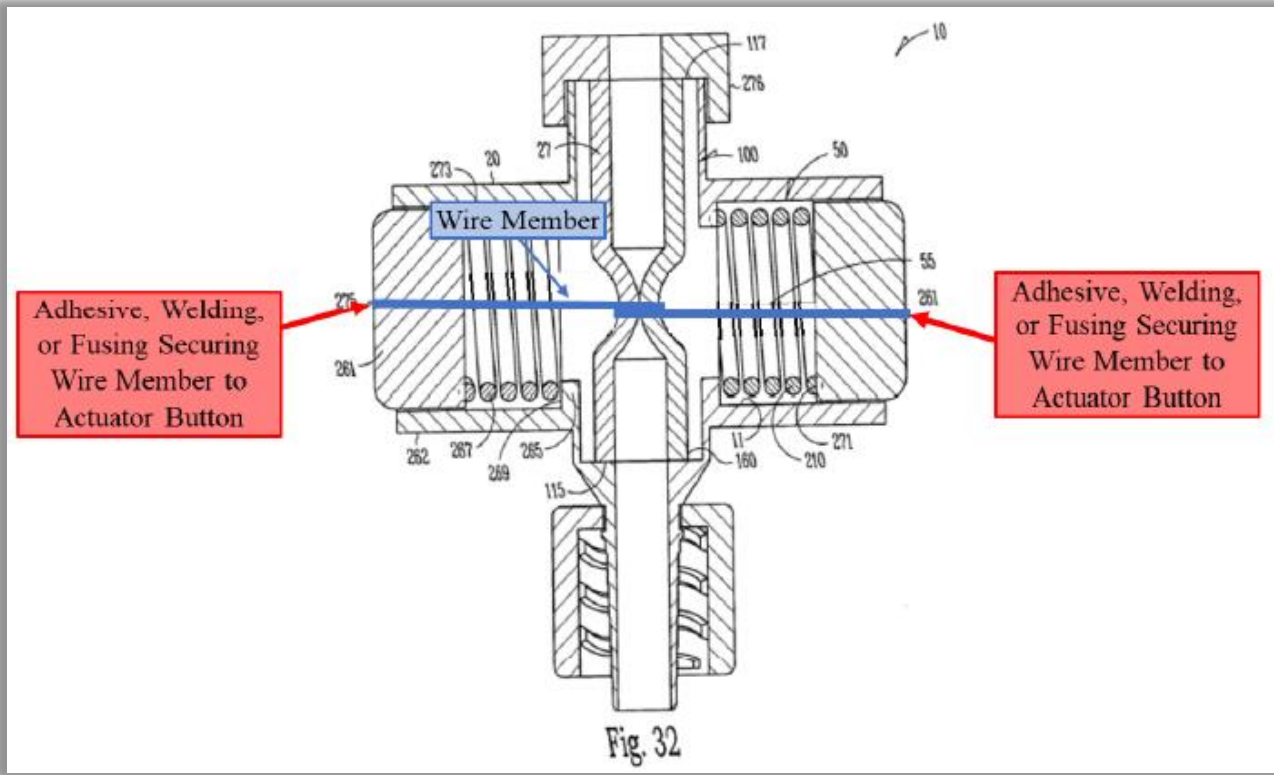


Pet. at 38.

Proposed modification is not a simple substitution of one known element for another.

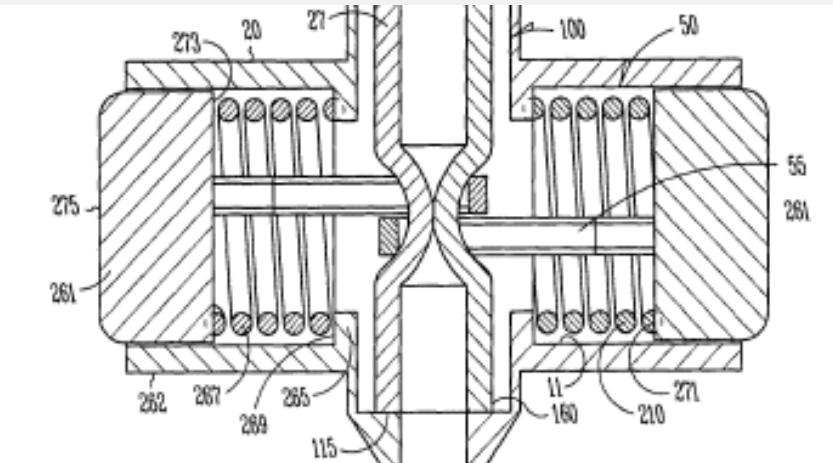


EX1008.



Pet. at 46.

Proposed modification is not a simple substitution of one known element for another.



EX1008 (portion).

THE WITNESS: Theoretically, a harder material would be able to deform a softer material more readily.

EX2011 (8-15-2025 Thornton Tr.) 36:11-12.

THE WITNESS: U-shaped members deform the seal module in areas that it's in contact with the seal module.

BY MR. HAMILTON:

Q And it's in contact along the longest side of each of those cross-sectional rectangles, correct?

A Yes. That's the part that's in contact with the seal module.

EX2011 (8-15-2025 Thornton Tr.) 41:18-24.

A That's the area in contact. That's where you're trying to compress the seal module. So it would compress the seal module in areas that are in contact with the string or wire or filament.

EX2011 (8-15-2025 Thornton Tr.) 4:35-8.

PO Sur-Reply at 19.

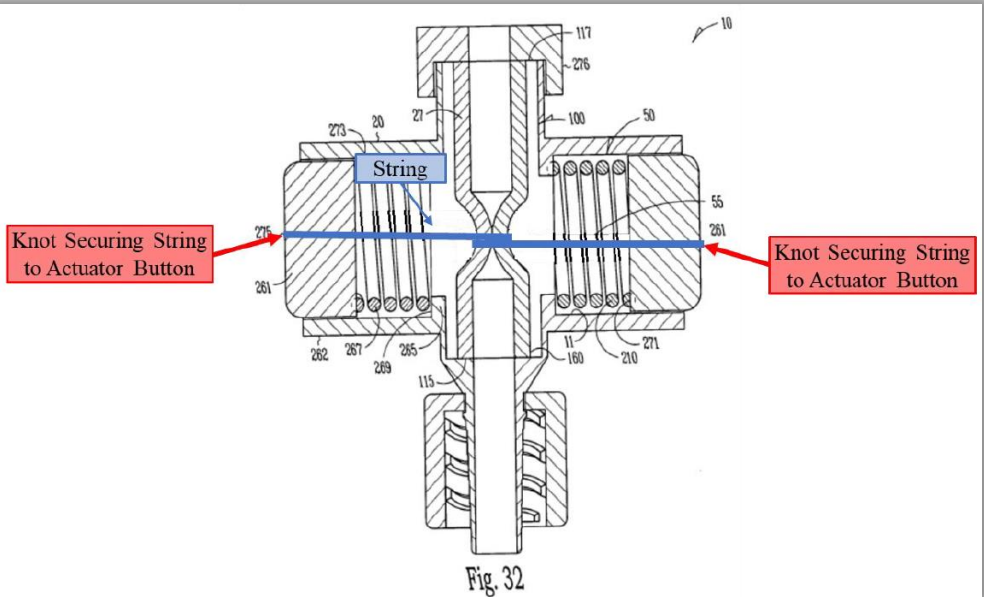


Fig. 32

Options are not finite, identified and known.

Q Do you think there's other ways that exist?

MR. STOWELL: Objection. Vague.

THE WITNESS: Could be other ways that exist.

BY MR. HAMILTON:

Q How many other?

A I don't know.

Q So when you say, These finite predictable options, you don't know how many other finite predictable options there are; is that correct?

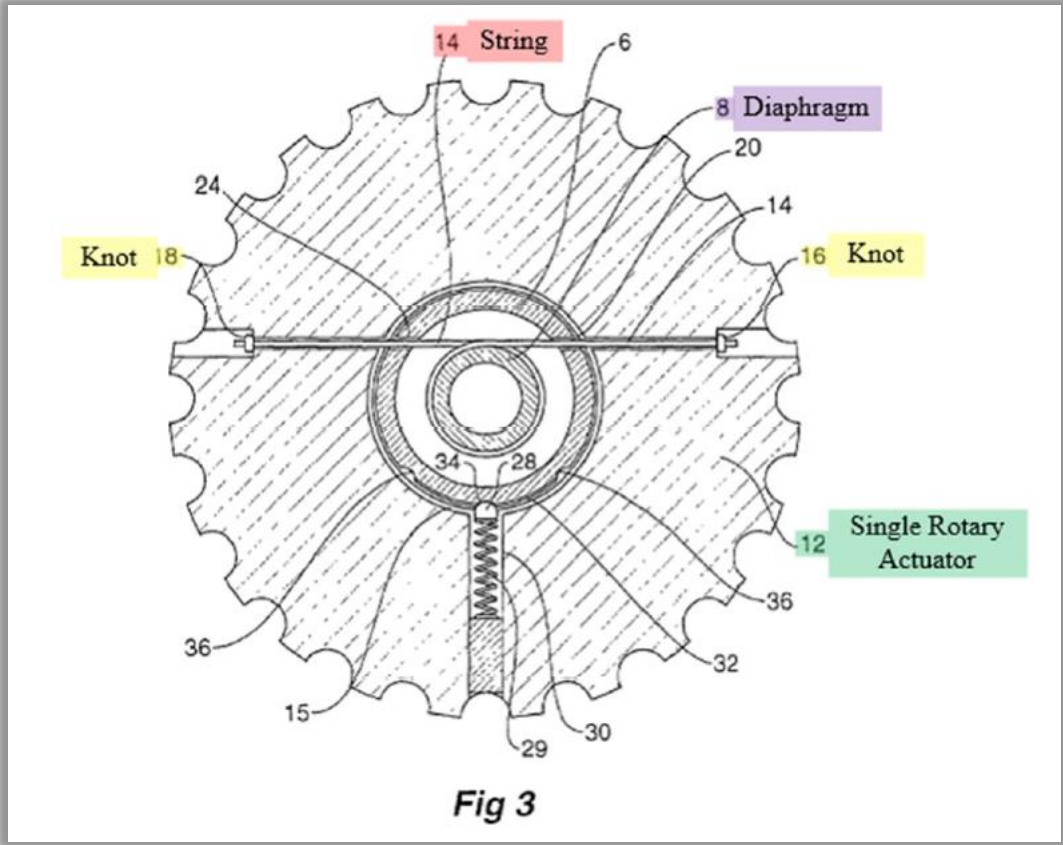
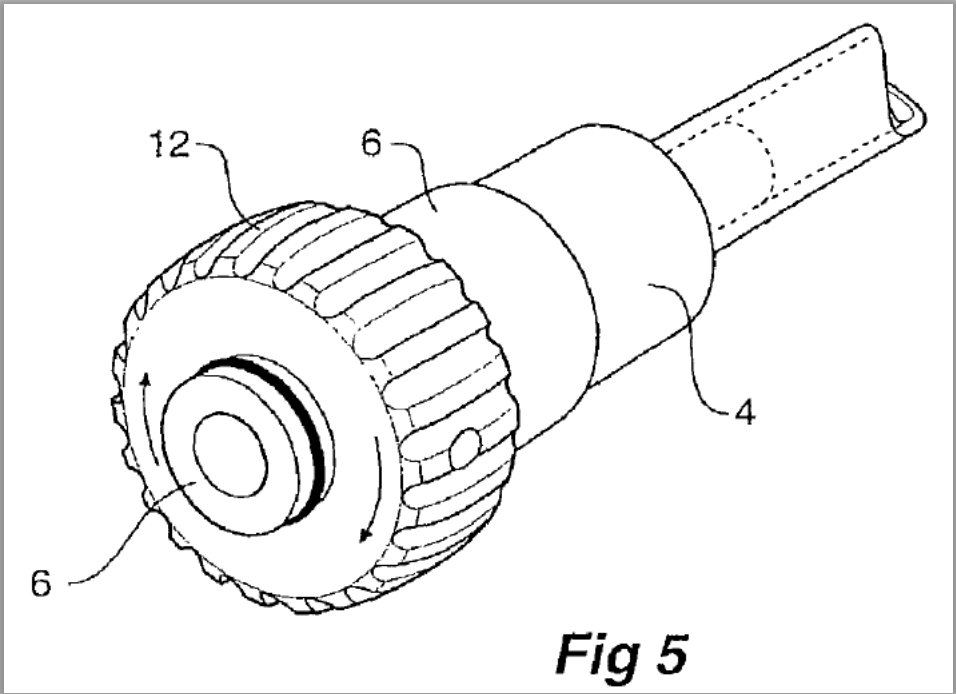
MR. STOWELL: Objection. Misstates testimony.

THE WITNESS: I don't know how many options could be used to compress a tube.

GROUND 5:

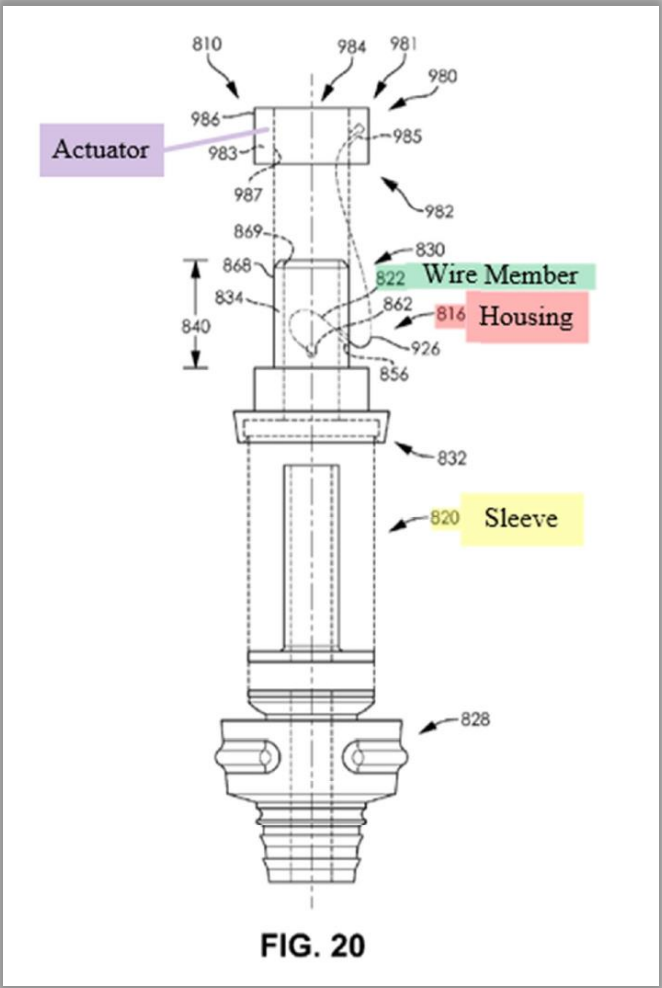
The combination of Hartley and Eller does not disclose “the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament” as recited in claim 1.

Hartley and Eller disclose an actuator with a single member.



EX1006 (Hartley).

Hartley and Eller disclose an actuator with a single member.



EX1007 (Eller).

US11,844,921 claims

1. A valve, comprising:
an elongate member defining a lumen;
an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and
a biasing member configured to bias the actuator to the first position.

EX1020 (citing '921 Patent) 13-14.

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.

US11,844,921 patent claims

10. The valve of claim 1 wherein the actuator is a first actuator, wherein the filament is a first filament, wherein the biasing member is a first biasing member, and wherein the active tensioning mechanism further comprises:

- a second actuator coupled to the elongate member via a second filament extending at least partially around the elongate member, wherein the second actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and
- a second biasing member configured to bias the second actuator to the first position.

EX1020 (citing '921 Patent) 13-14.

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.