The Patent Trial and Appeal Board

Imperative Care, Inc.,
Petitioner,
v.
Inari Medical Inc.,
Patent Owner.

Case No. IPR2025-00289 (US11,554,005)
Patent Owner Demonstratives

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

US11,554,005 (’005 Patent)

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

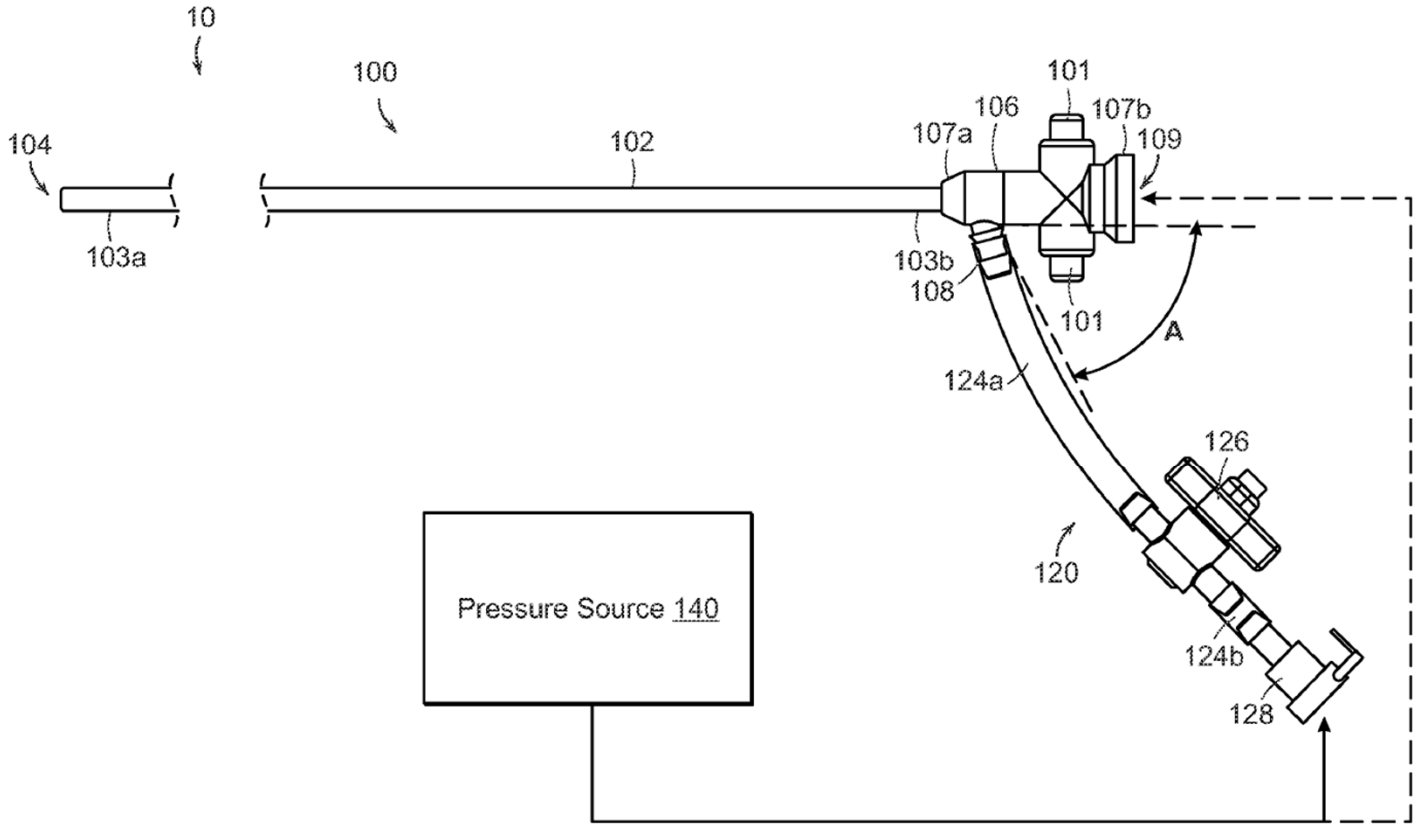


FIG. 1

EX1001 (’005 Patent).

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

’005 Patent, Claim 1

1. A vacuum aspiration system, comprising:
a housing;
a flow path extending through the housing;
an on-off control in the flow path;
a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;
a clot cannister fluidly coupled to the flow path; and
a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises:
a tubular member defining a lumen configured to slidably receive the second catheter;
a constricting mechanism including a 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 couped 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.

EX1001 (’005 Patent).

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

’005 Patent, Claim 10

10. A vacuum aspiration system, comprising:
a housing;
a flow path extending through the housing;
an on-off control in the flow path;
a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;
a clot cannister fluidly coupled to the flow path; and
a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises

(a) a support;
(b) an actuator having a least a first member movably coupled to the support;
(c) a collapsible tubular sidewall defining a lumen carried by the support;
(d) a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member; and
(e) a first spring configured to move the first member in a direction that pulls the first end portion such that a diameter of the lumen decreases in response to reducing a diameter of the loop.

EX1001 (’005 Patent).

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

’005 Patent, Claims 11, 12 (13-15)

11. The vacuum aspiration system of claim **10**, further comprising a second member movably coupled to the support.

12. The vacuum aspiration system of claim **11** wherein the filament further comprises a second end portion extending away from the loop to the second member.

13. The vacuum aspiration system of claim **12** first end portion, the loop, and the second end portion are one continuous filament.

EX1001 (’005 Patent).

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

’005 Patent Claim 1

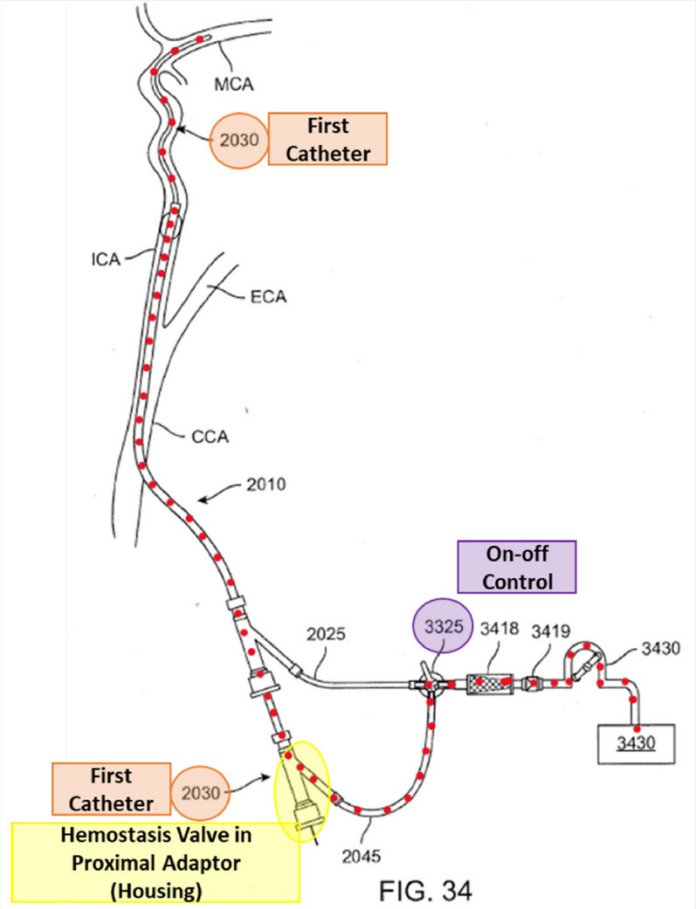


FIG. 34

Pet. at 25.

1. A vacuum aspiration system, comprising:
a housing;
a flow path extending through the housing;
an on-off control in the flow path;
a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;
a clot cannister fluidly coupled to the flow path; and
a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises:

EX1001 (’005 Patent).

A Garrison shows the on/off control or stopcock between the aspiration catheter and the vacuum source or aspiration source. It's not in the same housing where the hemostasis valve is housed.

EX2036, 35:21-24.

POR at 33-40.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

’005 Patent Specification

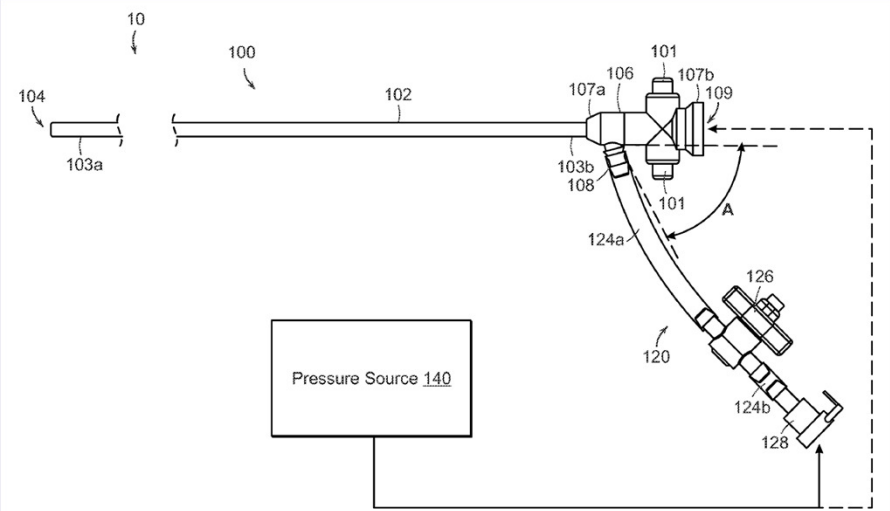


FIG. 1

EX1001 (’005 Patent).

[0038] The proximal cap 116 and the distal cap 120 are connected via a housing 128. The housing 128 can be a one-piece housing 128 or a multi-piece housing 128. In the embodiment

[0039] The housing 128 can define an interior channel 130 through which an elongate member 132, also referred to herein as a tubular member 132, a septum 132, or a tubular septum 132, can extend and connect the proximal cap 116 and the distal cap 120. The elongate member

EX1017 (’519 Application).

The tubing subsystem **120** fluidly couples the catheter subsystem **100** to the pressure source **140**. More specifically, the tubing subsystem **120** can include one or more tubing sections **124** (individually labeled as a first tubing section **124***a* and a second tubing section **124***b*), at least one fluid control device **126** (e.g., a valve), and at least one connector **128** for fluidly coupling the tubing subsystem **120** to the pressure source **140** and/or other suitable components. More specifically, in the illustrated embodiment, the fluid control device **126** is a stopcock that is fluidly coupled to (i) the side port **108** of the valve **106** via the first tubing section **124***a* and (ii) the connector **128** via the second tubing section **124***b*. In some embodiments, the fluid control device **126**

EX1001 (’005 Patent, 5:66-6:11).

In other embodiments, the tubing subsystem **120** can have more or fewer tubing sections, connectors, and/or fluid control devices, and can have other suitable configurations. In some embodiments, one or more of the components can be permanently connected and/or integrally formed.

EX1001 (’005 Patent, 6:45-49).

POR at 36-38.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

’005 Patent, File History

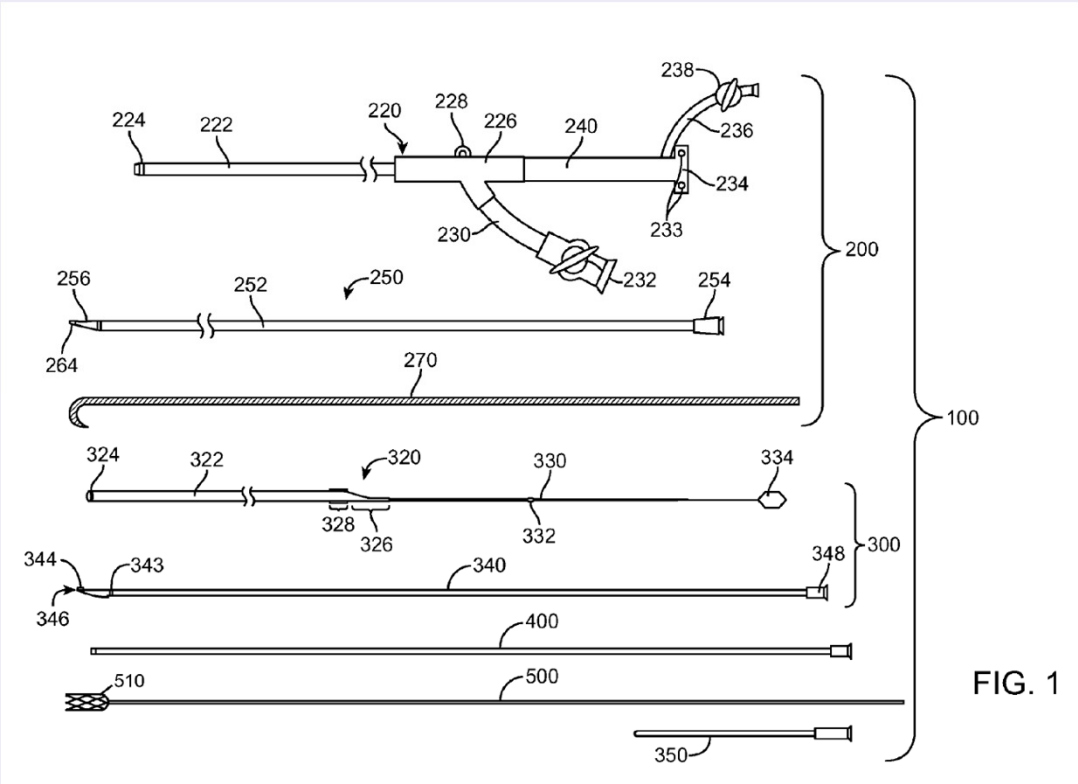


FIG. 1

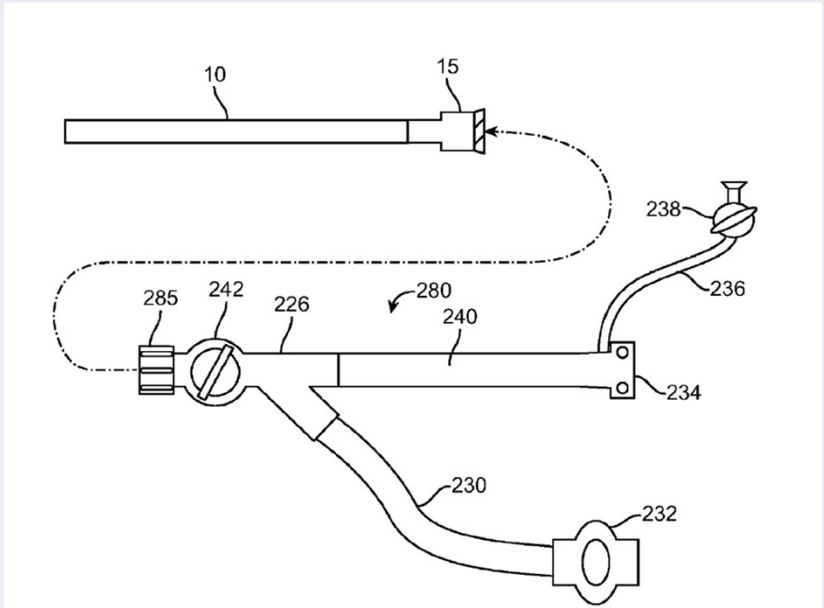


FIG. 5

EX1019.

POR at 38-40.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Zalesky's Testimony

The '005 Patent claims and description support that Garrison does not disclose that the valve 3325 is "in the flow path" "extending through the housing." First, claims 1 and 10 use the term "*in*" to describe the relative position of the on-off control relative to the flow path, but use the term "*fluidly coupled to*" to describe the relative position of the clot cannister to the flow path. A

EX2026, ¶93
(confirmed at EX1042, 130:20-134:3).

POR at 35;
PO Sur-Reply at 6.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Zalesky's Testimony

nents. The '005 Patent description reflects this difference as well, drawing a distinction between embodiments in which a fluid control device is fluidly coupled to a valve housing (e.g., via tubing), and embodiments in which the fluid control device is part of the valve housing. *E.g.*, compare EX1001, 6:3-11 and Figure 1 with EX1001, 6:45-49. Claims 1 and 10 clearly require the former.

EX2026, ¶93
(confirmed at EX1042, 130:20-134:3).

POR at 35;
PO Sur-Reply at 6.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Zalesky's Testimony

It is your opinion that Garrison does not disclose an on-off control in the flow path as recited in claim 1 because Garrison's valve 3325 is not located in the same housing as the hemostasis valve. Correct?

A. Yes, that is what I am stating.

EX1042, 83:17-22.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Zalesky's Testimony

Q. If we turn back to page 13 of your supplemental declaration -- or page 14, rather.

You would agree with me that, in the annotated version of figure 1 that you prepared, you illustrated a flow path that extends through the housing that extends well beyond the proximal and distal ends of the housing. Correct?

A. No, that is not exactly what I said.

Q. Why is that wrong?

A. Your descriptor suggests axial flow throughout the entire assembly.

Q. What descriptor?

A. The phrase that you just used for my interpretation.

Q. So in your own phrasing in paragraph 36 than is on page 13, you said, "Figure 1 of the '005 patent shows a vacuum aspiration system with a flow path extending through a housing."

Did I read that right?

A. Yes, we addressed this earlier. The key word here is "through." And "through" connotes completely through as opposed to partially through.

EX1042, 85:22-86:21.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Zalesky's Testimony

36. Figure 1 of the '005 Patent shows a vacuum aspiration system with a flow path extending through a housing, a valve 126 in the flow path (e.g., an on-off control), and a first catheter 102 in fluid communication with a pressure source 140 via a connector 108:

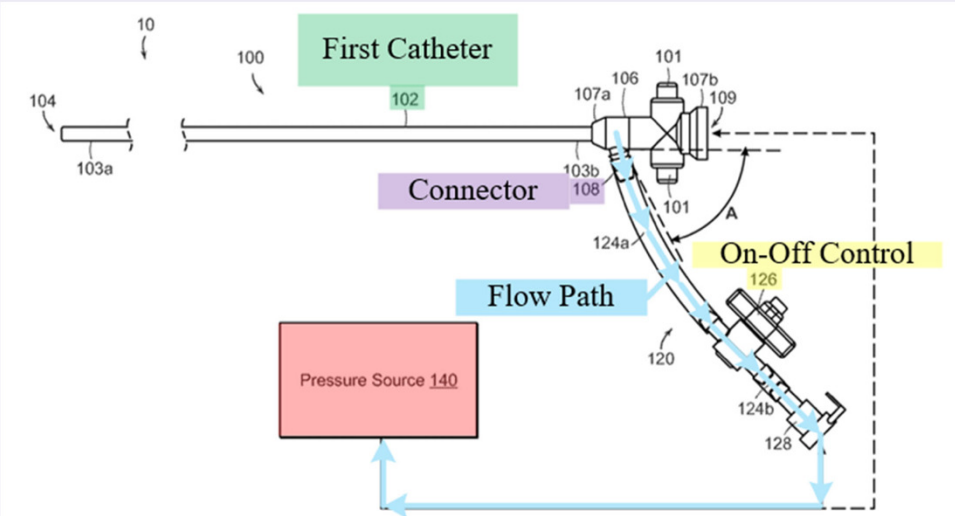


FIG. 1

EX2026, ¶36.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Zalesky's Testimony

Q. In paragraph 92, in the second sentence, you say, "First, the red dashed line that petitioner uses to denote the purported flow path extends well beyond either end of the alleged housing and thus tracks more than just 'the flow path' 'extending through the housing.' A POSITA would understand that the proper illustration of the flow path extending through the housing would be from one end of the proximal adapter to the other."

Did I read that correctly?

A. Yes.

EX1042, 85:10-21.

PO Sur-Reply at 3-6.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Zalesky's Testimony

A. Yes, I will try this one more time. "Through" can be interpreted different ways by different POSITAs. One interpretation is an axial flow through the entire length of the housing. Another interpretation is it goes through a part of the housing and certainly is still through, but a different flow path configuration.

Q. Which is the interpretation that applies to claim 1 of the '005 patent?

A. My interpretation is it covers both.

EX1042, 88:4-14.

PO Sur-Reply at 3-6.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Zalesky's Testimony

Q. You were asked questions by counsel about paragraphs 91 through 93 related to the housing. Can you take a moment and read those paragraphs for me.

A. Okay.

Q. And can you read the first sentence of paragraph 92 out loud?

A. "A POSITA would not have considered Garrison's valve 3325 to be in the flow path extending through the housing as recited in claims 1 and 10."

Do you want me to go on?

Q. No. That is okay.

Is that your testimony that you are submitting in connection with this IPR?

A. Yes.

Q. Is that testimony accurate?

A. Yes.

EX1042, 130:20-131:14.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

PO Sur-Reply at 6.

Petitioner's expert

Q (BY ATTORNEY MILLER) Do you have any opinion as to whether a person of ordinary skill in the art would understand the term "in the flow path" and "fluidly coupled to the flow path" to have the same meaning?

ATTORNEY STOWELL: Objection, vague.

A I didn't address that. I didn't think about that in the declarations that I have done so far.

EX2036 (36:23-37:6).

Q What is the difference between "in the flow path" and "fluidly coupled"?

ATTORNEY STOWELL: Objection, outside the scope of the supplemental declaration.

A I haven't considered those two terms' differences or similarities.

Q (BY ATTORNEY MILLER) So in forming your opinion with respect to the prior art in this IPR, you did not consider what "in the flow path" meant versus "fluidly coupled"?

ATTORNEY STOWELL: Objection, misstates testimony.

A I didn't consider what those terms mean similarly or if there are any differences between those two terms, no.

EX2036 (29:5-19).

PO Sur-Reply at 6.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

’005 Patent, Claims 1, 1 0

1. A vacuum aspiration system, comprising:
a housing;
a flow path extending through the housing;
an on-off control in the flow path;
a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;
a clot cannister fluidly coupled to the flow path; and
a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises:
a tubular member defining a lumen configured to slidably receive the second catheter;
a constricting mechanism including a 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

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10. A vacuum aspiration system, comprising:
a housing;
a flow path extending through the housing;
an on-off control in the flow path;
a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;
a clot cannister fluidly coupled to the flow path; and
a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises

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EX1001 (’005 Patent).

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Combinations of Garrison, Schaffer, Hartley or Eller (Grounds 1-4):

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Ground 4 (Garrison, Hartley, and Eller)

1. A vacuum aspiration system, comprising:
a housing;
a flow path extending through the housing;
an on-off control in the flow path;
a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;
a clot cannister fluidly coupled to the flow path; and
a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises:
a tubular member defining a lumen configured to slidably receive the second catheter;
a constricting mechanism including a 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 couped 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.

EX1001 ('005 Patent).

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

POR at 78-79.

Ground 4 (Garrison, Hartley, and Eller)

11. The vacuum aspiration system of claim **10**, further comprising a second member movably coupled to the support.

12. The vacuum aspiration system of claim **11** wherein the filament further comprises a second end portion extending away from the loop to the second member.

13. The vacuum aspiration system of claim **12** first end portion, the loop, and the second end portion are one continuous filament.

EX1001 ('005 Patent).

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

POR at 78-79, 83-84.

Grounds 1-3 (Garrison, Schaffer, Hartley, or Eller)

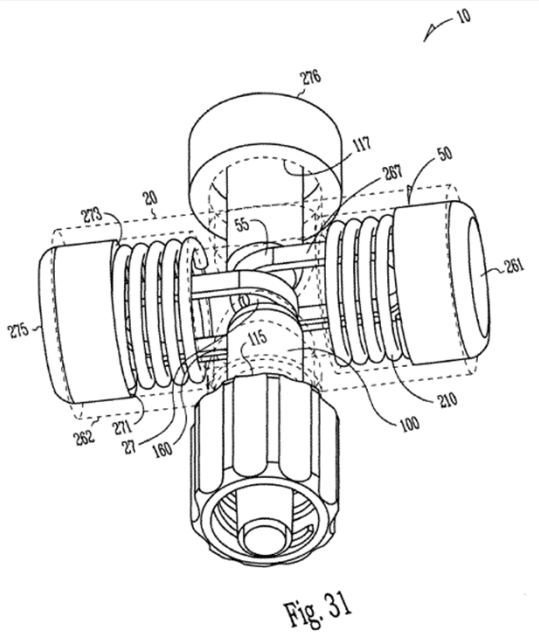


Fig. 31

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.

EX2029 (6-25-2025 Thornton Tr.) 57:13-22.

POR at 64.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Grounds 1-3 (Garrison, Schaffer, Hartley, or Eller)

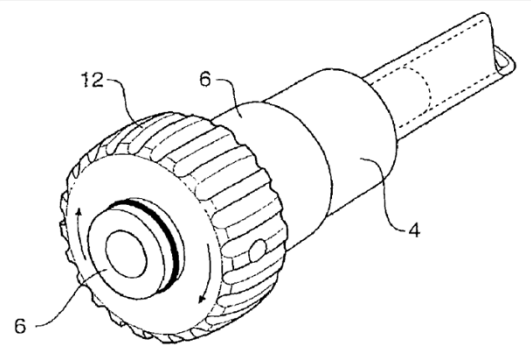


Fig 5

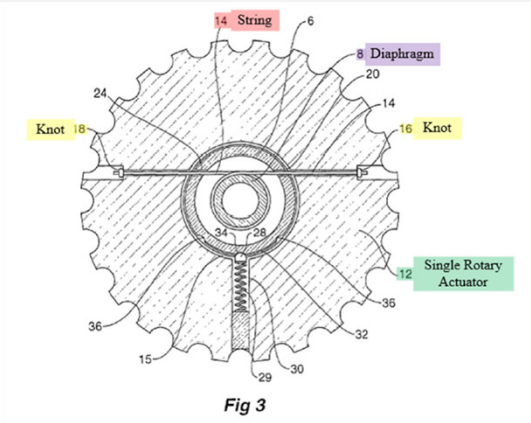


Fig 3

EX1006 (Hartley).

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.

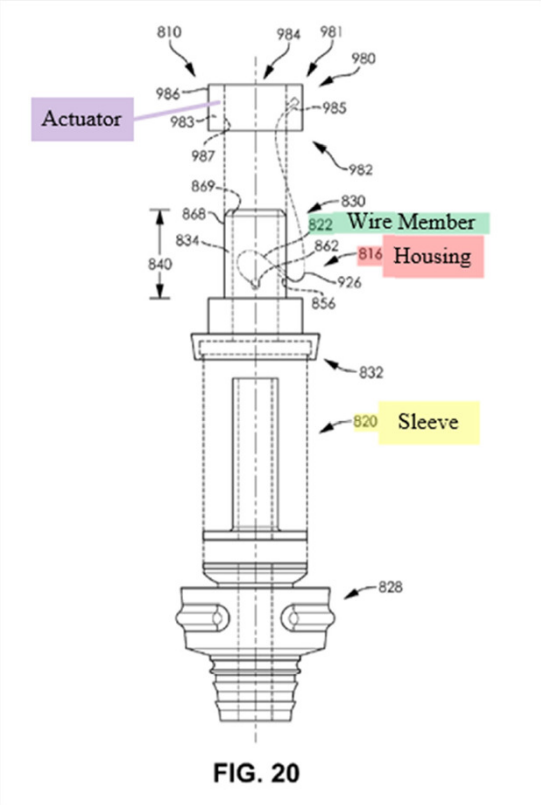
THE WITNESS: Yeah, they would move together as the actuator is rotated.

EX2029 (6-25-2025 Thornton Tr.) 77:12-22.

POR at 65.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Grounds 1-3 (Garrison, Schaffer, Hartley, or Eller)



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.

EX2029 (6-25-2025 Thornton Tr.) 80:21-81:3.

POR at 66.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

IPR2025-00289 (’005 Patent)

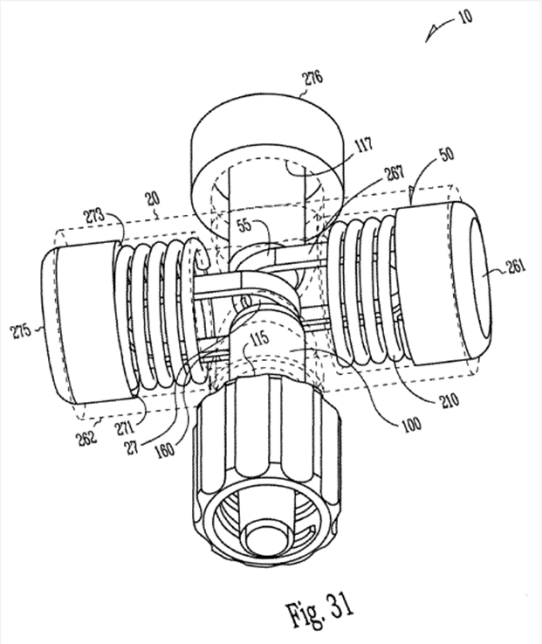


Fig. 31

EX1008.

shape of the seal module. For example, the actuating members could be formed from a thin, flexible sheet or flat ribbon of metal or plastic so that they have the flexibility to conform to the outer surface of the cylindrical seal module. A person of ordinary skill in the art would have reasonably expected success in making these simple and routine adjustments. Actuating members with this type of structure and flexibility would circumferentially constrict the lumen of Schaffer’s seal module when pulled in opposite directions by the actuator buttons. For these reasons, if

EX1003, Para 118 (cited in Pet. at 48-19).

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PO Sur-Reply at 21.

IPR2024-01157 (US11,697,011)

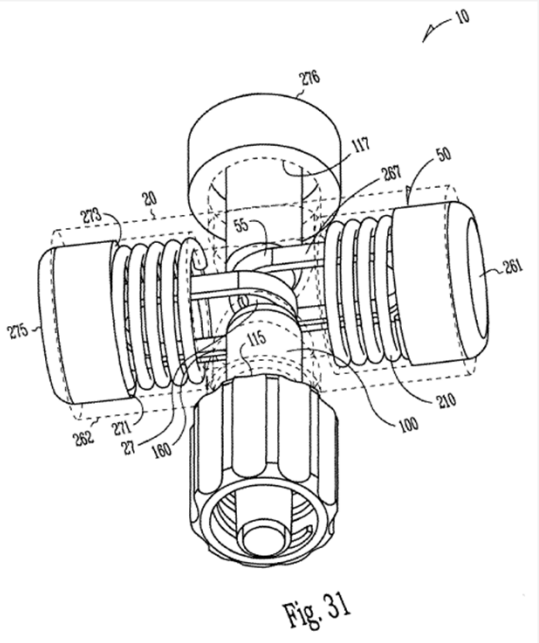


Fig. 31

EX1008.

create a seal" as claimed in the '011 patent, a POSITA would have found it obvious to modify the U-shaped actuating members to closely conform to the seal module to circumferentially constrict the lumen. (Ex. 1003, ¶75.) POSITAs would have been

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an example, POSITAs could have selected a thin, flexible sheet or flat ribbon of aluminum or plastic to form the actuating members. (*Id.*) Such members would have had the flexibility to conform to the outer surface of the cylindrical seal module. (*Id.*) Such actuating members would extend circumferentially around the outside of Schaffer's seal module and would therefore circumferentially constrict the lumen when pulled in opposite directions by the actuator buttons. (*Id.*)

IPR2024-01157, Paper 1 at 32-33 (citing EX1003).

PO Sur-Reply at 21-22.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

IPR2025-00728 (US11,844,921)

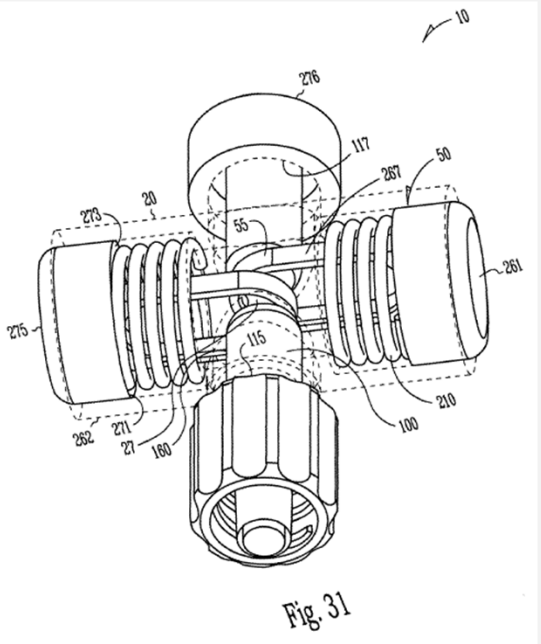


Fig. 31

EX1008.

the replacement of Schaffer's actuating members with string would merely entail substitution of one known element (Hartley's string) for another (plastic or aluminum members) to yield the predictable results of sealing Schaffer's valve. *KSR*, 550 U.S. at 416.

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replacement of Schaffer's actuating members with wire members would merely entail substituting one known element (Eller's wire members) for another (plastic or aluminum members) to yield the predictable result of sealing Schaffer's valve. *KSR*, 550 U.S. at 416.

IPR2025-00728, Paper 1 at 69, 70.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE