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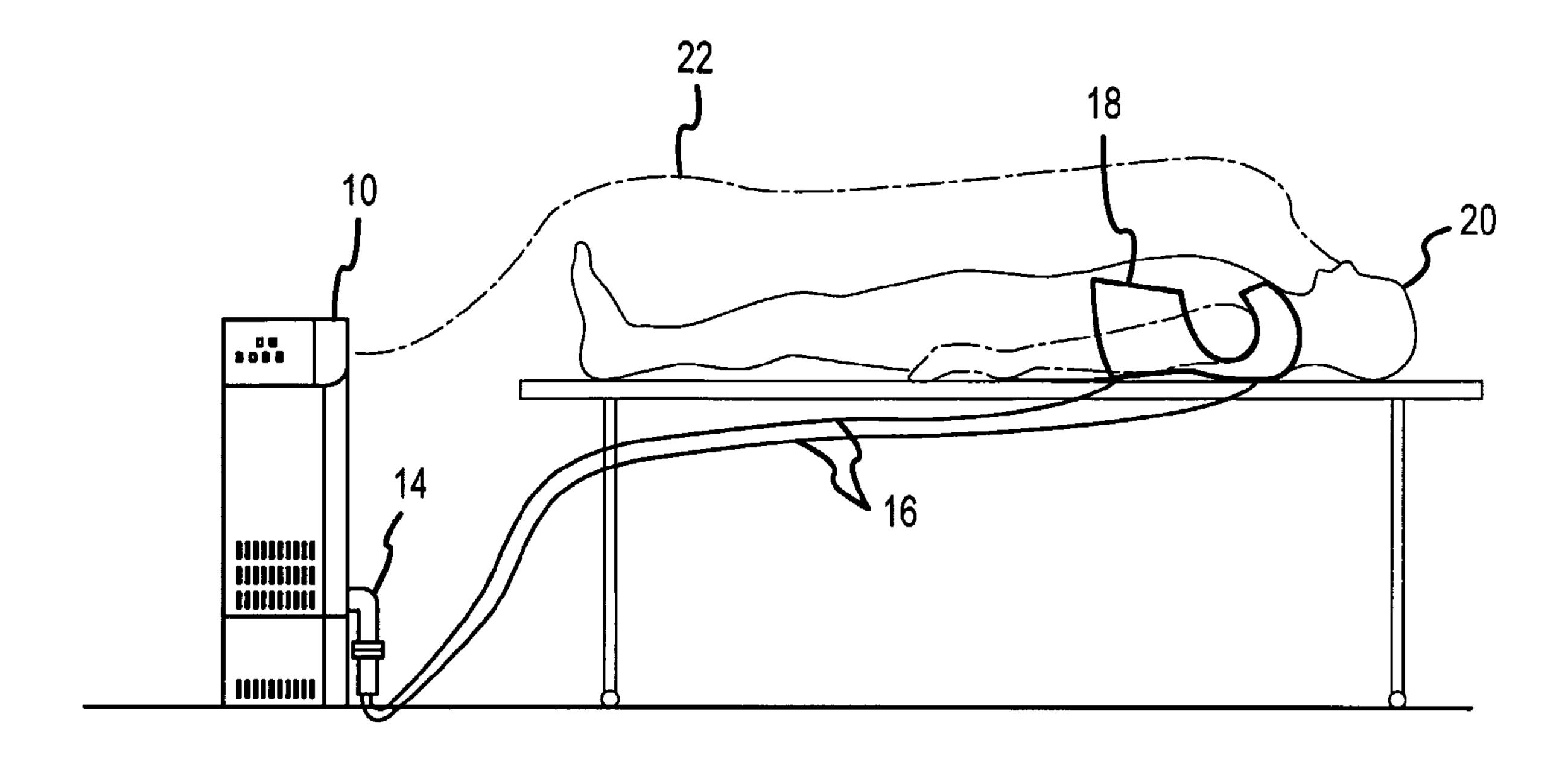
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- (72) Inventeurs/Inventors: CARSON, GARY A., US; ELLINGBOE, BRUCE, US; HOGLUND, MICHAEL R., US
- (73) Propriétaire/Owner: MEDIVANCE INCORPORATED, US
- (74) Agent: JOHNSON, ERNEST PETER

(54) Titre: SYSTEME DE REGULATION DE LA TEMPERATURE D'UN PATIENT

(54) Title: PATIENT TEMPERATURE CONTROL SYSTEM



#### (57) Abrégé/Abstract:

A system and method provide for the interconnection of a medical fluid processing system with at least one patient temperature control pad (18) positionable on a patient. Includable in the system is at least one connector (14) interconnected and/or interconnectable to the medical fluid processing system (10) and at least one connector (19) interconnected and/or interconnectable to the at least one temperature control pad, wherein the connectors include an orientation device (108) which provides for interconnection of the connectors at a predetermined orientation.





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- (71) Applicant: MEDIVANCE INCORPORATED [US/US]; 500 South Arthur Avenue, Suite 100, Louisville, CO 80027 (US).
- (72) Inventors: CARSON, Gary, A.; 21 McIntyre Court, Golden, CO 80401 (US). ELLINGBOE, Bruce; 10 Meadowbrook Road, Littleton, CO 80120 (US). HOGLUND, Michael, R.; 15301 Singletree Drive, Mead, CO 80542 (US).
- (74) Agent: MARSH FISCHMANN & BREYFOGLE LLP; JOHNSON, Kenneth J., 3151 South Vaughn Way, Suite 411, Aurora, CO 80014 (US).

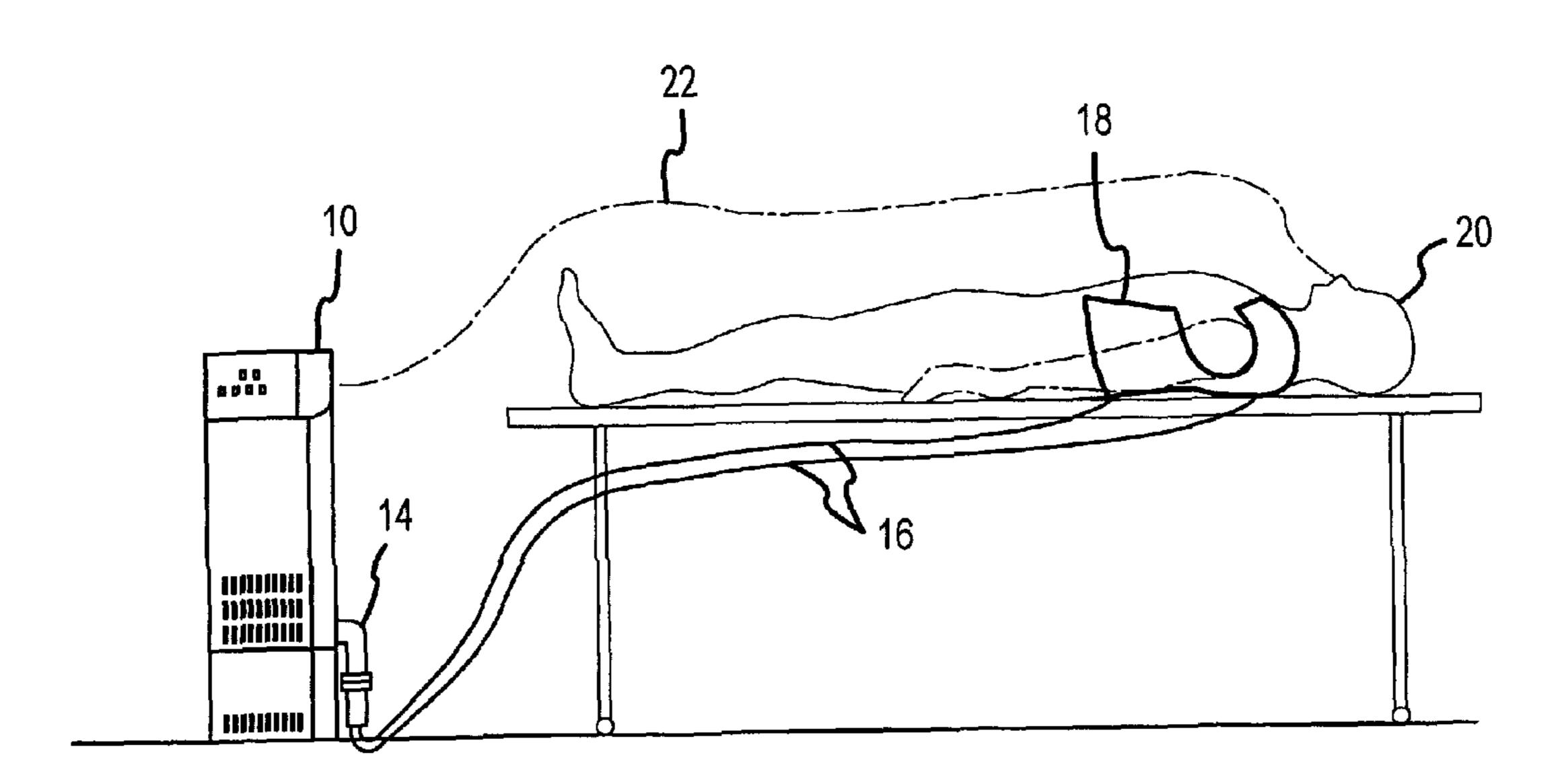
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(54) Title: PATIENT TEMPERATURE CONTROL SYSTEM



(57) Abstract: A system and method provide for the interconnection of a medical fluid processing system with at least one patient temperature control pad (18) positionable on a patient. Includable in the system is at least one connector (14) interconnected and/or interconnectable to the medical fluid processing system (10) and at least one connector (19) interconnected and/or interconnectable to the at least one temperature control pad, wherein the connectors include an orientation device (108) which provides for interconnection of the connectors at a predetermined orientation.

#### PATIENT TEMPERATURE CONTROL SYSTEM

#### FIELD OF THE INVENTION

The invention described herein relates to systems and methods for use in patient temperature control, and more specifically to devices employable for interconnecting a temperature control device such as a heating/cooling pad to a medical fluid processing apparatus.

#### BACKGROUND OF THE INVENTION

The use of contact pad system for selectively cooling and/or heating bodily tissue is known. In such systems a fluid, (e.g. water or air), is circulated through one or more pads to affect surface to surface thermal energy exchange with a patient. One highly effective contact pad and related system is disclosed in U.S. Patent No. 6,197,045. As noted in U.S. Patent No. 6,197,045, the ability to establish and maintain intimate pad to patient contact is often key importance to fully realizing medical efficacies with contact pad systems.

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Temperature management or thermal regulation can be viewed in two different ways. The first aspect of temperature management includes treating at normal body temperature (i.e. cooling the body for elevated temperatures or warming the body for lower temperature). The second aspect of thermal regulation is an evolving treatment that employs techniques that physically control a patient's temperature to provide a physiological benefit, such as cooling a stroke patient to gain some degree of neuro protection.

In view of the foregoing, it may be appreciated that recognized medical applications for contact pad systems are ever increasing. By way of example, cooling pad systems may be utilized in early therapy to reduce neurological damage incurred by stroke and head trauma patients. Additional applications include selected patient heating/cooling during surgical procedure such as cardio pulmonary bypass operation.

As these and other medical applications have evolved, the present inventors have recognized the desirability of enhancing the flexibility and portability of thermal exchange fluid systems. More particularly, while heating/cooling contact pads systems have proven effective for many applications, the present inventors have recognized that additional

performance and potential applications can be realized via implementation of further improved hose and connector device assemblies.

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#### SUMMARY OF THE INVENTION

Disclosed herein is a system employable for providing patient temperature control which includes a medical fluid circulating system which includes at least one reservoir for circulating medical fluid. Included in the system is at least one first connector apparatus which is interconnected and/or interconnectable to a patient temperature control pad, wherein the first connector includes a body portion with a plurality of channels extending therethrough, as well as a connection end. Also included in this system is at least one second connector apparatus which is interconnected and/or interconnectable to the medical fluid circulating system wherein the second connector apparatus includes a body portion with a plurality of channels extending therethrough and a connection end configured to engage the connection end of the first connector apparatus so as to create a plurality of sealed fluid paths through the first and second connectors when engaged. The first and second connectors are further configured to include at least one orientation device such that the first end second connectors are connectable at only a predetermined orientation.

In one configuration of the invention, the first connector apparatus may be configured as a male connector end with an insertion end configured in the body portion. The second connector may be configured as a female connector further configured with a receiving end. The male and female connectors may be configured to include at least one orientation device employable to connect the male and female connectors at a desired relative orientation. The orientation devices employed in the first male and female connectors may include an alignment flange positionable between openings in the insertion end of the male connector and an interference surface extending between the openings of the receiving end of the female connector such that upon attempting to interconnect the connectors at an orientation other than a predetermined orientation, the alignment flange and interference surface will come in contact, thus blocking insertion and interconnection.

In yet another configuration of the invention, the female connector apparatus may be configured with an engagement surface and the male connector may include an engagement device manipulable to engage and disengage the engagement surface of the

female connector upon insertion in the receiving end. This engagement surface may be configured as a ledge structure incorporated into the body portion of the female connector.

The engagement device for the male connector may include at least one flex arm which extends substantially perpendicular from the body portion, as well as a latch arm connectable to the flex arm which is rotatable substantially about the connection point to the flex arm. Incorporated into the latch arm is an engagement portion configured to interlock with the engagement surface of the female connector. In yet another configuration of the invention, both the engagement portion of the first connector end and the engagement surface of the second connector may be configured as interlocking lip structures.

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The female connector assembly may be further configured to include at least one spring loaded valve device locatable within each of the flow channels which is configured to open upon insertion of the male connector in the channel and close upon its removal. An additional feature incorporated into the interlocking connector is that once the insertion end of the male connector is within the female connector, the resistive force exerted by the valve spring on the insertion end of the male connector provides for maintaining contact between the engagement surface and engagement devices such that inadvertent disengagement of the connectors is substantially avoided.

In yet another configuration of the invention, the male connector includes a plurality of the engagement devices which require substantially simultaneous manipulation during the engagement and disengagement procedure. In particular, the male connector may be configured such that the insertion end of the male connector is not removable from the receiving end of the female connector until a further insertion force is exerted on the male connector further compressing the spring loaded valve device such that the interlocking lips are moved clear of each other. The plurality of engagement devices on the male connector are then simultaneously manipulated (such as with a thumb and finger) so as to clear the engagement surfaces. At this point, the insertion force is reversed and the male connector is removable.

In yet another configuration of the invention, the female connector may be further configured to include a rotatable engagement device in a receiving end and the male connector configured to include at least one engagement portion configure to receive the rotatable engagement device. Further, the male and female connectors may be configured such that at a first rotational orientation for the rotatable engagement device, the device

will pass within the engagement portion of the male connector, and at a second rotational orientation mechanically contact a portion of the male connector such that the male and female connectors are mechanically engaged.

The male connector may be further configured to be connectable and/or connected to a one piece hose section which includes a plurality of fluid channels formed therethrough. Still further, the one piece hose section may be connectable to at least one other connector. The other connector may be a female connector which includes one or more receiving ends for interconnecting with one or more male connectors which in turn are interconnected and/or interconnectable with a patient temperature control pad.

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Further described herein is a system for circulating medical fluid through a temperature control pad wherein the system includes a female machine connector portion which is mountable on a medical fluid processing system. The female connector is further interconnected and/or interconnectable to a patient temperature control pad assembly which includes a male connector configured to connect with the female machine connector, a hose assembly, and the patient temperature control pad(s). Incorporated in the female machine connector portion is a receiving end which is configured to receive and fluidly seal with a male connector end insertable therein. The receiving end is further configured to include an engagement device, wherein the engagement device, while positionable within the receiving end, may pass within a portion of a male connector insertable in the receiving end. The engagement device is further configured to be manipulated such that the male and female connectors are mechanically engaged, and a plurality of sealed fluid paths are established.

As part of the system described herein the female machine connector may be further configured such that the engagement device includes a rotatable element which is configured to pass within the engagement portion of a male connector at a first rotational orientation and engage the male connector at a second rotational orientation. The rotatable engagement device may include shaft portion with a semi circular shape and the engagement portion of the male connector may be configured as a slot which opens into a cylindrical section. In operation, the engagement device, at a first profile relative to the male connector, may pass within the slot and into to the cylindrical portion, and then upon rotation to the second rotational orientation, have a profile which is too large for the slot portion thus contacting the internal surfaces of the cylindrical portion and providing mechanical engagement between the male and female connectors. As an additional

feature the position of engagement portion in the male connector may provide for interconnection of the male and female machine connectors only at a predetermined orientation.

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As part of the temperature control pad assembly, the male connector may be further connected to a one piece hose section with a plurality of channels passing there through. The one piece hose section may be further connectable to an intermediate connector device which is also in fluid communication with the channels through the one piece section. The intermediate connector device may be further connectable to at least one other connector in the temperature control pad assembly. In one configuration of the invention, the intermediate connector device may be configured as a female intermediate connector connectable with one or more male intermediate connectors.

The male intermediate connectors, which are part of the temperature control pad assembly, may include a body portion with a plurality of fluid channels extending therethrough, and an insertion end specially configured for passing within a portion of the female intermediate connector. The female intermediate connector is also configured with a plurality of fluid channels formed therethrough, and further include at least one receiving end configured to receive an insertion end for the male intermediate connector. Incorporated into the external surfaces of both the intermediate connectors described herein may be at least one orientation device or surface employable to align the male and female connectors for interconnection purposes.

The orientation devices or surfaces may be incorporated in the body portion of the connectors such that the insertion end for the male connector and/or the receiving end of the female connector include at least one non-symmetrical feature. This non-symmetrical feature may comprise an alignment flange extending between the fluid channels on the male intermediate connector, and/or a member incorporated in the receiving end of the female connector which extends between two openings incorporated therein. In the situation where the male connector is inserted within the receiving end at an incorrect orientation, the alignment flange will contact the orientation surface, thus blocking insertion therein.

Further with regards to the male and female intermediate connectors, these devices may be further configured to include various external engagement surfaces and devices which maintain engagement during operation of the system described herein. In one configuration of the invention, the female connector may be configured with at least one

engagement surface and the male connector configured with at least one engagement device manipulable to engage and disengage with the engagement surface of female connector upon insertion in the receiving end. The engagement surface of the female connector portion may be configured as a ledge incorporated into body. The engagement device incorporated in the male connector may include at least one flex arm extending substantially perpendicular from the body portion of the male connector, a latch arm positionable at an end of the at least one flex arm. The flex arm may be further configured to include an engagement portion whereby the engagement portion is rotatable about the flex arm portion through manipulation of the flex arm at a point opposite the engagement surface relative to the flex arm.

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In employing the engagement devices described above, the female connector assembly may be further configured with at least one spring loaded valve device locatable within the fluid channels which opens and closes depending on the insertion status of a male connector end. The engagement surface of the female connector may be configured to include an interlocking lip portion which is configured to receive an interlocking lip configured into the latch arm of the male connector. These interlocking lips are specially configured such that upon insertion of the male connector within the insertion end of the female connector, the valve springs of the internal valve device are compressed and upon releasing the male connector the springs uncompress thus pushing the interlocking lips together. The relative surfaces of these lips are configured such that they resist any lateral movement of the connector device and connector surface with regards to the body portions of the male and female connectors.

In yet another configuration of the invention, the male intermediate connector may include a plurality of the engagement devices which require substantially simultaneous manipulation during the engagement and disengagement procedure. In particular, the male intermediate connector may be configured such that the insertion end of the male intermediate connector is not removable from the receiving end of the female intermediate connector until a further insertion force is exerted on the male intermediate connector further compressing the spring loaded valve device such that the interlocking lips are moved clear of each other. The plurality of engagement devices on the male intermediate connector are then simultaneously manipulated (such as with a thumb and finger) so as to clear the engagement surfaces. At this point, the insertion force is reversed and the male intermediate connector is removable.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a view of a patient temperature control system with which the present invention may be employed.

Fig. 2 is a view of one configuration of a hose and connector assembly.

Fig. 3a and b are views of the female machine connector.

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Figs. 4a-e disclose views of the male machine connector.

Fig. 5a and b disclose geometric views of the male and female machine connectors in operation.

Figs. 6a-c disclose views of one configuration of the female intermediate connector.

Figs. 7a -c disclose views of the male intermediate connector.

Figs. 8a-f disclose views of the male and female intermediate connectors in operation.

Figs. 9a-f disclose views of one configuration of the male connector assembly.

Fig. 10 discloses a geometric view of another configuration of the machine male connector assembly.

#### DETAILED DESCRIPTION

Disclosed in Fig. 1 is an exemplary configuration of the temperature control system which is employable to provide heating/cooling of a patient 20. By way of example, pads 18 positionable on a patient 20 may be of the type described in U.S. Patent No. 6,197,405. The system 10 is employable for circulating temperature control fluid through the pad 18. The system 10 may include a circulating pump for drawing fluid (e.g. water) through the pads, a circulating reservoir as well as one or more heat exchange devices for heating/cooling fluid circulating through the system. Also included may a temperature sensor 22 employable for monitoring patient temperature.

Interconnecting the patient temperature control system 10 and the pads 18 is hose and connector assembly 14. Included in the assembly 14 may be one or more individual connectors, as well as lengths of hose 16 which act as delivery and return lines for the fluid circulated between system 10 and pads 18.

Disclosed in Fig. 2 is a view of the hose and connector assembly 14 interconnected with system 10, specifically including the various connectors which may be employed in order to connect the patient temperature control system 10 to the patient

temperature control pad(s). Shown in particular is female machine connector 12 which provides for the attachment of the hose assembly 14 to the control system 10. The connector 12 may be incorporated into system 10 and be in fluid communication with the various reservoirs and heat exchange devices included therein. The system connector 12 may include at least one receiving end for receiving a male connector portion of the hose and connector assembly 14. To facilitate the connection with the male connector, the system connector may includes a connection device 108 which is manipulable to establish a fluid tight connection. The details of female machine connector 12 will be discussed in greater detail below.

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The hose assembly 14 may include a male machine connector 13 configured to be insertable within the female machine connector and be engaged. The connector 13 may be attached to one-piece hose apparatus 15 which is further in connection with female intermediate connector 19. As will be described in greater detail below, the female intermediate connector 19 may include one or more receiving ends configured to receive and engage any number male intermediate connectors 30. The male intermediate connectors are further connectable through hoses to 16 the patient temperature control pads. The connection to the patient temperature control pads may be through a single length of hose or through various lengths of hose interconnected using one or more male and female intermediate connector combinations.

With regards to the individual connectors, disclosed in Figs. 3a and b are perspective and front views of female machine connector 12 which is mountable within the housing for temperature control system 10. Included in the female connector 12 is a receiving end 112 specially configured for receiving a insertion end of a male connector. Included in particular is a wall structure 106 extending outward from the body 101 of connector 12. Within the wall structure is a cavity 113 which includes a cross section sized to fit with the insertion end of a male connector at a substantially close tolerance. Located within the receiving end 112 are openings for fluid channels 115 and 117 which extend above the floor of the cavity 113 and where each include at least one gasket device 116 for establishing a fluid tight seal. The fluid channels 115 and 117 pass through the female connector 12 and exit through channels 104 and 102 respectively. When installed in the temperature control system 10, these channels provide for the circulation of fluid to and from internal components of the system.

Extending within the cavity 113 is a rotational engagement device 108 which is configured to pass within an engagement portion of a male connector, and upon rotation mechanically engage said male connector. Included as part of the rotatable connection device is engagement shaft 110 which in the configuration of the invention shown in Fig. 2a is configured with a cross sectional shape of a semi-circle. The use of a semi-circle is exemplary, and any number other cross sectional shapes may be employable for this purpose.

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As can be better seen in the front view of Fig. 3b, the rotatable engagement device 108 further includes a retaining end 111 which passes through the wall portion of the cavity 113 and supports the engagement shaft at one end. At the opposite end of the engagement shaft is the rotatable handle 108 which is rotatable to provide for the rotation of the engagement shaft 110. The handle portion 108 further includes retaining end portion which also passes within the wall structure 110. At either end of the shaft, the hole through the wall provides a bearing surface for rotation of the shaft.

Disclosed in Fig. 4a is a geometric view of the male machine connector 13 employable to interconnect with female machine connector 12. The connector includes a body portion 121 through which two fluid channels 130 and 132 extend from insertion end 119 to attachment portions 134 and 136, respectively. The insertion end 119 disclosed herein is configured in a oval and/or race track type shape, although one skilled in the art would realize that any number of shapes are employable. Further, in the configuration shown in Fig. 3a, the fluid channels are configured to turn at substantially a 90° angle, however one skilled in the art would realize that any number of configurations are possible.

As is seen in the cross section view of the connector in Fig. 4d, the interior surface fluid channels 130 and 132 are configured with a tapering cross section shape so that a fluid type seal may be created when the surfaces contact the fluid channels 115 and 117 in female connector 12. Attachment ends 134 and 136 may be configured to each attach to a hose for employable for circulating fluid to a remote device such as a temperature control pad. This configuration is especially applicable to connecting two lengths of hose between the system 10 and the patient temperature control pads without the use of any intermediate connectors. Alternatively, the connector ends may be replaced by a one-piece structure connectable to the body portion, where the one-piece structure includes a plurality of fluid channels passing therethrough. The one-piece structure may be further

connectable to an intermediate connector. This configuration, including all its components, will be discussed in greater detail below.

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Further incorporated in the male connector 13 is at least one engagement portion 120 specially configured to receive and mechanically engage with the engagement shaft of the female connector. A view of the engagement portion 120 can be seen in the top view of the male connector in Fig. 4e. In this configuration, it is seen that the engagement portion includes a narrow, substantially rectangular slot 121 which opens up into a larger substantially circular area 123. This configuration allows the engagement shaft to pass within the smaller slot 121 at a first rotational orientation and then once within the cylindrical area 123, rotate to a second rotational position whereby the relative width of the shaft is greater than the slot. At this second orientation, shaft contacts a portion of the interior surface of the circular area such that the male and female connectors are mechanically engaged. The rectangular slot 121 may be further configured in the connector to act as an orientation device. In one configuration of the invention the slot is positioned closer to one channel through the connector than the other. This nonsymmetry has the effect that the male and female machine connectors may only be connected one relative orientation thus ensuring that fluid through the system flows in the proper direction.

The views showing the engagement and disengagement of the male and female machine connector are provided in Figs. 5a and b. Seen in particular in Fig. 5a, prior to interconnection of these components, the male connector head 13 is aligned with the receiving end 113 of the female connector assembly. In particular, it is seen that the exterior of head 113 is substantially the same shape as the receiving end 113 so that a substantially close tolerance fit may be achieved. Further, it is seen that the rotational connection device is in a first rotational position whereby the engagement shaft is at its minimum cross section with regards to its position relative to engagement slot 121.

Once the components are aligned, the male connector end may be inserted in receiving end 113 in a manner such that the rotational shaft passes within the slot 121. Once the internal channels of the male connector head contact the protruding openings of the female connector and the rotation shaft passes within the cylindrical area 123, the handle of the rotational engagement device 108 may be rotated in a manner which is shown in Fig. 4b. This movement of the handle acts to rotate the engagement shaft within the cylindrical portion of the engagement slot such that mechanical contact is created

between the engagement shaft and the interior surfaces of the cylindrical portion and a compressive force is applied between the male and female connector such that a plurality of fluidly sealed channels through both connectors is created.

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Returning again to Fig. 2, as part of a patient temperature control system, the male connector head 13 may be further connectable to a hose assembly employable for circulating medical fluid to and from the temperature patient temperature control pad. Included as part of the hose assembly may be one or more intermediate connector devices which are employed to connect with hoses in fluid communication with the patient temperature control pad. The one or more intermediate connector devices may comprise at least one male and female connector device specially configured to engage with one another and further provide a plurality of sealed flow paths between the temperature control system and the temperature control pad for circulation of the medical fluid.

A geometric view of one configuration of an female intermediate connector assembly 50 is disclosed in Fig. 6a. Incorporated in the female connector assembly are hose ends 54 which are configured to compressibility fit within the attachment portion of a plurality hoses which may be further connectable, for example, to male connector 13. In an alternate configuration which is shown in Fig. 2, and is to be described in greater detail below, the connection ends may be replaced the one-piece hose structure with a plurality of flow channels formed therein. The one-piece hose structure is further connectable to the male machine connector 13.

As seen in the cross sectional view of Fig. 6c, the female intermediate connector further includes fluid channels 51 and 53 which extend from the hose ends 54 through body portion 52. The channels exit through receiving end 58. Receiving end 58 is configured as a cavity in the body portion which is shaped to receive a portion of a male connector. Although the intermediate female connector disclosed in Figs. 5a-c is shown to include a single receiving end, other configurations of the female intermediate connector may include a plurality receiving ends wherein one female intermediate connector is connectable to a plurality of male intermediate connectors simultaneously.

Continuing on with the female intermediate connector assembly 50, further included within the body portion 52 of the female intermediate connector is a moveable valve device which is manipulable to open and close upon insertion of the male connector. Returning again to the cross sectional view of Fig. 6c, the details of the valve device may be better viewed. As was mentioned above, a moveable valve device is

positionable in each of the channels 51 and 53 for controlling the flow of medical fluid therethrough. Shown in particular, is a valve plunger 70 which has incorporated therein a number of openings 84, which depending on the position of the plunger in the channel, provide for fluid flow through the connector. Surrounding the body portion of the valve plunger are springs 79, which are compressible against spring stop 71 when the male connector end is inserted. The insertion of the male intermediate connector end initiates movement of the plunger within the channels, such that the openings in the plunger are moved to a position which provides for circulation of the medical fluid.

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Each plunger further includes an o-ring seal 72 which contacts an internal surface of the connector end of the male connector intermediate assembly when inserted. The plunger seal 74 is further employable to move with the plunger device and provide a fluid seal even while the plunger is moving or is moved. At the opposite end of the plunger device is a cap 73 which includes a valve seal 75 that provides for the sealing of the valve device upon removal of the male connector assembly. The sealing occurs when the valve spring decompresses and moves the plunger back towards the receiving end. At this point, the valve seal 75 contacts seat 84 and seals off any fluid flow therethrough.

Returning again to Fig. 6a, further incorporated into the body portion 52 are a number of engagement surfaces 63 configured for receiving and engaging an engagement arm portion of the male intermediate connector assembly. As was will be described in greater detail below, the engagement surface 63 is configured as a lip which interlocks with a corresponding lip configured on an engagement arm of an insertable male connector.

Disclosed in the view provided in Fig. 6b, is a view of orientation device 60 incorporated into the body portion 52. This orientation device provides a non-symmetrical feature to the receiving end 58 which in turn provides for the insertion of the male intermediate connector assembly at only a particular orientation. The desirability of this feature will be described in greater detail below.

Views of one configuration of the male intermediate connector 30 configured to be interconnectable with the female intermediate connector described above are provided in Figs. 7a-c. Disclosed in Fig. 7a is a geometric view of the male intermediate connector 30. The intermediate male connector includes a body portion 36 within which are formed fluid channels which pass from an insertion end 32 to a hose end 38. The hose end 38 is configured such that it is insertable within one end of a hose portion which in turn is

interconnected and/or interconnectable to a patient temperature control pad or another connector. The removal/insertion arm 40 is configured to be employed in the insertion and removal of the male intermediate connector with an female intermediate connector.

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The insertion end 32 is configured to be insertable in an intermediate female connector assembly. In particular, insertion end 32 may be configured to contact one or more sealing devices within a portion of the female connector upon insertion so as to establish a fluid seal. During operation, depending on the direction of the flow, fluid will pass from insertion end 32 unobstructed to hose end 38 and vice versa. A cross sectional view of one of the fluid channels 45 through the male connector is shown in detail in the view of Fig. 7c.

Also incorporated into the male connector assembly 30 are one or more devices which provide for the engagement and proper alignment of the intermediate male connector within an intermediate female connector. For engagement with the female connector assembly, extending from the body portion 36 are one or more flex arms 48. The flex arms may be constructed of a material which is the same or similar to the material use to form the body, wherein the flex arms have sufficient flexibility to deform about the point of the attachment of the flex arm to body 36. Further attached to the flex arm is latch arm 42 which is rotatable about an attachment point to flex arm 48 when a force is applied. When the force is removed, the elasticity of flex arm returns the latch arm to its original position.

Opposite the latch arm portion is the attachments arm portion 44. Incorporated into the attachment arm 44 is an engagement lip 46 which is configured to interlock with a corresponding lip on an engagement surface of a female intermediate connector. The attachment arm and interlocking lip portion of the male intermediate connector assembly are configured such that when a force is applied to the latch arms which moves them closer to the body portion 36, the engagement arm portion rotates away from the first end 32. When the force is released the elastic characteristics of the flex arm 48 returns the attachment arm with engagement lip to its original position so that the engagement lip 46 may contact a corresponding engagement surface on the female intermediate connector.

With regards to the alignment of the male and female intermediate connectors, further incorporated into the male intermediate connector assembly 30 is orientation flange 50. Orientation flange 50 extends between the channels incorporated into body 36 and provides the functionality such that the male intermediate connector assembly 30 may

only be insertable in a female intermediate connector portion at a particular orientation. In essence, this orientation device provides a non-symmetric feature to the insertable portion of male intermediate connector assembly.

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The engagement and disengagement of the male and female intermediate connectors may be better understood through study of Figs. 7a-d. In particular, Fig. 7b shows the engagement of the male and female connector assemblies while Fig. 8a shows the connectors in a disengaged state. In order to initially engage the intermediate connectors the male and female intermediate connectors are first aligned. As part of the alignment process the orientation flange 50 on the male connector is positioned in a manner to as not to contact orientation device 60 upon insertion. More specifically, if the orientation device 60 contacts orientation ledge 50 on the male intermediate connector assembly, the male intermediate connector assembly is not insertable into the receiving end. Conversely, if the orientation device 60 is opposite the orientation ledge 50, the male intermediate connector is insertable in the connector end and a fluid tight connection may be made. The orientation devices provide the advantage that the wrong channels through the male and female intermediate connectors will not be fluidly connected, potentially affecting circulation of the medical fluid through the system.

Prior to insertion of the male intermediate connector in the female connector, a force may be applied to attachment arms 42, preferably with one hand using, for example, the thumb and forefinger, which moves the attachment arms towards the body portion and the engagement arms 44 with interlocking lip 46 far enough away so as to clear the exterior body of the female intermediate connector.

The male intermediate connector end may then be inserted within the receiving end of the female intermediate connector such that the interior surface of the insertion of the insertion end contacts the o-ring seal 72 on the valve plunger 70 which in turn pushes the plunger and compresses the valve spring. The plunger is moved to the point that the openings in the plunger body allow for fluid flow through the female connector.

An example of an open valve within the female connector is shown in the cross sectional view provided in Fig. 8d. As can be seen, when the male connector is inserted, the valve spring 79 compressed and head 80, with seal 82, is moved clear of valve seat 84 thus providing a fluid through the connector. As can be seen, in a circulating system such as the one described herein, the fluid may flow in different directions in the different channels.

The fluid tight seal created between the male and female connector upon connection may be better understood through the sectional views provided in Figs. 8e and f. Disclosed in the view of Fig. 8e is a cross sectional view of the male connector and female connector in contact just prior to establishing the fluid tight seal. As can be seen the male connector 30 includes an internal, tapered surface 77 which contacts an O ring 72 mounted on the valve plunger 70. The valve plunger 70, has an external tapered surface 81, that contacts the opposite side of the O-ring.

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As the male intermediate connector 30 is pushed into the female intermediate connector 50, the O-ring 72 rolls between the two tapered surfaces 77 and 81. During the insertion, the O-ring rolls rather than slides against the mating surfaces so that wear of the O-ring is minimized. Further, rolling rather than sliding also reduces the force required to engage the two connectors. Since the two surfaces in contact with the O-ring are tapered, the O-ring is compressed as the male connector is moved along the axis of the flow channel for the female intermediate connector.

Shown in Fig.8f is a view of the male and female intermediate connectors fully engaged. As is seen, because the internal tapered surface 77 of the male connector has a larger taper angle than the external surface of the valve plunger, thus the O-ring is squeezed into a wedge shape. The O-ring gland area is tapered so that an increased vacuum inside the connectors pulls the O-ring into a smaller section of the gland. This increases the compression in the O-ring which, in turn, increases the contact stress between the O-ring and tapered surfaces. The result is that increased vacuum improves the seal by tightening the O-ring in the gland.

The fluid tight seal described above is maintained by the mechanic engagement of the male and female intermediate connectors. The mechanical engagement of the male and female intermediate connectors may be better understood through further study of Fig. 8d. Once the engagement portion 46 of attachment arm 44 passes within the engagement area 56 on the exterior of the female connector, the latch arm and male connector may be released which in turn rotates the engagement lip 46 such that it contacts engagement area 56. Releasing the male connector has the further effect that the compressed valve springs begin to uncompress thus moving the engagement lip 46 into engagement surface 63, thus interlocking the two surfaces. The compressive force applied by the valve springs keeps the two surfaces in contact, and the diagonal direction, relatively, of the surfaces resists lateral movement of the engagement arm with respect to

the female connector body thus maintaining engagement between the male and female connectors.

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In order to disengage the male intermediate connector from the female intermediate connector, an insertion force is applied to the male intermediate connector further moving the valve plunger and further compressing the valve spring. The further movement of the male intermediate connector acts to move the engagement devices and engagement surfaces clear of each other. Forces are then applied simultaneously (using the thumb and forefinger, for example) to all of the latch arms to move them towards the body of the male intermediate connector. The application of these forces acts to move the engagement arms 44 away from the body portion of the female intermediate connector, whereby maintaining the force on the latch arms the insertion force may be reversed and the male intermediate connector removed. It should be noted that in the configuration of the invention described herein, simultaneous application of force to all latch arms is necessary to perform the removal of the male intermediate connector. If one the engagement arms is not moved, the interlocking lip on the arm not moved will contact the corresponding interlocking lip on the engagement surface thus interfering with removal of the male connector. The necessity of this simultaneous movement is a safety feature which acts to avoid inadvertent disconnections of the male and female intermediate connectors.

As was discussed above, the male machine connector 13 may be included as part of a connector assembly. This connector assembly may include a male machine connector 13, an intermediate one-piece hose section, as well as an intermediate female connector assembly. In one configuration of the invention the connector may be a unitary piece, in that it may be made up of a number of different pieces, and manufactured in manner such that it cannot be disassembled without damaging its function. Disclosed in Fig. 9a-f are various views of this connector assembly.

Disclosed in Fig. 9a is a geometric view of the connector including a male machine connector head 139 connected to the one-piece hose section 140 which in turn is connected to female connector assembly 150. As seen in Fig. 9b and the cross sectional view of Fig. 9e, incorporated into the hose section 140 are fluid channels 140 and 142. The channels are in communications with channels through the male machine connector and the female intermediate connector assembly portions. Hose section 140 may be

formed out of any number of hard plastic, rubber, or composite materials of sufficient stiffness.

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In the configuration shown in Fig. 9, the female machine connector assembly is configured to interconnect with a maximum of two male intermediate connector assemblies. As seen in Fig. 9d, configured into the bottom of female connector assembly 150 are two receiving ends 171 and 173, where each end includes openings 170 and 172 to the fluid channels incorporated therein. As seen in the cross sectional view, each of the channels includes a valve assembly which operates in the same manner as described above for the intermediate female connector. For the channels which circulate fluid in the same direction, such as those shown in the cross sectional view of Fig. 9e, they are further in communication with a common manifold 166 which is further in communications with a channel, channel 142 in this view, of the hose section 140. It is further seen that each receiving end 171 and 173 includes a set of engagement surfaces 152 configured for engaging and interlocking with the engagement devices incorporated in the male connectors.

Yet another configuration of the male machine connector assembly is disclosed in Fig. 10. In this configuration the connector assembly 200 includes a female connector portion 202 with receiving ends 204-212 for interconnecting with a maximum 5 intermediate male connectors simultaneously. The configurations of the male machine connector assembly, especially the intermediate female connector, are exemplary, and one skilled in the art would know that the female intermediate connector portion can be configured with any number of receiving ends so as to connect with any number of male intermediate connectors. In this configuration it further seen that receiving ends may be incorporated in any number of surfaces of the intermediate female connector so as to facilitate the ergonomic design of the overall system.

The foregoing description of the present invention has been presented for purposes of illustration and description. Furthermore, the description is not intended to limit the invention to the form disclosed herein. Consequently, variations and modifications commensurate with the above teachings, and the skill or knowledge of the relevant art, within the scope of the present invention. The embodiments described hereinabove are further intended to explain best modes known for practicing the invention and to enable others skilled in the art to utilize the invention in such, or other, embodiments and with various modifications required by the particular applications or uses of the present

invention. It is intended that the appended claims be construed to include alternative embodiments to the extent permitted by the prior art.

#### CLAIMS

1. A system employable for patient temperature control including a fluid circulating system including at least one reservoir for circulating a fluid, comprising:

at least one male connector apparatus which is one of: interconnected and interconnectable to a patient temperature control pad, the male connector including a body portion with a plurality of fluid channels extending therethrough to an insertion end thereof;

at least one female connector apparatus which is one of: interconnected and interconnectable to the fluid circulating system, the female connector including a body portion with a plurality of channels extending therethrough to a receiving end thereof configured to receive and engage the insertion end of the male connector so as to create a plurality of sealed fluid paths through the male and female connectors when engaged;

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said male and female connectors further including at least one orientation means offset from said plurality of fluid channels of said male and female connectors and configured such that the male and female connectors are connectable only when said insertion end and said receiving end are oriented in a predetermined orientation relative to one another, and wherein predetermined different ones of said plurality of fluid channels of said male connector at said insertion end thereof are only interconnectable to predetermined different ones of said plurality of fluid channels of said female connector at said receiving end thereof when said insertion end and receiving end are oriented in said predetermined orientation; and,

wherein one of said male and female connectors includes an engagement device and the other of said male and female connectors includes an engagement surface which provide for engagement between said male and female connectors, wherein said engagement device is manipulatable for movement relative to the body portion of said one of said male and female connectors to provide for selective engagement and disengagement of said male and female connectors.

2. The system of claim 1, wherein said engagement device is manipulable upon application of a force to a first end thereof to move a second end thereof away from said body portion of said one of said male and female connectors, and wherein said engagement device is operable so that, upon removal of said force from said first end, the second end elastically moves toward said body portion of said one of said male and female connectors.

- 3. The system of claim 1 wherein the female connector includes the engagement surface and the male connector includes the engagement device.
- 4. The system of claim 3 wherein the engagement surface is configured as a lip incorporated into the body portion of the female connector.
  - 5. The system of claim 4 wherein the engagement device comprises:

at least one flex arm extending substantially perpendicular from the body portion of the male connector;

a latch arm positionable at an end of the at least one flex arm away from the body portion of the male connector substantially perpendicular to the at least one flex arm, wherein the latch arm includes a depressible portion configured on a first end and an engagement portion configured on a second end opposite the first end; and

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the at least one flex arm being connectable to the latch arm in a manner such that application of a force to the first end rotates the second end and flex arm about a point of attachment of the flex arm and the body, and removal of the force returns the flex arm and latch arm to an original position.

- 6. The system of claim 5 wherein the female connector further includes at least one spring loaded valve device locatable within each of the channels of the female connector, wherein the valve device is configured to open and provide a sealed fluid path upon insertion of the insertion end of the male connector in the receiving end of the female connector, and to close and seal the receiving end when the insertion end is removed.
- 7. The system of claim 6 wherein the engagement surface and engagement device are configured as interlocking lips so as to limit lateral movement of the latch arm when the male and female connectors are engaged and a pressure is exerted between the male and female connectors by the at least one spring loaded valve device in compression.
- 8. The system of claim 1 wherein the insertion ends and the receiving end each includes a cross sectional shape through a plane substantially perpendicular to one or more of the centerlines of the correspondingly fluid channels which is substantially non-symmetrical.
- 9. The system of claim 1 wherein the orientation means includes at least one of:

an alignment flange positionable between an opening in the insertion end of the male connector and an orientation member extending between the openings in the receiving end of the female connector.

- 10. The system of claim 1 wherein the female connector is further configured to include a plurality of receiving ends configured to engage a plurality of male connectors.
- 11. The system of claim 1 wherein the engagement device comprises a rotatable engagement device and the engagement surface is configured to receive the rotatable engagement device such that when the rotatable engagement device is received within the engagement surface and is rotated to a first rotational orientation, the male and female connectors are mechanically engaged and when the rotational engagement device is rotated to a second rotation orientation the male and female connectors are disengaged.
- 12. The system of claim 1 wherein the male connector further includes a one piece hose section having a first end connectable to the body portion opposite the insertion end, wherein the one piece hose section includes a plurality of fluid channels in fluid communication with the fluid channels of the body portion.

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- 13. The system of claim 12 wherein the male connector further includes an intermediate connector device connectable to a second end of the one piece hose section.
- 14. The system of claim 13 wherein the intermediate connector device comprises a female style connector configured with a one or more receiving ends for interconnecting with a plurality of male style connectors.
- 15. The system of claim 1 wherein the female connector is mountable on a housing for the medical fluid temperature circulating system.
- 16. The system of claim 1 wherein the receiving end of the female connector includes at least one O-ring positionable against a tapered surface and the insertion end of the male connector further includes an internal tapered surface within at least one of the channels, wherein upon insertion of the insertion end in the receiving end, the internal tapered surface of the male connector contacts the O-ring and rolls the O-ring along the tapered surface of the female connector so as to compress the at least one O-ring and create a fluid tight seal between the insertion end of the male connector and the receiving end of the female connector.
- 17. The system of claim 16 wherein the tapered surface of the male connector has a greater taper angle than the tapered surface of the female connector.

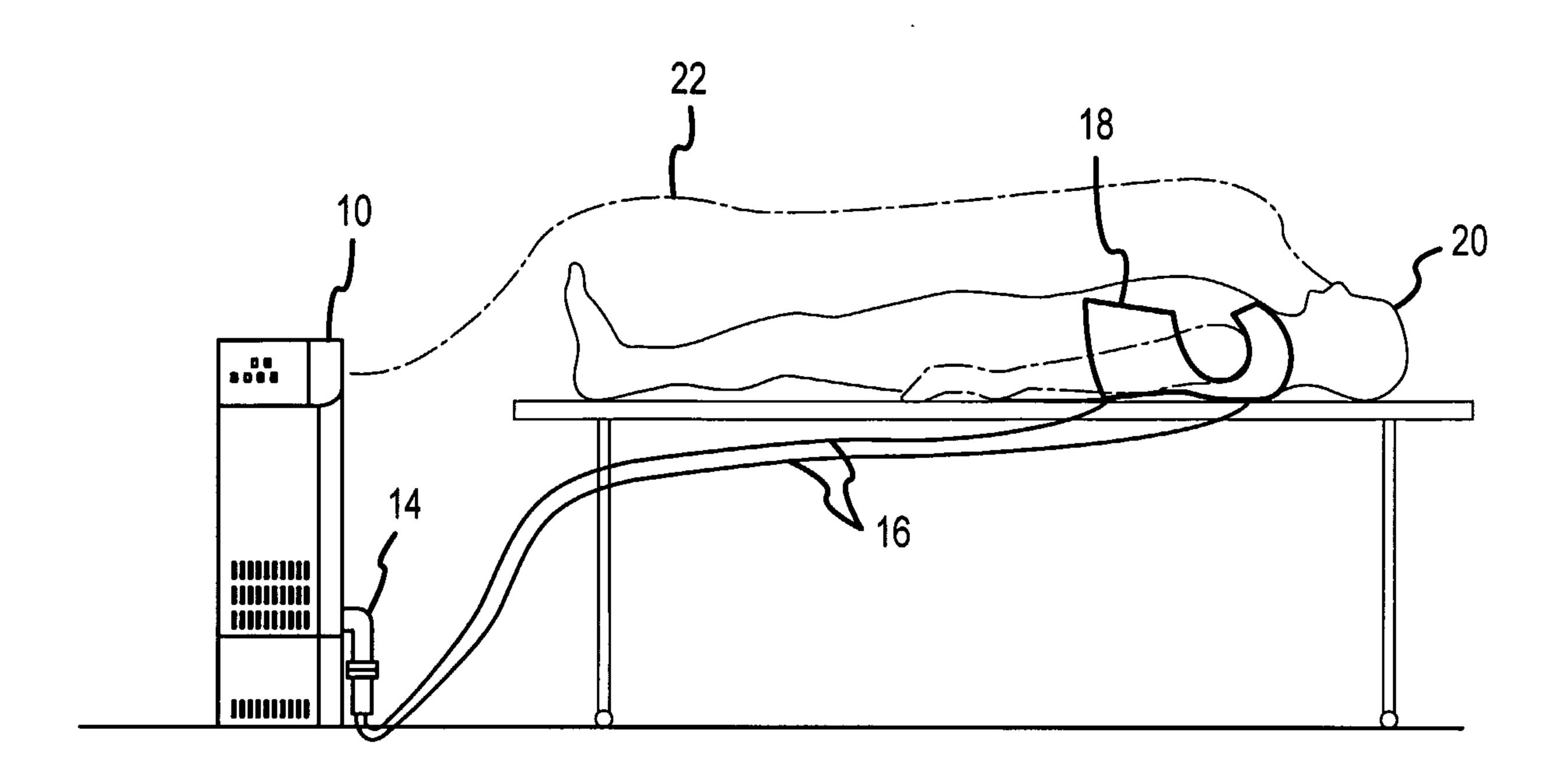


FIG.1

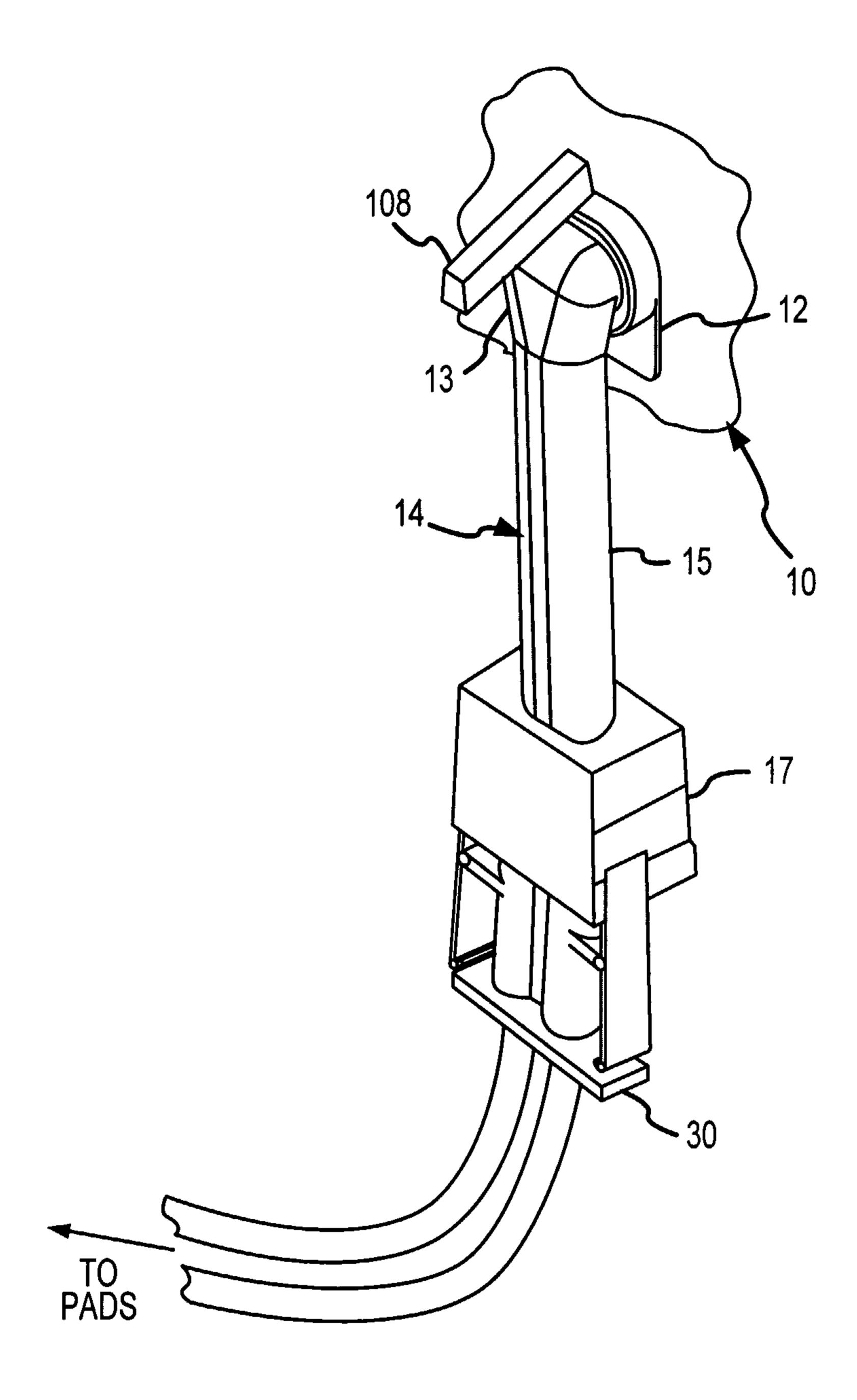


FIG.2

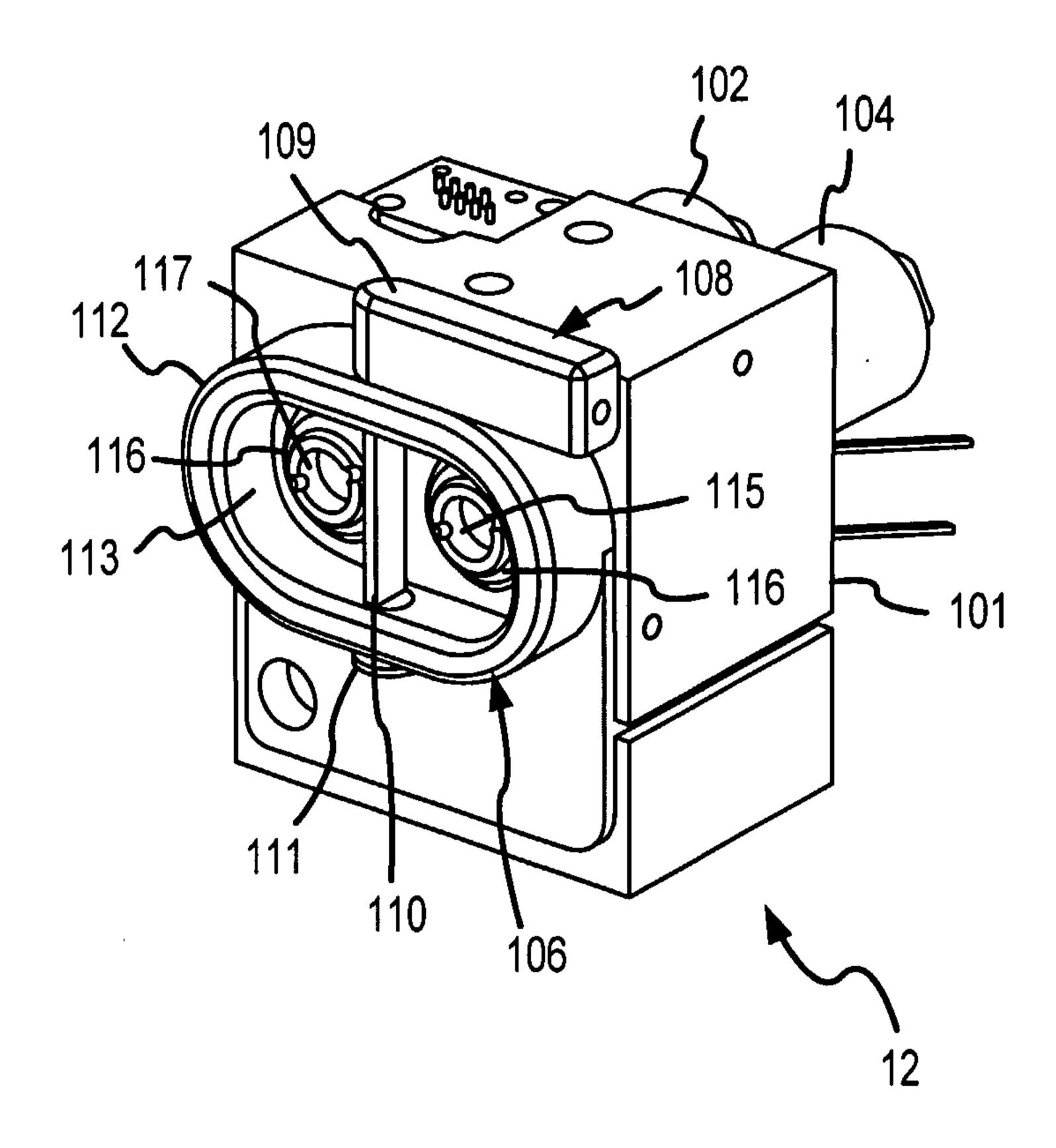


FIG.3a

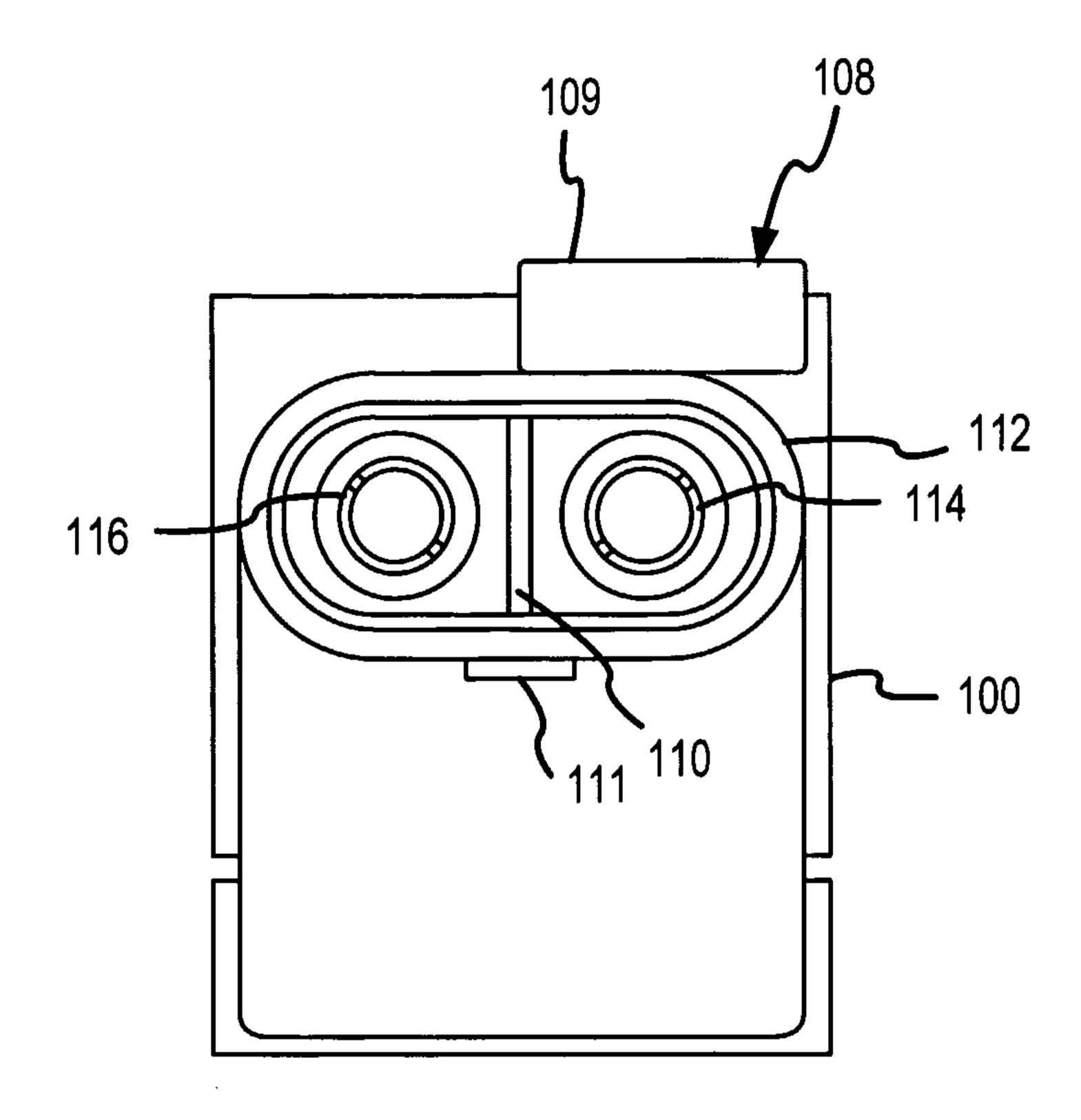


FIG.3b

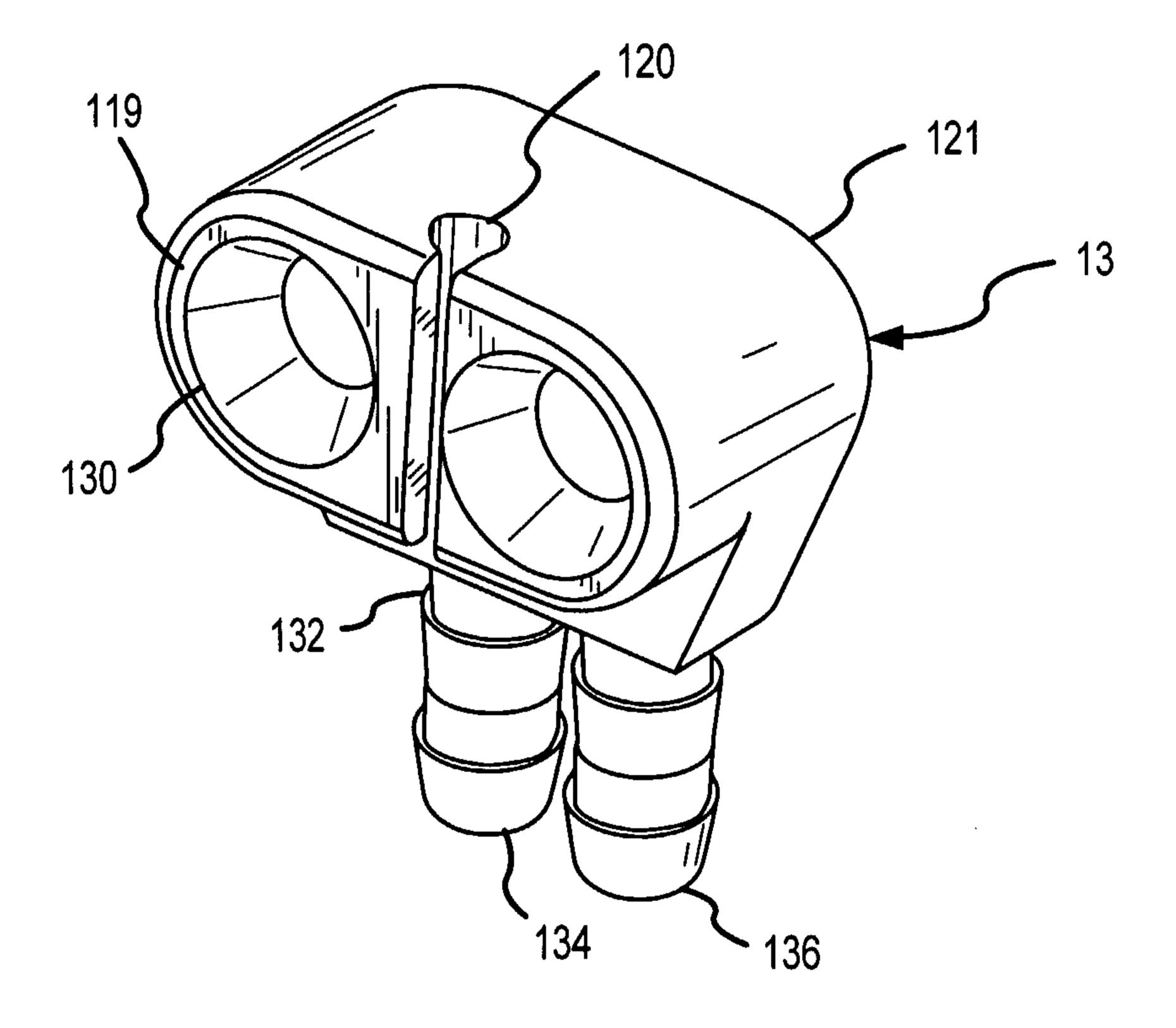


FIG.4a



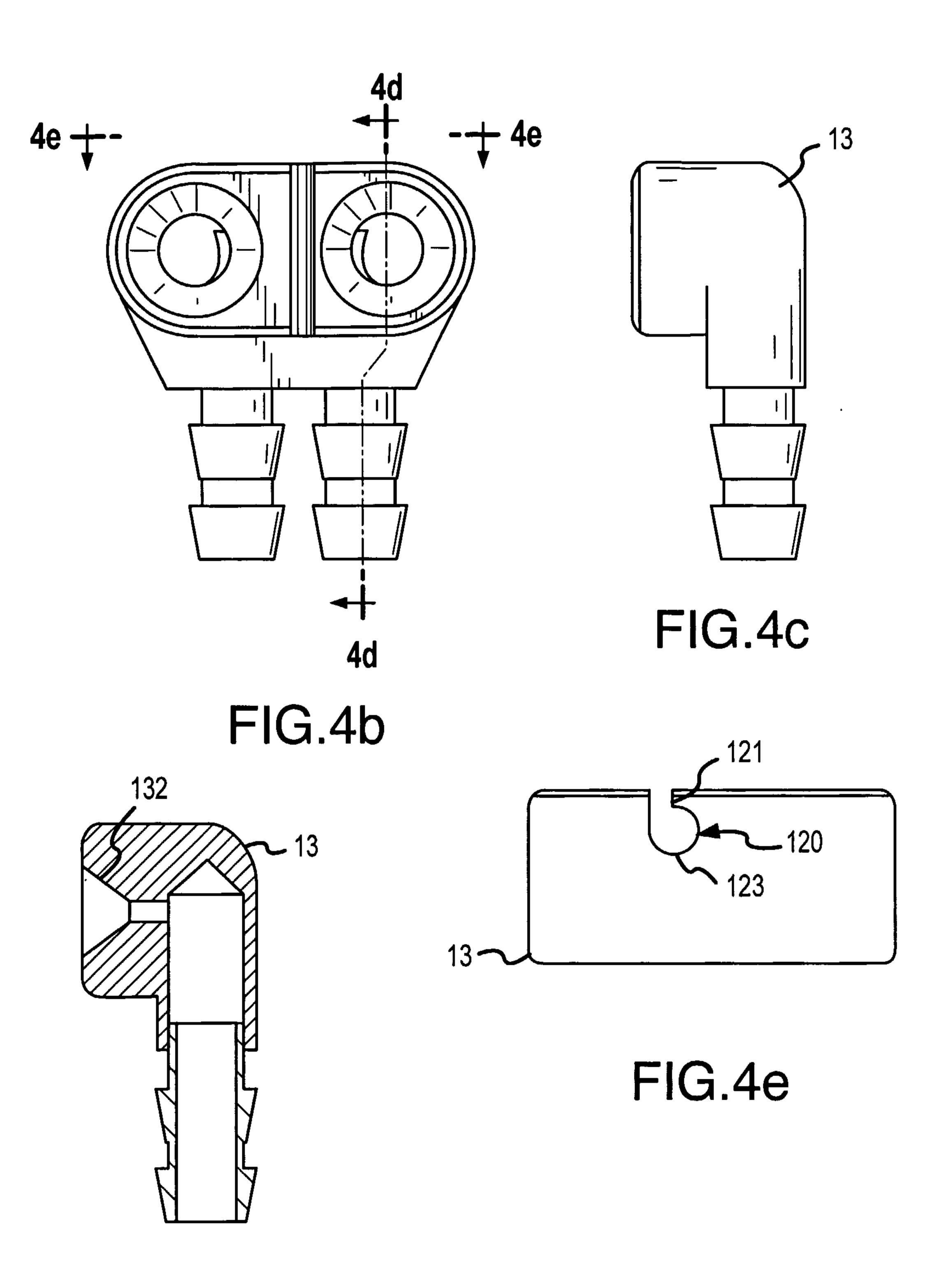


FIG.4d

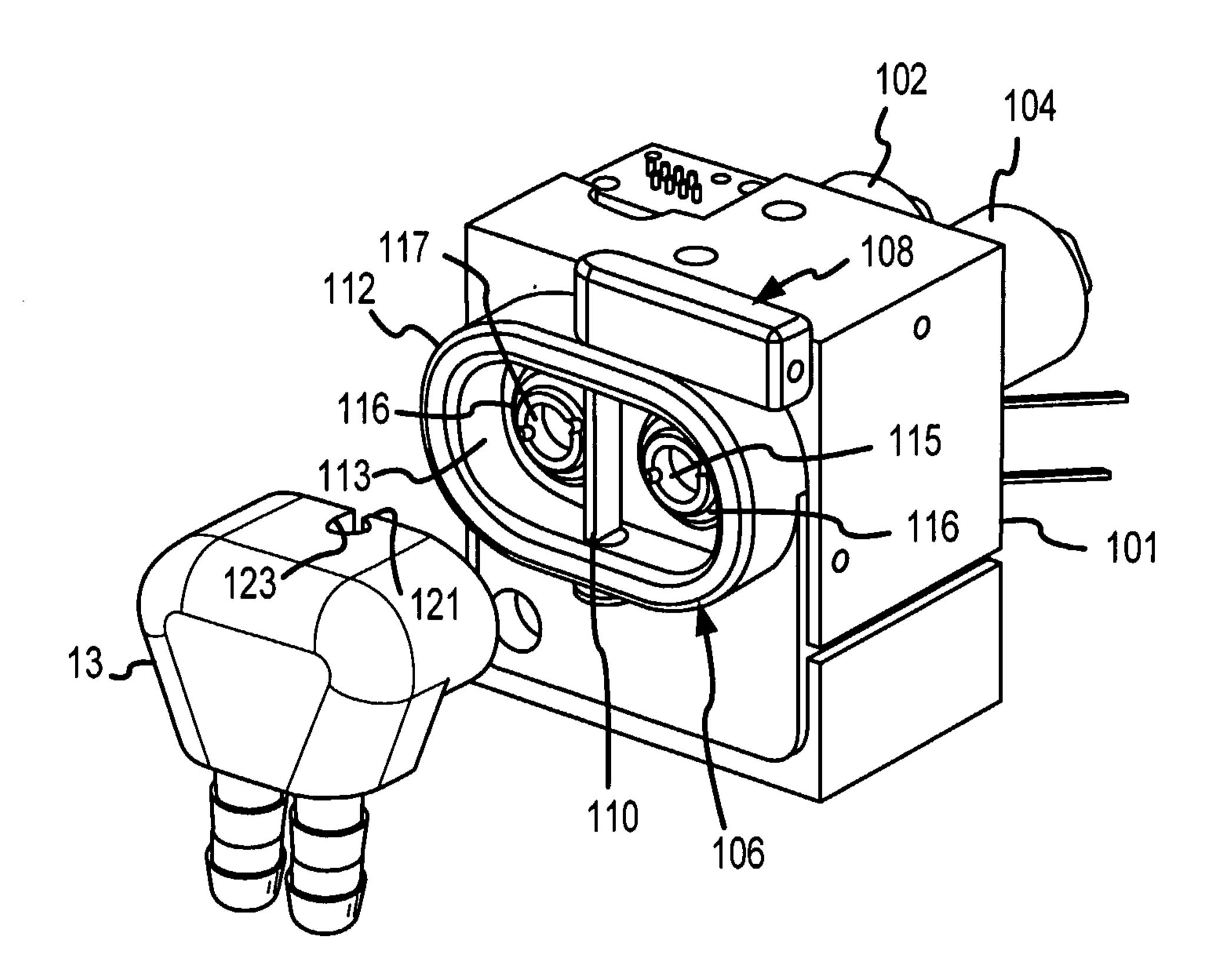


FIG.5a

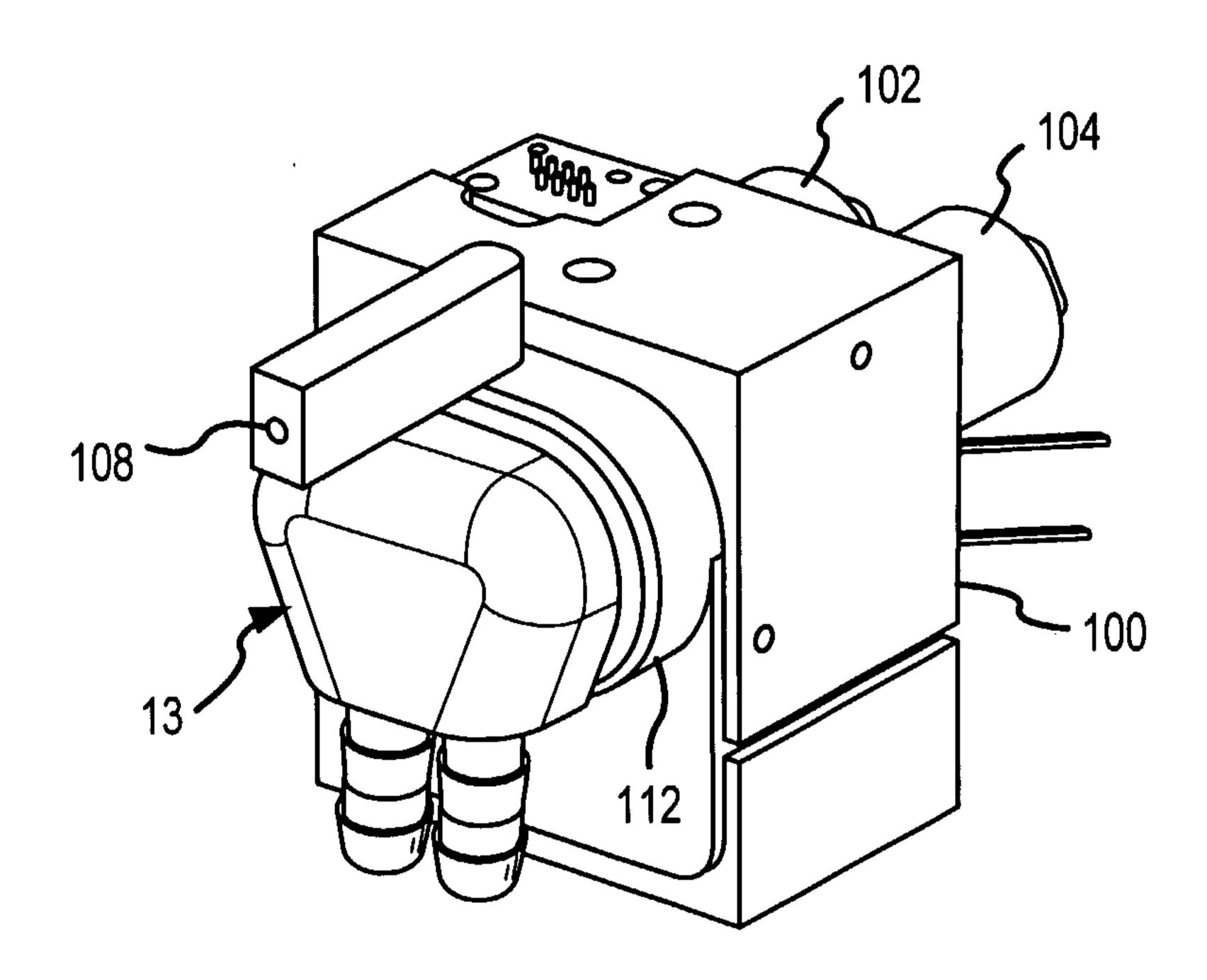


FIG.5b

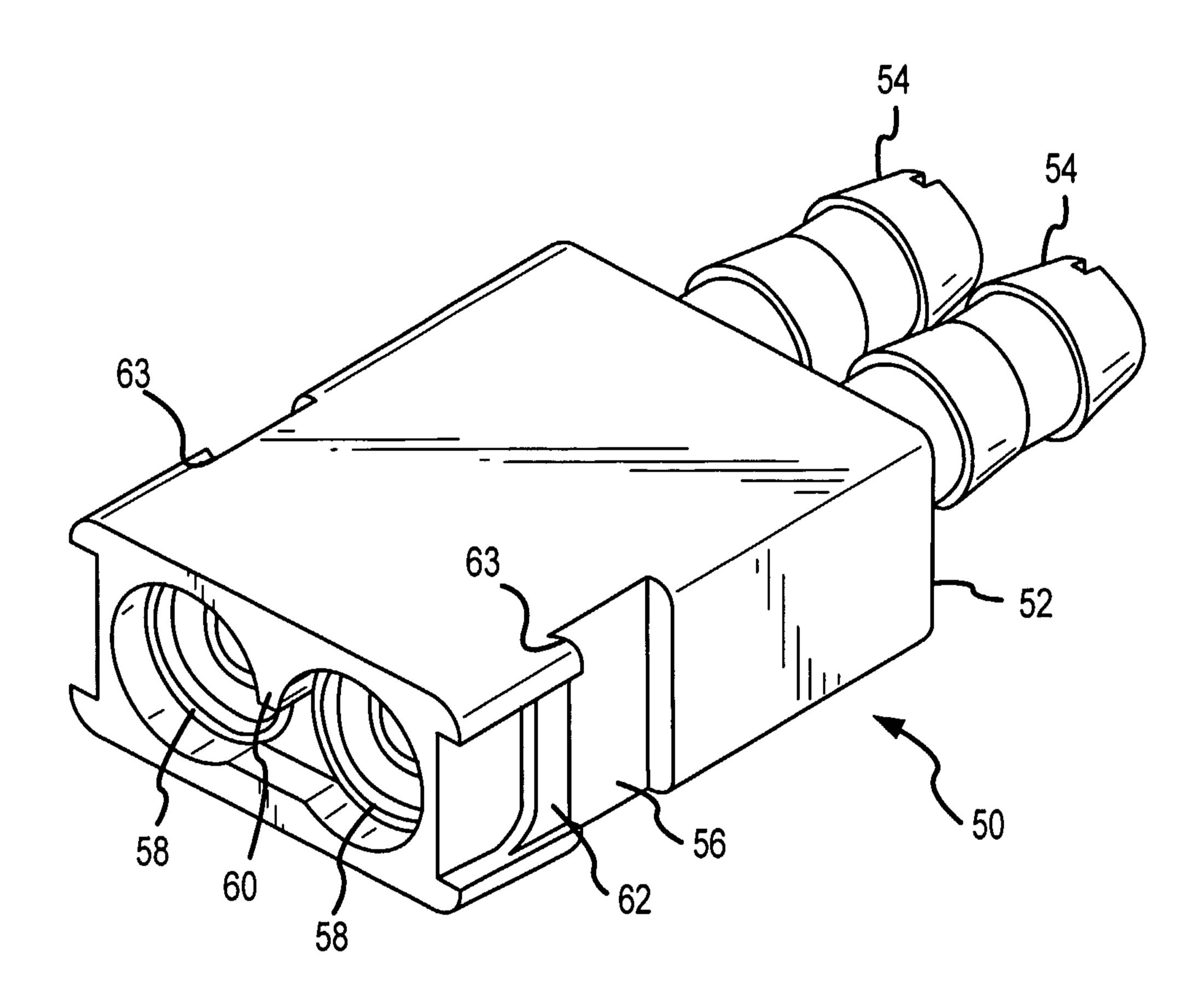
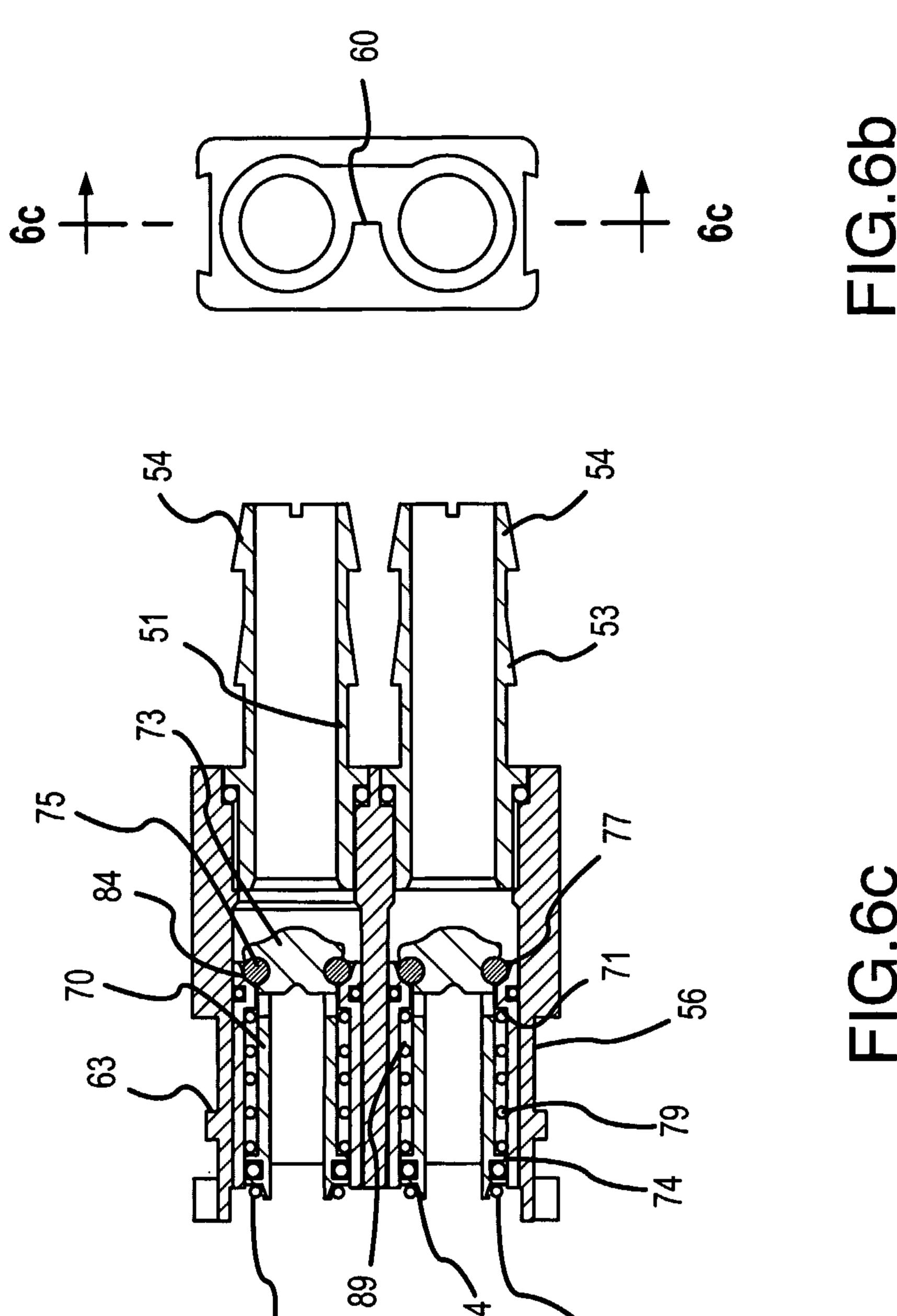


FIG.6a



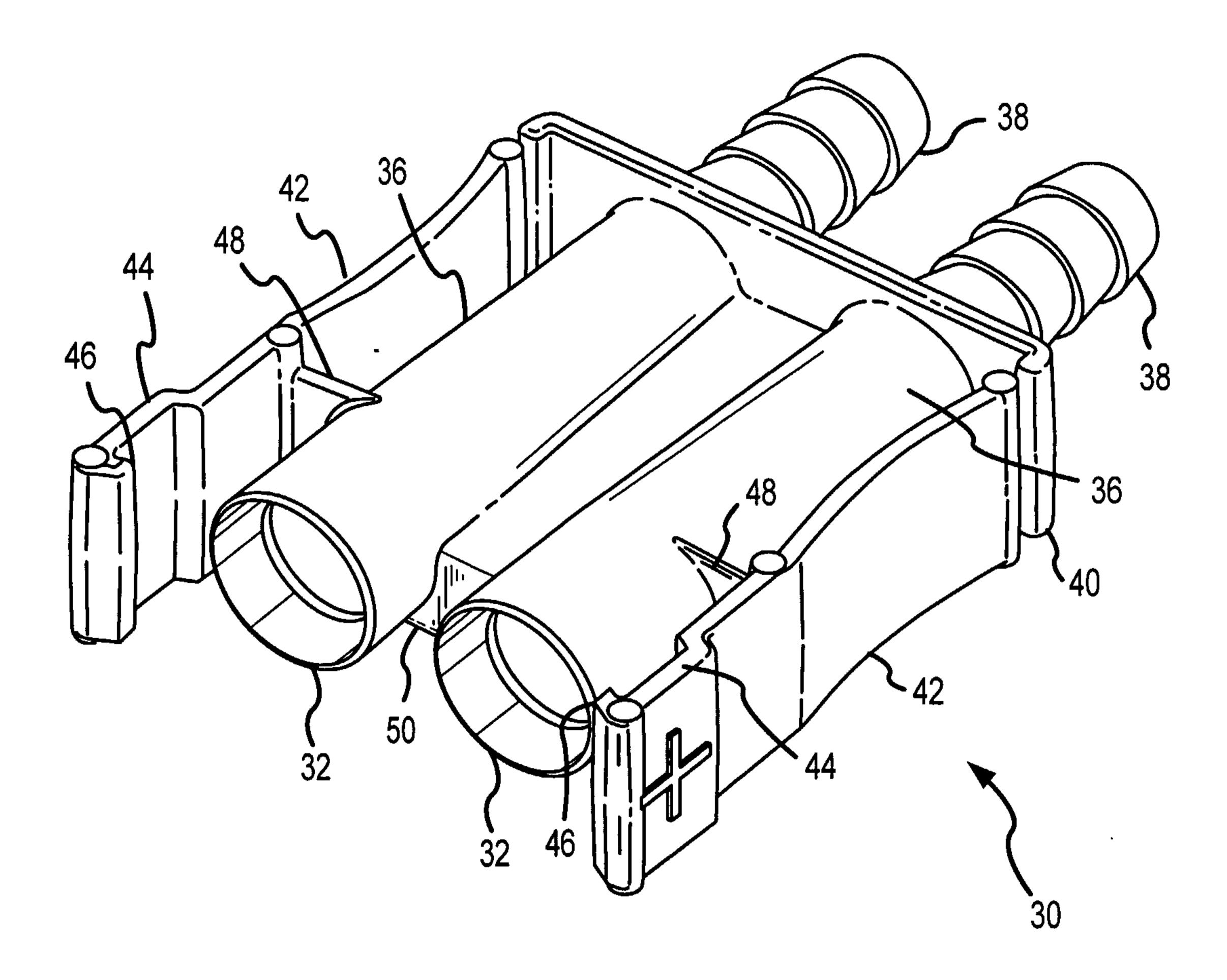


FIG.7a

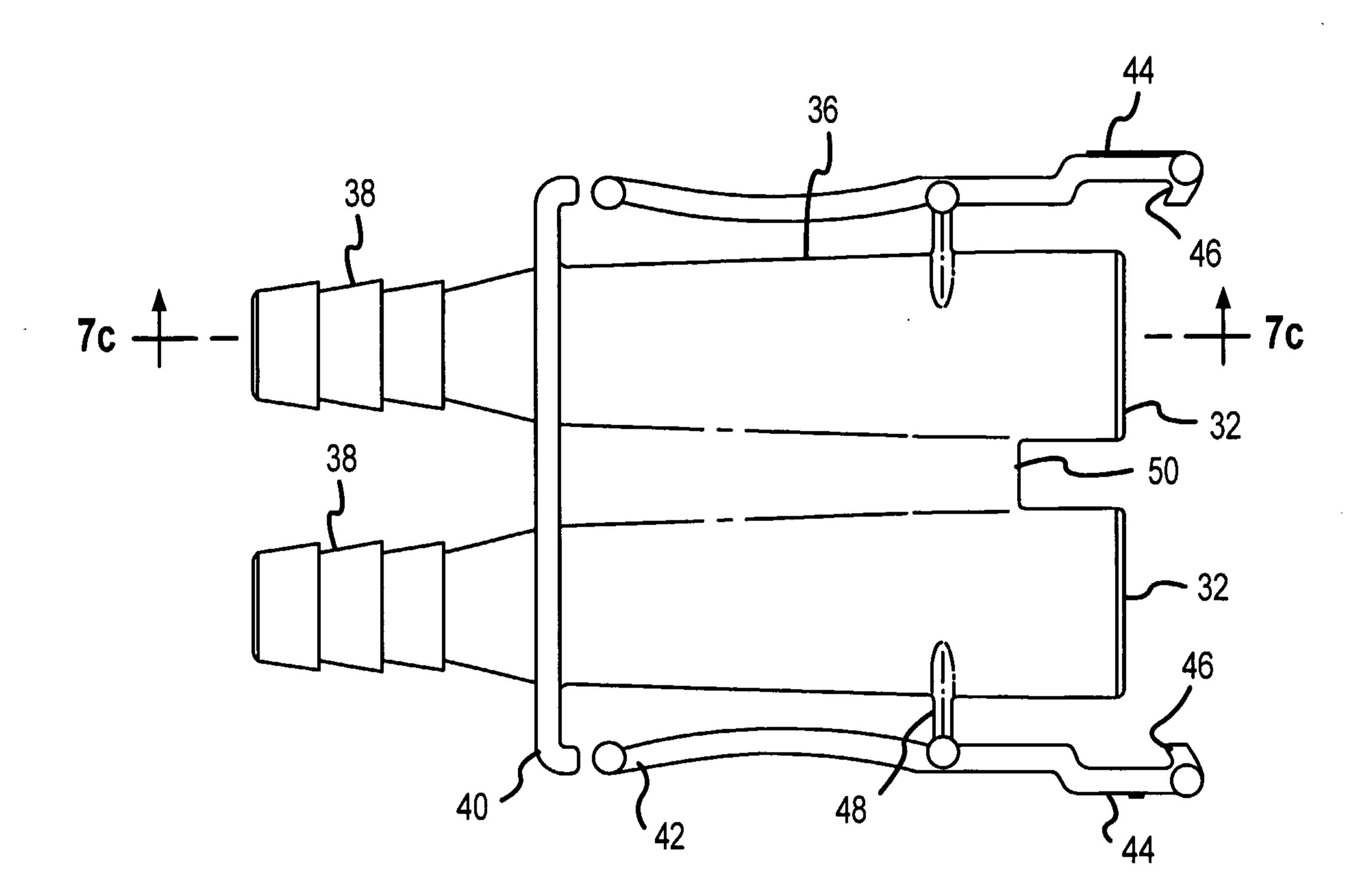


FIG.7b

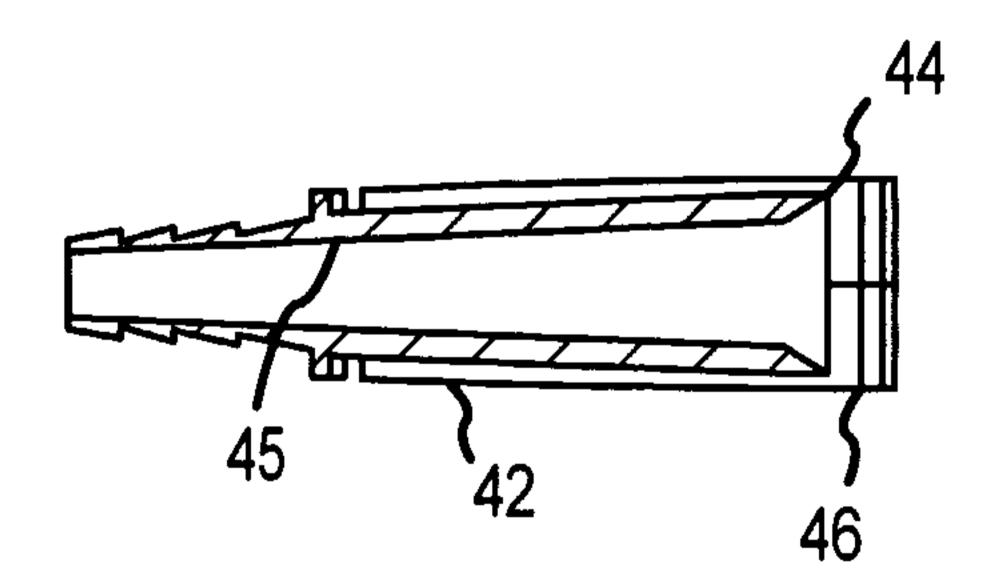
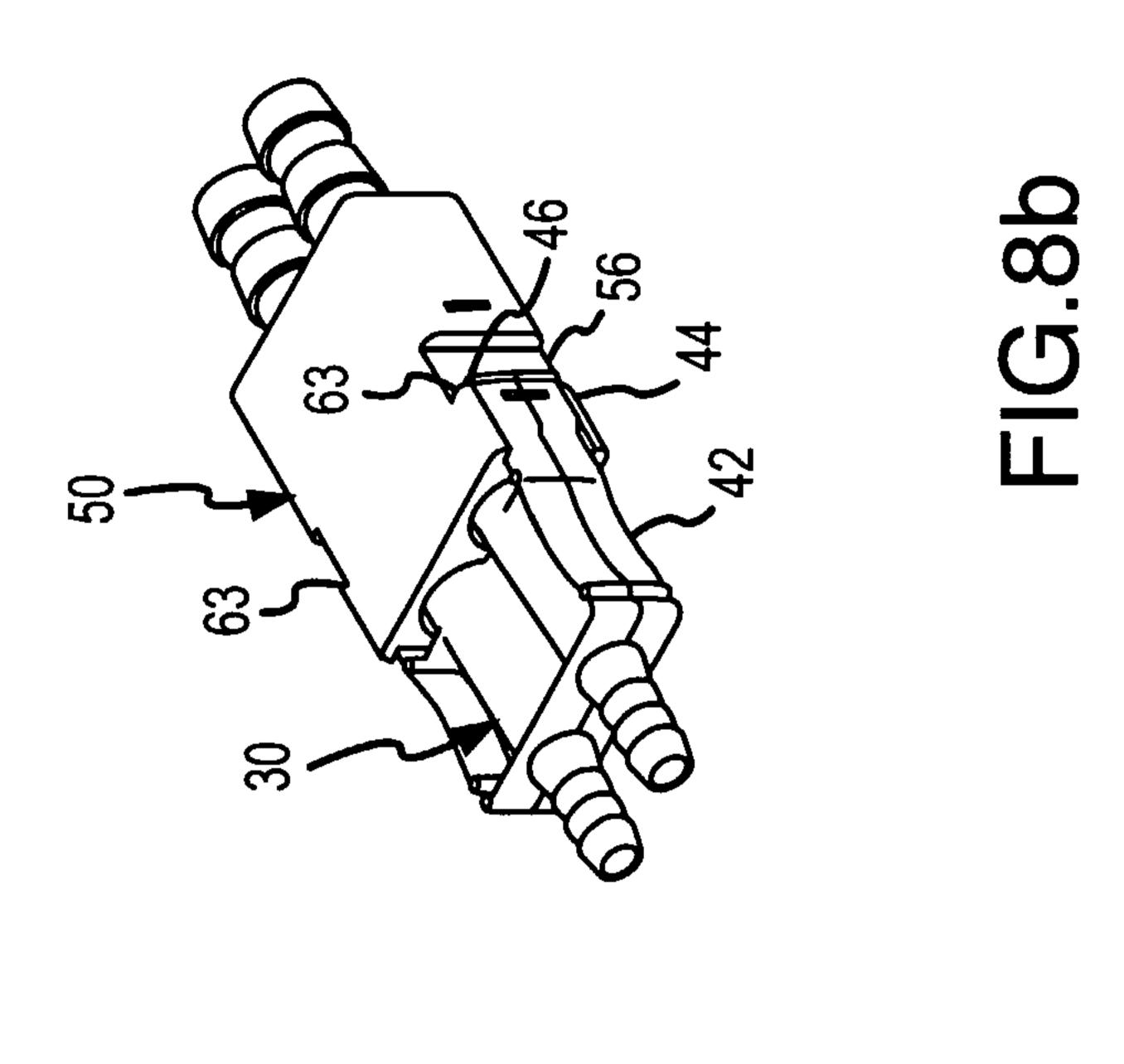
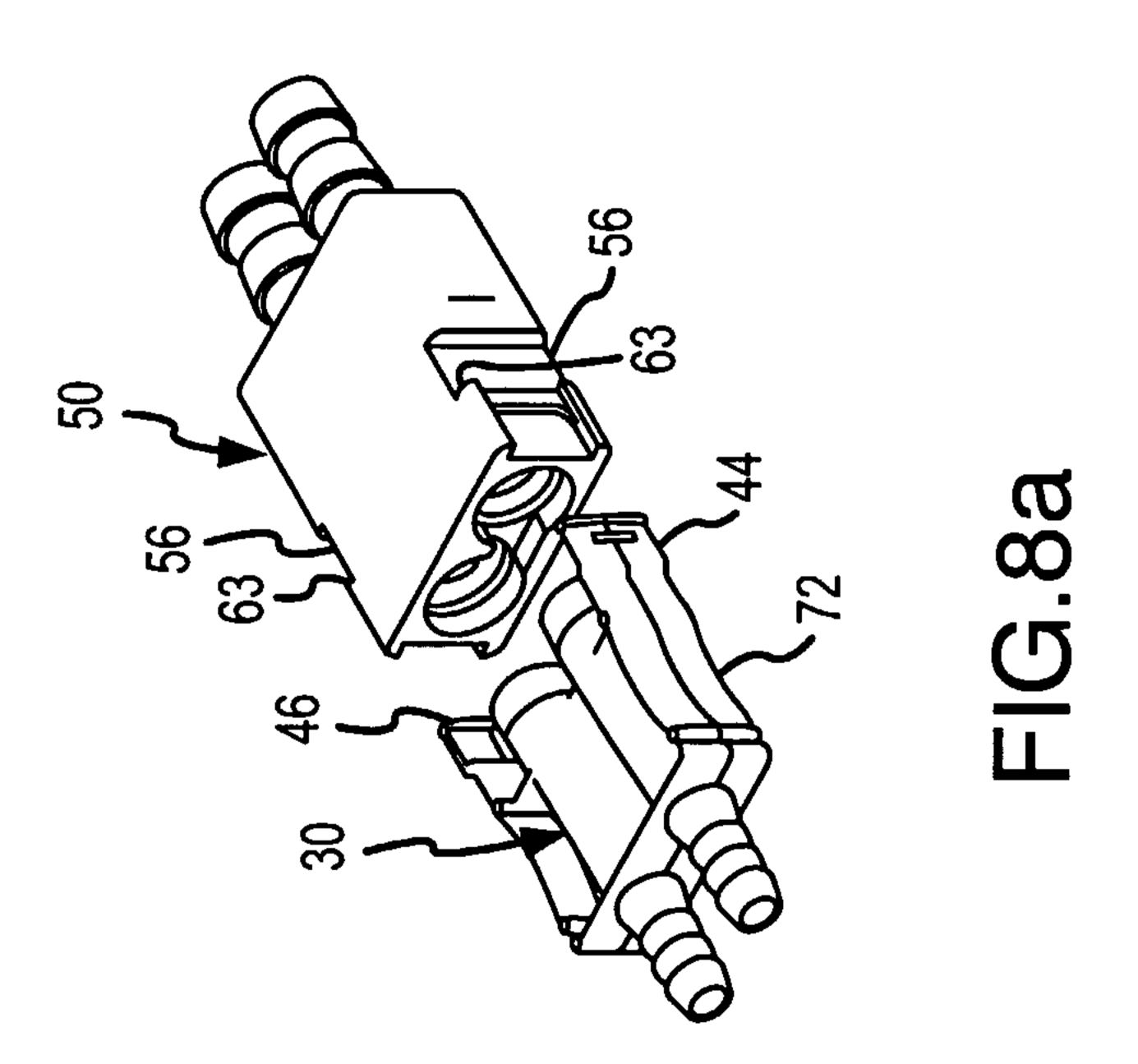


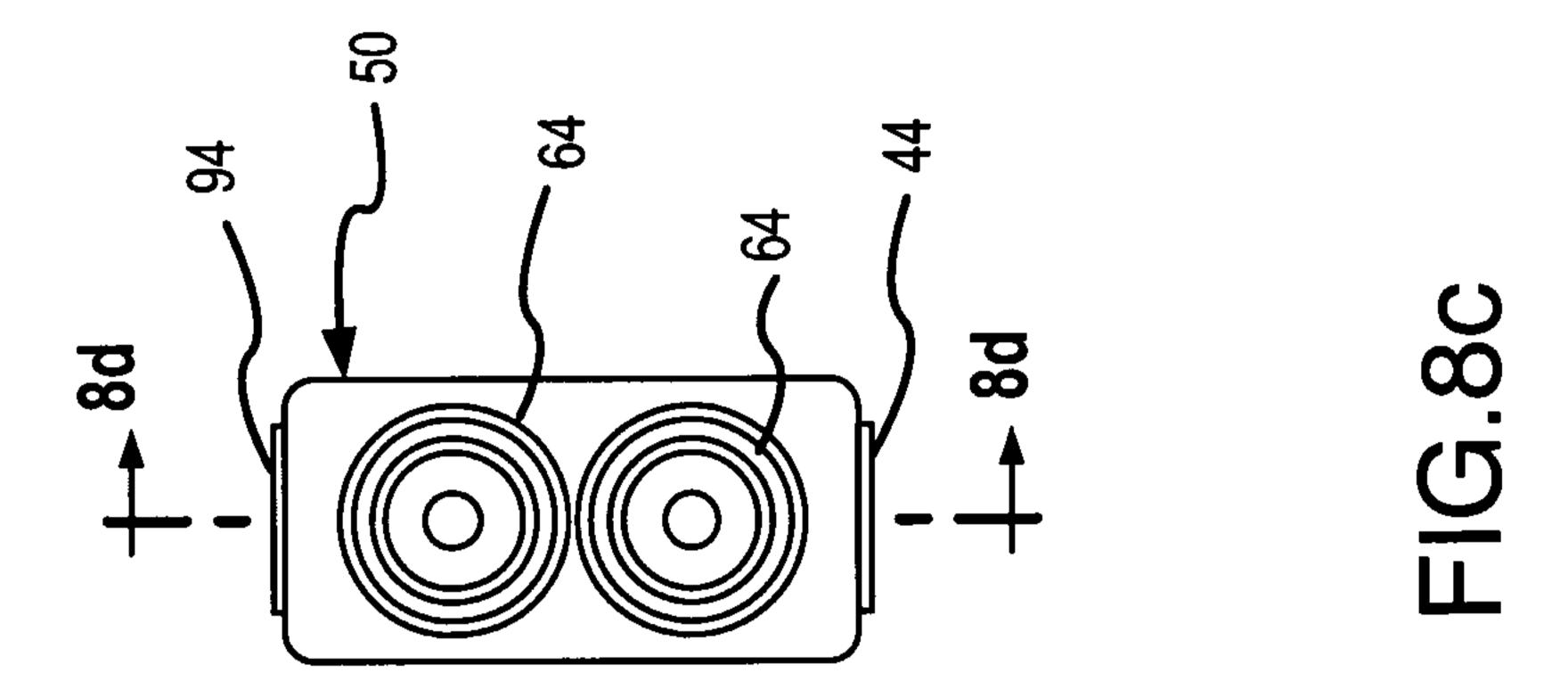
FIG.7c

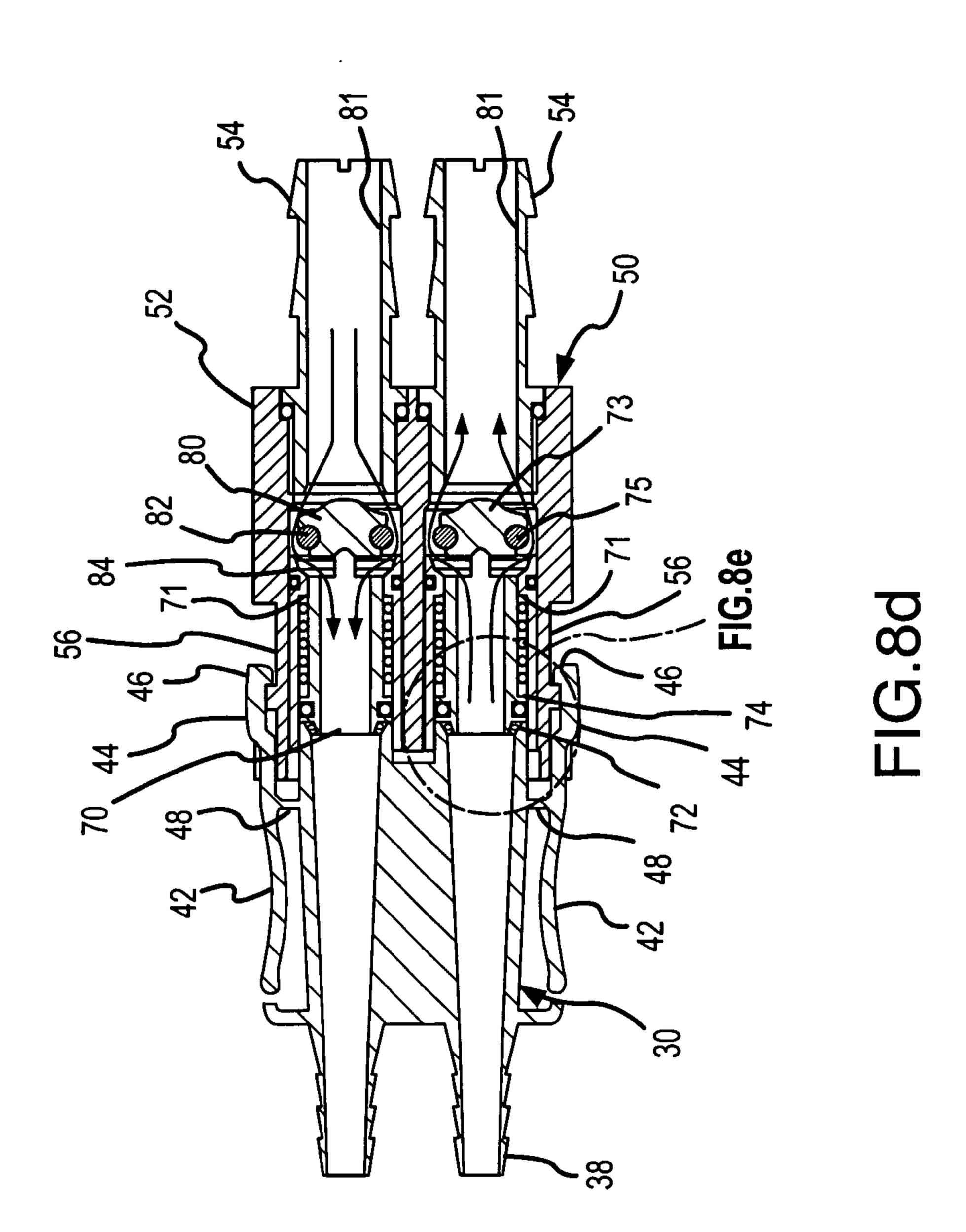
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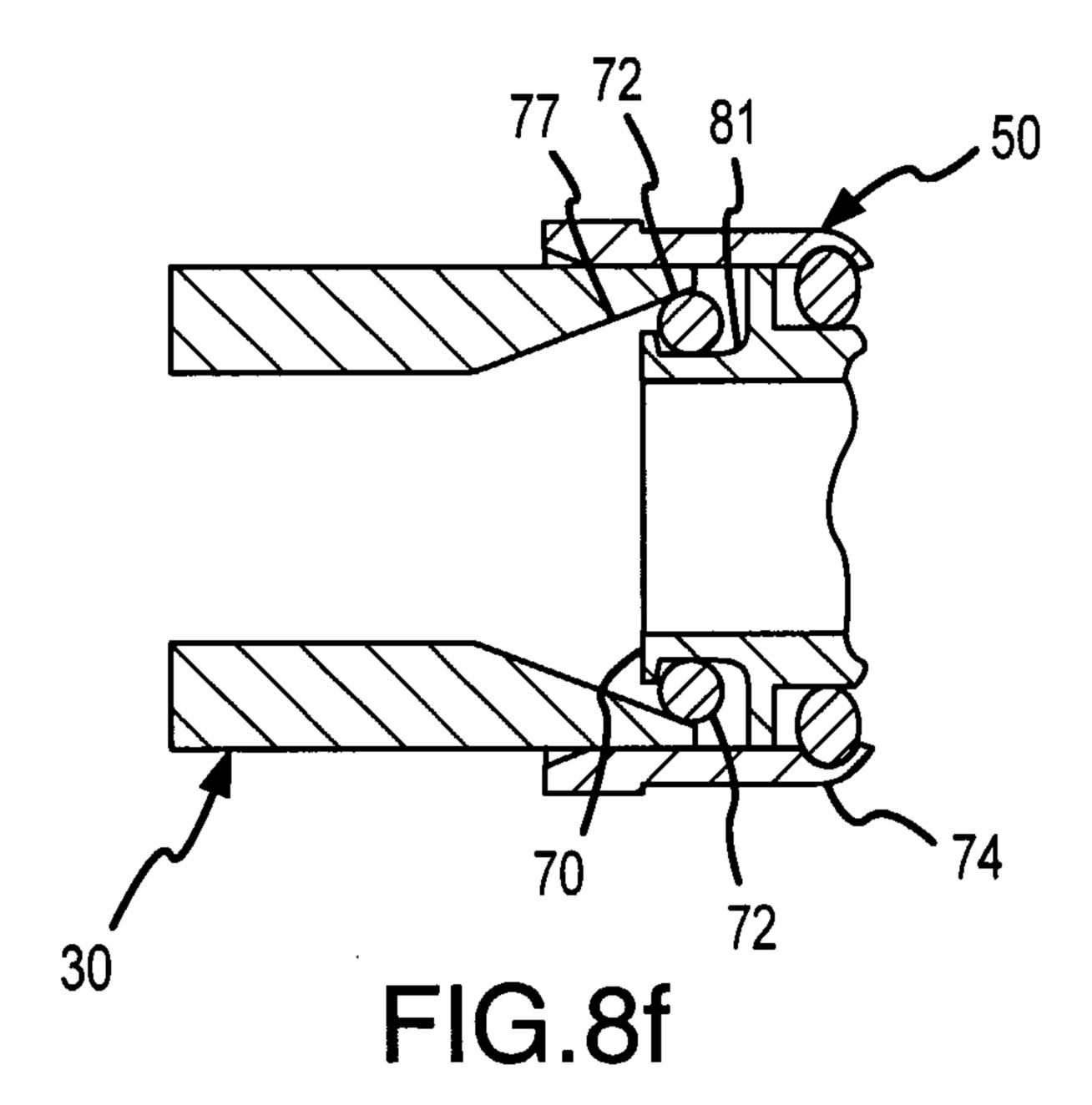




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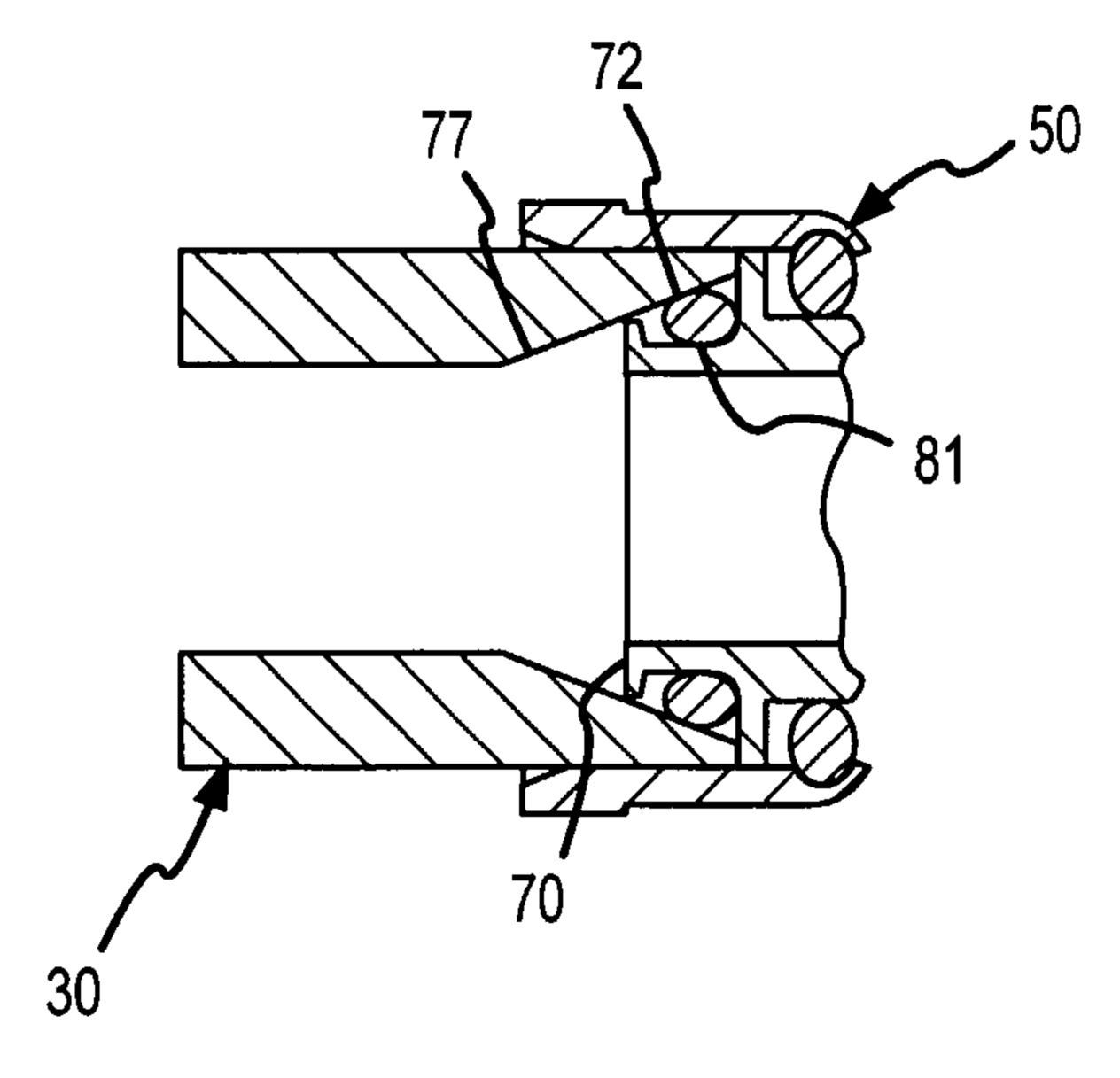


FIG.8e

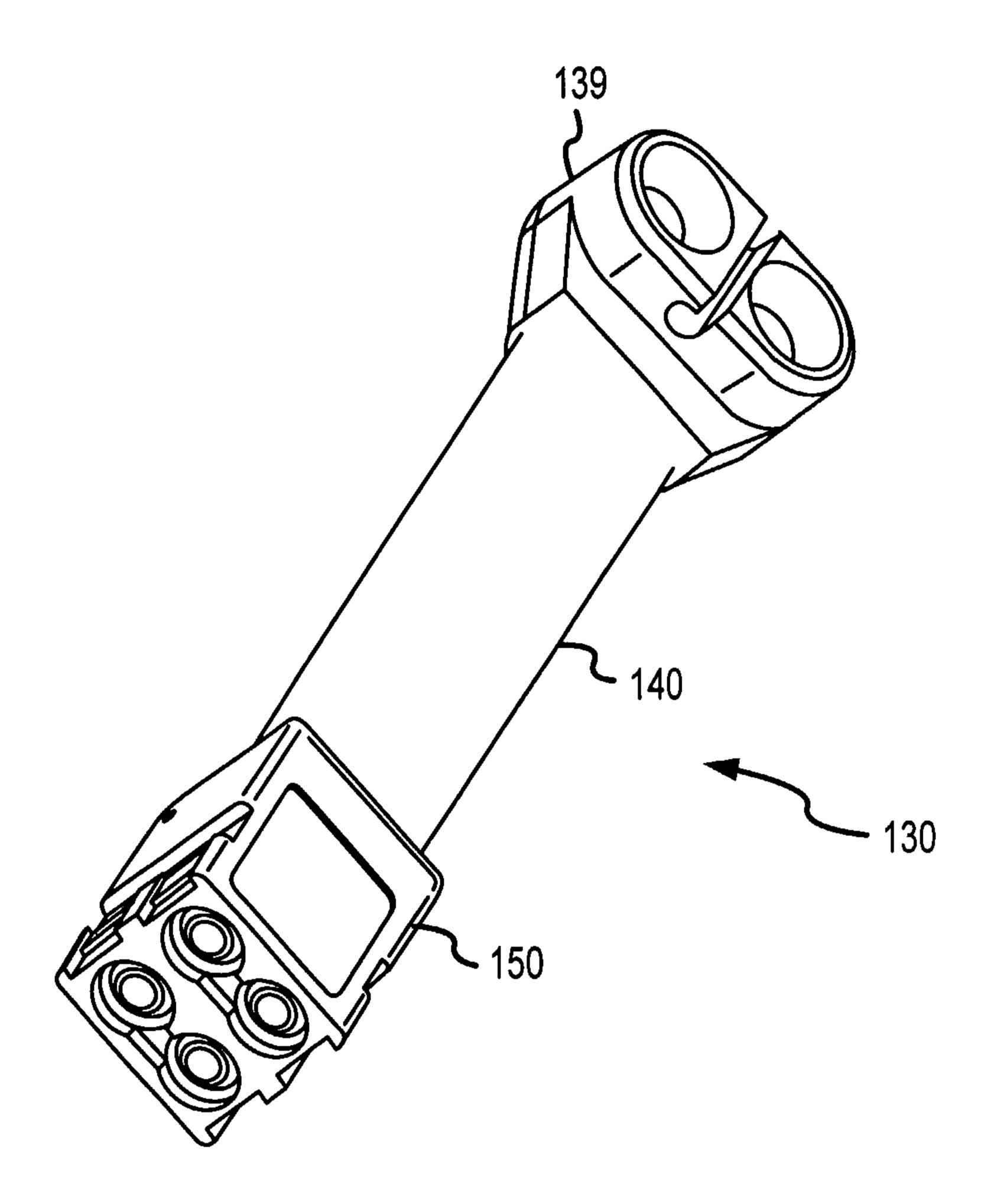
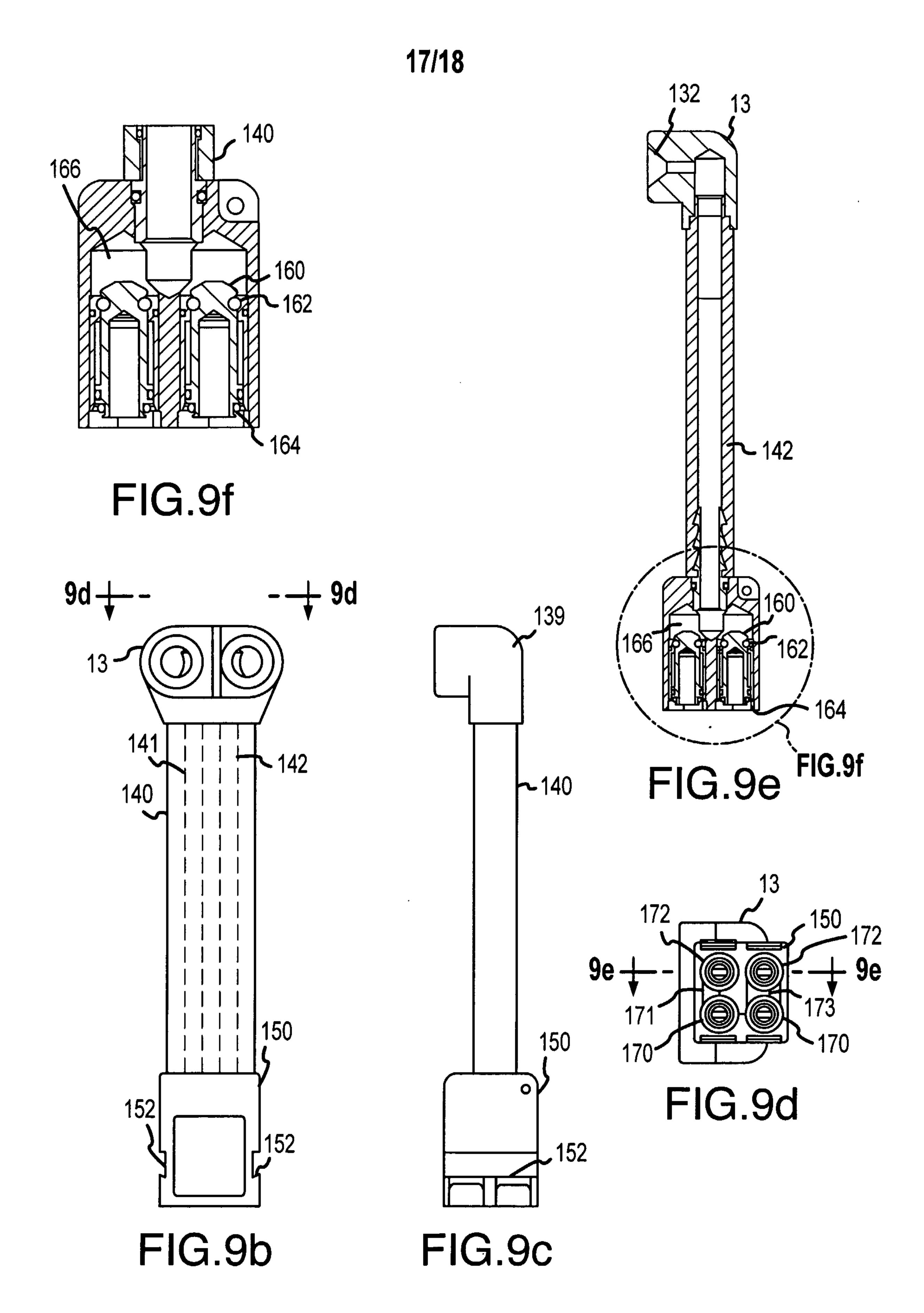


FIG.9a



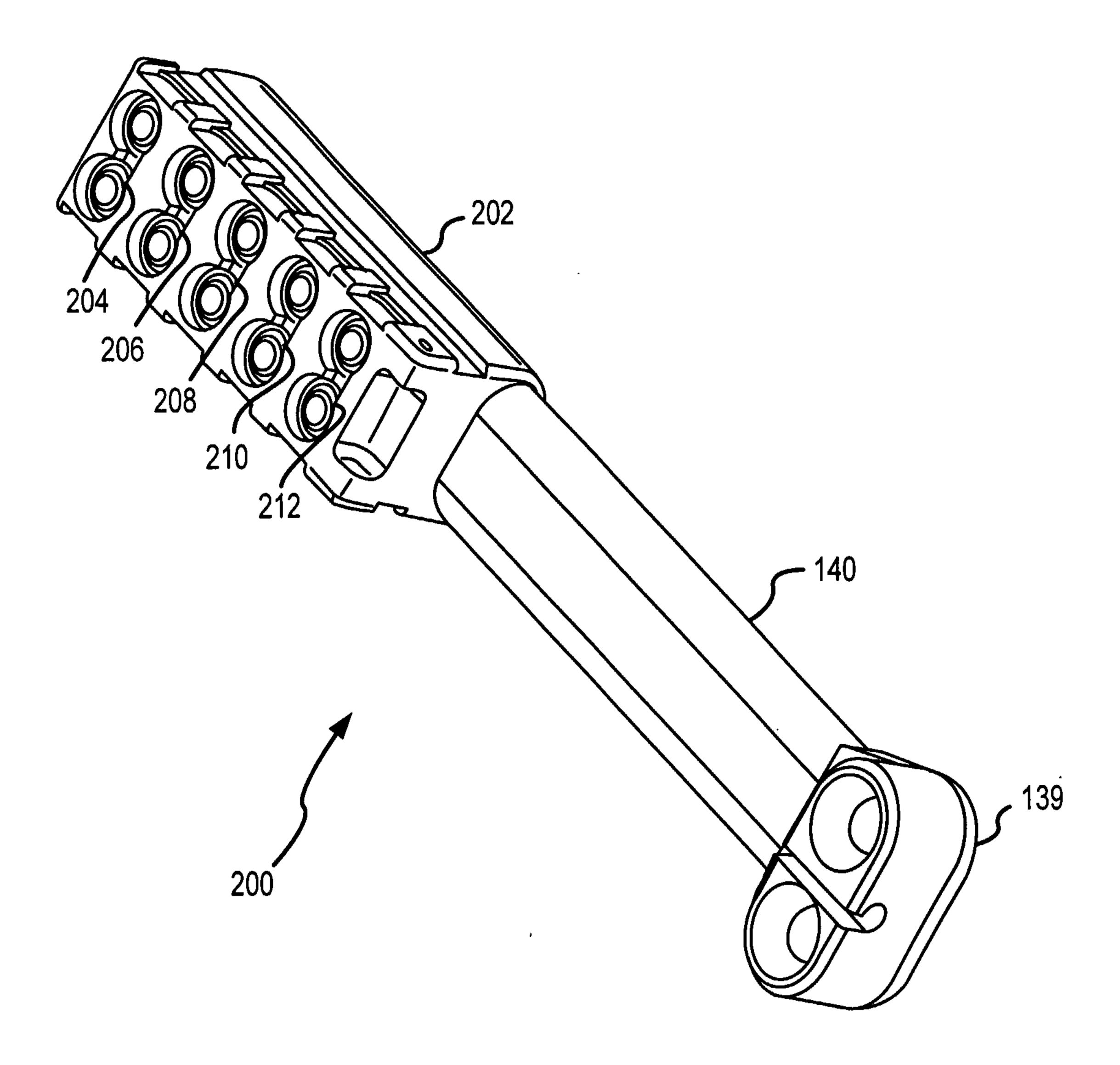


FIG.10

