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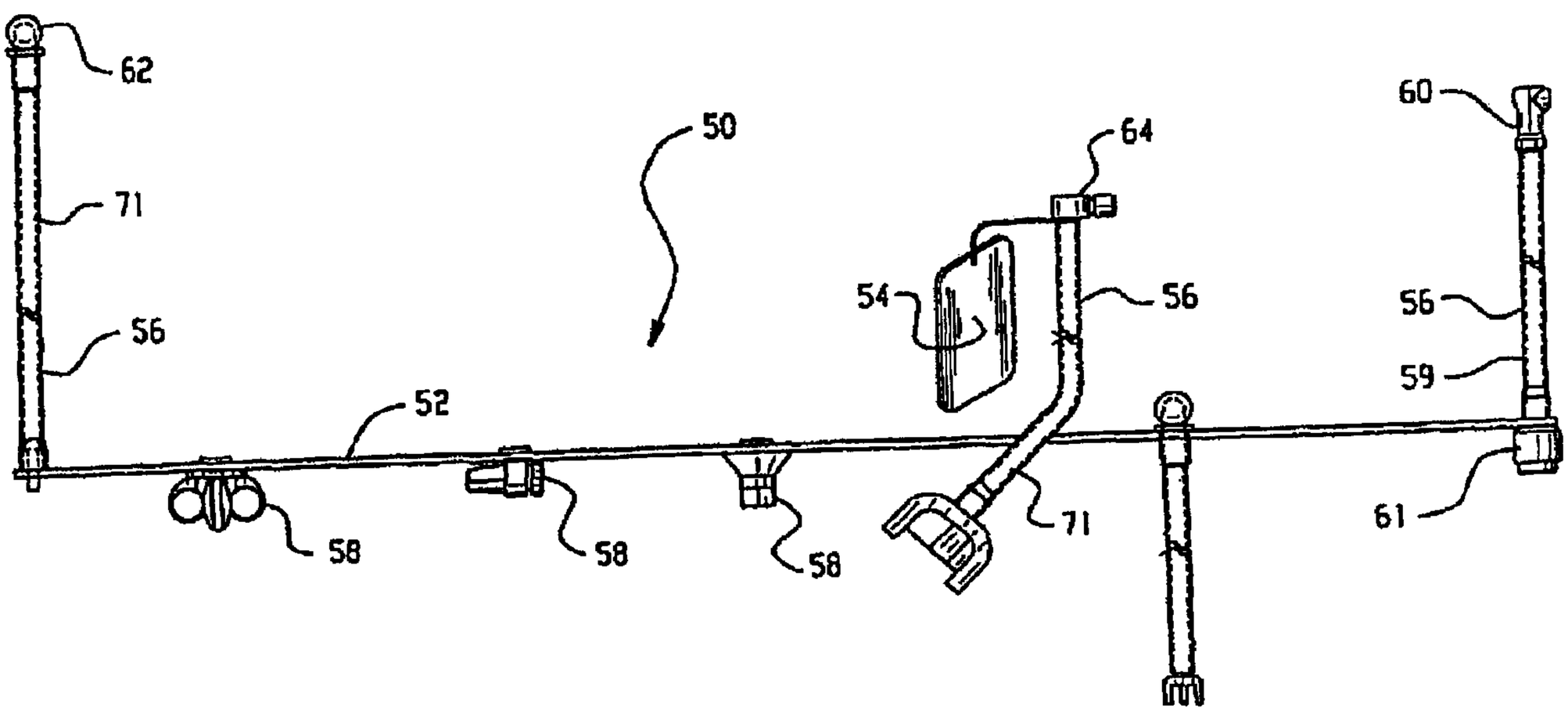
(54) Title: FLUID CONNECTION SYSTEM FOR ENDOSCOPE REPROCESSING WITH CONTROLLED LEAKAGE



(57) Abrégé/Abstract:
A tethered interconnection assembly (50) supplies an antimicrobial fluid to interior passages of an endoscope during a microbial decontamination cycle. The tethered connection assembly includes tube assemblies (56) with fittings (60, 62, 64) which are uniquely configured for interconnection with an appropriate one of a high pressure port (28), a low pressure port (28), and optionally a leak detector port (36). Fittings (74) at the other end of the tube assemblies are configured for interconnection with appropriate corresponding ports of the endoscope. The tube assemblies (56) are interconnected by a tether (52) to which plurality of plugs (58) for plugging appropriate ports of the endoscope are also connected. A tag (54) identifies the model(s) of endoscope that the tethered connection assembly is to be used with and provides a diagram showing the proper interconnection pattern.

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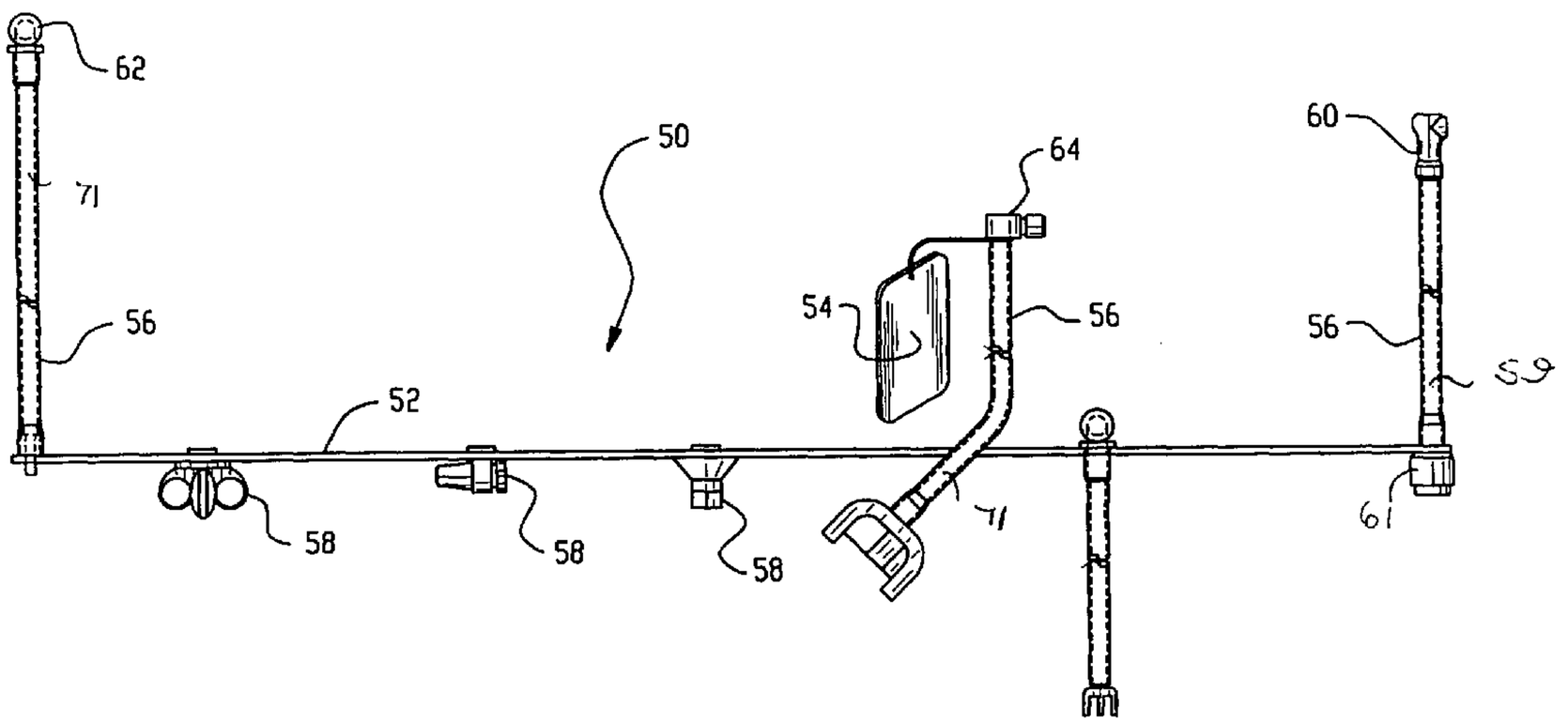

(57) Abstract: A tethered interconnection assembly (50) supplies an antimicrobial fluid to interior passages of an endoscope during a microbial decontamination cycle. The tethered connection assembly includes tube assemblies (56) with fittings (60, 62, 64) which are uniquely configured for interconnection with an appropriate one of a high pressure port (28), a low pressure port (28), and optionally a leak detector port (36). Fittings (74) at the other end of the tube assemblies are configured for interconnection with appropriate corresponding ports of the endoscope. The tube assemblies (56) are interconnected by a tether (52) to which plurality of plugs (58) for plugging appropriate ports of the endoscope are also connected. A tag (54) identifies the model(s) of endoscope that the tethered connection assembly is to be used with and provides a diagram showing the proper interconnection pattern.

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FLUID CONNECTION SYSTEM FOR ENDOSCOPE REPROCESSING WITH CONTROLLED LEAKAGE

Background of the Invention

The present application relates to the fluid handling arts. It finds particular application in conjunction with fluid sterilization and disinfection systems and will be described with reference thereto.

Fluid sterilization and disinfection systems are typically designed to cause microbes on the item to be removed or killed, i.e., microbially decontaminated, by a fluid anti-microbial agent. This is achieved in a variety of ways, including immersing the item in a bath of anti-microbial liquid, spraying the item with anti-microbial liquid, surrounding the item with anti-microbial vapor, and the like. While such systems work well for killing microbes on the exterior surface of the items to be decontaminated, internal lumens can be problematic. To be a viable commercial product, a sterilization or disinfection apparatus must provide assured contact between the anti-microbial agent and the microbes. On items with elongated lumens, such as endoscopes, it is desirable that the anti-microbial fluid assuredly contact all surfaces within the lumen. Typically, this is achieved by pumping or drawing the anti-microbial fluid through the lumen.

Often, endoscopes have a plurality of lumens which may have different cross-sections, length, internal obstructions, and the like. It is advantageous to supply the fluid to different lumens at different pressures. Further, some lumens have multiple openings. Typically, plugs are inserted into or over some of the openings to force the anti-microbial fluid to flow the entire length

of the lumen. Often, endoscopes have a lumen which does not need to be sterilized and worse yet, can be damaged by contact with fluids. Further, the lumens have a variety of connector styles, such as screw threads, bayonet pipe connectors, and the like, as well as different diameters.

Typically, the sterilization technicians are given a variety of individual plugs and fittings from which they select the most appropriate plugs and fittings for a specific endoscope to be sterilized or disinfected. Being small parts, they are sometimes lost. The technicians, in many cases, improvise by using another part which appears to work. In other cases, the technicians merely make a mistake in selecting fittings or plugs or in making the connections between the fluid supply, fittings, and lumens. When improper plugs or fittings are used and when improper interconnections are made, the assurance that the anti-microbial agent is contacting all microbes within the lumens is lost.

The fittings and plugs typically connect securely with the structures at the lumen ports. At the surfaces of interconnection, microbes can become trapped between the fittings or plugs and the structures at the lumen port. When there is a good frictional fit, the frictional fit protects these microbes from the anti-microbial agent. This creates the possibility that at the end of the cycle there may be active microbes on the surfaces adjacent the lumen ports destroying the assurance of disinfection or sterility. One solution to the trapped microbe problem is shown in U.S. Patent Nos. 5,552,115 and 5,833,935 of Malchesky in which the fittings and plugs are made of an open-celled plastic material. The porous fitting solution is effective, but does have some drawbacks. First, the porous plastic material is relatively soft. With repeated use, dimensions can change altering flow characteristics. Moreover, the plastic can be damaged or broken during use, again altering flow characteristics. After a disinfection or sterilization

cycle, the fittings are typically wet with water from the final rinse. Wet, porous materials can become breeding grounds for airborne microbes if not handled properly. One use, disposable porous connectors and fittings can be costly and there is no assurance that the operator will use a new fitting in each cycle rather than reusing an old one.

The present invention provides a new and improved method and apparatus which overcomes the above-referenced problems and others.

Summary of the Invention

In accordance with one aspect of the present invention, a method of disinfection or sterilization of an article having interior lumens is provided. The method includes placing an article in a chamber and interconnecting a lumen port of the article which provides access to its lumen with an antimicrobial fluid outlet. An exterior of the article is contacted with an antimicrobial fluid. The antimicrobial fluid is flowed through the lumen. The method further includes selectively fluidly connecting the anti-microbial fluid outlet and the lumen port of the article with a connector having a fitting which is configured for loose interconnection with surfaces adjacent the lumen port such that a first fraction of the antimicrobial fluid flows through the lumen port into the lumen and a second fraction of the anitmicrobial fluid flows between the lumen port and the fitting into the chamber, the interconnection being sufficiently loose that the fitting wobbles, changing momentary points of contact between the fitting and the surfaces adjacent the lumen port.

In accordance with another aspect of the present invention, a fluid disinfection or sterilization system is provided. A chamber receives a lumened article to be microbially decontaminated. At least one first fluid outlet in the chamber supplies antimicrobial fluid to

contact exterior surfaces of the lumened article. There is at least one second fluid outlet through which the antimicrobial fluid is suppliable to an interior lumen of the lumened article. A connector selectively fluidly connects the second fluid outlet with a lumen port of the article for supplying the antimicrobial fluid to the interior lumen. The connector includes a tube, a first fitting connected to one end of the tube for interconnection with the second fluid outlet, and a second fitting connected with the tube and configured for selective loose interconnection with the lumen port in such a manner that an annular gap forms between the fitting and the port and the fitting wobbles, changing momentary points of contact with surfaces adjacent the lumen port so that a first fraction of the antimicrobial fluid flows through the lumen port into the lumen and a second portion of the anti-microbial fluid flows between the lumen port and the second fitting into the chamber.

One advantage of the present invention resides in the anti-microbial fluid's assured contact with the surfaces abutting the fittings and plugs.

Another advantage of the present invention is that it promotes the use of the proper fittings and plugs with each endoscope.

Another advantage of the present invention is that it is easy and convenient to use.

Another advantage of the present invention resides in consistent, repetitive operation.

Another advantage of the present invention is that it provides anti-microbial fluid flow through dead-end passages.

Another advantage of the present invention is that it assures that the fittings and plugs are correctly matched to each type of endoscope.

Still further advantages and benefits of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating preferred embodiments and are not be construed as limiting the invention.

FIGURE 1 is diagrammatic illustration of an exemplary fluid disinfection/sterilization system in accordance with the present invention;

FIGURE 2 is a detailed view of an exemplary tethered fitting and plug assembly in accordance with the present invention;

FIGURE 3 illustrates another tethered plug and fitting assembly;

FIGURE 4 illustrates the interconnection between one of the tethered fittings and a port (shown in phantom) on an endoscope;

FIGURE 5 illustrates another fitting for interconnection between a tube assembly and an endoscope port;

FIGURE 6 is a cross-sectional view of another fitting for interconnection with an endoscope port;

FIGURE 6A is a cross-sectional view of yet another fitting for interconnection with an endoscope port;

FIGURE 7 is an elevational view in partial section of a plug assembly for interconnection with an endoscope port;

FIGURE 8 is a perspective view of yet another plug assembly for interconnection with an endoscope port;

FIGURE 9 is a perspective view of a plug assembly for interconnection with a pair of endoscope ports;

FIGURE 9A is a cross sectional view of the plug assembly of FIGURE 9;

FIGURE 10 is an elevational view of another plug assembly for interconnection with an endoscope port;

FIGURE 11 is a perspective view of yet another plug assembly for interconnection with a pair of adjacent ports of an endoscope;

FIGURE 12 is a perspective view of yet another plug assembly for interconnection with an endoscope port;

FIGURE 13 is a front view of the plug assembly of FIGURE 12;

FIGURE 14 is a side sectional view of the plug assembly of FIGURE 12 connected to an endoscope port;

FIGURE 15 is a side sectional view of yet another fitting for interconnection with an endoscope port;

FIGURE 16 is a top view of another exemplary fluid disinfection/sterilization system in accordance with the present invention; and

FIGURE 17 is a plumbing diagram of the disinfection/sterilization system of FIGURE 16.

Detailed Description of the Preferred Embodiments

With reference to FIGURE 1, a liquid washing and microbial decontamination system includes a pair of chambers **10a, 10b** for washing and microbially

decontaminating endoscopes and other goods. Chamber **10a** is described in detail, but it is to be appreciated that chamber **10b** is analogous. A rack **12** having a plurality of pegs around which the tubes of the endoscope **14** are wound is supported in the chamber. The rack can be hung in the chamber and the endoscope wrapped around it or the endoscope can be wrapped around the rack at a remote location and then the rack and scope are hung as a unit in the chamber. A cup or other ampule containing a washing solution, such as detergent, corrosion inhibitors, and an anti-microbial agent is loaded in a well **16** defined in a lowermost point of a sump **18** at the bottom of the chamber.

A manifold **20** permits any of a plurality of fluids to be connected with a pump **22**. In one state, the manifold connects outside water to the pump **22** which pumps the water through a heater **24** to nozzles **26** located around the chamber and fluid outlet ports **28** located in a rear wall of the chamber. Preferably, some of the ports **28** are high pressure ports and others are low pressure ports. Each of the ports includes a valve that has an open state and a leaky closed state that permits limited fluid flow to assure circulation through the tubing branch leading to it. In another state, the manifold **20** connects the pump with the well **16** at the bottom of the sump to recirculate fluid. In another state, the manifold connects the pump with a sterile water generator **30**. In yet another state, the manifold connects the nozzles (either through the pump or directly) with a source of sterile air **32**, preferably under pressure.

A leak detector **34** is connected with a leak test port **36**. The leak detector checks whether a lumen or other structure connected with port **36** is leaking, e.g., whether it holds a preselected vacuum or positive pressure.

It is to be appreciated that analogous elements are connected with the second chamber **10b**, although a common sterile water generator can supply both systems.

A common operator input device **40**, such as touch screen, enables the operator to put processing instructions into a common control **42** for the two chambers. The common control causes the leak check device to check whether the lumen connected with the port **36** is leaking or not. The automatic control also controls the manifold **20** and a cup opening device (not shown) in the well **16**, the pump **22**, the heater **24**, and a drain valve **44**. A typical cycle includes pumping cold water to the spray nozzles and the interior lumen ports to remove gross debris, after which the water is drained. Next, a washing solution section of the cup in the well **16** is opened as new water is brought in and circulated to the nozzles and the ports to wash the interior and exterior of the endoscope. After the wash and drain cycle, another rinse cycle removes excess detergent or other washing compounds. After the rinse is drained, air is blown through at least the outlet ports **28** and the interior lumens of the endoscope to remove excess fluid. A corrosion inhibitor compartment of the cup is then opened as additional water is brought into the system. The corrosion inhibitors, buffers, and other components in solution are circulated to the nozzles and output ports. Thereafter, a microbicide portion of the cup is opened to release a microbicide into the circulating solution. After the anti-microbial solution is drained, air again blows excess liquid from the lumens of the endoscope. One or more sterile water rinses follow concluding with a blow out of the water from the lumens. At the end of the cycle, the controller **42** causes an appropriate one of printers **46a, 46b** to print out a record of the completed sterilization or high level disinfection cycle.

With continuing reference to FIGURE 1, and further reference to FIGURES 2 and 3, after the endoscope **14** is mounted on the rack **12** in the chamber, the operator uses a tethered set of connectors and plugs **50** to interconnect various ports **51** of the endoscope with the

liquid ports **28** and the leak detector port **36** and to plug various ports of the endoscope. More specifically, each of the tethered plug and connector assemblies **50** includes a tether **52** which is connected to a tag **54**. The tag **54** carries an indicia of the model or family of models of endoscope which are to be used with tethered set of plugs and connectors. The tag further includes a diagram illustrating how each of the connectors is to be interconnected between the scope and the outlet ports **26** and the leak detector ports. Step by step instructions are also included. Each of the connectors **56** or plugs **58** include a sequential reference character, such as a number or letter, which identify each connector and each plug and correlate the connectors and plugs with the instructions and the order in which they are to be connected.

Typically, one of the connectors **56** includes a tube **59** with a fitting **60** at one end which is configured to mate only with the leak test port **36**. The other end of the connector tube has an appropriate fitting **61** for interconnection with the leak test port of the endoscope. The fluid ports **28** preferably include high pressure ports and low pressure ports. Optionally, the ports may have a larger number of dedicated pressures. Another of the connectors typically has a fitting **62** which is configured to be connected only with one of the high pressure fluid ports **28** and a fitting **74** configured for attachment to an endoscope port structure; while other connectors have a fitting **64** configured to be connectable only with one of the low pressure output ports **28**. Various techniques may be utilized to limit each fitting **62, 64** to be connected with only specific one or ones of the ports **28, 36,** such as different diameters, different connecting mechanisms (threaded, bayonet, etc.), different shapes, and the like. The plugs **58** are each configured to mate with the appropriate ports **51** on the scope identified by the tag. The length of the tether and the length of portions of the tether between the various plugs and connectors are

selected such that each of the connectors and fittings just reach a port **51** of the endoscope to which they are to be connected. In this manner, if one of the connectors or plugs is connected with the wrong port, the tether will be too short for other connectors or plugs to reach an available port on the endoscope. This provides a ready indication to the operator that the plugs and fittings have not been connected properly or that the wrong tether assembly has been selected.

While the decontamination system has been described in terms of a liquid system, it will be appreciated that other fluids, such as gaseous or vapor phase antimicrobial compositions may be used in place of the liquids (antimicrobial solution and water rinse) described above. Examples of other fluids include vaporized hydrogen peroxide (a mixture of hydrogen peroxide and water in vapor form), ion plasmas, ethylene oxide, formaldehyde, peracid vapors, such as performic acid, peracetic acid, perpropionic acid, and mixtures thereof.

Additionally, while the decontamination system has been described with reference to spray nozzles and a rack, it is also contemplated that an immersion system may be used in which the endoscope, or other lumened device, is coiled in a receiving tray, or other receptacle, and immersed in the antimicrobial solution. The tray is filled with sufficient antimicrobial solution from one or more fluid outlets to cover the endoscope.

A wide variety of plugs and fittings are connected with the various tethers. Different endoscope manufacturers, and even the same manufacturer within different families of endoscopes, use different types and sizes of port structures. The appropriate fittings **74** and plugs **58** for each of the outlet port structures is preassembled on the tether. Although each of the fittings and plugs is configured to conform with the outlet port structure on the intended endoscope, they are not designed

to couple in a fluid-tight connection. To the contrary, the fittings **74** (other than leak test fittings **61**) and plugs **58** are designed to allow limited leakage between their structure and the port structure of the endoscope to which they are mounted. While the fittings **74** and plugs **58** may touch the port structure in some positions at some points, vibration, water flow, and pressure variations cause sufficient movement that the point of contact shifts and all points on the port structure of the endoscope are subject to the anti-microbial fluid during a significant portion of the cycle. Preferably, the nozzles **26** operate in sets. That is, one group of nozzles operates for a while, and then shuts off as another group of nozzles starts operating. This change in spray direction again assists in rocking the fittings **74** and plugs **58** in the associated endoscope port structure.

With reference to FIGURE 4, many endoscope ports **51** are defined by extending tubular elements **70** with exterior barbs **72**. A suitable connector **56** for such a port includes a tubular portion **71** with an output port connection fitting **62** or **64** at one end and a fitting **74** adapted to connect to the port at the other. The tubular portion may be branched to allow for more than one fitting **74** on the tubular portion. The fitting **74** includes a body portion that defines a beveled annular ring **76** designed to be engaged partially into the interior of the tubular element **70**. A plurality, e.g., four peripheral leg members **78** surround and are spaced from the exterior of the barbs to maintain alignment and prevent excessive tipping. A plurality of small passages **80** cause a small amount of fluid to be ejected under relatively high pressure and flow over the barbs **72**. Additional fluid flows between the beveled surface **76** and the tubular element **70**. A wire bail **82** is dimensioned to pass under the last of the barbs **72**. The distance between the wire bail and beveled surface **76** is selected to be just slightly longer than the corresponding distance on the

fitting such that an annular gap forms between the beveled surface **76** and the port and between the bail and the barbs, although both will make contact from time to time. The housing body further includes a barbed element **84** for interconnection with tubing of the appropriate length for interconnection with the fluid ports. Again, the tubing just reaches the appropriate fluid port **28** to provide an indication that it has been properly connected to the scope. A collar element **86** provides a stop for the tubing and provides a detent over which the tether **52** is fit.

With a reference to FIGURE 5, some endoscope port structures include a tubular segment or internal bore **90** which has a small inward projecting lip or detent **92**. A housing body includes an annular groove in which a C-ring **94** is loosely retained. The C-ring is sufficiently spaced from the body that it can be compressed as it snaps past the lip **92**. Preferably, the C-ring spans about 300º of arc. The C-ring and a shoulder portion **96** of the body are spaced further than the thickness of the lip such that there is in and out play between the tube or bore **90** and the fitting. The fitting further includes a barbed tubular element **98** for interconnection with a length of tubing. A shoulder **100** provides a stop for the tubing and a detent over which the tether **52** is received.

In an alternative embodiment, the C-shaped ring **94** is replaced with an annular ridge, which is integral with the adapter body.

With reference to FIGURE 6, some endoscopes have raised port structures **110** supporting both a tubular structure **112** and a post **114**. The fitting **74** includes a fitting body having a lower surface **116** and inwardly projecting detents or arc segments **118** for snapping or twisting under a lip on the structure **110**. The spacing between the bottom surface **116** and the detents **118** is again slightly larger than the thickness of the lip of the raised portion **110** to provide a thin fluid flow path therebetween. The body further defines a bore **120** which

is dimensioned just larger than the tubular pipe **112** such that most of the fluid flow flows down its bore. A small amount flows around the periphery. A second bore **122** is again slightly larger in diameter than the post **114** to form a narrow angular cap therebetween. A portion of the fluid flowing between the bottom surface of housing and the mounting element **110** flows through the bore. Again, the dimensions are sufficiently loose that the fitting is movable short distances longitudinally and along canting directions. The fitting again includes a barb **124** for interconnection with associated tubing and a post **126** for interconnection with the tether **52**.

With reference to FIGURE 6A, a modification to the fitting **74** of FIGURE 6 is shown. The fitting **74** of FIGURE 6A includes a fitting body having a lower surface **116** and inwardly projecting detents or arc segments **118** for snapping or twisting under a lip on the structure **110**. The spacing between the bottom surface **116** and the detents **118** is again slightly larger than the thickness of the lip of the raised portion **110** to provide a thin fluid flow path therebetween. The body further defines a bore **120** which is dimensioned to receive the tubular pipe **112**. A second bore **122** is again slightly larger in diameter than the post **114** to form a narrow angular cap therebetween. A portion of the fluid flowing between the bottom surface of housing and the mounting element **110** flows through the bore. Again, the dimensions are sufficiently loose that the fitting is movable short distances longitudinally and along canting directions. The fitting again includes a barb **124** for interconnection with associated tubing and a post **126** for interconnection with the tether **52**. The barb, in this embodiment, takes the form of a moveable plunger. A widened proximal end **127** of the barb **124** is received within the bore **120** and biased toward a narrowed portion **128** of the bore by a compression spring **129**, or other biasing member. The leak rate is controlled by the force of the spring on the plunger. Under the force of the fluid

flowing through the barb, the plunger is pushed slightly outward, away from the narrow portion of the bore, allowing the fluid to leak between the outside of the tube **112** and the narrow portion of the bore.

With reference to FIGURE 7, some ports are defined by tubular elements **130** having an annular collar **132**. When it is appropriate to plug these ports, one type of plug **58** includes a housing body that tapers into an extension **134** slightly smaller in diameter than the interior bore of the tubular element **130**. A wire bail **136** is pivotally connected to the body to snap under the collar **132**. Again, the dimensions are such that during normal vibration, fluid flows between the plug and the tube and fluid flows between wire bail **136** and the collar **132**. An enlarged portion **138** is again provided for receiving the tether **52**.

Reference to FIGURE 8, for easier connection and disassembly, a plug **58** includes a plug element **140** which is slightly smaller in diameter than the bore of the port to be plugged. The plug element is connected by wire member **142** with a body portion **144**. A pair of wire handles **146** are pivotally connected through the body portion with a pair of wires to form gripping elements which engage a groove in or under the underside of a lip surrounding the port. In this manner, by squeezing and releasing the handles **146**, the plug can be inserted into the port and wire spring elements **148** can hold it loosely in place. A button **150** provides a convenient interconnection with the tether **52**.

With reference to FIGURE 9, some ports are surrounded by a tubular element having a pair of outward detents for a bayonet type interconnection. A plug housing body includes a tapered annular surface **160** analogous to surface **76** of FIGURE 4. The body further includes a rotatable portion **162** having an inward directed flange **164** with a pair of cutouts **166** for receiving the projecting detents on the port. After the detents are

received through the cutout portion **166**, the operator engages a handle portion **168** and rotates rotatable portion **162** by a quarter turn to lock it in place over the fitting. Again, the dimensions are such that the plug **58** wobbles sufficiently to provide flow over all surfaces. In some endoscopes, a projecting tubular element is disposed adjacent the other port. To this end, the housing body further includes a section **170** having a bore **172** of just slightly larger diameter than the tube to be received. Where appropriate, an internal bore extends between the bore **172** and the interior of the conical surface **160** to provide a controlled fluid flow path between the two ports. A button **174** provides a convenient connection point for the tether.

With reference to FIGURE 9A, in a modified embodiment of FIGURE 9, the plug housing body includes a pair of spring loaded plungers **175, 175A** received in bores **176, 176A.** The plungers define the tapered annular surface **160** and bore **172**, respectively, which receive the endoscope ports. As for FIGURE 9, a rotatable portion **162** having an inward directed flange with a pair of cutouts receives the projecting detents on the port and is rotated to lock the plug assembly to the port. The plungers are biased towards open ends of the bores **175** and **175A** by biasing members, such as springs **177, 177A.** The plungers have limited vertical motion, defined by widened portions **178, 178A** of the bores and corresponding widened potions of the plungers **179, 179A.** Under the pressure of the fluid entering the tapered annular surface **160** and bore **172**, the plungers move upwards slightly, away from the endoscope ports, and allow the fluid to leak around the sides of the endoscope port. The rate of leakage can be adjusted by changing the tension force supplied by the spring. In one embodiment, the two springs provide different forces so that fluid leaks preferentially from one of the ports.

With reference to FIGURE 10, a plug **58** includes a housing body **180** having two projecting feet **182** to hold the plug away from an associated surface of the endoscope. The plug body has an interior bore **184** that is internally threaded with non-sealing threads **186**. NPT threads are designed for a fluid tight seal, but other standard threads, e.g., acme threads, are not. The threads may also be redimensioned such that they leave gaps as they loosely engage the threads of the scope port. Wobble between the threads provides changing fluid flow paths through the threaded connection. Optionally, sections of the threads may be removed to create an enlargement **186** in one more locations down the side of the internal bore to provide for less restrictive fluid flow. The contact points **182** prevent the threads from being screwed down so tight that fluid is not permitted to flow between the bottom of the housing and the endoscope, and preventing closing of the gaps between the threads of the fitting and the threads of the endoscope. A button **188** provides a convenient mounting point for the tether **52**.

With reference to FIGURE 11, on some endoscopes there are pairs of ports to be plugged. In the embodiment of FIGURE 11, the housing body of the plug **58** includes a lower tab **190** which slides under outward extending lips on a pair of tubes on an associated structure. The body defines a pair of cylinders **192, 194** in which plungers **196, 198** are mounted. The plunger **196** is smaller in diameter than the tube to be plugged with a surrounding flange **200** of a diameter a little smaller than the internal diameter of the bore in which it is received. A spring (not shown) within the housing **192** biases the plug into the opening. A handle portion **202** enables the plug to be pulled up against the biasing portion of the spring. When pulled up and rotated, a detent **204** moves out of the corresponding slot to hold the plunger retracted. The plunger **198** has a beveled lower edge **206** which is biased against the surrounding edge of the scope port by a spring

(not shown) in the housing **194.** A handle **208** again enables the plunger **198** to be retracted and, when turned, held retracted. In this manner, the operator retracts both plungers and slides the tab **190** underneath surrounding lips. The two plungers are then released under the spring bias. The plunger handles **202** and **208** are dimensioned such that, upon release, they stop on the housing cylinders **192** and **194** before the plungers **196** and **198** contact the device, leaving a gap which allows fluid to flow around the port.

With reference to FIGURES 12-14, a plug **58** suited to use with an endoscope port having a flange **200** at its open end is shown. The plug includes a housing body **202** having an upper arm **204** and a shorter, U-shaped lower arm **206.** The flange **200** of the endoscope port is seated on legs **208, 210** of the U-shaped lower arm with a narrow portion **212** of the endoscope port positioned between the two legs. The upper arm defines a longitudinal slot **214** which receives a shaft **216** therethrough. A lower end of the shaft defines a plug element **218** which plugs the opening of the endoscope port. The plug element is biased toward the port by a spring **220** or other biasing element received in an annular groove **222** of the plug element (FIGURE 14). The spring is held under tension by a disk-shaped member **224** which is carried on the shaft between the plug element and the upper arm. To fit the plug on the endoscope, the shaft is pushed along the slot in the direction of arrow **D** until the shaft reaches the end of the slot **214.** The plug element is then seated on the endoscope port. The housing body **202** is then pushed toward the port until the flange **200** engages the U-shaped arms. Pressure may be applied to the upper arm during this operation for ease of attachment. The spring forces the plug into engagement with the opening. Under the pressure of fluid within the port, the plug element is biased away from the port, leaving a small annular gap through which the fluid leaks from the port.

A button **230** provides a convenient mounting point for the tether **52.**

With reference to FIGURE 15, a fitting has a housing body **240,** similar to housing body **180** of FIGURE 10, and has two projecting feet **242.** An interior bore **244** is internally threaded with non-sealing threads that leave gaps as they loosely engage the threads of the endoscope port. Wobble between the threads provides changing fluid flow paths through the threaded connection. A barb **246** for attachment to a tube **71** is connected with the housing by a thumb wheel **248,** which is free to spin relative to the housing. This allows the tube to remain untwisted while the fitting is being connected with an endoscope port. A button **250** provides a convenient mounting point for the tether **52.**

The above discussed fittings and plugs are exemplary only. Numerous additional leaky connections are contemplated. New and improved endoscopes are introduced regularly. The new and improved endoscopes in many instances will have different port configurations which require modifications to the foregoing exemplary fittings and plugs.

The clearance between the plug and the surrounding structure on the endoscope also varies with the degree of stoppage or leakage that is appropriate to the application. In some situations, it is desirable to allow the plug to pass a sufficient amount of fluid that the pressure downstream in the lumen is reduced to a preselected fraction of the upstream pressure. When such a pressure reduction is desired, the clearances between the plug and the endoscope are increased. Optionally, the plug may have a controlled leakage or feedback port or passage.

With reference to FIGURES 16 and 17, another embodiment of a microbial decontamination apparatus is configured to sit on a counter top or other convenient work surface. In this embodiment, an endoscope to be

microbially decontaminated is fully immersed in a sterilant/disinfectant solution, rather than being sprayed with the solution. A door or lid (not shown) is manually openable to provide access to a tray **312** which defines a receiving region **314** for receiving items to be microbially decontaminated. In the illustrated embodiment, the tray **312** is configured to receive an endoscope or other long, coilable item. Other trays with item receiving regions of different configurations for receiving the items themselves or item holding containers are also contemplated. A well **316** receives a cup **C** containing a unit dose of reagents for forming a sterilant, disinfectant, or other microbial decontaminating solution.

A tethered set **50** of connectors and plugs adapted to the particular endoscope to be decontaminated is interconnected with various ports **51** of the endoscope and with a liquid supply port or ports **28** within the tray or adjacent thereto in a similar manner to that described for the spray decontamination system.

With particular reference to FIGURE 17, a reagent containing package **C** is inserted into the well **316**. Once the items are loaded into the tray and the reagent carrying package **C** is inserted into the well **316**, the lid is closed and latched. Optionally, a fill valve **320** passes water through a microbe removing filter **322** in flow paths of a fluid circulating system. The microbe removing filter **322** provides a source of sterile water by passing water and blocking the passage of all particles the size of microbes and larger. The incoming water which has been sterilized by the filter **322** passes through a spray or distribution nozzle **324** and fills the item receiving region **314** in the tray **312**. The water may also be passed through the leaking connectors to the internal endoscope passages. As additional water is received, it flows into the well **316** dissolving powdered, crystalline, or other non-liquid reagents in the cup **C**, forming an anti-microbial solution. Filling is continued

until all air is forced through an air system **326** and an entire interior volume is filled with the sterile water. After the fill valve **320** is closed, a pump **328** circulates the fluid through a heater **330**, the item receiving region **314** of the tray **312**, and the well **316**. The pump also supplies the fluid under pressure via appropriate, separately adjustable presure regulators or valves **331** to the port(s) **28** and hence to the internal passages of the endoscope via the tethered connectors **56**, while the plugs **58** inhibit entry of the circulating fluid in the tray to those ports with which they are connected. Because of the difference in fluid pressure between the interior passages of the endoscope and the tray, there is some fluid leakage out of the endoscope via the leaking plugs. The pump also forces the anti-microbial solution through the filter **322** to a check valve **332** sterilizing the filter. Further, the pump forces the anti-microbial solution through another microbe filter **334** in the air system **326** to a check valve **336**. After the anti-microbial solution has been brought up to temperature and circulated for a selected duration, a drain valve **338** is opened, allowing the solution to drain. Air is drawn through the microbe filter **334** such that sterile air replaces the fluid within the system. Thereafter, the drain valve is closed and the fill valve **320** opened again to fill the system with a sterile rinse fluid. It will be noted, that because the pump **328** circulated the anti-microbial solution over all surfaces of the flow paths including all surfaces leading from the sterile rinse source **322**, the rinse cannot bring microbial contaminants into the item receiving region **314**. Sterile rinse fluid is fed to the internal passages of the endoscope via the leaking connectors **56**.

A cup opener **340** is disposed at the bottom of the well for engaging a lower surface of the package **C** as it is inserted into the well.

Having thus described the preferred embodiments, the invention is now claimed to be:

1. A method of disinfection or sterilization of an article having interior lumens, the method comprising placing the article in a chamber, interconnecting a lumen port of the article which provides access to its lumen with an antimicrobial fluid outlet, contacting an exterior of the article with an antimicrobial fluid and flowing the antimicrobial fluid through the lumen, the method comprising the step of:

fluidly interconnecting the anti-microbial fluid outlet and the lumen port of the article with a connector having a fitting which is configured for loose interconnection with surfaces adjacent the lumen port such that a first fraction of the antimicrobial fluid flows through the lumen port into the lumen and a second fraction of the antimicrobial fluid flows between the lumen port and the fitting into the chamber, the interconnection being sufficiently loose that the fitting wobbles, changing momentary points of contact between the fitting and the surfaces adjacent the lumen port.

2. The method as set forth in claim 1, further characterized by:

the article having a plurality of lumens, and the connector being connected by a tether to at least one of (i) another connector and (ii) a plug, the method further comprising:

connecting each of the connectors between an antimicrobial outlet and a lumen port; and

connecting each of the plugs with lumen ports.

3. The method as set forth in claim 2, further characterized by:

the article to be microbially decontaminated being an endoscope.

4. The method as set forth in claim 3, further characterized by:

attaching a tag to one of the tether, connector, and plug, which identifies at least one of (i) a model of endoscope or (ii) a family of endoscope models with which the tethered connection assembly is to be utilized.

5. The method as set forth in claim 4, further characterized by:

the tag including:

a diagram illustrating proper interconnection of the tethered connectors and plugs with the fluid outlets and the lumen ports.

6. The method as set forth in any one of preceding claims 2-5, further characterized by:

each of the connectors and plugs including an indicia of interconnection order and being attached to the tether in accordance with the interconnection order, the method further including:

attaching the connectors and plugs to their corresponding lumen ports in the order indicated.

7. The method as set forth in any one of preceding claims 2-6, further characterized by:

the plugs and connectors being interconnected with the tether in an appropriate order and spacing along the tether such that the tether allows each of the plugs and connectors to just reach a corresponding lumen port on the article while not reaching sufficiently far for at least some of the connectors and plugs to reach non-corresponding lumens on the article.

8. A fluid disinfection or sterilization system comprising a chamber for receiving a lumened article to be microbially decontaminated, a plurality of fluid outlets in the chamber for supplying antimicrobial fluid to contact exterior surfaces of the lumened article and at least one

fluid outlet port through which the antimicrobial fluid is suppliable to an interior lumen of the lumened article, the system comprising:

a connector for fluidly connecting said fluid outlet port with a lumen port of the article for supplying the antimicrobial fluid to the interior lumen, the connector including:

a tube;

a first fitting connected to one end of the tube for interconnection with said fluid outlet port; and

a second fitting connected with the tube and configured for loose interconnection with the lumen port in such a manner that an annular gap forms between the fitting and the port and the fitting wobbles, changing momentary points of contact with surfaces adjacent the lumen port so that (i) a first fraction of the antimicrobial fluid flows through the lumen port into the lumen and (ii) a second fraction of the antimicrobial fluid flows between the lumen port and the second fitting into the chamber.

9. The system as set forth in claim 8, further characterized by:

said fluid outlet port including a closure valve which has an open state and a leaky closed state that substantially but not completely closes said fluid outlet port when not interconnected with a fitting.

10. The system as set forth in any one of claims 8-9, further characterized by:

a plug configured for loose interconnection with a second lumen port in such a manner that a fraction of antimicrobial fluid flowing through the lumen flows out of the second lumen port, between the plug and the port.

11. The system as set forth in claim 10, further characterized by:

a tether which interconnects the connector and at

least the plug, whereby the connector and the plug remain tethered together as a tethered assembly.

12. The system as set forth in any one of claims 8-10, further characterized by:

at least a second connector; and

a tether which interconnects the first connector and the at least one second connector, whereby the first and second connectors remain tethered together as a tethered assembly.

13. The system as set forth in any one of claims 11 and 12, further characterized by:

the chamber further including a port interconnected with a leak detector;

the article having a leak test port;

a tube assembly having a fitting at one end configured for interconnection only with a port of the leak detector and another fitting at an opposite end configured for interconnection with the leak test port of the article, the tether tethering the tube assembly and the connector together.

14. The system as set forth in any one of claims 8-13, further characterized by:

the article to be microbially decontaminated being an endoscope.

15. The system as set forth in claim 14, further characterized by the tethered connection assembly further including:

a tag which identifies at least one of (i) a model of endoscope or (ii) a family of endoscope models with which the assembly is to be utilized, the tag being connected to the tether.

16. The system as set forth in claim 15, further characterized by:

the tag further including:

a diagram illustrating proper interconnection of the tethered connectors and plugs with the lumen ports of the endoscope.

17. The system as set forth in any one of claims 12-16, further characterized by:

the tethered assembly including a plurality of connectors and a plurality of plugs, all tethered together by the tether.

18. The system as set forth in claim 17, further characterized by:

each of the connectors and plugs including an indicia of interconnection order and being attached to the tether in accordance with the interconnection order.

19. The system as set forth in claim 17, further characterized by:

the article including a plurality of lumen ports;

each of the plugs and connectors being configured for being interconnected with a corresponding one of the lumen ports;

the plugs and connectors being interconnected with the tether in an appropriate order and spacing along the tether such that the tether allows each of the plugs and connectors to just reach the corresponding lumen port on the article while not reaching sufficiently far for at least some of the connectors and plugs to reach non-corresponding lumen ports on the article.

20. The system as set forth in any one of preceding claims 8-19, further characterized by:

the plurality of fluid outlets including spray nozzles which are operated in at least two groups facilitating movement between the fittings and corresponding lumen ports.

21. The system as set forth in any one of preceding claims 8-19, further characterized by:

a receiving tray which receives the article, the plurality of fluid outlets supplying fluid to the tray.

22. A disinfection or sterilization system comprising:

a chamber for receiving a lumened article to be microbially decontaminated;

a plurality of fluid outlets in the chamber for directing an anti-microbial fluid over exterior surfaces of the article;

a plurality of fluid ports in the chamber through which the anti-microbial fluid is suppliable to interior lumens of the article;

a tethered connection assembly for interconnection with the lumens of the article and the fluid ports, the tethered assembly including:

a first tube assembly having fittings at its ends, one fitting configured for interconnection with one of the fluid ports and the other fitting configured for interconnection with a lumen of the article, the tube assembly fittings configured for interconnection with the lumens and the plugs are configured to be sufficiently loose in structures that define ports to the lumens that a thin fluid passing gap is defined therebetween,

at least one of (i) a second tube assembly with fittings and (ii) a plug configured for interconnection with a lumen of the article, and

a tether which interconnects the tube assemblies and plugs.

23. The disinfection or sterilization system as set forth in claim 22 wherein the fluid chamber outlet are spray nozzles which are operated in at least two groups facilitating movement between the fittings and plugs and the structure defining the lumen ports.

24. The fluid disinfection or sterilization system as set forth in claim 22 wherein the fluid ports include a closure valve which has an open state and a leaky closed state that substantially but not completely closes the fluid outlet port when not interconnected with a fitting.

25. A fluid disinfection or sterilization system comprising:

a chamber for receiving a lumened article to be microbially decontaminated;

a plurality of first fluid outlets in the chamber for directing anti-microbial fluid over exterior surfaces of the article;

at least one second fluid outlet for discharging anti-microbial fluid and configured for interconnection with a first fitting; and

a tube assembly for interconnecting the second fluid outlet with surfaces adjacent a port to a lumen in the article, the tube assembly including:

a tube;

the first fitting connected to one end of the tube; and

a second fitting connected with the tube and configured for loose interconnection with the surfaces adjacent the lumen port in such a manner that (i) some of the anti-microbial fluid flows into the lumen and (ii) a remainder of the anti-microbial fluid flows between the fitting and the surfaces adjacent the lumen port, the interconnection being sufficiently loose that the fitting wobbles changing momentary points of contact with the surfaces adjacent the lumen port.

26. The system as set forth in claim 25 wherein the second fluid outlet has two states:

an open state and a leaky closed state that permits a limited discharge of the anti-microbial fluid therethrough.

27. The system as set forth in claim 25 further including:

a plug configured for loose interconnection with surfaces adjacent another lumen port in such a manner that a fraction of anti-microbial fluid flowing through the lumen flows between the plug and the surfaces adjacent the another lumen port.

28. A fluid disinfection or sterilization system comprising:

a chamber for receiving a lumened article to be microbially decontaminated;

at least one fluid outlet in the chamber for directing an anti-microbial fluid over exterior surfaces of the article; at least one fluid port in the chamber through which the anti-microbial fluid is suppliable to interior lumens of the article;

a connection assembly for interconnection with the lumens of the article and the at least one fluid ports, the assembly including:

a first tube assembly having fittings at its ends, one fitting configured for interconnection with the at least one fluid port and the other fitting configured for interconnection with a lumen of the article, the fitting configured for interconnection with the lumen being configured to be sufficiently loosely connected with a structure defining a lumen port as to provide a thin gap therebetween such that a portion of the anti-microbial fluid flows between the fitting and the structure defining the lumen ports.

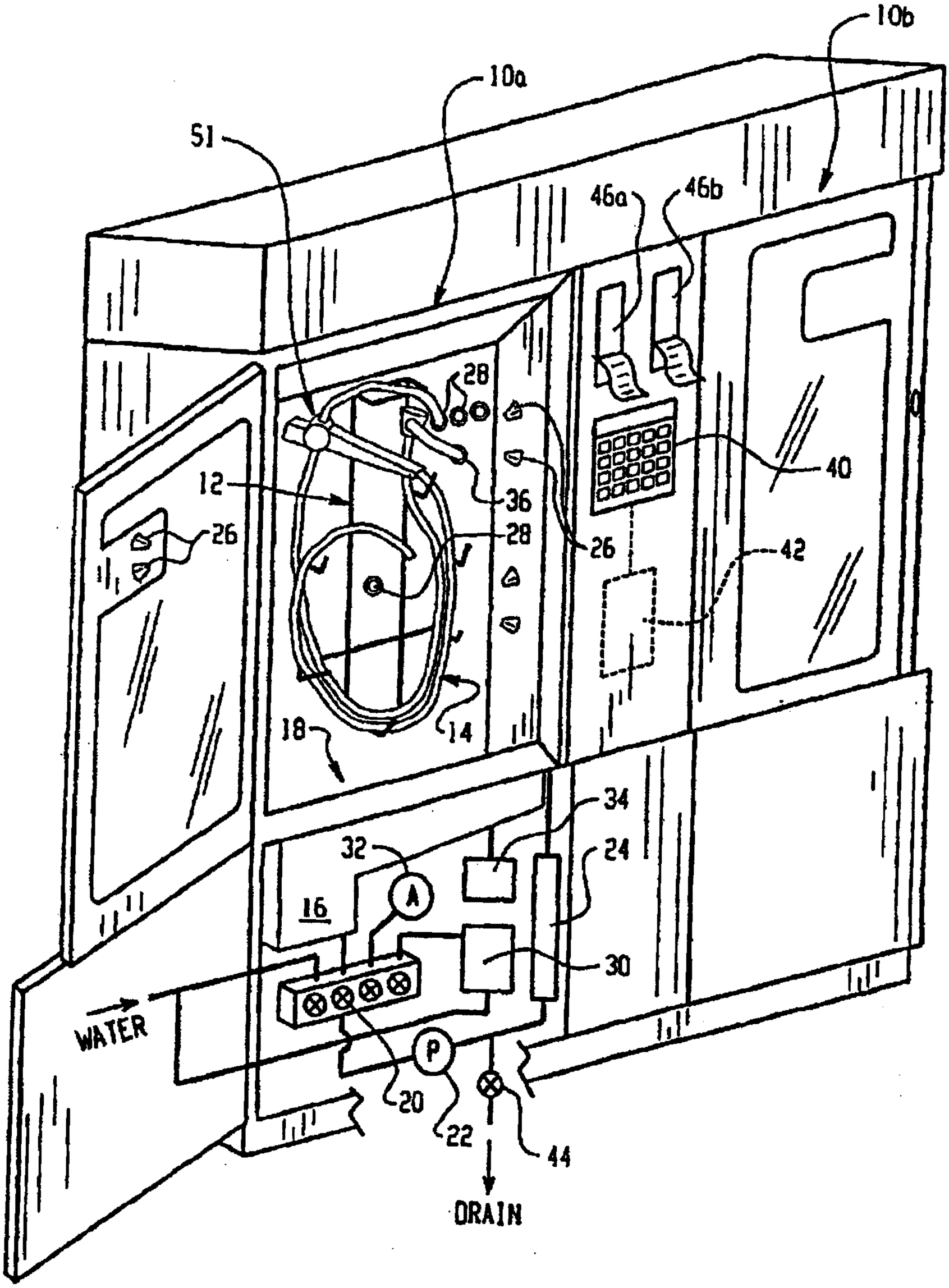
29. The fluid disinfection or sterilization system as set forth in claim 28, further including:

at least one of (i) a second tube assembly with fittings and (ii) a plug configured for interconnection with a second lumen of the article; and

a tether which interconnects the tube assemblies and

plugs.

30. The fluid disinfection or sterilization system as set forth in claim 29 wherein the article to be microbially decontaminated is an endoscope.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46b
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DRAIN

Fig. 1

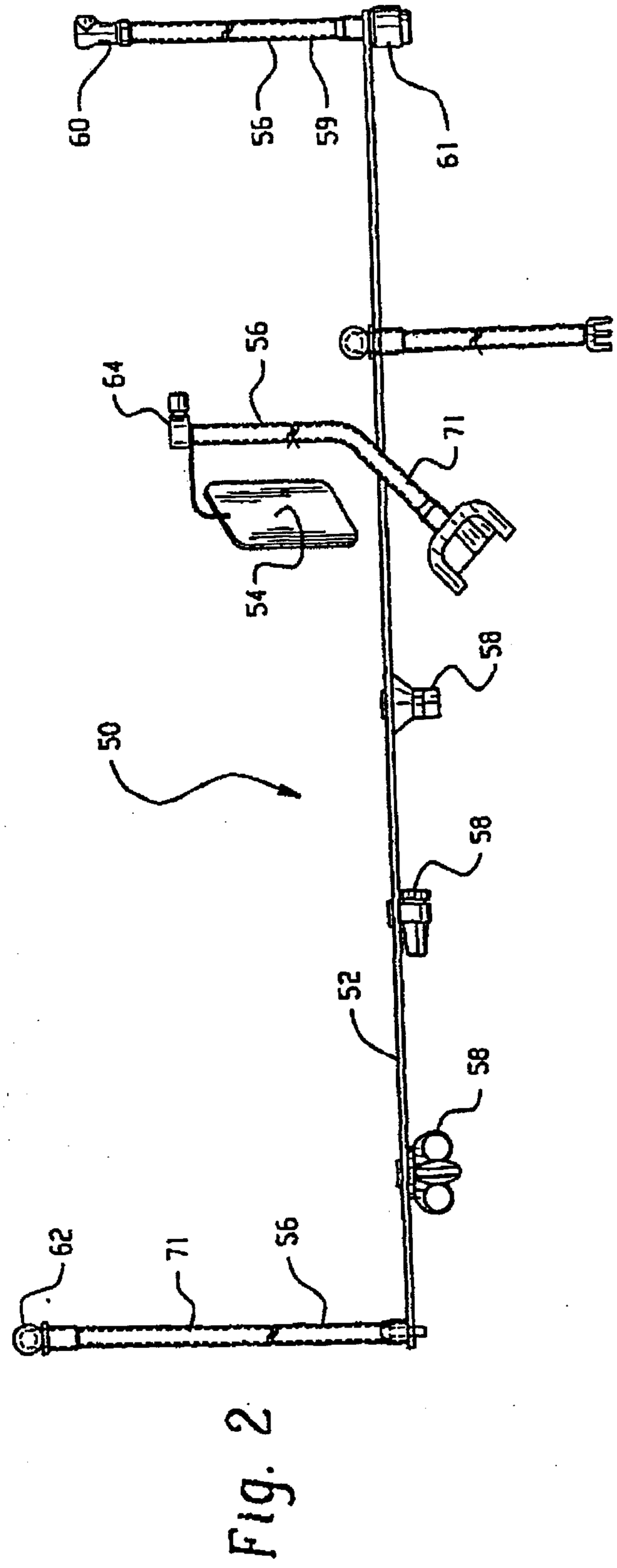
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Fig. 2

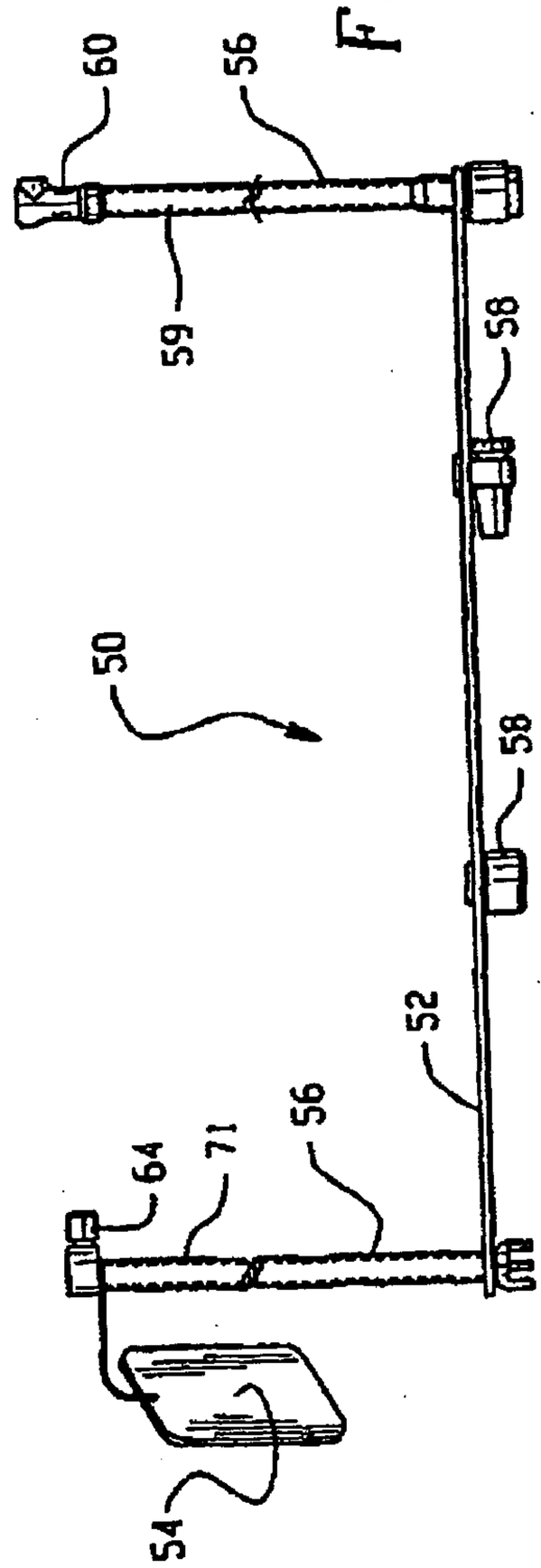
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Fig. 3

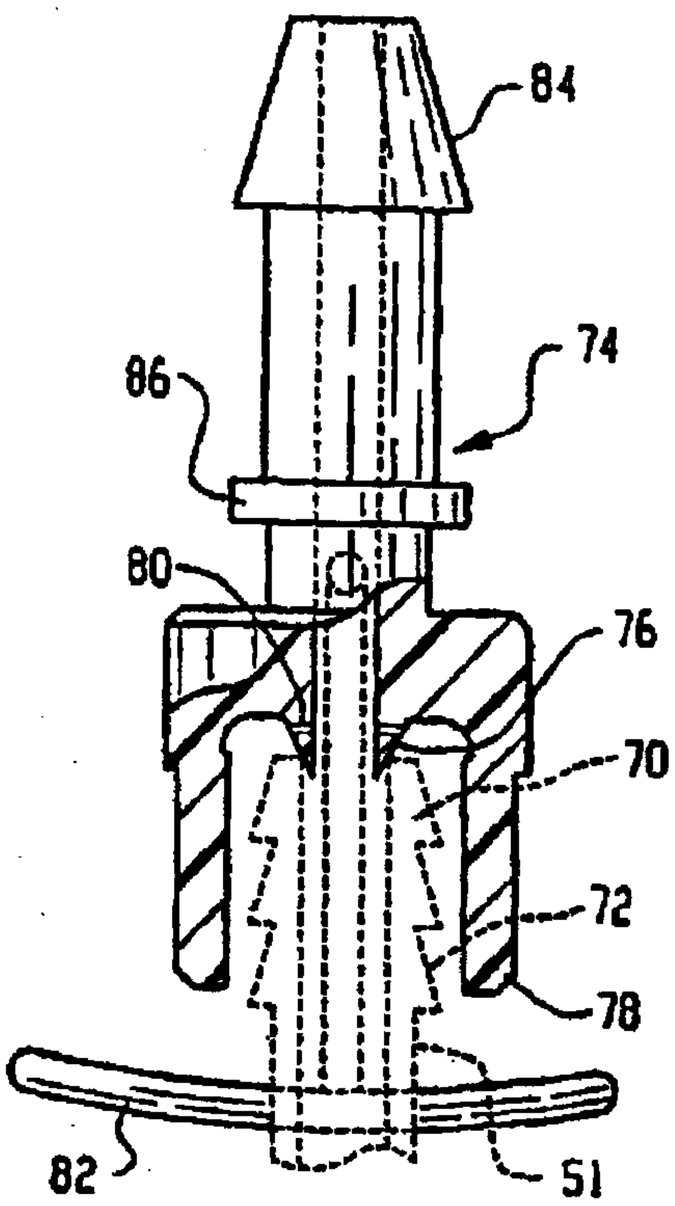

Fig. 4

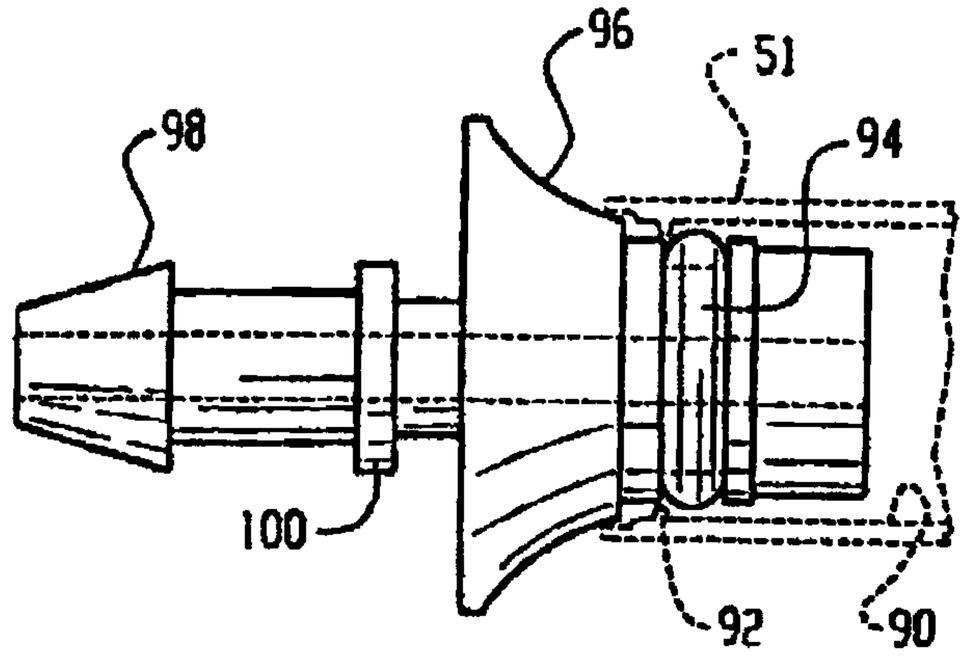

Fig. 5

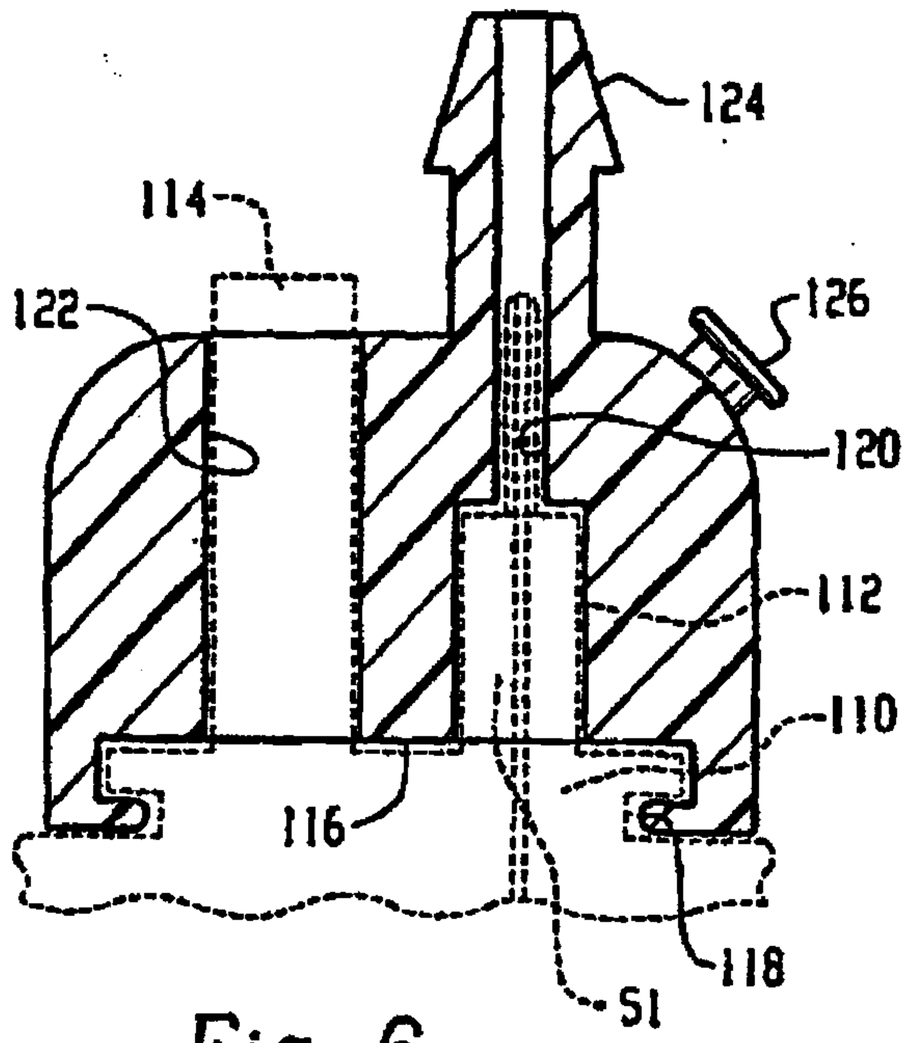

Fig. 6

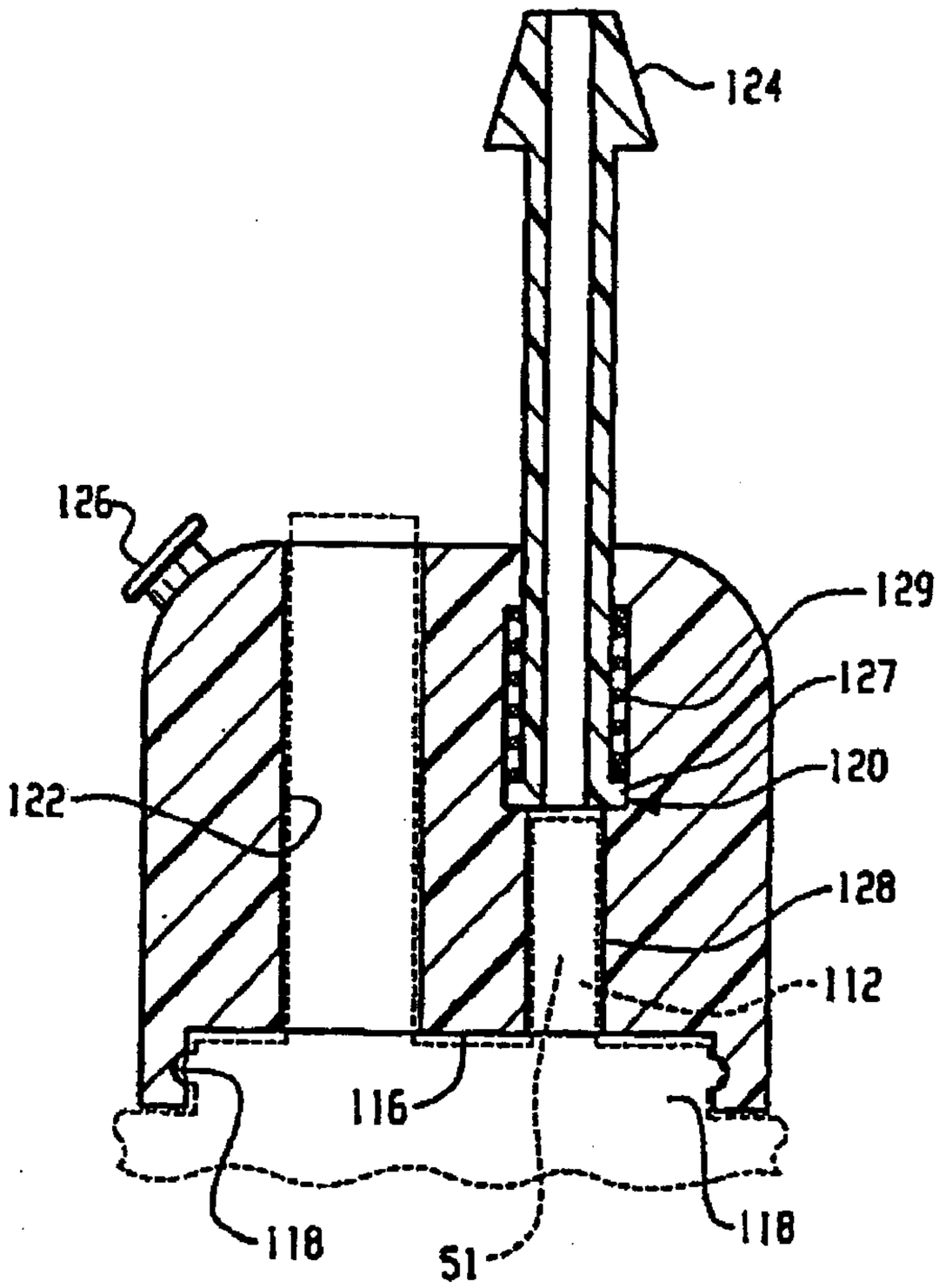
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Fig. 6A

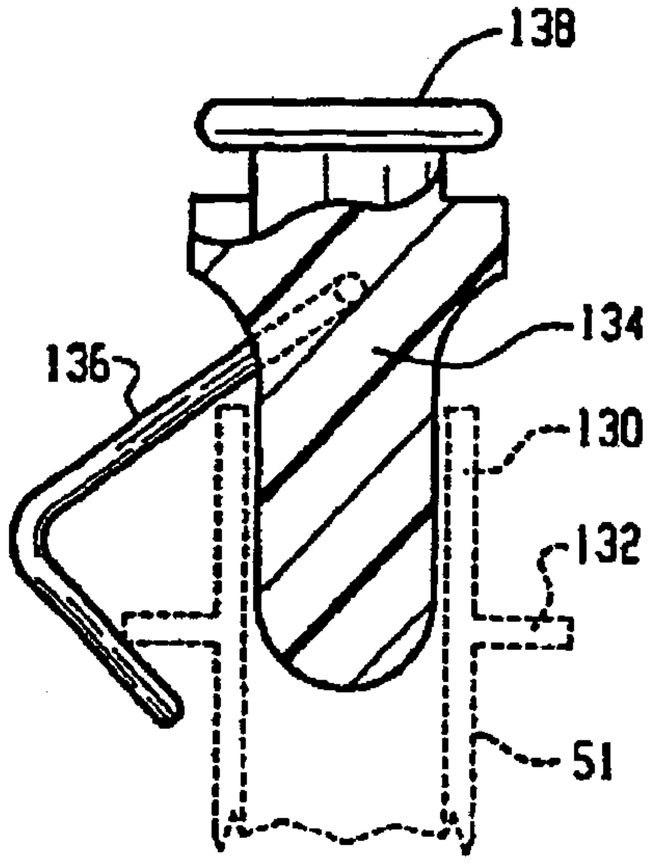
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Fig. 7

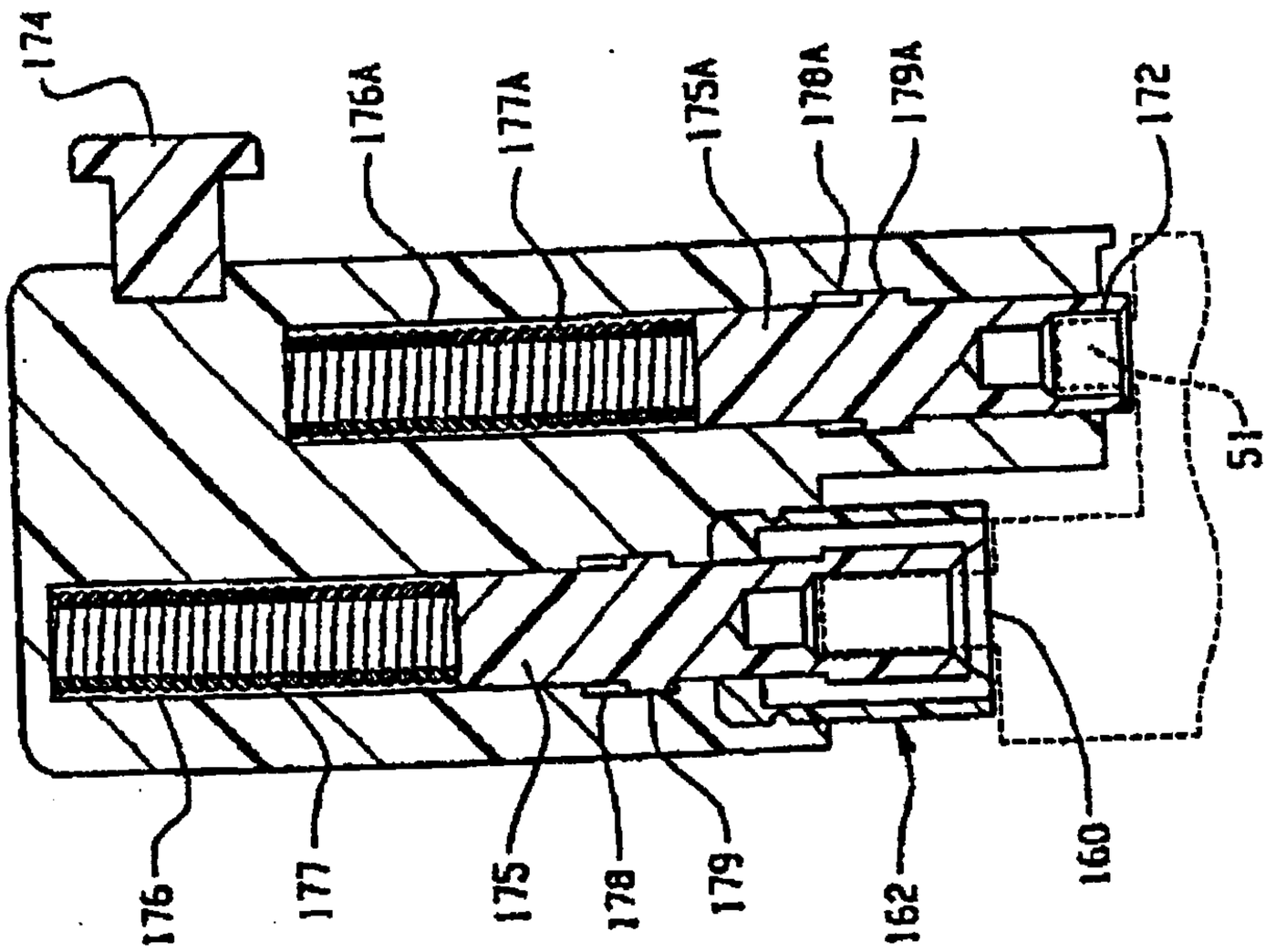


Fig. 9A

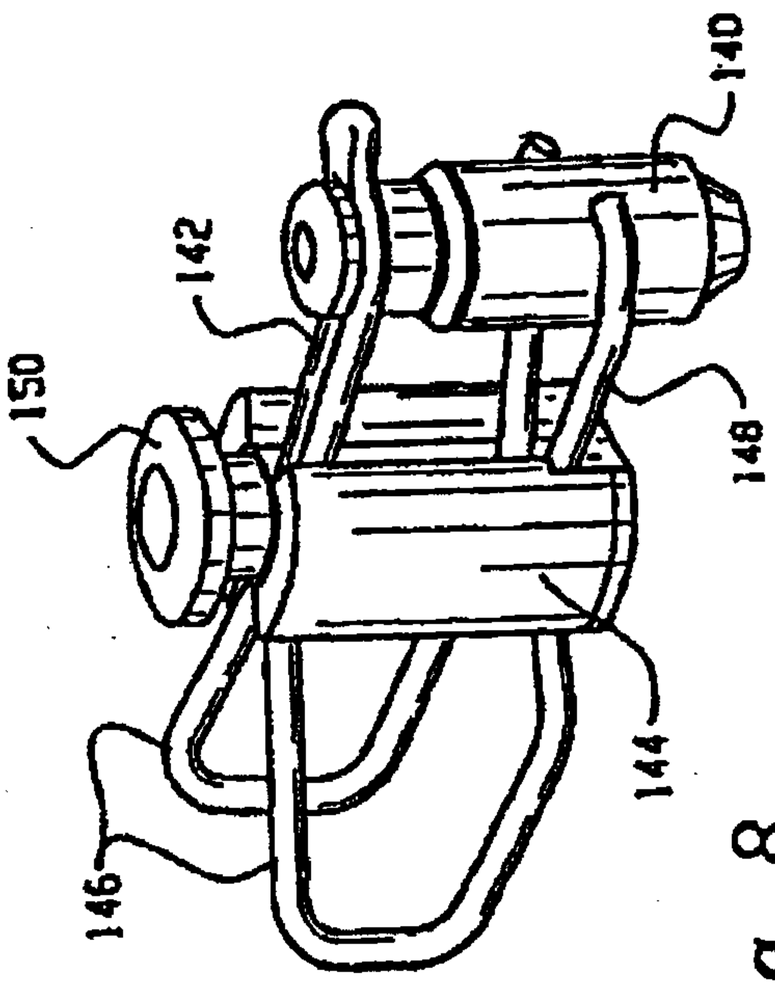


Fig. 8

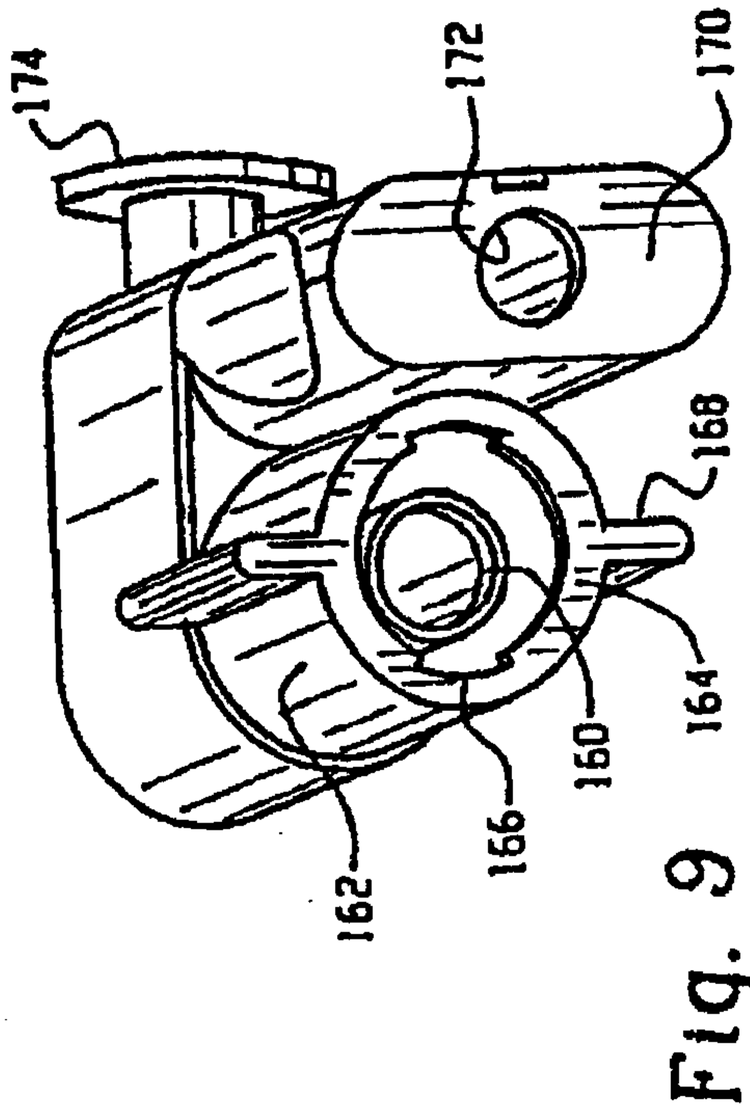


Fig. 9

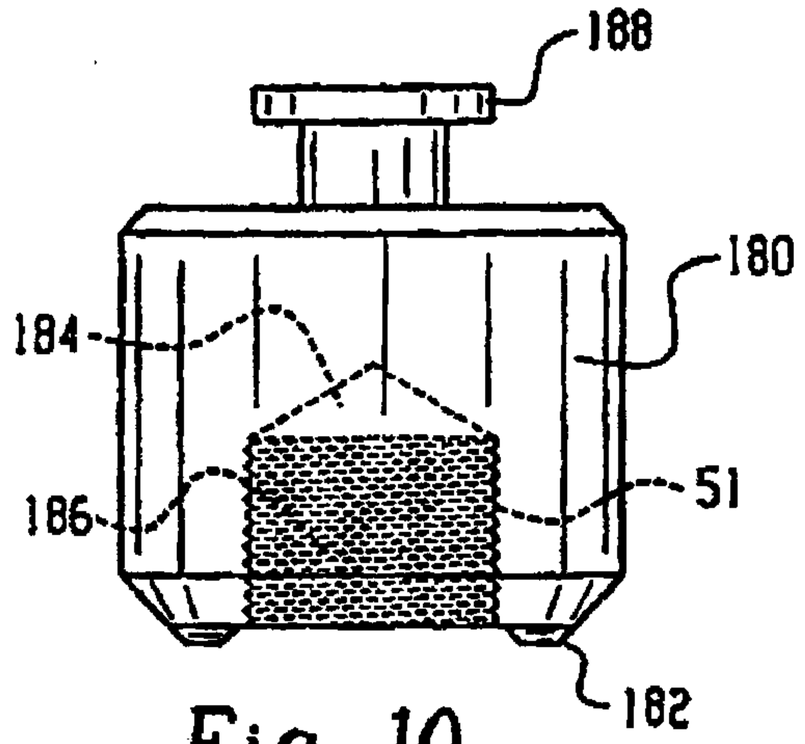


Fig. 10

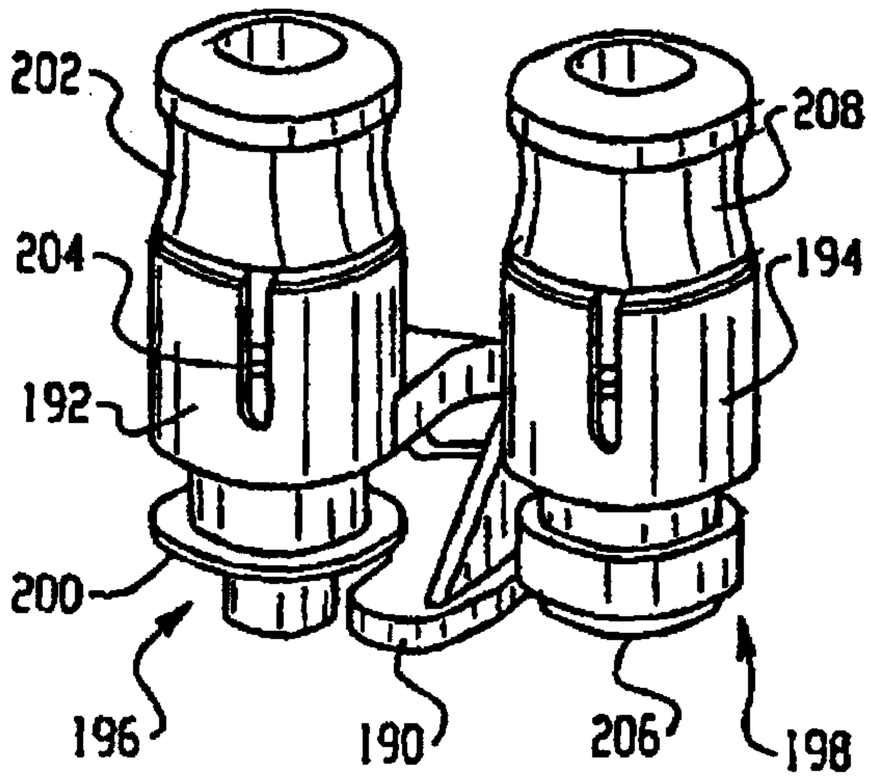


Fig. 11

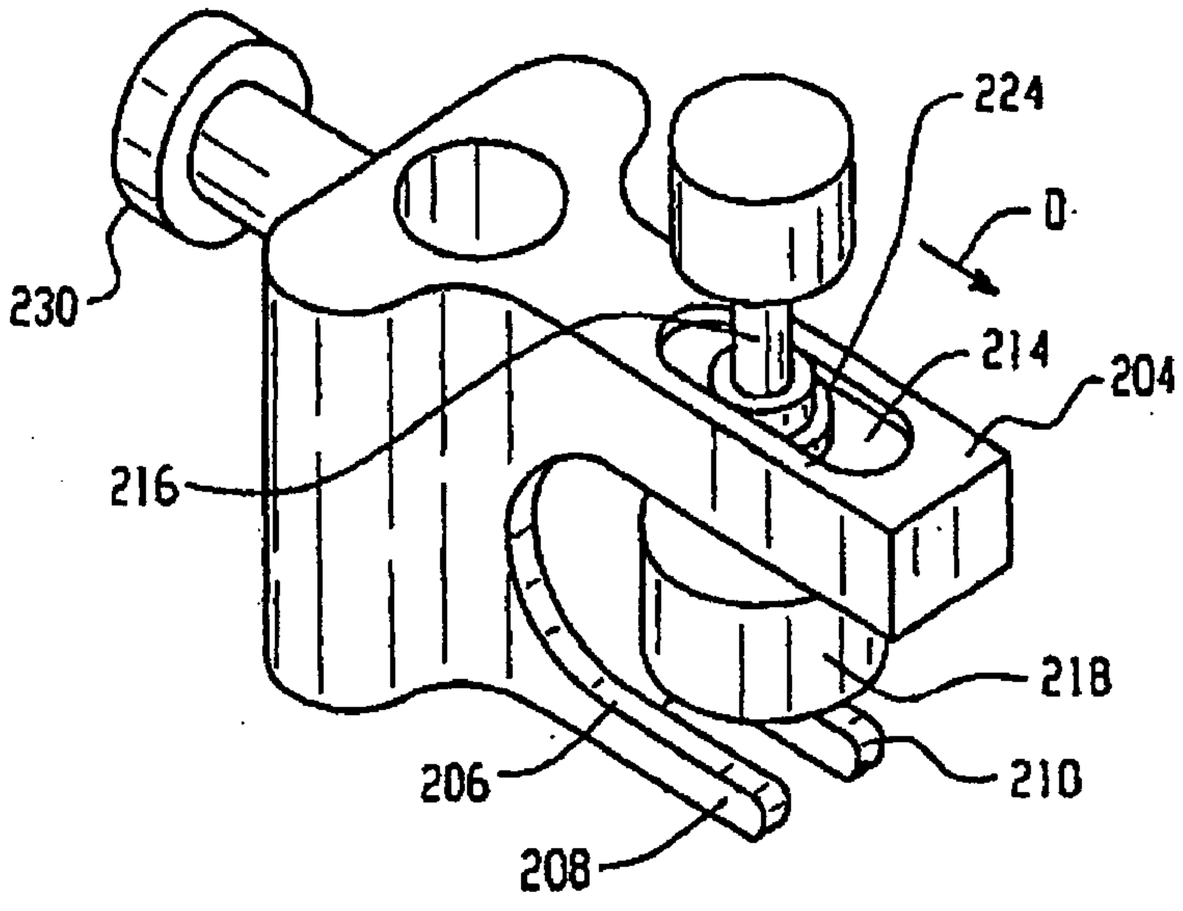


Fig. 12

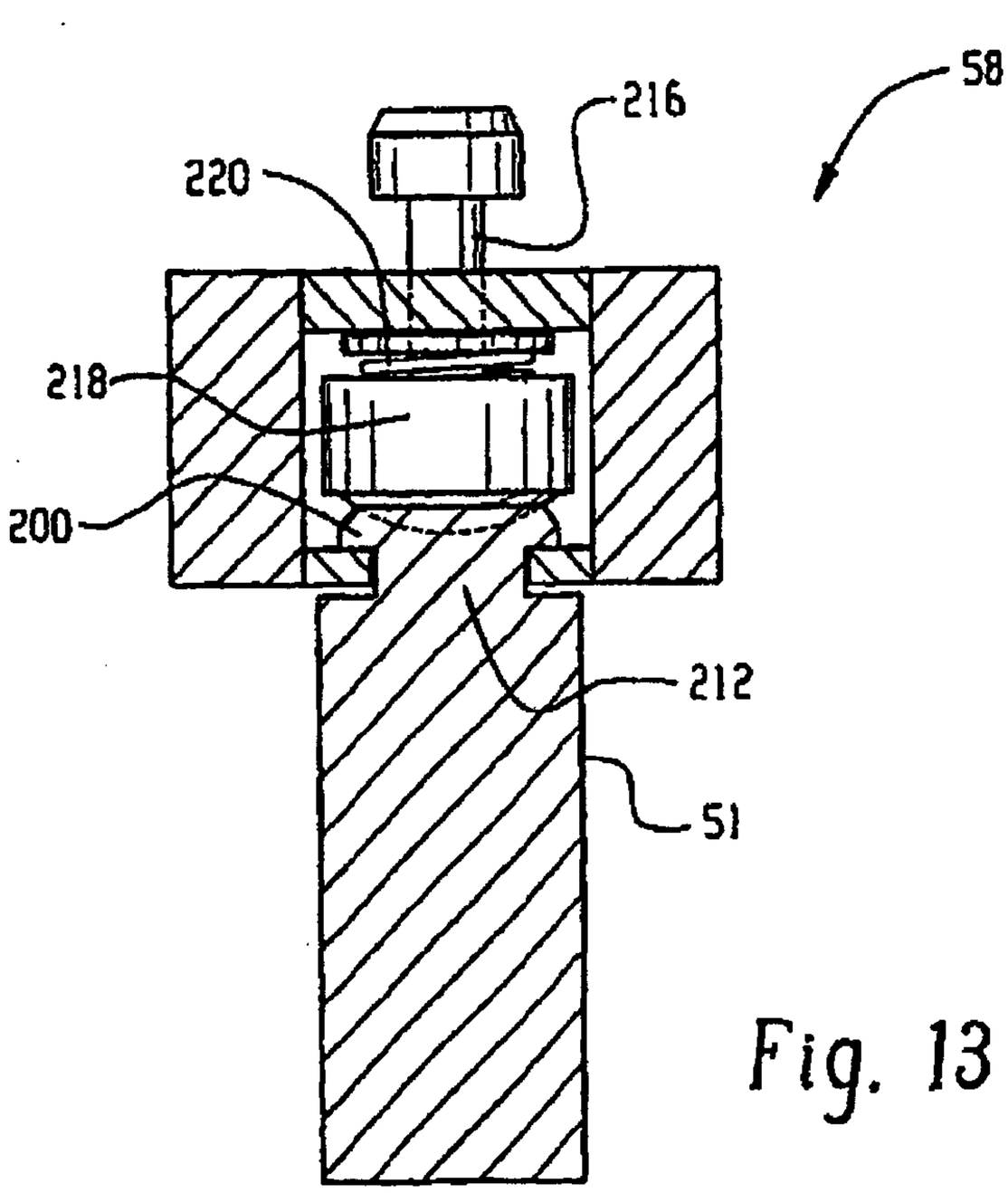


Fig. 13

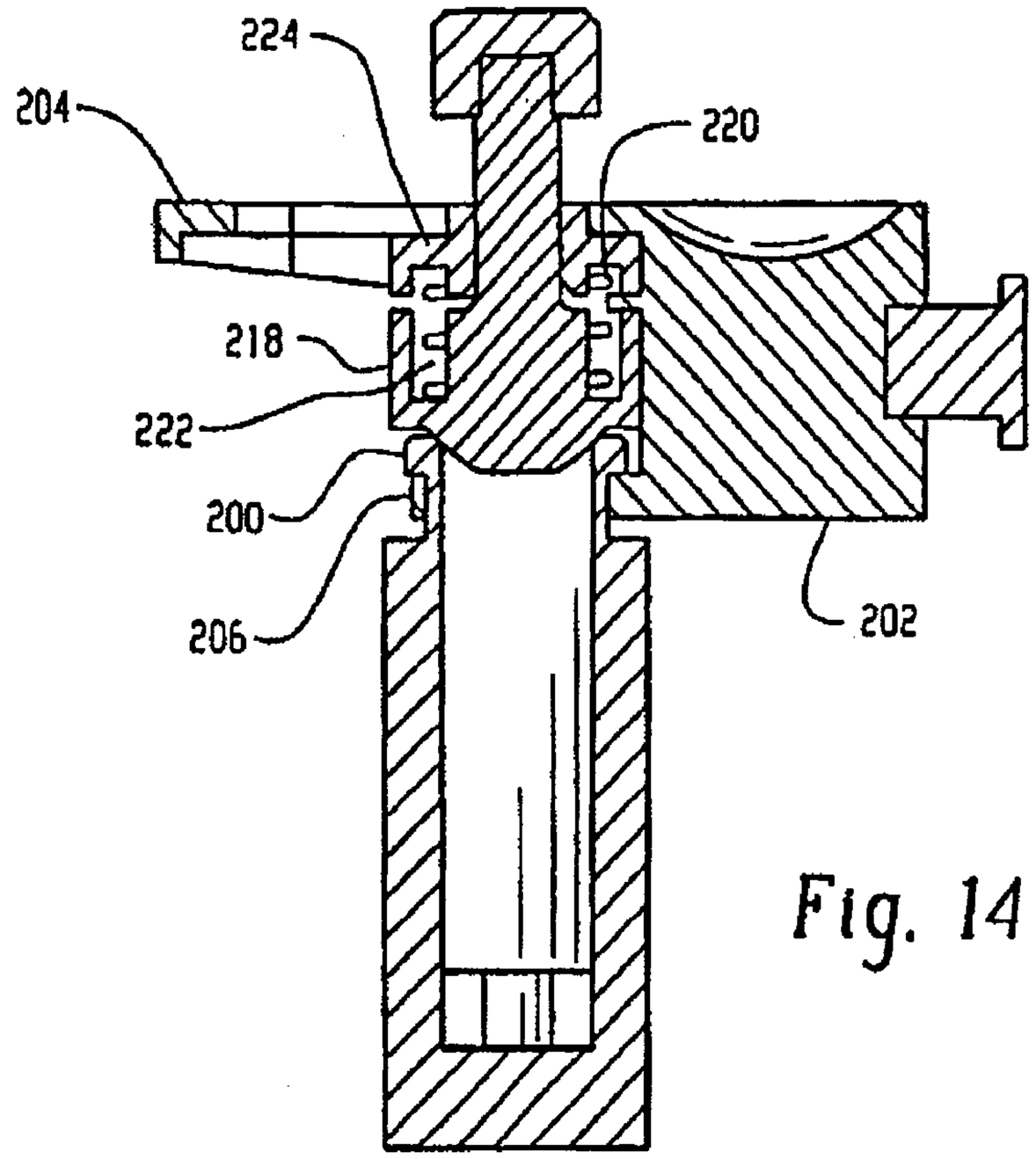
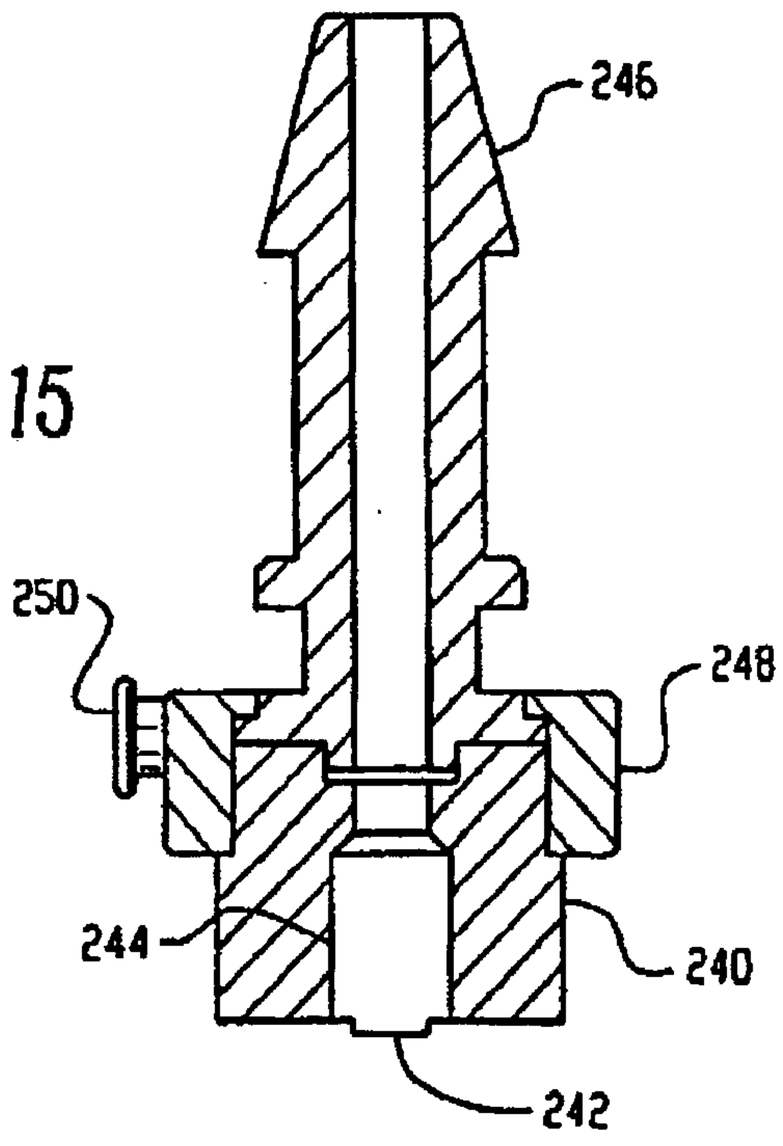


Fig. 14

Fig. 15



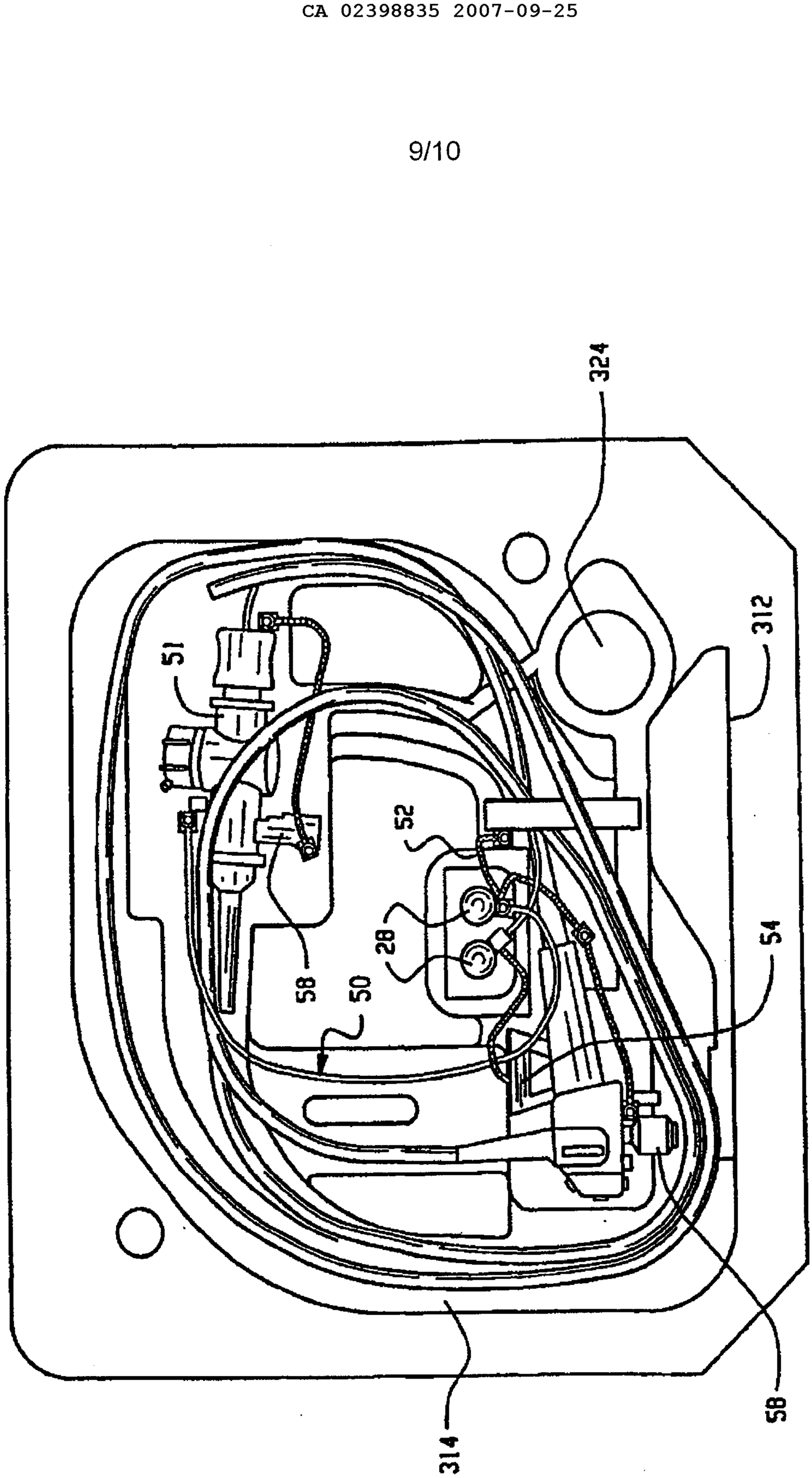
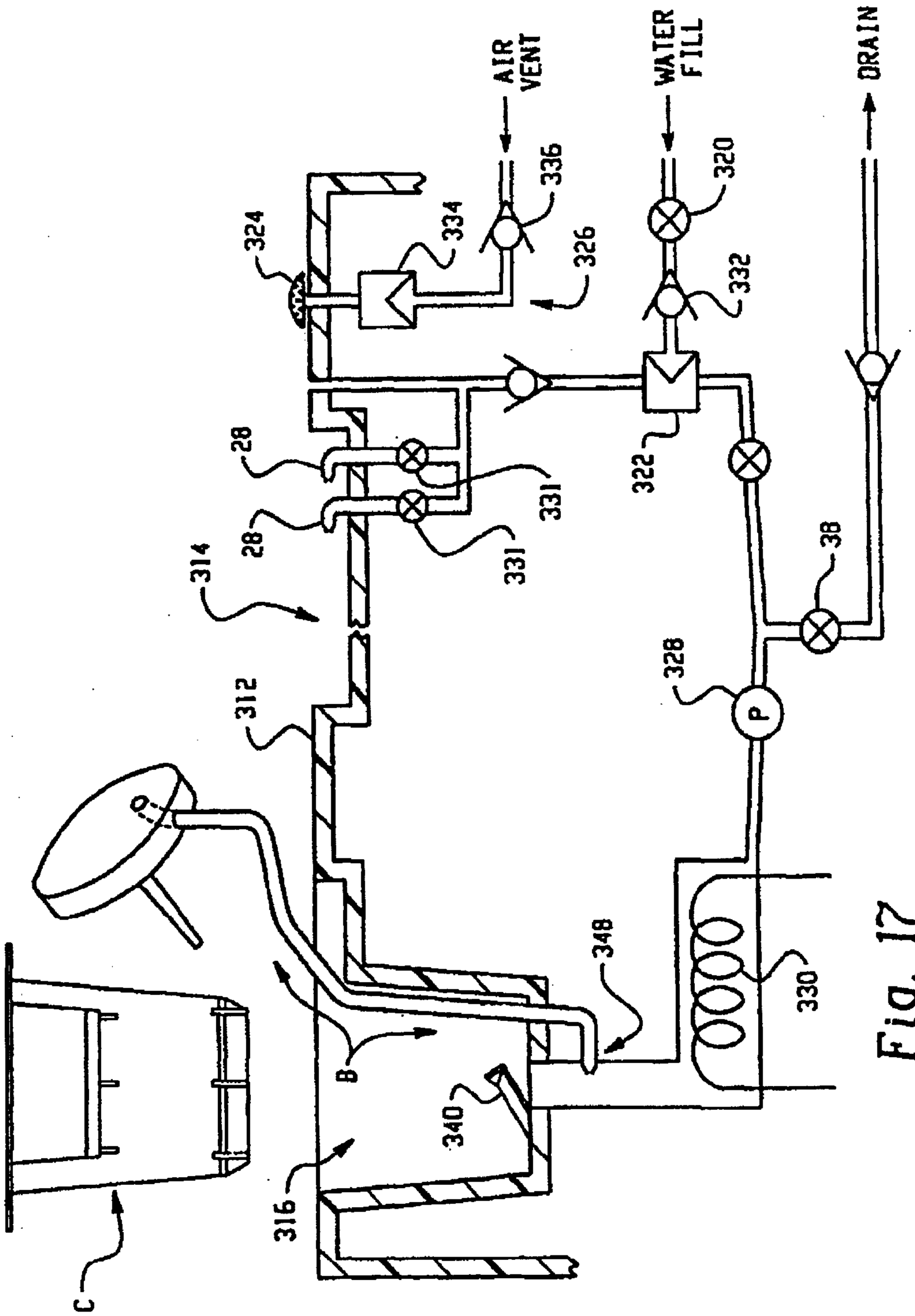


Fig. 16


AIR VENT
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P
348
330
B
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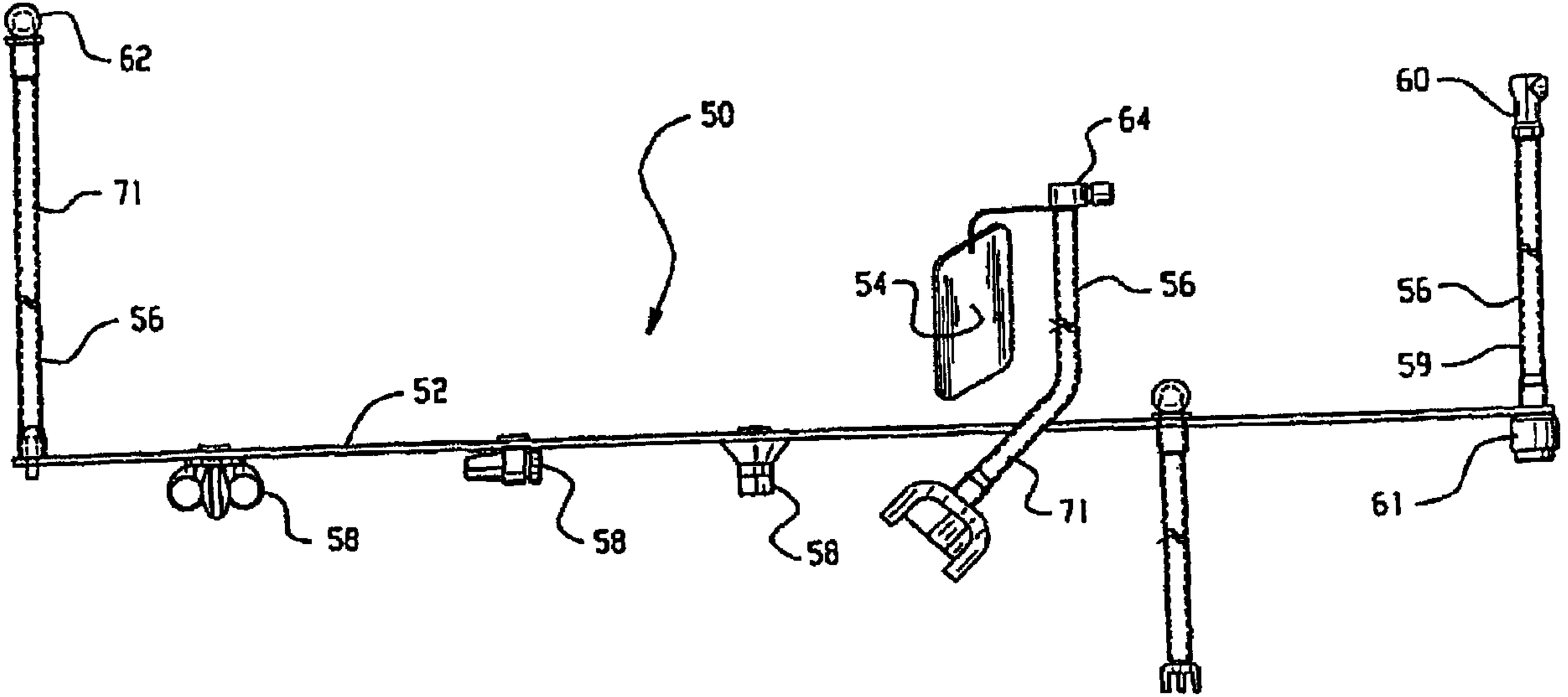
316
C

Fig. 17


62
71
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