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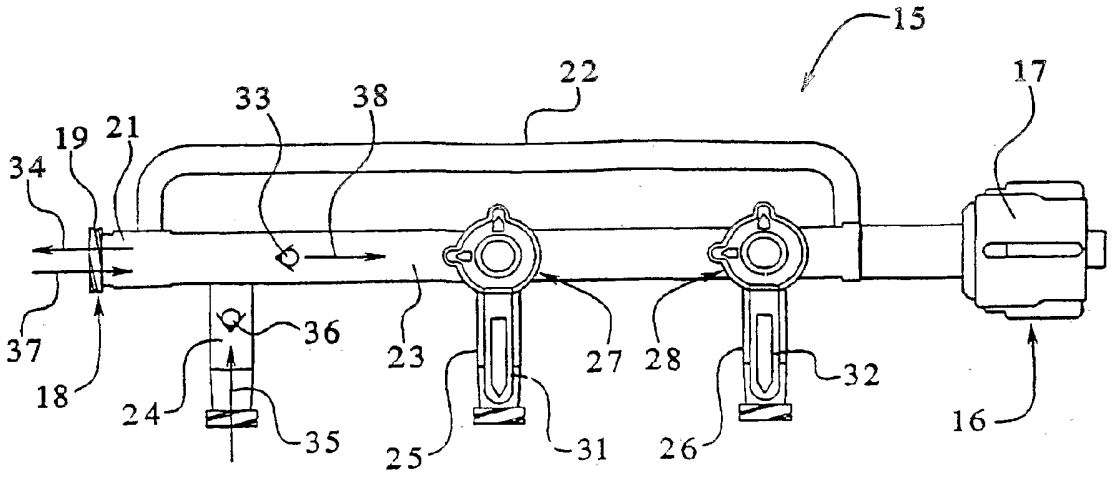
(54) Title: FLUID MANIFOLD CONTROL DEVICE



(57) Abstract: A manifold (15) is disclosed which includes a manifold body (22) that defines a main lumen (23), a primary injection line (21) and a port (24). A check valve system (33, 36) is also provided which permits flow from the primary injection line to the main lumen while selectively preventing back flow from the main lumen to the primary injection line and, simultaneously, permitting flow from the port to the primary injection line while preventing back flow from the primary injection line to the port.

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FLUID MANIFOLD CONTROL DEVICE

Field of the Invention

The present invention relates generally to devices used for injecting agents during intravascular medical procedures.

Background of the Invention

During angiography and angioplasty procedures, fluid manifolds also known as "fluids administration sets" are employed which are connected to a catheter and which enable the physician to administer saline, contrast solution and other agents and fluids to the patient.

Typical manifolds include a distal end that is connected to the catheter and a proximal end that is connected to an injection syringe or pump. The injection syringe or pump, is typically used to inject saline or a contrast agent solution into the catheter. The manifold typically includes a plurality of ports connected to the manifold through a stop cock connection. The ports are used to inject contrast solutions and other medicaments into the catheter and may also provide a connection to a pressure transducer or other analytical equipment. Further, the opening and closing of these ports typically requires the physician to rotate a stop cock handle or other manually operated valve.

Accordingly, there is a need for an improved manifold system for use with angiographic procedures which minimizes the need for manual operation of valves relating to the injection of saline and contrast fluid.

SUMMARY OF THE DISCLOSURE

A manifold control device is disclosed which can be used in catheterization and other procedures and which results in a simplified aspiration and injection of agents without the need for a manual valve operation by the physician.

An improved manifold is disclosed which comprises a main lumen having proximal and distal ends in a primary injection line connected to the proximal end of the main lumen. A port is connected to the main lumen between the proximal and distal ends thereof. A check valve is provided which permits flow between the primary injection line to the main lumen while selectively preventing back flow from the main lumen to the primary injection line. The check valve also permits flow from

the port to the primary injection line while preventing back flow from the primary injection line to the port.

A method for administering fluid is also disclosed which comprises injecting fluid through a primary injection line to a main lumen while selectively preventing back flow from the main lumen to the primary injection line and injecting fluid through a port to the primary injection line while preventing back flow from the primary injection line and main lumen to the port.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic plan view of an angiographic fluid manifold made in accordance with the present invention;

Fig. 2 is another schematic plan view of an angiographic fluid manifold made in accordance with the present invention;

Fig. 3 is yet another schematic plan view of an angiographic fluid manifold made in accordance with the present invention;

Fig. 4 is yet another schematic plan view of an angiographic fluid manifold made in accordance with the present invention;

Fig. 5 is yet another schematic plan view of an angiographic fluid manifold made in accordance with the present invention;

Fig. 6A is a partial sectional view of an angiographic fluid manifold made in accordance with the present invention in a first position and at a rest condition where the syringe, contrast port and primary injection line are isolated;

Fig. 6B is another partial sectional view of the angiographic fluid manifold shown in Fig. 6A, also in the first position but at a point in time where the syringe is being filled with contrast causing the valve to be flexed to permit flow between the contrast port and the syringe during aspiration of the syringe;

Fig. 6C is another partial sectional view of the angiographic fluid manifold shown in Figs. 6A and 6B where contrast is being injected from the syringe to the primary injection line thereby isolating the contrast port;

Fig. 7 is another partial sectional view the manifold shown in Fig. 6 but in a second position enabling free flow between the primary injection line and main lumen;

Fig. 8A is a partial sectional view of yet another angiographic fluid manifold made in accordance with the present invention and in a first position and at a rest condition where the syringe, contrast port and primary injection line are isolated;

Fig. 8B is another partial sectional view of the angiographic fluid manifold shown in Fig. 8A while still in the first position but with contrast being aspirated from the contrast port towards the syringe;

Fig. 8C is another partial sectional view of the angiographic fluid manifold shown in Figs. 8A and 8B, again in the first position, but with contrast being injected from the syringe towards the primary injection line thereby isolating the contrast port;

Fig. 9 is another partial sectional view of the angiographic fluid manifold shown in Fig. 8 but in a second position thereby permitting free flow between the primary injection line and main lumen;

Fig. 10 is a partial schematic sectional view of yet another angiographic fluid manifold made in accordance with the present invention and in a first position thereby permitting fluid flow from the port to the primary injection line;

Fig. 11 is another partial schematic sectional view of the angiographic fluid manifold of Fig. 10 but in a second position thereby permitting flow between the primary injection line and main lumen;

Fig. 12 is a schematic plan view of another angiographic fluid manifold made in accordance with the present invention;

Fig. 13 is a partial sectional view of the angiographic fluid manifold shown in Fig. 12 in a first position permitting flow from the primary injection line to the main lumen and flow from the port to the primary injection line;

Fig. 14 is another partial sectional view of the angiographic fluid manifold shown in Fig. 12 in a second position thereby permitting flow from the primary injection line to the port; and

Fig. 15 is another partial sectional view of the angiographic fluid manifold shown in Fig. 12 but in a third position thereby permitting free flow between the primary injection and main lumen.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

Fig. 1 illustrates a manifold 15 which includes a distal end 16 with a male connection 17 that can be connected to a catheter (not shown). The system 15 also

includes a proximal end 18 with a female connection 19 that may be connected to a syringe (not shown). The proximal end 18 and syringe (not shown) define a primary injection line 21. The system 15 further includes a manifold body 22 which has a main lumen 23 extending therethrough. In addition to the primary injection line 21, the main lumen 23 is connected to a port 24 and additional secondary ports 25, 26. Ports 24, 25, 26 are integrally connected to corresponding fluid lines (not shown). While the structure of the invention may be utilized for systems other than manifolds, it is anticipated that a primary use for the present invention may be utilized as a fluid manifold, and more particularly, for an angiographic fluid manifold. Accordingly, the port 24 will typically be connected to a contrast fluid or solution reservoir (not shown) via corresponding fluid lines (not shown). The additional ports 25, 26 may be connected to a pressure transducer or other analytical device (not shown) or may serve as a waste or fluid collector (not shown). The ports may be opened and closed with the stop cocks shown at 27, 28. The stop cocks 27, 28 are easily manipulated by way of the handles 31, 32.

In operation, a syringe connected to the female connector 19 of the primary injection line 21 can be used to inject saline or other fluid through the main lumen 23 to the catheter (not shown). The check valve 33 permits flow from the primary injection line 21, through the main lumen 23 to the catheter (not shown). The check valve 33 also prevents back flow from the main lumen 23 towards the primary injection line and syringe (not shown). Thus, the saline supply or other fluid at the syringe (or other pumping means such as, for example, an electric or manual pump) will not be contaminated by fluid disposed upstream in the main lumen 23 or catheter (not shown).

To inject fluid, *e.g.*, contrast fluid from the port 24 to the main lumen, the syringe or other pump (not shown) is aspirated by creating a pressure drop in the direction of the arrow 34. As fluid flow in this direction from the main lumen 23 is prevented by the check valve 33, fluid flows from the port 24 in the direction of the arrow 35 and through the primary injection line 21. The fluid flows past the check valve 36. Fluid from the port, *e.g.*, now being retained in the syringe or pump connected to the primary injection line, said fluid may be injected into the main lumen by generating pressure at the syringe or pump and create a pressure drop in the direction of the arrow 37 thereby causing the fluid that originated in the port 24 to flow past the check valve 33 in the direction of the arrow 38, into the main lumen and

thereafter into the catheter (not shown). The check valve 36 prevents back flow from the syringe or pump (not shown) connected to the primary injection line 21 from flowing past the check valve 36, into the port 24 and thereby contaminating the supply or reservoir or fluid connected to the port 24.

Thus, both the supply of saline or other fluid retained in the syringe or pump connected to the port 24 and the fluid, such as contrast fluid retained in the reservoir connected to the port 24 may be protected from contamination. The fluid retained in the reservoir connected to the port 24 may be protected from contamination both by fluid retained in the syringe or pump connected to the primary injection line 21 as well as fluid disposed in the main lumen 23 upstream of the check valve 33. Any fluid retained in the syringe or pump connected to the primary injection line 21 may be protected from contamination by any fluid disposed in the main lumen upstream of the check valve 33.

Using like reference numerals to refer to like or similar parts but with the suffix "a" an alternative embodiment system 15a is shown in Fig. 2. Instead of the check valve 36a being disposed in the port 24a, the two check valves 33a, 36a are disposed within a body 41. The body 41 includes a first lumen 42 and a second lumen 43. The first lumen 42 is disposed at least partially in the main lumen 23a and, in the embodiment shown in Fig. 2, accommodates both check valves 33a and 36a. The first and second lumens 42, 43 are connected to form a t-connection. As an alternative, the check valve 36a may be disposed in the second lumen 43 which is at least partially disposed within the port 24a.

Again using like reference numerals for like or similar parts except for the suffix "b," the check valve 33b of Fig. 3 is connected to a push button mechanism 44 which includes a movable body 45 which is connected to the check valve 33b as well as the body 22b which defines the main lumen 23b. Movement of the movable body 45 causes the check valve 33b to be disposed either in the main lumen 23b or be removed from the main lumen 23b.

In a further embodiment illustrated in Fig. 3, a movable body 45c as shown in Fig. 4 is rotatably connected to the manifold body 22c. The check valve 33c is disposed in the rotatable body 45c and can be moved from an activated position as shown in Fig. 4 where the handle 46 is disposed parallel to the main lumen 23c to the deactivated position shown in phantom in Fig. 4 where the check valve 33c is

removed from the main lumen 23c. In the embodiment 15c shown in Fig. 4, the check valve 36c is disposed in the port 24c.

In contrast, in the embodiment 15d shown in Fig. 5, the check valve 36d is disposed within a check valve line 48 that, along with a mechanical valve line are disposed between tube splitters 51, 52. The tube splitters 51, 52 are connected to the port 24d by way of the tubing 53 and male connector 54. The tubing 55 is connected to a fluid reservoir, such as, for example, a contrast fluid reservoir (not shown). The mechanical valve line 49 accommodates a manually operable mechanical valve 56. The check valve line 48 and mechanical valve line 49 may be rotated so as to permit one of the lines 48, 49 to be in communication with the tubings 53, 55 at a time.

The embodiment 15d shown in Fig. 5 is particularly useful if the syringe or pump connected to the primary injection line 21d has excess fluid in it or an air bubble. For example, excess contrast fluid may be injected from the primary injection line 21d back through the port 24d by rotating the lines 48, 49 so that the mechanical valve line 49 is in communication with the tubings 53, 55 and the valve 56 is opened. Thus, excess contrast fluid can be saved instead of wasted.

Turning to Figs. 6A-7, certain embodiments of the check valve are explained. For purposes of example, a dual check valve will be explained in greater detail. In Figs. 6A-6C and 7, the embodiment 15e provides a dual check valve mechanism by way of the sliding actuator or body 61. The body 61 comprises the port 24e, the female connector 29e, a palm pad 62 and a cylindrical wall 63 that defines a first lumen 64 disposed between the wall 63 and the check valve element 65 and a second lumen 66 that is disposed within the cylindrical wall 63. The wall 63 includes a protuberance 67.

The valve element 65 is fixed with respect to the manifold body 22e. The actuator body 61 slides within the cavity 68 disposed within the manifold body 22e and into which the main lumen 23e and primary injection line 21e extend. In Figs. 6A-6C, the actuator body 61 is in a first position whereby the first lumen 64 is in-line with the primary injection line 21e and main lumen 23e. In the rest position shown in Fig. 6A, the valve element 65 engages the protuberance 67 and the combination of the valve element 65 and protuberance 67 isolates the primary injection line 21e, main lumen 23e and contrast port 24e from one another. As contrast is aspirated in the direction of the arrow 15e, pressure generated in the port 24e biases the valve element 65 towards the right as shown in Fig. 6B and around protuberance 67 to permit fluid

flow in the direction of the arrows 15e and 34e (see Fig. 6B). As shown in Fig. 6C, when the contrast is injected from the syringe in the direction of the arrow 37e to the main lumen 23e, the valve element 65 is biased towards the left thereby isolating the secondary injection port 24e and permitting flow in the direction of the arrows 37e and 38e.

Thus, in the first position shown in Figs. 6A-6C, the secondary injection port 24e, the primary injection port 21e and the main lumen 23e may be isolated (Fig. 6A) or, pressure in the secondary injection port 24e can bias the valve element 65 to the right and around the protuberance 67 to permit flow in the direction of the arrows 35e, 34e as shown in Fig. 6B, or, the valve element 65 may be biased to the left when pressure is generated in the primary injection port 21e by action of the syringe pumping fluid in the direction of the arrows 37e, 38e thereby permitting fluid, such as contrast, to flow from the syringe to the main lumen 23e.

Turning to Fig. 7, the actuator body 61 has been moved to the left relative to the 72 and protuberance 67 thereby placing the second lumen 66 in-line with the main lumen 23e and primary injection line 21e. In this position, flow between the primary injection line 21e and main lumen 23e is provided and the port 24e is isolated from both the primary injection line 21e and main lumen 23e. Specifically, the first lumen 64 is blocked at both ends by the walls 71, 72 of the cavity 68. A spring 73 may be utilized to bias the actuator body 61 into the position shown in Figs. 6A-6C. The spring bias may be overcome by applying pressure to the palm pad 62 in the direction of the arrow 74.

The actuator body 61 may be unitary in design or fabricated from multiple components. The portions of the actuator body 61 defining the lumens 64 and 66 may be retained within the cavity 68 along with the spring 73 by way of the retainer plate 74. The palm pad 62 may be threadably connected or otherwise attached to the handle 75 after the handle 75 is extended through the aperture 76 disposed in the wall 77.

In the embodiment 15f shown in Figs. 8A-8C and 9, instead of a palm pad 62 and handle 75 as shown in Figs. 6A-6C and 7, finger grips 81, 82 are attached to the actuator body 61f between the port 24f and retainer plate 74f. The spring 73f is trapped between the cylindrical wall 63f of the actuator body 61f and the wall 77. The remaining elements are identical or functionally equivalent to the elements described above in Figs. 6A-6C and 7.

Turning to Figs. 10 and 11, the embodiment 15g includes a sliding actuator body 61g of a different configuration than the sliding actuator bodies 61 and 61f shown in Figs. 6-7 and 8-9, respectively. Specifically, while the actuator body 61g includes two lumens 64g, 66g like the lumens 64, 66 and 64f, 66f shown in Figs. 6-7 and 8-9, respectively, the lumen 64g includes a one-way check valve 83 that protects the primary injection line 21g and port 24g from back flow from the main lumen 23g. The check valve 83 does not protect the port 24g from back flow from the primary injection line 21g or syringe port. Instead, an additional check valve 84 is disposed upstream in the tubing shown at 53g, 55g. In the position shown in Fig. 10, fluid may be pumped through the check valve 84 in the direction of the arrow 35g, through the port 24g, through the lumen 64g and into the primary injection line 21g in the direction of the arrow 34g. The one-way check valve 83 prevents any contrast fluid from being pumped or drawn into the main lumen 23g during the aspiration of the syringe or pump mechanism (not shown). Upon syringe or pump injection, fluid is then pumped in the direction of the arrow 37d, through the one-way check valve 83 and into the main lumen 23g. The check valve 84 prevents any contaminated contrast solution from being injected or pumped into the contrast solution reservoir which is upstream of the tubing 55g. The actuator body 61g is accommodated within a sleeve 85 that is fixed to the manifold body 22g. The sleeve 85 is accommodated in a slot 86 disposed on the outer surface of the actuator body 61g. The actuator body can be slid from the first position shown in Fig. 10 to the second position shown in Fig. 11 by pushing or pulling on either of the handles 87, 88. In the position shown in Fig. 11, the lumen 66g is in-line between the primary injection line 21g and the main lumen 23g thereby providing uninhibited flow between the primary injection line 21g and main lumen 23g.

A further embodiment of a manifold system 15h is illustrated in Figs. 12-15. In the system 15h, a rotating valve body 91 is disposed at the junction of the primary injection line 21h, port 24h and main lumen 23h. As shown in Figs. 13-15, the rotating valve body 91 has three positions and movement between these positions can be effectuated by the handle 91a. In Fig. 13, the valve body 91 is a first position whereby the first lumen 42h of the body 41h is in-line between the primary injection line 21h and main lumen 23h. The check valve 33h prevents back flow from the main lumen 23h towards the main injection line 21h. The check valve 36h disposed in the second lumen 43h of the body 41h prevents back flow from the body 41h and the

primary injection line 21h to the port 24h. Thus, in the position shown in Fig. 13, fluid may flow from the primary injection 21h to the main lumen 23h and from 24h to 21h.

Turning to Fig. 14, the valve body 91 has been rotated 45° so that the check valve 33h is disposed in-line with the port or contrast line 24h. The check valve 36h is disposed in-line with the primary injection line 21h. The position shown in Fig. 14 is useful to dump excess contrast solution from the syringe or pump (not shown) back into the port 24h. Thus, excess contrast solution may be pumped from the primary injection line 21h through the check valves 36h, 33h and back into the port 24h to the contrast reservoir (not shown). The position shown in Fig. 14 is useful in the event that no injection has taken place for a period of time during a procedure. Instead of wasting contrast solution which may have been aspirated into the syringe or pump (not shown), the excess solution or solution that is not currently needed may be transferred into the port 24h instead of being wasted.

Turning to Fig. 15, the valve body 91 has been further rotated so that the tertiary lumen 92 is disposed in-line between the primary injection line 21h and main lumen 23h. The position shown in Fig. 15 is useful for aspirating the catheter. Fluid may be drawn through the main lumen 23h in the direction of the primary lumen 21h and aspirated into the syringe or pump and then pumped in the reverse direction toward one of the secondary ports 25h, 26h which can be used as a dump or waste collection.

Thus, an improved angiographic manifold is provided which, in turn, provides check valve protection for both the syringe or saline pump port as well as check valve protection for the contrast fluid reservoir without requiring the physician to manipulate cumbersome stop cock valves. In many of the embodiments, contrast fluid may be drawn into the syringe or pump from the contrast fluid reservoir and injected through the main lumen without manipulating any valve and while providing check valve protection against contamination from fluid disposed in the main lumen.

Although the disclosed devices and methods have been described with reference to preferred embodiments, those skilled in the art will recognize that changes may be made in form and detail with departing from the spirit and scope of this disclosure. As such, it is intended that the foregoing detailed description be regarded as illustrative rather than limiting and it is the following claims, including all equivalents thereof, which are intended to define the scope of the claimed invention.

What is Claimed is:

1. A manifold comprising:

a main lumen having proximal and distal ends,

a primary injection line connected to the proximal end of the main lumen,

a port connected to the main lumen between the proximal and distal ends thereof,

a check valve permitting flow from the primary injection line to the main lumen while selectively preventing back flow from the main lumen to the primary injection line and permitting flow from the port to the primary injection line while preventing back flow from the primary injection line to the port.

2. The manifold of claim 1 wherein the valve is a dual check valve.

3. The manifold of claim 2 wherein the dual check valve comprises a first check valve disposed in-line between the primary injection line and the main lumen and a second check valve disposed in-line between the primary injection line and the port.

4. The manifold of claim 2 wherein the dual check valve comprises a body comprising a first lumen at least partially disposed in the main lumen and a second lumen connected to the first lumen to form a T-connection and extending at least partially into the port, and

wherein the dual check valve comprises a first check valve disposed in the body and between the primary injection line and the main lumen and a second check valve disposed in the body and between the primary injection line and the port.

5. The manifold of claim 4 wherein the first check valve is disposed in the first lumen.

6. The manifold of claim 4 wherein the second check valve is disposed in the first lumen.

7. The manifold of claim 4 wherein the second check valve is disposed in the second lumen.

8. The manifold of claim 4 wherein the first check valve is disposed in the first lumen and the second check valve is disposed in the first lumen between the primary injection line and the port and between the first check valve and the primary injection line and the port.

9. The manifold of claim 3 wherein the first check valve is connected to a movable body that permits movement of the first check valve out of the main lumen thereby deactivating the first check valve.

10. The manifold of claim 9 wherein the movable body is movable between a first activated position where the first check valve is disposed in the main lumen and a second deactivated position where the first check valve is removed from the main lumen.

11. The manifold of claim 10 wherein the movable body comprises a finger rest for moving the movable body from the first activated position to the second deactivated position.

12. The manifold of claim 9 wherein the main lumen extends through a fixed body and the movable body is rotatably connected to the fixed body.

13. The manifold of claim 3 wherein the port comprises a pair of tube splitters and a check valve line and a mechanical valve line disposed in parallel and between the tube splitters, the second check valve being disposed in the check valve line.

14. The manifold of claim 2 wherein the dual check valve comprises a check valve element disposed between the port and both the primary injection line and the main lumen, the dual check valve further comprising a movable body comprising a secondary lumen, the movable body being movable between a first position where flow from the port to the primary injection line causes the check valve element to engage the movable body and permit flow from the port to the primary injection line while isolating the main lumen from fluid flow from both the port and the primary injection line, the movable body further being movable to a second position where the secondary lumen is in-line with the main lumen and the primary injection line thereby permitting fluid flow between the primary injection line and the main lumen while isolating the port.

15. The manifold of claim 14 wherein the movable body comprises a finger rest for moving the movable body from the first position to the second position.

16. The manifold of claim 14 wherein the movable body comprises a palm pad for moving the movable body from the first position to the second position.

17. The manifold of claim 14 wherein the movable body comprises at least one finger grip for moving the movable body from the first position to the second position.

18. The manifold of claim 2 wherein the dual check valve comprises a movable body extending transversely between the primary injection line and the main lumen, the movable body comprising a first end connected to the port, the movable body further comprising a secondary lumen and a tertiary lumen, the secondary lumen extending between the port and the primary injection line when the movable body is in a first position, the secondary lumen accommodating a one-way check valve that permits flow from the secondary injection line to the primary injection line when the movable body is in the first position and prevents flow from the main lumen to the primary injection line and the port when the movable body is in the first position, the tertiary lumen extending between the primary injection line and the main lumen when the movable body is in a second position, the port further comprising a second check valve that prevents flow from the main lumen or primary injection line to the port.

19. The manifold of claim 18 wherein the movable body comprises a finger rest for moving the movable body from the first position to the second position.

20. The manifold of claim 18 wherein the movable body comprises a palm pad for moving the movable body from the first position to the second position.

21. The manifold of claim 18 wherein the movable body comprises at least one finger grip for moving the movable body from the first position to the second position.

22. A fluid manifold comprising:

a main lumen having proximal and distal ends,

a primary injection line connected to the proximal end of the main lumen,

a port connected to the main lumen between the proximal and distal ends thereof,

a dual check valve comprising a first check valve disposed in-line between the primary injection line and the main lumen for permitting flow from the primary injection line to the main lumen while preventing back flow from the main lumen to the primary injection line and a second check valve disposed in-line between the primary injection line and the port permitting flow from the port to the primary injection line while selectively preventing back flow from the primary injection line to the port.

23. The manifold of claim 22 wherein the first check valve is connected to a movable body that permits movement of the first check valve out of the main lumen thereby deactivating the first check valve.

24. The manifold of claim 23 wherein the movable body is movable between a first activated position where the first check valve is disposed in the main lumen and a second deactivated position where the first check valve is removed from the main lumen.

25. The manifold of claim 24 wherein the movable body comprises a finger rest for moving the movable body from the first activated position to the second deactivated position.

26. The manifold of claim 24 wherein the main lumen extends through a fixed body and the movable body is rotatably connected to the fixed body.

27. The manifold of claim 22 wherein the port comprises a pair of tube splitters and a check valve line and a mechanical valve line disposed in parallel and between the tube splitters, the second check valve being disposed in the check valve line.

28. A manifold comprising:

a main lumen having proximal and distal ends,

a primary injection line connected to the proximal end of the main lumen,

a port connected to the main lumen between the proximal and distal ends thereof,

a body comprising a first lumen at least partially disposed in the main lumen and a second lumen connected to the first lumen to form a T-connection and extending at least partially into the port, and

a dual check valve comprising a first check valve disposed in the body and between the primary injection line and the main lumen and a second check valve disposed in the body and between the primary injection line and the port.

29. The manifold of claim 28 wherein the first check valve is disposed in the first lumen.

30. The manifold of claim 28 wherein the second check valve is disposed in the first lumen.

31. The manifold of claim 28 wherein the second check valve is disposed in the second lumen.

32. The manifold of claim 28 wherein the first check valve is disposed in the first lumen and the second check valve is disposed in the first lumen between the primary injection line and the port and between the first check valve and the primary injection line and the port.

33. A manifold comprising:

a main lumen having proximal and distal ends,

a primary injection line connected to the proximal end of the main lumen,

a port connected to the main lumen between the proximal and distal ends thereof,

a dual check valve comprising a check valve element disposed between the port and both the primary injection line and the main lumen, the dual check valve further comprising a movable body comprising a secondary lumen, the movable body being movable between a first position where flow from the port to the primary injection line causes the valve element to engage the movable body and permit flow from the port to the primary injection line while isolating the main lumen from fluid flow from the primary injection line and the port, the movable body further being movable to a second position where the movable body engages the valve element and isolates the port from fluid flow from both the primary injection line and the main lumen and further where the secondary lumen is in-line with the main lumen and the primary injection line thereby permitting fluid flow between the primary injection line and the main lumen, the port further comprising a second check valve that prevents flow from the main lumen or primary injection line to the port.

34. The manifold of claim 33 wherein the movable body comprises a finger rest for moving the movable body from the first position to the second position.

35. The manifold of claim 33 wherein the movable body comprises a palm pad for moving the movable body from the first position to the second position.

36. The manifold of claim 33 wherein the movable body comprises at least one finger grip for moving the movable body from the first position to the second position.

37. A manifold comprising:

a main lumen having proximal and distal ends,

a primary injection line connected to the proximal end of the main lumen,

a port connected to the main lumen between the proximal and distal ends thereof,

a movable body extending transversely between the primary injection line and the main lumen, the movable body comprising a first end connected to the port, the movable body further comprising a secondary lumen and a tertiary lumen, the secondary lumen extending between the secondary injection line and the primary injection line when the movable body is in a first position, the secondary lumen accommodating a one-way check valve that permits flow from the port to the primary injection line when the movable body is in the first position and prevents flow from the primary injection line and the main lumen to the port when the movable body is in the first position, the tertiary lumen extending between the primary injection line and the main lumen when the movable body is in a second position.

38. The manifold of claim 35 wherein the movable body comprises a finger rest for moving the movable body from the first position to the second position.

39. The manifold of claim 35 wherein the movable body comprises a palm pad for moving the movable body from the first position to the second position.

40. The manifold of claim 35 wherein the movable body comprises at least one finger grip for moving the movable body from the first position to the second position.

41. A manifold comprising:

a manifold body,

a main lumen extending through the manifold body, the main lumen having proximal and distal ends,

a primary injection line connected to the proximal end of the main lumen,

a port connected to the main lumen between the proximal and distal ends thereof,

a rotatable valve body comprising a first lumen, a second lumen connected to the first lumen to form a T-connection and a third lumen,

a first check valve disposed in the first lumen of the valve body and a second check valve disposed in the second lumen of the valve body,

the valve body being connected to the manifold body and rotatable between three positions including:

a first position wherein the first lumen is disposed in-line between the primary injection line and main lumen and the second lumen is disposed in-line with port line with the first check valve permitting flow from the primary injection line to the main lumen while preventing back flow from the main lumen towards the primary injection line and the second check valve permits flow from the port to the primary injection line while preventing back flow from the primary injection line and main lumen to the port,

a second position wherein the second lumen is disposed in-line with the primary injection line and the first lumen is disposed in-line with the port with the first and second check valves permitting flow from the primary injection line to the port while preventing back flow from the port to the primary injection line, and

a third position wherein the third lumen is disposed in-line between the primary injection line and the main lumen.

42. The manifold of claim 41 wherein the third lumen intersects the first lumen.

43. The manifold of claim 41 wherein the first and third lumens extend through the valve body and the valve body is rotatably disposed within a recess disposed in the manifold body so that, in the first position, opposing ends of the third lumen are sealed by engagement of the valve body with the manifold body and, in the third position, opposing ends of the first lumen are sealed by engagement of the valve body with the manifold body.

44. The manifold of claim 41 wherein the third lumen is free of check valves.

45. A method of administering fluids, the method comprising:

injecting fluid through a primary injection line to a main lumen while selectively preventing back flow from the main lumen to the primary injection line and

injecting fluid through a port to the primary injection line while preventing back flow from the primary injection line and main lumen to the port.

46. The method of claim 45 wherein

the injecting of fluid through the primary injection line to the main lumen further comprises injecting said fluid through a first check valve disposed between the primary injection line and the main lumen for preventing back flow from the main lumen to the primary injection line, and

the injecting of fluid through the port to the primary injection line further comprises injecting said fluid through a second check valve disposed between the port and the primary injection line for preventing back flow from the primary injection line and main lumen to the port.

47. The method of claim 46 wherein

the injecting of fluid through the port to primary injection line further comprises injecting said fluid through a movable body that is in a first position where flow through a check valve element causes the check valve element to engage the movable body and permit flow from the port to the primary injection line while isolating the main lumen from fluid flow from both the port and primary injection lines, and

the injecting of fluid through the primary injection line to the main lumen further comprises injecting said fluid though the movable body while the movable body is in a second position where a secondary lumen passing through the movable body is in-line with the main lumen and the primary injection line thereby permitting fluid flow between the primary injection line and the main lumen while isolating the port.

48. The method of claim 45 wherein

the injecting of fluid through the port to primary injection line further comprises injecting said fluid through a movable body that is in a first position wherein the movable body comprises secondary lumen extending between the port and the primary injection line when the movable body is in a first position, the secondary lumen accommodating a one-way check valve that permits flow from port to the primary injection line when the movable body is in the first position and prevents flow from the primary injection line and the main lumen to the port when the movable body is in the first position, and

the injecting of fluid from the primary injection line to the main lumen further comprises injecting said fluid through the movable body when the movable body is in a second position wherein the movable body further comprises a tertiary lumen extending between the primary injection line and the main lumen when the movable body is in a second position and the movable body isolates the port when the movable body is in the second position.

FIG.1

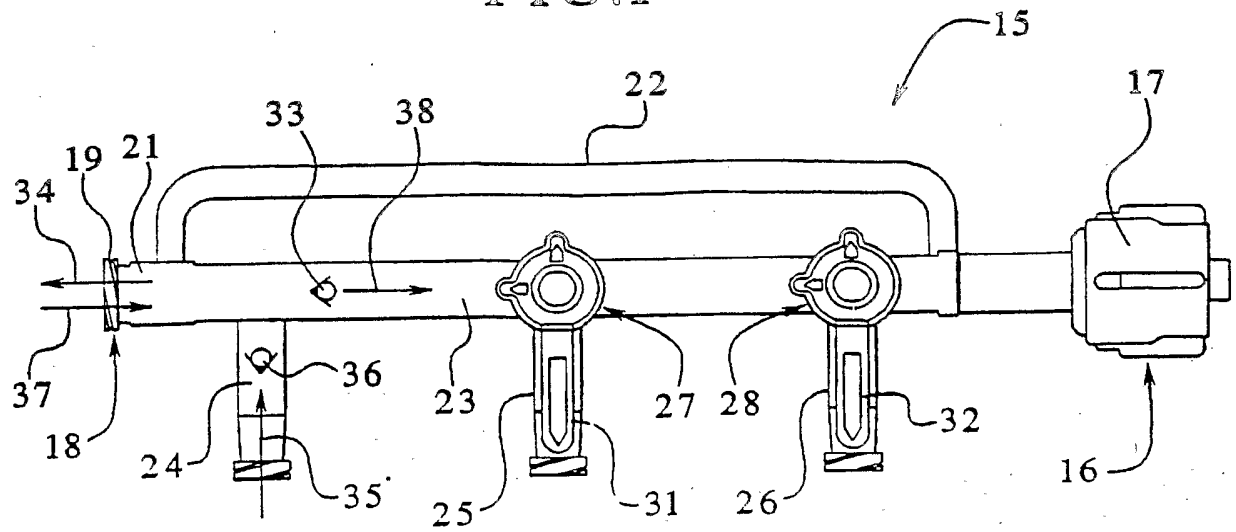
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FIG.2

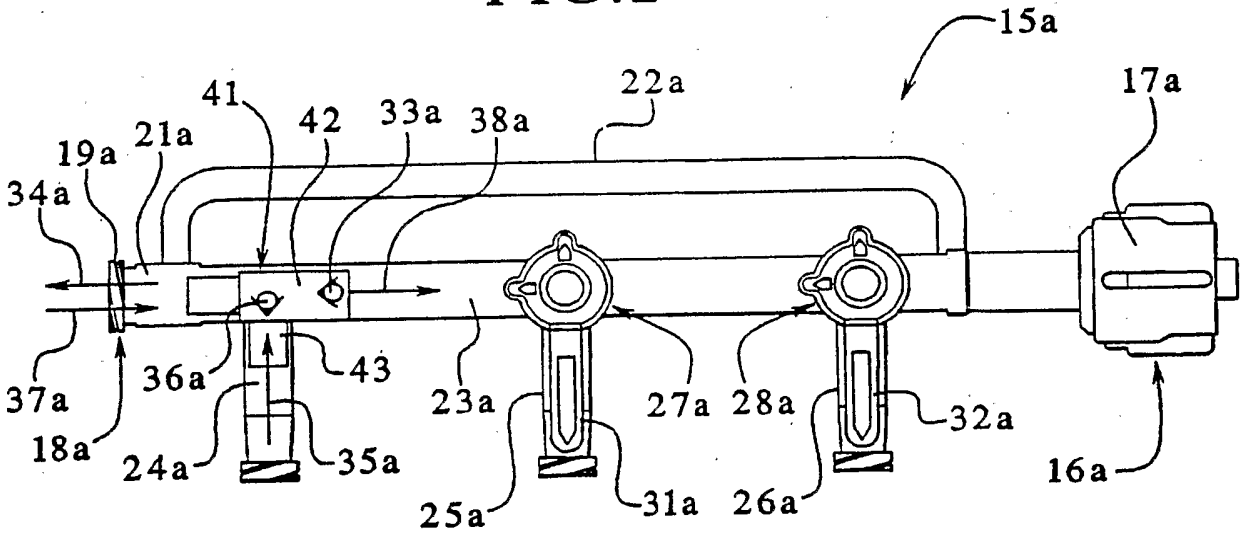
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FIG.3

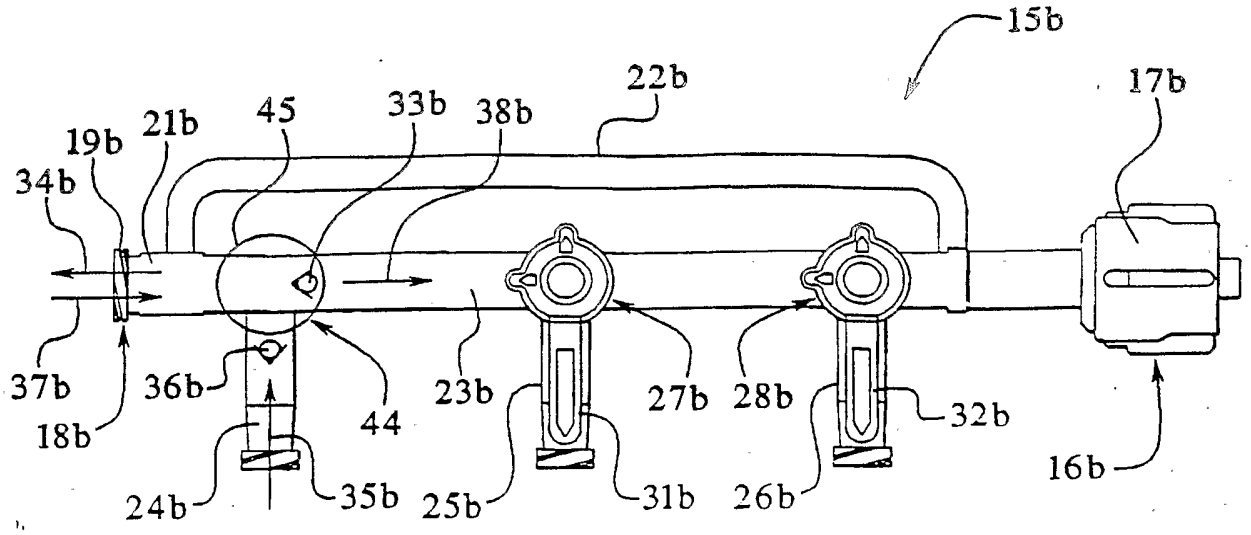
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FIG.4

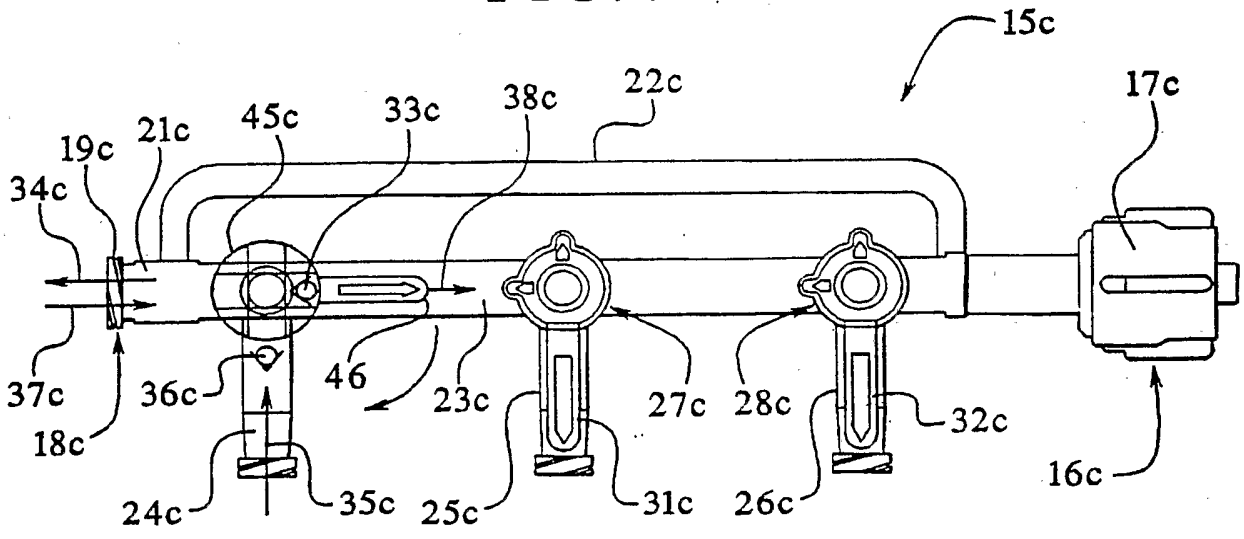
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FIG.5

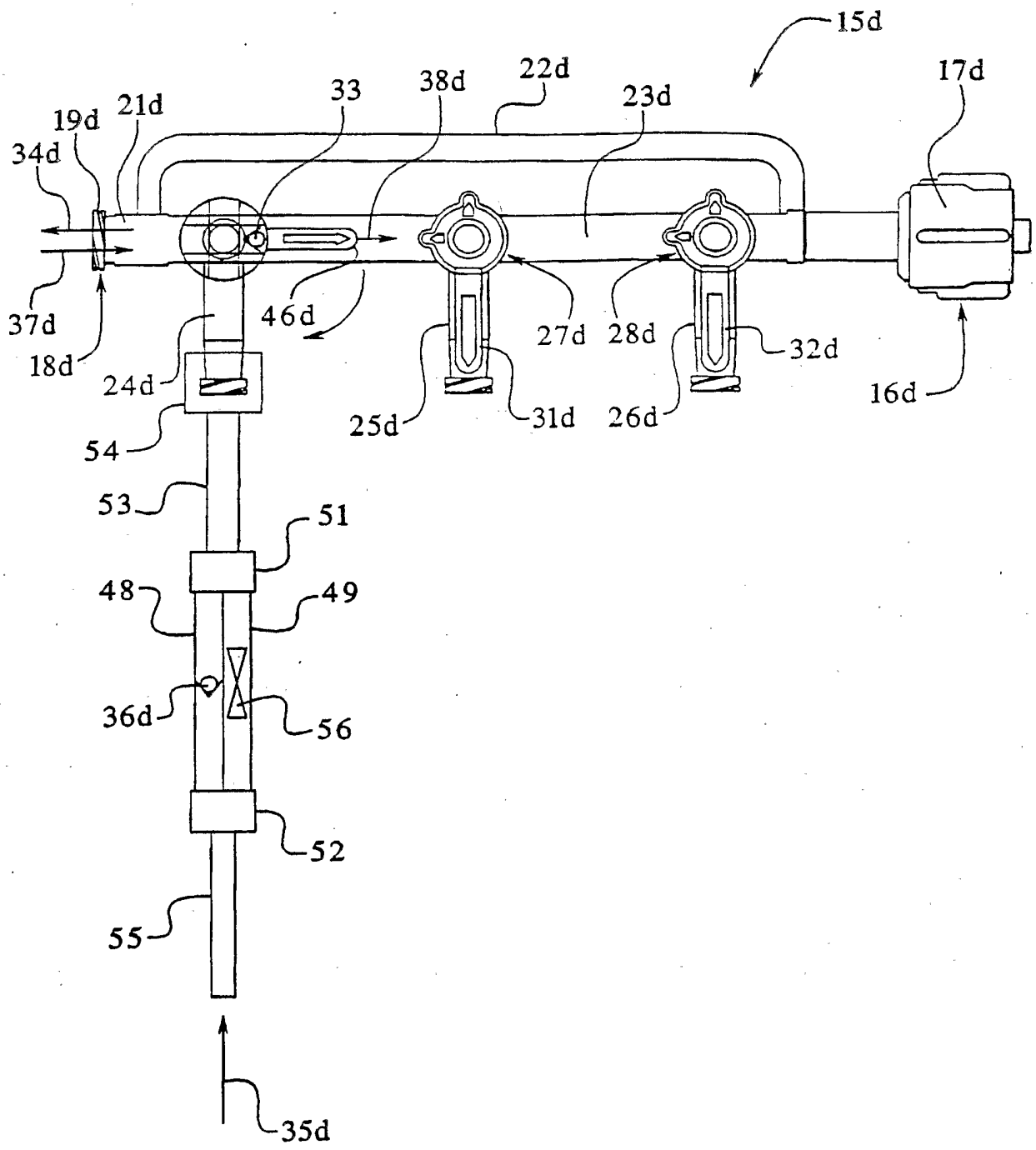
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FIG.6A

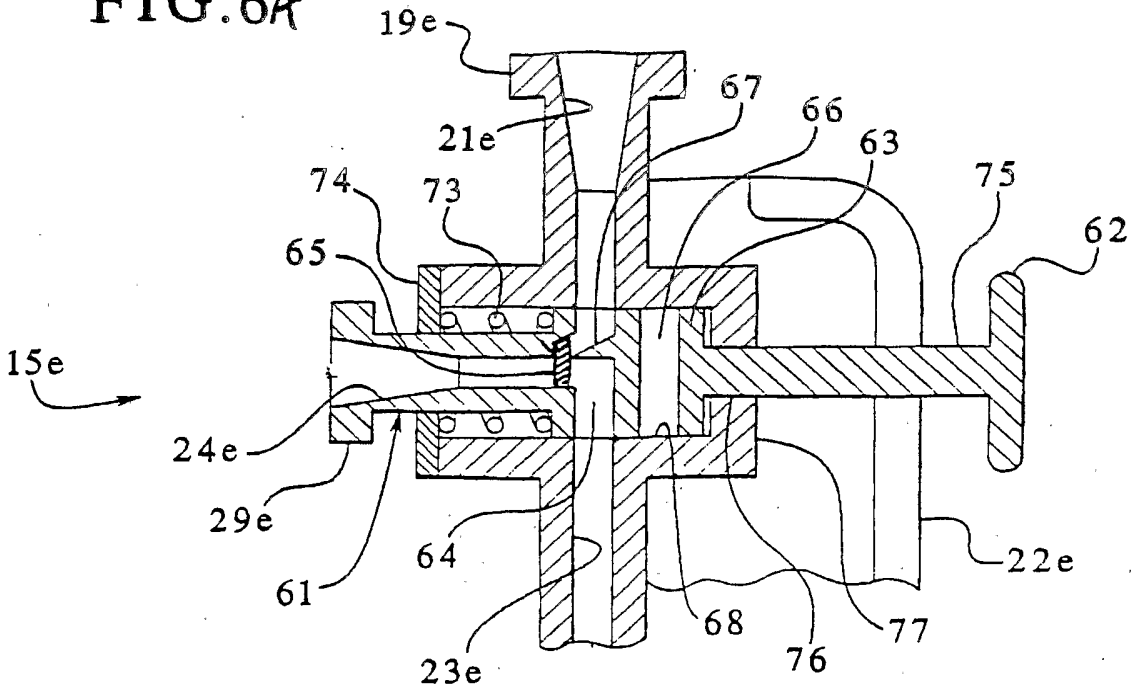
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FIG.7

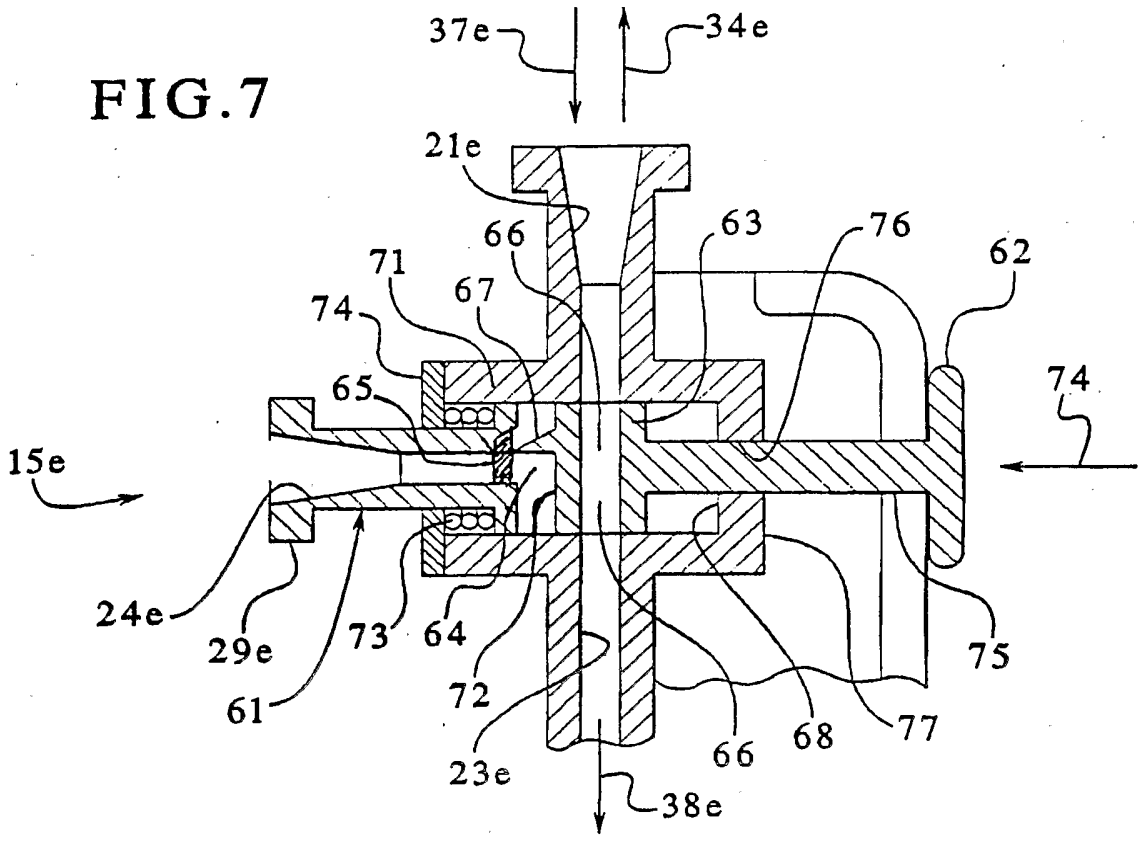
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FIG.6B

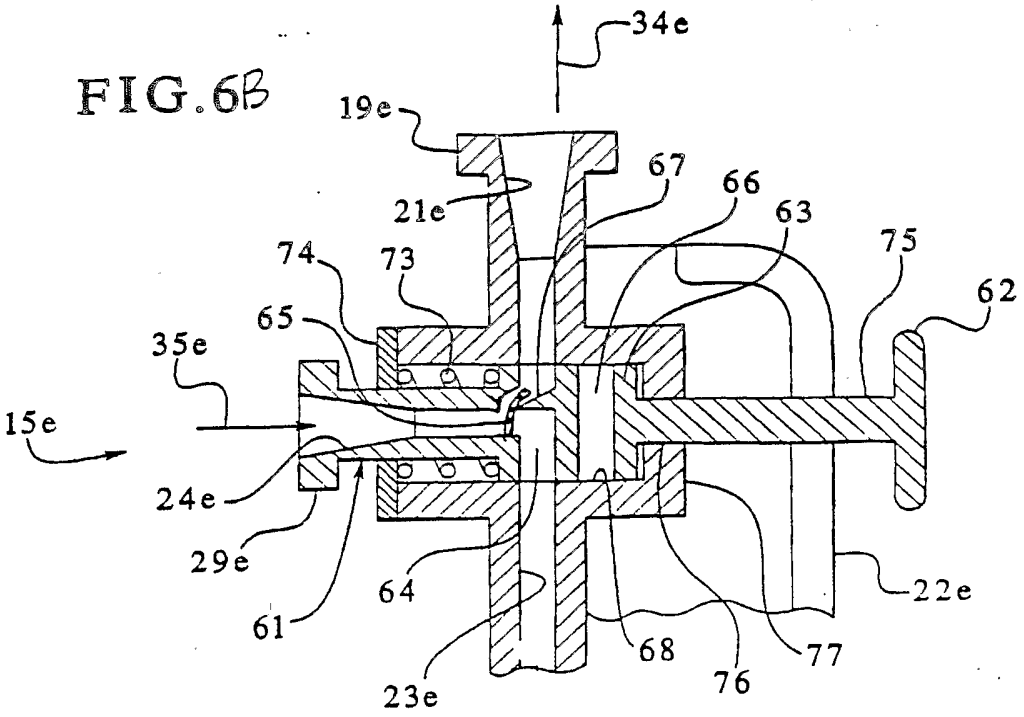
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FIG.6C

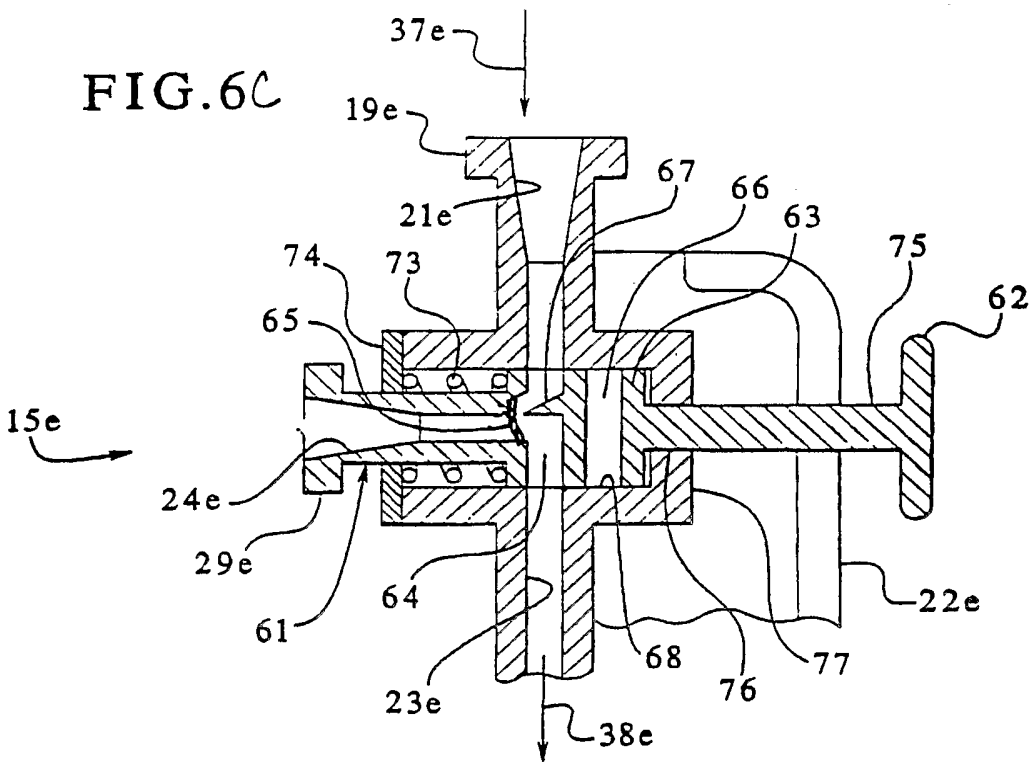
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FIG.8A

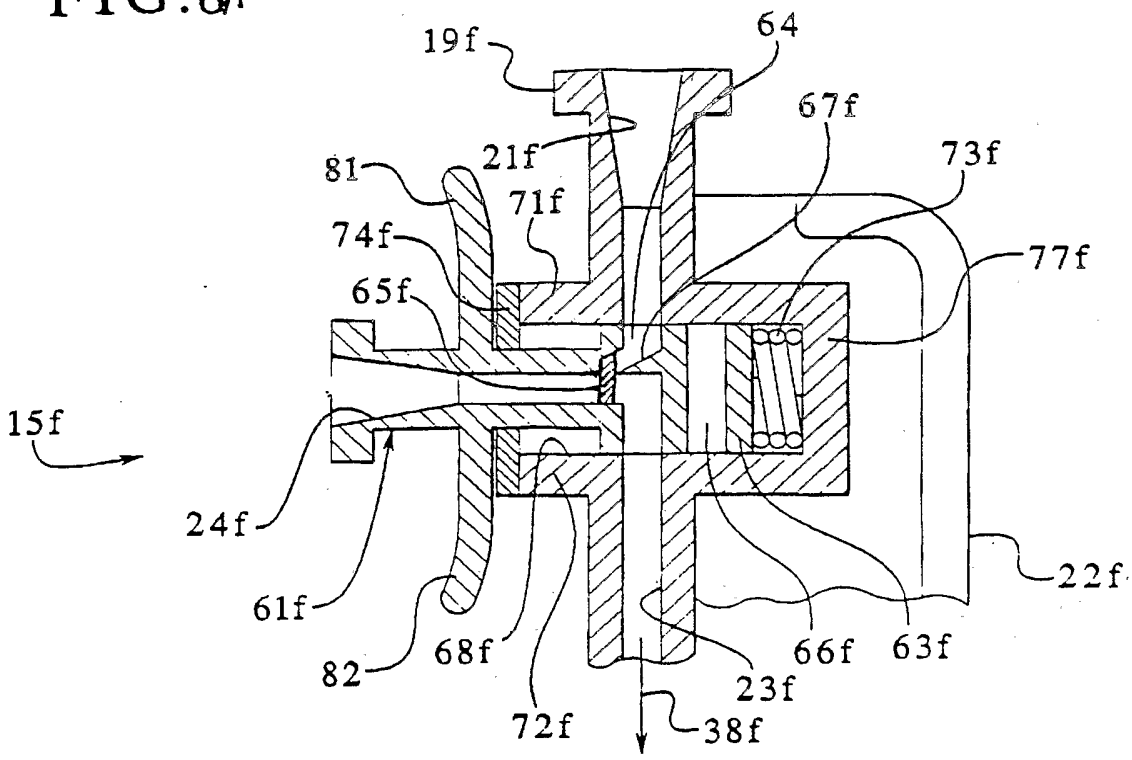
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FIG.9

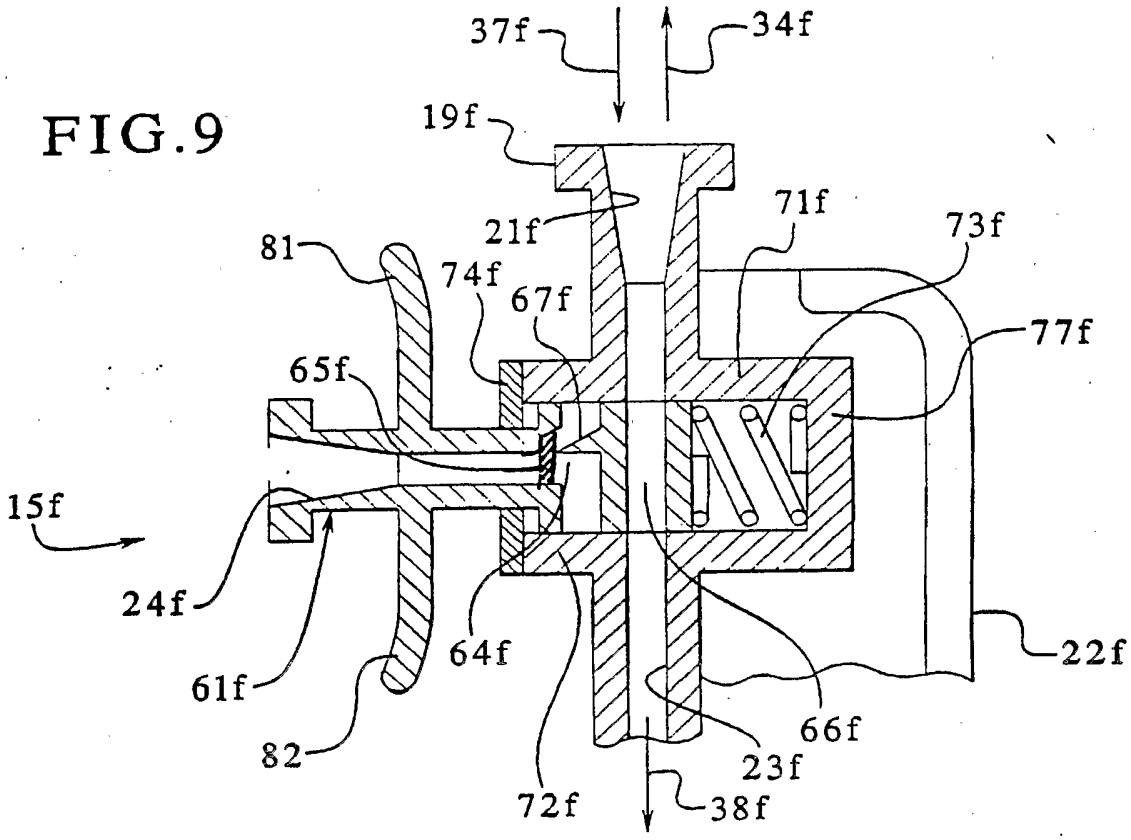
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FIG.8B

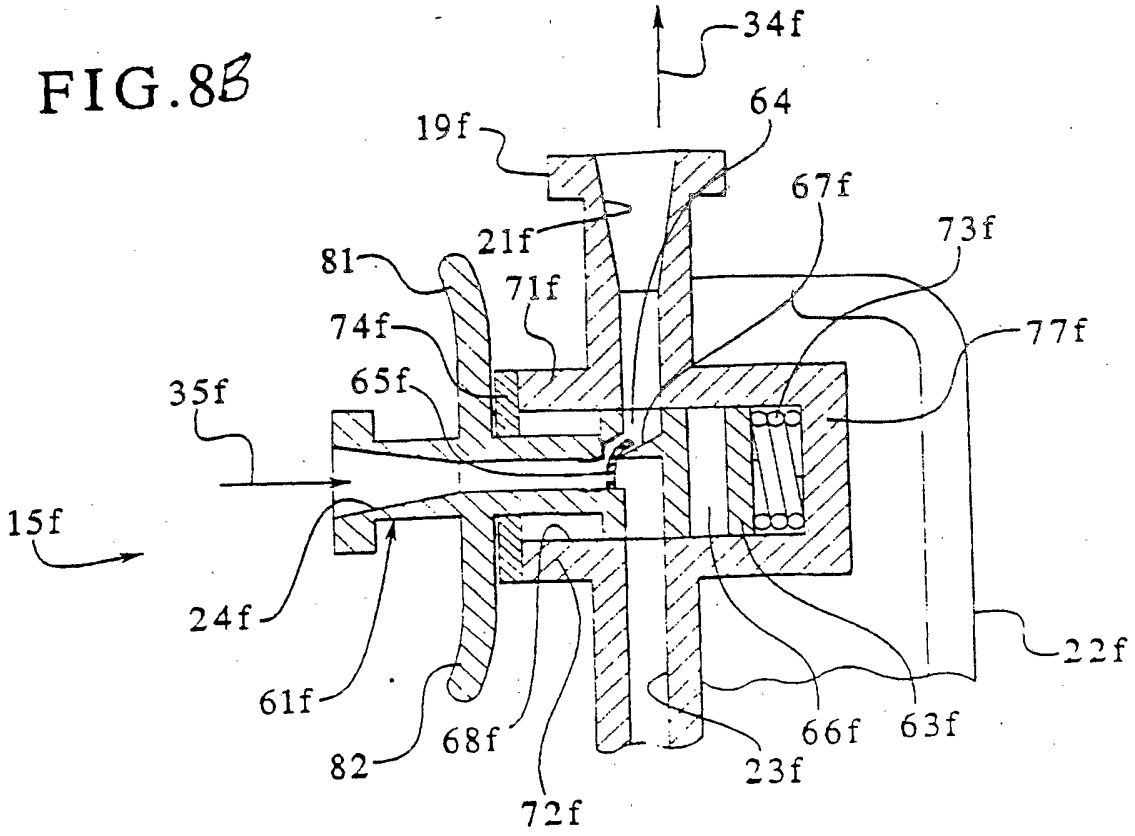
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FIG.8C

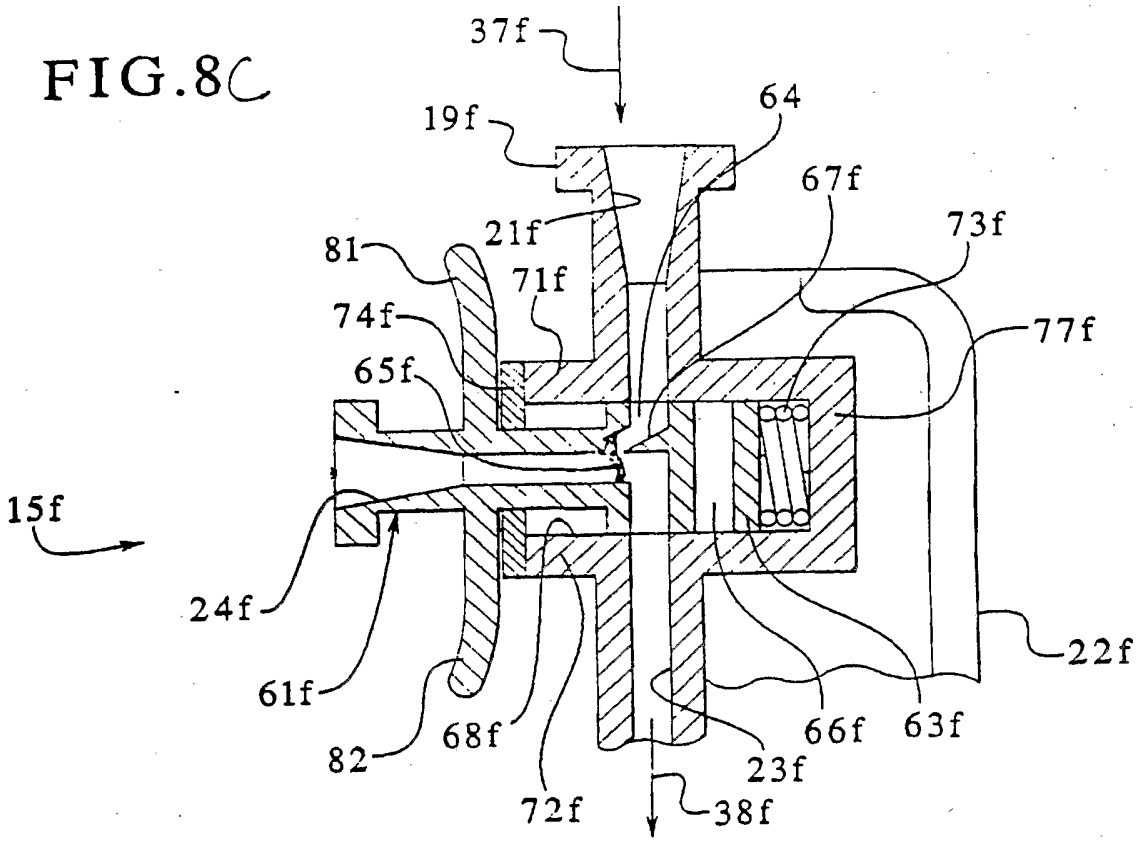
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FIG.10

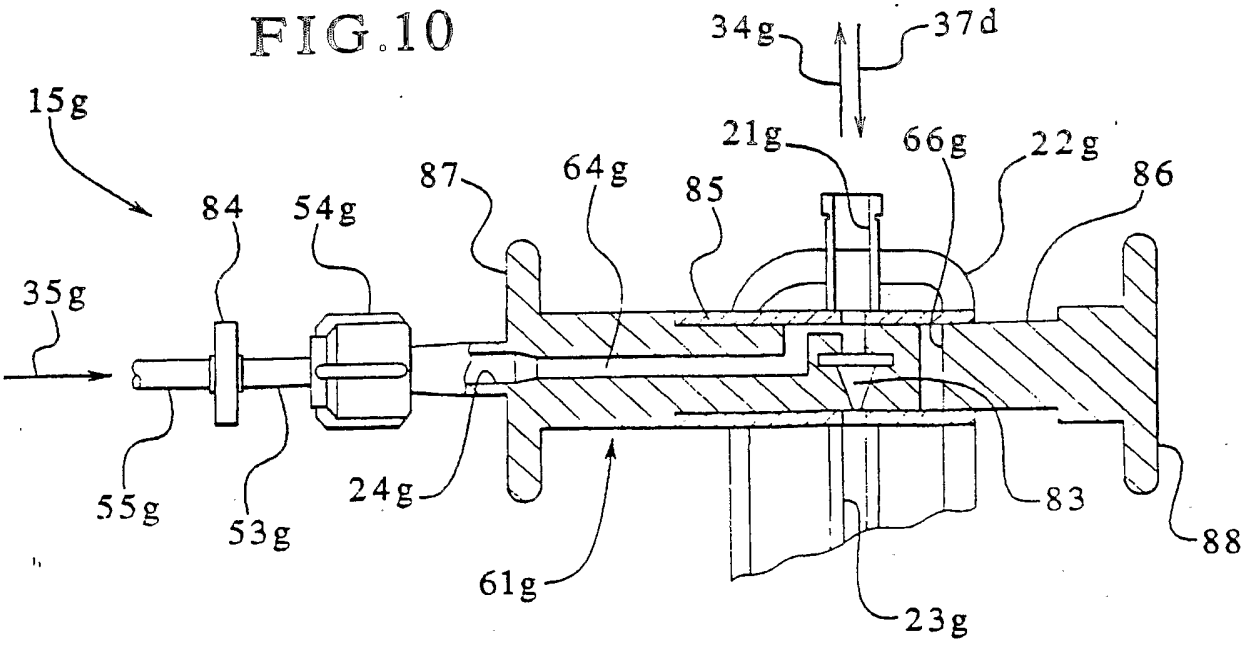
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FIG.11

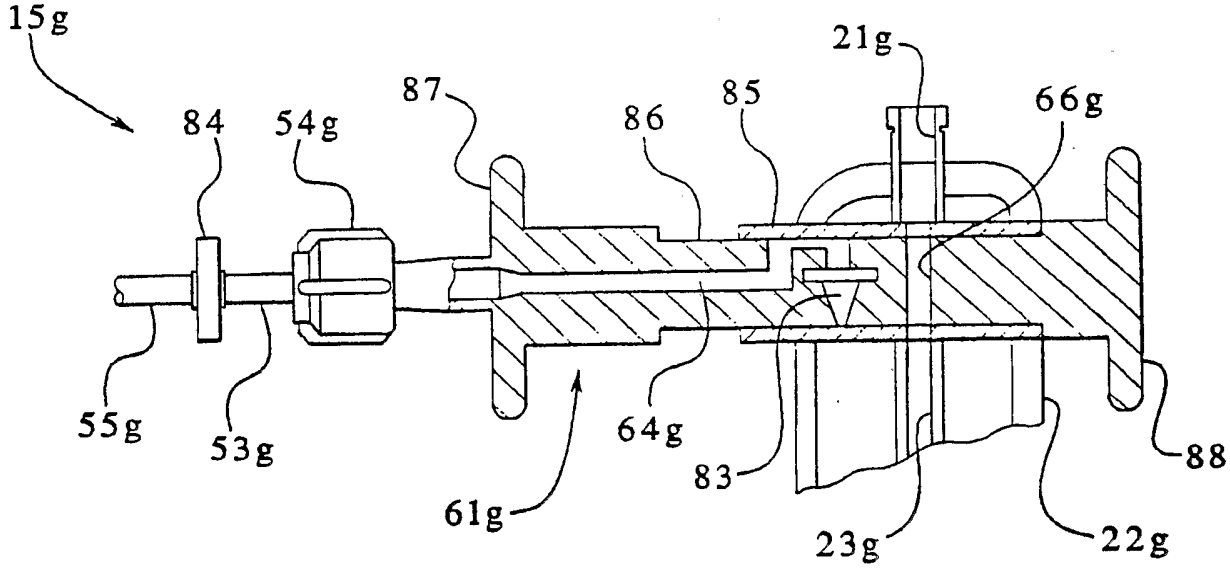
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FIG.12

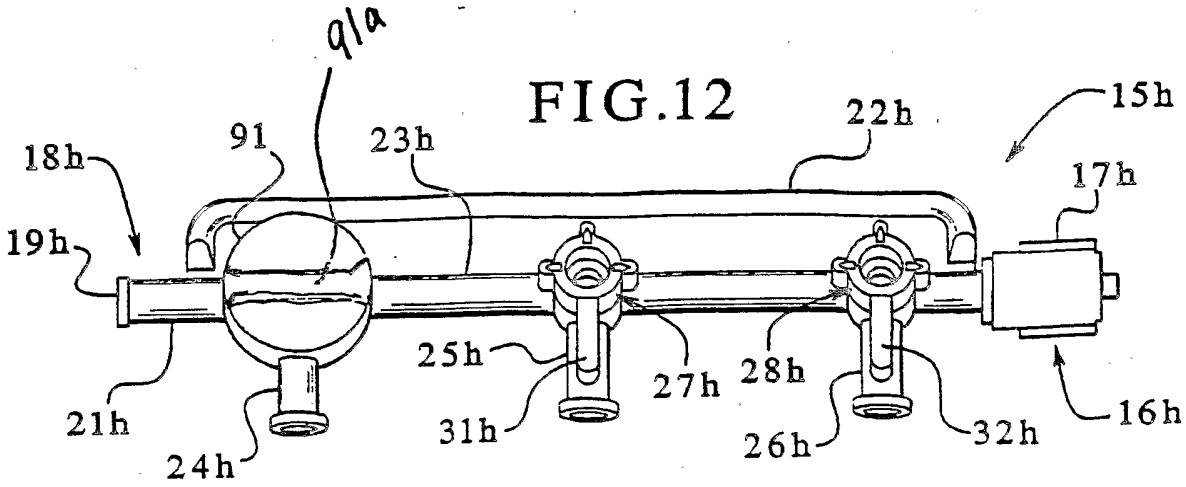


FIG.13

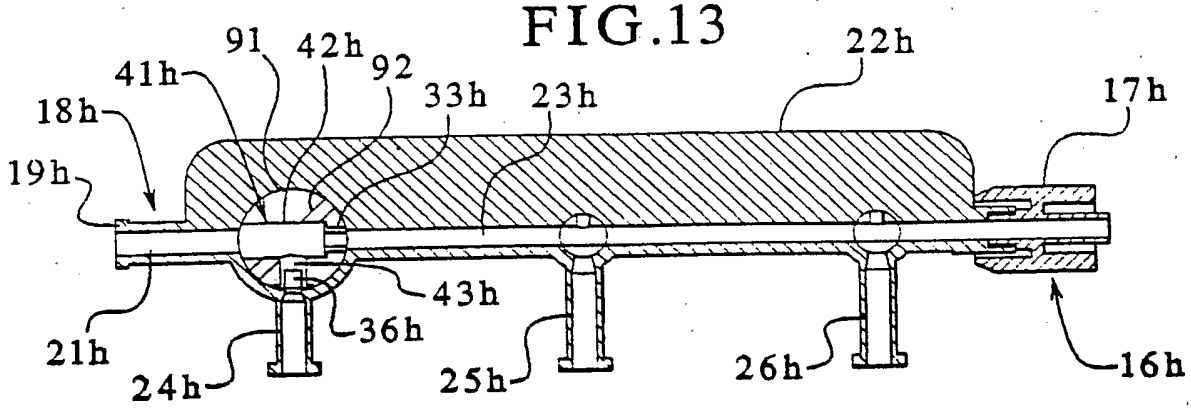


FIG.14

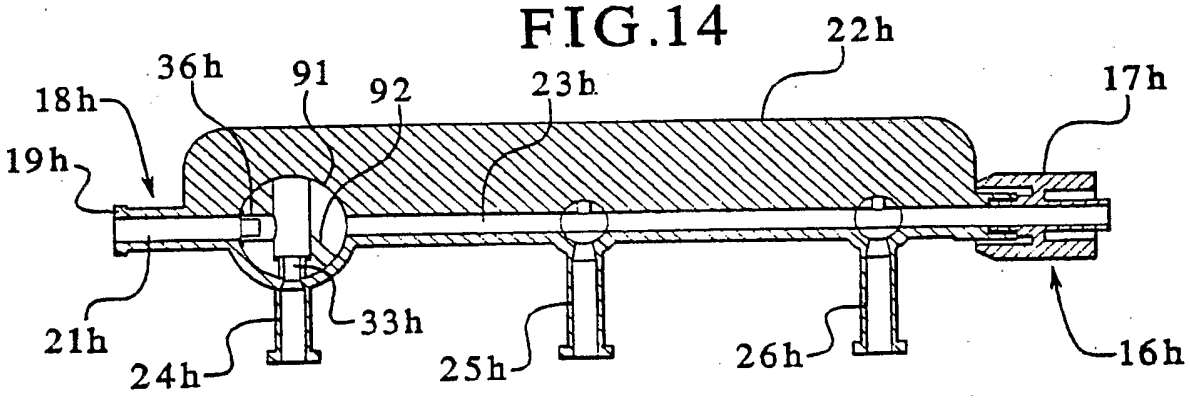
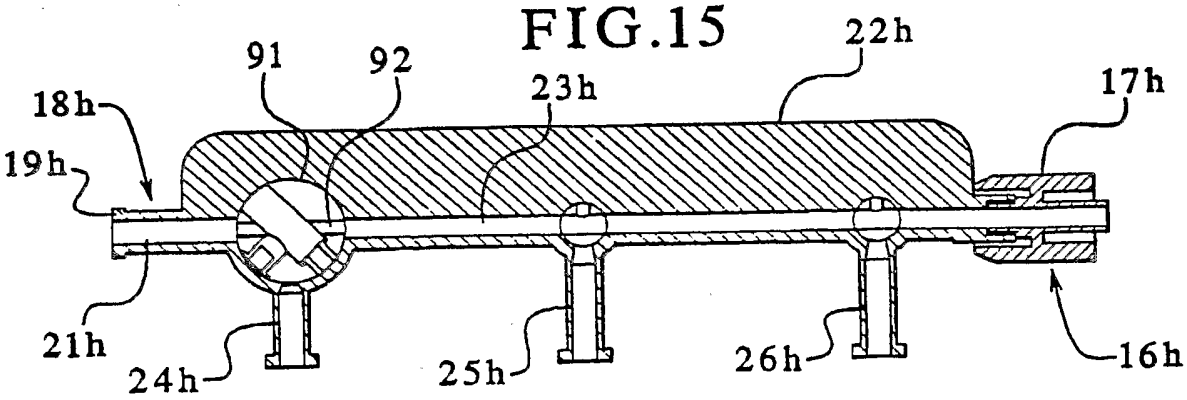


FIG.15



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/004612

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/14 A61M39/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 274 148 A (SHIU MAN FAI) 13 July 1994 (1994-07-13) page 3, line 35 - page 6, line 15 page 7, lines 23-33 figure 1	1-3,22
X	US 2002/038105 A1 (SCHWARTZ ROBERT S ET AL) 28 March 2002 (2002-03-28) page 1, paragraph 11 - page 2, paragraph 20	1-3,22
X	US 4 084 606 A (MITTLEMAN HERBERT) 18 April 1978 (1978-04-18) column 2, line 44 - column 3, line 66 figures	1,2

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 June 2004	17 09. 2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Azaïzia, M

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/004612

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 099 511 A (DEVOS GILLES J ET AL) 8 August 2000 (2000-08-08) the whole document -----	1
A	US 5 356 375 A (HIGLEY ROBERT E) 18 October 1994 (1994-10-18) the whole document -----	1-8, 28-32
A	EP 1 090 650 A (NEMOTO KYORINDO CO LTD) 11 April 2001 (2001-04-11) the whole document -----	1-8, 28-32

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/004612

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 45-48
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy and/or surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see annex

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 45-48

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy and/or surgery

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1(independent), 2-3, 4-8; 22(independent); 28(independent), 29-32

   A manifold which essentially comprises a body in form of a T-connection comprising check-valves such that the check-valves are more protected against damage and/or easily replaced as a unit.

   ---

2. claims: 1(independent), 2-3, 9-12, 14-21; 22(independent), 23-26; 33(independent), 34-36; 37(independent), 38-40; 41(independent), 42-44

   A manifold which essentially comprises a check valve connected to a movable body such that the operating mode of the manifold can be manually selected

   ---

3. claims: 1(independent), 2-3, 13 ; 22(independent), 27

   A manifold which essentially comprises a pair of tube splitters as well as a check valve line and a mechanical valve line such that the excess contrast fluid can be saved instead of wasted

   ---

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/004612

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2274148 A	13-07-1994	WO 9415664 A1	21-07-1994
US 2002038105 A1	28-03-2002	US 6371942 B1	16-04-2002
		AU 6057799 A	10-04-2000
		CA 2345229 A1	30-03-2000
		EP 1115453 A1	18-07-2001
		JP 2002526215 T	20-08-2002
		WO 0016849 A1	30-03-2000
US 4084606 A	18-04-1978	CA 1018422 A1	04-10-1977
		DE 2518091 A1	13-11-1975
		FR 2269010 A1	21-11-1975
		GB 1478564 A	06-07-1977
		JP 1166441 C	08-09-1983
		JP 50145931 A	22-11-1975
		JP 57060506 B	20-12-1982
US 6099511 A	08-08-2000	AU 3749600 A	09-10-2000
		EP 1163022 A1	19-12-2001
		WO 0056392 A1	28-09-2000
US 5356375 A	18-10-1994	NONE	
EP 1090650 A	11-04-2001	JP 2001104492 A	17-04-2001
		EP 1090650 A1	11-04-2001
		US 6650929 B1	18-11-2003