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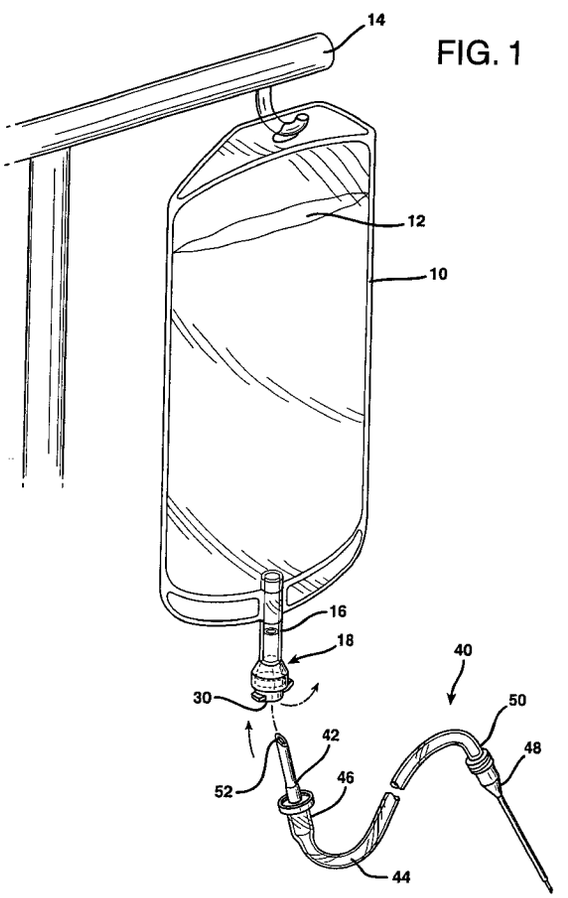
(54) Fluid-flow control apparatus for a medical fluid container

(57) A fluid-flow control apparatus, e.g., for a medical fluid container, includes a primary closure and a secondary closure. The primary closure may include a rupturable membrane while the secondary closure may include a re-positionable cover or lid which protects the primary closure during shipping and storage and which enables or disables fluid flow.

FIG. 1



EP 0 943 348 A2

Description

Background of the Invention

[0001] The present invention relates generally to an apparatus for controlling the flow of fluids and, more specifically, to such apparatus used in connection with a medical fluid container for closing the container and for receiving an external connector to transfer fluid from the container to a patient.

[0002] Medical fluid containers, e.g., medical solution bottles or pouches such as I.V. bags, include at least one initially-closed outlet port through which fluid held within the container passes in order to administer the fluid to a patient. The outlet port, typically referred to as a "spike port" for reasons that will become apparent, is generally affixed to a short length of "connector tubing" that is integral with the container and which extends through a wall, seam, or other portion of the container to allow a desired medical fluid (e.g., a saline or dextrose solution) to be both injected into the container and subsequently removed from the container during administration of the fluid to a patient. The outlet port is affixed to the connector tube after the container has been filled with medical fluid and serves to control, i.e., enable or prevent, the flow of fluid through the connector tube as desired.

[0003] Typically, the outlet port remains in a sealed-closed position during shipping and storage of the medical container in such a manner as to ensure the sterility of the packaged medical fluid. This is generally accomplished by a rupturable membrane that is integral with the outlet port and which prevents any fluid flow out of the container and through the port until the membrane is ruptured. An "administration set" is generally used to rupture the membrane and administer the medical fluid to a patient. The administration set includes a connector or "spike," which is a device having an internal channel therein and capable of rupturing and being held by the membrane in the outlet port, a length of administration tubing connected to the spike at one end of the tubing, and an I.V. needle or catheter connected to the administration tube at the other end. The spike, administration tubing, and needle are in fluid communication with one another so that, once the spike punctures the membrane in the outlet port, fluid from within the medical fluid container flows, either by gravity or with the aid of an in-line pump or pressure cuff applied to the outside of the container, out of the container, through the connector tube, outlet port, and administration set, and into a patient via the needle or catheter which is inserted into a vein or other part of the patient's body.

[0004] Outlet ports for medical containers would desirably meet a number of requirements. First, the outlet port preferably includes a secure cover for fully enclosing the rupturable membrane within the outlet port to maintain the sterility of the membrane during shipment and storage of the container. While many conventional outlet ports include a cover, such covers do not fully cover or enclose the membrane within the outlet port so that dust, dirt, and other contaminates are allowed to come into contact with the membrane during shipment or storage. Other available outlet ports fully enclose the membrane, but the cover is difficult to remove, often requiring a sharp instrument to remove the cover. Accordingly, it would be desirable for an medical container outlet port to have a secure yet easily removable cover.

[0005] Another desired feature in an outlet port would be for the cover to be re-positionable and permanently attached to the outlet port so that the medical fluid container can be re-closed after removal of the administration set. When the contents of the container have been fully dispensed and it is necessary to attach the administration set to a fresh container, some residual amount of fluid remains in the previously used container. In other instances, it is necessary to cease dispensation of the fluid after only a portion of the fluid has been used. In either case, i.e., after the contents of the container have been fully or partially dispensed, it is necessary to remove the administration set and dispose of the used container. During this process, care must taken to ensure that any residual or remaining fluid does not flow out of the container and onto or around the patient for obvious reasons of sanitation, safety, and patient comfort. Currently, medical workers must struggle to prevent used medical containers from leaking while disposing of the same and, in many cases, at the same time attempting to quickly attach the administration set to a fresh container in order to minimize the changeover time during which a patient's administration set is not connected to a container of medical fluid. A medical fluid container with a re-closure feature would greatly facilitate the disposal/change-over process without spillage of the used container by allowing the used container to be quickly re-closed to prevent spillage of residual fluid. The used container could then be quickly and easily disposed of without spillage at the convenience of the medical worker. That is, since the medical worker would not need to be concerned with immediately disposing of the used container and preventing it from spilling on or around the patient, the worker could attend to other matters which would otherwise warrant more immediate attention, such as attaching the administration kit to a fresh container of medical fluid.

[0006] Another requirement for outlet ports for medical fluid containers is that the outlet port must be able to withstand retort sterilization conditions. After a container has been filled with a medical fluid and closed by attachment of an outlet port, the completed container is subjected to a sterilization process prior to sending it to the end user, e.g., a hospital. This ensures that the medical fluid, as packaged in the container, will be substantially free from contamination. Typically, sterilization is conducted by retorting the container in an autoclave at about 250°F for periods of 15 to 30 minutes. Steam is generally used as the heat-transfer medium. The outlet

ports must be able to endure the high temperatures which are encountered during retort sterilization without deterioration or deformation. Preferably, the outlet port will form a secure bond, i.e., a heat-weld, with the connector tube at this time so that other bonding techniques, such as solvent or adhesive bonding, are not necessary. The latter bonding techniques are undesirable for reasons of cost and potential contamination.

[0007] It is also desirable that outlet ports are formed from materials other than polyvinylchloride (PVC), since PVC has been found to possess undesirable properties for use as in medical applications. For example, plasticizer can migrate from the PVC and into the fluid contained within the container so that the fluid may become contaminated by potentially toxic material. A question has also arisen concerning whether PVC itself is adequately chemically neutral to medical fluids. It also been found that PVC becomes brittle at relatively low temperatures.

[0008] Accordingly, there is a need in the art for an outlet port for a medical fluid container that meets the foregoing requirements and overcomes the shortcomings of conventional outlet ports.

Summary of the Invention

[0009] That need is met by the present invention which provides a fluid-flow control apparatus, comprising:

a. a primary closure comprising

1) connector means for connecting to and fluidly communicating with a fluid source, and
2) a first closure device for preventing fluid flow through the connector means but capable of being opened to enable fluid flow; and

b. a secondary closure comprising

1) a housing connected to the primary closure and in fluid communication therewith when the first closure device is opened,
2) a second closure device that is re-positionable and movable in relation to the housing between a closed position to prevent fluid flow through the housing and an open position to enable fluid flow through the housing, and
3) means for attaching the second closure device to the housing.

[0010] The fluid-flow control apparatus can be used in various applications in which a primary and secondary closure would be advantageous, such as, e.g., as the outlet port for a medical fluid container wherein the primary closure includes a rupturable membrane and the secondary closure includes a re-positionable lid or cap which also serves as a cover to protect the primary closure. Such an outlet port comprising a fluid-flow control apparatus in accordance with the present invention overcomes the shortcomings of conventional outlet ports. For example, as noted above, the cover (second closure device) is re-positionable and permanently attached to the outlet port so that the medical fluid container can be re-closed after removal of the administration set to thereby prevent spillage of residual medical fluid. In addition, the second closure device is optionally capable of assuming a loosely-closed position to provide a secure yet easily removable cover to prevent contamination of the first closure device (membrane) during shipping and storage. Moreover, the outlet port can be formed by injection molding from non-PVC materials such as polyolefins, e.g., polypropylenes or polyethylenes, as a single part. Not only is this a simple and economical manufacturing technique, but the proper selection of suitable polymeric materials as discussed below allows the outlet port to withstand retort-sterilization conditions and to form a secure bond, i.e., a heat-weld, with the connector tube of the medical fluid container during sterilization. In this manner, other bonding techniques, such as solvent or adhesive bonding, are not necessary.

Brief Description of the Drawings

[0011]

FIG. 1 is a perspective view of a medical fluid container in accordance with the present invention hanging from an I.V. pole and containing therein a medical fluid, the container including a connector tube with a fluid-flow control apparatus secured to the distal end thereof and serving as an outlet port for the container, the port in the closed position prior to being opened to receive the spike portion of an administration set as also shown in FIG. 1, the administration set including a spike attached at one end to an administration tube and an I.V. needle attached to the opposite end of the administration tube;

FIG. 2 is a partial, cross-sectional view of the container shown in FIG. 1, wherein the administration set has been attached to the container by opening the secondary closure (lid) of the outlet port and inserting the spike portion of the administration set through the primary closure (membrane) of the outlet port to allow the medical fluid in the container to flow through the administration set and into a patient;

FIG. 3 is similar to FIG. 2, except that the container has been drained, the administration set removed from the container, and the lid has been placed in the fully closed position to prevent any residual fluid from draining out of the container;

FIG. 4 is an elevational, cross-sectional view of the fluid-flow control apparatus (outlet port) shown in

FIGS. 1-3, wherein the secondary closure (lid) is in the fully open position;
FIG. 5 is similar to FIG. 4, except that the lid is in an intermediate, loosely-closed position;
FIG. 6 is similar to FIG. 5, except that the lid is in a fully-closed position;
FIG. 7 is a bottom view of the outlet port illustrated in FIG. 4;
FIG. 8 is a bottom view of the outlet port illustrated in FIG. 6; and
FIG. 9 is a partial elevational view of the secondary closure (lid) 30 prior to engaging with housing 28 of the fluid-flow control apparatus.

Detailed Description of the Invention

[0012] FIG. 1 shows a container 10 in accordance with the present invention for a medical fluid 12. Container 10 may be any suitable container for medical fluids such as a rigid bottle or a flexible pouch. Preferably, the container is a flexible pouch. More preferably, the container is made from a flexible polyolefin film, e.g., in accordance with U.S. Patent No. 5,695,840, the disclosure of which is hereby incorporated herein by reference. Any desired medical fluid 12 can be packaged in container 10, e.g., medical solutions such as dextrose or saline solutions or medical emulsions such as lipid emulsions. As shown, container 10 is in the form of an I.V. pouch and is suspended from I.V. pole 14 so that fluid 12 can drain from the container by force of gravity though connector tube 16 and outlet port 18. Preferably, connector tube 16 is bonded to and integral with container 10 and is used to introduce medical fluid 12 into and subsequently drain the fluid 12 out of container 10. The connector tube 16 is preferably formed from a polymeric material, such as, e.g., that disclosed in U.S. Patent No. 4,948,643, and may be heat-welded into the container, e.g., in accordance with U.S. Patent Nos. 5,324,233 or 5,484,375. The disclosures of each of the foregoing three U.S. patents are hereby incorporated herein by reference.

[0013] FIGS. 4-8 illustrate outlet port 18 in greater detail. In accordance with the present invention, outlet port 18 is preferably a fluid-flow control apparatus comprising a primary closure 20 and a secondary closure 22. Primary closure 20 includes a connector means 24 for connecting to and fluidly communicating with medical fluid container 10 or other fluid source (i.e., where the fluid-flow control apparatus is used in other applications), and also a first closure device 26 for preventing fluid flow through the connector means but capable of being opened to enable fluid flow. First closure device 26 preferably comprises a rupturable membrane affixed to connector means 24 such that fluid 12 is prevented from flowing through the connector means until the membrane is ruptured. This will be explained in more detail below.

[0014] Connector means 24 can be any suitable device or mechanism capable of making a mechanical and fluid connection with a fluid source so that the outlet port/fluid-flow control apparatus 18 is able to control the flow of fluid from the fluid source. As shown most clearly in FIGS. 2-3, connector means 24 is a tubular member adapted to engage with and be held by the inside of connector tube 16 of container 10. Preferably, the inner diameter of connector tube 16 and the outer diameter of connector means 24 are such that connector tube 16 holds the connector means 24 securely therein via a pressure fit. More preferably, connector means 24 is also or instead connected to the connector tube 16 via a heat-weld, preferably formed during retort-sterilization of the container 10 after outlet port 18 has been attached to the connector tube. That is, the connector tube 16 and connector means 24 are preferably formed from materials that are capable of welding (fusing) together under the application of heat as applied during retort-sterilization. Examples of suitable materials include, e.g., polypropylene homopolymer or copolymer, ethylene homopolymer or copolymer, and blends of the foregoing materials. This eliminates the extra and possibly contaminating steps of using solvent or adhesive bonding to secure the outlet port to the container.

[0015] As an aside, it should be noted that connector tube 16 is not a required component of container 10. Rather, it is simply a convenient means for facilitating the attachment of outlet port 18 to the container via connector means 24. If desired, connector means 24 can be configured to be connected to the container in a different manner, e.g., by being directly heat-welded to the container such as by heat-welding in-between the two film sheets comprising container 10.

[0016] Secondary closure 22 includes a housing 28, a second closure device 30, and means 32 for attaching second closure device 30 to housing 28. Housing 28 is connected to primary closure 20 and in fluid communication therewith when first closure device 26 is opened. Second closure device 30 is re-positionable and movable in relation to housing 30 between a closed position as shown in FIGS. 1, 3, 5-6 and 8 to prevent fluid flow through the housing, and an open position as shown in FIGS. 2, 4, and 7 to enable fluid flow through the housing. Preferably, the second closure device 30 is capable of assuming a tightly-closed position as shown in FIGS. 3 and 6, and a loosely-closed position, as shown in FIGS. 1 and 5, which is intermediate between the tightly-closed and open positions. Closure device 30 may be of any suitable form or shape. Preferably, the closure device 30 is a lid or cap-like structure of a size and shape corresponding to that of outer portion 29 of housing 28 to allow the closure device to be received and held securely within portion 29 of housing 28 as shown. In this manner, closure device 30 and housing 28 cooperatively form a closure that is sufficient to prevent fluid flow through the housing.

[0017] The fluid-flow control apparatus of the present invention will now be described in further detail in con-

nection with its preferred use as an outlet port for a medical fluid container. As shown in FIG. 1, medical fluid container 10 is un-opened, un-used, and has just been placed on I.V. pole 14 prior to administering medical fluid 12 to a patient (not shown). The container 10 is thus in the same condition as it was in after retort-sterilization and during shipping and storage. In this condition, both the first closure device 26 and the second closure device 30 of outlet port/fluid-flow control apparatus 18 are in closed positions. More specifically, the second closure device 30 is in the loosely-closed position as shown more clearly in FIG. 5. During retort, shipping, and storage, first closure device 26 prevents medical fluid 12 from exiting container 10 via connector tube 16, while second closure device 30 prevents dust, dirt, and other contaminates from coming into contact with first closure device 26, thereby maintaining the sterility of closure device 26. In order to accomplish this without making it difficult for a medical worker to subsequently move the second closure device 30 to the open position, the device 30 is retorted, shipped, and stored in a loosely-closed position as shown in FIGS. 1 and 5.

[0018] Preferably, the closure device 30 is retained in the loosely-closed position by providing the closure device with a plurality of radially-extending ribs 33 (see FIGS. 7 and 9) at the leading portion 34 of device 30. The ribs 33 truncate a spaced distance "d" from main portion 35 of closure device 30. Corresponding in size and shape with distance "d" of closure device 30, housing 28 includes a lip 36 at the outer end 29 thereof. In this manner, when closure device 30 is moved to the loosely-closed position as shown most clearly in FIG. 5, ribs 33 interlock with lip 36 to secure the closure device in that position. Preferably, the housing 28 and leading portion 34 of closure device 30 are formed from polymeric materials that form a slight tack-weld with one another during the heat of retort-sterilization to provide an extra measure of closure. However, the interlocking of ribs 33 with lip 36 and/or tack-welding thereof preferably retains the closure device 30 within housing 28 with a sufficiently low force that a medical worker can readily move the device 30 to the open position as desired. It is preferred that tab 37 be included on device 30 to assist the medical worker in opening the device 30 by providing a surface under which to place a thumb or finger. Tab 37 and protrusion 38 preferably also act as "stops" to prevent closure device from being inserted too far into housing 28 when the closure device is subsequently moved to the tightly-closed position as illustrated in FIG. 6.

[0019] It is to be understood that the ribs/lip interlocking configuration as presently illustrated is merely one means for retaining the closure device 30 in a loosely-closed position. For example, ribs 33 alone without a corresponding lip 36 may often be sufficient, particularly when the container 10 is to be retort-sterilized immediately after the container is filled with fluid to thereby cause a tack-weld between the ribs and the housing. A number of other configurations are also possible and the present invention is not intended to be limited to any particular one.

[0020] Administration set 40, as shown in FIG. 1, is positioned for insertion into container 10. The administration set includes a "spike" connector 42, a length of administration tubing 44 fluidly connected to the spike connector at one end 46 of the tubing 44, and an I.V. needle or catheter 48 fluidly connected to the administration tube 44 at the other end 50. The needle or catheter 48 is inserted into a patient (not shown) for delivery of fluid 12 thereto. All components of the administration set are in fluid communication with one another.

[0021] Reference is now made to FIGS. 2 and 4. Fluid-flow control apparatus/outlet port 18 is preferably adapted to engage and hold an external connector for transfer of fluid 12 from container 10 and into the external connector. As shown in FIG. 2, this is preferably accomplished when first closure device 26 is a rupturable membrane. The spike connector 42 is preferably a device having an internal channel 54 therein and capable of rupturing and being held by the membrane or first closure device 26 after the second closure device 30 has been moved to the open position as shown. Thus, after opening closure device 30, spike connector 42 is inserted into housing 28 of outlet port 18, through membrane/first closure device 26 which ruptures when sufficient pressure is exerted by the sharpened end 52 of spike 42, and into the connector means 24 of outlet port 18 and connector tube 16 of container 10. The ruptured membrane of first closure device 26 preferably maintains sufficient compressive force against the spike 42 to hold it in the position shown in FIG. 2. In this manner, with both first and second closure devices 26 and 30 are opened, fluid 12 flows from container 10, through administration tube 44 via spike connector 42 in fluid communication therewith, and into a patient via I.V. needle 48.

[0022] Reference is now made to FIGS. 3 and 6. After the medical fluid 12 has been fully or partially dispensed from container 10, the administration set 40 is removed, i.e., spike connector 42 is pulled out of outlet port 18, and the container is disposed. As indicated in FIG. 3, membrane/first closure device 26 has been ruptured. Thus, in order to facilitate the disposal process without spilling any residual or intentionally-remaining fluid from container 10, the second closure device 30 of outlet port 18 is re-positionable and can be moved to a closed position as shown in order to re-close the container. Since the outlet port 18 will, in most instances, not need to be subsequently reopened, the closure device 30 can be moved to the more secure, tightly-closed position as shown in FIGS. 3 and 6. Advantageously, attachment means 32 ensures that the closure device 30 is not unintentionally discarded or misplaced so that the device is readily available for closure of outlet port 18 at the convenience of the medical worker. The attachment means 32 can be any suitable device or mechanism that

allows the closure device 30 to be freely movable and re-positionable between the various open and closed positions shown in the Figures. Means 32 should, for example, allow closure device 30 to be opened sufficiently as to not interfere with the insertion of spike connector 42 into outlet port 18. Various hinge-like structures that pivotally join the closure device 30 with housing 28, for example, would be suitable. A preferred structure is a flexible, polymeric hinge as shown.

[0023] The fluid-flow control apparatus in accordance with the present invention, such as outlet port 18 as described above, may be formed from any desired and suitable material and may be made by any suitable process. For reasons of economy and ease of manufacture, the fluid-flow control apparatus is preferably a single, molded part formed from a polymeric material, e.g., by an injection molding process. Preferred polymeric materials include polypropylene homopolymer or copolymer, ethylene homopolymer or copolymer, and blends of the foregoing materials. A preferred polypropylene copolymer is propylene/ethylene copolymer. Preferred polyethylenes are ethylene/alpha-olefin copolymers, including both heterogeneous ethylene/alpha-olefins (i.e., made by conventional Ziegler-Natta catalysis) and homogeneous ethylene/ alpha-olefins (i.e., made by single-site (e.g., metallocene) catalysis). Blends of polypropylene homopolymer or propylene/ethylene copolymer with ethylene/alpha-olefin copolymer are also preferred. If such a blend is employed, the polypropylene component preferably ranges from about 70 to about 99 weight percent while the ethylene/alpha-olefin copolymer ranges from about 30 to about 1 weight percent.

[0024] The foregoing description of preferred embodiments of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed, and modifications and variations are possible in light of the above teachings or may be acquired from practice of the invention.

Claims

1. A fluid-flow control apparatus, comprising:

a. a primary closure comprising

1) connector means for connecting to and fluidly communicating with a fluid source, and
2) a first closure device for preventing fluid flow through said connector means but capable of being opened to enable fluid flow; and

b. a secondary closure comprising

1) a housing connected to said primary closure and in fluid communication therewith when said first closure device is opened,
2) a second closure device that is re-positionable and movable in relation to said housing between a closed position to prevent fluid flow through said housing and an open position to enable fluid flow through said housing, and
3) means for attaching said second closure device to said housing.

2. The apparatus of claim 1, wherein said second closure device is capable of assuming a tightly-closed position and a loosely-closed position, said loosely-closed position being intermediate between said tightly-closed position and said open position.

3. The apparatus of claim 1, wherein said apparatus is adapted to engage and hold an external connector for transfer of fluid from said fluid source and into said external connector.

4. The apparatus of claim 3, wherein said fluid source is a container for a medical fluid and said external connector is affixed to and in fluid communication with a tube for delivery of said medical fluid to a patient.

5. The apparatus of claim 1, wherein said first closure device comprises a rupturable membrane affixed to said connector means such that fluid is prevented from flowing therethrough until said membrane is ruptured.

6. The apparatus of claim 5, wherein said membrane is adapted to be ruptured by and then hold an external connector for transfer of fluid from said fluid source and into said external connector.

7. The apparatus of claim 6, wherein said fluid source is a container for a medical fluid and said external connector is affixed to and in fluid communication with a tube for delivery of said medical fluid to a patient.

8. The apparatus of claim 1, wherein said apparatus is a single molded part formed from a polymeric material.

9. The apparatus of claim 8, wherein said polymeric material is selected from the group consisting of polypropylene homopolymer or copolymer, ethylene homopolymer or copolymer, and blends of the foregoing materials.

10. The apparatus of claim 1, wherein said fluid source is a container for a medical fluid and said connector means is connected to said container via a heat-

weld.

11. A container for a medical fluid comprising a fluid-flow control apparatus, said fluid-flow control apparatus comprising:

a. a primary closure comprising

1) connector means for connecting to and fluidly communicating with said medical fluid container, and
2) a first closure device for preventing fluid flow through said connector means but capable of being opened to enable fluid flow; and

b. a secondary closure comprising

1) a housing connected to said primary closure and in fluid communication therewith when said first closure device is opened,
2) a second closure device that is re-positionable and movable in relation to said housing between a closed position to prevent fluid flow through said housing and an open position to enable fluid flow through said housing, and
3) means for attaching said second closure device to said housing.

12. The medical fluid container of claim 11, wherein said second closure device is capable of assuming a tightly-closed position and a loosely-closed position, said loosely-closed position being intermediate between said tightly-closed position and said open position.

13. The medical fluid container of claim 11, wherein said fluid-flow apparatus is adapted to engage and hold an external connector for transfer of fluid from said medical fluid container and into said external connector.

14. The medical fluid container of claim 13, wherein said external connector is affixed to and in fluid communication with a tube for delivery of said medical fluid to a patient.

15. The medical fluid container of claim 11, wherein said first closure device comprises a rupturable membrane affixed to said connector means such that fluid is prevented from flowing therethrough until said membrane is ruptured.

16. The medical fluid container of claim 15, wherein said membrane is adapted to be ruptured by and then hold an external connector for transfer of fluid from said medical fluid container and into said external connector.

17. The medical fluid container of claim 16, wherein said external connector is affixed to and in fluid communication with a tube for delivery of said medical fluid to a patient.

18. The medical fluid container of claim 11, wherein said fluid-flow control apparatus is a single, molded part formed from a polymeric material.

19. The medical fluid container of claim 18, wherein said polymeric material is selected from the group consisting of polypropylene homopolymer or copolymer, ethylene homopolymer or copolymer, and blends of the foregoing materials.

20. The medical fluid container of claim 1, wherein said connector means is connected to said medical fluid container via a heat-weld.

FIG. 1

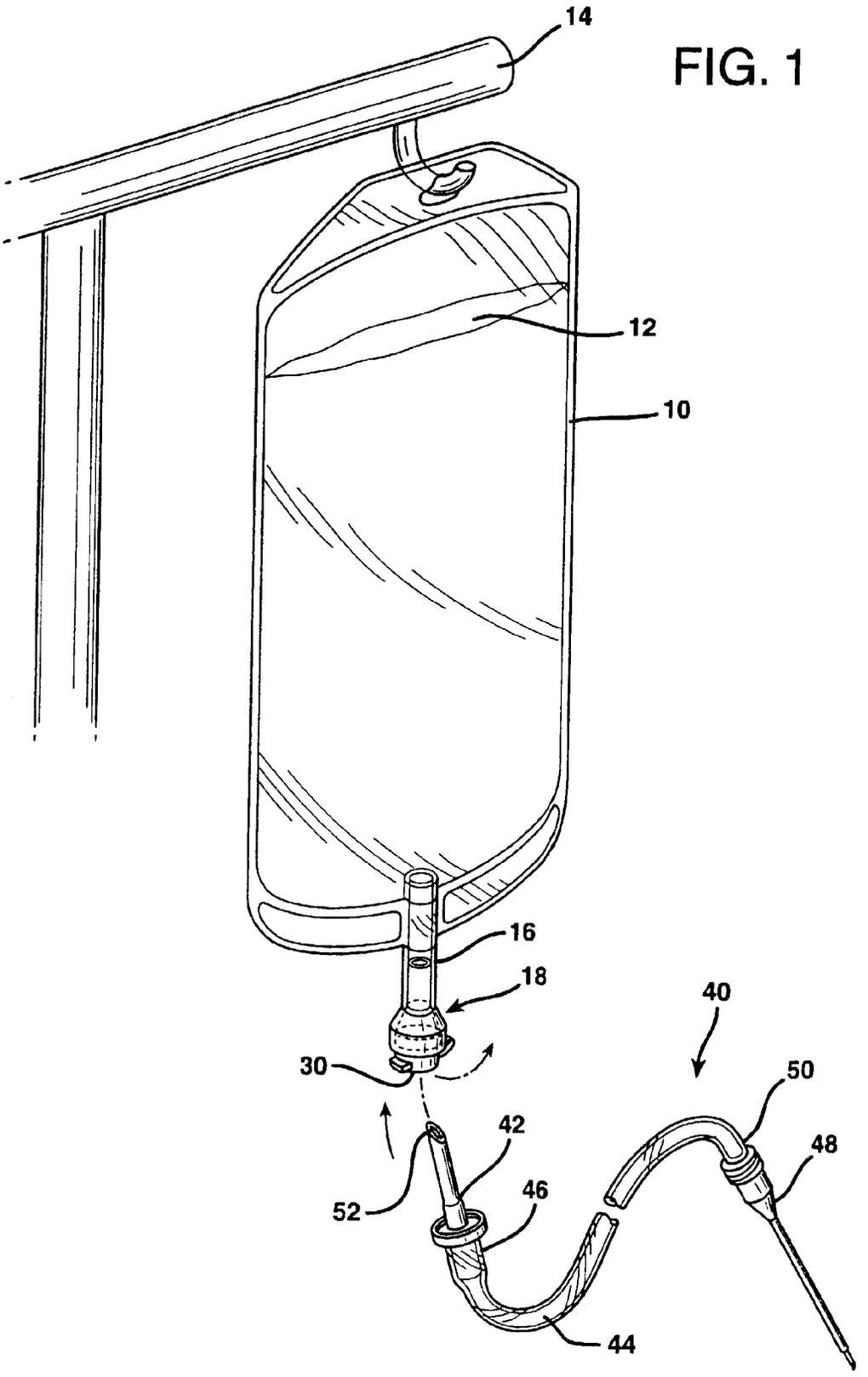


FIG. 2

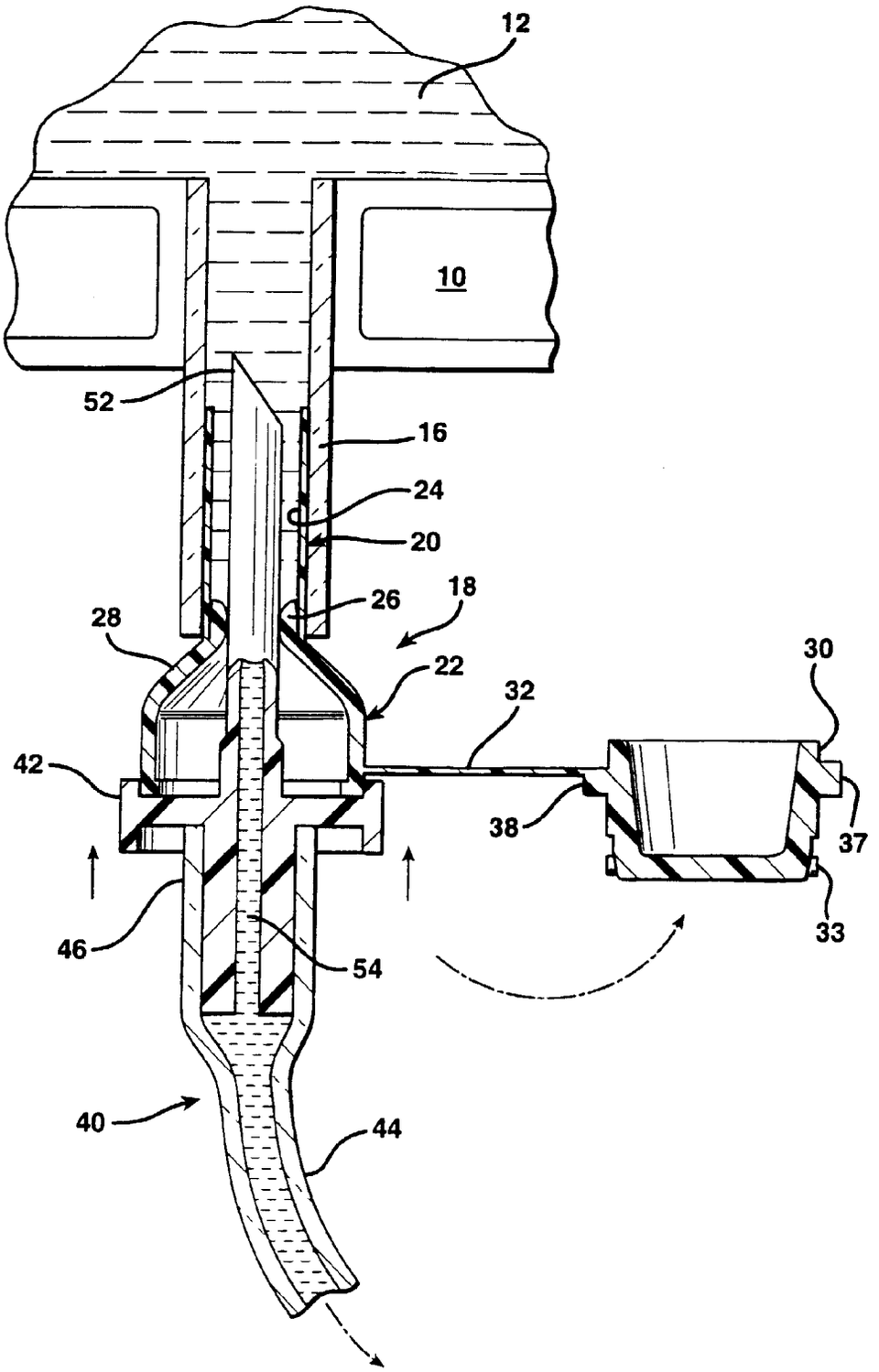


FIG. 3

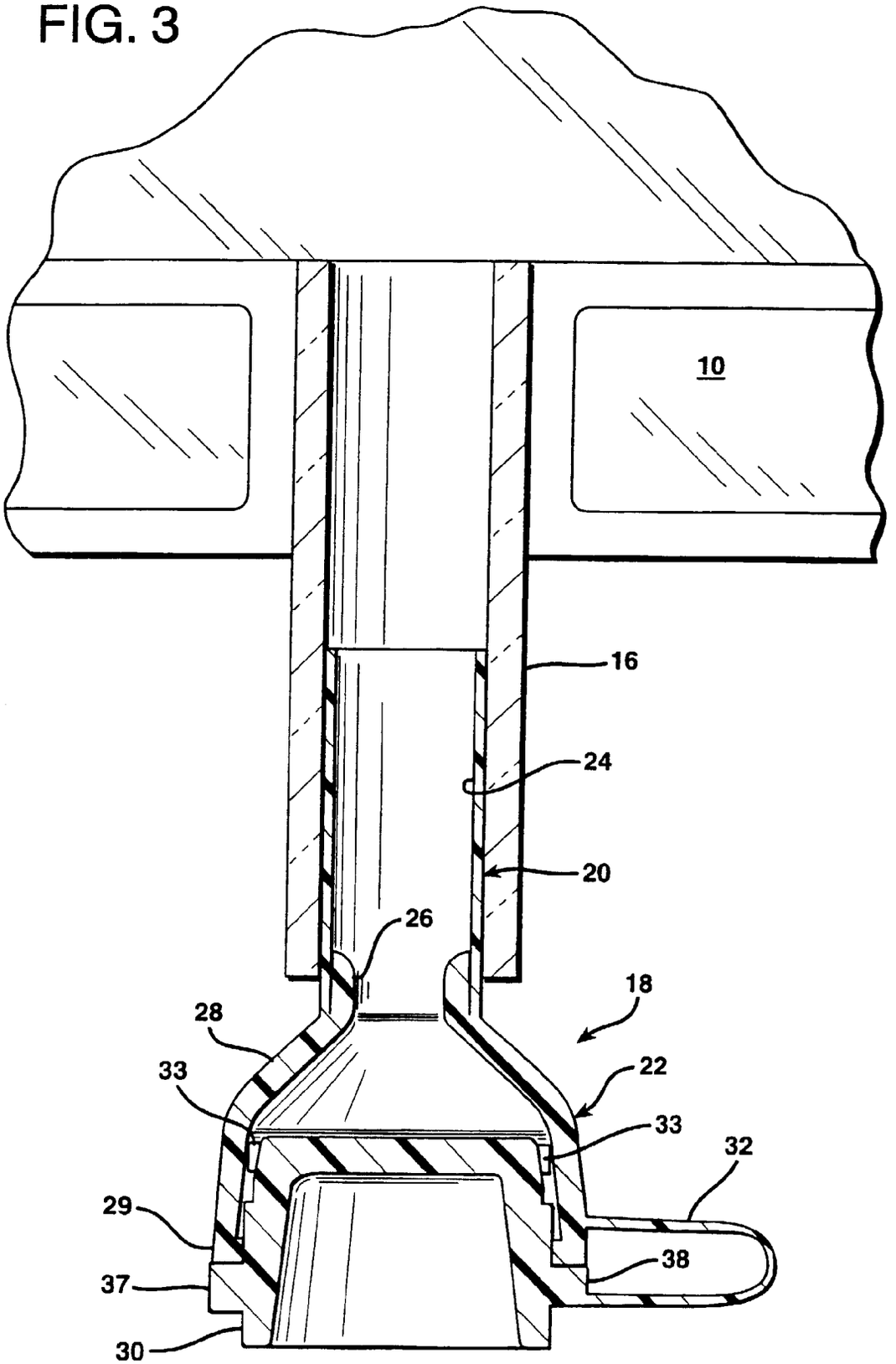


FIG. 4

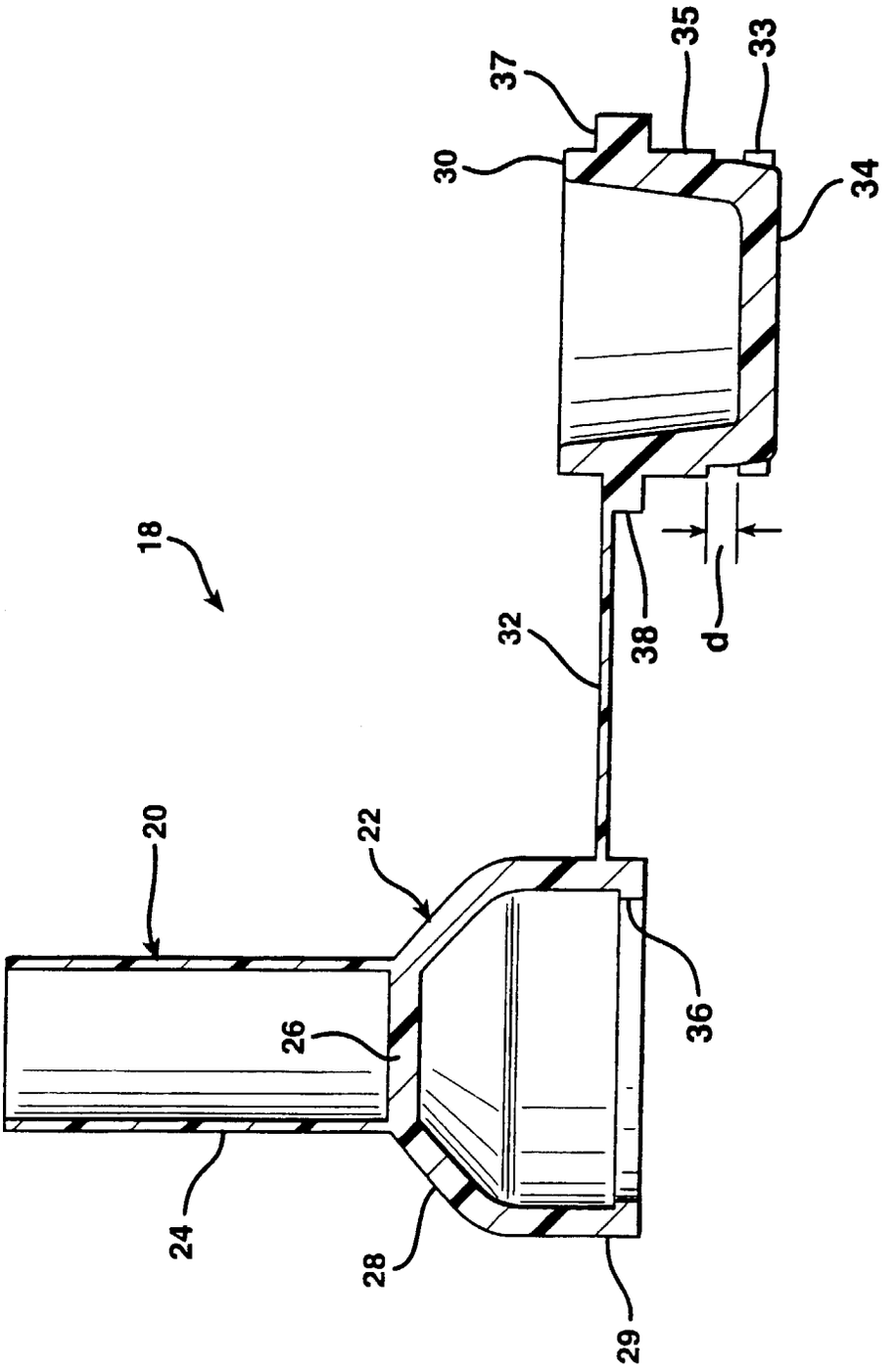


FIG. 6

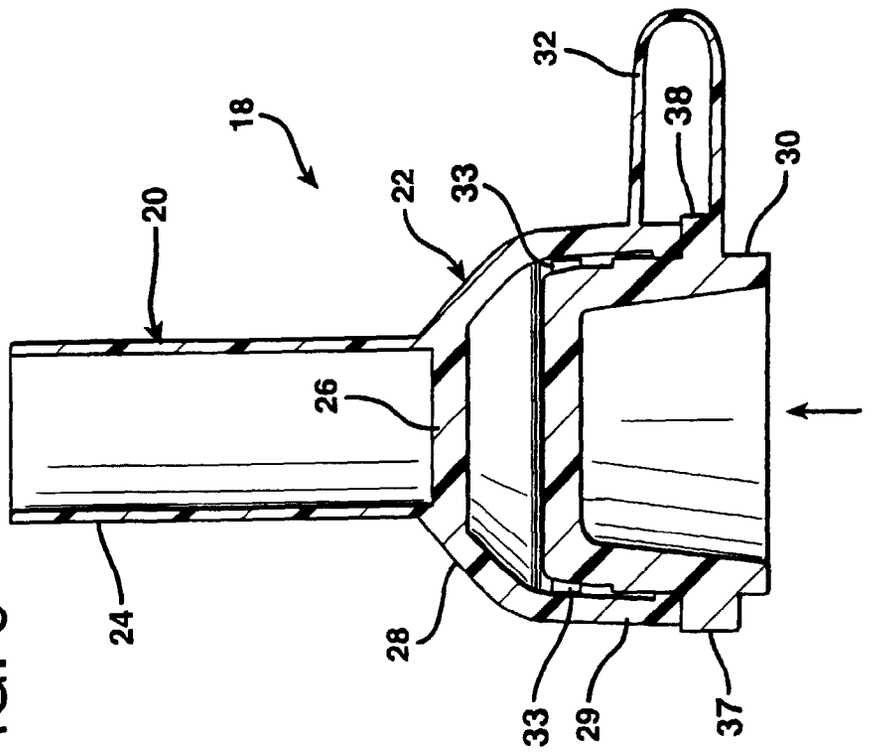

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FIG. 5

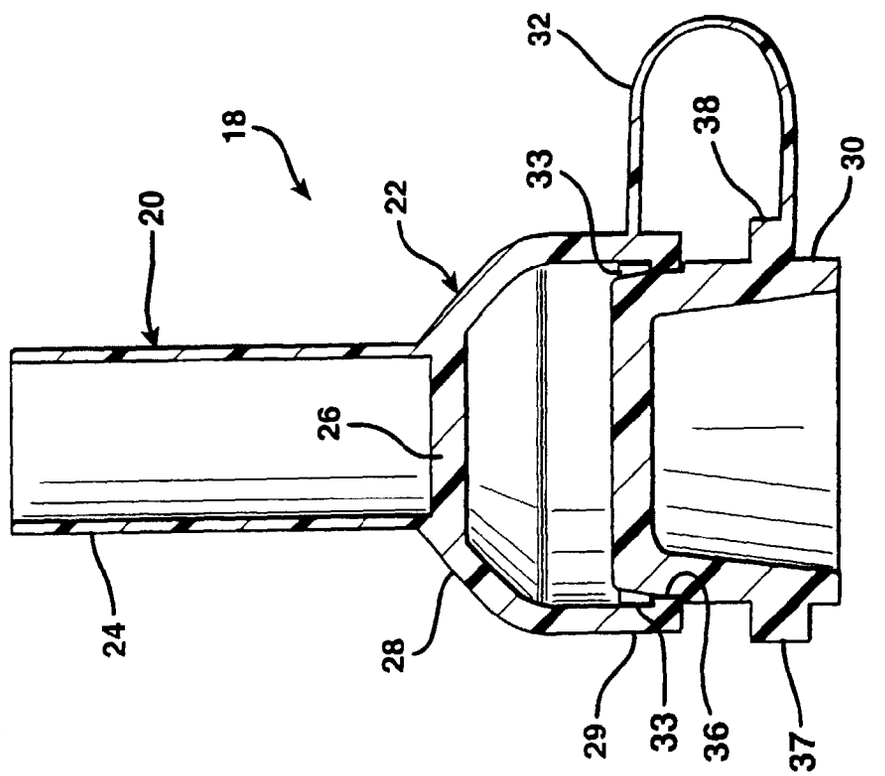
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FIG. 7

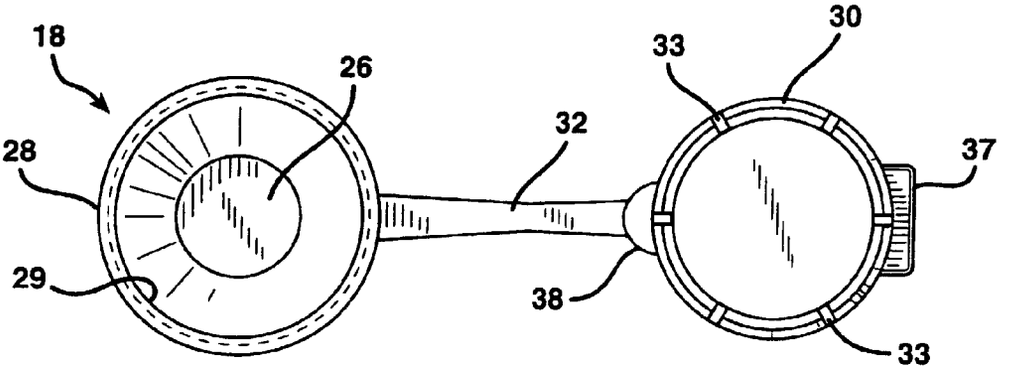

FIG. 8

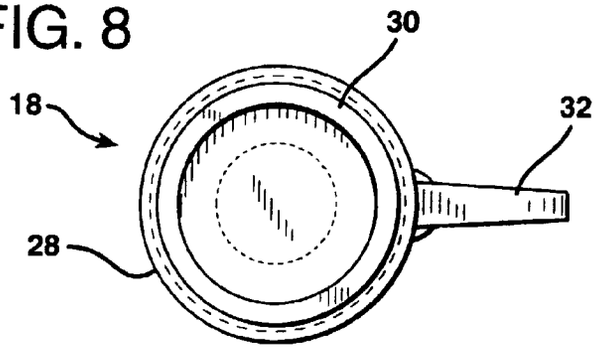

FIG. 9