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ENTERAL BOTTLE CAP WITH VENT VALVE

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(56) Prior Art Documents
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GB 2105695

(57) Claim

1. A connecting component arranged for attachment to the opening of a fluid container, said connecting component including a circular body portion having a top surface, a bottom rim surface and a bottom inside surface for covering said container opening, a pointed projecting member extending from said bottom inside surface toward said container at a position on said inside surface spaced apart from the ~~horizontal center~~ central axis of said body portion, a fluid channel passing through said body portion and said projecting member and wherein said fluid channel has a fluid receiving opening therein and wherein said connecting component further includes an air passageway in said body portion extending through said body portion from said bottom inside surface to said top surface wherein said air passageway includes a flexible member extending across said air passage and biased into a closed position across said air passage, said flexible member for selectively allowing air to pass through said air passageway.

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Complete Specification for the invention entitled:

ENTERAL BOTTLE CAP WITH VENT VALVE

Our Ref : 157900
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The following statement is a full description of this invention, including the best method of performing it known to applicant(s):

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ENTERAL BOTTLE CAP WITH VENT VALVE

Field of the Invention

The present invention relates to a connection component designed to be mounted on a tubing assembly for connecting the tubing assembly to a prefilled, foil-sealed container, and in particular to a connection component which includes a spike for penetrating the foil seal and an air vent having a flexible membrane therein. The present invention is also generally related to the subject matter of a Canadian patent application filed by Sherwood Medical Company on March 2, 1988, Serial No. 560,344 entitled "Vented Spike Connection Component".

Background of the Invention

In an enteral fluid delivery system for a patient, there is a need to provide a connecting component which will effect a quick connection of the fluid delivery set to a prefilled, foil-sealed container containing enteral fluid. In these fluid delivery systems, the connecting component is preferably a cap, which replaces the shipping cap on the prefilled container when the container is connected to the fluid delivery set for administration of the enteral fluid to the patient. The connecting component preferably includes a means for perforating the foil diaphragm on the container during attachment of the fluid delivery set to the container to simplify the assembly of the delivery system. It is further desireable that the connecting component provide a means to allow air to vent into the container as the enteral fluid flows from the container. This venting means should be designed to allow filtered air to flow into the container while preventing the air from flowing into and through the fluid passageway. Additionally, the venting means must prevent the passage of enteral fluid from the container through the air passageway.

One approach is illustrated in U.S. Patent 3,542,240, issued to Solowey on November 24, 1970. The first embodiment of Solowey illustrates the use of a single, centrally

positioned projection designed to puncture the diaphragm of the container. The projection includes parallel air and liquid passageways therein to allow vented air to flow into the container while the fluid is administered to the patient. Additionally, Solowey illustrates the use of a check valve consisting of a steel ball and coil spring movably positioned within the air passageway. Finally, the Solowey device includes a circular flange on the bottle which engages a flexible sleeve on the cap to prevent the removal of the cap during the operation of the administration set. Another embodiment of Solowey illustrates the use of a pair of parallel, spaced apart air and liquid passageways therein.

The present invention seeks to provide a connection component for effecting a quick and reliable coupling between the fluid delivery set and the prefilled, sealed container. The present invention minimizes the potential for contamination of the container by providing an efficient means for puncturing the foil diaphragm of the container while simultaneously tearing the diaphragm to create a passageway therein to allow for the flow of vented filtered air therethrough.

Summary of the Invention

An advantage of the present invention is that the connection component will puncture the protective diaphragm on the enteral fluid containing container as the connection component is being attached to the top of the container.

Another advantage of the present invention is that the air passageway is spaced apart from the liquid passageway to prevent the vented air from flowing into the liquid passageway.

Another advantage of the present invention is that the air passageway includes a flexible membrane therein to allow filtered air to flow into the enteral fluid container while preventing enteral fluid from leaking out of the container through the air passageway.

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Summary of the Invention

According to the present invention, there is provided a connecting component arranged for attachment to the opening of a fluid container, said connecting component including a circular body portion having a top surface, a bottom rim surface and a bottom inside surface for covering said container opening, a pointed projecting member extending from said bottom inside surface toward said container at a position on said inside surface spaced apart from the ~~horizontal center~~ central axis of said body portion, a fluid channel passing through said body portion and said projecting member and wherein said fluid channel has a fluid receiving opening therein and wherein said connecting component further includes an air passageway in said body portion extending through said body portion from said bottom inside surface to said top surface wherein said air passageway includes a flexible member extending across said air passage and biased into a closed position across said air passage, said flexible member for selectively allowing air to pass through said air passageway.

The present invention also provides a connection component for connecting a fluid delivery set to a fluid containing container having a top opening and a threaded connection thereon wherein the connection component comprises:

a cap shaped connection component including a circular body portion having top and bottom surfaces and a cylindrical rim portion extending from said bottom surface of said body portion;

a pointed projecting member having an apex and an opposing side opposite said apex wherein said projecting member extends from said bottom surface of said body portion beyond the edge of said rim portion farthest from said bottom surface, and wherein said projecting member is offset from the central axis of said body portion, said projecting member having a fluid passageway therein passing through said body portion, said fluid passageway having a fluid receiving opening and wherein said apex is located nearest to the central axis of said body portion and wherein said apex extends further from said body portion than the fluid receiving opening;

said body portion having an air passageway extending

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through said body portion and offset from the central axis of said body portion and wherein said air passageway is located on a line through the central axis of said body portion opposite said projecting member; and

a flexible member extending across said air passage and biased into a closed position across said air passage, said flexible member in flow communication with said air passageway to selectively allow air to flow into said container while preventing fluid from passing therethrough.

Furthermore the present invention provides a fluid delivery system consisting of a fluid containing container having a top opening, a pierceable protective diaphragm covering said opening, a connection neck for receiving a connection component thereon and a tubing set, wherein said connection component comprises:

a cap shaped member including a circular body portion having top and bottom surfaces and a cylindrical rim portion extending away from said bottom surface, said rim portion threadedly receiving the connecting neck on the container therein;

a pointed projecting member extending away from said bottom surface of said body portion, said projecting member having an apex laterally offset from the central axis of said body portion, said projecting member having a fluid receiving passageway therein extending through said body portion, said passageway having a fluid receiving opening therein which opens on said bottom surface of said projecting member, said projection member being cylindrical, said apex extending beyond said fluid receiving opening so that said apex pierces the diaphragm of the container to form an opening in the diaphragm larger than the diameter of said projecting member upon the connection of said cap shaped member to said container;

an air passageway in said body portion spaced laterally from the central axis of said body portion opposite said projecting member; and

wherein said air passageway extends through said body portion from said bottom surface to said top surface and includes a flexible member extending across said air passage and biased into a closed position across said air passage,

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said flexible member in flow communication with said air passageway to allow air to selectively flow through said air passageway into said container while preventing the flow of liquid therethrough.

An advantage of the present invention is that the connection component will puncture the protective diaphragm on the enteral fluid containing container as the connection component is being attached to the top of the container.

Another advantage of the present invention is that the air passageway is spaced apart from the liquid passageway to prevent the vented air from flowing into the liquid passageway.

Another advantage of an embodiment of the present invention is that the air passageway includes a flexible membrane therein to allow filtered air to flow into the enteral fluid container while preventing enteral fluid from leaking out of the container through the air passageway.

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Another advantage of the present invention is that the spike member is offset from the center of the cap so that as the cap is attached to the container, the spike member will tear the diaphragm to create a passageway therein for the vented air.

Another advantage of the present invention is that the opening of the air passageway is recessed from the diaphragm on the container to ensure that the diaphragm does not obstruct the flow of air from the air passageway.

The present invention provides a connection component which consists primarily of a cap specifically designed for attachment to the top opening of an enteral fluid containing container. The cap includes a spike member which extends inwardly from the body of the cap toward the container. The spike member is offset from the center of the cap body and includes a fluid passageway therein to allow for fluid communication between the container and the fluid delivery set. The cap further includes an air vent offset from the center of the cap body and oriented opposite the opening of the spike member. A flexible membrane is positioned adjacent to the inner opening of the air vent to allow the passage of air into the container while preventing enteral fluid from leaking out of the container through the air vent.

Brief Description of the Drawings

Fig. 1 is an enlarged cross-sectional view of the connection component of the present invention;

Fig. 2 is an enlarged cross-sectional view of the flexible disk and air passageway of the present invention shown in Fig. 1;

Fig. 3 is a top view of the foil diaphragm of the prefilled container after the diaphragm has been penetrated by the connection component of the present invention;

Fig. 4 is an exploded perspective view, partly in section taken along lines 4--4 of Fig. 6;

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Fig. 5 is a partial cut-away view illustrating the connection component attached to the container and tubing of the present invention; and

Fig. 6 is a bottom view of the connection component of the present invention.

Fig. 7 is a partial cut-away view illustrating the connection component piercing the foil diaphragm of the prefilled container.

Detailed Description of the Preferred Embodiment

One form of the present invention is illustrated in the drawings and is described generally herein as a connection component or cap 10. The cap 10 includes a top surface 12, a bottom inside surface 14 and a rim 16 adapted to be removably mounted on the neck 18 of a prefilled container 20. The cap 10 is preferably of a one-piece construction formed from a molded plastic such as styrene.

The top surface 12 includes a pair of cylindrically shaped first and second members, 22 and 24, respectively, extending outwardly from the top surface 12 of the cap 10. Both members, 22 and 24, are offset from the central axis C1 of the cap 10, with the second member 24 being positioned midway between the central axis C1 of the cap 10 and one side of the cap 10, while the first member 22 is offset slightly from the central axis C1 of the cap 10. The first member 22 includes an internal liquid passageway 26 and is adapted to be attached to a plastic tubing 28 which, along with the cap 10, forms part of the fluid delivery set. The second member 24 includes an internal air passageway 30 and a standard filter (not shown) which allows filtered air to flow into the prefilled container 20.

The bottom inner surface 14 of the cap 10 includes a spike member 32 which is formed by truncating the cylindrically shaped first member 22 at an angle starting at a location near the bottom inside surface 14 of the cap 10 and extending to an apex 34. The apex 34 of the spike member 32 extends beyond the bottom edge of the rim 16. The apex 34 is aligned on the bottom inside surface 14 of the cap 10

adjacent to the central axis C1 of the cap 10 while the opposing side 36 of the spike member 32 is positioned away from the central axis C1 of the cap 10 and in alignment with the apex 34 and central axis C1. The liquid passageway 26 in the first member 22 extends through spike member 32 to allow fluid communication between the tubing 28 and the container 20.

The bottom inside surface 14 of the cap 10 further includes first and second recesses, 42 and 44 respectively, and a flexible disk 38. The first recess 42 extends along nearly the entire bottom inside surface 14 of the cap 10 to provide a spaced apart relationship between the bottom inside surface 14 of the cap 10 and the diaphragm 46 on the container 20. The second recess 44 is positioned generally between the apex 34 of the spike member 32 and the rim 16 of the cap 10. The air passageway 30 of the second member 24 opens into the second recess 44 between the center of the second recess 44 and the rim 16 of the cap 10. The flexible disk 38 is retained in the second recess 44 by a spike shaped retainer 40. The retainer 40 is melted thermally or ultrasonically to retain the flexible disk 38 in the second recess 44. The flexible disk 38 is preferably constructed of a soft plastic or elastomeric, non-porous, material and is designed to overlap the rim of the second recess 44.

As illustrated in the drawings, the cap 10 has a central axis designated as C1, about which the cap 10 is rotated for attachment to the container 20. As further illustrated in the drawings, first and second members 22 and 24, respectively, are both offset from the central axis C1 and extend upwardly from the top surface 12 of the cap 10. Additionally, the apex 34 of spike member 32 on the bottom inside surface 14 of the cap 10 is oriented so that the opening of the liquid passageway 26 faces away from the opening of the second member 24. The center of the liquid passageway 26 in the first member 22 is designated in the drawings as axis C2. Axis C2 of the liquid passageway 26 is offset from the central axis C1 by approximately 0.1 inch (2.5 mm). The center of the air passageway 30 in the second

member 24 is designated in the drawings as axis C3. Axis C3 of the air passageway 30 is offset from the axis C2 of the liquid passageway 26 by approximately 0.5 inch (12.7 mm). This aligned separation of the respective passageways, along with the orientation of the apex 34 on the spike member 32 effectively prevents air bubbles from flowing directly into the liquid passageway 26 of the first member 22.

With this preferred orientation of the spike member 32 and the first and second recesses, 42 and 44 respectively, of the present invention, air is drawn into the air passageway 30 of the second member 24 without significant obstruction by the diaphragm 46. As illustrated in Fig. 3, the diaphragm 46 is deformed and torn by the offset spike member 32 to provide an opening in the diaphragm 46 which is sufficiently extended to permit fluid to flow freely through the liquid passageway 26 in the first member 22 into the tubing 28 and to allow air to flow freely through the second member 24 into the container 20. The first recess 42 ensures that the flexible disk 38 will be spaced apart from the diaphragm 46 a sufficient distance so that the flexible disk 38 is allowed to flex in response to the passage of air from the air passageway 30 into the container 20. The second recess 44 causes the flexible disk 38 to be biased slightly towards the inside of the container 20 and ensures that the air bubbles are deflected away from the liquid passageway 26.

The cap 10 of the present invention forms an integral part of an improved fluid delivery set. The enteral fluid containing container 20 is typically delivered with a specially designed shipping cap which must be removed prior to the attachment of the cap 10 on the container 20. In the preferred embodiment, the cap 10 is threaded onto the neck 18 of the container 20. As the cap 10 is threaded onto the container 20, the spike member 32 pierces the protective diaphragm 46 in the manner illustrated in Fig. 3. Next, the tubing 28 is attached to the first member 22 on the top surface 12 of the cap 10. The container 20 is then inverted and the air is removed from the tubing 28. Finally, the

safety cap 48 is removed from the second member 24 to allow the air passageway 30 to communicate through a filter (not shown) between the atmosphere and the interior of the container 20. The delivery set is now ready to administer the enteral fluid to the patient.

In operation, the enteral fluid flows from the container 20 through the liquid passageway 26 into the tubing 28. As this occurs, filtered air is drawn into the air passageway 30 through the second member 24. The air will flow through the air passageway 30 and bubble past the flexible disk 38. By extending the flexible disk 38 beyond the perimeter of the second recess 44, the flexible disk 38 operates as a flexible barrier against the bottom inside surface 14 of the cap 10 to direct the air bubbles away from the opening of the liquid passageway 26 in the container 20. The flexible disk 38 also prevents the loss of enteral fluid from the container 20 through the air passageway 30 by pressing against the second recess 44 whenever the pressure inside the container 20 is greater than the atmospheric pressure.

The detailed description of the preferred embodiment of the invention having been set forth herein for the purpose of explaining the principles thereof, it is known that there may be modifications, variations or changes in the invention without departing from the proper scope of the invention as defined by the claims attached hereto.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A connecting component arranged for attachment to the opening of a fluid container, said connecting component including a circular body portion having a top surface, a bottom rim surface and a bottom inside surface for covering said container opening, a pointed projecting member extending from said bottom inside surface toward said container at a position on said inside surface spaced apart from the ~~horizontal center~~ central axis of said body portion, a fluid channel passing through said body portion and said projecting member and wherein said fluid channel has a fluid receiving opening therein and wherein said connecting component further includes an air passageway in said body portion extending through said body portion from said bottom inside surface to said top surface wherein said air passageway includes a flexible member extending across said air passage and biased into a closed position across said air passage, said flexible member for selectively allowing air to pass through said air passageway.

2. The connection component as described in claim 1, where said projecting member is tapered and has an opposing side opposite the apex of said pointed projecting member and wherein said apex is located nearest to the central axis of said body portion and wherein said fluid receiving opening opens on said opposing side of said projecting member away from the central axis of said body portion.

3. The connecting component as defined in claim 1 or claim 2, wherein said air passageway is positioned in said body portion offset from said projecting member and the central axis of said body portion and wherein said air passageway is positioned generally linearly between the central axis of said body portion and said bottom rim surface opposite said projecting member.

4. The connecting component of any one of claims 1 to 3, wherein said projecting member is spaced laterally from the central axis of said body portion opposite said air passageway and wherein said fluid receiving opening of said projecting

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member opens away from said air passageway and wherein the apex of said projecting member is located on said projecting member farthest from said air passageway and extends beyond the bottom rim surface of the connecting component.

5. A connection component for connecting a fluid delivery set to a fluid containing container having a top opening and a threaded connection thereon wherein the connection component comprises:

a cap shaped connection component including a circular body portion having top and bottom surfaces and a cylindrical rim portion extending from said bottom surface of said body portion;

a pointed projecting member having an apex and an opposing side opposite said apex wherein said projecting member extends from said bottom surface of said body portion beyond the edge of said rim portion farthest from said bottom surface, and wherein said projecting member is offset from the central axis of said body portion, said projecting member having a fluid passageway therein passing through said body portion, said fluid passageway having a fluid receiving opening and wherein said apex is located nearest to the central axis of said body portion and wherein said apex extends further from said body portion than the fluid receiving opening;

said body portion having an air passageway extending through said body portion and offset from the central axis of said body portion and wherein said air passageway is located on a line through the central axis of said body portion opposite said projecting member; and

a flexible member extending across said air passage and biased into a closed position across said air passage, said flexible member in flow communication with said air passageway to selectively allow air to flow into said container while preventing fluid from passing therethrough.

6. The connecting component of claim 5, wherein said projecting member is cylindrical and said apex is formed by an angled plane beginning near said body portion and extending away from said bottom surface of said body portion to the side

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of said projecting member located nearest the central axis of said body portion.

7. The connecting component of claim 5 or claim 6, wherein said bottom surface of said body portion includes a first recess extending into said body portion from said bottom surface, said air passageway extending through said first surface, and wherein said flexible member covers said first recess.

8. The connecting component of claim 7, wherein said first recess is circular and said flexible member comprises a circular flexible disk wherein said flexible disk is attached to said body portion by a retainer which biases said flexible disk in contact with the circular edge of said first recess and said bottom surface of said body portion.

9. The connecting component of claim 8, wherein said bottom surface of said body portion includes a second recess extending into said bottom surface through said first recess, said second recess being smaller than said first recess, and wherein said flexible member is substantially displaced in said second recess, and wherein said retainer is attached to said bottom surface within said second recess.

10. A fluid delivery system consisting of a fluid containing container having a top opening, a pierceable protective diaphragm covering said opening, a connection neck for receiving a connection component thereon and a tubing set, wherein said connection component comprises:

a cap shaped member including a circular body portion having top and bottom surfaces and a cylindrical rim portion extending away from said bottom surface, said rim portion threadedly receiving the connecting neck on the container therein;

a pointed projecting member extending away from said bottom surface of said body portion, said projecting member having an apex laterally offset from the central axis of said body portion, said projecting member having a fluid receiving passageway therein extending through said body portion, said

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passageway having a fluid receiving opening therein which opens on said bottom surface of said projecting member, said projection member being cylindrical, said apex extending beyond said fluid receiving opening so that said apex pierces the diaphragm of the container to form an opening in the diaphragm larger than the diameter of said projecting member upon the connection of said cap shaped member to said container;

an air passageway in said body portion spaced laterally from the central axis of said body portion opposite said projecting member; and

wherein said air passageway extends through said body portion from said bottom surface to said top surface and includes a flexible member extending across said air passage and biased into a closed position across said air passage, said flexible member in flow communication with said air passageway to allow air to selectively flow through said air passageway into said container while preventing the flow of liquid therethrough.

11. The connection component of claim 10, wherein said flexible member comprises a circular disk affixed to said bottom surface of said body portion across said air passageway.

12. The connection component of claim 10 or claim 11, wherein said body portion of said connection component includes a first recess extending into said bottom surface around said air passageway wherein said flexible member substantially overlaps said first recess to resiliently block the flow of liquid from said container through said air passageway.

13. The connection component of claim 12, wherein said body portion of said connection component includes a second recess extending into said bottom surface through said first recess, said second recess being smaller than said second recess, said second recess to space said flexible member away from said diaphragm when said cap shaped member is attached to said container.

14. The connection component of any one of claims 10 to 13, wherein said flexible member comprises a nonporous member.

15. The connection component of any one of claims 10 to 14, wherein said top surface of said cap shaped member includes a first cylindrical member extending therefrom, and wherein said first cylindrical member is in flow communication with said projecting member for the connection of a tubing set thereon.

16. The connection component of any one of claims 10 to 15, wherein said top surface of said cap shaped member includes a second cylindrical member in flow communication with said air passageway for the passage of atmospheric air therethrough.

17. A connecting component arranged for attachment to the opening of a fluid container, substantially as herein described with reference to the accompanying drawings.

DATED: 14 September 1992
PHILLIPS ORMONDE & FITZPATRICK
Patent Attorneys For:
SHERWOOD MEDICAL COMPANY

David B Fitzpatrick

(3708h)

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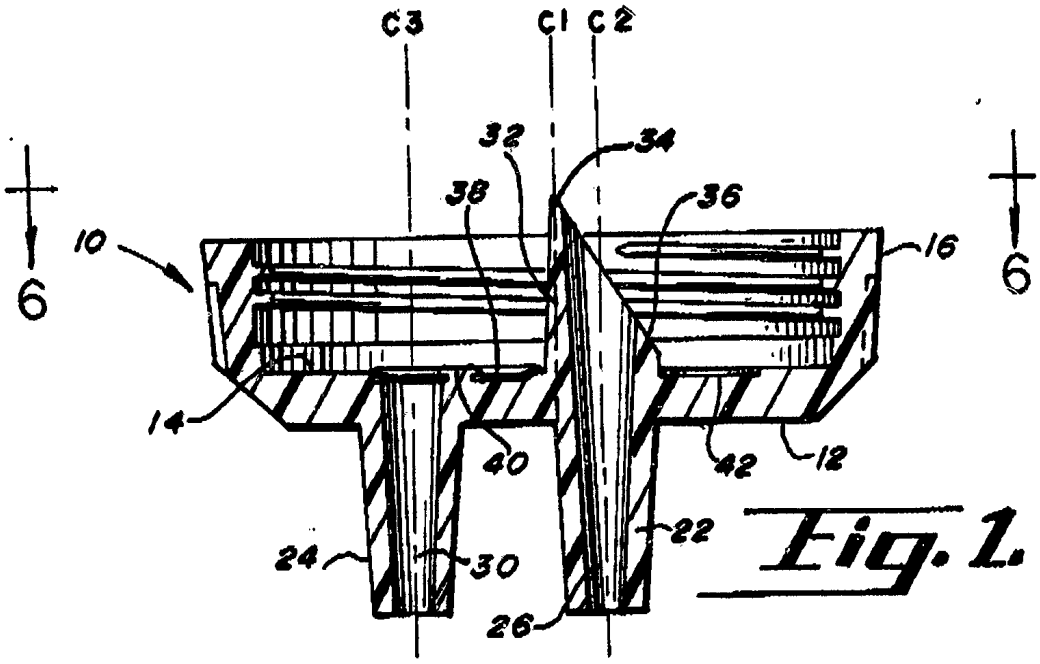


Fig. 1.

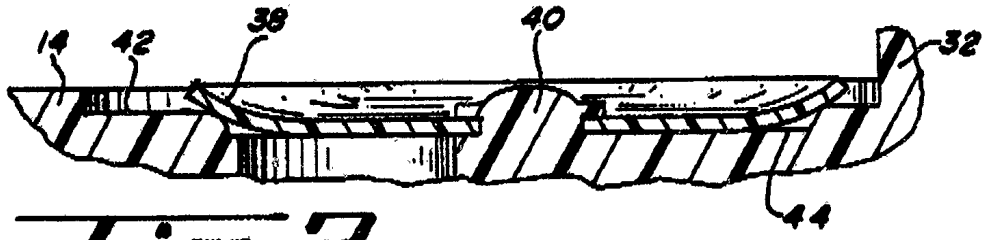


Fig. 2.

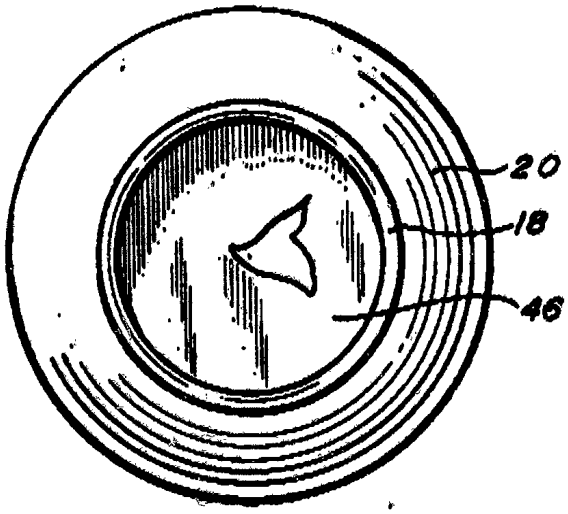


Fig. 3.

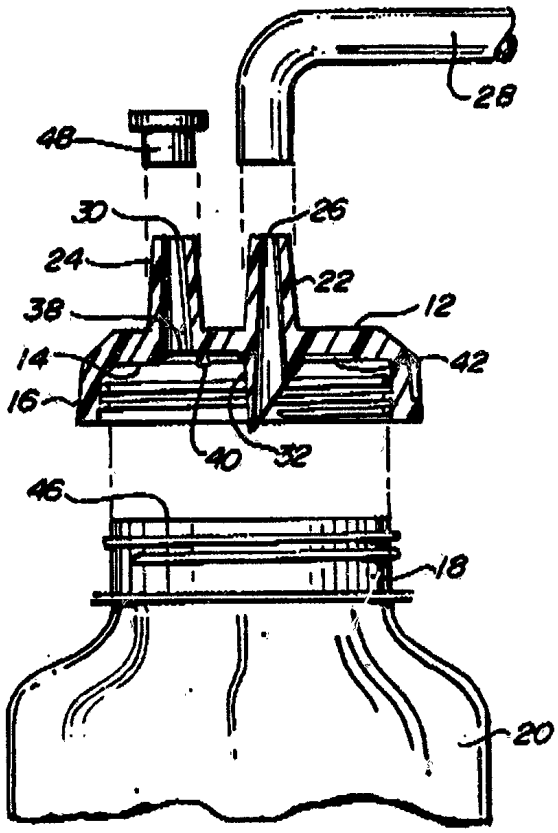

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Fig. 4.

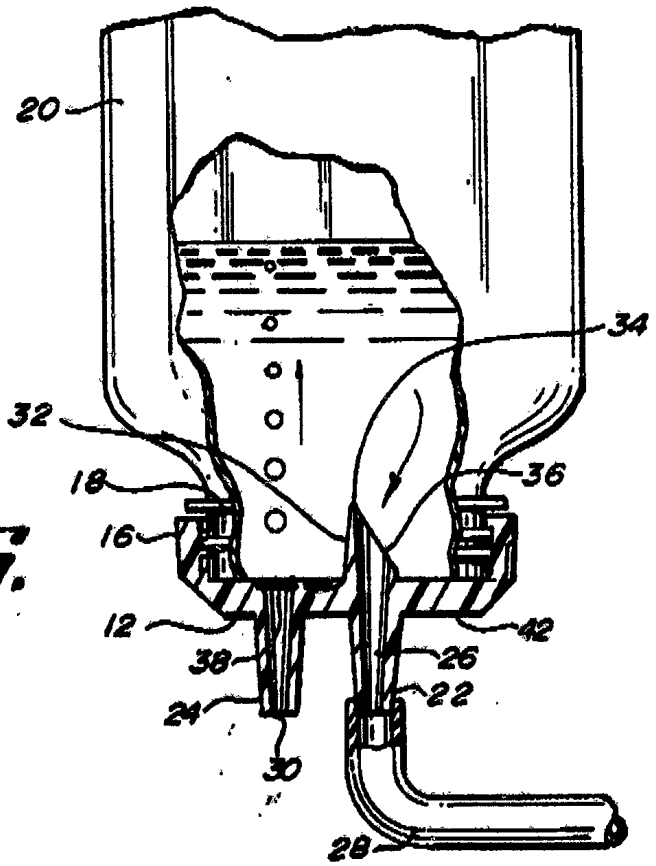

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Fig. 5.

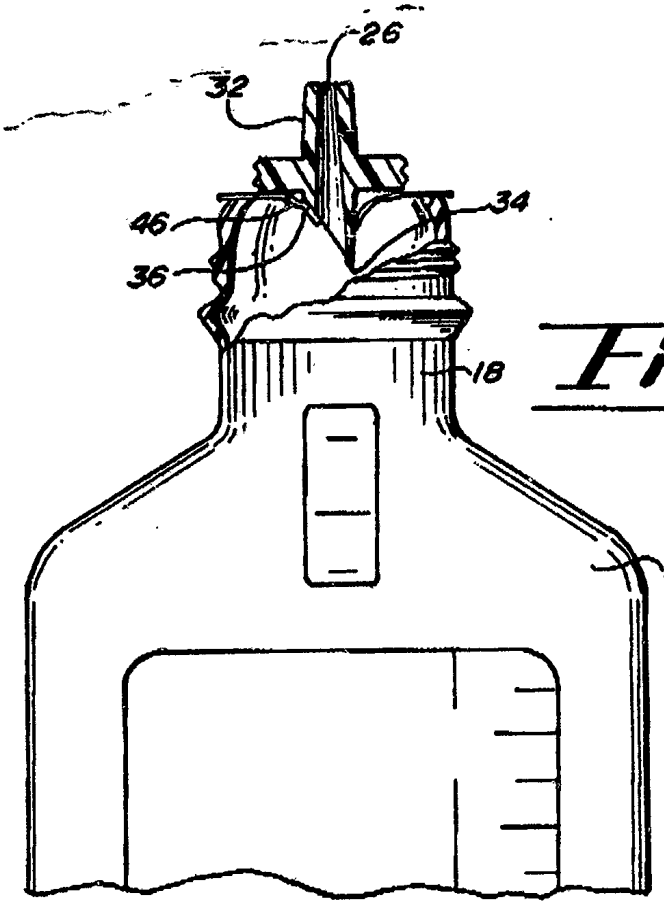


Fig. 7.

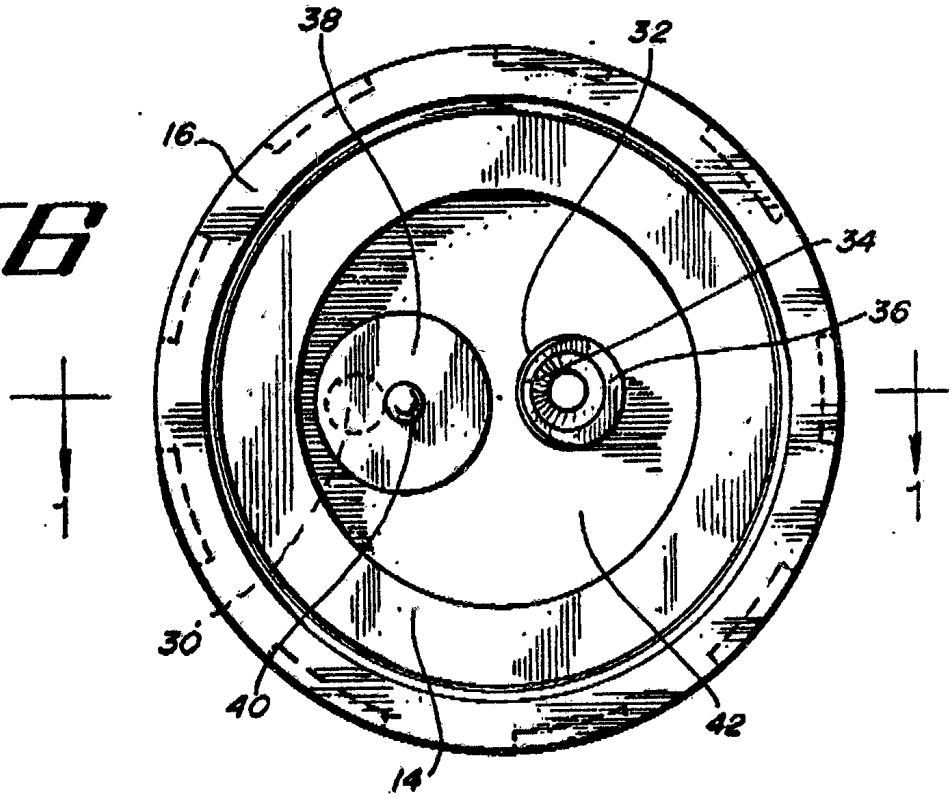


Fig. 6