

[54] DISPENSING CLOSURE FOR PARENTERAL FLUID CONTAINER

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[51] Int. Cl. F16k 15/04, F16k 15/14

[58] Field of Search 137/525.7, 533.11, 533.13, 137/533.15, 519.5, 539, 539.5, 202; 128/214 R, 214 C

[56]

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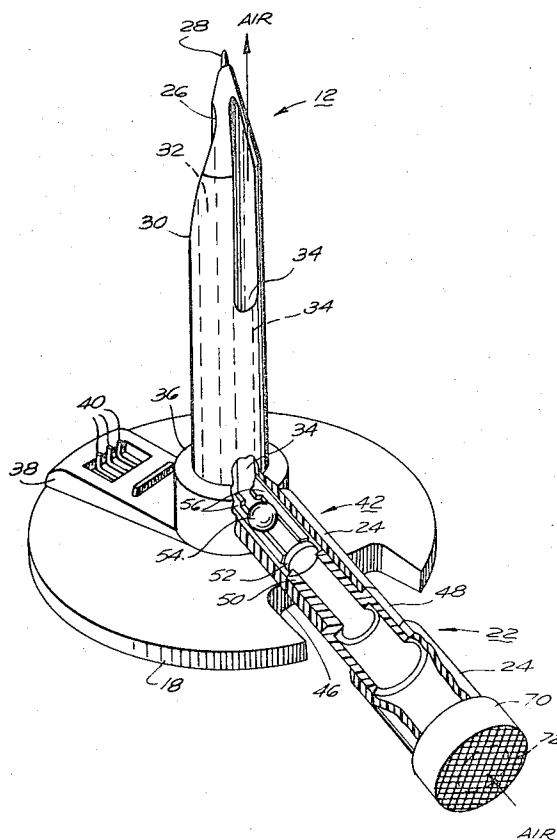
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ABSTRACT

The closure device has a novel, virtually leak-proof check-valve in its breather tube which allows air or other fluids to flow into the dispensing bottle to replace liquid which has been dispensed from the bottle, but does not allow liquid to flow out. The check-valve has a flexible disk which is seated against a valve-seat by a weighted ball. The ball travels inwardly away from the valve-seat and outwardly towards the valve-seat on longitudinal splines which form tracks on which the ball rolls. The weight of the ball forces the flexible disk against the seat until external pressure exceeds internal pressure by a moderate amount. Then, the ball moves upwardly along the tracks, the disk lifts off of the valve-seat, and air or other fluids under pressure are allowed to enter the bottle. The valve-seat is formed by a sharp raised edge around the fluid passage hole. At the innermost ends of the splines are projections forming a stop for the ball. The other ends of the splines form a stop for the disk. When the ball rests against the disk, it depresses its center portion inwardly to form a tight seal against the raised ridge of the valve seat.

14 Claims, 5 Drawing Figures

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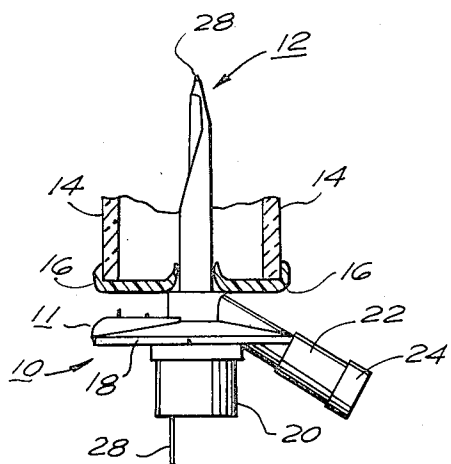


FIG. 1

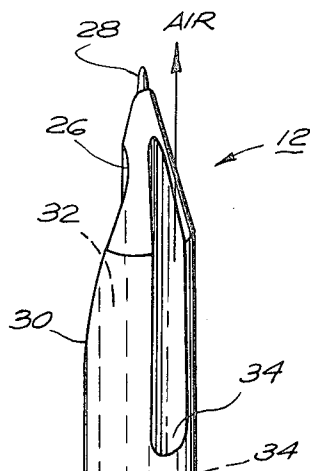


FIG. 2

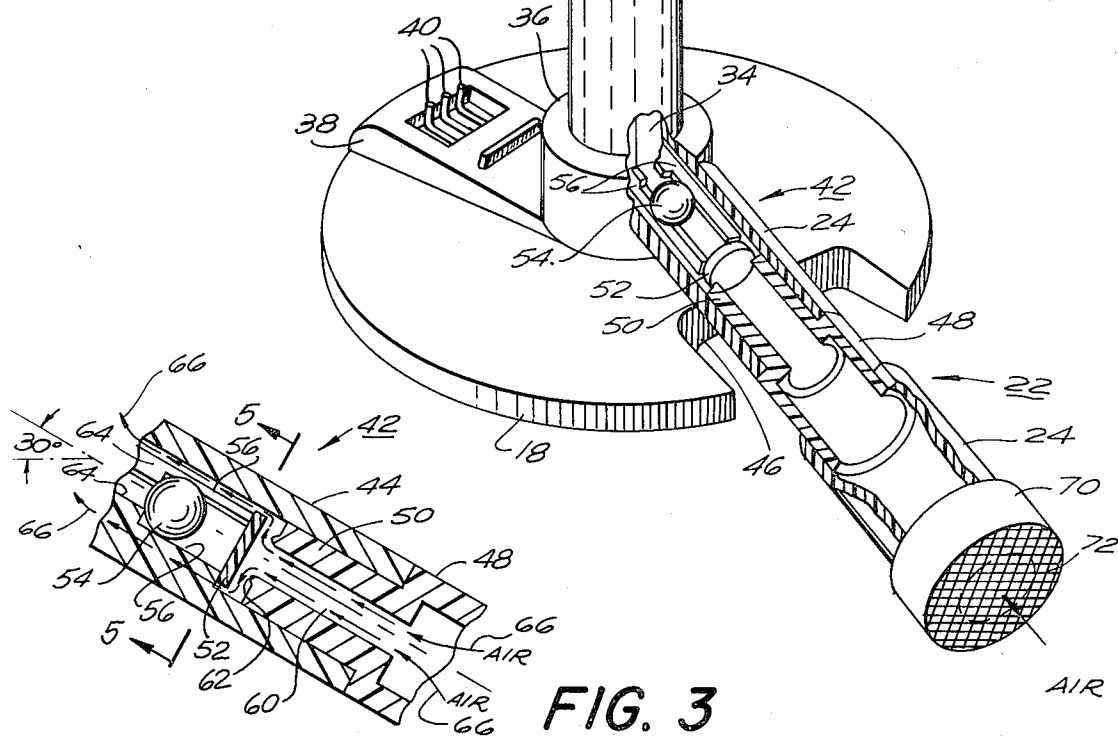


FIG. 3

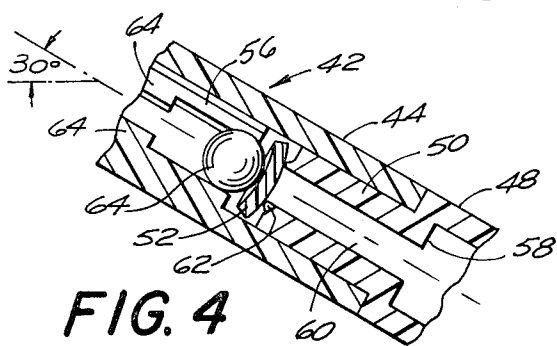


FIG. 4

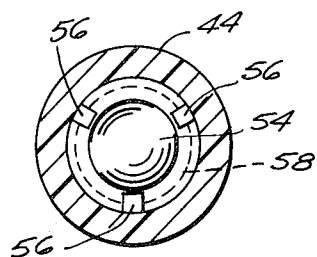


FIG. 5

DISPENSING CLOSURE FOR PARENTERAL FLUID CONTAINER

This invention relates to parenteral fluid dispensing devices, and particularly to closure means and their breather check valves for parenteral fluid dispensing containers. In a specific preferred embodiment described herein, the closure device is of the type in which a rubber bung closes the top of the fluid bottle, and a central projection is used to pierce the rubber bung.

The containers for dispensing parenteral fluids to which this invention pertains include the familiar dextrose or saline fluid dispensing bottles which often hang upside-down beside a patient's bed in a hospital. A closure is provided for the bottle which dispenses the fluid at a controlled rate through a tube into the patient's veins. The closure device usually has a "breather" tube which extends into the bottle and has an entrance through which air can enter the bottle from the atmosphere to replace liquid dispensed from the bottle. Inside the breather tube is a check-valve to prevent air or other fluids from entering the bottle until the pressure inside the bottle at the breather tube exit becomes less than the pressure outside the bottle, indicating a need for air in the bottle. At all other times, the check-valve is intended to prevent leakage of fluid from the bottle.

The check-valves used in prior breather tubes have not been entirely satisfactory. One type of valve, which is disclosed in U.S. Pat. No. 2,852,024, includes a steel ball and a molded plastic seat. When the external air pressure slightly exceeds the pressure on the ball created by the weight of the "head" of the fluid above it, the ball moves away from the seat and allows some air to enter the bottle until the pressure in the bottle equals or exceeds that outside the bottle.

One problem with the foregoing type of check-valve is that the valve-seat and ball should not have any significant scratches or imperfections; otherwise, it will leak. Of course, the seat can be made soft enough so that it distorts under the pressure of the ball to fill any imperfections in the seat or the ball. However, this solution to the problem is imperfect in that the ball often tends to stick to such a soft seat, and will not pull free unless a large pressure difference is developed to unseat the ball. The resulting sudden surge of air into the fluid in the bottle is quite undesirable. The ball tends to stick against the seat even more readily and tenaciously when viscous fluids are being dispensed. If the valve seat is made hard enough to prevent sticking, it easily can leak. If it leaks, fluid drops may form in the breather tube in a region exposed to atmospheric air and its bacteria. If the breather apparatus then inhales the partially formed drop, contaminated fluid is inhaled into the bottle with the air. This contaminates the fluid and endangers the health of the patient.

Another type of check-valve used in current breather tubes is simply a flap valve which has a small rubber disk which seats against a cylindrical valve seat. The rubber disk has a specific gravity slightly greater than that of water. Such a flap valve has the disadvantage that if the breather tube is oriented at the usual angle (30°-45°), the disk tends to be canted due to drag of the bottom of the disk along the side of the breather tube as the disk moves from the closed to the open position. Since the difference between the internal and

external pressure at the valve often will be very small immediately after closing of the valve, the disk often is not properly seated because it is canted. Leakage and the dangerous results described above can result. Also, the disk usually is made of hard rubber and is not sufficiently resilient to seal any imperfections in the disk or the seat.

It is the major object of the present invention to provide a parenteral fluid dispensing closure device with a breather check-valve which is free from the defects mentioned above. It is another object of the invention to provide such a structure which is relatively easy to manufacture and safe to use.

In accordance with the foregoing objects, the present invention provides a closure member for a parenteral fluid dispensing container with a check-valve which has a flexible flap member and a weighted member which rests against the flap member when the valve is closed. The weighted member, preferably a ball, holds the flap against the valve-seat and prevents it from becoming canted. Preferably, the ball travels inwardly away from the valve-seat and outwardly towards the valve-seat on longitudinal splines which form tracks on which the ball rolls. It also is preferred that the valve-seat is formed by sharp raised edge around the fluid passage hole. When the ball rests against the flap, the ball depresses the center portion of the flap inwardly to form a tight seal against the raised ridge.

The foregoing and other objects and advantages of the invention will be described in or apparent from the following description and drawings.

In the drawings:

FIG. 1 is a partially cross-sectional view of a closure member of the invention in use with an inverted parenteral fluid dispensing bottle;

FIG. 2 is a perspective, partially broken-away and partially cross-sectional enlarged view of the insertable dispensing portion of the closure device shown in FIG. 1;

FIG. 3 is a further enlarged cross-sectional view of a portion of the device shown in FIG. 3, with the check-valve open;

FIG. 4 is a view like that of FIG. 3, except that the check-valve is closed; and

FIG. 5 is a cross-sectional view taken along line 5-5 of FIG. 3.

FIG. 1 shows the closure device 10 of the present invention in use to dispense parenteral fluid from a bottle whose neck 14 is the only part seen in FIG. 1. The closure device 10 includes a rubber bung 16 closing the bottle opening, and an insertion-type dispensing unit 11 with a central pointed post 12 which pierces the center of and is inserted into the neck of the bottle. The dispensing unit 11 includes an outer flange 18, a downwardly-extending chamber 20, and a lower end 28 of a metal lever detector electrode whose upper pointed end extends out of the tip of the post 12. The unit 11 also includes a breather tube assembly 22 with an air filter 24 at its lower end.

FIG. 2 is an enlarged view of the dispensing unit 11 of the closure device 10 shown in FIG. 1. The unit 11 is made of molded non-toxic plastic, and includes a semi-annular liquid flow passageway 32 on one side of the post 12, and an air flow passageway 34 on the opposite side of the post. Liquid is allowed to flow in drops which are detected and used to control the flow rate of the fluid to the patient in the manner described in

greater detail in the co-pending U.S. Pat. application Ser. No. 156,854, filed on June 25, 1971, and entitled "Fluid Flow Control Means," which is assigned to the same assignee as this patent application. Three electrodes 40, mounted in a raised housing portion 38, are provided for connection to the electrical control circuit described in the above-identified co-pending patent application.

The breather tube assembly 22 joins with the post 12 and an enlarged hub 36 at the center of the base flange 18. The breather tube 22 extends downwardly through a cut-out portion 46 in the flange 18. As is shown in FIGS. 3 and 4, the breather tube assembly extends downwardly at an angle of 30° with horizontal when the post 12 is vertical as shown in FIG. 1.

FIGS. 3 through 5 show the check-valve structure 42 of the breather tube assembly 22 enlarged and in greater detail.

Referring to FIG. 3, the breather tube assembly 22 includes a barrel 44 which is integral with the hub 36 and the spike 12 and communicates with the air passageway 34. An insert 48 has an inner end 50 which is press-fitted into the barrel 44. The member 48 has an internal portion 58 of reduced cross-sectional area forming a central air flow passageway 60. A raised annular ridge 62 with a sharp edge surrounds the exit opening of the passageway 60 and forms a valve-seat.

A relatively thin disk-shaped closure member 52 made of flexible plastic material and having a diameter slightly less than that of the inside wall of the barrel 44 is positioned adjacent the valve-seat 62. As shown in FIG. 3, the disk 52 is in its most "inward" position; that is, it is in its position nearest to the longitudinal axis of the spike 12. The disk 52 is the closure member of the check-valve 42.

A stainless steel ball 54 is provided as a weighted member to force the disk 52 against the seat 62 to close the valve, in the manner shown in FIG. 4. The steel ball has a diameter less than that of the disk 52, but greater than that of the opening of the air passageway 60. The ball 54 rolls longitudinally in the barrel 44 on tracks formed by three longitudinal splines 56 which are spaced equi-distant from one another about the internal wall of the barrel 44, as is shown in FIG. 5. Each of the splines 56 is a projection extending towards the longitudinal axis of the barrel. Each spline has a projecting portion 64 at its inner-most end which provides a stop to prevent the ball 54 from moving further up into the passageway 34. The outer-most ends of the splines 56 form stop surfaces to prevent the disk 52 from moving too far inwardly when the valve is open, as is shown in FIG. 3.

The check-valve 42 operates as follows. When the pressure on the outer face of the disk 52 becomes somewhat greater than the pressure on the inner face of the disk, this pressure difference pushes the ball 54 and the disk 52 inwardly. As is shown in FIG. 3, the disk 52 comes to a stop against the inner ends of the splines 56, and the ball 54 rests against the stop projections 64. The fluid at the inlet (usually air) then flows into the breather tube assembly along paths indicated by the arrows 66 in FIG. 3. These paths extend through the central passageway 60, laterally along the outer surface of the disk 52, past its edges, along the spaces between the splines 56 and the ball 54, and into the passageway 34. The disk 52 is believed to bend slightly at

the center and thus provides a slightly enlarged flow passageway around its edges due to its flexing. Air bubbles then rise through the fluid in the bottle and into the air pocket above the fluid. It should be understood, of course, that other fluids, such as parenteral fluids, can be forced into the bottle under pressure through the same passageway. This can be a convenient way of replenishing the parenteral fluids.

When the pressure on the inner face of the disk 52 again exceeds the pressure on its outer face, the disk 52 moves into contact with the valve seat 62, and the ball 54 rolls along the splines 56 until it comes to rest against the center of the disk 52. This causes the center of the disk 52 to flex slightly in the manner shown in FIG. 4 so as to ensure a tight seal against the seat 62. The amount of flexing of the disk 52 is exaggerated in FIG. 4 for the sake of clarity. The weight of the ball 54 holds the disk 52 tightly against its seat 62 and prevents it from becoming canted. This prevents the leakage which would result from the canting of the disk.

The disk 52 preferably is made of a material having a specific gravity approximately equal to that of the parenteral fluid being dispensed. The steel ball preferably has a weight sufficient to hold the disk 52 tightly against its seat, but not so heavy that an excessive amount of pressure differential is required to open the valve.

The use of a sharp circular ridge for the seat 62 is advantageous in that it reduces the surface area of the seat and increases the intimacy of the contact between the disk 52 and its seat.

The use of the splines 56 decreases the amount of surface contact and friction between the ball 56 and the walls of the barrel 44 in which it rolls, and reduces the likelihood that the ball will stick in the barrel.

The stop projections 64 for the ball preferably have a corner or other pointed abutment edge so as to reduce surface contact between the projections and the ball and further reduce the likelihood of the ball sticking in the barrel.

The following dimensions and parameters were used in a breather tube device which has been built and successfully operated in accordance with the invention.

In the device tested, the diameter of the passageway 60 was 0.095 inch and the inside diameter of the barrel was 0.175 inch. The diameter of the disk 52 was 0.140 inch, and its thickness was 0.020 inch. The angle of the longitudinal axis of the barrel was approximately 30° with respect to the flange 18.

The stainless steel ball was two-thirtyseconds of an inch in diameter.

The material of the stainless steel ball was grade 200, type 302, passivated, suitable for use in intravenous devices.

The valve-seal disk was made of a polyurethane compound identified by No. UW70P and sold by Quality Synthetic Rubber Co., Cleveland, Ohio, and has the following properties:

Durometer Hardness	65-70 A
Surface finish RMS	16-32
Specific gravity	1.15
Concentricity	0.003 P.I.R.

The above description of the invention is intended to be illustrative and not limiting. Various changes or modification in the embodiments described may occur to those skilled in the art and these can be made with-

out departing from the spirit or scope of the invention.

I claim:

1. A dispenser device for a parenteral fluid-dispensing container, said device comprising means forming a fluid outlet conduit, means forming a fluid inlet passageway extending downwardly when said container is in a dispensing position, valve-seat means in said passageway, a flexible closure member positioned to move downwardly towards and upwardly away from said valve-seat, and an independently movable weighted member having a specific gravity greater than that of the fluid in said passageway and being movable in said passageway downwardly towards and upwardly away from said valve-seat, said flexible closure being positioned between said valve-seat and said weighted member.
2. A device as in claim 1 in which said weighted member and said closure member are separate members.
3. A device as in claim 2 in which said weighted member is shaped to roll longitudinally on the internal wall of said passageway.
4. A device in claim 1 including longitudinally-extending projections extending from the internal wall of said passageway and forming tracks for movement of said weighted member.
5. A device as in claim 1 in which said weighted member is substantially spherical in shape.
6. A device as in claim 1 in which said closure member is made of polyurethane material.
7. A device as in claim 1 in which said valve-seat has a sharp lip around the hole through the seat and adjacent said weighted member, said weighted member having a central projecting portion for depressing said closure member inwardly at its center when bearing against said closure member.
8. A device as in claim 4 including a stop-portion for at least one track at its end which is farthest from said valve-seat to stop the motion of said weighted member

away from said valve-seat.

9. A device as in claim 4 in which the ends of said tracks which are nearest to said valve-seat are spaced from said valve-seat and extend from said passageway wall by a distance sufficient to block the movement of said closure member away from said valve-seat by more than a pre-determined distance.

10. A dispensing closure for a parenteral fluid dispensing container, said closure including means for defining first and second fluid conduits extending downwardly when said container is in dispensing position, said first conduit being adapted for dispensing fluid from said container, said second fluid conduit having a check-valve for allowing fluid to flow into said container under a pressure greater than that in said container adjacent said second conduit, but preventing the flow of fluid from said container, said check-valve including valve-seat means in said second conduit, a flexible disk on the interior side of said valve-seat means, a metal ball on the interior side of said disk, said ball having a density greater than that of the fluid in said second conduit, a plurality of splines extending from the interior wall of said second conduit and embracing said ball loosely, said disk having a diameter less than the internal diameter of said second conduit.

11. A closure as in claim 10 in which said disk is made of a material having a specific gravity approximately equal to that of the fluid in said container.

12. A closure as in claim 10 in which said splines are spaced from said valve-seat and form an inward stop for said disk, and a stop portion extending further into said second conduit from at least one spline, at the inward end of said second conduit, to limit the inward movement of said ball.

13. A closure as in claim 10 in which said ball is made of stainless steel.

14. A closure as in claim 13 in which said disk is made of polyurethane.

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