

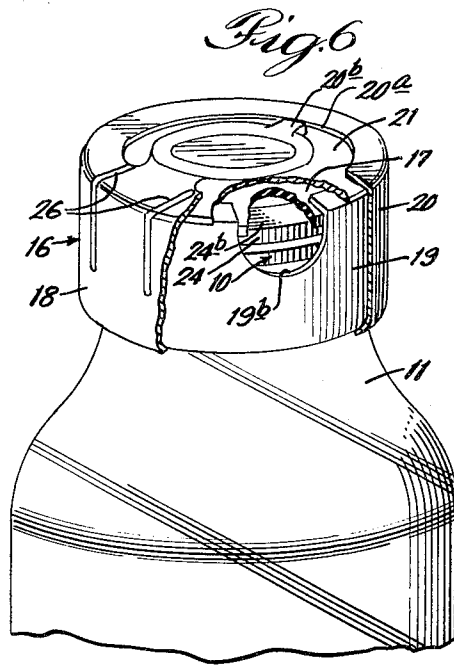
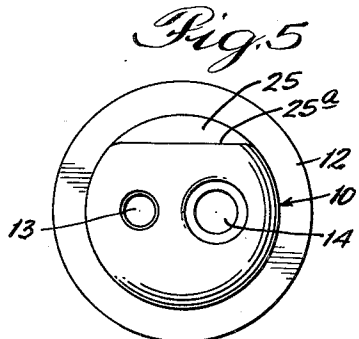
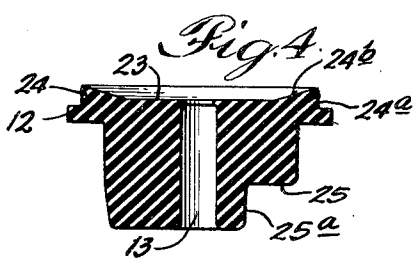
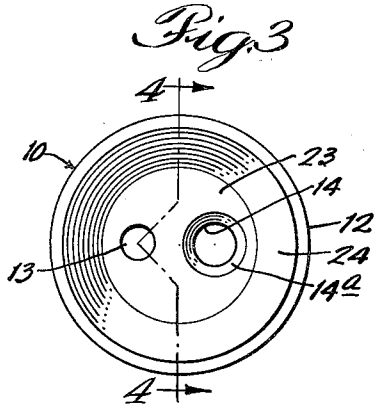
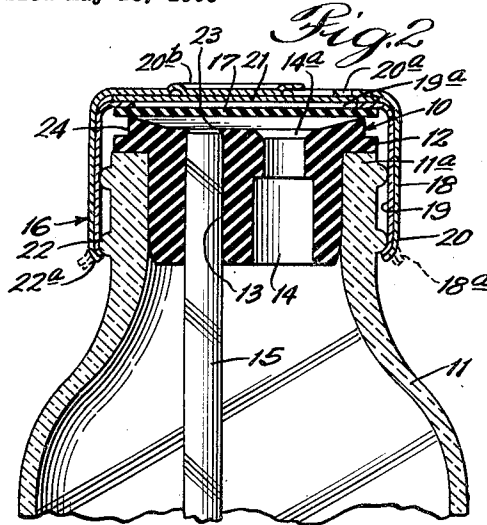
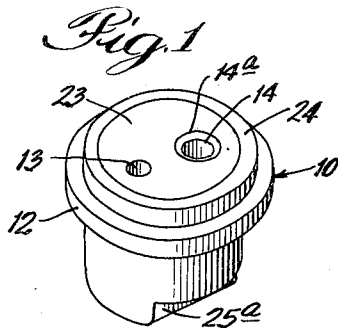
Dec. 11, 1962

R. C. REIMANN

3,067,898

PARENTERAL SOLUTION EQUIPMENT

Filed May 18, 1959



INVENTOR:

Robert C. Reimann,

By Dawson, Tilton, Talbot & Kunguine,
ATTORNEYS.

1

3,067,898

PARENTERAL SOLUTION EQUIPMENT

Robert C. Reimann, Morton Grove, Ill., assignor to
Baxter Laboratories, Inc., Morton Grove, Ill., a corporation of Delaware

Filed May 18, 1959, Ser. No. 814,089

2 Claims. (Cl. 215—37)

This invention relates to parenteral solution equipment, and, more particularly, to the bulk container employed for storing and dispensing of parenteral fluids such as glucose, saline, etc.

Parenteral fluids find wide use in surgery. Saline solution is normally administered intravenously in order to maintain the salt content of the patient's blood. Glucose is employed for furnishing nutriment, and a wide variety of other medicines can be administered contemporaneously. These are uniformly provided in glass bottles having an internal volume of a liter, or some fraction thereof. Usually, the container is sized to house 250 ml., 500 ml., or a liter of solution. As is well known, these solutions are dispensed with the bottle suspended in a mouth-downward position, the closure of the container or bottle being coupled to the patient by means of an elongated tube designated an administration set.

Inasmuch as these fluids are to be introduced into the patient's body and most generally directly into the blood stream, it is imperative that they be aseptic. Even the chance of contamination cannot be tolerated, since the blood stream provides a fertile area for the propagation of any microorganisms. It is a general practice in hospitals to store the solutions for future use. Many cases of parenteral solutions may be on hand at any one time, and since it cannot be known definitely when a given solution is going to be used, it is imperative that the bottle be absolutely sealed against the entry of any contamination. A problem has existed in the past in that the closures for the glass bottles have not met this need. A solution to this problem is provided by this invention. More specifically, it is an object of the invention to provide a novel closure for a parenteral solution bottle. Another object is to provide a novel resilient plug or stopper to be lodged in the neck of the parenteral solution bottle and in which the plug cooperates with the bottle and an overlying cap member to maintain the bottle interior in a sterile condition. Other objects and advantages of this invention can be seen as this specification proceeds.

This invention will be explained in conjunction with the accompanying drawing, in which—

FIG. 1 is a perspective view of a resilient plug or stopper embodying the teachings of this invention;

FIG. 2 is a fragmentary vertical sectional view of a parenteral solution bottle equipped with a closure embodying teachings of this invention;

FIG. 3 is a top plan view of the stopper seen in FIG. 1 and is presented in a scale slightly larger than that employed for the stopper of FIG. 1;

FIG. 4 is a sectional view taken along the line 4—4 of FIG. 3;

FIG. 5 is a bottom plan view of the stopper; and

FIG. 6 is a fragmentary perspective view of the structure seen in FIG. 2 with the closure partially broken

2

away to demonstrate the relationship of the various components thereof.

In the illustration given, the numeral 10 designates generally a stopper or plug employed to close the top opening of a glass parenteral solution bottle 11 (seen only in FIGS. 1 and 2).

As seen in the drawings, the stopper 10 includes a generally cylindrical body equipped with an annular flange 12 adjacent one end thereof. The flange 12 is provided integral with the body of the stopper 10, and the entire unit may be constructed of a resilient material such as rubber.

The stopper 10 is equipped with a pair of passageways 13 and 14 extending therethrough in a direction parallel with the axis of the stopper body. The passage 13 provides a mounting for an air tube 15 which extends inwardly and downwardly of the bottle 11 to a point adjacent the inner bottom. When the bottle 11 is suspended in a mouth-downward condition, air enters the air tube 15 to replace liquid that flows out of passageway 14 into a length of tubing (not shown). The bottle 11 (as seen in FIGS. 2 and 6) is equipped with a composite closure designated generally by the numeral 16. The closure 16 includes, in addition to stopper 10, a resilient thin sealing disc 17 and a composite cap 18. The cap 18 includes an inner cap member 19, an outer cap member 20, and a rigid closure disc 21.

The inner and outer cap members 19 and 20, respectively, are generally cup-shaped and at their open ends are "rolled" into clamping relation with a bead 22 on bottle 11, and as is designated by the numeral 22a in FIG. 2. In this condition, the cap 18 exerts a compressive force against the top of stopper 10, causing it to be firmly supported within the neck opening of bottle 11 and with the annular flange 12 mounted on the lip 11a of bottle 11.

As can be best seen in FIGS. 1, 3 and 4, the stopper 10 is equipped with a central depressed portion 23. The central depressed portion is provided by equipping the stopper 10 with a circular rib 24 on its top surface. The rib 24 has a straight or vertical side 24a and an inwardly and downwardly-inclined inner side 24b (designated only in FIG. 4). The inner and outer sides of the bead meet at their upper ends at an obtuse angle and provide, in effect, a rib having a sharp edge adapted to cooperate with the remaining part of the closure 16 to achieve a "line" type seal.

The flange 12 extends laterally outward a distance greater than the vertical side 24a of rib 24, the configuration of these elements as seen in FIG. 4 providing what amounts to a "stepped" flange.

The stopper 10, as is best seen in FIGS. 1 and 2, has the upper end of passage 14 outwardly tapered as at 14a. The stopper 10 is also equipped with a cut-out or notched portion 25 (best seen in FIG. 4) which has an inner straight wall 25a extending generally parallel with a line connecting the centers of the circular passages 13 and 14. The cut-out portion 25 may be employed for aligning the closure preparatory to mounting the air tube 15 in passage 13.

Each of the cap members 19 and 20 is apertured in the central base thereof as at 19a and 20a, respectively. The inner cap member 19, in addition to being apertured as

at 19a in the central portion of the base of the cup-shaped configuration, is additionally notched as at 19b (seen only in FIG. 6). The provision of the notched or cut-out portion 19b provides access to the edge of rubber disc 17 for pulling it out from under its position of securement between the inner cap member 19 and the top surface of stopper 10. Cooperating with the notched portion 19b in presenting a portion of the disc 17 for finger grasping, is the stepped, laterally-extending flange 12, all of which can be readily appreciated from a consideration of FIG. 6.

As also can be seen in FIG. 6, the outer cap member 20 is equipped with a tab portion 20b which occupies a portion of the central base cut-out 20a. The outer cap member 20 is weakened as at 26 along the base and side wall so that upward and outward movement of tab 20b severs the outer cap 20 and permits its removal from the bottle 11. Thereafter, the metal disc 21 may be lifted off of the inner cap member 19 to provide the exposure of the rubber disc 17.

Each cap member 19 and 20 is provided with a substantially flat base portion outward of the central apertured portion, which cooperates in urging the disc 17 against the upper edge of the rib 24, and providing thereby a gas-tight seal.

In the operation of the apparatus just described, the stopper 10 is first equipped with air tube 15 by a suitable machine which employs the cut-out portion 25 as the means for orienting the stopper 10 in proper position for the insertion of the air tube 15 into passage 13. Thereafter, a bottle suitably charged with a parenteral liquid is positioned to receive the air tube-equipped stopper 10. After the stopper 10 has been lodged within the neck of the bottle 11, the rubber disc 17 is placed over the stopper. The assembled structure is removed to a vacuum-inducing machine where the unit is subjected to a vacuum of the order of 20" Hg. Thereafter, the remainder of the closure 18, consisting of cap members 19 and 20 and aluminum disc 21, is applied. In its initial condition, the cap 18 has the inner and outer cap members 19 and 20 nested, with the metal disc 21 maintained therebetween. The side walls of the inner and outer cap members 19 and 20, respectively, are flanged outwardly as shown in dotted line in FIG. 2 and designated 18a. This permits ready hopping of the composite cap 18 onto the bottle. The next operation rolls the skirt of the cap 18 into the form shown in solid line in FIG. 2—thereby sealing the bottle interior in a less-than-atmospheric condition.

After the bottle and its closure have been provided in the form seen in FIGS. 2 and 6, the bottle is removed to a sterilizing area, which ordinarily includes an autoclave capable of developing internal temperatures of the order of 230–250° F. Ordinarily, a bottle is subjected to 12 p.s.i. (g.) steam for about 30 minutes.

As a result of the evacuating step, the flexible disc 17 is drawn downwardly against the top surface of the stopper 10 and partially into the passageways 13 and 14. The vacuum step, therefore, produces a "dimpling" of the flexible disc 17 and results in a series of folds radiating outwardly from the dimples in the disc 17. These dimples occur over the two passages 13 and 14.

During the sterilization procedure, the disc 17 is first drawn even more into the passages 13 and 14 by virtue of the greater external pressure. When the sterilization procedure starts, the pressure inside the autoclave is upwards of 12 p.s.i. (g.), while the interior of the bottle is still under vacuum. Only after the liquid contents of the bottle become heated sufficiently to generate steam, does the pressure differential disappear. However, at the end of the sterilization cycle, the reverse exists. The autoclave is quickly vented of its steam, returning its pressure to atmospheric, while the contents of the bottle cool at a slower rate. Thus, the interior of the bottle is under supra-atmospheric pressure, while the exterior of the bottle is at atmospheric. This causes the dimples to disappear temporarily and, in fact, a definite ballooning of the flexible

disc 17 is caused, which applies a rather pronounced stress in the cap 18. It is during this period following sterilization and where the steam generated inside the bottle during sterilization has not yet condensed, that a crucial situation exists in so far as contamination is concerned. The folds present in the disc 17 may provide avenues for the flow of contaminant-bearing fluid into the bottle 11. In particular, it is possible that pieces of metal, dirt, etc., could be drawn into the bottle 11 during the dissipation of the supra-atmospheric pressure therein following sterilization.

This is effectively overcome through the cooperation of the stopper 10 with the remaining portion of the closure 16. The line-tight seal effected between the rib 24 and the flat inner portion of the cap 18 effectively clamps the flexible disc 17 in such a fashion as to prevent any undesirable fluid flow which might carry contaminants into the bottle 11. Here, it is to be realized that subsequent to the cooling step in the sterilization cycle, the principal seal against contamination is provided by the contact between the flexible disc 17 and the upper ends of the passages 13 and 14. During the storage of the container following the sterilization cycle, the seal provided by the rib 24 and the closure 16 is thus a secondary seal.

The depressed central portion 23 of stopper 10 also is advantageous in minimizing the magnitude of the folds in disc 17, which necessarily result from the concurrent application of vacuum and clamping operation on the closure 16. The inwardly-tapered wall 24b of rib 24 effectively smooths out the ends of the fold so that a firm grip on disc 17 can be applied through the cooperation of the rib 24 and the inner bottom of the cap 18.

While, in the foregoing specification, a detailed description of an embodiment of the invention has been set forth for the purpose of explanation, many variations in the details herein given will be apparent to those skilled in the art without departing from the spirit and scope of the invention.

I claim:

1. In combination, a parenteral solution bottle equipped with an annular bead about the neck thereof with the upper edge of the neck defining a lip, a resilient plug mounted in said neck and closing the same, said plug having a pair of passages extending through it communicating the bottle interior with the atmosphere and defining openings in the plug outer end, said plug being equipped with an annular flange adjacent its outer end overlying the lip of said bottle, said plug also being equipped with a circular raised rib in its top surface having a triangular shape in cross section to provide a sharp upper edge and a tapered inner wall to provide a plug with a generally dish-shaped top, said sharp upper edge overlying said lip, a flexible diaphragm overlying said stopper and extending outwardly of said rib, a rigid cup-shaped member overlying said disc and rib and lockingly engaged with said bead, a metal disc overlying said inner cap member, and an outer cap member overlying said metal disc and also lockingly engaged with said bead, said inner and outer cap members being centrally apertured in the bases thereof, said outer cap member being equipped with tab means for rupturing the side wall thereof to permit removal of said outer cap member and metal disc from said bottle.

2. In combination, a parenteral solution bottle equipped with an annular bead about the neck thereof, with the upper edge of the neck defining a lip, a resilient plug mounted in said neck and closing the same, said plug having a pair of passages extending through it for communicating the bottle interior with the atmosphere, said plug having inner and outer end surfaces in which said passages define openings, said plug being equipped with an integral annular flange adjacent its outer end surface overlying said lip, said plug also being equipped with a circular raised rib in its outer end surface above said flange, said rib being defined by a cylindrical wall inset from the periphery of said flange and an inwardly-sloping

5

wall coating with said cylindrical wall to form a sharp edge positioned over said lip, whereby said raised rib is formed having a triangular cross section and providing a generally dished top in said outer end surface with said passage openings pre-formed in said dished top and within said circular raised rib, a flexible diaphragm overlying said plug and extending outwardly of said rib, and a rigid cup-shaped member overlying said disc and rib and lockingly engaged with said bead to compress said disc and provide a seal between said disc and rib.

5

10

6

References Cited in the file of this patent

UNITED STATES PATENTS

2,108,583	Falk	Feb. 15, 1938
2,190,054	Cutter et al.	Feb. 13, 1940
2,191,495	Nesset	Feb. 27, 1940
2,236,491	Campbell	Mar. 25, 1941
2,804,224	Barton	Aug. 27, 1957