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PARENTERAL SOLUTION EQUIPMENT

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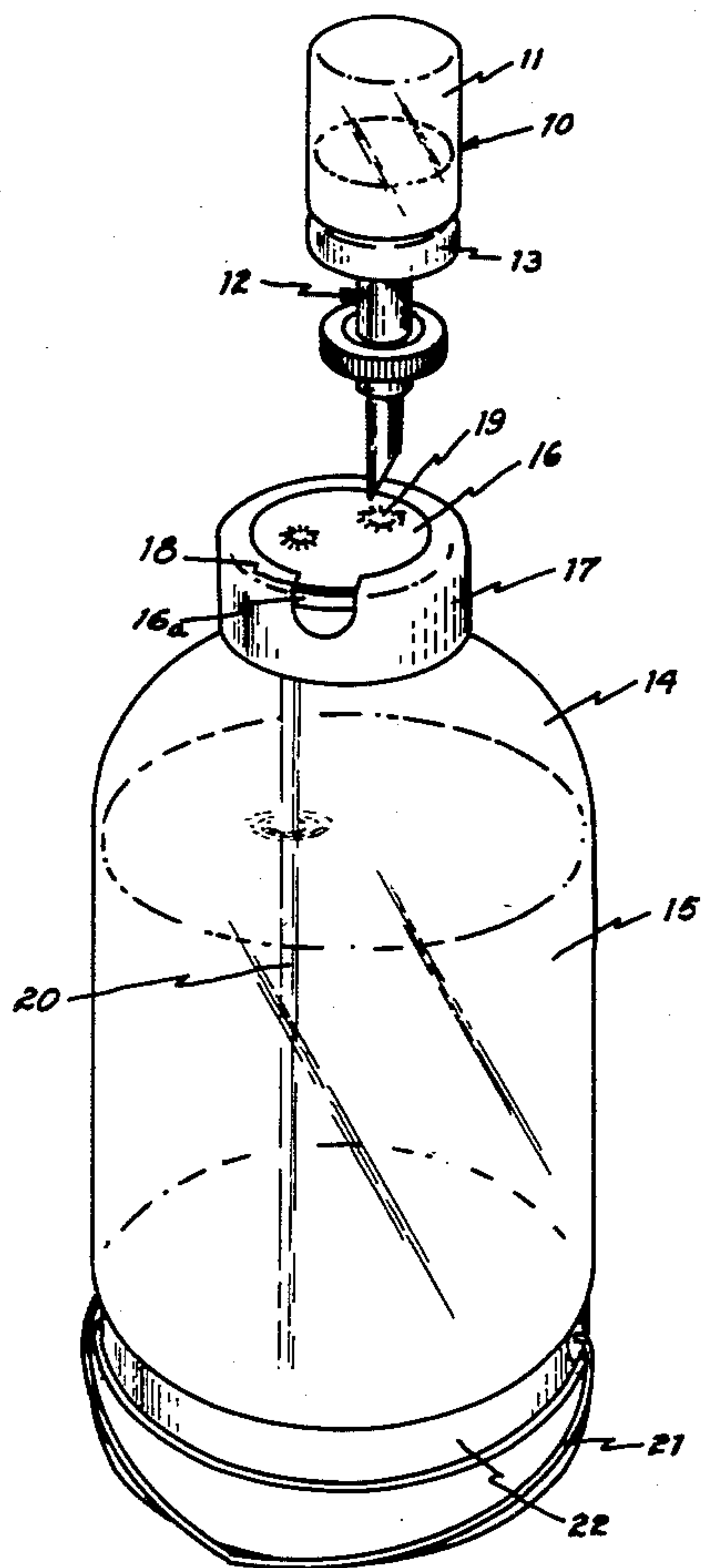


Fig. 1.

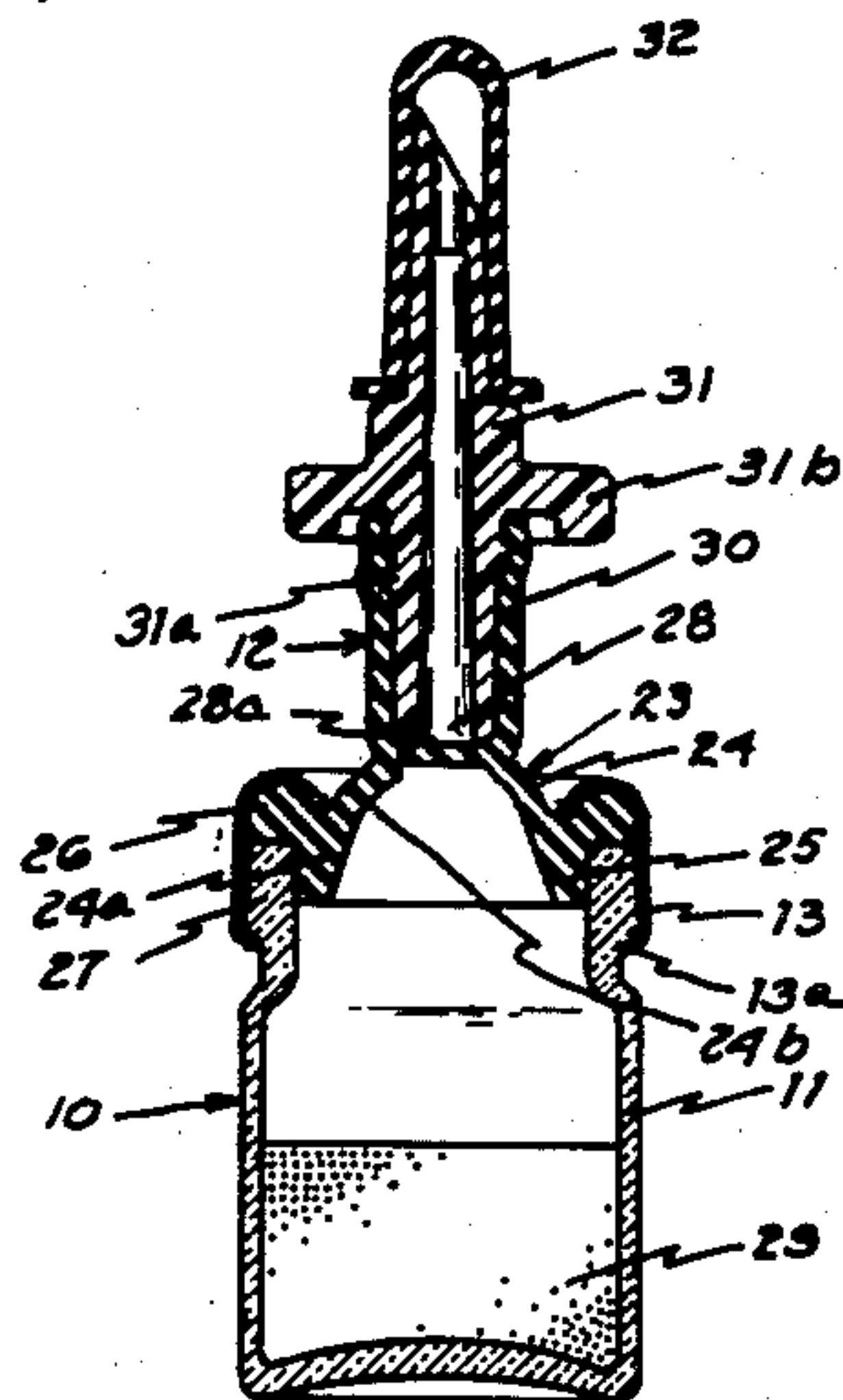


Fig. 2.

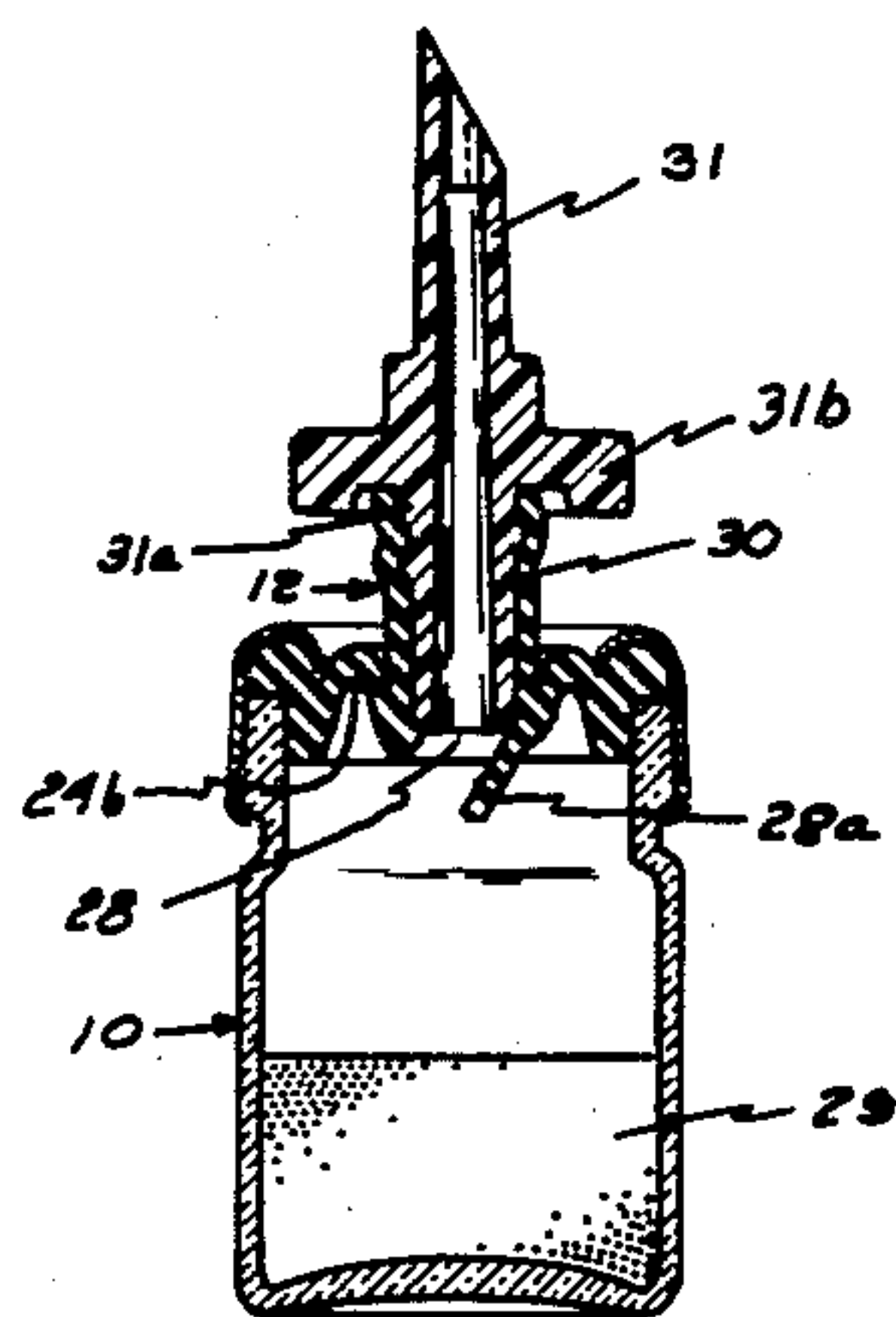


Fig. 3.

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PARENTERAL SOLUTION EQUIPMENT

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This invention relates to parenteral solution equipment and the method of using same and, more particularly, to container equipment adapted to unite parenteral medicaments just prior to administration thereof.

Inasmuch as parenteral solutions are commonly used in surgical procedures, they have been found to provide convenient vehicles for supplemental medication. Where, for example, the surgeon desires to administer a parenteral anesthetic, skeletal muscle relaxant, antibiotic, or the like, and a parenteral solution regimen such as saline is also contemplated, it is distinctively advantageous to combine the two. This eliminates the need for making an additional vein puncture which is oftentimes painful and inconvenient.

To achieve the foregoing, we have invented parenteral solution equipment including a container for the supplemental medication which is adapted to introduce the medicine into an already provided parenteral solution bottle, the introduction being performed under substantially aseptic conditions and without loss of the medicine which is usually expensive and carefully controlled in quantity.

The invention set forth in this application constitutes an improvement in the structure disclosed in John W. Richter's application Serial No. 536,140. Essentially, the additive vial structure described in that application includes a container closed by a flexible diaphragm whereby "flexing" of the diaphragm causes a pumping action which permits transfer of liquid into and out of the container.

Inasmuch as the parenteral solution bottle into which the contents of the additive vial are introduced is generally provided with an internal pressure less than atmospheric, a problem is presented in that the sub-atmospheric pressure bottle tends to exert an unusually strong pull upon the flexible diaphragm of the supplemental medication device when the two are interconnected. Then, when it is attempted to pull the supplemental medication device away from the parenteral solution bottle to achieve the desired pumping action by reversely flexing the diaphragm, a strong pull must be exerted that might well result in disconnecting the device from the bottle and bring about a loss of the device's contents. The present invention is designed to meet the foregoing problem and overcome the described difficulties.

Our invention will be explained in conjunction with the accompanying drawing in which Fig. 1 is a perspective view of the container of our invention in combination with a parenteral solution bottle; Fig. 2 is an enlarged cross-sectional view of the container of Fig. 1; and Fig. 3 is a view similar to Fig. 2 but showing the container in operative condition.

Referring now to the drawing and, in particular, to Fig. 1, the numeral 10 designates generally a container for a supplemental medicament which also might be termed as "additive vial." Vial 10 includes a glass container 11 having a mouth at one end. Closing the mouth

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of container 11 is a dispensing closure member generally designated 12 secured to container 11 by clamping ring 13, all of which can be seen more clearly from a consideration of Fig. 2.

The parenteral solution bottle hereinbefore referred to is designated 14 and contains a parenteral solution 15. Bottle 14 is provided with rubber stopper 16 mounted in its neck and provided with an annular flange 16a overlying the upper lip of bottle 14. Securing stopper 16 in the neck portion of the bottle 14 is clamping ring 17 which is "rolled on" in a conventional fashion. An annular bead (not shown) of bottle 14 provides the anchoring means for clamping ring 17. Overlying stopper 16 is frangible rubber disc 18.

Extending through stopper 16 is a solution outlet passage (not shown but indicated by vacuum "dimple" 19 in disc 18). Vacuum "dimple" 19 is evidence that a sub-atmospheric pressure exists within bottle 14.

Also extending through stopper 16 is a second passage constituting an air inlet to bottle 14 during administration of solution 15. Mounted in this second passage and extending inwardly of bottle 14 is air tube 20. When solution 15 is to be administered, bottle 14 is mounted in mouth-downward fashion by means of a suspension device consisting of bail 21 and band 22 so that air tube 20 permits air to enter bottle 14 to replace solution 15 discharged through the outlet passage of stopper 16.

When it is desired to supplement solution 15 with a medicament of the character hereinbefore described or with one that is relatively unstable when provided in a solution form, it is merely necessary to insert the dispensing closure portion 12 of medicament containing vial 10 into the outlet passage of stopper 16.

In Fig. 2, dispensing closure 12 is seen to include a cap-like plug generally designated 23 which covers the mouth of container 11. In the embodiment shown, the body of plug 23 is provided with an arched diaphragm portion 24 and a depending annular skirt 25 which permits convenient positioning of plug 23 in the mouth of container 11. Plug 23 is also provided with an annular upstanding shoulder 26 which, in combination with the annular bead 27 of container 11, permits securement of plug 23 to container 11 by clamping ring 13. This securement is readily achieved by providing ring 13 in the form of a metal collar and "rolling" the lower edge as at 13a to grip bead 27.

Diaphragm portion 24 is provided with a centrally positioned aperture 28 which permits outflow of supplemental medicament 29. In the embodiment shown in Fig. 2, aperture or passage 28 is closed by hinged valve 28a which is provided integral with diaphragm portion 24.

Integral with diaphragm portion 24 and extending outwardly therefrom is a neck-like portion 30. Neck-like portion 30 is positioned about aperture 28 and is adapted to receive dispensing spout 31 and hold the same in a substantially airtight grip achieved by integral male threads 31a. Prior to use of the thus assembled container 10, we provide a protector cap as indicated at 32 to close off the puncturing end of spout 31. We also provide annular flange 31b on spout 31 to serve as a gripping means for insertion and removal of spout 31 from the outlet passage of a parenteral solution bottle stopper.

The use of the container 10 can be appreciated with a consideration of Fig. 1 wherein the spout 31 of container 10 is shown positioned above the dispensing closure portion of a parenteral solution bottle prior to insertion therein. Spout 31 can be adapted to puncture any frangible closure means overlying stopper 16 such as disc 18 in the event such closure means is not removed prior to use. After spout 31 is inserted into stopper 16, thereby communicating the interior of container 10

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with that of bottle 14, medicament 29 can be forced downwardly through aperture 28 and the bore of spout 31 merely by "pumping" container 10. The pumping action referred to involves a relative longitudinal movement of container 10 with respect to the larger parenteral solution bottle so as to cause resilient diaphragm portion 24 to flex, thereby varying the internal volume of container 10.

We have discovered that the effect of the vacuum in container 14 after vial 10 has been attached can be overcome by filleting or thickening that portion of plug 23 at the juncture between diaphragm portion 24 and annular skirt 25 as at 24a. Thus, there is provided a heavy and relatively non-flexing annular portion that rests against the side and upon the top of the rim of container 10 which causes plug 23 to assume its static position shown in Fig. 2 whenever it has been flexed as shown in Fig. 3.

The arched, or steeply pitched diaphragm portion 24, as indicated specifically at 24b also urges a return to the structure of Fig. 2 after the diaphragm portion 24 has been doubled back substantially upon itself, as illustrated in Fig. 3. This return, therefore, is achieved irrespective of the influence of vacuum generally existing within bottle 14.

In contrast to the desirable result obtained by the structural features of plug 23 described above, the provision of a plug with a flat diaphragm portion would result in a tendency of the diaphragm to remain in the "doubled back" position of Fig. 3 under the influence of the vacuum in bottle 14. In addition, the arched diaphragm portion 24, the wall portions of which are extended upwardly in almost a vertical plane, permits the achievement of another new result—the substantial variation of the internal volume of vial 10 without having to flex diaphragm portion outwardly. Thus, we have further minimized the possibility of accidental disengagement of vial 10 from bottle 14 during "pumping." In the embodiment shown, it is only necessary to push vial 10 downwardly toward bottle 14 to achieve pumping, the vial returning to its normal or static position without the need for exerting a pulling force.

Operation

Once spout 31 has been inserted into the outlet passage indicated by "dimple" 19 as outlined above, it is only necessary to thrust down lightly on vial 10 to cause medicament 29 to be forced out of vial 10 into bottle 14. The same downward movement causes neck-like portion 30 to move toward the interior of vial 10, dislodging valve 28a from its seat in aperture 28. The portion of diaphragm 24 adjacent neck-like portion 30 tends to become folded or telescoped as seen in Fig. 3. This "rolling" of diaphragm 24 aids in opening valve 28a. In this fashion, none of the medicament 29 is lost since vial 10 is essentially a closed container until communication between it and bottle 14 is established.

The above procedure is followed when medicament 29 is a liquid, and in the event all medicament is not forced into bottle 14 by one thrust, subsequent relative movement of vial 10 with respect to bottle 14 causes the remaining medicament to flow through spout 30 into bottle 14. We prefer to refer to this as a pumping action since the inward flexing of diaphragm 24 results in a smaller

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internal volume in vial 10 with an attendant increase in pressure.

In an analogous fashion, medicament 29, if a solid, can be transferred. Such may be the case where it is impossible to provide certain drugs in a stable liquid form. When medicament 29 is a solid, it can be transferred by inverting the united containers so that the additive vial is lowermost. Thrusting vial 10 upwardly causes valve 28a to open and solution 29 from bottle 14 to run into vial 10. Upon reinversion of the united containers, solution-borne solid medicament 29 can be "pumped out" of vial 10 as set forth above with respect to the operation involving a medicament originally provided in liquid form.

The foregoing detailed description has been given for clearness of understanding only and no unnecessary limitations are to be inferred therefrom.

We claim:

1. In a device for adding a supplemental medicine to a parenteral solution container, a vial having an open mouth providing a closure-supporting lip and having an external bead about said mouth, a resilient closure over said mouth having an edge portion supported on said lip and having an outwardly arched flexible central portion, said closure also having an inwardly depending annular skirt received within the open mouth of said vial, a juncture between said central portion and said skirt being filleted to provide a relatively thick non-flexing skirt and a relatively thin central portion whereby the central portion is induced to return to its unflexed condition after being flexed, an aperture in said central portion and an outwardly extending integral tubular projection about said aperture, a rigid puncturing spout in said projection, and a circular metal clamping ring engaging said bead and said edge portion to seal said closure to said vial, said outwardly arched central portion being generally dome-shaped inwardly and outwardly thereof and providing an annular portion between said tubular projection and said closure edge portion, said annular portion being deformable upon movement of said spout inwardly of said vial, said annular portion, when so deformed, being generally folded on itself and thereby being effective to urge said spout outwardly of said vial.

2. The structure of claim 1 in which said edge portion is equipped with an upwardly extending generally rounded annular shoulder that, with said outwardly arched central portion, provides a circular recess in which one edge of said clamping ring is received.

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