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PARENTERAL SOLUTION EQUIPMENT

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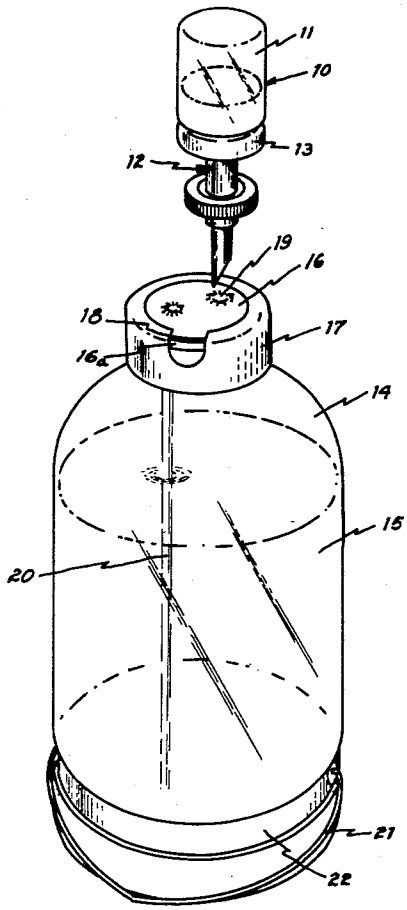

Fig. 1.

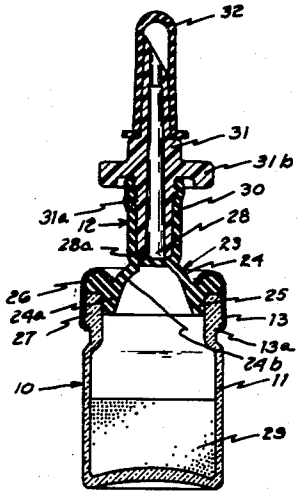

Fig. 2.

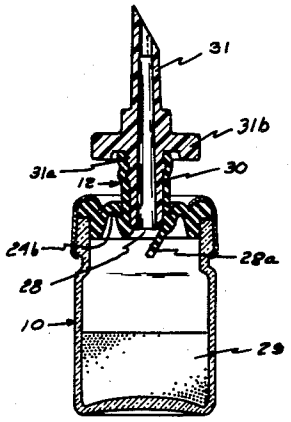

Fig. 3.

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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

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 **16***a* 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 **13***a* 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 **28***a* 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 **31***a*. 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 **31***b* 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**

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 **24***a*. 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 **24***b* 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 **28***a* 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 **28***a*. 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 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 **28***a* 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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