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## 3,001,525 PARENTERAL EQUIPMENT

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Many solutions may be shipped as concentrates and reconstituted at the point of use by mixing with distilled 10 water or with another solution. The reconstituted solution is then administered through an administration set which typically includes a needle, tubing and drip chamber. Heretofore, the typical steps required for use of reconstituted solutions have been (1) connecting a sterile container for the concentrate to the solution container which has been previously filled with distilled water or other solution, (2) mixing the concentrate with the solution to reconstitute, (3) disconnecting the concentrate container and (4) connecting an administration set to the 20 solution container.

This invention is intended to simplify the use of reconstituted solutions by shipping the concentrate in a container which can serve as a drip chamber so that the concentrate container need not be disconnected after 25 reconstitution but can remain as a part of the administration set. In a preferred form, the concentrate chamber is of resilient transparent walled plastic so that alternate squeezing and release will have a pumping action which speeds up the mixing necessary for reconstitution.

In the drawing FIG. 1 is a section through a solution container with the concentrate container connected thereto for reconstitution, FIG. 2 shows the administration set connected to the solution container ready for administration of the reconstituted solution, FIG. 3 is an elevation 35 of the concentrate container, and FIG. 4 is a sectional elevation of another form of concentrate container.

The concentrate for forming the solution may be either a powder or a liquid and is shipped in a sealed container 1 which may, for example, be made of vinvl plastic or other transparent resilient tubing. At the lower end the walls of the tube are pinched together at 2 and fused to each other and to a plastic drain tube 3 having its outer end covered by a removable cap seal 4. At the upper end the walls of the tubular body are pinched together at 5 and are fused to each other and to a plastic tube 6, the inner end 7 of which depends within the upper end of the body and provides a drip tube nozzle. The upper end of the tube 6 is fixed over a tubular projection 50 8 forming an extension of a cannula 9. Midway between the projection 8 and the cannula 9 is an integral flange 10 by which the cannula may be forced through the diaphragm seal 11 in a rubber stopper 12 for the flask 13 which contains the distilled water or other solution to be 55 mixed with the concentrate in the container 1. The stopper carries an air vent tube 14 having its upper end extending above the liquid level of the flask when the flask is inverted. The lower end of the air vent tube is sealed by a diaphragm 15 which may be suitably 60 punctured or removed when the contents of the flask are to be dispensed.

In FIG. 4 is shown another shipping container the lower end of which is of the same construction as the container shown in FIG. 3. The upper end of the plastic tubing 1 is sealed directly to the rim of the flange 10. This may be done by heat sealing. After sealing the tubular projection 8 at the lower side of the flange 10 depends within the upper end of the plastic body 1 and serves as a drip tube by means of which the rate of flow of fluid can be observed. The cannula 9 as in the FIG. 3 construction is closed by a cap 13a.

Both of the containers of FIGS. 3 and 4 are sterilized

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after filling, preferably by steam, and are sealed by the caps 4 and 13a to retain sterility. If sealed while the container is filled with vapor, the condensation of the vapor will produce a vacuum. Both the containers and contents are sealed in a sterile condition and will remain sterile during shipment and other handling preceding arrival at the point of use.

The first step for using the contents of either the FIG. 3 or the FIG. 4 container is to remove the cap 13a and to force the cannula 9 through the diaphragm 11 in the stopper closure 12 for the flask container. This establishes communication between the flask 13 and the container 1 and some liquid will flow from the flask to the container. The liquid flow may be accelerated by squeezing the walls of the container to expel air up through the cannula into the flask 13 and then releasing the container so that as the container walls expand due to their inherent resilience liquid will be drawn down into the container. By alternately squeezing and releasing the flexible walls of the container, liquid can be surged back and forth between the flask 13 and the container 1 to assist in mixing the solution with the concentrate to reconstitute the concentrate into solution. From one aspect, the container acts as an expansible chamber surge pump. The surging action is particularly useful when the concentrate is a powder. The reconstitution takes place with the flask 13 in the inverted position so that there will be a free flow of liquid into and out of the concentrate container 1. After reconstitution, the cap 4 may be removed and the upper end of the dispensing tubing 16 connected to the depending tube 3 at the lower end of the container. The dispensing tubing 16 is usually made of one of the flexible plastics and may have fixed to its lower end a hypodermic needle 17. The container 1 now serves as a drip chamber which can be used in the conventional manner. If the container 1 should be too full of liquid, the drip level can be adjusted by moving the flask 13 to an upright position and squeezing the container 1 to force liquid back into the flask. On the other hand, if the container should not have enough liquid in it, additional liquid can be drawn into the container by squeezing and releasing the side walls to suck liquid into the container from the flask.

By having the shipping container for the concentrate in a form such that it can be used as a drip chamber, the reconstitution of parenteral solutions can be effected with a minimum of handling and according a minimum of opportunity for contamination There further is a very substantial saving in expense. Heretofore when the concentrate containers were not usable as drip chambers, it was necessary that each concentrate container have a cannula such as illustrated at 9 and a cap for the cannula such as illustrated at 13a. The reconstitution started with the insertion of the concentrate container cannula through the diaphragm 11 in the rubber stopper 12. After reconstitution, it was then necessary to have the same drip chamber such as illustrated in FIG. 3 or 4 with another cannula 9 and another cap 13a so that the cannula of the drip chamber could be inserted through the diaphragm 11 after the concentrate container and cannula had been removed. Instead of having the added cost of a separate concentrate container and cannula. applicant has completely eliminated this cost by combining the functions of a shipping and storage container and drip chamber into the conventional drip chamber. This means that applicant is able to supply a throw away dispensing kit consisting of needle 17, tubing 16 and drip chamber 1 filled with the desired concentrate for substantially the same price as those elements would cost 70 without the concentrate when forming a one time user or throw away dispensing kit. The reason for this is that the major element in the cost of such kits is the

labor and cost of sterilizing which is unchanged whether the drip chamber container 1 is empty or is filled with concentrate.

What is claimed as new is:

1. A container having a tubular flexible walled body of resilient transparent material hermetically sealed at both its upper and its lower end, the structure for sealing the lower end of the body including a depending tube of size for connection to tubing for dispensing solutions and a removable cap seal over the lower end of the tube, 10 the structure for sealing the upper end of the body including a drip tube nozzle depending within the upper and of the body and an upwardly extending conducting means leading to said nozzle and a removable cap seal over the liquid conducting means, a concentrate within 15 the body for reconstitution into a solution, the container and concentrate being sterilized and sealed, the liquid conducting means being connectable to a liquid containing flask much larger than the shipping container, the body of the container when connected to the flask by 20 the liquid conducting means serving as an expansible chamber pump for surging liquid back and forth between the container and flask to mix the concentrate with the liquid for reconstitution into a solution and the container thereafter serving as a drip chamber, and the tube being 25 connectable to tubing for dispensing the solutions flowing through the drip chamber.

2. A container having a flexible body of resilient transparent material hermetically sealed at both its upper and its lower end, the structure for sealing the lower end of 30 the body including a depending small diameter tube permanently bonded to the body and of size for connection to tubing for dispensing solutions and a removable cap seal over the lower end of the tube, the structure for sealing the upper end of the body including a cannula 35 permanently bonded to the body and having an associated portion projecting interiorly inside the body to provide a drip tube nozzle and a removable cap seal over the cannula, a concentrate within the body for reconstitution into a solution, the container and concentrate 40 being sterilized and sealed to retain the inherent sterilization, the cannula being connectable to a liquid containing flask and the body of the container when so connected serving as an expansible chamber pump for surging liquid back and forth between the container and flask to mix  $_{45}$ the concentrate with the liquid for reconstitution into a solution and thereafter serving as a drip chamber, and the tube at the lower end of the body being connectable to tubing for dispensing solutions flowing through the drip chamber. 50

3. A container having a transparent chamber capable of expansion and contraction at will and hermetically sealed by seals breakable at both its upper and its lower end, the structure for sealing the lower end of the chamber including a depending tube of size for connection to 55tubing for dispensing solutions and a removable cap seal over the lower end of the tube, the structure for sealing the upper end of the chamber including an upwardly extending cannula, an associated tube depending into the body to provide a drip tube nozzle and a removable cap 60 over the cannula, a concentrate within the chamber for reconstitution into a solution, the container and concentrate being sterilized and sealed to retain the inherent sterilization, the cannula being connectable to a liquid containing flask and when connected serving as an ex-65 pansible chamber pump for surging liquid back and forth between the container and flask to mix the concentrate with the liquid for reconstitution into a solution and thereafter serving as a drip chamber, and the tube being connectable to tubing for dispensing solutions flowing 70 through the drip chamber.

4. A shipping or storage container for a parenteral solution concentrate which upon connection to a liquid containing flask can discharge its contents to the flask for mixing to form or reconstitute a parenteral solution 75 Science Library.)

and which thereafter need not be disconnected but can remain as part of a solution administration set, said container having a flexible body of resilient transparent material hermetically sealed at both its upper and its lower end, the structure for sealing the lower end of the body including a depending small diameter tube permanently bonded to the body and of size for connection to tubing for dispensing solutions and a removable cap seal over the lower end of the tube, the structure for sealing the upper end of the body including liquid conducting means permanently bonded to the body and having an outer end outside the body and an inner end projecting interiorly inside the body to provide a drip tube nozzle and a removable cap seal over the outer end of said liquid conducting means, a concentrate within the body for reconstitution into a solution, the container and concentrate being sterilized and sealed to retain the inherent sterilization, the outer end of said liquid conducting means being connectable to a liquid containing flask and the body of the container when so connected serving as an expansible chamber pump for surging liquid back and forth between the container and flask to mix the concentrate with the liquid for reconstitution into a solution and thereafter serving as a drip chamber, and the tube at the lower end of the body being connectable to tubing for dispensing solutions flowing through the drip chamber.

5. A shipping or storage container for a parenteral solution concentrate which upon connection to a liquid containing flask can discharge its contents to the flask for mixing to form or reconstitute a parenteral solution and which thereafter need not be disconnected but can remain as part of a solution administration set, said container having a flexible body of resilient transparent material hermetically sealed at both its upper and its lower end, the structure for sealing the lower end of the chamber including a depending tube of size for connection to tubing for dispensing solutions and a removable cap seal over the lower end of the tube, the structure for sealing the upper end of the chamber including an upwardly extending liquid conducting means, an associated tube depending into the body to provide a drip tube nozzle and a removable cap over the liquid conducting means, a concentrate within the chamber for reconstitution into a solution, the container and concentrate being sterilized and sealed to retain the inherent sterilization, the liquid conducting means being connectable to a liquid containing flask and when connected serving as an expansible chamber pump for surging liquid back and forth between the container and flask to mix the concentrate with the liquid for reconstitution into a solution and thereafter serving as a drip chamber, and the tube being connectable to tubing for dispensing solutions flowing through the drip chamber.

### References Cited in the file of this patent

### UNITED STATES PATENTS

2,682,268	Ryan et al June 29, 1954
2,704,544	Ryan Mar. 22, 1955
2,777,443	Thomas et al Jan. 15, 1957
2,786,467	Price Mar. 26, 1957
2,829,644	Anderson Apr. 8, 1958
2,855,131	Gewecke et al Oct. 7, 1958
FOREIGN PATENTS	
1,108,782	France Sept. 14, 1955
1,127,010	France Aug. 6, 1956
89,076	Norway Apr. 15, 1957
89.889	
02,002	Norway Aug. 26, 1957

### OTHER REFERENCES

Walter et al.: "A Closed Gravity Technique," Surgery, Gynecology and Obstetrics, volume 94, No. 6, June 1952, pp. 687-692 (pp. 687-689 relied on). (Available in Science Library.)