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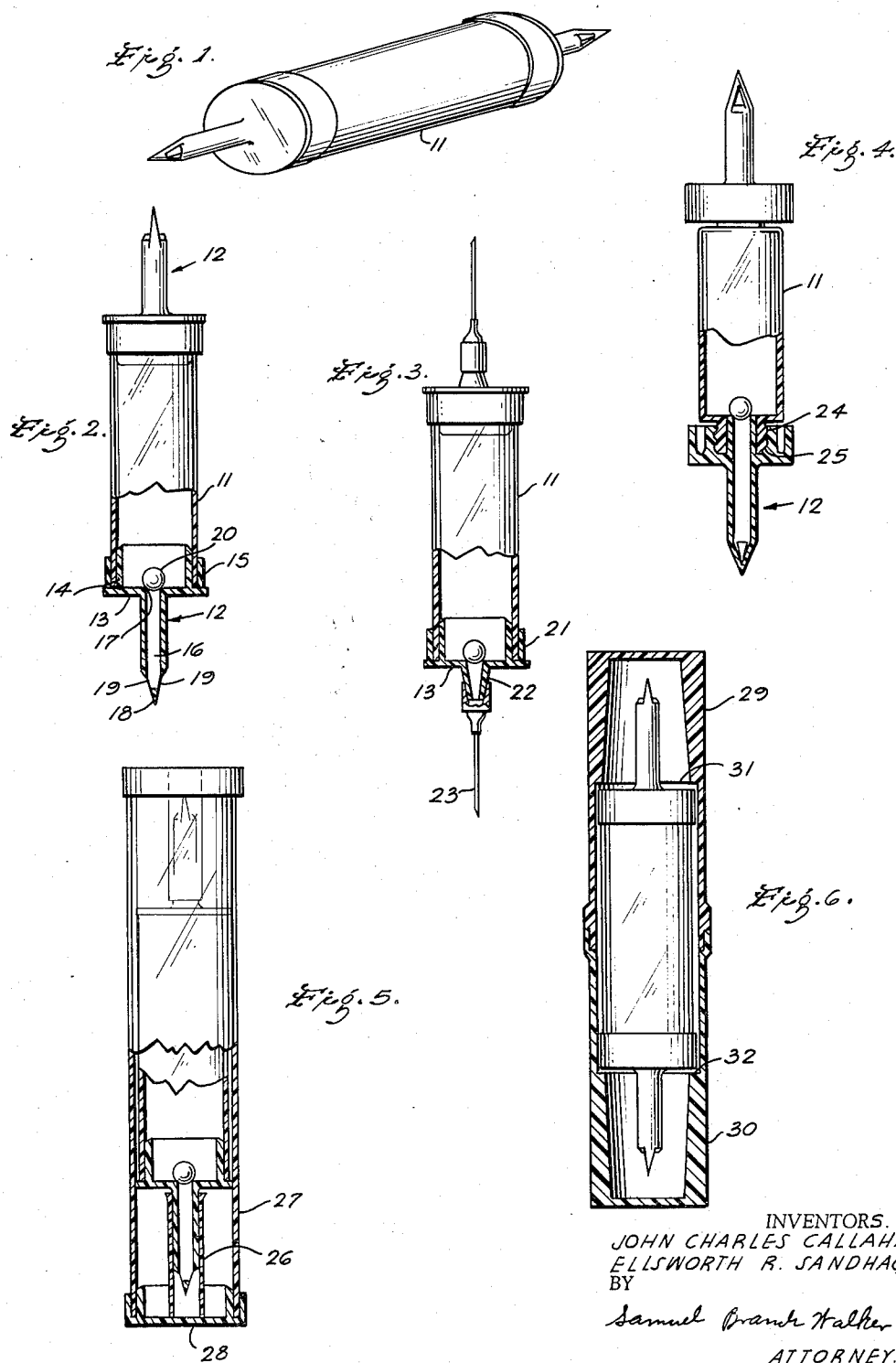
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ASEPTIC LIQUID TRANSFER APPARATUS

Filed Aug. 20, 1958

2 Sheets-Sheet 1



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2 Sheets-Sheet 2

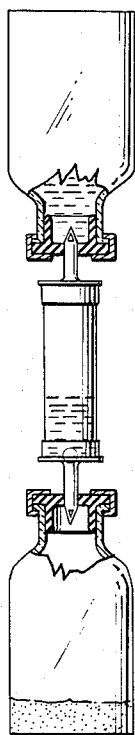
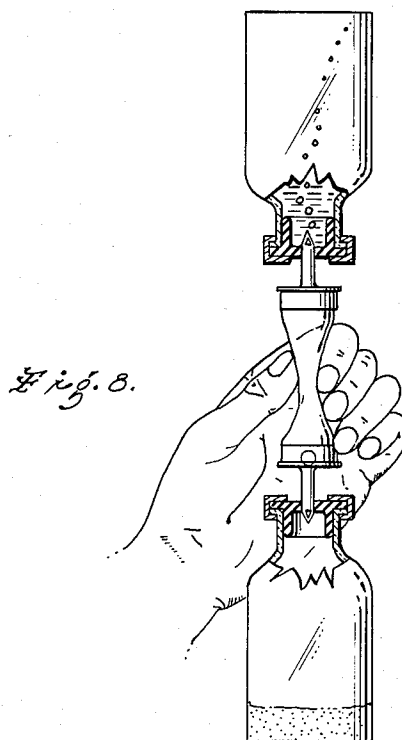
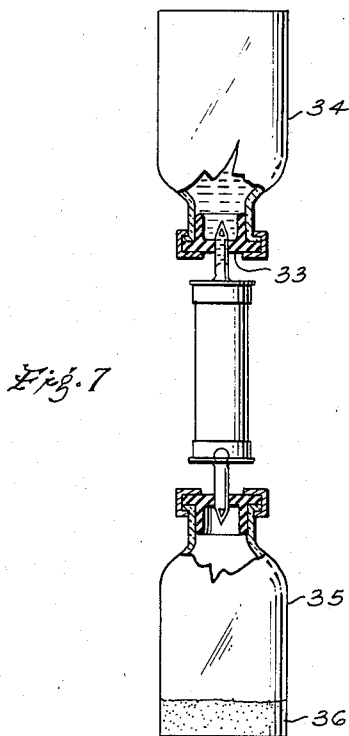


*Fig. 9.*

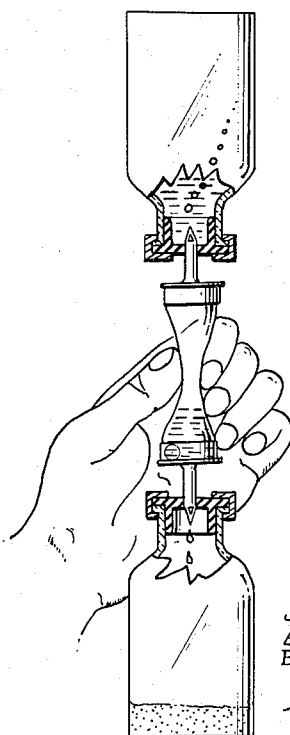


*Fig. 10.*

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1

2,954,769

## ASEPTIC LIQUID TRANSFER APPARATUS

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3 Claims. (Cl. 128—272)

This invention relates to a liquid transfer apparatus for the sterile transfer of liquids from one container to another in which a squeezable tube displaces fluid and a positionable ball and cooperating valve seat serve to control fluid flow, the ball being readily displaced from operating position, and a needle on each end of the tube serving to puncture two containers each having a puncturable elastic stopper.

In modern hospital practice liquids are frequently injected in patients for intravenous feeding, administration of blood, or plasma, or other liquids. Frequently vitamins or antibiotics or other materials must be added to the liquid just prior to injection. Sometimes these added materials are not storage stable in the presence of the liquid, sometimes the variety of materials chosen would present too large an inventory problem. For these reasons it is highly desirable that the liquid portion be stored in one sterile container and that additional liquid or solid portions be stored in other sterile containers and that the contents of the two be sterilely combined just prior to administration. This requires the transfer of part or all of the liquid from one container to a second container, mixing to insure solution and homogeneity, and perhaps transferring of the liquid back to the original container. For example, 20 milliliters may be transferred from a sterile intravenous gluconate solution to a smaller vial containing vitamins and then, after solution of the vitamins, the contents of the second container are transferred back to the first container, blended to uniformity and injected into the patient. In the past a usual method of such transfer was the use of hypodermic syringes in which liquid was drawn into the syringe through the stopper of the first container and injected through the stopper of the second container, and then drawn back into the syringe and re-injected into the first container. In such a method the risk of contamination is greater than desired. Obviously, the stoppers cannot be withdrawn from the bottles and the contents poured from bottle to bottle without an even greater risk of contamination.

Logically, a convenient method of transfer would be to use a double ended needle and permit the fluid to flow through the needle from one container to the other. Unfortunately, any convenient size conduit is subject to air-lock and fluids do not flow readily.

It has now been found that by using the present apparatus liquids may be easily and smoothly transferred from one container to another under sterile conditions so as to render convenient the mixing of fluids for injection without risk of compromising sterility.

Details of the apparatus and method of its use are given

2

in conjunction with certain specific embodiments shown in the accompanying drawings:

Figure 1 is a pictorial view of the liquid transfer apparatus.

Figure 2 is a front view, in partial section, of a liquid transfer apparatus having a single rim head, and a cylinder retaining sleeve.

Figure 3 is a front view, in partial section, of a modification in which detachable needles are shown.

Figure 4 is a front view in partial section, of a liquid transfer apparatus in which the tube is formed with screw threaded ends.

Figure 5 is a front view in partial section, of a liquid transfer apparatus in a built up outer container.

Figure 6 is a front view of a liquid transfer apparatus in a molded container, the container being shown in section.

Figure 7 is a view in partial section of the liquid transfer apparatus inserted in containers for use.

Figure 8 is a front view in partial section showing the flexible resilient cylinder being squeezed, to transfer air to the upper container.

Figure 9 is a front view in partial section showing the flexible resilient cylinder as released, partially filling with liquid.

Figure 10 is a front view in partial section showing the ball displaced and liquid flow being assisted by squeezing.

The main body of the liquid transfer apparatus is a flexible resilient tube 11 which is conveniently formed of polyethylene. Conveniently, but not necessarily, the tube is cylindrical in shape with a circular cross-section; although other configurations and cross-sections may be used. It is preferred that the tube be transparent so its contents are visible. Symmetrically placed on each end of the flexible resilient tube is a closure 12. This closure includes a cylinder head 13 including means for attaching the tube to the closure. As shown in Figure 2 a short cylindrical rim 14 which is an integral part of the closure, is of such size that the tube snugly fits over the rim. A retaining band 15 may be used to more firmly hold the tube against the rim. An adhesive may be used if desired. The tube and the two closures thus form a chamber the volume of which may be varied by squeezing the tube. Functionally attached to the cylinder head and conveniently integral therewith, as shown in Figure 2, is a hollow needle 16. The junction of the fluid passage in the hollow of the needle with the cylinder head forms a valve seat 17. At the free end of the needle is a needle point 18. If the closure and the needle are integrally formed, this point may be simultaneously molded conical in configuration with apertures 19 on one or both sides. By using a comparatively sharp point of say from 30 to 45° included angle, apertures may be formed by opening into the hollow of the needle thus forming a point which may readily puncture the ordinary rubber closure used on containers of injectable medicinals. Conveniently the entire closure, including needles, is molded in one piece, but built up construction can be used.

Inside of the chamber is a ball 20. Each end of the liquid transfer apparatus is the same and the ball rests by gravity at the lower end. The cylinder head 13 is of sufficient size that the ball may be either seated in the valve seat or displaced and held on the cylinder head adjacent to but out of working relationship with the valve seat. Conveniently, the closure including the needles is

3

molded of a single piece of transparent plastic such as polystyrene. The tube is conveniently of polyethylene.

Preferably the tubing is of polyethylene which cannot be heated sterilized without melting. Thus the liquid transfer apparatus is designed for single use and is so economical that it may be discarded more easily than sterilized. The apparatus may be constructed of nylon or other material which can be heat sterilized but such construction is usually slightly more expensive, and sterilization procedures as accomplished at an individual hospital are much more subject to suspicion than sterilization procedures in a manufacturing plant.

Other configurations for the cylinder heads may be used, such as shown in Figure 3 in which a second rim 21 is formed on the cylinder head and the tube slips between these second rims and is preferably adhesively united thereto. As shown in Figure 3 the closure may terminate in a male Luer fitting over which a metallic hypodermic needle 23 is placed.

As shown in Figure 4 the flexible resilient tube may be formed with tube screw threads 24 which engage with closure screw threads 25 formed in the closure, so that the closure is screwed on to the resilient tube rather than held by friction and/or an adhesive.

During shipment and storage it is desirable to protect the needle points from damage. This may be accomplished by a needle guard 26 which is a piece of hollow flexible tubing such as polyethylene slightly longer than the hollow needle which is slipped over the hollow needle and thus protects the point. The needle guards are easily pulled off and discarded at the time of use.

As shown in Figure 5 the assembled liquid transfer apparatus together with the needle guards is enclosed in an outer container 27 conveniently of a transparent plastic at least one end of which is a cap 28 which may be readily slipped off of the outer container.

Alternatively the outer container may be molded. As shown in Figure 6 the outer container consists of two molded pieces, a top 29 and a bottom 30 which slideably fit together to form the container, and which have positioning ledges 31 and 32 which hold the liquid transfer apparatus in position and thus protect the needle points from damage.

The liquid transfer device in the container may be sterilized by radiation or contact with a sterilizing gas such as ethylene oxide or formaldehyde which will destroy any micro-organisms. Apertures may be formed in the container to admit such a sterilizing gas but normally a change in external pressure is sufficient to cause the sterilizing gas to flow into contact with the assembled containers. For example, a group of the containers on trays may be placed in a sterilizing autoclave, the autoclave evacuated and the sterilizing gas admitted at a suitable dilution and under pressure. For example, a 10% ethylene oxide in carbon dioxide mixture may be admitted at a pressure of 30 pounds per square inch absolute and after a cycle of thirty minutes the pressure may be dropped and the autoclave opened to remove the sterile assemblies. The sterilizing gas may be flushed out of the containers by vacuum, sterile-air cycles if desired.

The use of the apparatus is illustrated in Figures 7 to 10. After sterilizing the external surface of the rubber stopper 33 in a liquid containing bottle 34, one of the needle points of the liquid transfer apparatus is forced through the rubber stopper. Similarly a powder containing bottle 35 has the stopper sterilized and punctured. The assembly of the liquid transfer apparatus with a bottle on each end is then positioned with the liquid containing bottle at the top, the ball on the valve seat, and the powder containing bottle at the bottom. By squeezing the flexible resilient tube, air in the tube is forced into the liquid containing bottle as shown in Figure 8. On release of the flexible resilient tube, liquid is forced down through the hollow needle into the chamber of the liquid transfer apparatus by the thus compressed air. By addi-

4

tional squeezing more of the trapped air is forced out of the liquid transfer apparatus chamber into the liquid containing bottle at the top.

Preferably the ball and the valve seat form an imperfect valve so that on squeezing, part of the contents of the chamber are forced passed the ball into the lower container with each stroke. While all of the liquid to be transferred can be forced passed the ball and imperfect valve seat into the lower container, it is more convenient and more rapid after the liquid transfer apparatus chamber becomes at least partially filled with liquid to shake the assembly slightly to one side so as to transfer the ball over on to the cylinder head, then the liquid can flow rapidly into the lower bottle and by rapidly squeezing the flexible resilient tube, air is displaced from the lower bottle into the chamber and from the chamber into the upper bottle while liquid flows down.

The volumetric efficiency as a pump is fairly low because both air and liquid can flow in both directions, but the quantities used in hospital practice may be transferred in a short time.

To transfer the liquid back to the original container after it has dissolved any powder 36 in the powder containing bottle is very simple because the liquid transfer apparatus is symmetrical and by reverting the inverted liquid containing bottle all liquids transferred to the powder bottle may be transferred back to the original container.

After mixing is accomplished the liquid transfer apparatus is withdrawn from the rubber stopper in the liquid containing bottle and discarded together with the empty powder containing bottle. The liquid containing bottle is then ready to be used in a conventional apparatus for administration to the patient.

The exact proportions of the various parts of the liquid transfer apparatus and materials of construction can be varied over a wide range without departing from the scope of this invention as set forth in the following claims.

We claim:

1. An apparatus for the aseptic transfer of liquids from one sterile container to another sterile container, each container having a puncturable elastic stopper, comprising: two hollow rigid needles, having elastic-stopper puncturing points and at least one fluid orifice adjacent each of said points, a flexible resilient tube of cylindrical configuration, a closure at each end thereof, said closure including a fluid passage through each said closure and in communication with one of said needles, an imperfect valve seat formed by the inner end of each fluid passage, and a flat cylinder head around said seat; and a single corrosion resistant ball in the thus formed chamber of such size that the ball may be readily positioned on the flat of the cylinder head, in inactive position, or in the valve seat, in active position, to restrict fluid flow through the lower said needle.

2. An apparatus for the aseptic transfer of liquids from one sterile container to another sterile container, each container having a puncturable elastic stopper, comprising: a flexible resilient tube of cylindrical configuration, a closure at each end thereof, said closure including (1) a hollow rigid needle having an elastic-stopper puncturing point, (2) at least one fluid orifice adjacent the point of each needle, (3) an imperfect valve seat at the base of each said needle, and (4) a flat cylinder head around said seat; and a single corrosion resistant ball in the thus formed chamber of such size that the ball may be readily positioned on the flat of the lower cylinder head, in inactive position, or on the valve seat, in active position, to restrict fluid flow through the lower said needle.

3. An apparatus for the aseptic transfer of liquids from one sterile container to another sterile container, each container having a puncturable elastic stopper, comprising: a flexible resilient tube, a closure at each end

5

thereof, a hollow rigid needle having an elastic-stopper puncturing point, functionally attached to each closure, a fluid passage through each said closure in communication with the hollow of the needle, an imperfect valve seat in position to control fluid flow through said passage, and, forming a part of said closure and, a flat cylinder head around each said seat integral with the said flexible resilient tube; and a single corrosion resistant ball in the thus formed chamber of such size that the ball may be readily positioned on the flat of the lower cylinder head, in inactive position, or on the valve seat, in

5

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active position, to restrict fluid flow through the lower said needle.

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