Aug. 23, 1960 F. W. BIEBERDORF ET AL 2,949,712

LIQUID PACKAGING METHOD

Original Filed March 24, 1950 2 Sheets-Sheet 1

Fig. 1

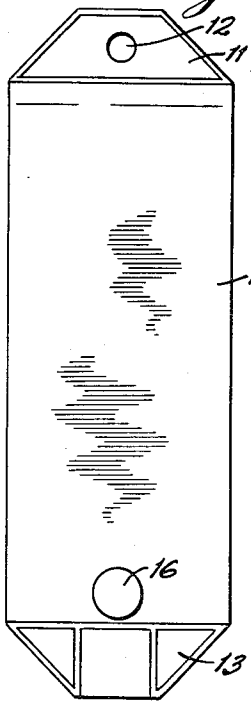


Fig. 2

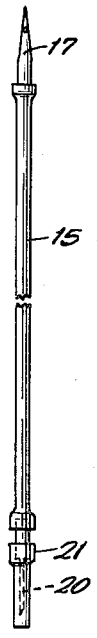


Fig. 3

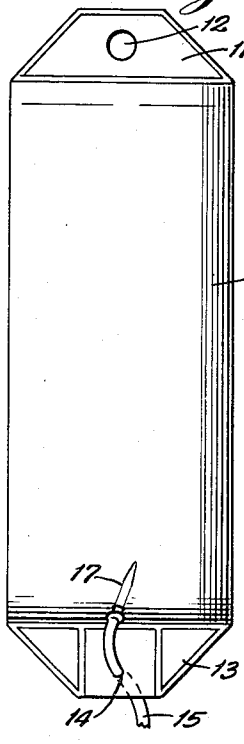


Fig. 4

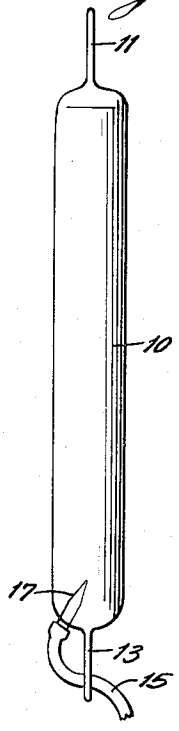
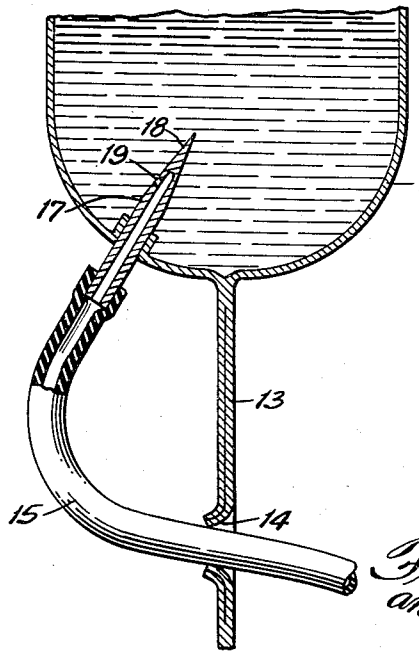


Fig. 5



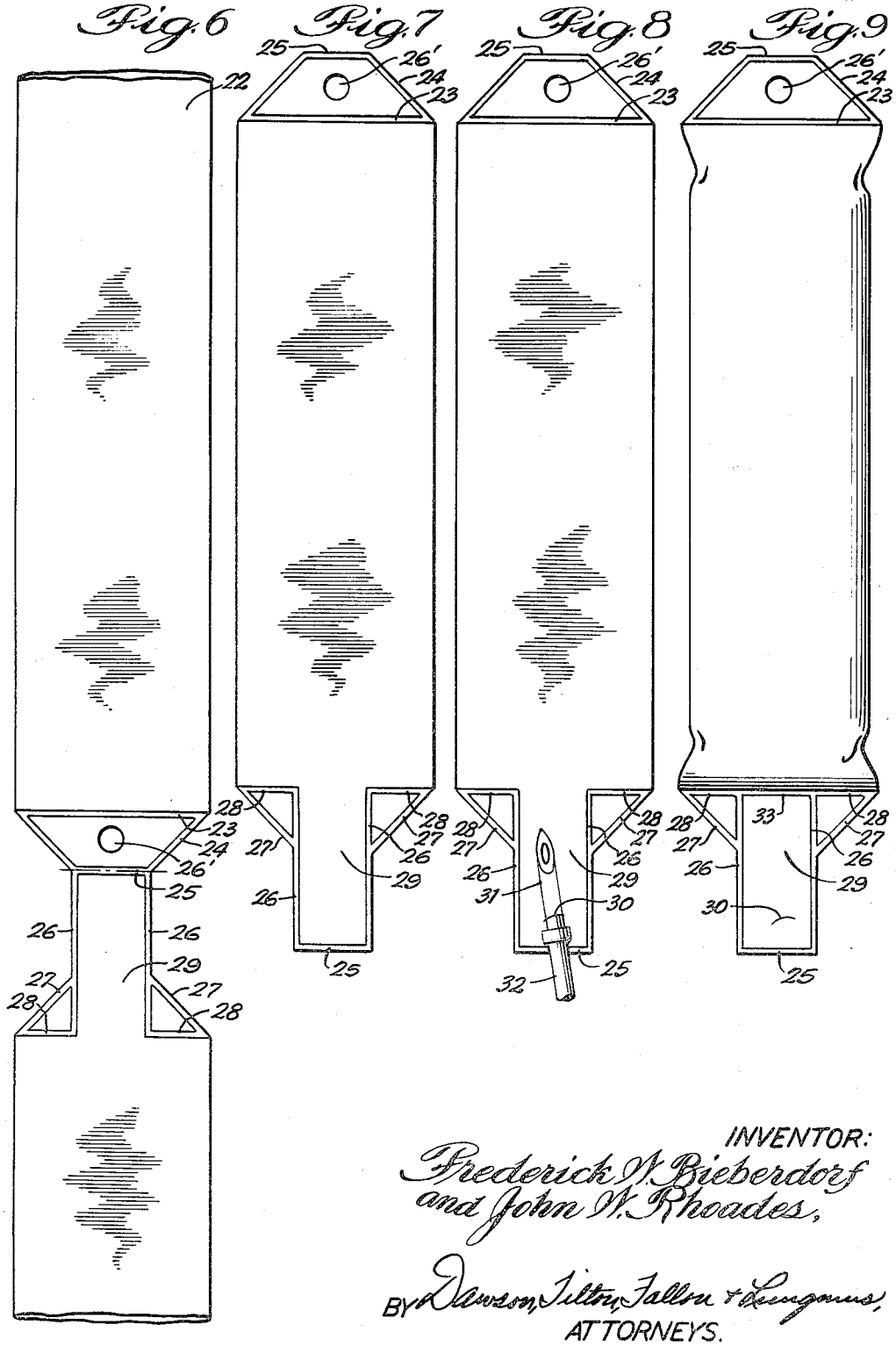
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LIQUID PACKAGING METHOD

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LIQUID PACKAGING METHOD

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Application Feb. 8, 1954, Ser. No. 408,733, which is a substitute for application Ser. No. 151,638, Mar. 24, 1950. Divided and this application Jan. 18, 1955, Ser. No. 485,541

10 Claims. (Cl. 53—29)

This invention relates to liquid packaging and dispensing means and method. The invention is particularly useful in connection with a container for parenteral solutions and for the packaging of sterile solutions therein and the dispensing of the solutions therefrom for injection.

This application is a division of our copending application, Serial No. 408,733, filed February 8, 1954, which in turn is a substitute for our copending application, Serial No. 151,638, filed March 24, 1950.

An object of the invention is to provide a packaging method and means for the storing and dispensing of sterile liquids. A further object is to provide a container having new and highly useful functions. A further object is to provide dispensing containers and means for storing therein liquids and more particularly parenteral solutions from which such solutions may be introduced parenterally into patients. A still further object is to provide a unique method for storing solutions within a sterile container without introducing unsterile material into the container while at the same time providing means for withdrawing the liquid without contamination thereof. Yet another object is to provide a method and means for filling a sterile container with a sterile solution while preventing contact between the solution and the inside surfaces of the container with the outside air and without requiring individual handling of the container until it is filled, labeled, and ready for the attachment of the dispensing tube and needles. Other specific objects and advantages will appear as the specification proceeds.

The invention is illustrated in specific embodiments, by the accompanying drawing, in which—

Fig. 1 is a side view in elevation of an empty container which may be employed in the practice of our invention; Fig. 2, a broken plan view of a tube equipped at each end with a needle; Fig. 3, a view similar to Fig. 1 but showing the container filled; Fig. 4, a side view in elevation of the container shown in Fig. 3; Fig. 5, a broken sectional view of a portion of the container and showing the withdrawal needle therein; Fig. 6, a top plan view of plastic tubing from which the containers may be formed and illustrating a method of forming the individual containers from the tubing; Fig. 7, a plan view of an unfilled but sealed container; Fig. 8, a plan view of the container shown in Fig. 7 but illustrating a means for introducing sterile liquid within the sterile container; and Fig. 9, a plan view of the filled container and after the withdrawal of the filling tube or needle.

In the illustration given, 10 designates a container which may be formed of any suitable material. We prefer to form the container of plastic material which may be sealed along its end portions. The container may be formed of extruded tubular thermoplastic material, or it may be formed of sheet material which is folded upon itself and then heat-sealed. It will be understood that the container may be formed by a variety of methods and in different shapes.

Methods are now known for the forming of plastic tubing so that the interior surfaces are sterile. In the forming of plastic tubes by extrusion, it is found that the interior surfaces of the tubes are sterile and the collapsed condition of the bag tends to maintain such interior surfaces sterile. We have discovered that after the extrusion or forming of the tubes with sterile inside surfaces, the tubes may be sealed while under the sterile conditions at the time of the forming of the tubes so that thereafter the interior surfaces are maintained in sterile condition. We have also discovered that the tubes may be filled readily and in the volume required for plant production, with sterile liquids and without introducing unsterile material into the container.

We have found that by employing a container having sterile inner surfaces and with the ends thereof sealed, liquid can be effectively introduced through a hollow needle or tube into the container and preferably through a passage at one end of the container so that the liquid is effectively introduced within the container and the container sealed thereafter before the withdrawal of the needle or tube. In other words, we have found a method and means for filling a sealed and sterile container with a sterile solution exposed only to the inner sterile walls of the container and, at no time, from the first formation of the container and through the filling process and the dispensing process, do the inside sterile surfaces come in contact with the outside air. Further, by the method and structure shown, it is not necessary that there be any individual handling of the container until it is filled, labeled, and ready for the attachment of the dispensing tubes and needles.

In the illustration given in Fig. 1, the container 10 is heat-sealed at the upper end 11 and this end may be provided with an opening 12 adapted for receiving a hook or the like for the suspending of the container when the liquid is to be dispensed. The lower end of the container consists of end flaps 13 which may be heat-sealed along the lines indicated. Preferably this end of the container is provided with an opening 14 for receiving the tube 15, as shown more clearly in Figs. 3, 4 and 5.

We prefer to provide a sterilized portion of the container 10 with a patch 16 which extends over a portion of the sterilized surface so that, upon the removal of the patch at a later time, there is provided a sterile surface for the insertion of the needle 17 attached to the tube 15. The patch may be plastic material or any other suitable material and may be secured to the plastic container 10 by heat-sealing along a thin line or by the application of any suitable adhesive, etc.

When the solution in the container is to be withdrawn for injection, the container is suspended upon a standard with the opening 12 in the upper edge thereof engaging a hook on the standard. The patch 16 is removed so as to leave a sterile surface therebelow. The needle 17 is then inserted through the sterile surface and into the interior of the container as shown more clearly in Figs. 3 to 5, inclusive. We prefer to draw the needle first through the opening 14 in the lower sealed-end portion 13 of the container, as illustrated best in Fig. 5. This procedure results in taking the strain off the tube 15 and the needle 17 which has pierced the container wall.

The needle 17 may be of any suitable type or construction. In the illustration given, it is provided with a tapered end portion 18 having an aperture 19.

At the lower end of the tube 15 the injection needle 20 is maintained in sterile condition by the use of a sealed tube 21. We prefer also to enclose the needle 17 with a similar sterile tube so as to maintain this

needle in sterile condition and ready for insertion into the filled container **10**.

We prefer to form the container **10** and also the tube **15** of plastic material, but it will be understood that other materials may be used. From the description heretofore set out it will also be understood that there is an advantage in employing a thermoplastic material in the fabrication of the container **10**. Any suitable plastic material may be employed. For example, polyethylene, polytetrafluoroethylene, polymerized vinyl acetate, vinyl chloride (copolymer) cellulose acetate, and a large number of other plastic materials may be used. By using specially treated or formed plastics which are heat-resistant, the filled container can be subject to heat sterilization, if desired.

While a number of methods may be employed for the forming of the container, we prefer to form the container and fill it in accordance with the sequence of steps illustrated in Figs. 6 to 9, inclusive. In Fig. 6, there is shown a tube **22** which may consist of a long body of tubing just as it is formed or extruded.

The lower end of the thermoplastic tubing may be heat-sealed as illustrated, or in any desired manner. In the illustration given, the lower end of the tubing is heat-sealed along the line **23** and the diagonal lines **24**, and then along the transverse line **25**. Also, the flap thus formed by the heat-sealing lines may be provided with an opening **26'** which corresponds to the opening **12** as described in Figs. 1 to 5, inclusive. In the same operation, the tube is heat-sealed along the spaced longitudinal or central lines **26** to form sealed passage **29**, along the horizontal lines **28**, and along the diagonal lines **27** which extend laterally and at different elevations from the spaced longitudinal lines **26**, as shown in Fig. 6.

While the sequence of operations may be varied, it will be assumed now for the purpose of illustration that there is a severance of the container portions outside of the lines of heat sealing **24** and **27** and that portion of line **26** contained between lines **24** and **27**, thus forming the structure as illustrated at the bottom of Fig. 6. In the same operation, the bag may be severed transversely along the center of the sealed area **25** so that the bag portions are left sealed on both sides of the line **25**. The severed portions of the line **25** are thus shown in Figs. 7, 8 and 9 at both ends of the container. A complete container is thus formed as illustrated in Figs. 7, 8 and 9 with both ends of the container sealed.

Figs. 7, 8 and 9 illustrate the bag formed as above described through several stages. The first stage is the sealed stage of the flat or collapsed bag as it comes from the extrusion machine and after the heat-sealing and cutting steps just described. The upper end of the container is sealed along the line **23**. The lower end of the container is sealed along the lines **28**, **26** and **25**.

Fig. 8 illustrates the method of filling. It will be noted that in the lower portion of the container as illustrated there is a sealed passage **29** lying between the walls **26**. We form a slit **30** in one wall of the container about the passage **29** and insert through this slit a hollow needle or tube **31**, to which there is connected a flexible tube **32** leading to a container of sterile liquid.

The neck of the container or side wall over the passage **29** is preferably sterilized by an alcohol swab or some other convenient method and after the forming of the slit, the needle, which may be sterilized by the same method, is inserted through the slit **30**, as illustrated in Fig. 8. Sterile liquid may thus be introduced into the sterile container without contamination of the inner surfaces thereof.

Fig. 9 shows the filled container. After the filling operation described in connection with Fig. 8, the container is heat-sealed along the line **33** to form a completely sealed end, as illustrated in Fig. 9. The needle **31** and tube **32** may then be removed. If desired, the lower end of the tubing may be cut away to form a lower flap somewhat similar to flap **13**, as described in connection with Figs. 1 to 5, inclusive.

Operation

The container **10** may be formed from a continuous extruded body of tubing as above described or from tubing formed in any other manner. The transparent plastic tubing is preferably sealed by heat-sealing, as described in Fig. 7, and the container is preferably filled by inserting the hollow filling needle through a wall thereof and the container after being filled is finally sealed, as illustrated in Figs. 8 and 9.

It will be understood that the container may have imprinted or impressed thereon directions or other indicia and may be provided with a suitable scale to indicate to the physician the amount of liquid dispensed at any particular time.

In the dispensing operation, the container is suspended upon a hook or support by inserting the hook, etc. through the opening **12**. The needle **17**, after the removal of its sterile covering, is inserted through the sterile surface below the tab or patch **16** and after the tab **16** has been removed, the position of the structure being as illustrated in Fig. 5. It is found that the plastic grips the needle **17** tightly and forms therewith a liquid- and air-tight seal. By bringing the tube **15** through the opening **14** of the end extension **13**, the weight of the tube **15** is carried by the flap or end **13** and there is no strain exerted against the wall of the container **10** at the point where the needle has pierced it.

In the usual practice, the dispensing tube **15**, which leads to the injection needle **20**, is provided with a clamp for controlling the flow of the solution and also the tube may, if desired, be provided with a sight glass containing a drip meter so that the quantity of liquid being introduced into the patient can be determined.

We prefer that the container be of transparent or translucent plastic material, although it will be understood that other suitable materials may be used. By employing a transparent or translucent plastic, the level of the liquid can be noted in connection with a scale or graduation marks on the container and the physician can thus determine the quantity of solution that is being dispensed.

Since the container is formed of flexible material, it is not necessary for air to be introduced into the container while the liquid is being dispensed, and thus contamination from contact with air is avoided. Further, after use, the plastic bag may be discarded along with the tube **15**, if desired.

While we have described a method of introducing sterile liquid into a sterile container and sealing the same without contaminating the liquid or inside surfaces of the container, the container may be formed under other conditions and by other methods and the liquid and container may be sterilized by heat, sterilizing rays, or other suitable means.

In the use of the container, we were surprised to find that the needle and plastic container form an unusually tight seal so that the liquid does not leak from the container during the dispensing operation; in fact, it has been found that leakage does not occur over long periods of time, and by reason of this, it is possible to ship the filled container with the needle **17** inserted therein, to the consumer in a carton or other shipping container, should this be desired. We prefer to ship the container without the needle in such position and to insert the needle as above described when it is ready to dispense the liquid and after the removal of the tab or patch **16** to provide a sterile spot for the insertion of the needle.

By the means described, it is possible to form the containers with great rapidity while at the same time completing them in sterile condition and filling them without introducing unsterile material into the containers. At the same time, the filled containers are effective in keeping

the liquids in sterile condition and through the insertion of the needle through the sterile spot in the container, the liquid may be withdrawn without contamination and in the withdrawal of the liquid air is not introduced into the container. Thus, at no time from the first formation of the sterile container and through the filling process and the dispensing process, do the inside sterile surfaces come in contact with the outside air.

While in the foregoing specification, we have set out certain structures and certain method steps in considerable detail for the purpose of illustrating the embodiments of the invention, it will be understood that such details may be varied widely by those skilled in the art without departing from the spirit of our invention.

We claim:

1. In a method for the sterile packaging of liquids, the steps of forming a thermoplastic tube with inside sterile surfaces, sealing a length of the tube with the walls thereof in collapsed condition at its ends to form a sealed container, introducing a tube through a side wall of a portion of the container to pierce the same, filling the container through said tube, heat-sealing the container inside of the point at which the side wall was pierced and while said tube is within said container wall to seal off said portion from the remainder of the container, and then withdrawing said tube.

2. In a method for the sterile packaging of liquids, the steps of sealing a thermoplastic tube length with the walls thereof in collapsed condition at its ends to form a container, the sealing at one end being transversely of the tube and also along closely spaced longitudinal lines to provide a passage of reduced width communicating with the interior of the container, inserting a tubular member through the side wall of the container about said passage to form a tight seal of the container wall about the tube, filling the container through said tubular member, heat-sealing the plastic walls of the container on the inner side of the point at which the tubular member enters said passage, and withdrawing said tubular member.

3. In a process for the sterile packaging of liquids, the steps of extruding a thermoplastic tube with sterile inside surfaces collapsing the walls of the tube, forming a seal between the walls of the tube at spaced distances to provide a sealed container therebetween, the seal at one end of the container being looped to form a narrow passage, inserting a tube through the wall of the container about said passage, filling the container with sterile liquid through said tube, heat-sealing the inner end of said passage to close off communication between said passage and the body of said container, and withdrawing said tube.

4. In a method of the character set forth, the steps of sealing one end of a collapsed plastic flexible tube, providing the opposite end of the tube with side flaps of thermo-plastic material, sealing the edges of said flaps, introducing a hollow member between said flaps and into said tube, filling the collapsed tube with liquid passed through said hollow member, and heat-sealing said flaps inwardly of the point of entrance of said hollow member.

5. In a method of the character set forth, the steps of collapsing and sealing the ends of a plastic flexible tube to form a sealed container, the seal at one end of the container being looped to form a passage, inserting a tube through the wall of the container about said passage, filling the container with sterile liquid through said tube, heat-sealing the inner end of said passage, while said tube is in said container wall, to close off communication between said passage and the body of said container, and withdrawing said tube.

6. In a method of the character set forth, the steps of sealing opposite ends of a collapsed plastic flexible tube to provide a sealed container, the seal at one end of the container being looped to form a passage communicating with the body of the container, introducing a hollow member through the wall of the container about said passage, filling the collapsed tube with liquid passed through said hollow member, heat-sealing the inner end of said passage, while said member is in said container wall, to close off communication between said passage and the body of said container, and withdrawing said tube.

7. In a method for the packaging of liquids, the steps of sealing at the ends a thermoplastic tube length with the walls thereof in collapsed condition, the sealing at one end being transversely of the tube and also along closely-spaced longitudinal lines to provide a passage of reduced width communicating with the interior of the container, inserting a tubular member through the side wall of the container about said passage to form a tight seal with the container wall about the tube, filling the container through said tubular member, heat-sealing the plastic walls of the container on the inner side of the point at which the tubular member enters said passage, and then withdrawing said tubular member from said container wall.

8. In a process for the packaging of liquids, the steps of extruding an elongated plastic tube with sterile inside surfaces collapsed against each other, heat-sealing the ends of said tube while in collapsed condition, forming a heat-seal across said tube at intermediate points to form separate sealed containers, severing said tube at said intermediate point within the heat-sealed portion to form at least one separate collapsed and sealed container, introducing a filling tube connected to a fluid container through a wall of said last-mentioned container to fill said container, and while said tube remains in the wall of said container heat-sealing the container inwardly of the point at which the tube extends through said wall to isolate said portion and the tube from the remainder of the container.

9. In a method of the character set forth, the steps of continuously extruding a thermoplastic tube having sterile inside surfaces provided by walls collapsed against each other, forming a seal between the walls of the tube at spaced distances to provide sealed containers, inserting a hollow member through a wall of the container to form a tight seal therewith, filling the container with liquid through said tube, heat-sealing the container inwardly of the hollow member while said member is in place within said wall to isolate said pierced portion of the container from the remaining filled portion of the container, and then withdrawing said hollow member.

10. In a method for the sterile packaging of fluids, the steps of extruding an elongated plastic tube having the walls thereof collapsed and providing sterile inside surfaces, heat-sealing the tube transversely thereof at spaced intervals to provide separate containers, inserting a hollow member through a wall of one of said containers and connecting said hollow member with a fluid container, heat-sealing said container through which said hollow member extends inwardly thereof to isolate the pierced portion of the container from the remaining portion thereof, and withdrawing said hollow member.

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