Nov. 2, 1965 G. COANDA ETAL 3,215,299

PARENTERAL SOLUTION CONTAINER

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FIG. 1.

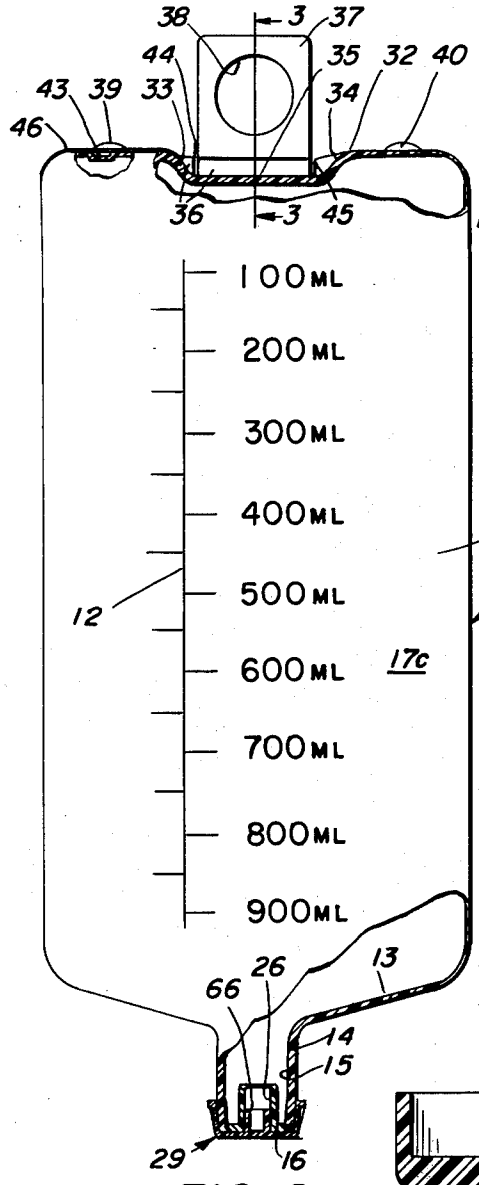

FIG. 2.

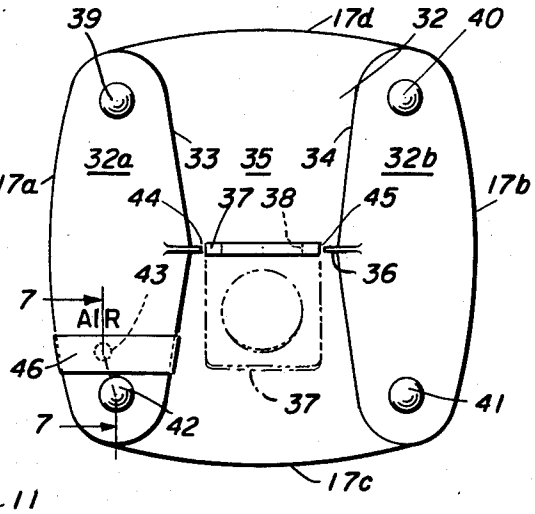

FIG. 3.

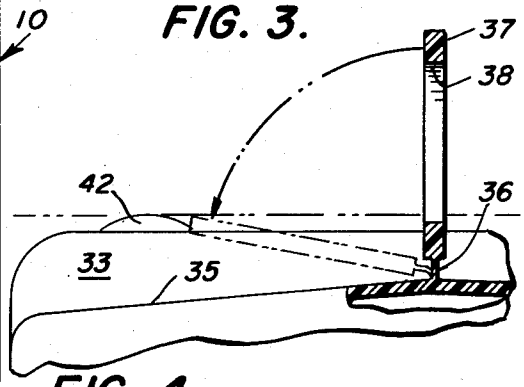

FIG. 4.

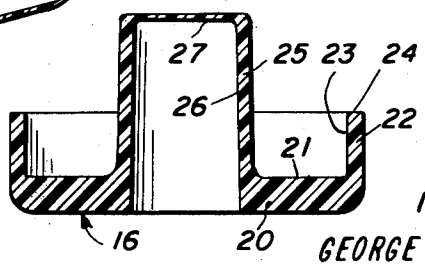

FIG. 8.

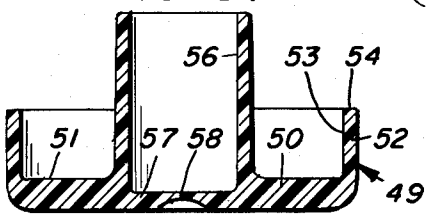

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FIG. 5.

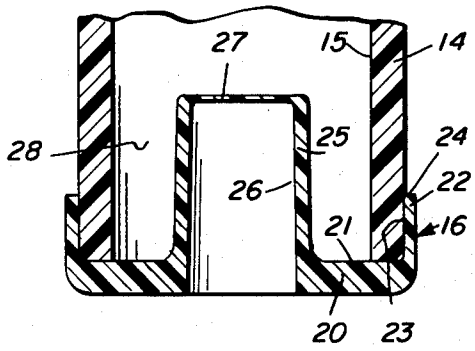


FIG. 6.

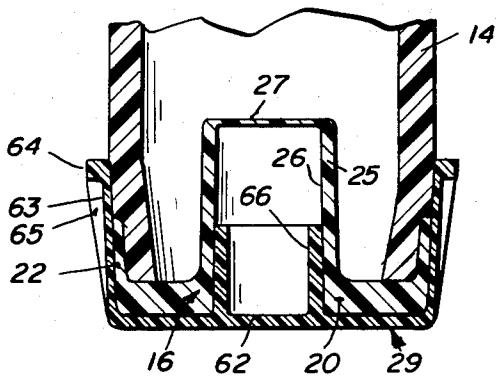
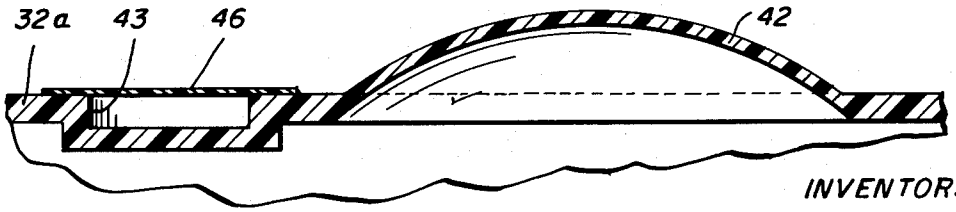


FIG. 7.



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United States Patent Office 3,215,299 Patented Nov. 2, 1965

3,215,299

PARENTERAL SOLUTION CONTAINER

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Filed Sept. 11, 1961, Ser. No. 137,336
6 Claims. (Cl. 215—100)

This invention relates to plastic parenteral solution containers, and particularly to suspension and closure means for such containers.

Parenteral solutions such as dextrose, saline, electrolyte mixtures, blood, and blood plasma are now usually provided in containers made of glass. While quite satisfactory in many ways, such containers are fragile, heavy, and expensive. Because of their cost the containers are often re-used. Occasionally an opening, such as a crack or pinhole, may develop in the container wall, and these are very difficult to detect. Such openings are undesirable in any container, but they are most serious in a container for sterile, parenteral solutions which are to be injected into human patients.

Plastic bags, the walls of which collapse against each other in the absence of fluid, have been proposed as parenteral solution containers. However, such containers are difficult to seal, and defective seals and pinholes near the seals are a serious problem. In use, it is sometimes necessary to interrupt the administration of a solution to administer blood. In this case the administration apparatus is disconnected from the solution container, leaving the outlet of the solution container open. In the case of a plastic bag the walls of which are not self-supporting, the remaining solution will flow through the open outlet when the container is placed on a flat surface. Also, the lack of rigidity makes handling of the empty, collapsed containers difficult and special machines must be used for production filling operations.

In recent years, blow-molded plastic containers have been suggested for many uses. Such containers have walls which are thin, flexible, and deformable, but which are self-supporting. Containers of this type are frequently referred to as "squeeze bottles" because they are normally expanded, but can be collapsed by external pressure. Blow-molded containers have been used for parenteral solutions, but the closures of such containers leave much to be desired. Some of these closures tend to leak, other difficult and expensive to assemble under production conditions, and still others are difficult or inconvenient to enter with an administration set to administer the parenteral solution.

For administration of parenteral solutions, the blow-molded containers must be provided with suspension devices, and these have also been unsatisfactory. Some such devices prevented the container from standing on a flat surface, others were so small they required the attachment of a separate supplementary extension, while still others unduly complicated the design and production of the containers.

It is, therefore, an object of this invention to provide a parenteral solution container of the blow-molded or "squeeze bottle" type having an inexpensive closure which is easy to assemble and to use.

Another object of the invention is to provide a parenteral solution container having an improved, inexpensive suspension device.

Further objects and advantages of the invention will be apparent from the examples described in the following specification and shown in the drawings, in which:

FIGURE 1 is an elevational view, partially cut away, of the container in inverted position ready to be suspended for administration of its contents;

FIGURE 2 is a plan view of the base of the container;

FIGURE 3 is an enlarged sectional view on the line 3—3 of FIGURE 1;

FIGURE 4 is a further enlarged sectional view of the outlet closure before attachment to the container;

FIGURE 5 is an enlarged sectional view showing the outlet closure placed loosely on the container neck prior to sealing;

FIGURE 6 is an enlarged sectional view showing details of the sealed closure and cap shown in FIGURE 1;

FIGURE 7 is a still further enlarged sectional view on the line 7—7 of FIGURE 2; and

FIGURE 8 is a view similar to FIGURE 4, but showing a modified form of the outlet closure.

Referring now to the drawings, the parenteral solution container **10** has a body **11**, preferably having flexible, generally rectangular side walls **17***a*, **17***b*, **17***c*, and **17***d*, and a generally rectangular transverse cross section. Graduations **12** run lengthwise and may be printed on or molded into the side wall **17***c*. At one end, the sides of the body join into a relatively stiff shoulder section **13** which slants upwardly toward the center of the container at an angle of about 15°. A rigid tubular neck **14** projects axially from the center of shoulder section **13**, providing an outlet opening **15** sealed by a closure **16**.

Container body **11** is preferably made of polypropylene plastic by extrusion blow-molding. In this process, a tubular parison is extruded and is then blown in a mold of the desired shape and size. The wall thickness of such containers varies, but we have found that the outer surface of neck **14** can be precisely shaped and dimensioned. Plastics other than polypropylene may also be used. However, polypropylene is the preferred plastic because it is heat sterilizable, remarkably compatible with solution ingredients, and provides the strength necessary for the suspension device to be subsequently described.

When container body **11** is formed of polypropylene, a one-liter container may have a weight of approximately 25 to 30 grams as compared to approximately 650 grams for an ordinary glass container. The flexible side walls of body **11** are preferably from about 0.015 to 0.030 inch thick. The relatively thick bottom and top sections taper from about 0.030 inch adjacent the side walls to about 0.10 inch near the center, and thus are quite stiff and rigid. The wall of tubular neck **14** may also be about 0.10 inch thick. This wall thickness plus the additional strength and stiffness of the small diameter tube results in a stiff, virtually unflexible neck.

The cap-like closure **16** can be formed by either injection molding or vacuum forming, and is preferably made of polypropylene. Closure **16** has a disc-like body **20** having an inner surface **21** adapted to seat on the annular end surface of neck **14**. An annular skirt **22** projects from body **20** and has a circumferential surface **23** facing radially inwardly and an end surface **24**. Near the center of body **20**, a thin-walled tube **25**, generally concentric with skirt **22**, projects axially into container neck **14**. The end of tube **25** adjacent body **20** is open, while the other end is closed by a thin, pierceable diaphragm **27** which preferably has a thickness of 0.005 to 0.015 inch. Tube **25** is substantially smaller in diameter than the inside of neck **14**, thus providing a space **28** between the tube and neck **14**.

As best shown in FIGURES 5 and 6, skirt **22** of closure **16** is shaped to fit snugly around the outer surface of tubular neck **14**. After the container is filled with solution, closure **16** is placed on neck **14** and skirt **22** heat-sealed to the outer surface of the neck **14**. This is preferably accomplished by placing a heated tool over skirt **22** and pressing the tool down over closure **16**. The tool may advantageously be cool when put in place and may

then be heated by electrical induction. The inwardly facing circumferential surface of the tool should be generally cylindrical and should be smaller than skirt **22** so as to press the skirt radilly inwardly against the outer surface of neck **14**. Preferably, the inwardly facing circumferential surface of the tool tapers axially inwardly toward the top so as to reform the outer surface of skirt **22** to a frusto-conical shape having its smaller base adjacent body **20**. This provides a strong, leakproof seal so that closure **16** will not break loose when pierced by an administration set connector, as will subsequently be described.

An outer cap **29**, having a disc-like head **62**, covers closure **16** and maintains diaphragm **27** and the tube bore **26** in a clean, sterile condition. A thin-walled flexible skirt **63** extends from head **62** and is adapted to fit around the outer surface of closure skirt **22** and neck **14** after they are sealed together. Skirt **63** has an annular reinforcing ring **64** around one end and longitudinal ribs **65** spaced around its circumferential surface. A hollow tube **66** extends axially from the inner surface of head **62** and fits tightly into bore **26** of closure tube **25**. The seal thus formed is surprisingly effective and cap **29** can be used to reseal the container temporarily during an emergency switch to blood.

The base of body **11**, generally indicated as **32**, has two protuberant base sections **32***a* and **32***b* separated by a centrally located recess. At one side of the recess, a wall **33** extends longitudinally inward between the center of base **32** and side wall **17***a*. Wall **33** is generally parallel to side wall **17***a*, but tapers away from said side wall toward the center of base **32** to make the recess narrower in the center than at the ends. A second wall **34** extends longitudinally inward between the center of base **32** and side wall **17***b* to form the other side of the recess. Walls **33** and **34** are connected by an indented base wall **35** which is spaced inwardly from base sections **32***a* and **32***b*, and which slants progressively away from the base sections as it approaches side walls **17***d* and **17***c*. Thus, a slot-like recess is formed by walls **33**, **34** and indented base wall **35**. This recess preferably extends completely across base **32** so that the mold in which the container is formed can open without raising the container.

A thin, flexible web **36** is formed as an integral, one-piece extension of indented base wall **35** which projects into the recess. At the sides, web **36** is disconnected from walls **33** and **34** as by the cuts **44**, **45**. A suspension tab **37** is formed as an integral one-piece extension of web **36** and projects therefrom. Tab **37** is preferably thicker and more rigid than web **36** and has an aperture **38**, suitable for receiving a hook or other hanging device. A particularly suitable suspension device can be formed of polypropylene by making web **36** approximately 0.010 to 0.020 inch thick.

As shown in FIGURES 2 and 3, suspension tab **37** preferably is quite large and in its extended position, extends from indented base wall **35** out of the slot-like recess and beyond the protuberant base sections **32***a*, **32***b*. It should be noted, however, that web **36** may easily be bent to allow tab **37** to reciprocate in and out of the recess defined by walls **33**, **34** and **35**. Also, web **36** can be provided with a permanent set in the bent position so that tab **37** normally lies in the recess until lifted out. Details of this process will be described subsequently. Thus, the container can be placed base down on a table and will stand upright with suspension tab **37** folded down into the recess as shown by the dotted lines in FIGURES 2 and 3. Tab **37** is also preferably folded down during shipping so that the container occupies a minimum of space. If desired, directions for used, sterile swabs, and other items of auxiliary equipment can be fastened in the recess with a piece of adhesive tape.

As shown in FIGURES 2 and 7, base **32** is also provided with four protuberances or feet **39**, **40**, **41**, and **42** projecting outwardly therefrom. An indented or depressed area **43** is provided in base **32** as an air inlet and is covered with a tape cover **46** held in place by a layer of pressure-sensitive adhesive. The container wall at the base of depressed area **43** serves as a puncturable diaphragm as will be described subsequently. It may have the same thickness as the adjacent wall of base **32***a*, but is preferably thinner to facilitate puncture.

FIGURE 8 shows a modified form of closure fitment **49** which does not require an outer cap. Closure fitment **49** has a disc-like body **50** having an inner surface **51** against which the annular end surface of a tubular container neck seats. A skirt **52** extends at approximately right angles from the periphery of body **50**, terminating in an end **54** and providing an inner skirt surface **53** which is sealed to the outer surface of the container neck. A centrally located tube projects from body **50** and is concentric with skirt **52**. The tube has a bore **56** which is closed by a diaphragm **57** at the end adjacent body **50** and which is open at the end spaced from body **50**. In the center of diaphragm **57** an indentation provides a thin pierceable wall portion **58**.

In use, the modified closure fitment shown in FIGURE 8 usually is swabbed across the top surface of body **50** with an antiseptic solution. The connecting spike of an adminstration set is then forced through diaphragm **57** and telescoped into tube **56**. During this step care must be taken to hold the container by the rigid neck **14** and shoulder section **13**. If the container is held by the flexible walls **17** pressure is developed in the container with consequent leakage around the connecting spike as the spike pierces diaphragm **57** and before it seals with the bore wall **56**.

In the manufacture of parenteral solutions, the molded container bodies **11** are washed, rinsed, and then filled with a suitable solution, such as dextrose or saline. A closure **16** or **49** is then placed over the neck of the container and the inner surface **23** or **54** heat-sealed to the outer surface of neck **14**, as previously described. The containers of solution are then placed in an upright position in an autoclave and sterilized by steam under pressure. During sterilization, the containers are preferably supported on the indented base wall **35** and may be held in position by neck **14**. Suspension tab **37** should be bent down against base wall **35** so as to give web **36** a permanent set with tab **37** completely within the base recess until it is deliberately lifted out.

Alternatively, the empty container can be heated with suspension tab **37** bent down against base wall **35** to provide web **36** with a permanent set. The container and solution can then be separately sterilized by any suitable means and the sterile solution filled into the sterile container.

In use, cap **29** is removed from closure **16**. The spike of an administration set is then telescoped into tube **25**, piercing diaphragm **27** and deforming the thin wall of tube **25** outward. Suitable administration set spikes are known in the art, as for example those shown in United States Patents 2,954,768, 2,784,733, 2,730,097, and 2,912,980. As the connecting spike of the administration set is telescoped into tube **25**, the outer surface of the spike seals with the bore wall **26** just prior to piercing of diaphragm **27**. This prevents fluid from leaking out past the connecting spike and also assures firm attachment of the administration set to the container. Suspension tab **37** is then lifted out of the base recess and the end of a hook or other hanging device passed through aperture **38**. When body **11** is formed of polypropylene, as previously described, bending of web **36** orients the polymer molecules and increases the strength of the web. For this reason, web **36** can be bent innumerable times without breaking or cracking.

As fluid is withdrawn from container **10**, the pressure of the surrounding atmosphere collapses the flexible side walls inwardly so that most of the fluid can be removed. In some cases however, it may be desirable to administer

all of the fluid or to increase the rate of administration. This can be done by providing an inlet passage in the base through which air can enter the container. Such a passage is conveniently provided by removing tape **46** from the indented area **43** and piercing the diaphragm at the base of indented area **43** with a spike or hypodermic needle, which preferably is provided with a cotton pledget or other air filter.

If it is necessary to disconnect the solution in order to administer blood or other emergency medication, the spike of the administration set can be removed from closure tube **25** and container **10** set base down on a table or shelf. Since diaphragm **27** has been pierced, the container is preferably closed by replacing cap **29** over closure **16**. When cap **29** is pressed down firmly against closure **16** a surprisingly effective seal is formed. We have found that this seal is sufficient to withstand considerable pressure on the container side walls, even though diaphragm **27** is pierced.

While we have shown and described certain embodiments of our invention, it should be understood that many changes and modifications can be made without departing from the spirit and scope of our invention, as described in the appended claims.

We claim:

1. A parenteral solution container comprising: a plastic body; a rigid tubular neck on said body; an outlet opening on at least one end of said neck; a closure having a disc-like body closing said outlet opening; a skirt projecting from said closure body and telescoped over the outside of the tubular container neck, the inner surface of said skirt being sealed to the outer surface of the container neck; an integral base on said body, said base including protuberant base sections adapted to rest on a flat surface and an indented base wall spaced from the base sections to form a recess; a thin, flexible web forming an integral unit with the indented base wall and extending therefrom; and a suspension tab integral with said web and extending beyond the protuberant base sections.

2. A parenteral solution container comprising: a plastic body; an integral base on said body, said base including protuberant base sections adapted to rest on a flat surface and an indented base wall spaced from the base sections to form a recess; a thin, flexible web forming an integral, one-piece unit with the indented base wall and extending into the recess; and a suspension tab forming an integral one-piece unit with said web and extending beyond the base sections.

3. A parenteral solution container as set forth in claim **2** wherein the protuberant base sections are provided with a plurality of protruding, thin-walled feet, the recess extends completely across the base, the indented base wall slants progressively toward a centrally located apex line constituting the part of the indented base wall closest to the protuberant base sections, and the web meets the base along said apex line.

4. A parenteral solution container as set forth in claim **2** wherein the web is normally bent so that the tab normally lies within the base recess.

5. A parenteral solution container as set forth in claim **2** wherein the body is formed of polypropylene plastic and the body, the web, and the suspension tab form an integral, one-piece structure.

6. A parenteral solution container comprising: a plastic body having thin, flexible, self-supporting side walls and a generally square transverse cross section; a relatively thick, stiff base on said body, said base including protuberant base sections and an indented base wall spaced from said base sections to form a recess across the base; longitudinal walls on each side of the indented base wall connecting said wall to the base sections and defining the sides of the recess; a thin, flexible web forming an integral, one-piece extension of the indented base wall and projecting into the recess; and a thick, stiff suspension tab forming an integral, one-piece extension of said web and projecting beyond the protuberant base sections, said web having a permanent set whereby the web is normally bent so the tab lies within the recess, but can be straightened so that the tab extends axially from the container base beyond the protuberant base sections.

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