United States Patent [19]

Lewis, Jr. et al.

[11] **3,905,368**

[45] **Sept. 16, 1975**

[54] **PIERCEABLE ACCESS PORT ASSEMBLY**

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[73] Assignee: **Cutter Laboratories, Inc.**, Berkeley, Calif.

[22] Filed: **Feb. 15, 1974**

[21] Appl. No.: **443,011**

[52] **U.S. Cl.** ..... **128/272**; 128/214 D; 222/212; 128/DIG. 24

[51] **Int. Cl.** **A61j 1/00**

[58] **Field of Search**..... 128/272, 214 D, DIG. 24, 128/227; 150/.5, 1; 222/92, 107, 212, 215

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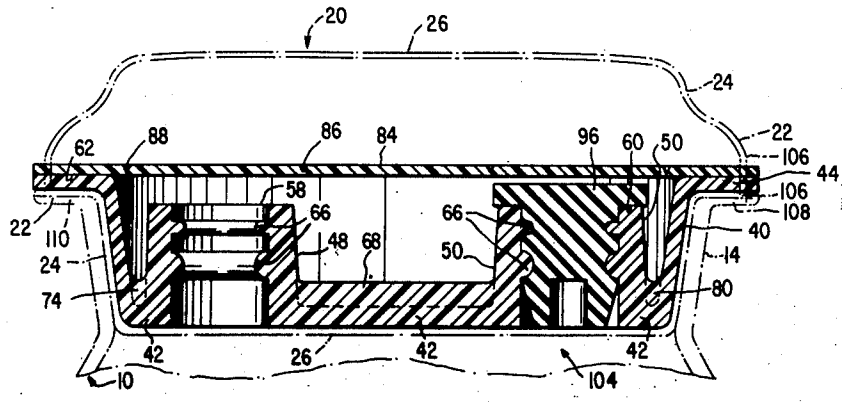
Primary Examiner—Richard A. Gaudet
Assistant Examiner—Henry S. Layton
Attorney, Agent, or Firm—Gardiner, Sixbey, Bradford & Carlson

[57] **ABSTRACT**

The pierceable access port assembly includes a container having a mounting flange formed at one end thereof and an access port unit having an assembly mounting flange which is hermetically sealed to the container flange. In one embodiment, the access port unit includes a sidewall which engages the inner surface of the neck of the container over substantially the entire periphery thereof and includes port means spaced inwardly from the sidewall which terminates within the confines of the sidewall. In a second embodiment, the access port unit extends outwardly from the container neck and employs a unitary container closure as a pierceable diaphragm and a double-walled flange. Both embodiments employ an access unit mounting flange sealed to a container mounting flange to provide a strong, reinforced flange structure which may be firmly grasped to facilitate the insertion of a spike or needle into the access port assembly.

33 Claims, 9 Drawing Figures



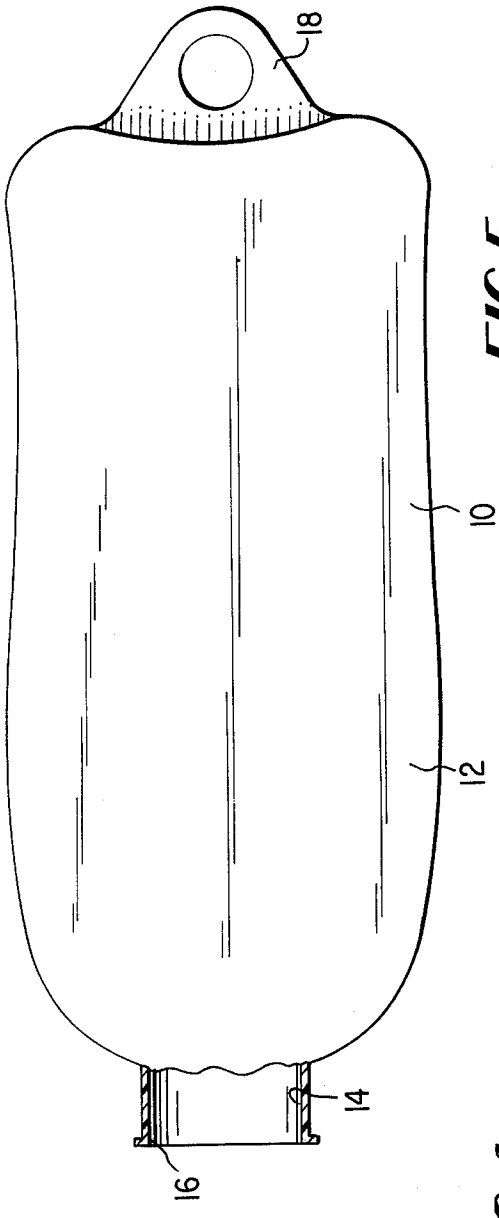


FIG. 1

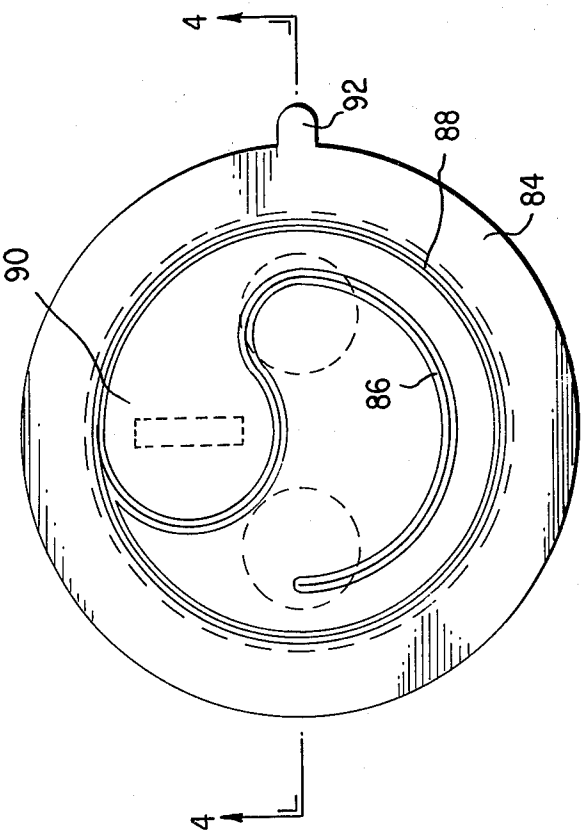


FIG. 5

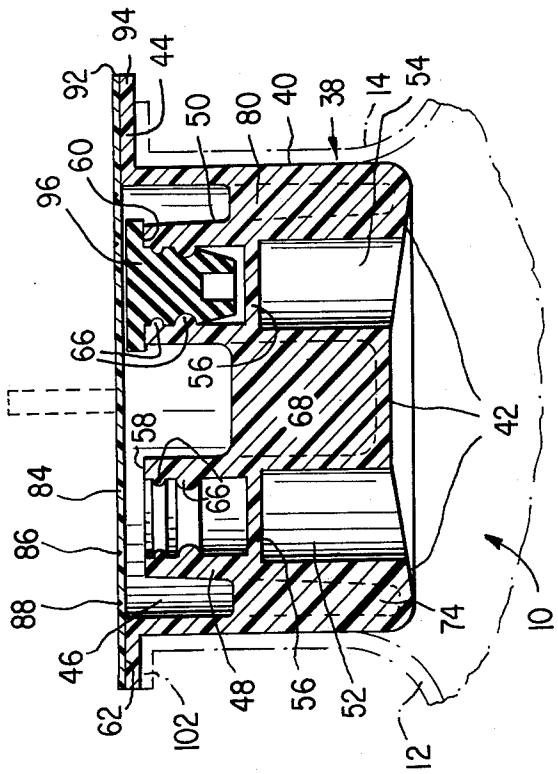


FIG. 4

FIG. 2

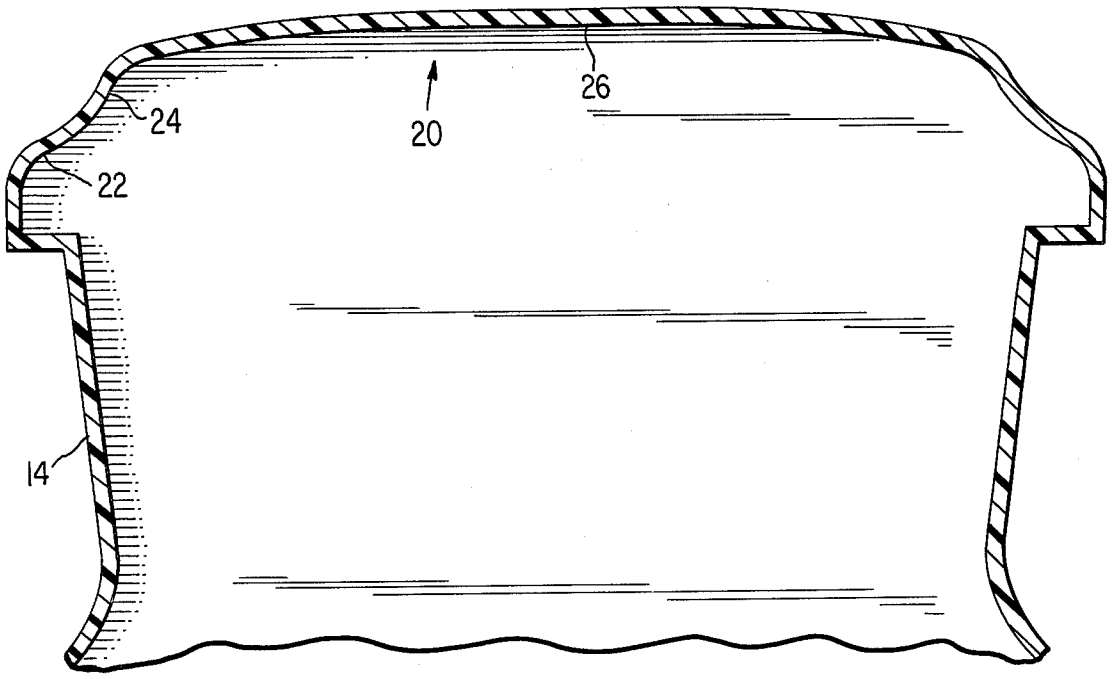
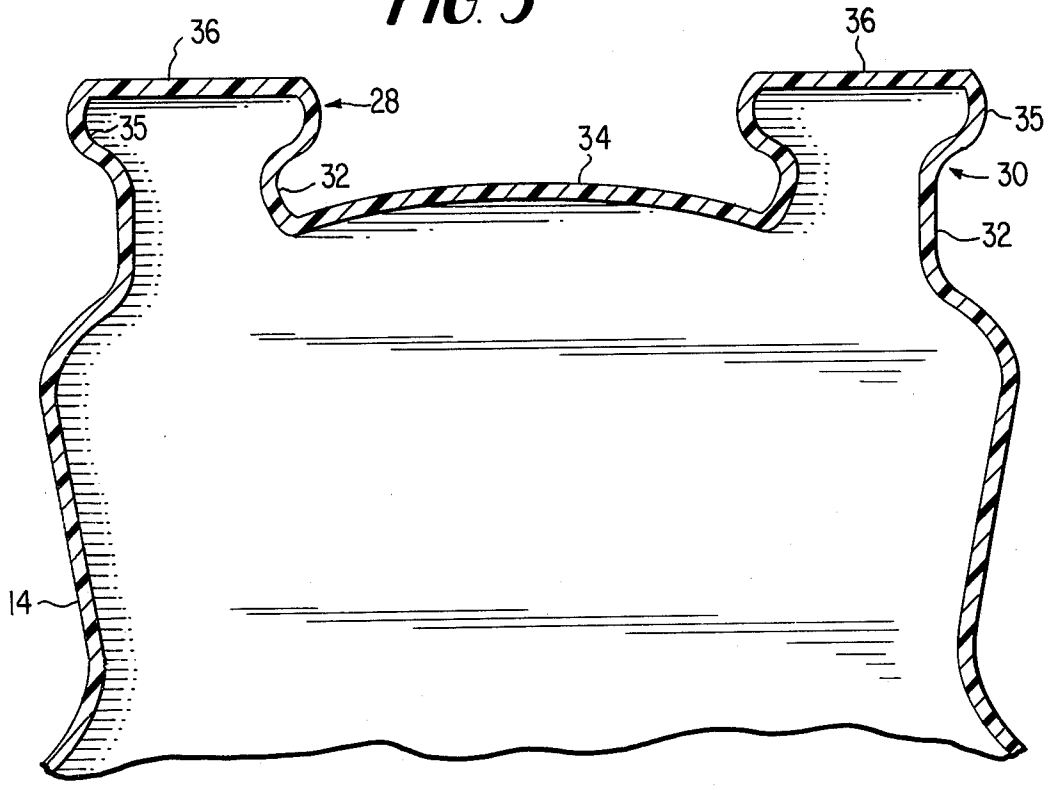
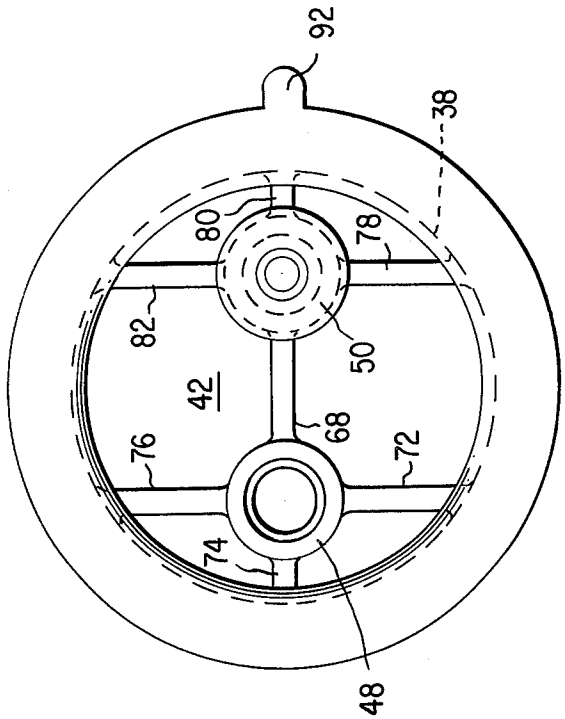


FIG. 3




92
38
80
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82
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72
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FIG. 6

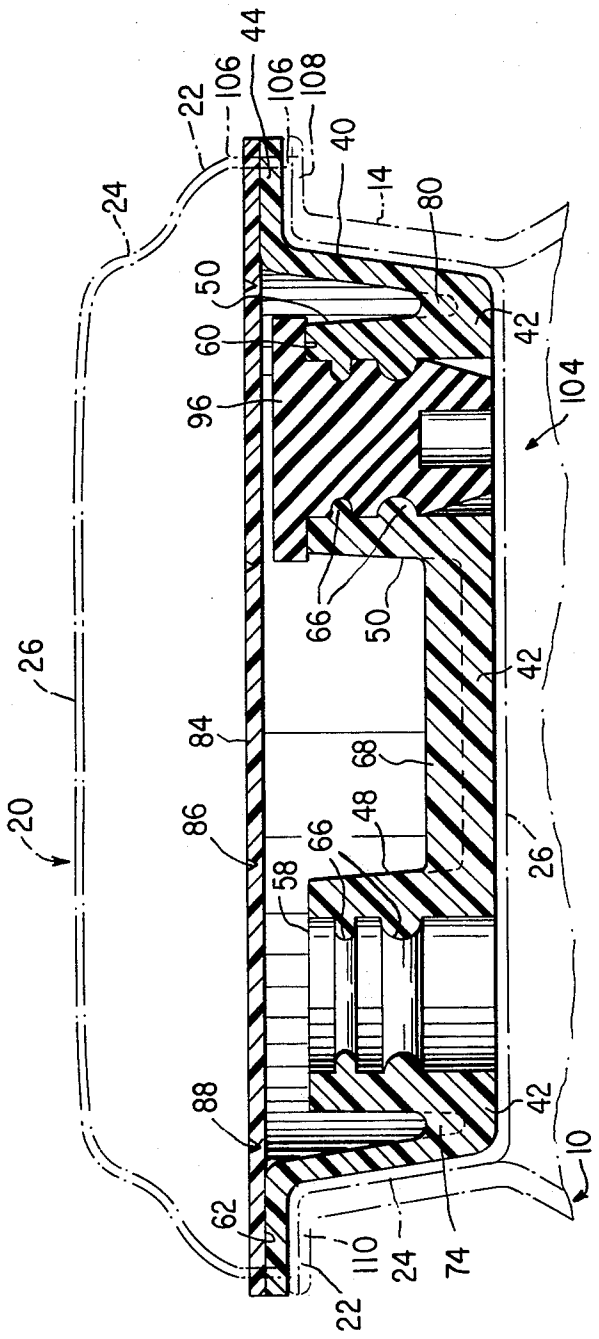
44
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FIG. 7

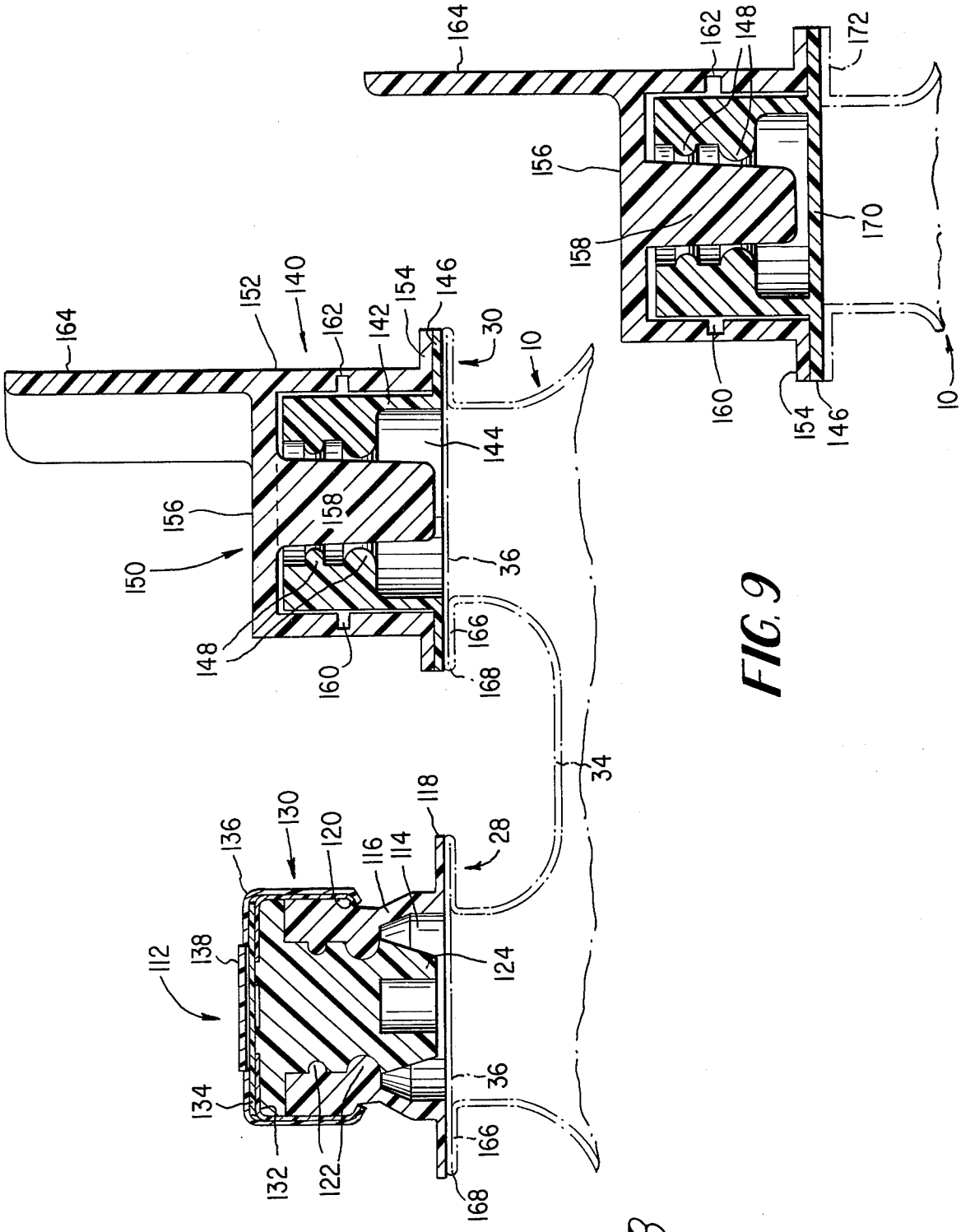
164
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FIG. 9

FIG. 8

PIERCEABLE ACCESS PORT ASSEMBLY

BACKGROUND OF THE INVENTION

For effective safe storage and use of parenteral fluids and similar sterile solutions, it is necessary that such fluids be stored in sterile, tamper proof containers provided with means to facilitate withdrawal of the fluid without a substantial sacrifice of sterility. Some containers or bags are formed of flexible plastic in such a manner as to enclose parenteral fluid or other sterile fluid. The container is later entered through a sealed port structure in order to dispense measured amounts of the contents therefrom. As the liquid contents from such flexible sealed plastic containers are dispensed, the container collapses, and therefore no venting of the container with air which might carry contaminants is required. Initially, it was necessary to provide the sealed bag containers with entry or exit ports constructed so that an entry spike or needle could be inserted through the port and retained in tight sealed relationship therewith. Often the port consisted of a tubular needle supporting structure secured at an end or in some cases on a wall of the bag by a flange or similar structural element. In some instances the portion of the bad enclosed by the tubular element served as a pierceable diaphragm. A resilient plug would then be fitted into the tubular element to hold the needle inserted through the plug in the side of the bag. Bag-like sealed containers provided with outlet fittings of this type are disclosed in U.S. Pat. Nos. **2,838,046** to Butler and **3,368,560** to Gewecke.

Some previously developed plastic bag containers have been formed of two plastic sheets sealed together with a plastic tube sealed between the two sheets at one end to provide a narrow neck portion. One known flexible bag container of this type includes a rather short pierceable access port assembly which is inserted into the open end of the longer neck portion of the bag. This particular port assembly is tubular in configuration and has outwardly extending ribs which project from the tubular walls thereof and engage the inner surface of the neck portion. It also has an annular flange which is sealed to a flange on the outer end of the neck portion. The outer end of the access port assembly is closed by a cover member which is sealed to the annular flange of the access port assembly. The central portion of such cover is provided with a frangible web connected to a projecting tear tab, so that the central portion of the cover may be opened by operating the tear tab. A spike is then inserted through this opening into the tubular body of the access port assembly until the spike pierces a diaphragm at the bottom of the tubular portion thereof to gain entry to the contents of the bag. Although the rib structure of the port assembly does provide some support for the neck portion so that the neck may be more firmly grasped during the insertion of the spike, these ribs have a disadvantage in that they define small compartments or dead spaces between the surface of the neck portion and the surface of the tubular member of the access port assembly. It is possible for additive solutions introduced into the container through such a port to be trapped in more or less undiluted form in these dead spaces so that not all the additive is delivered to the patient.

Generally, tubular access port assemblies for insertion in the neck of a flexible bag include only a single entry port, and after an entry spike has been installed

therein, it is necessary to have another fitting adjacent to the first port or on a side of the container if additives are to be supplied to the solution within the container. Also, conventional access port assemblies occupy only a portion of the space in the neck of the bag-like container, so that it is possible for additive solutions introduced through the access port or an adjacent additive port to layer in the neck area of the container without becoming diluted completely by the fluid contained in the body of the container. If a concentrated additive solution is not uniformly mixed with a parenteral solution in the container, an essentially undiluted portion of the additive might be administered to a patient. This could be very harmful if the additive were a potent, highly reactive drug.

Finally, the diaphragm in known access port assemblies is generally positioned at the bottom of the tubular portion of the port and a spike has to be inserted completely through the port before the diaphragm is penetrated. This means that the tapered terminal portion of the spike may be in the area of the ruptured diaphragm, and there is a tendency for the stretched resilient material of the diaphragm to exert a backward force on the tapered portion of the spike tending to dislodge the spike from the diaphragm.

Recently, interest has developed in the use of blow molded flexible containers as containers for sterile solutions. Such containers may be blow molded to provide a neck end which is sealed, and before the sealing of the neck end, sterile solution may be introduced into the container. In some instances, integral closed end access ports have been formed on the neck portion of such containers during the molding operation as is proposed by U.S. Pat. Nos. **3,589,422** to Bellamy and **3,746,001** to Ralston. Also in some instances, containers may be blow molded to provide a large open end or neck, and in these cases, integral access ports cannot be formed, and additional means must be provided for closing the container.

It is a primary object of the present invention to provide a novel and improved pierceable access port assembly for a flexible sterile solution container which may be effectively and easily secured to the container, and which operates to facilitate the introduction of an additive into the container or the withdrawal of fluid from the container without danger of contamination.

Another object of the present invention is to provide a novel and improved pierceable access port assembly for a flexible sterile solution container which may be readily sealed to the neck portion of conventional blow molded flexible containers to hermetically seal the container.

A further object of the present invention is to provide a novel and improved pierceable access port assembly for a flexible sterile solution container which constitues a unitary structure with access and dispensing ports recessed within the container neck and adapted to fill substantially the entire volume of the container neck to insure direct injection of an additive into a solution contained in the body of the container.

Another object of the present invention is to provide a novel and improved pierceable access port assembly for a flexible sterile solution container which includes an access port closed by a pierceable diaphragm which is positioned to enhance the retention of an inserted spike.

A further object of the present invention is to provide a novel and improved pierceable access port assembly particularly adapted for attachment to a dome shaped neck closure for an enclosed blow molded container.

Another object of the present invention is to provide a novel enclosed blow molded flexible sterile solution container having attached additive and dispensing port means secured to a dome shaped neck closure member formed integrally on the container during the blow molding process.

Yet another object of the present invention is to provide a novel enclosed blow molded flexible solution container with a pierceable access port assembly having flange means for grasping to facilitate the insertion of a spike member.

A still further object of the present invention is to provide a novel enclosed blow molded flexible sterile solution container wherein an integral portion of the container is employed as a mounting flange for a pierceable access port assembly. These and other objects of the present invention will become readily apparent upon consideration of the following specification and claims taken in conjunction with the accompanying drawings in which:

FIG. 1 is a partially sectioned view illustrating a conventional open neck blow molded flexible container for sterile solutions;

FIG. 2 is a sectional view of a closed neck embodiment adapted to replace the open neck of the blow molded container of FIG. 1;

FIG. 3 is a sectional view of a second embodiment of a closed neck adapted to replace the open neck of the blow molded container of FIG. 1;

FIG. 4 is a sectional view of the pierceable access port assembly of the present invention secured to the neck of the container of FIG. 1;

FIG. 5 is a plan view of the pierceable across port assembly of FIG. 4 with the cover section intact;

FIG. 6 is a plan view of the pierceable access port assembly of FIG. 4 with a frangible portion of the cover removed;

FIG. 7 is a sectional view of a second embodiment of the pierceable access port assembly of the present invention secured within the container neck of FIG. 2;

FIG. 8 is a sectional view of a third embodiment of the pierceable access port assembly of the present invention secured to the container neck of FIG. 3; and

FIG. 9 is a sectional view of a fourth embodiment of the pierceable access port assembly of the present invention.

Referring now to the drawings, FIG. 1 discloses a flexible plastic container **10** adapted for use in storing and dispensing sterile solutions such as parenteral solutions, blood plasma, blood, etc. The container **10** constitutes a collapsible container having a closed body member **12** formed by a blow molding process to any shape employed for such containers. During the blow molding process, the body member is provided with a large open neck, and this body member tapers to a neck portion **14** which terminates at a relatively large open end **16.** Generally, a hanger portion **18** will be formed at the end of the container opposite the neck **14.** The container **10** is formed of plastic material which is compatible with the particular sterile solution to be contained. For example, with parenteral solutions, the container may be formed of polyvinyl chloride, polyalkylenes such as polyethylene, polypropylene or copolymers of ethylene and propylene.

During the formation of a blow molded container **10,** it is often desirable to completely close the container and omit the open end **16** of FIG. **1.** To accomplish this, the container body and neck are first formed, the sterile solution is introduced into the container, and then the neck is closed by sealing. One form of closure for the neck **14** is illustrated in FIG. **2** wherein the closure indicated generally at **20** for the container neck includes a flange section **22** formed integrally with the wall of the container neck and a side wall **24** which tapers upwardly from the flange section to a crown closure wall **26.**

In FIG. **3,** a second closure embodiment for the neck **14** of the container **10** is disclosed wherein two closed button-like projections **28** and **30** are provided on the closed end during the blow molding process. Each of these button-like projections includes a neck portion **32** extending upwardly from a top closure wall **34** that extends across the terminal end of the neck portion **14.** The neck portions **32** are each formed with an outwardly extending flange section **35** which extends upwardly to a top closure wall **36.**

Referring now to FIGS. **4–6,** the pierceable access port assembly of the present invention indicated generally at **38** is illustrated in position within the open neck **14** of the container **10** of FIG. **1.** The pierceable access port assembly includes a substantially tubular side wall **40** which terminates at a bottom wall **42** formed integrally therewith. The opposite end of the tubular side wall includes an outwardly extending flange **44** which is formed annularly to define an opening **46.**

Integrally formed with the bottom wall **42** and extending upwardly therefrom are two spaced, open-ended ports **48** and **50** which are substantially tubular in structure. These ports define inner bores or channels **52** and **54** respectively which extend between the open ends thereof, each such bore being completely closed by a diaphragm or web **56** positioned substantially at the mid-point of each port and extending between the side walls thereof.

The upper open ends **58** and **60** of each of the ports **48** and **50** terminate at a position spaced below the uppermost surface **62** of the flange **44.** A plurality of annular, spaced inwardly projecting beaded projections **66** may be formed on the inner wall of each of the ports **48** and **50** adjacent the open ends **58** and **60.** These projections are formed in the portions of the wall above the diaphragms **56.** They provide greater interference fit for retention of an inserted spike or stopper.

A reinforcing rib **68** extends between the ports **48** and **50,** and reinforcing ribs **72, 74** and **76** extend between the port **48** and the side wall **40,** while reinforcing ribs **78, 80** and **82** extend between the port **50** and the side wall **40.** Although each of these reinforcing ribs extends upwardly from the bottom wall **42,** it should be noted that the upper surfaces thereof terminate well below the upper terminal ends **58** and **60** of the ports **48** and **50.**

The opening **46** in the pierceable access port assembly **38** is closed by a suitable cover **84** which is secured to the upper surface **62** of the flange **44.** This cover may include a frangible removable portion, which, when removed, exposes the upper ends **58** and **60** of the ports **48** and **50** as illustrated in FIG. **6.** Any known frangible cover suitable to perform this purpose may be

employed, such as covers with vertical pull tabs, tear strips, etc. To prevent accidental opening of the cover and contamination of the portions of the access port assembly enclosed therein, it is preferable that no outwardly projecting tear tabs which may be accidentally caught or snagged be included in the cover structure. Instead, the cover of FIG. **5** is preferable having score lines **86** and **88** which define the tear away portion. These score lines also define an enlarged push-in section **90** which, when pushed inwardly, is adapted to tear along the acore line and to permit removal of the tear away portion of the cover. This push-in section **90** is positioned above an open space which is defined by the ribs **68, 76** and **82** and the bottom wall **42.** To assure that the push-in section is properly positioned, both the cover **84** and the flange **44** are provided with alignment indicators **92** and **94** respectively. These alignment indicators merely constitute outwardly projecting tabs, and when the tab **92** of the cover **84** is aligned with the tab **94** on the flange **44,** the push-in section **90** is properly positioned.

The upper end of the one of the ports **48** or **50** above the diaphragm **56** is closed by a rubber stopper **96** which substantially fills the space between the upper end of the port and the lower surface of the cover **84.** The stopper is designed to receive the needle of an additive container when an additive is injected into the body **12** of the sterile solution container.

In the formation of the sterile container **10** with the pierceable access port assembly **38,** the container is first blow molded as illustrated in FIG. **1,** washed and the desired solution introduced therein. Then a pierceable access port assembly **38** is inserted into the neck of the container and, as will be noted in FIG. **4,** the outermost terminal portion of the container neck **14** is formed outwardly to provide a support flange **102** beneath the flange **44.** Then the flanges **44** and **102** and the cover **84** are all hermetically sealed together in the flange area by a suitable sealing method such as sealing by radio frequency energy, ultrasonic welding, or solvent sealing. The sealing of the three parts may occur simultaneously, or the flange **102** of neck **14** may first be sealed to the flange **44** and subsequently the cover **84** may be sealed to the flange **44.** The sealed container and its contents are then sterilized.

The sealed, three-layered flange portion offers a means for firm grasping of the port structure so that a spike of an administration set may more readily be inserted through the entry port.

The pierceable access port assembly **38** is preferably a unitary molded assembly which is preferably formed of the same material employed to form the container **10.** This unitary assembly provides both an entry port and an additive port without requiring the provision of two separate fittings for the container. It is significant to note the tubular wall **40** of the access port assembly is designed to fit tightly against the inner surface of the neck portion **14** for the container and leaves no dead spaces where additives might be trapped. Also of extreme importance is the fact that the tubular wall **40** contacts the inner wall of the neck portion **14** over substantially the entire extent thereof, and the access port assembly occupies substantially the complete volume of the neck portion of the container. Therefore, no dead spaces are present in the container neck where sn additive introduced through the stopper **96** could concentrate, and instead, the additive will be directly introduced into the body **12** of the container and be readily dispersed.

When entry spikes, which are generally fairly short in length and tapered near the tip portion, are introduced into the port **48,** the tip of the spike punctures the diaphragm **56** and projections **66** aid in firmly sealing the spike within the port. It is advantageous to position the diaphragm at least midway up the port, for otherwise, the diaphragm tends to dislodge the spike after puncture of the diaphragm occurs. If just the tapered tip portion of the spike is in the area of the ruptured diaphragm, there is a tendency for the resilient material of the diaphragm to push upwardly on the spike, thus resulting in dislodgement of the spike.

The stopper **96** is employed where an additive solution is added through a needle, but the stopper would not be required for an additive package which utilizes a spike. Where a needle is employed, it is not necessary to have both the stopper **96** and the diaphragm **56** present in the port **50,** but the diaphragm does assure that the solution in the container will not be discharged should the stopper become dislodged.

The plurality of ribs between the ports and the side wall **40** of the access port assembly stabilizes the individual ports relative to each other and to the neck of the container. These ribs help rigidify the neck portion of the container so that the neck can be more firmly held by an operator while manipulating a spike for insertion or while introducing an additive solution into the container. Since the ports **48** and **50** are recessed within the container and protected bythe outer wall thereof, these ports are not subjected to impacts which might occur with projecting ports and therefore damage to the ports and possible contamination during transportation and storage is minimized.

Referring now to FIG. **7,** there is illustrated a second embodiment of the pierceable access port assembly indicated generally at **104** which includes no internal diaphragms but which incorporates the closure **20** of the container of FIG. **2** as a diaphragm and mounting unit. The pierceable access port assembly **104** incorporates a structure which is substantially identical to the structure included above the diaphragms **56** of the pierceable access port assembly **38,** and therefore the reference numerals of FIGS. **4–6** will be employed for identical components illustrated in FIG. **7.**

The pierceable access port assembly **104** is preferably designed to completely fill the interior of the neck portion **14** for the container **10,** although in some instances, only the upper portion of the neck would be occupied thereby. The tubular siide wall **40** which engages the inner surface of the container neck terminates at the bottom wall **42** from which the ports **48** and **50** project. It will be noted, however, that the ports **48** and **50** contain no internal diaphragm, but instead employ the crown portion **26** of the container closure for this purpose. Thus, in providing the container of FIG. **2** with the pierceable access port assembly **104,** the container is formed then the sterile contents are injected therein, and subsequently the closure **20** is formed to seal the container. Initially, the closure **20** is in the dotted line position of FIG. **7,** and it will be noted that the side wall **24** and crown closure wall **26** thereof are formed to approximate the configuration of the side wall **40** and bottom wall **42** of the pierceable access port assembly. Also, the flange portion **22** of the clo-

sure 20 is formed to approximate the width of the flange 44.

Once the enclosed container of FIG. 2 is formed and filled with sterile solution, the pierceable access port assembly 104 is mounted thereon by first depressing the cover 20 into the neck 14 of the container as illustrated. This causes an outer side wall 106 of the flange portion 22 to be folded down tightly against a bottom wall 108 of the flange portion to form a double walled mounting flange 110 extending annularly about the container opening. This double walled annular flange is then sealed to the flange 44 of the pierceable access port assembly 104 in the manner previously described in connection with FIGS. 4–6. When sealed, by radio frequency energy for example, the bottom surface of flange 44 fuses to the top surface of flange 110 and at the same time the abutting surfaces of the walls 106 and 108 also fuse together. The coveer 84 may then be sealed to the flange 44.

The insertion of the pierceable access port assembly 104 into the neck 14 of the container 10 after the closure 20 has been inserted therein causes the side wall 24 of the closure to seal tightly against the surface of the neck portion 14 and provide a double wall for the neck portion. The side wall 24 now becomes the inner wall of the neck portion against which the side wall 40 of the access port assembly engages, while the crown portion 26 of the closure extends along the bottom wall 42. Thus, the crown portion 26 provides a pierceable diaphragm for both the port 48 and the port 50 which may then be subsequently pierced by a spike or needle inserted into one of the ports.

The embodiment of the pierceable access port assembly disclosed by FIG. 8 is adapted for the closed container of FIG. 3, and separate ports are sealed to double walled flanges provided by the button-like projections 28 and 30. Referring to FIG. 8, an additive port 112, is secured to the button-like projection 28 of the container 10. This additive port is of substantially open ended tubular configuration to define an inner bore 114, and the port includes a side wall 116, the lower end of which terminates at an outwardly projecting annular flange 118. The side wall 116 is thickened at the end thereof opposite the flange 118 to provide an annular cap retaining lip 120. The inner surfaces of the additive port adjacent to the lip 120 may be provided with annular beaded projections 122 to aid in retaining a stopper 124 which is inserted into the port.

Stopper 124 operates in combination with a cap structure 130 which is contained by the lip 120 to seal the additive port 112. The cap structure 130 includes a stopper retainer 132, a resilient disc 134, and a tear offcap 136. The tear off cap includes a tear away portion 138 which overlies the disc 134 and, with the remainder of the tear off cap, forms a relatively solid metallic backing for the disc. The stopper retainer 132 and the tear off cap 136 are engaged beneath the lip 120 so that the tear off cap imparts a compressive force to the disc 134.

In addition to the additive port 112, an entry port 140 is provided on the container 10 and is secured to the buttonlike projection 30 thereof. Entry port 140 is also of open ended tubular configuration and includes a substantially tubular side wall 142 which defines an innerbore 144. Side wall 142 terminates at one end in an outwardly projecting annular flange 146, and the inner surface of the side wall at the end opposite the flange 146 may be provided with annular beaded projections 148. These projections are adapted to seal and retain a spike inserted in the port 140 in the manner previously described in connection with the pierceable port assemblies 38 and 104.

The end of the entry port 140 adjacent the bead like projections 148 is closed by a protector member 150 formed of polyvinyl chloride or other suitable plastic or metal materials. The protector 150 includes a tubular side wall 152 adapted to fit tightly about the side wall 142 of the entry port, one end of the side wall 152 terminating in an outwardly extending annular flange 154 which is adapted to engage and overlie the flange 146. The end of the protector opposite the flange 154 is closed by a top closure wall 156 which is provided with an integral support projection 158 extending in the direction of the flange 154. The projection 158 is adapted to extend into the bore 144 when the protector is in position over the entry port 140 as disclosed in FIG. 8.

An annular groove 160 is formed in the inner surface of the side wall 152 to reduce the thickness of the side wall and provide a thin frangible area 162. A tab 164 is formed integrally with the side wall 152 and projects upwardly above the top wall 156. To gain access to the entry port 140, the tab 164 is pulled to cause the protector 140 to rupture at the thin frangible section 162 so that the upper portion of the protector may be removed.

The additive port 112 and the entry port 140 are attached to the container 10 in much the same manner as was the pierceable entry port assembly 104 of FIG. 7. After the container of FIG. 3 is formed, filled, and closed, the upper surface 36 of the button-like projections 28 and 30 is compressed downwardly causing flange sections 35 to flatten so that a portion of the upper surface 36 and a lower annular wall section 166 form an annular, double walled flange 168 at the top of each of the button-like projections. The flanges 118 and 146 of the ports 112 and 140 are sealed thereto in the manner previously described. This sealed, multilayered flange portion allows one to grasp the entry or additive port structure firmly so as to facilitate the insertion of a spike or needle. The flange 154 of the protector 150 is sealed to the flange 146, and this may occur separately or as a single operation involved in sealing the access port to the flange 168.

It will be noted that the top walls 36 of the button-like projections 28 and 30 operate as a pierceable diaphragm for the additive port 112 and the entry port 140.

FIG. 9 discloses a modification of the pierceable access port assembly of FIG. 8 which is adapted for use on open neck containers of the type shown by FIG. 1 or containers similar to that shown by FIG. 3 without the button-like closure projections 28 and 30. The structure shown in FIG. 9 is substantially identical to the entry port 140 of FIG. 8, the only modification being the provision of a bottom wall 170 contiguous with the flange 146. This bottom wall extends across the open end of the container 10 and provides a pierceable diaphragm and closure for the container. The flange 146 is sealed to a flange 172 formed about the open end of the container in the manner previously described. Obviously the structure of FIG. 9 could also be used for the additive port 112 of FIG. 8.

It will be readily apparent to those skilled in the art that the present invention provides improved pierceable entry port assemblies for blow molded or otherwise formed plastic containers which may be easily formed and used with no danger of container content contamination. The flange structure at the bottom of each assembly which cooperates with an annular flange integrally formed at the top of the container permits a very effective hermetic seal to be achieved through the use of radio frequency, ultrasonic, or solvent sealing techniques. Not only does the cooperating annular flange formed integrally with the container neck provide a strong mounting flange for the port assembly, but it also is designed to simplify the sealing process. It is quite simple to insert conventional sealing apparatus over the various port assembly embodiments to engage the outwardly projecting flange structure and achieve the desired hermetic seal between the container and the pierceable port assembly. Therefore, the manufacturing process involved is greatly simplified.

We claim:

1. A sealed unit for storing and dispensing a sterile solution comprising a container including wall means formed to provide a container body and a container neck section extending from said body, and a peripheral mounting flange formed integrally with said wall means of said neck section and extending laterally outward therefrom completely around the outermost end of said neck section, and an access port assembly sealed to said mounting flange, said access port assembly including sidewall means formed to engage the inner surface of the neck section over substantially the entire periphery of said assembly sidewall means, port means spaced inwardly from said assembly sidewall means and connected thereto, and an assembly mounting flange formed around the periphery of said assembly sidewall means and extending laterally outward from one end thereof, said assembly mounting flange overlying the peripheral mounting flange of said container and being sealed thereto, said port means including at least one port having an inner bore extending longitudinally therethrough, said inner bore being closed by a pierceable diaphragm, the outermost end of said container neck section being closed by a closure means formed integrally with said wall means of said neck section, said closure means providing a pierceable diaphragm across the internal bore of said port when the access port assembly is secured to the peripheral mounting flange of said container.

2. The sealed unit of claim **1** wherein said closure means is formed to provide the peripheral mounting flange for said container.

3. The sealed unit of claim **2** wherein said closure means includes a flange section formed by two spaced walls forming an upper and a lower wall for said flange section extending around said neck section and laterally outward therefrom, the ends of said upper and lower walls being joined outboard of said neck section, said upper and lower walls being forced into contact beneath said access port assembly to form a double walled peripheral mounting flange.

4. The sealed unit of claim **3** wherein the lower wall of said flange section is formed integrally with the neck section of said container, said closure means including a crown section extending from the upper wall of the flange section across the outermost end of the container neck section, said crown section being formed to extend around and beneath said access port assembly within said neck section.

5. The sealed unit of claim **4** wherein said container and closure means are formed of flexible plastic material as a unitary structure.

6. The sealed unit of claim **4** wherein said container wall means are shaped to provide a neck section of smaller cross sectional area than the cross sectional area of said container body, said neck section terminating at an outer open end spaced from said body, said outer open end being closed by said closure means.

7. A sealed unit for storing and dispensing a sterile solution comprising a container including wall means formed to provide a container body and a container neck section extending from said body, and a peripheral mounting flange formed integrally with said wall means of said neck section and extending laterally outward therefrom completely around the outermost end of said neck section, and an access port assembly sealed to said mounting flange, said access port assembly including assembly sidewall means formed to engage the inner surface of the neck section over substantially the entire periphery of said assembly sidewall means, port means including at least one port substantially coextensive with said assembly sidewall means spaced inwardly from said assembly sidewall means and integrally connected thereto, said port having an inner bore extending longitudinally therethrough, said inner bore being closed by a pierceable diaphram, and an assembly mounting flange formed around the periphery of said assembly sidewall means and extending laterally outward from one end thereof, said assembly mounting flange overlying the peripheral mounting flange of said container and being hermetically sealed thereto.

8. The sealed unit of claim **7** wherein said access port means is formed to extend longitudinally through substantially the entire extent of said neck section.

9. The sealed unit of claim **8** wherein said assembly sidewall means is formed to engage substantially the entire inner surface of said neck section.

10. A sealed unit for storing and dispensing a sterile solution comprising a container including wall means formed to provide a container body and a container neck section extending from said body, and a peripheral mounting flange formed integrally with said wall means of said neck section and extending laterally outward therefrom completely around the outermost end of said neck section, and an access port assembly sealed to said mounting flange, said access port assembly including assembly sidewall means formed to engage the inner surface of the neck section over substantially the entire periphery of said assembly sidewall means, port means spaced inwardly from said assembly sidewall means and connected thereto, and an assembly mounting flange formed around the periphery of said assembly sidewall means and extending laterally outward from one end thereof, said assembly mounting flange overlying the peripheral mounting flange of said container and being sealed thereto, said assembly sidewall means defining an open ended assembly body member, said access port assembly including a bottom wall connected to said sidewall means and closing one end of said assembly body member, said port means including at least one port extending from said bottom wall toward the opposite end of said assembly body member, said port having an inner bore extending longitudinally therethrough and through said bottom wall.

11. The sealed unit of claim 10 wherein said port extends from said bottom wall to a terminal end positioned within the confines of said assembly body.

12. The sealed unit of claim 11 wherein said assembly sidewall means is formed to engage substantially the entire inner surface of said neck section whereby said access port assembly occupies substantially the entire volume of said neck section.

13. The sealed unit of claim 12 wherein the inner bore of said port is closed by a pierceable diaphragm positioned within said bore intermediate and in spaced relationship to the ends thereof.

14. The sealed unit of claim 10 wherein said port means includes an entry port and an additive port extending from said bottom wall toward the opposite end of said assembly body member, both said entry and additive ports terminating at a terminal end positioned within the confines of said assembly body and including an inner bore extending longitudinally therethrough and through said bottom wall.

15. The sealed unit of claim 14 wherein the open end of said assembly body member opposite to said bottom wall is closed by a cover secured to said assembly mounting flange.

16. The sealed unit of claim 15 wherein a removable stopper of resilient material is inserted in the bore of said additive port.

17. The sealed unit of claim 14 wherein said entry and additive ports are joined to said assembly sidewall means by reinforcing ribs connected to said bottom wall and terminating between said bottom wall and a point spaced inwardly from the terminal ends of said entry and additive ports.

18. The sealed unit of claim 17 wherein said cover includes a tear out section, said tear out section having a tab adapted to be forced inwardly toward the bottom wall of said access port assembly, said cover and assembly mounting flange each being provided with an indicator means positioned to control the position of said tab, alignment of said assembly mounting flange and cover indicator means operating when said cover is secured to the assembly mounting flange to position said tab relative to said additive and entry ports.

19. The sealed unit of claim 14 wherein the bores of said entry and additive ports are closed by a pierceable diaphragm.

20. The sealed unit of claim 19 wherein the pierceable diaphragm in the bores of said additive and entry ports is positioned within each such bore intermediate and in spaced relationship to the ends thereof.

21. The sealed unit of claim 19 wherein the outermost end of said container neck section is closed by a closure means formed integrally with said wall means, said closure means providing a pierceable diaphragm across the internal bores of said entry and additive ports when the access port assembly is secured to the peripheral mounting flange of said container.

22. The sealed unit of claim 21 wherein said closure means is formed to provide the peripheral mounting flange for said container.

23. A sealed unit for storing and dispensing a sterile solution comprising a container including wall means formed to provide a completely closed container body, at least one flanged mount integrally formed on said wall means, said flanged mount including a neck portion extending outwardly from said wall means having an internal bore in communication with the interior of said container and a flanged closure integral with said neck portion and closing the outermost end thereof, said flanged closure including a lower wall surrounding said neck portion and extending laterally outward from the outermost end thereof, and an upperclosure wall extending across the terminal end of said neck portion above said lower wall and being joined to said lower wall outboard of said neck portion, said lower and closure walls being secured together to form a double walled flange extending outwardly from said neck portion, and an access port sealed to said double walled flange, said access port having a body with an access bore extending therethrough, said body being sealed at one end to said double walled flange with the access bore positioned above said closure wall, said closure wall providing a pierceable diaphragm closing the lower end of said access bore.

24. The sealed unit of claim 23 wherein two spaced flanged mounts are provided at one end of said container body, each of said flanged mounts having an access port sealed to the double walled flange thereof.

25. The sealed unit of claim 24 wherein one of said access ports is an entry port and the remaining access port is an additive port, both of said access ports including a port mounting flange formed at one end of said body and extending laterally outward therefrom completely around said body, said port mounting flange being secured to said double walled flange.

26. The sealed unit of claim 25 wherein the access bore of said additive port is closed by a removable stopper of resilient material inserted in the end thereof opposite to said port mounting flange, said stopper being covered by a removable cover secured to the body of said access port.

27. The sealed unit of claim 26 wherein the access bore of said entry port is closed by a closure cap having cap sidewall means which enclose the sides of the body of said entry port and a cap endwall which extends from said cap sidewall means across the end of said body opposite to said port mounting flange, the end of said capsidewall means opposite said cap endwall including an outwardly extending cap flange extending around said cap sidewall means, said cap flange being sealed to the port mounting flange for said entry port.

28. An access port assembly for installation within the neck of a container for storing and dispensing a sterile solution comprising a body member having a sidewall means defining an open end of said body member, a bottom wall extending from the end of said sidewall means opposite said body member open end to close one end of said body member, and at least one access port extending from said bottom wall in spaced relationship to said sidewall means and terminating at a terminal end adjacent to the open end of said body member but positioned within the confines of said sidewall means.

29. The access port assembly of claim 28 wherein an entry port and an additive port extend from said bottom wall toward the open end of said body member in spaced relationship to one another and to said sidewall means, both said entry and additive ports terminating at a terminal end positioned within the confines of said sidewall means and including an inner bore extending longitudinally therethrough and through said bottom wall.

30. The access port assembly of claim 29 wherein said body member is a unitary member including a first

reinforcing rib extending between said entry and additive ports and a plurality of reinforcing ribs extending between said sidewall means and said additive and entry ports respectively.

31. The access port assembly of claim **29** wherein the access bore of said entry port is closed by a pierceable diaphragm positioned intermediate the ends thereof.

32. The access port assembly of claim **29** which includes a mounting flange extending laterally and outwardly from said sidewall means about the periphery of the open end of said body member.

33. A sealed unit for storing and dispensing a sterile solution comprising a container including wall means formed to provide a container body and at least one open ended container neck section extending from said body, and a peripheral container mounting flange formed integrally with the wall means of said neck section and extending annularly about the open end of said neck section and laterally outward therefrom, and an access port sealed to said container mounting flange and extending outwardly therefrom away from said neck section, said access port having a body with an access bore extending longitudinally therethrough and an integral bottom wall extending one end of said body to close said bore, said bottom wall extending laterally outward beyond said body around one end thereof to form a port mounting flange, said port mounting flange being hermetically sealed to said container mounting flange.

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UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 3,905,368

DATED : September 16, 1975

INVENTOR(S) : Lewis, Dan, Jr.; Von Alven, Raymond D.; and Prouty, Myron R.

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 5, line 11, "acore" should be --score--.

Column 5, line 66, "sn" should be --an--.

Column 6, line 52, "siide" should be --side--.

Column 7, line 18, "coveer" should be --cover--.

Column 14, line 9, insert --across-- between "extending" and

Signed and Sealed this

twenty-third Day of *December 1975*

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks