(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 175 529**
B1

(12) # EUROPEAN PATENT SPECIFICATION

(45) Date of publication of the patent specification: **01.03.89**

(51) Int. Cl.⁴: **A 61 J 1/00**

(21) Application number: **85306369.1**

(22) Date of filing: **09.09.85**

(54) **Port free container.**

(30) Priority: **14.09.84 US 650400**

(43) Date of publication of application:
26.03.86 Bulletin 86/13

(45) Publication of the grant of the patent:
01.03.89 Bulletin 89/9

(84) Designated Contracting States:
AT BE CH DE FR GB IT LI LU NL SE

(56) References cited:
CH-A- 399 297
GB-A- 1 104 359
US-A- 2 949 712
US-A- 3 030 952
US-A- 3 177 870

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Description

This application relates to an improved container having flexible plastic walls, for sterile solutions or the like. Flexible plastic solution containers are used in great quantities in the medical field for holding sterile solution for intravenous use, blood, sterile washing solutions, peritoneal dialysis solutions and the like. Typical designs of flexible containers include the Viaflex® containers for intravenous solutions and the Dianeal® peritoneal dialysis solution containers sold by Travenol Laboratories, Inc.

Conventional flexible plastic containers carry tubular ports at one end which are proportioned to receive a spike connector of an administration set. The spike connector passes into a tubular port passing through a diaphragm into flow communication with the solution contents of the container.

The medical industry is currently under strong economic pressure to reduce costs. Thus, there is particularly important value to be obtained from container designs which can be manufactured with reduced cost.

One significant facet of the cost of a flexible container is the cost of the access port. In Bieberdorf et al. U.S. Patent 2 949 712, a design of flexible container is proposed which has no tubular access port on the outside of the container, but instead a puncture is made through the container wall itself. Problems, however, result from the fact that the spike which penetrates the container wall is not well supported for use. Thus leakage can develop around the puncture site of the spike, and the spike is susceptible to being accidentally dislodged from its bag-penetrating position.

US-A 3 030 952 discloses a container in which an insert is provided having a bore. The puncture member may be inserted through the flexible wall of the container into the bore so that the member is sealingly held in the bore. The insert is freely floating within the container.

GB-A 1 104 359 also discloses such an insert within a container, but the insert is heat-sealed to a side wall of the container.

CH-A 3 999 297 discloses such an insert which is held in place within a container by means of a band clamping a portion of the container wall about the insert.

The pre-characterising clause of Claim 1 is based on the disclosure of GB-A 1 104 359.

The present invention provides a container having opposed flexible walls sealed to each other at their edges and having a puncturable portion, an insert member positioned within the container and having a bore for sealingly receiving a puncture member after penetration of the latter through the puncturable portion so as to provide flow communication between the interior of the container and the puncture member, the insert member being held in a position with an end of the bore adjacent the puncturable portion, characterised in that said puncturable portion extends laterally of said flexible walls at one end of the container and the bore of the insert member is offset from the plane containing said edges and extends generally parallel to said plane.

As the puncture member passes into the bore, it typically causes an annular portion of the container wall to deform or stretch into a position between the puncture member and the aperture wall, where the annular portion can be sealingly locked and seated between the connected puncture member and bore wall. Thus, leakage can be prevented.

The container wall may define a flexible-walled protrusion communicating with the rest of the container through a relatively narrow neck portion, to permit flow communication between the protrusion and the rest of the container. The insert member is advantageously captured or retained in the protrusion, to provide it with a fixed location without the need to seal it to the inner wall of the container.

The container may also carry removable tape means on the outer surface of the flexible wall. The tape means may be applied to the container prior to sterilization, so that the tape means may be removed, when use of the container is desired, to expose a clean, typically sterile surface for puncturing by the puncture member. Thus, no alcohol swab or the like may be required prior to the use of the device of this invention.

The container of this invention may be made from a pair of plastic sheets, or a large, extruded, flattened tubular plastic sheet, by appropriate peripheral heat sealing in a manner analogous to present commercial container manufacture techniques. Alternatively, a plastic sheet may be folded over and then peripherally sealed together on all open sides to form the container. The insert member may in this circumstance be simply placed between facing plastic sheets within the newly-formed container before the peripheral sealing operation, to provide a very efficient, cost effective manufacturing technique, since no separate application of port tubes is required.

While a wide range of thermoplastic or other resilient materials may be used to make the container wall, one preferred material is DYPRO® Z4650 polypropylene copolymer, sold by the Arco Chemical Company. The plastic material used may, if desired, be about 0.25 mm (0.01 inch) thick and may optionally be a coextrusion of the above recited DYPRO plastic material as an inner layer, and polypropylene as an outer layer of the container wall. The insert member, in turn, may be made from a polypropylene material, for example having about 3 weight percent of copolymerized ethylene units in the formulation.

If desired, the insert member may comprise a pair of tubes in telescoping relation with each other and connected at one end, with the bore as defined above being defined by the bore of the inner tube. This structure provides a certain desirable resilience to the insert member, and facilitates the seal formed between a puncture member and the aperture wall.

In the specific instance of DYPRO® Z4650 copolymer, it is be desirable for the insert member to be made of a generally rigid material such as polypropylene as mentioned above. However, in other instances, for use with other resilient sheet materials, it may be disirable to use a softer, semiflexible insert member. The aperture of the insert member may be proportioned to be of a diameter which is dependent upon the wall thickness of the facing plastic sheets, so that on penetration of the container wall by a puncture member, the annular portion of the container wall is formed by deformation and stretching into the desired sealing position between the puncture member and the bore wall.

The various dimensions and proportions of the system may vary in accordance with frictional characteristics of the puncture member and insert member with the plastic of the container wall to optimize the formation of the desired deformed or stretched annular portion used for sealing between the connected puncture member and bore wall. Additionally, one may adjust the sharpness of the puncture member to provide the desired results. For example, it may be desired to provide a sharp spike with a highly resilient material, coupled with materials that provide a rather high coefficient of friction. On the other hand, when using a bag wall material that is not very resilient, a duller spike may be desired in some instances, and one may wish to use materials that have a realtively lower coefficient of friction. On the other hand, a sharp spike may be used in this instance as well for facilitating access to the container.

Accordingly, it is believed to be basically a routine matter to selct materials for the container wall and insert member, and to proportion them into proper dimensions, to achieve good results with a large number of different materials in accordance with this invention.

Description of the Drawings

In the drawings, Figure 1 is a plan view of a flexible, collapsible container (not in accordance with the invention) with a portion broker away.

Figure 2 is a side elevational view of the container of Figure 1, taken along line 2-2 of Figure 1.

Figure 3 is a fragmentary, longitudinal sectional view of a portion of the container of Figures 1 and 2, showing how a spike may penetrate the bag wall and the insert member to provide access to the contents of the container.

Figure 4 is a plan view of an insert member according to the invention.

Figures 5 and 6 are elevational views, rotated 90° about their longitudinal axis from each other, of the insert member of Figure 4.

Figure 7 is a plan view of design of flexible collapsible container in accordance with this invention.

Figure 8 is a fragmentary elevational view of the container of Figure 7, rotated 90° about its longitudinal axis.

Reterring to Figures 1 through 3, bag 10 is made of a pair of overlying thermoplastic sheets 12, 14, which are heat sealed together. A peripheral heat seal 16 is used. The seal may be made by conventional radio frequency sealing processes if polyvinylchloride sheeting is used, or by a hot bar seal if polyolefin sheeting or the like is used.

The top of container 10 may carry other peripheral seals 18, and a corner hanger hole 20 for suspension of the container. At the other end of container 10 from hanger hole 20, and at the opposed corner thereof, flexible-walled protrusion 22 is defined, being surrounded by the extension 24 of heat seal 16.

As shown in Figure 2, for example, sheet 12 defines a portion of protrusion 22 which may be thermoformed in conventional manner to form a pocket 26. Pocket 26, in turn, receives and holds insert member 28, which may be a molded plastic piece of a design shown in longitudinal section in Figure 3.

As another desired feature, tape member 30 may be provided, adhering to an outer end of pocket 26 as shown in Figure 2. Tape member 30 may be a known plastic foil tab which is sealed to bag 10, defining a handle portion 32, so it can be manually removed to expose the surface of pocket 26 underneath foil tab 30. If foil tab 30 is applied and then bag 10 is radiation or steam sterilized, for example, removal of tab 30 can present a sterile surface to the user for application of a spike connector 34 to bag 10 to obtain access thereto.

As shown in Figure 3, insert member 28 may be a single, molded plastic piece comprising a pair of tubular portions 36, 38, joined together at one end 40 in telescoping relation. The outer telescoping portion 36 serves as a good manual gripping member, so that one may hold protrusion 22 with the fingers, thus also gripping insert member 28. One may then manually advance spike 34, penetrating the wall of protrusion 22 to gain access to container 10. Portions of the container wall 42 may be stretched to fold inwardly into bore 44 of insert member 28 as spike 34 penetrates bore 44, so that wall portions 42 provide an added sealing lip or ring to the connection system between spike 34 and insert member 28. Accordingly, liquid 46 in container 10 may pass through the lumen of spike 34 into an administration set or the like, for flow communication between the bag interior and the set to which spike 34 is attached.

The telescoping tube structure of insert member 28 provides a certain resilience to the tube 38 defining bore 44 which can improve the sealing characteristics of the insert member with spike 34. Also, less plastic is used, when compared with a solid piece insert member which does not define annular space 48.

The illustration of Figure 3 is somewhat schematic. The inner wall of tube 38 defining bore 44 will be commonly expected to contact the outer wall of spike 34, to provide improved sealing along most of its length. The cut and folded-in

portions 42 of the bag wall provide extra sealing, typically stretching insert member 28 outwardly a small amount to accommodate for their presence.

The specific design of Figure 1 is contemplated to be made on a mass production basis by heat sealing together two overlapping continuous webs 50, 51 of plastic material to form the container walls 12, 14, respectively after inserting insert member 28 between webs 50, 51 in its desired position. The two overlapping, continuous plastic webs 50, 51 shown in phantom lines represent the portion of continuous plastic web material (for example, a roll of material) that typically may be allocated to the manufacture of a single container. It can be seen that high efficiency of use can be obtained, with excess portions of the plastic web material being, typically trimmed away by an automatic trimmer as part of the manufacturing process. If desired, an adjacent bag on the production line may be defined in continuous webs 50, 51 with its flexible-walled protrusin 22 facing bag 10 and occupying the area indicated by reference numeral 52, for further economy of manufacturing.

It can be seen that the heat seals 16 at the respective ends of container 10 are formed to be in angular relationship other than 90° to the lateral heat seals 16 of the edges of webs 50, 51. When container 10 hangs on a pin projecting through hole 20, protrusion 22 is the lowest point of container 10, so that all liquid will pass into protrusion 22 and thus out of spike 34. Even if container 10 is held perpendicular to the ground for draining, the slight downward slope of the lower end seal line 16 will assure that all liquid passes into protrusion 22.

Alternatively, protrusion 22 may be placed at a centered location of container 10 at the lower end thereof, and hanger hole 20 may also be centered.

Referring to Figures 4 to 6, a design of molded insert member 98 is disclosed, being capable of fitting in a flexible-walled collapsible bag of any desired design, either captured in a protrusion or adhered to the inner bag wall. Aperture or bore 100 is provided to receive a connecting spike penetrating through the bag wall, while various ribs 102, 104 are provided for ease of manually gripping the device through the bag wall.

Referring to Figures 7 and 8, a design of container 105 is disclosed, comprising a pair of thermoplastic sheets lying one on top of the other and sealed together with a peripheral heat seal 106. Relatively narrow neck portion 108 is defined by part of heat seal 106 in a centered position on the container. Insert member 98, which may be of the design of Figures 4 to 6, is carried within neck portion 108 in a manner analogous to the previous embodiments, so that bore 100 extending through insert member 98 faces the end wall 109 of neck portion 108 to receive a puncture member in a manner similar to that previously described. Neck portion 108 may carry an offset portion 111 made by a thermoforming step or the like, so that a spike 34 can pass through end wall 109 without interference by peripheral heat seal 106.

Wall 109 may carry removable tape portion 113, if desired, similar in structure and function to tape member 30.

As delivered from the sealing machine, flexible container 105 may have an open end 114 to serve as a temporary filling port when bag 105 is delivered to a filling machine. Thereafter, a subsequent heat seal line 116 may be applied as shown to seal off the bag, and an appropriate hangar hole may be punched into the plastic material 118 outside of the seal lines 106, 116 for hanging of the container.

The flexible containers of this invention may be made by mass production techniques as described above, with significant cost savings over the puncturable, collapsible containers of the prior art. At the same time, they provide great convenience, reliability, and facility of use, particularly as containers for enteral feeding, blood or its components, or dialysis, parenteral, or washing solutions. They may be manufactured in a continuous form, fill and seal manufacturing process if desired.

Claims

1. A container (105) having opposed flexible walls (12, 14) sealed to each other at their edges (106) and having a puncturable portion (109), an insert member (98) positioned within the container and having a bore (100) for sealingly receiving a puncture member (34) after penetration of the latter through the puncturable portion so as to provide flow communication between the interior of the container and the puncture member, the insert member (100) being held in a position with an end of the bore adjacent the puncturable portion, characterised in that said puncturable portion (109) extends laterally of said flexible walls (12, 14) at one end of the container and the bore (100) of the insert member is offset from the plane containing said edges (106) and extends generally parallel to said plane.

2. A container according to Claim 1, wherein the opposed flexible walls (12, 14) are sealed at their edges (106) by a heat weld.

3. A container according to Claim 2, wherein a flexible walled protrusion (111) is formed about the insert member to hold the latter in position, said puncturable portion (109) being defined by a portion of the protrusion.

4. A container according to Claim 1, 2 or 3 which carries removable tape means (113) on the flexible wall, whereby the tape means may be removed to expose a clean surface for puncturing by said puncture member (34).

5. A container according to any preceding claim in which the area of said insert member adjacent said one end of the bore is transversely enlarged relative to the area of the insert member adjacent the other end of said bore.

6. A container according to any preceding

claim in which the puncturable portion is of a material to permit the deforming of the wall as the puncture member passes into the bore to cause an annular portion (42) of the container wall to deform into the bore to seal the puncture member in the bore.

Patentansprüche

1. Behälter (105) mit gegenüberliegenden biegsamen Wandungen (12, 14), die an ihren Rändern (106) miteinander verschweisst sind und einen durchstechbaren Abschnitt (109) aufweisen, und mit einem im Behälter angeordneten Einsatz (98), der eine Bohrung (100) zur dichten Aufnahme eines Einstechorgans (34) nach dessen Eindringen in den durchstechbaren Abschnitt hat, so dass zwischen dem Behälterinnern und dem Einstechorgan eine Strömungsverbindung herstellbar ist, wobei der Einsatz (98) in einer solchen Lage gehalten ist, dass ein Ende der Bohrung an den durchstechbaren Abschnitt angrenzt, dadurch gekennzeichnet, dass sich der durchstechbare Abschnitt (109) seitlich von den biegsamen Wandungen (12, 14) am einen Ende des Behälters erstreckte und die Bohrung (100) des Einsatzes relativ zu der die Ränder (106) enthaltenden Ebene versetzt ist und im wesentlichen parallel zu dieser Ebene verläuft.

2. Behälter nach Anspruch 1, dadurch gekennzeichnet, dass die gegenüberliegenden biegsamen Wandungen (12, 14) an ihren Rändern (106) durch Thermoschweissen verbunden sind.

3. Behälter nach Anspruch 2, dadurch gekennzeichnet, dass ein biegsame Wandungen aufweisender Vorsprung (111) um den Einsatz herum geformt ist und diesen in seiner Lage hält, wobei der durchstechbare Abschnitt (109) durch einen Teil des Vorsprungs gebildet ist.

4. Behälter nach einem der Ansprüche 1, 2 oder 3, dadurch gekennzeichnet, dass der Behälter an der biegsamen Wand ein abnehmbares Band (113) trägt, das unter Freilegung einer sauberen Fläche zum Durchstechen mittels des Einstechorgans (34) entfernbar ist.

5. Behälter nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Fläche des Einsatzes angrenzend an das eine Ende der Bohrung relativ zur Fläche des Einsatzes angrenzend an das andere Ende der Bohrung in Querrichtung vergrössert ist.

6. Behälter nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der durchstechbare Abschnitt aus einem Werkstoff besteht, der die Verformung der Wand beim Eintritt des Einstechorgans in die Bohrung erlaubt, so dass ein Ringabschnitt (42) der Behälterwand sich in die Bohrung hinein verformt unter Abdichtung des Einstechorgans in der Bohrung.

Revendications

1. Récipient (105) ayant des parois flexibles opposées (12, 14) soudées l'une à l'autre le long de leurs bords (106) et comportant une partie perforable (109), un insert (98) placé à l'intérieur du récipient et comportant un passage traversant (100) pour recevoir de façon étanche un organe de perforation (34) après pénétration de ce dernier à travers la partie perforable, de manière à engendrer une communication d'écoulement entre l'intérieur du récipient et l'organe de perforation, l'insert (100) étant tenu en position de sorte qu'une extrémité du passage est adjacente à la partie perforable, ledit récipient étant caractérisé en ce que ladite partie perforable (109) s'étend latéralement par rapport auxdites parois flexibles (12, 14), à une extrémité du récipient, et le passage (100) de l'insert est décalé par rapport au plan contenant lesdits bords (106) et s'étend sensiblement parallèlement à ce plan.

2. Récipient suivant la revendication 1, dans lequel les parois flexibles opposées (12, 14) sont soudées le long de leurs bords (106) par soudage thermique.

3. Récipient suivant la revendication 2, dans lequel une protubérance à paroi flexible (111) est formée autour de l'insert pour tenir ce dernier en position, ladite paroi perforable (109) étant définie par une partie de la protubérance.

4. Récipient suivant la revendication 1, 2 ou 3, comportant un ruban séparable (113) sur la paroi flexible, de sorte qu'on peut enlever le ruban pour découvrir une surface propre, pour perforation par ledit organe de perforation (34).

5. Récipient suivant l'une quelconque des revendications précédentes, dans lequel la surface dudit insert adjacente à ladite extrémité du passage de l'insert est agrandie transversalement par rapport à la surface de l'insert adjacente à l'autre extrémité dudit passage.

6. Récipient suivant l'une quelconque des revendications précédentes, dans lequel la partie perforable est en une matière qui permet la déformation de la paroi lorsque l'organe de perforation pénètre dans le passage de l'insert, pour entraîner la déformation d'une partie annulaire (42) de la paroi du récipient dans le passge de l'insert de manière à engendrer une étanchéité de l'organe de perforation dans le passage.

FIG. 1

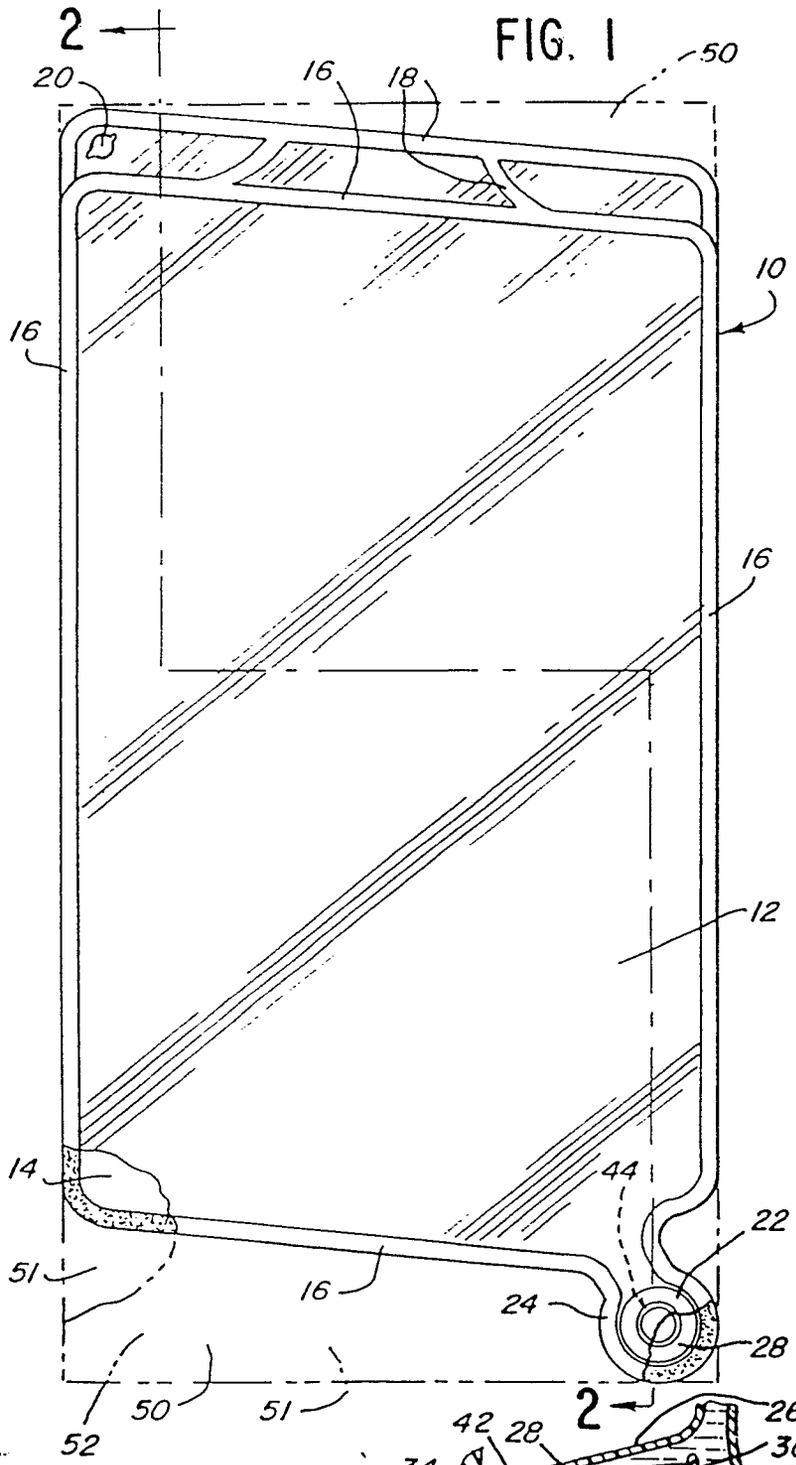


FIG. 2

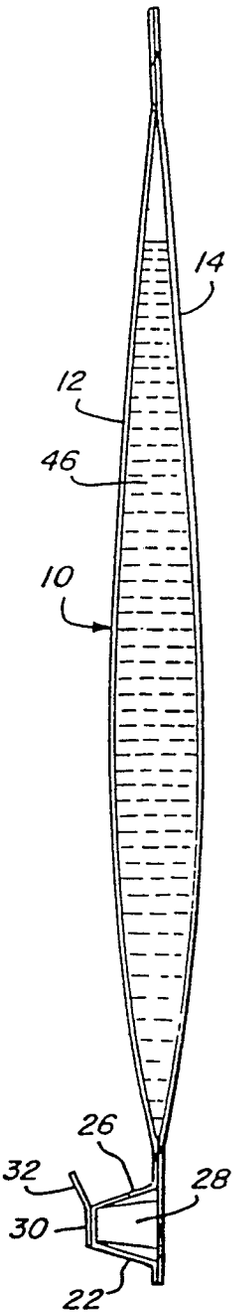
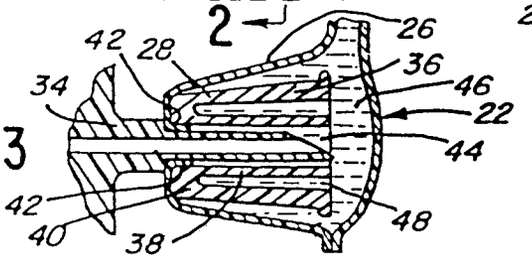


FIG. 3



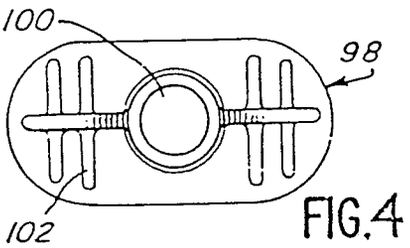


FIG.4

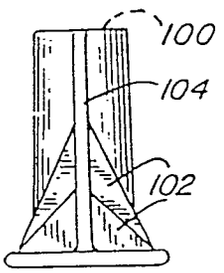


FIG.5

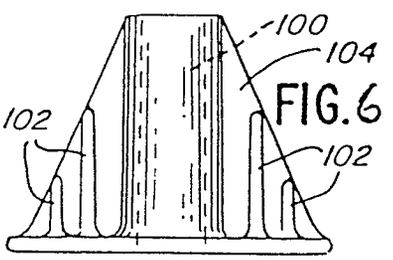


FIG.6

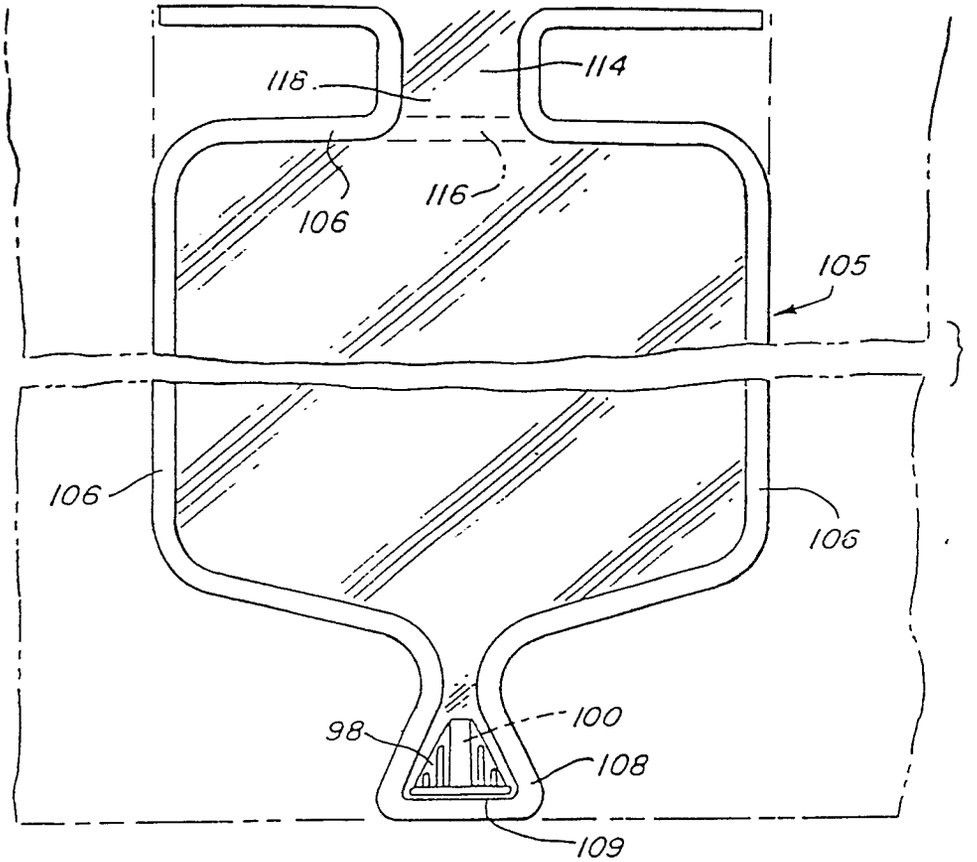

118
114
106
116
105
106
106
98
100
108
109

FIG. 7

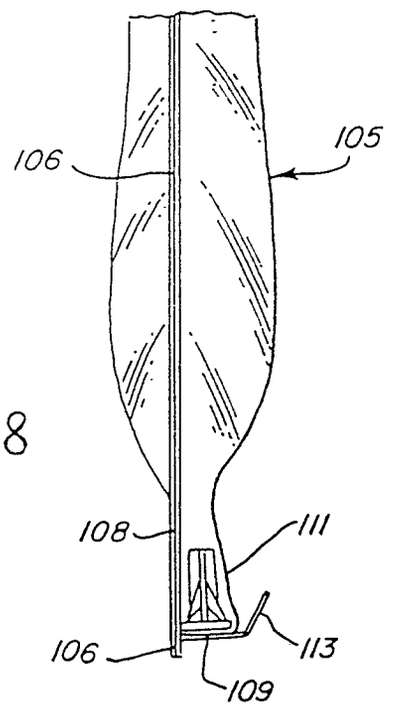

106
105
108
111
106
113
109

FIG. 8