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

(11) EP 0 960 616 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
01.12.1999 Bulletin 1999/48

(51) Int. Cl.[6]: **A61J 1/20**

(21) Application number: **99103563.5**

(22) Date of filing: **24.02.1999**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **16.05.1998 US 80091**

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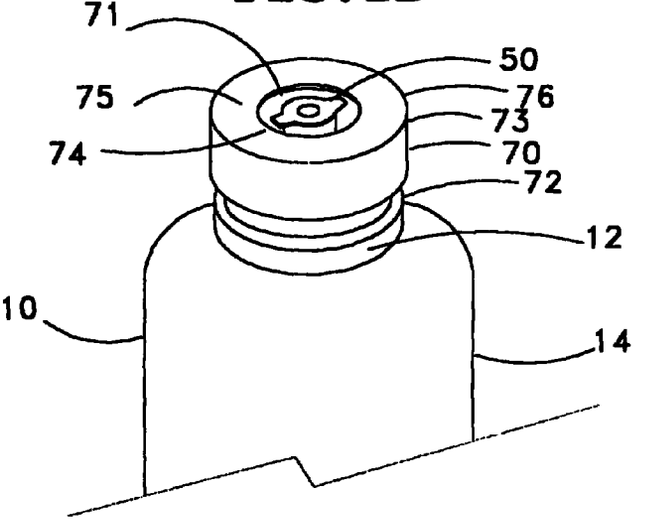
(54) Multiple use universal stopper

(57) A multiple use universal closure assembly designed for use in various containers (10) having receiving means for assessing to the content of the container (10). The multiple use universal closure assembly comprising an elastomeric membrane capable of being ruptured by an external access means such as a luer connector or a syringe having a sharp or blunt cannula or a sharp or blunt spike for fluid communication between the content of the container (10) and the access means. The elastomeric membrane reseals itself after being ruptured by an external access means.

FIG. 1B



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Description

Field of the Invention

[0001] This invention relates to an elastomeric stopper having a self-sealing means so that a pharmaceutical fluid contained in a container closed by the elastomeric stopper can be repeatedly accessed by the use of a luer connector or a syringe having a blunt or sharp needle cannula.

Background of the invention

[0002] The prior art has developed numerous devices to prevent accidental needle strike injuries to practitioners and patients. Such injuries are known to spread infectious diseases including hepatitis and AIDS. One of the main features of these devices is the lack of exposed sharp needles. The closures or stoppers have built in access means to the content of the containers, such as vials, cartridges and bottles. The closures or stoppers in these devices serve the dual function of hermetically sealing the container while allowing access to the content therethrough.

[0003] Stopper systems for containers such as vials and bottles are made of materials that are resistant to chemicals and pharmaceuticals such as corrosive materials, reagents, parenteral solutions and solid formulations reconstitutable with a solvent prior to use.

[0004] The most commonly used stopper/container system for such products has been glass or plastic bottles and vials equipped with stoppers made of elastomeric materials. The system provides for good hermetical seal, safe storage and easy access to the content through the elastomeric stopper via the use of an infusion spike or a syringe when withdrawal of the content is desired. The elastomeric stopper used generally comprises an elastomeric base, such as natural or synthetic rubber and an inert coating covering at least some portions of the stopper. The coating used includes chlorobutyl rubber, polymeric fluorocarbon resins such as polytetrafluoroethylene and various thermoplastic films. The coating is intended to insulate the elastomeric stopper base from the contents of the container in order to prevent contact and possible chemical reactions therebetween.

[0005] Generally, the elastomeric stopper is of cylindrical shape and has a flange head portion overlying the open top end of the container. Integral with the head portion is a body portion which extends into the open end and seated in the neck portion of the container, the diameter of the body portion being somewhat larger than the inside diameter of the container so that a tight seal is created between the body portion and the wall of the container. The lower end of the body portion is beveled towards the central, longitudinal axis of the body portion to facilitate the insertion of the body portion into the container. The circular bottom surface that faces the contents of the container is substantially planar and is imperforate, having no recess therein. The head portion of the stopper is provided with a central recess extending downwardly from the top thereof a substantial distance into the body portion so that the central recess and the circular bottom surface define a diaphragm. The walls forming the recess are generally cylindrical but may be provided with one or more circular protuberances extending inwardly to terminate just short of the center line of the stopper. The circular protuberances serve to press against and hold the needle of a syringe when the needle is inserted through the recess to penetrate the diaphragm for removal of the contents of the container. The elastomeric stopper is held in position by a metal ring or cap usually constructed of aluminum. The metal ring or cap has a removable centre opening for allowing insertion of the syringe needle into the container.

[0006] Various stopper and access systems exist in the prior art to hold and remove the contents of containers which are illustrated hereunder.

[0007] An example of a stopper according to the state of the art is reported in Figures 6 and 6A of the present application.

[0008] U.S. Patent No. 5,429,256 pertains to a drug withdrawal system for a vial. The withdrawal system comprises: a vial containing a medicament therein and closed with a rubber gasket; and an apparatus which snap fits on top of the vial. The apparatus comprises: a chassis and a cap which is attached to the cap by a living hinge. The chassis is cylindrical and has vertical grooves on the external sides to facilitate handling. The top of the chassis has a central opening. The chassis includes a removable male luer lock adapter, having external threads thereon, including a ferrule structure the lower end of which has a hollow sharpened lance. The apparatus is used with a syringe having a female luer lock connector which snap fits with the removable male luer lock adapter including the ferrule. In use, the cap cover is opened, and a syringe is screwed onto the outer end of the adapter, then tightened on the adapter which moves the lance downward thereby establishing flow communication with the content of the vial.

[0009] U.S. Patent No. 5,433,330 relates to a needleless access stopper used on containers with a cannula having a blunt, stopper penetrating tip. The stopper includes a disc and a plug extending from the disc into the container. Also included is a diaphragm defined by a target region in the upper face. Also included is a centrally located piercing point positioned to pre-slit the diaphragm. This stopper is not suitable for syringe, cartridge or IV tubing having a female luer connector. Moreover, after use, the pre-slit disc does not assure a complete seal of the contents of the container from

the environment and it is not useful for multiple use.

[0010] There is the need in this field of technique to provide a multiple use stopper system allowing repeatedly access to a medical fluid contained in a container and at the same time providing access means allowing the access to the container with various conventional external access means, such as cartridge or iv tubing equipped with a female luer connector or a syringe having sharp or blunt needle cannula or sharp and blunt spikes.

Summary of the invention

[0011] The present invention provides a multiple use universal closure assembly allowing repeatedly access to a medical fluid contained in a container with various external access means available to healthcare professionals and emergency practitioners and sometimes to patients requiring self-injections, such as cartridge or iv tubing equipped with a female luer connector or a syringe having sharp or blunt needle cannula or sharp and blunt spikes.

[0012] According to one aspect, the present invention provides a multiple use universal closure assembly allowing access to a medical fluid contained in a container comprising accessing (receiving) and sealing means designed for multiple use so that the medical fluid can be repeatedly accessed. After each withdrawal of the desired amount of the medical fluid, the sealing means self-seals itself thereby preventing contamination of the medical fluid by air-born particles, such as dust and bacteria.

[0013] More in particularly, the multiple use universal closure assembly according to the invention comprises:

an elastomeric stopper comprising sealing means; and
receiving means for external accessing means.

[0014] The elastomeric stopper according to the invention having a head portion and a skirt portion is made of an elastomeric base, such as a natural or synthetic rubber preferably having an inert, polymeric coating thereon covering at least the medical fluid contacting portions of the stopper. The coating may be of chlorobutyl rubber, polymeric fluorocarbon resins and thermoplastic films.

[0015] The elastomeric stopper is of cylindrical shape and has a flange head portion overlying the open top end of the container. Integral with the head portion is a skirt portion which extends into the open end and seated in the neck portion of the container, the diameter of the neck portion of the container being somewhat larger than the inside diameter of the skirt portion so that a tight seal is created between the skirt portion and the wall of the container.

[0016] In the centre portion of the elastomeric stopper there is a cylindrical opening extending through the head and the skirt portions of the stopper. The cylindrical opening through the stopper body would expose the content of the container to the environment allowing contamination therefrom. In accordance with the present invention, the cylindrical opening is closed by a sealing means, namely a rupturable sealing membrane. The rupturable sealing membrane may be made separately from the elastomeric stopper, positioned in the opening, and sealed into the elastomeric stopper using thermoplastic or other sealing means known in the art. Preferably, the elastomeric stopper and the sealing membrane are integral with each other and produced by blow molding or other suitable manufacturing techniques. The sealing membrane is preferably a protuberance residing in the top half of head portion of the elastomeric stopper and is resembling an M-shaped configuration comprising: vertical leg portions or cylindrical side wall; a top surface resembling a cup or U-shaped portion extending downwards and toward the bottom portion of the elastomeric stopper, forming an M-shaped configuration when taken together with the cylindrical side walls. The rupturable sealing membrane is of thin, elastomeric material preferably having a slit in its centre portion which slit does not completely traverse the centre portion of the rupturable sealing membrane.

[0017] The M-shaped sealing membrane in the elastomeric stopper would collapse, or at least deform when penetrated by a luer connector, sharp or blunt syringe cannula.

[0018] For preventing such occurrence a rigid, cylindrical housing or male element, open at both ends are provided to support the M-shaped sealing membrane and also serving as a receiving (accessing) means for an external access means. Such external access means is preferably female access means, such as a female luer connector.

[0019] Such external access means are threaded into the male connecting means thereby rupturing the sealing membrane to establish fluid communication with the content of the container.

[0020] The multiple use universal closure assembly further comprises (3) a cylindrical collar; and further (4) a removable cap.

[0021] The cylindrical collar, preferably made of metal such as aluminum, is fastened over the elastomeric stopper and the neck portion of the container to securely hold the elastomeric stopper in the open end of the container. The cylindrical collar comprises a central opening in its flat top portion to allow access to the cylindrical opening in the stopper and to the sealing membrane and receiving means (male element) located in the cylindrical opening.

[0022] The removable cap covers the flat top and rim portions of the cylindrical collar and comprises retaining ears which engage the cylindrical collar to maintain the closure assembly in aseptic condition.

[0023] According to another aspect, the present invention provides a multiple use universal closure assembly/container combination comprising:

a container;
a multiple use universal closure assembly according to the invention.

[0024] According to another further aspect, the present invention provides a method for repeatedly accessing a medical fluid contained in a container equipped with the multiple use universal closure assembly of the present invention comprising the steps of:

i) providing the multiple use universal closure assembly/container combination of the present invention;
ii) removing the removable cap from the flat top and rim portions of the cylindrical collar thereby exposing the sealing means and the receiving means in the cylindrical opening of the elastomeric stopper; and
iii) accessing the medical fluid contained in the container by an external access means.

[0025] The present invention provides sealing and accessing means for containers such as bottles or vials made of glass or plastic containing medical fluids, such as x-ray contrast media and parenteral liquids. The access means of the closure assembly of the present invention provides for hermetic sealing, safe handling, sterilization and storing. The sealing means are designed for multiple use so that the medical fluid can be accessed repeatedly. After each withdrawal of the desired amount of the medical fluid, the sealing means self-seals itself thereby preventing contamination of the medical fluid by air-born particles, such as dust and bacteria. For convenience the invention will be described in combination with glass medicinal bottles. It is to be understood, however, that the invention includes sealing and receiving (accessing) means for containers in general which comprise rigid or semi rigid access ports and are capable of receiving such sealing and access means.

[0026] The container is preferably made of glass, however, it can also be made of polymeric materials known in the art. The container has a neck portion terminating in an open end to receive the closure assembly which is inserted in the open end to seal the content therein and maintain it in sterile and aseptic condition

[0027] While the present invention provides access to medical fluids using various external access means, it is preferred that the access means comprise no "sharps", such as in sharp needle cannulas, in order to prevent accidental injuries and transmittance of contagious diseases, such as AIDS.

[0028] The external access means is preferably a syringe, cartridge or IV tubing having a female luer connector. However, other access means, such as a syringe having a sharp or blunt needle cannula or a spike may also be used to rupture the sealing membrane of the closure assembly.

Brief description of the drawings

[0029] With reference to the annexed drawings, illustrating the invention:

FIG. 1A is a perspective view of a container, a stopper with the multiple use receiving (access) means, and a cap covering the access means;
FIG. 1B is a perspective view of the container and the stopper with the multiple use receiving means shown in FIG. 1A without the cap;
FIG. 2 is a top plan view of the container and the cap shown in FIG. 1A;
FIG. 3 is a top plan view of the container, the stopper with the multiple use receiving means without the cap thereon shown in FIG. 1B;
FIG. 4 is a cross-sectional view of the container, the stopper with the multiple use access means and the cap covering the receiving means taken along the line 4-4 of FIG. 1A;
FIG. 4A is a greatly enlarged cross-sectional view of the top of the container, the stopper with the multiple use receiving means and cap shown in FIG. 4;
FIG. 4B is a greatly enlarged fragmentary cross-sectional view of the top of the M-shaped multiple use diaphragm shown in FIG. 4A;
FIG. 4C is a top plan view of the M-shaped multiple use diaphragm shown in FIG. 4A;
FIG. 5A is a bottom plan view of the cap removed from the container shown in FIG. 1A;
FIG. 5B is a sectional view of the of the cap removed from the container shown in FIG.5A;
FIG. 6 is a top plan view of a prior art stopper designed to be pierced by a spike;
FIG. 6A is a cross-section of the prior art stopper of FIG. 6;
FIG. 6B is a cross-section of the stopper of the present invention having a cylindrical protuberance in the centre thereof which constitutes the seal or diaphragm in the stopper penetrable by various external access means;

FIG. 7 is a top plan view of the multiple use receiving (access) means housing;

FIG. 7A is a cross-section of the multiple use receiving means housing;

FIG. 8 is a cross-section of the stopper, the receiving means housing in the stopper and elastomeric seal or diaphragm supported by the housing;

FIG. 9 is the cross-sectional view of a stopper used in lyophilization having the M-shaped multiple use diaphragm therein;

FIG. 10 is a top plan view of the stopper used in lyophilization having the U-shaped multiple use diaphragm therein shown in cross-sectional view in FIG. 9;

FIG. 11 shows a cross-section of a female luer connector with screw threads;

FIG. 12 is a cross-section of a female luer connector which is to engage receiving means housing shown in FIGS. 7,7A and 8, wherein the female luer connector and receiving means housing are shown prior to their engagement;

Fig. 12A is a cross-section of the female luer connector partially engaging receiving means housing and rupturing the elastomeric seal shown in Fig. 12;

FIG. 12B is a cross-sectional view of the female luer connector completely engaging receiving means housing; and

FIG. 13 is a cross-sectional view of the female luer connector disengaging receiving means housing.

Detailed description of the invention

[0030] Referring to FIGS. 1A, 1B, 2, 3, 4, and 4A, the container 10 having an open end in which the multiple use universal stopper is used comprises a neck portion 12, a side portion 14, and a bottom portion 16. In the open end of neck portion 12 is located the multiple use universal stopper held securely in place by cylindrical collar 70 having an open area 71 in its top centre portion, said open area being defined by the circular rim denoted by the numeral 74. Cylindrical collar further comprises a flat top surface 75 defined by circular rims 74 and 76 and top rim portion 73. Cylindrical collar 70 is crimped at its bottom rim 72 to neck portion 12 of the container. Flat top surface 75 is covered by a cylindrical, removable cap 18 which comprises a flat top portion 20, and a side rim portion 22 which overlaps top rim portion 73 of cylindrical collar 70. FIG. 1B shows locking ears 50 constituting a part of the universal stopper which is described later in reference to other Figures as the description of the invention proceeds.

[0031] Referring to FIGS. 1A, 1B, 5A and 5B, removable cap 18 covers flat top surface 75 and top rim portion 73 of cylindrical collar to maintain open area in top centre portion 71 of cylindrical collar and locking ears 50 in aseption condition during storage.

[0032] Removable cap 18 comprises: side rim portion 22, flexible retaining ears 24, and retainer button 26. When in place, retaining ears 24 are slid under circular rim 74 in cylindrical collar 70 providing a tight seal between removable cap 18 and flat top surface 75 of cylindrical collar. Retainer button 26 together with retaining ears 24 also serve to limit expansion of the thin elastomeric membrane or seal during sterilisation.

[0033] Referring to FIGS. 1A, 1B, 4, 4A, 6, 6A, 6B and 8, the open end of the container 10 is to receive an elastomeric stopper 60 having a top surface 63 and a bottom surface 65 and comprises: a head 62 and a skirt 64 integral therewith. The head comprises a flange 66, extending laterally outwardly from skirt 64 and is designed to cover the transverse end surface of the container. The elastomeric stopper shown in FIGS. 6 and 6A is conventionally used by the prior art. In the present invention, as best seen in FIGS. 4A and 8, the elastomeric stopper further comprises: a cylindrical opening 68 in its centre portion defined by cylindrical walls denoted by the numerals 80 and 80'; bottom ring portion denoted by the numerals 82 and 82'; and funnel shaped opening 83 extending downward from the bottom ring portion into the container defined by walls 84 and 84'. Projecting upward towards the top surface 63 of elastomeric stopper 60 is a hollow, vertically-oriented, cylindrical protuberance 85 defined by cylindrical walls 86 and 86' and top surface 120. Top surface 120, along with cylindrical walls 86 and 86', are designed to serve as the elastomeric seal in the elastomeric stopper. The cylindrical protuberance is preferably integral with the stopper body such as produced by blow molding technique or it may be produced separately and sealed into the central opening defined by walls 80 and 80' in the elastomeric stopper 60.

[0034] The vertically-oriented cylindrical protuberance is of thin, membrane-like material designed to be ruptured by an external force exerted on the protuberance by an external access means, such as a luer connector. As best seen in FIGS. 4B and 4C showing in cross-sectional and top plan views, the cylindrical protuberance is an M-shaped diaphragm wherein the numerals 86 and 86' denote the leg portions and the numeral 120 denotes the top surface resembling a cup shape. The lowest point in the top surface 120 is denoted by the numeral 121 which is the centre point in the cup-shaped portion. At the centre point 121 there is provided a slit 122 extending from the top surface or inside surface toward the bottom surface 125 of the cup-shaped portion of the M-shaped diaphragm. The slit, however, does not penetrate the bottom surface 125. The thickness between the slit 122 and the intact bottom surface 125 is typically of form about 0.001 to about 2.0 mm. The unpenetrated portion of the membrane denoting its thickness at the centre portion is denoted by the numeral 127 in FIGS. 4B and 4C. The unpenetrated membrane maintains the content of the container in sealed condition. In use, when this membrane is ruptured by an external access means, such as a needle

cannula, luer connector or spike, fluid communication is established between the content of the container and the external access means. Upon disengaging the external access means for the multiple use universal stopper, the cup-shaped portion of the diaphragm reseals itself for the reason that the membrane is resilient and springs back to its original configuration. As a results the container is re-sealed until the fluid withdrawal process is repeated.

[0035] In reference to FIGS. 7, 7A and 8, in order to support vertically-oriented cylindrical protuberance 85 and to provide a means for receiving a male luer connector, a cylindrical housing or male element (receiving means) generally designated as 100, is provided, located in the upper centre portion 68 of elastomeric stopper 60. Housing 100 comprises: cylindrical wall 102 having a top surface 104 and bottom surface 106.

[0036] Cylindrical wall 102 comprises an inside wall 108, an outside wall 110, locking ears 50, and horizontally-oriented bottom portion 112. Locking ears 50 is designed to securely hold the female element of a luer connector. Horizontally-oriented bottom portion 112 extends into the skirt 64 and sealed thereto at the bottom ring portion 82 and 82' of elastomeric stopper 60.

[0037] The cylindrical protuberance serving as a sealing membrane is of inert gas-impermeable polymeric material capable of flexing under internal or external pressures such as exerted during steam sterilisation. Preferably the membrane has a thickness of from about 0.001 mm to about 2.00 mm and a durometer of from about 25 to about 80 Shore A. Suitable elastomeric materials for constructing the membrane include:

natural rubber;
acrylate-butadiene rubber;
cis-polybutadiene;
chlorobutyl rubber;
chlorinated polyethylene elastomers;
polyalkylene oxide polymers;
ethylene vinyl acetate;
fluorosilicone rubbers;
hexafluoropropylene-vinylidene fluoride-tetrafluoroethylene terpolymers, such as sold under the tradenames of Fluorel and Viton;
butyl rubbers;
polyisobutene, such as sold under the tradename Vistanex;
synthetic polyisoprene rubber;
silicone rubbers;
styrene-butadiene rubbers;
tetrafluoroethylene propylene copolymers; and
thermoplastic-copolyesters.

[0038] The cylindrical M-shaped protuberance is positioned in elastomeric stopper 60 so that its top surface 120 is spaced about 2 to 3 mm form retainer button 26 of removable cap 18 when the cap is placed on container 10. The spacing allows the membrane to flex outwardly under pressure, such as created under heat sterilisation. However, spacing should not be more than about 2 to 3 mm so that under accidentally high pressures, bursting of the membrane is prevented by the retaining button 26 of removable cap 18.

[0039] The multiple use universal closure assembly of the present invention may also have a configuration shown in FIGS. 9 and 10. The stopper of this configuration is used when lyophilization of the content of the container is desired. Prior to use the lyophilized content is reconstituted by injecting into the container through the multiple use universal stopper water, saline or other liquids.

[0040] The universal closure assembly of the present invention is preferably used with an external female luer connector when fluid communication is desired with the content of the container stoppered by the universal stopper. A typical female luer connector 140 is shown in FIG. 11 and comprises: cylindrical outside wall 142 and cylindrical inside wall 143 having an opening in their centre portion for accommodating a tubing within the inside wall. Cylindrical ring 144 located in the top centre portion of cylindrical inside wall 143 tightly holds tubing 160 which has a fluid communicating channel 162.

[0041] Cylindrical inside wall 143 further comprises integral screw threads 146, 148, 150 and 152 which, upon connecting the female luer connector to the male luer connector, engages locking ears 50 on the housing or male element 100, as shown in FIGS. 7 and 7A. Other type of female luer connectors, such as snap-on connectors may also be used.

[0042] FIG. 12 shows, in cross-sectional view, a syringe having a female luer connector, which is to engage the multiple use universal stopper in the container 10, wherein the syringe and universal stopper are shown prior to their engagement. When it is desired to deliver medical fluid from container 10 to a patient, removable cap 18 is removed by an upward manual pressure exerted on its rim portion 22 thereby exposing locking ears 50 of the access means housing.

[0043] If the female luer connector of FIG. 11 is used, it is attached to the multiple use universal closure assembly by twisting motion wherein threads 146, 148, 150 and 152 engage locking ears 50 of access means housing 100. Upon turning the female luer connector 140, end portion of tubing 160 ruptures membrane of the universal stopper to establish fluid communication with the content of the container.

[0044] FIG. 12A shows, in cross-sectional view, the syringe having the female luer connector partially engaging the multiple use universal closure assembly.

[0045] FIG. 12B shows, in cross-sectional view, the syringe having the female luer connector completely engaging the multiple use universal closure assembly.

[0046] FIG. 13 shows, in cross-sectional view, the syringe having the female luer connector removed from the multiple use universal closure assembly after their engagement.

[0047] The multiple use universal closure assembly can be engaged by an external female luer connector having a blunt end which engages and ruptures the cylindrical M-shaped seal in the centre of the multiple use universal closure assembly. However, the multiple use universal stopper also allows access to the content of the container by a sharp or blunt needle cannula or a spike.

Materials of Construction and Use

[0048] The elastomeric stopper used in conjunction with the universal stopper of the present invention is fluid impervious, resilient, and inert without leachable additives therein in order to prevent any alteration of the product contained in the container. It may be of a single component or a blend of components. Examples of materials include synthetic and natural rubbers, such as butyl rubber, isoprene rubber, silicone rubber, halogenated rubber, ethylene propylene therpolymer and the like. Specific examples of a synthetic elastomeric rubber include the CH_2CF_2-C_3F_6(C_3F_5H) and the C_2F_4-$C_2F_3OCF_3$ series of elastomers made by DuPont under the trade names of VITON® and CARLEZ®; the fluoro-silicone rubbers, such as those made by Dow Corning under the trade name of SILASTIC®; and polyisobutylenes, such as VISTANEX MML-100 and MML-140; and halogenated butyl rubber, such as CHLOROBUTYL 1066, made by Exxon Chemical Company.

[0049] These or other suitable elastomers may be made into the desired stopper configuration by known methods. Such methods conventionally include the use of a curing agent, a stabilizer and a filler and comprise a primary and a secondary curing step at elevated temperatures.

[0050] The container used in conjunction with the present invention may be of glass or a polymeric material, i.e., plastic, which are well known in the pharmaceutical industry.

[0051] When the container is made of glass, it is in the shape of a vial or bottle. The vial or bottle is of rigid or semi-flexible polymeric material. In all shapes the container is provided with a neck portion which is rigid and retains its configuration so that it is capable of being hermetically sealed by the elastomeric universal stopper of the present invention. The container may have a volume capacity of from 5 ml to 1000 ml or more, preferably about 10 ml to 500 ml.

[0052] The mouth of the container is to receive the multiple use universal closure assembly. The external diameter of the stopper is slightly larger than the internal diameter of the neck of the container so that on insertion of the multiple use universal stopper into the mouth of the container, a tight, hermetic seal is achieved.

[0053] The cylindrical collar is preferably made of metal, such as aluminum, while the housing is made of hard plastic known by the prior art and used in conjunction with pharmaceutical fluids.

[0054] Prior to use, the container and component parts of the closure are sterilised and the container is filled with a pharmaceutical fluid, such as a parenteral solution. The multiple use universal stopper is inserted, hermetically sealing the content of the container. Cylindrical collar is then crimped onto the container to securely hold the multiple use universal closure assembly in the container. Lastly, the removable cap is snapped onto the cylindrical collar to complete the closing of the container.

PARTS LIST

Container	10
Neck portion of container	12
Side portion of container	14
Bottom portion of container	16
Removable cap	18
Flat top portion of removable cap	20
Side rim portion of removable cap	22
Flexible retaining ears	24
Retainer button	26
Locking ears	50
Elastomeric stopper	60
Head of elastomeric stopper	62
Top surface of elastomeric stopper	63
Skirt of elastomeric stopper	64
Bottom surface of elastomeric stopper	65
Flange of elastomeric stopper	66
Elastomeric seal in prior art stopper	67
Cylindrical opening in elastomeric stopper	68
Cylindrical collar on container	70
Open area in top centre portion of cylindrical collar	71
Top rim portion of cylindrical collar	73
Open area in top centre portion of cylindrical rim	74
Flat top surface of cylindrical collar	75
Funnel-shaped opening in skirt of elastomeric stopper	83
Circular rims defining flat top surface of cylindrical collar	74, 76
Cylindrical walls defining the cylindrical opening in elastomeric stopper	80, 80'
Bottom ring portion in the opening of elastomeric stopper defined by	82, 82'
Funnel-shaped opening in skirt of elastomeric stopper	83

Walls of funnel-shaped opening	84, 84'
Cylindrical protuberance constituting the seal in elastomeric stopper (sealing means)	85
Walls of cylindrical protuberance	86, 86'
Cylindrical housing or male element (receiving means)	100
Cylindrical wall of housing	102
Top surface of housing	104
Bottom surface of housing	106
Inside wall of housing	108
Outside wall of housing	110
Horizontally oriented bottom portion of housing	112
Inside surface membrane of M-shaped diaphragm	120
Centre of inside surface membrane of M-shaped diaphragm	121
Slit in cup-shaped portion of M-shaped diaphragm	122
Bottom surface of cup-shaped portion of M-shaped diaphragm	125
Thickness of unpenetrated membrane at centre portion	127
Female luer connector	140
Cylindrical outside wall of female luer connector	142
Cylindrical inside wall of female luer connector	143
Cylindrical ring of female luer connector	144
Integral screw threads in inside wall of female luer connector	146, 148, 150, 152
Tubing in female luer connector	160
Fluid communicating channel in tubing	162

[0055] The present invention has been described in connection with the preferred embodiment shown in the drawings, however, various changes and modifications will be apparent to those skilled in the art.

Claims

1. A multiple use universal closure assembly, allowing repeatedly access to a medical fluid contained in a container (10), comprising:

an elastomeric stopper (60) comprising sealing means able of self-sealing after each withdrawal of medical fluid; and
receiving means for conventional external accessing means;

2. The universal closure assembly of claim 1, wherein said elastomeric stopper (60) for hermetically sealing a container (10) at its open end comprises:

a head portion (62);
a skirt portion (64);
a cylindrical opening (68) in the centre of said head (62) and skirt (64) portions; and
said sealing means.

3. The universal closure according to claims 1-2, wherein said sealing means is integral with said elastomeric stopper.

4. The universal closure according to claims 1-3, wherein said sealing means is a protuberance (85) residing in the top half of head portion of the elastomeric stopper (60).

5. The multiple use universal closure assembly according to claims 1-4, wherein said sealing means is a rupturable membrane resembling an M-shaped configuration.

6. The universal closure of claim 5, wherein said self-sealing rupturable membrane resembling an M-shaped configuration comprises: vertical leg portions (86, 86'); a top surface (120) resembling a cup or U-shaped portion extending downwards and toward the bottom portion of the elastomeric stopper (60), forming an M-shaped configuration when taken together with the leg portions (86, 86'); said rupturable sealing membrane being made of thin, elastomeric material having a slit (122) in its centre portion which slit (122) does not completely traverse the bottom portion (125) of the rupturable sealing membrane.

7. The universal closure according to claims 5-6, wherein said rupturable membrane is of inert, gas-impermeable polymeric material selected from the group consisting of:

natural rubber;
acrylate-butadiene rubber;
cis-polybutadiene;
chlorobutyl rubber;
chlorinated polyethylene elastomers;
polyalkylene oxide polymers;
ethylene vinyl acetate;
fluorosilicone rubbers;
hexafluoropropylene-vinylidene fluoride-tetrafluoroethylene terpolymers;
butyl rubbers;
polyisobutene;
synthetic polyisoprene rubber;
silicone rubbers;
styrene-butadiene rubbers;
tetrafluoroethylene propylene copolymers; and
thermoplastic-copolyesters

8. The universal closure assembly according to claims 5-7, wherein said rupturable membrane has a thickness of from about 0.001 mm to about 1.00 mm and a durometer of from about 25 to about 80 Shore A.

9. The universal closure assembly according to claims 5-8, wherein said rupturable membrane reseals itself after puncture by an external access means.

10. The universal closure assembly according to claim 1, wherein said receiving means allows connection with any conventional external access means such as cartridge or iv tubing equipped with a female luer connector (140) or a syringe having sharp or blunt needle cannula or sharp and blunt spikes.

11. The universal closure assembly according to claim 10, wherein said receiving means receives an external female access means.

12. The universal closure assembly according to claim 11, wherein said external female access means is a female luer connector (140).

13. The universal closure assembly according to claim 1, wherein said receiving mean is a cylindrical housing (100).

14. The closure assembly according to claim 13, wherein said cylindrical housing (100) is located in the upper centre portion of elastomeric stopper (60) and comprising: cylindrical walls (102) having a top surface (104) and bottom surface (106); said cylindrical wall (102) comprises an inside wall (108), an outside wall (110), locking ears (50), and horizontally-oriented bottom portion (112); said locking ears (50) is designed to securely hold the female luer connector (140).

15. The universal closure assembly according to claims 1-14, further comprising a cylindrical collar (70) fastened over a portion of said elastomeric stopper (70) and neck portion (12) of a container (10) to securely hold the elastomeric stopper (60) in the open end of the container (10), said cylindrical collar (70) having a central opening in its flat top portion to allow access to receiving means and sealing means located in the centre portion of the elastomeric stopper (100).

16. The universal closure assembly according to claims 1-15, further comprising a removable cap (18) covering the flat top (20) and rim (22) portions of said cylindrical collar (70).

17. A multiple use universal closure assembly/container combination comprising:

a container (10); and
a multiple use universal closure assembly according to claims 1-16.

18. A universal closure assembly/container combination comprising:

a container (10) containing a medical fluid therein, having a neck portion (12) terminating in an open end; and

(b) said closure assembly, inserted into the open end of said container (10) comprises:

(1) an elastomeric stopper (60) for hermetically sealing the container (10) at its open end comprising:

a head portion (62);
a skirt portion (64);
a cylindrical opening (68) in the centre of said head (62) and skirt (64) portions;
a hollow, vertically oriented thin elastomeric protuberance (85) serving as a diaphragm for sealing the opening in the centre portion of the elastomeric stopper (60) designed to be ruptured by an external force, said elastomeric protuberance (85) having a generally M-shaped configuration comprising: vertical leg portions (86, 86'); a top surface (120) resembling a cup or U-shaped portion extending downwards and toward the bottom portion of the elastomeric stopper (60), forming an M-shaped configuration when taken together with the leg portions (86, 86'); said rupturable sealing membrane being made of thin, elastomeric material having a slit (122) in its centre portion which slit (122) does not completely traverse the bottom portion (125) of the rupturable sealing membrane;

(2) a rigid, cylindrical housing (100) having open ends enclosing said vertically oriented thin elastomeric protuberance (85) to support said vertically oriented thin elastomeric protuberance (85) and to serve as means for receiving and engaging a female luer connector (140) whereby an external force moves the female luer connector (140) which penetrates the thin elastomeric protuberance (85) to establish fluid communication with the medical fluid contained in said container (10), said rigid cylindrical housing (100) comprising: cylindrical walls having a top portion 104) and a bottom portion (106), said top portion (104) having locking ears (50) designed to hold a female element of a luer connector (140), and said bottom portion (106) sealed into the skirt portion (64) of the elastomeric stopper (60);
(3) a cylindrical collar (70) fastened over a portion of the elastomeric stopper (60) and neck portion (12) of the container (10) to securely hold the elastomeric stopper (60) in the open end of the container (10), said cylindrical collar (70) having a central opening in its flat top portion to allow access to the elastomeric protuberance (85) and the rigid cylindrical housing (100) located in the centre portion of said elastomeric stopper (60); and

said removable cap (18) covering the flat top (75) and rim (73) portions of said cylindrical collar (70) comprising

retaining ears engaging said cylindrical collar (70) to maintain said closure assembly in aseptic condition.

19. The combination according to claim 18, wherein said rupturable membrane is of inert, gas-impermeable polymeric material selected from the group consisting of:

natural rubber;
acrylate-butadiene rubber;
cis-polybutadiene;
chlorobutyl rubber;
chlorinated polyethylene elastomers;
polyalkylene oxide polymers;
ethylene vinyl acetate;
fluorosilicone rubbers;
hexafluoropropylene-vinylidene fluoride-tetrafluoroethylene terpolymers;
butyl rubbers;
polyisobutene;
synthetic polyisoprene rubber;
silicone rubbers;
styrene-butadiene rubbers;
tetrafluoroethylene propylene copolymers; and
thermoplastic-copolyesters

20. The combination according to claims 18-19, wherein said rupturable membrane has a thickness of from about 0.001 mm to about 1.00 mm and a durometer of from about 25 to about 80 Shore A.

21. The combination according to claims 18-20, wherein said rupturable membrane reseals itself after puncture by a external access means.

22. A method for repeatedly accessing a medical fluid contained in a container, accessible with various external access means, equipped with a multiple use universal closure assembly comprising the steps of:

providing a multiple use universal closure assembly/container combination comprising a container and a multiple use universal closure assembly; said closure assembly comprising:

(1) an elastomeric stopper (60) comprising sealing means able of self-sealing after each withdrawal of medical fluid; and
(2) receiving means for external accessing means;

ii) removing the removable cap (18) from the flat top (75) and rim portions (73) of the cylindrical collar (70) thereby exposing the sealing means and the receiving means in the cylindrical opening of the elastomeric stopper (60); and
iii) accessing the medical fluid contained in the container (10) by an external access means.

23. The method according to claim 22, wherein said elastomeric stopper (60) for hermetically sealing a container (10) at its open end comprises:

a head portion (62);
a skirt portion (64);
a cylindrical opening (100) in the centre of said head (62) and skirt (64) portions; and
said sealing means.

24. The method according to claims 22-23, wherein said sealing means is integral with said elastomeric stopper (60).

25. The method according to claims 22-24, wherein said sealing means is a protuberance (85) residing in the top half of head portion of the elastomeric stopper (60).

26. The method according to claims 22-25, wherein said sealing means is a rupturable membrane resembling an M-shaped configuration.

27. The method according to claim 26, wherein said self-sealing rupturable membrane resembling an M-shaped configuration comprising: vertical leg portions (86, 86'); a top surface (120) resembling a cup or U-shaped portion extending downwards and toward the bottom portion of the elastomeric stopper (60), forming an M-shaped configuration when taken together with the leg portions (86, 86'); said rupturable sealing membrane being made of thin, elastomeric material having a slit (122) in its centre portion which slit (122) does not completely traverse the bottom portion (125) of the rupturable sealing membrane.

28. The method according to claims 26-27, wherein said rupturable membrane is of inert, gas-impermeable polymeric material selected from the group consisting of:

natural rubber;
acrylate-butadiene rubber;
cis-polybutadiene;
chlorobutyl rubber;
chlorinated polyethylene elastomers;
polyalkylene oxide polymers;
ethylene vinyl acetate;
fluorosilicone rubbers;
hexafluoropropylene-vinylidene fluoride-tetrafluoroethylene terpolymers;
butyl rubbers;
polyisobutene;
synthetic polyisoprene rubber;
silicone rubbers;
styrene-butadiene rubbers;
tetrafluoroethylene propylene copolymers; and
thermoplastic-copolyesters

29. The method according to claims 26-28, wherein said rupturable membrane has a thickness of from about 0.001 mm to about 1.00 mm and a durometer of from about 25 to about 80 Shore A.

30. The method according to claims 26-29, wherein said rupturable membrane reseals itself after puncture by a external access means.

31. The method according to claim 22, wherein said receiving means allows connection with any conventional external access means such as cartridge or iv tubing equipped with a female luer connector or a syringe having sharp or blunt needle cannula or sharp and blunt spikes.

32. The method according to claim 31, wherein said receiving means receives an external female access means.

33. The method according to claim 32, wherein said external female access means is a female luer connector.

34. The method according to claim 22, wherein said medical fluid is a therapeutic liquid.

35. The method according to claim 22, wherein said medical fluid is a diagnostic liquid.

36. The method according to claim 22, wherein said medical fluid is a nutritional liquid.

37. The method according to claims 22-35, wherein the lyophilized content is reconstituted by injecting into the container through, said multiple use universal closure assembly, water, saline or other liquids.

FIG.1B

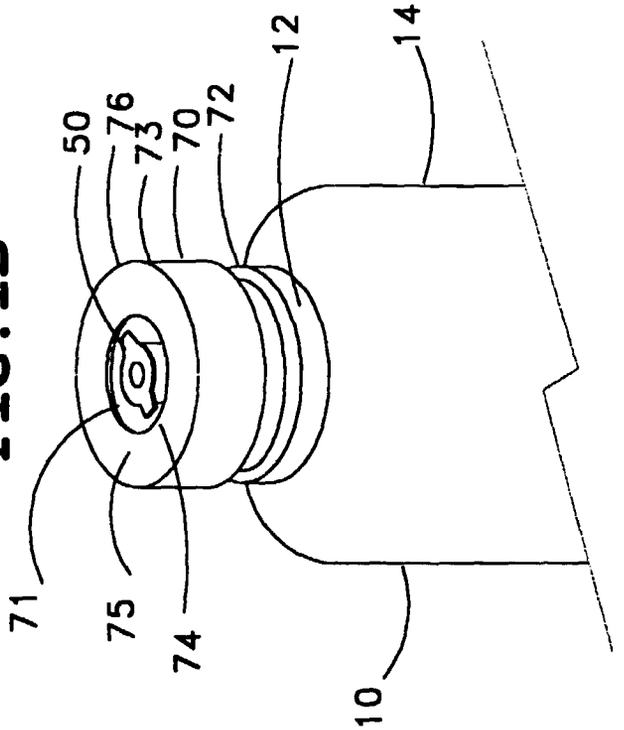
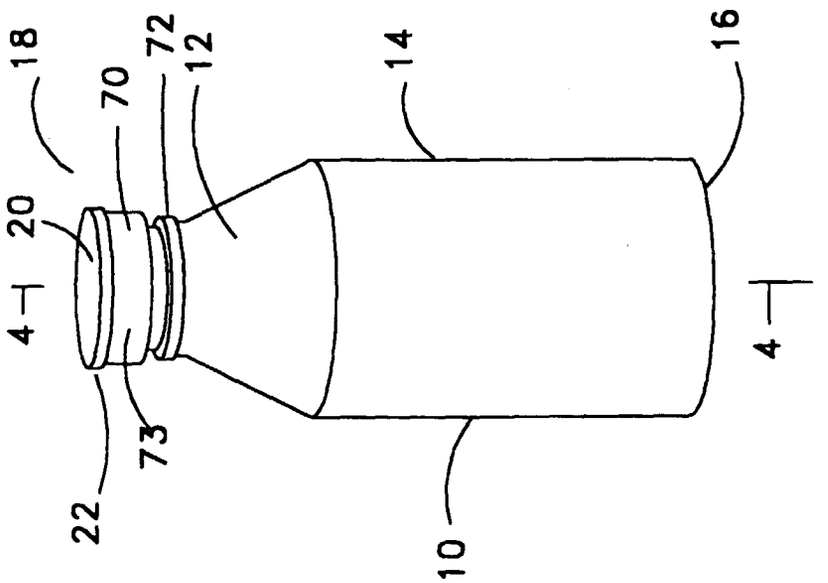


FIG.1A



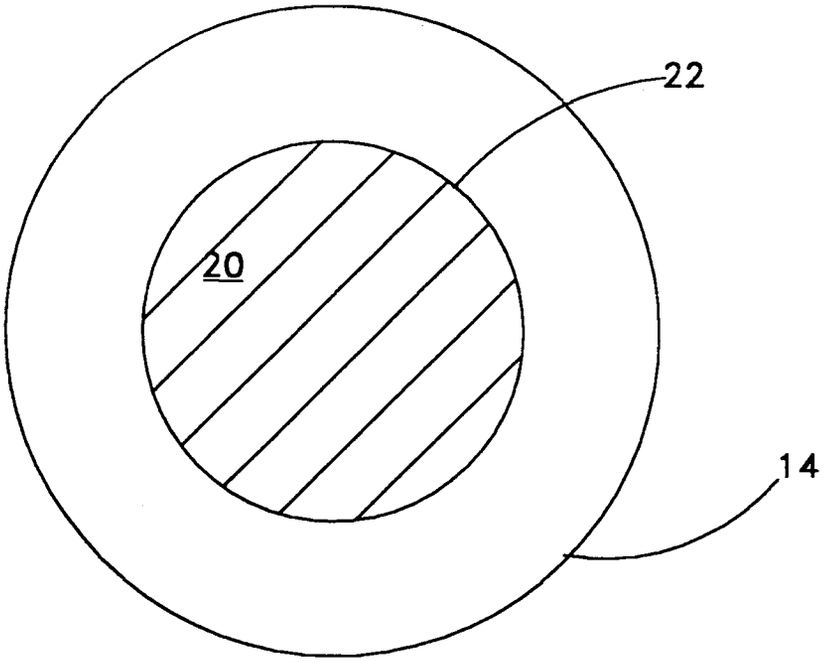


FIG. 2

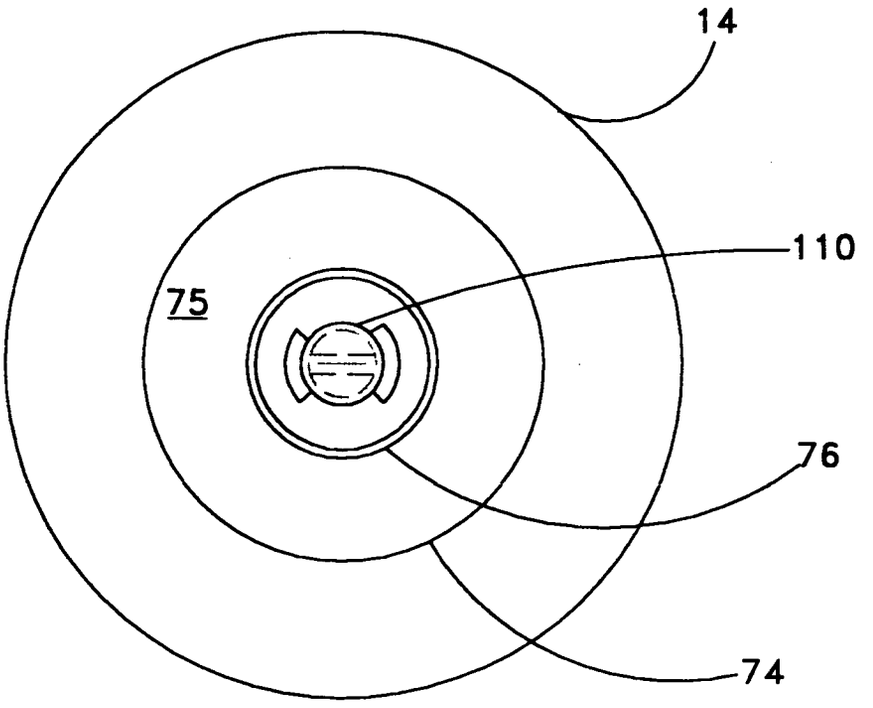


FIG. 3

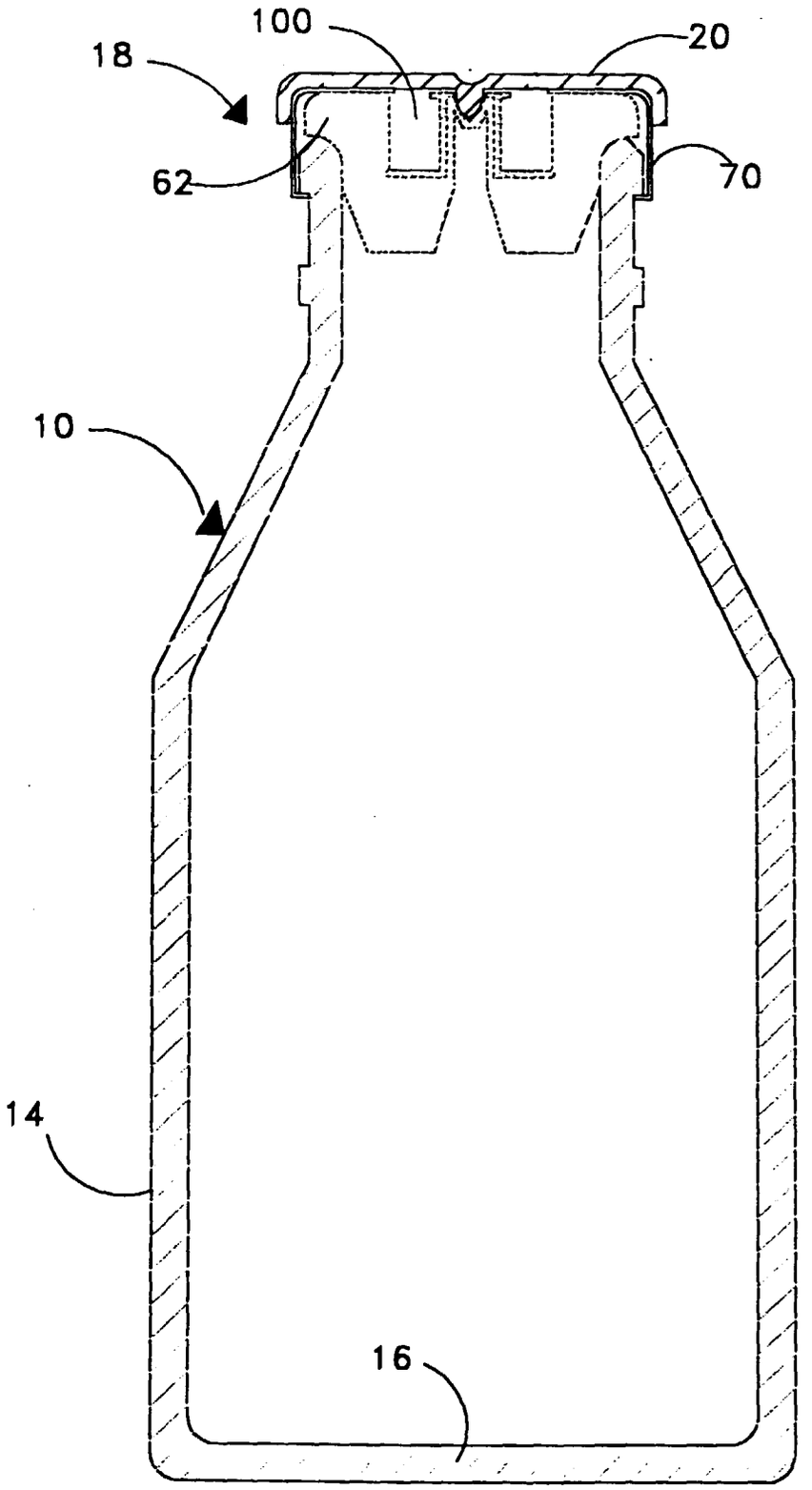


FIG. 4

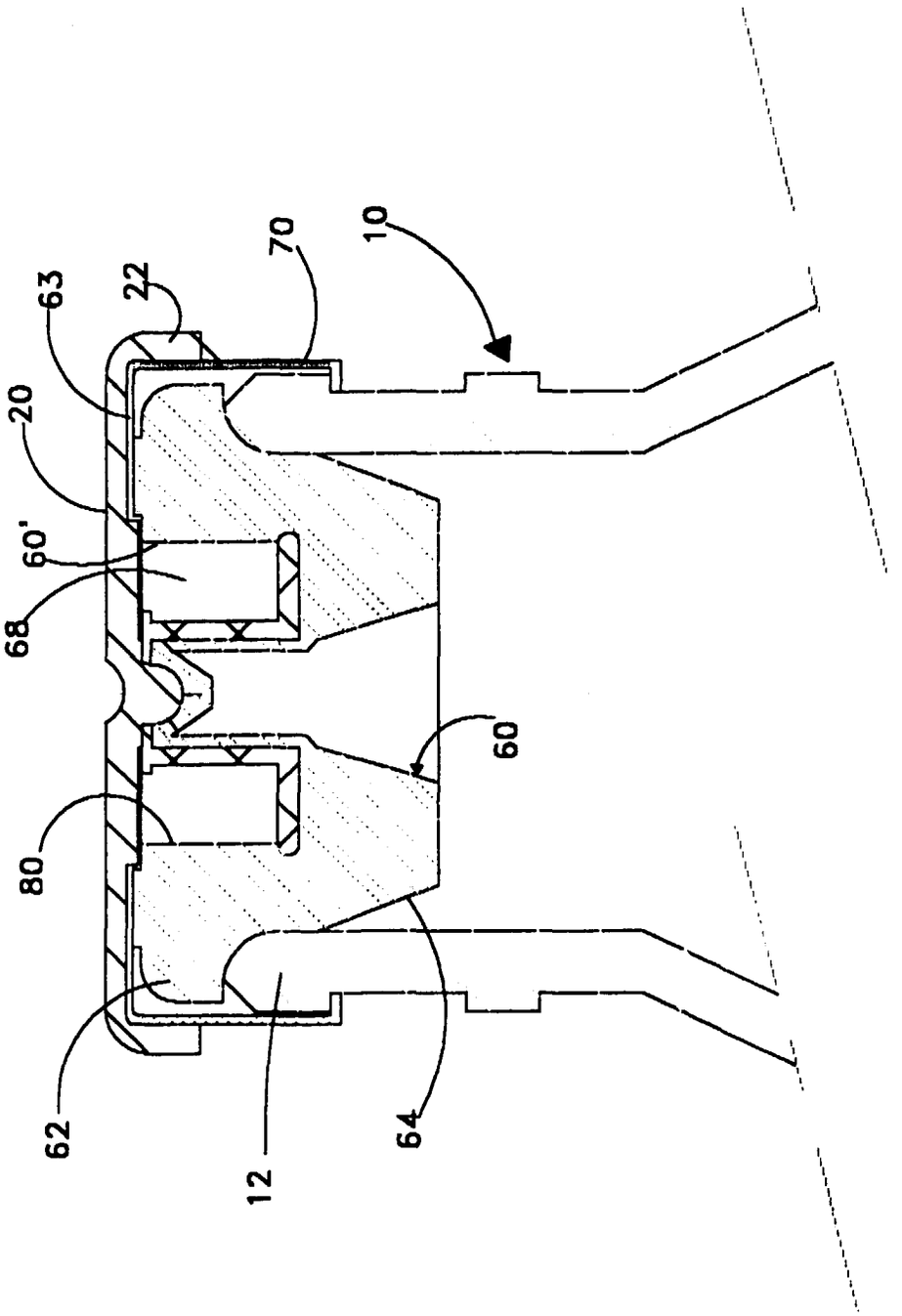


FIG. 4A

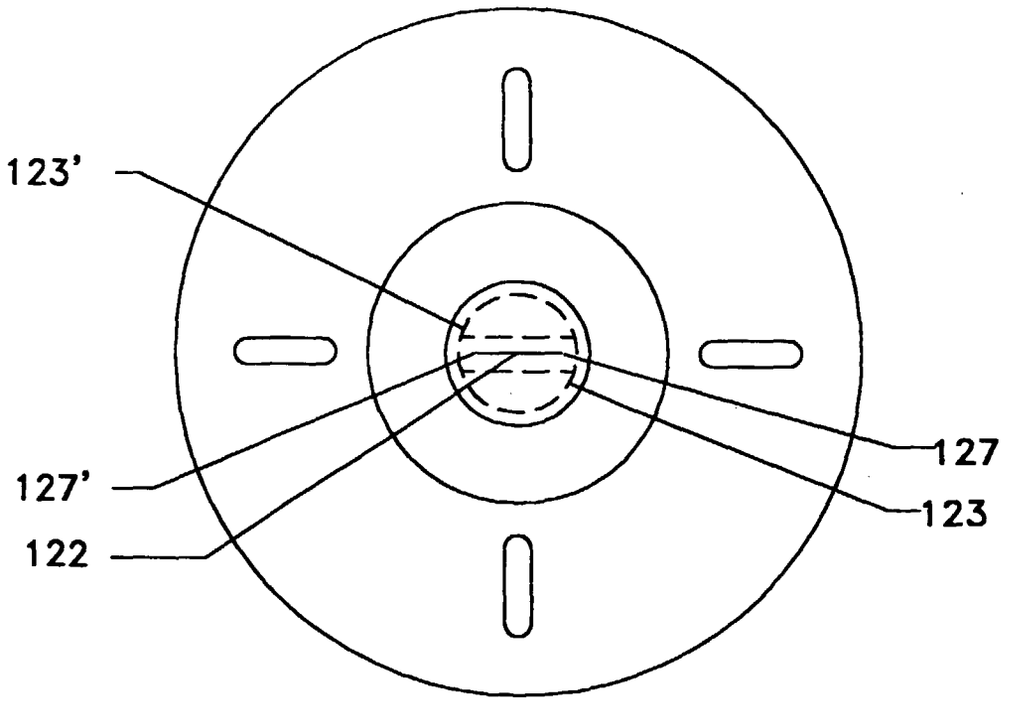


FIG. 4C

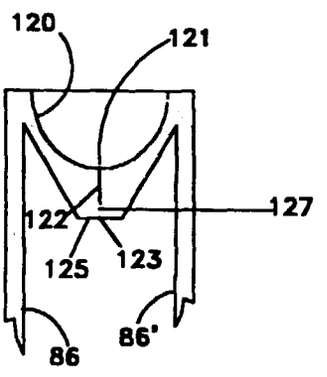


FIG. 4B

FIG. 5A

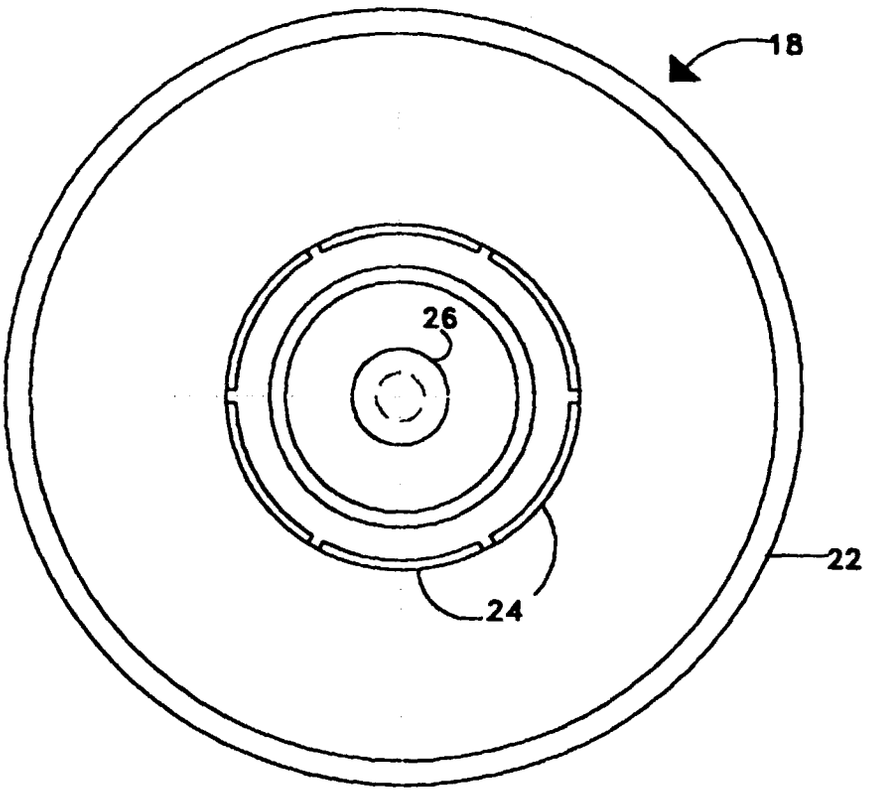


FIG. 5B

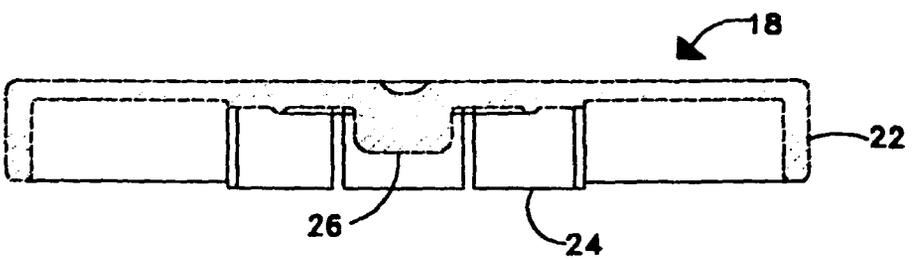


FIG. 6

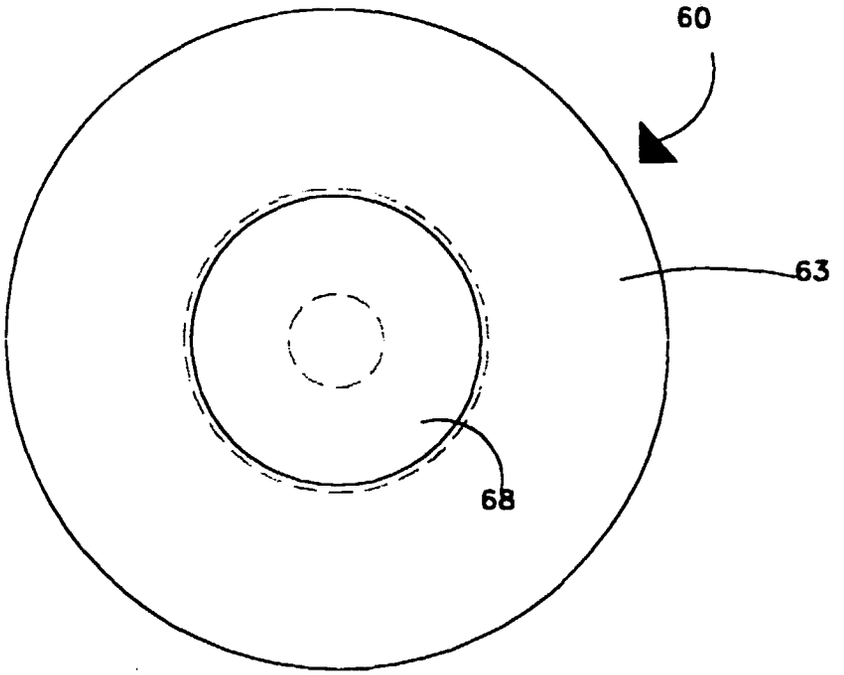
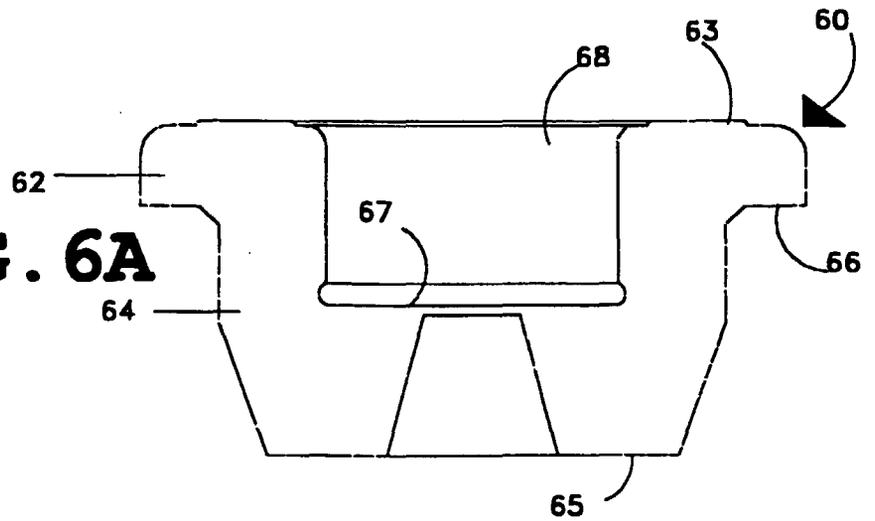


FIG. 6A



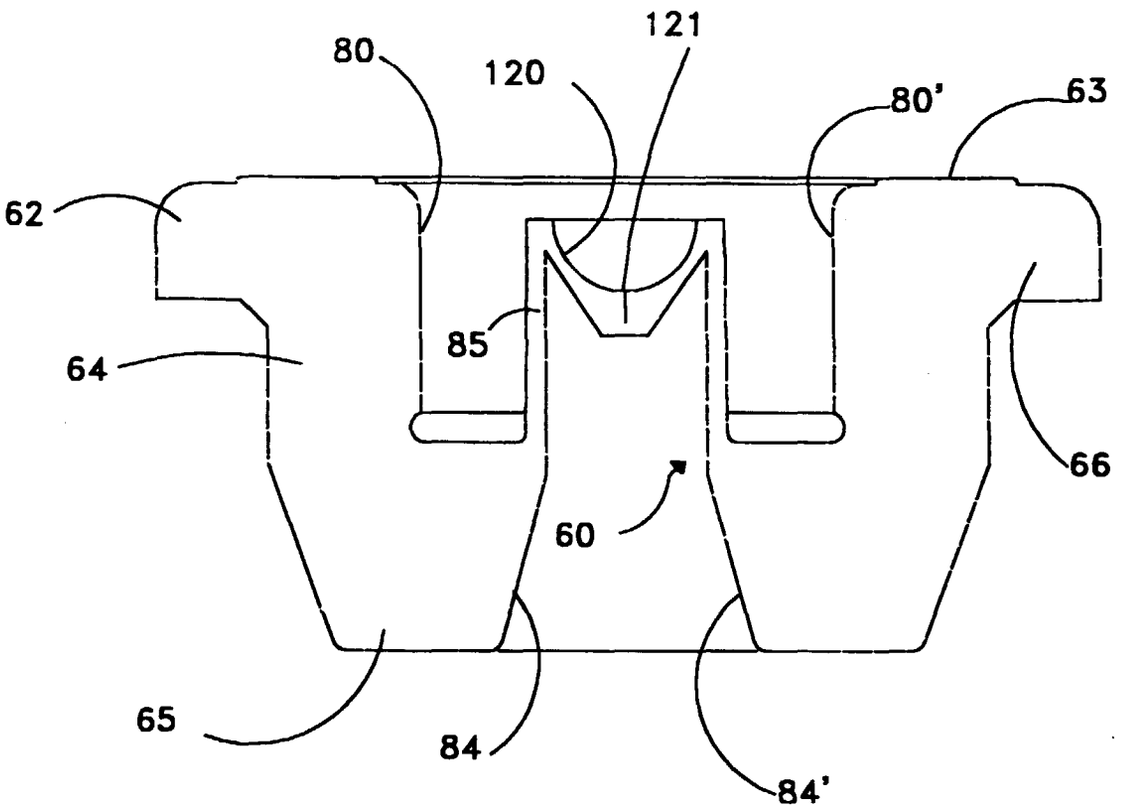


FIG. 6B

FIG. 7A

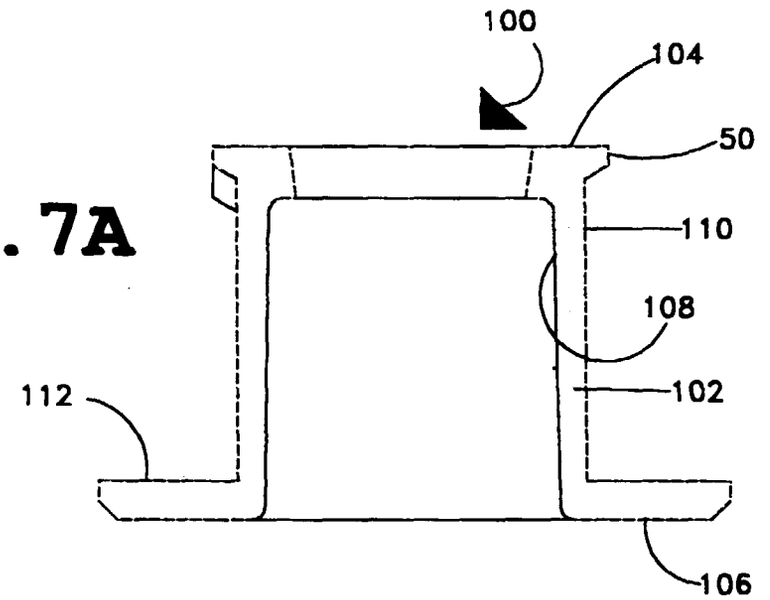
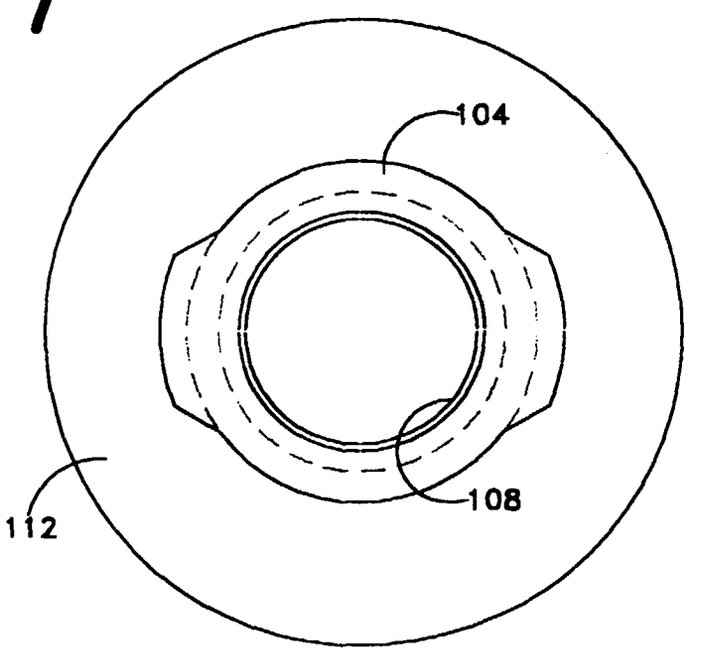


FIG. 7



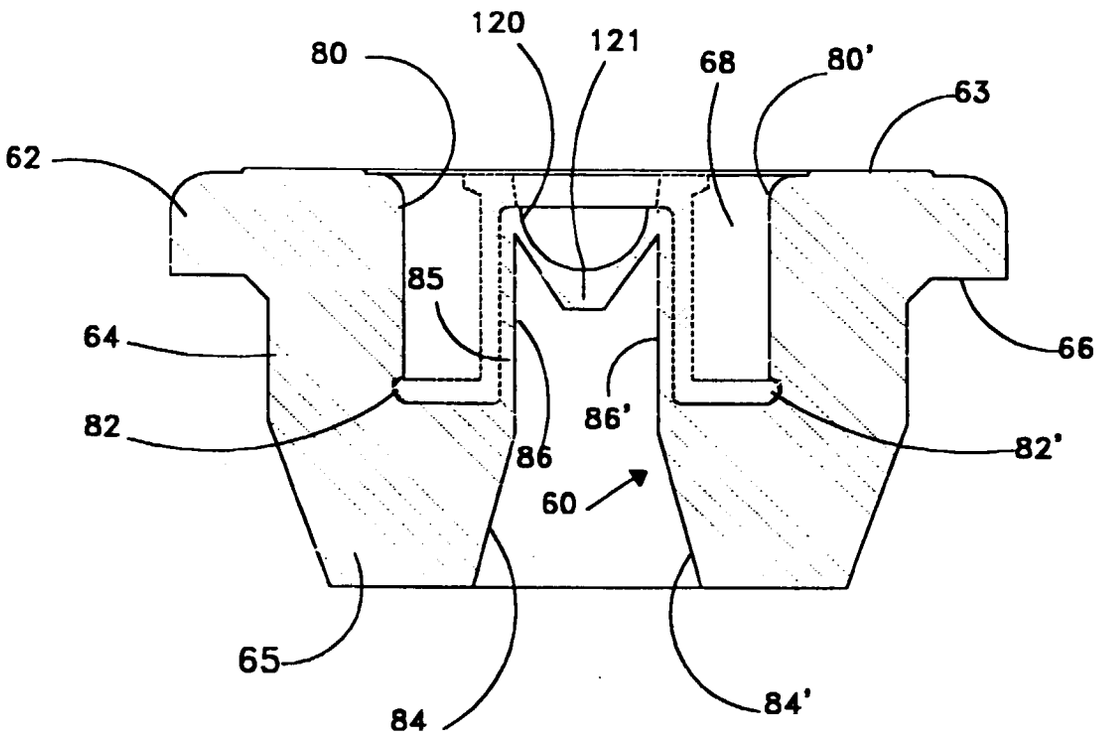


FIG. 8

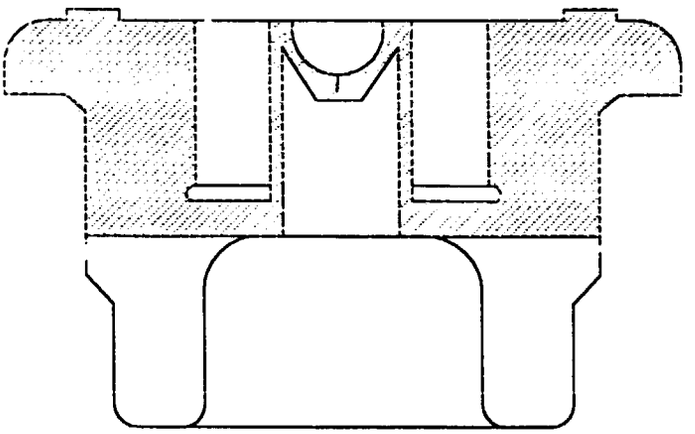


FIG. 9

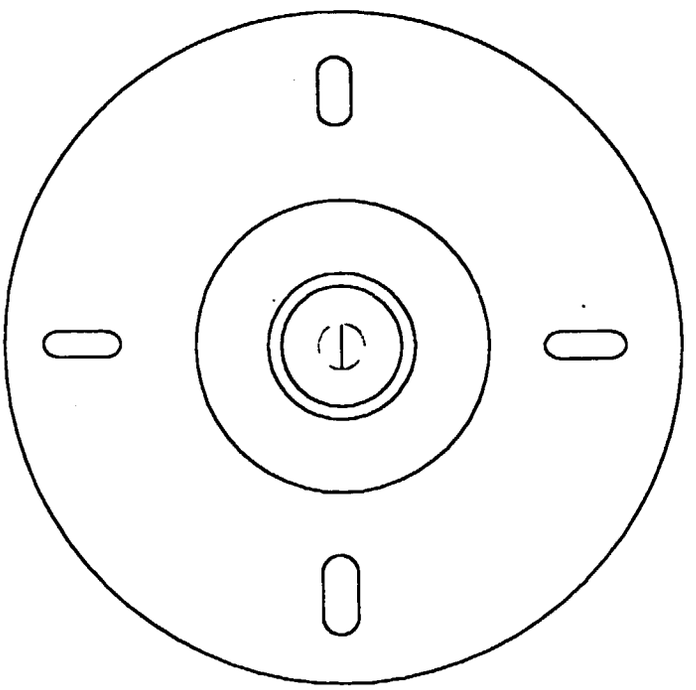
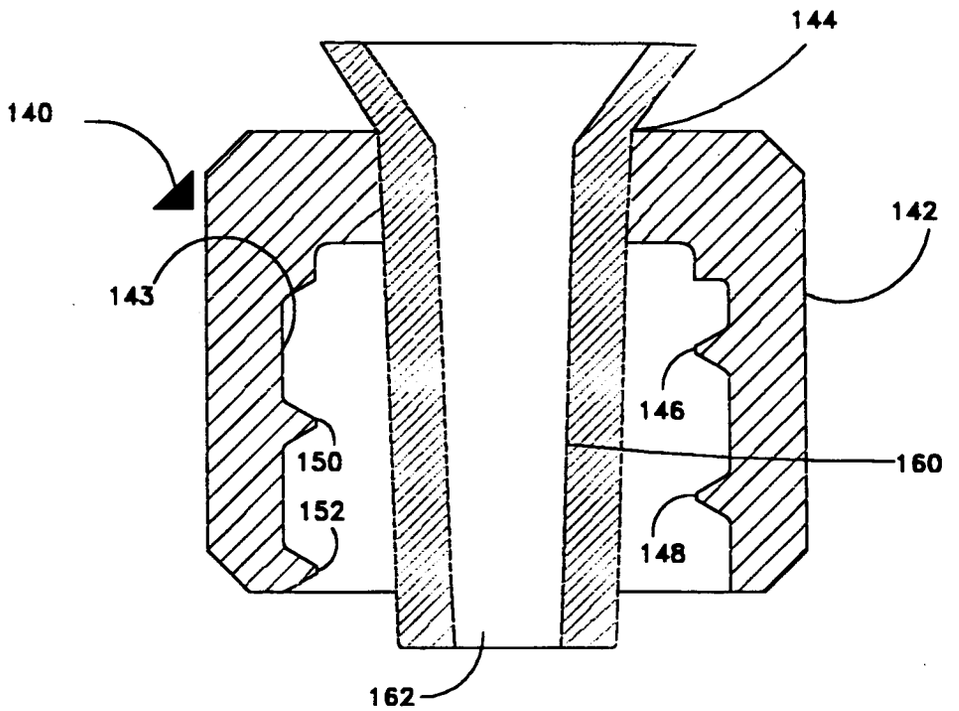


FIG. 10

FIG.11



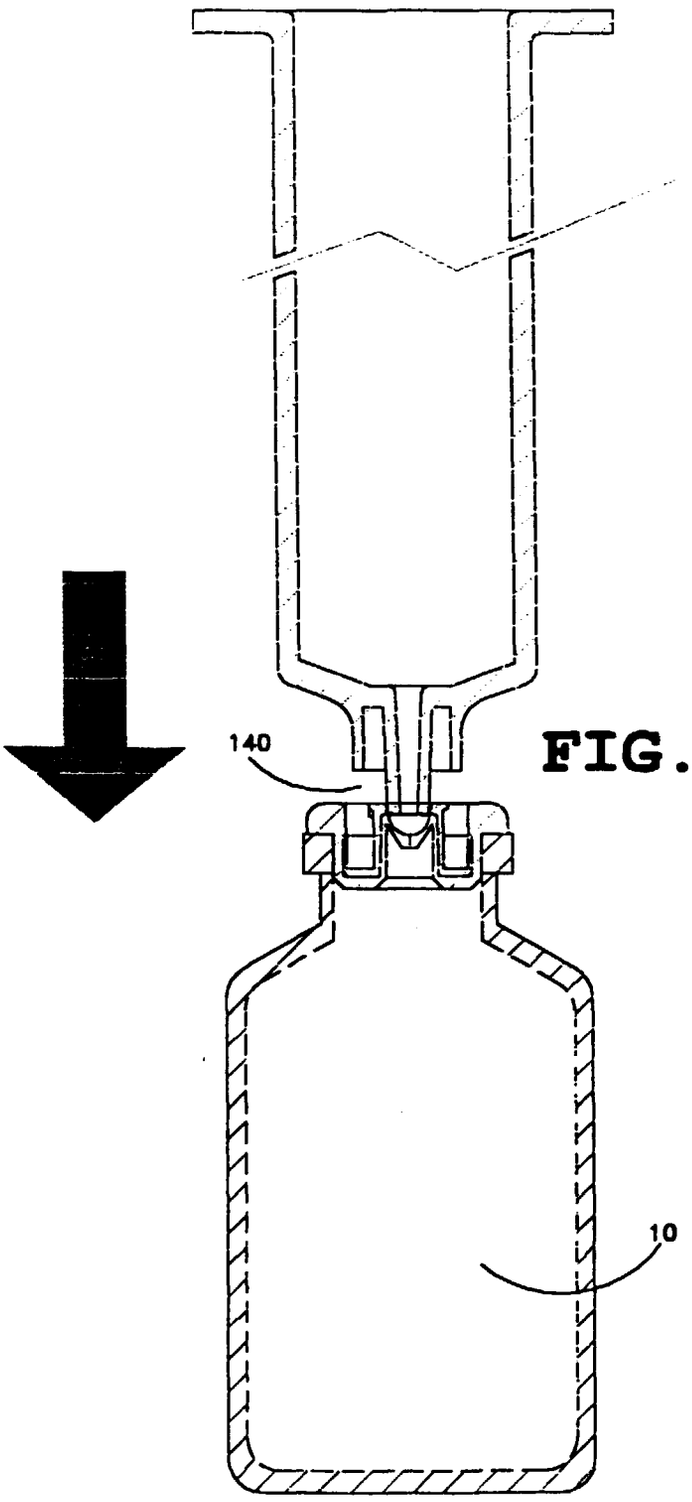


FIG. 12

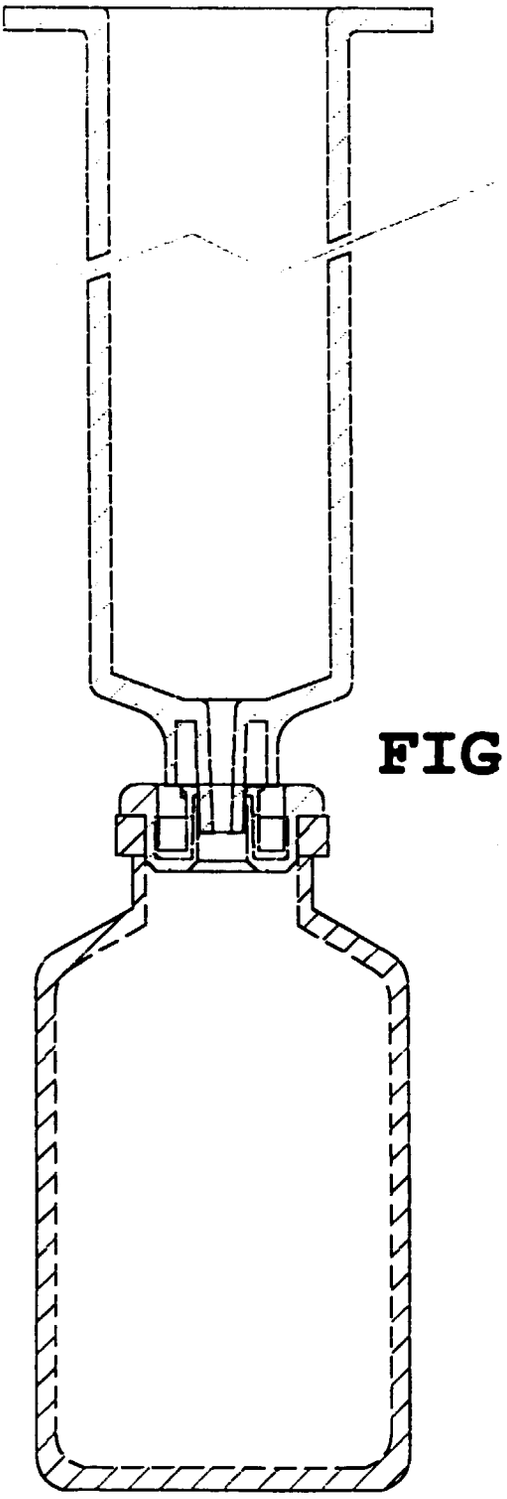


FIG. 12A

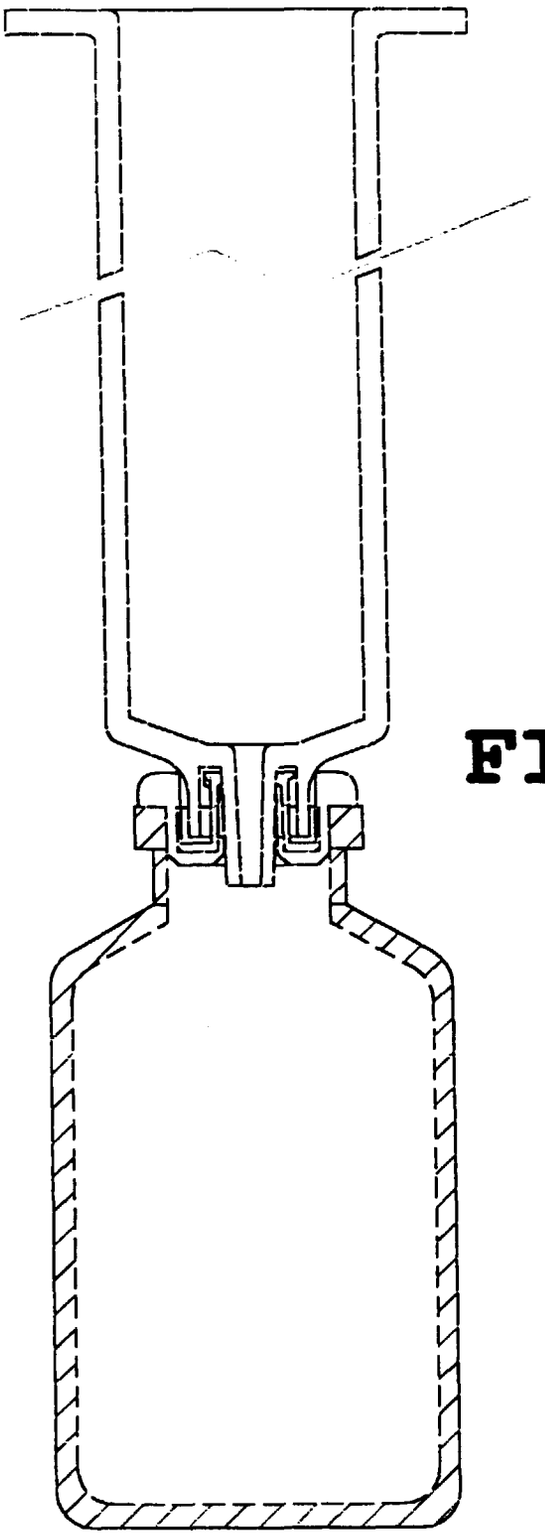


FIG.12B

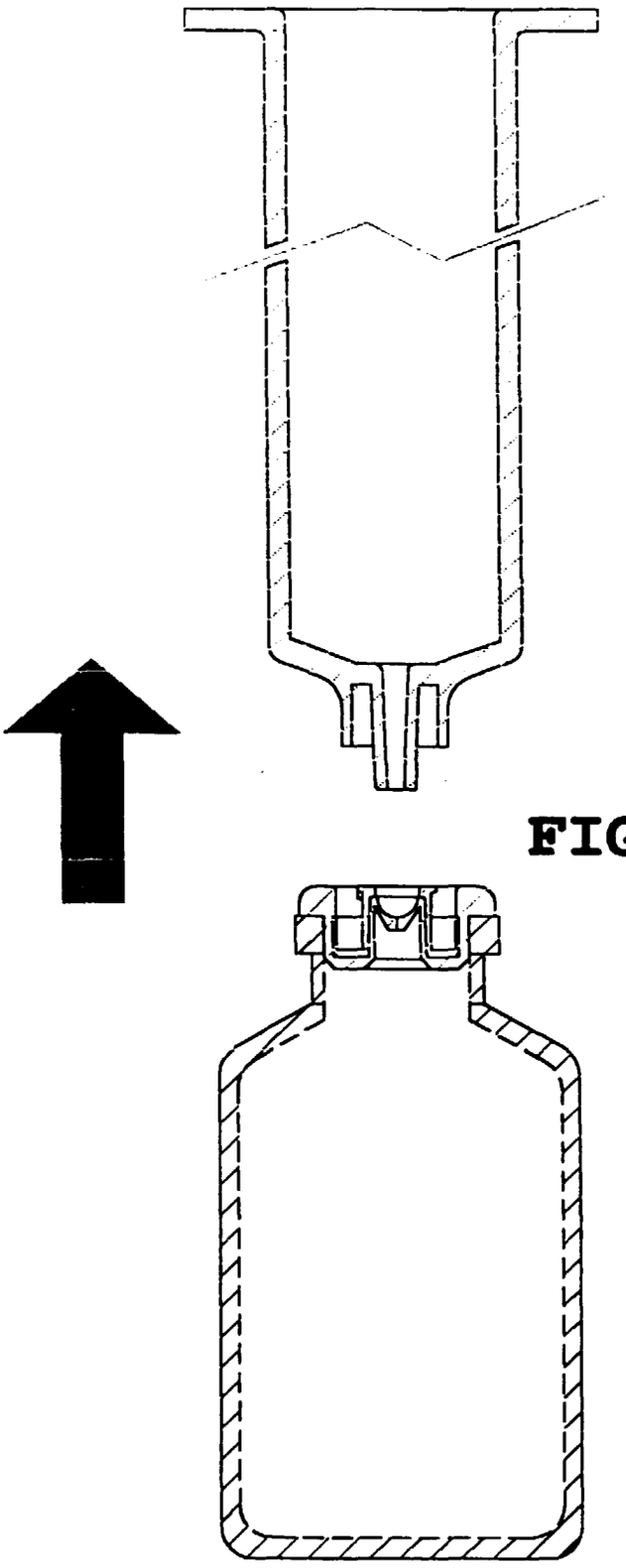


FIG. 13