PEELABLE SEAL CLOSURE ASSEMBLY

CROSS-REFERENCE TO RELATED APPLICATIONS:

Not Applicable.

FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT:

Not Applicable.

BACKGROUND OF THE INVENTION

The present invention relates to a container for delivering fluids. In particular, it relates to a fluid access assembly for a flowable materials container wherein a conduit of the assembly has an inlet closed by a peel seal structure. The peel seal is activatable by applying fluid pressure to the peel seal structure. This assembly can be used in flowable materials containers and has been found particularly useful with single chamber and multiple chamber medical solution containers.

Multiple chamber containers having sub-chambers separated by a peel seal, frangible seal or other fluid connecting device are widely used to separately store two or more components that are mixed inside the container prior to administering the mixed solution to a patient. The components can be in a powder or liquid form and are typically mixed together to form a therapeutic solution. Such solutions can include intravenous solutions, nutritional solutions, drug solutions, enteral solutions, parenteral solutions, dialysis solutions, pharmacological agents including gene therapy and chemotherapy agents, and many other fluids that may be administered to a patient.

Due to stability, compatibility, or other concerns, some medical solutions have to be stored separately prior to administration to a patient. These solutions may be stored in separate containers, but are often stored in separate chambers of a single container. The chambers and solutions are often separated by a frangible heat seal. Examples of such containers are disclosed in U.S. Patents Nos. 5,209,347; 5,176,634; and 4,608,043. These prior art containers have frangible seals to permit the seal to be broken by hand pressure against the sides of the bag to force the contents to break the seal and permit mixing between the components. Peelable seals are among the frangible seals used that permit the seal to be

separated by pulling on opposite sides of the container, or by squeezing the container sidewalls.

The chambered container is typically made from a web of flexible polymeric materials. Numerous polymeric films have been developed for use in such containers, and can be a monolayer structure or a multiple layer structure. Containers can also have multiple webs where the webs are joined along peripheral edges and the planar surface of individual webs are not necessarily attached to one another. The monolayer structure can be made from a single polymer, or from a polymer blend. Multiple layer structures can be formed by co-extrusion, extrusion lamination, lamination, or any suitable means. The multiple layer structures can include layers such as a solution contact layer, a scratch resistant layer, a barrier layer for preventing permeation of oxygen or water vapor, tie layers, or other layers. Selection of the appropriate film depends on the solution to be contained within the container.

The container is typically formed by placing one or more polymeric film sheets in registration by their peripheral portions and sealing the outer periphery to form a fluid tight pouch. The peripheral seals are permanent, and therefore, do not peel. The sheets are sealed by heat sealing, radio frequency sealing, thermal transfer welding, adhesive sealing, solvent bonding, ultrasonic or laser welding.

Blown extrusion is another method used to make the pouch. Blown extrusion is a process that provides a moving tube of extrudate exiting an extrusion die. Air under pressure inflates the tube. Longitudinal ends of the tube are sealed to form the pouch.

A peelable seal having a peel strength lower than the peripheral seal can be formed in the container by various methods such as using a lower heat sealing temperature than used to form the peripheral seal. A peelable seal typically has an initial or peak peel force required to initiate separation of the peelable seal, and a plateau force to propagate the separation. Before steam sterilization, these forces are essentially equal. After the chambered container is filled with solution, it is typically steam sterilized at a temperature of 121°C. During steam sterilization, stress is applied to the edges of the peelable seal. When stress is applied to the peelable seal at a temperature above the softening point of the container material during sterilization, deformation occurs at the seal edge. The deformation reduces stress concentrations at the edge of the seal, increasing the peak peel force necessary to initiate peeling of the peelable seal. After steam sterilization, the peak peel force can be significantly greater than the plateau force. This increased peak peel force is detrimental to use of the multichambered container by making it more difficult to initiate peeling to open the

container. This is especially true for patients using the medical solutions who may be infirmed or elderly and unable to provide the force necessary to initiate peeling. Moreover, the peak peel force is difficult to control, some containers remaining easy to initiate peeling in the peelable seal, while others becoming almost impossible to initiate by hand.

SUMMARY OF THE INVENTION

Disclosed herein is a flowable materials conveyance assembly having a conduit having a wall defining a first pathway for conveying flowable materials and having an inlet to the pathway and an outlet from the pathway; and a multiple layer structure having a first web and a second web connected together along an interface proximate the inlet, the multiple layer structure is capable of moving from a sealed position to an activated position in response to materials delivered under pressure to the structure along a second pathway different from the first pathway to allow flowable materials to enter the inlet.

Also disclosed herein is a closure assembly for a container having opposing sidewalls defining a chamber therebetween; and a conduit having a portion extending into the chamber and having a fluid inlet, interfacing portions of the sidewalls are connected together along a peel seal over the inlet to define a closure.

Also disclosed herein is a flowable materials container having a pair of opposing sidewalls defining a chamber therebetween, interfacing portions of opposed sidewalls are sealed together along a peel seal to define at least two separate sub-chambers; and a conduit having a portion extending into the chamber and having a fluid inlet, the fluid inlet is closed by a portion of the peel seal.

Also disclosed herein is a method for mixing two components separately stored in sub-chambers of a dual chamber container including the steps of: (1) providing a fluid container having a first chamber, a second chamber a peel seal dividing the first chamber from the second chamber, and a fluid access device having a fluid inlet positioned inside the chamber, the fluid inlet being sealed closed by a first portion of the peel seal; (2) activating a second portion of the peel seal to provide a fluid pathway between the first chamber and the second chamber without activating the first portion; and (3) activating the first portion of the peel seal to open the fluid inlet.

These and other aspects and attributes of the present invention will be discussed with reference to the following drawings and accompanying specification.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a plan view of a multichambered container including a peelable seal;

FIG. 2 is a cross-sectional view taken along lines 2-2 of FIG. 1;

FIG. 3 is a cross-sectional view of a multiple layer structure;

FIG. 4 is a cross-sectional view of another embodiment of a multiple layer structure;

FIG. 5 is a graph showing typical force vs. displacement curves for a peelable seal before and after sterilization;

FIG. 6 is a cross-sectional view of a peelable seal having a serrated edge;

FIG. 7 is an enlarged top view of a peelable seal;

FIG. 8 is a cross-sectional view of a peelable seal;

FIG. 9 is a force vs. displacement graph for a peelable seal;

FIG. 10 is a cross-sectional view of a peelable seal;

FIG. 11 is force vs. displacement graph for the seal of FIG. 10;

FIG. 12 is a cross-sectional view of a peelable seal;

FIG. 13 is a schematic plan view of a peelable seal;

FIG. 14 is a schematic plan view of a peelable seal;

FIG. 15 is a schematic plan view of a peelable seal;

FIG. 16 is a schematic plan view of a peelable seal;

FIG. 17 is a schematic plan view of a peelable seal;

FIG. 18 is a schematic top view of a peelable seal;

FIG. 19 is a schematic view of a three-chamber container with peel seals separating the chamber, and an administration port, one end of which is embedded in the peel seal;

FIG. 20 is a schematic view of a peelable seal;

FIG. 21 is a schematic view of a peelable seal;

FIG. 22 is a schematic view of a peelable seal;

FIG. 23 is a plan view of a peel seal having a width that varies along the length of the seal;

FIG. 24 is an exploded view of a peel seal having a texture;

FIG. 25 is a cross-sectional view of a closure assembly;

FIG. 26 is a cross-sectional view of a closure assembly;

FIG. 27 is a cross-sectional view of a closure assembly;

FIG. 28 is a perspective view of a container having an administration port;

FIG. 29 is an exploded isometric view of an administration port;

FIG. 30 is a section view of a cap of the administration port;

FIG. 31 is a sectional view of a user removing a cap of the administration port;

FIG. 32 is a sectional view of a needle inserted into the port;

FIG. 33 is a plan view of a peel seal container with an access member in an inactivated position;

FIG. 34 is a plan view of a peel seal container with an access member in an activated position;

FIG. 35 is a multiple chamber container with a peel seal conduit separating two chambers of the container;

FIG. 36 is a layered structure prior to peel initiation;

FIG. 37 is the layered structure during peeling; and

FIG. 38 is the former layered structure now completely delaminated.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is susceptible of embodiments in many different forms. Preferred embodiments of the invention are disclosed with the understanding that the present disclosure is to be considered as exemplifications of the principles of the invention and are not intended to limit the broad aspects of the invention to the embodiments illustrated.

FIGS. 1 and 2 show container **10** having a first sidewall **12** and a second sidewall **14** having a permanent peripheral seal **13** and a closure assembly **15**. The container has a chamber **16** that is divided into a first sub-chamber **18** and a second sub-chamber **20** by a peelable seal **22**. The seal **22** extends longitudinally of the container from end seam **24** to end seam **25**. The seal is effective in separating components such as two liquids, a solid and a liquid, two gasses, a gas and a liquid and a gas and a solid.

As best seen in FIG. 2, the closure assembly **15** has a conduit **30** having a fluid flow path **31**, a fluid inlet **32** and a fluid outlet **34**. A first portion **40** of the peelable seal **22** extends over the fluid inlet **32** to seal the conduit from fluid flow either inward to the chamber or outward from the chamber. The first portion **40** of the peel sealable seal may sometimes be referred to as a closure or peelable closure. As will be described in greater detail below, the peelable seal **22** has a peelable seal activation force required to move the seal from a closed or sealed position to an open or activated position. The peelable seal **22** is designed to first activate along a second portion **42** of the peelable seal followed by activation of the first portion **40**. The second portion **42** is spaced a distance from the first portion **40** to

ensure mixing of the components of the first and second sub-chambers **18, 20** before the outlet conduit inlet **32** is open and placed in fluid communication with the mixed contents. In a preferred form of the invention, the second portion **42** is generally centrally disposed along the length and width dimensions of the container.

The closure **40** is capable of blocking fluid traveling in either incoming or outgoing directions through the conduit **30**. For single or multiple chamber fluid containers, the peelable seal **22** will block an incoming or outgoing flow of fluid, until the flow of fluid is pressurized above the peel seal activation force. Thus, the peelable seal protects against unwanted ingress or egress of fluids from the container.

The Sidewall Materials and Layer Structures

The container **10** is preferably made principally of flexible polymeric materials, although the container could include non-polymeric materials such as metal foils without departing from the invention. Numerous polymeric films have been developed for use in containers. Suitable films may be of a monolayer structure or a multiple layer structure. The monolayer structure can be made from a single polymer, or from a polymer blend. The multiple layer structures can include layers such as a solution contact layer, a scratch resistant layer, a barrier layer for preventing permeation of oxygen or water vapor, tie layers, or other layers. It is also contemplated to use more than one web of film for one or both sidewalls. Selection of the appropriate film depends on the solution or solutions to be contained within the container. Appropriate polymeric materials are generally selected from homopolymers and copolymers of polyolefins, polyamides, polyesters, polybutadiene, styrene and hydrocarbon copolymers, polyimides, polyester-polyethers, polyamide-polyethers to name a few.

The seal layer for a multiple chamber container should display bi-modal behavior. What is meant by bi-modal behavior is that the material is capable of forming a permanent seal under one set of sealing or manufacturing conditions and a peelable seal at a second set of sealing or manufacturing conditions. The seal layer can be a homophase polymer, or a matrix-phase polymer system. Suitable homophase polymers include polyolefins and more preferably polypropylene and most preferably a propylene and ethylene copolymer as described in EP 0875231, which is incorporated herein by reference.

It is also possible to have a seal layer having wall **12** and **14** of differing materials that are not compatible with one another. United States Patent Application No. 10/351,004,

which is incorporated herein by reference, discloses that containers made from such incompatible material, in some instances, may not readily form permanent seals. This problem can be overcome by wrapping a section of one sidewall over an outside surface of the opposite sidewall and joined thereto. This method of sealing is disclosed in U.S. Patent No. 6,024,220 which is incorporated herein by reference and made a part hereof.

Suitable matrix-phase polymer systems will have at least two components. The two components can be blended together or can be produced in a two-stage reactor process. Typically, the two components will have different melting point or glass transition temperatures. In the case where one of the components is amorphous, its glass transition temperature will be lower than the melting point of the other components. Examples of suitable matrix-phase polymer system includes a component of a homopolymer or copolymer of a polyolefin and a second component of a styrene and hydrocarbon copolymer. Another suitable matrix-phase system includes blends of polyolefins such as polypropylene with polyethylene, or polypropylene with a high isotactic index (crystalline) with polypropylene with a lower isotactic index (amorphous), or a polypropylene homopolymer with a propylene and α-olefin copolymer.

Suitable polyolefins include homopolymers and copolymers obtained by polymerizing alpha-olefins containing from 2 to 20 carbon atoms, and more preferably from 2 to 10 carbons. Therefore, suitable polyolefins include polymers and copolymers of propylene, ethylene, butene-1, pentene-1, 4-methyl-1-pentene, hexene-1, heptene-1, octene-1, nonene-1 and decene-1. Most preferably the polyolefin is a homopolymer or copolymer of propylene or a homopolymer or copolymer of polyethylene.

Suitable homopolymers of polypropylene can have a stereochemistry of amorphous, isotactic, syndiotactic, atactic, hemiisotactic or stereoblock. In one preferred form of the invention, the homopolymer of polypropylene is obtained using a single site catalyst.

Suitable copolymers of propylene are obtained by polymerizing a propylene monomer with an α-olefin having from 2 to 20 carbons. In a more preferred form of the invention, the propylene is copolymerized with ethylene in an amount by weight from about 1% to about 20%, more preferably from about 1% to about 10% and most preferably from 2% to about 5% by weight of the copolymer. The propylene and ethylene copolymers may be random or block copolymers. The propylene copolymer may also be obtained using a single site catalyst.

It is also possible to use a blend of polypropylene and α–olefin copolymers wherein the propylene copolymers can vary by the number of carbons in the α–olefin. For example, the present invention contemplates blends of propylene and α–olefin copolymers wherein one copolymer has a 2 carbon α–olefin and another copolymer has a 4 carbon α–olefin. It is also possible to use any combination of α–olefins from 2 to 20 carbons and most preferably from 2 to 8 carbons. Accordingly, the present invention contemplates blends of propylene and α–olefin copolymers wherein a first and second α–olefins have the following combination of carbon numbers: 2 and 6, 2 and 8, 4 and 6, 4 and 8. It is also contemplated using more than 2 polypropylene and α–olefin copolymers in the blend. Suitable polymers can be obtained using a catalloy procedure. Suitable homopolymers of ethylene include those having a density of greater than 0.915 g/cc and includes low density polyethylene (LDPE), medium density polyethylene (MDPE) and high density polyethylene (HDPE).

Suitable copolymers of ethylene are obtained by polymerizing ethylene monomers with an α -olefin having from 3 to 20 carbons, more preferably 3-10 carbons and most preferably from 4 to 8 carbons. It is also desirable for the copolymers of ethylene to have a density as measured by ASTM D-792 of less than about 0.915 g/cc and more preferably less than about 0.910 g/cc and even more preferably less than about 0.900 g/cc. Such polymers are oftentimes referred to as VLDPE (very low density polyethylene) or ULDPE (ultra low density polyethylene). Preferably the ethylene α-olefin copolymers are produced using a single site catalyst and even more preferably a metallocene catalyst systems. Single site catalysts are believed to have a single, sterically and electronically equivalent catalyst position as opposed to the Ziegler-Natta type catalysts which are known to have a mixture of catalysts sites. Such single-site catalyzed ethylene α -olefins are sold by Dow under the trade name AFFINITY, DuPont Dow under the trademark ENGAGE®, Eastman Kodak under the trade name MXSTEN, and by Exxon under the trade name EXACT. These copolymers shall sometimes be referred to herein as m-ULDPE.

Suitable copolymers of ethylene also include ethylene and lower alkyl acrylate copolymers, ethylene and lower alkyl substituted alkyl acrylate copolymers and ethylene vinyl acetate copolymers having a vinyl acetate content of from about 8% to about 40% by weight of the copolymer. The term "lower alkyl acrylates" refers to comonomers having the formula set forth in Diagram 1:

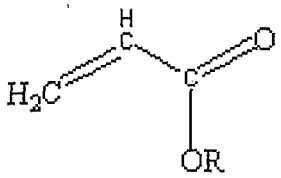


Diagram 1

The R group refers to alkyls having from 1 to 17 carbons. Thus, the term "lower alkyl acrylates" includes but is not limited to methyl acrylate, ethyl acrylate, butyl acrylate and the like.

The term "alkyl substituted alkyl acrylates" refers to comonomers having the formula set forth in Diagram 2:

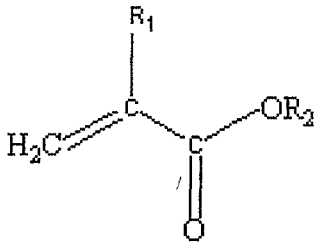


Diagram 2

R_1 and R_2 are alkyls having 1-17 carbons and can have the same number of carbons or have a different number of carbons. Thus, the term "alkyl substituted alkyl acrylates" includes but is not limited to methyl methacrylate, ethyl methacrylate, methyl ethacrylate, ethyl ethacrylate, butyl methacrylate, butyl ethacrylate and the like.

Suitable polybutadienes include the 1,2- and 1,4-addition products of 1,3-butadiene (these shall collectively be referred to as polybutadienes). In a more preferred form of the invention, the polymer is a 1,2-addition product of 1,3 butadiene (these shall be referred to as 1,2 polybutadienes). In an even more preferred form of the invention, the polymer of interest is a syndiotactic 1,2-polybutadiene and even more preferably a low crystallinity, syndiotactic 1,2 polybutadiene. In a preferred form of the invention, the low crystallinity, syndiotactic 1,2 polybutadiene will have a crystallinity less than 50%, more preferably less than about 45%, even more preferably less than about 40%, even more preferably the crystallinity will be from about 13% to about 40%, and most preferably from about 15% to about 30%. In a preferred form of the invention, the low crystallinity, syndiotactic 1,2 polybutadiene will have a melting point temperature measured in accordance with ASTM D 3418 from about 70°C to about 120°C. Suitable resins include those sold by JSR (Japan Synthetic Rubber) under the grade designations: JSR RB 810, JSR RB 820, and JSR RB 830.

Suitable polyesters include polycondensation products of di-or polycarboxylic acids and di or poly hydroxy alcohols or alkylene oxides. In a preferred form of the invention, the polyester is a polyester ether. Suitable polyester ethers are obtained from reacting 1,4 cyclohexane dimethanol, 1,4 cyclohexane dicarboxylic acid and polytetramethylene glycol ether and shall be referred to generally as PCCE. Suitable PCCE's are sold by Eastman under the trade name ECDEL. Suitable polyesters further include polyester elastomers which are block copolymers of a hard crystalline segment of polybutylene terephthalate and a second segment of a soft (amorphous) polyether glycols. Such polyester elastomers are sold by DuPont Chemical Company under the trade name HYTREL®.

Suitable polyamides include those that result from a ring-opening reaction of lactams having from 4-12 carbons. This group of polyamides therefore includes nylon 6, nylon 10 and nylon 12. Acceptable polyamides also include aliphatic polyamides resulting from the condensation reaction of di-amines having a carbon number within a range of 2-13, aliphatic polyamides resulting from a condensation reaction of di-acids having a carbon number within a range of 2-13, polyamides resulting from the condensation reaction of dimer fatty acids, and amide containing copolymers. Thus, suitable aliphatic polyamides include, for example, nylon 6,6, nylon 6,10 and dimer fatty acid polyamides.

Suitable styrene and hydrocarbon copolymers include styrene and the various substituted styrenes including alkyl substituted styrene and halogen substituted styrene. The alkyl group can contain from 1 to about 6 carbon atoms. Specific examples of substituted styrenes include alpha-methylstyrene, beta-methylstyrene, vinyltoluene, 3-methylstyrene, 4-methylstyrene, 4-isopropylstyrene, 2,4-dimethylstyrene, o-chlorostyrene, p-chlorostyrene, o-bromostyrene, 2-chloro-4-methylstyrene, etc. Styrene is the most preferred.

The hydrocarbon portion of the styrene and hydrocarbon copolymer includes conjugated dienes. Conjugated dienes which may be utilized are those containing from 4 to about 10 carbon atoms and more generally, from 4 to 6 carbon atoms. Examples include 1,3-butadiene, 2-methyl-1,3-butadiene (isoprene), 2,3-dimethyl- 1,3-butadiene, chloroprene, 1,3-pentadiene, 1,3-hexadiene, etc. Mixtures of these conjugated dienes also may be used such as mixtures of butadiene and isoprene. The preferred conjugated dienes are isoprene and 1,3-butadiene.

The styrene and hydrocarbon copolymers can be block copolymers including di-block, tri-block, multi-block, star block and mixtures of the same. Specific examples of diblock copolymers include styrene-butadiene, styrene-isoprene, and the hydrogenated

derivatives thereof. Examples of triblock polymers include styrene-butadiene-styrene, styrene-isoprene-styrene, alpha-methylstyrene-butadiene-alpha-methylstyrene, and alpha-methylstyrene-isoprene-alpha-methylstyrene and hydrogenated derivatives thereof.

The selective hydrogenation of the above block copolymers may be carried out by a variety of well known processes including hydrogenation in the presence of such catalysts as Raney nickel, noble metals such as platinum, palladium, etc., and soluble transition metal catalysts. Suitable hydrogenation processes which can be used are those wherein the diene-containing polymer or copolymer is dissolved in an inert hydrocarbon diluent such as cyclohexane and hydrogenated by reaction with hydrogen in the presence of a soluble hydrogenation catalyst. Such procedures are described in U.S. Pat. Nos. 3,113,986 and 4,226,952, the disclosures of which are incorporated herein by reference and made a part hereof.

Particularly useful hydrogenated block copolymers are the hydrogenated block copolymers of styrene-isoprene-styrene, such as a styrene-(ethylene/propylene)-styrene block polymer. When a polystyrene-polybutadiene-polystyrene block copolymer is hydrogenated, the resulting product resembles a regular copolymer block of ethylene and 1-butene (EB). As noted above, when the conjugated diene employed is isoprene, the resulting hydrogenated product resembles a regular copolymer block of ethylene and propylene (EP). One example of a commercially available selectively hydrogenated copolymer is KRATON G-1652 which is a hydrogenated SBS triblock comprising 30% styrene end blocks and a midblock equivalent is a copolymer of ethylene and 1-butene (EB). This hydrogenated block copolymer is often referred to as SEBS. Other suitable SEBS or SIS copolymers are sold by Kurrarry under the tradename SEPTON® and HYBRAR®. It may also be desirable to use graft modified styrene and hydrocarbon block copolymers by grafting an alpha,beta-unsaturated monocarboxylic or dicarboxylic acid reagent onto the selectively hydrogenated block copolymers described above.

The block copolymers of the conjugated diene and the vinyl aromatic compound are grafted with an alpha, beta-unsaturated monocarboxylic or dicarboxylic acid reagent. The carboxylic acid reagents include carboxylic acids per se and their functional derivatives such as anhydrides, imides, metal salts, esters, etc., which are capable of being grafted onto the selectively hydrogenated block copolymer. The grafted polymer will usually contain from about 0.1 to about 20%, and preferably from about 0.1 to about 10% by weight based on the total weight of the block copolymer and the carboxylic acid reagent of the grafted carboxylic

acid. Specific examples of useful monobasic carboxylic acids include acrylic acid, methacrylic acid, cinnamic acid, crotonic acid, acrylic anhydride, sodium acrylate, calcium acrylate and magnesium acrylate, etc. Examples of dicarboxylic acids and useful derivatives thereof include maleic acid, maleic anhydride, fumaric acid, mesaconic acid, itaconic acid, citraconic acid, itaconic anhydride, citraconic anhydride, monomethyl maleate, monosodium maleate, etc. The styrene and hydrocarbon block copolymer can be modified with an oil such as the oil modified SEBS sold by the Shell Chemical Company under the product designation KRATON G2705.

FIG. 3 shows a multiple layer film **49** having a seal layer **50** an intermediate layer **52** and an external layer **54**. Tie layers **56** may be employed to attach the seal layer **50** to the intermediate layer **52** and to attach the intermediate layer **52** to the external layer **54**. In a preferred form of the invention the seal layer is a blend of polypropylene, an ethylene α-olefin copolymer and a styrene and hydrocarbon copolymer. In a more preferred form of the invention, the polypropylene is a polypropylene ethylene copolymer, the ethylene α-olefin copolymer is a LLDPE having a density of less than 0.915 g/cc and the styrene and hydrocarbon copolymer is a block copolymer and preferably a tri-block copolymer of styrene-ethylene-butylene-styrene or a blend of an SEBS triblock with an SEBS diblock as a minor component. The relative proportions of the components are preferably from about 55% to 75% of the PP by weight, from 5% to 20% by weight of the LLDPE, and from 10% to 20% by weight of the SEBS. The ternary blend of the seal layer is capable of forming a permanent seal and a peel seal at a temperature of from about 123 to 128°C. A permanent seal is achieved at sealing temperatures above 160°C.

The intermediate layer **52** may be selected from any of the polyamides set forth herein and most preferably is a blend of from about 85 to 98% polyamide 6 and from 2 to 15% polyamide 6I6T.

The external layer **54** is selected from polypropylene polymer, and most preferably is a propylene ethylene copolymer with an ethylene content of less than 6% by weight of the copolymer.

The details of the film **49** are more fully set out in U.S. Patent Application serial no. 09/439,826, filed November 12, 1999, which is incorporated in its entirety herein by reference and made a part hereof.

Another suitable film is shown in FIG. 4 having three layers, external layer **60**, intermediate layer **62** and seal layer **64**. The external layer is a reactor made polypropylene

composition having a first component and a second component. The first component is a polypropylene homopolymer and is present in an amount by weight of the composition of 40%. The second component is an ethylene-propylene rubber (ethylene 20% and propylene 80%) and is present in an amount by weight of the composition of 60%. Suitable products for the external layer are sold by Mitsubishi Chemical Company under the trade name Zelas 7023. Zelas 7023 is the subject of U.S. Patent Application Publication No. 2001/0034416 A1 which is incorporated herein by reference in its entirety and made a part hereof.

The intermediate layer **62** is a polymer blend of Zelas 7023 70% by weight and 30% by weight of a random copolymer of styrene and butadiene that has been hydrogenated. Suitable random copolymers of styrene and butadiene are sold by JSR under the trade name Dynaron 2320 P.

The external layer **64** is a polymer blend of 60% by weight Zelas 7023 and 40% by weight of a random copolymer of propylene and ethylene such as the copolymer sold under the trade name Novatec EG 7C.

The film of FIG. 4 displays bi-modal behavior with peel seals being formed at sealing temperatures of about 125°C and permanent seals are obtained at about 160°C.

Other suitable films for this application include those disclosed in U.S. Patent Nos. 5,849,843; 5,998,019; 6,083,587; 6,297,046; 5,139,831; 5,577,369; and U.S. Application No. 2003/0077466 A1 which are incorporated herein in their entirety by reference and made a part hereof.

The container **10** is typically formed by placing one or more polymeric film sheets forming the first sidewall **12** and second sidewall **14** in registration by their peripheral portions and sealing their periphery **13** to form a fluid tight pouch. The sheets are typically sealed by heat sealing, radio frequency sealing, thermal transfer welding, adhesive sealing, solvent bonding, and ultrasonic or laser welding. Blown extrusion is another method that may be used to make the pouch. Blown extrusion is a process that provides a moving tube of extrudate exiting an extrusion die. Air under pressure inflates the tube. Longitudinal ends of the tube are sealed to form the pouch. Blown extrusion only requires seals along two peripheral surfaces, where the single or multiple sheet registration method requires seals along one, three, or four peripheral surfaces to form the pouch.

Peelable seal

The peelable seal **22** is preferably created by heat sealing, but may be made by any of the above-mentioned sealing or welding methods, or any other suitable method. The peelable seal **22** is peelable such that it may be peeled by hand pressure to separate the first sidewall **12** and second sidewall **14** to allow fluid communication between the first chamber **18** and second chamber **20**, thereby mixing the components contained in them. The peelable seal **22** is peeled, for example, by gripping the first sidewall **12** and second sidewall **14** of the container **10**, and pulling them apart, or be squeezing or pressing the first sidewall **12** and second sidewall **14** to force the fluid in chambers **18** and **20** against the peelable seal **22** with sufficient force to separate the peelable seal **22**. The peelable seal **22** is strong enough to withstand external stresses without peeling resulting from ordinary squeezing during handling, shipment, or from accidental dropping.

In a preferred form of the invention, the peel seal will have a peel seal activation force that falls within a range of from about 3 N/15 mm to about 30 N/15 mm. The peel seal can have varying peel seal activation forces across it length. In a preferred form of the invention, the peel seal activation force of the first portion **40** of the peel seal will be greater than the second portion **42**. This will promote activation of the second portion of the peel seal before the first portion to ensure mixing of any components in the chambers before the closure is opened to allow fluid flow through the inlet **32**. In a preferred form of the invention, the peel seal activation force of the first portion **40** of the peel seal **22** is from about 1 N/15mm to about 5 N/15 mm higher than the peel seal activation force of the second portion **42** of the peel seal **22**.

It is desirable for the peel seal **22** to be capable of adhesive release as opposed to cohesive release. Adhesive release of the peel seal means that the first sidewall **12** separates from the second sidewall **14** without removing any significant portion of one wall with the other. The release generates a minimum of particles to prevent or minimize contamination of the components of the chamber **16** with residual plastic particles.

The peelable seal **22** has edges **70** and **72**. The peelable seal **22** is shown in FIGS. 1 and 14 as extending along the length dimension of the container, but could also extend between lateral edges as shown in FIG. 13. Alternatively, the peelable seal **22** may be contained completely within the first sidewall **12** and second sidewall **14**, and not intersect any part of the peripheral seal **13** (FIG. 16). It is further contemplated that the peelable seal **22** can extend from a corner, a lateral edge, or a longitudinal edge, and terminate elsewhere in

the container **10** (FIGS. 15 and 17). The peelable seal **22** may be located anywhere between the first sidewall **12** and second sidewall **14** depending on the relative sizes of the chambers **18** and **20** desired. The chambers **18** and **20** may be filled with medical or other components for forming therapeutic solutions, including intravenous solutions, nutritional solutions, drug solutions, enteral solutions, parenteral solutions, dialysis solutions, pharmacological agents including gene therapy and chemotherapy agents, and many other fluids that may be administered to a patient. The components may be liquid, powder, lyophilized tablet, or other suitable form. The components are introduced into the container **10** and chambers **18** and **20** using any conventional means, such as delivering through a dedicated access port for each chamber **18** and **20**. The edges **70** and **72** of the peelable seal **22** abut the fluid in chambers **18** and **20**.

Containers are often filled at pressures of up to 60 pounds per square inch (psi). After being filled with solution, the container **10** is typically sterilized using steam. The sterilization typically occurs at a temperature of 121°C.

FIG. 5 shows typical force vs. displacement graph for a peelable seal **22** having straight edges **70** and **72**. The x axis of FIG. 5 shows displacement along the length of the peelable seal **22**. The y axis shows force necessary to peel the peelable seal **22** at specific points along its length. Curve **74** is the force vs. displacement curve before steam sterilization. Curve **76** is the force vs. displacement curve after steam sterilization. As can be seen from curve **74** of FIG. 5, a force **77** is necessary to initiate peeling the peelable seal **22** prior to steam sterilization. This force **77** is the same as a plateau force **78**, which is necessary to propagate peeling after initiation.

As curve **76** shows, after steam sterilization, a peak peel force **80** is required to initiate peeling the peelable seal **22**. The peak peel force **80** is significantly greater than a plateau force **82** necessary to propagate peeling. The peak peel force **80** occurs due to sterilization. Sterilization can cause boiling of the solution in the chambers **18** and **20** of the container **10**. Boiling can cause expansion of the fluids in the chambers **18** and **20**, and thereby further stresses the first sidewall and second sidewall **12** and **14** by forcing them apart. When stress is applied to the peelable seal **22** at a temperature above the softening point of the container material, deformation at the seal edges **70** and **72** occurs. Deformation can also occur because of water expansion and/or shrinkage of the container material due to crystallization, or in the case of stretched container films, stress relaxation. This deformation reduces stress concentration at the seal edges **70** and **72**, thereby increasing the force necessary to break the

peelable seal **22** to initiate the peeling process. This peak peel force **80** is detrimental to ease of use. Moreover, because of the variable nature of the causes, the peak peel force **80** is variable and hard to control. Some seals **22** may be too easy to activate, peeling during shipping, ordinary handling, or by dropping. Other seals **22** may become almost impossible to initiate peeling by hand.

The present invention overcomes these problems by reducing the peak peel **80** force necessary to initiate peeling at the seal edges **70** and **72**. It has been found that changing the shape of the seal edges **70** or **72** from a straight edge on at least the portion of the peelable seal **22** where peeling is to be initiated accomplishes this. This reduces the length of the peelable seal **22** that is subject to stress during exposure to high temperatures during steam sterilization. Thus, the peak peel force **80** occurs only on limited portions of the peelable seal **22**.

FIG. 6 shows a cross-sectional view of a peelable seal **90** in accord with an embodiment of the present invention prior to steam sterilization. First sidewall **92** and second sidewall **94** of a container are sealed at the seal **90**. The seal **90** defines chambers **96** and **98** in the container.

FIG. 7 is an enlarged top view of the seal **90** of FIG. 6 before steam sterilization. The seal **90** has a sealed area **100**, a first seal edge **102**, and a second seal edge **104**. The first seal edge **102** and second seal edge **104** are serrated, having outer points **106** and angular legs **108** extending at angles from and between the outer points **106**. The legs **108** intersect at inner points **110** thereby connecting with outer points **106**. Between the inner points **110** and outer points **106** is a depth **112**. Though FIG. 7 shows both first seal edge **102** and second seal edge **104** serrated, it is contemplated that only one or the other of the first seal edge **102** or second seal edge **104** may be serrated in accord with the present invention (FIG. 18). It also is contemplated that the serrations can occur over the entire length of the seal **90** or only on selected sections. It is preferred that the serrations be spaced from the peripheral seal **13** of the container **10** to permit peeling of the permanent seal **13**.

FIG. 8 shows a cross-sectional view of the seal **90** after steam sterilization taken along line **120** of FIG. 7 intersecting inner points **110**. As shown in FIG. 8, an angular joint **122** between the first sidewall **92** and second sidewall **94** occurs at the inner points **110**, and is maintained after steam sterilization.

FIG. 9 is a force vs. displacement graph for the serrated peel seal **90** of an embodiment of the present invention. The x axis shows displacement along the length of the

seal **90**. The y axis shows the force required to peel the seal **90** at points along the length of the seal **90**. Curve **124** is the force vs. displacement curve before steam sterilization. An initiation force **126** is necessary to initiate propagation. This force increases essentially linearly to a maximum plateau force **128** to propagate the peeling.

FIG. 9 also shows a curve **130** showing force vs. displacement for the serrated peel seal **90** after steam sterilization. Curve **130** demonstrates the peak peel force **132**. The peak peel force **132** is greater than the initiation force **126** before sterilization, however, it is less than a maximum propagation force **134** necessary to continue the peeling process. This results in a greater ease of use of the container because less force is required initiate the peeling process than with a seal with straight seal edges.

During sterilization, only the outer points **106** (FIG. 7) are subject to stress and deformation, and not the inner points **110** or angular legs **108**. The outer points **106** are subject to stress because the film tension is at a maximum at the outer points **106**. Thus, the stress concentrations present when the seal **90** is made is reduced only at the outer points **106**, and not at the angular legs **108** or the inner points **110**. Stress concentration is, therefore, retained at inner points **110**.

The outer points **106** define an outer stress bearing zone of the peelable seal **90**. The outer points **106** bear the stress caused by steam sterilization. The inner points **110** and angular legs **108** define an inner non-stress bearing zone of the seal **90**. Creation of a stress-bearing zone may also be accomplished using other shaped seal edges, such as a scalloped seal edge (FIGS. 20 and 22) or a trapezoidal seal edge (FIG. 21), other polygonal or geometric shape.

The stress bearing zone in FIGS. 20 and 22 are the crests **140** of the scallops **142**. The non-stress bearing zone includes the troughs **144** and sloping sides **146** of the scallops **142**. The stress-bearing zone in FIG. 21 is created by the flat portions **150** of the trapezoids **152**. The non-stress bearing zone includes the inner points **154** and sides **156** of the trapezoids **152**. The present invention also contemplates other seal edge shapes that create stress bearing zone and a non-stress bearing zone.

In the serrated seal embodiment of FIGS. 6 and 7, the first sidewall **12** and second sidewall **14** of the container are separated first at the inner points **110**. The angular joint at inner points **110** further facilitate separation of the first sidewall **12** and second sidewall **14**. As a result (FIG. 9), the peak peel force **132** is lower than plateau force **134** for propagating the seal **90**, which is the sum of the individual forces required to break the seal **90** at inner

points **110**, angular legs **108** and outer points **106**. Because the outer points **106** are a small length compared to the overall length of the seal **90**, the contribution of the points **106** is small when compared to that contributed by the inner points **110** and legs **108**. Hence, the plateau force **134** is reduced compared to a peelable seal **90** having straight edges **70** and **72**. This allows for providing varying strengths along the length of the peel seal. Peel seal activation forces are reduced in the areas of the serrations which allow for activating the second portion **42** of the peel seal before the first portion **40** (FIG. 1). It also improves the reproducibility of the peak peel force **132**. Yet the seal **90** is strong enough to protect the seal **90** against peeling during normal handling. Likewise for scalloped (FIGS. 20 and 22) and trapezoidal (FIG. 21) seal edges, the sidewalls of the container are initially separated at the non-stress bearing zone such that the peak peel force is lower than the plateau force.

For the serrated seal edge embodiment of FIG. 7, an important factor in reducing the peak peel force **132** is the depth **112** of the serrations. The depth **112** controls the slope of the peel force curve **130** before reaching the plateau value **134**. The depth **112** must be sufficiently great to permit separation between the peak peel force **132** and the plateau force **134**. The minimum depth for reducing the peak peel force **132** is highly dependent on plateau seal force **134** values, i.e., for lower peak peel forces, a greater depth **112** is necessary. Other factors include, mechanical properties of the materials making the container **10**, filling volume, filling pressure, and stress occurring during the sterilization process. The greater the volume, the higher the initiation force, and the higher the filling pressure, the higher the initiation force. The number of serrations per unit length is a factor in determining the reduction of the peak peel force **132**. The greater the number of serrations, the greater the peak peal force **132**. A balance must be struck between peeling force and ability of the seal to withstand normal handling. Experiments have indicated that symmetrical serrations angled at 90°, outer points **106** spaced 8 mm apart, and a depth **112** of 4 mm achieve an acceptable peak peel force **132**. Similarly, for embodiments such as the scalloped (FIGS. 20 and 22) or trapezoidal shaped (FIG. 21) seal edges, the depth between the stress-bearing zone and the non-stress-bearing zone must be controlled to balance peeling force and normal handling.

In another embodiment, the present invention includes a seal **160**. FIG. 10 shows a cross-sectional view of the seal **160** before steam sterilization. The seal **160** includes a first seal **162** and a second seal **164**. The second seal **164** is preferably located at a central portion **166** of the first seal **162**. The seal **160** separates chambers **18** and **20** of the container **10**. The first seal **162** also has a lower peel force than the second seal **164**. Preferably, the first seal

separation force is on the order of 5 N/15 mm, while the second seal separation force is on the order of 15 N/15 mm. The seal **160** is created preferably by heat sealing the first sidewall and second sidewall **12** and **14**, and by varying the temperature along the seal **160**, such that the temperature to create seal **164** is greater than that for the first seal **162**. This causes the first sidewall and second sidewall **12** and **14** at the second seal **164** to adhere together more at the second seal **164** than the first seal **162**. In turn, this requires a greater force to separate the first sidewall and second sidewall **12** and **14** at the second seal **164** than the first seal **162**. The first seal **162** has a first edge **170** and a second edge **172** that are each in contact with fluid in chambers **18** and **20**.

FIG. 11 shows a force vs. displacement graph for the seal **160**. Curve **174** shows force vs. displacement before steam sterilization. Curve **176** shows force vs. displacement after steam sterilization. As FIG. 11 demonstrates, the initial peak force **178** of first seal **162** after steam sterilization remains lower than maximum plateau force **180** of the second seal **164**.

When sterilized, deformation will occur at the first and second edges **170** and **172**. This will increase the peel force at first and second edges **170** and **172** of the first seal **162**. Thus, even if a peak peel force at first and second edges **170** and **172** appears as high as three times the plateau value of the first seal **162**, it will remain below the peel seal force required to separate the second seal **164** in the central portion. Thus, no peak peel force will occur in the second seal **164**. The seal **160** is created by heat sealing the second seal **164** at a higher temperature than the first seal **162**.

On a similar principle, an another embodiment shown in FIG. 12, a seal **180** has a peeling force gradient along the width of the seal **180**. The seal **180** has first and second edges **182** and **184**, and a central portion **186** between the first and second edges **182** and **184**. The peel force at the first and second edges **182** and **184** is less, preferably approximately three times less, than the peel force at the central portion **186**. As with seal **160** described above, the seal **180** is created by a heat seal having a temperature gradient across its width, greater in the middle and less at the edges. A gradient can be obtained, for instance, by a die having heating elements separated by an insulating material layer, and where the temperature of the central heating element is greater than at the edges. Thus, when a peak peal force occurs at the edges **182** and **184**, it remains below the peel force at the central portion **186**. The peel force at the edges **182** and **184** preferably being approximately 5 N/15 mm and at the central portion **186** being approximately 15 N/15 mm. In this manner, even if the edges

182 and **184** of the seal **180** experience a peel force increase of three times, it is still the same or less than that in the central portion **186**. Thus, no peak peal force occurs.

It is also possible to vary the peel seal activating force along the length of the peel seal by varying the width of the seal along its length as shown in FIG. 23. Wider seal portions **187** will activate at higher forces than thinner sections **188**. In the embodiment of FIG. 23, the wider seal portion **187** is positioned proximate the administration port and the weaker seal portion **188** is positioned distal from the administration port to ensure that mixing of the contents of the chambers by activating the thin sections **188** occurs prior to activating the wider seal portion **187**.

It is also possible to vary the peel seal strength by varying the sealing temperature along the length of the peel seal with the strength of the peel seal increasing with increasing temperature, provided of course the temperature is not so high to damage the film.

In yet another embodiment shown in FIG. 24, the peel seal is created with a textured sealing die to create a pattern **189** on the surface of the sidewalls along the peel seal. The pattern **189** has individual elements **191**. The size, shape, texture and density of the individual elements can impact the strength of the peel seal. The greater the height or depth of the elements the weaker the peel seal strength. The higher the density per unit area of the elements the lower the peel seal strength. The elements can be protuberances extending from the planar surface of the sidewall or can be indentations extending from the planar surface in a direction opposite from the protuberances. The pattern shown in FIG. 24 has an increasing density of elements with increasing distance from the closure assembly. This is to ensure peel seal activation first occurs at a location remote from the closure assembly to ensure mixing prior to delivering the mixed contents to the patient.

Closure Assemblies

FIGS. 1 and 2 show closure assembly **15** includes the conduit **30** having an inlet **32** and an outlet **34** with a closure **40**. The closure can be opened or activated from fluid pressure in the chamber or can be activated from providing fluid under pressure from the outlet **34** to the inlet and through the conduit. In a preferred form of the invention, the closure will be positioned inside the chamber **16** and will be activated by fluid in the chamber. This technique of activating uses fluid flowing along a pathway other than the pathway **31** of the conduit.

In a preferred form of the invention (FIG. 25), the conduit is an assembly of a membrane tube **200** concentrically mounted within a port tube **190**. The port tube/membrane tube assembly has a portion of the port tube extending into the chamber **16** and a portion of the membrane tube extending outward of the end seam outside the container **10**. The sidewalls **12, 14** are attached to an outer surface of the port tube typically by heat sealing.

In a preferred form of the invention, the port tube **190** is a multilayered structure and more preferably has a first layer **192** and a second layer **194**. The first layer **192** should be of a non-PVC containing material that is capable of being sealed to the sidewalls **12, 14** of the container **10**, and preferably sealed using radio frequency sealing techniques, but other techniques such as sonic welding, heat transfer induction sealing and the like could be used without departing from the scope of the present invention. In a preferred form of the invention, the first layer **192** is a polymer blend of: (a) from about 25% to about 50% by weight and more preferably from about 30% to about 40% by weight, of the first layer a first polyolefin selected from the group consisting of propylene containing polymers, (b) from about 0% to about 50% by weight, and more preferably from about 5% to 40% by weight, of the first layer a second polyolefin of an α-olefin containing polymer or copolymer and more preferably is an ethylene and α-olefin copolymer; (c) from about 0% to about 40% by weight, and more preferably from about 10% to about 40% by weight, of the first layer a radio frequency susceptible polymer selected from the group consisting of polyamides, ethylene acrylic acid copolymers, ethylene methacrylic acid copolymers, polyimides, polyurethanes, polyesters, polyureas, ethylene vinyl acetate copolymers with a vinyl acetate comonomer content from 18% to 50% by weight of the copolymer, ethylene methyl acrylate copolymers with methyl acrylate comonomer content from 18% to 40% by weight of the copolymer, ethylene vinyl alcohol with vinyl alcohol comonomer content from 15% to 70% by mole percent of the copolymer; and (d) from about 0% to about 40% by weight, and more preferably from 10% to about 40% by weight, of the first layer of a thermoplastic elastomer.

One particularly suitable blend for the port tube **190** first layer **192** is a four component blend having by weight the following components: from about 10% to about 40% and more preferably 30% of a dimer fatty acid polyamide, from about 0% to about 50% and more preferably from about 0% to about 10% of an ultra low density polyethylene, from about 25% to about 50% and more preferably from about 30% to about 40% of a polypropylene and from about 10% to about 40% and more preferably 30% styrene-ethylene-butylene-styrene block copolymer with maleic anhydride functionality.

The second layer **194** of the port tube **190** is of a non-PVC containing material that is capable of being solvent bonded to the membrane tube **200**. In a preferred form of the invention, the second layer **194** is a multiple component blend of the following components by weight: from about 25% to about 55% and more preferably from 33%-52% of a thermoplastic elastomer, from about 20% to about 45% and more preferably from about 25% to about 42% of a polyester polyether block copolymer, from about 0% to about 15% and more preferably from about 5% to about 12% by weight of the second layer an ethylene copolymerized with vinyl lower alkyl esters and preferably vinyl acetate, from about 0% to about 10% by weight and more preferably from about 1% to about 5% by weight of the second layer of a propylene containing polymer and from about 0% to about 35% by weight of a polymer selected from the group consisting of acrylonitrile butadiene styrene (ABS) block copolymer, styrene ethylene butylene copolymer, styrene acrylonitrile copolymer and cyclic olefin or bridged polycylic olefin containing polymers.

One particularly suitable blend of the second layer **194** of the port tube is a five-component blend having from about 33% to about 35% SEBS (Kraton 1660), from about 25% to about 29% polyester polyether block copolymers (Hytrel), from about 5% to about 9% EVA, from about 1% to about 3% polypropylene and from about 28% to about 32% ABS.

Another suitable blend of the second layer **194** of the port tube is a four-component blend having from about 48% to about 52% SEBS, from about 36% to about 42% polyester polyether block copolymer, from about 8% to about 12% EVA and from about 1% to about 4% polypropylene.

As shown in the FIG. 25, the first layer **192** has a thickness greater than the second layer **194**. In a preferred form of the invention the first layer will have a thickness of from about 15 mils to about 40 mils and more preferably from about 20 mils to about 30 mils. The second layer **194** will have a thickness from about 2 mils to about 12 mils and more preferably from about 5 mils to about 10 mils.

The membrane tube **200** should be fabricated from a non-PVC containing material and should be capable of being bonded, preferably using solvent bonding techniques, to the port tube **190**. In a preferred form of the invention, the membrane tube **200** is a multilayered structure. The membrane tube **200** has an outer layer **202** and an inner layer **204**. The outer layer **202** is of a material selected from the same materials as set forth for the second layer

194 of the port tube. Likewise, the inner layer **204** of the membrane tube **200** is selected from the same materials as the first layer **192** of the port tube **190**.

A particularly suitable inner layer of the membrane tube is a four-component blend by weight of the inner layer **204** that slightly varies from the most preferred first layer of the port tube. The components are by weight of the inner layer **204** as follows: 40% polypropylene, 40% ultra-low density polyethylene, 10% polyamide and 10% SEBS. It should be understood, however, that the inner layer **204** of the membrane tube could also be selected from the same components and weight percentage ranges as set forth above for the first layer of the port tube.

In a preferred form of the invention, the outer layer of the membrane tube **200** should have a thickness from about 15 mils to about 35 mils and more preferably from about 20 mils to about 30 mils. The inner layer **204** of the membrane tube **202** should have a thickness from about 2 mils to about 12 mils and more preferably from about 5 mils to about 10 mils.

FIG. 26 shows an alternate embodiment of the membrane tube having three layers. In addition to the outer layer **202** and inner layer **204** shown in FIG. 25, FIG. 26 shows an intermediate layer **210** interposed therebetween. The intermediate layer **210** preferably is a thermoplastic elastomer and more preferably an oil modified styrene-ethylene-butylene-styrene block copolymer sold by the Shell Chemical Company under the product designation KRATON G2705. The intermediate layer **210** can also be a blend of from about 99% to about 70% of a thermoplastic elastomer and from about 1% to about 30% of a propylene containing polymer.

In yet another preferred form of the invention (FIG. 27), the port tube **190** is a multilayered structure and more preferably has a first layer **192** and a second layer **194**. The first layer **192** should be of a non-PVC containing material that is capable of being sealed to the sidewalls **12** and **14** of the container **10**. In a preferred form of the invention, the first layer **192** is a polymer blend of: (a) from about 25% to about 50%, more preferably from about 30% to about 40%, by weight of the first layer a first polyolefin selected from the group consisting of polypropylene and polypropylene copolymers, (b) from about 0% to about 50%, more preferably from about 5% to about 40%, by weight of the first layer a second polyolefin of an α-olefin containing polymer or copolymer and more preferably is an ethylene and α-olefin copolymer; (c) from about 0% to about 40%, more preferably from about 10% to about 40% of the first layer a radio frequency susceptible polymer selected from polyamides, ethylene acrylic acid copolymers, ethylene methacrylic acid copolymers,

polyimides, polyurethanes, polyesters, polyureas, ethylene vinyl acetate copolymers with a vinyl acetate comonomer content from 12% to 50% by weight of the copolymer, ethylene methyl acrylate copolymers with methyl acrylate comonomer content from 12% to 40% by weight of the copolymer, ethylene vinyl alcohol with vinyl alcohol comonomer content from 12% to 70% by mole percent of the copolymer; and (d) from about 0% to about 40%, more preferably from about 10% to about 40% of a thermoplastic elastomer by weight of the first layer.

The second layer **194** of the port tube **190** is of a non-PVC containing material that is capable of being solvent bonded to the membrane tube **200**. In a preferred form of the invention, the second layer **194** is a thermoplastic elastomer or a blend of thermoplastic elastomers in an amount by weight of from about 80% to about 100% and a propylene containing polymer from about 0% to about 20% by weight of the second layer **194**. It is also desirable, but optional, that the second layer **194** softens slightly at autoclave temperatures so that when the port tube and membrane tube assembly is steam sterilized, the port tube more tightly adheres to the membrane tube.

As shown in FIG. 27, the first layer **192** has a thickness greater than the second layer **194**. In a preferred form of the invention the first layer will have a thickness of from about 15 mils to about 40 mils and more preferably from about 20 mils to about 30 mils. The second layer will have a thickness from about 2 mils to about 10 mils and more preferably from about 3 mils to about 7 mils.

The membrane tube **200** should be fabricated from a non-PVC containing material and should be capable of being bonded to the port tube **190**, preferably using solvent bonding techniques. Solvent bonding is well known in the art. Solvent bonding typically includes applying a solvent to a polymeric material to partially dissolve the polymer. While in this dissolved state the dissolved polymer material is placed in contact with a material, such as another polymer, that the polymeric material is to be bonded to. Suitable solvents for solvent bonding of the materials of the present invention include at least the following solvents: cyclohexane, cyclohexanone, toluene, tetrahydofuran, cumene, xylenes, diethyl benzene, decalin, tetralin and amyl benzene to name a few.

Accordingly, to solvent bond the membrane tube **200** to the port tube **190**, a portion of the membrane tube **200** that is to be in contact with the port tube is exposed to the solvent, typically by dipping the relevant portion of the membrane tube into the solvent. Then the membrane tube **200** is press-fitted into the port tube where a strong bond is formed.

In a preferred form of the invention, the membrane tube **200** is a multilayered structure having an outer layer **220**, a core layer **222** and an inner layer **224**. In a preferred form of the invention, the outer layer **220** is a polymer blend of: (a) from about 0% to about 60%, more preferably from about 20% to about 55% and most preferably from about 30% to about 50%, by weight of the outer layer of a polyolefin and (b) from about 40% to about 100%, more preferably from about 45% to about 80% and most preferably from about 50% to about 70%, by weight of the outer layer of a thermoplastic elastomer.

Also, in a preferred form of the invention the core layer **222** is a polymer blend of: (a) from about 35% to about 100%, more preferably from about 50% to about 90% and most preferably 70% to about 90%, by weight of the core layer of a thermoplastic elastomer and (b) from about 0% to about 65%, more preferably from about 10% to about 50% and most preferably from about 10% to about 30%, by weight of the core layer of a polyolefin.

Also, in a preferred form of the invention, the inner layer **224** is a polymer blend of: (a) from about 25% to about 55%, more preferably from about 25% to about 40%, by weight of the inner layer a polyolefin; (b) from about 0% to about 50%, more preferably from about 0% to about 40% and most preferably 0% to about 20%, by weight of the inner layer a polyolefin selected from α-olefin containing polymers or copolymers and more preferably is an ethylene and α-olefin copolymer; (c) from about 0% to about 40% by weight, more preferably from about 15% to about 40%, of the inner layer a radio frequency susceptible polymer selected from polyamides, ethylene acrylic acid copolymers, ethylene methacrylic acid copolymers, polyimides, polyurethanes, polyesters, polyureas, ethylene vinyl acetate copolymers with a vinyl acetate comonomer content from 12% to 50% by weight of the copolymer, ethylene methyl acrylate copolymers with methyl acrylate comonomer content from 12% to 40% by weight of the copolymer, ethylene vinyl alcohol with vinyl alcohol comonomer content from 12% to 70% by mole percent of the copolymer; and (d) from about 0% to about 40%, more preferably from about 15% to about 40%, by weight of the inner layer of a thermoplastic elastomer.

In a preferred form of the invention the outer layer **220** will have a thickness from about 3 mils to about 15 mils and more preferably from about 3 mils to about 10 mils. The core layer **222** will have a thickness from about 10 mils to about 35 mils and more preferably from about 10 mils to about 30 mils. The inner layer **224** will have a thickness from about 3 mils to about 15 mils and more preferably from about 5 mils to about 10 mils.

Medication Port

FIG. 28 generally illustrates a perspective view of a container **301** having a first end **323** and a second end **324**. The container **301** may be peripherally sealed and may have a liquid **305** or other solution in an interior of the container **301**. The container **301** may have a port **302** having a first end **318** and a second end **319**. The container **301** is illustrated in a position as is common in actual use. More specifically, the container **301** may be positioned up-right and may have the medication port **302** elevated above an administration port **315** in actual use. Additionally, a strap **312** for, for example, a hook may be provided to hang the container **301**.

Referring now to FIG. 29, the port **302** may have a housing **303** which may have a wall **325**. Preferably, the port **302** is a medication port through which a medicament may be added or a solution may be removed from the container **301**. The housing **303** and the wall **325** may be constructed from, for example, rubber, plastic or any other material generally known to those skilled in the art. Additionally, the housing **303** may be constructed of rigid polypropylene which may reduce risk of a needle **307** (FIG. 32) puncturing the wall **325**. Further, the housing **303** may be constructed using gamma-grade materials which are approved to withstand gamma irradiation prior to sterilization as a final stage of the manufacturing process. Gamma-grade materials allow for "pre-sterilization" and reduction in autoclaving exposure time.

As illustrated in FIG. 29, the wall **325** may be circular. The wall **325** of the housing **303** may have a first end **326** and a second end **327**. The second end **327** of the wall **325** may be integrally formed with the second end **319** of the medication port **302**. Additionally, the first end **326** of the wall **325** may be integrally formed with a cap **309** wherein the cap **309** may be separated from the first end **326** which will be described in further detail hereinafter.

The first end **326** of the wall **325** may also have a lip **339** which protrudes inward toward a center of the housing **303**. The lip **339** may be in contact with a septum **304**. The lip **339** may also secure the septum **304** within the housing **303** by friction, or, alternatively, the septum **304** may be sealed to the lip **339**. The lip **339** of the wall **325** may have an inner circumference **347** and an outer circumference **314** as shown in FIG. 29.

The wall **325** may have a height **328** and may have a first circumference **330** at the first end **326** and a second circumference **332** at the second end **327**. Additionally, the first circumference **330** at the first end **326** of the wall **325** may be smaller than the second circumference **332** at the second end **327** of the wall **325**. The smaller circumference **330** at

the first end **326** of the wall **325** may result in the wall **325** being tapered. More specifically, a taper **331** may result in the wall **325** tilting inward toward the center of the housing **303**.

The septum **304** of the medication port **302** may be located within the wall **325** of the housing **303**. Additionally, the septum **304** may be in contact with an inner wall **350** of the housing **303** as shown in FIG. 30.

The septum **304** may be constructed from, for example, rubber, plastic or any other material generally known to those skilled in the art. Additionally, the septum **304** may be constructed of a polyisoprene material which may allow for the septum **304** to re-seal after puncturing the septum **304** by, for example, the needle **307**.

As illustrated in FIG. 29, the septum **304** may be circular. The septum **304** may have a height **335** and may have a first circumference **336** and a second circumference **337**. Additionally, the septum **304** may have a first end **333** and a second end **334**. The first circumference **336** at the first end **333** of the septum **304** may be smaller than the second circumference **337** at the second end **334**. The smaller circumference **336** at the first end **333** may result in the septum **304** being tapered. More specifically, a taper wall **338** may result as shown in FIG. 29 wherein an opening at a top side of the septum **304** is greater than at a center of the septum **304**.

The first end **333** of the septum **304** may be in contact with the lip **339** of the wall **325**. The lip **339** may secure the septum **304** in place within the housing **303** and may provide a liquid-tight fit between the septum **304** and the wall **325** of the housing **303**.

The septum **304** may also have a target area **316** which may assist a health-care provider or other person with insertion of, for example, the needle **307** into the septum **304**. Of course, a cannula or other object may be used to pierce-the septum **304**. The target area **316** may also be colored, for example, red, to contrast with the color, for example, black, of the housing **303**. Use of different colors may result in the target area **316** being more visible and/or distinguishable to the health-care provider or other person.

As further illustrated in FIG. 29, a recess **321** may be located within the target area **316** of the first end **333** of the septum **304**. The recess **321** may assist the health-care provider or other person by providing a reduced resistance location to insert the needle **307** through the septum **304**. The target area **316** may also have a slit **354** instead of, or in addition to, the recess **321**.

The recess **321** may be formed by an internal wall **308** in the target area **316** of the septum **304**. More specifically, the wall **308** may have a first circumference **351** at the first

end **333** of the septum and a second circumference **352** at a valley **353** within the septum **304**. The first circumference **351** at the first end **333** of the septum **304** may be greater than the second circumference **352** at the valley **353** in the septum **304**. The difference in the circumferences of the internal wall **308** may result in the internal wall **308** being tapered.

The health-care provider or other person may puncture the septum **304** to establish fluid communication with the liquid **305** in the container **301**. A support ring **317** may support the septum **304** when an object, for example, the needle, is pressed down upon the septum **304**. As illustrated in FIG. 29, the support ring **317** may resemble, for example, a ring.

More specifically, when the health-care provider or other person inserts an object through the septum **304**, pressure is created on the septum **304**. The support ring **317** may allow pressure to be diverted from the outer periphery of the septum **304** onto the support ring **317**. As a result, the septum **304** may be able to withstand a greater pressure with the support ring **317** than without the support ring **317**. The support ring **317** may be constructed from, for example, rubber, plastic or any other material generally known to those skilled in the art.

The support ring **317** may be circular and may have a first outer circumference **344**, a second outer circumference **349** and an inner circumference **345**. Additionally, the support ring **317** may have a first end **340** and a second end **341**. The first outer circumference **344** may be at the first end **340** and a second outer circumference **349** may be at the second end **341**. The first outer circumference **344** may be greater than the second outer circumference **349**. As a result, the support ring **317** may taper downward. More specifically, the support ring **317** may have a taper **348**. The first outer circumference **344** and the second outer circumference **349** of the support ring **317** may be in contact with the inner wall **350** of the housing **303** as shown in FIG. 30.

The support ring **317** may also have a height **342** which may be smaller than the height **328** of the wall **325**. The inner circumference **345** of the support ring **317** may form a hollow interior area **343** through which the needle **307** or other object may extend after piercing the septum **304**.

The first end **340** of the support ring **317** may be in contact with the second end **334** of the septum **304**. Additionally, the second end **341** of the support ring **317** may be in contact with a lip **313** on the container **301**.

The housing **303** may also have a cap **309** that may be constructed from, for example, rubber, plastic or any other material generally known to those skilled in the art. The cap **309** of the housing **303** may have a cover **311** having a circumference **346**. The cap **309** may also have a ring handle **310**. As illustrated in FIG. 29, the cover **311** and the ring handle **310** may be circular. The ring handle **310** of the cap **309** may have a hollow opening **306** through which a user may insert, for example, a finger or hook.

The cover **311** of the cap **309** may also have a line of separation **320**. The line of separation **320** may be a perforation, a score line or other line of weakness formed between the cover **311** and the lip **339** of the wall **325**. The line of separation **320** may be formed at the circumference **346** of the cover **311**. More specifically, the line of separation **320** may provide a circumferential point at which the cover **311** may be removed from a remainder of the housing **303**.

The cover **311** may be integrally formed with the ring handle **310** by a connector **322** as generally shown in FIG. 29. The connector **322** may be secured to the cover **311** and the ring handle **310** so that a pulling force may break the line of separation **320**.

FIG. 30 illustrates an embodiment of the medication port **302** of the present invention with the cap **309** secured to the wall **325** of the housing **303**. More specifically, FIG. 30 illustrates the medication port **302** prior to removal of the cap **309**.

When the cap **309** is on the housing **303**, the cap **309** may protect the septum **304** and may create a sterile environment for the septum **304** by sealing the septum **304** from the surrounding environment. More specifically, when the cap **309** is secured to the wall **325** of the housing **303**, dust, pathogens and other harmful substances may not access the septum **304** located within the housing **303**.

Additionally, when the cap **309** is in the sealed position, the septum **304** may be protected from physical damage. The cap **309** may prevent accidental damage that may otherwise occur to the septum **304** if the septum **304** was unprotected.

FIG. 31 illustrates an embodiment of the present invention with the cap **309** of the medication port partially removed. The ring handle **310** of the cap **309** may be lifted by, for example, a finger of a user or a hook. When the user pulls on the ring handle **310**, the line of separation **320** may break and may allow the user to remove the cap **309**. When the cap **309** is removed, the septum **304** may be exposed. Upon removal of the cap **309**, the septum **304** may be ready for use through penetration of the septum **304** by, for example, the needle **307**.

FIG. 32 illustrates an embodiment of the medication port **302** of the present invention with the cap **309** removed from the wall **325** of the housing **303**. FIG. 32 also illustrates the needle **307** inserted through the septum **304** to provide fluid communication with the liquid **305** inside the interior of the container **301**.

The septum **304** may be punctured by the needle **307** or cannula (not shown). The needle **307** or other object may pierce the septum **304** through the target area **316** on the septum **304**. The needle **307** or other object may then pass through the hollow interior **343** of the support ring **317**. After the needle or other object is inserted into the container **301**, liquid may be added or withdrawn to from the container **301** as may be required.

Access Member

FIG. 33 shows a peel seal container **400** having an access device **402** associated therewith. The access member has a piercing cannula **404** defining a fluid pathway **406** therethrough, an activating member **408** to move the cannula **404** from an inactivated position where the piercing cannula **404** has not punctured a sidewall of the container (FIG. 33) to an activated position (FIG. 34) where the cannula pierces a sidewall of the container, a fluid line docking portion **410** and a tubing **412** connected to the docking portion **410**. A suitable access device **402** is disclosed in U.S. Patent Docket No. DI-5805, which is incorporated in its entirety herein by reference and made a part hereof.

FIG. 35 shows yet another embodiment of a peel seal container **440** having a fluid conduit **442** between a first and a second chambers **444**, **446**. The fluid conduit **442** has opposed ends having fluid outlets **448** with a peel seal **450** formed from the opposed sidewalls being sealed over the fluid outlets **448**. The top or the bottom chamber can be pressed to open the peel seal over either of the openings to allow the contents of the chambers to mix.

Using A Dual Chamber Peel Seal Container

FIGS. 36-38 show a sequence of activating a peel seal. FIG. 36 shows a layer structure **230** formed from the first wall having its planar surface in contact with a planar surface of the second wall to define a fully laminated state. FIG. 37 shows a portion of the first wall **12** lifting from the second wall **14** to define a partially delaminated state. Finally, FIG. 38 shows the wall **12** fully disconnected from the wall **14** to define a fully delaminated or open state.

As set forth above (FIG. 1), the first portion **40** of the peelable seal **22** has a higher peel seal activation energy than the second portion **42**. To activate the container shown in FIG. 1, one need only press on one of the sidewalls to apply a fluid pressure to the peel seal **22**. Upon generating sufficient pressure the second portion **42** of the peel seal delaminates thereby creating a fluid pathway from the first sub-chamber **18** to the second sub-chamber **20** thereby allowing the contents to mix. Upon adequate mixing of the components the container is pressed again to generate sufficient pressure to activate the first portion of the peel seal to open the closure to place the conduit fluid communication with the contents of the chamber.

The present invention contemplates having a second closure attached to the assembly that must be punctured or activated to draw fluid from the conduit. Such closures are well known in I.V. containers and CAPD containers, and are typically associated with fluid administration sets.

Method For Manufacturing And Filling A Dual Chamber Container

The container **10** is fabricated using standard heat sealing techniques. Separate rolled stock of the sidewall material are fed through packaging machinery where the sidewalls have peripheral edges placed in registration. Prior to sealing, the longitudinal end seams, a closure assembly **15** is inserted between the walls **12** and **14** and heat sealed in place. The peel seal **22** can be formed prior to, during or after forming the permanent seal and is preferably made using heat conduction sealing techniques. The welding die for the peel seal may have different temperatures and shapes along its length to achieve the desired peel seal.

It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

CLAIMS

The invention is claimed as follows:

1. A flowable materials conveyance assembly comprising:

a conduit having a wall defining a first pathway for conveying flowable materials and having an inlet to the pathway and an outlet from the pathway; and

a multiple layer structure having a first web and a second web connected together along an interface proximate the inlet, the multiple layer structure is capable of moving from a sealed position to an activated position in response to materials delivered under pressure to the structure along a second pathway different from the first pathway to allow flowable materials to enter the inlet.

2. The assembly of claim 1, wherein the multiple layer structure is attached to the conduit.

3. The assembly of claim 2, wherein the multiple layer structure has an attaching section and a sealing section, the attaching section having the conduit inserted between the first layer and the second layer, and wherein the sealing section has the first web attached to the second web in a fluid tight seal over the inlet.

4. The assembly of claim 3, wherein the first web is connected to the second web along a peel seal in the sealing section.

5. The assembly of claim 4, wherein the peel seal allows for adhesive release of the first web from the second web.

6. The assembly of claim 1, wherein the first web and the second web are capable of forming a peel seal and a permanent seal.

7. The assembly of claim 6, wherein the first web comprises a matrix-phase polymer system.

8. The assembly of claim 7, wherein the matrix polymer is a polyethylene homopolymer, an ethylene α-olefin copolymer, a polyethylene copolymer, a polypropylene homopolymer, or a polypropylene copolymer and the phase polymer is a styrene and hydrocarbon random copolymer, a styrene and hydrocarbon block copolymer, and an ethylene α-olefin copolymer.

9. The assembly of claim 4, wherein the first web comprises a homophase polypropylene.

10. The assembly of claim 4, wherein the peel seal can be activated by a force within the range of 3-30 N/15 mm.

11. A closure assembly for a flowable materials container comprising:

a container having opposing sidewalls defining a chamber therebetween; and

a conduit having a portion extending into the chamber and having a fluid inlet, interfacing portions of the sidewalls are connected together along a peel seal over the inlet to define a closure.

12. The assembly of claim 11, wherein the closure is capable of being moved from a closed position to an open position in response to fluid pressure.

13. The assembly of claim 12, wherein the fluid pressure can be generated by a fluid in the chamber or by a fluid outside the chamber.

14. The assembly of claim 13, wherein the peel seal divides the chamber into at least two sub-chambers.

15. The assembly of claim 14, wherein the peel seal has a first portion proximate the closure having a first peel seal activating force and a second portion distal from the closure having a second peel seal activating force wherein the second peel seal activating force is less than the first peel seal activating force.

16. The assembly of claim 15, wherein the difference between the first peel seal activating force and the second peel seal activating force is greater than about 1 N/15 mm and less than about 5 N/15 mm.

17. A flowable materials container comprising:

a pair of opposing sidewalls defining a chamber therebetween, interfacing portions of opposed sidewalls are sealed together along a peel seal to define at least two separate sub-chambers; and

a conduit having a portion extending into the chamber and having a fluid inlet, the fluid inlet is closed by a portion of the peel seal.

18. The container of claim 17, wherein the peel seal is moveable from a closed position to an activated position.

19. The container of claim 18, wherein the peel seal is moveable from a closed position to an activated position in response to fluid pressure applied to the peel seal.

20. The container of claim 19, wherein the peel seal has a first portion proximate the inlet having a first peel seal activating force and a second portion distal from the closure having a second peel seal activating force wherein the second peel seal activating force is less than the first peel seal activating force.

21. The container of claim 17, wherein the conduit is generally circular in cross-sectional shape and has an axis that extends in a direction parallel to the peel seal.

22. The container wherein the conduit is generally circular in cross-sectional shape and has an axis that extends in a direction transverse to the peel seal to define an angle.

23. The container of claim 22, wherein the angle is an obtuse angle.

24. The container of claim 22, wherein the angle is an acute angle.

25. The container of claim 22, wherein the angle is approximately a right angle.

26. The container of claim 17, wherein the peel seal has a length, the peel seal having a serrated portion along at least a portion of its length.

27. The container of claim 17, wherein the sidewalls are connected together along a permanent seal about a periphery of the container and the peel seal extends between two points on the periphery.

28. The container of claim 27, wherein the peel seal has a first edge and a second edge, and the serrated portion is located on one of the first edge or the second edge.

29. The container of claim 27, wherein the peel seal has a first edge and a second edge, and a serrated portion is located on both the first edge and the second edge.

30. The container of claim 17, wherein the serrated portion is spaced from the periphery.

31. The container of claim 27, wherein the serrated portion includes inner points, outer points, angular legs connecting the inner points and outer points, and a depth between the outer points and inner points.

32. The container of claim 27, wherein the first sidewall and second sidewall of the container form an angular joint at the inner points.

33. A method for mixing two components separately stored in sub-chambers of a dual chamber container comprising:

providing a fluid container having a first chamber, a second chamber a peel seal dividing the first chamber from the second chamber, and a fluid access device having a fluid inlet positioned inside the chamber, the fluid inlet being sealed closed by a first portion of the peel seal;

activating a second portion of the peel seal to provide a fluid pathway between the first chamber and the second chamber without activating the first portion; and

activating the first portion of the peel seal to open the fluid inlet.

34. A multiple chamber container comprising:

a sidewall defining a fluid chamber, a portion of the sidewall being sealed together to divide the fluid chamber into at least two sub-chambers along a peel seal; and

an access member attached to the sidewall for puncturing the sidewall to provide access to the fluid chamber.