



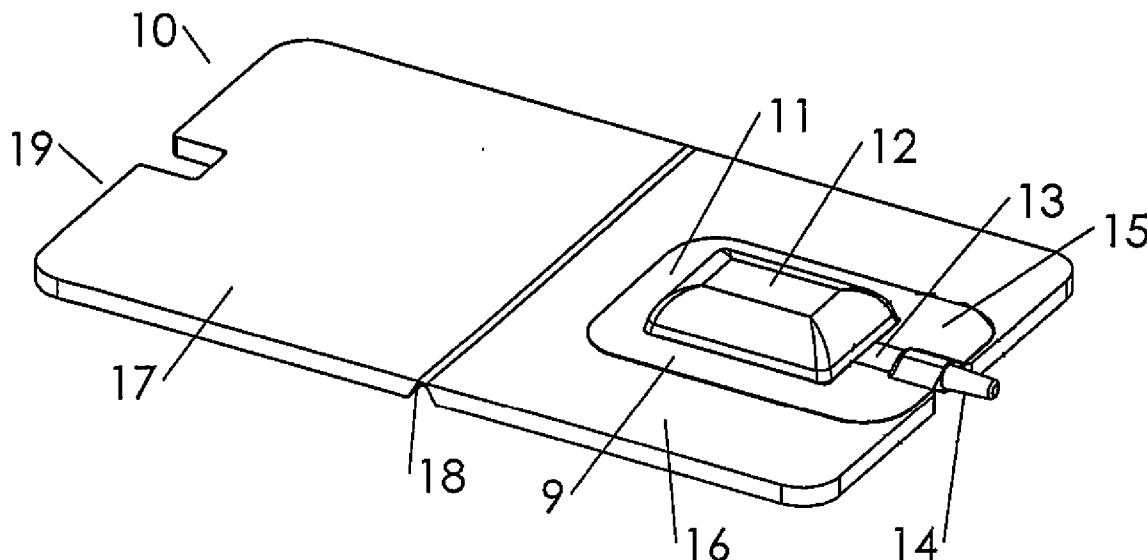
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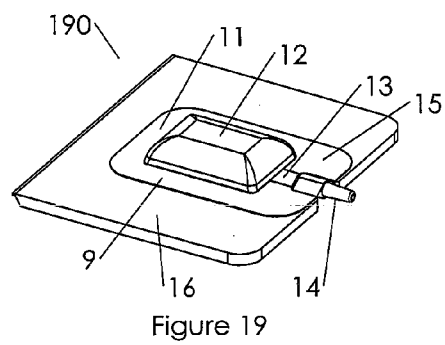
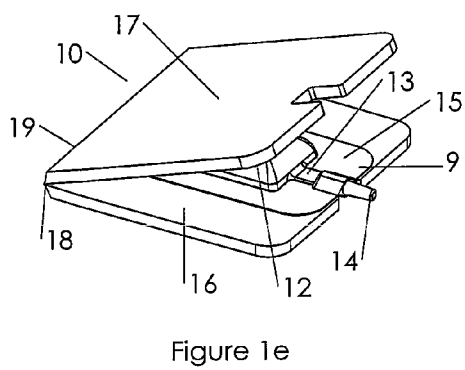
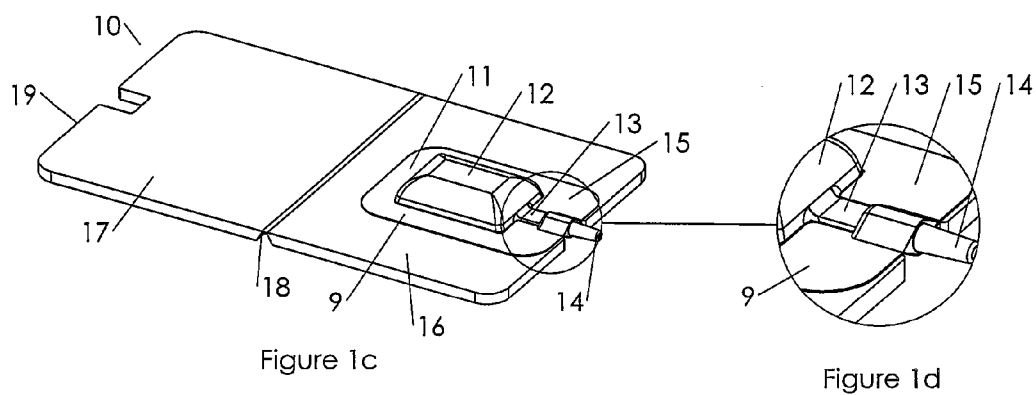
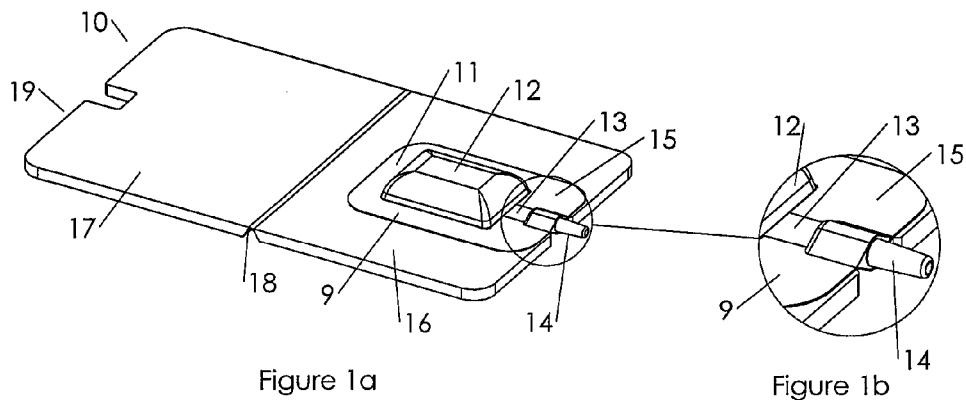
(19) **United States**(12) **Patent Application Publication**  
**Genosar et al.**(10) **Pub. No.: US 2012/0241465 A1**(43) **Pub. Date: Sep. 27, 2012**(54) **DISPENSING DEVICE ALONG WITH  
METHOD FOR DISPENSING PRODUCT**(75) Inventors: **Amir Genosar**, Boulder, CO (US);  
**Romi Genosar**, Boulder, CO (US)(73) Assignee: **AKTIVPAK, INC.**, Boulder, CO  
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(2), (4) Date: **Jun. 13, 2012**(30) **Foreign Application Priority Data**

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**B65D 35/56** (2006.01)(52) **U.S. Cl.** ..... **222/1; 222/105; 222/94; 222/103**(57) **ABSTRACT**

A device for storing and dispensing a product comprising: a package comprising at least a first compartment having a flexible wall portion; a fluid transport device; and a backing associated with said package which, during dispensing, supports the package to facilitate expression of a product from the package through said fluid transport device.





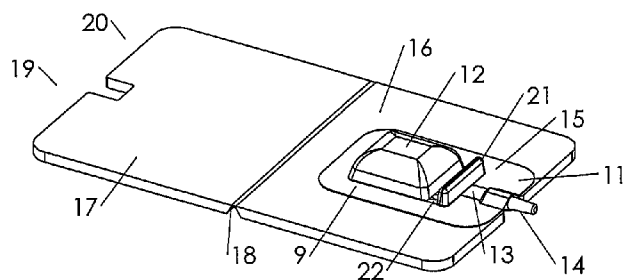


Figure 2a

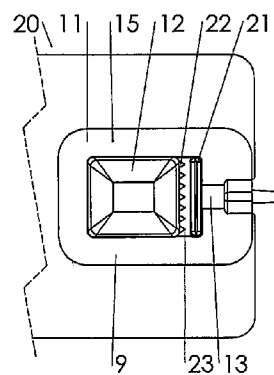


Figure 2b

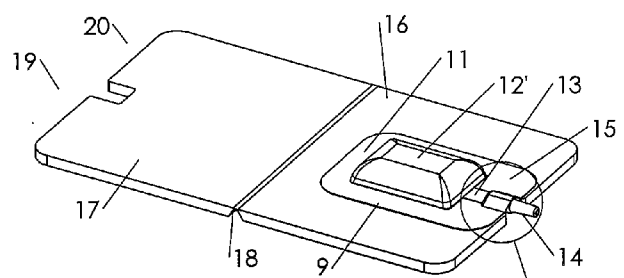


Figure 2d

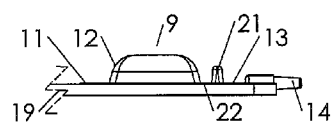


Figure 2c

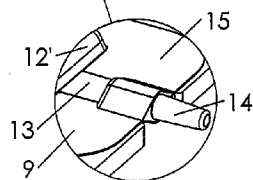


Figure 2e

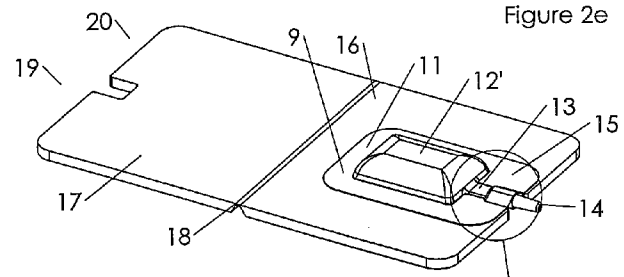


Figure 2f

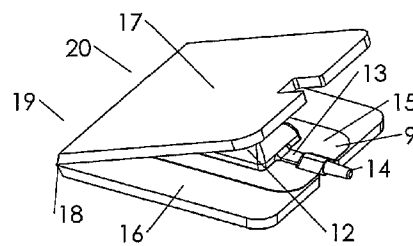


Figure 2h

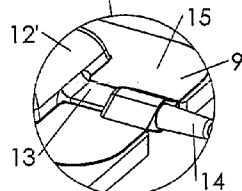


Figure 2g

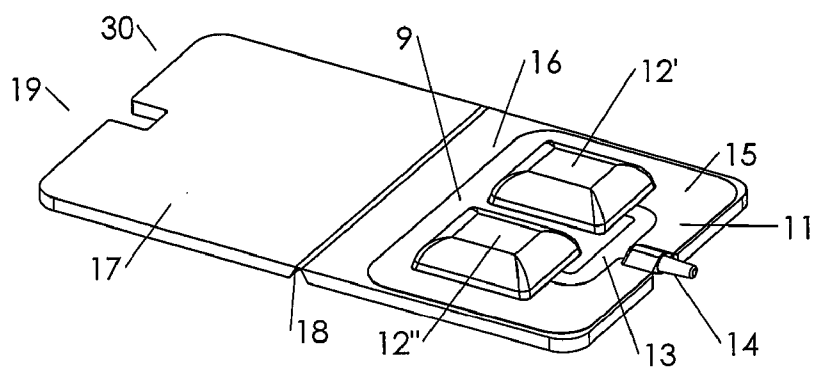


Figure 3

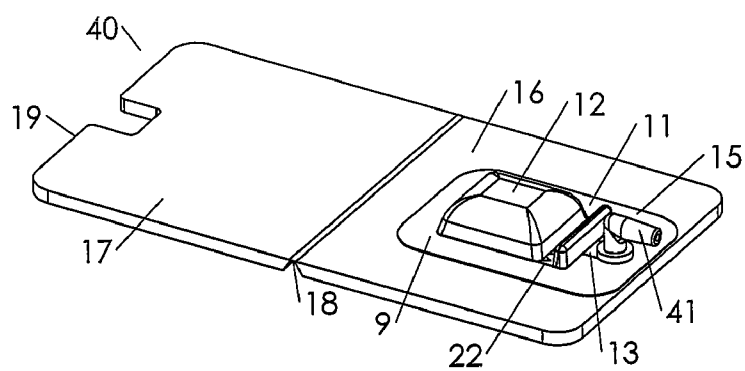


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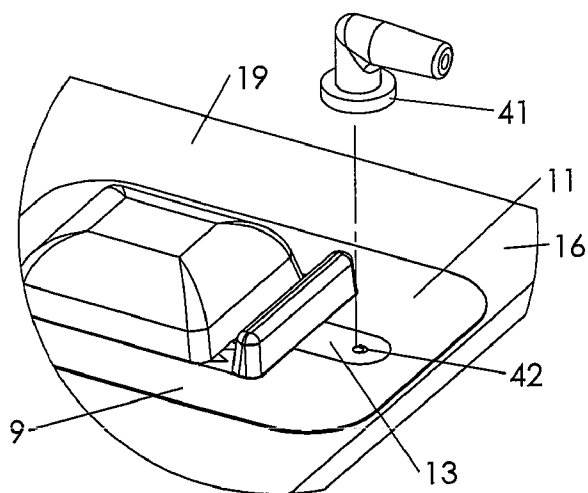


Figure 4b

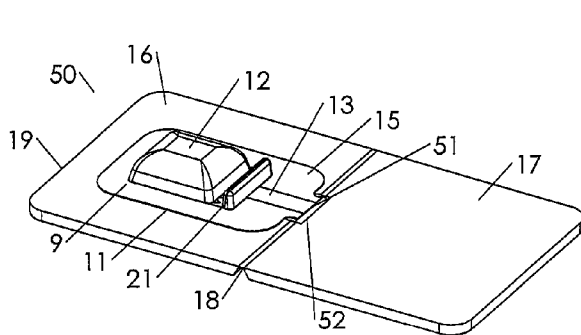


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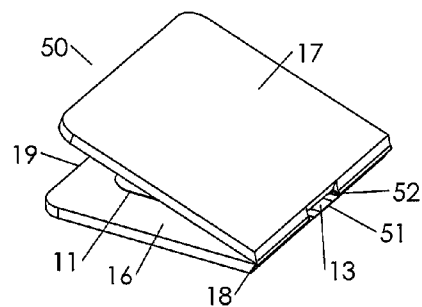


Figure 5b

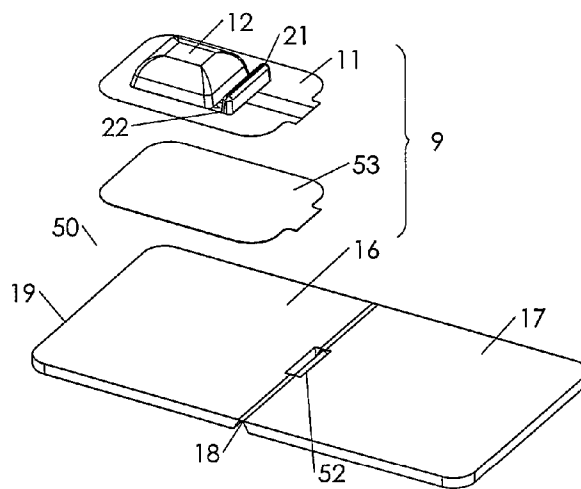


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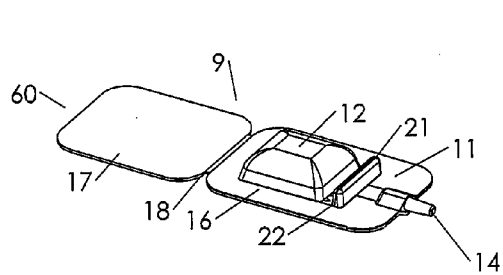


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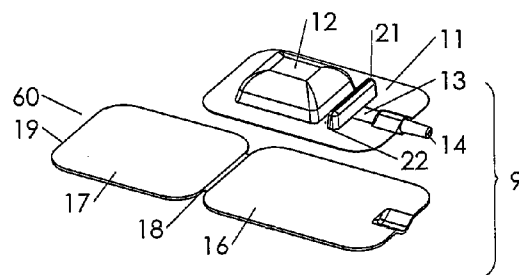


Figure 6b

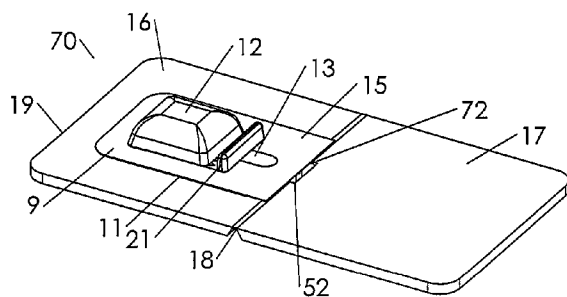


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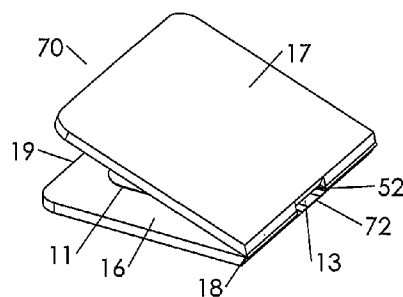


Figure 7b

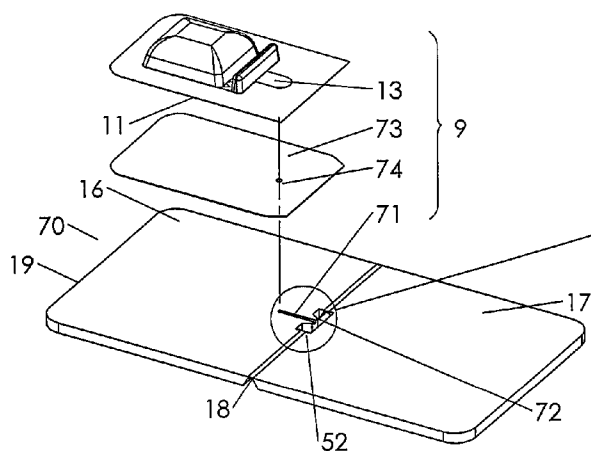


Figure 7c

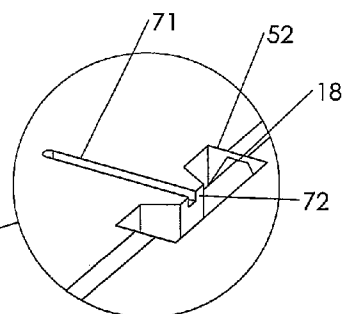


Figure 7d

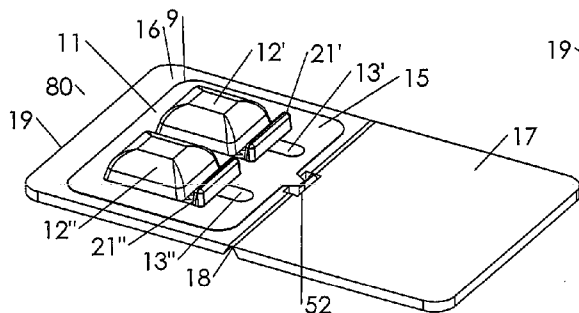


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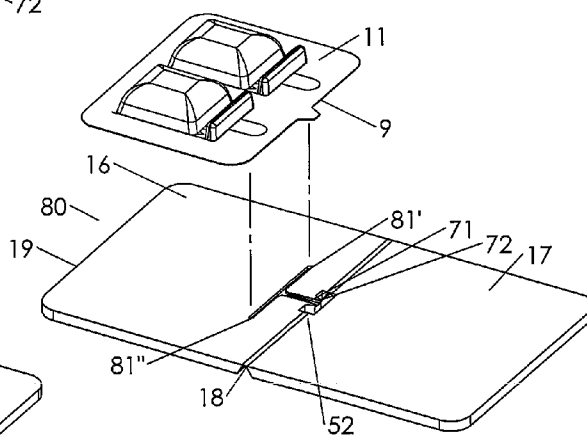


Figure 8c

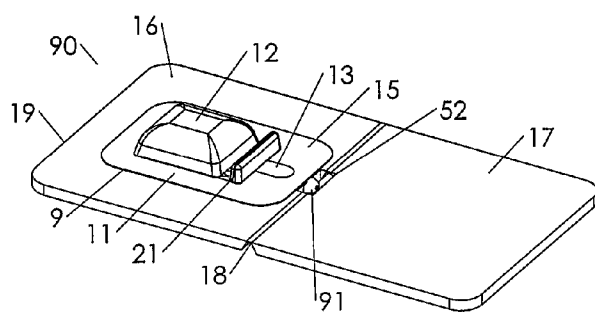


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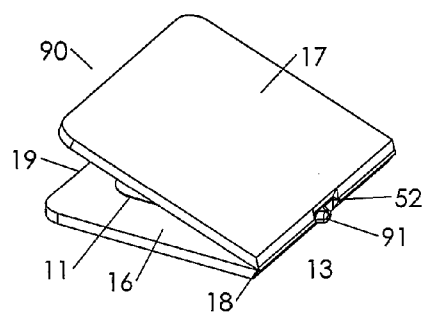


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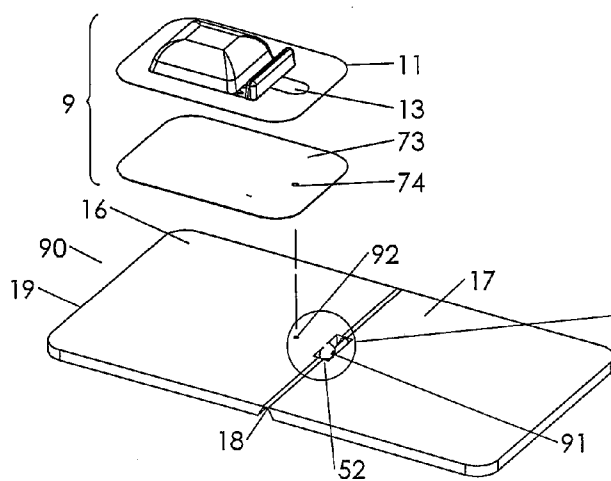


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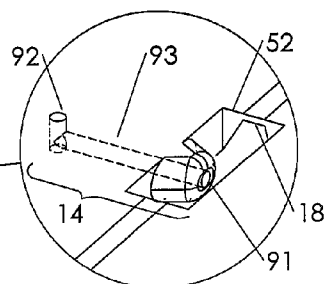


Figure 9d

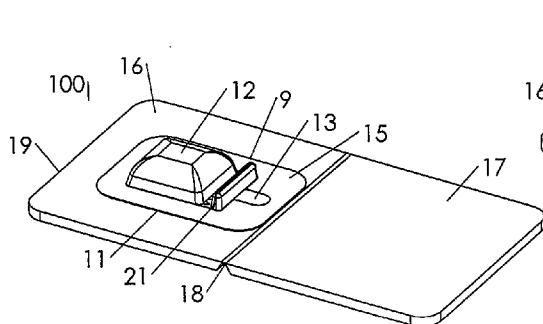


Figure 10a

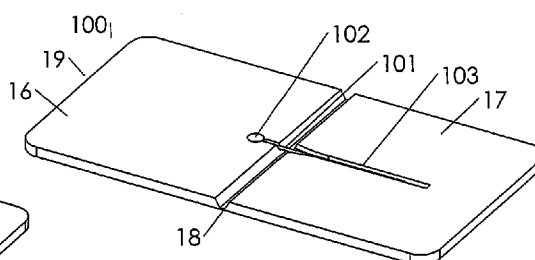


Figure 10b

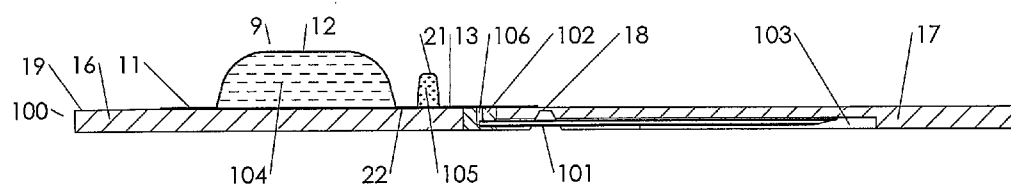


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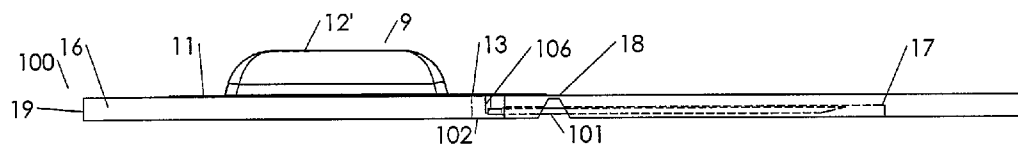


Figure 10d

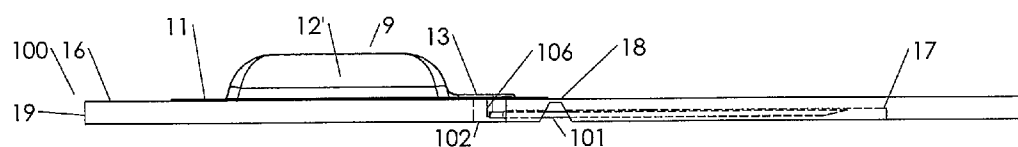


Figure 10e

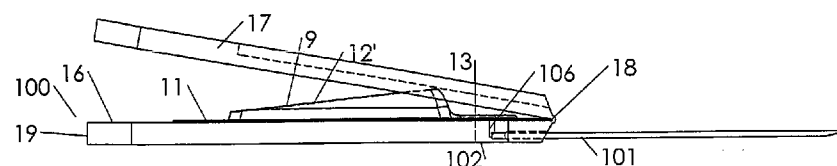
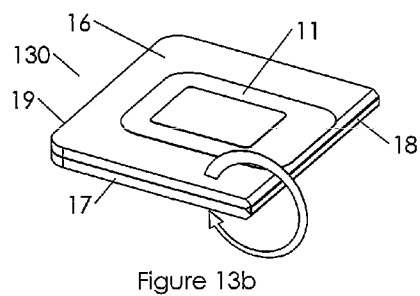
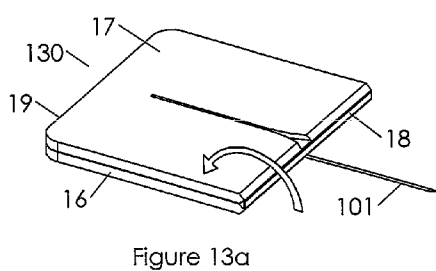
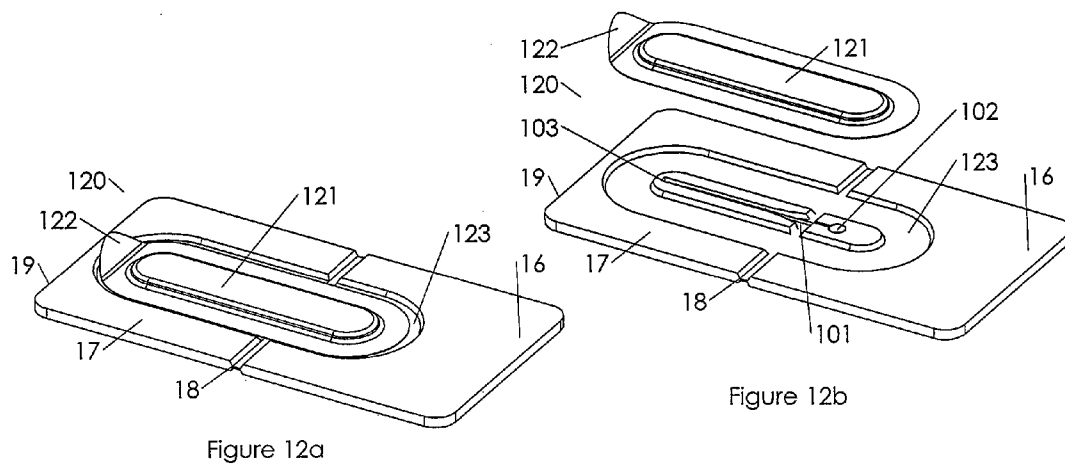
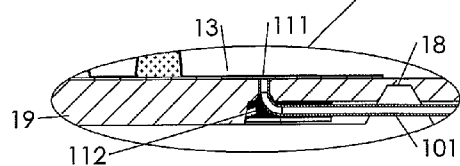
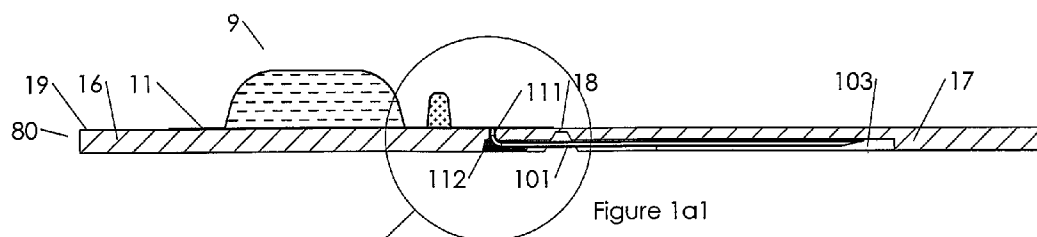


Figure 10f





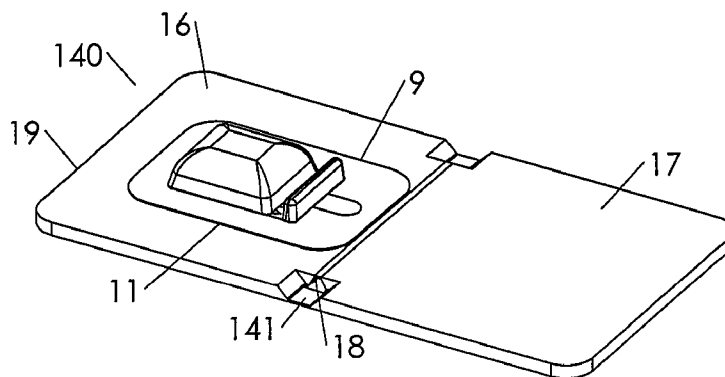


Figure 14

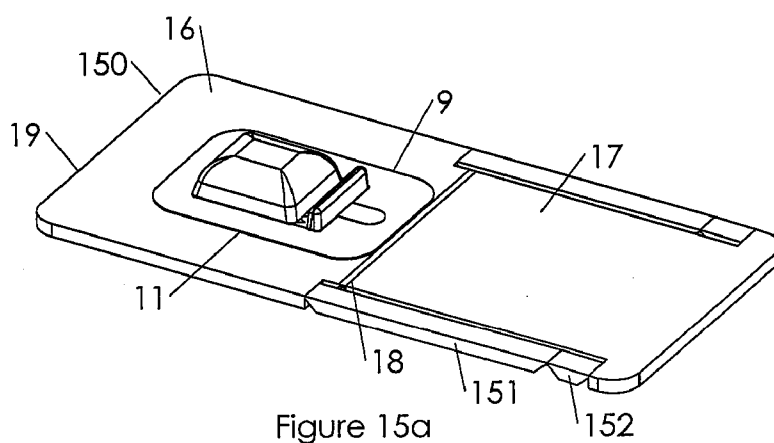


Figure 15a

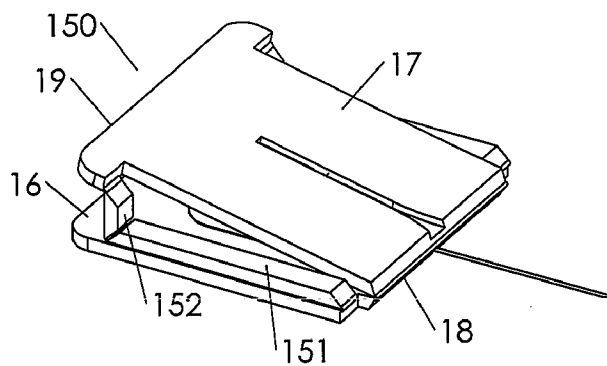


Figure 15b

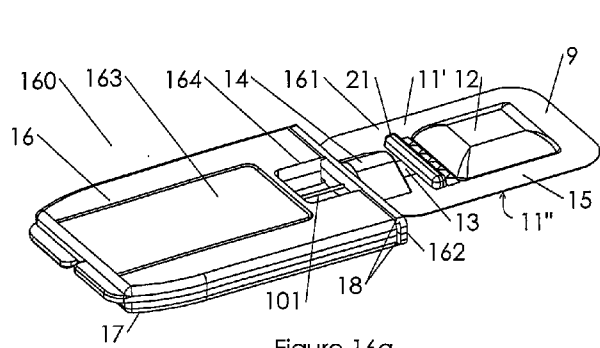


Figure 16a

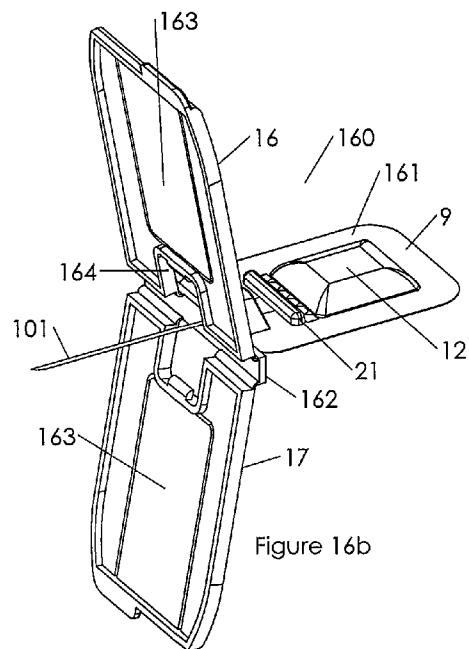


Figure 16b

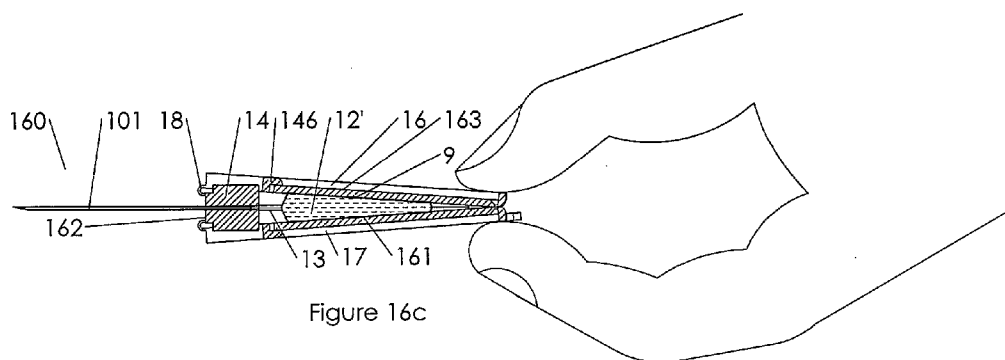


Figure 16c

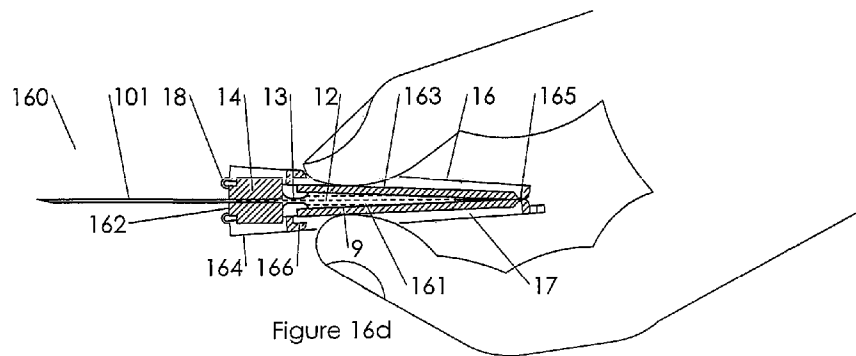
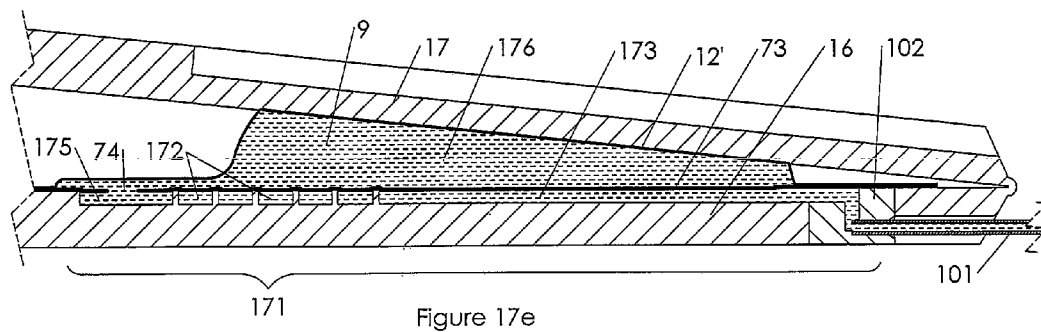
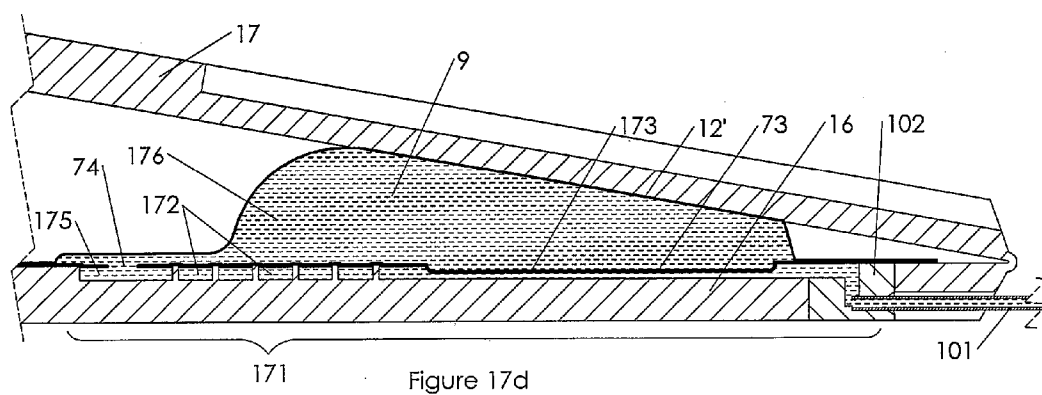
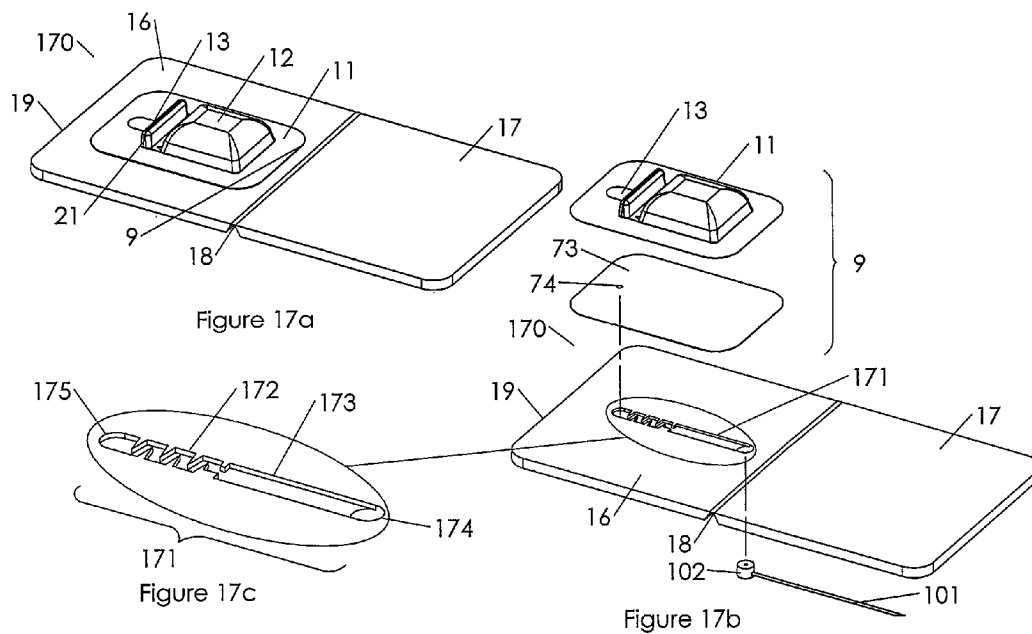


Figure 16d



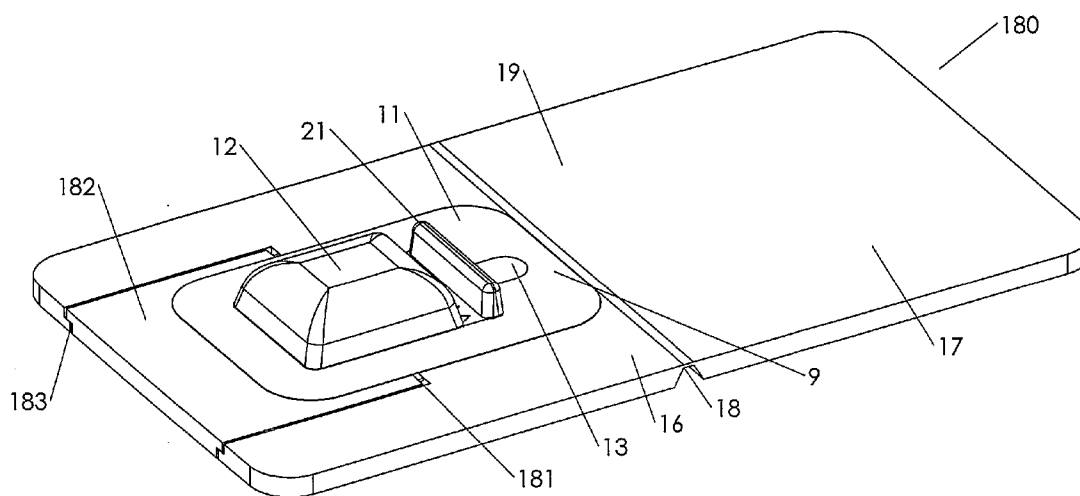


Figure 18a

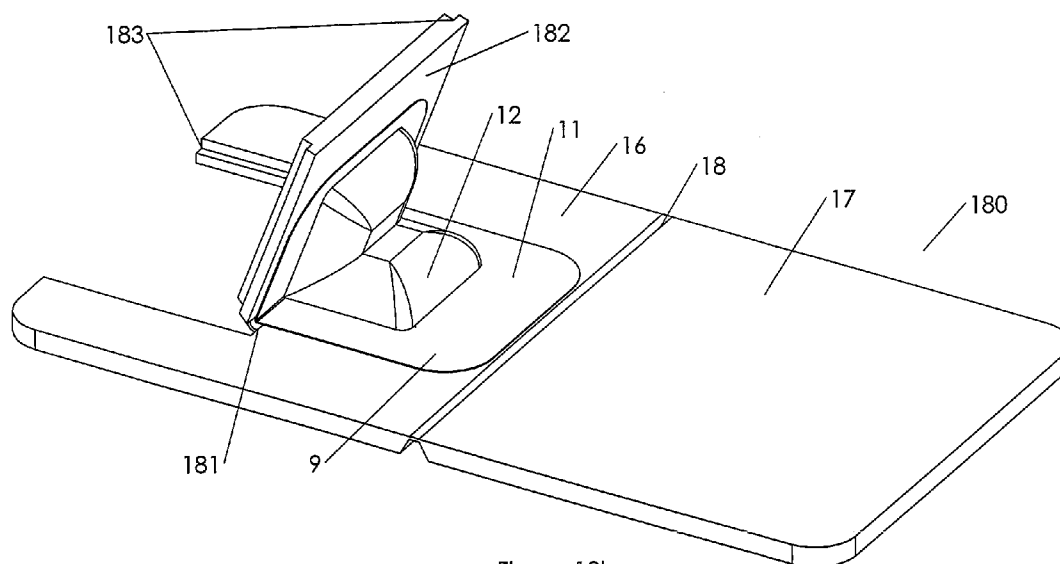


Figure 18b

## DISPENSING DEVICE ALONG WITH METHOD FOR DISPENSING PRODUCT

[0001] The present disclosure relates to a device for dispensing a prefilled product. More particularly the present disclosure relates to device for dispensing a prefilled product comprising a unit-dose prefilled package where the product of said package is stored in one or more film or foil compartments.

### ABSTRACT

[0002] A device for storing and dispensing a product comprising a pre-filled unit-dose package comprising at least a first flexible wall and having at least a first compartment prefilled with dispensable fluid; at least one rigid backing, and a fluid transport device for transferring the product from said fluid compartment to a target location in a desired fashion. Prior of use, said product is hermetically separated from said fluid transport device by a frangible outlet seal. The frangible seal is broken to establish fluid communication between the dispensable fluid and the fluid transport device. The arrangement is such that said rigid backing is manipulated to squeeze said package thereby causing said dispensable fluid to dispense through the fluid transport device.

### FIELD

[0003] The present disclosure relates to the field of dispensing packages in which the package is constructed from portions of films or foils (together here after sometimes referred to as “webs”) hermetically sealed about the perimeter of at least one chamber; and means to for rupturing said chamber to allow the content of said package to be dispensed.

[0004] U.S. Pat. No. 5,131,760 discloses a package which may contain a fluid material which is capable of being discharged from the package by the application of manual pressure from a thumb and forefinger to the package causing the package to burst in a controlled fashion to discharge the fluid material contained within the package. The package comprises a chamber which receives the fluid material discharged from a containing chamber after the containing chamber is burst by manual pressure, so as to control the rate and manner of discharge of the fluid material from the package. One disadvantage of the device taught by U.S. Pat. No. 5,131,760 is that the size of the package is substantially large to begin with and is further expanded when the containing chamber is merged with an outlet chamber. This makes it challenging to efficiently express the content of the package by directly depressing the flexible walls with the fingers or the palm. It is therefore desired to have a dispensing package having a more effective and practical expression capabilities. Furthermore U.S. Pat. No. 5,131,760 does not disclose a fluid transport device such as a hypodermic needle or a nozzle at the exit of the package, thus limiting its applications.

[0005] U.S. Pat. No. 5,176,634 and U.S. Pat. No. 6,203,535 each discloses a flexible container for the storage and mixing of diluents and medicaments. The container incorporates multiple compartments, separated by frangible seals, in which the diluents and medicaments are stored. The seals are ruptured by manipulation of said container to mix the contents. An additional frangible seal separates the merged diluents and medicaments compartment from the outlet compartment which for delivery through a standard IV arrangement to

a patient. These patents teach embodiments for gravitational IV applications and would have several short comings in unit-dose dispenser applications (e.g., where the dispensable fluid volume is smaller than 5 ml but would more likely be closer to 0.5 ml): As discussed above in the shortcomings of U.S. Pat. No. 5,131,760, the merger of the outlet compartment with the dispensable fluid compartment increasing the package size that needs to be depressed to dispense the contact making it inconvenient to perform efficiently. In the above invention the rupture of the frangible seal is achieved by folding the diluents compartment to pressurize the dispensable fluid compartment. While this folding approach may be practical in some embodiments of the present disclosure as will be demonstrated it is generally impractical for diluents compartments as small as 2 ml and in some embodiments as small as 0.5 ml. Furthermore U.S. Pat. No. 5,176,634 and U.S. Pat. No. 6,203,535 do not disclose means for forced delivery of the content.

[0006] U.S. Pat. No. 4,955,871 discloses a single-use disposable syringe. In the syringe, a product compartment is formed of two flexible sheets of thermoplastic material having expanded central portions that form a pair of convex domes. Both of the domes are compressible by directly applying force with two fingers. A product based on this invention is currently commercialized by Becton Dickinson and Company (Franklin Lakes, N.J.) under the product name Uniject™.

[0007] The expression rate of the dose contained within this syringe depends on the physiology of the user's finger pads and the form of depression of the fingers on the package; thus complete or consistent dose delivery can not be ensured. Another disadvantage of this embodiment is that the device is held at its one end between two fingers while the needle is fixed at the other end of the device with only films communicating between the two ends. Therefore the control of the needle and the firmness in the user hand is limited.

[0008] In the present disclosure the fluid transport device has the firmness and precision by incorporating a rigid backing that communicates the user hand and the fluid transport device through a rigid backing.

### SUMMARY

[0009] The present disclosure preferably discloses a pre-filled unit-dose product dispensing device comprising a package comprising at least one flexible wall and having at least one substance compartment prefilled with dispensable fluid; at least one rigid backing, and a fluid transport device for transferring the product from said fluid compartment to a target location in a desired fashion. Prior to use, the dispensable product is hermetically separated from the fluid transport device by a frangible outlet seal (hereafter sometimes referred to as “outlet seal”). At the point of use the outlet seal is broken to establish fluid communication between the dispensable product and the fluid transport device. The arrangement is such that said rigid backing facilitates efficient expression of the product from said package through the fluid transport device.

[0010] In the present disclosure a dispensable fluid compartment is squeezed directly or indirectly by pressing with the fingers on the flexible walls of a dispensable fluid compartment. The “footprint” of the compartment can be regarded as the actual area of the compartment that would need to be squeezed to efficiently expel the content of said compartment. In many flexible wall packages construction

the “footprint” is the perimeter of the dispensable fluid compartment about where said flexible wall is sealed to a second wall.

**[0011]** The package comprises at least one flexible wall that can be depressed to pressurize the product in at least one compartment of the package. Expression of the product from the package can occur by direct depression of the flexible wall against the rigid backing or by an instrument such as a compression panel that depresses the flexible wall against the rigid backing. The flexible wall is sealed about a perimeter of at least one compartment to at least one additional wall, to form two types of seals: a permanent seal and a frangible seal. The permanent seal is applied about the perimeter of the compartment(s) except where the seal needs to be ruptured to establish fluid communication between said compartment and an adjacent compartment or a compartment and a fluid transport device. U.S. Pat. No. 6,203,535, U.S. Pat. No. 5,176,634 and U.S. Pat. No. 5,131,760 disclose materials and methods for forming flexible packages with a combination of frangible and permanent seals and are incorporated herein by reference in their entirety. One multi-layer film material suitable for making a frangible seal and a permanent seal in designated areas of the package in a controlled fashion is X203-2113-L from PerfecSeal (Oshkosh, Wis.). The adhesive layer of this material will form an hermetic yet weak bond at about 130° C. and a strong permanent bond when sealed at about 170° C. In some embodiments the package comprise numerous compartments, containing different substances of the dispensable product, separated by frangible seals which are ruptured such that during operation the compartments are merged and substances can be mixed into the dispensable product. In some embodiments at least one of said compartments contains a diluent and at least one of said compartments contains dry substance; the dry substance can be in a form of loose flowing powder, compressed powder, granules, pellets, solid, pill, lyophilized cake, coating attached to a solid matrix, dry substance associated to a solid matrix, etc; In some embodiments at least one compartment contains diluents and at least one additional compartment contains a vaccine or a medication in a dry form. The compartments are merged prior to dispensing, in order to reconstitute the vaccine or medication.

**[0012]** The fluid transport device can be any mechanism suitably for transporting the product from the package to a target location in a preferred form. The fluid transport device can be formed in or between the walls of the package, or it can be a part or an assembly associated with the package as an insert or a fitment. Alternatively the fluid transport device can be implemented between a flexible wall and the rigid backing, or implemented in, or as an attachment to, the rigid backing. The fluid transport device can be in various forms and fashions such as a: dropper; spray nozzle; topical, optalmic, nasal, or ear applicator, dropper or sprayer; a brush, sponge, or other absorbent media for spreading the content to a surface; a tube, a canula, or capillary tube; a needle, a rigid or flexible canula or other sharp object for penetrating a tissue; a connector, a Luer Slip connector, a Luer Lock connector, for communicating with a fluidic system; a combination of the above; an extension, coupler, or connector to one of the above; etc.

**[0013]** The rigid backing may be made of at least one rigid member against which the package can be squeezed to cause the product to expel through the fluid transport device. In some embodiments the rigid backing also supports squeezing of at least one compartment of the package causing several

compartments to merge prior to delivery or to cause the outlet seal to rupture and establish fluid communication with the fluid transport device. The rigid backing further provides firm physical communication between the hand of the user and the fluid transport device, such that a user holding the rigid backing will have precise and sensitive control on moving and positioning the dispensing end of the fluid transport device, which is particularly important when the fluid transport device is a hypodermic needle, eye dropper or any other fluid transport device that requires sensitivity and precision in handling.

**[0014]** In some embodiments the package is permanently attached to the rigid backing. In other embodiments the package is attached to the rigid backing at the point of use.

**[0015]** In some embodiments the rigid backing provides one of the walls of the package.

**[0016]** In some embodiments the rigid backing provides protection to and from the fluid transport device before and after use.

**[0017]** In some embodiments the rigid backing accommodates a flow regulator for preventing the dispensable fluid from bursting through the fluid transport device when the package is ruptured.

**[0018]** In some embodiments the rigid backing accommodates a check valve for preventing backflow from the fluid transport device into the package.

**[0019]** In another embodiment a peelable flexible cover as proposed in U.S. Pat. No. 6,203,535 is attached to the surface of the package and covers at least part of the compartment(s) to further reduce light exposure of the product or substances and reduce oxygen or humidity transfer from and to the package.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0020]** FIG. 1 illustrates a preferred embodiment where the package comprises a single compartment, and the fluid transport device is an inserted fitment having a fashion of a Luer Slip connector;

**[0021]** FIG. 2 illustrates a preferred embodiment where the package comprises two compartments separated by a frangible seal, with the fluid transport device is an inserted fitment being in a fashion of a Luer Slip connector;

**[0022]** FIG. 3 illustrates a further preferred embodiment where the package comprises two compartments, each connected to the fluid transport device through a separate outlet seal;

**[0023]** FIG. 4 illustrates a further preferred embodiment where the fluid transport device is an external fitment attached to a wall of the package;

**[0024]** FIG. 5 illustrates a further preferred embodiment where the fluid transport device is formed by the walls of the package. The package comprises two sheets of material sealed together about a perimeter of the compartments;

**[0025]** FIG. 6 illustrates a further preferred embodiment where the package comprises one sheet of material sealed to the backing about a perimeter of the compartments;

**[0026]** FIG. 7 illustrates a further preferred embodiment where the fluid transport device is created between the package and the backing;

**[0027]** FIG. 8 illustrates a further preferred embodiment where the fluid transport device is embedded between the package and the backing and where the package comprises multiple compartments;

[0028] FIG. 9 illustrates a further preferred embodiment where the fluid transport device is embedded in the backing;

[0029] FIG. 10 illustrates a further preferred embodiment where the fluid transport device is a hypodermic needle which communicates with the package through a plastic hub;

[0030] FIG. 11 illustrates a further preferred embodiment where the fluid transport device is a hypodermic needle which communicates with the package without a plastic hub;

[0031] FIG. 12 illustrates a further preferred embodiment where the device comprises a sterile needle wrap;

[0032] FIG. 13 illustrates a further preferred embodiment which comprises a fluid transport device destruction mechanism at the end of the use;

[0033] FIG. 14 illustrates a further preferred embodiment where the backing comprises a spring feature for biasing the compression panel in a desired position relative to the backing;

[0034] FIG. 15 illustrates a further preferred embodiment comprising a latching arm for limiting movement of the compression panel relative to the backing;

[0035] FIG. 16 illustrates a further preferred embodiment where the package is not attached to the surface of the backing;

[0036] FIG. 17 illustrates a further preferred embodiment where the device comprises a flow regulator; and

[0037] FIG. 18 illustrates a further preferred embodiment where the reservoir product compartment is positioned over a fold line in the backing.

[0038] FIG. 19 illustrates a further preferred embodiment which does not include a compression panel.

#### DETAILED DESCRIPTION OF THE DRAWINGS

[0039] In reference to FIG. 1, a preferred embodiment of the device preferably in the form of a prefilled unit-dose dispensing package of the present disclosure present disclosure (hereafter “the device”) 10 is illustrated. FIG. 1a and its detail view in FIG. 1b generally illustrate general view of the device 10 prior to activation. The device 10 generally incorporates a package 9 comprising a product compartment 12, partially defined by a flexible wall 11, is prefilled with a dose of a dispensable product; a fluid transport device 14 for communicating the product to a target location in a desired fashion; and a rigid backing 16 supporting the package 9. The backing 16 joined with a compression panel 17 through a hinge 18. The compression panel 17 can be manipulated to rotate along the hinge 18 and depress the compartment 12 and cause said product to dispense through the fluid transport device 14. The device 10 further comprises a frangible outlet seal 13 which, until activation, hermetically separates the dispensable product in the compartment 12 from the fluid transport device 14, said outlet seal is rupturable when the product compartment 12 is pressurized beyond a predefined pressure threshold. The first flexible wall 11 is permanently seals along a first peripheral margin 15 of said first compartment 12 and non-permanently sealed along a second peripheral margin of said first compartment 12 to define a frangible outlet seal 13 located between said product compartment 12 and said fluid transport device 14 such that, when said outlet seal is ruptured, a fluid communication is established between product and said fluid transport device 14. In one embodiment the arrangement is such that by depressing the package 9, a pressure develops in the product compartment 12 which causes the outlet seal 13 to rupture by separating the frangible seal between the first flexible wall 11 and a second wall of the

compartment 12, establishing fluid communication of the product with the fluid transport device 14, thereby activating the device 10 to dispense the product to a target location in a defined fashion. The compartment 12 can be squeezed directly by a thumb, or by folding the compression panel 17 over the rigid backing 17, such that the package 9 is sandwiched between said compression panel 16 and the backing 17. Alternatively the package 9 can be depressed by another machine or apparatus, made to operate said device or by other means as appropriate.

[0040] The package 9 comprises at least one flexible wall 11 made from a thin laminate (commonly referred to as “web”) such as a film or a foil sealed about the perimeter of said product compartment 12, having a seal on one portion 13 of said perimeter which will separate under pressure in the product compartment 12, while the rest of the seal 15 is a permanent seal that will not separate under that threshold pressure. The permanent seal 15 continuous along the outlet seal 13 such that when the outlet seal 13 is ruptured a fluid passageway forms and strictly communicates the dispensable fluid with the fluid transport device 14.

[0041] In some embodiments the flexible wall 11 is sealed directly to the rigid backing 19 such that the product compartment 12 and the outlet seal 13 are formed between the rigid backing 19 and the flexible wall 11.

[0042] In another embodiment the package 9 is established by the flexible wall 11 sealed to at least one additional wall (not shown) such that the compartment 12 and the outlet seal 13 are formed interposed between the flexible wall 11 and said additional wall. The advantage of such embodiment is that the package can be produced on a more common Form-Fill-Seal or Fill-Seal line and introduced to the backing at a subsequent manufacturing stage.

[0043] In another embodiment a combination of certain foregoing embodiments is made such that the compartment 12 and the outlet seal 13 are formed partly between the flexible wall 11 and the rigid backing 16, and partly between the flexible wall 11 and at least one additional wall.

[0044] The rigid backing comprises a rectangular flap 16 joined along one edge with and a rectangular compression panel 17, via a thin flexible section which forms a hinge 18, and defines a fold line. Depending on the application requirements and the preferred form of manufacturing, the hinge 18 can be produced as a molded living hinge or in other forms and types of rotating hinges or flexible joints solutions known in the art. The rigid backing 16 can be made of various materials and in various processes including molded plastic, plastic sheet or board (single layer, multi-layer, extruded, blown, laminated, etc.), sheet metal, cast alloys, paper board, composite materials, ceramics, or a combination of the above. In some embodiments the living hinge 18 can be molded integrally with the backing. In other embodiments the backing 16 and the compression panel can be made as one integral molded part. When backing 16 is made from a sheet or a board the thin section for forming the living hinge can be formed by locally cutting out (machining, evaporating, laser cutting, etc.) part of the wall thickness along the designated fold line, selectively removing specific materials from the composition of the bulk material (such as removing a thermoplastic resin by heat, and leaving thermoset fibers or mash behind), or by compression or heat molding in a secondary section. Where the backing 16 is made from sheet metal, the living hinge can be formed by a flat section of said sheet while the backing 16 and the compression panel 17 are strengthened by folding up



their edges. In some embodiments the flexibility of the living hinge **18** vs. the rigidity of the backing **16** and the compression panel **17** is achieved at least partly due to material treatment such as local heat treatment, selective surface treatment or selective composition variation. In some embodiments the living hinge section **18** can be formed by an added layer of flexible material interposed between the rigid backing **16** and the compression panel **17** along the designated fold line. In one embodiment this flexible layer is a label. The additional layer can be locally attached along the edge closest to the fold line, or it can cover broader parts or an entire facet of the backing **16** and/or the compression panel **17**. The added on layer can be pre-printed with the desired graphics or information. In yet other embodiments, the living hinge section **18** can be made from a resilient material. The resilient material section can be formed by one of the means known in the art including pre-making and attaching between the flaps, co-molding, co-extrusion, insert-molding, etc. In one embodiment a wall of the package **9** is substantially rigid to provide the backing. In one embodiment a wall of the package **9** is substantially rigid and extends to provide the compression panel. It will be obvious to those skilled in the art that a folding hinge **18** can be formed in other methods such as in the form of a door hinge where an axis runs along the fold line through fixtures (such as bores) in each of the flaps **16** & **17**, or a socket and meniscus arrangement as is common in various plastic products. The backing and the compression panel **16** & **17** may have any shape and are not limited to the mostly thin-rectangular shape apparent in FIG. 1.

[0045] The fluid transport device **14** comprises a proximal end having a form of a pouch insert fitment commonly used in pouch containers for connecting a cap or a spout to a flexible package. The fitment is sealed in a fluid tight fashion between the flexible wall **11** and the additional wall (not shown) such that, upon activation, the product flowing in the fluid passageway **13** is restricted to flow into the inner passage of the fluid transport device **14**. The distal end of the fitment **14** is in a fashion of a Male Luer Slip connector which is commonly used in medical fluidic systems related to drug delivery or fluid management. The Luer Slip connector **14** can be used as a spout for directly dispensing the product to a target or to communicate with a Female Luer connector of another device or system such as a hypodermic needle hub, a Y-site injection point of an infusion system and so forth. Thus the fluid transport device **14** in a form of a Luer Slip connector creates a range of possible applications for the dispensing package **10** of the present disclosure. In one embodiment the device receives a hypodermic needle and functions as a medical syringe. In another embodiment the device **10** is a prefilled unit-dose of medication for introduction to an infusion set through a Y-Site. The fluid transport device may include a replaceable closure for resealing the package. In other embodiments the distal end of fluid transport device **14** is of different fashion such as a hypodermic needle attached directly to the fitment **14**; a connector to a tube, capillary tube or a hose; a Luer Lock connector; a foam or other absorbent pad for topical application to a surface such as the skin; a spray head; a nasal sprayer or dropper; an oral or eye dropper; an irrigation nozzle; a mini needle or needles; a micro-needle or micro-needles array; a jet injector; or an extension/coupling unit to one of the above.

[0046] Referring now to FIG. 1c and its enlarged detail view in FIG. 1d, the device **10** is illustrated at a post activation state, where the outlet seal **13** has been separated (the Figures

shows the frangible section inflated relative to FIGS. 1a and 1b) and fluid communication has been established between the compartment **12** and the fluid transport device **14**. It should be understood that the outlet seal has been separated either by: application of force directly to the compartment **12** (for instance by depressing with a thumb); by folding the rigid backing **19** and squeezing the product compartment, or by another apparatus that serves this approach. The outlet seal **13** is defined as a section produced such that the force required for separating the seal is lower than the force required for separating the permanent seal **15**. U.S. Pat. No. 5,176,634, U.S. Pat. No. 6,203,535, and U.S. Pat. No. 5,131,760 disclose materials, methods and processes for producing selective areas of frangible seal in an otherwise permanent seal package. One concern with frangible seals is that the excess pressure generated for rupturing the frangible seal may cause a burst of the product through the fluid transport device **14** at the instant that the frangible seal **13** is ruptured. In one embodiment at least part of the fluid path between the compartment **12** and the outlet of the fluid transport device **14** acts as a flow restrictor either by limiting the cross section of the passage, by extending the length of the flow passage, or by posing features in the flow passage which increase drag and pressure drop. In another embodiment the outlet seal **13** is made such that the seal strength is gradually or incrementally decreasing along the direction of the flow path. Thus a certain threshold pressure is required to initiate the separation of the frangible seal, while the following front of the separation requires lower pressure to separate and so forth until the frangible section **13** is completely separated and a flow communication is established between the product compartment **12** and the fluid transport device **14**, at which point the fluid passageway **13** is wide open and the resistance to the dispensing flow is relatively low.

[0047] FIG. 1e illustrates the device at a dispensing orientation where the compression panel **17** is folded over the rigid backing **16** such that the compartment **12** may be squeezed between the two.

[0048] In a further embodiment the device incorporates a one-way valve for preventing refill of the package **9** after its first use. The valve can be incorporated in the fluid transport device, or in the fluid passageway or in the compartment and can be formed or disposed: between the walls of the package; between the package and the backing; or in the backing.

[0049] Referring now to FIG. 19, a further preferred embodiment is illustrated which does not include a compression panel. The package **9** can be squeezed by direct depression of a thumb or by depressing a separate compression panel. In one embodiment the device is associated with and apparatus that is made to operate the device which includes a compression panel for depressing the package **9**. The compression panel is not limited to a flat pad that is apparent in FIG. 1, and can be in other forms known in the art such as a curved panel or a roller.

[0050] Referring now to FIG. 2, a further preferred embodiment **20** is illustrated which is similar to the embodiment of FIG. 1. Here, the first compartment **12** contains a first substance, and the flexible package **9** comprises a second compartment **21**, prefilled with a second substance. Prior to activation, the two compartments are hermetically separated by a second frangible seal **13** (hereafter sometimes referred to as the "mixing seal") which is ruptured at the point of use by pressurizing one or both of the compartments **12** and **21**. The first substance and the second substance need to be mixed to

form the dispensing (or mixed) product prior to dispensing. FIG. 2a illustrates the device 20 in the rest position, prior to activation showing the first compartment 12 and the second compartment 21 separated by the mixing seal 22. FIG. 2b shows a broken top view of the device 20 revealing in more details the form of the flexible wall 11. The mixing seal pattern resembles like saw teeth which, during activation, cause stress concentration to facilitate the rupture of the mixing seal 22.

[0051] FIG. 2c shows a broken side view of the pre-activation state of the device 20. The product compartment 12 and the second compartment 21 have a relatively deep form (i.e. deep cavity with small sealing footprint). Fluid pouches or blisters are commonly made relatively shallow, and the unique shape of the current compartments 12&21 are advantageous to reduce the depression surface during activation and dispensing resulting in higher pressure of the substances and a more efficient expression of the product. The deep cavities of compartment 12 and 21 also allow for longer depression travel and thus offer continuous pressure to allow for rupturing of the frangible seal 22 from end to end until the two compartments 12 and 21 form one continuous chamber. In conventional pouch where the compartments are relatively shallow to the compartments in this embodiment, it would be more challenging to completely rupture the frangible seal as after the initial rupture there would be no additional depression travel that will allow forcing the entire frangible seal to separate.

[0052] FIG. 2d and its enlarged detail view in FIG. 2e demonstrate the device 20 after merging the first compartment 12 with the second compartment 21 of the package 9, at a pre-activation state (i.e., before rupturing the outlet seal). The new merged compartment 12' (hereafter still sometimes referred to as "compartment 12" or "product compartment") has a continuous chamber form which facilitate mixing of the contents of the original package compartments 12&21. In some embodiments the second substance is a dry powder, gel, or paste or a solid which has the tendency to stick in corners and be difficult to dissolve, and the smooth integral shape of the merged compartment 12' facilitates mixing of the second substance with the first substance. In FIG. 2e it is apparent that the outlet seal 13 is in its flattened sealed state prior to activation. The pressure required for separating the outlet seal 13 is higher than the pressure required for separating the mixing seal 22, thus avoiding a situation where the device 20 is activated prior to a complete separation of the mixing seal 22 and the complete mixing of the contents of the two compartments 12 and 21 to form the dispensable product.

[0053] FIG. 2f and its detail view 2g illustrates the device 20 at a post-activation state, after the product compartment 12' has been further pressurized (pressure higher than that used to cause the compartments 12 and 21 to merge) and the outlet seal 13 has been ruptured. In FIG. 2g it is apparent that the fluid passageway 13 is inflated after the frangible outlet seal is ruptured. In another embodiment the rupturing force threshold for the outlet seal 13 is not higher than that of the mixing seal 22.

[0054] FIG. 2h demonstrates the device 20 in a dispensing position where the compression panel 17 is folded over the backing 16 to squeeze product compartment 12' and cause the product to disperse through fluid transport device 14. In some embodiments the mixing step, activation step, and dispensing steps which are illustrated above as a sequence of incremental steps, are combined into a single continuously flowing action

of folding and depressing the compression panel 17 over the backing 16 to cause the above sequence.

[0055] In another embodiment the dispensing package comprises at least one more compartment that is merged with the first compartment 12 in the same fashion as the second compartment 21 does. Embodiment 20 is particularly advantageous where the stability of the finished product can be extended by keeping a certain first substance separated from a second substance of the product until the point of use. In one embodiment the second compartment contains a dry medical substance such as vaccine or antibiotics that need to be reconstituted with a diluent prior to delivery. In other embodiments the second substance is a bio-pharmaceutical in a thick gel form (which extends its shelf life) which needs to be diluted with the first substance in order to be delivered through a thin needle.

[0056] Referring now to FIG. 3 a further preferred embodiment 30 is illustrated where the package 9 comprises two first compartments 12' and 12" which are activated and dispensed in parallel in the same fashion as done with the single compartment embodiment 10 of FIG. 1. The fluid passageway 13, which includes at least one outlet seal, interconnects the compartments 12' and 12", and directs their content to the fluid transport device 14. It will be obvious to those skilled in the art that each of the compartments 12' and 12" can incorporate companion substance compartments to be merged with the first compartments 12' and 12" to form the product, as illustrated with embodiment 20 in FIG. 2. Additionally it will be obvious to those skilled in the art that a similar embodiment to embodiment 30 may comprise more than two first compartments in parallel embodied in a single package or multiple packages. In a further embodiment the common section of the fluid passageway 13 to compartments 12' and 12" comprises features that facilitates mixing of the products of the two compartments 12' and 12", prior to reaching the fluid transport device 14. In another embodiment the fluid transport device comprises mixing elements for mixing the substances of the product. The mixing element can be at least partially disposed or formed in one or more of: between the walls of the package 9; between the package 9 and backing 16; in the backing 16.

[0057] Referring now to FIG. 4a a further preferred embodiment 40 is demonstrated where the fluid transport device 41 is a fitting joined to the external side of the flexible wall 11. FIG. 4b illustrates the device 40 in an exploded view. The proximal end of the fitting 41 has a form of a flange for sealing to the surface of the wall 11 around an opening 42 in the fluid passageway 13. The distal end of the fluid transport device 41 has the form of a Luer Slip connector.

[0058] Referring now to FIG. 5, a further preferred embodiment 50 is demonstrated where the fluid transport device 51 is merely the distal end of the fluid passageway 13 shaped like a tip 51. FIG. 5a demonstrates the arrangement such that the fluid passageway 13 leads to the fold line 18 of the backing 16 where an opening 52 in the hinge section 18, between the backing 16 and the compression panel 17, receives the dispensing tip 51 of the fluid passageway 13. Thus the fluid transport device 51 is integrated in the package 9. FIG. 5b illustrates the administration position of the device 50. The compression panel 17 is folded over the backing 16 such that the merged product compartment (not shown) is squeezed between the two. The dispensing tip 51 shows in the opening 52 allowing a convenient dispensing of the contents to a target when the device 50 is folded. The advantage of this arrange-

ment is that it avoids the fitment which is incorporated in some of the embodiments above which adds manufacturing cost and complexity to the manufacturing equipment. FIG. 5c illustrates an exploded view of the device 50 revealing a second wall 53 which seals with the flexible wall 11 to form the compartment 12. The dispensing tip 51 can be formed in various shapes to support a specific application including: a) long or short tip, b) wide or narrow outlet, c) single or multiple outlets, d) irrigation, dripping or spraying tip, e) topical applicator or dropper, etc.

[0059] Referring now to FIG. 6, a further preferred embodiment 60 is illustrated, mostly similar to embodiment 20 of FIG. 2, here with the flexible wall 11 covering the backing 16 and the compression panel 17 in its entirety, as shown in FIG. 6a. The compression panel 17 may be made to coincide with the footprint of the compartment. In addition, as shown in the exploded view in FIG. 6b, the flexible wall 11 seals directly against the backing 16 to form the package 9 (including the product compartment 12, the second frangible seal 22, the second compartment 21 and the frangible seal 13). The backing 16 can be made from a substantially rigid film or foil sheet, and can be printed with information such as graphics or texts.

[0060] Referring now to FIG. 7 a further preferred embodiment 70 is illustrated where the fluid transport device is partially embedded in the backing 16. FIG. 7a demonstrates the device 70 at a pre-activation position. The fluid passageway 13 is facing the fold line 18, where an opening 52 between the backing 16 and the compression panel 17 receives a pointy tip of the flexible package 9. The fluid passageway 13 ends before said tip 72 thus slightly chocking the outlet channel and restricting the product flow to the tip 72. FIG. 7b shows the device 70 in the dispensing position. The dispensing tip 72 is emerging through the opening 52 in the fold line 18 allowing for convenient dispensing of the product.

[0061] FIG. 7c and its detail view FIG. 7d illustrate exploded view of the device 70. The flexible wall 11 is sealed to a second wall 73 to form the package 9. A through hole 74 in the second wall 73 is aligned with the distal end of the fluid passageway 13 such that when the outlet seal 13 is separated, the product 9 flows through the fluid passageway 13 and out through hole 74 in the additional wall 73. The fluid transport device is a groove 71 in the backing 16 which is sealed over with the additional wall 73 to form a closed fluid passageway between the hole 74 and the dispensing tip 72. Thus the fluid passageway is partly interposed between the rigid backing and package 9. The dispensing tip is formed between the distal end of the groove 71 and the edge of the additional wall 73. The distal end of the groove can be formed in various shapes to generate the desired dispensing pattern including: single nozzle, multi nozzle, long or short nozzle, irrigation nozzle, drops nozzle, spray nozzle, etc. Thus at least a portion of the fluid transport device is partly interposed between the rigid backing and the package 9.

[0062] Referring now to FIG. 8, a further preferred embodiment 80 is illustrated which is mostly similar to embodiment 70 of FIG. 7, here embodiment 80 comprising multiple first compartments 12' and 12'' and additional compartments 21' and 21'' in parallel, as is apparent in FIG. 8a. FIG. 8b illustrates an exploded view of the device 80, exposing the T shape groove 81 which, when sealed on top with the package 9, forms a closed fluid passageway between the compartments and the dispensing tip 72. In one embodiment the groove 81

further comprises features for enhancing the mixture of the flows coming down from the different merged compartments. It will be obvious to those skilled in the art that similar embodiments can include more than two sets of compartments in parallel, embodied in one or more packages.

[0063] Referring now to FIG. 9, a further preferred embodiment 90 is illustrated. The embodiment 90 is substantially similar to the above embodiments 70, here with the fluid transport device being completely embedded in the backing 16. FIG. 9a illustrates the device 90 in the pre-activation position where the dispensing tip 91 is seen in the opening 52 in the fold line 18.

[0064] FIG. 9b illustrates the device 90 in the dispensing position where the backing 19 is folded and the dispensing tip 91 emerges from the opening 52 to conveniently dispense the product from the merged compartment.

[0065] FIG. 9c and its enlarged detail view in FIG. 9d illustrates an exploded view of the device 90. The hole 74 in the second wall 73 is aligned with a hole 91 in the backing 16 that communicates with an internal fluid passageway 93 in the backing 16 that leads to the dispensing tip 91 in a fashion of a dropper. The dispensing tip can be formed in various forms and can receive additional parts to form the desired nozzle form for specific applications such as irrigation, spray, jet, etc. Alternatively, the fluid transport device can merely be an adapter, connector, or extension to a nozzle of the kind mentioned above. Thus embodiment 90 illustrates a fluid transport device that is integrated in the backing 16, and a fluid passageway that is partially integrated in the backing.

[0066] It will be obvious to those skilled in the art that the fluid transport device can be a combination of those shown in FIGS. 5, 7 and 9 such that the fluid passage from the product compartment or merged compartment to the dispensing tip passes: a) between the flexible wall 11 and at least one additional wall, b) between the flexible wall 11 and the backing 16, c) in an internal passage in the backing 16, and in addition d) through an add on components that communicate with the backing 16.

[0067] Referring now to FIG. 10, a further preferred embodiment 100 is illustrated where the device 100 is a unit-dose prefilled reconstitution and delivery hypodermic syringe. FIG. 10 illustrates the first side of the device 100 which is similar in form and function to that of embodiment 90 of FIG. 9.

[0068] FIG. 10b illustrates the second side of the device 100 in the pre-activation state, showing that the fluid transport device incorporates a hypodermic needle 101 having its proximal end connected to a needle hub 102. The needle hub 102 is accommodated in a fluid tight fashion in an opening in the backing 16, and receives the product after activation. A recess 103 in the compression panel 17 accommodates the distal end of the needle 101 and provides protection from mechanical damage to it as well as protection from needle sticks to the user.

[0069] FIG. 10c illustrates a section view of the device 100 at the pre-activation stage. The second compartment 21 contains an active medical ingredient 105 such as dry powder or lyophilized vaccine or medication, and the product compartment 12 contains a diluent 104 for reconstituting the dry active ingredient 105 at the point of use. The communication channel 13 (which in this position is flattened and sealed) leads to a vertical channel 106 in the hub 102 which is in fluid communication with the needle 101, and the arrangement is

such that, after activation, fluid from the flexible package 9 can strictly flow to the needle 101 when the merged compartment is depressed.

[0070] FIG. 10d illustrates the device 100 after the first compartment 12 and the second compartment 21 of the package 9 have been merged 12' to create the product.

[0071] FIG. 10e illustrates the device 100 after activation where the outlet seal 13 has been ruptured (shown inflated relative to FIG. 10d) forming a fluid passageway (13) with the needle hub 102.

[0072] FIG. 10f shows the device in the dispensing position where the merged compartment 12' is squeezed between the backing 16 and the compression panel 17 expressing the product from compartment 12' through the needle 101. By folding over the compression panel 17 over the backing 16, the needle 101 is exposed to conveniently apply to a patient. It will be obvious to those skilled in the art that the sequence of incremental steps presented between FIGS. 10c and 10f can be performed as one continuous action by merely folding the compression panel 17 over the backing 16. It will also be obvious to those skilled in the art that the needle 101 can be directly associated to the backing 16 to eliminate the needle hub.

[0073] Referring now to FIG. 11, a further preferred embodiment is illustrated which is substantially similar to embodiment 100 of FIG. 10, here with the needle 101 directly attached to the backing 16, thereby avoiding the hub (102 in FIG. 10). The proximal end of the needle 111 is bent at a right angle toward the fluid passageway 13. In this embodiment the needle 101 is attached to the backing 16 in one of the means known in the art such as glue 112.

[0074] Referring now to FIG. 12, a further preferred embodiment is illustrated where the device 120 comprises an integral sterile cover. FIG. 12a demonstrates the device 120 comprising a peel away sterile cover 121 applied directly to a recessed surface 123 of the backing 16 forming an aseptic zone around the needle, and keeping it sterile and protected until the time of use. In one embodiment the device 120 is sterilized in this configuration, without any additional sterile overwrap to the entire device 120, thus the fluid transport device 101 remains sterile until the time of use. In one embodiment the product 120 is sterilized by Gamma radiation. In another embodiment the cover 121 is made from a breathable web (such as Tyvec, Dupont) and the product 120 is sterilized by ETO. The walls around recessed surface 123 form a cavity that protects cover 121. A loose tab 122 facilitates the peeling of the cover 121 prior to use.

[0075] FIG. 12b illustrates the device 120 after the cover 121 has been removed. The living hinge 18 is located such that it forms a continuous flat surface with the recessed surface 123, providing a flat surface for attaching the cover 121. The cover 121 may be removably joined to the recessed surface 123 by an adhesive layer or by welding, or any other means known in the art. The needle 101 is connected to the needle hub 102 which in return is connected to the backing 16 in the same fashion as in embodiment 100 of FIG. 10. The needle is protected in the groove 103 in the compression panel 17 until the latter is folded for squeezing the package 9.

[0076] FIG. 13 demonstrates a further preferred embodiment 130 which comprises a mechanism for destroying the needle 101 at the end of the use of the product 130. FIG. 13a demonstrates the device 130 at the end of the dispensing stage where the compression panel 17 is fully rotated in the direction of the arrow until it is in complete contact with backing

16, and the product is completely expelled. The living hinge is located at about the midline of the thickness of the backing 16 such that it allows the compression panel 17 to rotate both ways from the flat pre-use position. The needle 101 is revealed for conveniently introducing it to a patient.

[0077] FIG. 13b demonstrates the device 130 after the compression panel 17 has been turned in a reverse direction of FIG. 13a, in the direction of the arrow (i.e. approximately 360 degrees around fold line 18) bringing the opposite sides of the compression panel 17 and the backing 16 to contact, and disabling the fluid transport device 101 by the compression panel 17. As the proximal end of the needle 101 is fixed to the backing 16, the turning of the compression panel 17 forces the needle to bend and be destroyed such that the device 130 cannot be reused, or the remaining product in the package cannot be abused. In addition in this position the needle 101 tip is protected from causing needle sticks after the product has been discarded. In one embodiment the device 130 comprises a feature that latches the backing 16 and the compression panel 17 in the discarded position such that the flaps can not be separated and the needle cannot be accessed once the device 130 is folded to this position.

[0078] Referring now to FIG. 14, a further preferred embodiment is illustrated. Two integral springs 141 stretching between the backing 16 and the compression panel 17, and are located in an offset position to the fold line 18, such that the compression panel is biased into one of a first and a second angular position relative to the backing 16. In one embodiment, the springs 141 bias into a first stable position in which the compression panel 17 lays flat with the backing 16 and a second stable position in which the compression panel 17 is folded over the backing 16 in the dispensing position. In another embodiment, the first stable position is when the compression panel 17 is partly folded over the backing 16, such that when the device 140 is removed from the package and is released from the flat position, the compression panel 17 will snap to the semi-folded position.

[0079] FIG. 15 illustrates a further preferred embodiment. Here, the rigid backing 16 and the compression panel are interconnected by hinge 18. In addition the backing 16 and the compression panel 17 are interconnected by pairs of cooperating joints to restrict movement of said pivot section in one pivot direction. Each of the two joints comprises two segments 151 and 152 linked by a flexible hinge, and where the first segment 151 is connected at one end to the backing 16 by a flexible hinge, and the second segment 152 is connected at its other end to the compression panel 17 by a flexible hinge, such that when the compression panel is pivoted the compression panel 17, the backing 16, the first segment 151 and the second segment 152 act like a "four bar mechanism". FIG. 15a illustrates the device in a flat pre-activation position where the segments 151 and 152 of the joint lie flat with the backing 16 and the compression panel 17. FIG. 15b illustrates the device 150 where the compression panel 17 is folded to a position where it is partly squeezing the first compartment causing it to merge with the second compartment. The arms are now folded such that the second segment 152 prevents the compression panel 17 from further folding toward the backing 16, thus preventing an unintentional or uncontrolled compression of the package 9, and a burst of the contents of the package when the device 150 is activated. In order to dispense the contents of the device 150 the joints need to be: a) flipped to the opposite position, or b) the hinges between segments 151 and 152 need to be broken. It will be obvious to those

skilled in the art that other mechanical stoppers could be implemented that will eliminate the burst of the content once the device is activated.

[0080] Referring now to FIG. 16, a further preferred embodiment 160 is illustrated in which the flexible package 9 is supported by the rigid backing only at the point of use. FIG. 16a demonstrates the device 160 in the pre-activation configuration. A package 9 is formed from a first flexible wall 11' and a second reciprocal flexible wall 11" sealed about their perimeters such that they form a product compartment 12 and a second compartment 21 separated by a mixing seal 22. An outlet seal 13 separates the second compartment 21 and the fluid transport device 14. The proximal end of the fluid transport device 14 is in the form of a pouch insert fitment and is sealed between the two flexible walls 11' and 11". The distal end of the fluid transport device 14 is a hypodermic needle 101, which at the pre-use state is confined between the backing 16 and the compression panel 17 which serve as a needle protector. The fluid transport device 14 further comprises a laterally extending platform 162 to which the first flap 16 and the second flap 17 are joined via a living hinge 18, such that each of the backing 16 and the compression panel 17 can pivot in opposite directions about 180 degrees toward the package 9. Each of the backing 16 and compression panel 17 further comprises a cantilever spring section 163 which extends from the distal edge of the backing 16 and compression panel 17 toward their proximal end.

[0081] FIG. 16b illustrates an intermediate position during the turning of backing 16 and compression panel 17. The backing 16 and compression panel 17 are pivoted around their hinges 18 toward the package 9, thereby exposing the needle 101.

[0082] FIG. 16c illustrates the device 160 after the backing 16 and compression panel 17 have been completely folded back such that their distal ends are touching each other. At this position the backing 16 is supporting the package 9 and the compression panel 17 is partly squeezing the package 9 against the compression panel 16 causing the product compartment 12 to merge with the second compartment 21 and the outlet seal 13 to separate and establish fluid communication with the fluid transport device 14. The arrangement is such that an only insignificant portion of the contents of the merged compartment 12' may expel at this position through the fluid transport device 14. In one embodiment the rotation of the backing 16 and compression panel 17 to this position does not separate the frangible seal and fluid communication is not being established between the merged compartment 12' and the fluid transport device. In one embodiment the rotation of the backing 16 and compression panel 17 to this position causes the outlet seal 13 to only partly separate such that fluid communication is not being established between the merged compartment 12' and the fluid transport device. In a further embodiment the outlet seal 13 is made such that the seal force is gradually lowering toward the fluid transport device 14, and the frangible seal 13 is partly separated such that fluid communication is not being established between the merged compartment 12' and the fluid transport device, but the force for separating the remaining part of the outlet seal 13 is lower than the force that was required for separating the initial portion of the frangible seal 13.

[0083] FIG. 16d illustrates the device 160 at the dispensing stage. The fingers of the user are repositioned to press on the cantilevers 163 causing the cantilevers 163 to deflect and further squeeze the merged compartment 12' thereby causing

the contents to expel until the backing 16 and compression panel 17 contact one another and the merged compartment is emptied. In one embodiment the cantilever springs 163 are connected in at least one additional location beside the joint 18, through a rupturable bridge which will: a) provide initial resistance to avoid unintentional squeezing of the merged compartment 12', and b) serve as evidence that the device 160 has not been tampered with.

[0084] The device 160 provides a mechanism for avoiding unintentional dispensing (or bursting) by dividing the operation of the device 160 into two main stages (i.e. activation and dispensing) which requires finger repositioning between said two stages.

[0085] Referring now to FIG. 17, a further preferred embodiment 170 is illustrated which comprises a flow regulator in the dispensing passage to avoid a burst of the contents when the device 170 is activated. FIG. 17a illustrates a general view of the first side of the device, showing a package 9 similar to embodiment 100 of FIG. 10, here the arrangement of the package 11 is turned in the opposite direction such that the fluid passageway 13 is facing away from the fold line 18.

[0086] FIG. 17b and its enlarged detail in FIG. 17c illustrate an exploded view of the device 170 showing an embossed channel 170 in the surface of the first flap 16, which when sealed over with the second wall 74 of the compartment 12 forms a closed fluid passage that serves as a dynamic flow regulator. A receptacle section 175 at the distal left end of the channel 171 communicates with the fluid passageway 13 in the package 9 and receives the fluid expelling from the package 9 when said package 9 is squeezed. A labyrinth portion 172 of the channel 171 communicates between the receptacle 175 and the regulating straight section 173 of the channel 171. The proximal end of the channel (right side in this figure) comprises an opening for accommodating the needle hub 102 such that flow entering the channel 171 will proceed through the channel 171 and into the needle 101. The purpose of the labyrinth 172 is to cause pressure dampening which increases with the increase in the flow rate.

[0087] FIG. 17d illustrates a broken section view along the flow channel 171 of the device 170 showing the device immediately after activation. The device 170 is already activated and a relatively high pressure is generated in the merged compartment 12'. This situation may occur at the instant after the device 170 was activated when the fingers of the user still exert relatively high force on the backing 16 and compression panel 17, which was required to rupture the frangible seal 13. Referring back to FIG. 17d, under the high pressure condition, the flow advances from the merged compartment 12' through receptacle 175 and into labyrinth 172 where it loses substantial pressure such that the flow received in the regulating stretch 173 is substantially lower than the pressure in the merged compartment 12'. As a result of the pressure difference between the fluid in the merged compartment 12' and the flow in the regulating stretch 173, the package is distorted such that the section of the additional wall 73 is stretching down into the regulating straight 173 and the cross section of the regulating straight 173 is reduced. The distortion of the package reduces the flow rate of the expelling fluid, thereby preventing bursting of the dispensable fluid through the fluid transport device 14.

[0088] FIG. 17e illustrates the device 170 in the administration phase. As the force exerted by the fingers is adjusted (from activation state to administration state), and the pressure in the merged compartment 12 is lowered, the pressure

difference between the merged compartment **12** and the regulating straight **173** is lowered, causing the additional wall **74** to retract and reduce the flow restriction in the regulating channel **171**. The advantage of this embodiment is that an efficient means for avoiding burst of fluid contents during activation is achieved without significantly affecting the resistance to flow during the administration of the contents to a patient. It will be obvious to those skilled in the art that the labyrinth section **172** can be eliminated as long as sufficient pressure difference between the package **9** and the regulating straight **173** is developed to effectively manipulate the second wall **74** to warp into the flow path **171**. In another embodiment a piece of elastomer is accommodated in the flow channel. The elastomeric piece comprises a flow channel embossed in it, and the arrangement is such that the additional wall **73** presses on the elastomeric piece to regulate the cross-section of the channel in the elastomeric piece, thereby regulating the flow. It will be obvious to those skilled in the art that other arrangements for dynamically regulating the flow utilizing the pressure in the merged compartment exist and the one provided in this embodiment is by way of example only.

[0089] In further embodiments the device comprises a one way valve for avoiding refilling of the product compartment after completion of the intended first use. In further embodiments the device comprises a time indicator which indicates a period of time elapsed since activation. The device may further include child protection such that it will be challenging to operate the device by a child, thereby avoiding accidental dispensing or needle sticks.

[0090] Referring now to FIG. **18** a further preferred embodiment **180** is illustrated. The backing **16** now has a second fold line **181** which is located directly under the product compartment **12**, and defining a second compression panel **182** within the backing **16**. The package **9** is supported by the backing **16** and said second compression panel **182**. The arrangement is such that the flap **182** can only be manipulated to pivot toward the first compartment **12** (and not from the flat position away from the product compartment **12**), thereby causing the first compartment **12** to pressurize. In one embodiment the folding of the second compression panel **182** serves to squeeze the first compartment **12**, causing it to merge with the second compartment **21** and/or with additional compartments. In another embodiment the folding of the third flap **182** serves to squeeze the first compartment **12** and thereby rupture the frangible seal **13** and establish fluid communication with the fluid transport device **14**. In another embodiment the first compression panel **17** is eliminated and the second compression panel **182** serves for dispensing the product. FIG. **18a** illustrates the device **180** at a pre-activation position. The shoulder **183** in the backing **19** and the flap **182** prevent the flap **182** from pivoting downwardly and away from the product compartment. FIG. **18b** illustrates the device **180** after the flap **182** is rotated and the first compartment **12** has merged with the second compartment **21**.

[0091] Accordingly, the present disclosure has been described with some degree of particularity directed to the exemplary embodiments thereof. It should be appreciated, though, that the present disclosure is defined by the following claims construed in light of the prior art so that modifications or changes may be made to the exemplary embodiments of the present disclosure without departing from the inventive concepts contained herein.

What is claimed is:

1. A dispensing device, comprising:
  - a package comprising at least a first compartment having a flexible wall portion;
  - a fluid transport device; and
  - a backing associated with said package which, during dispensing, supports the package to facilitate expression of a product from the package through said fluid transport device.
2. A dispensing device according to claim **1** wherein said fluid transport device is hermetically separated from said product prior to activation and adapted, upon activation, to be placed in fluid communication with said product via a rupturable fluid passageway.
3. A dispensing device according to claim **1** where said flexible wall portion is permanently sealed along a first peripheral margin of said first compartment and non-permanently sealed along a second peripheral margin of said first compartment to define at least a first frangible outlet seal located between said first compartment and said fluid transport device such that, when said first frangible seal is ruptured, a fluid communication is established between said package and said fluid transport device.
4. A dispensing device according to claim **1** further comprising a compression panel for compressing at least a portion of said package relative to said backing.
5. A dispensing device according to claim **4** wherein said compression panel is moveably joined to the backing.
6. A dispensing device according to claim **4** wherein at least one of said backing and said compression panel is configured to coincide with a footprint of said at least a first compartment.
7. A dispensing device according to claim **1** further comprising at least a second compartment hermetically separated from said first compartment by a frangible mixing seal.
8. A dispensing device according to claim **1** wherein at least a portion of said fluid transport device is joined with said package through a fitment.
9. A dispensing device according to claim **2** having at least one of a plurality packages, a plurality of compartments, a plurality of passageways, a plurality of fluid transport devices, and a plurality of frangible seals.
10. A dispensing device according to claim **7** wherein a passageway interconnects said first and second compartments with said fluid transport device.
11. A dispensing device according to claim **1** wherein at least one of said fluid passageway and said fluid transport device is at least partially interposed between said rigid backing and said package, is formed partly in the rigid backing, is at least partially interposed between said flexible wall portion and a second wall of said package, or is at least partially integrated in at least one of said package and said backing.
12. A dispensing device according to claim **1** further comprising a plurality of compartments and at least one mixing seal disposed therebetween.
13. A dispensing device according to claim **1** wherein said package is formed from and comprises a plurality of walls.
14. A dispensing device according to claim **1** where in said backing defines a wall of said at least a first compartment.
15. A dispensing device according to claim **1** further comprising a flow control device at least partially disposed between the walls of the package, between the package and the backing or in the backing.

**16.** A dispensing device according to claim **1** further comprising a flow regulator at least partially formed between the backing and the package wherein product pressure in the package distorts the package to restrict flow through the fluid passageway.

**17.** A dispensing device according to claim **16** wherein said flow regulator is an embossed channel having a labyrinth portion.

**18.** A dispensing device according to claim **1** where said fluid transport device is selected from a group consisting of at least one of a needle, a mini-needle, a micro-needle, a connector, a fitting, a tube, a dropper, a topical applicator, a spray head, and a jet injector.

**19.** A dispensing device according to claim **4** where said package is at least partially supported by the compression panel.

**20.** A dispensing device according to claim **4** where said compression panel protects at least a portion of said fluid transport device prior to use.

**21.** A dispensing device according to claim **1** further comprising a cover removably joined to said backing to hermetically seal at least a portion of the fluid transport device.

**22.** A dispensing device according to claim **1** comprising a resealable said package.

**23.** A dispensing device according to claim **1** where said fluid transport device is disabled after use.

**24.** A dispensing device according to claim **4** where said compression panel disables said fluid transport device after use.

**25.** A method comprising:

(a) providing a device comprising:

a package comprising at least a first compartment containing a product,  
said first compartment having a flexible wall portion;  
a fluid transport device; and  
a backing; and

(b) compressing said package against said backing to dispense said product through said fluid transport device.

**26.** A method according to claim **25** wherein said device further comprises a compression panel for accomplishing (b), said method further comprising disabling said fluid transport device with said compression panel.

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