TWO COMPARTMENT SYRINGE ACCESSIBLE PACKAGE AND METHOD OF USING AND MAKING THE SAME

Applicants: John Sheridan Thomas, JR., Coopersburg, PA (US); Barry Lee Pritchard, Nazareth, PA (US)

Inventors: John Sheridan Thomas, JR., Coopersburg, PA (US); Barry Lee Pritchard, Nazareth, PA (US)

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ABSTRACT

The system of a dispensing package and a piercing assembly is disclosed. The package has at least one compartment in which a flowable material is located and a fitment secured to the outside of the package at the fitment. The fitment includes a passageway extending therethrough, which is temporarily sealed by a cover. When the cover is removed a piercing assembly can be extended through the fitment and the underlying portion of the package for communication with the flowable material within the compartment. The piercing assembly includes a septum arranged to be pierced by a needle of a syringe to enable the flowable material to be drawn into the syringe. The package is arranged to be formed, filled with the flowable material and sealed on a form, fill and seal machine.
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CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from Provisional Application Ser. No. 61/622,275, filed on Apr. 10, 2012, entitled TWO COMPARTMENT SYRINGE ACCESSIBLE PACKAGE AND METHOD OF USING AND MAKING THE SAME, which application is assigned to the same assignee as this application and whose disclosure is incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] This invention relates to flexible packages methods of using and making the same, and more particularly to systems including a flexible package for holding a flowable material, e.g., therapeutic or diagnostic agent, in a compartment and a piercing assembly arranged to be coupled to the package to enable a syringe to be used to gain access to the flowable material in the package to fill the syringe so that the flowable material may be injected into a patient and to methods of making and using such systems.

[0003] Various flexible packages are available commercially for holding flowable materials in the separate compartments to keep them from mingling until desired. For example, the prior art includes two compartment flexible packages or pouches having fitments sandwiched between the side seals of the package. This style of fitment is difficult to apply, particularly if the package is to be formed, filled and sealed on a vertical form, fill and seal machine. In particular, the package must be preassembled and filled in a separate operation. Moreover, maintaining sterility is more difficult, since all of the exterior surfaces of the fitment and pouch must be sterilized and remain sterilized during assembly and filling.

[0004] Thus, a need exists for a package which overcomes the disadvantages of the prior art. In addition a need exists for a method of readily making, filling and sealing such packages on automated equipment and for using such packages. The subject invention addresses those needs.

SUMMARY OF THE INVENTION

[0005] One aspect of this invention is directed to a packaging system comprising the combination of a dispensing package and a piercing assembly arranged to be coupled to the package. The package comprises a hollow body and a fitment. The hollow body is formed of a flexible material and includes at least one compartment (e.g., two compartments separated from each other by a separable interface) for holding a flowable material therein (e.g., the separable interface being arranged to be ruptured so that a liquid in one compartment can mix with the material in the other compartment to form the flowable material). The at least one compartment basically comprises a wall panel having an outer surface to which the fitment is secured, whereupon a portion of the wall panel underlies the fitment. The fitment includes a passageway extending therethrough and terminating at the portion of the wall panel underlying the fitment. The passageway is sealed, but openable, e.g., includes a cover releasably secured to the fitment by a releasably securable adhesive) to isolate the passageway from the ambient atmosphere.

[0006] The piercing assembly basically comprises a rubber stopper having a septum coupled to a tubular member (e.g., secured to it by a crimp ring). The tubular member has a piercing end and is arranged to be introduced through the passageway of the fitment after the passageway has been opened to enable the piercing end to pierce through the portion of the wall panel underlying the fitment to enter the interior of the compartment to thereby provide access to the flowable material in the compartment.

[0007] The septum is arranged to be pierced by a needle (e.g., a needle of a syringe) after the piercing end of the tubular member has entered into the interior of the compartment to enable the flowable contents of the compartment to be withdrawn from the compartment into the needle.

[0008] In accordance with one preferred aspect of this invention the package includes two compartments separated from each other by a separable interface, with at least one of the compartments holding a liquid material for mixing with the material of the other compartment when the separable interface is ruptured to form the flowable material.

[0009] In accordance with another preferred aspect of this invention the piercing assembly is sufficiently long so that when the tip of the needle is inserted through the septum, the tip of the needle is within the confines of the tubular member to prevent it from piercing any portion of the flexible material making up the package.

[0010] In accordance with still another preferred aspect of this invention the package additionally comprises an opposite wall panel portion located on the opposite side of the compartment from the side of the fitment. That opposite side wall portion is reinforced to prevent the penetration thereof by the piercing assembly.

[0011] In accordance with another preferred aspect of this invention the package is formed, filled with said flowable material and sealed in the at least one compartment on an automated form, fill and seal machine.

[0012] In accordance with another aspect of this invention there is provided a method of making a package for a packaging system. In addition to the package, the packaging system includes a piercing assembly having a septum. The piercing assembly is arranged to be coupled to the package to enable one to withdraw the sterile flowable material from the package via a needle penetrating the septum. The method entails forming the package from a flexible material to result in at least one compartment in said package filling the at least one compartment with a sterile flowable material under aseptic conditions. The fitment, which has a sterile passageway extending therethrough and which is sealed to maintain its sterility, is secured to at least one compartment of the package. Once that is accomplished the resulting combination can be used with the piercing assembly.

[0013] In particular, the piercing assembly is arranged to so that it may be inserted into the passageway of the fitment to enable the contents of the package to be withdrawn from the compartment via a needle inserted through the septum. Thus, another aspect of this invention entails the method of withdrawing a sterile flowable material by a needle from the packaging system. The packaging system comprises a package and a piercing assembly, with the piercing assembly comprising a septum. The method entails providing a package with a fitment secured thereto, the package being formed of a flexible material and having a compartment in which the flowable material is held under sterile conditions. The fitment is secured to the package at the compartment and has a sterile
passageway extending therethrough hermetically sealed to maintain the sterility of the passageway. The piercing assembly is inserted in the passageway of the fitment so that a portion of the piercing assembly is located within the compartment and in fluid communication with the flowable material. A needle can then be inserted through the septum and into fluid communication with the flowable material to withdraw the flowable material through the needle.

DESCRIPTION OF THE DRAWING

[0014] FIG. 1 is an exploded isometric view of a packaging system constructed in accordance with one aspect of this invention and including a package and a piercing assembly which when coupled together enable one to use a needle of a syringe (or other device) to gain access to a sterile flowable material within the package to withdraw the flowable material from the package;

[0015] FIG. 2A is a top plan view of a fitment forming a portion of the package shown in FIG. 1;

[0016] FIG. 2B is a side elevation view of the fitment shown in FIG. 2A;

[0017] FIG. 2C is an exploded isometric view of the fitment shown in FIGS. 2A and 2B;

[0018] FIG. 2D is an isometric view of the fitment shown in FIGS. 2A-2C, taken in a direction so that its underside can be readily seen;

[0019] FIG. 3A is an enlarged side elevation view of the piercing assembly shown in FIG. 1;

[0020] FIG. 3B is a bottom plan view of the piercing assembly shown in FIG. 3A taken along line 3B-3B of FIG. 3A;

[0021] FIG. 3C is an isometric view of the piercing assembly shown in FIGS. 3A and 3B;

[0022] FIG. 3D is an exploded isometric view of the piercing assembly shown in FIGS. 3A-3C;

[0023] FIG. 4A is an enlarged side elevation view of the package shown in FIG. 1;

[0024] FIG. 4B is an enlarged sectional view taken along line 4B/4C-4B/4C showing one alternative embodiment of the package;

[0025] FIG. 4C is an enlarged sectional view similar to FIG. 4B and taken along line 4B/4C-4B/4C but showing a second alternative embodiment of the package; and

[0026] FIG. 5 is an enlarged vertical sectional view showing the system of FIG. 1 with the piercing assembly coupled to the package and with a syringe needle piercing through the piercing assembly to gain access to the flowable material within the package.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0027] Referring now to the various figures of the drawing wherein like reference characters refer to like parts, there is shown in FIG. 1 an exemplary embodiment of a system 20 constructed in accordance with one aspect of this invention. The system basically comprises a flexible dispensing package 22 and a piercing assembly 24. The package is preferably arranged to hold a sterile flowable material therein so that it can be extracted or withdrawn from the package when desired by the use of a needle, e.g., a needle 12 of a syringe 10. To that end, the package includes at least one compartment (to be described later) in which a flowable material 14 (FIG. 5), e.g., a sterile therapeutic or diagnostic agent, is located for eventual extraction by the syringe to enable the material to be injected into a patient when desired. The piercing assembly 24 is arranged to be coupled to the package 22 to provide a sterile site at which the needle 12 of a syringe 10 can be inserted to gain access to flowable material 14 within the package 20.

[0028] In the exemplary embodiment shown the package 20 is in the form of a pouch or bag formed of two sheets of flexible material and sealed along respective seal lines into two compartments 22A and 22B. The flexible material can be of any suitable material, e.g., a plastic film of a single ply or multiple plies (e.g., a laminate coextrusion or any other construction), depending upon the type of flowable material to be held within the package’s compartments.

[0029] In exemplary contemplated use of this invention the compartments 22A and 22B are each arranged to hold a respective material therein which when mixed form the flowable material to be withdrawn by the needle. Those compartments are separated by a frangible interface portion 22C of the package, e.g., a rupturable interface, located between the compartments so that the materials in the two compartments can be mixed to form a flowable material when the interface is ruptured. To that end, one web or sheet of film or sheet 26 is permanently secured, e.g., thermally bonded or sealed, along its entire periphery to a second film or sheet 28 to form a peripheral seal 30 (FIGS. 1 and 4A-4C). The frangible interface 22C extends transversely to the long axis of the package between the permanent seals 30 along the two opposed long sides of the package. It can be formed by any suitable means, e.g., a peelable or otherwise rupturable layer of any suitable material located between the abutting inner surfaces of the flexible webs or sheets 26 and 28. Such materials are conventional, such as those typically used to make a peelable mouth for a flexible package. Examples of such materials are found in the following U.S. Pat. Nos.: 4,705,174 (Goglio); U.S. Pat. No. 4,518,087 (Goglio); U.S. Pat. No. 4,955,479 (Beer et al.); U.S. Pat. No. 6,213,645 (Beer); U.S. Pat. No. 6,355,732 (Beer); and U.S. Pat. No. 6,539,691 (Beer), all of whose disclosures are specifically incorporated by reference herein.

[0030] The package 20 may be readily formed, filled and sealed by use of a conventional automated vertical form, fill and seal machine. One such machine is the FSU-1000A machine sold by Fresa-co System USA, Inc., the assignee of the subject invention. Other form, fill and seal machines can also be used to form, fill and seal the package.

[0031] It should be pointed out at this juncture that the exemplary embodiment of the package 20 includes a pair of compartments 22A and 22B. It could, if desired, include more than two compartments. In fact, the package may make use of only a single compartment. Irrespective of the number of compartments that the package has, each of those compartments is arranged to hold any type of material therein that can be rendered flowable when mixed (or which is initially flowable) so that it can be extracted by a needle, a cannula or any other hollow piercing member. Thus, the materials can be granulated solids, liquids, foams, slurries or any other material that either on their own are suitable for being drawn into a hollow needle or cannula or else is mixable with some other material within another compartment in the package to render the mixture amenable to be drawn through the needle or cannula, e.g., into a syringe through the syringe’s needle.

[0032] In most expected uses of the packaging system of this invention it is contemplated that the flowable materials held in the respective compartments typically will be such
that mixing or mingling of them before desired use is to be precluded. Thus, the package includes the heretofore men-
tioned frangible interface 22C temporarily isolating the mate-
rials from each other until mixing is desired.

[0033] In use to mix the contents of the two compartments
22A and 22B all that is required is to apply pressure to
the compartment holding the liquid (if only one compartment
holds a liquid or to either or both compartments if both hold
a liquid) to cause the rupturable interface 22C to burst,
thereby enabling the materials in the compartments to mix
together. This can be accomplished by folding the package
along the frangible interface 22C so that the two compart-
ments 22A and 22B are juxtaposed. The user can then grasp
and squeeze the two juxtaposed compartments to break the
frangible seal 22C and mix the two components together.

[0034] In accordance with one exemplary embodiment of
this invention the package 20 is particularly suited for holding
a therapeutic or diagnostic agent or some other material that
is meant to be kept sterile. For example the compartment 22A
may contain sterile water and the compartment 22B may
contain a sterile dry formulation (e.g., a medication), which
is to be kept isolated from the water until mixing is desired,
at which time the rupturable interface is ruptured to cause the
water to flow through the now open interface into the com-
partment 22B to mix with the dry formulation therein to pro-
duce a sterile flowable therapeutic or diagnostic agent.

[0035] In order to enable the dispensing (withdrawal) of the
sterile flowable material 14 from the package 20, the package
includes a fitment 32 that is arranged to receive the piercing
assembly 24. The details of the piercing assembly will be
described later. Suffice for now to state that it is arranged to be
coupled to (e.g., inserted within) the fitment 32 to pierce
the package 22 to provide an access point to the flowable material
14. In particular, the piercing assembly 24 itself includes a
stopper having a septum that is pierceable by a needle or
cannula, so that the contents of the compartment can be drawn
into a syringe or any other instrument coupled to the needle or
cannula after the piercing assembly has pierced the compart-
ment of the package and the needle has pierced the septum (as
will be described later).

[0036] The fitment 32 is best seen in FIGS. 2A-2D and 4B
and 4C and basically comprises a tubular member formed of
any suitable material, e.g., polyethylene. The fitment has a
central passageway 34 extending through it from top to bot-
tom. The bottom or base of the fitment 32 is in the form of a
mounting flange 36. The top portion of the fitment includes a
small flange 38 forming the lip of the fitment. A removable
cover or lid 40 formed of any suitable material, e.g., 100 ga-
alu, is releasably secured to the flange 38 by a releasably
securable heat seal adhesive (not shown) on the undersurface
of the cover 40, so that the cover isolates the passageway 34
from the ambient atmosphere. A thin disc 42 formed of any
suitable flexible material, e.g., a film of polyethylene is fix-
edly secured (e.g., permanently welded) to the underside of
the mounting flange 36 to seal the other end of the passageway
34 from the end sealed by the cover 40. Before the cover 40
and the disc 42 are sealed to their respective ends of the
fitment the central passageway of the fitment as well as the
inner surfaces of the cover and disc can be irradiated, e.g.,
exposed to gamma radiation, to sterilize them. The cover and
disk can then be secured in place. Thus, the passageway 34 in
the fitment is hermetically sealed and sterile, and will remain
so even if when the outer surfaces of the fitment are exposed
to the ambient atmosphere. Other means to sterilize the pas-
sageway can be used and then the passageway hermetically
sealed.

[0037] The fitment 32 is arranged to be fixedly secured to
the outer surface of the film web or sheet making up one wall
of the package so that it will be located immediately adjacent
a compartment of the package at which the flowable material
14 will be located. In the exemplary embodiment shown the
mounting flange 36 of the fitment is fixedly secured, e.g.,
welded or adhesively bonded, to the outer surface of the film
sheet 26 making up the top wall of the compartment 22B, with
the disc 42 interposed between the flange and the sheet 26.

[0038] As mentioned earlier the fitment 32 that is arranged
to receive the piercing assembly 24 to ready the package to
have its contents withdrawn by a needle or cannula. Before
describing that operation, the details of the piercing assembly
will now be described with reference to FIGS. 3A-3D and 5.
In particular, the piercing assembly 24 basically comprises a
tubular body 46, a stopper 48 and a crimp cap 50. The tubular
body is formed of any suitable material, e.g., molded of
polypropylene, and has sidewall surrounding a central pas-
sageway 52 (FIG. 3B). The free or distal end of the sidewall of
the body 46 is in the form of a sharp circularly shaped cutting
edge 54 having a pair of piercing bars 54A. Four flexible
projections or locking bars 56, each having a respect proxim-
al or flaring cam surface, project outwardly spaced locations
of the outer surface of the sidewall immediately proximally of the cutting edge 54. Four
windows or apertures 58 extend through the sidewall of the tubu-
lar body between the locking bars. The lower portion of the
body 46, i.e., the portions including the cutting edge 54, the
locking bars 56 and the windows 58 form a bayonet-like
arrangement, whose action will be described later when a
discussion of the coupling of the piercing assembly 24 to the
fitment 32 is given.

[0039] As best seen in FIG. 5, the upper or proximal end 60
of the tubular body 46 is enlarged, includes peripheral flange
60A (FIG. 3D) extending thereabout and is configured to
accommodate the stopper 48. That stopper includes a septum
62 (FIG. 3D and 5) and is constructed like those commonly
used on conventional medicine-holding vials or bottles. To
that end, an enlarged central bore 60B is located in the
proximal end of the tubular body, is centered on the central
axis thereof and is in fluid communication with the central
passageway 52 extending to the distal end of the tubular body.
Thus, the bore 60B and communicating passageway 52 pro-
vide a fluid path through the entire length of the tubular body
46 from the stopper 48 to the cutting edge 54.

[0040] The enlarged bore 60B is arranged to tightly receive
a portion of the stopper 48 therein. Since the stopper is of
similar construction to stoppers used on conventional medi-
cine holding vials it is formed of any suitable resilient, pier-
cable material, e.g., rubber, and includes a generally planar
cap portion in the form of the heretofore identified septum 62.
The septum has an undersurface from which a cylindrical
portion 64 projects. The cylindrical portion is hollow, with its
upper end (the end immediately adjacent the septum 62)
being concave. The outer diameter of the cylindrical portion
64 is preferably just slightly greater than the inner diameter
of the bore 60B so that the hollow cylindrical portion of the
stopper can be tightly held within the bore, with the under-
surface of the stopper tightly engaging the top edge of the
tubular body and with the septum 62 disposed over and
aligned with the passageway 52 in the tubular body. The
stopper is arranged to be held permanently in place on the top of the tubular body by the crimp cap 50. To that end, the crimp cap, which is of conventional construction, is placed on the stopper when the stopper is within the bore and then is crimped in place (as is conventional done with medicine-holding vials) to lock the stopper in place.

[0041] As best seen in FIGS. 3A, 3C, 3D and 5 a plurality of annular ribs 66 project outward from the outer surface of the sidewall of the tubular body 46 immediately proximally of the windows 58. The outer diameter of the ribs 66 is slightly larger than the inner diameter of the passageway 34 in the fitment 32 so that they flex slightly to form a fluid-tight seal when the piercing assembly 24 is inserted into the passageway 34 of the fitment.

[0042] Since the piercing assembly 24 is used to gain access to the sterile contents of the package, the piercing assembly is kept sterile until ready for use, e.g., it may be kept within a sterile package or some other protective environment.

[0043] Operation of the system 20 to enable the withdrawal of the flowable contents 14 of the package 20 by the syringe 10 will now be described with reference to FIG. 5, it being assumed that the contents of the package have been mixed by rupturing the interface 22C as described above. In such a case the flowable material 14 will be within compartment 22B and immediately adjacent the fitment 32. The removable cover 40 can then be pulled off of the top of the fitment 32 by grasping a tab 40A (FIG. 2A) projecting from the cover and peeling the cover off its underlying flange 38. This action exposes the sterile central passageway 34 in the fitment, the sealing disk 42 and the portion of the film sheet 26 making up the wall of the compartment 22B, which portion will be bounded by the inner surface of the passageway 34 of the fitment.

[0044] The piercing assembly 24 can now be introduced into the passageway 34 of the fitment by orienting it such that its cutting end 54 is at the entrance of the fitment’s passageway 34. The piercing assembly can then be pushed inward (along the central longitudinal axis of the fitment) to slide its tubular body 46 down the passageway. During the movement of the tubular body down the passageway of the fitment, the locking barsbs 56 on the bayonet end portion of the tubular body will flex slightly inward as will the ribs 66. Continued pressure on the piercing member will bring the barsbs 54A of the cutting edge 54 to the sealing disk 42, whereupon further pressure on the piercing assembly causes those barsbs and the contiguous sharp edge to cut through the disk 42 and the underlying portion of the flexible sheet 26 making up the compartment 22B. Once the cam surfaces of the locking barsbs 56 have passed the mounting flange 36 of the fitment, they will flex outward so that their undercut surface will lock onto the inner surface of the sheet 26 contiguous with that flange. This action effectively locks the piercing assembly to the fitment 32, with the windows 58 in the piercing assembly in fluid communication with the interior of the chamber 22B. Accordingly, the flowable material 14 within the compartment enters the passageway 32.

[0045] The package 20 is now ready to have its flowable contents 14 withdrawn. To that end the needle 12 of a syringe 10 (or any other device for withdrawing a flowable material via a piercing needle or cannula) can then be used to pierce through the septum 62 of the stopper and into communication with the interior of the passageway 52 where the flowable material is now resident. Thus, the syringe can be operated to withdraw the flowable material through the needle and into the hollow interior of the syringe. Once within the syringe the flowable material can be injected into a patient.

[0046] In accordance with one preferred aspect of this invention, the length of the piercing assembly is selected to be longer than the length of the needle 12, so that when the needle has pierced through the septum of the stopper the free end 12A of the needle will be within the confines of the piercing assembly as clearly shown in FIG. 5. This feature ensures that the needle’s tip 12A does not pierce through the film sheet 28 making up the opposite wall of the compartment 22B.

[0047] In the further interest of preventing penetration or piercing of the film sheet opposite the sheet on which the fitment is mounted when the piercing assembly is used, a reinforcement disk 68, e.g., a thin disk of polyethylene, can be secured to either the outer surface of the sheet 28, such as shown in FIG. 4B or to the inner surface of the sheet, such as shown in FIG. 4C.

[0048] It should be pointed out at this juncture that the components of the systems as described above are merely exemplary of various components that can be used to achieve the ends of this invention. For example, in the embodiment of the package 20 shown in FIG. 1, the compartments 22 and 24 are of a generally rectangular shape. That is merely exemplary. Moreover, the size of the package can be any dimension desired for the particular application. While the fitment is shown as being secured to the outer surface of the package at a compartment, it is contemplated that the fitment be located within the compartment so that the piercing assembly first pierces the wall of the compartment and then enters the passageway in the interiorly-located fitment. Further still, if an external fitment is used the cover 40 may be formed of a porous material like Tyvek® and the passageway 34 in the fitment 32 may be sterilized with ethylene oxide. Further yet, while the piercing assembly is particularly suited to have a needle of a syringe inserted therethrough to manually withdraw some of the flowable contents of the package into the syringe for injection in a patient, other means including a piercing needle can be used to effect the withdrawal of the flowable material. Thus, a needle cannula connected to an infusion machine or other dispenser can be used to effect the withdrawal of the flowable material from the package through the piercing assembly.

[0049] Without further elaboration the foregoing will so fully illustrate our invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

We claim:

1. A packaging system comprising the combination of a package and a piercing assembly for enabling a needle to gain access to a flowable material held within the package, said package comprising a hollow body and a fitment, said hollow body being formed of a flexible material and including at least one compartment for holding a flowable material therein, said compartment comprising a wall panel having an outer surface to which said fitment is secured, wherein a portion of said wall panel underlies said fitment, said fitment including a passageway extending therethrough and terminating at the portion of said wall panel underlying said fitment, said passageway being sealed but openable to isolate said passageway from the ambient atmosphere, said piercing assembly comprising a septum coupled to a tubular member having a piercing tip, said tubular member being arranged to be introduced through said passageway of said fitment after said passage-
way has been opened to enable said piercing tip to pierce through said portion of said wall panel underlying said fitment to enter the interior of said compartment to thereby provide access to the flowable material in said compartment, said septum being arranged to be pierced by said needle after said piercing tip has entered into the interior of the compartment to enable the flowable contents of said compartment to be withdrawn from said compartment through the needle.

2. The system of claim 1 wherein said package comprises at least two compartments separated from each other by a frangible interface, each of said compartments holding a material therein, with at least one of said materials being a liquid, said frangible interface being arranged to be breached to cause said liquid of one compartment to mix with the material of the other compartment to form said flowable material.

3. The system of claim 1 wherein said openable cover is removable from said fitment.

4. The system of claim 3 wherein said openable cover comprises a sheet of material releasably secured to said fitment by a releasably securable adhesive.

5. The system of claim 1 additionally comprising a crimped member fixedly securing said septum to said tubular member of said piercing assembly.

6. The system of claim 1 wherein said tubular member of said piercing assembly comprises a distal portion arranged to be locked into place within said passageway after said piercing tip has pierced through said portion of said wall panel underlying said fitment.

7. The system of claim 6 wherein said distal portion of said tubular member has at least one aperture therein adjacent said piercing tip.

8. The system of claim 1 wherein said needle has a tip and wherein said piercing assembly is sufficiently long so that when the tip of the needle is inserted through said septum, the tip of the needle is within the confines of said tubular member to prevent the tip from piercing any portion of the flexible material making up said package.

9. The system of claim 1 wherein said package additionally comprises an opposite wall panel portion located on the opposite side of said compartment from the side of said fitment and wherein said opposite side wall portion is reinforced to prevent the penetration thereof by said piercing assembly.

10. The system of claim 9 wherein said opposite wall panel portion comprises an inner surface contiguous with said compartment and an outer surface, and wherein said reinforcement of said opposite side wall portion is achieved by a layer of protective material located on at least one of said inner and said outer surface of said opposite wall panel portion.

11. The package of claim 1, wherein said package is formed, filled with said material and sealed in said compartment on an automated form, fill and seal machine.

12. A method of making a package for a packaging system, said system additionally comprising a piercing assembly having a septum and being arranged to be coupled to said package to enable one to withdraw the sterile flowable material from the package via a needle penetrating said septum, said method comprising:

forming a package from a flexible material to result in at least one compartment in said package;

filling said at least one compartment with a sterile flowable material under aseptic conditions;

securing a fitment having a sterile passageway extending therethrough to said at least one compartment, said passageway being hermetically sealed to maintain its sterility, and providing said piercing assembly so that it may be inserted into said passageway of said fitment.

13. The method of claim 12 additionally comprising:

introducing said piercing assembly into said passageway of said fitment whereupon a portion of said piercing assembly penetrates said at least one compartment and into fluid communication with said flowable material therein, while maintaining the sterility of the flowable material within said package.

14. The method of claim 12 wherein said passageway in said fitment is maintained in said hermetically sealed state by a cover, said cover being removable to enable said piercing assembly to be introduced into said passageway of said fitment.

15. The method of claim 12 wherein said package is formed into said at least one compartment, said at least one compartment is filled with said flowable material, and said filled at least one compartment is sealed on an automated form, fill and seal machine.

16. The method of claim 15 wherein said package is formed into two compartments, with said fitment being secured to one of said compartments.

17. A method of withdrawing a sterile flowable material by a needle from a flexible packaging system comprising a package and a piercing assembly, said piercing assembly comprising a septum, said method comprising:

providing a package with a fitment secured thereto, said package being formed of a flexible material and having a compartment in which said flowable material is held under sterile conditions, said fitment being secured to said package at said compartment and having a sterile passageway extending therethrough hermetically sealed to maintain the sterility of said passageway;

inserting said piercing assembly in said passageway of said fitment so that a portion of said piercing assembly is located within said compartment and in fluid communication with said flowable material; and

inserting a needle through said septum and into fluid communication with said flowable material to withdraw said flowable material through said needle.

18. The method of claim 17 wherein said passageway in said fitment is maintained in said hermetically sealed state by a removable cover and wherein said method comprises removing said cover to enable said piercing assembly to be inserted into said passageway.

19. The method of claim 17 wherein said package comprises two compartments, wherein said compartments are separated from each other by a frangible interface and wherein each of said compartment comprises a material therein, said method additionally comprising causing said frangible interface to rupture whereupon said materials in said compartments mix together to form said flowable material.

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